UTAH NATURAL
PRODUCTS ALLIANCE

June 6, 1997

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

RE: Advance Notice of Proposed Rulemaking
Current Good Manufacturing Practice in Manufacturing,
Packing, or Holding Dietary Supplements
Docket No. 96N-0417

Dear Sirs/Mesdames:

These comments are filed by the Utah Natural Products Alliance (UNPA) in response to the Food and Drug Administration's (FDA) Advance Notice of Proposed Rulemaking with respect to Good Manufacturing Practices (GMP's) for dietary supplements. The UNPA notes that the proposal is based on a draft document submitted by the dietary supplement industry and has no further comments to the proposed rule itself but wishes to comment on the series of questions raised by the agency.

At the outset, the UNPA believes it is important to note the Dietary Supplement Health and Education Act (DSHEA) explicitly provides that should GMP's be proposed for dietary supplements, such regulations must be based on current food Good Manufacturing Practices. To the extent that the agency proposes to establish procedures or practices for which there is no precedent in food GMP's or which are essentially modeled on drug GMP's, the UNPA believes that both the agency and the dietary supplement industry have limited discretion in proposing or advancing any such regulation. Notwithstanding, to the extent that modifications to food GMP's serve the objective of producing and marketing safe, beneficial and properly labeled dietary supplements, our organization will continue to work with the agency and its allied trade organizations to meet these important objectives.

With respect to FDA's additional questions, the UNPA offers the following responses:

1) Is there a need to develop specific Defect Action Levels (DAL's) for dietary ingredients?

DAL's are unavoidable contaminants found in natural products that, of themselves, pose no inherent safety risks. If present at unusually high levels, such contaminates may render a botanical dietary supplement adulterated. Both the FDCA and the DSHEA provide FDA authority to act against such products. The UNPA does not believe that DAL's should be established as part of this current rulemaking but should be addressed

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separately. Moreover, the agency's view that spice or flavoring agent DAL's are inappropriate for dietary supplements because consumption patterns for botanicals as supplements are substantially higher than for spices is not accompanied by any data or evidence supporting this view. Absent compelling evidence that using relevant spice DAL's would create a public health risk when used for botanical dietary supplements, the UNPA believes that, in the interest of efficiency and proper use of resources, such DAL's should be looked to for guidance with respect to botanical supplements. In the absence of formal DAL's, the UNPA believes the agency should exercise discretion in using the "zero tolerance" standard as a basis for limiting the importation or sale of dietary supplements absent evidence that such contaminants pose a public health or safety risk.

2) What are appropriate testing requirements to provide positive identification of dietary ingredients, particularly "plant materials" used in dietary supplements?

Tests appropriate to confirm the identity of dietary ingredients, particularly plant materials, will vary according to factors including the physical form of the ingredient (whole plant, powders, liquid extracts, etc.) and the physical properties or characteristics of such materials. These draft GMP's should allow flexibility in using any valid and reliable procedure or method suitable to positively identify a dietary ingredient. This includes organoleptic, microscopic, chemical or other methodology.

Section 401(g)(2) of the act states that CGMP regulations may not impose standards for which there is not current and generally available analytical methodology. The dietary supplement industry, particularly the botanical sector, is actively working in concert with the U.S. Pharmacopeia, the AOAC and independent analytical laboratories to develop and publish methods to satisfy the "generally available" -- a requirement of this section of the act. At present, methods exist and are employed by manufacturers to confirm and identify various botanical dietary ingredients. The industry recognizes the importance of having reliable published analytical methods. The presently available and utilized methods to positively identify plant material are adequate, but in due course they will be enhanced by the availability by more widely recognized methods and techniques as a result of industry's current program and investment in this area.

3) Is a supplier certification adequate to assure that a dietary ingredient is not contaminated with filth, contaminates, pesticide residues or other impurities?

Provided that a supplier's reliability and procedures are confirmed, acceptance of a supplier's certification is adequate to assure that dietary ingredients are not contaminated with filth, contaminates, pesticide residues or other impurities. Such confirmation may be made by various means, including independent analysis, in-house testing and review protocols, etc. The UNPA believes the responsibility of both suppliers and manufacturers to confirm the suitability of raw materials and dietary ingredienets is provided for in the proposed GMP's.

4) Is there a need for CGMP to include requirements for manufacturers to establish procedures to document that the procedures prescribed for in the manufacture of a dietary supplement are followed on a continuing or day-to-day basis?

