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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

ThermoLife International, LLC, an Arizona limited liability company, Plaintiff, v. American Fitness Wholesalers, L.L.C., doing business as A1Supplements, a Tennessee corporation, Defendant.	Case No. **COMPLAINT** (Jury Trial Demanded)

For its Complaint against defendant American Fitness Wholesalers, L.L.C., doing business as A1Supplements ("A1"), ThermoLife alleges as follows:

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NATURE OF ACTION

1. Plaintiff ThermoLife International, LLC ("ThermoLife") brings claims against its competitor, A1, for false advertising, common law unfair competition, false patent marking, and civil conspiracy. Unfairly competing with ThermoLife in the Dietary Supplement market, A1 has willfully falsely advertised and sold aromatase inhibitors[1], anabolic steroids[2], and illegal and unsafe drug stimulants[3] as Dietary Supplements. A1 has deceived consumers on a massive scale into believing that ingredients which the Food and Drug Administration ("FDA") has determined are drugs, are legal, natural, and safe in Dietary Supplements. The truth is, however, **the falsely labeled and falsely advertised products sold by A1 are not Dietary Supplements and they are not safe, not natural, and not legal for sale.**

2. Competition in the Dietary Supplement industry is fierce, with each company seeking to discover and market the next breakthrough product that will help build muscle, increase performance, and/or decrease fat. Faced with stiff competition, A1 has sought to boost sales by illegally selling products falsely labeled as Dietary Supplements that actually contain ingredients that are aromatase inhibitors, anabolic steroids, and illegal and unsafe drug stimulants. None of the products that contain these ingredients are legal for sale as Dietary Supplements.

3. Worse still, in many of the products A1 falsely advertises and sells on its website[4], the illegal drug stimulant ingredients are not even listed on the product label.

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[1] The ingredients in this category include Arimistane (which is an aromatase inhibitor); in 2010, the FDA determined that "products containing aromatase inhibitors have a reasonable probability of resulting in permanent impairment of body structure or function in at risk consumers."

[2] The ingredients in this category include 1-DHEA and 4-DHEA (prohormones that convert to testosterone or testosterone derivatives in the body) and other prohormone and pro-steroid ingredients. The FDA has determined that 1-DHEA and 4-DHEA are not legal for use in Dietary Supplements and any product that include these ingredients is "misbranded as a food and/or drug."

[3] The ingredients in this category include: BMPEA, DMAA, DMHA, DMBA, and Methylsynephrine. These ingredients have all been deemed drugs by the FDA.

[4] A1 has sold all of the products identified herein within the past 2 years.

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Instead, the label falsely lists what has become known in the industry as a "botanical cover."[5] As a direct result of A1's willful false advertising, the consumer has no way of knowing the serious health risk they are taking.

4. Contrary to A1's false advertising, the FDA has concluded that the aromatase inhibitors, anabolic steroids, and the illegal drug stimulants in the products that are the subject of this suit are unsafe, misbranded, adulterated, and/or drugs that are illegal for sale in Dietary Supplements. A1's advertising of these drug ingredients as Dietary Supplements is false on its face and poses a serious health risk to consumers.

5. A1 has flooded the market with unsafe products that are not compliant with the Dietary Supplement Health and Education Act of 1994 ("DSHEA") or that are otherwise illegal for sale as Dietary Supplements. While recently the FDA has brought several enforcement actions against companies that are marketing drug ingredients in Dietary Supplements, the FDA is simply overwhelmed by the number of manufacturers, sellers, and products.

6. ThermoLife is able to protect its commercial interests where the FDA is unable to fully protect public health in the Dietary Supplement industry. In *ThermoLife International, LLC v. Gaspari Nutrition, Inc.*, 648 F. Appx 609, 612 (9th Cir. 2016), the Ninth Circuit Court of Appeals held that, "Lanham Act claims like ThermoLife's protect commercial interests by relying on the market expertise of competitors."

7. ThermoLife brings this action to enjoin A1 from continuing to falsely market the unsafe and illegal products identified herein. ThermoLife also seeks to recover for the competitive injury that A1 has proximately caused to ThermoLife's business through its false advertising, false marking, unfair competition and unlawful

[5] Botanical covers are plant names that are listed in a supplement facts panel to hide the drugs that are actually included in the product. The use of the botanical cover allows unscrupulous marketers of Dietary Supplements to claim that the drug(s) that are found in the product come from a botanical source; but none of the drug compounds listed in this Complaint actually include any natural material sourced from a botanical. All of the drug compounds discussed herein are 100% synthetic, yet falsely listed and/or advertised as botanicals or botanical extracts (botanical covers).

activity. While falsely advertising illegal and unsafe drug ingredients in "Dietary Supplements", A1 has also falsely marketed products as relying on patented technologies, when in fact the products are not licensed to practice any patented invention (if they were, they would need a license from ThermoLife to practice ThermoLife's patented technology). A1 must be stopped from continuing to profit from false and misleading statements, and any profit that A1 has already earned from this misconduct must be disgorged and exemplary damages imposed.

PARTIES, JURISDICTION AND VENUE

8. Plaintiff ThermoLife is an Arizona limited liability company with its principal place of business in Phoenix, Arizona.

9. Defendant American Fitness Wholesalers, L.L.C., doing business as A1Supplements ("A1") is a Tennessee limited liability company with its principal place of business in Louisville, Tennessee. A1 markets and distributes Dietary Supplements throughout the United States, including in Arizona. Its interactive website, A1supplements.com, offers for sale and sells the products at issue to Arizona customers and it ships products to such customers. A1 falsely advertises to Arizona customers and unfairly competes with ThermoLife in the state. Personal jurisdiction exists under Arizona's long-arm statute.

10. The Court has jurisdiction over Plaintiff's federal claims under 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331 and 1338(a). This Court has jurisdiction over Plaintiff's state law claims based on 28 U.S.C. §§ 1338(b) and 1367.

11. Venue is proper in this district under 28 U.S.C. § 1391(b)-(c), because a substantial part of the events or omissions giving rise to ThermoLife's claims occurred in this district. Venue with respect to A1 is also proper in this district because A1 is subject to personal jurisdiction in this district.

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FACTUAL ALLEGATIONS

THERMOLIFE

12. Ron Kramer ("Kramer") founded ThermoLife in 1998. Prior to founding ThermoLife, Kramer opened and operated a Gold's Gym in Santa Cruz, California.

13. In 1998, Kramer founded ThermoLife in order to provide the public with quality proven supplements.

14. ThermoLife currently holds 23 separate and distinct patents that protect its innovative development and use of ingredients in Dietary Supplements and food products.

15. ThermoLife holds several patents related to the use of amino acids combined with nitrates to increase athletic performance. For example, ThermoLife's U.S. Patent No. 8,178,572 protects and covers "a method for increasing the vasodilative characteristics of amino acids in a human, the method comprising administering orally to the human a pharmaceutically effective amount of an amino acid compound consisting essentially of a nitrate of an amino acid selected from the group consisting of Arginine, Agmatine, Beta Alanine, Citrulline, Creatine, Glutamine, L-Histidine, Isoleucine, Leucine, Norvaline, Ornithine, and Valine."

16. ThermoLife holds at least 14 of its patents with more than 450 claims related to novel uses of these Amino Acid/nitrate compounds and compositions in Dietary Supplements and food products.

17. With few exceptions, anytime an amino acid is combined with nitrate(s) and sold and marketed to consumers the product relies on ThermoLife's patented technology.

18. ThermoLife's patented creatine nitrate has proven exceedingly popular in the Dietary Supplement market.

19. Creatine is sold in many forms and has been used to promote muscle mass in individuals for decades. Creatine nitrate is a new form of creatine where the creatine molecule is ionically bound to a nitrate ion. Among its other benefits, the bonding of the

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creatine with the nitrate increases the solubility of the compound, which is beneficial for use in Dietary Supplements.

20. ThermoLife licenses and sells its patented creatine nitrate for use in Dietary Supplement products.

21. Sourced and licensed from ThermoLife, creatine nitrate and other Amino Acid Nitrates supplied by ThermoLife are included in many of the top-selling Dietary Supplements in the world.

22. These ingredients are sought after by consumers of Dietary Supplements looking to gain muscle and increase athletic performance or improve physical appearance. The "Sports Nutrition" category of Dietary Supplements caters to this subset of Dietary Supplement consumers.

23. As just one example, ThermoLife's creatine nitrate is the marquee ingredient in the world's top-selling pre-workout product: Cellucor's C4.

24. As a result of ThermoLife's Nitrates' popularity in the Sports Supplements market, ThermoLife's business is tied to the performance of Sports Nutrition products that rely on ThermoLife's patented technologies.

25. ThermoLife is harmed when consumers are misled into purchasing any falsely advertised product that competes[6] with any product that contains ingredients that are sourced from ThermoLife and/or products that are licensed by ThermoLife.

26. ThermoLife is harmed when consumers are misled into believing that one or more of A1's products are patented.

27. ThermoLife has an identifiable economic interest in the Dietary Supplement market, including the Sports Nutrition segment.

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[6] In fact, none of the products identified in this Complaint should have ever competed in the marketplace with any ThermoLife product or ThermoLife sourced product; none of the products listed here are "Dietary Supplements." All of the products are falsely labeled and illegal for sale as "Dietary Supplements" as each product listed here contains one or more drug ingredients rendering the product that contains the ingredient(s) adulterated, misbranded, and by law unsafe. Any revenue earned from the sale of these illegal products is ill-gotten gains and must be disgorged.

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A1SUPPLEMENTS.COM

28. A1 sells Dietary Supplements wholesale to consumers over the internet.

29. The United States Government, through the Food and Drug Administration and the Department of Justice has repeatedly made clear that Dietary Supplement product wholesalers and resellers, like A1, are responsible for the advertising on their website and the legality of the products they sell. As just one example, in 2012, criminal charges were filed against BodyBuildling.com, LLC and its former officers, for selling "misbranded drugs" labeled as Dietary Supplements. The charges arose from Bodybuilding.com, LLC's sale of five products, manufactured by other companies, that actually contained drugs. Bodybuilding.com and its former President eventually plead guilty to these criminal charges. In addition to pleading guilty to criminal charges the former President was also ordered to personally pay a $600,000 fine for his part in the criminal activity and Bodybuilding.com was fined $7,000,000.00 (twice the $3.5 million dollars of misbranded products they sold). Several other companies involved also plead guilty to corporate felonies for introduction and delivery for introduction of misbranded drugs into interstate commerce, with the intent to mislead and defraud. A1's activities are no different here; except, while Bodybuilding.com was guilty of selling just five misbranded products, A1 has marked and sold an unbelievable 142 number of products that contain drugs and are misbranded when labeled as Dietary Supplements.

30. A1 advertises that it is "the world's leading wholesale seller of Dietary Supplements."

31. According to A1, it is "America's Favorite Supplement Store."

32. When consumers visit A1's website, the website recommends certain supplements based on the sex, age, and goal of the specific customers.[7]

33. Every Dietary Supplement that A1 offers and sells is promoted on A1's website.

34. Upon information and belief, A1 places ads for each specific product on its

[7] A1's website recommends products for use by teen males.

own website. Those ads tout the benefits of each of the Dietary Supplements that A1 sells.

35. As the leading wholesaler of Dietary Supplements, A1's advertising content provides credibility for the products that are sold through its website where consumers believe that only legal and safe products can be sold.

36. Upon information and belief, when consumers view an advertisement on A1's website they understand that A1 is promoting: the use of that product as a Dietary Supplement; that the Dietary Supplement is legal for sale; and that the Dietary Supplement is safe.

37. Every page of A1's website includes the following disclaimer: "FDA: 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." As explained below, for the products identified below, this statement is false on its face. In fact, the FDA has evaluated the regulatory status, legality, and safety of the ingredients listed in this law suit and included in the products listed below and the FDA has determined that all of the products listed below contain ingredients that are drugs and/or are not legal for sale as Dietary Supplements because they are adulterated, misbranded, and unsafe.

38. A1's website also includes several products that contain ingredients and technology sourced and/or licensed from ThermoLife. For example, A1 lists "C4", which includes creatine nitrate, sourced and licensed from ThermoLife, as its top-selling Pre-Workout.

39. While A1 sells and markets several products that include patented creatine nitrate sourced from ThermoLife, A1 has sold many creatine nitrate products that are not sourced from ThermoLife. For example, A1's website falsely advertises its APS Nutrition "Creatine Nitrate" product as including "a vastly superior patented creatine [referring to creatine nitrate]." But this APS product does not include a "patented creatine", the patented creatine nitrate in this product is not sourced from ThermoLife.

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40. A1's false advertising of the APS "Creatine Nitrate" product is obvious, but that just the tip of the iceberg. Each of the products discussed below contains ingredients that are classified as drugs that are illegal for sale as Dietary Supplements. Yet each product listed below is falsely advertised by A1 as a Dietary Supplement. Accordingly, A1 makes specific product claims about each of these products that are blatantly false.

41. One of the top-selling companies on A1's website is Hi-Tech Pharmaceuticals ("Hi-Tech").[8] On or about September 28, 2017, the United States Attorney's Office for the Northern District of Georgia filed a First Superseding Criminal Indictment against defendants Hi-Tech, its Chief Executive Officer, Jared Wheat, and another Hi-Tech executive. *United States v. Hi-Tech Pharmaceuticals, et al.*, No.1:17-CR-0229 (N.D. Ga. 2017). The defendants are charged with 18 felony counts, including introducing misbranded products into interstate commerce.

THE ILLEGAL DIETARY SUPPLEMENT INGREDIENTS

42. While A1's false statements are readily identifiable as false on their own, a brief summary of the rules and regulations that govern the sale and marketing of Dietary Supplements is informative.

43. Congress determined which ingredients can be used in Dietary Supplements when it passed DSHEA in 1994.

44. In 21 U.S.C. § 321(ff), DSHEA defines "Dietary Supplements" as follows:

> The term "Dietary Supplement"—
> (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
> (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary

[8] Hi-Tech also does business using names including the following: ALR Industries, APS Nutrition, Innovative Laboratories, Formutech Nutrition, LG Sciences, iForce Nutrition, Top Secret Nutrition, Prime Nutrition, Blackstone Labs, Nature's Essentials, Genone Laboratories, Advanced Muscle Science, and Sports 1.

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> intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
> (2) means a product that—
> (A) (i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or (ii) complies with section 350(c)(1)(B)(ii) of this title;
> (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
> (C) is labeled as a Dietary Supplement; and
> (3) does—
> (A) include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification, or license, marketed as a Dietary Supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a Dietary Supplement under the conditions of use and dosages set forth in the labeling for such Dietary Supplement, is unlawful under section 342(f) of this title; and
> (B) not include—
> (i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or
> (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a Dietary Supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

45. Because there is no approval process for Dietary Supplements, prior to selling any product as a Dietary Supplement it is the seller's responsibility to ensure that the product complies with Federal Regulations, especially 21 U.S.C. § 321(ff).

46. Accordingly, 21 U.S.C. § 321 (ff)(3)(B)(i) specifically prohibits the use of any article approved as a drug from being included in a Dietary Supplement, and 21 U.S.C. § 321(ff)(3)(B)(ii) specifically prohibits the use in Dietary Supplements of "any

article authorized for investigation as a new drug, for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public."

47. As the FDA has explained many times, declaring a product a "Dietary Supplement" that includes ingredients on the label that are not in compliance with section 321(ff) "causes product[s] marketed as Dietary Supplements to be misbranded under 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false and misleading in any particular."

48. While 21 U.S.C. § 321(ff) defines what type of ingredients can and cannot be included in a "Dietary Supplement", 21 U.S.C. § 331 describes prohibited acts.

49. 21 U.S.C. § 331(a) prohibits "the introduction or delivery for introduction into interstate commerce any food [or] drug … that is adulterated or misbranded."

50. 21 U.S.C. § 331(ll) bars the sale of any "food[9] to which has been added a drug" in interstate commerce that includes any approved drug, or any ingredient upon which a "substantial clinical investigation has been instituted and made public." Products that contain a substance that has been authorized for investigation as a new drug are outside the definition of a Dietary Supplement set forth in 21 U.S.C. § 321(ff).

51. And, as discussed below, products that are adulterated under 21 U.S.C. § 350b are considered unsafe and prohibited from being sold in interstate commerce under 21 U.S.C. § 331(v).

52. 21 U.S.C. § 331(d) also bars the "introduction or delivery for introduction into interstate commerce" of any new drug that does not have the requisite FDA approval.

53. The FDA has declared time and time again, under 21 U.S.C. § 350b, Dietary Supplements are deemed "adulterated" under 21 U.S.C. § 342(f), and not legal

[9] Under 21 U.S.C. § 321(ff)(3)(B)(iii), Dietary Supplements are a sub-category of foods: "Dietary Supplement shall be deemed to be a food within the meaning of this Act."

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for sale, unless all of the ingredients included in the Dietary Supplement meet one of the following two requirements:

> (i) the dietary supplement contains only dietary ingredients that have been present in the food supply [since 1994] as an article used for food in a form in which the food has not been chemically altered; or
>
> (ii) there is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

54. The FDA has also declared that unless a new dietary ingredient ("NDI") has a history of use establishing safety (and a New Dietary Ingredient Notification ("NDIN") is submitted)[10], a product that includes the new dietary ingredient is deemed adulterated under 21 U.S.C. §§ 342(f)(1), 350b and prohibited for sale in interstate commerce under 21 U.S.C. § 331(a) and (v). As the FDA has explained in numerous warning letters:

> In the absence of a history of use or other evidence of safety establishing … when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, [a Dietary Supplement] is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)] because it contains a new dietary ingredient for which there is inadequate information

[10] As the FDA's website explains, "The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that manufacturers and distributors who wish to market Dietary Supplements that contain 'new dietary ingredients' notify the Food and Drug Administration about these ingredients." This notification must take place 75 days before the NDI is sold and the notification must provide sufficient documentation to establish that, "[t]here is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the Dietary Supplement will reasonably be expected to be safe." 21 U.S.C. § 350(b).

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> to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such product into interstate commerce is prohibited under section 301(a) and (v) of the Act [21 U.S.C. §§ 331(a) and (v)].

55. The FDA's website warns customers about the prevalence of "Fraudulent Dietary Supplements":

> Federal regulators continue to warn consumers about tainted, dangerous products that are marketed as Dietary Supplements. These fraudulent products can cause serious injury or even death.
>
> The Food and Drug Administration (FDA) has found nearly 300 fraudulent products—promoted mainly for weight loss, sexual enhancement, and bodybuilding—that contain hidden or deceptively labeled ingredients, such as
>
> - the active ingredients in FDA-approved drugs or their analogs (closely-related drugs)
> - other compounds, such as novel synthetic steroids, that do not qualify as dietary ingredients
>
> "These products are masquerading as Dietary Supplements—they may look like Dietary Supplements but they are not legal Dietary Supplements," says Michael Levy, director of FDA's Division of New Drugs and Labeling Compliance. "Some of these products contain hidden prescription ingredients at levels much higher than those found in an approved drug product and are dangerous."
>
> FDA has received numerous reports of harm associated with the use of these products, including stroke, liver injury, kidney failure, heart palpitations, and death.

56. The products A1 sells, identified below, are specific examples of the "Fraudulent Dietary Supplements" that the FDA has warned consumers about. A1 falsely advertises these products as Dietary Supplements. The ingredients found in these falsely advertised products have serious side effects and/or pose a significant risk even when taken by healthy individuals, yet A1's false advertising of these illegal, unsafe, and forbidden products as "Dietary Supplements" leads consumers to believe that these

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products contain ingredients that are safe, natural, and legal, when they are not. And, despite the fact that all of the ingredients identified herein are 100% synthetic drug ingredients that are manufactured in factories in China, A1 falsely advertises the products that incorporate these ingredients as "natural."

57. Each of the 142 products falsely advertised and falsely labeled as a Dietary Supplement identified herein contain ingredients that are properly classified as one or more of the following: (1) drugs under 21 U.S.C. §§ 321(g), 321(p), & 355; or (2) a New Dietary Ingredients (NDIs) for which a history of safety has not been established and which have not gone through the proper regulatory pre-market notification process to prove the ingredient will be safe if used as directed (New Dietary Ingredient Notification) under 21 U.S.C. §§ 342(f)(1)(B) & 350b. Accordingly, any product that contains any of these ingredients is "adulterated" and/or "misbranded."

"BOTANICAL COVERS"

58. In order to hide the inclusion of drugs in the products sold on A1's website, A1 falsely advertises exotic and/or obscure botanical ingredients in the supplement facts panels of the products it sells. However, the exotic and/or obscure botanical ingredients are not actually included in the product. The botanical names are only listed to hide the presence of illegal, synthetic drug ingredients. This deceptive practice has become known as "botanical covers."

59. In order to deceive consumers, A1 and its partners list exotic and/or obscure botanical ingredients on their product labels. But, in reality, the products do not contain any of the exotic and/or obscure botanical ingredients, instead the products actually include synthetic stimulant drugs, which A1 and its partners then claim are present in extremely minuscule amounts[11] in the exotic and/or obscure botanicals listed on the label (but are included in unsafe drug doses in the products). In some cases, A1 and its partners claim that the drugs they put in the products they sell are only found in

[11] The manufacturers of these products that actually contain drugs, assert exotic botanicals contain constituents of known drugs in quantities of only a few parts per billion.

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some species of the exotic and/or obscure botanicals listed on the product label. This deceptive tactic makes it very difficult for the FDA to prove that the miniscule constituents that A1 and its partners claim are part of the exotic and/or obscure botanical are not actually included in the exotic and/or obscure botanicals that are falsely listed on the product labels in this complaint. Nonetheless, all the drug ingredients falsely advertised as botanical dietary ingredients in this complaint are illegal for sale in Dietary Supplements.

60. Acacia rigidula and Senegalia berlandieri are botanical covers listed on product labels sold by A1. These are species of shrubs native to the Southern United States and Central Mexico, yet all the alleged Acacia rigidula and Senegalia berlandieri ingredients used in the products sold by A1 are synthetically made in factories in China.

61. "Geranium extract" or "Geranium oil" is another botanical cover listed on the product labels sold by A1. When "Geranium" of any sort is listed as an ingredient in the falsely labeled Dietary Supplement products discussed here, not even 1mg of geranium extract from a botanical is actually included in any of the products. Instead, synthetic DMAA, an ingredient the FDA and the courts have determined is an illegal and unsafe drug stimulant (described below) is included in the product(s).

62. When Acacia rigidula, Geranium extract, or Senegalia berlandieri are listed in the Supplement Facts panels of the Dietary Supplement products discussed here, there is not actually any Acacia rigidula, Geranium extract, or Senegalia berlandieri included in the product. Instead, the product includes one or more of the illegal drug stimulants identified below.

63. The FDA has recently gotten wise to this scheme. On March 7, 2016, the FDA officially declared that Acacia rigidula (the real plant material)—even if it were used in these products—is not legal for use in Dietary Supplements.

64. On March 7, 2016, the FDA issued warning letters to six companies regarding a total of six products for which the product labeling lists Acacia rigidula (A. rigidula) as a dietary ingredient.

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65. The FDA considers these products to be adulterated because they contain a New Dietary Ingredient for which a history of safety has not been established. As the FDA explained, to a company marketing and selling a product that listed A. rigidula on the product label:

> To the best of FDA's knowledge, there is no information demonstrating that A. rigidula was lawfully marketed as a dietary ingredient in the United States before October 15, 1994, nor is there information demonstrating that this ingredient has been present in the food supply as an article used for human food in a form in which the food has not been chemically altered. In the absence of such information, A. rigidula is subject to the notification requirement in section 413(a)(2) of the Act [21 U.S.C. § 350b(a)(2)] and 21 CFR 190.6. Because the required notification has not been submitted, your product is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)]. Even if the required notification had been submitted, we know of no evidence that would establish that your product is not adulterated. In the absence of a history of use or other evidence of safety establishing that A. rigidula, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, "NGN NATURAL generation nutrition ZXT2" is adulterated under sections 402(f)(1)(B) and 413(a) of the Act [21 U.S.C. §§ 342(f)(1)(B) and 350b(a)] because it contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such product into interstate commerce is prohibited under section 301(a) and (v) of the Act [21 U.S.C. § 331(a) and (v)]. To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that A. rigidula will reasonably be expected to be safe when used as a dietary ingredient.

66. Accordingly, while none of the products identified below actually include any plant material from Acacia rigidula (even though it is listed on the label), the FDA has already determined that Acacia rigidula is not legal for use in Dietary Supplements.

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THE ILLEGAL DRUG STIMULANTS SOLD AND FALSELY ADVERTISED AS DIETARY SUPPLEMENTS BY A1

I. DMAA

A. DMAA IS A DRUG

67. Several of the dangerous and illegal products sold and falsely advertised on A1's website includes the drug ingredient 1,3-dimethylamylamine, methylhexanamine, more commonly known as DMAA.

68. In order to mask the presence of DMAA in Dietary Supplement products, A1 sells products that A1 deceitfully advertises on its website as including "geranium extract" or "Geranabrun (geranium oil extract)", when in fact the product includes a synthetic drug.[12]

69. As explained above, geranium extract is a botanical cover that is not actually included in these products. Instead, the synthetic material DMAA, which is a drug that is manufactured in a factory in China, is included in the product.

70. The FDA has approved DMAA as a "drug." As such, DMAA does not meet the definition of a dietary ingredient and can never be included in a Dietary Supplement under 21 U.S.C. § 321(ff). Accordingly, any product labeled as a Dietary Supplement that includes the ingredient DMAA on the label is "misbranded" under 21 U.S.C. § 343(a)(1) because: listing a drug (DMAA) as an ingredient in the supplement facts panel of a Dietary Supplement constitutes "misbranding" "in that the labeling is false and misleading in any particular"; a drug (DMAA) is not, and cannot be, a dietary ingredient, thus any Dietary Supplement label that lists DMAA as a dietary ingredient is both false and misleading, therefore, any product that lists DMAA on the label is misbranded. Likewise, any product labeled as a Dietary Supplement that contains the

[12] Some of the products on A1's website do in fact list 1,3-dimethylamylamine as an ingredient in the product, but the product write-ups and other advertising by A1 for these products all suggest that the material is sourced from a botanical, not synthesized in a factory in China.

drug ingredient DMAA is "adulterated" under 21 U.S.C. §§ 342(f)(1)(b) and 350b because DMAA (even if it could be a Dietary Ingredient) is a New Dietary Ingredient (NDI) that (as a drug) has not, and cannot pass the long checklist of regulatory and safety requirements for a New Dietary Ingredient to become compliant, and legal for use in a Dietary Supplement. Accordingly, misbranded and adulterated products, like those that include the drug DMAA, cannot be sold in interstate commerce under 21 U.S.C. § 331(a), which prohibits "the introduction or delivery for introduction into interstate commerce any food [or] drug … that is adulterated or misbranded." Furthermore, because DMAA is "adulterated" under 21 U.S.C § 350b, any product that contains DMAA is, by law, unsafe and prohibited for sale under 21 U.S.C. § 331(v), which prohibits "the introduction or delivery for introduction into interstate commerce of a Dietary Supplement that is unsafe under section 350b of this title." Finally, because DMAA is an approved drug, for which substantial clinical trials have been conducted and made public, it can never be a dietary ingredient under 21 U.S.C. §§ 321(ff)(3)(B)(i) and 321(ff)(3)(B)(ii). For this reason as well, any product that includes DMAA is also prohibited for sale in interstate commerce as a Dietary Supplement under 21 U.S.C. § 331(ll), which prohibits "the introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 355 of this title, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public."

