UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN

UNITED STATES OF AMERICA, Plaintiff, v. SARANAC BRAND FOODS, INC., a corporation, and DENNIS M. NOWAK and DANIEL R. NOWAK, individuals, Defendants.	Case No. 1:18-cv-1332

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, 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 inherent equitable authority of this Court, to enjoin and restrain Saranac Brand Foods, Inc. ("Saranac" or "the company"), a corporation, and Dennis M. Nowak and Daniel R. Nowak, 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).

DEFENDANTS

4. Saranac was incorporated in the state of Michigan in 1971. The company's business operations involved the preparation, processing, packing, holding, and distribution of approximately 35 different ready-to-eat foods, including prepared salads, dips, and sauces (e.g., coleslaw, macaroni salad, spinach dip, and enchilada sauce). Defendants' manufacturing facility is located at 60 South Bridge Street, Saranac, Michigan 48881, within the jurisdiction of this Court.

5. Dennis M. Nowak is Saranac's President and part-owner. At all times relevant to the allegations in this Complaint, Dennis Nowak has been the most responsible person for the company and overseen day-to-day operations on site at its facility. His duties have included manufacturing and purchasing, and he has had the authority to hire and fire employees. Dennis Nowak has performed his duties at 60 South Bridge Street, Saranac, Michigan 48881, within the jurisdiction of this Court.

6. Daniel R. Nowak is Saranac's Vice President and co-owner with Dennis Nowak. Daniel Nowak also has had the authority to hire and fire employees. His duties have also involved the preparation of ingredients during food production, assisting in sanitation procedures, and directing employees processing food. Daniel Nowak has performed his duties at 60 South Bridge Street, Saranac, Michigan 48881, within the jurisdiction of this Court.

7. Defendants' ready-to-eat food products are food within the meaning of 21 U.S.C. § 321(f).

8. Defendants have introduced their food into interstate commerce by shipping it to two distributors in Michigan for further distribution, which includes to customers located outside

of Michigan. Defendants have received in interstate commerce one or more components used to manufacture their ready-to-eat food. For example, Defendants received pasta shells from Missouri, vinegar from Ohio, and seasonings from New Jersey.

LISTERIA MONOCYTOGENES

9. *Listeria monocytogenes* ("*L. monocytogenes*") is a species of pathogenic bacteria that causes listeriosis, an acute, life-threatening infection. *L. monocytogenes* is widespread in the environment and may be introduced into a food-processing facility from raw materials, humans, or equipment. *L. monocytogenes* can colonize on a variety of moist surfaces, such as floors, floor drains, and food-processing equipment. In addition, it can collect in condensation, standing water, and food residues. *L. monocytogenes* is particularly hardy because of its tendency to form biofilms, which protect the bacteria from ordinary cleaning processes.

10. Strict in-plant sanitation measures must be instituted to eliminate *L. monocytogenes* and prevent its growth. Without proper controls, *L. monocytogenes* can proliferate in food-processing facilities where it may contaminate food. Therefore, identifying the areas in a facility where *L. monocytogenes* can grow and survive, and taking corrective actions necessary to eradicate the microorganism by rendering these areas unable to support its growth and survival, is essential.

11. Consuming foods contaminated with *L. monocytogenes* can lead to listeriosis, which is a public health concern because of the severity of the disease, its high case-fatality rate, long incubation time, and tendency to affect vulnerable persons, including the elderly, newborns, and persons who are immune-compromised.

12. *L. monocytogenes* has been detected in various locations within Defendants' food-processing facility at 60 South Bridge Street, Saranac, Michigan 48881.

DEFENDANTS' CONDUCT AND VIOLATIONS

13. FDA most recently inspected Defendants' facility between October 23 and November 29, 2017 (the "November 2017 Inspection"). This inspection established that the ready-to-eat food products that Defendants manufactured, processed, packed, labeled, held, and distributed were 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. The insanitary conditions include the presence of pathogenic *L. monocytogenes* in the company's food-processing facility and Defendants' failure to implement effective monitoring and sanitation controls in accordance with the current Good Manufacturing Practice ("CGMP") requirements for food. *See* 21 C.F.R. Parts 110 and 117.[1] The FDA investigators documented insanitary conditions, including, but not limited to, the following:

A. Failure to conduct food manufacturing, processing, packing, and holding operations under conditions and controls necessary to minimize the potential for growth of microorganisms (as required by 21 C.F.R. § 117.80(c)(2)). Specifically, the FDA investigators collected ninety-seven environmental sub-samples from the processing and cooking areas of Defendants' facility, and twelve tested positive for *L. monocytogenes*. Two locations where *L. monocytogenes* was detected were the same locations in Defendants' facility's food-processing area where the pathogen was detected during a previous FDA inspection in February 2016.

[1] 21 C.F.R. Part 110 was modernized and codified in Subpart B of Part 117 by the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 C.F.R. Part 117). An establishment was subject to Part 110 until the Part 117 compliance date applicable to its business size. Because Saranac is a small business with fewer than 500 full-time equivalent employees, its compliance date for Part 117 was September 18, 2017.

L. monocytogenes was also found in various parts of the floor in the food-processing area and the center floor drain, including the plastic grates covering the center floor drain and the damaged floor around the center floor drain. Moreover, *Listeria innocua*, a non-pathogenic microorganism that is an indicator of insanitary conditions, was found in thirteen sub-samples;

B. Failure to construct the food processing facility in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and in good repair (as required by 21 C.F.R. § 117.20(b)(4)). Specifically, the FDA investigators observed that the flooring in Defendants' facility's food-processing areas was in poor repair with exposed aggregate (the rocky substrate beneath the surface of the concrete floor), chipped areas, ponded water, and debris;

C. Failure to conduct operations in accordance with adequate sanitation principles in manufacturing, processing, packing, and holding food, (as required by 21 C.F.R. § 117.80(a)). For example, the FDA investigators observed Defendants' employees spraying out the center drain (where *L. monocytogenes* was detected) and aerosolizing substances in the trench; employees using a pressurized hose to spray off a soiled food cart, causing spray to be deflected onto an uncovered food cart containing coleslaw; employees exiting and entering the food-processing area without washing their hands and then handling food and food-contact equipment; and an employee touching the processing room floor (contaminated with *L. monocytogenes*) and then touching food product without first washing his hands. The investigators also observed food build-up and condensate on the ceiling above pasta cookers, even after the employees stated that they had cleaned the area, and a thick, slimy food build-up on food-processing equipment after Defendants claimed to have performed a full sanitation procedure;

D. Failure to have all plant equipment and utensils used in manufacturing, processing, packing, and holding food designed and constructed to be adequately maintained to protect against allergen cross-contact and contamination (as required by 21 C.F.R. § 117.40). For example, the FDA investigators observed that white food carts used in the processing room to mix and hold food products were in poor condition, having deep grooves and stains making them not easily cleanable. Moreover, chipped paint was observed on the middle spindle in a cabbage spinner, which is a food-contact surface;

E. Failure to create and maintain adequate sanitary facilities and accommodations (as required by 21 C.F.R. § 117.37). For example, the FDA investigators observed hoses used in the processing area with inappropriate or no backflow prevention devices, and condensate drain lines terminating behind the facility's one-compartment sink and onto the floor of the food-processing area, rather than in the sink; and

F. Failure to ensure that cleaning compounds and sanitizing agents were safe and adequate under their conditions of use (as required by 21 C.F.R. § 117.35(b)(1)). Specifically, the FDA investigators observed that Defendants employed sanitizing agents that were not used according to their labeled directions for use. For example, Defendants and/or their employees washed cabbage used in the production of coleslaw in chlorinated water using chlorine not labeled for direct food contact; and Saranac used quaternary sanitizer, labeled for use at 200 ppm, to sanitize food-contact equipment and food-processing area surfaces at 400 ppm.

14. At the close of the November 2017 Inspection, the FDA investigators issued an eleven-item List of Inspectional Observations ("Form FDA-483") to Defendant Dennis Nowak, and discussed each of the observed deviations with Defendants Dennis and Daniel Nowak.

15. On December 13, 2017, Defendants responded to the November 2017 Form FDA-483, representing that actions had been and were being taken to correct the insanitary conditions identified during the November 2017 Inspection. After reviewing Defendants' submission, FDA determined that the proposed corrections were inadequate to fully address the insanitary conditions in Defendants' facility. For example, Defendants' response did not: (a) evaluate the root cause of the *L. monocytogenes* contamination within their facility; (b) provide sufficient documentation of training employees on sanitation procedures and cleaning its food carts in the processing room; or (c) demonstrate that the floor was repaired or provide a timetable for repairing the floor.

