

ingredient went to another manufacturer who, believing that the product was zinc picolinate, used the dietary ingredient to make its dietary supplement. The error was discovered after consumers who used the product started complaining of adverse reactions that are associated with niacin supplements, but the problem could have been avoided if the dietary ingredient manufacturer had taken steps to ensure that the correct labels were used.

Proposed § 111.70(d) would require that you repackaging or relabel dietary ingredients or dietary supplements if approved and appropriately documented by your quality control unit. The quality control unit would need to decide whether the improperly packaged product was adulterated by the incorrect package and could be repackaged and relabeled without reprocessing of the dietary ingredient or dietary supplement.

Proposed § 111.70(e) would require that you retest or reexamine any repackaged or relabeled dietary ingredients or dietary supplements. They must meet all specifications and the quality control unit must approve or reject their release for distribution. The reason this is necessary is to ensure for example, by testing or examination, that the repackaged or relabeled product meets specifications and that the container in which the product is repackaged meets specifications.

Proposed § 111.70(f)(1) would require that you control the issuance and use of packaging and labels and reconcile the issuance and use of discrepancies. It is important to control access to the storage of packaging and labels; for example, only the labels that are required for current label operations should be issued to prevent issuance of any incorrect labels during the label operation. Using batch or lot numbers on your labels may be one control method. Batch or lot numbers also help you (and us) to identify a particular product and to trace that product's manufacturing history through your CGMP records. They can help identify which products are affected by a product recall, if a recall is necessary, and this can help preserve consumer confidence in your product.

For example, if a recall covers batch A123, and a particular consumer has a product whose batch number is C456, he or she will know that the product is not covered by the recall. In contrast, if no batch numbers appear on the product label, the consumer would not be able to tell whether his or her product is covered by the recall and may continue to use it.

As another example, controlling access of labels can help identify instances when mislabeling may have occurred. If you issue only the necessary number of labels to cover a particular production run but use fewer labels than expected even though you labeled the expected number of containers for the production run, this discrepancy would suggest that you used some wrong labels during the run and that you should conduct an investigation to determine the cause of, or reconcile the discrepancy.

Proposed § 111.70(f)(2) would require that you must examine carefully, 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.

Proposed § 111.70(g) would require that the person who performs the requirement established in accordance with this section document, at the time of performance, that he or she performed the requirement. This would include, but not be limited to, documentation in the batch production record of:

- The identity and quantity of the packaging and labels used and reconciliation of any discrepancies between issuance and use;
- The examination of a representative sample (as proposed § 111.70(b)(7) would require);
- The conclusions you reached from retests conducted under proposed § 111.70(e); and
- Any material reviews and disposition decisions for packaging and labels.

Proposed § 111.70(h) would require that you keep the packaging and label operations records required under this section established in accordance with proposed § 111.125. These records are necessary to ensure that the correct packaging and label, *i.e.*, the packaging and label specified by the master manufacturing record, were used in and applied to the batch of dietary ingredient or dietary supplement. These records together with the master manufacturing records and batch production records will ensure that a complete history of each batch of dietary ingredient or dietary supplement including use of the correct packaging and label is available for your review in the event that a problem arises with a particular batch. 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

written procedures for packaging and label operations that implement the requirements of this section. 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. Further, we seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions 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. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

9. What Requirements Apply to Rejected Components, Dietary Ingredients, Dietary Supplements, Packaging, and Labels? (Proposed § 111.74)

Proposed § 111.74 is intended to ensure that you do not mistakenly use rejected materials that are determined by the quality control unit to be unsuitable for use to make a dietary ingredient or dietary supplement.

Proposed § 111.74(a) would require that you 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. The term "control under a quarantine system" indicates that you must prevent the use of any rejected component, dietary ingredient, dietary supplement, packaging, or label because such rejected product is unsuitable for use. For example, under this proposed rule, if a component, dietary ingredient, or dietary supplement is rejected and determined by the quality control unit