

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

ANDREA MORALES, Individually
and on Behalf of All Persons Similarly
Situating,

Case No.

Plaintiff,

JURY TRIAL DEMANDED

-v-

PURITY FIRST HEALTH PRODUCTS, INC.,
MIRA HEALTH PRODUCTS LTD.,

Defendants.

CLASS ACTION COMPLAINT

Plaintiff, Andrea Morales, brings this action on behalf of herself, and all others similarly situated, against defendants Purity First Health Products, Inc. (“Purity First”), and Mira Health Products Ltd. (“Mira Health”) (collectively “Defendants”), and states as follows:

NATURE OF ACTION

1. This is a consumer rights class action lawsuit because of Defendants' false, unfair and deceptive trade practices, false and misleading advertising and labeling practices, breaches of express and implied warranties, negligence and unjust enrichment arising from Defendants' manufacturing, marketing, labeling and selling dietary supplements containing extremely harmful ingredients including undisclosed anabolic steroids. Defendants, Purity First and Mira Health, collectively manufacture, distribute, market and sell Healthy Life Chemistry B-50 capsules, Health Life Chemistry Multi-

Mineral capsules, and Health Life Chemistry Vitamin C capsules (the “Subject Products”) containing Methasterone, Dimethazine, and Dimethyltestosterone.

2. Defendants collectively manufacture, label, market and sell a purported dietary supplement known as Healthy Life Chemistry Multi-Mineral capsules that contained the anabolic steroid Dimethyltestosterone.

3. Defendants collectively manufacture, label, market and sell a purported dietary supplement known as Healthy Life Chemistry B-50 capsules that contained the anabolic steroids Methasterone and Dimethazine.

4. Defendants collectively manufacture, label, market and sell a purported dietary supplement known as Healthy Life Chemistry Vitamin C capsules that contained the anabolic steroid Dimethyltestosterone.

5. Defendants worked together to manufacture, label, and market and sell the Subject Products to consumers, and achieved this success through broad-based advertising and marketing campaigns that purported the Subject Products to be safe and effective supplements providing health benefits.

6. In reality, no such proof exists. Contrary to Defendants’ implied and express representations, the Subject Products are dangerous and contain anabolic steroids. Defendants lacked any adequate substantiation for their advertising claims, including clinical support. Instead of being the safe and dietary supplements that Defendants promised, the Subject Products cause dangerous side effects, including without limitation: abnormal liver and thyroid function, kidney failure, increased risk of stroke and heart attack, unusual hair growth and missed menstruation in females, impotence and low testosterone levels in males, and short stature in children. Despite

these facts, Defendants marketed and sold the Subject Products to unsuspecting consumers. Plaintiff, and all others similarly situated, did not bargain for a product that causes adverse health effects in exchange for their payment of the purchase price.

7. The Drug Enforcement Administration (“DEA”) published a Final Rule on July 30, 2012, (77 Fed. Reg. 44,456) placing Methasterone into Schedule III of the federal Controlled Substances Act (“CSA”) as anabolic steroids. The DEA’s administrative scheduling of Methasterone, along with its salts, esters and ethers, became effective August 29, 2012.

8. As a result of misrepresentations and omissions to their customers about the safety and efficacy of the Subject Products, Defendants have taken millions of dollars from these consumers.

9. Defendants' advertising campaign has been extensive and comprehensive, and conveyed these deceptive messages of safety and efficacy to consumers throughout the United States including but not limited to the State of Florida. Defendants conveyed their deceptive claims about the SUBJECT PRODUCTS through a variety of media, including point of sale displays, magazines, the Internet and on the Subject Products' packaging. The only reason a consumer would buy Subject Products is to obtain the claimed advertised benefits of a safe and effective product.

10. As a result of the misleading messages conveyed through its campaign, Defendants have sold products that do not perform as advertised, and can cause serious, life-threatening harm to people who consume them. Further, Defendants have

been able to charge a premium price for their unsafe and ineffective nutritional supplement products.

