CERA
Products, LLC

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

Dear Sir or Madam:

My company supports the establishment of Current Good Manufacturing Practice (cGMP) in Manufacturing, Packing, or Holding Dietary Ingredients of Dietary supplements by the FDA.

Effective testing procedures had been in place at the company since early on to ensure product integrity. I am much concerned that many smaller companies will be faced with high costs to implement the rigid testing scheme proposed in the FDA rule. The financial costs outlined by the FDA are greatly underestimated and the economic impact of the proposed rule will be detrimental on the dietary supplement industry.

I recommend that the FDA adopt a more flexible testing scheme to reduce the number of tests required under the proposed rule, thereby reducing the cost of manufacturing the product.

I believe the FDA should also recognize the value of certificates of analysis in the manufacturing process and allow the use of statistically valid methods for control to finish product testing.

Furthermore, testing obligations of the finished product should fall upon the manufacturer of the product, and that manufacturer should have the sole obligation to test it.

I also hope the FDA will recognize the significance of having written procedures and documentation in control of the manufacturing process. These written procedures are necessary for cleaning and maintaining the equipment, the quality control units, laboratory records, reprocessing of batches, packing, and labeling.

Finally, I believe expiration dating and shelf-life dating should be on the product label. Consumers have also come to expect those dates on the product.

I truly hope the FDA will take these concerns into consideration before the finalization of the rule on cGMP.

Sincerely,

Charlene Riikonen

96N-0417

C229

8265-I Patuxent Range Rd. Jessup, MD 20794 USA
Phone: (301) 490-4941 Fax: (410) 792-8671 http://www.ceralyte.com