

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

OLENA MALICH, RACHEL CLUGSTON,  
ERIN SCOTT, IGOR KRAVCHENKO, and  
MONICA KAPOOR, on behalf of themselves  
and all others similarly situated,

Plaintiffs,

v.

NUTRACEUTICAL WELLNESS, INC.,

Defendant.

Civil Action No.

**CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

Plaintiffs Olena Malich, Rachel Clugston, Erin Scott, Igor Kravchenko, and Monica Kapoor bring this action on behalf of themselves and all others similarly situated against Nutraceutical Wellness, Inc. (“Defendant”). Plaintiffs make the following allegations based on the investigation of their counsel, and based upon information and belief, except as to those allegations specifically pertaining to themselves, which are based on their personal knowledge.

**NATURE OF THE ACTION**

1. Defendant Nutraceutical Wellness, Inc., uses a fraudulent advertising scheme to sell Nutrafol hair growth products<sup>1</sup> at \$88 apiece for just a one-month supply. Defendant sells the Products at this exorbitant price to consumers throughout the United States, month after month, primarily through major online retailers amazon.com and sephora.com, as well as on its own website.

2. Throughout its advertising campaign, Defendant uses a common fraudulent scheme that deceives consumers into believing that the Products are proven clinically effective and that the ingredients are medical grade treatments for hormone imbalances characteristic of common hair loss diseases. But, by using this deceitful scheme to create a false aura of scientific and

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<sup>1</sup>The products include Nutrafol Women, Nutrafol Women’s Balance, Nutrafol Women’s Vegan, Nutrafol Postpartum, and Nutrafol Men (collectively, the “Products”).

pharmaceutical legitimacy to sell the Products at a premium price, Defendant violates New York, California, New Jersey, and Illinois consumer protection law in at least three ways.

3. First, Defendant represents that the Products are “clinically proven,” “backed by science,” and/or “clinically effective” and touts clinical studies that purportedly prove the Products’ efficacy for hair growth. Defendant’s representations, however, are false and misleading because the supposed clinical studies that Defendant cites in its marketing to support these claims do not, in fact, offer any competent or reliable clinical proof to support Defendant’s claims. Even some of Defendant’s own study results suggest that the Products are no more effective than a placebo, and the results of other studies on the ingredients that Defendant touts as capable of addressing hormone imbalances, have shown no significant effect on hormones compared to placebo. As such, Defendant’s “clinically proven” statements are provably false and misleading in violation of state consumer protection laws.

4. Second, throughout its consistent and uniform nationwide advertising campaign, Defendant uses implied disease claims to lead consumers to believe that the Products are medical grade treatments for hormone imbalances that are the “root cause” of most hair loss in the population. Defendant’s implied disease claims that suggest that the Products treat underlying hormone imbalances that are characteristic of common hair loss diseases (detailed below) have not been approved by the FDA and have not been substantiated by competent reliable evidence. Defendant’s implied disease claims thus render the Products misbranded and illegal to sell as currently marketed under the Food, Drug, and Cosmetic Act (the “FDCA”). Accordingly, Defendant’s use of unlawful implied disease claims in its marketing violates the FDCA, parallel state laws incorporating the FDCA by reference, and state consumer protection law.

5. Third, throughout its consistent and uniform nationwide advertising campaign, Defendant makes improper and misleading health claims to lead consumers to believe the Products are supportive of hormonal and metabolic health. In fact, as detailed below, the Products contain dangerous levels of ingredients that function to *harm* health in the supplied or recommended dosage. Defendant’s improper health claims thus render the Products misbranded and illegal to

sell as currently marked under the FCDA. Accordingly, Defendant's use of unlawful health claims in its marketing violates the FDCA, parallel state laws incorporating the FDCA by reference, and state consumer protection laws.

6. As a result of this deceptive and unlawful conduct, Plaintiffs purchased the Products.

7. Defendant's deceptive marketing scheme has been enormously profitable. Indeed, in July 2022, Unilever acquired the majority stake in Nutrafol (80%) when it when it added to its existing 13% minority stake by purchasing an additional 67% majority share for over \$800 million euros.<sup>2</sup>

8. Accordingly, Plaintiffs bring this action for violation of New York, New Jersey, California, and Illinois consumer protection laws on behalf of themselves and all others situated person to obtain monetary damages for themselves and all other similarly situated purchasers in New York, New Jersey, California, and Illinois, as well as for injunctive relief.

#### **JURISDICTION AND VENUE**

9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(a) because this case is a class action where the aggregate claims of all members of the proposed class are in excess of \$5,000,000.00 exclusive of interest and costs, there are over 100 members of the putative class, and at least one class member is a citizen of a state different than Defendant. Complete diversity also exists between at least one plaintiff and Defendant.

10. This Court has personal jurisdiction over Defendant because Defendant maintains its principal place of business in New York. Furthermore, a substantial portion of the events giving rise to Plaintiff's claims occurred in New York, including at least one Plaintiff's purchase of the Products.

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<sup>2</sup> Form 6-K, Report of Foreign Issuer, Unilever PLC (Dated Feb. 9, 2023) <https://www.sec.gov/Archives/edgar/data/217410/000165495423001506/a4291p.htm> (last visited 7/1/2023).

11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(1) because Defendant is headquartered in this District.

**PARTIES**

12. Plaintiff Olena Malich is a citizen of New Jersey, residing in Monroe Township, New Jersey. Plaintiff Malich purchased Nutrafol Women for her personal use in or around May 28, 2022, June 29, 2022, July 26, 2022, September 9, 2022, October 9, 2022, November 11, 2022, December 12, 2022, January 11, 2023, February 11, 2023, March 11, 2023, on amazon.com. Plaintiff also purchased Nutrafol Women from sephora.com in or around April 20, 2023, and June 1, 2023. Plaintiff Malich made these purchases from Defendant's listings posted on amazon.com and sephora.com while residing in Monroe Township, New Jersey.

- a. Prior to making her purchases, on both amazon.com and sephora.com, Plaintiff Malich saw Defendant's claim that Nutrafol Women was "clinically proven" to promote hair growth as well as results from a clinical study suggesting proven efficacy. Defendant's "clinically proven" statements were a substantial factor in Plaintiff's decision to purchase the Product. However, the Product was not clinically proven to promote hair growth. In fact, Plaintiff Malich did not experience any meaningful hair growth or prevention of thinning despite using Nutrafol Women for one year. Had Plaintiff Malich known that Nutrafol Women was not "clinically proven," she would not have purchased it or would have paid substantially less for it.
- b. Prior to making her purchases, on both amazon.com and sephora.com, Plaintiff Malich also saw Defendant's claim that Nutrafol Women was "Dermatologist-Recommended" and that the ingredients in the Product target root causes of hair loss like stress and hormones. Based on these statements, Plaintiff Malich purchased Nutrafol Women believing it to be a medical grade treatment of hormone imbalances that cause hair loss. Had Plaintiff Malich known that Defendant's marketing statements were unapproved and unlawful, and that the Product was not

a medical grade treatment for hormone imbalances, she would not have purchased Nutrafol Women, or would have paid substantially less for it.

- c. Prior to making her purchases, on both amazon.com and sephora.com, Plaintiff Malich also saw Defendant's claims that the Product is supportive of hormonal and metabolic health. Based on these statements, Plaintiff Malich purchased Nutrafol Women believing it is supportive of metabolic and hormonal health. Had Plaintiff Malich known that Defendant's marketing statements were misleading and unlawful, and that the Product actually contains dangerous levels of ingredients that function to *harm* health in the supplied or recommended dosage, she would not have purchased Nutrafol Women, or would have paid substantially less for it.
- d. Plaintiff Malich still desires a product that can promote fuller hair and would thus buy Defendant's Products in the future if she believed that Defendant's representations were true. Indeed, if Defendant were to remove its misleading and unlawful marketing claims and lower the price of the Products accordingly, Plaintiff Malich would consider purchasing the Product again. Alternatively, if Defendant were to obtain clinical proof and FDA approval for its claims that the Product treats hormone imbalances, Plaintiff Malich would also consider purchasing the Product again. Plaintiff Malich is thus at risk of future harm because of her inability to rely on the validity of the information in Defendant's marketing on a going forward basis—despite her desire to purchase a product conferring its purported benefits.

13. Plaintiff Rachel Clugston is a citizen of California, residing in Los Angeles, California. Plaintiff Clugston purchased Nutrafol Women's Balance for her personal use on or around August 18, 2022. Plaintiff Clugston made this purchase from Defendant's listing posted on amazon.com while residing in Los Angeles, California.

- a. Prior to making her purchases, Plaintiff Clugston saw on amazon.com that Nutrafol Women's Balance was "clinically proven" to promote hair growth as well as results

from a clinical study suggesting proven efficacy. Defendant's "clinically proven" statements were a substantial factor in Plaintiff's decision to purchase the Product. However, the Product was not clinically proven to promote hair growth. In fact, Plaintiff Clugston did not experience any meaningful hair growth or prevention of thinning despite using Nutrafol Women's Balance for between one and four months. Had Plaintiff Clugston known that Nutrafol Women's Balance was not "clinically proven," she would not have purchased it or would have paid substantially less for it.

- b. Prior to making her purchases, Plaintiff Clugston also saw Defendant's claim that Nutrafol Women's Balance was a "Physician formulated supplement" that targets the root causes of thinning hair, including hormones. Based on these statements, Plaintiff Clugston purchased Nutrafol Women's Balance believing it to be a medical grade treatment of hormone imbalances that cause hair loss. Had Plaintiff Clugston known that Defendant's marketing statements were unapproved and unlawful, and that the Product was not a medical grade treatment for hormone imbalances, she would not have purchased Nutrafol Women's Balance, or would have paid substantially less for it.
- c. Prior to making her purchases, Plaintiff Clugston also saw Defendant's claims that the Product is supportive of hormonal and metabolic health. Based on these statements, Plaintiff Clugston purchased Nutrafol Women's Balance believing it is supportive of metabolic and hormonal health. Had Plaintiff Clugston known that Defendant's marketing statements were misleading and unlawful, and that the Product actually contains dangerous levels of ingredients that function to *harm* health in the supplied or recommended dosage, she would not have purchased Nutrafol Women's Balance, or would have paid substantially less for it.
- d. Plaintiff Clugston still desires a product that can promote fuller hair and would thus buy Defendant's Products in the future if she believed that Defendant's

representations were true. Indeed, if Defendant were to remove its misleading and unlawful marketing claims and lower the price of the Products accordingly, Plaintiff Clugston would consider purchasing the Product again. Alternatively, if Defendant were to obtain clinical proof and FDA approval for its claims that the Product treats hormone imbalances, Plaintiff Clugston would also consider purchasing the Product again. Plaintiff Clugston is thus at risk of future harm because of her inability to rely on the validity of the information in Defendant's marketing on a going forward basis—despite her desire to purchase a product conferring its purported benefits.

14. Plaintiff Erin Scott is a citizen of California, residing in West Hollywood, California. Plaintiff Scott purchased Nutrafol Women for her personal use on or around January 11, 2020. Plaintiff Scott made this purchase from Defendant's listing posted on amazon.com while residing in West Hollywood, California.

