October 1, 2004

Via Federal Express Delivery

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

Re: Docket No. 2004N-0230 – Food; Current Good Manufacturing Practice Regulations; Public Meetings

Dear Sir/Madam:

Nutraceutical Corporation (Nutraceutical) submits the attached comments on the Food and Drug Administration's (FDA's) proposed regulations for the current good manufacturing practices (CGMPs) in manufacturing, packing, or holding human food regulations. Nutraceutical acknowledges that the attached comments are submitted approximately three weeks after the date established by FDA, but requests that FDA exercise its discretion to consider these comments in any case. There should be no prejudice to any party since the FDA has had little time to even review the existing submissions.

Nutraceutical is one of the largest manufacturers and marketers of dietary supplement products in the United States, with over 3,000 SKUs of products manufactured, packaged or bottled in our facilities. The majority of these products are dietary supplements, but many of them are foods. Nutraceutical and other responsible manufacturers have already implemented effective CGMPs based in large part on prior industry submissions.

Nutraceutical has drafted its attached responses to the FDA's questions set out in docket by first listing the question and then listing Nutraceutical's response. Specifically, Nutraceutical has attempted to respond to the potential hazards in the food supply emphasized by the FDA during the production or warehousing of food: physical hazards, chemical hazards, and microbiological hazards.

Respectfully submitted,

NUTRACEUTICAL CORPORATION

Stanley E. Soper
Vice President, Legal Affairs

Attachment

2004N-0230 C11

Questions and Answers:

In general, do the current good manufacturing regulations (part 110) need to be revised or otherwise modernized? If yes, please describe generally the shortcomings of the current regulations.

At the outset, we note that Nutraceutical believes that the current food CGMPs do not need to be revised or updated. The few isolated cases in which manufacturers, packagers and bottlers of food products are experiencing or have experienced issues or problems seem to have arisen from failure to conform to existing CGMPs and would not be addressed or solved by revising or updating those CGMPs. FDA's focus should be on enforcement of existing CGMPs.

Please note that the remaining points in this letter are intended to address the specifics of each of FDA's questions and are submitted for consideration in the event FDA ultimately decides to revise or update the existing food CGMPs.

Preliminarily, we note that dietary supplement CGMPs have not yet been finalized by FDA. It is important that food CGMPs be generally consistent with dietary supplement CGMPs, and vice versa, since dietary supplements are a subset of foods. In many cases both foods and supplements are manufactured in the same facilities and on the same manufacturing lines. Examples include protein powder drink mixes, which can be labeled as foods or dietary supplements. It would make no sense to have significantly different CGMPs simply because the same product is labeled as a food or a dietary supplement.

1. Which practices specified in current part 110 are most effective at preventing each type of food hazard? Which practices are least effective at such prevention?

No comment.

2. In today's food manufacturing environment, what conditions, practices, or other factors are the principal contributors to each type of food hazard?

Biological – low level bacterial and microbial contamination can be an issue with certain raw materials. The conditions leading to this issue may be inherent in the types of materials themselves, but the materials are more susceptible if inadequate attention is paid to proper packaging, storage, shipping and humidity conditions. Existing regulations are unclear as to the proper method of addressing these conditions and there are inconsistencies in methods used by various suppliers. Greater clarity of acceptable practices and levels could assist in addressing this issue.

Chemical – one of the primary concerns for the modern food supply is the widespread existence of man-made chemicals in the environment. Their presence in the environment stems from their widespread use as pesticides, fungicides, herbicides and industrial chemicals, generally under approved federal and state guidelines and regulations. Because of their widespread use and presence, they are becoming more often present in the food supply, and yet there are no consistent or

logical regulatory or enforcement approaches to govern their presence in the food supply. States such as California have taken it into their hands to establish their own regulatory approaches (such as Proposition 65) that are often poorly conceived and enforced in an erratic and illogical manner (via private plaintiff lawyers). The federal government seems to take an approach that is often reactionary and based on political pressure or the "issue of the day" rather than on public health and safety. To the extent that the presence of chemicals is an issue in dietary supplements, it is more of an issue in the food supply, and the regulatory and enforcement program for the two should be similar (if not identical) and logical. Also, it is important that the approach be consistent and national, rather than created or enforced at a state level, which gives rise to inconsistencies between and among states and the federal government.

