



National Nutritional Foods Association

August 7, 2003

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

RE: Docket No. 96N-0417

1463 '03 AUG -7 P1:12

Dear Sir or Madam,

The National Nutritional Foods Association (NNFA) submits the following comments regarding Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements, Docket No. 96N-0417. NNFA is the oldest and largest, non-profit trade organization dedicated to protecting and advancing the natural products industry. Our 5,000 members include retailers, manufacturers and distributors of health food products, dietary supplements, and natural cosmetics.

FDA's proposal represents a significant amount of careful thinking and we appreciate having a document worthy of serious debate. Current good manufacturing practices (cGMP) rules for dietary supplements are vital to the dietary supplement industry to fully implement the Dietary Supplement Health and Education Act of 1994 (DSHEA) (21 U.S.C. section 342(g)) and provide uniform standards for the supplement industry to produce safe and accurately labeled dietary supplement products. Our customers are entitled to consistent high quality products.

NNFA has long supported and encouraged the publication, adoption and implementation of cGMPs that are fair and appropriate for the industry. In developing these comments NNFA solicited information, held meetings and surveyed the industry about FDA's proposal. We took very seriously our responsibility to base our arguments on "real life" scenarios, data gleaned from our members during an extensive review process, and expertise as a result of operating the first dietary supplement cGMP program in the industry.

We look forward to working with FDA to address issues raised in our comments below and ultimately to assist our membership in implementing the final rule.

Sincerely,

David Seckman
David Seckman
CEO/Executive Director

Paul Bennett
Paul Bennett
President

cc: I. Scott Bass, Esq., Sidley Austin Brown & Wood LLP
Daron Watts, Esq., Sidley Austin Brown & Wood LLP

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National Nutritional Foods Association
1220 19th Street, N.W., Suite 400
Washington, DC 20036
(202) 223-0250

Comments Regarding the Food and Drug Administration's Proposed Rule

On

Current Good Manufacturing Practice in Manufacturing, Packing, or Holding
Dietary Ingredients and Dietary Supplements; Proposed Rule;
68 Fed. Reg. 12158 (Proposed March 13, 2003)

Docket No. 96N-0417

August 7, 2003

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