- a. Prior to making her purchase on amazon.com, Plaintiff Scott saw Defendant's claim that Nutrafol Women was "clinically proven" to promote hair growth as well as results from a clinical study suggesting proven efficacy. Defendant's "clinically proven" statements were a substantial factor in Plaintiff's decision to purchase the Product. However, the Product was not clinically proven to promote hair growth. In fact, Plaintiff Scott did not experience any meaningful hair growth or prevention of thinning despite using Nutrafol Women for approximately one month. Had Plaintiff Scott known that Nutrafol Women was not "clinically proven," she would not have purchased it or would have paid substantially less for it.
- b. Prior to making her purchase on amazon.com, Plaintiff Scott also saw Defendant's claim that Nutrafol Women was "Dermatologist-Recommended" and that the ingredients in the Product target root causes of hair loss like stress and hormones. Based on these statements, Plaintiff Scott purchased Nutrafol Women believing it to be a medical grade treatment of hormone imbalances that cause hair loss. Had

Plaintiff Scott known that Defendant's marketing statements were unapproved and unlawful, and that the Product was not a medical grade treatment for hormone imbalances, she would not have purchased Nutrafol Women, or would have paid substantially less for it.

- c. Prior to making her purchase on amazon.com, Plaintiff Scott also saw Defendant's claims that the Product is supportive of hormonal and metabolic health. Based on these statements, Plaintiff Scott purchased Nutrafol Women believing it is supportive of metabolic and hormonal health. Had Plaintiff Scott known that Defendant's marketing statements were misleading and unlawful, and that the Product actually contains dangerous levels of ingredients that function to *harm* health in the supplied or recommended dosage, she would not have purchased Nutrafol Women, or would have paid substantially less for it.
- d. Plaintiff Scott still desires a product that can promote fuller hair and would thus buy Defendant's Products in the future if she believed that Defendant's representations were true. Indeed, if Defendant were to remove its misleading and unlawful marketing claims and lower the price of the Products accordingly, Plaintiff Scott would consider purchasing the Product again. Alternatively, if Defendant were to obtain clinical proof and FDA approval for its claims that the Product treats hormone imbalances, Plaintiff Scott would also consider purchasing the Product again. Plaintiff Scott is thus at risk of future harm because of her inability to rely on the validity of the information in Defendant's marketing on a going forward basis—despite her desire to purchase a product conferring its purported benefits.

15. Plaintiff Igor Kravchenko is a citizen of Illinois, residing in Wheeling, Illinois. Plaintiff Kravchenko purchased Nutrafol Men for his personal use on or around April 19, 2022. Plaintiff Kravchenko made this purchase from Defendant's listing posted on amazon.com while residing in Wheeling, Illinois.



- a. Prior to making his purchase, Plaintiff Kravchenko saw on amazon.com that Nutrafol Men was backed by science and data, that it had been clinically tested for effectiveness, as well as results from a clinical study suggesting proven efficacy. Defendant's clinically effective statements were a substantial factor in Plaintiff's decision to purchase the Product. However, the Product was not proven effective to promote hair growth. In fact, Plaintiff Kravchenko did not experience any meaningful hair growth or prevention of thinning despite using Nutrafol Men for six months. Had Plaintiff Kravchenko known that Nutrafol Men was not proven effective, he would not have purchased it or would have paid substantially less for it.
- b. Prior to making his purchase, Plaintiff Kravchenko also saw on amazon.com that Nutrafol Men was "physician formulated" and that it targets "root causes" of thinning hair, including stress and hormones like DHT. Based on these statements, Plaintiff Kravchenko purchased Men's Hair believing it a medical grade treatment of hormone imbalances that cause hair loss. Had Plaintiff Kravchenko known that Defendant's marketing statements were unapproved and unlawful, and that the Product was not a medical grade treatment for hormone imbalances, he would not have purchased Nutrafol Men, or would have paid substantially less for it.
- c. Prior to making his purchase, Plaintiff Kravchenko also saw on amazon.com Defendant's claims that the Product is supportive of hormonal and metabolic health. Based on these statements, Plaintiff Kravchenko purchased Nutrafol Men believing it is supportive of metabolic and hormonal health. Had Plaintiff Kravchenko known that Defendant's marketing statements were misleading and unlawful, and that the Product actually contains dangerous levels of ingredients that function to *harm* health in the supplied or recommended dosage, he would not have purchased Nutrafol Men, or would have paid substantially less for it.

- d. Plaintiff Kravchenko still desires a product that can promote fuller hair and would thus buy Defendant's Products in the future if he believed that Defendant's representations were true. Indeed, if Defendant were to remove its misleading and unlawful marketing claims and lower the price of the Products accordingly, Plaintiff Kravchenko would consider purchasing the Product again. Alternatively, if Defendant were to obtain clinical proof and FDA approval for its claims that the Product treats hormone imbalances, Plaintiff Kravchenko would also consider purchasing the Product again. Plaintiff Kravchenko is thus at risk of future harm because of his inability to rely on the validity of the information in Defendant's marketing on a going forward basis—despite his desire to purchase a product conferring its purported benefits.

16. Plaintiff Monica Kapoor is a citizen of New York, residing in New York, New York. Plaintiff Kapoor purchased Nutrafol Women for her personal use on or around March 27, 2023. Plaintiff Kapoor made this purchase from Defendant's listing posted on amazon.com while residing in New York, New York.

- a. Prior to making her purchase on amazon.com, Plaintiff Kapoor saw Defendant's claim that Nutrafol Women was "clinically proven" to promote hair growth as well as results from a clinical study suggesting proven efficacy. Defendant's "clinically proven" statements were a substantial factor in Plaintiff's decision to purchase the Product. However, the Product was not clinically proven to promote hair growth. In fact, Plaintiff Kapoor did not experience any meaningful hair growth or prevention of thinning despite using Nutrafol Women for two years. Had Plaintiff Kapoor known that Nutrafol Women was not "clinically proven," she would not have purchased it or would have paid substantially less for it.
- b. Prior to making her purchase on amazon.com, Plaintiff Kapoor also saw Defendant's claim that Nutrafol Women was "Dermatologist-Recommended" and that the ingredients in the Product target root causes of hair loss like stress and

hormones. Based on these statements, Plaintiff Kapoor purchased Nutrafol Women believing it to be a medical grade treatment of hormone imbalances that cause hair loss. Had Plaintiff Kapoor known that Defendant's marketing statements were unapproved and unlawful, and that the Product was not a medical grade treatment for hormone imbalances, she would not have purchased Nutrafol Women, or would have paid substantially less for it.

- c. Prior to making her purchase on amazon.com, Plaintiff Kapoor also saw Defendant's claims that the Product is supportive of hormonal and metabolic health. Based on these statements, Plaintiff Kapoor purchased Nutrafol Women believing it is supportive of metabolic and hormonal health. Had Plaintiff Kapoor known that Defendant's marketing statements were misleading and unlawful, and that the Product actually contains dangerous levels of ingredients that function to *harm* health in the supplied or recommended dosage, she would not have purchased Nutrafol Women, or would have paid substantially less for it.
- d. Plaintiff Kapoor still desires a product that can promote fuller hair and would thus buy Defendant's Products in the future if she believed that Defendant's representations were true. Indeed, if Defendant were to remove its misleading and unlawful marketing claims and lower the price of the Products accordingly, Plaintiff Kapoor would consider purchasing the Product again. Alternatively, if Defendant were to obtain clinical proof and FDA approval for its claims that the Product treats hormone imbalances, Plaintiff Kapoor would also consider purchasing the Product again. Plaintiff Kapoor is thus at risk of future harm because of her inability to rely on the validity of the information in Defendant's marketing on a going forward basis—despite her desire to purchase a product conferring its purported benefits.

17. Defendant Nutraceutical Wellness, Inc., is a Delaware corporation with its principal place of business in New York, New York. Defendant manufactures, markets, and sells the Products throughout New York and the United States.

**ALLEGATIONS COMMON TO ALL CLASS MEMBERS**

18. Defendant’s fraudulent scheme to sell the Products with false clinical proof and fake medical legitimacy violates state consumer protection law in at least three ways.

19. First, as detailed below, Defendant makes “clinically proven” statements that are false and misleading.

20. Second, as detailed below, Defendant makes implied disease claims that are unapproved in violation of the FDCA and corresponding state laws.

21. Third, as detailed below, Defendant makes improper health claims that are misleading in violation of the FDCA and corresponding state laws.

***A. Defendant’s Representation that the Products Are “Clinically Proven” Is False and Misleading***

22. Defendant uniformly claims that the Products are “Clinically Proven” hair supplements to drive sales at a premium price.

23. In fact, the Products are *not* “Clinically Proven” at all. As a result, Defendant’s “Clinically Proven” claims are false and misleading in violation of New York, California, New Jersey, and Illinois consumer protection laws.

***(i) Defendant Consistently Represents that the Products are “Clinically Proven” to Grow Hair***

24. Throughout its advertising campaign—including on the websites of the three major retailers of the Products (amazon.com, sephora.com, and nutrofol.com)—Defendant touts the Products as “Clinically Proven,” “backed by science,” and/or clinically effective, and then cites clinical studies that purportedly prove the Products’ efficacy for hair growth:

- a. **Nutrafol Women’s Balance.** Defendant represents that Nutrafol Women’s Balance provides clinically proven hair growth. For example, on amazon.com,

Defendant states that Nutrafol Women's Balance provides "CLINICALLY PROVEN HAIR GROWTH" and states that "100% of women showed improved hair growth after 9 months, 93% saw less dryness and brittleness, and 93% felt their hair looked healthier after 6 months in a clinical study." Defendant makes the same representations on sephora.com, nutrafol.com and throughout its nationwide advertising campaign. *See, e.g.*, Exhibit 1.

- b. **Nutrafol Women. Defendant** represents that Nutrafol Women is "Clinically Proven" to promote hair growth. For example, on amazon.com, Defendant states that Nutrafol Women is "Clinically Proven for Visibly Thicker and Stronger Hair" and that "90% of women saw improved hair overall, 86% saw better hair growth, and 84% saw less shedding after 6 months in a clinical study." Defendant makes the same representations on sephora.com, nutrafol.com and throughout its nationwide advertising campaign. *See, e.g.*, Exhibit 2.
- c. **Nutrafol Women's Vegan. Defendant** represents that Nutrafol Women's Vegan's "science-backed formula" is "Clinically Proven" to provide visibly thicker and stronger hair. For example, on amazon.com, Defendant states that Nutrafol Women's Vegan has "Clinically Proven Results" and that "[i]n a clinical study, 100% of users felt an improvement in their hair strength after 3 months while 100% of users saw their baby hairs growing out and more scalp coverage after 6 months." Defendant makes the same representations on sephora.com, nutrafol.com and throughout its nationwide advertising campaign. *See, e.g.*, Exhibit 3.
- d. **Nutrafol Postpartum. Defendant** represents that Nutrafol Postpartum is clinically tested and proven effective. For example, on amazon.com, Defendant states that Nutrafol Postpartum contains "clinically tested ingredients," that it has been "clinically tested for efficacy," and that "in a clinical study of women within one year postpartum 91% of users saw visibly thicker hair after 6 months" and "100% of users saw less hair shedding after 2 months." Likewise, on sephora.com,

Defendant represents that Nutrafol Postpartum has been clinically tested for efficacy by claiming that “[i]n a clinical study of women within one-year postpartum: 91% saw less hair shedding after 2 months [and] 98% saw improvement in their hairline after 4 months.” Similarly, on nutrafol.com, Defendant represents that Nutrafol Postpartum provides “Hair growth, backed by science” and that “91% of users saw less hair shedding after 2 months [and] 98% of users saw improvement in their hairline after 4 months.” *See, e.g.*, Exhibit 4. Defendant makes these representations throughout its nationwide advertising campaign.

