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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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