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

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