§ 111.535 Under this subpart N, what records must you make and keep?

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

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

(1) Written procedures for fulfilling the requirements of this subpart N.

(2) Any material review and disposition decision on a returned dietary supplement;

(3) The results of any testing or examination conducted to determine compliance with product specifications established under § 111.70(e); and,

(4) Documentation of the reevaluation by quality control personnel of whether the reprocessed dietary supplement meets product specifications established in accordance with § 111.70(e).

Subpart O—Product Complaints

§ 111.553 What are the requirements under this subpart O for written procedures?

You must establish and follow written procedures to fulfill the requirements of this subpart O.

§ 111.560 What requirements apply to the review and investigation of a product complaint?

(a) A qualified person must:

(1) Review all product complaints to determine whether the product complaint involves a possible failure of a dietary supplement to meet any of its specifications, or any other requirements of this part 111, including those specifications and other requirements that, if not met, may result in a risk of illness or injury; and

(2) Investigate any product complaint that involves a possible failure of a dietary supplement to meet any of its specifications, or any other requirement of this part, including those specifications and other requirements that, if not met, may result in a risk of illness or injury.

(b) Quality control personnel must review and approve decisions about whether to investigate a product complaint and review and approve the findings and followup action of any investigation performed.

(c) The review and investigation of the product complaint by a qualified person, and the review by quality control personnel about whether to investigate a product complaint, and the findings and followup action of any investigation performed, must extend to all relevant batches and records.

§ 111.570 Under this subpart O, what records must you make and keep?

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

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

(1) Written procedures for fulfilling the requirements of this subpart.

(2) A written record of every product complaint that is related to good manufacturing practice.

(i) The person who performs the requirements of this subpart must document, at the time of performance, that the requirement was performed.

(ii) The written record of the product complaint must include the following:

(A) The name and description of the dietary supplement;

(B) The batch, lot, or control number of the dietary supplement, if available;

(C) The date the complaint was received and the name, address, or telephone number of the complainant, if available;

(D) The nature of the complaint including, if known, how the product was used;

(E) The reply to the complainant, if any; and

(F) Findings of the investigation and followup action taken when an investigation is performed.

Subpart P—Records and Recordkeeping

§ 111.605 What requirements apply to the records that you make and keep?

(a) You must keep written records required by this part for 1 year past the shelf life date, if shelf life dating is used, or 2 years beyond the date of distribution of the last batch of dietary
Food and Drug Administration, HHS

supplements associated with those records.
(b) Records must be kept as original records, as true copies (such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records.
(c) All electronic records must comply with part 11 of this chapter.

§ 113.610 What records must be made available to FDA?
(a) You must have all records required under this part, or copies of such records, readily available during the retention period for inspection and copying by FDA when requested.
(b) If you use reduction techniques, such as microfilming, you must make suitable reader and photocopying equipment readily available to FDA.

PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

Subpart A—General Provisions

§ 113.3 Definitions.

For the purposes of this part, the following definitions apply:
(a) Aseptic processing and packaging means the filling of a commercially sterilized cooled product into pre-sterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.
(b) Bleeders means openings used to remove air that enters with steam from retorts and steam chambers and to promote circulation of steam in such retorts and steam chambers. Bleeders may serve as a means of removing condensate.
(c) Come-up-time means the time which elapses between the introduction of steam into the closed retort and the time when the retort reaches the required processing temperature.
(d) Commercial processor includes any person engaged in commercial, custom, or institutional (church, school, penal, or other organization) processing of food, including pet food. Persons engaged in the production of foods that are to be used in market or consumer tests are also included.
(e) Commercial sterility: (1) “Commercial sterility” of thermally processed food means the condition achieved—
(i) By the application of heat which renders the food free of—
(a) Microorganisms capable of reproducing in the food under normal non-refrigerated conditions of storage and distribution; and
(b) Viable microorganisms (including spores) of public health significance; or
(ii) By the control of water activity and the application of heat, which renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.
(2) “Commercial sterility” of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment that renders the equipment and containers free of viable microorganisms having public health significance, as well as microorganisms of nonhealth significance,