

to be unsuitable for use, such material would be adulterated and not be suitable for reprocessing. Therefore, to prevent contamination of nonrejected material, you must quarantine the rejected material before disposal. The proposed rule would not specify any particular mechanism for how you quarantine the material, instead, you would have discretion in deciding what actions to take or what process to use.

You also should note that, by referring to items that are rejected and unsuitable for use, proposed § 111.74(a) excludes items that can be reprocessed and made suitable for use. Those items that can be reprocessed and made suitable for use are dealt with in proposed § 111.82.

F. Holding and Distributing (Proposed Subpart F)

1. What Requirements Apply to Holding Components, Dietary Ingredients, Dietary Supplements, Packaging, and Labels? (Proposed § 111.80)

Proposed § 111.80 would require that you hold dietary ingredients and dietary supplements under conditions that will protect them against contamination and deterioration. Proposed § 111.80(a) would require that you hold components, dietary ingredients, and dietary supplements under appropriate conditions of temperature, humidity, and light so that the identity, purity, quality, strength, and composition of the components, dietary ingredients, and dietary supplements are not affected. This proposed provision includes the holding of components, dietary ingredients, dietary supplements in your physical plant and at any point in the distribution process, however, we would not extend the holding requirements under this proposed CGMP regulation to retail establishments, but would defer to State and local governments for regulating operations that provide dietary supplements to retail for sale to the consumer. However, if a retail holding area is filthy, we would not be prevented from taking an enforcement action under a legal authority other than section 402(g) of the act.

This requirement would ensure that products are not contaminated while they are held by the manufacturer, the wholesaler, or while being held at a warehouse. This would increase the likelihood that the products consumers purchase have the same quality as when they left the manufacturer. Note that proposed § 111.80(a) uses the words "not affected;" this means that the conditions under which you hold components, dietary ingredients, and dietary supplements must not adulterate

the components, dietary ingredients, or dietary supplements. For example, dried plants stored in a hot, humid warehouse may become moldy. Mold contamination could adversely affect the purity of the dietary ingredients and dietary supplements you manufacture. You will decrease the chances of mold contaminating your dried plants if you control temperature and humidity.

Proposed § 111.80(b) would require that you hold packaging and labels under appropriate conditions of temperature, humidity, and light so that the quality of the packaging and labels are not affected. For example, some plastics become brittle when exposed to extreme temperatures. If brittle plastic containers are used to hold dietary ingredients or dietary supplements, they could crack or break, thereby losing their protective qualities, and lead to contamination or deterioration of the dietary ingredient or dietary supplement. You need to know the conditions of temperature, humidity, and light that are appropriate for your packaging and labels and you need to hold the packaging and labels under such conditions.

Proposed § 111.80(c) would require that you hold components, dietary ingredients, dietary supplements, packaging, and labels under conditions that do not lead to mixup, contamination, or deterioration of the components, dietary ingredients, dietary supplements, packaging, and labels. For example, your holding conditions must include a system for identifying container contents and its status (e.g., segregated, approved for use) in a manner that prevents mixup or use of unsuitable materials in manufacturing. Further, the presence of rodents in your holding area may cause contamination or deterioration of components, dietary ingredients, dietary supplements, packaging, and labels. Therefore, your holding conditions must be rodent-free. Moreover, rodents in your holding area would adulterate your dietary ingredient or dietary supplement under section 402(g) of the act. Holding conditions that prevent mixup, contamination, or deterioration of components, dietary ingredients, dietary supplements, packaging, or labels are necessary to prevent the production of an adulterated dietary ingredient or dietary supplement.

We invite comment on whether we should require, in a final rule, that you establish and follow written procedures for holding components, dietary ingredients, dietary supplements, packaging, and labels. 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.

2. What Requirements Apply to Holding Inprocess Material? (Proposed § 111.82)

Proposed § 111.82 discusses proposed requirements for holding inprocess material. Proposed § 111.82 would require that you segregate any inprocess material that does not meet your specifications, is awaiting further processing, or needs further evaluation by the quality control unit (e.g., because the inprocess material does not meet specifications, or because of an unexpected occurrence) to determine if it is suitable for reprocessing.

Proposed § 111.82(a), therefore, would require that you identify and hold inprocess material under conditions that will protect such material against mixup, contamination, and deterioration.

Proposed § 111.82(b) would require that you hold inprocess material under appropriate conditions of temperature, humidity, and light. The intent here is to prevent any contamination or deterioration of that inprocess material.

We invite comment on whether we should require, in a final rule, that you establish and follow written procedures for holding inprocess material. 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.