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April 22, 1997
(Earth Day !)

Dockets Management Branch HFA-305
U.S. Food and Drug Administration
12420 Parklawn Drive, Room # 1-23
Rockville, Maryland 20857

97P 0417 JUN 26 PM 12:12

Comments Submitted On:
Advanced Notice of Proposed Rulemaking

Current Good Manufacturing Practices
in Manufacturing, Packing or Holding
Dietary Supplements

I. Background:

Having worked on the committee which developed the industry submission **we would like to recommend that the agency recognize the need for c.G.M.P.s for all suppliers of dietary supplements but as industry has pro-actively responded in a spirit of self regulation that the agency need not promulgate specific guidelines but only to mandate that "commonly accepted dietary supplement c.G.M.P.s" are required.**

II. The Industry Submission:

Definitions:

> Batch and Lot are distinct terms and, although related, are not synonymous and should be defined individually.

> "Manufacture" and "Manufacturing" should be expanded to include warehousing [sic. "holding"], transportation and distribution.

Quality Control and Laboratory Procedures:

> Add to (a) (i) "equipment"

> Revise (c) (1) to "..assure that the product meets *label claim*.."

Production and Process Controls:

> Simplify and clarify throughout by using the word "amount" in lieu of "weight or measure".

III. Economic Issues:

> Current G.M.P.s in the Dietary Supplements industry minimally conform to the industry submission.

> We contract with several small manufacturers; all of whom have reviewed the industry submission, agree with the guidelines and have indicated that nominal costs are anticipated to fully conform.

> As stated in I. above we recommend that the agency need not promulgate specific guidelines but only to mandate that "commonly accepted dietary supplement c.G.M.P.s" are required.

> Assuming that the agency eventually requires c.G.M.P.s, we estimate time needed to come into compliance at not less than 18 months from publication date of the final regulations.

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> The primary economic concerns of small manufacturers regarding full compliance with industry submitted or F.D.A. drafted c.G.M.P.s are:

- the costs of purchasing/installing appropriate air filtration systems to preclude cross-contamination.
- **the costs of additional ingredient validation by laboratory analysis for ingredients purchased from reputable suppliers when already accompanied by appropriate Certificate of Assay.**
- **the costs of additional process validation by laboratory analysis for finished dietary supplements to validate a minimum of 100% of each and all ingredient amounts at time of manufacture and through product shelf life when already validated by common industry practice of estimating by input.**
- additional liability exposure from redefining "responsible management"

IV. Request for Comments:

1. **Defect Action Levels:** The agency is making a possibly erroneous assumption in stating that "the use of a botanical in a dietary supplement may result in a much greater exposure to the botanical ingredient...than in a food as a spice or flavoring". Botanicals as dietary supplements are in amounts normally consumed as a food, except when a botanical is prepared and sold as an *extract* or a *concentrate*. In these cases the methods used to extract or concentrate the botanical also serve to remove materials which would normally trigger DALs, thus vitiating the need for the agency's concern. We agree with the Agency that current food DALs are inappropriate for refined or processed dietary ingredients but may be appropriate for unprocessed or unrefined dietary ingredients.

2. **Botanical Ingredient Identification:** Peer-reviewed published compendia with appropriate analytical methodology developed through scientific consensus is the optimal means to accurately identify botanical ingredients. For those ingredients for which no such compendial methodology is available it is incumbent for ingredient manufacturers/suppliers to provide a verifiable alternative to validate the ingredient. Traditional organoleptic methods and other sensory evaluations are appropriate if independently verifiable.

3. **Dietary Ingredient Contamination:** It is the responsibility of the manufacturer of the dietary supplement to ensure that each dietary ingredient and the finished dietary supplement are uncontaminated and safe. Standard analytical methods are critically necessary for any and all dietary ingredients and dietary supplements. A Certificate of Assay, prepared by the supplement manufacturer using compendial methodology, must accompany each dietary ingredient lot certifying that the lot is safe and uncontaminated. This due diligence would preclude the necessity for additional analytical verification that the finished dietary supplement is uncontaminated and safe.

4. Consistency Validation: c.G.M.P.s are, by definition, guidelines, and are therefore a self-regulatory mechanism. Their consistent application is inherent in their use and the validation of that is the responsibility of the Quality Control Unit as stipulated in the industry submission and any further documentation is unnecessary.

5. Personnel Medical Evaluation: **We STRONGLY object to the agency's erroneous statement that "Many dietary supplements contain pharmacologically active substances"** as dietary ingredients have only *physiologically active* substances and their subsequent comparisons with other foods is therefore erroneous also. We also disagree strongly with the agency's arbitrary, unilateral and unnecessary suggestions to override local and state health and safety codes and regulations. We feel that current food c.G.M.P.s are adequate; further, the dangerously vague "responsible management" obviates significant additional liability exposure - and therefore significantly increases potential operational costs.

6. Dietary Supplement Safety: We assert that the Act's allowance of permitting consumer information statements, including warnings and cautions, offers the optimal method for manufacturers to educate consumers about safe use of dietary supplements. We believe that it is the responsibility of the manufacturer, as a critical part of responsible due diligence, to evaluate safety of all ingredients, ingredient amounts and ingredient combinations of a dietary supplement and inform and educate consumers about product safety on the product label. The documents which validate any such label information must, however, be retained by the manufacturer. **We strongly object to any proposal by the agency to mandate a specific evaluation process or method as costly, unnecessary and onerous.**

7. Computer Validation: We assert that a computer's hardware and software are simply specialized "equipment" and therefore need no additional regulation beyond those in the industry submission.

8. Deferred for comments to be submitted at a later date.

9. We appreciate the agency's recognition of the segmentation and specialization of the industry. We recommend that if the owner of the branded product label is not physically involved in any phase of manufacturing, packaging, labeling or testing dietary supplements that additional S.O.P.s are still necessary to ensure that their branded products are safe and truthfully labeled. Such procedures ARE currently included in the industry submission but a section should be added that segments of the supply chain, other than conventional manufacturers, also need to develop and consistently observe, their own c.G.M.P.s.

Submitted on behalf of M.K. Health Foods, Inc., dba Nature's Life.

Karl Riedel,
C.E.O.

cc: N.N.F.A.: Scott Bass, Charles Raubicheck, Michael Ford
Nature's Life: Marianne Kostka, Callista Maclean, Diane Harper