

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

JILLIAN LUGO and ALLISON NOONAN individually  
and on behalf of all others similarly situated,

Plaintiffs,

v.

BYHEART, INC.,

Defendant.

Case No. 1:25-cv-10243

**CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

Plaintiffs JILLIAN LUGO and ALLISON NOONAN (collectively “Plaintiffs”), individually and on behalf of all others similarly situated, bring this class action against Defendant BYHEART, INC. (hereinafter “ByHeart” or “Defendant”).

**NATURE OF THE ACTION**

1. This action seeks to remedy the deceptive and misleading business practices of ByHeart with respect to the manufacturing, marketing, and sale of Defendant’s infant formula products, including the ByHeart Whole Nutrition Infant Formula cans and Anywhere Pack, throughout the United States (hereinafter the “Products”) which contained *Clostridium botulinum*.

2. Defendant has improperly, deceptively, and misleadingly labeled and marketed its Products to reasonable consumers, like Plaintiff, by omitting and not disclosing to consumers on its packaging that the Products are contaminated or are at risk of being contaminated with *Clostridium botulinum*, a bacteria which causes life threatening illnesses such as infant botulism.

3. On November 7, 2025, the FDA notified Defendant that the agency identified an estimated 83 cases of infant botulism, a rare but serious illness, occurring throughout the United States. Of those cases, 13 infants consumed Defendant’s formula.<sup>1</sup>

4. On November 8, 2025, Defendant released a press release announcing that they initiated a voluntary recall of two batches of the ByHeart Whole Nutrition Infant Formula in response to the Food and Drug Administration’s (FDA) investigation concerning Infant Botulism in babies across the United States.<sup>2</sup> Soon after, on November 11, 2025, ByHeart announced that they were expanding the recall to include all batches of Defendant’s Products (collectively the “Recall”).

5. Infant botulism is a rare, but an incredibly serious illness which is caused when infants consume spores produced by the bacteria *Clostridium botulinum*.<sup>3</sup> Consumption of the spores generally results in infants developing constipation, poor feeding, loss of head control, and difficult swallowing. In severe cases, consumption of *Clostridium botulinum* spores can result in infants experiencing flaccid paralysis, which can cause breathing difficulties and require hospitalization.<sup>4</sup>

6. On November 8, 2025, preliminary test results reported by the California Department of Public Health confirmed the presence of *Clostridium botulinum* in a can of ByHeart infant formula that was fed to an infant with confirmed infant botulism.

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<sup>1</sup> <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/response-broader-fda-investigation-byheart-initiates-voluntary-recall-two-batches-infant-formula> (last accessed Dec. 1 2025)

<sup>2</sup> <https://byheart.com/pages/nov-8-an-update-from-our-founders-on-our-voluntary-recall-november-2025> (last accessed Dec. 1 2025)

<sup>3</sup> <https://www.cdc.gov/botulism/about/index.html> (last accessed Dec. 1 2025)

<sup>4</sup> <https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/index.html> (last accessed Dec. 1 2025)

7. Parents who purchased Defendant’s formula for their families, such as Plaintiffs, reasonably expected that the formula they purchased would be safe for consumption and would not contain, or be at risk of containing, any harmful substances such as *Clostridium botulinum*.

8. Defendant is using a marketing and advertising campaign that omits from the packaging that the Products contain, or risk containing, *Clostridium botulinum*. Knowing of the presence of *Clostridium botulinum* is material to reasonable consumers. The presence of *Clostridium botulinum* was solely within the possession of Defendant, and consumers could only obtain such information by conducting by sending the products off to a laboratory for extensive testing. This omission leads a reasonable consumer to believe they are not purchasing a product with a known bacterium such as *Clostridium botulinum* when in fact they are purchasing a product that is indeed contaminated with the dangerous bacterium *Clostridium botulinum*.

9. A representative example of Defendant’s lack of disclosure on the Products is depicted below<sup>5</sup>:



<sup>5</sup> <https://www.wholefoodsmarket.com/product/byheart-organic-whole-nutrition-infant-formula-24-oz-b0cp1g65q7> (last accessed Dec. 1 2025)

10. Consumers, such as Plaintiffs, trust manufacturers like Defendant to sell products that are safe for their children to consume and are free from known harmful substances, including *Clostridium botulinum*.

