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

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Case No.

JURY TRIAL DEMANDED

RICHARD J. CARLSON, BRIANNE K. KITNER, MITCHELL A. PAYNE, AND NICOLE B. PAYNE, Each Individually And On Behalf Of All Persons Similarly Situated, and The General Public

Plaintiffs,
-v-

USPLABS, LLC, and
GNC CORPORATION

Defendants.

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**CLASS ACTION COMPLAINT FOR:**

**1.) VIOLATIONS OF THE FLORIDA DRUG AND COSMETIC ACT FLORIDA CIVIL CODE §499 *ET SEQ;***
***2.)* VIOLATIONS OF FLORIDA CONSUMER PROTECTION STATUES §501.201-§501.213, FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT; 3.) BREACH OF EXPRESS WARRANTY; MERCHANTABILITY; USAGE OF TRADE PURSUANT TO § 672.314 FLORIDA STATUTES;**
**4.) BREACH OF IMPLIED WARRANTY PURSUANT TO UNIFORM COMMERCIAL CODE §2-314;**
**5.) UNJUST ENRICHMENT**

Plaintiffs, RICHARD J. CARLSON, BRIANNE K. KITNER, MITCHELL A. PAYNE, AND NICOLE B. PAYNE, (collectively known as "Plaintiffs") bring this action on behalf of themselves, all others similarly situated, and the general public against defendants USPLabs, LLC ("USP" or "USPLabs") and GNC Corporation ("GNC") (collectively "Defendants"),

and states:

## JURISDICTION AND VENUE

1. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum or value of $5,000,000 and is a class action in which some of the members of the class of plaintiffs are citizens of states different from Defendants. Further, greater than two-thirds of the class members reside in states other than the state in which Defendants are citizens.

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

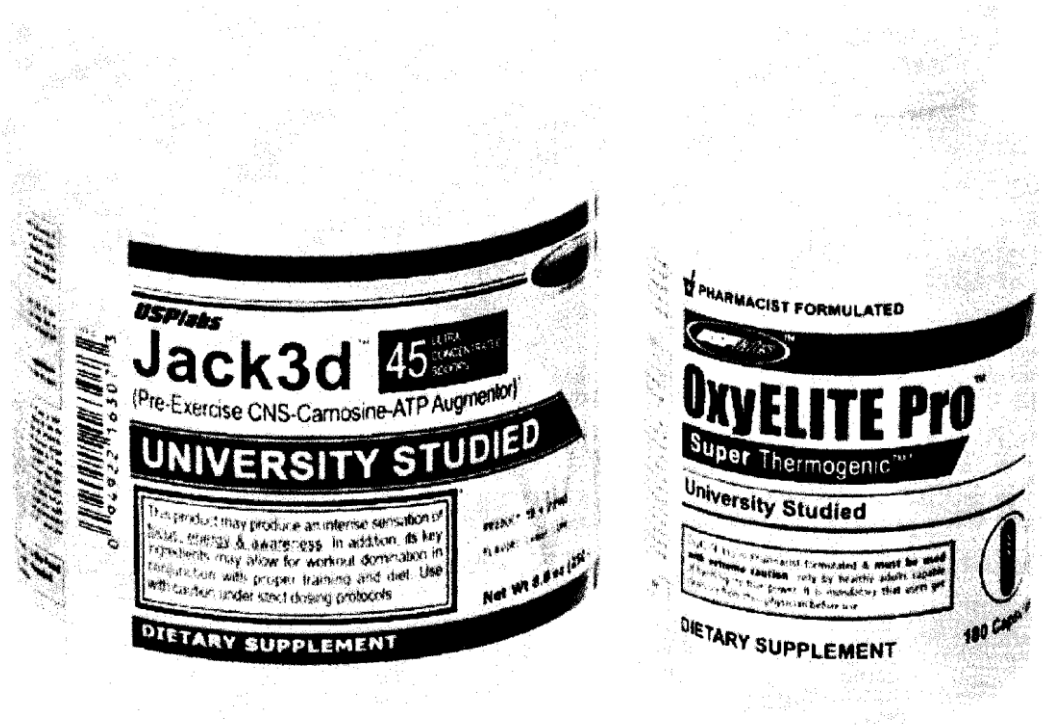
(a) are authorized to conduct business in this district and has intentionally availed itself of the laws and markets within this district through the promotion, marketing, distribution and sale of its products in this district;

(b) do substantial business in this district; and

(c) are subject to personal jurisdiction in this district

## NATURE OF ACTION

3. This is a consumer rights class action lawsuit about Defendants' false and misleading advertising of weight loss supplements containing a long-forgotten, ineffective, extremely dangerous and potentially lethal ingredient that was patented in 1944 as a nasal decongestant. Defendants manufacture, distribute, market and sell Jack3d and OxyELITE Pro (the "SUBJECT PRODUCTS"). The labeling for the SUBJECT PRODUCTS appears below:




4. Defendants worked together to sell the SUBJECT PRODUCTS to thousands of consumers, and achieved this success through broad-based advertising and marketing campaigns that promised the SUBJECT PRODUCTS were "UNIVERSITY STUDIED," "Scientifically Reviewed," supported by "clinical studies," and proven to be safe and effective supplements providing weight loss and energy health benefits. For example, USP states on its website that "NEWLY RELEASED, GROUNDBREAKING RESEARCH STUDIES SHOW USPLABS' DMAA SUPPLEMENTS ARE SAFE AND EFFECTIVE."[1]

5. In reality, no such proof exists. Contrary to Defendants' implied and express representations, the SUBJECT PRODUCTS are dangerous and not effective, and Defendants lacked any adequate substantiation for their advertising claims, including clinical support. Instead of being the safe and effective weight loss products that Defendants promised, the SUBJECT PRODUCTS cause dangerous cardiovascular side effects, including without limitation elevated blood pressure and heart rate, stroke, heart attack, atrial

[1] *See* http://usplabsdirect.com/dmaa-research (last visited August 22, 2012).

fibrillation, heart palpitations, shakiness, dizziness, and loss of consciousness. Despite knowing for years that the SUBJECT PRODUCTS resulted in severe injury and even death, Defendants marketed and sold the SUBJECT PRODUCTS to thousands of unsuspecting consumers. Further, while claiming the SUBJECT PRODUCTS are clinically proven to reduce weight, no such proof exists.

