In the Matter of The Dannon Company, 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 The Dannon Company, 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 DanActive, a probiotic dairy drink, and Activia, a probiotic yogurt. According to the FTC complaint, respondent represented, in various advertisements, that drinking DanActive reduces the liy3c reduc

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 consent order provision requiring FDA pre-approval before respondent makes a reduced cold or flu likelihood claim for its covered products in the future will facilitate compliance with and enforcement of the order and is reasonably related to the violations alleged.

Respondent may decide to make an advertising claim characterizing limited scientific evidence supporting the relationship between a covered product and a reduced likelihood of getting a cold or the flu. However, if the net impression of that advertising is that the covered product reduces the likelihood of getting a cold or the flu, 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 reduce the likelihood of getting a cold or the flu, 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 reduce the likelihood of getting a cold or the flu, then that claim would be covered under Part IV of the order.

Although Part I requires FDA approval before respondent can make claims that a covered product reduces the likelihood of getting a cold or the flu, 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 reduces the likelihood of getting a cold or the flu, respondent may use a variety of words and images to communicate that claim in its advertising. Conversely, regardless of the particular words or images used, if the net impression of an advertisement is that a covered product reduces the likelihood of getting a cold or the flu, 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 eating one serving of Activia yogurt daily relieves temporary irregularity and helps with slow intestinal transit time unless the representation is non-misleading and it conveys that eating three servings a day is required to obtain the benefit. Part II further provides, however, that the order does not prohibit respondent from representing that the benefit can be achieved from eating less than three servings a day if such claim is non-misleading and respondent possesses and relies upon competent and reliable scientific evidence that substantiates that such 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 or other differences in formulation to affect taste, texture, or nutritional value (so long as the other differences do not change the form of the product or involve the ingredients from which the functional benefit is derived), if reliable scientific evidence generally accepted by experts in the field demonstrates that the amount of additional ingredients, combination of additional ingredients, and any other differences in formulation are 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 that any covered product other than Activia yogurt relieves temporary irregularity and helps with slow intestinal transit time unless the representation is non-misleading and respondent possesses and relies upon competent and reliable scientific evidence that substantiates that such representation is true. For purposes of Part III, 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.

Part IV of the consent order prohibits respondent from making representations, other than representations covered under Parts I through III, 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