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SUPERIOR COURT FOR THE STATE OF CALIFORNIA

FOR THE COUNTY OF SANTA CRUZ

JASON FERGUSON, on behalf of himself and all others similarly situated,

Plaintiff,

v.

WALGREEN CO.,

Defendant.

Case No.: 26CV01339
Pleading Type: Class Action

CLASS ACTION COMPLAINT FOR VIOLATIONS OF:

THE UNFAIR COMPETITION LAW, THE FALSE ADVERTISING LAW, AND THE CONSUMER LEGAL REMEDIES ACT

No Jury Demand

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Plaintiff Jason Ferguson, on behalf of himself, all others similarly situated, and the general public, by and through his undersigned counsel, hereby sues Defendant Walgreen Co. ("Walgreens" or "Defendant") and alleges as follows:

I. JURISDICTION AND VENUE

1. Jurisdiction is proper because Plaintiff is a citizen of California, alleges only California-law claims which relate to a product that is sold in California, was purchased by Plaintiff in California, and is on behalf of a class limited to citizens of California.

2. Venue is proper because Plaintiff resides in and suffered injury in this County, and Defendant conducts continuous business in this County that includes the sale of the product at issue.

II. NATURE OF THE ACTION

3. During the class period, Walgreens marketed, distributed, and sold Walgreens Men's Testosterone Complex ("Testosterone Complex"). Defendant claims that Testosterone Complex "boost[s] free testosterone levels," "promotes an increase in free testosterone levels," increases "lean muscle mass, strength, & endurance," and improves "sexual function in men." Walgreens further claims that the product "has been clinically studied" and is "Walgreens pharmacist recommended."

4. These claims were fraudulent, as none of the ingredients in Testosterone Complex,

individually or in combination, safely and effectively increase testosterone or strength or improve sexual performance. These representations mislead consumers into believing that Testosterone Complex is legal, safe, and effective for its intended purposes.

5. In truth, Testosterone Complex is ineffective.

6. Further, Walgreens markets and sells Testosterone Complex with claims suggesting it has medical benefits akin to prescription drugs, hormone therapies, and aphrodisiac drugs.

7. These claims, even if they were true—they are not—are prohibited by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. ("FDCA"), and subject those manufacturing or selling Testosterone Complex to unapproved new drug liabilities and penalties.

8. Plaintiff Jason Ferguson purchased Testosterone Complex (1) in reliance on Defendant's deceptive efficacy claims (2) with the belief that the product was safe, (3) was effective, and (4) was sold in compliance with California and federal law.

9. Mr. Ferguson used Testosterone Complex as directed, but the product failed to deliver the benefits promised by Walgreens.

III. PARTIES

10. Defendant Walgreen Co. is an Illinois corporation with its principal place of business in Deerfield, Illinois.

11. Plaintiff Jason Ferguson is a citizen and resident of California who purchased Testosterone Complex during the class period for personal consumption.

IV. BACKGROUND ON UNAPPROVED "TESTERONE BOOSTING" DRUGS

12. The

> Dietary Supplement Health and Education Act (DSHEA) of 1994, which amended the Federal Food, Drug, and Cosmetic Act, transformed FDA's authority to regulate dietary supplements. Under DSHEA, **FDA is not authorized to approve dietary supplements for safety and effectiveness before they are marketed**. In fact, in many cases, firms can lawfully introduce dietary supplements to the market without even notifying FDA. Since DSHEA was enacted, the dietary supplement market has grown significantly. For example, the number of products

has expanded nearly twenty times since 1994.[1]

13. A January 2020 evaluation of "Testosterone Boosting" supplements, published by the National Library of Medicine found that

> [a]pproximately 50% of American adults consume dietary supplements to promote overall health and fill dietary gaps [4,5]. These over the counter "T boosters" are often taken with the hopes of raising endogenous [testosterone] production and doing this in a more "natural" manner.[2]

14. The evaluation further found that "[n]inety percent of 'T booster' supplements claimed to boost [testosterone]," and of these products, just "24.8% of these had data to support these claims." *Id.*

15. Further the same study found 10.1% of supplements "contained components with data suggesting a negative effect" on testosterone and insisted that "[p]atients should be informed that 'T booster' supplements may not have ingredients to support their claims." *Id.*

16. In February 2019, the Journal of Sexual Medicine published a study titled *Testosterone Imposters: An Analysis of Popular Online Testosterone Boosting Supplements*.[3]

17. The "investigation revealed that limited human studies have evaluated T-Boosters, resulting in no definitive findings of efficacy," and additionally warned that "[i]n the absence of additional human studies, patients should be cautioned before considering T-Boosters, given the availability of highly effective therapies approved by the Food and Drug Administration." *Id*.

18. Moreover, consumption of purported "testosterone boosters" imposes health risks. First, the product may directly harm the consumer. Second, consumers who purchase an ineffective product like those sold by Walgreens forgo actual treatment, wasting money and delaying effective treatment.

19. A 2017 case report examining a patient who had consumed one such purported "natural" testosterone booster found "[t]he risk of venous thromboembolic events is" "unclear with non-FDA-

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[1] U.S. Food & Drug Admin., Information for Consumers on Using Dietary Supplements (October 21, 2022), available at www.fda.gov/food/dietary-supplements/information-consumers-using-dietary-supplements.

[2] Glemesha, Chase (2020) '*Testosterone Boosting' Supplements Composition and Claims Are Not Supported by the Academic Literature*; WORLD J. MEN'S HEALTH 2020 Jan 38(1): 115-122.

Available at www.ncbi.nlm.nih.gov/pmc/articles/PMC6920068/.

[3] Balasubramanian, et al. *Testosterone Imposters: An Analysis of Popular Online Testosterone Boosting Supplements*, 16 J. SEXUAL MEDICINE 203-12 (Feb. 2019).

Available at www.sciencedirect.com/science/article/pii/S1743609518313821.

approved herbal supplements marketed as testosterone enhancers."[4]

20. The study noted that:

> Decreased testosterone levels in men are often a normal sign of aging. Testosterone replacement therapy (TRT) is a well-established option for those with symptomatic hypogonadism related to low testosterone levels. Conversely, designer herbal supplements in the context of testosterone supplementation are poorly studied, yet remain popular among aging men who seek the well-known, often enhancing, effects of testosterone that involve muscle mass and sexual function/drive.

21. The study further noted that

> [i]n 2014, the Food and Drug Administration (FDA) issued a warning about the significant risk of venous clots secondary to testosterone product use. Testosterone-induced polycythemia is one of the proposed mechanisms for this increased clotting propensity. Increased thromboxane A2 receptor density on platelets and increased platelet aggregation have also been linked to testosterone treatment in men.

22. Thus, there is "is an inherent risk for vascular events, such as pulmonary embolus, in testosterone supplement use." *Id.*

V. REGULATORY BACKGROUND

23. "The term 'drug' means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1).

24. A "new drug" is any drug "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof . . . ." 21 U.S.C. § 321(p)(1).

25. Pursuant to 21 U.S.C § 355(a), "No person shall introduce or deliver for introduction into interstate commerce any new drug . . ." without approval by the FDA.

26. Further, 21 U.S.C. § 331(a) prohibits the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded."

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[4] Nguyen S M, Ko Ko N, Sattar A S, et al. (August 06, 2017) *Pulmonary Embolism Secondary to Testosterone-Enhancing Herbal Supplement Use*. CUREUS 9(8): e1545. DOI 10.7759/cureus.1545.

27. Under 21 U.S.C. § 352(f), drugs are required to have adequate instructions for safe use.

28. Pursuant to 21 C.F.R. § 310.528,

> Any product that bears labeling claims that it will arouse or increase sexual desire, or that it will improve sexual performance, is an aphrodisiac drug product . . . Any OTC drug product that is labeled, represented, or prompted for use as an aphrodisiac is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act

VI. THE SALE OF UNAPPROVED DRUGS HARMS THE PUBLIC.

29. "Unapproved prescription drugs pose significant risks to patients because they have not been reviewed by FDA for safety, effectiveness or quality."[5]

30. "Without FDA review, there is no way to know if these drugs are safe and effective for their intended use, whether they are manufactured in a way that ensures consistent drug quality or whether their label is complete and accurate." *Id.*

31. "Unapproved drugs have resulted in patient harm, and the [FDA] works to protect patients from the risks posed by these drugs." *Id.*

32. Unapproved drugs lack "labels and prescribing information that has" "been reviewed by FDA for accuracy and completeness."[6]

33. Consumers using unapproved drugs run the risk of "unexpected and undocumented safety concerns due to lack of rigorous pre- and postmarket safety surveillance." *Id.*

34. Additionally, unapproved drugs lead consumers in need of medical treatment to forego medically proven therapies.

VII. "TESTOFEN" DOES NOT EFFECTIVELY INCREASE TESTOSTERONE.

35. On its website, Defendant claims that "Walgreens Men's Testosterone Complex is powered by Testofen, a unique standardized fenugreek extract that is recognized for hormone support."

[5] U.S. Food & Drug Admin., Unapproved Drugs (June 2, 2021), available at www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs.

[6] U.S. Food & Drug Admin., Unapproved Drugs and Patient Harm (June 2, 2021), www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs-and-patient-harm.

36. However, Testofen, the purported active ingredient in the product, does not increase testosterone.

37. A human clinical trial conducted in Australia comparing Testofen to placebo found that Testofen "did not affect testosterone" levels.[7]

38. Another study concluded that fenugreek extract has no effect on free testosterone levels:

> Despite no substantiated claims in human research models, fenugreek has been marketed in dietary products as having anabolic potential for resistance trained athletes. . . . The purpose of this study was to investigate the potential anabolic effects of fenugreek extract supplementation in conjunction with a controlled resistance training program. . . . No significant effects for groups or interactions were observed for the anabolic hormone[] free testosterone . . . ($p<0.05$). . . . [S]upplementation of fenugreek extract does not appear to affect hormonal status in resistance trained males and shows no anabolic potential as has been purported.[8]

39. An additional study examining the effects of fenugreek extract versus placebo on testosterone levels concluded that "No significant changes were detected among groups for . . . free testosterone."[9]

40. Another study found a significant difference in free testosterone levels between the group taking fenugreek extract and the placebo group, but the difference was *in favor of the placebo group,* whose free testosterone levels rose by an average of 10 ng/ml over the course of the study, compared to the fenugreek group, whose free testosterone levels declined by an average of 4 ng/ml.[10] The study concluded:

> Fenugreek supplementation is surrounded by assertions of having anabolic potential, even though there is no scientific data supporting this notion. In the present study we examined serum hormone variables that included free testosterone . . . . Although a between group

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[7] E. Steels, et al., *Physiological Aspects of Male Libido Enhanced by Standardized Trigonella foenum-graecum Extract and Mineral Formulation*, PHYTOTHERAPY RES. 25: 1294-1300 (2011).

[8] B. Bushey, et al., *Fenugreek Extract Supplementation Has No Effect on the Hormonal Profile of Resistance-Trained Males*, INT. J. EXERC. SCI. 2(1): S13, 2009

[9] C. Poole, et al., *Effects of TESTOSURGE supplementation on strength, body composition and hormonal profiles during an 8-week resistance training program*, J. INT. SOC. SPORTS NUTRITION 2009, 6(Suppl. I): P12

[10] C. Poole, et al., *The effects of a commercially available botanical supplement on strength, body composition, power output, and hormonal profiles in resistance-trained males*, J. INT. SOC. SPORTS NUTRITION 2010, 7:34

> difference was noted for free testosterone at T2 and T3, it has limited relevance due to the fact that it did not significantly change over time. . . . [D]aily consumption of the 500 mg commercially available [fenugreek] supplement in conjunction with a resistance training program has no anabolic effect on the hormonal status of resistance trained males.

Id.

41. Another review noted that

> In terms of fenugreek as a TRT supplement, in one clinical study, fenugreek (standardized to 70 % trigimannose) actually significantly reduced levels of free testosterone [218]. Men had a 40 ng/ml free testosterone at baseline, reduced to 33 ng/ml at 4 weeks, and then to 36 ng/ml at 8 weeks (p ¼ 0.02) when taking 500 mg per day. DHT levels were reduced in the fenugreek group. Other studies demonstrate that fenugreek either causes no change or slightly increases testosterone in men have been for those with an already normal testosterone at baseline.[11]

VIII. TESTOSTERONE COMPLEX'S SPECIFIC MISREPRESENTATIONS, MATERIAL OMISSIONS, AND DRUG CLAIMS.

A. Testosterone Complex's Packaging

42. During the class period, Defendant Walgreens marketed Testosterone Complex with fraudulent claims that suggest that the product affects the human body by increasing testosterone levels, strength, and sexual performance, and cure, mitigate, or treat disease, such as low testosterone, hormonal imbalance, and sexual dysfunction.

43. These claims also render Testosterone Complex a "drug" within the meaning of 21 U.S.C. § 321(g) and an aphrodisiac drug within the meaning of 21 C.F.R. § 310.528.

44. However, Walgreens failed to obtain FDA approval to market and distribute these drugs in violation 21 U.S.C. § 355 and Health & Safety Code § 111550.

45. These claims are misleading, as the ingredients in Testosterone Complex do not increase testosterone levels, strength, or sexual performance.

46. The packaging and label of Walgreens Men's Testosterone Complex packaging is pictured on the following pages.

[11] J. Mulhall, *Men's Sexual Health and Fertility: A Clinician's Guide*, SPRINGER (2014), available at tinyurl.com/mrn83djw.


Walgreens
Men's
Testosterone
Complex
DIETARY SUPPLEMENT
PROMOTES AN INCREASE IN FREE TESTOSTERONE*‡
Supports:
• A healthy libido*‡
• Lean muscle mass, strength & endurance††*
with clinically studied
Testofen
60 TABLETS
(30-day supply)
*THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.
Walgreens
Men's
Testosterone
Complex
DIETARY SUPPLEMENT
PROMOTES AN INCREASE IN FREE TESTOSTERONE*‡
Supports:
• A healthy libido*‡
• Lean muscle mass, strength & endurance††*
60 TABLETS
(30-day supply)
with clinically studied
Testofen

47. During the Class Period, the label claimed the product "boost[s] free testosterone levels," "promotes an increase in free testosterone," increases "lean muscle mass, strength, & endurance," and improves "sexual function in men." Walgreens further claims it "has been clinically studied" and is "Walgreens pharmacist recommended."

48. These claims are fraudulent.

49. These efficacy claims, in addition to being misleading, render original Testosterone Complex a "drug" as defined by 21 U.S.C. § 321(g) and an "aphrodisiac drug" as defined by 21 C.F.R. §

310.528.

B. Walgreens.com Product Page for Testosterone Complex

50. Walgreens advertises Testosterone Complex with further deceptive efficacy claims online that suggest the product can provide prescription steroid and aphrodisiac drug benefits.

51. The Testosterone Complex label and Defendant's website, walgreens.com, contained the following claims, which show that the product is intended to affect the structure and function of the body, and to cure, mitigate, treat, or prevent disease, during the Class Period:

- "Testosterone Complex"
- "Increase in Free Testosterone"
- "healthy libido"
- "lean muscle mass, strength, & endurance"
- "As men age, they are able to use less and less of the testosterone that their bodies produce. This can be felt by the aging male in areas such as strength, libido, muscle endurance—and a general 'less than prime' feeling."
- "Testofen has been clinically studied for its ability to:
    - Support the development of lean muscle mass
    - Support muscle strength & endurance
    - Boost free testosterone levels
    - Support sexual function in men"
- "Walgreens pharmacist recommended"

52. These claims suggest Testosterone Complex can treat low testosterone, hormonal imbalance, and sexual dysfunction, and affect the structure and function of the human body by increasing testosterone, muscle mass, and libido. However, Testosterone Complex fails to deliver the advertised benefits.

53. Further, these claims render Testosterone Complex a "drug" within the meaning of 21 U.S.C. § 321(g)(1) and an aphrodisiac drug within the meaning of 21 C.F.R. § 310.528.

54. True and correct copies of screenshots of the Testosterone Complex page from Defendant's website, walgreens.com, are attached hereto as **Exhibit 1.**

55. Walgreens failed to obtain FDA approval prior to marketing, distributing, and selling Testosterone Complex.

IX. TESTOSTERONE COMPLEX IS AN UNAPPROVED NEW DRUG.

56. "The term 'drug' means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1).

57. Here, Testosterone Complex is a "drug" because it is advertised as a product which will affect the structure or function of the body and cure, mitigate, treat, or prevent disease.

58. The claims on the packaging of Testosterone Complex and Walgreens.com product page for Testosterone Complex render the product an unapproved new drug.

59. The FDA has determined that the following claims, which are similar to those Defendant made regarding Testosterone Complex constitute "drug claims":

- "Natural testosterone booster" (**Exhibit 2**, FDA Warning Letter to Unlimited Nutrition);
- "[I]ncrease estrogen and testosterone levels" (**Exhibit 3**, FDA Warning Letter to Star Health & Beauty, LLC);
- "Increase Lean Muscle Mass" (**Exhibit 3**);
- "Highly anabolic" (**Exhibit 4**, FDA Warning Letter to AndroPharm, LLC);
- "Increase Muscle Mass" (**Exhibit 4**);
- "Activate Numerous Anabolic Pathways" (**Exhibit 4**);
- "Explosive Muscle & Strength Gains" (**Exhibit 4**);
- "100% Natural Male Performance Booster" (**Exhibit 5**, FDA Warning letter to Distributor RFR, LLC);
- "In just 30 minutes or less after consumption you will feel its effect, more energy, more sexual desire and more power." (**Exhibit 5**);
- "a male enhancement supplement that improves sexual performance" (**Exhibit 6**, FDA Warning letter to Umbrella);
- "no prescription needed male enhancement supplement that improves sexual performance as well as proven natural solution for erectile dysfunction" (**Exhibit 6**).

60. A "new drug" is any drug "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof . . . ." 21 U.S.C. § 321(p)(1). Here, Testosterone Complex is a "new drug" within the meaning of the FDCA because it is not generally recognized as safe and effective for the intended uses. See Title 21 of the Code of Federal

Regulations, Chapter I, Subchapter D; 21 C.F.R. § 330.1.

61. Defendant has not received approval from the FDA to sell Testosterone Complex.

62. The sale of unapproved new drugs is illegal and dangerous. First, consumers risk purchasing and using a product that will endanger their health. Second, consumers risk purchasing a product that will not effectively treat their condition, forgoing actual treatment of that condition in lieu of an unapproved new drug which may not treat their condition. The FDA's regulatory regimen helps ensure that such products are kept away from consumers.

63. Defendant's failure to comply with these regulations puts consumers at risk and gives Walgreens an unfair advantage over competitors that do commit the time and expense of complying with such necessary regulations.

64. Testosterone Complex does not qualify for the reduced level of regulation applicable to certain nutrition supplement products for several reasons. The Testosterone Complex label, Walgreens's website, and Walgreens's marketing materials neither describe the role of any nutrient or dietary ingredient intended to affect the structure or function in humans, characterize the documented mechanism by which any nutrient or dietary ingredient acts to maintain such structure or function, nor describe general well-being from consumption of any nutrient or dietary ingredient. 21 U.S.C. § 343(r)(6)(A).

65. California similarly prohibits the sale of unapproved new drugs. Health & Safety Code § 111550.

X. DEFENDANT'S PRACTICES WERE "UNFAIR" WITHIN THE MEANING OF THE UNFAIR COMPETITION LAW.

66. Defendant's practices as described herein are "unfair" within the meaning of the California Unfair Competition Law because Walgreens's conduct is immoral, unethical, unscrupulous, and substantially injurious to consumers, and the utility of this conduct to Defendant does not outweigh the gravity of the harm to Defendant's victims.

67. In particular, while Defendant's marketing of Testosterone Complex with deceptive efficacy and "drug" claims as defined by 21 U.S.C. § 321(g) and "aphrodisiac drug" claims as defined by 21 C.F.R. § 310.528 and absent FDA approval to do so allowed Walgreens to realize higher profit margins

than if it did not use unlawful marketing tactics, this utility is small and far outweighed by the gravity of the economic harm and potential physical harm that Defendant inflicts upon consumers. Further, the injury to consumers from Defendant's practices is substantial, not outweighed by benefits to consumers or competition, and not an injury that consumers themselves could reasonably have avoided.

XI. DEFENDANT'S PRACTICES WERE "UNLAWFUL" WITHIN THE MEANING OF THE CALIFORNIA UNFAIR COMPETITION LAW.

68. Defendant's practices as described herein are "unlawful" within the meaning of the California Unfair Competition Law because the marketing, sale, and distribution Testosterone Complex violate the California's Sherman Food, Drug, and Cosmetic Law, including federal provisions that have been adopted by California

- **Health & Safety Code § 110100 *et seq.***, which adopts all FDA labeling regulations as state regulations;
- **Health & Safety Code § 111330**, "Any drug or device is misbranded if its labeling is false or misleading in any particular.";
- **Health & Safety Code § 110398**, "It is unlawful for any person to advertise any food, drug, device, or cosmetic that is adulterated or misbranded.";
- **Health & Safety Code § 111440**, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.";
- **Health & Safety Code § 111445**, "It is unlawful for any person to misbrand any drug or device.";
- **Health & Safety Code § 111450**, "It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.";
- **Health & Safety Code § 111550**, prohibiting sale of new drugs unless approved under 21 U.S.C. § 355;
- **21 U.S.C. § 331(a)**, prohibiting the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded";
- **21 U.S.C. § 331(b)**, prohibiting the "adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce";
- **21 U.S.C. § 352(f)(1)**, requiring drugs to have adequate directions for use;
- **21 U.S.C. § 355(a)**, prohibiting the sale of unapproved new drugs; and
- **21 C.F.R. § 310.528**, prohibiting the sale of unapproved aphrodisiac drugs

69. The fraudulent marketing and advertising of Testosterone Complex also violates the CLRA and False Advertising Law and further constitutes a violation of the FDCA and the Sherman Law and, as such, violated the "unlawful" prong of the UCL.

70. Defendant's unlawful acts allowed it to sell more units of Testosterone Complex than it would have otherwise, and at a higher price and higher margin.

71. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendant from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices and requiring Defendant to commence a corrective advertising campaign.

72. Plaintiff also seeks an order for the disgorgement and restitution of all revenue received by Defendant from the sale of Testosterone Complex and has no adequate remedy at law.

73. Walgreens's unlawful and deceptive marketing and advertising of Testosterone Complex constitutes a violation of the FDCA and the Sherman Law and, as such, violated the "unlawful" prong of the UCL.

74. Defendant's unlawful acts allowed it to sell more units of Testosterone Complex than it would have otherwise, and at a higher price and higher margin.

75. In accordance with Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendant from continuing to conduct business through unlawful, unfair, and/or fraudulent acts and practices and to commence a corrective advertising campaign.

76. Plaintiff also seeks an order for the disgorgement and restitution of all revenue received by Defendant from the sale of Testosterone Complex.

XII. PLAINTIFF'S PURCHASE OF TESTOSTERONE COMPLEX

77. Plaintiff Jason Ferguson purchased Testosterone Complex at least three times from the Walgreens locations on Market Street in San Francisco and on East Avenue in Chico. His most recent purchase was in or about December 2023.

78. In deciding to purchase Testosterone Complex, Plaintiff relied on Defendant's deceptive efficacy representations and fraudulent omissions.

79. Plaintiff used Testosterone Complex as directed, but the product failed to deliver the

advertised benefits, nor any results at all.

80. Because Plaintiff expected these statements to be true and honest, but they were not, he did not receive the benefit of his purchase.

XIII. RELIANCE AND INJURY

81. Plaintiff purchased and used Testosterone Complex in reliance on Defendant's deceptive efficacy representations described herein and would not have purchased the product absent Defendants' deceptive advertising.

82. When Plaintiff purchased Testosterone Complex, he was seeking a safe and effective product which would increase testosterone levels, muscle mass, and libido, and which was sold in compliance with FDA regulations and California law.

83. Plaintiff purchased Testosterone Complex with the natural assumption that products sold in stores and online by large companies would deliver the advertised benefits and would be sold in compliance with FDA regulations and California law.

84. Plaintiff suffered economic injury when he purchased Testosterone Complex because the product was entirely ineffective for its intended purposes and was in violation of federal regulations and California law.

85. Plaintiff would not have purchased Testosterone Complex had he known that it was entirely ineffective for its intended purposes and was sold in violation of federal regulations and California law

86. Testosterone Complex was offered for sale in violation of California and federal law and had a value of $0 because it is both illegal and ineffective.

87. Plaintiff would consider purchasing Testosterone Complex in the future if he could be assured that the product (1) would deliver the advertised benefits, (2) was safe and effective, and (3) was sold in compliance with all FDA regulations and California law.

XIV. CLASS ACTION ALLEGATIONS

88. Plaintiff brings this action on behalf of himself and all others similarly situated (the "Class"), excluding Defendant's officers, directors, and employees, and the Court, its officers and their

families. The Class is defined as:

> All citizens and residents of California who purchased Testosterone Complex in California for their own personal or household use, and not for resale, from January 1, 2019 to the present.

89. Questions of law and fact common to Plaintiff and the Class include:

a. Whether Defendant's conduct violated the CLRA and UCL;

b. Whether Walgreens communicated efficacy messages through Testosterone Complex's labeling, packaging, and website

c. Whether those messages were material, or likely to be material, to a reasonable consumer;

d. Whether those messages were false, at variance with the truth, misleading, likely to deceive, and/or had the capacity to deceive the public and/or a reasonable consumer;

e. Whether Walgreens fraudulently omitted material information in advertising Testosterone Complex as safe and effective;

f. Whether Testosterone Complex is an unapproved new drug;

g. Whether Defendant's conduct was immoral, unethical, unscrupulous, or substantially injurious to consumers;

h. Whether Class members are entitled to restitution, damages, punitive damages, and injunction, or further relief;

90. Class representation is superior to other options for the resolution of the controversy. The relief sought for each Class member is small, as little as $32 for some Class members. Absent the availability of class action procedures, it would be infeasible for Class members to redress the wrongs done to them.

91. Questions of law and fact common to the Class predominate over any questions affecting only individual members.

CAUSES OF ACTION

First Cause of Action

Unfair Competition Law, Unlawful Prong

Bus. & Prof. Code §§ 17200, *et seq*.

92. In this and every cause of action, Plaintiff realleges and incorporates the preceding allegations as if fully set forth herein.

93. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendant as alleged herein constitute "unlawful" business acts and practices in that Defendant's conduct violates the

California False Advertising Law, and the California Consumer Legal Remedies Act, as alleged herein.

94. Walgreens leveraged its deception to induce Plaintiff and members of the Class to purchase products that were of lesser value and quality than advertised.

103. The fraudulent marketing of Testosterone Complex described herein constitutes a violation of the FDCA and the Sherman Law and, as such, violated the "unlawful" prong of the UCL.

104. Had Plaintiff known that Testosterone Complex was ineffective and offered for sale in violation of California and federal regulations, he would not have purchased it.

105. Plaintiff suffered injury in fact and lost money or property as a result of Defendant's deceptive advertising: he was denied the benefit of the bargain when he decided to purchase Testosterone Complex over competing products, which are effective, legal, less expensive, and do not make misleading or false drug claims on their packaging.

106. Defendant's unlawful acts allowed it to sell more units of Testosterone Complex than it would have otherwise, at a higher price, and higher margin.

107. Had Plaintiff been aware of Defendant's false and misleading advertising tactics, he would not have purchased Testosterone Complex, and had Defendant not advertised Testosterone Complex in a fraudulent manner, Plaintiff would have paid less for it.

108. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendant from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices, requiring Defendant to commence a corrective advertising campaign, and awarding the class restitution of all monies Defendant obtained from the sale of Testosterone Complex. Plaintiff has no adequate remedy at law.

Second Cause of Action

Unfair Competition Law, Fraudulent Prong

Bus. & Prof. Code §§ 17200, *et seq*.

95. Cal. Bus. & Prof. Code § 17200 prohibits any "unlawful, unfair or fraudulent business act or practice."

96. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendant as alleged herein constitute "fraudulent" business acts and practices in that Defendant's conduct has a

likelihood, capacity or tendency to deceive Plaintiff, the Class, and the general public.

97. Defendant leveraged its deception to induce Plaintiff and members of the Class to purchase products that were of lesser value and quality than advertised.

98. Plaintiff and class members suffered injury in fact and lost money or property as a result of Defendant's deceptive advertising: they were denied the benefit of the bargain when he decided to purchase Testosterone Complex over competing products, which are legal, less expensive, and do not make misleading or false drug claims on their packaging and websites.

99. Had Plaintiff been aware of Defendant's false and misleading advertising tactics, he would not have purchased Testosterone Complex, and had Defendant not advertised it in a fraudulent manner, Plaintiff would have paid less for it.

100. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendant from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices; requiring Defendant to commence a corrective advertising campaign; and awarding the class restitution of all monies Defendant obtained from the sale of Testosterone Complex. Plaintiff has no adequate remedy at law.

Third Cause of Action

Unfair Competition Law, Unfair Prong

Bus. & Prof. Code §§ 17200, *et seq*.

101. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendant as alleged herein constitute "unfair" business acts and practices because Defendant's conduct is:

- immoral, unethical, unscrupulous, and offends public policy;
- the gravity of Defendant's conduct outweighs any conceivable benefit of such conduct; and
- the injury to consumers caused by Defendant's conduct is substantial, not outweighed by any countervailing benefits to consumers or competition, and not one that consumers themselves could reasonably have avoided.

102. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendant from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices; requiring Defendant to commence a corrective advertising campaign; and awarding the class restitution of all monies Defendant obtained from the sale of Testosterone Complex. Plaintiff has no

adequate remedy at law.

Fourth Cause of Action

False Advertising Law

Cal. Bus. & Prof. Code §§ 17500, *et seq*.

103. In violation of Cal. Bus. & Prof. Code §§ 17500 *et seq*., the advertisements, labeling, policies, acts, and practices described herein were designed to, and did, result in the purchase and use of Testosterone Complex without the knowledge that the product makes misleading and unapproved claims.

104. Defendant knew and reasonably should have known that the claims made on Testosterone Complex's label, packaging, and website were untrue and misleading.

105. As a result, Plaintiff, the Class, and the general public are entitled to injunctive and equitable relief, restitution, and an order for the disgorgement of the funds by which Defendant was unjustly enriched.

106. Plaintiff seeks an order enjoining Defendant from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices; requiring Defendant to commence a corrective advertising campaign; awarding Plaintiff and the class restitution of all monies from the sale of Testosterone Complex in an amount of $200,000, actual and punitive damages, and interest to Plaintiff, an incentive award to Plaintiff in conjunction with a class award or injunction, and for attorney fees and costs to be awarded by the Court in accordance with applicable law, including the Private Attorney General Statute.

Fifth Cause of Action

Consumer Legal Remedies Act

Civil Code §§ 1750, *et seq*.

107. The CLRA prohibits deceptive practices in connection with the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.

108. Defendant's policies, acts and practices were designed to, and did, result in the purchase and use of Testosterone Complex for personal, family, or household purposes, and violated and continue to violate the following sections of the CLRA:

- **Civil Code § 1770(a)(5),** representing that goods have characteristics, uses, or benefits which they do not have;

- **Civil Code § 1770(a)(7),** representing that goods are of a particular standard, quality, or grade if they are of another;
- **Civil Code § 1770(a)(9)**, advertising goods with intent not to sell them as advertised; and
- **Civil Code § 1770(a)(16),** representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.

109. As a result, Plaintiff, the Class, and the general public are entitled to injunctive and equitable relief, restitution, and an order for the disgorgement of the funds by which Defendant was unjustly enriched.

110. As a further result, Plaintiff and the Class have suffered damages, and because the conduct was deliberate, immoral, oppressive, made with malice and contrary to public policy, they are entitled to punitive or exemplary damages.

111. Pursuant to section 1782 *et seq*. of the CLRA, Plaintiff notified Defendant in writing by certified mail of the particular violations of § 1770 of the Act as to Testosterone Complex and demanded that Defendant rectify the problems associated with the actions detailed above and give notice to all affected consumers of its intent to so act.

112. Defendant received Plaintiff's written notice on August 25, 2025 and refused to correct any of the violations described in Plaintiff's letter.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself, all others similarly situated, and the general public, prays for judgment against Defendant as follows:

a) An order confirming that this class action is properly maintainable as a class action as defined above, appointing Plaintiff Jason Ferguson and his undersigned counsel to represent the Class, and requiring Defendant to bear the cost of class notice;

b) An order requiring Defendant to pay $1,000 in restitution, damages, punitive damages, and interest to Plaintiff;

c) An order requiring Defendant to pay $200,000 in restitution and damages to the Class, and $15,000 to Plaintiff as an incentive award, or such greater amount the Court deems fair and reasonable;

d) An award of punitive damages;

e) An order requiring Defendant to disgorge any benefits received from Plaintiff and its unjust enrichment realized as a result of its improper and misleading advertising, marketing, sale, and distribution of Testosterone Complex;

f) An Order declaring the conduct complained of herein violates the CLRA and Unfair Competition Law;

g) An order requiring Defendant to cease and desist its deceptive, unconscionable, fraudulent, and unlawful practices;

h) An order requiring Defendant to engage in a corrective advertising campaign;

i) A temporary and permanent injunction prohibiting the conduct described in the Complaint;

j) An award of prejudgment and post judgment interest;

k) An award of attorney fees and costs;

l) Such other and further relief as this Court may deem just, equitable or proper.

NO JURY DEMAND

Plaintiff does not demand a jury trial.

Dated: April 20, 2026

Respectfully Submitted,

Gregory S. Weston

Counsel for Plaintiff

EXHIBIT 1

Shop all Walgreens

Walgreens Men's Testosterone Complex Tablets (60 days) (Packaging May Vary), 60.0 ea

4.0 ★★★★☆ 19

$31.99 $0.53/ea

When ordered online

Buy 1, Get 1 50% OFF
View qualifying products • Add two items to cart

Vitamin Angels will receive a donation with every purchases.
See details

Extra 15% off $35 Sitewide code AUG15 or Extra 20% off $50 code AUG20

Sign in to unlock savings and earn myWalgreens cash rewards on every purchase.

Store Pickup
Not sold at 3005 MIDWAY DR, San Diego, CA 92110
Check other stores

Same Day Delivery
As soon as 1 hour or schedule delivery.

Shipping
Arrives in 2-4 days

Save to shopping list

Description

- Promotes an increase in free testosterone*+
- Supports a healthy libido*+, lean muscle mass, strength, and endurance*++
- With clinically studied Testofen

Walgreens Men's Testosterone Complex is powered by Testofen, a unique standardized fenugreek extract that is recognized for hormone support.*

As men age, they are able to use less and less of the testosterone that their bodies produce. This can be felt by the aging male in areas such as: strength, libido, muscle endurance - and a general "less than prime" feeling. Testofen has been clinically studied for its ability to:

- Support the development of lean muscle mass*++
- Boost free testosterone levels*+
- Support sexual function in men*+

Walgreens Pharmacist Recommended^

Learn more about Walgreens brand products

^Our pharmacists recommend the Walgreens brand.

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

**Satisfaction Guarantee valid on Walgreens owned brand products only.

+Related to a normal decrease associated with aging.

++As part of a 12-week regular strength training and exercise program.

*Compare the regular retail price of Walgreens brand products to the regular retail price of similar national brand products.

100% satisfaction guaranteed

As a dietary supplement for men, take two (2) tablets daily, one (1) in the morning and one (1) in the evening. May be taken with our without food. Not intended for individuals under 18 years of age.

For optimal storage conditions keep in a cool, dry place with cap tightly closed. Avoid excessive heat or freezing.

Product Specifications

Ingredients

Nutrition Facts

Warnings

Shipping Specifications

Ratings and Reviews


Walgreens
Men's
Testosterone
Complex
DIETARY SUPPLEMENT
PROMOTES AN INCREASE IN FREE TESTOSTERONE
Supports:
• A healthy libido*‡
• Lean muscle mass, strength & endurance†‡*
with clinically studied
Testofen
60 TABLETS
(30-day supply)
Walgreens
Men's
Testosterone
Complex
DIETARY SUPPLEMENT
PROMOTES AN INCREASE IN FREE TESTOSTERONE
60 TABLETS
(30-day supply)
Testofen


Walgreens
Men's
Testosterone
Complex
DIETARY SUPPLEMENT
PROMOTES AN INCREASE IN FREE TESTOSTERONE
Supports:
• A healthy libido*‡
• Lean muscle mass, strength & endurance†‡*
with clinically studied
Testofen
60 TABLETS
(30-day supply)

Walgreens Men's Testosterone Complex is powered by Testofen®, a unique standardized fenugreek extract that is recognized for hormone support.*

As men age, they are able to use less and less of the testosterone that their bodies produce. This can be felt by the aging male in areas such as: strength, libido, muscle endurance — and a general "less than prime" feeling.

Testofen® has been clinically studied for its ability to:

Support the development of lean muscle mass*††

Support muscle strength & endurance*††

Boost free testosterone levels*‡

Support sexual function in men*‡

*THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.

TAMPER EVIDENT: DO NOT USE IF INNER SEAL UNDER CAP IS BROKEN OR MISSING.

Suggested use: As a dietary supplement for men, take two (2) tablets daily, one (1) in the morning and one (1) in the evening. May be taken with or without food. Not intended for individuals under 18 years of age.

Supplement Facts

Serving Size 1 Tablet

	Amount per Serving	% DV	Amount per Day (2 Tablets)	% DV
Vitamin B6 (as pyridoxine HCl)	4.9 mg	288%	9.8 mg	576%
Magnesium (as magnesium oxide)	16 mg	4%	32 mg	8%
Zinc (as zinc oxide)	15 mg	136%	30 mg	273%
Fenugreek Extract (*Trigonella foenum graecum*, seed, Testofen®)	300 mg	**	600 mg	**

**Daily Value (DV) not established.

OTHER INGREDIENTS: Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid, Magnesium Stearate, Silicon Dioxide, Hydroxypropyl Cellulose, Purified Water, Hypromellose, Polyethylene Glycol.

DISTRIBUTED BY: **WALGREEN CO.**
200 WILMOT RD., DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
walgreens.com 1-800-925-4733

EXHIBIT 2

Company: Unlimited Nutrition
Subject: Dietary Supplement/Labeling/Misbranded
Issuer: Atlanta District Office
Issued: Aug. 30, 2010 **Closed:** Not Issued
Source ucm225605 **Archive Code:** 20170111135340

Unlimited Nutrition 8/30/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

August 30, 2010

WARNING LETTER
10-ATL-19

HAND DELIVERED

Mr. Mike McCandless, Owner
Unlimited Nutrition
Scivation, Inc., President
1130 Cherry Lane
Graham, NC 27253

Dear Mr. McCandless:

On February 16 - 17, 2010, the U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 1130 Cherry Lane, Graham, NC 27253. We have also reviewed your firm's website, www.smartpowders.com .

This letter concerns your firm's marketing of the following products: "Smart Powders Piracetam," "Primaforce Piracetam," "Advanced Muscle Science Arom-X," "Advanced Muscle Science 4-AD UTT," "G.E.T ArimaDex," "iForce Nutrition Reversitol," and "Fizogen Off Cycle II Hardcore." These products are marketed in violation of the Federal Food, Drug, and Cosmetic Act (the Act) as described below.

Piracetam Containing Products

Your firm markets your piracetam products, "Smart Powders Piracetam" and "Primaforce Piracetam" as dietary supplements; however, both products are excluded from the definition of a "dietary supplement" under section 201(ff)(1) of the Act, 21 U.S.C. § 321(ff)(1). To be a dietary supplement a product must, among other things, "bear[ ] or contain[ ] one or more ... dietary ingredients" as defined in section 201(ff)(1) of the Act. Section 201(ff)(1) of the Act defines "dietary ingredient" as a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any dietary ingredient from the preceding categories. The only substance listed as a dietary ingredient on the labeling for your "Smart Powders Piracetam" and "Primaforce Piracetam" products is piracetam. Piracetam is not a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Further, piracetam is not a concentrate, metabolite, constituent, extract or combination of any such dietary ingredient. Thus, because your "Smart Powders Piracetam" and "Primaforce Piracetam" products do not bear or contain any dietary ingredients as defined in section 201 (ff)(1) of the Act, these products do not qualify as dietary supplements under section 201(ff) of the Act. [1]

Your website and labeling include statements such as the following:

Smart Powders Piracetam

- "Piracetam supports memory and concentration, overall well-being, cardiovascular health, and helps reduce stress and fatigue."

Primaforce Piracetam

- "Piracetam supports memory and concentration, overall well-being, cardiovascular health, and helps reduce stress and fatigue."

The claims listed above make clear that "Smart Powders Piracetam" and "Primaforce Piracetam," are intended to affect the structure or any function of the body of man or other animals. Accordingly, these ·products are drugs, under section 201(g)(1)(C) of the Act, 21 U.S.C. § 321(g)(1)(C), because they are not foods and they are intended to affect the structure or any function of the body. Moreover, these products are new drugs as defined by section 201(p) of the Act, 21 U.S.C. § 321(p), because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

Under sections 301(d) and 505(a) of the Act, 21 U.S.C. § 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA approved application is in effect for it. There are no approved applications for "Smart Powders Piracetam" and "Primaforce Piracetam." Your sale of these products without approved applications violates these provisions of the Act.

Body Building and Sport Performance Products

In addition, your firm's body building and sport performance products "Advanced Muscle Science Arom-X," "Advanced Muscle Science 4-AD UTT," "G.E.T ArimaDex," "iForce Nutrition Reversitol," and "Fizogen Off Cycle II Hardcore" are unapproved and misbranded drugs under the Act.

Your website, www.smartpowders.com . states that your products contain the following ingredients:

- **Advanced Muscle Science Arom-X** : 1,4,6-etioallocholan-dione
- **Advanced Muscle Science 4-AD UTT** : 3,17-keto-etiochol-triene
- **G.E.T ArimaDex** : 3,17-keto-etiochol-triene
- **iForce Nutrition Reversitol** : 6-Etioallochol-1 ,4-Diene-3,17-Dione
- **Fizogen Off Cycle II Hardcore** : 3 17 keto etiochol triene

The above-listed ingredient names are all synonyms for the same ingredient, commonly known as "ATD." "ATD" is an aromatase inhibitor. FDA is unaware of evidence that ATD occurs in vivo in humans or animals.

Your firm markets "Advanced Muscle Science Arom-X," "Advanced Muscle Science 4-AD UTT," "G.E.T ArimaDex," "iForce Nutrition Reversitol," and "Fizogen Off Cycle II Hardcore" as dietary supplements. To be a dietary supplement a product must, among other things, "bear[ ] or contain[ ] one or more ... dietary ingredients" as defined in section 201(ff)(1) of the Act. Section 201(ff)(1) of the Act defines "dietary ingredient" as a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any dietary ingredient from the preceding categories. ATD is not a vitamin, mineral, amino acid, herb or other botanical, or dietary substance for use by man to supplement the diet

by increasing the total dietary intake. Further, ATD is not a concentrate, metabolite, constituent, extract or combination of any such dietary ingredient. Therefore, ATD is not a dietary ingredient as defined in section 201 (ff)(1) of the Act, 21 U.S.C. § 321(ff)(1).

Your website includes statements such as the following:

Advanced Muscle Science Arom-X

- "Anti-estrogen complex."
- "Natural testosterone booster."
- "Libido enhancer."
- "Arom-X is scientifically formulated to suppress estrogen production and restore natural testosterone output while acting as a strong libido enhancer."

Advanced Muscle Science 4-AD UTT

- "4-AD UTT is a unique anabolic solution pro-hormone that converts at a high rate of testosterone (sic)."
- "[W]ill give you better strength and size increases than the old testosterone precursors."

G.E.T ArimaDex

- "A proprietary blend of 7 ingredients including an estrogen blocker ... that have all been shown to increase or maintain testosterone levels."

iForce Nutrition Reversitol

- "By regulating the production and levels of Testosterone, Estrogen, LH, and Cortisol an athlete will ensure PEAK. Performance Reversitol promotes the optimal Hormone Regulation for applying Maximum FORCE!"
- "Usage for promoting hormonal regulation ...."

Fizogen Off Cycle II Hardcore

- "Off Cycle" and "If you are subject to performance enhancing drug testing, do not use this product unless cleared by your sanctioning body"

The statements above make clear that "Advanced Muscle Science Arom-X," "Advanced Muscle Science 4-AD UTT," "G.E.T ArimaDex," "iForce Nutrition Reversitol," and "Fizogen Off Cycle II Hardcore" are intended to affect the structure or function of the body. Accordingly, these products are drugs under section 201(g)(1)(C) of the Act, 21 U.S.C. § 321(g)(1)(C).

As mentioned above, your firm markets "Advanced Muscle Science Arom-X," "Advanced Muscle Science 4-AD UTT," "G.E.T ArimaDex," "iForce Nutrition Reversitol," and "Fizogen Off Cycle II Hardcore" as dietary supplements. Under section 201(g)(1) (last sentence), the structure/function claims made for a dietary supplement must be made in accordance with section 403(r)(6) of the Act, 21 U.S.C. § 343(r)(6), or the product is subject to regulation as a drug. Section 403(r)(6) of the Act, 21 U.S.C. § 343(r)(6), authorizes claims that describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the body, or that characterize the way in which a nutrient or dietary ingredient maintains the structure or function of the body.

However, the claims quoted above for your body building and sport performance products, "Advanced Muscle Science Arom-X," "Advanced Muscle Science 4-AD UTT," "G.E.T ArimaDex," "iForce Nutrition Reversitol," and "Fizogen Off Cycle II Hardcore," do not describe the effects of nutrients or dietary ingredients in the products. Rather, the claims made for each product are made for the product as a whole and relate to its "ATD" content. Since "ATD" is not a nutrient or dietary ingredient, claims about improvement of the structure or function of the body do not conform to section 403(r)(6) of the Act, 21 U.S.C. § 343(r)(6). Accordingly, the claims for "Advanced Muscle Science Arom-X," "Advanced Muscle Science 4-AD UTT," "G.E.T ArimaDex," "iForce Nutrition Reversitol," and "Fizogen Off Cycle II Hardcore" render them drugs within the meaning of section 201(g)(1)(C) of the Act, 21 U.S.C. § 321(g)(1)(C).

Moreover, the above-listed body building and sport performance products are "new drugs," as defined by 201(p) of the Act, 21 U.S.C. § 321(p), because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Under sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your sale of "Advanced Muscle Science Arom-X," "Advanced Muscle Science 4-AD UTT," "G.E.T ArimaDex," "iForce Nutrition Reversitol," and "Fizogen Off Cycle II Hardcore" without approved applications violates these provisions of the Act.

Furthermore, "Advanced Muscle Science Arom-X," "Advanced Muscle Science 4-AD UTT," "G.E.T ArimaDex," "iForce Nutrition Reversitol," and "Fizogen Off Cycle II Hardcore" are prescription drugs as defined at section 503(b)(1)(A) of the Act, 21 U.S.C. § 353(b)(1)(A), because, in light of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to use, they are not safe for use except under the supervision of a practitioner licensed by law to administer them. Indeed, all aromatase inhibitors that have been approved for marketing by the FDA are limited by an approved new drug application to use under the professional supervision of a practitioner licensed by law to administer such drug.

According to section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1), a drug is misbranded if, among other things, it fails to bear adequate directions for its intended use(s). Under 21 C.F.R. § 201.5, "adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended. Prescription drugs can only be used safely at the direction, and under the supervision, of a licensed practitioner. Therefore, it is impossible to write "adequate directions for use" for prescription drugs. FDA-approved drugs which bear their FDA-approved labeling are exempt from the requirement that they bear adequate directions for use by a layperson. See 21 C.F.R. §§ 201.100(c)(2) and 201.115. Because there are no FDA-approved applications for your firm's "Advanced Muscle Science Arom-X," "Advanced Muscle Science 4-AD UTT," "G.E.T ArimaDex," "iForce Nutrition Reversitol," and "Fizogen Off Cycle II Hardcore" products, their labeling fails to bear adequate directions for its intended uses, causing it to be misbranded under section 502(f)(1) of the Act, 21 U.S.C. § 352(t)(1). The introduction or delivery for introduction into interstate commerce of these misbranded products violates section 301(a) of the Act, 21 U.S.C. § 331(a).

The issues and violations cited in this letter are not intended to be an all-inclusive statement of the violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action, without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you

will complete the corrections. Furthermore, please advise this office what actions you will take to address product that you have already distributed.

Additionally, if another firm manufactures the products identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the product is not the manufacturer, please include the name of your supplier in addition to the manufacturer.

Please send your reply to Derek C. Price, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, GA 30309. If you have any questions about the content of this letter, please contact Mr. Price at 404-253-2277.

Sincerely
/S/
John Gridley
District Director
Atlanta District Office

[1] We note that in 2003, **(b)(4)** submitted a New Dietary Ingredient Notification (NDIN) for piracetam, naming your firm as the distributor, pursuant to section 413(a)(2) of the Act, 21 U.S.C. §350b. Section 413(a)(2) of the Act requires premarket notification to CFSAN prior to the introduction of a new dietary ingredient into interstate commerce. The NDIN is required to contain infonnation which is the basis for the conclusion that a dietary supplement containing such new dietary ingredient will reasonably expected to be safe. CFSAN's response letter
to Mr. **(b)(4)** NDIN, which was issued on January 9, 2004, stated that piracetam is "not a dietary ingredient."

EXHIBIT 3

WARNING LETTER

Star Health & Beauty LLC

MARCS-CMS 516206 — MAY 26, 2017

Recipient:

Star Health & Beauty LLC

United States

Issuing Office:

Atlanta District Office

United States

U.S. FOOD & DRUG ADMINISTRATION

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

May 26, 2017

VIA UNITED PARCEL SERVICE
NEXT DAY - SIGNATURE REQUIRED

Mr. James W. Dukes, Chief Executive Officer (CEO)
Star Health & Beauty LLC
14500 Lochridge Blvd Ste E
Covington, GA 30014-4941

WARNING LETTER
(17-ATL-08)

Dear Mr. Dukes:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address, www.s-h-b.com in May 2017 and determined that you take orders there for the products Nu Essentials Royal Jelly Capsules, NuMan Male Enhancement Capsules, StarTop () Male Potency Tonic, Sculpting Crème, Royal Touch – Anti-Wrinkle Serum, Realyze Under Eye Seryum, proEASE Wild Yam Cream, ProK

Top

Professional Strength Vitamin K Cream, proDHEA™ Transdermal DHEA Cream, Professional Formulas Natural Analgesic Cream, proGen Anti-Aging Natural Growth Hormone Precursor Cream, ProPhytogen Cream, Sensual Lips, Sun Warrior Ginsing Moisturizer™, NuGen HP, She Max HP, and V Max HP. The claims on your website establish that the products are drugs under section 201(g)(1)(B) and/or 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B) and/or 201(g)(1)(C)] in that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or intended to affect the structure or any function of the human body. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You can find the Act and its implementing regulations through links on FDA's home page at http://www.fda.gov (http://www.fda.gov/).

FDA also inspected your drug, dietary supplement and cosmetic products manufacturing facility, Star Health & Beauty LLC, at Covington, GA, from October 17 to 26, 2016. Based on our inspection, we found serious violations of the Current Good Manufacturing Practice (CGMP) regulation for Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements, Title 21, Code of Federal Regulations, Part 111 (21 CFR Part 111). These violations cause your dietary supplement products to be adulterated within the meaning of section 402(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(g)(1)], in that they have been prepared, packed, or held under conditions that do not meet the CGMP regulations for dietary supplements found under 21 CFR Part 111.

In addition, our investigators identified significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals, Title 21, Code of Federal Regulations, Parts 210 and 211. These violations cause your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP."

At the conclusion of the inspection, you were issued a Form FDA 483 detailing our investigator's observations during the inspection. We did not receive a letter with your response to the observations.

Unapproved New Drugs

Examples of some of the claims that provide evidence that your products are intended for use as drugs include:

Nu Essentials Royal Jelly Capsules

- "Royal Jelly helps your body protect itself from viruses and can aide in preventing colds and infections..."
- "[I]mmune protection…fights against bacteria…antidepressive…"

NuMan Male Enhancement Capsules

- "[M]uira Puama is one of the best herbs to use for erectile dysfunction…"

Star's Male Potency Tonic

- "[U]sed as a remedy for impotence…"
- "[B]eneficial for prostate enlargement and infections."

Sculpting Crème

- "Sculpting Crème eliminates and prevents the accumulation of fats and wastes that become trapped in the susceptible cells just below the skin."
- "[S]timulates microcirculation to help your body reduce fat deposits."

Royal Touch – Anti-Wrinkle Serum

- "Natural Botox Alternative"
- "[S]timulate collagen growth…reduction of deep wrinkles…"
- "[P]revent aging of the skin …"
- "Emu Oil contains…healing properties…known to repair skin damage."

Top ()

Realyze Under Eye Seryum

- "Suppresses inflammatory enzymes, decreasing puffiness and swelling"
- "Strengthens capillaries, arteries and veins…"
- "It promotes collagen formation, thereby increasing capillary blood circulation, retards capillary leakage, reduces melanin production…to reduce swelling…"
- "Vitamin K…stimulates Epithelial growth…"
- "Vitamin C – Helps to protect against damaging UVA/UVB rays…and stimulates collagen production..."
- "Hexapeptide 3… reduces wrinkles… Also has been shown to prevent aging of the skin..."
- "Marine Collagen…helping cells to renew themselves… "
- "Emu Oil - … Vitamin E: anti-oxidant and healing agent…."
- "Vitamin E…healing agent, Vitamin A…skin repairer, Terpines: an antiseptic…"

proEASE Wild Yam Cream

- "Women…their first choice in addressing PMS and other hormone related issues."
- "Users experience less PMS symptoms, reduced stress and increased vitality."
- "To relieve cramping… apply the cream to the abdomen each half hour until the cramping subsides."
- "With hot flashes…apply…cream each time they have a hot flash."

ProK Professional Strength Vitamin K Cream

- "[S]timulates epithelial growth and promotes…clarification of the damaged skin."
- "Helps eliminates (sic) spider veins (dilated or broken capillaries) and bruising…"
- "[C]osmetic surgeons…use it for pre & post operative treatment to reduce post operative bruising, swelling, and to speed up the healing process and diminish scarring."
- "[C]lots the blood…"

proDHEA™ Transdermal DHEA Cream

- "Boost Immune Function"
- "Increase Lean Muscle Mass"
- "Reduce Body Fat"
- "Reduce Stress"
- "Combat Depression"
- "Enhance Sexual Drive & Desire"
- "Improve Memory"
- "Helps Prevent Osteoporosis & Cardiovascular Disease"
- "[I]ncrease estrogen and testosterone levels… increase IGF-1, increase lean body mass, and decrease appetite."
- "[I]mprove quality of sleep, decrease joint pain…"

Professional Formulas Natural Analgesic Cream

- "[L]ower blood pressure."
- "[I]ncreasing the blood supply, it reduces inflammation."
- "[A]nti-inflammatory properties."
- "[H]ighly effective in treating rheumatoid arthritis."

proGen Anti-Aging Natural Growth Hormone Precursor Cream

- "[A]cts as a precursor which may induce the pituitary to increase production of the bodies (sic) own natural HGH."
- "[M]ay assist in slowing down and even reversing the… aging process."
- "HGH is one of many endocrine hormones…"
- "Not only does it suppress biological aging…"
- "HGh affects almost every cell in the body…"
- "[S]trong anti-phlogiston (inflammation reducing) effect."
- "[V]ery powerful anti-inflammatory… more effective than aspirin in reducing inflammation and pain."

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- o "[T]reat swelling, inflammations, and sprains."
- o "[R]elieve pain …"
- o "[R]educe inflammation …"
- o "[R]elieved stiffness…"
- o "It's (sic) medicinal values include anti-inflammatory, antiseptic, carminative, antispasmodic and sedative as well as promoting wound healing."
- o "HGH has been found to reverse and/or slow down the aging process by:
  - § Restoring Muscle Mass
  - § Decreasing Body Fat
  - § Thickening of the skin
  - § Improving cholesterol profile
  - § Increasing sexual function
  - § Improving Memory
  - § Elevating Mood
  - § Normalizing blood pressure
  - § Increasing cardiac output and stamina
  - § Improving Immune Function
  - § Restoring lost hair growth
  - § Restoring size of organs that shrink with age
  - § Improving Sleep
  - § Increasing Energy"

ProPhytogen Cream

- o "[C]ontains phyto-hormones thatare identical to the human estrogens estradiol, estriol, and estrone…"
- o "It has a stabilizing effect on the entire endocrine system, calming hot flashes and night sweats, and restoring normal sleep patterns…"
- o "[E]xhibits dh-Testosterone blocking qualities to help reduce … facial hair growth."
- o "Black Cohosh Known….To restore healthy menstrual activity."
- o "Stimulates estrogen, cortisone and aldosterone production…"
- o "Assists with menopausal symptoms, helps to regulate menstruation and PMS."
- o "Helps liver problems, heart palpitations, high blood pressure, hypoglycemia and chronic bronchitis."
- o "Used to dissolve blood clots, strengthen the central nervous system and nourish the brain."
- o "[I]s helpful for hormonal balancing, PMS, weight control…"

Sensual Lips

- o "[S]timulates fat cells below lip tissue increasing the size of your lips."
- o "[E]xpand the cellular substructure of your lips..."

Sun Warrior Ginsing Moisturizer™

- o "[P]rovide healing…benefits to the skin…"
- o "[K]nown to protect again (sic) infections with its antibacterial and antiviral properties."
- o "[A]ssist the body's ability to utilize oxygen on a cellular level."

NuGen HP

- o "Fuller Thicker Hair In As Little As Two Months"
- o "[A] natural alternative to combat hair loss…"
- o "Restore thinning hair with visible results"
- o "[R]estores and maintains healthy hair."
- o "[P]roven to prevent DHT…from attaching to the hair follicle..."
- o "[W]orks to balance the hormones in the follicle…"
- o "[T]o restore thickness and prevent more hair from falling out."
- o "Nugen HP – The All-Natural Hair Restoration System?

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- "[R]evitalizes your hair follicles stimulating fuller, thicker hair."

She Max HP

- "She-Max HP contains natural herbs that have been proven to have the following actions: antibacterial, anti-depressant, anti-fatigue, aphrodisiac, improves: endurance, mental performance, physical performance, works as a urogenital tonic and uterine stimulant. Improves and maximizes ability to achieve orgasmic pleasure."
- "SHE-MAX stimulates sexual energy by expanding the blood vessels causing increased blood flow to the genital area causing increased sexual stimulation and sensation."
- "SHE-MAX HP contains the most essential active ingredients scientifically proven to enhance neurotransmission and blood flow in regions of the brain and genital organs that control sensation and sexual function!"

V Max HP

- "VMAX HPTM is helping men of all ages . . . overcome erectile dysfunction naturally!"
- "VMAX HP stimulates sexual energy by expanding the blood vessels causing increased blood flow to the penis."
- " . . . contains three active ingredients to help your body produce the proper blood flow to the penis."
- "To further enhance the erection process, VMAX HPTM contains the extract of the herb Ginko Biloba, which recently has been heavily documented for its ability to relax the body's arteries and improve blood flow."
- "VEP Protein . . . is a powerful vasodilator that further helps open flood vessels and increase circulation to the penis."
- "Erectile Dysfunction"
- Section entitled "Erectile Dysfunction Facts"
- "Results have shown over 80% success rate in treating Erectile Dysfunction."
- "I would like to share my clinical experience with using VMAX topical lotion for the treatment of erectile dysfunction . . . a valuable adjunct in treating the condition of erectile dysfunction; by increasing vascular flow to the penis and increasing the production of nitric oxide."
- "I am 48 and experienced ED for the first time a few months ago . . . that is when I began using VMAX HP –it works the same [as Viagra] without the side effects."

Your Nu Essentials Royal Jelly Capsules, NuMan Male Enhancement Capsules, Star's Male Potency Tonic, Sculpting Crème, Royal Touch – Anti-Wrinkle Serum, Realyze Under Eye Seryum, proEASE Wild Yam Cream, ProK Professional Strength Vitamin K Cream, proDHEA™ Transdermal DHEA Cream, Professional Formulas Natural Analgesic Cream, proGen Anti-Aging Natural Growth Hormone Precursor Cream, ProPhytogen Cream, Sensual Lips, Sun Warrior Ginsing Moisturizer™, NuGen HP, She Max HP, and V Max HP products are not generally recognized as safe and effective for the above referenced uses, and, therefore the products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

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Your Nu Essentials Royal Jelly Capsules, NuMan Male Enhancement Capsules and Star's Male Potency Tonic products are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, your Nu Essentials Royal Jelly Capsules, NuMan Male Enhancement Capsules and Star's Male Potency Tonic products fail to bear adequate directions for their intended use and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the Act [21 U.S.C. 331(a)].

Adulterated Dietary Supplements

The inspection revealed the following significant violations of the CGMP requirements for dietary supplements. These violations cause your dietary supplement products to be adulterated under section 402(g)(1) of the Act [21 U.S.C. § 342(g)(1)] in that they have been prepared, packed, or held under conditions which do not meet the CGMP regulations for dietary supplements in 21, Code of Federal Regulations, Part 111.

Our investigators observed specific violations, including, but not limited to, the following:

1. You failed to establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, as required by 21 CFR 111.103. Specifically, you stated that you had not established written quality control procedures during the inspection.

Additionally, once you have established your written procedure for quality control you must implement quality control operations into your manufacturing, packaging, labeling, and holding operations, as required by 21 CFR 111.65.

2. You failed to prepare a written master manufacturing record for each unique formulation of dietary supplement that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch as required by 21 CFR 111.205(a).

Specifically, you stated that you have not established master manufacturing records for any of your dietary supplement products and that you provide your staff with verbal production instructions and do not prepare written master manufacturing records for your dietary supplement products.

3. You also failed to prepare a batch production record every time you manufactured a batch of a dietary supplement as required by 21 CFR 111.255(a).

Specifically, you told our investigator that your firm does not establish batch production records for the majority of your dietary supplement products.

4. You failed to establish specifications for points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record, as required by 21 CFR 111.70. Specifically,

a. You failed to establish specifications for each component that you use in the manufacture of a dietary supplement. Specifically, you failed to establish the following: an identity specification; specifications to ensure purity, strength and composition of dietary supplements manufactured using the components are met; and specifications that establish the limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement to ensure the quality of the dietary supplement, as required by 21 CFR 111.70(b)(1)-(3).

Once you have established component specifications and before using a component, you must conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient, as required by 21 CFR 111.75(a)(1)(i), unless you petition the agency under 21 CFR 111.75(a)(1)(ii) and the agency exempts you from such testing, and you must confirm the identity of other components and determine whether other applicable component specifications established in accordance with 21 CFR 111.70(b) are met, as required by 21 CFR 111.75(a)(2).

b. You failed to establish specifications for dietary supplement labels (labeling specifications) and for packaging that may come in contact with dietary supplements (packaging specifications), as required by 21 CFR 111.70(d).

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c. You failed to establish specification for each dietary supplement that you manufacture, specifications for the identity, purity, strength, and composition of the finished batch of the dietary supplement, and for limits on those types of contamination that may adulterate, or that may lead to adulteration of, the finished batch of the dietary supplement to ensure the quality of the dietary supplement as required by 21 CFR 111.70(e).

Once you have established the above specifications, you must determine whether the specifications have been met as required by 21 CFR 111.75(c). We also note that you must make and keep records for established specifications, as required by 21 CFR 111.95(b)(1).

d. You failed to establish specifications that provide sufficient assurance that the product you receive from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) is adequately identified and is consistent with your purchase order, as required by 21 CFR 111.70(f).

e. You failed to establish specifications for the packaging and labeling of the finished packaged and labeled dietary supplements, including specifications that ensure that you used the specified packaging and that you applied the specified label, as required by 21 CFR 111.70(g).

Adulterated Drugs

In addition, our investigators identified significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals, Title 21, Code of Federal Regulations, Parts 210 and 211. These violations cause your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP."

Our investigators observed specific violations, including, but not limited to, the following.

1. Your firm failed to establish a quality control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products (21 CFR 211.22(a)).

Your firm lacks a quality control unit and any documentation of quality control review or approval of any of the firm's procedures or operations.

In response to this letter, provide your corrective actions to ensure that you establish a quality control unit with the responsibilities and authorities specified above.

2. Your firm does not have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release (21 CFR 211.165(a)).

You released finished drug products without testing your drug products to determine if they conformed to specifications.

In response to this letter, describe your corrective action plan to ensure that your drug products are tested before release.

3. Your firm failed to establish written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)).

Your firm has not validated the manufacturing processes for each of your drug products. Documented, successful process validation shows that each step of a manufacturing process is controlled and provides confidence that finished drug products meet all quality attributes, including specifications.

See FDA's guidance document, Process Validation: General Principles and Practices, for FDA's current thinking on elements of process validation at http://www.fda.gov/downloads/Drugs/.../Guidances/UCM070336.pdf (/media/71021/download).

In response to this letter, provide your complete process validation plan and specify the dates by which you expect to complete validation for each of your drug products. Also include the interim steps you will take to ensure the quality of your drug products prior to completing your validation activities.

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4. Your firm failed to ensure that your drug product bore an expiration date that was supported by appropriate stability testing (21 CFR

211.137(a)).

You have not established a written testing program to assess the stability characteristics of the drug products you manufacture. You do not have any data to support the two-year expiration date you assigned to all your drug products.

In response to this letter, provide a copy of your stability testing procedures of your drug products. For each product, specify the stability-indicating methods and acceptance criteria you will rely on for each test to support the labeled storage conditions and expiry dates for your drug products.

5. Your firm failed to establish and follow written procedures for the preparation of master production and control records designed to assure uniformity from batch to batch (21 CFR 211.186(a)). Your firm also failed to prepare batch production and control records for each batch of drug product produced that include an accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed (21 CFR 211.188(a)).

