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Attorneys for Plaintiffs and the Proposed Class

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

JEREMY GREENE and CETARIA WILKERSON, on behalf of themselves and all others similarly situated, Plaintiffs, v. GERBER PRODUCTS CO., a corporation, d/b/a NESTLE NUTRITION, NESTLE INFANT NUTRITION, and NESTLE NUTRITION NORTH AMERICA, Defendants.	No. 16-cv-1153 **CLASS-ACTION COMPLAINT** JURY TRIAL DEMANDED

1. Plaintiffs Jeremy Greene and Cetaria Wilkerson (together, "Plaintiffs"),

individually and on behalf of all persons who purchased Gerber Good Start Gentle infant formula ("Good Start"), allege the following based 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 ("Gerber" or "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 that Defendant made in promoting and selling Good Start. Specifically, beginning in 2011, Defendant has claimed in advertising and product labeling that: (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 certain allergies, such as atopic dermatitis. These statements are false and deceptive.

4. As demonstrated below, this is not the first time that Gerber's corporate parent—Nestle—has made false and misleading statements directly to U.S. consumers about the purported allergic benefits of Good Start. Nestle had, since the late 1980s, manufactured, promoted, marketed, and sold partially hydrolyzed whey-protein infant formulas under the Carnation (another U.S. company that Nestle acquired) Good Start brand name. Nestle had promoted this formula as being "hypoallergenic" but was forced to remove that claim from the product's labels after the FDA began questioning its scientific support. Nestle was also fined by nine states for falsely and misleadingly claiming in its advertisements that Good Start was

unlikely to trigger allergies.

5. As part of its recent scheme, Nestle petitioned the FDA to approve health claims that partially hydrolyzed whey protein reduced the risk of infants developing food allergies.

6. In 2006, the FDA rejected Nestle'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[.]" (*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., Nestle USA at 9 (May 11, 2006) ("2006 Letter"; attached as Exhibit A).)

7. In 2007, after FDA rejected Nestle's petition, Nestle acquired infant-food manufacturer Gerber. While at the time of the acquisition Gerber did not manufacture or sell infant formula, Good Start was eventually rebranded under the Gerber banner.

8. 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 a reduced risk of developing a specific infant allergy, atopic dermatitis.

9. The FDA rejected the language Defendant proposed because it misstated the relationship between partially hydrolyzed whey protein and infant allergies and, as a result, would mislead consumers. The FDA stated that 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.

10. Despite the FDA's rejection of Nestle's first petition (and compelling evidence contradicting Defendant's broad allergy claims), and the FDA's extremely qualified response to Defendant's second petition, Defendant began deceptively advertising Good Start as (among other things) the first and only infant formula to reduce the risk of allergies, generally, and (2) the first and only formula that the FDA endorsed to reduce the risk of atopic dermatitis, without indicating any of the qualifications mentioned by the FDA (i.e., that "little" or "very little" scientific evidence suggested a link between Good Start and atopic dermatitis). Defendant conveyed this misleading message directly to consumers through a pervasive advertising campaign that included, *inter alia*, print and television advertising and statements on Good Start labels. Defendant vastly overstated the actual properties of Good Start and disregarded the limitations imposed on it by the FDA.

11. 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."

12. 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 or had not authorized.

13. 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 unqualifiedly certified its health claims, Plaintiffs and the Class (as defined below) were injured by purchasing Good Start at an inflated cost.

14. 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 Ohio Consumer Sales Practices Act (Ohio Rev. Code Ann. §§ 1345.01 *et seq.*); the Ohio Deceptive Trade Practices Act (Ohio Rev. Code Ann. §§ 4165.01 *et seq.*); and the North Carolina Deceptive Trade Practices Act (N.C. Gen. Stat. Ann. §§ 75-1.1 *et seq.*). Plaintiffs also bring common-law claims for fraudulent concealment, intentional misrepresentation, negligent misrepresentation, and unjust enrichment.

PARTIES

15. Plaintiff Jeremy Greene is a resident of Saint Paris, Ohio, and a member of the Class. Mr. Greene began purchasing Good Start in September 2013 after seeing and relying on a number of Defendant's misleading advertisements, as described below.

16. Plaintiff Cetaria Wilkerson is a resident of Greensboro, North Carolina, and is a member of the Class. Ms. Wilkerson began purchasing Good Start in January 2014, after seeing and relying on a number of Defendant's misleading advertisements, as described below.

17. Defendant Gerber Products Company, also doing business as Nestle Nutrition, Nestle Infant Nutrition, or Nestle Nutrition North America, is a Michigan corporation with its headquarters located in Florham Park, New Jersey. Gerber is a subsidiary of Nestle USA, which

is a subsidiary of Nestle, S.A. Defendant regularly transacts business in this District, including by marketing, distributing, and selling Good Start in this District.

JURISDICTION

18. 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 Plaintiff Greene is a citizen of Ohio, Plaintiff Wilkerson is a citizen of North Carolina, 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.

19. 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 New York State, 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 New York. Defendant is also engaged in systematic and continuous business activity in New York. Thus, Defendant has sufficient minimum contacts with New York that maintenance of this action in this state does not offend traditional notions of fair play and substantial justice.

VENUE

20. Venue is proper pursuant to 28 U.S.C. § 1391(b)(1). 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. Defendant's history of falsely promoting the Allergenic Benefits of Good Start:

21. Nestle, Gerber's parent, has a long and checkered history of manufacturing, selling, promoting and marketing Good Start and other infant formulas in the United States and around the world. There have been numerous boycotts related to Nestle's direct-to-consumer sales and marketing practices in countries outside of the United States. These practices and the attendant boycotts led, in part, to the World Health Organization's adopting the International Code of Marketing Breast-Milk Substitutes (the "WHO Code"), which banned direct to consumer advertising in those countries that adopted the Code. While the United States has not adopted the WHO Code, there was—into the late 1980s—a voluntary ban on such advertising.

22. Though Nestle was a major supplier of infant formula worldwide, Nestle did not sell infant formula in the United States until the late 1980s. Nestle had acquired Carnation in 1984, and in 1988 announced that it would enter the United States infant formula market by promoting its Good Start formula (which it was already manufacturing and selling in Europe) directly to consumers in the United States under the banner of the Carnation brand. Nestle expected its formula to capture 25–30% of the infant-formula market in the United States within a few years of its introduction. Denise Gellene, *Carnation to Move Into U.S. Baby Formula Market*, L.A. Times, June 4, 1988, *available at* http://articles.latimes.com/1988-06-04/business/fi-3994_1_infant-formula-market.

23. The announcement of Nestle's plans to market the formula directly to consumers created an uproar in the pediatric community, including the American Academy of Pediatrics. As

the Los Angeles Times reported on July 2, 1988, in an article entitled "Marketing to Moms: Pediatricians Say Carnation Crosses a Fine Ethical Line in Direct Sales of Baby Formula":

> Carnation, which is owned by the Swiss company, Nestle, has unveiled plans to introduce a formula—called Good Start—for infants who are allergic to traditional milk and soybean-based formulas. Good Start and Good Nature, a formula for infants who have begun to eat solid foods, will be advertised in magazines that are read by new mothers—a break with the voluntary ban on such ads.

Jesus Sanchez, *Marketing to Moms: Pediatricians Say Carnation Crosses a Fine Ethical Line in Direct Sales of Baby Formula*, L.A. Times, July 2, 1988, *available at* http://articles.latimes.com/1988-07-02/business/fi-5340_1_baby-formula.

24. Nestle eventually resolved its dispute with the American Academy of Pediatrics "by agreeing not to link Carnation's name to a public information campaign on allergic reactions to infant formula." George White, *Carnation Says It Has Settled Dispute on Ads: Pediatrics Group Hit Campaign on Formulas*, L.A. Times, July 15, 1988, *available at* http://articles.latimes.com/1988-07-15/business/fi-7239_1_ad-campaign.

25. Nestle violated the spirit of this agreement, however, by promoting Good Start's purported hypoallergenic properties on its label. On March 11, 1989, the Los Angeles Times reported that, following a request from the FDA for more information on its purported allergy claims, "Carnation Co., under fire for using an infant formula label that has been called misleading, on Friday said it will remove the term 'hypo-allergenic' from its Good Start H.A. product. Carnation said the label change, which will be effective in April, is being made to eliminate potential consumer confusion . . . ." George White, *Carnation to Alter Label on Baby Formula*, L.A. Times, March 11, 1989, *available at* http://articles.latimes.com/1989-03-11/business/fi-773_1_infant-formula-label.

26. After agreeing to remove the term "hypoallergenic" from the Good Start label,

Carnation also agreed to pay fines to nine states over claims that "it used misleading advertising to promote its new infant formula as unlikely to trigger allergies." Jesus Sanchez, *Carnation to pay $90,000 fine in wake of claims its ads misled Los Angeles Times*, L.A. Times, July 7, 1989, *available at* http://articles.latimes.com/1989-07-07/business/fi-3433_1_health-claims.

27. By 1990, Nestle failed to gain the 25–30% share that it had projected. As Carnation's promotional efforts for Good Start floundered, on December 31, 1990, the Los Angeles Times reported that Carnation decided to reverse course on direct-to-consumer advertising and, "over the objections of pediatricians and advocates of breast feeding, will begin advertising its Good Start formula directly to mothers, beginning in January." Jesus Sanchez, *Nestle's New Accent*, L.A. Times, Dec. 31, 1990, *available at* http://articles.latimes.com/1990-12-31/business/fi-5671_1_food-industry.

28. But even after reviving its plan to advertise directly to consumers, Nestle was unable to capture its desired U.S. market share, which remained below 5%. Nestle eventually blamed this on a conspiracy between doctors and dominant formula makers to prevent direct-to-consumer advertising, and brought an antitrust action against these parties in 1993.

29. On June 21, 1995, jurors rejected Nestle's antitrust case. Thereafter, the Ninth Circuit rejected Nestle's appeal, affirming the district court's determination. *See Nestle Food Co. v. Abbott Labs, et al*, 105 F.3d 665 (9th Cir. 1997).

30. After losing in court, Nestle continued promoting Good Start directly to consumers. Nestle also looked to again promote the purported allergenic health benefits of its Good Start formula. As part of that strategy, and as described more fully below, in June 2005 Nestle petitioned the FDA for approval of a qualified health claim that Good Start can reduce the risk of common food-allergy symptoms. The FDA rejected that claim in May 2006, finding that

there was "no credible evidence" to support it.

31. Following the FDA's denial of its Good Start allergy claims, in 2007 Nestle acquired Gerber Products Company, which at the time was a leading manufacturer and seller of infant food but did not manufacture or sell infant formula. In a slide presentation from Nestle S.A. announcing the acquisition, dated April 12, 2007, Nestle touted that one important feature of the acquisition would be to allow Nestle to "Leverag[e] the trust and well-being reputation of the Gerber brand." At some point following Gerber's acquisition, Nestle rebranded "Good Start" as "Gerber Good Start."

32. Thereafter, and at least since 2011, Defendant has manufactured, distributed, promoted, offered for sale, and sold Good Start. Defendant has advertised and continues to advertise Good Start through television commercials, print advertisements, point-of-sale displays, product packaging, internet advertisements, and other promotional materials.

B. Federal law requires FDA approval before companies can make a legal "health claim."

33. Under federal regulations, 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).

34. 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).

35. 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 convincing 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 that it is not false or misleading to consumers.

36. 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 a qualified health claim linking partially hydrolyzed whey protein to a reduction of common food allergies.

37. 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)."

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

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

40. In June 2005, Nestle 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.

(Ex. A at 1–2.)

41. On May 11, 2006, the FDA rejected Nestle'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 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.* at 2, 9.) 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.* at 8.)

D. The FDA rejected Defendant's petition for a health claim linking partially hydrolyzed whey protein to a reduced risk of atopic dermatitis.

42. In May 2009, following the acquisition of Gerber, 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 Nestle Nutrition) at 1–2 (May 24, 2011) ("2011 Letter"; attached as Exhibit B).)

43. In May 2011, the FDA rejected Defendant's claim as proposed because it "mischaracterize[d] the strength of the evidence and [was] misleading." (*Id.* at 12–13.)

44. 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.* at 11.) 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.* at 10, 11.)

45. 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."

(*Id.* at 13.)

E. Scientific studies conclude that partially hydrolyzed whey formula does not lower the risk of allergic manifestations in infancy.

46. 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.

47. For example, a major long-term study published in June 2011—*after* the FDA sent Defendant its 2011 letter—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 ("Lowe Study"), *available at* http://www.jacionline.org/article/S0091-6749%2810%2900740-2/pdf.

48. 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.

49. 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.

50. The Lowe study, among others, thus *conclusively refuted* the idea that partially hydrolyzed whey protein reduced the risk of allergies; it did not simply determine that the relationship was uncertain or open for debate.

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

52. 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. 26, 2015).

F. Defendant begins falsely marketing Good Start.

53. Despite the FDA's clear statements detailed above, Defendant engaged in false and misleading marketing of Good Start as a product capable of reducing the risk of allergies, generally, and unqualifiedly reducing the risk of atopic dermatitis, specifically.

54. These claims allowed Defendant to charge a higher price for its formula than it otherwise could have; to attract more customers than it otherwise could have; and to earn more revenues than it otherwise could have.

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

56. In Exhibit C, 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 C 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.

57. In Exhibit D, 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 implies that the FDA fully endorsed Defendant's atopic-dermatitis claims, despite the fact that the FDA's endorsement was strictly reserved to claims indicating that there was "little" or "very little" evidence supporting the link between Good Start and atopic dermatitis. And, by not including any language indicating these reservations, or that its atopic-dermatitis claims were at best "uncertain," Defendant falsely or misleadingly implied that Good Start would *unqualifiedly* reduce the risk of atopic dermatitis, despite the fact that there was (again) "little" or "very little" evidence supporting this claim.[1]

58. Exhibit D 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

[1] The FDA's 2011 Letter, for example, notes that while Gerber attempted to support its atopic-dermatitis claims by citing a *number* of studies, only a handful were actually relevant: two studies found a beneficial link between Good Start and atopic dermatitis up the age of three, while two did not. As to benefits within the first year of life, only one study found a link; two did not. (Ex. B at 9–11.)

health claim" actually means the claim is supported by only lacking, limited, or contradictory scientific evidence.

59. Defendant included Exhibit D 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 suggesting any of the qualifications mentioned by the FDA.

60. In Exhibit E, 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 Dec. 8, 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.

61. In Exhibit F, a direct to consumer 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 F 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.

62. In Exhibit G, a direct-to-consumer 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 implies that the FDA fully endorsed Defendant's atopic-dermatitis claims, despite the fact that the FDA's endorsement was strictly reserved to claims indicating that there was "little" or "very little" evidence supporting the link between Good Start and atopic dermatitis. And, by not including any language indicating these reservations, or that its atopic-dermatitis claims were at best "uncertain," Defendant falsely or misleadingly implied that Good Start would *unqualifiedly* reduce the risk of atopic dermatitis, despite the fact that there was (again) "little" or "very little" evidence supporting this claim. The advertisement in Exhibit G 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.

63. Exhibit H, 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 implies that the FDA fully endorsed Defendant's atopic-dermatitis claims, despite the fact that the FDA's endorsement was strictly reserved to claims indicating that there was "little" or "very little" evidence supporting the link between Good Start and atopic dermatitis. And, by not including any language indicating these reservations, or that its atopic-dermatitis claims were at best "uncertain," Defendant falsely or misleadingly implied that Good Start would *unqualifiedly* reduce the risk of atopic dermatitis, despite the fact that there was (again) "little" or "very little" evidence supporting this claim. 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 supported by lacking or limited scientific evidence.

64. Further, none of the advertisements described above mention that Good Start's limited atopic-dermatitis benefits were only realizable (potentially) if Good Start was fed to infants under four-months old, as indicated in the FDA's 2011 Letter (*see supra* ¶ 44).

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

G. The FTC files a lawsuit against Defendant for violations of the Federal Trade Commission Act.

66. 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.

67. In its Complaint, the FTC specifically challenged Defendant's false, misleading, or 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 or misleading 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 warns Defendant that Good Start is misbranded and misleading in violation of federal law.

