



U.S. Pharmacopeia
The Standard of Quality™

The Regulation of Dietary Supplements

How are dietary supplements regulated?

The U.S. Food and Drug Administration (FDA) is responsible for regulating dietary supplements through its Center for Food Safety and Applied Nutrition. The Food Drug and Cosmetic Act (FDCA) as amended by the Dietary Supplement Health and Education Act of 1994 (DSHEA) is the law that regulates dietary supplements.

Under FDCA, the *United States Pharmacopeia* and *National Formulary (USP–NF)* are specifically recognized as providing specifications for dietary supplements. Adherence to these standards, however, is voluntary. Dietary supplement manufacturers are not legally required to meet these specifications.

The FDCA regulates dietary supplements as foods. Under the law, supplement regulations are the same as those that cover conventional foods.

- Dietary supplement manufacturers do not need to register with FDA, or obtain FDA approval before producing or selling their products.
- Prior to marketing a product, manufacturers are responsible for ensuring that a dietary supplement (or a new ingredient) is safe before it is marketed. FDA has the authority to take action against unsafe dietary supplement products.
- Manufacturers must ensure that their product label information is truthful and not misleading.

How is supplement safety monitored?

Dietary supplement manufacturers are not legally required to report “adverse events” to the FDA, including injuries or illnesses—that may be related to the use of their products. The FDA monitors supplement safety through such avenues as voluntary adverse event reporting, labeling claims, product literature, and occasional laboratory testing.

Who regulates dietary supplement advertising?

The Federal Trade Commission (FTC) regulates dietary supplement advertising for false and misleading health claims.

What are “good manufacturing practices,” and why are they important?

Good manufacturing practices, or GMPs, are strict, detailed procedures used to ensure quality manufacturing processes of products for human consumption, such as drugs, dietary supplements and food. GMPs put in place systems that help prevent product contamination, inconsistency from batch-to-batch, unsanitary manufacturing, errors in product labeling, and an enormous range of other important production activities that can affect human health. If problems do arise, they can be tracked, identified, and solved quickly, through GMP-mandated documentation for all processes, from production of raw ingredients to distribution of final product.

In 2003, the FDA issued a proposed rule for Current Good Manufacturing Practices (cGMPs) in manufacturing, packaging, or holding dietary ingredients and dietary supplements, which include several provisions developed by USP.¹ Although the law

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requires that dietary supplements adhere to GMPs, final regulations have not been issued. Manufacturers have the responsibility to produce products of good quality according to standardized practices but have no official GMPs for guidance. USP's Verification Program requires manufacturer compliance with the proposed FDA GMP standards and with USP's General Chapter on *Manufacturing Practices for Nutritional Supplements*. Together, these guidances provide safeguards that help assure manufacture of quality products.

Is USP's Verification Program part of FDA's regulation of dietary supplements?

No. USP and FDA share a common mission of actively promoting the public health. USP's Verification Program complements FDA's regulation of dietary supplement products, however, they are separate programs.

More information

For a summary of government regulations on dietary supplements, visit the FDA Web site at <http://www.cfsan.fda.gov/~dms/supplmnt.html>.