In the Matter of Nestlé HealthCare Nutrition, Inc.

ANALYSIS OF PROPOSED 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 Nestlé 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.