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**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA**

<p><b>ERICA AND MICKY GOLDFIN</b>, individually and as the parent and natural guardian of W.G., a minor, Plaintiffs,</p> <p>v.</p> <p><b>NARA ORGANICS, INC.</b>, a Delaware corporation; <b>TARGET CORPORATION</b>, a Minnesota corporation; <b>JOHN DOES 1–10</b> (Whole Fluid Milk Suppliers and/or Manufacturers); and <b>JOHN DOES 11–20</b> (Whole Powdered Milk Suppliers and/or Manufacturers), Defendants.</p>	<p>Case No.:</p> <p><b>COMPLAINT FOR DAMAGES and DEMAND FOR JURY TRIAL</b></p>
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Plaintiffs, by and through their undersigned counsel, and for their claims against the Defendants, allege as follows:

**I. PARTIES**

1. Plaintiffs Erica and Micky Goldfin are citizens of the Commonwealth of Pennsylvania, residing in Yardley, Bucks County, Pennsylvania, and are the parents and natural guardians of W.G., the minor child whose injuries are the subject of this action.

2. W.G. is a minor child and a citizen of the State of Pennsylvania who, at all times relevant to this Complaint, resided with Plaintiffs in Bucks County, Pennsylvania.
3. **Defendant Nara Organics, Inc.** (“Nara”) is a for-profit corporation organized and existing under the laws of the State of Delaware. Its principal place of business is located at 250 Greenwich St., 39<sup>th</sup> Floor, New York, New York. Nara conducts business throughout the United States, including in the Commonwealth of Pennsylvania, where it marketed, distributed, and sold the Formula directly to consumers through its website, [www.nara.com](http://www.nara.com), and through Target retail stores and [Target.com](http://Target.com). Therefore, Nara is a citizen of the State of Delaware and the State of New York and is not a citizen of the Commonwealth of Pennsylvania.
4. **Defendant Target Corporation** (“Target”) is a publicly traded, for-profit corporation organized and existing under the laws of the State of Minnesota. Its principal place of business is located at 1000 Nicollet Mall, Minneapolis, Minnesota 55403. Target conducts business throughout the United States, including in the Commonwealth of Pennsylvania, where it operates numerous retail stores and the e-commerce website [Target.com](http://Target.com), through which it sold the subject Nara Organics Whole Milk Organic Infant Formula to consumers including Plaintiffs. Therefore, Target is a citizen of the State of Minnesota and is not a citizen of the Commonwealth of Pennsylvania.
5. **Defendants John Does 1–10** are the presently unknown persons or entities that produced, supplied, and/or manufactured the whole fluid milk used to manufacture the whole milk powder that was incorporated into the subject Nara Organics infant formula. Their true names, identities, citizenship, and roles are not presently known to Plaintiffs and will be substituted by amendment once ascertained.

6. **Defendants John Does 11–20** are the presently unknown persons or entities that manufactured, processed, supplied, and/or sold the whole milk powder that was incorporated into the subject Nara Organics infant formula. Their true names, identities, citizenship, and roles are not presently known to Plaintiffs and will be substituted by amendment once ascertained.
7. At all relevant times, Defendants were engaged in the business of producing, designing, formulating, manufacturing, processing, importing, distributing, marketing, supplying, and/or selling the subject Nara Organics Whole Milk Organic Infant Formula and/or its whole milk and whole milk powder component ingredients, which were capable of harboring, and were adulterated with, *Clostridium botulinum* (“*C. botulinum*”) and/or its spores.

## II. JURISDICTION AND VENUE

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a). Plaintiffs are citizens of the Commonwealth of Pennsylvania. Defendant Nara is a citizen of the State of Delaware and the State of New York, and Defendant Target is a citizen of the State of Minnesota. There is complete diversity of citizenship between Plaintiffs and Defendants, none of whom is a citizen of the Commonwealth of Pennsylvania, and this is an action between citizens of different States within the meaning of 28 U.S.C. § 1332(a)(1). Upon information and belief, none of the John Doe Defendants 1–20 is a citizen of the Commonwealth of Pennsylvania, and the presence of these fictitiously named Defendants therefore does not defeat the complete diversity of citizenship required by 28 U.S.C. § 1332(a). The amount in controversy exceeds \$75,000, exclusive of interest and costs. Moreover, Defendants have certain minimum contacts within the Commonwealth of

Pennsylvania such that maintenance of the suit in this Court does not offend traditional notions of fair play and substantial justice.

9. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in the Eastern District of Pennsylvania.

