(2) Investigate any product complaint that involves a possible failure of a dietary supplement to meet any of its specifications, or any other requirements 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 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.

§ 111.610 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

Sec.

Subpart B [Reserved]

Subpart C—Equipment

Subpart D—Control of Components, Food Product Containers, Closures, and In-Process Material

Subpart E—Production and Process Controls