

8. What Requirements Apply to Packaging and Label Operations? (Proposed § 111.70)

Proposed § 111.70 would establish requirements for your packaging and label operations. The correct use of packaging and labels can affect whether your product is adulterated. For example, if a packaging material, intended only for use with a dry product, is used to package a liquid, unsafe substances could migrate from the packaging to the liquid, and adulterate your dietary ingredients or dietary supplements. In addition, if you apply the wrong label, your product would be adulterated under section 402(g) of the act because your label must be that which is specified in the master manufacturing record. In addition, your product would be misbranded under section 403 of the act.

Proposed § 111.70(a) would require that you take necessary actions to ensure each packaging container for holding dietary ingredients or dietary supplements meets its specifications so that the packaging container's condition will not contaminate your dietary ingredients or dietary supplements or cause them to deteriorate. As previously stated in the discussion of proposed § 111.35(e)(4), you must establish specifications for packaging materials that may come in contact with dietary ingredients or dietary supplements. Meeting such specifications would ensure that the packaging that is used is safe and suitable for the intended use and meets all of the statutory and regulatory requirements under the act. In that way, the packaging materials will not adulterate the dietary ingredient or dietary supplement. This proposed requirement would give you the discretion to establish the specifications for each packaging container, and would require that these specifications are routinely met. For example, if your product is sensitive to light, you would choose a container that protects the product from the light so that it does not deteriorate.

Proposed § 111.70(b) would require that you fill, assemble, package, and perform other related operations in a way that protects your dietary ingredients or dietary supplements against adulteration and misbranding. The proposal would require that you use any effective means to do this, which would include:

- Cleaning and sanitizing all filling and packaging equipment, utensils, and dietary ingredient or dietary supplement containers, as appropriate. This is important because cleaning and sanitizing all filling and packaging

equipment can help you avoid some common mistakes that can adulterate your products. For example, in one case, a consumer complained about receiving two different sized capsules in a bottle labeled as containing acidophilus capsules. We conducted an investigation and found that the manufacturer had received a similar report from a different consumer (Ref. 77). We analyzed the capsules and found that the smaller capsules were not acidophilus capsules but contained levels of stannous fluoride that would cause convulsions in certain persons and even exceeded the lethal dose in small children. We also collected unopened bottles of the acidophilus product and, after opening the product, found different sized capsules. The presence of smaller capsules containing stannous fluoride mixed in with the larger acidophilus capsules adulterated the product. The fact that these small stannous fluoride capsules mixed in with the larger acidophilus capsules indicated that the manufacturer had not cleaned the filling equipment properly.

In another case, consumer complaints about a vitamin C product prompted us and the product's manufacturer to investigate the product (Ref. 78). We both discovered that the products contained niacin instead of vitamin C, and the problem was the result of a failure to clean out the packaging equipment so that niacin that had been left in the packaging equipment was put into the capsules during the manufacturing operation for the vitamin C product. The manufacturer reviewed its packing operations and instructed its personnel at the manufacturing plant to prevent this problem from reoccurring.

- Protecting manufactured dietary ingredients and dietary supplements from contamination, particularly airborne particulates such as dust, dirt, or microbes that may contaminate your product when your product is exposed to the environment.

- Using sanitary handling procedures.

- Establishing physical or spatial separation of packaging and labels from operations on other dietary ingredients and dietary supplements to prevent mixups. It is important to keep inprocess material separate from finished product that is ready to be packaged and labeled so that inprocess material is not inadvertently packaged and labeled as finished product. In addition, this proposed requirement would prevent mixup of one type of dietary ingredient with another type of dietary ingredient during packaging and label operations such as the vitamin C and niacin mixup described earlier.

- Identifying, by any effective means, filled dietary ingredient or dietary supplement containers that are set aside and held in unlabeled condition for future label operations, to prevent mixups;

- Identifying the dietary ingredient or dietary supplement with a batch, lot, or control number that can be used to determine the manufacturing history and control of the batch. Using a unique identifier for each batch or lot is necessary for you to trace the manufacturing history for a particular batch, and thus help you investigate and correct any safety problems for a batch or to recall a dietary ingredient or dietary supplement batch. For example, if you discovered a particular batch had a safety problem, you could recall the batch by identifying the batch number for the problem product. If you did not have a unique identifier, consumers would be unable to determine which product was the subject of a recall, and they may not stop using the product or you will have to recall more of the product.

- Examining a representative sample of the packaged and labeled dietary ingredient or dietary supplement to ensure that it meets specifications and that the label specified in the master manufacturing record has been applied; and

- Suitably disposing of labels and other packaging for dietary ingredients or dietary supplements that are obsolete or incorrect to ensure that they are not used in any future packaging and label operations. The use of any obsolete or incorrect label would adulterate the product because it would not comply with the requirement that the correct label as specified in the master manufacturing record be used.

Proposed § 111.70(c) would require that you conduct a material review and make a disposition decision of any packaged and labeled dietary ingredients or dietary supplements that do not meet specifications. If packaged and labeled dietary ingredients or dietary supplements do not meet specifications, it means that there is a problem and that the dietary ingredient or dietary supplement may be or is adulterated and this step is needed to determine what to do and how to handle the product to ensure that it does not get distributed.

Sometimes problems arise because a manufacturer used the wrong label on a particular ingredient. For example, in one case, an ingredient manufacturer put the wrong label on its product so that a product labeled as containing zinc picolinate actually contained zinc polynicotinate (Ref. 79). The dietary