68. In addition to the FTC's lawsuit, on October 31, 2014, the FDA wrote a Warning Letter to Mr. Gary Tickle, a Nestle employee since the 1980s and a long-time Nestle senior executive and, President and CEO of Defendant Nestle Infant Nutrition, 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) ("Warning Letter"; attached as Exhibit I).)

69. In the Warning Letter, the FDA alleged the following statutory 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 1, 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 1–2.)

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 3.) Defendant also omitted to include key information in mandatory bold type and excluded other mandatory language entirely. (*Id.* at 3, 4–5.)

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. (*Id.* 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 5–6.) The FDA expressed concerns that such separation could mislead consumers. (*Id.*)

70. 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.)

71. 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.

72. Plaintiff Greene, an Ohio resident, is a member of the Class. Mr. Greene purchased roughly twenty-five canisters of powdered Good Start from September 2013 through March 2014, typically from a Walmart located near his home, at roughly $18 a canister. Mr. Greene's decision to purchase Good Start was based on Defendant's deceptive advertising and unfair business practices as set forth herein. For example, Mr. Greene saw and relied on Defendant's magazine advertisement (Ex. G) and television advertisement (Ex. E) in deciding to

purchase Good Start. Mr. Greene was also exposed to the claims on Good Start's label (Exs. C, D).

73. Plaintiff Wilkerson, a North Carolina resident, is a member of the Class. Ms. Wilkerson purchased roughly three canisters of powdered Good Start a week, beginning in January 2014, typically from Walmart, at $16–17 dollars per canister. Ms. Wilkerson also purchased Good Start from an Exxon near her home at $21–22 per canister. Ms. Wilkerson's decision to purchase Good Start was based on Defendant's false advertising and deceitful business practices as set forth herein. For example, in November 2013, Ms. Wilkerson viewed the magazine advertisement included herein as Exhibit H; viewed an advertisement similar to the magazine advertisement attached herein as Exhibit G (only the images varied); viewed the advertisement attached herein as Exhibit F; and—at various points between October and December 2014—viewed advertisements on Defendant's website touting the allergenic benefits of Good Start (the advertisements have since been removed). Mr. Wilkerson was also exposed to the claims on Good Start's label (Exs. C, D).

74. Reasonable consumers, including Plaintiffs, would and did attach importance to the health and FDA-approval claims specified herein when determining whether to purchase Good Start. For example, parents, like Plaintiffs, are obviously concerned with the health of their children, and their decision to purchase (or pay a premium for) a formula would be influenced by claims that: (1) partially hydrolyzed whey protein reduces the risk of allergies (including atopic dermatitis) in children, and (2) the FDA endorsed the health claims Defendant made on its labels, in its advertisements, and on its website.

75. Moreover, Nestle's corporate financial filings indicate that while Defendant was making false and misleading statements about Good Start, those statements had a beneficial

impact on sales of Good Start in the United States. As Nestle disclosed in its 2013 Annual Report, released in or around February 2014, "The US benefitted from the continued roll-out of innovations to help prevent colic and allergies, strengthening the *Gerber* brand franchise." Nestle 2013 Annual Report at 64. However, in its 2014 Annual Report, which was released after Defendant received the FDA warning letter and the FTC complaint, Nestle neither touted increased benefits from allergy "innovations" nor of "strengthening the *Gerber* brand franchise," but instead reported that in North America "the environment was more challenging." Nestle 2014 Annual Report at 52, *available at* https://www.nestle.com/asset-library/documents/library/documents/annual_reports/2014-annual-report-en.pdf (last visited February 26, 2016).

76. Further, Plaintiffs and the Class members reasonably relied on Defendant's health and FDA-approval claims, which were made by a nationally recognized baby-food manufacturer.

77. The prices Defendant charged for Good Start—which Plaintiffs and the Class paid—were inflated as a result of Defendant's misleading health claims. In 2012, for example, Walmart sold Parent's Choice, which did not make any allergenic health claims, at roughly $0.54 per ounce, and Good Start Gentle at $0.91 per ounce; i.e., Parent's Choice sold at a 41% discount to Good Start Gentle during the class period. *See* https://web.archive.org/web/20120812020834/http://www.walmart.com/browse/baby/formula/5427_133283_1001447/? (last visited Dec. 8, 2015). Moreover, Plaintiffs did not receive the benefit of their bargain insofar as they paid for a benefit (i.e., the reduced risk of allergies) that Good Start did not actually provide. At all times during the Class Period, alternative, less expensive infant formulas were available for purchase.

78. Because Plaintiffs and the Class paid a premium for Good Start that they would not have paid had they known that Good Start did *not* reduce the risk of allergies, or that

Defendant's atopic-dermatitis claims were at best "uncertain," Plaintiffs and the Class incurred damages resulting from Defendant's misconduct.

CLASS-ACTION ALLEGATIONS

79. Plaintiff Greene asserts his claims on behalf of:

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

80. Plaintiff Wilkerson asserts her claims on behalf of:

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

81. Plaintiffs collectively bring claims on behalf of:

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

82. Plaintiffs refer to the Ohio, North Carolina, and Nationwide Classes together as the "Class."

83. *Numerosity*: The Ohio, North Carolina, and Nationwide Classes are each so numerous that joinder of all members is impracticable. The Classes each include thousands of

consumers who purchased Defendant's Good Start products.

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

85. *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.

86. *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 capable of reducing the occurrence of allergies in infants;

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

c) whether Defendant violated the Ohio Consumer Sales Practices Act;

d) whether Defendant violated the North Carolina Unfair and Deceptive Trade Practices Act; and

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

87. 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.

88. 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.

89. 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.

90. 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.

91. 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.

92. Plaintiffs reserve the right to modify or amend the Class definition at any time before certification.

CLAIMS FOR RELIEF

COUNT I
Violations of the Ohio Consumer Sales Practices Act, Ohio Rev. Code Ann. §§ 1345.01 *et seq.*
(on behalf of Plaintiff Greene and the Ohio Class)

93. Plaintiff Greene realleges and incorporates the preceding paragraphs.

94. Defendant—one of the largest baby-food manufacturers in the world—is a "seller" under the Ohio Consumer Sales Practice Act ("OCSPA") in that (for example) it sold Good Start to the general public (even if indirectly) and otherwise effected and solicited sales of Good Start through the advertising campaigns described above. Ohio Rev. Code Ann. § 1345.01(C).

95. Plaintiff Greene is a "consumer" under the OCSPA in that, in purchasing Good Start, he engage in a consumer transaction with Defendant. Ohio Rev. Code Ann. § 1345.01(D).

96. Plaintiff Greene's purchase of Good Start, for consumption by his infant son, constituted a "consumer transaction" under the OCSPA in that it was the sale of a good intended primarily for personal, family, or household purposes. Ohio Rev. Code Ann. § 1345.01(C).

97. Defendant's false and misleading advertising, as described above, constituted an unfair or deceptive act or practice under the OCSPA. For example, by claiming that Good Start reduced the risk of an infant's developing certain allergies, despite the fact that scientific studies have disproven this claim (making it false), Defendants claimed that Good Start possessed performance characteristics and benefits that it did not in fact possess. Ohio Rev. Code Ann. § 1345.02(B)(1). And by suggesting that the FDA *unqualifiedly* approved of the atopic-dermatitis claim, without disclosing that qualified approval indicates that a health claim lacks any meaningful scientific support, Defendants falsely or misleadingly claimed that Good Start met a particular standard or possessed a quality or grade that it did not in fact possess. Ohio Rev. Code Ann. § 1345.02(B)(2).

98. Defendant was aware that its advertisements were false or misleading. For example, Defendant knew of the Lowe study (*see* ¶¶ 51–52, above), which disproved the notion that Good Start could prevent infants from developing certain allergies, before it claimed that

Good Start could, in fact, reduce the risk of infant allergies.

99. Given Defendant's knowledge of the falsity or misleading nature of its claims, these advertisements constituted an unconscionable act or practice under the OCSPA. Ohio Rev. Code Ann. § 1345.03. For example, because Defendant knew that its advertising was false or misleading, and—thus—that the price of Good Start had been inflated by false or misleading claims, Defendant "knew at the time the consumer transaction was entered into that the price was substantially in excess of the price at which similar property or services were readily obtainable." Ohio Rev. Code Ann. § 1345.03(B)(2). Defendant also "knew at the time the consumer transaction was entered into of the inability of the consumer to receive a substantial benefit" from Good Start (for example, that Good Start would reduce the risk of infant allergies).

100. Defendant was on notice that its advertising would violate the OCSPA. For example, Ohio's attorney general has issued regulations pursuant to the OCSPA specifically prohibiting sellers from making scientific claims that are not grounded in a "reasonable basis of fact." Ohio Rev. Code Ann. § 1345.09(B); Ohio Adm. Code 109:4-3-10(A). Because Defendant was aware of the Lowe study—which found that there was no link between Good Start and a reduced risk of developing certain allergies—before it made its allergy claims, Defendant lacked a reasonable basis in fact upon which to make its health claims. The Ohio attorney general has also published cases on its website putting Defendant on notice that falsely advertising Good Start's allergenic benefits would constitute a violation of the statute. Ohio Rev. Code Ann. § 1345.09(B). For example, the attorney general published *State ex rel Rogers v. Airborne Health, Inc.* (PIF No. 10002744), in January 2009, in which a defendant agreed to stop implying that its product could "mitigate, prevent, treat, or cure . . . allergies"; to make sure that its health claim was substantiated by sufficient scientific evidence; and to cease making allergy claims that were

"false, or could deceive or mislead consumers, or omitting any material information so that the express or implied statement deceives or tends to deceive consumers."[2] And, in *In re Gateway Distributors, Ltd.* (PIF No. 10002461), which was published in June 2006, a supplier agreed not to make any health claims without "competent and reliable scientific evidence that substantiates" the claims; not to make any health claims that lacked FDA support; not to "make any representations about a health-related product unless they clearly and conspicuously state all facts, including any qualifying information reasonably necessary to make the representation accurate and not misleading"; and not to "make statements or representations concerning an [sic] health-related product that are ambiguous."[3] In fact, a number of cases published by Ohio's attorney general were sufficient to put Defendant on notice that, by making false or exaggerated claims about Good Start's allergenic benefits, it would violate the OCSPA. *See State ex rel Cordray v. The Dannon Company, Inc.* (PIF No. 10002917) (enjoining a defendant from "making any express or implied claims that any of its products may be used in the . . . mitigation, treatment, or prevention of any disease" without "possess[ing] and rel[ying] upon competent and reliable scientific evidence that substantiates" the claim);[4] *In re: Michelin North America, Inc.* (PIF No. 10002782) (requiring a manufacturer to possess sufficient scientific evidence in support of a claim, and to ensure that that claim does not mislead consumers);[5] *State ex rel DeWine v. GlaxoSmithKline, LLC* (PIF No. 10002956) (prohibiting false claims about a product's approval

[2] *See* Online Public Inspection File, http://opif.ohioattorneygeneral.gov/CaseDetail/CaseDetail/3390 (last visited Dec. 10, 2015).

[3] *See* Online Public Inspection File, http://opif.ohioattorneygeneral.gov/CaseDetail/CaseDetail/3085 (last visited Dec. 10, 2015).

[4] *See* Online Public Inspection File, http://opif.ohioattorneygeneral.gov/CaseDetail/CaseDetail/3597 (last visited Dec. 10, 2015).

[5] *See* Online Public Inspection File, http://opif.ohioattorneygeneral.gov/CaseDetail/CaseDetail/3434 (last visited Dec. 10, 2015).

or certification);[6] *State ex rel DeWine v. Pfizer Inc.* (PIF No. 10003056) (prohibiting "mak[ing] any written . . . promotional claim of safety or efficacy . . . in a manner that violated the FFDCA, accompanying regulations, or voluntary agreements with the FDA, as interpreted by the FDA").[7]

101. Plaintiff Greene, or any reasonable customer, reasonably relied upon Defendant's allergy and qualified-approval claims in that Defendant is a well-established, national baby-food manufacturer.

102. Defendant's false advertisements were the proximate cause of Plaintiff Greene's injuries. Plaintiff Greene reviewed a number of Good Start advertisements prior to purchasing Good Start (including Exs. E and G), and relied on those representations in deciding to purchase Good Start. As a parent, the claimed ability of a formula to reduce an infant's risk of developing certain allergies would play a material role in deciding whether or not to purchase that formula. In addition, the price that Plaintiff paid for Good Start was inflated by premiums associated with Defendant's health claims; i.e., Defendant was able to charge more for Good Start than it could have had its health claims not been made. Insofar as Plaintiff paid for a formula that lacked the benefits ascribed to it, and was thus worth less than what Plaintiff paid for it, Plaintiff was denied the benefit of his bargain.

103. Plaintiff also seeks court costs and attorneys' fees as a result of Defendant's violations of the OCSPA. Ohio Rev. Code Ann. § 1345.09.

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[6] *See* Online Public Inspection File, http://opif.ohioattorneygeneral.gov/CaseDetail/CaseDetail/3641 (last visited Dec. 10, 2015).

[7] *See* Online Public Inspection File, http://opif.ohioattorneygeneral.gov/CaseDetail/CaseDetail/3746 (last visited Dec. 10, 2015).

COUNT II
Violation of the Ohio Deceptive Trade Practices Act, Ohio Rev. Code Ann. §§ 4165.01 *et seq.*
(on behalf of Plaintiff Greene and the Ohio Class)

104. Plaintiff Greene realleges and incorporates the preceding paragraphs.

105. As noted in detail above, Defendant's allergy and qualified-approval claims were deceptive.

106. Also as noted above, Defendant was aware that its advertisements were false and misleading.

107. Defendant's false or misleading advertising, described above, constitutes a deceptive trade practice under Ohio's Deceptive Trade Practices Act ("ODTPA"). Ohio Rev. Code Ann. § 4165.02. For example, by claiming that Good Start would reduce the risk of certain infant allergies, Defendant "[r]epresent[ed] that goods . . . have . . . characteristics, ingredients, uses, benefits, or quantities that they do not have[.]" *Id.* And by suggesting that these health claims had received an unqualified endorsement from the FDA, Defendant "[r]epresent[ed] that goods . . . have sponsorship, approval, [or] characteristics . . . that they do not have[.]" *Id.*

108. Defendant's claims actually deceived Plaintiff Greene and had the tendency to deceive any of the consumers targeted by Defendant's advertisements. Defendant is a well-established, national baby-food manufacturer, and a reasonable consumer would assume that its health claims were accurate.

109. Defendant's health claims were materially misleading in that Good Start's ability to reduce the risk of infant allergies, including atopic dermatitis, would influence a parent's decision to purchase Good Start.

110. Defendant's false advertisements were the proximate cause of Plaintiff Greene's injuries. Plaintiff Greene reviewed a number of Good Start advertisements prior to purchasing

Good Start and relied on those representations in deciding to purchase Good Start. In addition, the price that Plaintiff paid for Good Start was inflated by premiums associated with Defendant's health claims; i.e., Defendant was able to charge more for Good Start than it could have had (for example) the allergy-reduction and qualified-approval claims not been made. And insofar as Plaintiff paid for a formula that lacked the benefits ascribed to it, and was thus worth less than what Plaintiff paid for it, Plaintiff was denied the benefit of his bargain.

111. Plaintiff Greene seeks all appropriate relief under the ODTPA, including injunctive relief (Ohio Rev. Code Ann. § 4165.03(A)(1)) and attorney's fees (Ohio Rev. Code Ann. § 4165.03(B)).

COUNT III

Violations of the North Carolina Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. Ann. § 75-1.1
(on behalf of the North Carolina Class)

112. Plaintiff Wilkerson realleges and incorporates the preceding paragraphs.

113. Defendant's health claims constituted deceptive acts or practices and unfair methods of competition under the North Carolina Deceptive Trade Practices Act ("NCDTPA"). N.C. Gen. Stat. Ann. § 75-1.1. For example, these claims were false or misleading, and it is unethical and unscrupulous to boost a product's sales by making false health claims.

