NATURTECH
NATURAL TECHNOLOGY INCORPORATED

August 8, 2003

1494 '03 AUG 11 A9:21

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

Re: Docket # 96N-0417

To Whom It May Concern:

Concerning the FDA's Proposed Rule for Current Good Manufacturing Practice for Dietary Supplements I would like to offer the following comments and suggestions:

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We would strongly recommend that the term for qualification of staff should be expressed as a "background of education, training or experience." We find some employees who have the education but not the experience and others who have had training and experience and are very proficient in manufacturing processes and/or testing.

Also in this section concerning definitions, we have concerns for the definition of sanitize. First, if a surface is properly cleaned, it will have a small number of microorganisms. If a swab was tested before and after the sanitizing procedure, a 5k reduction would be impossible. The objective we are all attempting to achieve is equipment as nearly sterile as possible. Testing the sanitizing procedures with swabs after sanitizing on a scheduled basis would appear to be more than adequate. If the proposed regulations are requiring testing after each sanitizing procedure, that would mean that for a manufacturer open five days a week any kettle would only be available three days a week maximum. This would create a hardship, particularly for small manufacturers with more limited kettle space.

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The same observation as 111.12 is that the requirements should be "a background of education or experience or both for supervisors."

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Same comments on requirements as in 111.13

96N-0417

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V Subpart E

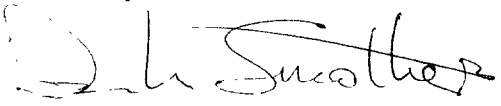
I choose to address Subpart E as a unit and not comment on each sub paragraph. As I understand this section what is proposed is that every raw material in a dietary supplement, even though we receive a Certificate of Analysis from a reliable vendor, must be analyzed to verify its composition, purity, identity, quality and strength. The finished product must then be analyzed upon completion to verify the existence and quantity of every ingredient. My concerns are as follows:

1. Many of the raw materials used in dietary supplements do not have a qualified, approved and validated analytical procedure to identify them in the terms described.
2. A small company, such as ours, usually purchases vitamins, minerals, herbs, amino acids and other specialty products in relatively small quantities to keep our cash flow under control. If we must have each one analyzed, it will materially increase our raw material cost. Even if we purchase larger quantities, it will impose much higher raw material costs on our company. If we can qualify a vendor as we do with active ingredients in OTC topical drugs and then use their Certificates of Analyses, that will give control and assurance of quality.
3. In the products where it is possible to analyze for all of the ingredients, it will be excessively expensive to have them analyzed in a complex formula, particularly in a small batch. In the case of many of our small marketers the increased unit-cost will increase dramatically.
4. I have consulted with some excellent analytical chemists in the supplement industry who have confirmed that it will be next to impossible to analyze for a complex mixture of herbs in a supplement formula. It might be possible to develop a curve that would constitute a "fingerprint" of such a batch and each manufactured batch could be compared to this and have to compare in this type of qualitative procedure to the standard within a certain percentage of points.

There will also be some other types of supplements that will interfere with other ingredients when analysis is a attempted.

In conclusion, I applaud the agency for the attempt to tighten the requirements for Dietary Supplements, but I plead with them to not regulate the small manufacturers and marketers out of business Most of us are sincerely trying to be in compliance to the best of our ability.

Sincerely,



Don L. Smothers
President