



## FACT SHEET

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# Good Manufacturing Practices for Dietary Supplements

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Good Manufacturing Practices (GMPs) are regulations that describe the methods, equipment, facilities, and controls required for producing foods (including dietary supplements), and other products such as drugs and medical devices. They define process controls that manufacturers use to build quality into their products. They provide assurance to consumers that high quality products are being produced.

The Dietary Supplement Health and Education Act (DSHEA), the law that regulates dietary supplements, provides that a product is adulterated if it has been prepared, packed, or held under conditions that do not meet current GMP regulations (under the Federal Food, Drug and Cosmetic Act). The Secretary of Health and Human Services may by regulation prescribe GMPs for dietary supplements. Such regulations shall be modeled after current GMP regulations for food and may not impose standards for which there is no current and generally available analytical methodology.

### TIMELINE:

- In 1986, CRN member companies voluntarily adopted manufacturing guidelines, which were later used as the basis for USP guidelines for supplement GMPs.
- CRN and other associations supported the DSHEA provision that gave FDA authority to develop GMP regulations for supplements.
- DSHEA unanimously passed, 1994.
- The Council for Responsible Nutrition (CRN) and other industry groups met with FDA officials and offered assistance in developing GMPs for dietary supplements after the passage of DSHEA.
- CRN and other industry groups submitted an industry draft on GMPs to FDA in November 1995.
- FDA published the industry draft in an advanced notice of proposed rulemaking (ANPR) in February 1997.
- FDA sought advice from the Food Advisory Committee in 1998 and held a series of public meetings to solicit more input from the industry, especially small businesses, in 1998 and 1999.
- FDA submitted GMP proposal to OMB for review in late 2000 and again in 2001 and 2002.
- On March 13, 2003, FDA published the proposed GMPs.
- CRN and other stakeholders submitted comments on the proposed GMP rule on or before the official deadline of Aug. 11, 2003.
- After FDA evaluates the comments, a final rule will be published, followed by an appropriate period allowing for implementation.

Although the FDA has not yet implemented GMPs as authorized by DSHEA, industry has instituted its own stringent good manufacturing practices to ensure quality products for the consumer. Once the FDA's GMPs are finalized, all dietary supplement manufacturers will have to incorporate those GMPs into their practices.

The Council for Responsible Nutrition (CRN) is one of the dietary supplement industry's leading trade associations representing ingredient suppliers and manufacturers. CRN members adhere to a strong code of ethics, comply with dosage limits and manufacture dietary supplements to high quality standards under good manufacturing practices.