114. Also as noted above, Defendant's health claims had the tendency and capacity to mislead. A reasonable consumer, for example, would tend to believe Defendant—one of the largest and most well-established baby-product manufacturers in the country—when it claims that Good Start can reduce the risk of infant allergies; particularly when Defendant also suggests that these claims had been approved by the FDA.

115. Defendant's false and misleading advertising affected commerce in that

Defendant advertised and sold Good Start throughout North Carolina, to the general public, as part of its regular day-to-day business activities.

116. Defendant's false advertisements were the proximate cause of Plaintiff Wilkerson's injuries. Plaintiff Wilkerson reviewed a number of Good Start advertisements prior to purchasing Good Start, including a print advertisement indicating that Good Start would reduce the risk of developing allergies (Ex. F), and relied on those advertisements in deciding to purchase Good Start. In addition, the price that Plaintiff paid for Good Start was inflated by premiums associated with Defendant's health claims. Insofar as Plaintiff paid for a formula that lacked the benefits ascribed to it (and was thus worth less than what Plaintiff paid for it), Plaintiff was denied the benefit of her bargain.

117. Plaintiff, individually and on behalf of the other North Carolina Class members, seeks treble damages pursuant to North Carolina General Statutes section 75-16, and an award of attorneys' fees pursuant to North Carolina General Statutes section 75-16.1.

COUNT IV
Fraudulent Concealment
(on behalf of all Plaintiffs and the Nationwide Class)

118. Plaintiffs Greene and Wilkerson reallege and incorporate the preceding paragraphs.

119. Defendant intentionally concealed the fact that Good Start did not in fact reduce the risk of infant allergies; that there was little scientific evidence supporting its atopic-dermatitis claims; and that the FDA had not, in fact, unqualifiedly endorsed these atopic-dermatitis claims (among other things).

120. Defendant's misrepresentations were contained in Good Start's labels and in national advertisements that were viewed by Plaintiffs prior to purchasing Good Start.

121. Defendant had a duty to disclose that Good Start did not reduce the risk of infant allergies; that there was very little scientific evidence supporting its atopic-dermatitis claim; and that the FDA did not unqualifiedly endorse Defendant's health claims (among other things).

122. Defendant's concealments were material because parents are concerned with the health of their newborns and their formula-purchasing decisions would be influenced by Defendant's allergenic health claims. Relatedly, if Defendant had not omitted certain facts, Plaintiffs would not have purchased Good Start, or would have done so only at a reduced price.

123. Defendant knew or recklessly disregarded that its representations were false when made because, among other things, it was aware of the Lowe study, which found no correlation between Good Start and allergy reduction; was aware that there was little support for its atopic-dermatitis claim; and was aware that the FDA only endorsed a heavily qualified atopic-dermatitis claim (among other things).

124. Defendant fraudulently concealed the above-mentioned information with the intent to deceive purchasers of Good Start, like Plaintiffs, in order to boost sales.

125. Plaintiffs and the other Class members relied on Defendant's reputation in purchasing Good Start.

126. As a result of their reliance, Plaintiffs and the other Class members have been injured in an amount to be proven at trial, including, but not limited to, their lost benefit of the bargain and overpayment at the time of purchase.

127. Defendant's conduct was knowing, intentional, with malice, demonstrated a complete lack of care, and was in reckless disregard for the rights of Plaintiffs and the other Class members. Plaintiffs and the other Class members are therefore entitled to an award of punitive damages.

COUNT V
Intentional Misrepresentation
(on behalf of all Plaintiffs and the Nationwide Class)

128. Plaintiffs Greene and Wilkerson reallege and incorporate the preceding paragraphs.

129. Defendant made several intentional misrepresentations, including: that Good Start was capable of reducing the risk of infant allergies; that sufficient scientific evidence supported its atopic-dermatitis claims; and that the FDA had endorsed these claims.

130. Defendant knew these representations were false when made. Among other things, Defendant was aware of the Lowe study, which found no correlation between Good Start and allergy reduction; was aware that there was little support for its atopic-dermatitis claim; and was aware of the FDA's limited endorsement of its health claims.

131. Defendant's misrepresentations were contained in national advertisements available to Plaintiffs at the time they purchased Good Start. For example, Plaintiff Greene viewed Exhibits C, D, and E prior to purchasing Good Start; Plaintiff Wilkerson viewed Exhibits C, D, F, G, H, and several internet advertisements touting Good Start's allergenic benefits (they have since been removed).

132. As noted in detail above, these advertisements were false and misleading: among other things, Good Start does not, in fact, reduce the risk of infant allergies, and Defendant's atopic-dermatitis claims lack any qualifying language.

133. Defendant had a duty to disclose that Good Start did not reduce the risk of infant allergies, or that there was very little scientific evidence supporting this claim, and that the FDA did not endorse Defendant's allergenic health claims.

134. The aforementioned misrepresentation were material in that the allergenic

benefits of an infant formula would influence a reasonable consumer's (i.e., a parent's or guardian's) decision as to whether or not to purchase that formula.

135. Defendant intentionally made the above-mentioned misrepresentations with the intent to deceive purchasers of Good Start, like Plaintiffs, in order to boost sales.

136. Plaintiffs justifiably relied upon the misrepresentations made by Defendant, one of this country's oldest and most recognizable baby-food manufacturers.

137. As a result of their reliance, Plaintiffs have been injured in an amount to be proven at trial, including, but not limited to, their lost benefit of the bargain and overpayment at the time of purchase.

138. Defendant's conduct was knowing, intentional, with malice, demonstrated a complete lack of care, and was in reckless disregard for the rights of Plaintiffs and the other Class members. Plaintiffs and the other Class members are therefore entitled to an award of punitive damages.

COUNT VI
Negligent Misrepresentation
(on behalf of all Plaintiffs and the Nationwide Class)

139. Plaintiffs Greene and Wilkerson reallege and incorporate the preceding paragraphs.

140. As alleged above, Defendant misrepresented the allergenic benefits of Good Start, and these purported benefits constituted a material fact; i.e.: a consumer's decision to purchase Good Start would be influenced by its purported allergenic benefits.

141. Defendant's misrepresentations were made in the course of a business transaction (the advertisement, sale, and purchase of Good Start) in which both Plaintiffs and Defendant have a pecuniary interest.

142. Defendant knew or should have known that these representations were false or misleading and failed to exercise reasonable care in disseminating the information contained in its advertisements.

143. Defendant intended that its representations would induce consumers like Plaintiffs into purchasing Good Start.

144. Plaintiffs' injuries were proximately caused by Defendant's misrepresentations: Plaintiffs viewed Defendant's advertisement prior to purchasing Good Start, and the allergenic benefits mentioned in the advertisements prompted them to purchase Good Start, as opposed to an alternative formula, or to pay an inflated price for Good Start. Had Plaintiffs been aware of Defendant's misrepresentations, they would have been unwilling to purchase Good Start, or to purchase Good Start at its advertised price.

COUNT VII
Unjust Enrichment
(on behalf of all Plaintiffs and the Nationwide Class)

145. Plaintiffs reallege and incorporate the preceding paragraphs.

146. Plaintiffs conferred a benefit on Defendant in the amount of the premium—associated with Defendant's allergy-reduction and qualified-approval claims—that Defendant was able to charge for Good Start, among other things.

147. Defendant consciously and voluntarily accepted this benefit.

148. This benefit was not conferred gratuitously or officiously by Plaintiffs.

149. It would be unjust and inequitable for Defendant to retain the above-mentioned benefits. For example, Defendant was only able to charge a premium for Good Start by intentionally withholding information from Plaintiffs, or otherwise misrepresenting Good Start's allergenic benefits.

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: March 8, 2016

Respectfully submitted,

/s/ *Miles Greaves*

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Attorneys for Plaintiffs

JS 44 (Rev. 11/15)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Jeremy Greene and Cetaria Wilkerson, on behalf of themselves and all others similarly situated

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Miles Greaves (Taus, Cebulash & Landau, LLP)
80 Maiden Lane, Suite 1204, New York, NY 10038
(646) 873-7650

DEFENDANTS

Gerber Products Co., a corporation, d/b/a Nestle Nutrition, Nestle Infant Nutrition, and Nestle Nutrition North America

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

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

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☒ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
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- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

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- ☐ 376 Qui Tam (31 USC 3729(a))
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- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
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- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
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REAL PROPERTY
- ☐ 210 Land Condemnation
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Habeas Corpus:
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- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

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

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332

Brief description of cause:
Plaintiffs allege that Defendant falsely claimed that its formula reduces the risk of an infant's developing allergies

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Margo K. Brodie DOCKET NUMBER 15-cv-2995

DATE 03/08/2016

SIGNATURE OF ATTORNEY OF RECORD /s/ Miles Greaves

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

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CERTIFICATION OF ARBITRATION ELIGIBILITY

Local Arbitration Rule 83.10 provides that with certain exceptions, actions seeking money damages only in an amount not in excess of $150,000, exclusive of interest and costs, are eligible for compulsory arbitration. The amount of damages is presumed to be below the threshold amount unless a certification to the contrary is filed.

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

☒ monetary damages sought are in excess of $150,000, exclusive of interest and costs,

☒ the complaint seeks injunctive relief,

☐ the matter is otherwise ineligible for the following reason

DISCLOSURE STATEMENT - FEDERAL RULES CIVIL PROCEDURE 7.1

Identify any parent corporation and any publicly held corporation that owns 10% or more or its stocks:

Not applicable

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

Please list all cases that are arguably related pursuant to Division of Business Rule 50.3.1 in Section VIII on the front of this form. Rule 50.3.1 (a) provides that "A civil case is "related" to another civil case for purposes of this guideline when, because of the similarity of facts and legal issues or because the cases arise from the same transactions or events, a substantial saving of judicial resources is likely to result from assigning both cases to the same judge and magistrate judge." Rule 50.3.1 (b) provides that " A civil case shall not be deemed "related" to another civil case merely because the civil case: (A) involves identical legal issues, or (B) involves the same parties." Rule 50.3.1 (c) further provides that "Presumptively, and subject to the power of a judge to determine otherwise pursuant to paragraph (d), civil cases shall not be deemed to be "related" unless both cases are still pending before the court."

NY-E DIVISION OF BUSINESS RULE 50.1(d)(2)

1.) Is the civil action being filed in the Eastern District removed from a New York State Court located in Nassau or Suffolk County: No

2.) If you answered "no" above:
a) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in Nassau or Suffolk County? No

b) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in the Eastern District? No

If your answer to question 2 (b) is "No," does the defendant (or a majority of the defendants, if there is more than one) reside in Nassau or Suffolk County, or, in an interpleader action, does the claimant (or a majority of the claimants, if there is more than one) reside in Nassau or Suffolk County? No

(Note: A corporation shall be considered a resident of the County in which it has the most significant contacts).

BAR ADMISSION

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

☒ Yes ☐ No

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

☐ Yes (If yes, please explain) ☒ No

I certify the accuracy of all information provided above.

Signature: /s/ Miles Greaves

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

JEREMY GREENE and CETARIA WILKERSON, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

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

Defendants.

No. 16-cv-1153

RELATED-CASE STATEMENT

Plaintiffs believe that this action is related to *Hasemann v. Gerber Products Co.*, 15-cv-2995 (E.D.N.Y.), which is currently before the Honorable Margo K. Brodie. Like the plaintiffs in *Hasemann*, Plaintiffs here allege that Defendant Gerber violated state consumer-protection laws by falsely advertising that its infant formula—Gerber Good Start—was capable of reducing the risk of an infant's developing certain allergies. Because both claims are primarily based on the same product, advertisements, and theories of liability, there is a substantial factual overlap between the two cases, and treating them as related would avoid the duplication of effort and expense.

DATED: March 8, 2016

Respectfully,

/s/ *Miles Greaves*

TAUS, CEBULASH & LANDAU, LLP
80 Maiden Lane, Suite 1204
New York, NY 10038
(646) 873-7650
mgreaves@tcllaw.com

Attorney for Plaintiffs

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of New York

JEREMY GREENE and CETARIA WILKERSON, on behalf of themselves and all others similarly situated,

Plaintiff(s)

v.

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

Defendant(s)

Civil Action No. 16-cv-1153

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* GERBER PRODUCTS CO.
12 Vreeland Road
Florham Park, NJ 07932

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Miles Greaves
TAUS, CEBULASH & LANDAU, LLP
80 Maiden Lane, Suite 1204
New York, NY 10038

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

DOUGLAS C. PALMER
CLERK OF COURT

Date: _____

Not applicable

Signature of Clerk or Deputy Clerk

Civil Action No. 16-cv-1153

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

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EXHIBIT A

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Qualified Health Claims: Letter 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

Ms. Melanie Fairchild-Dzanis
Director, Regulatory Issues - Special Nutritionals
Nestlé USA
Nutrition Division
800 North Brand Boulevard
Glendale, California 91203

RE: Qualified Health Claim Petition - 100 percent Partially Hydrolyzed Whey Protein in Infant Formula and Reducing the Risk of Food Allergy in Infants (Docket No. 2005Q-0298)

Dear Ms. Fairchild-Dzanis:

This letter responds to the health claim petition dated June 20, 2005, submitted to the Food and Drug Administration (FDA or the agency), pursuant to Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 343(r)(4)) and in accordance with the July 10, 2003 Task Force Final Report on the Consumer Health Information for Better Nutrition Initiative. The petition requested that the agency authorize a qualified health claim characterizing the relationship between the consumption of 100 percent partially hydrolyzed whey protein in infant formula and a reduced risk of food allergy in infants.

The petition proposed the following model health claim for infant formulas:

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.

While this formula may reduce the risk, it is not intended to treat existing allergy symptoms. If you suspect your baby is allergic to milk, use only under a doctor's supervision.[1]

FDA informed you on May 18, 2005, that the agency was not able to acknowledge receipt of the petition and begin its preliminary review of the petition because the petition was not complete. In response, you supplied the needed information in a supplemental submission received by FDA on June 20, 2005. FDA acknowledged the petition in a letter dated July 5, 2005, which initiated FDA's preliminary review of the petition. In that letter, FDA also informed you that it would either file or deny the petition by August 4, 2005.

The petition refers to food "allergy symptoms" in the claim language but refers to food "allergy" as the disease or health-related condition elsewhere in the petition.[2] FDA considers a claim about reduction of symptoms of disease as a drug claim rather than a health claim.[3] Thus, the agency reviewed the petition as a health claim petition about reducing the risk of food allergy.

FDA filed the petition on August 4, 2005 as a qualified health claim petition and posted the petition on the FDA website for a 60-day comment period, consistent with the agency's guidance for procedure on qualified health claims.[4]

The agency received five comments which included three from health professionals, one from an individual consumer, and one from an infant formula manufacturer. Two comments supported the proposed claim, stating that partially hydrolyzed whey protein in infant formula has shown less allergic manifestations compared to intact cow milk protein formulas, and thus is an appropriate alternative to breast milk for allergy prevention in infants at risk. One comment stated that the proposed claim should be denied, given the deficiency in scientific evidence provided in the petition and the risks posed by the presence of the claim on the label for infants who are allergic to cow's milk. One comment stated that cow's milk is unsafe and unhealthy for infants to drink. One comment stated that it is difficult to understand how partial hydrolysate of whey is protective, while complete hydrolysate of whey is not, and suggested more research on this subject. FDA considered the relevant comments in its evaluation of this petition.

This letter sets forth the basis of FDA's determination that there is no credible scientific evidence to support the proposed qualified health claim relating the consumption of 100 percent partially hydrolyzed whey protein in infant formula to a reduced risk of the development of food allergy in infants and the reasons the Agency is denying the qualified health claim.

