

April 4, 2023

VIA EMAIL

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Carolyn E. Becker, Director Office of Unapproved Drugs and Labeling Compliance Center for Drug Evaluation and Research U.S. Food and Drug Administration carolyn.becker@fda.hhs.gov

Re: Nutrafol's Widespread Deceptive Marketing Campaign

Dear Mr. Levine, Ms. Viswanathan and Ms. Becker:

A recent Truth in Advertising, Inc. ("TINA.org") investigation into Nutraceutical Wellness, Inc., doing business as Nutrafol, a supplement company acquired by Unilever last year,¹ revealed that the company is engaged in a widespread deceptive marketing campaign in violation of FTC and FDA law, as well as the Restore Online Shoppers' Confidence Act (ROSCA).²

Specifically, TINA.org's investigation found that Nutrafol advertises its supplements as "medical-grade" and "clinically proven" to increase hair growth and prevent hair loss, as well as able to balance hormones and help with the symptoms of hormonal imbalances, among other things, without FDA approval or competent and reliable scientific substantiation as required by FTC law. In addition, the company pushes consumers into automatically renewing subscription plans while failing to clearly and conspicuously disclose all material terms and conditions of the subscriptions, to obtain consumers' affirmative consents and to provide consumers with simple mechanisms for cancellation, in violation of ROSCA and FTC law. Further, numerous Nutrafol influencers are promoting the company's products without properly disclosing their material connection to the company, yet another violation of FTC law – and one that Unilever was warned about in October 2021 when it received the FTC's notice of penalty offense authority concerning endorsements and testimonials.³

Each of these deceptive acts and practices are examined more fully below.⁴

Unsubstantiated and Unapproved Disease-Treatment Claims

On its website, social media platforms, Amazon store and in national television commercials, among other places, Nutrafol touts its supplements as able to increase hair growth and prevent hair loss, as well as being "backed by science," "clinically proven," and "clinically effective for hair growth." The following are some examples.



*Nutrafol Website*⁵

Social Media Ads⁶





Amazon⁷



Television Commercials⁸



"Thinning hair is normal but it doesn't have to be your fate. You've got nothing to lose and everything to grow. The #1 dermatologist-recommended hair growth supplement. Get growing at Nutrafol.com."

In addition to such hair growth and hair loss prevention claims, the company also claims its products can help balance women's hormones, as well as address abnormal conditions associated with hormonal imbalances, such as anxiety, hot flashes and night sweats, as the below examples show.

Nutrafol Blog9 What ingredients help balance hormones for women? Experts have narrowed down some impressive ingredients to help support common female hormonal imbalances. Maca, found in Nutrafol Womens Balance, has demonstrated a fantastic ability to help to support healthy sex hormone production. Researchers attribute this to its ability to help strengthen hormone production by reinforcing the communication between the brain and our hormone-producing organs

like the ovaries and adrenal glands. Maca has also been <u>shown to</u> <u>improve</u> feelings of stress and anxiety, as well as lowered <u>hot flashes</u> and night sweats, which commonly stem from unhealthy hormone levels.



Nutrafol Website¹⁰

There are two primary problems with all of these health and disease-treatment claims (of which TINA.org has catalogued more than 100 and which are all available at <u>https://truthinadvertising.org/evidence/nutrafol-health-claims/</u>): (1) the products being marketed with these claims have not been approved by the FDA, and (2) the claims are not properly substantiated by competent and reliable scientific evidence.¹¹

With respect to FDA approval, the agency has made clear in numerous warning letters that claims that a product can stimulate hair growth and prevent, reduce or treat hair loss,¹² as well as balance hormones¹³ and treat anxiety,¹⁴ hot flashes and night sweats,¹⁵ are drug claims requiring FDA approval, which Nutrafol does not have.¹⁶

Moreover, the substantiation Nutrafol relies on for its treatment claims, which appears to be four studies that it references on its "Clinical Trials" webpage,¹⁷ do not amount to competent or reliable scientific evidence sufficient to substantiate Nutrafol's health and disease-treatment claims.

For starters, all four studies were funded by Nutrafol and conducted by its employees.¹⁸ Further, although more than a dozen products are sold on the Nutrafol website,¹⁹ only three products – Nutrafol Women, Nutrafol Women's Balance and Nutrafol Men – are associated with studies, and only one – Nutrafol Women's Balance – was studied in a randomized controlled trial (RCT),²⁰ and that RCT failed to substantiate Nutrafol's claims about the product because of an inadequate sampling and deficient results, among other things. Other products, including Nutrafol Postpartum, which the company touts as able to grow hair and reduce shedding in postpartum women,²¹ was not studied in the trials referenced on the company's "Clinical Trials" webpage. In addition, none of the studies examined the hormone balancing effects of the supplements, or their effect on anxiety, night sweats or hot flashes. These material limitations, as well as others, are discussed in more detail below.

Women's Trial

The first study cited on the Nutrafol website is its "Women's Trial."22



This six-month clinical trial contains numerous flaws that prevent it from properly substantiating Nutrafol's unqualified marketing claims, including but not limited to the following:

- **Different formulation:** The study examined "an earlier formulation" of the product, though the differences between the formulation studied and the formulation currently being marketed and sold to consumers are not provided.²³
- **Inadequate sampling:** The study used a small, homogenous sampling of 40 women with "self-perceived thinning" (as opposed to those with objective or diagnosed hair disorders²⁴), 80 percent of whom were Caucasian and 0 percent of whom were African American (5 percent were Asian and 15 percent were Hispanic).²⁵ In addition, the participants were unevenly split between the treatment and placebo groups, with 26 in the former and 14 in the latter,²⁶ and the placebo group was composed of individuals who were older, had less hair and reported significantly higher levels of stress (one of the root causes of hair loss, according to Nutrafol²⁷) than those in the active treatment group at baseline.²⁸ Further, the study excluded women with hair loss disorders; women over 65; women with diabetes, hyperthyroidism and hypothyroidism; women taking medication known to cause hair loss or affect hair growth; and women with active dermatologic conditions, among other conditions.²⁹ Finally, while participants agreed to maintain "their current diet, medications, exercise routines, hair shampooing, and color treatment frequency for the duration of the study," no mention is made regarding whether the participants were controlled for getting haircuts or otherwise altering their hair during the six-month trial, or whether the study measurements were taken before or after haircuts or other hair treatments.
- **Inadequate results:** The study results touted by Nutrafol on its "Clinical Trials" webpage "80% SAW BETTER HAIR GROWTH OVERALL 80% SAW THICKER HAIR 73% SAW IMPROVED GROWTH RATE" are the self-reported results of the study (i.e., results obtained from questionnaires completed by participants), not scientific, objective measurements by blinded investigators.³⁰ Further, even among the measurements obtained by the investigators, the study did not find any significant changes in mean hair diameter, which was measured using microscopic digital images.³¹
- **Biased researchers and company funding:** The study was funded by the company and was conducted by the company's cofounder, as well as a company promoter.³²

Two Menopause Studies

The second and third studies cited on the Nutrafol website are its menopause trial and menopause study.³³



The menopause trial, which examined only one Nutrafol product, the Women's Balance Capsules, contains numerous flaws that prevent it from properly substantiating Nutrafol's unqualified menopause-related marketing claims, including but not limited to the following:

- Inadequate sampling: The study used a small, homogenous sampling of 60 women with "self-perceived thinning" (again, as opposed to those with objective or diagnosed hair disorders), two-thirds of whom were Caucasian and none of whom were African American (22 percent were Hispanic, 8 percent were Asian and 3 percent were Pacific Islander).³⁴ In addition, more than half of the participants were postmenopausal, as opposed to perimenopausal (23 percent) or menopausal (18 percent).³⁵ Further, the study excluded women with hair loss disorders; women over 65; women who had experienced a stressful incident within the last six months;³⁶ and women with active dermatoses, among other things.³⁷ Finally, while participants "agreed...[to] maintain a consistent frequency of haircut and color treatments for the duration of the study," no mention is made of whether the participants were controlled for getting haircuts or otherwise altering their hair during the six-month trial, or whether the study measurements were taken before or after haircuts or other hair treatments.
- **Inadequate results:** The study did not find any statistically significant findings regarding hair shedding as measured by the study administrators.³⁸ In fact, both the treatment and placebo groups experienced an overall decrease in hair shedding. Further, the results touted by Nutrafol on the webpage that references this study "100% SHOWED VISIBLE IMPROVEMENT IN HAIR GROWTH AFTER 9 MONTHS. 76% SAW THICKER HAIR AFTER 6 MONTHS. 80% SAW LESS SHEDDING AFTER 3 MONTHS." all pertain to a different, non-RCT study (Nutrafol's "Menopause Study," which will be explained below), though the company only discloses this fact in fine print at the bottom of the webpage and not in any other marketing material.
- **Biased researchers and company funding:** The study was funded by the company and was conducted by the company's cofounder, as well as a company promoter.³⁹

The menopause study,⁴⁰ which again is not an RCT, contains numerous additional flaws that further prevent it from properly substantiating Nutrafol's unqualified menopause-related marketing claims, including but not limited to the following:

- Only one component of the product was studied: The study only examined the Nutrafol Synergen Plus Complex, one component of Nutrafol products.⁴¹ However, ingredient studies are generally insufficient on their own to substantiate serious health and disease-treatment claims about products.⁴²
- **Inadequate sampling:** The study used a small, homogenous sampling of 30 women with "self-perceived thinning" (yet again, as opposed to those with objective or diagnosed hair disorders).⁴³ Details of who was excluded from the sampling are not provided by Nutrafol. Further, there was no placebo group used in this study, and no mention is made regarding whether the participants were controlled for getting haircuts or otherwise altering their hair during the nine month study, or whether the study measurements were taken before or after haircuts or other hair treatments.
- **Inadequate results:** The study, which was not double-blind,⁴⁴ showed only "subjective improvement of hair growth and quality in menopausal women." There were no objective findings.
- **Biased researchers and company funding:** The study was funded by the company and was conducted by the company's cofounder, manager of clinical research, director of product development and marketing, and senior vice president of clinical and medical affairs.⁴⁵

Men's & Women's Ethnic Hair Study

The fourth study cited on the Nutrafol website is its "Men's & Women's Ethnic Hair Study."⁴⁶



This study, which was not an RCT and examined only Nutrafol Men and Women Capsules, also contains numerous flaws that prevent it from properly substantiating Nutrafol's unqualified marketing claims, including but not limited to the following:

- **Inadequate sampling:** The study used a small sampling of 43 men and 44 • women.⁴⁷ It also excluded participants who were pregnant or nursing; women over 45; men over 55; women who were menopausal or postmenopausal; participants with a diagnosis of a hair loss disorder, a history of hair transplant, severe hair loss, or brittle or damaged hair, and participants with a history of immunosuppression/immune deficiency disorder, among other things.⁴⁸ In addition, more than half the participants were Caucasian (either Hispanic or non-Hispanic), only 28 percent were Asian and 18 percent African American. With respect to skin type, only 3 percent of participants were a Skin Type VI on the Fitzpatrick scale, i.e., "Black skin. Heavily pigmented. Never burns, tans very easily"⁴⁹ while 40 percent were a Skin Type III, i.e., "Average skin color. Sometimes mild burn, tan about average."⁵⁰ Finally, while participants "agreed to ... maintain consistent hair product use, grooming, and color treatment frequency for the duration of the study," no mention is made regarding whether the participants were controlled for getting haircuts or otherwise altering their hair during the six month study.
- **Inadequate results:** None of the study results were objective or scientific as the study included only subjective self-assessments for hair growth and quality.
- **Biased researchers and company funding:** The study was funded by the company and was conducted by the company's cofounder, as well as other company employees. In addition, the study was an open-label study, meaning that both the researchers *and* participants were aware of the treatment given.⁵¹

In short, Nutrafol has neither the necessary substantiation nor the required FDA approval for any of its health and disease-treatment claims.⁵²

It is also troubling that the company, while featuring black men and women at the forefront of its marketing campaign,⁵³ did not study a single black man or women in either of its RCTs.⁵⁴ Even in Nutrafol's other "studies," including its "study" intended to examine hair growth in men and women of diverse ethnicities, the company only included seven black men and nine black women, total.⁵⁵





The exclusion of black study participants is egregious not only because the company's unqualified marketing for its "clinically proven" supplements is directed at black consumers, among others, but because, as Nutrafol recognized in its own study, "African hair has lower density and a slower growth rate."⁵⁶ Further, "the prevalence of alopecia areata is higher among African Americans," and "[p]eople with African hair types are prone to hair loss secondary to certain cultural styling practices…"⁵⁷

Subscriptions Are Not Adequately Disclosed and Are Reportedly Difficult to Cancel

Nutrafol also uses a subscription model to sell its products but does not adequately disclose the material terms of such subscriptions. For starters, on its product pages, the default – and only visible – option above the Add to Cart button is a "Monthly Delivery" option. It is not until a consumer clicks on the small downward arrow that a menu of other options is shown on the screen, the very last one being for a "Single Bottle."

	Women	
	Hair Growth Nutraceutical	
	Our daily hair growth supplement 1 a made for women 19 44 who are experiencing signs of hair threning. Physician-formulated with medical-ground thread thre	
	Choose an Option: \$79 Monthly Delivery Save 10% 568 A1-month supply such month - free doctor consults. V	
HAIR GROWTH NUTRACEUTICAL	Add to Cart	
#1 Dermatologist-Recommanded Hair Growth Supplement Brand*	Clinically proven O Natural, medical- formulas Get results in 3-6 mont	

Before Clicking the Small Downward Arrow



Further, nowhere during the checkout process does the company make it clear to consumers that the subscriptions will automatically renew at the end of the subscription period. In other words, the subscriptions continue indefinitely until terminated, meaning that consumers must take affirmative action in order to end recurring monthly charges. This material information is buried in the middle of a 8,800+ word Terms of Use document, which is hyperlinked at the end of the checkout process, after consumers are prompted for their credit card information.⁵⁸

In addition, one of the purported benefits of the subscription options, as opposed to the single bottle purchase, is that they come with "free doctor consults."

\$79	Monthly Delivery	Save 10%	
\$88	A 1-month supply each month + free doctor consults. Pause or cancel subscription anytime.		`

Given that the company boasts that it is the "#1 Dermatologist-Recommended Hair Growth Supplement Brand,"⁵⁹ that it was cofounded by Sophia Kogan, MD (who completed a dermatology fellowship),⁶⁰ and that its Postpartum supplement was developed by an OBGYN,⁶¹ reasonable consumers may be under the impression that this "doctor consult" is with a board-certified dermatologist or other Doctor of Medicine (MD). However, the consult is with a naturopathic doctor (or ND),⁶² a fact that is not clearly disclosed during the checkout process.

Finally, according to numerous consumers who have filed complaints with the Better Business Bureau, it is difficult to cancel the subscriptions.⁶³ Some recent examples are below:

I have tried multiple times to stop my subscription Product is amazing but cancellation policy is a night mare (2/16/23)

Placed an order for product discovered within 10 minutes I ordered the wrong version of the product and cancelled order and re-ordered the correct version. Received confirmation of cancellation. Next day order was dispatched and I was charged for the cancelled order plus the second order. Have tried contacting company and they won't respond. ... (2/16/23)

I canceled my subscription with Nutrafol bacon [sic] in September 2022. Today I was charge another shipment. The history of my account shows I have not received an order since September 2022 and do not know why all of a sudden they started my subscription back. I tried message and left messages. I want to be refunded and subscription cancelled (2/21/23)

In short, Nutrafol pushes consumers into autorenewal subscription plans while failing to clearly and conspicuously disclose all material terms and conditions, to obtain consumers' affirmative consents and to provide consumers with simple mechanisms for cancellation, in violation of ROSCA, as well as the FTC's general disclosure requirements for online marketing.

