



August 8, 2003

Small Business Guide  
Division of Market Studies, HFS-726  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, Maryland 20740

To Whom It May Concern:

Concerning current Good Manufacturing Practices for Dietary Supplements, a further defining of procedures that are in place and guidance for manufacturers to help make the end products more safe and effective would be useful. The proposed regulations, however, will, in my opinion, put thousands of small manufacturers out of the business and perhaps hundreds of thousands of small marketers out of business. The reason for this opinion is that the increased overhead would make the smaller manufacturers unable to compete with the large manufacturers who have large staffs and laboratories already in place. The small manufacturer would also have to pass on these additional expenses to their customers, many of whom are small and buy smaller quantities. These marketers will not be able to afford the additional costs.

While it is true that there are companies that participate in practices that result in products that are not safe or particularly effective, there are laws in place to control these practices. Establishing reasonable cGMPs for manufacturers of dietary supplements could be helpful to the industry and to the public, and many of the proposed cGMPs accomplish this. But some of the proposed regulations will, in my opinion, if implemented as proposed, increase the cost of goods drastically. For these reasons, my belief is that these proposed cGMPs as written will harm the small businesses mentioned above and will not benefit the public commensurately as intended by these regulations.

To be more specific concerning the economic consequences to a small manufacturer, such as ourselves we would have to do the following:

1. If we do the required analyses in-house, it would be necessary for us to purchase additional laboratory equipment totaling approximately \$227,000.00, which I will list below.
2. We would have to hire at least one qualified technician for a minimum of \$40,000.00 per year.

1996N-0417

C241

3. We would need an expansion of our present laboratory estimated at \$25,000.00 and service, maintenance and supplies for the equipment will be approximately \$25,000 per year.

Analytical Chemistry is not my area of expertise, but I have consulted with several experts in the field and feel that the above is an accurate accounting of the equipment. The list is as follows:

Ioncoupled Plasma Unit for Mineral analysis	\$80,000.00
HPLC with columns, pumps, etc.	55,000.00
Infrared Spectroscope	55,000.00
High Performance Thin Layer Chromatography	37,000.00

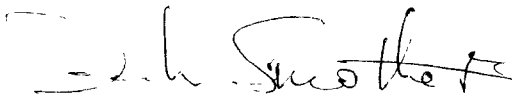
Our sales are currently \$1,500,000 to \$2,000,000 per year and we manufacture liquid dietary supplements along with personal care products and some OTC topical drugs. The above does not take into account the additional paperwork and time required for our current supervisors and technicians, possibly necessitating the need to hire additional personnel to cover this area.

The other option we have is to send all of the raw materials and finished products to outside laboratories for testing. If we do this, it will take additional time to achieve the results and release the products for shipping and it will be necessary to pass these costs to the customer. With some products the analyses are estimated to be more than \$1,000.00 which would make the unit-cost so high that it would not be feasible for the marketer to continue this product.

I hope the above information will be beneficial to your decision making.

Sincerely,

NATURTECH



Don L. Smothers  
President