UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

Jenna Gaeta, individually and on behalf of her minor child, A.G.,	)	Case No. 1:22-cv-05553
Plaintiff,	)	
v.	)	
Abbott Laboratories Inc. D/B/A Abbott Nutrition,	)	
Defendants.	)	

COMPLAINT

Plaintiff Jenna Gaeta ("Plaintiff'), individually and on behalf of her minor child, A.G., files this Complaint against Defendant Abbott Laboratories, Inc. D/B/A Abbott Nutrition. ("Abbott" or "Defendants"), and in support state the following:

NATURE OF THE ACTION

1. Plaintiff, Jenna Gaeta, is the mother of A.G., 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, A.G., consumed Defendant's Recalled Product and suffered injury as a result of the contamination of Defendant's product.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, as there is complete diversity of the parties, and the amount in controversy exceeds $75,000.

6. Venue is proper in this district because a substantial portion of the acts and conduct giving rise to the claims occurred within this district and the Defendant has a principal place of business within the District.

THE PARTIES

7. Plaintiff is a citizen and resident of Brunswick County, North Carolina, and at all times relevant hereto, has been a resident of Brunswick County. In or around January 2021, Plaintiff purchased Similac Pro-Advance, Similac Alimentum, and Similac Pro-Sensitive infant formula for A.G.. Based on the false and misleading claims by Defendant, Plaintiff was unaware that Defendant's Similac product may be adulterated with *salmonella*, *Cronobacter sakazakii*, and other contaminants. Plaintiff used the Defendant's product 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 Pro-Advance, Similac Pro-Sensative, and Similac Alimentum products had she known there was a risk the products may contain *salmonella*, *Cronobacter sakazakii*, and other contaminants.

8. Defendants, 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.

9. This Court has specific personal jurisdiction over Defendant because Defendant has purposefully availed itself of the privileges and benefits of doing business in North Carolina and Illinois.

10. Defendant subjected itself to jurisdiction in North Carolina and Illinois by doing business in North Carolina and Illinois and by contracting with North Carolina and Illinois businesses and by performing such contracts in part in North Carolina and Illinois and by committing torts where one or more elements of the tort or one or more of the tortious acts occurred in North Carolina and Illinois.

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/l9- 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." *See* FDA, https://www.fda.gov/consumers/powdered-infant-formula-recall-what-know (last visited March 16, 2022).

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

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.

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

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.

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%. *See* CDC.gov, https://www.cdc.gov/cronobacter/technical.html (last accessed on March 25, 2022). Other sources have described the mortality rate reaching as high as 80%. *See* 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-ll-285. PMID: 22410240.

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. *See* 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 lnformation Act Request. *Id*. (available at https://efoodalert.files.wordpress.com/2022/06/abbott-complaints-

spreadsheet- redacted.pdf)(last accessed on June 21, 2022). The FDA investigated 128 consumer complaints collected by the FDA between December 2021 and March 2022, including 25 described as "life-threatening illness/injury." *Id*. 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 powered 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.

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*; and

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, m 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; and

c. Failed to ensure numerous controls were m 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 powered 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. 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"). 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 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. *See* 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). 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. *See* 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).

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. § 33l(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). *See* 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 (last accessed on May 16, 2022).

41. In or around September 2021, Plaintiff used Similac Pro Advance, Similac Pro Total Care, and Similac Sensitive for her infant child after purchasing it.

42. Upon information and belief, the container used by Plaintiff for her minor child match the tainted lots identified by the FDA advisory and subsequently recalled by Defendant.

43. Plaintiffs' infant child consumed the tainted infant product.

44. Shortly after starting the Similac products, Plaintiff's infant suffered immediate and severe injury as a result of consuming the tainted product.

45. Plaintiffs' infant child became irritable, had a fever, and loose stools after consuming the tainted product necessitating medical intervention.

46. Plaintiff took her infant child to the emergency department on September 11 2021. Plaintiff's infant child has a fever, increased stools, and loose stools.

47. On September 12, 2012, Plaintiff's infant child developed diarrhea with blood. Plaintiff's infant child was started on IV fluids.

48. A GI-PCR test resulted positive for *Salmonella newport*.

49. Plaintiffs have incurred substantial medical bills as a result of many doctor visits and the recent hospital stay.

50. As a direct and proximate result of ingesting the contaminated formula, Plaintiff's infant child has suffered injuries in the past and will continue in the future.

First Cause of Action: Negligent Misrepresentation/Omission

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

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

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

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

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

56. 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.

57. Plaintiff reasonably relied upon such representations and omissions to their detriment.

58. By reason thereof, Plaintiff's infant child has suffered damages in an amount to be proven at trial.

Second Cause of Action: Breach of Express Warranty

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

60. 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.

61. 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."

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

63. 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*.

64. Plaintiff's infant child 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

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

66. 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.

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

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

69. Plaintiff was a foreseeable user of the Products.

70. Plaintiff used the Products in the manner intended.

71. 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*.

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

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

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

75. 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.

76. By reason thereof, Plaintiff's infant child has suffered damages in an amount to be proven at trial.

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

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

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

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

80. 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.

81. Defendant knew that the risk of infection of microorganisms, such as *Cronobacter sakazakii* and s*almonella*, 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*.

82. Defendant did not warn Plaintiff that Defendant's Similac, Alimentum, and EleCare Products contain harmful microorganisms, such as *Cronobacter sakazakii* and s*almonella*, or

about the dangers of the presence of microorganisms, such as *Cronobacter sakazakii* bacteria, in its Products.

83. Plaintiff's infant child 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.*

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

85. Plaintiff's infant child has suffered damages in an amount to be proven at trial.

Fifth Cause of Action: Strict Product Liability - Manufacturing Defect

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

87. 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 s*almonella*.

88. Plaintiff used the Products in a way that was reasonably foreseeable to Defendant.

89. As a result of the defects in the manufacture of the Defendant's Similac, Alimentum, and EleCare Products, Plaintiff's infant child suffered damages.

90. Accordingly, Plaintiff's infant child suffered damages in an amount to be proven at trial.

Sixth Cause of Action: Negligence Per Se

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

92. 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 powered infant formula at the final product stage and before distribution to ensure that the production aggregate met the required microbiological quality standards.

93. 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.

94. 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.

95. 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.

96. 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*.

97. 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*.

98. 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.

99. 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's infant child'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 1s adulterated or misbranded·" *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).

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) *See* 21 CFR 106.S(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)));

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).

100. 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 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).

101. 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.

102. Additionally, Plaintiff’s infant child 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."

103. 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.

Seventh Cause of Action: Plaintiffs Claim for Damages Incurred on Behalf of her Minor Child

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

105. Plaintiff's infant child was a minor at all times referenced in this Complaint.

106. As a direct and proximate result of Defendant's acts and/or omissions, Plaintiff 's infant child suffered physical injuries.

107. Plaintiff has a derivative claim for damages because her minor child has sustained physical injuries due to the Defendant's conduct.

108. As a result, Plaintiff has a legally recognized claim for damages and seeks reimbursement for medical expenses and other expenses incurred because of Plaintiff's minor child's injuries.

109. As a result of Defendant's conduct, 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 pray 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; and

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 October 10, 2022

/s/ Stacy K. Hauer

Timothy J. Becker (MN No. 256663)
Stacy H. Hauer (MN No. 0317093)
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CIVIL COVER SHEET

The ILND 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. ***(See instructions on next page of this form.)***

I. (a) PLAINTIFFS

Jenna Gaeta, individually and on behalf of her minor child, A.G.

(b) County of Residence of First Listed Plaintiff Brunswick County
(Except in U.S. plaintiff cases)

(c) Attorneys *(firm name, address, and telephone number)*

Stacy H. Hauer, Timothy J. Becker, Johnson Becker, PLLC, 444 Cedar St., #1800, St. Paul, MN 55101, 612-436-1800

DEFENDANTS

Abbott Laboratories Inc. D/B/A Abbott Nutrition

County of Residence of First Listed Defendant Lake County, IL
(In U.S. plaintiff cases only)
Note: In land condemnation cases, use the location of the tract of land involved.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Check **one** box, only.)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government not a party.)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate citizenship of parties in Item III.)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(For Diversity Cases Only.)*

*(Check **one** box, only for plaintiff and **one** box for defendant.)*

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business in This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Check **one** box, only.)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loan (Excludes Veterans)
- ☐ 153 Recovery of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 530 General
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Habeas Corpus:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

PROPERTY RIGHTS
- ☐ 820 Copyright
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016 (DTSA)

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729 (a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act (TCPA)
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Arts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/Accommodations
- ☐ 445 Amer. w/ Disabilities-Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus – Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAXES
- ☐ 870 Taxes (U.S. Plaintiff or Defendant
- ☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN *(Check **one** box, only.)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

(Enter U.S. Civil Statute under which you are filing and write a brief statement of cause.)
28 USC 1332 Diversity of Citizenship; Personal Injury-Product

VII. PREVIOUS BANKRUPTCY MATTERS

(For nature of suit 422 and 423, enter the case number and judge for any associated bankruptcy matter previously adjudicated by a judge of this Court. Use a separate attachment if necessary.)

VIII. REQUESTED IN COMPLAINT:

☐ Check if this is a **class action** under Rule 23, F.R.CV.P.

Demand $ 75000

CHECK Yes only if demanded in complaint:
Jury Demand: ☒ Yes ☐ No

IX. RELATED CASE(S) IF ANY *(See instructions):*

Judge Kennelly Case Number 22-cv-4148 (MDL 3037)

X. Is this a previously dismissed or remanded case? ☐ **Yes** ☐ **No** **If yes, Case #** **Name of Judge**

Date: 10/10/2022

Signature of Attorney of Record /s/ Stacy K. Hauer

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority for Civil Cover Sheet

The ILND 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use
(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the
(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.