Deceptive Social Media Influencer Ads

Nutrafol also employs a fleet of influencers to promote its products on social media but fails to ensure that these influencers clearly and conspicuously disclose their material connection to the company or disclose that the promotional posts are ads, in violation of FTC law.⁶⁴ Such violations are inexcusable given that, in October 2021, Unilever – Nutrafol's parent company – was reminded by the FTC that established legal precedent dictates that material connections between endorsers and brands must be clearly and conspicuously disclosed in a manner that will be easily understood by the intended audience.⁶⁵

The following are some examples of promotional posts that lack such disclosures.



Adding insult to injury is the fact that some Nutrafol influencers are using a purported "awareness campaign" created by the company called Shed the Silence⁶⁹ to market the products under the guise of offering community support to those suffering from hair loss.⁷⁰

TINA.org has catalogued a sampling of more than three dozen social media influencer posts that deceptively advertise Nutrafol products, all of which are available at https://truthinadvertising.org/evidence/nutrafol-influencer-database/.

Conclusion

Nearly 50 percent of women and more than 80 percent of men⁷¹ experience some form of hair loss. And the impact can be devastating – hair loss can lead to depression, anxiety, social phobia, negative self-esteem and even marital problems, among other issues.⁷² As a result, it is not surprising that hair loss treatment is a multibillion-dollar industry,⁷³ a market that the supplement industry appears to be jumping into with reckless abandon.⁷⁴ Nutrafol, which spends millions of dollars on advertising, is targeting this susceptible population of consumers to exploit their vulnerabilities with deceptively marketed supplements. As a well-established company owned by a global industry giant, there is simply no excuse for Nutrafol's multiple violations of the law. TINA.org urges the FTC and FDA to open investigations into Nutrafol and take appropriate enforcement action.

Sincerely,

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

Bonnie Patten, Esq. Executive Director Truth in Advertising, Inc.

Cc: Giorgos Tsetis, CEO, Nutrafol Maria Varsellona, Chief Legal Officer, Unilever

¹ Unilever to acquire majority stake in Nutrafol, May 30, 2022, <u>https://www.unilever.com/news/press-and-media/press-releases/2022/unilever-to-acquire-majority-stake-in-nutrafol/</u>.

² 15 U.S.C. §§ 8401-8405.

³ See FTC List of October 2021 Recipients of the FTC's Notice of Penalty Offenses Concerning Deceptive or Unfair Conduct around Endorsements and Testimonials, <u>https://www.ftc.gov/system/files/attachments/penalty-offenses-concerning-endorsements/list-recipients-endorsement-notice.pdf</u>; Notice of Penalty Offenses Concerning Deceptive or Unfair Conduct around Endorsements and Testimonials, <u>https://www.ftc.gov/system/files/attachments/penalty-offenses-concerning-endorsements/list-recipients-endorsements and Testimonials, https://www.ftc.gov/system/files/attachments/penalty-offenses-concerning-endorsements/notice-penalty_offenses-concerning-endorsements/notice-penalty_offenses-endorsements.pdf.</u>

⁴ The company has been aware of at least two of these issues since at least January 2020. Specifically, TINA.org reach out to the company for comment before publishing its January 2020 ad alert about Nutrafol, as well as prior to publishing its December 2022 article entitled "Nutrafol Needs to Shed Its Deceptive Hair Growth Claims." *See* TINA.org Nutrafol Ad Alert, Jan. 28, 2020, <u>https://truthinadvertising.org/articles/nutrafol/;</u> Nutrafol Needs to Shed Its Deceptive Hair Growth Claims, Dec. 5, 2022, <u>https://truthinadvertising.org/articles/nutrafol-needs-to-shed-itsdeceptive-hair-growth-claims/</u>. The company did not respond.

⁵ Nutrafol Women, <u>https://nutrafol.com/nutrafol-core-for-women/</u>. *See also* Nutrafol, <u>https://nutrafol.com/</u>; Nutrafol Results, <u>https://nutrafol.com/results/</u>.

⁶ See, e.g., Meta, Facebook Ad Library for Nutrafol ads,

https://www.facebook.com/ads/library/?active_status=all&ad_type=all&country=US&q=nutrafol &sort_data[direction]=desc&sort_data[mode]=relevancy_monthly_grouped&search_type=keywo rd_unordered&media_type=all.

⁷ Nutrafol Amazon Store, <u>https://www.amazon.com/stores/NUTRAFOL/page/8507A01F-9EA4-4E75-AF09-CC753776D37B?ref =ast bln</u>.

⁸ Nutrafol TV Spot, 'Everything to Grow,' <u>https://www.ispot.tv/ad/1knV/nutrafol-everything-to-grow</u>.

⁹ Nutrafol, Hormones & Hair Thinning: Your Top Qs, Answered, https://nutrafol.com/blog/hormones-hair-thinning-your-top-qs-answered/.

¹⁰ Nutrafol, <u>https://nutrafol.com/;</u> Nutrafol Women's Balance, <u>https://nutrafol.com/women-</u> <u>balance/?g campaignid=16703989808&g adid=589970571011&g adtype=search&g keyword=</u> <u>nutrafol%20menopause&g acctid=608-006-</u> 2368&g campaign=Google Search Brand Balance Exact&g network=g&g keywordid=kwd881515008929&g adgroupid=134959137796&g acctid=608-006-

2368&g adgroupid=134959137796&g adid=589970571011&g adtype=search&g campaign=G oogle Search Brand Balance Exact&g campaignid=16703989808&g keyword=nutrafol%20m enopause&g keywordid=kwd-881515008929&g network=g&utm campaign=Google-Search-Brand-Balance-

<u>Exact prospecting cpa&utm content=NA conversion all&utm id=&utm medium=cpc-brand&utm source=google&gclid=CjwKCAiA3pugBhAwEiwAWFzwdZtev5NQIXbbeuZjxIrFE iksjRajRXTSccvKQNlhHLwRgaOZPcSshxoCkz0QAvD BwE.</u>

¹¹ In addition to these issues, Nutrafol describes its supplements as containing "Medical Grade Ingredients." *See, e.g.*, Nutrafol Ingredients, <u>https://nutrafol.com/ingredients/</u>.



This term "medical-grade" to describe the supplement ingredients implies that the ingredients are medicine or otherwise medical. However, the FDA has not defined what would constitute a medical grade ingredient for a product like Nutrafol, and thus the term is meaningless and deceptive. It is also important to note that dietary supplements cannot legally contain medicines or drugs. *See* FDA Dietary Supplements,

<u>https://www.fda.gov/food/dietary-supplements;</u> Dietary Supplement Ingredient Directory, <u>https://www.fda.gov/food/dietary-supplements/dietary-supplement-ingredient-directory.</u>

