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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 No.: 2:14-cv-06771-SRC-CLW STIPULATED FINAL JUDGMENT AND ORDER FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF

Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), filed its Complaint

for Permanent Injunction and Other Equitable Relief in this matter (the "Action"), pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Commission and Defendant Gerber Products Company stipulate to the entry of this Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief (the "Order") to resolve all matters in dispute in this Action between them.

THEREFORE, IT IS ORDERED as follows:

FINDINGS

1. This Court has jurisdiction over this matter.

2. The Complaint charges that Defendant participated in deceptive acts or practices and false advertisements in violation of Sections 5 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. Specifically, the Complaint challenges Defendant's claims that: (a) 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; (b) the formula qualified or received approval for a health claim from the Food and Drug Administration. The Complaint does not challenge the claims Defendant made about infant atopic dermatitis, Including the four claims set forth in the FDA's letter of enforcement discretion dated May 24, 2011.

3. Defendant neither admits nor denies any of the allegations in the Complaint, except as specifically stated in this Order. Only for purposes of this Action, Defendant admits the facts necessary to establish jurisdiction. Accordingly, for instance, nothing in this Order constitutes, or may be deemed to constitute, an admission or finding of: (a) any of the other factual allegations in the Complaint; (b) any violation of law; or (c) any liability to any third party.

4. Defendant waives any claim that it may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this Action through the date of this Order, and agrees to bear its own costs and attorney fees.

5. Defendant waives all rights to appeal or otherwise challenge or contest the validity of this Order. This Action and the relief provided herein are in addition to, and not in lieu of, other remedies as may be provided by law.

ORDER

DEFINITIONS

For the purpose of this Order, the following definitions apply:

1. "Covered Product" means any infant formula, Including Gerber® Good Start® Gentle.

2. "Defendant" means Gerber Products Co. d/b/a Nestlé Nutrition, Nestlé Infant Nutrition, and Nestlé Nutrition North America, and its successors and assigns.

3. "Essentially Equivalent Product" means a product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers, excipients) in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

4. "Food" and "drug" mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

5. "Including" means including but not limited to.

6. "Person" means a natural person, an organization, or other legal entity, Including a

corporation, partnership, sole proprietorship, limited liability company, association, cooperative, or any other group or combination acting as an entity

I.

PROHIBITED REPRESENTATIONS: ALLERGY AND OTHER DISEASE CLAIMS

IT IS ORDERED that Defendant, Defendant's officers, agents, and employees, and all other Persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from making, expressly or by implication, Including through the use of a product name, endorsement, depiction, or illustration, any representation that the Covered Product;

A. prevents or reduces the risk of developing allergies, or

B. is effective in the cure, mitigation, or treatment of any disease;

unless the representation is non-misleading and, at the time of making such representation, Defendant possesses and relies upon competent and reliable scientific evidence substantiating that the representation is true. For purposes of this Section, competent and reliable scientific evidence shall consist of human clinical testing of the Covered Product, or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in Section IV of this Order must be available for inspection and production to the Commission.

Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II.

PROHIBITED REPRESENTATIONS: FDA OR OTHER APPROVAL

IT IS FURTHER ORDERED that Defendant, Defendant's officers, agents, and employees, and all other Persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from (1) using in any advertising the "badge" reflected on Exhibit A attached hereto, or (2) misrepresenting, expressly or by implication, that the Food and Drug Administration ("FDA") or any other governmental entity approved or authorized a Covered Product or any claim for a Covered Product.

III.

PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS FOR ANY COVERED PRODUCT

IT IS FURTHER ORDERED that Defendant, Defendant's officers, agents, and employees, and all other Persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from making, expressly or by implication, Including through the use of a product or program name, endorsement, depiction, or illustration, any representation, other than representations covered under Sections I and II of this Order, about the health benefits, performance, or efficacy of any Covered Product, unless the

representation is non-misleading, and, at the time of making such representation, Defendant possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Section, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product, or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing, as set forth in Section IV of this Order, must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

IV.

PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Defendant relies to substantiate any claim covered by this Order, Defendant

shall secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, Including:

A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other Person not employed by the research entity;

B. All documents referring or relating to recruitment; randomization; instructions, Including oral instructions, to participants; and participant compliance;

C. Documents sufficient to identify all test participants, Including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, Including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. All documents referring or relating to any statistical analysis of any test data, Including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. All documents referring or relating to the sponsorship of the test, Including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) Defendant; (2) Defendant's officers, agents, representatives, or employees; (3) any other Person or entity in active concert or participation with Defendant; (4) any Person or entity affiliated with or acting on behalf of Defendant; (5) any supplier of any ingredient contained in the product at

issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Section, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by Defendant, Defendant must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to Defendant's size and complexity, the nature and scope of Defendant's activities, and the sensitivity of the personal information collected from or about the participants.

V.

FDA APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order shall prohibit Defendant from:

A. For any drug, making a representation that is permitted in labeling for such drug under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. For any product, making a representation that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration

pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

VI.

ORDER ACKNOWLEDGMENTS

IT IS FURTHER ORDERED that Defendant obtain acknowledgments of receipt of this Order:

A. Defendant, within 7 days of entry of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 3 years after entry of this Order, Defendant must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for conduct related to the subject matter of the Order and all agents and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Section titled Compliance Reporting. Delivery must occur within 7 days of entry of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which Defendant delivered a copy of this Order, Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

VII.

COMPLIANCE REPORTING

IT IS FURTHER ORDERED that Defendant makes timely submissions to the Commission:

A. One year after entry of this Order, Defendant must submit a compliance report, sworn under penalty of perjury. Defendant must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Defendant; (b) identify all of Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, Including the goods and services offered, and, for any Covered Product, the means of advertising, marketing, and sales; (d) describe in detail whether and how Defendant is in compliance with each Section of this Order; and (e) provide a copy of each Order Acknowledgment obtained pursuant to this Order, unless previously submitted to the Commission.

B. For 10 years after entry of this Order, Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following: (a) any designated point of contact; or (b) the structure of Defendant or any entity that Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, Including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

C. Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against Defendant within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: *FTC v. Gerber Products Co.*, Matter No. X150016.

VIII.

RECORDKEEPING

IT IS FURTHER ORDERED that Defendant must create certain records for 10 years after entry of the Order, and retain each such record for 5 years. Specifically Defendant must create and retain the following records:

A. Accounting records showing the revenues from all goods or services sold;

B. Personnel records showing, for each Person providing services, whether as an employee or otherwise, that Person's: name; addresses; telephone numbers; job title

or position; dates of service; and (if applicable) the reason for termination;

C. Records of all consumer complaints and refund requests relating to any representation covered under this Order for any Covered Product, whether received directly or indirectly, such as through a third party, and any response;

D. all records necessary to demonstrate full compliance with each provision of this Order, Including all submissions to the Commission; and

E. a copy of each unique advertisement or other marketing material relating to any representation covered under this Order for any Covered Product.

IX.

COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Defendant's compliance with this Order:

A. Within 14 days of receipt of a written request from a representative of the Commission, Defendant must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury; appear for depositions; and produce documents for inspection and copying. The Commission is also authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (Including telephonic depositions), 31, 33, 34, 36, 45, and 69.

B. For matters concerning this Order, the Commission is authorized to communicate directly with each Defendant. Defendant must permit representatives of the Commission to interview any employee or other Person affiliated with any Defendant

who has agreed to such an interview. The Person interviewed may have counsel present.

C. The Commission may use all other lawful means, Including posing, through its representatives as consumers, suppliers, or other individuals or entities, to Defendant or any individual or entity affiliated with Defendant, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

X.

RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court retains jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

SO ORDERED this 11 day of July, 201_.

UNITED STATES DISTRICT JUDGE

SO STIPULATED AND AGREED:

FOR PLAINTIFF:

Michelle Rusk

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FOR DEFENDANT:

GERBER PRODUCTS COMPANY

By: _____
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Date: June 2nd, 2019

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EXHIBIT A