**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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| XACIL ARCHULETA, individually and on behalf of all others similarly situated,<br><br>*Plaintiff*,<br><br>v.<br><br>BYHEART, INC.<br><br>*Defendant*. | Case No.<br><br>**CLASS ACTION COMPLAINT**<br><br>**JURY TRIAL DEMANDED** |

Plaintiff Xacil Archuleta ("Plaintiff"), individually and on behalf of all others similarly situated, by her attorneys, alleges the following upon information and belief, except for those allegations pertaining to Plaintiff, which are based on personal knowledge.

## INTRODUCTION

1. ByHeart, Inc. ("ByHeart" or "Defendant") manufactures, markets, and sells ByHeart Whole Nutrition Infant Formula in both 24 oz cans and single-serve "Anywhere Pack" pouches (the "Products").[1] ByHeart aggressively marketed these Products as a revolutionary, premium infant formula that was safer, cleaner, and more rigorously tested than competing formulas, promising parents "A Better Formula for Formula®" and touting its "Clean Label Project Certified" status. However, despite these bold marketing claims, the Products were defectively manufactured and contaminated with Clostridium botulinum, the deadly bacteria that

[1] The Products include ByHeart Whole Nutrition Infant Formula 24 oz cans (UPC: 85004496800) and ByHeart Whole Nutrition Infant Formula Anywhere Pack single-serve pouches (UPC: 85004496802), as well as all substantially similar products designed, manufactured, marketed, distributed, and sold by ByHeart.

causes infant botulism (the "Defect"). ByHeart knew or should have known of serious manufacturing and contamination issues at its facilities through years of FDA inspections, Warning Letters documenting pathogenic contamination, and repeated findings of unsafe conditions. Despite this knowledge, ByHeart failed to disclose the Defect or its history of contamination problems to consumers in its labeling, packaging, or marketing materials (the "Material Omissions"). After a nationwide outbreak of infant botulism sickened at least fifteen infants across twelve states—with all affected babies having consumed ByHeart formula—Defendant initiated an inadequate and untimely recall on November 8, 2025, which it then expanded on November 11, 2025 to include all Products nationwide (the "Recall"). As a result, hundreds of thousands of dangerously defective Products were sold to unsuspecting parents who relied on ByHeart's promises of superior safety and quality. Plaintiff brings suit, individually and on behalf of all others similarly situated, to seek compensation and injunctive relief to fully compensate all consumers who purchased the Products and hold ByHeart accountable for placing profit over the health and safety of the nation's most vulnerable population—infants.

## PARTIES

***Plaintiff***

2. Plaintiff Xacil Archuleta is a citizen and domicile of Long Beach, California.

3. Plaintiff purchased ByHeart Whole Nutrition Infant Formula from Amazon.com on or around October 24, 2025.

4. Prior to purchasing the Products, Plaintiff reviewed the Products' labeling, packaging, and marketing materials. Plaintiff observed no safety warnings, no mention of a risk of harm from using the Products due to the Defect, nor any mention of ByHeart's history of contamination issues and FDA Warning Letters.

5. Based on ByHeart's labeling, packaging, and marketing materials, the Material Omissions, and ByHeart's reputation as a premium infant formula manufacturer, Plaintiff reasonably believed the Products did not suffer from the Defect and did not pose safety risks to infants.

6. Plaintiff relied on ByHeart's specific marketing claims regarding safety and quality.

7. Had Plaintiff known that the Products suffered from the Defect, posed a significant safety risk to infants, or that ByHeart had a history of pathogenic contamination at its facilities and FDA enforcement actions, Plaintiff would not have purchased the Products, or would have paid significantly less for them.

8. As such, Plaintiff has been directly financially injured by ByHeart's deceptive and misleading advertising, Material Omissions, and defective manufacture of the Products.

***Defendant***

9. Defendant ByHeart, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 131 Varick Street, 11th Floor, New York, New York 10013.

10. Defendant ByHeart is a citizen of the State of Delaware and the State of New York for purposes of diversity jurisdiction.

11. Defendant ByHeart is in the business of manufacturing, marketing, distributing, and selling infant formula products throughout the United States, including in the State of New York.

12. Defendant ByHeart owns and/or controls the manufacturing and packaging facilities where the Products were manufactured and where the Products were blended and packaged.

13. Defendant ByHeart's relevant business decision making, including its marketing for the Products and its response to contamination issues at its facilities, originated and continues to originate out of its New York headquarters and/or its presence in New York.

**JURISDICTION AND VENUE**

14. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(d)(2). The amount in controversy exceeds $5,000,000, exclusive of interest and costs, and the matter is a class action in which one or more members of the proposed class are citizens of a state different from Defendant.

15. This Court has personal jurisdiction over Defendant because Defendant's principal place of business and corporate headquarters are located at 131 Varick Street, 11th Floor, New York, New York 10013, within this District. Defendant conducts substantial business in this State and within this District, receives substantial compensation and profits from the marketing, distribution, and sale of the Products in this District, and has engaged in the unlawful practices described in this Complaint within this District. Moreover, Defendant has intentionally availed itself of the laws and markets within this District through its substantial business operations, including corporate decision-making, marketing strategy, and oversight of manufacturing operations emanating from its New York headquarters.

16. In accordance with 28 U.S.C. § 1391(b)(1), venue is proper in this District because Defendant ByHeart, Inc. resides in this District, as its principal place of business and corporate headquarters are located within the Southern District of New York. Additionally, 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 Plaintiff's claims occurred in this District, including Defendant's corporate decision-making regarding the Products' design, manufacturing oversight, marketing strategy, response to contamination issues at its facilities, and implementation of the inadequate Recall, all of which originated and continue to originate from Defendant's New York headquarters.

## COMMON FACTUAL ALLEGATIONS

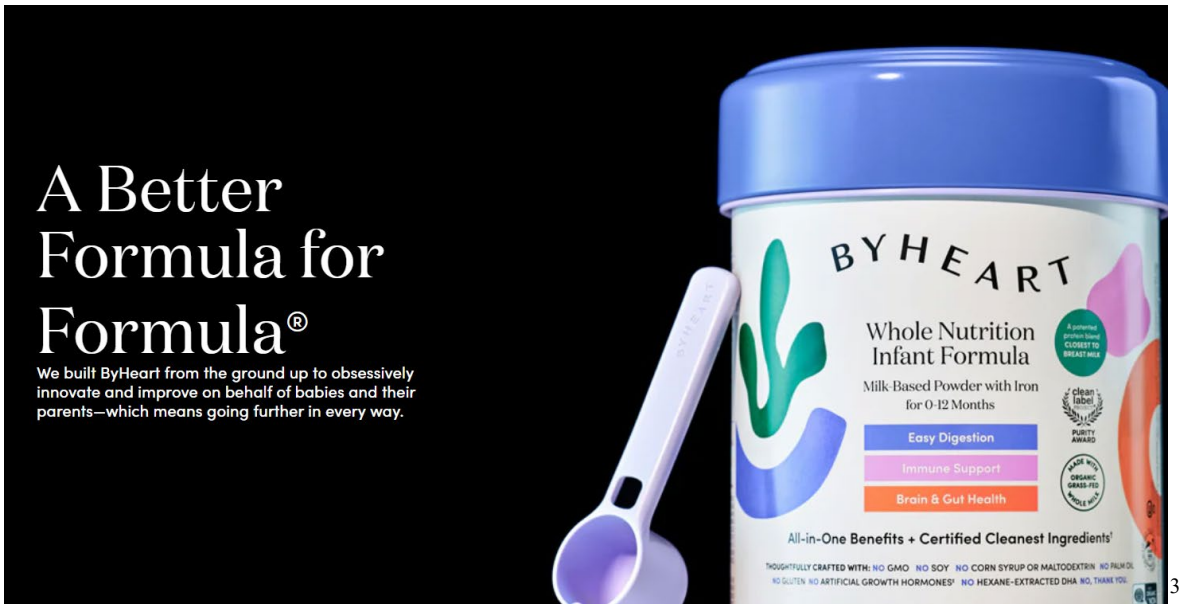
### I. ByHeart's Deceptive Marketing and "Clean Formula" Promise

17. ByHeart was founded in 2016 with the stated mission to create a revolutionary infant formula because, according to its marketing materials, existing formula manufacturers forced mothers and families to compromise the health and safety of infants by using substandard formula.[2]

18. ByHeart aggressively marketed the Products as superior to competing infant formulas and touted numerous safety and quality claims designed to differentiate its brand.