### III. FACTUAL ALLEGATIONS

#### A. The Nara Organics Infant Botulism Outbreak

10. The United States Food and Drug Administration (“FDA”) and the Centers for Disease Control and Prevention (“CDC”), in collaboration with the California Department of Public Health Infant Botulism Treatment and Prevention Program (“CDPH”) and other state and local partners, investigated and continued to investigate a multistate outbreak of infant botulism. Epidemiologic data identify Nara Organics Whole Milk Organic Infant Formula (the “Formula”) as the source of this outbreak.
11. As of June 13, 2026, the outbreak includes three confirmed or suspected cases of infant botulism among infants from three states: California, Pennsylvania, and Washington. All three infants were hospitalized. The CDPH reported that all three infants suffered *Clostridium botulinum* toxin type A infections, with illness onset dates between April and May 2026. The most recent reported illness onset was May 31, 2026.
12. All three infants included in the outbreak consumed the Formula. Public health officials in two states collected leftover Formula for laboratory testing; that testing is underway, with results expected in the coming weeks.

13. The Formula was distributed nationally through Target retail stores, “Target.com”, and “Nara.com” between July 2025 and June 2026. The Formula was not distributed outside of the United States. Nara manufactured the Formula in Germany.
14. Defendant Target was a primary retail distributor of the Formula, selling the product to consumers nationwide, including in Pennsylvania, through its retail stores and through “Target.com”. Specifically, Target sold 700-gram cans of the Formula throughout its retail stores and via “Target.com” to consumers in various states across the country, including Pennsylvania.
15. Because of the severity of the illnesses and the epidemiological signal linking the illnesses to its product, FDA contacted Nara and recommended that Nara conduct a recall. On June 13, 2026, Nara agreed to recall all of its Nara Organics-brand Whole Milk Organic Powdered Infant Formula then on the market in the United States.
16. In its recall notice, Nara identified the three specific product lots to which the outbreak infants were exposed as Lot Nos. 709125280E14F2, 709125288E14F2, and 708125174E14F2. Nara further recalled all of the following lot codes of the Formula:  
408125075E14F2, 708125076E14F2, 708125083E14F2, 408125139E14F2,  
708125141E14F2, 708125145E14F2, 708125174E14F2, 709125273E14F2,  
709125280E14F2, 709125288E14F2, 409125307E14F2, 70926019ENNB,  
70926029ENNB, 70926035ENNB, 70926039ENNB, and 70926042ENNB.

**B. The Formula and the Centrality of Whole Milk Powder**

17. Nara markets its product as the first and only USDA-certified organic whole-milk infant formula and represents that its formula contains more organic whole milk fat than any other

infant formula sold in the United States. Nara represents that it received a special designation from the FDA in order to use this elevated level of milk fat, and that it is the first USDA organic whole-milk formula to complete its own clinical trial.

18. The FDA does not, however, “approve” infant formula. Under the Federal Food, Drug, and Cosmetic Act, a manufacturer may market a new infant formula only after submitting a notification to the FDA under 21 U.S.C. § 350a and 21 C.F.R. Part 106; the agency issues no premarket approval of any infant formula. Notwithstanding this, Nara has represented to consumers—including in its marketing and on its website—that the Formula is “FDA-approved” and that the FDA granted it a special designation or clearance to use its elevated milk-fat level. Those representations conveyed a false assurance that the Formula had received governmental safety vetting that it had not in fact received. The representations were false or materially misleading, and Plaintiffs justifiably relied upon them in deciding to purchase the Formula and to feed it to W.G.

19. Whole milk—and the whole milk powder used to manufacture the Formula—is, by Nara’s own admission, the defining and dominant ingredient of the Formula. The very characteristic Nara promotes as its principal selling point, its uniquely high organic whole-milk-fat content, is also the ingredient that the FDA and CDC had, before and during the period in which Nara manufactured, distributed, and sold the recalled formula, publicly identified as a vehicle for *C. botulinum* contamination of powdered infant formula.

20. Upon information and belief, the whole milk powder incorporated into the subject Formula was manufactured, processed, and/or supplied by Defendants John Does 11–20 from whole fluid milk produced and/or supplied by Defendants John Does 1–10. Consistent with the FDA’s findings in the contemporaneous ByHeart outbreak described below, the whole

milk powder ingredient is the suspected vehicle by which *C. botulinum* was introduced into the finished Formula consumed by W.G.

