COMMENTS TO PROPOSED RULES ON CURRENT GOOD MANUFACTURING PRACTICE I MANUFACTURING, PACKING, OR HOLDING FOR DIETARY SUPPLEMENTS

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Re. Docket No. 95N-0417

From: Herb Pharm, Inc.
Box 116
Williams, Oregon 97544

Date: 4 June, 1997

Submitted by: Ed Smith, CEO of Herb Pharm, Inc.

96N-0417 C77

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From: Herb Pharm, Inc.
Box 116
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Date: 4 June, 1997

Submitted by: Ed Smith, CEO of Herb Pharm, Inc.

Who we are: Herb Pharm is a small business (50 employees) that grows herbal plants and manufactures herbal extracts.

General concerns regarding proposed cGMPs for dietary supplements

1 - They could add significant regulatory burdens to the industry.

2 - In many cases they appear inconsistent with the express terms and purposes of DSHEA.

3 - They could ultimately be crippling requirements for many smaller-size companies.

4 - FDA's apparent mis-assumption that many dietary ingredients do not have a history of food use in the USA before October 15, 1994.

5 - Could increase cost of dietary supplements to consumers and decrease the number and kinds of products available.

6 - FDA states its tentative judgment that section 402(g) of the Federal Food Drug and Cosmetic Act, which states that any cGMP regulations for dietary supplements be modeled after the cGMP regulations for food, doesn't preclude FDA from adopting cGMP regulations for dietary supplements that have no counterpart in part 110 (21 CFR 110) if there is an appropriate basis for doing so. We strongly disagrees with this judgments, and believes that the words "modeled after current good manufacturing regulations for food" only has meaning within the context of part 110, and that part's definitions and regulations.

We also submit that dietary supplement GMPs and the development of concurrent industry guidelines should follow historical models for the development of similar food GMPs and industry guidelines. Historically, the food industry and similar industries have been allowed and encouraged to develop voluntary guidelines for specific product and process issues. FDA has often later adopted these guidelines as GMPs or recommendations after industry has demonstrated their appropriateness empirically.

Comments Re. proposed cGMPs on page 5705

(7) (iii): We feel testing for aflatoxins is unnecessary and burdensome. Since presence of aflatoxins is linked to the presence of mold, our timely harvesting and processing of fresh botanical ingredients, to be dried or processed directly, will assure an alfatoxin-free product.

(7) (v): We find the language here too vague to be able to comment upon. What tests? What established specifications

Comments to Section IV: Summary and Request for Comments

1 - Re. Defect Action Levels:

Since DALs are a comparative measure of quality and not a safety issue, DALs should be evaluated within the context of the industry to which they are applied. That evaluation should be based on practical and historical amounts of unavoidable defects for the specific product in question. DSHEA and subsequent legislative discussions have confirmed that dietary supplements are a valuable and safe consumer product. Therefore, the current level of defects in most botanical products are well within acceptable tolerances for unavoidable natural defects. Specifically, this means that botanical DALs should be established based on botanical data, not on data from a similar but economically and practically different industry. Further as with the spice industry, DALs are best established through the promulgation of incremental industry guidelines for specific products based, as has historically been the case with other food industries.

2 - Re. Testing Requirements for Ingredient Identification:

We strongly believe that with whole (unground) herbs, organolyptic (sensory) analysis is a tried-and-true method for determining identity and is commonly used in the herb and spice industry worldwide. In the case of herbal powders, microscopic analysis and Thin Layer Chromotography are very dependable methods for identifying and are commonly used by the herb and spice industry worldwide.

As with any industry dealing with diverse materials, every dietary supplement ingredient, especially botanical materials, requires its own level of specificity and examination. The dietary supplement industry has developed and will continue to develop appropriate testing guidelines for industry members.

