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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

IN RE GERBER PROBIOTIC SALES  
PRACTICES LITIGATION

Civil Action No. 12-835(JLL)(CLW)

**CORRECTED FIFTH  
CONSOLIDATED AMENDED  
COMPLAINT and  
DEMAND FOR JURY TRIAL**

Plaintiffs, by way of complaint against Defendant Gerber Products Company (“Gerber” or “Defendant”), individually and on behalf of all others similarly situated, say:

**NATURE OF THE ACTION**

1. This consumer-protection class action addresses the immune system-related misrepresentations Gerber has made and continues to make on the packaging and labeling, and throughout its nationwide marketing and advertising campaigns for its infant and children formula and cereal products containing a purported probiotic bacteria.

2. More specifically, this action relates to Defendant’s false and misleading representations made regarding the following products, which all contain Defendant’s immune system misrepresentations based on infusion of the same probiotic bacteria – “Bifidus BL™” (collectively, “the Products”):

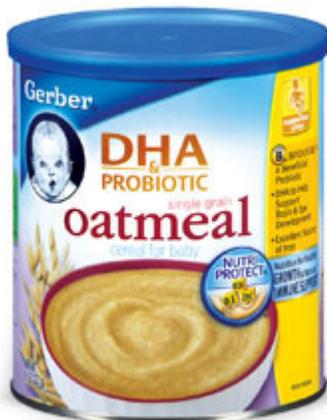
**Good Start Protect Infant Formula (Stages = Birth+ – Crawler (0 – 12 months) – Powder**



**Good Start 2 Protect Formula (Stages = Crawler & Toddler (9-24 months)) – Powder**



**DHA & Probiotic Cereal – Single Grain Oatmeal and Rice varieties (Stages = Supported Sitter, Sitter & Crawler (3 - 12 months))**



3. Defendant has manufactured, marketed and sold the Products since at least September 27, 2009. By at least September 27, 2009, Defendant began to manufacture, market and sell the Products as: Nestlé Good Start Protect Plus and Nestlé Good Start 2 Protect Plus. As of February 1, 2010, Gerber rebranded the Products and manufactured, marketed and sold the Products under the names Gerber Good Start Protect Plus, and Gerber Good Start 2 Protect Plus, containing the same or substantially the same false and misleading representations discussed below on the packaging and labeling and throughout Defendant's online advertising. Then, in early 2011, the Products were "renovated" or re-named, simply dropping the "Plus" from the Product names, with all other attributes, including the labeling and marketing message, remaining the same. However, the Gerber Good Start "Plus" formula Products still remain available for sale at discounters, such as Target, [www.drugstore.com](http://www.drugstore.com) and [www.diapers.com](http://www.diapers.com).

4. Defendant claims that the Products' significant immune system health benefits are the result of the infusion of a "probiotic" bacteria, specifically its trademarked probiotic Bifidus BL™, in the Products. However, numerous studies show the Products do not and cannot provide the immune-related health benefits Defendant claims. Thus, Defendant's representations are false, misleading and reasonably likely to deceive the public.

5. Defendant makes these false and misleading statements on the Products to increase and maintain the branding premium associated with the Gerber name. That is, Geber has positioned the Products as premium products by virtue of the attributes associated with the brand, which are reinforced by falsely advertised immune system benefits not associated with its own Gerber formula and cereal products, or branded competitor and private label formula and cereal products. Gerber does this to maintain the pricing of the product and to obtain new purchasers.

6. Prominently placed on its packaging and labeling, Gerber also represents that its formula products at issue contain “IMMUNIPROTECT™,” which is “beneficial cultures [that] provide advanced immune system support.” IMMUNIPROTECT™ contains the trademarked Bifidus BL probiotic bacteria. Similarly, Gerber represents its DHA & Probiotic cereal, which also contains Bifidus BL, will “help support a healthy immune system.” Gerber’s marketing department chose the “IMMUNIPROTECT™” and “BIFIDUS BL™” names to deceptively imply that the Products provide immunity health benefits for infants and children less than two years old. Indeed, the marketing strategy of including the word, “Protect” in the Good Start Protect Products highlights that the purported benefit of the product – the support of a baby or infant’s growing immune system, which could help protect them against illness – is the Products’ primary distinguishing feature from other brands and a deceptive marketing hook. *See* Exhibits A (collection of exemplar labeling for the Good Start formula products at issue) and B (collection of exemplar labeling for the DHA & Probiotic Cereal products at issue) attached hereto.

7. To reinforce the false and deceptive immune system message, Gerber represents that the Products’ “advanced” immune health benefits are also due to the fact they all contain Bifidobacterium (Bifidus BL), which is found in breastmilk. For example, Gerber states “For healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding 100% whey-protein partially hydrolyzed infant formula, like GOOD START Protect 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 first year of life.” On all of the labeling at issue, Gerber repeats and reinforces its false and deceptive breastmilk claim about the Bifidus BL in the Products. *See* Exhibit A (both the front and back labels for Good Start Protect

and Good Start 2 Protect formulas makes breastmilk representations, including “Specially Made with Nutrients found in Breastmilk,” “like those naturally found in breastmilk,” and “**♥GERBER RECOMMENDS BREASTMILK AS THE BEST START FOR BABIES,**” which is immediately followed by the sentence “Provides the live and active probiotic cultures Bifiobacterium lactis. Bifidobacteria are the most abundant type of culture found in the digestive system of breastfed babies.”) (emphasis in original), B (labeling for DHA & Probiotic Cereals states “*Provides the live and active probiotic cultures Bifidobacterium lactis. Bifidobacteria are the most abundant type of cultures found in the digestive system of breastfed babies.*”) (emphasis in original).

8. Gerber’s representations are designed to induce consumers, unaware that healthy babies’ bodies already maintain the proper balance of intestinal bacteria, to buy the Products. Gerber advertises the Products as the only formulas and cereals that include probiotics that will strengthen and support the immune systems of young children. However, Defendant’s marketing message is false and deceptive, as the “probiotic” bacteria in the Products do not perform as advertised, and scientific studies discussed herein demonstrate that probiotic supplementation in infant formula does not support infant immunity or provide the advertised health benefits because, among other reasons, such supplementation does not (a) decrease the levels of harmful pathogens in babies’ intestinal microflora, (b) increase the levels of good bacteria in babies’ intestinal micro-flora, or (c) reduce infections.

9. For example, a study published in 2012 concluded that data did “not support the routine supplementation of term infant formula with synbiotics, probiotics or prebiotics” because the addition of either probiotics or prebiotics (non-digestible food ingredient that stimulates the growth of bacteria – e.g., certain fibers) did not increase good bacteria or decrease pathogens, did

not have a significant effect on stool consistency, and did not decrease incidence of diarrhea as compared to outcomes for infants who were fed unsupplemented formula. Further, the data showed no difference in the frequency of infections between groups fed formula supplemented with synbiotics (probiotics and prebiotics combined) and the control groups fed unsupplemented formula.

10. The American Academy of Pediatrics (“AAP”) is the preeminent authoritative resource for parents and pediatricians when it comes to issues relating to pediatric health. The AAP recommends breastmilk as the “exclusive” source of a baby’s nutrition for the first six months of its life and further emphasizes that breastfeeding should be continued for at least the first year. *See Breastfeeding and the Use of Human Milk*, Pediatrics, Official Journal of the American Academy of Pediatrics, at page e828 (Feb. 27, 2012). The AAP states that the advantages of breastfeeding include “health, nutritional, immunologic, developmental, psychologic, social, economic, and environmental benefits.” *Id.* The AAP further states that “Research and practice ... have reinforced the conclusion that breastfeeding and the use of human milk confer *unique nutritional* and nonnutritional benefits to the infant and the mother, and, in turn, optimize infant, child, and adult health as well as child growth and development. Recently, published evidence-based studies have confirmed and quantitated the risks of not breastfeeding. Thus, infant feeding should not be considered a lifestyle choice but rather as a basic health issue.” *Id.* (emphasis added). Indeed, “[b]reast milk is widely acknowledged as the most complete form of nutrition for infants, with a range of benefits for infants’ health, growth, immunity and development.” *See Healthy People 2010, Centers for Disease Control and Prevention*, Atlanta, Georgia.

11. Additionally, mothers synthesize antibodies when they ingest, inhale, or otherwise come in contact with a disease-causing agent. Each antibody a mother makes is “specific to that agent; that is, it binds to a single protein, or antigen, on the agent and will not waste time attacking irrelevant substances. Because the mother makes antibodies only to pathogens in her environment, the baby receives the protection it most needs-against the infectious agents it is most likely to encounter...” See Newman, Jack, M.D., *How Breastmilk Protects Newborns* (1995). As stated by the American Pregnancy Association, “Leukocytes are living cells that are only found in breast milk. They help fight infection. It is the antibodies, living cells, enzymes, and hormones that make breast milk ideal. These cannot be added to formula.” Gerber’s Products do not contain antibodies specific to a child’s environment like breast milk does.

12. Because experts unanimously agree breastmilk is best for infants, Defendant cannot recommend its Products over breastfeeding. As a further marketing gimmick to make the choice to bottle feed more palatable, Defendant adds ingredients to the Products so that it can claim on its packaging and labeling, and throughout its marketing and advertising campaign that the Products possess nutritional qualities that are nearly equivalent to those of breastmilk. See Exhibits A-B attached.

13. Throughout its advertising, including on the Products’ labeling, Defendant also claims that the probiotics it adds to the Products are “like those promoted by breastmilk.” In truth, experts agree that breastmilk is demonstrably superior to formula in terms of providing nutrition and health benefits to infants that go well beyond just the benefits that can be provided by the ingredients in breastmilk. Thus, it is deceptive and misleading for Defendant to sell the Products as near-equivalents to breastmilk when infant and follow-on formula cannot and does

not provide the level of benefits offered from breastfeeding. *See, e.g., Bakker-Zierikzee et al.* (2006) (discussed below).

14. Through its advertising, Gerber “define[s] the issue of infant feeding in both the scientific world...and in its wider social context, reframing perceptions of what is appropriate and what is not.” *Baby Formula: What Baby Formula Makers Won’t Tell You About Formula*, Ecologist Magazine (2006). As such, Defendant’s advertising has a material impact on beliefs of consumers. For example, a “2005 NCT/UNICEF study in the UK determined that one third of British mothers who admitted to seeing formula advertisements in the previous six months believed that infant formula was as good or better than breastmilk.” *Id.*

15. Contrary to Defendant’s representations, scientific evidence proves that breastmilk provides unique nutritional benefits that Defendant’s Products do not provide.

16. In addition to the infant and toddler formulas, Gerber also manufactures, advertises and sells DHA & Probiotic Cereals in Rice and Oatmeal varieties. Like the formula at issue, Defendant’s cereal products at issue also are labeled and advertised as providing immune system benefits to healthy and unhealthy infants and toddlers because of the inclusion of a “beneficial probiotic” bacteria culture, Bifidus BL. *See* Exhibit B attached (the labeling for Defendant’s DHA & Probiotic Cereal products). However, scientific evidence shows that the inclusion of “Bifidus BL” in the Products does not support or strengthen the immune system. Thus, contrary to Defendants’ marketing and advertising, the inclusion of a probiotic bacteria culture in the Products does not provide any additional benefits as compared to predecessor products and similar products that do not contain probiotics.

17. Scientific studies demonstrate that probiotic supplementation in infant formula does not support infant immunity or provide the advertised health benefits, including because

such supplementation does not decrease the levels of pathogens in babies' intestinal microflora, increase the levels of good bacteria in babies' intestinal microflora, or reduce infections.

18. Scientific studies also show that probiotic supplementation is not associated with fewer episodes of diarrhea, a lower incidence of colic, spitting up/ regurgitation, restlessness, vomiting.

19. Defendant claims in its marketing, advertising and packaging that these health-related claims are based on "studies" and "research," implying that there is a proven scientific basis to support Defendant's health claims pertaining to the Products. In fact, the body of scientific evidence on probiotic supplementation in infant formula shows that the probiotic ingredient in the Products *does not* support the infant immune system and *does not* otherwise provide the advertised health benefits.

20. Additionally, no "studies" or "research" have demonstrated that the supplementation of formula supports Defendant's claim that the Products are really equivalent to breastmilk. In fact, scientific evidence proves that, contrary to Defendant's advertising, formula supplemented with probiotics does not provide breastmilk-quality nutrition.

21. Defendant conveyed and continues to convey to Plaintiffs and other consumers its uniform health claims about the Products prominently and conspicuously on the packaging and labeling, and throughout its other marketing and advertising for the Products, using a variety of media, including the Internet, television advertisements, print advertisements, press releases, in-store sampling, and point-of-sale displays.

22. As a result of the misleading messages conveyed through its advertising campaign, Gerber has charged a significant price premium for the Products over private label

formulas and cereals and, for periods of time, other branded formula and cereal products, including its own, that do not contain probiotics or advertise significant immune health benefits.

23. Plaintiffs bring this action on behalf of themselves and all other similarly situated consumers in the United States, to halt the dissemination of Defendant's deceptive and false advertising message about the Products, and to correct the false and misleading perception they have created in the minds of consumers who have purchased the Products. Plaintiffs allege violations of applicable state consumer protection statutes, as well as claims for breach of express warranty, breach of the implied warranty of merchantability and unjust enrichment.

### **PARTIES**

24. Plaintiff Irene Dourdoulakis is a citizen of the State of New Jersey, residing in Bergen County, New Jersey. From August 2009 through August 2010, Plaintiff Dourdoulakis purchased Gerber DHA & Probiotic cereals from Shoprite in Succusanna and Byram, New Jersey, and Pathmark in Landen, New Jersey. The retail price for an 8-ounce package of Gerber DHA & Probiotic cereals during that time period was approximately \$3.00. Plaintiff Dourdoulakis purchased the Gerber DHA & Probiotic cereals in reliance on Gerber's false and misleading claims that the Products contained probiotic bacteria strains that provide immunity-related health benefits and are near-equivalents to breastmilk. Plaintiff Dourdoulakis read and relied upon these claims made on the Gerber DHA & Probiotic cereal products' labeling, on Gerber's website, and in print advertisements. Plaintiff Dourdoulakis would not have purchased and paid a premium for the Gerber DHA & Probiotic cereals but for Gerber's misrepresentations, and she suffered injury in fact and lost money as a result of Gerber's deceptive, unfair, and fraudulent practices described herein.

25. Plaintiff Shavonda Hawkins is citizen of the State of California, residing in San Diego County, California. Beginning in or about December 2007 and continuing each month through July 2010, Plaintiff Hawkins purchased Gerber DHA & Probiotic Single Grain Cereal (Oatmeal) and Gerber DHA & Probiotic Single Grain Cereal (Rice) from Food for Less at 312 Euclid Avenue, San Diego, California, and Ralphs at 901 Euclid Avenue, National City, California. Plaintiff Hawkins paid approximately \$4.00 for each box of cereal purchased, and approximately \$9.00 for each canister of cereal purchased. Plaintiff Hawkins purchased the Gerber DHA & Probiotic Single Grain Cereal (Oatmeal) and Gerber DHA & Probiotic Single Grain Cereal (Rice) products in reliance on Gerber's false and misleading claims in its television advertisements and on the products' labeling that the DHA & Probiotic Single Grain Cereal (Oatmeal) and Gerber DHA & Probiotic Single Grain Cereal (Rice) products contained probiotic bacteria strains that provide immunity-related health benefits and are near-equivalents to breastmilk. Plaintiff Hawkins would not have purchased and paid a premium for the Gerber DHA & Probiotic Single Grain Cereal (Oatmeal) and Gerber DHA & Probiotic Single Grain Cereal (Rice) products but for Gerber's misrepresentations, and she suffered injury in fact and lost money as a result of Gerber's deceptive, unfair, and fraudulent practices described herein.

26. Plaintiff Saba Siddiqi is a citizen of the State of New York, residing in Nassau County, New York. During the Class Period, in or about 2009 through early 2011, Plaintiff Siddiqi began purchasing Gerber DHA & Probiotic Single Grain Cereal at Stop & Shop and CVS for her child. Plaintiff Siddiqi paid approximately \$4.00 for the Gerber DHA & Probiotic Single Grain Cereal. During the Class Period, Plaintiff viewed and specifically relied upon Defendant's claims made in television advertisements and by reading the representations made on the product label concerning the probiotic benefit of the Gerber DHA & Probiotic Single

Grain Cereal, purchased Gerber Products in reliance on these claims, and sustained injury in fact and lost money as a result of the wrongful conduct described herein. Plaintiff Siddiqi would not have purchased and paid a premium for Gerber DHA & Probiotic Single Grain Cereal but for Gerber's misrepresentations, and she suffered injury in fact and lost money as a result of Gerber's deceptive, unfair, and fraudulent practices described herein.

27. Defendant Gerber Products Company is incorporated under the laws of the state of Michigan with its principal place of business at 12 Vreeland Road, Florham Park, New Jersey 07932. The conduct at issue substantially emanates from New Jersey. For example, many of the marketing representations concerning the Products were disseminated through Gerber's Florham Park, New Jersey headquarters. Gerber, through its Nestlé Nutrition subsidiary, employs many of the individuals involved in the development, marketing and advertising of the Products in Florham Park, New Jersey. All of the marketing decisions underlying Plaintiffs' allegations were made in New Jersey. Additionally, the marketing and medical affairs departments at Nestlé Nutrition are located at the Florham Park campus.

28. By at least September 27, 2009, Defendant began to manufacture, market and sell the Products at issue. As the manufacturer, distributor, and marketer of the Products, including being the entity which trademarked the probiotic ingredient at issue, Defendant possesses specialized knowledge regarding the content and effects of the ingredients in the Products and knew or should have known that its health-benefit claims were false and misleading.

29. Defendant failed to disclose to Plaintiffs and the Class and Subclasses (defined herein) that the Products do not provide the specific health benefits claimed, specifically that they are not superior to other products or predecessor products nor do they provide the immune

health benefits represented and that well-conducted, clinical studies have found the ingredients in the Products to be ineffective in providing the immune health benefits represented by Defendant.

### **JURISDICTION AND VENUE**

30. This Court has original jurisdiction over this nationwide class action under 28 U.S.C. §1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum or value of \$5 million and is a class action in which at least one class member is a citizen of a state different from Gerber. Further, more than two-thirds of the members of the class are citizens of a state different from Gerber.

31. Venue is proper in this District pursuant to 28 U.S.C. §1391(a) because Gerber resides in this District and in that many of the acts and transactions giving rise to this action occurred in this District.

### **FACTUAL ALLEGATIONS**

32. At all times relevant herein, Defendant advertised, marketed, distributed, and sold the Products to consumers in the United States, transacting business in this District and throughout the United States. The Products at issue are offered as part of the *Start Healthy, Stay Healthy*<sup>TM</sup> nutrition program, which Defendant promotes as “a unique, integrated nutrition solution that provides products, information and guidance all ***backed by rigorous science and research*** to help parents make the right nutritional choices for their little ones from birth to 4 years. *Start Healthy, Stay Healthy* includes ***scientifically advanced***, high-quality infant formula, and baby, toddler and preschooler foods.”

33. Through the *Start Healthy, Stay Healthy*<sup>TM</sup> nutrition program, Defendant offers food for infants and toddlers based on developmental milestone stages. The “Birth+” stage is intended for infants 0 – 12 months of age; the “Supported Sitter” stage is intended for infants six

months old to 12 months; and the “Crawler” stage is intended for toddlers who have begun to crawl, pull themselves up, and attempt to self-feed with their own fingers, all developmental milestones that occur in children under the age of two. The Products at issue are offered within these milestone-based stages, and thus, are intended for consumption by children under the age of two years old.

34. Defendant touts its research capabilities and states the *Start Healthy, Stay Healthy*<sup>TM</sup> nutrition program is backed by “rigorous nutrition research.” According to the Gerber website, this so-called “rigorous nutrition research” led to the introduction of the Products into the marketplace, stating: “How Research Benefits Your Children, Nestlé and Gerber have helped achieve many nutrition breakthroughs. In 2007, Nestlé introduced the first infant formula in the United States with probiotics – beneficial *B. Lactis* cultures like those found in breastmilk – designed to support a baby’s healthy immune system.”

35. On August 16, 2007, Nestlé (which acquired Gerber two weeks later on September 1, 2007) introduced the first infant formula containing probiotics in the United States. In its announcement, the research behind “beneficial cultures,” or probiotics, was highlighted:

**NESTLÉ® GOOD START® NATURAL CULTURES<sup>TM</sup> Gives Moms a New Way to Help Support a Baby’s Healthy Immune System**

Glendale, Calif., (August 16, 2007) – Today, moms have a new way to provide protective benefits to their babies with the launch of NESTLÉ GOOD START NATURAL CULTURES. This innovative product is the first and only routine formula in the U.S. with probiotics, *beneficial cultures like those naturally promoted by breastmilk to support an infant’s healthy immune system. Years of scientific research have shown that adding beneficial cultures to a baby’s diet can offer health benefits beyond basic nutrition.*

Breastmilk is the ideal food for infants. For infants who do not receive the benefits of exclusive breastfeeding, *GOOD START NATURAL CULTURES provides complete nutrition and the beneficial cultures, BIFIDUS BL. Research has shown that these cultures can help support a baby’s healthy immune system in many ways, including increasing levels of key antibodies and supporting the*

*natural protective barrier in a baby's digestive tract.* A healthy immune system provides a baby with important natural defenses.

*“GOOD START NATURAL CULTURES goes a step further than providing basic nutrients for growth and development.* The inclusion of these beneficial cultures makes it truly the next generation of infant formula,” said José Saavedra, M.D., Medical and Scientific Director, Nestlé Nutrition. *“This is a major step toward providing formula-fed infants a part of the immune-related benefits that only breastfeeding can entirely provide,”* he added.

GOOD START NATURAL CULTURES also *contains DHA & ARA for brain and eye development,* plus COMFORT PROTEINS, gentle 100 percent whey protein broken down to be easy-to-digest in a baby's developing tummy. GOOD START NATURAL CULTURES is available nationwide in 12 ounce and 24 ounce powder sizes.

*Nestlé has global expertise in the research and development of food products containing probiotics. For more than 15 years and in 30 countries, Nestlé has been nourishing infants with formulas containing beneficial cultures.* To learn more about GOOD START NATURAL CULTURES and how beneficial cultures help support a healthy immune system, consumers are encouraged to visit <http://www.nestlegoodstart.com> for detailed background information and insights from medical experts.

#### About Nestlé Nutrition

Nestlé Nutrition, part of Nestlé S.A., the world's largest food company, is dedicated to infant, healthcare, and performance nutrition as well as weight management. With 140 years of global food experience that began with the creation of the world's first commercial infant food, Nestlé is a leader in worldwide food and nutrition research. Nestlé Nutrition offers the very best baby Resource Center, a program that supports expecting and new parents in the U.S. with expert advice on pregnancy, infant care, and nutrition. For more information, consumers can visit <http://www.verybestbaby.com>.

[Emphasis added.]

36. In 2008, Nestlé introduced a follow-on formula, Good Start 2 Natural Cultures, with probiotics aimed at older babies and toddlers. This press release also highlighted the purported “[y]ears of scientific research” behind offering “beneficial cultures” to babies and toddlers:

**NESTLÉ INTRODUCES FIRST AND ONLY OLDER-BABY FORMULA  
IN THE U.S. CONTAINING BENEFICIAL PROBIOTIC CULTURES**

— NESTLÉ GOOD START 2 NATURAL CULTURES Gives Parents a New Way to Help Support Toddler’s Healthy Immune System —

FLORHAM PARK, New Jersey (July 23, 2008) - Nestlé Nutrition is expanding its line of innovative formulas with the launch of *NESTLÉ GOOD START 2 NATURAL CULTURES*, giving parents a new way to provide protective benefits to their older babies and toddlers nine to 24 months of age. *This breakthrough product is the first and only older-baby formula in the U.S. with the probiotic, BIFIDUS BL™ — beneficial cultures like those found in breast milk that help support babies’ healthy immune system. Years of scientific research have shown that adding beneficial cultures to a baby’s diet can offer health benefits beyond basic nutrition.*

Experts agree that breast milk is the ideal source of nutrition and protection for babies. However, when formula is chosen or when there is a nutritional gap for older babies and toddlers between what they eat and what they need, *GOOD START 2 NATURAL CULTURES offers 100 percent complete nutrition and a unique combination of benefits no other formula provides.*

*“GOOD START 2 NATURAL CULTURES provides nutritional insurance for older babies as they transition from being formula-fed or breast-fed to something more developmentally appropriate like a sippy cup,”* said José Saavedra, M.D., Medical and Scientific Director, Nestlé Nutrition. *“The inclusion of these beneficial cultures is a major step toward providing older babies a part of the immune-related benefits that only breastfeeding can entirely provide,”* he added.

GOOD START 2 NATURAL CULTURES complements the GOOD START family of formulas, including GOOD START NATURAL CULTURES, the first and only infant formula with BIFIDUS BL beneficial cultures. *Research has shown that these cultures can help support a baby’s healthy immune system in many ways, including increasing levels of key antibodies and supporting the natural protective barrier in a baby’s digestive tract. A healthy immune system provides babies with important natural defenses.* Breast milk is still the ideal food for infants, but these products offer crucial benefits to those infants who are not exclusively breastfed.

Similar to other GOOD START formulas, GOOD START NATURAL CULTURES and GOOD START 2 NATURAL CULTURES *also contains DHA & ARA for brain and eye development*, plus COMFORT PROTEINS — gentle 100 percent whey protein broken down to be easy-to-digest in a baby’s developing tummy. GOOD START 2 NATURAL CULTURES is available nationwide in 24 ounce powder sizes, while GOOD START NATURAL CULTURES is available in 12 ounce and 24 ounce powder sizes.

Nestlé has global expertise in the research and development of food products containing probiotics. For more than 15 years and in 30 countries, Nestlé has been

nourishing infants with formulas containing beneficial cultures. To learn more about GOOD START 2 NATURAL CULTURES and GOOD START NATURAL CULTURES and how beneficial cultures help support a healthy immune system, visit [gerber.com](http://gerber.com) for detailed background information and insights from medical experts.

#### About Gerber

Gerber Products Company officially joined the Nestlé Nutrition Family — part of Nestlé S.A — on September 1, 2007. Combining resources, Nestlé and Gerber are leveraging research and expertise to become the leaders in early childhood nutrition. With headquarters in Florham Park, N.J. and manufacturing facilities located globally and across the U.S., Gerber is a worldwide provider of more than 200 food and baby care products that are labeled in 16 different languages and distributed to 80 countries. From GERBER® 1st FOODS® cereal and purees to GRADUATES® meals and snacks, the Gerber product line covers each phase of early childhood development with diverse flavors and textures. Since its founding in 1928, Gerber has been committed to helping parents raise happy, healthy babies through extensive research aimed at understanding and improving infant and toddler nutrition and feeding. In 2002, the Company launched the Start Healthy, Stay Healthy™ initiative, providing stage-by-stage information, tips, tools and advice for parents and their children 0-48 months. By laying a foundation of good nutrition and establishing good eating behaviors early, parents can help their children prevent later life health problems like obesity and related diseases. Over the last six years, Gerber's Start Healthy, Stay Healthy™ initiative has delivered groundbreaking research, science-based advice and practical feeding guidelines for parents to adopt. For more information about Gerber, please visit [www.gerber.com](http://www.gerber.com), or contact the Gerber Parents Resource Center (U.S. only) at 1-800-4-GERBER.

#### About Nestlé Nutrition

Nestlé Nutrition, part of Nestlé S.A., the world's largest food company, is dedicated to infant, healthcare, and performance nutrition and weight management. With 140 years of global food experience that began with the creation of the world's first commercial infant food, Nestlé is a leader in worldwide food and nutrition research. For clinical information about Nestlé Infant Nutrition products in the U.S., medical professionals can visit [www.nestleinfantnutrition.com](http://www.nestleinfantnutrition.com) or call the Medical Professional Information Line at (800) 510-7494. Nestlé Nutrition also offers the Start Healthy, Stay Healthy™ Resource Center, a program that supports expecting and new parents in the U.S. with expert advice on pregnancy, infant care, and nutrition. For more information, consumers can visit [www.gerber.com](http://www.gerber.com).

[Emphasis added.]

37. In approximately August 2008, Gerber began to manufacture, market and sell the following Nestlé Good Start products: Nestlé Good Start Natural Cultures formula and Nestlé Good Start 2 Natural Cultures.

38. By at least September 27, 2009, the Products were “renovated” and Gerber began to manufacture, market and sell the following Nestlé Good Start “Plus” formulas: Nestlé Good Start Protect Plus and Nestlé Good Start 2 Protect Plus.

39. In 2010, the Products were renovated again, this time to take advantage of Gerber’s marketing caché in the U.S. The Nestlé-branded Good Start products were transitioned to the Gerber name brand. Defendant continued to emphasize the purported scientific research behind adding the “probiotic” Bifidus BL to its Good Start formula:

**Meet the Newest Member of the Gerber Family! Gerber® Good Start® Infant Formula**

(FLORHAM PARK, New Jersey) – February 1, 2010 – A child’s nutrition journey begins at birth, and for more than 80 years, GERBER has been part of that journey helping parents raise happy, healthy babies. Now, Gerber is pleased to introduce GOOD START® formula as the newest member of the GERBER family of early childhood nutrition products.

“When it comes to childhood nutrition, GERBER is the name moms know and trust,” says Rick Jentis, head of infant formula and cereal marketing at Nestlé Nutrition. “Our commitment to science-based innovation and our portfolio of quality products has really established us as a leader in nutrition, health and wellness. Now we are proud to offer parents GOOD START® infant formula under the GERBER brand. Nestlé believes that breastfeeding is best and provides ideal nutrition for infants. So whether a mom chooses to breastfeed or formula feed, GERBER now offers a comprehensive nutrition system from birth to 48 months.”

Nestlé believes that GOOD START formula provides mothers, who cannot or who choose not to breastfeed, a healthy breastmilk alternative with unique features from the GERBER brand she knows and trusts.

Exclusive COMFORT PROTEINS® Ease Digestion

***The GERBER® GOOD START brand now replaces NESTLÉ® GOOD START® nationwide.*** GOOD START formulas are – and have always been – the only routine milk-based infant formula to offer partially hydrolyzed 100% whey

protein – what GERBER calls COMFORT PROTEINS® – in the U.S. COMFORT PROTEINS® result from a unique two-step process exclusive to GOOD START formula, and are designed to be gentle on a baby’s tummy. The process begins with 100% whey protein, the highest-quality protein available in infant formula.

Clinical evidence has shown that formula made with partially hydrolyzed 100% whey protein empties from babies’ tummies faster than other routine formulas, which may help reduce the potential for spitting up.

Probiotics for a Healthy Immune System

***GERBER® GOOD START® PROTECT PLUS® formulas were the first infant formulas with BIFIDUS BL™ - beneficial cultures like those found in breastmilk to help support a baby’s healthy immune system. Scientific research has shown that these beneficial cultures can help support babies’ healthy immune systems in many ways, including increasing levels of key antibodies, and helping to support the natural protective barrier in the digestive tract - where 70% of the body’s immune system is found.***

Product Line

GOOD START offers both milk-based and soy-based formulas and is available nationwide in six varieties, including:

- GERBER® GOOD START® Gentle PLUS™ Formula
- GERBER® GOOD START® Protect PLUS® Formula
- GERBER® GOOD START® Soy PLUS™ Formula
- GERBER® GOOD START® 2 Gentle PLUS™ Formula
- GERBER® GOOD START® 2 Protect PLUS® Formula
- GERBER® GOOD START® 2 Soy PLUS™ Formula

About Nestlé Nutrition and Gerber

Nestlé Nutrition, part of Nestlé S.A., the world leader in nutrition, health and wellness is dedicated to infant nutrition, healthcare nutrition, and performance nutrition and weight management. Gerber Products Company, founded in 1928, officially joined the Nestlé family on September 1, 2007. Nestlé and Gerber’s combined resources and scientific research expertise have enabled the company to become a worldwide leader in early childhood nutrition. Gerber produces more than 200 food products, all of which are a part of Nestlé’s proprietary Start Healthy, Stay Healthy™ integrated nutrition system. Start Healthy, Stay Healthy™ combines products, educational resources and services that are designed to encourage the early establishment of healthy eating habits in children from birth to preschool.

For more information on Nestlé Nutrition, Gerber and GOOD START Infant Formulas, visit [www.gerber.com](http://www.gerber.com).

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[Emphasis added.]

40. In early 2011, the Products were renovated one more time to drop the “Plus” from the Product names. However, the Good Start “Plus” Products still remain available for sale throughout the United States.

41. Since at least September 27, 2009 to the present and continuing, Defendant has manufactured, labeled, marketed, advertised, distributed, and sold the Products to the public throughout the United States, using various media as described herein.

42. Defendant primarily advertises and promotes the Products for sale through the front-of-pack and back-of-pack labeling claims. Exemplars of the labeling for the Products at issue are attached as Exhibits A and B to this Complaint.

43. Defendant also uses online advertising, including at its website [www.gerber.com](http://www.gerber.com), to advertise and promote the Products and the *Start Healthy, Stay Healthy*<sup>TM</sup> nutrition campaign for infants and toddlers.

### **Probiotic Bacteria**

44. The use of bacteria for probiotic use is in its scientific infancy. In fact, scientists have yet to settle on a definition of probiotic. The World Health Organization’s definition of probiotics is “Live microorganisms, which, when administered in adequate amounts, confer a health benefit on the host.” The National Center for Complementary and Alternative Medicine (“NCCAM”), one of the centers that makes up the National Institutes of Health, adds that probiotics have an ultimate goal of prevention and treatment of disease.

45. On its website, Defendant provides a definition of probiotics:

The word “probiotic” literally means “for life.” The World Health Organization describes probiotics as beneficial cultures that—when consumed in adequate amounts—provide specific health benefits. These benefits vary depending on the

types and quantities of beneficial cultures or probiotics that are used, and range from aiding digestion to supporting a healthy immune system.

The specific health benefits of probiotics vary with the types of beneficial cultures. One important benefit is supporting a healthy immune system. Probiotics can provide this benefit by increasing your baby's levels of key antibodies.

About 70% of the cells of the immune system are found in the digestive tract, which makes it a central part of the body's immune system. Another way probiotics help support your little one's healthy immune system is by helping to maintain a healthy balance of cultures in her digestive tract—which supports the natural protective environment found there.

46. A probiotic is defined by its genus (e.g., *Bifidobacterium*), species (e.g., *lactis*) and strain designation (often a combination of letters or numbers, e.g., Bb-12). Any benefits attributable to probiotic bacteria are “strain-specific.” Thus, study results testing one strain of probiotics (e.g., the *Bifidobacterium lactis* Bb-12 culture in General Mills' YoPlus yogurt) cannot be extrapolated to another probiotic strain (e.g., the *Bifidobacterium animalis* DN-173 010 in Dannon's Activia yogurt).

47. Because the benefits of probiotic bacteria, if any, are specific to the type and amount of bacteria in a product, a joint working group of the Food and Agriculture Organization of the United Nations (“FAO”) and the World Health Organization (“WHO”) recommended that the following information be described on the product label: “[g]enus, species and strain designation” and “[m]inimum viable numbers of each probiotic strain at the end of the shelf-life.”

48. Scientists have not yet mapped the tens of thousands of bacteria strains in the human body's intestinal flora, and do not know whether increasing one type of bacteria provides health benefits. It is also not known whether increasing one type of bacteria can prove harmful. The European Food Safety Authority (“EFSA”), established by the European Union to promote food safety and evaluate food claims, reports that “The numbers/proportions of bacterial groups

that would constitute a ‘balanced/healthy’ intestinal flora have not been established. Increasing the number of any groups of bacteria is not in itself considered as beneficial.” EFSA states that:

The gastrointestinal tract is populated with a large number of microorganisms and it normally acts as an effective barrier against generalized systemic infections. It is not possible to provide the exact number of bacterial groups that would constitute a beneficial microbiota.

49. There is almost no scientific support for the notion that healthy people, such as those targeted by Defendant, benefit from bacterial supplements, such as the bacteria at issue. If probiotic bacteria do have any health benefits, they must survive the digestive tract in sufficient quantities to achieve the possible benefit. However, there is no consensus on the quantities of probiotics people might need to ingest, or for how long, in order to achieve a probiotic effect, if probiotics have any such effect in healthy people.

