UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----------)(

UNITED STATES OF AMERICA,

Plaintiff,

Civil Action No. 1:13-cv-02909-RRM

v.

~~N.Y. FISH, INC., a corporation,~~
NEW YORK CITY FISH, INC., a corporation,
MAXIM KUTSYK, an individual,
PAVEL ROYTKOV, an individual,
LEONID STAROSELETSKY, an individual, and
~~STEVEN KOYFMAN, an individual~~,

~~PROPOSED~~ ORDER OF
: PERMANENT INJUNCTION

Defendants.

----------)(

INTRODUCTION

Plaintiff, the United States of America, having filed a Complaint for Injunction against N.Y. Fish, Inc., a corporation; New York City Fish, Inc., a corporation; and Maxim Kutsyk, Pavel Roytkov, Leonid Staroseletsky, and Steven Koyfman, individuals (collectively, "Defendants"), a Motion for Preliminary Injunction with a supporting memorandum of law, the declarations of (1) Ronald M. Pace, Director of the New York District Office of the U.S. Food and Drug Administration ("FDA"); (2) Mary E. Losikoff, Consumer Safety Officer, Office of Food Safety, FDA's Center for Food Safety and Applied Nutrition ("CFSAN"); and (3) Christine E. Keys, Microbiologist, CFSAN's Office of Regulatory Science; a reply memorandum in further support of its motion for preliminary injunction; a declaration in advance of trial from Peter M. Trunk, Consumer Safety Officer, Director of FDA's New York District Office; a second declaration in advance of trial from Mary Losikoff; and this Court having considered such documents, all documents filed by Defendants, and the arguments and live testimony at the hearing on July 9 and 10, 2013 consolidating the United States' Motion for Preliminary

Injunction and request for a permanent injunction in its Complaint for Injunction; and it appearing that Defendants are violating the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. ("the Act"), and unless restrained by order of this Court, may continue to violate the Act,

IT IS HEREBY ORDERED that:

I. This Court has jurisdiction over the subject matter and over all parties to this action pursuant to 21 U.S.C. § 302.

II. The Complaint for Injunction states a claim for relief against Defendants under the Act.

III. The United States has succeeded on the merits of its claims that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing, or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4), and the public interest weighs heavily in favor of granting the permanent injunctive relief sought by the United States.

IV. The United States has succeeded on the merits of its claim that Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more ingredients in interstate commerce, and the public interest weighs heavily in favor of granting the permanent injunctive relief sought by the United States.

V. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) are hereby 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, holding, and distributing articles of food, at or from their facility located at 738 Chester St., Brooklyn, New York 11236-1925 (the "Chester Street Facility"), and/or any other location(s) at or from which Defendants, now or in the future, receive, process, prepare, pack, hold, or distribute articles of food, unless and until:

A. Defendants retain, at their expense, an independent laboratory (the "laboratory") having no personal or financial ties (other than the retention agreement) to Defendants or their families, which is qualified to collect product and environmental samples from within the Chester Street Facility and analyze those samples for the presence of *Listeria monocytogenes* ("*L. mono*") using a method that is acceptable to the FDA. Defendants shall notify FDA in writing immediately upon retaining such laboratory and shall provide FDA a copy of the service contract. Such service contract shall contain provisions, acceptable to FDA, for regular environmental and finished product sample collection and analyses, including how and where to sample, the number and frequency of samples to be collected, and the methods of analyses, in accordance with the Listeria Monitoring Program discussed in paragraph V(C) below;

B. Defendants retain, at their expense, an independent expert(s) (the "Sanitation Expert") having no personal or financial ties (other than the retention agreement) to Defendants or their families, and who, by reason of background, education, training, and experience, is qualified to develop a Listeria Monitoring Program, to inspect the Chester Street Facility, and to determine whether the methods, facilities, and controls are operated and administered in conformity with the Act, its implementing regulations, and this Order. Defendants shall notify FDA in writing of the name(s) and qualifications of the Sanitation Expert

as soon as they retain such expert;

C. Defendants' Sanitation Expert, in consultation with the laboratory, after review of all FDA observations from 2006 to present, develops a written Listeria Monitoring Program, which shall include, at a minimum, the following:

