Ben F. Pierce Gore (SBN 128515)
PRATT & ASSOCIATES
1901 S. Bascom Avenue, Suite 350
Campbell, CA 95008
Telephone: (408) 429-6506
Fax: (408) 369-0752
pgore@prattattorneys.com

David Shelton (admitted *pro hac vice*)
SHELTON DAVIS PLLC
1223 Jackson Avenue, Suite 202
P.O. Box 2541
Oxford, MS 38655
david@sheltondavispllc.com

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

NATALIA BRUTON,

Plaintiff,

v.

GERBER PRODUCTS COMPANY,

Defendant.

Case No. 5:12-CV-02412-LHK

THIRD AMENDED COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Natalia Bruton ("Plaintiff"), through her undersigned attorneys, brings this lawsuit against Gerber Products Company ("Gerber" or "Defendant") as to her own acts upon personal knowledge, and as to all other matters upon information and belief.

DEFINITIONS

1. "Purchased Products" are the following products purchased by the Plaintiff: Gerber Nature Select 2nd Foods Fruit–Banana Plum Grape (Exhibit B); Gerber Nature Select 2nd Foods Fruit–Apples and Cherries (Exhibit C); Gerber Nature Select 2nd Foods Vegetables–Carrots (Exhibit D); Gerber Nature Select 2nd Foods Spoonable Smoothies–Mango (Exhibit E); Gerber Yogurt Blends Snack–Strawberry (Exhibit F); Graduates Lil' Crunchies–Mild Cheddar (Exhibit G); Graduates Fruit Puffs–Peach (Exhibit H); Graduates Wagon Wheels–Apple Harvest (Exhibit I); Graduates for Toddlers Animal Crackers–Cinnamon Graham (Exhibit J); Graduates for Toddlers Fruit Strips–Strawberry (Exhibit K); Gerber Nature Select 2nd Foods Vegetables–Sweet Potatoes & Corn (Exhibit L); Gerber Organic SmartNourish 2nd Foods-Banana Raspberry Oatmeal (Exhibit M); Gerber Organic SmartNourish 2nd Foods-Butternut Squash & Harvest Apple with Mixed Grains (Exhibit N); Gerber Organic SmartNourish 2nd Foods-Farmer's Market Vegetable Blend with Mixed Grains (Exhibit O); and Gerber Single Grain Cereals – Oatmeal (Exhibit P).[1]

2. "Substantially Similar Products" are Defendant's other products listed in Exhibit A. Each of these products are packaged the same way as the Purchased Products of the same type, (b) make the same label representation(s) as described herein that Defendant made on the Purchased Products; and (c) violate the same regulations of the Sherman Food & Drug Cosmetic Law, California Health & Safety Code § 109875, *et seq.* ("Sherman Law") in the exact same manner as the Purchased Products.

[1] Plaintiff will not burden the Court's docket with repetitive documents, thus all references to "Exhibits" herein refer to Plaintiff's Exhibits filed on the docket attached to her Second Amended Complaint.

3. "Misbranded Food Products" refers to both "Purchased Products" and "Substantially Similar Products," collectively.

SUMMARY OF THE CASE

Misbranding

4. This case seeks to recover for the injuries suffered by the Plaintiff as a direct result of Defendant's unlawful sale of misbranded food products. Defendant packaged and labeled its Misbranded Food Products in violation of California's Sherman Law, which adopts, incorporates, and is, in all relevant aspects, identical to the federal Food Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA") and the regulations adopted pursuant to that Act. These violations render Defendant's food products "misbranded." Defendant's actions violate California law.

5. Under California law, misbranded food products cannot be legally sold, have no economic value and are legally worthless.

6. By selling such products to the unsuspecting Plaintiff, Defendant profited at Plaintiff's expense and unlawfully deprived Plaintiff of the money she paid to purchase food products.

7. Gerber's products are misbranded and therefore unlawful. Food manufacturers are prohibited from making nutrient content claims with respect to food products intended to be consumed by children under two years old. This is because the nutritional needs of toddlers and infants are markedly different from those of adults. While a product that is low in fat may be a healthy choice for adults, for example, health experts advise against restricting fat in young children's diets because they need the calories and nutrients fat provides to grow and properly develop. Thus, nutrient content claims that may be helpful in making healthy choices with respect to products intended to be consumed by adults could in fact be misleading and harmful with respect to products intended to be consumed by infants and children under two years of age.

8. Defendant has violated the Sherman Law § 110760, which makes it unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is misbranded. As discussed herein, the sale of a misbranded product to a consumer results in an independent violation of the unlawful prong of the UCL that is separate and apart from the underlying unlawful labeling practice that resulted in the product being misbranded. While not required for these claims, the Plaintiff relied on the fact that Defendant's Purchased Products were legal and that its labeling and label claims were legal.

9. Due to Defendant's misbranding and sale of the Purchased Products, Plaintiff lost money by purchasing these products.

PARTIES, JURISDICTION AND VENUE

10. Plaintiff Natalia Bruton is a resident of San Jose, California who bought Defendant's Purchased Products, as described herein, in California.

