UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

Case No.

v.

Hon.

ABBOTT LABORATORIES, a corporation doing business as ABBOTT NUTRITION, and KEENAN S. GALE, TJ HATHAWAY, and LORI J. RANDALL, individuals,

Defendants.
_____/

**COMPLAINT FOR PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned counsel and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

1. This action for a statutory injunction is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin the defendants, Abbott Laboratories, a corporation doing business as Abbott Nutrition, and Keenan S. Gale, TJ Hathaway, and Lori J. Randall, individuals, (collectively, "Defendants") from violating:

(a) 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of food, namely infant formulas, as defined in 21 U.S.C. § 321(z), that are adulterated within the meaning of 21 U.S.C. § 350a(a)(3) in that they have been processed in a manner that does not comply with current good manufacturing practice requirements for infant formula set forth at 21 U.S.C. § 350a(b)(2) and 21 C.F.R. Part 106;

(b) 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered 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 or whereby they may have been rendered injurious to health;

(c) 21 U.S.C. § 331(k) by causing articles of food, namely infant formulas as defined in 21 U.S.C. § 321(z), that are held 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. § 350a(a)(3); and

(d) 21 U.S.C. § 331(k) by causing articles of food that are held 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. Defendants manufacture infant formulas, including infant formulas in powdered form ("powder infant formulas"), under conditions and practices that fail to protect the food against the risk of contamination from bacteria including, but not limited to, *Cronobacter sakazakii* ("*C. sak.*") and *Salmonella*.

3. *C. sak.* can live in dry foods, such as powder infant formula. In infants (children younger than 12 months), *C. sak.* can be deadly. *C. sak.* can cause sepsis (a serious blood infection) or meningitis (swelling of the linings surrounding the brain and spinal cord). Infants two months or younger are most at risk of developing meningitis if they become ill from *C. sak.* infection. Infants born prematurely are also more likely to become ill from *C. sak.* infection.

4. FDA testing of environmental samples collected on or about February 1 or 2, 2022, detected *C. sak.* in a Sturgis, Michigan facility where Defendants manufactured powder infant formula.

5. Furthermore, Defendants identified *Cronobacter* spp. in their manufacturing facility from their own environmental samples collected between February 6 and 20, 2022. "*Cronobacter* spp." refers to *Cronobacter* without a determination of the species, e.g., *C. sak*. The presence of *Cronobacter* spp. in the manufacturing environment indicates that conditions support bacterial growth and proliferation, including growth of pathogenic bacteria such as *C. sak.* If speciation is not conducted, the findings of *Cronobacter* spp. must be treated as if the bacteria are *C. sak.*, for adequate protection of public health.

6. On two previous occasions, Defendants detected *Cronobacter* spp. in their finished powder infant formulas. (The contamination was caught before the infant formulas were distributed to consumers.) Defendants processed/filled one batch of *Cronobacter* spp.-positive product on or about August 18-19, 2019, and processed/filled the other batch of *Cronobacter* spp.-positive product on or about June 12, 2020. The two finished product batches that tested positive for *Cronobacter* spp. had been processed on different equipment; for example, the products were dried on different spray dryers and filled on different filling lines. (Spray dryers process infant formula or other food from a liquid form to powder form; this process is known as "drying." Filling lines are used for putting infant formula or other food into containers and sealing the containers.) The presence of *Cronobacter* spp. on different processing equipment at different times indicates the possibility of multiple avenues for spreading bacterial contamination in the manufacturing environment.

7. Ongoing inadequacies in manufacturing conditions and practices at Defendants' facilities demonstrate that Defendants have been unwilling or unable to implement sustainable corrective actions to ensure the safety and quality of food manufactured for infants, a consumer group particularly vulnerable to foodborne pathogens. Defendants' violations of the Act and the likelihood that violations will recur in the absence of court action demonstrate that injunctive relief is necessary.

