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Dockets Management Branch
Food & Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

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Re: Docket # 96N-0417

August 8, 2003

To whom it may concern:

Concerning the FDA's Proposed Rule for Current Good Manufacturing Practice for Dietary Supplements I have the following comments, concerns and suggestions:

V Subpart E

My main concerns are regarding Subpart E and I would like to address it as a unit as opposed to comment on each sub paragraph. As I understand this section what is proposed is that every raw material in a dietary supplement, even though a certificate of analysis is received from a reliable vendor, must be analyzed to verify its composition, purity, identity, quality and strength. The finished product then must be analyzed upon completion to verify the existence and quantity of every ingredient. My concerns are as followed:

1. For my manufacturer to analyze both the raw materials and the finished products for every batch for every ingredient would make it cost prohibitive for me to produce my products. The price to the stores I supply and then to the consumer would be more than twice what they are now. I am concerned that the efforts to protect the consumer will result in denying them the opportunity to afford dietary supplements of quality.

a. I offer the suggestion that requiring analysis of finished products on a random 'spot checking' basis may be enough to pull unscrupulous manufacturers in line as well as demand quality manufacturers.

b. I offer the suggestion that the certificate of analysis that comes with the raw materials be sufficient to identify what the raw materials contain as long as the materials are sealed properly and have stayed sealed. Perhaps stricter regulations on sealing materials (random spot checking these suppliers may also encourage honesty).

2. Perhaps for certain ingredients it is easy to identify and analyze like synthetic vitamins and identifiable minerals. But as I understand it, in addition to excessively expensive, it is sometimes almost impossible to identify all the naturally occurring ingredients in herbs and plants. As I understand it, trying to analyze these would be very cumbersome, costly, time consuming and in some cases impossible at this point in time and science.

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