

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANDEEP BAROT,
individually and on behalf
of a class of others similarly
situated

Plaintiffs,

v.

JONATHAN VINCENT DOYLE and
JACOB GEISSLER (aka JACOBO
GEISSLER), owners of USP entities
USPLABS, LLC., a Texas corporation,
GENERAL NUTRITION CENTER
HOLDINGS INC., a Delaware
corporation,

Defendants.

**SECOND PROPOSED
AMENDED CLASS ACTION
COMPLAINT**

Plaintiff, SANDEEP BAROT ("Plaintiff"), by and through his attorney, William Riback, Esq., files this Class Action Complaint on behalf of himself and all others similarly situated, against Defendants, USPLABS, LLC., a Texas corporation ("USPLabs"), and GENERAL NUTRITION CENTER HOLDINGS, INC., a Delaware corporation ("GNC"), wherein Plaintiff hereby alleges upon information and belief as follows:

INTRODUCTION

1. This is an economic consumer protection action seeking monetary and injunctive relief. USPLabs manufactured and sold a variety of products marketed as energy and weight loss dietary supplements under the brand names OxyElite Pro™ and Jack3d (the hereinafter “Products”).

2. These Products¹ are dangerous, and failed to provide any benefit as advertised.

3. The Products contain adulterated substances and are not fit for human consumption.

4. Despite knowing that the Products were dangerous and ineffective, Defendants marketed and sold the Products to thousands of unsuspecting consumers.

¹ The specific products sold under the brand name OxyElite Pro™, which are included within the Product definition at issue in this action, include, but are not limited to:

- OxyElite Pro Super Thermo capsules
 - two count capsules UPC #094922417275
 - 10 count capsules UPC #094922417251
 - 10 count capsules UPC #094922417268
 - 21 count capsules UPC #094922426604
 - 90 count capsules UPC #094922395573
 - 90 count capsules “Pink label” UPC #094922447906
 - 180 count capsules UPC #094922447852

- OxyElite Pro Ultra-Intense Thermo capsules
 - three count capsules UPC #094922447883
 - three count capsules UPC #094922447876
 - 90 count capsules UPC #094922395627
 - 180 count capsules UPC #094922447869

- OxyElite Pro Super Thermo Powder
 - Fruit Punch 0.15 oz UPC #094922417237
 - Fruit Punch 0.15 oz UPC #094922447517
 - Fruit Punch 4.6 oz UPC #094922426369
 - Fruit Punch 5 oz. UPC #094922447487
 - Blue Raspberry 4.6 oz UPC #094922426376
 - Grape Bubblegum 4.6 oz UPC #094922447500
 - Green Apple 4.6 oz. UPC #094922426499

5. Ultimately these Products have been subject to a FDA recall.
6. Every consumer is entitled to restitution and all economic damages.
7. Defendants in this action assert the res judicata effect of the settlement in *Hogan v. USPLabs* precludes this complaint.
8. But that settlement was constitutionally infirm because it was by publication; the plaintiff interests were antagonistic to the entirety of the class and the settlement was not fair or reasonable.

PARTIES

9. Plaintiff, Sandeep Barot, is an individual who currently resides in the State of Florida. From March 2010 to October 2011 he lived in the State of New Jersey. While in New Jersey, he purchased one of the Products at issue: the OxyElite Pro™ 90 Count Super Thermo Capsules. Plaintiff purchased the Product approximately one bottle every two months while living in New Jersey. Plaintiff paid approximately \$40.00 each time he purchased the Product. Plaintiff purchased the Products from a GNC store located in Deptford, NJ.

10. Defendant, USPLabs, LLC., is a Texas corporation.

11. Jonathan Vincent Doyle and

12. Jacob Geissler (sometimes reported as Jacobo Geissler), who live in Denton, TX, are individuals having ownership interest in and executive positions in USPLabs, LLC, as well as USPLABS OXYELIT, LLC. USPLABS OXYEPHEDRINE PRO, LLC, USPLABSPOWERFUL HOLDING, LLC, USPLABS POWERFULL, LLC, and USPLABS

PRIME, LLC (collectively, the "USP entities"). Defendant lists with the Texas Secretary of State a principle place of business located at 10761 King William Drive, Dallas, TX 75220, and a registered agent for serviced of process by the name of CT Corporation System, 350 North St. Paul Street, Ste. 2900, Dallas, TX 75201. For purposes of diversity, USPLabs is a "citizen" of the State of Texas. USPLabs owns and maintains an interactive website, <http://www.usplabsdirect.com> which is accessible to citizens of this judicial district, and which sells the Product in this jurisdiction and in this judicial district.

13. Defendant, GNC Holdings, Inc., is a Delaware corporation that lists its principal place of business at 300 Sixth Avenue, Pittsburgh, Pennsylvania 15222. For purposes of diversity, GNC is a "citizen" of the state of Delaware. GNC owns and maintains an interactive website, <http://www.gnc.com/home/index.jsp> which is accessible to citizens of this judicial district, and which sells the Product in this jurisdiction and in this judicial district.

14. Plaintiff is informed and believes that Defendants and their employees, subsidiaries, affiliates and other related entities, were acting within the purpose and scope of their agency and employment.

15. Whenever reference in this Complaint is made to any act or transaction of Defendants, such allegation shall be deemed to mean that the principals, officers, directors, employees, agents, and/or representatives of Defendants committed, knew of, performed, authorized, ratified and/or directed such act or transaction on behalf of Defendants while actively engaged in the scope of their duties.

JURISDICTION

16. This Court has jurisdiction over the subject matter presented by this Complaint because it is a class action arising under the Class Action Fairness Act of 2005 (“CAFA”), Pub. L. No. 109-2, 119 Stat. 4 (2005), which explicitly provides for the original jurisdiction of the Federal Courts of any class action in which any member of the Plaintiff class is a citizen of a state different from any Defendants, and in which the matter in controversy exceeds in the aggregate the sum of \$5,000,000, exclusive of interest and costs. The amount in controversy is based upon information and belief, and the evidence to support the computation for the amount in controversy will be established during the course of discovery.

17. Plaintiff alleges that the total claims of individual members of the Class in this action are in excess of \$5,000,000 in the aggregate, exclusive of interest and costs, as required by 28 U.S.C. § 1332(d)(2), (5). Plaintiffs are mostly citizens of the State of New Jersey, and as set forth above, Defendant USPLabs is a citizen of the State of Texas and Defendant GNC is a citizen of the State of Delaware. Therefore, diversity of citizenship exists under CAFA as required by 28 U.S.C. § 1332(d)(2)(A).

18. Furthermore, Plaintiff alleges that more than two-thirds of all of the members of the proposed Plaintiff Class in the aggregate are citizens of a state other than New Jersey, where this action is originally being filed, and that the total number of members of the proposed Plaintiff Class is greater than 100, pursuant to 28 U.S.C. § 1332(d)(5)(B). In fact, there are well over thousands, and even millions of consumers affected by the purchase of the Product as herein described.

19. Venue in this district is proper pursuant to 28 U.S.C. §1391(a) because Defendants venue business within, may be found in, and is subject to personal jurisdiction in this district.

20. All witnesses to the transaction between GNC and Plaintiff are located in this vicinage.

21. Plaintiff's witnesses are predominantly located within this vicinage.

22. The actual transactions at issue occurred in this vicinage.

FACTUAL ALLEGATIONS

The Hogan v. USPLabs LLC Settlement provided insufficient notice that deprived class members of due process protections.

23. Prior to the instant action a lawsuit entitled *Hogan v. USPLabs, LLC*. (Case No. BC486925, Superior Court of the State of California - Los Angeles County) was initiated on June 21, 2012 against USPLabs, LLC for inclusion of DMAA in the Products.

24. Within one month, on July 10, 2012, USPLabs entered into a class action settlement releasing all claims of any purchaser of "OxyELITE Pro and Jack3d" from January 1, 2008 to August 17, 2012.

25. Plaintiffs failed to engage in any discovery prior to this settlement.

26. The settlement provided a \$2 million restitution settlement fund for everyone who purchased the Products.

27. Only \$500,000.00 of this \$2 million fund went to claimants.

28. Yet GNC alone sold \$151 million of this Product in 2011.²

² See <http://online.wsj.com/article/SB10001424052702304543904577396531034606416.html>

29. GNC sold at least \$300 million of this Product to 500,000 consumers during the entirety of the class period.³

30. Therefore, the settlement provided less than one half of one penny which went to 1,234 claimants in the Hogan Settlement.