11. FDA's July 9 – 17, 2013 inspection of Mira Health's facility (the "July 2013 inspection") established that the Subject Products that Mira Health distributed are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they were prepared, packed, and held in a manner that does not conform to dietary supplement current good manufacturing practice. Mira Health's significant deviations from dietary supplement current good manufacturing practice, include, but are not limited to, the following:

a. Failure to conduct at least one appropriate test or examination to verify the identity of a dietary ingredient prior to its use, as required by 21 C.F.R. § 111.75(a)(1)(i). Specifically, Defendants did not conduct identity testing on any dietary ingredients prior to their use in manufacturing the Subject Products;

b. Failure to qualify a supplier of a non-dietary component prior to using the component to manufacture the Subject Products, as required by 21 C.F.R. § 111.75(a)(2)(ii). Specifically, Defendants did not qualify any of their suppliers' certificates of analyses by confirming the results of such suppliers' tests or examinations.

c. Failure to verify that a finished batch of the Subject Products meet product specifications for identity, purity, strength, composition, and for limits on those types of contaminants that may adulterate or that may lead to adulteration of the finished batch of the SUBJECT PRODUCTS, as required by 21 C.F.R. § 111.75(c). Specifically, Defendants sent finished products for microbial testing, but they do not verify that their finished batches of the Subject Products meet product specifications for identity, purity, strength, and composition.

d. Failure to include complete information relating to the production and control of each batch in batch production records, as required by 21 C.F.R. § 111.255(b). Specifically, Defendants failed to include the following information in the batch production for Mineral Complex: the pre-encapsulation checklist; information about the capsules used in production; the pre-packing and labeling checklist; bottling count chart; documentation that quality assurance approved the product label; documentation of final product sampling; and documentation of final review by the QA/QC team.

e. Failure to ensure that manufacturing, labeling, and holding operations ensure the quality of the Subject Products and that the Subject Products were packaged and labeled as specific in the master manufacturing record, as required by 21 C.F.R § 111.105. Specifically, Defendants quality control personnel did not review batch records for completeness and accuracy prior to releasing certain finished dietary supplements.

f. Failure to hold components, dietary supplements, packaging, and labels under conditions that do not lead to their mix-up, contamination, or deterioration, as required by 21 C.F.R § 111.455(c). Specifically Defendants' raw materials, in-process materials, quarantined materials, and finished products are not clearly identified.¹

12. On July 26, 2013, the U.S. Food and Drug Administration ("FDA") issued a consumer warning that the public should not use or purchase Health Life Chemistry B-50 capsules manufactured and marketed by the Defendants because the product contained Methasterone and Dimethazine.

¹ *UNITED STATES OF AMERICA v. MIRA HEALTH et al.*, Case No.: 2:14-cv-03549-JFB-GRB

13. On July 31, 2013, Defendants issued a nationwide recall of specific lots of Health Life Chemistry B-50 capsules, Healthy Life Chemistry Multi-Mineral capsules and Healthy Life Chemistry Vitamin C capsules.

14. Defendants issued a recall of Health Life Chemistry B-50 capsules because this product contained Methasterone and Dimethazine.

15. Defendants issued a recall of Healthy Life Chemistry Multi-Mineral and Vitamin C capsules because these products contained Dimethyltestosterone.

16. Plaintiff brings this action on behalf of herself, and other similarly situated consumers who purchased the Subject Products in order to recover compensatory and punitive damages, attorney's fees, other remedies the Court finds appropriate, and to correct the false and misleading advertising and labeling of the Subject Products. Plaintiff alleges violations of the public policies against engaging in false and misleading advertising, unfair competition and deceptive conduct towards consumers as proscribed by Florida Deceptive and Unfair Trade Practices Act §§501.201-501.213.