(1) An effective written sanitation control program that establishes adequate methods, facilities, and controls for receiving, preparing, processing, packing, holding and distributing articles of food to minimize the risk of introducing *L. mono*, other pathogenic organisms, and filth 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 the Chester Street Facility and all equipment therein suitable for use in receiving, preparing, processing, packing, holding, and distributing articles of food to prevent such articles from becoming adulterated, and instituting standard sanitation operating procedures ("SSOPs") to ensure that the Chester Street Facility and equipment therein are continuously maintained in a sanitary condition. An effective written sanitation control program during the period of time when Defendants are enjoined under Paragraph V shall include completely disassembling all of the equipment and thoroughly cleaning and sanitizing the disassembled equipment by soaking the equipment parts in quaternary ammonia overnight, applying steam to larger pieces of equipment after they have been thoroughly cleaned and sanitized, and fogging rooms with a sanitizer solution;

(2) A written employee training program (in English, Spanish, Russian, and any other language that is necessary to convey the substance of the training program to the employees) that includes, at a minimum, instructions on sanitary food handling techniques and documentation that each employee has received such training. The employee

training program shall include, at a minimum, basic training for all employees on the importance of *Listeria* controls and their role in *Listeria* control strategies, training for all employees who handle or work in exposed finished product areas to ensure that they understand how to prevent cross-contamination of product, and training for all employees who conduct cleaning and sanitation tasks or activities to ensure that they understand the sanitation procedures necessary to reduce or eliminate *Listeria* in the plant. Defendants' Sanitation Expert shall ensure that each employee fully understands the substance of the employee training program;

(3) An effective program for environmental monitoring and testing of the Chester Street Facility to ensure that such organisms as *Listeria species* ("*L. spp.*") are controlled, and that the pathogen *L. mono* is not present within the facility. Environmental monitoring shall include, but not be limited to, collecting swab samples from food-contact surfaces, equipment, and other environmental sites throughout the Chester Street Facility (where the raw ingredients, in-process, and finished articles of foods are received, prepared, processed, packed, held, and/or distributed, and common areas that could be reservoirs for cross-contamination), and analysis of collected samples, in a manner acceptable to FDA. Defendants shall ensure that the results of all analyses conducted pursuant to this paragraph are sent to FDA within two (2) calendar days after receipt by Defendants; and

(4) A written plan for remedial action, which is acceptable to FDA, should *L. spp.* or *L. mono* be detected;

D. Defendants assign continuing responsibility for the operation of the Listeria Monitoring Program discussed in Paragraph V(C) above to a person (or persons), who, by reason of background, experience, or education, is competent to maintain the Chester Street Facility in a sanitary condition, coordinate with the laboratory, and implement any necessary

remedial action(s), and provide such person(s) with the authority to achieve the necessary corrections;

E. Defendants make versions of the Listeria Monitoring Program (in English, Spanish, Russian, and any other language necessary to convey the substance of the Listeria Monitoring Program to their employees) available and accessible to all their employees;

F. FDA approves, in writing, the Listeria Monitoring Program discussed in paragraph V(C) above;

G. The Sanitation Expert conducts a comprehensive inspection of the Chester Street Facility and the methods and controls used to receive, prepare, process, pack, hold, and distribute foods to determine whether the Defendants have effectively implemented all corrections and are operating in compliance with this Order, the Act, and its implementing regulations. The Sanitation Expert shall submit all findings to Defendants and FDA concurrently, within ten (10) business days after completion of the inspection;

H. Defendants retain a person or persons (the "HACCP Expert" or "HACCP Experts") who is/are without any personal or financial ties (other than the consulting agreement) to Defendants or their families, and who by reason of background, experience, and education, is qualified to:

(1) Conduct hazard analyses to develop adequate HACCP plans for the processing of each type of fish and fishery product Defendants intend to process, as required by 21 C.F.R. § 123.6(a)-(c);

(2) Verify the adequacy of Defendants' HACCP plans, as required by 21 C.F.R. § 123.8;

(3) Develop adequate SSOPs specific to Defendants, as required by 21

C.F.R. § 123.11;

(4) Evaluate Defendants' monitoring of key sanitation conditions and practices, as set forth in 21 C.F.R. § 123.11(b);

(5) Develop and conduct employee training programs (in English, Spanish, Russian, and any other language that is necessary to convey the substance of the training to the employees) on the seafood HACCP regulations;

(6) Inspect the Chester Street Facility and establish procedures to ensure that the methods, facilities, and controls for processing fish and fishery products are continuously operated and administered in conformity with the Act and all applicable regulations.

Defendants shall notify FDA in writing of the identity and qualifications of the HACCP Expert and provide FDA with information in writing regarding the HACCP Expert's qualifications, background, experience, and/or education under Paragraphs V(H)(1)-(6) as soon as such Expert is retained. Defendants' HACCP Expert may be the same individual or individuals as Defendants' Sanitation Expert;

I. The HACCP Expert retained by Defendants develops and submits to FDA:

(1) Adequate written HACCP plans for each type of fish and fishery product, received, prepared, processed, packed, held, and/or distributed by Defendants for which food safety hazards are identified, including appropriate critical control points, critical limits, monitoring procedures, recordkeeping, etc., as required by 21 C.F.R. § 123.6;

(2) Adequate written SSOPs, as required by 21 C.F.R. § 123.11;

(3) Adequate written corrective action plans, as part of the seafood HACCP plans, to be taken whenever there is a deviation from the critical limit, as described in

21 C.F.R. § 123.7(b);

(4) Employee training programs (in English, Spanish, Russian, and any other language necessary to convey the substance of the training programs to the employees) on the seafood HACCP regulations, SSOPs, and control strategies specific to Defendants' fish and fishery products;

J. FDA has approved, in writing, the seafood HACCP plan(s), SSOPs, and training program developed by the HACCP Expert, as specified in paragraphs V(I)(1)-(4);

K. Defendants successfully complete the employee training program developed by the HACCP Expert and approved by FDA according to paragraph VIII(J).

L. Defendants report to FDA, in writing, the actions they have taken to bring their seafood operations into compliance with this Order, the Act, and all applicable regulations, including the specific measures Defendants have taken to address each of the seafood HACCP deficiencies documented by FDA at the Chester Street Facility since August 2012;

M. The HACCP Expert conducts a comprehensive inspection of the facility and the methods and controls used to receive, prepare, process, pack, hold, and distribute fish and fishery products to determine whether Defendants' processing facility is sanitary and Defendants are fully prepared to operate in compliance with this Order, the Act, and all applicable regulations. The HACCP Expert shall verify that Defendants have corrected all of the seafood HACCP deficiencies documented by FDA. The HACCP expert shall submit all findings, in writing, to Defendants and FDA concurrently, within ten (10) business days of completion of the inspection;

N. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Order, the Act, and all applicable regulations, conducts inspections of the Chester

Street Facility, including the building, sanitation-related systems, equipment, utensils, articles of food, and relevant records, contained therein;

O. Defendants report to FDA in writing the actions they have taken to bring their operations into compliance with the Act and all applicable regulations, including:

(1) Documentation that Defendants have cleaned and sanitized the Chester Street Facility and equipment therein and made improvements, thereby rendering the facility and equipment suitable for receiving, processing, preparing, packing, holding, and distributing articles of food, and documentation that Defendants have conducted environmental testing in a manner acceptable to the FDA and received laboratory results showing that *L. mono* is no longer present in the facility;

(2) Specific measures that they have taken to address each of the violations documented by FDA since August 2012; and

(3) A copy of the Listeria Monitoring Program discussed in Paragraph V(C) above;

P. Within thirty (30) calendar days after entry of this Order, Defendants destroy, under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved in writing by FDA prior to implementation, all in-process and finished articles of food currently in their custody, control, or possession;

Q. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Order, the Act, and all applicable regulations, conducts inspections of the Chester Street Facility, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

R. FDA notifies Defendants in writing that Defendants appear to be in

compliance with the requirements set forth in paragraph V(A) through (P) of this Order, the Act, and its implementing regulations; and

S. Defendants have paid all costs of inspection, analyses, review, investigations, examination, and supervision for FDA's oversight with respect to paragraph V(A) through (R), at the rates set forth in paragraph XII below.

