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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

NUTRITION DISTRIBUTION LLC, an Arizona Limited Liability Company,

Plaintiff,

vs.

DURACAP LABS, LLC, a Georgia Limited Liability Company; **WES HOUSER**, an individual; **ACTIVE SPORTS SUPPLEMENTS, LLC**, dba ACTIVE SPORTS DISTRIBUTION, a Georgia Limited Liability Company; **EXCESSIVE SPORTS NUTRITION**, dba ALPHALAB TECHNOLOGIES, a Hawaiian Limited Liability Company; **ACCELERATED SPORTS NUTRITION**, dba WARRIOR LABZ, a Hawaiian Limited Liability Company; **SHAWN OGATA**, an individual; **JUSTIN GANIR**, an individual; and **DOES 1 through 10**, inclusive,

Defendants.

CASE NO:

COMPLAINT FOR:

(1) FALSE ADVERTISING IN VIOLATION OF THE LANHAM ACT § 42 (a)(1)(B)); AND

(2) VIOLATION OF THE CIVIL RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT (RICO)

[DEMAND FOR A JURY TRIAL]

Plaintiff Nutrition Distribution, LLC, dba Athletic Xtreme ("ND" or "Plaintiff"), by and through its undersigned attorneys, submits this Complaint against defendants DuraCap Labs, LLC ("DuraCap"), Wes Houser ("Houser"), Active Sports Supplements, LLC, dba Active Sports Distribution ("ASD"), Excessive Sports Nutrition, LLC, dba AlphaLab Technologies ("AlphaLab"), Accelerated Sports Nutrition, LLC, dba Warrior Labz ("Warrior Labz"), Justin Ganir ("Ganir"), and Shawn Ogata ("Ogata") (collectively, "Defendants"), and in support thereof, avers as follows:

INTRODUCTION

1. This is a civil action arising out of Defendants' false and misleading advertising regarding their products, "OSTAGENIN" and "XTREME OSTA" (collectively, the "Ostarine Products"), which are unlawfully marketed and misbranded by Defendants. Contrary to Defendants' representations, the active ingredient in their products is Ostarine – a "Selective Androgen Receptor Modulator" ("SARM"). SARMs, like the Ostarine Products, are synthetic drugs with similar effects to illegal anabolic steroids.

2. With respect to Warrior Labz's product "OSTAGENIN," Defendants have misbranded this product as "intended for research purposes only," while simultaneously advertising and selling it as a new miracle body building "drug" and "supplement." For example, Defendants advise consumers that they should "***consume*** 2-3 capsules daily" for "extreme results," which is completely contradictory to Defendants other disclaimers. Moreover, Defendants tout numerous purported physical benefits of OSTAGENIN, including "increased muscle gains," "muscle hardness," and "muscle recovery," despite their disclaimers that OSTAGENIN is for "research purposes only."

3. With respect to AlphaLab's product "XTREME OSTA," Defendants claim that their product is a "dietary supplement," which will result in numerous purported physical benefits, including but not limited to, increased strength, "dry lean gains," and "shredding body fat." In addition, Defendants claim that XTREME OSTA

"has also been shown to produce dose-dependent increases in bone mineral density and mechanical strength in addition to being able decrease body fat and increase lean body mass." Moreover, Defendants represent to consumers that SARMs, such as XTREME OSTA and OSTAGENIN, cause "muscle growth in the same manner as steroids, however unlike testosterone and other anabolic steroids and prohormones, SARMs (as nonsteroidal agents) don't produce the growth effect on prostate and other secondary sexual organs."

4. Despite the aforementioned completely contradictory statements by Defendants, the Ostarine Products contain the same active ingredient, Ostarine. However, Ostarine is not a "dietary supplement" and is currently under investigation as a new pharmaceutical drug. Thus, Defendants' Ostarine Products, and any other products containing SARMs, are not recognized as safe and effective for any of the uses suggested by Defendants and may pose significant health and safety risks to consumers.

5. Indeed, medical experts have opined that products containing SARMs "have ***many recognized potential serious side effects***, including hepatoxicity (liver damage), and markedly lower plasma HDL cholesterol (raising the risk of heart disease)," and may have even more serious consequences that are currently unknown. In fact, since Ostarine is only in phase II clinical trials, medical experts have emphasized that there is "no evidence that Ostarine is safe for humans to consume." Thus, medical experts have concluded that the sale of products containing SARMs, like Defendants' Ostarine Products, is "***highly dangerous to public safety***."

