DANIEL L. KELLER (SBN 191738)
DAN C. BOLTON (SBN 104236)
KELLER, FISHBACK & JACKSON LLP
28720 Canwood Street, Suite 200
Agoura Hills, CA 91301
Telephone: 818.342.7442
Facsimile: 818.342.7616
Email: dkeller@kfjlegal.com
Email: dbolton@kfjlegal.com

STEPHEN J. FEARON, JR. (*pro hac vice*)
PAUL V. SWEENY (*pro hac vice*)
SQUITIERI & FEARON, LLP
32 E. 57th St., 12th Floor
New York, NY 10022
Telephone: (212) 421-6492
Facsimile: (212) 421-6553
Email: stephen@sfclasslaw.com
Email: paul@sfclasslaw.com

Attorneys for Plaintiff and the Proposed Class

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

OULA ZAKARIA, individually and as a representative of the class,

Plaintiff,

vs.

GERBER PRODUCTS CO., a corporation, d/b/a NESTLE NUTRITION, NESTLE INFANT NUTRITION, AND NESTLE NUTRITION NORTH AMERICA,

Defendant.

Case No.: 2:15-cv-0200-JAK (Ex)

FIRST AMENDED CLASS ACTION COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

1. Plaintiff, Oula Zakaria ("Plaintiff") on behalf of herself and all other persons who purchased Gerber Good Start Gentle infant formula, alleges as follows on personal knowledge as to all facts related to herself and upon information and belief as to all other matters:

NATURE OF THE ACTION

2. This case involves a pattern of deceit and unfair business practices by Gerber Products Co. ("Defendant") in the marketing and sale of Good Start Gentle, a prominent line of infant formula produced, distributed, marketed, and sold by Defendant made from partially hydrolyzed whey protein.

3. Plaintiff brings this class action lawsuit challenging false representations and misleading practices knowingly made or undertaken by Defendant in Good Start Gentle's promotional campaign including, without limitation, (a) that Good Start Gentle was the "first and only" formula whose consumption reduced the risk of infants developing allergies; (b) that consumption of Good Start Gentle reduced the risk of developing infant atopic dermatitis, an inflammatory skin disorder; (c) that Good Start Gentle was the "first and only" formula endorsed by the Food and Drug Administration ("FDA") to reduce the risk of developing allergies; and (d) using the FDA term of art "Qualified Health Claim" to convey that Good Start Gentle received FDA approval for the health claims advertised and was fit for a particular purpose when, in actuality, the term "Qualified Health Claim" means that the FDA did not grant approval for the use of a non-qualified health claim and that the scientific support for the claim is limited or lacking (at best).

4. In 2005 and 2009, Defendant petitioned the FDA to approve claims that partially hydrolyzed whey protein reduced the risk of infants developing food allergies and atopic dermatitis.

5. No scientific or other evidence existed at the time linking a reduced risk of infant allergies, including atopic dermatitis (a form of eczema), to the consumption of partially hydrolyzed whey protein.

6. After reviewing the body of evidence at the time, the FDA rejected Defendant's proposed health claims, stating that "no credible evidence" supported the link between partially hydrolyzed whey protein and a reduced risk of food allergies. Concerning the link between the consumption of partially hydrolyzed whey protein and a reduced risk of atopic dermatitis, the FDA rejected the language proposed by Defendant because the language mischaracterized the connection and would mislead consumers. The FDA stated that it would only consider exercising its enforcement discretion regarding the atopic dermatitis claim if Defendant modified its claim and included highly qualifying language that very little or little scientific evidence (depending on infant age) existed to support the link.

7. Beginning in at least 2011, despite the FDA's clear rejections and the compelling evidence contradicting its claims, Defendant falsely advertised Good Start Gentle as the first and only infant formula endorsed by the FDA to reduce the occurrence of allergies in infants. Defendant made these unsupported claims in order to strategically outpace competitors and substantially increase its sales. Defendant undertook its marketing campaign with actual knowledge that its claims were untrue and notably failed to include any qualifying language or disclaimers in Good Start Gentle advertising.

8. Due to Defendant's pervasive and false marketing campaign that Good Start Gentle provided benefits to children's health beyond that offered by other baby formulas and that the FDA had certified this claim, Plaintiff and the other Class members (as defined below) purchased Good Start Gentle at an inflated cost.

9. Plaintiff and the Class were injured by Defendant's unlawful conduct and are entitled to actual, statutory, and punitive damages, restitution, interest, and the reimbursement of attorneys' fees.

10. In October 2014, the Federal Trade Commission ("FTC") brought suit against Defendant seeking to enjoin its deceptive practices in relation to the marketing and sale of Good Start Gentle, specifically citing Defendant's false or

misleading claim "that feeding Gerber Good Start Gentle formula to infants with a family history of allergies prevents or reduces the risk that they will develop allergies" and the false or misleading claim "that Gerber Good Start Gentle formula qualified for or received approval for a health claim from the Food and Drug Administration."

11. Also in October 2014, the FDA issued Defendant a warning letter listing a litany of misrepresentations and falsehoods in the promotion of Good Start Gentle that violated federal law and related regulations. Defendant was instructed by the FDA to cease its deceitful practices or face potential legal action by the FDA.

12. Plaintiff, on behalf of herself and other similarly situated consumers, brings this consumer protection action against Defendant based on its course of unlawful conduct. Plaintiff alleges violations of California's Unfair Competition Law, California False Advertising Law, the Consumer Legal Remedies Act, as well as Breach of Express Warranty, Breach of the Implied Warranty of Merchantability, Negligent Misrepresentation, and Intentional Misrepresentation.

PARTIES

13. Plaintiff is and was at all relevant times herein, a resident of Porter Ranch, California and is a member of the Class. Plaintiff frequently purchased Gerber Good Start Gentle infant formula based on Defendant's false advertising and deceitful business practices.

14. Defendant, also doing business as Nestle Nutrition, Nestle Infant Nutrition, and Nestle Nutrition North America, is a Michigan corporation with its headquarters located in Florham Park, New Jersey. Throughout the Class Period (as defined below), Defendant has transacted business in this district and throughout California, including marketing, distributing, and selling Good Start Gentle.

JURISDICTION AND VENUE

15. This Court has original jurisdiction over this case under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2). Plaintiff is a citizen of California and Defendant is a citizen, for diversity purposes, of New Jersey and Michigan. The amount in controversy in this action exceeds $5,000,000 and there are more than 100 members in the Class.

16. This Court has personal jurisdiction over Defendant because Defendant is authorized to conduct business in California, is doing business in California, is registered with the California Secretary of State, and maintains a registered agent in Sacramento, California. Alternatively, Defendant is engaged in systematic and continuous business activity in California, has sufficient minimum contacts in California, or otherwise intentionally avails itself of the California consumer market through the promotion, marketing, distribution, and sale of consumer goods, including Good Start Gentle. This purposeful availment renders the exercise of jurisdiction by this Court over Defendant appropriate under traditional notions of fair play and substantial justice.

17. Venue is proper in this District pursuant to 28 U.S.C. § 1391. Plaintiff resides in this District, Defendant regularly conducts business in this District, and a substantial portion of the events giving rise to the claims alleged herein occurred in this District.

18. All conditions precedent to this action have occurred, been performed, or have been waived.

FACTUAL ALLEGATIONS

A. Good Start Gentle Infant Formula Background Information

19. Since at least 2011, Defendant has manufactured, distributed, promoted, offered for sale, and sold Good Start Gentle infant formula. Defendant has advertised and continues to advertise Good Start Gentle formula through television

commercials, print advertisements, point-of-sale displays, product packaging, internet advertisements, and other promotional materials.

20. Gerber Good Start Gentle contains partially hydrolyzed whey protein. Whey protein is derived from cow's milk during the production of cheese. Partially hydrolyzed whey protein undergoes additional processing to break the protein into smaller fragments.

B. The FDA Rejected Defendant's Petition for a Qualified Health Claim Linking Partially Hydrolyzed Whey Protein with a Reduction of Common Food Allergies in 2006

21. Under federal law, the FDA is the governmental body tasked with reviewing and authorizing health claims relating to food products sold in the United States. *See* FDA, *Questions and Answers: Qualified Health Claims in Food Labeling* (Sept. 28, 2005), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm207974.htm (last visited Feb. 23, 2015).

22. A health claim characterizes the relationship between a substance and a disease or health-related condition. Such a claim explains that a food or food component may reduce the risk of a disease or a health related condition. An example of a health claim is: "Diets low in saturated fat and cholesterol may reduce the risk of heart disease." *Id.*

23. Health claims fall into two categories. An "unqualified health claim" must be supported by significant scientific agreement among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship. A "qualified health claim," on the other hand, is supported by scientific evidence, but does not meet the significant scientific agreement standard. As such, to ensure that they are not false or misleading to consumers, they must be accompanied by a disclaimer or other qualifying language to accurately communicate the level of scientific evidence supporting the claim. *Id.*

24. All health claims, whether qualified or unqualified, require pre-market review by the FDA. The FDA authorizes by regulation unqualified health claims on product labels only if the substance/disease relationship described by the health claims meets the "significant scientific agreement" standard. For approved qualified health claims, the FDA issues letters of enforcement discretion when there is credible evidence to support the claim. *Id.* Qualified health claims must include disclaimers that remedy any potential harm caused by potentially misleading claims. *Id.*

25. In June 2005, Defendant petitioned to have the following qualified health claim approved by the FDA:

> Breastfeeding is the best way to nourish infants. For infants who are not exclusively breastfed, emerging clinical research in healthy infants with family history of allergy shows that feeding a 100% Whey-Protein Partially Hydrolyzed formula may reduce the risk of common food allergy symptoms, particularly allergic skin rash, when used instead of whole-protein cow's milk formula from the initiation of formula feeding.

See Qualified Health Claims: Letters of Denial – 100 Percent Partially Hydrolyzed Whey Protein in Infant Formula and Reduced Risk of Food Allergy in Infants (Docket No. 2005Q-0298) (May 11, 2006), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073313.htm (last visited Feb. 23, 2015).

26. The FDA found that no scientific or other evidence supported Defendant's health claim that ingesting partially hydrolyzed whey protein reduces the risk that infants will develop allergies. For example, from a sampling of thirty-six studies evaluating the relationship at the time, none drew a sound scientific conclusion that partially hydrolyzed whey protein did, in fact, reduce such risk. *Id*. at Appendix 1 (explaining that the studies suffer from a multitude of deficiencies including improper controls and unacceptable diagnoses of food allergies.).

27. On May 11, 2006, after "its review of the totality of publicly available scientific evidence, [the] FDA conclude[d] that there is no credible evidence for a

relationship between the consumption of 100 percent partially hydrolyzed whey protein in infant formula and a reduced risk of food allergy." *Id.* After so concluding, the FDA denied Defendant's qualified health claim petition. *Id.* The FDA determined that "neither a disclaimer nor qualifying language would suffice to prevent consumer deception in this circumstance." *Id.*

28. The FDA's denial letter was addressed to Melanie Fairchild-Dzanis, Defendant's Director of Regulatory Issues—Special Nutritional. Fairchild-Dzanis is a lawyer and managed Defendant's regulatory function.

29. As a result of its dealing with the FDA, Defendant possessed actual knowledge that (a) its claim that partially hydrolyzed whey protein reduced the risk of infant allergies was baseless, false and incurable with qualifiers and (b) the FDA rejected its qualified health claim regarding the link.

C. The FDA Similarly Rejected Defendant's Petition for a Health Claim Linking Partially Hydrolyzed Whey Protein and a Reduced Risk of Atopic Dermatitis in Infants in 2011

30. In May 2009, Defendant petitioned to have the following qualified health claim approved by the FDA:

> Breastfeeding is the best way to nourish infants. For infants who are not exclusively breastfed, emerging clinical research shows that, in healthy infants with family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula instead of a formula containing intact cow's milk proteins may reduce the risk of developing the most common allergic disease of infancy—atopic dermatitis—throughout the 1st year of life and up to 3 years of age.

See Whey-Protein Partially Hydrolyzed Infant Formula and Reduced Risk of Atopic Dermatitis (May 24, 2011), available at http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm256731.htm (last visited Feb. 23, 2015).

31. In May 2011, after reviewing the totality of publicly available scientific evidence at the time, the FDA made two findings regarding Gerber's qualified health

claim. *Id.* First, the FDA concluded that there "is very little credible evidence for a qualified health claim about the relationship between feeding a 100 percent whey-protein partially hydrolyzed infant formula for the first 4 months of life and a reduced risk of atopic dermatitis throughout the first year of life and up to 3 years of age." *Id.* Second, it concluded "that there is little credible evidence for a qualified health claim about the relationship between feeding 100 percent whey-protein partially hydrolyzed infant formula for the first four months of life and a reduced risk of atopic dermatitis throughout the first year of life." *Id.*

32. As a result, the FDA rejected Defendant's claim as proposed because it "mischaracterized the strength of the evidence and [was] misleading." *Id.*

33. The FDA stated that it would only consider exercising its enforcement discretion regarding Defendant's atopic dermatitis claim if Defendant attached qualifying language to the effect that "very little scientific evidence" or "little scientific evidence" supports the link between partially hydrolyzed whey protein and a reduced risk of atopic dermatitis depending on the infant age included in the claim. *Id.*

34. The FDA's 2011 denial letter was similarly addressed to Ms. Fairchild-Dzanis.

35. As a result of its dealings with the FDA, Defendant possessed actual knowledge that (a) its claim that partially hydrolyzed whey protein reduced the risk of infants developing atopic dermatitis was false or supported by little or very little scientific evidence (at best at the time) and (b) the FDA rejected Defendant's qualified health claim regarding the link as proposed because the claim was misleading and required that if Defendant was to make the claim it do so with stringent qualifying statements.

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D. Compelling Scientific Studies Conclude That Partially Hydrolyzed Whey Formula Does Not Lower The Risk of Allergic Manifestations (Including Eczema) In Infancy Compared With Conventional Formula

36. Defendant's claims linking the consumption of Good Start Gentle (a partially hydrolyzed whey formula) with a reduced risk of developing infant allergies (including atopic dermatitis—a form of eczema) are false and misleading.

37. Several compelling scientific studies have concluded that partially hydrolyzed whey formula does not lower the risk of allergic manifestations, including eczema, during infancy (and up to age 7) when compared with conventional formula.

38. One such study published in June 2011 concluded that "[t]here was no evidence that introducing pHWF [(partially hydrolyzed whey formula)] at the cessation of breast-feeding reduced the risk of allergic manifestations, including eczema, asthma, and allergic rhinitis, in [a] study of high-risk infants." Adrian J. Lowe, PhD et al., *Effect of a partially hydrolyzed whey infant formula at weaning on risk of allergic disease in high-risk children: A randomized controlled trial*, 128 J. ALLERGY & CLIN. IMMUNOL. 2, Aug. 2011, at 360-65.e4 ("Lowe Study"), attached hereto as Exhibit A.

39. The Lowe Study further concluded that partially hydrolyzed whey formula did not reduce the risk of allergic manifestations, including eczema, (1) in children from birth to age 7 and (2) in children both with and without a family history of eczema when compared with conventional formula. *Id.*

40. The Lowe Study did "not support the recommendation that [partially hydrolyzed whey formula] should be used after breast-feeding as a preventative strategy for infants at high risk of allergic diseases." *Id.*

41. Upon information and belief, Defendant knew or should have known about the Lowe Study's rejection of its health claims because Nestec Ltd, a subsidiary of Nestle Australia Ltd, provided the Lowe Study with study formula and staff funding for the first 6 years of the study. *Id.* Upon information and belief, Nestec Ltd

and Nestle Australia Ltd are affiliated with Defendant. *See* Nestle S.A., Annual Report 2013 at 154, 165, 170, *available at* http://www.nestle.com/asset-library/documents/library/documents/annual_reports/2013-annual-report-en.pdf (last visited Feb. 23, 2015).

E. Defendant Widely Markets Good Start Gentle as the First and Only Infant Formula Endorsed by the FDA Which Prevents Allergies and Reduces the Risk of Atopic Dermatitis Without Qualification or Disclaimers

42. Despite the FDA's express guidance and compelling evidence contradicting Defendant's claims, Defendant falsely marketed and, upon information and belief, continues to market Good Start Gentle as a product endorsed by the FDA for reducing the risk of developing allergies and atopic dermatitis to attract customers, increase revenues, and edge out Defendant's competition.

43. Since at least 2011, Defendant knowingly disseminated or has caused to be disseminated advertisements, packaging, and promotional materials for Good Start Gentle in California containing false and misleading statements, as demonstrated by the following sample of Good Start Gentle promotional materials.

44. In Exhibit B, a label included on a formula canister, Defendant states that Good Start Gentle is the "1st and Only Routine Formula to Reduce the Risk of Developing Allergies." Exhibit B falsely communicates to consumers that Good Start Gentle reduced the risk of infants developing allergies despite the total lack of evidence supporting that proposition, an FDA letter rejecting Defendant's qualified health claim, and compelling evidence, such as the Lowe Study, contradicting the claim.

45. In Exhibit C, a product label, a gold badge with the words "Meets FDA" printed at the top, "1st and Only" printed in the center, and "Qualified Health Claim" printed at the bottom. The product label further includes a statement that Good Start Gentle "is the first and only formula brand . . . that meets the criteria for a FDA Qualified Health Claim for atopic dermatitis." This advertisement falsely

communicates to consumers that the FDA approved Defendant's qualified health claim regarding atopic dermatitis when the FDA, in fact, rejected the claim as proposed because it misled consumers. It also deceptively uses the FDA term of art "Qualified Health Claim" to convey that Good Start Gentle is fit for a particular purpose or certified by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited. The product label notably fails to include the qualifying language required by the FDA and federal law.

46. In Exhibit D (storyboard dated April 9, 2012), a television commercial, an announcer states that "You want your Gerber baby to have your imagination . . . your smile . . . your eyes . . . not your allergies. . . . [I]f you introduce formula, choose the Gerber Good Start Comfort Proteins Advantage." *See* Gerber Good Gentle Formula with Comfort Proteins Advantage Commercial, https://www.youtube.com/watch?v=h6l-CjygjEg (last visited Feb. 23, 2015). This advertisement falsely communicates to consumers that Good Start Gentle reduced the risk of infants developing allergies despite compelling evidence contradicting that proposition and an FDA letter rejecting Defendant's qualified health claim.

