JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Thursday, November 13, 2014

District Court Enters Permanent Injunction Against California Dietary Supplement Company and Chief Executive Officer to Stop Distribution of Adulterated Products

The U.S. District Court for the Central District of California entered a consent decree of permanent injunction against Scilabs Nutraceuticals Inc. of Irvine, California, and its board chairman and chief executive officer (CEO), Paul P. Edalat, to prevent the distribution of adulterated dietary supplements, the Department of Justice announced today.

SciLabs Nutraceuticals Inc. is a contract manufacturer of dietary supplements distributed under the brand name All Pro Science, including Complete Immune + capsules and various flavored powders called Complete, Recovery and Precharge. The department filed a complaint in the U.S. District Court for the Central District of California at the request of the U.S. Food and Drug Administration (FDA), alleging that the company's dietary supplements are manufactured under conditions that are inadequate to ensure the quality of its products.

In conjunction with the filing of the complaint, the defendants agreed to settle the litigation and be bound by a consent decree of permanent injunction that prohibits them from committing violations of the Federal Food, Drug, and Cosmetic Act. The consent decree requires the dietary supplement manufacturer to cease all operations and requires that, in order for defendants to resume manufacturing dietary supplements, the FDA first must determine that Scilabs' manufacturing practices have come into compliance with the law.

"The failure to comply with current good manufacturing practice requirements by a maker of dietary supplements can pose a risk to the public health," said Acting Assistant Attorney General Joyce R. Branda of the Justice Department's Civil Division. "The Department of Justice will continue to bring enforcement actions against those who do not follow the necessary procedures to comply with the safety laws for dietary supplements."

According to the complaint, FDA inspections performed in 2012, 2013 and 2014 revealed that the company's dietary supplements are adulterated within the meaning of the Food, Drug, and Cosmetic Act. The complaint alleges, for example, that the company failed to conduct at least one appropriate test or examination to verify the identity of every dietary ingredient before using them. The complaint also alleges that the company failed to establish product specifications for the identity, purity, strength and composition of finished batches of dietary supplements. In addition, as alleged in the complaint, defendants failed to document equipment use, maintenance, cleaning and sanitization in individual equipment logs as required by law.

The government is represented by Trial Attorney Heide L. Herrmann of the Civil Division's Consumer Protection Branch, with the assistance of Senior Counsel Claudia Zuckerman of the Food and Drug Division of the U.S. Department of Health and Human Services' Office of General Counsel.

14-1262
Consumer Protection

Civil Division

JOYCE R. BRANDA
Acting Assistant Attorney General
JONATHAN F. OLIN
Deputy Assistant Attorney General
MICHAEL S. BLUME
Director
JEFFREY STEGER
Assistant Director
HEIDE L. HERRMANN
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 Fifth Street, NW, Suite 6400 South
Washington, DC 20530
(202) 532-4882 (phone)
(202) 514-8742 (fax)
Heide.Herrmann@usdoj.gov

Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. SCILABS NUTRACEUTICALS, INC., a corporation, and PAUL P. EDALAT, an individual, Defendants.	Civil No. 8:14-CV-1759 COMPLAINT FOR PERMANENT INJUNCTION

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

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the equitable authority of this Court, to

permanently enjoin against SciLabs Nutraceuticals, Inc., a corporation, and Paul P. Edalat, an individual, (collectively, "Defendants") from: (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 articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and (b) violating 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to be adulterated within the meaning of 21 U.S.C. § 342(g)(1).

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332(a).

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

Defendants

4. Defendant SciLabs Nutraceuticals, Inc., is incorporated under the laws of the state of California. SciLabs Nutraceuticals manufactures, prepares, packs, labels, holds, and distributes dietary supplements. SciLabs Nutraceuticals does business at 17809 Gillette Avenue, Irvine, California, within the jurisdiction of this court.

5. Defendant Paul P. Edalat is Chairman of the Board and Chief Executive Officer of SciLabs Nutraceuticals. Mr. Edalat is the most responsible person at the firm. He has ultimate authority over all of the firm's operations, including, but not limited to, product quality, financial decisions, hiring and firing personnel, and product marketing and sales. Defendant Paul P. Edalat performs his duties at SciLabs Nutraceuticals, 17809 Gillette Avenue, Irvine, California, within the jurisdiction of this court.

