IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	CIVIL ACTION NO. 12-cv-1312 WJ/SMV
	)	
v.	)	
	)	
SUNLAND, INC.,	)	CONSENT DECREE OF
a corporation, and	)	PERMANENT INJUNCTION
JIMMIE D. SHEARER,	)	
an individual,	)	
	)	
Defendants.	)	

Plaintiff, the United States of America, by its undersigned attorney, having filed a Complaint for Permanent Injunction (the "Complaint") against Sunland, Inc. ("Sunland"), and Jimmie D. Shearer (collectively, "Defendants") alleging that Defendants violate 21 U.S.C. § 331(a) – by introducing and causing to be introduced into interstate commerce, and delivering and causing to be delivered for introduction into interstate commerce, articles of food, as defined by 21 U.S.C. § 321(f) ("food"), that is adulterated within the meaning of 21 U.S.C. § 342(a)(1) and (4) – and 21 U.S.C. § 331(k) – by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(1) and (4) while held for sale by Defendants after shipment of one or more components in interstate commerce – and Defendants, without admitting or denying the allegations in the Complaint and disclaiming any liability in connection therewith, 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 that:

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

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

3. For the purposes of this Decree, the following definitions shall apply:

A. "The Sunland Facility" shall refer to Defendants' facility located at 42593 US Highway 70, Portales, New Mexico;

B. "The Peanut Butter Plant" shall refer to the building located at the Sunland Facility at and from which Defendants receive, prepare, process, pack, hold, and distribute food, including peanut butter and blanched and roasted nuts;

C. "The Peanut Mill Plant" shall refer to the building located at the Sunland Facility at and from which Defendants receive, prepare, process, pack, hold, and distribute raw in-shell peanuts and raw shelled peanuts (collectively "raw peanuts");

D. "The Peanut Storage Buildings" shall refer to the buildings located at the Sunland Facility at and from which Defendants receive, hold, and distribute raw in-shell farmer stock peanuts, but shall not refer to the Peanut Butter Plant, the Peanut Mill Plant, or any other building at which Defendants prepare, process, and/or pack food; and

E. "Ready-to-eat food" shall refer to food that is intended to be consumed by humans or animals without further processing, including, but not limited to, nut butters and

blanched and roasted nuts, but shall not refer to raw shelled peanuts labeled with the warning in paragraph 7.A.ii.2. or raw in-shell peanuts.

4. Upon entry of this Decree, FDA shall reinstate the Sunland Facility food facility registration under 21 U.S.C. § 350d(b)(3)(B).

The Peanut Butter Plant

5. Defendants and each and all of their officers, agents, representatives, employees, attorneys, successors, assigns, and any persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) (collectively, the "Associated Persons"), who receive notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly receiving, preparing, processing, packing, holding, and/or distributing articles of food at or from the Peanut Butter Plant unless and until:

A. Defendants retain, at Sunland's expense, an independent person(s) (the "Sanitation Expert") 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 that will protect food, food-contact surfaces, and food-packaging materials in the Peanut Butter Plant from contamination from any source, including, but not limited to, *Salmonella spp.*, and to inspect the Peanut Butter Plant to determine whether Defendants comply with this Decree, the Act, and its implementing regulations, including, but not limited to, the current good manufacturing practice ("cGMP") requirements for food, see 21 C.F.R. part 110,

and notify FDA in writing of the name(s) and qualifications of the Sanitation Expert within fifteen (15) calendar days after entry of this Decree;

B. The Sanitation Expert develops a written sanitation control program (the "Peanut Butter Plant Program") that will protect food, food-contact surfaces, and food-packaging materials in the Peanut Butter Plant from contamination from any source, including, but not limited to, *Salmonella spp.*, and shall at a minimum:

i. Establish an effective program for environmental monitoring and testing of the facility to ensure that pathogenic organisms, including, but not limited to, *Salmonella spp.*, are not present in the Peanut Butter Plant;

ii. Establish an effective program for testing Defendants' in-process and finished food to ensure that Defendants' food is not contaminated with pathogenic organisms including, but not limited to, *Salmonella spp.*;

iii. Establish a written plan for remedial action should *Salmonella spp.* or any other pathogenic organism(s) be detected in any test result under the Peanut Butter Plant Program;

iv. Ensure that any and all test results under the Peanut Butter Plant Program that detect the presence of *Salmonella spp.* or any other pathogenic organisms are sent to FDA within two (2) business days of receipt by Defendants;

v. Establish practices and procedures to ensure that the Peanut Butter Plant and equipment therein are continuously maintained in a sanitary condition and the methods and controls used to receive, prepare, process, pack, hold, and distribute food at or from the

Peanut Butter Plant comply with the Act and its implementing regulations, including, but not limited to, cGMP requirements for food; and

vi. Establish practices and procedures to ensure that all ready-to-eat food prepared, processed, packed, held, and/or distributed at the Sunland Facility is prepared, processed, packed, held, and/or distributed at or from the Peanut Butter Plant;

C. Defendants submit to FDA in writing the Peanut Butter Plant Program and receive written notification from FDA approving the Peanut Butter Plant Program;

D. Defendants assign responsibility and authority for implementing and monitoring the Peanut Butter Plant Program on a continuous basis to an employee who is trained in sanitation control requirements and qualified to implement and monitor the Peanut Butter Plant Program;

E. The Sanitation Expert conducts a comprehensive inspection of the Peanut Butter Plant and the methods and controls used to receive, prepare, process, pack, hold, and distribute food at or from the Peanut Butter Plant to determine whether Defendants have effectively established and implemented the FDA-approved Peanut Butter Plant Program and whether Defendants comply with this Decree, the Act, and its implementing regulations, including, but not limited to, cGMP requirements for food, and submits all findings to Defendants and FDA concurrently, within ten (10) business days after completing the inspection;

F. The Sanitation Expert certifies in writing to FDA and Defendants that based upon the inspection described in paragraph 5.E., Defendants continuously maintain the FDA-approved Peanut Butter Plant Program and appear to be in compliance with this Decree,

the Act, and its implementing regulations, including, but not limited to, cGMP requirements for food;

G. Defendants report to FDA in writing the actions they have taken to bring their operations into compliance with this Decree, the Act, and its implementing regulations, including, but not limited to:

i. Documentation that Defendants have cleaned and sanitized the Peanut Butter Plant and equipment therein, thereby rendering the Peanut Butter Plant and equipment suitable for receiving, preparing, processing, packing, holding, and distributing articles of food; and

ii. Documentation that Defendants have conducted environmental testing in a manner acceptable to FDA and received laboratory results showing that *Salmonella spp.* are no longer present in the facility;

H. FDA, as it deems necessary, inspects the Peanut Butter Plant to evaluate Defendants' compliance with the terms of this Decree, the Act, and its implementing regulations; and

I. Defendants receive written authorization from FDA to resume receiving, preparing, processing, packing, holding, and distributing articles of food at and from the Peanut Butter Plant.

6. After receiving the written authorization in paragraph 5.I., Defendants shall continuously maintain the FDA-approved Peanut Butter Plant Program.

The Peanut Mill Plant

7. Defendants and each and all Associated Persons who receive notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly receiving, preparing, processing, packing, holding, and/or distributing food at or from the Peanut Mill Plant, unless and until:

A. Defendants develop a written sanitation control program (the "Peanut Mill Program") that shall at a minimum:

i. Establish practices and procedures to ensure that the Peanut Mill Plant and equipment therein are continuously maintained in a sanitary condition and the methods and controls used to receive, prepare, process, pack, hold, and distribute food at and from the Peanut Mill Plant comply with the Act and its implementing regulations, including, but not limited to, cGMP requirements for food; and

ii. Establish practices and procedures to ensure that no food other than raw peanuts is received, processed, packed, held, and/or distributed at or from the Peanut Mill Plant and that all raw peanuts distributed from the Peanut Mill Plant are:

1. Packed in quantities of no less than 25 pounds; and

2. Prominently labeled with a warning that raw peanuts may be contaminated with food borne pathogens and may cause serious adverse health consequences or death to humans or animals and must be further processed in a manner adequate to kill food borne pathogens before consumption;

B. Defendants demonstrate, in a manner and to extent acceptable to FDA, that the Peanut Mill Program complies with the requirements of paragraph 7.A.;

C. Defendants assign responsibility and authority for implementing and monitoring the Peanut Mill Program on a continuous basis to an employee who is trained in sanitation control requirements and qualified to implement and monitor the Peanut Mill Program;

D. Defendants report to FDA in writing the actions they have taken to clean and sanitize the Peanut Mill Plant and equipment therein, thereby rendering the Peanut Mill Plant and equipment suitable for receiving, preparing, processing, packing, holding, and distributing articles of food;

E. FDA, as it deems necessary, inspects the Peanut Mill Plant to evaluate Defendants' compliance with the terms of this Decree, the Act, and its implementing regulations; and

F. Defendants receive written authorization from FDA to resume receiving, preparing, processing, packing, holding, and distributing raw peanuts at or from the Peanut Mill Plant.

8. After receiving the written authorization in paragraph 7.F., Defendants shall continuously maintain the Peanut Mill Program.

The Peanut Storage Buildings

9. Nothing in paragraphs 5 or 7 shall prevent Defendants or any and all Associated Persons from receiving, holding, and/or distributing raw in-shell farmer stock peanuts at or from the Peanut Storage Buildings.

Other Provisions

10. Within forty-five (45) calendar days after entry of this Decree, Defendants shall destroy, under FDA's supervision and in accordance with a destruction plan submitted in writing

to and approved by FDA prior to destruction, all food held by Defendants at the Sunland Facility at the time this Decree is signed by the parties, except that:

A. This paragraph shall not apply to raw peanuts; and

B. Within fifteen (15) calendar days after entry of this decree, Defendants may submit a list of ingredients used to manufacture ready-to-eat foods and the location and manner in which such ingredients are held; this paragraph shall not apply to any ingredient(s) that FDA notifies Defendants, in writing, is exempt from destruction.

11. Upon entry of this Decree, Defendant Sunland and Defendant Jimmie D. Shearer, for so long as he is in a position of responsibility with Defendant Sunland, and each and all of the Associated Persons who receive actual 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 of the following acts:

A. Introducing, or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(1) and (4); and/or

B. Causing articles of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(1) and (4), while such articles are held for sale after shipment of one or more components in interstate commerce.

12. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Sunland Facility, and any other or new locations at which Defendant Sunland receives, prepares, processes, packs, holds, and/or distributes 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 its 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 receiving, preparing, processing, packing, holding, and/or 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. FDA will provide Defendants with a receipt for any samples taken under this paragraph or 21 U.S.C. § 374, and with copies of any photographs or video recordings made after receipt of a written request by Defendants for such copies, and at the Defendants' expense.

13. Defendant Sunland 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; $0.555 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. FDA shall submit a reasonably detailed bill of costs to Defendant Sunland at the address specified in paragraph 24.

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.

14. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, or any 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 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 with respect to the Sunland Facility, including, but not limited to, one or more of the following actions:

A. Cease receiving, preparing, processing, packing, holding, and/or distributing any articles of food from the Peanut Butter Plant and/or the Peanut Mill Plant;

B. Recall all articles of food that have been distributed and/or are under the custody and control of Defendants' agents, distributors, customers, and/or consumers from the Peanut Butter Plant and/or the Peanut Mill Plant;

C. Submit samples of raw ingredients, other than raw peanuts, and/or in-process or finished articles of food to a qualified laboratory to determine whether they are contaminated with chemicals, toxins, microorganisms, or filth; and/or

D. Take any other corrective actions as FDA deems necessary to protect the public health and/or bring Defendants into compliance with this Decree, the Act, and its implementing regulations.

The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA. Any FDA order issued pursuant to this paragraph shall specify the noncompliance giving rise to the order.

15. The following process and procedures shall apply when FDA issues an order under paragraph 14, except as provided in subparagraph D below:

A. Unless a different time frame is specified by FDA in its order, Defendants shall, within ten (10) business days after receiving such order, notify FDA in writing that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order, unless the Court sets aside, stays, reverses, vacates, or

modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 18 of this Decree.

D. The process and procedures set forth in paragraph 15.A.-C. shall not apply to any order issued under paragraph 14 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief.

16. If any Defendant fails to comply with the provisions of this Decree, the Act, and/or its implementing regulations, then Defendant Sunland shall pay to the United States of America liquidated damages in the sum of two thousand five hundred dollars ($2,500.00) for each day that the Defendant fails to comply with this Decree; an additional sum of two thousand five hundred dollars ($2,500.00) in liquidated damages per day for each violation of this Decree, the Act, and/or its implementing regulations; and an additional sum equal to twice the retail value of each shipment of adulterated food. The amount of liquidated damages imposed under this paragraph shall not exceed one hundred thousand dollars ($100,000.00) in any one calendar year. 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.

