



U.S. Food and Drug Administration
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U.S. Food & Drug Administration

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Dietary Supplements

Guidance Documents

Guidance documents contain nonbinding recommendations

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Current Good Manufacturing Practice (CGMP)

- **Small Entity Compliance Guide:** [Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements](#)¹ December 2010
- **Final Rule:** Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements
 - Federal Register Final Rule June 25, 2007
 - Federal Register Interim Final Rule (IFR): [Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements](#)² June 25, 2007
 - Fact Sheet: [Dietary Supplement Current Good Manufacturing Practices \(CGMPs\) and Interim Final Rule \(IFR\) Facts](#)³ June 22, 2007
 - Consumer Update: [Final Rule Promotes Safe Use of Dietary Supplements](#)⁴ June 22, 2007
 - FDA Press Release: [FDA Issues Dietary Supplements Final Rule](#)⁵ June 22, 2007
- **Proposed Rule:** Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements
 - [Federal Register Proposed Rule](#)⁶ March 13, 2003
 - [Extension of Comment Period](#)⁷ Federal Register, May 19, 2003
 - [Guidance for Small Businesses: Submission of Comments for CFSAN Rulemaking](#)⁸ October 21, 2002
- **Advance Notice of Proposed Rule:** [Current Good Manufacturing Practice in Manufacturing, Packaging and Holding of Dietary Supplements](#)⁹ Federal Register, February 6, 1997
- **New Dietary Ingredients**
 - [Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues](#)¹⁰ July 2011
 - Final Rule: [Premarket Notification for a New Dietary Ingredient](#)¹¹ Federal Register, September 23, 1997
 - [New Dietary Ingredients in Dietary Supplements](#)¹² (Explanation including: definition, notification process, and table of notifications received) February 2001
- **Special Issues**
 - **BSE ("Mad Cow Disease")**
 - [FDA: Bovine spongiform encephalopathy \(BSE\)](#)¹³ (background, industry and consumer information, recent actions, etc.)
 - **Ephedrine Alkaloids**
 - See [Special Issues](#)¹⁴ web page.
- **Warnings and Safety Information**
 - [Dietary Supplement Alerts and Safety Information](#)¹⁵ (consumer advisories on

specific supplements including kava, PC SPES, St. John's Wort, etc.; how to report problems; and other safety information)

Labeling and Regulation

- **New Dietary Ingredients (NDI):** [New Dietary Ingredient Notifications and Related Issues](#)¹⁶ July 2011
- **Liquid Dietary Supplements:** [FDA Letter to Industry Concerning Liquid Vitamin D Dietary Supplements](#)¹⁷ June 2010
- **Liquid Dietary Supplements:** [Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods](#)¹⁸ December 2009
- **Labeling:** [Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act](#)¹⁹ December 2007; Revised December 2008 and September 2009
- [A Dietary Supplement Labeling Guide](#)²⁰ April 2005
- **Ephedrine Alkaloids:** [Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk](#)²¹ July 17, 2008
- **Label Warning Statements:** [Iron-Containing Supplements and Drugs: Label Warning Statements: Small Entity Compliance Guide](#)²² October 17, 2003
- **Labeling:** [Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide](#)²³ January 1999
- **Nutrient Content Claims:** [Food Labeling; Nutrient Content Claims; Definition for "High Potency" and Definition for "Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods Small Entity Compliance Guide](#)²⁴ July 2008
- **Structure/Function Claims:** [Small Entity Compliance Guide](#)²⁵ January 9, 2002
- **Substantiation for Claims:** [Substantiation for Dietary Supplement Claims Made Under Section 403\(r\) \(6\) of the Federal Food, Drug, and Cosmetic Act](#)²⁶ November 2004

Health Claims

- [Evidence-Based Review System for the Scientific Evaluation of Health Claims](#)²⁷ January 2009
- [Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements](#)²⁸ December 1999
- [Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body](#)²⁹ June 1998

Qualified Health Claims

- [Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements](#)³⁰ July 10, 2003

Adverse Events Reporting

- **Adverse Event Reporting and Recordkeeping:** [Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act](#)³¹ June 2009

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