

Final Rule Promotes Safe Use of Dietary Supplements



Eyewire

There may be negative interactions associated with some dietary supplements and other medicines you are taking. Consult a health care provider before using any dietary supplement.

Some dietary supplements are beneficial when taken appropriately. Calcium supplements may strengthen bones and folic acid lowers the risk of certain birth defects. But some supplements pose health risks. They may contain harmful ingredients or be improperly manufactured or handled.

On June 22, 2007, FDA announced a final rule establishing current good manufacturing practice requirements (CGMPs) for dietary supplements. In addition, by the end of the year, industry will be required to report all serious dietary supplement adverse events to FDA.

Ensuring Quality

Under the final rule, manufacturers are required to evaluate the identity, purity, quality, strength, and composition of dietary supplements.

“The dietary supplement CGMPs should increase consumers’ confidence in the quality of the dietary supplement products that they purchase,” says Robert E. Brackett, PhD, Director of FDA’s Center for Food Safety and Applied Nutrition. “These regulations provide more accountability in the manufacturing process

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so that consumers can be confident that the products they purchase contain what is on the label.”

The final rule aims to ensure that dietary supplements do NOT have:

- wrong ingredients
- too much or too little of a dietary ingredient
- improper packaging
- improper labeling
- contamination problems due to natural toxins, bacteria, pesticides, glass, lead, or other substances

How FDA Regulates Supplements

The final rule on CGMPs is a critical component of the Dietary Supplement Health and Education Act of 1994 (DSHEA).

Under DSHEA, dietary supplements are regulated like foods. Unlike new drugs, dietary supplements don't have to go through review by FDA for safety and effectiveness or be “approved” before they can be marketed. But manufacturers must provide premarket notice and evidence of safety for any supplements they plan to sell that contain dietary ingredients that were not marketed as dietary supplements before DSHEA was passed—except that the premarket notice is not needed if the new dietary ingredient had previously been used as an ingredient in food.

Manufacturers are responsible for substantiating the safety of dietary ingredients and also for determining that certain structure/function and other claims they make about their products are substantiated by adequate evidence to show that the claims are truthful and not misleading.

FDA evaluates the safety of dietary supplements after they are on the

market through research and adverse event monitoring. The agency is responsible for taking action against any unsafe dietary supplement product after it reaches the market.

The final rule on CGMPs gives industry clear expectations for manufacturing, packaging, labeling, and holding dietary supplements. If dietary supplements are found to be contaminated or lacking the appropriate ingredients, FDA will consider those products in violation of the law and will evaluate its enforcement options.

Advice for Consumers

- **Talk with a health care provider before using a dietary supplement.**

This is a good idea, especially for certain population groups. If you are pregnant, nursing a baby, or have a chronic medical condition such as diabetes or heart disease, be sure to consult your doctor or pharmacist before purchasing or taking any supplement.

- **Know that some supplements may interact with prescription and over-the-counter medicines.**

Taking a combination of supplements or using these products together with medications (whether prescription or OTC drugs) could produce adverse effects, some of which could be life-threatening.

For example, Coumadin (a prescription medicine), ginkgo biloba (an herbal supplement), aspirin (an OTC drug), and vitamin E (a vitamin supplement) can each thin the blood, and

taking any of these products together can increase the potential for internal bleeding.

- **Inform your doctor about all the supplements you use, especially before surgery.** Some supplements can have unwanted effects during surgery. You may be asked to stop taking these products at least 2-3 weeks ahead of the procedure to avoid potentially dangerous interactions. These interactions could cause changes in heart rate or blood pressure, increased bleeding, or other problems that could adversely affect the outcome of your surgery.

- **Report adverse effects from the use of dietary supplements to MedWatch.** If you think you have been harmed by a dietary supplement, contact your health provider and report it to FDA's MedWatch program by calling (800) FDA-1088, or visiting www.fda.gov/medwatch/how.htm

For more information about the safe use of dietary supplements, visit www.cfsan.fda.gov/~dms/ds-info.html

To see the final rule on CGMPs for dietary supplements, visit www.fda.gov/OHRMS/DOCKETS/98fr/cf0441.pdf 