71. Starting in 1944, Eli Lilly developed and patented DMAA and used it as an ingredient in a nasal decongestant.

72. In 1948, Eli Lilly introduced DMAA as the active ingredient in the Forthane® inhaler.

73. Eli Lilly sold Forthane, containing DMAA, until the 1980s. Several serious adverse drug reactions were reported, which were directly attributable to DMAA. In 1983, at the request of Eli Lilly, the FDA withdrew Forthane's approval.

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74. Because DMAA was marketed and sold as a drug, and removed from the market due to its serious side effects, there is a long list of known possible series adverse reactions from DMAA. These include: Insomnia, Headaches, Tremor, Shortness of Breath, Panic Attacks, Heat Stroke, Increased Blood Pressure (significant), Hypertension (in normal individuals), Increased Heart Rate, Increased Rate Pressure Product (Cardiac Hemodynamic Stress), Tachycardia, Cardiac Dysrhythmia (Irregular Heartbeat), Chest Pain, Seizures, Convulsions, Heat Stroke, Heart Attack, Cerebral Hemorrhage (Stroke), Acute Liver Injury and Failure, Rhabdomyolysis, Renal Injury, Nervous System and Psychiatric Disorders, and, last but not least, Sudden Death.

75. In April 2012, the FDA issued several Warning Letters to the manufacturers of products that included DMAA.

76. These warning letters informed Dietary Supplement companies that:

> DMAA does not qualify as a dietary ingredient under section 201(ff)(1) of the Act because it is not a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any aforementioned substance.

77. In a warning letter addressed to the manufacture of a product that included DMAA, the FDA also stated: "DMAA was approved as a drug in 1948 under section 505 of the Act and, to the best of the FDA's knowledge, was not marketed in food prior to such approval."

78. Since 2012, the FDA has continued to send companies that manufacture and sell DMAA related products warning letters. The FDA has ordered the destruction of thousands of products that illegally included DMAA and it has also seized products that incorporate this illegal ingredient.

79. In a press release, dated July 16, 2013, the FDA stated: "Dietary Supplements containing DMAA are illegal and the FDA is doing everything within its authority to remove these products from the market. In 2012, the FDA issued warning letters to companies notifying them products with DMAA need to be taken off the

market or reformulated to remove this substance. Most companies warned are no longer distributing products with DMAA. While the FDA is working to get these products off the market, consumers should not buy or use any Dietary Supplement product containing DMAA."

80. In mid-2013, the FDA seized over $2,000,000.00 in DMAA-products that were manufactured and sold by one of A1's top-selling companies: Hi-Tech Pharmaceuticals ("Hi-Tech").

81. On November 6, 2013, a Complaint for Forfeiture was filed in United States District Court for the Northern District of Georgia by the United States of America alleging that all of Hi-Tech's products containing DMAA were illegal for sale in the United States.

82. On April 3, 2017, the District Court entered summary judgment against Hi-Tech. The court's order "find[s] that DMAA is not a botanical and thus not a dietary ingredient." *United States v. Quantities of All Articles of Finished and In-process Foods*, 2017 WL 4456903, *3 (N.D. Ga. Apr. 3, 2017). The District Court subsequently denied Hi-Tech's motion for reconsideration. 2017 WL 4475940 (N.D. Ga. June 2, 2017).

83. DMAA is banned for use by athletes by the World Anti-Doping Agency ("WADA"). None of the products listed in this Complaint contain a warning that the ingredient is banned by the WADA, the NCAA, Olympics, and other legitimate sports organizations.

84. DMAA is known to cause individuals to fail drug tests by testing positive for amphetamines. None of the products listed in this Complaint include a warning that they can cause a false positive for recreational drugs.

85. DMAA cannot legally be included in any Dietary Supplement, ever, because it has been "approved as a new drug." *See* 21 U.S.C. § 321(ff)(3)(B)(i) (Dietary Supplements may not include "an article that is approved as a new drug").

86. DMAA can also never be legally included in any "Dietary Supplement" because DMAA is "an article authorized for investigation as a new drug, antibiotic, or

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biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public." *See* 21 U.S.C. § 321(ff)(3)(B)(ii).

87. And finally, as stated above, any product that includes DMAA cannot be sold as a "Dietary Supplement." Any product labeled as a "Dietary Supplement" that includes DMAA is:

- misbranded under 21 U.S.C. § 343(a)(1);
- adulterated under 21 U.S.C. § 342(f)(1)(b);
- not legal for sale as a Dietary Supplement under 21 U.S.C. § 331(a) (because it is adulterated and misbranded);
- unsafe and adulterated under 21 U.S.C. § 350(b);
- prohibited for sale under 21 U.S.C. § 331(v); and
- not legal for sale because it includes an article approved as a drug for which clinical trials have been made public under 21 U.S.C. § 331(ll).

88. Any product that includes DMAA cannot reasonably be expected to be "safe." DMAA is not safe.

89. In addition, the labels and advertising for products that contain DMAA falsely represent to consumers that the statements made on the label have not been evaluated by the FDA. In truth, the FDA has evaluated DMAA and determined that DMAA is a drug and that products labeled as Dietary Supplements that contain DMAA are not safe, and not legal for sale as Dietary Supplements.

B. A1's FALSE ADVERTISING OF DMAA PRODUCTS

90. In direct violation of federal law, A1 marketed and sold products labeled as Dietary Supplements that included DMAA, which competed directly with products sourced from ThermoLife.

91. These products include the following[13]:

[13] Screen shots from A1's website establishing A1's false marketing of these supplements are attached as Exhibit A. Exhibit A includes advertising for most of the 142 products identified in this Complaint.

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LG Sciences	Adipokinetix
Innovative Laboratories	Black Mamba Hyper Rush
Hi-Tech Pharmaceuticals	Black Piranha
Hi-Tech Pharmaceuticals	Black Widow
Chaos and Pain	Cannibal Riot
iForce Nutrition	Dexaprine
Innovative Laboratories	Diablos ECA Fire Caps
Innovative Laboratories	Diablos Hyperburn V-10
In Vitro Labs	Dragon Fire
Blackstone Labs	Dust Extreme
Greymark Pharmaceuticals	DynaDrene
NICWL/Hi-Tech Pharmaceuticals	ECA Xtreme
Delta Health Products	EPH 100
Prime Nutrition	EXO-13
Hi-Tech Pharmaceuticals	Fastin
Centurion Labz	God of Rage
Centurion Labz	God of Rage XXX
Innovative Laboratories	HellFire
Hi-Tech Pharmaceuticals	HydroxyElite
Hi-Tech Pharmaceuticals	Jack'D Up
Blackstone Labs	King Cobra
Xcel Sports Nutrition (XLSN)	Kranked Pre-Workout
Hi-Tech Pharmaceuticals	Lipodrene Elite
Hi-Tech Pharmaceuticals	Lipodrene Ephedra
Hi-Tech Pharmaceuticals	Lipodrene Hardcore Ephedra
Hi-Tech Pharmaceuticals	Lipodrene Xtreme
APS Nutrition (APS)	Mesomorph
Cloma Pharma Laboratories	Methyldrene Elite
Cloma Pharma Laboratories	Methyldrene EPH
CTD Sports	Noxipro
Hi-Tech Pharmaceuticals	Off the Chain
APS Nutrition (APS)	Phenadrine
Prime Nutrition	PWO-Max
Serious Nutrition Solutions (SNS)	Rapid Fire Take 2
Prime Nutrition	Redux
Hi-Tech Pharmaceuticals	Stimerex Hardcore
Hi-Tech Pharmaceuticals	Stimerex-ES Ephedra
Gaspari Nutrition	SuperPump 250
Hi-Tech Pharmaceuticals	Synadrene
Hi-Tech Pharmaceuticals	Ultimate Orange
ALR Industries (ALRI)	Viper Hyperdrive 5.0

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Product Manufacturer	Product Name
APS Nutrition (APS)	White Lightning
Innovative Laboratories	Wicked
Hi-Tech Pharmaceuticals	Yellow Scorpion
APS Nutrition (APS)	Yellow Thunder

92. All of the products listed above include the drug ingredient DMAA, yet all of the products have been sold and falsely marketed on A1's website as Dietary Supplements.

93. A1's website includes numerous false and material claims about DMAA and the products A1 sells that include DMAA.

94. As one example, on its website, A1 includes an article titled "DMAA's Descent into Legal Hell." Shockingly, this article documents the FDA's efforts to enforce the law by seizing DMAA products. As the article notes, "Based on the FDA warning letters, one would assume that DMAA would be illegal. … The FDA has clearly stated that DMAA is not safe."

95. After acknowledging that, according to the FDA, DMAA is not legal for use in Dietary Supplements because it is not safe, A1 then proceeds to explain that one Dietary Supplement manufacture, Hi-Tech, asserts that DMAA is legal. A1 then further notes that Hi-Tech is involved in a lawsuit with the FDA after the FDA seized over $2,000,000.00 worth of Hi-Tech's DMAA products (referring to the forfeiture case discussed above).

96. The article concludes noting, "Most of you reading this couldn't give a rip about DMAA's legality, you're just concerned with what it does or how it feels following ingestion." The article then goes on to tout the alleged benefits of taking this illegal ingredient.

97. Despite knowing that DMAA is a drug ingredient not legal for sale in a Dietary Supplement, A1 made the conscious decision to profit from its false marketing of DMAA products as Dietary Supplements. Critically, every single reputable Dietary Supplement seller has pulled DMAA products from its offerings.

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98. By marketing DMAA (a drug) as an ingredient in "Dietary Supplements" on A1supplements.com, "America's Favorite Supplement Store", A1 has created a serious health risk to consumers. The labels and advertising for the DMAA products falsely represent to consumers that the statements made have not been evaluated by the FDA, but, in fact, the FDA has determined that: DMAA is not a dietary ingredient; products labeled as Dietary Supplements that contain DMAA are illegal; products labeled as Dietary Supplements that include DMAA are not safe; and DMAA is a drug that is illegal for sale in Dietary Supplements. Motivated by greed, A1 made the conscious decision to profit from its false marketing of the DMAA products identified above. To do so, A1 has made false and material representations to consumers regarding DMAA and intentionally misled consumers to believe that when the products A1 sells include DMAA, the ingredient DMAA: (1) has not been evaluated by the FDA; (2) is legal for sale in a Dietary Supplement; (3) is safe; (4) is natural; and (5) is a Dietary Ingredient.

99. Accordingly, A1's intentionally mislabeled, misbranded, adulterated, unsafe, illegal, and falsely advertised products that contain the drug ingredient DMAA should never have been in the marketplace, nor entitled to any sales. Any revenue earned from the sale of these misbranded, adulterated, unsafe, and illegal products is ill-gotten gains and must be disgorged.

II. DMHA

A. DMHA IS A DRUG

100. Several products sold and advertised on A1's website include the drug ingredient: 2-amino-6-methylheptane, 6-methyl-2-heptanamine, 1,5-dimethylhexylamine, and 2-aminoisoheptane. These synonyms for this ingredient are all commonly referred to as DMHA.

101. In order to mask the presence of DMHA in Dietary Supplement products, many of the products that A1 sells include this drug ingredient deceitfully listed as a botanical (botanical cover) on their product labels.

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102. Here, the botanical cover is either Juglans Regia Extract (Walnut Bark), Aconitum Kusnezoffii Extract, or Kigelia Africana Extract. None of those herbs are included in any of the products identified here; instead, the synthetic material DMHA, which is a drug manufactured in a factory in China, is included in the product(s).

103. The FDA has approved DMHA as a "drug." As such, DMHA does not meet the definition of a dietary ingredient and can never be included in a Dietary Supplement under 21 U.S.C. § 321(ff). Accordingly, any product labeled as a Dietary Supplement that includes the ingredient DMHA on the label is "misbranded" under 21 U.S.C. § 343(a)(1) because: listing a drug (DMHA) as an ingredient in the supplement facts panel of a Dietary Supplement constitutes "misbranding" "in that the labeling is false and misleading in any particular"; a drug (DMHA) is not, and cannot be, a dietary ingredient, thus any Dietary Supplement label that lists DMHA as a dietary ingredient is both false and misleading, therefore, any product that lists DMHA on the label is misbranded. Likewise, any product labeled as a Dietary Supplement that contains the drug ingredient DMHA is "adulterated" under 21 U.S.C. §§ 342(f)(1)(b) and 350b because DMHA (even if it could be a Dietary Ingredient) is a New Dietary Ingredient (NDI) that (as a drug) has not, and cannot pass the long checklist of regulatory and safety requirements for a New Dietary Ingredient to become compliant, and legal for use in a Dietary Supplement. Accordingly, misbranded and adulterated products, like those that include the drug DMHA, cannot be sold in interstate commerce under U.S.C. 21 § 331(a), which prohibits "the introduction or delivery for introduction into interstate commerce any food [or] drug … that is adulterated or misbranded." Furthermore, because DMHA is "adulterated" under 21 U.S.C. § 350b, any product that contains DMHA is, by law, unsafe and prohibited for sale under 21 U.S.C. § 331(v), which prohibits "the introduction or delivery for introduction into interstate commerce of a Dietary Supplement that is unsafe under section 350b of this title." Finally, because DMHA is an approved drug, for which substantial clinical trials have been conducted and made public, it can never be a dietary ingredient under 21 U.S.C. §§ 321(ff)(3)(B)(i)

and 321(ff)(3)(B)(ii). For this reason as well, any product that includes DMHA is also prohibited for sale in interstate commerce as a Dietary Supplement under 21 U.S.C. § 331(ll), which prohibits "the introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 355 of this title, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public."

104. The FDA approved DMHA as a new drug in 1946 for use by nasal administration. The drug company Smith, Kline, and French introduced DMHA as the active ingredient in the Eskay® Oralator inhaler.

105. In 2017, Australia banned the sale of DMHA over the counter.

106. Like DMAA, because of DMHA's prior extensive use as an approved drug, we know it has several potential very serious adverse side effects, including: Insomnia, Headaches, Shortness of Breath, Panic Attacks, Tremor, Increased Blood Pressure), Increased Heart Rate, Increased Rate Pressure Product (Cardiac Hemodynamic Stress), Tachycardia, Cardiac Dysrhythmia (Irregular Heartbeat), Chest Pain, Heat Stroke, Heart Attack, Cerebral Hemorrhage (Stroke), Acute Liver Injury and Failure, Rhabdomyolysis, and Renal Injury.

107. DMHA is banned for use by athletes by the WADA. None of the products contain a warning that the ingredient is banned by the WADA, the NCAA, Olympics, and other legitimate sports organizations.

108. Also, like DMAA, DMHA cannot legally be included in any Dietary Supplement, ever, because DMHA has been "approved as a new drug." *See* 21 U.S.C. § 321(ff)(3)(B)(i) (Dietary Supplements may not include "an article that is approved as a new drug").

109. DMHA can also never be legally included in any "Dietary Supplement" because DMHA is "an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for

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which the existence of such investigations has been made public." *See* 21 U.S.C. § 321(ff)(3)(B)(ii).

110. And finally, as stated above, any product that includes DMHA cannot be sold as a "Dietary Supplement." Any product labeled as a "Dietary Supplement" that includes DMHA is:

- misbranded under 21 U.S.C. § 343(a)(1);
- adulterated under 21 U.S.C. § 342(f)(1)(b);
- not legal for sale as a Dietary Supplement under 21 U.S.C. § 331(a) (because it is "adulterated" and "misbranded");
- unsafe and adulterated under 21 U.S.C. § 350(b);
- prohibited for sale under 21 U.S.C. § 331(v); and
- not legal for sale because it includes an article approved as a drug for which clinical trials have been made public under 21 U.S.C. § 331(ll).

111. Any product that includes DMHA cannot reasonably be expected to be "safe." DMHA is not safe.

112. In addition, the labels and advertising for products that contain DMHA falsely represent to consumers that the statements made on the label have not been evaluated by the FDA. In truth, the FDA has evaluated DMHA and determined that DMHA is a drug. Accordingly, products labeled as Dietary Supplements that contain DMHA are not safe, and not legal for sale as Dietary Supplements.

B. A1's FALSE ADVERTISING OF DMHA PRODUCTS

113. In direct violation of federal law, A1 has marketed and sold products labeled as Dietary Supplements that contain DMHA, which compete directly with products sourced from ThermoLife.

114. These products include the following:

Product Manufacturer	Product Name
Condemned Labz	Arsyn
Olympus Labs	Bloodshr3d
Repp Sports	Broken Arrow

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Product Manufacturer	Product Name
Chaos and Pain	Cannibal Riot
Steel Supplements	Charged-AF
Condemned Labz	Convict
Xcel Sports Nutrition (XLSN)	Crackhead Xtreme Pre-Workout
Redcon1	Double Tap
In Vitro Labs	Dragon Fire
Blackstone Labs	Dust Extreme
Inspired Nutraceuticals	DVST8 Crimson
Inspired Nutraceuticals	DVST8 White Cut
Metabolic Nutrition	E.S.P. Extreme
InnovaPharm	Enduralean
Killer Labz	Executioner
Prime Nutrition	EXO-13
Killer Labz	Exterminator
Man Sports	Game Day
Sparta Nutrition	Hydra Shred
Hi-Tech Pharmaceuticals	HydroxyElite
Olympus Labs	Ignit3
Inspired Nutraceuticals	KOR
Sparta Nutrition	Kraken
InnovaPharm	Limitless
Outbreak Nutrition	Pathogen
ANS Performance	Rave
Repp Sports	Raze
Olympus Labs	Re1gn
Repp Sports	Reactr
Outbreak Nutrition	Reclaim
Iron Addicts	Sidewalk Kraka
Hi-Tech Pharmaceuticals	Synadrene
Metabolic Nutrition	Synedrex
Redcon1	Total War
GoldStar	Triple X
GoldStar	Viper
Iron Addicts	Will Power

115. All of the products listed above include the drug ingredient DMHA, yet all of the products have been sold and falsely marketed on A1's website as Dietary Supplements.

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116. A1's website includes numerous false and material claims about DMHA and the products A1 sells that include DMHA.

117. As one example, on its website, in its advertisement for "Kraken", A1 states: "Not many stimulants can par up with banned ingredients, but when you combine power of Eria Jarensis with DMHA, you have an unparalleled stimulant matrix." Obviously, this statement is false, since the drug DMHA is in fact prohibited for use in Dietary Supplements.

118. In its advertisement for "Triple X" (another DMHA product), A1 states, "2-Aminoisoheptane (DMHA) is the new replacement after the FDA's removal of DMAA from the marketplace. It is an EXTREME stimulant, and has effects very similar to 1,3 Dimethyamylamine. Triple X is currently the ONLY pre-workout with this crazy energy enhancing ingredient, and it may not be out for long if the FDA gets wind of it, so try it today!" Again, A1's advertising statement is false because DMHA is a drug that is prohibited for use in Dietary Supplements.

119. In its advertisement for "Killer Labz Executioner", which includes DMHA, A1 touts the product as, "Strongest Legal Pre-Workouts Available on Market!" DMHA though, as A1 knows, is a drug, and is not a "Legal Pre-Workout" product.

120. Despite knowing that DMHA is a drug ingredient not legal for sale in a Dietary Supplement, A1 made the conscious decision to profit from its false marketing of DMHA products as Dietary Supplements.

121. By marketing DMHA (a drug) as an ingredient in "Dietary Supplements" on A1supplements.com, "America's Favorite Supplement Store", A1 has created a serious health risk to consumers. The labels and advertising for the DMHA products falsely represent to consumers that the statements made have not been evaluated by the FDA, but, in fact, the FDA has determined that DMHA is a drug. Accordingly, products that include DMHA are not safe and products that contain DMHA are illegal for sale as Dietary Supplements. Motivated by greed, A1 made the conscious decision to profit from its false marketing of the DMHA products identified above. To do so, A1 has made

false and material representations to consumers regarding DMHA and intentionally misled consumers to believe that when the products A1 sells include DMHA, the ingredient DMHA: (1) has not been evaluated by the FDA; (2) is legal for sale in a Dietary Supplement; (3) is safe; (4) is natural; and (5) is a Dietary Ingredient.

122. Accordingly, A1's intentionally mislabeled, misbranded, adulterated, unsafe, illegal, and falsely advertised products that contain the drug ingredient DMHA should never have been in the marketplace, nor entitled to any sales. Any revenue earned from the sale of these misbranded, adulterated, unsafe, and illegal products is ill-gotten gains and must be disgorged.

IV. BMPEA

A. BMPEA IS A DRUG

123. Several products sold and advertised on A1's website include the ingredient: beta-methyl-phenylethylamine, beta-methylphenethylamine, R-beta-methylphenylethylamine. These synonyms for this ingredient are more commonly known as "BMPEA."

124. In order to mask the presence of BMPEA in Dietary Supplement products, many of the products that A1 sells include this drug ingredient deceitfully listed as a botanical (botanical cover) on their product labels.

125. Here, the botanical cover is either Acacia rigidula or Senegalia berlandieri. Neither of these plant materials is included in any of the products identified here; instead, the synthetic material BMPEA, which is a drug manufactured in a factory in China, is included in the product.

126. The FDA has determined that BMPEA is not a dietary ingredient. As such, BMPEA can never be included in a Dietary Supplement under 21 U.S.C. § 321(ff). Accordingly, any product labeled as a Dietary Supplement that includes the ingredient BMPEA on the label is "misbranded" under 21 U.S.C. § 343(a)(1) because: listing a drug (BMPEA) as an ingredient in the supplement facts panel of a Dietary Supplement constitutes "misbranding" "in that the labeling is false and misleading in any particular";

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a drug (BMPEA) is not, and cannot be, a dietary ingredient, thus any Dietary Supplement label that lists BMPEA as a dietary ingredient is both false and misleading, therefore, any product that lists BMPEA on the label is misbranded. Likewise, any product labeled as a Dietary Supplement that contains the drug BMPEA is "adulterated" under 21 U.S.C. §§ 342(f)(1)(b) and 350b because BMPEA (even if it could be a Dietary Ingredient) is a New Dietary Ingredient (NDI) that has not, and cannot pass the long checklist of regulatory, and safety requirements for a New Dietary Ingredient to become compliant, and legal for use in a Dietary Supplement. Accordingly, misbranded and adulterated products, like those that include the drug BMPEA, cannot be sold in interstate commerce under U.S.C. 21 § 331(a), which prohibits "the introduction or delivery for introduction into interstate commerce any food [or] drug, that is adulterated or misbranded." Finally, because BMPEA is "adulterated" under 21 U.S.C § 350b, any product that contains BMPEA is, by law, unsafe and prohibited for sale under 21 U.S.C. § 331(v), which prohibits "the introduction or delivery for introduction into interstate commerce of a Dietary Supplement that is unsafe under section 350b of this title." The FDA has conclusively determined that BMPEA is not legal for sale in Dietary Supplements. It has sent warning letters to at least seven different companies that market and sell Dietary Supplements that include this ingredient.

127. As just one example, in an April 22, 2015 warning letter to Better Body Sports, LLC, the FDA unequivocally stated, "BMPEA is not a dietary ingredient." Continuing, the FDA noted, "Declaring BMPEA in your product labeling as a dietary ingredient causes your product marketed as Dietary Supplement to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular." Any misbranded product cannot be sold in commerce under 21 U.S.C. § 331(a)(1).

128. And finally, as stated above, any product that includes BMPEA cannot be sold as a "Dietary Supplement." Any product labeled as a "Dietary Supplement" that includes BMPEA is:

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- misbranded under 21 U.S.C. § 343(a)(1);
- adulterated under 21 U.S.C. § 342(f)(1)(b);
- not legal for sale as a Dietary Supplement under 21 U.S.C. § 331(a) (because it is adulterated and misbranded);
- unsafe and adulterated under 21 U.S.C. § 350(b);
- prohibited for sale under 21 U.S.C. § 331(v); and
- not permitted for sale in interstate commerce under 21 U.S.C. § 331(d).

129. Any product that includes BMPEA cannot reasonably be expected to be "safe." BMPEA is not safe.

130. In addition, the labels and advertising for products that contain BMPEA falsely represent to consumers that the statements made on the label have not been evaluated by the FDA. In truth, the FDA has evaluated BMPEA and determined that BMPEA is not a dietary ingredient and that products labeled as Dietary Supplements that contain BMPEA are not safe, and not legal for sale as Dietary Supplements.

B. A1'S FALSE ADVERTISING OF BMPEA PRODUCTS

131. In direct violation of federal law, A1 continues to market and sell pre-workout products labeled as Dietary Supplements that contain BMPEA, which compete directly with products sourced from ThermoLife.

132. These products include the following:

Product Manufacturer	Product Name
Hi-Tech Pharmaceuticals	Adderex SR
Chaos and Pain	Cannibal Ferox
Cloma Pharma Laboratories	China White
NICWL/Hi-Tech Pharmaceuticals	ECA Xtreme
Schwartz Labs	Green Stinger
CTD Sports	Hyper Cuts
Hi-Tech Pharmaceuticals	Lipodrene
Hi-Tech Pharmaceuticals	Lipodrene Hardcore
Hi-Tech Pharmaceuticals	Lipodrene Xtreme
Hi-Tech Pharmaceuticals	N.O. Overload

Product Manufacturer	Product Name
CTD Sports	Noxipro
APS Nutrition (APS)	Phenadrine
Cloma Pharma Laboratories	Razzadrene
Lecheek Nutrition	Speed X3
Hi-Tech Pharmaceuticals	Stimerex Hardcore
Hi-Tech Pharmaceuticals	Stimerex-ES EPH
iForce Nutrition	Thermoxyn
Schwartz Labs	Ultimate Burn
Prosupps	Vanish
ALR Industries (ALRI)	Viper Hyperdrive
ALR Industries (ALRI)	Viper Hyperdrive 5.0
Hi-Tech Pharmaceuticals	Yellow Scorpion
APS Nutrition (APS)	Yellow Thunder

133. All of the products listed above include the drug ingredient BMPEA, yet all of the products have been sold and falsely marketed on A1's website as Dietary Supplements.

134. A1's website includes numerous false and material claims about BMPEA and the products A1 sells that include BMPEA.

135. Despite knowing that BMPEA is not legal for sale as a Dietary Supplement, A1 made the conscious decision to profit from its false marketing of BMPEA products as Dietary Supplements.

