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

April 13, 1997

RE: Docket no. 96N-0417
RIN 0910-AA59

I am writing to comment on the proposed Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements (21 CFR).

As Quality Control Manager for a Dietary Supplement Manufacturer, it is my opinion that the proposed GMPs, are in general, good business practices. They reflect our commitment and responsibility to the health and well being of our consumers.

The proposed GMPs will require us to operate our businesses in a more professional manner. The proposed GMPs also allow for us as manufacturers, packers, and handlers to regulate ourselves and our industry more closely. It is my experience that self regulation is the most responsible and accountable way to operate in business.

My concerns with the proposed GMPs are specific to Subpart E - Production and Processing Controls, (c) Handling and storage of raw materials, in-process materials and rework, (7) Raw material sampling and testing, sections (ii) and (iv).

> In section (ii) concerning microbial testing of raw materials prior to use..... I am against the idea of blanket testing and processing of all fresh and dried botanical materials. It is important to consider fresh herbal products in the same way one would consider fresh produce. Fresh herbal products need to be processed immediately upon receipt. Typically, fresh products are either dried or processed into liquid extracts. These processes (drying and liquid extraction) should meet the requirements of the phrase " shall be otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated".
>
> In section (iv) concerning each lot of raw material shall undergo at least one test by the manufacturer to verify identity. Gross organoleptic analysis is included here and I want to emphasize that it is essential that sensory tests be completely acceptable for identity verification.

Thank you for the opporttunity to respond to the proposed Good Manufacturing Practices.

Sincerely,

Candiace J Carnes

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