3 - Re. Contamination, Quality and Identification Criteria:

It is already an established cGMP for food that a manufacturer to accept certification from suppliers that ingredients are free from filth, pesticide residues, or other harmful contaminants or other impurities; that ingredients are microbiologically safe; and that they meet specified quality and identity standards.

FDA erroneously states that many ingredients used in dietary supplements do not have a history of food use in the United States, and in so stating questions the validity of suppliers certification with regard to both identity and adulteration. In fact, almost all of the dietary ingredients used in dietary supplements were marketed in the United States before October 15, 1994. Any dietary ingredient that was not marketed in the United States before October 15, 1994 is defined by DSHEA as a "new dietary ingredient" and is subject to specific requirements to attest to its safety.

DSHEA specifically acknowledges that dietary supplements are "safe within a broad range of intake", and that "safety problems with the supplements are relatively rare". Industry has continually monitored records from the Center for Disease Control, Poison Control Centers and the FDA and can find no substantial historical or contemporary data which contradicts the record of sale consumption of dietary supplements which is noted in DSHEA. AHPA therefore believes that it is neither necessary nor appropriate to subject dietary supplements to a more stringent requirement that the certification that is mandated for foods in order to assure that dietary supplements are free from adulteration, provided that the manufacturers of the dietary supplements establishes the reliability of the suppliers certification.

4 - Re. Documentation Procedures:

As FDA acknowledges, there is no provision of part 110 (cGMP Regulations for Foods) that require such documentation.

DSHEA specifically states that any cGMP regulations prescribed for dietary supplements be modeled after cGMP regulations for food. One of the most significant differences between cGMP regulations for food and those prescribed for drugs is the requirement for manufacturers of drugs to document that the

procedures prescribed for the manufacture of a drug are followed. We believe that such documentation is not necessary to ensure that dietary supplements are safe for their intended use, and that the agency would be ignoring the statute's intent in this regard if it were to require such documentation.

FDA states that its tentative judgment is that section 402(g) of the Federal Food Drug and Cosmetic Act, which states that any cGMP regulations for dietary supplements be modeled after the cGMP regulations for food, does not preclude FDA from adopting cGMP regulations for dietary supplements that have no counterpart in part 110 (21 CFR 110) if there is an appropriate basis for doing so. We strongly disagrees with this judgment, and believes that the words "modeled after current good manufacturing regulations for food" only has meaning within the context of part 110, and that part's definitions and regulations.

5 - Re. Reporting of injuries or illnesses:

The FDA already has an ample program for such reporting in its MEDWATCH.

6 - Re. Establishing procedures to identify, evaluate and respond to potential safety concerns:

We strongly disagree with FDA's statement that "many dietary ingredients have little history of use in food in the United States or use in the amounts that would be used in a dietary supplement." Both DSHEA and historical data substantiate the general safety associated with the consumption of dietary supplements. Also, this safe-use history is related to the amount of dietary ingredients historically used in dietary supplements.

We do not understand how FDA's statement that "Moreover, dietary ingredients are excepted from the definition of "food additive" ..." is in any way relevant to its proposals.

8 - Re. Relevance of HACCP:

FDA is asking if Hazard Analysis and Critical Control Point (HACCP), rather than proposed cGMP, may more effectively address the requirements for manufacturing and handling dietary products.

Subjecting the dietary supplement industry to HACCP requirements is an over-kill and will represent a major change in our processing, distributing and retailing approach. We strongly oppose the mandating of HACCP and legislative

or administrative action. We feel that cGMPs are sufficient to assure the safety of dietary supplement ingredients.

9 - Appropriateness of Broad cGMP Regulations:

The difference between supply, manufacture and marketing entities in the dietary supplement industry are largely the same as for the same entities in the food industry. As in the food industry, Certificates of Analysis supplied by original vendors are, and should continue to be, acceptable documentation for identity, quality and contamination provided that the original vendor fully complies with GMPs.

Respectfully submitted

Ed Smith

Ed Smith
CEO of Herb Pharm, Inc.