- e. **Nutrafol Men.** Defendant represents that Nutrafol Men is clinically tested and proven effective. For example, on amazon.com, Defendant represents that Nutrafol Men provides “Hair Growth, Backed by Science,” that “[o]ur formulas are backed by clinical studies so your hair is backed by data,” that “84% of men showed improvement in hair quality,” and that “72% saw more scalp coverage.” Defendant makes the same representations on sephora.com, nutrafol.com and throughout its nationwide advertising campaign. *See, e.g.*, Exhibit 5.

(ii) *Defendant’s Representations that the Products are “Clinically Proven” to Grow Hair Are False and Misleading*

25. Defendant’s representations that the Products are “clinically proven” to cause hair growth are false and misleading because the studies Defendant references do not, in fact, amount to competent or reliable evidence of Defendant’s hair growth claims.

- a. **Nutrafol Women’s Balance.** The clinical trial that Defendant cites in support of its clinically proven claims about Nutrafol Women’s Balance contains numerous flaws that belie Defendant’s assertion that it provides clinical proof. As detailed in Truth in Advertising’s letter to the FTC, the Nutrafol Women’s Balance study suffered from both inadequate sampling and inadequate results. Exhibit 6 at pp. 7. For example, with respect to sampling, the study excluded women with hair loss

disorders and women over 65—*i.e.*, exactly the population of women to whom Defendant markets Nutrafol Women’s Balance formula.<sup>3</sup> In another example, regarding results, in phase 1 of the study there was no significant difference between treatment and placebo groups regarding hair shedding as measured by study administrators.<sup>4</sup> Defendant’s only other menopause study is not a randomized controlled trial (RCT) and had no objective findings; thus, it does not provide clinical proof.<sup>5</sup>

- b. **Nutrafol Women.** The clinical trial that Defendant cites in support of its clinically proven claims about Nutrafol Women suffers from numerous flaws rendering Defendant’s claims that Nutrafol Women is clinically proven to promote hair growth false and misleading. As detailed in Truth in Advertising’s letter to the FTC, the Nutrafol Women study suffered from both inadequate sampling and inadequate results. Exhibit 6 at pp. 5-6.<sup>6</sup> For example, with respect to sampling, the study

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<sup>3</sup> Exhibit 6 at 7 (citing 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)

<sup>4</sup> *Id.* (citing 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 57-58 (Fig. 4; Table 4); *see also* 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, 21(7) J. Drugs Dermatol at 779 (same).

<sup>5</sup> Exhibit 6 at 8 (citing 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/hcKBGbjP> ASDS Abstract and EPoster Menopausal Women 9 Month Prospective Study.pdf. *See also* 2020 ASDS Virtual Annual Meeting, Abstracts, <https://www.asds.net/Portals/0/PDF/AM20-Abstracts.pdf#page=57>).

<sup>6</sup> *See id.* (citing 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

excluded women with hair loss disorders—*i.e.*, it excluded the types of hair loss most common in females, including anyone with any form of diagnosed hair loss at all.<sup>7</sup> Regarding results, the study relied on non-scientific subjective measurements self-reported by participants. 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.<sup>8</sup>

- c. **Nutrafol Women’s Vegan.** The survey that Defendant relies on in support of its claims that Nutrafol Women’s Vegan has science-backed formula with clinically proven results does not support those claims.<sup>9</sup> Defendant’s survey did not include any objective measurements, was not a double-blind placebo-controlled trial, and is thus not scientific clinical support.
- d. **Nutrafol Postpartum.** The survey that Defendant relies on in support of its claims that Nutrafol Postpartum has science-backed formula with proven results does not support those claims.<sup>10</sup> Defendant’s survey did not include any objective measurements, was not a double-blind placebo randomized controlled trial, and is thus not scientific clinical support.
- e. **Nutrafol Men.** The clinical study that Defendant cites on its website to support its clinically proven claims does not support those claims. The study was not a double-

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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/>).

<sup>7</sup> See *id.* See also, *e.g.*, <https://perfecthairhealth.com/nutrafol-review/> (last visited June 23, 2023).

<sup>8</sup> See Exhibit 6 at 6 (citing 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) at 562).

<sup>9</sup> See <https://nutrafol.com/womens-vegan/> (citing IQVIA Provoice survey for 12 months ending March 31, 2023).

<sup>10</sup> See <https://nutrafol.com/nutrafol-postpartum-for-women/> (citing IQVIA Provoice survey for 12 months ending March 31, 2023).



blind placebo randomized controlled trial and thus none of the study results were objective or scientific as the study included only subjective self-assessment.<sup>11</sup> The study also excluded participants with hair loss disorders that commonly cause hair loss.

26. Notably, contrary to Defendant's representations that the Products are clinically proven to provide hair growth, as mentioned above, even the results of some of the objective measurements in Defendant's own studies suggest the Products do not provide the hair growth benefits Defendant advertises.<sup>12</sup>

27. Other studies also support the conclusion that the key ingredients in the Products do not provide hair growth benefits and that Defendant's representations that the Products are clinically proven are false and misleading. For example, while Defendant claims the saw palmetto in the Products impacts DHT hormone to promote hair growth, the only study to examine the effect of saw palmetto on DHT in humans showed no effect.<sup>13</sup> Similarly, although Defendant claims

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<sup>11</sup> See <https://nutrafol.com/men/products/thinning-hair-growth-supplement/> (citing Stephens, T., et al. JCAD. 2022./Nutrafol Data on File 2022). See also Exhibit 6 at 8-9 (citing 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)).

<sup>12</sup> Exhibit 6 at 7 (citing 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 57-58 (Fig. 4; Table 4); see also 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, 21(7) J. Drugs Dermatol at 779 (same); see also *id.* at 6 (citing 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) at 562).

<sup>13</sup> See <https://menscript.com/uk/articles/saw-palmetto-for-hair-loss-popular-but-ineffective> ("The only study to examine the effect of saw palmetto on DHT in humans found no effect.") (citing Georges Strauch, Comparison of Finasteride (Proscar®) and Serenoa repens (Permixon®) in the Inhibition of 5-Alpha Reductase in Healthy Male Volunteers, European Urology (1994) 26 (3): 247-252); *id.* ("Saw palmetto has not been effective in treating hair loss.").

Ashwagandha is an adaptogen that balances stress hormones like cortisol to promote hair growth, at least one study has found that, when compared to a placebo, Ashwagandha had no effect on stress hormones like cortisol.<sup>14</sup> Other ingredients in the Products, such as selenium, biotin, vitamin A (as beta-carotene) would only impact hair growth in rare cases of extreme dietary deficiency.<sup>15</sup> It is thus unsurprising that Plaintiffs did not experience any hair growth from Defendant's Products.

***B. The FDCA and Parallel State Laws Prohibit Defendant's Implied Disease Claims***

28. To make matters worse, in addition to its false claims that the Products are proven clinically effective, Defendant markets the Products with unlawful disease claims that suggest the Products mitigate, treat, cure, or prevent diseases associated with hair loss.

*(i) Statutory Framework*

29. While manufacturers may make structure/function claims under certain circumstances, manufacturers of dietary supplements are prohibited from making any statement that "claims to diagnose, mitigate, treat, cure, or prevent disease," either explicitly or implicitly. 21 C.F.R. § 101.93(g); *see also* 21 U.S.C. § 343(r)(6).

30. "Implied disease claims do not mention the name of a specific disease, but refer to identifiable characteristics of a disease from which the disease itself may be inferred." 65 Fed. Reg. at 1012.

31. A disease claim requires FDA pre-approval. 21 C.F.R. § 101.93(f).

32. Generally, a statement is a disease claim if it states explicitly or implicitly that the product: (a) has an effect on a disease, a characteristic sign or symptom of a disease, or an abnormal condition that is either uncommon or can cause significant harm; (b) has an effect on a disease by

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<sup>14</sup> *See, e.g.*, Lorpresti, Adrian L. et al, A Randomized, Double-Blind, Placebo-Controlled, Crossover Study Examining the Hormonal and Vitality Effects of Ashwagandha (*Withania somnifera*) in Aging, Overweight Males, *Am J Mens Health*. 2019 Mar-Apr; 13(2): 1557988319835985.

<sup>15</sup> *See, e.g.*, <https://perfecthairhealth.com/nutrafol-review/> (last visited June 23, 2023).

implication through, for example, the product name, an ingredient in the product, citation to literature referencing a disease or other product label details implying connection to a disease; (c) is a substitute for, is similar to, or augments a product that does diagnose, treat, or prevent a disease; (d) has a role in the body's response to a disease; or treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events themselves constitute diseases. 21 C.F.R. § 101.93(g)(2).

33. California, New York, New Jersey, and Illinois broadly prohibit the misbranding of food in language largely identical to that found in the FDCA.

34. California's Sherman Food, Drug, and Cosmetic Law (the "Sherman Law"), Health & Saf. Code § 109875 *et seq.*, provides that food is misbranded "if its labeling is false or misleading in any particular." *Id.* The Sherman Law explicitly incorporates by reference "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the [FDCA]," as the food labeling regulations of California. Cal. Health & Saf.Code, § 110100, subd. (a).

35. New York's Agriculture and Marketing law similarly provides in relevant part that food shall be deemed misbranded "[i]f its labeling is false or misleading in any particular," and incorporates the FDCA's labeling provisions found in 21 C.F.R. part 101. Agriculture and Markets Law § 201(1); N.Y. Comp. Codes R. & Regs. tit. 1, § 259.1(a)(3).

36. Likewise, New Jersey law provides that "a food shall ... be deemed misbranded ... [i]f its labeling is false or misleading in any particular," and incorporates by reference the FDCA's labeling regulations in 21 C.F.R. part 101. N.J.S.A. 24:5-17(a), N.J. Admin. Code tit. 8, § 24-3.6.

37. Finally, the Illinois Food, Drug and Cosmetic Act ("IFDCA") also provides that "[a] food is misbranded . . . [i]f its labeling is false or misleading in any particular." 410 ILCS 620/11. The IFDCA directly tracks the requirements of the FDCA, stating that the Illinois Food and Drug Commission should "make the regulations promulgated under [the IFDCA] conform, in so far as practicable, with those promulgated under the Federal Act." 410 ILCS 620/21(a).

Additionally, the IFDCA provides that “a federal regulation adopted pursuant to [the IFDCA] takes effect in this State on the date it becomes effective as a Federal regulation.” 410 ILCS 620/21(j).

38. California, New York, New Jersey, and Illinois each also discourage the misbranding of food through the availability of remedies pursuant to the respective state’s consumer protection laws.

