UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

UNITED STATES OF AMERICA, Plaintiff, v. ROOS FOODS, INC., a corporation, and ANA A. ROOS and VIRGINIA MEJIA, individuals, Defendants.	)	Civil No._____ COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 332(a), and the equitable authority of this Court, to enjoin and restrain Roos Foods, Inc. ("Roos Foods"), a corporation, and Ana A. Roos and Virginia Mejia, individuals, (collectively, "Defendants"), from violating: (a) 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4); and (b) 21 U.S.C. § 331(k) by causing articles of food that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

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

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

THE DEFENDANTS

4. Roos Foods has been incorporated in the state of Delaware since 1989. The firm received, prepared, processed, packed, held, and distributed several varieties of ready-to-eat cheese, including ricotta, queso fresco, and fresh cheese curd. All of these food products were manufactured at Roos Foods' facility located at 251 Roos Lane, Kenton, Delaware, within the jurisdiction of this Court.

5. Ana A. Roos is the co-owner of a 50% interest in Roos Foods. She is also the firm's President and CEO. Mrs. Roos holds ultimate decision-making authority for all aspects of the firm's operations. Mrs. Roos performed her duties at 251 Roos Lane, Kenton, Delaware, within the jurisdiction of this Court.

6. Virginia Mejia is the co-owner of a 50% interest in Roos Foods. She is also the firm's Controller, and is responsible for the firm's day-to-day operations, including overseeing all aspects of the plant, warehouse, and delivery operations. Mrs. Mejia performed her duties at 251 Roos Lane, Kenton, Delaware, within the jurisdiction of this Court.

7. Defendants have been engaged, at 251 Roos Lane, Kenton, Delaware, in receiving, preparing, processing, packing, holding, and distributing various articles of food—namely, ready-to-eat cheese. Defendants' ready-to-eat cheese is food within the meaning of 21 U.S.C. § 321(f).

8. Defendants sold their ready-to-eat cheese to wholesale customers, including supermarkets in Maryland and Virginia. Roos Foods received in interstate commerce one or more components used to manufacture its cheese, including salt from Maryland.

LISTERIA MONOCYTOGENES

9. *Listeria monocytogenes* ("*L. mono*") is the bacterium that causes the disease listeriosis. Listeriosis is most commonly contracted by eating food contaminated with *L. mono*. Listeriosis can be serious, even fatal, for high-risk groups such as unborn babies, newborns, and those with impaired immune systems. The most serious forms of listeriosis can result in meningitis and septicemia. Pregnant women may contract flu-like symptoms from listeriosis, and complications from the disease can result in miscarriage, or septicemia in the newborn.

10. Unlike many other foodborne microbes, *L. mono* bacteria are capable of adapting and growing even at refrigerator temperatures. *L. mono* is also capable of surviving and growing under other adverse conditions, such as high salt or high acid (low pH) conditions. Thus, the presence of *L. mono* in ready-to-eat foods is a particularly significant public health risk.

LISTERIOSIS OUTBREAK

11. On February 15, 2014, the Virginia Department of Agriculture and Consumer Services ("VDACS") reported that *L. mono* had been isolated from cheese manufactured by Roos Foods and collected by VDACS at a retail store in Virginia.

12. On February 19, 2014, the Maryland Department of Health and Mental Hygiene ("MDHMH") reported that its testing of cheese products manufactured by Roos Foods was presumptively positive for *Listeria.* On February 24, 2014, MDHMH confirmed the presence of *L. mono* in the Roos Foods' cheese products that it tested.

13. On February 21, 2014, the Centers for Disease Control and Prevention ("CDC") reported that it was collaborating with the U.S. Food and Drug Administration ("FDA") and several states to investigate a multi-state outbreak of listeriosis linked to *L. mono* infection. CDC reported that a total of eight people (5 adults and 3 newborns) in two states (Maryland and

California) were infected with *L. mono*, with isolation dates of *L. mono* ranging from August 1–November 27, 2013. CDC stated that several of the patients in Maryland reported eating soft or semi-soft cheese in the month before becoming ill. CDC announced that VDACS had identified the outbreak strain of *L. mono* in cheese produced by Roos Foods.

DEFENDANTS' VIOLATIONS

14. Following VDACS' initial report, FDA inspected Defendants' Kenton, Delaware facility from February 18 to March 4, 2014 (the "March 2014 Inspection"). This inspection established that the ready-to-eat cheese products that Defendants manufacture, process, pack, label, hold, and distribute 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 become contaminated with filth or rendered injurious to health. At the close of the March 2014 Inspection, FDA investigators issued a ten-item List of Inspectional Observations ("Form FDA-483") that contained the following observations of failures to implement effective monitoring and sanitation controls in accordance with the current Good Manufacturing Practice ("CGMP") requirements for food, *see* 21 C.F.R. Part 110, among others:

A. Failure to construct the facility in such a manner as to prevent drip from contaminating food-contact surfaces and food-packaging materials, as required by 21 C.F.R. § 110.20(b)(4);

B. Failure to clean food-contact surfaces as frequently as necessary to protect against contamination of food, as required by 21 C.F.R. § 110.35(d);

C. Failure to store raw materials and ingredients in a manner that protects against contamination, as required by 21 C.F.R. § 110.80(a)(1);

D. Failure to construct the facility in such a manner as to allow floors, walls, and ceilings to be adequately cleaned and kept clean and in good repair, as required by 21 C.F.R. § 110.20(b)(4); and

E. Failure to use equipment and utensils in a manner that precludes the adulteration of food with contaminated water and contaminants, as required by 21 C.F.R. § 110.40(a).

15. At the close of the March 2014 Inspection, the FDA investigators discussed all of the observations listed on the Form FDA-483 with Defendants Ana A. Roos and Virginia Mejia.

LABORATORY TEST RESULTS

16. FDA and VDACS performed Whole Genome Sequencing ("WGS") on the *L. mono* strains isolated from the Roos Foods cheese products. These strains were found to be highly related by WGS to the *Listeria* strains isolated from patients in the *L. mono* outbreak. WGS analysis also showed that the clinical isolates of *L. mono* originated from a single bacteria lineage and that it is reasonably likely that the lineage shares the same geographic locale.

POST-INSPECTION ACTIONS

17. On February 23, 2014, after FDA initiated the March 2014 Inspection, Roos Foods recalled all lots of its Cuajada En Terron, Cuajada/Cuajadita Cacera, Cuajada Fresca, Queso Fresca Round, and Queso Dura Viejo hard cheeses marketed under its Mexicana, Amigo, and Santa Rosa De Lima brands due to potential for *L. mono* contamination. On February 25, 2014, Roos Foods expanded the scope of the recall to include all lots of Amigo and Mexicana brands of Requesón (part-skim ricotta) and Amigo, Mexicana, and Santa Rosa De Lima brands of Queso de Huerta (fresh curd cheese). On March 1, 2014, Roos Foods further expanded their recall to include all product sizes and containers of Santa Rosa de Lima Queso Duro Blando

(hard cheese) and Mexicana Queso Cojito Molido, as well as all lots and sizes of its sour cream products.

18. On February 26, 2014, FDA held a Regulatory Meeting with Defendants to discuss the ongoing March 2014 Inspection. At the meeting, Defendants committed that Roos Foods would not manufacture any food products in the facility and would notify FDA before the firm resumed manufacturing food.

19. On February 28, 2014, Delaware's Division of Public Health issued a cease and desist letter to Roos Foods ordering them to cease production and distribution of milk and dairy products.

20. On March 11, 2014, FDA suspended the food facility registration of Roos Foods after determining there was a reasonable probability that food manufactured, processed, packed, or held by Roos Foods would cause serious adverse health consequences or death to humans (the "suspension order"). A company without a food facility registration cannot distribute any food products. The suspension order remains in effect.

21. Defendants violate 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), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or rendered injurious to health.

22. Defendants violate 21 U.S.C. § 331(k) by causing 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 of their components in interstate commerce.

ADDITIONAL INSPECTIONS AND PRIOR WARNINGS

23. FDA previously inspected Defendants' facility most recently between June 3–4, 2013 (the "June 2013 Inspection"). Some of the CGMP deviations observed during the February 2014 Inspection, discussed in paragraph 14, are the same as, or similar to, those observed by FDA during the June 2013 Inspection. For example, during the June 2013 Inspection, FDA documented Defendants' failure to: (a) clean food-contact surfaces as frequently as necessary to protect against contamination of food (similar to paragraph 14(B) above); (b) handle work-in progress in a manner that protects against contamination (similar to paragraph 14(C) above); and (c) maintain buildings, fixtures, or other physical facilities in a sanitary condition (similar to paragraph 14(D) above). At the close of the June 2013 Inspection, FDA investigators issued an eight-item Form FDA-483 to Defendant Virginia Mejia and discussed each of the observations with her.

24. FDA also previously inspected Defendants' facility between July 13–20, 2010 (the "July 2010 Inspection"). Some of the CGMP deviations observed during the February 2014 Inspection, discussed in paragraph 14, are the same as, or similar to, those observed by FDA during the July 2010 Inspection. For example, during the July 2010 Inspection, FDA documented Defendants' failure to: (a) construct the plant in such a manner as to prevent drip and condensate from contaminating food and food-contact surfaces (similar to paragraph 14(A) above); (b) construct the plant in such a manner as to allow ceilings to be adequately cleaned and kept clean (similar to paragraph 14(D) above); and (c) conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials (similar to paragraph 14(E) above). At the close of the

July 2010 Inspection, FDA investigators issued a ten-item Form FDA-483 to Defendant Ana M. Roos and discussed each of the observations with her.

25. Defendants did not respond in writing to the Form FDA-483s issued after the June 2013 and July 2010 Inspections.

26. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, the United States respectfully requests that this Court:

I. Permanently and perpetually restrain and enjoin Defendants Roos Foods, Inc., a corporation, and Ana A. Roos and Virginia Mejia, individuals, 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 the Court's Order, from doing or causing to be done, directly or indirectly, any of the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, or the causing thereof, any article of food that is adulterated; and

B. Violating 21 U.S.C. § 331(k) by causing the adulteration of any article of food while such article of food is held for sale after shipment of one or more of its components in interstate commerce.

II. Permanently and perpetually restrain and enjoin, under 21 U.S.C. § 332(a) and the equitable authority of this Court, 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), from doing or causing to be done, directly or indirectly, any act that adulterates food within the meaning of 21 U.S.C. § 342(a)(4).

III. 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 the Court's Order, to cease receiving, preparing, processing, packing, holding, and distributing all food at or from their facility, or at any other location(s) from which Defendants receive, prepare, process, pack, hold, or distribute food, unless and until Defendants bring their receiving, preparing, processing, packing, holding, and distribution operations into compliance with the Act and its implementing regulations to FDA's satisfaction.

IV. Grant the United States its costs and such other and further relief as the Court deems just and proper.

Dated this 22nd day of January, 2016.

Respectfully submitted,

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