UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

CUSTOMPAX, INC., a corporation, and CEDRIC P. LING, an individual,

Defendant.

Case No.: 5:17-cv-05269-SVK

~~[PROPOSED]~~ STIPULATED CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, United States of America, by its undersigned attorneys having filed a Complaint for Permanent Injunction ("Complaint") against Custompax Inc. ("Custompax" or the "firm"), a corporation, and Cedric P. Ling (collectively, "Defendants") and Defendants without admitting or denying the allegations in the complaint, having appeared and consented to the entry of this Consent Decree of Permanent Injunction (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 of this action and has personal jurisdiction over all parties to this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 332. Venue is proper in this district under 21 U.S.C. § 1391(b) and (c).

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399f (the "Act"), including that:

A. Defendants violate 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce 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, and held under conditions that do not comply with the current

good manufacturing practice regulations for dietary supplements ("Dietary Supplement CGMP"), see 21 C.F.R. Part 111; and

B. Defendants violate 21 U.S.C. § 331(k) by causing 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), in that they have been prepared, packed, and held under conditions that do not comply with the Dietary Supplement CGMP, see 21 C.F.R. Part 111.

3. Upon entry of this Decree, Defendants represent to the Court that Defendants are not directly or indirectly engaged in manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any dietary supplements in interstate commerce. If Defendants later intend to resume any such operations at 40963 Encyclopedia Circle, Fremont, CA, 94538 or any other location (collectively, "Defendants' facility"), Defendants must first notify FDA in writing at least ninety (90) calendar days in advance of resuming operations and comply with Paragraphs 4(A)-(G) of this Decree. This notice shall identify the type(s) of dietary supplements Defendants intend to manufacture, prepare, process, pack, label, hold, and/or distribute, and the location at which Defendants intend to resume operations. Defendants shall not resume operations until FDA has inspected Defendants' facility and operations pursuant to Paragraph 4(E), Defendants have paid all costs pursuant to Paragraph 4(F), and Defendants have received written notice from FDA, as required by Paragraph 4(G), and then shall resume operations only to the extent authorized in FDA's written notice.

4. 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 who receive actual notice of this Decree by personal service or otherwise (collectively, "Associated Persons"), are permanently restrained and enjoined under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from introducing or delivering for introduction, and/or causing to be introduced or delivered, into interstate commerce any dietary supplement from or at Defendants' facility, directly or indirectly receive, prepare, process, manufacture, label, pack, hold, and/or distribute dietary supplements unless and until all of the following occur:

A. Defendants retain, at Defendants' expense, an independent person or persons (the "Expert"), who is without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants or their families, and who by reason of background, experience, education, and training, 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 as soon as they retain such expert;

B. The Expert performs a comprehensive inspection of Defendants' facility and the methods and controls used to manufacture, prepare, pack, label, hold, and distribute dietary supplements, and certifies in writing to FDA that (1) he or she has inspected Defendants' facility, methods, processes, and controls; and (2) whether Defendants' operations are, in the Expert's opinion, in compliance with 21 U.S.C. § 342(g)(1), 21 C.F.R. Part 111, and this Decree. The Expert's report of the inspection shall be submitted concurrently to Defendants and FDA no later than twenty (20) calendar days after he or she completes the inspection. This report shall include, but not be limited to, the following:

i. A determination as to whether Defendants have established identity specifications for each component used in the manufacture of finished dietary supplements, as required by 21 C.F.R. § 111.70(b)(1), and whether these specifications are met, as required by 21 C.F.R. §§ 111.73 and 111.75;

ii. A determination as to whether Defendants have established product specifications for the identity, purity, strength, and composition of the finished batch of dietary supplement, and limits on contaminants that may adulterate the finished batch of dietary supplement, in violation of 21 C.F.R. § 111.70(e), and whether these specifications are met, as required by 21 C.F.R. § 111.75 (c);

iii. A determination as to whether Defendants continuously maintain adequate documentation to show that compliance with certain finished product specifications ensures that the finished batch of dietary supplements meets all specifications for identity, strength, purity, and composition, as required by 21 C.F.R. § 111.75(c)(3);

iv. A determination as to whether Defendants continuously maintain all of the required elements of a Master Manufacturing Record (MMR), as required by 21 C.F.R. § 111.210; and

v. A determination as to whether Defendants continuously maintain all of the required elements of a batch production record, as required by 21 C.F.R. § 111.260.

C. Should the Expert identify any deficiencies in the reports as described in Paragraph 4(B):

i. Defendants shall report to FDA and the Expert in writing the actions they have taken to correct all such deficiencies; and

ii. The Expert shall certify in writing to FDA, based upon the Expert's further review and/or inspection(s), whether Defendants' facility and the methods, processes, and controls used to manufacture, prepare, pack, label, hold, and distribute their dietary supplement products appear to be in compliance with the Act, its implementing regulations, and this Decree;

D. Should the Expert determine in the report required in Paragraph 4(B), or should FDA determine through its review of the Expert's report or an inspection of Defendants' facility pursuant to Paragraph 4(E), that any product that is in Defendants' possession at the entry of this Decree was not manufactured and labeled in conformity with the Act and its implementing regulations, including, but not limited to the CGMP requirements found in 21 C.F.R. Part 111, then Defendants shall destroy, under FDA's supervision and in accordance with the procedures provided in Paragraph 4, any such non-compliant product;

E. 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. Such inspection shall commence within thirty (30) business days after receiving Defendants' Expert's complete reports required by Paragraph 4(B) and any other materials FDA requires to evaluate Defendants' operations;

F. Defendants have paid all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews with respect to Paragraph 4, at the rates set forth in Paragraph 11 below; and

G. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 4(A)–(F). In no circumstance shall FDA's silence be construed as a substitute for written notification.

H. The terms of Paragraph 4 shall not apply to the manufacture, processing, packaging, labeling, holding, and/or distributing of a dietary supplement that was never sold or offered for sale in domestic commerce and that is intended solely for export from the United States, provided that the applicable requirements of 21 U.S.C. § 381(e)(1) and 21 C.F.R. § 1.101 have been satisfied with respect to any such dietary supplement.

5. Within fifteen (15) calendar days after the entry of this Decree and within thirty (30) calendar days after receiving any recalled products, Defendants, under FDA's supervision, shall destroy all dietary supplements that are in Defendants' possession, custody, or control, pursuant to a method approved in advance in writing by FDA. Defendants shall bear the costs of destruction and, at the rates set forth in Paragraph 11, 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 of any State or Territory, as defined in the Act, in which dietary supplements are disposed.

6. After Defendants have complied with Paragraph 4(A)–(F) and received FDA's written notification pursuant to Paragraph 4(G), Defendants shall retain an independent person or persons who shall meet the criteria described in Paragraph 3(B) (hereinafter, the "Auditor") to conduct audit inspections of Defendants' facility no less frequently than once every six (6) months for a period of no less than two (2) years, and then no less than once a year for the following three (3) years. The first audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to Paragraph 4(G). If Defendants choose, the Auditor may be the same person retained as the Expert described in Paragraph 4(B).

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 for their dietary supplement operations and identifying any deviations from such requirements ("Audit Report Observations").

B. 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's San Francisco District Office, at the address provided in Paragraph 14 by courier service or overnight delivery service, no later than fifteen (15) business days after the date the Audit Inspection is completed. In addition, Defendants shall maintain their 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 observations indicating that Defendants' dietary supplements are not in compliance with the Act, its implementing regulations, and/or this Decree, Defendants shall, within twenty (20) calendar days of 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 may take longer than twenty (20) calendar days, Defendants shall, within ten (10) calendar days of 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.

D. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor. Within thirty (30) calendar 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.

7. Upon entry of this Decree, Defendants and all Associated Persons are permanently restrained and enjoined from directly or indirectly doing or causing any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, 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 to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components;

8. If, at any time after this Decree has been entered, FDA determines, based on a review of inspection results, a report prepared by Defendants' Expert or the Auditor, or any other information, that 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 the Act, applicable regulations, and/or this Decree, 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, processing, packing, labeling, holding, and/or distributing any or all dietary supplements;

B. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

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

D. Pay liquidated damages as provided in Paragraph 15 below;

E. Recall any article(s) at Defendants' expense; or

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants and their products into compliance with the Act, applicable regulations, and/or this Decree. 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.

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 Decree, the Act, and its implementing regulations, and that Defendants may resume operations. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 8 shall be borne by Defendants at the rates specified in Paragraph 11.

10. FDA representatives shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted immediate access to buildings, equipment, in-process and finished materials, containers; to take photographs and make video recordings; and to take samples of Defendants' finished and unfinished materials and products, containers. 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 conduct inspections under the Act, 21 U.S.C. § 374.

11. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Decree or that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $93.26 per hour or fraction thereof per representative for inspection and investigative work; $111.77 per hour or fraction thereof per representative for analytical or review work; $0.535 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 or the equivalent for the areas in which the inspections are performed per-day, per-representative 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.

12. Within ten (10) calendar days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return

receipt requested), to each and all of their Associated Persons. Within thirty (30) calendar days after the entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this Paragraph and identifying the names and positions of all Associated Persons who have received a copy of this Decree and the manner of notification. In the event that Defendants become associated, at any time after the entry of this Decree, with new Associated Persons, Defendants shall: (a) within fifteen (15) calendar days of such association, provide a copy of this Decree to each such Associated Person by personal service or certified mail (restricted delivery, return receipt requested), and (b) on a quarterly basis, notify FDA in writing when, how, and to whom the Decree was provided.

13. Defendants shall notify FDA, in writing, at the address specified in Paragraph 14, at least fifteen (15) calendar days before any change in ownership, character, or name of its business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchises, affiliates, or "doing business as" entities, or any other change in the corporate structure of Custompax or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this Paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

14. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be addressed to the District Director, San Francisco District Office, Human and Animal Food West Division 5, United States Food and Drug Administration, **1431 Harbor Bay Parkway, Alameda, CA 94502-7070, and shall reference the case name and civil action number**.

15. If Defendants fail to comply with the Act, its implementing regulations, and/or any provision of this Decree, including any time frame imposed by this Decree, Defendants shall pay to the United States of America: (a) two thousand five hundred dollars ($2,500) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree; (b) an

additional one thousand dollars ($1,000) in liquidated damages per day, per violation, for each violation of the Act, its implementing regulations, and/or this Decree; and (c) 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 the Act, its implementing regulations, and/or this Decree. Defendants understand and agree that the liquidated damages specified in this Paragraph are not punitive in nature, and the remedy in this Paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

16. 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, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

17. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. If contested, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review 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.

18. If Defendants (i) resume operations, after receiving written notice from FDA, as described in Paragraph 4(g), (ii) petition the Court for relief from this Decree and, (iii) at the time of the petition, in FDA's judgment, Defendants have maintained a state of continuous compliance with the Act, its implementing regulations, and this Decree for the sixty (60) months preceding the petition, Plaintiff will not oppose such petition.

19. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

PURSUANT TO STIPULATION, IT IS SO ORDERED.

Dated this 12th day of October, 2017.

UNITED STATES MAGISTRATE JUDGE

Entry consented to:

For Defendants

CEDRIC P. LING
Individually and on behalf of Custompax, Inc., as its CEO

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