



### OVERVIEW

#### Summary

- The Food and Drug Administration (FDA) has issued a final rule regarding current good manufacturing practices (cGMP) for dietary supplements that establishes the minimum requirements for manufacturing, packaging, labeling or holding of dietary supplements to ensure that products meet appropriate quality standards.

*Refer to Part 111 – Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements:*

<http://www.cfsan.fda.gov/~lrd/fr07625a.html>

- Compliance dates were staggered dependent on the size of the company:
  - June 25, 2008 – companies > 500
  - June 25, 2009 – companies of 20-500
  - June 25, 2010 – companies < 20

#### Definition of Dietary Supplement

A dietary supplement:

- Is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.
- Is intended for ingestion in pill, capsule, tablet, or liquid form.
- Is not represented for use as a conventional food or as the sole item of a meal or diet.
- Is labeled as a "dietary supplement."
- Includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).

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## WHO DOES THIS APPLY TO

- Manufacturers, Packagers, Labelers, and storage facilities.

## KEY POINTS

The GMPs are divided into various sections and in every case written procedures and records are required.

### Personnel

- Microbial contamination is avoided through appropriate health and hygienic practices.
- The person responsible for quality control is identified.
- Personnel performing quality control functions are qualified and have distinct and separate responsibilities when performing these functions.
- Personnel have the education training or experience necessary to perform the assigned functions.

### Facility

- Grounds are maintained so as to prevent contamination.
- The physical plant is maintained in a clean and sanitary condition.
- Water used must meet all Federal, State and local requirements.
- There must be written procedures and records for cleaning and pest control of the facility.
- The plant must be designed so as to prevent contamination and mix-ups and to allow for appropriate cleaning and maintenance of equipment.
- There must be adequate ventilation or environmental control equipment to prevent contamination.
- There must be adequate lighting.

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## Equipment and Utensils

- Equipment used in the manufacturing and testing must be routinely calibrated.
- There must be procedures for maintaining, cleaning and sanitizing equipment and utensils in direct contact with the dietary supplement.
- The equipment must be designed to prevent contamination of the product.
- Cold storage equipment must be fitted with a temperature monitoring device and must have an automated device for regulating temperature, or be connected to automated alarm system.
- Instruments or controls used must be accurate and precise, adequately maintained, and sufficient in number.
- All equipment must be maintained, cleaned and sanitized.
- Automated mechanical or electronic equipment must be selected to ensure that product specifications are consistently met, that the equipment is capable of operating within the required operating limits.

## Production and Process Controls

- There must be a quality control operation.
- Specifications must be established for every stage in the process where control is required:
  - All components used and each product manufactured must have specifications including identity, purity, strength and limits on contamination.
  - In-process specifications must be established for any part of the process where control is necessary.
  - Packaging and labeling must have approved specifications.
- Reprocessing may only occur if quality control has conducted an investigation and approved the reprocessing based on scientifically valid reasoning.

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The following records must be maintained:

- Specifications
- Supplier qualification
- Justification for in-process testing
- Justification for reduced finished product testing, if applicable

## Quality Control

- Quality control is responsible to:
  - Approve all processes, specifications, procedures, controls, tests and deviations.
  - Ensure all samples are taken and that reserve samples are held.
  - Determine that all specifications are met.
  - Review and approve laboratory processes.
  - Conduct an investigation if specifications are not met, there is a deviation or an unanticipated occurrence during manufacture.
  - Review and approve all master manufacturing records, in-process tests and reprocessing.
  - Review and release of each batch of finished product.
  - Review and approve the condition of any product returned to the facility, prior to re-distribution.
  - Review and approve decisions regarding the investigation of any complaint received.

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## Raw Materials, Packaging and Labeling

- Each receipt must be inspected, sampled and results of testing compared against specifications.
- Each lot must be uniquely identified.
- Lots are released by quality control.
- Rejected items must be clearly labeled and held under quarantine.

## Master Manufacturing Records

- A master manufacturing record must be prepared for each unique formulation and batch size, including instructions for each stage of production, sampling and specifications for each control point, expected yields and provisions for verifications of the weights and additions of each component.

## Batch Production Record

- There must be a production record for each batch produced, referencing cleaning and sanitization actions, the lot numbers of each component used, yields, test results and dates, times and initials of the activities.

## Laboratory Operations

- Procedures must be appropriate and scientifically valid. They must be signed by quality control.
- Records of all tests conducted must be maintained.