**C. Defendants Were on Notice as to the Risks of the Use of Whole Milk Powder in Infant Formula**

21. *C. botulinum* is a spore-forming bacterium. Its spores are found naturally in the environment, including in soil and dust, and can enter food-manufacturing facilities and home environments on hands, shoes, and other contaminated surfaces. Unlike non-spore-forming pathogens such as *Cronobacter sakazakii* and *Salmonella*, *C. botulinum* forms a protective spore that survives typical pasteurization and harsh environmental conditions for long periods, making it especially difficult to eliminate from food and from processing environments.
22. When ingested by an infant, *C. botulinum* spores can germinate in the infant's immature gastrointestinal tract and produce a potent neurotoxin, causing infant botulism—a life-threatening, flaccid paralysis that can progress to respiratory failure and death.
23. Detecting *C. botulinum* and its spores is a complex, multi-stage laboratory process that requires specialized resources and that can take two or more weeks to complete. The unique resilience of spore-forming bacteria means that controlling for, and testing for, *C. botulinum* requires prevention and testing strategies that differ fundamentally from those used for non-spore-forming pathogens.
24. The risk that whole milk powder used in powdered infant formula could harbor *C. botulinum* was neither new nor unique to the ByHeart outbreak described below. National and international food-safety authorities had long recognized that *C. botulinum* is a spore-forming organism of the dairy-farm environment that passes into raw milk and survives

both pasteurization and the drying process by which milk is rendered into powder, and that powdered infant formula is not a sterile product and may contain such pathogens.

25. Most directly, on March 8, 2023—more than two years before the illnesses at issue, and before Nara began distributing the Formula—the FDA issued a written “Call to Action” letter to the powdered-infant-formula industry, signed by the Commissioner of Food and Drugs and the Director of the Center for Food Safety and Applied Nutrition. The letter was expressly directed to “manufacturers, packers, distributors, exporters, importers, and retailers” of powdered infant formula—a description that encompassed Nara—and it named the hazard, stating that “historical associations between powdered infant formula and pathogens such as *Cronobacter* spp., *Salmonella*, and *Clostridium botulinum* should be considered when designing and implementing controls for the safe manufacture of all foods for infants and young children.”
26. The FDA reinforced this warning thereafter. In March 2025, as part of its “Operation Stork Speed” initiative, the FDA announced that it would increase testing of infant formula and its ingredients for spore-forming microbiological contaminants, expressly including *Clostridium botulinum* and *Bacillus cereus*.
27. From late 2025 through early 2026—before and during the period in which Nara manufactured, distributed, and sold the recalled formula—FDA and CDC, in collaboration with CDPH and other partners, investigated a separate, highly publicized multistate outbreak of infant botulism linked to ByHeart Whole Nutrition Infant Formula (the “ByHeart outbreak”). In total, 48 infants became ill across 17 states. CDC declared that outbreak over on February 26, 2026.

28. FDA’s investigation of the ByHeart outbreak identified *C. botulinum* in whole milk powder used to manufacture the infant formula. Whole genome sequencing (“WGS”) analysis showed that two samples from one lot of organic whole milk powder matched both a clinical sample obtained from a sickened infant and a positive finished-product sample of infant formula. The FDA publicly identified incoming dairy ingredients, including whole milk powder, as the focus of the root-cause investigation.
29. Following the ByHeart outbreak, and as publicly memorialized on FDA’s “Post-Outbreak Response Activities: Clostridium botulinum Illnesses Associated with Consumption of Powdered Infant Formula” webpage (last updated June 3, 2026, ten days before the Nara recall), the FDA announced that it was conducting surveillance sampling to assess the presence of *C. botulinum* in powdered milk, and that it had advocated for a Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (“JEMRA”) risk assessment of spore-forming pathogens—expressly including *C. botulinum*—in powdered infant formula. The FDA engaged and communicated with the infant-formula industry about enhancing infant-formula safety in light of these risks.
30. As a result, by the time Nara manufactured, imported, distributed, marketed, and sold the Formula—and certainly during the outbreak’s April through May 2026 illness-onset window and Nara’s July 2025 through June 2026 distribution window—the powdered-infant-formula industry generally, and Nara in particular, knew or in the exercise of reasonable care should have known that whole milk powder used to manufacture powdered infant formula could harbor *C. botulinum* and cause infant botulism. Nara’s knowledge was heightened by the fact that its product was formulated to contain more organic whole milk fat than any other infant formula sold in the United States.

**D. Nara’s Testing Regime Did Not Guard Against the Known Risk**

31. Notwithstanding the known and publicized risk that whole milk powder used in powdered infant formula could harbor *C. botulinum*, Nara, by its own public account, did not test its finished infant formula directly for *C. botulinum*. Instead, Nara screened each batch for sulphite-reducing clostridia (“SRC”) as a proxy for *C. botulinum* and screened for *Clostridium perfringens* and *Bacillus cereus* and certain other microbiological parameters.
32. Nara’s SRC-proxy screening and other quality-control measures did not prevent infant formula capable of causing, and linked to, infant botulism from being manufactured, distributed, sold, and consumed. Despite the known risk, Nara placed and kept its whole-milk-based powdered infant formula in the stream of commerce, where it reached and was consumed by infants, including W.G.
33. The Nara Organics Whole Milk Organic Infant Formula that Nara manufactured, distributed, and sold was adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 342, and the Pennsylvania Food Safety Act, 3 Pa.C.S. § 5721 *et seq.* (including the adulteration provision at 3 Pa.C.S. § 5728), in that it bore or contained a poisonous or deleterious substance—*C. botulinum* and/or its spores and toxin—which rendered it injurious to health, and in that it was unfit for its intended use as infant nutrition.

**E. Infant Botulism Symptoms, Treatment, and Prognosis**

34. Infant botulism is a rare but serious condition caused by the ingestion of *C. botulinum* spores, which can grow in the intestines of infants (typically those under one year old) and produce a potent toxin. The spores can germinate in the immature gastrointestinal tract of infants, leading to toxin production and subsequent illness.

35. Symptoms of infant botulism may include constipation, often the first sign; general lethargy or decreased muscle tone (hypotonia), often described as “floppy baby syndrome”; poor feeding and difficulty sucking or swallowing; a weak or altered cry; drooping eyelids or poor eye movement (ptosis); decreased facial expression; loss of head control; respiratory difficulty and, in severe cases, respiratory arrest; reduced ability to move the arms and legs; and irritability or unusual crying. Symptoms can take as long as several weeks to develop following ingestion.
36. Infants diagnosed with botulism typically require hospitalization to monitor respiratory function and overall health. Treatment focuses on supportive care, including nutritional support (often via intravenous fluids or feeding tubes) and monitoring and management of respiratory function, which in severe cases may require mechanical ventilation.
37. In the United States, a specific treatment called BabyBIG® (Botulism Immune Globulin Intravenous) is administered to infants diagnosed with botulism to neutralize the botulinum toxin and reduce the duration and severity of illness. Antibiotics are not typically used to treat infant botulism, as they do not affect toxin already produced and may promote additional toxin release.
38. With early diagnosis and appropriate treatment, many infants recover, but recovery can be prolonged and the course of illness is severe. Symptoms may resolve over several weeks, and in some cases full recovery, particularly of muscle strength and tone, can take months. Affected infants may require ongoing follow-up to monitor recovery and any residual weakness.

**F. W.G.'s Botulism Illness**

39. W.G. was born on March 2, 2026. Plaintiffs began feeding W.G. the Formula on or about March 5, 2026.
40. Plaintiffs purchased the Formula consumed by W.G. from Target located at 2331 Lincoln Hwy, Langhorne, PA 19047 and Target.com with pick-up at 500 Nassau Park Blvd., Princeton NJ 08540.
41. Beginning on or about May 4, 2026, W.G. began to exhibit symptoms consistent with infant botulism, including constipation, poor feeding, weak cry, loss of head control, hypotonia, and difficulty swallowing.
42. On or about June 1, 2026, W.G. was taken to Children's Hospital of Philadelphia, where he was examined and admitted.
43. W.G. remained in the ICU for 2 nights where he was given fluids intravenously; vitals were monitored every hour, and a respiratory check was conducted every 4 hours. Once admitted to the ICU, W.G. was not allowed to eat for over 18 hours until BabyBIG was delivered the morning of Tuesday, June 2, 2026 and administered intravenously at approximately 5:00 a.m., and the speech team cleared him for feeding. During a feeding evaluation with CHOP's speech team, it was found that W.G. also had thrush, and W.G. began receiving Nystatin, an oral anti-fungal to treat. W.G. moved to general pediatric floor late Wednesday afternoon, where he remained for general monitoring and vital checks, weight checks, and feeding observations until discharge on Saturday, June 6.
44. W.G. is showing substantial improvement after receiving BabyBIG treatment. He is more vocal, smiling, is able to hold his head up, is back to eating 4–5-ounce bottles, is more

efficient at eating and generally displays more movement with arms and legs. W.G. is still being treated for thrush. After evaluation through Pennsylvania's early intervention program, W.G. will be receiving weekly Physical Therapy due to substantial head lag, poor ability to lift and keep head up, and general delay with gross and fine motor skills. Lab testing confirmed W.G. contracted infant botulism Type A.

45. As a direct and proximate result of consuming the Formula contaminated with *C. botulinum*, W.G. suffered serious personal injuries, including infant botulism and its sequelae, and Plaintiffs have suffered injuries and damages as set forth below.

**IV. CAUSES OF ACTION**  
**COUNT I**  
**STRICT PRODUCTS LIABILITY**  
*(Against all Defendants)*

46. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 45 as though fully set forth herein.

47. At all relevant times, Defendants were each engaged in the business of selling, manufacturing, producing, processing, supplying, and/or distributing the Formula and/or its whole milk and whole milk powder component ingredients, and each sold and placed those products into the stream of commerce in a defective condition unreasonably dangerous to the user or consumer, which products were expected to and did reach the user or consumer without substantial change in the condition in which they were sold.