47. In Exhibit E, a print advertisement depicting a baby's face on a canister of Good Start Gentle, the caption reads, "I love Mommy's eyes, not her allergies. If you have allergies in your family, breastfeeding your baby can help reduce their risk. And if you decide to introduce formula research shows the formula you first provide to your baby may make a difference." Exhibit E falsely communicates to consumers that Good Start Gentle reduced the risk of infants developing allergies despite compelling evidence contradicting that proposition and an FDA letter rejecting Defendant's qualified health claim. The advertisement also notably fails to include the qualifying language required by the FDA and federal law.

48. In Exhibit F, a magazine advertisement, Defendant falsely promoted Good Start Gentle as "the first and only infant formula that meets the criteria for a

FDA Qualified Health Claim." This advertisement falsely communicates to consumers that the FDA approved Defendant's health claims when, in reality, the FDA rejected both of Defendant's health claims. This advertisement also deceptively uses the FDA term of art "Qualified Health Claim" to convey that Good Start Gentle is fit for a particular purpose or certified by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited. Notably, the advertisement fails to include the qualifying language required by the FDA.

49. In Exhibit G, a gold badge as part of a supermarket display depicting a canister of Good Start Gentle, the words "Meets FDA" are printed at the top, "1st and Only" is printed in the center, and "Qualified Health Claim" is printed at the bottom. This advertisement falsely communicates to consumers that the FDA approved Defendant's health claims when, in reality, the FDA rejected both of Defendant's health claims. This advertisement also misleadingly conveys the FDA term of art "qualified health claim" in order to convince consumers that Good Start Gentle was fit for a particular purpose or certified for quality by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited. Notably, the display fails to include the qualifying language required by the FDA.

50. In Exhibit H, a magazine advertisement printed in People Magazine on August 5, 2013, a mother is depicted feeding an infant and a badge is included which states that Good Start Gentle is the "1st Formula with FDA Qualified Health Claim." This advertisement falsely communicates to consumers that the FDA approved Defendant's health claims when, in reality, the FDA rejected both of Defendant's health claims. This advertisement also misleadingly conveys the FDA term of art "qualified health claim" in order to convince consumers that Good Start Gentle was fit for a particular purpose or certified for quality by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited. Notably, the advertisement fails to include the qualifying language required by the FDA.

51. Based on this limited sampling, it is reasonable to infer that discovery

would demonstrate a protracted course of purposeful, false, and misleading advertising by Defendant to induce consumers to purchase Good Start Gentle during the Class Period.

52. Reasonable consumers, including Plaintiff, would/did attach importance to the health and FDA approval claims specified herein when determining whether to purchase Gerber Good Start. Defendant's misrepresentations were/are material. Under *In Re Tobacco II Cases*, 46 Cal.4th 298, 326-327, "a presumption, or at least an inference, of reliance arises wherever there is a showing that a misrepresentation was material."

F. The FTC Sues Defendant Seeking A Permanent Injunction and Other Equitable Relief for Violations of the Federal Trade Commission Act Committed During Defendant's Promotional Campaign for Good Start Gentle

53. On October 29, 2014, the FTC filed a lawsuit in the District of New Jersey against Defendant "under Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b) to obtain preliminary and permanent injunctive relief . . . for Defendant's acts or practices, in violation of Section 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the labeling, advertising, marketing, distribution, and sale of Gerber Good Start Gentle, an infant formula that purports to prevent or reduce the risk of the development of allergies." *Federal Trade Commission v. Gerber Products Co.*, 2:14-cv-06771-SRC-CLW, Dkt. No. 1, at 1 (D.N.J. Oct. 29, 2014).

54. In its complaint, the FTC specifically challenged Defendant's false and unsubstantiated claim that "feeding Gerber Good Start Gentle formula to infants with a family history of allergies prevents or reduces the risk that they will develop allergies" and Gerber's false assertions that "Good Start Gentle formula qualified for or received approval for a health claim from the Food and Drug Administration." *Id.* at 9-10.

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G. The FDA Issues a Warning Letter to Defendant Stating that Good Start Gentle is Misbranded and Misleading in Violation of Federal Law

55. In addition to the lawsuit filed by the FTC on October 29, 2014, on October 31, 2014, the FDA wrote a warning letter addressed to Mr. Gary Tickle, Defendant's President and CEO, outlining various false and misleading representations made in the promotion of Good Start Gentle that violate federal law and related federal regulations. *See generally* Warning Letter, Nestle Infant Nutrition 10/31/14, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm423087.htm (last visited Feb. 23, 2015) ("Warning Letter").

56. The violations cited by the FDA include, without limitation, that:

a) Good Start Gentle was misbranded under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, because Good Start Gentle's labeling and website "bear health claims that were not authorized by the FDA." *See* Warning Letter at 2;

b) Defendant's health claim that the consumption of 100% partially hydrolyzed whey protein reduces the risk of infants developing allergies was a health claim previously considered and denied by the FDA and therefore unauthorized. *See* Warning Letter at 2-3;

c) Defendant failed to ensure consumer safety by not properly informing consumers that Good Start Gentle should not be fed to infants with milk allergies and that such infants' "care and feeding choices should be under a doctor's supervision." *See* Warning Letter at 2-4 (Defendant omitted to include key information in mandatory bold type and excluded other mandatory language entirely.);

d) Good Start Gentle is misbranded because Defendant wrongly identified "100% whey partially hydrolyzed" as the substance linked to a reduced risk of atopic dermatitis on Good Start Gentle's label and website. *See*

Warning Letter at 3. However, the substance that was the subject of Defendant's 2011 qualified health claim petition to the FDA was "100% whey protein partially hydrolyzed." *Id.* As such, Defendant's health claim regarding atopic dermatitis misleads consumers because it suggests "that the partial hydrolysis of whey could refer to any or all of the components in whey being hydrolyzed (*i.e.*, oligosaccharides, fats, and protein)," and no evidence exists to support such claim. *See* Warning Letter;

e) Defendant separated qualifying language related to its atopic dermatitis health claim in a way not approved by the FDA in its 2011 letter of enforcement discretion to Defendant. *See* Warning Letter at 5. The FDA expressed concerns that such separation could mislead consumers.

57. In the letter, the FDA instructed Defendant to "take prompt action to correct the violations described above" or face potential legal action. *See* Warning Letter at 5.

58. As a whole, the Warning Letter further demonstrates Defendant's willful and deceitful pattern of promoting Good Start Gentle in a way that would mislead consumers and induce purchase of Good Start Gentle.

H. Plaintiff Begins Consistently Purchasing Good Start Gentle Based on Defendant's False Promotional Campaign and Suffers Damages

59. On September 4, 2013, Plaintiff's daughter, Layla, was born. Plaintiff originally fed her daughter a mix of other infant formulas but did not feed her daughter Gerber Good Start.

60. In October 2013, Plaintiff took her daughter to a meeting with her pediatrician who introduced Plaintiff to Gerber Good Start infant formula and provided Plaintiff with three or four containers of Gerber Good Start infant formula. Plaintiff received two types of Gerber Good Start infant formula from her daughter's pediatrician: Gerber Good Start Gentle and Gerber Good Start Soothe, another line of

formula offered for sale by Gerber.

61. Plaintiff did not know that Defendant produced infant formula. In October 2013 and November 2013, Plaintiff researched Good Start formula and reviewed statements made by Defendant on its website highlighting Good Start Gentle's endorsement by the FDA and its ability to protect infants from developing allergies.

62. Based on this false and misleading information, Plaintiff ceased buying other infant formulas, and instead, began routinely purchasing Good Start Gentle formula. Plaintiff purchased Good Start Gentle infant formula in various containers, including containers with the misleading label: "1st & Only Routine Formula to Reduce Risk of Developing Allergies" as depicted in Exhibit B.

63. Plaintiff first saw and relied on the information depicted in Exhibit B in November 2013.

64. Plaintiff also purchased Good Start Gentle misbranded containers that mischaracterized the relationship between "100% whey partially hydrolyzed" and a reduced risk of atopic dermatitis as described in Paragraph 56(d), *supra*.

65. Plaintiff bought these mislabeled Gerber Good Start Gentle infant formula containers from stores in Porter Ranch, California, including Target, Babies "R" Us, and Walmart for prices generally ranging between $25 and $26.

66. On average, Plaintiff used one container of Gerber Good Start Gentle per week from October 2013 to November 2014.

67. Plaintiff made those purchases based on Gerber's false and misleading promotional materials and labeling that Gerber Good Start Gentle was approved by the FDA to reduce the risk of infants developing allergies, even though Defendant knew that such health claims were baseless and rejected by the FDA.

68. Plaintiff would not have purchased Gerber Good Start Gentle had she known (1) that partially hydrolyzed whey protein does not reduce the risk of allergies (including atopic dermatitis) in children or (2) that the FDA did not endorse, approve,

or certify the health claims Defendant made on its labels, in its advertisements, and on its website.

69. For these reasons, Plaintiff and other Class members incurred damages from Defendant's misconduct.

CLASS ACTION ALLEGATIONS

70. Plaintiff asserts her claims on behalf of the following proposed Class:

> All persons who have purchased Gerber Good Start Gentle infant formula in California during the applicable statute of limitations. The Class excludes any judge or magistrate assigned to this case, Defendant and any entity in which Defendant has a controlling interest, and its officers, directors, legal representatives, successors and assigns. Also excluded from the class are those who purchased Gerber Good Start Gentle infant formula for the purpose of resale and those who assert claims for personal injury.

71. Numerosity: The Class is so numerous that joinder of all Class members is impracticable. The Class includes hundreds, and likely thousands, of Defendant's customers.

72. Typicality: Plaintiff's claims are typical of the members of the Proposed Class because, like the other Class members, she was exposed to Defendant's deceptive advertising and business practices and purchased Good Start Gentle in reliance thereon.

73. Adequacy: Plaintiff will fairly and adequately protect the interests of the Class, and has retained counsel experienced in complex class action litigation. Plaintiff has no interests which are adverse to those of the Class that she seeks to represent.

74. Commonality: Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual

members of the Class, including:

a) Whether Defendant falsely advertised Good Start Gentle as a product endorsed by the FDA to reduce the occurrence of allergies and atopic dermatitis in infants;

b) Whether Defendant disseminated misleading labels, commercials, print advertisement, point-of-sale displays, and other promotional materials in an effort to convince customers to purchase Good Start Gentle based on false representations – namely that the FDA issued a qualified health claim that Good Start Gentle reduced the occurrence of infant allergies;

c) Whether Defendant used the term "qualified health claim" in order to mislead consumers into believing that the FDA certified the quality of Good Start Gentle or that Good Start Gentle was fit for a particular purpose, rather than convey that any potential health claim was limited, restricted, or insufficient;

d) Whether Defendant violated the unlawful prong of California's Unfair Competition Law;

e) Whether Defendant violated the unfair and fraudulent prongs of California's Unfair Competition Law;

f) Whether Defendant violated California's False Advertising Law;

g) Whether Defendant violated California's Legal Remedies Act;

h) Whether Defendant breached Good Start Gentle's express warranty;

i) Whether Defendant breached the implied warranty of merchantability;

j) Whether Defendant negligently misrepresented the FDA endorsement and health benefits of Good Start Gentle;

k) Whether Defendant intentionally misrepresented the health benefits and FDA endorsement of Good Start Gentle;

l) Whether Plaintiff and the Class are entitled to actual, statutory, and punitive damages; and

m) Whether Plaintiff and the Class are entitled to restitution.

75. These and other questions of law and fact are common to the Class and predominate over any questions affecting only individual members of the Class.

76. Plaintiff cannot be certain of the form and manner of proposed notice to class members until the class is finally defined and discovery is completed regarding the identity of class members. Plaintiff anticipates, however, that notice by mail will be given to class members who can be identified specifically. In addition, notice may be published in appropriate publications, on the internet, in press releases and in similar communications in a way that is targeted to reach those who may have purchased Gerber Good Start Gentle infant formula. The cost of notice, after class certification, trial, or settlement before trial, should be borne by Defendant.

77. Plaintiff is a member of the Class and will fairly and adequately represent and protect the interests of the Class. Plaintiff has no claims antagonistic to those of the Class. Plaintiff has retained counsel competent and experienced in complex class actions, including all aspects of this litigation. Plaintiff's counsel will fairly, adequately, and vigorously protect the interests of the Class.

78. Class action status is warranted under Rule 23(b)(1)(A) because the prosecution of separate actions by or against individual members of the Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class, which would establish incompatible standards of conduct for Defendant.

79. Class action status is also warranted under Rule 23(b)(1)(B) because the prosecution of separate actions by or against individual members of the Class would create a risk of adjudications with respect to individual members of the Class which would, as a practical matter, be dispositive of the interests of the other members not parties to the adjudications, or substantially impair or impede their ability to protect their interests.

80. Class action status is also warranted under Rule 23(b)(3) because

questions of law or fact common to the members of the Class predominate over any questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

81. Plaintiff reserves her right to modify or amend the definition of the proposed Class at any time before the Class is certified by the Court.

FIRST CLAIM FOR RELIEF

VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW

(California Business and Professions Code §§ 17200 *et seq.*)

(Unlawful)

82. Plaintiff realleges and incorporates by reference the allegations elsewhere in the Complaint as if set forth fully herein.

83. Plaintiff brings this claim on behalf of herself and the proposed Class.

84. California Business and Professions Code §§ 17200 *et seq.*, prohibits acts of unfair competition, including any "unlawful, unfair or fraudulent business act or practice."

85. Defendant engaged in unlawful business acts and practices in violation of California Business and Professions Code §§ 17200 *et seq*. by engaging in the false and misleading advertising specified elsewhere in this Complaint.

86. Defendant has manufactured, advertised, distributed, and sold products misbranded under California Law. *See* California Health & Safety Code § 110660. Misbranded products cannot be legally manufactured, advertised, distributed, or sold or held and are legally worthless.

87. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendant as alleged herein constitute "unlawful" business acts and practices in that Defendant's conduct violates:

a) California's False Advertising Law, CAL. BUS. & PROF. CODE §§ 17500 *et seq.*;

b) California's Consumers Legal Remedies Act ("CLRA"), CAL. CIV. CODE

§§ 1750 *et seq.*;

c) California Health & Safety Code §§ 109885 and 110390 which make it unlawful to disseminate false or misleading food advertisements that include statements on products and product packaging or labeling or any other medium used to directly or indirectly induce the purchase of a food product;

d) California Health & Safety Code §§ 109885 and 110390 which make it unlawful to disseminate false or misleading food advertisements that include statements on products and product packaging or labeling or any other medium used to directly or indirectly induce the purchase of a food product;

e) California Health & Safety Code § 110395 which makes it unlawful to deliver or proffer for delivery any food that has been falsely advertised;

f) California Health & Safety Code §110760 which makes it unlawful for any person to manufacture, sell, deliver, hold, or offer or sale any food that is misbranded;

g) California Health & Safety Code § 110765 which makes it unlawful for any person to misbrand food;

h) California Health & Safety Code § 110770 which makes it unlawful for any person to receive in commerce any food that is misbranded or to deliver or proffer for delivery any such food;

i) Section 5(a) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce; and

j) Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics.

88. Defendant's conduct is further "unlawful" because it violates the following provisions of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301 *et seq.*, and its implementing regulations:

a) Sections 321(n) and 403(a) of the FFDCA, 21 U.S.C. §§ 321(n) & 343(a), which deems food misbranded when the label contains a statement that is "false or misleading in any particular" or "its advertising is false or misleading in a material respect";

b) 21 C.F.R. § 101.14(e), which proscribes express and implied health claims on food labeling unless, *inter alia*, such a claim is specifically provided for by regulation and complies therewith; and

c) Alternatively, 21 C.F.R. § 101.14(d), which, *inter alia*, (i) requires all health claim based food labeling to conform to regulation, (ii) requires that all health claims made on food labels are limited to describing the value that ingestion of a certain substance may have on a particular disease or health-related condition, (iii) proscribes incomplete, untruthful, and misleading health claims on food labels, and (iv) requires reference to or complete health claims to be in the immediate proximity of all graphic material constituting a health claim (*e.g.*, a heart symbol).

89. Defendant leveraged its deception to induce Plaintiff and the Class to purchase products that were of lesser value and quality than advertised.

90. The foregoing acts and practices have detrimentally impacted competition and caused substantial harm to Plaintiff, the Class, and the consuming public. Plaintiff and members of the Class were misled and suffered injuries and lost money or property as a direct and proximate result of Defendant's unlawful business practices.

91. Plaintiff and the Class could have reasonably avoided the harm alleged herein. Plaintiff and the Class were denied the benefit of the bargain when they decided to purchase Good Start Gentle over competitor products which are less

expensive, make medically and scientifically supported health claims, do not falsely purport to be endorsed for quality or fit for a particular purpose by the FDA, or which do not make health claims linking the consumption of partially hydrolyzed whey protein and a reduced risk of food allergies in infants. Had Defendant not made false and misleading statements and used false and misleading advertising tactics, Plaintiff and the Class would have paid less than what they did for Good Start Gentle, or would have not purchased the product at all.

92. Defendant's misuse of FDA endorsement and FDA terms of art were/are likely to deceive reasonable consumers. Likewise, Defendant's false health claims were/are likely to deceive reasonable consumers.

93. The false and misleading advertising and labeling described elsewhere in the Complaint presents a continuing threat to consumers in that such advertising will continue to mislead consumers to purchase legally worthless Good Start Gentle on false premises.

94. By reason of the foregoing, Defendant should be required to disgorge its illicit profits, make restitution to Plaintiff and the Class, and pay for Plaintiff's and the Class' attorneys' fees.

95. Plaintiff reserves the right to identify additional provisions of law violated by Defendant as further investigation and discovery warrants.

SECOND CLAIM FOR RELIEF

VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW

(California Business and Professions Code §§ 17200 *et seq.*)

(Unfair and Fraudulent)

96. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

97. Plaintiff brings this claim on behalf of herself and the proposed Class.

98. California Business and Professions Code §§ 17200 *et seq.* prohibits acts of unfair competition, including any "unlawful, unfair or fraudulent business act or

practice."

