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SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF ROCKLAND

ERIN SHEEHAN, on behalf of herself and all others similarly situated,

Plaintiff,

v.

NUTRACEUTICAL WELLNESS, INC., d/b/a NUTRAFOL,

Defendant.

SU	JN	M	\mathbf{O}	٧S

Index No.	
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Date Purchased: 02/09/2023

Plaintiff designates Rockland County as the place of trial.

The basis for venue is Plaintiff's residence.

To the above-named Defendant:

YOU ARE HEREBY SUMMONED to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance on the Plaintiff's attorney at the address set forth below, within 20 days after the service of this summons (not counting the day of service itself), or within 30 days after service is complete if the summons is not delivered personally to you within the State of New York.

YOU ARE HEREBY NOTIFIED THAT in the case of your failure to appear or to answer the complaint, a judgment will be entered against you by default for the relief demanded in the complaint.

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Dated: February 9, 2023

White Plains, New York

DENLEA & CARTON LLP

By:

James R. Denlea Jeffrey I. Carton Stan Sharovskiy 2 Westchester Park Drive, Suite 410 White Plains, New York 10604

Tel.: (914) 331-0100
Fax: (914) 331-0105
jdenlea@denleacarton.com
jcarton@denleacarton.com
ssharovskiy@denleacarton.com

KRAVIT SMITH LLP

Philip M. Smith 75 South Broadway, Suite 400 White Plains, New York 10601

Tel.: (646) 433-8004 Fax: (917) 858-7101

psmith@kravitsmithllp.com

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COUNTY OF ROCKLAND	
ERIN SHEEHAN on behalf of herself and all others similarly situated,	Case No.:
Plaintiff,	
v.	COMPLAINT
NUTRACEUTICAL WELLNESS, INC. d/b/a NUTRAFOL,	
Defendant.	
	X

CUDDEME COUDT OF THE CTATE OF NEW YORK

Plaintiff Erin Sheehan, on behalf of herself and all others similarly situated ("Plaintiff"), by and through her undersigned counsel, Denlea & Carton LLP, states for her Complaint against Nutraceutical Wellness, Inc. ("Nutrafol" or "Defendant"), as follows:

PRELIMINARY STATEMENT



- 1. This action seeks to redress the false, misleading, and deceptive advertising and packaging claims that Nutrafol has made in connection with the sale of its purportedly "clinically proven" anti-hair loss supplement marketed under the brand name Nutrafol Women.¹
- 2. It is estimated that more than 50% of women will experience some form of hair loss in their lifetime, with approximately a third suffering from female pattern hair loss ("FPHL") as a result of natural aging and hormone imbalances in the body.²

https://nutrafol.com/nutrafol-core-for-women/

https://my.clevelandclinic.org/health/diseases/16921-hair-loss-inwomen#:~:text=However%2C%20it%20is%20estimated%20that,women%20in%20the%20United%20States.

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3. Compounding the problem, the emotional and psychological stressors associated with the COVID-19 pandemic have resulted in a new class of hair loss sufferers, men and women alike. With more people seeking relief from the symptoms of alopecia (the complete absence of hair from the body where hair naturally occurs), a proliferation of opportunistic and unscrupulous supplement manufacturers are looking to tap into that lucrative market.³

4. Despite claims that *Nutrafol Women* is "[p]hysician formulated" and uses "medical-grade, natural ingredients" which have been proven in a clinical setting, the purported active ingredient, pseudo-scientifically branded as "Synergen Complex," is nothing more than an unremarkable assemblage of collagen and common supplements such as ashwagandha, saw palmetto, curcumin extract, palm extract, and hyaluronic acid. The remaining ingredients are a muddled cocktail of everyday vitamins (such as Vitamins A and C), and various fruit extracts and amino acids marketed as "Nutrafol Blend":

Serving Size: 4 Capsules Servings Per Container: 30		
AMOUNT PER	SERVING	%D\
Vitamin A (as Beta-Carotene) (5000 IU) 150	0 mcg RAE	1679
Vitamin C (as Camu Camu Fruit, Ascorbic Acid)	100 mg	1119
Vitamin D (as Cholecalciferol) (2500 IU	J) 62.5 mcg	3139
Vitamin E (as a-tocopherol)	3.5 mg	239
Biotin (as D-Biotin)	3000 mcg	100009
lodine (from Organic Kelp) (Laminaria Digitata)	225 mcg	1509
Zinc (as Zinc Amino Acid Chelate)	25 mg	2279
Selenium (as Selenium Amino Acid Chelate)	200 mcg	3649
SYNERGEN COMPLEX®	1680 mg	•
Hydrolyzed Marine Collagen Type I & III, Sens (Root and Leaf) Extract (10% Withanolides), S (Fruit) CO₂ Extract (245% Fatty Acids), BCM- Curcumin (Rhizome) Extract (95% Total Curci Full Spectrum Palm Extract (20% Tocotrienol Complex), Hyaluronic Acid	aw Palmetto 95® Bio-Cu uminoid Con	rcumin [®] nplex),
NUTRAFOL® BLEND	530 mg	•
L-Cysteine, L-Lysine, L-Methionine, Solubilize (Stem and Leaf) Extract, Japanese Knotweed (50% Resveratrol), Black Pepper (Fruit) Extra	(Root) Extr	act

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

OTHER INGREDIENTS: Vegetable Cellulose Capsule (Hypromellose).

