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. 2:11-cv-01498-AJS

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction ("Complaint") against ATF Fitness Products, Inc. ("ATF"), and Manufacturing ATF Dedicated Excellence, Inc. ("MADE"), corporations currently manufacturing and distributing dietary supplements at 140 Pennsylvania Avenue, Oakmont, Pennsylvania, and James G. Vercellotti, an individual (collectively, "Defendants"), and Defendants having appeared and consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399d (the "Act").

3. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing, or delivering for introduction, into interstate commerce articles of food (dietary supplements, as defined by 21 U.S.C. § 321(ff)), that are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they

have been manufactured, prepared, packed, labeled, and held in violation of current good manufacturing practice ("cGMP") regulations, as set forth at 21 C.F.R. Part 111.

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

5. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of food (dietary supplements) that are misbranded within the meaning of 21 U.S.C. § 343(a)(1), in that their labeling is false or misleading, and 21 U.S.C. § 343(s)(2)(A)(i), in that their labeling fails to name each ingredient that is described in 21 U.S.C. § 321(ff).

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

7. Defendants violate the Act, 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.

8. Upon entry of this Decree, 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 who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, preparing, packing, labeling, holding, and/or distributing any dietary supplements unless and until:

A. Defendants' facilities, methods, processes, and controls used to manufacture, prepare, pack, label, hold, and distribute dietary supplements are established, operated, and administered in compliance with this Decree, the Act, and its implementing regulations;

B. Defendants retain, at Defendants' expense, an independent person or persons (the "Expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to: (1) inspect Defendants' dietary supplement manufacturing facilities to determine whether the facilities, methods, processes, and controls are operated and administered in conformity with cGMP, 21 C.F.R. Part 111; and (2) evaluate Defendants' compliance with 21 U.S.C. §§ 343 and 379aa-1. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity and qualifications of the Expert as soon as they retain such Expert;

C. The Expert performs a comprehensive inspection of Defendants' facilities, methods, processes, and controls used to manufacture, prepare, pack, label, hold, and distribute dietary supplements to determine whether they are in compliance with cGMP, including, but not limited to, ensuring that Defendants:

(1) Implement a system of production and process controls that covers all stages of manufacturing, preparing, packing, labeling, and holding of dietary supplements to ensure the quality of the dietary supplements and that the dietary supplements are packed and labeled as specified in the master manufacturing records ("MMRs"), as required by 21 C.F.R. § 111.55;

(2) Prepare and follow a written 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;

(3) Include all the required information in the MMR, as required by 21 C.F.R. § 111.210;

(4) Ensure a qualified person timely and thoroughly reviews and/or investigates 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, including those specifications and other requirements that, if not met, may result in a risk of illness or injury, as required by 21 C.F.R. § 111.560(a);

(5) Implement written procedures to ensure that Defendants' quality control personnel conduct a material review and make a disposition decision if an established specification is not met, a batch deviates from the MMR, and/or an unanticipated occurrence happens during the manufacturing operations, as required by 21 C.F.R. § 111.113(a);

(6) Establish and follow written procedures that specify the responsibilities of the quality control operations, as required by 21 C.F.R. § 111.103;

(7) Implement written procedures specifying the retention of records, as required by 21 C.F.R. §§ 111.605 and 111.610;

(8) Make and keep documentation of the qualification of a supplier for the purpose of relying on the supplier's certificate of analysis, as required by 21 C.F.R. § 111.95(b)(2);

(9) Establish and follow written procedures to fulfill the requirements regarding product complaints set forth in 21 C.F.R. §§ 111.560 and 111.570, as required by 21 C.F.R. § 111.553;

(10) Make and keep documentation of any calibration, each time the calibration is performed, for instruments and controls, as required by 21 C.F.R. § 111.35(b)(3);

(11) Identify and use an appropriate scientifically valid method for each established specification for which testing or examination is required to determine whether the specification is met, as required by 21 C.F.R. § 111.320(b);

(12) Ensure batch production records include documentation whether quality control personnel approved and released, or rejected, a batch for distribution, as required by 21 C.F.R. § 111.260(1)(3);

(13) Make and keep documentation, in individual equipment logs, of the date of the use, maintenance, cleaning, and sanitizing of equipment, unless such documentation is kept with the batch record, as required by 21 C.F.R. § 111.35(b)(2);

(14) Make and keep records of written procedures for laboratory operations, including written procedures for the tests and examinations conducted to determine whether specifications are met, as required by 21 C.F.R. § 111.325(b)(1);

(15) 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 labels, as required by 21 C.F.R. § 111.455(c);

(16) 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);

(17) 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); and

(18) 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).

