



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

JUL 16 2004

Food and Drug Administration
College Park, MD 20740

Jonathan W. Emord, Esq.
Emord & Associates, P.C.
5282 Lyngate Court
Burke, Virginia 22015

Re: Reply to June 4, 2004 Letter to Acting Commissioner, Dr. Lester Crawford

Dear Mr. Emord:

This letter is in response to your June 4, 2004 letter to Acting Commissioner Dr. Lester Crawford on behalf of your client Weider Nutritional International, Inc. The letter expresses your client's dissatisfaction with the "Tentative Conclusions" document that FDA provided to the Food Advisory Committee and its Dietary Supplements Subcommittee (collectively, "the Committee") for the Committee meeting held June 7-8, 2004. We have received another letter from you dated July 1, 2004 on other issues related to the Committee meeting and plan to respond to that letter at a later date.

The purpose of the Committee meeting was to gather information and to receive advice and recommendations relating to the etiology of osteoarthritis, its modifiable risk factors, and the relevance of scientific studies cited in the petitions to substantiating the substance-disease relationship. FDA sought the Committee's opinion on our tentative conclusions on these issues. The Committee meeting provided an avenue for FDA to hear other opinions and conclusions and assured that the Agency did not overlook any pertinent information that might affect our final decision on the petitions.

Providing Advisory Committees with tentative conclusions for discussion by the Committee is not new. For example, the Advisory Committees that deliberated scientific

2004P-0059

ANS 1

issues related to the Calgene FLAVR SAVR™ tomatoes¹, Olestra² and Plan B® (Levonorgestrel)³ were provided with the FDA's review, including tentative conclusions on safety issues, prior to their respective meetings. FDA considers providing an Advisory Committee with the Agency's tentative positions and underlying reasoning with regard to the issues under consideration useful to help the Committee focus its deliberations. Knowing FDA's tentative thinking helps the Committee identify any flaws in the Agency's reasoning or information the Agency may have overlooked. Therefore, providing a preliminary Agency position on scientific issues to be considered by the Committee is an acceptable means for receiving specific feedback from experts in an open forum.

The assertion that "Weider was not given the opportunity to publish and post on the web its position on the state of the scientific evidence in support of its proposed claims" is not correct. The Committee was provided with varying points of view on the issues, including the petitioners'. The briefing materials provided to the Committee and posted on the Internet included: (1) the petitions from your client Weider Nutrition International, Inc. and from Rotta Pharmaceuticals, Inc. (represented by Martin Hahn); (2) petition summaries prepared by FDA; (3) three review articles (two of which were cited in the petitions); (4) questions for the Committee; and (5) the tentative conclusions document. The petition summaries prepared by FDA included the conclusions reached by the petitioners and provided a footnote to where in the petitions these conclusions are found. Moreover, the petitions, by definition, are the petitioner's summary of the state of the scientific evidence in support of its proposed claims. Each petitioner was also given ample time during the committee meeting to present its position to the Committee.

In your letter, you state that "The publication is an unacceptable exercise of FDA influence over the FAC panel and a conflict of interest for the agency. This is especially so because FDA selects the members of the FAC." As you know, in this instance the Agency asked you and Martin Hahn to suggest experts to serve on the Committee for this meeting. In fact, scientists recommended by both petitioners were appointed as expert voting consultants at the June 7-8 meeting. The Agency's willingness to consider scientists recommended by the petitioners as candidates to serve on the Committee as expert voting consultants is further evidence of FDA's commitment to ensuring full consideration of the issues at the Committee meeting.

The focus of the Committee meeting was to gather information and to receive advice and recommendations relating to very specific scientific issues on osteoarthritis. The Committee was not being asked to offer advice and recommendations as to the validity of

¹ See "Summary of FDA's Evaluation of APH(3')II Encoded by the *kan* Gene" Appendix 5, Tab 3 of Briefing Materials for the Food Advisory Committee, April 6-8, 1994

² See "Overview Document" Tab E of Briefing Materials for the Food Advisory Committee Special Working Group, Review of Olestra, November 14-16, 1995

³ See Briefing Information for the Nonprescription Drugs Advisory Committee and the Advisory Committee for Reproductive Health Drugs, December 16, 2003 (<http://www.fda.gov/ohrms/dockets/ac/03/briefing/4015b1.htm>)

Page 3 - Jonathan W. Emord, Esq.

the health claims under review. This was repeatedly pointed out to the Committee throughout the meeting. The purpose for providing the Committee with FDA's tentative views prior to the meeting was to focus the discussion in order to assist FDA to reach science-based final conclusions on the issues raised by the petitions. In the document's title and throughout the text of the document, FDA repeatedly identified its conclusions as tentative. The petitioners' conclusions, summarized in the petitions, were also given to the Committee prior to the meeting as part of the briefing materials, and the petitioners were allowed to make presentations during the Committee meeting. FDA will make a final decision on the petitions only after fully considering the information gathered at the meeting, along with the advice and recommendations of the Committee related to the questions asked.

Sincerely yours,

A handwritten signature in black ink, reading "Barbara Schneeman". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Barbara O. Schneeman, Ph.D.
Director
Office of Nutrition Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition