

Dietary Supplement cGMP Final Rule

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February 22nd, 2008

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Where is the Final Rule Published?

- **Federal Register/Volume 72, No. 121/Monday, June 25, 2007**
- **cGMP regulation is on pp. 34942-34958 of the Federal Register**

FDA Resources for cGMP Regulation

- **FDA website – “Dietary Supplements”**
- **www.fda.gov**
- **Satellite broadcast – discussion of regulation**

Who is Subject to the Regulation?

- **Manufacture, package, label, or hold a dietary supplement**
- **Dietary supplements sold in US (foreign and domestic firms)**
- **Does not apply to ingredient suppliers**

What is the Compliance Date?

- **500 + Employees – June, 2008**
- **20 – 499 Employees – June, 2009**
- **Fewer than 20 Employees – June, 2010**

Existing Laws & Regulations

- **Compliance with all other dietary supplements laws and regulations**

Overview of cGMP Regulation

- **Divided into 16 subparts (Subparts A-P)**
- **Recommendation – read headers of all 16 subparts and titles of all parts, as well as definitions**

Overview of cGMP Regulation

- **Implementation of measures to ensure quality of dietary supplements**
- **Definition of “Quality”**

Overview of cGMP Regulation

- **Documented Quality Management/Process Control program**

Overview of cGMP Regulation

- **Subpart B – Personnel: Quality Control must have “distinct and separate responsibilities”**
 - Documented education, training, and/or experience
- **Subpart C – Physical Plant and Grounds**
 - Sanitation, design construction
- **Subpart D – Equipment and Utensils**
 - Calibration

Overview of cGMP Regulation

- **Subpart E – Requirements to Establish a Production and Process Control System**
- **Subpart F – Production and Process Control System: Requirements for Quality Control**
 - Role of QC

Overview of cGMP Regulation

- **Subpart G – Production and Process Control System: Requirements for Components, Packaging, and Labels and for Product That You Receive for Packaging or Labeling as a Dietary Supplement**
- **Subpart H – Production and Process Control System: Requirements for the Master Manufacturing Record**

Overview of cGMP Regulation

- **Subpart I – Production and Process Control System: Requirements for the Batch Production Record**
- **Subpart J – Production and Process Control System: Requirements for Laboratory Operations**
 - Third party laboratories

Overview of cGMP Regulation

- **Subpart K – Production and Process Control System: Requirements for Manufacturing Operations**
 - Sanitation, prevent contamination
- **Subpart L – Production and Process Control System: Requirements for Packaging and Labeling Operations**

Overview of cGMP Regulation

- **Subpart M – Holding and Distributing**
 - Components, in-process, finished product
- **Subpart N – Returned Dietary Supplements**
 - Investigation

Overview of cGMP Regulation

- **Subpart O – Product Complaints**
 - QC Personnel
- **Subpart P – Records and Recordkeeping**
 - Records for FDA Inspection

Compliance with cGMP Regulation

- **Personnel**
- **Review of existing QA/QC program**
- **Internal and 3rd party audit**
- **Vendor verification – all service providers**

Thank you!

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