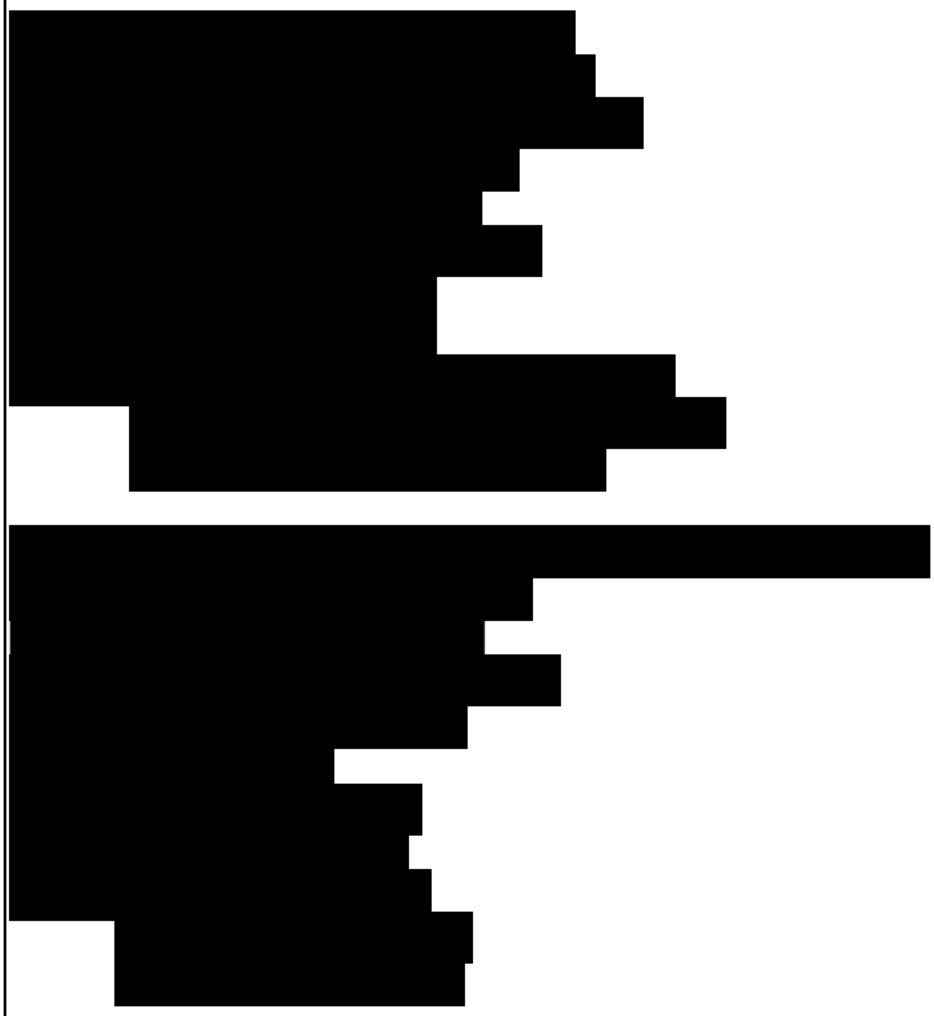

Attorneys for Plaintiff and the Proposed Classes

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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

ARTURO ANDALUZ, on behalf of themselves and all others similarly situated,

Plaintiff,

vs.

ABBOTT LABORATORIES, INC. D/B/A ABBOTT NUTRITION;

DEFENDANT.

CASE NO.

CLASS ACTION COMPLAINT

1. Unjust Enrichment
2. Negligent Misrepresentation/ Omission
3. Breach of Express Warranty
4. Breach of Implied Warranty
5. Strict Product Liability- Failure to Warn
6. Strict Product Liability- Manf. Defect
7. False and Misleading Advertising in Violation of Business & Professions Code § 17200, et seq.
8. False and Misleading Advertising in Violation of Business & Professions Code § 17500, et, seq.
9. Violation of California Civil Code § 1750, et, seq.
10. Negligence Per Se

DEMAND FOR JURY TRIAL

To the Court, to all interested parties and to the attorneys of record herein:

Plaintiff Arturo Andaluz ("Plaintiff"), on behalf of himself and all others similarly situated, files this Class Action Complaint ("CAC") against Defendant Abbott Laboratories, Inc. D/B/A Abbott Nutrition. ("Abbott" or "Defendant"), and in support state the following:

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NATURE OF THE ACTION

1. This is a class action lawsuit by Plaintiff, and others similarly situated, who purchased Similac, Alimentum, and EleCare Infant formula manufactured, sold and distributed by Defendant.

2. Defendant distributes, markets and sells several infant formulas under the brand names Similac, Alimentum, and EleCare. Several of Defendant's Similac products (identified below) have been shown to be adulterated with Cronobacter sakazakii. The presence of Cronobacter sakazakii in Defendant's Similac, Alimentum, and EleCare products was not disclosed in the products' label, in violation of state and federal law. Plaintiff and the putative classes suffered economic damages due to Defendant's misconduct (as set forth below) and they seek injunctive relief and restitution for the full purchase price of the Similac product(s) they purchased. Plaintiff alleges the following based upon personal knowledge as well as investigation by counsel, and as to all other matters, upon information and belief. Plaintiff further believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

JURISDICTION AND VENUE

3. This Court has original jurisdiction pursuant to 28 U.S.C. §1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum or value of $5,000,000 and is a class action in which there are in excess of 100 class members and Plaintiff is a citizen of a state different from Defendant.

