UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

S. SERRA CHEESE COMPANY,
a corporation,

and

FINA SERRA and
STEFANO SERRA,
individuals,

Defendants.
_____/

Civil No. 14-cv-13077

Honorable Avern Cohn
Mag. Judge Michael J. Hluchaniuk

ORDER OF INJUNCTION

Plaintiff, United States of America, having filed a complaint for permanent injunction against S. Serra Cheese Company ("Serra Cheese"), a corporation, and Fina Serra and Stefano Serra, individuals (collectively, "Defendants"), a motion for summary judgment with supporting briefs and declarations; and this Court having considered such documents and documents filed by Defendants, having held a hearing on Plaintiff's summary judgment motion, and having issued an order granting summary judgment in Plaintiff's favor on October 20, 2015,

IT IS HEREBY ORDERED 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 Act, 21 U.S.C. § 301, *et seq*.

3. This Court has found that Defendants violate 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 articles of food, within the meaning of 21 U.S.C. § 321(f), that are adulterated within the meaning of 21 U.S.C. § 342(a)(4). The articles of food are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health.

4. This Court has found that Defendants violate the Act, 21 U.S.C. § 331(k), by doing an act that causes the adulteration, within the meaning of 21 U.S.C. § 342(a)(4), of articles of food while such articles are held for sale after shipment of one or more components in interstate commerce.

5. Defendants are subject to the following requirements:

Testing of Cheese in Defendants' Existing Inventory

A. Defendants shall, within fifteen (15) business days of this Order, submit for approval by the United States Food and Drug Administration ("FDA") a written plan for sampling and analysis (hereafter, "Testing Plan") of the cheese in their existing inventory. "Existing inventory" is defined as all finished and in-process cheese in Defendants' custody, control, or possession at the facility, located at 19717 15 Mile Road, Clinton Township, Michigan ("the facility"), or any other location where Defendants store or hold their cheese products, at the time of the entry of this Order. At minimum, the Testing Plan submitted by Defendants shall:

(1) include written documentation showing that Defendants have retained, at their expense, a person or persons, 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 microorganism testing plan for cheese products. Defendants' submission shall include the name(s), curriculum vitae, and other evidence of the qualifications of such person(s).

(2) include written documentation showing that Defendants have retained, 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 and analyze product samples for Listeria species ("*L. spp*."), *Listeria monocytogenes* ("*L. mono*"), pathogenic *Escherichia coli* ("*E. coli*"), *staphylococcus aureus* ("*Staph*"), and to determine the levels of non-pathogenic, generic *E. coli* and *Staph*, using sampling and analysis parameters and method(s) that are acceptable to the FDA. Defendants' documentation shall include a copy of the service contract;

(3) include a written list of their existing inventory. This list shall include the following information: the type of each and all cheese products; the manufacturing date of each finished cheese product; for each type of cheese, the number of individual cheese products in a batch; the number of batches of each cheese type; for each type of cheese, the number of cheese wheels per batch (if cheese are organized in wheels); and the pH and water activity level of each cheese type; and

(4) include provisions, developed by the person(s) described in paragraph 5.A(1) and in consultation with the laboratory described in paragraph 5.A(2), and that are acceptable to FDA, for product sampling and analysis to: (i) detect the presence of *L. spp.*, *L. mono*, pathogenic *E. coli*, and *Staph;* and (ii) detect the presence and determine the levels of non-pathogenic, generic *E. coli* and of *Staph* in the cheese products in Defendants' existing inventory. Such provisions shall, at a minimum, specify: the types and quantities (i.e., number of individual products) of cheese Defendants propose to sample; the number and frequency of samples to be collected for each type of cheese; the methods of sampling and analysis; the definition of the term "batch"; and the batch(es) of cheese products each sample is designated to represent.

B. Within twenty (20) business days of receiving Defendants' proposed Testing Plan, FDA will, in writing, either:

(1) notify Defendants that their proposed Testing Plan appears adequate; or

(2) notify Defendants of any deficiencies in their proposed Testing Plan, and specify what sampling and testing parameters, methods, and/or protocols FDA would approve, hereafter referred to as "the FDA-approved Testing Plan."

No later than five (5) business days of receiving FDA's notification, Defendants shall implement, at their expense, the proposed Testing Plan that FDA determines to be adequate under paragraph 5.B(1) or the FDA-approved Testing Plan under paragraph 5.B(2).

C. Defendants shall ensure that all sample collection reports and results of all analyses conducted pursuant to paragraph 5.B are forwarded to FDA within two (2) business days after receipt by Defendants.