11. In fact, Defendant repeatedly highlights the quality of their products, emphasizing that their formula encourages healthy growth for infants compared to commercially available infant formula.<sup>6</sup>

12. Defendant's marketing and advertising campaign includes the one place that every consumer looks when purchasing a product—the packaging and labels themselves. As such, a reasonable consumer reviewing Defendant's labels reasonably believes that they are purchasing a product that is safe for consumption and does not contain any harmful bacteria. Thus, reasonable consumers would not think that Defendant is omitting that the Products contain, or are at risk of containing, *Clostridium botulinum*.

13. Defendant's advertising and marketing campaign is false, deceptive, and misleading because the Products do contain, or risk containing, *Clostridium botulinum*, which is dangerous to one's health and well-being. Nevertheless, Defendant does not list or mention *Clostridium botulinum* anywhere on the Products' packaging or labeling.

14. As set forth below, infant formula, such as that manufactured, marketed, and sold by Defendant, containing or at risk of containing *Clostridium botulinum* are by no means safe for consumption and thus are entirely worthless.

15. Plaintiffs and Class Members paid a price premium for the Products based upon Defendant's marketing and advertising campaign including its false and misleading representations and omission on the Products' labels. Given that Plaintiff and Class Members paid

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<sup>6</sup> <https://byheart.com/pages/clinical-trial> (last accessed Dec. 1 2025)

a premium for the Products, Plaintiffs and Class Members suffered an injury in the amount of the premium paid.

16. Accordingly, Defendant's conduct violated and continues to violate, *inter alia*, New York General Business Law §§ 349 and 350. Defendant also breached and continues to breach its warranties regarding the Products.

17. Plaintiffs bring this action against Defendant on behalf of themselves and Class Members who purchased the Products during the applicable statute of limitations period (the "Class Period").

### **JURISDICTION AND VENUE**

18. This Court has subject matter jurisdiction under the Class Action Fairness Act, 28 U.S.C. section §1332(d) in that (1) the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interest and costs, (2) the action is a class action, (3) there are Class members, including Plaintiff Lugo, who are diverse from Defendant, and (4) there are more than 100 Class members .

19. This Court has personal jurisdiction over Defendant because Defendant conducts and transacts business in the state of New York, contracts to supply goods within the state of New York, and supplies goods within the state of New York.

20. Venue is proper because Defendant's principal place of business is located in this District. Additionally, a substantial part of the events or omissions giving rise to the Classes' claims occurred in this district.

### **PARTIES**

#### **Plaintiffs**

21. Plaintiff Jillian Lugo is a citizen and resident of Will County, Illinois.

22. During the relevant period, Plaintiff Lugo regularly purchased Defendant's Products that possibly contained or had the risk of containing *Clostridium botulinum*. Most recently, Plaintiff Lugo purchased two containers of Defendant's Organic Whole Nutrition Infant Formula for approximately \$37.99 per can directly from Defendant's website in October, 2025. Prior to purchasing the Product, Plaintiff Lugo saw the packaging of the Product and reviewed information on Defendant's website concerning their Products. Based on the packaging, Plaintiff Lugo believed that Products was safe for her child to consume.

23. Plaintiff Allison Noonan is a citizen and resident of State of New York.

24. During the relevant period, Plaintiff Noonan regularly purchased Defendant's Products that possibly contained or had the risk of containing *Clostridium botulinum*. Most recently, Plaintiff Noonan purchased four containers of Defendant's Organic Whole Nutrition Infant Formula and one Anywhere Pack for approximately \$140.93 in total directly from Defendant's website in October, 2025. Prior to purchasing the Product, Plaintiff Noonan saw the packaging of the Product and reviewed information on Defendant's website concerning their products. Based on the packaging and Defendant's representations on their website, Plaintiff Noonan believed that Products was safe for her child to consume.

25. Had Defendant not made the false, misleading, and deceptive representations and omissions regarding the contents of the Products, Plaintiffs would not have been willing to purchase the Products or pay as much for the Products. Plaintiffs purchased, purchased more of, and/or paid more for, the Products than they would have had they known the truth about the Products. The Products Plaintiffs received were worthless because they possibly contained *Clostridium botulinum*. Alternatively, Plaintiffs paid a price premium based on Defendant's false,

misleading, and deceptive misrepresentations and omissions. Accordingly, Plaintiffs were injured in fact and lost money as a result of Defendant's improper conduct.

**Defendant**

26. Defendant, ByHeart Inc. is a Delaware corporation with its headquarters and principal place of business in New York, New York.

27. Defendant manufactures, markets, advertises, and distributes the Products throughout the United States. Defendant created and/or authorized the false, misleading, and deceptive advertisements, packaging, and labeling of its Products.

