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July 24, 2003

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Docket No. 96N-0417

Dr. McClellan,

HerbaSway is a natural products manufacturer. We fully support official good manufacturing practices (GMPs) for dietary supplements; however, we are concerned about the FDA's proposal for them and believe that the final rule needs to satisfactorily address the following areas:

- **The proposal will eliminate too many small businesses.** FDA's own estimate, provided during public workshops explaining the rule, is that the final GMP rule will put up to 250 supplement manufacturers out of business because they cannot afford to comply. Other industry experts consider this to be a great underestimation. Assuming an average of 50 employees per small company, we will see at least 12,500 cases of unemployment. Add all the losses in related industries, we could see tens of thousands of cases or more. This is unacceptable to me. Products supplied by these companies are vital to the diversity, quality and price of products in a health food store.

Small manufacturers, like HerbaSway Laboratories, will have difficulty fulfilling all the proposed requirements. For example, the analytical testing for a multiple vitamin cost over \$1500. Our largest batch size to date is 70 gallons, or 5000 bottles. The analysis costs add a minimum of \$0.30 to our product costs.

New product batches would be considerably smaller, perhaps 1000 bottles. This brings the additional costs to at least \$1.50 per bottle. This would price our product out of the market before we even had the chance to launch it. Add several similar products to the line, and the costs will skyrocket.

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The ruling favors larger manufacturers that can support larger batches and distribute the additional costs over more units. Ironically, smaller batches can provide more consistent product quality. The consumer, therefore, loses out when forced to rely on huge manufacturing operations for their product.

We believe that the FDA's estimation about increased manufacturing costs are greatly underestimated and that substantially more than 250 manufacturers will disappear from the field. This hurts not only the company and their employees but also the American Consumer.

- **The proposal will eliminate too many products.** As the number of manufacturers drops, so will the offering of products on the market. New product development will be severely restricted. The additional start-up costs would be prohibitive for a small company to launch a new product, such as the above mentioned multiple vitamin. The result will be a few, big-name products for the consumer.
- **The final rule needs to be more flexible.** FDA must finalize and implement this rule so that responsible companies are able to meet flexible standards, which enable them to continue offering affordable products and stay in business. FDA must eliminate redundant testing requirements and focus more on mandating only those requirements necessary to produce safe and accurately labeled products for consumers.
- **The final rule needs to require expiration or shelf life dating.** This ensures that products are not sold to consumers beyond their predicted point of full quality. Such a requirement could be met if FDA allowed a reasonable approach to establishing and confirming such dates. FDA should require expiration dates or statements of shelf life on dietary supplements by taking a reasonable and flexible approach in the final rule to how manufacturers establish these dates and the supportive data, which must be maintained to substantiate them.

FDA should finalize GMPs in a timely fashion for the industry provided they are fair and adequately address the concerns raised by these comments. American consumers are entitled to consistent high quality and to a choice of manufacturers.

Sincerely Yours,

Jonathan Selzer

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