4. This Court has jurisdiction over each Defendant because Defendant is authorized to conduct and does business in California. Defendant has marketed, promoted, distributed, and sold Similac, Alimentum, and EleCare products, including the recalled Products identified below, in California, and Defendant has sufficient minimum contacts with this State and/or sufficiently avail themselves of

the markets in this State through promotion, sales, distribution and marketing within this State to render the exercise of jurisdiction by this Court permissible.

5. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred while she resided in this judicial district. Venue is also proper under 18 U.S.C. §1965(a) because Defendant transacts substantial business in this District.

THE PARTIES

6. Plaintiff is a citizen and resident of Los Angeles County, California, and at all times relevant hereto, has been a resident of Los Angeles County. In or around January 2022, Plaintiff began purchasing Defendant's product at Target and Costco retail stores located in Granada Hills, California. Plaintiff paid approximately $8-12 each for the infant formula. He continued to purchase the product for approximately three months, until he learned of the recall. Plaintiff confirmed that the products he purchased matched the lots that had been recalled. At the time of purchase, based on the false and misleading claims by Defendant, Plaintiff was unaware that Defendant's Similac, Alimentum, and EleCare products may be adulterated with cronobacter sakazakii. Plaintiff purchased the Defendant's products on the assumption that the labeling of Defendant's products were accurate and that the products were unadulterated, safe and effective. Plaintiff would not have purchased Defendant's Similac, Alimentum, and EleCare products had he known there was a risk the products may contain Cronobacter sakazakii. As a result, Plaintiff suffered injury in fact when he spent money to purchase products, he would not otherwise have purchased absent Defendant's misconduct, as alleged herein. Plaintiff may purchase the products again if the product is not contaminated and is properly labeled.

7. Defendant ABBOTT LABORATORIES, INC. D/B/A ABBOTT NUTRITION, is a Delaware Corporation with its principal place of business in

Abbott Park, Lake County, Illinois. Defendant manufactures, markets, advertises, labels, distributes and sells the recalled products at issue in this litigation.

INTRODUCTION

8. The following infant formulas are manufactured, marketed, and sold by Defendant Abbott Laboratories:

- Similac. Similac is a brand of powdered infant formula produced by Abbott which Abbott promises will "give babies a strong start by helping to keep them fed, happy, and healthy." See Why Similac, https://www.similac.com/why-similac.html (last visited February 18, 2022). According to Abbott, Similac "is the #1 Pediatrician Recommended Brand for Immune Support." *Id.*
- Alimentum. Alimentum is a brand of powdered infant formula produced by Abbott for infants with lactose sensitivity which Abbott claims is "the #1 infant formula brand fed for cow's milk protein allergy in the US." See Alimentum Product Description, https://www.similac.com/products/baby-formula/alimentum-powder/19-8oz-can-4pack.html (last visited February 18, 2022).
- EleCare. EleCare is a brand of powdered infant formula produced by Abbott for infants who cannot tolerate intact or hydrolyzed protein due to conditions such as severe food allergies or short bowel syndrome. See EleCare Product Information, https://elecare.com/ (last visited February 18, 2022).

9. Abbott distributes these powdered infant formula products both nationwide and internationally.

10. On February 17, 2022, the FDA, in conjunction with the CDC, announced a warning to consumers to not purchase or use Recalled Product, stating: "Do not use recalled Similac, Alimentum and EleCare powdered infant

formulas produced in Sturgis, Michigan."[1]

11. As part of the Warning, the FDA Deputy Commissioner for Food Policy and Response stated, "As this is a product used as the sole source of nutrition for many of our nation's newborns and infants, the FDA is deeply concerned about these reports of bacterial infections. We want to reassure the public that we're working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible."

12. Specifically, the FDA announced that it is investigating consumer complaints of Cronobacter sakazakii and Salmonella Newport infections connected to powdered infant formula products produced by Abbott.

13. The FDA has so far linked two infant deaths and multiple illnesses to Cronobacter sakazakii contamination of its Similac, Alimentum, and EleCare powdered infant formulas produced in its Sturgis, Michigan plant.

14. The initial recall notice included Similac, Alimentum, and EleCare powdered infant formula with the following characteristics:

- the first two digits of the code are 22 through 37; and
- the code on the container contains K8, SH or Z2; and
- the expiration date is 4-1-2022 (APR 2022) or later.

15. On February 18, 2022, Abbott announced a recall of its powdered infant formulas. However, the recall does not include a refund, reimbursement, or replacement for consumers who purchased or used Recalled Products.[2]

16. On February 28, 2022, the Recall was expanded to include one lot of Similac PM 60/40 (Lot # 27032K80 (can) / Lot # 27032K800 (case)), which was

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[1] https://www.fda.gov/consumers/powdered-infant-formula-recall-what-know (last visited March 16, 2022)

[2] Recall Notice, https://www.similacrecall.com/us/en/home.html (last visited March 16, 2022)

also manufactured in Abbott's Sturgis, Michigan facility.

