Cape Apothecary, Inc
1384 Cape St. Claire Rd.
Annapolis, MD 21401
757-3522

September 25, 2003

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

Dear Sir or Madam,

I am writing this letter to express comments in regard to your recent publication of Good Manufacturing Practices for the Dietary Supplement Industry. I applaud your publication of proposed regulations but request that you re-think the proposal in the following manner.

I believe that it is important that manufacturers of dietary supplements be required to:

1) Conduct Dissolution and Disintegration Testing of Supplements.
2) Conduct Stability Testing and Label their products with Expiration Dates.
3) Insure Production Performance through the use of written Standard Operating Procedures.
4) Develop, validate and follow written Cleaning and Sanitation Procedures.
5) Utilize an On-Site Laboratory and Quality Control Department.
6) Utilize the above 5 points as part of a comprehensive quality control program – not rely so totally as proposed on 100% inspection of finished production batches.

The economic impact analysis that you have included in the proposed regulations is flawed because it does not address the above necessary components in the quality control program. In addition the economic analysis that you have done, dramatically underestimates the costs that would be required to implement your proposal. I am concerned that because the proposal and economic analysis is flawed, this could have a negative impact on the choices of supplements that I rely on for my customers.

I request that you incorporate my comments into a revised set of regulations and revise the economic impacts to more accurately reflect the true cost of the program.

Best regards,

T. Wilson

Owner / Operator