**FACTUAL BACKGROUND**

28. Defendant manufactures, markets, advertises, and sells infant formula.

29. Consumers, such as families purchasing infant formula, have become increasingly concerned about the effects of ingredients in products that are being orally ingested by their children. Companies, such as Defendant, have capitalized on consumers' desire for healthy food products which promote the wellbeing and growth of their children, and indeed, consumers are willing to pay, and have paid, a premium for these products.

30. Consumers lack the meaningful ability to test or independently ascertain or verify whether a product contains unsafe substances, such as *Clostridium botulinum*, especially at the point of sale, and therefore must and do rely on Defendant to truthfully and honestly report what the Products contain or are at risk of containing on the Products' packaging or labels.

31. The Products' packaging does not identify *Clostridium botulinum*. Indeed, *Clostridium botulinum* is not listed anywhere on the packaging, nor is there any warning about the inclusion (or even potential inclusion) of *Clostridium botulinum* in the Products. This leads

reasonable consumers to believe the Products do not contain, and are not at risk of containing, *Clostridium botulinum*.

32. However, the Products contain, or are at risk of containing, *Clostridium botulinum*.

33. Defendant is a large and sophisticated corporation that has been in the business of producing, manufacturing, selling, and distributing food products for many years, including producing and manufacturing the contaminated Products.

34. Defendant is in the unique and superior position of knowing the ingredients and raw materials used in the manufacturing of its Products and possesses unique and superior knowledge regarding the manufacturing process of the Products, the manufacturing process of the ingredients and raw materials the Products contain, and the risks associated with those processes, such as the risk of *Clostridium botulinum* contamination, as well as the ability to test the Products for *Clostridium botulinum* contamination prior to releasing the Products into the stream of commerce. Such knowledge is solely within the possession of Defendant.

35. For example, in August 2023, the FDA sent Defendant a warning letter that they were in violation of the FDCA because “FDA investigators found significant violations of Title 21, Code of Federal Regulations, Part 106 (21 C.F.R. Part 106), Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications (“the Infant Formula Rule”).”<sup>7</sup>

36. Accordingly, Defendant possesses superior knowledge regarding the risks involved in the production and manufacturing of its Products. Such knowledge is not readily available to consumers like Plaintiffs and Class Members.

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<sup>7</sup> <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/byheart-inc-653854-08302023> (last accessed Dec. 1, 2025)

37. Defendant has a duty to provide consumers, like Plaintiffs and Class Members, with accurate information about the contents of the Products.

38. Therefore, Defendant's false, misleading, and deceptive omissions regarding the Products containing *Clostridium botulinum* is likely to continue to deceive and mislead reasonable consumers, as they have already deceived and misled Plaintiffs and Class Members.

39. Defendant's misrepresentations and omissions were material and intentional because families are concerned with what is in the products that are orally ingested by their children. Consumers such as Plaintiffs and Class Members are influenced by Defendant's marketing and advertising campaign, the Products' labels, and the listed ingredients. Defendant knows that if they had not omitted that the Products contained *Clostridium botulinum*, then Plaintiffs and the Class would not have purchased the Products, or, at the very least, would not have paid nearly as much for the Products.

40. Consumers rely on marketing and information in making purchasing decisions.

41. By omitting that the Products include botulism on the labels of the Products throughout the Class Period, Defendant knows that those omissions are material to consumers since they would not purchase a product that contained *Clostridium botulinum*.

42. Defendant's deceptive representations and omissions are material in that a reasonable person would attach importance to such information and would be induced to act upon such information in making purchase decisions.

43. Defendant's false, misleading, and deceptive misrepresentations and omissions are likely to continue to deceive and mislead reasonable consumers and the public, as they have already deceived and misled Plaintiffs and Class Members.

44. In making the false, misleading, and deceptive representations and omissions described herein, Defendant knew and intended that consumers would pay a premium for a product marketed without *Clostridium botulinum* over comparable products not so marketed.

45. As an immediate, direct, and proximate result of Defendant's false, misleading, and deceptive representation and omission, Defendant injured Plaintiffs and Class Members in that they:

- a. Paid a sum of money for Products that were not as Defendant represented;
- b. Paid a premium price for Products based on Defendant's false and misleading misrepresentations;
- c. Were deprived of the benefit of the bargain because the Products they purchased was different from what Defendant warranted;
- d. Were deprived of the benefit of the bargain because the Products they purchased had less value than what Defendant represented; and
- e. Were denied the benefit of the properties of the Products Defendant promised.