Physical – one of the primary concerns for our food supply is the ability of those with ties to terrorist organizations to enter and leave the geographical boundaries of the United States and the apparent inability of the federal government to manage or control the country's borders. Trying to impose highly stringent controls at a local level (i.e., with each food manufacturer) is far less effective than implementing more effective controls at the border as well as increased enforcement and prosecution by appropriate law enforcement agencies. Once a person with inappropriate intentions is inside the country, he or she could find ways to infiltrate and contaminate the food supplies even if highly stringent controls and physical procedures were in place and followed. For example, there is almost no way to prevent contamination of foods at a retail level (i.e., to prevent contamination of produce or bulk foods). Therefore, the most effective means of addressing this issue is at a national level and involves better controls on immigration and border access.

3. If the CGMP regulations were revised, which type or types of food hazards could be most readily prevented through CGMP-type controls?

Biological and chemical.

4. Are there preventive controls, in addition to those set out in part 110, needed to reduce, control, or eliminate each of the three types of food hazards? If yes, please identify the specific hazard and the particular controls, that would reduce, control, or eliminate the hazard.

To the extent possible, the specifics of the controls should be left to the manufacturer and only general rules and concepts should be found in the CGMPs. However, as mentioned above, any preventive controls adopted for foods should be generally consistent with those adopted for dietary supplements.

5. What concepts or underlying principles should guide FDA's adoption of new preventive controls?

See previous comments. Also, the purpose of food CGMPs should be to improve and harmonize processes and sanitation rather than prevent adulteration.

6. How should the effectiveness of preventive controls for each of the three types of hazards be most accurately measured?

Random testing and audits.

7. In today's food manufacturing environment, what are the principal contributors to the presence of undeclared allergens in food? For example, do labeling errors or cross-contamination contribute? Which preventive controls could help reduce, control, or eliminate the presence of undeclared allergens in food?

The ingredients found in foods, as well as those found in dietary supplements, can come from a wide variety of sources, including numerous countries. Often these ingredients are subjected to processing steps at various stages of the supply chain, and are sometimes sold by a broker or other party who may not have knowledge of these specific processes or manufacturing steps. The labels of these ingredients may not disclose the specifics of these steps or of the contents of every minute residue or component found in the raw material. This is due in part to ambiguities in labeling regulations, to the difficulty of locating obscure regulations, to potential conflicts between regulations issued by different regulatory bodies (i.e., FDA, EPA, California, etc.) and to subjective interpretations by vendors and brokers. Because of the foregoing, it is often difficult for a manufacturer to learn about the presence of small amounts of potential allergens or contaminants, or even to be aware of the need to test for the same. However, it is often not the manufacturing process that is the issue or the problem, but these underlying ambiguities and conflicts that result in lack of awareness and disclosure by the supplier. Greater clarity with respect to the regulations themselves, and greater clarity with respect to the responsibility of suppliers in the food chain to provide information about their raw material ingredients, would be helpful.

With regard to the manufacturing steps, we have no comments other than those previously provided.

8. Are there existing quality systems or standards (such as international standards) that FDA should consider as part of the agency's exploration of food CGMP modernization? Please identify these systems or standards and explain what their consideration might contribute to this effort.

No comment.

9. There is a broad variation within the food manufacturing and processing industry, including variations in size of establishments, the nature of the food produced, the degree to which the food is processed, and the vulnerability of a particular operation to physical, chemical, or microbial hazards. How, if at all, should the CGMP regulations be revised to take into account such variation? For example, should there be different sets of preventive controls for identifiable segments of the food industry, such as different storage temperature limits?

Any final regulations should apply equally to and on the same dates to large and small businesses. Otherwise, consumers would not be able to determine which food products comply with the food CGMPs and which do not. It is unreasonable to reduce the economic burden on small entities at the expense of the public's health.

Additionally, as stated previously, CGMPs should provide broad principles and concepts, not specific details. Requiring different storage temperature limits would violate this approach.

10. There are a number of measures, procedures, and programs that help to ensure that preventive controls are carried out adequately. These include the following items:

- Training programs for managers and/or workers;
- Audit programs;
- Written records, e.g., batch records, sanitation records;
- Validation of control measures;
- Written sanitation standard operating procedures;
- Food label review and control program; and
- Testing of incoming raw materials, in process materials, or finished products.

Which (if any) of these should be required practices for food and manufacturers and why? Which (if any) of these should be recommended practices for food manufacturers and processors and why?

Previous comments already address the fact that the food CGMPs need to be generally consistent with dietary supplement CGMPs, as well as the fact that food CGMPs should focus on general principles and concepts rather than specific details and requirements.

11. Are there preventive controls in addition to those already set out in part 110 for food distributors, wholesalers, and warehousers that are needed to help ensure the safe and sanitary holding of food? If yes, please identify the controls by hazard and sector of the industry.

See comments to Number 7 above.