

other requirements of this part, including those specifications and other requirements that, if not met, may result in a possible risk of illness or injury.

(b) Your quality control unit must review all consumer complaints involving the possible failure of a dietary ingredient or 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 possible risk of illness or injury, to determine whether there is a need to investigate the consumer complaint.

(c) Your quality control unit must investigate a consumer complaint when there is a reasonable possibility of a relationship between the quality of a dietary supplement and an adverse event.

(d) Your quality control unit's investigation of a consumer complaint must include the batch records associated with the dietary ingredient or dietary supplement involved in the consumer complaint. Your quality control unit must extend the investigation to other batches of dietary ingredients or dietary supplements that may have been associated with an adverse event.

(e) You must make and keep a written record of every consumer complaint that is related to good manufacturing practices. For the purposes of the regulations in this part, a consumer complaint about product quality may or may not include concerns about a possible hazard to health. However, a consumer complaint does not include an adverse event, illness, or injury related to the safety of a particular

dietary ingredient independent of whether the product is produced under good manufacturing practices. The consumer complaint written record must include, but is not limited to, the following:

(1) The name and description of the dietary ingredient or dietary supplement;

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

(3) The name of the complainant, if available;

(4) The nature of the complaint including how the consumer used the product;

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

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

(f)(1) The person who performs the requirements in accordance with this section must document at the time of performance that the requirement was performed.

(2) You must keep consumer complaint records in accordance with § 111.125.

11. Add subpart H to part 111 to read as follows:

Subpart H—Records and Recordkeeping

§ 111.125 What requirements apply to recordkeeping?

(a) You must keep written records required by this part for 3 years beyond the date of manufacture of the last batch of dietary ingredients or dietary supplements associated with those records.

(b) Records required under this part 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. If you use reduction techniques, such as microfilming, you must make suitable reader and photocopying equipment readily available to FDA. All electronic records must comply with part 11 of this chapter.

(c) You must have all records required under this part, or copies of such records, readily available during the retention period for authorized inspection and copying by FDA when requested.

12. Part 112 is added to read as follows:

PART 112—RESTRICTIONS FOR SUBSTANCES USED IN DIETARY SUPPLEMENTS

Subpart A—General Provisions [Reserved]

Subpart B—New Dietary Ingredients [Reserved]

Subpart C—Restricted Dietary Ingredients [Reserved]

Authority: 21 U.S.C. 321, 342, 343, 371.

Dated: January 29, 2003.

Mark B. McClellan,

Commissioner of Food and Drugs.

Dated: January 29, 2003.

Tommy G. Thompson,

Secretary of Health and Human Services.

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