LEINER
HEALTH PRODUCTS

901 E. 233rd Street
Carson, California
90745-6204
310/835-8400
Fax 310/835-6615

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April 25, 1997

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

Re: CURRENT GOOD MANUFACTURING PRACTICE
IN MANUFACTURING, PACKING OR HOLDING
DIETARY SUPPLEMENTS
DOCKET NO: 96N-0417

Leiner Health Products, Inc., a manufacturer and marketer of nutritional supplements products, hereby submits its comments in response to FDA's advanced notice of proposed rulemaking (ANPR) that appeared in the Federal Register of February 6, 1997.

This first section will address specific FDA requests for comments.

1. **Defect Action Levels (DAL's)**

We believe defect action levels may be necessary for certain types of dietary ingredients (i.e., herbals) that are minimally processed (i.e., dried and ground). This will ensure that suppliers of these products implement appropriate controls to maintain compliance to pre-established requirements. We feel the FDA should work with industry, trade associations and others to develop reasonable standards.

2. **Identification Testing**

We agree that identification techniques may be required for reasons of public safety and economic adulteration; however, we believe it is the intent of DSHEA that these requirements can only be set if reliable methodology exists. Identification testing methods for multiple ingredient preparations including identification of marker constituents for herbal products need to be established.

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3. Suppplier Certification

We feel that supplier issued certificates of analysis must provide reasonable assurance that a dietary ingredient is what it labeled to be. We believe that reputable manufacturers must certify their suppliers as well as indirectly assess raw material quality through end product testing.

4. Written Procedures

We believe that the dietary supplement GMP should require written documentation (i.e., SOP's, Record Forms) to document control and conformance to critical unit operational requirements and specifications. Wherever written documentation is concerned we feel the word "shall" must be used to make it a mandatory requirement.

5. Illness/Injury Reporting

We do not feel that this should be a provision of the GMP because of the number of unsubstantiated injuries and illnesses that are inherent in the food industry. We feel this process would create an unnecessary burden and also the industry will act responsibly when the need arises. We strongly believe the "Complaint Files" provision of the ANPR adequately addresses the requirement for complaint investigations.

6. Safety Evaluation

No comments at this time.

7. Controls for Computer Controlled Operations

No comments at this time.

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8. HACCP Approach to GMP's

We feel that the HACCP approach to GMP's is not appropriate since dietary supplements have a long history of safety.

9. Specific GMP's for Industry Segments

We feel that the GMP's can be applied to both suppliers of raw materials and finished product manufacturers.

In addition to the comments mentioned above we provide the following comments:

10. Equipment and Utensils (b) (7)

We feel that this section implies that cleaning validation is necessary to establish the effectiveness of cleaning facilities, procedures or machines. We do not feel this is necessary as the cleaning and sanitizing agents used in the industry are approved for food use and their effectiveness and safety when used in accordance with labeled directions has been established by the supplier. Since dietary supplements have been affirmed as "foods" by DSHEA asking for cleaning validation is inappropriate.

11. Quality Control and Laboratory Operations (c)

We feel that it is unrealistic to perform stability on each and every formulation, especially when a multivitamin and multimineral combination typically contains more that 20 components. The GMP standard should allow for establishing shelf life and expiring dating based on the stability characteristics of similar formulations and other historical data.

12. Commingling of Herbal Products (not covered in ANPR except under DAL's)

We believe that a provision for commingling herbal products is necessary to allow suppliers to standardize these materials to ensure that the intermediate user (manufacturer) and end user (consumer) will obtain a product that will have a consistent metabolic effect.

Respectfully submitted,

Michael S. Bradley
Director of Regulatory Affairs

Patrick Dunn
Vice President of Technical Affairs

MSB/mm