

and composition of the components (upon receipt only) and for dietary ingredients or dietary supplements (at all of these control points).

You may establish additional specifications (*i.e.*, those in addition to identity, purity, quality, strength, and composition) at these same control points. For example, you may determine that an inprocess specification is necessary during the manufacturing process to prevent adulteration. That inprocess specification would be a regulatory specification. Specifications also are needed for the inprocess materials to ensure that inprocess materials are not adulterated by the manufacturing process and are in compliance with the master manufacturing record. Additional specifications also may be needed for the finished product stage. Specifications are needed for dietary ingredients and dietary supplements you manufacture to ensure that the manufacturing process produces the correct dietary ingredient or dietary supplement and that adulterated and misbranded dietary supplements do not reach the marketplace.

Containers and closures are a form of packaging. The containers and closure or other packaging, such as blister pack, that comes in contact with dietary ingredients or dietary supplements must not be reactive or absorptive so as to affect the safety of the dietary ingredient or dietary supplement and must be composed of substances that are authorized by the agency for use as a food additive, the subject of a valid notification under section 409 of the act, authorized by a prior sanction issued by the agency, or GRAS for such use.

Thus, under this proposed requirement, you would be required to establish specifications for any point, step, or stage in the manufacturing process where control is necessary to prevent adulteration. Specific specifications that would be required for you to establish include:

- The identity, purity, quality, strength, and composition of components, dietary ingredients, or dietary supplements that you receive;
- The inprocess controls in the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements;
- The identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement that you manufacture; and
- The packaging that may come in contact with dietary ingredients and dietary supplements. The packaging

must be safe and suitable for its intended use and comply with all other applicable statutory and regulatory requirements under the act and must not be reactive or absorptive so as to affect the safety of the dietary ingredient and dietary supplement.

Proposed § 111.35(f) would require that, for each point, step, or stage, for which a specification is established under proposed § 111.35(e), you must monitor the production and inprocess control points, steps, or stages to ensure that they meet specifications and to detect any unanticipated occurrence that may result in adulteration. Regular monitoring of these points is necessary to ensure that the product meets the specifications under proposed § 111.35(e) and to ensure that any trend toward loss of control is quickly identified. Quick identification of any trends that may lead to a deviation from a specification could mean that adjustments may be made to prevent a deviation from occurring. In the event that a deviation or unexpected occurrence (such as leakage from a pipe onto a component) occurs, effective corrective actions can be taken to remove the adulterated product from the system.

Under proposed § 111.35(g) you must ensure through testing or examination that each specification that you establish under § 111.35(e) is met. Under § 111.35(e), you would have to determine the points, steps, or stages where control is necessary to prevent adulteration. However, there are certain points, steps, or stages in proposed § 111.35(e) that we tentatively have determined to be those where control is necessary to prevent adulteration. Specifically, we tentatively have determined that such control points include the receipt of components, dietary ingredients, or dietary supplements, the inprocess stage of manufacturing, and the finished product batch stage. Further, we tentatively have determined that at each of those control points, there need to be specifications for the identity, purity, quality, strength, and composition of components (only at receipt stage for components), dietary ingredients and dietary supplements (at all of these control points). In addition, we tentatively have determined that specifications are necessary for dietary ingredient and dietary supplement labels and packaging.

The testing and examination requirements in proposed § 111.35(g) would require that you conduct a test or examination to ensure that specifications that you established are met; *i.e.*, that you conduct a test or examination at those points, steps, or

stages in the manufacturing process where you determined that a specification is needed to ensure that the specification, in fact, is met. For certain specifications that we would require, *i.e.*, the identity, purity, quality, strength, and composition upon receipt, inprocess, and at the finished product batch stage, we are providing some flexibility for testing. To illustrate, testing or examination requirements for specifications that you establish (*e.g.*, those other than the identity, purity, quality, strength, and composition of the dietary ingredients or dietary supplements received; inprocess, or finished product), such as for a botanical extraction process that uses a specific heat temperature for spray drying, you would be required to ensure by testing or examination that the specified temperature was used. You would be required to perform such a test or examination at the inprocess point, step, or stages where control is necessary. As another example, if a specific temperature is used on a finished batch of dietary ingredient or dietary supplement as a heat treatment to inactivate or remove objectionable microorganisms that pose a health hazard, and thus, the heat treatment temperature is a critical control point specification, then you must perform testing or examination to determine that the specific temperature was used. You would be required to perform such a test on each finished batch of dietary ingredient or dietary supplement that is manufactured.

For those specifications that we tentatively have determined are necessary (identity, purity, quality, strength, and composition) at receipt, inprocess, and finished product stage, we are proposing specific testing requirements that provide some flexibility. Under § 111.35(g)(1), we would require that you test each finished batch of the dietary ingredient or dietary supplement produced before releasing for distribution to confirm that specifications are met for the identity, purity, quality, strength, and composition intended, provided that there are scientifically valid analytical methods available to perform such testing. We recognize that certain tests for identity, purity, quality, strength, or composition for certain finished product may not be available due to complex finished matrices that would make such testing impracticable. Further, even though there may not be a scientifically valid analytical method that you could use to provide you with the information to evaluate, for example, the identity and composition of the finished