

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

Monica Valenzuela, individually and on
behalf of all others similarly situated,

Case No. 25-cv-6333

Plaintiff,

v.

CLASS ACTION COMPLAINT

ByHeart, Inc.,

JURY TRIAL DEMANDED

Defendant.

Plaintiff Monica Valenzuela (“Plaintiff”), individually and on behalf of all others similarly situated (“Class,” as defined below), by and through her attorneys, brings this class action complaint against Defendant ByHeart, Inc. (“Defendant” or “ByHeart”) and alleges the following upon information and belief, except for those allegations pertaining to Plaintiff, which are based on personal knowledge:

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 formula product throughout the United States, including New York (“Products”)¹

¹ See <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/response-broader-fda-investigation-byheart-initiates-voluntary-recall-two-batches-infant-formula> (last acceded on November 12, 2025).

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 with *Clostridium botulinum*, which can cause infant botulism.

3. As described in further detail below, the Products contain *Clostridium botulinum*, which could lead to serious and life-threatening adverse health consequences. Infant botulism is a rare but potentially fatal illness that poses a serious threat to the health of infants. It occurs when *Clostridium botulinum* spores are ingested and colonize the intestinal tract, producing botulinum neurotoxins in the immature gut of infants. Affected infants can present with some or all of the following signs and symptoms: constipation, poor feeding, ptosis (drooping eyelid), sluggish pupils, low muscle tone, difficulty sucking and swallowing, weak or altered cry, generalized weakness, respiratory difficulty, and possibly respiratory arrest.

4. Plaintiff and a class of nationwide purchasers of the Products (“Class Members”) certainly expect that the infant baby formula products they purchase will not contain, or risk containing, any knowingly harmful substances that cause severe disease and even be life-threatening.

5. Unfortunately for consumers, like Plaintiff and all reasonable consumers, the infant formula Products they purchased contain, or risk containing, *Clostridium botulinum*.

6. Defendant is using a marketing and advertising campaign that omits from the packaging that the Products contain *Clostridium botulinum*. Knowing of the presence *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 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 when, in fact, they are purchasing a product contaminated with, or at risk of being contaminated with, *Clostridium botulinum*.

7. A representative example of Defendant's lack of disclosure on the Products is depicted below:



8. Consumers like Plaintiff and reasonable consumers trust manufacturers such as Defendant to sell products that are safe and free from harmful known substances, including *Clostridium botulinum*.

9. Plaintiff and Class Members certainly expect that the food products they purchase will not contain, or risk containing, any knowingly harmful substances that cause disease.

10. Unfortunately for consumers, like Plaintiff, the baby infant Products they purchased contained, or were at risk of containing, *Clostridium botulinum*.

11. Defendant's own recall and other testing confirmed and demonstrated the presence of *Clostridium botulinum* in the Plaintiff's Product.

12. Plaintiff seeks economic damages only. Plaintiff does not assert personal injury claims in this action. Plaintiff seeks recovery solely for economic losses — including price-premium damages and benefit-of-the-bargain damages — resulting from purchasing products that had no value, or substantially reduced value, due to contamination or the risk of contamination with *Clostridium botulinum*.

Defendant's Recall is Insufficient

13. Defendant issued a recall of its Products on November 8, 2025.

14. On November 11, 2025, ByHeart expanded its recall to include all ByHeart formula nationwide, including cans and single-serve sticks.²

15. In addition, on November 11, 2025, Defendant publicly announced on its official website the following:

“We’re writing to you today to tell you that we have decided to voluntarily recall all ByHeart formula nationwide—this includes both our cans and our single-serve Anywhere Pack™ sticks. This decision was made to ensure your baby’s safety.

² See, <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025> (last accessed on November 12, 2025).

It's important that you know that neither we, nor the FDA or CDC, have found Clostridium botulinum spores or toxins in any unopened can of ByHeart formula.

The decision to broaden our recall to all ByHeart products comes after a call with the FDA late last night, informing us that they found two more cases of infant botulism in babies that had also consumed ByHeart at some point. The FDA's investigation into infant botulism in the U.S. is still ongoing, and we feel that there are still too many unanswered questions. Your baby's safety is, and always will be, our biggest priority.

Upon learning about this outbreak on Friday evening, we immediately began conducting our own extensive testing on all ByHeart batches. Additionally, we are providing the FDA complete and unrestricted access to all of our facilities and products for their investigation, which has been done regularly at our owned facilities. We will share the results of our own testing as they become available.

At this moment, the most important thing for you to know is that all ByHeart product must be discarded. We know that switching formulas is not an easy process or decision. We have resources to help here.”³

16. Defendant's own public statement confirms that the FDA identified at least two additional cases of infant botulism in infants who consumed ByHeart formula, which triggered the expanded nationwide recall. Defendant therefore admits that the ByHeart formula was linked to confirmed infant botulism cases.

17. To be eligible for a refund, a consumer must retain the Products. This recall was deliberately designed to exclude the vast majority of consumers from receiving notification.

18. Defendant is well aware that any consumer who was made aware of the recall would be predisposed to throwing the Products away. Defendant is also cognizant that consumers

³ See <https://byheart.com/pages/an-update-from-our-founders-on-our-voluntary-recall-november-2025?srsltid=AfmBOopt26DfG9TIYtSLF1Hc2lSQqU7reCVknX7IZf1JoFcPWgMhjzDy>. (last accessed on November 12, 2025).

shop in multiple locations and may or may not purchase the Products at the exact location each time. Additionally, many consumers do not retain receipts and therefore cannot obtain a refund at the original purchase location for the recalled Products.

19. Accordingly, Defendant's recall is designed to reach very few people and is designed to benefit very few of the consumers who purchased the Products.

20. The class action remedy is superior to Defendant's failed recall in every conceivable fashion.

21. Defendant is using a marketing and advertising campaign that omits from the packaging that the Products contain infant botulism. This omission leads a reasonable consumer to believe they are not purchasing a product that contains foodborne illness caused by *Clostridium botulinum*, when in fact they are purchasing a product contaminated with, or at risk of contamination with, *Clostridium botulinum*.

22. 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 products that are safe for oral ingestion and do not contain any harmful ingredients. Indeed, consumers expect the packaging and labels to accurately disclose the presence of such foodborne illness within the Products. Thus, reasonable consumers would not think that Defendant is omitting that the Products contain, or are at risk of containing, *Clostridium botulinum*.

23. 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.

24. Defendant's misrepresentations and omissions of the safety of the Products and what is in the Products were material to Plaintiff and Class Members. Consequently, Plaintiff and Class Members lost the entire benefit of their bargain when what they received was a food product contaminated with, or at risk of contamination with, *Clostridium botulinum* that is harmful to consumers' health.

25. That is because Defendant's Products containing, or at risk of infant botulism, have no value, or at the very least, Defendant was able to charge significantly more for the Products than they would have had they not omitted the fact that the Products contain—or possibly contain—*Clostridium botulinum*.

26. As set forth below, food products, such as Defendant's Products, are in no way safe for human consumption and are entirely worthless.

27. Alternatively, Plaintiff 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 omissions on the Products' labels. Given that Plaintiff and Class Members paid a premium for the Products, Plaintiff and Class Members suffered an injury in the amount of the premium paid.

28. Accordingly, Defendant's conduct violated and continues to violate, *inter alia*, New York General Business Law §§ 349 and 350, in addition to the common law violations below.

29. Plaintiff brings this action against Defendant on behalf of herself and Class Members who purchased the Products during the applicable statute of limitations period (the "Class Period").

FACTUAL BACKGROUND

30. Defendant manufactures, markets, advertises, and sells food products, specifically baby formula.

31. Consumers have become increasingly concerned about the effects of ingredients on products that they orally ingest. Companies, such as Defendant, have capitalized on consumers' desire for food products, and indeed, consumers are willing to pay, and have paid, a premium for these products.

32. Consumers lack the meaningful ability to test or independently ascertain or verify whether a product contains unsafe substances, such as infant botulism, 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.

33. The Products' packaging does not identify *Clostridium botulinum* or infant botulism. Indeed, infant botulism is not listed anywhere on the packaging, nor is there any warning about the inclusion (or even potential inclusion) of infant botulism in the Products. This leads reasonable consumers to believe the Products do not contain, and are not at risk of containing, *Clostridium botulinum*.

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

35. 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.

36. 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.

37. In August 2023, the FDA issued a Warning Letter to ByHeart identifying serious violations of Current Good Manufacturing Practices (“cGMP”), including deficient pathogen-control procedures, inadequate environmental monitoring, and failures in contamination-prevention systems at its Pennsylvania facility. These same systemic deficiencies directly increased the risk of contamination with *Clostridium botulinum* and are directly relevant to the defects and recall at issue in this case.⁴

38. 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 Plaintiff and Class Members.

Defendant’s Misrepresentations Financially Harmed Plaintiff and Class Members

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

40. Therefore, Defendant’s false, misleading, and deceptive omissions regarding the Products containing infant botulism are likely to continue to deceive and mislead reasonable consumers and the public, as they have already deceived and misled Plaintiff and the Class Members.

41. Defendant’s misrepresentations and omissions were material and intentional because people are concerned with what is in the products that they orally ingest. Consumers such

⁴ <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/byheart-inc-653854-08302023> (last visited Nov. 11, 2025).

as Plaintiff and the Class Members are influenced by the marketing and advertising campaign, the Products' labels, and the listed ingredients. Defendant knows that if it had not omitted that the Products contained *Clostridium botulinum*, then Plaintiff and the Class would not have purchased the Products, or, at the very least, would not have paid nearly as much for the Products.

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

43. By omitting that the Products include, or risk having, *Clostridium botulinum* 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, or risked containing, *Clostridium botulinum*.

44. 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.

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

46. 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 sold.

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

- a. Paid a sum of money for Products that were not what Defendant represented;
- b. Paid a premium price for Products that were not what Defendant

represented;

- c. Were deprived of the benefit of the bargain because the Products they purchased were 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.

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

49. Plaintiff and the Class Members paid for Products that do not contain, or are not at risk of containing, *Clostridium botulinum*. Since the Products do indeed or possibly contain infant botulism, the Products Plaintiff and the Class Members received were worth less than the Products for which they paid.

50. Plaintiff and the Class Members all paid money for the Products; however, Plaintiff and the Class Members did not obtain the full value of the advertised Products due to Defendant's misrepresentations and omissions. Plaintiff and the 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, Plaintiff and the Class Members have suffered injury in fact and lost money as a result of Defendant's wrongful conduct.

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

JURISDICTION AND VENUE

52. This Court has subject matter jurisdiction under the Class Action Fairness Act (“CAFA”), 28 U.S.C. § 1332(d). Plaintiff is a citizen of New York. Defendant ByHeart Inc. is a New York corporation with its principal place of business in the state of New York. Minimal diversity exists, the proposed Class contains more than 100 members, and the aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and costs, and at least one Class member is diverse from Defendant.

53. 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.

54. Venue is proper because Plaintiff resides in this District. A substantial part of the events or omissions giving rise to the Classes’ claims occurred in this district.

PARTIES

Plaintiff Monica Valenzuela

55. Plaintiff Monica Valenzuela is a citizen and resident of Brooklyn, New York. During the applicable statute of limitations period, Plaintiff purchased and used Defendant’s Products that possibly contained *Clostridium botulinum*, including Products that were subject to the warning. Most recently, Plaintiff purchased an Anywhere Pack for \$43.53 on September 28, 2025, and later purchased an additional Whole Nutrition Infant Formula and an Anywhere Pack for \$81.05 on October 21, 2025. Prior to purchasing the Product, Plaintiff saw the packaging of the Product and reasonably relied on Defendant’s labeling when purchasing the Product.

