

1 MELINDA HAAG, CSBN 132612
United States Attorney

2 ALEX G. TSE, CSBN 152348
Assistant United States Attorney
3 Chief, Civil Division

4 MELANIE L. PROCTOR, CSBN 228971
Assistant United States Attorney

5 450 Golden Gate Avenue, Box 36055
6 San Francisco, California 94102
Telephone: (415) 436-6730
7 FAX: (415) 436-7169
E-mail: melanie.proctor@usdoj.gov

8 Attorneys for Plaintiff

9 UNITED STATES DISTRICT COURT
10 NORTHERN DISTRICT OF CALIFORNIA
11 SAN FRANCISCO DIVISION

12 UNITED STATES OF AMERICA,)
13 Plaintiff,)

No. 3:12-cv-04369-EDL

14 v.)

CONSENT DECREE OF
CONDEMNATION AND
PERMANENT INJUNCTION

15 24/94 kg bags, more or less, of an article of)
16 food, labeled in part:)
"*** SENNA PODS *** PRODUCE OF)
17 INDIA *** NETT 94 KGS *** Item#)
W1520 *** Lot # 110220 ***)
18 Nt. Wt. # 211.2 LBS *** Country)
of Origin: INDIA ***")

19 and)

20 all other articles of food in various sizes and)
21 types of containers (excluding metal and)
glass containers) that are located anywhere)
22 on the premises of San Francisco Herb and)
Natural Food Company, 47444 Kato Road,)
23 Fremont, California, which are unlabeled or)
affixed with labels bearing, among other)
24 things, the name and address of the)
manufacturer, packer, or distributor located)
25 outside the State of California, or which are)
otherwise determined to consist in whole or)
26 in part of components that have originated)
from outside the State of California,)

27 Defendants.)
28)

1 On August 20, 2012, the United States of America, by and through its attorneys, filed a
2 Verified Complaint for Forfeiture *In Rem* (“Complaint”) against the above-captioned articles.
3 The articles proceeded against are articles of food within the meaning of the Federal Food, Drug,
4 and Cosmetic Act (“the Act”), 21 U.S.C. § 321(f). The Complaint alleges that the seized articles
5 are adulterated while held for sale after shipment in interstate commerce, within the meaning of
6 21 U.S.C. § 342(a)(4), in that they have been held under insanitary conditions whereby they may
7 have become contaminated with filth.

8 In response to the Complaint, on August 21, 2012, this Court issued a Warrant for Arrest
9 *In Rem* directing the United States Marshal for this district (“U.S. Marshal”) to seize the articles.
10 The U.S. Marshal executed the seizure on August 21, 2012. Thereafter, the United States caused
11 notice of the Complaint and seizure to be published in accordance with the applicable rules of
12 this Court and Rule G of the Supplemental Rules for Admiralty or Maritime Claims and Asset
13 Forfeiture Actions of the Federal Rules of Civil Procedure.

14 On August 23, 2012, San Francisco Herb and Natural Food Company (“Claimant”) filed
15 a verified claim to the seized articles (“Condemned Articles”). Claimant filed a First Amended
16 Verified Statement of Interest on August 29, 2012, and an Answer on September 12, 2012. In
17 consenting to the entry of this Consent Decree, Claimant’s Chief Executive Officer and President
18 Barry Meltzer and its Chief Operating Officer Fahimeh Niroomand have neither admitted nor
19 denied any allegation in the Complaint, and nothing in this Consent Decree is an admission by
20 either of them or by Claimant (collectively, “Defendants”) that they have committed any
21 violation of the Act. Claimant and Defendants acknowledge and agree that they have entered
22 into this civil Consent Decree voluntarily and that it does not address or limit, in any respect, any
23 other actions, including criminal proceedings or civil claims, of the United States or any agency
24 thereof.

25 Claimant agrees to indemnify and hold the United States harmless should any party or
26 parties hereafter file or seek to file a claim or to intervene in this action and obtain the
27 Condemned Articles. Claimant and Defendants, having appeared and voluntarily consented to
28

1 the entry of this Decree without contest, before any testimony has been taken, and waiving the
2 filing and service of an amended complaint seeking injunctive relief, and the United States
3 having consented to this Decree:

4 IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

5 1. This Court has jurisdiction over the subject matter herein and has personal jurisdiction
6 over all parties to this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. §§ 332 and 334. Venue
7 is proper in this district under 28 U.S.C. §§ 1391(b)-(c) and 1395.

8 2. The seized articles are articles of food that are adulterated while held for sale after
9 shipment in interstate commerce, within the meaning of 21 U.S.C. § 342(a)(4), in that they have
10 been held under insanitary conditions whereby they may have become contaminated with filth.

11 3. The seized articles are hereby condemned pursuant to 21 U.S.C. § 334(a) and forfeited
12 to the United States.

13 4. Pursuant to 21 U.S.C. § 334(e), Claimant shall pay to the United States all court costs
14 and fees, storage, and other proper expenses of this proceeding incurred to date, including, but
15 not limited to, those incurred by the U.S. Marshal, and such additional expenses as may
16 hereinafter be incurred and taxed. Claimant shall pay these costs within ten (10) business days
17 after receiving notice of such costs from the United States Food and Drug Administration
18 (“FDA”), the U.S. Marshal, or the United States Attorney for the Northern District of California.

19 5. Within twenty (20) calendar days of the entry of this Decree, Claimant shall execute
20 and file with the clerk of this Court a good and sufficient penal bond (the “Bond”) with surety in
21 the amount of five hundred eighty five thousand and two hundred dollars (\$585,200) to be
22 applied to Lot 1 (as described in Subpart A of Paragraph 9 of this Decree), and held for
23 application to succeeding Lots 2-10 (as described in Subparts B-J of Paragraph 9 of this Decree).
24 The Bond shall be in a form acceptable to the clerk of this Court and payable to the United States
25 of America, and conditioned on Claimant’s abiding by and performing all of the terms and
26 conditions of this Decree and of such further orders and decrees as may be entered in this
27 proceeding.

1 6. After paying the costs pursuant to paragraph 4 and posting the Bond with the clerk of
2 this Court pursuant to paragraph 5, Claimant shall give written notice to FDA at the address
3 listed in paragraph 30 that Claimant, at its own expense, is prepared to attempt to bring the
4 Condemned Articles into compliance with the law under the supervision of a duly authorized
5 FDA representative.

6 7. Claimant shall either: (a) submit to FDA evidence that it will no longer use the
7 facility located at 47444 Kato Road, Fremont, CA (the “Kato Road Facility”), for receiving,
8 manufacturing, preparing, processing, packing, holding, or distributing articles of food; or (b) in
9 the event that Claimant elects to use the Kato Road Facility for receiving, manufacturing,
10 preparing, processing, packing, holding, or distributing articles of food, clean and renovate, at its
11 own expense, the Kato Road Facility and render it sanitary and fit for the storage and handling of
12 articles of food, and thereafter, submit a written request to FDA for an inspection of the Kato
13 Road Facility. Following receipt of Claimant’s request, FDA will conduct an inspection of the
14 Kato Road Facility to determine whether it is sanitary and fit for the proper storage and handling
15 of articles of food and will promptly inform Claimant, in writing, of the results of that inspection.

16 8. Claimant shall not commence, permit any other person to commence, or cause any
17 other person to commence attempting to bring the Condemned Articles into compliance with the
18 law unless and until Claimant: (a) receives notice from FDA, in writing, that either it has
19 submitted adequate evidence to FDA that it will no longer use the Kato Road Facility for
20 receiving, manufacturing, preparing, processing, packing, holding, or distributing articles of
21 food, or it appears, based on FDA’s inspection, that the Kato Road Facility has been made
22 sanitary and fit for the proper storage and handling of articles of food; (b) submits a written
23 statement to FDA detailing the proposed plan to bring the Condemned Articles into compliance
24 (the “Reconditioning Plan”), which includes, but is not limited to, either rendering the Kato
25 Road Facility sanitary and fit for the proper storage and handling of articles of food or moving
26 the Condemned Articles to another location, approved by FDA, for reconditioning; (c) receives
27 written approval of the Reconditioning Plan from FDA; and (d) receives written authorization
28

1 from FDA to commence reconditioning. FDA's decisions regarding the adequacy of evidence
2 that Claimant will no longer use the Kato Road Facility for receiving, manufacturing, preparing,
3 processing, packing, holding, or distributing articles of food, the cleanliness of the Kato Road
4 Facility, and the Reconditioning Plan shall be final.