11. Defendant Gerber Products Company is a privately held Michigan corporation with its principal place of business in Fremont, Michigan. Gerber is one of the leading producers of retail food products sold in California and nationwide. More specifically, Defendant is one of the leading producers of retail baby food products, including the Purchased Products. Defendant sells its Misbranded Food Products to consumers through grocery stores and other retail stores throughout the United States and California.

12. California law applies to all claims set forth in this Third Amended Complaint because Plaintiff lives in California and purchased Gerber products in California. All of the misconduct alleged herein was contrived in, implemented in, and has a shared nexus with California. The formulation and execution of the unlawful practices alleged herein occurred in, or emanated from, California. Accordingly, California has significant contacts and/or a significant aggregation of contacts with the claims asserted by Plaintiff.

13. This Court has jurisdiction over all claims alleged herein pursuant to 28 U.S.C. § 1332, because the matter in controversy exceeds the sum or value of $75,000, and is between citizens of different states.

14. This Court has personal jurisdiction over Defendant because: (i) a substantial portion of the wrongdoing alleged in this Third Amended Complaint occurred in California, (ii) Defendant is authorized to do business in California, (iii) Defendant has sufficient minimum contacts with California, and (iv) Defendant otherwise intentionally availed itself of the markets in California through the promotion, marketing and sale of merchandise, sufficient to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

15. Because a substantial part of the events or omissions giving rise to these claims occurred in this district and because this Court has personal jurisdiction over Defendant, venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (b).

BACKGROUND

Gerber Products Company

16. Gerber claims to be "the world's most trusted name in baby food." http://www.gerber.com/nestle_nutrition/default.aspx. Gerber offers more than 190 products in 80 countries, with labeling in 16 languages. Nestlé SA purchased the Gerber brand in 2007 for $5.5 billion in cash. Gerber reportedly controls between 70 and 80 percent of the baby food market in the United States.

17. Gerber packages and sells such products as puree baby food, snacks, yogurts, side dishes, and beverages for infants and children under two years of age. Gerber organizes its products by "stages" as follows: Birth+, Supported Sitter, Sitter, Crawler, Toddler, and Preschooler. According to Gerber's website, a "supported sitter" is 4 to 5 months old; a "sitter" is 6 to 7 months old; a "crawler" is 8 to 11 months old; and a "toddler" is 12 months old. www.gerber.com. Therefore, all Gerber product categories other than "Preschooler" describe children under two years old.

18. With the recent increase in children's disease and illness caused by poor nutrition

and excessive consumption of fats and sugars, including conditions such as diabetes and obesity, parents are increasingly aware of the need to provide healthy food for their children. To make healthy food choices for their children, parents rely on nutritional information on food product labels. Indeed, Plaintiff Bruton relies on the representations made on product labeling to make choices about what food to purchase for her child.

19. Intending to profit from parents' increasing desire to purchase healthy food for their children, Defendant misbrands its baby food products by, among other things, making nutrient content claims that are strictly prohibited by the Food and Drug Administration ("FDA"), and by misleading purchasers into believing that its products are healthier because there is "no sugar added" and/or healthier for children under two years of age, in order to induce parents into purchasing Gerber products.

Gerber Labeling Claims

20. Defendant has utilized a number of specific unlawful, improper, unauthorized, misleading, and false claims on their products' labeling. A chart listing Defendant's unlawful labeling claims on both the Purchased Products and the Substantially Similar Products is attached hereto as Exhibit A.

21. As depicted in Exhibits A-P, the Purchased Products contain nutrient content claims and/or sugar-related claims.

22. As depicted in Exhibit A, the Substantially Similar Products also contain nutrient content claims and/or sugar-related claims.

23. The Misbranded Food Products identified in Exhibit A are all intended for children under two years of age.

24. Gerber's website, which is specifically referenced on its product labels, also makes nutrient content claims and sugar-related claims.

IDENTICAL CALIFORNIA AND FEDERAL LAW REGULATE FOOD LABELING

25. Food manufacturers are required to comply with identical state and federal laws and regulations that govern the labeling of food products. First and foremost among these is the FDCA and its labeling regulations, including those set forth in 21 C.F.R. § 101.

26. Pursuant to the Sherman Law, California has expressly adopted the federal labeling requirements as its own and indicated that "[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food regulations of this state." California Health & Safety Code § 110100.

27. Under both the Sherman Law and FDCA Section 403(a), food is "misbranded" if "its labeling is false or misleading in any particular," or if it does not contain certain information on its label or its labeling. Cal. Health & Safety Law §§ 110660, 110705; 21 U.S.C. § 343.