99. The false and misleading labeling and advertising of Good Start Gentle, as alleged herein, constitutes "unfair" business acts and practices because such conduct is immoral, unscrupulous, and offends public policy. Further, the harm of Defendant's conduct to Plaintiff, the Class, and the consumer public outweighs any conceivable benefit of such conduct.

100. Defendant's false and misleading labeling and advertising have detrimentally impacted competition and caused substantial harm to Plaintiff, the Class, and the consuming public. Plaintiff and members of the Class were deceived, suffered injuries, and lost money or property as a direct and proximate result of Defendant's unlawful business practices.

101. The false and misleading labeling and advertising of Good Start Gentle, as alleged herein, also constitutes "fraudulent" business acts and practices because members of the consuming public, including Plaintiff and the Class, were/are likely to be deceived by the false and misleading advertising and labeling described elsewhere in the Complaint.

102. Plaintiff and the Class could have reasonably avoided the harm alleged herein. Plaintiff and the Class were denied the benefit of the bargain when they decided to purchase Good Start Gentle over competitor products which are less expensive, contain healthier ingredients, do not purport to be endorsed by the FDA for quality, make medically and scientifically supported health claims, or which do not make health claims linking the consumption of partially hydrolyzed whey protein and a reduced risk of food allergies in infants. Had Defendant not engaged in its false and misleading advertising tactics, Plaintiff and the Class would have paid less than what they did for Good Start Gentle, or not purchased the product at all.

103. Defendant either knew or reasonably should have known that the health claims on the labels and advertising alleged herein were untrue and misleading.

104. In addition, Defendant's *modus operandi* constitutes an unfair and

fraudulent practice in that Defendant knew or should have known that consumers rely on health claims made concerning infant formula but are unlikely to possess the expertise required to make a scientific and medical conclusion linking the consumption of partially hydrolyzed whey protein and any potential reduced risk of food allergies in infants. Particularly, Defendant knew or should have known that consumers rely on unqualified and qualified health claims made under the guise of FDA approval or consent.

105. By reason of the foregoing, Defendant should be required to disgorge its illicit profits, make restitution to Plaintiff and the Class, and pay for Plaintiff's and the Class' attorneys' fees.

THIRD CLAIM FOR RELIEF

VIOLATION OF THE CALIFORNIA FALSE ADVERTISING LAW

(California Business and Professions Code §§ 17500 *et seq.*)

106. Plaintiff realleges and incorporates by reference the allegations elsewhere in the Complaint as if set forth fully herein.

107. Plaintiff brings this claim on behalf of herself and the proposed Class.

108. Defendant's acts and practices as described herein have deceived and/or are likely to deceive Plaintiff, the Class, and the public. Defendant has repeatedly advertised that Good Start Gentle reduces the risk of allergies (including atopic dermatitis) in infants despite the falsity of this statement.

109. The advertisements, labeling, policies, acts, and practices described herein were designed to, and did, result in the purchase and use of Good Start Gentle without consumer knowledge that Defendant never received FDA approval for its health claims and misled consumers with its qualified health claim representations.

110. Defendant's advertising and labeling has deceived and is likely to deceive Plaintiff, the Class, and the public in the future because it misrepresented the FDA's endorsement of Good Start Gentle's ability to reduce the risk of allergies (i.e., a reasonable consumer does not understand the definition of an "FDA Qualified

Health Claim" without appropriate explanation). Reasonable consumers do not interpret "qualified" as "[n]ot complete or absolute; limited", but instead interpret it as "[o]fficially recognized as being trained to perform a particular job; certified." *See Qualified Definition*, OXFORD ENGLISH DICTIONARY, http://www.oxforddictionaries.com/definition/english/qualified (last visited Dec. 18, 2014).

111. Defendant knew or by the exercise of reasonable care should have known that its advertisements concerning Good Start Gentle's ability to reduce the risk of allergies in infants and the representation that the FDA endorsed these claims were untrue or misleading. Plaintiff and the Class based their decisions to purchase Good Start Gentle in substantial part on Defendant's misrepresentations and omitted material facts.

112. Defendant disseminated and continues to disseminate uniform advertising concerning Good Start Gentle which is unfair, deceptive, untrue, or misleading within the meaning of California Business & Professions Code §§ 17500 *et seq.* Such advertisements are likely to deceive, and continue to deceive, the consuming public for the reasons detailed elsewhere in the Complaint.

113. Plaintiff and the Class have suffered injury in fact and have lost money or property as a result of Defendant's violation of California Business & Professions Code §§ 17500 *et seq.*

114. The misrepresentations and omissions by Defendant of the material facts detailed elsewhere in this Complaint constitute false and misleading advertising.

115. As a result of Defendant's wrongful conduct, Plaintiff and the Class are entitled to restitution and an order for the disgorgement of the funds by which Defendant was unjustly enriched.

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FOURTH CLAIM FOR RELIEF

VIOLATION OF THE CONSUMERS LEGAL REMEDIES ACT

(California Civil Code §§ 1750 *et seq.*)

116. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

117. Plaintiff brings this claim on behalf of herself and the proposed Class.

118. The CLRA has adopted a statutory scheme prohibiting various deceptive practices in connection with the conduct of a business providing goods, property, or services primarily for personal, family, or household purposes.

119. Defendant's policies, acts, and practices were intended to, and did, result in the purchase and use of the products primarily for personal, family, or household purposes, and violated and continue to violate at least the following sections of the CLRA:

a) § 1770(a)(2), which proscribes "[m]isrepresenting the source, sponsorship, approval, or certification of goods or services" in the sale of consumer goods;

b) § 1770(a)(3), which proscribes "[m]isrepresenting the affiliation, connection, or association with, or certification by, another" in the sale of consumer goods;

c) § 1770(a)(5), which proscribes "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have";

d) § 1770(a)(7), which proscribes "[r]epresenting that goods or services are of a particular standard, quality or grade"; and

e) § 1770(a)(9), which proscribes "[a]dvertising goods or services with intent not to sell them as advertised."

120. Defendant's wrongful acts and practices as described elsewhere were

willful, oppressive, and fraudulent.

121. As a proximate result of these violations by Defendant, Plaintiff and the Class have suffered irreparable harm and are entitled to the payment of costs and attorneys' fees and such other relief as deemed appropriate and proper by the Court under California Civil Code § 1780.

122. In compliance with California Civil Code § 1782, Defendant received written notice by certified mail on January 20, 2015 of Plaintiff's claims and of her intention to seek damages under California Civil Code § 1750 *et seq*. unless Defendant provides an appropriate refund plus interest and other appropriate relief to all members of the Class entitled to relief under the CLRA.

123. Defendant has failed to provide such relief and has not adequately responded to the demand to pay refunds and otherwise rectify the wrongful conduct described above on behalf of all members of the Class who may be entitled to relief under the CLRA.

124. Accordingly, Plaintiff seeks an award of all actual and punitive damages permitted for violation of the CLRA, including for statutory damages of $1,000 per Class member and up to $5,000 per each Class member who qualifies as a "senior citizen" under the CLRA.

FIFTH CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTY

(California Commercial Code § 2313)

125. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

126. Plaintiff brings this claim on behalf of herself and the proposed Class.

127. As set forth hereinabove, Defendant made representations to the public, including Plaintiff and the Class, by its advertising, packaging, labeling, and other means, that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants.

That promise and related promises became part of the basis of the bargain between the parties and thus constituted an express warranty.

128. Thereon, Defendant sold the goods to Plaintiff and the Class, who bought the goods from Defendant.

129. However, Defendant breached the express warranty in that the goods were in fact not FDA approved, did not comply with the FDA's limited qualified health claim language requirements, and do not reduce the risk of allergies in infants. As a result of this breach, Plaintiff and the Class in fact did not receive goods as warranted by Defendant.

130. As a proximate result of this breach of warranty by Defendant, Plaintiff and the Class have been damaged in an amount to be determined at trial.

SIXTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(California Commercial Code § 2314)

131. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

132. Plaintiff brings this claim on behalf of herself and the proposed Class.

133. Defendant made representations to the public, including Plaintiff and the Class, by its advertising, packaging, labeling, and other means that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants.

134. Defendant was a merchant with respect to goods of this kind (*e.g.*, infant formula and baby food) which were sold to Plaintiff and the Class, and there was in the sale to Plaintiff and the Class an implied warranty that those goods were merchantable.

135. Defendant breached the implied warranty of merchantability when it sold Plaintiff and the Class infant formula that, *inter alia*, did not conform to the promises or affirmations of fact made on the container or label.

136. As a result of Defendant's conduct, Plaintiff and the Class did not receive goods as impliedly warranted by Defendant to be merchantable.

137. As a proximate result of this breach of warranty by Defendant, Plaintiff and the Class have been damaged in an amount to be determined at trial.

SEVENTH CLAIM FOR RELIEF

NEGLIGENT MISREPRESENTATION

138. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

139. Plaintiff brings this claim on behalf of herself and the proposed Class.

140. As set forth above, Defendant represented to the public, including Plaintiff and the Class, by packaging, labeling, advertising, and other means, that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants. These misrepresentations are described in greater detail elsewhere in the Complaint.

141. Defendant's representations were untrue in that the FDA did not approve Good Start Gentle's health claims for qualified use, Good Start Gentle did not comply with the FDA's limited qualified health claim language requirements, and Good Start Gentle does not reduce the risk of allergies in infants.

142. Defendant made the representations without reasonable grounds for believing in their veracity.

143. Defendant made the representations herein alleged with the intention of inducing the public to purchase Defendant's products.

144. Plaintiff, the Class, and the consuming public saw, believed, and reasonably relied on Defendant's advertising, labeling, and packaging when purchasing Good Start Gentle.

145. As a proximate result of Defendant's negligent misrepresentations, Plaintiff and the Class were induced to spend an amount to be determined at trial on Defendant's products.

146. As a proximate result of Defendant's negligent misrepresentations, Plaintiff and the Class have been damaged in an amount to be determined at trial.

EIGHTH CLAIM FOR RELIEF

INTENTIONAL MISREPRESENTATION

147. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

148. Plaintiff brings this claim on behalf of herself and the proposed Class.

149. As set forth above, Defendant represented to the public, including Plaintiff and the Class, by packaging, labeling, advertising, and other means, that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants. These misrepresentations are described in greater detail elsewhere in the Complaint.

150. Defendant's representations were untrue in that the FDA did not approve Good Start Gentle's health claims for qualified use, Good Start Gentle did not comply with the FDA's limited qualified health claim language requirements, and Good Start Gentle does not reduce the risk of allergies in infants.

151. Defendant made these misrepresentations with actual knowledge of their falsity.

152. Defendant made the misrepresentations herein alleged with the intention of inducing the public to purchase Defendant's products.

153. Plaintiff, the Class, and the consuming public saw, believed, and reasonably relied on Defendant's advertising, labeling, and packaging when purchasing Good Start Gentle.

154. As a proximate result of Defendant's intentional misrepresentations, Plaintiff and the Class were induced to spend an amount to be determined at trial on Good Start Gentle infant formula.

155. As a proximate result of Defendant's intentional misrepresentations, Plaintiff and the Class have been damaged in an amount to be determined at trial.

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PRAYER FOR RELIEF

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

a) Determining that this action may proceed as a class action under Rule 23 of the Federal Rules of Civil Procedure;

b) Designating Plaintiff as the Class representative;

c) Designating Plaintiff's counsel as counsel for the Class;

d) Issuing proper notice to the Class at Defendant's expense;

e) Awarding restitution and disgorgement of Defendant's revenues obtained by means of any wrongful act or practice to Plaintiff and Class members;

f) Awarding actual, statutory, and punitive damages and interest to Plaintiff and Class members;

g) Awarding reasonable attorneys' fees, interest, and costs to the full extent permitted by law; and

h) All such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff and the Class demand a trial by jury.

Dated: February 27, 2015

Respectfully submitted,

By: */s/ Dan C. Bolton*

Daniel L. Keller
Dan C. Bolton
KELLER, FISHBACK & JACKSON LLP
28720 Canwood Street, Suite 200
Agoura Hills, CA 91301
Telephone: (818) 342-7442

Facsimile: (818) 342-7616
Email: dkeller@kfjlegal.com
Email: dbolton@kfjlegal.com

STEPHEN J. FEARON, JR (*pro hac vice)*
PAUL V. SWEENY(*pro hac vice*)
SQUITIERI & FEARON, LLP
32 East 57th St., 12th Floor
New York, New NY 10022
Telephone: (212) 421-6492
Facsimile: (212) 421-6553
Email: stephen@sfclasslaw.com
Email: paul@sfclasslaw.com

Attorneys for Plaintiff and the Proposed Class

Appendix

DANIEL L. KELLER (SBN 191738)
DAN C. BOLTON (SBN 104236)
KELLER, FISHBACK & JACKSON LLP
28720 Canwood Street, Suite 200
Agoura Hills, CA 91301
Telephone: 818.342.7442
Facsimile: 818.342.7616
Email: dkeller@kfjlegal.com
Email: dbolton@kfjlegal.com

STEPHEN J. FEARON, JR. (~~subject to~~ *pro hac vice*)
PAUL V. SWEENY (~~subject to~~ *pro hac vice*)
SQUITIERI & FEARON, LLP
32 E. ~~-~~57th St., 12th Floor
New York, NY 10022
Telephone: (212) 421-6492
Facsimile: (212) 421-6553
Email: stephen@sfclasslaw.com
Email: paul@sfclasslaw.com

Attorneys for Plaintiff and the Proposed Class

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

OULA ZAKARIA, individually and as a representative of the class,

Plaintiff,

vs.

GERBER PRODUCTS CO., a corporation, d/b/a NESTLE ~~NURTRITION~~NUTRITION, NESTLE INFANT NUTRITION, AND NESTLE NUTRITION NORTH AMERICA,

Defendant.

Case No.: 2:15-cv-0200-JAK (Ex)

FIRST AMENDED CLASS ACTION COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

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1. Plaintiff, Oula Zakaria ("Plaintiff") on behalf of herself and all other persons who purchased Gerber Good Start Gentle infant formula, alleges as follows on personal knowledge as to all facts related to herself and upon information and belief as to all other matters:

NATURE OF THE ACTION

2. This case involves a pattern of deceit and unfair business practices by Gerber Products Co. ("Defendant") in the marketing and sale of Good Start Gentle, a prominent line of infant formula produced, distributed, marketed, and sold by Defendant made from partially hydrolyzed whey protein.

3. Plaintiff brings this class action lawsuit challenging false representations and misleading practices knowingly made or undertaken by Defendant in Good Start Gentle's promotional campaign including, without limitation, (a) that Good Start Gentle was the "first and only" formula whose consumption reduced the risk of infants developing allergies; (b) that consumption of Good Start Gentle reduced the risk of developing infant atopic dermatitis, an inflammatory skin disorder; (c) that Good Start Gentle was the "first and only" formula endorsed by the Food and Drug Administration ("FDA") to reduce the risk of developing allergies; and (d) using the FDA term of art "Qualified Health Claim" to convey that Good Start Gentle received FDA approval for the health claims advertised and was fit for a particular purpose when, in actuality, the term ~~conveys that a~~ "Qualified Health Claim" means that the FDA did not grant approval for the use of a non-qualified health claim and that the scientific support for the claim is limited or lacking (at best).

4. In 2005 and 2009, Defendant petitioned the FDA to approve claims that partially hydrolyzed whey protein reduced the risk of infants developing food allergies and atopic dermatitis.

5. No scientific or other evidence existeds at the time linking a reduced risk of infant allergies, including atopic dermatitis (a form of eczema), to the consumption of partially hydrolyzed whey protein. Moreover, little or very little scientific evidence supports the claim that the consumption of partially hydrolyzed whey protein reduces the risk of infants developing atopic dermatitis.

6. After reviewing theis body of evidence at the time, the FDA rejected Defendant's proposed health claims, stating that "no credible evidence" supported the link between partially hydrolyzed whey protein and a reduced risk of food allergies. Concerning the link between the consumption of partially hydrolyzed whey protein and a reduced risk of atopic dermatitis, the FDA rejected the language proposed by Defendant because the language mischaracterized the connection and would mislead consumers. The FDA stated that it would only consider exercising its enforcement discretion regarding the atopic dermatitis claim if Defendant modified its claim and included highly qualifying language that very little or little scientific evidence (depending on infant age) existed to support the link.

7. Beginning in at least 2011, despite the FDA's clear rejections and the absence ofcompelling evidence contradictingsupporting its claims, Defendant falsely advertised Good Start Gentle as the first and only infant formula endorsed by the FDA to reduce the occurrence of allergies in infants. Defendant made these unsupported claims in order to strategically outpace competitors and substantially increase its sales. Defendant undertook its marketing campaign with actual knowledge that its claims were untrue and notably failed to include any qualifying language or disclaimers in Good Start Gentle advertising.

8. Due to Defendant's pervasive and false marketing campaign that Good Start Gentle provided benefits to children's health beyond that offered by other baby formulas and that the FDA had certified this claim, Plaintiff and the other Class members (as defined below) purchased Good Start Gentle at an inflated cost.

9. Plaintiff and the Class were injured by Defendant's unlawful conduct and

are entitled to actual, statutory, and punitive damages, restitution, ~~injunctive and declaratory relief,~~ interest, and the reimbursement of attorneys' fees.

10. In October 2014, the Federal Trade Commission ("FTC") brought suit against Defendant seeking to enjoin its deceptive practices in relation to the marketing and sale of Good Start Gentle, specifically citing Defendant's false or misleading claim "that feeding Gerber Good Start Gentle formula to infants with a family history of allergies prevents or reduces the risk that they will develop allergies" and the false or misleading claim "that Gerber Good Start Gentle formula qualified for or received approval for a health claim from the Food and Drug Administration."

11. Also in October 2014, the FDA issued Defendant a warning letter listing a litany of misrepresentations and falsehoods in the promotion of Good Start Gentle that violated federal law and related regulations. Defendant was instructed by the FDA to cease its deceitful practices or face potential legal action by the FDA.

12. Plaintiff, on behalf of herself and other similarly situated consumers, brings this consumer protection action against Defendant based on its course of unlawful conduct. Plaintiff alleges violations of California's Unfair Competition Law, California False Advertising Law, the Consumer Legal Remedies Act, as well as Breach of Express Warranty, Breach of the Implied Warranty of Merchantability, Negligent Misrepresentation, and Intentional Misrepresentation.

PARTIES

13. Plaintiff is and was at all relevant times herein, a resident of Porter Ranch, California and is a member of the C~~e~~lass. Plaintiff frequently purchased Gerber Good Start Gentle infant formula based on Defendant's false advertising and deceitful business practices.

14. Defendant, also doing business as Nestle Nutrition, Nestle Infant Nutrition, and Nestle Nutrition North America, is a Michigan corporation with its

headquarters located ~~at 12 Vreeland Road,~~in Florham Park, New Jersey ~~07932~~. Throughout the Class Period (as defined below), Defendant has transacted business in this district and throughout California, including marketing, distributing, and selling Good Start Gentle.

JURISDICTION AND VENUE

15. This Court has original jurisdiction over this case under the Class Action Fairness Act, 28 U.S.C. ~~-~~§ 1332(d)(2). Plaintiff is a citizen of California and Defendant is a citizen, for diversity purposes, of ~~a different state,~~ New Jersey and Michigan. The amount in controversy in this action exceeds $5,000,000 and there are more than 100 members in the Class.

16. This Court has personal jurisdiction over Defendant because Defendant is authorized to conduct business in California, is doing business in California, is registered with the California Secretary of State, and maintains a registered agent in Sacramento, California. Alternatively, Defendant is engaged in systematic and continuous business activity in California, has sufficient minimum contacts in California, or otherwise intentionally avails itself of the California consumer market through the promotion, marketing, distribution, and sale of consumer goods, including Good Start Gentle. This purposeful availment renders the exercise of jurisdiction by this Court over Defendant appropriate under traditional notions of fair play and substantial justice.

17. Venue is proper in this District pursuant to 28 U.S.C. ~~-~~§ 1391. Plaintiff resides in this District, Defendant regularly conducts business in this District, and a substantial portion of the events giving rise to the claims alleged herein occurred in this District.

~~17.~~18. All conditions precedent to this action have occurred, been performed, or have been waived.

FACTUAL ALLEGATIONS

A. Good Start Gentle Infant Formula Background Information

~~18.~~19. Since at least 2011, Defendant has manufactured, distributed, promoted, offered for sale, and sold Good Start Gentle infant formula. Defendant has advertised and continues to advertise Good Start Gentle formula through television commercials, print advertisements, point-of-sale displays, product packaging, internet advertisements, and other promotional materials.

~~19.~~20. Gerber Good Start Gentle contains partially hydrolyzed whey protein. Whey protein is derived from cow's milk during the production of cheese. Partially hydrolyzed whey protein undergoes additional processing to break the protein into smaller fragments.

B. The FDA Rejected Defendant's Petition for a Qualified Health Claim Linking Partially Hydrolyzed Whey Protein with a Reduction of Common Food Allergies in 2006

~~20.~~21. Under federal ~~regulation and~~ law, the FDA is the governmental body tasked with reviewing and authorizing health claims relating to food products sold in the United States. *See* FDA, *Questions and Answers: Qualified Health Claims in Food Labeling* (Sept. ~~-~~28, 2005), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm207974.htm (last visited ~~Jan.uary 6~~Feb. 23, 201~~4~~5).

~~21.~~22. A health claim characterizes the relationship between a substance and a disease or health-related condition. Such a claim explains that a food or food component may reduce the risk of a disease or a health related condition. An example of a health claim is: "Diets low in saturated fat and cholesterol may reduce the risk of heart disease." *Id.*

~~22.~~23. Health claims fall into two categories. An "unqualified health claim" must be supported by significant scientific agreement among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a

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substance/disease relationship. A "qualified health claim," on the other hand, is supported by scientific evidence, but does not meet the significant scientific agreement standard. As such, to ensure that they are not false or misleading to consumers, they must be accompanied by a disclaimer or other qualifying language to accurately communicate the level of scientific evidence supporting the claim. *Id.*

~~23.~~24. All health claims, whether qualified or unqualified, require pre-market review by the FDA. The FDA authorizes by regulation unqualified health claims on product labels only if the substance/disease relationship described by the health claims meets the "significant scientific agreement" standard. For approved qualified health claims, the FDA issues letters of enforcement discretion when there is credible evidence to support the claim. *Id.* Qualified health claims must include disclaimers that remedy any potential harm caused by potentially misleading claims. *Id.*

~~24.~~25. In June 2005, Defendant petitioned to have the following qualified health claim approved by the FDA:

> Breastfeeding is the best way to nourish infants. For infants who are not exclusively breastfed, emerging clinical research in healthy infants with family history of allergy shows that feeding a 100% Whey-Protein Partially Hydrolyzed formula may reduce the risk of common food allergy symptoms, particularly allergic skin rash, when used instead of whole-protein cow's milk formula from the initiation of formula feeding.

See Qualified Health Claims: Letters of Denial – 100 Percent Partially Hydrolyzed Whey Protein in Infant Formula and Reduced Risk of Food Allergy in Infants (Docket No. ~~-~~2005Q-0298) (May 11, 2006), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073313.htm (last visited ~~Jan. 6~~Feb. 23, 2015~~4~~).

~~25.~~26. The FDA found that n~~N~~o scientific or other evidence supported~~s~~ Defendant's health claim that ingesting partially hydrolyzed whey protein reduces the risk that infants will develop allergies. For example, from a sampling of thirty-six studies evaluating the relationship at the time, none drew a sound scientific

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conclusion that partially hydrolyzed whey protein did, in fact, reduce such risk. *Id.* at Appendix 1 (explaining that ~~T~~the studies suffer from a multitude of deficiencies including improper controls and unacceptable diagnoses of food allergies.).

~~26.~~27. On May 11, 2006, after "its review of the totality of publicly available scientific evidence, [the] FDA conclude[d] that there is no credible evidence for a relationship between the consumption of 100 percent partially hydrolyzed whey protein in infant formula and a reduced risk of food allergy." *Id.* After so concluding, the FDA denied Defendant's qualified health claim petition. *Id.* The FDA determined that "neither a disclaimer nor qualifying language would suffice to prevent consumer deception in this circumstance." *Id.*~~reviewing these studies and other available scientific evidence, the FDA rejected Defendant's petition, concluding that there was "no credible evidence to support the qualified health claim relating consumption of 100 percent partially hydrolyzed whey protein in infant formula to a reduced risk of food allergy[.]" *Id.* Due to this complete lack of credible scientific evidence, the FDA further rejected the "use of a disclaimer or qualifying language to accompany the proposed claim." *Id.*~~

~~27.~~28. The FDA's denial letter was addressed to Melanie Fairchild-Dzanis, Defendant's Director of Regulatory Issues—Special Nutritional. Fairchild-Dzanis is a lawyer and managed Defendant's regulatory function.

~~28.~~29. As a result of its dealing with the FDA, Defendant possessed actual knowledge that (a) its claim that partially hydrolyzed whey protein reduced the risk of infant allergies was baseless, false and incurable with qualifiers and (b) the FDA rejected its qualified health claim regarding the link.

C. The FDA Similarly Rejected Defendant's Petition for a Health Claim ~~——~~Linking Partially Hydrolyzed Whey Protein and a Reduced Risk of Atopic Dermatitis in Infants in 2011

~~29.~~30. In May 2009, Defendant petitioned to have the following qualified health claim approved by the FDA:

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> Breastfeeding is the best way to nourish infants. For infants who are not exclusively breastfed, emerging clinical research ~~in healthy infants~~ shows that, in healthy infants with family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula instead of a formula containing intact cow's milk proteins may reduce the risk of developing the most common allergic disease of infancy—atopic dermatitis—throughout the 1st year of life and up to 3 years of age.

See Whey-Protein Partially Hydrolyzed Infant Formula and Reduced Risk of Atopic Dermatitis (May 24, 2011), available at http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm256731.htm (last visited ~~Jan.uary 6~~Feb. 23, ~~2014~~2015).

~~30. Little or very little evidence exists to support Defendant's claim that partially hydrolyzed whey protein reduced the risk of developing atopic dermatitis in infants. From a sampling of twenty studies, sixteen did not draw a sound scientific conclusion that partially hydrolyzed whey protein did, in fact, reduce such risk, and two demonstrated that no beneficial relationship existed at all. *Id.*~~

31. In May 2011, after reviewing the totality of publicly available ~~these studies and other~~ scientific evidence at the time, the FDA made two findings regarding Gerber's qualified health claim. *Id.* First, the FDA concluded that there "is very little credible evidence for a qualified health claim about the relationship between feeding a 100 percent whey-protein partially hydrolyzed infant formula for the first 4 months of life and a reduced risk of atopic dermatitis throughout the first year of life and up to 3 years of age." *Id.* Second, it concluded "that there is little credible evidence for a qualified health claim about the relationship between feeding 100 percent whey-protein partially hydrolyzed infant formula for the first four months of life and a reduced risk of atopic dermatitis throughout the first year of life." *Id.*

32. As a result, the FDA rejected Defendant's claim as proposed because it "mischaracterized the strength of the evidence and [was] misleading." *Id.*

33. The FDA stated that it would only consider exercising its enforcement

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discretion regarding Defendant's atopic dermatitis claim if Defendant attached qualifying language to the effect that "very little scientific evidence" or "little scientific evidence" supports the link between partially hydrolyzed whey protein and a reduced risk of atopic dermatitis depending on the infant age included in the claim. *Id.*

34. The FDA's 2011 denial letter was similarly addressed to Ms. -Fairchild-Dzanis.

35. As a result of its dealings with the FDA, Defendant possessed actual knowledge that (a) its claim that partially hydrolyzed whey protein reduced the risk of infants developing atopic dermatitis was false or supported by little or very little scientific evidence (at best at the time) and (b) the FDA rejected Defendant's qualified health claim regarding the link as proposed because the claim was misleading and required that if Defendant was to make the claim it do so with stringent qualifying statements.

D. Compelling Scientific Studies Conclude That Partially Hydrolyzed Whey Formula Does Not Lower The Risk of Allergic Manifestations (Including Eczema) In Infancy Compared With Conventional Formula

36. Defendant's claims linking the consumption of Good Start Gentle (a partially hydrolyzed whey formula) with a reduced risk of developing infant allergies (including atopic dermatitis—a form of eczema) are false and misleading.

37. Several compelling scientific studies have concluded that partially hydrolyzed whey formula does not lower the risk of allergic manifestations, including eczema, during infancy (and up to age 7) when compared with conventional formula.

38. One such study published in June 2011 concluded that "[t]here was no evidence that introducing pHWF [(partially hydrolyzed whey formula)] at the cessation of breast-feeding reduced the risk of allergic manifestations, including eczema, asthma, and allergic rhinitis, in [a] study of high-risk infants." Adrian J. Lowe, PhD et al., *Effect of a partially hydrolyzed whey infant formula at weaning on*

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risk of allergic disease in high-risk children: A randomized controlled trial, 128 J. ALLERGY & CLIN. IMMUNOL. 2, Aug. 2011, at 360-65.e4 ("Lowe Study"), attached hereto as Exhibit A.

39. The Lowe Study further concluded that partially hydrolyzed whey formula did not reduce the risk of allergic manifestations, including eczema, (1) in children from birth to age 7 and (2) in children both with and without a family history of eczema when compared with conventional formula. *Id.*

40. The Lowe Study did "not support the recommendation that [partially hydrolyzed whey formula] should be used after breast-feeding as a preventative strategy for infants at high risk of allergic diseases." *Id.*

~~35.~~41. Upon information and belief, Defendant knew or should have known about the Lowe Study's rejection of its health claims because Nestec Ltd, a subsidiary of Nestle Australia Ltd, provided the Lowe Study with study formula and staff funding for the first 6 years of the study. *Id.* Upon information and belief, Nestec Ltd and Nestle Australia Ltd are affiliated with Defendant. *See* Nestle S.A., Annual Report 2013 at 154, 165, 170, *available at* http://www.nestle.com/asset-library/documents/library/documents/annual_reports/2013-annual-report-en.pdf (last visited Feb. 23, 2015).

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~~D.~~E. Defendant Widely Markets Good Start Gentle as the First and Only Infant Formula Endorsed by the FDA Which Prevents Allergies and Reduces the Risk of Atopic Dermatitis Without Qualification or Disclaimers

~~36.~~42. Despite the FDA's express guidance and compelling~~a lack of scientific~~ evidence contradicting~~supporting~~ Defendant's claims, Defendant falsely marketed and, upon information and belief, continues to market Good Start Gentle as a product endorsed by the FDA for reducing the risk of developing allergies and atopic

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dermatitis to attract customers, increase revenues, and edge out Defendant's competition.

~~37.~~43. Since at least 2011, Defendant knowingly disseminated or has caused to be disseminated advertisements, packaging, and promotional materials for Good Start Gentle in California containing false and misleading statements, as demonstrated by the following sample of Good Start Gentle promotional materials.

~~38.~~44. In Exhibit B~~A~~, a label included on a formula canister, Defendant states that Good Start Gentle is the "1st and Only Routine Formula to Reduce the Risk of Developing Allergies." Exhibit B~~A~~ falsely communicates to consumers that Good Start Gentle reduced the risk of infants developing allergies despite the total lack of evidence supporting that proposition, ~~and~~ an FDA letter rejecting Defendant's qualified health claim, and compelling evidence, such as the Lowe Study, contradicting the claim.

~~39.~~45. In Exhibit C~~B~~, a product label, a gold badge with the words "Meets FDA" printed at the top, "1st and Only" printed in the center, and "Qualified Health Claim" printed at the bottom. The product label further includes a statement that Good Start Gentle "is the first and only formula brand . ~~-~~. ~~-~~. ~~-~~that meets the criteria for a FDA Qualified Health Claim for atopic dermatitis." This advertisement falsely communicates to consumers that the FDA approved Defendant's qualified health claim regarding atopic dermatitis when the FDA, in fact, rejected the claim as proposed because it misled consumers. It also deceptively uses the FDA term of art "Qualified Health Claim" to convey that Good Start Gentle is fit for a particular purpose or certified by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited. The product label notably fails to include the qualifying language required by the FDA and federal law.

~~40.~~46. In Exhibit D~~C~~ (storyboard dated April 9, 2012), a television commercial, an announcer states that "You want your Gerber baby to have your imagination . ~~-~~. ~~-~~. your smile . ~~-~~. ~~-~~. ~~-~~your eyes . ~~-~~. ~~-~~. ~~-~~not your allergies~~-~~. ~~-~~. ~~-~~. . [I]~~i~~f you introduce formula,

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choose the Gerber Good Start Comfort Proteins Advantage." *See* Gerber Good Gentle Formula with Comfort Proteins Advantage Commercial, https://www.youtube.com/watch?v=h6l-CjygjEg (last visited ~~Jan.uary, 9~~Feb. 23, 2015). This advertisement falsely communicates to consumers that Good Start Gentle reduced the risk of infants developing allergies despite ~~the total lack of~~compelling evidence contradicting~~supporting~~ that proposition and an FDA letter rejecting Defendant's qualified health claim.

~~41.~~47. In Exhibit E~~D~~, a print advertisement depicting a baby's face on a canister of Good Start Gentle, the caption reads, "I love Mommy's eyes, not her allergies. If you have allergies in your family, breastfeeding your baby can help reduce their risk. And if you decide to introduce formula research shows the formula you first provide to your baby may make a difference." Exhibit E~~D~~ falsely communicates to consumers that Good Start Gentle reduced the risk of infants developing allergies despite compelling~~the total lack of~~ evidence contradicting~~supporting~~ that proposition and an FDA letter rejecting Defendant's qualified health claim. The advertisement also notably fails to include the qualifying language required by the FDA and federal law.

~~42.~~48. In Exhibit F~~F~~, a magazine advertisement, Defendant falsely promoted Good Start Gentle as "the first and only infant formula that meets the criteria for a FDA Qualified Health Claim." This advertisement falsely communicates to consumers that the FDA approved Defendant's health claims when, in reality, the FDA rejected both of Defendant's health claims. This advertisement also deceptively uses the FDA term of art "Qualified Health Claim" to convey that Good Start Gentle is fit for a particular purpose or certified by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited. Notably, the advertisement fails to include the qualifying language required by the FDA.

~~43.~~49. In Exhibit G~~F~~, a gold badge as part of a supermarket display depicting a canister of Good Start Gentle, the words "Meets FDA" are printed at the top, "1st and

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Only" is printed in the center, and "Qualified Health Claim" is printed at the bottom. This advertisement falsely communicates to consumers that the FDA approved Defendant's health claims when, in reality, the FDA rejected both of Defendant's health claims. This advertisement also misleadingly conveys the FDA term of art "qualified health claim" in order to convince consumers that Good Start Gentle was fit for a particular purpose or certified for quality by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited. Notably, the display fails to include the qualifying language required by the FDA.

~~44.~~50. In Exhibit H~~G~~, a magazine advertisement printed in People Magazine on August 5, 2013, a mother is depicted feeding an infant and a badge is included which states that Good Start Gentle is the "1st Formula with FDA Qualified Health Claim." This advertisement falsely communicates to consumers that the FDA approved Defendant's health claims when, in reality, the FDA rejected both of Defendant's health claims. This advertisement also misleadingly conveys the FDA term of art "qualified health claim" in order to convince consumers that Good Start Gentle was fit for a particular purpose or certified for quality by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited. Notably, the advertisement fails to include the qualifying language required by the FDA.

51. Based on this limited sampling, it is reasonable to infer that discovery would demonstrate a protracted course of purposeful, false, and misleading advertising by Defendant to induce consumers to purchase Good Start Gentle during the Class Period.

~~45.~~52. Reasonable consumers, including Plaintiff, would/did attach importance to the health and FDA approval claims specified herein when determining whether to purchase Gerber Good Start. Defendant's misrepresentations were/are material. Under *In Re Tobacco II Cases*, 46 Cal.4th 298, 326-327, "a presumption, or at least an inference, of reliance arises wherever there is a showing that a misrepresentation was material."

