

**SUPERIOR COURT OF THE DISTRICT OF COLUMBIA
CIVIL DIVISION**

_____)	
THE NATIONAL CONSUMERS LEAGUE)	
)	SECOND AMENDED COMPLAINT
)	
Plaintiff,)	
v.)	Civil Action No. 2014 CA 008202 B
)	
)	Hon. Anita Josey-Herring
GERBER PRODUCTS CO.)	
)	
Defendant.)	
_____)	

Plaintiff, the National Consumers League (“Plaintiff” or “NCL”) by its undersigned attorneys, brings this action on behalf of itself and its members, against Nestlé Infant Nutrition and its wholly owned subsidiaries (“Defendant”), and alleges the following:

INTRODUCTION

1. This action is brought by Plaintiff on behalf itself and its members¹ pursuant to District of Columbia Code §28-3905(k)(1). Plaintiff National Consumers League is a non-profit organization located in the District of Columbia.

2. Defendant, to induce parents to purchase their formula, has represented in various advertisements and commercials that Gerber® Good Start Gentle® formula would prevent or reduce the risk of babies’ developing allergies.

3. Gerber makes these claims despite having twice petitioned the FDA for approval in making the claims and twice being denied for lack of scientific support.

¹ All references to the “on behalf of the General Public” were struck by the Court on February 3, 2017 and reiterated on October 13, 2017. Plaintiff has removed this language throughout in this amendment but expressly preserves its rights to appeal both rulings.

4. Defendant falsely represented to consumers, through marketing and advertising campaigns, that its Good Start Gentle® formula product will prevent or reduce the risk of babies' developing allergies when it has not been proven to do so.

5. Defendant touted such false product attributes in order to induce parents into purchasing Good Start Gentle® formula for their children.

6. NCL, through its agents, viewed advertising and labeling for, evaluated the marketing and labeling, and purchased Good Start Gentle® formula, on two occasions.

7. Defendant deprived Plaintiff and the General Public of the District of Columbia of the right to truthful information regarding Good Start Gentle® formula.

8. Plaintiff is entitled to damages because NCL purchased Good Start Gentle® formula.

JURISDICTION AND VENUE

9. Jurisdiction of this Court is founded on D.C. Code § 11-921. This Complaint arises under the District of Columbia Consumer Protection Procedures Act, D.C. Code § 28-3901 *et seq.* and the Court, therefore, has subject matter jurisdiction thereunder.

10. Venue is proper in this District. The claims asserted in this complaint arise, in part, within this District. Plaintiff resides in this District and seeks to represent residents of this District who have purchased Gerber® Good Start Gentle® formula from the Defendant. Many of these transactions occurred in retail stores located in this District. Defendant transacts business in this District and has caused injury within this District.

11. As a result of the facts alleged in this Complaint, this Court has personal jurisdiction over the Defendant. The Defendant sells and markets its products to stores and consumers in the District of Columbia. The Defendant has transacted business in the District of

Columbia; caused tortious injury in the District of Columbia via acts or omissions occurring therein; and derived substantial revenue from products sold in the District of Columbia.

PARTIES

12. Plaintiff, National Consumers League, is a non-profit, 501(c)(3) public interest organization located in the District of Columbia at 1701 K Street, #1200, NW, Washington, District of Columbia 20006.

13. Plaintiff purchased Gerber® Good Start Gentle® formula containers. On December 16, 2014, it purchased a 12.7 oz container from CVS at 1101 Connecticut Ave, N.W. and on December 17, 2014, it purchased a 23.2 oz container from Safeway at 5545 Connecticut Ave, N.W.

14. Defendant Gerber Products Company, Inc., doing business as Nestlé Infant Nutrition, is a Michigan Corporation with its principal place of business at 12 Vreeland Road, #2, Florham Park, NJ 07932. Gerber Products Company, Inc. operates as a subsidiary of Nestlé Holdings, Inc. Nestlé Holdings, Inc. is incorporated under the laws of the State of Delaware and with its principal office or place of business at 1209 Orange Street, Wilmington, DE 19801. Nestlé Holdings, Inc. is a wholly-owned subsidiary of, and is controlled by, Nestlé S.A., a corporation organized, existing, and doing business under and by virtue of the laws of Switzerland, with its principal executive offices located at Avenue Nestlé 55, CH-1800 Vevey, Switzerland. In 2007, when Gerber was acquired by Nestlé, Gerber made over \$300 million in net operating profit. Gerber supplies some 71% of the American market for baby food. According to the Fortune Global 500, Nestlé S.A. is the 72nd largest company in the world, with revenues of nearly \$100 billion in 2014.

15. At all times material to this complaint, defendant has labeled, advertised, distributed and/or sold Good Start Gentle® formula to consumers throughout the United States.

THE INTERESTS OF NCL

16. Plaintiff acts pursuant to authority granted it District of Columbia Code §28-3905(k)(1)(A),(C),and (D).

17. The NCL has worked diligently to promote accurate labeling of consumer goods. It has investigated, publicized, and/or litigated on mislabeling for lemon juice, tomatoes, extra-virgin olive oil, sunflower seeds, bread, cereal, and adulterated honey.

18. Plaintiff focuses its advocacy on consumer protection, including efforts to promote accurate labeling on food products.

19. Specific to this case, the NCL has educated the public on nutritional needs of infants and compared formula to breast milk, and helps consumers understand label disclosures on infant formula containers.

20. Defendant Gerber® marketed its Good Start Gentle® infant formula to District of Columbia residents with false representations that the formula would prevent or reduce the risk of babies' developing allergies.

FACTUAL BACKGROUND

21. Defendant began selling canned baby food in 1927 in Fremont, Michigan.

22. Since at least 2011 it has manufactured, packaged, labeled, advertised, offered for sale, distributed and sold Good Start Gentle® formula.

23. The price of Good Start Gentle® formula ranges from approximately \$16-25 per 12.7 oz container of powdered formula.

24. Good Start Gentle® formula is made with partially hydrolyzed whey proteins, which defendant advertises as easier to digest than formula made with intact cow's milk proteins.

25. Defendant further claims that feeding this formula to infants will prevent or reduce the infant's risk of developing allergies.

26. Defendant, to induce parents to purchase their formula, has represented in various advertisements and commercials that Gerber® Good Start Gentle® formula would prevent or reduce the risk of babies' developing allergies. Gerber makes these claims despite having twice petitioned the FDA for approval in making the claims and twice being denied for lack of scientific support.

27. Defendant has made such health claims on the packages of their Good Start Gentle® formula, including the following:

- A gold label sticker on the front of the formula can reads: "1st & ONLY Routine Formula TO REDUCE THE RISK OF DEVELOPING ALLERGIES. See label inside."
- Badge on product label reads: "1st & Only Meets FDA Qualified Health Claim."

28. The advertising for Good Start Gentle® formula also contains health claims, including the following:

- A television commercial wherein the announcer says "You want your Gerber baby to have your imagination ... Your smile ... Your eyes ... Not your allergies. The Gerber Generation knows that breastfeeding is the best way to naturally protect your baby. But if you introduce formula, choose the Gerber Good Start Comfort Proteins Advantage. It's what makes Good Start formula easy to digest and may also provide protective benefits for your baby. Gerber Good Start Gentle. Nutrition inspired by breastmilk."
- A print advertisement depicting a baby's face and a Good Start Gentle® formula can, the text of which reads: "The Gerber Generation says, 'I love Mommy's

eyes, not her allergies.’ If you have allergies in your family, breastfeeding your baby can help reduce their risk. And, if you decide to introduce formula, research shows the formula you first provide your baby may make a difference. In the case of Gerber Good Start Gentle Formula, it’s the Comfort Proteins Advantage that is easy to digest and may also deliver protective benefits. That’s why Gerber Good Start Gentle Formula is nutrition inspired by breastmilk.”

- Another print advertisement reads: “The first formula fed may make a difference. Gerber Good Start is the first and only infant formula that meets the criteria for a FDA Qualified Health Claim.”
- Other print advertisements contain the badge reading “1st Formula With FDA Qualified Health Claim.”

29. The United States Food and Drug Administration (“FDA”) defines a health claim as one that “characterizes the relationship between a substance and a disease or health-related condition.”

30. Authorized health claims (aka “unqualified” health claims) “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.”

31. Qualified health claims do not meet the standard for an authorized health claim, and so instead “must be accompanied by a disclaimer or other qualifying language to accurately communicate the level of scientific evidence supporting the claim.” “All health claims, whether unqualified or qualified, require pre-market review by FDA.”²

32. In June 2005, Defendant asked the FDA to authorize a health claim that partially hydrolyzed whey protein formula reduced the risk of food allergies in infants.

² 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 Dec. 22, 2014)

33. In May 2006, the FDA denied the petition, on the grounds that there was “no credible” evidence to support the relationship between partially hydrolyzed whey protein infant formula and a reduced risk of food allergy in infants.³

34. In reaching its decision in 2006, the FDA reviewed the 216 articles and reports cited by Defendant.

35. In 2009, Defendant asked the FDA to approve a qualified health claim for their partially hydrolyzed whey protein formula, this time the more limited claim that the formula reduced the risk of developing *atopic dermatitis* in infants.

36. The FDA issued a letter of enforcement discretion stating it would consider allowing Defendant to make the highly-qualified claim that “the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of atopic dermatitis is uncertain, because there is little scientific evidence for the relationship.”⁴

37. The claims made on the packaging of the Gerber® Good Start Gentle® formula, as well as those made in the advertisements for the product in various media, do not contain the limiting language mandated in the FDA letter of enforcement discretion.

³ See Qualified Health Claims: Letter of Denial – 100 percent Partially Hydrolyzed Whey Protein in Infant Formula and Reduced Risk of Food Allergy in Infants (Docket No. 2005Q-0298) (May 11, 2006), available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073313.htm> (last visited Dec 22, 2014).

⁴ See 100% 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 Dec. 22, 2014).

