The Korner Pharmacy

P.O. Box 946 • 4141 Highway 525 • Clinton, WA 98236
(360) 341-3880 • Fax (360) 341-3886

May 27, 2003

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

Dear Sir or Madam,

I have reviewed a recent publication released by your office entitled "Good Manufacturing Practices for the Dietary Supplement Industry." I own a retail pharmacy that promotes the use of supplements and I agree with your proposed regulations. I also have a few suggestions for your consideration.

The following issues do not seem to be addressed in your publication and I have concern that manufacturers are not required to:

- Conduct stability testing and label products with earliest expiration dates
- Utilize standard operating procedures to ensure consistent production performance
- Test supplements for dissolution and disintegration such as USP testing that is done for pharmaceutical grade products
- Follow manufacturing equipment cleaning and sanitation procedures

It is my opinion that the above components are necessary for a quality control program. In order to incorporate these elements the economic impact analysis included in your proposed regulations would need to be modified. I am concerned that if these components are not included and the financial implications are not considered, this could have a negative impact on the choices of supplements that I rely on for my customers.

It is my request that the above suggestions be incorporated into a revised regulatory document that is inclusive of the economic impacts for accurate reflection of program costs.

Thank you,

Karen L. Thomas
Owner

96N-0417 C 117