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UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

LOS ANGELES DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. MICHEL CORDON BLEU, INC., a corporation, and MICHEL G. BLANCHET, an individual, Defendants.	No. CV 2:17-cv-07273 COMPLAINT FOR PERMANENT INJUNCTION

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

INTRODUCTION

1. This action is brought by the United States of America pursuant to the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Michel Cordon Bleu, Inc., ("Michel Cordon Bleu" or "the company"), a California corporation, and individual Michel G. Blanchet (collectively, "Defendants"),

from violating: (a) 21 U.S.C. § 331(a), by causing to be introduced or delivered for introduction into interstate commerce food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4); and (b) 21 U.S.C. § 331(k), by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such food is held for sale after shipment of one or more of its components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a), and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Michel Cordon Bleu, Inc. is a California corporation that conducts business at a facility located at 3625 South Western Avenue, Los Angeles, California 90018 ("the facility"), within the jurisdiction of this Court.

5. Defendant Michel G. Blanchet is Michel Cordon Bleu's owner and President. He is the most responsible person at the company. He makes all operational decisions and oversees all aspects of the business. Defendant Blanchet is directly responsible for Michel Cordon Bleu's day-to-day operations, including product ordering, receiving, processing, packaging, storing, marketing, distribution, facility maintenance, and sanitation. He is responsible for preventing, detecting, and correcting violations and has the authority to hire and fire employees.

6. Defendants prepare, process, pack, hold, and distribute refrigerated, vacuum-packed, ready-to-eat cured, cold, and hot smoked fish or fishery products, including, but not limited to, smoked salmon, trout, and sturgeon.

7. Defendants receive raw fish for manufacturing their ready-to-eat, smoked fish or fishery products from outside of California, including salmon from Florida and trout from Idaho. About 70% of Michel Cordon Bleu's products are sold to distributors, 25% sold to restaurants, hotels, and retailers, and 5% sold to cruise ship lines, located in

Orlando, Florida and Las Vegas, Nevada. Michel Cordon Bleu ships about 30% of its products in interstate commerce.

HAZARDS PRESENTED BY DEFENDANTS' FOOD

Clostridium Botulinum

8. *Clostridium botulinum* ("*C. bot*") is an anaerobic bacterium, meaning that it thrives in oxygen-free environments. All people are susceptible to the potent neurotoxin that *C. bot* spores can produce in food. Ingestion of even a small amount of this neurotoxin can cause botulism, a rare but life-threatening disease. Although the incidence of botulism is rare, the disease can cause paralysis and has a high mortality rate if treatment is not treated promptly.

9. *C. bot* is widely distributed in nature and can be found in any raw fish or fishery product. Because its spores are heat-resistant, *C. bot*. can survive cooking. *C. bot.* can also survive in food that has been incorrectly or minimally processed. Certain *C. bot* strains, called proteolytic strains, produce offensive odors and tastes in food products. In contrast, non-proteolytic strains of *C. bot* do not produce the same sensory signals. These non-proteolytic strains are particularly dangerous because they can grow at refrigeration temperatures and render a food toxic without any signs of spoilage. Toxin formation by non-proteolytic *C. bot* can occur at temperatures above 38°F. To inhibit the growth of non-proteolytic *C. bot*., processors must employ adequate levels of salt or salt-nitrite combinations in brining solutions in conjunction with proper smoking and drying, in addition to adequate refrigeration temperatures.

Listeria Monocytogenes

10. *Listeria monocytogenes* ("*L. mono*") is the bacterium that causes listeriosis, a disease commonly contracted by eating food contaminated with *L. mono*. Listeriosis can be serious, even fatal, for vulnerable groups such as 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.

L. mono is the major pathogen, and one of several bacterium, contained within the *Listeria species* ("*L. spp.*").

11. *L. mono* can survive and grow under adverse conditions, such as refrigeration temperatures and high salt or high acid conditions. *L. mono* can colonize on moist surfaces such as floors, floor drains, wet areas, and processing equipment. To minimize the potential for *L. mono* contamination, it is necessary to have sanitation procedures that prevent contamination of food contact surfaces and to eliminate niches where *L. mono* can become established, grow, and persist. Strict in-plant sanitation measures must be taken to eliminate *L. mono* and prevent its proliferation.

12. The presence of *L. mono* in a facility processing ready-to-eat foods presents a particularly significant public health risk.

13. The Act and its implementing regulations require a seafood processor to control the risk of *C. bot.* and *L. mono* formation if the bacteria are reasonably likely to grow in the processor's seafood products. See 21 U.S.C. § 342(a)(4); 21 C.F.R. §§ 123.6(a)-(c).

LEGAL FRAMEWORK

14. Defendants' ready-to-eat fish and fishery products are "food" within the meaning of the Act, 21 U.S.C. § 321(f).

15. Food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) "if 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."

16. A seafood processor's failure to comply with the requirements of the seafood Hazard Analysis and Critical Control Point ("HACCP") regulations, 21 C.F.R. Part 123, renders its fish or fishery products adulterated under the Act. See 21 U.S.C. § 342(a)(4); 21 C.F.R. §§ 123.6(g), 123.12(d).

17. The seafood HACCP regulations require every fish and fishery product processor to "conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur" during the processing of

each kind of fish or fishery product that it processes. 21 C.F.R. § 123.6(a). A food safety hazard is "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." 21 C.F.R. § 123.3(f).

18. Whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur during processing, the processor must develop and implement an adequate HACCP plan to control the identified food safety hazards. 21 C.F.R. § 123.6(b). Among other things, a HACCP plan must:

a. Identify critical control points ("CCPs"), which are points, steps, or procedures in a food manufacturing process at which controls can be applied to prevent, eliminate, or reduce to an acceptable level a food safety hazard, 21 C.F.R. §§ 123.3(b), 123.6(c)(2); and

b. Identify critical limits at each CCP, which are the maximum or minimum values within which a physical, biological, or chemical parameter must be maintained to prevent, eliminate, or reduce to an acceptable level, the occurrence of the identified food safety hazard(s). 21 C.F.R. §§ 123.3(c), 123.6(c)(3).

19. Seafood processors must monitor their CCPs and critical limits for each type of fish or fishery product they manufacture to ensure they are controlling for known food safety hazards such as *L. mono* and *C. bot.* in their seafood.

20. Seafood processors must also:

a. Take corrective action whenever a deviation from a critical limit occurs, 21 C.F.R. § 123.7;

b. Verify that its HACCP plan is adequate to control food safety hazards reasonably likely to occur and that the plan is being effectively implemented, 21 C.F.R. § 123.8(a);

c. Record its sanitation activities, 21 C.F.R. § 123.11(c), and maintain additional appropriate records, such as documentation of CCPs, corrective actions taken, and HACCP plan verification activities, 21 C.F.R. §§ 123.6-123.9; and

d. Monitor, with sufficient frequency, sanitation controls and practices used during processing to ensure that they conform with the food current Good Manufacturing Practice ("cGMP") requirements, 21 C.F.R. § 123.11(b).

21. Defendants are subject to the seafood HACCP regulations because they engage in the "processing," as defined at 21 C.F.R. § 123.3(k)(1), of "fish" or "fishery product," as defined at 21 C.F.R. §§ 123.3(d) and (e).

22. It is a violation of the Act, 21 U.S.C. § 331(a), to cause 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).

23. It is a violation of the Act, 21 U.S.C. § 331(k), to cause articles of food to become 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 of their components in interstate commerce.

DEFENDANTS' VIOLATIONS

24. Defendants violate 21 U.S.C. § 331(a) by 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).

25. Defendants violate 21 U.S.C. § 331(k) by causing articles of food to become 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 of their components in interstate commerce.

26. Defendants' food 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 may have been rendered injurious to health. Such insanitary conditions include:

a. Defendants' failure to comply with the seafood HACCP regulations, 21 C.F.R. Part 123 by, among other deficiencies, failing to adequately control the risk of *L. mono* and *C. bot* toxin formation in their vacuum-packed fish or fishery products; and

b. Chronic presence of *L. mono* in the Michel Cordon Bleu facility, including in the processing area.

HISTORY OF VIOLATIONS

27. The U.S. Food and Drug Administration ("FDA") has conducted at least nine (9) inspections of Defendants' facility since 1998.

28. FDA most recently inspected Defendants' facility between July 5 and August 2, 2016. At the close of this inspection, FDA investigators issued Defendants a twelve-item List of Inspectional Observations ("Form FDA-483") listing observations that included, but were not limited to, the following:

a. Failure to manufacture, package, and store food under conditions and controls necessary to minimize the potential for microorganism growth and contamination, including *L. mono*;

b. Failure to monitor the sanitation conditions and practices, resulting in findings of *L. mono* in the company's processing areas;

c. Failure to develop the verification procedures and frequencies listed in the HAACP plan in accordance with federal regulation to ensure that the HACCP plan is adequate to control food safety hazards, and is being effectively implemented; and

d. Failure to implement the monitoring and verification procedures listed in the HACCP plan.

29. Defendants' deficient cleaning and sanitation practices have led to the contamination of surfaces near food preparation areas with pathogenic bacteria. FDA's analysis of environmental samples collected during the July-August 2016 inspection revealed the presence of *L. mono* contamination in multiple locations throughout the Michel Cordon Bleu facility. Strict in-plant measures are necessary to control *L. mono*'s proliferation in the Michel Cordon Bleu facility and to protect the public health.