17. These products may contain Cronobacter sakazakii bacteria.

18. Per the CDC website, Cronobacter sakazakii is a germ that can live in very dry places. The germs can live in dry foods, such as powdered infant formula.

19. Cronobacter bacteria can get into formula powder if contaminated raw materials are used to make the formula or if the formula powder touches a contaminated surface in the manufacturing environment.

20. Cronobacter bacteria can cause severe, life-threatening infections, meningitis, and symptoms include: poor feeding, irritability, temperature changes, jaundice, grunting, and abnormal body movements. As set forth by the Centers for Disease Control and Prevention:

> Infants (<12 months old): In infants, Cronobacter usually causes sepsis or severe meningitis. Some infants may experience seizures. Those with meningitis may develop brain abscesses or infarcts, hydrocephalus, or other serious complications that can cause long-term neurological problems. The mortality rate for Cronobacter meningitis may be as high as 40%.[3]

Other sources have described the mortality rate reaching as high as 80%.[4]

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

22. The FDA conducted several inspections, which uncovered numerous,

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[3] CDC.gov, https://www.cdc.gov/cronobacter/technical.html (last accessed on March 25, 2022).

[4] Norberg S, Stanton C, Ross RP, Hill C, Fitzgerald GF, Cotter PD. Cronobacter spp. in powdered infant formula. J Food Prot. 2012 Mar;75(3):607-20. doi: 10.4315/0362-028X.JFP-11-285. PMID: 22410240.

egregious violations of statutes and regulations set forth herein in Defendant's manufacture, processing, packing, and holding of Similac, Alimentum and EleCare powdered infant formulas.

23. As documented in the FDA Form 483 issued on September 24, 2019, Defendants failed to test a representative sample of an infant formula production aggregate of powered infant formula at the final product stage and before distribution to ensure that the production aggregate met the required microbiological quality standards.

24. Subsequent inspections establish a pattern of Defendant's disregard of reasonable, responsible industry practices, as well as applicable statutes and regulations, with respect to manufacture, processing, packing, and holding of Similac, Alimentum and EleCare powdered infant formulas. As documented in the FDA Form 483 issued on September 24, 2021:

a. Defendant failed to maintain a building used in the manufacture, processing, packing, or holding of infant formula in a clean and sanitary condition; and

b. Defendant personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wash hands thoroughly in a hand washing facility at a suitable temperature after the hands may have become soiled or contaminated.

25. As documented in the FDA Form 483 issued on March 18, 2022:

a. Defendant failed to set in place and/or maintain a system of process controls that cover all stages of infant formula processing to ensure the product does not become adulterated due to the presence of microorganisms (such as cronobacter) in the formula or in the processing environment;

b. Defendant further failed to ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated with microorganisms, (such as cronobacter);

c. Defendant failed to document any determination as to whether a hazard to health exists due to contamination with microorganisms (such as cronobacter);

d. Defendant's personnel that worked directly with infant formula, its raw materials, packaging, equipment, or utensil contact surfaces failed to wear necessary protective apparel.

26. Additionally, Abbott's own records indicate that, in June 2020, it destroyed products because of a previous cronobacter contamination.

27. This establishes that Abbott, at various times:

a. Had knowledge that Cronobacter contaminated its powdered infant formula manufactured, processed, and packaged at its Sturgis, Michigan plant;

b. Failed to adequately test for Cronobacter in its powdered infant formula;

c. Failed to ensure numerous controls were in place to prevent contamination of its powdered infant formula manufactured, processed, and packaged at its Sturgis, Michigan plant.

28. The results of these investigations demonstrate a pattern of Defendant not only failing to take adequate, reasonable measures to protect the health and lives of infants consuming its powered infant formula products, but also failing to take even the common-sense measures, such as washing hands, upon learning of the risk of contamination of its products with microorganisms.

29. Defendant demonstrates an unwillingness or incapability to learn from not only from the lessons of its own misconduct, but also from the historical

misconduct of others engaged in the manufacture, processing, packing, and holding of infant formula that resulted in widespread, serious and often fatal harm to the same especially vulnerable population, such as the "swill milk" scandal during the 1850s in New York City.[5] Thousands of infants were reported to have died from bacterial infection after ingesting contaminated milk sold to their poor and middle class parents by unscrupulous distillers who fed the grain distillation byproduct to dairy cattle kept in fetid conditions.

30. More recently, in September 2008, the deaths of infants and sickness of over 300,000 babies were traced to contamination of infant formula with melamine believed to have been used as a protein additive.[6]

31. Defendant's conduct therefore represents a repeated, conscious disregard for the safety and lives of among the most vulnerable individuals—infants—that rises to the level of recklessness, wantonness, and malice.

32. In January 2022, Plaintiff began purchasing Similac Special care for his infant child.

33. Upon information and belief, multiple containers purchased by Plaintiff match the tainted lots identified by the FDA advisory.

34. Plaintiff's infant child consumed the tainted infant formula.

35. Plaintiff's infant child suffered injury as a result of consuming the tainted formula.

36. Plaintiff's infant child became irritable and displayed problems

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[5] Tyler Moss, "The 19th-Century Swill Milk Scandal That Poisoned Infants With Whiskey Runoff," AtlasObscura.com (November 27, 2017) available at https://www.atlasobscura.com/articles/swill-milk-scandal-new-york-city (last accessed on Mar. 25, 2022).

