

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

ZAIEMA ROULAND, individually and on
behalf of all others similarly situated,

Plaintiff,

vs.

ABBOTT LABORATORIES D/B/A
ABBOTT NUTRITION,

Defendant.

Case No. _____

Hon.: _____

CLASS ACTION COMPLAINT

JURY TRIAL DEMAND

COMES NOW, ZAIEMA ROULAND (“Plaintiff”), individually and on behalf of the
Class, who states and alleges as follows:

INTRODUCTION

1. This case is a class action brought by Plaintiff on behalf of herself and similarly situated Pennsylvania consumers who purchased Abbott Laboratories, Inc.’s (“Abbott” or “Defendant”) powdered infant formula products, including Similac®, Similac PM 60/40®, Alimentum® and EleCare® products, which were manufactured at the Abbott Nutrition facility in Sturgis, Michigan (“Sturgis Facility”). The United States Food and Drug Administration (“FDA”), in conjunction with the Center for Disease Control (“CDC”), announced on February 17, 2022, that it was investigating Defendant’s Similac®, Alimentum®, and EleCare® products following several consumers’ complaints of Cronobacter sakazakii and Salmonella Newport contamination. The FDA’s advisory notice alerted consumers to avoid purchasing or using Defendant’s Similac®, Alimentum® and EleCare® products.

2. Abbott later announced that it found evidence of *Cronobacter sakazakii* at the Sturgis Facility. Abbott learned of the death of an infant who tested positive for *Cronobacter sakazakii* and . . . consumed Similac PM 60/40.

3. As discussed further herein, Abbott knew about the ongoing risk of contamination and related noncompliance issues at its Sturgis Facility, and Abbott should have initiated preventative measures in September of 2021.

4. The consequences were dire. Abbott's failures harmed consumers, sickened infants, and ultimately led to the death of at least two children and may have led to the deaths of as many as nine children. Abbott is now telling consumers it is not safe for their infants to consume these products, but many consumers rely on them to feed their children, Abbott leaves many consumers with no safe option but to pay full price for a newer or alternative version. Furthermore, as the leading supplier of milk formula in the United States Abbott has driven a well-documented nationwide infant formula shortage making finding a suitable alternative even more challenging.

5. As more particularly set forth herein, Plaintiff maintains that the purchased products are defective, dangerous to human health, unfit and were unsuitable to be advertised, marketed and sold in the United States, and lacked proper warnings of the dangers associated with their use. ("Contaminated Products").

6. Plaintiff and similarly situated consumers purchased one or more Contaminated Products on the assumption that the labeling was accurate and that the Contaminated Products were unadulterated, safe, and effective and would not have purchased the Contaminated Products had they known there was a risk the Contaminated Products may contain harmful microbes.

7. Under the circumstances that existed, no sales of the products should have taken place.

8. As a result of Abbott's unfair, deceptive, and/or fraudulent business practices, consumers of these products, Plaintiff and those similarly situated who she seeks to represent have suffered ascertainable losses, injury-in-fact, and otherwise have been harmed by Abbott's conduct.

9. Plaintiff, on behalf of herself and all others similarly situated, seek declaratory and injunctive relief, including restitution, damages, penalties, interest, and attorneys' fees and costs to the full extent permitted by applicable law.

PARTIES

10. Plaintiff is a resident of the City of Allentown, County of Lehigh, Pennsylvania.

11. Defendant is an Illinois corporation with its principal place of business in Illinois. Defendant's headquarters is located at 100 Abbott Park Road, Abbott Park, Illinois 60064.

12. Defendant is the leading supplier of milk formula in the United States.¹ Abbott manufactures, markets, advertises, labels, distributes and sells several infant formulas, including the Contaminated Products, under the brand names Similac®, Alimentum® and EleCare®.

13. Defendant may accept service via its registered agent CT Corporation System, 208 South LaSalle Street, Suite 814, Chicago, Illinois 60604.

JURISDICTION AND VENUE

14. This Court has original jurisdiction of this action under the Class Action Fairness Act of 2005. Pursuant to 28 U.S.C. §§ 1332(d) *et seq.*, this Court has original jurisdiction because the aggregate claims of the members of the putative class exceeds \$5 million, exclusive of costs, and at least one of the Class members is a citizen of a different state than Abbott.

15. This Court has jurisdiction over this matter because Abbott is an Illinois business, with its principal place of business in Illinois.

¹<https://www.reuters.com/business/healthcare-pharmaceuticals/abbott-could-restart-infant-formula-production-michigan-plant-2022-05-11/> (last visited Sept. 28, 2022).

16. Venue is proper under 28 U.S.C. § 1391, because Defendant maintains its principal place of business in this District, transacts business in this District, and a substantial part of the acts and/or omissions giving rise to the claims occurred in this District.

FACTUAL BACKGROUND AND GENERAL ALLEGATIONS

I. ABBOTT'S PRODUCTS AND POWDERED INFANT FORMULAS.

17. Abbott Laboratories is an American multinational medical devices and health care company with its headquarters in Abbott Park, Illinois, United States. Abbott was founded 130 years ago, and its products are currently distributed and sold in over 160 countries.² In 2021, Abbott Laboratories' gross sales were \$43.1 billion USD.³

18. Abbott's nutrition division (Abbott Nutrition) was created in 1903, and, since that time, Abbott has earned consumer's trust as the number one seller of pediatric nutrition products.⁴

19. According to the Global Infant Formula Market Report 2021-2025, Abbott is considered one of the most dominant players in the baby formula market, which is expected to be valued at \$93 billion by the year 2025.⁵

20. Abbott, through Abbott Nutrition, was and is engaged in the manufacture, distribution, marketing, and sale of several powdered infant formula brands, including the Contaminated Product brands Similac®, Similac PM 60/40 ®, Alimentum® and EleCare®.

²<https://dam.abbott.com/en-us/abbottcorpnews/pdf/Corporate-Fact-Sheet.pdf> (last visited October 2, 2022).

³ *Id.*

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See, https://dam.abbott.com/global/documents/pdfs/newsroom/Abbott_FactSheet_Nutrition_2015.pdf (last visited October 2, 2022).

⁵<https://www.businesswire.com/news/home/20210309005489/en/Global-Infant-Formula-Market-Report-2021-2025-Featuring-Nestle-S.A.-Danone-S.A.-Abbott-Laboratories-Royal-FrieslandCampina-N.V.-Reckitt-Benckiser-and-Kraft-Heinz---ResearchAndMarkets.com> (last visited October 2, 2022).

21. Abbott's products are marketed, distributed, and sold in a uniform manner throughout the United States, and are available for purchase at thousands of retail locations and online through Abbott's website and other major retailers such as Walmart, Target, and Amazon.

22. Consumer trust is a valuable asset to Abbott, which holds itself out as a safe and responsible company that is committed to scientific research and to "nourishing every stage of life":

Every day, our team of passionate scientists and experts works hard to discover and develop nutrition products that better life for people of all ages.

As a leader in nutrition science, research and development, our goal is to deliver nutrition products and education that meet the changing needs of families across the world.⁶

23. Abbott, on its website and elsewhere, emphasizes its commitment to developing and manufacturing nutrition products that are safe for infants to consume:

We make products to help babies and children grow, that work to keep bodies strong, and that support the unique nutritional and therapeutic needs of adults.

Nutrition is the foundation to healthy living and here at Abbott Nutrition, we provide resources to help people live their best life⁷

24. Despite these and other representations about the safety of its products, and with knowledge or reckless disregard, Abbott marketed, distributed, and sold contaminated infant formulas throughout the United States, including in the state of Pennsylvania.

Specialty Infant Formulas

25. In addition to the Similac product line, Abbott manufactures, markets, distributes, and sells several different types of specialty infant formula products.

⁶ <https://nutrition.abbott/in/about-us> (last visited October 2, 2022).

⁷ *Id.*

26. Abbott advertises that its specialty infant formulas are a safe alternative for infants who suffer from pre-existing health conditions or severe food allergies, and, in doing so, targets an especially at-risk subset of an already vulnerable class of consumers.

EleCare Powdered Infant Formula

27. Abbott's website and the product's front label advertise that EleCare is "#1 Recommended by Pediatric Gastroenterologists" and safe for "Severe Food Allergies and GI Disorders." Abbott also states that the products is "clinically shown to support the growth of exclusively formula-fed infants . . . EleCare helps manage symptoms of severe food allergies and various gastrointestinal (GI) conditions."⁸

28. EleCare is advertised as "Hypoallergenic" and safe for infants with gastrointestinal conditions, and severe food allergies. Abbott, through its website and marketing materials states:

Help your child—help yourself—feel better. Talk to your doctor about EleCare or EleCare Jr. They are amino acid-based, hypoallergenic formulas for infants and children with severe food allergies and various GI disorders.⁹

29. Defendant also advertises and promotes EleCare as safe and effective for "dietary management" of the following:

For cows [*sic*] milk protein allergy and other severe food allergies

Eosinophilic Gastrointestinal Disorders (EGIDs) . . . chronic digestive system disorders in which certain food proteins trigger an overproduction of eosinophils (white blood cells that help fight certain infections) in different areas of the digestive tract.

Short Bowel Syndrome (SBS) . . . a group of problems affecting individuals who have lost the use of a major part of their small intestine."

Food Protein-Induced Enterocolitis Syndrome (FPIES) . . . an immune reaction in the gastrointestinal system to one or more specific foods. It's commonly characterized by profuse vomiting and diarrhea.

⁸ <https://elecare.com/product-information/elecare> (Last visited October 2, 2022).

⁹ <https://elecare.com/conditions> (last visited October 2, 2022).

Malabsorption, and Other Conditions¹⁰

30. EleCare costs \$46.99 per 14.1 oz. canister. (Sales tax and shipping costs excluded).¹¹

Similac PM 60/40 Powdered Infant Formula

31. Abbott's website and Similac PM 60/40's packaging advertise that the product is designed "[f]or infants who would benefit from lowered mineral intake, including those with impaired renal function. Calcium-to-phosphorus ratio and content designed to manage serum calcium disorders - both hypercalcemia and hypocalcemia due to hyperphosphatemia."¹²

32. Similac PM 60/40 is sold by the case, which includes six 14.1-ounce cans, and costs \$93.00 (sales tax and shipping costs excluded).¹³

Similac Alimentum Powdered Infant Formula

33. Similac Alimentum is advertised and promoted as "suitable for lactose sensitivity and has broken-down protein that is easy to digest for babies with food allergies or colic due to protein sensitivity;" containing "an immune-nourishing ingredient" and as reducing "excessive crying and colic symptoms due to protein sensitivity within 24 hours."¹⁴

34. Similac Alimentum was sold in 12.1-ounce cans and costs \$29.49 per can (sales tax and shipping costs excluded).¹⁵

II. STURGIS FACILITY AND FDA INVESTIGATION.

¹⁰ <https://elecare.com/conditions> (last visited October 2, 2022).

¹¹ <https://abbottstore.com/infant-and-child/elecare/elecare/elecare-powder/elecare-14-1-oz-can-55251e.html> (last visited October 2, 2022).

¹² <https://abbottstore.com/infant-and-child/similac/similac-pm-60/similac-pm-60-40-infant-formula-powder-14-1-oz-can-case-of-6-00850.html> (last visited October 2, 2022).

¹³ *Id.*

¹⁴ <https://abbottstore.com/infant-and-child/similac/similac-alimentum/similac-alimentum-infant-formula-powder/similac-alimentum-infant-formula-powder-12-1-oz-can-64715e.html> (last visited October 2, 2022).

¹⁵ *Id.*

35. Over the years, the FDA conducted several inspections of Abbott's Sturgis facility, which have uncovered numerous, egregious violations of statutes and regulations set forth herein in Defendant's manufacture, processing, packing, and holding of Similac®, Similac PM 60/40®, Alimentum® and EleCare® powdered infant formulas.

36. As documented in the FDA Form 483 issued on September 24, 2019, Defendants 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.¹⁶

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

38. 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.¹⁷

¹⁶ <https://www.fda.gov/media/157319/download> (last visited October 2, 2022).

¹⁷ <https://www.fda.gov/media/157317/download> (last visited October 2, 2022).

39. At approximately the same time, the FDA issued an Establishment Inspection Report in September 2021 based on its inspections of Abbott's Sturgis, Michigan factory.¹⁸ This report set forth that Abbott received at least 17 complaints over its powdered infant formula products between September 1, 2019 and September 20, 2021, of which at least 15 related to infants having contracted Salmonella and another for Cronobacter. The same report also described finding Cronobacter in at least two batches of Abbott's finished powdered infant product on September 25, 2019 as well as in 5 different environmental samples.

40. The Minnesota Department of Health investigated a case of an infant who was sickened by Cronobacter sakazakii in September 2021.¹⁹

41. Minnesota state health officials "knew that the infant had consumed powdered formula produced at an Abbott Nutrition facility in Sturgis, Michigan, and shared this information with the FDA and CDC in September."²⁰

42. The FDA received reports of the first illness on September 21, 2021, and the agency notified Abbott Laboratories the following day on September 22, 2022.²¹

43. Two more reports of Cronobacter sakazakii happened sometime between September and December, according to FDA.²²

44. On January 31, 2022, the FDA found "several positive Cronobacter results" from environmental samples during an inspection of the Sturgis facility, and an FDA review of Abbott's

¹⁸ *New York Times*, <https://int.nyt.com/data/documenttools/abbott-nutrition-fei-1815692-9-2021-eir/c47a8151d05b513a/full.pdf> (last visited October 11, 2022).

¹⁹ <https://www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226> (last visited October 2, 2022).

²⁰ *Id.*

²¹ <https://www.politico.com/news/2022/02/26/senators-demand-answers-from-abbott-on-infant-formula-recall-00012073?cid=apn> (last visited October 2, 2022).

²² *Id.*

internal documents indicated that Abbott Laboratories previously destroyed infant formulas in connection with the contamination issue.²³

45. The FDA also received one complaint of an infant with Salmonella infection who consumed formula from the Sturgis facility. However, they later concluded there is not enough information available to definitively link the illness with the recalled infant formula.²⁴

46. On February 17, 2022, the FDA, in conjunction with the CDC, announced a warning to consumers to not purchase or use the Contaminated Products.²⁵

47. 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.²⁶

48. Abbott took no action for nearly five months after it learned about the first reported illness, potential contamination issues at the Sturgis Facility, and the FDA inspection which indicated that there were serious noncompliance issues at the Sturgis Facility.²⁷ Only then did Abbott announce that it had found evidence of Cronobacter sakazakii in the non-product contact areas of the Sturgis Facility.

²³ *Id.*

²⁴ <https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutrition-facility> (last visited October 2, 2022).

²⁵ *Id.*

²⁶ <https://thehill.com/policy/healthcare/public-global-health/594856-three-kinds-of-baby-formula-recalled-by-abbott/> (last visited April 28, 2022).

²⁷ See <https://www.cdc.gov/cronobacter/outbreaks/infant-formula.html> (last visited October 2, 2022).

49. Abbott has not explained why it waited nearly five months to make this announcement or warn consumers about the inherent risk of products manufactured at the Sturgis Facility.

50. Cronobacter bacteria can cause severe, life-threatening infections (sepsis) or meningitis (an inflammation of the membranes that protect the brain and spine).²⁸

51. 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.

52. 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%.²⁹

53. Other sources have described the Cronobacter meningitis mortality rate reaching as high as 80%.³⁰

54. As reported in medical and scientific literature:

Among *C. sakazakii* infant case consultations conducted by CDC during 1998–2005, 92% of infants for whom information on feeding practices were available had received a PIF product.³¹

²⁸ <https://www.cdc.gov/cronobacter/outbreaks/infant-formula.html> (last visited October 2, 2022).

²⁹ CDC.gov, <https://www.cdc.gov/cronobacter/technical.html> (last accessed on March 25, 2022).

³⁰ 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.

³¹ Kalyantanda G, Shumyak L and Archibald LK, (2015) Cronobacter species contamination of powdered infant formula and the implications for neonatal health. *Front. Pediatr.* 3:56. doi:10.3389/fped.2015.00056.

55. 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.

56. Symptoms of sepsis and meningitis may include poor feeding, irritability, temperature changes, jaundice (yellow skin and whites of the eyes), grunting breaths, abnormal movements, and even death.³²

57. *Cronobacter* infection may also cause bowel damage and may spread through the blood to other parts of the body.³³

58. *Salmonella* are a group of bacteria that can cause gastrointestinal illness and fever called salmonellosis. Most people with salmonellosis develop diarrhea, fever and abdominal cramps. More severe cases of salmonellosis may include a high fever, aches, headaches, lethargy, a rash, blood in the urine or stool, and in some cases, may become fatal.³⁴

59. Around the time of a second infant death, on February 25, 2022, Senator Patty Murray of Washington and Senator Bob Casey of Pennsylvania demanded Abbott Nutrition hand over information and documents related to the company's Contaminated Infant Formulas.³⁵

60. 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*) in the formula or in the processing environment;

³² <https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutrition-facility> (last visited October 2, 2022).

³³ *Id.*

³⁴ *Id.*

³⁵ <https://www.politico.com/news/2022/02/26/senators-demand-answers-from-abbott-on-infant-formula-recall-00012073> (last visited October 2, 2022).

- b. Defendant further failed to ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated with microorganisms, (such as cronobacter);
- c. Defendant failed to document any determination as to whether a hazard to health exists due to contamination with microorganisms (such as cronobacter);
- 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.³⁶

61. 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 2021.³⁷ The FDA investigated 128 consumer complaints collected by the FDA between December 2021 and March 2022, including 25 described as “life-threatening illness/injury.”³⁸ 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*.

³⁶ <https://www.fda.gov/media/157708/download> <https://www.similacrecall.com/us/en/home.html> (last visited October 2, 2022).

³⁷ Phyllis Entis, “Nine baby deaths reported to FDA during Abbott Nutrition investigation,” [efoodalert.com](https://efoodalert.com/2022/06/08/nine-baby-deaths-reported-to-fda-during-abbott-nutrition-investigation) (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).

³⁸ *Id.*

62. 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:

On multiple occasions, and in various ways, records have been knowingly falsified... This included testing seals on empty cans...

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”).

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.

63. 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.³⁹ 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.

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

65. 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 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”).

66. 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.⁴⁰ 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.⁴¹

67. Abbott eventually joined the DOJ’s consent decree that incorporates 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).

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, namely infant formula as defined in 21 U.S.C. § 321(z), that are adulterated within the meaning of 21 U.S.C. § 350a(a)(3), 21 U.S.C. § 350a(b)(2), and 21 C.F.R. Part 106.

The Complaint alleges that Defendants violate 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).

The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of food, namely infant formula as defined in 21 U.S.C. § 321(z), that are

⁴⁰ 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).

⁴¹ 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).

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).⁴²

68. During a hearing before two subcommittees of the United States House of Representatives that related to Abbott's production of infant formula FDA Commissioner Robert Califf, M.D., described the conditions at the Sturgis, Michigan plant:

Let's say you had a next-door neighbor who had leaks in the roof, they didn't wash their hands, they have bacteria growing all over the kitchen. You walked in, and there was standing water on the counters and the floor, and the kids were walking through with mud on their shoes and no one cleaning it up. You probably wouldn't want your infant eating in that kitchen. And that's in essence what the inspection showed."⁴³

69. Dr. Califf further described "shocking" and "egregiously unsanitary" structural and equipment issues.⁴⁴

70. During a joint media conference, Dr. Califf joined Director of FDA's Center for Food Safety and Applied Nutrition, Dr. Susan Mayne, and FDA's Deputy Commissioner for Food Policy, Frank Yiannas. Dr. Mayne disputed Abbott's claims that the FDA's findings represented a rejection of any link between Abbott's Sturgis Factory and the sickened infants, stating:

We had multiple strains of Cronobacter that were isolated from the environment in the Sturgis plant. So there certainly is the possibility that other strains that we didn't detect at the time we were in the plant for the inspection certainly could have been in there.⁴⁵

⁴² 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); *U.S. v. Abbott Lab., et al.*, 1:22-cv-00441 (W.D. Mich. May 16, 2022) (J. Hala Jarbou)

⁴³ NPR.org, <https://www.npr.org/2022/05/25/1101307685/2-house-subcommittees-are-trying-to-get-answers-about-the-baby-formula-shortage> (last accessed on Oct. 11, 2022).

⁴⁴ Delauro.house.gov, <https://delauro.house.gov/media-center/press-releases/delauro-statement-abbott-facility-reopening> (last access on October 11, 2022).

⁴⁵ YouTube.com, <https://www.youtube.com/watch?app=desktop&v=uFg9mpDDuzk> (last access October 11, 2022).

71. Deputy Commissioner Frank Yiannas cautioned the public “not to read too much into the fact that there’s been negative test results of finished product or that there hasn’t been a genetic link established.”⁴⁶ As he further explained, “It’s important to remember that an over reliance on end product testing is not really the best way to assure food safety. It’s really about process control.”⁴⁷

72. The evidence set forth herein demonstrates 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 the common-sense measures, such as washing hands, upon learning of the risk of contamination of its products with microorganisms. Abbott, therefore:

- 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.

III. HARM TO PLAINTIFF AND OTHER CONSUMERS.

73. As described herein, Abbott, through its acts and omissions, violated state statutes, equity and common law.

⁴⁶ *Id.*

⁴⁷ *Id.*

74. Plaintiff purchased Defendant's powdered infant formula products, including the Contaminated Products, on the assumption that the labeling was accurate and that the Contaminated Products were unadulterated, safe, and effective and would not have purchased the Contaminated Products if they had known that the products were contaminated with—or at substantial risk of being contaminated with—*Cronobacter sakazakii*, *Salmonella*, and/or other harmful bacteria at the time of purchase.

75. Abbott continued distributing and selling the Contaminated Products for nearly five months after it had learned about the first infant illness before the first recall and FDA inspections indicated that the Sturgis Facility was unfit for the safe manufacture of infant formulas.

76. Under the circumstances that existed, no sales of the Contaminated Products should have taken place. Furthermore, Abbott should have alerted or otherwise warned consumers that harmful bacteria was discovered at the Sturgis Facility in September 2021, but it concealed this fact for nearly five months. Throughout this time period, Abbott fraudulently misrepresented that the Contaminated Products were safe for consumption.

77. Plaintiff and the proposed Class paid full retail value price for the Contaminated Products, based on the false and misleading claims by Defendant. Under the circumstances that existed, no sales of the Contaminated Products should have taken place, and thus a full refund is applicable.

78. Assuming the Products had any value, that value had diminished due to the possibility, likelihood or presence of alleged bacterial contamination and because they could not reasonably be used (consumed) or resold.

79. Plaintiff seeks a full refund, or alternatively a partial refund equal to the diminished value of the Contaminated Products, including any and all other damages and available relief for the injuries they have sustained as a result of Abbott's false and misleading claims with respect to

the defective and Contaminated Products. Under the circumstances that existed, no sales of the products should have taken place.

IV. PLAINTIFF'S USE OF ABBOTT'S CONTAMINATED PRODUCTS.

80. Plaintiff has purchased Abbott's powdered infant formulas since June 2021, including the Contaminated Products.

81. Plaintiff has regularly fed their infant with Abbott's powdered infant formulas.

82. In and around February 2022, Plaintiff purchased Abbott's Similac powdered infant formula.

83. The first two digits of the product are 33 and the code on the container contains "k8," and the use-by date is October 1, 2024.

84. During that time, based on the false and misleading claims by Defendant, Plaintiff Rouland was unaware that the Contaminated Products may be adulterated with harmful microbes.

85. Rouland purchased the Contaminated Products on the assumption that the labeling was accurate and that the Contaminated Products were unadulterated, safe, and effective. Rouland would not have purchased the Contaminated Products had she known there was a risk the products may contain harmful microbes. Under the circumstances that existed, no sales of the Contaminated Products should have taken place.

86. As a result, Rouland suffered injury in fact when she spent money to purchase the Contaminated Products, which she would not otherwise have purchased absent Defendant's misconduct, as alleged herein. Rouland further suffered injury in fact as such the Contaminated Products had diminished value due to the presence of alleged bacterial contamination and because they could not be used (consumed) or resold.

CLASS ACTION ALLEGATIONS

87. Plaintiff brings this action on behalf of herself and all other similarly situated individuals (the “Class” or “Classes”) pursuant to Rule 23(a), (b)(1), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Classes against Defendant for violations of state laws:

Pennsylvania Class

All consumers who purchased a Contaminated Product in the State of Pennsylvania from April 1, 2021 to the present for personal use or consumption.

88. Plaintiff reserves the right to modify or amend the definition of the proposed Class and/or to add subclasses, if necessary, before this Court determines whether class certification is appropriate.

89. Excluded from each of the classes above are consumers who allege personal bodily injury resulting from the use of a Contaminated Product. Also excluded are Defendant, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice or judicial officer presiding over this matter.

90. The class definitions identify unnamed class members by describing a set of common characteristics sufficient to allow a member of that group to identify themselves as having a right to recover damages from Defendant. Other than by direct notice by mail or email, alternatively proper and sufficient notice of this action may be provided to the Class through notice published online through internet posting and/or publication.

91. *Numerosity – Federal Rule of Civil Procedure 23(a)(1)*. The members of each of the proposed class are so numerous that joinder of all members is impracticable. While the exact number of class members is presently unknown to Plaintiff, and can only be determined through appropriate discovery, Plaintiff is informed and believe that each of the proposed classes contain

thousands of purchasers of the Contaminated Products who have been damaged by Defendant's conduct as alleged herein.

92. *Commonality and Predominance – Federal Rule of Civil Procedure 23(a)(2) and 23(b)(3)*. Plaintiff's claims raise questions of law and fact common to all members of the proposed classes, and they predominate over any questions affecting only individual class members. The claims of Plaintiff and all prospective class members involve the same alleged defect. These common legal and factual questions include the following:

- a. Whether Defendant was unjustly enriched by the sale of Contaminated Products;
- b. Whether Defendant was negligent in selling the Contaminated Products;
- c. Whether the Contaminated Products fail under the implied warranty of usability;
- d. Whether Defendant failed to reasonably warn consumers regarding the risks of the Contaminated Products;
- e. Whether the marketing, advertising, packaging, labeling, and other promotional materials for the Contaminated Products are deceptive;
- f. Whether Defendant's actions violate the state consumer protection statute invoked below;
- g. Whether Defendant's alleged conduct violates public policy;
- h. The appropriate nature of class-wide equitable relief; and
- i. The proper method or methods to determine and measure Plaintiff's and the class' damages.

93. *Typicality – Federal Rule of Civil Procedure 23(a)(3)*. Plaintiff's claims are typical to those of the other members of the class because all class members are similarly injured through Defendant's uniform misconduct described above and were subject to Defendant's deceptive claims that accompanied each and every Contaminated Product. Plaintiff is advancing the same

claims and legal theories on behalf of themselves and all members of the class. Further, there are no defenses available to Defendant that are unique to Plaintiff or to any particular class member.

94. *Adequacy of Representation – Federal Rule of Civil Procedure 23(a)(4)*. Plaintiff will fairly and adequately protect the interests of the proposed classes. Plaintiff has retained competent counsel experienced in class action litigation to ensure such protection. There are no material conflicts between the claims of each representative Plaintiff and the class they seek to represent that would make class certification inappropriate. Additionally, Plaintiff's Counsel are competent to advance the interests of the Class having been designated as Lead Counsel in dozens, if not hundreds, of class cases. Plaintiff and their Counsel intend to prosecute this action vigorously.

95. *Insufficiency of Separate Actions – Federal Rule of Civil Procedure 23(b)(1)*. Absent a representative class action, members of the class would continue to suffer the harm described herein, for which they would have no remedy. Even if separate actions could be brought by individual consumers, the resulting multiplicity of lawsuits would cause undue burden and expense for both the Court and the litigants, as well as create a risk of inconsistent rulings and adjudications that might be dispositive of the interests of similarly situated purchasers, substantially impeding their ability to protect their interests, while establishing incompatible standards of conduct for Defendant.

96. *Declaratory and Injunctive Relief – Federal Rule of Civil Procedure 23(b)(2)*. The classes also may be certified because Defendant has acted or refused to act on grounds applicable to the classes, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the classes as a whole. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the entirety of each of the classes, on grounds generally applicable to the classes, to enjoin and prevent Defendant from engaging in the acts described above and

requiring Defendant to provide a full refund of the purchase price of the Contaminated Products to Plaintiff and members of the class.

97. *Superiority – Federal Rule of Civil Procedure 23(b)(3)*. A class action is superior to all other available methods for the fair and efficient adjudication of this matter because the injuries suffered by the individual class members are relatively small. As such, the expense and burden of individual litigation would make it virtually impossible for Plaintiff and the class members to individually seek redress for Defendant’s wrongful conduct. Even if any individual person or group(s) of the Class could afford individual litigation, it would be unduly burdensome to the courts in which the individual litigation would proceed. The class action device is preferable to individual litigation because it provides the benefits of unitary adjudication, economies of scale, and comprehensive adjudication by a single court. In particular, for every count pleaded below, calculations of damages are susceptible to well-established class wide damage modeling methods.

98. In contrast, the prosecution of separate actions by individual class members would create a risk of inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for the party (or parties) opposing the class and would lead to repetitious trials of the numerous common questions of law and fact. Plaintiff knows of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action. As a result, a class action is superior to other available methods for the fair and efficient adjudication of this action. Absent a class action, Plaintiff and the class members will continue to suffer losses, thereby allowing Defendant’s violations of law to proceed without remedy and allowing Defendant to retain the proceeds of their ill-gotten gains.

CAUSES OF ACTION

COUNT I

BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

(On Behalf of Plaintiff and the Pennsylvania Class)

99. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.

100. By operation of law, Defendant, as manufacturer of the Contaminated Products, impliedly warranted to Plaintiff and members of the Classes that the Contaminated Products were of merchantable quality and safe for their ordinary and intended use pursuant to 13 Pa. Cons. Stat. §§ 2314, *et seq.*

101. As demonstrated in the FDA Forms 483 discussed herein, Defendant engaged in a pattern of unsafe and unsanitary manufacturing, processing, packing, and holding practices of its infant formula and knew or should have known that its products were manufactured, processed, packed, and held in a manner which could foster bacterial growth and otherwise render Defendant's products dangerous to consumers. Yet, Defendant repeatedly advertised, both on the Contaminated Product labels and on its website, through a national advertising campaign, among other items, that the Contaminated Products were safe for infants to consume, including representations that the specialty formulas were safe for infants with pre-existing health conditions and severe food allergies. Defendant did not disclose that the Contaminated Products contained harmful microbes such as *Cronobacter sakazakii* and *Salmonella Newport*.

102. Defendant breached the implied warranty of merchantability in connection with the sale and distribution of the Contaminated Products. At the point of sale, the Contaminated Products while appearing normal—contained defects as set forth herein rendering them unsuitable and unsafe for personal use.

103. Had Plaintiff and the members of the Class known the Contaminated Products were unsafe for use, they would not have purchased them.

104. Defendant did not provide appropriate warranty relief notwithstanding the risks of using the Contaminated Products. Plaintiff and the members of the Class reasonably expected, at the time of purchase, that the Contaminated Products were safe for their ordinary and intended use.

105. As a direct and proximate result of Abbott's breach of the implied warranty of merchantability, Plaintiff and the members of the Class have sustained damages in an amount to be determined at trial.

COUNT II

VIOLATION OF PENNSYLVANIA'S UNFAIR TRADE PRACTICES AND CONSUMER

PROTECTION LAW

(On Behalf of Plaintiff and the Pennsylvania Class)

106. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.

107. The Pennsylvania Unfair Trade Practices and Consumer Protection Law ("Pennsylvania CPL") prohibits unfair or deceptive acts or practices, including, "[e]ngaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or misunderstanding." 73 P.S. § 201-2(4).

108. Defendant's conduct of manufacturing, producing, and selling Contaminated Products as alleged herein is a violation of the Pennsylvania CPL including but not limited to:

- (ii) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services;
- (iii) Causing likelihood of confusion or of misunderstanding as to affiliation, connection or association with, or certification by, another;
- (v) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have;

(vi) Representing that goods are original or new if they are deteriorated, altered, reconditioned, reclaimed, used or secondhand;

(vii) Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another;

(ix) Advertising goods or services with intent not to sell them as advertised;

(xxi) Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

73 Pa. Stat. § 201-2(4).

109. For example, in the course of Defendant's business, Defendant concealed and suppressed material facts, including that the Contaminated Products contained harmful microbes such as *Cronobacter sakazakii* and *Salmonella* Newport. These microorganisms are not identified as an ingredient on the Contaminated Products' label.

110. Defendant repeatedly advertised, both on the Contaminated Product labels and on its website, through a national advertising campaign, among other items, that the Contaminated Products were safe for infants to consume, including representations that the specialty formulas were safe for infants with pre-existing health conditions and severe food allergies.

111. Yet, as demonstrated in the FDA Forms 483 discussed herein, Defendant engaged in a pattern of unsafe and unsanitary manufacturing, processing, packing, and holding practices of its infant formula. Thus, Defendant knew or should have known that its products were manufactured, processed, packed, and held in a manner which could foster bacterial growth and otherwise render Defendant's products dangerous to consumers.

112. Plaintiff and the members of the Pennsylvania Class were deceived by Defendant's claims that, inter alia, the Contaminated Products "keep [infants] fed, happy, and healthy."

113. Defendant's unfair and deceptive acts or practices occurred repeatedly in Defendant's trade or business, were capable of deceiving a substantial portion of the purchasing public, and imposed a serious safety risk on the public.

114. Defendant knew that the risks inherent in the Contaminated Products made them not suitable for their intended use.

115. Defendant knew or should have known that its conduct violated the Pennsylvania CPL.

116. Had Plaintiff and the members of the Pennsylvania Class known the truth about the Contaminated Products, they would not have purchased the Contaminated Products. Plaintiff and the members of the Pennsylvania Class did not receive the benefit of their bargain as a result of Defendant's misconduct.

117. Defendant owed Plaintiff and the members of the Pennsylvania Class a duty to disclose the truth about the Contaminated Products because Defendant: (a) possessed exclusive, specific and superior knowledge of the true risks of the Contaminated Products; (b) intentionally concealed the foregoing from Plaintiff and the members of the Pennsylvania Class; and/or (c) made incomplete representations regarding the Contaminated Products, while purposefully withholding material facts from Plaintiff and the members of the Pennsylvania Class that contradicted these representations.

118. Plaintiff and the members of the Pennsylvania Class suffered injury in fact to a legally protected interest. As a result of Defendant's conduct, Plaintiff and the members of the Pennsylvania Class were harmed and suffered actual damages.

119. Defendant's violations present a continuing risk to Plaintiff and the members of the Pennsylvania Class, as well as to the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

120. Defendant is liable to Plaintiff and the members of the Pennsylvania Class for treble their actual damages or \$100, whichever is greater, and attorneys' fees and costs under 73 P.S. § 201-9.2(a).

121. Plaintiff and the members of the Pennsylvania Class are also entitled to an award of punitive damages given that Defendant's conduct was malicious, wanton, willful, oppressive, or exhibited a reckless indifference to the rights of others.

122. Plaintiff and the members of the Pennsylvania Class also seek reasonable attorneys' fees and costs pursuant to 73 Pa. Stat. § 201-9.2(a).

COUNT III

NEGLIGENT MISREPRESENTATION

(On Behalf of Plaintiff and the Pennsylvania Class)

123. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.

124. Defendant has a duty to provide accurate information to consumers concerning the nutrition and safety of its powdered infant formula products, including the Contaminated Products and not to make false representations.

125. As demonstrated in the FDA Forms 483 discussed herein, Defendant engaged in a pattern of unsafe and unsanitary manufacturing, processing, packing, and holding practices of its infant formula and knew or should have known that its products were manufactured, processed, packed, and held in a manner which could foster bacterial growth and otherwise render Defendant's products dangerous to consumers. Thus, Defendant knew or should have known that its products were manufactured, processed, packed, and held in a manner which could foster bacterial growth and otherwise render Defendant's products dangerous to consumers.

126. Yet, Defendant repeatedly and negligently advertised, both on the Contaminated Product labels and on its website, through a national advertising campaign, among other items, that the Contaminated Products were safe for infants to consume, including representations that the specialty formulas were safe for infants with pre-existing health conditions and severe food allergies. Defendant did not disclose that the Contaminated Products contained harmful microbes such as Cronobacter sakazakii and Salmonella Newport.

127. Defendant failed to fulfill its duty and obligations when it made false representations regarding the quality and safety of the Contaminated Products as detailed above and was negligent in representing the safety of the infant formula products manufactured at its Sturgis facility.

128. Plaintiff and the members of the Pennsylvania Class did not, and could not, know that Defendant's representations about the safety of its infant formula products were false and believed them to be true. Plaintiff and these Class members reasonably relied upon the misrepresentations made by Defendant to them.

129. In justifiable reliance upon Defendant's negligent misrepresentations, Plaintiff and the members of the Pennsylvania Class were induced to purchase the Contaminated Products that the FDA recommends be discarded.

130. Plaintiff and the members of the Pennsylvania Class suffered economic harm, in an amount to be proven at trial, in that they have purchased the Contaminated Products in reliance upon the misrepresentations of the safety and nutrition of said products by Defendant.

COUNT IV

UNJUST ENRICHMENT

(On Behalf of Plaintiff and the Pennsylvania Class)

131. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.

132. As a result of Defendant's wrongful and deceptive conduct alleged herein, Defendant knowingly and voluntarily accepted and retained wrongful benefits in the form of money paid by the Plaintiff and members of the Class when they purchased the Contaminated Products.

133. In so doing, Defendant acted with conscious disregard for the rights of Plaintiff and members of the Class.

134. As a result of Defendant's wrongful conduct as alleged herein, Defendant has been unjustly enriched at the expense of, and to the detriment of, Plaintiff and members of the Class.

135. Defendant's unjust enrichment is traceable to, and resulted directly and proximately from, the conduct alleged herein.

136. Plaintiff and members of the Class may assert an unjust enrichment claim even though a remedy at law may otherwise exist.

137. Under the doctrine of unjust enrichment, it is inequitable for Defendant to retain the benefits it received, and is still receiving, without justification, from the false and deceptive labeling and marketing of the Contaminated Products to Plaintiff and members of the Class.

138. It is unjust and inequitable for Abbott to retain these sums of money because, among other facts, Defendant: (1) negligently failed to prevent the *Cronobacter sakazakii* and *Salmonella* contamination; (2) failed to discover the presence of these and other bacterial contaminants; (3) falsely and misleadingly represented that the Contaminated Products were safe for infants to consume; (4) concealed known contamination risks at the Sturgis Facility; (5) continued to sell the Contaminated Products for five months instead of initiating a recall in

September 2021; and (6) under the circumstances that existed, no sales of the Contaminated Products should have taken place.

139. Defendant's misrepresentations have injured Plaintiff and members of the Class because Plaintiff and members of the Class would not have purchased (or paid a price premium) for the Contaminated Products had they known the true facts regarding the Contaminated Products' contamination risks.

140. The financial benefits derived by Defendant from obtaining and retain Plaintiff's property rightfully belong to Plaintiff and members of the Class.

141. Because it is unjust and inequitable for Defendant to retain non-gratuitous benefits conferred on it by Plaintiff and members of the Class, Defendant must make restitution to Plaintiff and members of the Class, as ordered by the Court

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the Class, demands a jury trial on all claims so triable and judgment as follows:

A. determine that the claims alleged herein may be maintained as a class action under Rule 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure on behalf of the Pennsylvania Class defined above, and designate Plaintiff as the class representative and Plaintiffs' counsel as counsel for the Pennsylvania Class;

B. award declaratory, equitable and injunctive relief, including but not limited to, requiring Defendants to institute a corrective advertising campaign, restitution, and disgorgement of profits;

C. award all actual, general, special, incidental, punitive, and consequential damages to which Plaintiff and Class members are entitled;

D. award pre-judgment and post-judgment interest on such monetary relief;

- E. award reasonable attorneys' fees and costs; and
- F. grant such further and other relief that this Court deems appropriate.

DEMAND FOR JURY TRIAL

Plaintiff, individually and on behalf of the Class, hereby demands a trial by jury on all issues in this Class Action Complaint that are so triable.

Dated: January 27, 2023

Respectfully submitted,

s/ Timothy J. Becker

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