

U.S. Food and Drug Administration

FDA News

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FDA Proposes Labeling and Manufacturing Standards For All Dietary Supplements

The Food and Drug Administration today took action to help consumers get accurately labeled and unadulterated dietary supplements by proposing a new regulation to require current good manufacturing practices (CGMPs) in their manufacturing, packing, and holding. The proposed rule would, for the first time, establish standards to ensure that dietary supplements and dietary ingredients are not adulterated with contaminants or impurities, and are labeled to accurately to reflect the active ingredients and other ingredients in the product.

This proposed rule includes requirements for designing and constructing physical plants, establishing quality control procedures, and testing manufactured dietary ingredients and dietary supplements. It also includes proposed requirements for maintaining records and for handling consumer complaints related to CGMPs.

"Americans must have confidence that the dietary supplements they purchase are not contaminated and that they contain the dietary ingredients and the amounts claimed on the labels," said HHS Secretary Tommy G. Thompson. "Millions of Americans use dietary supplements, and we owe it to them to ensure that they are getting the products they're paying for."

In recent years, analyses of dietary supplements by a private sector laboratory suggest that a substantial number of dietary supplement products analyzed may not contain the amounts of dietary ingredients that would be expected to be found based on their product labels. For example:

- Five of 18 soy and/or red clover-containing products were found to contain only 50 percent to 80 percent of the declared amounts of isoflavones.
- Of 25 probiotic products tested, 8 contained less than 1 percent of the claimed number of live bacteria or the number of bacteria that would be expected to be found in such a product.

FDA has also encountered products being marketed that are not accurately labeled or contain contaminants that should not be present or may be harmful. For example:

- One firm recalled its dietary supplements that were contaminated with excessive amounts of lead, which may have posed a health risk to many consumers, especially children and women of childbearing age.
- Another firm recalled a niacin product after it received reports of nausea, vomiting, liver

damage, and heart attack associated with the use of its product. A dietary ingredient manufacturing firm had mislabeled a bulk ingredient container that subsequently was used by another firm in making a product that contained almost ten times more niacin than the amount that may be safe.

- Another firm recalled its product after it was found that a dietary supplement containing folic acid, which is often taken by women to reduce the risk of having a baby with neural tube defects, contained only 35 percent of the amount of folic acid claimed on the label.

"This proposed regulation is another major step in our efforts to help Americans take more control over their own health. Too often, consumers purchase dietary supplements based on inaccurate or incomplete information on what they are getting. This proposed regulation would require that dietary supplements provide accurate information on the type and amount of ingredients they contain and that dietary supplements are produced using safe methods," said Mark B. McClellan, M.D., Ph.D., Commissioner of Food and Drugs. "Consumers should have access to dietary supplements that are accurately labeled and are free from contaminants."

FDA's action will also permit more informative research on dietary supplements, to improve the science available on their safety and effectiveness. "We commend FDA for proposing good manufacturing practices that will help ensure that all dietary supplements are of the quality that the public deserves. Since credible research studies cannot be performed using many of the current, highly variable products, these practices will also speed our ability to provide the public with more definitive data about the safety and effectiveness of popular dietary supplements," said Dr. Stephen Straus, Director, National Center for Complementary and Alternative Medicine at the National Institutes of Health.

This proposed regulation follows the agency's consumer initiative announced last December intended to improve FDA's policies on providing information about health consequences of food and dietary supplements and to increase enforcement efforts to prevent misleading health claims made by certain dietary supplement manufacturers. By putting in place requirements that will ensure universal good manufacturing practices, the proposed regulation should serve to eliminate the guesswork for consumers about which dietary supplements may or may not be of high quality. In turn, manufacturers of dietary supplements will have to compete based on the quantity of their product, not through potentially misleading labels or inexpensive but less safe manufacturing processes.

Under the CGMP proposal, manufacturers would be required to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements. If dietary supplements contain contaminants or do not contain the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated. Some product quality problems the CGMPs would help prevent include products that are superpotent or subpotent; that contain the wrong ingredient, a drug contaminant, or other contaminants (e.g., bacteria, pesticide, glass, lead); that contain foreign material; and that are improperly packaged and mislabeled.

This proposal is intended to cover all types of dietary supplements. However, to limit any disruption for dietary supplements produced by small businesses, FDA is proposing a three-year phase-in of a final rule for small businesses. The proposal includes flexible standards that can evolve with improvements in the state of science, such as in validating tests for identity, purity, quality, strength, and composition of dietary ingredients.

FDA is soliciting comments from the public and industry on how this proposed regulation can best achieve the goals of promoting accurate labeling information and preventing adulteration without imposing unnecessary regulatory burdens. Written comments will be received until 90 days after the date of publication in the Federal Register and may be addressed to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Additional information, including the proposed rule, may be found on FDA's Website at the following addresses:

- [Fact Sheet](#)
- [Backgrounder](#)
- [Proposed Rule \(PDF 89.5 MB\)](#)

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