**Jurisdiction and Venue**

8. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

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

**Defendants and Their Operations**

10. Defendant Abbott Laboratories, doing business as Abbott Nutrition, is a corporation formed under the laws of the State of Illinois. Abbott Nutrition manufactures infant formulas at facilities located at 901 North Centerville Road, Sturgis, Michigan 49091 ("AN-Sturgis"), within the jurisdiction of this Court. AN-Sturgis has over 400 employees.

11. Defendant Keenan S. Gale holds the title of Director of Quality at AN-Sturgis and oversees all quality assurance including, but not limited to, sanitation, compliance, and corrective and preventive actions. Defendant Gale has the authority to detect, correct, and prevent violations of the Act and its implementing regulations. Defendant Gale performs his duties at AN-Sturgis, within the jurisdiction of this Court.

12. Defendant TJ Hathaway is the Site Director at AN-Sturgis. Defendant Hathaway has identified himself as the most responsible individual at the Sturgis Facility. Defendant

Hathaway is responsible for ensuring the safety and quality of products made at AN-Sturgis. Defendant Hathaway performs his duties at AN-Sturgis, within the jurisdiction of this Court.

13. Defendant Lori J. Randall is Abbott Nutrition's Division Vice-President of Quality Assurance. Defendant Randall has overall responsibility for quality operations for global Abbott Nutrition, which includes, but is not limited to, oversight of manufacturing locations and food safety, product quality, supplier quality, compliance, complaint management, and corrective and preventive actions. Defendant Randall was responsible for approving the decision made during FDA's most-recent inspection at AN-Sturgis to initiate a recall of certain infant formulas manufactured at AN-Sturgis. Defendant Randall performs her duties at Abbott Laboratories' corporate office located in Abbott Park, Illinois, where she conducts her oversight duties for Abbott Laboratories' manufacturing sites including, but not limited to, AN-Sturgis.

14. During their regular course of business, Defendants manufacture, process, pack, label, hold, and distribute articles of food, including infant formulas defined in 21 U.S.C. § 321(z), and food for older children. Defendants' infant formulas and other food are marketed under several brand names, including Similac (including Similac Alimentum) and EleCare.

15. Defendants distribute their infant formulas throughout the United States, including to Minnesota, Ohio, and Texas.

16. Defendants manufacture their infant formulas using ingredients that were shipped in interstate commerce, including ingredients from Illinois, Iowa, and Wisconsin.

## Legal Framework

*Infant Formula, Generally*

17. "Infant formula" means "a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk." 21 U.S.C. § 321(z).

18. Subject to an exemption described below, the Act deems infant formulas adulterated if they are not made in compliance with FDA's current good manufacturing practice ("CGMP") requirements for infant formulas established by regulation. *See* 21 U.S.C. §§ 350a(a)(3) and 350a(b)(2); 21 C.F.R. §§ 106.1(a) and 106.5(b).

19. FDA promulgated CGMP regulations for infant formulas at 21 C.F.R. Part 106, Subpart B ("Infant Formula CGMP Regulations"). These regulations are designed to ensure the safety of infant formula and prevent the manufacture of adulterated infant formula, and they require manufacturers to implement a system of controls to cover all stages of manufacturing. Infant Formula CGMP Regulations contain requirements for specific controls including, but not limited to, controls to prevent adulteration of infant formula from microorganisms. *See* Interim Final Rule, Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula. 79 Fed. Reg. 7934, 7935 (Feb. 10, 2014); *see also* Final Rule, Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula. 79 Fed. Reg. 33,057 (June 10, 2014).

20. In conjunction with Infant Formula CGMP Regulations, FDA also promulgated requirements for record-keeping, including a requirement that manufacturers have procedures for handling all written and oral complaints ("Infant Formula Record Requirements"). *See* 21 U.S.C. § 350a(b)(4); 21 C.F.R. § 106.100(k). Under Infant Formula Record Requirements, manufacturers must conduct an investigation when a complaint shows a possible health hazard.

The failure to comply with Infant Formula Record Requirements, including the requirement for complaint-handling procedures, renders infant formulas adulterated within the meaning of 21 U.S.C. § 350a(a)(3). *See* 21 C.F.R. §§ 106.1(c) and 106.100(r).

