

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

**COMMISSIONERS: Jon Leibowitz, Chairman
William E. Kovacic
J. Thomas Rosch
Edith Ramirez
Julie Brill**

In the Matter of

**NESTLÉ HEALTHCARE NUTRITION, INC.,
a corporation.**

DOCKET NO. C-4312

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by the respondent that the law has been violated as alleged in such complaint, or that any of the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comment, and having duly considered the comments filed thereafter by interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, and having modified the Decision and Order in certain respects, now in further conformity with the procedure described in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Nestlé HealthCare Nutrition, Inc. (“Nestlé HCN”) is a Delaware corporation with its principal office or place of business at 12 Vreeland Road, Florham Park, New Jersey 07932-0697.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent and this proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. Unless otherwise specified, “respondent” means Nestlé HealthCare Nutrition, Inc., a corporation, its successors and assigns and their officers, and each of the above’s agents, representatives, and employees.
2. “Commerce” means as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
3. “Adequate and well-controlled human clinical study” means a human clinical study conducted by persons qualified by training and experience to conduct such study. Such study shall be randomized, and, unless it can be demonstrated that blinding or placebo control cannot be effectively or ethically implemented given the nature of the intervention, shall be double-blind and placebo-controlled.
4. “Covered product” means BOOST Kid Essentials, any drink product containing probiotics, or any nutritionally complete drink, other than infant formula, medical foods, and any product not sold primarily through conventional retail channels.
5. “Essentially equivalent product” means a product that contains the identical ingredients, except for inactive ingredients (e.g., inactive binders, flavors, preservatives, 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 or other differences in formulation to affect taste, texture, or nutritional value (so long as the other differences do not change the form of the product or involve the ingredients from which the functional benefit is derived), if reliable scientific evidence generally accepted by experts in the field demonstrates that the amount of additional ingredients, combination of additional ingredients, and any other differences in formulation are unlikely to impede or inhibit the effectiveness of the ingredients in the essentially equivalent product.
6. “Dosage” means the quantity of the substance taken in or absorbed over a specified, biologically relevant time period to achieve the intended effect.

7. The term “including” in this order means “without limitation.”
8. The terms “and” and “or” in this order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, that such product prevents or reduces the risk of upper respiratory tract infections, including, but not limited to, cold or flu viruses, unless the representation 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.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, that such product:

- A. Reduces the duration of acute diarrhea in children up to the age of thirteen; or
- B. Reduces absences from daycare or school due to illness;

unless the representation is non-misleading and, at the time of making such representation, the respondent possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this Part, competent and reliable scientific evidence shall consist of at least two adequate and well-controlled human clinical studies of the product, or of an essentially equivalent product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true. Respondent shall have the burden of proving that a product satisfies the definition of essentially equivalent product.

III.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, other than representations covered under Parts I or 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, the respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, 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 Part, competent and reliable scientific evidence means tests, analyses, research, studies, or other evidence that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results.

IV.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

V.

IT IS FURTHER ORDERED that nothing in this order shall prohibit respondent from making any representation for any product 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.

VI.

IT IS FURTHER ORDERED that respondent Nestlé HCN, and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon reasonable notice make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and

- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VII.

IT IS FURTHER ORDERED that respondent Nestlé HCN, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and other employees having primary responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent Nestlé HCN, and its successors and assigns, shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VIII.

IT IS FURTHER ORDERED that respondent Nestlé HCN, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent Nestlé HCN, and its successors and assigns, learn less than thirty (30) days prior to the date such action is to take place, respondent Nestlé HCN, and its successors and assigns, shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that respondent Nestlé HCN, and its successors and assigns, shall, within sixty (60) days after service of this order file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form in which respondent has complied with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, respondent shall submit additional true and accurate written reports.

X.

This order will terminate on January 12, 2031, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Donald S. Clark
Secretary

ISSUED: January 12, 2011