TRUTH IN ADVERTISING.ORG

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VIA EMAIL AND REGULAR MAIL

Michelle Wilson, General Counsel
Modere, Inc.
588 South 2000 West
Springville, UT 84663
michellew@modere.com

Ivan Wasserman
Amin Talati
5185 MacArthur Blvd. NW, Suite 230
Washington, DC 20007
ivan@amintalati.com

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.

[5] 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).

[6] 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.

[7] *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'").

[8] *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.").

[9] 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.").

[10] *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'").

[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.").