

### 3. What Requirements Apply to Holding Reserve Samples of Components, Dietary Ingredients, and Dietary Supplements? (Proposed § 111.83)

Earlier, we discussed a provision concerning the collection of reserve samples. Proposed § 111.50(h) would require that you collect representative reserve samples of each batch of dietary ingredient or dietary supplement. Proposed § 111.83 would set forth requirements for holding any reserve samples collected.

Proposed § 111.83(a) would require that you hold any reserve samples of components or dietary ingredients collected in a manner that protects against contamination and deterioration.

Proposed § 111.83(b) would require that you hold such reserve samples of dietary supplements in a manner that protects against contamination and deterioration. Further, this provision would require that you hold the reserve samples under conditions of use recommended or suggested in the label of the dietary supplement and, if no conditions of use are recommended or suggested in the label, then under ordinary conditions of use. This proposed requirement also would require that you use the same container-closure system in which the dietary supplement is marketed or one that provides the same level of protection against contamination or deterioration as the marketed container-closure system. It is necessary to hold the reserve sample of a dietary supplement under the same conditions and in the same packaging as you would expect a consumer to hold that dietary supplement so that, if you need to later test that reserve sample, the testing would reflect current conditions under which the dietary supplement is held by the consumer prior to being consumed.

### 4. What Requirements Apply to Returned Dietary Ingredients or Dietary Supplements? (Proposed § 111.85)

Proposed § 111.85 would establish requirements for returned dietary ingredients or dietary supplements. "Returned" dietary ingredients or dietary supplements are those products that a distributor, wholesaler, or retailer returns to a manufacturer. Proposed § 111.85(a) would require that you identify returned dietary ingredients or dietary supplements and to quarantine them until your quality control unit conducts a material review and makes a disposition decision. (Your quality control unit would do this under proposed § 111.37.) For example, you could attach a tag or other identifier on the returned dietary ingredient or

dietary supplement to show that it is "returned." We would require that you identify and quarantine (not just identify and segregate) returned dietary ingredients or dietary supplements so that they cannot be used. We propose to require that you quarantine returned products because you must assume that the returned product is adulterated until tests show otherwise. Thus, the product should not have physical closeness or contact with nonreturned product to ensure that it will not be mixed up mistakenly with nonreturned product, redistributed or reused in manufacturing.

Proposed § 111.85(b)(1) states that you may salvage returned dietary ingredients and dietary supplements only if:

- Evidence from their packaging (or, if possible, an inspection of the premises where the dietary ingredients and dietary supplements were held) indicates that the dietary ingredients and dietary supplements were not subjected to improper storage conditions. This would require that you have personal knowledge of the exact conditions under which the returned dietary ingredients or dietary supplements were held. Normally, for most types of packaging, simply examining the packaging will not tell you about the storage conditions that existed. However, we are aware of some technologies that are being used, such as temperature-sensitive materials that change colors, that could provide some information about storage conditions; and
- Tests demonstrate that the dietary ingredients or dietary supplements meet all specifications for identity, purity, quality, strength, and composition. This requirement will ensure that you do not return to distribution a dietary ingredient or dietary supplement that does not meet specifications. Salvage is available for only those products for which testing can be performed on finished product.

For purposes of this discussion, "salvage" means to return to distribution without reprocessing the dietary ingredient or dietary supplement.

Proposed § 111.85(c) would require that you destroy or suitably dispose of the returned dietary ingredients or dietary supplements if they do not meet specifications for identity, purity, quality, strength, and composition, unless the quality control unit conducts a material review and makes a disposition decision to allow reprocessing.

Proposed § 111.85(d) would require that you conduct an investigation of

your manufacturing processes and those other batches if the reason for a dietary ingredient or a dietary supplement being returned implicates other batches. The point of the investigation would be to determine whether, for example, the other implicated batches may have the same problem or have been subject to the same problematic manufacturing process for which the dietary ingredient or dietary supplement was returned. Other batches may be implicated if the component or dietary ingredient used in the returned product also was used in additional batches or if your investigation indicates that there was a problem with a step in the manufacturing process that affected additional batches. The proposal also would require that you document the investigation and include your conclusions and followup.

Proposed § 111.85(e) would require you to establish and keep records for any material review and disposition decision and any required testing to determine compliance with specifications done for any returned dietary ingredient or dietary supplement. You should include the following information in your records:

- The name of the person or company or both the name of the person and company who returned the dietary ingredients or dietary supplements;
- A description of the returned dietary ingredient or dietary supplement;
- The batch or lot number of the returned dietary ingredient or dietary supplement and any reprocessed batch or batch manufactured using the returned dietary ingredient or dietary supplement;
- The reason for the return;
- The quantity returned;
- The disposition of the dietary ingredient or dietary supplement; and
- The date of disposition.

Proposed § 111.85(f) would require that you make and keep records for returned dietary ingredients and dietary supplements in accordance with § 111.125. These records are necessary to ensure that returned products that could be adulterated are not inadvertently redistributed or inadvertently used in manufacturing. Further, records of any reprocessed batch or batch manufactured using the returned product will be useful in the event that a problem arises with a particular batch that is manufactured with returned product. These records also are necessary to demonstrate compliance with the CGMP and quality control procedures. We invite comment on whether we should require, in a final rule, that you establish and follow