

(k) You must test or examine components, dietary ingredients, and dietary supplements for those types of contamination that may adulterate or may lead to adulteration. You must use an appropriate scientifically valid method for the test or examination. The types of contamination include, but are not limited to, the following:

- (1) Filth, insects, or other extraneous material;
- (2) Microorganisms; and
- (3) Toxic substances.

(l) Tests in accordance with this section must include at least one of the following:

- (1) Gross organoleptic analysis;
- (2) Microscopic analysis;
- (3) Chemical analysis; or
- (4) Other appropriate test.

(m) You must record results of all testing and examinations performed in accordance with this section. If a test or examination is performed on a batch production you must record the test or examination result in the batch production record in accordance with § 111.50(c)(10). Your records must document whether the testing and examination demonstrates that specifications are met.

(n) For any specification that is not met, you must conduct a material review and disposition decision under paragraph (i) of this section.

(o) You must make and retain records, in accordance with § 111.125, to ensure that you follow the requirements of this section. The records must include, but are not limited to:

- (1) The specifications established;
- (2) The actual results obtained during the monitoring operation;
- (3) Any deviation from specifications and any unanticipated occurrences;
- (4) Any corrective actions taken;
- (5) The disposition decisions and followup; and
- (6) The identity of the individual qualified by training and experience who investigated any deviation from specifications or unanticipated occurrence and the identity of the individual from the quality control unit who reviewed the results of that investigation.

§ 111.37 What requirements apply to quality control?

(a) You must use a quality control unit to ensure that your manufacturing, packaging, label, and holding operations in the production of dietary ingredients and dietary supplements are performed in a manner that prevents adulteration and misbranding, including ensuring that dietary ingredients and dietary supplements meet specifications for identity, purity, quality, strength, and composition.

(b) Your quality control unit must do the following:

- (1) Approve or reject all processes, specifications, controls, tests, and examinations, and deviations from or modifications to them, that may affect the identity, purity, quality, strength, and composition of a dietary ingredient or dietary supplement;
- (2) Determine whether all components, dietary ingredients, dietary supplements, packaging, and labels conform to specifications;
- (3) Approve or reject all components, dietary ingredients, dietary supplements, packaging, and labels;
- (4) Review and approve all master manufacturing records and all modifications to the master manufacturing records;
- (5) Review and approve all batch production-related records which include, but are not limited to, cross referencing receiving and batch production records, approval of a material review and disposition decision, approval for reprocessing, and approval for releasing for distribution;
- (6) Review and approve all processes for calibrating instruments or controls;
- (7) Review all records for calibration of instruments, apparatus, gauges, and recording devices;
- (8) Review all records for equipment calibrations, inspections, and checks;
- (9) Review and approve all laboratory control processes, and testing results;
- (10) Review and approve all packaging and label records which include, but are not limited to, cross-referencing receiving and batch production records, approval for repackaging and relabeling, and approval for releasing for distribution;
- (11) Collect representative samples of:
 - (i) Each shipment lot of components, dietary ingredients, dietary supplements, packaging, and labels received to determine whether the component, dietary ingredient, dietary supplement, packaging, or labels meet specifications;
 - (ii) Inprocess materials at points, steps, or stages, in the manufacturing process as specified in the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements;
 - (iii) Each batch of dietary ingredient or dietary supplement manufactured to determine, before releasing for distribution, whether the dietary ingredient or dietary supplement meets its specifications for identity, purity, quality, strength, and composition; and
 - (iv) Each batch of packaged and labeled dietary ingredients or dietary

supplements to determine that you used the packaging specified in the master manufacturing record and applied the label specified in the master manufacturing record.

(12) Keep the reserve samples for 3 years from the date of manufacture for use in appropriate investigations including, but not limited to, consumer complaint investigations to determine, for example, whether the dietary ingredient or dietary supplement associated with a consumer complaint failed to meet any of its specifications for identity, purity, quality, strength, and composition. The reserve samples must:

- (i) Be identified with the batch or lot number; and
- (ii) Consist of at least twice the quantity necessary for tests.

(13) Perform appropriate tests and examinations of:

- (i) Components, dietary ingredients, dietary supplements, packaging, and labels received to ensure that they meet specifications;
- (ii) Dietary ingredient and dietary supplement batch production at points, steps, or stages identified in the master manufacturing record where control is necessary to prevent adulteration;
- (iii) Dietary ingredients and dietary supplements that you manufacture to ensure that they meet specifications; and
- (iv) Packaged and labeled dietary ingredients and dietary supplements to ensure that you used the packaging specified in the master manufacturing record and you applied the label specified in the master manufacturing record.

(14) Review and approve all material review and disposition decisions; and

(15) Approve the reprocessing or distribution of returned dietary ingredients or dietary supplements.

(c) Your quality control unit must establish and maintain written documentation at the time of performance that it performed the review, approval, or rejection requirements of this section by recording the following:

- (1) Date the required review, approval, or rejection was performed; and
- (2) Signature of the person performing the requirement.

(d) You must keep quality control records in accordance with § 111.125.

§ 111.40 What requirements apply to components, dietary ingredients, dietary supplements, packaging, and labels you receive?

(a) For components, dietary ingredients, or dietary supplements you receive, you must: