

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 111

[Docket No. FDA-2008-N-0152] (formerly Docket No. 1996N-0417)

RIN 0910-AB88

**Current Good Manufacturing Practice in Manufacturing, Packaging,
Labeling, or Holding Operations for Dietary Supplements; Technical
Amendment**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of June 25, 2007 (72 FR 34752). The final rule established current good manufacturing practice (CGMP) requirements in manufacturing, packaging, labeling, or holding operations for dietary supplements. The final rule was published with an inadvertent error in the codified section. This document corrects that error. This action is being taken to improve the accuracy of the agency's regulations.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Vasilios H. Frankos, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1696.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 25, 2007 (72 FR 34752), FDA established CGMP requirements in manufacturing, packaging, labeling, or holding operations for dietary supplements (part 111 (21 CFR part

cf0820

FDA-2008-N-0152

NFR

DDM
Display Date 5-13-08
Publication Date 5-14-08
Certifier Slase

111)). In the codified section of the rule, § 111.75(c)(3) provides that “You must provide adequate documentation of your basis for determining compliance with the specification(s) selected under paragraph (c)(1) of this section, through the use of appropriate tests or examinations conducted under paragraph (c)(2) of this section, will ensure that your finished batch of the dietary supplement meets all product specifications for identity, purity, strength, and composition, and the limits on those types of contamination that may adulterate, or that may lead to the adulteration of, the dietary supplement” (72 FR 34752 at 34949). Due to an inadvertent error, the word “that” was omitted between “determining” and “compliance.” This document corrects that error.

List of Subjects in 21 CFR Part 111

Dietary foods, Drugs, Foods, Packaging and containers.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 111 is amended as follows:

PART 111—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS

■ 1. The authority citation for 21 CFR part 111 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 371, 374, 381, 393; 42 U.S.C. 264.

■ 2. Section 111.75 is amended by revising paragraph (c)(3) to read as follows:

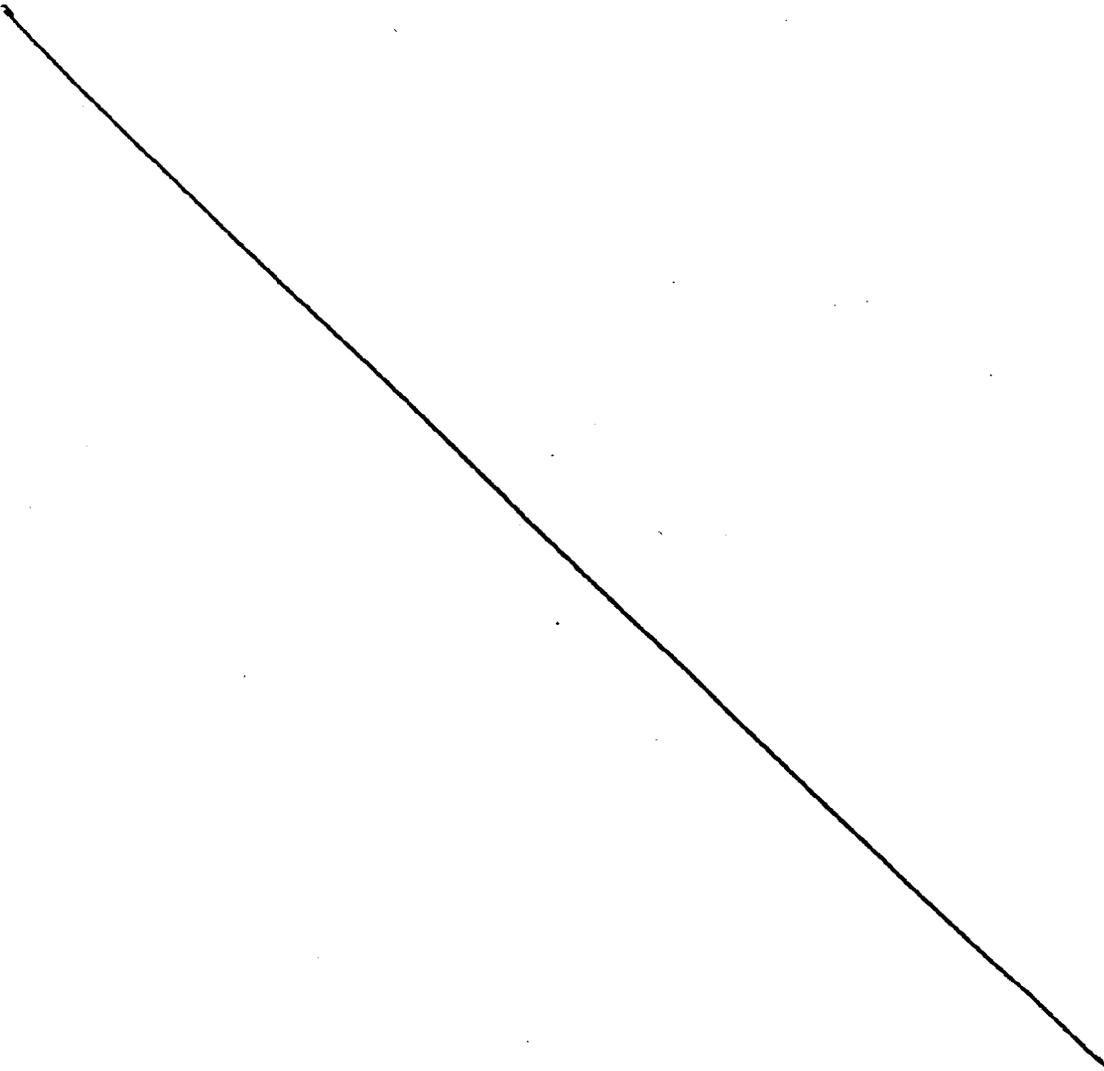
§ 111.75 What must you do to determine whether specifications are met?

* * * * *

(c) * * *

(3) You must provide adequate documentation of your basis for determining that compliance with the specification(s) selected under paragraph (c)(1) of this section, through the use of appropriate tests or examinations conducted under paragraph (c)(2) of this section, will ensure that your finished batch of the dietary supplement meets all product specifications for identity, purity, strength, and composition, and the limits on those types of contamination that may adulterate, or that may lead to the adulteration of, the dietary supplement; and

* * * * *



Dated: May 7, 2008.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE C

Sepele