^{3.} https://www.theatlantic.com/health/archive/2021/11/pandemic-hair-loss-treatment-products/620696/

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- 5. Contrary to the claims made by Nutrafol, none of the ingredients in its "clinically proven formula" are "medical grade," and they have never been approved for the treatment of any medical condition, let alone hair loss or alopecia. Indeed, the only approved drugs for the treatment of androgenetic hair loss currently on the market are Minoxidil and Finasteride.⁴ A third drug, Baricitinib, has only recently been approved by the FDA for the treatment of alopecia areata, which is a form of hair loss suffered by those with certain autoimmune disorders.⁵ Significantly, none of these drugs is present in Nutrafol Women.
- 6. Nutrafol further misleads consumers by falsely claiming that *Nutrafol Women* is "physician-formulated," thereby creating the impression that doctors have long been prescribing the supplement for the treatment of hair loss, or were otherwise involved in its development after years of effective use in a patient population:

Women

Hair Growth Nutraceutical

Our daily hair growth supplement is made for women 18-44 who are experiencing signs of hair thinning. Physician-formulated with medical-grade, natural ingredients to target root causes of thinning such as stress, lifestyle and nutrition, our award-winning formula results in faster-growing, thicker, fuller, stronger hair. And it's an effortless addition to your daily wellness routine: 4 pills, 1 easy step, all the results. 1-2

7. There is no indication, however, that *Nutrafol Women* was ever developed by physicians or, for that matter, was ever anything other than a marketing gimmick to fleece unsuspecting consumers and, specifically, the growing number of health-conscious women for whom the symptoms of hair loss (whether as a result of age, genetics, or other underlying conditions) can be understandably devastating.

^{4.} https://emedicine.medscape.com/article/1070167-treatment

https://www.fda.gov/news-events/press-announcements/fda-approves-first-systemic-treatment-alopecia-areata#:~:text=Today%2C%20the%20U.S.%20Food%20and,in%20the%20U.S.%20each%20year

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> 8. The face behind Nutrafol is the current CEO, co-founder, and former male model Giorgos Tsetis. ⁶ Tsetis founded Nutrafol in 2015 to market hair loss supplements to those "looking" for a natural yet effective solution in the marketplace," in contrast to costly prescription medications.7

> 9. Nutrafol's deceptive advertising campaign is centered upon sharing Tsetis' own alleged experiences taking prescription hair loss drugs that he claims saved his hair, but came at the cost of reduced sexual function.⁸ Purportedly fed up with the pursuit of "external beauty over everything else," Tsetis claims he then embarked upon a journey of discovering and sharing the concept of "hair wellness" as an alternative to the debilitating side effects associated with taking expensive prescription drugs for hair loss.

> Tsetis' claim that the efficacy of Nutrafol is shown by science and clinical studies 10. is unequivocal: "Our proprietary blend of medical-grade botanicals and standardized ingredients work naturally in the body to combat the underlying causes of thinning hair: stress, hormones, nutrition, and environmental factors. Bottom line: the efficacy of our supplements is backed by science and clinical studies."9

> 11. Extraordinary claims, as the saying goes, require extraordinary evidence and there is none. Despite the absence of legitimate scientific evidence for its claims, Nutrafol extensively markets its hair loss products to unsuspecting consumers knowing full well that the only thing growing "thicker, fuller, and stronger" is its bottom line.

https://medium.com/authority-magazine/giorgos-tsetis-of-nutrafol-five-things-you-need-to-know-tosucceed-in-the-modern-beauty-industry-9481a9ba548b (emphasis added).

Id.

Id.

Id. (emphasis added).

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12. To be sure, there has been an uptick in recent years in legal actions against unscrupulous manufacturers claiming to have harnessed the secrets of hair rejuvenation and regrowth. From caps and combs fitted with lasers¹⁰ to pyramid scheme hucksters peddling strange "detoxifying" shampoos,¹¹ the market for hair loss treatments is littered with those looking to take advantage of desperate consumers. Nutrafol's oral supplement, dubbed by its model front man as the "holistic" philosophy of "hair wellness," is the latest evolution of the same old canard.

13. By this action, Plaintiff seeks to redress Nutrafol's unfair and deceptive marketing campaign built upon the misleading claims that it makes and to obtain the financial recompense to which Plaintiff and her fellow class members are entitled.

THE PARTIES

- 14. Plaintiff Erin Sheehan is an individual who resides in Pearl River, New York.
- 15. Defendant Nutraceutical Wellness, Inc., d/b/a Nutrafol, is a Delaware corporation with its principal address at 136 Madison Avenue, Floor 10, New York, NY 10016.
- 16. Nutrafol manufactures, markets, and sells *Nutrafol Women* through Nutrafol.com and Amazon, as well as brick-and-mortal retail stores such as Walmart. Additionally, *Nutrafol Women* is sold by physicians and hairstylists within Nutrafol's network.¹³

 $[\]frac{10.}{\text{https://www.vitallaw.com/news/advertising-n-d-cal-customer-s-false-advertising-claims-over-hair-regrowth-products-survive/ald01607cb6767daa1000bca8005056881d2304}$

^{11.} https://www.foxbusiness.com/features/monat-shampoo-hair-loss-balding-consumers-claim

https://hamptons.com/lifestyle-for-your-health-26827-interview-greek-born-engineer-entrepreneur-html/

^{13. &}lt;a href="https://nutrafol.com/partners/">https://nutrafol.com/partners/

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JURISDICTION AND VENUE

- 17. This Court has jurisdiction over this action because Plaintiff and the members of the Class she seeks to represent are all New York residents, and the acts and events at issue in this case took place in New York.
- 18. Venue is proper in this Court because Plaintiff is a resident of Rockland County, and a substantial part of the underlying events took place in Rockland County.