*Exempt Infant Formula*

21. The Act exempts certain infant formulas from several aspects of 21 U.S.C. § 350a—the specific provision of the Act governing the manufacture and adulteration of infant formula—including provisions relating to compliance with Infant Formula CGMP Regulations and Infant Formula Record Requirements. *See* 21 U.S.C. § 350a(h) (providing exemption from, among others, the requirements in 21 U.S.C. §§ 350a(a)(3), 350a(b)(2), and 350a(b)(4)). The exemption applies to infant formula "which is represented and labeled for use by an infant—(A) who has an inborn error of metabolism or a low birth weight, or (B) who otherwise has an unusual medical or dietary problem." 21 U.S.C. § 350a(h)(1). This type of product is known as an "exempt infant formula." FDA promulgated regulations that establish conditions with which a manufacturer must comply to obtain and retain this exemption. *See* 21 U.S.C. §§ 350a(h)(1) and 350a(h)(2); 21 C.F.R. § 107.50.

22. Inborn errors of metabolism are rare, inherited (genetic) disorders in which the body cannot properly turn food into energy. They are caused by defects in specific proteins (enzymes) that help break down (metabolize) certain nutrients in food. These disorders result in the buildup of toxic compounds in the brain and other important organ systems, and they can cause a wide range of medical problems. Several inborn errors of metabolism are life-threatening and known to cause severe and permanent brain damage and associated problems such as developmental delay, movement disorder, and/or coma. Infants with inborn errors of metabolism cannot tolerate certain nutrients (e.g., certain amino acids) found in infant formulas;

therefore, these infants need specialty infant formulas to meet their nutritional needs to support and promote growth while avoiding the offending nutrient(s). Other types of disorders requiring specialty infant formulas are severe allergies where infants cannot tolerate proteins that are not broken down and require alternate types of infant formulas, such as amino acid-based formulas.

23. This Complaint refers to the exempt infant formulas that Defendants manufacture at AN-Sturgis as "the Specialty Infant Formulas," and the non-exempt infant formulas that Defendants manufacture at AN-Sturgis as "the Standard Infant Formulas." The Specialty Infant Formulas are intended to address inborn errors of metabolism, such as maple syrup urine disease ("MSUD"), urea cycle disorders ("UCD"), and glutaric aciduria type 1 ("GA-1"), and other conditions, such as severe food allergies.

24. Microbiological contamination of any infant formula, including the Specialty Infant Formulas and the Standard Infant Formulas, can have devastating and potentially deadly effects on vulnerable infants.

*Food, Generally*

25. Under the Act, all infant formulas are "food" (see definition of "infant formula" above) and, therefore, are subject to the Act's requirements applicable to food.

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

27. Food manufacturers must adhere to FDA's current good manufacturing practice regulations ("CGMP Regulations for Human Food"), codified at 21 C.F.R. Part 117, Subpart B, which establish basic practices that must be followed and conditions that must be maintained during food manufacturing operations. *See* 21 C.F.R. §§ 117.10 through 117.110.

28. CGMP Regulations for Human Food require, among other things, that manufacturing conditions and practices protect against contamination of food and food-contact surfaces from any source. *See generally* 21 C.F.R. Part 117, Subpart B.

29. The failure to comply with CGMP Regulations for Human Food renders food adulterated within the meaning of 21 U.S.C. § 342(a)(4). *See* 21 C.F.R. § 117.1(a)(1)(ii).

30. The Specialty Infant Formulas, the Standard Infant Formulas, and the other food that Defendants manufacture at AN-Sturgis are required to be made in compliance with CGMP Regulations for Human Food. The Standard Infant Formulas are also required to be made in compliance with Infant Formula CGMP Regulations.

*Violations of the Act*

31. The Act, 21 U.S.C. § 331(a), prohibits introducing into interstate commerce:

(a) Articles of food, namely infant formulas as defined in 21 U.S.C. § 321(z), that are adulterated within the meaning of 21 U.S.C. § 350a(a)(3) in that they have been processed in a manner that does not comply with current good manufacturing practice requirements for infant formula set forth at 21 U.S.C. § 350a(b)(2) and 21 C.F.R. Part 106; and

(b) 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 whereby they may have been rendered injurious to health.