I. Overview of Data and Eligibility for a Qualified Health Claim

A health claim characterizes the relationship between a substance and a disease or health-related condition (21 CFR 101.14(a)(1)). The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup is at risk (21 CFR 101.14(b)(1)). Health claims characterize the relationship between the substance and a reduction in risk of contracting a particular disease.[5] In a review of a qualified health claim, the agency first identifies the substance and disease or health-related condition that is the subject of the proposed claim and the population to which the claim is targeted.[6] FDA considers the data and information provided in the petition, in addition to other written data and information available to the agency, to determine whether the data and information could support a relationship between the substance and the disease or health-related condition.[7] The agency then separates individual reports of human studies from other types of data and information. FDA focuses its review on reports of human intervention and observational studies.[8]

In addition to individual reports of human studies, the agency also considers other types of data and information in its review, such as meta-analyses,[9] review articles,[10] and animal and *in vitro* studies. These other types of data and information may be useful to assist the agency in understanding the scientific issues about the substance, the disease or health-related condition, or both, but cannot by themselves support a health claim relationship. Reports that discuss a number of different studies, such as meta-analyses and review articles, do not provide sufficient information on the individual studies reviewed for FDA to determine critical elements such as the study population characteristics and the composition of the products used. Similarly, the lack of detailed information on studies summarized in review articles and meta-analyses prevents FDA from determining whether the studies are flawed in critical elements such as design, conduct of studies, and data analysis. FDA must be able to review the critical elements of a study to determine whether any scientific conclusions can be drawn from it. Therefore, FDA uses meta-analyses, review articles, and similar publications[11] to identify reports of additional studies that may be useful to the health claim review and as background about the substance-disease relationship. If additional studies are identified, the agency evaluates them individually.

FDA uses animal and *in vitro* studies as background information regarding mechanisms of action that might be involved in any relationship between the substance and the disease. The physiology of animals is different than that of humans. *In vitro* studies are conducted in an artificial environment and cannot account for a multitude of normal physiological processes such as digestion, absorption, distribution, and metabolism that affect how humans respond to the consumption of foods and dietary substances (IOM, 2005). Animal and *in vitro* studies can be used to generate hypotheses or to explore a mechanism of action but cannot adequately support a relationship between the substance and the disease.

FDA evaluates the individual reports of human studies to determine whether any scientific conclusions can be drawn from each study. The absence of critical factors such as a control group or a statistical analysis means that scientific conclusions cannot be drawn from the study (Spilker et al., 1991, Federal Judicial Center, 2000). Studies from which FDA cannot draw any scientific conclusions do not support the health claim relationship, and these are eliminated from further review.

Because health claims involve reducing the risk of a disease in people who do not already have the disease that is the subject of the claim, FDA considers evidence from studies in individuals diagnosed with the disease that is the subject of the health claim only if it is scientifically appropriate to extrapolate to individuals who do not have the disease. That is, the available scientific evidence must demonstrate that: (1) the mechanism(s) for the mitigation or treatment effects measured in the diseased populations are the same as the

mechanism(s) for risk reduction effects in non-diseased populations; and (2) the substance affects these mechanisms in the same way in both diseased people and healthy people. If such evidence is not available, the agency cannot draw any scientific conclusions from studies that use diseased subjects to evaluate the substance-disease relationship.

Next, FDA rates the remaining human intervention and observational studies for methodological quality. This quality rating is based on several criteria related to study design (e.g., use of a placebo control versus a non-placebo controlled group), data collection (e.g., type of dietary assessment method), the quality of the statistical analysis, the type of outcome measured (e.g., disease incidence versus validated surrogate endpoint), and study population characteristics other than relevance to the U.S. population (e.g., selection bias and whether important information about the study subjects – e.g., age, smoker vs. non-smoker – was gathered and reported). For example, if the scientific study adequately addressed all or most of the above criteria, it would receive a high methodological quality rating. Moderate or low quality ratings would be given based on the extent of the deficiencies or uncertainties in the quality criteria. Studies that are so deficient that scientific conclusions cannot be drawn from them cannot be used to support the health claim relationship, and these are eliminated from further review.

Finally, FDA evaluates the results of the remaining studies. The agency then rates the strength of the total body of publicly available evidence.[12] The agency conducts this rating evaluation by considering the study type (e.g., intervention, prospective cohort, case-control, cross-sectional), the methodological quality rating previously assigned, the quantity of evidence (number of the various types of studies and sample sizes), whether the body of scientific evidence supports a health claim relationship for the U.S. population or target subgroup, whether study results supporting the proposed claim have been replicated,[13] and the overall consistency[14] of the total body of evidence.[15] Based on the totality of the scientific evidence, FDA determines whether such evidence is credible to support the substance/disease relationship, and, if so, determines the ranking that reflects the level of comfort among qualified scientists that such a relationship is scientifically valid.

A. Substance

A health claim characterizes the relationship between a substance and a disease or health-related condition (21 CFR 101.14(a)(1)). A substance means a specific food or component of food, regardless of whether the food is in conventional food form or a dietary supplement (21 CFR 101.14(a)(2)). The petition identified 100 percent partially hydrolyzed whey protein in infant formula as the substance for the proposed health claims. Infant formulas are foods (Section 201(z) of the Act (21 U.S.C. § 321(z)) and partially hydrolyzed whey protein is an ingredient of infant formula, and thus a component of food; therefore, the agency concludes that 100 percent partially hydrolyzed whey protein in infant formula meets the definition of substance in the health claim regulation (21 CFR 101.14(a)(2)).

B. Disease or Health-Related Condition

A disease or health-related condition means damage to an organ, part, structure, or system of the body such that it does not function properly or a state of health leading to such dysfunctioning (21 CFR 101.14(a)(5)). The petition has identified "food allergy" as the disease or health-related condition for the proposed claim. The term food allergy encompasses a group of disorders characterized by immunologic responses to food proteins.[16] Symptoms of allergic reactions to foods include hives, atopic dermatitis or eczema (i.e., a skin condition characterized by itchy, scaly, red skin), asthma symptoms (e.g., coughing, wheezing, or difficulty breathing due to narrowed airways), and gastrointestinal symptoms (e.g., vomiting, diarrhea and abdominal cramping, and a

red rash around the mouth, itching and swelling of the mouth and throat, nausea, abdominal pain, and gas). [17] In severe cases, consuming a food to which one is allergic can cause a life-threatening reaction called anaphylaxis – a systemic allergic reaction that can be severe and sometimes fatal.[18] The agency concludes that food allergy is a disease or health-related condition because there is damage to an organ, part, structure, or system of the body such that is does not function properly, or a state of health leading to such dysfunctioning. Therefore, FDA concludes that the petitioner has satisfied the requirement in 21 CFR 101.14(a)(5).

C. Safety Review

Under 21 CFR 101.14(b)(3)(ii), if the substance is to be consumed at other than decreased dietary levels, the substance must be a food or a food ingredient or a component of a food ingredient whose use at levels necessary to justify a claim has been demonstrated by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the Act.

It is not necessary for FDA to make a determination about the safety of 100 percent partially hydrolyzed whey protein in infant formula in this letter because the agency is denying the proposed claim for lack of credible evidence, as discussed in sections II and III.

II. The Agency's Consideration of a Qualified Health Claim

FDA has identified the following endpoints to use in identifying a reduced risk of a food allergy for purposes of a health claim: incident cases of food allergies. FDA identified no validated surrogate endpoints to use in assessing food allergy risk reduction. The diagnosis of a food allergy is based on a thorough history (medical and dietary), physical examination, diagnostic testing (skin prick test or food specific IgE antibodies), and double-blind food challenge (Sicherer, 2002; Sampson, 2003). No one of the above alone is sufficient for diagnosis of a food allergy. Skin prick tests and food specific IgE antibodies are markers of sensitization, but are not definitive tests to document cases of food allergy under normal circumstances (Sicherer, 2002; Sampson 2003). In cases of allergy to egg, milk, peanuts, fish, and tree nuts, the diagnosis may also be made by history, physical examination and ImmunoCAP Specific IgE fluoroenzyme-immunoassay (FEIA). The ImmunoCAP System FEIA measures food specific IgE levels and has a high predictive value when compared to a double-blind, placebo-controlled food challenge for the specific foods listed in children (Sicherer, 2002 and Sampson, 2003).

The petition cited 216 articles/reports as evidence to substantiate the relationship for the claim. These data consisted of 25 review articles; four abstracts; one meta-analysis; four *in vitro* studies; five animal studies; 109 articles describing studies that did not provide 100 percent partially hydrolyzed whey protein in formula to subjects and/or attempt to measure food allergy in the study subjects, the substance and disease that are the subject of the proposed claim, (e.g., studies involving other types of infant formula or studies of family history and allergies); three federal reports/book chapters; eight letters to the editor; five website printouts; 16 articles in a foreign language with no translation; and 36 studies evaluating the consumption of 100 percent partially hydrolyzed whey protein in infant formula on food allergies (see docket number 2005Q-0298 for bibliography).

A. Assessment of Background Materials

"Background materials" here refers to review articles, meta-analyses, abstracts, book reviews, letters to the editor, federal reports, and website print-outs. Although useful for background information, these materials do not contain sufficient information on the individual studies that they reviewed and, therefore, FDA could not

draw any scientific conclusions from this information. FDA could not determine factors such as the study population characteristics or the composition of the products used (e.g., food, dietary supplement). Similarly, the lack of detailed information on studies summarized in these materials prevents FDA from determining whether the studies are flawed in critical elements such as design, conduct of studies, and data analysis. FDA must be able to review the critical elements of a study to determine whether any scientific conclusions can be drawn from it. As a result, the background materials supplied by the petitioner do not provide information from which scientific conclusions can be drawn regarding the substance-disease relationship claimed by the petitioner.

B. Assessment of Animal and *In Vitro* Studies

FDA also uses animal and *in vitro* studies as background information regarding mechanisms of action that might be involved in any relationship between the substance and the disease, and they can also be used to generate hypotheses or to explore a mechanism of action, but they cannot adequately support a relationship between the substance and the disease in humans. FDA did not consider the animal or *in vitro* studies submitted with the petition as supportive information about the substance - disease relationship because such studies cannot mimic the normal human physiology that may be involved in the risk reduction of any type of food allergy, nor can the studies mimic the human body's response to the consumption of 100 percent partially hydrolyzed whey protein in infant formula. Therefore, FDA cannot draw any scientific conclusions from the animal or *in vitro* studies regarding 100 percent partially hydrolyzed whey protein in infant formula and the reduction of risk of food allergies.

C. Assessment of the Intervention Studies

There were a total of 36 studies that evaluated the relationship between the consumption of 100 percent partially hydrolyzed whey protein in infant formula and a reduced risk of food allergy. FDA determined that scientific conclusions about the relationship between the consumption of 100 percent partially hydrolyzed whey protein in infant formula and a reduced risk of food allergies could not be drawn from these 36 studies for one or more of the reasons discussed below (see Appendix 1).

Three studies (see Appendix 1) used infants/children previously diagnosed with food allergies. Health claims characterize the relationship between the substance and a reduction in risk of contracting a particular disease. [19] These claims involve reducing the risk of a disease in people who do not already have the disease that is the subject of the claim. As a result, FDA considers evidence from studies in individuals already diagnosed with food allergies only if it is scientifically appropriate to extrapolate to individuals who do not have the disease. That is, the available scientific evidence must demonstrate that: (1) the mechanism(s) for the mitigation or treatment effects measured in the diseased populations are the same as the mechanism(s) for risk reduction effects in non-diseased populations; and (2) the substance affects these mechanisms in the same way in both diseased people and healthy people. Given that such evidence was not available, the agency cannot draw any scientific conclusions from these three studies.

One study (Vandenplas et al., 1989) was a republication of another study being evaluated (Vandenplas et al., 1988) for the substance and disease relationship. Since this republication provided no new data or information, the original publication was relied upon for review.

The thirty-two remaining studies did not demonstrate that any observed reduction in food allergy is attributable to the partially hydrolyzed whey protein in infant formula, because these studies did not properly control for the removal of casein as a confounding variable.[20] The petitioner proposed to attribute a reduction in food allergy

to the 100 percent partially hydrolyzed whey protein contained in its infant formula (PHF-W) when compared to whole protein cow's milk formula (CMF). The two proteins in CMF are non-hydrolyzed (intact) whey and casein. CMF typically contains non-hydrolyzed (intact) whey and casein proteins in a 20:80 ratio or a 40:60 ratio, whereas the petitioner's PHF-W contains a 100 percent partially hydrolyzed form of whey protein and no casein.

A study comparing CMF to PHF-W cannot attribute a decrease in food allergy due to the partially hydrolyzed whey proteins, because any decrease in food allergy may be due to the elimination of casein proteins. Casein and whey proteins are the major allergens found in cow's milk (Allergy Report, American Academy of Allergy, Asthma, and Immunology, page 69). Therefore, eliminating one of the major allergens (casein) from a formula could reduce the incidence of food allergy when compared to the cow's milk formula that contains casein, notwithstanding any potential effect of the partial hydrolysis of whey protein on food allergy risk. To demonstrate a relationship between the consumption of partially hydrolyzed whey protein and risk of food allergies, studies would need to include a control group fed infant formula containing non-hydrolyzed (intact) whey protein and no casein. Including three formulas, CMF, 100 percent PHF-W, and a non-hydrolyzed (intact) whey protein formula without casein, would allow evaluation of whether any observed reduction in food allergy is attributable to the elimination of casein, the partial hydrolysis of whey protein (as the petitioner suggests), or a combination of these factors. None of the 32 studies included a control group which evaluated a formula containing only non-hydrolyzed (intact) whey protein formula without casein, therefore no scientific conclusions can be drawn about a relationship between the consumption of partially hydrolyzed whey protein in infant formula and a reduced risk of food allergies.

Twenty-nine studies (see Appendix 1) did not definitively diagnose food allergy incidence in the study's subjects, which, as explained above, is the appropriate endpoint for measuring the food allergy risk reduction that is the subject of the proposed claim. As discussed above, diagnosing food allergy requires several steps including a thorough dietary and medical history, physical examination, diagnostic testing (skin prick test or food specific IgE antibodies), and a double-blind food challenge (Sicher, 2002; Sampson, 2003). In cases of allergy to egg, milk, peanuts, fish, and tree nuts, the diagnosis may also be made by a dietary and medical history, a physical examination, and an ImmunoCAP Specific IgE fluoroenzyme-immunoassay (FEIA). For a study to measure food allergy incidence, the study must demonstrate that the double-blind food challenge or ImmunoCAP FEIA was positive in individuals with physical symptoms (asthma, atopic dermatisis, urticaria etc.) of food allergy for definitive diagnosis (Sicherer, 2002). Physical symptoms, skin prick tests, and/or serum IgE blood levels alone are not sufficient to diagnose food allergy (Sampson, 2003). Many of the studies evaluated by FDA used only symptoms of allergic disease (i.e., atopic dermatitis, wheezing) and/or skin prick tests or serum IgE levels. Since these studies did not definitively diagnose food allergies, no scientific conclusions can be drawn from them concerning the incidence of food allergy in the subjects.

Twelve studies (see Appendix 1) provided no information on the nutritional status of the infants in their studies that would indicate, for example, that these infants experienced normal physical growth during the study. An infant's immune system can be impaired when adequate nutrition is not provided (Cunningham-Rundles et al., 2005), thereby potentially altering any immune mediated response, and making an allergic reaction less likely. Without information on nutritional status, such as measurements of physical growth for the infants in the studied populations or other assurances that infants were properly nourished during the study, it cannot be determined whether infants are consuming the cow's milk control formula or the intervention formula in the same quantity (e.g., because of potential differences in formula taste). If infants in one group become undernourished because of differing consumption rates, their immune systems become impaired, and observed incidence of allergic reaction may be attributable, not to the test formula or control formula, but to the

impaired immune system of the subjects. Without nutritional status information, it is not possible to compare the incidence of food allergy between the intervention and control groups. As a result, no scientific conclusions about the relationship between PHF-W consumption and food allergy risk can be drawn from studies without accounting for this potential confounding factor.

Sixteen studies (Appendix 1) evaluated PHF-W and CMF consumption in infants who were partially breastfed during the studies. Consumption of breast milk may influence the development of food allergy in infants (Friedman and Zeiger, 2005). These sixteen studies did not document whether the duration and extent of breast and formula feeding was similar between the intervention and control groups. If the duration and/or extent of breastfeeding was different between the intervention group and control group, then it could not be determined whether the observed food allergy incidence was due to the test formula, the control formula, or the amount of breast milk an infant received. Therefore, scientific conclusions cannot be drawn from these studies about the relationship between PHF-W consumption and food allergy risk.

