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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

OULA ZAKARIA, individually and as a representative of the class,

Plaintiff,

vs.

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

Defendant.

Case No.:

CLASS ACTION COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

1. Plaintiff, Oula Zakaria ("Plaintiff") on behalf of herself and all other persons who purchased Gerber Good Start Gentle infant formula, alleges as follows on personal knowledge as to all facts related to herself and upon information and belief as to all other matters:

NATURE OF THE ACTION

2. This case involves a pattern of deceit and unfair business practices by Gerber Products Co. ("Defendant") in the marketing and sale of Good Start Gentle, a prominent line of infant formula produced, distributed, marketed, and sold by Defendant made from partially hydrolyzed whey protein.

3. Plaintiff brings this class action lawsuit challenging false representations and misleading practices knowingly made or undertaken by Defendant in Good Start Gentle's promotional campaign including, without limitation, (a) that Good Start Gentle was the "first and only" formula whose consumption reduced the risk of infants developing allergies; (b) that consumption of Good Start Gentle reduced the risk of developing infant atopic dermatitis, an inflammatory skin disorder; (c) that Good Start Gentle was the "first and only" formula endorsed by the Food and Drug Administration ("FDA") to reduce the risk of developing allergies; and (d) using the FDA term of art "Qualified Health Claim" to convey that Good Start Gentle was fit for a particular purpose when in actuality the term conveys that a "Qualified Health Claim" is limited or lacking.

4. In 2005 and 2009, Defendant petitioned the FDA to approve claims that partially hydrolyzed whey protein reduced the risk of infants developing food allergies and atopic dermatitis.

5. No scientific or other evidence exists linking a reduced risk of infant allergies to the consumption of partially hydrolyzed whey protein. Moreover, little or very little scientific evidence supports the claim that the consumption of partially hydrolyzed whey protein reduces the risk of infants developing atopic dermatitis.

6. After reviewing this body of evidence, the FDA rejected Defendant's proposed claims, stating that "no credible evidence" supported the link between partially hydrolyzed whey protein and a reduced risk of food allergies. Concerning the link between the consumption of partially hydrolyzed whey protein and a reduced risk of atopic dermatitis, the FDA rejected the language

proposed by Defendant because the language mischaracterized the connection and would mislead consumers. The FDA stated that it would only consider exercising its enforcement discretion regarding the atopic dermatitis claim if Defendant modified its claim and included highly qualifying language that very little or little scientific evidence (depending on infant age) existed to support the link.

7. Beginning in at least 2011, despite the FDA's clear rejections and the absence of evidence supporting its claims, Defendant falsely advertised Good Start Gentle as the first and only infant formula endorsed by the FDA to reduce the occurrence of allergies in infants. Defendant made these unsupported claims in order to strategically outpace competitors and substantially increase its sales. Defendant undertook its marketing campaign with actual knowledge that its claims were untrue and notably failed to include any qualifying language or disclaimers in Good Start Gentle advertising.

8. Due to Defendant's pervasive and false marketing campaign that Good Start Gentle provided benefits to children's health beyond that offered by other baby formulas and that the FDA had certified this claim, Plaintiff and the other Class members (as defined below) purchased Good Start Gentle at an inflated cost.

9. Plaintiff and the Class were injured by Defendant's unlawful conduct and are entitled to actual, statutory, and punitive damages, restitution, injunctive and declaratory relief, interest, and the reimbursement of attorneys' fees.

10. In October 2014, the Federal Trade Commission ("FTC") brought suit against Defendant seeking to enjoin its deceptive practices in relation to the marketing and sale of Good Start Gentle, specifically citing Defendant's false or misleading claim "that feeding Gerber Good Start Gentle formula to infants with a family history of allergies prevents or reduces the risk that they will develop allergies" and the false or misleading claim "that Gerber Good Start Gentle formula qualified for or received approval for a health claim from the Food and Drug Administration."

11. Also in October 2014, the FDA issued Defendant a warning letter listing a litany of misrepresentations and falsehoods in the promotion of Good Start Gentle that violated federal law

and related regulations. Defendant was instructed by the FDA to cease its deceitful practices or face potential legal action by the FDA.

12. Plaintiff, on behalf of herself and other similarly situated consumers, brings this consumer protection action against Defendant based on its course of unlawful conduct. Plaintiff alleges violations of California's Unfair Competition Law, California False Advertising Law, the Consumer Legal Remedies Act, as well as Breach of Express Warranty, Breach of the Implied Warranty of Merchantability, Negligent Misrepresentation, and Intentional Misrepresentation.

PARTIES

13. Plaintiff is and was at all relevant times herein, a resident of Porter Ranch, California and is a member of the class. Plaintiff frequently purchased Gerber Good Start Gentle infant formula based on Defendant's false advertising and deceitful business practices.

14. Defendant, also doing business as Nestle Nutrition, Nestle Infant Nutrition, and Nestle Nutrition North America, is a Michigan corporation with its headquarters located at 12 Vreeland Road, Florham Park, New Jersey 07932. Throughout the Class Period (as defined below), Defendant has transacted business in this district and throughout California, including marketing, distributing, and selling Good Start Gentle.

JURISDICTION AND VENUE

15. This Court has original jurisdiction over this case under the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2). Plaintiff is a citizen of California and Defendant is a citizen of a different state, New Jersey. The amount in controversy in this action exceeds $5,000,000 and there are more than 100 members in the Class.

