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

UNITED STATES OF AMERICA, Plaintiff, v. QUALITY FORMULATION LABORATORIES, INC., and AMERICAN SPORTS NUTRITION, INC., corporations, SPORTS NUTRITION INTERNATIONAL, LLC, a limited liability company, and MOHAMED S. DESOKY, an individual, Defendants.	Civ. No. COMPLAINT FOR INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Honorable Court as follows:

INTRODUCTION

1. This proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 332(a), to enjoin Quality Formulation Laboratories, Inc., and American Sports Nutrition, Inc., corporations, Sports Nutrition International, LLC, a limited liability company, and Mohamed S. Desoky, an individual (collectively "Defendants"), from violating 21 U.S.C. § 331(a) by introducing, or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) or (c) and misbranded within the meaning of 21 U.S.C. § 343(w), (i)(2), or (r)(1)(A); and from violating 21 U.S.C. § 331(k) by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) or (c) and misbranded within the meaning of 21 U.S.C. § 343(w), (i)(2), or (r)(1)(A), while such articles are held for sale after shipment of one or more ingredients in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

THE DEFENDANTS

3. The Defendant, Quality Formulation Laboratories, Inc., is incorporated under the laws of New Jersey and is doing business at 110 Pennsylvania Avenue, Paterson, New Jersey, within the jurisdiction of this Court. Two other businesses – Defendants American Sports Nutrition, Inc., and Sports Nutrition International, LLC – are located in the same building as

Quality Formulation Laboratories, Inc. The building borders on three streets, and each business has its own address, which corresponds to a different street entrance to the building.

4. The Defendant, American Sports Nutrition, Inc., is incorporated under the laws of New Jersey and is doing business at 51 Kentucky Avenue, Paterson, New Jersey, within the jurisdiction of this Court.

5. The Defendant, Sports Nutrition International, LLC, is a limited liability company operating under the laws of New Jersey and is doing business at 78 Iowa Avenue, Paterson, New Jersey, within the jurisdiction of this Court.

6. The Defendant, Mohamed S. Desoky, president of Quality Formulation Laboratories, Inc., chief executive officer of American Sports Nutrition, and an officer of Sports Nutrition International, LLC, is responsible for all business and financial decisions at Quality Formulation Laboratories, Inc., American Sports Nutrition, Inc., and Sports Nutrition International, LLC. Defendant Desoky has final authority over all decisions regarding product manufacturing, labeling, and distribution at Quality Formulation Laboratories, Inc., American Sports Nutrition, Inc., and Sports Nutrition International, LLC. He conducts his business at 110 Pennsylvania Avenue, 51 Kentucky Avenue, and 78 Iowa Avenue, Paterson, New Jersey, within the jurisdiction of this Court.

7. The Defendants manufacture and distribute food including many varieties of protein powder mixes, as well as other powder mixes and dietary supplements. Many of the Defendants' products are distributed under the American Sports Nutrition brand to locations throughout the United States, including Illinois, North Carolina, Kentucky, and Tennessee. The raw ingredients the Defendants use to manufacture their products are shipped to New Jersey from

locations in Illinois, Indiana, New York, and elsewhere outside of New Jersey. The Defendants also manufacture powder mixes and dietary supplements for sale to private label customers within and outside the United States.

8. The Defendants adulterate articles of food by manufacturing them in a manner that fails to conform to current good manufacturing practice ("CGMP") requirements (21 C.F.R. Part 110), and that causes the articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth (as a result of rodent activity) or may have been rendered injurious to health (as a result of cross-contamination with a major food allergen).

9. The Defendants adulterate an article of food (American Stamina Lemon-Lime Explosion powder mix) within the meaning of 21 U.S.C. § 342(c) in that it contains a color additive that is unsafe within the meaning of 21 U.S.C. § 379(e)(a) because it is not declared on the product label in accordance with 21 C.F.R. § 74.705(d)(2).

