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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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1 **NATURE OF THE ACTION**

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

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

18 **JURISDICTION AND VENUE**

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

23 4. This Court has jurisdiction over each Defendant because Defendant is
24 authorized to conduct and does business in California. Defendant has marketed,
25 promoted, distributed, and sold Similac, Alimentum, and EleCare products,
26 including the recalled Products identified below, in California, and Defendant has
27 sufficient minimum contacts with this State and/or sufficiently avail themselves of
28

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

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

7 **THE PARTIES**

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

26 7. Defendant ABBOTT LABORATORIES, INC. D/B/A ABBOTT
27 NUTRITION, is a Delaware Corporation with its principal place of business in
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1 Abbott Park, Lake County, Illinois. Defendant manufactures, markets, advertises,
2 labels, distributes and sells the recalled products at issue in this litigation.

3 **INTRODUCTION**

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

- 6 • Similac. Similac is a brand of powdered infant formula produced by
7 Abbott which Abbott promises will “give babies a strong start by helping
8 to keep them fed, happy, and healthy.” See Why Similac,
9 <https://www.similac.com/why-similac.html> (last visited February 18,
10 2022). According to Abbott, Similac “is the #1 Pediatrician
11 Recommended Brand for Immune Support.” *Id.*
- 12 • Alimentum. Alimentum is a brand of powdered infant formula produced
13 by Abbott for infants with lactose sensitivity which Abbott claims is “the
14 #1 infant formula brand fed for cow’s milk protein allergy in the US.” See
15 Alimentum Product Description,
16 [https://www.similac.com/products/baby-formula/alimentum-powder/19-
17 8oz-can-4pack.html](https://www.similac.com/products/baby-formula/alimentum-powder/19-8oz-can-4pack.html) (last visited February 18, 2022).
- 18 • EleCare. EleCare is a brand of powdered infant formula produced by
19 Abbott for infants who cannot tolerate intact or hydrolyzed protein due
20 to conditions such as severe food allergies or short bowel syndrome. See
21 EleCare Product Information, <https://elecare.com/> (last visited February
22 18, 2022).

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

25 10. On February 17, 2022, the FDA, in conjunction with the CDC,
26 announced a warning to consumers to not purchase or use Recalled Product,
27 stating: “Do not use recalled Similac, Alimentum and EleCare powdered infant
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1 formulas produced in Sturgis, Michigan.”¹

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

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

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

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

- 17
- 18 • the first two digits of the code are 22 through 37; and
 - 19 • the code on the container contains K8, SH or Z2; and
 - 20 • the expiration date is 4-1-2022 (APR 2022) or later.

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

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

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

² Recall Notice, <https://www.similarecall.com/us/en/home.html> (last visited March 16, 2022)

1 also manufactured in Abbott's Sturgis, Michigan facility.

2 17. These products may contain Cronobacter sakazakii bacteria.

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

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

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

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

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

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

23 22. The FDA conducted several inspections, which uncovered numerous,
24

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

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

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

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

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

- 14 a. Defendant failed to maintain a building used in the manufacture,
15 processing, packing, or holding of infant formula in a clean and
16 sanitary condition; and
17 b. Defendant personnel working directly with infant formula, its raw
18 materials, packaging, or equipment or utensil contact surfaces did
19 not wash hands thoroughly in a hand washing facility at a suitable
20 temperature after the hands may have become soiled or
21 contaminated.

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

- 23 a. Defendant failed to set in place and/or maintain a system of process
24 controls that cover all stages of infant formula processing to ensure
25 the product does not become adulterated due to the presence of
26 microorganisms (such as cronobacter) in the formula or in the
27 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

1 misconduct of others engaged in the manufacture, processing, packing, and holding
2 of infant formula that resulted in widespread, serious and often fatal harm to the
3 same especially vulnerable population, such as the “swill milk” scandal during the
4 1850s in New York City.⁵ Thousands of infants were reported to have died from
5 bacterial infection after ingesting contaminated milk sold to their poor and middle
6 class parents by unscrupulous distillers who fed the grain distillation byproduct to
7 dairy cattle kept in fetid conditions.

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

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

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

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

18 34. Plaintiff’s infant child consumed the tainted infant formula.

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

21 36. Plaintiff’s infant child became irritable and displayed problems
22

23
24 ⁵ Tyler Moss, “The 19th-Century Swill Milk Scandal That Poisoned Infants With Whiskey
25 Runoff,” AtlasObscura.com (November 27, 2017) available at
26 <https://www.atlasobscura.com/articles/swill-milk-scandal-new-york-city> (last accessed on Mar.
27 25, 2022).

28 ⁶ Gossner CM, Schlundt J, Ben Embarek P, Hird S, Lo-Fo-Wong D, Beltran JJ, Teoh KN, Tritescher 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.

1 sleeping after consuming the tainted formula necessitating medical intervention.

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

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

7 **CLASS ALLEGATIONS**

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

13 **Multi-State Class Action**

14 All consumers who purchased any Similac, Alimentum, and EleCare
15 Product in the United States of America and its territories from April
16 1, 2021 to the present for personal use or consumption.

17
18 Excluded from the Class are individuals who allege personal bodily
19 injury resulting from the use of Similac, Alimentum, and EleCare.
20 Also excluded from this Class are Defendant, any parent companies,
21 subsidiaries, and/or affiliates, officers, directors, legal representatives,
22 employees, co-conspirators, all governmental entities, and any judge,
23 justice or judicial officer presiding over this matter.

24 40. In the alternative, Plaintiff brings this action on behalf of himself and
25 all other similarly situated California consumers pursuant to Rule 23(a), (b)(2) and
26 (b)(3) of the Federal Rules of Civil Procedure and seeks certification of the
27 following Sub-Classes:
28

1 **California Sub-Class**

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

5
6 Excluded from the Class are individuals who allege personal
7 bodily injury resulting from the use of Similac, Alimentum, and
8 EleCare formula. Also excluded from this Class are Defendant,
9 any parent companies, subsidiaries, and/or affiliates, officers,
10 directors, legal representatives, employees, co-conspirators, all
11 governmental entities, and any judge, justice or judicial officer
12 presiding over this matter.

13 41. Plaintiff reserves the right to modify these definitions.

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

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

26 44. Plaintiff's claims raise questions of law and fact common to all
27 members of the Class, and they predominate over any questions affecting only
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1 individual Class members. The claims of Plaintiff and all prospective Class
2 members involve the same alleged defect. These common legal and factual
3 questions include the following:

- 4 (a) whether Defendant's Products contained Cronobacter bacteria;
- 5 (b) whether Defendant's omissions are true, or are misleading, or
6 objectively reasonably likely to deceive;
- 7 (c) whether the alleged conduct constitutes violations of the laws
8 asserted;
- 9 (d) whether Defendant's alleged conduct violates public policy;
- 10 (e) whether Defendant's engaged in false or misleading advertising;
11 and
- 12 (f) whether Plaintiff and the Class members are entitled to damages
13 and/or restitution and the proper measure of that loss.

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

21 46. A class action is superior to the other available methods for a fair and
22 efficient adjudication of this controversy. The damages or other financial detriment
23 suffered by the Plaintiff and individual Class members is relatively small compared
24 to the burden and expense that would be entailed by individual litigation of their
25 claims against Defendant. It would thus be virtually impossible for Plaintiff and
26 Class members, on an individual basis, to obtain meaningful and effective redress
27 for the wrongs done to them. Further, it is desirable to concentrate the litigation of
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1 the Class members' claims in one forum, as it will conserve party and judicial
2 resources and facilitate the consistency of adjudications. Plaintiff knows of no
3 difficulty that would be encountered in the management of this case that would
4 preclude its maintenance as a class action.

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

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

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

20 **FIRST CAUSE OF ACTION**

21 **Unjust Enrichment**

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

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

25 51. As a result of Defendant's wrongful and deceptive conduct alleged
26 herein, Defendant knowingly and voluntarily accepted and retained wrongful
27 benefits in the form of money paid by the Plaintiff and members of the Classes
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1 when they purchased the Defendant's Similac, Alimentum, and EleCare Products.

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

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

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

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

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

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

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

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

23 **SECOND CAUSE OF ACTION**

24 **Negligent Misrepresentation/Omission**

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

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

1 Products.

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

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

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

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

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

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

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

18 **FIFTH CAUSE OF ACTION**

19 **Strict Product Liability – Failure to Warn**

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

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

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

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

27 89. In addition, Defendant had a duty to warn Plaintiff and the other Class
28

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

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

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

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

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

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

21 **SIXTH CAUSE OF ACTION**

22 **Strict Product Liability – Manufacturing Defect**

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

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

26 96. The Defendant's Similac, Alimentum, and EleCare Products contained
27 a manufacturing defect when they left the possession of Defendant. Specifically,
28

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

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

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

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

10 **SEVENTH CAUSE OF ACTION**

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

13 **(By Plaintiff and California Class against all Defendants)**

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

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

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

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

25 104. As alleged in the preceding paragraphs, the misrepresentations and
26 omissions by Defendants of the material facts detailed above constitute an unfair
27 and fraudulent business practice within the meaning of California *Business &*
28

1 *Professions Code* §17200.

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

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

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

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

23 **EIGHTH CAUSE OF ACTION**

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

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

27 109. Plaintiff repeats and realleges the allegations set forth in the preceding
28

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

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

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

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

13 113. As alleged in the preceding paragraphs, the misrepresentations by
14 Defendants of the material facts detailed above constitute an unfair and fraudulent
15 business practice within the meaning of California *Business & Professions Code*
16 §17500.

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

24 115. Pursuant to *Business & Professions Code* §§17203 and 17535,
25 Plaintiff and the members of the Classes seek an order of this Court enjoining
26 Defendants from continuing to engage, use, or employ their practice of advertising
27 the sale and use of the Similac, Alimentum, and EleCare Products. Likewise,
28

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

6 **NINTH CAUSE OF ACTION**

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

8 **(By Plaintiff and California Class against all Defendants)**

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

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

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

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

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

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

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

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

26 (b) Whether the existence, extent and significance of the major
27 misrepresentations, concealments and omissions regarding the purported benefits,
28

1 characteristics and efficacy of the Product violate the Act; and

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

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

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

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

26 126. Defendants’ actions as described hereinabove were done with
27 conscious disregard of Plaintiff’s rights and Defendants were wanton and malicious
28

1 in their concealment of the same.

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

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

10 **TENTH CAUSE OF ACTION**

11 **NEGLIGENCE PER SE**

12 **(By Plaintiff and California Class against all Defendants)**

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

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

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

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

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

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

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

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

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

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

26 _____
27
28 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

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)))

1 were designed to prevent.

2 140. Additionally, plaintiffs were members of the class of persons these
3 statutes and regulations were intended to protect. Indeed, as set forth in 21 C.F.R.
4 § 106.5, “compliance with these provisions is necessary to ensure that such infant
5 formula ... is manufactured in a manner designed to prevent its adulteration.

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

10 **PRAYER FOR RELIEF**

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

- 14 A. An order declaring this action to be a proper class action, appointing
15 Plaintiff and their counsel to represent the Class/Sub-Classes, and
16 requiring Defendant to bear the costs of class notice;
- 17 B. An order requiring Defendant to engage in a corrective advertising
18 campaign and engage in any further necessary affirmative injunctive
19 relief;
- 20 C. An order awarding declaratory relief, and any further retrospective or
21 prospective injunctive relief permitted by law or equity, including
22 enjoining Defendant from continuing the unlawful practices alleged
23 herein, and injunctive relief to remedy Defendant’s past conduct;
- 24 D. An order requiring Defendant to pay restitution/damages to restore all
25 funds acquired by means of any act or practice declared by this Court
26 to be an unlawful, unfair, or fraudulent business act or practice,
27 untrue or misleading advertising in violation of the above-cited
28

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

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

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

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

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

14 **DEMAND FOR JURY TRIAL**

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

16 DATED: March 25, 2022

BRADLEY/GROMBACHER LLP

17
18 By: /s/ Kiley Grombacher

19 Marcus J. Bradley, Esq.
20 Kiley L. Grombacher, Esq.
21 Lirit A. King, Esq.
Attorneys for Plaintiff

22 DATED: March 25, 2022

**AYLSTOCK, WITKIN, KREIS &
OVERHOLTZ, PLLC**

23
24 By: /s/ Sin- Ting Mary Liu

25 Sin-Ting Mary Liu,
26 E. Samuel Geisler,
27 *pro hac vice* to be submitted
28 Caitlyn Prichard Miller,
pro hac vice to be submitted