

contamination and mixups. A dietary ingredient or dietary supplement under this proposed rule would require a material review and disposition decision when the components, dietary ingredients, or dietary supplements deviate from specifications. As previously explained, the specifications established as production and process controls under proposed subpart E of part 111, are regulatory specifications. Thus, a deviation from such a specification means that the components, dietary ingredients, or dietary supplements may be adulterated. Any component, dietary ingredient, or dietary supplement that may be adulterated must be segregated from such material that meets specifications so that it does not become a source of contamination. The proposal would require that you hold these components, dietary ingredients, and dietary supplements in a manner that protects against contamination and mixups.

Proposed § 111.65(c)(8) would require that you perform mechanical manufacturing steps (such as cutting, sorting, inspecting, shredding, drying, grinding, blending, and sifting) by any effective means to protect the dietary ingredients or dietary supplements against contamination. Such steps must include consideration of cleaning and sanitizing contact surfaces, using temperature controls, and using time controls. For example, when blending components, if you use a mixer that has not been cleaned and sanitized, your blended material may become contaminated with microorganisms, including microbial pathogens. Thus, it is important to clean and sanitize your mixer before use.

Proposed § 111.65(c)(9) would require that you use effective measures, such as filters, traps, magnets, or electronic metal detectors, to protect against the inclusion of metal or other foreign material in your components, dietary ingredients, or dietary supplements. This proposed requirement is intended to exclude foreign and extraneous matter that would contaminate components, dietary ingredients, or dietary supplements. The purpose of this proposed requirement is not to exclude dietary ingredients that are intended to be used and that are of mineral origin.

One comment to the ANPRM suggested that we require the use of effective measures to protect against the inclusion of metal or other extraneous material in dietary products when there is reason to suspect that the product is contaminated by metal or other extraneous material. The comment

stated that manufacturers typically are able to identify the particular piece of equipment that is the source of the metal contamination.

We disagree with the comment. The purpose behind proposed § 111.65(c)(9) is to ensure that no metal or foreign material becomes a source of possible contamination and not to establish mechanisms to be used after contamination has or is suspected to have occurred. We believe that the most practical way to protect against the inclusion of metal and foreign material is to require that you use effective measures during the manufacturing operations. The source of metal contamination is not limited to equipment and we previously emphasize the need to maintain equipment to prevent such contamination. Metal contamination also may occur during harvesting of natural products and use of utensils such as metal brushes. Therefore, because we believe that it is not possible to identify and eliminate all possible sources of metal contamination or to determine when measures would be necessary to eliminate such contamination, proposed § 111.65(c)(9) would require that you use effective measures to protect against the inclusion of metal and foreign material for all your manufacturing operations.

Proposed § 111.65(c)(10) would require that you segregate and identify all containers for a specific batch of dietary ingredients or dietary supplements to identify their contents and, where necessary, the phase of manufacturing. This proposed requirement is intended to protect ingredients or dietary supplements from potential contamination or misuse during manufacturing or storage. Identifications of these items will enable you to determine accurately the status of all batches of dietary ingredients or dietary supplements during all stages of the manufacturing process, will help to prevent mixups in the addition of components or dietary ingredients to the dietary supplement and will facilitate prompt action if any problems in processing are identified.

Proposed § 111.65(c)(11) would require that you identify all processing lines and major equipment used during manufacturing and to indicate their contents, including the name of the dietary ingredient or dietary supplement and the specific batch or lot number and, when necessary, the phase of manufacturing. The same reasons given for proposed § 111.65(c)(10) apply to this proposed requirement.

Proposed § 111.65(d) would require that you conduct a material review and

make a disposition decision in accordance with proposed § 111.35(i) for any component, dietary ingredient, or dietary supplement that fails to meet specifications or that is, or may be, adulterated. If the material review and disposition decision allows you to reprocess the component, dietary ingredient, or dietary supplement, proposed § 111.65(d) would require that you retest or reexamine it to ensure that it meets specifications and is approved by the quality control unit.

The person who performs the material review and disposition review required in accordance with this section would be required to document at the time of performance the results of the material review and disposition decision. In accordance with § 111.50(d), such documentation must be maintained with the batch production record.

We invite comment on whether we should require, in a final rule, that you establish and follow written procedures to implement the manufacturing operations required in proposed § 111.65. If comments assert that written procedures are necessary, comments should include an explanation of why the requirement is necessary to prevent adulteration including how such a requirement would ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement.

Further, we seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.