10. The Defendants misbrand articles of food within the meaning of 21 U.S.C. § 343(w)(1) in that those articles contain a major food allergen (milk) that is not declared on the product labels.

11. The Defendants misbrand articles of food (American Soy Vanilla Extreme powder mix and Branched Chain Amino Acid tablets) within the meaning of 21 U.S.C. § 343(i)(2) in that those articles contain an ingredient (whey) whose common or usual name is not listed on the product labels.

12. The Defendants misbrand an article of food (American Whey powder mix, in Natural, Orange Creme Deluxe, Tropical Banana Bomb, and Peach Cobbler flavors) within the

meaning of 21 U.S.C. § 343(r)(1)(A) in that it contains a "low calorie" claim on the product label that does not comply with 21 C.F.R. § 101.60(b)(2) because the caloric intake per serving exceeds the maximum calorie limit.

THE DEFENDANTS' CGMP VIOLATIONS

13. CGMP requires, among other things, that:

(a) All aspects of food manufacturing are conducted in accordance with adequate sanitation principles and appropriate quality controls to ensure that food is suitable for human consumption, and all reasonable precautions are taken to ensure that production procedures do not contribute contamination from any source, including food allergens (see 21 C.F.R. § 110.80);

(b) Chemicals are stored properly, the plant is maintained in a sanitary, pest-free condition, and equipment and utensils are cleaned and sanitized in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials (see 21 C.F.R. § 110.35); and

(c) Employees have the appropriate education, experience, and training in food safety to perform their jobs (see 21 C.F.R. § 110.10).

14. The United States Food and Drug Administration ("FDA") conducted three inspections of the Defendants' plant located at 110 Pennsylvania Avenue between 2007 and 2009. The "February 2007 inspection" took place on January 25-26, 29-30, and February 1, 6, 12, 2007. The "April 2008 inspection" took place on February 27-28, March 3-6, 12, 18, 25, 27 and April 9, 2008. The "January 2009 inspection" took place on December 10-11, 15-16, 18, 30, 2008, and January 13, 2009.

15. FDA's inspections establish that the Defendants do not comply with CGMP requirements and that they manufacture articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) because the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health.

16. As a result of the presence of rodents in the Defendants' facility, articles of food may have become contaminated with filth.

17. As a result of the Defendants' failure to have adequate sanitizing and cleaning operations and follow their own procedures for manufacturing products on dedicated equipment, articles of food may have become contaminated with a major food allergen (milk). Contamination with a food allergen (also called "cross-contamination" or "cross-contact") occurs when a residue or other trace amount of a food allergen is present on a food-contact surface or equipment, or is airborne, and unintentionally becomes incorporated into food not intended to contain the allergen. Food that is cross-contaminated with a major food allergen such as milk may have been rendered injurious to health because its consumption may lead to adverse reactions in susceptible individuals.

18. The January 2009 inspection revealed that the Defendants' facility is infested with rodents. The FDA investigators observed evidence of rodent activity – rodent excreta pellets and urine staining – throughout the facility, including the blending room and the warehouse. See 21 C.F.R. § 110.35(c). For example:

(a) A dead rodent – cut in half – was found on a blender motor platform;

(b) An accumulation of rodent excreta pellets was seen near several of the blenders;

(c) Rodent tracks were observed on the platform that holds one of the blender motors;

(d) A dead rodent, surrounded by rodent excreta pellets, was found in an area used to store near-finished product;

(e) On two occasions, a live rodent was seen running through the blending room, and a live rodent was also seen under pallets of product packaging; and

(f) A bag-by-bag examination of 21 bags of whey protein concentrate revealed that the majority of the bags exhibited rodent contamination – rodent gnawing, urine staining, and excreta pellets.

