PFANSTIEHL

The source for carbohydrate chemistry

May 19, 1997

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

To Whom It May Concern:

Pfanstiehl Laboratories has reviewed the proposed Current Good Manufacturing Practice in Manufacturing, Packaging or Holding Dietary Supplements and believe that this will be a welcome addition in control of dietary supplement quality. There are currently manufacturers of both dietary supplements and dietary ingredients that do not have adequate cGMP systems. However, we would like to stress that should this rule be implemented, for it to be effective it must be mandatory rather than voluntary. Additionally, the resources must be available for the FDA to enforce this rule. The question arises as to whether such resources will be available, particularly with foreign manufacturers which currently provide significant supplies of dietary ingredients. Implementation of this rule without being enforced will only serve to widen the gap between the reputable dietary product and ingredient manufacturers and the other manufacturers not practicing cGMP. Also, it would increase the economic advantage that such manufacturers not operating under cGMP's currently enjoy.

The only recommendation we have for revision is under Equipment and Utensils, Item #11, "a written record of major equipment cleaning shall be maintained in individual equipment logs." We would suggest the addition of the same exclusion that exists in CFR 211.182 eliminating the requirement to have such logs provided the equipment is dedicated. It is suggested that the following statement be added: "If equipment is dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence." This exclusion would relieve the burden of equipment logsheets where equipment is dedicated to one product.

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As stated above, we support the implementation of the cGMP's for the dietary supplement industry provided they are enforced uniformly across the industry. As a manufacturer of Active Pharmaceutical Ingredients (API's), we already follow cGMP's and understand their benefit in providing greater assurance of product quality. We look forward to additional information regarding dietary supplement cGMP's, and would be pleased to provide an industry perspective from the standpoint of a dietary ingredient manufacture. Please feel free to contact the undersigned.

Sincerely,

PFANSTIEHL LABORATORIES, INC.

Stephen B. Neil
Director Quality Assurance/
Regulatory Affairs

cc: Edward Holstein
George Holstein