46. Had Defendant not made the false, misleading, and deceptive representations and omissions, Plaintiffs and Class Members would not have been willing to pay the same amount for the Products they purchased and/or Plaintiffs and Class Members would not have been willing to purchase the Products.

47. Plaintiffs and Class Members paid for Products that do not contain *Clostridium botulinum*. Since the Products do indeed or possibly contain *Clostridium botulinum*, the Products Plaintiffs and Class Members received were worth less than the Products for which they paid.

48. Plaintiffs and Class Members all paid money for the Products; however, Plaintiffs and Class Members did not obtain the full value of the advertised Products due to Defendant's

misrepresentations and omissions. Plaintiffs and Class Members purchased, purchased more of, and/or paid more for, the Products than they would have had they known the truth about the Products. Consequently, Plaintiffs and Class Members have suffered injury in fact and lost money as a result of Defendant's wrongful conduct.

49. Plaintiffs and Class Members saw the Products' packaging prior to purchasing the Products. Had Plaintiffs and Class Members known the truth about the Products, i.e., that they do or possibly contain *Clostridium botulinum*, they would not have been willing to purchase them at any price, or, at minimum, would have paid less for them.

### **CLASS ALLEGATIONS**

50. Plaintiffs, individually and on behalf of all others similarly situated, bring this class action pursuant to Fed. R. Civ. P. 23.

51. The proposed Class is defined as follows:

**Nationwide Class:** All persons within the United States who purchased Defendant's affected Products.

**New York subclass:** All persons within the State of New York, who purchased Defendant's affected Products.

**Illinois subclass:** All persons within the State of Illinois, who purchased Defendant's affected Products.

52. Plaintiffs reserve the right to modify, change, or expand the definitions of the proposed Classes based upon discovery and further investigation.

53. *Numerosity:* The proposed Class is so numerous that joinder of all members is impracticable. Plaintiffs believe that there are thousands of consumers in the Class who are Class Members as described above who have been damaged by Defendant's deceptive and misleading practices.

54. *Commonality*: Questions of law or fact common to the Class include, without limitation:

- a. Whether the Products in question were unsafe;
- b. Whether Defendant was responsible for the conduct alleged herein which was uniformly directed at all consumers who purchased the Products;
- c. Whether Defendant's misconduct set forth in this Complaint demonstrates that Defendant has engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sale of its Products;
- d. Whether Defendant made false and/or misleading statements and omissions to the Class and the public concerning the contents of its Products Whether Defendant had a duty to disclose, prior to purchase, the defective nature of the Products to consumers;
- e. Whether Defendant's false and misleading statements and omissions concerning its Products were likely to deceive the public;
- f. Whether Defendant's conduct constitutes an unlawful breach of the implied warranty of merchantability;
- g. Whether Defendant's conduct constitutes an unlawful breach of express warranties;
- h. Whether Defendant's fraudulently omitted material information in its interactions with consumers;
- i. Whether Defendant was unjustly enriched; and
- j. Whether Plaintiffs and the Class are entitled to money damages under the same causes of action as the other Class Members.

55. *Typicality*: The claims or defenses of Plaintiffs are typical of the claims or defenses of the Class. Class Members were injured and suffered damages in substantially the same manner as Plaintiffs, Class Members have the same claims against Defendant relating to the same course of conduct, and Class Members are entitled to relief under the same legal theories asserted by Plaintiffs.

56. *Adequacy*: Plaintiffs will fairly and adequately protect the interests of the proposed Class and have no interests antagonistic to those of the proposed Class. Plaintiffs have retained counsel experienced in the prosecution of complex class actions.

57. *Predominance*: Questions of law or fact common to proposed Class members predominate over any questions affecting only individual members. Common questions such as whether Defendant owed a duty to Plaintiffs and the Class and whether Defendant breached its duties predominate over individual questions such as measurement of economic damages.

58. *Superiority*: A class action is superior to other available methods for the fair and efficient adjudication of these claims because individual joinder of the claims of the Class is impracticable. Many members of the Class are without the financial resources necessary to pursue this matter. Even if some members of the Class could afford to litigate their claims separately, such a result would be unduly burdensome to the courts in which the individualized cases would proceed. Individual litigation increases the time and expense of resolving a common dispute concerning Defendant's actions toward an entire group of individuals. Class action procedures allow for far fewer management difficulties in matters of this type and provide the unique benefits of unitary adjudication, economies of scale, and comprehensive supervision over the entire controversy by a single judge in a single court.