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~~E.~~F. The FTC Sues Defendant Seeking A Permanent Injunction and Other Equitable Relief for Violations of the Federal Trade Commission Act Committed During Defendant's Promotional Campaign for Good Start Gentle

~~46.~~53. On October 29, 2014, the FTC filed a lawsuit in the District of New Jersey against Defendant "under Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. ~~-~~§ 53(b) to obtain preliminary and permanent injunctive relief . ~~-~~. ~~-~~. ~~-~~for Defendant's acts or practices, in violation of Section 5(a) and 12 of the FTC Act, 15 U.S.C.~~-~~ §§ 45(a) and 52, in connection with the labeling, advertising, marketing, distribution, and sale of Gerber Good Start Gentle, an infant formula that purports to prevent or reduce the risk of the development of allergies." *Federal Trade Commission v. ~~-~~Gerber Products Co.*, 2:14-cv-06771-SRC-CLW, Dkt. ~~-~~No. ~~-~~1, at 1 (D.N.J. ~~-~~Oct. ~~-~~29, 2014).

~~47.~~54. In its complaint, the FTC specifically challenged Defendant's false and unsubstantiated claim that "feeding Gerber Good Start Gentle formula to infants with a family history of allergies prevents or reduces the risk that they will develop allergies" and Gerber's false assertions that "Good Start Gentle formula qualified for or received approval for a health claim from the Food and Drug Administration." *Id.* at 9-10.

~~##~~

~~F.~~G. The FDA Issues a Warning Letter to Defendant Stating that Good Start Gentle is Misbranded and Misleading in Violation of Federal Law

~~48.~~55. In addition to the lawsuit filed by the FTC on October 29, 2014, on October 31, 2014, the FDA wrote a warning letter addressed to Mr. ~~-~~Gary Tickle, Defendant's President and CEO, outlining various false and misleading representations made in the promotion of Good Start Gentle that violate federal law and related federal regulations. *See generally* Warning Letter, Nestle Infant Nutrition 10/31/14, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm423087.ht

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m (last visited ~~Jan. 9~~Feb. 23, 2015) ("Warning Letter").

~~49.~~56. The violations cited by the FDA include, without limitation, that:

a) Good Start Gentle was misbranded under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301~~,~~ *et seq.*~~,~~ because Good Start Gentle's labeling and website "bear health claims that were not authorized by the FDA." *See* Warning Letter at 2;

b) Defendant's health claim that the consumption of 100% partially hydrolyzed whey protein reduces the risk of infants developing allergies was a health claim previously considered and denied by the FDA and therefore unauthorized. *See* Warning Letter at 2-3;

c) Defendant failed to ensure consumer safety by not properly informing consumers that Good Start Gentle should not be fed to infants with milk allergies and that such infants' "care and feeding choices should be under a doctor's supervision." *See* Warning Letter at 2-4 (Defendant omitted to include key information in mandatory bold type and excluded other mandatory language entirely.);

d) Good Start Gentle is misbranded because Defendant wrongly identified "100% whey partially hydrolyzed" as the substance linked to a reduced risk of atopic dermatitis on Good Start Gentle's label and website. *See* Warning Letter at 3. However, the substance that was the subject of Defendant's 2011 qualified health claim petition to the FDA was "100% whey protein partially hydrolyzed." *Id.* As such, Defendant's health claim regarding atopic dermatitis misleads consumers because it suggests "that the partial hydrolysis of whey could refer to any or all of the components in whey being hydrolyzed (*i.e.*, oligosaccharides, fats, and protein)," and no evidence exists to support such claim. *See* Warning Letter;

e) Defendant separated qualifying language related to its atopic dermatitis health claim in a way not approved by the FDA in its 2011 letter of

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enforcement discretion to Defendant. *See* Warning Letter at 5. The FDA expressed concerns that such separation could mislead consumers.

~~50.~~57. In the letter, the FDA instructed Defendant to "take prompt action to correct the violations described above" or face potential legal action. *See* Warning Letter at 5.

~~51.~~58. As a whole, the Warning Letter further demonstrates Defendant's willful and deceitful pattern of promoting Good Start Gentle in a way that would mislead consumers and induce purchase of Good Start Gentle.

~~G.~~H. Plaintiff Begins Consistently Purchasing Good Start Gentle Based on ~~Defendant~~Gerber's False Promotional Campaign and Suffers Damages

~~52.~~59. On September 4, 2013, Plaintiff's daughter, Layla, was born. Plaintiff originally fed her daughter a mix of other ~~Enfamil and Similac~~ infant formulas but did not feed her daughter Gerber Good Start.

~~53.~~60. In October 2013, Plaintiff took her daughter to a meeting with her pediatrician who ~~recommended~~ introduced Plaintiff to Gerber Good Start infant formula and provided Plaintiff with three or four containers of Gerber Good Start infant formula. Plaintiff received two types of Gerber Good Start infant formula from her daughter's pediatrician: Gerber Good Start Gentle and Gerber Good Start Soothe, another line of formula offered for sale by Gerber.

~~54.~~61. ~~After the meeting,~~ Plaintiff~~, who~~ did not know that Defendant produced infant formula. In October 2013 and November 2013, Plaintiff~~,~~ researched Good Start formula and reviewed statements by Defendant on its website highlighting Good Start Gentle's endorsement by the FDA and its ability to protect infants from developing allergies.

62. Based on this false and misleading information, Plaintiff ceased buying other~~Similac and Emfamil~~ infant formulas, and instead, began routinely purchasing Good Start Gentle formula. Plaintiff purchased Good Start Gentle infant formula in various containers, including containers with the misleading label: "1st & Only

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Routine Formula to Reduce Risk of Developing Allergies" as depicted in Exhibit BA.

55.63. Plaintiff first saw and relied on the information depicted in Exhibit B in November 2013.

56.64. Plaintiff also purchased Good Start Gentle misbranded containers that mischaracterized the relationship between "100% whey partially hydrolyzed" and a reduced risk of atopic dermatitis as described in Paragraph 5648(d), *supra*.

57.65. Plaintiff bought these mislabeled Gerber Good Start Gentle infant formula containers from stores in Porter Ranch, California, including Target, Babies "R" Us, and Walmart for prices generally ranging between $25 and $26.

58.66. On average, Plaintiff used one container of Gerber Good Start Gentle per week from October 2013 to November 2014.

67. Plaintiff made those purchases based on Gerber's false and misleading promotional materials and labeling that Gerber Good Start Gentle was approved by the FDA to reduce the risk of infants developing allergies, even though Defendant knew that such health claims were baseless and rejected by the FDA.

59.68. Plaintiff would not have purchased Gerber Good Start Gentle had she known (1) that partially hydrolyzed whey protein does not reduce the risk of allergies (including atopic dermatitis) in children or (2) that the FDA did not endorse, approve, or certify the health claims Defendant made on its labels, in its advertisements, and on its website.

69. For these reasons, Plaintiff and other Class members incurred damages from Defendant's misconduct.

CLASS ACTION ALLEGATIONS

60.70. Plaintiff asserts her claims on behalf of the following proposed Class:

> All persons who have purchased Gerber Good Start Gentle infant formula in California during the applicable statute of limitations. The Class excludes any judge or magistrate

assigned to this case, Defendant and any entity in which Defendant has a controlling interest, and its officers, directors, legal representatives, successors and assigns. Also excluded from the class are those who purchased Gerber Good Start Gentle infant formula for the purpose of resale and those who assert claims for personal injury.

~~61.~~71. Numerosity: The Class is so numerous that joinder of all Class members is impracticable. The Class includes hundreds, and likely thousands, of Defendant's customers.

~~62.~~72. Typicality: Plaintiff's claims are typical of the members of the Proposed Class because, like the other Class members, she was exposed to Defendant's deceptive advertising and business practices and purchased Good Start Gentle in reliance thereon.

~~63.~~73. Adequacy: Plaintiff will fairly and adequately protect the interests of the Class, and has retained counsel experienced in complex class action litigation. Plaintiff has no interests which are adverse to those of the Class that she seeks to represent.

~~64.~~74. Commonality: Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class, including:

a) Whether Defendant falsely advertised Good Start Gentle as a product endorsed by the FDA to reduce the occurrence of allergies and atopic dermatitis in infants;

b) Whether Defendant disseminated misleading labels, commercials, print advertisement, point-of-sale displays, and other promotional materials in an effort to convince customers to purchase Good Start Gentle based on false representations – namely that the FDA issued a qualified health claim that Good Start Gentle reduced the occurrence of infant allergies;

c) Whether Defendant used the term "qualified health claim" in order to mislead consumers into believing that the FDA certified the quality of Good Start Gentle or that Good Start Gentle was fit for a particular purpose, rather than convey that any potential health claim was limited, restricted, or insufficient;

d) Whether Defendant violated the unlawful prong of California's Unfair Competition Law;

e) Whether Defendant violated the unfair and fraudulent prongs of California's Unfair Competition Law;

f) Whether Defendant violated California's False Advertising Law;

g) Whether Defendant violated California's Legal Remedies Act;

h) Whether Defendant breached Good Start Gentle's express warranty;

i) Whether Defendant breached the implied warranty of merchantability;

j) Whether Defendant negligently misrepresented the FDA endorsement and health benefits of Good Start Gentle;

k) Whether Defendant intentionally misrepresented the health benefits and FDA endorsement of Good Start Gentle;

l) Whether Plaintiff and the Class are entitled to actual, statutory, and punitive damages; and

~~m)~~ Whether Plaintiff and the Class are entitled to restitution.~~;~~

~~n)~~m) ~~Whether the Plaintiff and the Class are entitled to injunctive and declaratory relief.~~

~~65.~~75. These and other questions of law and fact are common to the Class and predominate over any questions affecting only individual members of the Class.

~~66.~~76. Plaintiff cannot be certain of the form and manner of proposed notice to class members until the class is finally defined and discovery is completed regarding the identity of class members. ~~-~~Plaintiff anticipates, however, that notice by mail will be given to class members who can be identified specifically. ~~-~~In addition, notice

may be published in appropriate publications, on the internet, in press releases and in similar communications in a way that is targeted to reach those who may have purchased Gerber Good Start Gentle infant formula. The cost of notice, after class certification, trial, or settlement before trial, should be borne by Defendant.

~~67.~~77. Plaintiff is a member of the Class and will fairly and adequately represent and protect the interests of the Class. Plaintiff has no claims antagonistic to those of the Class. Plaintiff has retained counsel competent and experienced in complex class actions, including all aspects of this litigation. Plaintiff's counsel will fairly, adequately, and vigorously protect the interests of the Class.

~~68.~~78. Class action status is warranted under Rule 23(b)(1)(A) because the prosecution of separate actions by or against individual members of the Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class, which would establish incompatible standards of conduct for Defendant.

~~69.~~79. Class action status is also warranted under Rule 23(b)(1)(B) because the prosecution of separate actions by or against individual members of the Class would create a risk of adjudications with respect to individual members of the Class which would, as a practical matter, be dispositive of the interests of the other members not parties to the adjudications, or substantially impair or impede their ability to protect their interests.

~~70. Class action status is also warranted under Rule 23(b)(2) because Defendant has acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.~~

~~71.~~80. Class action status is also warranted under Rule 23(b)(3) because questions of law or fact common to the members of the Class predominate over any questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

~~72.~~81. Plaintiff reserves her right to modify or amend the definition of the proposed Class at any time before the Class is certified by the Court.

FIRST CLAIM FOR RELIEF

VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW

(California Business and Professions Code §§ 17200 *et seq.*)

(Unlawful)

~~73.~~82. Plaintiff realleges and incorporates by reference the allegations elsewhere in the Complaint as if set forth fully herein.

~~74.~~83. Plaintiff brings this claim on behalf of herself and the proposed Class.

~~75.~~84. California Business and Professions Code §§ 17200 *et seq.*~~,~~ prohibits acts of unfair competition, including any "unlawful, unfair or fraudulent business act or practice."

~~76.~~85. Defendant engaged in unlawful business acts and practices in violation of California Business and Professions Code §§ 17200 *et seq.*, by engaging in the false and misleading advertising specified elsewhere in this Complaint.

~~77.~~86. Defendant has manufactured, advertised, distributed, and sold products misbranded under California Law. *See* California Health & Safety Code § 110660. Misbranded products cannot be legally manufactured, advertised, distributed, or sold or held and are legally worthless ~~as a matter of law~~.

~~78.~~87. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendant as alleged herein constitute "unlawful" business acts and practices in that Defendant's conduct violates:

a) California's False Advertising Law, CAL. BUS. & PROF. CODE §§ 17500 *et seq.*;

b) California's Consumers Legal Remedies Act ("CLRA"), CAL. CIV. CODE §§ 1750 *et seq.*;

c) California Health & Safety Code §§ 109885 and 110390 which make it unlawful to disseminate false or misleading food advertisements that

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include statements on products and product packaging or labeling or any other medium used to directly or indirectly induce the purchase of a food product;

d) California Health & Safety Code §§ 109885 and 110390 which make it unlawful to disseminate false or misleading food advertisements that include statements on products and product packaging or labeling or any other medium used to directly or indirectly induce the purchase of a food product;

e) California Health & Safety Code § 110395 which makes it unlawful to deliver or proffer for delivery any food that has been falsely advertised;

f) California Health & Safety Code §110760 which makes it unlawful for any person to manufacture, sell, deliver, hold, or offer or sale any food that is misbranded;

g) California Health & Safety Code § 110765 which makes it unlawful for any person to misbrand food;

h) California Health & Safety Code § 110770 which makes it unlawful for any person to receive in commerce any food that is misbranded or to deliver or proffer for delivery any such food;

i) Section 5(a) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce; and

j) Section 12 of the FTC Act, 15 U.S.C. ~~-~~§ 52, which prohibits the dissemination of any false advertisement in or affecting commerce for the purpos~~eing~~ of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics.

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~~79.~~88. Defendant's conduct is further "unlawful" because it violates the following provisions of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. ~~-~~§§ 301 *et seq.*, and its implementing regulations:

a) Sections 321(n) and 403(a) of the FFDCA, 21 U.S.C. §§ 321(n) & 343(a), which deems food misbranded when the label contains a statement that is "false or misleading in any particular" or "its advertising is false or misleading in a material respect";

b) 21 C.F.R. § 101.14(e), which proscribes express and implied health claims on food labeling unless, *inter alia*, such a claim is specifically provided for by regulation and complies therewith; and

c) Alternatively, 21 C.F.R. § 101.14(d), which, *inter alia*, (i) requires all health claim based food labeling to conform to regulation, (ii) requires that all health claims made on food labels are limited to describing the value that ingestion of a certain substance may have on a particular disease or health-related condition, (iii) proscribes incomplete, untruthful, and misleading health claims on food labels, and (iv) requires reference to or complete health claims to be in the immediate proximity of all graphic material constituting a health claim (*e.g.*, a heart symbol).

~~80.~~89. Defendant leveraged its deception to induce Plaintiff and the Class to purchase products that were of lesser value and quality than advertised.

~~81.~~90. The foregoing acts and practices have detrimentally impacted competition and caused substantial harm to Plaintiff, the Class, and the consuming public. Plaintiff and members of the Class were misled and suffered injuries and lost money or property as a direct and proximate result of Defendant's unlawful business practices.

91. Plaintiff and the Class could have reasonably avoided the harm alleged herein. Plaintiff and the Class were denied the benefit of the bargain when they decided to purchase Good Start Gentle over competitor products which are less expensive, make medically and scientifically supported health claims, do not falsely purport to be endorsed for quality or fit for a particular purpose by the FDA, or which do not make health claims linking the consumption of partially hydrolyzed whey

protein and a reduced risk of food allergies in infants. Had Defendant not made false and misleading statements and used false and misleading advertising tactics, Plaintiff and the Class would have paid less than what they did for Good Start Gentle, or would have not purchased the product at all.

~~82.~~92. Defendant's misuse of FDA endorsement and FDA terms of art were/are likely to deceive reasonable consumers. Likewise, Defendant's false health claims were/are likely to deceive reasonable consumers.

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~~83.~~93. The false and misleading advertising and labeling described elsewhere in the Complaint presents a continuing threat to consumers in that such advertising will continue to mislead consumers to purchase legally worthless Good Start Gentle on false premises.

~~84.~~94. By reason of the foregoing, Defendant should be required to disgorge its illicit profits, make restitution to Plaintiff and the Class, ~~be enjoined from continuing in such practices pursuant to Sections 17203 and 17204 of the California Business and Professions Code,~~ and pay for Plaintiff's and the Class' attorneys' fees.

~~85.~~95. Plaintiff reserves the right to identify additional provisions of law violated by Defendant as further investigation and discovery warrants.

SECOND CLAIM FOR RELIEF

VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW

(California Business and Professions Code §§ 17200 *et seq.*)

(Unfair and Fraudulent)

~~86.~~96. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

~~87.~~97. Plaintiff brings this claim on behalf of herself and the proposed Class.

~~88.~~98. California Business and Professions Code §§ 17200 *et seq.*~~,~~ prohibits acts of unfair competition, including any "unlawful, unfair or fraudulent business act or practice."

~~89.~~99. The false and misleading labeling and advertising of Good Start Gentle,

as alleged herein, constitutes "unfair" business acts and practices because such conduct is immoral, unscrupulous, and offends public policy. Further, the harm of Defendant's conduct to Plaintiff, the Class, and the consumer public outweighs any conceivable benefit of such conduct.

~~90.~~100. Defendant's false and misleading labeling and advertising have detrimentally impacted competition and caused substantial harm to Plaintiff, the Class, and the consuming public. Plaintiff and members of the Class were deceived, suffered injuries, and lost money or property as a direct and proximate result of Defendant's unlawful business practices.

~~91.~~101. The false and misleading labeling and advertising of Good Start Gentle, as alleged herein, also constitutes "fraudulent" business acts and practices because members of the consuming public, including Plaintiff and the Class, were/are likely to be deceived by the false and misleading advertising and labeling described elsewhere in the Complaint.

~~92.~~102. Plaintiff and the Class could have reasonably avoided the harm alleged herein. Plaintiff and the Class were denied the benefit of the bargain when they decided to purchase Good Start Gentle over competitor products which are less expensive, contain healthier ingredients, do not purport to be endorsed by the FDA for quality, make medically and scientifically supported health claims, or which do not make health claims linking the consumption of partially hydrolyzed whey protein and a reduced risk of food allergies in infants. Had Defendant not engaged in its false and misleading advertising tactics, Plaintiff and the Class would have paid less than what they did for Good Start Gentle, or not purchased the product at all.