6. As a result of misrepresentations and omissions to their customers about the safety and efficacy of the SUBJECT PRODUCTS, Defendants have taken millions of dollars from these consumers. For example, according to a Wall Street Journal report, which singled out USP's Jack3d, GNC's retail sales of products containing DMAA are estimated to be $151 million in 2011 alone.[2]

7. Defendants' advertising campaign has been extensive and comprehensive, and conveyed these deceptive messages of safety and efficacy to consumers throughout the United States. Defendants conveyed and continue to convey their deceptive claims about the SUBJECT PRODUCTS through a variety of media, including point of sale displays, magazines, the Internet and on the SUBJECT PRODUCTS' packaging. The only reason a consumer would buy SUBJECT PRODUCTS is to obtain the advertised benefits.

8. As a result of the misleading messages conveyed through its campaign, Defendants have sold products that do not perform as advertised, and can cause serious, life-threatening harm to people who consume them. Further, Defendants have been able to charge a significant price for their unsafe and ineffective nutritional supplement products. A 250 gram container of Jack3d retails for approximately $44.99, and a 90-count bottle of OxyELITE Pro retails for approximately $59.99.

9. On April 27, 2012, the FDA warned USPLabs, and others that it had received

[2] *See* http://online.wsj.com/article/SB10001424052702304543904577396531034606416.html visited August 23, 2012).

42 adverse event reports on products containing DMAA (defined below), including cardiac disorders, nervous system disorders, and death. On February 2, 2012, and following the deaths of two soldiers after heart attacks during fitness exercises, the Defense Department removed the SUBJECT PRODUCTS and other dietary supplements containing DMAA from stores on military bases in the United States. 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.

10. Plaintiffs bring this action on behalf of themselves, other similarly situated consumers who purchased the SUBJECT PRODUCTS in order to halt the dissemination of this false and misleading advertising message, correct the false and misleading perception Defendants have created in the minds of consumers, and to obtain redress for those who have purchased the SUBJECT PRODUCTS. Plaintiff alleges violations of the Consumers Legal Remedies Act, the Unfair Competition Law, breach of implied warranty, breach of express warranty, and unjust enrichment.

## PARTIES

***Plaintiffs Richard J. Carlson, Brianne K. Kitner, Mitchell A. Payne, And Nicole B. Payne***

11. Plaintiffs, Richard J. Carlson, Brianne K. Kitner, Mitchell A. Payne, And Nicole B. Payne (collectively known as "Plaintiffs") are residents of Crawfordville, Florida. During the class period, and before making their purchases, Plaintiffs were exposed to and read Defendants' advertising claims, including the SUBJECT PRODUCT's labeling and Internet

websites, including USP's websites. In or about June 2010 through October 2013, Plaintiffs purchased Jack3d for approximately $30 from SupplementWarehouse.com and GNC in Oceanside, CA. Plaintiffs purchased and used the product as directed believing it was reasonably safe and effective as a dietary supplement. Plaintiffs did not know the product posed serious adverse health risks and was not proven effective when they purchased the product. Prior to filing their complaint, Plaintiffs learned of the potential serious health-risks caused by the products and they have stopped consuming the products and will no longer purchase them. Plaintiff, Nicole B. Payne is currently 7 months pregnant. As a result of their purchases, Plaintiffs have suffered injury in fact and have lost money and property as a result of the unfair, deceptive, untrue and misleading advertising described herein, including the purchase price for products that are of little or no value and are dangerous. Had Plaintiffs known of the potential health risks and that it was not effective as advertised they would not have purchased the products.

***Defendant USPLabs, LLC***

12. Defendant USPLabs, LLC is a Texas corporation, headquartered in Dallas, TX and was and is regularly engaged in the business of licensing, manufacturing, formulating, packaging, distributing, marketing, advertising, and/or selling, either directly or indirectly, through third parties or related entities, non-prescription nutritional/dietary supplements for sale to, and use by, members of the general public, and as a part of their business, USPLabs, LLC, directly or indirectly was and is engaged in the manufacturing/formulating/distributing/selling/marketing/ advertising of purported nutritional/dietary supplements under the proprietary, trademarked names, Jack3d and OxyELITE Pro in interstate commerce and in Florida, which Plaintiff and the Class purchased as alleged herin.

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

14. At all relevant times, USPLabs expected or should have expected that its acts would have consequences within the United States of America and within the State of Florida.

15. Jonathan Vincent Doyle and 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 UPSLABS OXYELIT, LLC. USPLABS OXYEPHEDRINE PRO, LLC, USPLABSPOWERFUL HOLDSING, LLC, USPLABS POWERFULL, LLC, and USPLABS PRIME, LLC (collectively, the "USP entities"). Upon information and belief, Jonathan Vincent Doyle and Jacob Geissler are shareholders in each of the USP entities, are corporate officers in each of the USP entities, direct and participate in the day to day operations of the USP entities, were responsible for the acts of the USP entities and for all intents and purposes own, operate and act through the USP entities.

16. Furthermore, the USP entities were at all times alleged herein under the control of their founders and dominant principals, Jonathan Vincent Doyle and Jacob Geissler. The Corporate filing for USPLabs, LLC with the Texas Secretary of State states "The limited liability company is to be managed by managers, the names and addresses of the governing persons are set forth below" wherein Jonathan Vincent Doyle and Jacob Geissler are named.

17. At all times herein alleged, each of the acts of the employees, including but not limited to Jonathan Vincent Doyle and Jacob Geissler, were on behalf of, for the benefit of, at the direction of, and at the behest of USPLabs, LLC and were ratified by USPLabs, LLC. Further, each of the acts of the employees, including but not limited to Jonathan Vincent

Doyle and Jacob Geissler were done pursuant to an in accordance with corporate policy.

***Defendant GNC Corporation***

18. Defendant GNC Corporation ("GNC") is a Delaware corporation with its principal place of business located in Pittsburgh, Pennsylvania.

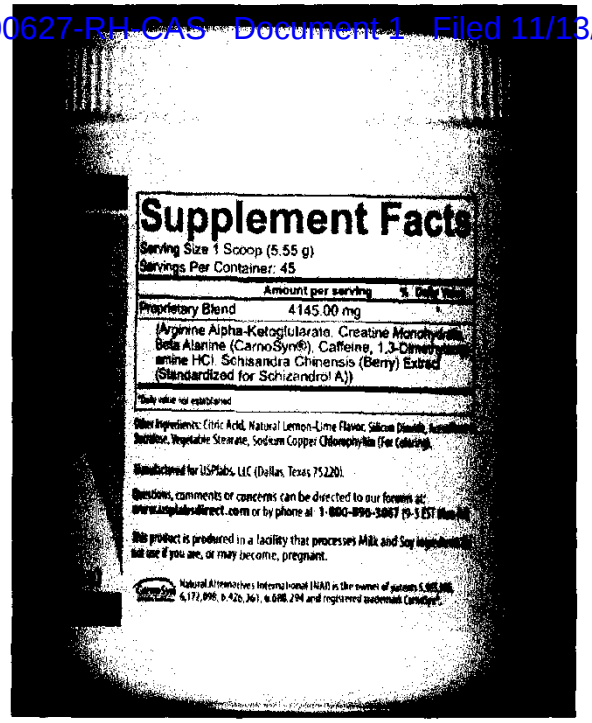
19. Defendant GNC conducted regular and sustained business in the State of Florida and throughout the nation, including through the sale of the SUBJECT PRODUCTS by its retail outlets, affiliates and franchisees. During the class period GNC was regularly engaged in the business of packaging, distributing, marketing, and/or selling, either directly or indirectly, through third parties or related entities, non-prescription nutritional/dietary supplements for sale to, and use by, members of the general public, and as a part of their business GNC sold and continues to sell the SUBJECT PRODUCTS purchased by Plaintiff and the Class as alleged herein. Since 2007, GNC has sold over 440 million doses of products containing DMAA.

20. At all times herein alleged, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and joint venturer of each of the remaining Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their conduct constituted a breach of duty owed to Plaintiffs.

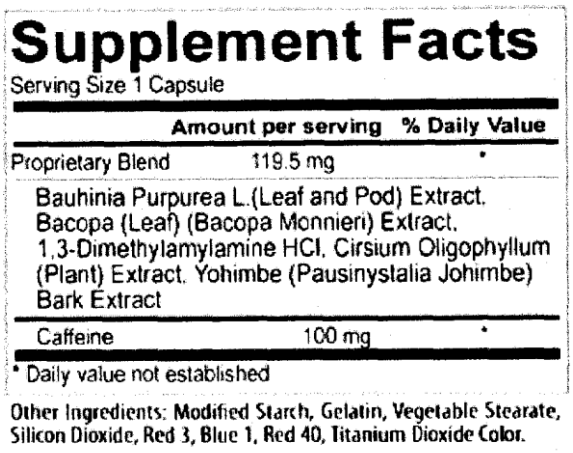
## FACTUAL ALLEGATIONS

***The Jack3d and OxyELITE Pro Products***

21. Jack3d is a trademarked product sold and marketed by USP. ]ack3d contains the following ingredients as depicted on its label, which appears as follows:

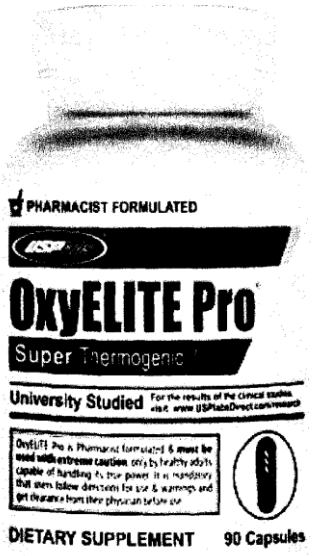



22. OxyELITE Pro, a trademarked product also sold and marketed by USP, contains the following ingredients:

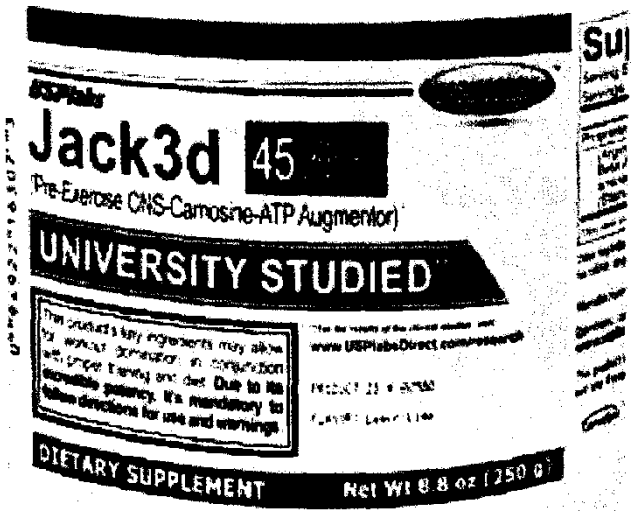



23. Throughout the class period, both of the SUBJECT PRODUCTS contained overlapping ingredients that caused them to be dangerous. They also did not work as advertised.

24. The labeling for each OxyELITE Pro supplement purchased by Class members substantially appears as follows:




25. The labeling for e a ch Jack3d supplement purchased by Class members substantially appears as follows:




26. Throughout the class period both Jack3d and OxyELITE Pro have contained the ingredient 1,3-dimethylamylamine (also known as, and hereinafter referred to, as "DMAA"), a dangerous sympathomimetic, which increases blood pressure and heart rate which can cause adverse cardiovascular events such as heart attack, stroke, heart arrhythmias, heart palpitations, dizziness, loss of consciousness and death.

27. The SUBJECT PRODUCTS also contain caffeine, which increases the sympathomimetic qualities and dangers of DMAA.

28. Jack3d and OxyELITE Pro additionally do not work.

29. Jack3d and OxyELITE Pro are sold through retailers such as GNC in Florida and across the country.

***DMAA. A Dangerous Chemical***
***Shunned by the Pharmaceutical Industry. Reemerges in Dietary Supplements***

30. 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 nerous system. As such it belongs to a group of compounds known as "sympathomimetics." Members of this class include ephedrine and amphetamines.

31. 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.

32. 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".

33. 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 from1983. No other prescription or over-the-counter drugs or dietary supplements used DMAA from 1983 until approximately 2005. 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 marked as an alternative to ephedrine. The use of DMAA in dietary supplements spread and eventually found its way into SUBJECT PRODUCTS.

34. 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.

***Defendants' Jack3d and OxyELITE Claims***

35. Defendants conveyed their deceptive claims about the SUBJECT PRODUCTS through a variety of media, including magazines, the Internet, and on the SUBJECT PRODUCTS' label and packaging. In addition, retailers, including Defendant GNA promote, market and sell the SUBJECT PRODUCTS in stores, on their websites and through other advertising media.

36. On the Jack3d label, a representative sample of which is reproduced above, Defendants prominently claim:

- **"UNIVERSITY STUDIED"**
- **"**For the result of the clinical studies, visit:**

  **www.USPLabsDirect.com/research**

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

- **"PHARMACIST FORMULATED"**
- **"Super Thermogentic™"**
- **"University Studied"**
- **"For the results of the clinical studies, visit: www/USPLabsDirect.com/research"**

38. In their advertisements and on their webstire, USP makes the following representation about OxyELITE Pro:

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

39. In their advertisements and on their website, USP represents that the safety and efficacy of Jack3d is proven and supported by clinical research, including stating:

- "Backed by 2 Peer-Reviewed Published Clinical University Research Studies"
- "Jack3d is now backed by multiple University studies, **including double-blind, placebeo-controlled research."**
- "Jack3d is THE original University Studies Ultra-Concentrated Pre-Workout…"
- "Jack3d – **proven in the real world & in the lab…"**

40. USP's website repeasts and reinforces its messaging contained throughout other advertising media, including on the SUBJECT PROCDUTS packaging and labeling including stating:

- "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."
- "Jack3d, which contains DMAA, was well tolerated and no serious adverse events were noted."
- "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."
- **"NEWLY RELEASED< GROUNDBREAKING RESEARCH STUDIES SHOW USPLABS DMAA SUPPLEMENTS ARE SAFE AND EFFECTIVE"**

41. USP also advertises on fitness blogs and websites such as bodybuilding .com throughout these blogs and websites. USP makes similar claim and misrepresentations. In fact, USP's Jacob Geissler also writes letters on such sites claiming Jack3d:

- will make "everyone dominate the weights and have crazy, lasting energy along with sick, muscle engorging pumps."
- contains a "synergistic combination (which) is KEY"
- is not like other products, which are "a bunch of ingredients thrown together haphazardly, "and
- uses "only the highest quality ingredients."

However these like the other misrepresentations with respect to the safety, efficacy, and purity of SUBJECT PRODUCTS, are false, misleading and deceptive.

42. USP has also issued press release, which promote the purported safety and efficacy of the SUBJECT PRODUCTS. For example, on February 24, 2012, just weeks after the Defense Department pulled the SUBJECT PRODUCTS from military store shelves, USPLabs issued a press release entitled "USPLabs Jack3d Peer-Review Clinical Safety Study Published."[3] 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 clinicl trial supporting the safe use of DMAA when used as directed, in addition to an industry estimated over one billion serings consumed by satisfied customers. More specifically, Jack3d™ & OxyElite Pro® have 5 clincial trials that shows they are safe when used as directed.

43. USP made similar statements about the purported safety and efficacy of the SUBJECT 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®."[4]

44. USP also utilized false and deceptive print and Internet advertisements, which

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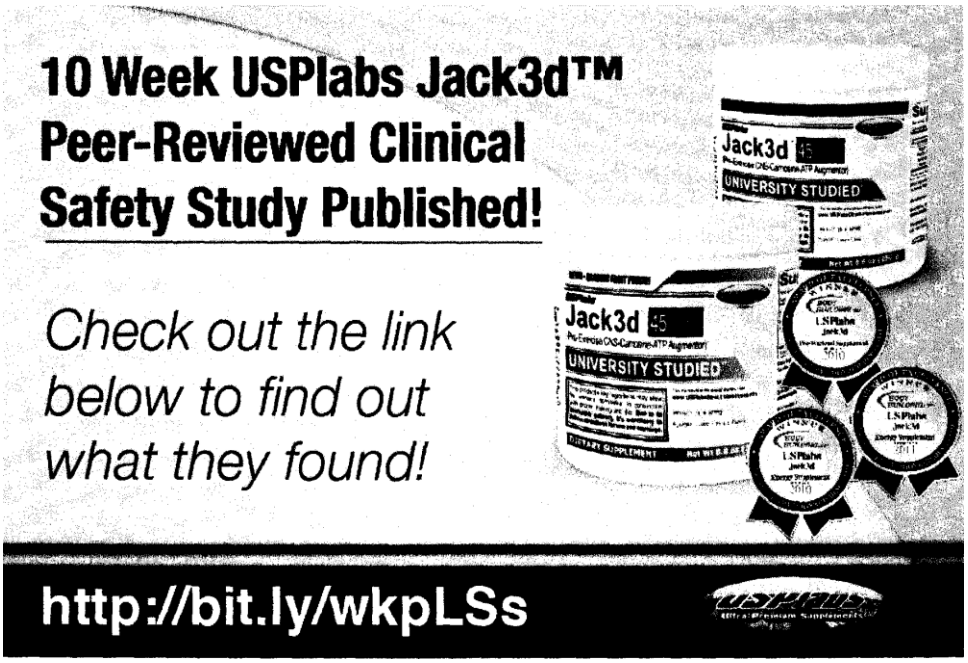
[3] *See* http://www.prnewswire.com/news-releases/usplabs-Jack3d-peer-reviewed-clinical-safety-study-published-140331103.html?utm_expid=43414375-18&utm_referrer=http%3A%2F%2Fwww.google.com%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3DJack3d%2520usplabs%2520prnewswire%26source%3Dweb%26cd%3D1%26ved%3DOCDAQFjAA%26url%3Dhttp%253A%252F%252Fwww.prnewswire.com%252Fnews-releases%252Fusplabs-Jack3d-peer-reviewed-clinical-safety-study-published-140331103.htrnl%26ei%3DnW41UPWLKumM2gW394GwAw%26usg%3DAFQjCNHBao8VBs7cFDKxg2zvNk94yxZBP A (last visited August 22, 2012).

[4] *See* http://www.prnewswire.com/news- releases/usplabs-shares-results-of-seven-peer- reviewed-dmaa-safety-studies-as-part-of-scientific-review-on-Jack3d-and-oxyelite-pro-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-oxyelite-pro-141812313.html%26ei%3DnW 41UPWLKumM2gW394GwAw%26usg%3DAFQjCNFcogyfqBOYM8QhP8vCHl-Q6eMWfg (last visited August 22, 2012).

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 SUBJECT PRODUCTS off its military store shelves. USP utilized the following Internet advertisement:




45. USP owns and operates another website, www.dmaaresearch.com, where it makes similar statements about the purported research supporting the safety and efficacy of DMAA. For example, on its dmaaresearch.com website USP lists "(a)ll current available clinical data on DMAA," which are also purportedly "conducted by independent experts and published in respected journals."[5] As discussed herein, the "seven" studies cited by USP and discussed on its websites, are not conducted by independent experts, are not published in legitimate journals, and furthermore, demonstrate that Defendants' claims about the safety and efficacy of the SUBJECT PRODUCTS are unsubstantiated, false and deceptive.

46. USP's website, including www.USPLabsDirect.com and

[5] *See* http://dmaaresearch.com/research (last visited August 22, 2012).

www.DMAAResearch.comare available to the general public and USP's advertisements in other media promote these websites.

47. In addition to its own independent misleading advertising about the SUBJECT PRODUCTS. Defendant GNC participated in, controlled, enabled, and adopted USP's representations concerning the safety and efficacy of the SUBJECT PRODUCTS. GNA, which sold the SUBJECT PRODUCTS, adopted and is responsible for the representations made on the packaging and labeling of the SUBJECT PRODUCTS regarding the safety and efficacy, when its decided to place such SUBJECT PRODUCTS on its store shelves and retail websites, and thereafter advertised and sold such SUBJECT PRODUCTS to Plaintiff and other members of the Class.

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

49. GNC also utilized in-store, point of sale displays to market to SUBJECT 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":**


50. 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.

51. Despite the overwhelming evidence that Jack3d and OxyELITE Pro are neither safe nor effective, GNC continues 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 safety used products containing DMAA in millions of doses will also oppose it." GNC further stated that "DMAA is perfectly safe when taken as

directed."[6]

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

53. Without requisite proof, Defendants also claim that SUBJECT PRODUTS 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.

54. The health problems associated with SUBJECT PRODUCTS manifest themselves when consumers consume the SUBJECT PRODUCTS at recommended dosage levels.

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

> …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 safety establishing that dimethylamylamine ill reasonably be expected to be safe as a dietary ingredient. In fact, dimethylamylamine narrows the blood vessels and arteries, which increases

[6] *See* http://www.nutraingredients-usa.com/Regulation/G NC-FDA-action-on-DMAA-is- factually-and-legally unfounded (last visited August 23, 2012).

> cardiovascular resistance and frequently leads to elevated blood pressure. This rise in blood pressure many 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 infraction (heart attack).[7]

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

57. For example, in a further attempt to downplay the true risks of consuming the SUBJECT PRODUCTS, USP has even filed suit in the Northern District of Texas (Case 3:12-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." USP continues to not only make misrepresentations to the public about the nature of DMAA and SUBJECT PRODUCTS as alleged above. It so vehemently denies their sympathomimetic qualities that it is suing individuals for defamation.

58. Making their actions even more unfair and reprehensible is that USP's own funded studies, which make conclusions that are consistent with the FDA's 2012 warning letter to USP concede that DMAA is a "simple aliphatic amine with sympathomimetic properties."[8]

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[7] *See* http://www.fda.gov/ICECVEnforcementActions/WarningLetters/2012/ucm302167.htm (last visited August 22, 2012).

[8] *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. Nutiition and Metabolic h1sights 2012:5

***Scientific Studies Demonstrate That the SUBJECT PRODUCTS Are Unsafe and Ineffective***

59. Defendants also claim that the SUBJECT PRODUCTS safety and efficacy have been shown in clinical studies. For example, it is usplabsdirect.com and dmaaresearch.com websites, USP 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.

60. Despite claims made by USP in its marketing and advertising, as detailed above, the SUBJECT 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, USP's marketing claims that the SUBJECT PRODUCTS are proven, including because they are "UNIVERSITY STUDIED," Scientifically Reviewed," and "PHARMACIST FORMULATED" are false, misleading, and likely to deceive the ordinary consumer.

61. Properly-conducted human studies do not demonstrate the safety or efficacy of the SUBJECT PRODUCTS or DMAA. In fact, human data regarding the safety or efficacy of DMAA are few and are the majority are funded by the USP Defendants.

62. Even Defendants' own purported clinical proof demonstrates the falsity of its claims. On its websites, usplabsdirect.com (which is referred to on the SUBJECT PRODUCTS' labeling) and dmaaresearch.com, USP lists "seven" studies on DMAA containing products. USP characterizes one study that had male and female cohorts as two studies in order to state "seven" DMAA studies substantiate its claims. USP admits its involvement and funding of five of the

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33-39.

seven studies. Furthermore, none of these studies provide substantiation for the marketing claims.

- 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 swears, 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 pressue. 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."
- 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 n increase in resting heart rate for those consuming OxyELITE Pro and noted that the lack of control of subjects' dietary intake was a limitation.
- 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.

- 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]."
- 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.

63. However, While USP 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 USP. Moreover, Bloomer, Harvey *et al* 2011, which USP claims was conducted by an independent scientists, 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"[9]

64. 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]

65. 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.

66. 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

[9] *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 Sportsmed39:* 111-120, 2011.

[10] *See* http://umwa.memphis.edu/fcv/viewprofile.php?uuid=rbloomer (last visited August 22, 2012).

less pharmacologically clean effect and result in a greater increase in rate-pressure products ("RPP," a measure of myocardial work or cardiovascular risk).

67. In studies known to and funded by USP, 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. [11] These findings represent the effect of the drug at rest. Indeed, the authors conclude that the drug increase myocardial work.

68. USP does not adequately warn of the sympathomimetic effects, specifically including the statistically significant increased blood pressure found by one study[12] 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.

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[11] 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. *NutJition and Metabolic Insights* 5: 23, 2011.

[12] 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.

69. In making this and similar representations, USP mislead users about the risks of SUBJECT PRODUCTS. USP attempted to mislead consumer about the health dangers of increased blood pressue 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. USP also failed to adequately warn users of the potential serious dangers of DMAA toxicity in susceptible users which USP knew or should have known might results from consuming the SUBJECT PRODUCTS. USP 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.

70. Accordingly, and contrary to the marketing and promotional campaign disseminated by USP, including the language on the SUBJECT PRODUCTS labels and websites, DMAA has not been demonstrated to be safe. For example, DMAA products such as the SUBJECT 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 SUBJECT PRODUCTS' packaging nor included in the materials made available to potential purchases, including Plaintiff and the Class.

71. The advertising, marketing and promotion of SUBJECT PRODUCTS was deceptive and misleading, in that it concealed the risks of cardiovascular injury and other serious health risks that USP knew or should have known.

72. The "seven" cited studies do not constitute substantiation for Defendants' claims relating to safety and efficacy, and in fact, are proof that the SUBJECT 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 USP, and are led by a researcher who has received over $500,000 from USP. 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 excerise (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 SUBJECT PRODUCTS. In fact, Defendants do not deny the synergistic effects of DMAA and caffeine stating on their website "a common synergistic combination."

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

74. USP similarly knew, or in the exercise of reasonable care ought to have known, that the SUBJECT PRODUCTS are not effective for weight loss or any other health benefits

claimed by USP.

75. In fact, USP 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.

76. USP knew that consumers believe that natural supplements are more healthful and less dangerous than synthetic, chemically produced supplements. USP represented in its advertising and marketing that its SUBJECT PRODUCTS were natural dietary supplements, when inf act 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. USP further knew that DMAA is not contained in natural substances like geranium oil. It made these false representations that the SUBJECT PRODUCTS were natural products to mislead and falsely reassure consumers that the SUBJECT PRODUCTS were safe products.

77. 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.

78. GNC joined in the misrepresentations about DMAA, by asserting in its marketing of the SUBJECT 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 From DMAA Pile Up and FDA Warns USP***

79. On December 6th 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 SUBEJCT PRODUCTS. A case series from NEW Zealand reported three ases of cerebral hemorrhage in adults taking DMAA.[13] 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 braind. Another published reports attributes stress-induced cardiomyopathy to use of DMAA.[14] Pieter Cohem, a Harvard internist, has recently drawn attention to DMAA in a letter to the Archives of International Medicine. [15]

80. 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.

81. 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 prior to 1994. Finally, the FDA denied that DMAA is a natural as opposed to synthetically-created compound:

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[13] Gee P, Tallon C, Long N, Moore G, Boet R, JacksonS. Use of Recreational Drug 1,3-Dimethylethylamine (DMAA) Associated With Cerebral Hemorrhage.

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

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

"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."

82. 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

83. USP 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 USP to display sympthomimetic side effects. A single Chinese study claims that DMAA occurs naturally in geranium oil.[16] However, the New Zealand National Measurement Institute performed a rigorous evaluation of this claim and found it impossible to substantiate.[17] Health Canada likewise could find no evidence that DMAA occurs in nature. [18]

84. 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 contain ***no*** detectable levels of DMAA.[19] This research refutes any claims that synthetic DMAA is identical

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

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

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

[19] 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:

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 levls of DMAA.

85. 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:

- DMAA has no health benefits and is a toxic substance
- Risks associated with its use include high blood pressure, psychiatric disorders, bleeding in the brain and stroke
- Its long term safety has not been demonstrated
- DMAA presents a high risk of abuse, misuse and illicit use.[20]

86. Despite these facts, USPlabs has publicized a letter purporting to have proof form 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. USP 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.

87. USP 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." USP failed to inform consumers and the public, including Plaintiff herein who relied on USP's representations and misleading comments, that in fact the FDA had received dozens of serious adverse events from people taking DMAA, including death.

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published online.

[20] See http://www.tga.gov.au/newsroorn/btn-tga-statement-dmaa-120803.htm (last visited August 23, 2012).

## CLASS DEFINITION AND ALLEGATIONS

88. The proposed, ascertainable Class consists of:

All persons who purchased Jack3d and OxyELITE Pro (the SUBJECT PRODUCTS) until the date notice is disseminated to the Class. Excluded from the Class are Defendants and their officers, directors and employees and those who purchased the SUBJECT PRODUCTS for the purpose of resale.

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

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

a) Whether Defendants had adequate substantiation for their claims prior to marking them;

b) Whether the SUBJECT PRODUCTS were reasonably safe for consumption;

c) Whether Defendants concealed or omitted material information concerning the safety of the SUBJECT PRODUCTS:

d) Whether the claims discussed above are true, or are misleading, or reasonably likely to deceive;

e) Whether Defendants' alleged conduct violates public policy

f) Whether the alleged conduct constitutes violations of the laws asserted herein:

g) Whether Defendants engaged in false or misleading advertising:

h) Whether Plaintiff and Class members have sustained monetary loss and proper measure of that loss;

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

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

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

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

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

94. Unless a class is certified Defendant will retain monies received as a result of

their conduct that was taken from Plaintiff and prosed Class members. Unless a classwide Injunction is issued, Defendants will continue to commit the violations alleged, and the members of the Class and the general public will continue to be misled.

95. Defendants have acted and refused to act on grounds generally applicable to the Class, making appropriate final injunctive relief with respect to the Class as a whole.

**COUNT I**

**VIOLATIONS OF THE FLORIDA DRUG AND COSMETIC ACT FLORIDA CIVIL CODE §499 *ET SEQ.***

96. Plaintiff realleges and incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.

97. This cause of action is brought pursuant to Chapter 499 of the Florida Drug and Cosmetic Act §499 et seq (the "Act"). *See* Florida Statutes §499.001 to §499.067 (2012). Plaintiff is a consumer as defined by. The SUBJECT PRODUCTS are goods within the meaning of the Act.

98. Defendants violated and continue to violate the Act by engaging in the following practices proscribed by §499.001 to §499.067 Florida Statues (2012):

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

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

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

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

misbranded

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

99. Defendants violated the Act by representing through their advertisements the SUBJECT PRODUCTS were safe and effective as described above when they knew, or should have known, that the representations and advertisements were unsubstantiated, false and misleading.

100. Pursuant to §499.001 to §499.067 Florida Statues (2012) Plaintiff and the Class seeks a Court order enjoining the above-described wrongful acts and practices of Defendants and for restitution and disgorgement.

**COUNT II**

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

105. Plaintiff realleges and Incorporates by reference the allegations contained in the paragraph above as if fully set forth herein.

106. Florida Consumer Protection Statue §501.204 (2012) prohibits any "unlawful," "fraudulent" or "unfair" business act or practice and any false or misleading advertising. For the reasons discussed above, and through statements including but not limited to that SUBJECT PRODUCTS were safe and effective, university studied and approved, were made from natural substances, did not cause adverse side effect, etc., Defendants have engaged in unfair, deceptive, untrue and misleading advertising in violation of Florida Consumer Protection Statue§501.

107. The Florida Deceptive and Unfair Trade Practices Act also prohibits any "unfair

methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce. Defendants have violated §501.204's prohibition against engaging in unlawful acts and practices by, *intet alia*, making the representations and omissions of material facts, as set forth more fully herein, and have violated 21 U.S.C. §343. 21 U.S.C. §379aa-1, 15 U.S.C. §45 (a)(I), 49 Fed. Reg. 30999 (Aug. 2, 1984), Federal Food, Drug and Cosmetic Act §402(f)(1)(A) (21 U.S.C. §342), and the common law.

108. Plaintiff and the Class reserve the right to allege other violations of law which constitute other unlawful business acts or practices. Such conduct is ongoing and continues to this date.

109. Defendants' acts, omissions, misrepresentations, practices and non-disclosures as alleged herein also constitute "unfair" business acts and practices within the meaning of The Florida Deceptive and Unfair Trade Practices Act §501.201-§501.213 *et seq* in that their conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive and unscrupulous as the gravity of the conduct outweighs any alleged benefits attributable to such conduct.

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

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

112. Defendants' claims, nondisclosures and misleading statements, as more fully set

forth above and collectively as a scheme, were false, misleading and likely to deceive the consuming public within the meaning of Florida Deceptive and Unfair Trade Practices Act.

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

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

115. Plaintiff, on behalf of himself, all other similarly situated, and the general public, seeks restitution and disgorgement of all money obtained from Plaintiff and the members of the Class collected as a result of unfair competitions, an injunction prohibiting Defendants from containing such practices, corrective advertising, including providing notification of the SUBJECT PRODUCTS' health risks, and all other relief this Court deems appropriate, consistent with Florida Deceptive and Unfair Trade Practices Act.

## COUNT III

## BREACH OF EXPRESS WARRANTY; MERCHANTABILITY; USAGE OF TRADE PURSUANT TO § 672.314 FLORIDA STATUTES

116. Plaintiff realleges and incorporates by reference the allegations contained in the paragraphs above as if fully set forth herein.

117. Plaintiff, and each member of the Class, formed a contract with Defendants to the time Plaintiff and the other members of the Class purchased the SUBJECT PRODUCTS. The terms of that contract include the promises and affirmations of fact made by Defendants on the SUBJECT PRODUCTS packaging and through their marketing campaign, as described above. The SUBJECT PRODUCTS packaging and advertising constitutes express warranties, became part of the basis of the bargain, and is part of a standardized contract between Plaintiff and the

members of the Class on the one hand, and Defendants on the other.

118. At all times, and as detailed above, Defendants expressly warranted that SUBJECT PRODUCTS were safe, effective and fit for use by consumer and users, including Plaintiff and the Class, for their intended use, that they were of merchantable quality, that they did not produce dangerous side effects, that they were made from natural ingredients (i.e. geranium), ad that they were adequately tested and fit for their intended purpose.

119. At the time of making these and other warranties with respect to the safety, efficacy, testing and characteristics of SUBJECT PRODUCTS, Defendants knew or should have known that despite the above and other warranties alleged herein, it had breached the terms of his contract, including the express warranties with Plaintiff and the Class by not providing the SUBJECT PRODUCTS as safe for consumption and effective for weight loss, including because:

a) Studies, including those relied upon and cited by USP, demonstrate that the SUBJECT PRODUCTS are unsafe and ineffective;

b) Studies relating to DMAA generally and/or the SUBJECT PRODUCTS specifically, including studies cited and/or funded by USP itself, found statistically increased blood pressure, myocardial work and RPP:

c) Participants in the studies relating to DMAA generally and/or the SUBJECT PRODUCTS specifically, including studies by cited and/or funded by USP itself did experience adverse cardiovascular effects from use of products even if not serious;

d) USP's studies, given their underpowered size, did not and could not prove that SUBJECT PRODUCTS do not result in serious adverse events:

e) USP's claims of safety and efficacy were not supported by the studies

conducted by researchers at the University of Memphis even though the researchers were financially interested and biased researchers:

f) The SUBJECT PRODUCTS contained DMAA, which was synthetically derived, and not natural;

g) Geranium plaints and oil do not contain detectable amounts of DMAA and therefore synthetic DMAA cannot be equivalent to geranium;

h) The FDA had received 42 serious adverse events from DMAA products, and thus the SUBJECT PRODCUTS containing DMAA were unsafe; and

i) GNC stopped selling the SUBJECT PRODUCTS at its stores on military bases and internationally.

120. Members of the public, including Plaintiff, reasonably relied upon the skill and judgment of Defendants, and upon said express warranties in purchasing the SUBJECT PRODUCTS.

121. Plaintiff and the Class purchased the SUBJECT PRODUCTS for their intended purpose.

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

123. Due to Defendant's wrongful conduct as alleged herein, Plaintiff and the Class could not have known about the nature of the risks and side effects associated with the SUBJECT PRODUCTS.

124. As a direct and proximate result of Defendant's breach of their contract, including

the breach of express warranties with respect to SUBEJCT PRODUCTS, Plaintiff suffered injuries as set forth above, entitling Plaintiff to judgment and equitable relief against Defendants, as well as restitution, including all monies paid for the SUBJECT PRODUCTS and disgorgement of profits from Defendants received from sales of the SUBJECT PRODUCTS, attorneys' fees, punitive damages, and costs, as set forth in the Prayer or Relief.

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

**COUNT IV**

**BREACH OF IMPLIED WARRANTY PURSUANT TO UNIFORM COMMERCIAL CODE §2-314**

126. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

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

128. At all times, Florida and the following 48 states, including the District of Columbia, have codified and adopted the provisions the Uniform Commercial Code governing the implied warranty of merchantability: Ala. Code §7-2-314; Alaska Stat. §45.02.314; Ariz. Rev. Stat. Ann. §47-2314; Ark. Code Ann §4-2 314; Cal. Comm. Code §2314; Colo. Rev. St §4-2-314; Conn. Gen. Stat. Ann. §42a-2-314; 6 Del. C. §2-314; D.C. Code §28:2-314; Fla. Stat. Ann §672.314; Ga. Code. Ann. §11-2-314; Haw. Rev. Stat. §490:2-314; ld. Code §28-2- 314; Ill. Comp. Stat. Ann. Ch 810, 5/2-314; Ind. Code. Ann. §26-1-2-314; Iowa Code Ann. §554.2314; Kansas Stat. Ann. §84-2-314; Ky. Rev. Stat. Ann §355.2-314; La. Civ. Code Ann. Art. §2520; 11 Maine Rev. Stat. Ann. §2-314; Md. Code Ann. §2-314; Mass.

Gen. Laws. Ch. 106 §2-314; Mich. Comp. Laws Ann. §440.2.314; Minn. Stat. Ann §336.2-314; Miss. Code. Ann. §75-2-314; Missouri Rev. Stat §400.2-314; Mont. Code. Ann §30-2-314; Nev. Rev. Stat. U.C.C §104.2314; N.H. Rev. Ann. §382-A:2-314; *N.J.* Stat. Ann. §12A:2-314; N.M. Stat. Ann §55-2-314; N.Y. U.C.C. Law 2-314; N.C. Gen. Stat. Ann §25-2-314; N.D. Stat. §41-02-314; Ohio Rev. Code Ann. §1302.27; Okla. Stat. §2-314; Or. Rev. Stat. §72.3140; Pa. Stat. Ann §2314; R.I. Gen Laws §6A-2-314; S.C. Code Ann. §36-2-314; S.D. Stat. 57A-2-314; Tenn. Code Ann. §47-2-314; Tex. Bus. & Com. Code Ann. §2-314; Ut. Code Ann. §70A-2-314; VA Code §8.2-314; Vt. Stat. Ann §9A-2-314; W.VA. Code §46-2-314; Wis. Stat. Ann §402.314; and Wyo. Stat. §34.1-2-314

129. The SUBJECT PRODUCTS are "good" as defined in the various states' commercial codes governing the implied warranty of merchantability

130. As designers, manufacturers, licensors, producers, marketers, and sellers of the SUBJECT PRODUCTS, Defendants are merchants" within the meaning of the various states' commercial codes governing the implied warranty of merchantability.

131. By placing the SUBJECT PRODUCTS in the stream of commerce, Defendants impliedly warranted that the SUBJECT PRODUCTS are reasonably safe, effective and adequately tested for their intended use, i.e. to be used for weight loss, fat-burning, energy enhancing, and as a diet aids, and that they were merchantable quality.

132. As merchants of the SUBJECT PRODUCTS, Defendants knew that purchasers relied upon them to design, manufacture, license and sell dietary supplements that were reasonably safe and effective, and in fact members of the public, including Plaintiff, reasonably relied upon the skill and judgment of Defendants and upon said implied warranties in purchasing and consuming the SUBJECT PRODUCTS.

133. Plaintiff and the Class members purchased the SUBJECT PRODUCTS for their intended purpose.

134. In breach of their implied warranty, the SUBJECT PRODUCTS are unsafe, ineffective and not merchantable, in that they cause serious and even fatal health problems, have not been proven effective for their intended uses, and are not effective for their intended uses.

135. The SUBJECT PRODUCT were not reasonably safe for their intended use when they left Defendant's control and entered the market.

136. The SUBJECT PRODUCTS' defects were not open or obvious to consumers. Including Plaintiff and the Class, who could not have known about the nature of the risks and side effects associated with SUBJECT PRODUCTS until after they purchased or used them.

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

**COUNT V**

**UNJUST ENRICHMENT**

138. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

139. At all times relevant hereto, Defendants designed, manufactured, licenses, produced, promoted, marketed and/or sold the ineffective and dangerous SUBJECT PRODUCTS.

140. Plaintiff and members of the Class conferred upon Defendants non-gratuitous payments for the SUBJECT PRODUCTS that were not safe and effective as advertised, and may expose them to serious illnesses, which can be fatal. Defendants accepted or retained the non-gratuitous benefits conferred by Plaintiff and members of the Class, with full knowledge and awareness that, as a result of Defendants' unconscionable wrongdoing, Plaintiff and members of the Class were not receiving products of the quality, nature, fitness or value that had been represented by Defendants and reasonable consumers would have expected.

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

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

## PRAYER FOR RELIEF

**WHEREFORE**, plaintiff prays for judgment:

A. Certifying the Class as requested herein;

B. That the Court adjudge and decree that Defendants have engaged in the conduct alleged herein;

C. Awarding declaratory and injunctive relief as permitted by law or equity, including: enjoining Defendants from continuing the unlawful practices as set forth herein, and directing Defendants to identify, with Court supervision, victims of their conduct and pay them restitution and disgorgement of all monies acquired by Defendants by means of any act or practice declared by this Court to be wrongful;

D. Ordering Defendants to engage in a corrective advertising campaign;

E. Awarding Plaintiff and the proposed Class members damages;

F. Awarding restitution and disgorgement to Plaintiff and the other Class members;

G. Awarding Plaintiff and the Classes punitive damages;

H. Awarding Plaintiff treble damages;

I. Awarding attorneys' fees and costs; and

J. Providing such further relief as may be just and proper

**JURY DEMAND**

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

Dated: November 12, 2013

Respectfully submitted,

/s/ Tim Howard

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