



Rebecca's NATURAL FOOD

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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 Supplements.
- 2) Conduct Stability Testing and Label their products with Expiration Dates.
- 3) Ensure Production Performances through the use of written Standard Operating Procedures.
- 4) Develop, validate and follow written Cleaning and Sanitation Procedures.
- 5) Utilize the above 4 points as part of a comprehensive quality control program—not rely on 100% inspection of finished production batches.

The economic impact analysis that you have included in the proposed regulations 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 the current proposal and economic analysis 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.

Sincerely,

Susan Dunlap
Nutrition Information Specialist, Rebecca's Natural Food

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