FACTUAL BACKGROUND

- I. <u>Due to the Premium Consumers are Willing to Pay for Products that are Backed by Science, Manufacturers Routinely Misrepresent That Their Products Have Been Scientifically Proven to be Effective</u>
- 19. Consumers who are seeking help for symptoms of hair loss or alopecia are particularly vulnerable targets for unscrupulous manufacturers and advertisers. In a bid to avoid the negative side effects of pharmaceutical hair loss drugs, consumers are willing to pay a premium for nutraceutical supplements that are scientifically proven to be effective. This is especially true where there are putative claims that the product does not have negative side effects. In an overcrowded marketplace where beneficial health claims are ubiquitous, being able to convince the consuming public about the efficacy of a product is critical.
- 20. In order to differentiate their products and gain a competitive edge, manufacturers and advertisers routinely mislead consumers by claiming that the efficacy of their products is backed by science (*i.e.*, "establishment claims"), when, in fact, it is not. That is why Courts are particularly wary of claims by manufacturers that their product has been scientifically proven to be effective when, as here, those claims are false.
- 21. An advertiser's health-related claims about the efficacy of a product must "be supported with 'competent and reliable scientific evidence," which the Federal Trade Commission

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(the "FTC") defines as "'tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."¹⁴ As the FTC has stated, "well-controlled human clinical studies are the most reliable form of evidence."¹⁵

II. <u>Nutrafol Falsely Markets Its Hair Loss Supplement as "Clinically Proven" and "Medical Grade"</u>

- 22. Nutrafol's online advertisements are ubiquitous. However, Nutrafol also leverages its brand through television advertising and, most recently, with a broad, exploitive and cynical marketing campaign called "Shed the Silence," which is ostensibly intended to help "connect women to other women, experts and influencers ... [to] empower women to share personal stories and recommendations, and educate and raise awareness around the toll of hair thinning both physically and mentally." ¹⁶
- 23. The campaign to raise "awareness," however, is simply a transparent smokescreen to raise awareness of Nutrafol's snake oil by using paid "partners" whose job is to influence consumers using social media and online forums while masquerading as everyday consumers.¹⁷
- 24. Nutrafol's website is littered with claims by paid actors touting *Nutrafol Women* and its false claims that Nutrafol is "clinically effective," and that "[c]linical studies show that

¹⁴. FTC, Dietary Supplements: An Advertising Guide to Industry, Section II(B), at https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry

¹⁵. FTC, Dietary Supplements: An Advertising Guide to Industry, Section II(B)(2), at https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry

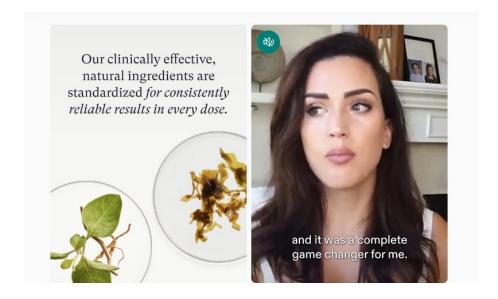
^{16. &}lt;u>https://www.thedrum.com/news/2022/09/09/nutrafol-encourages-women-talk-about-hair-thinning-and-break-the-taboo-around-it</u>

^{17. &}lt;a href="https://truthinadvertising.org/articles/nutrafol-needs-to-shed-its-deceptive-hair-growth-claims/">https://truthinadvertising.org/articles/nutrafol-needs-to-shed-its-deceptive-hair-growth-claims/

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Nutrafol works." Nutrafol even expresses feigned disdain for other supplements that are "never clinically tested for efficacy:"



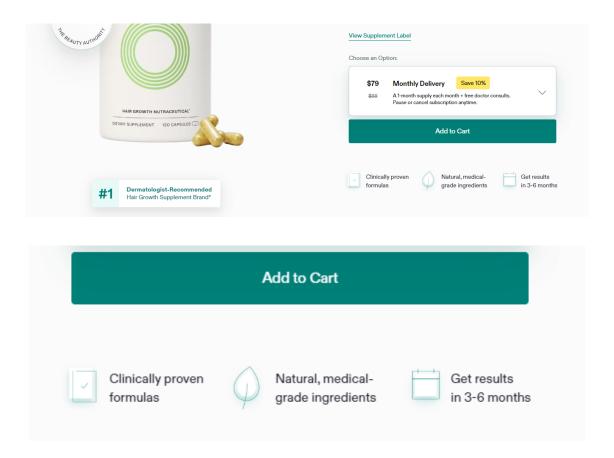


Clinical studies show that Nutrafol works.

25. At other portions of its website, Nutrafol falsely claims, without any qualification or conditions, that *Nutrafol Women* has been "clinically proven":

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26. As such, it is clear that *Nutrafol Women* is deliberately and conspicuously marketed to unsuspecting consumers as a scientifically proven supplement that was not only subject to the rigors of clinical testing, but is also comprised of "medical-grade" ingredients, thereby creating the false impression among consumers that they are purchasing a supplement with pharmacologic characteristics that are able to produce medically significant changes in the body when consumed.

III. The "Clinically Proven" and "Medical Grade" Claims are False and Mislead Consumers

27. Reasonable consumers understand that the "clinically proven" and "medical grade" claims convey that *Nutrafol Women* has been proven to increase the rate of hair growth, result in thicker and fuller hair, and to medically address the root causes of compromised hair health by

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regulating stress, hormones, metabolism, nutrition, and the effects of aging. Indeed, these metrics are expressly stated by *Nutrafol Women* as the benefits of taking the supplement.¹⁸

- 28. The "clinically proven" and "medical grade" claims, however, are patently false since the only clinical trial conducted by Nutrafol to test its *Nutrafol Women* supplement *did not* prove its effectiveness.
- 29. To support its claims in connection with the marketing of *Nutrafol Women* as a "clinically proven" or "medical grade" supplement, Nutrafol cites to one clinical trial, conducted by Dr. Sophia Kogan and Dr. Glynis Ablon, whose results were published in the May 2018 issue of the Journal of Drugs in Dermatology.¹⁹
- 30. Unsurprisingly, Dr. Kogan is listed as a co-founder of *Nutrafol Women* and holds the position as its Chief Medical Advisor.²⁰ Dr. Ablon, on the other hand, received a research grant from Nutrafol to "study" the very product Nutrafol was heavily invested in marketing. Apart from the glaringly obvious conflicts of interest, however, the parameters of the clinical trial also reveal it to have been a curated exercise in self-affirming data manipulation.
- 31. At the outset, the double-blind clinical trial was limited to just 40 female participants. It is well understood and accepted that such small sample sizes are not a sufficient foundation to draw scientifically reliable conclusions with respect to the efficacy of a tested drug or supplement.²¹
- 32. Further, for reasons that are not disclosed, nearly twice the number of participants in *Nutrafol Women's* clinical trial were assigned to the active supplement group, numbering at 26,

https://nutrafol.com/nutrafol-core-for-women/

^{19. &}lt;u>https://jddonline.com/articles/a-six-month-randomized-double-blind-placebo-controlled-study-evaluating-the-safety-and-efficacy-of-a-S1545961618P0558X/</u>

https://nutrafol.com/story/

https://www.winchesterhospital.org/health-library/article?id=21861

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whereas only 14 women were assigned to the placebo group. Such unequal allocations, likewise, denigrate the internal validity of any such clinical trial, with equal 1:1 allocation recognized as the proverbial gold standard.²²

- 33. Additionally, the participants in the active supplement group were also 5 years younger as compared to those in the placebo group. Notably, although the age range for participants was 21 to 65 years, the authors of the clinical trial failed to disclose the precise ages of the participants allocated to each group. Given that age and concomitant hormone loss in women is a prominent factor in hair loss, as Nutrafol itself acknowledges, the allocation of older participants to the already small placebo group is designed to skew the results and it worked as designed.
- 34. Inexplicably, the participants "randomly" assigned to the placebo group had a consistent and significantly higher level of baseline stress than those in the group receiving the supplement (78.6% vs 42.3%). In other words, the placebo group participants suffered from stress at nearly double the rate, which is critical because Nutrafol Women itself highlights that stress has been shown to "make hair follicles shift from a growth state to a rest state ... [and] if not addressed, the follicle may receive a signal to prematurely stop growing":

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3873626/

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- 35. However, there are even more fundamental problems with the clinical study which render its dubious "scientific" conclusions particularly deceptive to its target consumers.
 - 36. On its website, Nutrafol unabashedly proclaims:

No matter your gender, age, genetics, or hair goals, there's a formula for you.

37. Further, in the "Common Questions" section of the website, Nutrafol answers the question "How do Nutrafol hair growth Nutraceuticals work?" as follows:

Cutting-edge hair science tells us that genetics isn't the only factor at play when it comes to thinning hair; there are multiple imbalances in the body that can lead to compromised hair health. That's why our clinically proven Hair Growth Nutraceuticals are formulated to target multiple root causes—including stress, hormones, aging, metabolism, nutrition, and lifestyle—all with medical-grade, natural ingredients that support whole-body health from within.²³

38. The notion that *Nutrafol Women* is effective without regard for its user's age or genetics, and targets hormonal imbalances and metabolic factors, or is certain to achieve every

https://nutrafol.com/results/(emphasis added)

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woman's "hair goals," is blatantly false and belied by the very parameters of Nutrafol's clinical trial.

- 39. Nutrafol's deceptive advertising conceals from consumers the broad exclusion criteria employed by the clinical trial which include (1) pregnancy and nursing; (2) use of hormones therapies or initiation of hormones as a method of birth control; (3) the prior use of minoxidil or light therapy for hair regrowth; (4) the use of any medications whose side effects include hair loss or have an effect on hair growth; and (5) women suffering from diabetes or thyroid disorders.
- 40. Moreover, according to Nutrafol's disclosures on clinicaltrials.gov,²⁴ female participants with well-known hair loss conditions like alopecia areata, scarring alopecia, androgenetic alopecia and telogen effluvium were excluded, as were women with any history of flaking or itching of the scalp, any known allergies or sensitivity to shampoo and/or conditioner, women with depression and, egregiously, any women that had experienced a "stressful incident" within six months prior to the clinical trial.
- 41. In addition to the above exclusion criteria, the clinical trial broadly excluded all women with "hair loss disorders and active dermatologic or other health conditions that, *in the opinion of the investigator*, might place the subject at risk or interfere with the study treatment and clinical evaluations." (Emphasis added). The Nutrafol to English translation is, "if you suffer from hair loss for any reason, we will exclude you from our study."
- 42. Nutrafol does not disclose what other considerations guided its investigator in excluding a broad range of women from participation in the clinical trial. Nevertheless, it is clear that in actively limiting its pool of participants to "healthy women" with "self-perceived thinning

https://clinicaltrials.gov/ct2/show/NCT03206567?term=Nutrafol&draw=2&rank=1

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hair," and excluding every woman with any objectively documented condition of the hair or skin that would imperil Nutrafol obtaining the exact answers it needed to obtain, Nutrafol's deceptive advertising promises far more than its supplement could ever hope to deliver.

- 43. Rather than being a hair loss panacea suitable for all women regardless of "age, genetics, or hair goals," as Nutrafol falsely claims, the clinical trial excluded from participation precisely that population of women that are most likely to purchase the product that is, women with "hair loss disorders and active dermatologic or other health conditions."
- 44. Diabetes and thyroid disorders, for example (both of which constituted exclusion criteria under the clinical trial) are, by definition, *hormone* imbalances.²⁵ ²⁶ Yet, Nutrafol's website actively identifies hormonal imbalances as one of the major root causes that *Nutrafol Women* is designed to "target" in order to improve hair health:

https://www.endocrine.org/patient-engagement/endocrine-library/diabetes-and-endocrine-function#:~:text=Diabetes%20occurs%20when%20the%20pancreas,or%20stored%20for%20the%20future.

https://www.mayoclinic.org/diseases-conditions/hypothyroidism/symptoms-causes/syc-20350284#:~:text=Hypothyroidism%20happens%20when%20the%20thyroid,symptoms%20in%20its%20early%20stages.

Targets 6 key root causes of compromised hair health.