136. By marketing BMPEA as an ingredient in "Dietary Supplements" on A1supplements.com, "America's Favorite Supplement Store", A1 has created a serious health risk to consumers. The labels and advertising for the BMPEA products falsely represent to consumers that the statements made have not been evaluated by the FDA, but, in fact, the FDA has determined that BMPEA is not a dietary ingredient and that products that contain BMPEA are misbranded. Motivated by greed, A1 made the conscious decision to profit from its false marketing of the BMPEA products identified above. To do so, A1 has made false and material representations to consumers regarding BMPEA and intentionally misled consumers to believe that when the products A1 sells

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include BMPEA, the ingredient BMPEA: (1) has not been evaluated by the FDA; (2) is legal for sale in a Dietary Supplement; (3) is safe; (4) is natural; and (5) is a Dietary Ingredient.

137. Accordingly, A1's intentionally mislabeled, misbranded, adulterated, unsafe, illegal, and falsely advertised products that contain the drug ingredient BMPEA should never have been in the marketplace, nor entitled to any sales. Any revenue earned from the sale of these misbranded, adulterated, unsafe, and illegal products is ill-gotten gains and must be disgorged.

V. METHYLSYNEPHRINE

A. METHYLSYNEPHRINE IS A DRUG

138. Several products sold and advertised on A1's website include the ingredient: oxilofrine, oxyfrine, oxyephedrine, and 4-[1-hydroxy-2(methylaminoprpyl)phenol. These synonyms for this ingredient are referred to herein as "Methylsynephrine." Methylsynephrine is also known also as Suprifen or Carnigen.

139. In order to mask the presence of Methylsynephrine in Dietary Supplement products, many of the products that A1 sells include this drug ingredient deceitfully listed as a botanical (botanical cover) on their product labels.

140. Here, the botanical cover is either Acacia rigidula or Senegalia berlandieri. Neither of these plant materials is included in any of the products identified here; instead, the synthetic material Methylsynephrine, which is a drug manufactured in a factory in China, is included in the product.

141. The FDA has determined that Methylsynephrine is not a dietary ingredient. As such, Methylsynephrine can never be included in a Dietary Supplement under 21 U.S.C. § 321(ff). Accordingly, any product labeled as a Dietary Supplement that includes the ingredient Methylsynephrine on the label is "misbranded" under 21 U.S.C. § 343(a)(1) because: listing a drug (Methylsynephrine) as an ingredient in the supplement facts panel of a Dietary Supplement constitutes "misbranding" "in that the labeling is false and misleading in any particular"; a drug (Methylsynephrine) is not, and

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cannot be, a dietary ingredient, thus any Dietary Supplement label that lists Methylsynephrine as a dietary ingredient is both false and misleading, therefore, any product that lists Methylsynephrine on the label is misbranded. Likewise, any product labeled as a Dietary Supplement that contains the drug ingredient Methylsynephrine is "adulterated" under 21 U.S.C. §§ 342(f)(1)(b) and 350b because Methylsynephrine (even if it could be a dietary ingredient) is a New Dietary Ingredient (NDI) that has not, and cannot, pass the long checklist of regulatory and safety requirements for a New Dietary Ingredient to become compliant, and legal for use in a Dietary Supplement. Accordingly, misbranded and adulterated products, like those that include Methylsynephrine, cannot be sold in interstate commerce under U.S.C. 21 § 331(a), which prohibits "the introduction or delivery for introduction into interstate commerce any food, [or] drug, that is adulterated or misbranded." Furthermore, because Methylsynephrine is "adulterated" under 21 U.S.C § 350b, any product that contains Methylsynephrine is, by law, unsafe and prohibited for sale under 21 U.S.C. § 331(v), which prohibits "the introduction or delivery for introduction into interstate commerce of a Dietary Supplement that is unsafe under section 350b of this title." Finally, because Methylsynephrine is a new drug, for which substantial clinical trials have been conducted and made public, it can never be a dietary ingredient under 21 U.S.C. § (ff)(3)(B)(ii). For this reason as well, any product that includes Methylsynephrine is also prohibited for sale in interstate commerce as a Dietary Supplement under 21 U.S.C. § 331(ll), which prohibits "the introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 355 of this title, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public."

142. Methylsynephrine is used as the drug Oxilofrine as a treatment for hypotension in Europe. Medical studies on the use of this drug in Europe have found

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that it has significant effects on blood pressure and products that contain Methylsynephrine may present a risk for those with cardiovascular problems.

143. Because of the use of this material as a drug in Europe, we know it has several potential very serious adverse side effects, including: Insomnia, Headaches, Shortness of Breath, Panic Attacks, Tremor, Increased Blood Pressure, Hypertension (in normal individuals), Increased Heart Rate, Increased Rate Pressure Product (Cardiac Hemodynamic Stress), Tachycardia, Cardiac Dysrhythmia (Irregular Heartbeat), Chest Pain, Heat Stroke, Heart Attack, Cerebral Hemorrhage (Stroke), Acute Liver Injury and Failure, Rhabdomyolysis, and Renal Injury.

144. According to Medwatch.com, the use of Methylsynephrine as Dietary Supplement has resulted in several adverse event reports filed with the FDA through July 2016. Individuals that took supplements that contained this material have been hospitalized. Consistent with the significant side effects demonstrated by the use of this ingredient as a drug in Europe, the majority of these adverse event reports indicate that the individual suffered a cardiac-related episode.

145. Methylsynephrine is banned for use by athletes in competition by the WADA. None of the products that incorporate this ingredient contain a warning that the ingredient is banned by the WADA, the NCAA, Olympics, and other legitimate sports organizations.

146. The Department of Defense has also listed Methylsynephrine as a banned substance, barring service members from using products that contain this ingredient.

147. The FDA has conclusively determined that Methylsynephrine is not legal for sale in Dietary Supplements. It has sent warning letters to at least six different companies that market and sell Dietary Supplements that include this ingredient.

148. As just one example, in a March 31, 2016 warning letter to NutraClipsa, Inc., the FDA unequivocally stated:

> Methylsynephrine is not a vitamin, a mineral, an herb or other botanical, or an amino acid. In addition, according to our research, methylsynephrine is not a dietary substance for use

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> by man to supplement the diet by increasing the total dietary intake. Finally, methylsynephrine is not a concentrate, metabolite, constituent, extract, or combination of a vitamin; mineral; herb or other botanical; amino acid; or dietary substance for use by man to supplement the diet by increasing the total dietary intake. Accordingly, methylsynephrine is not a dietary ingredient within the definition set forth in section 201(ff)(1) of the Act. ***Declaring methylsynephrine in your product labeling as a dietary ingredient causes your products marketed as dietary supplements to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.***

(Emphasis added.)

149. And finally, as stated above, any product that includes Methylsynephrine cannot be sold as a "Dietary Supplement." Any product labeled as a "Dietary Supplement" that includes Methylsynephrine is:

- misbranded under 21 U.S.C. § 343(a)(1);
- adulterated under 21 U.S.C. § 342(f)(1)(b);
- not legal for sale as a Dietary Supplement under 21 U.S.C. § 331(a) (because it is adulterated and misbranded);
- unsafe and adulterated under 21 U.S.C. § 350(b);
- prohibited for sale under 21 U.S.C. § 331(v);
- not legal for sale because it includes an unapproved new drug under 21 U.S.C. § 355(a); and
- not permitted for sale in interstate commerce under 21 U.S.C. § 331(d).

150. Any product that includes Methylsynephrine cannot reasonably be expected to be "safe." Methylsynephrine is not safe.

151. In addition, the labels and advertising for products that contain Methylsynephrine falsely represent to consumers that the statements made on the label have not been evaluated by the FDA. In truth, the FDA has evaluated Methylsynephrine and determined that Methylsynephrine is not a dietary ingredient and that products

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labeled as Dietary Supplements that contain Methylsynephrine are not safe, and not legal for sale as Dietary Supplements.

B. A1'S FALSE ADVERTISING OF METHYLSYNEPHRINE

152. In direct violation of federal law, A1 continues to market and sell products labeled as Dietary Supplements that contain Methylsynephrine, which compete directly with products sourced from ThermoLife.

153. These products include the following:

Product Manufacturer	Product Name
Innovative Laboratories	Black Mamba Hyper Rush
Hi-Tech Pharmaceuticals	Black Piranha
Hi-Tech Pharmaceuticals	Black Widow
Chaos and Pain	Cannibal Ferox
Cloma Pharma Laboratories	China White
Innovative Laboratories	Diablos ECA Fire Caps
Innovative Laboratories	Diablos Hyperburn V-10
NICWL/Hi-Tech Pharmaceuticals	ECA Xtreme
Hi-Tech Pharmaceuticals	Fastin
Schwartz Labs	Green Stinger
Innovative Laboratories	HellFire
Hi-Tech Pharmaceuticals	Lipodrene
Hi-Tech Pharmaceuticals	Lipodrene Elite
Hi-Tech Pharmaceuticals	Lipodrene Ephedra
Hi-Tech Pharmaceuticals	Lipodrene Hardcore Ephedra
Hi-Tech Pharmaceuticals	Lipodrene Xtreme
APS Nutrition (APS)	Mesomorph V3
MuscleMeds	MethylBurn Extreme
Cloma Pharma Laboratories	Methyldrene Elite
Delta Health Products	Methylzene
Hi-Tech Pharmaceuticals	N.O. Overload
Hard Rock Supplements	OxyXtreme
APS Nutrition (APS)	Phenadrine
Cloma Pharma Laboratories	Razzadrene
Prime Nutrition	Redux
Hi-Tech Pharmaceuticals	Stimerex Hardcore
Hi-Tech Pharmaceuticals	Stimerex-ES Ephedra
iForce Nutrition	Thermoxyn
Extreme Products Group (EPG)	Turnt Up

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Product Manufacturer	Product Name
Schwartz Labs	Ultimate Burn
GoldStar	Viper
ALR Industries (ALRI)	Viper Hyperdrive
ALR Industries (ALRI)	Viper Hyperdrive 5.0
Hi-Tech Pharmaceuticals	Yellow Scorpion
APS Nutrition (APS)	Yellow Thunder

154. All of the products listed above include the drug Methylsynephrine, yet all of the products have been sold and falsely marketed on A1's website as Dietary Supplements.

155. By marketing Methylsynephrine (a drug) as an ingredient in "Dietary Supplements" on A1supplements.com, "America's Favorite Supplement Store", A1 has created a serious health risk to consumers. The labels and advertising for the Methylsynephrine products falsely represent to consumers that the statements made have not been evaluated by the FDA, but, in fact, the FDA has determined that: Methylsynephrine is not a dietary ingredient; products that contain Methylsynephrine are illegal; products that include Methylsynephrine are not safe; and, Methylsynephrine is a drug that is illegal for sale in Dietary Supplements. Motivated by greed, A1 made the conscious decision to profit from its false marketing of the Methylsynephrine products identified above. To do so, A1 has made false and material representations to consumers regarding Methylsynephrine and intentionally misled consumers to believe that when the products A1 sells include Methylsynephrine, the ingredient Methylsynephrine: (1) has not been evaluated by the FDA; (2) is legal for sale in a Dietary Supplement; (3) is safe; (4) is natural; and (5) is a Dietary Ingredient.

156. Accordingly, A1's intentionally mislabeled, misbranded, adulterated, unsafe, illegal, and falsely advertised products that contain the drug ingredient Methylsynephrine should never have been in the marketplace, nor entitled to any sales. Any revenue earned from the sale of these misbranded, adulterated, unsafe, and illegal products is ill-gotten gains and must be disgorged.

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VI. ISOPROPYLNORSYNERPHRINE

A. ISOPROPYLNORSYNERPHRINE IS A DRUG

157. Several products sold and advertised on A1's website include the ingredient: Isopropyloctopamine hydrochloride, isopropyloctopamine, deterenol, Betaphrine, and dl-M.I.39. These synonyms for this ingredient are more commonly known as "Isopropylnorsynephrine."

158. Isopropylnorsynephrine is a synthetic drug manufactured in a factory in China.

159. The FDA has determined that Isopropylnorsynephrine is a new drug. As such, Isopropylnorsynephrine can never be included in a Dietary Supplement under 21 U.S.C. § 321(ff). Accordingly, any product labeled as a Dietary Supplement that includes the ingredient Isopropylnorsynephrine on the label is "misbranded" under 21 U.S.C. § 343(a)(1) because: listing a drug (Isopropylnorsynephrine) as an ingredient in the supplement facts panel of a Dietary Supplement constitutes "misbranding" "in that the labeling is false and misleading in any particular"; a drug (Isopropylnorsynephrine) is not, and cannot be, a dietary ingredient, thus any Dietary Supplement label that lists Isopropylnorsynephrine as a dietary ingredient is both false and misleading, therefore, any product that lists Isopropylnorsynephrine on the label is misbranded. Likewise, any product labeled as a Dietary Supplement that contains the drug ingredient Isopropylnorsynephrine is "adulterated" under 21 U.S.C. §§ 342(f)(1)(b) and 350b because Isopropylnorsynephrine (even if it could be a dietary ingredient) is a New Dietary Ingredient (NDI) that (as a drug) has not, and cannot pass the long checklist of regulatory and safety requirements for a New Dietary Ingredient to become compliant, and legal for use in a Dietary Supplement. Accordingly, misbranded and adulterated products, like those that include Isopropylnorsynephrine, cannot be sold in interstate commerce under U.S.C. 21 § 331(a), which prohibits "the introduction or delivery for introduction into interstate commerce any food, drug, that is adulterated or misbranded." Furthermore, because Isopropylnorsynephrine is "adulterated" under 21 U.S.C § 350b,

any product that contains Isopropylnorsynephrine is, by law, unsafe and prohibited for sale under 21 U.S.C. § 331(v), which prohibits "the introduction or delivery for introduction into interstate commerce of a Dietary Supplement that is unsafe under section 350b of this title." Finally, because Isopropylnorsynephrine is a "new drug" any product that includes Isopropylnorsynephrine is also prohibited for sale in interstate commerce under 21 U.S.C. § 335(a), and not permitted for sale in interstate commerce under 21 U.S.C. § 331(d).

