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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,

Plaintiff,

v.

LIFESoy, INC., a corporation,
and LONG H. LAI,
an individual,

Defendants.

Case No. 10CV1059JM(JMA)

**CONSENT DECREE OF
PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned attorneys, has filed a Complaint for Permanent Injunction against Lifesoy, Inc. ("Lifesoy"), a corporation, and Long H. Lai, an individual (collectively, "defendants"). Defendants have appeared through counsel and have consented to the entry of this Consent Decree of Permanent Injunction (the "Decree") without contest and before any testimony has been taken. The United States of America has consented to this Decree and the parties have jointly moved for its entry.

THEREFORE, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

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, 21 U.S.C. §§ 301-397 ("the Act").
3. Defendants violate 21 U.S.C. § 331(k) of the Act by causing ready-to-eat soy products, articles of food within the meaning of 21 U.S.C. § 321(f) (hereafter, "food"), to

1 become adulterated within the meaning of 21 U.S.C. § 342(a)(4). The articles of food are
2 adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed,
3 or held under insanitary conditions whereby they may have been rendered injurious to health,
4 or whereby they may have become contaminated with filth. Defendants also violate 21 U.S.C.
5 § 331(dd) by failing to register with FDA in accordance to 21 U.S.C. § 350d.

6 4. Defendants and each and all of their officers, agents, employees, representatives,
7 successors, assigns, heirs, attorneys, and any and all persons in active concert or participation
8 with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and
9 partnerships) are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C.
10 § 332(a) and the equitable authority of this Court, from directly or indirectly receiving,
11 preparing, processing, packing, holding, and distributing articles of food, at or from their facility
12 located at 4849 University Avenue, San Diego, California, (the "San Diego facility"), and any
13 other locations at or from which defendants, now or in the future, receive, prepare, process, pack,
14 hold, or distribute any articles of food, unless and until:

15 (A) Defendants select an expert or experts (the "sanitation expert") having no
16 personal or financial ties (other than a consulting agreement) to defendants or defendants'
17 manufacturing operations and who, by reason of background, education, training, and
18 experience, is qualified to develop and implement a written sanitation control program and to
19 assure that the defendants' comply with the Current Good Manufacturing Practice (CGMP)
20 requirements, 21 C.F.R. Part 110, and:

21 I. Defendants inform the United States Food and Drug Administration ("FDA") in
22 writing of the name and qualifications of the sanitation expert as soon as they retain the expert;

23 II. The sanitation expert develops a written sanitation control program for
24 manufacturing, preparing, packing, holding, and distributing articles of food, as described in
25 Paragraph 4(A), and such plan is submitted to FDA prior to implementation;

26 III. Defendants receive written notification from FDA approving the sanitation control
27 program developed by the sanitation expert;

28 IV. Defendants make the sanitation control program available and accessible (in

1 English, Spanish, or any other language(s) so that it is understood by all employees) to all their
2 employees;

3 V. The sanitation expert develops a written employee training program that includes,
4 at a minimum, instruction in sanitation control requirements for food-handling and
5 manufacturing, and the sanitation expert provides the training to each employee and documents
6 that each employee has received and understood the training;

7 VI. Defendants assign the responsibility and authority for implementing and
8 monitoring the sanitation control program on a continuing basis to an employee who is trained
9 in sanitation control requirements, and qualified and authorized to implement and monitor the
10 sanitation control program;

11 VII. The sanitation expert inspects the defendants' facility, including the buildings,
12 sanitation-related systems, equipment, utensils, articles of food, and relevant records contained
13 therein, to determine whether defendants have adequately established and implemented the
14 FDA-approved sanitation control program, whether the defendants have adequately addressed
15 the FDA investigators' inspectional observations listed on each Form FDA-483 issued to the
16 defendants since November 2007, and whether the defendants comply with the CGMP
17 requirements, 21 C.F.R. Part 110, and the Act; and

18 VIII. The sanitation expert certifies to FDA in writing that the defendants have
19 adequately established and implemented the FDA-approved sanitation control program, have
20 adequately addressed the Form FDA-483 observations, and comply with the CGMP
21 requirements, 21 C.F.R. Part 110, and the Act and, as part of the certification, provides to FDA
22 a written report describing in detail the actions the defendants have taken to ensure that, on an
23 ongoing basis, they adequately implement the FDA-approved sanitation control program and
24 comply with the CGMP requirements, 21 C.F.R. Part 110, and the Act;

25 (B) Defendants shall destroy under FDA's supervision, and according to a
26 destruction plan submitted in writing by Defendants and approved prior to implementation, in
27 writing, by FDA, all raw ingredients and all in-process and finished articles of food in their
28 custody, control, or possession at the time this decree is signed by the parties;

1 (C) FDA, as it deems necessary to evaluate defendants' compliance with the
2 terms of this Decree, the Act, and all applicable regulations, conducts inspections of the San
3 Diego facility, including the buildings, sanitation-related systems, equipment, utensils, all
4 articles of food, and relevant records contained therein;

5 (D) Any display or sales racks or container that defendants provide retailers are
6 capable of refrigerating (or controlling the temperature of) the defendants' product;

7 (E) Defendants register with FDA under 21 U.S.C. § 350d, and the
8 implementing regulations, 21 C.F.R. Part 1, Subpart H;

9 (F) FDA notifies defendants in writing that defendants appear to be in
10 compliance with the requirements set forth in Paragraphs 4(A) through (E) of this Decree, the
11 Act, and 21 C.F.R. Part 110; and

12 (G) Defendants have paid all costs of inspection, analysis, review,
13 investigations, examination, and supervision for FDA's oversight with respect to Paragraphs
14 4(A) through (F), at the rates set forth in Paragraph 7 below.

15 5. After defendants receive written notification from FDA pursuant to Paragraph 4(F)
16 that they appear to be in compliance with Paragraphs 4(A) through (E) of this Decree, the Act,
17 and 21 C.F.R. Part 110, defendants and each and all of their officers, agents, employees,
18 successors, assigns, attorneys, and any persons in active concert or participation with any of
19 them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships)
20 who receive actual notice of this Decree, are permanently restrained and enjoined from:

21 (A) directly or indirectly doing or causing any act that violates 21 U.S.C.
22 § 331(k), by causing articles of food to become adulterated within the meaning of 21 U.S.C.
23 § 342(a)(4) after shipment of one or more of their components in interstate commerce;

24 (B) violating 21 U.S.C. § 331(dd) by failing to register with FDA in accordance
25 to 21 U.S.C. § 350d; and

26 (C) failing to implement and continuously maintain the requirements of this
27 Decree.

28 6. Representatives of FDA shall be permitted, without prior notice and as and when

1 FDA deems necessary, to make inspections of defendants' facility at its current location or at
2 any new locations, and, without prior notice, take any other measures necessary to monitor and
3 ensure continuing compliance with the terms of this Decree. Such inspections may, at FDA's
4 discretion, include, but are not limited to, taking photographs and samples and examining and
5 copying all records that relate to the receipt, processing, preparation, packing, holding, or
6 distribution of any article of food. Such inspections shall be permitted upon presentation of a
7 copy of this Decree and appropriate credentials. The inspection authority granted by this Decree
8 is apart from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C.
9 § 374.

10 7. Defendants shall reimburse FDA for the costs of all FDA inspections,
11 investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to
12 evaluate defendants' compliance with this Decree. The costs of such inspections shall be borne
13 by defendants at the prevailing rates in effect at the time the costs are incurred. As of the date
14 that this Decree is signed by the parties, these rates are: \$87.57 per hour and fraction thereof per
15 representative for inspection work; \$104.96 per hour or fraction thereof per representative for
16 analytical or review work; \$0.50 per mile for travel expenses by automobile; government rate
17 or the equivalent for travel by air or other means; and the published government per diem rate
18 or the equivalent for the areas in which the inspections are performed per day, per representative
19 for subsistence expenses, where necessary. In the event that the standard rates applicable to
20 FDA supervision of court-ordered compliance are modified, these rates shall be increased or
21 decreased without further order of this Court.

22 8. If any defendant violates this Decree and is found in civil or criminal contempt,
23 defendants shall, in addition to other remedies, reimburse plaintiff for its attorney fees (including
24 overhead), investigational expenses, expert witness fees, and court costs relating to such
25 contempt proceedings.

26 9. If, at any time after this Decree has been entered, FDA determines, based on the
27 results of an inspection, the analyses of samples, a report or data submitted by defendants or the
28 expert, or any other information, that defendants have failed to comply with any provision of this

1 Decree, or have violated the Act or its implementing regulations, or that additional corrective
2 actions are necessary to achieve compliance with this Decree, the Act, or its implementing
3 regulations, FDA may, as and when it deems necessary, notify defendants in writing of the
4 noncompliance and order defendants to immediately:

5 (A) Cease receiving, processing, preparing, packing, holding, and distributing
6 any articles of food;

7 (B) Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this
8 Decree;

9 (C) Submit additional reports or information to FDA;

10 (D) Recall all articles of food that have been distributed or are under the custody
11 and control of defendants' agents, distributors, customers, or consumers; or

12 (E) Take any other corrective actions that FDA, in its discretion, deems
13 necessary to bring defendants into compliance with this Decree, the Act, and its implementing
14 regulations.

15 10. Upon receipt of notification from FDA under Paragraph 9, defendants shall
16 immediately and fully comply with the terms of the notice. All costs of such recall(s) and
17 corrective actions shall be borne by defendants. The costs of FDA inspections, sampling,
18 testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph
19 9 shall be borne by defendants at the rates specified in Paragraph 7. This provision shall be
20 separate and apart from, and in addition to, all other remedies available to FDA.

21 11. Any cessation of operations as described in Paragraph 9 shall continue until
22 defendants receive written notification from FDA that defendants appear to be in compliance
23 with the Act, its implementing regulations, and this Decree.

24 12. Within ten (10) calendar days after the entry of this Decree, defendants shall
25 provide a copy of the Decree, by personal service or by certified mail, return receipt requested,
26 to each and all of defendants' officers, agents, employees, attorneys, and any persons in active
27 concert or participation with any of them (including individuals, directors, corporations,
28 subsidiaries, affiliates, and partnerships). Within thirty (30) calendar days of the date of entry

1 of this Decree, defendants shall provide to FDA an affidavit of compliance stating the fact and
2 manner of compliance with the provisions of this Paragraph and identifying the names and
3 positions of all persons who have received a copy of this Decree.

4 13. Defendants shall notify FDA in writing at least fifteen (15) calendar days before
5 any change in ownership, name, or character of their business that occurs after entry of this
6 Decree, including: a reorganization, relocation, dissolution, assignment, or sale resulting in the
7 emergence of a successor entity or corporation; the creation or dissolution of subsidiaries or any
8 other change in the corporate structure or identity of Lifesoy, or any other current or future food
9 processing business of defendants; or the sale or assignment of any business assets, such as
10 buildings, equipment, or inventory that may affect compliance with this Decree. Defendants
11 shall provide a copy of this Decree to any prospective successor or assignee at least thirty (30)
12 calendar days prior to such sale or change of business. Defendants shall furnish FDA with an
13 affidavit of compliance with this Paragraph no later than ten (10) calendar days prior to such sale
14 or change of business.

15 14. If defendants fail to comply with any of the provisions of this Decree, then
16 defendants shall pay to the United States of America the sum of one thousand dollars
17 (\$1,000.00) in liquidated damages for each calendar day defendants are in violation of the
18 Decree, and an additional one thousand dollars (\$1,000.00) for each violation of this Decree.

19 15. All notifications, correspondence, and communications to FDA required by the
20 terms of this Decree shall be submitted to the Director, FDA Los Angeles District Office, 19701
21 Fairchild, Irvine, California, 92612, and shall reference this civil action by case name and civil
22 action number in such communications.

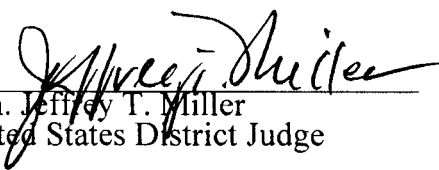
23 16. All decisions specified in this Decree shall be vested in the discretion of FDA.
24 FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall
25 be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C.
26 § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall
27 be based exclusively on the written record before FDA at the time the decision was made. No
28 discovery shall be taken by either party.

1 17. No sooner than seven (7) years after entry of this Decree, defendants may petition
2 this Court for an order dissolving this Decree. If defendants have maintained, to FDA's
3 satisfaction, a state of continuous compliance with this Decree, the Act, and all applicable
4 regulations for seven (7) years preceding defendants' petition, the government will not oppose
5 such petition.

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

9
10 IT IS SO ORDERED:

11 Dated this 2nd day of June, 2010.

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13 
14 Hon. Jeffrey T. Miller
United States District Judge

15
16 We hereby consent to the entry of the foregoing Decree:

17 For the Plaintiff:

KAREN P. HEWITT
Acting United States Attorney
Southern District of California

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20 TOM STAHL
Assistant U.S. Attorney

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25 Of Counsel:


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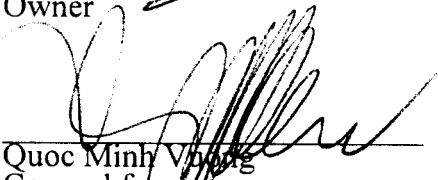
27
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8 For Defendants:

9 Lifesoy, Inc

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11 Long H. Lai,
Owner

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13 Quoc Minh Vuong
14 Counsel for
15 Long H. Lai and Lifesoy, Inc.
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