

Docket No. 2004N-0454

BEFORE  
THE UNITED STATES OF AMERICA  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

REQUEST FOR EXTENSION OF COMMENT PERIOD  
BY THE

AMERICAN HERBAL PRODUCTS ASSOCIATION  
CONSUMER HEALTHCARE PRODUCTS ASSOCIATION  
COUNCIL FOR RESPONSIBLE NUTRITION  
NATIONAL NUTRITIONAL FOODS ASSOCIATION  
UTAH NATURAL PRODUCTS ALLIANCE

ON THE OCTOBER 20, 2004 NOTICE ON  
PREMARKET NOTIFICATIONS FOR NEW DIETARY INGREDIENTS

November 3, 2004

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## **REQUEST FOR EXTENSION OF COMMENT PERIOD**

Pursuant to 21 CFR Secs. 10.35 and 10.40(b)(3) the undersigned trade associations of the dietary supplement industry – the American Herbal Products Association, the Consumer Healthcare Products Association, the Council for Responsible Nutrition, the National Nutritional Foods Association and the Utah Natural Products Alliance – request an extension of time to and including February 1, 2005 within which to submit comments upon the Notice regarding the Agency's premarket notification program for new dietary ingredients.

## **NOTICE INVOLVED AND ACTION REQUESTED**

The Notice regarding the Agency's premarket notification program for new dietary ingredients was published in the Federal Register on October 20, 2004 (69 Fed. Reg. 61680). This is a request for an extension to and including February 1, 2005 within which to file comments on the Notice.

## **STATEMENT OF GROUNDS**

The American Herbal Products Association ("AHPA") is comprised of companies doing business as growers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs.

The Consumer Healthcare Products Association ("CHPA"), founded in 1881, is committed to promoting the increasingly vital role of over-the-counter medicines and nutritional supplements in America's healthcare system through science, education, and advocacy. CHPA represents manufacturers and distributors of over-the-counter drugs products and dietary supplements.

The Council for Responsible Nutrition ("CRN"), founded in 1973, is comprised of companies that manufacture and market ingredients for dietary supplements and dietary supplements.

The National Nutritional Foods Association (“NNFA”) was founded in 1936 and represents the interests of some 3000 retailers and 1000 manufacturers, suppliers and distributors of natural products, including health foods, dietary supplements, and cosmetics.

The Utah Natural Products Alliance (“UNPA”) was organized in 1991 and represents the interests of the \$3 billion dietary supplement industry based in Utah.

The members of these trade associations represent the majority of the manufacturers, distributors and retailers of dietary supplements that will be required to conduct their businesses in accordance with the Notice for which an extension of time to comment is requested.

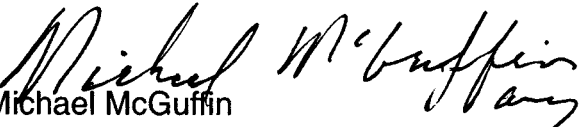
Each of the trade associations making this request for an extension of time within which to file comments on the Notice has examined the Notice and discussed it with members. It is clear that the detail of the Notice, the need to examine carefully the information contained in the Notice, and the impact of the Notice on members will require more than the 45 days that FDA has provided for comments. In particular, this Notice needs to be assessed in the context of the many small businesses that will be subject to it. In addition, members will need time to review the transcript from the November 15, 2004 Premarket Notification for New Dietary Ingredients Notifications public meeting. Given that comments are now due on December 3<sup>rd</sup>, it is unlikely the transcript from this meeting will be publicly available before comments are due.

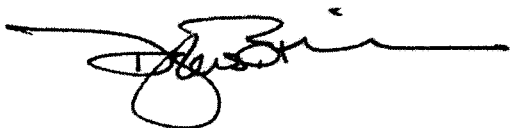
The importance of comments to this Notice is highlighted by the Notice itself. That Notice contains 27 specific questions (for which there are subparts), many of which will require extended industry discussion. In view of FDA's specific request for comments on the Notice, these associations will need more time to obtain and to sort out opinions and responses from member companies.


The public interest will not be disserved by allowing the additional time requested for comment upon this Notice. Allowing an additional 60 days over and above the 45 days proposed for comments in the Federal Register on October 20, 2004 will provide time for the affected industry to submit more focused and


detailed comments. Presently, these associations intend to meet with their members to encourage and assure input and to endeavor to reach consensus on issues of concern.


Respectfully submitted,

  
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