

§ 111.95

(c) Any batch of dietary supplement that is reprocessed, that contains components that you have treated, or to which you have made in-process adjustments to make them suitable for use in the manufacture of the dietary supplement must be approved by quality control personnel and comply with § 111.123(b) before releasing for distribution.

§ 111.95 Under this subpart E, what records must you make and keep?

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

(b) Under this subpart E, you must make and keep the following records:

- (1) The specifications established;
- (2) Documentation of your qualification of a supplier for the purpose of relying on the supplier's certificate of analysis;
- (3) Documentation for why meeting in-process specifications, in combination with meeting component specifications, helps ensure that the dietary supplement meets the specifications for identity, purity, strength, and composition; 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
- (4) Documentation for why the results of appropriate tests or examinations for the product specifications selected under § 111.75(c)(1) ensure that the dietary supplement meets all product specifications;
- (5) Documentation for why any component and in-process testing, examination, or monitoring, and any other information, will ensure that a product specification that is exempted under § 111.75(d) is met without verification through periodic testing of the finished batch, including documentation that the selected specifications tested or examined under § 111.75 (c)(1) are not able to verify that the production and process control system is producing a dietary supplement that meets the exempted product specification and there is no scientifically valid method for testing or examining such exempted product specification at the finished batch stage.

21 CFR Ch. I (4–1–25 Edition)

(6) Documentation of FDA's response to a petition submitted under § 111.75(a)(1)(ii) providing for an exemption from the provisions of § 111.75(a)(1)(i).

[72 FR 34942, June 25, 2007, as amended at 72 FR 34968, June 25, 2007]

Subpart F—Production and Process Control System: Requirements for Quality Control

§ 111.103 What are the requirements under this subpart F for written procedures?

You must establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing.

§ 111.105 What must quality control personnel do?

Quality control personnel must ensure that your manufacturing, packaging, labeling, and holding operations ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. To do so, quality control personnel must perform operations that include:

- (a) Approving or rejecting all processes, specifications, written procedures, controls, tests, and examinations, and deviations from or modifications to them, that may affect the identity, purity, strength, or composition of a dietary supplement;
- (b) Reviewing and approving the documentation setting forth the basis for qualification of any supplier;
- (c) Reviewing and approving the documentation setting forth the basis for why meeting in-process specifications, in combination with meeting component specifications, will help ensure that the identity, purity, strength, and composition of the dietary supplement are met;
- (d) Reviewing and approving the documentation setting forth the basis for why the results of appropriate tests or examinations for each product specification selected under § 111.75(c)(1) will ensure that the finished batch of the

dietary supplement meets product specifications;

(e) Reviewing and approving the basis and the documentation for why any product specification is exempted from the verification requirements in §111.75(c)(1), and for why any component and in-process testing, examination, or monitoring, or other methods will ensure that such exempted product specification is met without verification through periodic testing of the finished batch;

(f) Ensuring that required representative samples are collected;

(g) Ensuring that required reserve samples are collected and held;

(h) Determining whether all specifications established under §111.70(a) are met; and

(i) Performing other operations required under this subpart.

§ 111.110 What quality control operations are required for laboratory operations associated with the production and process control system?

Quality control operations for laboratory operations associated with the production and process control system must include:

(a) Reviewing and approving all laboratory control processes associated with the production and process control system;

(b) Ensuring that all tests and examinations required under §111.75 are conducted; and

(c) Reviewing and approving the results of all tests and examinations required under §111.75.

§ 111.113 What quality control operations are required for a material review and disposition decision?

(a) Quality control personnel must conduct a material review and make a disposition decision if:

(1) A specification established in accordance with §111.70 is not met;

(2) A batch deviates from the master manufacturing record, including when any step established in the master manufacturing record is not completed and including any deviation from specifications;

(3) There is any unanticipated occurrence during the manufacturing operations that adulterates or may lead to

adulteration of the component, dietary supplement, or packaging, or could lead to the use of a label not specified in the master manufacturing record;

(4) Calibration of an instrument or control suggests a problem that may have resulted in a failure to ensure the quality of a batch or batches of a dietary supplement; or

(5) A dietary supplement is returned.

(b)(1) When there is a deviation or unanticipated occurrence during the production and in-process control system that results in or could lead to adulteration of a component, dietary supplement, or packaging, or could lead to the use of a label not specified in the master manufacturing record, quality control personnel must reject the component, dietary supplement, packaging, or label unless it approves a treatment, an in-process adjustment, or reprocessing to correct the applicable deviation or occurrence.

(2) When a specification established in accordance with §111.70 is not met, quality control personnel must reject the component, dietary supplement, package or label, unless quality control personnel approve a treatment, an in-process adjustment, or reprocessing, as permitted in §111.77.

(c) The person who conducts a material review and makes the disposition decision must, at the time of performance, document that material review and disposition decision.

§ 111.117 What quality control operations are required for equipment, instruments, and controls?

Quality control operations for equipment, instruments, and controls must include:

(a) Reviewing and approving all processes for calibrating instruments and controls;

(b) Periodically reviewing all records for calibration of instruments and controls;

(c) Periodically reviewing all records for calibrations, inspections, and checks of automated, mechanical, or electronic equipment; and

(d) Reviewing and approving controls to ensure that automated, mechanical, or electronic equipment functions in accordance with its intended use.