You do not have master production and control records for any of your drug products. Furthermore, you do not prepare batch production and control records for any of your drug products. Instead you provide verbal manufacturing instructions to your staff.

In response to this letter, provide a copy of your master production and control records for each of your drug products to assure the uniformity of your drug products from batch to batch. Also provide a copy of one executed batch production and control record for each of your drug products.

6. Your firm failed to establish and follow adequate written procedures describing the handling of all written and oral complaints regarding a drug product, including provisions for review by the quality control unit of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with 21 CFR 211.192 (21 CFR 211.198).

You have not established procedures to handle complaints for any of your drug products.

In response to this letter, provide a copy of your written procedures to handle all complaints about your drug products.

Misbranded Dietary Supplements

Additionally, your dietary supplement products are misbranded under Section 403 of the Act [21 U.S.C. § 343], in that they fail to comply with the labeling requirements for dietary supplements. Your label violations include the following:

1. Your Contour Too Breast Enhancing Capsules, ProPhytogen Plus, and NuMan Male Enhancement Capsule products are misbranded within the meaning of section 403(s)(2)(B) of the Act [21 U.S.C. § 343 (s)(2)(B)] because the product labels fail to identify the products using the term “dietary supplement”, as required by 21 CFR 101.3(g).

2. Your Contour Too Breast Enhancing Capsules, Bentonite Magma, ProPhytogen Plus, and NuMan Male Enhancement Capsule products are misbranded within the meaning of section 403(y) of the Act [21 U.S.C. § 343(y)] in that the labels fail to bear a domestic address or domestic phone number through which the responsible person (as described in section 761) may receive a report of a serious adverse event with such dietary supplement. “Domestic address or domestic phone number” means a complete address or phone number. The labels for these products do not include complete addresses or phone numbers.

3. Your Liu Jun Zi Tang product is misbranded within the meaning of section 403(f) of the Act [21 U.S.C. §343(f)] because the product label contains the product name in a foreign language, but does not repeat all the required information in both English and the foreign language. As required by 21 CFR 101.15(c), if a product label contains any representation in a foreign language or foreign characters, all words, statements, and other information required by or under authority of the Act to appear on the label must appear in the foreign language.

4. Your Clear Spiro, Contour Too Breast Enhancing Capsules, and Liu Jun Zi Tang products are misbranded within the meaning of section 403(r)(6)(C) of the Act [21 U.S.C. §343(r)(6)(C)] because the labels bear structure/function claims but fails to bear the required FDA dietary supplement disclaimer as required by, 21 CFR 101.93(c). Under section 403(r)(6) of the Act, a dietary supplement may bear certain claims, generally called "structure/function claims," on its label or in its labeling provided that the firm has substantiation that the claim is truthful and not misleading; the firm has notified FDA within 30 days of marketing the product bearing the claim; and the claim includes a mandatory disclaimer.

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5. Your NuMan Male Enhancement Capsule, Clear Spiro, and Liu Jun Zi Tang products are misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. §343(i)(2)] in that the product labels fail to declare the common or usual names of each ingredient used, as required by 21 CFR 101.36 and 21 CFR 101.4. For example, "Horny Goat Weed", "Que Bracho", "White Atractylodes", "Ledebouriella", and "Morus" are not standardized common names as noted in Herbs of Commerce. The Latin binomial name of a botanical is required when the botanical lacks a standardized common name.

Conclusion

The violations cited in this letter are not meant to be an all-inclusive statement of violations that exist in connection with your products and their labeling. It is your responsibility to ensure that all your products comply with the Act and its implementing regulations.

We offer you the following dietary supplement labeling comments:

o Your Bentonite Magma product label bears the statement "Percent Daily Values are based on a 2,000 calorie diet." This statement is only permitted when the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein as required by 21 CFR 101.9(c) and 21 CFR 101.36(b)(2)(iii)(D).

o Your Bentonite Magma product label places the (b)(2)-dietary ingredients in an incorrect order which does not follow the order provided under 21 CFR 101.36(b)(2).

o Your Clear Spiro and Liu Jun Zi Tang products list dietary ingredients in the Supplement Facts labels along with additional text that is a further description of the dietary ingredient but in Latin terms. We note that the Latin binomial name of a botanical may be listed in parentheses following the standardized common name of a botanical consistent in accordance with 21 CFR 101.4.

o Your ProPhytogen Plus and Bentonite Magma product labels do not follow the format requirements under 21 CFR 101.36(e), such as the requirements for heavy bar placement.

You should take prompt action to correct the violations cited in this letter and prevent their future recurrence. Failure to promptly correct these violations may result in legal action without further notice. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products [21 U.S.C. §§ 332 and 334].

Please notify this office in writing within fifteen (15) working days from your receipt of this letter as to the specific steps you have taken to correct the violations noted above. Your response should include any documentation that would assist in evaluating your corrections. If you cannot complete all corrections within fifteen (15) working days, please explain the reason for the delay and the date by which the corrections will be completed.

Please direct your response to my attention at the address above. If you have any questions about the content of this letter you may contact Janice L. King, Compliance Officer, at 843-746-2990, X16 or by email at Janice.king@fda.hhs.gov (mailto:Janice.king@fda.hhs.gov).

Sincerely,
/S/
Ingrid A. Zambrana
District Director
U.S. Food & Drug Adminisration
FDA Atlanta District
Office of Human and Animal Foods- Division 3 East
(Georgia- North Carolina-South Carolina)
Office of Regulatory Affairs

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

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EXHIBIT 4

WARNING LETTER

Andropharm, LLC

MARCS-CMS 522784 — JUNE 05, 2017

Recipient:

Andropharm, LLC

United States

Issuing Office:

Dallas District Office

United States

Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204

June 5, 2017

CMS Case # 522784

WARNING LETTER

VIA UPS EXPRESS

Anthony J. Ventrella, President
AndroPharm LLC
1140 Holland Drive, Suite 12
Boca Raton, Florida 33487

Dear Mr. Ventrella:

This is to advise you that your firm's marketing and distribution of the products "Sten Z" and "M1 Alpha" violates the Federal Food, Drug, and Cosmetic Act (FD&C Act), as described below.

According to your product labels, your products contain the following ingredients:

- **Sten Z:** 2,17a-Dimethyl-17b-hydroxy-5a-androst-1-en-3-one and 17b-hydroxy-2a, 17b-dimethyl-5a-

androstan-3-one-azine

- **M1 Alpha:** Methyl-1-Etiocholenolol-Epietiocholanollone

"Sten Z" and "M1 Alpha" are represented as dietary supplements on their labels and other labeling; however, these products do not meet the definition of a dietary supplement in section 201(ff) of the FD&C Act [21 U.S.C. § 321(ff)]. To be a dietary supplement, a product must, among other things, "bear[ ] or contain[ ] one or more ... dietary ingredients" as defined in section 201(ff)(1) of the FD&C Act [21 U.S.C.§ 321(ff)(1)]. Section 201(ff)(1) defines "dietary ingredient" as a vitamin; mineral; amino acid; herb or other botanical; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of any dietary ingredient from the preceding categories.

The following ingredients listed on your product labels are synthetic steroids and do not constitute dietary ingredients under section 201(ff)(1) of the FD&C Act: 2,17a-Dimethyl-17b-hydroxy-5a-androst-1-en-3-one; 17b-hydroxy-2a, 17b-dimethyl-5a-androstan-3-one-azine; and methyl-1-etiocholenolol-epietiocholanollone. Therefore, because "Sten Z" and "M1 Alpha" do not bear or contain any dietary ingredients as defined in section 201(ff)(1) of the FD&C Act, the products are not dietary supplements under section 201(ff) of the FD&C Act.

Further, your product labels include claims about the effects of these products, such as the following:

Sten Z

- "Activate Numerous Anabolic Pathways"
- "Increase Muscle Mass"

M1 Alpha

- "Explosive Muscle & Strength Gains"
- "Highly Anabolic"

Under section 201(g)(1)(C) of the FD&C Act [21 U.S.C. § 321(g)(1)(C)], products (other than foods) that are intended to affect the structure or function of the body are defined as drugs. The intended use of a product may be determined by, among other things, its labeling, advertising, and the circumstances surrounding its distribution. 21 C.F.R. § 201.128. Your products are intended to affect the structure or function of the body by, among other things, building muscle and increasing strength. Accordingly, "Sten Z" and "M1 Alpha" are drugs.

Moreover, these products are "new drugs," as defined by section 201(p) of the FD&C Act [21 U.S.C. § 321 (p)], because they are not generally recognized as safe and effective for their labeled uses. The introduction or delivery for introduction, or causing the introduction or delivery for introduction, of any new drug lacking an FDA-approved new drug application (NDA) is a violation of sections 301(d) and 505(a) of the FD&C Act [21 U.S.C. §§ 33 1(d) and 355(a)]. Your sale of the new drugs "Sten Z" and "M1 Alpha" without approved NDAs violates these provisions of the FD&C Act.

Furthermore, your products are "prescription drugs" as defined at section 503(b)(1)(A) of the FD&C Act [21 U.S.C. § 353(b)(1)(A)], in that because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, it is not safe for use except under the supervision of a practitioner licensed by law to administer it. Indeed, all anabolic steroid drugs which have been approved for marketing by the FDA are limited by an approved new drug application to use under the professional supervision of a practitioner licensed by law to administer such drug. Anabolic steroids may cause serious long-term adverse health consequences in men, women, and children. These include liver toxicity, testicular atrophy and male infertility, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke.

According to section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)], a drug is misbranded if, among other things, it fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended. 21 C.F.R. § 201.5. Prescription drugs can only be used safely at the direction, and under the supervision, of a licensed practitioner. Therefore, it is impossible to write "adequate directions for use" for prescription drugs. FDA-approved drugs which bear their FDA-approved labeling are exempt from the requirement that they bear adequate directions for use by a layperson. But otherwise, all prescription drugs by definition lack adequate directions for use by a layperson. 21 U.S.C. § 352(f)(1); 21 U.S.C. § 353(b)(2).

In light of the fact that they are unapproved prescription drugs, the labeling of "Sten Z" and "M1 Alpha" fails to bear adequate directions for the products' intended uses; therefore, the products are misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)]. Because they

lack the required approved application, these drugs are not exempt from this requirement under 21 C.F.R. § 201.115. Therefore, the introduction or delivery for introduction, or causing the introduction or delivery for introduction, into interstate commerce of these misbranded products violates section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Furthermore, please advise this office what actions you will take to address product that you have already distributed. Additionally, if another firm manufactures the products identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the products is not the manufacturer, please include the name of your supplier in addition to the manufacturer. Your written notification should refer to the Warning Letter Number above (**CMS Case # 522784**).

Please address your reply to John W. Diehl, Acting Director, Compliance Branch at the FDA address provided on the first page of this letter. In addition, please submit a signed copy of your response on your firm's letterhead to john.diehl@fda.hhs.gov (mailto:john.diehl@fda.hhs.gov).

If you have questions regarding the contents of this letter, please contact John W. Diehl at (214) 253-5288.

Sincerely,
/S/
Monica R. Maxwell
Acting Program Division Director
Office of Pharmaceutical Quality Operations, Division II

CC:

Anthony J. Ventrella
9200 Rutledge Avenue
Boca Raton, Florida 33434

Anthony J. Ventrella
8583 Breezy Oak Way
Boynton Beach, Florida 33473

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

EXHIBIT 5

WARNING LETTER

Distributor RFR, LLC

MARCS-CMS 643724 — JANUARY 09, 2023

Delivery Method:

VIA Electronic Mail

Product:

Drugs

Recipient:

Mr. Roger L. Flores

Owner and Manager

Distributor RFR, LLC

3580 NW 85th Ct Apt 150
Doral, FL 33122-1986
United States

rfr.distributor@gmail.com (mailto:rfr.distributor@gmail.com)

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

WARNING LETTER

January 9, 2023

RE: 643724

Dear Mr. Flores:

The U.S. Food and Drug Administration (FDA) inspected your facility located in Doral, FL, on June 2-3, 7, 10, and 14, 2022. FDA obtained a sample and labeling of your product "SANGTER Natural Male Energy Supplement" (hereinafter "SANGTER Energy Supplement") during the inspection. We also reviewed your firm's website at www.sangter.com.

Based on the inspection and review of your product labeling, including your firm's website, FDA determined that "SANGTER Energy Supplement" is an unapproved new drug sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355(a) and 331(d). Furthermore, the

product is a misbranded drug under section 502 of the FD&C Act, 21 U.S.C. 352, and sold in violation of section 301(a) of the FD&C Act, 21 U.S.C. 331(a). As explained further below, introducing or delivering this product for introduction into interstate commerce violates the FD&C Act.

FDA confirmed through laboratory analysis that a sample of your product, "SANGTER Energy Supplement," contains the undeclared active pharmaceutical ingredient (API), sildenafil, which is a phosphodiesterase type-5 (PDE-5) inhibitor. Sildenafil is the active pharmaceutical ingredient in Viagra, an FDA-approved prescription drug used to treat erectile dysfunction (ED).[1]

Information on the labels and/or labeling of "SANGTER Energy Supplement" demonstrates that the sampled product is marketed as a dietary supplement. However, under section 201(ff)(3)(B)(i) of the FD&C Act, 21 U.S.C. 321(ff)(3)(B)(i), a dietary supplement may not include an article that is approved as a new drug under section 505 of the FD&C Act unless that article was marketed as a dietary supplement or food before its approval as a drug. FDA approved Viagra (containing sildenafil as the active ingredient) as a new drug on March 27, 1998. Prior to that date, sildenafil had not been marketed as a food or dietary supplement. Given that sildenafil was not marketed as a dietary supplement or as a food before Viagra was approved, "SANGTER Energy Supplement" is excluded from the definition of a dietary supplement under section 201(ff)(3)(B)(i) of the FD&C Act, 21 U.S.C. 321(ff)(3)(B)(i).

