UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

CONFIDENCE U.S.A. INC.,
HELEN CHIAN, and JIM CHAO,

Defendants.

COMPLAINT

Case No.

CV19 3073
AZRACK, J.

LOCKE, M. J.

Plaintiff, the United States of America ("Plaintiff" or the "United States"), on behalf of the United States Food and Drug Administration ("FDA"), by and through their attorney, Richard P. Donoghue, United States Attorney for the Eastern District of New York, as and for its Complaint against defendants Confidence U.S.A., Inc. ("Confidence"), Helen Chian ("Chian"), and Jim Chao ("Chao") (collectively, the "Defendants"), alleges as follows:

INTRODUCTION

1. This is a statutory injunction proceeding brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, seeking to permanently enjoin 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, as defined by 21 U.S.C. § 321(ff)) 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, as defined by 21 U.S.C. § 321(ff)) that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

THE PARTIES

2. Plaintiff is the United States of America. Through the FDA, the United States protects the public health by, *inter alia*, ensuring the safety of the U.S. food supply, including assessing dietary supplements for safe and proper labeling, and ensuring the safety and efficacy of human and veterinary drugs.

3. Defendant Confidence is a corporation organized and existing under the laws of the state of New York. Confidence manufactures and distributes over fifty dietary supplements under brand names including Confidence USA, American Best, USA Natural, and The Herbal Store. Confidence does business at 138 Haven Avenue, Suite 101, Port Washington, New York (the "Port Washington Facility"), within the jurisdiction of this Court. Confidence also has a facility at 152 Haven Avenue, Port Washington, New York, which it uses to store packaging components.

4. At all times relevant to this action, defendant Chian has been and is Confidence's President and Chief Executive Officer, and is the most responsible person at Confidence. Chian performs her duties at the Port Washington Facility, within the jurisdiction of this Court.

5. At all times relevant to this action, defendant Chao has been and is Confidence's Vice President and General Manager, overseeing Confidence's day-to-day operations, including production and manufacturing operations, research and development, sales, marketing and advertising, and employee hiring. Chao also owns The Herbal Store, a retail store located within the jurisdiction of this Court at 42-35 Main Street, Unit 1C, Flushing, New York. The Herbal Store sells products manufactured by Confidence and is the exclusive retailer of The Herbal Store brand products. Chao has performed, and continues to perform, his duties at the Port Washington Facility, within the jurisdiction of this Court.

JURISDICTION AND VENUE

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

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

FACTS

8. Defendants have been and are now engaged in the business of manufacturing and distributing "dietary supplements," which is defined by the Act as "a product (other than tobacco) intended to supplement the diet" that contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of any of them. 21 U.S.C. § 321(ff). In addition, a dietary supplement must be "labeled as a dietary supplement" and must not be "represented for use as a conventional food or as a sole item of a meal or the diet." *Id.* With exceptions not relevant here, dietary supplements are deemed to be food under the Act. *Id.*

9. Defendants receive raw materials that they use to manufacture their dietary supplements from outside the state of New York. Defendants distribute their dietary supplements to customers both within and outside the state of New York.

Defendants' Dietary Supplement CGMP Violations

10. The Act requires dietary supplement manufacturers to operate in compliance with current good manufacturing practices 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 ensure a finished product of acceptable, predictable, and reliable quality. Dietary supplements

not manufactured, prepared, packed, or 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 and apply to any person who manufactures, packages, labels, or holds dietary supplements.

11. Numerous FDA inspections demonstrate that Defendants repeatedly failed, and continue to fail, to comply with CGMP for dietary supplements, rendering Defendants' products adulterated pursuant to 21 U.S.C. § 342(g)(1). Defendants, therefore, violate 21 U.S.C. § 331(a) by introducing adulterated dietary supplements into interstate commerce, and violate 21 U.S.C. § 331(k) by causing dietary supplements to become adulterated while held for sale after shipment of one or more of their component ingredients in interstate commerce.

Defendants' Most Recent Dietary Supplement CGMP Violations

12. FDA investigators most recently inspected Defendants' Port Washington Facility between July 2018 and August 2018 (the "2018 inspection"), which inspection revealed that the dietary supplements Defendants distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), because they are prepared, packed, or held in a manner that does not conform to Dietary Supplement CGMP. FDA investigators documented significant deviations from the Dietary Supplement CGMP regulations, including, but not limited to:

A. Failure to verify the identity of each dietary component used in the manufacture of a dietary supplement prior to its use, as required by 21 C.F.R. § 111.75(a)(1)(i). Specifically, Confidence failed to conduct appropriate tests to verify the identity of ingredients used in a number of its products. The same violation was observed in 2017, 2016, 2012, and 2010.

B. Failure to verify that finished dietary supplement batches met product specifications for identity, purity, strength, composition, and contamination limits, as required by 21 C.F.R. § 111.75(c). Specifically, the finished product specifications for some Confidence products did not contain finished product testing to verify the presence of all dietary ingredients in each finished batch of products. The same or similar violations were observed in 2017, 2016, 2012, and 2010.

C. Failure to verify that the laboratory examination and testing methodologies are appropriate for their intended use, as required by 21 C.F.R. § 111.320. Specifically, Defendants' finished product assay testing results on products manufactured between March 2016 and October 2017 identified several instances where the tested components failed specifications. These failures demonstrate the inadequacy of Defendants' rotational testing plan, and that Defendants do not have scientifically valid support for their rotational testing plan to ensure that it is appropriate for its intended use.

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

E. Failure to establish and follow written procedures for quality control operations, as required by 21 C.F.R. § 111.103.

F. Failure to establish and follow laboratory control processes that are reviewed and approved by quality control personnel, as required by 21 C.F.R. § 111.315.

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

within the meaning of 21 U.S.C. § 342(g)(1), because they have been prepared, packed, or held under conditions that do not meet Dietary Supplement CGMP, 21 C.F.R. Part 111.

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

History

15. FDA conducted inspections at Confidence's Port Washington Facility in 2010, 2012, 2016, 2017 and 2018. In each of these five inspections, FDA observed Defendants' significant and ongoing violations of the Dietary Supplement CGMP regulations.

16. After each of the five inspections, FDA warned Defendants about their ongoing violations.

17. For example, on November 2, 2010, after the October 25 – November 2, 2010 inspection, FDA issued a List of Inspectional Observations ("Form FDA-483") to Confidence.

18. Following an initial inadequate response from Defendants, FDA issued a Warning Letter to Defendant Chian on July 7, 2011. On July 15, 2011, Confidence submitted a written response to that Warning Letter that promised corrective action.

19. However, when FDA re-inspected the Port Washington Facility on January 10, 2012 to January 26, 2012 and again on July 9, 2012 to July 13, 2012, the investigators documented ongoing Dietary Supplement CGMP violations and issued Forms FDA-483 to Defendants Confidence and Chian on both occasions. Although Defendants again submitted written responses following each of these inspections promising corrective action, they failed to adequately implement corrective actions necessary to address the violations.

20. As a result of the repeated and ongoing violations, in September 2012, FDA initiated an *in rem* seizure of approximately $60,000 worth of adulterated and/or misbranded Confidence products. Defendants did not file a claim and instead, submitted written responses to FDA promising corrective action. The court entered a default judgment against the seized articles on September 13, 2013. However, when U.S. Marshals attempted to execute the order and destroy the products, the products were missing from the Confidence facility where they had been seized in place. Confidence claimed to have destroyed the products but could present no evidence of the destruction.

21. When FDA inspected the Port Washington Facility on March 23, 2016 – April 12, 2016, investigators again found Dietary Supplement CGMP violations. Moreover, FDA learned that Confidence had expanded its operations to include manufacturing as well as distribution, had introduced a new product line, and had opened two retail store locations in New York.

22. At the close of the April 2016 inspection, FDA issued a Form FDA-483 to Confidence and Defendant Chao, who again submitted multiple written responses to FDA promising corrective action. Their proposed corrective action, however, was inadequate to address the ongoing and significant CGMP violations that FDA identified.

23. During FDA's most recent inspections on December 16, 2016 – January 12, 2017 and July 5, 2018 – August 10, 2018, FDA investigators documented numerous significant violations of the Dietary Supplement CGMP regulations. Several of these violations were the same as or similar to violations observed during inspections in 2016, 2012, and 2010.

24. 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.

CAUSE OF ACTION
CLAIM FOR PERMANENT INJUNCTION

25. Plaintiff repeats and incorporates paragraphs 1-24 above as if fully set forth herein.

26. 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), because they have been prepared, packed, or held under conditions that fail to conform with the Dietary Supplement CGMP regulations, 21 C.F.R. Part 111.

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

28. Defendants' history of Dietary Supplement CGMP violations and failure to take adequate corrective action demonstrate that there is a reasonable likelihood of recurrence and that Defendants will continue to violate the Act, unless Plaintiff's requested injunction is granted.

29. Upon a showing that the Defendants are violating 21 U.S.C. § 331, the United States may obtain a permanent injunction enjoining such violations. 21 U.S.C. § 332(a).

30. As a result of the foregoing, Defendants' conduct should be enjoined pursuant to 21 U.S.C. § 332.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests that, pursuant to 21 U.S.C. § 332(a) and the inherent equitable authority of the Court, that the Court issue an Order and Final Judgment, ordering:

I. Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, to cease receiving, manufacturing, preparing, packing, repacking, labeling, holding, or distributing dietary supplements, unless and until the Defendants' facilities, methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements are established, operated, and administered in conformity with the Dietary Supplement CGMP regulations and the Act, in a manner acceptable to FDA;

II. Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, to 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 for introduction into interstate commerce, articles of food (including but not limited to dietary supplements and their components) 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 (including but not limited to dietary supplements and their components) that are held for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

III. 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 injunction, and that the Defendants bear the costs of such inspections at the rates prevailing at the time of the inspection(s) are accomplished;

IV. that the United States be awarded costs incurred in pursuing this action, including the costs of investigation to date; and

V. such other and further relief as this Court may deem just and proper.

Dated: May 23, 2019
Central Islip, NY

Respectfully submitted,

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