

Commission anticipates that the competitive problems alleged in the Complaint will be resolved. The purpose of this analysis is to inform and invite public comment on the Consent Agreement, including the proposed divestitures, and to aid the Commission in its determination of whether to make the Consent Agreement final. This analysis is not intended to constitute an official interpretation of the Consent Agreement, nor is it intended to modify the terms of the Consent Agreement in any way.

By direction of the Commission.

**Donald S. Clark**

*Secretary.*

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## FEDERAL TRADE COMMISSION

[File No. 092 3087]

### Nestle' HealthCare Nutrition, Inc.; Analysis of Proposed Consent Order to Aid Public Comment

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed Consent Agreement.

**SUMMARY:** The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

**DATES:** Comments must be received on or before August 16, 2010.

**ADDRESSES:** Interested parties are invited to submit written comments electronically or in paper form. Comments should refer to “Nestle, File No. 092 3087” to facilitate the organization of comments. Please note that your comment—including your name and your state—will be placed on the public record of this proceeding, including on the publicly accessible FTC website, at (<http://www.ftc.gov/os/publiccomments.shtml>).

Because comments will be made public, they should not include any sensitive personal information, such as an individual's Social Security Number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records or other individually

identifiable health information. In addition, comments should not include any “[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential. . . .” as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and Commission Rule 4.10(a)(2), 16 CFR 4.10(a)(2). Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c), 16 CFR 4.9(c).<sup>1</sup>

Because paper mail addressed to the FTC is subject to delay due to heightened security screening, please consider submitting your comments in electronic form. Comments filed in electronic form should be submitted by using the following weblink: (<https://ftcpublic.commentworks.com/nestle>) and following the instructions on the web-based form. To ensure that the Commission considers an electronic comment, you must file it on the web-based form at the weblink: (<https://ftcpublic.commentworks.com/nestle>). If this Notice appears at (<http://www.regulations.gov/search/index.jsp>), you may also file an electronic comment through that website. The Commission will consider all comments that regulations.gov forwards to it. You may also visit the FTC website at (<http://www.ftc.gov/>) to read the Notice and the news release describing it.

A comment filed in paper form should include the “Nestle, File No. 092 3087” reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex D), 600 Pennsylvania Avenue, NW, Washington, DC 20580. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions.

The Federal Trade Commission Act (“FTC Act”) and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives,

<sup>1</sup> The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. See FTC Rule 4.9(c), 16 CFR 4.9(c).

whether filed in paper or electronic form. Comments received will be available to the public on the FTC website, to the extent practicable, at (<http://www.ftc.gov/os/publiccomments.shtml>). As a matter of discretion, the Commission makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at (<http://www.ftc.gov/ftc/privacy.shtml>).

#### FOR FURTHER INFORMATION CONTACT:

Karen Mandel (202-326-2491), Bureau of Consumer Protection, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 the Commission Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for July 14, 2010), on the World Wide Web, at (<http://www.ftc.gov/os/actions.shtml>). A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before the date specified in the **DATES** section.

#### Analysis of Agreement Containing Consent Order to Aid Public Comment

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Nestle; HealthCare Nutrition, Inc. (“respondent”). The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record.

After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves the advertising and promotion of BOOST Kid Essentials, a children's nutritional drink that also delivers probiotics via an attached straw. According to the FTC complaint, respondent represented, in various advertisements, that BOOST Kid Essentials prevents upper respiratory tract infections in children; strengthens the immune system, thereby providing protection against cold and flu viruses; and reduces absences from daycare or school due to illness. The complaint alleges that these claims are unsubstantiated and thus violate the FTC Act.

The FTC complaint further charges that respondent represented that clinical studies prove that BOOST Kid Essentials reduces the general incidence of illness in children, including upper respiratory tract infections; reduces the duration of acute diarrhea in children up to age thirteen (the age group for which the product is marketed); and strengthens the immune system, thereby providing protection against cold and flu viruses. The complaint alleges that these claims are false and thus violate the FTC Act.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts or practices in the future. The order covers representations made in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, in or affecting commerce. The order defines a covered product as 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.

Part I of the consent order is designed to address the complaint allegations concerning respondent's allegedly unsubstantiated representations that its products prevent upper respiratory tract infections (URTIs). Part I prohibits respondent from making representations that a covered product prevents or reduces the risk of URTIs, 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 (FDA) pursuant to the Nutrition Labeling and Education Act of 1990 (NLEA). Under this provision, therefore, respondent

cannot make a claim of URTI risk reduction unless the FDA has issued a regulation authorizing the claim based on a finding that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, considering the totality of publicly available scientific evidence. As noted in the Commission's Enforcement Policy Statement on Food Advertising, "[t]he Commission regards the 'significant scientific agreement' standard, as set forth in the NLEA and FDA's regulations, to be the principal guide to what experts in the field of diet-disease relationships would consider reasonable substantiation for an unqualified health claim." Enforcement Policy Statement on Food Advertising (1994), available at (<http://www.ftc.gov/bcp/policystmt/ad-food.shtm>). Thus, although the Enforcement Policy Statement does not say that the only way a food advertiser can adequately substantiate a disease risk-reduction claim is through FDA authorization, the Commission has determined that requiring FDA pre-approval before respondent makes a URTI risk-reduction claim for its covered products will facilitate compliance with the order and is reasonably related to the enforcement of this order.