[6] Gossner CM, Schlundt J, Ben Embarek P, Hird S, Lo-Fo-Wong D, Beltran JJ, Teoh KN, Tritscher A. The melamine incident: implications for international food and feed safety. Environ Health Perspect. 2009 Dec;117(12):1803-8. doi: 10.1289/ehp.0900949. Epub 2009 Aug 6. PMID: 20049196; PMCID: PMC2799451.

sleeping after consuming the tainted formula necessitating medical intervention.

37. Plaintiff's infant child's stool became discolored after consuming the tainted formula.

38. As a direct and proximate result of Plaintiff's infant child ingesting the contaminated formula, Plaintiff has suffered injuries in the past and will continue in the future.

CLASS ALLEGATIONS

39. Plaintiff bring this action on behalf of himself and all other similarly situated class members (the "Class" or "Classes") pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Class and/or Sub-Classes against Defendant for violations of California state laws and/or similar laws in other states:

Multi-State Class Action

> All consumers who purchased any Similac, Alimentum, and EleCare Product in the United States of America and its territories from April 1, 2021 to the present for personal use or consumption.
>
> Excluded from the Class are individuals who allege personal bodily injury resulting from the use of Similac, Alimentum, and EleCare. Also excluded from this Class are Defendant, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice or judicial officer presiding over this matter.

40. In the alternative, Plaintiff brings this action on behalf of himself and all other similarly situated California consumers pursuant to Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the following Sub-Classes:

California Sub-Class

All consumers who purchased any Similac, Alimentum, and EleCare formula in the State of California from April 1, 2018 to the present for personal use or consumption.

Excluded from the Class are individuals who allege personal bodily injury resulting from the use of Similac, Alimentum, and EleCare formula. Also excluded from this Class are Defendant, any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, employees, co-conspirators, all governmental entities, and any judge, justice or judicial officer presiding over this matter.

41. Plaintiff reserves the right to modify these definitions.

42. The members of the Class are so numerous that joinder of all members of the Class is impracticable. Plaintiff is informed and believes that the proposed Class/Sub-Classes contains thousands of purchasers of Defendant's Similac, Alimentum, and EleCare Products who have been damaged by Defendant's conduct as alleged herein. The precise number of Class members is unknown to Plaintiff at this time.

43. Plaintiff's claims are typical to those of all Class members because members of the Class are similarly injured through Defendant's uniform misconduct described above and were subject to Defendant's deceptive claims that accompanied each and every Similac, Alimentum, and EleCare Product. Plaintiff is advancing the same claims and legal theories on behalf of himself and all members of the Class/Sub-Class.

44. Plaintiff's claims raise questions of law and fact common to all members of the Class, and they predominate over any questions affecting only

individual Class members. The claims of Plaintiff and all prospective Class members involve the same alleged defect. These common legal and factual questions include the following:

(a) whether Defendant's Products contained Cronobacter bacteria;

(b) whether Defendant's omissions are true, or are misleading, or objectively reasonably likely to deceive;

(c) whether the alleged conduct constitutes violations of the laws asserted;

(d) whether Defendant's alleged conduct violates public policy;

(e) whether Defendant's engaged in false or misleading advertising; and

(f) whether Plaintiff and the Class members are entitled to damages and/or restitution and the proper measure of that loss.

45. Plaintiff and their counsel will fairly and adequately protect and represent the interests of each member of the class. Plaintiff have retained counsel experienced in complex litigation and class actions. Plaintiff's counsel has successfully litigated other class action cases similar to that here and have the resources and abilities to fully litigate and protect the interests of the class. Plaintiff intends to prosecute this claim vigorously. Plaintiff has no adverse or antagonistic interests to those of the Class, nor are Plaintiff subject to any unique defenses.

46. A class action is superior to the other available methods for a fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by the Plaintiff and individual Class members is relatively small compared to the burden and expense that would be entailed by individual litigation of their claims against Defendant. It would thus be virtually impossible for Plaintiff and Class members, on an individual basis, to obtain meaningful and effective redress for the wrongs done to them. Further, it is desirable to concentrate the litigation of

the Class members' claims in one forum, as it will conserve party and judicial resources and facilitate the consistency of adjudications. Plaintiff knows of no difficulty that would be encountered in the management of this case that would preclude its maintenance as a class action.

47. The Class also may be certified because Defendant has acted or refused to act on grounds applicable to the Class, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class as a whole.

48. Plaintiff seek preliminary and permanent injunctive and equitable relief on behalf of the entire Class, on grounds generally applicable to the entire Class, to enjoin and prevent Defendant from engaging in the acts described above and requiring Defendant to provide a full refund of the purchase price of the Defendant's Similac, Alimentum, and EleCare Products. Products to Plaintiff and Class members.

49. Unless a Class is certified, Defendant will retain monies received as a result of their conduct that were taken from Plaintiff and the Class members. Unless a Class-wide injunction is issued, Defendant will continue to commit the violations alleged and the members of the Class and the general public will continue to be misled.

