Michael R. Reese
George V. Granade
REESE LLP
875 Avenue of the Americas, 18th Floor
New York, New York 10001
Telephone: (212) 643-0500
Facsimile: (212) 253-4272
Email: *mreese@reesellp.com*
ggranade@reesellp.com

Shanon J. Carson
Sarah R. Schalman-Bergen
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, Pennsylvania 19103
Telephone: (215) 875-4656
Facsimile: (215) 875-4604
Email: *scarson@bm.net*
sschalman-bergen@bm.net

Kevin Landau
TAUS, CEBULASH & LANDAU, LLP
80 Maiden Lane, Suite 1204
New York, New York 10038
Telephone: (646) 873-7654
Facsimile: (212) 931-0703
Email: *klandau@tcllaw.com*

John A. Yanchunis
MORGAN & MORGAN
COMPLEX LITIGATION GROUP
201 N. Franklin Street, 7th Floor
Tampa, Florida 33602
Telephone: (813) 275-5275
Facsimile: (813) 222-4736
jyanchunis@forthepeople.com

Attorneys for Plaintiffs and the Proposed Class

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

JENNIFER HASEMANN and DEBBIE HOTH, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

GERBER PRODUCTS COMPANY (d/b/a Nestlé Nutrition, Nestlé Infant Nutrition, or Nestlé Nutrition North America),

Defendant.

No. _____

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

1. Plaintiffs Jennifer Hasemann and Debbie Hoth (together, "Plaintiffs"), individually and on behalf of all persons who purchased Gerber Good Start Gentle infant formula ("Good Start"), allege the following on personal knowledge as to all facts related to themselves and upon information and belief as to all other matters.

NATURE OF THE ACTION

2. This case involves a pattern of deceptive and unfair business practices by Gerber Products Company (doing business as Nestlé Nutrition, Nestlé Infant Nutrition, or Nestlé Nutrition North America) ("Defendant") in the marketing and sale of Good Start, a line of infant formula made with whey protein concentrate that Defendant produces, distributes, markets, and sells.

3. Plaintiffs bring this class action lawsuit challenging deceptive and misleading representations Defendant makes in promoting and selling Good Start. Specifically, beginning in 2011, Defendant has claimed: (a) Good Start is the first and only formula whose consumption reduces the risk of infants developing allergies, and (b) Good Start is the first and only formula that the United States Food and Drug Administration ("FDA") endorses to reduce the risk of developing allergies. These statements are false and deceptive.

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

5. The FDA rejected Defendant's proposed health claims, stating: "Based on FDA's consideration of the scientific evidence and other information submitted with the petition, and other pertinent scientific evidence and information, FDA concludes that there is ***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, and thus, FDA is denying the petition[.]"

6. In 2009, Defendant again petitioned the FDA to approve a claim characterizing the relationship between the consumption of partially hydrolyzed whey protein infant formula and reduced risk of a specific infant allergy, atopic dermatitis.

7. The FDA rejected the language Defendant proposed because the language misstated the relationship between partially hydrolyzed whey protein and infant allergies and, as a result, would mislead consumers. The FDA stated it would only consider exercising its enforcement discretion regarding the atopic dermatitis claim if Defendant modified the claim and included highly qualifying language that "very little scientific evidence" or "little scientific evidence" exists to support a link between partially hydrolyzed whey protein infant formula and atopic dermatitis; that such a link has been observed only when infants consumed partially hydrolyzed whey protein infant formula during the first four months of life; and that the FDA considers any such link to be "uncertain" in light of studies that have found no beneficial relationship.

8. Despite the FDA's rejection of Defendant's first petition, the FDA's extremely qualified response to Defendant's second petition (in which the FDA rejected Defendant's proposal but stated an intent to "consider" exercising enforcement discretion in very limited circumstances), and the compelling evidence contradicting Defendant's claims, in 2011, Defendant began deceptively advertising Good Start as the first and only infant formula that the FDA endorsed to reduce the occurrence of allergies in infants.

9. Due to Defendant's deceptive representations that Good Start provided health benefits beyond the benefits other baby formulas offered and Defendant's misleading representations that the FDA had certified Gerber's qualified health claims, Plaintiffs and the Class (as defined below) were injured by purchasing Good Start at an inflated cost.

10. In October 2014, the United States Federal Trade Commission ("FTC") brought suit against Defendant seeking to enjoin its deceptive practices in relation to the marketing and sale of Good Start, specifically citing Defendant's false or misleading claim "that feeding Good Start 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 Good Start formula qualified for or received approval for a health claim from the Food and Drug Administration."

11. On October 31, 2014, the FDA informed Defendant in a "Warning Letter" that Good Start was misbranded because the product's label and the company's website made health claims that the FDA had rejected and/or had not authorized.

