



Advancing Quality Healthcare
Through Over-the-Counter Medicines
and Nutritional Supplements

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

January 13, 2004

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

Via Fax (301/827-6870)

Re: Docket No. 2003N-0496 – Food Labeling: Health Claims; Dietary Guidance.
68 Fed. Reg. 66040-66048 (November 25, 2003)

Dear Sir or Madam:

On behalf of member companies who manufacture and distribute dietary supplement products, the Consumer Healthcare Products Association (CHPA)¹ requests a 60-day extension of the comment period on the Advance Notice of Proposed Rulemaking for Food Labeling for Health Claims and Dietary Guidance.

This is the first time the Food and Drug Administration has published for a rulemaking its perspectives on regulatory alternatives for qualified health claims. Specifically, the Agency has proposed three regulatory options and has asked for comments on the strengths and weaknesses of each option and whether there may be other options for regulating qualified health claims. Given the complexity and implications of the proposed options, we need additional time in order to adequately assess the implications of each of the proposed regulatory alternatives. The Agency also asked for perspective on many issues raised by the Task Force on Consumer Health Information for Better Nutrition. This will also require more than the 60 days to adequately address and to provide the Agency with our most thoughtful and helpful perspectives.

Therefore, due to the breadth and extent of the comments requested by the Agency, we request that comments on the Advance Notice of Proposed Rulemaking for Food Labeling for Health Claims and Dietary Guidance be accepted up to 26 March 2004, rather than the current due date of 26 January 2004.

¹ CHPA, founded in 1881, is the national trade associating representing manufacturers and distributors of dietary supplements and OTC drugs.

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The Dietary Supplement Manufacturers appreciate FDA's consideration of our request for adequate additional time to provide constructive comments and useful perspective for this proposed rulemaking.

Sincerely,



Douglas W. Bierer, Ph.D.
Vice President, Regulatory and Scientific Affairs

cc: Paulette Gaynor (HFS-800)

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