(ii) *Defendant Consistently Uses Unapproved Implied Disease Claims to Sell the Products*

39. Throughout its advertising campaign—including on the websites of the three major retailers of the Products (amazon.com, sephora.com, and nutrofol.com)—Defendant claims the Products target the “root causes” of hair loss by balancing hormones that are characteristic of the diseases that cause the majority of hair loss in the developed world—androgenetic alopecia<sup>16</sup> and telogen effluvium.<sup>17</sup> In doing so, Defendant makes unlawful, unapproved, and misleading implied disease claims about its Products.

40. Going beyond a structure/function claim, Defendant’s claims that the Products balance hormones characteristic of hair loss diseases implies that the Products mitigate, treat, cure, or prevent disease. Specifically, Defendant’s implied disease claims suggest the Products treat or cure the DHT imbalance characteristic of alopecia and the stress hormone imbalance characteristic

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<sup>16</sup> Erling Thom PhD, Stress and the Hair Growth Cycle: Cortisol-Induced Hair Growth Disruption, *JU Drugs Dermatol*, 2016;15(8):1001-1004 (“Androgenetic alopecia is the most common hair growth disorder in women and men. The large majority of hair growth disorders occur due to a change in the hair growth cycle, which is usually androgen dependent and genetically determined. In the case of androgenetic alopecia, testosterone is converted to dihydrotestosterone (DHT) via 5a-reductase. DHT then binds to androgen receptors in the hair follicle, which results in the shortening of the anagen phase and simultaneous prolongation of the telogen phase, combined with hair follicle miniaturization. Symptoms of hair thinning and loss results from a gradual reduction in hair diameter and a visibly widened hair parting.”).

<sup>17</sup> *Id.* (“Telogen effluvium is one of the major hair growth disorders and is closely related to stress. Occurring mainly in women, telogen effluvium can be induced as a result of stress or extreme hormonal imbalance. This creates a disruption to the normal hair growth cycle in which antegen (growing) hairs prematurely enter the telogen (resting) phase. Consequently, symptoms begin to appear in the form of short, sudden bouts of hair shedding with little to no hair growth.”)

of telogen effluvium. Defendant further implies treatment of these hair loss diseases by framing the Products as “physician formulated” or “dermatologist recommended,” by claiming the Products are clinically proven to work, and by including before and after images of people appearing to have recovered from significant hair loss.

41. Specifically, Defendant makes the following disease claims that imply the Products treat hormone imbalances characteristic of common hair loss diseases:

- a. **Nutrafol Women’s Balance.** Defendant represents on amazon.com that Nutrafol Women’s Balance is “Dermatologist Recommended,” and that it is a “Physician formulated supplement” that targets “root causes” of thinning hair including “hormone shifts.” *See, e.g.*, Exhibit 7. Defendant also represents that Ashwagandha in the Nutrafol Women’s Balance “targets stress hormones” and that Saw Palmetto in the Product “targets hair-thinning DHT hormone.” *Id.* Defendant also includes before and after pictures showing significant hair growth. *Id.* Similarly, on sephora.com, Defendant represents that Nutrafol Women’s Balance is “Physician-formulated,” that Ashwagandha in the Product is a “stress-relieving adaptogen that reduces hair shedding,” and that Saw Palmetto in the Product is “concentrated fatty acids that reduce hair-inhibiting DHT hormones.” *Id.* Defendant also includes before and after pictures showing significant hair growth. *Id.* Likewise, on Nutrafol.com, along with statements that Nutrafol Women’s Balance is physician formulated and pictures showing significant hair growth, Defendant also includes images of hair follicles and the human body next to statements that describe the hormone imbalances associated with the disease conditions alopecia and telogen effluvium.
- b. **Nutrafol Women.** Defendant represents on amazon.com that Nutrafol Women is “Dermatologist-Recommended,” that “Ashwagandha targets stress hormones,” and that “Saw Palmetto” “Targets hair-thinning DHT hormones.” *See, e.g.*, Exhibit 8. Defendant also includes before and after pictures showing significant hair growth.

*Id.* Similarly, on sephora.com, Defendant claims that Ashwagandha is a “stress-relieving adaptogen that reduces hair shedding” and includes before and after pictures depicting noticeable hair growth. *Id.* Likewise, on Nutrafol.com, along with statements that Nutrafol Women is physician formulated and pictures showing significant hair growth, Defendant also includes images of hair follicles and the human body next to statements that describe the hormone imbalances associated with the disease conditions alopecia and telogen effluvium.

- c. **Nutrafol Women’s Vegan.** Defendant represents on amazon.com that Nutrafol Women’s Vegan targets the “root causes” of thinning hair, including “hormones.” *See, e.g.,* Exhibit 9. Defendant also includes before and after pictures showing significant hair growth. *Id.* Similarly, on sephora.com, Defendant claims Ashwagandha is a “stress-relieving adaptogen that reduces hair shedding” and includes before and after pictures depicting noticeable hair growth. *Id.* Likewise, on Nutrafol.com, along with statements that Nutrafol Women’s Vegan is physician formulated and pictures showing significant hair growth, Defendant also includes images of hair follicles and the human body next to statements that describe the hormone imbalances associated with the disease conditions alopecia and telogen effluvium. *Id.*
- d. **Nutrafol Postpartum.** Defendant represents on amazon.com that Nutrafol Postpartum is “OBGYN-Developed” and “dermatologist-recommended,” and claims it contains clinically tested ingredients that target the “root causes” of thinning hair for women in postpartum recovery, such as “hormonal shifts.” *See, e.g.,* Exhibit 10. Defendant also includes before and after pictures showing significant hair growth. *Id.* Similarly, on sephora.com, Defendant represents that Nutrafol Postpartum is “OBGYN-formulated to multi-target the key root causes of postpartum hair thinning—such as physical and emotional stress, hormone changes, and nutrition depletion” and that it contains a “Stress-relieving adaptogen

that reduces hair shedding.” Likewise, on Nutrafol.com, along with statements that Nutrafol Postpartum is OBGYN-developed and that it targets “key root causes” of postpartum thinning like emotional stress, and hormonal changes, Defendant also includes images of hair follicles and the human body next to statements that describe the hormone imbalances associated with the disease conditions alopecia and telogen effluvium. *Id.*

- e. **Nutrafol Men.** Defendant represents on amazon.com that Nutrafol Men is “physician formulated” and that it targets “root causes” of thinning hair “including stress and hormones like DHT.” Exhibit 11. Defendant also represents that Ashwagandha in the Nutrafol Men “targets stress hormones” and that Saw Palmetto in the Nutrafol Men “targets hair-thinning DHT hormone.” Defendant also includes before and after pictures showing significant hair growth. *Id.* Similarly, on sephora.com, Defendant represents that Saw Palmetto in Nutrafol Men are “concentrated fatty acids that reduce hair-inhibiting DHT hormones” and that the Product is “physician-formulated” to multi-target the “key root causes” of thinning, such as hormones and stress. *Id.* Defendant also includes pictures depicting notable hair growth. *Id.* Likewise, on Nutrafol.com, Defendant frames Nutrafol Men as “dermatologist-recommended” and claims that Nutrafol Men targets “root causes” of thinning “like hormone imbalances” and stress with “medical-grade ingredients.” *Id.* Defendant also includes pictures depicting noticeable hair growth along with images of hair follicles and the human body next to statements that describe the hormone imbalances associated with the disease conditions alopecia and telogen effluvium. *Id.*
42. Defendant’s marketing thus suggests that the Products have the ability to mitigate, treat, cure, or prevent diseases, and is barred by the FDCA’s requirement that a product cannot make a claim to “diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases”

without prior approval. Accordingly, Defendant makes implied disease claims under 21 C.F.R. § 101.93(g)(2) and the Products are misbranded under 21 U.S.C. § 343(r)(6).

43. Defendant's implied disease claims that suggest the Products treat the hormone imbalances associated with common hair loss diseases also mislead and confuse consumers into believing that the Products are medical grade and intended to treat or prevent such diseases.

44. In guidance published in the Federal Register, the FDA has said that it "strongly believes that dissemination of [information about disease states] on dietary supplement labels increases the likelihood that consumers will believe that the supplements are intended to treat or prevent the diseases described in the labeling" and, therefore, finds "it important that any disease claim in dietary supplement labeling continue to subject to prior FDA review to evaluate the safety and effectiveness of the product for the use described or suggested by the claim."<sup>18</sup>

45. The FDA has further suggested that consumer confusion resulting from "unproven disease claims, *i.e.*, those that have not met the requirements for health claim authorization or new drug approval, can pose serious risks," because "[s]uch claims may encourage consumers to self-treat for a serious disease without benefit of a medical diagnosis or treatment" and "may also cause consumers to substitute potentially ineffective products for proven ones."<sup>19</sup>

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<sup>18</sup> Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000-01, 1005 (Jan. 6, 2000).

<sup>19</sup> *Id.* at 1001. *See also id.* at 1013 ("There are also serious public health questions raised by implied disease claims. Treatment and prevention of disease are serious matters, and the statute reflects a congressional judgment that consumers deserve to have claims for such uses reviewed by experts for proof of safety and effectiveness. In addition, permitting dietary supplement manufacturers to make implied disease claims without prior review would allow them to compete unfairly with prescription and OTC drugs, which are required to establish their safety and effectiveness for disease treatment and prevention before being marketed.").



***C. The FDCA and Parallel State Laws Prohibit Defendant's Improper Health Claims***

46. In addition to its false claims that the Products are proven clinically effective and its unlawful disease claims, as described above, Defendant markets the Products with misleading health claims that the Products are supportive of hormonal and metabolic health.

*(i) Statutory Framework*

47. A health claim is “any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition.” 21 C.F.R. § 101.14(a)(1). Substance “means a specific food or component of food. . .” 21 C.F.R. § 101.14(a)(2). “Disease or health-related condition means damage to an organ, part, structure, or system of the body such that it does not function properly . . . or a state of health leading to such dysfunctioning.” 21 C.F.R. § 101.14(a)(5).

48. The Products are foods, and hormone imbalance and metabolic function are health-related conditions.

49. A product that makes unauthorized health claims is misbranded pursuant to 21 U.S.C. § 343(r). Further, as stated above, California, New York, New Jersey, and Illinois broadly prohibit the misbranding of food in language largely identical to that found in the FDCA.

*(ii) Defendant Consistently Uses Improper Health Claims to Sell the Products*

50. Throughout its advertising campaign—including on the websites of the three major retailers of the Products (amazon.com, sephora.com, and nutrafol.com)—Defendant claims the Products treat the purported “root causes” of hair loss by regulating metabolic function and balancing hormones when, in fact, the Products contain dangerous levels of ingredients that function to harm health in the supplied or recommended dosages. In doing so, Defendant makes unlawful and misleading health claims about its Products.

51. As an initial matter, all versions of Defendant's Products bear the phrase “Hair Wellness from Within” on the label or the side of the package.

52. It appears that Defendant is in the process of transitioning away from making the “Hair Wellness from Within” representation on its label. In its marketing, Defendant shows a “New” label, which shows that “Hair Wellness from Within” has been replaced with “Hair Growth Nutraceutical,”<sup>20</sup> which is nevertheless actionable when considered in totality with Defendant’s marketing and packaging representations, as set forth below.