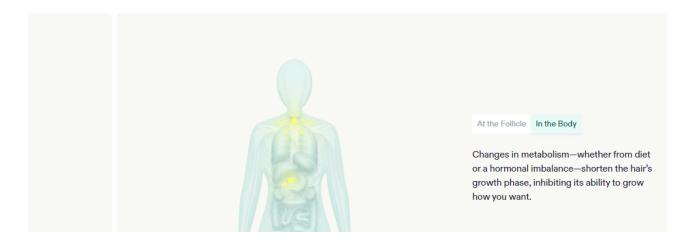
Our proprietary blend pinpoints the internal imbalances behind hair thinning and shedding to promote a healthy growth cycle—because hair and health grow together.



45. Worse still, when identifying the source of hormonal imbalances in the body that *Nutrafol Women* is intended to "target," Nutrafol deceptively uses an anatomical depiction of the female body with prominent highlighting of (a) the area around the *pancreas*, disorders of which lead to diabetes, (b) the area of the *thyroid*, disorders which lead to hyperthyroidism and hypothyroidism:

Targets 6 key root causes of compromised hair health.

Our proprietary blend pinpoints the internal imbalances behind hair thinning and shedding to promote a healthy growth cycle—because hair and health grow together.



- 46. It is estimated that as many as 1 in 8 women will develop thyroid problems during their lifetimes.²⁷ Further, 1 in 9 women are estimated²⁸ to have diabetes at present. Thus, millions of women who fell within the exclusion criteria of *Nutrafol Women*'s clinical trial are falsely led to believe, based on Nutrafol's deceptive advertising, that *Nutrafol Women* will not only help them regrow hair, but will regulate their hormonal imbalances in the process. Nutrafol literally and figuratively highlight the two organs responsible for female hormone imbalance, then implicitly disclaims any ability to help those subjects by exclusion from its study.
- 47. Women using hormone-based contraceptives (*i.e.*, the "Pill") were likewise excluded from the clinical trial, and yet statistics reveal that 21.6% of women between the ages of 20-29 use the Pill, and 10.9 percent of women between the ages of 30-39 use the Pill.²⁹ Thus,

^{27.} https://www.womenshealth.gov/a-z-topics/thyroid-

disease#:~:text=One%20in%20eight%20women%20will,helps%20control%20your%20menstrual%20cycle.

^{28. &}lt;u>https://www.womenshealth.gov/a-z-</u>

topics/diabetes#:~:text=About%2015%20million%20women%20in,in%20every%209%20adult%20women.

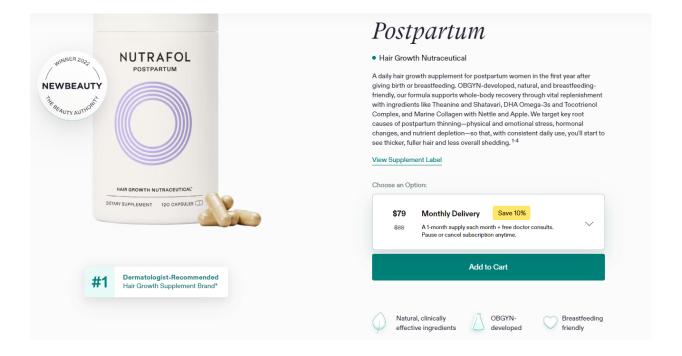
https://www.statista.com/statistics/1235827/share-women-contraceptive-method-by-age-us/

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among the target demographic of women between the ages of 18-44, usage of hormone based contraceptive measures is significant, amounting to millions of women. Yet, Nutrafol nowhere discloses in its marketing that the *Nutrafol Women*'s clinical study excluded this broad swath of women who suffer hair loss.

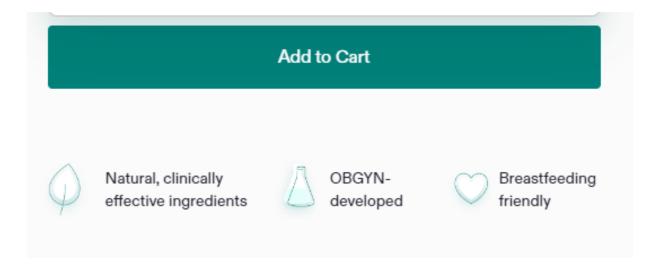
48. The clinical trial also categorically excluded women that are nursing, constituting approximately 83% of all mothers with newborns, 30 which is particularly insidious since Nutrafol uses the same manipulated data to advertise another spin-off supplement, touted as containing "clinically effective" ingredients and specifically formulated for breastfeeding mothers, under the name *Nutrafol Postpartum*:



^{30. &}lt;a href="https://www.cdc.gov/breastfeeding/data/reportcard.htm">https://www.cdc.gov/breastfeeding/data/reportcard.htm

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- 49. Indeed, *Nutrafol Postpartum* consists of largely the same ingredients as the original formula --- with a similar blend of amino acids L-Cysteine, L-Methionine, L-Lysine; iodine, zinc, and selenium; palm extract; biotin, hydrolyzed marine collagen; and vitamins A, B, D, and E.³¹ Though there are some differences in the postpartum blend, such as the addition of a host of B vitamins and shatavari root extract (otherwise known as asparagus root), which is believed to help nursing women lactate, ³² Nutrafol does not claim to have conducted any clinical trials on *Nutrafol Postpartum* with respect to hair growth. Nutrafol is simply repackaging the same basic (and, ineffectual) building blocks of its original formula and superficially "spicing" them up with an assemblage of holistic herbal cocktails that have no known link to or benefit on hair growth.
- 50. Nutrafol's sleight of hand in manipulating its clinical trial data by cherry picking participants is well documented.³³ Given that the exclusion criteria widely screened out women with a broad array of conditions that is, everything from allergies to alopecia to taking the Pill one hair loss expert exposed *Nutrafol Women's* clinical trial as not "designed to truly evaluate

^{31.} https://nutrafol.com/nutrafol-postpartum-for-women/

https://www.webmd.com/vitamins-and-supplements/are-there-health-benefits-of-shatavari-powder