6. Defendants have been and are now engaged in the business of manufacturing, preparing, packing, labeling, holding, and distributing dietary supplements, within the meaning of 21 U.S.C. § 321(ff). They are contract manufacturers of dietary supplement products distributed under the brand name All Pro Science, including Complete Immune + capsules and variously flavored powders called Complete, Recovery, and Precharge. Except for the purposes of 21 U.S.C. §§ 321(g) and 350f, dietary supplements are deemed to be food under the Act. 21 U.S.C. § 321(ff).

7. Defendants manufacture their dietary supplements using components shipped to them from locations outside the state of California, including Wisconsin, Illinois, and New Jersey. Defendants distribute their dietary supplements to All Pro Science, Inc., which distributes them to locations outside the state of California, such as Oregon, Arizona, Utah, Oklahoma, and Illinois. All Pro Science holds Defendants' dietary supplements in leased warehouse space in SciLabs Nutraceuticals' facility. Defendant Edalat is the director and a shareholder of All Pro Science.

Defendants' Violations of the Act

8. The Act requires manufacturers of dietary supplements to operate in compliance with current good manufacturing practice for dietary supplements ("Dietary Supplement 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 assure a finished product of acceptable, predictable, and reliable quality. Dietary supplements not manufactured, prepared, packed, and held in conformance with Dietary Supplement CGMP 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.

9. FDA conducted an inspection of Defendants' facility on January 21, 22, 29, and February 4, 2014. That inspection established that the dietary supplements Defendants manufacture, prepare, pack, label, hold, and distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they are prepared, packed, or held in a manner that does not conform to Dietary Supplement CGMP. FDA investigators documented many significant deviations, which include, but are not limited to, the following:

(A) Failure to 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);

(B) Failure to determine whether component specifications that must be established in accordance with 21 C.F.R. § 111.70(b) are met before using such component, as required by 21 C.F.R. § 111.75(a)(2);

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

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

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

(F) Failure to document equipment use, maintenance, cleaning, and sanitization in individual equipment logs, as required by 21 C.F.R. § 111.35(b)(2); and

(G) Failure to establish and follow written procedures for the responsibilities of the quality control operations set forth in 21 C.F.R. § 111.105, as required by 21 C.F.R. § 111.103.

10. 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), in that they have been prepared, packed, or held under conditions that do not meet Dietary Supplement CGMP, 21 C.F.R. Part 111.

11. Defendants also violate 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.

Previous Violations

12. Defendants have previously violated the Act. Several of the Dietary Supplement CGMP deviations observed during the most recent inspection (referenced in Paragraph 9 above) are the same as, or similar to, those observed by FDA during a previous inspection of Defendants' facility on September 17-20, 25, and October 25, 2013. For example, FDA documented Defendants' failure to 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) (the same as Paragraph 9(A) above). FDA also documented Defendants' failure to determine whether component specifications that must be established in accordance with 21 C.F.R. § 111.70(b) are met before using such component, as required by 21 C.F.R. § 111.75(a)(2) (the same as Paragraph 9(B) above). In addition, FDA documented Defendants' failure to verify that finished batches of dietary supplements meet product specifications for identity, purity, strength, and composition, as required by 21 C.F.R.

§ 111.75(c) (similar to Paragraph 9(C) above). Further, FDA documented the following deviations, all of which were subsequently observed during the January/February 2014 at Defendants' facility: failure to prepare and follow a complete written master manufacturing record for each unique formulation of a dietary supplement, and for each batch size, to ensure uniformity in the finished product from batch to batch; failure to prepare a batch production record for each batch of a dietary supplement that contains complete information relating to the production and control of the batch; and, failure to establish and follow written procedures for the responsibilities of the quality control operations set forth in 21 C.F.R. § 111.105.

13. FDA also inspected Defendants' facility on July 31 and August 1, 2, 14, 2012, and documented the following deficiencies, all of which were subsequently observed during FDA's September/October 2013 inspection described in Paragraph 12 above: failure to conduct at least one appropriate test or examination to verify the identity of every component that is a dietary ingredient before using such component; failure to determine whether component specifications that must be established in accordance with 21 C.F.R. § 111.70(b) are met before using such component; failure to verify that finished batches of dietary supplements meet product specifications for identity, purity, strength, and composition; failure to prepare and follow a complete written master manufacturing record for each unique formulation of a dietary supplement, and for each batch size, to ensure uniformity in the finished product from batch to batch; and, failure to prepare a batch production record for each batch of a dietary supplement that contains complete information relating to the production and control of the batch.

14. FDA has warned Defendants about their ongoing Dietary Supplement CGMP violations. At the close of the January/February 2014 inspection, FDA investigators issued a List of Inspectional Observations ("Form FDA-483") to, and discussed each of the observed

deviations with, Defendant Edalat. FDA investigators also issued a Form FDA-483 to Defendant Edalat at the close of the September/October 2013 inspection and discussed each observation with him. In addition, FDA investigators issued a Form FDA-483 to the firm's management at the close of the July/August 2012 inspection. After each inspection, Defendants responded to FDA in writing, promising to take corrective action to ensure that they would come into compliance with Dietary Supplement CGMP.

15. Following the July/August 2012 inspection, FDA issued a Warning Letter to Defendants on January 25, 2013, detailing violations of the Dietary Supplement CGMP regulations observed during the inspection. All of the CGMP violations described in the letter are the same as, or similar to, the violations FDA observed in the September/October 2013 inspection. The Warning Letter emphasized the serious nature of the violations. The Warning Letter also stated that it was Defendants' responsibility to ensure compliance with the Act and its implementing regulations and that failure to take prompt action to correct the violations may result in legal action, including injunction.

16. Defendants responded in writing to the Warning Letter with promises to correct their Dietary Supplement CGMP violations. However, Defendants either did not follow through on their promises to correct or failed to fully correct the Dietary Supplement CGMP violations, as shown by the FDA investigators' observation and documentation of ongoing, significant CGMP deficiencies during the September/October 2013. In response to the CGMP deficiencies documented during the September/October 2013 inspection, Defendants again responded in writing with similar promises to take corrective action. Once more, Defendants failed to come into compliance with Dietary Supplement CGMP requirements, as FDA documented during the January/February 2014 inspection at Defendants' facility.

17. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons in active concert or participation with any of them, cease receiving, manufacturing, preparing, packing, labeling, holding, or distributing dietary supplements, unless and until Defendants' methods, facilities, and controls used to receive, manufacture, prepare, pack, label, hold, and distribute dietary supplements are established, operated, and administered in conformity with Dietary Supplement CGMP and the Act, in a manner that has been found 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 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 for introduction, or causing to be introduced or delivered or 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(k), by causing dietary supplements that Defendants hold for sale after shipment of one or more of their components in interstate commerce to be adulterated within the meaning of 21 U.S.C. § 342(g)(1);

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, preparing, packing, labeling, holding, and distribution of all of Defendants' products to ensure continuing

compliance with the terms of the injunction, 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 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 __4th__ day of __November_, 2014.

Respectfully submitted,

JOYCE R. BRANDA
Acting Assistant Attorney General
JONATHAN F. OLIN
Deputy Assistant Attorney General
MICHAEL S. BLUME
Director
JEFFREY I. STEGER
Assistant Director

_/s/ Heide L. Herrmann_____
HEIDE L. HERRMANN
Trial Attorney
Consumer Protection Branch
Department of Justice
Civil Division
450 Fifth Street, NW, Suite 6400 South
Washington, D.C. 20530
(202)532-4882 (phone)
(202) 514-8742 (fax)
Heide.Herrmann@usdoj.gov

OF COUNSEL:
WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

CLAUDIA J. ZUCKERMAN
Senior Counsel
Office of the Chief Counsel

Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 31, Room 4550
Silver Spring, MD 20993-0002
301-796-8609

JS-6

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. SCILABS NUTRACEUTICALS, INC., a corporation, and PAUL P. EDALAT, an individual, Defendants.	Case No.: SACV 14-01759-JLS (ANx) **CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Permanent Injunction against Scilabs Nutraceuticals, Inc., a corporation, and Paul P. Edalat, an individual (collectively, "Defendants"), and Defendants, without admitting or denying the allegations in the Complaint, and disclaiming any liability in connection therewith, 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 and 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 *et seq.* (the "Act").

3. The Complaint alleges that 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 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"), as set forth in 21 C.F.R. Part 111.

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to be adulterated within the meaning of 21 U.S.C. § 342(g)(1).

5. 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 equitable authority of this Court, from directly or indirectly manufacturing, preparing, packing, labeling, holding, or distributing any dietary supplements, at 17809 Gillette Avenue, Irvine, California 92614-6501, or at or from any other locations at which Defendants now, or in the future, directly or indirectly manufacture, prepare, pack, repack, label hold, and/or distribute dietary supplements ("the facility"), unless and until:

A. 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/or their families, and who, by reason of background, training, education, or experience, is qualified to inspect Defendants' facility to determine whether the facility, 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 Expert within three (3) business days of retaining such expert;

B. The Expert performs a comprehensive inspection of Defendants' facility and the methods and controls used to manufacture, prepare, pack, label, and hold dietary supplements, and certifies in writing to FDA that: he or she has inspected Defendants' facility, methods, processes, and controls; all Dietary Supplement CGMP deviations brought to Defendants' attention by FDA, the Expert, and any other source have been, in the Expert's opinion, corrected; and, Defendants' facility and the methods and controls used to manufacture, prepare, pack, label, and hold dietary supplements are, in the Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. The 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) 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);

(2) Determine whether component specifications that must be established in accordance with 21 C.F.R. § 111.70(b) are met before using such component, as required by 21 C.F.R. § 111.75(a)(2);

(3) 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 the dietary supplement are met; and limits on those types of contamination that may 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);

(4) Establish in-process specifications for any point, step, or stage in the master manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the dietary supplements and, as necessary, for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement, as required by 21 C.F.R. § 111.70(c)(1);

(5) Establish product specifications for the identity, purity, strength, and composition of the finished batch of the dietary supplement, and for limits on those types of contamination that may adulterate, or that may lead to adulteration of, the finished batch of the dietary supplement to ensure its quality, as required by 21 C.F.R. § 111.70(e);

(6) Determine, in the manner specified by 21 C.F.R. § 111.75(c), 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);

(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 from batch to batch, as required by 21 C.F.R. §§ 111.205 and 111.210;

(8) Prepare and maintain a 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) Document, in individual equipment logs or within the batch record, equipment use, maintenance, cleaning, and sanitization, as required by 21 C.F.R. §§ 111.35(b)(2) and 111.260(c); and

(10) Establish and follow written procedures for the responsibilities of the quality control operations set forth in 21 C.F.R. § 111.105, as required by 21 C.F.R. § 111.103;

C. Defendants recall and destroy in accordance with the procedures provided in paragraph 6 all dietary supplements that were manufactured, prepared, packed, labeled, held or distributed between August 1, 2012, and the date of entry of this Decree;

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

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

(2) ensure that the methods 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 Dietary Supplement CGMP;

E. As and when FDA deems necessary, FDA representatives inspect Defendants' facility 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;

F. Defendants have paid all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews with respect to paragraph 5, at the rates set forth in paragraph 13; and

G. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in paragraphs 5(A)-(D) and (F) of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

6. Within fifteen (15) business days after entry of this Decree, Defendants, under FDA's supervision, shall destroy all dietary supplements in Defendants' possession, custody, or control, excluding reserve samples retained under 21 C.F.R. 111.83, which shall be held in accordance with the requirements of 21 C.F.R. 111.83(b). Defendants shall bear the costs of destruction and the costs of FDA's supervision. Defendants shall not dispose of any dietary supplements 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 dietary supplements are disposed.

