Micro Powders & Braig, Inc.

The Oyster Shell & Calcium Carbonate Specialist

May 12, 2003

To Whom it May Concern:

Not only do I agree with and applaud the FDA's goal to protect the consumer and assure that all dietary supplements are what they are reported to be on the label, and that they are safe for consumption. After reading the proposal several times and discussing them with representatives from a number of companies in our industry, the proposal as written is in my opinion excessive to the point of putting dietary ingredients/supplements under more stringent regulations than drugs. It is also my belief that the consumer would be better served if the industry, FDA, and FTC could work together on weeding out the "bad apples" in our industry. I believe that it would benefit the American public greatly if together we could eliminate grossly outrageous label claims, which trick the consumer into over paying for supplements that really have no additional benefits than a cheaper comparable product. An example of this would be Coral Calcium, which claims that it can cure cancer, or the weight loss products that are advertised to help you lose weight and inches while you modify nothing else in your life. These are the issues that in my mind are more harmful to the consumer than anything else. I would be lying if I stated to the FDA that every company in my industry produces their product under some form of GMPs and their goal is to produce the highest quality product possible. Unfortunately, even with this extremely restrictive proposal, these companies will still be in business. If they are not following currently enforceable Federal Laws, why should we believe they would follow any new guidelines?

In section 111.35 (g), (1) and (2) of the proposal, the agency states: "(1) You must test each finished batch of the dietary ingredient or dietary supplement produced before releasing for distribution to determine whether established specifications for identity, purity, quality, strength, and composition are met, provided that there are scientifically valid analytical methods available to conduct such testing. (2) For any specification for identity, purity, quality, strength, or composition for which you document cannot be tested on the finished batch of dietary ingredient or dietary supplement, because there is no scientifically valid analytical method available for such testing, then you must: (i) Perform testing on each lot of components, dietary ingredients or dietary supplements received to determine whether such specification is met; and..."

This section clearly defines that it is the intent of the agency that manufacturers of dietary ingredients/supplements must test every ingredient in the finished product at some point in the manufacturing process or upon receipt of the raw material, before use. These tests would have to be done on every shipment received of the material, even if you have received and tested that same lot number in the past. This section, in my opinion, clearly puts our industry under stricter regulations than a drug firm, whose products consumers take to sustain not only life, but also the quality of life.

In CFR 21 section 211.64 it states: "(a) For each batch of a drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release."
Using one of my finished products as an example, Calcium Carbonate Granulation. I would be required to test not only the level of the active ingredient (Calcium) in my product, but also the Acacia Gum and Maltodextrin that I used as binders in the granulation, at some point in the manufacturing process. In comparison, if I were granulating synthetic levothyroxine sodium, the active ingredient in the drug Synthroid. I would only be required to test the level of the active ingredient (levothyroxine) in the finished product. The Acacia Gum and Maltodextrin could be released to manufacturing based on the manufacture's C of A, and skip lot tested, as needed. It is my belief that someone who has to take Synthroid everyday for the rest of their life would be better served if the drug were subject to stricter

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3909 B Park Road · Benicia, CA 94510 · Ph 707-745-1446 Fax 707-745-1646

testing, than someone who takes a Calcium tablet. Also, the person taking the Calcium tablet has more choices in what brand they buy and trust, than the person whose doctor prescribes the drug.

I have one important question for the agency. Why is it that a drug firm can release raw materials into manufacturing based on a supplier's C of A, but a dietary firm cannot? The agency's response to this issue seems to be one that everyone in our industry would like to hear.

The proposal defines **sanitize** as "to adequately treat equipment, containers, utensils, or any other dietary product contact surface by applying cumulative heat or chemicals on cleaned food contact surfaces that when evaluated for efficacy, yield a reduction of 5 logs, which is equal to 99.999 percent reduction, of representative disease microorganisms of public health significance and substantially reduce the numbers of other undesirable microorganisms, but without adversely affecting the product or its safety to the consumer." This would mean shutting down a piece of equipment for at least one week, while the swabs are out for testing. Also, requiring a 5 log reduction as part of the definitions is over kill. What if my test results will not allow a 5 log reduction, because the equipment is sterilized? If I were producing a drug product I would be required under CFR 21 211.67 Equipment cleaning and maintenance to "(a) Equipment and utensils shall be cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond official or other established requirements." This is another example of the proposal treating dietary ingredients/supplements to a higher standard than a drug.

At the FDA meeting on May 6, 2003 in Oakland, Ca, FDA representative Steve Musser stated that we cannot use a supplier's C of A to release material, but we must not only have the C of A on file, but also all the supporting laboratory analytical documentation from the supplier on file supporting their C of A. It is my belief that requiring all of this documentation for a document that they agency has all but stated is useless, puts an unnecessary burden on every manufacture of in the dietary industry. Based on Mr. Musser statement, I would be required to have not only my suppliers' C of As and all of their supporting documentation, my outside laboratories results and documentation on file, but I would have to send all of this documentation to my customer who would be required to have it on file, in addition to all of their test results and documentation on the products in their files. This would create a mountain of paperwork to be collected at every step of the dietary manufacturing chain for documents (C of As) that the agency has declared useless.

In addition, Mr. Musser stated that we could use our suppliers as an outside laboratory, if we collect a representative sample and send it to the supplier for analysis. This statement has me at a loss, on one hand the agency is telling me that I cannot trust my suppliers' results on their C of A, but can trust their results on material that I send them to analyze.

At the same meeting, FDA representative Peter Vardon stated that the agency has estimated that the cost to comply with the proposal for a small business would be a one time $37,000 cost. Not only is this estimation extremely low, it has no basis in reality. In doing my own calculations in order to estimate the annual increased cost for my small business, I am calculating a cost in excess of $550,000/year. These costs will only increase over time, not decrease as Mr. Verdon stated. I have only used 3 factors in my calculation:

1. Cost of additional labor
2. Cost of additional laboratory testing
3. Cost of an additional warehouse and trucking

Mr. Vardon also stated that the agency considers it reasonable that 15 to 23% of the firms in the current dietary manufacturing chain are forced to cease operations, due to this proposal. It seems excessive for 15 to 23% of our industry to suffer because of the 1 to 2% of "bad apples".

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It is my hope that the agency will look at this proposal, and compare it to the established regulations for both Food and Drug manufactures and brings the dietary manufactures into the middle ground between the two. If not, I would urge the agency to declare dietary ingredients and supplements as drugs and allow us to follow the less restrictive drug cGMP-s. In other countries our industry falls under the drug category.

Sincerely,

Kenneth Abramowitz
Operations Manager

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