UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. ATF FITNESS PRODUCTS, INC., and MANUFACTURING ATF DEDICATED EXCELLENCE, INC., corporations, and JAMES G. VERCELLOTTI, an individual, Defendants.	)	CIVIL ACTION NO._____

COMPLAINT FOR INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, avers as follows:

INTRODUCTION

1. This proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 332(a), and the equitable authority of this Court, to permanently enjoin ATF Fitness Products, Inc. ("ATF"), and Manufacturing ATF Dedicated Excellence, Inc. ("MADE"), corporations, and James G. Vercellotti, an individual (collectively, "Defendants"), from violating:

a. 21 U.S.C. § 331(a), by introducing, or delivering for introduction, into interstate commerce articles of food (dietary supplements, as defined in 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(a)(1) and (s)(2)(A)(i);

b. 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), and misbranded within the meaning of 21 U.S.C. §§ 343(a)(1) and (s)(2)(A)(i), while such articles are held for sale after shipment of one or more of their components in interstate commerce; and/or

c. 21 U.S.C. § 331(e), by failing to maintain or submit serious adverse event reports associated with the use of their dietary supplements, as required by 21 U.S.C. § 379aa-1.

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.

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

DEFENDANTS

4. Defendant MADE is incorporated under the laws of Pennsylvania and is doing business at 140 Pennsylvania Avenue, Oakmont, Pennsylvania. MADE manufactures, prepares, packs, labels, and holds more than four hundred dietary supplements, including vitamins and minerals, for sale under the brands "Sci-Fit," "Nature's Science," and "For Store Only."

5. Defendant ATF is also incorporated under the laws of Pennsylvania and doing business at 140 Pennsylvania Avenue, Oakmont, Pennsylvania. ATF purchases dietary supplements exclusively from MADE and distributes them in interstate commerce.

6. Defendant Vercellotti, an individual, is the owner, president, and chief executive officer of MADE and ATF, as well as ATF Business Labor Elite, Inc. (ABLE), a Pennsylvania payroll company for MADE and ATF that is also located at the same address. Although incorporated separately in 2008, MADE, ATF, and ABLE operate as one entity, at the same location, under the direction of Defendant Vercellotti, who has the ultimate responsibility for and authority over these corporations. Defendant Vercellotti oversees and makes final decisions over all of their operations, including, but not limited to, manufacturing, packaging, labeling, holding, advertising, distributing, and financial operations. He approves all products before they are distributed, and he reviews and approves all receiving, production, and distribution records. He conducts business at 140 Pennsylvania Avenue, Oakmont, Pennsylvania.

7. Defendants have been, and are now engaged in, manufacturing, preparing, packing, labeling, holding, and distributing dietary supplements within the meaning of 21 U.S.C. § 321(ff).

8. Defendants regularly manufacture dietary supplements using components they receive in interstate commerce and introduce, or deliver for introduction, finished dietary supplements into interstate commerce.

DEFENDANTS ADULTERATE THEIR DIETARY SUPPLEMENTS

9. The United States Food and Drug Administration ("FDA") inspected Defendants' facility between March 15 and April 12, 2011. This inspection established that the dietary supplements that Defendants manufacture and distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that the methods and processes used in, or the facilities or controls used for, their manufacture, preparation, packing, labeling, and holding do not conform to or are not operated or administered in conformity with the current good manufacturing practice ("cGMP") requirements for dietary supplements.

10. Manufacturing according to cGMP means that the manufacturing process incorporates a set of controls in the design and production processes to assure a quality finished product. Dietary supplements not manufactured, prepared, packed, labeled, or held in conformance with cGMP are deemed adulterated. 21 U.S.C. § 342(g)(1). The cGMP regulations for dietary supplements are set forth at 21 C.F.R. Part 111.