38. In 2014, Defendant received a warning letter from the FDA informing Defendant that its Gerber® Good Start Gentle® formula was misbranded in violation of the Federal Food, Drug, and Cosmetic Act.⁵

39. The FDA stated that it had previously “considered and denied” Defendant’s petition “to make a qualified health claim characterizing the relationship between the consumption of 100% partially hydrolyzed whey protein infant formula and reduced risk of food allergy in infants.”

40. The FDA stated that it reviewed the scientific evidence Defendant submitted to the FDA and concluded that there was “no credible evidence to support a qualified health claim relating the consumption of 100 percent whey protein partially hydrolyzed to a reduced risk of food allergy in infants.”

41. As of 2014, the FDA continued to be “aware of no such credible evidence that has been developed since the time the petition was denied that would provide support for making a claim characterizing the relationship between the consumption of 100% partially hydrolyzed whey protein infant formula and reduced risk of food allergy in infants.”

42. The misrepresentations on the labels of Gerber® Good Start Gentle® formula and in its advertising create the false impression that the product reduces the risk of developing allergies when in fact there is “no credible evidence” between 100% partially hydrolyzed whey protein infant formula and food allergies and “little scientific evidence” between 100% whey-protein partially hydrolyzed and atopic dermatitis.

⁵See Warning Letter (Oct. 31, 2014), available at: <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm423087.htm> (last visited Dec.22, 2014).

43. The gold seal logos depicted on the Gerber® Good Start Gentle® formula label and in its print advertisements creates the false impression that the FDA has approved the statement that use of the formula reduces the risk of developing allergies.

44. The logos also create a false impression that the FDA approved the references to multiple “allergies” (plural), when in fact the FDA only permitted significantly limited language for one allergy (atopic dermatitis).

45. Defendant affirmatively misrepresented the “benefits” of Gerber® Good Start Gentle® formula in order to convince the public to purchase and use the product, resulting in substantial profits to Gerber to the detriment of the D.C. general public.

46. Defendant’s representations mislead and/or have the ability to mislead parents to believe that the Gerber® Good Start Gentle® formula has the tangible result of reducing the risk of allergy development. These claims are false, deceptive and misleading. Gerber has little to no scientific or clinical proof to support its claims about Good Start Gentle® formula as beneficially impacting the incident rates of food allergies or atopic dermatitis.

47. Defendant knows, or should know, that its statements misrepresent the attributes of Gerber® Good Start Gentle® formula and that the formula does not have the purported affect on infants’ allergy development.

48. Defendant’s deceptive advertising had a material effect on purchasers of Gerber® Good Start Gentle® formula.

COUNT I
(Violation of the District of Columbia Consumer Protection Procedures Act)

49. This Count is brought pursuant to the District of Columbia Consumer Protection Procedures Act (“CPPA”), D.C. Code § 28-3901 *et seq.*

50. This Count is alleged against the Defendant pursuant to District of Columbia Code § 28-3905(k)(1)(A), (C) and (D).

51. D.C. Code § 28-3904 makes it an unlawful trade practice “whether or not any consumer is in fact misled, deceived or damaged thereby,” to, among other things:

- (a) represent that goods or services have a source, sponsorship, approval, certification, accessories, characteristics, ingredients, uses, benefits, or quantities that they do not have;
- (d) represent that goods or services are of particular standard, quality, grade, style, or model, if in fact they are of another;
- (e) misrepresent as to a material fact which has a tendency to mislead;
- (f) fail to state a material fact if such failure tends to mislead;
- (f-1) use innuendo or ambiguity as to a material fact, which has a tendency to mislead;
- (h) advertise or offer goods or services without the intent to sell them as advertised or offered;
- (u) represent that the subject of a transaction has been supplied in accordance with a previous representation when it has not;

52. In marketing its Good Start Gentle® formula, Gerber violated the above provisions of the District of Columbia Consumer Procedures Protection Act by, *inter alia*, falsely misrepresenting that feeding a baby the formula would reduce his or her risk of developing allergies and failing to disclose that it has not been proven that Good Start Gentle® formula will prevent or reduce the risk of babies’ developing allergies.

53. Plaintiff, on behalf of itself, hereby seeks restitution and treble damages or statutory damages in the amount of \$1,500 per violation, whichever is greater, pursuant to D.C. Code § 28-3905(k)(2). Plaintiff further seeks reasonable attorneys’ fees and costs plus interest.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendant, and the Court granting the following relief:

- a) granting Plaintiff treble damages or statutory damages in the amount of \$1,500 per violation, whichever is greater;
- b) granting Plaintiff its costs of prosecuting this action, including attorneys' fees, experts' fees and costs together with interest;
- c) a declaration that Defendant's conduct is in violation of the CPPA;
- d) enjoining Defendant's conduct found to be in violation of the CPPA; and
- e) granting such other relief as this Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury on all issues so triable.

DATED: November 4, 2017

/s/ Tracy D. Rezvani
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CERTIFICATE OF SERVICE

I hereby certify that on November 4, 2017, the foregoing was filed and served on all counsel of record through the Court's CaseFileXpress system.

*/s/ Tracy D. Rezvani*_____