160. On September 4, 2004, Syntech International, Inc. submitted a "Premarket Notification for a New Dietary Ingredient: Betaphrine" to the FDA. This Premarket Notification identified Isopropyloctopamine hydrochloride as one of the "chemical names" for Betaphrine.

161. In response to Syntech International, Inc.'s submission, on December 6, 2004, the FDA stated: "FDA has carefully considered the information in your submission and we have concluded that 'Betaphrine' is not a dietary ingredient under 21 U.S.C. 321(ff)(1). Betaphrine appears to be a chemically synthesized substance."

162. The FDA further concluded, "Insomuch as such product is clearly not a dietary ingredient, as discussed above, or a conventional food, this is a 'drug' under 21 U.S.C. 321(g)(1)(C)."

163. Isopropylnorsynephrine was recently detected in Dietary Supplements that caused adverse events in consumers in the Netherlands. Adverse effects such as cardiac arrest, heart palpitations, chest pain, nausea, and headache were reported by the users of these products.

164. Isopropylnorsynephrine is banned for use by athletes in competition by WADA. None of the products that incorporate this ingredient contain a warning that the ingredient is banned by the WADA, the NCAA, Olympics, and other legitimate sports organizations.

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165. And finally, as stated above, any product that includes Isopropylnorsynephrine cannot be sold as a "Dietary Supplement." Any product labeled as a "Dietary Supplement" that includes Isopropylnorsynephrine is:

- misbranded under 21 U.S.C. § 343(a)(1);
- adulterated under 21 U.S.C. § 342(f)(1)(b);
- not legal for sale as a Dietary Supplement under 21 U.S.C. § 331(a) (because it is "adulterated" and "misbranded");
- unsafe and adulterated under 21 U.S.C. § 350(b);
- prohibited for sale under 21 U.S.C. § 331(v); and
- not legal for sale because it includes an unapproved new drug under 21 U.S.C. § 355(a); and
- not permitted for sale in interstate commerce under 21 U.S.C. § 331(d).

166. Any product that includes Isopropylnorsynephrine cannot reasonably be expected to be "safe." Isopropylnorsynephrine is not safe.

167. In addition, the labels and advertising for products that contain Isopropylnorsynephrine falsely represent to consumers that the statements made on the label have not been evaluated by the FDA. In truth, the FDA has evaluated Isopropylnorsynephrine and determined that Isopropylnorsynephrine is a drug. Accordingly, products labeled as Dietary Supplements that contain Isopropylnorsynephrine are not safe, and not legal for sale as Dietary Supplements.

B. A1'S FALSE ADVERTISING OF ISOPROPYLNORSYNERPHRINE PRODUCTS

168. In direct violation of federal law, A1 continues to market and sell Dietary Supplements that contain Isopropylnorsynephrine, which compete directly with products sourced from ThermoLife.

169. These products include the following:

Product Manufacturer	Product Name
Extreme Products Group (EPG)	Blue Ice

Product Manufacturer	Product Name
Chaos and Pain	Cannibal Ferox
Chaos and Pain	Cannibal Riot
Psycho Pharma	Edge of Insanity
Hi-Tech Pharmaceuticals	Fastin
Hi-Tech Pharmaceuticals	Lipodrene Xtreme
APS Nutrition (APS)	Mesomorph V3
Hard Rock Supplements	OxyXtreme
Extreme Products Group (EPG)	Turnt Up
ALR Industries (ALRI)	Viper Hyperdrive
ALR Industries (ALRI)	Viper Hyperdrive 5.0
APS Nutrition (APS)	Yellow Thunder

170. All of the products listed above include the drug Isopropylnorsynephrine, yet all of the products have been sold and falsely marketed on A1's website as Dietary Supplements.

171. A1's website includes numerous false and material claims about Isopropylnorsynephrine and the products A1 sells that include Isopropylnorsynephrine.

172. Despite knowing that Isopropylnorsynephrine is a drug ingredient that is not legal for sale in a Dietary Supplement, A1 made the conscious decision to profit from its false marketing of Isopropylnorsynephrine products as Dietary Supplements.

173. By marketing Isopropylnorsynephrine (a drug) as an ingredient in "Dietary Supplements" on A1supplements.com, "America's Favorite Supplement Store", A1 has created a serious health risk to consumers. The labels and advertising for the Isopropylnorsynephrine products falsely represent to consumers that the statements made have not been evaluated by the FDA, but, in fact, the FDA has determined that: Isopropylnorsynephrine is not a dietary ingredient; products that contain Isopropylnorsynephrine are illegal; products that include Isopropylnorsynephrine are not safe; and Isopropylnorsynephrine is a drug that is illegal for sale in Dietary Supplements. Motivated by greed, A1 made the conscious decision to profit from its false marketing of the Isopropylnorsynephrine products identified above. To do so, A1 has made false and material representations to consumers regarding Isopropylnorsynephrine and intentionally misled consumers to believe that when the

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products A1 sells include Isopropylnorsynephrine, the ingredient Isopropylnorsynephrine: (1) has not been evaluated by the FDA; (2) is legal for sale in a Dietary Supplement; (3) is safe; (4) is natural; and (5) is a Dietary Ingredient.

174. Accordingly, A1's intentionally mislabeled, misbranded, adulterated, unsafe, illegal, and falsely advertised products that contain the drug ingredient Isopropylnorsynephrine should never have been in the marketplace, nor entitled to any sales. Any revenue earned from the sale of these misbranded, adulterated, unsafe, and illegal products is ill-gotten gains and must be disgorged

THE ILLEGAL AROMATASE INHIBITORS AND ANABOLIC STEROIDS SOLD AND FALSELY ADVERTISED AS DIETARY SUPPLEMENTS BY A1

I. ARIMISTANE

A. ARIMISTANE IS A DRUG.

175. Several products sold and marketed on A1's website include the ingredient androsta 3,5-diene-7, 17-dione, commonly referred to as "Arimistane."

176. Arimistane is an aromatase inhibitor.

177. Aromatase inhibitors are a class of prescription drugs prescribed for the treatment of breast cancer in postmenopausal woman.

178. Aromatase inhibitors, like Arimistane, are used, by bodybuilders to block an enzyme called aromatase. Aromatase helps convert testosterone into estrogen. By blocking aromatase, aromatase inhibitors decrease estrogen, while at the same time causing the body to increase testosterone production.

179. In 2010, the FDA issued warning letters to several Dietary Supplement companies that were illegally including aromatase inhibitors in products falsely advertised as Dietary Supplements. Summarizing its own warning letters, in an advisement to consumers, the FDA explained, "The FDA concludes that products containing aromatase inhibitors have a reasonable probability of resulting in permanent impairment of a body structure or function in at risk consumers. The FDA has notified

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manufactures that these products do not meet the definition of a dietary ingredient and therefore the product is in violation of provisions of the Food, Drug, and Cosmetic Act."

180. The FDA has declared Arimistane a "new drug" as defined by 21 U.S.C. § 321 (p), because "it is not generally recognized as safe and effective." 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 21 U.S.C. §§ 331(d) and 355(a). As such, Arimistane does not meet the definition of a dietary ingredient and can never be included in a Dietary Supplement under 21 U.S.C. § 321(ff). Accordingly, any product labeled as a Dietary Supplement that includes the ingredient Arimistane on the label is "misbranded" under 21 U.S.C. § 343(a)(1) because: listing a drug (Arimistane) as an ingredient in the supplement facts panel of a Dietary Supplement constitutes "misbranding" "in that the labeling is false and misleading in any particular"; a drug (Arimistane) is not, and cannot be, a dietary ingredient, thus any Dietary Supplement label that lists Arimistane as a dietary ingredient is both false and misleading, therefore, any product that lists Arimistane on the label is misbranded. Likewise, any product labeled as a Dietary Supplement that contains the drug ingredient Arimistane is "adulterated" under 21 U.S.C. §§ 342(f)(1)(b) and 350b because Arimistane (even if it could be a dietary ingredient) is a New Dietary Ingredient (NDI) that (as a drug) has not, and cannot pass the long checklist of regulatory and safety requirements for a New Dietary Ingredient to become compliant and legal for use in a Dietary Supplement. Accordingly, misbranded and adulterated products, like those that include Arimistane, cannot be sold in interstate commerce under U.S.C. 21 § 331(a), which prohibits "the introduction or delivery for introduction into interstate commerce any food [or] drug … that is adulterated or misbranded." Furthermore, because Arimistane is "adulterated" under 21 U.S.C § 350b, any product that contains Arimistane is, by law, unsafe and prohibited for sale under 21 U.S.C. § 331(v), which prohibits "the introduction or delivery for introduction into interstate commerce of a Dietary Supplement that is unsafe under section 350b of this title." Finally, because

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Arimistane is an unapproved new drug any product that includes Arimistane is also prohibited for sale in interstate commerce under 21 U.S.C. §§ 335(a) and 21 U.S.C. § 331(d).

181. On October 22, 2013, Proprietary Wellness submitted a New Dietary Ingredient Notification (NDIN) for Arimistane. The FDA responded to that NDIN on November 27, 2013, stating: "the agency has significant concerns …. [whether] androsta 3,5-diene-7, 17-dione [Arimistane] will reasonably be expected to be safe." As the FDA concluded, Arimistane is a not a dietary ingredient.

182. More recently, on May 18, 2018, the FDA sent a Warning Letter to Performance Nutrition Formulators, LLC, directed at the company's sale of an Arimistane product. In that letter, the FDA stated: "The 'Arimistane' ingredient listed on your product label, Androsta-3,5-Diene-7,17-Dione, is an aromatase inhibitor and does not constitute a dietary ingredient under section 201(ff)(1) of the FD&C Act." The FDA further explained, "[Arimistane] is a 'prescription drug' under 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."

183. The FDA also indicated that Arimistane is not legal for use in Dietary Supplements when it sought forfeiture of products that included this ingredient. On March 19, 2018, the United States of America filed its Amended Verified Complaint for Forfeiture in the United States District Court for the Northern District of Georgia, Case No. 1:17-CV-4442, United States of America v. 1,810,490.34 Seized from Touchmark National Bank Account, et. al. (hereinafter "the Amended Forfeiture Complaint").

184. In paragraph 90 of the Amended Forfeiture Complaint, the United States listed a set of products that it seized after the "FDA… determined that the following ingredients contained on the respective Supplement Facts Panel for each of the

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[products] is a non-dietary ingredient, thereby rendering each of the [products] a "misbranded food and/or drug." A cut-and-paste from the Amended Complaint is below:

90. FDA/CFSAN/ODSP determined that the following ingredients contained on the respective Supplement Facts Panel for each of the Defendant Products is a non-dietary ingredient, thereby rendering each of the Defendant Products a misbranded food and/or drug.

PRODUCT NAME	NON-DIETARY INGREDIENT INCLUDED ON LABEL
Helladrol	• 4-Androstene-3b-ol, 17-one • Androsta 3,5-diene-7,17-dione
Stanabol Depot	• Androstene-3b,7b,17b-triol
1-Andro	• 3b-hydroxy-5a-androst-1-en-17-one
Metanabol	• Androsterone • 4-Androstene-3b-ol, 17-one • 1-androstene-3b-ol, 17-one
Arimiplex	• NAC (N-acetyl Cysteine) • Androsta 3,5-diene-7,17-dione
Dianabol	• 5-Methoxy-7-isoflavone • 7-Isopropoxyisoflavone • Androsterone

Arimistane

185. The Amended Forfeiture Complaint makes clear that Arimistane is a "non-dietary ingredient included on the label [of the products]."

186. And finally, as stated above, any product that includes the drug Arimistane cannot be sold as a "Dietary Supplement." Any product labeled as a "Dietary Supplement" that includes Arimistane is:

- misbranded under 21 U.S.C. § 343(a)(1);
- adulterated under 21 U.S.C. § 342(f)(1)(b);
- not legal for sale as a Dietary Supplement under 21 U.S.C. § 331(a) (because it is "adulterated" and "misbranded");
- adulterated and unsafe under 21 U.S.C. § 350(b);
- prohibited for sale under 21 U.S.C. § 331(v);
- not legal for sale because it includes an unapproved new drug under 21 U.S.C. § 355(a); and
- not permitted for sale in interstate commerce under 21 U.S.C. § 331(d).

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187. Any product that includes Arimistane cannot reasonably be expected to be "safe." Arimistane is not safe.

188. In addition, the labels and advertising for products that contain Arimistane falsely represent to consumers that the statements made have not been evaluated by the FDA. In truth, the FDA has evaluated Arimistane and determined that Arimistane is an unapproved new drug and that products that contain Arimistane are not safe, and not legal for sale as Dietary Supplements.