¹² See, e.g., FDA warning letter to Santhigram Kerala Ayurvedic Co. of U.S., Inc., May 19, 2022, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warningletters/santhigram-kerala-ayurvedic-co-us-inc-625892-05192022 ("Examples of claims observed on your website and social media websites that establish the intended use of your Santhigram ayurvedic products as drugs included, but are not limited to, the following: ... 'Benefits: Triphala has several health benefits, such as; ... stimulates hair growth..."); FDA warning letter to Speedwinds Nutrition, Inc., Dec. 22, 2020, https://www.fda.gov/inspections-complianceenforcement-and-criminal-investigations/warning-letters/speedwinds-nutrition-inc-609298-12222020 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include the following: ... 'With Sephren, you can feel confident that Sephren will: ... Stop the root causes of hair [sic] female hair loss."); FDA warning letter to KetoKerri LLC, Mar. 31, 2020, https://www.fda.gov/inspections-compliance-enforcement-andcriminal-investigations/warning-letters/ketokerri-llc-598163-03312020 ("Examples of some of the claims observed on your website, www.ketokerri.com, that provide evidence that these products are intended for use as drugs include the following: ... 'People take MSM by mouth for ... hair loss..."); FDA warning letter to Soleo, Dec. 13, 2018, https://www.fda.gov/inspectionscompliance-enforcement-and-criminal-investigations/warning-letters/soleo-567046-12132018 ("Unapproved New Drugs 'GEN+LE THERAPY Shampoo' Examples of claims ... that establish the intended uses of the product as defined in 21 CFR 201.128 include, but may not be limited to, the following: ... 'Prevents Hair Loss ... Hair Loss Prevention ... ' ... Based on the above claims, 'GEN+LE THERAPY Shampoo' is a 'drug' as defined by section 201(g)(1)(B) of the FD&C Act (21 U.S.C. 321(g)(1)(B)) because it is intended for the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act (21 U.S.C. 321(g)(1)(C) because it is intended to affect the structure or any function of the body. Specifically, this product is intended as a hair growth, hair loss prevention, and anti-dandruff drug product."); FDA warning letter to Silver Armor, Inc., May 17, 2018,

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warningletters/silver-armor-inc-543786-05172018 ("Examples of some of the claims on the product labels, accompanying promotional literature, and your website that provide evidence that your products are intended for use as drugs include, but are not limited to the following: ... 'Stimulated hair growth'''); FDA warning letter to Star Health & Beauty LLC, May 26, 2017, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warningletters/star-health-beauty-llc-516206-05262017 ("Examples of some of the claims that provide evidence that your products are intended for use as drugs include: ... 'HGH has been found to reverse and/or slow down the aging process by: ... Restoring lost hair growth' ... 'Fuller Thicker Hair In As Little As Two Months,' '[A] natural alternative to combat hair loss...,' 'Restore thinning hair with visible results,' '[R]estores and maintains healthy hair.,'... '[T]o restore thickness and prevent more hair from falling out.,' 'Nugen HP – The All-Natural Hair Restoration System?,' '[R]evitalizes your hair follicles stimulating fuller, thicker hair.'').

¹³ See, e.g., FDA warning letter to Ayuryoga, Inc., May 19, 2022,

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warningletters/ayuryoga-inc-628168-05192022 ("Examples of claims observed on your website and social media websites that establish the intended use of your ... products as drugs include, but may not be limited to, the following: ... 'It can help correct hormonal imbalance...'"); FDA warning letter to Irie Star LLC, July 6, 2017, https://www.fda.gov/inspections-complianceenforcement-and-criminal-investigations/warning-letters/irie-star-llc-524242-07062017 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include... 'helps balance hormones, ...'...'assist with hormone balancing, ...'"); FDA warning letter to Star Health & Beauty LLC, May 26, 2017, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warningletters/star-health-beauty-llc-516206-05262017 ("Examples of some of the claims that provide evidence that your products are intended for use as drugs include: ... 'Women...their first choice in addressing PMS and other hormone related issues.' ... '[I]s helpful for hormonal balancing ...' ... '[W]orks to balance the hormones in the follicle..."). See also FDA warning letter to Bonagens, Nov. 17, 2020, https://www.fda.gov/inspections-compliance-enforcement-andcriminal-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'"); FDA warning letter to Homeocare Laboratories, Inc., June 22, 2020, https://www.fda.gov/inspectionscompliance-enforcement-and-criminal-investigations/warning-letters/homeocare-laboratories-inc-603532-06222020 ("Examples of statements on the websites ... that provide evidence of the intended uses of your products include, but are not limited to, the following: ... 'you'll get the balancing support women need - especially in the years before menopause -' ... 'it's safe for your long-term use - from perimenopause through post-menopause - for symptom relief""); FDA warning letter to McDaniel Life-Line LLC, May 16, 2019, https://www.fda.gov/inspectionscompliance-enforcement-and-criminal-investigations/warning-letters/mcdaniel-life-line-llc-571303-05162019 ("Examples of claims on your product label and websites ... establishing the intended use of your product include, but may not be limited to, the following: ... It has been historically used for treatment for ... menopause..."); FDA warning letter to Star Health & Beauty LLC, May 26, 2017, https://www.fda.gov/inspections-compliance-enforcement-andcriminal-investigations/warning-letters/star-health-beauty-llc-516206-05262017 ("Examples of some of the claims that provide evidence that your products are intended for use as drugs include: ... 'Assists with menopausal symptoms...'").

¹⁴ See, e.g., FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, <u>https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-</u> <u>letters/muscle-sports-products-llc-625731-09232022</u> ("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, <u>https://www.fda.gov/inspections-complianceenforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021</u> ("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.'").

¹⁵ See, e.g., FDA warning letter to Organa International Corp., Oct. 13, 2021, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warningletters/organa-international-corp-613018-10132021 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: ... 'Potential benefits to health: ... hot flashes..."); FDA warning letter to Clarke Pharmaceutical Manufacturing, Inc., Feb. 2, 2021, https://www.fda.gov/inspections-compliance-enforcementand-criminal-investigations/warning-letters/clarke-pharmaceutical-manufacturing-inc-610642-02022021 ("Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:... 'Natural Progesterone cream is used in hormone replacement therapy and for treating menopausal symptoms such as hot flashes.""); FDA warning letter to Star Health & Beauty LLC, May 26, 2017, https://www.fda.gov/inspections-compliance-enforcementand-criminal-investigations/warning-letters/star-health-beauty-llc-516206-05262017 ("Examples of some of the claims that provide evidence that your products are intended for use as drugs include: ... 'It has a stabilizing effect on the entire endocrine system, calming hot flashes and night sweats, and restoring normal sleep patterns..."); FDA warning letter to Duncan's Botanical Products, Inc., May 8, 2017, https://www.fda.gov/inspections-compliance-enforcement-andcriminal-investigations/warning-letters/duncans-botanical-products-inc-519077-05082017 ("Examples of some of the claims that provide evidence that these products are intended for use as drugs include: ... "[T]reatment of ... night sweats"").

¹⁶ Nutrafol, <u>https://nutrafol.com/</u>.

© 2023 Nutraceutical Wellness Inc. All Rights Reserved. These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

¹⁷ Nutrafol Clinical Studies, <u>https://nutrafol.com/clinical/</u>.

¹⁸ Glynis Ablon MD FAAD and Sophia Kogan MD, A Six-Month, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of a Nutraceutical Supplement for Promoting Hair Growth in Women With Self-Perceived Thinning Hair, 17(5) J. Drugs Dermatol. 558 (May 2018),

https://jddonline.com/articles/a-six-month-randomized-double-blind-placebo-controlled-studyevaluating-the-safety-and-efficacy-of-a-S1545961618P0558X/ ("Financial support was provided by Nutraceutical Wellness, Inc., New York, NY."); Glynis Ablon MD FAAD and Sophia Kogan MD, A Randomized, Double-Blind, Placebo-Controlled Study of a Nutraceutical Supplement for Promoting Hair Growth in Perimenopausal, Menopausal, and Postmenopausal Women With Thinning Hair, 20(1) J. Drugs Dermatol. 55 (Jan. 2021), <u>https://jddonline.com/articles/arandomized-double-blind-placebo-controlled-study-of-a-nutraceutical-supplement-for-promotinghair-S1545961621P0055X/? page=6 ("Financial support was provided by Nutraceutical</u> Wellness, Inc., New York, NY."); Sheryl Berkowitz, MS, et al., Evaluating the Efficacy of a Standardized Nutraceutical to Improve Hair Growth and Quality in Menopausal Women: A Nine Month Subjective Single-Blind Prospective Study," 2020 ASDS Virtual Annual Meeting, https://pdfhost.io/v/hcKBGbqjP ASDS Abstract and EPoster Menopausal Women 9 Month Prospective_Studypdf.pdf ("All authors are employed by Nutraceutical Wellness LLC"); A Prospective_Six-MonthSingle-blind_Study_Evaluating Changes in Hair Growth and Quality Using a Nutraceutical Supplement in Men and Women of Diverse Ethnicities, 15(1) J. Clin. Aesthet. Dermatol. 21 (Jan. 1, 2022), https://jcadonline.com/hair-growth-supplement-diverse-ethnicities/ ("FUNDING: This study was sponsored by Nutraceutical Wellness, LLC, in New York, New York.")