## Manufacturing Operations

- Manufacturing operations must be carried out under conditions that guard against the contamination of the product.

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## Packaging and Labeling Operations

- Packaging operations must be carried out under conditions that guard against contamination of the product.
- An actual label or representation must be retained and must be compared to the label in the master production record.
- Packaging and labels must be reconciled unless the label on the finished product is examined electromechanically.

## Holding and Distributing

- Products and components must be held and distributed under appropriate storage conditions.
- Distribution records must be maintained.

## Returns

- Returns must be quarantined on receipt and only released after a material review is conducted by quality control.

## Product Complaints

- All complaints must be reviewed and any possible failure must be investigated. This review and any subsequent investigation must be reviewed by quality control.

## Records and Recordkeeping

- Records must be maintained for one year past the shelf life of the product or two years past the date of distribution of the last batch of product associated with those records.
- Required records must be available for review by the FDA on request.

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## FAQ

### 1. What is a dietary supplement?

A dietary supplement:

- Is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.
- Is intended for ingestion in pill, capsule, tablet, or liquid form.
- Is not represented for use as a conventional food or as the sole item of a meal or diet.
- Is labeled as a "dietary supplement."
- Includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).

### 2. What is a new dietary ingredient?

A new dietary ingredient is a dietary ingredient that was not sold in the United States in a dietary supplement before October 15, 1994.

### 3. What claims can manufacturers make for dietary supplements and drugs?

The label of a dietary supplement or food product may contain one of three types of claims: a health claim, nutrient content claim, or structure/function claim.

Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition. Nutrient content claims describe the relative amount of a nutrient or dietary substance in a product.

A structure/function claim is a statement describing how a product may affect the organs or systems of the body and it can not mention any specific disease. Structure/function claims do not require FDA approval but the manufacturer must provide FDA with the text of the claim within 30 days of putting the product on the market.

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Product labels containing such claims must also include a disclaimer that reads, "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."

Drug manufacturers may claim that their product will diagnose, cure, mitigate, treat, or prevent a disease. Such claims may not legally be made for dietary supplements.

#### 4. How does FDA regulate dietary supplements?

In addition to regulating label claims, FDA regulates dietary supplements in other ways. Supplement ingredients sold in the United States before October 15, 1994, are not required to be reviewed by FDA for their safety before they are marketed because they are presumed to be safe based on their history of use by humans.

For a new dietary ingredient (one not sold as a dietary supplement before 1994) the manufacturer must notify FDA of its intent to market a dietary supplement containing the new dietary ingredient and provide information on how it determined that reasonable evidence exists for safe human use of the product. FDA can either refuse to allow new ingredients into or remove existing ingredients from the marketplace for safety reasons.

Manufacturers do not have to provide FDA with evidence that dietary supplements are effective or safe; however, they are not permitted to market unsafe or ineffective products. Once a dietary supplement is marketed, FDA has to prove that the product is not safe in order to restrict its use or remove it from the market.

The label of a dietary supplement product is required to be truthful and not misleading. If the label does not meet this requirement, FDA may remove the product from the marketplace or take other appropriate actions.

#### 5. Is there a monograph system for dietary supplements?

There is no system in the U.S.A. for dietary supplement monographs and no requirement to standardize them. The presence of the word "standardized" on a supplement label does not necessarily indicate product quality.

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## 6. What methods are used to evaluate the health benefits and safety of a dietary supplement?

Scientists use several approaches to evaluate dietary supplements for their potential health benefits and safety risks, including their history of use and laboratory studies using cell or animal studies. Studies involving people (individual case reports, observational studies, and clinical trials) can provide information that is relevant to how dietary supplements are used. Researchers may conduct a systematic review to summarize and evaluate a group of clinical trials that meet certain criteria. A meta-analysis is a review that includes a statistical analysis of data combined from many studies.

## 7. What are some additional sources of information on dietary supplements?

- PubMed - <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?holding=nih>
- FDA - <http://www.cfsan.fda.gov/~dms/ds-info.html>
- For general information on botanicals and their use as dietary supplements, see *Background Information About Botanical Dietary Supplements* - <http://ods.od.nih.gov/factsheets/botanicalbackground.asp>

**Contact NHP Compliance**  
 with your questions about Natural Health Products.  
 Phone Graham Mills toll-free at 1-877-877-5152,  
 extension 210, or email him at [gmills@qualityandcompliance.com](mailto:gmills@qualityandcompliance.com).

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