



Office of the Secretary

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

March 22, 2011

VIA UNITED STATES MAIL

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

Re: In the Matter of NBTY, Inc., et al., File No. 102 3080, Docket No. C-4318

Dear Mr. Thomason:

Thank you for commenting on the Federal Trade Commission's proposed consent agreement in the above-referenced proceeding. The Commission has placed your comment on the public record pursuant to Rule 4.9(b)(6)(ii) of the Commission's Rules of Practice, 16 C.F.R. § 4.9(b)(6)(ii), and has given it serious consideration.

Your comment expresses concerns that the Commission overreached its authority because, in your view, the challenged advertising claims were not false or unsubstantiated but perhaps "reasonably avoidable by consumers themselves," and because the U.S. Food and Drug Administration ("FDA") has authority over issues involving the labeling of various products.

The Commission's proposed complaint alleges that respondents misrepresented the significance of the amount of docosahexaenoic acid ("DHA") in the relevant products and made unsubstantiated claims that the amount of DHA in these products promotes healthy brain and eye development in children two years of age and older. The Commission evaluates an advertisement in its totality – including both text and graphics – to determine the net impression that it conveys to reasonable consumers. As highlighted in the proposed complaint, print advertisements, the front panels of product packages, and labels for the products at issue contained prominent graphics with bold text that touted the purported significance of the DHA within the products, such as a prominent red starburst-shaped graphic containing large text that read "with DHA*." Moreover, the asterisk referred consumers to language that helped further the impression that the amount of DHA in these products was significant. Second, while the report issued by the Institute of Medicine of the National Academies, which you referenced in your comment, discusses evidence suggesting that supplementation of DHA combined with arachidonic acid ("ARA" – an Omega-6 fatty acid) might have positive effects on the visual

development of fetuses and young infants,¹ the products at issue in the proposed complaint are intended for children two years of age and older. Moreover, scientific evidence evaluating the effect of DHA on fetuses and infants involve significantly larger amounts of DHA than provided by a daily serving of the products challenged in the proposed complaint. Finally, as mentioned, the challenged claims were made in print advertisements, on product packaging, and on product labels. In addition, the Memorandum of Understanding between the FTC and FDA, which provides that the FDA has “primary jurisdiction over all matters regulating the labeling of foods, drugs, devices, and cosmetics,” while the FTC has “primary responsibility with respect to the regulation of the truth or falsity of all advertising,” does not mean that the FTC lacks authority to challenge deceptive marketing claims that appear on product labels as well as in other forms of advertising.²

In light of these considerations, the Commission has determined that the public interest would best be served by issuing the Decision and Order in final form without modification. The final Decision and Order and other relevant materials 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 thank you again for your comment.

By direction of the Commission.

Donald S. Clark
Secretary

¹ In closing letters issued by the Commission staff in 2004 to Martek Biosciences Corp. (File No. 022-3238) and Beech-Nut Nutrition Corp. (File No. 022-3250), the staff concluded that there was emerging scientific evidence to provide some support for limited development claims for baby food and infant formula containing DHA and ARA.

² “Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration,” 4 Trade Reg. Rep. (CCH) ¶ 9,851 (1971).