28. In addition to its blanket adoption of federal labeling requirements, California has also enacted a number of laws and regulations that adopt and incorporate specific enumerated federal food laws and regulations. As described herein, Defendant has violated the following Sherman Law sections: California Health & Safety Code § 110390 (unlawful to disseminate false or misleading food advertisements that include statements on products and product packaging or labeling or any other medium used to directly or indirectly induce the purchase of a food product); California Health & Safety Code § 110395 (unlawful to manufacture, sell, deliver, hold or offer to sell any falsely advertised food); California Health & Safety Code §§ 110398 and 110400 (unlawful to advertise misbranded food or to deliver or proffer for delivery any food that has been falsely advertised); California Health & Safety Code § 110660 (misbranded if label is false and misleading); California Health & Safety Code § 110665 (misbranded if label fails to conform to the requirements set forth in 21 U.S.C. § 343(q)); California Health & Safety Code § 110670 (misbranded if label fails to conform with the requirements of 21 U.S.C. § 343(r)); California Health & Safety Code § 110705 (misbranded if words, statements and other information required by the Sherman Law are either missing or not sufficiently conspicuous); California Health & Safety Code § 110765 (which makes it unlawful for any person to misbrand

any food); and California Health & Safety Code § 110770 (unlawful for any person to receive in commerce any food that is misbranded or to deliver or proffer for delivery any such food).

29. Plaintiff's claims are based on violations of the Sherman Law.

FDA ENFORCEMENT HISTORY

30. In recent years the FDA has become increasingly concerned that food manufacturers have been disregarding food-labeling regulations. To address this concern, the FDA elected to place the food industry on notice concerning the enforcement of food labeling regulations. In October 2009, the FDA issued a *Guidance for Industry: Letter Regarding Point Of Purchase Food Labeling* and on March 3, 2010 the FDA issued "*Open Letter to Industry from [FDA Commissioner] Dr. Hamburg*" to inform the food industry of its concerns and to place the industry on notice that food labeling compliance was an area of enforcement priority.

31. Dr. Margaret Hamburg's letter stated in pertinent part:

> [The] FDA is notifying a number of manufacturers that their labels are in violation of the law and subject to legal proceedings to remove misbranded products from the marketplace. While the warning letters that convey our regulatory intentions do not attempt to cover all products with violative labels, they do cover a range of concerns about how false or misleading labels can undermine the intention of Congress to provide consumers with labeling information that enables consumers to make informed and healthy food choices. For example:
>
> - Nutrient content claims that FDA has authorized for use on foods for adults are not permitted on foods for children under two. Such claims are highly inappropriate when they appear on food for infants and toddlers because it is well known that the nutritional needs of the very young are different than those of adults.

32. In fact, the FDA has sent warning letters directly to Defendant Gerber and related companies. *See* Exhibits Q and R.

33. More specifically, the FDA sent Defendant a warning letter for some of the same types of misbranded labels and deceptive labeling claims described herein. *See* Exhibit Q (February 22, 2010 FDA warning letter addressed to Nestle Nutrition, with a copy to Mark Shipley, Plant Manager at Gerber Products Company in Fremont, Michigan). In that letter, the FDA wrote in pertinent part:

> The products in your Gerber Graduates Fruit Puffs line are misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because their labeling includes unauthorized nutrient content claims. Except for claims regarding the percentage of a vitamin or mineral for which there is an established Reference Daily Intake (RDI), a nutrient content claim may not be made for a food intended specifically for use by infants and children less than 2 years of age unless the claims is [sic] specifically provided for in parts 101, 105, or 107 of FDA regulations. 21 CFR 101.13(b)(3). Your Graduates Fruit Puffs products are specifically intended for infants and children under age 2. For example, the labeling indicates that the products are designed for the "crawler" stage of a child's life. The labeling for these products includes nutrient content claims such as "good source of iron, zinc, and vitamin E for infants and toddlers." The circumstances under which "good source" claims are permitted are defined in 21 CFR 101.54. That regulation does not allow such claims for foods intended specifically for infants and children under 2.
>
> Your 2nd Foods Carrots product is misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because its labeling includes unauthorized nutrient content claims. This product is also intended specifically for infants and children under the age of two. For example, its labeling states that the product is appropriate for a "sitter," and sitting is a developmental milestone that generally occurs by the age of one. The 2nd Foods Carrots product label bears the nutrient content claim "healthy" as part of the statement "As Healthy as Fresh," and nutrient content claims such as "Excellent Source…of Vitamin A" and "No Added Sugar." These circumstances under which such claims are permitted are defined in 21 CFR 101.65(d), 21 CFR 101.54(b), and 21 CFR 101.60(c). However, these regulations do not allow the claim for products specifically intended for children under two years of age.
>
> The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that your firm and all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

34. The FDA also wrote a letter to Nestle U.S.A., a sister company to Defendant. *See* Exhibit R (December 4, 2009 warning letter to Brad Alford, Chairman and CEO of Nestle U.S.A.). In that letter, the FDA wrote in pertinent part:

> Your Juicy Juice Brain Development Fruit Juice Beverage product is misbranded within the meaning of section 403(r) of the Act [21 USC 343(r)] because its labeling includes unauthorized nutrient content claims. Except for statements that describe the percentage of a vitamin or mineral in relation to a Reference Daily Intake (RDI), a nutrient content claim cannot be made for a food intended for use by infants and children less than 2 years of age unless the claim is specifically provided for in parts 101, 105, or 107 of FDA regulations. 21 CFR 101.13(b)(3). This product is marketed specifically for children under two years of age, as indicated by the claim "Helps support brain development***in children under two years old," which appears on the product label. The label also bears the nutrient content claim "no sugar added." The circumstances under which a "no sugar added" claim is permitted are defined in 21 CFR 101.60(c). That regulation does not allow the claim for conventional food products intended for use in children under age 2. 21 CFR 101.60(c)(4). Therefore, the claim "no sugar added" misbrands your product.