^{33.} https://perfecthairhealth.com/nutrafol-review/

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the effectiveness of the supplement on a group of hair loss sufferers representative of their target consumer; it was just designed to reap positive results to showcase to all consumers."³⁴

- 51. Conditions such as alopecia areata, scarring alopecia, androgenetic alopecia and telogen effluvium constitute approximately 95% of all hair loss cases among women in the developed world.³⁵ Yet, Nutrafol was so convinced that it would be inappropriate for these populations to use their products, that they didn't even permit them to be a part of the study. Disturbingly, however, Nutrafol does not exclude such women from its marketing and packaging because they are obviously the most eager consumers of Nutrafol's false claims. Accordingly, these populations purchased Nutrafol, at a premium, completely unaware that no study regarding its efficacy for them had ever been conducted. Thus, beyond the fact that Nutrafol's study is scientifically meaningless, the ultimate deceit is that no study was ever conducted of Nutrafol's effectiveness for the women who are most likely to lose hair.
- 52. Tallying the statistics, women with any of the following conditions or characteristics that is, nursing mothers (approximately 83.2% of new mothers), women with diabetes (approximately 12% of women), women with androgenetic hair loss disorders (approximately 50% of women), women with depression (approximately 10 15% of women), women using hormone based contraception (approximately 12% of women), women with iron deficiencies (approximately 12% of women).

³⁴. *Id*.

³⁵. *Id*.

https://www.cdc.gov/media/releases/2018/p0820-breastfeeding-report-card.html

³⁷. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

^{38.}https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706984/#:~:text=The%20genetically%20determined%20progressive%20process,males%20and%2050%25%20of%20women.

https://clinicaltrials.gov/ct2/show/NCT03206567?term=Nutrafol&draw=2&rank=1

^{40.} https://www.cnn.com/2018/12/19/health/contraceptive-use-cdc-study/index.html

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17% of women)⁴¹ – collectively account for the near entirety of the American female population and certainly comprise most, if not all, the women who would actively seek to purchase a product such as *Nutrafol Women*. And yet, these women are precisely those whose genetic and physiological profiles were excluded from Nutrafol's study and, as such, comprise the class of deceived consumers.

- 53. As such, Nutrafol's advertising is a dual pronged deception. In the first instance, female consumers with any of the myriad conditions that constituted exclusion criteria in Nutrafol's study are deceived into purchasing a product that, while directly targeting them as consumers, deliberately conceals from them the fact that the study was designed to demonstrate efficaciousness *only by virtue of their exclusion*. In other words, Nutrafol knows that its product does nothing for the overwhelming supermajority of women, which is precisely why Nutrafol did not even bother testing them in the first place.
- 54. Secondly, Nutrafol's study is so flawed in its basic construction and design that, even if a subset of perfectly healthy women with no hair problems existed among the general population in any significant measure, these women would likewise be deceived as consumers since the study failed, at a fundamental level, to establish *any* causal relationship between consumption of the supplement and hair regrowth. Put another way, the study proved nothing --- and, certainly, nothing even remotely approaching the "clinical" significance Nutrafol falsely advertises to the public.
- 55. It is unsurprising, therefore, to find a plethora of women complaining about seeing absolutely no results after using the supplement since, given the incredibly restrictive criteria for

^{41. &}lt;a href="https://www.cuimc.columbia.edu/news/are-we-underestimating-prevalence-iron-deficiency#:~:text=About%2017%25%20of%20premenopausal%20women,deficient%20under%20the%20current%20thresholds.">https://www.cuimc.columbia.edu/news/are-we-underestimating-prevalence-iron-deficiency#:~:text=About%2017%25%20of%20premenopausal%20women,deficient%20under%20the%20current%20thresholds.

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participation in the clinical trial, Nutrafol's overblown and deceptive advertising simply cannot comport with the reality of what everyday women, as opposed to Nutrafol's paid influencers and carefully selected participants, truly experience:



Penny Clark

★☆☆☆☆ It hasn't worked for me

Reviewed in the United States on November 22, 2022

Verified Purchase

This is a very expensive "vitamin" -\$95.00/month thru Amazon. The directions call for taking 4 tablets at a time. They aren't as big as some I've taken, but larger than I'd like. The worst part is I haven't seen any improvement in 2 months. I do still have some left from my last order, but am not likely to order any more unless I see some miraculous effects before I use them up.



Tammy H

★☆☆☆☆ Waste of money!

Reviewed in the United States on December 17, 2022

Verified Purchase

I've been very skeptical about this product but since the dermatologist recommended thought I'd give it a try. After 6-7 bottles there was ZERO improvement on hair growth, what a waste of money!

The glass bottle arrived broken too and you can't return or exchange.



IVIN

★☆☆☆☆ Disappointed DID NOT WORK

Reviewed in the United States on December 11, 2022

Verified Purchase

Have been taking Nutrafol for one year and there's no hair regrowth. Expensive Product with No Results was Very Disappointed. (I Started losing hair from restrictive diet with micronutrient deficiency and was recommended by friend to try this product)



K.A.

★☆☆☆☆ Not impressed

Reviewed in the United States on August 15, 2022

Verified Purchase

I have thin hair and as I am getting older it has been a challenge finding the right balance in hair products for moisture to prevent shedding and hair loss during washing. Anyway we women of a certain age have these challenges, so I thought I'd try Nutrafol. I gave it the full 6 months plus for actual results as per the instructions. My hair is still thin in specific areas around my temple and the top . I don't see where it's worth spending \$88 on a product that doesn't so what it claims. So my suggestion is to not waste your money. Invest in something that really works.

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Stacy F. Allen

★☆☆☆☆ Didn't Work For Me

Reviewed in the United States on December 4, 2022

Verified Purchase

I'm on my third or fourth month I can't even remember and my hair still falls out in the shower drain as bad if not worse than before. And it's so expensive. Don't waste your money.



Christine Walker

★☆☆☆☆ It doesn't work. Save your money.