6. Moreover, Defendants fail to disclose that SARMs are specifically prohibited for use in sporting events by the World Anti-Doping Agency and the U.S. Anti-Doping Agency, despite the fact that Defendants specifically markets their Ostarine Products to body builders and other competitive athletes.

7. Defendants' continuing false, misleading, illegal and deceptive practices have violated the Lanham Act and the Civil Racketeer Influenced and Corrupt

Organizations Act of 1970. Defendants' actions have unjustly enriched Defendants at the expense of Plaintiff, and have caused Plaintiff extensive and irreparable harm, including but not limited to, loss of revenue, disparagement, and loss of goodwill.

8. Moreover, Defendants are engaged in a conspiracy and scheme to defraud and mislead consumers by way of their false and misleading advertisements concerning the Ostarine Products, and to market and sell these products using false and fraudulent labeling claims, representations, and promises in violation of federal law.

9. Among other things, this action seeks to enjoin Defendants from the marketing and sale of its Ostarine Products, and any other products containing Ostarine and/or other SARMs, as Defendants are illegally and falsely marketing such products in violation of the Lanham Act and the Civil Racketeer Influenced and Corrupt Organizations Act of 1970.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. § 1121 and 28 U.S.C. § 1331 (federal question jurisdiction) and 28 U.S.C. 1332 (diversity jurisdiction) because Plaintiff asserts causes of action arising under federal law and the parties are citizens of different states and the controversy exceeds the value of $75,000.

11. This Court has personal jurisdiction over Defendants because they have, directly or through their intermediaries (including distributors, retailers, and others), developed, licensed, manufactured, shipped, distributed, offered for sale, sold, and advertised their nutritional supplement products in the United States, the State of Arizona, and this district, including but not limited to, the Ostarine Products and/or other products containing SARMs. Defendants have purposefully and voluntarily placed these products into the stream of commerce with the expectation that they will be purchased in this district.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions which gave rise to the claim occurred in this district. *See Rowpar Pharm., Inc. v. Lornamead, Inc.*, No. CV13-01071-PHX DGC, 2013 WL 5530825 (D. Ariz. Oct. 7, 2013) (finding venue in Arizona proper). Alternatively, venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(3).

PARTIES

13. Plaintiff Nutrition Distribution, LLC, dba Athletic Xtreme ("ND" or "Plaintiff") is an Arizona limited liability company with its principal place of business at 14215 N. 8th Pl., Phoenix, Arizona, 85022.

14. Defendant DuraCap Labs, LLC ("DuraCap") was previously registered as a Georgia limited liability company, which lists 6080 McDonough Drive, Suite A, Norcross, Georgia, 30093 as its business address.

15. Defendant Wes Houser ("Houser") is an individual who, on information and belief, resides in Georgia. Houser controls Duracap who manufactures illicit products to multiple distributors.

16. Defendant Active Sports Supplements, LLC, dba Active Sports Distribution ("ASD") is a Georgia limited liability company, which lists 6080 McDonough Drive, Suite A, Norcross, Georgia, 30093 as its business address.

17. Defendant Excessive Sports Nutrition, LLC dba AlphaLab Technologies ("AlphaLab") is a Hawaiian limited liability company, which lists P.O. Box 3725, Lihue, Hawaii, 96766 as its business address.

18. Defendant Accelerated Sports Nutrition, LLC dba Warrior Labz ("Warrior Labz") is a Hawaiian limited liability company, which lists P.O. Box 3947, Lihue, Hawaii, 96766 as its business address.

19. Justin Ganir is an individual who, on information and belief, resides in Hawaii.

20. Shawn Ogata is an individual who, on information and belief, resides in Hawaii.

21. Upon information and belief, AlphaLab and Warrior Labz are owned, managed, and operated by Justin Ganir and Shawn Ogata.

22. Plaintiff is unaware of the true names and capacities of defendants sued herein as Does 1- 10, inclusive, and therefore sued these defendants by such fictitious names. Plaintiff will amend this Complaint to allege their true names and capacities when ascertained. Plaintiff is informed and believes and thereon alleges that each of these fictitiously named defendants is responsible in some manner for the occurrences herein alleged, and that Plaintiff's injuries as herein alleged were proximately caused by the aforementioned defendants.

FACTUAL ALLEGATIONS

23. The nutritional supplement industry is one of the fastest growing and most lucrative in the United States. A recent Forbes article estimates that nutritional supplement sales accounted for $32 billion in revenue in 2012 and predicts this number to grow to $60 billion within ten years. The growth and size of the nutritional supplement market and the relatively low barriers to entry provide perverse incentives for false advertising and unfair competition prohibited by the Lanham Act, among other illegal activity.