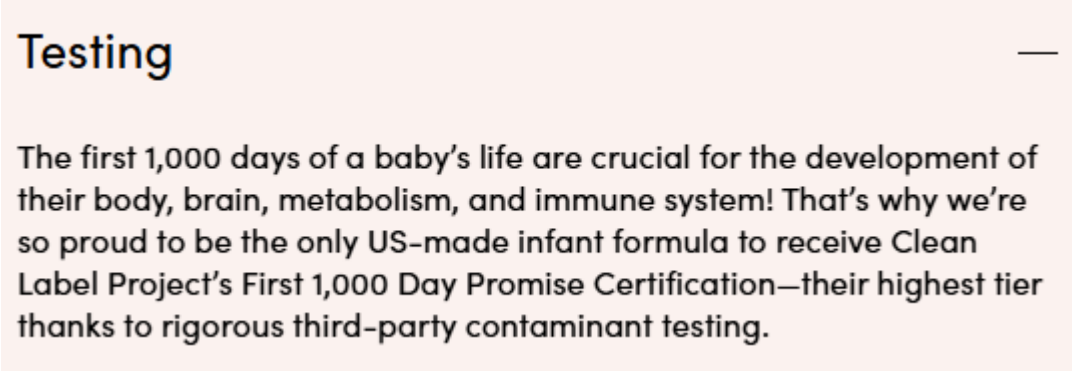
19. Through highly sophisticated marketing and advertising across various platforms, including social media, ByHeart consistently positioned quality as central components of its brand image, making specific representations as demonstrated below:

[2] https://canvasbusinessmodel.com/blogs/brief-history/byheart-brief-history (last accessed Nov. 14, 2025).



[3]

20. ByHeart prominently featured its "Clean Label Project Certified" status in its marketing:



[4]

21. Nowhere on ByHeart's labels, packaging, or marketing materials does it disclose the risk of the Defect to infants drinking the formula, as evidenced by the photographs above.

22. ByHeart's marketing materials also emphasize that it owns "end-to-end manufacturing…[which is] a big deal because what you own, you can control."[5]

[3] https://byheart.com/pages/our-standards (last accessed Nov. 14, 2025).

[4] *Id.*

[5] *Id.*

23. As a result of ByHeart's targeted marketing regarding the safety and quality of the Products, consumers recognized the ByHeart brand as a reliable source for safe, premium infant formula.

24. Consequently, these consumers reasonably relied on ByHeart to produce safe, reliable infant products that were cleaner and more rigorously tested than competing formulas.

25. Parents' trust was essential for ByHeart's commercial success, and ByHeart advertised its commitment to safety by leading reasonable consumers to believe that ByHeart ensured the Products were safe and superior to competing formulas.

26. ByHeart's marketing was a commercial success, with the company selling approximately 200,000 cans of infant formula per month through online channels and major retailers nationwide.

## II. The Product is Adulterated and Dangerously Defective

27. Unbeknownst to consumers, the Products suffer from the Defect which poses severe health risks to infants.

28. Specifically, the Defect involved contamination of the Products with *Clostridium botulinum*, the deadly bacteria that produces botulinum toxin and causes infant botulism.

29. Infant botulism is a rare but serious condition caused by the ingestion of *Clostridium botulinum* spores, which can grow in the intestines of infants (typically those under one year old) and produce a potent toxin.

30. The spores can germinate in the immature gastrointestinal tract of infants, leading to toxin production and subsequent illness.

31. Symptoms of infant botulism typically appear between 12 to 36 hours after ingestion of the spores, though the incubation period can range from 3 to 30 days, and may include:

- Constipation, often the first sign;
- Weakness and general lethargy or decreased muscle tone (hypotonia), often described as "floppy baby syndrome";
- Poor feeding, difficulty feeding or sucking;
- Cranial nerve dysfunction, including weak cry or inadequate vocalization, difficulty swallowing, drooping eyelids or poor eye movement;
- Respiratory problems, including difficulty breathing due to muscle weakness; and
- Weakness in movement, including reduced ability to move arms and legs.

32. Infant botulism is a medical emergency requiring immediate hospitalization. Most infants with infant botulism will initially develop constipation, poor feeding, loss of head control, and difficulty swallowing, which can progress to difficulty breathing and respiratory arrest.

33. Treatment for infant botulism requires hospitalization to monitor respiratory function and general health, with infants often requiring:

- Supportive care, including nutritional support via intravenous fluids or feeding tubes;
- Monitoring and management of respiratory function, with mechanical ventilation required in some cases;
- Administration of Botulism Immune Globulin (BabyBIG), a specific treatment that helps neutralize the botulinum toxin and can reduce the duration and severity of symptoms; and
- Occupational, physical, and speech therapy during recovery.

34. BabyBIG is an extremely scarce medication that must be obtained from the Infant Botulism Treatment and Prevention Program and flown to hospitals for administration.

35. Recovery time from infant botulism varies, with symptoms usually resolving over several weeks, but in some cases, full recovery can take months, especially regarding muscle strength and tone.

36. Botulism can be fatal, and infants who have consumed contaminated formula and are experiencing symptoms require immediate medical attention.

37. Infant formula should be designed and manufactured with robust contamination control systems to ensure that deadly pathogens such as *Clostridium botulinum* do not contaminate the product, as exposure to infant botulism is dangerous and potentially fatal to infants.

38. At the time of the Recall, at least fifteen infants across twelve states had been sickened with suspected or confirmed infant botulism after consuming the Products, with all fifteen infants requiring hospitalization and treatment with BabyBIG.

39. ByHeart acknowledged the Defect and initiated the Recall, which Plaintiff discusses in more depth later in this Complaint.

## III. ByHeart Knew Its Manufacturing Processes Were Unsafe

40. ByHeart's representations regarding its control over manufacturing and commitment to safety were contrary to its actual business practices and knowledge of serious contamination issues at its facilities.

41. ByHeart owns and/or controls the manufacturing and packaging facilities where the Products were manufactured, including Blendhouse LLC in Reading, Pennsylvania, where the infant formula base was manufactured, Blendhouse Allerton, LLC in Allerton, Iowa, and Blendhouse Portland LLC in Portland, Oregon, where the Products were blended and packaged.

42. The Reading facility achieved its FDA registration on April 28, 2022 and was subjected to an initial FDA inspection in June 2022.

43. In 2022, testing revealed the possibility of contamination of ByHeart's products with *Cronobacter sakazakii*, another deadly bacteria, and ByHeart issued a recall.[6]

[6] https://www.threesquare.org/images/about-threesquare/agency-partners/recalls/2023_recalls/Byheart_Issues_Voluntary_Recall_of_Five_Batchespdf.pdf (last accessed Nov. 14, 2025).

44. After the 2022 contamination event, when child illnesses were linked to *Cronobacter sakazakii* and infant formula, the FDA chose to take an in-depth look at all powdered infant formula manufacturing sites, including ByHeart's facilities.

45. The FDA investigation team uncovered numerous serious problems at ByHeart's Reading facility, which were summarized in a Warning Letter dated August 30, 2023.[7]

46. The FDA Warning Letter documented that "a batch of ByHeart Whole Nutrition Infant formula finished product" had tested positive for the deadly *Cronobacter sakazakii* bacteria.

47. The FDA Warning Letter noted that the contaminated finished product was part of a continuous manufacturing process starting with infant formula base manufactured at ByHeart's Reading, Pennsylvania facility, directly contradicting ByHeart's public claims that the contamination was unrelated to its own manufacturing.

48. The FDA Warning Letter documented a lack of process control system, as evidenced by a finding of *Cronobacter sakazakii* in a batch of ByHeart Whole Nutrition Infant Formula finished product, with the infant formula base incorporated into that batch having been manufactured in continuous process from July 13, 2022 through August 23, 2022.

49. The FDA Warning Letter noted that ByHeart's root cause analysis of the *Cronobacter* contamination problem blamed a third-party laboratory rather than any manufacturing issue.

50. According to the FDA Warning Letter, ByHeart's conclusion was simply not supportable by the evidence and ByHeart failed to take "any additional efforts to evaluate other routes of contamination."[8]

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[7] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/byheart-inc-653854-08302023 (last accessed Nov. 14, 2025).

[8] *Id.*

51. The FDA Warning Letter documented "Multiple notifications from third party lab of positive *Cronobacter sakazakii* findings from July 25, 2022 through August 27, 2022 within the processing environment."[9]

52. The FDA Warning Letter documented two water events, during which water leaked into the manufacturing areas from outside ByHeart's facilities.

53. In 2022, ByHeart had actual notice of manufacturing issues resulting in pathogenic contamination but chose to blame others and protect its brand rather than fully evaluate its production processes in light of the contamination.

54. Despite this extensive history of safety failures and contamination issues, ByHeart continued to aggressively market the Products as exceptionally safe, and manufactured with rigorous quality and safety testing.

55. ByHeart's marketing claims of owning and controlling its entire manufacturing process "soup to nuts" and having "control over every can" were false in light of its documented failure to maintain adequate process controls, sanitary conditions, and contamination prevention measures at its facilities.

## IV. The Nationwide Infant Botulism Outbreak Linked to ByHeart

56. In late October and early November 2025, the CDC detected an increase in the expected number of infant botulism cases and began investigating possible causes.