59. *Manageability*: Plaintiffs are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

60. The Class may be certified pursuant to Rule 23(b)(2) because Defendant has acted on grounds generally applicable to the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.

61. The Class may also be certified pursuant to Rule 23(b)(3) because questions of law and fact common to the Class will predominate over questions affecting individual members, and a class action is superior to other methods for fairly and efficiently adjudicating the controversy and causes of action described in this Complaint.

62. Particular issues under Rule 23(c)(4) are appropriate for certification because such claims present particular, common issues, the resolution of which would advance the disposition of this matter and the parties' interests therein.

### **CAUSES OF ACTION**

#### **FIRST CAUSE OF ACTION**

##### **Violation of New York GBL § 349**

**(On behalf of Plaintiff Noonan and the New York Subclass members)**

63. Plaintiffs repeat and reallege each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

64. New York General Business Law Section 349 (“GBL § 349”) declares unlawful “[d]eceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state . . .”

65. The conduct of Defendant alleged herein constitutes recurring, “unlawful” deceptive acts and practices in violation of GBL § 349, and as such, Plaintiff Noonan and the New York Subclass Members seek monetary damages against Defendant.

66. Defendant misleadingly, inaccurately, and deceptively advertises and markets its Products to consumers.

67. Defendant’s improper consumer-oriented conduct—including failing to disclose that its Products contained *Clostridium botulinum*—is misleading in a material way in that it, *inter*

*alia*, induced Plaintiff Noonan and the New York Subclass Members to purchase Defendant's Products and to use the Products when they otherwise would not have. Defendant made the untrue and/or misleading statements and omissions willfully, wantonly, and with reckless disregard for the truth.

68. Plaintiff Noonan and the New York Subclass Members have been injured inasmuch as they purchased Products that were mislabeled. Accordingly, Plaintiff Noonan and the New York Subclass Members received less than what they bargained and paid for.

69. Defendant's advertising and Products' packaging and labeling induced Plaintiff Noonan and the New York Subclass Members to buy Defendant's Products.

70. Defendant's deceptive and misleading practices constitute a deceptive act and practice in the conduct of business in violation of New York General Business Law §349(a) and Plaintiff Noonan and the New York Subclass Members have been damaged thereby.

71. As a result of Defendant's recurring, "unlawful" deceptive acts and practices, Plaintiff Noonan and the New York Subclass Members are entitled to monetary, statutory, and compensatory damages, restitution, and disgorgement of all moneys obtained by means of Defendant's unlawful conduct, interest, and attorneys' fees and costs.

**SECOND CAUSE OF ACTION**

**Violation of New York GBL § 350**

**(On behalf of Plaintiff Noonan and the New York Subclass members)**

72. Plaintiffs repeat and reallege each and every allegation contained in all the foregoing paragraphs as if fully set forth herein .

73. N.Y. Gen. Bus. Law § 350 provides, in part, as follows:

False advertising in the conduct of any business, trade, or commerce or in the furnishing of any service in this state is hereby declared unlawful.

74. N.Y. Gen. Bus. Law § 350a(1) provides, in part, as follows:

The term ‘false advertising, including labeling, of a commodity, or of the kind, character, terms or conditions of any employment opportunity if such advertising is misleading in a material respect. In determining whether any advertising is misleading, there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity or employment to which the advertising relates under the conditions proscribed in said advertisement, or under such conditions as are customary or usual . . .

75. Defendant’s labeling and advertisements contain untrue and materially misleading statements and omissions concerning its Products inasmuch it misrepresents that the Products are safe for consumption and doesn’t list that the Products contain *Clostridium botulinum*.

76. Plaintiff Noonan and the New York Subclass Members have been injured inasmuch as they relied upon the labeling, packaging, and advertising and purchased Products that were mislabeled, dangerous, and entirely worthless. Accordingly, Plaintiffs and the New York Subclass Members received less than what they bargained and paid for.

77. Defendant’s advertising, packaging, and Products’ labeling induced Plaintiffs and the New York Subclass Members to buy Defendant’s Products.

78. Defendant made its untrue and/or misleading statements and representations willfully, wantonly, and with reckless disregard for the truth.

79. Defendant’s conduct constitutes multiple, separate violations of N.Y. Gen. Bus. Law § 350.

80. Defendant made the material omissions described in this Complaint in its advertising and on the Products’ packaging and labeling.

