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July 8, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

To whom it may concern:

I am writing to comment on the proposed GMP (Good Manufacturing Practices) regulations for dietary supplements mandated under the DSHEA law.

My wife and I are the owners of a small family business that distributes dietary and herbal supplement products to healthcare professionals such as chiropractors, acupuncturists, naturopaths, nutritionists and medical doctors. We have been in business for twenty-four years and employ five people in the office, with an additional four outside sales representatives. Our products include a nationally distributed, professional dietary supplement label and a proprietary label, produced for us by contract manufacturers.

First, I would like to state that I am fully in favor of the adoption of GMPs. I agree that standards regulating such areas as accurate record keeping, procedures for storage and management of ingredients, and high standards of manufacturing quality and cleanliness should be adopted and enforced. Universal implementation of GMPs by dietary supplement manufacturers can only be of benefit to our industry.

I do, however, have serious concerns that one aspect of the proposed GMPs in particular is misguided and would do serious harm to my business and my customers' opportunity to obtain the variety and quality of products they desire. Specifically, I understand that the proposed GMPs require multiple and redundant assays of the ingredients in each formula manufactured for me. Because the batch size of my proprietary label products is normally between 100,000 and 250,000 tablets or capsules, this requirement would dramatically increase the cost of a multiple-ingredient formula, rendering it noncompetitive.

Conducting multiple assays would increase cost but do nothing to enhance product quality. It is my long-standing policy to *not* put production contracts out for a low bid. Rather, for the past twenty years I have done virtually all of my contract business with a single manufacturer, Formulation Technologies, Inc. of Oakdale California. I have done this specifically because they maintain GMPs and have very high product quality standards. While this may make my products a bit more expensive, my customers recognize our quality and appreciate it. This extra expense, and the quality it buys, is important to our success and longevity in business and is well worth it. Additionally, I believe that my attitude is not unique, but is typical of all ethical businesses in the dietary supplement industry. Quality, assured by reasonable GMPs, is feasible without the expense of excessive product testing. Ethical, quality conscious small businesses in the dietary supplement industry should be supported, not punished by the adoption of GMPs!

There are, however, two categories of companies that would not be negatively effected by adoption of GMPs that mandate an onerous testing requirement. The first is the mega-corporation whose batch sizes are in the millions. No doubt large corporations would warmly welcome a government-imposed competitive advantage that could drive many small manufacturers and distributors out of business. The fairness issue aside, the formulas that big corporations mass-produce could never duplicate the quality and diversity of dietary and herbal supplements now available to practitioners and consumers.

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The second category of business that will be unaffected by GMPs generally and a product testing requirement in particular, are the very companies which make GMPs necessary. These are unethical, fly-by-night fringe companies, which will seek to evade GMPs under any circumstance. The implementation of expensive and redundant testing would not effect such "outlaw" companies, even as it harms honest, ethical small businesses. Only regular, thorough inspections and strict enforcement will be effective.

I believe the *only* thing that can guarantee the quality of dietary and herbal supplements is strict, *fair* enforcement of *well thought-out* GMPs. Ingredient purity and quality can best be assured, in an economically responsible manner, by monitoring product quality and record keeping at companies that manufacture and supply raw materials. Ethical, well-managed suppliers will be eager for the opportunity to certify the purity and quality of their products to the industry. In regard to companies that produce finished product, regular inspection of facilities and monitoring of record keeping, along with a program of testing a percentage of randomly selected products from retained samples, would identify problem companies while not penalizing ethical companies who work hard to produce high quality products.

I ask that you please do implement GMPs that insure the production of high quality dietary and herbal supplements. Please do implement GMPs that increase the confidence consumers have in our industry by weeding out truly unethical companies from our industry. But please *do not* impose excessive and expensive testing requirements that will not add to *real* product quality, while making it difficult for small, ethical companies such as ours to continue in business. Please do not deny consumers the opportunity to choose, at an affordable price, the products they desire to help maintain their good health.

Sincerely,

David Werum

cc: Formulation Technology, Inc.
Orrin Hatch, US Senate
John Doolittle, US House of Representatives