ORGANICALLY GROWN HERBS

June 4, 1997

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

RE: 21 CFR Ch.1 (Docket No. 96N-0417) RIN 0910-AA59
Current Good Manufacturing Practice in Manufacturing, Packing or Holding Dietary Supplements

Response to Advance Notice of Proposed Rulemaking by Trout Lake Farm Co.

Background: Trout Lake Farm Co. is the largest certified grower of diversified botanicals in the United States. We specialize in growing over 70 species of the highest quality medicinal, culinary and beverage herbs. The Farm, which is located in the Cascade mountains of Washington State, was founded in 1973. The Farm and its sister company, Flora Laboratories, Inc., conducted approximately 8 million dollars in sales during 1996.

The Farm is aware of the Advanced Notice of Proposed Rulemaking for the "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements" and wishes to comment.

- Issue #1 - FDA asks if there is a need to develop specific defect action levels (DAL's) for dietary ingredients.

Response: Defect action levels are "guidelines for acceptable levels for substances that are natural or unavoidable defects that pose no health hazard for Humans." Trout Lake Farm understands that DAL's are not usually covered by GMP's and therefore are not appropriate for this document. We would also like to challenge the idea that the suggested greater exposure for botanicals over

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spices is relevant, as DAL's pose no health hazard. We also challenge the assumption that exposure to botanicals in dietary supplements exceeds that of spices. For instance, the quantity of basil in pesto exceeds that in most dietary supplements. Also some plants, such as garlic, mint, parsley, etc., are used both as dietary supplements and as spices.

- Issue #2 - "FDA requests comments on appropriate testing requirements to provide positive identification of dietary ingredients, particularly plant materials, used in dietary supplements." " FDA is asking for comments on the technical and scientific feasibility for the identification of different types of dietary ingredients."

Assuring the identity of plant materials means determination of the correct species as defined by a Latin binomial name. A second step may be the assurance of the presence of chemical constituents and/or biological activity appropriate for that plant material. It is appropriate for the supplier of the raw material to verify the identity of the plant material and for the finished product manufacturer to verify the presence of appropriate constituent chemicals and/or biological activity.

The primary way to identify plant material is through the use of voucher specimens. (These are preserved specimens identified by a trained botanist with the aid of published descriptions and comparisons with previously identified specimens.) As the whole plant is needed, this form of identification is most appropriate for the primary suppler of the plant material, i.e. the farm or the plant collector. It would be appropriate for a "Certificate of Botanical Identity" to be produced at this point and for this "Certificate" to follow the material through the manufacturing process forming a paper trail. Thus the identity of the plant material could be traced through all stages of processing to the final consumer product. Any questions of identity could be addressed through examination of the voucher specimen which would be held for a specified period of time or if necessary serve as a permanent record.

Other means of identification of plant material are covered in monographs specific to the plant. General descriptions as to appearance or sensory (organoleptic) information can be very useful to those experienced with plant materials. Milled or powdered plant material can be identified using microscopic analysis, although there are few trained with the expertise to do so. Simple chemical spot tests are indicative of identity but are not definitive.

Verification of the presence of chemical constituents is important, especially for processed materials. These can include simple chemical spot tests for classes of chemicals or determination of presence of essential oil content which can be easily set up. More sophisticated analysis such as chromatographic techniques

(thin layer (TLC, HPTLC), high pressure liquid (HPLC), gas (GC), capillary electrophoresis (CE)) and spectroscopic analysis (infra-red (FTIR)), are more definitive, but standards and methods of analysis are not easily available for all botanicals. As official monographs are developed and approved, analytical methodology and guidelines for identity, quality and composition will be provided for the industry.

- Issue #3 - "... the agency asks for comments on whether a certification will provide assurance that dietary ingredients are not contaminated or whether specific testing requirements are necessary and would effectively ensure the safety and wholesomeness of these products."

Response: Trout Lake Farm Co. believes that either testing or a Certificate of Analysis will serve to determine the ingredient is free of harmful contaminants. Section c (7) (ii) and (iii) of the proposed Rulemaking adequately cover this requirement. We recognize that it is the responsibility of the purchasing manufacturer to determine that the Certificate of Analysis is accurate and valid. In addition, we would like to see a section added to the CGMP that considers adulteration with heavy metal contaminants.

- Issue #4 - "The agency asks for comments on whether there is a need for CGMP to include requirements for manufacturers to establish procedures to document that the procedures prescribed for the manufacture of a dietary supplement are followed on a continuing or day to day basis."

Response: Trout Lake Farm does not believe there is a need for a separate procedure documenting compliance with the procedure. The initial GMP procedure should include such documentation as appropriate for the procedure.

- Issue #5 - "The agency asks for comments on whether dietary supplement CGMP should require that reports of injuries or illness to a firm be evaluated by competent medical authorities to determine whether follow-up action is necessary to protect public health."

Response: The standard food GMP's provide for documentation to record illness due to food substances in the market. There are also systems in place through such agencies as the Center for Disease Control and Poison Control Centers to monitor and record injuries or illness due to products on the market. It is our belief that reporting of illness is covered by these procedures and that there is no need for the dietary supplement manufacturer to call in medically trained personnel.

- Issue #6 - FDA asks for comments on whether a manufacturer critically evaluate the available scientific information on the safety of the dietary ingredients that it intends to use in its products to assure itself that those products will be safe. If this evaluation is necessary, what elements need to be included in such an evaluation and their relative importance. Should such an evaluation be documented in a firm's records? What types of records would be adequate to document that such an evaluation had occurred?

Response: Historical precedence for products on the world market before October 15, 1994 is sufficient to indicate safety under the DSHEA act. However, Trout Lake Farm Co. believes that it would be appropriate for manufacturers of finished goods to consult the generally known and generally available scientific information on the safety of the ingredients of a product before marketing that product to the public. Such information, or bibliographic sources for that information, should be held in files by the manufacturer.

- Issue #7 - "The agency asks for comments on whether specific controls are necessary for computer controlled or assisted operations."

Response: Trout Lake Farm believes that it is appropriate to test and validate computer assisted controls against manual operations.

- Issue #8 - The agency asks for comments on whether certain, or all, of the requirements for the manufacturing and handling dietary ingredients may be more effectively addressed by a regulation based on the principals of Hazard Analysis and Critical Control Points (HACCP), rather than the system outlined in the industry submission.

Response: Trout Lake Farm agrees with the need for flexibility in an industry where the functions range from raw material supplier to finished goods manufacturer. We also agree that a HACCP program would be more flexible than the proposed CGMP's and that it would be more suitable to this industry with its great diversity of manufacturing types. We propose that HACCP be presented as an optional alternative to CGMP's.

- Issue #9 - "The agency asks for comments on whether broad CGMP regulations will be adequate, or whether it will be necessary to address the operations of particular segments of the dietary supplement industry."

Response: Trout Lake Farm Co. would like to suggest that individual companies come up with their own GMP's meeting certain minimal guidelines as directed by

broad CGMP regulations. This option would allow for specific details in the GMP's to be tailored to the specific operation(s) of the company. This flexibility is advantageous due to the diversity of the dietary supplement industry, which includes raw goods suppliers and processing manufacturers to finished goods distributors. There is a precedence for establishing tailored GMP's with broad guidelines in the CFR 21 in respect to OTC drugs.

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Respectfully submitted,

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