81. Defendant's material misrepresentations were substantially uniform in content, presentation, and impact upon consumers at large. Moreover, all consumers purchasing the Products were and continue to be exposed to Defendant's material misrepresentations.

82. As a result of Defendant's recurring, "unlawful" deceptive acts and practices, Plaintiff Noonan and New York Subclass Members are entitled to monetary, statutory, and compensatory damages, restitution, and disgorgement of all moneys obtained by means of Defendant's unlawful conduct, interest, and attorneys' fees and costs.

**THIRD CAUSE OF ACTION**

**Violation of Illinois' Consumer Fraud and Deceptive Business Practices Act**

**815 Ill. Comp. Stat. 505/2**

**(On Behalf of Plaintiff Lugo and the Illinois Subclass)**

83. Plaintiffs repeat and reallege each and every allegation contained in all the foregoing paragraphs as if fully set forth herein .

84. Plaintiff Lugo brings this claim on behalf of the Illinois Subclass (the "Class" for purposes of this Count).

85. The Illinois Consumer Fraud Act, 815 Ill. Comp. Stat. 505/2 ("ICFA"), prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act', approved August 5, 1965."

86. In the course of its business, Defendant made affirmative misrepresentations regarding the Products that were deceptive and/or unconscionable. Specifically, Defendant represented that the Products were safe for consumption. Defendant, however, failed to disclose

material facts, namely, that (1) the Products contain, or are at risk of containing, *Clostridium botulinum*; and (2) Defendant failed to properly inspect and test their Products for such contaminations. Defendant had a duty to disclose these material facts because the Products were unsafe and because Defendant made affirmative representations about the ingredients of their Products being safe. If Plaintiff Lugo had known that the Products contained, or were at risk of containing, *Clostridium botulinum*, or that Defendant failed to properly inspect and test the Products adequately, Plaintiff Lugo would not have purchased the Products.

87. Defendants violated 815 Ill. Comp. Stat. 505/2 by:

- a. causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
- b. representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have;
- c. representing that goods are original or new if they are deteriorated, altered, reconditioned, reclaimed, used, or secondhand;
- d. representing that goods or services are of a particular standard, quality, or grade or that goods are a particular style or model, if they are of another;
- e. advertising goods or services with intent not to sell them as advertised; and
- f. engaging in any other conduct which similarly creates a likelihood of confusion or misunderstanding.

815l. Comp. Stat. 510/2 §§ (a)(2), (5), (6), (7), (9), and (12).

88. Plaintiff Lugo and Class members had no way of discerning that Defendant's representations were false and misleading because Plaintiff Lugo and Class members did not have access to Defendant's internal policies or procedures, or any internal documents regarding how they test their Products to ensure it is safe for consumption.

89. Defendant thus violated the ICFA by making statements, when considered as a whole from the perspective of the reasonable consumer, that conveyed that the Products were safe

for consumption. Defendant also failed to disclose and warn that the Products were unsafe and contaminated with, or was risk of being contaminated with, *Clostridium botulinum*; and that Defendant failed to properly test the Products for potential contamination or health hazards.

90. Defendant intentionally and knowingly misrepresented material facts regarding the Products with intent to mislead Plaintiff and the Class.

91. Defendant knew or should have known that its conduct violated the ICFA.

92. Defendant owed Plaintiff Lugo and the Class a duty to disclose the true and unsafe nature of the Products.

93. Defendant's concealment of the true characteristics of the Products was material to Plaintiff and the Class.

94. Defendant's unfair or deceptive acts or practices were likely to and did in fact deceive reasonable consumers, including Plaintiff Lugo and the Class, about the true nature of the Products.

95. Defendant's violations present a continuing risk to Plaintiff Lugo, the Class, and the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

96. Plaintiff Lugo and the Class suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's misrepresentations and concealment of and failure to disclose material information.

97. As a direct and proximate result of Defendant's violations of the ICFA, Plaintiff Lugo and the Class have suffered injury-in-fact and/or actual damage.

98. Pursuant to 815 Ill. Comp. Stat. 505/10a, Plaintiff Lugo and Class Members seek monetary relief against Defendant to recover (1) actual economic damages; (2) an order enjoining

Defendant's unfair, unlawful, and/or deceptive practices; (3) reasonable attorneys' fees and costs; and (4) punitive damages and/or any other relief which the court may deem proper.