¹⁹ Nutrafol Products, <u>https://nutrafol.com/products/</u>.

²⁰ See FTC Health Products Compliance Guidance,

https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf ("Even when an advertiser doesn't make a specific claim about the level of support, claims about the health benefits of a product must still meet the basic substantiation standard of 'competent and reliable scientific evidence.' Randomized, controlled human clinical trials (RCTs) are the most reliable form of evidence and are generally the type of substantiation that experts would require for health benefit claims. Although there is no requirement for a specific number of RCTs, the replication of research in an independently-conducted study adds to the weight of the evidence. Replication in a second study by independent researchers reduces the chance that the results of a single RCT may be influenced by unanticipated, undetected, systematic biases that may occur despite the best intentions of sponsors and investigators. An additional, independently conducted study to corroborate findings provides much greater confidence in the validity of the initial results. As discussed in the next section, however, the quality of the research is more important than the quantity. For that reason, numerous flawed and inadequate studies are unlikely to add up to competent and reliable scientific evidence sufficient to substantiate a claim.")

²¹ Nutrafol Postpartum, <u>https://nutrafol.com/nutrafol-postpartum-for-women/</u>.

²² Glynis Ablon MD FAAD and Sophia Kogan MD, A Six-Month, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of a Nutraceutical Supplement for Promoting Hair Growth in Women With Self-Perceived Thinning Hair, 17(5) J. Drugs Dermatol. 558 (May 2018),

https://jddonline.com/articles/a-six-month-randomized-double-blind-placebo-controlled-studyevaluating-the-safety-and-efficacy-of-a-S1545961618P0558X/.

²³ See Glynis Ablon MD FAAD and Sophia Kogan MD, A Randomized, Double-Blind, Placebo-Controlled Study of a Nutraceutical Supplement for Promoting Hair Growth in Perimenopausal, Menopausal, and Postmenopausal Women With Thinning Hair, 20(1) J. Drugs Dermatol. 55 (Jan. 2021), <u>https://jddonline.com/articles/a-randomized-double-blind-placebo-controlled-study-of-anutraceutical-supplement-for-promoting-hair-S1545961621P0055X/? page=6</u> ("A previous study evaluating an earlier formulation for women showed similar objective progressive improvements in hair growth and hair quality at 3 and 6-months," and citing to Glynis Ablon MD FAAD and Sophia Kogan MD, A Six-Month, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of a Nutraceutical Supplement for Promoting Hair Growth in Women With Self-Perceived Thinning Hair, 17(5) J. Drugs Dermatol. 558 (May 2018)).

²⁴ As the study states, "The perception of hair loss for an individual can be distinct from clinical diagnosis and the observations of the treating physician." Glynis Ablon MD FAAD and Sophia

Kogan MD, A Six-Month, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of a Nutraceutical Supplement for Promoting Hair Growth in Women With Self-Perceived Thinning Hair, 17(5) J. Drugs Dermatol. at 563.

 25 *Id.* at 561 ("Subjects in the active treatment group (n=26) and placebo group (n=14) ... [t]wo subjects identified themselves as Asian, 32 as Caucasian, and 6 as Hispanic.")

 26 *Id*.

²⁷ See, e.g., Nutrafol FAQs, <u>https://nutrafol.com/faq/</u> ("How does stress negatively impact the hair growth cycle? Stress can cause the hair follicles to shift from a growth state to a rest state. It can also disrupt hormones and nutrient absorption, impacting hair on multiple levels. We're the only hair supplement that uses Sensoril® Ashwagandha to balance elevated cortisol (stress hormone) and help you build resistance to stress.")

²⁸ Glynis Ablon MD FAAD and Sophia Kogan MD, A Six-Month, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of a Nutraceutical Supplement for Promoting Hair Growth in Women With Self-Perceived Thinning Hair, 17(5) J. Drugs Dermatol. at 561 ("Subjects in the active treatment group (n=26) and placebo group (n=14) had mean (SD) ages of 48.3 (10.5) years and 53.14 (5.7) years, respectively, which were not significantly different. ... The 2 groups did not demonstrate any significant differences in lifestyle attributes or baseline mental attitude qualifies except for a higher level of stress among subjects in the placebo group (42.3% vs 78.6%; P=0.028).")

²⁹ *Id.* at 560 ("Eligible subjects were healthy women 21 to 65 years old...Reasons for exclusion from study participation included: ... medications that are known to cause hair loss or affect hair growth ... subjects with a self-reported history of uncontrolled diseases (eg, diabetes, hyperthyroidism, hypothyroidism)...or with the presence of other hair loss disorders and active dermatologic or other health conditions that, in the opinion of the investigator, might place the subject at risk or interfere with the study treatment and clinical evaluations.")

³⁰ *Id.* at 563.

% of Nutrafol			
Subjects Improved at Day 180	Quality		
80.8%*	Overall hair growth		
73.1%*	Overall hair volume		
80.8%*	Thickness of hair body		
23.1%*	Hair color		
76.9%*	Amount of noticeable new hair		
73.1%*	Hair growth rate		
15.4%*	Stress level		
15.4%*	Anxiety level		
15.4%*	Sleep quality		
19.2%*	Overall well-being		
23.1%*	Skin smoothness		
26.9%*	Overall skin health		

*Statistically significant improvement P≤0.05

³¹ *Id.* at 562 ("There were no significant changes in mean hair diameter.")

³² Id. at 564 ("Financial support was provided by Nutraceutical Wellness, Inc., New York, NY.").

Sophia Kogan MD is Nutrafol's Co-Founder and Chief Medical Advisor. *See* Nutrafol, Story, <u>https://nutrafol.com/story/</u>; Nutrafol, Dr. Sophia Kogan, MD, <u>https://nutrafol.com/blog/author/dr-sophia-kogan-md/</u>.

Glynis Ablon, MD, FAAD promotes Nutrafol on her website and social media platforms. *See*, *e.g.*, Ablon Skin Institute & Research Center, <u>https://abloninstitute.com/hair-regrowth/</u>; drablon August 15, 2022 Instagram post, https://www.instagram.com/p/ChTUDXXrViK/?igshid=MDJmNzVkMjY%3D.

³³ Glynis Ablon MD FAAD and Sophia Kogan MD, A Randomized, Double-Blind, Placebo-Controlled Study of a Nutraceutical Supplement for Promoting Hair Growth in Perimenopausal, Menopausal, and Postmenopausal Women With Thinning Hair, 20(1) J. Drugs Dermatol. 55 (Jan. 2021), <u>https://jddonline.com/articles/a-randomized-double-blind-placebo-controlled-study-of-anutraceutical-supplement-for-promoting-hair-S1545961621P0055X/? page=6</u>.

³⁴ *Id.* at 56-57.

³⁵ *Id.* at 57.

³⁶ Of note, Nutrafol markets its products as able to treat stress-related hair loss, among other things. *See, e.g.*, Nutrafol De-Stress Hair Growth Duo,

<u>https://nutrafol.com/de-stress-hair-growth-duo/;</u> Nutrafol, Meet The De-Stress Hair Growth Kit, Oct. 23, 2020, <u>https://nutrafol.com/blog/stress-hair-growth-kit/;</u> Nutrafol, How To Take Control Of Stress & Hair Thinning, Jan. 8, 2021, <u>https://nutrafol.com/blog/hair-thinning-from-stress/</u>.