53. Nonetheless, Defendant has been selling the Products with the “Hair Wellness from Within” representation during the relevant class periods and is specifically targeting people who want to resolve hair loss problems “from within” *i.e.*, by resolving underlying health issues, including hormone imbalance and metabolic function.

54. Also, in its marketing materials on its website and third-party retail websites, Defendant represents that the Products “[t]arget[] 6 key root causes of hair health,” and that its “proprietary blend pinpoints the internal causes of hair thinning and shedding to promote a healthy hair growth cycle—because hair and health grow together.”<sup>21</sup>

55. Defendant touts on its website various ingredients in the Products that it uses to “target” 6 hair growth obstacles: stress, hormones, lifestyle, metabolism, nutrition, and aging. For example, Defendant states:

- a. “Ashwagandha is an adaptogen that *helps balance stress hormones in the body.*”
- b. “Saw Palmetto is one way Nutrafol’s Hair Growth Nutraceuticals *support normal hormonal changes with aging that impact hair.* [It] helps lower the conversion of testosterone to follicle-shrinking DHT hormone to promote hair growth.”
- c. “Curcumin, standardized with 45% curcuminoids, is one way Nutrafol’s Hair Growth Nutraceuticals *support metabolism. It is a robust ingredient with*

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<sup>20</sup> See, e.g., [https://www.amazon.com/Nutrafol-Growth-Thicker-Stronger-Capsules/dp/B00LU4CZP8/ref=sr\\_1\\_2\\_sspa?crd=V42LJV3SV4S7&keywords=nutrafol+women&qid=1688661142&sprefix=nutrafol+women%2Caps%2C116&sr=8-2-spons&sp\\_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1&smid=ADA50KZ98575L](https://www.amazon.com/Nutrafol-Growth-Thicker-Stronger-Capsules/dp/B00LU4CZP8/ref=sr_1_2_sspa?crd=V42LJV3SV4S7&keywords=nutrafol+women&qid=1688661142&sprefix=nutrafol+women%2Caps%2C116&sr=8-2-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1&smid=ADA50KZ98575L) (last visited July 6, 2023).

<sup>21</sup> See, e.g., <https://nutrafol.com/nutrafol-core-for-women/> (last visited July 6, 2023).

*antioxidant activity that supports metabolic function and multiple root causes of hair thinning.*<sup>22</sup>

56. Despite these representations that the Products support hormonal and metabolic health, the Products, in fact, contain dangerous levels of ingredients, including biotin, beta-carotene, iodine from kelp, zinc, and selenium that function to *harm* health in the supplied or recommended dosage:

*Nutrafol Women*

### Supplement Facts

Serving Size: 4 Capsules  
Servings Per Container: 30

	AMOUNT PER SERVING	%DV
Vitamin A (as Beta-Carotene)	(5000 IU) 1500 mcg RAE	167%
Vitamin C (as Camu Camu Fruit, Ascorbic Acid)	100 mg	111%
Vitamin D (as Cholecalciferol)	(2500 IU) 62.5 mcg	313%
Vitamin E (as $\alpha$ -tocopherol)	3.5 mg	23%
Biotin (as D-Biotin)	3000 mcg	10000%
Iodine (from Organic Kelp) ( <i>Laminaria Digitata</i> )	225 mcg	150%
Zinc (as Zinc Amino Acid Chelate)	25 mg	227%
Selenium (as Selenium Amino Acid Chelate)	200 mcg	364%
<b>SYNERGEN COMPLEX®</b>	<b>1680 mg</b>	<b>**</b>
Hydrolyzed Marine Collagen Type I & III, Sensoril® Ashwagandha (Root and Leaf) Extract (10% Withanolides), Saw Palmetto (Fruit) CO <sub>2</sub> Extract (>45% Fatty Acids), BCM-95® Bio-Curcumin® Curcumin (Rhizome) Extract (95% Total Curcuminoid Complex), Full Spectrum Palm Extract (20% Tocotrienol/Tocopherol Complex), Hyaluronic Acid		
<b>NUTRAFOL® BLEND</b>	<b>530 mg</b>	<b>**</b>
L-Cysteine, L-Lysine, L-Methionine, Solubilized Keratin, Horsetail (Stem and Leaf) Extract, Japanese Knotweed (Root) Extract (50% Resveratrol), Black Pepper (Fruit) Extract (95% Piperine), Capsicum (Fruit) Extract (2% Capsaicinoids)		

\*\*Daily Value (DV) not established

- 100% drug- and hormone-free
- Free of gluten, dairy, and binders
- No artificial additives or flavoring
- 4 capsules per day
- One bottle = One month

**OTHER INGREDIENTS:** Vegetable Cellulose Capsule (Hypromellose), Organic Rice Hulls.  
**CONTAINS:** Fish (Atlantic Cod, Haddock, Pollock).

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<sup>22</sup> <https://nutrafol.com/science/> (last visited July 6, 2023) (emphasis added).

<sup>23</sup> [https://www.amazon.com/Nutrafol-Growth-Thicker-Stronger-Capsules/dp/B00LU4CZP8/ref=sr\\_1\\_2\\_sspa?crd=3PM3NWAFC2BW&keywords=nutrafol+women&qid=1688659446&sprefix=nutrafol+m%2Caps%2C122&sr=8-2-spons&sp\\_csd=d21kZ2V0TmFtZT1zcF9hdGY&psc=1&smid=ADA50KZ98575L](https://www.amazon.com/Nutrafol-Growth-Thicker-Stronger-Capsules/dp/B00LU4CZP8/ref=sr_1_2_sspa?crd=3PM3NWAFC2BW&keywords=nutrafol+women&qid=1688659446&sprefix=nutrafol+m%2Caps%2C122&sr=8-2-spons&sp_csd=d21kZ2V0TmFtZT1zcF9hdGY&psc=1&smid=ADA50KZ98575L) (last visited July 6, 2023).

*Nutrafol Women's Vegan***Supplement Facts**

Serving Size: 4 Capsules  
Servings Per Container: 30

	AMOUNT PER SERVING	%DV
Vitamin A (as Beta-Carotene)	(5000 IU) 1500 mcg RAE	167%
Vitamin C (as Ascorbic Acid)	40 mg	44%
Vitamin D (as Algae)	(2500 IU) 62.5 mcg	313%
Vitamin E (α-tocopherol)	3.5 mg	23%
Vitamin K2 (as Menaquinone-7)	50 mcg	42%
Vitamin B12 (as Methylcobalamin)	120 mcg	5000%
Iodine (from Organic Kelp) ( <i>Laminaria Digitata</i> )	225 mcg	150%
Zinc (as Zinc Amino Acid Chelate)	25 mg	227%
Selenium (as Selenium Amino Acid Chelate)	200 mcg	364%
<b>SYNERGEN PLANT COMPLEX</b>	<b>1100 mg</b>	<b>**</b>
Sensoril® Ashwagandha (Root and Leaf) Extract (10% Withanolides), Saw Palmetto (Fruit) CO <sub>2</sub> Extract (>45% Fatty Acids), Moldavian Dragonhead (Flower) Extract, Liposomal Curcumin (>45% Curcuminoids), Full Spectrum Palm Extract (20% Tocotrienol/Tocopherol Complex), Hyaluronic Acid		
<b>NUTRAFOL® BIO-BLEND</b>	<b>490 mg</b>	<b>**</b>
Chlorella ( <i>Chlorella Vulgaris</i> ), Pea (Sprout) Extract, L- Cysteine, L- Lysine, Beet (Root) Powder, Bacillus Subtilis DE111® (1 Billion CFU), Bamboo (Leaf) Extract (70% Silica), Capsicum (Fruit) Extract (2% Capsaicinoids)		

\*\*Daily Value (DV) not established

100% Vegan

100% drug- and hormone-free

Free of gluten, dairy, and binders

No artificial additives or flavoring

4 capsules per day  
One bottle = One month

**OTHER INGREDIENTS:** Vegetable Cellulose, Organic Rice Hulls.

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<sup>24</sup> [https://www.amazon.com/Nutrafol-Supplement-Plant-Based-Lifestyles-Dermatologist-Recommended/dp/B0B61TZ676/ref=sr\\_1\\_1\\_sspa?crd=1K774Y2DO7OYP&keywords=nutrafol+women%27s+vegan&qid=1688659641&sprefix=nutrafol+women%27s+vegan%2Caps%2C119&sr=8-1-spons&sp\\_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1](https://www.amazon.com/Nutrafol-Supplement-Plant-Based-Lifestyles-Dermatologist-Recommended/dp/B0B61TZ676/ref=sr_1_1_sspa?crd=1K774Y2DO7OYP&keywords=nutrafol+women%27s+vegan&qid=1688659641&sprefix=nutrafol+women%27s+vegan%2Caps%2C119&sr=8-1-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1) (last visited July 6, 2023).

## Nutrafol Women's Balance

# Supplement Facts

Serving Size: 4 Capsules  
Servings Per Container: 30

	AMOUNT PER SERVING	%DV
Vitamin A (as Beta-Carotene)	(5000 IU) 1500 mcg RAE	167%
Vitamin C (as Ascorbic Acid)	100 mg	111%
Vitamin D (as Cholecalciferol)	(2500 IU) 62.5 mcg	313%
Vitamin E (as $\alpha$ -tocopherol)	2.6 mg	17%
Biotin (as D-Biotin)	2500 mcg	8333%
Iodine (from Organic Kelp) ( <i>Laminaria Digitata</i> )	225 mcg	150%
Zinc (as Zinc Amino Acid Chelate)	20 mg	182%
Selenium (as L-Selenomethionine)	200 mcg	364%
<b>SYNERGEN COMPLEX® PLUS</b>	<b>1875 mg</b>	<b>**</b>
Organic Gelatinized Maca (Root) Powder, Saw Palmetto (Fruit) CO <sub>2</sub> Extract (>45% Fatty Acids), Hydrolyzed Marine Collagen Type I & III, Sensoril® Ashwagandha (Root and Leaf) Extract (10% Withanolides), Liposomal Curcumin (Rhizome) Extract (>45% Curcuminoids), Full Spectrum Palm Extract (20% Tocotrienol/Tocopherol Complex), Astaxanthin ( <i>Haematococcus Pluvialis</i> )		
<b>NUTRAFOL® BLEND</b>	<b>480 mg</b>	<b>**</b>
L-Lysine, L-Methionine, L-Cysteine, Horsetail (Stem and Leaf) Extract, Japanese Knotweed (Root) Extract (50% Resveratrol), Black Pepper (Fruit) Extract (95% Piperine), Capsicum (Fruit) Extract (2% Capsaicinoids)		

\*\*Daily Value (DV) not established

**OTHER INGREDIENTS:** Vegetable Cellulose Capsule (Hypromellose), Organic Rice Hulls.

**CONTAINS:** Fish (Atlantic Cod, Haddock, Pollock).

100% drug- and hormone-free

Free of gluten, dairy, and binders

No artificial additives or flavoring

4 capsules per day  
One bottle = One month

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<sup>25</sup> [https://www.amazon.com/Nutrafol-Supplements-Clinically-Dermatologist-Recommended/dp/B07QZ5CTTF/ref=sr\\_1\\_1\\_sspa?crd=12JM5WLEXFXGL&keywords=nutrafol+women%27s+balance&qid=1688659788&sprefix=nutrafol+women%27s+balance%2Caps%2C118&sr=8-1-spons&sp\\_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1](https://www.amazon.com/Nutrafol-Supplements-Clinically-Dermatologist-Recommended/dp/B07QZ5CTTF/ref=sr_1_1_sspa?crd=12JM5WLEXFXGL&keywords=nutrafol+women%27s+balance&qid=1688659788&sprefix=nutrafol+women%27s+balance%2Caps%2C118&sr=8-1-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1) (last visited July 6, 2023).

*Nutrafol Postpartum***Supplement Facts**

Serving Size: 4 Capsules

Servings Per Container: 30

	AMOUNT PER SERVING	%DV*
Vitamin A (as Beta-Carotene)	(1000 IU) 300 mcg RAE	23%
Vitamin C (as Camu Camu Fruit, Ascorbic Acid)	100 mg	83%
Vitamin D (as Cholecalciferol)	(2000 IU) 50 mcg	333%
Vitamin E (as $\alpha$ -tocopherol)	3.5 mg	18%
Vitamin B1 (as Thiamin HCL)	2 mg	143%
Vitamin B2 (as Riboflavin)	1.5 mg	94%
Vitamin B3 (as Niacinamide)	10 mg	56%
Vitamin B5 (as Calcium Pantothenate)	6 mg	86%
Vitamin B6 (as Pyridoxine HCL)	10 mg	500%
Vitamin Biotin (as D-Biotin)	3000 mcg	8571%
Vitamin B9 (as 5-MTHF)	100 mcg	17%
Vitamin B12 (as Methylcobalamin)	250 mcg	8929%
Iodine (from Organic Kelp) ( <i>Laminaria Digitata</i> )	225 mcg	77%
Selenium (as Selenium Amino Acid Chelate)	150 mcg	214%
Zinc (as Zinc Amino Acid Chelate)	15 mg	125%

**SYNERGEN RECOVERY COMPLEX** 1210 mg \*\*

Hydrolyzed Marine Collagen (5% Orthosilicic Acid), Omega 3 Algae Extract (&gt;45% Fatty Acids, 50:1 DHA:EPA), Shatavari (Root) Extract (40% Saponins), L-Theanine, Apple (Fruit) Extract (60% Polyphenols), Nettle (Root) Extract, Full Spectrum Palm Extract (20% Tocopherol/Tocotrienol Complex)

**POSTPARTUM HAIR BLEND** 410 mg \*\*

L-Cysteine, L-Methionine, Pea (Sprout) Extract, Sea Buckthorn (Fruit) Powder, L-Lysine

\*Based on DV for lactating women \*\*Daily Value (DV) not established

100% drug- and hormone-free

No artificial sweeteners or flavors

Free of gluten, soy, and binders

4 capsules per day  
One bottle = One month**OTHER INGREDIENTS:** Vegetable Cellulose Capsule (Hypromellose), Organic Rice Hulls.**CONTAINS:** Fish (Tilapia, Basa, Sutchi, Yellow Pangasius and/or Sharptooth Clarias)

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<sup>26</sup> [https://www.amazon.com/Nutrafol-Breastfeeding-friendly-Ingredients-Thicker-Looking-Stronger-Feeling/dp/B096L5SGLT/ref=sr\\_1\\_1\\_sspa?crd=2W54KD8DBR4OC&keywords=nutrafol+postpartum&qid=1688659980&sprefix=nutrafol+post+partum%2Caps%2C102&sr=8-1-spons&sp\\_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1](https://www.amazon.com/Nutrafol-Breastfeeding-friendly-Ingredients-Thicker-Looking-Stronger-Feeling/dp/B096L5SGLT/ref=sr_1_1_sspa?crd=2W54KD8DBR4OC&keywords=nutrafol+postpartum&qid=1688659980&sprefix=nutrafol+post+partum%2Caps%2C102&sr=8-1-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1) (last visited July 6, 2023).

## NUTRAFOL MEN

### Supplement Facts

Serving Size: 4 Capsules  
Servings Per Container: 30

	AMOUNT PER SERVING	%DV
Vitamin A (as Beta-Carotene)	(5000 IU) 1500 mcg RAE	167%
Vitamin C (as Camu Camu Fruit, Ascorbic Acid)	60 mg	67%
Vitamin D (as Cholecalciferol)	(2500 IU) 62.5 mcg	313%
Vitamin E (as $\alpha$ -tocopherol)	3.5 mg	23%
Biotin (as D-Biotin)	3000 mcg	10000%
Iodine (from Organic Kelp) ( <i>Laminaria Digitata</i> )	225 mcg	150%
Zinc (as Zinc Amino Acid Chelate)	25 mg	227%
Selenium (as Selenium Amino Acid Chelate)	200 mcg	364%
<b>SYNERGEN COMPLEX®</b>	<b>1720 mg</b>	<b>**</b>
Saw Palmetto (Fruit) CO <sub>2</sub> Extract (>45% Fatty Acids), Hydrolyzed Marine Collagen Type I & III, Sensoril® Ashwagandha (Root and Leaf) Extract (10% Withanolides), BCM-95® Bio-Curcumin® Curcumin (Rhizome) Extract (95% Total Curcuminoid Complex), Full Spectrum Palm Extract (20% Tocotrienol/Tocopherol Complex), Hyaluronic Acid		
<b>NUTRAFOL® BLEND</b>	<b>575 mg</b>	<b>**</b>
L-Cysteine, L-Lysine, L-Methionine, Horsetail (Stem and Leaf) Extract, Japanese Knotweed (Root) Extract (50% Resveratrol), Solubilized Keratin, Black Pepper (Fruit) Extract (95% Piperine), Capsicum (Fruit) Extract (2% Capsaicinoids)		

\*\*Daily Value (DV) not established

**OTHER INGREDIENTS:** Vegetable Cellulose Capsule (Hypromellose), Organic Rice Hulls.

**CONTAINS:** Fish (Atlantic Cod, Haddock, Pollock).

100% drug- and hormone-free

Free of gluten, dairy, and binders

No artificial additives or flavoring

4 capsules per day  
One bottle = One month

57. Scientific studies have found that high concentrations of biotin may cause negative side effects, including insomnia or trouble sleeping, acne, digestive upset, skin rashes, interference

<sup>27</sup> [https://www.amazon.com/Nutrafol-Strengthening-Physician-Formulated-Thicker-Looking-Stronger-Feeling/dp/B09R82NLYC/ref=sr\\_1\\_2\\_sspa?crd=RRRHECMZYLYI&keywords=nutrafol+men&qid=1688659211&sprefix=nutrafol+men%2Caps%2C102&sr=8-2-spons&sp\\_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1](https://www.amazon.com/Nutrafol-Strengthening-Physician-Formulated-Thicker-Looking-Stronger-Feeling/dp/B09R82NLYC/ref=sr_1_2_sspa?crd=RRRHECMZYLYI&keywords=nutrafol+men&qid=1688659211&sprefix=nutrafol+men%2Caps%2C102&sr=8-2-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1) (last visited July 6, 2023).

with laboratory test results, excessive thirst and kidney problems.<sup>28</sup> Consuming high levels of biotin can also impair absorption of certain anti-seizure medications and can interfere with a variety of laboratory tests.<sup>29</sup>

58. Beta-carotene supplementation has been linked with increased mortality and is not recommended for the general population.<sup>30</sup>

59. Iodine from kelp, which is included in the Products, *including* Nutrafol Postpartum, has a risk of being contaminated with arsenic, which is particularly concerning if used by women who are pregnant or nursing (yet it is included in Nutrafol Postpartum).<sup>31</sup>

60. Excessive zinc consumption can lead to copper deficiency.<sup>32</sup>

61. Excessive use of selenium by people who already have adequate or high levels (which is typical in the U.S.) may actually *cause* hair loss and has been linked with increased risk of diabetes, prostate cancer, and/or death.<sup>33</sup>

62. Defendant has not addressed the foregoing concerns and includes no warning label on their packaging.

63. Defendant's representations that the Products are supportive of hormonal and metabolic health are false and misleading to a reasonable consumer. As demonstrated by the foregoing scientific studies, the Products function to harm health in the supplied or recommended dosages; thus, the label, which claims the Products *support* hormonal and metabolic health, are misleading under 21 U.S.C. § 343(r)(6)(B).

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<sup>28</sup> <https://longevity.technology/lifestyle/8-potential-side-effects-to-know-before-taking-biotin-supplements/#:~:text=When%20biotin%20is%20not%20appropriately,excessive%20thirst%20and%20kidney%20problems> (last visited July 13, 2023).

<sup>29</sup> Todd Cooperman, M.D., *Do Hair Loss Supplements, Such as Viviscal, Hair La Vie, and Nutrafol, or Topical Essential Oils Work?*, ConsumerLab.com, <https://www.consumerlab.com/answers/do-any-supplements-help-for-hair-loss/hair-loss/?search=nutrafol#nutrafol>.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*



64. Defendant's false, deceptive, and misleading label statements violate 21 U.S.C. § 343(a)(1) and statutes adopted by California, New York, New Jersey, and Illinois deeming food misbranded when "its labeling is false or misleading in any particular."

**CLASS ACTION ALLEGATIONS**

65. Plaintiffs incorporate and reallege the above paragraphs.

66. Plaintiffs Clugston and Scott bring this action on behalf of herself and the members of the proposed California Subclass, which consists of:

All California consumers who purchased a Product for personal, family, or household purposes from the beginning of the applicable statutory period until the date notice is disseminated. Excluded from the California Subclass are Defendant; any entity in which Defendant has a controlling interest; and any legal representative, heir or assign of Defendant. Also excluded from the California Subclass are any federal, state, or local governmental entities, any judicial officer presiding over this action and the members of his/her immediate family and judicial staff, and any juror assigned to this action.

67. Plaintiff Kapoor brings this action on behalf of herself and the members of the proposed New York Subclass, which consists of:

All New York consumers who purchased a Product for personal, family, or household purposes from the beginning of the applicable statutory period until the date notice is disseminated. Excluded from the New York Subclass are Defendant; any entity in which Defendant has a controlling interest; and any legal representative, heir or assign of Defendant. Also excluded from the New York Subclass are any federal, state, or local governmental entities, any judicial officer presiding over this action and the members of his/her immediate family and judicial staff, and any juror assigned to this action.

68. Plaintiff Malich brings this action on behalf of herself and the members of the proposed New Jersey Subclass, which consists of:

All New Jersey consumers who purchased a Product for personal, family, or household purposes from the beginning of the applicable statutory period until the date notice is disseminated. Excluded from the New Jersey Subclass are Defendant; any entity in which Defendant has a controlling interest; and any legal representative, heir or assign of Defendant. Also excluded from the New Jersey Subclass are any federal, state, or local governmental entities, any judicial officer presiding over this action and the members of his/her immediate family and judicial staff, and any juror assigned to this action.

69. Plaintiff Kravchenko brings this action on behalf of himself and the members of the proposed Illinois Subclass, which consists of:

All Illinois consumers who purchased a Product for personal, family, or household purposes from the beginning of the applicable statutory period until the date notice is disseminated. Excluded from the Illinois Subclass are Defendant; any entity in which Defendant has a controlling interest; and any legal representative, heir or assign of Defendant. Also excluded from the Illinois Subclass are any federal, state, or local governmental entities, any judicial officer presiding over this action and the members of his/her immediate family and judicial staff, and any juror assigned to this action.

70. The members of the Classes are so numerous that joinder is impractical. The Classes consist of thousands of members, the precise number which is within the knowledge of and can be ascertained only through Defendant's records.

71. There are numerous questions of fact and law common to the Classes which predominate over any questions affecting only individual members of the Classes. Among the questions of law and fact common to the Classes are:

- (a) Whether Defendant's representations that the Products are "clinically proven" to grow hair are false and misleading;
- (b) Whether Defendant's advertising claims constitute unlawful implied disease claims;
- (c) Whether Defendant's advertising claims constitute unlawful health claims;
- (d) Whether Defendant's marketing conduct described herein constitutes violations of the laws asserted;
- (e) Whether Plaintiffs and the members of the Classes have suffered damages as a result of Defendant's actions and the amount thereof;
- (f) Whether Plaintiffs and the members of the Classes are entitled to statutory damages;
- (g) Whether Plaintiffs and the members of the Classes are entitled to other appropriate remedies including injunctive relief, and attorneys' fees and costs.

72. Plaintiffs' claims are typical of the claims of the members of the Classes because Plaintiffs, like all members of the Classes, were exposed to Defendant's false and misleading marketing, purchased Defendant's illegal Products, and suffered a loss as a result of those purchases.

73. Plaintiffs are representatives who will fully and adequately assert and protect the interests of the Classes and have retained counsel who are experienced in prosecuting class actions. Accordingly, Plaintiffs are adequate representatives and will fairly and adequately protect the interests of the Classes.

74. A class action is superior to all other available methods for the fair and efficient adjudication of this lawsuit because individual litigation of the claims of all members of the Classes is economically unfeasible and procedurally impracticable.

75. While the aggregate damages sustained by the Classes are in the millions of dollars, the individual damages incurred by each member of the Classes resulting from Defendant's wrongful conduct are too small to warrant the expense of individual lawsuits. The likelihood of individual members of the Classes prosecuting their own separate claims is remote, and, even if every member of the Classes could afford individual litigation, the court system would be unduly burdened by individual litigation of such cases.

76. Defendant has acted or refused to act on grounds that apply generally to the Classes, thereby making appropriate final injunctive and corresponding declaratory relief with respect to the Classes as a whole.

77. The prosecution of separate actions by members of the Classes would create a risk of establishing inconsistent rulings and/or incompatible standards of conduct for Defendant. For example, one court might enjoin Defendant from performing the challenged acts, whereas another might not. Additionally, individual actions may be dispositive of the interests of the Classes, although certain class members are not parties to such actions.

**CAUSES OF ACTION**

**COUNT I**

**Violation of New York G.B.L. § 349  
(On Behalf of Plaintiff Kapoor and the New York Subclass)**

78. Plaintiff Kapoor incorporates by reference the allegations contained in paragraphs 1-77 of this Complaint as though fully set forth herein.

79. New York's General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

80. In its sale of Products throughout the state of New York, at all relevant times herein, Defendant conducted business and trade within the meaning and intendment of New York's General Business Law § 349.

81. Plaintiff Kapoor and the New York Subclass members are consumers who purchased the Products from Defendant for their personal use.

82. By the acts and conduct alleged herein, Defendant engaged in deceptive, unfair, and misleading acts and practices by conspicuously representing on the marketing of the Products that they are "clinically proven" to promote hair growth. The studies Defendant relies on to support those representations do not constitute clinical proof. As a result, Defendant's representations are materially false and misleading. In fact, studies suggest the key ingredients in the Products do not affect hormones and thus do not provide the hair growth benefits Defendant touts.

83. Defendant also engaged in deceptive, unfair, and misleading acts by misbranding the Products, including by making unlawful implied disease claims in violation of New York's Agriculture and Marketing law, which incorporates the FDCA by reference.

84. Defendant also engaged in deceptive, unfair, and misleading acts by misbranding the Products, including by making unlawful health claims that the Products are supportive of metabolic and hormonal health when they contain harmful levels of ingredients that function to harm health in the supplied or recommended dosage, in violation of New York's Agriculture and Marketing law, which incorporates the FDCA by reference.

85. The foregoing deceptive acts and practices were directed at consumers.

86. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the nature and value of the Products.

87. As a result of Defendant's deceptive practices, Plaintiff Kapoor and the New York Class members suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known the Products were not, indeed, "clinically proven" to promote hair growth.

88. Plaintiff Kapoor and the New York Class members also suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known Defendant's representation that the Products could cure hormone imbalances characteristic of common hair loss diseases and thus promote hair growth were misleading and unapproved implied disease claims, which render the Products misbranded and illegal to sell.

89. Plaintiff Kapoor and the New York Class members also suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known Defendant's representations that the Products are supportive of metabolic and hormonal health were misleading health claims, which render the Products misbranded and illegal to sell.

90. On behalf of herself and the New York Subclass members, Plaintiff Kapoor seeks to recover actual damages or fifty dollars, whichever is greater, three times the actual damages, reasonable attorneys' fees and costs, and equitable relief, including injunctive relief enjoining Defendant from continuing its misleading marketing campaign.

**COUNT II**  
**Violation of New York G.B.L. § 350**  
**(On Behalf of Plaintiff Kapoor and the New York Subclass)**

91. Plaintiff Kapoor incorporates by reference the allegations contained in paragraphs 1-77 of this Complaint as though fully set forth herein.

92. New York's General Business Law § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

93. Defendant violated New York General Business Law § 350 by misrepresenting that the Products are “clinically proven” to promote hair growth. The studies Defendant relies on to support those representations do not constitute clinical proof. As a result, Defendant’s representations are materially false and misleading. In fact, studies suggest the key ingredients in the Products do not affect hormones and thus do not provide the hair growth benefits Defendant touts.

94. Defendant also engaged in deceptive, unfair, and misleading acts by misbranding the Products, including by making unlawful implied disease claims in violation of New York’s Agriculture and Marketing law, which incorporates the FDCA by reference.

95. Defendant also engaged in deceptive, unfair, and misleading acts by misbranding the Products, including by making unlawful health claims that the Products are supportive of metabolic and hormonal health when they contain harmful levels of ingredients that function to harm health in the supplied or recommended dosage, in violation of New York’s Agriculture and Marketing law, which incorporates the FDCA by reference.

96. The foregoing advertising was directed at consumers and was likely to mislead a reasonable consumer acting reasonably under the circumstances.

97. Defendant’s misrepresentations have resulted in consumer injury or harm to the public interest.

98. As a result of Defendant’s deceptive practices, Plaintiff Kapoor and the New York Class members suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known the Products were not, indeed, “clinically proven” to promote hair growth.

99. Plaintiff Kapoor and the New York Class members also suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known Defendant’s representation that the Products could cure hormone imbalances characteristic of common hair loss diseases and thus promote hair growth were misleading and unapproved implied disease claims, which render the Products misbranded and illegal to sell.

100. Plaintiff Kapoor and the New York Class members also suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known Defendant's representation that the Products had they known Defendant's representations that the Products are supportive of metabolic and hormonal health were misleading health claims, which render the Products misbranded and illegal to sell.

101. On behalf of herself and the New York Subclass members, Plaintiff Kapoor seeks to recover actual damages or five hundred dollars, whichever is greater, three times the actual damages, reasonable attorneys' fees and costs, and equitable relief, including injunctive relief enjoining Defendant from continuing its misleading marketing campaign.

**COUNT III**

**Violation of the Consumer Legal Remedies Act, Cal. Civ. Code § 1750, et. seq  
(On Behalf of Plaintiffs Clugston and Scott and the California Subclass)**

102. Plaintiffs Clugston and Scott incorporate by reference the allegations contained in paragraphs 1-77 of this Complaint as though fully set forth herein

103. At all relevant times, Plaintiffs Clugston and Scott were "consumers" as defined by Cal. Civ. Code § 1761(d).

104. At all relevant times, the Products were "goods" as defined by Cal. Civ. Code § 1761(a).

105. At all relevant times, Defendant was a "person" as defined by Cal. Civ. Code § 1761(c).

106. Cal. Civ. Code § 1770(a) prohibits "unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any consumer[.]"

107. By the acts and conduct alleged herein, Defendant engaged in deceptive, unfair, and misleading acts and practices by conspicuously representing in the marketing of the Products that they are "clinically proven" to promote hair growth. The studies Defendant relies on to support those representations do not constitute clinical proof. As a result, Defendant's representations are

materially false and misleading. In fact, studies suggest the key ingredients in the Products do not affect hormones and thus do not provide the hair growth benefits Defendant touts.

108. Plaintiffs Clugston and Scott and the California Subclass members are reasonable consumers who expected the Products to have the characteristics as represented.

109. As a result of Defendant's conduct and unfair or deceptive acts or practices, Plaintiffs Clugston and Scott and the California Subclass members suffered actual damages in that the Products are not as advertised and are not worth the amount paid, and Defendant has deprived Plaintiffs Clugston and Scott and California Subclass members the benefit of their bargain.

110. Plaintiffs Clugston and Scott and the California Subclass seek an order enjoining Defendant's unfair or deceptive acts or practices, equitable relief, and an award of attorneys' fees and costs under Cal. Civ. Code § 1780(e).

2. Pursuant to Cal. Civ. Code § 1782, Plaintiffs Clugston and Scott notified Defendant in writing by certified mail sent on July 14, 2023, of its violations of § 1770 described above and demanded that it correct the problems associated with the actions detailed above and give notice to all affected consumer of Defendant's intent to do so. If Defendant does not agree to rectify the problems identified and give notice to all affected consumers within 30 days of the date of written notice, Plaintiffs will amend this Complaint to seek actual, punitive and statutory damages, as appropriate.

#### **COUNT IV**

#### **Violation of the "Unlawful" Prong of the UCL Cal. Bus. & Prof. Code § 17200, et. seq (On Behalf of Plaintiffs Clugston and Scott and the California Subclass)**

111. Plaintiffs Clugston and Scott incorporate by reference the allegations contained in paragraphs 1-77 of this Complaint as though fully set forth herein.

112. California's Unfair Competition Law ("UCL") defines unfair business competition to include any "unlawful, unfair or fraudulent" act or practice, as well as any "unfair, deceptive, untrue or misleading" advertising. Cal. Bus. & Prof. Code § 17200.



113. A business act or practice is “unlawful” under the UCL if it violates any other law or regulation.

114. Defendant has violated the unlawful prong by virtue of its violations of the Sherman Food Drug & Cosmetics Laws by making unlawful implied disease and health claims. In addition, Defendant has violated the unlawful prong by virtue of its violation of the CLRA.

115. As a result of the conduct described above, Defendant has been unjustly enriched at the expense of Plaintiffs Clugston and Scott and the members of the proposed California Subclass. Specifically, Defendant has been unjustly enriched by obtaining revenues and profits that it would not otherwise have obtained absent its false, misleading, and deceptive conduct.

