



Consumer Healthcare
Products Association

November 1, 2004

Leila G. Saldanha, Ph.D.
Department of Health and Human Services
c/o Office of Dietary Supplements
6100 Executive Boulevard
Room 3B01, MSC 7517
Bethesda, MD 20892-7517

Re: Solicitation of Written Comments on Proposed Definition of Bioactive Food
Components. 69 Fed. Reg. 55821-55822 (16 September 2004)

Dear Dr. Saldanha:

The Consumer Healthcare Products Association (CHPA) appreciates the opportunity to provide comments on the proposed definition of bioactive food components (69 Fed. Reg. 55821-55822, September 16, 2004). CHPA, founded in 1881, is a national trade association representing manufacturers and distributors of dietary supplements and over-the-counter drug products.

The Office of Disease Prevention and Health Promotion, Office of Public Health and Science, Department of Health and Human Services, acting on behalf of an ad hoc Federal working group, requested comments on the proposed definition of bioactive food components. Without a better understanding of how the use of this definition will be applied, CHPA member companies with dietary supplement products are unable to provide meaningful comments on the proposed definition. We request clarification about how this definition will be used and an appropriate extension of the comment period subsequent to the receipt of this necessary information.

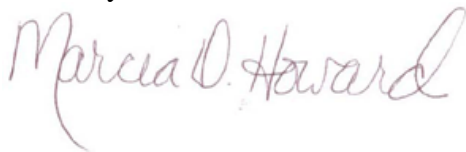
Additionally, any substance under this definition, whether it is water or lycopene, could be considered "bioactive." Thus, CHPA considers the term "bioactive" too broad and all-encompassing and therefore vague. Use of a single term may not be appropriate for what the working group is trying to accomplish. Rather than constructing a new or special definition for the word "bioactive," which could apply broadly to situations not intended by the Federal working group, the group should explain the concept based on its intended use. Instead of defining which compounds are or are not "bioactive," the group should specify the types or categories of compounds or food components that are of interest, perhaps by providing a more descriptive statement, such as food components, including essential nutrients, that may promote health and/or prevent disease. Essential nutrients should be included in any expository definitions developed.

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If the group were to reject our suggestions and decide to use the proposed definition, CHPA would support the inclusion of synthetically derived components used in fortified food and dietary supplements under that definition. We see no obvious reason to exclude synthetically derived components from this descriptive statement.

CHPA looks forward to continued cooperation with the Department of Health and Human Services in the clarification and use of the term "bioactive." We welcome the opportunity to work with HHS and other interested parties towards this end. Thank you for considering our views.

Sincerely,

A handwritten signature in cursive script, reading "Marcia D. Howard". The ink is a reddish-brown color. The signature is written in a fluid, connected style.

Marcia D. Howard, Ph.D.
Associate Director of Scientific Affairs