PARTIES

17. Plaintiff, Andrea Morales, is an individual and resident of Florida. During the class period, and before making her purchases, Plaintiff was exposed to and read Defendants' advertising claims, including the Subject Products' product labeling and Internet websites. Plaintiff was led to believe that the Subject Products were safe and effective. Plaintiff purchased each of the Subject Products within the class period. Specifically, Plaintiff purchased and consumed Defendants' Health Life Chemistry B-50 capsules, Healthy Life Chemistry Multi-Mineral capsules and Healthy

Life Chemistry Vitamin C capsules within the class period. Unbeknownst to Plaintiff, the Subject Products contained anabolic steroids. Plaintiff purchased and used the Subject Products as directed, believing it was reasonably safe and effective as a dietary supplement. Plaintiff did not know the Subject Products posed serious adverse health risks and was not proven effective when they purchased them.

Defendant Purity First

18. Defendant, Purity First, is a corporation incorporated under the laws of the State of New York, authorized to do business in the State of Florida, which maintained its principal place of business at 51 Florida Street, Farmingdale, New York 11735.

19. At all relevant times, Purity First transacted, solicited, and conducted business whether through retail stores or through internet merchants in the State of Florida and derived substantial revenue from such business.

Defendant Mira Health

20. Defendant, Mira Health, is a corporation incorporated under the laws of the State of New York, authorized to do business in the State of Florida, which maintained its principal place of business at 65 E. Carmans Road, East Farmingdale, New York 11735.

21. Defendant Mira Health conducted regular and sustained business in the State of Florida and throughout the nation. During the class period Mira Health was regularly engaged in the business of packaging, distributing, and/or selling, either directly or indirectly, through third parties or related entities, non-prescription nutritional/dietary supplements for sale to, and use by, members of the general

public.

22. At all times herein alleged, each of Defendant was the agent, servant, partner, aider and abettor, co-conspirator and joint venture of the other Defendant herein, and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture, and rendered substantial assistance and encouragement to the other Defendant, knowing that their conduct constituted unlawful business practices, thereby breaching the duties owed to Plaintiff and the Class.

JURISDICTION AND VENUE

23. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum or value of \$5,000,000 and is a class action in which some of the members of the class of plaintiff are citizens of states different from Defendants.

24. Venue is proper in this Court pursuant to 28 U.S.C. §1391 in that many of the acts and transactions giving rise to this action occurred in this district and because Defendants:

- (a) are authorized to conduct business in this district and has intentionally availed itself of the laws and markets within this district through the promotion, marketing, distribution and sale of its products in this district;
- (b) do substantial business in this district; and
- (c) are subject to personal jurisdiction in this district.

FACTUAL ALLEGATIONS

25. Healthy Life Chemistry B-50 capsules, Health Life Chemistry Multi-Mineral capsules, and Health Life Chemistry Vitamin C capsules are a trademarked product sold and marketed by Purity First, and manufactured by Mira Health. The Subject Products contained the anabolic steroids: Methasterone, Dimethazine and Dimethyltestosterone. The anabolic steroids are known to be active ingredients that lead to serious adverse health consequences as previously stated, and Methasterone is also a schedule III controlled substances.

26. Throughout the class period, the Subject Products contained anabolic steroids that caused them to be dangerous. They also did not work as advertised.

27. Methasterone, also known as Superdrol, Methasteron, or Methyltestosterone, is an oral anabolic steroid. As such it has been classified as a Schedule III Controlled Substance, and any unauthorized manufacturing, distribution and sale of this compound for human consumption is prohibited.

28. Dimethazine, with the chemical name 17b-OH-2a, 17-dimethyl-5a-androstan-3-one-3.3'azine also known as DMZ, is an oral anabolic steroid

29. Dimethyltestosterone, also known as 17alpha-dimethyltestosterone or calusterone, is an oral anabolic steroid.

30. While anabolic steroids are used by physicians to treat various medical conditions, such as systemic vasculitis and myositis, they are also widely abused because of their perceived ability to enhance athletic performance and muscle growth.

31. Steroids were originally developed in the 1930's as a synthetic form of testosterone to treat male patients suffering from low testosterone levels. Steroids remained in use through World War II after it was discovered that they could be useful in

nourishing soldiers who suffered from malnutrition, and eventually, during the 1956 Olympics, became a popular drug among Soviet athletes.

