UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case Number 12-11400
Honorable David M. Lawson

GREEN HOPE, LLC and PHIL G. YE,

Defendants.
_____/

CONSENT DECREE

The parties stipulate as follows:

1. This Court has jurisdiction over the subject matter of this case and all parties to this action.

2. Plaintiff the United States of America has filed a complaint for permanent injunction against Green Hope, LLC ("Green Hope"), d/b/a Rosewood Products, and Phil G. Ye.

3. The complaint states a cause of action against the defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*.

4. The defendants have violated the Act, 21 U.S.C. § 331(a), by introducing, or delivering for introduction, into interstate commerce articles of food, within the meaning of 21 U.S.C. § 321(f), that are adulterated within the meaning of 21 U.S.C. § 342(a)(4). The defendants have also violated the Act, 21 U.S.C. § 331(k), by causing the adulteration, within the meaning of 21 U.S.C. § 342(a)(4), of articles of food, within the meaning of 21 U.S.C. § 321(f), while such articles are held for sale after shipment of one or more components in interstate commerce. The articles of food are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been

prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth.

5. The defendants have appeared and consented to the entry of this consent decree of permanent injunction without contest, without admitting or denying the allegations of the complaint, and before any testimony has been taken.

6. The United States of America consents to the entry of this decree.

Accordingly, pursuant to the stipulation and consent of the parties, the following is **ORDERED**:

1. Upon entry of this decree, the defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) are hereby permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly receiving, processing, manufacturing, preparing, packing, holding, or distributing at or from their facility located at 738 Airport Boulevard, Suite 6, Ann Arbor, Michigan 48108 (and any other or new location at or from which Defendants receive, process, manufacture, prepare, pack, hold, or distribute food) any article of food, unless and until:

A. Defendants retain, at their expense, an independent expert or experts having no personal or financial ties (other than the retention agreement) to defendants or their families, and who, by reason of background, education, training, and experience, is qualified to develop, and ensure adequate implementation of, a written sanitation control program encompassing all of defendants' operations and to ensure that defendants comply with the

Act and current good manufacturing practice ("cGMP") requirements, 21 C.F.R. Part 110;

B. Defendants notify the United States Food and Drug Administration in writing of the name and qualifications of the expert within five (5) days of retention;

C. Defendants' expert, after review of all FDA observations, develops an effective written sanitation control program, acceptable to FDA, which shall, at a minimum:

(1) establish in writing a sanitation control program with adequate methods, facilities, and controls for receiving, processing, manufacturing, preparing, packing, holding, and distributing articles of food to ensure that they are not processed, packed or held under insanitary conditions whereby they may be contaminated with filth or pathogens;

(2) ensure that defendants adhere to the Act, its implementing regulations at 21 C.F.R. Part 110, and cGMP; and

(3) establish a written plan for remedial action should filth or pathogens be detected;

D. FDA approves, in writing, the sanitation control program developed by the expert;

E. Defendants make written copies of the sanitation control program available and accessible to all their employees;

F. Defendants assign responsibility and authority for implementing and monitoring the sanitation control program on a continuing basis to an employee who is trained in sanitation control requirements, and provide such person with the authority to achieve the necessary corrections;

G. The expert develops a written employee training program that includes, at a minimum, instruction in sanitation control requirements for receiving, processing, manufacturing, preparing, packing, holding, and distributing food, and defendants document that each employee has received and understood such training;

H. The expert conducts a comprehensive inspection of defendants' facility, including the buildings, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein, to determine whether defendants have adequately established and implemented the written sanitation control program as approved by FDA, whether defendants have adequately addressed the FDA investigators' inspection observations listed on each Form FDA-483 issued to defendants since 2009, and whether defendants comply with the Act, its implementing regulations at 21 C.F.R. Part 110, and cGMP;

I. The expert certifies, in writing, to FDA that defendants:

(1) have properly established and implemented the sanitation control program;

(2) have properly made all structural repairs to the facility necessary to protect against contamination of raw ingredients, in-process and finished articles of food, containers, and packaging materials;

(3) have properly addressed and corrected the FDA Form FDA-483 observations; and

(4) comply with the Act, its implementing regulations at 21 C.F.R. Part 110, and cGMP;

J. FDA, as it deems necessary to evaluate defendants' compliance with the terms of this decree, the Act, and all applicable regulations, conducts inspections of defendants' facility, including the buildings, sanitation-related systems, equipment, utensils, raw ingredients, in-process and finished articles of food, containers, packaging material, and relevant records contained therein;

K. Defendants have paid all costs of inspection, analysis, review, investigations, examination, and supervision for FDA's oversight with respect to paragraph 1, at the rates set forth in paragraph 4 below; and

L. FDA notifies defendants in writing that defendants appear to be in compliance with the requirements set forth in subparagraphs 1(A) through (K) of this decree.

2. Upon resuming operations after completing the requirements of paragraph 1, defendants shall continuously and effectively implement, on an ongoing basis, the written sanitation control program developed pursuant to paragraph 1(C). In the event that defendants or their expert determines that the sanitation control program needs to be revised, defendants shall provide proposed changes to FDA in writing at least twenty (20) days prior to their planned implementation, and shall not implement the proposed changes until FDA approves those changes in writing.

3. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of defendants' facility at 738 Airport Boulevard, Suite 6, Ann Arbor, Michigan 48108, and any other or new locations at which defendants receive, process, manufacture, prepare, pack, hold, or distribute articles of food and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this decree, the Act, and the Act's implementing regulations. During the inspections, FDA shall be permitted to have

immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, and packaging material; to take photographs and make video recordings; to take samples of defendants' raw ingredients, in-process and finished articles of food, containers, and packaging material; and to examine and copy all records related to defendants' receiving, processing, manufacturing, preparing, packing, holding, and distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this decree and appropriate credentials. The inspection authority granted by this decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

4. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with 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: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour or fraction thereof per representative for analytical or review work; 55.5 cents per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day 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.

5. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who

have received notice of this decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce articles of food, within the meaning of 21 U.S.C. § 321(f), that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. violates the Act, 21 U.S.C. § 331(k), by causing articles of food, within the meaning of 21 U.S.C. § 321(f), to be adulterated within the meaning of 21 U.S.C. § 342(a)(4), while such articles are held for sale after shipment of one or more components in interstate commerce; or

C. results in the failure to implement and continuously maintain the requirements of this decree.

6. If, at any time after entry of this decree, FDA determines, based on the results of an inspection, sample analysis, or 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 the Act's implementing regulations, FDA may, as and when it deems necessary, notify defendants in writing of the noncompliance and order defendants to take appropriate action, including, but not limited to, ordering defendants immediately to take one or more of the following actions:

A. Cease receiving, processing, manufacturing, preparing, packing, holding, or distributing articles of food, until defendants receive written notification from FDA that defendants appear to be in compliance with the decree, the Act, and the Act's implementing regulations, and that defendants may resume operations;

B. Recall all articles of food that have been distributed or are under the custody and control of defendants' agents, customers, or consumers;

C. Submit samples of raw ingredients, in-process or finished articles of food, containers, and packaging materials to a qualified laboratory to determine whether it is contaminated with filth or pathogens; or

D. Take any other corrective actions as FDA deems necessary to bring defendants into compliance with this decree, the Act, or the Act's implementing regulations, including, but not limited to, requiring that defendants re-implement or re-institute any of the requirements of this decree.

7. The provisions of paragraph 6 shall be apart from, and in addition to, all other remedies available to FDA. Defendants shall pay all costs of any recalls and other corrective actions under this decree, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews to implement and monitor recalls and other corrective actions, at the rates specified in paragraph 4 of this decree.

8. If any defendant fails to comply with the provisions of this decree, the Act, or the Act's implementing regulations, then defendants shall pay to the United States of America liquidated damages in the sum of one thousand dollars ($1,000.00) for each day that the defendant fails to comply with this decree; an additional sum of five hundred dollars ($500.00) in liquidated damages for each violation of the Act, its implementing regulations, or this decree; and an additional sum equal to twice the retail value of each shipment of adulterated or unauthorized food. 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, and the

Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

9. Should the United States bring, and prevail in, a contempt action to enforce the terms of this decree, the defendants shall, in addition to other remedies, reimburse the United States for its attorney's fees (including overhead), investigational and analytical expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs, and any other costs or fees relating to such contempt proceedings.

10. Defendants shall provide notice of this decree in the following manner:

A. Within ten (10) calendar days after entry of this decree, defendants shall:

(1) provide a copy of this decree, personally or, when necessary, by certified mail, return receipt requested, to each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships);

(2) post a copy of this decree on a bulletin board in the employee common area at defendants' facility, and shall ensure that the decree remains posted so long as it remains in effect; and

(3) hold a general meeting or series of smaller meetings for their employees, at which they shall describe the terms and obligations of this decree.

B. Within twenty (20) calendar days after entry of this decree, defendants shall provide FDA with an affidavit signed by defendants attesting to their compliance with subparagraph (A) of this paragraph, stating the fact and manner of compliance, and

identifying the names and positions of all persons who were notified under the requirements in subparagraph (A).

C. Within ten (10) calendar days from the date of employment of each new employee hired by defendants after defendants have complied with the provisions in subparagraph (A), defendants shall provide the new employee with a copy of this decree, personally or, when necessary, by certified mail, return receipt requested.

11. Defendants shall notify FDA in writing at least thirty (30) calendar days before any change in ownership, name, or character of their business, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this decree. Defendants shall provide any prospective successor or assign with a copy of this decree at least thirty (30) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this paragraph within fifteen (15) calendar days of providing a copy of this decree to any prospective successor or assign.

12. Defendants shall address all communications with FDA required under this decree to Director, Detroit District Office, Food and Drug Administration, 300 River Place Drive, Suite 5900, Detroit, Michigan 48207, and shall reference this civil action by case name and civil action number in such communications.

13. All decisions specified in this decree shall be vested in the discretion of FDA. FDA's decisions shall be final 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.

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

s/David M. Lawson
DAVID M. LAWSON
United States District Judge

Dated: January 25, 2013

Consented to by:

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PROOF OF SERVICE

The undersigned certifies that a copy of the foregoing order was served upon each attorney or party of record herein by electronic means or first class U.S. mail on January 25, 2013.

s/Shawntel Jackson
SHAWNTEL JACKSON