D. Assessment of Observational Studies

There were no observational studies that evaluated the relationship between PHF-W and risk of food allergies.

III. Strength of the Scientific Evidence

Below, the agency rates the strength of the total body of publicly available evidence. The agency conducts this rating evaluation by considering the study type (e.g., intervention, prospective cohort, case-control, cross-sectional), the methodological quality rating previously assigned, the quantity of evidence (number of various types of studies and sample sizes), whether the body of evidence supports a health claim relationship for the U.S. population or target subgroup, whether study results supporting the proposed claim have been replicated,[21] and the overall consistency[22] of the total body of evidence. Based on the totality of the scientific evidence, FDA determines whether such evidence is credible to support the substance/disease relationship, and if so, determines the ranking that reflects the level of comfort among qualified scientists that such a relationship is scientifically valid.

As discussed in Section II, there were no intervention or observational studies from which scientific conclusions could be drawn about the relationship between the consumption of 100 percent partially hydrolyzed whey protein in infant formula and a reduced risk of food allergy. Based on its review of the totality of publicly available scientific evidence, FDA concludes 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.

IV. Agency's Consideration of Disclaimers or Qualifying Language

We considered but rejected use of a disclaimer or qualifying language to accompany the proposed claim. We concluded 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. Adding a disclaimer or incorporating qualifying language that effectively characterizes the claim as baseless is not a viable regulatory alternative because neither the disclaimer nor the qualifying language can rectify the message conveyed by the unsubstantiated claim. *See, e.g., In re* Warner-Lambert Co., 86 F.T.C. 1398, 1414 (1975), *aff'd*, 562 F.2d 749 (D.C. Cir. 1977) (pro forma statements of no absolute prevention followed by promises of fewer colds did not cure or correct the false message that Listerine will prevent colds); *Novartis Consumer Health, Inc. v.*

Johnson & Johnson-Merck Consumer Pharms. Co., 290 F.3d 578, 598 (3d Cir. 2002) ("We do not believe that a disclaimer can rectify a product name that necessarily conveys a false message to the consumer."); *Pearson v. Shalala*, 164 F.3d 650, 659 (D.C. Cir 1999) (the court stated that, where the weight of evidence was against the claim, FDA could rationally conclude that the disclaimer "The FDA has determined that no evidence supports this claim" would not cure the misleadingness of a claim). In such a situation, adding a disclaimer or qualifying language does not provide additional information to help consumer understanding but merely contradicts the claim. *Resort Car Rental System, Inc. v. FTC*, 518 F.2d 962, 964 (9th Cir.) (per curiam) (upholding FTC order to excise "Dollar a Day" trade name as deceptive because "by its nature [it] has decisive connotation for which qualifying language would result in contradiction in terms."), *cert denied,* 423 U.S. 827 (1975); *Continental Wax Corp. v. FTC,* 330 F.2d 475, 480 (2d Cir. 1964) (same); *Pasadena Research Labs v. United States,* 169 F.2d 375 (9th Cir. 1948) (discussing "self-contradictory labels"). In the FDA context, courts have repeatedly found such disclaimers ineffective. *See, e.g., United States v. Millpax, Inc.,* 313 F.2d 152, 154 & n.1 (7th Cir. 1963) (disclaimer stating that "no claim is made that the product cures anything, either by the writer or the manufacturer" was ineffective where testimonials in a magazine article promoted the product as a cancer cure); *United States v. Kasz Enters., Inc.,*855 F. Supp. 534, 543 (D.R.I.) ("The intent and effect of the FDCA in protecting consumers from . . . claims that have not been supported by competent scientific proof cannot be circumvented by linguistic game-playing."), *judgment amended on other grounds*, 862 F. Supp. 717 (D.R.I. 1994).

V. Conclusions

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 for the following proposed qualified health claim:

> 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.
>
> While this formula may reduce the risk, it is not intended to treat existing allergy symptoms. If you suspect your baby is allergic to milk, use only under a doctor's supervision.

Please note that scientific information is subject to change, as are consumer consumption patterns. FDA intends to evaluate new information that becomes available to determine whether it necessitates a change in this decision. For example, scientific evidence may become available that will support the use of a qualified health claim or that will support significant scientific agreement for a health claim.
Sincerely,

Michael M. Landa
Deputy Director for Regulatory Affairs

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Appendix 1

Please see the petition in Docket No. 2005Q-0298 for full citation.

Treating infants previously diagnosed with food allergies

Aanpreung et al., 2003
Niggermann et al., 2001
Ragno et al., 1993

Republication

Vandenplas et al., 1989

Improper Controls

Akimoto et al., 1997
Becker et al., 2004
Chan-Yeung et al., 2000
Chan et al., 2002
[23]Chandra et al., 1989
Chandra et al., 1991
Chandra et al., 1997
Chiroco et al., 1997
D'Agata et al., 1996
De Seta et al., 1994
Exl et al., 1998; 2000
Fukushima et al., 1997
Galli et al. 1994
Giampietro et al., 2001
Halken et al., 2000
Iikura et al., 1995
Laforgia et al., 1996
Lam et al., 1992
Marini et al., 1996
Nentwich et al., 2001
Valverde (Thesis)
Porch et al., 1998
Schmidt et al., 1995
Silva Rey (Thesis)
Tsai et al., 1991
Vandenplas et al., 1988; 1992; 1995
Vierucci et al., 1993
Vonberg et al., 2003
Williems et al., 1993

Not an acceptable diagnosis of food allergy

Akimoto et al., 1997
Becker et al., 2004
Chan-Yeung et al., 2000

Chan et al., 2002
Chandra et al., 1989
Chandra et al., 1991
Chiroco et al., 1997
D'Agata et al., 1996
De Seta et al., 1994
Exl et al., 1998/2000
Fukushima et al., 1997
Galli, et al. 1994
Giampietro et al., 2001
Halken et al., 2000
Iikura et al., 1995
Laforgia et al., 1996
Lam et al., 1992
Marini et al., 1996
Nentwich et al., 2001
Valverde (Thesis)
Porch et al., 1998
Schmidt et al., 1995
Silva Rey (Thesis)
Tsai et al., 1991
Vandenplas et al., 1988
Vierucci et al., 1993
Vonberg et al., 2003
Williems et al., 1993

No nutritional assessment on study subjects

Akimoto et al., 1997
Becker et al., 2004
Chan-Yeung et al., 2000
D'Agata et al., 1996
De Seta et al., 1994
Galli et al., 1994
Iikura et al., 1995
Porch et al., 1998
Vandenplas et al., 1992
Vandenplas et al., 1995
Vierucci et al., 1993
Williems et al., 1993

Breastfeeding is a confounder

Akimoto et al., 1997
Becker et al., 2004
Chan-Yeung et al., 2000
Exl et al., 1998; 2000

Fukushima et al., 1997
Iikura et al., 1995
Halken et al., 2000
Laforgia et al., 1996
Lam et al., 1992
Marini et al., 1996
Nentwich et al., 2001
Schmidt et al., 1995
Silva Rey (Thesis)
Tsai et al., 1991
Von Berg et al., 2003

Notes

[1] The petition originally proposed a different second paragraph of claim language: "Partially hydrolyzed formulas are not intended to treat existing food 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 should be under a doctor's supervision." On March 29, 2006, the petitioner asked that this original paragraph be replaced with the language listed here.

[2] *See, e.g.,* Executive Summary, page 2 ("for primary prevention of allergy")

[3] *See Whitaker v. Thompson*, 353 F.3d 947, 950-51 (D.C. Cir.) (finding FDA's distinction between disease prevention claims, regulated as health claims, and disease treatment claims, regulated as drug claims, to be reasonable), *cert. denied*, 125 S. Ct. 310 (2004).

[4] "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" (July 10, 2003).

[5] See *Whitaker v. Thompson*, 353 F.3d 947, 950-51 (D.C. Cir.) (upholding FDA's interpretation of what constitutes a health claim), *cert. denied*, 125 S. Ct. 310 (2004).

[6] See guidance entitled "Interim Evidence-based Ranking System for Scientific Data," July 10, 2003.

[7] For brevity, "disease" will be used as shorthand for "disease or health-related condition" in the rest of this letter.

[8] In an intervention study, subjects similar to each other are randomly assigned to either receive the intervention or not to receive the intervention, whereas in an observational study, the subjects (or their medical records) are observed for a certain outcome (i.e., disease). Intervention studies provide the strongest evidence for an effect. See Guidance entitled "Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements" (December 22, 1999).

[9] A meta-analysis is the process of systematically combining and evaluating the results of clinical trials that have been completed or terminated (Spilker, 1991).

[10] Review articles summarize the findings of individual studies.

[11] Other examples include book chapters, abstracts, letters to the editor, and committee reports.

[12] See *supra*, note 6.

[13] Replication of scientific findings is important for evaluating the strength of scientific evidence (An Introduction to Scientific Research, E. Bright Wilson Jr., pages 46-48, Dover Publications, 1990).

[14] Consistency of findings among similar and different study designs is important for evaluating causation and the strength of scientific evidence (Hill A.B. The environment and disease: association or causation? Proc R Soc Med 1965;58:295-300); See also **Systems to rate the scientific evidence (http://www.ahrq.gov/clinic/epcsums/strengthsum.htm#Contents)**, Agency for Healthcare Research and Quality defining "consistency" as "the extent to which similar findings are reported using similar and different study designs."

[15] See *supra*, note 6.

[16] **Food Allergy (http://www.aaaai.org/patients/gallery/Default.asp?topic=foodallergy)**, American Academy of Allergy Asthma & Immunology,

[17] **Tips to Remember: Food Allergy (http://www.aaaai.org/patients/publicedmat/tips/foodallergy.stm)**, American Academy of Allergy Asthma & Immunology, http://www.aaaai.org/patients/publicedmat/tips/foodallergy.stm

[18] See *supra*, note 17.

[19] See *supra*, note 3.

[20] Confounders are factors that are associated with the outcome in question and the intervention and prevent the measured outcome from being attributed unequivocally to the intervention (Epidemiology Beyond the Basics, page 190 Aspen Publishers, 2000)

[21] See *supra*, note 13.

[22] See *supra*, note 14.

[23] The three publications by Chandra et al., 1989, 1991, and 1997 are under investigation for scientific validity and Nestle has requested that the Agency not rely on them for the scientific review of this petition (see docket 2005Q-0298, Letter from Nestle March 31, 2006, signed by José M. Saavedra, MD.)

More in Labeling & Nutrition (/Food/IngredientsPackagingLabeling/LabelingNutrition/default.htm)

Label Claims (/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006873.htm)

Front-of-Package Labeling Initiative (/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm202726.htm)

Nutrition Facts Label Programs & Materials

(/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm20026097.htm)

Nutrition Labeling Information for Restaurants & Retail Establishments (/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm459729.htm)

EXHIBIT B

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

100% Whey-Protein Partially Hydrolyzed Infant Formula and Reduced Risk of Atopic Dermatitis

Back to Qualified Health Claims: Letters of Enforcement Discretion (/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072756.htm)

May 24, 2011

Ms. Melanie Fairchild-Dzanis
Regulatory Discretion, Inc
12 Vreeland Road – Box 697
Florham Park, NJ 08932-0697

RE: Qualified Health Claim Petition for the Relationship Between 100% Whey-Protein Partially Hydrolyzed Infant Formula and Reduced Risk of Atopic Dermatitis (Docket No. FDA-2009-Q-0301)

Dear Ms. Fairchild-Dzanis:

This letter responds to the qualified health claim petition received by the Food and Drug Administration (FDA or the agency) on May 22, 2009, which you submitted on behalf of Nestlé Nutrition. The petition was submitted pursuant to Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 343(r)(4)) and in accordance with FDA's guidance on the procedures for the submission of qualified health claim petitions ("FDA procedures guidance").[1] The petition requested that the agency exercise enforcement discretion for a qualified health claim characterizing the relationship between the consumption of 100 percent whey-protein partially hydrolyzed infant formula and reduced risk of atopic dermatitis.

The petition proposed the following model health claim to be used on the labels or in the labeling of infant formulas:

> 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.

> Partially hydrolyzed formulas are not intended to treat existing food 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.

FDA filed the petition on July 6, 2009 and posted the petition on the FDA website for a 60-day comment period, consistent with the FDA procedures guidance. One comment was submitted to the docket; however, the comment concerned nutrition labeling issues that were unrelated to the qualified health claim petition and the agency's decision concerning such petition. Therefore, the agency is not addressing the comment in this letter.

The initial date for the agency's response to your petition was February 16, 2010. After mutual agreements, the date for the agency's response was extended to April 16, 2010. Based on your March 2, 2010 request to meet with FDA to discuss the scientific evidence supporting the claim, FDA met with Nestlé on May 11, 2010. At the May 11, 2010 meeting, FDA requested additional data from Nestlé in order for FDA to complete its review of the petition. On November 8, 2010, FDA received the requested information from Nestlé, which included a supplemental to Section B of the original petition and a pamphlet from the American Academy of Allergy Asthma and Immunology. On February 4, 2011, FDA requested specific information from Nestlé on the infant formulas used in the studies to support the petitioned claim. Nestlé provided this information on February 11, 2011.

FDA has determined that the current scientific evidence is appropriate for considering the exercise of enforcement discretion with respect to a qualified health claim concerning the relationship between 100% whey-protein partially hydrolyzed infant formula and a reduced risk of atopic dermatitis for a specific infant population who is fed such formula during a specific period of time.

Accordingly, this letter sets forth the basis of FDA's determination that the current scientific evidence is appropriate for consideration of a qualified health claim on 100 percent whey-protein partially hydrolyzed infant formulas. In addition, this letter sets forth (in the "Conclusions" section) qualified health claim language for which FDA intends to exercise enforcement discretion. This letter also sets out the factors that FDA intends to consider in the exercise of its enforcement discretion for a qualified health claim with respect to consumption of 100 percent whey-protein partially hydrolyzed infant formula and a reduced risk of atopic dermatitis.

I. Overview of Data and Eligibility for a Qualified Health Claim

A health claim characterizes the relationship between a substance and a disease or health-related condition (21 CFR 101.14(a)(1)). The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup is at risk (21 CFR 101.14(b)(1)). Health claims characterize the relationship between the substance and a reduction in risk of contracting a particular disease or health-related condition.[2] In a review of a qualified health claim, the agency first identifies the substance and disease or health-related condition that is the subject of the proposed claim and the population to which the claim is targeted.[3]

FDA considers the data and information provided in the petition, in addition to other written data and information available to the agency, to determine whether the data and information could support a relationship between the substance and the disease or health-related condition.[4] The agency then separates

individual reports of human studies from other types of data and information. FDA focuses its review on reports of human intervention and observational studies.[5]

In addition to individual reports of human studies, the agency also considers other types of data and information in its review, such as meta-analyses,[6] review articles,[7] and animal and *in vitro* studies. These other types of data and information may be useful to assist the agency in understanding the scientific issues about the substance, the disease, or both, but cannot by themselves support a health claim relationship. Reports that discuss a number of different studies, such as meta-analyses and review articles, do not provide sufficient information on the individual studies reviewed for FDA to determine critical elements such as the study population characteristics and the composition of the products used. Similarly, the lack of detailed information on studies summarized in review articles and meta-analyses prevents FDA from determining whether the studies are flawed in critical elements such as design, conduct of studies, and data analysis. FDA must be able to review the critical elements of a study to determine whether any scientific conclusions can be drawn from it. Therefore, FDA uses meta-analyses, review articles, and similar publications[8] to identify reports of additional studies that may be useful to the health claim review and as background about the substance-disease relationship. If additional studies are identified, the agency evaluates them individually.

FDA uses animal and *in vitro* studies as background information regarding mechanisms of action that might be involved in any relationship between the substance and the disease. The physiology of animals is different than that of humans. *In vitro* studies are conducted in an artificial environment and cannot account for a multitude of normal physiological processes such as digestion, absorption, distribution, and metabolism that affect how humans respond to the consumption of foods and dietary substances (IOM, 2005). Animal and *in vitro* studies can be used to generate hypotheses or to explore a mechanism of action but cannot adequately support a relationship between the substance and the disease.