116. Through its unlawful acts and practices, Defendant has improperly obtained money from Plaintiffs Clugston and Scott and the California Subclass.

117. Consequently, Plaintiffs Clugston and Scott request the Court cause Defendant to restore this money to Plaintiffs and all California Subclass members, and enjoin Defendant from continuing to violate the UCL as discussed herein and/or from violating the UCL in the future. Plaintiffs Clugston and Scott seeks an injunction prohibiting Defendant from selling the Products with the current labeling and marketing, which contain implied disease and health claims, in violation of California’s Sherman Law and, accordingly, by the unlawful prong of the UCL. Plaintiffs Clugston and Scott and the California Subclass may be irreparably harmed and/or denied an effective and complete remedy if such an order is not granted.

**COUNT V**

**Violation of the New Jersey Consumer Fraud Act, N.J. Stat. § 56:8-1, et seq  
(On Behalf of Plaintiff Malich and the New Jersey Subclass)**

118. Plaintiff Malich incorporates by reference the allegations contained in paragraphs 1-77 of this Complaint as though fully set forth herein.

119. The Products are considered “merchandise” within the meaning of N.J. Stat. § 56:8-1(c).

120. Plaintiff Malich and members of the New Jersey Subclass are “persons” and “consumers” within the meaning of N.J. Stat. § 56:8-1(d).

121. The New Jersey Consumer Fraud Act prohibits “deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission” in connection with the sale or advertisement of any merchandise. N.J. Stat. § 56:8-2.

122. Defendant violated the New Jersey Consumer Fraud Act by misrepresenting that the Products are “clinically proven” to promote hair growth. The studies Defendant relies on to support those representations do not constitute clinical proof. As a result, Defendant’s representations are materially false and misleading. In fact, studies suggest the key ingredients in the Products do not affect hormones and thus do not provide the hair growth benefits Defendant touts.

123. Defendant also engaged in deceptive, unfair, and misleading acts by misbranding the Products, including by making unlawful implied disease claims in violation of New Jersey Law, which incorporates the FDCA by reference. *See* N.J.S.A. 24:5–17(a), N.J. Admin. Code tit. 8, § 24–3.6

124. Defendant also engaged in deceptive, unfair, and misleading acts by misbranding the Products, including by making misleading health claims in violation of New Jersey Law, which incorporates the FDCA by reference. *See* N.J.S.A. 24:5–17(a), N.J. Admin. Code tit. 8, § 24–3.6

125. As a result of Defendant’s deceptive practices, Plaintiff Malich and the New Jersey Class members suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known the Products were not, indeed, “clinically proven” to promote hair growth.

126. Plaintiff Malich and the New Jersey Class members also suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known Defendant’s representation that the Products could cure hormone imbalances characteristic

of common hair loss diseases and thus promote hair growth were misleading and unapproved implied disease claims, which render the Products misbranded and illegal to sell.

127. Plaintiff Malich and the New Jersey Class members also suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known Defendant's representation that the Products are supportive of metabolic and hormonal health were misleading health claims, which render the Products misbranded and illegal to sell.

128. Plaintiff Malich and the New Jersey Subclass members demand judgment pursuant to N.J. Stat. § 56:8-19 against Defendant for treble damages, statutory remedies made available under the New Jersey Consumer Fraud Act, and injunctive relief requiring Defendant to enjoin Defendant from continuing its misleading marketing campaign.

129. Through its conduct, Defendant has violated, and continues to violate, the New Jersey Consumer Fraud Act, which makes deception, fraud, false promise, and/or misrepresentation of goods unlawful. As a direct and proximate cause of Defendant's violation of the New Jersey Consumer Fraud Act, as described above, Plaintiff Malich and the members of the New Jersey Subclass have suffered damages.

**COUNT VI**

**Violation of the Illinois Consumer Fraud and Deceptive Trade Practices Act, 815 ILCS 505/1, et seq.**

**(On Behalf of Plaintiff Kravchenko and the Illinois Subclass)**

130. Plaintiff Kravchenko incorporates by reference the allegations contained in paragraphs 1-77 of this Complaint as though fully set forth herein.

131. Plaintiff Kravchenko asserts that Defendant violated the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), which prohibits the use of "unfair and deceptive practices" in the conduct of trade or commerce. 815 ILCS 505/2. The ICFA is to be liberally construed to effectuate that purpose.

132. Plaintiff Kravchenko and the Illinois Subclass members are persons and consumers as defined in 815 ILCS 505/1(c) and (e).

133. The Products are merchandise as defined in 815 ILCS/1(b).

134. Defendant's misconduct took place in the course of trade or commerce in Illinois, arose out of transactions that occurred in Illinois, and/or harmed individuals located in Illinois.

135. Defendant violated the ICFA by misrepresenting that the Products are "clinically proven" to promote hair growth. The studies Defendant relies on to support those representations do not constitute clinical proof. As a result, Defendant's representations are materially false and misleading. In fact, studies suggest the key ingredients in the Products do not affect hormones and thus do not provide the hair growth benefits Defendant touts.

136. Defendant also engaged in deceptive, unfair, and misleading acts by misbranding the Products, including by making unlawful implied disease claims in violation of Illinois Law, which incorporates the FDCA by reference. *See* 410 ILCS 620/21(a) & (j).

137. Defendant also engaged in deceptive, unfair, and misleading acts by misbranding the Products, including by misleading health claims in violation of Illinois Law, which incorporates the FDCA by reference. *See* 410 ILCS 620/21(a) & (j).

138. As a result of Defendant's deceptive practices, Plaintiff Kravchenko and the Illinois Subclass members suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known the Products were not, indeed, "clinically proven" to promote hair growth.

139. Plaintiff Kravchenko and the Illinois Subclass members also suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known Defendant's representation that the Products could cure hormone imbalances characteristic of common hair loss diseases and thus promote hair growth were misleading and unapproved implied disease claims, which render the Products misbranded and illegal to sell.

140. Plaintiff Kravchenko and the Illinois Subclass members also suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known Defendant's representation that the Products are supportive of metabolic and hormonal health were misleading health claims, which render the Products misbranded and illegal to sell.

141. Defendant, at all relevant times, knew or should have known that Plaintiff Kravchenko and the Illinois Subclass members did not know and could not have reasonably discovered its deceptive and unfair acts.

142. As a direct and proximate result of Defendant's conduct, Plaintiff Kravchenko and the Illinois Subclass members sustained damages.

143. On behalf of himself and the Illinois Subclass members, Plaintiff Kravchenko seeks statutory and actual damages, punitive damages, injunctive relief, attorneys' fees and costs, and all other relief allowed under the ICFA.

**COUNT VII**  
**VIOLATION OF THE ILLINOIS**  
**UNIFORM DECEPTIVE TRADE PRACTICES ACT, 815 Ill. Comp. Stat. 510/2, et seq.**  
**(By Plaintiff Kravchenko on Behalf of the Illinois Subclass)**

138. Plaintiff Kravchenko incorporates by reference the allegations contained in paragraphs 1-77 of this Complaint as though fully set forth herein.

139. Plaintiff Kravchenko brings this cause of action individually and on behalf of the Illinois Subclass.

140. The Illinois Deceptive Trade Practices Act ("UDTPA"), 815 Ill. Comp. Stat. 510/2, *et seq.*, prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact."

141. 815 ILCS 510/2 provides in pertinent part that a "person engages in a deceptive trade practice when, in the course of his or her business, vocation, or occupation," the person does any of the following: "(5) represents that goods or services have . . . uses, benefits or quantities that they do not have . . .; (7) represents that goods or services are of a particular standard, quality, or grade or that goods are a particular style or model, if they are of another; . . . [or] (12) engages in any other conduct which similarly creates a likelihood of confusion or misunderstanding."

142. Defendant engaged in unfair and deceptive acts in violation of 815 Ill. Comp. Stat. 510/2 when it misrepresented that the Products are “clinically proven” to promote hair growth. The studies Defendant relies on to support those representations do not constitute clinical proof. As a result, Defendant’s representations are materially false and misleading. In fact, studies suggest the key ingredients in the Products do not affect hormones and thus do not provide the hair growth benefits Defendant touts. Plaintiff Kravchenko and the Illinois Subclass Members were injured by Defendant’s unfair and deceptive conduct at the time of purchasing the Products.

143. Defendant also engaged in deceptive, unfair, and misleading acts by misbranding the Products, including by making unlawful implied disease claims in violation of Illinois Law, which incorporates the FDCA by reference. *See* 410 ILCS 620/21(a) & (j).

144. Defendant also engaged in deceptive, unfair, and misleading acts by misbranding the Products, including by misleading health claims in violation of Illinois Law, which incorporates the FDCA by reference. *See* 410 ILCS 620/21(a) & (j).

145. As a result of Defendant’s deceptive practices, Plaintiff Kravchenko and the Illinois Subclass members suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known the Products were not, indeed, “clinically proven” to promote hair growth.

146. Plaintiff Kravchenko and the Illinois Subclass members also suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known Defendant’s representation that the Products could cure hormone imbalances characteristic of common hair loss diseases and thus promote hair growth were misleading and unapproved implied disease claims, which render the Products misbranded and illegal to sell.

147. Plaintiff Kravchenko and the Illinois Subclass members also suffered an economic injury because they would not have purchased (or paid a premium for) the Products had they known Defendant’s representation that the Products are supportive of metabolic and hormonal health were misleading health claims, which render the Products misbranded and illegal to sell.

148. Defendant, at all relevant times, knew or should have known that Plaintiff Kravchenko and the Illinois Subclass members did not know and could not have reasonably discovered its deceptive and unfair acts.

149. Defendant's deceptive acts occurred in a course of conduct involving trade and commerce in Illinois and throughout the United States.

150. Defendant's deceptive acts proximately caused actual injury and damage to Plaintiff Kravchenko and the Illinois Subclass Members at the time of purchase.

151. Plaintiff Kravchenko and the Illinois Subclass Members would not have purchased, or would have paid less for, Defendant's Products but for Defendant's material misrepresentations as described in this Complaint.

152. Defendant intended Plaintiff Kravchenko and the Illinois Subclass Members to rely on its deceptive acts when purchasing the Products.

**PRAYER FOR RELIEF**

144. WHEREFORE, Plaintiffs, individually and on behalf of all others similarly situated, seek judgement against Defendant, as follows:

- (a) For an order certifying the Classes under Rule 23 of the Federal Rules of Civil Procedure, naming Plaintiffs as representatives of the Classes, and naming Plaintiffs' counsel as Class Counsel to represent the Classes;
- (b) For an order finding in favor of Plaintiffs and the Classes on all counts asserted herein;
- (c) For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;
- (d) For injunctive relief as permitted by law or equity to enjoin Defendant from continuing the unlawful practices as set forth herein;
- (e) For restitution and disgorgement in an amount to be determined at trial;
- (f) For reasonable attorneys' fees, costs, and expenses;
- (g) For pre- and post-judgment interest on any amounts awarded; and

(h) For such other and further relief as may be just and proper.

**DEMAND FOR TRIAL BY JURY**

Plaintiffs demand a trial by jury of any and all issues in this action so triable as of right.

Dated: July 17, 2023

Respectfully submitted,

*/s/ Melissa S. Weiner*

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forthcoming