³⁷ Glynis Ablon MD FAAD and Sophia Kogan MD, A Randomized, Double-Blind, Placebo-Controlled Study of a Nutraceutical Supplement for Promoting Hair Growth in Perimenopausal, Menopausal, and Postmenopausal Women With Thinning Hair, 20(1) J. Drugs Dermatol. at 56 ("Study participants were healthy female subjects, 40 to 65 years old ... Reasons for exclusion from study included: allergy or sensitivity to any shampoo or conditioner; a stressful incident within the last 6 months (eg, death in family); ... the use of other medications that are known to cause hair loss or affect growth within the last 6 months... Subjects with a known or self-reported history of uncontrolled disease in the opinion of the investigator (eg, autoimmune disorders, thyroid disease, diabetes)... Other reasons for exclusion were presence of other hair loss disorders as diagnosed by the investigator, as well as active dermatoses or other health conditions which, in the opinion of the investigator, might place the subject at greater risk or interference with clinical evaluations.")

³⁸ *Id.* at 58-59



³⁹ Id. at 61 ("Financial support was provided by Nutraceutical Wellness, Inc., New York, NY.").

⁴⁰ Sheryl Berkowitz, MS, et al., Evaluating the Efficacy of a Standardized Nutraceutical to Improve Hair Growth and Quality in Menopausal Women: A Nine Month Subjective Single-Blind Prospective Study," 2020 ASDS Virtual Annual Meeting, <u>https://pdfhost.io/v/hcKBGbqjP ASDS Abstract and EPoster Menopausal Women 9 Month Prospective Studypdf.pdf</u>. *See also* 2020 ASDS Virtual Annual Meeting, Abstracts, <u>https://www.asds.net/Portals/0/PDF/AM20-Abstracts.pdf#page=57</u>.

⁴¹ See, e.g., Nutrafol Women's Balance, <u>https://nutrafol.com/women-balance/</u>.

AMOUNT F	PERSERVING	%DV
Vitamin A (as Beta-Carotene) (5000 IU) 1	1500 mcg RAE	167%
Vitamin C (as Ascorbic Acid)	100 mg	111%
Vitamin D (as Cholecalciferol) (250)	0 IU) 62.5 mcg	313%
Vitamin E (as a-tocopherol)	2.6 mg	17%
Biotin (as D-Biotin)	2500 mcg	8333%
lodine (from Organic Kelp) (Laminaria Digitato	a) 225 mcg	150%
Zinc (as Zinc Amino Acid Chelate)	20 mg	182%
Selenium (as L-Selenomethionine)	200 mcg	364%
SYNERGEN COMPLEX® PLUS	1875 mg	
Organic Gelatinized Maca (Root) Powder, Co ₂ Extract (>45% Fatty Acids), Hydrolyzc Type I & III, Sensoril® Ashwagandha (Root . Withanolides), Liposomal Curcumin (Rhizc Curcuminoids), Full Spectrum Palm Extrac Tocopherol Complex), Astaxanthin (<i>Haem</i>	ed Marine Collag and Leaf) Extract ome) Extract (>4 ct (20% Tocotrie	gen ct (10% 5% nol/
NUTRAFOL [®] BLEND	480 mg	
L-Lysine, L-Methionine, L-Cysteine, Horse Extract, Japanese Knotweed (Root) Extrac Black Pepper (Fruit) Extract (95% Piperine	ct (50% Resvera	trol),
Extract (2% Capsaicinoids)		

⁴² See, e.g., FTC v. Nat'l Urological Group, Inc., 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008) (the federal district court adopted the FTC's expert's position that "a study that uses higher doses of the active ingredients or a different combination of active ingredients would not be sufficient to support the efficacy of another product that used lower doses of the active ingredients or a different combination of the ingredients."); FTC Health Products Compliance Guidance, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf ("A common problem in the substantiation of advertising claims is that an advertiser has valid studies, but the studies don't support the claim made in its ad. Advertisers should make sure that the research on which they rely isn't just internally valid, but also relevant to their specific product and to the specific advertised benefit. Therefore, advertisers should ask questions such as: How do the dosage and formulation of the advertised product compare to the product used in the study? Is the ingredient or combination of ingredients in the advertised product the same as what was used in the study?").

⁴³ Sheryl Berkowitz, MS, et al., Evaluating the Efficacy of a Standardized Nutraceutical to Improve Hair Growth and Quality in Menopausal Women: A Nine Month Subjective Single-Blind Prospective Study," 2020 ASDS Virtual Annual Meeting ("The purpose of this study was to assess the perception of the efficacy of a standardized nutraceutical (Nutrafol® Synergen Plus Complex)... Thirty women (mean age = 55 + 7.2 y) completed the study.")

⁴⁴ *Id.* ("Nine-month single-blinded prospective study...")

⁴⁵ *Id.* ("All authors are employed by Nutraceutical Wellness LLC").

Sheryl Berkowitz appears to be Nutrafol's Manager of Clinical Research. *See* ZoomInfo, Sheryl Berkowitz, <u>https://www.zoominfo.com/p/Sheryl-Berkowitz/3874678560</u>.

Sophia Kogan MD is Nutrafol's Co-Founder and Chief Medical Advisor. *See* Nutrafol, Story, <u>https://nutrafol.com/story/</u>; Nutrafol, Dr. Sophia Kogan, MD, <u>https://nutrafol.com/blog/author/dr-sophia-kogan-md/</u>.

Tess Marshall, ND was Nutrafol's Director of Product Development & Marketing until September 2022. *See* Tess Marshall, ND LinkedIn profile, <u>https://www.linkedin.com/in/drtessmarshallnd/</u>.

Isabelle Raymond, PhD, is Nutrafol's Senior Vice President of Clinical and Medical Affairs. *See* Isabelle Raymond, PhD LinkedIn profile, <u>https://www.linkedin.com/in/isabelle-raymond-phd-3402b111/</u>.

⁴⁶ A Prospective Six-Month Single-blind Study Evaluating Changes in Hair Growth and Quality Using a Nutraceutical Supplement in Men and Women of Diverse Ethnicities, 15(1) J. Clin. Aesthet. Dermatol. 21 (Jan. 1, 2022), <u>https://jcadonline.com/hair-growth-supplement-diverse-ethnicities/</u> ("**FUNDING:** This study was sponsored by Nutraceutical Wellness, LLC, in New York, New York.")

⁴⁷ *Id*.

⁴⁸ *Id*.

TABLE 1. Selection Criteria
INCLUSION CRITERIA
Female, 20—45 years of age or male, 20—55 years of age
Stratified sample group into one of more following race/ethnicities
African American
Asian
Hispanic Caucasian
Non-Hispanic Caucasian
General good health
Self-perceived mild-to-moderate hair thinning
EXCLUSION CRITERIA
History of skin cancer within the past 5 years
Use of minoxidil, finasteride or oral supplements known to prevent or promote hair growth within the past 3 months
Diagnosis of a hair loss disorder
History of hair transplant
Severe hair loss
Brittle or damaged hair from chemical treatments and excessive tension
Use of devices, prescription or over-the-counter drugs that are known to affect the hair growth cycle within the past 6 months
Hormone replacement therapy or hormones for birth control less than 6 months prior to study
History of immunosuppression/immune deficiency disorder
Currently or regularly used systemic or topical corticosteroids during the previous 4 weeks.

⁴⁹ Cutaneous Melanoma: Etiology and Therapy, Table I Fitzpatrick Classification of Skin Types I through VI, <u>https://www.ncbi.nlm.nih.gov/books/NBK481857/table/chapter6.tl/</u>.

⁵⁰ *Id*.

⁵¹ *Id.* ("The primary limitations of this study were the open-label study design and including only subjective assessments for hair growth and quality.")

⁵² On various webpages, Nutrafol references other medical literature. *See, e.g.*, Nutrafol Science, <u>https://nutrafol.com/science/;</u> Nutrafol Clinical, <u>https://nutrafol.com/clinical/;</u> Nutrafol Women, <u>https://nutrafol.com/nutrafol-core-for-women/;</u> Nutrafol Postpartum, <u>https://nutrafol.com/nutrafol-postpartum-for-women/;</u> Nutrafol Women's Balance, <u>https://nutrafol.com/women-balance/;</u> Nutrafol Men, <u>https://nutrafol.com/men/products/thinning-hair-growth-supplement/</u>.

However, in March 2022, the Journal of Clinical and Aesthetic Dermatology published an article that evaluated current studies to assess the efficacy of Nutrafol (as well as another supplement marketed for hair growth) and which determined that "these supplements typically lack the rigorous testing and statistically significant data that apply to pharmaceuticals. Therefore, the potential benefits of oral nutraceuticals for conditions of hair loss, such as androgenetic alopecia, have yet to be fully understood by dermatologists." Christina Ring , MD, et al., Nutraceuticals for Androgenetic Alopecia, 15(3) J. Clin. Aesthet Dermatol. 26 (Mar. 2022),

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8944288/#:~:text=Subjects%20taking%20Nutraf 01%20also%20reported,to%20friends%20with%20hair%20loss.

It is also interesting to note that while Nutrafol touts that its supplements are "clinically proven" to provide the advertised results, the company also uses the term "clinically tested" in certain places. *See, e.g.*, Nutrafol, <u>https://nutrafol.com/</u>.

The #1 dermatologist-recommended hair growth supplement brand.

Nutrafol[®] is built on a science-backed approach to whole-body wellness and hair health. Our products are clinically tested and physician-formulated to support different bio-specific needs during various life stages and lifestyles so that you can grow into the best version of yourself.

Both terms, however, relay the same deceptive message – that the company's products have been proven to work.

As Richard Cleland, Assistant Director of Advertising Practices at the Bureau of Consumer Protection at the FTC, has stated:

a significant number of consumers would not see any difference between the statement "clinically or scientifically proven" and the statement "clinically or scientifically tested." Both statements, one express and the other implied, convey that there is substantial scientific evidence supporting the underlying claim. With regard to the tested claim, whatever reason would there be for the advertiser to claim that a product had been "clinically or scientifically tested" if those tests did not support the underlying claim.

See August 9, 2021 email from R. Cleland to TINA.org.

This statement is consistent with others made by the FTC. In the Commission's Advertising Guide for the Dietary Supplements Industry, for example, the FTC states:

If an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate. Therefore, as a starting point, advertisers must have the level of support that they claim, expressly or by implication, to have. ... Example []: An advertiser claims that its product has been "studied for years abroad" and is now the "subject of U.S. government sponsored research." In addition to the explicit claim that the product has been studied, such phrases likely convey to consumers an implied claim that there exists a substantial body of competently-conducted scientific research supporting the efficacy of the product. The advertiser would be responsible for substantiating both claims."

See FTC's Dietary Supplements: An Advertising Guide for Industry, available at <u>https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplementsadvertising-guide-industry</u>.

Similarly, in an analysis by the FTC of trends in weight-loss advertising, the Commission stated:

Many marketers attempt to bolster the credibility of their claims by asserting that the advertised product has been scientifically tested and proven to work. Phrases like "the clinically proven healthy way to lose weight," "clinically tested," "scientifically proven," and "studies confirm" bestow products with an aura of scientific legitimacy and aim to persuade consumers that they should feel confident that a product will work.

See An Analysis of Current Trends, Sept. 2002, available at <u>https://www.ftc.gov/sites/default/files/documents/reports/weight-loss-advertisingan-analysis-current-trends/weightloss_0.pdf</u>.

Finally, in administrative decisions, the FTC has held that advertisers must be able to substantiate implicit establishment claims, such as "clinic tested ingredients," in the same way it must be able to substantiate explicit establishment claims. *See In the Matter of Porter & Dietsch, Inc.*, 90 F.T.C. 770, 865 (finding that the statement "clinic tested ingredients" "not only implied the existence of substantiation but . . . also represented that this substantiation consisted of competent scientific proof."); *In the Matter of Bristol-Myers Co., et al.*, 102 F.T.C. 21, 321, 331 (1983) (finding that "[a]lthough an establishment claim may be made by such words and phrases as 'established,' 'here's proof,' and 'medically proven' . . . the representation of establishment need not be made explicitly in an ad but may be implicit" (citations omitted), and explaining that "when an advertiser represents that there is scientific proof or support for a claim, such proof—proof that is generally accepted by the relevant scientific community—must exist.")

⁵³ See, e.g., Nutrafol Results, <u>https://nutrafol.com/results/;</u> Nutrafol, <u>https://nutrafol.com/nutrafol-core-for-women/;</u> Nutrafol Women's Balance, <u>https://nutrafol.com/women-balance/;</u> Nutrafol Men, <u>https://nutrafol.com/men/products/thinning-hair-growth-supplement/;</u> Nutrafol Service, <u>https://nutrafol.com/service/;</u> Nutrafol Instagram post, March 12, 2023, <u>https://www.instagram.com/p/CpsPcM9Aca1/?hl=en;</u> Nutrafol Instagram post, March 2, 2023, <u>https://www.instagram.com/p/Cps5_8Zp1Rm/?hl=en</u>. *See also* Nutrafol TV commercial, "Identity," <u>https://www.ispot.tv/ad/bEGb/nutrafol-identity</u>.

⁵⁴ Glynis Ablon MD FAAD and Sophia Kogan MD, A Six-Month, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of a Nutraceutical Supplement for Promoting Hair Growth in Women With Self-Perceived Thinning Hair, 17(5) J. Drugs Dermatol. 558 (May 2018),

https://jddonline.com/articles/a-six-month-randomized-double-blind-placebo-controlled-studyevaluating-the-safety-and-efficacy-of-a-S1545961618P0558X/ (zero black women studied); Glynis Ablon MD FAAD and Sophia Kogan MD, A Randomized, Double-Blind, Placebo-Controlled Study of a Nutraceutical Supplement for Promoting Hair Growth in Perimenopausal, Menopausal, and Postmenopausal Women With Thinning Hair, 20(1) J. Drugs Dermatol. 55 (Jan. 2021), <u>https://jddonline.com/articles/a-randomized-double-blind-placebo-controlled-study-of-a-nutraceutical-supplement-for-promoting-hair-S1545961621P0055X/? page=6</u> (zero black women studied).

⁵⁵ See Sheryl Berkowitz, MS, et al., Evaluating the Efficacy of a Standardized Nutraceutical to Improve Hair Growth and Quality in Menopausal Women: A Nine Month Subjective Single-Blind Prospective Study," 2020 ASDS Virtual Annual Meeting, <u>https://pdfhost.io/v/hcKBGbqjP ASDS Abstract and EPoster Menopausal Women 9 Month</u> <u>Prospective Studypdf.pdf</u> (race of participants not disclosed); A Prospective Six-Month Singleblind Study Evaluating Changes in Hair Growth and Quality Using a Nutraceutical Supplement in Men and Women of Diverse Ethnicities, 15(1) J. Clin. Aesthet. Dermatol. 21 (Jan. 1, 2022), <u>https://jcadonline.com/hair-growth-supplement-diverse-ethnicities/</u> (seven black men and nine black women studied).

⁵⁶ A Prospective Six-Month Single-blind Study Evaluating Changes in Hair Growth and Quality Using a Nutraceutical Supplement in Men and Women of Diverse Ethnicities, 15(1) J. Clin. Aesthet. Dermatol. 21 (Jan. 1, 2022), <u>https://jcadonline.com/hair-growth-supplement-diverse-ethnicities/</u>.