17. If any Defendant violates this Decree and is found in civil or criminal contempt thereof, Defendant Sunland shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees, travel expenses incurred by attorneys and witnesses, expert witness fees,

administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to contempt proceedings.

18. All decisions specified in this Decree shall be vested in the discretion of the FDA. FDA's decisions shall be final and, if challenged, 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.

19. Within ten (10) calendar days after 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 the Associated Persons. Defendants shall provide to FDA within thirty (30) calendar days after the date of the entry of this Decree, an affidavit of compliance with this paragraph stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

20. In the event that any Defendant becomes associated with any additional directors, officers, agents, representatives, employees, attorneys, successors, assigns, or any additional persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) at any time after entry of this Decree, Defendants shall, within ten (10) business days of the commencement of such associations, provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such persons. On a quarterly basis, Defendants shall provide to FDA an affidavit stating the fact and manner of Defendants' compliance with this paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to

this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

21. Within ten (10) calendar days after entry of this Decree, Defendants shall post a copy of this Decree prominently in an employee common area at the facility and, thereafter, Defendants shall ensure that a copy of this Decree remains posted at all times while this Decree remains in effect.

22. Defendants shall notify FDA in writing at least fifteen (15) 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 ten (10) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this paragraph within ten (10) calendar days of providing a copy of this Decree to a prospective successor or assign.

23. Defendant Jimmie D. Shearer shall notify FDA if, at any time after entry of this Decree, he ceases to be employed by or affiliated in any way with Defendant Sunland. Such individual Defendant may, after providing FDA thirty (30) calendar days' written notice, petition the Court to be released from this Decree. Unless, within such 30-day period, FDA determines that Mr. Shearer has not ceased to be employed by or affiliated with Defendant Sunland, FDA will not oppose release of such individual Defendant from this Decree pursuant to such petition.

24. Defendants shall address all communications required under this Decree to: District Director, Denver District Office, United States Food and Drug Administration, 6th & Kipling Street, Denver, CO 80225-0087, and shall reference this civil action by case name and civil action number. All notifications, correspondence, and communications required to be sent to Defendants under this Decree shall be addressed to Jimmie D. Shearer, President, Sunland, Inc., P.O. Box 1059, Portales, New Mexico, 88130, and may be sent by email to such person until either Defendant notifies FDA in writing that such documentation should be addressed and sent elsewhere.

25. If Defendants have maintained a state of continuous compliance with this Decree, the Act, and its implementing regulations for a period of at least sixty (60) months after satisfying all of their obligations under paragraphs 5 and 7, Defendants may petition this Court for relief from this Decree and Plaintiff will not oppose such petition.

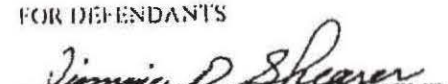
26. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED this 21st day of December, 2012.

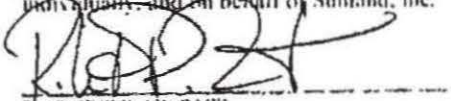
WILLIAM P. JOHNSON
United States District Judge

We hereby consent to the entry of the forgoing Decree:

FOR DEFENDANTS



JIMMIE D. SHEARER,
individually, and on behalf of Sunland, Inc.



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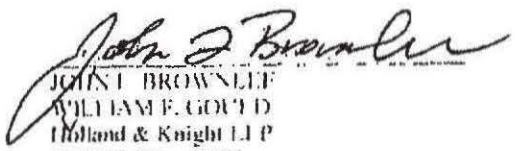

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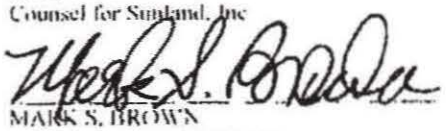

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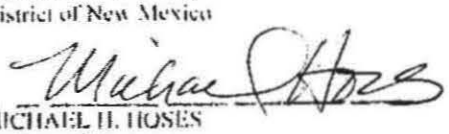

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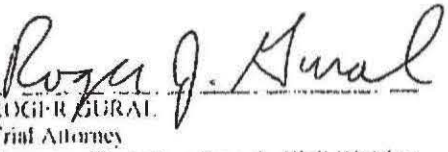

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