57. State and local public health officials interviewed caregivers about the foods infants were fed in the month before they got sick.

58. Although, upon information and belief, ByHeart's formula represents less than 1% of the formula market, public health investigators soon found that multiple infants from

[9] *Id.*

different states with infant botulism had all consumed ByHeart formula in the days and weeks before their diagnosis.

59. As of November 14, 2025, the outbreak included twenty-three infants with suspected or confirmed infant botulism.[10]

60. For fourteen cases with illness onset information available, illnesses started on dates ranging from August 9, 2025 to November 10, 2025.

61. Fifteen infant botulism cases were identified that were fed ByHeart Whole Nutrition powdered infant formula before getting sick.

62. Preliminary laboratory results reported by the California Department of Public Health suggest the presence of the bacteria that produce botulinum toxin in an open can of ByHeart infant formula (lot 206VABP/251131P2) that was fed to an infant with infant botulism.[11]

63. The positive test result from California confirmed that the Products contained the deadly bacteria responsible for the nationwide outbreak.

## V. The Recall Was Untimely and Inadequate

64. On November 7, 2025, ByHeart was notified by the FDA that an estimated eighty-five cases of infant botulism were reported nationwide since August 2025, with thirteen babies having consumed ByHeart formula at some point.

65. Only after being notified by the FDA of an active outbreak investigation did ByHeart take any action to recall the Products.

[10] https://www.bostonglobe.com/2025/11/14/business/botulism-baby-formula-byheart-fda/ (last accessed Nov. 14, 2025).

[11] https://www.cdph.ca.gov/Programs/OPA/Pages/NR25-017.aspx (last accessed Nov. 14, 2025).

66. On November 8, 2025, within twenty-four hours of FDA notification, ByHeart issued an initial limited recall of two specific batches of the Products.[12]

67. The initial recall was inadequate because parents and caregivers had reported feeding infants in the outbreak different lots of ByHeart infant formula that were not included in the initial recall.

68. On November 11, 2025, ByHeart expanded the recall to include all ByHeart formula products nationwide, including both cans and single-serve Anywhere Pack sticks.[13]

69. The expanded recall applied to all batches of ByHeart Whole Nutrition Infant Formula cans and all Anywhere Packs.

70. ByHeart described the Recall as voluntary and claimed it was conducted in close collaboration with the FDA.

71. The Recall failed to provide an adequate remedy for consumers who had purchased the Products.

72. ByHeart instructed consumers to "immediately discontinue use and dispose of the product" but offered no refund or replacement for the contaminated Products.

73. The Recall's "remedy" of simply disposing of the product failed to make consumers whole for their economic loss.

74. The Recall's failure to offer refunds or replacements provided little incentive for consumers to remove the dangerous product from circulation and properly dispose of it.

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[12] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/response-broader-fda-investigation-byheart-initiates-voluntary-recall-two-batches-infant-formula (last accessed Nov. 14, 2025).

[13] https://byheart.com/pages/byheart-broadens-voluntary-recall-while-investigation-continues (last accessed Nov. 14, 2025).

75. Consumers who purchased the Products, including Plaintiff, suffered economic loss by purchasing defective and contaminated infant formula that could not safely be used for its intended purpose. Plaintiff and the Class never would have purchased the Products absent the Material Omissions regarding the Defect made on the Products labeling, packaging, and marketing materials.

76. The inadequate Recall left consumers without compensation for the premium price they paid for Products.

## PLAINTIFF'S SPECIFIC ALLEGATIONS

77. Plaintiff purchased ByHeart Whole Nutrition Infant Formula from Amazon.com on or around October 24, 2025.

78. Prior to purchasing the Products, Plaintiff reviewed the Products' labeling, packaging, and marketing materials. She purchased ByHeart Formula because of its purported healthier ingredients and because it was organic. Plaintiff observed no safety warnings, no mention of a risk of harm from using the Products due to the Defect, nor any mention of ByHeart's history of contamination issues and FDA Warning Letters.

79. Based on ByHeart's labeling, packaging, and marketing materials, the Material Omissions, and ByHeart's reputation as a premium infant formula manufacturer, especially one promoting healthy, organic formula, Plaintiff reasonably believed the Products did not suffer from the Defect and did not pose safety risks to infants.

80. When Plaintiff learned of the Recall, she immediately discarded her ByHeart formula and switched brands. The ByHeart formula she purchased was literally worthless to her, as she could not use it for its express purpose—feeding her baby—because of the Recall and hazardous contamination.

81. Alternatively, Plaintiff paid a price premium for ByHeart Formula, and she would have paid significantly less than she paid but for ByHeart's Material Omissions.

## CLASS ACTION ALLEGATIONS

82. Plaintiff brings this action individually and on behalf of all others similarly situated, pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), 23(b)(3), 23(c)(4), and 23(c)(5), on behalf of herself and the members of the following proposed nationwide class ("**Nationwide Class**"):

> **During the fullest period allowed by law, all persons in the United States who purchased ByHeart Whole Nutrition Infant Formula for personal use and not for resale.**

83. Alternatively, Plaintiff brings this action individually and on behalf of all others similarly situated, pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), 23(b)(3), 23(c)(4), and 23(c)(5), on behalf of herself and the members of the following proposed California class ("**California Class**"):

> **During the fullest period allowed by law, all persons in the state of California who purchased ByHeart Whole Nutrition Infant Formula for personal use and not for resale.**

84. Specifically excluded from this definition are: (1) Defendant, any entity in which Defendant has a controlling interest, and its legal representatives, officers, directors, employees, assigns and successors; (2) the Judge to whom this case is assigned and any member of the Judge's staff or immediate family; and (3) Class Counsel. Plaintiff reserves the right to amend the Class definition as necessary.

85. Plaintiff seeks only damages and equitable relief on behalf of herself and the putative Class. Plaintiff disclaims any intent or right to seek any recovery in this action for personal injuries, wrongful death, or emotional distress suffered by Plaintiff and/or putative Class Members.

86. Plaintiff reserves the right to modify the class definition, if necessary, to include additional products made by Defendant with the same Defect and/or other products manufactured by Defendant with the common Defect but bearing different brand names.

87. ***Numerosity:*** The Members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class Members is presently unknown, it likely consists of at least hundreds of thousands of people throughout the United States. Defendant sold approximately 200,000 cans of infant formula per month through online channels and major retailers nationwide. The number of Class Members can be determined by sales information and other records. Moreover, joinder of all potential Class Members is not practicable given their numbers and geographic diversity. The Class is readily identifiable from information and records in the possession of Defendant and its authorized distributors and retailers.

88. ***Typicality:*** The claims of the representative Plaintiff are typical in that Plaintiff, like all Class Members, purchased ByHeart Whole Nutrition Infant Formula that was manufactured, marketed, advertised, distributed, and sold by Defendant. Plaintiff, like all Class Members, was damaged by Defendant's uniform misconduct in that, inter alia, they have incurred or will continue to incur damage as a result of overpaying for the Products that were manufactured with the Defect, which makes the Products unusable, inherently dangerous, and not fit for their intended use, and which is subject to an inadequate Recall. Furthermore, the factual basis of Defendant's misconduct is common to all Class Members because Defendant engaged in systematic fraudulent behavior that was deliberate, includes negligent misconduct, and results in the same injury to all Class Members. Plaintiff is advancing the same claims and legal theories on behalf of herself and all members of the Class she seeks to represent.

89. ***Commonality:*** Common questions of law and fact exist as to all Members of the Class. These questions predominate over questions that may affect only individual Class Members because Defendant has acted on grounds generally applicable to the Class. Such common legal or factual questions include, *inter alia*:

- Whether the Products are defective;
- Whether the Products are defectively designed and/or manufactured;
- Whether Defendant knew or should have known about the Defect in its Products prior to distributing and selling them to Plaintiff and Class Members;
- Whether Defendant knew or should have known about the Defect in its Products after distributing and selling them to Plaintiff and Class Members;
- Whether Defendant concealed from and/or failed to disclose to Plaintiff and Class Members that the Products contained a uniform Defect;
- Whether Defendant failed to adequately warn Plaintiff and Class Members that the Products contained the Defect, were contaminated with *Clostridium botulinum*, and posed serious health risks including infant botulism;
- Whether Defendant engaged in unfair, unconscionable, or deceptive trade practices by selling and/or marketing the Products containing the Defect;
- Whether Defendant has violated consumer protection statutes;
- Whether Defendant has been unjustly enriched;
- Whether Defendant breached the implied warranties;
- Whether Defendant's conduct was negligent;
- Whether Defendant breached express warranties relating to the Products;

90. Defendant engaged in a common course of conduct giving rise to the legal rights sought to be enforced by Plaintiff, on behalf of herself and other Class Members. Similar or identical statutory violations, common law wrongs, business practices, and injuries are involved. Individual questions, if there are any, pale by comparison, in both quality and quantity, to the numerous common questions that predominate in this action.