12. Plaintiffs and the Class members bring this consumer protection action against Defendant based on the course of unlawful conduct set forth herein. Plaintiffs allege violations of the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201 *et seq.*, and the Wisconsin Deceptive Trade Practices Act, Wis. Stat. § 100.01 *et seq*.

PARTIES

13. Plaintiff Jennifer Hasemann is a resident of Maitland, Florida, and is a member of the Class. Ms. Hasemann frequently purchased Good Start infant formula based on Defendant's deceptive advertising and unfair business practices set forth herein.

14. Plaintiff Debbie Hoth is a resident of Birnamwood, Wisconsin, and is a member of the Class. Ms. Hoth frequently purchased Good Start infant formula based on Defendant's false advertising and deceitful business practices set forth herein.

15. Defendant Gerber Products Company, also doing business as Nestlé Nutrition, Nestlé Infant Nutrition, or Nestlé Nutrition North America, is a Michigan corporation with its headquarters located in Florham Park, New Jersey. Defendant regularly transacts business in this District, including by marketing, distributing, and selling Good Start in this District.

JURISDICTION

16. This Court has original jurisdiction over this case under the provisions of the Class Action Fairness Act codified at 28 U.S.C. § 1332(d)(2). There is diversity of citizenship because, among other reasons: (i) Plaintiff Hasemann is a citizen of Florida, and Plaintiff Hoth is a citizen of Wisconsin, and (ii) 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.

17. This Court has personal jurisdiction over Defendant for reasons including but not limited to the following: Defendant purposefully avails itself of the privilege of conducting business activities within the territorial boundaries of the United States District Court for the Eastern District of New York, thus invoking the benefits and protections of the laws of the State of New York, through Defendant's promotion, marketing, distribution, and sale of consumer goods, including Good Start, in the consumer markets within the Eastern District of New York. Defendant knows (or should reasonably anticipate) that its activities within the Eastern District of New York render it foreseeable that it may be haled into court here. Further, Defendant is engaged in systematic and continuous business activity in the Eastern District of New York, such that Defendant is essentially at home in Eastern District of New York. Litigating Plaintiffs' suit in the Eastern District of New York is not so gravely difficult and inconvenient for Defendant that Defendant is put at a severe disadvantage in comparison to Plaintiffs. Thus, Defendant has sufficient minimum contacts with the Eastern District of New York that maintenance of this action in this Court does not offend traditional notions of fair play and substantial justice.

18. Venue is proper pursuant to 28 U.S.C. § 1391(b)(1) because Defendant resides in this District for venue purposes in that Defendant would be subject to personal jurisdiction in the Eastern District of New York. 28 U.S.C. § 1391 (c)(2), (d).

FACTUAL ALLEGATIONS

A. Good Start Infant Formula Background Information.

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

20. Defendant maintains that Good Start contains partially hydrolyzed whey protein. The first ingredient on the Good Start label is "Whey Protein Concentrate (from cow's milk, enzymatically hydrolyzed, reduced in minerals)."

21. Whey protein is derived from cow's milk during the production of cheese.

22. Partially hydrolyzed whey protein undergoes additional processing to break the protein into smaller fragments.

B. Federal Law Requires FDA Approval Before Companies Can Make A Legal "Health Claim."

23. A "health claim" is "any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including 'third party' references, written statements (*e.g.*, a brand name including a term such as 'heart'), symbols (*e.g.*, a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition." 21 C.F.R. § 101.14(a)(1).

24. The FDA may promulgate a regulation allowing a health claim if the FDA "determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported

by such evidence." 21 U.S.C. § 343(r)(3)(B)(i).

25. In the absence of "significant scientific agreement" on a claim, the FDA may nevertheless allow a company to make a "qualified health claim" if it is supported by less scientific evidence. Because of the lack of scientific agreement, the claim must use qualifying language to accurately communicate the level of scientific evidence supporting the claim, to ensure it is not false or misleading to consumers.

26. All health claims, whether qualified or unqualified, require pre-market review by the FDA.

C. The FDA Determined That "There Is No Credible Scientific Evidence" To Support Defendant's Petition For A Qualified Health Claim Linking Partially Hydrolyzed Whey Protein To A Reduction Of Common Food Allergies.

27. 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 Letter from Michael M. Landa, Deputy Dir. for Regulatory Affairs, U.S. Food & Drug Admin., to Melanie Fairchild-Dzanis, Dir. Regulatory Issues/Special Nutritionals, Nutrition Div., Nestlé USA (May 11, 2006), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073313.htm.

28. On May 11, 2006, the FDA rejected Defendant's petition. The FDA considered "scientific evidence and other information submitted with the petition, and other pertinent scientific evidence and information" and rejected the petition because it concluded that "there is 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.* The FDA determined that "neither a disclaimer nor qualifying language would suffice to prevent consumer deception in this circumstance, where there is no credible evidence to support the claim." *Id.*

D. The FDA Rejected Defendant's Petition For A Health Claim Linking Partially Hydrolyzed Whey Protein To A Reduced Risk Of Atopic Dermatitis, Although The FDA Stated It Would "Consider" Exercising Its Enforcement Discretion In Very Limited Circumstances, Which The FDA Delineated.

