Roman, J. KY

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. THE SMOKEHOUSE OF NEW YORK, LLC, BRETT H. PORTIER, and PANAGIOTA SOUBLIS, Defendants.	17 Civ. 4830 (NSR) **CONSENT DECREE**

WHEREAS, on June 27, 2017, Plaintiff, the United States of America (the "United States"), on behalf of the United States Food and Drug Administration ("FDA"), filed a complaint for injunctive relief (the "Complaint") against The Smokehouse of New York, LLC ("Smokehouse"), Brett H. Portier ("Portier"), and Panagiota Soublis ("Soublis," and together with Smokehouse and Portier, "Defendants"), alleging that Defendants have violated, and threaten to violate in the future, the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act"), and related regulations;

WHEREAS the United States and Defendants (collectively, the "Parties") agree, and the Court by entering this Consent Decree finds, that this consent decree is fair, reasonable, and in the public interest;

NOW, THEREFORE, with the consent of the Parties, it is hereby ORDERED, ADJUDGED, and DECREED as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

2. Venue is appropriate pursuant to 28 U.S.C. § 1391, because Defendants conduct business in this district.

ADMISSIONS

3. Defendants admit, acknowledge, and accept responsibility for the following:

A. Defendant Smokehouse prepares, processes, packs, holds, and distributes food, including fish and fishery products, primarily at a facility located at 434 Waverly Avenue, Mamaroneck, New York 10543 (the "Facility").

B. Defendant Soublis is Smokehouse's President, sole corporate officer, and owner.

C. Defendant Portier is Smokehouse's Director of Operations, responsible for Smokehouse's day-to-day operations, including product ordering, receiving, packaging, storing, Facility maintenance, sanitation, and oversight of employees, as well as preventing, detecting, and correcting violations of food safety regulations.

D. Defendants process food at the Facility, including raw salmon that originates in Canada. Defendants also sell and ship their fish and fishery products in further interstate commerce.

E. Items processed, packed, and held in Defendants' facility, including Defendants' fish and fishery products, are food within the meaning of the Act, 21 U.S.C. § 321(f).

F. Between 2011 and 2015, FDA conducted five inspections of Defendants' Facility.

G. At each of these inspections FDA found the bacterium *Listeria monocytogenes* ("*L. mono*") in the Facility, including on a food-contact surface and in packaged, ready-to-eat food.

H. Following the 2011-2015 inspections, Defendants took a number of corrective actions that they stated would address the conditions found by investigators.

I. Between March 8 and April 5, 2017, FDA conducted another inspection of the Facility. *L. mono* was found on food-contact surfaces, including a stainless steel table where food is processed and on a plastic tray used interchangeably to hold raw and finished products.

J. Defendants have repeatedly prepared, packed, or held food under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health, and failed to manufacture, package, and store food under conditions and controls necessary to minimize the potential for microorganism growth and contamination.

INJUNCTIVE RELIEF

4. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who received actual notice of this Decree by personal service or otherwise are **hereby permanently restrained and enjoined**, under the provisions of 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly receiving, preparing, processing, packing, labeling, holding, and/or distributing articles of food, at or from the Facility at 434 Waverly Avenue, Mamaroneck, New York 10543 and/or any other location(s) at or from which Defendants, now or in the future, directly or indirectly receive, prepare, process, pack, label, hold, and/or distribute articles of food, unless and until the following occurs:

A. Defendants retain, at their expense, an independent person or persons (the "Expert" or "Experts") having no personal or financial ties (other than the retention agreement) to Defendants or their families, and who, by reason of background, education, training, and

experience, is qualified to assist Defendants in controlling for the risk of *L. mono*, in complying with the current good manufacturing practice regulations for food, 21 C.F.R. Part 110, and in complying with the seafood Hazard Analysis and Critical Control Point ("HACCP") regulations, 21 C.F.R. Part 123. The Expert's (or Experts' collective) qualifications shall include, but not be limited to: developing procedures to adequately control for the risk of *L. mono* in all of Defendants' food products, as described in Paragraph 4 above, including, but not limited to, fish and fishery products; developing an effective written Sanitation Control and Food Safety Plan ("Sanitation Plan") covering receiving, preparing, processing, packing, labeling, holding, and/or distributing articles of food; developing adequate written Standard Sanitation Operating Procedures ("SSOPs") covering fish and fishery products, as required by 21 C.F.R. § 123.11; establishing a Pathogen Control Program, pursuant to Paragraph 4(B)(1) herein, for the genus Listeria ("*L. spp.*"); and developing and conducting employee training programs (in English and Spanish) on sanitation and pathogen controls, and on complying with this Decree, the Act, and 21 C.F.R. Parts 110 and 123. Defendants shall notify the FDA in writing of the name(s) and qualifications of the Expert(s) under Paragraph 4(A) within five (5) calendar days of retaining such Expert(s);