91. ***Adequate Representation:*** Plaintiff will fairly and adequately protect the interests of Class Members. Plaintiff has no interests antagonistic to those of other Class Members. Plaintiff retained attorneys experienced in the prosecution of class actions, including consumer products, infant products, product defects, misrepresentation, mislabeling, and false advertising, and Plaintiff intends to prosecute this action vigorously.

92. ***Injunctive/Declaratory Relief:*** The elements of Rule 23(b)(2) are met. Defendant will continue to commit the unlawful practices alleged herein, and Plaintiff and Class Members will continue to be deceived by Defendant's Material Omissions and unknowingly be exposed to the risk of serious and life-threatening harm associated with the Products. Defendant has acted and refused to act on grounds that apply generally to the Class, such that final injunctive relief, public injunctive relief, and corresponding declaratory relief are appropriate respecting the Class as a whole. Injunctive relief, and specifically public injunctive relief, is necessary in this action.

93. Plaintiff further seeks injunctive and declaratory relief requiring Defendant to cease its unfair, deceptive, and unlawful conduct, including a complete recall of the entire product line and reimbursement of the full purchase price.

94. Plaintiff also seeks a declaration that the Products suffer from the Defect and that all warranties cover the Defect, which existed at the time of sale of the Products to consumers, which was known to Defendant and unknown to consumers.

95. Plaintiff and Class Members have been harmed and will experience irreparable future harm should Defendant's conduct not be enjoined because consumers will continue to use the Products, which still contain the Defect.

96. ***Predominance and Superiority:*** Plaintiff and Class Members have all suffered and will continue to suffer risk of harm and damages as a result of Defendant's unlawful and

wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the controversy. Absent a class action, Class Members would likely find the cost of litigating their claims prohibitively high given the average price point of the Products and would therefore have no effective remedy at law. Because of the relatively small size of Class Members' individual claims, it is likely that few Class Members could afford to seek legal redress for Defendant's misconduct. Absent a class action, Class Members will continue to incur damages, and Defendant's misconduct will continue without remedy. Class treatment of common questions of law and fact would also be a superior method to multiple individual actions or piecemeal litigation in that class treatment will conserve the resources of the courts and the litigants and will promote consistency and efficiency of adjudication.

97. The claims presented in this case predominate over any questions of law or fact affecting individual Class Members.

98. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

99. Defendant's failure to implement an adequate recall for the Products arises out of a common omission or failure to act, which has a uniform effect on Plaintiff and all Class Members. Plaintiff seeks preliminary and permanent injunctive relief and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to require Defendant to discontinue its unlawful conduct.

100. Defendant implemented uniform procedures relating to the Recall, which resulted in uniform damage to Plaintiff and Class Members. As a result, Defendant has acted or refused to act on grounds generally applicable to each Class Member, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.

101. Because Plaintiff seeks injunctive and corresponding declaratory and equitable relief for the entire Class, the prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications with respect to individual Class Members, which would establish incompatible standards of conduct for Defendant.

## CLAIMS FOR RELIEF

### COUNT I
### VIOLATIONS OF NEW YORK GENERAL BUSINESS LAW §§ 349 & 350
### (*On Behalf of Plaintiff and the Nationwide Class*)

102. Plaintiff Xacil Archuleta, individually and on behalf of the Nationwide Class, adopts and incorporates by reference the allegations contained in all preceding paragraphs as though fully set forth herein.

103. This Count is brought pursuant to New York General Business Law §§ 349 and 350 ("GBL §§ 349 & 350"), which prohibit deceptive acts or practices and false advertising in the conduct of any business, trade or commerce in New York State.

104. GBL § 349 provides that "[d]eceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state are hereby declared unlawful."

105. GBL § 350 provides that "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful."

106. GBL § 350-a(1) provides that "[t]he term 'false advertising' means advertising, including labeling, of a commodity . . . if such advertising is misleading in a material respect."

107. Defendant's design, manufacture, distribution, marketing, advertising, labeling, and sale of the Products constitutes "business, trade or commerce" under GBL § 349(a) and GBL § 350.

108. Defendant's conduct violates GBL §§ 349 and 350 because Defendant engaged in the deceptive acts and practices and false advertising described herein.

109. As detailed above, Defendant made false or misleading statements to Plaintiff and Class Members regarding the safety of the Products through its aggressive marketing campaign, including representations that the Products were exceptionally safe, manufactured with rigorous quality and safety testing, and that Defendant owned and controlled its entire manufacturing process with "control over every can."

110. Defendant's representations were false and misleading because the Products contain the Defect and are not safe for infant consumption. The Products were contaminated with *Clostridium botulinum*, a deadly bacteria that causes infant botulism.

111. Defendant's conduct was further deceptive because Defendant failed to disclose the Defect associated with the Products. Specifically, Defendant failed to adequately warn Plaintiff and Class Members that the Products contained the Defect, were contaminated with *Clostridium botulinum*, posed serious health risks including infant botulism, and could cause and had caused infants to become seriously ill and require hospitalization.

112. Defendant has a duty to disclose the truth regarding the safety of the Products, because the safety of the Products has a direct impact on the health and safety of the infants who consume them. This duty arose from the fact that Defendant:

- Had exclusive and/or far superior knowledge and access to knowledge regarding the safety and contamination of the Products;
- Affirmatively and intentionally concealed material facts from Plaintiff and Class Members; and
- Knew that the Products were contaminated with *Clostridium botulinum* and posed serious health risks to infants.

113. The material facts Defendant represented and omitted to disclose were made to Plaintiff and members of the Nationwide Class when they purchased the Products.

114. Defendant intended that its misrepresentations and Material Omissions would deceive or mislead Plaintiff and members of the Nationwide Class and induce them to purchase the Products.

115. Plaintiff and members of the Nationwide Class justifiably relied on Defendant's misrepresentations and Material Omissions regarding the Products, as described above.

116. Plaintiff decided to purchase the Products based in part on Defendant's representations regarding the safety and quality of the Products, including its claims of being "Clean Label Project Certified" and conducting "rigorous quality and safety testing."

117. Defendant's implementation of the inadequate Recall also violates GBL §§ 349 and 350. The Recall came far too late, following a nationwide outbreak of infant botulism that sickened at least fifteen infants in twelve states. The Recall is egregious, ineffective, and inadequate because it fails to prevent the risk of illness or injury to infants; ignores Defendant's longstanding, uniform, and pervasive marketing campaign and Material Omissions regarding the Defect; fails to provide reasonable consumers proper monetary relief considering the premium price they paid for the specific and vital quality of safety; and fails to adequately reach a sufficient number of consumers.

118. Defendant's violations of GBL §§ 349 and 350 were willful and knowing.

119. Defendant's violations present a continuing risk to Plaintiff and Class Members, as well as to the general public. Defendant's actions impact the public interest because Plaintiff and the Class have been injured in exactly the same way as hundreds of thousands of other consumers by Defendant's deceptive acts and practices as described herein.

120. Defendant's acts and practices described above were likely to mislead a reasonable consumer acting reasonably under the circumstances, including Plaintiff and members of the Nationwide Class.

121. Defendant's misrepresentations, misleading statements, and Material Omissions were material to Plaintiff's and Class Members' decisions to purchase the Products.

122. Had Plaintiff and the members of the Class known of Defendant's misrepresentations, deceptive acts, and practices including its misleading statements and Material Omissions about the Products, they would not have purchased them or would have paid less for them.

123. Because of Defendant's unfair and deceptive conduct, Defendant was able to charge more for the Products than they were worth.

124. Plaintiff and Class Members suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's concealment, misrepresentations, and/or failure to disclose material information, and because of the inadequate Recall.

125. As a direct and proximate result of Defendant's conduct in violation of GBL §§ 349 and 350, Plaintiff and the members of the Class have been injured in an amount to be proven at trial, with a statutory minimum of fifty dollars ($50) per Class member under § 349 and five hundred ($500) per Class member under § 350. Because Defendant's violations were knowing and willful, Plaintiff is entitled to treble damages under GBL § 349(h).

126. Plaintiff also seeks injunctive relief, including a state-of-the-art notice program for the wide dissemination of a factually accurate recall notice for the Products, modification of the Recall to cure the problems described herein, and implementation of a corrective advertising campaign by Defendant.

127. Additionally, pursuant to GBL §§ 349 and 350, Plaintiff and the Class seek attorneys' fees and costs.

**COUNT II**
**BREACH OF EXPRESS WARRANTY**
**(*On Behalf of Plaintiff and the Nationwide Class or, in the Alternative, the California Class*)**

128. Plaintiff Xacil Archuleta, individually and on behalf of the Nationwide Class or, in the alternative, the California Class, adopts and incorporates by reference the allegations contained in all preceding paragraphs as though fully set forth herein.

129. Plaintiff brings this cause of action on behalf of herself and the Nationwide Class. Breach of express warranty claims are substantially similar in all fifty states. In the alternative, Plaintiff brings this claim under California law on behalf of herself and the Members of the California Class.

130. Defendant is and was at all relevant times a "merchant" with respect to the Products under U.C.C. Law § 2-104(1), and a "seller" of the Products under § 2-103(1)(d).

131. Plaintiff and all Class Members who purchased the Products are "buyers" within the meaning of U.C.C. Law § 2-103(1)(a).

132. The Products are and were at all relevant times "goods" within the meaning of U.C.C. Law § 2-105(1).

133. In connection with the purchase of the Products, Defendant provided Plaintiff and Class Members with written express warranties that the Products were free of defects and safe for infant consumption.

134. Further, through its aggressive marketing campaign described herein, Defendant expressly warranted and represented that the Products were exceptionally safe, and manufactured

with rigorous quality and safety testing since Defendant owned and controlled its entire manufacturing process

135. These express warranties formed the basis of the bargain that was reached when Plaintiff and Class Members purchased the Products.

136. Defendant breached the express warranties because the Products are not safe for infant consumption and contain the Defect, as described herein. Specifically, the Products were contaminated with *Clostridium botulinum*, a deadly bacteria that causes infant botulism.

137. The Products were not manufactured with "rigorous quality and safety testing" or "clean" processes, as evidenced by the 2022 *Cronobacter sakazakii* contamination event, the FDA Warning Letter dated August 30, 2023, and the FDA inspection ending January 19, 2024 documenting serious violations including failure to implement adequate production controls, failure to maintain sanitary conditions, failure to minimize contamination potential, and failure to exclude pests from the food plant.

138. As a direct and proximate result of Defendant's breach of its express warranties, Plaintiff and Class Members have been damaged in an amount to be proven at trial.

139. Plaintiff provided notice of Defendant's breach of warranties in a letter dated November 19, 2025.

**COUNT III**
**BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY**
**(*On Behalf of Plaintiff and the Nationwide Class or, in the Alternative, the California Class*)**

140. Plaintiff Xacil Archuleta, individually and on behalf of the Nationwide Class or, in the alternative, the California Class, adopts and incorporates by reference the allegations contained in all preceding paragraphs as though fully set forth herein.

141. Plaintiff brings this claim herself, and on behalf of the Nationwide Class against Defendant. Breach of implied warranty claims are materially similar in all fifty states. In the alternative, Plaintiff brings under California law (U.C.C. Law § 2-314) for herself and Members of the California Class.

142. California's implied warranty of merchantability statute provides that "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." U.C.C. Law § 2-314.

143. California's implied warranty of merchantability statute also provides that "[g]oods to be merchantable must be at least such as . . . (f) [c]onform to the promises or affirmations of fact made on the container or label if any." U.C.C. Law § 2-314(2)(f).

144. Defendant is a "merchant" and the Products are "goods" as defined in the Uniform Commercial Code governing the implied warranty of merchantability. U.C.C. Law §§ 2-104, 2-105.

145. Defendant impliedly warranted that the Products were merchantable and fit for the ordinary purposes for which they were intended to be used, which includes safe consumption by infants.

146. Pursuant to U.C.C. Law § 2-314, a warranty that the Products were appropriate for safe infant consumption was implied by law.

147. By placing the Products in the stream of commerce, Defendant impliedly warranted that the Products were safe for their customary and intended use, namely safe consumption by infants.

148. As a merchant, Defendant knew that consumers, including Plaintiff and the Class, relied upon Defendant to design, manufacture, distribute, market, advertise, label, and sell products

that are safe and not deceptively marketed. Members of the public, including Plaintiff and the Class, reasonably relied upon the skill and judgment of Defendant, and Defendant's reputation as a premium infant formula manufacturer, and upon said implied warranties in purchasing the Products.

149. Defendant impliedly warranted that the Products, which Defendant manufactured and sold, were fit for the particular purposes for which they were intended to be used, namely safe consumption by infants.

150. Plaintiff and the Class purchased the Products for the particular purpose of safely feeding their infants.

151. Defendant breached its implied warranty of merchantability because the Products, which were marketed as exceptionally safe infant formula, to be merchantable, must be safe for consumption by infants. For the reasons stated above, the Products are not safe and, in fact, are dangerous for infants. The Products were contaminated with *Clostridium botulinum*, a deadly bacteria that causes infant botulism, and at least fifteen infants were sickened with infant botulism after consuming the Products.

152. These Products, when sold and at all times thereafter, were not fit for the particular purpose for which consumers purchased them, specifically safe infant consumption.

153. The Products are unsafe and dangerous because they are of such a character that when used in their expected manner they are a source of potential serious illness, hospitalization, and injury to infants.

154. Plaintiff and members of the Class are among those intended to be ultimate consumers of the Products.

155. At all times that Defendant warranted and sold the Products, they knew or should have known that their warranties were false, and yet they did not disclose the truth, or stop manufacturing or selling the Products, and instead continued to issue false warranties, and continued to insist the Products are safe.

156. Plaintiff and Class Members that purchased the Products as described above have had sufficient direct dealings with Defendant to establish privity of contract between Defendant on one hand and Plaintiff and Class Members on the other hand.

157. Plaintiff's and each Class Member's acquisition of the Products suffices to create privity of contract between Plaintiff and all other members of the Class, on the one hand, and Defendant, on the other hand; however, privity of contract need not be established nor is it required because Plaintiff and the Class Members are intended third-party beneficiaries of contracts between Defendant and its distributors and retailers, and, specifically, of Defendant's implied warranties.

158. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiff and the Class are entitled to damages in an amount to be determined at trial.

159. Plaintiff also seeks injunctive relief, including a state-of-the-art notice program for the wide dissemination of a factually accurate recall notice for the Products, modification of the Recall to cure the problems described herein, and implementation of a corrective advertising campaign by Defendant.

160. Plaintiff provided notice of Defendant's breach of warranties in a letter dated November 19, 2025.

**COUNT IV**
**VIOLATION OF THE CONSUMERS LEGAL REMEDIES ACT, CAL. CIVIL CODE §§ 1750, ET SEQ.**
**(*On Behalf of Plaintiff and the California Class*)**

156. Plaintiff Xacil Archuleta, individually and on behalf of the California Class, repeats, realleges, and incorporates by reference the allegations contained in all preceding paragraphs as though fully set forth herein.

157. This Count is brought on behalf of Plaintiff and the California Class ("Class" for the purposes of this Count) for violations of the Consumers Legal Remedies Act, California Civil Code § 1750, *et seq.* ("CLRA").

158. The Products at issue are "goods" within the meaning of Cal. Civ. Code § 1761(a).

159. Plaintiff and the members of the California Class are "consumers" within the meaning of Cal. Civ. Code § 1761(d) because they purchased the Products for personal, family, or household use.

160. Plaintiff and the members of the California Class engaged in "transactions" within the meaning of Cal. Civ. Code § 1761(e) when they purchased the Products.

161. The CLRA prohibits "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any consumer." Cal. Civ. Code § 1770(a).

162. In the course of its business, Defendant violated the CLRA by knowingly and intentionally misrepresenting, omitting, concealing, and failing to disclose material facts regarding the safety, quality, and characteristics of the Products. Defendant represented its Products as safe for infants while failing to disclose that the Products were contaminated with, or at risk of contamination with, *Clostridium botulinum*, a deadly bacteria that causes infant botulism.

163. By engaging in the false, deceptive, and misleading labeling and marketing described herein, Defendant engaged in one or more of the following unfair or deceptive business practices as defined in Cal. Civ. Code § 1770(a): (i) Representing that the Products have characteristics, uses, and benefits that they do not have, namely that they are safe for infants. Cal. Civ. Code § 1770(a)(5); (ii) Representing that the Products are of a particular standard, quality, or grade when they are of another, namely by representing them as safe, high-quality infant products when they were in fact contaminated with a dangerous bacterium and unfit for their intended purpose. Cal. Civ. Code § 1770(a)(7); (iii) Advertising the Products with intent not to sell them as advertised, by advertising safe and effective infant products but selling products that were contaminated and unsafe. Cal. Civ. Code § 1770(a)(9); and (iv) Representing that the Products have been supplied in accordance with a previous representation when they have not. Cal. Civ. Code § 1770(a)(16).

164. Defendant's violations of the CLRA were willful and knowing. As a sophisticated manufacturer, Defendant knew, or by the exercise of reasonable care, should have known that its Products were contaminated. Defendant possessed unique and superior knowledge of its raw materials and manufacturing processes, and the risks of contamination associated with them. Despite this knowledge, Defendant misrepresented the safety of its Products and omitted the material fact of contamination in order to increase its profits at the expense of consumer safety.

165. Defendant's violations of the CLRA were further willful and knowing in its implementation of the untimely and inadequate Recall. The Recall came only after countless units of contaminated Products were sold and fails to fully compensate consumers for the economic harm they suffered. It does not provide a full refund for the worthless Products purchased and fails

to adequately notify all affected consumers of the risks. This inadequate response demonstrates Defendant's ongoing disregard for consumer rights and safety.

166. Defendant's violations present a continuing risk to Plaintiff, the Class, and the general public. Defendant's unlawful acts and practices impact the public interest because hundreds of thousands of consumers were injured in the same way by Defendant's common course of deceptive conduct.

167. Defendant's acts and practices described above were likely to mislead a reasonable consumer acting reasonably under the circumstances to believe that the Products were safe and free from harmful contaminants.

168. Defendant's misrepresentations and Material Omissions regarding the *Clostridium botulinum* contamination were material to Plaintiff's and the Class Members' decisions to purchase the Products. A reasonable consumer would attach importance to whether an infant product is contaminated with a dangerous bacterium.

169. Had Plaintiff and the members of the California Class known the truth about the Products' contamination, they would not have purchased them or would have paid substantially less for them.

170. Because of Defendant's unfair and deceptive conduct, Defendant was able to sell the Products and charge more for them than they were worth, as the contaminated Products are entirely worthless.

171. As a direct and proximate result of Defendant's violations of the CLRA, Plaintiff and the members of the California Class suffered ascertainable loss and actual damages, in that they paid for Products that are worthless and cannot be used as intended. The damage sustained is the purchase price of the Products, or at a minimum the price premium paid for the Products.

172. Pursuant to Cal. Civ. Code § 1780(a)(2), Plaintiff and the Class seek an order enjoining Defendant from continuing to engage in the unlawful practices described herein. Plaintiff and the Class also seek injunctive relief requiring Defendant to engage in a corrective advertising campaign and to implement a new, adequate recall program that provides a full refund to all affected consumers.

173. Pursuant to Cal. Civ. Code § 1782(a), on or about November 19, 2025, Plaintiff sent a letter via certified mail to Defendant, providing notice of its violations of the CLRA and demanding that Defendant correct such violations for all affected consumers. If Defendant fails to correct such violations, Plaintiff intends to amend her complaint thirty days after Defendant's receipt of the letter.

174. A CLRA venue declaration is attached.

**COUNT V**
**VIOLATION OF THE UNFAIR COMPETITION LAW,**
**CAL. BUS. & PROF. CODE §§ 17200, ET SEQ.**
**(*On Behalf of Plaintiff and the California Class*)**

175. Plaintiff Xacil Archuleta, individually and on behalf of the California Class, repeats, realleges, and incorporates by reference the allegations contained in all preceding paragraphs as though fully set forth herein.

176. This Count is brought on behalf of Plaintiff and the California Class ("Class" for the purposes of this Count).

177. The Unfair Competition Law, Cal. Business & Professions Code § 17200, *et seq.* ("UCL"), prohibits any "unlawful," "unfair," or "fraudulent" business act or practice and any false or misleading advertising.

178. **Unlawful Prong:** In the course of conducting business, Defendant committed unlawful business practices by, *inter alia*, making the representations and omissions of material

facts, as set forth more fully herein, and violating California's Consumers Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.*, and California's False Advertising Law, Cal. Bus. & Prof. Code § 17500, *et seq.*

179. Plaintiff, individually and on behalf of the other members of the Class, reserves the right to allege other violations of law which constitute other unlawful business acts or practices. As a result of Defendant's unlawful business acts and practices, Defendant has unlawfully obtained money from Plaintiff and the Class Members.

180. **Unfair Prong:** Under the UCL, a business act or practice is "unfair" if its conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and unscrupulous, as the benefits for committing such acts or practices are outweighed by the gravity of the harm to the alleged victims.

181. Defendant's actions constitute "unfair" business acts or practices because, as alleged above, Defendant engaged in deceptive and false advertising, and misrepresented and omitted material facts regarding the safety of its Products. Defendant's conduct offends the established public policy of ensuring that formula sold to consumers are safe, sanitary, and free from harmful contamination. This conduct is immoral, unethical, oppressive, and unscrupulous, and is substantially injurious to consumers.

182. **Fraudulent Prong:** The UCL also prohibits any "fraudulent business act or practice." A business act or practice is fraudulent under the UCL if it is likely to deceive members of the public.

183. Defendant's actions, claims, nondisclosures, and misleading statements, as alleged herein, constitute "fraudulent" business practices in violation of the UCL because they are false,

misleading, and/or likely to deceive reasonable consumers into believing that the Products are safe for their intended use for infants, when in fact they are contaminated.

184. Defendant's conduct was fraudulent because Defendant failed to disclose the contamination defect associated with the Products. Specifically, Defendant failed to adequately warn Plaintiff and Class Members that the Products contained, or were at risk of containing, a dangerous bacterium that rendered them unsafe and worthless. As a result of Defendant's fraudulent business acts and practices, Defendant has and continues to fraudulently obtain money from Plaintiff and the Class Members.

185. Defendant's implementation of the Recall also violates the UCL. The Recall was untimely, occurring only after hundreds of thousands of units of contaminated Products had been sold to unsuspecting consumers. The Recall is also inadequate and ineffective because it fails to fully compensate consumers for the premium price they paid for products they believed were safe, fails to guarantee a full refund for the now-worthless Products, and fails to adequately reach and notify all affected consumers of the potential health risks.

186. There were reasonably available alternatives to further Defendant's legitimate business interests, other than the conduct described herein, such as adequate quality control, transparent labeling, and a timely and comprehensive recall that fully compensated consumers.

187. Defendant's violations present a continuing risk to Plaintiff, the Class, and the general public. Defendant's unlawful, unfair, and fraudulent acts and practices impact the public interest because Plaintiff and the Class Members were injured in the same way by Defendant's common course of deceptive conduct.

188. Defendant's acts and practices described above were likely to mislead a reasonable consumer acting reasonably under the circumstances, including Plaintiff and members of the Class.

189. Defendant's misrepresentations and omissions were material to Plaintiff and members of the Class, as a reasonable consumer would consider the presence of a dangerous bacterium in infant formula important to their purchasing decision.

190. All of the conduct alleged herein occurred in the course of Defendant's business and was part of a pattern or generalized course of illegal conduct that continues to this day.

191. As a result of their deception, Defendant has been able to reap unjust revenue and profit in violation of the UCL.

192. Had Plaintiff and the members of the Class known of Defendant's misrepresentations and deceptive acts and practices, including their Material Omissions about the *Clostridium botulinum* contamination, they would not have purchased the Products or would have paid substantially less for them.

193. As a direct and proximate result of Defendant's conduct in violation of the UCL, Plaintiff and the members of the Class have suffered injury-in-fact and lost money or property, in that they paid for Products that are worthless and cannot be used as intended, and/or paid a price premium for the Products that they would not otherwise have paid.

194. Plaintiff and the Class Members do not have an adequate remedy at law because damages alone will not stop Defendant's deceptive practices. Only injunctive relief can prevent future harm to the public by compelling Defendant to cease its unlawful conduct and engage in corrective action.

195. Plaintiff and the Class Members seek restitution if monetary damages are not available. Indeed, restitution under the FAL can be awarded in situations where the entitlement to damages may prove difficult. But even if damages were available, such relief would not be adequate to address the injury suffered by Plaintiff and other Class Members. Unlike damages, the

Court's discretion in fashioning equitable relief is very broad. Thus, restitution would allow recovery even when normal consideration associated with damages would not.

**COUNT VI**
**VIOLATION OF THE FALSE ADVERTISING LAW**
**CAL. BUS. & PROF. CODE §§ 17500, ET SEQ.**
**(*On Behalf of Plaintiff and the California Class*)**

196. Plaintiff Xacil Archuleta, individually and on behalf of the California Class, repeats, realleges, and incorporates by reference the allegations contained in all preceding paragraphs as though fully set forth herein.

197. This Count is brought on behalf of Plaintiff and the California Class ("Class" for the purposes of this Count).

198. Defendant's conduct described herein constitutes deceptive and false advertising in violation of California's False Advertising Law ("FAL"), Cal. Bus. & Prof. Code §§ 17500, *et seq.*

199. The FAL makes it "unlawful for any person . . . to make or disseminate or cause to be made or disseminated before the public in this state . . . in any advertising device . . . or in any other manner or means whatever, including over the Internet, any statement, concerning that . . . personal property or those services, professional or otherwise, or performance or disposition thereof, which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading." Cal. Bus. & Prof. Code § 17500.

200. Defendant misrepresented, omitted, concealed, and failed to disclose material facts regarding the safety, quality, and characteristics of the Products, as detailed throughout this Complaint.

