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Ms. Karen Strauss
Center for Food Safety and Applied Nutrition (HFS-821)
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

Via Fax (301)-436-2636

Dear Ms. Strauss:

Kemin Foods, L.C. is pleased to have an opportunity to comment on the proposed rules governing good manufacturing practices (GMP) for dietary supplements. As a general observation, we are concerned that these rules when finally promulgated be readily enforceable without undue legal challenges. It appears to us that in some instances certain proposed rules are *ultra vires* of the statutory language in the Federal Food Drug and Cosmetic Act directing the FDA to model these rules on the food GMPs. In certain areas of the rules, the proposed language exceeds even existing drug GMPs. We advocate a flexible approach to these rules so that manufacturers such as ourselves can continue to supply high quality, safe, dietary supplements and ingredients to the marketplace.

We are in accord with the comments the FDA has received from NNFA and we adopt those comments as our own. We have additional comments on rule 111.6 relating to the exclusionary language included in the rule.

We are also concerned that these rules do not work at cross-purposes with regulations associated with bioterrorism. As much as possible we believe these rules should be harmonized to reduce costs and increase efficiencies for manufacturers.

Our final concern is the effective date for these regulations and the difference in time for compliance between large and small firms. We believe that there should be no difference for compliance periods. All firms should be required to comply with the proposed rules at the same time.

COMMENTS:

SECTION 111.6 Exclusions

The rule provides that the "regulations in this part do not apply to a person engaged solely in activities related to the harvesting, storage, or distribution of raw agricultural commodities that will be incorporated into a dietary ingredient or dietary supplement by other persons".

We seek clarification of the FDA's position regarding whether manufacturers that control either by contract or with a separate subsidiary or otherwise, their source of botanicals for dietary supplements or ingredients are subject to these rules. The use of the word "solely" appears to limit the exclusionary language to those entities whose only business is the harvesting, storage or distribution of raw agricultural commodities.

We believe that rule should read as follows:

> The regulations in this part do not apply to a person engaged in activities related to the harvesting, storage, or distribution of raw agricultural commodities where these activities do not create a distinct commodity or product that will be incorporated into a dietary ingredient or dietary supplement by other persons.

Omitting the word "solely" from the rule will make the rule more flexible and workable. If manufacturers contract for raw agricultural commodities or if a manufacturer grows a botanical itself, the exclusionary language is not broad enough to exclude producers from the GMP requirements set forth in the rule because Section 111.1 is so broad. (You are subject to the regulations in this part if you manufacture, package, or hold a dietary ingredient or dietary supplement.)

Manufacturers using contract growers would be required to make sure that their growers were adhering to all of the requirements of the GMPs; requirements that these concerns could not meet because of the inherent nature of the business of agriculture (e.g., a potato grower could not ensure a 5 log reduction of soil pathogens on potatoes as the grower harvests potatoes).

Moreover, the use of the word "solely" does not further the stated goals of the rule to achieve identity, purity, quality, strength and composition of a dietary supplement because while contamination can occur in the raw agricultural stage of a process, the real concern is in the further processing of the raw agricultural commodity where contaminants can be removed and the dietary supplement is produced. It is at this point where the rule will be most effective in preventing contaminated products from entering the food supply.

The additional language we have suggested draws a reasonably bright line between activities that preserve a raw agricultural commodity for storage and transportation and

those activities that create a distinct commodity or product. This interpretation is consistent with the legislative history of 21 USC §321(r) and was adopted by the EPA when it was attempting to determine a boundary line between processed food and raw agricultural commodities. See 61 Fed. Reg. at 2386 (January 25, 1996).

The legislative history of 21 USC § 32(r), explains that the term raw agricultural commodity is intended to apply to "food in its raw or natural state as usually purchased by the consumer or food processor." H. Rep. No. 1385, 83d Cong., 2d Sess. 6 (1954), XII Leg. Hist. 838. Both House and Senate committee reports list the following examples of foods Congress considered to be raw agricultural commodities: "fresh fruits and vegetables, grains, nuts, eggs, and milk and similar agricultural produce grown or produced at the farm level." Id.; S. Rep. 1635, 83d Cong., 2d Sess. 6, XII Leg. Hist. at 1014. On the other hand, both reports mention apple juice and applesauce as examples of processed foods not considered to be raw agricultural commodities. Id. The Senate report alone also notes that "sun-dried or artificially dehydrated fruits" should not be considered raw agricultural commodities. S. Rep. 1635, 83d Cong., 2d Sess. 6, XII Leg. Hist. at 1014.

The legislative history suggests that Congress intended to draw a distinction between routine drying for storage and transportation purposes and drying intended to create a new product. Under this approach, grains and nuts, and similar commodities such as legumes, hays, and hops, would be treated as raw agricultural commodities because such commodities are routinely dried for storage or transportation purposes. Dried fruits for example, would not be raw agricultural commodities because the drying of these commodities would be done to create a distinct commodity. This approach treats the Senate report's reference to dried fruit not as an example of a process (drying) that removes a food from the raw agricultural commodity category but as a type of food (newly created food products) that would not be considered raw agricultural commodities.

I attempted to post these comments electronically to the FDA's web site but I received an error message on each attempt. I will be pleased to send these comments to you electronically at your convenience.

Thank you for this opportunity to comment on these rules.

Sincerely,

KEMIN FOODS, L.C.

Elizabeth A. Nelson

Elizabeth A. Nelson
Corporate Counsel

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