30. Defendants responded to the FDA Form-483 on August 10, 2016, however their response failed to address the violations noted during the July-August 2016 Inspection. For example, Defendants did not respond to FDA's observation as to the *L. mono* findings, failed to identify and correct any conditions or procedures that led to the

contamination, and failed to implement a pathogen control plan with specific sanitation controls for *L. mono*.

31. FDA also inspected the facility between January 25 and February 16, 2016. At the close of the inspection, FDA investigators issued Defendants an eleven-item Form FDA-483, listing observations that included, but were not limited to the following:

a. Failure to manufacture, package, and store food under conditions and controls necessary to minimize the potential for microorganism growth and contamination, including *L. mono*;

b. Failure to monitor the sanitation conditions and practices with sufficient frequency to assure conformance with current good manufacturing practices;

c. Failure to implement the monitoring, recordkeeping and verification procedures listed in the HACCP plan; and

d. Failure to take corrective actions when critical limits were not reached.

32. FDA's analysis of environmental samples collected during the January-February 2016 inspection also revealed the presence of *L. mono* contamination in multiple locations throughout the Michel Cordon Bleu facility.

33. FDA received Defendants' response to the FDA Form-483 on February 29, 2016, however their response failed to address the violations noted during the January-February 2016 Inspection. For example, Defendants did not respond to FDA's observation as to the *L. mono* findings, failed to identify and correct any conditions or procedures that led to the contamination, and failed to implement a pathogen control plan with specific sanitation controls for *L. mono*.

34. Repeat deficiencies were observed at each of the 2016 inspections which included the Defendants': (1) failure to manufacture, package and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination; (2) failure to monitor sanitation conditions and practices with sufficient frequency to assure conformance with current good

manufacturing practices; and (3) failure to take corrective action that ensured affected product was not entered into commerce and the cause of the deviation was corrected.

35. During the 2016 inspections, FDA inspectors observed conditions that could lead to C. bot growth and toxin development or formation. For example, during the July-August inspection, FDA inspectors noted that the company's HACCP plan does not list a critical limit that ensures control of one or more hazards and lists a critical limit that does not ensure control of one or more hazards.

36. FDA conducted earlier inspections of the facility in August 2010, April 2006, September 2004, October 2002, March 2002, June 2001, December 1999, February 1999, and June 1998.

37. In addition to the inspections conducted during this period of time, FDA held a regulatory meeting with Defendants in April 2005.

38. At the meeting, Defendants committed to building a culture of compliance at their facility by promising to revise and adequately implement their seafood HACCP plans.

39. Despite these promises, Defendants have been unable to bring their operations into compliance, as demonstrated by the evidence collected by FDA during the most recent two inspections.

PRIOR WARNINGS

40. Defendants have a history of non-compliance. FDA has conducted at least nine (9) previous inspections of the facility since 1998, observing violations similar to those FDA investigators observed in 2016. Defendants received ample notice that their operations violate the law. At the close of each inspection, FDA investigators discussed their observations with Defendant Blanchet and issued Defendants Forms FDA 483 listing the observed objectionable conditions and practices at the facility. Moreover, as described above, FDA held a regulatory meeting with Defendants in April 2005. FDA also issued a Warning Letter in February 1999 and an Untitled Letter in June 1998.

41. Defendants have repeatedly promised to comply with the statutory and regulatory requirements. However, their deviations from the seafood HACCP regulations remain systemic and persistent. As a result, Defendants continue to fail to bring their operations into compliance with the law, and unless restrained by order of this court, Defendants are likely to continue to violate 21 U.S.C. §§ 331(a) and (k).

WHEREFORE, the United States respectfully requests this Court to:

I. Order that Defendants and each and all of their officers, agents, employees, representatives, 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) who have received actual notice of the Court's order by personal service or otherwise, cease receiving, preparing, processing, packing, labeling, holding, and distributing food at or from the facility or at any other location(s) at or from which Defendants, now or in the future, receive, prepare, process, pack, label, hold, and distribute food, unless and until Defendants bring their operations into compliance with the Act and applicable regulations, to FDA's satisfaction;

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), 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 (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who have received actual notice of the Court's order by personal service or otherwise, from directly or indirectly violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, adulterated articles of food into interstate commerce, within the meaning of 21 U.S.C. § 342(a)(4), violating 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4);

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receiving, preparing,

processing, packing, labeling, holding, and distribution of food to ensure continuing compliance with the terms of the injunction, the costs of such inspection to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award the Plaintiff its costs incurred in pursuing this action, including the costs of investigation to date, and such other relief as the Court deems just and proper.

Dated this 3rd day of October, 2017.

Respectfully submitted,

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