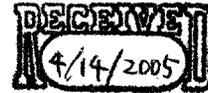


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April 5, 2005

Kathy Ellwood, Ph.D.
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Martek Biosciences Corporation FDAMA Notification

Dear Dr. Ellwood:

We are writing in response to your request that Martek Biosciences Corporation (Martek) amend the FDAMA notification it submitted on January 21, 2005 regarding nutrient content claims for alpha-linolenic acid (ALA) and docosahexaenoic acid (DHA). You specifically asked whether Martek would amend the notification to delete the proposed nutrient content claims for DHA because the agency does not believe there is an authoritative statement that can serve as the basis for the claim. For the reasons explained below, we respectfully decline your request to eliminate the nutrient content claims for DHA from Martek's FDAMA notification.

During our telephone call, you identified several reasons why the agency did not believe there is an authoritative statement that would support FDAMA nutrient content claims for DHA. You noted that the Institute of Medicine Macronutrient Report (IOM Report) did not establish a daily intake that is specific to DHA. ^{1/} While the IOM report recognized that DHA could contribute up to 10 percent of the adequate intake (AI) for ALA, you noted that the "up to 10 percent" language could not serve as a basis for a daily value because the IOM did not establish a specific numeric value for DHA intake. Indeed, you noted that a product

^{1/} Institute of Medicine (IOM), a division of the National Academy of Sciences (NAS), *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids* (2002)(IOM Report) (prepublication).

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containing no DHA would comport with the "up to 10 percent" language of the IOM Report. You also noted that the "up to 10 percent" language is not found in the Executive Summary or in boxed text at the beginning of each chapter, places within the Macronutrient Report identified by the IOM as sources for authoritative statements. ^{2/}

Because the agency does not believe there is an authoritative statement that would serve as the basis for DHA nutrient content claims, you noted that the agency could not issue a letter identifying the terms under which DHA and ALA nutrient content claims could be made. You noted that the agency would be able to issue such a letter if Martek would amend the FDAMA notification by deleting the recommended nutrient content claims for DHA and limiting the claims to ALA nutrient content claims.

Martek realizes that the agency has raised similar concerns with the omega-3 fatty acid FDAMA notification filed by Olsson, Frank & Weeda in 2004 (OF&W Notification). ^{3/} Indeed, the docket for the OF&W Notification contained letters in which the agency specifically acknowledged that it disagreed with the basis for the DHA nutrient content claims. ^{4/} FDA, however, made it clear that

^{2/} See Letter from Susanne A. Stoiber, Executive Director, Institute of Medicine to Laura Tarantino, Acting Director, ONPLDS/CFSAN, FDA (May 5, 2004).

^{3/} FDAMA Notification submitted by Olsson, Frank and Weeda, P.C. (OF&W Notification) on January 16, 2004 proposing nutrient content claims for foods and dietary supplements containing DHA, EPA, and ALA. Filed on behalf of Alaska General Seafoods, Ocean Beauty Seafoods, Inc., and Trans-Ocean Products, Inc., the OF&W Notification received no objection or response from FDA and became effective under operation of law on May 15, 2004.

^{4/} See Letter to Nancy Chapman, President, Advocates for Better Children's Diets, from Shellee Anderson, ONPLDS/CFSAN (June 25, 2004); letter to Barbara J. Moore, President and CEO, Shape Up America!, from Shellee Anderson, ONPLDS/CFSAN (June 25, 2004); letter to Jeffrey R. Prince, Vice President, American Institute for Cancer Research, from Shellee Anderson, ONPLDS/CFSAN (June 25, 2004). The three FDA letters noted that, because the 120-day period passed on May 15, 2004, manufacturers may lawfully label qualifying foods with the nutrient content claims detailed in the OF&W Notification. However, FDA emphasized that "because the agency disagrees with [sic] basis for the notified nutrient content claims for EPA and DHA, FDA intends to initiate rulemaking" to define those claims. In a more recently issued letter, FDA merely states "[w]e are

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DHA nutrient content claims could be made consistent with the OF&W Notification until the agency pursued rulemaking to address its concerns. Martek met with the agency prior to filing its FDAMA Notification for the specific purpose of gaining a better understanding of the agency's concerns and providing an explanation as to why there are competitive and business factors that, nonetheless, made it necessary for Martek to file a FDAMA notification.

We filed the notification, in large part, to address the uneven playing field created by the OF&W Notification that limited DHA "excellent source" claims to those products providing 100 percent of the calculated daily value for DHA rather than 20 percent or greater, the level established in the FDA regulations for excellent source claims . 5/ Whereas the Martek FDAMA notification covers "excellent source of DHA" nutrient content claims on products providing 32 mg of DHA (*i.e.*, 20 percent of the calculated daily value for DHA) per reference amount customarily consumed (RACC), the OF&W Notification required products to contain 130 mg of DHA per RACC.

Martek realizes that by failing to amend the notification, it should expect the same agency reception as the OF&W Notification, which the agency allowed to go into effect while signaling its disagreement with the basis for the claims. We are aware that under FDAMA, if the agency does not agree with the notification, it may pursue one of three options through rulemaking: (1) prohibit the use of the claims, (2) modify the claims, or (3) conclude that the requirements of FDAMA have not been satisfied by the notification. 6/

We regret that we are unable to accommodate the agency request of modifying the FDAMA notification. Martek generally tries to work cooperatively with the agency and we wish that we could do so here as well. However, given the uneven playing field created by the existing FDAMA Notification, Martek believes it is necessary to keep the DHA nutrient content claims in its notification to enable the use of the claim on products providing 20 percent of the calculated daily value for DHA.

considering what to do in response to the notification." (Letter to Carol Tucker Foreman, Consumer Federation of America, from Lester M. Crawford, Acting Commissioner, FDA (Nov. 23, 2004).)

5/ 21 C.F.R. § 101.54(b)(1).

6/ Federal Food Drug and Cosmetic Act § 403(r)(2)(H); 21. U.S.C. § 343(r)(2)(H).

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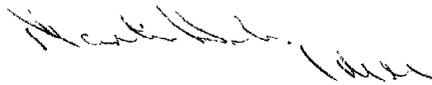
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We appreciate the opportunity to clarify our position for the agency. We thank you for your consideration and look forward to continuing to work together in the future.

If you have any questions or comments, please contact us.

Sincerely,



Martin J. Hahn

cc: Dr. Paula Trumbo, CFSAN/FDA