purity, strength, and composition of the dietary supplements and for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement; and

(3) Quality control personnel must review and approve the documentation that you provide under paragraph (c)(2) of this section.

(d) You must establish specifications for dietary supplement labels (label specifications) and for packaging that may come in contact with dietary supplements (packaging specifications). Packaging that may come into contact with dietary supplements must be safe and suitable for its intended use and must not be reactive or absorptive or otherwise affect the safety or quality of the dietary supplement.

(e) For each dietary supplement that you manufacture you must establish product specifications for the identity, purity, strength, and composition of the finished batch of the dietary supplement, and for limits on those types of contamination that may adulterate, or that may lead to adulteration of, the finished batch of the dietary supplement to ensure the quality of the dietary supplement.

(f) If you receive a product from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), you must establish specifications to provide sufficient assurance that the product you receive is adequately identified and is consistent with your purchase order.

(g) You must establish specifications for the packaging and labeling of the finished packaged and labeled dietary supplements, including specifications that ensure that you used the specified packaging and that you applied the specified label.

§ 111.73 What is your responsibility for determining whether established specifications are met?

You must determine whether the specifications you establish under § 111.70 are met.

§ 111.75 What must you do to determine whether specifications are met?

(a) Before you use a component, you must:

(1)(i) Conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient, unless you petition the agency under paragraph (a)(1)(ii) of this section and the agency exempts you from such testing;

(ii) You may submit a petition, under 21 CFR 10.30, to request an exemption from the testing requirements in paragraph (a)(1)(i) of this section. The petition must set forth the scientific rationale, and must be accompanied by the supporting data and information, for proposed alternative testing that will demonstrate that there is no material diminution of assurance, compared to the assurance provided by 100 percent identity testing, of the identity of the dietary ingredient before use when the dietary ingredient is obtained from one or more suppliers identified in the petition. If FDA grants the petition, you must conduct the tests and examinations for the dietary ingredient, otherwise required under § 111.75(a)(1)(i), under the terms specified by FDA when the petition is granted; and

(2) Confirm the identity of other components and determine whether other applicable component specifications established in accordance with § 111.70(b) are met. To do so, you must either:

(i) Conduct appropriate tests or examinations; or

(ii) Rely on a certificate of analysis from the supplier of the component that you receive, provided that:

(A) You first qualify the supplier by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of the supplier's tests or examinations;

(B) The certificate of analysis includes a description of the test or examination method(s) used, limits of the test or examinations, and actual results of the tests or examinations;

(C) You maintain documentation of how you qualified the supplier;

(D) You periodically re-confirm the supplier's certificate of analysis; and