FIRST CAUSE OF ACTION

Unjust Enrichment

(On Behalf of the Multi-State Class and All State Classes)

50. Plaintiff incorporate by reference and re-alleges each and every allegation contained above, as though fully set forth herein.

51. As a result of Defendant's wrongful and deceptive conduct alleged herein, Defendant knowingly and voluntarily accepted and retained wrongful benefits in the form of money paid by the Plaintiff and members of the Classes

when they purchased the Defendant's Similac, Alimentum, and EleCare Products.

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

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

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

55. Under the common law doctrine of unjust enrichment, it is inequitable for Defendant to be permitted to retain the benefits it received, and is still receiving, without justification, from the false and deceptive labeling and marketing of Defendant's Similac, Alimentum, and EleCare Products to Plaintiff and members of the Classes.

56. Defendant's retention of such funds under circumstances making it inequitable to do so constitutes unjust enrichment.

57. The financial benefits derived by Defendant rightfully belong to Plaintiff and members of the Classes.

58. Defendant should be compelled to disgorge in a common fund for the benefit of Plaintiff and members of the Classes all wrongful or inequitable proceeds received by them.

59. Finally, Plaintiff and members of the Classes may assert an unjust enrichment claim even though a remedy at law may otherwise exist.

SECOND CAUSE OF ACTION

Negligent Misrepresentation/Omission

(On Behalf of the Multi-State Class and All State Classes)

60. Plaintiff incorporate by reference and re-allege each and every allegation contained above, as though fully set forth herein.

61. Through their labeling and advertising, Defendant made representations to Plaintiff and the Class members concerning the safety of their Similac, Alimentum, and EleCare Products.

62. Defendant has a duty to provide accurate information to consumers with respect to the ingredients identified in Defendant's Similac, Alimentum, and EleCare Products as detailed above.

63. Additionally, Defendant has a duty to not make false representations with respect to the safety of their Products.

64. Defendant failed to fulfill its duty when it made false representations regarding the quality and safety of the Products as detailed above.

65. Such failures to disclose on the part of Defendant amount to negligent omission and the representations regarding the quality and safety of the product amount to negligent misrepresentation.

66. Plaintiff and the other members of the Classes reasonably relied upon such representations and omissions to their detriment.

67. By reason thereof, Plaintiff and the other Class members have suffered damages in an amount to be proven at trial.

THIRD CAUSE OF ACTION

Breach of Express Warranty

(On Behalf of the Multi-State Class and All State Classes)

68. Plaintiff incorporates by reference and re-allege each and every allegation contained above, as though fully set forth herein.

69. As detailed above, Defendant, through its written literature, packaging and labeling, and written and media advertisement, expressly warranted that the Similac, Alimentum, and EleCare Products were safe and fit for the purposes intended, that they were of merchantable quality, and that they did not pose dangerous health risks.

70. Plaintiff and the other Class members read and relied on these express warranties provided by Defendant in the packaging and written advertisements.

71. Defendant breached its express warranties because Similac, Alimentum, and EleCare Products were defective and not reasonably safe for their intended use.

72. Defendant knew or should have known that the Similac, Alimentum, and EleCare Products did not conform to their express warranties and representations and that, in fact, the Products are not safe and pose serious health risks because they contain Cronobacter sakazakii.

73. Plaintiff and the other Class members have suffered harm on account of Defendant's breach of its express warranty regarding the fitness for use and safety of these Products and are entitled to damages to be determined at trial.

FOURTH CAUSE OF ACTION

Breach of Implied Warranty

(On Behalf of the Multi-State Class and All State Classes)

74. Plaintiff incorporates by reference and re-allege each and every allegation contained above, as though fully set forth herein.

75. Because the Similac, Alimentum, and EleCare Products contained Cronobacter sakazakii, they were not of the same quality as those generally acceptable in the trade and were not fit for the ordinary purposes for which such Infant Formula Products are used.

76. Plaintiff and members of the Classes purchased these Products in reliance upon Defendant's skill and judgment and the implied warranties of fitness for the purpose.

77. The Defendant's Similac, Alimentum, and EleCare Products were not altered by Plaintiff or members of the Classes.

78. Plaintiff and members of the Classes were foreseeable users of the

Products.

79. Plaintiff and members of the Classes used the Products in the manner intended.

80. As alleged, the Defendant's Similac, Alimentum, and EleCare Products were not adequately labeled and did not disclose that they contain harmful Cronobacter sakazakii.

81. The Products did not measure up to the promises or facts stated in the written literature, media advertisement and communications by and from Defendant.

82. Defendant impliedly warranted that the Products were merchantable, fit and safe for ordinary use.

83. Defendant further impliedly warranted that the Products were fit for the particular purposes for which they were intended and sold.

84. Contrary to these implied warranties, the Products were defective, unmerchantable, and unfit for their ordinary use when sold, and unfit for the particular purpose for which they were sold.

85. By reason thereof, Plaintiff and the other Class members have suffered damages in an amount to be proven at trial.

FIFTH CAUSE OF ACTION

Strict Product Liability – Failure to Warn

(On Behalf of the Multi-State Class and All State Classes)

86. Plaintiff incorporates by reference and re-allege each and every allegation contained above, as though fully set forth herein.

87. Defendant knew or should have known that the Defendant's Similac, Alimentum, and EleCare Products contained Cronobacter sakazakii.

