

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 111 and 112

[Docket No. 96N-0417]

RIN 0910-AB88

Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing current good manufacturing practice (CGMP) regulations for dietary ingredients and dietary supplements. The proposed rule would establish the minimum CGMPs necessary to ensure that, if you engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, you do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements. The provisions would require manufacturers to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements. The proposed rule is one of many actions related to dietary supplements that we (FDA) are taking to promote and protect the public health.

DATES: Submit written or electronic comments by June 11, 2003. Submit written or electronic comments on the collection of information by April 14, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

Fax written comments on the information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Stuart Shapiro, Desk Officer for FDA, Fax (202) 395-6974, or electronically mail comments to sshapiro@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Karen Strauss, Center for Food Safety and Applied Nutrition (HFS-821), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2375.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

- A. Dietary Supplement Health and Education Act (DSHEA)
- B. The Advance Notice of Proposed Rulemaking
- C. Industry and Consumer Outreach
 - 1. Dietary Supplement Strategic Plan Meetings
 - 2. Small Business Outreach Meetings
 - 3. Site Visits to Dietary Supplement Manufacturing Firms
- D. Food Advisory Committee Report
- E. FDA's Decision To Propose a Rule
 - 1. Why Are CGMPs Needed?
 - a. CGMPs help protect the public health
 - b. CGMPs benefit consumers
 - 2. How Will CGMP Regulations Take Into Account Technical Feasibility?
 - 3. How Can FDA Help Industry Achieve Compliance With CGMPs?
- F. Proposal Highlights and Requests for Comments

II. General Issues

- A. Legal Authority
- B. Issues From the ANPRM

III. Description of the Proposed Rule

- A. General Provisions (Proposed Subpart A)
 - 1. Who Is Subject to These Part III Regulations? (Proposed § 111.1)
 - 2. What Are These Regulations Intended to Accomplish? (Proposed § 111.2)
 - 3. What Definitions Apply to this Part? (Proposed § 111.3)
 - 4. Do Other Statutory Provisions and Regulations Apply? (Proposed § 111.5)
 - 5. Exclusions (Proposed § 111.6)
- B. Personnel (Proposed Subpart B)
 - 1. What Microbial Contamination and Hygiene Requirements Apply? (Proposed § 111.10)
 - 2. What Personnel Qualification Requirements Apply? (Proposed § 111.12)
 - 3. What Supervisor Requirements Apply? (Proposed § 111.13)
- C. Physical Plant (Proposed Subpart C)
 - 1. What Sanitation Requirements Apply to Your Physical Plant? (Proposed § 111.15)
 - 2. What Design and Construction Requirements Apply to Your Physical Plant? (Proposed § 111.20)
- D. Equipment and Utensils (Proposed Subpart D)
 - 1. What Requirements Apply to the Equipment and Utensils You Use? (Proposed § 111.25)
 - 2. What Requirements Apply to Automatic, Mechanical, or Electronic Equipment? (Proposed § 111.30)
- E. Production and Process Controls (Proposed Subpart E)
 - 1. What Production and Process Controls Must You Use? (Proposed § 111.35)
 - 2. What Requirements Apply to Quality Control? (Proposed § 111.37)
 - 3. What Requirements Apply to Components, Dietary Ingredients, Dietary Supplements, Packaging, and Labels You Receive? (Proposed § 111.40)
 - 4. What Requirements Apply to Establishing a Master Manufacturing Record? (Proposed § 111.45)
 - 5. What Requirements Apply to Establishing a Batch Production Record? (Proposed § 111.50)

- 6. What Requirements Apply to Laboratory Operations? (Proposed § 111.60)
- 7. What Requirements Apply to Manufacturing Operations? (Proposed § 111.65)
- 8. What Requirements Apply to Packaging and Label Operations? (Proposed § 111.70)
- 9. What Requirements Apply to Rejected Components, Dietary Ingredients, Dietary Supplements, Packaging, and Labels? (Proposed § 111.74)
- F. Holding and Distributing (Proposed Subpart F)
 - 1. What Requirements Apply to Holding Components, Dietary Ingredients, Dietary Supplements, Packaging, and Labels? (Proposed § 111.80)
 - 2. What Requirements Apply to Holding In-Process Material? (Proposed § 111.82)
 - 3. What Requirements Apply to Holding Reserve Samples of Components, Dietary Ingredients, and Dietary Supplements? (Proposed § 111.83)
 - 4. What Requirements Apply to Returned Dietary Ingredients or Dietary Supplements? (Proposed § 111.85)
 - 5. What Requirements Apply to Distributing Dietary Ingredients or Dietary Supplements? (Proposed § 111.90)
- G. Consumer Complaints—What Requirements Apply to Consumer Complaints? (Proposed Subpart G, § 111.95)
- H. Records and Recordkeeping—What Requirements Apply to Recordkeeping? (Proposed Subpart H, § 111.125)
- IV. Statement Concerning the Use of Plain Language
- V. Paperwork Reduction Act of 1995
- VI. Environmental Impact Considerations
- VII. Analysis of Impacts
 - A. Introduction
 - B. Preliminary Regulatory Impact Analysis
 - 1. The Need for the Proposed CGMP Regulations
 - 2. Regulatory Options
 - a. No new regulatory action
 - b. Fewer requirements for vitamins and minerals
 - c. More restrictive CGMP regulations than the proposed regulations
 - d. HACCP without the other elements of CGMP regulations
 - e. Require final product testing only
 - f. Regulate only high-risk products
 - 3. Coverage of the Proposed Rule
 - 4. Baseline Practices
 - 5. Baseline Risk
 - 6. Benefits and Costs
 - a. Reduced illnesses
 - b. Fewer products recalled
 - c. Reduced hypothetical search costs as a measure of the benefit from increased assurance of quality
 - d. Other benefits
 - e. Total measured benefits
 - 7. Costs
 - a. Description of the costs
 - b. Costs of general activity
 - c. Major costs by type of activities
 - d. Estimating costs
 - 8. Summary of Benefits and Costs
- C. Initial Regulatory Flexibility Analysis
 - 1. Introduction