BEYOND A CENTURY, INC.

173 Lily Bay Road
Greenville, ME 04441
p. 207 695 4301
f. 207 695 2492

nutrition@beyond-a-century.com

August 7, 2003

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

RE: Docket No. 96N-0417; Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements.

Dear Sir or Madame,

Although my company supports the establishment of current good manufacturing practices (cGMPs) rules for dietary supplements, below is a list of our concerns relative to the establishment of those regulations. I am primarily concerned that even responsible companies such as ourselves will be faced with costs beyond FDA's estimate due to an especially rigid and unnecessarily burdensome testing scheme. Economic costs outlined by FDA are grossly underestimated and will have a significant and detrimental impact on the dietary supplement industry; particularly the "small and very small" as defined by FDA.

The proposed rule appears to rely on an unnecessarily exhaustive and rigid testing scheme. As drafted and interpreted by virtually the entire industry, the proposed rule requires manufacturers to test every batch of finished product, if possible. If it is not possible to test the finished product, then dietary ingredients need to be tested upon receipt and throughout the manufacturing process. Testing must be performed at every level of the supply chain.

Raw ingredient manufacturers are the only entities in the supply chain in some instances, such as with some botanicals or unique formulations, with the expertise to evaluate a raw material. We support NNFA's recommendation that FDA modify its approach to product testing to recognize verified certificates of analysis, to allow for a statistically based approach to finished product testing, and not require unnecessarily redundant testing throughout the supply chain. FDA must allow for the use of verified certificates of analysis to show scientifically valid analytical testing has been conducted. We

recommend that the final regulation make it clear that testing obligations fall primarily upon the manufacturer of the finished dosage form and that only one company in the chain has to perform the appropriate testing. For instance, companies which merely bottle and/or label finished dosage forms need to be held responsible for potency, identity, and purity, but not be required to do batch testing.

The economic costs outlined by FDA are grossly underestimated. The economic and financial impact of the proposed rule will have a significant and detrimental impact on the dietary supplement industry. Most adversely affected will be very small and small (as defined by the FDA) establishments -- companies like ours who produce in relatively small batches. One company put out of business is too many, especially in our country's present economic state, however, FDA officials stated during a public meeting to explain their proposed rule, held in Oakland, California on May 6, 2003, that the rule would put approximately 250 companies out of business! We have been informed by NNFA, however, that based on their research this number is probably much higher. Many products, especially multi-ingredient products, will no longer be economical to manufacture and will disappear from retailers' shelves. We understand that prices of the products that remain will increase considerably. FDA has miscalculated costs most significantly by underestimating the (a) the number of batches produced by companies per year; (b) the cost to perform specific analytical tests; and (c) the number of tests that would need to be required under the proposal.

Adopting a more reasonable economic burden on companies, especially by decreasing the testing burden on the bottler, packager and distributor, would give companies more flexibility to develop testing programs around established specifications. Allowing companies to rely on verified certificates of analysis reduces the testing burden on companies. Allowing a statistical approach to finished product testing, along will allowing more flexibility in general, will also reduce costs.

We urge FDA to give full consideration to our comments while also acting swiftly to issue a final rule that is not overly burdensome and will allow the industry to continue to provide consumers with a wide variety of safe, affordable, and high-quality dietary supplements.

Sincerely,

Warren Cochrane
Owner, President