35. Despite these warning letters, Defendant did not change the labels on its Misbranded Food Products that contained the labeling claims that were in violation.

36. Additionally, the FDA has sent warning letters to the industry, including many of Defendant's peer food manufacturers. Defendant also ignored the numerous warning letters the FDA sent to other companies for similar violations and posted on the FDA website as guidance for food manufacturers. Defendant also ignored the FDA's Guidance for Industry, A Food Labeling Guide, which details the FDA's guidance on how to make food-labeling claims.

37. Despite the FDA's numerous warnings to industry, Defendant has continued to sell products bearing unlawful food labeling claims without meeting the requirements to make those claims. Defendant's Misbranded Food Products continue to run afoul of FDA guidance as well as federal and California law, as Defendant continues to utilize unlawful claims on the labels of its Misbranded Food Products.

38. Plaintiff did not know, and had no reason to know, that the Defendant's Misbranded Food Products were misbranded and bore food-labeling claims despite failing to meet the requirements to make those food-labeling claims.

39. Defendant had actual knowledge of these warning letters, or Defendant should have known of these warning letters. Upon information and belief, Defendant did not change its labels in response to any warning letters, or for any other reason. As described herein, Defendant continues to misbrand its food products intended for children under two years of age, despite the fact that the FDA has warned Defendant that its products are misbranded.

SHERMAN LAW VIOLATIONS

Defendant's Misbranded Food Products

40. Pursuant to Section 403 of the FDCA, a claim that characterizes the level of a nutrient in a food is a "nutrient content claim" that must be made in accordance with the regulations that authorize the use of such claims. 21 U.S.C. § 343(r)(1)(A). California expressly adopted the requirements of 21 U.S.C. § 343(r) in § 110670 of the Sherman Law. Further, 21 C.F.R. § 101.13 provides the general requirements for nutrient content claims, which California has expressly adopted. California Health & Safety Code § 110100.

41. Nutrient content claims are claims about specific nutrients contained in a product. They are typically made on food packaging in a font large enough to be read by the average consumer. Because consumers rely upon these claims when making purchasing decisions, the regulations govern what claims can be made in order to prevent misleading claims.

42. Section 403(r)(1)(A) of the FDCA governs the use of expressed and implied nutrient content claims on labels of food products that are intended for sale for human consumption.

43. An "expressed nutrient content claim" is defined as any direct statement about the level (or range) of a nutrient in the food (*e.g.*, "low sodium" or "contains 100 calories"). *See* 21 C.F.R. § 101.13(b)(1). An "implied nutrient content claim" is defined as any claim that: (i) describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or

present in a certain amount (*e.g.*, "high in oat bran"); or (ii) suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (*e.g.*, "healthy, contains 3 grams (g) of fat"). 21 C.F.R. § 101.13(b)(2)(i-ii).

44. FDA regulations authorize the use of a limited number of defined nutrient content claims. In addition, FDA's regulations authorize the use of only certain synonyms for these defined terms. If a nutrient content claim or its synonym is not included in the food labeling regulations, it cannot be used on a label. Only those claims, or their synonyms, that are specifically defined in the regulations may be used. All other claims are prohibited. 21 CFR §101.13(b).

45. Only approved nutrient content claims will be permitted on the food label, and all other nutrient content claims will misbrand a food. It should thus be clear which type of claim is prohibited and which permitted. Food manufacturers are on notice that the use of an unapproved nutrient content claim is prohibited conduct. 58 FR 2302. In addition, 21 USC §343(r)(2) prohibits using unauthorized undefined terms, and it declares foods that do so to be misbranded.

46. 21 C.F.R. § 101.13(b)(3) limits nutrient claims that may be made on "food intended specifically for use by infants and children less than 2 years of age" to claims regarding vitamins and minerals "that describe the percentage of a vitamin or mineral in the food, including foods intended specifically for use by infants and children less than 2 years of age, in relation to a Reference Daily Intake (RDI)." Except for those claims describing a percentage in relation to the RDI, "no nutrient content claims may be made on food intended specifically for use by infants and children less than 2 years of age."

47. Misbranded products cannot be legally sold under California Law. *See* Cal. Health and Safety Code § 110760. Misbranded products cannot be legally sold under Federal Law. *See* 21 U.S.C. §§ 331, 333.

Defendant Made Unlawful and Misleading
Nutrient Content Claims on Products Intended for Children

48. Despite the clear directive, as described herein, prohibiting Defendant from making nutrient content claims on food intended specifically for use by infants and children less than two years of age, Defendant make such claims on its Gerber food products intended for use by such infants and children, as depicted in Exhibits A-P.

a. *"Excellent Source" and "Good Source"* – As described herein, and in Exhibit A, Gerber food products which are intended for use by infants and children less than two years of age claim to be an "Excellent Source" and "Good Source" of certain vitamins and minerals. All such Gerber products are misbranded within the meaning of FDCA § 403(r)(1)(A) and 21 U.S.C. § 343(r)(1)(A) because their labeling includes unauthorized nutrient content claims. Except for claims regarding the percentage of a vitamin or mineral for which there is an established Reference Daily Intake (RDI), a nutrient content claim may not be made for a food intended specifically for use by infants and children less than two years of age unless the claims are specifically provided for in parts 101, 105, or 107 of FDA regulations. *See* 21 CFR § 101.13(b)(3). The circumstances under which "source" claims are permitted are defined in 21 CFR §101.54, and that regulation does not allow such claims for foods intended specifically for infants and children under two years of age.

b. *"Healthy"* - As described herein, and in Exhibit A, Gerber food products which are intended for use by infants and children less than two years of age bear the nutrient content claim "Healthy" as part of the following statements: "As Healthy as Fresh," "Nutrition for Healthy Growth & Natural Immune Support," and "Supports Healthy Growth & Development." All such products are misbranded within the meaning of section FDCA § 403(r)(1)(A) and 21 U.S.C. § 343(r)(1)(A) because the labeling includes unauthorized nutrient content claims. The circumstances under which such claims are permitted are defined in 21 CFR §101.65(d). However, these regulations do not allow the claim for products specifically intended for children under two years of age.

c. *"No Added Sugar"* – As described herein, and in Exhibit A, Gerber food products which are intended for use by infants and children less than two years of age claim to have "No Added Sugar" or "No Added Refined Sugar." Such nutrient content claims may not be made on food products intended for children under two. *See* 21 CFR § 101.13(b)(3) (prohibiting all nutrient content claims on products intended for children under two, except as specifically provided for elsewhere); 21 CFR § 101.60(c)(4) (allowing "No Added Sugar" claims only with respect to dietary supplements or vitamins intended for children under two). All such products are misbranded within the meaning of section FDCA § 403(r)(1)(A) and 21 U.S.C. § 343(r)(1)(A) because the labeling includes unauthorized nutrient content claims. The circumstances under which such claims are permitted are defined in 21 CFR §101.60(c). These regulations do not allow the claim for products specifically intended for children under two years of age.

49. Nutrient content claims on products intended to be consumed by children under two are barred because the nutritional needs of children are very different from those of adults, and thus such nutritional claims on infant and toddler food can be highly misleading.

50. In the FDA warning letter attached as Exhibit Q, the FDA specifically found that Defendant's Gerber Graduates Fruit Puffs products were misbranded in that they are intended to be consumed by children under two and make the prohibited nutrient content claims described herein. The FDA specifically wrote that the Puffs were misbranded because their labels claimed to be "good source of iron, zinc, and vitamin E for infants and toddlers." Upon information and belief, Gerber removed these specific claims for "good source" from its Puffs' labels after receiving this warning letter. Nevertheless, Gerber continues today to make specific "good source" and "excellent source" claims on other baby food products despite the FDA's warning that this was a violation on the Puffs label. Despite the FDA warning, Gerber also continues to make the improper claims about their Puffs on their website.
http://www.gerber.com/AllStages/products/snacks/puffs_apple_cinnamon.aspx

51. Defendant's 2nd Food Carrots is another Gerber product that is intended specifically for infants and children under the age of two. Defendant's labeling states that this

product is appropriate for a "Sitter," and sitting is a developmental milestone that generally occurs by the age of one. According to Gerber's own website, a "sitter" is a child 6 to 7 months old. Defendant's 2nd Foods Carrots product is misbranded because its labeling includes unauthorized nutrient content claims. The 2nd Foods Carrots product label bears the nutrient content claim "healthy" as part of the statement "As Healthy as Fresh," and nutrient content claims such as "Excellent Source of Vitamin A" and "No Added Refined Sugar." The circumstances under which such claims are permitted are defined in 21 CFR §101.65(d), 21 CFR §101.54(b), and 21 CFR §101.60(c). These regulations, however, do not allow any claim of this type to be made on the label of products specifically intended for children under two years of age.

52. In the February 22, 2010 FDA warning letter, the FDA specifically found that Defendant's 2nd Foods Carrots product is misbranded in that it is intended to be consumed by children under two and makes the prohibited nutrient content claims set forth above. *See* Exhibit Q. Defendant nevertheless continue to misbrand their baby food with this and other similar claims in violation of the law.

53. Despite the FDA's warning that the phrase "As Healthy as Fresh" caused its carrots product to be misbranded, Gerber continues to use "As Healthy as Fresh" on many of its baby food labels. It also improperly uses a similar claim that a product "Supports Healthy Growth & Development" and "Nutrition for Healthy Growth & Natural Immune Support."

54. As depicted on Exhibit A, many of Defendant's products intended for infants and children under two also contain a marketing logo using the phrase "NUTRI PROTECT" which typically shows small blocks in the arms of a child, labeled with iron, zinc, or a vitamin such as Vitamin E. In using those symbols, Defendant is either expressly or by implication making nutrient content claims, which are also prohibited as described herein.

55. The violations identified by the FDA in its warning letters were not a comprehensive compilation of Defendant's violations, but were instead merely representative examples. Many of Defendant's other products continue to be misbranded in that they include other similar nutrient content claims on products intended to be consumed by children under two.

For example, Defendant's label on Graduates for Toddlers Banana Cookies product states that it is a "Good Source of Vitamin E, Iron, Zinc & Calcium." Similarly, the "Graduates For Toddlers Fruit Strips Real Fruit Bars" claim to be an "Excellent Source of Vitamin C;" the "Graduates Lil' Crunchies" corn snack claims to be a "Good Source of Vitamin E, Iron, & Zinc;" the Graduates Arrowroot Cookies claim to be a "Good Source of Vitamin E, Zinc, & Calcium;" the Graduates "Lil' biscuits" claim to be a "Good Source of Calcium, Iron & Vitamin E & Zinc;" and the "Graduates For Toddlers Animal Crackers" claim to be a "Good Source of Vitamin E, Iron, Zinc and Calcium." *Id*. Each of Defendant's Gerber 2nd Foods products also claim to be an "Excellent Source" of various vitamins and to be "As Healthy As Fresh." *See* Exhibit A for a detailed list.

56. The circumstances under which such claims are permitted are defined in 21 CFR §101.65(d) and 21 CFR §101.54(c). These regulations, however, do not allow such a claim for products specifically intended for children under two years of age. Defendant's products listed herein are therefore misbranded. Defendant has also made the same unlawful claims on its websites and in its advertising in violation of federal and California laws.

57. Plaintiff relied on these nutrient content claims. Because of these improper nutrient content claims, Plaintiff purchased these products and paid a premium for them. The regulations relating to nutrient content claims discussed herein are intended to ensure that consumers are not misled as to the actual or relative levels of nutrients in food products. Defendant has violated these referenced regulations. Therefore, Defendant's Misbranded Food Products are misbranded as a matter of federal and California law.

Defendant Makes Unlawful and Misleading Sugar-Related Claims

58. As depicted in Exhibit A, Defendant also claims that several of its products, such as its Gerber 2nd Foods products, contain "No Added Refined Sugar" or contain "No Added Sugar." Many of the Defendant's products that are labeled with a "No Added Sugar" or similar sugar-related nutrient content claim contain disqualifying levels of calories that prohibit the claim

from being made absent a mandated disclosure statement warning of the higher caloric level of the products and thus violate 21 CFR §101.60(c)(2).

59. Federal and California regulations regulate such sugar claims as a particular type of nutrient content claim. Specifically, 21 C.F.R. § 101.60 contains special requirements for nutrient claims that use the terms "no sugar added." Pursuant to the Sherman Law, California has expressly adopted the federal labeling requirements of 21 C.F.R. § 101.60 as its own. California Health & Safety Code § 110100.

60. 21 C.F.R. § 101.60(c)(2) provides in pertinent part:

> (2) The terms "no added sugar," "without added sugar," or "no sugar added" may be used only if:
>
> > (i) No amount of sugars, as defined in §101.9(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging; and
> >
> > (ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice; and
> >
> > (iii) The sugars content has not been increased above the amount present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a food, and a functionally insignificant increase in sugars results; and
> >
> > (iv) The food that it resembles and for which it substitutes normally contains added sugars; and
> >
> > (v) The product bears a statement that the food is not "low calorie" or "calorie reduced" (unless the food meets the requirements for a "low" or "reduced calorie" food) and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content.

61. 21 C.F.R. § 101.60(b)(2) provides that:

> The terms "low-calorie," "few calories," "contains a small amount of calories," "low source of calories," or "low in calories" may be used on the label or in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that: (i)(A) The food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and does not provide more than 40 calories per reference amount customarily consumed; or (B) The food has a reference amount customarily

> consumed of 30 g or less or 2 tablespoons or less and does not provide more than 40 calories per reference amount customarily consumed and, except for sugar substitutes, per 50 g ….(ii) If a food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the caloric content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "celery, a low-calorie food").

62. Defendant's products labeled "no sugar added" are not low-calorie and/or not suitable for weight control as they contain more than the 40 calories per reference amount customarily consumed; or for foods with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and does not provide more than 40 calories per reference amount customarily consumed and per 50 grams, which is the maximum amount allowed under 21 C.F.R. § 101.60(b)(2).

