

written procedures for identifying, quarantining, and salvaging returned dietary ingredients and dietary supplements. 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.

5. What Requirements Apply to Distributing Dietary Ingredients or Dietary Supplements? (Proposed § 111.90)

Proposed § 111.90 would establish requirements concerning the distribution of dietary ingredients and dietary supplements. Proposed § 111.90(a) would require any distribution of dietary ingredients or dietary supplements to be under conditions that will protect them from contamination and deterioration. This is to protect dietary ingredients and dietary supplements from distribution practices that may adulterate them.

As discussed previously, proposed part 111 also would apply to foreign firms that manufacture, package, or hold dietary ingredients and dietary supplements that are imported or offered for import into the United States, unless imported for further processing and export under section 801(d)(3) of the act. It also would apply to persons who distribute imported dietary ingredients and dietary supplements, and to persons who export dietary ingredients and dietary supplements from the United States unless exported in compliance with section 801(e) of the act.

We recognize that the safety of dietary supplements cannot be adequately ensured if the imports are not subject to the same controls as domestic products. In addition, we believe that the importer who distributes a foreign product should share responsibility with the foreign manufacturer for safety. More often than not, it is a U.S. importer, rather than the foreign manufacturer, who actually distributes imported dietary supplements for sale in the United States. Thus, we believe that importers of dietary ingredients or

dietary supplements should take steps to ensure that their shipments are obtained from manufacturers that follow these proposed CGMP requirements.

In addition, these proposed CGMPs would apply to manufacturers who export their dietary ingredient or dietary supplement, unless exported in compliance with section 801(e) of the act. Section 801(e)(1) of the act states that a food intended for export must not be deemed to be adulterated or misbranded under the act if it:

- Accords to the foreign purchaser's specifications;
- Is not in conflict with the laws of the country to which it is intended for export;
- Is labeled on the outside of the shipping package that it is intended for export; and
- Is not sold or offered for sale in domestic commerce.

Dietary ingredients and dietary supplements for export are subject to section 801(e)(1) of the act and would be subject to the notification and recordkeeping requirements of § 1.101 (21 CFR 1.101) and you would be required to comply with the export requirements of § 1.101.

We invite comment on whether we should require, in a final rule, that you make and keep records on the distribution of dietary ingredients and dietary supplements that you manufacture, package, or hold.

G. Consumer Complaints—What Requirements Apply to Consumer Complaints? (Proposed Subpart G, § 111.95)

Proposed § 111.95 would establish requirements for receiving and handling consumer complaints. Consumer complaints can be helpful in alerting you to possible manufacturing and safety problems associated with your dietary ingredients or dietary supplements.

As stated in § 111.3, consumer complaint refers to a possible failure of a dietary ingredient or dietary supplement to meet any of the requirements of this part, including those that, if not met, may result in a possible risk of illness or injury. Proposed § 111.95(e) would require that you keep a written record of every consumer complaint that is related to good manufacturing practices. Thus, whether the complaint was sent by regular mail, electronic mail, or any other form of written communication, or whether received orally, you would be required to keep a written record of each consumer complaint. You should include all information that would allow your quality control unit to

determine whether an investigation of the complaint is necessary.

Proposed § 111.95(a) would require that you have a qualified person 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 other requirements of this part, including those specifications and other requirements that, if not met, may result in a possible risk of illness or injury. A “qualified person” would be a person who has the training and experience to determine whether a complaint represents a possible failure of a dietary ingredient or dietary supplement to meet any of the requirements in this part, or represents a possible risk of illness or injury that is unrelated to such failure. The qualified person's review is important for distinguishing between those consumer complaints that your quality control unit must review and those consumer complaints that represent a consumer's dissatisfaction with a dietary ingredient or dietary supplement that is unrelated to a possible failure to meet specifications that would be required by this proposal, or any other requirement in this part. For example, some consumer complaints about quality may simply express a personal dislike of the taste, color, odor, or size of tablet, which would probably not require your quality control unit to review them. As stated earlier, consumer complaints related to an illness or injury related to a pharmacologically active substance of a particular dietary ingredient, such as aristolochic acid, would not be a consumer complaint within the meaning of that term in this proposal and thus would not be of the type that the quality control unit must review under this proposed rule.

Proposed § 111.95(b) would require that your quality control unit review all consumer complaints involving the possible failure of a dietary ingredient or dietary supplement to meet any of its specifications, or any of the other requirements in this part, including those specifications and other requirements that, if not met, may result in a possible risk of illness or injury, to determine whether there is a need to investigate the consumer complaint. When there is a reasonable possibility of a relationship between the quality of a dietary supplement and an adverse event, such as a report of an illness or injury that may be due to a wrong ingredient or wrong label, then the manufacturer would be required to do an investigation that includes both batch records associated with the