48. At all relevant times, Defendant Nara and Defendants John Does 1–20 were the manufacturers, producers, processors, suppliers, and/or distributors of the Formula, and its whole milk and whole milk powder component ingredients, that are the subject of this

action. At all relevant times, Defendant Target was a seller and retail distributor of the Formula that is the subject of this action and sold and placed the Formula into the stream of commerce in the defective condition described herein, which Formula was expected to and did reach the user or consumer without substantial change in the condition in which Target sold it. As a seller of the defective Formula in the chain of distribution, Defendant Target is subject to strict liability for the resulting harm to the same extent as the other Defendants, without regard to fault.

49. The Formula and its component ingredients were defective and not reasonably safe because, when they left the respective Defendants' control, they deviated in a material way from the manufacturer's design specifications or performance standards, and from otherwise identical units of the same product line, in that they were contaminated with, or harbored, *C. botulinum* and/or its spores. The Formula and its component ingredients were thereby in a defective condition unreasonably dangerous to the user or consumer and were dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased them, with the ordinary knowledge common to the community as to their characteristics. Defendant Nara, Defendants John Does 1–20, and Defendant Target are therefore subject to strict liability for the resulting harm, without regard to fault.

50. The Formula, and its component ingredients, that Defendant Nara and Defendants John Does 1–20 manufactured, produced, processed, supplied, and/or distributed, and that Defendant Target sold and distributed, were, at the time they left those Defendants' control, defective and unreasonably dangerous for their ordinary and expected use because they were contaminated with, or harbored, *C. botulinum* and/or its spores.

51. The Formula was delivered to Plaintiffs without any change in its defective condition. The Formula was used in the manner expected and intended, and was consumed by W.G.
52. Defendant Nara and Defendants John Does 1–20 owed a duty of care to Plaintiffs to design, manufacture, produce, process, supply, and/or distribute food and food ingredients that were not adulterated, that were fit for human consumption, that were reasonably safe in construction, and that were free of pathogenic bacteria, spores, or other substances injurious to human health. These Defendants breached this duty.
53. Defendant Nara and Defendants John Does 1–20 owed a duty of care to Plaintiffs to design, prepare, manufacture, process, supply, distribute, and sell food and food ingredients that were fit for human consumption, and that were safe to the extent contemplated by a reasonable consumer. These Defendants breached this duty.
54. Plaintiffs suffered injury and damages as a direct and proximate result of the defective and unreasonably dangerous condition of the Formula and its component ingredients that Defendant Nara and Defendants John Does 1–20 manufactured, produced, processed, supplied, and/or distributed, in an amount to be proven at trial.

**COUNT II**  
**BREACH OF EXPRESS AND IMPLIED WARRANTIES**

*(Against Defendant Nara)*

55. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 54 as though fully set forth herein.
56. Defendant Nara, at all relevant times a merchant with respect to goods of the kind, expressly and impliedly warranted that the Formula was fit for human consumption as infant nutrition and was free of adulteration and defect. Among other things, Nara expressly

affirmed—on the Formula's packaging and labeling, on its website, and through its marketing—that the Formula was a USDA-certified organic whole-milk infant formula, that it contained more organic whole milk fat than any other infant formula sold in the United States, and that it was the first USDA organic whole-milk formula to complete its own clinical trial. These affirmations of fact and promises became part of the basis of the bargain on which Plaintiffs relied in purchasing the Formula and feeding it to W.G. The Formula did not conform to Defendant Nara's express warranties, in breach of the warranty arising under Pennsylvania law; was not merchantable and would not pass without objection in the trade, in breach of the implied warranty of merchantability arising under Pennsylvania law; and was not fit for the particular purpose for which it was sold and consumed, in breach of the implied warranty of fitness arising under Pennsylvania law.

57. Nara further expressly affirmed, in its marketing and on its website, that the Formula was “FDA-approved” and that the FDA had granted it a special designation or clearance to use its elevated milk-fat level. That affirmation of fact became part of the basis of the bargain on which Plaintiffs relied, and it was false and was breached, because the FDA does not approve infant formula and because the Formula was, in any event, adulterated and unfit as alleged herein.

58. Defendant Nara is liable to Plaintiffs for breaching express and implied warranties it made regarding the Formula that Plaintiffs purchased. These warranties included the implied warranties of merchantability and fitness for a particular purpose. Specifically, Nara expressly and impliedly warranted, through its sale and supply of the Formula to the public and through the statements and conduct of its employees and agents, that the infant formula

it manufactured, distributed, marketed, and sold was fit for human consumption as infant nutrition and was not otherwise adulterated or injurious to health.

59. The *C. botulinum*-contaminated Formula that Nara sold and/or supplied would not pass without objection in trade and was therefore in breach of the implied warranty of merchantability.

60. The *C. botulinum*-contaminated Formula that Nara sold and/or supplied was not fit for the use and purpose intended—human consumption as infant nutrition—and was therefore in breach of the implied warranty of fitness for its intended use.

61. As a direct and proximate result of Nara’s breach of warranties, Plaintiffs sustained injuries and damages in an amount to be proven at trial.

**COUNT III  
NEGLIGENCE**

***(Against all Defendants)***

62. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 61 as though fully set forth herein.

63. Under Pennsylvania law, each Defendant owed Plaintiffs a duty to exercise reasonable care with respect to the Formula and its component ingredients, breached that duty, and each Defendant is liable in negligence for the harm thereby proximately caused. Defendant Nara and Defendants John Does 1–20 are liable for their negligence as manufacturers, producers, processors, importers, suppliers, and/or distributors of the Formula and its component ingredients; and Defendant Target, as a product seller, is liable for the harm caused by the Formula to the extent that harm was proximately caused by Target’s own negligence, as alleged herein.

64. Defendants each owed Plaintiffs a duty to use reasonable care in the production, design, formulation, manufacture, processing, importation, testing, inspection, distribution, marketing, storage, display, and sale of the Formula and its whole milk and whole milk powder component ingredients, so as to prevent the product from being, becoming, or remaining contaminated with *C. botulinum* or any other dangerous pathogen. This duty was heightened by the known and publicized risk that whole milk powder used in powdered infant formula could harbor *C. botulinum*, and by the fact that the product was intended for consumption by infants. Defendants breached these duties.
65. Defendant Nara and Defendants John Does 1–20 had a duty to use and supply ingredients, supplies, and constituent materials—including whole fluid milk and whole milk powder—that were reasonably safe, wholesome, free of defects, and free of adulteration, and to implement testing and process controls adequate to detect and prevent contamination by spore-forming pathogens such as *C. botulinum*. These Defendants breached this duty.
66. Because Nara manufactured the Formula outside the United States and imported it for sale in this country, Nara was also subject to the Foreign Supplier Verification Programs requirements, 21 C.F.R. Part 1, Subpart L, which obligated it, as importer, to evaluate the known and reasonably foreseeable hazards associated with the Formula—including spore-forming pathogens such as *C. botulinum* in its dairy ingredients—and to verify that its foreign supplier or suppliers adequately controlled those hazards. Nara failed to conduct an adequate hazard analysis and foreign-supplier verification as to the *C. botulinum* hazard in whole milk powder and breached these duties.
67. Defendant Target had a duty to use reasonable care in receiving, handling, storing, displaying, marketing, and selling the Formula, including a duty to remove from sale, and

to refrain from selling, product that was subject to recall or that Target knew or in the exercise of reasonable care should have known was unsafe. Target breached this duty.

68. Defendants had a duty to comply with all applicable statutes, laws, regulations, and safety codes pertaining to the production, manufacture, importation, processing, testing, distribution, storage, and sale of infant formula and its component ingredients, and to properly supervise, train, and monitor their employees, agents, and suppliers to ensure such compliance. Defendants breached these duties. Plaintiffs are among the class of persons these statutes, laws, regulations, and safety codes were designed to protect, and the harm suffered is of the type they were designed to prevent.

69. As a direct and proximate result of Defendants' negligence, Plaintiffs sustained injuries and damages in an amount to be proven at trial.

**COUNT IV  
NEGLIGENCE PER SE**

*(Against Defendant Nara and Defendants John Does 1–20)*

70. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 69 as though fully set forth herein.

71. Defendant Nara and Defendants John Does 1–20 had a duty to comply with all applicable state and federal statutes and regulations intended to ensure the purity and safety of the Formula and its component ingredients, including but not limited to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, the infant formula regulations at 21 C.F.R. Parts 106 and 107, the new-infant-formula requirements of 21 U.S.C. § 350a, the adulteration prohibition of 21 U.S.C. § 342(a)(1), the Foreign Supplier Verification Programs regulations at 21 C.F.R. Part 1, Subpart L, and the Pennsylvania Food Safety

Act, 3 Pa.C.S. § 5721 *et seq.* The purpose of these statutes and regulations is, at least in part, to protect a class of persons—including infant consumers of infant formula such as W.G.—from the type of harm suffered here, and they clearly apply to these Defendants’ conduct.

72. Defendant Nara and Defendants John Does 1–20 failed to comply with these statutes and regulations, and were therefore negligent per se in their manufacture, production, processing, importation, supply, distribution, and/or sale of the Formula and its component ingredients that were adulterated in that they bore or contained *C. botulinum* and/or its spores and toxin, a poisonous and deleterious substance that rendered the product injurious to health and unfit for human consumption.

73. As a direct and proximate result of the conduct of Defendant Nara and Defendants John Does 1–20 that was negligent per se, Plaintiffs sustained injury and damages in an amount to be proven at trial.

**COUNT V  
PUNITIVE DAMAGES**

***(Against Defendant Nara and Defendants John Does 1–20)***

74. Plaintiffs incorporate by reference the allegations in paragraphs 1 through 73 as though fully set forth herein.

75. At all relevant times before and during the period in which it manufactured, imported, distributed, marketed, and sold the Formula, Defendant Nara had actual, subjective knowledge of the specific and substantial risk that the whole milk powder used to manufacture the Formula could harbor *C. botulinum* and cause infant botulism in the infants who consumed it. As alleged above, that knowledge arose from, among other

things: (a) the contemporaneous, highly publicized multistate ByHeart outbreak, in which 48 infants across 17 states became ill and in which the FDA identified *C. botulinum* in a whole milk powder ingredient and publicly identified incoming dairy ingredients, including whole milk powder, as the focus of its root-cause investigation; (b) the FDA's public post-outbreak response activities, including surveillance sampling of powdered milk for *C. botulinum* and its advocacy for a JEMRA risk assessment of spore-forming pathogens—expressly including *C. botulinum*—in powdered infant formula; (c) the FDA's direct engagement and communication with the infant-formula industry concerning these risks; and (d) Nara's own knowledge that it had formulated its product to contain more organic whole milk fat than any other infant formula sold in the United States, making the very ingredient identified as the vehicle of contamination the defining and dominant component of its product. Nara's actual, subjective knowledge was further established by the FDA's written March 8, 2023 Call-to-Action letter to the powdered-infant-formula industry, which named *C. botulinum* as a hazard that manufacturers were to consider and control for, and by the FDA's March 2025 announcement, as part of Operation Stork Speed, that it would increase testing of infant formula and its ingredients for *C. botulinum*.

76. With subjective appreciation of that risk, Defendant Nara consciously disregarded it. Despite knowing of the specific *C. botulinum* hazard in whole milk powder, Nara chose not to test the finished Formula directly for *C. botulinum*, relying instead on a screen for sulphite-reducing clostridia as a mere proxy, and Nara placed and kept the Formula in the stream of commerce, where it reached and was consumed by infants, including W.G. Nara's conduct was not a mere failure of reasonable care; it was outrageous and was

undertaken with a reckless and conscious indifference to, and in conscious disregard of, the health and safety of the infant consumers of its product, including W.G.

77. Under the common law of Pennsylvania, punitive damages are recoverable for conduct that is outrageous because of the defendant's evil motive or reckless indifference to the rights of others. *See* Restatement (Second) of Torts § 908(2); *Feld v. Merriam*, 506 Pa. 383, 395, 485 A.2d 742, 747 (1984) (quoting *Chambers v. Montgomery*, 411 Pa. 339, 192 A.2d 355 (1963)). The conduct of Defendant Nara, and of Defendants John Does 1–20 to the extent discovery establishes that they shared the same knowledge and acted with the same conscious disregard, satisfies that standard. Plaintiffs are therefore entitled to an award of punitive damages against these Defendants in an amount sufficient to punish them for their conduct and to deter them and others similarly situated from like conduct in the future.

### **DAMAGES**

78. As a direct and proximate result of the acts and omissions of Defendants, Plaintiffs have suffered general, special, incidental, and consequential damages in an amount to be fully proven at the time of trial. These damages include, but are not limited to, damages for past and future general pain and suffering; past and future loss of enjoyment of life; past and future physical impairment and disability; reasonable and necessary past and future medical care and related expenses; past and future mental anguish and emotional distress; past and future disfigurement; the parent Plaintiffs' past and future expenses, loss of services, and emotional distress arising from the injury to their child; and all other ordinary, incidental, or consequential damages that would or could reasonably be anticipated to arise under the circumstances.

### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs pray for judgment and relief against Defendants as follows:

- a. That the Jury award Plaintiffs judgment against Defendants in such sums as shall be determined to fully and fairly compensate Plaintiffs for all general, special, incidental, and consequential damages incurred, or to be incurred, as the direct and proximate result of the acts and omissions of Defendants, in an amount to be proven at trial;
- b. That the Jury award Plaintiffs punitive damages against Defendant Nara and Defendants John Does 1–20 in an amount sufficient to punish those Defendants for their conduct and to deter them and others similarly situated from like conduct in the future;
- c. That the Court award Plaintiffs their costs, disbursements, and reasonable attorneys' fees to the extent permitted by law;
- d. That the Court award Plaintiffs prejudgment and post-judgment interest as allowed by law;
- e. That the Court award Plaintiffs leave to amend or modify this Complaint as necessary or appropriate after further discovery and after all appropriate parties have been served; and
- f. That the Court award such other and further relief as it deems just and proper.