16. This Court has personal jurisdiction over Defendant because Defendant is authorized to conduct business in California, is doing business in California, is registered with the California Secretary of State, and maintains a registered agent in Sacramento, California. Alternatively, Defendant is engaged in systematic and continuous business activity in California, has sufficient minimum contacts in California, or otherwise intentionally avails itself of the California consumer

market through the promotion, marketing, distribution, and sale of consumer goods, including Good Start Gentle. This purposeful availment renders the exercise of jurisdiction by this Court over Defendant appropriate under traditional notions of fair play and substantial justice.

17. Venue is proper in this District pursuant to 28 U.S.C. § 1391. Plaintiff resides in this District, Defendant regularly conducts business in this District, and a substantial portion of the events giving rise to the claims alleged herein occurred in this District.

FACTUAL ALLEGATIONS

A. Good Start Gentle Infant Formula Background Information

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

19. Gerber Good Start Gentle contains partially hydrolyzed whey protein. Whey protein is derived from cow's milk during the production of cheese. Partially hydrolyzed whey protein undergoes additional processing to break the protein into smaller fragments.

B. The FDA Rejected Defendant's Petition for a Qualified Health Claim Linking Partially Hydrolyzed Whey Protein with a Reduction of Common Food Allergies in 2006

20. Under federal regulation and law, the FDA is the governmental body tasked with reviewing and authorizing health claims relating to food products sold in the United States. *See* FDA, *Questions and Answers: Qualified Health Claims in Food Labeling* (Sept. 28, 2005), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm207974.htm (last visited January 6, 2014).

21. A health claim characterizes the relationship between a substance and a disease or health-related condition. Such a claim explains that a food or food component may reduce the risk of a disease or a health related condition. An example of a health claim is: "Diets low in saturated fat and cholesterol may reduce the risk of heart disease." *Id.*

22. Health claims fall into two categories. An "unqualified health claim" must be supported by significant scientific agreement among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship. A "qualified health claim," on the other hand, is supported by scientific evidence, but does not meet the significant scientific agreement standard. As such, to ensure that they are not false or misleading to consumers, they must be accompanied by a disclaimer or other qualifying language to accurately communicate the level of scientific evidence supporting the claim. *Id.*

23. All health claims, whether qualified or unqualified, require pre-market review by the FDA. The FDA authorizes by regulation unqualified health claims on product labels only if the substance/disease relationship described by the health claims meets the "significant scientific agreement" standard. For approved qualified health claims, the FDA issues letters of enforcement discretion when there is credible evidence to support the claim. *Id.* Qualified health claims must include disclaimers that remedy any potential harm caused by potentially misleading claims. *Id.*

24. In June 2005, Defendant petitioned to have the following qualified health claim approved by the FDA:

> Breastfeeding is the best way to nourish infants. For infants who are not exclusively breastfed, emerging clinical research in healthy infants with family history of allergy shows that feeding a 100% Whey-Protein Partially Hydrolyzed formula may reduce the risk of common food allergy symptoms, particularly allergic skin rash, when used instead of whole-protein cow's milk formula from the initiation of formula feeding.

See Qualified Health Claims: Letters of Denial – 100 Percent Partially Hydrolyzed Whey Protein in Infant Formula and Reduced Risk of Food Allergy in Infants (Docket No. 2005Q-0298) (May 11, 2006), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073313.htm (last visited Jan. 6, 2014).

25. No scientific or other evidence supports Defendant's health claim that ingesting partially hydrolyzed whey protein reduces the risk that infants will develop allergies. For example, from a sampling of thirty-six studies evaluating the relationship, none drew a sound scientific conclusion that partially hydrolyzed whey protein did, in fact, reduce such risk. *Id.* at Appendix 1

(The studies suffer from a multitude of deficiencies including improper controls and unacceptable diagnoses of food allergies.).

26. On May 11, 2006, after reviewing these studies and other available scientific evidence, the FDA rejected Defendant's petition, concluding that there was "no credible evidence to support the qualified health claim relating consumption of 100 percent partially hydrolyzed whey protein in infant formula to a reduced risk of food allergy[.]" *Id.* Due to this complete lack of credible scientific evidence, the FDA further rejected the "use of a disclaimer or qualifying language to accompany the proposed claim." *Id.*

27. The FDA's denial letter was addressed to Melanie Fairchild-Dzanis, Defendant's Director of Regulatory Issues—Special Nutritional. Fairchild-Dzanis is a lawyer and managed Defendant's regulatory function.

28. As a result of its dealing with the FDA, Defendant possessed actual knowledge that (a) its claim that partially hydrolyzed whey protein reduced the risk of infant allergies was baseless, false and incurable with qualifiers and (b) the FDA rejected its qualified health claim regarding the link.

C. The FDA Similarly Rejected Defendant's Petition for a Health Claim Linking Partially Hydrolyzed Whey Protein and a Reduced Risk of Atopic Dermatitis in Infants in 2011

29. In May 2009, Defendant petitioned to have the following qualified health claim approved by the FDA:

> Breastfeeding is the best way to nourish infants. For infants who are not exclusively breastfed, emerging clinical research in healthy infants shows that, in healthy infants with family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula instead of a formula containing intact cow's milk proteins may reduce the risk of developing the most common allergic disease of infancy—atopic dermatitis—throughout the 1st year of life and up to 3 years of age.

See Whey-Protein Partially Hydrolyzed Infant Formula and Reduced Risk of Atopic Dermatitis (May 24, 2011), available at http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm256731.htm (last visited January 6, 2014).

30. Little or very little evidence exists to support Defendant's claim that partially hydrolyzed whey protein reduced the risk of developing atopic dermatitis in infants. From a sampling of twenty studies, sixteen did not draw a sound scientific conclusion that partially hydrolyzed whey protein did, in fact, reduce such risk, and two demonstrated that no beneficial relationship existed at all. *Id.*

31. In May 2011, after reviewing these studies and other scientific evidence, the FDA made two findings regarding Gerber's qualified health claim. *Id.* First, the FDA concluded that there "is very little credible evidence for a qualified health claim about the relationship between feeding a 100 percent whey-protein partially hydrolyzed infant formula for the first 4 months of life and a reduced risk of atopic dermatitis throughout the first year of life and up to 3 years of age." *Id.* Second, it concluded "that there is little credible evidence for a qualified health claim about the relationship between feeding 100 percent whey-protein partially hydrolyzed infant formula for the first four months of life and a reduced risk of atopic dermatitis throughout the first year of life." *Id.*

32. As a result, the FDA rejected Defendant's claim as proposed because it "mischaracterized the strength of the evidence and [was] misleading." *Id.*

33. The FDA stated that it would only consider exercising its enforcement discretion regarding Defendant's atopic dermatitis claim if Defendant attached qualifying language to the effect that "very little scientific evidence" or "little scientific evidence" supports the link between partially hydrolyzed whey protein and a reduced risk of atopic dermatitis depending on the infant age included in the claim. *Id.*

34. The FDA's 2011 denial letter was similarly addressed to Ms. Fairchild-Dzanis.

35. As a result of its dealings with the FDA, Defendant possessed actual knowledge that (a) its claim that partially hydrolyzed whey protein reduced the risk of infants developing atopic dermatitis was supported by little or very little scientific evidence and (b) the FDA rejected Defendant's qualified health claim regarding the link as proposed because the claim was misleading and required that if Defendant was to make the claim it do so with stringent qualifying statements.

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D. Defendant Widely Markets Good Start Gentle as the First and Only Infant Formula Endorsed by the FDA Which Prevents Allergies and Reduces the Risk of Atopic Dermatitis Without Qualification or Disclaimers

36. Despite the FDA's express guidance and a lack of scientific evidence supporting Defendant's claims, Defendant falsely marketed and, upon information and belief, continues to market Good Start Gentle as a product endorsed by the FDA for reducing the risk of developing allergies and atopic dermatitis to attract customers, increase revenues, and edge out Defendant's competition.

37. Since at least 2011, Defendant knowingly disseminated or has caused to be disseminated advertisements, packaging, and promotional materials for Good Start Gentle in California containing false and misleading statements, as demonstrated by the following sample of Good Start Gentle promotional materials.

38. In Exhibit A, a label included on a formula canister, Defendant states that Good Start Gentle is the "1st and Only Routine Formula to Reduce the Risk of Developing Allergies." Exhibit A falsely communicates to consumers that Good Start Gentle reduced the risk of infants developing allergies despite the total lack of evidence supporting that proposition and an FDA letter rejecting Defendant's qualified health claim.

39. In Exhibit B, a product label, a gold badge with the words "Meets FDA" printed at the top, "1st and Only" printed in the center, and "Qualified Health Claim" printed at the bottom. The product label further includes a statement that Good Start Gentle "is the first and only formula brand . . . that meets the criteria for a FDA Qualified Health Claim for atopic dermatitis." This advertisement falsely communicates to consumers that the FDA approved Defendant's qualified health claim regarding atopic dermatitis when the FDA, in fact, rejected the claim as proposed because it misled consumers. It also deceptively uses the FDA term of art "Qualified Health Claim" to convey that Good Start Gentle is fit for a particular purpose or certified by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited. The product label notably fails to include the qualifying language required by the FDA and federal law.

40. In Exhibit C (storyboard dated April 9, 2012), a television commercial, an announcer

states that "You want your Gerber baby to have your imagination . . . your smile . . . your eyes . . . not your allergies . . . if you introduce formula, choose the Gerber Good Start Comfort Proteins Advantage." *See* Gerber Good Gentle Formula with Comfort Proteins Advantage Commercial, https://www.youtube.com/watch?v=h6l-CjygjEg (last visited January, 9, 2015). This advertisement falsely communicates to consumers that Good Start Gentle reduced the risk of infants developing allergies despite the total lack of evidence supporting that proposition and an FDA letter rejecting Defendant's qualified health claim.

41. In Exhibit D, a print advertisement depicting a baby's face on a canister of Good Start Gentle, the caption reads, "I love Mommy's eyes, not her allergies. If you have allergies in your family, breastfeeding your baby can help reduce their risk. And if you decide to introduce formula research shows the formula you first provide to your baby may make a difference." Exhibit D falsely communicates to consumers that Good Start Gentle reduced the risk of infants developing allergies despite the total lack of evidence supporting that proposition and an FDA letter rejecting Defendant's qualified health claim.

42. In Exhibit E, a magazine advertisement, Defendant falsely promoted Good Start Gentle as "the first and only infant formula that meets the criteria for a FDA Qualified Health Claim." This advertisement falsely communicates to consumers that the FDA approved Defendant's health claims when, in reality, the FDA rejected both of Defendant's health claims. This advertisement also deceptively uses the FDA term of art "Qualified Health Claim" to convey that Good Start Gentle is fit for a particular purpose or certified by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited.

43. In Exhibit F, a gold badge as part of a supermarket display depicting a canister of Good Start Gentle, the words "Meets FDA" are printed at the top, "1st and Only" is printed in the center, and "Qualified Health Claim" is printed at the bottom. This advertisement falsely communicates to consumers that the FDA approved Defendant's health claims when, in reality, the FDA rejected both of Defendant's health claims. This advertisement also misleadingly conveys the FDA term of art "qualified health claim" in order to convince consumers that Good Start Gentle was fit for a particular purpose or certified for quality by the FDA when "Qualified Health Claim"

actually means that the claim is lacking or limited.

44. In Exhibit G, a magazine advertisement printed in People Magazine on August 5, 2013, a mother is depicted feeding an infant and a badge is included which states that Good Start Gentle is the "1st Formula with FDA Qualified Health Claim." This advertisement falsely communicates to consumers that the FDA approved Defendant's health claims when, in reality, the FDA rejected both of Defendant's health claims. This advertisement also misleadingly conveys the FDA term of art "qualified health claim" in order to convince consumers that Good Start Gentle was fit for a particular purpose or certified for quality by the FDA when "Qualified Health Claim" actually means that the claim is lacking or limited.

45. Based on this limited sampling, it is reasonable to infer that discovery would demonstrate a protracted course of purposeful, false, and misleading advertising by Defendant to induce consumers to purchase Good Start Gentle during the Class Period.

E. The FTC Sues Defendant Seeking A Permanent Injunction and Other Equitable Relief for Violations of the Federal Trade Commission Act Committed During Defendant's Promotional Campaign for Good Start Gentle

46. On October 29, 2014, the FTC filed a lawsuit in the District of New Jersey against Defendant "under Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b) to obtain preliminary and permanent injunctive relief . . . for Defendant's acts or practices, in violation of Section 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the labeling, advertising, marketing, distribution, and sale of Gerber Good Start Gentle, an infant formula that purports to prevent or reduce the risk of the development of allergies." *Federal Trade Commission v. Gerber Products Co.*, 2:14-cv-06771-SRC-CLW, Dkt. No. 1, at 1 (D.N.J. Oct. 29, 2014).

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

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F. The FDA Issues a Warning Letter to Defendant Stating that Good Start Gentle is Misbranded and Misleading in Violation of Federal Law

48. In addition to the lawsuit filed by the FTC on October 29, 2014, on October 31, 2014, the FDA wrote a warning letter addressed to Mr. Gary Tickle, Defendant's President and CEO, outlining various false and misleading representations made in the promotion of Good Start Gentle that violate federal law and related federal regulations. *See generally* Warning Letter, Nestle Infant Nutrition 10/31/14, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm423087.htm (last visited Jan. 9, 2015) ("Warning Letter").

49. The violations cited by the FDA include, without limitation, that:

a) Good Start Gentle was misbranded under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.301, *et seq.* because Good Start Gentle's labeling and website "bear health claims that were not authorized by the FDA." *See* Warning Letter at 2;

b) Defendant's health claim that the consumption of 100% partially hydrolyzed whey protein reduces the risk of infants developing allergies was a health claim previously considered and denied by the FDA and therefore unauthorized. *See* Warning Letter at 2-3;

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

d) Good Start Gentle is misbranded because Defendant wrongly identified "100% whey partially hydrolyzed" as the substance linked to a reduced risk of atopic dermatitis on Good Start Gentle's label and website. *See* Warning Letter at 3. However, the substance that was the subject of Defendant's 2011 qualified health claim petition to the FDA was "100% whey protein partially hydrolyzed." *Id.* As such, Defendant's health claim regarding atopic dermatitis misleads consumers because it suggests "that the

partial hydrolysis of whey could refer to any or all of the components in whey being hydrolyzed (*i.e.*, oligosaccharides, fats, and protein)," and no evidence exists to support such claim. *See* Warning Letter;

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

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

51. As a whole, the Warning Letter further demonstrates Defendant's willful and deceitful pattern of promoting Good Start Gentle in a way that would mislead consumers and induce purchase of Good Start Gentle.

G. Plaintiff Begins Consistently Purchasing Good Start Gentle Based on Gerber's False Promotional Campaign and Suffers Damages

52. On September 4, 2013, Plaintiff's daughter, Layla, was born. Plaintiff originally fed her daughter a mix of Enfamil and Similac infant formula.

53. In October 2013, Plaintiff took her daughter to a meeting with her pediatrician who recommended Gerber Good Start infant formula and provided Plaintiff with three or four containers of Gerber Good Start infant formula. Plaintiff received two types of Gerber Good Start infant formula from her daughter's pediatrician: Gerber Good Start Gentle and Gerber Good Start Soothe, another line of formula offered for sale by Gerber.

54. After the meeting, Plaintiff, who did not know that Defendant produced infant formula, researched Good Start formula and reviewed statements by Defendant highlighting Good Start Gentle's endorsement by the FDA and its ability to protect infants from developing allergies.

55. Based on this false and misleading information, Plaintiff ceased buying Similac and Emfamil infant formula, and instead, began routinely purchasing Good Start Gentle formula. Plaintiff purchased Good Start Gentle infant formula in various containers, including containers with the misleading label: "1st & Only Routine Formula to Reduce Risk of Developing Allergies"

as depicted in Exhibit A.

56. Plaintiff also purchased Good Start Gentle misbranded containers that mischaracterized the relationship between "100% whey partially hydrolyzed" and a reduced risk of atopic dermatitis as described in Paragraph 48(d), *supra.*

57. Plaintiff bought these mislabeled Gerber Good Start Gentle infant formula containers from stores in Porter Ranch, California, including Target, Babies "R" Us, and Walmart for prices generally ranging between $25 and $26.

58. On average, Plaintiff used one container of Gerber Good Start Gentle per week from October 2013 to November 2014.

59. Plaintiff made those purchases based on Gerber's false and misleading promotional materials and labeling that Gerber Good Start Gentle was approved by the FDA to reduce the risk of infants developing allergies, even though Defendant knew that such health claims were baseless and rejected by the FDA.

60. For these reasons, Plaintiff and other Class members incurred damages from Defendant's misconduct.

CLASS ACTION ALLEGATIONS

61. Plaintiff asserts her claims on behalf of the following proposed Class:

> All persons who have purchased Gerber Good Start Gentle infant formula in California during the applicable statute of limitations. The Class excludes any judge or magistrate assigned to this case, Defendant and any entity in which Defendant has a controlling interest, and its officers, directors, legal representatives, successors and assigns. Also excluded from the class are those who purchased Gerber Good Start Gentle infant formula for the purpose of resale and those who assert claims for personal injury.

62. Numerosity: The Class is so numerous that joinder of all Class members is impracticable. The Class includes hundreds, and likely thousands, of Defendant's customers.

63. Typicality: Plaintiff's claims are typical of the members of the Proposed Class

because, like the other Class members, she was exposed to Defendant's deceptive advertising and business practices and purchased Good Start Gentle in reliance thereon.

64. Adequacy: Plaintiff will fairly and adequately protect the interests of the Class, and has retained counsel experienced in complex class action litigation. Plaintiff has no interests which are adverse to those of the Class that she seeks to represent.

65. Commonality: Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class, including:

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

b) Whether Defendant disseminated misleading labels, commercials, print advertisement, point-of-sale displays, and other promotional materials in an effort to convince customers to purchase Good Start Gentle based on false representations – namely that the FDA issued a qualified health claim that Good Start Gentle reduced the occurrence of infant allergies;

c) Whether Defendant used the term "qualified health claim" in order to mislead consumers into believing that the FDA certified the quality of Good Start Gentle or that Good Start Gentle was fit for a particular purpose, rather than convey that any potential health claim was limited, restricted, or insufficient;

d) Whether Defendant violated the unlawful prong of California's Unfair Competition Law;

e) Whether Defendant violated the unfair and fraudulent prongs of California's Unfair Competition Law;

f) Whether Defendant violated California's False Advertising Law;

g) Whether Defendant violated California's Legal Remedies Act;

h) Whether Defendant breached Good Start Gentle's express warranty;

i) Whether Defendant breached the implied warranty of merchantability;

j) Whether Defendant negligently misrepresented the FDA endorsement and health benefits of Good Start Gentle;

k) Whether Defendant intentionally misrepresented the health benefits and FDA endorsement of Good Start Gentle;

l) Whether Plaintiff and the Class are entitled to actual, statutory, and punitive damages;

m) Whether Plaintiff and the Class are entitled to restitution;

n) Whether the Plaintiff and the Class are entitled to injunctive and declaratory relief.

66. These and other questions of law and fact are common to the Class and predominate over any questions affecting only individual members of the Class.

67. Plaintiff cannot be certain of the form and manner of proposed notice to class members until the class is finally defined and discovery is completed regarding the identity of class members. Plaintiff anticipates, however, that notice by mail will be given to class members who can be identified specifically. In addition, notice may be published in appropriate publications, on the internet, in press releases and in similar communications in a way that is targeted to reach those who may have purchased Gerber Good Start Gentle infant formula. The cost of notice, after class certification, trial, or settlement before trial, should be borne by Defendant.

68. Plaintiff is a member of the Class and will fairly and adequately represent and protect the interests of the Class. Plaintiff has no claims antagonistic to those of the Class. Plaintiff has retained counsel competent and experienced in complex class actions, including all aspects of this litigation. Plaintiff's counsel will fairly, adequately and vigorously protect the interests of the Class.

69. Class action status is warranted under Rule 23(b)(1)(A) because the prosecution of separate actions by or against individual members of the Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class, which would establish incompatible standards of conduct for Defendant.

70. Class action status is also warranted under Rule 23(b)(1)(B) because the prosecution of separate actions by or against individual members of the Class would create a risk of adjudications with respect to individual members of the Class which would, as a practical matter, be dispositive of the interests of the other members not parties to the adjudications, or substantially impair or impede their ability to protect their interests.

71. Class action status is also warranted under Rule 23(b)(2) because Defendant has acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.

72. Class action status is also warranted under Rule 23(b)(3) because questions of law or fact common to the members of the Class predominate over any questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

73. Plaintiff reserves her right to modify or amend the definition of the proposed Class at any time before the Class is certified by the Court.

FIRST CLAIM FOR RELIEF

VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW

(California Business and Professions Code §§ 17200 *et seq.*)

(Unlawful)

74. Plaintiff realleges and incorporates by reference the allegations elsewhere in the Complaint as if set forth fully herein.

75. Plaintiff brings this claim on behalf of herself and the proposed Class.

76. California Business and Professions Code §§ 17200 *et seq.*, prohibits acts of unfair competition, including any "unlawful, unfair or fraudulent business act or practice."

77. Defendant engaged in unlawful business acts and practices in violation of California Business and Professions Code §§ 17200 *et seq*., by engaging in the false and misleading advertising specified elsewhere in this Complaint.

78. Defendant has manufactured, advertised, distributed, and sold products misbranded under California Law. *See* California Health & Safety Code § 110660. Misbranded products cannot be legally manufactured, advertised, distributed, or sold or held and are legally worthless as a matter of law.

79. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendant as alleged herein constitute "unlawful" business acts and practices in that Defendant's conduct violates:

a) California's False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 *et seq.*;

b) California's Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750 *et seq.*;

c) California Health & Safety Code §§ 109885 and 110390 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;

d) California Health & Safety Code §§ 109885 and 110390 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;

e) California Health & Safety Code § 110395 which makes it unlawful to deliver or proffer for delivery any food that has been falsely advertised;

f) California Health & Safety Code §110760 which makes it unlawful for any person to manufacture, sell, deliver, hold, or offer or sale any food that is misbranded;

g) California Health & Safety Code § 110765 which makes it unlawful for any person to misbrand food;

h) 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;

i) Section 5(a) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce; and

j) Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits the dissemination of any false advertisement in or affecting commerce for the purposing of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics.

