

manufacture a batch of a dietary ingredient or dietary supplement and the batch production record must include complete information relating to the production and control of each batch.

(b) Your batch production record must accurately follow the appropriate master manufacturing record and you must perform each step in producing the batch.

(c) The batch production record must include, but is not limited to, the following information:

(1) The batch, lot, or control number;

(2) Documentation at the time of performance, showing the date on which each step of the master manufacturing record was performed, and the initials of the persons performing each step, including but not limited to:

(i) The person responsible for weighing or measuring each component used in the batch; and

(ii) The person responsible for adding the component to the batch.

(3) The identity of equipment and processing lines used in producing the batch;

(4) The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch;

(5) The shipment lot unique identifier of each component, dietary ingredient, dietary supplement, packaging, and label used;

(6) The identity and weight or measure of each component used;

(7) The initials at the time of performance or at the completion of the batch of the person responsible for verifying the weight or measure of each component used in the batch;

(8) The initials at the time of performance or at the completion of the batch of the person responsible for verifying the addition of components to the batch;

(9) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;

(10) The actual test results for any testing performed during the batch production;

(11) Documentation that the dietary ingredient and dietary supplement meets specifications;

(12) Copies of all container labels used and the results of examinations conducted during the label operation to ensure that the containers have the correct label;

(13) Any documented material review and disposition decision in accordance with § 111.35(j); and

(14) Signature of the quality control unit to document batch production

record review and any approval for reprocessing or repackaging.

(d) The quality control unit must review in accordance with § 111.37(b)(5) the batch production record established in paragraph (c) of this section.

(1) If a batch deviates from the master manufacturing record, including any deviation from specifications, the quality control unit must conduct a material review and make a disposition decision and record any decision in the batch production record.

(2) The quality control unit must not approve and release for distribution any batch of dietary ingredient or dietary supplement that does not meet all specifications.

(e) The quality control unit must document in accordance with § 111.37(c) the review performed in accordance with paragraph (d) of this section and it must be documented at the time of performance. The review and documentation must include, but is not limited to, the following:

(1) Review of component, dietary ingredient, and dietary supplement receiving records including review of testing and examination results;

(2) Identification of any deviation from the master manufacturing record that may have caused a batch or any of its components to fail to meet specifications identified in the master production record;

(3) Records of investigations, conclusions, and corrective actions performed in accordance with paragraph (d) of this section; and

(4) The identity of the person qualified by training and experience who performed the investigation in accordance with paragraph (d) of this section.

(f) You must not reprocess a batch that deviates from the master manufacturing record unless approved by the quality control unit. You must not reprocess a dietary ingredient or dietary supplement if it is rejected because of contamination with microorganisms of public health significance or other contaminants, such as heavy metals;

(g) Any batch of dietary ingredient or dietary supplement that is reprocessed must meet all specifications for the batch of dietary ingredient or dietary supplement and be evaluated and approved by the quality control unit before releasing for distribution. The results of the reevaluation by the quality control unit must be documented in the batch production record;

(h) You must collect representative reserve samples of each batch of dietary ingredient or dietary supplement and 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 whether, for example, 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; and

(i) You must keep batch production records in accordance with § 111.125.

#### **§ 111.60 What requirements apply to laboratory operations?**

(a) You must use adequate laboratory facilities to perform whatever testing and examinations are necessary to determine that components, dietary ingredients, and dietary supplements received meet specifications; that specifications are met during in-process, as specified in the master manufacturing record; and that dietary ingredients and dietary supplements manufactured meet specifications.

(b)(1) You must establish and follow laboratory control processes that are approved by the quality control unit. Laboratory control processes must include, but are not limited to, the following:

(i) Use of criteria for selecting appropriate examination and testing methods;

(ii) Use of criteria for establishing appropriate specifications; and

(iii) Use of sampling plans for obtaining representative samples of:

(A) Components, dietary ingredients, and dietary supplements received to determine whether specifications are met;

(B) In-process materials during the batch manufacturing when testing or examination is required in the master manufacturing record;

(C) Each batch of dietary ingredient or dietary supplement manufactured to determine that the dietary ingredient or dietary supplement meets specifications;

(D) Packaging and labels received to determine that the materials meet specifications; and

(E) Each batch of packaged and labeled dietary ingredients or dietary supplements to ensure that the label specified in the master manufacturing record has been applied.

(iv) Use of criteria for selecting standard reference materials used in performing tests and examinations;

(v) Use of appropriate test method validations; and

(vi) Use of test methods and examinations in accordance with established criteria.

(2) The person who conducts the testing and examination at the time of