19. The April 2008 and January 2009 inspections revealed that the Defendants fail to have adequate control over their manufacturing process, sanitizing and cleaning operations, and employee training. The FDA investigators observed that the Defendants:

(a) Fail to assign responsibility for overall sanitation to a competent individual, which resulted in the Defendants' failure to detect numerous cleaning deviations in their log book for blender cleaning (see 21 C.F.R. § 110.80);

(b) Do not adequately maintain equipment through appropriate cleaning and sanitizing in that blenders – as well as the hoses, pipes, walls, and/or loading platform surfaces and railings near the blenders – were covered with dust of various colors or encrusted with product residue (see 21 C.F.R. § 110.80(b)(1));

(c) Fail to manufacture in a way to minimize cross-contamination in that (i) during at least 31 occasions in December 2008 and at least 26 occasions between February 27-March 27, 2008, the Defendants did not follow their own standard operating procedure to use designated blenders for specific products, based on the presence or absence of allergenic ingredients, and (ii) manufacturing processes allowed product residue to accumulate inside plastic bags set up for use at the blender discharge port (see 21 C.F.R. § 110.80(b)(2));

(d) Fail to clean as frequently as necessary to protect against cross-contamination in that (i) there were 35 and 28 cleaning deviations, documented during the April 2008 and January 2009 inspections, respectively, in the Defendants' log book for blender cleaning in between products containing different allergens or between allergenic and non-allergenic products, and (ii) employees routinely re-used drums that hold plastic bags for storing finished product until final packaging without cleaning the drums, regardless of whether the drums previously contained allergenic product (see 21 C.F.R. § 110.35(d));

(e) Do not have adequate procedures for cleaning and sanitizing equipment in that (i) various parts of a blender were not cleaned during a wet cleaning process or were caked with residue after a purported wet cleaning, observed during the April 2008 and January 2009 inspections, respectively, (ii) a sanitizing agent was not used during cleaning, (iii) brooms with bristles containing product particles were used to sweep out any product remaining inside the blenders, and (iv) rags for cleaning the blending room were not stored in a sanitizer solution (see 21 C.F.R. § 110.35(d)(5)); and

(f) Have not adequately trained the blending supervisor, who was unable to identify which ingredients were allergens and when blenders needed to be cleaned to minimize cross-contamination with allergens (see 21 C.F.R. § 110.10(c)).

20. The FDA investigators also observed, during the April 2008 and January 2009 inspections, respectively, that the Defendants:

(a) Changed entries in their log book for blender cleaning (see 21 C.F.R. § 110.35(d)); and

(b) Improperly store toxic chemicals, in that a bathroom cleaner and a hornet/wasp killer were stored on a blender motor platform and two containers of insect spray were stored above product packaging materials (see 21 C.F.R. § 110.35(b)(2)).

21. The February 2007 inspection revealed that the Defendants failed to maintain equipment adequately through appropriate cleaning and sanitizing, failed to manufacture in a way to minimize contamination, failed to clean adequately between allergenic and non-allergenic products, and failed to have adequate procedures for cleaning and sanitizing equipment. For example, FDA investigators observed:

(a) Excessive accumulations of old product residue on equipment surfaces close to blenders and on the work surface and scale for weighing raw materials (see 21 C.F.R. § 110.80(b)(1));

(b) Milk-based and non-milk-based products being blended in close proximity, residue from products not part of the in-progress batch on equipment surfaces close to blenders, and residue accumulating on plastic bags set up for use at the blender discharge port (see 21 C.F.R. § 110.80(b)(2));

(c) Blenders not being adequately cleaned when manufacturing switched from a milk-based product to a non-milk-based product (see 21 C.F.R. § 110.35(d)); and

(d) A large amount of dust being created during implementation of the cleaning method for the blending room – dry cleaning by using pressurized air (see 21 C.F.R. § 110.35(d)).

