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April 21, 2003

Hand Delivered

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Dear Sir/Madam:

Enclosed herewith for filing are an original and three copies of The American Herbal Products Association's, National Nutritional Foods Association's and Utah Natural Product's Alliance's Request for Extension of the Comment Period on the Proposed Rules for Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Deitary Ingredients and Dietay Supplements Proposed Pursuant to Section 9 of DSHEA.

Thank you for your assistance.

Sincerely,

Anthony L. Young

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Enclosures

96N-0417

EXT 5

Docket No. 96N-0417

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

NATIONAL NUTRITIONAL FOODS ASSOCIATION

UTAH NATURAL PRODUCTS ALLIANCE

ON THE PROPOSED RULES FOR

CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS

PROPOSED PURSUANT TO

Section 9 of the Dietary Supplement Health and Education of 1994

(21 U.S.C. Sec. 342(g))

April 21, 2003

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 National Nutritional Foods Association and the Utah Natural Products Alliance – request an extension of time to and including August 11, 2003 within which to submit comments upon the proposed rules regarding Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements.

PROPOSAL INVOLVED AND ACTION REQUESTED

The proposed rules regarding Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements were published in the Federal Register on March 13, 2003. 68 Fed. Reg. 12157. This is a request for an extension to and including August 11, 2003 within which to file comments on the proposal.

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 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 implement the proposed rules for which an extension of time to comment is requested.

The Dietary Supplement Health and Education Act ("DSHEA") was signed into law on October 25, 1994. Before DSHEA's enactment and shortly thereafter, the trade associations represented here and others drafted and circulated among their members CGMP regulations for dietary supplements. On November 20, 1995 these associations and one other submitted this draft to the FDA for consideration as a starting point for the regulations presently proposed. FDA published the industry draft in the Federal Register of February 6, 1997 (62. Fed. Reg. 5700) and held various outreach meetings to discuss and to receive input on CGMP for dietary supplements from consumers and industry. FDA addressed CGMP for dietary supplements in its Food Advisory Committee and in dietary supplement strategic plan meetings. These trade associations and their members have been active participants in all of these FDA activities. In addition, these associations have urged relevant Congressional committees to support and encourage FDA to publish a proposal for CGMP for dietary supplements so that the process leading to promulgation and implementation of final regulations could be initiated.

Each of the trade associations making this request for a sixty day extension of time within which to file comments on the proposed rule has examined the proposal and discussed it with members. It has become clear from this examination and the discussion with members that the detail of these proposed regulations and the need to examine carefully their requirements and impact on members will require more than the ninety days that FDA has provided for comments because this proposal differs from the

1995 industry draft in significant respects. In particular, these regulations need to be assessed in the context of the many small businesses that will be subject to their requirements. These associations and their members need to assess whether FDA's proposal to address the impact on small businesses by providing two additional years for compliance adequately addresses the situation faced by these entities.

The importance of comments to this proposal is highlighted in FDA's proposal preamble. That preamble contains 86 specific requests for comments, many of which will require extended industry discussion. In view of FDA's specific request for comments on particular provisions, these associations will need more time to obtain and to sort out opinions and responses from member companies. In addition, the application of these proposed CGMP regulations to foreign manufacturers means that these associations must reach out to those manufacturers for comment.

The public interest will not be disserved by allowing an additional 60 days for comment upon this proposal. Allowing the effected industry five months to comment instead of three will provide time for the industry to provide 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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