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INTERIOR DESIGN®
NUTRITIONALS

June 6, 1997

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

Food and Drug Administration:

Thank you for the opportunity to respond to Docket No. 96N-0417, rule making regarding the issue of Current Good Manufacturing Practice in Manufacturing, Packaging , or Holding Dietary Supplements.

Interior Design Nutritionals is an MLM organization with a major focus in the distribution of dietary supplements in the United States and world wide. We are very much in favor of the development of CGMP regulations for the Dietary Supplement Industry and feel that rules established should apply to companies large and small. We are aware that there are frequent abuses of the current GMP's in the nutrient supplement manufacturing under CFR section 110 and feel that the industry would benefit as a whole from implementation of CGMP procedures.

We would like to comment on the following points:

1. Dietary ingredients need to have specific defect action levels established. These levels should not violate Subpart G of CFR 110 Section 110.110 where the current law addresses "Natural or unavoidable defects in food for human use that present no health hazard." Specific defects that can occur in nutrients or food products used to prepare dietary supplements include:
a. Heavy metal contamination, e.g. Cadmium, Mercury, Lead
b. Microbial contamination, e.g. Excessive plate counts of aerobic organisms, presence of *E. Coli, Staphylocci, Salmonella,* as well as high levels of yeast and mold.
c. Pesticide and herbicide residuals in excess of EPA standards for processed foods and ingredients.
d. Contamination from foreign substances.

These defect action levels need to be tied to CFR 110.110 with additional emphasis on the U.S.P. monographs for nutritional supplements found in the U.S.P. XXIII and it's supplements.

We would suggest consideration of the use of new technology for determination and testing of the defect levels in inbound materials for compliance and acceptance. Procedures using

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75 WEST CENTER ▪ PROVO, UTAH 84601 ▪ 801-345-2700

enhanced laboratory equipment such as HPLC, Gas Chromatography, Atomic Absorption, and Infrared Spectrophotometry for analytical procedures and BAM methodology for microbial analysis.

2. We agree with the FDA intent to propose appropriate testing requirements be utilized to positively identify dietary ingredients. The U.S.P. XXIII procedures to identify individual compounds bearing monographs may form the basis for this testing. FCC or National Formulary Guide lines may also be used.

The greatest benefit for this approach would be to permit evaluation of phytochemicals, both positive and negative items, found in dietary supplements employing herbs and other plants. Development of CGMP procedures is suggested for identification on a standardized basis for the following:
a. HPLC qualification of levels of expected phytochemicals, e.g., flavones, sterols, carotenoids, catechins, etc.
b. Reference standards for raw materials via infrared spectrophotometry
c. Evaluation of heavy metals in raw materials through Atomic Absorption
d. HPLC spot testing for offensive herbicide and pesticide residues per EPA guidelines.
e. Use of Custom's Declarations and Commerce Department cross-checks to validate Country of Origin data concerning the raw material.
f. Issuance of Continuing Guarantees of Product non-adulteration by vendors.

3. We suggest that the FDA would be well served to adopt the quality control standards found in the U.S.P. XXIII monographs governing dietary supplements and promulgating these standards for this industry.

4. The tightening of contamination regulations proposed by the FDA is a basic restatement of HACCP standards. We suggest that the HACCP model be followed.

5. Documentation of day to day compliance by the manufacturer is a requirement of the CGMP. We support the effort to require such documentation. Failure to establish these procedures will result in product recalls, potential injury and litigation for damages for defective goods.

6. The system for reporting incidents should be to the FDA and not to individual physicians. Use of SOP procedures in this area is critical and suggest that the FDA not try to step away from this part of their duty.

7. Certification of ingredient safety by the manufacturer prior to use would be a process that should be considered essential for protecting the public health and reducing the level of product in the marketplace that has great risk associated with it's consumption. We endorse this approach at legitimate and science based self policing.

Elements that should be considered are:
a. Compliance with NLEA
b. Compliance with DSHEA provisions
c. Compliance with DEA and EPA standards concerning illegal, toxic or hazardous substances.
d. Compliance with U.S.P. XXIII standards, if applicable (i.e., existence of monographs)
e. Compliance with the British Pharmacopeia
f. Compliance with Consumer Products Safety Commission Data
g. Evaluation of Toxicity studies on laboratory animals.
h. Evaluation of drug-nutrient interactions.

8. Both computer and manual control of operations need to be run in parallel with a system which consist of computer driven and paper supported adherence to CGMP issues. We believe that the FDA should continue with this program insisting on routine validation through cycle counts, retained document paper trail testing, retained sample testing and maintenance of full traceability both electronically and in paper format.

9. Implementation of the HACCP principles to nutritional supplement manufacturing may be a profitable exercise if they do not directly contradict Section 110 of the CFR or the U.S.P. XXIII monographs governing manufacture of nutritional supplements.

10. Broad CGMP regulations should be promulgated and then modified to specific industries on a cause basis. Failure to adequately set standards for the entire industry would cause less than ethical members to claim 'exemptions' under obscure and illogical exclusionary language. Small companies cannot be excluded from this regulation in that a majority of this fragmented industry may remain unregulated.

Again we are in strong support of implementation of CGMP regulations to the Dietary Supplement industry with our exclusion and ask that you seriously consider the issues raised above.

Sincerely,

James Winter Duersch

James Winter Duersch, Ph.D.
Chairman, Technical Advisory Board

FAX TRANSMISSION

IDN - MKTG. & P.D.
75 WEST CENTER STREET
PROVO, UTAH 84601
801-345-2700
FAX: 801-345-2799

To: Robert J. Moore **Date:** June 6, 1997

Fax #: 202-205-5295 **Pages:** 7, including this cover sheet.

From: Win Duersch

Subject: Comment to Docket No. 96N-0417

COMMENTS:

Please find attached two copies of our comment to the FDA Docket No. 96N-0417.

I am going to assume that you can get them to the proper file in that you were the person referred to in the Federal Register for added information.

Thank you for you assistance in this matter.