201. Defendant made or caused to be made and disseminated throughout California advertising, marketing materials, packaging, and labeling containing statements that were untrue or misleading, and which were known, or which by the exercise of reasonable care should have

been known to Defendant, to be untrue and misleading to consumers, including Plaintiff and the Class Members.

202. Through its deceptive labeling and marketing, Defendant made representations to the public, including Plaintiff and the Class Members, about the safety and quality of the Products for use as infant formula. These representations were false and misleading because the Products were contaminated with, or at risk of contamination with, the dangerous bacterium *Clostridium botulinum*.

203. Defendant also made material omissions concerning the safety of the Products. Specifically, Defendant concealed and failed to disclose that the Products were contaminated. As a direct result of Defendant's material omissions, reasonable consumers, including Plaintiff, formed the mistaken belief that the Products were safe and fit for use when, in fact, they were not.

204. Because Defendant disseminated misleading information and omitted material information regarding the Products, and Defendant knew or should have known through the exercise of reasonable care that its representations and accompanying omissions were and continue to be misleading, Defendant has violated the FAL.

205. Defendant's misrepresentations, concealments, and omissions of material facts had the capacity to and did mislead and create a false impression in consumers, and were likely to and did in fact deceive reasonable consumers, including Plaintiff and the Class Members, about the true safety, quality, and value of the Products.

206. Defendant's violations present a continuing risk to Plaintiff, the Class Members, and the general public. Defendant's unlawful acts and practices complained of herein affect the public interest and will continue to do so unless enjoined.

207. As a direct and proximate result of Plaintiff's and the Class Members' reliance on Defendant's false and misleading advertising, they suffered injury-in-fact and lost money or property by purchasing Products that were contaminated, unsafe, and worthless. Had Plaintiff and the Class Members known the truth, they would not have purchased the Products or would have paid substantially less for them.

208. Plaintiff and the Class Members do not have an adequate remedy at law because damages alone will not stop Defendant from continuing its misconduct. Plaintiff and the Class seek injunctive relief, including an order requiring Defendant to cease its deceptive practices, engage in a corrective advertising campaign to inform consumers of the truth about the contamination, and implement an adequate recall program that provides full refunds to all affected consumers.

209. Pursuant to the FAL, Plaintiff, on behalf of herself and the Class, seeks restitution if monetary damages are not available. Indeed, restitution under the FAL can be awarded in situations where the entitlement to damages may prove difficult. But even if damages were available, such relief would not be adequate to address the injury suffered by Plaintiff and other Class Members. Unlike damages, the Court's discretion in fashioning equitable relief is very broad. Thus, restitution would allow recovery even when normal consideration associated with damages would not..

## COUNT VII
## NEGLIGENCE AND NEGLIGENCE PER SE
**(*On Behalf of Plaintiff and the Nationwide Class or, in the Alternative, the California Class*)**

210. Plaintiff Xacil Archuleta, individually and on behalf of the Nationwide Class or, in the alternative, the California Class, adopts and incorporates by reference the allegations contained in all preceding paragraphs as though fully set forth herein.

211. Plaintiff brings this claim herself, and on behalf of the Nationwide Class against Defendant. Common law negligence claims are materially similar in all fifty states. In the alternative, Plaintiff brings under California law for herself and Members of the California Class.

212. Defendant directly or indirectly, caused the Products to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff and the other Class Members.

213. At all times relevant, Defendant had a duty to exercise reasonable care in the design, testing, research, manufacture, marketing, advertisement, supply, promotion, packaging, sale, and distribution of the Products, including the duty to take all reasonable steps necessary to manufacture, promote, and/or sell a product that was not unreasonably dangerous to consumers and users of the Products.

214. At all times relevant, Defendant had a duty to exercise reasonable care in the marketing, advertisement, and sale of the Products. Defendant's duty of care owed to consumers and the general public included providing accurate, true, and correct information concerning the risks of using the Products and appropriate, complete, and accurate warnings concerning the potential safety risks regarding the use of the Products, and, in particular, the Defect.

215. At all times relevant, Defendant knew or, in the exercise of reasonable care, should have known of the safety hazards and dangers the Products and, specifically, the Defect.

216. Defendant knew, or otherwise should have known, that the Products posed serious safety risks to infants, including Plaintiff's and the other Class Members' infants, because of, among other things, its own internal testing, data, and surveys; the 2022 *Cronobacter sakazakii* contamination event; the FDA Warning Letter dated August 30, 2023; and the multiple reports of infant illness linked to the Products.

217. Accordingly, at all times relevant, Defendant knew or, in the exercise of reasonable care, should have known that use of the Products created a dangerous and unreasonable risk of serious illness and injury to the infants consuming the Products, including Plaintiff's and the other Class Members' infants.

218. Defendant also knew or, in the exercise of reasonable care, should have known that users and consumers of the Products were unaware of the safety risks and the magnitude of the safety risks associated with consumption of the defective Products.

219. Defendant omitted, concealed, and failed to disclose to consumers that the Products posed serious safety risks to infants, including that the Products were inherently defective; unreasonably dangerous; not fit to be used for their intended purpose; contained the Defect; and were contaminated with *Clostridium botulinum*. Defendant failed to adequately warn Plaintiff and Class Members that the Products contained the Defect, were contaminated with deadly bacteria, posed serious health risks including infant botulism, and could and had caused infants to become seriously ill and require hospitalization. Rather than disclose this information, Defendant, through its aggressive marketing campaign, marketed the Products as exceptionally safe, "Clean Label Project Certified," and manufactured with "rigorous quality and safety testing."

220. A reasonable manufacturer, distributor, or seller of the Products, under the same or similar circumstances, would have warned of the danger or instructed on safe use of the Products.

221. Defendant did not warn of the particular risks associated with the Products as detailed above, for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about.

222. As such, Defendant breached the duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, supply,

promotion, advertisement, packaging, sale, and distribution of the Products, in that Defendant manufactured, marketed, promoted, and sold the Products with the Defect, knew or had reason to know of the Defect inherent in the Products, knew or had reason to know that an infant's consumption of the Products created a significant risk of serious illness and injury and was unreasonably dangerous for infants, and failed to prevent or adequately warn of these risks and injuries.

223. In breach of its duties, Defendant negligently:

- Failed to design, manufacture, formulate, and package the Products without the Defect;
- Designed, manufactured, and formulated the Products such that they contained the Defect;
- Failed to conduct adequate research and testing to determine the extent to which the Products were likely to be contaminated with *Clostridium botulinum*; and
- Failed to warn that the Products were contaminated with *Clostridium botulinum*, posed serious health risks including infant botulism, and could and had caused infants to become seriously ill and require hospitalization.

224. Despite an ability and means to investigate, study, and test the Products and to provide adequate warnings, Defendant has failed to do so. Indeed, Defendant has wrongfully concealed information and has further made false and/or misleading statements concerning the safety of the Products.

225. Defendant was negligent in the following respects:

- Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing the Products without thorough and adequate pre-and post-market testing;
- Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and/or distributing the Products while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and, consequently, the risk of serious illness and injury associated with consumption of the Products;

- Failing to undertake sufficient studies and conduct necessary testing and adverse event analysis to determine whether the Products were safe for their intended use, infant consumption;

- Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Products to avoid the risk of serious harm to infants associated with the consumption of the Products;

- Failing to provide adequate instructions, guidelines, and safety precautions to those consumers who Defendant could reasonably foresee would use the Products;

- Failing to disclose to Plaintiff, Class Members, users/consumers, and the general public that consumption of the Products presented risks of serious illness or injury to infants;

- Failing to warn Plaintiff and Class Members, consumers, and the general public that the Products' risk of harm was unreasonable and that there were safer alternative infant formulas available to Plaintiff and other consumers;

- Systematically suppressing or downplaying contrary evidence about the risks, incidence, and prevalence of the Defect uniformly present in the Products;

- Representing that the Products were safe for their intended use when, in fact, Defendant knew or should have known that the Products were not safe for their intended purpose;

- Failing to make and/or submit any changes to the Products' labeling or other promotional materials that would alert consumers and the general public of the risks of the Products;

- Advertising, marketing, and recommending the use of the Products while concealing and failing to disclose or warn of the dangers known by Defendant to be associated with or caused by the consumption of the Products;

- Continuing to disseminate information to its consumers, which indicates or implies that Defendant's Products are exceptionally safe and superior to competing formulas; and

- Continuing the manufacture and sale of the Products with the knowledge that the Products were unreasonably unsafe and dangerous to infants.

226. Defendant knew, or otherwise should have known, that it was foreseeable that consumers' infants, including Plaintiff's and the other Class Members' infants, would be placed

at risk of serious illness and injury as a result of Defendant's failure to exercise ordinary care in the manufacturing, marketing, promotion, labeling, distribution, and sale of the Products.

227. Plaintiff and the other Class Members did not know the nature and extent of the injuries that could result from the intended use of the Products.

228. Defendant's negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiff and the other Class Members suffered, as described herein, including the injuries suffered by Plaintiff's and the other Class Members' infants.

229. Defendant's failure to warn or instruct was a substantial factor in causing Plaintiff and other Class Members' harm.

230. As a direct and proximate result of conduct by Defendant that was negligent per se, Plaintiff and Class Members sustained injury and damages in an amount to be determined at trial.

231. Defendant's conduct, as described above, was reckless. Defendant regularly risked the lives of consumers and users of the Products, including Plaintiff and the other Class Members and their infants, with full knowledge of the dangers of the Products. Defendant made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiff and the other Class Members.

232. Defendant further made the decision to issue the ineffective, insufficient and inadequate Recall, as described herein.

233. Defendant's reckless conduct therefore warrants an award of aggravated or punitive damages.

234. As a direct and proximate result of Defendant's wrongful acts and omissions in placing the defective Products into the stream of commerce without adequate warnings of the risks

of serious illness and injury to infants, Plaintiff and the other Class Members have been damaged and their infants have been placed at risk of serious illness and injury.

**COUNT V**
**FRAUDULENT CONCEALMENT**
**(*On Behalf of Plaintiff and the Nationwide Class or, in the Alternative, the California Class*)**

235. Plaintiff Xacil Archuleta, individually and on behalf of the Nationwide Class or, in the alternative, the California Class, adopts and incorporates by reference the allegations contained in all preceding paragraphs as though fully set forth herein.

236. Plaintiff brings this claim herself, and on behalf of the Nationwide Class against Defendant. Common law fraudulent concealment claims are materially similar in all fifty states. In the alternative, Plaintiff brings under California law for herself and Members of the California Class.

237. As alleged above, Defendant knowingly, willfully, fraudulently, and/or recklessly concealed and suppressed material facts regarding the Products.

238. Defendant's conduct here was and continues to be fraudulent because it has the effect of deceiving consumers into believing the marketing claims related to the Products' safety, when in fact the Products are unsafe for infant consumption due to contamination with *Clostridium botulinum*.

239. Defendant concealed information related to whether the Products possessed the Defect and the attendant safety risks. Specifically, Defendant concealed its history of pathogenic contamination at its facilities, including the 2022 *Cronobacter sakazakii* contamination event, and the FDA Warning Letter dated August 30, 2023.

240. Defendant failed to adequately warn Plaintiff and Class Members that the Products contained the Defect, were contaminated with *Clostridium botulinum*, posed serious health risks

including infant botulism, and could cause and had caused infants to become seriously ill and require hospitalization.

241. Defendant has a duty to disclose material facts about the safety of the Products due to its superior knowledge and the vulnerability of its users (infants). This duty arose from the fact that Defendant:

- Had exclusive and/or far superior knowledge and access to knowledge regarding the safety and contamination of the Products;
- Affirmatively and intentionally concealed material facts from Plaintiff and Class Members, including its history of contamination issues and FDA enforcement actions;
- Made affirmative representations about the exceptional safety and quality of the Products through its aggressive marketing campaign; and
- Knew that the Products were contaminated with deadly pathogens and posed serious health risks to infants, the most vulnerable consumers.

242. The material facts Defendant concealed and failed to disclose were known to Defendant but not to Plaintiff and Class Members.

243. Defendant intended that Plaintiff and Class Members would rely on the Material Omissions and aggressive marketing claims to induce purchases of the Products.

244. Plaintiff and members of the Nationwide Class and the California Class justifiably relied on Defendant's Material Omissions and marketing representations regarding the Products, as described above.

245. Plaintiff decided to purchase the Products based in part on Defendant's representations regarding the safety and quality of the Products and the absence of any warnings about contamination risks or Defendant's history of regulatory violations.

246. Defendant intentionally concealed its history of contamination and regulatory violations to induce purchases and maintain its premium brand image and pricing.

247. Had Plaintiff and the members of the Class known of Defendant's concealment and the true nature of the Products, including that they contained the Defect and posed serious health risks to infants, they would not have purchased the Products or would have paid significantly less for them.

248. Defendant's concealment and misrepresentations were material to Plaintiff's and Class Members' decisions to purchase the Products.

249. Defendant's fraudulent concealment was a substantial factor and proximate cause in causing damages and losses to Plaintiff and Class Members.

250. Plaintiff and Class Members were injured as a direct and proximate result of Defendant's conduct because Plaintiff and Class Members would not have purchased the Products, or would have paid significantly less for them, if they knew the Products were dangerously defective and contaminated.

251. As a direct and proximate result of Defendant's fraudulent concealment, Plaintiff and the members of the Class have been injured in an amount to be proven at trial.

252. Defendant's conduct showed malice, motive, and a reckless disregard of the truth such that an award of punitive damages is appropriate.

## COUNT VI
## UNJUST ENRICHMENT
**(*On Behalf of Plaintiff and the Nationwide Class or, in the Alternative, the California Class*)**

253. Plaintiff Xacil Archuleta, individually and on behalf of the Nationwide Class or, in the alternative, the California Class, adopts and incorporates by reference the allegations contained in all preceding paragraphs as though fully set forth herein.

254. Plaintiff brings this claim herself and on behalf of the Members of the Nationwide Class against Defendant. In the alternative, Plaintiff brings this claim under California law for herself and Members of the California Class against Defendant.

255. As a result of Defendant's material, deceptive design, manufacture, distribution, marketing, advertising, labeling and sale of the Products, Defendant was unjustly enriched at the expense of Plaintiff and all other Class Members through the purchase of the Products, because the Products do not provide the benefits as represented and expose infants to greater and more serious risks than represented.

256. Defendant deceptively represented the Products as being exceptionally safe, and manufactured with rigorous quality and safety testing in their packaging, labeling, marketing, advertising, and promotions. Contrary to these representations, the Products pose an unreasonable risk of serious illness and injury to infants due to contamination with *Clostridium botulinum*.

257. Further, Defendant omitted, concealed, and failed to disclose to consumers that the Products pose serious safety risks to infants, including that the Products are inherently defective; are unreasonably dangerous; not fit to be used for their intended purpose; and contain the Defect that renders the Products unsafe for infant consumption. Rather than disclose this information, Defendant marketed the Products as exceptionally safe and superior to competing formulas through its aggressive marketing campaign.

258. Plaintiff and Class Members conferred significant financial benefits and paid substantial compensation to Defendant for the Products, which were not as Defendant represented them to be.

259. Defendant knowingly accepted payment for the Products that were defective, dangerous, and ultimately worthless for their intended purpose of safely feeding infants.

260. Defendant has been unjustly enriched in retaining the revenues and profits derived from Plaintiff's and Class Members' purchases of the Products.

261. Under the circumstances, it would be against equity and good conscience to permit Defendant to retain the ill-gotten benefits they received from Plaintiff and the Class as the result of their deceptive marketing and advertising practices and sale of contaminated Products.

262. Retention of those monies under these circumstances is unjust and inequitable because Defendant's marketing claims were misleading and the Products contained the Defect and were contaminated with *Clostridium botulinum*, which Defendant failed to disclose to Plaintiff and Class Members, were unfit for their intended use, and provided no value.

263. It would be inequitable for Defendant to retain the benefit without restitution to Plaintiff and the Class for the amounts paid by them for the Products.

264. Plaintiff and Class Members are entitled to restitution from Defendant and seek disgorgement and restitution of the wrongful profits, revenues, and benefits Defendant obtained from them.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff, on behalf of herself and all others similarly situated, respectfully requests that this Court:

A. An order certifying this case as a class action on behalf of the proposed Class defined above, appointment of Plaintiff as Class representative, and appointment of her counsel as Class Counsel;

B. A declaratory judgment that ByHeart's conduct, as described herein, was unlawful;

C. An award of all applicable damages, including compensatory damages (to cover economic losses including the cost of the Products), statutory damages, and punitive damages (to punish and deter ByHeart's reckless conduct);

D. An award to Plaintiff and the Class of restitution and disgorgement of all ill-gotten gains and unjust enrichment that ByHeart obtained from Plaintiff and the Class as a result of its unlawful, unfair, and fraudulent business practices described herein;

E. An award of pre-judgment and post-judgment interest, to the extent allowable;

F. An order granting injunctive relief, including:

- Compelling ByHeart to institute a proper recall with full refunds to all consumers;

  Funding a corrective advertising campaign to inform the public of the true risks associated with the Products; and

- Prohibiting ByHeart from engaging in the unlawful acts and practices described above;

G. An award of reasonable attorneys' fees and litigation costs;

H. Any other relief the Court deems just and proper.

**JURY DEMAND**

Plaintiff, on behalf of herself and the proposed Class, hereby demands a jury trial with respect to all issues triable of right by jury.

Dated: November 21, 2025

Respectfully submitted,

*/s/ Russell M. Busch*

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