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Via Electronic Transmission and Federal Express

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

Re: FDA Docket No. 96N-0417, Proposed Rule: Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements

Dear Sir or Madam:

The Enzyme Technical Association ("ETA") respectfully submits these initial comments with regard to the Food and Drug Administration's ("FDA") proposed rule entitled, "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements" ("proposed rule") which was published in the Federal Register on March 13, 2003. 68 Fed. Reg. 12158. ETA is a trade association of companies that represent manufacturers and distributors of enzyme preparations in the United States, Canada, and Mexico. ETA has been in existence since 1970 and has taken an active role in assisting in the development of regulations and policies that affect the enzyme industry. Its membership represents a majority of the North American enzyme industry.

Enzymes are proteins with highly specialized catalytic functions. They are responsible for all metabolic processes. Although like all other proteins, enzymes are composed of amino acids, they differ in function in that they have the unique ability to facilitate biochemical reactions without undergoing change themselves. As a result, enzymes are highly efficient catalysts in biochemical reactions, that is, they help a chemical reaction take place quickly and efficiently. Enzymes play a diversified role in many aspects of every day life, the most salient for purposes of these comments are their role in the production of food and dietary supplements and as a dietary ingredient that facilitates digestion.

Because enzymes may be incorporated in dietary supplement products, ETA is interested in the terms and scope of the proposed rule. ETA commends FDA on this effort to ensure consumers' access to safe dietary supplements and supports this goal. However, to provide comments on the "depth and breadth of what should be considered by the agency in developing a final rule," as FDA requests in the preamble to its proposed rule at 68 Fed. Reg. 12161, ETA respectfully requests that the comment period be extended by three months.

I. Action Requested

Because the proposed rule is over 105 pages and imposes substantial requirements on the dietary supplement industry relative to the manufacture of final supplement products and the incorporation of dietary supplement ingredients, ETA respectfully requests that the period for comment be extended to September 11, 2003, 90 days beyond the originally proposed date of June 11, 2003, to provide industry sufficient time to review the proposed rule and prior administrative record on dietary supplement current good manufacturing practice ("CGMP") regulations.

II. Discussion

In issuing the proposed rule on dietary supplement CGMPs, FDA has asked for comments on a number of aspects of the proposed rule. Among others, FDA specifically asked for comments on:

> "The depth and breadth of what should be considered by the agency in developing the final rule."
>
> "Whether each of the proposed provisions are necessary to ensure the safety and quality of dietary ingredients and dietary supplements and whether they are adequate to protect the public health."
>
> "Whether there are certain provisions that are not proposed but that may be necessary."
>
> "Whether the gains to consumers in product safety and quality are warranted."
>
> "Whether there is any reason to apply different requirements, including greater or lesser requirements on small firms as compared to larger firms and the rationale for doing so."

68 Fed. Reg. at 12161. FDA has also requested "supporting data where appropriate." Id.

ETA believes these items and others are important factors to be considered when developing final CGMP regulations. However, ETA is concerned that FDA has not provided industry and other interested parties sufficient time in which to prepare and submit comments to the proposed rule given its length and the complexity of issues surrounding dietary supplement CGMP regulations.

A. Length of Proposed Rule

FDA's proposed rule on dietary supplement CGMPs is over 100 pages. It includes 12 pages of proposed regulations, 61 pages of preamble discussion on the background to the proposed rule and its specific provisions, and 31 pages of analysis of the economic implications of the proposed rule. Based on the mere size of this document, ETA believes that additional time is necessary for interested parties to thoroughly review, analyze, and prepare substantive comments to the proposed rule.

B. Complexity of Issues and Administrative Record

FDA has been examining the question of dietary supplements CGMP regulations since the passage of the Dietary Supplement Health and Education Act ("DSHEA") in 1994. In preparing the proposed rule, FDA "considered public comment in response to the ANPRM [advance notice of proposed rulemaking] and to public meetings, observations at site visits to dietary supplement manufacturers, and advisory group reports." 68 Fed. Reg. at 12161. Because the proposed rule has such a long administrative history and requires a complex analysis of the proposed rule's scope, impact, and specific requirements, ETA questions whether substantive comments can be provided within the current comment period of three months.

The complexity of issues surrounding dietary supplement CGMP regulations must be clear to FDA when one considers the length of time and amount of resources FDA has already dedicated to this matter between October 25, 1994, the date DSHEA was signed into law, and March 13, 2003, the date the proposed rule was issued. While DSHEA specifically allows FDA to prescribe good manufacturing practices for dietary supplements, the agency did not issue an advance notice of proposed rulemaking until February 1997. 62 Fed. Reg. 5700 (Feb. 6, 1997). This advance notice was issued a year and a half after the agency received an outline for CGMP regulations from representatives of the dietary supplement industry in November 1995. According to the preamble discussion in both the advance notice and the proposed rule, FDA considered the industry outline to be a "useful starting point" and identified other issues for discussion that were not included in the outline.

Almost eight years have passed since the industry outline was submitted to FDA and over six years have passed since FDA issued its advance notice of proposed rulemaking. Given this time line and the clear complexity of issues and regulatory impact, ETA believes more than three months are necessary to provide comments to the proposed rule. Not only does a 105 page document need to be reviewed and "supporting data" generated, but the substance of the proposed rule needs to be compared to the intent of DSHEA, the industry outline reprinted in the advance notice, and the comments that have been generated since 1997 through submissions to FDA and public meetings. Additional issues may also be raised as a result of the public meetings to discuss the proposed rule scheduled for April 29 and May 6, 2003.

III. Conclusion

Based on the length of the proposed rule and the complexity of issues and administrative record, ETA sincerely questions whether comprehensive and cogent comments to the proposed rule can be provided within the limited time frame of three months. For this reason, ETA respectfully requests that FDA extend the comment period by 90 days to September 11, 2003.

ETA appreciates the opportunity to provide its initial comments on the proposed rule on dietary supplement CGMP requirements and welcomes any questions FDA may have on this request.

Sincerely,

Alice Caddow

Alice Caddow, Chair
ETA