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LONDON

787 SEVENTH AVENUE
NEW YORK, NEW YORK 10019
TELEPHONE 212 839 5300
FACSIMILE 212 839 5599
www.sidley.com

FOUNDED 1866

LOS ANGELES
NEW YORK
SAN FRANCISCO
SHANGHAI
SINGAPORE
TOKYO
WASHINGTON, D.C.

WRITER'S DIRECT NUMBER
(212) 839-5613

WRITER'S E-MAIL ADDRESS
sbass@sidley.com

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Leila G. Saldanha
Dept. of Health and Human Services
Office of Dietary Supplements
6100 Executive Blvd.
Rm. 3B01, MSC 7517
Bethesda, MD 20892

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

To Whom It May Concern:

The National Nutritional Foods Association ("NNFA") is submitting these comments to the Department of Health and Human Services ("HHS") Office of Dietary Supplements in response to the September 16, 2004 publication of its "Solicitation of Written Comments on Proposed Definition of Bioactive Food Components," published at 69 Fed. Reg. 55821 (2004).

NNFA is a trade association representing the interests of more than 8,000 retailers, manufacturers, suppliers, and distributors of foods, dietary supplements, and other natural products throughout the United States. NNFA appreciates the efforts of the HHS Office of Dietary Supplements to use the best science available as it explores the meaning of "bioactive food component." At the same time, NNFA urges HHS to carefully consider the broader policy implications of any definition that is adopted.

The Food and Drug Administration ("FDA") already administers statutes and regulations that regulate "new dietary ingredients." The term "new dietary ingredient" is not defined in any existing statutory or regulatory law; nevertheless, it is generally understood to apply to the ingredients in dietary supplements that arguably provide some health benefit to the body. In this sense, the term potentially overlaps with "bioactive food component."

FDA is holding a public hearing on November 15, 2004 to take comment on issues relating to "new dietary ingredients," including how to determine whether such

an ingredient falls within the dietary supplement definition and whether synthetic substances should be considered "new dietary ingredients."

The dietary supplement industry has long suffered from a lack of clarity in the definition of "new dietary ingredient" and hopes the FDA initiative will help remedy this situation. NNFA urges HHS to work closely with the agency to ensure that any definition developed does not compound the confusion that already surrounds this aspect of the dietary supplement regulatory environment.

I. Specific Responses to Questions Raised in the Federal Register

A. What Categories/Classes of Compounds Should or Should Not be Considered as Bioactive Food Components

NNFA believes that there should not be limitations on the categories of compounds that may be considered as bioactive food components. A broad array of scientific research has established that a wide variety of ingredients can have positive health impacts.

Based on this research, NNFA recommends that ingredients from all of the following categories be considered as potentially within the definition of "bioactive food component:"

- Amino acids and peptides
- Fats and Oils
- Botanicals
- Biochemicals (e.g., Inositol, Coenzyme Q10)
- Enzymes
- Probiotics and Single Cell Products (e.g., yeast powder)
- Minerals and Trace Elements; and
- Vitamins

NNFA takes the position that constituents of these categories should also be considered bioactive food components. This approach comports with science showing that constituents have health benefits and is also consistent with the definition of "dietary supplement" contained in the Dietary Supplement Health and Education Act of 1994 ("DSHEA").[1]

[1] DSHEA defines "dietary supplement" in 21 U.S.C. § 321(ff)(1) as:
a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake;

B. Should Essential Nutrients be Included as Bioactive Food Components?

NNFA takes the position that essential nutrients should be included in the definition of bioactive food components. An extensive body of literature on the health benefits stemming from essential nutrients already exists, and therefore there is no reason to exclude such compounds from a definition.

Moreover, it is important to continue supporting research of these essential nutrients. Scientists have repeatedly uncovered new health benefits from well known ingredients. For example, it is only in recent years that the functionality of the essential nutrient magnesium in the body has become better understood.

To the extent that the HHS definition of "bioactive food component" may be used as a guide to further research or research funding, there is no reason to leave any known substance that benefits human health out of the definition.

C. Should Synthetically Derived Components Used In Fortified Foods And Dietary Supplements Be Considered Under This Definition?

NNFA feels strongly that synthetically derived components should also fall within the definition of "bioactive food component" to the extent that such components are substantially equivalent to their natural counterparts.

In the GRAS context, FDA has long acknowledged that an ingredient that is "substantially equivalent" to a GRAS ingredient should itself also be GRAS, as long as it meets requisite safety parameters. 62 Fed. Reg. 18945. Thus, FDA states:

> [I]n the case of a chemically synthesized substance that is structurally identical to a naturally occurring substance in commonly consumed food, compositional differences between the synthesized and naturally occurring substance may include the presence of any residues of potentially harmful chemicals carried over to the synthetic substance from the manufacturing process. 62 Fed. Reg. 18946.

Synthetic bioactive food components that meet this substantial equivalence standard should similarly be included in the definition of bioactive food components. NNFA believes that greater availability of substances that have positive health benefits will help increase the overall health profile of Americans.

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or (F) a concentrate, metabolite, **constituent**, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E). (emphasis added).

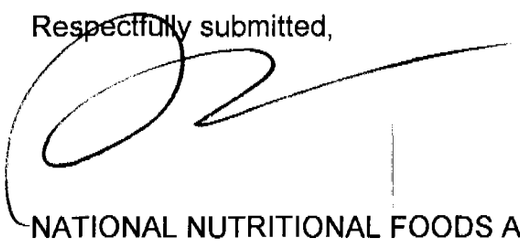
Further FDA already has regulations in place to ensure that ingredients used in conventional foods and dietary supplements meet requisite safety standards. Ingredients added to conventional foods must either be approved food additives or GRAS. 21 C.F.R. Part 170. Dietary ingredients used in dietary supplements that were not present on the market as of October 15, 1994 must be the subject of a safety submission to FDA under 21 U.S.C. §350b. Given the existence of these safeguards, NNFA takes the position that the HHS definition does not need to specifically exclude ingredients on safety grounds.

II. Conclusion

In conclusion, NNFA urges HHS to develop a wide definition of "bioactive food component" that includes all ingredients that have the potential to benefit human health. NNFA takes the position that only such an approach will ensure that all of these ingredients are adequately researched and examined and that the greatest benefit will flow to the American public.

NNFA appreciates the opportunity to comment on the proposed definition of "bioactive food component" and looks forward to further communications with HHS' Office of Dietary Supplements on this issue.

Respectfully submitted,



NATIONAL NUTRITIONAL FOODS ASSOCIATION
Paul Bennett, President
David Seckman, Executive Director

Scott Bass
General Counsel
SIDLEY AUSTIN BROWN & WOOD LLP
1501 K. Street, N.W.
Washington, D.C. 20005