B. A1'S FALSE ADVERTISING OF ARIMISTANE PRODUCTS

189. In direct violation of federal law, A1 marketed and sold products that contain Arimistane falsely labeled as Dietary Supplements. These products unfairly competed directly with Dietary Supplements sourced from ThermoLife. These products include the following:

Product Manufacturer	Product Name
Lecheek Nutrition	AD-3
Redcon 1	Aftermath
EPG	Arimestage PCT 50
EPG	Arimezone 50
Olympus Labs	Arimicare Pro
Hi-Tech Pharmaceuticals	Arimiplex
Hi-Tech Pharmaceuticals	Arimistane
Repp Sports	Arimivar
VMI Sports	A-XR PCT
LG Sciences	Battle Hardener Kit
LG Sciences	Cutting Andro Kit
Ironmag Labs	E-Control Rx 2.0
Olympus Labs	Eliminate
Blackstone Labs	Eradicate
Platinum Nutraceuticals	E-Slash
LG Sciences	Form-XT
Innovative Labs	Helladrol
LG Sciences	M1D Andro
Primeval Labs	Mega Test
Man Sports	Nolvadren XT
Gaspari Nutrition	Novadex XT
Hard Rock Supplements	PCT Sustain
Platinum Nutraceuticals	PCT-RX

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Product Manufacturer	Product Name
Lecheek Nutrition	P-X4
Repp Sports	R-PCT
EPG	Steel 75
Killer Labz	Terminator-Test
EPG	Testoshred
LG Sciences	Trifecta Kit
Double Dragon Pharma	TST 750

190. All of the products listed above include the drug ingredient Arimistane, yet all of the products have been sold and falsely marketed on A1's website as Dietary Supplements.

191. A1's website includes numerous false and material claims about Arimistane and the products A1 sells that include Arimistane.

192. Despite knowing that Arimistane is a drug that is not legal for sale in a Dietary Supplement, A1 made the conscious decision to profit from its false marketing of Arimistane products as Dietary Supplements.

193. By marketing Arimistane (a drug) as an ingredient in "Dietary Supplements" on A1supplements.com, "America's Favorite Supplement Store", A1 has created a serious health risk to consumers. The labels and advertising for the Arimistane products falsely represent to consumers that the statements made have not been evaluated by the FDA, but, in fact, the FDA has determined that Arimistane is a drug, that Arimistane is not safe, and that Arimistane is illegal for sale in Dietary Supplements. Motivated by greed, A1 made the conscious decision to profit from its false marketing of the Arimistane products identified above. To do so, A1 has made false and material representations to consumers regarding Arimistane and intentionally misled consumers to believe that when the products sold by A1 include Arimistane, the ingredient Arimistane: (1) has not been evaluated by the FDA; (2) is legal for sale in a Dietary Supplement; (3) is safe; (4) is natural; and (5) is a Dietary Ingredient.

194. Accordingly, A1's intentionally mislabeled, misbranded, adulterated, unsafe, illegal, and falsely advertised products that contain the drug ingredient Arimistane should never have been in the marketplace, nor entitled to any sales. Any

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revenue earned from the sale of these misbranded, adulterated, unsafe, and illegal products is ill gotten gains and must be disgorged.

II. 1-DHEA

A. 1-DHEA IS A DRUG.

195. Several products marketed and sold on A1's website included the ingredient 3bhydroxy-androst-1-ene-17-one, commonly referred to as "1-DHEA."

196. 1-DHEA is a prohormone that converts to 1-testosterone (a substance banned by the DEA in 2005) when ingested.

197. 1-DHEA is not a dietary ingredient. On August 29, 2011, Proprietary Wellness submitted an NDIN for 1-DHEA. The FDA responded to that NDIN on November 30, 2011, finding 1-DHEA was not a "dietary ingredient" permitted to be used in a "Dietary Supplement" under 21 U.S.C. § 321(ff) because it was not: "(A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)." The FDA further concluded that there was insufficient evidence that a product that included the ingredient 1-DHEA "will reasonably be expected to be safe."

198. As such, 1-DHEA does not meet the definition of a dietary ingredient and can never be included in a Dietary Supplement under 21 U.S.C. § 321(ff). Accordingly, any product labeled as a Dietary Supplement that includes the ingredient 1-DHEA on the label is "misbranded" under 21 U.S.C. § 343(a)(1) because: listing a drug (1-DHEA) as an ingredient in the supplement facts panel of a Dietary Supplement constitutes "misbranding" "in that the labeling is false and misleading in any particular"; a drug (1-DHEA) is not, and cannot be, a dietary ingredient, thus any Dietary Supplement label that lists 1-DHEA as a dietary ingredient is both false and misleading, therefore, any product that lists 1-DHEA on the label is misbranded. Likewise, any product labeled as a Dietary Supplement that contains the drug ingredient 1-DHEA is "adulterated" under 21

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U.S.C. §§ 342(f)(1)(b) and 350b because 1-DHEA (even if it could be a dietary ingredient) is a New Dietary Ingredient (NDI) that (as a drug) has not, and cannot pass the long checklist of regulatory and safety requirements for a New Dietary Ingredient to become compliant, and legal for use in a Dietary Supplement. Accordingly, misbranded and adulterated products, like those that include 1-DHEA, cannot be sold in interstate commerce under U.S.C. 21 § 331(a), which prohibits "the introduction or delivery for introduction into interstate commerce any food [or] drug … that is adulterated or misbranded." Furthermore, because 1-DHEA is "adulterated" under 21 U.S.C § 350b, any product that contains 1-DHEA is, by law, unsafe and prohibited for sale under 21 U.S.C. § 331(v), which prohibits "the introduction or delivery for introduction into interstate commerce of a Dietary Supplement that is unsafe under section 350b of this title." Finally, because 1-DHEA is an unapproved new drug any product that includes 1-DHEA is also prohibited for sale in interstate commerce under 21 U.S.C. § 335(a) and 21 U.S.C. § 331(d).

199. After the FDA declared that 1-DHEA was not a dietary ingredient, Proprietary Wellness, LLC violated the FDA's directive and sold 1-DHEA products. In a September 27, 2016 Warning Letter to Proprietary Wellness, LLC, the FDA stated:

> 3b-hydroxy-androst-1-ene-17-one [***1-DHEA***] and … are not vitamins, minerals, herbs or other botanicals, or amino acids. In addition, neither 3b-hydroxy-androst-1-ene-17-one … are dietary substances for use by man to supplement the diet by increasing the total dietary intake. Finally, 3b-hydroxyandrost-1-ene-17-one and … are not concentrates, metabolites, constituents, extracts, or combination of vitamins; minerals; herbs or other botanicals; amino acids; or dietary substances for use by man to supplement the diet by increasing the total dietary intake. Accordingly, 3b-hydroxyandrost-1-ene-17-one and … are not a dietary ingredients within the definition set forth in section 201(ff)(1) of the Act. ***Declaring these ingredients in your product labeling as dietary ingredients causes your products marketed as Dietary Supplements to be misbranded under section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is false or misleading in any particular.***

(Emphasis added.)

200. The FDA also indicated that 1-DHEA was not a legal dietary ingredient in the Amended Forfeiture Complaint. In paragraph 90, the FDA listed "3bhydroxy-androst-1-en-17-one", which is 1-DHEA, as not a dietary ingredient:

> 90. FDA/CFSAN/ODSP determined that the following ingredients contained on the respective Supplement Facts Panel for each of the Defendant Products is a non-dietary ingredient, thereby rendering each of the Defendant Products a misbranded food and/or drug.

PRODUCT NAME	NON-DIETARY INGREDIENT INCLUDED ON LABEL
Helladrol	• 4-Androstene-3b-ol, 17-one • Androsta 3,5-diene-7,17-dione
Stanabol Depot	• Androstene-3b,7b,17b-triol
1-Andro	• 3b-hydroxy-5a-androst-1-en-17-one
Metanabol	• Androsterone • 4-Androstene-3b-ol, 17-one • 1-androstene-3b-ol, 17-one
Arimiplex	• NAC (N-acetyl Cysteine) • Androsta 3,5-diene-7,17-dione
Dianabol	• 5-Methoxy-7-isoflavone • 7-Isopropoxyisoflavone • Androsterone

1-DHEA

201. As the Amended Forfeiture Complaint makes clear, any product that contains 1-DHEA is a "misbranded food[s] and/or drug[s]."

202. And finally, as stated above, any product that includes 1-DHEA cannot be sold as a "Dietary Supplement." Any product labeled as a "Dietary Supplement" that includes 1-DHEA is:

- misbranded under 21 U.S.C. § 343(a)(1);
- adulterated under 21 U.S.C. § 342(f)(1)(b);
- not legal for sale as a Dietary Supplement under 21 U.S.C. § 331(a) (because it is "adulterated" and "misbranded");
- unsafe and adulterated under 21 U.S.C. § 350(b);
- prohibited for sale under 21 U.S.C. § 331 (v); and

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- not legal for sale because it includes an unapproved new drug under 21 U.S.C. § 355(a); and
- not permitted for sale in interstate commerce under 21 U.S.C. § 331(d).

203. Any product that includes 1-DHEA cannot reasonably be expected to be "safe." 1-DHEA is not safe.

204. In addition, the labels and advertising for products that contain 1-DHEA falsely represent to consumers that the statements made on the label have not been evaluated by the FDA. In truth, the FDA has evaluated 1-DHEA and determined that 1-DHEA is a new drug and that products that contain 1-DHEA are not safe, and not legal for sale as Dietary Supplements.

B. A1'S FALSE ADVERTISING OF 1-DHEA PRODUCTS

205. In direct violation of federal law, A1 marketed and sold products that contain 1-DHEA falsely labeled as Dietary Supplements. These products unfairly competed directly with Dietary Supplements sourced from ThermoLife. These products include the following:

Product Manufacturer	Product Name
Hi-Tech Pharmaceuticals	1-AD
LG Sciences	1-Andro
Advanced Muscle	1-Andro
Ironmag Labs	1-Andro RX
Hi-Tech Pharmaceuticals	1-Testosterone
Hi-Tech Pharmaceuticals	Anavar
Primeval Labs	Andro Quad
APS Nutrition	Androbolic 250
EPG	Androzome 1
Blackstone Labs	Chosen 1
LG Sciences	Cutting Andro Kit
Gaspari Nutrition	Halodrol
ALRI	Metanabol
Innovative Labs	Monster Plexx
Hi-Tech Pharmaceuticals	Superdrol

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206. All of the products listed above include the drug ingredient 1-DHEA, yet all of the products have been sold and falsely marketed on A1's website as Dietary Supplements.

207. A1's website includes numerous false and material claims about 1-DHEA and the products A1 sells that include 1-DHEA.

208. Despite knowing that 1-DHEA is not legal for sale in a Dietary Supplement, A1 made the conscious decision to profit from its false marketing of 1-DHEA products as Dietary Supplements.

209. By marketing 1-DHEA (a drug) as an ingredient in "Dietary Supplements" on A1supplements.com, "America's Favorite Supplement Store", A1 has created a serious health risk to consumers. The labels and advertising for the 1-DHEA products falsely represent to consumers that the statements made have not been evaluated by the FDA, but, in fact, the FDA has determined that: 1-DHEA is not a dietary ingredient; products labeled as Dietary Supplements that contain 1-DHEA are illegal; products labeled as Dietary Supplements that include 1-DHEA are not safe; and 1-DHEA is an unapproved new drug that is illegal for sale in Dietary Supplements. Motivated by greed, A1 made the conscious decision to profit from its false marketing of the 1-DHEA products identified above. To do so, A1 has made false and material representations to consumers regarding 1-DHEA and intentionally misled consumers to believe that when the products A1 sells include 1-DHEA, the ingredient 1-DHEA: (1) has not been evaluated by the FDA; (2) is legal for sale in a Dietary Supplement; (3) is safe; (4) is natural; and (5) is a Dietary Ingredient.

210. Accordingly, A1's intentionally mislabeled, misbranded, adulterated, unsafe, illegal, and falsely advertised products that contain the drug ingredient 1-DHEA should never have been in the marketplace, nor entitled to any sales. Any revenue earned from the sale of these misbranded, adulterated, unsafe, and illegal products is ill-gotten gains and must be disgorged.

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III. 4-DHEA

A. 4-DHEA IS A DRUG.

211. Several products sold on A1's website include the ingredient 4-Androstene-3b-ol, 17-one, which is commonly referred to as "4-DHEA."

212. 4-DHEA is a prohormone that converts to 4-androstenediol (a substance banned by the DEA in 2005) and then to testosterone when ingested.

213. 4-DHEA is not a dietary ingredient. On April 20, 2012, Proprietary Wellness submitted an NDIN for 4-DHEA. The FDA responded to that NDIN on November 30, 2011, finding 4-DHEA was not a "dietary ingredient" permitted to be used in a "Dietary Supplement" under 21 U.S.C. § 321(ff) because it was not: "(A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)." The FDA further concluded that there was insufficient evidence that a product that included 4-DHEA "will reasonably be expected to be safe."

214. As such, 4-DHEA does not meet the definition of a dietary ingredient and can never be included in a Dietary Supplement under 21 U.S.C. § 321(ff). Accordingly, any product labeled as a Dietary Supplement that includes the ingredient 4-DHEA on the label is "misbranded" under 21 U.S.C. § 343(a)(1) because: listing a drug (4-DHEA) as an ingredient in the supplement facts panel of a Dietary Supplement constitutes "misbranding" "in that the labeling is false and misleading in any particular"; a drug (4-DHEA) is not, and cannot be, a dietary ingredient, thus any Dietary Supplement label that lists 4-DHEA as a dietary ingredient is both false and misleading, therefore, any product that lists 4-DHEA on the label is misbranded. Likewise, any product labeled as a Dietary Supplement that contains the drug ingredient 4-DHEA is "adulterated" under 21 U.S.C. §§ 342(f)(1)(b) and 350b because 4-DHEA (even if it could be a dietary ingredient) is a New Dietary Ingredient (NDI) that (as a drug) has not, and cannot pass

the long checklist of regulatory and safety requirements for a New Dietary Ingredient to become compliant, and legal for use in a Dietary Supplement. Accordingly, misbranded and adulterated products, like those that include 4-DHEA, cannot be sold in interstate commerce under U.S.C. 21 § 331(a), which prohibits "the introduction or delivery for introduction into interstate commerce any food [or] drug … that is adulterated or misbranded." Furthermore, because 4-DHEA is "adulterated" under 21 U.S.C § 350b, any product that contains 4-DHEA is, by law, unsafe and prohibited for sale under 21 U.S.C. § 331(v), which prohibits "the introduction or delivery for introduction into interstate commerce of a Dietary Supplement that is unsafe under section 350b of this title." Finally, because 4-DHEA is an unapproved new drug any product that includes 4-DHEA is also prohibited for sale in interstate commerce under 21 U.S.C. § 335(a) and 21 U.S.C. § 331(d).

