Analysis of Proposed Consent Order to Aid Public Comment

In the Matter of NBTY, Inc., File No. 102 3080

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from NBTY, Inc., NatureSmart LLC, and Rexall Sundown, Inc. (collectively, “Respondents”).

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 and take appropriate action or make final the agreement’s proposed order.

This matter involves the advertising and promotion of the following products in Respondents’ Disney/Marvel line of children’s multivitamin and mineral dietary supplements: 1) Disney Princess Complete; 2) Disney Princess Gummies; 3) Disney Pixar Cars Gummies; 4) Disney Winnie the Pooh Gummies; 5) Disney Tigger & Pooh Gummies; 6) Disney Pixar Finding Nemo Gummies; 7) Disney Pixar Wall-E Gummies; 8) Disney Pixar Toy Story Gummies; 9) Marvel Heroes Complete; and 10) Marvel Heroes Gummies (collectively, the “NBTY Products”).

According to the FTC complaint, Respondents represented, in advertisements, that the NBTY Products contained a significant amount of DHA (docosahexaenoic acid, a polyunsaturated Omega-3 fatty acid) or an amount comparable to 100 mg of DHA. The complaint alleges that this claim is false or misleading because, in fact, a daily serving of the NBTY products only contained either 0.1 mg of DHA (which is one thousandth of 100 mg) or 0.05 mg of DHA (which is five ten-thousandths of 100 mg).

The Commission also charges that Respondents represented that the DHA provided by a daily serving of the NBTY Products promoted healthy brain and eye development in children two years of age and older. The FTC alleges that this claim is false or misleading because Respondents failed to have evidence to substantiate it.

The proposed consent order contains provisions designed to prevent Respondents from engaging in similar acts and practices in the future. Part I of the proposed order prohibits Respondents from misrepresenting that any product contains a specific ingredient or specific numerical amount of any ingredient.

Part II of the proposed order prohibits Respondents from making any representations in advertising for any product about the health benefits, performance, or efficacy of the product, unless the representation is true and non-misleading. In addition, Respondents must possess competent and reliable scientific evidence sufficient in quality and quantity, when considered in light of the entire body of relevant and reliable scientific evidence, to support such claims as true.
Part III of the proposed order states that the order does not prohibit Respondents from making representations for any drug that are permitted in labeling for that drug under any tentative or final standard promulgated by the FDA, or under any new drug application approved by the FDA. This part of the proposed order also states that the order does not prohibit Respondents from making representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Part IV of the proposed order requires Respondents to pay two million, one hundred thousand dollars ($2,100,000) to the Commission to be used for equitable relief, including restitution, consumer redress, and any attendant expenses for the administration of such equitable relief.

Parts V through VIII of the proposed order require Respondents to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain 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 IX 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.