UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Secretary

January 12, 2011

VIA UNITED STATES MAIL
Lee Thomason, Esq.
Spalding & Thomason
106 North 4th Street
P.O. Box 745
Bardstown, KY 40004

Re: Nestlé HealthCare Nutrition, Inc. (File No. 0823145)

Dear Mr. Thomason:

Thank you for your comment on the proposed consent order accepted by the Federal Trade Commission for public comment in the above-captioned matter. Your comment expresses concern that Part I of the order effectively would restrain advertisers, other than respondent, from making substantiated claims about the relationship between probiotics and upper respiratory tract infections. In addition, your comment suggests that the order unreasonably expands the substantiation requirements for health claims. The Commission has placed your comment on the public record and reviewed it in connection with its decision concerning whether to accord the order final approval.

The order would apply, in fact, only to respondent. Part I addresses the alleged false and unsubstantiated upper respiratory tract infection prevention or risk reduction claims (challenged URTI claims). Under Part I, before respondent can make the challenged URTI claims in future advertising, the FDA must approve the claims for labeling by regulations under the Nutrition Labeling and Education Act's significant scientific agreement standard. In other words, for the challenged URTI claims, Part I only requires respondent to meet for advertising the same standard it already must meet for labeling. The Commission believes this remedy is reasonably related to the challenged practices and provides an easily enforceable compliance standard. Part II of the order specifically applies only to two of the challenged claims[1] and requires, as substantiation, two adequate and well-controlled human clinical studies. The Commission believes this standard is appropriate here based on the factors articulated in *Pfizer, Inc.*, 81 F.T.C. 23, 64 (1972), and *Thompson Medical Co.*, 104 F.T.C. 648, 821 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986). Part III merely adds clarifying language to the traditional substantiation order provision to aid order compliance. Taken together, Parts II and III do not expand respondent's substantiation requirements beyond what the Commission has long required.

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[1] Part II covers claims 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.

Moreover, the Commission does not believe that these order provisions will impede the flow of useful, beneficial, and credible information to consumers. Instead, they will help ensure that respondent does not make false or unsubstantiated health claims in violation of the FTC Act in the future.

After considering your comment, the Commission has determined that the public interest would best be served by issuing the Decision and Order in final form without the suggested modifications. A copy of the final Decision and Order is enclosed for your information. Relevant materials also are available from the Commission's Website at http://www.ftc.gov.

It helps the Commission's analysis to hear from a variety of sources in its work, and we appreciate your interest in this matter.

By direction of the Commission.

Donald S. Clark
Secretary