7. Upon resuming operations after complying with paragraphs 5(A)-(D) and (F), and receiving FDA's written notification pursuant to paragraph 5(G), Defendants shall retain an independent person or persons (hereinafter, the "Auditor") who shall meet the criteria described in paragraph 5(A) to conduct audit inspections of Defendants' facility 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 5(G). If Defendants choose, the Auditor may be the same person or persons retained as the Expert described in paragraph 5(A).

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 Dietary Supplement CGMP and identifying any deviations from such requirements ("Audit Report Observations"). As a part of every 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 ten (10) 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.

B. If an Audit Report contains any observations indicating that Defendants' dietary supplements are not in compliance with the Dietary Supplement CGMP, 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 deviations 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. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor. Within twenty (20) business days after the Auditor's receipt of Defendants' documentation of corrections, 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 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.

8. Upon entry of this Decree, and after receiving FDA's written notification pursuant to paragraph 5(G), 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 articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1);

B. Violating 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to be adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

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

9. 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 Defendants have failed to comply with any provision of this Decree, have violated the Act, or its implementing regulations, or that 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 Defendants in 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 manufacturing, preparing, packing, labeling, holding, or distributing any or all dietary supplements;

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

C. Revise, modify, expand, or continue to submit any reports or plans 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.

10. The following process and procedures shall apply if FDA issues an order pursuant to paragraph 9:

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such an order, Defendants shall notify FDA in writing either that:

(i) Defendants are undertaking or have undertaken corrective action, in which event Defendant shall describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or

(ii) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable) and may bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to implement and comply with FDA's order, unless and until the Court stays, reverses, or modifies FDA's order. Any judicial review of FDA's order under this paragraph shall be made in accordance with the terms set forth in paragraph 22 of this Decree.

D. The process and procedures set forth above in paragraphs 10(A)-(C) shall not apply to any order issued pursuant to paragraph 9 if such an order states that, in FDA's judgment, the matter raises a significant public health concern. In such case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition the Court for relief while they implement FDA's order. Any judicial review of FDA's order under this paragraph shall be made in accordance with the terms set forth in paragraph 22 of this Decree.

11. Any cessation of operations or other action described in paragraph 9 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 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 9, at the rates specified in paragraph 14.

12. 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 manufacture, preparing, packing, 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.

13. Defendants shall promptly provide any information or records to FDA upon request regarding the manufacturing, preparing, packing, labeling, holding, and distribution of Defendants' food (dietary supplement) products.

14. 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: $88.45 per hour or fraction thereof per representative for inspection and investigative work; $106.03 per hour or fraction thereof per representative for analytical or review work; $0.56 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.

15. 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 at any other location at which Defendants manufacture, prepare, pack, label, hold, or distribute articles of food, including dietary supplements, 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.

16. Within ten (10) business days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all employees who, directly or indirectly, manufacture, prepare, pack, label, hold, or distribute any dietary supplement, 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.

17. 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 in the manufacturing, preparing, packing, labeling, holding, or distributing any dietary supplement ("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 and positions of all persons who have received a copy of this Decree, and attaching copies of proof of service.

18. 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 and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching copies of proof of service.

19. Defendants shall notify FDA in writing at least ten (10) business days before any of the following events occur: any corporate reorganization, relocation, dissolution, bankruptcy, assignment or sale or any other change in the structure or identity of the business, the creation or dissolution of subsidiaries, 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.

20. Should any defendant fail 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, and/or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail value of any distributed dietary supplements that are adulterated or otherwise 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.

21. 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), travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

22. 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.

23. 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, Los Angeles District Office, United States Food and Drug Administration, 19701 Fairchild, Irvine, California 92612-2506, and shall reference this civil action by case name and civil action number.

24. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

25. If Defendants petition the Court for relief from this Decree and, at the time of the petition, in FDA's judgment, Defendants have maintained a state of continuous compliance with

this Decree, the Act, and all applicable regulations for the preceding sixty (60) months, the United States will not oppose such petition.

26. 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:

Dated: November 12, 2014

Honorable Josephine L. Staton
United States District Judge