**FOURTH CAUSE OF ACTION**  
**Violation of Illinois' Uniform Deceptive Trade Practices Act**  
**815 Ill. Comp. Stat. 510/2**  
**(On Behalf of Plaintiff Lugo and the Illinois Subclass)**

99. Plaintiffs repeat and reallege each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

100. Plaintiff Lugo brings this claim on behalf of the Illinois State Class (the "Class" for purposes of this Count).

101. The Illinois Uniform Deceptive Trade Practices Act, 815 Ill. Comp. Stat. 510/2 ("Illinois UDTPA"), prohibits deceptive trade practices in the course of his or her business, vocation, or occupation.

102. By misrepresenting the Products as safe while in use, and by failing to disclose and actively concealing that their Products were contaminated or at risk of being contaminated with *Clostridium botulinum*, Defendant engaged in one or more of the following unfair or deceptive business practices prohibited by 815 Ill. Comp. Stat. 510/2.

103. Defendant violated 815 Ill. Comp. Stat. 510/2 by:

- g. causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
- h. representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have;
- i. representing that goods are original or new if they are deteriorated, altered, reconditioned, reclaimed, used, or secondhand;
- j. representing that goods or services are of a particular standard, quality, or grade or that goods are a particular style or model, if they are of another;

- k. advertising goods or services with intent not to sell them as advertised; and
- l. engaging in any other conduct which similarly creates a likelihood of confusion or misunderstanding.

8151. Comp. Stat. 510/2 §§ (a)(2), (5), (6), (7), (9), and (12).

104. Plaintiff Lugo and Class members had no way of discerning that Defendant's representations were false and misleading because Plaintiff Lugo and Class members did not have access to Defendant's internal policies or procedures, or any internal documents regarding the Products' defect or how they test their Products to ensure its safe for use.

105. Defendant thus violated the Illinois UDTPA by making statements, when considered as a whole from the perspective of the reasonable consumer, that conveyed that the Products were safe for use. Defendant also failed to disclose and warn that the Products were unsafe and unsuitable for consumption; that the Products contain, or are at risk of containing, *Clostridium botulinum*, resulting in injury or putting users of the Product at risk of injury; and that Defendant failed to properly inspect and test the Products for possible defects that would harm consumers' families.

106. Defendant intentionally and knowingly misrepresented material facts regarding the Products with intent to mislead Plaintiff and the Class.

107. Defendant knew or should have known that its conduct violated the Illinois UDTPA.

108. Defendant owed Plaintiff Lugo and the Class a duty to disclose the true and unsafe nature of the Products.

109. Defendant's concealment of the true characteristics of the Products was material to Plaintiff Lugo and the Class.

110. Defendant's unfair or deceptive acts or practices were likely to and did in fact deceive reasonable consumers, including Plaintiff Lugo and the Class, about the true nature of the Products.

111. Defendant's violations present a continuing risk to Plaintiff Lugo, the Class, and the general public. Defendant's unlawful acts and practices complained of herein affect the public interest.

112. Plaintiff Lugo and the Class suffered ascertainable loss and actual damages as a direct and proximate result of Defendant's misrepresentations and concealment of and failure to disclose material information.

113. As a direct and proximate result of Defendant's violations of the Illinois UDTPA, Plaintiff Lugo and the Class have suffered injury-in-fact and/or actual damage.

114. Pursuant to 815 Ill. Comp. Stat. 510/3, Plaintiff Lugo and the Class seek an order enjoining Defendant's unfair, unlawful, and/or deceptive practices, along with reasonable attorneys' fees and any other just and proper relief available.

**FIFTH CAUSE OF ACTION**

**Negligence**

**(On Behalf of Plaintiffs and the Nationwide Class)**

115. Plaintiffs repeat and reallege each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

116. The conduct of Defendant in manufacturing, distributing, and selling the Products with the contamination of infant botulism constituted negligence in failing to reasonably act in accordance with all applicable standards of care. Defendant owed Plaintiffs and Class members a duty not to disseminate a materially contaminated, product. Defendant breached said duty of care

when it nevertheless manufactured, distributed, and sold the Products with the contamination of *Clostridium botulinum* to consumers, including Plaintiffs.

117. Defendant also breached its duty of care by negligently failing to timely and/or adequately warn Plaintiffs and the Class of the contamination of *Clostridium botulinum*, even after Defendant was, or should have been, fully aware of that the Products were contaminated.

118. As a direct and proximate result of Defendant's negligence, Plaintiffs and Class Members suffered economic injury, entitling them to just compensation, as detailed below.

