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NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION

*Better Health Through Responsible Self-Medication*



April 7, 1997

Dr. Robert J. Moore
Center for Food Safety and Applied Nutrition (HFS-456)
Food and Drug Administration
200 C St., SW
Washington, DC 20204

**RE: Docket No. 96N-0417 -- Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements**

Dear Dr. Moore;

I am writing regarding FDA's advance notice of proposed rulemaking for Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements published in the *Federal Register* on February 6, 1997. Comments are due on the proposal by May 7, 1997. I am writing on behalf of the NDMA Vitamin/Mineral Task Group to request a ninety day extension of the comment period.

Our Task Group has been evaluating the proposal which includes industry proposed GMPs for dietary supplements. In addition to the industry proposal, FDA requests comments on eight issues related to GMPs for dietary supplements. NDMA intends to provide FDA with comments on these points. However, a response to the point raised by FDA on the appropriateness of the principles of Hazard Analysis and Critical Control Points (HACCP) to dietary supplements, requires education of dietary supplement manufacturers on HACCP.

While HACCP has been around for many years for the food industry, it is a concept unfamiliar to the drug industry. NDMA members marketing dietary supplements are also drug products manufacturers and hence are not necessarily familiar with HACCP. As we have been considering responses to FDA's request for information, it has become evident that more time is needed to fully understand HACCP and its implications to the dietary supplement industry. At this point in time, we do not know enough to make an informed decision regarding the appropriateness of HACCP for dietary supplements and to provide the agency with a reasonable rationale for our conclusions. It is our hope that the agency will provide additional time to enable us to achieve this goal.

Given that HACCP is new to the dietary supplement industry, I trust FDA will carefully consider the

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request for the extension of the comment period. The extension will allow for the formulation of useful comments on an issue with far reaching implications for members of the diverse dietary supplement industry.

Thank you for your consideration.

Sincerely,

Patrice Wright

Patrice B. Wright, Ph.D.
Director, Pharmacology & Toxicology

cc: Dockets Management Branch
Dr. Elizabeth Yetley

*EXTLET.REQ*