

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

Gabrielle Arispe, individually and on)	
behalf of her minor child, N.J.,)	
)	Civil Action No. 1:23-cv-01453
Plaintiffs,)	
)	
v.)	JURY TRIAL DEMANDED
)	
Abbott Laboratories Inc. D/B/A Abbott)	
Nutrition,)	
)	
Defendant.)	

COMPLAINT

Plaintiff Gabrielle Arispe (“Plaintiff”), individually and on behalf of her minor child, N.J., files this Complaint against Defendant Abbott Laboratories, Inc. D/B/A Abbott Nutrition. (“Abbott” or “Defendant”), and in support state the following:

NATURE OF THE ACTION

1. Plaintiff, Gabrielle Arispe, is the mother of N.J., a minor.
2. Defendant Abbott Laboratories, Inc., manufactures, labels, markets, distributes, and sells infant formulas under the Similac, Alimentum, and EleCare brands that have been recalled due to bacterial contamination.
3. On February 17, 2022, the U.S. Food and Drug Administration (“FDA”), along with the Center for Disease Control (“CDC”), announced that it was investigating Defendant Abbott’s Similac, Alimentum, and EleCare infant formula products manufactured at Defendant Abbott’s facility in Sturgis, Michigan (“Sturgis Facility”), following several consumer complaints of Cronobacter sakazakii and Salmonella Newport contamination. The FDA’s advisory notice told

consumers to avoid purchasing or using Defendant Abbott's Similac, Alimentum, and EleCare, and Defendant Abbott subsequently initiated a voluntary recall of those products.

4. Plaintiff, N.J., consumed Defendant's Recalled Product and suffered bloody diarrhea, fever, fussiness, abdominal discomfort, vomiting, lethargy, weight loss, UTI, rash, and sepsis and was diagnosed with Salmonella, enterica serotype Gaminara as a result of the contamination of Defendant's product.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action because Abbott is an Illinois business with its principal place of business in Illinois.

6. Abbott regularly and systematically conducts business and sells its products in this District to customers in this District. As such, Abbott is subject to jurisdiction of this Court.

7. Venue is likewise proper in this district pursuant to 28 U.S.C. § 1391 because Abbott is subject to personal jurisdiction in this District and regularly conducts business in this District.

THE PARTIES

8. Plaintiff is a citizen and resident of Tangipahoa Parish, Louisiana, and at all times relevant hereto, has been a resident of Tangipahoa Parish. In or around September 2021, Plaintiff's infant child, N.J., began using Defendant's product: Similac Total Comfort/Total Care. Based on the false and misleading claims by Defendant, Plaintiff was unaware that Defendant's Similac Total Comfort/Total Care products may be adulterated with Salmonella, Cronobacter sakazakii, and other contaminants. Plaintiff used the Defendant's products on the assumption that the labeling of Defendant's products were accurate and that the products were unadulterated, safe and

effective. Plaintiff would not have used Defendant's Similac Total Comfort/Total Care products had she known there was a risk the products may contain Salmonella, Cronobacter sakazakii, and other contaminants.

9. Defendant ABBOTT LABORATORIES, INC. D/B/A ABBOTT NUTRITION, is a Delaware Corporation with its principal place of business in 100 Abbott Park Road, Abbott Park, Illinois. Defendant manufactures, markets, advertises, labels, distributes and sells the Recalled Product at issue in this litigation.

10. Defendant is engaged in the business of manufacturing and selling medical devices and products, including powdered infant formulas through its Abbott Nutrition Division.

INTRODUCTION

11. The following infant formulas are manufactured, marketed, and sold by Defendant Abbott Laboratories:

- Similac. Similac is a brand of powdered infant formula produced by Abbott which Abbott promises will “give babies a strong start by helping to keep them fed, happy, and healthy.” *See* Why Similac, <https://www.similac.com/why-similac.html> (last visited February 18, 2022). According to Abbott, Similac “is the #1 Pediatrician Recommended Brand for Immune Support.” *Id.*
- Alimentum. Alimentum is a brand of powdered infant formula produced by Abbott for infants with lactose sensitivity which Abbott claims is “the #1 infant formula brand fed for cow’s milk protein allergy in the US.” *See* Alimentum Product Description, <https://www.similac.com/products/baby-formula/alimentum-powder/19-8oz-can-4pack.html> (last visited February 18, 2022).

- EleCare. EleCare is a brand of powdered infant formula produced by Abbott for infants who cannot tolerate intact or hydrolyzed protein due to conditions such as severe food allergies or short bowel syndrome. *See* EleCare Product Information, <https://elecare.com/> (last visited February 18, 2022).

12. Abbott distributes these powdered infant formula products both nationwide and internationally.

13. As mentioned above, on February 17, 2022, the FDA, in conjunction with the CDC, announced a warning to consumers to not purchase or use Recalled Product, stating: “Do not use recalled Similac, Alimentum and EleCare powdered infant formulas produced in Sturgis, Michigan.”¹

14. As part of the warning, the FDA Deputy Commissioner for Food Policy and Response stated, “As this is a product used as the sole source of nutrition for many of our nation’s newborns and infants, the FDA is deeply concerned about these reports of bacterial infections. We want to reassure the public that we’re working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible.”²

15. Specifically, the FDA announced that it is investigating consumer complaints of *Cronobacter sakazakii* and *Salmonella* Newport infections connected to powdered infant formula products produced by Abbott.

¹ <https://www.fda.gov/consumers/powdered-infant-formula-recall-what-know> (last visited March 16, 2022).

² <https://thehill.com/policy/healthcare/public-global-health/594856-three-kinds-of-baby-formula-recalled-by-abbott/> (last visited April 28, 2022).

16. The FDA has so far linked two infant deaths and multiple illnesses to *Cronobacter sakazakii* contamination of its Similac, Alimentum, and EleCare powdered infant formulas produced in the Sturgis, Michigan plant.

17. The initial recall notice included Similac, Alimentum, and EleCare powdered infant formula with the following characteristics:

- the first two digits of the code are 22 through 37; and
- the code on the container contains K8, SH or Z2; and
- the expiration date is 4-1-2022 (APR 2022) or later.

18. On February 17, 2022, Abbott announced a recall of its powdered infant formulas. However, the recall does not include a refund, reimbursement, or replacement for consumers who purchased or used Recalled Products.³

19. On February 28, 2022, the recall was expanded to include one lot of Similac PM 60/40 (Lot # 27032K80 (can) / Lot # 27032K800 (case)), which was also manufactured in Abbott's Sturgis, Michigan facility.

20. These products may contain *Cronobacter sakazakii* bacteria and *Salmonella*.

21. Per the CDC website, *Cronobacter sakazakii* is a germ that can live in very dry places. The germs can live in dry foods, such as powdered infant formula.

22. *Cronobacter* bacteria can get into formula powder if contaminated raw materials are used to make the formula or if the formula powder touches a contaminated surface in the manufacturing environment.

³ Recall Notice, <https://www.similacrecall.com/us/en/home.html> (last visited March 16, 2022).

23. Cronobacter bacteria can cause severe, life-threatening infections, meningitis, and symptoms include: poor feeding, irritability, temperature changes, jaundice, grunting, and abnormal body movements. As set forth by the Centers for Disease Control and Prevention:

Infants (<12 months old): In infants, Cronobacter usually causes sepsis or severe meningitis. Some infants may experience seizures. Those with meningitis may develop brain abscesses or infarcts, hydrocephalus, or other serious complications that can cause long-term neurological problems. The mortality rate for Cronobacter meningitis may be as high as 40%.⁴

Other sources have described the mortality rate reaching as high as 80%.⁵

24. Specifically, the FDA announced that it is investigating consumer complaints of Cronobacter sakazakii and Salmonella Newport infections connected to powdered infant formula products produced by Abbott.

25. While initially the FDA reported that two children had died and two others were sickened after consuming formula from the Sturgis plant that contained Cronobacter sakazakii, Agency documents received via public records requests indicate the Agency had investigated seven additional deaths of children following their ingestion of Abbott formula produced at the Sturgis plant since 2021.⁶ The FDA investigated 128 consumer complaints collected by the FDA between December 2021 and March 2022, including 25 described as “life-threatening

⁴ CDC.gov, <https://www.cdc.gov/cronobacter/technical.html> (last accessed on March 25, 2022).

⁵ Norberg S, Stanton C, Ross RP, Hill C, Fitzgerald GF, Cotter PD. Cronobacter spp. in powdered infant formula. J Food Prot. 2012 Mar;75(3):607-20. doi: 10.4315/0362-028X.JFP-11-285. PMID: 22410240.

⁶ Phyllis Entis, “Nine baby deaths reported to FDA during Abbott Nutrition investigation,” efoodalert.com (June 8, 2022), <https://efoodalert.com/2022/06/08/nine-baby-deaths-reported-to-fda-during-abbott-nutrition-investigation>. See also the FDA spreadsheet of Abbott Complaints received by the article’s author pursuant to a Freedom of Information Act Request. *Id.* (available at <https://efoodalert.files.wordpress.com/2022/06/abbott-complaints-spreadsheet-redacted.pdf>) (last accessed on June 21, 2022).

illness/injury.”⁷ These additional complaints include reports of multiple forms of infection, inclusive of *Cronobacter sakazakii*, *Proteus mirabilis*, COVID-19, *Salmonella*, CDIFF (*Clostridioides difficile*), *Shigella*, astrovirus, and “shigelloides.” Two of the deaths reported mentioned *Salmonella*.

26. The FDA then conducted several inspections, which uncovered numerous egregious violations of statutes and regulations set forth herein in Defendant’s manufacturing, processing, packing, and holding of Similac, Alimentum and EleCare powdered infant formulas.

27. As documented in the FDA Form 483 issued on September 24, 2019, Defendant failed to test a representative sample of an infant formula production aggregate of powdered infant formula at the final product stage and before distribution to ensure that the production aggregate met the required microbiological quality standards.

28. Subsequent inspections establish a pattern of Defendant’s disregard of reasonable, responsible industry practices, as well as applicable statutes and regulations, with respect to manufacture, processing, packing, and holding of Similac, Alimentum and EleCare powdered infant formulas. As documented in the FDA Form 483 issued on September 24, 2021:

- a. Defendant failed to maintain a building used in the manufacture, processing, packing, or holding of infant formula in a clean and sanitary condition; and
- b. Defendant’s personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wash hands thoroughly in a hand washing facility at a suitable temperature after the hands may have become soiled or contaminated.

⁷ *Id.*

29. As documented in the FDA Form 483 issued on March 18, 2022:

- a. Defendant failed to set in place and/or maintain a system of process controls that cover all stages of infant formula processing to ensure the product does not become adulterated due to the presence of microorganisms (such as *Cronobacter sakazakii*) in the formula or in the processing environment;
- b. Defendant further failed to ensure that all surfaces that came in contact with infant formula were properly maintained to protect infant formula from being contaminated with microorganisms, such as *Cronobacter sakazakii*;
- c. Defendant failed to document any determination as to whether a hazard to health exists due to contamination with microorganisms such as *Cronobacter sakazakii*;
- d. Defendant's personnel that worked directly with infant formula, its raw materials, packaging, equipment, or utensil contact surfaces failed to wear necessary protective apparel.

30. Additionally, Abbott's own records indicate that, in June 2020, it destroyed products because of a previous *Cronobacter sakazakii* contamination.

31. This establishes that Abbott, at various times:

- a. Had knowledge that its powdered infant formula manufactured, processed, and packaged at its Sturgis, Michigan plant had been contaminated with microorganisms, (such as *Cronobacter sakazakii*);
- b. Failed to adequately test for *Cronobacter sakazakii* and other contaminants in its powdered infant formula;

- c. Failed to ensure numerous controls were in place to prevent contamination of its powdered infant formula manufactured, processed, and packaged at its Sturgis, Michigan plant.

32. The results of these investigations demonstrate a pattern of Defendant not only failing to take adequate, reasonable measures to protect the health and lives of infants consuming its powdered infant formula products, but also failing to take even common sense measures, such as adequately washing hands, upon learning of the risk of contamination of its products with microorganisms.