32. The Act, 21 U.S.C. § 331(k), prohibits causing:

(a) Articles of food, namely infant formulas as defined in 21 U.S.C. § 321(z), that are held 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. § 350a(a)(3); and

(b) Articles of food that are held 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).

33. The evidence gathered during FDA's recent inspection at AN-Sturgis (described below) demonstrates that Defendants adulterate food within the meaning of 21 U.S.C. §§ 342(a)(4) and 350a(a)(3).

34. The evidence also demonstrates that Defendants manufacture their products from ingredients shipped to them in interstate commerce and distribute their adulterated food in interstate commerce.

35. Therefore, Defendants violate the Act by: (a) introducing into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. §§ 342(a)(4) and 350a(a)(3); and (b) causing articles of food that are held 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) and/or 350a(a)(3). *See* 21 U.S.C. §§ 331(a) and 331(k), respectively.

**FDA's 2022 Inspection at AN-Sturgis**

36. FDA conducted its most recent inspection at AN-Sturgis between January 31 and March 18, 2022 ("2022 Inspection"). During the 2022 Inspection, FDA investigators documented conditions and practices that fail to control microbiological growth within the food-processing areas at AN-Sturgis.

37. FDA's inspectional findings from the 2022 Inspection establish that Defendants lack adequate measures to ensure the safety and quality of the Specialty Infant Formulas, the Standard Infant Formulas, and the powdered food for older children that Defendants manufacture

at AN-Sturgis. Among other things, Defendants use shared equipment for manufacturing their products. As a result, these products are at risk of contamination from bacteria, such as *C. sak.*

38. FDA investigators collected samples from surfaces in AN-Sturgis's production areas for powder infant formula. FDA laboratory analysis of those samples detected *C. sak.* on several surfaces, including:

(a) The cover of a scoop hopper, which is used to feed scoops that are placed directly inside infant formula containers and come in contact with product. At the time the sample from the scoop hopper cover had been collected, a batch of infant formula was being packaged; and

(b) A structural support and the immediately surrounding floor of a spray dryer, and two areas in the dehumidification room on the fourth level of that spray-dryer tower, i.e., the floor between a duct-taped spot and the wall, and the floor and seam of the first door. At the time the samples on or near the spray dryer had been collected, the spray dryer was in a cleaning cycle, which introduces water into this dry-production environment and the equipment interiors.

39. Additionally, Defendants' own environmental samples between September 25, 2019, and February 20, 2022, confirmed the presence of *Cronobacter* spp. on surfaces in AN-Sturgis's production areas for powder infant formula.

40. The 2022 Inspection also documented Abbott's failure to control water in areas of AN-Sturgis's facilities that are intended to be used for processing powder infant formulas. The uncontrolled wet environment in processing areas, in conjunction with the presence of *C. sak.* and deteriorating equipment that enables harborage of *C. sak.* (i.e., cracks in food-contact

surfaces of equipment, as described below), create an unacceptable risk of bacterial contamination of Defendants' products.

41. On January 31, 2022, FDA investigators observed water on several levels of a spray-dryer tower, while the spray dryer was being used to process a batch of powder infant formula, as follows:

(a) On the tower's fifth level, the investigators observed water on the floor from a steam-condensate leak in the inlet steam coils; the water was dripping from the valves onto the floor of the tower's fourth level. FDA investigators noted that, according to Defendants' records, AN-Sturgis had prior water leaks (on January 21, 2022, November 4, 2021, and February 1, 2021) associated with inlet steam coils;

(b) On the tower's second level, the investigators observed water around the floor drain near the potassium hydroxide tanks, which are used for pH adjustment in the production of powder infant formula, and at the floor-wall junction near the floor scrubber used to clean the floors of the spray-dryer tower; and

(c) On the tower's basement level, the investigators observed water on the floor by an eye-wash station, which is adjacent to the air-handling system of a vibratory fluid bed used to further cool the powder infant formula as it comes out of the main chamber of the spray dryer.