16. Defendants violated 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

17. Defendants violated 21 U.S.C. § 331(k) by causing the adulteration, within the meaning of 21 U.S.C. § 342(a)(4), of food while such article is held for sale after shipment of one or more of its components in interstate commerce.

DEFENDANTS' HISTORY OF VIOLATIVE CONDUCT

18. During the past six years, interactions between Defendants and both FDA and the Michigan Department of Agriculture & Rural Development ("MDARD") demonstrate a pattern of non-compliance at Defendants' facility and their failure to follow through on corrections.

19. FDA conducted a comprehensive surveillance inspection of Defendants' facility between February 7 and 8, 2012 (the "February 2012 Inspection") and observed insanitary

conditions. For example, during the February 2012 Inspection, the FDA investigators observed that the painted floor in Defendants' food-processing facility was chipped and missing in places, exposing porous concrete aggregate beneath. Water and food particles were observed pooling around the chipped floor underneath Defendants' dicing and chopping machines. Furthermore, the FDA investigators observed Defendants' employees spraying a dicing machine with pressurized water before switching to dicing green peppers, in a manner that caused the aerosolized water to deflect off the floor and strike the dicing machine.

20. At the close of the February 2012 Inspection, the FDA investigators issued a two-item Form FDA-483 to Defendant Dennis Nowak and discussed each of the observations with him. In addition, during a close-out meeting, the FDA investigators discussed the condition of Defendants' facility's floors with Defendants Dennis and Daniel Nowak, who stated that new flooring was a "top priority" repair for the facility and that they expected to install new flooring by September 2012.

21. On March 5, 2012, Defendants responded in writing to the February 2012 Form FDA-483 by providing a floor repair estimate from 2009 with marginalia stating, "Will be done when we can afford it."

22. MDARD conducted a MDARD-FDA contract inspection of Defendants' facility between June 2 and 11, 2014 (the "June 2014 Inspection") and found that the floors throughout the food-processing area (i.e., floor in the peeling room, packing/processing room, and cook room) were difficult to clean due to heavy erosion from the water used in the processing of vegetables, pasta, and other ingredients prepared on site. In addition to Defendants' poor floor condition, MDARD observed, among other things, inadequate sanitation practices (including finding visible food residues on mechanical cutting equipment after completion of a cleaning

procedure) and the failure to subject food-processing equipment to a three-step wash, rinse, and sanitize procedure at the end of the production schedule.

23. MDARD collected 100 environmental swabs of locations throughout Defendants' facility. Thirteen were positive for *L. monocytogenes*, which was found in the multiple locations, including the floor underneath the mixing cart and the floor underneath the hand washing sink. The environmental sampling also revealed the presence of other *Listeria* species in Defendants' facility, including *Listeria innocua* and *Listeria ivanovii*. MDARD also noted that Defendants did not have an environmental testing program.

24. Defendants responded to the June 2014 Inspection observations in writing on September 19, 2014, stating, among other things, that its peeling room was no longer in use and that they moved their peeling equipment to the north end of the processing room "where [they] have no flooring issues." They further claimed that the floor in the packing/processing room had been "patched [] where needed and [e]poxy painted" to make it smooth and easier to clean. Moreover, they stated that the cook room floor would be patched and painted in September 2014.

25. FDA conducted a compliance follow-up inspection of Defendants' facility between February 1 and 9, 2016 (the "February 2016 Inspection"). The FDA investigators observed: (a) employees cleaning the processing floor with pressurized hoses that created overspray that adhered to ingredient containers; (b) ceilings and floors remained in poor repair, with debris visible in the floor expansion joints and the floors were eroded with exposed concrete aggregate; (c) food-contact surfaces of several pieces of equipment were damaged and did not appear easily cleanable (e.g., cutting boards were scored and discolored, food-contact surfaces in food carts had deep gouges, and a steel mixing bowl had pitting evident in the interior of the

bowl, making it rough); (d) condensate was on the ceiling above pasta cookers; and (e) hose drops had incorrect backflow prevention devices or no backflow devices.

