



PHARMAVITE

6 5 7 8 04 FEB 25 10:11

February 24, 2004

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Via Fax & Federal Express

Re: Docket No. 2003N-0496

Dear Sir or Madam:

In response to the Advance Notice of Proposed Rulemaking published in the November 25, 2003 Federal Register (68 FR 66040), Pharmavite LLC would like to communicate our comments. Pharmavite LLC is a major manufacturer and marketer of dietary supplements.

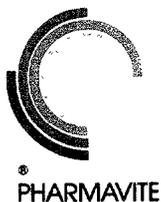
The FDA has specifically requested comment on three potential options for handling the approval and/or enforcement of use of health claims on foods (including supplements). We will address what we believe to be the strengths and weaknesses of each option.

Option 1 would formalize the Agency's current procedure for addressing applications for qualified health claims by codifying it through regulation. In our opinion, the current procedure is relatively straightforward, expeditious and flexible. Codifying it by regulation addresses the requirement of the Food, Drug and Cosmetic Act (21 U.S.C. 343(r)) that the procedure for authorizing health claims be in regulations promulgated by the Secretary, and option 1 would maintain the flexibility of the current system. The one disadvantage of establishing unified regulations under option 1, as opposed to the older practice of codifying each health claim review into a separate regulation, is that under the older system all health claims could be found in a single resource (21 CFR Part 101, Subpart E). The current letters of enforcement discretion can be found on the FDA website, although in some cases in various places. We strongly suggest the Agency establish a unified location on the website to publish the decisions arising from the review of qualified health claim applications.

Option 2 would treat petitions for qualified health claims in a manner similar to full health claims, i.e. through individual notice-and-comment rulemaking. The Agency notes this would require a reversal of the Agency's position that the "Significant Scientific Agreement" cited in the Act refers to the underlying nutrient/disease

**2003N-0496**

**C14**



Division of Dockets Management (HFA-305)  
Food and Drug Administration  
February 24, 2004  
Page 2

relationship rather than the wording of the claim. We believe the Agency recognizes, and we concur, that this option lacks the flexibility and responsiveness of option 1. We do not recommend its adoption. This recommendation notwithstanding, we do not see why not pursuing this option would preclude a reevaluation of the meaning of "Significant Scientific Agreement." We strongly urge the Agency to so modify their perspective, which has the added benefit of bringing the Agency's efforts in alignment with *Shalala v. Pearson*.

Option 3 would address manufacturer's use of health claims from strictly an enforcement perspective. The Agency has proposed reviewing health claims on marketed products, using the criteria that they may not be "false or misleading." We do not believe this is a viable option, either from a legal or practical standpoint. It lacks transparency, adequate stakeholder input, and economic parity in taking a strictly postmarketing approach. We urge the Agency to reject this option.

If you have any questions about our comments, please do not hesitate to contact us.

Sincerely,

David Kropp  
Director, Regulatory and Consumer Affairs

DK:ak\FDA\HC Proposal Response