56. Had Defendant not made the false, misleading, and deceptive representations and omissions regarding the contents of the Products, Plaintiff would not have been willing to purchase

the Products or pay as much for the Products. Plaintiff purchased, purchased more of, and/or paid more for the Products than she would have had she known the truth about the Products. The Products Plaintiff received were worthless because they possibly contained Clostridium botulinum (infant botulism). Alternatively, Plaintiff paid a price premium based on Defendant's false, misleading, and deceptive misrepresentations and omissions. Accordingly, Plaintiff was injured in fact and lost money as a result of Defendant's improper conduct.

Defendant ByHeart, Inc.

57. Defendant, ByHeart, Inc., is a New York company with its principal place of business in New York.

58. 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.

CLASS ALLEGATIONS

59. Plaintiff brings this matter on behalf of herself and those similarly situated. As detailed at length in this Complaint, Defendant orchestrated deceptive marketing and labeling practices. Defendant's customers were uniformly impacted by and exposed to this misconduct. Accordingly, this Complaint is uniquely situated for class-wide resolution.

60. The Class is defined as: **All persons who purchased the Products anywhere in the United States during the Class Period (the “Nationwide Class”).**

61. Plaintiff also seeks certification, to the extent necessary or appropriate, of a subclass of: **All persons who purchased the Products in the state of New York at any time during the Class Period (the “New York Subclass”).**

62. The Class and New York Subclass are referred to collectively throughout the Complaint as the “Class” unless stated otherwise.

63. Excluded from the Class are: (1) any Judge or Magistrate presiding over this action and any members of their families; (2) Defendant, Defendant’s subsidiaries, parents, successors, predecessors, and any entities in which Defendant or its parents and any entities in which Defendant has a controlling interest and their current or former employees, officers, and directors; (3) individuals who allege personal bodily injury resulting from the use of the Products; and (4) resellers of the Products.

64. Plaintiff reserves the right to amend the class definition based on facts learned through further investigation and/or discovery.

65. The Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

66. Numerosity: Class Members are so numerous that joinder of all members is impracticable. Plaintiff believes 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.

67. Commonality: The questions of law and fact common to the Class Members which predominate over any questions which may affect individual Class Members include, but are not limited to:

- a. Whether Defendant was responsible for the conduct alleged herein, which was uniformly directed at all consumers who purchased the Products;
- b. 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;
- c. Whether Defendant made false and/or misleading statements and omissions to the Class and the public concerning the contents of its Products;
- d. Whether Defendant's false and misleading statements and omissions concerning its Products were likely to deceive the public;
- e. Whether Defendant's actions and omissions violate NY GBL 349; and
- f. Whether Plaintiff and the Class are entitled to money damages under the same causes of action as the other Class Members.

68. Typicality: Plaintiff is a member of the Class. Plaintiff's claims are typical of the claims of each Class Member in that every member of the Class was susceptible to the same deceptive, misleading conduct and purchased Defendant's Products. Plaintiff is entitled to relief under the same causes of action as the other Class Members.

69. Adequacy: Plaintiff is an adequate Class representative because her interests do not conflict with the interests of the Class Members she seeks to represent, her consumer fraud claims are common to all members of the Class, she has a strong interest in vindicating her

rights, she has retained counsel competent and experienced in complex class action litigation, and counsel intends to vigorously prosecute this action.

70. Predominance: Pursuant to Rule 23(b)(3), common issues of law and fact identified above predominate over any other questions affecting only individual members of the Class. The Class issues fully predominate over any individual issues because no inquiry into individual conduct is necessary; all that is required is a narrow focus on Defendant's deceptive and misleading marketing and labeling practices.

71. Superiority: A class action is superior to the other available methods for the fair and efficient adjudication of this controversy because:

a. The joinder of thousands of individual Class Members is impracticable, cumbersome, unduly burdensome, and a waste of judicial and/or litigation resources;

b. The individual claims of the Class Members may be relatively modest compared with the expense of litigating the claims, thereby making it impracticable, unduly burdensome, and expensive—if not totally impossible—to justify individual actions;

c. When Defendant's liability has been adjudicated, all Class Members' claims can be determined by the Court and administered efficiently in a manner far less burdensome and expensive than if it were attempted through filing, discovery, and trial of all individual cases;

d. This class action will promote orderly, efficient, expeditious, and appropriate adjudication and administration of Class claims;

e. Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude their maintenance as a class action;

f. This class action will assure uniformity of decisions among Class Members;

g. The Class is readily definable, and prosecution of this action as a class action will eliminate the possibility of repetitious litigation;

h. Class Members' interests in individually controlling the prosecution of separate actions are outweighed by their interest in efficient resolution by a single class action; and

i. It would be desirable to concentrate in this single venue the litigation of all Class Members who were induced by Defendant's uniform false advertising to purchase its Products.

72. Accordingly, this Class is properly brought and should be maintained as a class action under Rule 23(b)(3) because questions of law or fact common to Class Members predominate over any questions affecting only individual members, and because a class action is superior to other available methods for fairly and efficiently adjudicating this controversy.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

Violation of New York GBL § 349

(On Behalf of Plaintiff and Nationwide Class, or alternatively, the New York Subclass)

73. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

74. 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 . . ."

75. The conduct of Defendant alleged herein constitutes recurring, "unlawful" deceptive acts and practices in violation of GBL § 349, and as such, Plaintiff and other Class Members seek monetary damages against Defendant, enjoining them from inaccurately describing, labeling, marketing, and promoting the Products.

76. There is no adequate remedy at law.

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

78. Defendant's improper consumer-oriented conduct—including failing to disclose that the Products have infant botulism —is misleading in a material way in that it, *inter alia*, induced Plaintiff and other Class 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.

79. Plaintiff and other Class Members have been injured since they purchased Products that were mislabeled, unhealthy, and entirely worthless. Accordingly, Plaintiff and the Class Members received less than what they bargained and paid for.

80. Defendant's advertising and Products' packaging and labeling induced Plaintiff and other Class Members to buy Defendant's Products.

81. 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 and other Class Members have been damaged thereby.

82. As a result of Defendant's recurring, "unlawful" deceptive acts and practices, Plaintiff and other Class Members are entitled to monetary, statutory, compensatory, treble, and punitive damages, interest, and attorneys' fees and costs.

SECOND CAUSE OF ACTION
Violation of New York GBL § 350

(On Behalf of Plaintiff and the Nationwide Class, or alternatively the New York Subclass)

83. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

84. 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.

85. 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 . . .

86. Defendant’s labeling and advertisements contain untrue and materially misleading statements and omissions concerning its Products inasmuch as it misrepresents that the Products are safe for use and doesn’t list that the Products contain infant botulism.

87. Plaintiff and the other Class Members have been injured inasmuch as they saw the labeling, packaging, and advertising and purchased Products that were mislabeled, unhealthy, and entirely worthless. Accordingly, Plaintiff and other Class Members received less than what they bargained and paid for.

88. Defendant’s advertising, packaging, and Products’ labeling induced Plaintiff and other Class Members to buy Defendant’s Products.

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

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

91. Defendant made the material misrepresentations described in this Complaint in its advertising and on the Products' packaging and labeling.

92. 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.

93. As a result of Defendant's recurring, "unlawful" deceptive acts and practices, Plaintiff and other Class Members are entitled to monetary, statutory, compensatory, treble, and punitive damages, interest, and attorneys' fees and costs.

THIRD CAUSE OF ACTION
Negligence
(On Behalf of Plaintiff and the Nationwide Class)

94. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

95. The conduct of Defendant in manufacturing, distributing, and selling the Product with the contamination of, or risk of contamination of, *Clostridium botulinum* constituted negligence in failing to reasonably act in accordance with all applicable standards of care. Defendant owed Plaintiff and Class members a duty not to disseminate a materially defective product. Defendant breached said duty of care when it nevertheless manufactured, distributed, and sold the Products with the contamination of infant botulism to consumers, including Plaintiff.

96. Defendant also breached its duty of care by negligently failing to timely and/or adequately warn Plaintiff and the Class of the risk of contamination of *Clostridium botulinum*, even after Defendant was, or should have been, fully aware of the manufacturing defect in the Products.

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

FOURTH CAUSE OF ACTION
Unjust Enrichment
(On Behalf of Plaintiff and the Nationwide Class)

98. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

99. Defendant was unjustly enriched at the expense of Plaintiff and other Class Members in the form of monies that Plaintiff and other Class Members paid for the Products.

100. This claim is brought in the alternative to the other Counts. The Federal Rules of Civil Procedure allow Plaintiff to plead alternative theories.

101. Defendant's conduct violated, *inter alia*, state and federal law by manufacturing, advertising, labeling, marketing, distributing, and selling the Products while misrepresenting and omitting material facts, including by making the misrepresentations and omissions alleged herein.

102. Defendant's unlawful conduct allowed Defendant to knowingly realize substantial revenues from selling the Products at the expense of, and to the detriment or impoverishment of, Plaintiff and Class members and to Defendant's benefit and enrichment. Defendant has violated fundamental principles of justice, equity, and good conscience.

103. Plaintiff and Class members conferred significant financial benefits and paid substantial compensation to Defendant directly and via retailers for the Products, which were not as Defendant represented them to be.

104. Defendant knowingly received and enjoyed the benefits conferred by Plaintiff and Class members.

105. It is inequitable for Defendant to retain the benefits conferred by Plaintiff and Class members' overpayments.

106. Plaintiff and Class members seek to establish a constructive trust from which Plaintiff and Class members may seek restitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and the Class, prays for judgment as follows:

- (a) Declaring this action to be a proper class action and certifying Plaintiff as the representative of the Class under Fed. R. Civ. P. 23;
- (b) Declaring that Defendant is financially responsible for notifying the Class members of the pendency of this suit;
- (c) Awarding monetary damages and treble damages;
- (d) Awarding statutory damages of \$50 per transaction, and treble damages for knowing and willful violations, pursuant to N.Y. GBL § 349;
- (e) Awarding statutory damages of \$500 per transaction pursuant to N.Y. GBL § 350;
- (f) Award punitive damages;
- (g) Awarding Plaintiff and Class Members their costs and expenses incurred in this action, including reasonable allowance of fees for Plaintiff's attorneys, experts, and reimbursement of Plaintiff's expenses;
- (h) Granting such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury of all claims so triable.

Dated: November 13, 2025

Respectfully submitted,

REESE LLP

/s/ Michael R. Reese

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Counsel for Plaintiff and the Putative Class

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Monica Valenzuela

(b) County of Residence of First Listed Plaintiff Kings County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Michael R. Reese (212) 643-0500
REESE LLP 100 W. 93 Street, NY, NY 10025

DEFENDANTS

ByHeart, Inc.

County of Residence of First Listed Defendant New York County
(IN U.S. PLAINTIFF CASES ONLY)NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF
THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

<input type="checkbox"/> 1 U.S. Government Plaintiff	<input type="checkbox"/> 3 Federal Question (U.S. Government Not a Party)
<input type="checkbox"/> 2 U.S. Government Defendant	<input checked="" type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