Unapproved New Drug

"SANGTER Energy Supplement" is a drug as defined by section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1) because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or intended to affect the structure or any function of the body.

Examples of claims observed on your website homepage, www.sangter.com, that establish the intended use of this product as a drug include, but may not be limited to, the following:

• "100% Natural Male Performance Booster"
• "Damiana (turnera diffusa) It is a plant known for its aphrodisiac qualities that help stimulate the sexual appetite or libido"
• "In just 30 minutes or less after consumption you will feel its effect, more energy, more sexual desire and more power."
• "Its main use applies to erectile dysfunction and low sexual desire, but it is also used against general weakness, painfulness, spontaneous sweat."

"SANGTER Energy Supplement" is not generally recognized as safe and effective for its above referenced uses and, therefore, is a "new drug" under section 201(p) of the FD&C Act, 21 U.S.C. 321(p). With certain exceptions not applicable here, a new drug may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a). There is no FDA-approved application in effect for "SANGTER Energy Supplement." Introduction or delivery of this product into interstate commerce without an approved application violates sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C. 355(a) and 331(d).

Misbranded Drug

"SANGTER Energy Supplement" is also misbranded under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), in that the labeling fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended, 21

C.F.R. 201.5. All PDE-5 inhibitors which have been approved for marketing by FDA are limited by an approved new drug application to use under the supervision of a practitioner licensed by law to administer such drugs. Prescription drugs can only be used safely at the direction and under the supervision of a licensed practitioner. "SANGTER Energy Supplement," which contains undeclared sildenafil, is also a prescription drug as defined in section 503(b)(1)(A) of the FD&C Act, 21 U.S.C. 353(b)(1)(A), in light of its toxicity or potential for harmful effects, methods of use, or collateral measures necessary for its use. Therefore, it is impossible to write "adequate directions for use" for prescription drugs, including "SANGTER Energy Supplement." "SANGTER Energy Supplement" is not exempt from the requirements that its labeling bear adequate directions for use by a layperson, 21 CFR 201.100(c)(2) and 201.115, because there is no FDA-approved application in effect for this product. For these reasons, "SANGTER Energy Supplement" is misbranded under section 502(f)(1) of the FD&C Act.

Additionally, "SANGTER Energy Supplement" is misbranded under section 502(a) of the FD&C Act, 21 U.S.C. 352(a). Under section 502(a) of the FD&C Act, 21 U.S.C. 352(a), a drug is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act, 21 U.S.C. 321(n), provides that, in determining whether an article's labeling or advertising "is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations." The labeling for "SANGTER Energy Supplement" does not declare that the product contains a PDE-5 inhibitor. The use of PDE-5 inhibitors can be associated with significant safety issues and the risk of serious adverse events. The undeclared PDE-5 inhibitors in "SANGTER Energy Supplement" may pose serious health risks because consumers with underlying medical issues may take the products without knowing that they can cause serious harm or interact in dangerous ways with other drugs they may be taking. For example, PDE-5 inhibitors may interact with nitrates found in some prescription drugs (such as nitroglycerin) and can lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, or heart disease often take nitrates. The failure to disclose this ingredient in the product's labeling renders "SANGTER Energy Supplement" misbranded under section 502(a) of the FD&C Act.

The undeclared sildenafil in "SANGTER Energy Supplement" also causes the product to be misbranded under section 502(f)(2) of the FD&C Act, 21 U.S.C. 352(f)(2), because the labeling lacks adequate warning for the protection of users. As previously noted, there is a potential for serious health risks associated with this product, particularly since anyone who takes these products would be unaware of the presence of the undeclared drug ingredient and placed at risk for the associated adverse events.

The introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of this misbranded drug is a prohibited act under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Conclusion

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your product. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure and injunction.

FDA acknowledges that on August 1, 2022, you initiated a voluntary nationwide recall of Lot #48656, Exp.

01/2025 of “SANGTER Energy Supplement,” 3000 mg, packaged in 7-count blister packs within a carton to the consumer level. We also acknowledge that you notified your customers of the recall by press release on August 2, 2022.

Please notify FDA in writing, within fifteen working days of receipt of this letter, of the specific steps you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations as well as copies of related documentation. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your response should be sent to U.S. Food and Drug Administration, Center for Drug Evaluation and Research/Office of Compliance/Office of Unapproved Drugs and Labeling Compliance by e-mail to FDAADVISORY@fda.hhs.gov.

Sincerely,
/S/

CAPT Tina Smith
Acting Director
Office of Unapproved Drugs and Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

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1 FDA has issued a warning to consumers not to use “SANGTER Energy Supplement.” U.S. Food & Drug Administration, *Public Notification: Sangter Natural Male Energy Supplement contains hidden drug ingredient*, (November 10, 2022), https://www.fda.gov/drugs/medication-health-fraud/public-notification-sangter-natural-male-energy-supplement-contains-hidden-drug-ingredient (https://www.fda.gov/drugs/medication-health-fraud/public-notification-sangter-natural-male-energy-supplement-contains-hidden-drug-ingredient).

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

EXHIBIT 6

WARNING LETTER

Umbrella

MARCS-CMS 612037 — MAY 18, 2021

Delivery Method:

SIGNATURE CONFIRMED DELIVERY

Product:

Dietary Supplements
Drugs

Recipient:

Brendan Mullins

Umbrella

3280 E. Hemisphere Loop, Suite 190
Tucson, AZ 85706
United States

Issuing Office:

Division of Pharmaceutical Quality Operations IV

United States

WARNING LETTER

May 18, 2021

Dear Mr. Mullins:

This letter is to advise you that the United States Food and Drug Administration (FDA) reviewed your website at the Internet address https://umbrella.us in November 2020 and again in February 2021 and has observed that this website directs consumers to your additional websites at the Internet addresses https://umbrellalabs.is, https://alphamaleplus.us, https://etanicals.us, and https://supplementor.com, which we also reviewed, and where you take orders for "Alpha Male Plus," "Red Vein Bali Kratom Powder Mitragyna Speciosa," "Red Ketapang Kratom Powder Mitragyna Speciosa," "Tianeptine Sodium Solution," "NACET Powder Nootropic," and numerous products marketed as selective androgen receptor modulators (SARMs), including but not limited to "GW-501516 Cardarine – 20 MG/ML," "MK-2866 Ostarine SARM – 20 MG/ML," "MK-677 Ibutamoren Nutrobal Powder," "RAD-140 Testolone," "S-4 Andarine SARM Powder," and "S-4 Andarine SARM 50 mg/mL." We also have reviewed your Facebook and Instagram social media websites at the

Internet addresses https://www.facebook.com/umbrellasarms and https://www.instagram.com/umbrella_labs_research/, respectively; these social media websites direct consumers to your website https://umbrellalabs.is/ to purchase your products. In addition, FDA has obtained a sample of and labeling for your product, "Alpha Male Plus," which is also referred to as "Alpha Male+" on your product labeling and on the website http://alphamaleplus.us. As described below, these products are unapproved new drugs sold in violation of sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. §§ 355(a) and 301(d)] and misbranded drugs sold in violation of sections 502 and 301(a) of the FD&C Act [21 U.S.C. §§ 352 and 331(a)].

"Alpha Male Plus"

FDA confirmed through laboratory analysis that a sample of your "Alpha Male Plus" contains the undeclared active pharmaceutical ingredient tadalafil, which is a phosphodiesterase type-5 (PDE-5) inhibitor. Tadalafil is the active ingredient in the FDA-approved prescription drug Cialis, used to treat erectile dysfunction. This undeclared ingredient may interact with nitrates found in some prescription drugs, such as nitroglycerin, and may lower blood pressure to dangerous levels. People with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

FDA has issued a warning to consumers not to use "Alpha Male Plus" (see Alpha Male Plus Immediate Public Notification https://www.fda.gov/drugs/medication-health-fraud/publicnotification-alpha-male-plus-contains-hidden-drug-ingredient).

"Alpha Male Plus," which you offer for sale on the website https://alphamaleplus.us, is labeled as a dietary supplement. However, under section 201(ff)(3)(B)(i) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)(i)], a dietary supplement may not include an article that is approved as a new drug under section 505 of the FD&C Act unless that article was marketed as a dietary supplement or food before its approval as a drug. FDA approved Cialis™ (containing tadalafil as the active ingredient) as a new drug on November 21, 2003. Given that tadalafil was not marketed as a dietary supplement or as a food before Cialis was approved, "Alpha Male Plus," which contains tadalafil, is excluded from the definition of a dietary supplement under section 201(ff)(3)(B)(i) of the FD&C Act.

We also note that your "Alpha Male Plus," which is labeled as a dietary supplement, bears directions for sublingual administration. However, the term "dietary supplement" is defined in section 201(ff)(2)(A)(i) of the FD&C Act [21 U.S.C. §§ 321(ff)(2)(A)(i)] as a product that is "intended for ingestion." Even if your "Alpha Male Plus" were not excluded from the definition of dietary supplement under section 201(ff)(3)(B)(i), because sublingual products are intended to enter the body directly through the skin or mucosal tissues, your "Alpha Male Plus" is excluded from the definition of a dietary supplement for this additional reason.

A list of tainted products marketed as dietary supplements discovered by FDA can be found at http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted_supplements_cder

"Alpha Male Plus" is a drug as defined by section 201(g)(1) of the FD&C Act [21 U.S.C. § 321(g)(1)] because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or intended to affect the structure or any function of the body. Examples of claims observed on your product labeling and website that establish the intended use of your product as a drug include, but may not be limited to, the following:

From the product label:

? “Alpha Male Plus is a male enhancement supplement that improves sexual performance as a truly unique natural solution for erectile dysfunction. . . .”

From the website https://alphamaleplus.us:

? “In simple terms, AMP(Alpha Male Plus) is a [sic] all natural, no prescription needed male enhancement supplement that improves sexual performance as well as proven natural solution for erectile dysfunction. . . . AlphaMale+ helps to improve performance & helps to prevent & slow erectile dysfunction. Has also been shown to help decrease prostate growth. . . .”

From the website https://alphamaleplus.us/alpha-strips.html:

? “Alpha Male Plus (AMP) is the most effective and advanced all-natural male enhancer available in todays [sic] market that is made from 100% natural sources . . . Put an end to premature ejaculation and erectile dysfunction with our safe, proven formula.”

Kratom Products

As previously noted, we have reviewed your website at https://etanicals.us and determined that you take orders there for kratom products, including but not limited to, “Red Vein Bali Kratom Powder Mitragyna Speciosa” and “Red Ketapang Kratom Powder.” Examples of claims observed on your website that establish the intended use of your kratom products as drugs include, but may not be limited to, the following:

“Red Vein Bali Kratom Powder Mitragyna Speciosa”

From the product webpage at https://etanicals.us/shop/kratom/red-ketapang-kratompowder-mitragyna-speciosa/:

? “Red Vein Bali Kratom Powder Mitragyna Speciosa . . . Aside from helping with anxiety, and depression, this superb strain induces alertness and clarity so you will be able to think straight when using our premium Red Vein Bali Kratom. Thanks to its sedative effects, you can finally get a good night’s sleep and if you are experiencing chronic pain, try using Red Vein Bali Kratom as it is also an excellent analgesic and a great muscle agent as well. Some say this strain conjointly helps with narcotic addiction withdrawal and attention deficit disorder. . . .”

“Red Ketapang Kratom Powder Mitragyna Speciosa”

From the product webpage at https://etanicals.us/shop/kratom/red-ketapang-kratompowder-mitragyna-speciosa/:

? “Red Ketapang kratom is known for its painkiller-like qualities. It is said to be useful for managing chronic pain and a sedative effect that can aid sleep. . . . For those withdrawing from opiates, kratom has shown some benefit. Some varieties of kratom work like a stimulant and can be used for focus. At higher doses, psychological states may be affected. . . .”

Nootropic Products

We have reviewed your website at https://supplementor.com and determined that you take orders there for “Tianeptine Sodium Solution” and “NACET Powder Nootropic.” Examples of claims observed on your website and Instagram social media website that establish the intended use of your “Tianeptine Sodium Solution” and “NACET Nootropic Powder” products as drugs include, but may not be limited to, the following:

“Tianeptine Sodium Solution”

From the product webpage at https://supplementor.com/online-store/Tianeptine-Sodium-Solution-50MG-ML-30ML-Bottle-Nootropic-p203879912:

? “Tianeptine Sodium Solution is a potent mood brightener and nootropic, celebrated for its effects on wellbeing and cognition, providing immediate and also long term benefits. Within an hour of use, it provides mental stability and clarity, functioning as a medium duration productivity tool. Additionally, its beneficial effects compound over extended use, resulting in a long-term effect which reduces feelings of stress, sadness and anxiety.”