#### **Defendant’s Probiotic-Related Health Claims**

50. Since the launch, Defendant has consistently conveyed the message to consumers throughout the United States that the Products, with their unique, patented probiotic bacteria Bifidus BL, provides advanced immune system benefits and nutrition similar to breast milk. According to Defendant, the benefits of the Products are backed by rigorous scientific studies supporting the “first formula in the U.S. to have the probiotic *Bifidobacterium lactis*.” These claims are not substantiated and are factually baseless.

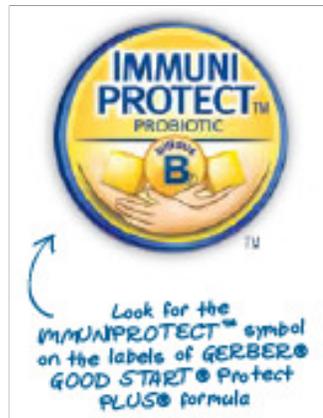
51. Defendant adds a purported “probiotic” bacteria, *Bifidobacterium lactis* Bb-12, to Good Start Protect and Good Start 2 Protect formulas and its DHA & Probiotic cereals. However, probiotic supplementation in infant formula does not support infant immunity or natural defenses as Defendant claims. Scientific evidence demonstrates that probiotic supplementation does not decrease levels of pathogens in babies’ intestinal microflora, increase

the levels of good bacteria in babies' intestinal microflora, or reduce infections. In fact, increasing one type of bacteria may even prove harmful.

52. **Good Start Protect** and **Good Start 2 Protect Formula** are promoted on the front-of-the-label as having “Advanced Immune Support,” “IMMUNIPROTECT PROBIOTIC,” and “Complete Nutrition & Bifidus BL™ for **ADVANCED IMMUNE SUPPORT.**” See Exhibit A. The side-of-the-label ingredient list states these formulas contain following probiotic: “*B. LACTIS* CULTURES.” The labeling for Good Start Protect also states: “Specially Made with Nutrients found in Breastmilk,” “like those naturally found in breastmilk,” and “♥GERBER RECOMMENDS BREASTMILK AS THE BEST START FOR BABIES,” which is immediately followed by the sentence “Provides the live and active probiotic cultures Bifiobacterium lactis. Bifidobacteria are the most abundant type of culture found in the digestive system of breastfed babies.” *Id.* (emphasis in original). Similarly, the labeling for Good Start Protect 2 states: “♥GERBER RECOMMENDS BREASTMILK AS THE BEST START FOR BABIES,” which is immediately followed by the sentence “Provides the live and active probiotic cultures Bifiobacterium lactis. Bifidobacteria are the most abundant type of culture found in the digestive system of breastfed babies.” *Id.* (emphasis in original). The 12.4 oz. powder variety also includes a graphic on the label stating: IMMUNIPROTECT – supports healthy growth, includes a special blend of antioxidant vitamins C & E, zinc, vitamin A and probiotic cultures, *like those naturally found in breastmilk.*” (emphasis added).

53. Defendant specifically introduced the IMMUNIPROTECT™ symbol (below) to “help [consumers] recognize Gerber foods with important vitamins and minerals that support healthy growth as well as nutrients and ingredients that support a healthy immune system.”

Defendant tells consumers to look for the symbol on the packaging, seen below, which states IMMUNIPROTECT™ PROBIOTIC:



54. **DHA & Probiotic Cereal** is promoted on the front-of-the-label with the claim “BIFIDUS BL™ – a Beneficial Probiotic” and on the side-of-the-label with the claim “Did You Know? The beneficial probiotic cultures BIFIDUS BL\* help support a healthy immune system” with the asterisked statement: “\*Provides the live and active probiotic cultures Bifidobacterium lactis. Bifidobacteria are the the most abundant type of cultures found in the digestive system of breastfed babies.” See Exhibit B attached. The side-of-the-label ingredient list states these formulas contain following probiotic: “*B. LACTIS* CULTURES.” *Id.*

55. Gerber’s advertisements in other media repeat and reinforce the false and misleading claims made on the packaging and labeling. For example, the DHA & Probiotic Cereal products at issue also are advertised on Gerber’s website with the following claims: “**Contains beneficial probiotic cultures, BIFIDUS BL™, that help support a healthy immune system.**”

56. Similarly, **Good Start Protect Infant Formula** is advertised on the Gerber website with the following claims: “Natural probiotic Cultures *B. lactis*” and “IMMUNIPROTECT™ probiotic – *B. lactis* and nutrition to help strengthen a healthy immune

system.” and “IMMUNIPROTECT - supports healthy growth, includes a special blend of antioxidant vitamins C & E, zinc, vitamin A and probiotic cultures, *like those naturally found in breastmilk.*” And “These beneficial cultures, BIFIDUS BL\*, offer advanced immune system support. \*Provides the live and active probiotic cultures *Bifidobacterium lactis*. Bifidobacteria are the most abundant type of culture found in the digestive system of breastfed babies.”

[Emphasis added.]

57. The FAQs on the Good Start Protect webpage explain:

Q: What is GOOD START Protect?

A: GOOD START Protect is the Nestlé trademark for ***GOOD START formula with BIFIDUS BL™ – beneficial cultures like those naturally found in breastmilk to help support Baby’s healthy immune system. Some beneficial cultures, like BIFIDUS BL, also called “probiotics” (meaning “for life”), can provide specific health benefits beyond basic nutrition.*** One of the many health benefits provided by certain probiotics is to help support Baby’s healthy immune system.

Q: What is BIFIDUS BL?

A: BIFIDUS BL is the Nestlé trademarked name for the unique type of beneficial cultures used in GOOD START® Protect. ***BIFIDUS BL is similar to the type of beneficial cultures naturally found in breastmilk, and BIFIDUS BL can help support Baby’s healthy immune system. BIFIDUS BL has been studied for nearly two decades, and clinical studies at leading scientific institutions around the world have demonstrated its benefit and safety in infants and young children.*** GOOD START Protect with BIFIDUS BL provides what some experts might consider the most advanced feature of any infant formula on the market today.

\* \* \*

Q: If I supplement breastfeeding with GOOD START Protect, will my baby consume too many beneficial cultures?

A: . . . GOOD START Protect contains beneficial cultures *like those naturally promoted by breastmilk.*

Many experts believe that high levels of certain beneficial cultures called Bifidobacteria may be one of the reasons breastfed babies are generally so

healthy. GOOD START Protect is *designed to help bring the balance of cultures in the digestive tracts of formula-fed babies closer to that of breastfed babies.*

Q: What scientific evidence is there for the benefit and safety of GOOD START Protect?

A: Nestlé has worked with leading scientific research institutions around the world in the research and development of GOOD START Protect:

The beneficial cultures BIFIDUS BL have been studied for nearly two decades, and numerous clinical studies have demonstrated their benefit and safety in infants and young children.

Nestlé first included beneficial cultures in infant formula in Europe more than 15 years ago.

Beneficial cultures have been used in more than 30 countries around the world.

\* \* \*

Q: What are beneficial cultures?

A: . . . Scientific research has shown that beneficial cultures can help support Baby's healthy immune system in many ways, including increasing levels of key antibodies and helping to support the natural protective barrier in the digestive tract – where 70% of the body's immune system is found.

That's why GOOD START Protect is specially *designed with beneficial cultures like those found in breastmilk to help support Baby's healthy immune system.*

Disclaimers/Notes: Approximately 70% of the cells of the immune system are found in Baby's digestive tract.

\* \* \*

Q: What beneficial cultures are added to GOOD START Protect?

A: The beneficial cultures added to GOOD START Protect are B. lactis (or Bifidobacterium lactis). The Nestlé trademarked name for the B. lactis in GOOD START Protect is BIFIDUS BL. B. lactis is one of the types of beneficial cultures found naturally in the digestive tracts of breastfed babies, called Bifidobacterium. While all healthy infants have varying amounts and types of cultures in their digestive tracts, Bifidobacterium make up as much as 90% of the cultures in the digestive tracts of breastfed infants. Many experts believe that these higher levels

provide immune-system support and may be one of the reasons why breastfed babies are generally so healthy.

\* \* \*

Q: How is BIFIDUS BL™ similar to the beneficial cultures naturally found in breastmilk?

A: All healthy babies' digestive tracts contain different types of bacteria, also known as cultures. "Beneficial cultures" refers to those groups of "good" or "friendly" bacteria that help Baby remain healthy. Scientists have learned that the digestive tracts of breastfed babies appear to have much more of one type of beneficial culture, called Bifidobacterium. Many experts believe that these high levels may be one of the reasons breastfed babies are generally healthy.

BIFIDUS BL, the beneficial cultures in GOOD START Protect, are a type of cultures, called Bifidobacterium, found naturally in the digestive tracts of breastfed babies. GOOD START Protect is specially designed to help bring the balance of cultures in formula-fed babies closer to that of breastfed babies. No other formula provides beneficial cultures to help support your baby's healthy immune system . . . .

Q: How does GOOD START Protect compare with breastmilk?

A: . . . GOOD START Protect is the first and only formula that ***contains beneficial cultures BIFIDUS BL, like those naturally promoted by breastmilk, to help support your baby's healthy immune system.***

[Emphasis added.]

58. The webpage for Good Start 2 Protect Formula contains the same or substantially similar representations as in the preceding paragraph, and in addition:

Q: How does GOOD START 2 Protect compare with breastmilk?

A: . . . GOOD START 2 Protect contains beneficial cultures like those naturally found in breastmilk to help support Baby's healthy immune system. This formula is specially designed to help bring the balance of cultures in the digestive tracts of formula-fed babies closer to that of breastfed babies. Higher levels of beneficial cultures can help support Baby's healthy immune system in many ways, including increasing levels of key antibodies. And a healthy immune system provides Baby with important natural defenses.

Q: How is GOOD START 2 Protect different from other formulas that claim immune system support?

A: GOOD START 2 Protect is the only older-baby formula that contains beneficial cultures BIFIDUS BL, like those found in breastmilk, to help support your baby's healthy immune system.

One way these cultures can help support Baby's healthy immune system is by increasing levels of key antibodies.

Another way is to help support the natural protective barrier found in Baby's digestive tract – where 70% of the body's immune system is found.

No other formula provides an immune-system support benefit in this way. Like other older-baby formula brands, GOOD START 2 Protect contains both antioxidants and nucleotides – ingredients found naturally in breastmilk that also may help support Baby's healthy immune system.

Disclaimers/Notes: Approximately 70% of the cells of the immune system are found in Baby's digestive tract.

59. Gerber's television commercials reinforce the same messages conveyed by Gerber in other media, including such claims as: "The Gerber generation has discovered a breakthrough. The immune-supporting probiotics like those in breastmilk can be found in Gerber GOOD START® Protect formula."

60. Television commercials for the Products have aired regularly across the country since the Products' launch. Gerber's consistent marketing representations about the ability of its "probiotic" Bifidus BL to have a beneficial effect on a baby or toddler's immune system are provably false and misleading.

61. Defendant's labeling and advertising claims are false and deceptive including because they imply the Products provide more health benefits than other, less costly predecessor and regular formulas that do not contain probiotics, Bifidus BL™, or "IMMUNIPROTECT™."

62. These claims made on the Products' packaging and labeling, and repeated and reinforced throughout Gerber's other advertising for the Products, are likely to mislead consumers acting reasonably under the circumstances into believing that Defendant's infant and

follow-on formula is near-equivalent to breastmilk, and that its use will result in superior immune function and health.

63. Defendant's characterization of the Products as nutritionally near-equivalent to breastmilk is false and misleading, given the scientific evidence showing breastmilk is demonstrably superior to formula in terms of infant nutrition and quite dissimilar in composition. The AAP writes that the advantages of breastfeeding include "health, nutritional, immunologic, developmental, psychologic, social, economic, and environmental benefits." Thus, breastmilk offers innumerable health benefits to infants well-beyond just the benefits provided from probiotics.

**Scientific Evidence Proves that Defendant's  
Claims Are Objectively False and Misleading**

64. Defendant's labeling and advertising is further false and misleading because the Products, including the infused probiotic, do not "help[] support a healthy immune system" or provide "Advanced Immune Support."

