Health Concerns®
COMBINING MODERN RESEARCH
AND ANCIENT WISDOM™

May 13, 2003

Re: Docket 96N-0417, Opposed to Proposed GMP in Manufacturing, Packing Dietary Ingredients and Dietary Supplements

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

Dear Sir:

As a small U.S. manufacturing company of dietary supplements, we find that the se proposed regulations are unfair and will probably put us out of business. At a minimum the proposed GMP's would increase our testing costs by $300,000 per year.

While we think GMP's are a good idea, we find that the exhausting testing procedures that appear to involve testing every herb or raw material separately, and then testing the finished product will add layers of expense which are not supported by market. In addition we do not feel that there will be significantly improved safety, as most safety issues involve imported herbal products, not domestically manufactured products. It would seem therefore that only the overseas herbal products should bear the burden of this expensive testing.

Our specific comment is that either the raw material or the finished product be tested by the manufacturer. The suppliers of the herbs do their own testing and this should be sufficient to assure quality ingredients. We are not opposed to greater testing of the finished material; however we feel that once the raw material is tested by either the supplier or the manufacturer that should be sufficient.

Finally a cost effect solution to multi ingredient products ought to be created. As most of our finished products involve multi ingredients we request that unless the regulations allow us to confirm the identity of herbs organoleptically (through the senses) that testing procedures via analytical tests or microscopic may increase our annual cost to well over $300, 000, an expense our small business cannot afford.

Sincerely,

Andrew Gaeddert
Health Concerns
President

96N-0417 C 109

tel. 510-639-0280 fax. 510-639-9140 8001 Capwell Drive, Oakland, CA 94621 www.healthconcerns.com/pro