22. Based on the insanitary conditions at the Defendants' facility, the products manufactured by the Defendants may have become contaminated with filth or may have been rendered injurious to health. The rodent infestation at the Defendants' facility, documented during the most recent inspection, establishes that there is a reasonable possibility that the Defendants' food may have become contaminated with filth. Moreover, in light of the Defendants' manufacturing conditions and practices, there is a reasonable possibility that (a) an allergenic ingredient from one product will be incorporated into other products not intended to contain the allergen, and (b) consuming products cross-contaminated with a food allergen will lead to adverse reactions in susceptible individuals.

23. Because articles of food at the Defendants' facility are prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health, they are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

24. The Defendants violate 21 U.S.C. § 331(a) by introducing, or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

25. The Defendants violate 21 U.S.C. § 331(k) by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more ingredients in interstate commerce.

THE DEFENDANTS' LABELING VIOLATIONS

26. Pursuant to 21 U.S.C. § 342(c), a food is adulterated if it bears or contains a color additive that is unsafe within the meaning of 21 U.S.C. § 379e(a). A color additive is unsafe unless its use in food conforms to the applicable regulation prescribing the conditions under which such additive may be safely used. 21 U.S.C. § 379e(a).

27. FDA's regulation at 21 C.F.R. § 74.705(d)(2) provides conditions for safe use in food of FD&C Yellow No. 5, which includes a requirement that a food that contains FD&C Yellow No. 5 must specifically declare the presence of the color additive in the list of ingredients on the product label.

28. Certain color additives, including FD&C Yellow No. 5, must be certified by FDA prior to their use in food as a color additive. If a food contains an ingredient that is certifiable as a color additive, then the color additive is deemed to be unsafe unless its presence in the food is declared among the list of ingredients on the product label, pursuant to 21 C.F.R. § 74.705(d)(2).

29. FDA laboratory testing of samples of the Defendants' American Stamina Lemon-Lime Explosion powder mix collected by FDA investigators during the April 2008 inspection confirmed the presence of the compound tartrazine. Tartrazine is certifiable by FDA as the color additive, FD&C Yellow No. 5. However, FD&C Yellow No. 5 is not declared on the product label. Therefore, the color additive is unsafe, and the Defendants' American Stamina Lemon-Lime Explosion power mix is adulterated under 21 U.S.C. § 342(c).

30. The Defendants violate 21 U.S.C. § 331(a) by introducing, or delivering for introduction, into interstate commerce an article of food that is adulterated within the meaning of 21 U.S.C. § 342(c).

31. The Defendants violate 21 U.S.C. § 331(k) by causing an article of food to be adulterated within the meaning of 21 U.S.C. § 342(c) while such article is held for sale after shipment of one or more ingredients in interstate commerce.

32. Pursuant to 21 U.S.C. § 343(w)(1), a food that is, or contains an ingredient that bears or contains, a major food allergen is misbranded unless the name of the food source from which the major food allergen is derived is declared on the product label. Milk, and any food ingredient that contains protein derived from milk, is a major food allergen. 21 U.S.C. § 321(qq).

33. According to product labels collected by FDA investigators during the April 2008 inspection, whey is an ingredient in the Defendants' American Mass Smooth & Creamy Vanilla, Double Dutch Chocolate, Wild Berry, and Tropical Banana; American Whey Natural, Orange Creme Deluxe, Tropical Banana Bomb, and Peach Cobbler; Bargain Whey Double Dutch Chocolate Supreme; and Tone-It-Fast Double Dutch Chocolate Supreme and Creamy Vanilla Extreme powder mixes. The ingredient whey contains milk proteins, but the product labels do not declare the source of the major food allergen, milk. Therefore, the products are misbranded pursuant to 21 U.S.C. § 343(w)(1) because their labels fail to declare a major food allergen.

34. During the January 2009 inspection, FDA investigators saw new labels, with allergen statements, for the American Mass, American Whey, and Bargain Whey products (and printer proofs for new labels for the Tone-It-Fast products) that, according to Dr. Desoky, are to

be used for only one of the Defendants' customers. The new labels do not list all of the ingredients that are documented by the batch records to be present in the products. The failure to list the common or usual name of each ingredient of a food that is made from two or more ingredients is a violation of 21 U.S.C. § 343(i)(2).

35. FDA laboratory analysis of samples collected during the April 2008 inspection detected the presence of milk proteins in the Defendants' American Soy Vanilla Extreme powder mix and Branched Chain Amino Acid tablets. The product labels do not declare the presence of milk. Therefore, the products are misbranded pursuant to 21 U.S.C. § 343(w)(1) because their labels fail to declare a major food allergen.

36. The Defendants' American Soy Vanilla Extreme powder mix and Branched Chain Amino Acid tablets are also misbranded pursuant to 21 U.S.C. § 343(i)(2). The labels for the Defendants' American Soy Vanilla Extreme and Branched Chain Amino Acid products do not list the ingredient (e.g., whey) that contains the milk proteins. Therefore, the products are misbranded pursuant to 21 U.S.C. § 343(i)(2) because their labels fail to list all ingredients by common or usual name.

37. The Defendants violate 21 U.S.C. § 331(a) by introducing, or delivering for introduction, into interstate commerce articles of food that are misbranded within the meaning of 21 U.S.C. § 343(w) or (i)(2).

38. The Defendants violate 21 U.S.C. § 331(k) by causing articles of food to be misbranded within the meaning of 21 U.S.C. § 343(w) or (i)(2), while such articles are held for sale after shipment of one or more ingredients in interstate commerce.

39. Pursuant to 21 U.S.C. § 343(r)(1)(A), (2)(A) and (q)(1), a food is misbranded if it makes a "low calorie" claim unless the "characterization of the level made in the claim uses terms which are defined in regulations."

40. FDA's regulation at 21 C.F.R. § 101.60(b)(2) permits the term "low calorie" to be used on the label of a food provided that the "reference amount customarily consumed" per eating occasion ("RACC"), among other things, does not provide more than 40 calories. According to the product labels collected by FDA investigators during the April 2008 and January 2009 inspections, the Defendants' American Whey products, in Natural, Orange Creme Deluxe, Tropical Banana Bomb, and Peach Cobbler flavors, are "low in calories." The products, however, do not meet the regulatory definition of "low calorie."

41. The RACC for the Defendants' American Whey products, in Natural, Orange Creme Deluxe, Tropical Banana Bomb, and Peach Cobbler flavors, is one ounce, which is the amount of powder mix that would be used to make an eight-ounce serving. See 21 C.F.R. § 101.12(b), (c)(1). According to the new product labels collected during the January 2009 inspection, one ounce of powder mix provides 110 calories (or 104 calories, on the old labels). The calorie intake per serving exceeds the calorie limit for a "low calorie" claim. Therefore, the products are misbranded pursuant to 21 U.S.C. § 343(r)(1)(A) because their labels make a "low calorie" claim that does not comport with the "low calorie" characterization defined by regulation.

42. The Defendants violate 21 U.S.C. § 331(a) by introducing, or delivering for introduction, into interstate commerce articles of food that are misbranded within the meaning of 21 U.S.C. § 343(r)(1)(A).

43. The Defendants violate 21 U.S.C. § 331(k) by causing articles of food to be misbranded within the meaning of 21 U.S.C. § 343(r)(1)(A), while such articles are held for sale after shipment of one or more ingredients in interstate commerce.

HISTORY

44. The Defendants are well aware that their practices violate the Act and FDA regulations but they are resistant to taking corrective action. For example, as recently as May 2008, Defendant Desoky was distributing Defendants' Branched Chain Amino Acid tablets containing whey with a label that failed to list whey and declare milk.

45. FDA inspections also serve as repeated warnings of the Defendants' violations. At the close of each of the three inspections between 2007 and 2009, FDA investigators presented Defendant Desoky with Lists of Inspectional Observations (Forms FDA-483) and discussed the documented deviations with him.

46. FDA issued a Warning Letter, dated July 13, 2007, to Defendant Desoky, informing him of the CGMP violations that FDA investigators observed during the February 2007 inspection. The letter explained that the Defendants' Egg Protein III Vanilla powder mix was adulterated as a result of insanitary conditions and misbranded because the labeling was misleading in that it failed to declare milk, a major food allergen. Further, the letter noted that the Defendants' Major Egg powder mixes were misbranded because their labels did not list the names of all ingredients and declare all major allergens.

47. In the Defendants' response, dated August 6, 2007, Defendant Desoky stated that, in addition to discontinuing the production of Egg Protein III and updating the labels for Major Egg, he was modifying labels for all other products to contain an allergen statement. The

Defendants' August 2007 response also stated that (a) the procedure for cleaning the blenders and areas in the blending room was updated, and (b) blenders were assigned for manufacturing different products in an effort to minimize cross-contamination.

48. Subsequently, in response to a request by FDA in a letter dated September 10, 2007, Defendant Desoky provided to FDA, in a letter dated October 10, 2007, copies of the new cleaning procedures, examples of cleaning records, and procedures to minimize cross-contamination that he referred to in his response to the Warning Letter. In the Defendants' October 2007 letter, Defendant Desoky also reiterated that he had performed a comprehensive label review for all products.

49. FDA's reply, dated October 19, 2007, noted deficiencies with the sample updated label and with the cleaning procedure submitted by Defendant Desoky. The agency's reply also noted that the batch record log submitted to FDA showed that the Defendants were not following their own cleaning procedure.

50. Despite the Defendants' promises to conduct label reviews for all products and to institute procedures to minimize cross-contamination in response to the violations documented in FDA's 2007 inspection and Warning Letter, FDA investigators observed many of the same objectionable conditions and practices during the inspections in 2008 and 2009. The attempts that the Defendants have made to correct their product labels have been inadequate. The Defendants have shown that they are unwilling or unable to take the necessary steps to prevent recurrence of CGMP and labeling violations

REQUEST FOR RELIEF

51. Because FDA's inspections have been insufficient to obtain the Defendants' voluntary compliance with the Act and FDA regulations, Plaintiff believes that injunctive relief is necessary to restrain Defendants from continuing to manufacture and distribute adulterated and misbranded articles of food.

WHEREFORE, the Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin the Defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and any persons in active concert or participation with any of them who receive notice of the Court's order:

A. From violating 21 U.S.C. § 331(a) by introducing, or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) or (c);

B. From violating 21 U.S.C. § 331(a) by introducing, or delivering for introduction, into interstate commerce articles of food that are misbranded within the meaning of 21 U.S.C. § 343(w), (i)(2), or (r)(1)(A);

C. From violating 21 U.S.C. § 331(k) by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) or (c) while such articles are held for sale after shipment of one or more ingredients in interstate commerce; and

D. From violating 21 U.S.C. § 331(k) by causing articles of food to be misbranded within the meaning of 21 U.S.C. § 343(w), (i)(2), or (r)(1)(A) while such articles are held for sale after shipment of one or more ingredients in interstate commerce.

II. Order the Defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and any persons in active concert or participation with any of them who receive notice of the Court's order, to cease manufacturing, preparing, packing, labeling, and distributing at their plant located at 110 Pennsylvania Avenue, Paterson, New Jersey, or its other street addresses, 51 Kentucky Avenue and 78 Iowa Avenue, also in Paterson, New Jersey, any article of food until the Defendants bring their plant and operations into compliance with the Act and its implementing regulations to the satisfaction of FDA; and

III. Award the Plaintiff its costs incurred in pursuing this action and such other relief as the Court may deem just and proper.

Dated: July 1, 2009.

Respectfully submitted,

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