	PTF	DEF	PTF	DEF
Citizen of This State	<input type="checkbox"/> 1	<input checked="" type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4 <input type="checkbox"/> 4
Citizen of Another State	<input checked="" type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5 <input type="checkbox"/> 5
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6 <input type="checkbox"/> 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881	<input type="checkbox"/> 422 Appeal 28 USC 158
<input type="checkbox"/> 120 Marine	<input type="checkbox"/> 310 Airplane	<input type="checkbox"/> 365 Personal Injury - Product Liability	<input type="checkbox"/> 690 Other	<input type="checkbox"/> 423 Withdrawal 28 USC 157
<input type="checkbox"/> 130 Miller Act	<input type="checkbox"/> 315 Airplane Product Liability	<input type="checkbox"/> 367 Health Care/ Pharmaceutical Personal Injury Product Liability		INTELLECTUAL PROPERTY RIGHTS
<input type="checkbox"/> 140 Negotiable Instrument	<input type="checkbox"/> 320 Assault, Libel & Slander	<input type="checkbox"/> 368 Asbestos Personal Injury Product Liability		<input type="checkbox"/> 820 Copyrights
<input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment	<input type="checkbox"/> 330 Federal Employers' Liability	<input type="checkbox"/> 340 Marine		<input type="checkbox"/> 830 Patent
<input type="checkbox"/> 151 Medicare Act	<input type="checkbox"/> 345 Marine Product Liability	<input type="checkbox"/> 350 Motor Vehicle		<input type="checkbox"/> 835 Patent - Abbreviated New Drug Application
<input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans)	<input type="checkbox"/> 355 Motor Vehicle Product Liability	<input type="checkbox"/> 360 Other Personal Injury		<input type="checkbox"/> 840 Trademark
<input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits	<input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<input type="checkbox"/> 370 Other Fraud		<input type="checkbox"/> 880 Defend Trade Secrets Act of 2016
<input type="checkbox"/> 160 Stockholders' Suits		<input type="checkbox"/> 371 Truth in Lending		
<input type="checkbox"/> 190 Other Contract		<input type="checkbox"/> 380 Other Personal Property Damage		SOCIAL SECURITY
<input type="checkbox"/> 195 Contract Product Liability		<input type="checkbox"/> 385 Property Damage Product Liability		<input type="checkbox"/> 861 HIA (1395ff)
<input type="checkbox"/> 196 Franchise				<input type="checkbox"/> 862 Black Lung (923)
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS		
<input type="checkbox"/> 210 Land Condemnation	<input type="checkbox"/> 440 Other Civil Rights	Habeas Corpus:	<input type="checkbox"/> 791 Employee Retirement Income Security Act	<input type="checkbox"/> 863 DIWC/DIWW (405(g))
<input type="checkbox"/> 220 Foreclosure	<input type="checkbox"/> 441 Voting	<input type="checkbox"/> 463 Alien Detainee		<input type="checkbox"/> 864 SSID Title XVI
<input type="checkbox"/> 230 Rent Lease & Ejectment	<input type="checkbox"/> 442 Employment	<input type="checkbox"/> 510 Motions to Vacate Sentence		<input type="checkbox"/> 865 RSI (405(g))
<input type="checkbox"/> 240 Torts to Land	<input type="checkbox"/> 443 Housing/ Accommodations	<input type="checkbox"/> 530 General		FEDERAL TAX SUITS
<input type="checkbox"/> 245 Tort Product Liability	<input type="checkbox"/> 445 Amer. w/Disabilities - Employment	<input type="checkbox"/> 535 Death Penalty		<input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant)
<input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 446 Amer. w/Disabilities - Other	<input type="checkbox"/> 540 Mandamus & Other		<input type="checkbox"/> 871 IRS—Third Party 26 USC 7609
	<input type="checkbox"/> 448 Education	<input type="checkbox"/> 550 Civil Rights		
		<input type="checkbox"/> 555 Prison Condition		
		<input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement		
IMMIGRATION				
		<input type="checkbox"/> 462 Naturalization Application		
		<input type="checkbox"/> 465 Other Immigration Actions		

V. ORIGIN (Place an "X" in One Box Only)

<input checked="" type="checkbox"/> 1 Original Proceeding	<input type="checkbox"/> 2 Removed from State Court	<input type="checkbox"/> 3 Remanded from Appellate Court	<input type="checkbox"/> 4 Reinstated or Reopened	<input type="checkbox"/> 5 Transferred from Another District (specify)	<input type="checkbox"/> 6 Multidistrict Litigation - Transfer	<input type="checkbox"/> 8 Multidistrict Litigation - Direct File
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Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. 1332(d)

VI. CAUSE OF ACTION

Brief description of cause:
contaminated baby formula

VII. REQUESTED IN COMPLAINT:

 CHECK IF THIS IS A CLASS ACTION
UNDER RULE 23, F.R.Cv.P.