42. FDA investigators observed that Defendants' records documented a total of 310 water events, e.g., water leaks and condensation, at AN-Sturgis between January 1, 2020, and February 1, 2022. Those water events occurred in dry-production areas for powder infant formulas, e.g., during spray-drying the infant formula and/or filling the infant formula into containers. Defendants' records describe several water leaks as necessitating repairs of the AN-

Sturgis roof. When *C. sak.* is present in a manufacturing environment, it can be further spread to other processing areas, particularly where water is poorly controlled.

43. FDA investigators observed that Defendants had not validated the "dry-out" step for their spray dryers to ensure that complete drying is achieved after water is introduced into the spray-dryer environment during cleaning.

44. FDA investigators observed that Defendants' records documented a history of internal deterioration of the spray dryers at AN-Sturgis, dating back to September 2018. Defendants' last spray-dryer inspection, which occurred in August 2021, showed damage including, but not limited to, cracks and pits inside the dryers' main chambers. This type of damage creates the potential for niches and harborage sites for bacterial contamination to persist, particularly in the presence of moisture.

45. Additionally, FDA investigators observed that AN-Sturgis personnel (employees or contractors) working in infant formula processing areas did not wear necessary protective apparel to protect against contamination of infant formula. For example:

(a) On January 31, 2022, FDA investigators observed an employee exit the elevator in a spray-dryer tower and enter the room containing the vibratory fluid bed—and pass the shoe sanitizing station without spraying the soles of his/her shoes with sanitizer. When this inspectional observation was made, the nozzle of the sanitizer bottle was improperly set to stream instead of spray, which does not allow a uniform coating of sanitizer on the shoe soles. At the time the employee failed to sanitize his/her shoes, the spray dyer was processing a batch of powder infant formula; and

(b) Between January 31 and February 12, 2022, FDA investigators observed that AN-Sturgis employees and contractors were not required to spray their "captive shoes" (i.e.,

shoes that are to be worn only inside the facilities) with sanitizer before entering the production area. Part of that time (specifically, between January 31 and February 4, 2022, and February 8, 2022), FDA investigators observed that AN-Sturgis employees had been wearing their captive shoes while walking in hallways and the cafeteria and exiting the restroom.

46. Further, the investigators found that Defendants failed to follow their own procedures to determine the root cause of consumer complaints associated with their products. Specifically, FDA investigators reviewed Defendants' complaint investigations for consumer complaints received by FDA, identified as FDA Consumer Complaint Nos. 171222, 170177, 171771, 171087, that are associated with (but not definitively caused by) powder infant formulas manufactured at AN-Sturgis, including reported *C. sak.* illnesses and a reported illness from *Salmonella newport*. The FDA investigators found that Defendants closed their complaint investigations without having identified a root cause for the reported illnesses associated with bacterial infection.

47. FDA investigators observed that, although Defendants' standard operating procedure ("Complaint Management and Investigations" v. 26, s. 5.2.2.8 on page 26) states that retained samples are to be evaluated for microbial analysis when "there is a potential for the distributed product not to comply with specifications," Defendants closed their complaint investigations without having evaluated any retained samples of the Consumer Complaint-related powder infant formulas for microbiological contamination.

48. At the close of the 2022 Inspection, FDA investigators issued a Form FDA-483, List of Inspectional Observations ("FDA-483"), to Defendant TJ Hathaway and discussed the FDA-483 observations with him.

**Adulteration Based on Violations of CGMP Regulations for Human Food**

49. The evidence gathered during the 2022 Inspection establishes that Defendants violate CGMP Regulations for Human Food. Among other requirements, Defendants do not comply with the CGMP Regulations for Human Food set forth at 21 C.F.R. §§ 117.80(a)(1), 117.35(d), and 117.10(b), as described below.

50. Defendants fail to conduct food manufacturing operations in accordance with adequate sanitation principles, as required by 21 C.F.R. § 117.80(a)(1). Examples of this failure are discussed in paragraph 41 (the presence of dripping water in Defendants' spray-dryer tower) and paragraph 42 (water leaks and condensation in various powder infant formula production areas).