80. Defendant's conduct is further "unlawful" because it violates the following provisions of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301 *et seq.*, and its implementing regulations:

a) Sections 321(n) and 403(a) of the FFDCA, 21 U.S.C. §§ 321(n) & 343(a), which deems food misbranded when the label contains a statement that is "false or misleading in any particular" or "its advertising is false or misleading in a material respect";

b) 21 C.F.R. § 101.14(e), which proscribes express and implied health claims on food labeling unless, *inter alia*, such a claim is specifically provided for by regulation and complies therewith; and

c) Alternatively, 21 C.F.R. § 101.14(d), which, *inter alia*, (i) requires all health claim based food labeling to conform to regulation, (ii) requires that all health claims made on food labels are limited to describing the value that ingestion of a certain substance may have on a particular disease or health-related condition, (iii) proscribes incomplete, untruthful, and misleading health claims on food labels, and (iv) requires reference to or complete health claims to be in the immediate proximity of all graphic material constituting a health claim (*e.g.*, a heart symbol).

81. Defendant leveraged its deception to induce Plaintiff and the Class to purchase products that were of lesser value and quality than advertised.

82. The foregoing acts and practices have detrimentally impacted competition and caused substantial harm to Plaintiff, the Class, and the consuming public. Plaintiff and members of the Class were misled and suffered injuries and lost money or property as a direct and proximate result of Defendant's unlawful business practices.

83. Plaintiff and the Class could have reasonably avoided the harm alleged herein. Plaintiff and the Class were denied the benefit of the bargain when they decided to purchase Good Start Gentle over competitor products which are less expensive, make medically and scientifically supported health claims, do not falsely purport to be endorsed for quality or fit for a particular purpose by the FDA, or which do not make health claims linking the consumption of partially hydrolyzed whey protein and a reduced risk of food allergies in infants. Had Defendant not made false and misleading statements and used false and misleading advertising tactics, Plaintiff and the Class would have paid less than what they did for Good Start Gentle, or would have not purchased the product at all.

84. The false and misleading advertising and labeling described elsewhere in the Complaint presents a continuing threat to consumers in that such advertising will continue to mislead consumers to purchase Good Start Gentle on false premises.

85. By reason of the foregoing, Defendant should be required to disgorge its illicit profits, make restitution to Plaintiff and the Class, be enjoined from continuing in such practices pursuant to Sections 17203 and 17204 of the California Business and Professions Code, and pay for Plaintiff's and the Class' attorneys' fees.

86. Plaintiff reserves the right to identify additional provisions of law violated by Defendant as further investigation and discovery warrants.

SECOND CLAIM FOR RELIEF

VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW

(California Business and Professions Code §§ 17200 *et seq.*)

(Unfair and Fraudulent)

87. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

88. Plaintiff brings this claim on behalf of herself and the proposed Class.

89. California Business and Professions Code §§ 17200 *et seq.*, prohibits acts of unfair competition, including any "unlawful, unfair or fraudulent business act or practice."

90. The false and misleading labeling and advertising of Good Start Gentle, as alleged herein, constitutes "unfair" business acts and practices because such conduct is immoral, unscrupulous, and offends public policy. Further, the harm of Defendant's conduct to Plaintiff, the Class, and the consumer public outweighs any conceivable benefit of such conduct.

91. Defendant's false and misleading labeling and advertising have detrimentally impacted competition and caused substantial harm to Plaintiff, the Class, and the consuming public. Plaintiff and members of the Class were deceived, suffered injuries, and lost money or property as a direct and proximate result of Defendant's unlawful business practices.

92. The false and misleading labeling and advertising of Good Start Gentle, as alleged herein, also constitutes "fraudulent" business acts and practices because members of the consuming

public, including Plaintiff and the Class, were/are likely to be deceived by the false and misleading advertising and labeling described elsewhere in the Complaint.

93. Plaintiff and the Class could have reasonably avoided the harm alleged herein. Plaintiff and the Class were denied the benefit of the bargain when they decided to purchase Good Start Gentle over competitor products which are less expensive, contain healthier ingredients, do not purport to be endorsed by the FDA for quality, make medically and scientifically supported health claims, or which do not make health claims linking the consumption of partially hydrolyzed whey protein and a reduced risk of food allergies in infants. Had Defendant not engaged in its false and misleading advertising tactics, Plaintiff and the Class would have paid less than what they did for Good Start Gentle, or not purchased the product at all.

94. Defendant either knew or reasonably should have known that the health claims on the labels and advertising alleged herein were untrue and misleading.

95. In addition, Defendant's *modus operandi* constitutes an unfair and fraudulent practice in that Defendant knew or should have known that consumers care about health claims made concerning infant formula but are unlikely to be aware and/or able to come to a scientific and medical conclusion linking the consumption of partially hydrolyzed whey protein and any potential reduced risk of food allergies in infants. Particularly, Defendant knew or should have known that consumers rely on unqualified and qualified health claims made under the guise of FDA approval or consent.

96. By reason of the foregoing, Defendant should be required to disgorge its illicit profits, make restitution to Plaintiff and the Class, be enjoined from continuing in such practices pursuant to Sections 17203 and 17204 of the California Business and Professions Code, and pay for Plaintiff's and the Class' attorneys' fees.

THIRD CLAIM FOR RELIEF

VIOLATION OF THE CALIFORNIA FALSE ADVERTISING LAW

(California Business and Professions Code §§ 17500 *et seq.*)

97. Plaintiff realleges and incorporates by reference the allegations elsewhere in the Complaint as if set forth fully herein.

98. Plaintiff brings this claim on behalf of herself and the proposed Class.

99. Defendant's acts and practices as described herein have deceived and/or are likely to deceive Plaintiff, the Class, and the public. Defendant has repeatedly advertised that Good Start Gentle reduces the risk of allergies (including atopic dermatitis) in infants despite the falsity of this statement.

100. The advertisements, labeling, policies, acts, and practices described herein were designed to, and did, result in the purchase and use of Good Start Gentle without consumer knowledge that Defendant never received FDA approval for its health claims and misled consumers with its qualified health claim representations.

101. Defendant's advertising and labeling has and is likely to deceive Plaintiff, the Class, and the public in the future because it misrepresented the FDA's endorsement of Good Start Gentle's ability to reduce the risk of allergies (i.e., a reasonable consumer does not understand the definition of an "FDA Qualified Health Claim" without appropriate explanation). Reasonable consumers do not interpret "qualified" as "[n]ot complete or absolute; limited", but instead interpret it as "[o]fficially recognized as being trained to perform a particular job; certified." *See Qualified Definition*, OXFORD ENGLISH DICTIONARY, http://www.oxforddictionaries.com/definition/english/qualified (last visited Dec. 18, 2014).

102. Defendant knew or by the exercise of reasonable care should have known that its advertisements concerning Good Start Gentle's ability to reduce the risk of allergies in infants and the representation that the FDA endorsed these claims were untrue or misleading. Plaintiff and the Class based their decisions to purchase Good Start Gentle in substantial part on Defendant's misrepresentations and omitted material facts.

103. Defendant disseminated and continues to disseminate uniform advertising concerning Good Start Gentle which is unfair, deceptive, untrue, or misleading within the meaning of California Business & Professions Code §§ 17500 *et seq.* Such advertisements are likely to deceive, and continue to deceive, the consuming public for the reasons detailed elsewhere in the Complaint.

104. Plaintiff and the Class have suffered injury in fact and have lost money or property as a result of Defendant's violation of California Business & Professions Code §§ 17500 *et seq.*

105. The misrepresentations and omissions by Defendant of the material facts detailed elsewhere in this Complaint constitute false and misleading advertising.

106. As a result of Defendant's wrongful conduct, Plaintiff and the Class are entitled to an injunction barring Defendant from continuing to violate the California Business & Professions Code §§ 17500 *et seq.*, restitution, and an order for the disgorgement of the funds by which Defendant was unjustly enriched.

FOURTH CLAIM FOR RELIEF

VIOLATION OF THE CONSUMERS LEGAL REMEDIES ACT

(California Civil Code §§ 1750 *et seq.*)

107. Plaintiffs realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

108. Plaintiff brings this claim on behalf of herself and the proposed Class.

109. The CLRA has adopted a statutory scheme prohibiting various deceptive practices in connection with the conduct of a business providing goods, property, or services primarily for personal, family, or household purposes.

110. This claim for relief does not currently seek monetary relief and is limited solely to injunctive relief. Plaintiff intends to amend this Complaint to seek monetary relief in accordance with the CLRA after providing Defendant with notice pursuant to Civil Code § 1782.

111. At the time of any amendment seeking damages under the CLRA, Plaintiff will demonstrate that the violations of the CLRA were willful, oppressive, and fraudulent, thus supporting an award of punitive damages.

112. Consequently, Plaintiff and the Class will be entitled to actual and punitive damages against Defendant for its violation of the CLRA. In addition, pursuant to Civil Code § 1780(a)(2), Plaintiff and the Class will be entitled to an order enjoining the above-described acts and practices, providing restitution to Plaintiff and the Class, ordering payment of costs and attorneys' fees, and any other relief deemed appropriate and proper by the Court pursuant to California Civil Code §

1780.

113. Defendant's policies, acts, and practices were intended to, and did, result in the purchase and use of the products primarily for personal, family, or household purposes, and violated and continue to violate at least the following sections of the CLRA:

a) § 1770(a)(2): which proscribes "[m]isrepresenting the source, sponsorship, approval, or certification of goods or services" in the sale of consumer goods;

b) § 1770(a)(3): which proscribes "[m]isrepresenting the affiliation, connection, or association with, or certification by, another" in the sale of consumer goods;

c) § 1770(a)(5): which proscribes "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have";

d) § 1770(a)(7) which proscribes "representing that goods or services are of a particular standard, quality or grade[.];" and

e) § 1770(a)(9): which proscribes "[a]dvertising goods or services with intent not to sell them as advertised."

114. As a proximate result of these violations by Defendant, Plaintiff and the Class have suffered irreparable harm and damages in an amount to be determined at trial.

115. At this time, Plaintiff only seeks an injunction pursuant to California Civil Code § 1782(d) enjoining Defendant from continuing to employ the unlawful methods, acts, and practices alleged elsewhere in this Complaint. If Defendant is not restrained from engaging in these practices in the future, Plaintiff and the Class will continue to suffer harm.

FIFTH CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTY

(California Commercial Code § 2313)

116. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

117. Plaintiff brings this claim on behalf of herself and the proposed Class.

118. Beginning at an exact date unknown to Plaintiff, but at least since four years prior to

the filing date of this action, and as set forth hereinabove, Defendant made representations to the public, including Plaintiff and the Class, by its advertising, packaging, labeling, and other means, that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants. That promise and related promises became part of the basis of the bargain between the parties and thus constituted an express warranty.

119. Thereon, Defendant sold the goods to Plaintiff and the Class, who bought the goods from Defendant.

120. However, Defendant breached the express warranty in that the goods were in fact not FDA approved, did not comply with the FDA's limited qualified health claim language requirements, and do not reduce the risk of allergies in infants. As a result of this breach, Plaintiff and the Class in fact did not receive goods as warranted by Defendant.

121. As a proximate result of this breach of warranty by Defendant, Plaintiff and the Class have been damaged in an amount to be determined at trial.

SIXTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

(California Commercial Code § 2314)

122. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

123. Plaintiff brings this claim on behalf of herself and the proposed Class.

124. Defendant made representations to the public, including Plaintiff and the Class, by its advertising, packaging, labeling, and other means that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants.

125. Defendant was a merchant with respect to goods of this kind (e.g., infant formula and baby food) which were sold to Plaintiff and the Class, and there was in the sale to Plaintiff and the Class an implied warranty that those goods were merchantable.

126. Defendant breached the implied warranty of merchantability when it sold Plaintiff and the Class infant formula that, *inter alia*, did not conform to the promises or affirmations of fact

made on the container or label.

127. As a result of Defendant's conduct, Plaintiff and the Class did not receive goods as impliedly warranted by Defendant to be merchantable.

128. As a proximate result of this breach of warranty by Defendant, Plaintiff and the Class have been damaged in an amount to be determined at trial.

SEVENTH CLAIM FOR RELIEF

NEGLIGENT MISREPRESENTATION

129. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully herein.

130. Plaintiff brings this claim on behalf of herself and the proposed Class.

131. Beginning at an exact date unknown to Plaintiff, but at least since three years prior to the filing date of this action, and as set forth above, Defendant represented to the public, including Plaintiff and the Class, by packaging, labeling, advertising, and other means, that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants. These misrepresentations are described in greater detail elsewhere in the Complaint.

132. Defendant's representations were untrue in that the FDA did not approve Good Start Gentle's health claims for qualified use, Good Start Gentle did not comply with the FDA's limited qualified health claim language requirements, and Good Start Gentle does not reduce the risk of allergies in infants.

133. Defendant made the representations without reasonable grounds for believing in their veracity.

134. Defendant made the representations herein alleged with the intention of inducing the public to purchase Defendant's products.

135. Plaintiff, the Class, and the consuming public saw, believed, and reasonably relied on Defendant's advertising, labeling, and packaging when purchasing Good Start Gentle.

136. As a proximate result of Defendant's negligent misrepresentations, Plaintiff and the Class were induced to spend an amount to be determined at trial on Defendant's products.

137. As a proximate result of Defendant's negligent misrepresentations, Plaintiff and the Class have been damaged in an amount to be determined at trial.

EIGHTH CLAIM FOR RELIEF

INTENTIONAL MISREPRESENTATION

138. Plaintiff realleges and incorporates the allegations elsewhere in the Complaint as if set forth fully

139. Plaintiff brings this claim on behalf of herself and the proposed Class.

140. Beginning at an exact date unknown to Plaintiff, but at least since three years prior to the filing date of this action, and as set forth above, Defendant represented to the public, including Plaintiff and the Class, by packaging, labeling, advertising, and other means, that Good Start Gentle was FDA approved to reduce the risk of allergies in infants and that Good Start Gentle did in fact reduce the risk of allergies in infants. These misrepresentations are described in greater detail elsewhere in the Complaint.

141. Defendant's representations were untrue in that the FDA did not approve Good Start Gentle's health claims for qualified use, Good Start Gentle did not comply with the FDA's limited qualified health claim language requirements, and Good Start Gentle does not reduce the risk of allergies in infants.

142. Defendant made these misrepresentations with actual knowledge of their falsity.

143. Defendant made the misrepresentations herein alleged with the intention of inducing the public to purchase Defendant's products.

144. Plaintiff, the Class, and the consuming public saw, believed, and reasonably relied on Defendant's advertising, labeling, and packaging when purchasing Good Start Gentle.

145. As a proximate result of Defendant's intentional misrepresentations, Plaintiff and the Class were induced to spend an amount to be determined at trial on Good Start Gentle infant formula.

146. As a proximate result of Defendant's intentional misrepresentations, Plaintiff and the Class have been damaged in an amount to be determined at trial.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and the Class, prays for relief as follows:

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

b) Designating Plaintiff as the Class representative;

c) Designating Plaintiff's counsel as counsel for the Class;

d) Issuing proper notice to the Class at Defendants' expense;

e) An order enjoining Defendant from:

i. marketing Good Start Gentle as the "first and only" infant formula to meet an FDA qualified health claim;

ii. marketing Good Start Gentle as a product which reduces the incidence of common food allergies in infants;

iii. marketing Good Start Gentle as a product which reduces the incidence of atopic dermatitis in infants;

iv. misusing the FDA term of art "qualified health claim" as a means to mislead consumers into believing that Good Start Gentle is of higher quality or certified by the FDA;

f) An order compelling Defendant to conduct a corrective advertising campaign to inform the public that Good Start Gentle does not reduce the likelihood of infants developing allergies and that the FDA did not endorse or certify such claims;

g) An order compelling Defendant to destroy all misleading and deceptive advertising materials and products;

h) Awarding restitution and disgorgement of Defendant's revenues obtained by means of any wrongful act or practice to Plaintiff and Class members;

i) Awarding actual, statutory, and punitive damages and interest to Plaintiff and Class members;

j) Awarding reasonable attorneys' fees, interest, and costs to the full extent permitted

k) An order issuing declaratory relief; and

l) All such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

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

Dated: January 9, 2015

Respectfully submitted,

By: _____

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