DEMAND \$

5000000

CHECK YES only if demanded in complaint:

JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

SIGNATURE OF ATTORNEY OF RECORD

November 13, 2025

/s/ Michael R. Reese

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE

CERTIFICATION OF ARBITRATION ELIGIBILITY

Local Arbitration Rule 83.7 provides that with certain exceptions, actions seeking money damages only in an amount not in excess of \$150,000, exclusive of interest and costs, are eligible for compulsory arbitration. The amount of damages is presumed to be below the threshold amount unless a certification to the contrary is filed.

Case is Eligible for Arbitration

I, _____, counsel for _____, do hereby certify that the above captioned civil action is ineligible for compulsory arbitration for the following reason(s):

- monetary damages sought are in excess of \$150,000.00 exclusive of interest and costs,
- the complaint seeks injunctive relief, or
- the matter is otherwise ineligible for the following reason:

DISCLOSURE STATEMENT - FEDERAL RULES CIVIL PROCEDURE 7.1

Identify any parent corporation and any publicly held corporation that owns 10% or more or its stocks. Add an additional page if needed.

None

RELATED CASE STATEMENT (Section VIII on the Front of this Form)

Please list all cases that are arguably related pursuant to Division of Business Rule 3 in Section VIII on the front of this form. Rule 3(a) provides that "A civil case is "related" to another civil case for purposes of this guideline when, because of the similarity of facts and legal issues or because the cases arise from the same transactions or events, a substantial saving of judicial resources is likely to result from assigning both cases to the same judge and magistrate judge." Rule 3(a) provides that "A civil case shall not be deemed "related" to another civil case merely because the civil case involves identical legal issues, or the same parties." Rule 3 further provides that "Presumptively, and subject to the power of a judge to determine otherwise pursuant to paragraph (b), civil cases shall not be deemed to be "related" unless both cases are still pending before the court."

NEW YORK EASTERN DISTRICT DIVISION OF BUSINESS RULE 1(d)(3)

If you answer "Yes" to any of the questions below, this case will be designated as a Central Islip case and you must select Office Code 2.

1. Is the action being removed from a state court that is located in Nassau or Suffolk County? Yes No
2. Is the action—not involving real property—being brought against United States, its officers or its employees AND the majority of the plaintiffs reside in Nassau or Suffolk County? Yes No
3. If you answered "No" to all parts of Questions 1 and 2:
 - a. Did a substantial part of the events or omissions giving rise to claim or claims occur in Nassau or Suffolk County? Yes No
 - b. Do the majority of defendants reside in Nassau or Suffolk County? Yes No
 - c. Is a substantial amount of any property at issue located in Nassau or Suffolk County? Yes No
4. If this is a Fair Debt Collection Practice Act case, was the offending communication received in either Nassau or Suffolk County? Yes No

(Note, a natural person is considered to reside in the county in which that person is domiciled; an entity is considered a resident of the county that is either its principal place of business or headquarters, or if there is no such county in the Eastern District, the county within the District with which it has the most significant contacts).

BAR ADMISSION

I am currently admitted in the Eastern District of New York and currently a member in good standing of the bar of this court.

Yes No

Are you currently the subject of any disciplinary action (s) in this or any other state or federal court?

Yes (If yes, please explain) No

I certify the accuracy of all information provided above.

Signature: _____

UNITED STATES DISTRICT COURT
for the
Eastern District of New York

Monica Valenzuela, individually and on behalf of all others similarly situated,

)))))))))))))

Plaintiff(s)

V.

ByHeart, Inc.

Defendant(s)

Civil Action No. 25-cv-6333

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

ByHeart, Inc.
31 Varick Street, 11th Floor
New York, New York 10013

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Michael J. P. D.

Michael R. Reese
REESE LLP
100 West 93rd Street, 16th Floor
New York, New York 10025
(212) 643-0500
mreese@reesellp.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

DOUGLAS C. PALMER
CLERK OF COURT

Date:

Signature of Clerk or Deputy Clerk