



Consumer Healthcare  
Products Association

6 July 2004

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

Re: FDA Docket Nos. 1994P-0390 and 1995P-0241 Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Reopening of the Comment Period. 69 Fed. Reg. 24541-24547 (4 May 2004)

Dear Sir/Madam:

The Consumer Healthcare Products Association (CHPA) is pleased to provide comments regarding the reopening of the comment period for Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims; Reopening of the Comment Period, 69 Fed. Reg. 24541-24547 (4 May 2004). CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of dietary supplements and over-the-counter drug products.

CHPA welcomes the opportunity to provide comments to this 1995 proposed rule on nutrient content and health claims and supports the Agency's efforts to facilitate the communication of truthful and non-misleading information to consumers about health claims on food and dietary supplements. CHPA previously submitted comments to the Advance Notice of Proposed Rulemaking for Food Labeling: Health Claims and Dietary Guidance (FDA Docket No. 2003N-0496).

The Agency requested comment on several aspects of the proposed regulation on nutrient content claims and health claims in order to provide additional flexibility in the use of these claims on food products.

I. Abbreviated Health Claims

FDA is interested in consumer research data or other information on consumer understanding of abbreviated health claims, whether abbreviated health claims would mislead consumers, and whether and how the discontinued use of the word "may" in health claims would affect the use of, or need for, abbreviated claims.

CHPA supports the NNFA petition to permit abbreviated health claims in which a clear statement of the ability of the substance to reduce the risk of a disease or health-related condition can be placed on the front of the package and any additional labeling requirements of the health claim can appear elsewhere on the label. We do not believe abbreviated health claims will mislead consumers as long as the statements are truthful and not misleading, and there is a prominent and immediate adjacent reference that refers consumers to additional labeling which fulfills the elements of the model language. We are not aware of any specific testing of abbreviated health claims, but our experience from OTC drug products teaches that the more simple and less complex the label statement, the easier it is for the consumer to comprehend the message. Therefore a simple statement such as “soluble fiber from [name soluble fiber source] reduces the risk of heart disease” which is followed by a statement such as “see additional important information on the back [or side] panel,” should be permitted on the principal display panel of the package.

CHPA also supports the Task Force on Consumer Health Information for Better Nutrition recommendation that FDA consider removing the requirements for use of the word “may” or “might” in unqualified health claims. As described in the FDA comments in the Federal Register announcement (69 Fed. Reg. 24544, 4 May 2004), the word “may” could have several meanings. One use could be to indicate the multifactorial nature of the disease in that the substance “may” reduce the risk of a disease or health-related condition, while another interpretation could be a reflection of the science supporting the claim. Thus, use of the same word with different meanings is likely to lead to consumer confusion, especially if consumers are trying to decide if the health claim represents an unqualified or qualified health claim. As stated above, a simple declaration of the association of the substance with the disease or health-related condition for an unqualified health claim will be the clearest to the consumer.

CHPA looks forward to continued cooperation with FDA in the development of a regulatory process for health claims. We welcome the opportunity to work with the Agency and other interested parties towards this end.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Douglas Ws. Bierer', with a long horizontal line extending to the right.

Douglas Ws. Bierer, Ph.D.  
Vice President, Regulatory & Scientific Affairs

DB/mm

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