IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Chief Judge Marcia S. Krieger

Civil Action No. 17-cv-00633-MSK-MJW

UNITED STATES OF AMERICA,

Plaintiff,

v.

EONNUTRA, LLC;
CDSM, LLC;
HABW, LLC, corporations; and
MICHAEL FLOREN,

Defendants.

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Permanent Injunction against EonNutra, LLC, CDSM, LLC, and HABW, LLC, corporations, and Michael Floren, 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:

THE PARTIES AGREE THAT:

1. This Court has jurisdiction over the subject matter and all parties to this action.
2. The Complaint sates a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "Act").
3. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements), as defined by 21 U.S.C § 321(ff), that are:

A. Adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held in violation of current good manufacturing practice regulations for dietary supplements ("Dietary Supplement CGMP"), set forth in 21 C.F.R. Part111; and

B. Misbranded within the meaning of 21 U.S.C. § 343 because their labels fail to list each ingredient; list he correct serving size and number of servings per container; and/or identify the part of the plant from which each botanical dietary ingredient in the product is derived.

4. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) that they hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. §§ 342(g) (1) and 343.

5. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) because their labeling fails to bear adequate directions for use.

6. Defendants violate 21 U.S.C. 331(k) by causing articles of drug that they hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

7. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i).

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 have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly manufacturing, preparing, packing, repacking, labeling, holding or distributing any dietary supplements (including components) and/or articles of drug, at or from 3506 N. El Paso Street, Colorado Springs, Colorado, or at or from any other location(s) at which Defendants now or in the future directly or indirectly manufacture, prepare, pack, repack, label, hold, or distribute any dietary supplements (including components) and/or articles of drug ("Defendants' Facility" or "the Facility"), unless and until:

   A. Defendants retain, at Defendants' expense, an independent person (the "CGMP Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to inspect the Facility to determine whether the methods, processes, and controls are operated and administered in conformity with Dietary Supplement CGMP (21 C.F.R. Part 111). Defendants shall notify FDA in writing of the identity and qualifications of the CGMP Expert within three (3) business days of retaining such expert;

   B. The CGMP Expert performs a comprehensive inspection of the Facility and the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements and certifies in writing to FDA that:

(1) he or she has inspected the Facility, methods, processes, and controls; (2) all Dietary Supplement CGMP deviations that have been brought to Defendants' attention by FDA, the CGMP Expert, and any other source have been corrected; and (3) the Facility and the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements, are, in the CGMP Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. The CGMP Expert's report of the inspection, which shall be submitted to FDA, shall include, but not be limited to, a determination that Defendants have methods, processes, and controls to ensure that they:

(1) Establish specifications for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of dietary supplements, as required by 21 C.F.R. § 111.70(a);

(2) Establish product specifications for the identity, purity, strength, and composition of the finished batch of the dietary supplement, as required by 21 C.F.R. §111.70(e);

(3) Determine whether finished dietary supplement batches meet the product specifications that must be established in accordance with 21 C.F.R. § 111.70(e), as required by 21 C.F.R. § 111.75(c);

(4) Establish specifications for each component that include: an identity specification; component specifications to ensure that specifications for the purity, strength, and composition of the finished batch of dietary supplement are met; and limits on those types of contamination that may adulterate or may lead to adulterate or may lead to adulteration of the finished batch of the

dietary supplement to ensure the quality of the dietary supplement, as required by 21 C.F.R. 111.70(b);

(5) Conduct at least one appropriate test or examination to verify the identity of every component that is a dietary ingredient before using such component, as required by 21 C.F.R. § 111.75(a)(1)(i);

(6) Determine whether applicable component specifications established in accordance with 21 C.F.R. § 111.70(b) are met by conducting appropriate tests or examinations, as specified in 21 C.F.R. § 111.75(h), or relying on component suppliers' certificates of analysis, as specified by 21 C.F.R. § 111.75(a)(2)(ii), as required by 21 C.F.R. § 111.75(a)(2);

(7) Prepare, follow, and maintain a complete written master manufacturing record for each unique formulation of dietary supplement, and for each batch size, to ensure uniformity in the finished batch and from batch to batch, as required by 21 C.F.R. § 111.205 and 111.210;

(8) Prepared, follow, and maintain a written batch production record for each batch of the dietary supplement that contains complete information relating to the production and control of each batch, as required by 21 C.F.R. §§111.255 and 111.260;

(9) Approve, and release from quarantine, all components, packaging, and labeling before they are used, as required by 21 C.F.R. § 111.120(e), and make and keep written documentation, at the time of performance, that quality control personnel performed the review, approval, or rejection requirements, as required by 21 C.F.R. § 111.140(b)(2);

(10) Establish and follow procedures to ensure that reserve samples of each lot of packaged and labeled dietary supplement that is distributed are collected and held, as required by 21 C.F.R. § 111.83(a); and

(11) Establish and follow written procedures to ensure product distribution records are maintained, as required by 21 C.F.R. 111.475(b)(2);

C. Defendants retain, at Defendants' expense, an independent person (the "Labeling Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, except that this person may be the same as the CGMP Expert described in paragraph 8(A), and who, by reason of background, training, education, or experience, is qualified to review Defendants' dietary supplement labeling (including but not limited to labels, catalogs, and websites) and other promotional/informational material to determine whether: (1) the labeling complies with 21 U.S.C. § 343 and applicable regulations; and (2) Defendants' claims cause any dietary supplement that they receive, manufacture, prepare, pack, repack, label, hold, or distribute to be a drug within the meaning of 21 U.S.C. § 321(g)(1). Defendants shall notify FDA in writing of the identity and qualifications of the Labeling Expert within three (3) business days of retaining such expert;

D. The Labeling Expert conducts a comprehensive review of Defendants' dietary supplement labeling (including but not limited to labels, catalogs, and websites) and other promotional/informational material and certifies in writing to FDA that: (1) he or she has reviewed Defendants' dietary supplement labeling and other promotional/informational material; (2) all labeling violations brought to Defendants'

attention by FDA, the Labeling Expert, and any other source, have been corrected; and (3) Defendants' dietary supplement labeling and claims are, in the Labeling Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. The Labeling Expert shall prepare a detailed report of this review, which shall be submitted to FDA, that shall include, but not be limited to, a determination that:

(1) Defendants have implemented procedures that are adequate to ensure that their dietary supplement labeling complies with 21 U.S.C. § 343 and applicable regulations; and

(2) Defendants have implemented procedures that are adequate to ensure that their claims do not cause any dietary supplement that they receive, manufacture, prepare, pack, repack, label, hold, or distribute to be a drug within the meaning of 21 U.S.C. § 321(g)(1), unless and until the product is the subject of an approved new drug application or abbreviated new drug application, or is exempt from approval under an investigational new drug application, 21 U.S.C. §§ 355(a), (b), (i), (j);

E. Defendants recall and destroy, under FDA's supervision and in accordance with the procedures provided in paragraph 9, all dietary supplements and/or articles of drug (including raw and in-process materials and finished products) that were received, manufactures, prepared, packed, repacked, labeled, held, or distributed between June 23, 2015, and the date of entry of this Decree;

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

(1) Correct the Dietary Supplement CGMP and labeling deviations brought to Defendants' attention by FDA, the CGMP Expert, Labeling Expert, and any other source;

(2) Ensure that the facilities, methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements are and will be continuously operated in conformity with Dietary Supplement CGMP;

(3) Ensure that Defendants' dietary supplement labeling complies with 21 U.S.C. §343 and applicable regulations; and

(4) Ensure that Defendants' claims do not cause any dietary supplement that they receive, manufacture, prepare, pack, repack, label, hold, or distribute to be a drug within the meaning of 21 U.S.C. § 321(g)(1) unless the product is the subject of an approved new drug application or abbreviated new drug application, or is exempt from approval under an investigation new drug application, 21 U.S.C. §§ 355(a), (b), (i), and (j);

G. As and when FDA deems necessary, FDA representatives inspect Defendants' Facility, including the buildings, equipment, products, labeling, and all relevant records contained therein, to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with the Act, its implementing regulations, and this Decree;

H. Defendants have paid all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews with respect to paragraph 8, at the rates set forth in paragraph 16; and

I. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in paragraphs 8(A)-(F) and (H) of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

9. Within fifteen (15) business days after entry of this Decree, Defendants, under FDA's supervision, shall destroy all dietary supplements and/or articles of drug (including raw and in-process materials and finished products) that are in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and the costs of FDA's supervision. Defendants shall not dispose of any products in a manner contrary to the provisions of the Act, any other federal law, or the laws or any State or Territory, as defined in the Act, in which the products are disposed.

10. Upon resuming operations after complying with paragraphs 8(A)-(F) and (H), and receiving FDA's written notification pursuant to paragraph 8(I), Defendants shall retain an independent person (the "Auditor") who shall meet the criteria for, and may be the same person as, the CGMP Expert and Labeling Expert described in paragraphs 9(A) and 8(C), to conduct audit inspections of the Facility and the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements, and of Defendants' dietary supplement labeling (including but not limited to labels, catalogs, and websites) and other promotional/informational material. Thereafter:

A. The Auditor shall conduct audit inspections no less frequently than once every six (6) months for a period of no less than five (5) years and then at least once every year thereafter. The first audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to paragraph 9(I).

B. 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 from such requirements ("Audit Report Observations"). As a part of every Audit Report (except the first one), the Auditor shall assess the adequacy of 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 five (5) business days after the audit inspection is completed. In addition, Defendants shall maintain the Audit Reports in separate files at Defendants' Facility and shall promptly make the Audit Reports available to FDA upon request.

C. If an Audit Report contains an Audit Report Observations, Defendants shall, within ten (10) business days after 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 Audit Report Observations will take longer than ten (10) business days, Defendants shall, within five (5) business days after receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit 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 Audit Correction Schedule. Within twenty (2) business days after Defendants' receipt of an Audit Report, unless FDA notifies

Defendants that a shorter time period is necessary, or within the time period provided in an FA-approved Audit Correction Schedule, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within five (5) business days after 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.

11. Upon entry of this Decree, and after receiving FDA's written notification pursuant to paragraph 8(I), Defendants 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. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce dietary supplements (including components) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343;

B. Violating 21 U.S.C. § 331(k), by causing dietary supplements (including components) that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343;

C. Violating 21 U.S.C § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352;

D. Violating 21 U.S.C. § 331(k) by causing articles of drug that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352;

E. Violating 21 U.S.C § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i); and

F. Failing to implement and continuously maintain the requirements of this Decree.

12. 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 CGMP Expert, Labeling Expert, Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree. Defendants have violated the Act or its implementing regulations, or additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendant sin writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease receiving, manufacturing, preparing, packing, repacking, labeling, holding, or distributing any and all products;

B. Recall, at Defendants' expense, any product that in FDA's judgment is adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports, plans, procedures, or other records prepared pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

E. Institute or re-implement any of the requirements set forth in this Decree;

F. Issue a safety alert; and/or

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

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

13. Upon receipt of any order issued by FDA pursuant to paragraph 12, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 12 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. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in paragraph 12, at the rates specified in paragraph 16.

14. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' operations and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and all applicable regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to Defendants' places of business including, but not limited to all buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other

material therein; take photographs and make video recordings; take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material; and examine and copy all records relating to the receipt, manufacture, preparing, packing, repacking, labeling, holding, and distribution of any and all of Defendants' products and their 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.

15. Defendants shall promptly provide any information or records to FDA upon request regarding the receipt, manufacture, preparing, packing, repacking, labeling, holding, and distribution of Defendants' products.

16. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $90.65 per hour or fraction thereof per representative for inspection and investigative work; $108.63 per hour or fraction thereof per representative for analytical or review work; $0.54 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 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. Defendants shall make payment in full to FDA within twenty (20) business days of receiving written notification

from FDA of the costs.

17. Within five (5) business days after entry of this Decree, Defendants shall post a copy of this Decree in a conspicuous location in a common area at Defendants' Facility and shall ensure that the Decree remains posted for as long as the Decree remains in effect. Within ten (10) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

18. Within ten (10) business days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all employees, at which they shall describe the terms and obligations of this Decree. Within fifteen (15) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

19. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to 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 that are in the business of manufacturing, preparing, packing, repacking, labeling, holding and/or distributing dietary supplements and/or drug products ("Associated Persons"). Within twenty (20) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this

paragraph, identifying the names, addresses, and positions of all Associated Persons who have received a copy of this Decree, and attaching a copy of the executed certified mail return receipts.

20. 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 shall immediately provide a copy of this Decree, by personal service or certified mail (return receipt requested) to such Associated Person(s). Within five (5) business days of each time that any of the Defendants becomes associated with any additional Associated Person, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of 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, and attaching a copy of the executed certified mail return receipts.

21. Defendants shall notify FDA in writing at least ten (10) business days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of EonNutra, LLC, CDSM, LLC, and/or HAWB, LLC, 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 twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this

paragraph no later than ten (10) business days prior to such assignment or change in ownership.

22. If any Defendant fails to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: seven thousand five hundred dollars ($7,500) in liquidated damages for each day such violation continues; an additional sum of seven thousand five hundred dollars ($7,500) in liquidated damages per day per violation, for each violation of this Decree, the Act, or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail value of any product distributed in violation of this Decree, the Act, or its implementing regulations. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

23. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

24. 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, to the extent that these decisions are subject to review, shall be reviewed by the Court

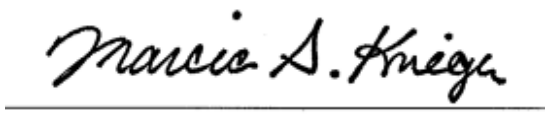
under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

25. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Decree Correspondence" and addressed to the District Director, Denver District Office, U.S. Food and Drug Administration, 6th Avenue and Kipling Street, P.O. Box 25087, Building 20-DFC, Denver, Colorado 80225-0087, and shall reference this civil action by case name and civil action number.

There being full agreement between the parties and all issues having been resolved, the parties' agreement is approved and the Clerk shall close this case.

DATED this 13th day of March, 2017.

BY THE COURT:



Marcia S. Krieger
United States District Court