Reviewed in the United States on October 27, 2022

Verified Purchase

It does absolutely nothing. I took them everyday like clockwork and saw no results after four months and it will keep increasing on price. Put your money somewhere else.



Lisa

★☆☆☆☆ More hair fell out

Reviewed in the United States on July 11, 2022

Verified Purchase

My hair has been always very thin but after giving birth to my children and being over 40 my hair is thinner than ever. Nutrafol made my hair fall out even more, I didn't see any improvement. I took it for a month and was too scared to continue. Pure Rosemary oil works much better along with scalp massage. I already see less hair falling after stopping Nutrafol and applying Rosemary oil.



Cathy A

★☆☆☆☆ 90 days and no results

Reviewed in the United States on July 14, 2022

Verified Purchase

I had heard this was a good product - but alas, not helped me at all. No change in my hair in any form or fashion. That will teach me to throw \$240+ away on others' recommendations. Perhaps they should print out who exactly it won't work for. I would love to get some of my \$\$ back.

56. Notably, as the above Amazon review from "Cathy A" points out, consumers unfortunately learn the hard way, after wasting hundreds of dollars, that *Nutrafol Women* works, if it "works" at all, only for an extreme minority of women that happen, by chance, to match the exact attributes of the cherry-picked participants in Nutrafol's rigged clinical trial. In other

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words, the study was specifically engineered to obtain a result that fit in with Nutrafol's confirmation bias.

- 57. The notion that *Nutrafol Women* is a universal supplement that confers benefits upon women regardless of their age or genetics, or that it will address key underlying problems, such as hormone imbalances and metabolic conditions as a precursor to healthier hair, is plainly false.
- 58. In short, Nutrafol broadly and deliberately markets its supplement to millions of women with underlying health issues and conditions that are known to affect hair growth while, at the same time, pointing to a grossly unrepresentative clinical trial whose participants were healthy women that, at best, may have subjectively perceived their hair to be thinning.

IV. Plaintiff Purchased Nutrafol Women

- 59. Plaintiff first purchased *Nutrafol Women* on or about November 7, 2021, on Amazon.com and again over the course of the next several months, with the latest purchase being made on March 23, 2022. Plaintiff consumed the supplement as directed over the course of several months, with no apparent benefit.
- 60. Prior to purchasing *Nutrafol Women*, Plaintiff was exposed to Nutrafol's marketing online and on social media, which touted it as being "clinically proven" and containing "medical-grade" ingredients.
- 61. Plaintiff purchased *Nutrafol Women* believing that, as a clinically proven product, it would help her regrow and improve the thickness and quality of her hair. However, Plaintiff soon discovered that *Nutrafol Women* had no effect.
- 62. Had Plaintiff known that *Nutrafol Women* was not clinically proven to regrow and improve the thickness and quality of hair, she would not have purchased it or, at the very least,

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would not have paid the premium charged. For example, a six month supply of *Nutrafol Women* costs \$528 on Amazon (six 120 capsule bottles, four capsules per day), while the clinically proven oral Minoxidil 2.5 mg costs merely \$13 to \$36 for the same period.⁴²

CLASS DEFINITION AND ALLEGATIONS

63. Plaintiff brings this action on behalf of herself and all other similarly situated consumers in the State of New York pursuant to CPLR § 901, and seeks certification of the following class (the "Class"):

All consumers who, within the applicable statute of limitations period, purchased in the State of New York (whether online or inperson) Nutrafol supplements — manufactured, marketed, distributed, and/or sold by Defendant which Defendant warranted as being "Clinically Proven" and "Medical Grade" (the "Class Product"). Excluded from the class are Defendant, its parents, subsidiaries, affiliates, officers and directors, judicial officers and their immediate family members and associated court staff assigned to this case, and those who purchased the Class Product for resale.

- 64. Plaintiff expressly disclaims any intent to seek any recovery in this action for personal injuries that she or any Class member may have suffered.
- 65. <u>Numerosity</u>. This action is appropriately suited for a class action. The members of the Class are so numerous that joinder of all members of the Class is impracticable. Plaintiff is informed, believes, and thereon alleges, that the proposed Class contains thousands of purchasers of the Class Product who have been damaged by Defendant's conduct as alleged herein. The precise number of Class members is unknown to Plaintiff.

⁴² https://www.goodrx.com/minoxidil?form=tablet&dosage=2.5mg&quantity=180&label_override=minoxidil

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- 66. Existence and Predominance of Common Questions of Law and Fact. This action involves questions of law and fact common to the Class. The common legal and factual questions include, but are not limited to, the following:
 - Whether Defendant's conduct, as alleged herein, constitutes violations of New York General Business Law Section 349.
 - Whether Defendant's conduct, as alleged herein, constitutes violations of New York General Business Law Section 350.
 - Whether Defendant labeled, advertised, marketed, and/or sold the Class Product as "Clinically Proven" and "Medical Grade."
 - Whether Defendant's labeling, advertising, marketing, and/or selling of the Class Product as "Clinically Proven" and "Medical Grade" was and/or is false, fraudulent, deceptive, and/or misleading.
- 67. <u>Typicality</u>. Plaintiff's claims are typical of the claims of the members of the Class, because, *inter alia*, all Class members have been injured through the uniform misconduct described above and were subject to Defendant's blatant misrepresentation that the Class Product was "Clinically Proven" and "Medical Grade."
- 68. Moreover, Plaintiff's claims are typical of the Class members' claims. Plaintiff is advancing the same claims and legal theories on behalf of herself and all members of the Class.
- 69. Adequacy of Representation. Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff purchased the Class Product, and she was harmed by Defendant's deceptive misrepresentations. Plaintiff has therefore suffered an injury in fact as a result of Defendant's conduct, as did all Class members who purchased the Class Product. Plaintiff has retained counsel who are adept, sophisticated, and experienced in the field of class action litigation, and have adequate resources to fully and zealously advocate on behalf of the class.

