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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. SCANDINAVIAN SMOKE HOUSE, INC., et al. Defendants.	No. CV 06-6610 EMC **[PROPOSED] AMENDED CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, filed a complaint for injunctive relief against Scandinavian Smoke House, Inc. ("Scandinavian Smoke House") and Odd Anders Holm (collectively, "Defendants") on October 24, 2006. Defendants appeared and consented to entry of a Consent Decree of Permanent Injunction (the "Decree") without contest and before any testimony had been taken, and the United States of America consented to the Decree. This Court entered the Decree on December 1, 2006.

Plaintiff, the United States of America, by Melinda Haag, United States Attorney for the Northern District of California, and Defendants, having appeared and having consented to entry of this Amended Consent Decree of Permanent Injunction ("Amended Decree") without contest and before any testimony has been taken:

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 injunction stated a claim for relief against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 et seq.

3. Defendants violated the Act, 21 U.S.C. § 331(a), by causing to be introduced into interstate commerce articles of food, as defined by 21 U.S.C. § 321(f), namely cold-smoked fishery products, that were adulterated within the meaning of 21 U.S.C. § 342(a)(1) and 21 U.S.C. § 342(a)(4); and 21 U.S.C. § 331(k), by causing such articles of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(1) and 21 U.S.C. § 342(a)(4) after shipment in interstate commerce.

4. Defendants represent to the Court that, at the time of entry of this Amended Decree, they are not engaged in receiving, holding, manufacturing, processing, preparing, packaging, packing, or distributing any type of food in any State or Territory. As used in this Amended Decree, the terms "holding," "manufacturing," "processing," "packaging," and "packing" are defined as provided in 21 C.F.R. § 1.227(b); the terms "State" and "Territory" are defined as provided in 21 U.S.C. § 321(a).

5. Except as provided below, Defendants and each and all of their officers, agents, employees, successors, assigns, attorneys, and those persons in active concert or participation with any of them, remain perpetually restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from manufacturing, preparing, processing, packaging, packing, holding and/or distributing food at or from any location in any State or Territory.

6. If, at some future date, the Defendants wish to resume manufacturing, processing, packaging or otherwise preparing any smoked fish or fishery products at or from any location in any State or Territory, the sole method by which such authorization may be sought is by Defendants filing a motion with and obtaining the leave of this Court. Defendants shall simultaneously notice FDA of any such motion.

7. If Defendants later determine that they wish to resume or begin receiving, holding, manufacturing, preparing, processing, packaging, packing, or distributing food (other than

manufacturing, processing, packaging or otherwise preparing any smoked fish or fishery products, as described in Paragraph 6 above) in any State or Territory, including receiving, holding, and/or distributing smoked fish and fishery products completely manufactured, prepared, processed and/or packaged by persons other than Defendants, they must first notify FDA in writing, at least ninety (90) calendar days in advance of the date they propose to resume or begin any such operations. The notice must provide a detailed description of the food-related business Defendants intend to operate. This description shall include, among other things, the address and location of any business establishments or facilities for these food-related activities; the type(s) of food Defendants intend to receive, hold, manufacture, prepare, process, package, pack, and/or distribute; and how they intend to comply with Paragraph 8 below.

8. As a condition precedent to FDA's authorization for Defendants to resume or begin the receiving, holding, manufacturing, preparing processing, packaging, packing, and/or distributing of food:

A. Defendants must thoroughly clean and sanitize any facilities from which they intend to operate, all equipment therein, and all vehicles or containers to be used to transport or hold food, and make all necessary improvements to said facilities, equipment, vehicles or containers, thereby rendering them suitable for receiving, holding, manufacturing, preparing, processing, packaging, packing, and/or distributing articles of food;

B. Defendants must select a person ("Sanitation expert"), who is without any personal or financial ties (other than a consulting agreement) to the Defendants or their families, and who, by reason of background, experience, and education, is qualified to and has developed a Sanitation Standard Operation Procedure ("SSOP") and an employee training program on sanitary food handling techniques and personal hygiene practices, and FDA has approved in writing the SSOP and training program developed by the Sanitation expert;

C. Defendants must conduct appropriate hazard analyses and prepare Hazard and Critical Control Points ("HACCP") plans, as required by 21 C.F.R. § 123.6(b), for

all fish and fishery products received, held, manufactured, processed, packaged, packed and/or distributed at or from Defendants' facilities; said analyses and plans must have been approved in writing by FDA and must be implemented to the satisfaction of FDA;

D. FDA, as it deems necessary to evaluate Defendants' compliance with this Paragraph, conducts inspections of the facilities;

E. Defendants pay the costs of inspections, supervision, analyses, and examination by FDA at the rates specified in Paragraph 11; and

F. FDA notifies Defendants in writing that Defendants appear to be in compliance with the relevant requirements set forth in this paragraph and with all requirements of 21 C.F.R. Parts 110 and 123.

9. After completing the applicable requirements of Paragraph 8 above, and receiving FDA notification in writing that Defendants appear to be in compliance withParagraph 8 and with all applicable requirements of 21 C.F.R. Parts 110 and 123, Defendants may resume or begin operations to the extent described in the written FDA authorization. If the FDA denies Defendants' request to begin or resume operations, the written notice will set forth the grounds for denial. Defendants shall continuously and effectively implement any plans developed pursuant to Paragraph 8, unless Defendants submit, and FDA approves in writing, an alternative plan.

10. All ready-to-eat ("RTE") food products, including any smoked fish or fishery products, whether received, held, manufactured, prepared, processed, packaged, packed, or distributed by Defendants, that are at any time determined to contain *L. monocytogenes* shall be promptly destroyed by Defendants, or promptly reconditioned by Defendants pursuant to a reconditioning plan approved in writing by FDA. Any such destruction or reconditioning shall be under FDA's supervision and at Defendants' cost.

11. Defendants shall pay the costs of FDA's supervision, inspection, review, examination, and analyses conducted pursuant to this Amended Decree at the standard rates prevailing at the time the activities are accomplished. As of the date this Amended Decree is

signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative for inspection and supervision work other than laboratory and analytical work; $104.96 per hour and fraction thereof per representative for laboratory and analytical work; $0.555 per mile for travel by automobile; the government rate or equivalent for travel by air; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day per representative for subsistence expenses, where necessary. In the event that the standard rates generally applicable to FDA supervision, inspection, review, examination, or analysis are modified, these rates shall be increased or decreased without further order of the Court.

12. Duly authorized representatives of FDA shall be permitted, as FDA deems necessary and without prior notice, to make inspections of the Defendants' facilities, including any new locations, and all equipment, finished and unfinished materials and products, containers, labeling and other promotional material; to take photographs and make videotape recordings; to collect samples of any finished and unfinished materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, holding, manufacturing, processing, packaging, packing, labeling, promotion, and distribution of any and all of the Defendants' products to ensure continuing compliance with the terms of this Amended Decree. During inspections, Defendants shall cooperate fully with FDA, by, among other things, promptly providing FDA investigators with requested documents and materials. The costs of all such inspections, supervision, review, examination, and analyses are to be borne by Defendants at the rates specified in Paragraph 11. The inspections shall be permitted upon presentation of a copy of this Amended Decree and appropriate credentials. The inspection authority granted by this Amended Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

13. After the applicable requirements of Paragraph 8 have been met and FDA authorizes Defendants to receive, hold, manufacture, prepare, process, package, pack, or distribute food, Defendants and each and all of their officers, agents, employees, successors, assigns, attorneys, and those persons in active concert or participation with any of them, are permanently restrained and enjoined from doing or causing to be done, directly or indirectly, any act that violates 21

U.S.C. § 331(a), by causing the introduction into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(1) or 21 U.S.C. § 342(a)(4); 21 U.S.C. § 331(c), by receiving in interstate commerce articles of food which are adulterated within the meaning of 21 U.S.C. § 342(a)(1) or 21 U.S.C. § 342(a)(4) and the delivery or proffered delivery thereof for pay or otherwise; or 21 U.S.C. § 331(k), by causing articles of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(1) or 21 U.S.C. § 342(a)(4) after shipment in interstate commerce.

14. If, at any time after entry of this Amended Decree, FDA determines, based on the results of an inspection, analysis of a sample or samples, or other information, that the Defendants have failed to comply with any provision of this Amended Decree, FDA regulations and/or the Act, or that additional corrective actions are necessary to achieve compliance with this Amended Decree, FDA regulations, and/or the Act, FDA may, as and when it deems necessary, notify the Defendants in writing of the noncompliance and order the Defendants to take appropriate action, including, but not limited to, ordering the Defendants to immediately take one or more of the following actions:

A. Cease receiving, holding, manufacturing, preparing, processing, packaging, packing, and/or distributing any article of food;

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

C. Pay liquidated damages as described in Paragraph 17, below; and/or

D. Take any other corrective actions as FDA deems necessary to bring the Defendants into compliance with this Amended Decree, FDA regulations, and the Act.

Defendants shall pay all costs of such recalls and corrective actions, including the costs of FDA supervision, inspections, analyses, examinations, review, travel, and subsistence expenses to implement recalls and other corrective actions, at the rates specified in Paragraph 11 of this Amended Decree. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

15. Upon receipt of any such order as described in Paragraph 14 from FDA, Defendants shall immediately comply with the order. Any ordered cessation of operations shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Amended Decree, FDA regulations, and the Act. After a cessation of operations, and while determining whether Defendants are in compliance with the Amended Decree and the Act, FDA may require that Defendants re-institute or re-implement any of the requirements of this Amended Decree.

16. Defendants shall maintain copies of their Sanitation and HACCP plans, along with copies of any Sanitation or HACCP records required by the plans and by 21 C.F.R. §§ 123.6(c)(7), 123.7(d) and 123.8(d), at all of their facilities covered by plans and records in a location where they are readily available for reference and inspection by FDA officials. All records required to be kept by the Sanitation and HACCP plans and by these sections of the Code of Federal Regulations shall be retained for at least three (3) years after the date the records are prepared.

17. If Defendants fail to comply with any of the provisions of this Amended Decree, including any time frame imposed by this Amended Decree, then, on written notice of the FDA, Defendants shall pay to the United States of America: (a) five hundred dollars ($500) in liquidated damages for each day Defendants fail to comply with this Amended Decree; (b) an additional sum of five hundred dollars ($500) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Amended Decree; and (c) an additional sum in liquidated damages equal to twice the retail value of any shipments of adulterated or misbranded food. The amount of liquidated damages imposed under this Paragraph shall not exceed one hundred thousand dollars ($100,000) 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 the payment of liquidated damages.

18. All decisions specified in this Amended 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 shall be based on the written record before FDA at the time the decision was made. No discovery shall be had by either party.

19. Defendants shall provide a copy of this Amended Decree to each of Defendants' directors, officers, and employees at any facility or business location in any State or Territory within ten (10) calendar days from the date of entry of this Amended Decree by the Court, and shall provide a copy of this Amended Decree to any new directors, officers or employees within ten (10) calendar days of their appointment or employment. Defendants shall provide to FDA within thirty (30) calendar days of either the date of entry of this Amended Decree, or for new directors, officers or employees appointed or hired after entry of the Amended Decree, within thirty (30) calendar days for their appointment or employment, 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. Defendants shall, in writing, notify FDA at least thirty (30) calendar days before any change in ownership, character, or name of their businesses, including reorganization, relocation, dissolution, assignment, or sale resulting in the emergence of a successor entity or corporation; the creation or dissolution of new corporations, limited liability corporations, fictitious business entities (also known as "DBAs"), subsidiaries, or any other change in the corporate structure or identity of food-related businesses owned or operated by or with Odd Anders Holm or Scandinavian Smoke House in any State or Territory; or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Amended Decree. Defendants shall serve a copy of this Amended Decree on any prospective successor or assign no later than thirty (30) calendar days prior to such sale or change in business and shall furnish the United States with an affidavit of compliance with this Paragraph within fifteen (15) calendar days of such service on a prospective successor or assign.

21. Defendants shall post a copy of this Amended Decree on a bulletin board in an employee common area at the facility within ten (10) calendar days of the entry of this Amended

Decree, or within ten (10) calendar days of the opening of any new facility or business location in any State or Territory at or from which Defendants receive, hold, manufacture, prepare, process, package, pack or distribute food, and shall ensure that the Amended Decree remains posted at all times.

22. Defendants shall, within ten (10) calendar days of the entry of this Amended Decree, or within ten (10) calendar days of resuming or beginning operations at any facility or business location in any State or Territory at or from which Defendants receive, hold, manufacture, prepare, process, package, pack or distribute food, hold a general meeting or series of smaller meetings for all employees of the facility, at which they shall describe the terms and obligations of this Amended Decree.

23. Any notices, test results or other information this Amended Decree requires Defendants to give to FDA shall be given in writing to the District Director, FDA San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

24. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Amended Decree, Defendants agree to pay attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, court costs, expert witness fees and investigational and analytical expenses incurred in bringing such action.

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

SO ORDERED:

Dated 4/15/13.

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UNITED STATES DISTRICT COURT
IT IS SO ORDERED
Judge Edward M. Chen
NORTHERN DISTRICT OF CALIFORNIA

We hereby consent to the entry of the foregoing Amended Decree.

FOR DEFENDANTS:

Dated: April 9, 2013 By: /S/ signature on file
ODD ANDERS HOLM,
individually and on behalf of
Scandinavian Smoke House, Inc.

SWANSON & McNAMARA LLP

Dated: April 10, 2013 By: /S/ signature on file
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