⁵⁷ Id.

⁵⁸ Nutrafol Terms of Use, <u>https://nutrafol.com/terms-of-use/</u>.

VII. SUBSCRIPTION PROCESS, RENEWAL AND CANCELLATION

By signing up for a subscription, your subscription will automatically renew on the first day following the end of such subscription period indicated on your Order Summary (each a "<u>Renewal Commencement Date</u>") and continue for an additional period equal to the number of days of your initial subscription period, at our price for such subscription, plus applicable shipping and taxes. You agree that your account will be subject to this automatic renewal feature unless you (i) defer your next order or (ii) cancel your subscription. You can cancel at any time from your account page, until the day your next subscription period begins to prevent renewal charges but you will not receive a refund for the remainder of your then-current subscription period. Upon the expiration of your deferral period, your subscription shall again be subject to the automatic renewal process described above.

By subscribing, you authorize us to charge your payment provider for your initial subscription period, and again at the beginning of any subsequent subscription renewal period for the fees agreed upon. Your charges may change if we change our pricing with notice to you. If you choose to cancel your subscription at any time, your subscription will no longer renew and we will not charge your payment provider for the subsequent subscription period. Upon renewal of your subscription, if we do not receive payment from your payment provider (a) you agree to pay all amounts due on your account upon demand and/r (b) you agree that Company may either terminate or suspend your subscription and continue to attempt to charge your payment provider until payment is received (upon receipt of payment, your account will be activated and for purposes of automatic renewal, your new subscription commitment period will begin as of the day payment was received).

Nutrafol Payment Page, <u>https://nutrafol.com/checkout/index#payment</u>.

Payment Method			
Credit Card		VISA	Master Card DISC VER
PayPal Express Checkout			PayPal
Add a Gift Card			
			Apply
By placing an order, you accept our Terms of	f Use and Pr	ivacy Po	licy.

⁵⁹ Nutrafol, <u>https://nutrafol.com/</u>.

⁶⁰ Nutrafol Story, <u>https://nutrafol.com/story/</u>; Nutrafol TV Spot, 'Medical School,' <u>https://www.ispot.tv/ad/nve6/nutrafol-medical-school</u>; Sophia Kogan, MD LinkedIn profile, <u>https://www.linkedin.com/in/sophia-kogan-md-9874a5172/</u> ("…she completed a research fellowship in pediatric dermatology").

⁶¹ Nutrafol Postpartum, <u>https://nutrafol.com/nutrafol-postpartum-for-women/</u>.

⁶² Nutrafol Service, <u>https://nutrafol.com/service/;</u> Nutrafol Doctors, <u>https://nutrafol.com/doctors/</u>.

⁶³ See Complaints Nutrafol, BBB, <u>https://www.bbb.org/us/ny/new-york/profile/vitamins-and-supplements/nutrafol-0121-182368/complaints</u>.

⁶⁴ FTC, Disclosures 101 for Social Media Influencers,

https://www.ftc.gov/system/files/documents/plain-language/1001a-influencer-guide-508_1.pdf; FTC, Guides Concerning the Use of Endorsements and Testimonials in Advertising, https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-publishes-final-guidesgoverning-endorsements-testimonials/091005revisedendorsementguides.pdf.

The Nutrafol influencer posts in TINA.org's database include posts that fail to include any disclosure at all, as well as those that include insufficient disclosures, such as those that appear below the fold (i.e., below the "more" button), as well as those that rely on the social media platform's built-in disclosure tool.

⁶⁵ See FTC List of October 2021 Recipients of the FTC's Notice of Penalty Offenses Concerning Deceptive or Unfair Conduct around Endorsements and Testimonials, <u>https://www.ftc.gov/system/files/attachments/penalty-offenses-concerning-endorsements/list-recipients-endorsement-notice.pdf</u>; Notice of Penalty Offenses Concerning Deceptive or Unfair Conduct around Endorsements and Testimonials, https://www.ftc.gov/system/files/attachments/penalty-offenses-concerning-endorsements/noticepenalty_offenses-endorsements.pdf.

⁶⁶ DesignXAllie, June 17, 2022 TikTok post, <u>https://www.tiktok.com/t/ZTRWpmatM/</u>.

⁶⁷ Jacin Marie Smith, Jan. 27, 2023 Instagram post, <u>https://www.instagram.com/p/Cn8NhoopK_8/?igshid=MDJmNzVkMjY%3D</u>.

⁶⁸ Loren & Alex Brovarnik, Nov. 2, 2022 Facebook post, <u>https://m.facebook.com/photo.php?fbid=665333321618714&id=100044261567772&set=a.28555</u> <u>6356263081&eav=AfaL_aF9i-7COd4ZAAeBNDDJQaVWZxu7oVa_T5BYnAC-</u> <u>7OKGNDaoGh2_TeGTZJDof_o&paipv=0&source=57</u>.

⁶⁹ Nutrafol, Shed the Silence, <u>https://nutrafol.com/shedthesilence/</u>; Facebook, Shed the Silence by Nutrafol, <u>https://www.facebook.com/groups/shedthesilence</u>.

⁷⁰ See, e.g., Patty Jeffrey, Nov. 19, 2022 Facebook post in Shed the Silence group, <u>https://truthinadvertising.org/wp-content/uploads/2022/12/Patty-Jeffrey-FB-11</u> 19 22-crop.jpeg.



⁷¹ Most Men Experience Hair Loss – But It Isn't Inevitable, NYU Langone, <u>https://nyulangone.org/news/most-men-experience-hair-loss-it-isnt-inevitable</u>. *See also* Nutrafol Review: Does This Popular Hair Loss Supplement Work?, Mar. 14, 2023, <u>https://www.forbes.com/health/body/nutrafol-review/</u>; Types of Hair Loss, NYU Langone, <u>https://nyulangone.org/conditions/hair-</u> <u>loss/types#:~:text=Androgenetic%20alopecia%20is%20the%20most,managed%20with%20medi</u> cation%20or%20surgery.

⁷² Psychological effects of hair loss, DermNet, April 2019,

https://dermnetnz.org/topics/psychological-effects-of-hair-loss; The Link Between Female Hair Loss and Depression, Belgravia Centre, <u>https://www.belgraviacentre.com/blog/the-link-between-female-hair-loss-and-depression</u>; The Emotional Toll Of Hair Loss That No One Talks About, Nov. 21, 2018, <u>https://www.refinery29.com/en-us/female-hair-loss-mental-health-effects</u>; Nutrafol, The Link Between Depression & Hair Loss, Nov. 4, 2019, <u>https://nutrafol.com/blog/depression-related-hair-loss/</u>. ⁷³ Hair Loss Treatment Manufacturing in the US – Market Size 2005-2028, Oct. 11, 2022, <u>https://www.ibisworld.com/industry-statistics/market-size/hair-loss-treatment-manufacturing-united-states/</u>; Global Alopecia Market Size To Reach USD 130.80 Billion In 2028, Says Reports and Data, Mar. 10, 2022, <u>https://www.bloomberg.com/press-releases/2022-03-10/global-alopecia-market-size-to-reach-usd-13-80-billion-in-2028-says-reports-and-data</u>.

⁷⁴ Today, TINA.org also sent letters to 25 other hair growth product companies notifying them of the law as it pertains to hair growth and hair loss prevention claims. *See* TINA.org Hair Growth Product Marketing Industry Action, <u>https://truthinadvertising.org/industries/hair-growth-product-marketing/</u>. In addition, TINA.org issued a Consumer Alert regarding hair growth products and deceptive marketing claims frequently used to promote such products. *See* TINA.org Consumer Alert: Hair Growth Products, <u>www.truthinadvertising.org/articles/consumer-alert-hair-growth-products/</u>.