UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, Plaintiff, v. ATRIUM, INC., ASPEN GROUP, INC., and NUTRI-PAK OF WISCONSIN, INC., corporations, and JAMES F. SOMMERS, and ROBERTA A. SOMMERS, individuals, Defendants.	)	No: 2015-C-927 COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

INTRODUCTION

1. This statutory injunction proceeding is brought pursuant to the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to enjoin and restrain Atrium, Inc., Aspen Group, Inc., and Nutri-Pak of Wisconsin, Inc., corporations, and James F. Sommers and Roberta A. Sommers, individuals (collectively, "Defendants"), from violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) and misbranded within the meaning of 21 U.S.C. § 343.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties.

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Atrium, Inc. is incorporated under the laws of the state of Wisconsin. It does business at 460 S. Townline Road, Wautoma, Wisconsin 54982 (the "facility").

5. Defendant Aspen Group, Inc. is incorporated under the laws of the state of Wisconsin. It does business at the facility in Wautoma, Wisconsin.

6. Defendant Nutri-Pak of Wisconsin, Inc. is incorporated under the laws of the state of Wisconsin. It does business at the facility in Wautoma, Wisconsin.

7. Defendant James F. Sommers is the President and co-owner of Atrium, Inc., the Aspen Group, Inc., and Nutri-Pak of Wisconsin, Inc. Employees report to him and he has ultimate responsibility for, and authority over, the firm's day-to-day operations, including, but not limited to, manufacturing, preparing, packing, repackaging, labeling, holding, and distributing Defendants' dietary supplement products. Defendant James F. Sommers performs his duties at the facility in Wautoma, Wisconsin.

8. Defendant Roberta A. Sommers is the Vice President and co-owner of Atrium, Inc., the Aspen Group, Inc., and Nutri-Pak of Wisconsin, Inc. Employees report to her and she has the authority to hire and fire employees and to authorize capital expenditures. She performs her duties at the facility in Wautoma, Wisconsin.

9. Defendants have been, and are now engaged in, manufacturing, preparing, packing, repackaging, labeling, holding, and distributing dietary supplements within the meaning

of 21 U.S.C. § 321(ff). Such products include, but are not limited to, Atrium brand Chole-Sterin, Atrium brand Di-Acid Stim, Atrium brand Natto, Atrium brand Oco-Comp, Atrium brand Super-Flex, Aspen brand Flexile-Plus, Nutri-Pak brand Glucobiotic Supreme, and Nutri-Pak brand Ocu-Comp.

10. Defendants also manufacture dietary supplements for private label customers.

11. Defendants introduce or deliver for introduction into interstate commerce, including but not limited to California, finished dietary supplements.

DEFENDANTS' VIOLATIONS OF THE ACT

12. The Act requires dietary supplement manufacturers to operate in compliance with current good manufacturing practice for dietary supplements ("cGMP"). 21 U.S.C. § 342(g)(1). Manufacturing according to dietary supplement cGMP means that the manufacturing process incorporates a set of controls in the design and production processes to ensure a finished product of acceptable, predictable, and reliable quality. Dietary supplements not manufactured, prepared, packed, or held in conformance with cGMP requirements are deemed to be adulterated. 21 U.S.C. § 342(g)(1). The dietary supplement cGMP regulations are set forth at 21 C.F.R. Part 111.

13. FDA inspected Defendants' facility between July 8 and 17, 2014 ("July 2014 inspection"). The July 2014 inspection established that the dietary supplements that Defendants manufacture, prepare, pack, repack, label, hold, and distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, and held under conditions that do not comply with dietary supplement cGMP regulations.

14. During the July 2014 inspection, the FDA investigator documented numerous deviations from cGMP. These deviations include, but are not limited to, the following:

a. Defendants failed to establish an identity specification for each component, as well as specifications that ensure that the purity, strength, and composition of dietary supplements manufactured using components are met, as required by 21 C.F.R. § 111.70(b)(1) and (b)(2);

b. Defendants failed to establish, for each dietary supplement that they manufacture, product specifications for the identity, purity, strength, and composition of the finished dietary supplement, and limits on contaminants, as required by 21 C.F.R. § 111.70(e);

c. Defendants failed to qualify the supplier of a component received by establishing the reliability of the supplier's certificate of analysis ("COA"), through confirmation of the results of the supplier's tests or examinations, as required by 21 C.F.R. § 111.75(a)(2)(ii);

d. Defendants failed to ensure that the tests and examinations they used to determine whether the specifications are met are appropriate, scientifically valid methods, as required by 21 C.F.R. § 111.75(h)(1);

e. Defendants failed to establish and follow written procedures for the responsibilities of the quality control operations, as required by 21 C.F.R. § 111.103;

f. Defendants' master manufacturing records ("MMR") failed to include written instructions, including: 1) specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified; 2) procedures for sampling and a cross-reference to procedures for tests or examinations; and 3) corrective action plans for use when a specification is not met, all of which is required by 21 C.F.R. § 111.210(h); and

g. Defendants failed to examine, before packaging and labeling operations,

packaging and labels for each batch of dietary supplement to determine whether the packaging and labels conform to the MMR, as required by 21 C.F.R. § 111.410(c).