FDA evaluates the individual reports of human studies to determine whether any scientific conclusions can be drawn from each study. The absence of critical factors such as a control group or a statistical analysis means that scientific conclusions cannot be drawn from the study (Spilker et al., 1991, Federal Judicial Center, 2000). Studies from which FDA cannot draw any scientific conclusions do not support the health claim relationship, and these are eliminated from further review.

Because health claims involve reducing the risk of a disease in people who do not already have the disease that is the subject of the claim, FDA considers evidence from studies in individuals diagnosed with the disease that is the subject of the health claim only if it is scientifically appropriate to extrapolate to individuals who do not have the disease. That is, the available scientific evidence must demonstrate that: (1) the mechanism(s) for the mitigation or treatment effects measured in the diseased populations are the same as the mechanism(s) for risk reduction effects in non-diseased populations; and (2) the substance affects these mechanisms in the same way in both diseased people and healthy people. If such evidence is not available, the agency cannot draw any scientific conclusions from studies that use diseased subjects to evaluate the substance-disease relationship.

Next, FDA rates the remaining human intervention and observational studies for methodological quality. This quality rating is based on several criteria related to study design (e.g., use of a placebo control versus a non-placebo controlled group), data collection (e.g., type of dietary assessment method), the quality of the statistical analysis, the type of outcome measured (e.g., disease incidence versus validated surrogate endpoint), and study population characteristics other than relevance to the U.S. population (e.g., selection bias and whether important information about the study subjects – e.g., age, smoker vs. non-smoker – was

gathered and reported). For example, if the scientific study adequately addressed all or most of the above criteria, it would receive a high methodological quality rating. Moderate or low quality ratings would be given based on the extent of the deficiencies or uncertainties in the quality criteria.

Studies that are so deficient that scientific conclusions cannot be drawn from them cannot be used to support the health claim relationship, and these are eliminated from further review.

Finally, FDA evaluates the results of the remaining studies. The agency then rates the strength of the total body of publicly available evidence.[9] The agency conducts this rating evaluation by considering the study type (e.g., intervention, prospective cohort, case-control, cross-sectional), the methodological quality rating previously assigned, the quantity of evidence (number of the various types of studies and sample sizes), whether the body of scientific evidence supports a health claim relationship for the U.S. population or target subgroup, whether study results supporting the proposed claim have been replicated,[10] and the overall consistency[11] of the total body of evidence.[12] Based on the totality of the scientific evidence, FDA determines whether such evidence is credible to support the substance/disease relationship, and, if so, determines the ranking that reflects the level of comfort among qualified scientists that such a relationship is scientifically valid.

A. Substance

A health claim characterizes the relationship between a substance and a disease or health-related condition (21 CFR 101.14(a)(1)). A substance means a specific food or component of food, regardless of whether the food is in conventional food form or a dietary supplement (21 CFR 101.14(a)(2)). The petition identified 100 percent whey-protein partially hydrolyzed infant formula as the substance for the proposed health claims. Infant formulas are foods (Section 201(z) of the Act (21 U.S.C. § 321(z)); therefore, the agency concludes that 100 percent whey-protein partially hydrolyzed infant formula meets the definition of substance in the health claim regulation (21 CFR 101.14(a)(2)).

B. Disease or Health-Related Condition

A disease or health-related condition means damage to an organ, part, structure, or system of the body such that it does not function properly or a state of health leading to such dysfunctioning (21 CFR 101.14(a)(5)). The petition has identified atopic dermatitis as the disease or health-related condition for the proposed claim. Atopic dermatitis[13] is a complex disease with unknown cause and many factors that can make it worse. It is likely caused by genetic and environmental factors. Atopic dermatitis[14] is a form of eczema that generally begins in early infancy. In severe cases, scratching the skin can cause redness, swelling, cracking, scaling and occasionally oozing clear fluid and crusting that is more commonly seen in early life (Sampson 2005). Atopic dermatitis is identified by a constellation of symptoms using standard diagnostic criteria (Hanifin-Rajka, 1980). The agency concludes that atopic dermatitis is a disease or health-related condition because there is damage to an organ, part, structure, or system of the body such that is does not function properly, or a state of health leading to such dysfunctioning. Therefore, FDA concludes that the petitioner has satisfied the requirement in 21 CFR 101.14(a)(5).

C. Safety Review

Under 21 CFR 101.14(b)(3)(ii), if the substance is to be consumed at other than decreased dietary levels, the substance must be a food or a food ingredient or a component of a food ingredient whose use at levels necessary to justify a claim has been demonstrated by the proponent of the claim, to FDA's satisfaction, to be

safe and lawful under the applicable food safety provisions of the Act.

FDA evaluates whether the substance is "safe and lawful" under the applicable food safety provisions of the Act. For conventional foods, this evaluation involves considering whether the substance, which is either a food or an ingredient that is the source of the substance, is generally recognized as safe (GRAS), approved as a food additive, or authorized by a prior sanction issued by FDA (see 21 CFR 101.70(f)).

100 percent whey-protein partially hydrolyzed infant formula is a substance as defined in 101.14(a)(2). Section 201(z) of the Act defines infant formula as a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

100 percent whey-protein partially hydrolyzed infant formulas have been marketed in the United States for decades. Nestlé's 100 percent whey-protein partially hydrolyzed infant formulas have been the subject of several New Infant Formula notifications filed pursuant to Section 412 of the Act and are safely and lawfully marketed in this country. Based on the evidence above, FDA concludes that under the preliminary requirements of 21 CFR 101.14(b)(3)(ii), the use of 100 percent whey-protein partially hydrolyzed infant formula as described in the qualified health claim petition is safe and lawful.

However, 100 percent whey-protein partially hydrolyzed infant formula is not safe for all populations. 100 percent whey-protein partially hydrolyzed infant formulas are not considered hypoallergenic and may cause allergic reactions in one-third to one-half of milk allergic infants (Ellis et al, 1991; Gampietro et al., 2001; Bahna et al. 2008). Hypersensitivity reactions in milk allergy infants represent a significant medical concern, as they may range from cutaneous reactions (e.g., urticaria, worsening eczema) to severe gastrointestinal reactions (food protein induced enterocolitis syndrome) or life-threatening anaphylaxis. Although rare, death from cow's milk anaphylaxis has been reported in voluntary registries of fatal food anaphylaxis cases (Chapman et al, 2006; Bock et al., 2001; Bock et al., 2007). Therefore, 100 percent whey-protein partially hydrolyzed infant formula should not be fed to infants who are known to be allergic to milk or who have existing milk allergy symptoms.

II. The Agency's Consideration of a Qualified Health Claim

FDA has identified the following endpoint to use in identifying a reduced risk of atopic dermatitis for purposes of a health claim: incident cases of atopic dermatitis. FDA identified no validated surrogate endpoints to use in assessing atopic dermatitis risk reduction.[15] The diagnosis of atopic dermatitis is based on health history and physical examination (Fitzpatrick, 1993). Physical examination using the Hanifin-Rajka criteria must include 3 or more basic findings: pruritus, typical morphology and distribution; facial and extensor involvement in infants and children; chronic or chronically-relapsing dermatitis; and/or personal or family history of atopy (asthma, allergic rhinitis, atopic dermatitis) (Hanifin-Rajka, 1980).

The petition cited 128 articles/reports as evidence to substantiate the relationship for the claim. The articles submitted consisted of 19 book chapters, review articles, or federal reports; 1 website; 4 editorials; 1 article written in a foreign language with no translation; 9 abstracts; 2 animal studies; 1 reference to computer software; 71 articles describing studies that did not provide 100% whey-protein hydrolyzed infant formula to subjects and/or did not measure atopic dermatitis in the study subjects, the substance and disease that are the subject of the proposed claim, (e.g., studies involving other types of infant formula or studies of family history

and allergies); and 20 articles on infant studies relevant to the proposed qualified health claim on 100 percent whey-protein partially hydrolyzed infant formula and reduced risk of atopic dermatitis (see docket number 2009-Q-0301 for bibliography).

In addition, a supplement to the petition dated November 8, 2010 provided 20 references including 5 book chapters, review articles, or federal reports; 2 meta-analyses, 1 website reference, 1 educational pamphlet, and 11 articles describing studies that did not provide 100 percent whey-protein hydrolyzed infant formula to subjects and/or did not measure atopic dermatitis in the study subjects to substantiate the relationship for the claim. The two meta-analyses submitted as a supplement to the petition (Szajewksa and Horvath, 2010; Alexander and Cabana, 2010) also provided an analysis of the relative risk[16] and confidence intervals (CI)[17] for two individual studies (Marini et al., 1996; Vandenplas et al., 1995) that lacked statistical analysis in the original articles. They are discussed in section II C. It is important to note that the meta-analyses[18] were not relied upon for the combined results of all studies included.

A. Assessment of Review Articles, Meta-analyses, and Book Chapters

Although useful for background information, the review articles, meta-analyses, and book chapters that were provided as part of your petition do not contain sufficient information on the individual studies reviewed and, therefore, FDA could not draw any scientific conclusions from this information. The lack of detailed information on studies summarized in the review articles, meta-analyses, and book chapters prevented FDA from determining whether the studies were flawed in critical elements such as design, conduct of studies, and data analysis. FDA must be able to review the critical elements of a study to determine whether any scientific conclusions can be drawn from it. As a result, the review articles, meta-analyses, and book chapters submitted with the petition or during the public comment period did not provide information from which scientific conclusions can be drawn regarding the substance-disease relationships claimed by the petitioner.

B. Assessment of Animal Studies

FDA uses animal studies as background information regarding mechanisms of action that might be involved in any relationship between the substance and the disease, and they can also be used to generate hypotheses or to explore a mechanism of action, but they cannot adequately support a relationship between the substance and the disease in humans. FDA did not consider the animal studies submitted with the petition as providing any supportive information about the substance-disease relationship because such studies cannot mimic the normal human physiology that may be involved in the risk reduction of atopic dermatitis, nor can the studies mimic the human body's response to the consumption of 100 percent whey-protein partially hydrolyzed infant formula. Therefore, FDA could not draw any scientific conclusions regarding the intake of 100 percent whey-protein partially hydrolyzed infant formula and the reduction of risk of atopic dermatitis.

C. Assessment of the Intervention Studies

FDA evaluated 20 reports of intervention studies that were designed to evaluate the relationship between the consumption of 100 percent whey-protein partially hydrolyzed infant formula and a reduced risk of atopic dermatitis for which the petition requested a qualified health claim. Scientific conclusions could not be drawn from 16 of these 20 reports for the reasons discussed below.

Three studies (Exl et al. 2000; Vandenplas et al., 1989, von Berg et al., 2008) were a republication of another study being evaluated (Exl et al. 1998; Vandenplas et al., 1988; von Berg et al., 2003, 2007) for the substance and disease relationship. Since these republications provided no new data or information pertinent to the

qualified health claim, the original publications were relied upon for review.

Three studies were excluded from the scientific review due to unresolved concerns regarding data integrity (Chandra et al., 1989, 1991 and 1997). Nestlé has excluded them from their scientific review submitted with this petition (see docket 2009-Q-0301, sections B and I).

Two studies did not select infants that were healthy and had a family history of allergy (Exl et al. 1998; Fukushima et al. 1997), the population identified by the qualified health claim. Since the petition focuses on infants at risk of developing atopic dermatitis, these publications were not relied upon for review.

Six studies did not definitively diagnose cases of atopic dermatitis in the study's subjects (D'Agata et al., 1996; Exl et al., 1998; Fukushima et al., 1997; Tsai et al., 1991; Vandenplas et al., 1988; Williems et al., 1993). As discussed above, diagnosing atopic dermatitis is based on a combination of historic and morphologic findings because there are no single distinguishing features of atopic dermatitis (Fitzpatrick, 1993). As there is no objective laboratory biomarker for this disease, the Hanifin-Rajka criteria remain a standard for the diagnosis of atopic dermatitis and are frequently used in randomized controlled clinical trials (Hanifin-Rajka, 1980). For a study to measure atopic dermatitis incidence, physical examination using the Hanifin-Rajka criteria must include three or more basic findings: pruritus (itching); typical morphology and distribution; facial and extensor (outer surface of limbs) involvement in infants and children; chronic or chronically-relapsing dermatitis; and/or personal or family history of atopy (e.g., asthma, allergic rhinitis, atopic dermatitis) (Hanifin-Rajka, 1980). Atopic dermatitis is a complex disease both multifactorial and heterogeneous with regard to etiology and aggravating factors (Fitzpatrick, 1993). Extensive research has been performed but interpretation of the literature is complicated by the lack of standardization with regard to diagnosis, measures of severity and the lack of an objective test to measure the activity of disease (Fitzpatrick, 1993). Since these studies did not definitively diagnose atopic dermatitis, no scientific conclusions can be drawn from them concerning the incidence of atopic dermatitis in the subjects.

One study by Chirico et al. (1997) did not specify that 100 percent whey-protein hydrolyzed infant formula, the substance of the claim, was used in the study nor did supplemental information in the petition confirm that the formula used was the substance of the claim. Partially hydrolyzed infant formulas made from cow's milk may contain casein in addition to whey protein. Because the formula was not specifically described as 100 percent whey protein hydrolyzed infant formula, the agency could not determine that the formula used in the study was the substance of the claim.[19] Thus, scientific conclusions could not be drawn from this study about the relationship between 100 percent whey-protein partially hydrolyzed infant formula and reduced risk of atopic dermatitis.

One study by De Seta et al. (1994) was a randomized study not designed with atopic dermatitis as a primary outcome. Infants at risk for atopy were randomized to 100 percent whey-protein partially hydrolyzed formula (*n*=23) or conventional cow's milk formula (n=39) for six months. Information on blinding of the study, compliance with formula consumption, and weaning recommendations were not reported. Therefore, the agency could not determine if infants consumed their assigned formulas and adhered to the study protocol. In addition, no information was provided about factors that could influence atopic dermatitis (e.g., house pets, dust mites, smoking in the home, weaning foods). Known modifiers of disease risk need to be collected and adjusted for to minimize bias so that the substance-disease relationship is accurately measured.[20] Furthermore, results for cumulative incidence of atopic dermatitis and cow's milk protein allergy intolerance were combined and reported together (e.g., at 24 months, there were 3 cases of atopic dermatitis and cow's milk protein allergy intolerance combined in the 100 percent whey-protein partially hydrolyzed formula group). Thus, the agency could not determine *the independent role of the substance in reducing the risk of disease.*[21]

Statistical analysis between the 100 percent whey-protein partially hydrolyzed formula and cow's milk formula groups was also not reported by the authors.[22] Due to the shortcomings described above, this study is so deficient in methodological quality that it is considered to be of low-quality design. Based on the above reasons, scientific conclusions could not be drawn from this study about the relationship between 100 percent whey-protein partially hydrolyzed formula and reduced risk of atopic dermatitis.

There were four intervention studies (Vandenplas et al. (1992), Chan et al. (2002), von Berg et al. (2003), Marini et al. (1996)) published in six reports (two studies have follow-up analysis to the initial study report, von Berg et al. (2007), Vandenplas et al. (1995)) available from which scientific conclusions could be drawn about the relationship between the consumption of 100 percent whey-protein partially hydrolyzed infant formula and a reduced risk of atopic dermatitis for which the petition requested a qualified health claim. These studies are discussed below.

Vandenplas et al. (1992, 1995) was a randomized, partially blinded 6 month intervention study of moderate methodological quality. A total of 58 Belgian infants with family history of atopy (two first degree relatives) were randomly assigned to receive either 100 percent whey-protein partially hydrolyzed infant formula (*n*=28) or cow's milk infant formula (*n*=30) (control) exclusively for 6 months. The incidence of atopic dermatitis, including eczema, was determined by physical exams conducted every 6 months from the age of 6 months to 5 years. Direct statistical comparisons of the incidence of eczema between the two groups were not reported by the authors. However, an analysis of the Vandenplas et al. (1995) data by Szajewksa and Horvath (2010) showed no significant difference between the two groups when relative risk and 95% CI were calculated from the cumulative incidence data. At 0 to 12 months of age, the relative risk was 0.46 and CI was 0.13 – 1.60. At 0 to 36 months of age, the relative risk was 1.07 and the CI = 0.43 – 2.67.

