§ 111.420 What requirements apply to repackaging and relabeling?

(a) You may repackage or relabel dietary supplements only after quality control personnel have approved such repackaging or relabeling.

(b) You must examine a representative sample of each batch of repackaged or relabeled dietary supplements to determine whether the repackaged or relabeled dietary supplements meet all specifications established in accordance with §111.70(g).

(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
§ 111.530 When must an investigation be conducted of your manufacturing processes and other batches?

You must identify and quarantine returned dietary supplements until quality control personnel conduct a material review and make a disposition decision.

§ 111.515 When must a returned dietary supplement be destroyed, or otherwise suitably disposed of?

You must destroy, or otherwise suitably dispose of, any returned dietary supplement unless the outcome of a material review and disposition decision is that quality control personnel do the following:

(a) Approve the salvage of the returned dietary supplement for redistribution or

(b) Approve the returned dietary supplement for reprocessing.

§ 111.520 When may a returned dietary supplement be salvaged?

You may salvage a returned dietary supplement only if quality control personnel conduct a material review and make a disposition decision to allow the salvage.

§ 111.525 What requirements apply to a returned dietary supplement that quality control personnel approve for reprocessing?

(a) You must ensure that any returned dietary supplements that are reprocessed meet all product specifications established in accordance with §111.70(e); and

(b) Quality control personnel must approve or reject the release for distribution of any returned dietary supplement that is reprocessed.

§ 111.530 When must an investigation be conducted of your manufacturing processes and other batches?

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