29. 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 Letter from Barbara O. Schneeman, Ph.D., Dir., Office of Nutrition, Labeling, & Dietary Supplements, Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., to Melanie Fairchild-Dzanis, Regulatory Discretion, Inc. (on behalf of Nestlé Nutrition) (May 24, 2011), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm256731.htm.

30. In May 2011, the FDA rejected Defendant's claim as proposed because it "mischaracterize[d] the strength of the evidence and [was] misleading." *Id.*

31. After reviewing the scientific evidence relevant to the petition, the FDA determined that there was no evidence to support the broad claim Defendant wished to assert. The only testing that showed any beneficial connection between consumption of 100% whey protein partially hydrolyzed formula and a reduction in atopic dermatitis "included the feeding of

such formula to infants only during the first 4 months of life." *Id.* Without language specifying the time period in which the infants were fed the formula (*i.e.*, birth to four months), the FDA "would consider the qualified health claim to be misleading . . . because the record contains no evidence that feeding an infant the formula at a different time period would have any effect on reducing the risk of atopic dermatitis." *Id.* 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" and "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. In its letter responding to Defendant's May 2009 petition, the FDA stated that it "intends to consider the exercise of its enforcement discretion" for the following four qualified health claims, which it enumerated in the letter:

> 1. "Very little scientific evidence suggests that, for healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life and up to 3 years of age."
>
> 2. "Little scientific evidence suggests that, for healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life."
>
> 3. "For healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life and up to 3 years of age. FDA has concluded that the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of atopic dermatitis is uncertain, because there is very little scientific evidence for the relationship."

> 4. "For healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life. FDA has concluded that the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of atopic dermatitis is uncertain, because there is little scientific evidence for the relationship."

Letter from Barbara O. Schneeman, Ph.D., Dir., Office of Nutrition, Labeling, & Dietary Supplements, Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., to Melanie Fairchild-Dzanis, Regulatory Discretion, Inc. (on behalf of Nestlé Nutrition) (May 24, 2011).

33. In its 2014 Warning Letter to Nestlé Infant Nutrition (the "Warning Letter"), the FDA stated:

> In announcing our intention to consider the exercise of enforcement discretion, we explained that the use of any of the four specified claims would need to be accompanied by the following statement:
>
> > Partially hydrolyzed formulas **should not be fed to infants who are allergic to milk or to infants with existing milk allergy symptoms**. If you suspect your baby is already allergic to milk, or if your baby is on a special formula for the treatment of allergy, your baby's care and feeding choices should be under a doctor's supervision.

Letter from William A. Correll, Jr., Dir., Office of Compliance, Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., to Gary Tickle, President & CEO, Nestlé Infant Nutrition (Oct. 31, 2014), *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm423087.htm (emphasis in original) (last visited May 15, 2015).

E. Scientific Studies Conclude That Partially Hydrolyzed Whey Formula Does Not Lower The Risk Of Allergic Manifestations (Including Eczema) In Infancy.

34. 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.

35. For example, a 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, Ph.D., *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 & Clinical Immunology 2, Aug. 2011, at 360–65.e4 ("Lowe Study"), *available at* http://www.jacionline.org/article/S0091-6749%2810%2900740-2/pdf.

36. 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.* at 362–63.

37. 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.* at 365.

38. Nestec Ltd, a subsidiary of Nestlé Australia Ltd, provided the Lowe Study with study formula and staff funding for the first six years of the study. *Id.* at 360 (note).

39. Upon information and belief, Nestec Ltd and Nestlé Australia Ltd are affiliated with Defendant. *See* Nestlé S.A., Annual Report 2013 154, 165, 170 (2014), *available at* http://www.nestle.com/asset-library/documents/library/documents/annual_reports/2013-annual-report-en.pdf

F. Defendant Falsely Markets Good Start As The First And Only Formula To Reduce The Risk Of Developing Allergies And To Have The FDA's Endorsement For This Claim.

40. Despite the FDA's clear statements detailed above, Defendant falsely marketed and, upon information and belief, continues to market Good Start as a product endorsed by the FDA for reducing the risk of developing allergies.

41. Defendant does so to charge a higher price for its formula than it otherwise could charge absent the false claims, to attract customers, and to increase revenues.

42. Since at least 2011, Defendant has disseminated, or has caused dissemination of, advertisements, packaging, and promotional materials for Good Start (including in Florida and Wisconsin) containing false and misleading statements, as the following sample of Good Start promotional materials demonstrates.

43. In Exhibit A, a safety-seal sticker included on a formula canister, Defendant states that Good Start is the "1st & Only Routine Formula TO REDUCE THE RISK OF DEVELOPING ALLERGIES." This statement is deceptive and misleading. Exhibit A deceptively communicates to consumers that Good Start reduced the risk of infants developing allergies, despite the lack of evidence supporting that proposition, an FDA letter rejecting such a broad health claim, and compelling evidence contradicting the claim. Further, Exhibit A does not include the qualifying language that federal law and the FDA require.

44. In Exhibit B, Defendant includes 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 packaging further includes a statement that Good Start "is the first and only formula brand . . . that meets the criteria for a FDA Qualified Health Claim for atopic dermatitis." This advertisement deceptively communicates to consumers that the FDA approved Defendant's health claim regarding atopic dermatitis when the FDA, in fact, rejected the claim

Defendant proposed because it would be misleading to consumers, and the FDA stated that it intended to "consider" exercising its enforcement discretion with respect to four claims (and an accompanying paragraph) that Defendant did not propose.

45. Exhibit B also deceptively uses the FDA term of art "qualified health claim" to convey that Good Start is fit for a particular purpose or certified by the FDA when "qualified health claim" actually means the claim is lacking or limited.

46. Exhibit B fails to include the qualifying language that the FDA and federal law require. The absence of the qualifying language is especially troubling because, in the words of the FDA:

> The articulation of this relationship [between partially hydrolyzed whey protein and reduced risk of developing the allergic disease of atopic dermatitis] could mislead consumers into thinking that 100% whey-protein partially hydrolyzed infant formula is appropriate to feed to infants who are allergic to milk and to infants with existing food allergy symptoms. This would pose a significant public health risk because ***100 percent whey-protein partially hydrolyzed infant formulas may cause allergic reactions in one-third to one-half of milk allergic infants*** [citing studies from 1991, 2001, and 2008]; ***these reactions can be serious and even life-threatening***.

Letter from Barbara O. Schneeman, Ph.D., Dir., Office of Nutrition, Labeling, & Dietary Supplements, Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., to Melanie Fairchild-Dzanis, Regulatory Discretion, Inc. (on behalf of Nestlé Nutrition) (May 24, 2011) (emphasis added).

47. Defendant included Exhibit B on exterior product packaging. Defendant also featured the gold badge in Exhibit B (including the words "MEETS FDA," "1st AND ONLY," and "QUALIFIED HEALTH CLAIM") on supermarket displays advertising Good Start, without the qualifying language that the FDA and federal law require.

48. In Exhibit C, a television commercial (storyboard dated April 9, 2012), 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 Start® Gentle Formula with Comfort Proteins Advantage®* (Gerber Prods. Co. television commercial), *available at* https://www.youtube.com/watch?v=h6l-CjygjEg (last visited May 15, 2015). This advertisement deceptively communicates to consumers that Good Start reduces the risk of infants developing allergies, despite compelling evidence contradicting that proposition and an FDA letter rejecting Defendant's health claim. The advertisement also fails to include the qualifying language that the FDA and federal law require.

49. In Exhibit D, a print advertisement depicting a baby's face on a canister of Good Start, the caption reads:

> The Gerber Generation 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.

Exhibit D deceptively communicates to consumers that Good Start reduces the risk of infants developing allergies, despite compelling evidence contradicting that proposition and an FDA letter rejecting Defendant's health claim. The advertisement also fails to include the qualifying language that the FDA and federal law require.

50. In Exhibit E, a magazine advertisement, Defendant deceptively promoted Good Start as "the first and only infant formula that meets the criteria for a FDA Qualified Health Claim." This advertisement deceptively communicates to consumers that the FDA approved Defendant's health claims when, in reality, the FDA rejected both of Defendant's proposed claims and set forth qualified health claims with respect to which the FDA stated it intends to

"consider" using exercising its enforcement discretion. The advertisement in Exhibit E also deceptively uses the FDA term of art "qualified health claim" to convey that Good Start is fit for a particular purpose or certified by the FDA when "qualified health claim" actually means the claim is lacking or limited. Furthermore, the advertisement fails to include the qualifying language that federal law and the FDA require.

51. Exhibit F, an advertisement printed in People Magazine on August 5, 2013, depicts a mother feeding an infant and includes a badge stating that Good Start is the "1st FORMULA WITH FDA QUALIFIED HEALTH CLAIM." This advertisement deceptively communicates to consumers that the FDA approved Defendant's health claims when, in reality, the FDA rejected both of Defendant's proposed claims and set forth qualified health claims with respect to which the FDA stated it intends to "consider" using exercising its enforcement discretion. This advertisement also misleadingly employs the FDA term of art "qualified health claim" to convince consumers that Good Start was fit for a particular purpose or certified for quality by the FDA when "qualified health claim" actually means the claim is lacking or limited. The advertisement fails to include the qualifying language that federal law and the FDA require.

52. Based on this limited sampling, it is reasonable and plausible to infer that discovery will demonstrate a protracted course of purposeful, deceptive, and misleading advertising by Defendant to induce consumers to purchase Good Start during the Class period.

53. Reasonable consumers, including Plaintiffs and the Class members, would and did attach importance to Defendant's health and FDA-approval claims specified herein when determining whether to purchase Good Start. Plaintiffs and the Class members relied on the health and FDA-approval claims, and Defendant's misrepresentations were and are material.

G. The FTC's Lawsuit Against Defendant Seeking A Permanent Injunction And Other Equitable Relief For Violations Of The Federal Trade Commission Act.

54. On October 29, 2014, the FTC filed a lawsuit in the United States District Court for the District of New Jersey against Defendant "under Section 13(b) of the Federal Trade Commission Act ('FTC Act'), 15 U.S.C. § 53(b), to obtain preliminary and permanent injunctive relief . . . for Defendant's acts or practices, in violation of Sections 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." Complaint at 2, *F.T.C. v. Gerber Prods. Co.*, No. 2:14-cv-06771-SRC-CLW (D.N.J. Oct. 29, 2014), ECF No. 1.

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

H. The FDA's Warning Letter To Defendant Stating That Good Start Is Misbranded And Misleading In Violation Of Federal Law.

56. In addition to the FTC's lawsuit, on October 31, 2014, the FDA wrote a Warning Letter to Mr. Gary Tickle, Defendant's President and CEO, outlining various false and misleading representations made in the promotion of Good Start that violate federal law and related federal regulations. Letter from William A. Correll, Jr., Dir., Office of Compliance, Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., to Gary Tickle, President & CEO, Nestlé Infant Nutrition (Oct. 31, 2014).

57. In the Warning Letter, the FDA cited the following violations, without limitation:

a) Good Start was misbranded under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*., because Good Start's labeling and website "bear health claims that were not authorized by the FDA." *Id.* 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 the FDA previously considered and denied and was therefore unauthorized. *Id* at 2–3.

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

d) Good Start is misbranded because Defendant wrongly identified "100% whey partially hydrolyzed" as the substance linked to a reduced risk of atopic dermatitis on Good Start's label and website. Warning Letter at 3–4. 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. *Id.*

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

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

59. As a whole, the Warning Letter further demonstrates Defendant's willful and deceitful pattern of promoting Good Start in a way that misleads consumers and wrongfully induces them to purchase Good Start.

I. Plaintiffs Purchased Good Start Based On Defendant's Misleading Campaign.

60. Plaintiff Hasemann began regularly feeding her baby Good Start in May 2012.

61. Plaintiff Hasemann did so after researching Good Start and reviewing statements Defendant made on its website and on the product itself that highlighted Good Start's supposed endorsement by the FDA and its purported ability to protect infants from developing allergies.

62. Based on Defendant's deceptive and misleading information, Plaintiff Hasemann purchased falsely labeled 12 ounce Good Start containers from stores in Florida for prices ranging from $16 to $17.

63. Plaintiff Hoth began using Good Start in February 2014.

64. She did so after researching Good Start and reviewing statements Defendant made on its website and on the product itself highlighting Good Start's supposed endorsement by the FDA and its purported ability to protect infants from developing allergies.

65. Based on this deceptive and misleading information, Plaintiff Hoth purchased Good Start infant formula in various containers, including containers with the misleading label "1st & Only Routine Formula TO REDUCE THE RISK OF DEVELOPING ALLERGIES." (*See* Ex. A.)

66. Plaintiff Hoth purchased deceptively labeled 23 ounce Good Start infant formula containers from retail stores for prices ranging between $25 and $26.

67. The prices Defendant marketed to Plaintiffs, which Plaintiffs paid, for Good Start

were inflated as a result of Defendant's deceptive and misleading health claims. Plaintiffs would not have purchased Good Start at these inflated prices had they known: (1) that partially hydrolyzed whey protein does not reduce the risk of allergies (including atopic dermatitis) in children and/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.

68. For these reasons, Plaintiffs and the Class incurred damages from Defendant's misconduct.

CLASS ACTION ALLEGATIONS

69. Plaintiff Hasemann asserts her claims on behalf of:

> All persons who have purchased Good Start infant formula in the state of Florida from May 15, 2011, to the present (the "Florida Class"). The Florida Class excludes the judge or magistrate assigned to this case and the members of their respective staffs, Defendant, any entity in which Defendant has a controlling interest, and Defendant's officers, directors, legal representatives, successors, and assigns. Also excluded from the Florida Class are persons who purchased Good Start infant formula for the purpose of resale and persons who assert claims for personal injury.

70. Plaintiff Hoth asserts her claims on behalf of:

> All persons who have purchased Good Start infant formula in the state of Wisconsin from May 15, 2012, to the present (the "Wisconsin Class"). The Wisconsin Class excludes the judge or magistrate assigned to this case and the members of their respective staffs, Defendant, any entity in which Defendant has a controlling interest, and Defendant's officers, directors, legal representatives, successors, and assigns. Also excluded from the Wisconsin Class are persons who purchased Good Start infant formula for the purpose of resale and persons who assert claims for personal injury.

71. Plaintiffs refer to the Florida Class and the Wisconsin Class, together, as the "Class."

72. *Numerosity*: The Florida Class and the Wisconsin Class are each so numerous that joinder of all members is impracticable. The Florida Class and the Wisconsin Class each include thousands of consumers who purchased Defendant's Good Start products.

73. *Typicality*: Plaintiffs' claims are typical of the claims of the Class members because, like the other Class members, Plaintiffs were exposed to Defendant's deceptive advertising and business practices and purchased Good Start at inflated prices as a result of Defendant's misrepresentations.

74. *Adequacy*: Plaintiffs will fairly and adequately protect the interests of the Class and have retained counsel experienced in class action litigation. Plaintiffs have no interests that are adverse to the members of the Class they seek to represent.

75. *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, without limitation:

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

b) whether Defendant sold Good Start at inflated prices as a result of its misrepresentations;

c) whether Defendant violated the Florida Deceptive and Unfair Trade Practices Act;

d) whether Defendant violated the Wisconsin Deceptive Trade Practices Act; and

e) whether Plaintiffs and the Class are entitled to damages.

76. 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.

77. Discovery will inform the proper form and manner of notice to Class members. Plaintiffs anticipate, however, that notice by direct mail will be given to Class members who can be specifically identified, including, without limitation, by the use of store records where Good

Start was purchased and the use of reward clubs that record all purchases. 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 Good Start infant formula. Defendant should bear the cost of notice, regardless of whether notice occurs after class certification, trial, or settlement before trial.

78. Class certification 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 certification 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 that 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 certification 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. Plaintiffs reserve the right to modify or amend the definition of Class, including the Florida Class and the Wisconsin Class, at any time before certification.

FIRST CLAIM FOR RELIEF
Violation of the Florida Deceptive and Unfair Trade Practices Act
(Fla. Stat. § 501.201 *et seq.*)
On behalf of Plaintiff Hasemann and the Florida Class

82. Plaintiff Hasemann realleges and incorporates the preceding allegations.

83. Plaintiff Hasemann brings this claim for relief on behalf of the Florida Class pursuant to the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. §§ 501.201–501.213 (the "FDUTPA").

84. The express purpose of the FDUTPA is to "protect the consuming public . . . from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.202(2).

85. Section 501.204(1) of the Florida Statutes declares as unlawful "unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.204(1).

86. Defendant's sale of Good Start was a "consumer transaction" within the scope of the FDUTPA.

87. Plaintiff Hasemann and the Florida Class are "consumers" within the definition of section 501.203 of the Florida Statutes.

88. Defendant's Good Start infant formula is a "good" within the meaning of the FDUTPA, and Defendant is engaged in trade or commerce within the meaning of the FDUTPA.

89. Defendant's unfair and deceptive practices are likely to mislead—and have misled—reasonable consumers, such as Plaintiff Hasemann and the Florida Class, and, consequently, they violate section 500.04 of the Florida Statutes.

90. Defendant has violated FDUTPA by engaging in the unfair and deceptive practices described above, which offend public policies and are immoral, unethical,

unscrupulous, and substantially injurious to consumers.

91. Specifically, Defendant has represented: (1) that Good Start reduces the risk of an infant developing certain allergies when, in fact, there is no scientific evidence supporting this claim, and (2) that the FDA approved of this claim, when, in fact, it did not.

92. Plaintiff Hasemann and the Florida Class have been aggrieved by Defendant's unfair and deceptive practices in violation of FDUTPA in that they purchased and consumed Defendant's mislabeled products.

93. Reasonable consumers must and do rely on Defendant to honestly represent the true nature of the ingredients of its food products, including Good Start.

94. Defendant has deceived reasonable consumers, including Plaintiff Hasemann and the Florida Class, into believing that Good Start was something it was not (for example, that Good Start would reduce the risk of atopic dermatitis and that the FDA had approved of this health claim).

95. The knowledge required to discern the allergenic benefits of Good Start—whether it does or does not reduce an infant's risk of developing atopic dermatitis—is beyond that of the reasonable consumer. Reasonable consumers are also likely to believe an established baby food manufacturer, like Defendant, when it asserts the FDA has endorsed its product's health claims.

96. Plaintiff Hasemann and the Florida Class suffered damages and are entitled to injunctive relief. Thus, pursuant to sections 501.211(2) and 501.2105 of the Florida Statutes, Plaintiff Hasemann and the Florida Class make claims for damages, attorneys' fees, costs, and expenses.

97. Defendant's deceptive, misleading, and unfair practices directly and proximately caused the damages Plaintiff Hasemann and the Florida Class suffered.

98. Pursuant to Florida Statutes section 501.211(1), Plaintiff Hasemann and the

Florida Class seek for the Court to enjoin, among other things, Defendant's above-described wrongful acts and practices, and they seek restitution and disgorgement.

SECOND CLAIM FOR RELIEF
Misleading advertising in violation of Florida Statutes section 817.41
On behalf of Plaintiff Hasemann and the Florida Class

99. Plaintiff Hasemann realleges and incorporates the preceding allegations.

100. Under Florida Statutes section 817.14(1), it is illegal "for any person to make or disseminate or cause to be made or disseminated before the general public of the state, or any portion thereof, any misleading advertisement," if it is "designed and intended for obtaining money or property under false pretenses." Fla. Stat. § 817.14(1).

101. Defendant has made representations to the Florida general public in that Defendant made the false and misleading health claims regarding the allergenic benefits of Good Start, and the false and misleading statements regarding the approval of these claims by the FDA, on television commercials in Florida, in various print advertisements available in Florida, on Defendant's website, and on Good Start packaging, among other advertisement media.

102. Defendant made its false and misleading statements—which would, if true, increase the appeal of Good Start—with the intent of inducing customers to purchase Good Start, and Defendant intended that consumers rely upon the statements in purchasing Good Start.

103. On its website, on product labels, in print advertisements, and in other forms of advertisement, Defendant made numerous misrepresentations of material fact, including but not limited to:

a) statements on Good Start's safety-seal stickers indicating the formula "reduce[d] the risk of developing allergies," despite the existence of no scientific evidence in support of this claim and the fact that the FDA rejected the claim (*see supra* ¶ 43 (citing Ex. A));

b) statements in television and print advertisements indicating Good Start

would reduce the risk of an infant developing allergies, despite the lack of scientific evidence in support of this claim and the fact that the FDA rejected the claim (*see supra* ¶¶ 48, 49 (citing Exs. C, D)); and

c) statements on exterior product packaging, in magazine advertisements, and in supermarket displays indicating Good Start was the first formula to receive FDA approval for an allergy-reducing qualified health claim, despite the fact that the FDA never approved the claim (*see supra* ¶¶ 44–47, 50, 51 (citing Exs. B, E, F)).

104. Defendant knew or should have known these statements were deceptive and misleading.

105. Plaintiff Hasemann and the Florida Class did in fact rely upon these statements in purchasing Good Start. Reliance was reasonable and justified given Defendant's reputation as an established producer of infant foods.

106. As a result of Defendant's misrepresentations, Plaintiff Hasemann and the Florida Class have suffered damages in the amount of the excess price they paid for Good Start over and above what they would have paid had Defendant not led them to believe that the formula would reduce the risk of an infant developing allergies or that the FDA had approved of an allergy-reducing qualified health claim.

107. Plaintiff Hasemann and the Florida Class seek actual damages, punitive damages, and injunctive relief.

THIRD CLAIM FOR RELIEF
Violation of the Wisconsin Deceptive Trade Practices Act
(Wis. Stat. § 100.01 *et seq.*)
On behalf of Plaintiff Hoth and the Wisconsin Class

108. Plaintiff Hoth realleges and incorporates the preceding allegations.

109. Plaintiff Hoth brings this claim for relief on behalf of the Wisconsin Class

pursuant to the Wisconsin Deceptive Trade Practices Act, Wis. Stat. §§ 100.01–100.65 (the "WDTPA").

110. Under the WDTPA, "no . . . corporation[,] . . . with intent to induce the public in any manner to enter into any contract or obligation relating to the purchase . . . [of] merchandise[,] . . . shall make . . . an advertisement, announcement, statement or representation of any kind to the public . . . which . . . contains any assertion, representation or statement of fact which is untrue, deceptive or misleading." Wis. Stat. § 100.18(1).

111. Defendant has made misrepresentations to the public in that it made false and misleading health claims on television commercials, in various print advertisements, and on Good Start packaging, among other advertisement media.

112. Defendant made its false and misleading health claims—which would, if true, increase the appeal of Good Start—with the intent of inducing customers to purchase Good Start.

113. Defendant's health claims were "untrue, deceptive or misleading" in that, as noted above, there are no scientific grounds for concluding Good Start actually reduced an infant's risk of developing certain allergies, among other claims.

114. Plaintiff Hoth and the Wisconsin Class relied on Defendant's untrue, deceptive, and misleading health claims in deciding to purchase Good Start.