Plaintiff Nutrition Distribution & "Advanced PCT"

24. Plaintiff is a cutting edge sports supplement manufacturer and marketer. From its inception, Plaintiff was a leader in the nutritional supplement market, specifically for bodybuilding.

25. Plaintiff has products in several categories of body building products, including pre-workouts, muscle-gainers, fat burners and male performance enhancement.

26. After devoting its resources for over a year on product development and testing, Plaintiff introduced their formulations of "Advanced PCT" & "Ultra Reps" in

July 2009 and January 2012, respectively. Advanced PCT is a natural nutritional supplement that is designed to boost testosterone.

Defendants And Their Ostarine Products

27. Defendant AlphaLab is a competing nutritional supplement company located in Hawaii.

28. Defendant Warrior Labz is also a competing nutritional supplement company located in Hawaii.

29. Upon information and belief, AlphaLab and Warrior Labz are owned, managed, and operated by the same individuals, Justin Ganir and Shawn Ogata.

30. DuraCap is "a manufacturer of Nutraceuticals/Dietary Supplements." DuraCap claims to be "a GMP compliant and an FDA registered company," which specializes "in encapsulation manufacturing, sports nutrition and raw health powders, product formulation, brand design and distribution." DuraCap formulates, manufactures, sells, distributes, and/or markets the Ostarine Products at issue here along with numerous other products not compliant with federal law.

31. ASD is DuraCap's sister company. Through ASD, DuraCap markets and sells "some of the health and fitness industry's most popular supplements to retail stores worldwide." ASD formulates, manufactures, sells, distributes, and/or markets the Ostarine Products at issue here.

32. DuraCap and ASD promote themselves to consumers as the "leader" in the "nutraceutical industry," which according to Defendants is "approaching $85 billion annually." DuraCap and ASD also disingenuously claim that they are "committed to bringing ethics and professionalism to the forefront of the industry."

33. Contrary to the foregoing representations, Defendants are engaged in a conspiracy and scheme to defraud and mislead consumers by way of their false and misleading advertisements concerning the Ostarine Products, and to market and sell these

products using false and fraudulent labeling claims, representations, and promises in violation of federal law.

34. According to Defendants' representations on their websites and otherwise, the active ingredient in the Ostarine Products is a pharmaceutical ingredient known as Ostarine / MK-2866 ((2S)-3-(4-cyanophenoxy)-N-[4-cyano-3-(trifluoromethyl)phenyl]-2-hydroxy-2-methylpropanamide).

35. With respect to Warrior Labz's product OSTAGENIN, Defendants have misbranded this product as "intended for research purposes only," while simultaneously advertising and selling it as a new miracle body building "drug" and "supplement." For example, Defendants advise consumers that they should "consume 2-3 capsules daily" for "extreme results," which is completely contradictory to Defendants other disclaimers. Moreover, Defendants tout numerous purported physical benefits of OSTAGENIN, including "increased muscle gains," "muscle hardness," and "muscle recovery," despite their disclaimers that OSTAGENIN is for "research purposes only."

36. With respect to AlphaLab's product XTREME OSTA, Defendants claim that their product is a "dietary supplement," which will result in numerous purported physical benefits, including but not limited to, increased strength, promoting "dry lean gains," and "shredding body fat." In addition, Defendants claim that XTREME OSTA "has also been shown to produce dose-dependent increases in bone mineral density and mechanical strength in addition to being able decrease body fat and increase lean body mass." Moreover, Defendants represent to consumers that SARMs, such as XTREME OSTA and OSTAGENIN, cause "muscle growth in the same manner as steroids, however unlike testosterone and other anabolic steroids and prohormones, SARMs (as nonsteroidal agents) don't produce the growth effect on prostate and other secondary sexual organs."

37. As a preliminary matter, to the extent Defendants' Ostarine Products do not contain any label statements on their packages or containers, Defendants violate the

United States Federal Food, Drug, and Cosmetic Act ("FDCA"). The FDCA requires a "statement of identity," among other things, on all products. According to the U.S. Food and Drug Administration ("FDA"), "Products lacking a statement of identity are either defaulted as a dietary supplement or a misbranded drug and referred to the DEA."

38. Moreover, Ostarine is not a "dietary supplement" and is currently under investigation as a new pharmaceutical drug. Thus, Defendants' Ostarine Products and any other products containing SARMs are not recognized as safe and effective for any of the uses suggested by Defendants and may pose significant health and safety risks to consumers.

39. The FDCA, 21 U.S.C. § 321(ff)(1) defines a "dietary supplement" as a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Defendants' Ostarine Products and/or Ostarine / MK-2866 ((2S)-3-(4-cyanophenoxy)-N-[4-cyano-3-(trifluoromethyl)phenyl]-2-hydroxy-2-methylpropanamide) are not vitamins, minerals, herbs, botanicals, or amino acids. Thus, Defendants' Ostarine Products cannot be legally sold as "dietary supplements" and their inclusion in such products deems them adulterated. *See* 21 U.S.C. 350(b).

40. Pursuant to Section 201(ff)(3)(B)(ii) of the FDCA [21 U.S.C. § 321 (ff)(3)(B)(ii)], a dietary supplement may not include an article authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, unless the article was marketed as a dietary supplement or food before its authorization as a new drug. According to the FDA, Ostarine is a selective androgen receptor modulator for which substantial clinical investigations have been instituted and made public with regard to the treatment of cancer cachexia, or muscle wasting. The FDA has concluded that Ostarine was not marketed as a dietary supplement or as a food until after it was under substantial clinical investigation. Thus,

Defendants' Ostarine Products, which primarily contain the pharmaceutical ingredient Ostarine, are also excluded from the definition of a dietary supplement under section 201(ff)(3)(B)(ii) of the FDCA.

41. Under the FDCA, 21 U.S.C. § 201(g)(1) the term "drug" includes any articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and articles (other than food) intended to affect the structure or any function of the body of man or other animals. The Ostarine Products are actually "drugs" as defined by section 201(g)(1) of the FDCA [21 U.S.C. § 321(g)(1)], because they are intended to cure, mitigate, treat, or prevent disease conditions and affect the structure and function of the body. The intended use of a product may be determined by, among other things, its labeling claims, advertising, and circumstances surrounding its distribution. *See* 21 C.F.R § 201.128.

42. Defendants' statements and advertisements indicate that their Ostarine Products are intended to affect the structure and function of the body and are also intended for use in the treatment of certain conditions. Defendants' statements demonstrating the intended use of their Ostarine Products include, but are not limited to, the following:

a. OSTAGENIN will purportedly result in "increased muscle gains," "muscle hardness," and "muscle recovery."
b. XTREME OSTA will result in numerous purported physical benefits, including but not limited to, increased strength, promoting "dry lean gains," and "shredding body fat."
c. Defendants claim that XTREME OSTA "has also been shown to produce dose-dependent increases in bone mineral density and mechanical strength in addition to being able decrease body fat and increase lean body mass."

d. Defendants represent to consumers that SARMs, such as XTREME OSTA and OSTAGENIN, cause "muscle growth in the same manner as steroids, however unlike testosterone and other anabolic steroids and prohormones, SARMs (as nonsteroidal agents) don't produce the growth effect on prostate and other secondary sexual organs."

43. Defendants' Ostarine Products are also "new drugs" as defined by section 201(p) of the FDCA [21 U.S.C. § 321(p)], because they are not generally recognized among experts as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Under sections 301(d) and 505(a) of the FDCA [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA approved application is in effect for the new drug. No approved applications are in effect for Defendants' Ostarine Products. Consequently, Defendants' marketing and sale of their Ostarine Products without such approved applications also violates the FDCA.

44. Defendants' Ostarine Products are also "prescription drugs" as defined in section 503(b)(1)(A) of the FDCA [21 U.S.C. § 353(b)(1)(A)], because due to their toxicity or potentiality for harmful effect, the method of their use, or the collateral measures necessary for their use, they are not safe for use except under the supervision of a practitioner licensed by law to administer them.

45. The FDA has previously concluded that products like Ostarine and Defendants' Ostarine Products are prescription drugs because they contain SARMs and, therefore, "present significant potential safety risks to consumers who take them without the supervision of a practitioner licensed by law to administer such drugs."

46. According to section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)], a drug is misbranded if, among other things, it fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended [21 CFR Part 201.5].

Prescription drugs can be used safely only at the direction, and under the supervision of a licensed practitioner. Thus, it is impossible to write "adequate directions for use" for prescription drugs. FDA-approved prescription drugs that bear the FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson [21 CFR Part 201.100(c)(2) and 201.115]. Because there are no FDA-approved applications for Defendants' Ostarine Products, their labeling fails to bear adequate directions for their intended use, causing them to be misbranded under section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)].

47. The introduction or delivery for introduction into interstate commerce of any misbranded drug is prohibited by 21 U.S.C. § 331(a). Among other things, a drug is misbranded if its labeling is false or misleading. 21 U.S.C. § 352(a). The introduction or delivery for introduction into interstate commerce of a misbranded drug is a felony. 21 U.S.C. § 333(a)(2).

48. Defendants have falsely marketed and advertised their Ostarine Products, giving consumers the massive gains of illegal steroids and a false sense of security regarding their safety. In reality, Defendants and their executives, knew all along that their Ostarine Products were not recognized among experts as safe and effective for use under the conditions suggested by Defendants and may pose significant potential health and safety risks to consumers.

49. Defendants' false advertising is harmful to the marketplace for dietary and nutritional supplements and potentially to individual consumers. Defendants have created an illegitimate marketplace of young bodybuilders who will gain muscle "at all costs," but who are not informed of the dangers of Defendants' products. Users of Defendants' Ostarine Products have little incentive to use a natural product like Advanced PCT until they are hurt or the product is taken off the shelves.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(False Advertising in Violation of Section 43(a)(1)(B) of the Lanham Act)

50. Plaintiff incorporates the allegations contained in the foregoing paragraphs as though fully set forth herein in their entirety.

51. Defendants have purposely made false and misleading descriptions of fact concerning the nature, characteristics and qualities of their Ostarine Products.

52. For example, Defendants have misbranded OSTAGENIN as "intended for research purposes only," while simultaneously advertising and selling this product as a new miracle body building "drug" and "supplement." In this regard, Defendants advise consumers that they should "consume 2-3 capsules daily" for "extreme results," which is completely contradictory to Defendants other disclaimers. Moreover, Defendants tout numerous purported physical benefits of OSTAGENIN, including "increased muscle gains," "muscle hardness," and "muscle recovery," despite their disclaimers that OSTAGENIN is for "research purposes only."

53. Defendants claim that XTREME OSTA is a "dietary supplement," which will result in numerous purported physical benefits, including but not limited to, increased strength, promoting "dry lean gains," and "shredding body fat." In addition, Defendants claim that XTREME OSTA "has also been shown to produce dose-dependent increases in bone mineral density and mechanical strength in addition to being able decrease body fat and increase lean body mass." Moreover, Defendants represent to consumers that SARMs, such as XTREME OSTA and OSTAGENIN, cause "muscle growth in the same manner as steroids, however unlike testosterone and other anabolic steroids and prohormones, SARMs (as nonsteroidal agents) don't produce the growth effect on prostate and other secondary sexual organs."

54. To the extent Defendants' Ostarine Products do not contain any label statements on their packages or containers, Defendants violate the FDCA. The FDCA

requires a "statement of identity," among other things, on all products. According to the FDA, "Products lacking a statement of identity are either defaulted as a dietary supplement or a misbranded drug and referred to the DEA."

55. Moreover, Ostarine is not a "dietary supplement" and is currently under investigation as a new pharmaceutical drug. Thus, Defendants' Ostarine Products and any other products containing SARMs are not recognized as safe and effective for any of the uses suggested by Defendant and may pose significant health and safety risks to consumers.

56. The FDCA, 21 U.S.C. § 321(ff)(1) defines a "dietary supplement" as a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances. Defendants' Ostarine Products and/or Ostarine / MK-2866 ((2S)-3-(4-cyanophenoxy)-N-[4-cyano-3-(trifluoromethyl)phenyl]-2-hydroxy-2-methylpropanamide) are not vitamins, minerals, herbs, botanicals, or amino acids. Thus, Defendants' Ostarine Products cannot be legally sold as "dietary supplements" and their inclusion in such products deems them adulterated. *See* 21 U.S.C. 350(b).

57. Pursuant to Section 201(ff)(3)(B)(ii) of the FDCA [21 U.S.C. § 321 (ff)(3)(B)(ii)], a dietary supplement may not include an article authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, unless the article was marketed as a dietary supplement or food before its authorization as a new drug. According to the FDA, Ostarine is a selective androgen receptor modulator for which substantial clinical investigations have been instituted and made public with regard to the treatment of cancer cachexia, or muscle wasting. The FDA has concluded that Ostarine was not marketed as a dietary supplement or as a food until after it was under substantial clinical investigation. Thus, Defendants' Ostarine Products, which primarily contain the pharmaceutical ingredient

Ostarine, is also excluded from the definition of a dietary supplement under section 201(ff)(3)(B)(ii) of the FDCA.

58. Under the FDCA, 21 U.S.C. § 201(g)(1) the term "drug" includes any articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and articles (other than food) intended to affect the structure or any function of the body of man or other animals. The Ostarine Products are actually "drugs" as defined by section 201(g)(1) of the FDCA [21 U.S.C. § 321(g)(1)], because they are intended to cure, mitigate, treat, or prevent disease conditions and affect the structure and function of the body. The intended use of a product may be determined by, among other things, its labeling claims, advertising, and circumstances surrounding its distribution. *See* 21 C.F.R § 201.128.

59. Defendants' statements and advertisements indicate that their Ostarine Products are intended to affect the structure and function of the body and are also intended for use in the treatment of certain conditions. Defendants' statements demonstrating the intended use of their Ostarine Products include, but are not limited to, the following:

a. OSTAGENIN will purportedly result in "increased muscle gains," "muscle hardness," and "muscle recovery."
b. XTREME OSTA will result in numerous purported physical benefits, including but not limited to, increased strength, promoting "dry lean gains," and "shredding body fat."
c. Defendants claim that XTREME OSTA "has also been shown to produce dose-dependent increases in bone mineral density and mechanical strength in addition to being able decrease body fat and increase lean body mass."
d. Defendants represent to consumers that SARMs, such as XTREME OSTA and OSTAGENIN, cause "muscle growth in the same manner

> as steroids, however unlike testosterone and other anabolic steroids and prohormones, SARMs (as nonsteroidal agents) don't produce the growth effect on prostate and other secondary sexual organs."

60. Defendants' Ostarine Products are also "new drugs" as defined by section 201(p) of the FDCA [21 U.S.C. § 321(p)], because they are not generally recognized among experts as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Under sections 301(d) and 505(a) of the FDCA [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA approved application is in effect for the new drug. No approved applications are in effect for Defendants' Ostarine Products. Consequently, Defendants' marketing and sale of their Ostarine Products without such approved applications also violates the FDCA.

61. Defendants' Ostarine Products are also "prescription drugs" as defined in section 503(b)(1)(A) of the FDCA [21 U.S.C. § 353(b)(1)(A)], because due to their toxicity or potentiality for harmful effect, the method of their use, or the collateral measures necessary for their use, they are not safe for use except under the supervision of a practitioner licensed by law to administer them.

62. The FDA has previously concluded that products like Ostarine and Defendants' Ostarine Products are prescription drugs because they contain SARMs and, therefore, "present significant potential safety risks to consumers who take them without the supervision of a practitioner licensed by law to administer such drugs."

63. According to section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)], a drug is misbranded if, among other things, they fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layman can use a drug safely and for the purposes for which it is intended [21 CFR Part 201.5]. Prescription drugs can be used safely only at the direction, and under the supervision of a licensed practitioner. Thus, it is impossible to write "adequate directions for use" for

prescription drugs. FDA-approved prescription drugs that bear the FDA-approved labeling are exempt from the requirements that they bear adequate directions for use by a layperson [21 CFR Part 201.100(c)(2) and 201.115]. Because there are no FDA-approved applications for Defendants' Ostarine Products, their labeling fails to bear adequate directions for their intended use, causing them to be misbranded under section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)].

64. The introduction or delivery for introduction into interstate commerce of any misbranded drug is prohibited by 21 U.S.C. § 331(a). Among other things, a drug is misbranded if its labeling is false or misleading. 21 U.S.C. § 352(a). The introduction or delivery for introduction into interstate commerce of a misbranded drug is a felony. 21 U.S.C. § 333(a)(2).

65. Defendants have also engaged in unlawful, unfair and fraudulent conduct by way of their false and misleading statements that their Ostarine Products afford similar benefits to testosterone and other anabolic steroids, without the negative side effects. For example, Defendants claim that their products cause "muscle growth in the same manner as steroids, however unlike testosterone and other anabolic steroids and prohormones, SARMs (as nonsteroidal agents) don't produce the growth effect on prostate and other secondary sexual organs."

66. However, SARM drugs such as the Ostarine Products are still in the research and testing phases and are currently undergoing investigation and development from a number of pharmaceutical companies. Thus, Defendants' Ostarine Products, and any other products containing SARMs, are not recognized as safe and effective for any of the uses suggested by Defendants and may pose significant health and safety risks to consumers.

67. Indeed, medical experts have opined that products containing SARMs "have ***many recognized potential serious side effects***, including hepatoxicity (liver damage), and markedly lower plasma HDL cholesterol (raising the risk of heart disease)," and may

have even more serious consequences that are currently unknown. In fact, since Ostarine is only in phase II clinical trials, medical experts have emphasized that there is "no evidence that Ostarine is safe for humans to consume." Thus, medical experts have concluded that the sale of products containing SARMs, like Defendants' Ostarine Products, is "***highly dangerous to public safety***."

68. Moreover, Defendant fails to disclose that SARMs are specifically prohibited for use in sporting events by the World Anti-Doping Agency and the U.S. Anti-Doping Agency, despite the fact that Defendants specifically market their products to body builders and other competitive athletes.

69. The use of such falsely marketed substances has the tendency to deceive a substantial segment of the public and consumers, including those in Arizona, into believing that they are purchasing a product with different characteristics.

70. The deception is material because it is likely to influence a consumer's purchasing decision, especially if the consumer is concerned about the consequences of taking steroids or illegal substances.

71. Defendants have introduced their false and misleading statements into interstate commerce via marketing and advertising on various websites and shipment of their products into interstate commerce containing false and misleading advertising.

72. Plaintiff has suffered both an ascertainable economic loss of money and reputational injury by the diversion of business from Plaintiff to Defendants and the loss of goodwill in Plaintiff's products. Indeed, Defendants' conduct is a black eye on the industry as a whole, and has the tendency to disparage Plaintiff's products and goodwill.

73. Defendants' actions, as described above, constitute false and misleading descriptions and misrepresentations of fact in commerce that, in commercial advertising and promotion, misrepresent the nature, characteristics, and qualities of their products in violation of Section 43(a)(1)(B) of the Lanham Act.

SECOND CLAIM FOR RELIEF

(Violation of the Civil Racketeer Influenced and Corrupt Organizations Act)

74. Plaintiff incorporates the allegations contained in the foregoing paragraphs as though fully set forth herein in their entirety.

75. As demonstrated above, Defendants are engaged in a conspiracy and scheme to defraud and mislead consumers regarding their Ostarine Products, which are unlawfully marketed and misbranded by Defendants.

76. With respect to Warrior Labz's product OSTAGENIN, Defendants have misbranded this product as "intended for research purposes only," while simultaneously advertising and selling it as a new miracle body building "drug" and "supplement." For example, Defendants advise consumers that they should "consume 2-3 capsules daily" for "extreme results," which is completely contradictory to Defendants other disclaimers. Moreover, Defendants tout numerous purported physical benefits of OSTAGENIN, including "increased muscle gains," "muscle hardness," and "muscle recovery," despite their disclaimers that OSTAGENIN is for "research purposes only."

77. With respect to AlphaLab's product XTREME OSTA, Defendants claim that their product is a "dietary supplement," which will result in numerous purported physical benefits, including but not limited to, increased strength, promoting "dry lean gains," and "shredding body fat." In addition, Defendants claim that XTREME OSTA "has also been shown to produce dose-dependent increases in bone mineral density and mechanical strength in addition to being able decrease body fat and increase lean body mass." Moreover, Defendants represent to consumers that SARMs, such as XTREME OSTA and OSTAGENIN, cause "muscle growth in the same manner as steroids, however unlike testosterone and other anabolic steroids and prohormones, SARMs (as nonsteroidal agents) don't produce the growth effect on prostate and other secondary sexual organs."

78. Contrary to Defendants' false and misleading representations, Ostarine is not a "dietary supplement" and is currently under investigation as a new pharmaceutical drug. Thus, Defendants' Ostarine Products and any other products containing SARMs are not recognized as safe and effective for any of the uses suggested by Defendants and may pose significant health and safety risks to consumers, as demonstrated above.

79. DuraCap is "a manufacturer of Nutraceuticals/Dietary Supplements." DuraCap claims to be "a GMP compliant and an FDA registered company," which specializes "in encapsulation manufacturing, sports nutrition and raw health powders, product formulation, brand design and distribution." DuraCap formulates, manufactures, sells, distributes, and/or markets the Ostarine Products at issue here.

80. ASD is DuraCap's sister company. Through ASD, DuraCap markets and sells "some of the health and fitness industry's most popular supplements to retail stores worldwide." ASD formulates, manufactures, sells, distributes, and/or markets the Ostarine Products at issue here.

81. Houser controls both DuraCap and ASD and, on information and belief, secretly provides illicit products to many other companies.

82. DuraCap and ASD promote themselves to consumers as the "leader" in the "nutraceutical industry," which according to Defendants is "approaching $85 billion annually." DuraCap and ASD also disingenuously claim that they are "committed to bringing ethics and professionalism to the forefront of the industry."

83. Contrary to the foregoing representations, Defendants are engaged in a conspiracy and scheme to defraud and mislead consumers by way of their false and misleading advertisements concerning the Ostarine Products, and to market and sell these products using false and fraudulent labeling claims, representations, and promises in violation of federal law.

84. Defendants have knowingly sold the Ostarine Products to be delivered by commercial interstate carrier, including but not limited to, use of the mails in furtherance of their scheme to defraud and mislead consumers of their products.

85. Defendants have also knowingly advertised, marketed, sold, and/or distributed the Ostarine Products by using interstate telephone calls and/or electronic communications, including but not limited to, using the internet and various online retailers in furtherance of their scheme to defraud and mislead consumers of their products.

86. Defendants have violated the substantive RICO statute, 18 U.S.C.A. § 1962, as detailed above by receiving income from a pattern of racketeering activity involving interstate commerce, interstate telephone calls, and electronic communications.

87. Plaintiff has been injured in its business or property by reason of Defendants' violation of section 1962 by, *inter alia*, the diversion of sales to Defendants, which sell products directly in competition with Plaintiff's products, including the Ostarine Products at issue here.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury.

PRAYER

Wherefore, Plaintiff Nutrition Distribution LLC prays for judgment against defendants DuraCap Labs, LLC, Wes Hauser Active Sports Distribution, Excessive Sports Nutrition, LLC, d/b/a AlphaLab Technologies, Accelerated Sports Nutrition, LLC, d/b/a Warrior Labz, Ganir, and Ogata (collectively, "Defendants") as follows:

1. For preliminary and permanent injunctive relief enjoining Defendants from producing, licensing, marketing, and selling their Ostarine Products, or any other products containing Ostarine and/or other Selective Androgen Receptor Modulators ("SARMs");

2. For an award of compensatory damages to be proven at trial in accordance with 15 U.S.C. § 1117;
3. For an award of any and all of Defendants' profits arising from the foregoing acts in accordance with 15 U.S.C. § 1117 and other applicable laws;
4. For restitution of Defendants' ill-gotten gains;
5. For treble damages in accordance with 15 U.S.C. § 1117;
6. For treble damages in accordance with 18 U.S.C. § 1964;
7. For punitive damages;
8. For costs and attorneys' fees; and
9. Any other relief the Court may deem appropriate.

RESPECTFULLY submitted this 18th day of February 2016.

MIRANDA LAW FIRM

By: s/ Daniel Miranda
Daniel L. Miranda
Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

Civil Cover Sheet

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is authorized for use only in the District of Arizona.

The completed cover sheet must be printed directly to PDF and filed as an attachment to the Complaint or Notice of Removal.

Plaintiff (s): **Nutrition Distribution, LLC**	**Defendant (s):** **Duracap Labs, LLC ; Wes Houser ; Active Sports Supplements, LLC dba Active Sports Distribution ; Excessive Sports Nutrition dba AlphaLab Technologies ; Accelerated Sports Nutrition dba Warrior Labz ; Shawn Ogata ; Justin Ganir**
County of Residence: Maricopa	County of Residence: Outside the State of Arizona
County Where Claim For Relief Arose: Maricopa	
Plaintiff's Atty(s):	Defendant's Atty(s):
Daniel Leonardo Miranda **Miranda Law Firm** **633 E. Ray Road #106** **Gilbert, Arizona 85296** **(480) 719-8482**	

II. Basis of Jurisdiction: **3. Federal Question (U.S. not a party)**

III. Citizenship of Principal Parties **(Diversity Cases Only)**
Plaintiff:- **N/A**
Defendant:- **N/A**

IV. Origin : **1. Original Proceeding**

V. Nature of Suit: **890 Other Statutory Actions**

VI.Cause of Action: **Case involves claim for False Advertising under the Lanham Act.**

VII. Requested in Complaint

Class Action: **No**

Dollar Demand: **damages/inj.**

Jury Demand: **Yes**

VIII. This case **is not related** to another case.

Signature: Daniel L. Miranda

Date: 2/18/2016

If any of this information is incorrect, please go back to the Civil Cover Sheet Input form using the *Back* button in your browser and change it. Once correct, save this form as a PDF and include it as an attachment to your case opening documents.

Revised: 01/2014