The proposed GMP's require that written procedures be established for many processes and functions. At the discretion of the manufacturer, written procedures can take the form of SOP's, to the extent that such procedures ensure that the manufacturing practices are followed on a consistent basis. These can and should be employed by industry. The UNPA does not believe that it is necessary or appropriate to require manufacturers to establish additional procedures to document that procedures prescribed for the manufacture of dietary supplements are followed on a continuing basis. The CGMP's inherently require manufacturers to take responsibility for the ultimate quality and reliability of dietary supplements, and this additional procedure is unnecessary.

5) Should dietary supplement CGMP require that reports to a firm of serious injuries or illnesses be evaluated by competent medical authorities to determine whether follow-up action is necessary to protect the public health?

It is both the practice and responsibility of a manufacturer to establish procedures, whether within the quality assurance department or elsewhere, to appropriately respond to a report of a serious illness or injury as a result of the consumption of a dietary supplement. The proposed GMP's address the handling of complaint files which inherently include the management of serious reports of illness or injury. Given the ambiguity of the term "serious" and the absence of agency authority to require what is essentially post-market surveillance, the UNPA believes that an additional requirement that a company evaluate serious reports of illness or injury by a competent medical authority is beyond the scope of the FDCA and DSHEA. The agency's statement that the presence of pharmacologically active substances in dietary supplements but not in foods is perhaps inaccurate. An important number of foods contain substances which are pharmacologically or physiologically active or which may provoke serious reactions when consumed. The UNPA does not believe it is appropriate to distinguish dietary supplements and foods on this basis but recognizes the importance of assuring that any serious report of illness or injury be swiftly and appropriately handled and investigated.

6) Should CGMP for dietary supplements require that manufacturers establish procedures to identify, evaluate and respond to potential safety concerns with dietary ingredients?

The DSHEA clearly establishes the standard of safety to which dietary supplements will be held. The agency's request for comments to this question appears to go beyond the scope of CGMP and may be inconsistent with other provisions of the DSHEA. The vast majority of dietary ingredients have been sold for many years in the United States without incident or without any significant concern as to health or safety risks. In the event of a potential safety concern with a dietary ingredient, the UNPA believes the industry will

recognize its responsibility to identify and resolve such issues, both in the public interest and to maintain consumer confidence in dietary supplements. No additional requirement, either with CGMP or otherwise, is required to address such concerns.

7) Are specific controls necessary for computer controlled or assisted operations?

Reasonable manufacturer controls are required to evaluate whether computer controls are operating as planned. Such requirements should not extend to "validation" of operations as is required under drug GMP's. The ability of computer software programs used in the manufacture of dietary supplements should perform their intended functions and should be confirmed by adequate and documented testing.

8) Should certain or all of the requirements for manufacturing and handling dietary ingredients and dietary supplements be addressed by a regulation based on the principles of HACCP rather than GMP?

The dietary supplement trade associations have extensively discussed this question and have concluded that the type of hazards which HACCP is designed to control are largely not relevant to dietary supplements. The dietary supplement industry is committed to establishing manufacturing practices and procedures which will assure that dietary supplements will be manufactured under conditions which are reliable and which will produce safe and beneficial products. The proposed GMP's will serve to achieve these objectives. The UNPA believes that the HACCP approach was conceived and developed for industries and products where critical manufacturing or handling practices are crucial to product safety. The manufacture of dietary supplements is largely a matter of consistently observing practices and procedures to assure the ongoing quality and integrity of the manufacturing process. The UNPA is committed to the completion and implementation of the proposed GMP's and does not support the establishment of HACCP as the basis for the manufacture of dietary supplements.

9) Are broad CGMP regulations adequate for the wide spectrum of firms that manufacture dietary supplements? Is it necessary to address the operations of particular segments of the dietary supplement industry?

The proposed CGMP are adequate to address the broad range of manufacturers and ingredients within the dietary supplement industry. To the extent that special circumstances or requirements are identified, the UNPA believes that industry standards and practices and informal regulatory guidance are appropriate to address such needs or requirements.

Many of the issues raised by the agency are the subject of ongoing programs and discussions within the dietary supplement industry. The UNPA and its sister organizations are committed to manufacturing products that are safe, properly labeled and made to quality standards. These draft

GMP's as submitted by industry and published by FDA for comment are the appropriate means to meet these objectives. The UNPA and all responsible members of the dietary supplement industry are fully aware of the responsibility to manufacture, hold and distribute dietary supplements in a manner that assures that dietary supplements are safe, made to consistently high standards of quality and which will continue to enjoy the confidence of the consuming public. Accordingly, the UNPA confirms its continued willingness to work with the agency to achieve these important objectives.

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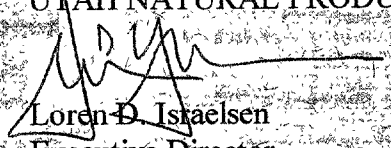

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