

specifications, *i.e.*, identity, purity, quality, strength, and composition, for components, dietary ingredients, and dietary supplements upon receipt. However, in § 111.35(g), we are proposing to provide some flexibility for when testing is required for the identity, purity, quality, strength, and composition specifications. Specifically, if you perform finished product testing under § 111.35(g)(1) for identity, purity, quality, strength, and composition, then under § 111.40(a)(2) we would require that you visually compare the supplier's invoice, guarantee, or certification with your purchase order to confirm consistency between your order and the supplier's invoice, guarantee, or certification. You would not need to do testing upon receipt. That is why we have added language to § 111.40(a)(2) that states, "and perform testing, as needed, to determine whether specifications are met." Alternatively, for specifications that you establish (*e.g.*, other than the identity, purity, quality, strength, and composition of the components, dietary ingredients or dietary supplements received), such as for a holding temperature necessary during transportation to your physical plant to avoid adulteration, you would be required to ensure by testing or examination that the specified temperature was used.

If you do not perform finished product testing under § 111.35(g)(1) for identity, purity, quality, strength, or composition, then you would need to test for that nontested finished product specification upon receipt. In that case, testing would be needed under both proposed §§ 111.35(g)(2) and 111.40(a)(2). You still would need to visually compare the supplier's invoice, guarantee, or certification with your purchase order to confirm consistency between your order and the supplier's invoice, guarantee, or certification.

Thus, for those specifications of identity, purity, quality, strength, or composition for which your quality control unit determines that you cannot test for at the finished product stage (because there are no available scientifically valid methods), then you would be required, under § 111.35(g)(2)(i) to test incoming shipment lots of components, dietary ingredients, or dietary supplements for any such specification to determine whether it is met, and such a test also would be considered to be necessary under § 111.40(a)(2). As discussed earlier, you may not rely on a supplier's certification or guaranty in lieu of such testing, and in addition to such testing, still would need to visually examine the

supplier's invoice, guarantee, or certification.

Under § 111.40(b)(3) through (b)(5), we would require that you:

- Quarantine components, dietary ingredients, or dietary supplements until your quality control unit reviews the supplier's invoice, guarantee, or certification and performs testing, as needed under proposed § 111.35(g), of a representative sample to determine that specifications are met. These are the specifications that you would set in accordance with proposed § 111.35(e) and appropriate tests or examinations used in accordance with proposed § 111.35(g) for materials that you receive. If specifications are not met, proposed § 111.40(a)(3) would require that you conduct a material review and make a disposition decision. Your quality control unit must approve and release the components, dietary ingredients, and dietary supplements from quarantine before you use them;

- Identify each lot of components, dietary ingredients, or dietary supplements in a shipment in a manner that allows you to trace the shipment to the supplier, the date received, the name of the component or dietary supplement, and the status (*e.g.*, quarantined, approved, or rejected) and to trace the shipment lot to the dietary ingredient or dietary supplement manufactured and distributed. You must use this unique identifier whenever you record the disposition of each shipment lot received. Using a unique identifier throughout the manufacturing process will make it possible to track and account for components, dietary ingredients, and dietary supplements you receive and is necessary to conduct investigations of consumer complaints; and

- Hold components, dietary ingredients, or dietary supplements under conditions that will protect against contamination, deterioration, and avoid mixups. For example, you must segregate components that your quality control unit has not released for use from those components that have been released for use. This provision would require that you refrigerate components that are subject to contamination or deterioration without such refrigeration or that otherwise require storage at a certain temperature.

Proposed § 111.40(b) would apply to packaging and labels you receive and would require that you:

- Visually examine each container or grouping of containers in a shipment for appropriate content labels, container damage, or broken seals to determine whether the container's condition has resulted in contamination or

deterioration of the packaging and labels;

- Quarantine packaging and labels until your quality control unit tests or examines a representative sample to determine that specifications are met. You must conduct at least a visual identification on the containers and closures. If specifications are not met, the proposal would require that you conduct a material review and make a disposition decision and also require your quality control unit to approve and release packaging and labels from quarantine before you use them;

- Identify each shipment lot of packaging and labels in a manner that allows you to trace the shipment lot to the supplier, the date received, the name of the packaging and label, and the status (*e.g.*, quarantined, approved, or rejected) and to trace the shipment lot to the dietary ingredient or dietary supplement manufactured and distributed. Like proposed § 111.40(a)(4), proposed § 111.40(b)(3) would require that you use this unique identifier whenever you record the disposition of each shipment lot received; and

- Hold packaging and labels under conditions that will protect against contamination and deterioration and avoid mixups.

Proposed § 111.40(c) deals with written documentation and records. Proposed § 111.40(c)(1) would require that the person who performs the requirements established in accordance with this section to document, at the time of performance, that he or she performed the requirements. The documentation would have to include, but not be limited to, the date that the requirement was performed; the signature of the person performing the requirement; any test results; and any material review and disposition decision conducted, and the disposition of any rejected material.

Proposed § 111.40(c)(2) would require that you keep component, dietary supplement, packaging, and label receiving records in accordance with proposed § 111.125. These records are necessary to be able to determine the source of the component, dietary ingredient, dietary supplement, packaging, and labels, so that if adulteration of dietary ingredient or dietary supplement occurs, the records will show the source of the material so that its use can be stopped. In addition, the records will show the basis on which each component, dietary ingredient, dietary supplement, packaging, or label was released for use in dietary ingredient or dietary supplement production. These records