

Natural Product Retailers for Supplement Quality

June, 2003

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs

RE: Docket No. 96N-0417

Dr. McClellan,

I am a natural products retailer. I fully support official good manufacturing practices (GMPs) for dietary supplements; however, I am 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. 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.

Health food stores are distinguishable from other retail establishments where supplements are sold, in part, because of their ability to offer unique products and a larger supplement selection. I want these brands, which are familiar to my customers and essential to my business, to remain available. FDA absolutely must make compliance with this rule more affordable for the companies that supply these products.

- **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. Our customers are entitled to consistent high quality and to a choice of manufacturers.

Sincerely,

Mother Earth
Name and address of store:

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