32. In 1958, an American physician named Dr. Zeigler created a more selective form of what is now widely known as anabolic steroids. From that point on, steroids increased in popularity among professional and amateur athletes until the International Olympic Committee finally banned the use of steroids in 1975.²

33. In 1988, the first major federal regulation of steroids was introduced as part of the Anti-Drug Abuse Act, eventually leading to Congress passing the Anabolic Steroid Enforcement Act of 1990 which placed certain anabolic steroids on Schedule III of the Controlled Substances Act (CSA). In spite of these efforts, the sale of anabolic steroids is still prevalent and on the rise.

34. The FDA July 26, 2013 News Release revealed 29 reports of adverse incidents, associated with the use of Healthy Life Chemistry B-50 Capsules. These reports included fatigue, muscle cramping, and myalgia (muscle pain), as well as abnormal laboratory findings for liver and thyroid function, and cholesterol level. Additional adverse effects include, but are not limited to: abnormal blood lipid levels, increased risk of heart attack and stroke, masculinization of women, shrinkage of the testicles, breast enlargement, infertility in males, and short stature in children.³

35. Despite these facts, Defendants conveyed their deceptive claims about the Subject Products through a variety of media, including magazines, the Internet, and on

²Journal of Sport History, Vol. 20. No. 1 (Spring 1993), *Isometric or Steroids? Exploring New Frontiers Of Strength in the Early 1960s*, Fair, John, D.

<http://www.la84foundation.org/SportsLibrary/JSH/JSH1993/JSH2001/jsh2001b.pdf>

³ July 26, 2013, FDA News Release

<http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm362799.htm>

the Subject Products' label and packaging. In addition, retailers market and sell the Subject Products in stores, on their websites and through other advertising media.

36. In addition to its own independent misleading advertising about the Subject Products, Defendant Purity Health participated in, controlled, enabled, and adopted Mira Health's representations concerning the safety and efficacy of the Subject Products. Purity First, which sold the Subject Products, adopted and is responsible for the representations made on the packaging and labeling of the Subject Products regarding the safety and efficacy, when it decided to place such Subject Products on store shelves and retail websites, and thereafter advertised and sold such Subject Products to Plaintiff and other members of the Class.

37. The health problems associated with Subject Products manifest themselves when consumers consume the Subject Products at recommended dosage levels.

38. Mira Health similarly knew, or in the exercise of reasonable care ought to have known, that the Subject Products are not effective or safe, and contained anabolic steroids.

39. Plaintiff is suing for conduct that violates the FDA and FDCA, but Plaintiff is not suing *because* the conduct violates the FDA and FDCA. *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013). Rather, Plaintiff's claims are based on Florida Statutes as well as common law. As such, Plaintiff's claims are not preempted by federal regulation.

CLASS DEFINITION AND ALLEGATIONS

40. The proposed, ascertainable Class consists of:

All consumers in Florida who purchased the Subject Products from July 2012 through July 26, 2013. Excluded from the Class are Defendants and their officers, directors and

employees and those who purchased the Subject Products for the purpose of resale.

41. *Numerosity*. The members of the Class are so numerous that their individual joinder is impracticable. Plaintiff is informed and believes, and on that basis alleges, that the proposed Class contains many thousands of members. The precise number of Class members is unknown to Plaintiff.

42. *Existence and Predominance of Common Questions of Law and Fact*
Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

- a) Whether Defendants had adequate substantiation for their claims prior to marking them;
- b) Whether the Subject Products were reasonably safe for consumption;
- c) Whether Defendants concealed or omitted material information concerning the safety of the Subject Products;
- d) Whether the claims discussed above are true, or are misleading, or reasonably likely to deceive;
- e) Whether Defendants' alleged conduct violates public policy
- f) Whether the alleged conduct constitutes violations of the laws asserted herein:
- g) Whether Defendants engaged in false or misleading advertising:
- h) Whether Plaintiff and Class members have sustained

monetary loss and proper measure of that loss;

i) Whether Plaintiff and Class members are entitled to an award of punitive damages; and

j) Whether Plaintiff and Class members are entitled to declaratory and injunctive relief

43. **Typicality.** Plaintiff's claims are typical of the claims of the members of the Class in that Plaintiff asserts the same claims.

44. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has retained counsel highly experienced in complex consumer class action litigation, as well as large, complex, multi-Plaintiff litigation involving dietary supplements, and Plaintiff intends to prosecute this action vigorously. Plaintiff has no averse or antagonistic interests to those of the Class

45. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against the Defendants. It would thus be virtually impossible for the Class, on an individual basis, to obtain effective redress for the wrongs done to them.

46. Unless a class is certified Defendants will retain monies received as a result of their conduct that was taken from Plaintiff and proposed Class members. Unless a class wide Injunction is issued, Defendants will continue to commit the violations alleged, and the members of the Class and the general public will continue to be misled.

47. Defendants have acted and refused to act on grounds generally applicable

to the Class, making appropriate final injunctive relief with respect to the Class as a whole.

COUNT I

VIOLATIONS OF FLORIDA CONSUMER PROTECTION STATUTES §501.201-§501.213, FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT

48. Plaintiff realleges and incorporates the allegations contained in the paragraphs 1-47 above as if fully set forth herein.

49. Defendants violated Chapter 499 of the Florida Drug and Cosmetic Act (the “Act”) by engaging in the following practices proscribed by §499.001 to §499.067 Florida Statutes (2014):

(a) the dissemination of any false advertisement of [the SUBJECT PRODUCT].... [the] advertisement is false if it is false or misleading in any way

(b) the distribution in commerce of [the SUBJECT PRODUCT with] labeling or advertis[ment that] is in violation of this part.

(c) the manufacturing, repackaging, packaging, selling, delivery, holding, or offering for sale of [the SUBJECT PRODUCT in]which the advertising or labeling is false or misleading.

(d) the advertising of [the SUBJECT PRODUCT] that is adulterated or misbranded.

(e) the receiving in commerce of [the SUBJECT PRODUCT] that is falsely advertised or labeled or the delivering or proffering for delivery of [the SUBJECT PRODUCT].

50. Defendants violated the Act by representing through their product labeling

and advertisements the Subject Products were safe and effective as described above when they knew, or should have known, that the representations and advertisements were unsubstantiated, false and misleading.

51. Florida Consumer Protection Statue §501.204 (2014) prohibits any “unlawful,” “fraudulent” or “unfair” business act or practice and any false or misleading advertising. For the reasons discussed above, and through statements including but not limited to that Subject Products were safe and effective, did not cause adverse side effect, etc., Defendants have engaged in unfair, deceptive, untrue and misleading advertising in violation of Florida Consumer Protection Statue§501.

52. The Florida Deceptive and Unfair Trade Practices Act also prohibits any “unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce. Defendants have violated §501.204’s prohibition against engaging in unlawful acts and practices by, *inter alia*, making the representations and omissions of material facts, as set forth more fully herein, and have violated 21 U.S.C. §343. 21 U.S.C. §379aa-1, 15 U.S.C. §45 (a)(I), 49 Fed. Reg. 30999 (Aug. 2, 1984), Federal Food, Drug and Cosmetic Act, Fla. Stat. §499.001 to §499.067 (2014), and the common law.

53. Plaintiff and the Class reserve the right to allege other violations of law which constitute other unlawful business acts or practices.

54. Defendants’ acts, omissions, misrepresentations, practices and non-disclosures as alleged herein also constitute “unfair” business acts and practices within the meaning of The Florida Deceptive and Unfair Trade Practices Act §501.201-§501.213 *et. seq.* in that their conduct is substantially injurious to consumers, offends

public policy, and is immoral, unethical, oppressive and unscrupulous as the gravity of the conduct outweighs any alleged benefits attributable to such conduct.

55. As stated in this Complaint, Plaintiff alleges violations of consumer protection, unfair competition, and truth-in-advertising laws in Florida resulting in harm to consumers. Defendants' conduct constitutes violations of the public policies against engaging in false and misleading advertising, unfair competition and deceptive conduct towards consumers as proscribed by Florida Deceptive and Unfair Trade Practices Act §§501.201-501.213.