5 9. The U.S. Marshal, upon receiving notice from the United States Attorney for this
6 District that Claimant is authorized to commence reconditioning, shall release the appropriate
7 Lot of Articles (as described in Subparts A-J, below) to the custody of Claimant in accordance
8 with the terms and conditions set forth as follows:

9 A. The Condemned Articles in Lot 1, consisting of approximately 1/10 of the
10 Condemned Articles (by value), to be further designated by the FDA representative in
11 consultation with Claimant, shall be released to Claimant for the sole purpose of attempting to
12 bring the Condemned Articles in Lot 1 into compliance with the law pursuant to the approved
13 Reconditioning Plan described in paragraph 8.

14 B. If and only if Claimant complies with all of the terms of this Consent
15 Decree with respect to Lot 1 and has paid all costs assessed to date pursuant to paragraph 22, the
16 Condemned Articles in Lot 2, consisting of approximately a second 1/10 of the Condemned
17 Articles (by value), to be further designated by the FDA representative in consultation with
18 Claimant, shall be released to Claimant for the sole purpose of attempting to bring the
19 Condemned Articles in Lot 2 into compliance with the law pursuant to the approved
20 Reconditioning Plan described in paragraph 8.

21 C. If and only if Claimant complies with all of the terms of this Consent
22 Decree with respect to Lot 2 and has paid all costs assessed to date pursuant to paragraph 22, the
23 Condemned Articles in Lot 3, consisting of approximately a third 1/10 of the Condemned
24 Articles (by value), to be further designated by the FDA representative in consultation with
25 Claimant, shall be released to Claimant for the sole purpose of attempting to bring the
26 Condemned Articles in Lot 3 into compliance with the law pursuant to the approved
27 Reconditioning Plan described in paragraph 8.

1 D. If and only if Claimant complies with all of the terms of this Consent
2 Decree with respect to Lot 3 and has paid all costs assessed to date pursuant to paragraph 22, the
3 Condemned Articles in Lot 4, consisting of approximately a fourth 1/10 of the Condemned
4 Articles (by value), to be further designated by the FDA representative in consultation with
5 Claimant, shall be released to Claimant for the sole purpose of attempting to bring the
6 Condemned Articles in Lot 4 into compliance with the law pursuant to the approved
7 Reconditioning Plan described in paragraph 8.

8 E. If and only if Claimant complies with all of the terms of this Consent
9 Decree with respect to Lot 4 and has paid all costs assessed to date pursuant to paragraph 22, the
10 Condemned Articles in Lot 5, consisting of approximately a fifth 1/10 of the Condemned
11 Articles (by value), to be further designated by the FDA representative in consultation with
12 Claimant, shall be released to Claimant for the sole purpose of attempting to bring the
13 Condemned Articles in Lot 5 into compliance with the law pursuant to the approved
14 Reconditioning Plan described in paragraph 8.

15 F. If and only if Claimant complies with all of the terms of this Consent
16 Decree with respect to Lot 5 and has paid all costs assessed to date pursuant to paragraph 22, the
17 Condemned Articles in Lot 6, consisting of approximately a sixth 1/10 of the Condemned
18 Articles (by value), to be further designated by the FDA representative in consultation with
19 Claimant, shall be released to Claimant for the sole purpose of attempting to bring the
20 Condemned Articles in Lot 6 into compliance with the law pursuant to the approved
21 Reconditioning Plan described in paragraph 8.

22 G. If and only if Claimant complies with all of the terms of this Consent
23 Decree with respect to Lot 6 and has paid all costs assessed to date pursuant to paragraph 22, the
24 Condemned Articles in Lot 7, consisting of approximately a seventh 1/10 of the Condemned
25 Articles (by value), to be further designated by the FDA representative in consultation with
26 Claimant, shall be released to Claimant for the sole purpose of attempting to bring the
27 Condemned Articles in Lot 7 into compliance with the law pursuant to the approved
28

1 Reconditioning Plan described in paragraph 8.

2 H. If and only if Claimant complies with all of the terms of this Consent
3 Decree with respect to Lot 7 and has paid all costs assessed to date pursuant to paragraph 22, the
4 Condemned Articles in Lot 8, consisting of approximately an eighth 1/10 of the Condemned
5 Articles (by value), to be further designated by the FDA representative in consultation with
6 Claimant, shall be released to Claimant for the sole purpose of attempting to bring the
7 Condemned Articles in Lot 8 into compliance with the law pursuant to the approved
8 Reconditioning Plan described in paragraph 8.

9 I. If and only if Claimant complies with all of the terms of this Consent
10 Decree with respect to Lot 8 and has paid all costs assessed to date pursuant to paragraph 22, the
11 Condemned Articles in Lot 9, consisting of approximately a ninth 1/10 of the Condemned
12 Articles (by value), to be further designated by the FDA representative in consultation with
13 Claimant, shall be released to Claimant for the sole purpose of attempting to bring the
14 Condemned Articles in Lot 9 into compliance with the law pursuant to the approved
15 Reconditioning Plan described in paragraph 8.

16 J. If and only if Claimant complies with all of the terms of this Consent
17 Decree with respect to Lot 9 and has paid all costs assessed to date pursuant to paragraph 22, the
18 Condemned Articles in Lot 10, consisting of the remaining 1/10 of the Condemned Articles (by
19 value), to be further designated by the FDA representative in consultation with Claimant, shall
20 be released to Claimant for the sole purpose of attempting to bring the Condemned Articles in
21 Lot 10 into compliance with the law pursuant to the approved Reconditioning Plan described in
22 paragraph 8.

23 10. Claimant shall at all times, until the Condemned Articles have been released in
24 writing by an FDA representative, retain the Condemned Articles intact for examination or
25 inspection by an FDA representative in a place made known to and approved by FDA, and shall
26 maintain the records or other proof necessary to establish the identity of the articles to the
27 satisfaction of the FDA representative.

28

1 11. Within ninety (90) calendar days of receiving written authorization to commence
2 reconditioning, Claimant shall complete its attempt to bring the Condemned Articles into
3 compliance with the law, in accordance with the approved Reconditioning Plan described in
4 paragraph 8 under the supervision of FDA. Claimant shall destroy, at its own expense and under
5 the supervision of FDA, all articles of the Condemned Articles that have not been brought into
6 compliance with the law within the ninety (90) calendar day period within ten (10) calendar days
7 thereafter and shall file a notice with the Court certifying that such articles have been destroyed.

8 Because of the provisions in paragraph 9 that provide for the release of the Condemned
9 Articles in ten (10) lots for reconditioning purposes and the administrative time that will be
10 involved in that lot-by-lot procedure, the parties agree that the ninety (90) calendar day deadline
11 may be reasonably expanded, from time-to-time, in its discretion by the FDA without the need
12 for either the Claimant or the United States to file a motion with the Court.

13 12. Claimant shall at no time, and under no circumstances whatsoever, directly or
14 indirectly, cause or permit the shipment, sale, offer for sale, or other disposal of any part of the
15 Condemned Articles until: (a) FDA has had free access to the Condemned Articles in order to
16 take any samples or make any tests or examinations that are deemed necessary; (b) FDA has
17 released, in writing, all of the Condemned Articles for shipment, sale, or other disposition; and
18 (c) in the event that Claimant elects to use the Kato Road Facility for receiving, manufacturing,
19 preparing, processing, packing, holding, or distributing articles of food, FDA has notified
20 Claimant, in writing, that the Kato Road Facility has been made sanitary and fit for the proper
21 storage and handling of articles of food.

22 13. Claimant shall not sell, ship, destroy, or dispose of, or permit or cause another person
23 to sell, ship, destroy, or dispose of, the Condemned Articles or any part of them in a manner
24 contrary to the provisions of the Act, or other laws of the United States, or of any State or
25 Territory (as defined in the Act), in which they are disposed of or sold.

26 14. If Claimant breaches any condition of this Decree, or any subsequent decree or order
27 in this proceeding, Claimant shall, at its own expense, immediately return any of the Condemned
28

1 Articles that have not been released by FDA pursuant to paragraph 9 to the U.S. Marshal, or
2 otherwise dispose of them pursuant to an order of this Court. In the event that return of any of
3 the Condemned Articles becomes necessary pursuant to this paragraph, Claimant shall be
4 responsible for all costs of storage and disposition incurred by the United States.

5 15. If Claimant does not avail itself, in the manner stated in this Decree, of the
6 opportunity to: (a) post the Bond pursuant to paragraph 5 of this Decree; (b) submit a
7 Reconditioning Plan for the Condemned Articles to FDA pursuant to paragraph 8 of this Decree;
8 or (c) successfully recondition or destroy the Condemned Articles pursuant to paragraphs 8 and
9 11 of this Decree, the U.S. Marshal shall destroy the Condemned Articles and make due return to
10 this Court regarding their disposition. Claimant shall bear the costs of storage and destruction
11 incurred by the United States pursuant to this paragraph, and shall pay such costs within ten (10)
12 calendar days of receiving an invoice from FDA.

13 16. Should Claimant fail to abide by and perform all the terms and conditions of this
14 Decree with respect to disposition of the Condemned Articles, or of the Bond, or any such
15 further order or decree as may be entered in this proceeding with respect to the disposition of the
16 Condemned Articles, then the Bond described in paragraph 5 shall, on motion of the United
17 States in this proceeding, be forfeited in its entirety to the United States and judgment entered
18 thereon, and any Condemned Articles remaining in the custody of the U.S. Marshal shall be
19 forfeited and disposed of pursuant to further order of this Court.

20 17. The U.S. Attorney, upon being advised by an FDA representative that all of the
21 Condemned Articles have been brought into compliance with the Act and the requirements of
22 this Decree, or destroyed in compliance with this Decree, and that Claimant has paid all costs
23 submitted to Claimant as of that date, will transmit such information to the clerk of this Court,
24 whereupon the Bond filed in this proceeding shall be returned to the Claimant.

25 18. Upon entry of this Decree, Defendants and each and all of their officers, directors,
26 agents, representatives, employees, successors, assigns, attorneys, and any and all persons in
27 active concert or participation with any of them (including individuals, directors, corporations,
28

1 subsidiaries, affiliates, and partnerships) are hereby restrained and enjoined under 21 U.S.C.
2 § 332(a) from receiving, manufacturing, preparing, processing, packing, holding, and
3 distributing at or from the Kato Road Facility, unless and until Defendants:

4 A. Establish and implement an effective written sanitation control program, which
5 shall set out the details for sanitation control over the manufacturing and storage process for the
6 Kato Road Facility, and all food handling and storage equipment therein. The written sanitation
7 control program shall be designed to ensure that the Kato Road Facility and all equipment
8 therein are maintained continuously in a sanitary condition to prevent conditions under which
9 food may become contaminated with filth or whereby it may be rendered injurious to health.
10 Defendants shall assign responsibility for the implementation of the written sanitation control
11 program to a person or persons who, by reason of education, training, and experience in
12 sanitation work, is competent to maintain the Kato Road Facility and all equipment therein in a
13 sanitary condition. Defendants shall provide FDA with a copy of the written sanitation program
14 and the name(s) of the person(s) assigned authority and responsibility for continuously
15 implementing the program, and the written sanitation control program shall be approved in
16 writing by FDA prior to implementation. Such program shall, at a minimum include, but not be
17 limited to, the provisions of subparagraphs (B)-(F) of this paragraph;

18 B. Thoroughly clean, sanitize, renovate, and render the Kato Road Facility and all
19 equipment therein suitable for use in receiving, manufacturing, preparing, processing, packing,
20 holding, and distributing articles of food, and institute procedures to ensure that the Kato Road
21 Facility and equipment therein are maintained continuously in such condition;

22 C. Remove from the Kato Road Facility and all equipment therein rodents, insects,
23 other pests, the filth contributed by them, and microbial and physical contaminants, and
24 adequately repair the floors, ceilings, walls, doors, windows, and building in order to prevent
25 rodents, insects, or other pests from entering the Kato Road Facility;

26 D. Ensure that the grounds in the immediate vicinity of the Kato Road Facility are
27 adequately maintained, including, but not limited to, removing litter and waste, and cutting
28

1 weeds and grass that may constitute an attractant, breeding place or harborage for rodents and
2 other pests;

3 E. Establish adequate methods and controls for receiving, manufacturing,
4 preparing, processing, packing, holding, and distributing articles of food in the Kato Road
5 Facility that are designed to ensure that articles of food do not become contaminated by pests, or
6 with filth, or microbial or physical contaminants;

7 F. Establish a regularly scheduled employee training program (no less
8 frequently than every six months) that includes, at a minimum, instruction on sanitary food
9 handling techniques and personal hygiene practices;

10 G. Report to FDA in writing that Defendants have fully complied with the terms
11 of subparagraphs (A)-(F) of this paragraph; and

12 H. Receive written notification from FDA stating that Defendants appear to be in
13 compliance with the Act, applicable regulations, and this Decree, and authorizing Defendants to
14 resume operations.

15 19. Within thirty (30) calendar days after FDA has notified the firm in writing pursuant
16 to paragraph 18(H) that it may resume operations:

17 A. Defendants shall retain at their expense, an independent person or persons (the
18 “Auditor”) to conduct audit inspections of the Kato Road Facility not less than once every six
19 months for a period of two years and not less than once every twelve months for a period of three
20 years thereafter, for a total of five years of auditing. The Auditor shall be qualified by education,
21 training, and experience to conduct such inspections, and shall be without personal or financial
22 ties (other than the consulting agreement) to any of the Defendants, any San Francisco Herb and
23 Natural Food Company officer or employee, or their immediate families. Defendants shall
24 notify FDA of the Auditor’s qualifications in writing as soon as the Auditor is retained.

25 B. The audit shall evaluate whether Defendants are in compliance with the Act and
26 applicable regulations, including, but not limited to, whether: (i) there is evidence of rodents,
27 insects, or other pests in the food storage areas; (ii) Defendants have adequately closed off
28

1 entryways for rodents, insects, or other pests; (iii) food is stored an appropriate distance from the
2 walls to minimize infestations by rodents, insects, or other pests; (iv) employees follow proper
3 sanitation procedures; and (v) there is evidence of overcrowding that would contribute to
4 infestation by rodents, insects, or other pests.

5 C. At the conclusion of each audit inspection, the Auditor shall prepare a written
6 audit report (the "Audit Report") identifying in detail any deviations from the Act and applicable
7 regulations ("Audit Report Observations"). As part of every Audit Report, except the first Audit
8 Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to
9 correct all previous Audit Report Observations. The Audit Reports shall be delivered
10 contemporaneously to Defendants and FDA by courier service or overnight delivery service, no
11 later than ten (10) calendar days after the date each audit inspection is completed. If an Audit
12 Report contains any Audit Report Observations, FDA may, in its discretion, require that the five
13 year auditing cycle begin anew. In addition, Defendants shall maintain the complete Audit
14 Reports and all of their underlying data in separate files at the Kato Road Facility and shall make
15 the Audit Reports and underlying data available to FDA upon request.

16 D. If an Audit Report contains any Audit Report Observations, Defendants shall,
17 within ten (10) calendar days of receipt of the Audit Report, correct those observations, unless
18 FDA notifies them that a shorter time period is necessary. If, after receiving the Audit Report,
19 Defendants believe that correction of an Audit Report Observation will take longer than ten (10)
20 calendar days, Defendants shall, within seven (7) calendar days of receipt of the Audit Report,
21 propose to FDA a schedule for completing corrections ("Correction Schedule") and provide
22 justification describing why the additional time is necessary. If FDA does not approve
23 Defendants' proposed Correction Schedule, Defendants shall correct the Audit Report
24 Observations within three (3) calendar days of receiving notice of FDA's disapproval.
25 Defendants shall complete all corrections according to the approved Correction Schedule.
26 Within thirty (30) calendar days of Defendants' receipt of an Audit Report, or within the time
27 period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions
28

1 taken by Defendants to correct the Audit Report Observations. Within ten (10) calendar days of
2 the beginning of that review, the Auditor shall report in writing to FDA whether each of the
3 Audit Report Observations has been corrected.