11. During the March-April 2011 inspection, FDA investigators documented numerous deviations from cGMP. These deviations include, but are not limited to, the following:

a. Failure to prepare and follow a written master manufacturing record ("MMR") for each unique formulation of dietary supplement and for each batch size to ensure uniformity in the finished batch, from batch to batch, as required by 21 C.F.R. § 111.205(a);

b. Failure to include all the required information in the MMR, including (1) an accurate statement of the weight or measure of each component, the identity and weight or measure of each dietary ingredient declared on the "Supplement Facts" label, and the identity of each ingredient declared on the ingredients list of the dietary supplement, as required by 21 C.F.R. §§ 111.210(c)&(d); and (2) written instructions for manual operation that includes having

one person weigh or measure a component and another person verify the weight or measure, and having one person add the component and another person verify the addition, as required by 21 C.F.R. §§ 111.210(h)(3)(ii)(A)-(B);

c. Failure of the quality control personnel to ensure the quality of the dietary supplement and that it is packaged and labeled as specified in the MMR, as required by 21 C.F.R. § 111.105;

d. Failure to test or examine, using a statistically valid sampling plan, a subset of finished dietary supplement batches to verify that the batch meets product specifications for identity, purity, strength, and composition and for limits on those types of contamination that may adulterate the finished batch of the dietary supplement, as required by 21 C.F.R. § 111.75(c)(2);

e. Failure to confirm the identity of components by either conducting appropriate tests or examinations or qualifying the components' supplier, as required by 21 C.F.R. § 111.75(a);

f. Failure to document in the batch production record, at the time such activity was performed, that quality control personnel approved and released, or rejected, the batch for distribution, including any reprocessed batch, as required by 21 C.F.R. § 111.260(l)(3);

g. Failure to maintain, clean, and sanitize, as necessary, all equipment, utensils, and any other contact surfaces used to manufacture, prepare, pack, label, or hold components or dietary supplements, as required by 21 C.F.R. § 111.27(d);

h. Failure to have a qualified person review and/or investigate all product complaints to determine whether the complaints involve a possible failure of a dietary supplement to meet any of its specifications or any other requirements of 21 C.F.R. Part 111, as required by 21 C.F.R. § 111.560(a);

i. Failure to hold components, dietary supplements, packaging, and labels under conditions that do not lead to the mixup, contamination, or deterioration of components, dietary supplements, packaging, and labeling, as required by 21 C.F.R. § 111.455(c); and

j. Failure of quality control personnel to (1) conduct a material review and make a disposition decision when a batch deviates from the MMR, as required by 21 C.F.R. § 111.113(a)(2); and (2) review and approve modifications to the MMR, as required by 21 C.F.R. § 111.123(a)(1).

12. The deviations from cGMP documented during FDA's March-April 2011 inspection establish that Defendants' dietary supplements are adulterated within the meaning of 21 U.S.C. § 342(g)(1).

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

14. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS MISBRAND THEIR DIETARY SUPPLEMENTS

15. FDA's March-April 2011 inspection also revealed that Defendants engaged in ingredient and product substitutions that resulted in their finished dietary supplements being misbranded. These substitutions include, but are not limited to, the following:

a. Substituting the dietary ingredient Sea Vegetable for the dietary ingredient Bladderwrack in the product Vita Sport Thyrostim and, as a result, the product does not contain Bladderwrack as listed on the product's label;

b. Substituting the product Nitrox II for Nitrox, the label for which does not list all of the dietary ingredients contained in Nitrox II, including, for example, Citrulline-malate, L-Taurine, Alpha Lipoic Acid, and Vanadyl Sulfate; and

c. Substituting the products ATF Free Form Amino Soft Gels for BCAA AKG 1000 Soft Gels, the label for which does not list all of the dietary ingredients contained in ATF

Free Form Amino Soft Gels, including, for example, L-Glutamine Acid-akg, L-Glycine-akg, L-Asparatic Acid-akg, and L-Taurine-akg.

16. Under 21 U.S.C. § 343(a)(1), a dietary supplement is deemed to be misbranded if its labeling is false or misleading in any particular. Because Defendants' dietary supplements routinely contain ingredients that are not listed on the label or do not contain ingredients listed on the label, the labels for these products are false and/or misleading under 21 U.S.C. § 343(a)(1).

17. Under 21 U.S.C. § 343(s)(2)(A)(i), a dietary supplement is deemed to be misbranded if its label or labeling fails to list the name of each ingredient of the dietary supplement that is described in 21 U.S.C. § 321(ff). Because Defendants routinely fail to list accurately ingredients on the labels for their dietary supplements, these products are misbranded under 21 U.S.C. § 343(s)(2)(A)(i).

18. Defendants violate 21 U.S.C. § 331(a) by introducing, or delivering for introduction, into interstate commerce articles of food (dietary supplements) that are misbranded within the meaning of 21 U.S.C. §§ 343(a)(1) and (s)(2)(A)(i).

19. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) to be misbranded within the meaning of 21 U.S.C. §§ 343(a)(1) and (s)(2)(A)(i), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS FAIL TO SUBMIT SERIOUS ADVERSE EVENT REPORTS

20. The Act requires the manufacturer, packer, or distributor of a dietary supplement whose name (pursuant to 21 U.S.C. § 343(e)(1)) appears on the label of a dietary supplement marketed in the United States to submit any report received of a serious adverse event associated with such dietary supplement when used in the United States no later than fifteen business days after the report is received. 21 U.S.C. § 379aa-1(b)&(c). Under 21 U.S.C. § 331(e), the "failure to . . . maintain any record, or make any report, required under" 21 U.S.C. § 379aa-1, is a prohibited act.

21. During the March-April 2011 inspection, FDA investigators determined that Defendants ATF and MADE failed to report serious adverse events. For example, Defendants received a complaint on or about July 28, 2010, in which Defendants' customer stated that Defendants' "Kreation Powder" (used in the United States) caused a high blood pressure spike requiring hospitalization and a subsequent mild heart attack. Defendants did not report to FDA or investigate this adverse event.

22. Defendants violate 21 U.S.C. § 331(e) by failing to maintain and/or submit serious adverse event reports associated with the use of their dietary supplements in the United States, as required by 21 U.S.C. § 379aa-1.

HISTORY

23. Defendants have had ample warning that their manufacturing operations do not comply with cGMP. As discussed above, FDA's inspection of MADE in March-April 2011 documented numerous cGMP violations. At the close of this inspection, FDA investigators presented Defendant Vercellotti with a List of Inspectional Observations (Form FDA-483) and discussed the cGMP deficiencies with him. Defendants did not respond to the Form FDA-483 or promise to correct all of the deficiencies.

24. Even before FDA documented Defendants' gross cGMP deficiencies in March-April 2011, Defendants were already on notice of their deviations from cGMP based on a January 2010 audit report prepared by an outside consultant retained to assess MADE's compliance with cGMP. The outside consultant identified seventy-six cGMP deviations that it deemed "significant," many of which were the same as those FDA cited in its 2011 inspection.

25. In addition to their current cGMP violations, Defendants have a long history of violating the Act, including, but are not limited to, the following:

a. FDA issued a Warning Letter in March 2004 to Scientific Fitness, one of ATF's brand names, regarding ATF's distribution of an adulterated dietary supplement;

b. FDA issued another Warning Letter in November 2004 to Defendant Vercollotti as president of ATF, concerning ATF's distribution of adulterated dietary

supplements. When Defendants ATF and Vercellotti continued to distribute the adulterated products, the government filed a seizure action in 2005 against those products; and

c. FDA's October-November 2005 inspection of ATF revealed that, despite a prior warning and seizure action in February 2005, ATF continued to possess with the intent to distribute adulterated dietary supplements. The government filed another seizure action in January 2006.

26. Despite this extensive history of violations, Defendants continue to manufacture and distribute dietary supplements that are adulterated and misbranded as set forth above. Thus, the United States is informed and believes that, unless restrained by this Court, Defendants will continue to violate the Act, 21 U.S.C. §§ 331(a), (e), and (k), in the manner herein alleged.

RELIEF REQUESTED

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Order that Defendants ATF Fitness Products, Inc., Manufacturing ATF Dedicated Excellence, Inc., and James G. Vercellotti, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons or entities in active concert or participation with any of them, be permanently restrained and enjoined from manufacturing, preparing, packing, labeling, holding, and/or distributing dietary supplements, unless and until Defendants' methods, facilities, and controls used to manufacture, prepare, pack, label, hold, and distribute dietary supplements are established, operated, and administered in conformity with cGMP and the Act, in a manner that has been found to be acceptable by FDA;

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons or entities in active concert or participation with any of them, 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 acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce dietary supplements that are adulterated within

the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. §§ 343(a)(1) and (s)(2)(A)(i);

B. Violating 21 U.S.C. § 331(k) by causing dietary supplements that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. §§ 343(a)(1) and (s)(2)(A)(i); and/or

C. Violating 21 U.S.C. § 331(e) by failing to maintain and/or submit serious adverse event reports associated with the use of Defendants' dietary supplements in the United States, as required by 21 U.S.C. § 379aa-1;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, preparing, packing, labeling, holding, and distribution of all of Defendants' dietary supplements 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; and

IV. Order that Plaintiff be awarded costs and other such equitable relief as this Court deems just and proper.

Dated this 23rd day of November, 2011.

Respectfully submitted,
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