65. Defendant's labeling and advertising is further false and misleading because the claim "ImmuniProtect Probiotic" implies that the type of probiotic in the Products is somehow superior to other types of commercially available probiotics in providing immune support in a developing child.

66. Mary N. Mugambi, Alfred Musekiwa, Martani Lombard, Taryn Young, and Reneé Blaauw conducted a study, published in 2012, that focused on growth and clinical outcomes in term infants fed only infant formula containing either prebiotics, probiotics, or synbiotics as compared to conventional infant formula. Mugambi, Mary N., et al., *Synbiotics, probiotics or prebiotics in infant formula for full term infants: a systematic review*, Nutrition Journal, Vol. 11 (2012).

67. Mary N. Mugambi, Martani Lombard, and Reneé Blaauw are members of the Faculty of Medicine and Health Sciences, in the Division of Human Nutrition at Stellenbosch University, in Stellenbosch, Western Cape, South Africa.

68. Alfred Musekiwa and Taryn Young are members of the Faculty of Health Sciences, in the Centre for Evidence-Based Health Care, at Stellenbosch University, in Stellenbosch, Western Cape, South Africa.

69. Mugambi et al. followed the Cochrane methodology using all the randomized controlled trials (“RCTs”) that compared infant formula containing probiotics, prebiotics or synbiotics to a conventional infant formula among healthy full term infants.

70. To provide background information, the study states that “[t]he intestinal micro flora of breastfed infants have a greater concentration of bifidobacteria and fewer potentially pathogenic bacteria compared to formula fed infants.”

71. The study considered “[a]ll randomized controlled trials (RCTs), irrespective of language, which compared the use of term infant formula containing synbiotics, probiotics or prebiotics to conventional infant formula” amongst infants that were age “0-12 months, with no disease, congenital abnormality, allergy or eczema.”

72. The 2012 Mugambi et al. study concluded that the review of *all* RCTs did “not support the routine supplementation of term infant formula with synbiotics, probiotics or prebiotics.”

73. Based on all published studies (and abstracts if sufficient information could be obtained to assess study quality and obtain relevant study findings), that compared formula with probiotics, prebiotics or synbiotics to a control formula without supplementation, Mugambi, et

al. made the following findings about the impact of probiotics, prebiotics and synbiotics in infant formula on infant health and immunity:

- a) “Probiotics failed to increase counts of bifidobacteria and lactobacillus [good bacteria].”
- b) The “data shows that probiotics did not have any significant effect on stool frequency or consistency.”
- c) “Probiotic supplementation was not associated with fewer episodes of diarrhea, a lower incidence of colic, spitting up/regurgitation, restlessness, vomiting.”
- d) Probiotics “failed to reduce counts of bacteriodes [pathogens].”
- e) “Prebiotics supplementation failed to increase counts of bifidobacteria, lactobacillus [good bacteria], or decrease the levels of pathogens (entrobacteria, bacteroides, E-coli).”
- f) Prebiotic supplementation “failed to improve stool consistency or decrease incidence of diarrhea.”
- g) “Prebiotic supplementation failed to significantly reduce upper respiratory infections.”
- h) The data showed no difference in the frequency of infections between groups fed formula supplemented with synbiotics (probiotics and prebiotics combined) and the control groups fed unsupplemented formula.

74. The 2012 Mugambi et al. study objectively demonstrates that Defendant’s misrepresentations about the advanced immune system health benefits of the Products are provably false and misleading.

75. Another study that examined whether prebiotic or probiotic supplemented milk-formulas modulate the fecal microbiota of bottle-fed infants in comparison to breast fed infants did not find a significant increase of bifidobacteria (good bacteria) when infants were fed with probiotic or prebiotic supplemented formula. The study also did not observe a difference in lactobacilli (good bacteria) when infants were fed with unsupplemented formula versus formula supplemented by probiotics or prebiotics. Further, the study found no difference in the number of pathogens, Bacteriods, between the probiotic and prebiotic supplemented groups, and the groups without supplementation. Brusner, Oscar et al, *Effects of probiotic or prebiotic supplemented milk formulas on fecal microbiota composition of infants*, Asia Pac J Clin. Nutr., Vol. 15, No. 3, pp. 368-376 (2006).

76. Another 2012 study, conducted by Ackerberg et al., of the Nutrition Information Centre, Stellenbosch University, similarly concluded that “[p]rebiotic-supplemented formula did not have a significant effect on the reduction of pathogenic bacteria.” Ackerberg TS et al., *The Use of Prebiotics and Probiotics in Infant Formula*, S. Afr. Fam. Pract., Vol. 54, No. 4, pp. 322 (2012).

77. Moreover, G. Puccio, C. Cajozzo, F. Meli, F. Rochat, D. Grathwohl, and P. Steenhout conducted an RCT that evaluated the effect of adding synbiotics (probiotics and prebiotics combined) to infant formula. Their reported data on stool consistency showed no statistically significant differences between the control group fed unsupplemented formula and the group fed formula supplemented with synbiotics. Their data on frequency of crying, restlessness, colic, spitting and vomiting also showed no statistically significant differences between the two study groups. Further, they reported data on frequency of respiratory tract

infections, but there were no significant differences between the synbiotic and control treated groups.

78. Similarly, results from a study conducted by Vlieger, et al. in 2009 showed no differences in the frequency of vomiting and colic between the control study group and the group given formula supplemented with synbiotics. The study also found no differences in the number of parent-diagnosed infections, antibiotic use, and visits to the general practitioner between control groups fed with unsupplemented formula and formula supplemented with probiotics. Vlieger, Arine M. et al., *Tolerance and safety of Lactobacillus paracasei ssp. paracasei in combination with Bifidobacterium animalis ssp. lactis in a prebiotic-containing infant formula: a randomised controlled trial*, British Journal of Nutrition / Volume 102 / Issue 06 / September 2009, pp. 869-875

79. Additionally, in 2002, a joint working group of scientists for the Food and Agriculture Organization of the United Nations and the World Health Organization (“FAO/WHO”) generated guidelines for evaluating probiotics in food, and defined the data necessary to evaluate probiotic health claims.

80. The Joint FAO/WHO Working Group Report concluded that “[p]robiotics for human use will require substantiation of efficacy with human trials.” The report emphasized that the human study must utilize appropriate sample sizes and “[s]tatistically significant differences [between the placebo and test products] must apply to biologically relevant outcomes.” And the report recommended that at least a second, independent double-blinded, randomized, placebo-controlled human trials (“DBPC”) test confirm the test results.

81. Thus, a properly conducted clinical or scientific study is the well-designed, RCT. In RCTs, human study subjects similar to each other are randomly assigned to receive either the

test substance or a placebo. DBPCs, where neither the patient nor the administering researcher knows which intervention is placebo, is preferred and considered more accurate than a single-blind RCT. As such, there is widespread consensus within the legitimate scientific community concerning the proper research and testing that must be conducted to evaluate a claim made for a given effect ascribed to a probiotic bacteria.

82. As discussed above, the 2012 Mugambi, et al. study reviewed all of the RCTs currently available that compared supplemented and unsupplemented formula and concluded that the cumulative results of all RCTs did not support the routine supplementation of term infant formula with synbiotics, probiotics or prebiotics.

83. Defendant cites no scientific studies that effectively support its claim that “certain probiotics in the digestive tract create a natural protective barrier and help support a baby’s developing immune system.” Although Defendant cites 12 sources, the studies actually demonstrate the falsity of Defendant’s advertising and otherwise do not support its immunity strengthening claims.

84. For example, Defendant relies upon L.G. Fooks & G.R. Gibson, *Probiotics as modulators of the gut flora*, BR J NUTR 88, (Suppl 1): S39-49 (2002). This survey of the scientific literature does not specifically reference the particular strain of “beneficial culture” present in the Products, and concludes that, “for probiotics, many promising studies have been published. However, it is relevant to note that studies on particular strains may not necessarily be extrapolated to all probiotic microorganisms. Each should be assessed on their individual merits. Moreover, it is important that reliable labeling information on microbial contents and numbers are given.” *Id.* at S46.

85. Defendant also relies on Y. Fukushima, Y. Kawata, H. Hara, A. Terada, & T. Mitsuoka, *Effect of a probiotic formula on intestinal immunoglobulin A production in healthy children*, INT J FOOD MICROBIOL, 42:39-44 (1998). This study, which lacked a control group and was paid for by Nestlé Japan, examined the effect of a cow milk-based formula containing *Bifidobacterium lactis* Bb-12 (in an amount that differs from that in the Products) on a tiny statistical sample of seven children aged 15-31 months, and concluded that traces of the bacteria survived in the five of the seven subjects' feces and that the fecal levels of certain antibodies increased. However, no bacteria increased other than bifidobacteria and “[t]he increase was not statistically significant compared to the level [of bacteria] before intake.” No clinically relevant immunity benefits were demonstrated. Moreover, as mentioned above, formula does not include the antibodies that babies need most because they do not include the specific antibodies that a mother makes in response to her environment. Demonstrating why feeding bacteria to an otherwise healthy population is not beneficial, the authors stated “[t]he composition of the microflora in the intestines of healthy adults is known to be stable.” In fact, the authors concluded that “[t]hese results suggest that the intestinal microflora of young healthy children seems to be as stable as that of adults, and the intake of probiotics does not drastically modify the microflora.” Moreover, in 2011, an EFSA panel of scientists reviewed Fukushima et al. (1998) and stated that “[t]he Panel notes the small sample size of this study and that it was not controlled (lack of a control group), and considers that no conclusions can be drawn from this uncontrolled study for the scientific substantiation of the claimed effect [of immune defense against pathogens].”

86. Defendant also relies on J.P. Langhendries, J. Detry, & J. Van Hees, *et al.*, *Effect of a fermented infant formula containing viable Bifidobacteria on the fecal flora composition*

*and pH of healthy full-term infants*, J PEDIATR GASTROENTEROL NUTR, 21(2):177-81 (1995). This study examined the effects of *Streptococcus thermophilus* and *Lactobacillus helveticus* (neither of which are contained in the Products) with *Bifidobacterium bifidum* administered orally via formula to healthy full-term infants on fecal flora and composition, and concluded that some bacteria survived the digestive process and that the fecal pH was lower in breast fed infants than in the non-acidified bottle-fed infants. Again, no particular immunity benefits were studied or demonstrated. Indeed, when Mugambi, et al. reviewed the data reported by J.P. Langhendries et al., Mugambi et al. concluded that the study “showed that probiotics failed to significantly reduce counts of Bacteriodes [pathogens] compared to controls,” and that “the *control* group had significantly increased counts of bifidobacteria [good bacteria] compared to [the] probiotic group.”

87. Defendant also relies on S. Rautava, H. Arvilommi, & E. Isolauri, *Specific probiotics in enhancing maturation of IgA responses in formula-fed infants*, PEDIATR RES, 60(2):221-4 (2006). This study concluded that “[s]upplementation with the probiotics *Lactobacillus* GG and *Bifidobacterium lactis* Bb-12 starting at the time of introduction of cow’s milk in the infant’s diet increased protective cow’s milk-specific IgA responses.” However, the between-group differences in terms of either the total number of IgA-secreting cells or serum concentrations of IgA-inducing substances were not statistically significant. Moreover, the only reported clinical endpoint, the incidence of atopic eczema, “did not differ significantly between the groups.” Once more, this study, which analyzed a combination of bacteria strain not in the Products with Bifidus BL (in an amount that differs from that in the Products), does not demonstrate that the specific “probiotic” in the Products, Bifidus BL, strengthens or supports the immune system.

88. None of these studies, even if they could be characterized as clinical – which they cannot – supports the conclusion that Gerber Products in fact strengthen and support a baby and toddler’s immune system as labeled and advertised.

89. Additional studies, not cited by Defendant, objectively demonstrate that the Products’ marketing and advertising is false and deceptive. For example, in 2011, EFSA reviewed the substantiation in relation to *Bifidobacterium animalis ssp. lactis* Bb-12 (the probiotic in the Products) and claimed effects in a healthy population of natural defense / immune system defense against pathogens, decreasing potentially pathogenic gastro-intestinal microorganisms, reduction of the symptoms of inflammatory bowel conditions and maintenance of normal cholesterol concentrations. Based on its analysis of reviews, book chapters, and human studies, EFSA concluded that “a cause and effect relationship has not been established between the consumption of *Bifidobacterium animalis ssp. lactis* Bb-12 and immune defence against pathogens” and that “a cause and effect relationship has not been established between the consumption of *Bifidobacterium animalis ssp. lactis* Bb-12 and decreasing potentially pathogenic gastro-intestinal microorganisms.”

90. Similarly, in 2009, EFSA reviewed the scientific substantiation relating to the consumption of Bb-12 and fiber in fermented dairy products and promoting the growth of beneficial bacteria and decreasing potentially pathogenic intestinal microorganisms in a healthy population. Based on its review of sixteen human studies involving Bb-12, EFSA concluded that “a cause and effect relationship has not been established between the consumption of *Bifidobacterium animalis ssp. lactis* Bb-12 and soluble fibre in fermented dairy products and decreasing potentially pathogenic intestinal microorganisms.”

91. In a 7-week double-blind, placebo-controlled intervention study published in 2006, Christensen et al., analyzed the changes in immune parameters in 75 healthy subjects who were provided either a capsule containing Bb-12 and *Lactobacillus paracasei* CRL-431 or placebo. Risager et al. concluded that “no solid effect on the immune function of young healthy adults supplemented with even high doses [of the probiotics] was demonstrated.” For example, “[t]here was no statistically significant difference between the amount of fecal IgA found before the intervention [] and immediately after [] of 2 weeks after [] for any of the doses of CRL-431 and BB-12.” The authors also concluded “fecal recovery of BB-12 exhibited dose-response relationship [] with  $10^{10}$  CFU day<sup>-1</sup> being the lowest dose giving a statistically significant chance of recovering viable BB-12 from the faeces.” However, according to Defendant, the Products only contain  $10^6$  Bb-12.

92. Bakker-Zierikzee *et al.* (2006), conducted a randomized, placebo-controlled, double-blind study on 57-infants who were not breast-fed: nineteen received a prebiotic formula, nineteen received a probiotic formula containing Bb-12, and nineteen received a standard infant formula. The study analyzed whether formula-fed infants could receive immune system antibodies from prebiotic or probiotic (Bb-12) supplementation comparable to the immune benefits in breastmilk. The authors analyzed the levels of faecal SIgA antibodies in the study subjects at different intervals throughout this 32-week study. The level of SIgA antibodies is associated with gastrointestinal and immune defenses. The authors concluded that Bb-12 was ineffective and that “[a]dding viable *B. animalis* strain Bb-12 to infant formula did not reveal any sign for [increased faecal SIgA].” Moreover, there was no difference between the groups in terms of frequency of vomiting or diarrhea, stool frequency or consistency.

93. Despite scientific studies that demonstrate that supplementing infant formula with probiotics does not provide the benefits that Gerber claims, Gerber continues to deceptively market and advertise the Products as helping to strengthen and support a baby or toddler's immune system.

94. Furthermore, the AAP does not recommend routine usage of probiotics.

95. In December 2010, the AAP issued a new clinical report, "Probiotics and Prebiotics in Pediatrics," in which the AAP reviewed the evidence surrounding the use of probiotics and prebiotics for children. The AAP concluded that "Probiotics or prebiotics added to infant formula and other foods marketed for use in children do not appear to be harmful to *healthy* infants and children, but the clinical efficacy for their addition is insufficient to recommend their routine use in these formulas."

96. The AAP further observed, "There are also safety concerns with the use of probiotics in infants and children who are immunocompromised, chronically debilitated, or seriously ill with indwelling medical devices."

97. The Committee on Nutrition of the European Society of Pediatric Gastroenterology, Hepatology and Nutrition ("ESPGHAN") concluded that more studies are required to establish the safety and efficacy of probiotic and prebiotic products in children.

98. Most recently, a review of the available scientific research was completed and concluded: "Routine application of probiotic- and/or prebiotic-supplemented formulae is not recommended ...."

99. The Products are not as close to breast milk as Defendant would lead a consumer to believe and reliable scientific evidence does not support probiotic supplementation of infant formula. Those facts are material to the reasonable consumer who would not want to pay for

claimed attributes that are not provided. For example, that the AAP does not recommend routine use of products supplemented with probiotics is material because parents hold AAP recommendations in extremely high regard. As such, Defendant had a duty to disclose this information.

100. A reasonable consumer would not have purchased these Products but for Defendant's misrepresentations made on the Products' packaging and labeling, and repeated and reinforced throughout the advertising campaign, pertaining to the claimed health benefits. Further, Plaintiffs and the Class and Subclasses have been harmed as they paid more than they otherwise would have for predecessor and regular products that are not advertised as providing the same claimed health benefits.

101. As a result of the messaging at issue, Geber was able to charge more for the Products than it otherwise would have.

102. Plaintiffs and Class members are able to assign a value to the Products as promised – the price Plaintiffs and Class members willingly paid believing the Products provided probiotic health benefits over alternative formula and infant cereal products. The difference in value between the Products as promised to Plaintiffs and Class members and the products they received can be reasonably quantified or measured in several different ways.

103. First, to the extent that consumer perception of the probiotic health benefits messaging impacts the purchase decision and price that consumers were willing to pay for the Products, this is a brand communication issue. Developing a brand requires a concentrated and targeted effort by the marketer to “teach” consumers what the brand is, what it represents, and why they should care about it. It includes not only creating awareness of the attributes of a product or service, but also the creation of a brand promise, comprised of the functional and

emotional benefits of the product, that will influence consumer decision making. One of the ways that companies communicate their brand promise to consumers is through product labeling. A core task of the marketer in building a successful brand is to design a product that will appeal to the consumer. A primary means of accomplishing this is to design a product label that communicates the product's benefits and convinces the consumer that the product will fulfill his/her needs. Every consumer that purchases a product in the retail environment is exposed to the product's label:

The package becomes a critical factor in the consumer decision-making process because it communicates to consumers at the time they are actually deciding in the store. How they perceive the subjective entity of products, as presented through communication elements in the package, influences choice and is the key to success for many food products marketing strategies.<sup>1</sup>

104. The defendant in this case, Gerber, is a sophisticated marketer who owns, manages, and markets some of the world's most well-known brands. Gerber's probiotic health benefits messaging was a deliberate choice by Gerber to communicate certain (contested) product attributes to consumers for the purpose of impacting consumer purchasing behavior. Here, Gerber deliberately and successfully utilized strong labeling communications about digestive and immune benefits of the Products' probiotics for the purpose of impacting consumer purchasing behavior.

105. Consumer survey research provides reliable, widely-accepted empirical evidence as to consumer perceptions about the probiotic health benefits messaging as related to the Products, as well as the impact that the probiotic health benefits messaging had on consumers' decision to purchase and the price they were willing to pay for the Products. Gerber's own

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<sup>1</sup> Silayoi, P., & Speece, M. (2007). The importance of packaging attributes: a conjoint analysis approach. *European Journal of Marketing*. Vol. 41 No. 11/12, p. 1495-1517.

surveys it conducted or commissioned measure the extent to which the probiotic health benefits messaging impacted consumers' decisions to purchase and the prices they were willing to pay for the Products. These surveys demonstrate that the probiotic health benefits messaging is a major driver of purchase intent and consumer value.

106. The difference in value between the Products as promised to Plaintiffs and Class members and the products they received can also be reasonably quantified or measured by analysis of retail pricing data as it relates to the Products at issue and comparable products. This pricing data, which is possessed by retailers, manufacturers (including Gerber), and aggregators such as Nielsen, is widely accepted as accurate, and is routinely relied on by Gerber, other food manufacturers, and experts in the field.

107. For example, retail pricing data demonstrates that as a result of the false advertising at issue, Gerber was able to charge – and Class members paid – approximately \$0.10 per ounce more for Gerber's Good Start Protect formulas versus Gerber's other comparable infant formula products (Good Start Gentle Plus and Good Start Soy Plus), which do not contain the advertised, purported advanced digestive and immune support benefits provided only by Good Start Protect's "IMMUNIPROTECT™ PROBIOTIC," Bifidus BL. For example, in 2010, Class members paid approximately \$14.74 on average for a 12-ounce canister of Good Start Protect versus approximately \$12.99 for a 12-ounce canister of Good Start Gentle Plus, and \$13.85 for a 12.9 ounce canister of Good Start Soy Plus. In 2010, Class members paid approximately \$22.99 on average for a 24-ounce canister of Good Start 2 Protect versus approximately \$20.99 for 24-ounce canisters of Good Start 2 Gentle Plus and Good Start 2 Soy Plus. Likewise, because of the false advertising at issue, Gerber was able to charge more per ounce for its Good Start Protect formula versus Enfamil Premium, Enfamil Gentlease, and

Similac Early Shield. Enfamil Premium and Similac Early Shield are Good Start Protect's branded competitors, and do not contain the advertised, purported advanced digestive and immune system benefits provided by Gerber Good Start Protect's Bifidus BL probiotic. For example, retail pricing data from 2010 demonstrates that Class members paid approximately \$0.04 per ounce more for Gerber's Good Start Protect formula versus Similac Early Shield and Similac Sensitive, and \$0.20 per ounce more for Gerber's Good Start Protect formula versus Enfamil Gentlease. In 2009, retail pricing data demonstrates that Class members paid approximately \$0.14 and \$0.08 per ounce more for Gerber's Good Start Protect formula versus Similac Early Shield and Enfamil Premium, respectively.

108. Gerber was also able to charge more per ounce for its Good Start Protect formula versus its private label competitor formula products that are not sold on the basis of the challenged, advertised, advanced digestive and immune system benefits provided by Gerber Good Start Protect's Bifidus BL probiotic. According to Gerber's data, it was able to charge approximately \$0.45 per ounce more for its Good Start Protect formulas versus the aggregate "private label" competitor infant formulas as identified by Nielsen. Examples of these private label competitor products include Target's up & up Infant Formula products, Walgreens Premium Infant Formula, and Wal-Mart's Parent's Choice formula. In 2010, retail pricing data demonstrates that Class members paid approximately \$0.61 per ounce more for Gerber's Good Start Protect formula versus Target's up & up Infant Formula with DHA. In 2011 and 2012, retail pricing data demonstrates that Class members paid approximately \$0.33 per ounce more for Gerber's Good Start Protect formula versus Walgreen Premium Infant Formula with Iron Powder.

109. Likewise, retail pricing data also demonstrates that Gerber was also able to charge more – and Class members paid more – for Gerber’s DHA & Probiotic Cereal over comparable infant cereal products that are not advertised as providing the immune system benefits associated with DHA & Probiotic Cereal. These comparable infant cereal products include Gerber’s other infant cereal products: Gerber’s oatmeal & banana and oatmeal & apple peach infant cereals. For example, Gerber is able to charge approximately \$0.20 more per ounce for its DHA & Probiotic Cereal over its own oatmeal & banana, rice & banana apple, and oatmeal & apple peach infant “base” infant cereals. The retail price for 8 ounces of Gerber’s cereal without probiotics (what Gerber refers to as its “base” cereals) was approximately \$1.89 - \$2.19. However, the retail price for 8 ounces of Gerber’s DHA & Probiotic cereals was approximately \$2.79 - \$2.99. Likewise, as a result of Gerber’s false advertising, consumers paid more for Gerber’s DHA & Probiotic cereals versus the non-Gerber, branded, comparable infant cereal products. For example, an 8-ounce container of Beechnut, one of the major, branded infant cereal competitors to Gerber’s DHA & Probiotic cereals retails for approximately \$1.99 and does not contain probiotics or the purported digestive and immune system benefits advertised for Gerber’s DHA & Probiotic cereals. Likewise, an 8-ounce box of Earth’s Best Organic Baby Cereal, another of the major, branded infant cereal competitors to Gerber’s DHA & Probiotic cereals retails for approximately \$2.70 - \$2.74 and does not contain probiotics or the purported digestive and immune system benefits advertised for Gerber’s DHA & Probiotic cereals.