B. The Expert(s), in conjunction with Defendants:

(1) Develop(s) and submit(s) to FDA an effective program ("Pathogen Control Program") for monitoring and testing, at appropriate frequencies, finished products, food-contact surfaces, equipment, and other environmental sites where fish is received, prepared, processed, packed, held, and distributed, up to and including final packaging, and common areas that could be reservoirs for cross-contamination, to ensure that *L. spp.* is controlled within the Facility and that *L. mono* does not occur in the finished product. Environmental testing shall be

performed, in accordance with timetables submitted to and approved in writing by FDA before testing begins, by a qualified, independent laboratory having no personal or financial ties (other than the retention agreement) to Defendants or their families (the "Laboratory"), identified in the Pathogen Control Program. Defendants shall ensure that the Laboratory performs its analysis in a manner acceptable to FDA. Defendants shall ensure that all of the Laboratory's test results are provided to FDA within two (2) calendar days after receipt by Defendants. The Pathogen Control Program must include a plan for remedial action when *L. spp.* is detected through environmental or product testing. The plan for remedial action shall, at a minimum, establish procedures to address the root cause of the problem, establish intensive sanitation procedures, and ensure that adulterated food shall not be released from the Facility;

(2) Develop(s) and submit(s) to FDA an effective written Sanitation Plan that establishes adequate methods, facilities, and controls, for receiving, preparing, processing, packing, labeling, holding, and/or distributing articles of food to minimize the risk of introduction of *L. mono* into Defendants' food, and to ensure that foods are not adulterated, within the meaning of 21 U.S.C. § 342(a). Such methods, facilities, and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering Defendants' plant and all equipment therein suitable for use in receiving, processing, preparing, packing, holding, and distributing articles of food to prevent the articles of food from becoming adulterated, and instituting procedures to ensure that the plant and equipment therein are continuously maintained in a sanitary condition. The Sanitation Plan shall ensure that Defendants are required to adhere to the requirements of 21 C.F.R. Part 110, which sets forth good manufacturing practices in manufacturing, packaging, and holding food;

(3) Develop(s) and submit(s) to FDA adequate written SSOPs, as required by 21 C.F.R. § 123.11, that at a minimum, ensure on an ongoing basis that Defendants' Facility and all equipment contained therein are clean, sanitized, and suitable for receiving, preparing, processing, packing, holding, and distributing articles of food, and that Defendants' operations comply with the Act and its implementing regulations;

(4) Conduct(s) hazard analyses for each type of fish and fishery product Defendants intend to process to identify all food safety hazards reasonably likely to occur, in accordance with 21 C.F.R. § 123.6(a);

(5) Develop(s) and submit(s) to FDA adequate written seafood HACCP plans, which include, for each food safety hazard reasonably likely to occur in each of Defendants' seafood products, critical control points, critical limits, and written corrective action plans addressing deviations from critical limits. Defendants' seafood HACCP plans must effectively control for all food safety hazards reasonably likely to occur for each type of fish and fishery product that Defendants intend to process;

(6) Provide(s) evidence of the adequacy of the critical limits listed in Defendants' seafood HACCP plans to control for all food safety hazards reasonably likely to occur for each type of fish and fishery product that Defendants intend to process; and

(7) Develop(s) and submit(s) to FDA written employee training programs (in English and Spanish) on Defendants' Sanitation Plan, seafood HACCP plans, the SSOPs, and the Pathogen Control Program. Defendants shall make English and Spanish versions of the Sanitation Plan, seafood HACCP plans, the SSOPs, and the Pathogen Control Program available and accessible to all their employees, including part-time, temporary, or seasonal

employees. The Expert shall test to confirm that each employee fully understands the substance of the employee training programs;

