

(1) Visually examine each container or grouping of containers in a shipment for appropriate content label, container damage, or broken seals to determine whether the container condition has resulted in contamination or deterioration of the components, dietary ingredients, or dietary supplement;

(2) Visually examine the suppliers invoice, guarantee, or certification to ensure that the components, dietary ingredients, or dietary supplements are consistent with your purchase order and perform testing, as needed, to determine whether specifications are met.

(3) Quarantine components, dietary ingredients, or dietary supplements until your quality control unit reviews the suppliers invoice, guarantee, or certification and performs testing, as needed, of a representative sample to determine that specifications are met. If specifications are not met, you must 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;

(4) 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; and

(5) Hold components, dietary ingredients, or dietary supplements under conditions that will protect against contamination, deterioration, and avoid mixups.

(b) For packaging and labels you receive, you must:

(1) Visually examine each container or grouping of containers in a shipment for appropriate content label, container damage, or broken seals to determine whether the container condition has resulted in contamination or deterioration of the packaging and labels;

(2) 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, you must conduct a material review and make a disposition decision. Your quality control unit must approve and

release packaging and labels from quarantine before you use them;

(3) 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. You must use this unique identifier whenever you record the disposition of each shipment lot received; and

(4) Hold packaging and labels under conditions that will protect against contamination, deterioration, and avoid mixups.

(c)(1) The person who performs the component, dietary ingredient, dietary supplement, packaging, or label requirements of this section must document, at the time of performance, that the requirements were followed. The documentation must include, but not be limited to:

(i) The date that the components, dietary ingredients, dietary supplements, packaging, or labels were received;

(ii) The signature of the person performing the requirement;

(iii) Any test results; and

(iv) Any material review and disposition decision you conducted in accordance with § 111.35(i) and disposition of any rejected material under § 111.74.

(2) You must keep component, dietary supplement, packaging, and label receiving records in accordance with § 111.125.

§ 111.45 What requirements apply to establishing a master manufacturing record?

(a) You must prepare and follow a written master manufacturing record for each type of dietary ingredient or dietary supplement that you manufacture and for each batch size to ensure uniformity from batch to batch. The master manufacturing record must:

(1) Identify specifications for the points, steps, or stages in the manufacturing process where control is necessary to prevent adulteration; and

(2) Establish controls and procedures to ensure that each batch of dietary ingredient or dietary supplement manufactured meets those specifications.

(b) The master manufacturing record must include the following information:

(1) The name of the dietary ingredient or dietary supplement to be manufactured and the strength, concentration, weight, or measure of

each dietary ingredient for each batch size;

(2) A complete list of components to be used;

(3) An accurate statement of the weight or measure of each component to be used;

(4) The identity and weight or measure of each dietary ingredient that will be declared on the Supplement Facts label and the identity of each ingredient that will be declared on the ingredients list of the dietary supplement in compliance with section 403(s) of the Federal Food, Drug, and Cosmetic Act;

(5) A statement that explains any intentional excess amount of a dietary ingredient;

(6) A statement of theoretical yield of a manufactured dietary ingredient or dietary supplement expected at each point, step, or stage of the manufacturing process where control is needed to prevent adulteration, and the expected yield when you finish manufacturing the dietary ingredient or dietary supplement, including the maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a batch is performed and material review is conducted and disposition decision is made;

(7) A description of packaging and a copy of the label to be used; and

(8) Written instructions including, but not limited to, the following:

(i) Specifications for each point, step, or stage in manufacturing the dietary ingredient or dietary supplement necessary to prevent adulteration;

(ii) Sampling and testing procedures;

(iii) Specific actions necessary to perform and verify points, steps, or stages, necessary to meet specifications and otherwise prevent adulteration, including, but not limited to, one person weighing or measuring a component and another person verifying the weight or measure and one person adding the component and another person verifying the addition;

(iv) Special notations and precautions to be followed; and

(v) Corrective action plans for use when a specification is not met.

(c) You must have the quality control unit review and approve each master manufacturing record and any modifications to a master manufacturing record.

(d) You must keep master manufacturing records in accordance with § 111.125.

§ 111.50 What requirements apply to establishing a batch production record?

(a) You must prepare a batch production record every time you