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- A class action is superior to other methods for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendant. It would be virtually impossible for a member of the Class, on an individual basis, to obtain effective redress for the wrongs done to him or her. Further, even if the Class members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no management difficulties under the circumstances here.
- 71. Plaintiff seeks monetary damages, including statutory damages on behalf of the entire Class, and other equitable relief on grounds generally applicable to the entire Class. Unless a Class is certified, Defendant will be allowed to profit from its deceptive practices, while Plaintiff and the members of the Class will have suffered damages.

COUNT I (Violation of New York General Business Law Section 349)

- 72. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1 through 68 as if fully set forth herein.
- 73. New York General Business Law § 349 prohibits "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in [New York]."
- 74. By labeling, advertising, marketing, distributing, and/or selling the Class Product to Plaintiff and the other Class members as "Clinically Proven" and "Medical Grade," Defendant

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engaged in, and continues to engage in, deceptive acts and practices because the Class Product has not been proven to be effective.

- 75. In taking these actions, Defendant failed to disclose material information about its product, which omissions were misleading in a material respect to consumers and resulted in the purchase of the Class Product.
- 76. Defendant has deceptively labeled, advertised, marketed, promoted, distributed, and sold the Class Product to consumers.
 - 77. Defendant's conduct was consumer oriented.
- 78. Defendant engaged in the deceptive acts and/or practices while conducting business, trade, and/or commerce and/or furnishing a service in New York.
- 79. Defendant's false "Clinically Proven" and "Medical Grade" claim was and is misleading in a material respect as to whether the Class Product was, in fact, clinically tested and proven effective with respect to the consumers Nutrafol targeted.
- 80. Based on, among other things, Defendant's knowledge that the Class Product was not proven in a clinical setting, Defendant knew that by making the misrepresentations addressed herein, Plaintiff and other consumers would be misled into purchasing the Class Product and/or paying a premium price for the Class Product.
- 81. Plaintiff and the Class members have been aggrieved by and have suffered losses as a result of Defendant's violations of Section 349 of the New York General Business Law. By virtue of the foregoing unfair, unconscionable, and deceptive acts in the conduct of trade or commerce, Plaintiff and the members of the Class have been substantially injured by purchasing and/or overpaying for the Class Product which is not what Defendant represents it to be.

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- 82. By reason of the foregoing, Defendant's conduct, as alleged herein, constitutes deceptive acts and practices in violation of Section 349 of the New York General Business Law, and Defendant is liable to Plaintiff and the Class for the actual damages that they have suffered as a result of Defendant's actions, the amount of such damages to be determined at trial, plus statutory damages, treble damages, and attorneys' fees and costs.
- 83. Defendant's conduct, as alleged herein, in violation of Section 349 of the New York General Business Law was engaged in by Defendant willfully and/or knowingly. Accordingly, Plaintiff and members of the Class are entitled to an award of damages above and beyond their actual damages in accordance with Section 349(h) of the New York General Business Law.

COUNT II (Violation of New York General Business Law Section 350)

- 84. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1 through 80 as if fully set forth herein.
- 85. Defendant's labeling, marketing, and advertising of the Class Product is "misleading in a material respect," as it fails to disclose to consumers material information in Defendant's sole possession and, thus, is "false advertising."
- 86. No rational individual would purchase the Class Product at the premium price at which it is sold if that individual knew that the Class Product was not "Clinically Proven" or "Medical Grade," which is how Defendant markets the Class Product.
- 87. Defendant's advertisements and marketing of the Class Product as "Clinically Proven" and "Medical Grade" were consumer oriented.
- 88. Defendant's advertisements and marketing of the Class Product as "Clinically Proven" and "Medical Grade" were misleading in a material respect.

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89. By virtue of the foregoing unfair, unconscionable, and deceptive acts in the conduct of trade or commerce in New York, Plaintiff and the members of the Class have been substantially injured by overpaying for a product that has diminished value due on account of the false claim that it has been tested clinically and proven effective.

90. Defendant's conduct, as alleged herein, constitutes false advertising in violation of Section 350 of the New York General Business Law, and Defendant is liable to Plaintiff and the members of the Class for the actual damages that they have suffered as a result of Defendant's actions, the amount of such damages to be determined at trial, statutory damages, plus treble damages, and attorneys' fees and costs.

91. Defendant continues to violate Section 350 of the New York General Business Law and continues to aggrieve Plaintiff and the members of the Class.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter judgment against Defendant as follows:

- A. Certifying this action as a class action as soon as practicable, with the Class as defined above, designating Plaintiff as the named Class representative, and designating the undersigned as Class Counsel.
- B. On Plaintiff's Count I, awarding against Defendant the damages that Plaintiff and the other members of the Class have suffered as a result of Defendant's actions, the amount of such damages to be determined at trial, plus statutory damages and treble damages.
- C. On Plaintiff's Count II, awarding against Defendant the damages that Plaintiff and the other members of the Class have suffered as a result of Defendant's actions, the amount of such damages to be determined at trial, plus statutory and treble damages.

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- D. On Plaintiff's Count I and II, awarding Plaintiff and the Class interest, costs, and attorneys' fees.
- E. Awarding Plaintiff and the Class such other and further relief as this Court deems just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: February 9, 2023

White Plains, New York

DENLEA & CARTON LLP

By:

James R. Denlea Jeffrey I. Carton Stan Sharovskiy

2 Westchester Park Drive, Suite 410 White Plains, New York 10604

Tel.: (914) 331-0100
Fax: (914) 331-0105
jdenlea@denleacarton.com
jcarton@denleacarton.com
ssharovskiy@denleacarton.com

KRAVIT SMITH LLP

Philip M. Smith 75 South Broadway, Suite 400 White Plains, New York 10601

Tel.: (646) 433-8004 Fax: (917) 858-7101

psmith@kravitsmithllp.com

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: <u>Nutrafol Women Falsely Advertised as 'Clinically Proven' to Treat Hair Loss, Class Action Alleges</u>