

product, there may be methods available for testing at the finished product stage for other required specifications of purity, quality, and strength. Under proposed § 111.35(g)(3), your quality control must document that a scientifically valid analytical method is not available to perform finished product testing for any one of the required specifications for identity, purity, quality, strength or composition. If your quality control unit documents that a scientifically valid analytical method for testing each batch of dietary ingredient or dietary supplement is not available for any one of those required specifications, then you would be required, under § 111.35(g)(2)(i) and (g)(2)(ii) to test incoming shipment lots of components, dietary ingredients, or dietary supplements for any such specification to determine whether it is met and to test inprocess for any such specification in accordance with the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements.

Using a supplier certification, guarantee, or certification in lieu of performing testing on each shipment lot of components, dietary ingredients, or dietary supplements required in accordance with this section is not appropriate because it is possible that a supplier's certification or guarantee may not ensure the identity, purity, quality, strength, or composition of a component, dietary ingredient or dietary supplement. For example, a supplier of the dietary ingredient plantain provided a "certificate of analysis" indicating that the plant material was plantain powder, with a description of certain of its physical characteristics (Ref. 6). The plantain was contaminated with *D. lanata* (a plant that contains powerful heart stimulants that can cause life-threatening reactions including cardiac arrest, if ingested) and was distributed to at least 150 manufacturers, distributors, and retailers. Thus, 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 and inprocess as specified in the master manufacturing record to ensure that adulterated dietary ingredients or dietary supplements are not distributed to the marketplace.

If you are able to perform testing on each finished batch of dietary ingredient or dietary supplement to confirm that specifications are met for the identity, purity, quality, strength, and composition intended, then we would

recommend, but would not require, that you also test materials received for these same specifications to ensure that they are the right ingredients and so that you do not end up having to destroy an entire batch of finished product after using an erroneous ingredient that could have otherwise been identified earlier before being added to a batch.

For example, if you manufacture a batch of dietary supplements that contains only one single dietary ingredient, St. John's Wort extract (*Hypericum perforatum*), and there are scientifically valid analytical methods available to test the finished dietary ingredient or supplement to confirm that the specifications are met for the identity, purity, quality, strength, and composition intended, then you must test each batch using such methods. In this example, you would not be required to perform testing of incoming shipment lots of St. John's Wort to confirm identity, purity, quality, strength, and composition to confirm that specifications are met nor would you be required to perform testing of inprocess for these same specifications in accordance with the master manufacturing record. As discussed later under proposed § 111.40(b)(2), although testing would not be needed at receipt stage for identity, purity, quality, strength, and composition, you would be required under that section, to visually compare the label, supplier's invoice, guarantee, or certification with your purchase order for consistency. In another example, if you manufacture a dietary supplement that contains multiple dietary ingredients (e.g., Ginkgo Biloba, vitamin C, and folic acid) and you do not perform testing on the finished dietary supplement because there are not scientifically valid analytical methods available to confirm that the specifications for identity, purity, quality, strength, and composition are met for each dietary ingredient in the finished batch mixture, then you would be required to perform testing of incoming shipment lots of each dietary ingredient to confirm that such specifications are met and perform inprocess testing in accordance with the master manufacturing record to ensure that such specifications are met. Thus, the proposed testing requirements provide flexibility for testing for identity, purity, quality, strength, and composition, based on the availability of scientifically valid testing methods to perform testing on each batch of dietary ingredients or dietary supplements.

Proposed § 111.35(h) would require that you use an appropriate test or examination to determine whether your specifications are met. An appropriate

test is one that is a scientifically valid analytical method. If there is an AOAC or FDA method available that is appropriate for your purpose, you should use that test method. For example, if your dietary supplement claims to contain vitamin C, there is a specific test for identifying vitamin C, and so proposed § 111.35(h) would require that you use that test (Ref. 68). If an AOAC or FDA method is not available, a scientifically valid analytical method is one that is based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research. While there may not be an AOAC or FDA method available, we are not aware of a situation where an appropriate scientifically valid analytical method is not available. You could perform the tests yourself or have someone perform these tests for you.

Proposed § 111.35(i) would require that you must:

- Establish corrective action plans for use when an established specification is not met. We believe that this requirement is necessary because you may need to take corrective action quickly, and the best way to ensure that a corrective action is appropriate is to determine the action in advance. For example, if, during the production of a specific batch, the temperature specified for tablet coating drying is not met, you would be able to consult the corrective action plan to see whom you should contact, what correction to make, and when to make the correction. Having corrective action plans in place before a problem occurs can help you deal with those problems quickly and efficiently. As another example, if during production an operator notes that too low a temperature is used during a tablet coating drying operation, it would be best for the operator to have an action plan for immediate implementation, rather than having to stop the drying process to wait for instructions on what to do. Quick action may reduce the possibility of diminished changes in tablet dissolution or an adulterated product and enable you to avoid having to destroy incorrect tablets that are too moist or clump together or to avoid recalling a product because it settled into a clump or became moldy in the container;

- Review the results of the monitoring required by this section and conduct a material review of any component, dietary ingredient, dietary supplement, packaging or label for which you establish a specification that is not met, or any unanticipated occurrence that adulterates or could result in adulteration of the component,