63. Notwithstanding the fact that 21 C.F.R. § 101.60(c)(2) bars the use of the terms "no added sugar" on foods that are not low-calorie unless they bear a disclaimer referring to the nutrient facts table, Defendant has touted its non low-calorie products as containing "no added sugar" or "no added refined sugar" and have chosen to omit the mandated disclaimer statement.

64. In doing so, Defendant has ignored the language of 21 C.F.R. § 101.60(c)(1) that states that:

> Consumers may reasonably be expected to regard terms that represent that the food contains no sugars or sweeteners e.g., "sugar free," or "no sugar," as indicating a product which is low in calories or significantly reduced in calories.

65. Because consumers may reasonably be expected to regard terms that represent that the food contains "no added sugar" or sweeteners as indicating a product which is low in calories or significantly reduced in calories, consumers are misled when foods that are not low-calorie as a matter of law are falsely represented, through the unlawful use of phrases like "no added sugar" that they are not allowed to bear due to their high calorific levels and absence of mandated disclaimer or disclosure statements.

66. The labeling for Defendant's products violate California law and federal law. For these reasons, Defendant's "no added sugar" claims at issue in this Complaint are misleading and in violation of 21 C.F.R. § 101.60(c)(2) and California law, and the products at issue are

misbranded as a matter of law. Misbranded products cannot be legally sold and are legally worthless.

67. Defendant is in violation despite numerous enforcement actions and warning letters pertaining to several other companies addressing the type of misleading sugar-related nutrient content claims described herein.

68. Plaintiff did not know, and had no reason to know, that Defendant misbranded the Purchased Products, and bore nutrient content claims despite failing to meet the requirements to make those nutrient content claims.

69. Defendant's products in this respect are misbranded under federal and California law.

Plaintiff Bought Defendant's Purchased Products

70. Plaintiff is concerned about the nutritional content of the food she purchased for her child's consumption, and seeks to ensure that her child maintains a healthy diet.

71. As indicated in Exhibits A-P, and based on the definition of Purchased Products herein, Plaintiff purchased Defendant's food products intended for children under two. Plaintiffs spent more than $25.00 on the Purchased Products.

72. Plaintiff read and reasonably relied on the labels as described herein when buying the Purchased Products. In relying on Defendant's labeling, Plaintiff based and justified her decision to purchase Defendant's products, in substantial part, on these labels.

73. Defendant's labeling claims were a material factor in Plaintiff's decisions to buy the Purchased Products. Based on Defendant's claims, Plaintiff believed that the products were a better and healthier choice than other available products.

74. At point of sale, Plaintiff did not know, and had no reason to know, that Defendant's products were misbranded as set forth herein, and would not have bought the products had she known the truth about them. At point of sale, Plaintiff did not know, and had no reason to know, that Defendant's nutrient content claims on the products' labels were unlawful as set forth herein, and would not have bought the products had she known the truth about them.

75. As a result of Defendant's misrepresentations, Plaintiff purchased the products at issue.

76. After Plaintiff learned that Defendant's Purchased Products were falsely labeled, Plaintiff stopped purchasing them.

77. Defendant's labeling, advertising, and marketing as alleged herein are false and misleading and designed to increase sales of the products at issue. Defendant's misrepresentations are part of an extensive labeling, advertising and marketing campaign, and a reasonable person would attach importance to Defendant's representations in determining whether to purchase the products at issue.

78. A reasonable person would attach importance to whether Defendant's products were "misbranded," *i.e.* neither legally salable, and to Defendant's representations about these issues in determining whether to purchase the products at issue. Plaintiff would not have purchased the Defendant's products had she known they were not capable of being legally sold or held.

79. Plaintiff had cheaper alternatives available and paid an unwarranted premium for the Purchased Products.

Defendant Has Violated California Laws

80. Defendant has manufactured, advertised, distributed, and sold products that are misbranded under California law. Misbranded products cannot be legally manufactured, advertised, distributed, sold or held, and are legally worthless as a matter of law.

81. Defendant has violated California Health & Safety Code provisions, including those which make it unlawful to disseminate false or misleading food advertisements that include statements on products and product packaging or labeling or any other medium used to directly or indirectly induce the purchase of a food product. *See* §§ 109885 and 110390.

82. Defendant has violated California Health & Safety Code § 110395 which makes it unlawful to manufacture, sell, deliver, hold, or offer to sell any falsely advertised food.

83. Defendant has violated California Health & Safety Code §§ 110398 and 110400 which make it unlawful to advertise misbranded food or to deliver or proffer for delivery any food that has been falsely advertised.

