FDA U.S. Food and Drug Administration Department of Health and Human Services

BACKGROUNDER

Final Rule for Current Good Manufacturing Practices (CGMPs) for Dietary Supplements

June 25, 2007

Overview

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), dietary supplement manufacturers have the essential responsibility to substantiate the safety of the dietary ingredients used in manufacturing a product. Manufacturers are also responsible for determining that any representations or claims made about their products are substantiated by adequate evidence to show that they are not false or misleading. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. FDA accomplishes its responsibilities through monitoring safety literature; dietary supplement adverse event reports; and product information, such as labeling, claims, package inserts, and accompanying literature.

As part of DSHEA, Congress gave the Secretary of Health and Human Services and the FDA by delegation, the express authority to issue regulations establishing current good manufacturing practice requirements (CGMPs) for dietary supplements. The FDA has issued a final rule establishing requirements for the production of dietary supplements.

Specifically this rule:

- Requires certain activities in manufacturing, packaging, labeling and holding of dietary supplements to ensure that a dietary supplement contains what it is labeled to contain and is not contaminated with harmful or undesirable substances such as pesticides, heavy metals, or other impurities.
- Requires certain activities that will ensure the identity, purity, quality, strength, and composition of dietary supplements, which is a significant step in assuring consumers they are purchasing the type and amount of ingredients declared.

History

- 1994 - Dietary Supplement Health and Education Act is passed by Congress.
- 1997 - The FDA issued an advance notice of proposed rulemaking that contained CGMPs submitted by representatives of the dietary supplement industry as well as nine specific questions from FDA. Approximately 100 comments were received
- 1999 - FDA conducted numerous outreach activities to include public meetings to ascertain the best approach to rulemaking for dietary supplements.
- 2003 - The FDA issued a proposed rule to establish CGMPs for dietary supplements and dietary supplement ingredients. There were approximately 400 comments submitted in response to the proposal. The comments came from trade associations, government organizations and officials, health care professionals, consumer groups, manufacturers of dietary supplement and dietary ingredients, and individuals. The dietary supplement CGMP final rule and interim final rule (IFR), issued today are based on the comments received and FDA's expertise.
- 2007 - Today the FDA took action to help Americans get accurately labeled and properly manufactured dietary supplements, through its final rule establishing dietary supplement CGMPs. An IFR has also been issued to allow the manufacturer to petition the FDA for an exemption to the 100 percent testing requirement for the identity of dietary ingredients to be used in dietary supplements. The manufacturer would have to provide data demonstrating that less than 100 percent identity testing does not materially diminish assurance that the dietary ingredient is the correct dietary ingredient.

Science-Based Consumer Protection

- FDA has found that manufacturing problems have been associated with dietary supplements. Products have been recalled because of microbiological, pesticide, and heavy metal contamination and because they do not contain the dietary ingredients they are represented to contain or they contain more or less than the amount of the dietary ingredient claimed on the label.
- In the past, several private sector laboratories analyses found that a substantial number of dietary supplement products analyzed did not contain the amount of dietary ingredients claimed in their product labels.
- FDA has taken enforcement actions against dietary supplements due to undeclared ingredients, subpotency and contamination. Some examples include:
    - 2006 - FDA warned several firms after FDA analysis of dietary supplements found undeclared active ingredients used in prescription drugs for erectile dysfunction and their analogs in several dietary supplement products.

- 2005 - FDA issued a Warning Letter to a firm after FDA analysis of two of the firm's products were found to be significantly subpotent in several components, such as Vitamin A, Folic Acid, and Vitamin C.
- 2004 - FDA issued a Warning Letter to a firm after FDA analysis found the firm's tablets to be underweight, such that the weight of the tablets could not contain the amount of nutrients declared on the label. Also, FDA initiated a seizure action against ginseng because analysis found the product to contain illegal pesticide residues