SWANSON
Health Products

August 5, 2003

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

Dear Sir or Madam,

The purpose of this letter is to express comments in regard to your publication of the proposed rule for Good Manufacturing Practices (GMP's) for the Dietary Supplement Industry. As a marketer of dietary supplement products, we applaud your publication of the proposed regulations and view the document as a step toward achieving a more positive view of nutritional supplements in the eyes of government regulatory agencies as well as consumers. However, we request that you please reconsider certain areas of the proposal as outlined in this letter.

We purchase nutritional supplements in bulk quantities from contract manufacturers and bottle them into our own labels. In order to assure that we provide consumers with high quality products, we rely on a comprehensive quality control program that includes:

- Detailed product specifications
- Vendor approval program
- Vendor documentation review including certificate of analysis
- Physical inspection of products upon receipt
- Analytical testing according to an established testing schedule to verify the information provided by the vendor
- Standard operating procedures (SOP's) for every process to assure our customers receive only high quality, properly packaged and labeled products

In fact, our SOP's have been reviewed and certified with an "A" rating by the National Nutritional Foods Association (NNFA) through their Good Manufacturing Practices certification program.

We feel the proposed rule relies too heavily on finished product testing rather than requiring systems to maintain the integrity and control over the entire process. We consider finished product testing to be extremely important; however, the increased

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testing that would be required of us, as the rule is currently written, would have a huge financial impact on our company. The proposed rule requires testing every time goods or ingredients are shipped to a new location meaning we would be required to repeat the very same testing already conducted by the manufacturer for every lot of every product. Our approximate yearly testing costs would increase an estimated 450% from $325,000 with our current testing schedule to $1,450,000 per year. As you can see, our financial impact estimates are far greater than the figures stated in the proposed rule. Unfortunately, the increased costs due to the redundant testing would inevitably be passed on to consumers.

The Food and Drug Administration must specifically delineate testing responsibilities. The final rule should specify that the testing obligation falls primarily upon the manufacturers who control the production and can monitor and test throughout the manufacturing process. The rule should allow for repackaging companies such as ours to rely on vendor approval and surveillance programs rather than performing redundant testing on every lot of every product received.

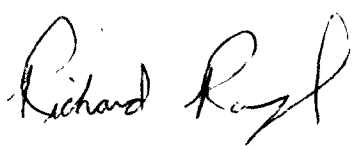
As a repackaging company, we can and do hold our contract manufacturers accountable through random independent testing of finished products. We demand that they meet or exceed our quality expectations in order to continue to supply their products to our company. Because of this contractor accountability, we are confident that we can continue to supply consumers with the highest quality products possible without relying so heavily on finished product testing of every lot.

In conclusion, we ask that you consider our comments and address the following issues in the final rule:

- Place less emphasis on final product testing
- Place more emphasis on controls throughout the entire process (require SOP's)
- Clearly delineate testing responsibilities
- Specify that the testing obligation lies primarily with the manufacturer
- Allow the use of vendor evaluation programs and vendor data verification in lieu of redundant testing

Thank you for your consideration.

Sincerely,



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