



September 10, 2004

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

**Re: Docket No. 2004N-0230: Current Good Manufacturing Practice Regulations**

To Whom It May Concern:

The National Nutritional Foods Association (“NNFA”) is submitting these brief comments to the Food and Drug Administration (“FDA”) in response to the May 21, 2004 Notice “Food; Current Good Manufacturing Practice Regulations; Public Meetings,” 69 Fed. Reg. 29220 (May 21, 2004).

NNFA is a trade association representing the interests of more than 8,000 retailers, manufacturers, suppliers, and distributors of foods, dietary supplements, and other natural products throughout the United States. NNFA appreciates the opportunity to comment on the questions posed by FDA and applauds FDA’s ongoing efforts to guard the safety of the food supply.

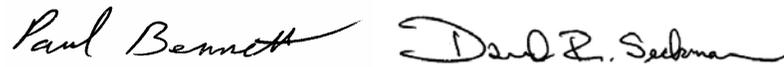
NNFA has always supported the use of Good Manufacturing Practices (“GMPs”) as an effective tool for ensuring the safety of foods and dietary supplements. In fact, on the dietary supplement front, NNFA had developed strong GMPs for use by its members well before FDA issued its own proposed GMPs. The NNFA dietary supplement GMPs serve as a model for the industry even to the current day.

In the food arena, NNFA urges FDA to review and update the GMPs to allow the implementation of new and/or emerging technologies. Competition demands the use of such technology and manufacturers need to address the safety of foods produced using new and/or emerging technologies. Specifically, NNFA suggests that the agency adopt a risk-based assessment approach for food GMPs. Such an approach would encourage manufacturers to identify potential risk-based control points in the manufacturing and packaging processes, and to establish critical limits to monitor and control these risks.

This kind of model has already been embraced by companies in specific food industries. It is likely that mandatory use of such an approach more broadly in food manufacturing could significantly reduce hazards in all three of the areas – physical, chemical and biological – identified by FDA. Toward this end, NNFA suggests that FDA explore the adoption of a risk minimization approach for food GMPs.

NNFA appreciates the opportunity to comment on this rulemaking.

Respectfully submitted,

Handwritten signatures of Paul Bennett and David R. Seckman.

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