31. The Class Representatives were not adequate because their interests became antagonistic to the class.

32. The settlement provided the pro rata recovery would be reduced by aggregate claims exceeding \$2 million.

33. Therefore, the Notice Plan was designed to reduce aggregate claims.

34. There has been no showing that publication reached over 70% of the class.

35. Even if it had, notice was deficient because it failed to provide actual notice that was reasonably available.

36. Despite GNC, BodyBuilding.com, and even USPLabs having mailing addresses through their respective online customer accounts and online purchases, no actual notice occurred.

37. GNC has a loyalty program wherein customers pay \$15 per year to receive additional discounts on online and in store purchases with use of the card. To become a

³The number of purchasers is a conservative estimate. In 2011 there were 210,000 purchasers, and the numbers of customers from prior years was adjusted toward by 50,000 customers per year, to wit: 150,000 in 2010, 100,000 in 2009, and 50,000 in 2008 for a total consumer base of approximately 500,000 during the class period. As 210,000 purchasers resulted in approximately \$151,000,000.00 in sales, \$300,000,000.00 is likewise a conservation estimate for the sales generated by 500,000 consumers.

member, consumers must provide their credit card information and shipping address.⁴ Yet there was no attempt to provide these consumers with actual notice.

38. The Court approving the settlement was never advised that a publically listed company marketed the Product. The Court was left in the dark as to the aggregate sales of the Product. The Hogan Court could have no idea whether the settlement was fair or reasonable. No party gave a justification or excuse of the \$500,000 payout being a fraction of a penny of all sales.

39. Notice was constitutionally deficient because it was by publication not by mail.

40. Tens of thousands of GNC, BodyBuilding.com, Amazon and USPLabs consumers purchased online or were members of the loyalty program – making their contact information readily available. But not a single purchaser was actually notified.

41. The class was not adequately represented in *Hogan* because the six plaintiffs were antagonistic to a large claims rate. The \$2 million fund would have been exhausted if even 10% of GNC consumers made claims and all those filing claims including the named plaintiffs would get pennies on the dollar.

The Hogan v. USPLabs LLC settlement was grossly inadequate and unfair to members of the class whose mailing information was available.

42. The named class representatives of the *Hogan* settlement only purchased directly from USPLabs, the only named defendant, yet the settlement seeks to bar all purchasers of the Products without allowing the absent class to have any meaningful recovery.

⁴ See <http://www.gnc.com/helpdesk/index.jsp?display=account&subdisplay=group>

43. The settlement defined the “settlement class” as “all persons who purchased for personal consumption, and not for re-sale, one or more of the USPLabs Products in the United States during the Class Period,” defendant as USPLabs and “released parties” as “USPLabs and its past and present officers, directors, employees, stockholders, investors, owners, agents, representatives, attorneys, administrators, successor, subsidiaries, assigns, affiliates, joint-ventures, partners, members, divisions, predecessors, spokespersons, public relations firms, advertising and production agencies, manufacturers, distributors, suppliers, wholesalers, retailers, vendors, licensees and licensors.”

44. Yet, the case was settled within 30 days of filing the complaint; there was no meaningful discovery to ascertain gross sales. The plaintiffs had no idea of the settlement value of their case. Consequently, the court in approving the \$2,000,000.00 settlement had no idea of the amount of product sold or whether the settlement was fair, reasonable and adequate. The \$2,000,000.00 settlement for in excess of \$300,000,000.00 in sales is a penny on the dollar. The settlement failed to disclose the adequacy of the settlement or any explanation why 1% would be reasonable to absent class members.

45. By failing to adequately represent the class as a whole, the class representatives entered into a grossly unfair settlement to the detriment of their fellow classmates, particularly those members who purchased from GNC. Failure to pursue claims against USPLabs and its wholesalers, retailers, and vendors while simultaneously agreeing to bind future claims against them created an inequitable result and is a violation of the fiduciary duty owed to the absent class members.

46. In determining the fairness, reasonableness and adequacy of a settlement, the record and findings must demonstrate the judge has made the requisite inquiries and considered

the diverse interests of the parties. Discovery would have shown that GNC, having made \$151,000,000 in sales, had both the resources and ability to pay a much greater settlement than the meager \$2,000,000 received from USPLabs. By failing to consider the resources of USPLabs' wholesalers, retailers and vendors, the interests of the absent class members, a great number of whom were GNC purchasers, were not protected.

USPLabs sale of products containing DMAA and aegeline

47. Defendant USPLabs sells a variety of OxyElite Pro™ dietary supplements.

48. GNC sold OxyElite Pro™ products in the State of New Jersey from Jan. 27, 2008 to Nov. 9, 2013.

49. On April 27, 2012, the United States Food and Drug Administration ("FDA") issued a warning to Defendant USPLabs regarding use of dimethylamylamine ("DMAA") in OxyElite Pro™ and Jack3d because it had received 42 adverse event reports on products containing DMAA, including cardiac disorders, nervous system disorders, and death.⁵

The harmful effects of DMAA and Defendants' misrepresentations regarding same

50. DMAA, also known as methlhexanamine (MHA) and Geranamine, is an aliphatic amine compound that has properties mimicking those of the endogenous neurotransmitters of the sympathetic nervous system. As such it belongs to a group of compounds known as "sympathomimetics." Members of this class include ephedrine and amphetamines.

⁵ See FDA Warning Letter, dated April 12, 2013 (located at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm302167.htm>)(last visited Jan. 27, 2014)

51. While sympathomimetics are used by physicians to increase blood pressure and to constrict blood vessels, they are also widely abused because of their perceived ability to enhance athletic performance and in some cases induce euphoria.

52. Sympathomimetics compounds were originally developed in the 19th century as drugs for the treatment of cold symptoms. Compounds capable of constricting blood vessels were actively sought. First cocaine, then epinephrine, and in 1925 ephedrine, were used for this purpose. However, the adverse effects, inability to provide long term relief and addictiveness eventually resulted in the search for a similarly structured chemical. Through trial and error, it was eventually determined that slight modification of the ephedrine molecule would result in molecules having equivalent vasoconstrictor properties to ephedrine. These modifications eventually led to the development of DMAA, originally named "Fouramine".

53. In 1943, DMAA was introduced as a nasal decongestant by Eli Lilly under the trade name of Forthane. For unexplained reasons Eli Lilly voluntarily withdrew Forthane from the market in 1983. No other prescription or over-the-counter drugs or dietary supplements used DMAA from 1983. No other prescription or over-the-counter drugs or dietary supplements used DMAA from 1983 until approximately 2005.

54. In 2005, Patrick Arnold, a chemist convicted for his role in the BALCO baseball steroid scandal, reintroduced MHA/DMAA as an over-the-counter dietary supplement with amphetamine-like qualities. It was marketed as an alternative to ephedrine. The use of DMAA in dietary supplements spread and eventually found its way into the Products.

55. Animal testing in a variety of models demonstrated that DMAA was a potent pressor drug causing increase in blood pressure that is comparable to ephedrine. The

structure of and mechanism by which DMAA increases blood pressure is thus similar to ephedrine. Dietary supplements containing ephedra, the natural form of ephedrine, were ordered off the market by the FDA in 2004, because the blood pressure and heart rate effects were associated with a number of serious adverse events to users including heart attack, stroke and death.

56. On February 2, 2012, and following the deaths of two soldiers after heart attacks during fitness exercises, the Defense Department removed the Products and other dietary supplements containing DMAA from stores on military bases in the United States.

57. In addition, regulatory agencies in the United Kingdom, Canada, New Zealand, France, Germany, Sweden, and Italy have also launched investigations and/or banned products containing DMAA, specifically including Jack3d and OxyELITE Pro. In April 2012, New Zealand banned all products containing DMAA. As of August 8, 2012, the use of DMAA is illegal in Australia. New South Wales has classified DMAA as a "highly dangerous substance" on the poisons list. DMAA is also on the World Anti-Doping Agency and Major League Baseball lists of banned substances.

58. Despite the known dangers of DMAA, Defendants conveyed their deceptive claims about the Products through a variety of media, including magazines, the Internet, and on the Products' label and packaging. In addition, retailers, including GNC promote, market and sell the Products in stores, on their websites and through other advertising media.

59. On the OxyElite Pro label, a representative sample of which is reproduced above, Defendants prominently claim:

- a. "PHARMACIST FORMULATED"
- b. "Super Thermogenic™"
- c. "University Studied"
- d. "For the results of the clinical studies, visit:

[www/USPLabsDirect.com/research](http://www.USPLabsDirect.com/research)"

60. USPLabs made the following claims about OxyElite Pro:

- a. "Introducing a burner coined the 'Super Thermogenic™' by those familiar with its effectiveness..."
- b. "Backed by 3 Peer Reviewed Clinical University Research Studies"
- c. "Potent 'Super Thermogenic'"

61. USP's website repeats and reinforces its messaging contained throughout other advertising media, including on the SUBJECT PRODUCTS packaging and labeling including stating:

- a. "The hemodynamic response to acute ingestion was assessed as well.

OxyElite Pro did not result in a statistically significant change in heart rate or diastolic pressure, but did cause a statistically significant change in systolic blood pressure from baseline. This increase was mild and transients, and was similar to the changes reported in the scientific literature for subjects ingesting an amount of caffeine equivalent to 2-3 cups of coffee."

- b. "At the beginning and end of the study, blood pressure, heart rate and various indicators of renal and liver function were assessed. The study found that there were no statistically significant changes from baseline to the end of the study. No serious adverse events were noted."

c. “NEWLY RELEASED< GROUNDBREAKING RESEARCH STUDIES SHOW USPLABS DMAA SUPPLEMENTS ARE SAFE AND EFFECTIVE”

62. USPLabs has also issued press releases, which promote the purported safety and efficacy of the Products. For example, on February 24, 2012, just weeks after the Defense Department pulled the Products from military store shelves, USPLabs issued a press release entitled “USPLabs Jack3d Peer-Review Clinical Safety Study Published.”⁶ In its press release USPLabs stated:

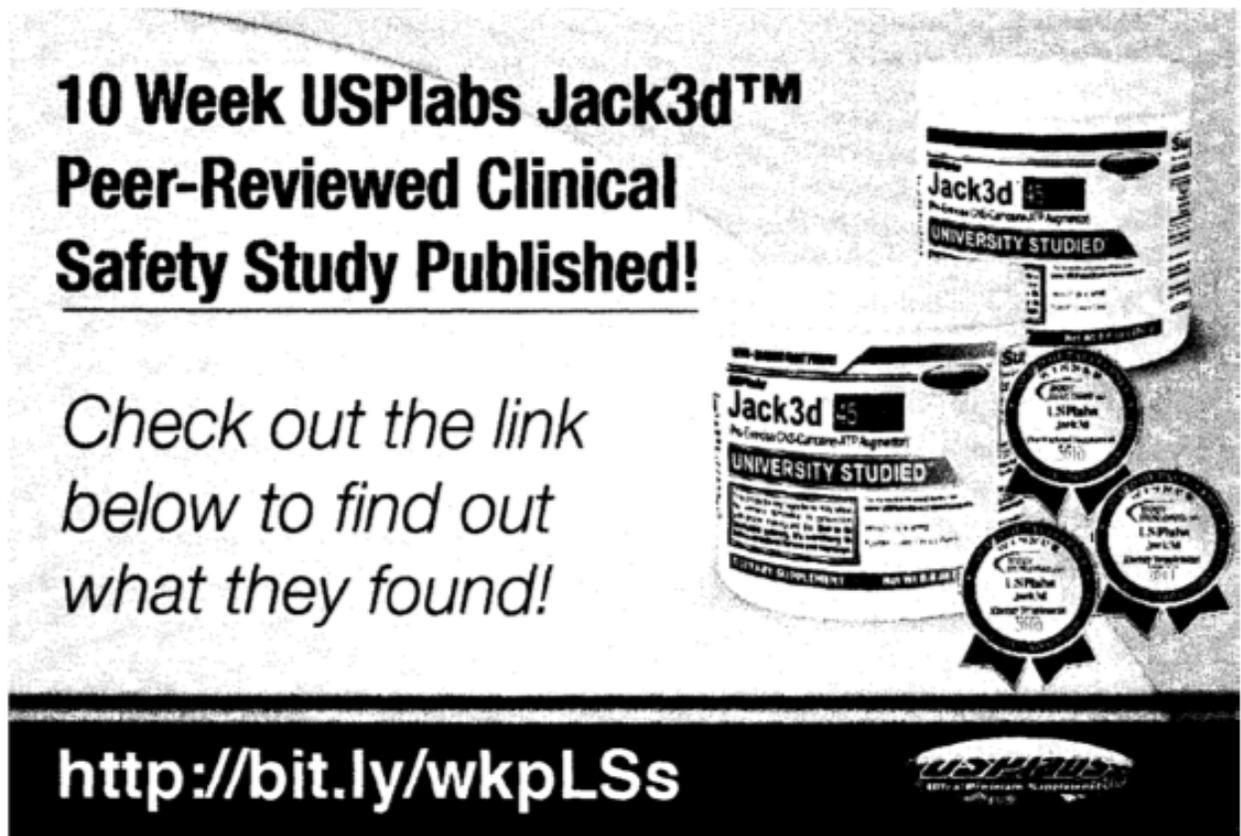
USPLabs Jack3d™ and OxyElite Pro® are among the most studied finished dietary supplements ever sold. This most recent study is the 7th peer-reviewed, published clinical trial supporting the safe use of DMAA when used as directed, in addition to an industry estimated over one billion servings consumed by satisfied customers. More specifically, Jack3d™ & OxyElite Pro® have 5 clinical trials that shows they are safe when used as directed.

63. USPLabs made similar statements about the purported safety and efficacy of the Products in another press release, dated March 7, 2012 entitled “USPLabs Shares Results of Seven Peer-Reviewed DMAA Safety Studies as Part of Scientific Review on Jack3d™ and OxyElite Pro®.”⁷

⁶ See http://www.prnewswire.com/news-releases/usplabs-jack3d-peer-reviewed-clinical-safety-study-published-140331103.html?utm_expid=43414375-18&utm_referrer=http%3A%2F%2Fwww.google.com%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3Djack3d%2520usplabs%2520prnewswire%26source%3Dweb%26cd%3D1%26ved%3DOCDQAQFjAA%26url%3Dhttp%253A%252F%252Fwww.prnewswire.com%252Fnews-releases%252Fusplabs-jack3d-peer-reviewed-clinical-safety-study-published-140331103.html%26ei%3DnW41UPWLKumM2gW394GwAw%26usg%3DAFQjCNHBao8VBs7cFDKxg2zvNk94yxZBP A

⁷ [studies-as-part-of-scientific-review-on-jack3d-and-oxyelite-pro-](#)

64. USPLabs also utilized false and deceptive print and Internet advertisements, which reinforced and promoted the purported scientific studies demonstrating the safety of Jack3d. For example, in or around March 2012, weeks after the Defense Department forced the Products off its military store shelves. USPLabs utilized the following Internet advertisement:



141812313.html?utm_expid=43414375-18&utm_referrer=http%3A%2F%2Fwww.google.com%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3DJack3d%2520usplabs%2520prnewswire%26source%3Dweb%26cd%3D2%26ved%3DOCDYQFjAB%26url%3Dhttp%253A%252F%252Fwww.prnewswire.com%252Fnews-releases%252Fusplabs-shares-results-of-seven-peer-reviewed-dmaa-safety-studies-as-part-of-scientific-review-on-Jack3d-and-oxylite-pro-141812313.html%26ei%3DnW41UPWLKumM2gW394GwAw%26usg%3DAFQjCNFcogyfqBOYM8QhP8vCHI-Q6eMWfg

65. USPLabs owns and operates another website, www.dmaaresearch.com, where it makes similar statements about the purported research supporting the safety and efficacy of DMAA. This website now acknowledges the FDA warning letter, but nonetheless maintains the safety and efficacy of DMAA.

66. USPLabs' website, including www.USPLabsDirect.com and www.DMAAResearch.com are available to the general public and USPLabs' advertisements in other media promote these websites.

67. In addition to its own independent misleading advertising about the Products. Defendant GNC participated in, controlled, enabled, and adopted USPLabs' representations concerning the safety and efficacy of the Products.

68. GNC, which sold the Products, adopted and is responsible for the representations made on the packaging and labeling of the Products regarding the safety and efficacy, when its decided to place such Products on its store shelves and retail websites, and thereafter advertised and sold such Products to Plaintiff and other members of the Class.

69. Further, GNC advertised and included a prominent link on its own website to USPLabs' Jack3d and OxyELITE Pro websites. GNC also engaged in Internet marketing, including through email blasts for the Products. GNC also controlled the content of any advertising for GNC's promotions of Jack3d.

70. GNC also utilized in-store, point of sale displays to market to Products. An exemplar of GNC's in store marketing for Jack3d appears below, and states in bold prints. **"Ultra-intense University-Studied pre-workout formula":**



71. GNC's marketing and advertising further reinforces these claims of safety and efficacy. For example, it states that it "OxyELITE Pro is Pharmacist-formulated to deliver fast results" and that Jack3d is "**University Studied.**" GNC's representation that Jack3d is "**University Studied**" reasonably implies that the studies demonstrate the product's safety. In truth, studies involving Jack3d demonstrate that consuming Jack3d at the recommended levels is unsafe, including because it leads to elevated blood pressure and heart rate.

72. Despite the overwhelming evidence that Jack3d and OxyELITE Pro are neither safe nor effective, which GNC knew or should have known, GNC continued to make public statements to the contrary, assuring consumers that DMAA is safe. For example, in

response to the FDA's 2012 warning letter GNC stated: "We are completely opposed to this unilateral, factually and legally unfounded action by the FDA and we believe the large consumer base that has safely used products containing DMAA in millions of doses will also oppose it." GNC further stated that "DMAA is perfectly safe when taken as directed."⁸

73. In February 2012, under pressure from the Department of Defense, GNC agreed to pull its DMAA-containing products, including the Products, from its store on military bases. Nevertheless, GNC continued to market and sell the Products to consumers in its other retail stores and through its online website.

74. Without requisite proof, Defendants also claim that SUBJECT PRODUCTS are safe, effective, and proven by research. For the types of marketing claims at issue, the Federal Trade Commission rules, mirroring common law duties of fair representation, require the Defendants actually have the level of proof claimed, here clinical proof, at the time the claims are made. However, Defendants did not, and have never possessed the requisite proof.

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

76. For example, in a warning letter sent to USP on April 24, 2012, the FDA stated that the Products are adulterated under §402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §342, because the Products present a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling:

⁸ See <http://www.nutraingredients-usa.com/Regulation/GNC-FDA-action-on-DMAA-is-factually-and-legally-unfounded> (last visited August 23, 2012).

...OxyELITE Pro and Jack3d are adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a) because they contain a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such products into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v). To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that dimethylamylamine will reasonably be expected to be safe as a dietary ingredient. In fact, dimethylamylamine narrows the blood vessels and arteries, which increases cardiovascular resistance and frequently leads to elevated blood pressure. This rise in blood pressure may increase the work of the heart such that it could precipitate a cardiovascular event, which could range from shortness of breath to tightening of the chest and/or a possible myocardial infarction (heart attack).⁹

77. Notwithstanding significant and mounting evidence that the Products are falsely labeled, ineffective, and pose significant health risks. Defendant did not recall the Products, which remained on the market. Despite the evidence of significant health risks. Defendants continued to make material misrepresentations and omissions in their advertising for the Products, including on the Products' packaging and labeling. Moreover, as stated herein, Defendants continue to downplay the true health risks involved with consuming the Products.

78. For example, in a further attempt to downplay the true risks of consuming the Products, USPLabs has even filed a SLAPP suit in the Northern District of Texas (Case 3:12-

⁹ See <http://www.fda.gov/ICECVEnforcementActions/WarningLetters/2012/ucm302167.htm> (last visited August 22, 2012).

cv-01605-O) against an individual and entity for allegedly making false and disparaging statements about Jack3d. The allegedly false statements included well-known, incontrovertible facts about Jack3d such as that it is an “amphetamine-like compound,” and that it “speeds up your heart rate.” USPLabs continues to not only make misrepresentations to the public about the nature of DMAA and the Products as alleged above. It so vehemently denies their sympathomimetic qualities that it is suing individuals for defamation.

79. Making their actions even more unfair and reprehensible is that USPLabs’ own funded studies, which make conclusions that are consistent with the FDA’s 2012 warning letter to USPLabs concede that DMAA is a “simple aliphatic amine with sympathomimetic properties.”¹⁰

**Scientific studies demonstrate that
the Products are unsafe and ineffective**

80. Defendants also claim that the Products safety and efficacy have been shown in clinical studies. For example, it is usplabsdirect.com and dmaaresearch.com websites, USPLabs lists seven studies involving DMAA and states: “NEWLY RELEASED, GROUNDBREAKING RESEARCH STUDIES SHOW USPLABS’ DMA SUPPLEMENTS ARE SAFE AND EFFECTIVE”. However, none of these studies constitute reliable scientific or clinical proof.

¹⁰ See Whitehead, PN, Schilling, BK, Farney, TM, Bloomer, Rj. Impact of a dietary supplement containing 1,3-dimethylamulamine on blood pressure and bloodborne markers of health: a 10-week intervention study. Nutrition and Metabolic h1sights 2012:5

81. Despite claims made by USPLabs in its marketing and advertising, as detailed above, the Products are not scientifically tested or proven to provide, and do not provide the advertised health benefits of “**increase**[d]...fat breakdown **and** energy expenditure,” “reduced fat mass,” “weight loss” and other similar benefits. Accordingly, USPLabs’ marketing claims that the Products are proven, including because they are “UNIVERSITY STUDIED,” “Scientifically Reviewed,” and “PHARMACIST FORMULATED” are false, misleading, and likely to deceive the ordinary consumer.

82. Properly-conducted human studies do not demonstrate the safety or efficacy of the Products or DMAA. In fact, human data regarding the safety or efficacy of DMAA are few and the majority are funded by the USPLabs Defendants.

83. Even Defendants’ own purported clinical proof demonstrates the falsity of its claims. On its websites, usplabsdirect.com (which is referred to on the Products’ labeling) and dmaaresearch.com, USP lists “seven” studies on DMAA containing products. USPLabs characterizes one study that had male and female cohorts as two studies in order to state “seven” DMAA studies substantiate its claims. USPLabs admits its involvement and funding of five of the seven studies. Furthermore, none of these studies provide substantiation for the marketing claims:

a. McCarthy, Farney *et al.* 2012: Twelve subjects ingested OxyELITE Pro or a placebo over two days. USPLabs provided funding for the study, which analyzed subjects’ blood markers and metabolic rates. The authors acknowledge that “little objective scientific evidence is available” on DMAA and that “some subjects reported feeling jittery’, “on-edge’, “sweaty’ and ‘shaky’, sometimes involving cold sweats, a racing heart beat, and poor sleep quality on the night of treatment. According to the

authors and with respect to DMAA. *“no published reports are available pertaining to these [weight/fat loss] effects in human subjects.”* (emphasis added). The authors also noted that subjects consuming OxyELITE Pro experienced increased heart rate and blood pressure. The study concluded that “well-controlled intervention trails are needed in order to determine the chronic effects of the supplement on the body weight/fat loss and associated metabolic and biomechanical markets of health.”

b. McCarthy, Canale *et al.* 2012: Thirty-two subjects ingested OxyELITE Pro or a placebo over eight weeks. The study was funded by USPLabs. Five of sixteen subjects who consumed OxyELITE Pro reported jitters and sleeplessness when consuming two capsules per day. The authors observed an increase in resting heart rate for those consuming OxyELITE Pro and noted that the lack of control of subjects’ dietary intake was a limitation.

c. Farney, McCarthy *et al* 2012: Once per day for two weeks seven men ingested Jack3d, and six subjects ingested OxyELITE Pro. The study was funded by USPLabs. The authors noted that the lack of a placebo is a limitation of this study. Because appetite was lower on subjects consuming OxyELITE Pro, but not Jack3d, the authors observed that it was possible that ingredients other than DMAA or caffeine may be responsible for appetite suppression. According to the study, “Based on our data, which admittedly involved a very small number of subjects, it appears that such products should be avoided by individuals who are hypersensitive [] or who are pre-hypersensitive.” Subjects reported sleeplessness anxiousness, feeling of chills, tingling, sweating, and shakiness.

d. Bloomer, Schilling *et al* 2012: Twenty-five men were assigned to consume a placebo or Jack3d. The study was funded by USPLabs. Systolic blood pressure increased in those consuming Jack3d. The authors stated that “Due to the fact that our sample size is small, additional well-designed experiments of similar scope, inclusive of larger sample sizes, are needed to extend the findings presented within.” The authors also noted that only “some support” for safety was provided, and that “more work is needed involving a larger intervention period and the inclusion of additional measures of health [], to more fully elucidate the safety or oral [DMAA].”

e. Bloomer, McCarthy *et al* 2011: Twelve subjects ingested placebo, caffeine, DMAA, or DMAA plus caffeine over four days and immediately prior to competing a 10k run. The authors noted that “[t]he literature pertaining to the use of [DMAA] is scant.” The authors concluded that DMAA increases systolic blood pressure, and had no impact on the outcome of greatest interest – run time.

84. However, while USPLabs claims on its website that two studies conducted by Dr. Richard Bloomer were conducted by an “independent scientist without the involvement of the company,” these studies like the other five are *all* from the same laboratory at the University of Memphis. Dr. Bloomer was a lead researcher in each of the seven studies cited by USPLabs. Moreover, Bloomer, Harvey *et al* 2011, which USPLabs claims was conducted by an independent scientist, concedes that the opposite is true by stating at the conclusion of the study “CONFLICT OF INTEREST STATEMENT – Richard J. Bloomer, PhD discloses conflicts of interest with... USPLabs”¹¹

¹¹ See Bloomer RJ, Harvey IC, Farney TM, Bell ZW, and Canale RE. Effects of 1,3- dimethylamylamine and caffeine alone or in combination on heart rate and blood pressure in healthy men and women. *PJ ys*

85. Dr. Bloomer has received \$524,332 in funding from USPLabs: \$132,860 (2010-2011), \$225,600 (2011-2012), \$128,860 (2012-2013), and \$37,012 (2012-2013).¹⁰

86. Even this so-called “independent” study conducted by Bloomer reported that consumption of DMAA results “in a significant increase in blood pressure.” This was a placebo-controlled study of a DMAA supplement, the result of which showed a significant increase in systolic blood pressure in the DMAA group over the controls.

87. A Bloomer study also performed an investigation of the effects of DMAA and caffeine separately and combined. Bloomer, Harvey *et al* 2011, also reported that both caffeine and DMAA increased diastolic and systolic blood pressure separately (with that effect of DMAA being greater than caffeine), and that when the two ingredients were combined the healthy study volunteers experienced mean blood pressure of 140mm Hg. A 20% increase consistent with hypertension despite low normal pre-exposure pressure. The data from Bloomer, Harvey *et al* 2011 demonstrates that DMAA given in the proprietary formulation as compared to alone has a less pharmacologically clean effect and result in a greater increase in rate-pressure products (“RPP,” a measure of myocardial work or cardiovascular risk).

88. In studies known to and funded by USPLabs, the acute ingestion of proprietary DMAA products such as Jack3d and OxyELITE Pro is associated with highly significant increases in blood pressure and RPP within 30 minutes.¹² These findings represent the effect of the drug at rest. Indeed, the authors conclude that the drug increase myocardial work.

*Sportsmed*39: 111-120, 2011.

¹² McCarthy CG, Farney TM, Canale RE, Jr RJA, and Bloomer RJ. A Finished Dietary Supplement Stimulates Lipolysis and Metabolic Rate in Young Men and Women. *Nutrition and Metabolic Insights* 5: 23, 2011.

89. USPLabs did not adequately warn of the sympathomimetic effects, specifically including the statistically significant increased blood pressure found by one study¹³ caused by Jack3d and OxyELITE Pro, by comparing the risk to mild amounts of coffee:

The Hemodynamic response to *acute* ingestion was assessed as well.

OxyElite Pro did not result in a statistically significant change in heart rate or diastolic pressure, but did cause a statistically significant change in systolic blood pressure from baseline. This increase was mild and transient, and was similar to the changes reported in the scientific literature for subjects ingesting an amount of caffeine equivalent to 2-3 cups of coffee. (emphasis added)

The statement with respect to acute ingestion is misleading given the study results demonstrate that “compared to pre-ingestion and in general, both supplements resulted in an increase in SBP, DBP, and RPP from 5%-15%, with a peak occurring at the 60 or 90 minute post-ingestion time.” The study went onto highlight the acute cardiovascular risk:

As expected based on the pharmacologic profiles of caffeine and of 1,3-dimethylamylamine, acute intake of dietary supplements containing these agents results in an increase in myocardial work. Specifically, SBP is increased significantly in response to treatment, while DBP, and RPP increase to a lesser extent.

90. In making this and similar representations, USPLabs mislead users about the risks of the Products. USPLabs attempted to mislead consumer about the health dangers of

¹³ McCarthy CG, Farney TM, Canale RE, Jr RJA, and Bloomer RJ. Hemodynamic and Hematologic Profile of Health Adults Ingesting Dietary Supplements Containing 1,3- Dimethylamylamine and Caffeine. *Nutrition and Metabolic h1sights* 5: 1, 2012.

increased blood pressure and consequent risks caused by DMAA by comparing the risk to consumption of mild to moderate amounts of caffeine, a universally regarded safe sympathomimetic when used in isolation. USPLabs also failed to adequately warn users of the potential serious dangers of DMAA toxicity in susceptible users which USPLabs knew or should have known might result from consuming the Products. USPLabs widely and successfully marketed the product throughout the United States by, among other things, conducting a marketing campaign which misrepresented the testing efficacy and potential risks of the products in order to induce widespread consumption.

91. Accordingly, and contrary to the marketing and promotional campaign disseminated by USPLabs, including the language on the Products labels and websites, DMAA has not been demonstrated to be safe. For example, DMAA products such as the Products are unsafe and unfit for human consumption because they cause serious injury from cardiovascular toxicity in susceptible users. This potential hazard was not disclosed on the Products' packaging nor included in the materials made available to potential purchasers, including Plaintiff and the Class.

92. The advertising, marketing and promotion of Products was deceptive and misleading, in that it concealed the risks of cardiovascular injury and other serious health risks that USPLabs knew or should have known.

93. The "seven" cited studies do not constitute substantiation for Defendants' claims relating to safety and efficacy, and in fact, are proof that the Products are unsafe and ineffective. First, there are no independent studies performed by researchers without conflicts: each of the studies come from a single laboratory funded by USPLabs, and are led by a researcher who has received over \$500,000 from USPLabs. Second, the studies, which

contain a total of 99 subjects, are grossly underpowered (a fact repeatedly conceded in the reports themselves), restricted to a very young population, and there is no attempt to characterize the pharmacokinetics or purity of the drugs. Despite the lack of reliability or validity of the purportedly independent studies, the studies present a relatively consistent picture. DMAA, particularly when combined with caffeine or other agents, causes highly significant increases in blood pressure in healthy, resting individuals within one hour of consumption in a manner consistent with its known action as a vasoconstrictor. These sorts of changes should be anticipated to cause substantial and possibly dangerous increases in blood pressure during exercise (particularly weight lifting, cycling, or other resistance exercise). Vasoconstriction during exercise would increase myocardial oxygen consumption leading to an increased risk for ischemia and triggers coronary vasospasm in vulnerable subjects. In other words, the studies themselves, flawed as they are, demonstrate the dangerous and synergistic sympathomimetic effects of the DMAA formulation contained in the Products. In fact, Defendants do not deny the synergistic effects of DMAA and caffeine stating on their website “a common synergistic combination.”

94. Thus, USPLabs knew, or in the exercise of reasonable care ought to have known from their own studies that DMAA, when used in isolation or in conjunction with the other ingredients contained in the Products including caffeine, is dangerous and could injure or kill consumers.

95. USPLabs similarly knew, or in the exercise of reasonable care ought to have known, that the Products are not effective for weight loss or any other health benefits claimed by USPLabs.

96. In fact, USPLabs knew or should have known long before its own studies that DMAA could cause cardiovascular adverse effect based on the fact DMAA is in the same class of chemicals as amphetamines.

97. USPLabs knew that consumers believe that natural supplements are more healthful and less dangerous than synthetic, chemically produced supplements. USPLabs represented in its advertising and marketing that its Products were natural dietary supplements, when in fact it knew that the active ingredient DMAA, was not a natural ingredient but was a chemically compounded, synthetic ingredient. In fact, in a response letter to FDA on May 15, 2012, it acknowledge DMAA was synthetically created. USPLabs further knew that DMAA is not contained in natural substances like geranium oil. It made these false representations that the Products were natural products to mislead and falsely reassure consumers that the Products were safe products.

98. Likewise, GNC knew or should have known that DMAA could cause cardiovascular adverse effects based on the fact DMAA is in the same class of chemicals as amphetamines.

99. GNC joined in the misrepresentations about DMAA, by asserting in its marketing of the Products that GNC conducts a review and has a requirement that the products it sells have labels that truthfully disclose health and safety issues and that the ingredients be safe. GNC represents that it exercises the highest standard of care in the nutritional supplement industry by "demanding truth in labeling, ingredient safety." Moreover, on information and belief, GNC considered, reviewed and rejected the idea of selling its own propriety products containing DMAA with knowledge that DMAA could injure consumers.

Adverse Events Pile Up and FDA Warns USP

100. On December 6, 2011, the US Army removed all DMAA containing compounds from its commissaries. This action followed the death of two soldiers believed to be due to SUBJECT PRODUCTS. A case series from New Zealand reported three cases of cerebral hemorrhage in adults taking DMAA.¹⁴

101. In one case, a 41 year old man developed a systolic blood pressure of 240 mm HG thirty minutes after taking a DMAA supplement and bled into his brain. Another published report attributes stress-induced cardiomyopathy to use of DMAA.¹⁵ Pieter Cohem, a Harvard internist, has recently drawn attention to DMAA in a letter to the Archives of International Medicine.¹⁶

102. In a letter addressed to USPLabs from the FDA dated April 27, 2012, the Agency warned that it had received 42 adverse events reports on products containing DMAA, including cardiac disorders, nervous system disorders, and death. Many of those adverse events reports were specifically for Jack3d and OxyELITE Pro and stretch back to early 2010, if not earlier.

103. Daniel Fabricant, director of FDA's Dietary Supplement Program (DSP) stated "Before marketing products containing DMAA, manufacturers and distributors have a responsibility under the law to provide evidence of the safety of their products. They haven't done that and that makes the products adulterated." Additionally, the FDA challenged manufacturers to demonstrate that DMAA was in use as a dietary supplement

¹⁴ Gee P, Tallon C, Long N, Moore G, Boet R, Jackson S. Use of Recreational Drug 1,3-Dimethylethylamine (DMAA) Associated With Cerebral Hemorrhage.

¹⁵ Salinger L, Daniels B, Sangalli B, Bayer M. Recreational use of bodybuilding supplement resulting in severe cardiotoxicity. Clin Toxicol. 2011;49(6):573-574.

¹⁶ Cohen PA. DMAA as a Dietary Supplement Ingredient. Arch Intern Med. 2012 May 7 [Epub ahead of print].

prior to 1994. Finally, the FDA denied that DMAA is a natural as opposed to synthetically-created compound: “The agency additionally warned the companies that synthetically-produced DMAA is not a ‘dietary ingredient’ and, therefore, is not eligible to be used as an active ingredient in a dietary supplement. DSHEA defines a dietary ingredient as a vitamin, mineral, amino acid, herb or other botanical, a dietary substance for use by man to supplement the diet, or a concentrate, metabolite, constituent, extract, or combination of these substances.”

104. The purpose of these submission requirements for dietary supplements is to protect consumers from exposure to new, synthetically created dietary supplements which are not demonstrated to be safe and effective, the exact situation here

105. USPLabs attempted to assuage concerns from critics, the FDA and concerned consumers about the safety of DMAA by suggesting DMAA comes from a naturally occurring herb and therefore safe. However, DMAA is a dangerous synthetically-created chemical known by industry insiders like USPLabs to display symptomimetic side effects. A single Chinese study claims that DMAA occurs naturally in geranium oil.¹⁷ However, the New Zealand National Measurement Institute performed a rigorous evaluation of this claim and found it impossible to substantiate.¹⁸ Health Canada likewise could find no evidence that DMAA occurs in nature.¹⁹

106. Additionally, in a study published June 25, 2012, the authors concluded, after numerous and varied tests of geranium oils and plants, that geranium oils and plants

¹⁷ Ping Z, Jun Q, and Qing L. A study on the chemical constituents of geranium oil. Journal of Guizhou Institute of Technology 25: 1996.

¹⁸ Lisi A. Hasick N, Kazlauskas R. and Goebel C. Studies of methylhexaneamine in supplements and geranium oil. Drug Test Anal 2011.

¹⁹ Health Canada, Health Products and Food Branch. Classification of 1,3- dimethylamylamine (DMAA). <http://www.scribd.com/dod82744576/DMAA-HealthCanada-2011> (last visited March 22, 2012).

contain *no* detectable levels of DMAA.²⁰ This research refutes any claims that synthetic DMAA is identical to naturally derived ingredients. It is impossible for synthetic DMAA to be identical to the natural geranium plant and oil since geranium plant and oil do not contain detectable levels of DMAA.

107. The Australian government's Therapeutic Goods Administration ("TGA") has banned the use of the DMAA, which it describes as "a toxic substance with dangerous side effects." According to the TGA, "[a]mong the reasons DMAA is banned are:

- a. DMAA has no health benefits and is a toxic substance
- b. Risks associated with its use include high blood pressure, psychiatric disorders, bleeding in the brain and stroke
- c. Its long term safety has not been demonstrated
- d. DMAA presents a high risk of abuse, misuse and illicit use.²¹

108. Despite these facts, USPLabs has publicized a letter purporting to have proof from two laboratories claiming that DMAA can be found in geranium oil. The data are allegedly not available for review because they have been submitted for publications. USPLabs persists in its representation that DMAA is a natural chemical to reassure consumers that the product is safe and natural, when in fact it is neither.

109. USPLabs further attempted to deflect attention away from safety concerns and to misrepresent the actual risks of DMAA by stating numerous times on its website that "no serious adverse events were noted in the study." USPLabs failed to inform consumers

²⁰ ElSohly, MA, et al., Pelargonium oil and Methyl Hexaneamine (MHA): Analytical approaches supporting the absence of MHA in authenticated Pelargonium graveolens plant material and oil. *Journal of Toxicology*: published online.

²¹ See <http://www.tga.gov.au/newsroom/btn-tga-statement-dmaa-120803.htm> (last visited August 23, 2012).

and the public, including Plaintiffs herein who relied on USPLabs' representations and misleading comments, that in fact the FDA had received dozens of serious adverse events from people taking DMAA, including death.

USPLabs, LLC replaces DMAA with a new dangerous ingredient, aegeline

110. Aegeline is an organic compound the same as DMAA. However, it is too scarce to be included in these Products. Instead the Products continued to contain DMMA.

111. The *Hogan* action was based upon USPLabs' inclusion of the ingredient DMAA in those products.

112. During and subsequent to *Hogan v. USPLabs, LLC*, Defendant USPLabs contained and or included another dangerous ingredient in OxyElite Pro™ named Aegeline.

113. Upon information and belief, the *Hogan* settlement was based upon the same adulteration theory as alleged here. Therefore, Defendants knew or should have known of the consequences of adulteration.

114. On October 11, 2013, the FDA issued a warning letter to Defendant USPLabs regarding the Product.²²

115. The labeling of this Product shows that it contains Aegeline, also referred to as N-[2-hydroxy-2(4-methoxyphenyl) ethyl]-3-phenyl-2-propenamide, identified as a dietary ingredient.

²² See FDA Warning Letter, dated October 11, 2013 (located at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm371203.htm>)(last visited January 27, 2014).

116. Because Aegeline is a “new dietary ingredient” (i.e., not marketed in the United States before October 15, 1994), it was deemed adulterated under 21 U.S.C. 342(f).²³

117. Neither aegeline nor DMAA, upon information and belief, was lawfully marketed as a dietary ingredient in the United States before October 15, 1994.

118. Neither aegeline nor DMAA, upon information and belief, has been demonstrated as an ingredient in the food supply as an article used for food in a form in which food has not been chemically altered.²⁴

119. Neither aegeline nor DMAA, upon information and belief, is reasonably expected to be safe when used under the conditions recommended on the Products’ labeling.

120. Public health officials throughout the United States are actively investigating a number of severe illnesses characterized by hepatotoxicity by consumers of the Product relating to aegeline.²⁵

121. Several findings present a causal connection exist between ingestion of the Product and the illnesses reported.

122. In a review of twenty (20) medical records initially submitted to FDA by the Hawaii Department of Health, fourteen (14) patients (70%) had ingested the Product prior to becoming ill.

123. There were no other consistent commonalities among the fourteen (14) patients other than exposure to the Product.

²³*Id.*

²⁴*Id.*

²⁵*Id.*

124. Importantly, eight (8) patients reported the Product as the sole dietary supplement they took prior to becoming ill, and most of these patients had been entirely healthy before they became ill.

125. Upon discontinuing the Product following onset of illness, most patients recovered from their illness, implying the Product was the cause of the illness.

126. Several patients sustained injuries to the liver that required transplantation, and one patient died before transplantation could be undertaken.

127. Rigorous clinical protocols were followed in the care of the patients to exclude and/or rule out known causes of liver disease. The absence of these causes of liver disease increases the likelihood that the Product played a hepatotoxic role in these patients. Therefore, in the absence of a history of use or other evidence of safety establishing that Aegeline is reasonably expected to be safe under the conditions recommended or suggested in the labeling of the Product, it is deemed to be adulterated under 21 U.S.C. 342(f).²⁶

128. In response to the FDA's warning letter stating "[f]ailure to immediately cease distribution of all products containing aegeline may result in enforcement action by FDA without further notice."

129. Thus, Defendant USPLabs issued a recall of the Product nearly a month later on or about November 9, 2013.²⁷

130. In addition to the Products being recalled, the FDA continues to advise consumers not to use any of the Products.²⁸

²⁶*Id.*

²⁷ FDA Website, USPLabs LLC recalls OxyElite Pro dietary supplements; products linked to liver illness (available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm374395.htm>) (last visited December 4, 2013).

²⁸*Id.*

131. But Defendants have taken no action to provide notice to purchasers.

132. As of November 10, 2013, a review of 46 medical records submitted to the FDA by the Hawaii Department of Health, 27 patients, or 58 percent, had taken the Product prior to becoming ill.

133. Seventeen of the 27 patients (or 63 percent) reported that the Product was the only dietary supplement they were taking.

134. One death has occurred among these patients, another patient has required a liver transplant, and others await liver transplants.²⁹

135. Defendant USPLabs is voluntarily conducting a national recall of all lots and sizes of the Product because they contain aegeline, a synthesized version of a natural extract from the Bael tree.³⁰

136. Epidemiological evidence shows that use of the Product has been associated with the reported serious adverse health consequences.³¹

137. Defendants USPLabs and GNC marketed and sold the Product without a proper and adequate warning, and without modifying the Product so it could be fit for human consumption.

138. Defendants USPLabs and GNC make affirmative representations they are a reputable, reliable, safe manufacturer and distributor(s) respectively.

²⁹*Id.*

³⁰*FDA Website*, USPLabs LLC Announces a Recall of OxyElite Pro Dietary Supplements Due to Possible Health Risk (available at <http://www.fda.gov/safety/recalls/ucm374394.htm>) (last visited December 4, 2013).

³¹*Id.*

139. Plaintiff purchased the Product based on the Product's affirmative representation that it would safely provide energy, increase weight loss, and increase mental focus so long as the consumer used the Product as directed.

140. Plaintiff has suffered economic damages as a result of purchasing the Product, in that, among other things, he spent money on a Product that was unfit for human consumption – and therefore lacked the value he had been led to believe the Product had – and for which he paid in the purchase price of the Product.

141. An average and reasonable consumer would not expect the Product to inflict such adverse side effects when consumed as instructed.

142. Defendant USPLabs' labeling convey a series of implied claims and/or omissions which it knows are material to the reasonable consumer, and which it intended for consumers to rely upon when choosing to purchase the Product.

143. Defendant USPLabs' inadequate labeling is an unfair trade practice because the ingredients render it unfit for safe use and reasonable consumers have suffered severe adverse side effects from taking it.

144. Plaintiff, and no other reasonable consumer, would not have purchased the Product had they known about the severe adverse effects the Product can cause to humans. A lack of an adequate warning and the severity of the adverse side effects is material to the average consumer.

145. Plaintiff would not have purchased the Product had he known the truth about it.

CLASS ALLEGATIONS

146. Plaintiff incorporates all previous paragraphs alleged in this Complaint as if fully alleged herein.

147. Plaintiff brings this action on behalf of himself and all other similarly situated consumers pursuant to Federal Rules of Civil Procedure 23(a) and 23(b). The Class of persons whom Plaintiffs seek to represent is defined as:

- a) All consumers who purchased the Product in New Jersey from January 1, 2008 through January 27, 2104.
- b) Plaintiff reserves the right to broaden or narrow the Class after a reasonable opportunity to conduct discovery.
- c) Excluded from the Class are Defendants, any parent, subsidiary or affiliate of Defendants, any entity in which Defendants have a controlling interest, and the respective officers, directors, employees, agents, legal representatives, heirs, predecessors, successors, and assigns of such excluded persons or entities.

148. Plaintiff and Class members are so numerous that joinder of all members individually, in one action or otherwise, is impracticable.

149. There are questions of law and fact common to the Class.

150. Plaintiff's claims are typical of the claims of other Class members. The named Plaintiff is a member of the Class of affected consumers described herein.

151. The named Plaintiff is willing and prepared to serve the Court and the proposed Class in a representative capacity with all of the obligations and duties material thereto. Plaintiff will fairly and adequately protect the interests of the Class and has no

interests adverse to or which directly and irrevocably conflict with the interests of other members of the Class.

152. The self-interests of the named Class representatives are co-extensive with, and are not antagonistic to, those of the absent Class members. The proposed representative will undertake to represent and protect the interests of the absent Class members.

153. The named Plaintiff has engaged the services of counsel indicated below. Counsel are adequately experienced in complex class action litigation, will effectively prosecute this action, and will assert and protect the rights of, and otherwise will represent the named Class representative and absent Class members.

154. This action is also appropriate as a class action pursuant to Rule 23(b)(2) and (b)(3) of the Federal Rules of Civil Procedure.

155. This action involves questions of law and fact common to Plaintiff and all members of the Class. These common questions predominate over any issues affecting individual members of the Class and include:

- a) Whether Plaintiff's are entitled to punitive damages;
- b) Whether Defendants' business activities within New Jersey should be curtailed or prohibited;
- c) Whether as a condition of continuing business in New Jersey, Defendants should be required to establish or subject to independent review of its products;
- d) Whether Defendants engaged in unfair methods of competition; unconscionable acts and practices, and unfair and deceptive acts and practices in the conduct of its labeling and advertising of the Product;

- e) Whether Defendants materially misrepresented that the Product was safe to consume even though it has harmful and adverse effects;
- f) Whether Defendants knew that the Product has harmful effects;
- g) Whether Plaintiff and Class members are entitled to injunctive relief enjoining Defendants from continuing to fail to disclose that the Product has severe adverse and harmful effects that may require hospitalization;
- h) Whether Defendants should be made to engage in a corrective advertising campaign advising consumers that the Product has the adverse and harmful effects; and
- i) Whether Plaintiff and Class Members have been harmed and the proper measure of relief.

156. Judicial determination of the common legal and factual issues essential to this case would be far more efficient and economical as a class action than in piecemeal individual determinations.

157. There is no plain, speedy or adequate remedy other than by maintenance of this lawsuit as a class action because individual damages are relatively small, making it economically infeasible for Class members to pursue remedies individually.

158. The prosecution of separate actions by individual members of the Class, even if theoretically possible, would create a risk of inconsistent or varying adjudications with respect to individual Class members against Defendants and would establish incompatible standards of conduct for Defendants.

159. A class action is superior to other available methods for the fair and efficient adjudication of this controversy for at least the following reasons:

a) Given the complexity of issues involved in this action and the expense of litigating the claims, few, if any, Class members could afford to seek legal redress individually for the wrongs that Defendants committed against them, and absent Class members have no substantial interest in individually controlling the prosecution of individual actions;

b) When Defendants' liability has been adjudicated, claims of all Class members can be determined by the Court;

c) This action will cause an orderly and expeditious administration of the Class claims and foster economies of time, effort and expense, and ensure uniformity of decisions; and

d) Without a class action, many Class members would continue to suffer injury, and Defendants' violations of law will continue without redress while Defendants continue to reap and retain the substantial proceeds of its wrongful conduct.

160. Plaintiff knows of no difficulty that will be encountered in the management of this litigation, which would preclude its maintenance as a class action.

161. Defendants have acted on grounds applicable to the Class generally; therefore, Plaintiff seeks equitable and injunctive relief on behalf of the entire Class on grounds generally applicable to the entire Class.

COUNT ONE
NEW JERSEY CONSUMER FRAUD ACT ("NJ CFA")

162. Plaintiff hereby incorporates the allegations set forth in the preceding paragraphs as if set forth herein at length.

163. Plaintiff brings this action pursuant to the New Jersey Consumer Fraud

Act, N.J.S.A. 56:8-1, et seq. ("NJ CFA").

164. Defendants have engaged in unlawful conduct by selling supplements that cause physical harm in the sState of New Jersey.

165. As a result of this unlawful conduct, Plaintiffs have suffered economic damage, physical damage and emotional distress damages.

166. Defendants made affirmative representations regarding safety and efficacy.

167. Defendants have sold PRODUCTS which are not merchantable because the Product contains adulterated substances.

168. Defendants are liable *per se* under the NJ CFA.

169. Defendants conduct is otherwise unconscionable.

WHEREFORE, Plaintiffs pray for judgment against Defendants for damages and relief as set forth below.

COUNT TWO
UNJUST ENRICHMENT

170. Plaintiff re-alleges and incorporates by reference the allegations set forth in paragraphs one (1) through (169) of this Complaint as if fully set forth herein.

171. Plaintiff and Class members conferred a benefit on Defendants by purchasing the Product at a premium price.

172. Defendants received the money paid by Plaintiff and Class members and thus knew of the benefit conferred upon them.

173. Defendants accepted and retained the benefit in the amount of the profits it earned from sales to Plaintiff and Class members.

174. Defendants have profited from its unlawful, unfair, misleading, and deceptive practices and advertising at the expense of Plaintiff and Class members, under circumstances in which it would be unjust for Defendant to be permitted to retain the benefit.

175. As a result of purchasing the Product, Plaintiff and the Class spent money on a useless Product that they otherwise would not have purchased.

176. There was no and/or an inadequate warning/disclaimer on the Product informing Plaintiff of the severity of the adverse health effects, the potential for hospitalization and liver illness, the true strength of the Product, and the dangers of consuming the Product.

177. Pursuant to Fed. R. Civ. P. 8(d)(2)-(3), Plaintiff (alternatively) does not have an adequate remedy at law against Defendants.

178. Plaintiff and Class members are entitled to restitution of the excess amount paid for the Product, over and above what they would have paid had they known that the Product was not safe when consumed in that it had harmful effects. Because Plaintiff and the Class would not have paid anything for the Product had they known it was unfit, Plaintiff and the Class are entitled to restitution of the full purchase price.

WHEREFORE, Plaintiffs seek relief in the form of injunctive relief in the form of corrective advertising, equitable relief including restitution, pre and post judgment interest, reimbursement of costs, reasonable attorney's fees, and for any other relief that this Court

deems just and proper, as set forth more fully below in the Prayer for Relief section of this Complaint.

COUNT THREE
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

179. Plaintiff re-alleges and incorporates by reference the allegations set forth in paragraphs one (1) through (178) of this Complaint as if fully set forth herein.

180. Plaintiff and other members of the Class sought an energy enhancing and weight loss product that would safely provide the purported benefits. In doing so, Plaintiff and other Members of the Class reasonably relied on Defendants' skill and judgment to select and furnish suitable goods for that purpose, and on or about that time, Defendants sold the Product to Plaintiff and other members of the Class.

181. Plaintiff and Class members were the foreseeable users of the Product.

182. At the time of sale, Defendants had reason to know the of the ordinary and intended purpose for which the goods were required, to safely provide energy, increase weight loss, improvement in mental focus, and that Plaintiff and members of the Class were relying on Defendants' skill and judgment to select and furnish suitable and harmless goods, so there was an implied warranty that the goods were fit for this intended and ordinary purpose.

183. However, Defendants breached the warranty implied at the time of sale in that Plaintiff and members of the Class did not receive suitable goods, but rather defective and non-merchantable goods, and the goods were not reasonably fit for the intended purpose for which they were made, as set forth above. The Products defective nature

existed at the time the Product left the possession of the Defendants. Additionally, as set forth above, the Product was inadequately packaged and labeled.

184. The Product was used in its intended manner by Plaintiff and the Class.

185. As a proximate result of this breach of warranty by Defendants, Plaintiff and members of the Class have suffered actual damages in an amount to be determined at trial, in that they were induced to purchase a product they would not have purchased had they known the true facts about, and that lacks the value Defendants represented the Product had, which was reflected in the purchase price.

WHEREFORE, Plaintiffs seek relief in the form of actual and compensatory damages, injunctive relief in the form of corrective advertising, equitable relief including restitution, pre and post judgment interest, reimbursement of costs, reasonable attorney's fees, and for any other relief that this Court deems just and proper, as set forth more fully below in the Prayer for Relief section of this Complaint.

COUNT FOUR
VIOLATION OF THE MAGNUSON-MOSS WARRANTY ACT (15 U.S.C. §§ 2301 *et seq.*)

186. Plaintiff re-alleges and incorporates by reference the allegations set forth in paragraphs one (1) through (185) of this Complaint as if fully set forth herein.

187. Defendants have breached implied warranties regarding the Product. Thus, pursuant to Fed. R. Civ. P. 10, Plaintiff re-alleges and incorporates by reference the allegations in paragraphs 91 through 97 as if fully set forth herein.

188. Plaintiff and the Class are consumers as defined in 15 U.S.C. § 2301(3).

189. Defendants are a supplier and warrantor as defined in 15 U.S.C. § 2301(4)(5).

190. The Product is a consumer product as defined in 15 U.S.C. § 2301(6).

191. By reason of Defendants' breach of the above implied warranty of merchantability, Defendants have violated the statutory rights due to Plaintiff and members of the Class pursuant to the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301 *et seq.*, thereby economically damaging Plaintiff and the Class. The Act is intended to increase the enforceability of these warranties.

192. **Therefore**, Plaintiff and the Class seek all available remedies, damages, and awards under the Magnuson-Moss Warranty act.

DAMAGES

197. Plaintiff hereby incorporates the allegations set forth in the preceding paragraphs as if set forth herein at length.

198. As a direct and proximate result of the above-described conduct, Plaintiff has in the past suffered, and will in the future continue to suffer, damages including:

- (a) Physical injury;
- (b) Loss of wages;
- (c) Medical expenses;
- (d) Costs for investigation and repair; and
- (e) Attorneys' fees and costs of suit.

WHEREFORE, Plaintiffs seeks judgment against the Defendants as follows:

- (a) That the Court and jury enter a declaratory judgment and find that Defendants violated the NJ CFA, were unjustly enriched, breached the implied warranty of merchantability, and violated the Magnuson-Moss Warranty Act;

(b) That the Court and jury award an injunction against unlawful practices including:

i. revoking the certificate of authority for Defendants to do business in this state under the NJ CFA;

ii. That Defendant GNC be required to establish a fund to provide for an independent group of chemists and physicians to ensure all products sold are safe for consumption and;

iii. notice to consumers that the product is dangerous;

(c) That the Court and jury award Plaintiff restitution as permitted under the NJ CFA;

(d) That the Court award Plaintiff such treble damages as allowed under the NJ CFA;

(e) That the Court and jury award such punitive damages as are allowed under the NJ CFA;

(f) That the Court and jury award Plaintiff such compensatory damages allowable by law;

(g) That the Court and jury award such declaratory, actual and nominal damages as are allowed at law;

(h) That the Court award such attorney fees, costs and expenses, pre- and post- judgment interest as are allowed at law;

(i) That the Court order such further relief as the Court deems appropriate.

JURY TRIAL

Plaintiff demands a jury as to all issues.

WILLIAM RIBACK, LLC

Dated: 5/16/2014

/s/ William Riback

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