~~93.~~103. Defendant either knew or reasonably should have known that the health claims on the labels and advertising alleged herein were untrue and misleading.

~~94.~~104. In addition, Defendant's *modus operandi* constitutes an unfair and fraudulent practice in that Defendant knew or should have known that consumers rely

on~~care about~~ health claims made concerning infant formula but are unlikely to possess the expertise required to make~~be aware and/or able to come to~~ a scientific and medical conclusion linking the consumption of partially hydrolyzed whey protein and any potential reduced risk of food allergies in infants. Particularly, Defendant knew or should have known that consumers rely on unqualified and qualified health claims made under the guise of FDA approval or consent.

~~95.~~105. By reason of the foregoing, Defendant should be required to disgorge its illicit profits, make restitution to Plaintiff and the Class, ~~be enjoined from continuing in such practices pursuant to Sections 17203 and 17204 of the California Business and Professions Code,~~ and pay for Plaintiff's and the Class' attorneys' fees.

THIRD CLAIM FOR RELIEF

VIOLATION OF THE CALIFORNIA FALSE ADVERTISING LAW

(California Business and Professions Code §§ 17500 *et seq.*)

~~96.~~106. Plaintiff realleges and incorporates by reference the allegations elsewhere in the Complaint as if set forth fully herein.

~~97.~~107. Plaintiff brings this claim on behalf of herself and the proposed Class.

~~98.~~108. Defendant's acts and practices as described herein have deceived and/or are likely to deceive Plaintiff, the Class, and the public. Defendant has repeatedly advertised that Good Start Gentle reduces the risk of allergies (including atopic dermatitis) in infants despite the falsity of this statement.

~~99.~~109. The advertisements, labeling, policies, acts, and practices described herein were designed to, and did, result in the purchase and use of Good Start Gentle without consumer knowledge that Defendant never received FDA approval for its health claims and misled consumers with its qualified health claim representations.

~~100.~~110. Defendant's advertising and labeling has deceived and is likely to deceive Plaintiff, the Class, and the public in the future because it misrepresented the

FDA's endorsement of Good Start Gentle's ability to reduce the risk of allergies (i.e., a reasonable consumer does not understand the definition of an "FDA Qualified Health Claim" without appropriate explanation). Reasonable consumers do not interpret "qualified" as "[n]ot complete or absolute; limited", but instead interpret it as "[o]fficially recognized as being trained to perform a particular job; certified." *See Qualified Definition*, OXFORD ENGLISH DICTIONARY, http://www.oxforddictionaries.com/definition/english/qualified (last visited Dec. -18, 2014).

~~101.~~111. Defendant knew or by the exercise of reasonable care should have known that its advertisements concerning Good Start Gentle's ability to reduce the risk of allergies in infants and the representation that the FDA endorsed these claims were untrue or misleading. Plaintiff and the Class based their decisions to purchase Good Start Gentle in substantial part on Defendant's misrepresentations and omitted material facts.

~~102.~~112. Defendant disseminated and continues to disseminate uniform advertising concerning Good Start Gentle which is unfair, deceptive, untrue, or misleading within the meaning of California Business & Professions Code §§ 17500 *et seq.* Such advertisements are likely to deceive, and continue to deceive, the consuming public for the reasons detailed elsewhere in the Complaint.

~~103.~~113. Plaintiff and the Class have suffered injury in fact and have lost money or property as a result of Defendant's violation of California Business & Professions Code §§ 17500 *et seq.*

~~104.~~114. The misrepresentations and omissions by Defendant of the material facts detailed elsewhere in this Complaint constitute false and misleading advertising.

~~105.~~115. As a result of Defendant's wrongful conduct, Plaintiff and the Class are entitled to ~~an injunction barring Defendant from continuing to violate the California Business & Professions Code §§ 17500 *et seq.*,~~ restitution~~,~~ and an order for

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the disgorgement of the funds by which Defendant was unjustly enriched.

FOURTH CLAIM FOR RELIEF

VIOLATION OF THE CONSUMERS LEGAL REMEDIES ACT

(California Civil Code §§ 1750 *et seq.*)

~~106.~~116. Plaintiff~~s~~ realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

~~107.~~117. Plaintiff brings this claim on behalf of herself and the proposed Class.

~~108.~~118. The CLRA has adopted a statutory scheme prohibiting various deceptive practices in connection with the conduct of a business providing goods, property, or services primarily for personal, family, or household purposes.

~~109. This claim for relief does not currently seek monetary relief and is limited solely to injunctive relief. Plaintiff intends to amend this Complaint to seek monetary relief in accordance with the CLRA after providing Defendant with notice pursuant to Civil Code § 1782.~~

~~110. At the time of any amendment seeking damages under the CLRA, Plaintiff will demonstrate that the violations of the CLRA were willful, oppressive, and fraudulent, thus supporting an award of punitive damages.~~

~~111. Consequently, Plaintiff and the Class will be entitled to actual and punitive damages against Defendant for its violation of the CLRA. In addition, pursuant to Civil Code § 1780(a)(2), Plaintiff and the Class will be entitled to an order enjoining the above-described acts and practices, providing restitution to Plaintiff and the Class, ordering payment of costs and attorneys' fees, and any other relief deemed appropriate and proper by the Court pursuant to California Civil Code § 1780.~~

~~112.~~119. Defendant's policies, acts, and practices were intended to, and did, result in the purchase and use of the products primarily for personal, family, or household purposes, and violated and continue to violate at least the following

sections of the CLRA:

a) § 1770(a)(2),~~:~~ which proscribes "[m]isrepresenting the source, sponsorship, approval, or certification of goods or services" in the sale of consumer goods;

b) § 1770(a)(3),~~:~~ which proscribes "[m]isrepresenting the affiliation, connection, or association with, or certification by, another" in the sale of consumer goods;

c) § 1770(a)(5),~~:~~ which proscribes "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have";

d) § 1770(a)(7), which proscribes "[r]epresenting that goods or services are of a particular standard, quality or grade"~~[.]~~;~~"~~ and

e) § 1770(a)(9),~~:~~ which proscribes "[a]dvertising goods or services with intent not to sell them as advertised."

120. Defendant's wrongful acts and practices as described elsewhere were willful, oppressive, and fraudulent.

121. As a proximate result of these violations by Defendant, Plaintiff and the Class have suffered irreparable harm and are entitled to the payment of costs and attorneys' fees and such other relief as deemed appropriate and proper by the Court under California Civil Code § 1780.~~damages in an amount to be determined at trial.~~

122. In compliance with California Civil Code § 1782, Defendant received written notice by certified mail on January 20, 2015 of Plaintiff's claims and of her intention to seek damages under California Civil Code § 1750 *et seq.*~~,~~ unless Defendant provides an appropriate refund plus interest and other appropriate relief to all members of the Class entitled to relief under the CLRA.

123. Defendant has failed to provide such relief and has not adequately responded to the demand to pay refunds and otherwise rectify the wrongful conduct described above on behalf of all members of the Class who may be entitled to relief

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under the CLRA.

~~113.~~124. Accordingly, Plaintiff seeks an award of all actual and punitive damages permitted for violation of the CLRA, including for statutory damages of $1,000 per Class member and up to $5,000 per each Class member who qualifies as a "senior citizen" under the CLRA.

~~114. At this time, Plaintiff only seeks an injunction pursuant to California Civil Code § 1782(d) enjoining Defendant from continuing to employ the unlawful methods, acts, and practices alleged elsewhere in this Complaint. If Defendant is not restrained from engaging in these practices in the future, Plaintiff and the Class will continue to suffer harm.~~

FIFTH CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTY

(California Commercial Code § 2313)

~~115.~~125. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

~~116.~~126. Plaintiff brings this claim on behalf of herself and the proposed Class.

~~117.~~127. ~~Beginning at an exact date unknown to Plaintiff, but at least since four years prior to the filing date of this action, and~~ As set forth hereinabove, Defendant made representations to the public, including Plaintiff and the Class, by its advertising, packaging, labeling, and other means, that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants. That promise and related promises became part of the basis of the bargain between the parties and thus constituted an express warranty.

~~118.~~128. Thereon, Defendant sold the goods to Plaintiff and the Class, who bought the goods from Defendant.

~~119.~~129. However, Defendant breached the express warranty in that the

goods were in fact not FDA approved, did not comply with the FDA's limited qualified health claim language requirements, and do not reduce the risk of allergies in infants. As a result of this breach, Plaintiff and the Class in fact did not receive goods as warranted by Defendant.

~~120.~~130. As a proximate result of this breach of warranty by Defendant, Plaintiff and the Class have been damaged in an amount to be determined at trial.

SIXTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(California Commercial Code § 2314)

~~121.~~131. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

~~122.~~132. Plaintiff brings this claim on behalf of herself and the proposed Class.

~~123.~~133. Defendant made representations to the public, including Plaintiff and the Class, by its advertising, packaging, labeling, and other means that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants.

~~124.~~134. Defendant was a merchant with respect to goods of this kind (*e.g.*, infant formula and baby food) which were sold to Plaintiff and the Class, and there was in the sale to Plaintiff and the Class an implied warranty that those goods were merchantable.

~~125.~~135. Defendant breached the implied warranty of merchantability when it sold Plaintiff and the Class infant formula that, *inter alia*, did not conform to the promises or affirmations of fact made on the container or label.

~~126.~~136. As a result of Defendant's conduct, Plaintiff and the Class did not receive goods as impliedly warranted by Defendant to be merchantable.

~~127.~~137. As a proximate result of this breach of warranty by Defendant, Plaintiff and the Class have been damaged in an amount to be determined at trial.

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SEVENTH CLAIM FOR RELIEF

NEGLIGENT MISREPRESENTATION

~~128.~~138. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

~~129.~~139. Plaintiff brings this claim on behalf of herself and the proposed Class.

~~130.~~140. ~~Beginning at an exact date unknown to Plaintiff, but at least since three years prior to the filing date of this action, and~~ As~~a~~s set forth above, Defendant represented to the public, including Plaintiff and the Class, by packaging, labeling, advertising, and other means, that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants. These misrepresentations are described in greater detail elsewhere in the Complaint.

~~131.~~141. Defendant's representations were untrue in that the FDA did not approve Good Start Gentle's health claims for qualified use, Good Start Gentle did not comply with the FDA's limited qualified health claim language requirements, and Good Start Gentle does not reduce the risk of allergies in infants.

~~132.~~142. Defendant made the representations without reasonable grounds for believing in their veracity.

~~133.~~143. Defendant made the representations herein alleged with the intention of inducing the public to purchase Defendant's products.

~~134.~~144. Plaintiff, the Class, and the consuming public saw, believed, and reasonably relied on Defendant's advertising, labeling, and packaging when purchasing Good Start Gentle.

~~135.~~145. As a proximate result of Defendant's negligent misrepresentations, Plaintiff and the Class were induced to spend an amount to be determined at trial on Defendant's products.

~~136.~~146. As a proximate result of Defendant's negligent

misrepresentations, Plaintiff and the Class have been damaged in an amount to be determined at trial.

EIGHTH CLAIM FOR RELIEF

INTENTIONAL MISREPRESENTATION

~~137.~~147. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

~~138.~~148. Plaintiff brings this claim on behalf of herself and the proposed Class.

~~139.~~149. ~~Beginning at an exact date unknown to Plaintiff, but at least since three years prior to the filing date of this action, and as~~As set forth above, Defendant represented to the public, including Plaintiff and the Class, by packaging, labeling, advertising, and other means, that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants. These misrepresentations are described in greater detail elsewhere in the Complaint.

~~140.~~150. Defendant's representations were untrue in that the FDA did not approve Good Start Gentle's health claims for qualified use, Good Start Gentle did not comply with the FDA's limited qualified health claim language requirements, and Good Start Gentle does not reduce the risk of allergies in infants.

~~141.~~151. Defendant made these misrepresentations with actual knowledge of their falsity.

~~142.~~152. Defendant made the misrepresentations herein alleged with the intention of inducing the public to purchase Defendant's products.

~~143.~~153. Plaintiff, the Class, and the consuming public saw, believed, and reasonably relied on Defendant's advertising, labeling, and packaging when purchasing Good Start Gentle.

~~144.~~154. As a proximate result of Defendant's intentional misrepresentations, Plaintiff and the Class were induced to spend an amount to be

determined at trial on Good Start Gentle infant formula.

~~145.~~155. As a proximate result of Defendant's intentional misrepresentations, Plaintiff and the Class have been damaged in an amount to be determined at trial.

~~//~~

~~//~~

PRAYER FOR RELIEF

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

a) Determining that this action may proceed as a class action under Rule 23 of the Federal Rules of Civil Procedure;

b) Designating Plaintiff as the Class representative;

c) Designating Plaintiff's counsel as counsel for the Class;

~~d)~~ Issuing proper notice to the Class at Defendant's~~'~~ expense;

d)

~~e) An order enjoining Defendant from:~~

~~f) marketing Good Start Gentle as the "first and only" infant formula to meet an FDA qualified health claim;~~

~~i. marketing Good Start Gentle as a product which reduces the incidence of common food allergies in infants;~~

~~ii. marketing Good Start Gentle as a product which reduces the incidence of atopic dermatitis in infants;~~

~~iii. misusing the FDA term of art "qualified health claim" as a means to mislead consumers into believing that Good Start Gentle is of higher quality or certified by the FDA;~~

~~iv. An order compelling Defendant to conduct a corrective advertising campaign to inform the public that Good Start Gentle does not reduce the likelihood of infants developing allergies and~~

~~that the FDA did not endorse or certify such claims;~~

~~g) An order compelling Defendant to destroy all misleading and deceptive advertising materials and products;~~

~~h)~~e) Awarding restitution and disgorgement of Defendant's revenues obtained by means of any wrongful act or practice to Plaintiff and Class members;

~~i)~~ Awarding actual, statutory, and punitive damages and interest to Plaintiff and Class members;

f)

~~j)~~ Awarding reasonable attorneys' fees, interest, and costs to the full extent permitted by law; and

~~An order issuing declaratory relief; and~~

~~k)~~g) All such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff and the Class demand a trial by jury.

Dated: February 24, 2015 Respectfully submitted,

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By: _____

Daniel L. Keller
Dan C. Bolton
KELLER, FISHBACK & JACKSON LLP
28720 Canwood Street, Suite 200
Agoura Hills, CA 91301
Telephone: (818) 342-7442
Facs~~e~~imile: (818) 342-7616
Email: dkeller@kfjlegal.com
Email: dbolton@kfjlegal.com

STEPHEN J. FEARON, JR (subject to *pro hac vice)*
PAUL V. SWEENY(subject to *pro hac vice*)
SQUITIERI & FEARON, LLP
32 East 57th St., 12th Floor
New York, New NY 10022
Telephone: (212) 421-6492
Facsimile: (212) 421-6553
Email: stephen@sfclasslaw.com
Email: paul@sfclasslaw.com

Attorneys for Plaintiff and the Proposed Class

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Exhibit A

Effect of a partially hydrolyzed whey infant formula at weaning on risk of allergic disease in high-risk children: A randomized controlled trial

Adrian J. Lowe, PhD,[a,b] Clifford S. Hosking, FRACP,[c] Catherine M. Bennett, PhD,[a] Katrina J. Allen, PhD,[b] Christine Axelrad, RN,[b] John B. Carlin, PhD,[a,b] Michael J. Abramson, PhD,[d] Shyamali C. Dharmage, PhD,[a] and David J. Hill, FRACP[b] *Melbourne and Newcastle, Australia*

Background: Partially hydrolyzed whey formula (pHWF) has been recommended for infants with a family history of allergic disease at the cessation of exclusive breast-feeding to promote oral tolerance and prevent allergic diseases.
Objective: To determine whether feeding infants pHWF reduces their risk of allergic disease.
Methods: A single-blind (participant) randomized controlled trial was conducted to compare allergic outcomes between infants fed a conventional cow's milk formula, a pHWF, or a soy formula. Before birth, 620 infants with a family history of allergic disease were recruited and randomized to receive the allocated formula at cessation of breast-feeding. Skin prick tests to 6 common allergens (milk, egg, peanut, dust mite, rye grass, and cat dander) were performed at 6, 12, and 24 months. The primary outcome was development of allergic manifestations (eczema and food reactions) measured 18 times in the first 2 years of life.
Results: Follow-up was complete for 93% (575/620) at 2 years and 80% (495/620) at 6 or 7 years of age. There was no evidence that infants allocated to the pHWF (odds ratio, 1.21; 95% CI, 0.81-1.80) or the soy formula (odds ratio, 1.26; 95% CI, 0.84-1.88) were at a lower risk of allergic manifestations in infancy compared with conventional formula. There was also no evidence of reduced risk of skin prick test reactivity or childhood allergic disease.
Conclusion: Despite current dietary guidelines, we found no evidence to support recommending the use of pHWF at weaning for the prevention of allergic disease in high-risk infants.
(J Allergy Clin Immunol 2011;128:360-5.)

Key words: *Allergy prevention, infant formulas, partially hydrolyzed whey formula, conventional cow's milk formulas, eczema, asthma, allergic rhinitis, randomized control trial*

Partially hydrolyzed whey formulas (pHWFs) have been widely recommended to prevent the development of allergic diseases in early childhood.[1-6] If beneficial, the use of pHWF is an attractive preventive strategy, because pHWFs are relatively inexpensive to manufacture. These formulas contain smaller, less immunogenic milk protein–derived peptides[7] of reduced allergenicity that potentially enhance induction of tolerance to cow's milk protein.[8,9]

The widespread support for the use of pHWF appears to be based on the results of a Cochrane review that found "a significant reduction in infant allergy" (p 11) to be associated with prolonged feeding with pHWF compared with feeding with conventional cow's milk formula (CMF).[10] Despite the authors' caution that further studies were required, this meta-analysis has been widely used to underpin many clinical guidelines in Europe, the United States, and Australia.[1-6,11] A major problem with meta-analyses is that often only published reports are analyzed.[12] These are more likely to be positive studies because of publication bias, leading the review to overestimate the effectiveness of a treatment.[13] Publication bias may have affected the results of the Cochrane review on the value of pHWF in preventing allergic disease.[10] There is some evidence of asymmetry in the funnel plot[14] generated for the meta-analysis reported within the Cochrane review[10] (Harbord $P = .06$[14]), with the smaller studies tending to report stronger protective effects of the pHWF than the larger studies. The German Infant Nutritional Intervention Study (GINI),[15] the largest in this field, reported that pHWF reduced the incidence of eczema in early childhood in a per-protocol analysis that excluded children exclusively breast-fed to 4 months of age. However, an intention-to-treat (ITT) analysis failed to show any benefit of pHWF compared with conventional CMF.[16]

The primary aim of the current study was to determine whether the use of a pHWF reduced the incidence of allergic manifestations (eczema and food reactions) up to 2 years of age in high-risk infants compared with a conventional CMF. We also report results

From [a]the Centre for Molecular, Environmental, Genetic and Analytic Epidemiology, School of Population Health, University of Melbourne; [b]the Murdoch Children's Research Institute, Royal Children's Hospital, Melbourne; [c]the Department of Paediatrics, John Hunter Children's Hospital, Newcastle; and [d]the Department of Epidemiology and Preventive Medicine, Monash University, Melbourne.

Nestec Ltd, a subsidiary of Nestlé Australia, provided the study formula and staff funding for the first 6 years of the study.
Disclosure of potential conflict of interest: A. J. Lowe has received research support from Dairy Australia. K. J. Allen has received speaker's honoraria from Wyeth and Nutricia. D. J. Hill has received research support from Nestlé Australia, SHS International, and Nutricia. The rest of the authors have declared that they have no conflict of interest.
Editor's note: Following acceptance of this manuscript, several inadvertent errors in data transcription were identified. The authors have made the necessary revisions. This process has resulted in a delay between the paper's original acceptance date and its publication date.
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Reprint requests: David J. Hill, FRACP, Senior Consultant Allergist, Murdoch Children's Research Institute, Royal Children's Hospital, Melbourne, Victoria 3053, Australia. E-mail: davidjlhill@bigpond.com.
0091-6749/$36.00

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Abbreviations used
CMF: Cow's milk formula
GINI: German Infant Nutritional Intervention Study
ITT: Intention to treat
MACS: Melbourne Atopy Cohort Study
OR: Odds ratio
pHWF: Partially hydrolyzed whey formula
SPT: Skin prick test

from a third comparison group in which infants received a soy formula.

METHODS

Inclusion and exclusion criteria

Between 1990 and 1994 expectant mothers attending the Mercy Maternity Hospital, Melbourne, Australia, were invited to participate in a study of the effect of modification of the infant diet on the risk of infant allergy. Mother-baby pairs were enrolled if the unborn child had a first-degree relative with a history of eczema, asthma, allergic rhinitis, or food allergy. Information leaflets and posters outlined the project's aim. Nurse research staff assessed eligibility and enrolled participants. This study was approved by the Mercy Maternity Hospital Ethics Committee, and all mothers provided written informed consent.

Intervention

There were 2 intervention formulas: a soy-based formula (ProSobee; Mead Johnson Nutrition/Bristol Myers, Melbourne, Australia) and a pHWF (NAN HA; Nestlé, Biessenhoffen, Germany). The control formula was a CMF (NAN; Nestlé, Tongala, Australia). In accordance with World Health Organization guidelines,[17] mothers were encouraged to initiate and maintain breast-feeding for at least 6 months. Study formulas were introduced only at cessation, or partial cessation, of breast-feeding or as a breast milk substitute if breast-feeding was not intended.

Trial design

The trial was registered (retrospectively) with the Australian and New Zealand Clinical Trials Registry (ACTRN12609000734268). The trial commenced before the pHWF was available. The first 97 infants were randomized to either the CMF or soy study groups. When the pHWF became available, a new random allocation series was generated with a higher proportion allocated to the pHWF to obtain equal numbers in each formula group. An independent statistician created each of the computer generated allocation schedules. The random allocation list, containing the coded allocations, was available to research staff. Staff were blind to these allocation codes and to the group of allocation at the time of outcome assessment. Mother-baby pairs were allocated to the next sequential number as they were enrolled in the study and were assigned to the formula code allocated to that number. The cans of formula were labeled at an independent location. Parents of participants were informed of the identity of the assigned formula only after the child's second birthday.

Introduction of rice cereal, pureed apple, and pear was recommended from 4 months of age, and vegetables and other fruit from 6 months. Meats were introduced from 8 months, and nonrice cereals from 9 months. Dairy products, egg, fish, peanut, and nuts were avoided until 12 months of age.

Skin prick tests (SPTs) were performed at 6, 12, and 24 months according to a standard technique[18] by 1 of 3 allergy-trained research nurses. Allergen extracts used were cow's milk, egg white, peanut, house dust mite, rye grass, and cat dander (Bayer, Spokane, Wash), and SPTs were read at 15 to 20 minutes.

Definitions

Outcomes up to 2 years of life, as assessed during 18 telephone interviews with parents (every 4 weeks until 64 weeks, then at 78 and 104 weeks), were defined as follows:

- *Eczema*: Doctor-diagnosed eczema or any rash that was treated with topical steroid preparation (excluding rash that only affected the scalp or nappy region).[19]
- *Food reaction*: Within 2 hours of ingesting that food, the child developed an acute skin rash (urticaria, angioedema, erythematous, or morbilliform), a flare of pre-existing eczema, signs of anaphylaxis, or vomiting.[20]
- *Any allergic manifestation*: Presence of eczema or food reaction within the first 2 years of life.
- *Positive SPT:* A wheal of at least 3 mm (mean) diameter with a positive (histamine) control.

Childhood outcomes, based on parent report during telephone interviews conducted when children were age 6 or 7 years, were defined as follows:

- *Current childhood eczema*: Eczema diagnosed by the family physician in the previous 12 months.
- *Current childhood asthma*: Asthma diagnosed by the family physician in the previous 12 months.
- *Persistent childhood asthma*: Asthma diagnosed by the family physician in the previous 12 months on at least 2 occasions at the follow-up at 5, 6, or 7 years.
- *Current childhood allergic rhinitis:* One or more episodes of nasal discharge and/or congestion in the absence of an upper respiratory tract infection in the previous 12 months that either the family physician or parent attributed to allergic rhinitis (hay fever) and that was treated with an antihistamine and/or nasal steroid.[21]

Outcomes

The primary outcome was *any allergic manifestation* (cumulative incidence) up to 2 years of age. Secondary outcomes were the individual incidence of eczema and food reactions, reported in the first 2 years of life, and SPT reactivity at 6, 12, and 24 months. Additional secondary outcomes were the 2-year period prevalence of eczema, asthma, and allergic rhinitis at ages 6 and 7 years.

Sample size

A total of 176 infants per group were required to have 80% power to detect a 15% absolute difference in risk of allergic manifestation between the formula groups, assuming an α level of 0.05 and a 45% baseline risk of allergic disease within the first 2 years of life. Allowing for approximately a 15% dropout rate over the first 2 years of life, a total of 206 children per group were required.

Statistical methods

The primary analysis followed the ITT principle and compared the risk of *any allergic manifestation* between the allocated formula groups by using simple proportions and χ^2 tests. The estimated associations are presented as odds ratios (OR) with 95% CIs, with the CMF as the reference group.

Secondary analyses were also performed for the outcomes of sensitization to cow's milk and any allergen (assessed separately at 6, 12, and 24 months, and also combined by using logistic regression models, estimated by the generalized estimating equations approach) and childhood asthma, allergic rhinitis, and eczema at ages 6 and 7 years (again by using the generalized estimating equations approach).

A number of per-protocol analyses were performed. First, infants were excluded if they were exclusively breast-fed beyond 4 months of life. The 4-month cut-off period was selected to allow direct comparison of results with the GINI study.[15,16] Second, a per-protocol analysis was performed including only those infants who had received some of the allocated formula by 4 months of age.

To determine whether the effect of the formula on risk of allergic disease varied between those with a family history of eczema (either the mother or father) and those without (neither the mother nor father),[15] a stratified analysis was performed. Interaction effects were assessed by using Wald tests.

Adjusted associations were also estimated, to allow for any confounding due to chance imbalances at baseline. Adjustment was made for infant sex,

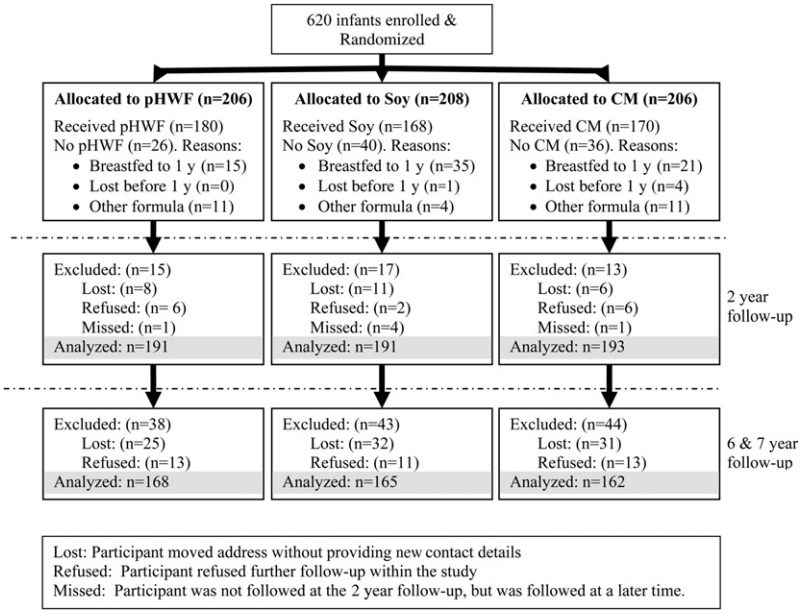

FIG 1. Flow chart of participation in the MACS. *CM,* Cow's milk formula.

parental smoking during pregnancy, and family history of allergic disease in all models. All statistical analysis was performed by A.J.L. using Stata statistical software (release 9.2; Stata Corp, College Station, Tex).

RESULTS

A total of 620 infants were recruited (Fig 1). Infants allocated to the CMF and pHWF groups were similar on baseline risk factors (see this article's Table E1 in the Online Repository at www.jacionline.org). Infants allocated to the soy formula had a higher proportion of parents with food allergy and siblings with allergic disease (Table E1). There were no differences between the groups in terms of duration of exclusive breast-feeding or age of introduction of solids (Table E1).

Approximately 50% of infants received some of the allocated formula by 4 months of age; 16.5% of infants never received their allocated formula because of either continuing breast-feeding (13.6%; n = 78/575) or using a nonallocated formula (2.9%; n = 17/575). There were no differences in rates of exposure to the allocated formula between the groups (Fig 2). The majority of mothers fully adhered to the study formula feeding protocol (breast-feeding and then weaning onto allocated formula with no other formula exposures) during the first 6 months of the child's life (91.2%, 86.9%, and 87.4% for the CMF, pHWF and soy groups, respectively) despite only 63% of children having been exposed to the allocated formula by this age. The rates of adherence declined by 12 months of age (75.7%, 69.1%, and 76.4%, respectively).

There were 575 (92.7%) infants followed until 24 months of age (Fig 1); 25 children were lost to follow-up (shifted residence without informing the study), 14 refused ongoing participation, and 6 children did not complete the 2-year follow-up but subsequently rejoined the study (Fig 1).

Primary outcome

Neither the pHWF nor the soy formula reduced the risk of allergic manifestations in the first 2 years of life (Table I).

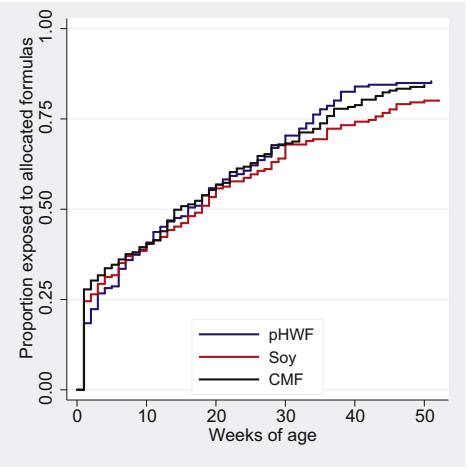

FIG 2. Proportion of infants exposed to the allocated formula from the time of birth (0 weeks) until 52 weeks of age.

Secondary outcomes in the first 2 years

There was no evidence of differences between the groups on any secondary clinical outcome (Table I) or SPT reactivity (Table II). Using a 2-mm mean wheal diameter to define a positive SPT did not change the overall pattern of results or the conclusion that there was no evidence of a difference between the groups. There were 19 (3.2%) children with large SPT (≥6 mm) wheals to cow's milk, consistent with IgE-mediated cow's milk allergy,[22] and these children were evenly distributed between the groups (CMF, 6/197; pHWF, 4/196; and soy, 9/201).

Secondary outcomes at ages 6 and 7 years

Between 6 and 7 years of age, 80% (495/620) of children had a telephone interview. There were no differences between the groups in the rates of childhood eczema, asthma, or allergic rhinitis (Table I).

TABLE I. Unadjusted associations between allocated formula and risk of allergic disease

Outcome	Conventional formula (CMF) % (n/N)	Hydrolyzed formula (pHWF) % (n/N)	Hydrolyzed formula (pHWF) Crude OR (95% CI)	Soy formula % (n/N)	Soy formula Crude OR (95% CI)
Any allergic manifestation: 0-1 y (228/575)	37.3 (72/193)	37.7 (72/191)	1.02 (0.67-1.54)	44.0 (84/191)	1.32 (0.88-1.98)
Any allergic manifestation: 0-2 y (300/575)	48.7 (94/193)	53.4 (102/191)	1.21 (0.81-1.80)	54.5 (104/191)	1.26 (0.84-1.88)
Secondary outcomes					
Eczema within first 2 y	43.0 (83/193)	48.7 (93/191)	1.26 (0.84-1.88)	46.1 (88/191)	1.13 (0.76-1.69)
Food reactions within first 2 y					
Any food (92/575)	13.5 (26/193)	15.2 (29/191)	1.15 (0.65-2.04)	19.4 (37/191)	1.54 (0.89-2.67)
Cow's milk protein (17/575)	3.1 (6/193)	1.6 (3/191)	0.50 (0.12-2.02)	4.2 (8/191)	1.36 (0.46-4.00)
Cow's milk with + SPT to cow's milk (3/575)	0 (0/193)	0.5 (1/191)	NE	1 (2/191)	NE
Peanut with + SPT to peanut (1/575)	0.5 (1/193)	0 (0/191)	NE	0 (0/191)	NE
Egg with + SPT to egg (8/575)	1.0 (2/193)	0.5 (1/191)	0.50 (0.04-5.59)	2.6 (5/191)	2.57 (0.49-13.40)
Childhood outcomes (period prevalence at 6-7 y)					
Eczema (157/493)	31.5 (51/162)	33.5 (56/167)	1.08 (0.69-1.68)	30.5 (50/164)	0.95 (0.60-1.48)
Asthma (148/495)	32.1 (52/162)	28.0 (47/168)	0.91 (0.57-1.45)	29.7 (49/165)	0.97 (0.61-1.54)
Rhinitis (117/495)	22.2 (36/162)	22.0 (37/168)	0.94 (0.56-1.58)	26.7 (44/165)	1.27 (0.77-2.10)
Persistent asthma (120/494)	25.5 (41/161)	24.2 (40/165)	0.88 (0.53-1.46)	24.2 (40/165)	0.94 (0.57-1.55)

NE, OR not estimable.

TABLE II. Unadjusted associations between allocated formula and risk of positive SPT

Outcome	Conventional formula (CMF) % (n/N)	Hydrolyzed formula (pHWF) % (n/N)	Hydrolyzed formula (pHWF) Crude OR (95% CI)	Soy formula % (n/N)	Soy formula Crude OR (95% CI)
Positive SPT (any allergen) at					
6 mo (95/552)	16.9 (30/177)	18.3 (35/191)	1.10 (0.64-1.88)	16.3 (30/184)	0.95 (0.55-1.66)
12 mo (146/544)	29.2 (52/178)	25.0 (47/188)	0.81 (0.51-1.28)	26.4 (47/178)	0.87 (0.55-1.38)
2 y (136/449)	31.6 (50/158)	26.0 (38/146)	0.76 (0.46-1.25)	33.1 (48/145)	1.07 (0.66-1.73)
Repeated measures*	—	—	0.90 (0.61-1.33)	—	0.98 (0.67-1.44)
Positive SPT to cow's milk at					
6 mo (23/552)	5.1 (9/177)	4.2 (8/191)	0.82 (0.31-2.16)	3.3 (6/184)	0.63 (0.22-1.81)
12 mo (32/544)	5.1 (9/178)	5.9 (11/188)	1.17 (0.47-2.89)	6.7 (12/178)	1.36 (0.56-3.31)
2 y (16/449)	3.8 (6/158)	1.4 (2/146)	0.35 (0.07-1.77)	5.5 (8/145)	1.48 (0.50-4.37)
Repeated measures*	—	—	0.89 (0.40-1.99)	—	1.01 (0.44-2.30)

*These estimates are based on repeated measures (combining results from the 6, 12, and 24 month SPT using the generalized estimating equations approach), meaning it is not possible to report simple proportions.

Adjusted analysis

Adjustment for sex, parental smoking, and family history of allergic disease did not alter the associations between the allocated group and the risk of any allergic manifestation in the first 2 years of life or any of the secondary outcomes and did not change the interpretation of the results (see this article's Table E2 in the Online Repository at www.jacionline.org).

Interactions with family history of eczema

There was no evidence that pHWF protected against the development of allergic manifestation in those children with or without a family history of eczema (see this article's Table E3 in the Online Repository at www.jacionline.org; all *P* values for all interaction terms >.15).