(1) If any cheese product is positive for *L. mono* or pathogenic *E. coli* ("positive cheese samples"), then Defendants shall immediately cease production and distribution and notify FDA that production and distribution have ceased. In addition, Defendants shall, at Defendants' expense, under FDA's supervision, and pursuant to a written destruction plan approved in writing by FDA prior to implementation, (i) destroy the positive cheese samples and all batch(es) of cheese products in their existing inventory represented by such positive cheese samples; and (ii) expand their sampling and analysis, in accordance with parameters and methods Defendants submitted for FDA approval and approved by FDA in writing prior to implementation, to cover all additional cheese products in their existing inventory and destroy any additional batch(es) of cheese products for which a representative cheese sample is positive for *L. mono* or pathogenic *E. coli*.

(2) If any cheese product is positive for *Staph* at levels equal to or greater than 10,000 colony forming units (CFU) per gram in one or more subsamples, then Defendants shall expand their analysis, in accordance with parameters and methods Defendants submitted for FDA approval and approved by FDA in writing prior to implementation, to determine whether such samples are also positive for *Staph* toxin(s). If any cheese sample is positive for *Staph* toxin(s), Defendants shall: (i) destroy such positive cheese sample and all batch(es) of cheese products in their existing inventory represented by the sample; and (ii) expand their sampling and

analysis, in accordance with parameters and methods Defendants submitted for FDA approval and approved by FDA in writing prior to implementation, to cover all cheese products in their existing inventory and destroy any additional batch(es) of cheese products for which a representative cheese sample is positive for *Staph* toxin(s). All destruction shall be at Defendants' expense, under FDA's supervision, and in accordance with a written destruction plan approved in writing by FDA prior to implementation.

(3) If FDA otherwise determines, based on Defendants' submission pursuant to paragraph 5.C, or any other information, that it is necessary for Defendants to cease production and distribution, destroy or recall their products, or take any other corrective actions, then paragraph 12 shall apply.

Testing of Cheese Manufactured After Entry of the Order

D. Defendants shall, using sampling and analysis parameters and methods Defendants submitted for FDA approval and approved by FDA in writing prior to implementation, conduct ongoing testing of the finished cheese products that they manufacture after the entry of this Order in the following manner:

(1) Defendants shall have tested all batches of finished cheese products for *L. mono* and *E. coli* for at least five consecutive production days;

(2) After the completion of testing under paragraph 5.D(1), Defendants shall have tested at least one batch of each finished cheese product per day for the next twenty (20) production days;

(3) After the completion of testing under paragraph 5.D(2), Defendants shall have tested at least one batch of each finished cheese product every five (5) production days for the next three (3) months; and

(4) After the completion of testing under paragraph 5.D(3), Defendants shall have tested at least one batch of each finished cheese product monthly thereafter.

(5) If any finished cheese product tested pursuant to paragraphs 5.D(1)-(4) is positive for *L. mono* or pathogenic *E. coli* (collectively, "positive cheese samples"), then Defendants must immediately cease production and distribution and notify FDA that production and distribution have ceased. Defendants shall also, at Defendants' expense, under FDA's supervision, and pursuant to a written destruction plan approved in writing by FDA prior to implementation, destroy (i) all positive cheese samples, as well as all batch(es) of cheese products represented by such positive cheese samples; and (ii) either destroy all in-process and finished cheese products manufactured since the time the positive cheese samples were collected, or expand their sampling and analysis, in accordance with parameters and methods that Defendants submitted to FDA approval and approved by FDA in writing prior to implementation, to cover all cheese products manufactured since the time the positive cheese samples were collected and destroy, at Defendants' expense, under FDA's supervision, and pursuant to a written destruction plan approved in writing by FDA prior to implementation, any additional batch(es) of cheese products for which a representative sample is positive for *L. mono* or pathogenic *E. coli*. Defendants may resume production and distribution only when they have determined and corrected the

root cause(s) 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 21 C.F.R. Part 110. After correcting the cause(s) 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 pursuant to this paragraph are forwarded to FDA within two (2) business days after receipt by Defendants.

(6) If any finished cheese products completed pursuant to paragraphs 5.D(1)-(4) shows the presence of *Listeria spp.* but not *L. mono*, then Defendants must: immediately quarantine and hold in the facility the affected cheese products; expand testing to other cheese products (finished and/or in-process cheese) in the facility to determine: (i) the extent and scope of the contamination and (ii) whether any other food in the facility has been contaminated with *L. mono*; investigate and determine the root cause(s) of the contamination; and correct the cause(s) of the contamination. If testing under paragraph 5.D(6) detects *L. mono* in any finished cheese product, then Defendants shall comply with the requirements set forth in paragraph 5.D(5).

Laboratory Contract for Ongoing Environmental Testing

E. Defendants shall, no later than twenty (20) business days from the entry of this Order, submit written documentation to FDA showing that Defendants have retained, at their expense, an independent laboratory having no personal or financial ties (other than the retention agreement) to Defendants or their families, which is qualified to collect environmental samples from within their facility, located at 19717 15

Mile Road, Clinton Township, Michigan, and analyze those samples for the presence of *Listeria ssp.*, including *L. mono*, using a method that is acceptable to FDA. This laboratory may be the same laboratory Defendants retained pursuant to paragraph 5.A(2). Defendants' submission shall, at minimum, include a copy of the service contract. Such service contract shall contain certain provisions, acceptable to FDA, for regular environmental collection and analysis, including how and where to sample, the number and frequency of samples to be collected, and the methods of analysis, in accordance with the Pathogen Control and Monitoring Program described in paragraph 5.G below.

Sanitation Expert

F. Defendants shall, no later than twenty (20) business days from the entry of this Order, submit written documentation to FDA showing that Defendants have retained, 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 inspect Defendants' facility and to determine whether the methods, facility, and controls are operated and administered in conformity with the Act, 21 C.F.R. Part 110, and this Order. Defendants' submission shall include the name(s), curriculum vitae, and other evidence of the qualifications of the sanitation expert(s).

Pathogen Control and Monitoring Program

G. Defendants shall, no later than twenty (20) business days from the entry of this Order, submit to FDA a written Pathogen Control and Monitoring Program that: (i) shall have been developed by Defendants' sanitation expert, in consultation with

the laboratory and after reviewing all FDA and Michigan Department of Agriculture & Rural Development ("MDARD") observations from January 2013 to present, and (ii) shall include, at a minimum, the following:

(1) An effective written sanitation program that establishes adequate methods, facility, and controls for receiving, preparing, processing, packing, holding, and distributing articles of food to minimize the risk of introduction of pathogenic *Listeria* or any other poisonous or deleterious substances, or contamination with filth, including excessive levels of *E. coli* that are indicators of insanitary conditions, to ensure that Defendants' foods are not adulterated within the meaning of 21 U.S.C. § 342(a)(4). Such methods, facility, and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering the 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 facility and equipment therein are continuously maintained in a sanitary condition;

(2) A written employee training program that includes, at a minimum, instruction on sanitary food handling techniques, regular refresher training, and documentation that Defendants and all other persons who perform duties at the facility for Defendants have received such training. Defendants and their expert shall ensure that all employees fully understand the substance of the employee training program;

(3) An effective program of environmental monitoring and testing of the facility to ensure that microorganisms such as pathogenic *Listeria*, or any

poisonous or deleterious substances, and filth are 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 facility (where the raw ingredients, in-process, and finished articles of foods are received, prepared, processed, packed, held, or distributed, and common areas that could be reservoirs for cross-contamination), and analyzing 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 four (4) business days of receipt by Defendants; and

(4) A written plan for remedial action should pathogenic *E. coli*, *Listeria*, any other poisonous or deleterious substance, or filth be detected either in Defendants' facility environment or products.

H. Defendants shall, no later than twenty (20) business days from the entry of this Order, submit written documentation to FDA showing that Defendants have assigned continuing responsibility for implementing the Pathogen Control and Monitoring Program to a person or persons who, by reason of background, experience, or education, is competent to maintain the 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.

I. FDA will provide Defendants, within fifteen (15) business days of receiving Defendants' submission under paragraph 5.E-H, or as soon as practicable in the event that FDA representatives are attending to FDA matters that cannot be

rescheduled, either a written notice of approval of the Pathogen Control and Monitoring Program or an explanation that details the deficiencies.

(1) If FDA notifies Defendants that they must make a revised submission to show correction of the identified deficiencies, Defendants shall make such revised submission to FDA within fifteen (15) business days of receipt of FDA's explanation. FDA will review the revised submission and provide Defendants a written notice of approval or further detailed explanation of any new or remaining deficiencies. Defendants shall respond in writing to each of the identified deficiencies within fifteen (15) business days of receipt of FDA's explanation. The program approved by FDA under this paragraph is hereinafter referred to as the "FDA-approved Pathogen Control and Monitoring Program."

(2) If FDA does not approve the Pathogen Control and Monitoring Program submitted by Defendants pursuant to paragraph 5.I(1), or if FDA determines that it is necessary for Defendants to cease operations because of other deficiencies, Plaintiff, through its counsel of record, will file a request with the Court and request an order that enjoins Defendants from operating unless and until they implement necessary corrections. If Plaintiff makes such a request to the Court, then Defendants shall not manufacture, process, prepare, pack, hold, or distribute food from the facility unless and until the Court declines Plaintiff's request or the Court otherwise orders that Defendants may manufacture and distribute food. The review of FDA's determination concerning the Pathogen Control and Monitoring Program shall be made in accordance with the terms set forth in paragraph 15.

J. Defendants shall make the FDA-approved Pathogen Control and Monitoring Program available and accessible to all of their employees in English, Spanish, and in any other language spoken commonly by such employees.

Expert Inspection and Report

K. Defendants shall, within seven (7) business days after receiving FDA's written approval pursuant to paragraph 5.I, have the sanitation expert conduct a comprehensive inspection of the facility, the methods and controls used to receive, prepare, process, pack, hold, and distribute foods to determine whether: (i) Defendants have effectively implemented the FDA-approved Pathogen Control and Monitoring Program; (ii) Defendants have corrected all observations in Forms FDA 483 issued to Defendants since January 2013; and (iii) Defendants are operating in compliance with this Order, the Act, and 21 C.F.R. Part 110.

L. Defendants shall, within ten (10) business days after the inspection described in paragraph 5.K, have the sanitation expert submit concurrently to FDA and Defendants a written report of all findings from the inspection, which shall include a list of observed deviations, if any, from compliance with the FDA-approved Pathogen Control and Monitoring Program, the Act, and 21 C.F.R. Part 110.

M. Defendants shall, within fifteen (15) business days after receiving the expert report described in paragraph 5.L, submit to FDA written documentation of all actions they have taken to bring their operations into compliance with the FDA-approved Pathogen Control and Monitoring Program, the Act, and all applicable regulations, including:

(1) Documentation that Defendants have cleaned and sanitized the facility and equipment therein and made improvements, thereby rendering the facility and equipment suitable for receiving, preparing, processing, packing, holding, and distributing articles of food; and

(2) Specific measures that they have taken to address each and all of the deviations listed in the sanitation expert's report, if any.

Other Requirements

6. Upon entry of this Order, 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 pursuant to paragraphs 16 and 19 below, 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 articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. violates 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 components in interstate commerce; or

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

7. Defendants shall, in consultation with the laboratory and the sanitation expert, continuously implement the following requirements:

A. Effectively implement, on an ongoing basis, the FDA-approved Pathogen Control and Monitoring Program described in paragraph 5.I;

B. Upon entry of this Order, conduct environmental monitoring and testing as set forth in paragraph 5.G(3). Environmental testing shall be performed by the laboratory in accordance with timetables and methods that Defendants submit in writing to FDA for prior written approval by FDA. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) business 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 tests positive for *Listeria spp*. during routine testing, intensified sampling must be initiated immediately, in conjunction with intensified sanitation measures. Intensified sampling requires that three (3) samples per day must be collected and analyzed until a total of nine (9) consecutive samples (three (3) days of intensified sampling) have tested negative for *Listeria spp*. from the site where the *Listeria spp*. was identified. After nine (9) consecutive samples have tested negative for *Listeria spp*., that site may be subject to routine sampling; and

(2) all food in contact with a site that tests positive for *Listeria spp*. must be quarantined in the facility and tested for pathogenic *Listeria*. If any test completed pursuant to this paragraph shows the presence of *L. mono* in any article of

food, then Defendants must immediately cease production and distribution and notify FDA that production and distribution have ceased. Food that tests positive for *L. mono*, as well as all food manufactured since the positive laboratory sample(s) were collected, must be destroyed pursuant to a written destruction plan approved in writing by FDA prior to implementation. Defendants shall bear the costs of such destruction and the costs of FDA's supervision of such destruction, at the rates specified in paragraph 11.

8. If Defendants terminate or alter in any way their service contract with the laboratory retained pursuant to paragraph 5.E, Defendants shall notify FDA within five (5) business days after such termination or alteration. 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 after such services contract is executed.

9. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the facility 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.

10. Defendants shall notify FDA in writing at least fifteen (15) business 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) business days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this paragraph within ten (10) business days after providing a copy of this Order to a prospective successor or assign.

11. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Order. The costs of such activities shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Order is signed by the Court, these rates are: $89.35 per hour and fraction thereof per representative for inspection or investigative work; $107.09 per hour or fraction thereof per representative for analytical or review work; $0.575 per mile for travel expenses 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-day, per-representative 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. This provision does not apply to costs expended by FDA prior to the entry of this Order.

12. A. If, at any time after entry of this Order, FDA determines, based on the results of an inspection, sample analysis, the sanitation expert's report, 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, as and when it deems necessary, may notify Defendants in writing and direct Defendants to take appropriate action, including, but not limited to, directing Defendants to immediately take one or more of the following actions:

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

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

(3) Submit samples of articles of food to a qualified laboratory to determine whether they are contaminated with microorganisms or filth; and/or

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

Any written directive issued by FDA pursuant to this paragraph will include the deficiencies or violations giving rise to the directive.

B. Unless a different time frame is specified by FDA in its written directive, within ten (10) business days after receiving the directive pursuant to paragraph 12.A, Defendants shall notify FDA in writing either that:

(1) Defendants are undertaking or have undertaken the action(s) specified in FDA's directive; or

(2) Defendants do not agree with FDA's directive. If Defendants notify FDA that they do not agree with FDA's directive, Defendants shall explain in writing the basis for their disagreement. In so doing, Defendants also may propose specific alternative actions and specific time frames for achieving the FDA's objectives.

(3) If Defendants notify FDA that they do not agree with FDA's written directive, FDA will review Defendants' objections and thereafter, in writing, affirm, modify, or withdraw its directive, as FDA deems appropriate. If FDA affirms or modifies its directive, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

(4) If FDA affirms or modifies its written directive, Defendants, upon receipt of the affirmation or modification, shall immediately implement the directive (as modified, if applicable) and, if they choose, may object to the affirmed or modified written directive by making an appropriate filing with the Court on an expedited basis. Defendants shall continue to diligently implement FDA's directive unless the Court reverses, modifies, or stays FDA's written directive. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 15.

C. Any cessation of operations as described in paragraphs 12.A or B shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Order, the Act, and its implementing regulations.

D. 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 corrective actions, at the rates specified in paragraph 11.

13. If any Defendant fails to comply with the provisions of the Act, its implementing regulations, and/or this Order, then Defendants shall pay, upon receiving notice of such violation from FDA, to the United States of America liquidated damages in the sum of two thousand dollars ($2,000.00) for each day that Defendants fail to comply with this Order; an additional sum of one thousand dollars ($1,000.00) in liquidated damages per day for each violation of the Act, its implementing regulations, and/or this Order; and an additional sum equal to twice the retail value of each shipment of adulterated food. The liquidated damages specified in this paragraph are not punitive in nature.

14. If any Defendant violates this Order and is found in contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff 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.

15. All decisions specified in this Order shall be vested in the discretion of FDA. FDA's decisions shall be final agency action 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 by the Court of any FDA decision rendered pursuant to this Order shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

16. Within ten (10) business 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). Moreover, within ten (10) business days after entry of this Order, the Defendants shall provide a copy of the Order, translated by a competent interpreter, in the native language of employees who do not speak and understand English. Defendants shall provide to FDA within twenty (20) business days after the date of 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.

17. Defendants shall prominently post a copy of this Order in an employee common area at the facility within ten (10) business days after entry of this Order and shall ensure that the Order remains posted for a period of at least six (6) months.

18. Defendants shall, within ten (10) business days after entry of this Order, hold a general meeting or series of smaller meetings for employees of the facility, at which they shall describe the terms and obligations of this Order.

19. 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) business days after each instance that any Defendant becomes associated with any such additional 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 person 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) business days after 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.

20. Defendants shall address all communications with FDA required under this Order to Director, Detroit District Office, Food and Drug Administration, 300 River Place Drive, Suite 5900, Detroit, Michigan, 48207, and shall reference this civil action by case name and civil action number in such communications.

21. No sooner than five years after entry of this Order, Defendants may petition this Court to terminate the Order. If Defendants have maintained a state of continuous compliance with this Order, the Act, and all applicable regulations during the five years preceding Defendants' petition, the United States will not oppose such petition.

22. The Court retains jurisdiction of this action and the parties hereto for the purpose of enforcing or modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED.

s/Avern Cohn
AVERN COHN
UNITED STATES DISTRICT JUDGE

Dated: April 4, 2016
Detroit, Michigan