88. Defendant had a duty to warn Plaintiff and the other Class members about the presence of Cronobacter sakazakii in their Products.

89. In addition, Defendant had a duty to warn Plaintiff and the other Class

members about the dangers of the presence of Cronobacter sakazakii in their Products.

90. Defendant knew that the risk of Cronobacter sakazakii infection from use of its products was not readily recognizable to an ordinary consumer and that consumers would not inspect the product for Cronobacter sakazakii content.

91. Defendant did not warn Plaintiff and the other Class members that Defendant's Similac, Alimentum, and EleCare Products contain Cronobacter sakazakii or about the dangers of the presence of Cronobacter sakazakii bacteria in their Products.

92. Plaintiff and the other Class members suffered damages by purchasing the Defendant's Similac, Alimentum, and EleCare Products in a manner promoted by Defendant, and in a manner that was reasonably foreseeable by Defendant. Plaintiff and the members of the Classes would not have purchased Defendant's Similac, Alimentum, and EleCare Products had they known they contained Cronobacter sakazakii bacteria.

93. Plaintiff and the other Class members were justified in their reliance on Defendant's labeling and advertising of the product for use as a safe Infant Formula.

94. Plaintiff and the other Class members have suffered damages in an amount to be proven at trial.

SIXTH CAUSE OF ACTION

Strict Product Liability – Manufacturing Defect

(On Behalf of the Multi-State Class and All State Classes)

95. Plaintiff incorporates by reference and re-allege each and every allegation contained above, as though fully set forth herein.

96. The Defendant's Similac, Alimentum, and EleCare Products contained a manufacturing defect when they left the possession of Defendant. Specifically,

the Products differ from Defendant's intended result or from other lots of the same product line because they contain Cronobacter sakazakii bacteria.

97. Plaintiff and the other Class members used the Products in a way that was reasonably foreseeable to Defendant.

98. As a result of the defects in the manufacture of the Defendant's Similac, Alimentum, and EleCare Products, Plaintiff and the other Class members suffered damages.

99. Accordingly, Plaintiff and members of the Classes suffered damages in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION

FALSE AND MISLEADING ADVERTISING IN VIOLATION OF BUSINESS & PROFESSIONS CODE §17200, *et seq*.

(By Plaintiff and California Class against all Defendants)

100. Plaintiff repeats and realleges the allegations set forth above, and incorporates the same as if set forth herein at length.

101. This cause of action is brought pursuant to *Business and Professions Code* §17200, *et seq*.

102. In the advertising of the Similac, Alimentum, and EleCare Products, Defendants makes false and misleading statements and material omissions including, as set forth above, Defendants represents their product "give babies a strong start by helping to keep them fed, happy, and healthy." In fact, the Product is contaminated and injurious to babies.

103. Defendants are aware that the claims that they make about the Similac, Alimentum, and EleCare Products are false, misleading and unsubstantiated.

104. As alleged in the preceding paragraphs, the misrepresentations and omissions by Defendants of the material facts detailed above constitute an unfair and fraudulent business practice within the meaning of California *Business &*

Professions Code §17200.

105. In addition, Defendants' use of various forms of advertising media to advertise, call attention to or give publicity to the sale of goods or merchandise which are not as represented in any manner constitute unfair competition, unfair, deceptive, untrue or misleading advertising, and an unlawful business practice within the meaning of *Business & Professions Code* §§17531 and 17200, which advertisements have deceived and are likely to deceive the consuming public, in violation of *Business & Professions Code* §17500.

106. There were reasonably available alternatives to further Defendants' legitimate business interests, other than the conduct described herein.

107. All of the conduct alleged herein occurs and continues to occur in Defendants' business. Defendants' wrongful conduct is part of a pattern or generalized course of conduct repeated on thousands of occasions daily.

108. Pursuant to *Business & Professions Code* §§17203 and 17535, Plaintiff and the members of the Classes seek an order of this Court enjoining Defendants from continuing to engage, use, or employ their practice of advertising the sale and use of the Similac, Alimentum, and EleCare Products. Likewise, Plaintiff and the members of the Classes seek an order requiring Defendants to disclose such misrepresentations, and additionally request an order awarding Plaintiff restitution of the money wrongfully acquired by Defendants by means of responsibility attached to Defendants' failure to disclose the existence and significance of said misrepresentations.

EIGHTH CAUSE OF ACTION

FALSE AND MISLEADING ADVERTISING IN VIOLATION OF BUSINESS & PROFESSIONS CODE §17500, *et seq.*

(By Plaintiff and California Class against all Defendants and Does 1-10)

109. Plaintiff repeats and realleges the allegations set forth in the preceding

paragraphs, and incorporates the same as if set forth herein at length.

110. This cause of action is brought pursuant to *Business and Professions Code* §17500, *et seq.* (the "FAL"). The FAL prohibits the dissemination of any advertisement which is untrue or misleading, and which is known, or which by exercise of reasonable care should be known, to by untrue or misleading. Cal. Bus. & Prof. Code §17500.

111. In its advertising OF Similac, Alimentum, and EleCare Products, Defendants make false and misleading statements. Specifically, as set forth above, Defendants labels their products as healthy for babies.