Per-protocol analysis

None of the per-protocol analyses produced substantially different findings from the ITT analysis. Limiting the analysis to children whose parents were compliant with the study feeding protocol did not alter the study conclusions (primary outcome OR, 1.20; 95% CI, 0.75-1.93, for pHWF [n = 132 and 146]). Excluding infants exclusively breast-fed for more than 4 months did not alter the results (OR, 1.22; 95% CI, 0.72-2.04, for pHWF [n = 110 and 121]). Similarly, including only infants who had consumed some of the allocated formula (OR, 1.16; 95% CI, 0.66-2.02 [n = 97 and 102]) or consumed the allocated formula for at least 2 weeks during the first 4 months of life (OR, 1.10; 95% CI, 0.59-2.04 [n = 82 and 80]) did not alter the results. Similar results were obtained when the analysis was limited to children who consumed the allocated formula for at least 4 (OR, 1.06; 95% CI, 0.55-2.03 [n = 73 and 73]) and 8 weeks (OR, 1.00; 95% CI, 0.48-2.09 [n = 62 and 55]) in the first 4 months of life. Limiting the analysis to children who consumed at least 100 mL per day for each of these durations produced similar results. Finally, limiting the analysis to children who were exposed to the allocated formula within the first 2 weeks of life again did not produce any evidence of benefit (OR, 0.91; 95% CI, 0.41-2.01 [n = 43 and 58]), although the reduced numbers limited the precision of this comparison. Similarly, interpretation for all secondary outcomes did not change in any of these analyses (data not shown).

DISCUSSION

This randomized controlled trial failed to show any beneficial effect of the pHWF for the prevention of any allergic disease

outcome up to 7 years of age in high-risk children compared with a conventional cow's milk–based formula.

This is the second largest trial to randomize individual infants to receive either pHWF or a conventional cow's milk formula. An ITT analysis of the largest study, the GINI study,[15,16,23] also failed to demonstrate a clear benefit of pHWF over conventional formula for the outcomes of allergic manifestations and eczema up to 12 months, and childhood eczema, asthma, or allergic rhinitis (2-year period prevalence at 6 years).[23] Although 1 report from GINI showed some benefit for the cumulative prevalence of allergic manifestations up to 3 years of age (relative risk, 0.77; 95% CI, 0.61-0.98),[23] a previous analysis of the same outcome within GINI did not (population odds ratio, 0.94; 95% CI, 0.73-1.20).[16] Most of the reported benefits of pHWF in GINI are from a per-protocol analysis in which children were excluded if they had not received the allocated formula within the first 4 months of life. It is well accepted that the main conclusions of a randomized controlled trial should be based on an ITT analysis because per-protocol analysis can bias the findings.[24]

The Cochrane review and meta-analysis of 6 studies of this topic[10] suggested a benefit of pHWF for the prevention of "any allergic manifestation in infancy" compared with conventional CMF (pooled OR, 0.73; 95% CI, 0.59-0.90). However, when our results are added to this pooled estimate, there is no longer evidence of a protective effect of pHWF for "any allergic disease in infancy" (pooled OR, 0.91; 95% CI, 0.79-1.05). The ITT analysis of the 2 largest studies in this area (GINI[23] and Melbourne Atopy Cohort Study [MACS]) failed to show any benefit of pHWF compared with conventional CMF, whereas studies with far fewer participants showed stronger protective effects of the pHWF.[25-27] These conflicting results suggest that publication bias may have had an impact on this Cochrane review.[10]

Alternatively, the effect of pHWF may be influenced by previous breast-feeding. The studies that demonstrated a strong protective effect of pHWF were of a small number of children who received pHWF *without receiving any breastfeeding*.[25-28] By contrast, studies including MACS that randomized a larger number of infants to pHWF *at weaning* from breast milk showed a much weaker effect.[23,29] The negative findings of our study, and others that randomized before birth, may be a result of infants having less formula than those starting pHWF from birth. In addition, the effect of pHWF may be modified by previous breast-feeding; human breast milk contains a number of important immunologically active components[30] that may both modify induction of allergen tolerance[31] and have an effect on the impact of pHWF on the risk of allergic disease. These possibilities might explain why the per-protocol (exposure within the first 4 months) analysis of the GINI study showed stronger evidence of a protective effect than the ITT, because the per-protocol analysis would have selected out those who were predominantly breast-fed. To resolve this issue conclusively, studies that randomize large numbers of infants to specific infant formula and preclude previous breast-feeding are required. However, this may be logistically difficult and potentially unethical given the current evidence on benefits of breast-feeding.

The importance of the first 4 months of life for dietary interventions to prevent allergic disease has been emphasized in the literature[32,33] because this is believed to be the critical time of oral immune tolerance development. However, we were unable to show an impact of the pHWF even when we limited our analysis to those children exposed within this time frame. Similarly, including only infants with a significant exposure to the allocated formula within the first 4 months of life did not reveal a protective effect of pHWF.

In contrast with the GINI study,[15] we did not observe any difference in the effect of a pHWF between children with or without a family history of eczema. It is highly unlikely that pHWF has a differential effect on the basis of family history of eczema.

Our study has a number of important strengths. We have studied the effect of a pHWF on high-risk children until they were 7 years of age, when the diagnosis of asthma[34] and allergic rhinitis is clearer. Skin prick tests were performed on 3 occasions to cow's milk as well as 5 other common allergens. This allowed the assessment of a specific effect of pHWF on the risk of cow's milk sensitization as well as on atopic diseases. The rate of follow-up during early life was exceptional. The sample size in this study was sufficient to detect important differences between the formulas in allergy prevention. It was not designed to demonstrate equivalence.

The design of our study has some weaknesses. The allocation sequence was available to the research staff throughout the study. Therefore, the research staff would have known the *coded* group of allocation for the next participant to be enrolled. Despite this, examination of the enrollment into the study indicates that it was time-consecutive, and the staff members undertaking the distribution of formulas were blind to the formula codes. Thus selection bias and ascertainment bias were unlikely to influence the results of this study. In addition, we relied in part on parent-reported outcomes that have not been validated. However, none of the current definitions of eczema[35,36] have been validated in children under the age of 2 years, although a standardized assessment at the time of SPTs within this study may have improved the measurement of this outcome. We have demonstrated good agreement between the International Study of Asthma and Allergies in Childhood definitions of eczema, asthma, and hay fever and those used in this study at age 6 to 7 years (all κ values $\geq$.74; unpublished data A. Lowe, December 2007).

This study tested the effect of a pHWF at weaning on the incidence of allergic manifestations. It does not provide information concerning the impact of exclusive feeding with pHWF nor other forms of partially or extensively hydrolyzed or amino acid-based formula.

Conclusion

There was no evidence that introducing pHWF at the cessation of breast-feeding reduced the risk of allergic manifestations, including eczema, asthma, and allergic rhinitis, in this study of high-risk infants. Our findings do not support the recommendation that pHWF should be used after breast-feeding as a preventive strategy for infants at high risk of allergic diseases.

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Clinical implications: The authors found no evidence to support the use of pHWF at weaning for the prevention of allergic disease in infants with a family history of allergic disease.

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TABLE E1. Comparison of baseline factors between the allocated formula groups

Baseline factor	Hydrolyzed formula (pHWF) (n = 206)	Soy formula (n = 208)	Conventional formula (CMF) (n = 206)
Male infant	50.8%	51.0%	51.9%
Maternal history of allergic disease			
Asthma	42.9%	46.6%	40.3%
Eczema	38.5%	36.1%	42.2%
Hay fever	61.5%	59.1%	61.2%
Food allergy	37.4%	43.8%	34.5%
Paternal history of allergic disease			
Asthma	21.6%	27.1%	28.4%
Eczema	19.1%	18.4%	24.0%
Hay fever	47.5%	48.3%	42.6%
Food allergy	20.6%	28.5%	14.7%
Demographic factors			
Median maternal age (y) (IQR)	31 (29-34)	32 (29-34.5)	31 (28-34)
Median paternal age (y) (IQR)	33 (30-36)	33 (31-36)	32.5 (29.5-36.5)
Median maternal education (y) (IQR)	15 (12-15)	15 (12-15)	15 (11-15)
Median paternal education (y) (IQR)	15 (12-15)	15 (12-15)	15 (11-15)
Median SES of father's occupation (IQR)*	48.6 (34.0-61.9)	43.6 (29.2-62.6)	41.6 (27.2-61.9)
Home environment			
Owner-occupied home	84.0%	81.7%	80.1%
Any gas cooking	75.1%	73.2%	79.7%
Any gas heating	74.1%	66.8%	71.8%
Any pet	70.1%	70.8%	65.7%
Maternal smoking during pregnancy	7.8%	4.8%	10.2%
Paternal smoking during pregnancy	19.0%	16.4%	22.7%
Sibling factors			
No older siblings	43.2%	33.7%	43.7%
Any older sibling with food allergy	35.4%	50.5%	26.2%
Any older sibling with eczema	35.0%	46.6%	33.5%
Any older sibling with asthma	32.5%	45.7%	27.7%
Any older sibling with hay fever	19.5%	26.4%	19.4%
Early diet (wk)			
Median duration of exclusive breast-feeding (IQR)	14 (3-20)	15 (1-21)	13 (1-20)
Median duration of any breast-feeding (IQR)†	42 (22-60)	47 (17-64)	44 (24-60)
Median age of introduction to solid foods (IQR)	20 (18-22)	19 (16-24)	20 (17-22)

IQR, Interquartile range; *SES,* socioeconomic status.

*SES classified using the Australian National University (ANU)-3 system,[E1] which ranges from 0 to 100, with higher values indicating higher SES.

†Excludes 37 infants who were not breast-fed.

TABLE E2. Adjusted associations between allocated formula and risk of positive SPT and allergic disease

Outcome	Hydrolyzed formula (pHWF) adjusted OR (95% CI)	Soy formula adjusted OR (95% CI)
Any allergic manifestation		
0-1 y (228/575)†	0.97 (0.63-1.48)	1.23 (0.81-1.88)
0-2 y (300/575)†	1.22 (0.81-1.85)	1.21 (0.80-1.84)
Secondary outcomes		
Eczema within first 2 y (264/575)†	1.24 (0.82-1.88)	1.11 (0.73-1.68)
Positive SPT within first 2 y*		
Any allergen	0.88 (0.59-1.30)	0.92 (0.61-1.38)
Cow's milk	0.79 (0.35-1.77)	0.78 (0.32-1.92)
Any food reaction within first 2 y	0.95 (0.51-1.75)	1.21 (0.67-2.19)
Childhood outcomes (period prevalence) at 6-7 y		
Eczema (157/493)	1.10 (0.70-1.72)	0.90 (0.57-1.42)
Asthma (148/495)‡	0.82 (0.50-1.33)	0.82 (0.50-1.34)
Rhinitis (117/495)§	0.91 (0.54-1.55)	1.24 (0.74-2.09)

All ORs compared to the conventional CMF group. All models adjusted for infant sex and parental smoking during pregnancy unless otherwise stated. Also adjusted for *parent and sibling food allergy, †parent and sibling eczema, ‡parent and sibling asthma, or §parent and sibling allergic rhinitis.

TABLE E3. Unadjusted associations between allocated formula and risk of allergic disease outcomes according to family history of eczema

	No family history of eczema			Family history of eczema present			
	Conventional formula (CMF)	Hydrolyzed formula (pHWF)		Conventional formula (CMF)	Hydrolyzed formula (pHWF)		*P* value for interaction
Outcome	% (n/N)	% (n/N)	OR (95%CI)	% (n/N)	% (n/N)	OR (95% CI)	
Primary outcome							
Any allergic manifestation: 0-2 y	49.4 (38/77)	49.4 (41/83)	1.00 (0.54-1.86)	47.4 (54/114)	55.7 (59/106)	1.39 (0.82-2.37)	.43
Secondary outcomes							
Eczema in first 2 y	40.3 (31/77)	44.6 (37/83)	1.19 (0.64-2.24)	44.7 (51/114)	50.9 (54/106)	1.28 (0.75-2.18)	.86
Positive SPT within first 2 y							
Cow's milk (3 mm+)*	—	—	0.95 (0.24-3.84)	—	—	0.88 (0.34-2.30)	.93
Any allergen (3 mm+)*	—	—	1.18 (0.63-2.18)	—	—	0.78 (0.47-1.28)	.31
Childhood outcomes at age 6-7 y							
Eczema	16.4 (11/67)	25.4 (18/71)	1.83 (0.79-4.23)	40.9 (38/93)	38.9 (37/95)	0.89 (0.52-1.53)	.16
Asthma	28.4 (19/67)	26.8 (19/71)	1.10 (0.53-2.32)	35.5 (33/93)	28.4 (27/95)	0.76 (0.41-1.38)	.44
Allergic rhinitis	17.9 (12/67)	25.4 (18/71)	1.54 (0.67-3.51)	24.7 (23/93)	20.0 (19/95)	0.73 (0.37-1.44)	.17

*These estimates are based on repeated measures (combining results from the 6, 12, and 24 month SPT using the generalized estimating equations approach), meaning it is not possible to report simple proportions.

Exhibit B

Exhibit B

Exhibit C

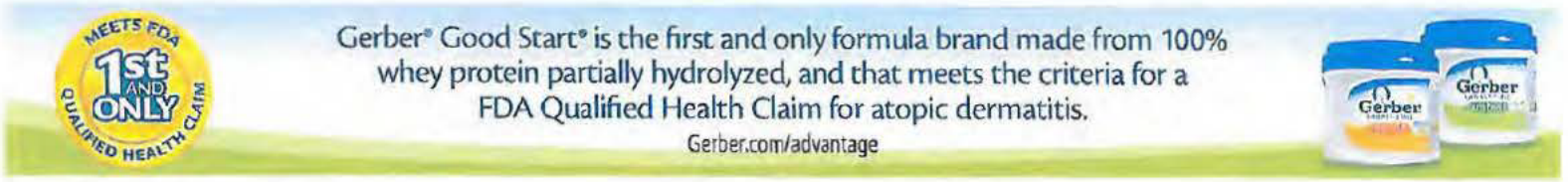

MEETS FDA
1st AND ONLY
QUALIFIED HEALTH CLAIM
Gerber® Good Start® is the first and only formula brand made from 100% whey protein partially hydrolyzed, and that meets the criteria for a FDA Qualified Health Claim for atopic dermatitis.
Gerber.com/advantage
Gerber
Gerber

Exhibit C

Exhibit D

What Babies Want :30 TVC

April 9th, 2012

Gerber. DRAFTFCB

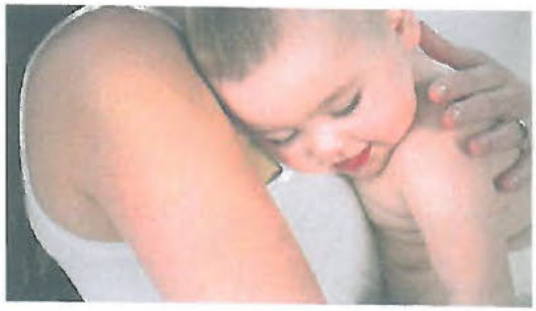
AVO: You want your Gerber baby to have your imagination...

AVO: Your smile...

AVO: your eyes...

AVO: Not your allergies.

AVO: The Gerber Generation knows that breastfeeding



AVO: is the best way to naturally protect your baby.

1

Exhibit D-1

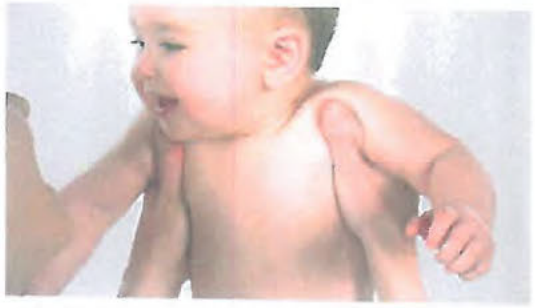
What Babies Want :30 TVC

April 9th, 2012

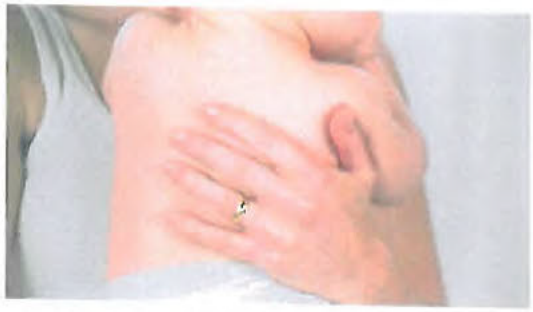
Gerber. DRAFTFCB

AVO: But if you introduce formula

AVO: choose the Gerber Good Start Comfort Proteins Advantage.



AVO: It's what makes Good Start formula easy to digest



AVO: and may also provide protective benefits for your baby.

AVO: Gerber Good Start Gentle.

AVO: Nutrition inspired by breastmilk.

What Babies Want :30 TVC

April 9th, 2012

DRAFTFCB

AVO: Gerber

AVO: Nourishing Generation Healthy.

Exhibit D-3

Exhibit E

Learn more here.

The Gerber Generation

birth+

says "I love Mommy's eyes, not her allergies"

If you have allergies in your family, breastfeeding your baby can help reduce their risk. And, if you decide to introduce formula, research shows the formula you first provide your baby may make a difference. In the case of Gerber® Good Start® Gentle Formula, it's the Comfort Proteins® Advantage that is easy to digest and may also deliver protective benefits. That's why Gerber® Good Start® Gentle Formula is nutrition inspired by breastmilk.

Nourishing Generation Healthy™

Nestlé
Good Food, Good Life

Exhibit F

The first formula fed may make a difference

Gerber Good Start is the first and only infant formula that meets the criteria for a FDA Qualified Health Claim.

Breastfeeding helps reduce the risk of developing atopic dermatitis – the most common allergy of infancy. Now there is a formula that can help too, especially for those babies with a family history of allergy. The 100% whey protein partially hydrolyzed used in our Gerber Good Start formulas is easy to digest and may provide protective benefits. This is our Comfort Proteins® Advantage and only Good Start has it.

Gerber Good Start should not be fed to infants who are allergic to milk or infants with existing milk allergy symptoms. Not for allergy treatment.

Scan here to learn more

Gerber Good Start is expanding its portfolio with two new formulas

Gerber Good Start Soothe
Designed to reduce excessive crying and colic

Gerber Good Start Nourish for Babies Born Prematurely

For more information visit gerber.com

Exhibit G

Your formula choice may make a difference.

MEETS FDA 1st AND ONLY QUALIFIED HEALTH CLAIM

Learn about the Gerber® Good Start® difference at Gerber.com/difference

PICK ONE UP!

The formula that's whey different!

AFFILIATED FOODS MIDWEST

11/06/11 - 11/19/11

$0.00

23.2 OZ

UPC: 0-50000-11173

Exhibit H

People Magazine 8/5/13

Exhibit H