4 20. If, at any time after entry of this Decree, FDA determines, based on the results of an
5 inspection, sample analysis, Audit Report, or other information, that Defendants have failed to
6 comply with any provision of this Decree, have violated the Act or applicable regulations, or that
7 additional corrective actions are necessary to achieve compliance with this Decree, the Act, or
8 applicable regulations, FDA may, as and when it deems necessary, notify Defendants in writing
9 of the noncompliance and order Defendants to take appropriate action, including but not limited
10 to ordering them to take one or more of the following actions immediately:

11 A. Cease receiving, manufacturing, preparing, processing, packing, holding, or
12 distributing articles of food until Defendants receive written notification from FDA that they
13 appear to be in compliance with the Decree, the Act, and applicable regulations, and that
14 Defendants may resume operations;

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

17 C. Submit samples of articles of food to a qualified laboratory to determine
18 whether the food is contaminated with filth; and

19 D. Take any other corrective actions as FDA deems necessary to protect the public
20 health or bring Defendants into compliance with this Decree, the Act, and applicable regulations,
21 including, but not limited to, requiring that Defendants reimplement or reinstitute any of the
22 requirements of this Decree.

23 The provisions of this paragraph shall be apart from, and in addition to, all other
24 remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions,
25 including the costs of FDA's supervision, inspections, investigations, analyses, examinations,
26 and reviews to implement and monitor recalls and other corrective actions, at the rates specified
27 in paragraph 22 of this Decree.

1 21. Upon entry of this Decree, Defendants and each and all of their officers, directors,
2 agents, representatives, employees, successors, assigns, attorneys, and any and all persons in
3 active concert or participation with any of them (including individuals, directors, corporations,
4 subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree, are
5 permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or
6 indirectly doing or causing any act that: (a) violates the Act, 21 U.S.C. § 331(a), by introducing,
7 or delivering for introduction, into interstate commerce articles of food that are adulterated
8 within the meaning of 21 U.S.C. § 342; or (b) violates the Act, 21 U.S.C. § 331(k), by causing
9 articles of food to be adulterated within the meaning of 21 U.S.C. § 342 while such articles are
10 held for sale after shipment of one or more ingredients in interstate commerce.

11 22. Defendants other than Defendant Niroomand shall reimburse the United States for
12 the costs of supervising Defendants' compliance with the terms of this Decree, including
13 Defendants' reconditioning or destruction of the Condemned Articles, and for costs associated
14 with any inspections, examinations, reviews, evaluations, and analyses conducted pursuant to
15 this Decree, at the standard rates prevailing at the time the activities are accomplished. As of the
16 date this Decree is signed by the parties, the rates are \$87.57 per hour or fraction thereof per
17 representative for time spent on supervision other than laboratory and analytical work; \$104.96
18 per hour or fraction thereof per representative for laboratory and analytical work; and \$0.555 per
19 mile for travel expenses. In the event that the standard rates generally applicable to FDA's
20 supervision of court-ordered compliance are modified, these rates shall be increased or decreased
21 without further order of this Court.

22 23. Representatives of FDA shall be permitted, without prior notice and as and when
23 FDA deems necessary, to make inspections of the Kato Road Facility and any other location at
24 or from which Defendants, now or in the future, receive, manufacture, prepare, process, pack,
25 hold, or distribute articles of food (collectively the "facilities"), and, without prior notice, take
26 any other measures necessary to monitor and ensure continuing compliance with the terms of
27 this Decree. During such inspections, FDA representatives shall be permitted access to
28

1 buildings, equipment, articles of food, containers, and packaging material(s) therein; to take
2 photographs and make video recordings; to take samples of Defendants' articles of food,
3 containers, and packaging material(s); to examine and copy all records relating to the receiving,
4 manufacturing, preparing, processing, packing, holding, and distributing of any and all articles of
5 food, and to the sanitation of the facilities. The inspections shall be permitted upon presenting a
6 copy of this Decree and appropriate credentials. The inspection authority granted by this Decree
7 is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C.
8 § 374.

