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May 9, 2002

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

Re: Docket No. 02N-0062

To Whom It May Concern:

The National Nutritional Foods Association ("NNFA") is submitting these comments to the Food and Drug Administration ("FDA") in response to the March 19, 2002 Notice "Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification for a New Dietary Ingredient."

NNFA is a trade association representing the interests of more than 3,000 retailers and 1,000 manufacturers, suppliers and distributors of natural foods, dietary supplements and other natural products throughout the United States. NNFA has consistently supported FDA's ability and efforts to enforce the Dietary Supplement Health and Education Act of 1994 ("DSHEA") and to ensure that dietary supplements continue to be safe.

NNFA appreciates FDA's solicitation of comments on ways to enhance the quality, utility and clarity of the Premarket Notification Requirement for a New Dietary Ingredient under section 413 of the Federal Food, Drug and Cosmetic Act ("FFDCA"). We believe FDA can use this opportunity to provide the industry with much needed guidance on new dietary ingredient submissions.

NNFA believes that as written, section 413 of the FFDCA is unclear both as to: (1) when a New Dietary Ingredient notification is required; and (2) the type of information to be included. NNFA urges FDA to issue a guidance clarifying the agency's interpretation of section 413.

Specifically, FDA should address the issues of:

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- Whether, and under what conditions, a dietary ingredient that is a component of food (i.e. lycopene in tomatoes) would be exempt from the 413(a)(2) notification requirement, as outlined by section 413(a)(1);

- The quantity and quality of information that would be considered to satisfy the "history of use or other evidence of safety" standard articulated in section 413(a)(2) of the FFDCA; and

- The type of evidence needed to establish that an ingredient was "marketed in the United States before October 15, 1994" under section 413(c).

NNFA would also like to comment that it believes that FDA must continue collecting notifications of new dietary ingredients under Section 413(a)(2) of the FFDCA, as implemented by 21 C.F.R. §190.6.[1] In fact, section 413(a)(2) of the FFDCA mandates that such notifications be submitted. Any change would need to be achieved by a statutory modification.

Section 413(a)(2) of the FFDCA is an important part of FDA's monitoring of the dietary supplement industry under DSHEA. The submission of notifications protects consumers from unsafe dietary supplements and ensures that manufacturers and distributors are complying with the safety standards of the FFDCA. Moreover, the information gives the agency a clear monitoring role for dietary supplements and helps silence critics who claim that there is no federal oversight of dietary supplement safety.

The section is not burdensome, and involves no more than sharing safety information with the agency that a company in compliance with the FFDCA should have on file.

NNFA appreciates the opportunity to submit these comments.

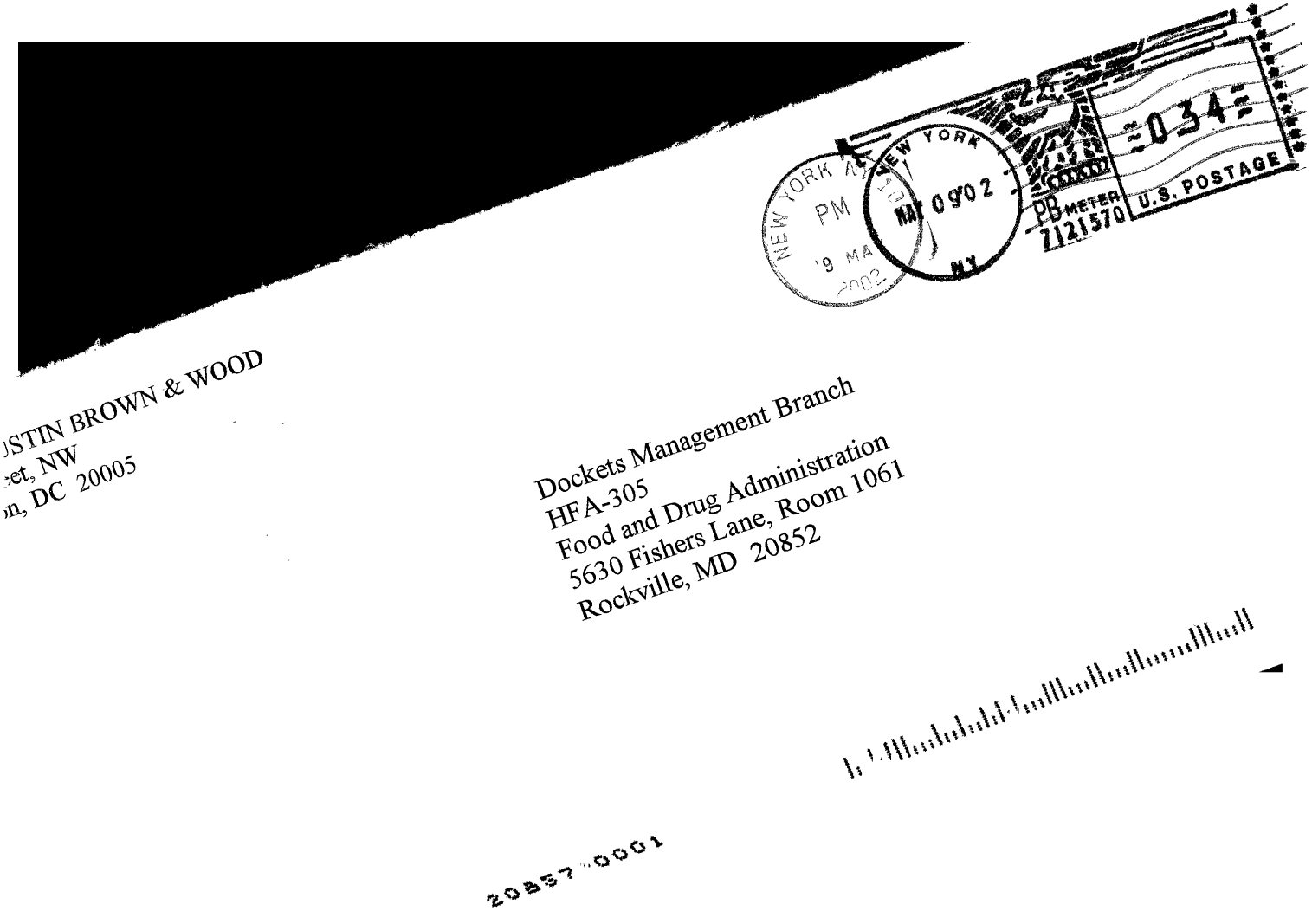
Respectfully submitted,

NATIONAL NUTRITIONAL FOODS ASSOCIATION
Mark Stowe, President
David Seckman, Executive Director

SIDLEY AUSTIN BROWN & WOOD
General Counsel

By_____
J. Scott Bass

[1]Section 413(a) of the FFDCA provides that a manufacturer or distributor of a "new dietary ingredient," as defined by §413(c), is to submit information to FDA upon which it has based its conclusion that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe. This submission is required at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient.



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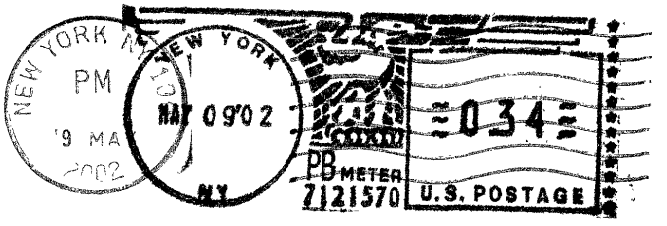

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