15. During the July 2014 inspection, the FDA investigator collected samples of Defendants' product labeling. Defendants cause their dietary supplements to be misbranded within the meaning of the Act, 21 U.S.C. § 343, in several ways, including, but not limited to, the following:

a. Food (including dietary supplements) is misbranded within the meaning of 21 U.S.C. § 343(q)(1)(A) if its label or labeling fails to declare the serving size which is an amount customarily consumed. Some of Defendants' dietary supplements' labels or labeling (for example, the labels or labeling for Atrium brand Chole-Sterin) fail to declare an accurate serving size that is the amount customarily consumed, as required by 21 C.F.R. § 101.9(b)(1);

b. Food (including dietary supplements) is misbranded within the meaning of 21 U.S.C. § 343(q)(1)(B) if its label or labeling fails to declare the number of servings or other units of measure per container. Some of Defendants' dietary supplements' labels or labeling (for example, the labels or labeling for Atrium brand Chole-Sterin, Atrium brand Di-Acid Stim, Atrium brand Natto, Atrium brand Oco-Comp, Atrium brand Super-Flex, Aspen brand Flexile-Plus, Nutri-Pak brand Glucobiotic Supreme, and Nutri-Pak brand Ocu-Comp) do not list the servings per container under the serving size subheading on the left hand side of the nutrition label and do not declare this information in the net quantity of contents declaration, as required by 21 C.F.R. § 101.36(b)(1)(ii); and

c. Food (including dietary supplements) is misbranded within the meaning of 21 U.S.C. § 343(s)(2)(C) if the label or labeling contains an ingredient described in 21 U.S.C. § 321(ff)(1)(C) (an herb or other botanical), but fails to identify the part of the plant from which

the ingredient derives. Some of Defendants' dietary supplements' labels or labeling (for example, the labels or labeling for Atrium brand Oco-Comp, Atrium brand Super-Flex, Aspen brand Flexile-Plus, Nutri-Pak brand Glucobiotic Supreme, and Nutri-Pak brand Ocu-Comp) do not include the part of the plant from which the dietary ingredient is derived, as required by 21 C.F.R. § 101.4(h)(1).

16. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1), and misbranded within the meaning of 21 U.S.C. § 343.

DEFENDANTS' HISTORY OF VIOLATIONS

17. Defendants are well aware that their operations deviate from the cGMP regulations and that their failure to cease their violative conduct and implement corrections could lead to regulatory action.

18. FDA previously inspected Defendants' facility and/or Defendants' previous location at 440 S. Townline Road, Wautoma, Wisconsin 54982, between April 30, 2013 and May 20, 2013 ("May 2013 inspection") and January 10 and 24, 2012 ("January 2012 inspection"). During both inspections, FDA observed significant violations of the Act and cGMP regulations. During one or both of these previous inspections, FDA investigators found some of the same violations as those observed during the July 2014 inspection of the facility, including, but not limited to, violations involving: failure to establish an identity specification for each component, as required by 21 C.F.R. § 111.70(b)(1); failure to establish product specifications, as required by 21 C.F.R. § 111.70(e); failure to qualify the supplier of a component received by establishing the reliability of the supplier's COA, as required by 21

C.F.R. § 111.75(a)(2)(ii); failure to ensure that the tests and examinations used to determine whether specifications are met are appropriate, scientifically valid methods, as required by 21 C.F.R. § 111.75(h)(1); and failure to establish and follow written procedures for the responsibilities of the quality control operations, as required by 21 C.F.R. § 111.103.

19. At the conclusion of the May 2013 and January 2012 inspections, FDA investigators issued to Defendant James F. Sommers a Form FDA-483, List of Inspectional Observations ("Form FDA-483"), detailing Defendants' numerous deviations of the Act and cGMP requirements. During the January 2012 inspection, the FDA investigator also discussed the observations with Defendants James F. Sommers and Roberta A. Sommers.

20. On November 2, 2012, FDA issued a Warning Letter to Defendant James F. Sommers, informing him that the significant cGMP violations that FDA documented during the January 2012 inspection rendered Defendants' dietary supplements adulterated under the Act. The Warning Letter emphasized the serious nature of the violations and further cautioned Defendants that their failure to correct the violations promptly, and prevent future violations, could lead to additional regulatory action, including enjoining their operations.

21. Based on their repeated course of conduct, Defendants, unless restrained by order of this Court, will continue to violate 21 U.S.C. § 331(a).

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, franchisees, affiliates, and "doing business as" entities), cease manufacturing, preparing, packing, repackaging, labeling, holding, and/or distributing dietary

supplements at or from the facility or at or from any other location(s) at which Defendants manufacture, prepare, pack, repackage, label, hold, and/or distribute dietary supplements, now or in the future, unless and until Defendants bring their manufacturing, preparing, packing, repackaging, labeling, holding, and/or distributing operations into compliance with the Act, cGMP, and labeling requirements.

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, franchisees, affiliates, and "doing business as" entities), be permanently restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any of the following:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, dietary supplements that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and causing the introduction or delivery for introduction into interstate commerce, dietary supplements that are misbranded within the meaning of 21 U.S.C. § 343.

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business and all records relating to the manufacturing, preparing, packing, repackaging, labeling, holding, and distributing of all of Defendants' products to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

IV. Order that Plaintiff be awarded costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

Dated this 31st day of July, 2015.

Respectfully submitted,

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