

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

In the Matter of)	FILE NO. 092 3087
NESTLÉ HEALTHCARE NUTRITION, INC.,)	AGREEMENT CONTAINING
a corporation.)	CONSENT ORDER
)	

The Federal Trade Commission (“Commission”) has conducted an investigation of certain acts and practices of Nestlé HealthCare Nutrition, Inc., a corporation (“proposed respondent”). Proposed respondent, having been represented by counsel, is willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between Nestlé HealthCare Nutrition, Inc., by its duly authorized officers, and counsel for the Federal Trade Commission that:

1. Proposed 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. Proposed respondent admits all the jurisdictional facts set forth in the draft complaint.
3. Proposed respondent waives:
 - a. Any further procedural steps;
 - b. The requirement that the Commission’s decision contain a statement of findings of fact and conclusions of law; and
 - c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.
4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of thirty (30) days and information about it will be publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.
6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time frame provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondent's address as stated in this agreement by any means specified in Section 4.4(a) of the Commission's Rules shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.
7. Proposed respondent has read the draft complaint and consent order. Proposed respondent understands that it may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

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 if reliable scientific evidence generally accepted by experts in the field demonstrates that the amount and combination of additional ingredients is 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 twenty (20) years from the date of its issuance, 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.

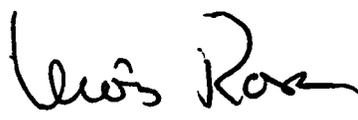
Provided, further, that if such complaint is dismissed or a federal court rules that respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been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

Signed this 18th day of May, 2010.

NESTLÉ HEALTHCARE NUTRITION, INC.

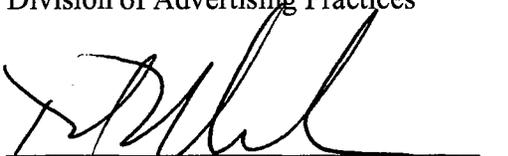
By: 
KEVIN L. GOLDBERG, ESQUIRE
HEAD OF LEGAL
Nestlé HealthCare Nutrition, Inc.


LEWIS ROSE, ESQUIRE
DANA ROSENFELD, ESQUIRE
KELLEY DRYE & WARREN LLP
3050 K STREET, NW
WASHINGTON, DC 20007
202-342-8400
Counsel for Nestlé HCN


KAREN MANDEL
Counsel for the Federal Trade Commission

APPROVED:


MARY K. ENGLE
Associate Director
Division of Advertising Practices


DAVID C. VLADECK
Director
Bureau of Consumer Protection