UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

NOT FOR PUBLICATION

UNITED STATES OF AMERICA,
Plaintiff,

– against –

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

Defendants.

19–CV–3073 (ERK) (SIL)

KORMAN, *J.*:

ORDER OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Permanent Injunction and a Motion for Summary Judgment against Confidence U.S.A. Inc. ("Confidence"), a corporation, and Helen Chian and Jim Chao, individuals (collectively, "Defendants"), and Defendants having appeared and it having been shown that Defendants are violating, and unless restrained by order of this Court, will continue to violate the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. §§ 301 *et seq*.;

IT IS HEREBY ORDERED 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 Act, 21 U.S.C. §§ 301 *et seq*.

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 adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held in violation of the current good manufacturing practice regulations for dietary supplements ("Dietary Supplement CGMP"), set forth in 21 C.F.R. Part 111.

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).

5. 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 Order 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 receiving, manufacturing, preparing, packing, repacking, labeling, holding, or distributing any articles of food (including but not limited to dietary supplements and their components) at or from 138 Haven Avenue, Suite 101, Port Washington, New York, or 152 Haven Avenue, Port Washington, New York, or at or from any other

location(s) at which Defendants now or in the future directly or indirectly receive, manufacture, prepare, pack, repack, label, hold, or distribute any articles of food (including but not limited to dietary supplements and their components) ("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 after 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 Order, 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 the identity, purity, strength, and composition of the finished batch of dietary supplements, as required by 21 C.F.R. § 111.70(e);

2) Verify that finished dietary supplement batches meet product specifications for identity, purity, strength, composition, and contamination limits, as required by 21 C.F.R. § 111.75(c);

3) Document any product specifications that are determined to be exempt from the verification requirements of 21 C.F.R. § 111.75(c), by documenting that these specifications cannot verify that the production and process control system will produce a dietary supplement that meets the specifications, and by documenting the lack of scientifically valid methods for testing or examining the product specifications at the finished batch stage, as required by 21 C.F.R. § 111.75(d);

4) Conduct at least one appropriate test or examination to verify the identity of each dietary ingredient, as required by 21 C.F.R. § 111.75(a)(1)(i);

5) Establish and follow written procedures for quality control operations, as required by 21 C.F.R. § 111.103;

6) Establish and follow laboratory control processes that are reviewed and approved by quality control personnel, as required by 21 C.F.R. § 111.315; and

7) Verify that laboratory examination and testing methodologies are appropriate for their intended use, as required by 21 C.F.R. § 111.320;

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

1) Correct the Dietary Supplement CGMP violations brought to Defendants' attention by FDA, the CGMP Expert, or any other source; and

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;

D. 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 Order have been met and whether Defendants are operating in conformity with the Act, its implementing regulations, and this Order;

E. 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 12; and

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

6. Upon resuming operations after complying with paragraphs 5(A)-(C) and (E), and receiving FDA's written notification pursuant to paragraph 5(F), Defendants shall retain an independent person (the "Auditor") who shall meet the criteria for, and may be the same person as, the CGMP Expert described in paragraphs 5(A), 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. 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 5(F).

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 Order, 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 any 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 (20) 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 FDA-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.

7. Upon entry of this Order, and after receiving FDA's written notification pursuant to paragraph 5(F), 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 (including but not limited to dietary supplements and their components) 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 (including but not limited to dietary supplements and their 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); and

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

8. If, at any time after entry of this Order, 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, Auditor, or any other information, that Defendants have failed to comply with any provision of this Order, Defendants have violated the Act or its implementing regulations, or additional corrective actions are necessary to achieve compliance with this Order, 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 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 or otherwise in violation of this Order, 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 Order;

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

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

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 Order, 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 Order or under the law.

9. Upon receipt of any order issued by FDA pursuant to paragraph 8, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 8 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Order, 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 8, at the rates specified in paragraph 12.

10. 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 Order, 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 Order and appropriate credentials. The inspection authority granted by this Order is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

11. 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.

12. 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 Order at the standard rates prevailing at the time the costs are incurred. As of the date that this Order is signed by the parties, these rates are: $97.57 per hour or fraction thereof per representative for inspection and investigative work; $132.89 per hour or fraction thereof per representative for analytical or review work; $0.58 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.

13. Within five (5) business days after entry of this Order, Defendants shall post a copy of this Order in a conspicuous location in a common area at Defendants' Facility and shall ensure that the Order remains posted for as long as the Order remains in effect. Within ten (10) business days after entry of this Order, 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.

14. Within ten (10) business days after entry of this Order, 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 Order. Within fifteen (15) business days after entry of this Order, 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.

15. Within ten (10) business days after entry of this Order, Defendants shall provide a copy of the Order 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 ("Associated Persons"). Within twenty (20) business days after entry of this Order, 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 Order, and attaching a copy of the executed certified mail return receipts.

16. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Order, Defendants shall immediately provide a copy of this Order, 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 Order pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

17. 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 Order, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Confidence U.S.A. Inc., or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Order. Defendants shall provide a copy of this Order 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.

18. If any Defendant fails to comply with any provision of this Order, the Act, or its implementing regulations, including any time frame imposed by this Order, 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 Order, 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 Order, 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.

19. Should the United States bring and prevail in a contempt action to enforce the terms of this Order, 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.

20. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Order 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 Order 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.

21. All notifications, correspondence, and communications to FDA required by the terms of this Order shall be prominently marked "Order Correspondence" and addressed to the District Director, New York District Office, U.S. Food and Drug Administration, 158-15 Liberty Avenue, Room 4050, Jamaica, NY 11433, and shall reference this civil action by case name and civil action number.

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

SO ORDERED.

Edward R. Korman
Edward R. Korman
United States District Judge

Brooklyn, New York
March 3, 2021