

the quality control unit must approve or reject their release for distribution.

(f)(1) You must control the issuance and use of packaging and labels and reconciliation of any issuance and use discrepancies; and

(2) You must examine, before packaging operations, packaging and labels for each batch of dietary ingredient or dietary supplement to ensure that the label and packaging conform to the master manufacturing record.

(g) The person that performs the requirements of this section must document at the time of performance that the requirements are performed including, but not limited to, documentation in the batch production record of:

(1) The identity and quantity of the packaging and labels used and reconciliation of any discrepancies between issuance and use;

(2) The examination conducted in accordance with paragraph (b)(7) of this section;

(3) The conclusions you reached from retests conducted in accordance with paragraph (e) of this section; and

(4) Any material reviews and disposition decisions for packaging and labels.

(h) You must keep packaging and label operations records required under this section in accordance with § 111.125.

§ 111.74 What requirements apply to rejected components, dietary ingredients, dietary supplements, packaging, and labels?

You must clearly identify, hold, and control under a quarantine system any component, dietary ingredient, dietary supplement, packaging, and label that is rejected and unsuitable for use in manufacturing, packaging, or label operations.

9. Add subpart F to part 111 to read as follows:

Subpart F—Holding and Distributing

Sec.

111.80 What requirements apply to holding components, dietary ingredients, dietary supplements, packaging, and labels?

111.82 What requirements apply to holding in-process material?

111.83 What requirements apply to holding reserve samples of components, dietary ingredients, and dietary supplements?

111.85 What requirements apply to returned dietary ingredients or dietary supplements?

111.90 What requirements apply to distributing dietary ingredients or dietary supplements?

Subpart F—Holding and Distributing

§ 111.80 What requirements apply to holding components, dietary ingredients, dietary supplements, packaging, and labels?

(a) You must 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.

(b) You must hold packaging and labels under appropriate conditions of temperature, humidity, and light so that the quality of the packaging and labels are not affected.

(c) You must hold components, dietary ingredients, dietary supplements, packaging, and labels under conditions that do not lead to the mixup, contamination, or deterioration of components, dietary ingredients, dietary supplements, packaging, and labels.

§ 111.82 What requirements apply to holding in-process material?

(a) You must identify and hold in-process material under conditions that will protect them against mixup, contamination, and deterioration.

(b) You must hold in-process material under appropriate conditions of temperature, humidity, and light.

§ 111.83 What requirements apply to holding reserve samples of components, dietary ingredients, and dietary supplements?

(a) For any reserve samples of components or dietary ingredients you collect, you must hold such reserve samples in a manner that protects against contamination and deterioration.

(b) You must hold reserve samples of dietary supplements in a manner that protects against contamination and deterioration. This includes, but is not limited to:

(1) Holding 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; and

(2) Using the same container-closure system in which the dietary supplement is marketed or in one that provides the same level of protection against contamination or deterioration.

§ 111.85 What requirements apply to returned dietary ingredients or dietary supplements?

(a) You must identify and quarantine returned dietary ingredients or dietary

supplements until the quality control unit conducts a material review and makes a disposition decision.

(b) You must not salvage returned dietary ingredients and dietary supplements, unless:

(1) 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; and

(2) Tests demonstrate that the dietary ingredients or dietary supplements meet all specifications for identity, purity, quality, strength, and composition.

(c) You must destroy or suitably dispose of the returned dietary ingredients or dietary supplements if such dietary ingredients or dietary supplements 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.

(d) If the reason for a dietary ingredient or a dietary supplement being returned implicates associated batches, you must conduct an investigation of your manufacturing processes and those other batches to determine compliance with specifications.

(e) You must establish and keep records for this section on the material review and disposition decision and any testing conducted to determine compliance with established specifications in the master manufacturing record for the type of dietary ingredient or dietary supplement that was returned.

(f) You must keep returned dietary ingredient and dietary supplement records in accordance with § 111.125.

§ 111.90 What requirements apply to distributing dietary ingredients or dietary supplements?

Distribution of dietary ingredients and dietary supplements must be under conditions that will protect the dietary ingredients and dietary supplements against contamination and deterioration.

10. Add subpart G to part 111 to read as follows:

Subpart G—Consumer Complaints

§ 111.95 What requirements apply to consumer complaints?

(a) A qualified person must review all consumer complaints to determine whether the consumer complaint involves a possible failure of a dietary ingredient or dietary supplement to meet any of its specifications, or any