33. Defendant demonstrates an unwillingness or incapability to learn from its own misconduct, and from the historical misconduct of others engaged in the manufacture, processing, packing, and holding of infant formula that resulted in widespread, serious and often fatal harm to the same vulnerable population, such as the “swill milk” scandal during the 1850s in New York City. Thousands of infants were reported to have died from bacterial infection after ingesting contaminated milk sold to their poor and middle class parents by unscrupulous distillers who fed the grain distillation byproduct to dairy cattle kept in fetid conditions.

34. More recently, in September 2008, the deaths of infants and sickness of over 300,000 babies were traced to contamination of infant formula with melamine believed to have been used as a protein additive.

35. Further, a whistleblower report dated October 19, 2021, noted that violations taking place at the Sturgis Facility were “neither inadvertent nor minor in nature.” Attached as Exhibit A to this Complaint. Further findings from that report include:

- a. “On multiple occasions, and in various ways, records have been knowingly

falsified... This included testing seals on empty cans...”

- b. “The Sturgis site performed a time code removal after the discovery of microorganisms (“micros”) in a batch of infant formula. The remaining portion of the batch outside the time code removal was released without additional testing. On another occasion product was not re-called from the market even after management became aware of a nonconformity (“NC”).”
- c. “Aside from the mandate of FDA regulations, Abbott’s inaction is directly at odds with the mandate of Sarbanes-Oxley mandating adequate internal controls and the Department of Justice’s policy mandating effective compliance programs.”

36. The whistleblower report sets forth Abbott’s failures with regard to maintaining sanitary conditions, testing outgoing product, as well as falsifying records and concealing information from regulators.⁸ The whistleblower’s account corroborates many of the deficient food safety practices described in the FDA’s 2019, 2021, and 2022 Form 483 reports as set forth herein.

37. Abbott was alerted to the whistleblower’s complaint about its Sturgis-based factory as far back as February 2021. Despite this, Abbott delayed recalling its formula for another year.

38. Defendant’s conduct therefore represents a repeated, conscious disregard for the safety and lives of among the most vulnerable individuals—infants—that rises to the level of

⁸ The whistleblower report was posted on Marler Blog. *See* Bill Marler, “Mr. Abbott, you are going to jail for manufacturing tainted infant formula,” Marler Blog (April 28, 2022) available at <https://www.marlerblog.com/lawyer-oped/mr-abbott-you-are-going-to-jail-for-manufacturing-tainted-infant-formula/> (last accessed on May 16, 2022) (hereafter referred to as “Whistleblower Report”).

recklessness, wantonness, and malice.

39. On May 16, 2022, the U.S. Department of Justice (“DOJ”) announced its filing of a Complaint and proposed consent decree applicable to Abbott’s Sturgis plant.⁹ As the DOJ explains in the Complaint:

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.¹⁰

40. The DOJ’s proposed consent decree sets forth numerous violations of statutes and regulations by Abbott in relation to its management of the Sturgis plant, such as:

The Complaint alleges that Defendants violate 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).¹¹

41. In or around September 2021, Plaintiff was provided Similac Total Comfort/Total Care at the hospital and, thereafter, began purchasing Similac Total Comfort/Total Care for her infant child from various retailers.

42. Plaintiff’s infant child consumed tainted infant formula product produced by Defendant.

⁹ DOJ, “Justice Department Files Complaint and Proposed Consent Decree to Ensure Safety of Abbott Laboratories’ Infant Formula” (May 16, 2022) available at <https://www.justice.gov/opa/pr/justice-department-files-complaint-and-proposed-consent-decree-ensure-safety-abbott> (last accessed on May 16, 2022).

¹⁰ Complaint for Permanent Injunction at 4, ECF 1, 1:22-cv-00441 (W.D. Mich. May 16, 2022), available at <https://www.justice.gov/opa/press-release/file/1506081/download> (last accessed on May 16, 2022).

¹¹ Proposed Consent Decree at 1-2, ECF 2-1, 1:22-cv-00441 (W.D. Mich. May 16, 2022), available at [file:///serverdata/UserProfiles\\$/sgeisler/Desktop/abbott_proposed_consent_decree_0.pdf](file:///serverdata/UserProfiles$/sgeisler/Desktop/abbott_proposed_consent_decree_0.pdf) (last accessed on May 16, 2022).

43. After ingesting the Similac product, Plaintiff's infant child suffered severe injuries as a result of consuming the tainted formula, which required medical intervention in November 2021.

44. Plaintiff's infant child began suffering from bacterial infection (including Salmonella), bloody diarrhea, fever, fussiness, abdominal discomfort, vomiting, lethargy, weight loss, UTI, rash, and sepsis.

45. Plaintiff's infant child was treated at St. Tammary Parish Hospital, Lallie Kemp Regional Medical Center and Our Lady of the Lake Children's Hospital and was diagnosed with Salmonella and sepsis.

46. As a result of consuming Defendant's Similac Product, Plaintiff's infant child was in the hospital for approximately 10 days.

47. Plaintiffs have incurred substantial medical bills as a result of many doctor visits and extended hospital stays.

48. As a direct and proximate result of ingesting the contaminated formula, Plaintiff N.J. has suffered injuries in the past and will continue in the future.

First Cause of Action: Negligent Misrepresentation/Omission

49. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

50. Through its labeling and advertising, Defendant made representations to Plaintiff concerning the safety of their Similac, Alimentum, and EleCare Products.

51. Defendant has a duty to provide accurate information to consumers with respect to their Similac, Alimentum, and EleCare Products as detailed above.

52. Additionally, Defendant has a duty to not make false representations with respect to the safety of their Products.

53. Defendant failed to fulfill its duty when it made false representations regarding the quality and safety of the Products as detailed above.

54. Such failures to disclose on the part of Defendant amount to negligent omission and the representations regarding the quality and safety of the product amount to negligent misrepresentation.

55. Plaintiff reasonably relied upon such representations and omissions to her detriment.

56. By reason thereof, Plaintiff N.J. has suffered damages in an amount to be proven at trial.

Second Cause of Action: Breach of Express Warranty

57. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

58. As detailed above, Defendant, through its written literature, packaging and labeling, and written and media advertisement, expressly warranted that the Similac, Alimentum, and EleCare Products were safe and fit for the purposes intended, that they were of merchantable quality, and that they did not pose dangerous health risks.

59. Plaintiff read and relied on these express warranties provided by Defendant in the packaging and written advertisements, including that the “infant formula” was a “ready to feed” formula that “starts reducing excessive crying and colic symptoms in most babies within 24 hours, so your baby can start feeling better today.”

60. Defendant breached its express warranties because Similac, Alimentum, and EleCare Products were defective and not reasonably safe for their intended use.

61. Defendant knew or should have known that the Similac, Alimentum, and EleCare Products did not conform to its express warranties and representations and that, in fact, the Products are not safe and pose serious health risks because they contain microorganisms, such as Cronobacter sakazakii and Salmonella.

62. Plaintiff N.J. has suffered harm as a result of Defendant's breach of its express warranty regarding the fitness for use and safety of these Products and is entitled to damages to be determined at trial.

Third Cause of Action: Breach of Implied Warranty

63. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

64. Because the Similac, Alimentum, and EleCare Products contained Cronobacter sakazakii and salmonella, they were not of the same quality as those generally acceptable in the trade and were not fit for the ordinary purposes for which such infant formula products are used.

65. Plaintiff used these Products in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

66. The Defendant's Similac, Alimentum, and EleCare Products were not altered by Plaintiff.

67. Plaintiff was a foreseeable user of the Products.

68. Plaintiff used the Products in the manner intended.

69. As alleged, the Defendant's Similac, Alimentum, and EleCare Products were not adequately labeled and did not disclose that they contain harmful microorganisms, such as *Cronobacter sakazakii* and salmonella.

70. The Products did not measure up to the promises or facts stated in the written literature, media advertisement and communications by and from Defendant.

71. Defendant impliedly warranted that the Products were merchantable, fit and safe for ordinary use.

72. Defendant further impliedly warranted that the Products were fit for the particular purposes for which they were intended and sold.

73. Contrary to these implied warranties, the Products were defective, unmerchantable, and unfit for their ordinary use when sold, and unfit for the particular purpose for which they were sold.

74. By reason thereof, Plaintiff N.J. has suffered damages in an amount to be proven at trial.

Fourth Cause of Action: Strict Product Liability – Failure to Warn

75. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

76. Defendant knew or should have known that the Defendant's Similac, Alimentum, and EleCare Products contained *Cronobacter sakazakii* and Salmonella.

77. Defendant had a duty to warn Plaintiff about the presence of microorganisms, such as *Cronobacter sakazakii* and Salmonella, in its Products.

78. In addition, Defendant had a duty to warn Plaintiff about the dangers of the presence of harmful microorganisms, such as Cronobacter sakazakii and Salmonella, in its Products.

79. Defendant knew that the risk of infection of microorganisms, such as Cronobacter sakazakii and Salmonella, from use of its products was not readily recognizable to an ordinary consumer and that consumers would not inspect the product for harmful microorganisms such as Cronobacter sakazakii and Salmonella.

80. Defendant did not warn Plaintiff that Defendant's Similac, Alimentum, and EleCare Products contain harmful microorganisms, such as Cronobacter sakazakii and Salmonella, or about the dangers of the presence of microorganisms, such as Cronobacter sakazakii bacteria, in its Products.

81. Plaintiff suffered damages by purchasing the Defendant's Similac, Alimentum, and EleCare Products in a manner promoted by Defendant, and in a manner that was reasonably foreseeable by Defendant. Plaintiff would not have used Defendant's Similac, Alimentum, and EleCare Products had she known they contained harmful microorganisms, such as Cronobacter sakazakii bacteria and Salmonella.

82. Plaintiff was justified in her reliance on Defendant's labeling and advertising of the product for use as a safe infant formula.

83. Plaintiff N.J. has suffered damages in an amount to be proven at trial.

Fifth Cause of Action: Strict Product Liability – Manufacturing Defect

84. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

85. The Defendant's Similac, Alimentum, and EleCare Products contained a manufacturing defect when they left the possession of Defendant. Specifically, the Products differ from Defendant's intended result or from other lots of the same product line because they contain harmful microorganisms, such as Cronobacter sakazakii bacteria and Salmonella.

86. Plaintiff N.J. used the Products in a way that was reasonably foreseeable to Defendant.

87. As a result of the defects in the manufacture of the Defendant's Similac, Alimentum, and EleCare Products, Plaintiff N.J. suffered damages.

88. Accordingly, Plaintiff N.J. suffered damages in an amount to be proven at trial.

Sixth Cause of Action: Negligence *Per Se*

89. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

90. As documented in the FDA Form 483 issued on September 24, 2019, Defendant failed to test a representative sample of an infant formula production aggregate of powdered infant formula at the final product stage and before distribution to ensure that the production aggregate met the required microbiological quality standards.

91. As documented in the FDA Form 483 issued on September 24, 2021, Defendant failed to maintain a building used in the manufacture, processing, packing, or holding of infant formula in a clean and sanitary condition.

92. As documented in the FDA Form 483 issued on September 24, 2021, Defendant personnel working directly with infant formula, its raw materials, packaging, or equipment or

utensil contact surfaces did not wash their hands thoroughly in a hand washing facility at a suitable temperature after their hands may have become soiled or contaminated.

93. As documented in the FDA Form 483 issued on March 18, 2022, Defendant failed to set in place and/or maintain a system of process controls that cover all stages of infant formula processing to ensure the products do not become adulterated due to the presence of microorganisms, including Cronobacter, in the formula or in the processing environment.

94. As documented in the FDA Form 483 issued on March 18, 2022, Defendant further failed to ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated with microorganisms, including Cronobacter and Salmonella.

95. As documented in the FDA Form 483 issued on March 18, 2022, Defendant failed to document any determination as to whether a hazard to health exists due to contamination with microorganisms, including Cronobacter.

96. As documented in the FDA Form 483 issued on March 18, 2022, Defendant's personnel that worked directly with infant formula, its raw materials, packaging, equipment, or utensil contact surfaces failed to wear necessary protective apparel.

97. The conduct set forth herein, including that documented in the FDA Form 483 reports represent Defendant's conduct in violation of the following statutes or regulations that caused Plaintiff N.J.'s injury, including the risk of infection and infection of life-threatening microorganisms:

a. 21 U.S.C. § 331 - "The following acts and the causing thereof are prohibited:

(a) The introduction or delivery . . . of any food . . . that is adulterated or

misbranded. (b) The adulteration or misbranding of any food(g) The manufacture . . . of any food . . . that is adulterated or misbranded;”¹²

- b. 21 CFR § 106.5 (failing to maintain good manufacturing practices that are to be used in, and the facilities or controls that are to be used for, the manufacture, processing, packing, or holding of infant formula);¹³
- c. 21 CFR § 106.10 (failing to ensure personnel washed hands);
- d. 21 CFR § 106.20(a) (failing to maintain building in a clean, sanitary condition);
- e. 21 CFR § 106.30(d) (failing to maintain instruments used to measure, regulate, control parameter);
- f. 21 CFR § 106.30(e)(5) (failing to monitor the temperature in thermal processing equipment at a frequency as is necessary to maintain temperature control); and
- g. 21 CFR § 106.30(g) (failing to install a filter capable of retaining particles 0.5 micrometer or smaller when compressed gas is used at a product filling machine).

98. Under 21 U.S.C. § 350a, an infant formula, including an infant formula powder, shall be deemed to be adulterated if such infant formula does not meet the quality factor

¹² See 21 U.S.C. § 342 (A food shall be deemed to be adulterated (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health . . . or (4) if it has been prepared, packed, or held under insanitary conditions . . .); and 21 U.S.C. § 343 (A food shall be deemed to be misbranded . . . if (1) its labeling is false or misleading. . .).

¹³ See 21 CFR 106.5(b) (The failure to comply with any regulation in this subpart in the manufacture, processing, packing, or holding of an infant formula shall render such infant formula adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a)(3)))

requirements prescribed by the Secretary under subsection (b)(1), or (3) the processing of such infant formula is not in compliance with the good manufacturing practices and the quality control procedures prescribed by the Secretary under subsection (b)(2).

99. The injury caused to Plaintiffs by Defendant's conduct, which violated these statutes and regulations, was the type of injury that the statutes and regulations were designed to prevent.

100. Additionally, Plaintiff N.J. was a member of the class of persons these statutes and regulations were intended to protect. Indeed, as set forth in 21 C.F.R. § 106.5, "compliance with these provisions is necessary to ensure that such infant formula ... is manufactured in a manner designed to prevent its adulteration."

101. As a result of Defendant's conduct in the manufacture of the Defendant's Similac, Alimentum, and EleCare Products violating the foregoing statutes and regulations, Plaintiff N.J. suffered damages in an amount to be proven at trial.

Seventh Cause of Action: Plaintiff's Claim for Damages Incurred on Behalf of her Minor Child, N.J.

102. Plaintiff incorporates by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

103. Plaintiff, N.J. was a minor at all times referenced in this Complaint.

104. As a direct and proximate result of Defendant's acts and/or omissions, Plaintiff N.J. suffered physical injuries.

105. Plaintiff Gabrielle Arispe has a derivative claim for damages because her minor child, N.J., has sustained physical injuries due to the Defendant's conduct.

106. As a result, Plaintiff Gabrielle Arispe has a legally recognized claim for damages and seeks reimbursement for medical expenses and other expenses incurred because of Plaintiff N.J.'s injuries.

107. As a result of Defendant's conduct in the manufacture of the Defendant's Similac, Alimentum, and EleCare Products violating the foregoing statutes and regulations, Plaintiff suffered damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and her minor child, N.J. prays for judgment against the Defendant as to each and every count, including:

- a. Actual damages in the amount to be determined at trial;
- b. Exemplary damages sufficient to punish Defendant Abbott and deter it and others from future wrongful conduct;
- c. Treble damages as allowed by law;
- d. Attorneys' fees as allowed by law;
- e. Costs and expenses as allowed by law;
- f. Pre- and post- judgment interest as allowed by law;
- g. Any other relief the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

DATED: March 8, 2023

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