### **JURY DEMAND**

Plaintiffs demand a trial by jury on all issues so triable.

DATED this 22<sup>nd</sup> day of June, 2026.

Respectfully submitted,

**Ferrara & Gable, LLC**

By: */s/ Michael A. Ferrara, Jr.*

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**Marler Clark, Inc., P.S.**

By: */s/ William D. Marler*

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*Attorneys for Plaintiffs*

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

Place of Accident, Incident, or Transaction: Yardley, Bucks County, Pennsylvania

RELATED CASE IF ANY: Case Number: Judge:

- 1. Does this case involve property included in an earlier numbered suit? Yes
2. Does this case involve a transaction or occurrence which was the subject of an earlier numbered suit? Yes
3. Does this case involve the validity or infringement of a patent which was the subject of an earlier numbered suit? Yes
4. Is this case a second or successive habeas corpus petition, social security appeal, or pro se case filed by the same individual? Yes
5. Is this case related to an earlier numbered suit even though none of the above categories apply? Yes

I certify that, to the best of my knowledge and belief, the within case is / is not related to any pending or previously terminated action in this court.

Civil Litigation Categories

A. Federal Question Cases:

- 1. Indemnity Contract, Marine Contract, and All Other Contracts
2. FELA
3. Jones Act-Personal Injury
4. Antitrust
5. Wage and Hour Class Action/Collective Action
6. Patent
7. Copyright/Trademark
8. Employment
9. Labor-Management Relations
10. Civil Rights
11. Habeas Corpus
12. Securities Cases
13. Social Security Review Cases
14. Qui Tam Cases
15. Cases Seeking Systemic Relief \*see certification below\*
16. All Other Federal Question Cases. (Please specify):

B. Diversity Jurisdiction Cases:

- 1. Insurance Contract and Other Contracts
2. Airplane Personal Injury
3. Assault, Defamation
4. Marine Personal Injury
5. Motor Vehicle Personal Injury
6. Other Personal Injury (Please specify):
7. Products Liability
8. All Other Diversity Cases: (Please specify):

I certify that, to the best of my knowledge and belief, that the remedy sought in this case does / does not have implications beyond the parties before the court and does / does not seek to bar or mandate statewide or nationwide enforcement of a state or federal law including a rule, regulation, policy, or order of the executive branch or a state or federal agency, whether by declaratory judgment and/or any form of injunctive relief.

ARBITRATION CERTIFICATION (CHECK ONLY ONE BOX BELOW)

I certify that, to the best of my knowledge and belief:

[X] Pursuant to Local Civil Rule 53.2(3), this case is not eligible for arbitration either because (1) it seeks relief other than money damages; (2) the money damages sought are in excess of \$150,000 exclusive of interest and costs; (3) it is a social security case, includes a prisoner as a party, or alleges a violation of a right secured by the U.S. Constitution, or (4) jurisdiction is based in whole or in part on 28 U.S.C. § 1343.

[ ] None of the restrictions in Local Civil Rule 53.2 apply and this case is eligible for arbitration.

NOTE: A trial de novo will be by jury only if there has been compliance with F.R.C.P. 38.

CIVIL COVER SHEET

The JS 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
Erica & Micky Goldfin for W.G. (a minor)
(b) County of Residence of First Listed Plaintiff Bucks County
(c) Attorneys (Firm Name, Address, and Telephone Number) Ferrara & Gable LLC

DEFENDANTS
Nara Organics Inc & Target Corporation
County of Residence of First Listed Defendant New York County
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)
1 U.S. Government Plaintiff
2 U.S. Government Defendant
3 Federal Question
4 Diversity

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
PTF DEF
Citizen of This State
Citizen of Another State
Citizen or Subject of a Foreign Country

IV. NATURE OF SUIT (Place an "X" in One Box Only) Click here for: Nature of Suit Code Descriptions.

Table with columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Personal Injury, Property Damage, Labor, etc.

V. ORIGIN (Place an "X" in 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
6 Multidistrict Litigation - Transfer
8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. §1332(a) Diversity
Brief description of cause:
Infant food poisoning via Clostridium botulinum

VII. REQUESTED IN COMPLAINT:
CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.
DEMAND \$
CHECK YES only if demanded in complaint:
JURY DEMAND: [X] Yes [ ] No

VIII. RELATED CASE(S) IF ANY
(See instructions):
JUDGE
DOCKET NUMBER

DATE SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY
RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

**INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44**

## Authority For Civil Cover Sheet

The JS 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 only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (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 time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (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" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.  
 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 to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.  
 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. Section 1407.  
 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 statute.
- 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.