**SIXTH CAUSE OF ACTION**  
**Unjust Enrichment**  
**(On Behalf of Plaintiffs and the Nationwide Class)**

119. Plaintiffs repeat and reallege each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

120. Defendant represented to Plaintiffs and Class members that its Products were reliable, merchantable, and safe to consume.

121. The Products to fail to conform to the performance, durability, capability, and reliability that Defendant represented and were therefore of a substantially lesser quality and value than Defendant represented.

122. Defendant knew or should have known that its Products could not conform to its representations because of the contamination of *Clostridium botulinum*.

123. Defendant misrepresented, concealed, and omitted material information concerning the *Clostridium botulinum* found in its Products.

124. The contamination of *Clostridium botulinum* and the facts misrepresented, concealed, and omitted by Defendant are material because a reasonable consumer would have considered them to be important in deciding whether to purchase their Products.

125. Defendant misrepresented, concealed, and omitted material information concerning the contamination of *Clostridium botulinum* in order to induce Plaintiffs and Class members to purchase their Products at a substantially higher price than what they would otherwise have paid.

126. Plaintiffs and Class members reasonably and justifiably relied on Defendant's representations and advertisements when purchasing the Products.

127. Plaintiffs and Class members would not have purchased the Products if they knew that they were contaminated with *Clostridium botulinum*, or they would have only paid substantially less.

128. Plaintiffs and Class members conferred substantial benefits on Defendant by purchasing contaminated Products at a premium without receiving a product that conformed to Defendant's representations.

129. Defendant knowingly and willingly accepted and enjoyed these benefits.

130. Defendant's retention of these benefits would be inequitable because Defendant obtained benefits to the detriment of Plaintiffs and Class members when Plaintiffs and Class members did not obtain their promised benefits.

131. As a direct and proximate result of Defendant's conduct, Plaintiffs and Class members are entitled to restitution.

**SEVENTH CAUSE OF ACTION**  
**Breach of Implied Warranty of Merchantability**  
**(on behalf of Plaintiffs and all Class Members)**

132. Plaintiffs repeat and reallege each and every allegation contained in all the foregoing paragraphs as if fully set forth herein .

133. The sale of Defendant's Products created an implied warranty of merchantability pursuant to U.C.C. § 2-314.<sup>8</sup>

134. Defendant, as the manufacturer, marketer, and distributor, impliedly warranted that the Products are merchantable as infant formula.

135. Plaintiffs and Class Members purchased the Products relying on Defendant's skill and judgment in properly manufacturing, packaging and labeling the Products.

136. Defendant breached the warranty implied in the contract for the sale of the Products because they could not "pass without objection in the trade under the contract description," the Products were not "of fair average quality within the description," were not "adequately contained, packaged, and labeled as the agreement may require," and did not "conform to the promise or affirmations of fact made on the container or label if any." *See* U.C.C. § 2-314(2) (listing requirements for merchantability). As a result, Plaintiffs and Class Members did not receive the goods as impliedly warranted by Defendant to be merchantable.

137. Defendant knowingly breached the implied warranties by including *Clostridium botulinum* in the Products sold to Plaintiffs and the Class without properly notifying them of their inclusion in the Products.

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<sup>8</sup> All fifty States, the District of Columbia, and Puerto Rico have codified and adopted U.C.C. § 2-314: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code. Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code. Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; La. Civ. Code Art. 2520; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code. Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; Wis. Stat. Ann. § 402.314; and Wyo. Stat. § 34.1-2-314.

138. Within a reasonable time after it knew or should have known, Defendant did not change the Products' label to include *Clostridium botulinum* in the ingredients list.

139. As a direct and proximate result of Defendant's breach of the implied warranties, Plaintiffs and Class members have been injured and sustained damages.

140. Defendant has actual notice of the warranty claims alleged herein due to its recall of the Products.

**PRAYER FOR RELIEF**

WHEREFORE, the following relief is requested:

- a. An order certifying this action as a class action.
- b. An award of statutory, compensatory, incidental, consequential, and punitive damages and restitution to the extent permitted by law in an amount to be proven at trial.
- c. An order enjoining Defendant's unlawful conduct.
- d. An award of attorneys' fees, expert witness fees, costs, and Class representative incentive awards as provided by applicable law.
- e. An award of interest as provided by law, including pre-judgment and post-judgment interest.
- f. Such other and further relief as this Court may deem just, equitable, or proper.

Dated: December 10, 2025

Respectfully submitted,

/s/ Brett R. Cohen

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