56. There were reasonably available alternatives to further Defendants' legitimate business interests, other than the conduct described herein

57. Defendants' claims, nondisclosures and misleading statements, as more fully set forth above and collectively as a scheme, were false, misleading and likely to deceive the consuming public within the meaning of Florida Deceptive and Unfair Trade Practices Act. Plaintiff was in fact deceived by Defendant's conduct, and thus suffered injury in fact.

58. Defendants' conduct caused substantial injury to Plaintiff and the other Class members. Plaintiff and Class members have suffered injury in fact and have lost money as a result of Defendants' unlawful, unfair and fraudulent conduct.

59. Unless restrained and enjoined, Defendants will continue to engage in the above-described conduct. Accordingly, injunctive relief is appropriate.

60. Plaintiff, on behalf of herself, all others similarly situated, seeks restitution and disgorgement of all money obtained from Plaintiff and the members of the Class collected as a result of unfair competitions, an injunction prohibiting Defendants from

containing such practices, corrective advertising, including providing notification of the Subject Products' health risks, punitive damages, attorney's fees and costs, and all other relief this Court deems appropriate, consistent with Florida Deceptive and Unfair Trade Practices Act.

COUNT II

VIOLATION OF FLORIDA INTENTIONAL FALSE ADVERTISING STATUTE §817.44

61. Plaintiff realleges and incorporates the allegations contained in the paragraphs 1-47 above as if fully set forth herein.

62. Defendants knowingly and intentionally engaged in false advertising concerning effectiveness and safety of the Subject Products. Defendants' conduct was consumer-oriented and this conduct had a broad impact on consumers at large.

63. Defendants' actions were unlawful and under the circumstances, Defendants had actual knowledge of the falsity, or at the very least ought to have known of the falsity thereof.

64. Fla. Stat. § 817.44 (2014) defines "false advertising" as "invitations for offers for the sale of any property, real or personal, tangible or intangible, or any services, professional or otherwise, by placing or causing to be placed before the general public, by any means whatever, an advertisement describing such property or services as part of a plan or scheme with the intent not to sell such property or services so advertised."

65. Defendants intentionally, falsely advertised the safety and effectiveness of the Subject Products in Florida and throughout the United States.

66. As fully alleged above, by intentionally and knowingly advertising, marketing, distributing and selling the Subject Products to Plaintiff and other members of the Class who purchased the Subject Products in Florida, Defendants engaged in false advertising in violation of Fla. Stat. § 817.44 (2014).

67. Defendants' misleading marketing, advertising, packaging and labeling of the Subject Products were likely to deceive reasonable consumers.

68. Plaintiff and other members of the Class who purchased the Subject Products in Florida were in fact deceived.

69. As a direct and proximate cause of Defendants' violation of Fla. Stat. § 817.44 (2014), Plaintiff and the members of the Class who purchased the Subject Products in Florida were injured when they paid good money for these illegal, harmful, and worthless products.

70. As a result of Defendants' unlawful false advertising practices, Plaintiff and the members of the Class who purchased the Subject Products in Florida, are entitled to an order enjoining such future conduct and such other orders and judgments which may be necessary to disgorge Defendants' ill-gotten gains and to restore to Plaintiff and the members of the Class any money paid for the Subject Products pursuant to Fla. Stat. § 817.44 (2014).

71. Plaintiff and the members of the Class are also entitled to attorneys' fees.

COUNT III

BREACH OF EXPRESS WARRANTY

72. Plaintiff realleges and incorporates the allegations contained in the paragraphs 1-47 above as if fully set forth herein.

73. Plaintiff and the Class formed a contract with Defendants when they purchased the products. The terms of that contract include the promises and affirmations of fact made by Defendants on the packaging and through their marketing campaign. The packaging and advertising constitute express warranties that are a part of the contract, basis for the bargain, between the consumers and Defendants.

74. Defendants expressly warranted that the products were safe, effective and fit for use. Defendants also expressly warranted that the products were of merchantable quality, that they did not produce dangerous side effects, and that they were adequately tested and fit for their intended purpose.

75. Defendants knew or should have known that despite the warranties, they had breached the terms of the contract with the consumers by not providing safe and effective dietary supplement products because:

- i. Laboratory analysis revealed that the products contained harmful anabolic steroids, and were therefore unsafe and ineffective;
- ii. Mira Health's claims of safety and efficacy could not be substantiated as no studies or laboratory analysis were conducted to test the safety of the product;
- iii. The FDA had received 29 serious adverse events associated with the use of Defendants' products;

76. Members of the public, including Plaintiff, reasonably relied upon the skill and judgment of Defendants, and upon the express warranties in purchasing the subject products.

77. Plaintiff and the Class purchased the products for their intended purpose.

78. Defendants breached these express warranties because the products were not safe, effective and fit for their intended purpose, were not of merchantable quality, and in fact, caused serious and potentially lethal side effects to consumers when taken in their recommended dose.

79. Due to Defendants' wrongful conduct, Plaintiff and the Class could not have known about the true nature of the risks and side effects associated with the subject products.

80. As a direct and proximate result of Defendants' breach of their contract, including the breach of express warranties, Plaintiff suffered injuries entitling Plaintiff to judgment and equitable relief against Defendants, as well as restitution, including all monies paid for the subject products and disgorgement of profits from Defendants received from sales of the subject products, attorneys' fees, punitive damages, and costs, as set forth in the Prayer for Relief.

81. All conditions precedent to Defendants' liability under this contract, including notice, has been performed by Plaintiff and the Class.

82. In purchasing the Defendants' product, Plaintiff and the Class Members relied on the representations of the Defendants and had no reason to doubt or dispute those representations. Indeed, due to the uniformity of the representations to all Class Members, Plaintiff and the Class, at all times, are presumed to have reasonably and justifiably relied both directly and indirectly on the actions and representations of the Defendant.

83. As a direct and proximate result of Defendants' breach of warranties, Plaintiff and the Class have suffered actual damages in an amount not presently known,

but has acted on grounds applicable to all purchasers of all relevant products.

COUNT IV

BREACH OF IMPLIED WARRANTY

84. Plaintiff realleges and incorporates the allegations contained in the paragraphs 1-47 above as if fully set forth herein.

85. The Uniform Commercial Code § 2-314 provides that, unless excluded or modified, a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind.

86. At all times, Florida has codified and adopted the provisions of the Uniform Commercial Code governing the implied warranty of merchantability. Fla. Stat. §672.314 (2014).

87. The subject products are “goods” as defined in the various states’ commercial codes governing the implied warranty of merchantability.

88. By placing the products in the stream of commerce, Defendants impliedly warranted that the products were reasonably safe, effective and adequately tested for their intended use, and that they were of merchantable quality.

89. Defendants knew that purchasers relied upon them to design, manufacture, license and sell dietary supplements that were reasonably safe and effective, and in fact members of the public, including Plaintiff, reasonably relied upon the skill and judgment of Defendants and upon the implied warranties in purchasing and consuming the subject products.

90. Plaintiff and the Class purchased the products for their intended purpose

and use.

91. In breach of their implied warranty, the subject products are unsafe, ineffective and not merchantable, in that they cause serious and even fatal health problem, have not been proven effective for their intended uses, and are not effective for their intended uses.

92. The subject products were not reasonably safe for their intended use when they left Defendants' control and entered the marketplace.

93. The defects were not open or obvious to consumers, including Plaintiff and the Class, who could not have known about the nature of the risks and side effects associated with the subject products until after they purchased or used them.

94. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff and Class Members have sustained injuries by purchasing the subject products, which were not safe or effective as represented, thus entitling Plaintiff to judgment and equitable relief against Defendants, as well as restitution, including all monies paid for the subject products, and disgorgement of profits from the sale of the subject products, attorneys' fees, punitive damages, and costs, as set forth in the Prayer for Relief.

COUNT V

NEGLIGENCE

95. Plaintiff realleges and incorporates the allegations contained in the paragraphs 1-47 above as if fully set forth herein.

96. Defendants had a duty to represent their products accurately. Defendants breached that duty by purposefully or negligently making misrepresentations of fact and omissions of material fact to Plaintiff and the other Class members about the Subject

Products.

97. Defendants failed to label or advertise the Subject Products in a lawful manner and violated their duties owed to consumers by purposefully or negligently engaging in the conduct described herein.

98. Plaintiff and the other Class members, as a direct and proximate cause of Defendants' breach of their duties, were damaged by receiving harmful and worthless products, or at the very least, misbranded deceptively labeled products.

99. As described above, Defendants' actions violated a number of express statutory provisions designed to protect Plaintiff and the Class.

100. Defendants' illegal actions constitute negligence *per se*.

101. Moreover, the labeling and misbranding provisions violated by Defendants are strict liability provisions.

102. By reason of the foregoing, Plaintiff and the other Class members have suffered damages in an amount to be determined at trial, together with punitive damages.

COUNT VI

UNJUST ENRICHMENT

103. Plaintiff realleges and incorporates the allegations contained in the paragraphs 1-47 above as if fully set forth herein.

104. Defendants designed, manufactured, licensed, produced, promoted, marketed, and/or sold the ineffective and dangerous products.

105. Plaintiff and Class Members conferred upon Defendants non-gratuitous payments for the products that were not safe and effective as advertised, and many

expose them to serious illness, which can be fatal. Defendants accepted or retained the non-gratuitous benefits conferred by Plaintiff and Class Members with full knowledge and awareness that, as a result of Defendants' unconscionable wrongdoing, Plaintiff and the Class Members were not receiving products of the quality, nature, fitness or value that had been represented by Defendants and reasonable consumers would have expected.

106. Retaining the non-gratuitous benefits conferred upon Defendants by Plaintiff and Class Members under these circumstances made Defendants' retention of the non-gratuitous benefits unjust and inequitable.

107. Defendants' retention of the non-gratuitous benefits conferred by Plaintiff and Class Members is unjust and inequitable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment:

- A. Certifying the Class as requested herein;
- B. That the Court adjudge and decree that Defendants have engaged in the conduct alleged herein;
- C. Awarding declaratory and injunctive relief as permitted by law or equity, including: enjoining Defendants from continuing the unlawful practices as set forth herein, and directing Defendants to identify, with Court supervision, victims of their conduct and pay them restitution and disgorgement of all monies acquired by Defendants by means of any act or practice declared by this Court to be wrongful;
- D. Ordering Defendants to engage in a corrective advertising campaign;
- E. Awarding Plaintiff and the proposed Class members damages;

- F. Awarding restitution and disgorgement to Plaintiff and the other Class members;
- G. Awarding Plaintiff and the Classes punitive damages;
- H. Awarding Plaintiff treble damages;
- I. Awarding attorneys' fees and costs; and
- J. Providing such further relief as may be just and proper

JURY DEMAND

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

Dated: November 3, 2014

Respectfully submitted,

/s/ Tim Howard _____

Tim Howard, J.D., Ph.D.
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AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Florida



ANDREA MORALES, Individually and on Behalf of All Persons Similarly Situated

Plaintiff(s)

v.

PURITY FIRST HEALTH PRODUCTS, INC., MIRA HEALTH PRODUCTS LTD.,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Purity First Health Products, Inc. 51 Florida Street Farmingdale, New York 11735

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Tim Howard
Howard & Associates, P.A.
2120 Killarney Way, Ste. 125
Tallahassee, FL 32309

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify)*:

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00 _____ .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Florida



ANDREA MORALES, Individually and on Behalf of All
Persons Similarly Situated

Plaintiff(s)

v.

PURITY FIRST HEALTH PRODUCTS, INC., MIRA
HEALTH PRODUCTS LTD.,

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) Mira Health Products, Ltd.
65 E. Carmans Road,
East Farmingdale, New York 11735

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Tim Howard
Howard & Associates, P.A.
2120 Killarney Way, Ste. 125
Tallahassee, FL 32309

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

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Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc: