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

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

GERBER PRODUCTS CO., a corporation,
d/b/a
NESTLÉ NUTRITION,
NESTLÉ INFANT NUTRITION, and
NESTLÉ NUTRITION NORTH AMERICA,

Defendant.

Case Number:

**COMPLAINT FOR PERMANENT
INJUNCTION AND OTHER
EQUITABLE RELIEF**

Plaintiff, the Federal Trade Commission (“FTC”), for its Complaint alleges:

1. The FTC brings this action under Section 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 53(b), to obtain preliminary and permanent injunctive relief, rescission or reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for Defendant’s acts or practices, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the labeling, advertising, marketing, distribution, and sale of Gerber Good Start Gentle, an infant formula that purports to prevent or reduce the risk of the development of allergies.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345.

3. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c) and 15 U.S.C. § 53(b).

PLAINTIFF

4. Plaintiff FTC is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce. The FTC also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce.

5. The FTC is authorized to initiate federal district court proceedings, by its own attorneys, to enjoin violations of the FTC Act and to secure such equitable relief as may be appropriate in each case, including rescission or reformation of contracts, restitution, the refund

of monies paid, and the disgorgement of ill-gotten monies. 15 U.S.C. §§ 53(b) and 56(a)(2)(A).

DEFENDANT

6. Defendant Gerber Products Co. (“Gerber”), also doing business as Nestlé Nutrition, Nestlé Infant Nutrition, and Nestlé Nutrition North America, is a Michigan Corporation with its principal place of business at 12 Vreeland Road, #2, Florham Park, NJ 07932. Gerber transacts or has transacted business in this district and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, Gerber has labeled, advertised, marketed, distributed, or sold Good Start Gentle infant formula to consumers throughout the United States.

COMMERCE

7. At all times material to this Complaint, Defendant has maintained a substantial course of trade in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANT’S BUSINESS ACTIVITIES

8. Since at least 2011, Defendant has manufactured, advertised, labeled, offered for sale, distributed, and sold Gerber Good Start Gentle infant formula to the public. Defendant has advertised this infant formula through television commercials, magazine ads, point-of-sale displays, product packaging, online ads, and other advertising and promotional materials. Defendant has represented, among other things, that Gerber Good Start Gentle prevents or reduces the risk of developing allergies.

Gerber Good Start Gentle

9. Gerber Good Start Gentle formula is made with partially hydrolyzed whey proteins. Defendant advertises that the formula is easier to digest than formula made with intact cow's milk protein. Defendant further advertises that feeding this formula to infants with a family history of allergies prevents or reduces the risk that they will develop allergies.

10. Gerber Good Start Gentle is sold online and in grocery, department, and specialty baby stores. It retails for approximately \$24 for 23.2 ounces of powdered formula.

11. To induce consumers to purchase Gerber Good Start Gentle, Defendant has disseminated or has caused to be disseminated advertisements, packaging, and promotional materials for Gerber Good Start Gentle, including, but not necessarily limited to, the attached Exhibits A through G. These materials contain the following statements and depictions, among others:

A. *Television commercial depicts smiling baby in various poses. Female 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.

Baby is shown drinking from a bottle. Announcer says:

But if you introduce formula, choose the Gerber Good Start Comfort Proteins Advantage.

Canister of Gerber Good Start Gentle is shown.

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.

-Exhibit A, Television Commercial (video and storyboard attached)

- B. *Print advertisement depicts baby's face, canister of Gerber Good Start Gentle.*

The Gerber Generation says, “I love Mommy’s eyes, not her allergies.”

If you have allergies in your family, breastfeeding your baby can help reduce their risk. And, if you decide to introduce formula, research shows the formula you first provide your baby may make a difference. In the case of Gerber Good Start Gentle Formula, it’s the Comfort Proteins Advantage that is easy to digest and may also deliver protective benefits. That’s why Gerber Good Start Gentle Formula is nutrition inspired by breastmilk.

-Exhibit B, Magazine Advertisement

- C. *Gold label sticker on formula canister.*

1st & ONLY Routine Formula TO REDUCE THE RISK OF DEVELOPING ALLERGIES

See label inside.
(with QSR code)

-Exhibit C, Sticker on Product

- D. *Print advertisement depicts canister of Gerber Good Start Gentle.*

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

-Exhibit D, Magazine Advertisement

- E. *Gold badge as part of supermarket display depicting canister of Gerber Good Start Gentle and price.*

PICK ONE UP!

The formula that's **wh**ey different!



-Exhibit E, Supermarket Display

- F. *Badge on product label.*

1st and Only Meets FDA Qualified Health Claim

-Exhibit F, Product Label

- G. *Magazine print advertisement. Depicts mother feeding infant from a bottle. Shows canisters of Gerber Good Start Gentle, Gerber Good Start Soothe, and Gerber Good Start Protect formulas.*

Badge underneath ad copy says:

1st FORMULA
WITH FDA QUALIFIED
HEALTH CLAIM

-Exhibit G, Magazine Advertisement

DEFENDANT'S PETITION FOR FDA APPROVAL OF LABEL CLAIMS

12. The U.S. Food and Drug Administration ("FDA") evaluates health claims before permitting their use on labels for foods or dietary supplements. Under FDA regulations, a *health*

claim explains the relationship between a substance (food or food component) and the reduced risk of a disease or health-related condition, e.g., “Diets low in saturated fats and cholesterol may reduce the risk of heart disease.” To receive FDA approval for a health claim, a petitioner must demonstrate “significant scientific agreement among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship.”

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 May 16, 2014). Pursuant to the 1990 Nutrition Labeling and Education Act, FDA can only issue a regulation authorizing a health claim in food labeling if the claim meets this significant scientific agreement standard.

13. If the relationship between a substance and a disease is not supported by significant scientific agreement, FDA may not issue a regulation to authorize the claim. A party, however, may petition the FDA to consider exercising its enforcement discretion for use of the claim in food labeling. If, after evaluating the petition, FDA determines there is some credible but limited evidence to support the claim, the agency will issue a letter outlining the circumstances under which it intends to consider exercising its enforcement discretion not to challenge the claim. The letter will specify, among other conditions, the specific language that must be used to communicate the limited evidence supporting the claim. If FDA concludes there is no credible evidence, it may deny the petition.

14. In June 2005, Defendant petitioned the FDA for a health claim explaining the relationship between partially hydrolyzed whey protein (“PHWP”) infant formula and reduced risk of *food allergies* in infants. In May 2006, FDA rejected Defendant’s request, finding that

there was “no credible” evidence to support the relationship between PHWP infant formula and a reduced risk of food allergy in infants. *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 May 19, 2014).

15. In 2009, Defendant petitioned the FDA for permission to use a qualified health claim describing the relationship between PWHP infant formula and reduced risk of *atopic dermatitis* in infants. Specifically, Defendant sought authorization for a claim stating that “emerging clinical research” shows that PHWP infant formula may reduce the risk of atopic dermatitis. FDA rejected the request and issued a letter indicating that it would consider exercising its enforcement discretion to allow Defendant to make a highly qualified health 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.” *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 May 19, 2014). Notwithstanding the FDA’s letter of enforcement discretion, Defendant advertises its Gerber Good Start Gentle infant formula with, among other things, a circular gold seal or badge emblazoned with “1st and Only” in the center, “Meets FDA” in the top perimeter, and “Qualified Health Claim” in the bottom perimeter. *See* Paragraph 11.E, Exhibit E.

VIOLATIONS OF THE FTC ACT

16. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits unfair or deceptive acts or practices in or affecting commerce.

17. Misrepresentations or omissions of material fact constitute deceptive acts or practices prohibited by Section 5(a) of the FTC Act.

18. Section 12 of the FTC Act, 15 U.S.C. § 52, prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of Section 12 of the FTC Act, Gerber Good Start Gentle is a “food” or “drug” as defined in Section 15(b) and (c) of the FTC Act, 15 U.S.C. § 55(b), (c).

COUNT I

FALSE OR UNSUBSTANTIATED ALLERGY CLAIM

19. Through the means described in Paragraph 11, Defendant has represented, directly or indirectly, expressly or by implication, 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.

20. The representation set forth in Paragraph 19 is false or misleading, or was not substantiated at the time the representation was made.

21. Therefore, the making of the representation as set forth in Paragraph 19 constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT II

FALSE FDA APPROVAL CLAIM

22. Through the means described in Paragraph 11, Defendant has represented, directly or indirectly, expressly or by implication, that Gerber Good Start Gentle formula qualified for or received approval for a health claim from the Food and Drug Administration.

23. The representation set forth in Paragraph 22 is false or misleading.

24. Therefore, the making of the representation as set forth in Paragraph 22 constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

CONSUMER INJURY

25. Consumers have suffered and will continue to suffer substantial injury as a result of Defendant's violations of the FTC Act. In addition, Defendant has been unjustly enriched as a result of its unlawful acts or practices. Absent injunctive relief by this Court, Defendant is likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

THIS COURT'S POWER TO GRANT RELIEF

26. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations of any provision of law enforced by the FTC. The Court, in the exercise of its equitable jurisdiction, may award ancillary relief, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies, to prevent and remedy any violation of any provision of law enforced by the FTC.

PRAYER FOR RELIEF

Wherefore, Plaintiff FTC, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and the Court's own equitable powers, requests that the Court:

- A. Award Plaintiff such preliminary injunctive and ancillary relief as may be necessary to avert the likelihood of consumer injury during the pendency of this action and to preserve the possibility of effective final relief, including, but not limited to, a preliminary injunction;
- B. Enter a permanent injunction to prevent future violations of the FTC Act by Defendant;
- C. Award such relief as the Court finds necessary to redress injury to consumers resulting from Defendant's violations of the FTC Act, including, but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies; and

D. Award Plaintiff the costs of bringing this action, as well as such other and additional relief as the Court may determine to be just and proper.

Respectfully submitted,

JONATHAN E. NUECHTERLEIN
General Counsel

Dated: 10/29/14

s/ Victor F. DeFrancis
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FEDERAL TRADE COMMISSION

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GERBER PRODUCTS CO., a corporation,
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NESTLÉ NUTRITION,
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**DESIGNATION FOR AGENT OF
SERVICE**

Pursuant to Local Rule 101.1(f), because the Federal Trade Commission (the “Commission”) does not have an office in this District, the United States Attorney for the District of New Jersey is hereby designated as eligible as an alternative to the Commission to receive service of all notices or papers in the above-captioned action. Therefore, service upon the United States or its authorized designee, Paul Blaine, Chief, Civil Division, United States Attorney’s Office for the District of New Jersey, 970 Broad Street, 7th Floor, Newark, NJ 07102,

shall constitute service on the Commission for purposes of this action.

Respectfully submitted,

s/ Victor F. DeFrancis

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