84. Defendant has violated California Health & Safety Code § 110660 because its food products are misbranded in one or more ways, as follows:

a. They are misbranded under California Health & Safety Code § 110665 because their labeling fails to conform to the requirements for nutrient labeling set forth in 21 U.S.C. § 343(q) and the regulations adopted thereto;

b. They are misbranded under California Health & Safety Code § 110670 because their labeling fails to conform with the requirements for nutrient content and health claims set forth in 21 U.S.C. § 343(r) and the regulations adopted thereto; and

c. They are misbranded under California Health & Safety Code § 110705 because words, statements, and other information required by the Sherman Law to appear on their labeling either are missing or not sufficiently conspicuous.

85. Defendant has violated California Health & Safety Code § 110760 which makes it unlawful for any person to manufacture, advertise, distribute, hold, sell, or offer for sale any food that is misbranded.

86. Defendant has violated California Health & Safety Code § 110765 which makes it unlawful for any person to misbrand any food.

87. Defendant has violated California Health & Safety Code § 110770 which makes it unlawful for any person to receive in commerce any food that is misbranded or to deliver or proffer for delivery any such food.

88. Defendant has violated the standards set by 21 CFR §§ 101.13, 101.54, 101.60, and 101.65, which have been adopted by reference in the Sherman Law, as more fully described herein, by including unauthorized nutrient content claims on their products.

89. Defendant's labeling, advertising, and marketing as alleged herein is false and misleading and designed to increase sales of the products at issue. Defendant's misrepresentations

are part of an extensive labeling, advertising and marketing campaign, and a reasonable person would attach importance to Defendant's representations in determining whether to purchase the products at issue. A reasonable person would attach importance to whether Defendant's products were legally salable and to Defendant's representations about these issues in determining whether to purchase the products at issue. Plaintiff would not have purchased the Defendant's Misbranded Food Products had she known they were not capable of being legally sold.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
Business and Professions Code § 17200, *et seq.*
Unlawful Business Acts and Practices

90. Plaintiff incorporates by reference each allegation set forth herein.

91. Defendant's conduct constitutes unlawful business acts and practices.

92. Defendant sold Misbranded Food Products in California and the United States.

93. Defendant is a corporation and, therefore, each is a "person" within the meaning of the Sherman Law.

94. Defendant's business practices are unlawful under § 17200, *et seq*. by virtue of Defendant's violations of the advertising provisions of Article 3 of the Sherman Law and the misbranded food provisions of Article 6 of the Sherman Law (Article 6).

95. Defendant's business practices are unlawful under § 17200, *et seq*. by virtue of Defendant's violations of § 17500, *et seq.*, which forbids untrue and misleading advertising.

96. Defendant's business practices are unlawful under § 17200, *et seq*. by virtue of Defendant's violations of the Consumer Legal Remedies Act, Cal. Civ. Code. § 1750 *et seq.*

97. Defendant sold Plaintiff Misbranded Food Products that were not capable of being sold or held legally and which were legally worthless. Plaintiff paid a premium price for the Misbranded Food Products.

98. As a result of Defendant's business practices, Plaintiff, pursuant to Business and Professions Code § 17203, is entitled to an order to disgorge Defendant's ill-gotten gains and to restore any money paid for the Misbranded Food Products.

SECOND CAUSE OF ACTION

Restitution Based on Unjust Enrichment/Quasi-Contract

99. Plaintiff incorporates by reference each allegation set forth above.

100. As a result of Defendant's unlawful and misleading labeling, advertising, marketing, and sales of Defendant's Misbranded Food Products, Defendant was enriched at the expense of Plaintiff.

101. Defendant sold Misbranded Food Products to Plaintiff that were not capable of being sold or held legally and which were legally worthless. Plaintiff paid a premium price for the Misbranded Food Products.

102. It would be against equity and good conscience to permit Defendant to retain the ill-gotten benefits received from Plaintiff, in light of the fact that the products were not what Defendant purported them to be. Thus, it would be unjust and inequitable for Defendant to retain the benefit without restitution to Plaintiff of all monies paid to Defendant for the products at issue.

103. As a direct and proximate result of Defendant's actions, Plaintiff has suffered damages in an amount to be proven at trial.

JURY DEMAND

Plaintiff hereby demands a trial by jury of her claims.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, and on behalf of the general public, prays for judgment against Defendant as follows:

A. For an order awarding, as appropriate, damages, restitution or disgorgement to Plaintiff for all causes of action;

B. For an order awarding attorneys' fees and costs;

C. For an order awarding punitive damages;

D. For an order awarding pre-and post-judgment interest; and

E. For an order providing such further relief as this Court deems proper.

Dated: March 2, 2018.

Respectfully submitted,

David Shelton

David Shelton (admitted *pro hac vice*)
SHELTON DAVIS PLLC
1223 Jackson Avenue, Suite 202
P.O. Box 2541
Oxford, MS 38655
662-281-1212
david@sheltondavispllc.com

Ben F. Pierce Gore (SBN 128515)
PRATT & ASSOCIATES
1871 The Alameda, Suite 425
San Jose, CA 95126
(408) 429-6506
pgore@prattattorneys.com

CERTIFICATE OF SERVICE

I hereby certify that I have this day filed and served through the Court's ECF system a true and correct copy of the foregoing.

David Shelton