Madis Botanicals, Inc.
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MADIS BOTANICALS

May 7, 1997

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857

Dear Sirs:

In response to the FDA Advance Notice Of Current Good Manufacturing Practice Regulations (CGMP) for Dietary Supplements dated February 6, 1997 as published in the Federal Register, and the subsequent call for comments, we have the following statements and comments:

Madis Botanicals, Inc. ("Madis") has been a small manufacturer of botanical extracts and derivatives since 1959 and operates under FDA Registration Number 22-10504, NDC Labeler Code 045442. Currently Madis' complies with CGMP's for Bulk Pharmaceutical Drugs. Madis has evolved over the years to where we currently are committed to providing the Dietary Supplement Industry with the highest quality botanical derivatives and standardized extracts. Madis welcomed the NNFA proposed CGMP's for the Dietary Supplement Industry in 1995. After careful review of the proposals and considering that Madis is a manufacturer of ingredients as opposed to finished consumer products, we implemented, in late 1996 the proposed CGMP's. These CGMP's are currently in effect and supplement the existing Bulk Pharmaceutical regulations.

Madis has believed in the need for the standardization of day to day operations of industry practices, especially with respect to raw material and finished product quality. The following procedures which Madis has adopted should be adopted as industry standard.

1. Written procedures for cleaning, documentation of cleaning and validation of cleaning with batch to batch documentation should be mandatory.

2. The Seller shall perform or have performed the analysis for raw materials and finished goods. A so-called "Transcript of Record" from a supplier should not be a sufficient indication of product quality. A Certificate of Analysis that is issued should reflect the analysis performed by the issuer ("seller").

3. In analyzing raw materials and finished products, a minimum test requirement should be performed to assure product identity, quality, purity and strength.

4. The FDA requirement for mandatory water testing for pharmaceutical product manufacture should be included in the GMP's.

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5. The FDA requirement for validation of analytical instrumentation utilized in assaying active ingredients should apply to the manufacture of dietary supplement ingredients. Currently instrumental validation applies only to equipment being used to assay U.S.P./N.F. products.

6. Continuing education of production and laboratory personnel should be mandatory.

7. Although the implementation of the proposed CGMP's will be costly to the members of the industry, we feel that this expense is justified and necessary to assure consumer product quality and safety.

8. Currently Defect Action Levels are virtually non-existent for botanicals. Since these raw materials are products of nature, arbitrary levels would not be realistic. We propose a joint Industry/FDA committee to establish these levels.

9. The question of Botanical Identity is relatively straightforward. Thin Layer Chromatography is a valuable tool to establish and verify the botanical substance. Current technology, i.e. HPLC, GC, etc. is more than sufficient.

10. CGMP's should require documentation that standard operating procedures are followed routinely on a day to day basis.

11. Separate GMP's for industry segments, i.e. raw materials, manufacturers, distributors and retailers should be in place.

Sincerely,

MADIS BOTANICALS, INC.

Voldemar Madis
Vice Chairman

VM:lc

cc: Natalie I. Koether, President