UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNITED STATES OF AMERICA,

Plaintiff,

v.

UNDETERMINED QUANTITIES OF AN ARTICLE OF FOOD, CHEESE, LABELED IN PART ESTRELLA FAMILY CREAMERY (RED DARLA), et al.,,

Defendants.

CASE NO. C10-5772 BHS

PERMANENT INJUNCTION

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. §§ 332 and 334, and personal jurisdiction over all parties to this action. Venue is proper in this district under 28 U.S.C. §§ 1391(b) (e) and 1395.

2. The Defendants in rem are articles of food that are adulterated while held for sale after shipment in interstate commerce, within the meaning of 21 U.S.C. §

342(a)(4), in that they have been prepared, packed, and held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

3. The Defendants in rem are, therefore, condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

4. Because Defendants represent that they have destroyed the Defendants in rem without the knowledge of the United States Food and Drug Administration ("FDA") or the permission of this Court, no further order is required regarding their disposition. If Defendants currently know of, or later discover, the existence of any remaining seized articles, Defendants shall immediately report to the FDA District Director for the Seattle District the status of any remaining seized articles. After reporting the existence of the seized articles to FDA, Defendants shall destroy any remaining seized articles at their own expense and under the supervision of FDA.

5. Pursuant to 21 U.S.C. § 334(e), Defendants shall pay to the United States all court costs and fees, storage, and other proper expenses of this proceeding incurred to date, including, but not limited to, those incurred by the United States Marshal, and such additional expenses as may hereinafter be incurred and taxed. Defendants shall pay these costs within ten (10) days after receiving notice of such costs from FDA, the United States Marshals Service, or the United States Attorney for the Western District of Washington.

6. The terms "process," "processed," and "processing" refer to manufacturing, preparing, packaging, holding, and/or distributing food.

7. Defendants represent to the Court that, as of October 2010 they have ceased interstate processing operations for their cheese. If Defendants later intend to resume their interstate food processing operations, including processing products using any component that has traveled in interstate commerce, at any location, or if Defendants sell or lease their facility at 659 Wynoochee Valley Road, Montesano, Washington ("Montesano facility") to a third party for use in processing food, Defendants must first notify FDA in writing at least sixty (60) calendar days in advance of such activity. This notice should include, at a minimum, identification of the type(s) of food Defendants and/or the party(-ies) to whom Defendants sold or leased the Montesano facility intend to process. Before resuming such operations at the Montesano facility, Defendants shall fully complete the requirements of Paragraph 9 of this Order. Under no circumstance shall Defendants and/or the party(-ies) to whom Defendants sold or leased the Montesano facility resume interstate food processing operations or enter a sale or lease of the Montesano facility for food processing activities, until receiving written notice from FDA, under Paragraph 8(H), and then such activities shall resume only to the extent authorized in FDA's written notice.

8. Defendants and each and all of their officers, directors, agents, representatives, employees, 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), are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from engaging in interstate food processing operations at or from the Montesano facility and any other location at or from

which Defendants (now or in the future) process food in interstate commerce ("Defendants' facilities"). This perpetual restraint and injunction shall continue unless and until Defendants provide FDA with the 60 day advance notice required by Paragraph 7 of this Order and Defendants complete to FDA's satisfaction all of the following:

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 Defendants' facilities and analyze those samples for the presence of Listeria monocytogenes ("L. mono") in a method that is acceptable to 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 certain provisions, acceptable to FDA, for regular environmental and finished product sample 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 Listeria Monitoring Program discussed in Paragraph 8(D) 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 inspect Defendants' facilities and to determine whether the methods, facilities, and

controls are operated and administered in conformity with the Act and 21 C.F.R. Part 110. Defendants shall notify FDA in writing of the name(s) and qualifications of the sanitation expert(s) as soon as they retain such expert(s);

C. Defendants remove from their facilities and all equipment therein rodents, insects, other pests, the filth contributed by them, and microbial and physical contaminants, and adequately repair the floors, ceilings, walls, doors, windows, and building in order to prevent rodents, insects, or other pests from entering Defendants' facilities;

D. Defendants' sanitation expert, in consultation with the laboratory, after review of all observations from the September 2010 FDA and Washington State Department of Agriculture ("WSDA") inspection and any other relevant information, develops a written Listeria Monitoring Program, acceptable to FDA, which shall include, at a minimum, the following:

i. An effective written sanitation control program that establishes adequate methods, facilities, and controls for receiving, processing, preparing, packing, holding, and 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' facilities 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 facilities and equipment therein are continuously maintained in a sanitary condition;

ii. A written employee training program that includes, at a minimum, instruction on sanitary food handling techniques and documentation that each employee has received such training;

iii. An effective program of environmental monitoring and testing of the facilities, conducted by the laboratory, to ensure that Listeria species ("L. spp.") are controlled and 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 facilities (where the raw ingredients, in process, and finished articles of foods are received, processed, prepared, 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 of receipt by Defendants;

iv. A plan for remedial action should L. spp., L. mono, or any other pathogenic organism be detected in Defendants' food or facilities;

v. Assigning continuing responsibility for the operation of the Listeria Monitoring Program to a person or persons who, by reason of background, experience, or education is competent to maintain the facilities in a sanitary condition, coordinate with the laboratory, and implement any necessary remedial action(s), and providing such person with the authority to achieve the necessary corrections; and

vi. Defendants make the Listeria Monitoring Program available and accessible to all their employees;

E. The sanitation expert conducts a comprehensive inspection of Defendants' facilities and the methods and controls used to receive, process, prepare, pack, hold, and distribute foods to determine whether Defendants have effectively implemented all necessary changes and are operating in compliance with this Order, the Act, and 21 C.F.R. Part 110.

The expert shall submit his/her findings to Defendants and FDA concurrently, within ten (10) business days of completing of the inspection;

F. 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:

i. Documentation that they have cleaned and sanitized their facilities and have received laboratory results showing that L. mono is no longer present in the facilities;

ii. Specific measures that they have taken to address each of the violations documented by FDA and WSDA during their September 2010 inspection; and

iii. A copy of the Listeria Monitoring Program;

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

H. Defendants receive written notification from FDA (i) stating that Defendants appear to be in compliance with the Act, all applicable regulations, and this Order, and (ii) authorizing Defendants to resume: (a) receiving at any of Defendants' facilities articles of food in interstate commerce, and (b) introducing, delivering for introduction, and causing the

introduction or delivery for introduction into commerce of food manufactured, prepared, packaged, held, or distributed at the facilities;

I. Defendants have paid all costs of inspection, analysis, review, investigations, examination, and supervision for FDA's oversight with respect to Paragraphs 8(A) through (H), at the rates set forth in Paragraph 13 of this Order.

9. Upon resuming interstate food processing operations after completing the requirements of Paragraph 8, Defendants shall continuously implement the following steps to prevent further L. mono contamination of their food products and facility:

A. Effectively implement, on an ongoing basis, the Listeria Monitoring Program developed pursuant to Paragraph 8(D), unless Defendants submit, and FDA approves in writing, an alternative L. mono control program, consisting of validated methods and controls that are shown to FDA's satisfaction to eliminate L. mono in food. In the event that Defendants, their sanitation expert, or laboratory determines that the Listeria Monitoring Program needs to be revised, Defendants shall provide suggested changes to FDA in writing at least twenty (20) calendar days prior to their implementation.

B. Conduct finished product testing in the following manner:

i. Immediately upon resumption of operations after the completion of the requirements of Paragraph 8, Defendants shall test for L. mono in all lots of each food

product for at least five consecutive production days, using a sampling protocol and testing method acceptable to FDA. Defendants shall ensure that the results of all analyses conducted pursuant to this sub paragraph, including the initial and/or any repeat test results, are sent to FDA within two (2) calendar days of receipt by Defendants;

ii. After the completion of testing under Paragraph 9(B)(i), Defendants shall test at least one lot of each food product per day for the next twenty (20) production days. Defendants shall ensure that the results of all analyses conducted pursuant to this sub paragraph, including the initial and/or any repeat test results, are sent to FDA within two (2) calendar days of receipt by Defendants;

iii. After the completion of testing under Paragraph 9(B)(ii), Defendants shall test at least one lot of each food product per every five (5) production days for the next three (3) months. Defendants shall ensure that the results of all analyses conducted pursuant to this sub paragraph, including the initial and/or any repeat test results, are sent to FDA within two (2) calendar days of receipt by Defendants; and

iv. After the completion of testing under Paragraph 9(B)(iii), Defendants shall test at least one lot of each food

product per quarter thereafter. Defendants shall ensure that the results of all analyses conducted pursuant to this sub paragraph, including the initial and/or any repeat test results, are sent to FDA within two (2) calendar days of receipt by Defendants.

If any laboratory test completed pursuant to Paragraphs 9(B)(i) (iv) shows the presence of L. mono in any article of food, Defendants must immediately cease production until they have determined and corrected the cause of the microbial contamination. Once the cause of the contamination has been corrected, Defendants shall reinstate the complete sequence of testing under this paragraph anew.