C. FDA has approved, in writing, the Sanitation Plan, seafood HACCP plans, SSOPs, Pathogen Control Program, and employee training programs developed by the Expert(s), as applicable and as specified in Paragraphs 4(B)(1)-(7);

D. Defendants successfully implement quarterly employee training programs (in English and Spanish) developed by the Expert(s) and approved by FDA according to Paragraph 4(C);

E. Defendants, at their expense, clean, sanitize, and renovate their Facility and equipment and make such improvements to the physical property as are necessary to render the Facility and equipment suitable for receiving, preparing, processing, packing, holding, and distributing articles of food, and Defendants ensure that the Facility and equipment will be continuously maintained in a sanitary condition;

F. Defendants recall, to the retail level, all fish or fishery products distributed since May 3, 2017, at their own expense. Defendants shall certify to FDA in writing that they have completed the recall.

G. Defendants report to FDA, in writing, the actions they have taken to bring their operations into compliance with this Decree, the Act, and all applicable regulations, including the specific measures Defendants have taken to address each of the deficiencies documented by FDA since 2000;

H. The Expert(s) conduct a comprehensive inspection of the Facility and the methods and controls used to receive, prepare, process, pack, hold, and distribute food to determine whether Defendants' Facility is sanitary and Defendants are fully prepared to operate in

compliance with this Decree, the Act, and all applicable regulations. At a minimum, the comprehensive inspection should include environmental swabbing of Defendants' Facility for *L. spp.*, identifying and eliminating harborage sites for *L. mono*, and conducting a root cause analysis of the *L. mono* contamination. The Expert(s) shall verify that Defendants have corrected all of the observations listed on FDA Forms-483 since 2000. The Expert(s) shall submit all findings, in writing, to Defendants and FDA concurrently, within ten (10) business days of completion of the inspection;

I. Defendants assign continuing responsibility for implementing and monitoring the Sanitation Control and Pathogen Control Program to a person(s), who, by reason of background, education, training or experience, is competent to maintain Defendants' facility in a sanitary condition, coordinate with the laboratory, and implement any necessary remedial action(s), and provide such person with the authority to achieve the necessary corrections. By assigning responsibility for implementing and monitoring the Sanitation Control and Pathogen Control Program, Defendants are not relieved from the requirements of this Decree, the Act, or its implementing regulations.

J. FDA, if and when it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and its implementing regulations, has completed to its satisfaction an inspection of the Facility, including the building, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein;

K. Defendants pay all costs of the inspection, analyses, review, investigations, examination, and supervision for FDA's oversight with respect to Paragraphs 4(A) through 4(I), at the rates set forth in Paragraph 13 below; and

L. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 4(A) through 4(K) of this Decree, the Act, and its implementing regulations.

5. Within thirty (30) calendar days after entry of this Decree, Defendants shall destroy, under FDA's supervision and pursuant to a destruction plan approved in writing by FDA, all raw ingredients, in-process, and finished articles of foods, and any other foods Defendants receive, prepare, process, pack, label, or hold, which are in Defendants' custody, control, and/or possession at the time this Decree is signed by both parties. FDA will consider on a case-by-case basis whether Defendants must destroy any third-party products Defendants sell at retail or whether Defendants may distribute such products upon receiving FDA's notification under Paragraph 4(L).

6. Immediately upon resuming operations after completing the requirements of Paragraph 4, Defendants shall, in consultation with the Expert(s), continuously implement the FDA-approved seafood HACCP plans, SSOPs, Sanitation Plan, Pathogen Control Program, and the quarterly employee training program, as approved by FDA. In the event that Defendants or their Expert(s) determine that the FDA-approved Pathogen Control Program needs to be revised, Defendants shall provide proposed changes to FDA in writing at least twenty (20) calendar days before their implementation, and shall not implement their proposed changes until FDA approves those changes in writing. Any alternative Pathogen Control Program submitted to FDA shall consist of methods and controls that are shown to FDA's satisfaction to systemically control organisms such as *L. spp.* and ensure that *L. mono* does not occur in finished products, and shall otherwise be consistent with Paragraph 4(B)(1).