112. In fact, the Similac, Alimentum, and EleCare Products are contaminated and injurious to babies. Defendants are aware that the claims that they make about Product are false, misleading and unsubstantiated.

113. As alleged in the preceding paragraphs, the misrepresentations by Defendants of the material facts detailed above constitute an unfair and fraudulent business practice within the meaning of California *Business & Professions Code* §17500.

114. In addition, Defendants' use of various forms of advertising media to advertise, call attention to or give publicity to the sale of goods or merchandise which are not as represented in any manner constitutes unfair competition, unfair, deceptive, untrue or misleading advertising, and an unlawful business practice within the meaning of *Business & Professions Code* §§ 17531 and 17200, which advertisements have deceived and are likely to deceive the consuming public, in violation of *Business & Professions Code* §17500.

115. Pursuant to *Business & Professions Code* §§17203 and 17535, Plaintiff and the members of the Classes seek an order of this Court enjoining Defendants from continuing to engage, use, or employ their practice of advertising the sale and use of the Similac, Alimentum, and EleCare Products. Likewise,

Plaintiff and the members of the Classes seek an order requiring Defendants to disclose such misrepresentations, and additionally request an order awarding Plaintiff restitution of the money wrongfully acquired by Defendants by means of responsibility attached to Defendants' failure to disclose the existence and significance of said misrepresentations.

NINTH CAUSE OF ACTION

VIOLATION OF CALIFORNIA CIVIL CODE §1750, *et seq*.

(By Plaintiff and California Class against all Defendants)

116. Plaintiff repeats and realleges all the allegations of the previous paragraphs, and incorporates the same as if set forth herein at length.

117. This cause of action is brought pursuant to *Civil Code* §1750, *et seq*., the Consumers Legal Remedies Act.

118. Plaintiff, as well as each member of the Consumer Class, constitutes a "consumer" within the meaning of *Civil Code* §1761(d).

119. Defendants' sales of the Product constitute "transactions" within the meaning of *Civil Code* §1761(e).

120. The Product purchased by Plaintiff and the Consumer Class constitute "goods" under *Civil Code* §1761(a).

121. The Consumer Class consists of thousands of persons, the joinder of whom is impracticable.

122. There are questions of law and fact common to the classes, which questions are substantially similar and predominate over questions affecting the individual members, including but not limited to:

(a) Whether Defendants represented that the Product has characteristics, benefits, uses or quantities which it does not have;

(b) Whether the existence, extent and significance of the major misrepresentations, concealments and omissions regarding the purported benefits,

characteristics and efficacy of the Product violate the Act; and

(c) Whether Defendants knew of the existence of these misrepresentations, concealments and omissions.

123. The policies, acts, and practices heretofore described were intended to result in the sale of Similac, Alimentum, and EleCare Products to the consuming public and violated and continue to violate: (1) Section 1770(a)(5) of the Act which prohibits, *inter alia*, "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have;" (2) Section 1770(a)(7) of the Act, which prohibits, "[r]epresenting that goods or services are of a particular standard, quality, grade, or that goods are of a particular style or model , if they are of another;" (3) Section 1770(a)(9), which prohibits, '[a]dvertising goods or services with intent not to sell them as advertised" and section 1770(a)(14) which bars Similac, Alimentum, and EleCare Products from "representing that a transaction confers or involves rights, remedies, or obligations which it does not have or involve."

124. Defendants fraudulently deceived Plaintiff and the Classes by representing that Similac, Alimentum, and EleCare Products have certain characteristics, benefits, uses and qualities which it does not have. In doing so, Defendants intentionally misrepresented and concealed material facts from Plaintiff and the Classes, specifically and not limited to that the product promotes health and is fit for consumption. Said misrepresentations and concealment were done with the intention of deceiving Plaintiff and the Classes and depriving them of their legal rights and money.

125. Defendants knew that Similac, Alimentum, and EleCare Products were contaminated and not safe for consumption.

126. Defendants' actions as described hereinabove were done with conscious disregard of Plaintiff's rights and Defendants were wanton and malicious

in their concealment of the same.

127. Pursuant to California *Civil Code* §1780(a) of the Act, Plaintiff seeks injunctive relief in the form of an order enjoining the above-described wrongful acts and practices of Defendants including, but not limited to, an order enjoining Defendants from distributing such false advertising and misrepresentations. Plaintiff shall be irreparably harmed if such an order is not granted.

128. Plaintiff reserves the right to amend this complaint to include a request for damages under the CLRA after complying with California *Civil Code* §1782(a) within thirty days after the commencement of this action.

TENTH CAUSE OF ACTION

NEGLIGENCE PER SE

(By Plaintiff and California Class against all Defendants)

129. Plaintiff repeats and realleges all the allegations of the previous paragraphs, and incorporates the same as if set forth herein at length.

130. As documented in the FDA Form 483 issued on September 24, 2019, Defendants failed to test a representative sample of an infant formula production aggregate of powered infant formula at the final product stage and before distribution to ensure that the production aggregate met the required microbiological quality standards.

131. As documented in the FDA Form 483 issued on September 24, 2021, Defendant failed to maintain a building used in the manufacture, processing, packing, or holding of infant formula in a clean and sanitary condition.

