October 7, 2024

VIA EMAIL AND REGULAR MAIL

Leanne Wilhardt, President
21st Century HealthCare, Inc.
443 West Alameda Dr.
Tempe, AZ 85282
leannew@21stcenturyvitamins.com

Re: 21st Century's Menopause Supplement Marketing Practices

Dear Ms. Wilhardt:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges 21st Century to review its marketing, which includes, among other things, claims that its Estro Support Max + Energy supplement can have a beneficial impact on menopausal symptoms,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Estro Support Max + Energy, 21st Century, https://www.21stcenturyvitamins.com/products/national-brand-equivalents/estro-support-max-energy.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Rainey Repins, General Counsel
Amway
7575 Fulton Street East
Ada, MI 49355-0001
rainey.repins@amway.com

Re: Amway's Menopause Supplement Marketing Practices

Dear Ms. Repins:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Amway to review its marketing, which includes, among other things, claims that its Nutrilite™ Complete Menopause Support supplement "helps alleviate common, natural symptoms associated with menopause," such as hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Amway should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

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[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood

Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

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[13] *See, e.g.*, Nutrilite™ Complete Menopause Support, Amway, https://www.amway.com/en_US/Nutrilite%E2%84%A2-Complete-Menopause-Support-p-126154.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, Fed. Trade Comm'n (updated May 11, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, Fed. Trade Comm'n (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] *FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024*, Fed. Trade Comm'n (Jan. 11, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

BB Company
304 S. Jones Blvd.
Las Vegas, NV 89107
contact@betterbody.co

Re: BB Company's Menopause Supplement Marketing Practices

To Whom It May Concern:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges BB Company to review its marketing, which includes, among other things, claims that its Provitalize supplement can address "hot flashes, night sweats, mood swings, brain fog, low energy, or any other menopause-related symptoms caused by hormonal fluctuations,"[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

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include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Provitalize, BB Company, https://betterbody.co/products/provitalize.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Suzie Welsh Devine, CEO
Binto
1516 N. 5th St., Suite 116
Philadelphia, PA 19122
suzie@mybinto.com

Re: Binto's Menopause Supplement Marketing Practices

Dear Ms. Devine:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Binto to review its marketing, which includes, among other things, claims that its Menopause Relief Kit can "Reduce and prevent hot flashes" and "Improve sleep"[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Relief Kit | Menopause Support, Binto, https://mybinto.com/products/relief-kit-menopause-support.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Steven Meyers, Vice President
Bio Nutrition
3055 New St.
Oceanside, NY 11572
steven@bionutritioninc.com

Re: Bio Nutrition's Menopause Supplement Marketing Practices

Dear Mr. Meyers:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Bio Nutrition to review its marketing, which includes, among other things, claims that its Harmon X with Lifenol supplement addresses menopausal symptoms such as hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Bio Nutrition should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

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[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

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[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Harmon X with Lifenol, Bio Nutrition, https://bionutritioninc.com/product/harmon-x-with-lifenol/.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Matt Davis, CEO
BioSchwartz
239 2nd Avenue S., Suite 200
St. Petersburg, FL 33701
support@bioschwartz.com
matt@bioschwartz.com

Re: BioSchwartz's Menopause Supplement Marketing Practices

Dear Mr. Davis:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges BioSchwartz to review its marketing, which includes, among other things, claims that its Menopause Support Probiotics for Women helps with menopausal symptoms such as hot flashes,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

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[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Support Probiotics for Women, BioSchwartz, https://bioschwartz.com/products/menopause-support-probiotics-for-women.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Christine Burdick-Bell, General Counsel
Pharmavite
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West Hills, CA 91304
cburdick-bell@pharmavite.net

Sara O'Brien, General Counsel
Bonafide Health
500 Mamaroneck Ave., Suite 510
Harrison, NY 10528-1611
so'brien@bonafide.com
support@hellobonafide.com

Re: Pharmavite / Bonafide Health's Menopause Supplement Marketing Practices

Dear Ms. Burdick-Bell & Ms. O'Brien:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Pharmavite to review its marketing of Bonafide Health products, which includes, among other things, claims that its supplement Relizen can relieve hot flashes and night sweats and make "life bearable,"[13] that its supplement Thermella can relieve hot flashes and night sweats "in just two weeks,"[14] and that its supplement Serenol can relieve menopausal mood swings, irritability and uneasiness and is a "miracle" pill that can treat intrusive thoughts and anxiety,[15] and take the necessary steps to ensure compliance with FTC and FDA law. Pharmavite

should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[16] which notified the company that failing to adequately support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[17] Currently, the maximum civil penalty amount is $51,744 per violation.[18] Finally, as you may know, there is evidence that Pharmavite is engaged in deceptive marketing for another menopause supplement brand, Equelle, prompting TINA.org to file a complaint with the FTC and FDA last week. As such, we strongly urge Pharmavite to promptly review the marketing for Equelle as well.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information,

https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

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[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Relizen, Bonafide, https://hellobonafide.com/products/relizen.

[14] *See, e.g.*, Thermella, Bonafide, https://hellobonafide.com/products/thermella.

[15] *See, e.g.*, Serenol, Bonafide, https://hellobonafide.com/products/serenol.
[16] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, Fed. Trade Comm'n (updated May 11, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.
[17] Sample Cover Letter re: Notices of Penalty Offices, Fed. Trade Comm'n (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.
[18] *FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024*, Fed. Trade Comm'n (Jan. 11, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Tim Cleland, President
Indiana Botanic Gardens, Inc.
3401 West 37th Avenue
Hobart, IN 46342-1751
tim.cleland@botanicchoice.com
custsvc@botanichealth.com

Re: Botanic Choice's Menopause Supplement Marketing Practices

Dear Mr. Cleland:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Botanic Choice to review its marketing, which includes, among other things, claims that its Hot Flash Ease™ supplement can help ease menopausal symptoms including hot flashes, night sweats, and sleeplessness,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

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[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

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include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Hot Flash Ease, Botanic Choice, https://www.botanicchoice.com/womens-health/menopause-support/hot-flash-ease-60-capsules.axd.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Brew Blue Tea Pty Ltd.
10 Buchanan Street
West End, QLD 4101
Australia
help@brewbluelife.com
support@brewbluelife.com

Re: Brew Blue's Menopause Supplement Marketing Practices

To Whom It May Concern:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Brew Blue which is available to U.S. consumers to review its marketing, which includes, among other things, claims that its Hormone Bliss supplement, which is available to U.S. consumers, "relieves menopause symptoms," including hot flushes, night sweats, and brain fog,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Hormone Bliss, Brew Blue, https://brewbluelife.com/products/hormone-balance-bliss.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Carlyle Nutritionals LLC
Attn: General Counsel
20 Broadhollow Road, Suite 304
Melville, NY 11747
customerservice@carlylenutritionals.com

Re: Carlyle's Menopause Supplement Marketing Practices

To Whom It May Concern:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Carlyle to review its marketing, which includes, among other things, claims that its Menopause Support supplement "Helps with Hot Flashes and Night Sweats,"[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

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include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[13] *See, e.g.*, Menopause Support, Carlyle, https://carlylenutritionals.com/products/menopause-support-capsules-helps-with-hot-flashes-and-night-sweats-180-count.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Adrian Morris, General Counsel
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The Heights
Weybridge, Surrey
KT13 0NY
United Kingdom

Haleon US
184 Liberty Corner Road
Warren, NJ 07059
mystory.us@haleon.com

Re: Haleon's Menopause Supplement Marketing Practices

Dear Mr. Morris:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Haleon to review its marketing, which includes, among other things, claims that its Centrum Complete Multivitamin + Hot Flash Support supplement relieves menopausal hot flashes, its Centrum Menopause Support Restful Sleep supplement minimizes hot flashes at night, and that its Centrum Menopause Support Clear Mind & Calm Mood supplement relieves brain fog,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Haleon should take particular care due to the fact that the company received a Notice of Penalty

Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

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[13] *See, e.g.*, Centrum Menopause Support, Centrum, https://www.centrum.com/products/menopause-support/.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Tyler Cooper, CEO
Cooper Complete
12330 Preston Road
Dallas, TX 75230
tccooper@cooperaerobics.com
customerservice@coopercomplete.com

Re: Cooper Complete's Menopause Supplement Marketing Practices

Dear Mr. Cooper:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Cooper Complete to review its marketing, which includes, among other things, claims that its Menopause Health Supplement is addresses menopausal symptoms including hot flashes, night sweats, and anxiety,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Health Supplement, Cooper Complete, https://coopercomplete.com/product/menopause-health-supplement/.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Mike Richtmyer, COO
Country Life
101 Corporate Drive
Hauppauge, NY 11788
mrichtmyer@countrylifevitamins.com
ConsumerAffairs@CountryLifeVitamins.com

Re: Country Life's Menopause Supplement Marketing Practices

Dear Mr. Richtmyer:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Country Life to review its marketing, which includes, among other things, claims that its Menopause Rescue supplement reduces menopausal symptoms such as hot flashes, night sweats, sleeplessness, and vaginal dryness,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Country Life should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product

health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

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[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Rescue, Country Life, https://countrylifevitamins.com/products/womens-menopause-rescue.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, Fed. Trade Comm'n (updated May 11, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, Fed. Trade Comm'n (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] *FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024*, Fed. Trade Comm'n (Jan. 11, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Sue McKinney, Director
Crila Health
120 NE 26th St.
Oklahoma City, OK 73105
sue@crilahealth.com
info@crilahealth.com

Re: Crila Health's Menopause Supplement Marketing Practices

Dear Ms. McKinney:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Crila Health to review its marketing, which includes, among other things, claims that Menopause Health supplement "reduces the frequency and intensity of hot flashes and sleep-disrupting night sweats,"[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

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2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Health from Crila, Crila Health, https://crilahealth.com/products/natural-menopause-treatment?_pos=1&_sid=c73908f03&_ss=r.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Emil Hodzovic, Founder & Owner
Dr. Emil Nutrition
3700 Butler St.
Pittsburgh, PA 15201
info@dremilnutrition.com
emilh@dremilnutrition.com

Re: Dr. Emil Nutrition's Menopause Supplement Marketing Practices

Dear Dr. Hodzovic:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Dr. Emil Nutrition to review its marketing, which includes, among other things, claims that its Menopause Support supplement can relieve menopausal symptoms such as hot flashes, night sweats, and memory issues,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18,

2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Support, Dr. Emil Nutrition, https://dremilnutrition.com/products/menopause-support.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Dr. Kellyann Petrucci
Dr. Kellyann LLC
4470 W. Sunset Blvd.
Los Angeles, CA 90027-6302
info@drkellyann.com

Re: Dr. Kellyann LLC's Menopause Supplement Marketing Practices

Dear Dr. Petrucci:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Dr. Kellyann LLC to review its marketing, which includes, among other things, claims that its Dr. Kellyann & ME Peri + Menopause supplements can help ease menopausal symptoms such as hot flashes, night sweats, and brain fog,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

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[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

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2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Dr. Kellyann &ME Peri + Menopause, Dr. Kellyann, https://drkellyann.com/products/peri-menopause?variant=40555395874929.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Bryan Tran, Co-Founder
DrFormulas
13805 Alton Pkwy., Suite E
Irvine, CA 92618
help@drformulas.com
bryan@drformulas.com

Re: DrFormulas' Menopause Supplement Marketing Practices

Dear Mr. Tran:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges DrFormulas to review its marketing, which includes, among other things, claims that its Menopause Support supplement addresses menopausal symptoms such as hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

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[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, DrFormulas Menopause Supplement, DrFormulas, https://drformulas.com/products/mendapause-menopause-supplement-for-hot-flashes-night-sweats-mood-swings-low-energy.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Brandon Passwaters, International Sales Director
Earth's Creation
18 Page Ct.
Travelers Rest, SC 29690
info@earthscreationusa.com
brandonmp@earthscreationusa.com

Re: Earth's Creation's Menopause Supplement Marketing Practices

Dear Mr. Passwaters:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Earth's Creation to review its marketing, which includes, among other things, claims that its Menopause Relief supplement can relieve menopausal symptoms such as hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Relief, Earth's Creation, https://earthscreationshop.com/products/menopause-relief.

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Elissa Corrigan, Founder
Elle Sera
9 Dunnings Bridge Road
Liverpool
L30 6UU
United Kingdom
customer@elle-sera.com

Re: Elle Sera's Menopause Supplement Marketing Practices

Dear Ms. Corrigan:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Elle Sera to review its marketing, which includes, among other things, claims that The Golden Pill supplement, which is available to U.S. consumers, can provide relief from menopausal symptoms such as hot flushes, night sweats, insomnia, inflammation, and brain fog, and can even improve memory and circulation and lower blood pressure,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause, Elle Sera, https://elle-sera.com/pages/menopause.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Deborah Vaughn, Senior Vice President & Chief Counsel
Walmart Headquarters
702 S.W. 8th St.
Bentonville, AK 72716
help@walmart.com
deborah.vaughn@walmart.com

Re: Equate / Walmart's Menopause Supplement Marketing Practices

Dear Ms. Vaughn:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Walmart to review its marketing, which includes, among other things, claims that its Equate Multi-Symptom Menopause Formula Supplement can address menopausal symptoms such as hot flashes, sweating, anxiety, vaginal dryness, and sleep problems,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Walmart should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil penalties

pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Equate Multi-Symptom Menopause Formula Supplement, Walmart, https://www.walmart.com/ip/Equate-Multi-Symptom-Menopause-Formula-Supplement-60-Count/565992617.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL

Estrocare
support@estrocare.life

Re: Estrocare's Menopause Supplement Marketing Practices

To Whom It May Concern:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Estrocare to review its marketing, which includes, among other things, claims that its supplement can relieve menopausal symptoms such as hot flashes, night sweats, and sleeplessness,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Estrocare 1 Month Supply, Estrocare, https://estrocare.life/collections/all/products/estrocare-1-month-supply.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Julie Bagley, Dir. of Regulatory Affairs
i-Health
55 Sebethe Drive
Cromwell, CT 06416
CS@i-HealthInc.com
julie.bagley@dsm.com

Re: i-Health's Menopause Supplement Marketing Practices

Dear Ms. Bagley:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges i-Health, to review its marketing, which includes, among other things, claims that its Estroven menopause supplements can relieve menopausal symptoms such as hot flashes, night sweats, and sleeplessness,[13] and take the necessary steps to ensure compliance with FTC and FDA law. i-Health should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims

could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Estroven, https://estroven.com/.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Rachel Sexton, Senior Vice President
Wellbeam Consumer Health
2654 W. Horizon Ridge Pkwy., Suite B5 #1087
Henderson, NV 89052
rachel@wellbeam.com
info@eunatural.com

Re: Eu Natural / Wellbeam Consumer Health's Menopause Supplement Marketing Practices

Dear Ms. Sexton:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Wellbeam Consumer Health to review its marketing, which includes, among other things, claims that its Eu Natural Staying Cool supplement can provide relief from menopausal symptoms including hot flashes, night sweats, vaginal dryness, and inconsistent sleep,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Wellbeam Consumer Health should take particular care due to the fact that it has already received a warning letter from the FTC and FDA in 2021 regarding its use of unapproved and unsubstantiated disease-treatment claims in marketing materials for certain fertility supplements.[14]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, STAYING COOL — Total Hot Flash & Menopause Relief, Eu Natural, https://store.eunatural.com/products/staying-cool-for-hot-flashes-and-menopause-relief.

[14] FDA and FTC Warning Letter to Eu Natural, May 20, 2021, https://www.ftc.gov/system/files/warning-letters/fda-eu-natural-inc.pdf.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Boris Hodakel, Founder
Feel Holdings Ltd.
81-87 High Holborn
London
WC1V 6DF
United Kingdom
hello@wearefeel.com

Re: Feel Holdings' Menopause Supplement Marketing Practices

Dear Mr. Hodakel:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Feel Holdings to review its marketing, which includes, among other things, claims that its menopause supplement, which is available to U.S. consumers, can combat menopausal symptoms such as hot flushes, night sweats, and brain fog,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Feel Holdings should take particular care due to the fact that the Advertising Standards Authority determined in July 2024 that an advertisement for the company's menopause supplement made prohibited claims that the product

could prevent, treat or cure disease, and therefore breached the Committee of Advertising Practice Code.[14]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

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[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

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[13] *See, e.g.*, Menopause, Feel, https://wearefeel.com/products/menopause.

[14] ASA Ruling on Feel Holdings Ltd t/a Feel, ASA (July 17, 2024), https://www.asa.org.uk/rulings/feel-holdings-ltd-a24-1246372-feel-holdings-ltd html.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Adele Wragg, Founder
Feminapause Ltd.
3rd Floor, 86-90 Paul Street
London
EC2A 4NE
United Kingdom
info@feminapause.com

Re: Feminapause's Menopause Supplement Marketing Practices

Dear Ms. Wragg:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Feminapause to review its marketing, which includes, among other things, claims that its supplements, which are available to available to U.S. consumers, can address menopausal symptoms such as hot flashes, night sweats, insomnia, and memory loss,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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[13] *See, e.g.*, Feminapause Fortified CBD Menopause Supplement, Feminapause, https://www.feminapause.store/products/feminapause-cbd-menopause-supplement/.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Gerianne DiPiano, CEO
FemmePharma
175 Strafford Ave.
Building 4
Wayne, PA 19087
support@femmepharma.com
gerianne@fpghc.com

Re: FemmePharma's Menopause Supplement Marketing Practices

Dear Ms. DiPiano:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges FemmePharma to review its marketing, which includes, among other things, claims that its Mia Vita® Hot Flash Relief supplement can "reduce or eliminate menopausal hot flashes and night sweats,"[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Mia Vita® Hot Flash Relief, FemmePharma, https://femmepharma.com/product/mia-vita-hot-flash-relief/.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

James Frame, CEO
Symphony Natural Health
2550 S. Decker Lake Blvd., Unit #28
West Valley City, UT 84119
customer.service@symphonynaturalhealth.com
james.frame@symphonynaturalhealth.com

Re: Symphony Natural Health / Femmenessence's Menopause Supplement Marketing Practices

Dear Mr. Frame:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges to Symphony Natural Health review its marketing, which includes, among other things, claims that its Femmenessence perimenopause and menopause supplements can address menopausal symptoms such as hot flashes, night sweats, and vaginal dryness,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

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[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

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[13] *See, e.g.*, Femmenessence MacaLife For Perimenopause, Femmenessence, https://femmenessence.com/products/macalife; Femmenessence MacaPause For Post Menopause, Femmenessence, https://femmenessence.com/products/macapause.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

John Feeney, Chief Marketing Officer
Gaia Herbs
101 Gaia Herbs Rd.
Brevard, NC 28712
john.feeney@gaiaherbs.com
info@gaiaherbs.com

Re: Gaia Herbs' Menopause Supplement Marketing Practices

Dear Mr. Feeney:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Gaia Herbs to review its marketing, which includes, among other things, claims that its Menopause Support Daytime supplement combats menopausal hot flashes,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Gaia Herbs should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Support Daytime, Gaia Herbs, https://www.gaiaherbs.com/products/menopause-support-daytime.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Garden of Life, LLC
c/o Barbara Sanchez, Head of Legal
Nestlé Health Science
1007 US Highway 202/26
Building JR2
Bridgewater, NJ 08807
Barbara.sanchez@us.nestle.com
info@gardenoflife.com

Re: Garden of Life's Menopause Supplement Marketing Practices

Dear Ms. Sanchez:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Garden of Life to review its marketing, which includes, among other things, claims that its Herbals Menopause + Hair Growth Softgels supplement relieves "hot flashes, night sweats, interrupted sleep, low energy, stress, and irritability" as well as "sleep problems and muscle & joint discomfort related to menopause"[13] and take the necessary steps to ensure compliance with FTC and FDA law. Garden of Life should take particular care due to the fact

that the company, as well as its parent company Nestlé, received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified them that failing to adequately support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] Herbals Menopause + Hair Growth Softgels, Garden of Life, https://www.gardenoflife.com/herbals-menopause-hair-growth-softgels.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Jill Angelo, CEO
Gennev, Inc.
85 S. Atlantic St.
Seattle, WA 98134
support@gennev.com
jill@gennev.com

Re: Gennev's Menopause Supplement Marketing Practices

Dear Ms. Angelo:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Gennev to review its marketing, which includes, among other things, claims that its Vitality Menopause Supplement can address menopausal hot flashes, poor sleep, brain clarity, joint pain, and inflammation,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Vitality Menopause Supplement, Gennev, https://shop.gennev.com/products/vitamins-for-menopause-fatigue.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Samantha Clancy, VP, Assistant General Counsel
GNC
75 Hopper Place, Suite 501
Pittsburgh, PA 15222
customerservice@gnc-hq.com
samantha-clancy@gnc-hq.com

Re: GNC's Menopause Supplement Marketing Practices

Dear Ms. Clancy:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges GNC to review its marketing, which includes, among other things, claims that its Menopause Formula supplement reduces hot flashes, night sweats, and other menopause symptoms,[13] and take the necessary steps to ensure compliance with FTC and FDA law. GNC should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil

penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Formula, GNC, https://www.gnc.com/sexual-health/148321.html.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Djenaba Parker, General Counsel
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djenaba@goop.com

Re: Goop's Menopause Supplement Marketing Practices

Dear Ms. Parker:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

Should Goop restock its menopause supplement, Madame Ovary, TINA.org urges the company to review its marketing for the product,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Introducing Madame Ovary, Goop, https://goop.com/wellness/health/introducing-madame-ovary-a-supplement-regimen-for-your-40s-and-beyond/; Madame Ovary: The Story Behind the goop Wellness Protocol | goop, YouTube (Jan. 13, 2019), https://www.youtube.com/watch?v=wyVT_OXt53k.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Kylie Lewis, Owner
Happy Healthy Hippie
P.O. Box 600312
San Diego, CA 92160
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Re: Happy Healthy Hippie's Menopause Supplement Marketing Practices

Dear Ms. Lewis:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Happy Healthy Hippie to review its marketing, which includes, among other things, claims that its Go With The Flow supplement can provide relief from menopause symptoms,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

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include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

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[13] *See, e.g.*, Go With The Flow, Happy Healthy Hippie, https://happyhealthyhippieco.com/products/go-with-the-flow-hormone-balance.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Matthew Murphy, CEO & Founder
Happy Mammoth
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Cheyenne, WY 82001
support@happymammoth.co
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Re: Happy Mammoth's Menopause Supplement Marketing Practices

Dear Mr. Murphy:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Happy Mammoth to review its marketing, which includes, among other things, claims that its Hormone Harmony supplement "Relieves symptoms of Menopause," "Improves sleep quality," and "Supports mental function,"[13] and that its MenoDaily supplement relieves menopause symptoms like hot flashes and night sweats,[14] and take the necessary steps to ensure compliance with FTC and FDA law.[15] Happy Mammoth should take particular care due to the fact that it has already received a letter from the BBB National Programs' National Advertising Division on August 20, 2024, recommending that it discontinue making certain health-related

claims (including that it relieves symptoms of menopause and hot flashes) regarding its Hormone Harmony supplement.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Hormone Harmony, Happy Mammoth, https://store happymammoth.com/products/the-new-ultra-potent-hormone-harmony.

[14] *See, e.g.*, MenoDaily, Happy Mammoth, https://store.happymammoth.com/products/meno-daily.

[15] As Happy Mammoth is aware, TINA.org published an ad alert regarding the deceptive marketing of Hormone Harmony in 2023. *Ad Alert: Happy Mammoth Hormone Harmony*, TINA.org (Mar. 30, 2023), https://truthinadvertising.org/articles/happy-mammoth-hormone-harmony/.

[16] National Advertising Division Recommends Happy Mammoth Discontinue Certain Health-Related Claims for Hormone Harmony Dietary Supplement, Aug. 20, 2024, https://bbbprograms.org/media-center/dd/happy-mammoth.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Kate Bache, Co-founder & CEO
Health & Her Ltd., Unit D
Tramshed Tech
Pendyris St.
Cardiff
CF11 6BH
United Kingdom
contact@healthandher.com

Re: Health & Her's Menopause Supplement Marketing Practices

Dear Ms. Bache:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Health & Her to review its marketing, which includes, among other things, claims that its Menopause Multi-Nutrient Support Supplement, which is available to U.S. consumers, can address menopause symptoms and improve cognitive function,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

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[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Health & Her Menopause Multi-Nutrient Support Supplement, Health & Her, https://healthandher.com/en-us/collections/menopause/products/health-her-menopause-multi-nutrient-support-supplement.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Tyler Garner, Vice President of Legal
SilverOnyx
16171 S. Bringhurst Blvd., Suite 600
Bluffdale, UT 84065
admin@hellolovely.net
tyler@silveronyx.com

Re: SilverOnyx's Menopause Supplement Marketing Practices

Dear Mr. Garner:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges SilverOnyx to review its marketing of its Hello Lovely! brand, which includes, among other things, claims that its Menopause Relief and Menopause Complete supplements can relieve menopausal symptoms like hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

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TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Henry Wang, Chief Legal Officer
Herbalife, Inc.
950 W. 190th St.
Torrance, CA 90502
AER@Herbalife.com
henryw@herbalife.com

Re: Herbalife's Menopause Supplement Marketing Practices

Dear Mr. Wang:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Herbalife to review its marketing, which includes, among other things, claims that its Woman's Choice supplement addresses menopause and its symptoms,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Herbalife should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Woman's Choice, Herbalife, https://www herbalife.com/en-us/u/products/womans-choice-30-tablets-1061.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Walter Faulstroh, CEO & Co-founder
HUM Nutrition, Inc.
Healthy Towers
6922 Hollywood Blvd., Suite 922
Los Angeles, CA 90028
healthy@humnutrition.com
walter@humnutrition.com

Re: HUM Nutrition's Menopause Supplement Marketing Practices

Dear Mr. Faulstroh:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges HUM Nutrition to review its marketing, which includes, among other things, claims that its Fan Club supplement provides "multi-symptom relief for perimenopause and menopause," including that it reduces hot flashes, night sweats, vaginal dryness, sleeplessness, and joint and muscle discomfort,[13] and take the necessary steps to ensure compliance with FTC and FDA law. HUM Nutrition should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the

FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

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[13] *See, e.g.*, Fan Club, HUM Nutrition, https://www.humnutrition.com/product/75/fan-club.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Nathan Hamilton, President
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774 Mays Blvd., Suite 10, PMB 489
Incline Village, NV 89451-9613
cs@juvenon.com
hamilton@juvenon.com

Re: Juvenon's Menopause Supplement Marketing Practices

Dear Mr. Hamilton:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Juvenon to review its marketing, which includes, among other things, claims that its SeroLastin supplement can "[h]elp to provide quick relief from menopausal and hormonal symptoms,"[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, SeroLastin, Juvenon, https://juvenon.com/products/serolastin.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Donna Ledwidge, Co-Founder
Femtech Healthcare Limited
Commercial House, Millbank Business Park
Lucan, Co.
Dublin, Ireland
K78X5W6
hello@keyforher.com

Re: Femtech's Menopause Supplement Marketing Practices

Dear Ms. Ledwidge:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Femtech to review its marketing, which includes, among other things, claims that its Key Peri + Menopause supplement, which is available to U.S. consumers, can relieve menopausal hot flashes, night sweats, and brain fog,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Key Peri + Menopause, Key for Her, https://keyforher.com/products/key-for-peri-menopause.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Mathew Pilot, Brand Manager
Liddell Laboratories, Inc.
201 Apple Blvd.
Woodbine, IA 51579
webinfo@liddell.net
mathew@peacefulmountain.com

Re: Liddell Laboratories' Menopause Supplement Marketing Practices

Dear Mr. Pilot:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Liddell Laboratories to review its marketing, which includes, among other things, claims that its Menopause oral spray relieves menopause symptoms, including hot flashes,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Liddell Laboratories should take particular care due to the fact that its parent company, Energique, company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product

health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

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[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause, Liddell Laboratories, https://www.liddell net/product/menopause/.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Jason Greenstein, General Counsel
Life Extension
900 N. Federal Hwy.
Fort Lauderdale, FL 33304
jgreenstein@lifeextension.com

Re: Life Extension's Menopause Supplement Marketing Practices

Dear Mr. Greenstein:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Life Extension to review its marketing, which includes, among other things, claims that its Menopause Relief supplement "relieves 11 different signs of menopause," including hot flashes and night sweats,[13] and that its Estrogen for Women supplement provides relief from hot flashes and night sweats,[14] and take the necessary steps to ensure compliance with FTC and FDA law. Life Extension should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[15] which notified the company that failing to adequately support product health

claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[16] Currently, the maximum civil penalty amount is $51,744 per violation.[17]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022

("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Relief, Life Extension, https://www.lifeextension.com/vitamins-supplements/item02204/menopause-731.

[14] *See, e.g.*, Estrogen for Women, Life Extension, https://www.lifeextension.com/vitamins-supplements/item01894/estrogen-for-women.

[15] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[16] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[17] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Monica M. Diaz, Regulatory Manager
Mason Vitamins, Inc.
15750 NW 59th Ave.
Miami Lakes, FL 33014
mdiaz@masonvitamins.com

Re: Mason Vitamins' Menopause Supplement Marketing Practices

Dear Ms. Diaz:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Mason Vitamins to review its marketing, which includes, among other things, claims that its Menopause Trio supplement alleviates menopausal hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Mason Vitamins should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

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[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Trio, Mason Vitamins, https://www.masonvitamins.com/products/menopause-trio-black-cohosh-flaxseed-soy-extended-release/.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Danielle Jacobs, Co-founder
MenoLabs
107 College Rd. E.
Princeton, NJ 08540
customercare@menolabs.com
danielle.jacobs@menolabs.com

Re: MenoLabs' Menopause Supplement Marketing Practices

Dear Ms. Jacobs:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges MenoLabs to review its marketing, which includes, among other things, claims that its MenoFit and MenoGlow supplements relieve menopause symptoms including hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law. MenoLabs should take particular care due to the fact that its parent company, Dr. Reddy's Laboratories, Inc., received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support

product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

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[13] *See, e.g.*, MenoFit, MenoLabs, https://menolabs.com/products/menofit-probiotic-menopause-relief-supplement-plus-weight-metabolism-support; MenoGlow, MenoLabs, https://menolabs.com/products/menoglow-probiotic-menopause-relief-supplement-plus-aging-vitality-support.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

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October 7, 2024

VIA EMAIL AND REGULAR MAIL

Melissa Neisler Dickinson, Founder
Menopause Vitamin Company Limited
17 Chilton Road
Ipswich, Suffolk
IP3 8PD
United Kingdom
melissa@menopausevitamincompany.co.uk

Re: Menopause Vitamin Company's Menopause Supplement Marketing Practices

Dear Ms. Dickinson:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Menopause Vitamin Company to review its marketing, which includes, among other things, claims that its Vibrancy Blend supplement, which is available to U.S. consumers, can address menopause symptoms and improve cognitive function,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Vibrancy Blend, Menopause Vitamin Co., https://menopausevitamincompany.co.uk/product/vibrancy-blend/.

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Approved Science
30 N. Gould St.
Ste. 2503
Sheridan, WY 82801
support@approvedscience.com

Re: Approved Science's Menopause Supplement Marketing Practices

To Whom It May Concern:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Approved Science to review its marketing, which includes, among other things, claims that its Menoprin supplement can relieve menopausal symptoms such as hot flashes, night sweats, and insomnia, and improve concentration,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menoprin, https://menoprin.com/index.php.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

WellMe
8500 Normandale Lake Blvd., Suite 350
Bloomington, MN 55437
Support@WellMe.com

Re: WellMe's Menopause Supplement Marketing Practices

To Whom It May Concern:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges WellMe to review its marketing, which includes, among other things, claims that its MenoRescue supplement can relieve menopause symptoms including hot flashes, night sweats, brain fog, and sleep issues,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

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[13] *See, e.g.*, MenoRescue, https://menorescue.com/.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Paul Konney, General Counsel
Metagenics LLC.
25 Enterprise, Suite 200
Aliso Viejo, CA 92656
paulkonney@metagenics.com
info@metagenics.com.au

Re: Metagenics' Menopause Supplement Marketing Practices

Dear Mr. Konney:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Metagenics to review its marketing, which includes, among other things, claims that its Estrovera Menopause Relief supplement "Relieves hot flashes, night sweats, sleep disturbances, [and] menopausal anxiety,"[13] and take the necessary steps to ensure compliance with FTC and FDA law. Metagenics should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health

claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Estrovera® Menopause Relief, Metagenics, https://www.metagenics.com/estrovera.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Jess Toolson, Founder
Mixhers
4030 S. 500 W., Suite 40
Salt Lake City, UT 84123
Help@mixhers.com
jess@mixhers.com

Re: Mixhers' Menopause Supplement Marketing Practices

Dear Ms. Toolson:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Mixhers to review its marketing, which includes, among other things, claims that its Menopause supplement can reduce menopausal symptoms including hot flashes, brain fog, and vaginal dryness,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

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[13] *See, e.g.*, Menopause, Mixhers, https://mixhers.com/products/menopause.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Michelle Wilson, General Counsel
Modere, Inc.
588 South 2000 West
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Ivan Wasserman
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Re: Modere's Menopause Supplement Marketing Practices

Dear Ms. Wilson and Mr. Wasserman:

Since our 2023 investigation into Modere's marketing of its Project 23 supplements,[1] TINA.org has undertaken a larger investigation into the menopause supplement industry as a whole. This investigation has revealed that marketing menopause supplements without the necessary scientific substantiation required by the FTC or the required FDA approval is a trend that is currently prevalent in the industry.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[2] In general, as Modere is aware,[3] "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[4] Advertising a product's attributes – including a product's ability to treat menopause symptoms[5] – without substantiation to back up those claims constitutes deceptive marketing.[6]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[7] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[8] moderate to severe vaginal pain and dryness,[9] depression and anxiety,[10] cognitive function,[11] insomnia,[12] and joint and muscle pain[13]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[14]

While Modere has made changes to its marketing of its menopause supplement since we were last in touch, TINA.org urges Modere to again review its marketing, which still includes, among other things, claims that its Ova-m supplement can reduce symptoms of perimenopause and menopause, including hot flashes, night sweats, brain fog, insomnia, and vaginal dryness,[15] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *Modere*, Truth in Advertising, Inc., https://truthinadvertising.org/brands/modere/; Letter from Truth in Advertising, Inc. to DSSRC re: Modere's Use of Illegal Health and Income Claims to Promote Project 23, Feb. 17, 2023, https://truthinadvertising.org/wp-content/uploads/2021/12/2_17_23-Complaint-to-DSSRC-re-Modere.pdf.

[2] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[3] FTC Warning Letter to Modere, Apr. 24, 2020, https://www.ftc.gov/system/files/warning-letters/covid-19-letter_to_modere_inc.pdf ("It is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made.").

[4] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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[11] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[12] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[13] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy …'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[14] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[15] *See, e.g.*, Modere Ova-m, Modere, https://www modere.com/productdetail/modere-ova-m; Modere (@modere_us), Instagram (May 20, 2024), https://www.instagram.com/p/C7M_JJ4oOIJ/?hl=en; Modere (@modere_us), Instagram (May 21, 2024), https://www.instagram.com/modere_us/p/C7Pj9UfJW11/?img_index=3; Modere (@modere_us), Instagram (May 21, 2024), https://www.instagram.com/p/C7Pjt0Runfr/?hl=en; Modere

(@modereca), Instagram (July 29, 2024), https://www.instagram.com/p/C-AzX0Is6YI/?api=postMessage; Modere (@modere_us), Instagram (Dec. 18, 2023), https://www.instagram.com/p/C1AIMBTsMFe/?hl=en.

TINA.org acknowledges that the Direct-Selling Self-Regulatory Council determined that Modere could substantiate claims that its supplements could alleviate certain symptoms of menopause. BBB National Programs, DSSRC, NGO Inquiry: Modere, Inc., Case No. 140-20232023 (Dec. 18, 2023), https://truthinadvertising.org/wp-content/uploads/2021/12/DSSRC-Modere-Case-Decision.pdf. However, not only does Modere keep its purported substantiation for its marketing claims secret and therefore unavailable for consumers to read, review, or analyze, the DSSRC's decision is at odds with FTC law and guidance, as well as with the opinion of medical experts. *See e.g.*, Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf (finding that there is "negative or insufficient evidence" for the use of supplements to treat vasomotor symptoms associated with menopause and they are therefore not recommended); *Menopausal Symptoms: In Depth*, NIH (May 2017), https://www nccih.nih.gov/health/menopausal-symptoms-in-depth ("Many nutritional approaches such as dietary supplements have been studied for menopause symptoms. However, none has clearly been shown to be helpful. There's little information on the long-term safety of dietary supplements, and some can have harmful side effects or interact with drugs.").

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL

Andrea Donsky, Co-founder
Morphus
support@wearemorphus.com
andrea@wearemorphus.com

Re: Morphus' Menopause Supplement Marketing Practices

Dear Ms. Donsky:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Morphus to review its marketing, which includes, among other things, claims that its Cool & Flash-Free Bundle can relieve menopause symptoms such as night sweats, hot flashes, anxiety, and joint and muscle pain,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Cool & Flash-Free Bundle, Morphus, https://wearemorphus.com/products/cool-flash-free-bundle?variant=45279510364458.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Naomi Whittel, Founder
Naomi Whittel Brands
8609 Westwood Center Dr., Ste. #110
Tysons Corner, VA 22182
nwhittel@wproductslimited.com

Re: Naomi's Menopause Supplement Marketing Practices

Dear Ms. Whittel:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Naomi to review its marketing, which includes, among other things, claims that its Naomi Harmony supplement can manage menopausal hot flashes, night sweats, vaginal dryness, insomnia, and joint discomfort,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Naomi Harmony, Naomi, https://naomiw.com/products/naomi-harmony-free-bottle.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Jonathan Leventhal, General Counsel
Natrol
15233 Ventura Blvd., Suite 900
Sherman Oaks, CA 91403
jleventhal@natrol.com
natrolsupport@vytalogy.com

Re: Natrol's Menopause Supplement Marketing Practices

Dear Mr. Leventhal:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Natrol to review its marketing, which includes, among other things, claims that its Complete Balance Menopause Relief supplement provides menopause relief and helps relieve hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Natrol should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil

penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Complete Balance Menopause Relief, Natrol, https://www natrol.com/products/complete-balance-am-pm-formula-menopause-relief-capsules.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Scott Seedall, General Counsel
Nature's Answer Inc.
85 Commerce Dr.
Hauppauge, NY 11788
sseedall@naturesanswer.com
customerservice@naturesanswer.com

Re: Nature's Answer's Menopause Supplement Marketing Practices

Dear Mr. Seedall:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Nature's Answer to review its marketing, which includes, among other things, claims that its Pueraria Mirifica supplement reduces hot flashes, night sweats, and mood instability associated with menopause,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Nature's Answer should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health

claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

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[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Pueraria Mirifica, Nature's Answer, https://www naturesanswer.com/product/pueraria-mirifica-60-veggie-capsules/.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Barbara Sanchez, Head of Legal
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Bridgewater, NJ 08807
Barbara.sanchez@us.nestle.com

Nature's Bounty
Attn: Consumer Affairs
110 Orville Dr.
Bohemia, NY 11716
info@naturesbounty.com

Re: Nature's Bounty's Menopause Supplement Marketing Practices

Dear Ms. Sanchez:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Nestlé and Nature's Bounty to review their marketing, which includes, among other things, claims that Nature's Bounty Black Cohosh supplement helps with menopausal hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Nestlé and Nature's Bounty should take particular care due to the fact that the companies each received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified them that failing to adequately support product health claims

could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

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[13] *See, e.g.*, Black Cohosh, Nature's Bounty, https://naturesbounty.com/products/black-cohosh-540-mg-100-capsules.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Meir Leff, CEO
Nature's Craft
239 2nd Ave. S., 2nd Floor
St. Petersburg, FL 33701
meirl@shopnaturescraft.com
hello@shopnaturescraft.com

Re: Nature's Craft's Menopause Supplement Marketing Practices

Dear Mr. Leff:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Nature's Craft to review its marketing, which includes, among other things, claims that its Menopause Support supplement can relieve menopausal hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Support, Nature's Craft, https://shopnaturescraft.com/products/menopause-support.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Tara Falsani, General Counsel and Vice President
Nature's Way
International Department
825 Challenger Dr.
Green Bay, WI 54311
tara.falsani@naturesway.com

Re: Nature's Way's Menopause Supplement Marketing Practices

Dear Ms. Falsani:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Nature's Way to review its marketing, which includes, among other things, claims that its AM/PM Menopause Formula supplement provides relief from menopause symptoms, including hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Nature's Way should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product

health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, AM/PM Menopause Formula, Nature's Way, https://naturesway.com/products/ampm-menopause-formula.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Bradley Marr, Director, Quality Assurance & Regulatory Compliance
New Chapter
90 Technology Dr.
Brattleboro, VT 05301
marr@newchapter.com
info@newchapter.com

Re: New Chapter's Menopause Supplement Marketing Practices

Dear Mr. Marr:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges New Chapter to review its marketing, which includes, among other things, claims that its Estrotone: Chaste Tree Blend supplement reduces menopause symptoms including hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law. New Chapter should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims

could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

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[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Estrotone: Chaste Tree Blend, New Chapter, https://newchapter.com/products/estrotone-herbal-supplement.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Richard Taylor, General Counsel
Nordic Naturals
111 Jennings Dr.
Watsonville, CA 95076
rtaylor@nordicnaturals.com
customerservice@nordicnaturals.com

Re: Nordic Naturals' Menopause Supplement Marketing Practices

Dear Mr. Taylor:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Nordic Naturals to review its marketing, which includes, among other things, claims that its Menopause Support supplement relieves menopause symptoms, including hot flashes,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Nordic Naturals should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil

penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Support, Nordic Naturals, https://www nordic.com/products/menopause-support/.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

TRUTH IN ADVERTISING.ORG

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Dr. Vonda Wright, Founder
HydroNova / NovaMD
160 W. Camino Real, #1163
Boca Raton, FL 33432
support@drvonda.com

Re: HydroNova's Menopause Supplement Marketing Practices

Dear Dr. Wright:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges HydroNova to review its marketing, which includes, among other things, claims that its NovaMD Advanced Menopause Support supplement can relieve menopausal hot flashes, vaginal dryness, joint discomfort, brain fog, and sleep issues,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Advanced Menopause Support, NovaMD, https://novamd.com/products/advanced-menopause-support.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Sara Emme, Corporate Counsel
NOW Health Group, Inc.
244 Knollwood Dr.
Bloomingdale, IL 60108
sara.emme@nowfoods.com
productinfo@nowfoods.com

Re: NOW Health Group's Menopause Supplement Marketing Practices

Dear Ms. Emme:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges NOW Health Group to review its marketing for its Menopause Support supplement,[13] and take the necessary steps to ensure compliance with FTC and FDA law. NOW Health Group should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Support, NOW Health Group, https://www.nowfoods.com/products/supplements/menopause-support-veg-capsules.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

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Re: Nutrafol's Menopause Supplement Marketing Practices

Dear Ms. Bone & Ms. Varsellona:

Since our 2023 investigation into Nutrafol's supplements,[1] TINA.org has undertaken an investigation into the menopause supplement industry. This investigation has revealed that marketing menopause supplements without the necessary scientific substantiation required by the FTC or the required FDA approval is a trend that is currently prevalent in the industry.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[2] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[3] Advertising a product's attributes – including a product's ability to treat menopause symptoms[4] – without substantiation to back up those claims constitutes deceptive marketing.[5]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[6] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[7] moderate to severe vaginal pain and dryness,[8] depression and anxiety,[9] cognitive function,[10] insomnia,[11] and joint and muscle pain[12]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[13]

TINA.org urges Nutrafol to review its marketing, which includes, among other things, claims that its Women's Balance supplement helps with menopause symptoms, including hot flashes,[14] and take the necessary steps to ensure compliance with FTC and FDA law. Nutrafol should take particular care due to the fact that its parent company, Unilever, received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[15] which notified the company that failing to adequately support product health claims could result in civil

penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[16] Currently, the maximum civil penalty amount is $51,744 per violation.[17]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *Nutrafol*, Truth in Advertising, Inc., https://truthinadvertising.org/brands/nutrafol/.
[2] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.
[3] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.
[4] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).
[5] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.
[6] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").
[7] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").
[8] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[9] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[10] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[11] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[12] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[13] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[14] *See, e.g.*, Women's Balance, Nutrafol, https://nutrafol.com/women-balance/.

[15] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[16] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[17] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Martin Ye, Chief Marketing Officer
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Los Angeles, CA 90049
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Re: O Positiv's Menopause Supplement Marketing Practices

Dear Mr. Ye:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges O Positiv to review its marketing, which includes, among other things, claims that its Menopause Vitamin Capsules and Menopause Gummy Vitamins target menopause symptoms including hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

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[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022

("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Vitamin Capsules & Menopause Gummy Vitamin, O Positiv, https://opositiv.com/products/meno-menopause-vitamin-capsules.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Bill Dodero, General Counsel
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Re: Bayer's Menopause Supplement Marketing Practices

Dear Mr. Dodero:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Bayer to review its marketing, which includes, among other things, claims that its One A Day Women's Menopause Formula supplement eases menopause symptoms including hot flashes,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Bayer should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil

penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, One A Day Women's Menopause Formula, One A Day, https://www.oneaday.com/vitamins/vitamins-for-women/womens-multivitamin-for-menopause.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Lai Yan, CEO
Onecare
1979 Marcus Ave., Suite 210
Lake Success, NY 11042
laiyan@onecarewellness.com

Re: Onecare's Menopause Supplement Marketing Practices

Dear Ms. Yan:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Onecare to review its marketing, which includes, among other things, claims that its lolvita supplement relieves menopausal symptoms, including hot flashes, night sweats, depression, and anxiety, protects against liver diseases, improves focus and memory, and prevents dementia and Alzheimer's disease,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

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include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, lolvita, Onecare, https://www.onecare.store/buy/lolvita.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Will Smelko, CEO
Ora Organic
411 W. Monroe St.
Austin, TX 78704
will@ora.organic
info@ora.organic

Re: Ora Organic's Menopause Supplement Marketing Practices

Dear Mr. Smelko:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Ora Organic to review its marketing, which includes, among other things, claims that its Hormonal Balance & Support supplement can reduce menopausal symptoms,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Hormonal Balance & Support, Ora Organic, https://ora.organic/products/hormonal-balance-support-capsules.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Catherine Balsam-Schwaber, Founder & CEO
Our Kindra
1920 Olympic Blvd.
Santa Monica, CA 90404
catherine@ourkindra.com
hello@ourkindra.com

Re: Our Kindra's Menopause Supplement Marketing Practices

Dear Ms. Balsam-Schwaber:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Our Kindra to review its marketing, which includes, among other things, claims that The Core Supplement can reduce menopausal hot flashes, night sweats, vaginal dryness, joint pain, anxiety, and insomnia, and improve cognitive function,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, The Core Supplement, Our Kindra, https://ourkindra.com/collections/menopause/products/the-core-dietary-supplement.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Ian Brady, CEO
Hologram Sciences/Phenology
177 Huntington Ave.
Ste. 1703 PMB 71158
Boston, MA 02115
ian@hologramsciences.com
support@myphenology.com

Re: Phenology's Menopause Supplement Marketing Practices

Dear Mr. Brady:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Phenology to review its marketing, which includes, among other things, claims that its Daily Balance supplement can relieve multiple symptoms of menopause, including hot flashes, night sweats, and brain fog,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Daily Balance, Phenology, https://myphenology.com/products/daily-balance.

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Andy Funk, Founding Director
Pink Lotus Elements, LLC
100 Wilshire Blvd., Ste. 700
Santa Monica, CA 90401
dfunk@pinklotus.com

Re: Pink Lotus Elements' Menopause Supplement Marketing Practices

Dear Mr. Funk:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Pink Lotus Elements to review its marketing, which includes, among other things, claims that its Menopause Miracle supplement relieves symptoms such as hot flashes, night sweats, vaginal dryness, insomnia, headaches, and joint pain,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Miracle, Pink Lotus Elements, https://pinklotus.com/elements/menopausemiracle/.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Amy Upchurch, CEO & Founder
Pink Stork
30 Iroquois Ave.
St. Augustine, FL 32084
amy@pinkstork.com
cs@pinkstork.com

Re: Pink Stork's Menopause Supplement Marketing Practices

Dear Ms. Upchurch:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Pink Stork to review its marketing, which includes, among other things, claims that its Menopause Support supplement can address menopausal symptoms like hot flashes, night sweats, and sleeplessness,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Support, Pink Stork, https://pinkstork.com/products/menopause-supplement.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Barbara Sanchez, Head of Legal
Nestlé Health Science
1007 US Highway 202/26
Building JR2
Bridgewater, NJ 08807
Barbara.sanchez@us.nestle.com

Pure Encapsulations
490 Boston Post Road
Sudbury, MA 01776
support@pureforyou.com

Re: Pure Encapsulations' Menopause Supplement Marketing Practices

Dear Ms. Sanchez:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Nestlé and Pure Encapsulations to review their marketing, which includes, among other things, claims that Pure Encapsulations' MenoVive 60's supplement addresses menopausal symptoms such as hot flashes, night sweats, and maintaining cognitive function,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Nestlé and Pure Encapsulations should take particular care due to the fact that the companies each received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified them that failing to adequately support product health claims could result

in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

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[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, MenoVive 60's, Pure Encapsulations, https://www.pureencapsulationspro.com/menovive-60-s.html.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Jason Watkin, CEO
Purica
6157 Scott Rd.
Duncan, BC V9L 6Y8
Canada
jason@purica.com
shop@purica.com

Re: Purica's Menopause Supplement Marketing Practices

Dear Mr. Watkin:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Purica to review its marketing, which includes, among other things, claims that its Menopause Relief supplement, which is available to U.S. consumers, "calms" hot flashes and night sweats, and prevents mood swings,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Relief, Purica, https://purica.com/products/menopause-relief.

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Justin Hai, President & CEO
Rebalance Health, Inc.
1855 S. 57th Ct.
Suite 100
Boulder, CO 80301
jhai@rebalancehealth.com

Re: Rebalance Health's Menopause Supplement Marketing Practices

Dear Mr. Hai:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Rebalance Health to review its marketing, which includes, among other things, claims that The Hot Flash System supplements can provide relief from menopausal hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, The Hot Flash System, Rebalance Health, https://rebalancehealth.com/products/hot-flash-system.

TRUTH IN ADVERTISING.ORG

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Stephanie Hudson & Nathan Summers, Founders
Rejuvit Sciences LLC
312 W. 2nd Street
Casper, WY 82601
customer@rejuvit.co

Re: Rejuvit's Menopause Supplement Marketing Practices

Dear Ms. Hudson & Mr. Summers:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Rejuvit to review its marketing, which includes, among other things, claims that its Menopause Relief supplement can relieve menopausal symptoms including hot flashes, night sweats, and brain fog,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

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[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy …'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Rejuvit Menopause Relief, Rejuvit, https://rejuvit.co/products/rejuvit-menopause-weight-management-1-bottles-30-days-subscription.

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Nils Ole Wolcke, Managing Director
Schaper & Brümmer GmbH & Co. KG
Remifemin
Bahnhofstraße 35
D-38259 Salzgitter
Germany
info@schaper-bruemmer.de

Re: Remifemin's Menopause Supplement Marketing Practices

Dear Mr. Wolcke:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Remifemin to review its marketing, which includes, among other things, claims that its Remifemin Menopause Relief supplement, which is available to U.S. consumers,[13] is clinically proven to reduce hot flashes and night sweats,[14] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Remifemin, Amazon, https://www.amazon.com/Menopause-Symptoms-Relief-Ingredients-Estrogen-Free/dp/B0CRKXS5LJ.

[14] *See, e.g.*, Remifemin, https://www.remifemin.de/remifemin/.

TRUTH IN ADVERTISING.ORG

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Lauren Lee, CEO & Co-Founder
Semaine
130 Boulevard N.E. #6
Atlanta, GA 30312
lauren@semainehealth.com
support@semainehealth.com

Re: Semaine's Menopause Supplement Marketing Practices

Dear Ms. Lee:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Semaine to review its marketing, which includes, among other things, claims that its Peri/Menopause Essentials supplement can relieve symptoms of menopause including hot flashes, night sweats, and brain fog,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Peri/Menopause Essentials, Semaine, https://www.semainehealth.com/products/menopause-essentials.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Anna Pavisha, Compliance Director
SMNutrition
239 2nd Ave. S., Ste. 200
St. Petersburg, FL 33701
anna@smnutrition.com
email@smnutrition.com

Re: SMNutrition's Menopause Supplement Marketing Practices

Dear Ms. Pavisha:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges SMNutrition to review its marketing, which includes, among other things, claims that its Menopause Support Complex supplement can address hot flashes, night sweats, and brain fog,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

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[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Support Complex, SMNutrition, https://smnutrition.com/collections/menopause/products/estro-aid-estrogen-free-herbal-supplement.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Stan Soper, Chief Legal Officer
Better Being Company
222 S. Main St.
Salt Lake City, UT 84101
ssoper@betterbeing.com
info@solaray.com

Re: Better Being Company's Menopause Supplement Marketing Practices

Dear Mr. Soper:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Better Being Company to review its marketing, which includes, among other things, claims that its Solaray Her Life Stages Menopause supplement helps with menopausal symptoms including hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Better Being Company should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately

support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Her Life Stages Menopause, Solaray, https://solaray.com/products/her-life-stages-menopause?selling_plan=948994108.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Keith Didion, President
Solgar
500 Willow Tree Rd.
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didionke@solgar.com

Barbara Sanchez, Head of Legal
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1007 US Highway 202/26
Building JR2
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Re: Solgar's Menopause Supplement Marketing Practices

Dear Mr. Didion & Ms. Sanchez:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Solgar to review its marketing, which includes, among other things, claims that its Menopause Relief supplement provides relief for "a full range of the most common menopausal symptoms," including hot flashes, night sweats, joint and muscle discomfort, anxiety, and vaginal dryness,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Solgar should take particular care due to the fact that the company, as well as its parent company Nestlé, received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified them that failing to adequately support

product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

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[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Relief, Solgar, https://www.solgar.com/products/menopause-relief-tablets/.

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October 7, 2024

VIA EMAIL AND REGULAR MAIL

Carl R. Wiseman, CFO & COO
Threshold Enterprises
23 Janis Way
Scotts Valley, CA 95066
carlw@thresholdent.com

Re: Source Naturals / Threshold Enterprises' Menopause Supplement Marketing Practices

Dear Mr. Wiseman:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Threshold Enterprises to review its marketing, which includes, among other things, claims that its Source Naturals Eternal Woman Hot Flash supplement can reduce menopausal hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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TRUTH IN ADVERTISING.ORG

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Cara Kamenev, CEO
Stripes
9100 Wilshire Blvd
Beverly Hills, CA 90212
policy@iamstripes.com

Dan Reid, COO & General Counsel
L Catterton
599 West Putnam Ave.
Greenwich, CT 06830
dan.reid@lcatterton.com

Re: Stripes' Menopause Supplement Marketing Practices

Dear Ms. Kamanev & Mr. Reid:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Stripes to review its marketing, which includes, among other things, claims that The Inside Addition supplement can address menopausal symptoms including hot flashes, night sweats, and brain fog,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, The Inside Addition, Stripes, https://stripesbeauty.com/products/the-inside-addition.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Ilana Vaks
Supplements Studio
8903 Glades Rd.
Ste. A14 #4050
Boca Raton, FL 33434
ilana@supplementsstudio.com
support@supplementsstudio.com

Re: Supplements Studio's Menopause Supplement Marketing Practices

Dear Ms. Vaks:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Supplement Studio to review its marketing, which includes, among other things, claims that its Optimal DIM supplement can relieve menopausal symptoms including hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

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[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

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[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Optimal DIM Supplement, Supplements Studio, https://supplementsstudio.com/collections/menopause-supplements.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Susie Brient, CEO
SusieWho
87 Norwich Road
Fakenham, Norfolk
NR21 8HH
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Re: SusieWho's Menopause Supplement Marketing Practices

Dear Ms. Brient:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges SusieWho to review its marketing, which includes, among other things, claims that its Natural Menopause Support supplement, which is available to U.S. consumers, can reduce hot flushes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

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[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

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include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[13] *See, e.g.*, Natural Menopause Support, SusieWho, https://susiewho.co.uk/products/natural-menopause-support?_pos=1&_psq=menopau&_ss=e&_v=1.0&variant=45401025020180.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Jim Hamel, CEO
Swanson Health Products
P.O. Box 2803
Fargo, ND 58108-2803
jim.hamel@swansonvitamins.com

Re: Swanson Health Products' Menopause Supplement Marketing Practices

Dear Mr. Hamel:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Swanson Health Products to review its marketing for its Black Cohosh Menopause Support supplement, and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Diego Alegria Carmelino, Brand Marketing Coordinator
Pronova
5000 SW 75th Ave., Ste. 113
Miami, FL 33155
dalegriacarmelino@pronovacorp.com
info@pronovacorp.com

Re: Pronova's Menopause Supplement Marketing Practices

Dear Mr. Alegria Carmelino:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Pronova to review its marketing, which includes, among other things, claims that its Tempo Hot Flash Relief supplement can relieve menopausal symptoms including hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

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include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Tempo Hot Flash Relief, Pronova, https://www.store.pronovacorp.com/pages/tempo-about.

TRUTH IN ADVERTISING.ORG

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Terry Lemerond, Founder & Director
EuroPharma / Terry Naturally Vitamins
955 Challenger Dr.
Green Bay, WI 54311
tlemerond@europharmausa.com

Re: EuroPharma / Terry Naturally Vitamins' Menopause Supplement Marketing Practices

Dear Mr. Lemerond:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges EuroPharma to review its marketing, which includes, among other things, claims that its Terry Naturally Vitamins Menopause Relief Plus supplement reduces menopausal symptoms such as hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law. EuroPharma should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Relief* Plus, Terry Naturally Vitamins, https://www.terrynaturallyvitamins.com/menopause-relief-plus.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

TRUTH IN ADVERTISING.ORG

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Moira Batista, Associate General Counsel
The Vitamin Shoppe
300 Harmon Meadow Blvd.
Secaucus, NJ 07094
moira.batista@vitaminshoppe.com

Re: The Vitamin Shoppe's Menopause Supplement Marketing Practices

Dear Ms. Batista:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges The Vitamin Shoppe to review its marketing, which includes, among other things, claims that its TrueYou Grace Period supplement addresses menopausal symptoms such as hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law. The Vitamin Shoppe should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022

("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, TrueYou Grace Period, The Vitamin Shoppe, https://www.vitaminshoppe.com/p/grace-period-60-vegetable-capsules/vs-4184.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

TRUTH IN ADVERTISING.ORG

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Heather Van Blarcom, General Counsel
Thorne
152 West 57th St.
44th Floor
New York, NY 10019
hvanblarcom@thorne.com
info@thorne.com

Re: Thorne's Menopause Supplement Marketing Practices

Dear Ms. Van Blarcom:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Thorne to review its marketing, which includes, among other things, claims that its Menopause Bundle supplements can address hot flashes, night sweats, sleeplessness, and memory lapses,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, Advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

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include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Bundle, Thorne, https://www.thorne.com/products/dp/menopause-bun028.

TRUTH IN ADVERTISING.ORG

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

UltaLife
8045 NW 36th St., Suite 508
Doral, FL 33166
support@ultalife.co

Re: UltaLife's Menopause Supplement Marketing Practices

To Whom It May Concern:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges UltaLife to review its marketing, which includes, among other things, claims that its Her Harmony Advanced Menopause supplement can help with menopause-related hot flashes, night sweats, anxiety, and depression,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Her Harmony Advanced Menopause Supplement, UltaLife, https://ultalife.com/products/her-harmony.

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Jane Pemberton, CEO & President
Vital Nutrients
45 Kenneth Dooley Dr.
Middletown, CT 06457
jane@vitalnutrients.net
support@vitalnutrients.co

Re: Vital Nutrients' Menopause Supplement Marketing Practices

Dear Ms. Pemberton:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Vital Nutrients to review its marketing, which includes, among other things, claims that its Menopause Support supplement can alleviate menopausal symptoms such as hot flashes,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Support, Vital Nutrients, https://www.vitalnutrients.co/products/menopause-support.

TRUTH IN ADVERTISING.ORG

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Lanesha Minnix, Global Chief Legal Officer
Walgreens Boots Alliance
108 Wilmot Rd., MS #2002
Deerfield, IL 60015
lanesha.minnix@walgreensbootsalliance.com

Re: Walgreens' Menopause Supplement Marketing Practices

Dear Ms. Minnix:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Walgreens to review its marketing, which includes, among other things, claims that its Menopause Multi-Symptom Support supplement addresses hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Walgreens should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

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[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

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[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy …'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Multi-Symptom Support, Walgreens, https://www.walgreens.com/store/c/walgreens-free-&-pure-menopause-multi-symptom-support-capsules/ID=300447421-product.

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

October 7, 2024

VIA EMAIL AND REGULAR MAIL

Leighton Richards, CEO
WelleCo
2A Railway Street
Cottesloe, Western Australia 6011
leighton.richards@welleco.com

Re: WelleCo's Menopause Supplement Marketing Practices

Dear Mr. Richards:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges WelleCo to review its marketing, which includes, among other things, claims that The Goddess Elixir supplement, which is available to U.S. consumers, "[r]elieves symptoms of menopause including mood balance, drive, hot flushes and night sweats,"[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] The Goddess Elixir, WelleCo, https://www.welleco.com/products/the-goddess-elixir.

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Rajaa Grar, Chief Marketing Officer
Nameless CPG
P.O. Box 11286
630 N.E. Killingsworth St.
Portland, OR 97211-3857
rajaa@namelesscpg.com
info@wilewomen.com

Re: Wile / Nameless CPG's Menopause Supplement Marketing Practices

Dear Ms. Grar:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Nameless CPG to review its marketing, which includes, among other things, claims that its Wile Hot Flash and Wile Perimenopause Support supplements can reduce hot flashes and night sweats,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Hot Flash Supplement, Wile, https://wilewomen.com/products/hot-flash-plant-based-herbal-supplement; Perimenopause Support, Wile, https://wilewomen.com/products/perimenopause-support-supplement.

TRUTH IN ADVERTISING.ORG

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Windsor Botanicals
19c Trolley Square
Wilmington, DE 19806
hello@windsorbotanicals.com

Re: Windsor Botanicals' Menopause Supplement Marketing Practices

To Whom It May Concern:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Windsor Botanicals to review its marketing, which includes, among other things, claims that its Menopause Relief supplement can relieve menopause-related hot flashes, night sweats and insomnia,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

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include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Menopause Relief, Windsor Botanicals, https://www.windsorbotanicals.com/products/menopause-relief-for-women-60-capsules.

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Jessica Mulligan, Founder
Winged Wellness
2110 W. Slaughter Lane, Ste. 107-313
Austin, TX 78748
jess@wingedwellness.com
hi@wingedwellness.com

Re: Winged Wellness's Menopause Supplement Marketing Practices

Dear Ms. Mulligan:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Winged Wellness to review its marketing, which includes, among other things, claims that its Hot Momma Menopause Support Capsules can address menopause and perimenopause symptoms such as hot flashes,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Hot Momma Menopause Support Capsules, Winged Wellness, https://wingedwellness.com/products/hot-momma.

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Sally Mueller, Co-Founder & CEO
Well Found, Inc. d.b.a. Womaness
P.O. Box 28705
St. Paul, MN 55128
sally@womaness.com
info@womaness.com

Re: Womaness' Menopause Supplement Marketing Practices

Dear Ms. Mueller:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Womaness to review its marketing, which includes, among other things, claims that its Me.No.Pause. supplement addresses menopause symptoms including hot flashes, night sweats, brain fog, and vaginal dryness,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, Advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

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[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

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[13] *See, e.g.*, Me.No.Pause., Womaness, https://womaness.com/collections/menopause-support-supplements/products/me-no-pause.

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Wesleigh Hayes, Marketing Director
Wonder Laboratories
115 S.C.T. Court, P.O. Box 820
White House, TN 37188
wesleigh@wonderlabs.com
wonder@wonderlabs.com

Re: Wonder Laboratories' Menopause Supplement Marketing Practices

Dear Ms. Hayes:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Wonder Laboratories to review the marketing for its Black Cohosh Menopause Support and Women's Health supplement,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

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[13] *See, e.g.*, Black Cohosh, Wonder Laboratories, https://wonderlabs.com/BLACK-COHOSH-FORMULA-182.

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Simon Doig, CEO
XtendLife
12 Mary Muller Dr.
Hillsborough, Christchurch 8022
New Zealand
simon@xtend-life.com
customer.service@xtend-life.com

Re: XtendLife's Menopause Supplement Marketing Practices

Dear Mr. Doig:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges XtendLife to review its marketing, which includes, among other things, claims that its Hormone-Support For Her supplement, which is available to U.S. consumers, improves menopause symptoms, alleviates headaches and hormonal acne, strengthens bones and improves bone density,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, Advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

[3] Stipulated Order, *FTC v. Lunada Biomedical et al.*, C.D. Cal, May 16, 2020, Case 2:15-cv-03380 (preventing defendants from representing that their menopause supplement "relieves hot flashes, night sweats, irritability, mood swings, inability to concentrate, sleeplessness, lack of energy, decreased libido, stress, anxiety, weight gain, headache, or muscle or joint aches associated with menopause" without randomized, double-blind, placebo-controlled human clinical testing that substantiates that the representation is true, and requiring defendants to pay $40 million).

[4] Specifically with respect to vasomotor symptoms – e.g., hot flashes and night sweats, the most common symptoms of menopause – it is worth noting that The North American Menopause Society, the nation's preeminent resource on menopause to both healthcare providers and the public, has indicated that there is not sufficient evidence-based scientific research to substantiate claims that supplements can effectively relieve vasomotor symptoms of menopause. Chrisandra L. Shufelt et al, *The 2023 Nonhormone Therapy Position Statement of The North American Menopause Society*, 30 Menopause: J. North Am. Menopause Soc'y 573-590, https://www.menopause.org/docs/default-source/professional/2023-nonhormone-therapy-position-statement.pdf.

[5] *See, e.g.*, FDA warning letter to Bonagens, Nov. 17, 2020, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:… 'alleviate the effects of menopausal syndrome … menopausal and sleeping disorders'").

[6] *See* Veozah Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216578s000lbl.pdf ("VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause."); Brisdelle Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf ("BRISDELLE is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause.").

[7] Osphena Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/203505s015lbl.pdf ("INDICATIONS AND USAGE… The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause[;] The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause.").

[8] *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs

include: … 'Has been noted to have powerful reductions in anxiety'"); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: … 'The Only Doctor Designed Depression Pill, Enlifta Depression Supplement – Best Natural Antidepressant.' … 'ENLIFTA: OUR #1 BEST-SELLING DEPRESSION SUPPLEMENT'… 'A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'… 'Unlike other supplements and prescription medications, Enlifta Anxiety helps to manage stress and associated anxiety without causing excess fatigue'… 'for the treatment of insomnia and anxiety'").

[9] *See, e.g.*, FDA warning letter to Beeyoutiful.com, LLC, July 12, 2021, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/beeyoutifulcom-llc-613682-07122021 ("Examples of some of the claims observed on your www.beeyoutiful.com website that provide evidence that your products are intended for use as drugs include: . . . On the product page, under the Product Description tab (in the 'Who can benefit from taking Omega 3?' section): … '4. Cognitive function – including both dementia/Alzheimer's and Depression/Mental disorders…'"); FDA warning letter to Let's Talk Health, Inc., Aug. 6, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/lets-talk-health-inc-576771-08062019 ("Examples of the claims that provide evidence that your products are intended for use as drugs include the following: . . . vii. 'Carnitine . . . [has been used to show significant improvement in those with] mild cognitive impairment.'").

[10] *See, e.g.*, FDA warning letter to Enlifta, LLC, Feb. 18, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021 ("Examples of some of the website claims that provide evidence that your "Enlifta Mood Elevator" and "Enlifta Anxiety" are intended for use as drugs include: '... for the treatment of insomnia and anxiety'").

[11] *See, e.g.*, FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: … 'zuRelief: Reduce Pain…'… 'I am an MD and there is no product on the conventional over the counter market that approaches the combination of safety and effectiveness of zuRelief for my own joint and muscle aches.'"); FDA warning letter to ActiveHerb Technology, Inc., May 15, 2019, https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/activeherb-technology-inc-574615-05152019 ("Examples of some of the labeling claims that provide evidence that your products are intended for use as drugs include: … JointsJoy…'shown to inhibit inflammation reactions and to inhibit pain'… 'relieves pain'… 'relieve muscle aches'"); FDA warning letter to Emmbros Overseas Lifestyle PVT LTD., Feb. 5, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/emmbros-overseas-lifestyle-pvt-ltd-565631-02052019 ("Examples of some of the claims observed on your websites that provide evidence that your products are intended for use as drugs include the following: . . . 'If you are suffering from joint pain & inflammation, the recommended dosage is 2 Arthcare Capsules…'").

[12] In addition to approving Veozah, Brisdelle, and Osphena for the treatment of menopause symptoms, as well as several hormone therapies for menopause, the FDA has also approved one other drug for the treatment of conditions associated with menopause. Evista Highlights of Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020815s034lbl.pdf (Evista is approved for the treatment and prevention of osteoporosis and reduction of invasive breast cancer in postmenopausal women). *See also* Menopause: Medicines to Help You, FDA, https://www fda.gov/consumers/free-publications-women/menopause-medicines-help-you.

[13] *See, e.g.*, Hormone-Support For Her, XtendLife, https://www.xtend-life.com/products/hormone-support-for-her.

TRUTH IN ADVERTISING.ORG

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Taneesha Routier, Director of Regulatory Affairs
Xymogen
6900 Kingspointe Pkwy.
Orlando, FL 32819
taneesha.routier@xymogen.com
info@xymogen.com

Re: Xymogen's Menopause Supplement Marketing Practices

Dear Ms. Routier:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Xymogen to review its marketing, which includes, among other things, claims that its Femquil Healthy Hormone Support for Women supplement eases common symptoms associated with menopause symptoms,[13] and take the necessary steps to ensure compliance with FTC and FDA law. Xymogen should take particular care due to the fact that the company received a Notice of Penalty Offenses Concerning Substantiation of Product Claims from the FTC in 2023,[14] which notified the company that failing to adequately support product health

claims could result in civil penalties pursuant to 15 U.S.C. § 45(m)(1)(B).[15] Currently, the maximum civil penalty amount is $51,744 per violation.[16]

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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[1] *See* FTC, Advertising Substantiation Principles, https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf; FTC Health Products Compliance Guidance, https://www ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

[2] FTC Health Products Compliance Guidance, 12, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf. Further, Advertisers relying on ingredient studies should consult with a qualified expert in the relevant field to determine whether a clinical study of the product itself is required, rather than reliance on isolated ingredient studies, to substantiate benefits. *Id*. at 13.

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[13] *See, e.g.*, Xymogen, Femquil, https://www.xymogen.com/product/Femquil-120-C

[14] List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation of Product Claims, FTC (updated May 11, 2023), https://www ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

[15] Sample Cover Letter re: Notices of Penalty Offices, FTC (Apr. 13, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Sample-cover-letter-substantiaton.pdf.

[16] FTC Publishes Inflation-Adjusted Civil Penalty Amounts for 2024, https://www.ftc.gov/news-events/news/press-releases/2024/01/ftc-publishes-inflation-adjusted-civil-penalty-amounts-2024.

TRUTH IN ADVERTISING.ORG

Oct. 7, 2024

VIA EMAIL AND REGULAR MAIL

Jordan Dorn, Co-Founder
Zuma Nutrition
23823 Malibu Rd., Ste. 50-470
Malibu, CA 90265
jordan@zumanutrition.com
info@zumanutrition.com

Re: Zuma Nutrition's Menopause Supplement Marketing Practices

Dear Mr. Dorn:

On behalf of Truth in Advertising, Inc. ("TINA.org"), a nonprofit consumer advocacy organization dedicated to protecting consumers from deceptive advertising, we write to alert you to a deceptive marketing trend that is currently prevalent in the menopause supplement industry. Namely, many menopause supplements are marketed without the necessary scientific substantiation required by the FTC or the required FDA approval.

First, companies in this industry are marketing their supplements as treating menopause and its symptoms without competent and reliable scientific evidence to substantiate their claims, in violation of the Federal Trade Commission Act.[1] In general, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard."[2] Advertising a product's attributes – including a product's ability to treat menopause symptoms[3] – without substantiation to back up those claims constitutes deceptive marketing.[4]

Second, as made clear in several FDA warning letters, as well as agency drug approvals, in order to market products as able to treat menopause[5] and many of its symptoms (including, for example, moderate to severe hot flashes and night sweats,[6] moderate to severe vaginal pain and dryness,[7] depression and anxiety,[8] cognitive function,[9] insomnia,[10] and joint and muscle pain[11]), marketers must first obtain FDA approval, which supplement companies generally do not have. As such, marketers of menopause supplements should take care to ensure that their products are not being advertised as drugs without the requisite FDA approval.[12]

TINA.org urges Zuma Nutrition to review its marketing, which includes, among other things, claims that its Women's Hormones Tonic supplement can relieve hot flashes and other menopausal symptoms,[13] and take the necessary steps to ensure compliance with FTC and FDA law.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Laura Smith, Esq., Legal Director
Eliza Duggan, Esq.
Truth in Advertising, Inc.

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