

Re: Docket No. 2005N-0097

Dear Sir or Madam:

In the March 30, 2005 Federal Register, the FDA published a Notice requesting comments on the proposed collection of information regarding consumer inferences on two qualified health claims (60 FR 16291). Specifically, FDA requested comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. Pharmavite LLC ("Pharmavite") wishes to comment on the above topics. Pharmavite is a major manufacturer and distributor of dietary supplements in the United States.

In regard to topic (1), Pharmavite believes it is entirely appropriate and necessary for FDA to seek to understand how the American consumer understands and interprets the labeling of foods (including dietary supplements) he or she consumes. This is particularly important as to statements relating the relationship between the nutrients in food and diseases because we believe Americans are turning more and more to consuming healthy foods (including dietary supplements) as a way to preserve and better their overall health and help prevent disease. Interpretation of health claim by consumers is particularly important in two areas: (a) the consumer's understanding of claims as to how beneficial nutrients may be in the prevention of disease, and (b) the consumer's understanding of claims as to the reliability of the scientific data supporting the claimed beneficial effects of nutrients. Both of these concepts must be accurately conveyed in a qualified health claim, and the specific wording of the claim is the primary means by which consumers make this interpretation. It is therefore essential for FDA to understand fully how various alternative wordings of these claims are interpreted by consumers.

With respect to topic (2), the Notice indicates the data will be collected through a voluntary internet panel of approximately 600,000 people, and the total burden of collection is based on FDA prior experience. Insufficient information is disclosed in the Notice to assess either the accuracy of the estimate of the burden or the validity of the methodology. We urge the agency to disclose the factual basis on which it believes that the burden of the proposed collection of information is not unreasonable and that the proposed methodology is valid and will produce reliable results to that the accuracy of the agency's estimates can be properly assessed.

Topic (3) addresses ways to enhance the quality, utility and clarity of the information to be collected. We have no comment on this topic other than to endorse the collection of data on a range of alternative wordings for the claims, to determine the differences perceived between these wordings by consumers. This will allow FDA to verify the most useful and effective manner to convey to consumers accurately the benefits of these health claims.

Finally, on topic (4) we believe electronic data collection through the internet as FDA intends to do in this case is an effective method that minimizes the burden of collection and has the ability to gather accurate, reliable data provided the methodology used is reliable and verifiable. We suggest FDA take steps to assure the methodology is in fact reliable and verifiable.

This concludes our comments. If you have any questions, please do not hesitate to contact us for clarification.

Sincerely,

David Kropp
Director, Regulatory Affairs
Pharmavite LLC