110. Routinely maintained retail pricing and other data also allow for the precise determination of the value of the promised probiotic health benefits. Using well-established statistical regression technique that focuses on the Products’ attributes, the value of the challenged probiotic health benefits messaging can be isolated. This technique, known as

Hedonic regression is a commonly used economic method that measures the value of various product attributes. Hedonic regression is based on the concept that each product attribute has a different and measurable impact on consumer utility, i.e., consumers will pay a certain amount for each product attribute. Thus, application of such Hedonic regression methodology to data regularly maintained by Gerber and third parties such as Nielsen is another reliable manner in which to measure or quantify the value attributable to the challenged probiotic health benefits.

### **CLASS ACTION ALLEGATIONS**

111. The Class is defined as:

All persons in the United States who purchased one or more of the Products until the date notice is disseminated (“Class Period”) for personal or household use, and not for resale or distribution purposes. Excluded from the Class are governmental entities, Defendant, any entity in which Defendant has a controlling interest, and Defendant’s officers, directors, parents, holding companies, affiliates, legal representatives, employees, co-conspirators, successors, subsidiaries, assigns, shareholders, marketing consultants, licensees, distributors, and agents. Also excluded from the Class are those who assert claims for personal injury and any judge, justice, or judicial officer presiding over this matter and the members of their immediate families and judicial staff.

Or, in the alternative,

All persons located within any state that has consumer protection statutes which do not materially differ from New Jersey’s consumer protection statutes, who purchased the Products until the date notice is disseminated (“Class Period”), for personal or household use, and not for resale or distribution purposes (the “Class”). Excluded from the Class are governmental entities, Defendant, any entity in which Defendant has a controlling interest, and Defendant’s officers, directors, parents, holding companies, affiliates, legal representatives, employees, co-conspirators, successors, subsidiaries, assigns, shareholders, marketing consultants, licensees, distributors, and agents. Also excluded from the Class are those who assert claims for personal injury and any judge, justice, or judicial officer presiding over this matter and the members of their immediate families and judicial staff.

#### **California Subclass**

All persons located within California who purchased the Products until the date notice is disseminated (“Class Period”), for personal or household use, and

not for resale or distribution purposes (the “Class”). Excluded from the Class are governmental entities, Defendant, any entity in which Defendant has a controlling interest, and Defendant’s officers, directors, parents, holding companies, affiliates, legal representatives, employees, co-conspirators, successors, subsidiaries, assigns, shareholders, marketing consultants, licensees, distributors, and agents. Also excluded from the Class are those who assert claims for personal injury and any judge, justice, or judicial officer presiding over this matter and the members of their immediate families and judicial staff.

### **New Jersey Subclass**

All persons located within New Jersey who purchased the Products until the date notice is disseminated (“Class Period”), for personal or household use, and not for resale or distribution purposes (the “Class”). Excluded from the Class are governmental entities, Defendant, any entity in which Defendant has a controlling interest, and Defendant’s officers, directors, parents, holding companies, affiliates, legal representatives, employees, co-conspirators, successors, subsidiaries, assigns, shareholders, marketing consultants, licensees, distributors, and agents. Also excluded from the Class are those who assert claims for personal injury and any judge, justice, or judicial officer presiding over this matter and the members of their immediate families and judicial staff.

### **New York Subclass**

All persons located within New York who purchased the Products until the date notice is disseminated (“Class Period”), for personal or household use, and not for resale or distribution purposes (the “Class”). Excluded from the Class are governmental entities, Defendant, any entity in which Defendant has a controlling interest, and Defendant’s officers, directors, parents, holding companies, affiliates, legal representatives, employees, co-conspirators, successors, subsidiaries, assigns, shareholders, marketing consultants, licensees, distributors, and agents. Also excluded from the Class are those who assert claims for personal injury and any judge, justice, or judicial officer presiding over this matter and the members of their immediate families and judicial staff.

112. The members of the Class and Subclasses respectively are sufficiently numerous, as the Class and Subclasses include thousands of persons who have purchased the Products. Thus, joinder of such persons in a single action or bringing all members of the Class and Subclasses before the Court is impracticable for purposes of Fed.R.Civ.P. 23(a)(1). The disposition of the Class and Subclass members’ claims in this class action will substantially benefit both the parties and the Court.

113. The Class and Subclasses are readily ascertainable through Defendant's business records. Notice can be provided to Class and Subclass members by publication of notice by internet, radio, newspapers and magazines.

114. There are questions of law and fact common to the Class and Subclasses for purposes of Fed.R.Civ.P. 23(a)(2). Defendant's advertising, marketing, labeling and promotional practices were supplied uniformly to all members of the Class and Subclasses, so that the questions of law and fact are common to all members of the Class and Subclasses. All Class and Subclass members were and are similarly affected by having purchased the Products for their intended and foreseeable purpose as promoted, marketed, advertised, packaged and labeled by Defendant as set forth in detail herein, and the relief sought herein is for the benefit of Plaintiffs and other members of the Class and Subclasses.

115. Plaintiffs assert claims that are typical of the claims of the members of the Class and Subclasses for purposes of Fed.R.Civ.P. 23(a)(3). Plaintiffs and all Class and Subclass members have been subjected to the same wrongful conduct because they have purchased the Products that do not possess the benefits that Defendant represents. Plaintiffs and the Class and Subclasses have thus all overpaid for the Products and/or purchased the Products when they otherwise would not have but for the false and misleading representations.

116. Plaintiffs will fairly and adequately represent and protect the interests of the other members of the Class and Subclasses for purposes of Fed.R.Civ.P. 23(a)(4). Plaintiffs have no interests antagonistic to those of other members of the Class and Subclasses. Plaintiffs are committed to the vigorous prosecution of this action and have retained counsel experienced in litigation of this nature to represent him. Plaintiffs anticipate no difficulty in the management of this litigation as a class action.

117. Class certification is appropriate under Fed.R.Civ.P. 23(b)(2) because Defendant has acted on grounds that apply generally to the Class and Subclasses, so that declaratory relief is appropriate respecting the Class and each Subclass as a whole. Defendant's advertising, marketing, labeling and promotional practices were supplied uniformly to all members of the Class and Subclasses.

118. Class certification is appropriate under Fed.R.Civ.P. 23(b)(3) because common questions of law and fact substantially predominate over any questions that may affect only individual members of the Class and Subclasses. Among these common questions of law and fact are:

- (a) whether Defendant misrepresented or omitted material facts in connection with the promotion, marketing, advertising, packaging, labeling and sale of the Products;
- (b) whether Defendant represented that the Products have characteristics, benefits, uses or qualities that they do not have;
- (c) whether Defendant knew or should have known that Defendant's claims regarding the Products, including, but not limited to, claims regarding these Products' effect on immunity, were false and/or misleading;
- (d) whether Defendant's acts and practices in connection with the promotion, marketing, advertising, packaging, labeling, distribution and sale of the Products violated the laws alleged herein;
- (e) whether Defendant's conduct, as set forth herein, injured members of the Class and Subclasses and whether they have been damaged by the wrongs complained

of herein, and if so, the measure of those damages and the nature and extent of other relief that should be provided.

119. Proceeding as a class action provides substantial benefits to both the parties and the Court because this is the most efficient method for the fair and efficient adjudication of the controversy. Class and Subclass members have suffered, and will suffer, irreparable harm and damages as a result of Defendant's wrongful conduct.

120. Because of the nature of the individual Class and Subclass members' claims, few, if any, could or would otherwise afford to seek legal redress against Defendant for the wrongs complained of herein, and a representative class action is therefore appropriate, the superior method of proceeding, and essential to the interests of justice insofar as the resolution of Class and Subclass members' claims is concerned. Absent a representative class action, Class and Subclass members would continue to suffer losses for which they would have no remedy, and Defendant would unjustly retain the proceeds of its ill-gotten gains. Even if separate actions could be brought by individual members of the Class and Subclass, the resulting multiplicity of lawsuits would cause undue hardship, burden and expense for the Court and the litigants, as well as create a risk of inconsistent rulings which might be dispositive of the interests of the other Class and Subclass members who are not parties to the adjudications and/or may substantially impede their ability to protect their interests. The trial and the litigation of Plaintiffs' claims are manageable.

**COUNT ONE**

**(Violations of the New Jersey Consumer Fraud Act, N.J.S.A. §56:8-1, *et seq*,  
On Behalf of Plaintiff Dourdoulakis and the Class or the New Jersey Subclass)**

121. Plaintiffs repeat the allegations contained in the paragraphs above as is fully set forth herein.

122. Plaintiff Dourdoulakis brings this claim individually, on behalf of the nationwide Class, and alternatively, on behalf of the other members of the New Jersey Subclass.

123. At all times relevant to this action, there was in full force and effect the New Jersey Consumer Fraud Act (“NJCFA”), N.J.S.A. 56:8-1 *et seq.*, which was enacted and designed to protect consumers against unfair, deceptive, or fraudulent business practices.

124. N.J.S.A. 56:8-2 provides:

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact . . . Whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice.

125. At all relevant times, Plaintiff Dourdoulakis, the other Class and New Jersey Subclass members, and Defendant were “persons” within the meaning of N.J.S.A. §56:8-1.

126. The Products manufactured, marketed, and sold by Defendant are merchandise within the meaning of the NJCFA, and Plaintiff Dourdoulakis and the other Class and New Jersey Subclass members are consumers within the meaning of the NJCFA and entitled to the statutory remedies made available therein.

127. Defendant violated and continues to violate the NJCFA by representing that the Products have characteristics, uses, and benefits which they do not have and advertising the Products to have characteristics, uses, and benefits which Defendant knows the Products do not have.

128. Defendant violated the NJCFA by advertising the Products in the manner(s) described above, when they knew, or should have known, that those representations and advertisements were false and/or misleading.

129. Defendant intended that Plaintiff Dourdoulakis and the other members of the Class and Subclass would rely on its deception by purchasing the Products, unaware of the

material facts described above. This conduct constitutes consumer fraud within the meaning of the NJCFA.

130. Defendant's conduct, as alleged herein, constitutes unlawful, unfair, and/or deceptive business practices within the meaning of the NJCFA.

131. Defendant's conduct is malicious, fraudulent, and wanton, and provides misleading information that the Products provide health benefits that less expensive predecessor and other products do not, when in fact scientific evidence demonstrates that the Products do not provide the advertised health benefits.

132. Defendant's conduct has proximately caused damage to Plaintiff Dourdoulakis and the other Class and New Jersey Subclass members, in the form of, *inter alia*, monies spent to purchase the Products they otherwise would not have, in an amount to be proven at trial.

133. Had Defendant disclosed all material information regarding the Products in its advertising and marketing, Plaintiff Dourdoulakis and the Class and New Jersey Subclass would not have purchased the Products or would have paid less for the Products.

134. As a result of Defendant's violations of the foregoing state consumer protection statute, Plaintiff Dourdoulakis and the other members of the Class and New Jersey Subclass are entitled to compensatory damages, double damages, treble damages, statutory damages, punitive or exemplary damages, restitution, and/or injunction relief.

**COUNT TWO**  
**(Violations of the Consumers Legal Remedies Act,  
California Civil Code §1750, et seq., On Behalf of Plaintiff  
Hawkins and the California Subclass)**

135. Plaintiffs repeat the allegations contained in the paragraphs above as if fully set forth herein.

136. Plaintiff Hawkins brings this claim individually and on behalf of the other members of the California Subclass.

137. This cause of action is brought pursuant to the Consumers Legal Remedies Act, Civil Code §1750, *et seq.* (the “Act”). Plaintiff Hawkins and the California Subclass members are consumers as defined by Civil Code §1761(d). The Products are goods within the meaning of the Act.

138. Gerber violated and continues to violate the Act by engaging in the following practices proscribed by §1770(a) of the Act in transactions with Plaintiff Hawkins and the California Subclass which were intended to result in, and did result in, the sale of the Products:

- (a) Representing that [the Products have] . . . characteristics, . . . uses [or] benefits . . . which they do not have . . . .
- (b) Representing that [the Products are] of a particular standard, quality or grade . . . if they are of another.
- (c) Advertising goods . . . with intent not to sell them as advertised.
- (d) Representing that [the Products have ] been supplied in accordance with a previous representation when [they have] not.

139. Gerber violated the Act by representing through its labeling, marketing and advertising of the Products as described above when it knew, or should have known, that the representations and advertisements were false and misleading.

140. Plaintiff Hawkins and the California Subclass members suffered injuries caused by Gerber’s misrepresentations because they purchased and paid a price premium due to the false, misleading and/or deceptive advertising of the Products.

141. Pursuant to §1782 of the Act, Plaintiffs notified Gerber in writing by certified mail of the particular violations of §1770 of the Act and demanded that Gerber rectify the

problems associated with the actions detailed above and give notice to all affected consumers of its intent to so act.

142. Pursuant to §1782(d) of the Act, Plaintiff Hawkins and the California Subclass seek a Court order for restitution and disgorgement.

143. Gerber has failed to rectify the problems identified above with its representations relating to the Products and, thus, Plaintiffs and the California Subclass are entitled to seek damages pursuant to California Civil Code §1781(a) on behalf of themselves and other members of the California Subclass resulting from Gerber's wrongful acts and practices.

144. Plaintiff Hawkins also seeks an order requiring Gerber to pay costs and attorneys' fees and any other relief deemed appropriate and proper by the Court under California Civil Code §1780.

145. Gerber's conduct is malicious, fraudulent and wanton, and provides misleading information that can lead to the delayed treatment of serious and life-threatening illness and diseases, and, as a result, Plaintiff Hawkins and the California Subclass are entitled to recover punitive damages.

### **COUNT THREE**

#### **(Unlawful Business Acts and Practices in Violation of California Business & Professions Code Section 17200, *et seq.*, On Behalf of Plaintiff Hawkins and the California Subclass)**

146. Plaintiffs repeat the allegations contained in the paragraphs above, as if fully set forth herein.

147. Plaintiff Hawkins brings this claim individually and on behalf of the other members of the California Subclass.

148. Business & Professions Code §17200 prohibits any "unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." For

the reasons discussed above, Gerber has violated each of these provisions of Business & Professions Code §17200.

149. Gerber has violated §17200's prohibition against engaging in unlawful acts and practices by, *inter alia*, making the representations and omissions of material facts, as set forth more fully herein, and violating California Civil Code §§1572, 1573, 1709, 1710, 1711, 1770, California Business & Professions Code §17200 *et seq.*, California Health & Safety Code §11333, 21 U.S.C. §321, by misbranding the Products in violation of federal law, and by violating the common law.

150. Plaintiff Hawkins and the California Subclass reserve the right to allege other violations of law which constitute other unlawful business acts or practices. Such conduct is ongoing and continues to this date.

151. Gerber's acts, omissions, misrepresentations, practices and non-disclosures as alleged herein also constitute "unfair" business acts and practices within the meaning of Business & Professions Code §17200 *et seq.* in that its conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and unscrupulous as the gravity of the conduct outweighs any alleged benefits attributable to such conduct.

152. As stated in this Complaint, Gerber has engaged, and continues to engage, in conduct that is immoral, unethical, oppressive, unscrupulous and/or substantially injurious to Plaintiffs and the other members of the California Subclass. This conduct includes, but is not limited to labeling, advertising, marketing and selling based on deceptive promises of health benefits of the Products when, in fact, Gerber knew or should have known those qualities did not exist. Gerber's scheme was and is immoral, unethical, oppressive, unscrupulous and/or substantially injurious to Plaintiffs and the other members of the California Subclass.

153. Plaintiff Hawkins alleges violations of consumer protection, unfair competition and truth in advertising laws in California and other states resulting in harm to consumers. Plaintiff Hawkins assert violations of the public policy of engaging in false and misleading advertising, unfair competition and deceptive conduct towards consumers. This conduct constitutes violations of the unfair prong of Business & Professions Code §17200 *et seq.*

154. There were reasonably available alternatives to further Gerber's legitimate business interests, other than the conduct described herein.

155. Gerber's claims, nondisclosures and misleading statements, as more fully set forth above, were also false, misleading and/or likely to deceive the consuming public within the meaning of Business & Professions Code §17200.

156. Gerber's advertising, including its labeling, as described herein, also constitutes unfair, deceptive, untrue and misleading advertising.

157. Gerber's conduct caused and continues to cause substantial injury to Plaintiff Hawkins and the other California Subclass members. Plaintiff Hawkins and the California Subclass have suffered injury in fact and have lost money as a result of Gerber's conduct. Plaintiffs and the California Subclass would not have purchased the Products at all or paid such a high price for the Products, but for Gerber's false promotion of the Products. Consumers have thus overpaid for the Products.

158. Such injury is not outweighed by: (i) any countervailing benefits to consumers or competition; or (ii) any utility to Gerber. Indeed, no benefit to consumers or competition or to Gerber results from Gerber's conduct. Since consumers reasonably rely on Gerber's representations of the Products and injury results from ordinary use of the Products, consumers could not have reasonably avoided such injury.

159. Gerber has thus engaged in unlawful, unfair and fraudulent business acts and practices and false advertising, entitling Plaintiffs to judgment and equitable relief against defendant, as set forth below.

**COUNT FOUR**  
**(Violations of the New York Consumer Protection Act,  
On Behalf of Plaintiff Siddiqi and the New York Subclass)**

160. Plaintiffs repeat the allegations contained in the paragraphs above as is fully set forth herein.

161. Plaintiff Siddiqi brings this claim individually and on behalf of the other members of the New York Subclass.

162. Plaintiff Siddiqi and the New York Subclass bring their statutory fraud claims pursuant to N.Y. Gen. Bus. Law § 349, *et seq.* which was enacted and designed to protect consumers against unfair, deceptive and/or fraudulent business practices.

163. New York's Consumer Fraud Act (N.Y. Gen. Bus. Law § 349) provides:

Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful.

164. Gerber's promotion of the allegedly healthful qualities of the Products is an act or practice in the conduct of trade or commerce.

165. The promotion of food products to be consumed by infants and toddlers, such as the Products, impacts the public interest.

166. As is detailed above, Gerber's promotion of the Products is deceptive because Gerber states that the Products have healthful qualities which they do not have.

167. Plaintiff Siddiqi and members of the New York Subclass suffered economic injury as a direct and proximate result of Gerber's products by paying more for the Products than they otherwise would have because Gerber falsely touted the Products' healthful qualities.

168. Gerber committed deceptive acts or practices within the meaning of the Consumer Act by engaging in the acts and practices alleged herein.

**COUNT FIVE**  
**(Breach of Express Warranty  
On Behalf of Plaintiffs and the Class)**

169. Plaintiffs repeat the allegations contained in the paragraphs above as if fully set forth here.

170. Each Plaintiff brings this Count for breach of express warranty on behalf of himself or herself as a nationwide Class under N.J.S.A. §12A:2-313 or, in the alternative, on behalf of a Class of similarly situated persons from his or her respective state of residence pursuant to the applicable provision, identified below, from his or her respective state of residence.

171. The Uniform Commercial Code §2-313 provides that an affirmation of fact or promise, including a description of the goods, becomes part of the basis of the bargain and creates an express warranty that the goods shall conform to the promise and to the description.

172. At all times, New Jersey and the following 48 states, including the District of Columbia, have codified and adopted the provisions the Uniform Commercial Code governing the express warranty of merchantability: Ala. Code 1975 §7-2-313; Alaska Stat. §45.02.313; Ariz. Rev. Stat. §47-2313; Ark. Code Ann. §4-2-313; Cal. Com. Code §2313; Colo. Rev. Stat. Ann. §4-2-313; Conn. Gen. Stat. §42a-313; Del. Code Ann. tit. 6 §2-313; D.C. Code §28:2-313; Fla. Stat. Ann. §672.313; Ga. Code Ann. §11-2-313; Haw. Rev. Stat. §490:2-313; Idaho Code Ann. §28-2-313; 810 Ill. Comp. Stat. 5/2-313; Ind. Code. Ann. §26-1-2-313; Iowa Code Ann. §554.2313; Kansas Stat. Ann. §84-2-313; Ky. Rev. Stat. Ann. §355.2-313; Me. Rev. Stat. Ann. tit. 11, §2-313; Md. Com. Law Code Ann. §2-313; Mass. Gen. Laws ch.106, §2-313; Mich.

Comp. Laws Ann. §440.2313; Minn. Stat. Ann. §336.2-313; Miss. Code. Ann. §75-2-313; Mo. Rev. Stat. §400.2-313; Mont. Code. Ann. §30-2-313; Nev. Rev. Stat. Ann. §104.2313; N.H. Rev. Stat. Ann. §382-A:2-313; N.J. Stat. Ann. §12A:2-313; N.M. Stat. Ann. §55-2-313; N.Y. U.C.C. Law §2-313; N.C. Gen. Stat. Ann. §25-2-313; N.D. Cent. Code §41-02-30; Ohio Rev. Code Ann. §1302.26; Okla. Stat. Ann. tit. 12A, §2-313; Or. Rev. Stat. §72.3130; Pa. Stat. Ann. §2313; R.I. Gen. Laws §6A-2-313; S.C. Code Ann. §36-2-313; S.D. Codified Laws §57A-2-313; Tenn. Code Ann. §47-2-313; Tex. Bus. & Com. Code Ann. §2.313; Utah Code Ann. §70A-2-313; Va. Code Ann. §8.2-313; Vt. Stat. Ann. tit. 9A, §2-313; Wash. Rev. Code. Ann. §62A.2-313; W. Va. Code Ann. §46-2-313; Wis. Stat. Ann. §402.313; and Wyo. Stat. Ann. §34.1-2-313.

173. Plaintiffs, and each Class member, formed a contract with the Defendant at the time Plaintiffs and other members of the Class purchased Products. The terms of that contract include the promises and affirmations of fact relating to the Products' purported immunity-related health benefits and near-equivalence to breastmilk made by Defendant on its product labels and repeated throughout its marketing campaign, as described above. This product labeling and advertising became part of the basis of the bargain and is part of a standardized contract between Plaintiffs and the members of the Class on the one hand, and Defendant on the other, and thus constituted an express warranty.

174. Defendant sold the goods to Plaintiffs and other Class members, who bought the goods from Defendant.

175. All conditions precedent to Defendant's liability under this contract, including notice, have been performed by Plaintiffs and the Class.

176. Defendant is in privity with Plaintiffs and members of the Class. Plaintiffs and Class members were the intended beneficiaries of the Products. Defendant created the

advertising at issue and warranted the Products to them directly and/or through the doctrine of agency. Further, Defendant knew the identity, purpose and requirements of Plaintiffs and members of the Class and manufactured the Products to meet their requirements.

177. Defendant breached the terms of this contract, including the express warranties, by not providing the Products capable of delivering the claimed health benefits. As a result of this breach, Plaintiffs and the Class did not receive goods as warranted by Defendant.

178. As a proximate result of Defendant's breach of its contract and its warranties, Plaintiffs and the Class have been damaged in an amount to be determined at trial.

WHEREFORE, Plaintiffs and the Class and Subclasses pray for relief as follows:

A. That the Court determine that the claims alleged herein may be maintained as a class action under Fed.R.Civ.P. 23(a), (b)(2) and (b)(3);

B. That the Court adjudge and decree that Defendant has engaged in the conduct alleged herein;

C. For a judgment awarding Plaintiffs compensatory damages, statutory damages, punitive damages and/or multiple damages as provided by applicable statute;

D. For an award of attorneys' fees and costs to Plaintiffs pursuant to applicable statutes, the common fund doctrine and/or any other appropriate legal theory;

E. That Defendant be required to conduct a corrective advertising campaign;

F. That Plaintiffs and the Class and Subclass members be awarded restitution, including disgorgement of profits obtained by Defendant as a result of its acts of unfair, unlawful or deceptive practices and acts of unjust enrichment and breach of the covenant of good faith and fair dealing;

G. That Plaintiffs and the Class and Subclass members be awarded both pre-and post-judgment interest at the maximum allowable rate on any amounts awarded;

H. That Plaintiffs and the Class and Subclass members recover their costs of suit, including reasonable attorneys' fees as provided by law; and

I. That Plaintiffs and the Class and Subclass members be awarded such other and further relief as may be necessary and appropriate.

CARELLA, BYRNE, CECCHI,  
OLSTEIN, BRODY & AGNELLO, P.C.  
Interim Class Counsel

By: /s/ James E. Cecchi  
JAMES E. CECCHI

Dated: November 21, 2014

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**JURY DEMAND**

Plaintiffs hereby demand a trial by jury for all issues so triable.

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Interim Class Counsel

By: /s/ James E. Cecchi  
JAMES E. CECCHI

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