51. The presence of *C. sak.* on the cover of a scoop hopper during packaging of a batch of infant formula, as discussed in paragraph 38(a), adds to the risk of contamination posed by uncontrolled water dripping, leaking, and condensing in production areas.

52. Defendants fail to (a) ensure that food-contact surfaces of equipment that are wet-cleaned are thoroughly dried before subsequent use, and (b) maintain food-contact surfaces, including utensils and food-contact surfaces of equipment, used for manufacturing low-moisture food (which includes powder infant formula) in a clean, dry, and sanitary condition before use, as required by 21 C.F.R. § 117.35(d)(1). Examples of these failures are discussed in paragraph 43 (failure to validate the "dry-out" step for spray dryers, which means there is no assurance that complete drying is achieved after water is introduced during cleaning) and paragraph 44 (damage, such as cracks and pits, inside the spray dryers' main chambers).

53. Defendants fail to ensure that personnel working in direct contact with food, food-contact surfaces, and food-packaging materials conform to hygienic practices including wearing

suitable outer garments to protect against contamination of food, food-contact surfaces, and food-packaging materials, as required by 21 C.F.R. § 117.10(b)(1). Examples of this failure are discussed in paragraph 45 (failure to sanitize footwear before entering production areas).

54. Defendants' violations of CGMP Regulations for Human Food render Defendants' products (including the Specialty Infant Formulas, the Standard Infant Formulas, and the other food manufactured at AN-Sturgis) 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 or been rendered injurious to health. *See* 21 C.F.R. § 117.1(a)(1)(ii).

**Adulteration Based on Violations of Infant Formula CGMP Regulations**

55. The evidence gathered during the 2022 Inspection also establishes that Defendants violate the Infant Formula CGMP Regulations and the Infant Formula Records Requirements. Among other requirements, Defendants do not comply with the Infant Formula CGMP Regulations set forth at 21 C.F.R. §§ 106.20(a), 106.55(a), 106.30(b), 106.10(b)(1), and 106.100(k)(2), as described below.

56. Defendants fail to maintain buildings used in the manufacture of infant formula in a clean and sanitary condition, as required by 21 C.F.R. § 106.20(a). Examples of this failure are described in paragraph 41 (the presence of dripping water in Defendants' spray-dryer tower) and paragraph 42 (water leaks and condensation in various powder infant formula production areas).

57. Defendants fail to have an adequate system of process controls covering all stages of processing that is designed to ensure that infant formula does not become adulterated within the meaning of the Act (21 U.S.C. §§ 342(a)(4) and 350a(a)(3), among others) as a result of the presence of microorganisms in the formula or in the processing environment, as required by 21

C.F.R. § 106.55(a). Examples of this failure are described in paragraph 38 (*C. sak.* detected in the processing environment) and paragraph 39 (*Cronobacter* spp. detected in the processing environment).

58. Defendants fail to ensure that all surfaces of equipment and utensils that contact raw ingredients, in-process materials, or infant formula are cleaned, sanitized, and maintained in a manner that protects infant formula from being contaminated by any source, as required by 21 C.F.R. § 106.30(b). Examples of this failure are described in paragraph 43 (failure to validate the "dry-out" step for spray dryers, which means there is no assurance that complete drying is achieved after water is introduced during cleaning) and paragraph 44 (damage, such as cracks and pits, inside the spray dryers' main chambers).

59. Defendants fail to ensure that personnel working directly with infant formula, infant formula raw ingredients, infant formula packaging, or infant formula equipment or utensil contact surfaces, conform to hygienic practices, including wearing suitable outer garments, to protect infant formula against contamination, as required by 21 C.F.R. § 106.10(b)(1). Examples of this failure are discussed in paragraph 45 (failure to sanitize footwear before entering production areas).

