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To FDA	From D. Kropp		
Co./Dept. Div. of Docket	Co. Pharmavite		
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July 7, 2004

Division of Dockets Management  
 Food and Drug Administration  
 5630 Fishers Lane  
 Room 1061  
 Rockville, MD 20852

FAX: 301-827-6870

Re: Docket Nos. 1994P-0390 and 1995P-0241

Dear Sir or Madam:

In the May 4, 2000 Federal Register (69 FR 24541) the Food and Drug Administration published a proposed rule; reopening of the comment period regarding several aspects of health claims and nutrient content claims in food labeling. Specifically, the FDA solicited comments in the following areas: (1) levels of qualifying nutrients in a product for eligibility to use a health claim on the labeling; (2) levels of disqualifying nutrients in a product for eligibility to use a health claim on the labeling; (3) use of "may" in health claims; (4) use of synonyms in nutrient content claims; and (5) use of abbreviated health claims.

Pharmavite hereby submits its comments on one or more of the above areas of interest. Pharmavite is a major manufacturer and distributor of dietary supplements in the United States.

With regard to areas (1) and (2), these areas are rarely of concern for dietary supplement products. For health claims that are limited to a single nutrient, such as calcium/osteoporosis, it is appropriate that there be minimum levels of the subject nutrient in the product in order to for the claim to have utility and meaning for the consumer. The general nature of dietary supplements makes it unlikely that disqualifying levels of nutrients are ever a factor, and we have no comments with respect to that issue.

Area (3) requested information on the use of "may" in health claims. We have extensive expertise in consumer perceptions and opinions, based on many years of involvement in consumer surveys. We have found, consistently and overwhelmingly, that consumers perceive "may" as an indication of uncertainty, not (as the FDA apparently intended) as

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an indication of multiple factors in a health claim. We strongly suggest a simply-worded alternative that explains the multiple-factor issue in place of use of "may."

Area (4) deals with the use of synonyms in place of defined terms in nutrient content claims. We believe English to be a rich and descriptive language, which unfortunately may lead to misunderstanding or misinterpretation. In a highly competitive market, manufacturers may rely on consumers' lack of sophistication or knowledge to make implications about their products that are otherwise unsupportable. One example is "natural." Unscrupulous manufacturers, particularly of botanical products, may use "natural" as an implied endorsement of the safety of their product, when the scientific data may not be fully supportive. We suggest that nutrient content claims, which describe specific nutritional aspects of foods, should continue to be described with defined terms only.

Lastly, area (5) requests information about abbreviated health claims. Based on our overall experience in consumer surveys, particularly with dietary supplements consumers do not tend to purchase products based on what they see on the front panel alone. Typically, if a consumer sees a claim of interest on the front panel, they will examine the entire label for additional information. Our research indicates that abbreviated health claims are entirely appropriate and useful to consumers, provided they include a statement referring to the location of the additional information necessary to fully understand the claim, and assuming that location is easily found and the entire claim is easily legible. This type of labeling has also long been useful for nutrient content claims as well.

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

Sincerely,



David Kropp  
Director, Regulatory Affairs  
Pharmavite LLC

DK\ak\FDA\Health & Nutrient Content Claims Issues