7. If, after notifying FDA of the name of the Laboratory retained to conduct sample collection and analyses in the Pathogen Control Program, Defendants terminate or in any way alter

their service contract with the Laboratory, Defendants shall notify FDA within seven (7) calendar days. If Defendants terminate their service contract, Defendants shall promptly obtain the services of another Laboratory and shall provide a copy of the service contract with a new Laboratory to FDA within five (5) business days of execution. At all times while this Decree is in effect, Defendants shall have in place a service agreement with a laboratory to institute the testing required by the Pathogen Control Program.

8. After receiving notice from FDA pursuant to Paragraph 4(L), Defendants shall not import, receive, prepare, process, pack, hold, label, or distribute any fish or fishery product not identified in a written seafood HACCP plan approved by FDA until Defendants submit for FDA's review a written seafood HACCP plan for such fish or fishery product and receive FDA's written approval. In no circumstances shall FDA's silence be construed as a substitute for written approval.

9. Within thirty (30) calendar days after receiving FDA's notification under Paragraph 4(L), the Expert(s) shall conduct a comprehensive inspection of the Facility and the methods and controls used to receive, prepare, process, pack, label, hold, and distribute foods to determine whether Defendants are operating in compliance with this Decree, the Act, and all applicable regulations. The Expert(s) shall submit a report documenting all findings, including but not limited to the findings related to the Pathogen Control Program, to Defendants and FDA concurrently, within ten (10) calendar days after completing the inspection. Thereafter, the Expert(s) shall conduct quarterly audits for one year, and then one audit every six (6) months for the next two (2) years. Beginning in the fourth year after Defendants resume their operations after completing the requirements of Paragraph 4, the Expert(s) shall conduct inspections annually

unless FDA informs Defendants in writing that more frequent expert inspections and reporting are required.

A. During each inspection conducted by the Expert(s), the Expert(s) shall verify that Defendants' Facility and the methods and controls Defendants use to receive, prepare, process, pack, label, hold, and distribute articles of food are in compliance with the requirements of this Decree, the Act, and its implementing regulations, and shall certify such in the Expert's report submitted to Defendants and FDA concurrently as described in this Paragraph.

B. If the Audit Report contains any observations indicating that Defendants are not in compliance with this Decree, the Act, or its implementing regulations, Defendants shall, within fifteen (15) business days after receipt of the Expert's report, make all necessary corrections and notify FDA about the corrections in writing, unless FDA notifies Defendants in writing that a shorter timeframe is required or that a longer timeframe is appropriate.

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

A. Violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce, any article of food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. Violates the Act, 21 U.S.C. § 331(k), by causing any article of food to become adulterated under 21 U.S.C. § 342(a)(4) while such article is held for sale after shipment of one or more of its components in interstate commerce; or

C. Results in the failure to implement and continuously maintain the requirements of this Decree.

FUTURE COMPLIANCE

11. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' Facility 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, other foods Defendants distribute at retail, containers, and packaging material; to take photographs and make video recordings; to take samples of Defendants' in-process and finished articles of food, other foods Defendants distribute at retail, containers, and packaging material; and to examine and copy all records related to receiving, processing, manufacturing, preparing, 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.

12. 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.

13. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time costs are incurred, and Defendants shall make payment in full to FDA within (30) calendar days of receiving written notification from FDA of the costs. As of the date that this Decree is signed by the parties, these rates are (i) $93.26 per hour and fraction thereof per representative for inspection work, (ii) $111.77 per hour or fraction thereof per representative for analytical or review work, (iii) $0.535 per mile for travel by automobile, (iv) the government rate or the equivalent for travel by air or other means, and (v) the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates for 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, audit, analysis of a sample, report submitted by the Expert(s), or other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing and order Defendants to take appropriate action, including, but not limited to, ordering Defendants immediately to take one or more of the following actions:

A. Cease receiving, preparing, processing, packing, labeling, holding, and distributing any articles of food;

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

C. Submit additional samples to a qualified Laboratory for analysis;

D. Institute or re-implement any of the requirements set forth in this Decree; and

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

15. The provisions of Paragraph 14 shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, review, travel, and subsistence expenses to implement and monitor recalls and other actions, at the rates specified in Paragraph 13 of this Decree.

16. Upon receipt of any order issued by FDA pursuant to Paragraph 14, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action as described in Paragraph 14 shall be implemented immediately upon notice from FDA and shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Decree, the Act, and its implementing regulations, and that Defendants may resume operations. After a cessation of operations, and while determining whether Defendants are in compliance with this Decree, the Act, and its implementing regulations,

FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree.

17. Defendants shall maintain copies of their Pathogen Control Program, Sanitation Plan, SSOPs, and seafood HACCP plans, along with copies of all records required by such plans, 21 C.F.R. Parts 110 and Part 123, and this Decree, at the Facility in a location where they are readily available for reference and inspection by FDA. All records required to be kept by Defendants' Pathogen Control Program, SSOPs, Sanitation Plan, the seafood HACCP plans, 21 C.F.R. Part 123, and this Decree shall be retained for at least three (3) years after the date the records are prepared and shall be presented immediately to FDA investigators upon request.

LIQUIDATED DAMAGES AND FEES

18. If Defendants fail to comply with the provisions of the Act, its implementing regulations, or this Decree, then Defendants shall pay to the United States of America liquidated damages in the sum of three thousand dollars ($3,000) for each day that such violation continues; an additional sum of three thousand dollars ($3,000) in liquidated damages per day for each violation of the Act, its implementing regulations, or this Decree; and a further sum equal to twice the retail value of each shipment of food that is adulterated or otherwise in violation of the Act, its implementing regulations, or this Decree. 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 this Court to impose, additional civil or criminal penalties based on the conduct that may also be the basis for payment of liquidated damages pursuant to this Paragraph.

19. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States 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 the contempt proceedings.

MISCELLANEOUS PROVISIONS

20. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. If contested, FDA's decisions under this Decree 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 the FDA at the time the decision was made. No discovery shall be taken by either party.

21. Within ten (10) calendar days after entry of this Decree, Defendants shall provide a copy of this Decree by personal service or certified mail (return receipt requested) to each and all of their officers, agents, employees (who shall receive a copy of the Decree in English and Spanish), representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships). Defendants shall provide to FDA, within thirty (30) calendar days after entry of this Decree, an affidavit stating the fact and manner of compliance with this Paragraph and identifying the names and positions of all persons notified and attaching copies of the executed certified mail return receipts or other proof of service if the Decree was delivered by personal service.

22. Defendants shall prominently post a copy of this Decree in English and Spanish in any employee common areas at Defendants' Facility within ten (10) calendar days after entry of this Decree and shall ensure that the Decree remains posted for as long as the Decree remains in effect.

23. Defendants shall, within ten (10) calendar days after entry of this Decree, hold a general meeting or a series of smaller meetings for employees of the Facility, at which they shall describe the terms and obligations of this Decree in English and Spanish. Defendants shall provide to FDA, within thirty (30) calendar days after entry of this Decree, an affidavit stating the fact and manner of compliance with this Paragraph and identifying the names and positions of all meeting attendees and attaching a copy of the meeting sign-in sheet(s).

24. In the event that any Defendant becomes associated with any additional officers, agents, employees, representatives, successors, assigns, attorneys, or any additional persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (return receipt requested), to such persons. Within ten (10) calendar days after each instance that any Defendant becomes associated with any such person, 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.

25. Defendants shall address all communications required under this Decree to the Director, New York District Office, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433, and shall reference this civil action by case name and civil action number and shall prominently mark "Decree Correspondence" in all such communications.

26. The provisions of this Decree shall become effective immediately as to all Parties upon execution thereby.

27. This Court retains jurisdiction of this action and the parties hereto for the purpose of enforcing and modifying this Decree, once entered by the Court, and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this _____ day of _____, 2017.

_____
THE HON. NELSON S. ROMÁN
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to entry of the foregoing Decree.

FOR DEFENDANTS:

FOLEY & LARDNER LLP
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June 22, 2017

PANAGIOTA SOUBLIS, on behalf of The Smokehouse of New York, LLC, as its President and Owner

June 22 2017

PANAGIOTA SOUBLIS, in her individual capacity

June 22 2017

BRETT H. PORTIER, in his individual capacity

June 21 2017

FOR PLAINTIFF:

JOON H. KIM
Acting United States Attorney
Attorney for the United States

By: SCh/C

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June 27, 2017

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So Ordered:

U.S.D.J.

Dated:

June 29, 2017