115. Plaintiff Hoth and the Wisconsin Class were damaged by Defendant's false or misleading health claims in that they paid a premium for Defendant's formula, which promised certain health benefits, but received a product that lacks these health benefits, *i.e.*, they were denied the benefit of their bargain. Plaintiff Hoth and the Wisconsin Class have thus suffered pecuniary losses in the amount of the premium.

116. Defendant's untrue, deceptive, and misleading practices directly and proximately caused the damages Plaintiff Hoth and the Wisconsin Class suffered.

117. At all relevant times, alternative formulas were available that did not make the same health claims as Good Start and that cost less than Good Start.

118. Pursuant to Wisconsin Statutes section 100.18(11)(b)(2), Plaintiff Hoth and the Wisconsin Class ask the Court to enjoin Defendant's above-described wrongful acts and practices, for restitution and disgorgement, and for attorneys' fees, costs, and expenses .

FOURTH CLAIM FOR RELIEF
False representations in violation of Wisconsin Statutes sections 895.446 and 943.20
On behalf of Plaintiff Hoth and the Wisconsin Class

119. Plaintiff Hoth realleges and incorporates the preceding allegations.

120. Wisconsin Statutes section 895.446 permits civil causes of action for violations of certain criminal statutes, including Wisconsin Statutes section 943.20, which prohibits "[o]btain[ing] title to property of another person by intentionally deceiving the person with a false representation which is known to be false, made with intent to defraud, and which does defraud the person to whom it is made." Wis. Stat. § 943.20.

121. Defendant has made false representations, including but not limited to:

a) statements on Good Start's safety-seal stickers indicating the formula "reduce[d] the risk of developing allergies," despite the existence of no scientific evidence in support of this claim and the fact that the FDA rejected the claim (*see supra* ¶ 43 (citing Ex. A));

b) statements in television and print advertisements indicating Good Start would reduce the risk of an infant developing allergies, despite the lack of scientific evidence in support of this claim and the fact that the FDA rejected the claim (*see supra* ¶¶ 48, 49 (citing Exs. C, D)); and

c) statements on exterior product packaging, in magazine advertisements, and in supermarket displays indicating Good Start was the first formula to receive FDA approval for an allergy-reducing qualified health claim, despite the fact that the FDA never approved the

claim (*see supra* ¶¶ 44–47, 50, 51 (citing Exs. B, E, F)).

122. Because Defendant is an established baby food manufacturer, it was reasonable for Plaintiff Hoth and the Wisconsin Class to rely on Defendant's representations.

123. Defendant knew its representations were deceptive and misleading.

124. Defendant made the representations at issue with the intent to deceive and defraud Plaintiff Hoth and the Wisconsin Class.

125. Plaintiff and the Wisconsin Class were in fact deceived and defrauded by Defendant's representations.

126. As a result of its false representations, Defendant obtained money via the sale of Good Start to Plaintiff Hoth and the Wisconsin Class.

127. Plaintiff Hoth and the Wisconsin Class are thus entitled to actual damages, attorneys' fees, costs and expenses, and puntive damages, as Wisconsin Statutes section 895.446(3)(a)(b)(c) authorizes.

PRAYER FOR RELIEF

Plaintiffs, individually and on behalf of the Class members, pray for an Order:

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

b) designating Plaintiffs as the Class representatives;

c) designating Plaintiffs' 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 Plaintiffs and the Class;

f) awarding actual, statutory, and punitive damages and interest to Plaintiffs and the Class;

g) awarding reasonable attorneys' fees, costs, and expenses to the full extent the law permits to Plaintiffs and the Class; and

h) for all other and further relief this Court may deem just and proper.

DEMAND FOR JURY TRIAL

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

Dated: May 21, 2015

Respectfully submitted,

/s/ Michael R. Reese
Michael R. Reese
George V. Granade
REESE LLP
875 Avenue of the Americas, 18th Floor
New York, New York 10001
Telephone: (212) 643-0500
Facsimile: (212) 253-4272
Email: *mreese@reesellp.com*
ggranade@reesellp.com

Kevin Landau
TAUS, CEBULASH & LANDAU, LLP
80 Maiden Lane, Suite 1204
New York, New York 10038
Telephone: (646) 873-7654
Facsimile: (212) 931-0703
Email: *klandau@tcllaw.com*

Shanon J. Carson
Sarah R. Schalman-Bergen
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, Pennsylvania 19103
Telephone: (215) 875-4656
Facsimile: (215) 875-4604
Email: *scarson@bm.net*
sschalman-bergen@bm.net

John A. Yanchunis
MORGAN & MORGAN COMPLEX LITIGATION GROUP
201 N. Franklin Street, 7th Floor
Tampa, Florida 33602
Telephone: (813)275-5275
Facsimile: (813) 222-4736
jyanchunis@forthepeople.com

Attorneys for Plaintiffs and the Proposed Class