“NACET Powder Nootropic”

From the product webpage at https://supplementor.com/online-store/NACET-POWDERNOOTROPIC-p166674568:

? “BUY NACET FOR COVID-19 PREPARATION & SYMPTOM MITIGATION . . . Dietary supplementation with NACET improves the bioavailability of NAC in tissue cells (i.e. lung tissue at risk of COVID-19 induced oxidative damage). . . . Increased antioxidant potential and defense from COVID-19 induced oxidation”

From your Instagram social media website https://www.instagram.com/p/B97lyUiHYqA/”

? From a March 19, 2020 post – “. . . [W]e have great news in regards to the Corona Virus. Have you checked out our Nacet Powder? If you haven't yet, did you know it will mitigate the symptoms of COVID-19? . . . Given the rapid spread and global pandemic status of COVID-19, health profesionals [sic] are increasingly focusing on disease mitigation rather [sic] than disease containment. With over 2,000 confirmed cases in the US spread across 47 states, your odds of contracting COVID-19 are rapidly rising. The safe bet now is to prepare to deal with infeciton [sic] rather than naively hoping to avoid it. Crucially, a large body of the primary research demonstrates that dietary supplementation with the potent antioxidant N-acetylcysteine (NAC) can inhibit RNA virus replication and reduce the severity of associated diseases. NAC is a simple amino acid who [sic] antioxidant power adn [sic] bioavailability can be dramatically improved by simple enzymatic modication [sic] to N-acetylcysteine ethyl ester (NACET). This modification of NAC permits unprecedented protection of your blood cells from oxidative damage, thus enabling your body's immune system to effectively defend your body from ravages of COVID-19 . . . Visit our website learn more and buy NACET POWDER! . . . www.UmbrellaLabs.is . . . #COVID_19 #CoronaVirus #COVID” accompanied by a video displaying the text “PREPARE & MITIGATE WITH,” images of “NACET Nootropic Powder” and virus particles and the text “COVID-19”

From your Instagram social media website https://www.instagram.com/p/B90ECHinoy0/:

? From a March 16, 2020 post - “With all the news about Corona Virus (COVID-19), the thoughts and worries are escalating quickly! It's time to take action and do what needs to be done to keep ourselves and our love ones protected! . . . Did you know . . . that dietary supplementation with NACET improves the bioavailability of NAC in tissue cells (i.e. lung tissue at risk of COVID-19 induced oxidative damage). . . . Boost your NAC levels and protect yourself from the worst symptoms of COVID-19! Visit our website and check out our BLOG to learn more! . . . www.UmbrellaLabs.is . . . #Corona #CoronaVirus #COVID . . .” accompanied by images of “NACET Powder Nootropic and virus particles with the text “COVID-19” and “PROTECT YOURSELF”

As noted here, we observed that your website https://supplementor.is offers “NACET Powder Nootropic,” a

product that is intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people.[1] Furthermore, FDA has warned consumers (https://www.fda.gov/food/dietarysupplement-products-ingredients/tianeptine-dietary-supplements) about products containing tianeptine, which is used as a prescription drug in some European, Asian, and Latin American countries, but is not approved as a drug in the United States. The FDA is aware of several serious adverse event reports associated with tianeptine. Further, consumers may find themselves addicted to tianeptine.

Selective Androgen Receptor Modulators (SARMs)

We have reviewed your website at https://umbrellalabs.is and determined that you take orders there for numerous products marketed as SARMS including, but not limited to, "GW-501516 Cardarine – 20 MG/ML," "MK-2866 Ostarine SARM – 20 MG/ML," "MK-677 Ibutamoren Nutrobal Powder," "RAD-140 Testolone," "S-4 Andarine SARM Powder" and "S-4 Andarine SARM 50 mg/mL" (hereinafter collectively referred to as SARMs products).

FDA has safety concerns about products that contain SARMs (Selective Androgen Receptor Modulators). Life-threatening reactions, including liver toxicity, have occurred in people taking products containing SARMs. SARMs also have the potential to increase the risk of heart attack and stroke. Despite statements on your website and product labels marketing your SARMs products for "RESEARCH USE ONLY" and "Not for Human Consumption," evidence obtained from your website and social media websites establish that your products are intended to be drugs for human use. Examples of claims observed on your website that establish the intended use of your SARMs products as drugs intended for human use include, but may not be limited to, the following:

From the website https://umbrellalabs.is/best-place-to-buy-sarms-in-2021/: December 24, 2020 blog page titled "BEST PLACE TO BUY SARMS IN 2021":

? "There are many reasons why you may be considering adding Selective Androgen Receptor Modulators (SARMs) to your health and well routine. As we get older, the natural aging process can catalyze many changes to our psychological processes. You might notice that your muscles aren't as solid as they used to be, and your bones are feeling frailer. You may also find that your energy levels have dipped. Many of these concerns and challenges are linked back to a decline in testosterone levels, which can affect both men and women. The best SARMs on the market work to replenish those levels, helping you build stronger bones and muscles over time."

? "SARMS VS ANABOLIC STEROIDS[,] SARMs are unique compounds widely used as a form of testosterone therapy and replacement. . . . Unlike steroids, SARMs only activate the androgen receptors in your bone and muscle tissues, rather than generating a full-body response. This helps to protect the tissues in your prostate and cardiovascular system. As SARMs do not contain the same molecular ring structure as steroids, they are not classified as such. . . . As such, it's specially positioned to address a range of health conditions, including breast cancer. The premise behind this mechanism is simple: Targeted tissues will respond to SARMs in a similar way as they would to testosterone or another anabolic steroid. However, other tissues that my produce undesirable side effects if targeted are not triggered. This allows you to receive many of the same benefits as conventional testosterone therapy, without incurring many of the associated risks."

? "UNIQUE BENEFITS FOR WOMEN[,] Women who suffer from low testosterone might find that steroid therapies leave them feeling unfeminine, with a deeper voice than they're [sic] normal. This is one of the unique benefits of SARMs. These supplements are tissue-specific, focusing on your bones along with your muscles. This means they only raise testosterone levels there, rather than amplifying them throughout your

body. This is excellent news for women, who are more likely than men to develop osteoporosis as they age. . . . By undergoing SARMs therapy, women and men alike can take a targeted approach to strengthening their bones and muscles together."

? "WHERE CAN I FIND THE BEST SARMS?[,] . . . Before you begin your quest, take the time to consider why you're looking to buy SARMs in the first place. Which particular ailments are you looking to address? Will these SARMS be for your personal use or are you looking to help a loved one who has tried traditional therapies in the past to no avail? Once you know the answers to these questions, you can begin to look for the specific kinds of SARMs you need to address your particular pain points. In our online store, we offer a variety of SARM compounds in liquid and powder form . . . You can learn more about each product and discover more by browsing our online shop." The words "online shop" are hyperlinked and direct consumers to the product page on your website https://umbrellalabs.is/online-store/SARMs-c33887656 where your SARMs products are available for purchase.

From the website https://umbrellalabs.is/a-practical-guide-to-sublingual-absorption/: September 21, 2020 blog page titled "A PRACTICAL GUIDE TO SUBLINGUAL ABSORPTION":

? "The goal of sublingual absorption is to get substances (i.e. SARMs) into systemic circulation and delivered to target organs (i.e. muscles and bones) without first passing through the liver. . . . Every substance this absorbed in the gastrointestinal tract passes through the liver before it gets distributed throughout the body. To bypass this "first-pass effect", follow these steps:

o Step 1. Using the dropper, measure your Poly-Cell Formula and deposit it under your tongue.

o Step 2. Leave it under your tongue for 1-2 minutes without swallowing. Keep your head tilted slightly back to prevent saliva from pooling in your mouth.

o Step 3. After 1-2 minutes, you can swallow to clear out your mouth, but avoid drinking anything for at least 10 minutes in order to swallow any residual Poly-Cell Formula to fully absorb in your mouth, throat and upper esophagus. . . .

Poly-Cell Formula Products

o GW 501516 CARDARINE

o RAD-140 TESTOLONE SARM. . ."

Your Facebook and Instagram pages also contain evidence of intended use in the form of personal testimonials recommending or describing the use of SARM products for use in affecting the structure or function of the body of humans. Examples of such testimonials, which are endorsed or promoted by Umbrella Labs, include:

From your Facebook social media website https://www.facebook.com/umbrellasarms:

? From an October 7, 2020 post - Umbrella Labs "liked" the following comment made on your post advertising "RAD-140 Testolone": "Rad 140 works for me, my muscles became firm and larger at around the 4th -6th week"

? From an August 19, 2020 post - Umbrella Labs "liked" the following comments made in response to your post advertising your various SARM products:

o "I bought mk677 and rad 140. You need to see my transformation in less than 30 days . . ."

o "Was on . . . rad140, . . . 1 andro, ostarine. Gained 13 lbs in 6 weeks. Looking to put that muscle on again . . ."

From your Instagram social media website https://www.instagram.com/p/CDq88DpHDZa/:

? From an August 9, 2020 post – Learn more: https://UmbrellaLabs.is . . . #Bulking . . . #GYM . . . #Bodybuilding . . . #Bodybuilder #SARMs . . . #WorkOut . . . SARM Stack" and display an image with the text "REVIEWS . . . I've only used the liquids. I'm 5 weeks in and have went [sic] from 191 lbs to 206 lbs. These products make you feel like you are in your 20s. I'm using very small doses and reaping huge benefits. Try . . . GW-501516, . . . and mk-677. . . . I can shovel dirt, and chop wood all day and still have energy for yoga and kettlebells."

Unapproved New Drugs

Your "Alpha Male Plus," "Red Vein Bali Kratom Powder Mitragyna Speciosa," "Red Ketapang Kratom Powder Mitragyna Speciosa," "Tianeptine Sodium Solution," "NACET Powder Nootropic," and SARMs products are not generally recognized as safe and effective for the above referenced uses and, therefore are "new drugs" under section 201(p) of the FD&C Act [21 U.S.C. § 321(p)]. As previously stated, new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the FD&C Act [21 U.S.C. §§ 331(d) and 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective. No approved applications pursuant to section 505 of the FD&C Act [21 U.S.C. § 355] are in effect for these products. Accordingly, the introduction or delivery for introduction into interstate commerce of these products violates sections 301(d) and 505(a) of the FD&C Act [21 U.S.C. §§ 331(d) and 355(a)].

Misbranded Drugs

In addition, your "Alpha Male Plus," "Red Vein Bali Kratom Powder Mitragyna Speciosa" "Red Ketapang Kratom Powder Mitragyna Speciosa," "NACET Powder Nootropic," "GW-501516 Cardarine – 20MG/ML," "MK-2866 Ostarine SARM – 20MG/ML," "MK-677 Ibutamoren Nutrobal Powder," "RAD-140 Testolone," "S-4 Andarine SARM Powder,"and "S-4 Andarine SARM 50 mg/mL" products are also misbranded within the meaning of section 502(f)(1) of the FD&C Act [21 U.S.C. § 352(f)(1)], in that their labeling fails to bear adequate directions for use. "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended. (See 21 CFR 201.5) The aforementioned products are prescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act [21 U.S.C. § 353(b)(1)(A)] because they are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. FDA-approved prescription drugs that bear their FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson. However, your products are not exempt from the requirement that their labeling bear adequate directions for use, 21 CFR 201.100(c)(2) and 201.115, because no FDA-approved applications are in effect for them.

Additionally, under section 502(a) of the FD&C Act [21 U.S.C. § 352(a)], a drug is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the FD&C Act [21 U.S.C. § 321(n)], provides that, in determining whether an article's labeling or advertising "is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in light of such representations . . .." The labeling for "Alpha Male Plus" does not declare that it contains tadalafil. The failure to disclose the presence of tadalafil in the product's labeling renders "Alpha Male Plus" misbranded under section 502(a) of the FD&C Act. The presence of undeclared PDE-5 inhibitors contained in your product may pose serious health risks because consumers with underlying medical issues may take this product without knowing that it can cause serious harm or interact in dangerous ways with other drugs they may be taking. Those consumers who have been advised against taking PDE-5 inhibitors because of comorbidities or potential drug interactions may seek products like "Alpha Male Plus" because it is

not labeled as containing PDE-5 inhibitors.

The undeclared tadalafil in “Alpha Male Plus” also causes this product to be misbranded under section 502(f)(2) of the FD&C Act [21 U.S.C. § 352(f)(2)] in that the product’s labeling lacks adequate warnings for the protection of users. As previously noted, there is potential for adverse events associated with the use of PDE-5 inhibitors. Consumers who use “Alpha Male Plus” would be unaware of the presence of the undeclared drug ingredient and placed at risk for its associated adverse events.

The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates section 301(a) of the FD&C Act [21 U.S.C. § 331(a)].

Conclusion

This letter is not intended to be an all-inclusive statement of violations that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

This letter notifies you of our concerns and provides you an opportunity to address them. Failure to adequately address this matter may result in legal action including, without limitation, seizure and injunction.

Please notify FDA in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to address any violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective actions within 15 working days, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

Your response should refer to unique identifier CMS 612037 and be sent electronically to ORAPHARM4_Responses@fda.hhs.gov or mailed to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food and Drug Administration
19701 Fairchild Road
Irvine, CA 92612

If you have any questions regarding this letter, please contact LCDR Rumany Penn, Compliance Officer, at (301) 633-6789, or by email at Rumany.Penn@fda.hhs.gov.

Sincerely,
/S/

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

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1 There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2). The disease caused by the virus has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, the Department of Health and Human

Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS. Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx. In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19. Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://trumpwhitehouse.archives.gov/presidentialactions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

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