215. The FDA also indicated that 4-DHEA was not a legal dietary ingredient in the Amended Forfeiture Complaint. In paragraph 90, the FDA listed "Androstene-3b-ol, 17-one", which is 4-DHEA, as not a dietary ingredient:

> 90. FDA/CFSAN/ODSP determined that the following ingredients contained on the respective Supplement Facts Panel for each of the Defendant Products is a non-dietary ingredient, thereby rendering each of the Defendant Products a misbranded food and/or drug.

PRODUCT NAME	NON-DIETARY INGREDIENT INCLUDED ON LABEL
Helladrol	• 4-Androstene-3b-ol, 17-one → 4-DHEA • Androsta 3,5-diene-7,17-dione
Stanabol Depot	• Androstene-3b,7b,17b-triol
1-Andro	• 3b-hydroxy-5a-androst-1-en-17-one
Metanabol	• Androsterone • 4-Androstene-3b-ol, 17-one • 1-androstene-3b-ol, 17-one
Arimiplex	• NAC (N-acetyl Cysteine) • Androsta 3,5-diene-7,17-dione
Dianabol	• 5-Methoxy-7-isoflavone • 7-Isopropoxyisoflavone • Androsterone

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216. As the Amended Forfeiture Complaint explained, products that contain 4-DHEA are "misbranded food[s] and/or drug[s]."

217. And finally, as stated above, any product that includes 4-DHEA cannot be sold as a "Dietary Supplement." Any product labeled as a "Dietary Supplement" that includes 4-DHEA is:

- misbranded under 21 U.S.C. § 343(a)(1);
- adulterated under 21 U.S.C. § 342(f)(1)(b);
- not legal for sale as a Dietary Supplement under 21 U.S.C. § 331(a) (because it is "adulterated" and "misbranded");
- unsafe and adulterated under 21 U.S.C. § 350(b);
- prohibited for sale under 21 U.S.C. § 331(v);
- not legal for sale because it includes an unapproved new drug under 21 U.S.C. § 355(a); and
- not permitted for sale in interstate commerce under 21 U.S.C. § 331(d).

218. Any product that includes 4-DHEA cannot reasonably be expected to be "safe." 4-DHEA is not safe.

219. In addition, the labels and advertising for products that contain 4-DHEA falsely represent to consumers that the statements made on the label have not been evaluated by the FDA. In truth, the FDA has evaluated 4-DHEA and determined that 4-DHEA is an unapproved new drug and that products that contain 4-DHEA are not safe, and not legal for sale as Dietary Supplements.

B. A1'S FALSE ADVERTISING OF 4-DHEA PRODUCTS

220. In direct violation of federal law, A1 marketed and sold products that contain 4-DHEA falsely labeled as Dietary Supplements. These products unfairly competed directly with Dietary Supplements sourced from ThermoLife.

221. These products include the following:

Product Manufacturer	Product Name
Hi-Tech Pharmaceuticals	1-AD

Product Manufacturer	Product Name
LG Sciences	1-Andro
Advanced Muscle	1-Andro
Ironmag Labs	1-Andro RX
Hi-Tech Pharmaceuticals	1-Testosterone
Hi-Tech Pharmaceuticals	Anavar
Primeval Labs	Andro Quad
APS Nutrition	Androbolic 250
EPG	Androzome 1
Blackstone Labs	Chosen 1
LG Sciences	Cutting Andro Kit
Gaspari Nutrition	Halodrol
ALRI	Metanabol
Innovative Labs	Monster Plexx
Hi-Tech Pharmaceuticals	Superdrol

222. All of the products listed above include the drug ingredient 4-DHEA, yet all of products they have been sold and falsely marketed on A1's website as Dietary Supplements.

223. A1's website includes numerous false and material claims about 4-DHEA and the products A1 sells that include 4-DHEA.

224. Despite knowing that the ingredient 4-DHEA is a drug that is not legal for sale in a Dietary Supplement, A1 made the conscious decision to profit from its false marketing of products that contain the drug ingredient 4-DHEA in Dietary Supplements.

225. By marketing 4-DHEA (a drug) as an ingredient in "Dietary Supplements" on A1supplements.com, "America's Favorite Supplement Store", A1 has created a serious health risk to consumers. The labels and advertising for the 4-DHEA products falsely represent to consumers that the statements made have not been evaluated by the FDA, but, in fact, the FDA has determined that: 4-DHEA is not a dietary ingredient; products labeled as Dietary Supplements that contain 4-DHEA are illegal; products labeled as Dietary Supplements that include 4-DHEA are not safe; and 4-DHEA is an unapproved new drug that is illegal for sale in Dietary Supplements. Motivated by greed, A1 made the conscious decision to profit from its false marketing of the 4-DHEA products identified above. To do so, A1 has made false and material representations to

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consumers regarding 4-DHEA and intentionally misled consumers to believe that when the products A1 sells include 4-DHEA, the ingredient 4-DHEA: (1) has not been evaluated by the FDA; (2) is legal for sale in a Dietary Supplement; (3) is safe; (4) is natural; and (5) is a Dietary Ingredient.

226. Accordingly, A1's intentionally mislabeled, misbranded, adulterated, unsafe, illegal, and falsely advertised products that contain the drug ingredient 4-DHEA should never have been in the marketplace, nor entitled to any sales. Any revenue earned from the sale of these misbranded, adulterated, unsafe, and illegal products is ill-gotten gains and must be disgorged.

FIRST CLAIM FOR RELIEF

(Lanham Act § 43(a))

227. Plaintiff realleges and incorporates herein by reference each and every allegation of this Complaint as is fully set forth herein.

228. A1 uses, offers for sale, and sells the products at issue in interstate and foreign commerce and has caused the false statements alleged herein to enter interstate and foreign commerce.

229. In connection with any goods or services, A1 has used one or more words, terms, names, symbols, or devices, alone or in combination thereof, as well as any false designations of origin, false or misleading descriptions of fact, or false or misleading representations of fact in commercial advertising or promotion, and it misrepresents the nature, characteristics, qualities, or geographic origin of its or another person's goods, services, or commercial activities.

230. As alleged above, A1 has made false statements of fact in commercial advertisements about the products sold on its website, including the false statements identified above.

231. A1's deception is material and made in bad faith for the purpose of influencing and deceiving the market, the public, consumers, potential customers and

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competitors. The deception is likely to influence the purchasing decisions of the public for whom it was intended and others.

232. ThermoLife has suffered a commercial injury to its reputation or sales, which was directly and proximately caused by A1's false statements and other acts as alleged above.

233. ThermoLife's injury is competitive, i.e., harmful to the ThermoLife's ability to compete in the Dietary Supplement market.

234. By reason of A1's statements and conduct, it has willfully violated § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and ThermoLife has suffered, and will continue to suffer damage to its business, reputation and good will and has lost sales and profits that ThermoLife would otherwise have made.

235. ThermoLife's Lanham Act claim does not seek to enforce the provisions of DSHEA through private action. Neither DSHEA nor the Federal Food, Drug and Cosmetics Act preclude a claim under § 43(a) of the Lanham Act. Further, the FDA has already addressed the legality of the ingredients included in the products at issue in here; the FDA declared that the products identified above are improperly marketed as Dietary Supplements and that those products include materials that are classified as drugs. To the extent any claim ThermoLife has asserted mentions the DSHEA, it is in relation to A1's violations of DSHEA that have been affirmed by the FDA. ThermoLife seeks to hold A1 liable for misleading consumers about the products it sells by informing consumers that the FDA had not evaluated the statements made about the ingredients in the products identified above; when, in fact, the FDA has determined that the ingredients in the products listed are drugs, illegal for use in Dietary Supplements. A1 makes affirmative false statements related to these products by labeling them as Dietary Supplements and implying that they are "legal", "natural", and "safe."

236. ThermoLife has been irreparably harmed by A1's acts in violation of the Lanham Act and it has suffered damages in an amount to be determined at trial. Further,

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A1's conduct as alleged is in bad faith, willful and exceptional, such that ThermoLife is entitled to an award of treble damages and its attorneys' fees.

SECOND CLAIM FOR RELIEF

(Common Law Unfair Competition)

237. Plaintiff realleges and incorporates herein by reference each and every allegation of this Complaint as is fully set forth herein.

238. As alleged above, A1 has made false statements of material fact in commercial advertisements about the products sold on its website, including but not limited to the false statements identified above.

239. Common law unfair competition prevents business conduct that is contrary to honest practice in commercial matters, including deception.

240. ThermoLife has been injured as a result of A1's false statements.

241. ThermoLife has suffered a commercial injury based upon a misrepresentation by A1.

242. ThermoLife's injury is competitive, *i.e.,* harmful to the ThermoLife's ability to compete in the Dietary Supplement market.

243. As alleged above, ThermoLife's unfair competition claim does not seek to enforce the Federal Food Drug and Cosmetics Act and DSHEA through private action relating to the misbranding of food through false or misleading labeling.

244. ThermoLife has been irreparably harmed by A1's acts of unfair competition and it has suffered damages in an amount to be determined at trial.

THIRD CLAIM FOR RELIEF

(False Marking 35 U.S.C. § 292)

245. Plaintiff realleges and incorporates herein by reference each and every allegation of this Complaint as is fully set forth herein.

246. ThermoLife currently holds 23 separate and distinct patents that protect its innovative development and use of ingredients in Dietary Supplements and food products.

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247. ThermoLife also holds several patents related to the use of amino acids to increase athletic performance. For example, ThermoLife's U.S. Patent No. 8,178,572 protects and covers "a method for increasing the vasodilative characteristics of amino acids in a human, the method comprising administering orally to the human a pharmaceutically effective amount of an amino acid compound consisting essentially of a nitrate of an amino acid selected from the group consisting of Arginine, Agmatine, Beta Alanine, Citrulline, Creatine, Glutamine, L-Histidine, Isoleucine, Leucine, Norvaline, Ornithine, and Valine."

248. With few exceptions, anytime an amino acid is combined with nitrate(s) and sold and marketed to consumers the product relies on ThermoLife's patented technology.

249. ThermoLife's patented creatine nitrate has proven exceedingly popular in the Dietary Supplement market.

250. Through its website, A1's website falsely advertises its products that include "Creatine Nitrate" as including "a vastly superior patented creatine [referring to creatine nitrate]."

251. Except for its sale of products licensed from ThermoLife, A1 is not licensed or otherwise authorized to practice any patented invention related to "Creatine Nitrate."

252. A1 falsely marked their "Creatine Nitrate" products as patented with full knowledge that A1 does not possess the advertised patent rights under 35 U.S.C. § 292(a).

253. ThermoLife has suffered competitive injury as a result of A1'S false marking and, under 35 U.S.C. § 292(b) is entitled to recover damages adequate to compensate for the injury in an amount to be proven at trial.

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FOURTH CLAIM FOR RELIEF

(Civil Conspiracy)

254. Plaintiff realleges and incorporates herein by reference each and every allegation of this Complaint as is fully set forth herein.

255. At all relevant times, A1 has acted in concert, agreed, combined and conspired for an unlawful purpose or for a lawful purpose by unlawful means, i.e., to engage in false advertising and deceptive practices, with the makers and distributors of the products alleged above.

256. An overt act by one member of the conspiracy is chargeable to all members.

257. The agreement and overt acts were done intentionally and with malice.

258. As a direct and proximate result of the civil conspiracy, ThermoLife has been injured in an amount to be proven at trial in excess of $75,000, exclusive of interest and costs.

JURY TRIAL DEMAND

1. Plaintiff requests a trial by jury on all aspects of the Complaint.

PRAYER FOR RELIEF

WHEREFORE, ThermoLife demands judgment against defendants A1 as follows:

A. For an award disgorging any and all monies earned by A1 in connection with the sale of the products identified above;

B. For an award of compensatory and/or restitutionary damages in favor of ThermoLife in an amount to be proven at trial;

C. For an award of treble damages under 15 U.S.C. §§ 1117, 1125(a);

D. For an award of ThermoLife's attorneys' fees and costs under 15 U.S.C. § 1117, A.R.S. § 13-2314.04, and any applicable law;

E. For an award of ThermoLife's damages, treble damages, and attorneys' fees under 18 U.S.C. § 1961 *et seq.*

F. For prejudgment interest on any liquidated sum determined to be due Plaintiff;

G. For post-judgment interest on any judgment;

H. For punitive damages in an amount sufficient to deter A1 from future wrongful and outrageous conduct;

I. An Order permanently enjoining, A1 and all those persons in active concert or participation with them, from making false statements on the internet about their products and an order requiring A1 and those acting in concert or participation with them to remove the false statements from the internet regarding A1's products;

J. For such other and further relief as the Court deems just and proper.

DATED this 21st day of November, 2018.

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