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(c) Quality control personnel must approve or reject each batch of repackaged or relabeled dietary supplement prior to its release for distribution.

§ 111.425 What requirements apply to a packaged and labeled dietary supplement that is rejected for distribution?

You must clearly identify, hold, and control under a quarantine system for appropriate disposition any packaged and labeled dietary supplement that is rejected for distribution.

§ 111.430 Under this subpart L, what records must you make and keep?

(a) You must make and keep records required under this subpart L in accordance with subpart P of this part.

(b) You must make and keep records of the written procedures for packaging and labeling operations.

Subpart M—Holding and Distributing

§ 111.453 What are the requirements under this subpart for M written procedures?

You must establish and follow written procedures for holding and distributing operations.

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

(a) You must hold components and dietary supplements under appropriate conditions of temperature, humidity, and light so that the identity, purity, strength, and composition of the components and dietary supplements are not affected.

(b) You must hold packaging and labels under appropriate conditions so that the packaging and labels are not adversely affected.

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

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

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

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

§ 111.465 What requirements apply to holding reserve samples of dietary supplements?

(a) You must hold reserve samples of dietary supplements in a manner that protects against contamination and deterioration. This includes:

(1) Holding the reserve samples under conditions consistent with product labels or, if no storage conditions are recommended on the label, under ordinary storage conditions; and

(2) Using the same container-closure system in which the packaged and labeled dietary supplement is distributed, or if distributing dietary supplements to be packaged and labeled, using a container-closure system that provides essentially the same characteristics to protect against contamination or deterioration as the one in which you distribute the dietary supplement for packaging and labeling elsewhere.

(b) You must retain reserve samples for 1 year past the shelf life date (if shelf life dating is used), or for 2 years from the date of distribution of the last batch of dietary supplements associated with the reserve samples, for use in appropriate investigations.

§ 111.470 What requirements apply to distributing dietary supplements?

You must distribute dietary supplements under conditions that will protect the dietary supplements against contamination and deterioration.

§ 111.475 Under this subpart M, what records must you make and keep?

(a) You must make and keep records required under this subpart M in accordance with subpart P of this part.

(b) You must make and keep the following records:

(1) Written procedures for holding and distributing operations; and

(2) Records of product distribution.