26. During the February 2016 inspection, the FDA investigators collected environmental samples from various locations at Defendants' facility. Three of the eighty-nine environmental swabs tested positive for *L. monocytogenes*. Specifically, *L. monocytogenes* was found on the floor near food carts and the two-compartment sink, on the floor alongside the interior legs of a stand mixer, and on the floor under the one-compartment sink. These locations were near the facility's food products and food-contact surfaces.

27. At the close of the February 2016 Inspection, FDA issued a five-item Form FDA-483 to Defendant Dennis Nowak and discussed the observed violations with him and Defendant Daniel Nowak. In addition, the FDA investigators discussed, among other things, the general state of repair of food-processing equipment, utensil storage, concerns regarding cleaning procedures used throughout the facility, and ensuring proper employee handwashing. Defendants claimed they would have "many of the corrections in place by March 2016."

28. Defendants also responded to the five-item Form FDA-483 in writing on February 19, 2016, stating that they (a) educated employees on use of low pressure water to avoid overspray onto food containers; (b) repainted and patched floors so aggregate is not exposed and water no longer pools in certain locations, and filled expansion gaps with silicone; (c) replaced cutting boards and discontinued using the damaged food carts and mixing bowl; (d) ran ventilation fans in the cooking room to reduce condensation, and covered pasta cookers during the cool-down process; and (e) continued working on proper water backflow prevention.

29. FDA issued a Warning Letter to Defendants dated August 12, 2016, informing them that, due to FDA finding *L. monocytogenes* in their facility near food and food-contact

surfaces and observing numerous violations of CGMP during FDA's February 2016 Inspection, Defendants' food products were adulterated within the meaning 21 U.S.C. § 342(a)(4). The Warning Letter further noted that Defendants' response to the Form FDA-483 issued after the February 2016 Inspection was inadequate. For example, Defendants did not address re-training employees on cleaning operations, repairing the ceiling in the food-processing room, and determining whether the ventilation fans in the cook room were adequate. In addition, the Warning Letter referenced MDARD detecting *L. monocytogenes* in Defendants' facility during the June 2014 Inspection, and that Defendants should reassess their cleaning and sanitation operations. The Warning Letter emphasized the serious nature of the deficiencies, stated that it was not intended to be an all-inclusive review of Defendants' facility and products, and explained that it was Defendants' responsibility to ensure that their products comply with the Act and its implementing regulations.

30. Defendants responded to the August 2016 Warning Letter by stating that, among other things, they had purchased a new stand mixer to replace the older mixer where *L. monocytogenes* was detected and that they had sealed the expansion gap where *L. monocytogenes* was detected; however, Defendants did not address the poor condition of their processing room floor.

31. MDARD conducted an inspection of Defendants' facility on September 14, 2017 (the "September 2017 Inspection") and observed insanitary conditions. For example, the floor was pitted in various locations throughout the facility. In addition, several pieces of food processing equipment had food-residue accumulation, a paddle for the pasta cooker was standing on the floor grating around the cooker (a source of contamination), and paint was peeling off the wall behind the floor mixer in the food-processing room.

32. FDA analyzed the environmental samples collected from Defendants' facility during the June 2014, February 2016, and November 2017 inspections, and determined through Whole Genome Sequencing that Defendants' facility contained a resident strain of the pathogen *L. monocytogenes.* Specifically, the strain of *L. monocytogenes* detected during the June 2014 Inspection on the floor under the hand washing sink, on the floor under a table in the processing room, and in the central floor drain of the processing room, is identical to the *L. monocytogenes* strain detected in those areas during the February 2016 and November 2017 inspections. The June 2014 MDARD samples and the FDA samples are genetically identical, which indicates that this pathogen has been present in Defendants' facility since at least 2014.

33. When Defendants responded to the Form FDA-483 issued after the November 2017 Inspection (Paragraph 15, above) they failed to address the root cause of the *L. monocytogenes* contamination in their facility.

34. To ensure that Defendants do not further violate the Act in the manner set forth above, the entry of injunctive relief by this Court is appropriate.

WHEREFORE, the United States respectfully requests that this Court:

I. Permanently and perpetually restrain and enjoin Defendants Saranac Brand Foods, Inc., a corporation, and Dennis M. Nowak and Daniel R. Nowak, 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, franchisees, partnerships, and "doing business as" entities) who receive actual notice of this 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 inherent 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 this 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 this Court deems just and proper.

Dated this 29th day of November, 2018.

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