VI. Immediately upon resuming operations after completing the requirements of paragraph V, Defendants shall, in consultation with the laboratory and the Sanitation Expert and HACCP Expert, continuously implement the following steps to prevent further contamination from *L. mono*, other pathogenic organisms, or filth in their food products and facility:

A. Effectively implement on an ongoing basis, the Listeria Monitoring Program developed pursuant to paragraph V(C).

B. Conduct environmental monitoring and testing to ensure that the SSOPs continue to eliminate the *L. mono* hazard and that the SSOPs are consistently being followed. Environmental monitoring shall include collecting swab samples from food-contact and non-food-contact surfaces, equipment, and other environmental sites throughout the Chester Street Facility (where articles of food are received, prepared, processed, packed, and held, up to and including final packaging, as well as common areas), and analyzing such samples for the presence of *L. spp.* Environmental testing for *L. spp.* shall be performed by the laboratory in accordance with timetables and methods that Defendants submit to FDA in writing for approval by FDA in writing before testing begins. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) calendar days after receipt by Defendants. Defendants' environmental testing must include, at a minimum, all of the following:

(1) If a food- or non-food-contact surface is found to be positive for *L. spp*. during routine sampling performed in accordance to the timetables and methods approved by FDA in Paragraph VI(B), intensified sampling must be done as soon as possible, in conjunction with intensified sanitation measures. Intensified sampling requires that three (3) samples per day must be collected and analyzed until at least nine (9) consecutive samples (three (3) days of intensified sampling) have been taken and are negative for *L. spp*. from the site where the *L. spp*. was identified. After nine (9) consecutive samples are tested and found to be negative, that site may return to routine sampling; and

(2) All food products that have been present in a site that tests positive for the general strain *L. spp*. must be placed on hold pending laboratory test results. The products can be released only if laboratory test results are negative for *L. mono*; if the laboratory results are positive for *L. mono*, all food products held, packed, and processed since the date of the last negative environmental swab for that site must be destroyed at Defendants' expense, under FDA's supervision, and according to a written destruction plan submitted by Defendants and approved, in writing, by FDA prior to implementation; and

C. Conduct finished product testing in the following manner:

(1) Defendants shall test for *L. mono* in each batch food product for at least five (5) consecutive production days using a testing method approved in writing in advance by FDA;

(2) After the completion of testing under paragraph VI(C)(1), Defendants shall test at least one lot of each food product per day for the next twenty (20) production days;

(3) After the completion of testing under paragraph VI(C)(2),

Defendants shall test at least one lot of each food product per every five (5) production days for the next three (3) months; and

(4) After the completion of testing under paragraph VI(C)(3), Defendants shall test at least one lot of each food product per month thereafter.

If any laboratory test completed pursuant to paragraphs VI(C)(1)-(4) shows the presence of *L. mono* in any article of food, then Defendants must immediately cease production and notify FDA that production has ceased. Defendants shall also destroy, at Defendants' expense, under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved prior to implementation, in writing, by FDA, all food products held, packed, and processed since the date of the last negative environmental swab for that site. Defendants may resume production only when they have determined and corrected the cause of the contamination and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements of this Order, the Act, and its implementing regulations. After correcting the cause of the contamination, Defendants shall reinstate the complete sequence of testing under this paragraph anew. Defendants shall ensure that the results of all testing conducted under this paragraph are forwarded to FDA within two (2) calendar days after receipt by Defendant.

VII. If, after notifying FDA of the name of the laboratory retained to conduct sample collection and analyses pursuant to paragraph V(A), Defendants terminate or in any way alter their service contract with the laboratory, Defendants shall notify FDA within five (5) business days. If Defendants terminate their service contract, Defendants shall provide a copy of the service contract with the new laboratory to FDA within five (5) business days of execution.

VIII. Immediately upon resuming operations after completing the requirements set forth in paragraph V, Defendants shall, in consultation with the Sanitation Expert and HACCP

Expert, continuously implement the SSOPs, and seafood HACCP and training programs developed by the HACCP Expert and approved by FDA according to paragraph V(J). Within thirty (30) days after Defendants' resumption of their seafood operations, the HACCP expert shall conduct a comprehensive inspection of the facility and the methods and controls used to receive, prepare, process, pack, hold, and distribute foods to determine whether the Defendants are operating in compliance with this Order, the Act, and all applicable regulations. The HACCP Expert shall conduct one inspection after ninety (90) days, and then one inspection every one hundred and eighty days (180) for the next three (3) years, and then one inspection annually for an additional two (2) years.

IV. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, 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 Order, are 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 and/or delivering for introduction into interstate commerce, any article of food, within the meaning of 21 U.S.C. § 321(f), that is adulterated, within the meaning of 21 U.S.C. § 342(a)(4);

B. Violates 21 U.S.C. § 331(k), by causing any article of food within the meaning of 21 U.S.C. § 321(f) to become adulterated within the meaning of 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; and/or

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

X. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Chester Street Facility, and any other locations at which Defendants receive, prepare, process, pack, hold, or distribute articles of food and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order, the Act, and its implementing regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, and packaging material therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process, and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, preparing, processing, packing, holding, and distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

XI. 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 Order. Defendants shall provide any prospective successor or assign with a copy of this Order 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 Order to a prospective successor or assign.

XII. 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 Order, 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 Order is signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative inspection work; $104.96 per hour or fraction thereof per representative analytical or review work; $0.565 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

XIII. If, at any time after entry of this Order, FDA determines, based on the results of an inspection, sample, analyses, or other information, that Defendants have failed to comply with any provision of this Order, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Order, 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 to immediately take one or more of the following actions:

A. Cease receiving, preparing, processing, packing, 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 samples of articles of food to a qualified laboratory to determine whether they are contaminated with chemicals, toxins, microorganisms, or filth;

D. Assess liquidated damages, as provided by paragraph XVI of this Order; and/or

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

The provisions of this paragraph 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 XII of this Order.

XIV. Upon receipt of any order issued by FDA pursuant to paragraph XIII, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action as described in paragraph XIII 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 Order, the Act, and its implementing regulations. After a cessation of operations, and while determining whether Defendants are in compliance with this Order, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Order.

XV. Defendants shall maintain copies of their HACCP plans, along with copies of all records required by the plans and by 21 C.F.R. Part 123, at their facility in a location where they are readily available for reference and inspection by FDA officials. All records required to be kept by the HACCP plans and by the regulations shall be retained for at least three (3) years after the date the records are prepared.

XVI. If any Defendant violates this Order and is found in contempt thereof, 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.

XVIII. All decisions specified in this Order shall be vested in the discretion of FDA. FDA's decisions shall be final and shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Order 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.

XIX. Within ten (10) calendar days after entry of this Order, Defendants shall provide a copy of this Order to each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) (in English, Spanish, Russian, and any other language necessary to convey the substance of the Order to those individuals). Defendants shall provide to FDA within thirty (30) calendar days of the date of the entry of this Order, 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.

XX. Defendants shall prominently post a copy of this Order (in English, Spanish, Russian, and any other language necessary to convey the substance of the Order to the employees) in an employee common area at the Chester Street Facility within ten (10) calendar days of the entry of this Order and shall ensure that the Order remains posted for a period of at least six (6) months.

XXI. Defendants shall, within ten (10) calendar days of the entry of this Order, 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 Order (in English, Spanish, Russian, and any other language necessary to convey the substance of the Order to the employees).

XXII. In the event that any Defendant becomes associated with any additional officers, agents, employees, representatives, successors, assigns, heirs, 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 Order, Defendants shall immediately provide a copy of this Order, by personal service or certified mail (restricted delivery, return receipt requested), to such persons. Within ten (10) calendar days of each instance that Defendant becomes associated with any such individual persons, 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 Order pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

XXIV. Defendants shall address all communications required under this Order to the Director, New York District Office, United States 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 in such communications.

XXV. This Court retains jurisdiction of this action and the parties hereto for the purpose of enforcing and modifying this Order and for the purpose of granting such additional relief as

may be necessary and appropriate.

SO ORDERED:

Dated this 30th day of March, 2014

Roslynn R. Mauskopf

HON. ROSLYNN R. MAUSKOPF
UNITED STATES DISTRICT JUDGE