132. As documented in the FDA Form 483 issued on September 24, 2021, Defendant personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wash hands thoroughly in a hand washing facility at a suitable temperature after the hands may have become soiled or contaminated.

133. As documented in the FDA Form 483 issued on March 18, 2022, Defendant failed to set in place and/or maintain a system of process controls that cover all stages of infant formula processing to ensure the product does not become adulterated due to the presence of microorganisms, including cronobacter, in the formula or in the processing environment.

134. As documented in the FDA Form 483 issued on March 18, 2022, Defendant further failed to ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated with microorganisms, including cronobacter.

135. As documented in the FDA Form 483 issued on March 18, 2022, Defendant failed to document any determination as to whether a hazard to health exists due to contamination with microorganisms, including cronobacter.

136. As documented in the FDA Form 483 issued on March 18, 2022, Defendant's personnel that worked directly with infant formula, its raw materials, packaging, equipment, or utensil contact surfaces failed to wear necessary protective apparel.

137. The conduct set forth herein, including that documented in the FDA Form 483 reports represent Defendant's conduct in violation of the following statutes or regulations that caused the plaintiffs' injury, including the risk of infection and infection of life-threatening microorganisms:

a. 21 U.S.C. § 331 - "The following acts and the causing thereof are prohibited: (a) The introduction or delivery . . . of any food . . . that is adulterated or misbranded. (b) The adulteration or misbranding of any food . . ..(g) The manufacture . . . of any food . . . that is adulterated or misbranded."[7]

[7] See 21 U.S.C. § 342 (A food shall be deemed to be adulterated (1) If it bears or contains any

b. 21 CFR § 106.5 (failing to maintain good manufacturing practices that are to be used in, and the facilities or controls that are to be used for, the manufacture, processing, packing, or holding of infant formula).[8]

c. 21 CFR § 106.10 (failing to ensure personnel washed hands)

d. 21 CFR § 106.20(a) (failing to maintain building in a clean, sanitary condition)

e. 21 CFR § 106.30(d) (failing to maintain instruments used to measure, regulate, control parameter)

f. 21 CFR § 106.30(e)(5) (failing to monitor the temperature in thermal processing equipment at a frequency as is necessary to maintain temperature control)

g. 21 CFR § 106.30(g) (failing to install a filter capable of retaining particles 0.5 micrometer or smaller when compressed gas is used at a product filling machine).

138. Under 21 U.S.C. § 350a, an infant formula, including an infant formula powder, shall be deemed to be adulterated if…such infant formula does not meet the quality factor requirements prescribed by the Secretary under subsection (b)(1), or (3) the processing of such infant formula is not in compliance with the good manufacturing practices and the quality control procedures prescribed by the Secretary under subsection (b)(2).

139. The injury caused to plaintiffs by Defendant's conduct, which violated these statutes and regulations, was the type of injury that the statutes and regulations

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poisonous or deleterious substance which may render it injurious to health . . . or (4) if it has been prepared, packed, or held under insanitary conditions . . . .); and 21 U.S.C. § 343 (A food shall be deemed to be misbranded . . . if (1) its labeling is false or misleading. . .).

[8] See 21 CFR 106.5(b) (The failure to comply with any regulation in this subpart in the manufacture, processing, packing, or holding of an infant formula shall render such infant formula adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(a)(3)) . . . .)

were designed to prevent.

140. Additionally, plaintiffs were members of the class of persons these statutes and regulations were intended to protect. Indeed, as set forth in 21 C.F.R. § 106.5, "compliance with these provisions is necessary to ensure that such infant formula … is manufactured in a manner designed to prevent its adulteration.

141. As a result of Defendant's conduct in the manufacture of the Defendant's Similac, Alimentum, and EleCare Products violating the foregoing statutes and regulations, Plaintiff and the other Class members suffered damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and all others similarly situated, pray for judgment against the Defendant as to each and every count, including:

A. An order declaring this action to be a proper class action, appointing Plaintiff and their counsel to represent the Class/Sub-Classes, and requiring Defendant to bear the costs of class notice;

B. An order requiring Defendant to engage in a corrective advertising campaign and engage in any further necessary affirmative injunctive relief;

C. An order awarding declaratory relief, and any further retrospective or prospective injunctive relief permitted by law or equity, including enjoining Defendant from continuing the unlawful practices alleged herein, and injunctive relief to remedy Defendant's past conduct;

D. An order requiring Defendant to pay restitution/damages to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, untrue or misleading advertising in violation of the above-cited

authority, plus pre- and post-judgment interest thereon (Plaintiff does not seek monetary damages pursuant to his Ninth Cause of Action);

E. An order requiring Defendant to disgorge any ill-gotten benefits received from Plaintiff and members of the Class/Sub-Classes as a result of any wrongful or unlawful act or practice (Plaintiff does not seek monetary damages pursuant to his Ninth Cause of Action);

F. An order requiring Defendant to pay all actual and statutory damages permitted under the counts alleged herein (Plaintiff does not seek monetary damages pursuant to his Ninth Cause of Action);

G. An order awarding attorneys' fees and costs to Plaintiff and the Class/Sub-Classes; and

H. An order providing for all other such equitable relief as may be just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

DATED: March 25, 2022

[redacted]

DATED: March 25, 2022

[redacted]