10. If, after notifying FDA of the name of the laboratory retained to conduct sample collection and analysis pursuant to Paragraph 8(A), Defendants terminate or alter their service contract with the laboratory in anyway, Defendants shall notify FDA within five (5) business days. If Defendants contract with a new laboratory for collection and analysis services, Defendants shall provide a copy of the new service contract to FDA within five (5) business days of execution.

11. If, at any time after entry of this Order, FDA determines, based on the results of an inspection, sample analysis, or other information, that Defendants have failed to comply with any provision of this Order, have violated the Act or applicable regulations, or that additional corrective actions are necessary to achieve compliance with this Order, the Act, or applicable regulations, FDA may, as and when it deems necessary, issue a directive notifying Defendants in writing of the noncompliance and ordering

Defendants to take appropriate action, including but not limited to ordering them to take one or more of the following actions immediately:

A. Cease receiving, preparing, packing, labeling, holding, or distributing articles of food until Defendants receive written notification from FDA that they appear to be in compliance with the Order, the Act, and applicable regulations, and that Defendants may resume operations;

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

C. Submit samples of articles of food to a qualified laboratory to determine whether it is contaminated with chemicals, toxins, microorganisms, or filth; and/or

D. Take any other corrective actions as FDA deems necessary to protect the public health or bring Defendants into compliance with this Order, the Act, and applicable regulations, including, but not limited to, requiring that Defendants re implement or re institute any of the requirements of this Order.

The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA.

12. Any notification issued by FDA pursuant to Paragraph 11 of this Order shall be issued by FDA's Seattle District Director, a person acting in that capacity, or a designee of the Seattle District Director and shall specify the failures giving rise to the

notification. Defendants shall, upon receipt of FDA's notification, immediately comply with the terms of the notification and shall notify FDA in writing of the corrective action(s) taken and, if appropriate, its schedule for completion.

13. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews to implement and monitor recalls and other corrective actions, at the standard rates prevailing at the time the activities are accomplished. As of the date this Order is proposed, the rates are $87.57 per hour or fraction thereof per representative for time spent on supervision other than laboratory and analytical work; $104.96 per hour or fraction thereof per representative for laboratory and analytical work; and 55.5 cents per mile for travel expenses. In the event that the standard rates generally applicable to FDA's supervision of court ordered compliance are modified, these rates shall be increased or decreased without further order of this Court.

14. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them who receive notice of this Order, 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, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342;

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 while such articles are held for sale after shipment of one or more ingredients in interstate commerce; or

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

15. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of any of Defendants' facilities, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order. During such inspections, FDA representatives shall be permitted access to buildings, equipment, articles of food, containers, and packaging material(s) therein; to take photographs and make video recordings; to take samples of Defendants' articles of food, containers, and packaging material(s); to examine and copy all records relating to the receiving, manufacturing, preparing, packing, holding, and distributing of any and all articles of food, and to the sanitation of the facility. The inspections shall be permitted upon presenting a copy of this Order and appropriate credentials. The inspection authority granted by this Order is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

16. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Order shall be vested in FDA's discretion and, if contested, shall be reviewed by this 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.

17. Defendants shall provide a copy of this Order, personally or, when necessary, by registered mail, within ten (10) calendar days from the date of entry of the Order, to each of their officers, directors, agents, representatives, employees, successors, assigns, and attorneys. Defendants shall also post a copy of this Order in the employee common areas at each of their facilities as long as it remains in effect. Within thirty (30) calendar days of the date of entry of this Order, Defendants shall provide to FDA an affidavit of compliance, stating the facts and manner of compliance with the provisions of this paragraph.

18. Defendants shall notify FDA in writing at least thirty (30) calendar days before any subsequent change in location, ownership, or character of their business, such as reorganization, dissolution, assignment, or sale resulting in the emergence of a successor corporation or business entity, the creation or dissolution of subsidiaries, or any other change in the corporate or business structure of any newly formed business entity (including any "doing business as" entity) over which Defendants have any authority, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Order. Defendants shall provide a copy of this Order to any successor or assignee at least thirty (30) calendar days prior to the assignment or change in ownership. Defendants shall furnish FDA with an affidavit of

compliance with this paragraph at least thirty (30) calendar days prior to such assignment or change in ownership.

19. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Order, Defendants agree to pay all attorney's fees, travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such an action.

20. All notifications, correspondence, and communications to FDA required by the terms of this Order shall be addressed to:

District Director
Seattle District Office
U.S. Food and Drug Administration
Department of Health and Human Services
22201 23rd Drive SE
Bothell, WA 98021 4421

12. This Court retains jurisdiction to issue such further decrees and orders as may be necessary to the proper disposition of this proceeding.

Dated this 24th day of October, 2012.

BENJAMIN H. SETTLE
United States District Judge