Chan et al. (2002) reported on a randomized, single-blind 4 month intervention study of moderate methodological quality with 110 Singaporean infants with a family history (first degree relative) of atopy. The exclusively formula fed infants received either 100 percent whey-protein partially hydrolyzed infant formula (*n*=53) or cow's milk based formula (*n*=57) (control). Infants were monitored by a physician for atopic dermatitis at 3, 6, 12, 18, 24, and 30 months. Compliance with the intervention was not addressed and there were no restrictions with regard to consumption of weaning foods. Factors that could exacerbate atopic dermatitis such as socioeconomic status, house pets and use of air-conditioning were considered; however, other factors, such as timing and types of weaning foods consumed were not addressed. There was a significantly lower incidence of atopic dermatitis for the treatment group compared to the control group from 3 months of age (odd ratio[23] = 0.20; chi-square (X^2) [24] p value = 0.011) up to 2 years of age (odds ratio = 0.37; X^2 p value = 0.019).

von Berg et al. (2003, 2007) was a high quality, randomized, double blind 4 month intervention trial that compared the effect of differently hydrolyzed infant formulas with cow's milk formula on allergic diseases including atopic dermatitis in infants with family history of atopy. Mothers were encouraged to exclusively breast-feed for at least 4 months. If mothers chose not to breast-feed exclusively or not at all, infants were randomized to 100 percent whey-protein partially hydrolyzed formula (*n*=241) or cow's milk formula (control) (*n*=256). Information on the quantity of breast milk fed and duration of breastfeeding was not reported. The intervention consisted of study formula for the first 4 months of age and recommendations on introduction and type of weaning foods after 4 months. Atopic dermatitis was determined by clinical exams conducted at 1, 4, 8, 12, and 36 months of age. The incidence of atopic dermatitis from birth to one year of age was 22 in the 100 percent whey-protein partially hydrolyzed formula group and 38 in the cow's milk formula group. There was a significantly lower incidence of atopic dermatitis when infants consumed the 100 percent whey-protein partially

hydrolyzed formula compared to the control group (odds ratio = 0.56; CI = 0.32 – 0.99) when adjusted for atopic dermatitis in family history, sex, and maternal smoking after birth. At follow-up at 3 years of age, the incidence of atopic dermatitis from birth to 3 years of age was 34 in the 100 percent whey-protein partially hydrolyzed formula group (*n*=229) and 55 in the cow's milk formula group (*n*=245). The significant effect of 100 percent whey-protein partially hydrolyzed formula on reduced risk of atopic dermatitis persisted at 3 years of age (odds ratio = 0.60; CI = 0.37-0.97 when adjusted for atopic dermatitis in family history, sex, and maternal smoking after birth) (von Berg et al., 2007).

Marini et al. (1996) reported on a 5 to 6 month intervention study of moderate methodological quality with 279 Italian infants with parental history of atopy. The intervention included randomization to formula, instruction on maternal diet and weaning foods, as well as environmental advice. Exclusively formula fed infants received 100 percent whey-protein partially hydrolyzed formula (*n*=48) or conventional cow's milk formula (*n*= 47) (control group). Data were reported for infants that received breast milk in addition to 100 percent whey-protein partially hydrolyzed formula (*n*=32) and breast milk in addition to cow's milk formula (*n*=28). Atopic dermatitis was determined by clinical exams conducted at 3, 6, 12, 24, and 36 months of age. Compliance with maternal and infant diet recommendations and environmental advice was collected. Statistical comparison of cumulative incidence of atopic dermatitis for the treatment and control groups was not reported by the authors. However, an analysis of the incidence data from 0 to 12 and 0 to 36 months (Marini et al.,1996) by Alexander and Cabana (2010) showed no significant difference between the treatment and control group at 1 year of age (relative risk = 0.48; CI=0.13-1.78) and at 3 years of age (relative risk = 0.42; CI= 0.14-1.26).

D. Assessment of Observational Studies

There were no observational studies that evaluated the relationship between 100 percent whey-protein partially hydrolyzed infant formula and a reduced risk of atopic dermatitis.

III. Strength of the Scientific Evidence

Below, the agency rates the strength of the total body of publicly available evidence. The agency conducts this rating evaluation by considering the study type (e.g., intervention, prospective cohort, case-control, cross-sectional), the methodological quality rating previously assigned, the number of studies and number of subjects per group, whether the body of scientific evidence supports a health claim relationship for the U.S. population or target subgroup, whether study results supporting the proposed claim have been replicated,[25] and the overall consistency of the total body of evidence.[26] Based on the totality of the scientific evidence, FDA determines whether such evidence is credible to support a qualified health claim for the substance/disease relationship and, if so, considers what qualifying language should be included to convey the limits on the level of scientific evidence supporting the relationship or to prevent the claim from being misleading in other ways.

As discussed in section II, the evidence about a possible relationship between 100 percent whey-protein partially hydrolyzed infant formula and reduced risk of atopic dermatitis is based on four intervention studies published in six reports (Chan et al., 2002; Marini et al., 1996; Vandenplas et al. 1992 and 1995; von Berg et al., 2003 and 2007). Of the four above studies, two studies (Chan et al., 2002; von Berg et al., 2003 and 2007) reported a beneficial relationship between 100 percent whey-protein partially hydrolyzed infant formula and reduced risk of atopic dermatitis.

von Berg et al. (2003, 2007) reported a large, high quality intervention study in which infants were randomized to either 100% whey protein partially hydrolyzed infant formula (*n*=241) or cow's milk formula (*n*=256) for the first 4 months of life. Infants in both groups may have had breast milk in addition to the study formula. The study found a statistically significant reduction in the incidence of atopic dermatitis at 1 and 3 years of age in infants who consumed 100 percent whey-protein partially hydrolyzed infant formula compared to those who consumed cow's milk formula. Chan et al. (2002) was a moderate quality intervention study in which exclusively formula fed infants were given either 100 percent whey-protein partially hydrolyzed infant formula or cow's milk formula for the first 4 months of life. The study found a statistically significant reduction in the incidence of atopic dermatitis throughout the first year of life and up to 2 years of age for infants who consumed the 100 percent whey-protein partially hydrolyzed infant formula compared to those who consumed cow's milk formula.

Two other studies showed no beneficial relationship in exclusively formula fed infants who consumed 100 percent whey-protein partially hydrolyzed infant formula and reduced risk of atopic dermatitis up to 3 years of age (Marini et al., 1996; Vandenplas et al., 1992 and 1995). Both studies were of moderate methodological quality with intervention periods from birth through 5 to 6 months of age. There were no significant reductions in risk of atopic dermatitis between the intervention and control groups at 1 year and 3 years of age. Consistency of findings among similar and different study designs is important for evaluating the strength of the scientific evidence.[27]

Thus, two studies (von Berg et al., 2003; Chan et al., 2002) supported a beneficial relationship between the consumption of 100 percent whey-protein partially hydrolyzed infant formula during the first 4 months of life and reduced risk of atopic dermatitis throughout the first year of life. One was a large high quality intervention study (*n*= 241 in the treatment and *n*=256 in the control group) while the other was a smaller moderate quality intervention study (*n*=53 in the treatment and *n*=57 in the control group). Two studies did not support a beneficial relationship between the consumption of 100 percent whey-protein partially hydrolyzed infant formula during the first 4 months of life and risk of atopic dermatitis throughout the first year of life. Both were smaller moderate quality intervention studies (*n*=48 and 28 in the treatment and *n*=47 and 30 in the control groups, respectively). Because there are only two intervention studies that support the substance-disease relationship throughout the first year of life, while two other intervention studies do not support that relationship, there is little evidence from which to conclude that a risk reduction relationship actually exists during this timeframe.

Based on the above, FDA concludes that there is 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 four months of life and a reduced risk of atopic dermatitis throughout the first year of life. The agency concludes that the relationship between feeding a 100 percent whey-protein partially hydrolyzed infant formula for the first four months of life and a reduced the risk of atopic dermatitis throughout the first year of life is uncertain.

Only one study reported a beneficial relationship when feeding a 100 percent whey-protein partially hydrolyzed infant formula for the first 4 months of life and reduced risk of atopic dermatitis up to 3 years of age (von Berg et al., 2007). Although the study was a large high quality intervention study (*n*=241 in the treatment and *n*=256 in the control group), these findings at 3 years of age have not been replicated, and replication of scientific findings is important in order to substantiate results.[28] Two studies did not support a beneficial relationship of feeding a 100 percent whey-protein partially hydrolyzed infant formula for the first 4 months of life and reduced risk of atopic dermatitis up to 3 years of age. Both were smaller moderate quality intervention studies (*n*=48 and 28 in the treatment and *n*=47 and 30 in the control groups, respectively). Because there is only one

intervention study that supports the substance-disease relationship throughout the first year of life and up to 3 years of age, while two intervention studies do not support that relationship, there is very little evidence from which to conclude that a risk reduction relationship actually exists during this timeframe.

Based on the above, FDA concludes 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. The agency concludes that 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 is uncertain.

Early infant nutrition may have an important influence on the development of atopic diseases such as atopic dermatitis (Greer et al. 2008). Further, the study design of the two intervention studies (von Berg et al., 2003; Chan et al., 2002) that supported a beneficial relationship between the consumption of 100 percent whey-protein partially hydrolyzed infant formula and reduced risk of atopic dermatitis included the feeding of such formula to infants only during the first 4 months of life. Therefore, the agency is considering, as a factor in the exercise of its enforcement discretion, that the claim language state the time period in which the infants in these studies were fed the formula (i.e., from birth up to 4 months). Without this information, the agency would consider the qualified health claim to be misleading under sections 403(a)(1) and 201(n) of the Act 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.

IV. Other Enforcement Discretion Factors

The proposed qualified health claim contains more information than the substance-disease relationship, as italicized below:

> *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.
>
> *Partially hydrolyzed formulas are not intended to treat existing food 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.*

The first sentence in the first paragraph states "Breastfeeding is the best way to nourish infants." FDA does not object to the placement of this statement in the labeling based on the context in which such language is used, but FDA does not consider it to be part of the qualified health claim because it does not relate to the substance and disease relationship of the qualified health claim.

FDA also does not object to the placement of the phrase "the most common allergic disease of infancy" in the second sentence of the first paragraph, but FDA does not consider this phrase to be part of the qualified health claim because it does not relate to the substance and disease relationship of the qualified health claim.

The second paragraph of the proposed language explains that partially hydrolyzed formulas are not intended to treat existing food allergy symptoms. As Nestlé appears to have recognized, a second paragraph is necessary because the first paragraph identifies a relationship between the consumption of 100% whey-protein partially hydrolyzed infant formula and a reduced risk of developing the allergic disease of atopic dermatitis. The articulation of this relationship 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 (Ellis et al, 1991; Gampietro et al., 2001; Bahna et al. 2008); these reactions can be serious and even life-threatening.

The language proposed by Nestlé is not sufficient to prevent consumers from being misled in the manner described above. Nestlé's proposed language states that these formulas are not intended to treat existing food allergy symptoms, but it does not make clear that these formulas should not be fed to infants who are allergic to milk or to infants with existing milk allergy symptoms. Therefore, the agency is considering, as a factor in the exercise of its enforcement discretion, that the second paragraph state:

> 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.

Without this information, and without the bold text, the agency would consider the qualified health claim to be misleading under sections 403(a)(1) and 201(n) of the Act because it would fail to reveal facts material in the light of the representations being made and facts material with respect to consequences which may result from the use of these formulas. FDA has concluded that the use of bold type as set forth above is necessary, in light of the significant public health risk that would be created by the feeding of these formulas to infants who are allergic to milk or to infants with existing milk allergy symptoms, and the fact that the articulation of a relationship between the consumption of 100% whey-protein partially hydrolyzed infant formula and a reduced risk of developing the allergic disease of atopic dermatitis could mislead consumers to think that these formulas are an appropriate choice for such infants.

V. Conclusions

Based on FDA's consideration of the scientific evidence submitted with the petition and other pertinent scientific evidence, FDA concludes that that the current scientific evidence is appropriate for consideration of a qualified health claim regarding the relationship between the consumption of 100 percent whey-protein partially hydrolyzed infant formula and a reduced risk of atopic dermatitis, provided that the qualified health claims are appropriately worded so as not to mislead consumers.

The proposed qualified health claim states "emerging clinical research" shows that 100 percent whey-protein partially hydrolyzed infant formula may reduce the risk of atopic dermatitis that is the subject of the proposed claims. As discussed in sections II and III of this letter, only two studies showed a reduced risk of atopic dermatitis throughout the first year of life, and only one study showed a reduced risk of atopic dermatitis up to 3 years of age; two other studies showed no beneficial relationship at 1 year of age or at 3 years of age. The agency concludes that the language requested in the petition, "emerging clinical research," mischaracterizes

the strength of the evidence and is misleading because such language suggests that there is currently more scientific evidence available than what is described or that such evidence will soon be available to show that consumption of 100 percent whey-protein partially hydrolyzed infant formula reduces the risk of atopic dermatitis.

Furthermore, the reduced risk of atopic dermatitis was observed only when infants consumed the 100 percent whey-protein partially hydrolyzed infant formula during the first 4 months of life. Without this information regarding the time period in which the formula was fed to infants, the evidence does not support the proposed claim.

In light of the above considerations, FDA intends to consider the exercise of its enforcement discretion for the following qualified health claims:

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."

As discussed above, inclusion of the following language with any of the above qualified health claims is a factor in FDA's consideration of enforcement discretion:

> "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."

FDA intends to consider exercising its enforcement discretion for the above qualified health claims when all the factors for enforcement discretion identified in this letter are met.

Please note that scientific information is subject to change, as are consumer consumption patterns. FDA intends to evaluate new information that becomes available to determine whether it necessitates a change in this decision. For example, scientific evidence may become available that will support significant scientific agreement, that will support a qualified health claim for one or more claims that were denied, that will no longer support the use of the above qualified health claims, or that may raise safety concerns about the substance that is the subject of the claims.

Sincerely yours,

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Notes

[1] "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" (July 10, 2003). **[http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053832.htm (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053832.htm)]**

[2] See *Whitaker v. Thompson*, 353 F.3d 947, 950-51 (D.C. Cir.) (upholding FDA's interpretation of what constitutes a health claim), *cert. denied*, 125 S. Ct. 310 (2004).

[3] See guidance entitled "Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims - Final," January 2009. [**http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073332.htm)**]

[4] For brevity, "disease" will be used as shorthand for "disease or health-related condition" in the rest of this letter.

[5] In an intervention study, subjects similar to each other are randomly assigned to either receive the intervention or not to receive the intervention, whereas in an observational study, the subjects (or their medical records) are observed for a certain outcome (i.e., disease). Intervention studies provide the strongest evidence for an effect. See *supra* note 3.

[6] A meta-analysis is the process of systematically combining and evaluating the results of clinical trials that have been completed or terminated (Spilker, 1991).

[7] Review articles summarize the findings of individual studies.

[8] Other examples include book chapters, abstracts, letters to the editor, and committee reports.

[9] Certain meta-analyses may be used as part of the health-claim review process. See *supra*, note 3.

[10] Replication of scientific findings is important for evaluating the strength of scientific evidence (An Introduction to Scientific Research, E. Bright Wilson Jr., pages 46-48, Dover Publications, 1990).

[11] Consistency of findings among similar and different study designs is important for evaluating causation and the strength of scientific evidence (Hill A.B. The environment and disease: association or causation? Proc R Soc Med 1965;58:295-300); See also Systems to rate the scientific evidence, Agency for Healthcare Research and Quality [**http://archive.ahrq.gov/clinic/epcsums/strengthsum.htm (http://archive.ahrq.gov/clinic/epcsums/strengthsum.htm)**], defining "consistency" as "the extent to which similar findings are reported using similar and different study designs."

[12] See *supra*, note 3.