Respondent may decide to make an advertising claim characterizing limited scientific evidence supporting the relationship between a covered product and URTIs. However, if the net impression is that a covered product prevents or reduces the risk of URTIs, and not merely that there is limited scientific evidence supporting the claim, the advertisement would be covered under Part I. The Commission notes that its experience and research show that it is very difficult to adequately qualify a disease risk-reduction claim in advertising to indicate that the science supporting the claimed effect is limited. In other words, reasonable consumers may interpret an advertisement to mean that the product will prevent or reduce the risk of URTIs, even if respondent includes language indicating that the science supporting the effect is limited in some way. However, if respondent possesses reliable empirical testing demonstrating that the net impression of an advertisement making a qualified claim for a covered product does not convey that it will prevent or reduce the risk of URTIs, then that claim would be covered under the relevant subsequent parts of the order.

Although Part I requires FDA approval before respondent can make claims that a covered product prevents

or reduces the risk of URTIs, the Commission does not intend Part I to limit respondent to using the precise language specified in an FDA-approved health claim. To the contrary, if the FDA has approved a claim that a covered product can prevent or reduce the risk of URTIs, respondent may use a variety of words and images to communicate that claim in its advertising. Likewise, regardless of the particular words or images used, if the net impression of an advertisement is that a covered product prevents or reduces the risk of URTIs, then for the ad to comply with the order, the FDA must have authorized a health claim based on significant scientific agreement that such product provides such a benefit.

Part II of the consent order prohibits respondent from making representations that a covered product reduces the duration of acute diarrhea in children up to the age of thirteen, or reduces absences from daycare or school due to illness, unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of Part II, competent and reliable scientific evidence means 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. For purposes of the order, 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.

Part III of the consent order prohibits respondent from making representations, other than representations covered under Parts I or II, 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, 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 Part III, 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.

Part IV of the consent order prohibits respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part V of the consent order provides that nothing in the 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 FDA pursuant to the NLEA.

Parts VI, VII, VIII, and IX of the consent order require respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to its personnel; to notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and to file compliance reports with the Commission.

Part X provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify their terms in any way.

By direction of the Commission.

**Richard C. Donohue**

*Acting Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Solicitation of Nomination for Appointment to the Advisory Committee on Minority Health

**AGENCY:** Office of Minority Health, Office of Public Health and Science, Office of the Secretary, Department of Health and Human Services.

#### **ACTION:** Notice.

**Authority:** 42 U.S.C. 300u-6, Section 1707 of the Public Health Service Act, as amended. The Advisory Committee is governed by provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

**SUMMARY:** The Department of Health and Human Service (HHS), Office of Public Health and Science (OPHS), is seeking nominations of qualified candidates to be considered for appointment as a member of the Advisory Committee on Minority Health (ACMH). In accordance with Public Law 105-392, the Committee provides advice to the Deputy Assistant Secretary for Minority Health, on the development of goals and specific program activities of the Office of Minority Health (OMH) designed to improve the health of racial and ethnic minority groups. Nominations of qualified candidates are being sought to fill current and impending vacant positions on the Committee.

**DATES:** Nominations for membership on the Committee must be received no later than 5 p.m. EST on October 20, 2010, at the address listed below.

**ADDRESSES:** All nominations should be mailed or delivered to Dr. Garth Graham, Deputy Assistant Secretary for Minority Health, Office of Minority Health, Office of Public Health and Science, Department of Health and Human Services, 1101 Wootton Parkway, Suite 600, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Ms. Monica Baltimore, Executive Director, Advisory Committee on Minority Health, Office of Minority Health, Office of Public Health and Science, Department of Health and Human Services, 1101 Wootton Parkway, Suite 600, Rockville, MD 20852; Telephone: (240) 453-2882.

A copy of the Committee charter and list of the current membership can be obtained by contacting Ms. Baltimore or by accessing the Web site managed by OMH at <http://www.minorityhealth.gov/acmh>.

#### **SUPPLEMENTARY INFORMATION:**

Pursuant to Public Law 105-392, the Secretary of Health and Human Services established the ACMH. The Committee shall provide advice to the Deputy Assistant Secretary for Minority Health in carrying out the duties stipulated under Public Law 105-392. This includes providing advice to improve the health of each racial and ethnic minority group and in the development of goals and specific activities of the OMH, which are:

(1) Establish short-range and long-range goals and objectives and coordinate all other activities within the Public Health Service that relate to disease prevention, health promotion, service delivery, and research concerning such individuals;

(2) Enter into interagency agreements with other agencies of the Public Health Service;

(3) Support research, demonstrations, and evaluations to test new and innovative models;

(4) Increase knowledge and understanding of health risk factors;

(5) Develop mechanisms that support better information dissemination, education, prevention, and service delivery to individuals from disadvantaged backgrounds, including individuals who are members of racial or ethnic minority groups;

(6) Ensure that the National Center for Health Statistics, within the Centers for Disease Control and Prevention, collects data on the health status of each minority group;

(7) With respect to individuals who lack proficiency in speaking the English language, enter into contracts with public and nonprofit private providers of primary health services for the purpose of increasing the access of these individuals to such services by developing and carrying out programs to provide bilingual or interpretive services;

(8) Support a national minority health resource center to carry out the following:

(a) Facilitate the exchange of information regarding matters relating to health information and health promotion, preventive health services, and education in appropriate use of health care;

(b) Facilitate access to such information;

(c) Assist in the analysis of issues and problems relating to such matters;

(d) Provide technical assistance with respect to the exchange of such information (including facilitating the development of materials for such technical assistance);

(9) Carry out programs to improve access to health care services for individuals with limited proficiency in speaking the English language. Activities under the preceding sentence shall include developing and evaluating model projects; and

(10) Advising in matters related to the development, implementation, and evaluation of health professions education in decreasing disparities in health care outcomes, including cultural competency as a method of eliminating health disparities.