

§ 111.303

(4) Approved and released, or rejected, the packaged and labeled dietary supplement, including any repackaged or relabeled dietary supplement.

(m) Documentation at the time of performance of any required material review and disposition decision.

(n) Documentation at the time of performance of any reprocessing.

Subpart J—Production and Process Control System: Requirements for Laboratory Operations

§ 111.303 What are the requirements under this subpart J for written procedures?

You must establish and follow written procedures for laboratory operations, including written procedures for the tests and examinations that you conduct to determine whether specifications are met.

§ 111.310 What are the requirements for the laboratory facilities that you use?

You must use adequate laboratory facilities to perform whatever testing and examinations are necessary to determine whether:

(a) Components that you use meet specifications;

(b) In-process specifications are met as specified in the master manufacturing record; and

(c) Dietary supplements that you manufacture meet specifications.

§ 111.315 What are the requirements for laboratory control processes?

You must establish and follow laboratory control processes that are reviewed and approved by quality control personnel, including the following:

(a) Use of criteria for establishing appropriate specifications;

(b) Use of sampling plans for obtaining representative samples, in accordance with subpart E of this part, of:

(1) Components, packaging, and labels;

(2) In-process materials;

(3) Finished batches of dietary supplements;

(4) Product that you receive for packaging or labeling as a dietary supple-

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ment (and for distribution rather than for return to the supplier); and

(5) Packaged and labeled dietary supplements.

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

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

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

§ 111.320 What requirements apply to laboratory methods for testing and examination?

(a) You must verify that the laboratory examination and testing methodologies are appropriate for their intended use.

(b) You must identify and use an appropriate scientifically valid method for each established specification for which testing or examination is required to determine whether the specification is met.

§ 111.325 Under this subpart J, what records must you make and keep?

(a) You must make and keep records required under this subpart J in accordance with subpart P of this part.

(b) You must make and keep the following records:

(1) Written procedures for laboratory operations, including written procedures for the tests and examinations that you conduct to determine whether specifications are met;

(2) Documentation that laboratory methodology established in accordance with this subpart J is followed.

(i) The person who conducts the testing and examination must document, at the time of performance, that laboratory methodology established in accordance with this subpart J is followed.

(ii) The documentation for laboratory tests and examinations must include the results of the testing and examination.