9 24. Defendants shall abide by the decisions of FDA and its representatives, which shall
10 be final. All decisions specified in this Decree shall be vested in FDA's discretion and, if
11 necessary, shall be reviewed by this Court pursuant to the arbitrary and capricious standard as set
12 forth in 5 U.S.C. § 706(2)(A). Review by a court of any FDA decision rendered pursuant to this
13 Decree shall be conducted without any discovery and shall be based exclusively upon the written
14 record that was before FDA at the time of the decision.

15 25. Defendants shall provide a copy of this Decree, personally or by registered mail,
16 within ten (10) calendar days from the date of entry of the Decree, to each of Defendants'
17 officers, directors, agents, representatives, employees, successors, assigns, and attorneys.
18 Defendants shall also post a copy of this Decree in the employee common areas at the Kato Road
19 Facility as long as it remains in effect. Within thirty-five (35) calendar days of the date of entry
20 of this Decree, Defendants shall provide to FDA an affidavit of compliance, stating the facts and
21 manner of compliance with the provisions of this paragraph.

22 26. Upon entry of this Decree, Defendants shall report to FDA in writing the location of
23 the facilities at which they hold articles of food. If, at that time, Defendants have no facilities
24 other than the Kato Road Facility, they shall state that fact to FDA in writing. Following entry
25 of this Decree, Defendants shall immediately notify FDA in writing of the location of any new
26 facility or facilities at which they hold food.

27 27. Defendants shall notify FDA in writing at least thirty (30) calendar days before any
28

1 subsequent change in location, ownership, or character of their business, such as reorganization,
2 dissolution, assignment, or sale resulting in the emergence of a successor corporation or business
3 entity, the creation or dissolution of subsidiaries, or any other change in the corporate or business
4 structure of any newly-formed business entity (including any “doing business as” entity) over
5 which Defendants have any authority, or the sale or assignment of any business assets, such as
6 buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants
7 shall provide a copy of this Decree to any successor or assignee at least thirty (30) calendar days
8 prior to the assignment or change in ownership. Defendants shall furnish FDA with an affidavit
9 of compliance with this paragraph at least thirty (30) calendar days prior to such assignment or
10 change in ownership.

11 28. If any Defendant fails to comply with any of the provisions of this Decree, including
12 any time frame imposed by this Decree, then, on motion of the United States in this proceeding,
13 Defendants other than Defendant Niroomand shall pay to the United States of America the sum
14 of five thousand dollars (\$5,000) in liquidated damages for each day such violation continues
15 and an additional sum of one thousand dollars (\$1,000) in liquidated damages for each violation
16 of the Act, its implementing regulations, and/or this Decree.

17 29. Should the United States bring, and prevail in, a contempt action to enforce the terms
18 of this Decree, Defendants agree to pay all attorneys’ fees, travel expenses incurred by attorneys
19 and witnesses, court costs, expert witness fees, and investigational and analytical expenses
20 incurred in bringing such an action.

21 30. All notifications, correspondence, and communications to FDA required by the terms
22 of this Decree shall be addressed to the District Director, San Francisco District Office, U.S.
23 Food and Drug Administration, Department of Health and Human Services, 1431 Harbor Bay
24 Parkway, Alameda, CA 94502-7096.

25 31. This Consent Decree constitutes the entire agreement between each of the
26 undersigned Parties, and cannot be amended, except in writing and signed by each of the
27 undersigned Parties to this Consent Decree, and approved by the Court.

1 32. This Court retains jurisdiction to issue such further decrees and orders as may be
2 necessary to the proper disposition of this proceeding.

3 SO ORDERED

4 Dated this 17th day of October, 2012

5 *Elizabeth D. Laporte*
6

7 ELIZABETH D. LAPORTE
8 United States Magistrate Judge
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