D. The Expert certifies in writing to FDA that:

(1) He or she has inspected Defendants' facilities, methods, processes, and controls used by Defendants to manufacture, prepare, pack, label, hold, and distribute dietary supplements;

(2) All cGMP deviations brought to Defendants' attention by FDA, the Expert, or any other source, including but not limited to any experts hired prior to the entry of this Decree, have been corrected;

(3) Such facilities, methods, processes, and controls are in compliance with the requirements of cGMP. As part of this certification, the Expert shall include a full and complete detailed report of the results of his or her inspection;

(4) The Expert has reviewed the labeling for all of Defendants' dietary supplements and has determined that such labeling is in full compliance with 21 U.S.C. § 343; and

(5) The Expert has reviewed all complaints Defendants have received regarding their dietary supplements and determined that all serious adverse events associated with the use of Defendants' dietary supplements in the United States have been reported to FDA as required by 21 U.S.C. § 379aa-1;

E. Defendants report to FDA in writing the actions they have taken to:

(1) Correct all deviations brought to Defendants' attention by FDA, the Expert, and any other source, including but not limited to any experts hired prior to the entry of this Decree;

(2) Ensure that the methods and processes used in, and the facilities and controls used for, manufacturing, preparing, packing, labeling, holding, and distributing dietary supplements are operated and will be continuously administered in conformity with cGMP, 21 C.F.R. Part 111;

(3) Ensure that their dietary supplements are labeled in accordance with 21 U.S.C. § 343; and

(4) Ensure that all serious adverse event reports associated with the use of their dietary supplements are timely reported to FDA, as required by 21 U.S.C. § 379aa-1;

F. FDA representatives inspect Defendants' facilities, methods, processes, and controls to determine whether the requirements of this Decree have been met, including whether (1) Defendants are operating in conformity with 21 U.S.C. § 342(g)(1) and 21 C.F.R. Part 111; (2) Defendants' dietary supplements are labeled in conformance with 21 U.S.C. § 343; and (3) Defendants are operating in compliance with 21 U.S.C. § 379aa-1; and

G. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in subparagraphs 8(A)-(E). In no circumstance shall FDA's silence be construed as a substitute for written notification.

9. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons and entities in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are 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. Introducing, or delivering for introduction, into interstate commerce any dietary supplement that is adulterated within the meaning of 21 U.S.C. § 342(g)(1);

B. Causing the adulteration of any dietary supplement within the meaning of 21 U.S.C. § 342(g)(1), while such dietary supplement is held for sale after shipment of one or more of its components in interstate commerce;

C. Introducing, or delivering for introduction, into interstate commerce any dietary supplement that is misbranded within the meaning of 21 U.S.C. § 343(a)(1) or 343(s)(2)(A)(i);

D. Causing the misbranding of any dietary supplement within the meaning of 21 U.S.C. § 343(a)(1) or 343(s)(2)(A)(i), while such dietary supplement is held for sale after shipment of one or more of its components in interstate commerce; and

E. 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.

10. Within fifteen (15) calendar days of entry of this Decree, Defendants shall, under FDA supervision, destroy all dietary supplements in Defendants' possession, custody, and/or control that are adulterated because they were not manufactured, prepared, packed, labeled, held, and/or distributed in accordance with cGMP. Defendants shall reimburse FDA for the supervision of the destruction at the rates set forth in paragraph 13 of this Decree. Defendants shall not dispose of any dietary supplements in a manner contrary to any federal, state, or local laws, including but not limited to, the National Environmental Policy Act of 1969.

11. After Defendants have complied with paragraphs 8(A)-(E) and FDA has notified them pursuant to paragraph 8(G), Defendants shall retain an independent person or persons who shall meet the criteria described in paragraph 8(B) to conduct audit inspections of their dietary supplement manufacturing and labeling operations at least once every three (3) months, for a period of no less than two (2) years, and then at least once every six (6) months for the subsequent three (3) years (hereinafter, "Auditor"). If Defendants choose, the Auditor may be the same person or persons retained as the Expert in paragraph 8(B).

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance

with this Decree, the Act, and its implementing regulations and identifying any deviations ("audit report observations"). As a part of every audit report, except the first audit report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the audit inspection(s) is completed. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any observations indicating that Defendants are not in compliance with this Decree, the Act, and/or its implementing regulations, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the deviations will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule"). The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the Auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

12. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' operations and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree,

the Act, and its implementing regulations. During such inspections, FDA representatives shall be permitted: (a) access to Defendants' places of business including, but not limited to, all buildings, equipment, finished and unfinished materials and products, containers, labeling, and other promotional material therein; (b) to take photographs and make video recordings; (c) to take samples of Defendants' finished and unfinished materials and products, containers, labeling, and other promotional material; and (d) to examine and copy all records relating to the receipt, manufacture, packaging, labeling, holding, and distribution of any and all of Defendants' dietary supplements, including components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

13. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree. The costs of such activities shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative for inspection or investigative work; $104.96 per hour or fraction thereof per representative for analytical or review work; $0.51 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

14. Within ten (10) calendar days of the entry of this Decree, Defendants shall post a copy of this Decree on a bulletin board in a common area at 140 Pennsylvania Avenue, Oakmont, Pennsylvania, and at any other location at which Defendants conduct business, and shall ensure that the Decree remains posted at each location for as long as the Decree remains in effect.

15. Within ten (10) calendar days of the date of entry of this Decree, Defendants shall provide a copy of the Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, persons or entities for whom Defendants contractually manufacture dietary supplements, and private label distributors with whom Defendants are affiliated, and any and all persons in active concert or participation with any of them (collectively referred to as "Associated Persons"). If any Associated Person is a corporate entity, Defendants shall provide the Decree to the chief executive officer and chief legal officer of such entity, with instructions to them to ensure that appropriate persons within the entity receive the Decree. Within thirty (30) calendar days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to this paragraph.

16. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within ten (10) calendar days of each time any of the Defendants becomes associated with any such additional Associated Person, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph. Within ten (10) calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

17. Defendants shall notify FDA, in writing, at least fifteen (15) calendar days before any change in ownership, character, or name of any of their businesses, including incorporation, reorganization, bankruptcy, assignment, sale resulting in the emergence of a successor business or corporation, or any other change in the structure or identity of MADE or ATF, or any of their

parents or subsidiaries, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least ten (10) calendar days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

18. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report or data prepared or submitted by Defendants, the Expert, the Auditor, or any other information, that (a) Defendants have failed to comply with any provision of this Decree or have violated the Act or its implementing regulations, and/or (b) additional corrective actions are necessary to achieve compliance with this Decree, the Act, and/or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective actions, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease all manufacturing, packaging, labeling, holding, and/or distributing any or all dietary supplement(s);

B. Recall, at Defendants' own expense, any dietary supplement that is adulterated, misbranded, or otherwise in violation of this Decree, the Act, and/or its implementing regulations;

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

D. Submit additional reports or information to FDA;

E. Issue a safety alert; and/or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with this Decree, the Act, and/or its implementing regulations.

19. Upon receipt of any order issued by FDA pursuant to paragraph 18, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 18 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in paragraph 18 shall be borne by Defendants at the rates specified in paragraph 13.

20. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, Defendants shall pay to the United States of America: fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues; an additional sum of fifteen thousand dollars ($15,000) in liquidated damages for each violation of this Decree, the Act, and/or its implementing regulations; and an additional sum equal to twice the retail value of each shipment of adulterated and/or misbranded dietary supplements in liquidated damages for each such unlawful shipment. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

21. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered under this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

22. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be addressed to the District Director, FDA Philadelphia District Office, U.S. Customhouse, 200 Chestnut Street, Philadelphia, Pennsylvania, 19106.

23. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this 9th day of March, 2012.

UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of this Decree:

For Defendants:

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JAMES G. VERCELLOTTI,
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