60. Defendants fail to conduct an adequate investigation into the validity of a complaint that shows that a health hazard possibly exists. Specifically, Defendants' complaint investigations do not document a determination whether a health hazard exists (and the basis for such determination), as required by 21 C.F.R. § 106.100(k)(2). Examples of this failure are described in paragraph 46 (failure to identify a root cause for illnesses associated with (but not definitively caused by) powder infant formulas manufactured at AN-Sturgis) and paragraph 47 (failure to test any retained samples for microbiological contamination of an infant formula).

61. Defendants' violations of Infant Formula CGMP Regulations cause the Standard Infant Formulas to be adulterated within the meaning of 21 U.S.C. § 350a(a)(3) in that they have been processed in a manner that does not comply with current good manufacturing practice requirements for infant formula set forth at 21 U.S.C. § 350a(b)(2) and 21 C.F.R. Part 106.

**Prior Warning**

62. The 2022 Inspection was not the first time FDA warned Defendants of their failure to comply with FDA requirements to control microbiological growth. FDA previously conducted an inspection at AN-Sturgis between September 20-24, 2021 ("2021 Inspection"). During the 2021 Inspection, FDA investigators documented several conditions and practices that fail to control microbiological growth within the food-processing areas at AN-Sturgis including, but not limited to, some of the same or similar observations made during the 2022 Inspection. The inspectional observations from the 2021 Inspection that are repeated in the 2022 Inspection include:

a) Defendants' failure to maintain buildings used in the manufacture of infant formula in a clean and sanitary condition, as required by 21 C.F.R. § 106.20(a). Specifically, an FDA investigator observed standing water in several locations in a building that houses a spray dryer, including under and adjacent to the air handling unit of a vibratory fluid bed, outside an air-lock door associated with the Dry Blending Room, and in an area used for cleaning; and

(b) Defendants' failure to ensure that personnel working directly with infant formula, infant formula raw ingredients, infant formula packaging, or infant formula equipment or utensil contact surfaces, conform to hygienic practices to protect infant formula against contamination, as required by 21 C.F.R. § 106.10(b). Specifically, an FDA investigator observed a processing operator touch non-food-contact surfaces and immediately afterwards touch food-

contact surfaces, such as the inside of an ingredient bag and a plastic bag used to store the weighed ingredient, without sanitizing or changing his gloves. In addition, the FDA investigator observed that the processing operator's exposed wrists, between his glove and smock cuff, entered the inside of the ingredient bag when scooping ingredients.

63. At the close of the 2021 Inspection, FDA investigators issued an FDA-483 to Defendant TJ Hathaway and discussed the inspectional observations with him.

64. Although Defendants promised corrective actions, they did not implement sustained corrections to achieve ongoing compliance with the Act and its implementing regulations.

**Request for Relief**

65. Despite the seriousness of having detected *Cronobacter* spp. in their products and processing areas, Defendants have not taken adequate steps to come into compliance, as evidenced by the observations made by FDA investigators during the 2022 Inspection.

66. Accordingly, the United States believes that, unless restrained by the Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and 331(k) in the manner alleged herein.

WHEREFORE, the United States respectfully requests that this Court:

I. Order that Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, cease manufacturing, processing, preparing, packing, labeling, holding, and/or distributing any article of food unless and until Defendants bring their manufacturing, processing, preparing, packing, labeling, holding, and distribution operations into compliance with the Act and its implementing regulations to the satisfaction of FDA;

II. Order that Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce any article of food that is adulterated within the meaning of 21 U.S.C. §§ 342(a)(4) and/or 350a(a)(3); and

B. Violating 21 U.S.C. § 331(k) by causing any article of food that is held for sale after shipment of one or more of its components in interstate commerce to become adulterated within the meaning of 21 U.S.C. §§ 342(a)(4) and/or 350a(a)(3);

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, processing, preparing, packing, labeling, holding, and distribution of any article of food to ensure continuing compliance with the terms of the injunction, and that Defendants bear the costs of such inspections, including testing and sampling, at the rates prevailing at the time the inspections are accomplished;

IV. Award the United States costs incurred in pursuing this action, including the costs of investigation to date; and

V. Order such other and further relief as this Court deems just and proper.

Dated: May 16, 2022.

Respectfully submitted,

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