

1 Robert Tauler (SBN 241964)
2 Matthew J. Smith (SBN 240353)
3 Tauler Smith LLP
4 11111 Santa Monica Blvd., Suite 500
5 Los Angeles, California 90025
6 Telephone: (310)746-5601
7 rtauler@taulersmith.com

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9 Attorneys for Plaintiff
10 NUTRITION DISTRIBUTION LLC
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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NUTRITION DISTRIBUTION LLC,
an Arizona Limited Liability
Company,

Plaintiff,

vs.

IronMag Labs, LLC, a Nevada
Limited Liability Company, Robert
DiMaggio, an individual, and DOES
1 through 10, inclusive,

Defendants.

COMPLAINT FOR:

- 1) **FALSE ADVERTISING**
(Lanham Act § 43 (a)(1)(B));
- 2) **CALIFORNIA UNFAIR**
COMPETITION (Bus. & Prof.
Code § 17200, et seq.);
- 3) **FALSE ADVERTISING (Bus.**
& Prof. Code § 17500, et seq.)

[DEMAND FOR A JURY TRIAL]

1 Plaintiff Nutrition Distribution, LLC, dba Athletic Xtreme (“ND” or “Plaintiff”),
2 by and through its undersigned attorneys, submits this Complaint against defendant
3 IronMag Labs, Inc. (“IMG”) and Robert P. DiMaggio (“DiMaggio”) (collectively,
4 “Defendants”), and in support thereof, avers as follows:

5 **INTRODUCTION**

6 1. This is a civil action arising out of Defendants’ false and misleading
7 advertising regarding its product “OSTA RX” and “Super DMZ 4.0” which are
8 unlawfully marketed by Defendants as a “dietary supplements” and falsely marketed as
9 having no side effects. Contrary to Defendants’ representations, OSTA RX and Super
10 DMZ contain Ostarine – a “Selective Androgen Receptor Modulator” (“SARM”).
11 SARMS like Ostarine are synthetic drugs with similar effects to illegal anabolic steroids.
12 Thus, Defendants have misbranded OSTA RX and Super DMZ as a “dietary
13 supplements,” and marketed and sold OSTA RX as a new “miracle” bodybuilding drug,
14 when in fact it is a pharmaceutical whose side effects are not completely known.

15 2. For example and without limitation, Defendants claim that OSTA RX
16 “increases lean muscle mass,” “increases strength [and] endurance,” “promotes fat loss,”
17 “promotes recovery,” “increases libido,” “increase[s] bone density,” and “causes muscle
18 growth in the same manner as steroids” — all with no adverse side effects and “no
19 toxicity.” Defendants also falsely represent that OSTA RX “has been shown to produce
20 dose-dependent increases in bone mineral density and mechanical strength in addition to
21 being able [to] decrease body fat and increase lean body mass,” among other things.
22 (Emphasis in original.) Moreover, Defendants claim that OSTA RX “represent[s] a new
23 potential treatment option for a wide spectrum of conditions from muscle wasting
24 diseases (from AIDS to cancer-related)” and “also has immense potential for muscle
25 building for Bodybuilders, fitness, athletes, and an agent to minimize atrophy during
26 recovery periods from serious surgery or similar situations.” Defendants further
27 represent that “SARMS are currently in advanced stage tests to treat a number of
28 ailments.”

1 3. Contrary to Defendants’ representations, Ostarine is not without published
2 side effects and is currently under investigation as a new pharmaceutical drug. Thus,
3 Ostarine (and OSTA RX) are not recognized as safe and effective for any of the uses
4 suggested by Defendants and may pose significant health and safety risks to consumers.

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

13 5. Moreover, Defendants fail to disclose that SARMs, like Ostarine and OSTA
14 RX, are specifically prohibited for use in sporting events by the World Anti-Doping
15 Agency and the U.S. Anti-Doping Agency, despite the fact that Defendants specifically
16 market their products to body builders and other competitive athletes.

17 6. This action seeks to enjoin Defendants from the marketing and sale of
18 OSTA RX, and any other product containing Ostarine and/or other SARMs, as
19 Defendants are illegally and falsely marketing such products.

20 7. Defendants’ false, misleading, illegal and deceptive practices have unjustly
21 enriched Defendants at the expense of Plaintiff, and have caused Plaintiff extensive and
22 irreparable harm, including, but not limited to, loss of revenue, disparagement, and loss
23 of goodwill.

24 8. Defendants’ continuing false, misleading, illegal and deceptive practices
25 have violated the Lanham Act and the California Unfair Competition Law and False
26 Advertising Law (Cal. Bus. & Prof. Code §§ 17200 and 17500, *et seq.*) and have unjustly
27 enriched Defendants at the expense of Plaintiff, and has caused Plaintiff extensive and
28

1 irreparable harm, including but not limited to, loss of revenue, disparagement, and loss of
2 goodwill.

3 **JURISDICTION AND VENUE**

4 9. This Court has subject matter jurisdiction over this action pursuant to 15
5 U.S.C. § 1121 and 28 U.S.C. § 1331 (federal question jurisdiction) and 28 U.S.C. 1332
6 (diversity jurisdiction) because Plaintiff asserts causes of action arising under federal law
7 and the parties are citizens of different states and the controversy exceeds the value of
8 \$75,000.

9 10. This Court has personal jurisdiction over IMG because defendant has,
10 directly or through its intermediaries (including distributors, retailers, and others),
11 developed, licensed, manufactured, shipped, distributed, offered for sale, sold, and
12 advertised its nutritional supplement products in the United States, the State of
13 California, and this district, including but not limited to, the product “OSTA RX.”
14 Defendants have directly marketed their products in the central district directly by, *inter*
15 *alia*, marketing their products at the Orange County Muscle Classic, the LA Pro Expo
16 and sponsoring the LA Pro Expo.¹ Additionally, Defendants have purposefully and
17 voluntarily placed OSTA RX into the stream of commerce with the expectation that it
18 will be purchased in this district.

19 11. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2)
20 because a substantial part of the events or omissions which gave rise to the claim
21 occurred in this district as explained above. Alternatively, venue is proper in this judicial
22 district pursuant to 28 U.S.C. § 1391(b)(3).

23 **PARTIES**

24 12. Plaintiff Nutrition Distribution, LLC, dba Athletic Xtreme (“ND” or
25 “Plaintiff”) is an Arizona limited liability company with its principal place of business at
26 14215 N. 8th Pl., Phoenix, Arizona, 85022.

27 _____
28 ¹ Defendant Iron Mag has also filed suit in this forum to enforce its intellectual property rights (Case
No. 2:15-cv-03984)

1 13. Defendant IronMag Labs, LLC (“IMG”) is a Nevada limited liability
2 company which lists 1860 Whitney Mesa Dr., Ste. 120, Henderson, Nevada 89014-2095
3 as its business address.

4 14. Defendant Robert DiMaggio (“DiMaggio”) is an individual, who on
5 information and belief, is based in Nevada. Upon information and belief, DiMaggio is
6 the Founder, Owner, Chief Executive Officer, and Managing Member of IMG.

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

14 **FACTUAL ALLEGATIONS**

15 16. The nutritional supplement industry is one of the fastest growing and most
16 lucrative in the United States. A recent Forbes article estimates that nutritional
17 supplement sales accounted for \$32 billion in revenue in 2012 and predicts this number
18 to grow to \$60 billion within ten years. The growth and size of the nutritional
19 supplement market and the relatively low barriers to entry and minimal regulation
20 provide perverse incentives for false advertising and unfair competition prohibited by the
21 Lanham Act and the California Unfair Competition Law and False Advertising Law
22 (Business and Professions Code §§ 17200 and 17500, *et seq.*), among other illegal
23 activity.

24 **Plaintiff Nutrition Distribution & “Advanced PCT”**

25 17. Plaintiff is a cutting edge sports supplement manufacturer and marketer.
26 From its inception, Plaintiff was a leader in the nutritional supplement market,
27 specifically for body building.
28

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

3 19. Around 2010, Plaintiff began developing a new product in the muscle-gainer
4 sub-market of the nutritional supplement world.

5 20. After devoting its resources for over a year on product development and
6 testing, Plaintiff introduced “Advanced PCT” in May 2011. Advanced PCT is an all
7 natural nutritional supplement that is designed to boost testosterone. Advanced PCT is
8 still in the market today and directly competes with OSTA RX.

9 **IronMag Labs & Ostarine**

10 21. Defendant IMG is a competing nutritional supplement company in Nevada.

11 22. According to OSTA RX’s product label, the active ingredient is a
12 pharmaceutical ingredient known as Ostarine / MK-2866 ((2S)-3-(4-cyanophenoxy)-N-
13 [4-cyano-3-(trifluoromethyl)phenyl]-2-hydroxy-2-methylpropanamide).

14 23. On their website, IMG advertises OSTA RX as a “Selective Androgen
15 Receptor Modulator” (“SARM”). IMG further represents on its website and other
16 promotional materials that OSTA RX “causes muscle growth in the same manner as
17 steroids,” with no adverse side effects and “no toxicity.”

18 24. In truth, SARMs, like Ostarine and OSTA RX, are synthetic drugs intended
19 to have the same kind of effects as androgenic drugs like illegal anabolic steroids.

20 25. Defendants’ statements and advertisements indicate that OSTA RX is
21 intended to affect the structure and function of the body and is also intended for use in
22 the treatment of certain conditions. For example and without limitation, Defendants
23 claim that OSTA RX “represent[s] a new potential treatment option for a wide spectrum
24 of conditions from muscle wasting diseases (from AIDS to cancer-related)” and “also has
25 immense potential for muscle building for Bodybuilders, fitness, athletes, and an agent to
26 minimize atrophy during recovery periods from serious surgery or similar situations.”

27 Defendants further represent that “SARMs are currently in advanced stage tests to treat a
28

1 number of ailments.” Defendants’ statements further demonstrating the intended use of
2 OSTA RX include, but are not limited to, the following:

- 3 a. OSTA RX “has been shown to produce dose-dependent
4 increases in bone mineral density and mechanical
5 strength in addition to being able [to] decrease body fat
6 and increase lean body mass;” (Emphasis in original)
- 7 b. “Increases lean muscle mass;”
- 8 c. “Increases strength [and] endurance;”
- 9 d. “Promotes fat loss;”
- 10 e. “Promotes recovery;”
- 11 f. “Increases libido;”
- 12 g. “Increase[s] bone density;” and
- 13 h. “Causes muscle growth in the same manner as steroids,”
14 without the adverse side effects.

15 26. In reality, OSTA RX and Ostarine are “prescription drugs” as defined in
16 section 503(b)(1)(A) of the FDCA [21 U.S.C. § 353(b)(1)(A)], because due to their
17 toxicity or potentiality for harmful effect, the method of their use, or the collateral
18 measures necessary for their use, they are not safe for use except under the supervision of
19 a practitioner licensed by law to administer them.

20 27. The FDA has previously concluded that products like Ostarine and OSTA
21 RX are prescription drugs because they contain SARMS and, therefore, “present
22 significant potential safety risks to consumers who take them without the supervision of a
23 practitioner licensed by law to administer such drugs.”

24 28. In addition to the foregoing, Defendants have failed to disclose that SARMS,
25 like Ostarine and OSTA RX, are prohibited for use in sporting events by the World Anti-
26 Doping Agency and the U.S. Anti-Doping Agency, despite the fact that Defendants
27 specifically market their products to body builders and other competitive athletes.
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1 29. SARM drugs such as OSTA RX are still in the research and testing phases
2 and are currently undergoing investigation and development from a number of
3 pharmaceutical companies. Accordingly, OSTA RX is not recognized among experts as
4 safe and effective for use under the conditions suggested by Defendants and may pose
5 significant potential health and safety risks to consumers.

6 30. Defendants have falsely marketed and advertised OSTA RX as a natural
7 product giving users the massive gains of an illegal steroid and a false sense of security
8 regarding its safety. IMG and its executives, including DiMaggio, have known all along
9 that their product, OSTA RX, was a synthetic substance whose side effects are not
10 completely known.

11 31. Defendants' false advertising is harmful to the marketplace for dietary and
12 nutritional supplements and potentially to individual consumers. Defendants have
13 created an illegitimate marketplace of young bodybuilders who want to gain muscle and
14 are not informed of the dangers of Defendants' products. Users of OSTA RX have little
15 incentive to use a natural product like Advanced PCT until they are hurt or the product is
16 taken off the shelves.

17 32. Similar representations are also made by Defendants on their product Super
18 DMZ 4.0. The product label again lists ((2S)-3-(4-cyanophenoxy)-N-[4-cyano-3-
19 (trifluoromethyl)phenyl]-2-hydroxy-2-methylpropanamide) as an ingredient, which is the
20 SARM Ostarine. Defendant falsely claims on its website for Super DMZ 4.0 that "unlike
21 many steroids, side effects are basically non-existent." Again, Ostarine has many
22 recognized side effects.

23 **CLAIMS FOR RELIEF**

24 **FIRST CLAIM FOR RELIEF**

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

26 33. Plaintiff incorporates the allegations contained in the foregoing paragraphs
27 as though fully set forth herein in their entirety.
28

1 34. Defendants have purposely made false and misleading descriptions of fact
2 concerning the nature, characteristics and qualities of OSTA RX and Super DMZ 4.0.
3 Contrary to Defendants' representations, the active ingredient in OSTA RX is Ostarine, a
4 SARM. SARMS like Ostarine (and OSTA RX) are synthetic drugs with similar effects to
5 illegal anabolic steroids. Thus, Defendants have misbranded OSTA RX as a natural
6 supplement with no side effects and marketed and sold OSTA RX as a new "miracle"
7 body building drug.

8 35. For example and without limitation, Defendants claim that OSTA RX
9 "increases lean muscle mass," "increases strength [and] endurance," "promotes fat loss,"
10 "promotes recovery," "increases libido," "increase[s] bone density," and "causes muscle
11 growth in the same manner as steroids" —with no adverse side effects and "no toxicity."
12 Defendants also falsely represent that OSTA RX "has been shown to produce dose-
13 dependent increases in bone mineral density and mechanical strength in addition to being
14 able [to] decrease body fat and increase lean body mass," among other things. (Emphasis
15 in original.) Moreover, Defendants claim that OSTA RX "represent[s] a new potential
16 treatment option for a wide spectrum of conditions from muscle wasting diseases (from
17 AIDS to cancer-related)" and "also has immense potential for muscle building for
18 Bodybuilders, fitness, athletes, and an agent to minimize atrophy during recovery periods
19 from serious surgery or similar situations."

20 36. Defendants have also purposely made false and misleading statements that
21 OSTA RX has no adverse side effects and "no toxicity," among other things. Defendants
22 also falsely claim that the Ostarine in Super DMZ 4.0 has "basically non-existent" side
23 effects. However, The FDA has previously concluded that similar products containing
24 Ostarine "present significant potential safety risks to consumers who take them without
25 the supervision of a practitioner licensed by law to administer such drugs." Thus, OSTA
26 RX is not recognized among experts as safe and effective for use under the conditions
27 suggested by Defendants and may pose significant health and safety risks to consumers.
28

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

9 38. Moreover, Defendants have failed to disclose that SARMs, like Ostarine and
10 OSTA RX, are prohibited for use in sporting events by the World Anti-Doping Agency
11 and the U.S. Anti-Doping Agency, despite the fact that Defendants specifically market
12 their products to body builders and other competitive athletes.

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

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

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

22 42. Defendants have introduced their false and misleading statements into
23 California via marketing and advertising on various websites and at fitness-related
24 promotional events, such as the Orange County Muscle Classic, the LA Pro Expo and
25 sponsoring the LA Pro Expo, and via shipment of their products containing false and
26 misleading advertising into California.

27 43. Plaintiff has suffered both an ascertainable economic loss of money and
28 reputational injury by the diversion of business from Plaintiff to IMG and the loss of

1 goodwill in Plaintiff's products. Indeed, IMG's conduct is a black eye on the industry as
2 a whole, and has the tendency to disparage Plaintiff's products and goodwill.

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

7 **SECOND CLAIM FOR RELIEF**

8 **(Unlawful Business Practices**

9 **In Violation of California Business And Professions Code § 17200)**

10 **(Against All Defendants)**

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

13 46. California Business & Professions Code § 17200 provides that "unfair
14 competition shall mean and include any unlawful, unfair or fraudulent business act or
15 practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by
16 Chapter 1 (commencing with Section 17500) of Part 3 of Division 7 of the Business and
17 Professions Code."

18 47. Defendants have engaged in unlawful, unfair and fraudulent conduct by way
19 of their false, deceptive, and misleading marketing, advertising, and sale of OSTA RX
20 and Super DMZ 4.0. For example, Defendants have purposely misrepresented and sold
21 its product OSTA RX as a "dietary supplement."

22 48. Contrary to Defendants' representations, OSTA RX is primarily composed
23 of the unapproved new investigational drug Ostarine / MK-2866 ((2S)-3-(4-
24 cyanophenoxy)-N-[4-cyano-3-(trifluoromethyl)phenyl]-2-hydroxy-2-
25 methylpropanamide).

26 49. In truth, SARMs, like Ostarine and OSTA RX, are synthetic drugs intended
27 to have the same kind of effects as androgenic drugs like illegal anabolic steroids.
28 Critically, SARMs are not legal as ingredients in any type of dietary supplement.

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

9 51. Pursuant to Section 201(ff)(3)(B)(ii) of the FDCA [21 U.S.C. § 321
10 (ff)(3)(B)(ii)], a dietary supplement may not include an article authorized for
11 investigation as a new drug for which substantial clinical investigations have been
12 instituted and made public, unless the article was marketed as a dietary supplement or
13 food before its authorization as a new drug. According to the U.S. Food and Drug
14 Administration (“FDA”), Ostarine is a selective androgen receptor modulator for which
15 substantial clinical investigations have been instituted and made public with regard to the
16 treatment of cancer cachexia, or muscle wasting. The FDA has concluded that Ostarine
17 was not marketed as a dietary supplement or as a food until after it was under substantial
18 clinical investigation. Thus, OSTA RX, which primarily contains the pharmaceutical
19 ingredient Ostarine, is also excluded from the definition of a dietary supplement under
20 section 201(ff)(3)(B)(ii) of the FDCA.

21 52. Under the FDCA, 21 U.S.C. § 201(g)(1) the term “drug” includes any
22 articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of
23 disease in man or other animals, and articles (other than food) intended to affect the
24 structure or any function of the body of man or other animals. Although Defendants have
25 falsely advertised and misbranded OSTA RX as a “dietary supplement,” OSTA RX is
26 actually a “drug” as defined by section 201(g)(1) of the FDCA [21 U.S.C. § 321(g)(1)],
27 because it is intended to cure, mitigate, treat, or prevent disease conditions and affect the
28 structure and function of the body. The intended use of a product may be determined by,

1 among other things, its labeling claims, advertising, and circumstances surrounding its
2 distribution. *See* 21 C.F.R § 201.128.

3 53. Defendants' statements and advertisements indicate that OSTA RX is
4 intended to affect the structure and function of the body and is also intended for use in
5 the treatment of certain conditions. For example and without limitation, Defendants
6 claim that OSTA RX "represent[s] a new potential treatment option for a wide spectrum
7 of conditions from muscle wasting diseases (from AIDS to cancer-related)" and "also has
8 immense potential for muscle building for Bodybuilders, fitness, athletes, and an agent to
9 minimize atrophy during recovery periods from serious surgery or similar situations."
10 Defendants further represent that "SARMs are currently in advanced stage tests to treat a
11 number of ailments." Defendants' statements demonstrating the intended use of OSTA
12 RX include, but are not limited to, the following:

- 13 i. OSTA RX "has been shown to produce dose-dependent
14 increases in bone mineral density and mechanical
15 strength in addition to being able [to] decrease body fat
16 and increase lean body mass;" (Emphasis in original)
- 17 j. "Increases lean muscle mass;"
- 18 k. "Increases strength [and] endurance;"
- 19 l. "Promotes fat loss;"
- 20 m. "Promotes recovery;"
- 21 n. "Increases libido;"
- 22 o. "Increase[s] bone density;" and
- 23 p. "Causes muscle growth in the same manner as steroids,"
24 without the adverse side effects.

25 54. OSTA RX and Ostarine are also "new drugs" as defined by section 201(p)
26 of the FDCA [21 U.S.C. § 321(p)], because they are not generally recognized among
27 experts as safe and effective for use under the conditions prescribed, recommended, or
28 suggested in their labeling. Under sections 301(d) and 505(a) of the FDCA [21 U.S.C.

1 §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction
2 into interstate commerce unless an FDA approved application is in effect for the new
3 drug. No approved applications are in effect for OSTA RX or Ostarine. Consequently,
4 Defendants' marketing and sale of Ostarine and OSTA RX without such approved
5 applications also violates the FDCA.

6 55. OSTA RX and Ostarine are also "prescription drugs" as defined in section
7 503(b)(1)(A) of the FDCA [21 U.S.C. § 353(b)(1)(A)], because due to their toxicity or
8 potentiality for harmful effect, the method of their use, or the collateral measures
9 necessary for their use, they are not safe for use except under the supervision of a
10 practitioner licensed by law to administer them.

11 56. The FDA has previously concluded that products like Ostarine and OSTA
12 RX are prescription drugs because they contain SARMS and, therefore, "present
13 significant potential safety risks to consumers who take them without the supervision of a
14 practitioner licensed by law to administer such drugs."

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

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

27 58. The introduction or delivery for introduction into interstate commerce of any
28 misbranded drug is prohibited by 21 U.S.C. § 331(a). Among other things, a drug is

1 misbranded if its labeling is false or misleading. 21 U.S.C. § 352(a). The introduction or
2 delivery for introduction into interstate commerce of a misbranded drug is a felony. 21
3 U.S.C. § 333(a)(2).

4 59. Defendants have also engaged in unlawful, unfair and fraudulent conduct by
5 way of their false and misleading statements that OSTA RX has no adverse side effects
6 and “no toxicity,” among other things. However, SARM drugs such as OSTA RX are
7 still in the research and testing phases and are currently undergoing investigation and
8 development from a number of pharmaceutical companies. Accordingly, OSTA RX is
9 not recognized among experts as safe and effective for use under the conditions
10 suggested by Defendants and may pose significant potential health and safety risks to
11 consumers.

12 60. Indeed, medical experts have opined that products containing SARMS “have
13 many recognized potential serious side effects, including hepatotoxicity (liver damage),
14 and markedly lower plasma HDL cholesterol (raising the risk of heart disease),” and may
15 have even more serious consequences that are currently unknown. In fact, since Ostarine
16 is only in phase II clinical trials, medical experts have emphasized that there is “no
17 evidence that Ostarine is safe for humans to consume.” Thus, medical experts have
18 concluded that the sale of products containing SARMS, like Ostarine, is “highly
19 dangerous to public safety.”

20 61. Defendants have also have engaged in unlawful, unfair and fraudulent
21 conduct by purposely misrepresenting and selling its product OSTA RX as a “dietary
22 supplement,” when in fact SARMS, like Ostarine and OSTA RX, are prohibited for use in
23 sporting events by the World Anti-Doping Agency and the U.S. Anti-Doping Agency.

24 62. By reason of Defendants’ acts of unfair competition, Plaintiff has suffered
25 and will continue to suffer irreparable injury unless and until this Court enters an order
26 enjoining Defendants from any further acts of unfair competition. Defendants’
27 continuing acts of unfair competition, unless enjoined, will cause irreparable damage to
28 Plaintiff in that it will have no adequate remedy at law to compel Plaintiff to cease such

1 acts, and no way to determine its losses proximately caused by such acts of Defendants.
2 Plaintiff is therefore entitled to a preliminary injunction and a permanent injunction
3 against further unlawful and unfair conduct by Defendants.

4 63. As a direct and proximate result of the Defendants' acts of unfair
5 competition, Defendants have wrongfully taken Plaintiff's profits and the benefit of their
6 creativity and investment of time, energy and money. Defendants should therefore
7 disgorge all profits from the above conduct and further should be ordered to perform full
8 restitution to Plaintiff as a consequence of Defendants' unlawful and unfair activities.

9 **THIRD CLAIM FOR RELIEF**

10 **(False And Misleading Advertising**

11 **In Violation of California Business And Professions Code § 17500)**

12 **(Against All Defendants)**

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

15 65. This cause of action is brought pursuant to the False Advertising Law at
16 California Business & Professions Code § 17500 *et seq.*

17 66. Defendants have disseminated advertising before the public and consumers
18 in California that: (a) contain statements that are illegal, untrue and/or misleading; (b)
19 Defendants knew, or in the exercise of reasonable care should have known, are illegal,
20 untrue and/or misleading; (c) concern the sale of a product; and (d) are likely to mislead
21 or deceive a reasonable consumer. The illegal, untrue and/or misleading statements and
22 representations made by these Defendants include, but are not limited to, the following:

- 23 a. Defendants have purposely made false and misleading descriptions of
24 fact concerning the nature, characteristics and qualities of its product
25 OSTA RX, such as misrepresenting that OSTA RX is a "dietary
26 supplement."
27 b. Defendants have purposely made false and misleading statements that
28 OSTA RX has no adverse side effects and "no toxicity," among other

1 things. However, The FDA has previously concluded that similar
2 products containing Ostarine “present significant potential safety risks
3 to consumers who take them without the supervision of a practitioner
4 licensed by law to administer such drugs.” Thus, OSTA RX is not
5 recognized among experts as safe and effective for use under the
6 conditions suggested by Defendants and may pose significant health
7 and safety risks to consumers.

8 c. Defendants have failed to disclose that SARMS, like Ostarine and
9 OSTA RX, are prohibited for use in sporting events by the World
10 Anti-Doping Agency and the U.S. Anti-Doping Agency, despite the
11 fact that Defendants specifically market their products to body
12 builders and other competitive athletes.

13 d. Defendants also falsely claim that the Ostarine in Super DMZ 4.0 has
14 side effects that are “basically non-existent.”

15 67. The use of such falsely marketed substances has the tendency to deceive a
16 substantial segment of the public and consumers in California into believing that they are
17 purchasing a product with different characteristics.

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

21 69. Defendants have introduced their false and misleading statements into
22 California via marketing and advertising on various websites and shipment of its product
23 containing false and misleading advertising into California.

24 70. Plaintiff has suffered both an ascertainable economic loss of money and
25 reputational injury by the diversion of business from Plaintiff to IMG and the loss of
26 goodwill in Plaintiff’s products. Indeed, IMG’s conduct is a black eye on the industry as
27 a whole, and has the tendency to disparage Plaintiff’s products and goodwill.
28

1 71. Defendants' actions, as described above, constitute false and misleading
2 descriptions and misrepresentations of fact in California that, in commercial advertising
3 and promotion, misrepresent the nature, characteristics, and qualities of their products in
4 violation of the False Advertising Law at Business & Professions Code § 17500, *et seq.*

5 **PRAYER**

6 Wherefore, Plaintiff Nutrition Distribution LLC prays for judgment against
7 Defendants as follows:

- 8 1. For preliminary and permanent injunctive relief enjoining Defendants from
9 producing, licensing, marketing, or selling OSTA RX, and any other product
10 containing Ostarine and/or other Selective Androgen Receptor Modulators;
- 11 2. For an award of compensatory damages to be proven at trial in accordance
12 with 15 U.S.C. § 1117;
- 13 3. For an award of any and all of Defendants' profits arising from the
14 foregoing acts in accordance with 15 U.S.C. § 1117 and other applicable
15 laws;
- 16 4. For restitution of Defendants' ill-gotten gains;
- 17 5. For treble damages in accordance with 15 U.S.C. § 1117;
- 18 6. For punitive damages;
- 19 7. For costs and attorneys' fees; and
- 20 8. Any other relief the Court may deem appropriate.

21
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23 DATED: October 20, 2015

TAULER SMITH LLP

24
25
26 By: /s/ Robert Tauler
27 Robert Tauler
28 NUTRITION DISTRIBUTION LLC

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury.

DATED: October 20, 2015

TAULER SMITH LLP

By: /s/ Robert Tauler _____

Robert Tauler
NUTRITION DISTRIBUTION LLC