

Biologics Evaluation and Research (CBER) has developed guidances for industry that describe steps that manufacturers should take. For example, CBER guidances have recommendations that address viral safety, infections, disease risks, and BSE-risk reduction of biologic products that are animal-derived (*see* 63 FR 51074, September 24, 1998, and 63 FR 50244, September 21, 1998) (Refs. 51 and 52). Because we believe that the use of an animal-derived material, substance, or tissue in a dietary supplement may raise many of the same serious public health and safety issues as animal-derived materials, substances, or tissues, in a biologic, we are considering whether the procedures that CBER recommends for a product with animal-derived materials, substances, or tissues would be appropriate for dietary ingredients and dietary supplements that contain animal-derived materials, substances, or tissues. We, therefore, invite comment on whether there should be specific CGMP requirements for the use of animal-derived materials, substances, or tissues in dietary ingredients and dietary supplements. We invite comment on these issues and specifically on whether there is a scientific basis for FDA to treat animal-derived dietary ingredients in a manner that is different from, or that would offer less protection than, what is recommended for animal-derived biologics when the same public health and safety risks may be present. We also invite comment on our legal authority with respect to these issues.

5. Exclusions (Proposed § 111.6)

Proposed § 111.6 would state that these CGMP regulations 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. This proposed exclusion is similar to the exclusion in § 110.19 for raw agricultural commodities. Accordingly, persons who engage in such activities related to raw agricultural commodities (which are defined in section 201(r) of the act), although not subject to these proposed CGMP regulations under section 402(g) of the act, would continue to be subject to other adulteration provisions in section 402 of the act.

We recognize that including in the proposed rule persons who engage in the activities related to the harvesting, storage, or distribution of such commodities, as described previously, could reduce the risk of microbial

contamination in dietary ingredients and dietary supplements. Nevertheless, the proposal does not contain requirements for persons handling such commodities before distribution to a dietary ingredient or dietary supplement manufacturer because the scientific basis for reducing or eliminating pathogens in various settings is evolving. We invite comments on whether we should include provisions in the CGMP proposal that would include persons who handle raw agricultural commodities.

Even though the proposed rule would not cover persons who harvest or otherwise handle raw agricultural commodities before distribution of these commodities to a dietary ingredient or dietary supplement manufacturer, we recommend some practices to help you minimize microbial food safety hazards in such commodities that you may use in a dietary ingredient or dietary supplement. We recommend that you adapt, to your practices, the good agricultural practices (GAPs) and good manufacturing practices for fruits and vegetables that we issued as a guidance document: "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (Ref. 53). This guidance document includes recommended GAPs for water, worker health and hygiene, sanitary facilities, field sanitation, packing, and transportation. Those who harvest, store, or distribute raw agricultural commodities for incorporation into dietary ingredients or dietary supplements should adapt these practices to their specific operations.

B. Personnel (Proposed Subpart B)

Proposed subpart B contains three provisions dealing with personnel matters. In general, the proposed provisions are similar to the current CGMP requirements for food personnel in § 110.10.

1. What Microbial Contamination and Hygiene Requirements Apply? (Proposed § 111.10)

Individuals who handle components or dietary supplements may affect the purity or quality of those components or dietary supplements if they fail to take precautions to guard against microbial contamination or other types of contamination. For example, an employee who has an illness could unintentionally transfer bacteria or viruses causing such illness to a dietary supplement by simply handling the dietary supplement.

Proposed § 111.10(a), therefore, would require that you take measures to exclude from any operations any person

who might be a source of microbial contamination of any material including components, dietary ingredients, dietary supplements, or contact surfaces used in the manufacture, packaging, or holding of a dietary ingredient or a dietary supplement. We based proposed § 111.10(a) on similar requirements in § 110.10.

Proposed § 111.10(a)(1) would require that you exclude any person who, by medical examination or supervisory observation, is shown to have, or appears to have an illness, open lesion (such as a boil, sore, or an infected wound), or any other abnormal source of microbial contamination from any operations, which may be expected to result in microbial contamination of components, dietary ingredients, dietary supplements, or contact surfaces, from working in any operations until the condition is corrected. For example, if an employee tells you that his or her physician has diagnosed that the employee has a fever, and the employee normally handles your dietary supplements, you must take steps to ensure that the employee does not come into contact with your dietary supplements because the fever may suggest that the employee has an infection and there is a reasonable possibility of contamination. Likewise, if your supervisors see that an employee has an open wound or sore, and the employee normally handles dietary ingredients, you must take steps to ensure that he or she is excluded from handling dietary ingredients because the open wound or sore could be a source of microbial contamination and because there is a reasonable possibility of contamination.

Proposed § 111.10(a)(2) would require that you instruct your employees to notify their supervisor(s) if they have, or if there is a reasonable possibility that they have, a health condition that could contaminate any components, dietary ingredients, dietary supplements, or any contact surface.

Proposed § 111.10(b) would apply if you work in operations where adulteration of components, dietary ingredients, dietary supplements, or contact surfaces may occur. The proposal would require that you use hygienic practices to the extent necessary to protect against contamination of those components, dietary ingredients, dietary supplements, or contact surfaces.

These hygienic practices would include, but would not be limited to:

- Wearing outer garments in a manner that protects against contamination of components, dietary ingredients, dietary supplements, or any