[13] National Institute of Arthritis and Musculoskeletal and Skin Diseases Fact Sheet: What is atopic dermatitis? [**http://www.niams.nih.gov/Health_Info/Atopic_Dermatitis/atopic_dermatitis_ff.pdf (http://www.niams.nih.gov/Health_Info/Atopic_Dermatitis/atopic_dermatitis_ff.pdf)**]

[14] The distribution of the rash varies with age and involves the cheeks and outer surfaces of the arms and legs in infancy, the inner surfaces of the arms and legs in the young child, and inner surfaces of the arms and legs, hands, and feet in teenagers and young adults. See *supra*, note 13.

[15] National Institute of Arthritis and Musculoskeletal and Skin Diseases, Handout on health: Atopic Dermatitis.
[http://www.niams.nih.gov/Health_Info/Atopic_Dermatitis/default.asp (http://www.niams.nih.gov/Health_Info/Atopic_Dermatitis/default.asp)]

[16] Relative risk, also known as risk ratio, is expressed as the ratio of the risk (e.g., incidence of the disease) in exposed individuals to that in unexposed individuals (Epidemiology: Beyond the Basics, page 93, Aspen Publishers, 2000).

[17] Confidence intervals are ranges that provide a statistical analysis of comparative measures of risk (e.g., relative risk, odds ratio and hazard ratio). Confidence intervals are significant when the entire range is less than or greater than "1" (e.g., 0.7-0.9 or 1.1-1.5). If the confidence interval includes "1", then it can be concluded that a relationship does not exist between the substance and the disease.

[18] See *supra*, note 6.

[19] See *supra* note 3.

[20] See *supra*, note 3 [Section III.E].

[21] See *supra*, note 3 [Section III.D].

[22] See *supra*, note 3 [Section III.D].

[23] Odds ratio is the odds of developing the disease in exposed compared to unexposed individuals (Epidemiology: Beyond the Basics, page 29, Aspen Publishers, 2000). Odds ratio is a measure of risk and is calculated in case-control studies by measuring development of a disease.

[24] Chi-square (X^2) is a test to determine whether observed differences in proportions between study groups are statistically significant. (Epidemiology in Medicine, page 249, Little, Brown and Co. 1987).

[25] See *supra* note 3.

[26] See *supra* note 3.

[27] See *supra* note 3.

[28] See *supra* note 3.

More in Labeling & Nutrition (/Food/IngredientsPackagingLabeling/LabelingNutrition/default.htm)

Label Claims (/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006873.htm)

Front-of-Package Labeling Initiative (/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm202726.htm)

Nutrition Facts Label Programs & Materials

(/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm20026097.htm)

Nutrition Labeling Information for Restaurants & Retail Establishments (/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm459729.htm)

EXHIBIT C


1ST &
ONLY
TO REDUCE RISK
OF DEVELOPING
ALLERGIES
MAKES

EXHIBIT D

EXHIBIT E

What Babies Want :30 TVC

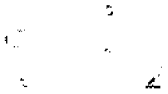
April 9th, 2012

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.

What Babies Want :30 TVC

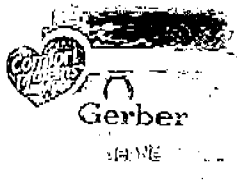
April 9th, 2012

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

AVC: Gerber

AVO: Nourishing Generation Healthy.

EXHIBIT F

Learn more here.

birth+

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.

Nourishing Generation Healthy™

Nestlé
Good Food, Good Life

EXHIBIT G

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 H


Discover the formula from the most recognized name in infant nutrition.
Inspired by the miracle of breast milk. Gerber® Good Start® formulas offer the Comfort Proteins® Advantage. It's the extra step we take to break down whey proteins so they are easy to digest and may provide unique protective benefits. Good Start also has expert-recommended levels of DHA, making it an ideal first formula
Learn more at gerber.com/allergy.
Gerber
GOOD START
1ST FORMULA
WITH FDA QUALIFIED HEALTH CLAIM
Breastfeeding is best for baby.
Gerber.

EXHIBIT I

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Nestle Infant Nutrition 10/31/14

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
College Park, MD 20740

OCT 31, 2014

WARNING LETTER

VIA EXPRESS DELIVERY

Mr. Gary Tickle
President and CEO
Nestle Infant Nutrition
12 Vreeland Rd, 2nd Floor
Florham Park, NJ 07932-0697

Re: 441393

Dear Mr. Tickle:

The Food and Drug Administration (FDA or we) reviewed the label for your Gerber Good Start Gentle Infant Formula (23.2 ounce milk based powder) product in August 2014, which label directs consumers to your website at the Internet address www.gerber.com. We reviewed your website at www.gerber.com in October 2014. Based on our review, we have concluded that your Gerber Good Start Gentle Infant Formula (23.2 ounce milk based powder) is in violation of the Federal Food, Drug, and Cosmetic Act (the Act) [Title 21, United States Code (U.S.C.), sections 301 et seq.] and the applicable regulations found in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

Your Gerber Good Start Gentle Infant Formula product is misbranded within the meaning of section 403(r)(1)(B) of the Act [21 U.S.C. § 343(r)(1)(B)] in that the labeling bears health claims that were not authorized by FDA. Your product is also misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the labeling is misleading.

Your product label bears a series of statements that, taken together, characterize the

relationship of a nutrient to a disease or health-related condition. Your product label refers to your Gerber Good Start Gentle Infant Formula (23.2 ounce milk based powder) product as the "1st and ONLY Routine Formula TO REDUCE RISK OF DEVELOPING ALLERGIES." Language next to this statement refers consumers to the inside label of the product for further information: "See Label Inside." The inside label for the product includes the following statement:

> If you choose to introduce formula and have a family history of allergy, feeding a formula exclusively made with 100% whey partially hydrolyzed, like GOOD START Gentle formula, during the first 4 months of life may reduce the risk of atopic dermatitis* throughout the 1st year, compared to formulas made with intact cow's milk protein. The scientific evidence for this is limited and not all babies will benefit.
> **the most common allergy in infancy.*

Underneath this statement appears the following language: "GOOD START Gentle formula **should not be fed to infants who are allergic to milk or infants with existing milk allergy symptoms.** Not for allergy treatment" (bold type in original).

Additionally, your website at www.gerber.com bears the following statement:

> Comfort Proteins are easy for your baby to digest and may also provide protective benefits. Certain formulas made from 100% whey protein partially hydrolyzed—like milk-based GOOD START formulas—may reduce the risk of Atopic Dermatitis throughout the first year of life, compared to formulas made with intact cow's milk protein.**

The double asterisk is linked to the following statement, which appears in non-bold type: "**The scientific evidence is limited and not all babies will benefit. It is important to note that GOOD START formulas should not be fed to infants who are allergic to milk or to infants with existing milk allergy symptoms."

A health claim expressly or by implication characterizes the relationship between a substance and a disease or health-related condition [21 CFR 101.14(a)(1)]. Substance means a specific food or component of food [21 CFR 101.14(a)(2)]. Your product label identifies your infant formula product generally as being used "to reduce risk of developing allergies." Your product label and your website further assert that 100% whey partially hydrolyzed may reduce the risk of atopic dermatitis. Infant formulas are foods as defined in section 201(z) of the Act [21 U.S.C. § 321(z)], and partially hydrolyzed whey protein is an ingredient of infant formula, and thus a component of food. Your product as a whole and the 100 percent partially hydrolyzed whey that is a component of the product are substances within the meaning of 21 CFR 101.14(a)(2), and your label and website characterize the relationship of these substances to a disease or health-related condition (i.e., allergies, atopic dermatitis). Because the product label and your website bear health claims that were not authorized by FDA, the product is misbranded within the meaning of section 403(r)(1)(B) of the Act.

We have previously considered and denied a petition requesting authorization to

make a qualified health claim characterizing the relationship between the consumption of 100% partially hydrolyzed whey protein infant formula and reduced risk of food allergy in infants.**[1]** After reviewing the petition, the scientific evidence submitted with the petition, and other pertinent scientific evidence and information, FDA concluded that there is no credible evidence to support a qualified health claim relating the consumption of 100 percent whey protein partially hydrolyzed to a reduced risk of food allergy in infants. We are aware of no such credible evidence that has been developed since the time the petition was denied that would provide support for making a claim characterizing the relationship between the consumption of 100% partially hydrolyzed whey protein infant formula and reduced risk of food allergy in infants. If you are aware of additional evidence that would support a health claim by regulation or a qualified health claim, we encourage you to submit a petition pursuant to section 403(r)(4) of the Act [21 U.S.C. § 343(r)(4)]; see also FDA's guidance on qualified health claims, which includes the procedures for submitting qualified health claim petitions.**[2]**

Additionally, in a May 24, 2011, letter announcing that FDA would consider the exercise of enforcement discretion,**[3]** we articulated four claims for which we intend to consider the exercise of enforcement discretion, each of which references the "very little scientific evidence" or "little scientific evidence" linking the consumption of 100% whey-protein partially hydrolyzed infant formula with a reduction in the risk of atopic dermatitis. 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.

(bold type in original). Though the claims on your product label and your website asserting the limited evidence linking the benefit between consumption of "100% whey partially hydrolyzed" and atopic dermatitis are generally consistent with the claims suggested in the 2011 letter announcing the claims for which FDA would consider the exercise of enforcement discretion, your label and website fail to include the following statement: "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." As discussed further below, this statement provides essential information necessary to ensure the safety of consumers.

We further note that in your claim regarding atopic dermatitis that appears on your product label and your website, the substance characterized as having a relationship with atopic dermatitis is identified as a feeding formula exclusively made with "100% whey partially hydrolyzed." The substance that was the subject of the 2011 letter announcing that FDA would consider the exercise of enforcement discretion was an infant formula exclusively made with 100% whey-protein partially hydrolyzed. An infant formula made with 100% whey-protein partially hydrolyzed is not the same as

an infant formula made with 100% whey partially hydrolyzed because whey-protein and whey are different substances. Whey is the liquid obtained by separating the coagulum from milk, cream, and/or skim milk in cheese making and that is rich in lactose, minerals, vitamins, protein, and fat.**[4]**, **[5]** In contrast, "whey protein" is a mix of globular proteins (i.e., alpha-lactalbumin and beta-lactoglubulin) that are separated from "whey" into concentrate, isolate, or hydrolysate forms.**[6]** Evidence reviewed in our 2011 letter announcing our intention to consider the exercise of enforcement discretion for the qualified health claim on atopic dermatitis relied on studies that used formulas containing 100% whey-protein partially hydrolyzed. In addition, Gerber's Good Start Gentle Infant Formula label lists whey-protein concentrate as the first ingredient in the ingredient statement. As presently worded, "whey partially hydrolyzed" suggests to the consumer 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 we have seen no evidence to support the relationship between risk of atopic dermatitis and oligosaccharides, fats, and proteins, except for 100% whey-protein partially hydrolyzed. For all of the above-noted reasons, your product is misbranded within the meaning of section 403(r)(1)(B) of the Act.

Your product is also misbranded within the meaning of section 403(a)(1) of the Act, in that the labeling is misleading. Under section 201(n) of the Act [21 U.S.C. § 321(n)], one consideration in determining whether a product's labeling is misleading is the extent to which the labeling fails to reveal facts material in the light of such representations with respect to consequences which may result from the use of the article under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual. The labeling of your Gerber Good Start Gentle Infant Formula product and your website are misleading within the meaning of section 201(n) of the Act because your label and website each contain a qualified health claim regarding 100% whey protein partially hydrolyzed infant formula and atopic dermatitis, but neither your product label nor your website provide a statement regarding the need for parents of infants who are allergic or suspected to be allergic to milk to consult with a doctor regarding the baby's care and feeding choices.

As explained in the 2011 letter announcing that FDA would consider the exercise of enforcement discretion, without this information, the agency considers the use of a claim characterizing the relationship between 100% whey-protein partially hydrolyzed infant formula and atopic dermatitis to be misleading under sections 403(a)(1) and 201(n) of the Act, because it would fail to reveal facts material in the light of the representations being made and facts material with respect to consequences which may result from the use of these formulas. We consider the need for a statement advising consumers with infants suspected of having a milk allergy of the need for a doctor's supervision to be a necessary factor to prevent the qualified health claim regarding 100% whey protein partially hydrolyzed infant formula and atopic dermatitis from being misleading. Your label and website include the sentence regarding milk-sensitive infants ("Partially hydrolyzed formulas should not be fed to infants who are allergic to milk or to infants with existing milk allergy symptoms"), but neither provides the statement that a baby's care and feeding choices should be made under a doctor's supervision if the parent suspects that their infant is allergic to milk or if their infant is being fed a special formula for the treatment of allergy. Studies show that one hundred percent whey-protein partially hydrolyzed infant formulas may cause

allergic reactions in a significant percentage of infants allergic to milk. Such reactions can be serious and even life threatening, and feeding decisions in infants at risk for atopic dermatitis are most appropriately made under the guidance of a qualified healthcare professional.

Your website also fails to include the following information in bold type: "should not be fed to infants who are allergic to milk or to infants with existing milk allergy symptoms." As explained in the 2011 letter announcing that FDA would consider the exercise of enforcement discretion, the use of bold type is necessary in light of the significant public health risk that would be created by the feeding of these formulas to infants who are allergic to milk or to infants with existing milk allergy symptoms, and the fact that the articulation of a relationship between the consumption of 100% whey-protein partially hydrolyzed infant formula and a reduced risk of developing the allergic disease of atopic dermatitis could mislead consumers to think that these formulas are an appropriate choice for such infants. Therefore, because essential information is not included on the product label and other essential information is not displayed in a sufficiently prominent manner, this product is misbranded within the meaning of section 403(a)(1) of the Act because its labeling is misleading.

The above violations are not intended to be an all-inclusive list of deficiencies associated with your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the Act and its implementing regulations.

You should take prompt action to correct the violations described above. Failure to promptly correct the violations may result in legal action without further notice, such as seizure or injunction.

We also have a comment regarding the following claims that can be found on your website at **www.gerber.com (http://www.gerber.com/)**:

- "Atopic Dermatitis (aka eczema) is a chronic skin condition that affects nearly 1 in 5 babies by six months of age. If your baby is not exclusively breastfed starting her on a formula like GERBER GOOD START Gentle may reduce the risk of atopic dermatitis, the most common skin allergy in infants.*" The asterisk links to a separate portion of the website with one of the qualified health claims for which FDA has announced that we will consider the exercise of enforcement discretion.
- "100% whey partially hydrolyzed formulas may help reduce the risk of your baby developing atopic dermatitis, a type of allergic skin rash, when fed exclusively as a starter formula or as a supplement to breast milk when compared to intact cow's milk protein formulas.**" The double asterisk links to a separate portion of the website with one of the qualified health claims for which FDA has announced that we will consider the exercise of enforcement discretion.

There is no provision in FDA's 2011 letter announcing our consideration of the exercise of enforcement discretion that provides for separating the qualification language from the substance/disease link in the manner done on your webpage. We have concerns regarding the consumer's understanding of the limitations of the

science with regard to how the information in this qualified health claim is separately displayed. We encourage you to provide any consumer studies you may have that demonstrate that consumers understand the connection between the statements in spite of the separate manner in which the statements are displayed on your website.

Please respond to this letter within 15 working days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and steps being taken to prevent the occurrence of similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the correction.

Please send your reply to the U.S. Food and Drug Administration, Attention: Carrie Lawlor, Compliance Officer, Division of Enforcement, Office of Compliance, 5100 Paint Branch Parkway, College Park, MD 20740. You may also contact Ms. Lawlor via email at Carrie.Lawlor@fda.hhs.gov if you have any questions about this letter.

Sincerely,

/S/
William A. Correll, Jr.
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc: FDA **New Jersey District**

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[1] See Qualified Health Claims: Letter 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 (http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073313.htm)**.
[2] Available at **http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm053843.htm (http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm053843.htm)**.
[3] Available at **http://www.fda.gov/food/IngredientsPackagingLabeling/LabelingNutrition/ucm256731.htm (http://www.fda.gov/food/IngredientsPackagingLabeling/LabelingNutrition/ucm256731.htm)**.
[4] 2014 Food Chemicals Codex 9th Edition, Monograph
[5]http://www.merriam-webster.com/dictionary/whey
[6] 2014 Food Chemicals Codex 9th Edition, Whey Protein Concentrate Monograph

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