

as needed, in consumer complaint investigations;

2. Inprocess materials at points, steps, or stages, in the manufacturing process as specified in the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements;

3. Each batch of dietary ingredient or dietary supplement that is manufactured to determine, before you release it for distribution, whether it meets its specifications for identity, purity, quality, strength, and composition; and

4. Each batch of packaged and labeled dietary ingredients or dietary supplements to determine that you used the packaging specified in the master manufacturing record and applied the label specified in the master manufacturing record;

- Review and approve all material review and disposition decisions; and
- Collect representative reserve samples of each shipment lot of components, dietary ingredients, and dietary supplements and each batch of dietary ingredient or dietary supplement. The proposal would require that you keep the reserve samples for 3 years from the date of manufacture for use in appropriate investigations, such as, consumer complaint investigations to determine, for example, whether the dietary ingredient or dietary supplement associated with a consumer complaint failed to meet any of its specifications for identity, purity, quality, strength, and composition. We tentatively decide to require that you keep reserve samples for 3 years because we believe that 3 years would be a reasonable time period beyond the date of manufacture for appropriate followup of consumer complaints received during the marketing period. Because we have not proposed requirements for expiration dating of dietary supplements, we tentatively conclude that the date of manufacture is an appropriate starting time for the retention period. This requirement in proposed § 111.37(b)(11) also would require that the reserve samples be identified with the batch or lot number and consist of at least twice the quantity necessary for tests;

- Perform appropriate tests and/or examinations of:

1. Components, dietary ingredients, dietary supplements, packaging, and labels received to ensure that they meet specifications;

2. Dietary ingredient and dietary supplement batch production at points, steps, or stages identified in the master

manufacturing record where control is necessary to prevent adulteration;

3. Dietary ingredients and dietary supplements that you manufacture to ensure that they meet specifications; and

4. Packaged and labeled dietary ingredients and dietary supplements to ensure that you used the packaging specified in the master manufacturing record and you applied the label specified in the master manufacturing record;

- Review and approve all material review and disposition decisions; and
- Approve the reprocessing or distribution of returned dietary ingredients or dietary supplements.

Proposed § 111.37 would impose duties on your quality control unit that are necessary to the quality control unit. The duties proposed in § 111.37 are important in any CGMP standards to ensure that the dietary ingredient or dietary supplement manufactured has the identity, purity, quality, strength, and composition intended. If a quality control unit did not do, that is, lacked the responsibility and authority to do, the actions described in proposed § 111.37, coordination between various parts of your manufacturing, packaging, or holding operation might become haphazard and the product could be adulterated. For example, if your quality control unit did not make decisions concerning use of components, dietary ingredients, and dietary supplements you receive, you could use the wrong component, or a contaminated component in manufacturing a dietary ingredient or dietary supplement. If your quality control unit makes decisions concerning releasing dietary ingredients and dietary supplements for distribution, it will prevent you from releasing for distribution an adulterated dietary ingredient or dietary supplement before the necessary tests results confirm that the dietary ingredient or dietary supplement meets specifications for identity, purity, quality, strength, and composition.

Your quality control unit must document, at the time of performance, that it performed the review, approval, or rejection requirements established in accordance with proposed § 111.37 by recording the date when the review, approval, or rejection and requirement was performed, and the signature of the person performing the requirement. As we explained elsewhere in this document, one of the ways we determine compliance with CGMP's is by conducting inspections, so records enable you to show, and for us to determine, compliance with CGMP's. We invite comment on whether we

should require, in a final rule, written procedures for the quality control unit duties required in § 111.37. 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.

3. What Requirements Apply to Components, Dietary Ingredients, Dietary Supplements, Packaging, and Labels You Receive? (Proposed § 111.40)

Proposed § 111.40 would establish requirements to ensure that the components, dietary ingredients, dietary supplement, packaging, and labels you receive are, in fact, what you ordered. We are proposing these requirements because receiving the wrong materials can lead to mixups or the use of wrong materials and this could result in the manufacture of an adulterated and misbranded dietary ingredient or dietary supplement.

Proposed § 111.40(a)(1) and (a)(2) would apply to components, dietary ingredients, or dietary supplements you receive, and would require that you:

- Visually examine each container or grouping of containers in a shipment for appropriate content label, container damage, or broken seals to determine whether the container's condition has resulted in contamination or deterioration of the components, dietary ingredients, or dietary supplements;

- Visually examine the supplier's invoice, guarantee, or certification to ensure that the components, dietary ingredients, or dietary supplements are consistent with your purchase order and perform testing, as needed, under proposed § 111.35(g), to determine whether specifications are met.

We state in proposed § 111.40(a)(2) that you must perform testing "as needed." This flexibility is necessary, given the proposed testing scheme in § 111.35(g). As previously discussed in proposed § 111.35(e), you must establish specifications for any points, steps, or stages in the manufacturing process where control is necessary to prevent adulteration. In addition, we propose to require, under § 111.35(e), certain