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IN THE UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

APPLIED POLYMER SYSTEMS, INC., D/B/A APS PHARMACO, a corporation, and NUKA V. REDDY, an individual,
Defendants.

COMPLAINT FOR PERMANENT INJUNCTION

CIVIL ACTION NO._____

CV 14 4935

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:

BIANCO, J.
WALL, M.J.

1. This statutory injunction proceeding is brought by the United States of America pursuant to 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 Applied Polymer Systems, Inc., d/b/a APS Pharmaco, a corporation, and Nuka V. Reddy, 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)(l); 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 21U.S.C. § 342(g)(l).

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 Applied Polymer Systems, Inc., d/b/a APS Pharmaco, is incorporated under the laws of the state of New York. Applied Polymer Systems manufactures, prepares, packs, labels, holds, and distributes dietary supplements. Applied Polymer Systems does business at 200 Bangor Street, Lindenhurst, New York, within the jurisdiction of this court.

5. Defendant Nuka V. Reddy is the president of Applied Polymer Systems. Mr. Reddy has ultimate authority over all of the firm's operations, including, but not limited to, manufacturing, preparing, packing, labeling, holding, and distributing Applied Polymer Systems' dietary supplement products. He is also the most responsible individual for the firm's day-to-day operations. Defendant Nuka V. Reddy performs his duties at Applied Polymer Systems, 200 Bangor Street, Lindenhurst, New York, 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). Such products are in capsule, tablet, or powder forms and include Ultimate Joint, Forza, and Nitrobol. 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 New York, including New Jersey. Defendants distribute their dietary supplements in interstate commerce to locations outside the state of New York, such as Florida and Oregon.

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)(l). 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)(l). The Dietary Supplement cGMP regulations are set forth at 21 C.F.R. Part 111.

9. FDA conducted an inspection of Defendants' facility on March 7-8, 12, and 14, 2013. 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)(l), in that they are prepared, packed, or held in a manner that does not conform to Dietary Supplement cGMP. An FDA investigator 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)(l)(i);

(B) Failure to use adequate methods 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 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 dietary supplements, as required by 21C.F.R. § 111.70(c)(1);

(E) Failure to establish specifications for dietary supplement labels and for packaging that may come in contact with dietary supplements, as required by 21 C.F.R.§ 111.70(d);

(F) Failure to include in the master manufacturing record a description of packaging and a representative label, or a cross-reference to the physical location of the actual or representative label, as required by 21 C.F.R. § 111.210(g);

(G) Failure to establish written procedures for maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture dietary supplements, as required by 21 C.F.R. § 111.25(c); and

(H) Failure to make and keep written documentation, at the time of performance, that quality control personnel performed the review, approval or rejection requirements set forth in 21 C.F.R. § 111.120(e) (requiring approval and release of .all components, packaging, and labels before they are used) by recording the date that the review, approval, or rejection was performed and the signature of the person performing that activity, as required by 21 C.F.R. § 111.140(b)(2).

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)(l), 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)(l), 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

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 an inspection of Defendants' facility on May 7, 10, and 14, 2012. 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)(l)(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. § (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).

12. FDA has warned Defendants about their ongoing Dietary Supplement cGMP violations. At the close of the March 2013 inspection, an FDA investigator issued a List of Inspectional Observations ("Form FDA-483") to, and discussed each of the observed deviations with, Defendant Reddy. Defendants responded to FDA in writing with promises to correct the Dietary Supplement cGMP violations. In addition, at the close of the May 2012 inspection, FDA investigators issued a Form FDA-483 to Defendant Reddy

13. Following the May 2012 inspection, FDA issued a Warning Letter to Defendants on September 27, 2012, detailing violations of the Dietary Supplement cGMP regulations observed during the inspection. Several of the violations described in the letter are the same as, or similar to, the violations FDA observed in its March 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.

14. 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 investigator's observation and documentation of ongoing, significant Dietary Supplement cGMP violations during the March 2013 inspection at Defendants' facility.

15. 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 oftheir 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;

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, 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)(l); 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)(l);

II. 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

III. 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 21st day of July, 2014.

Respectfully submitted,

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