ACUPUNCTURE Today

FDA Proposes New Standards for Dietary Supplements

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Dietary supplements are an underappreciated but important part of the practice of Oriental medicine in the United States. Although dietary supplements and herbal remedies are usually lumped into the same category, they are occasionally treated as separate entities. According to a survey conducted by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM), almost 82 percent of practitioners utilize nutritional supplements in their practices,[1] and approximately 20 states already include dietary advice and/or nutritional counseling as distinct components separate from herbs in the scope of practice for acupuncturists or doctors of Oriental medicine.

The regulation of dietary supplements falls under the auspices of the Dietary Supplement and Health and Education Act (DSHEA), which was passed by Congress in 1994. Under DSHEA, supplement makers have an "essential responsibility" to substantiate the safety of the ingredients used in manufacturing a product, and are responsible for determining whether any claims made about their products are substantiated by adequate evidence to show that such claims are not false or misleading. However, supplement makers are not subject to mandatory standards for manufacturing or labeling, and if a product already on the market is found to be harmful, the FDA bears the burden of proving it's hazardous, not the manufacturer.

In a decision sure to spark discussion throughout the profession, the Food and Drug Administration has proposed new guidelines for dietary supplement regulation in the U.S. The proposal, announced March 7, would implement new, industry-wide standards in the manufacturing, packaging and holding of supplements, and ensure that they are labeled accurately and do not contain impurities or other contaminants.

"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 Secretary of Health and Human Services Tommy Thompson in a news release. "Millions of Americans use dietary supplements, and we owe it to them to ensure that they are getting the products they're paying for."[2]

The new rules do not address product safety or effectiveness of supplements; rather, they focus on quality control, and require manufacturers to follow new Good Manufacturing Practices (GMPs) to help increase supplement purity and quality. Specifically, manufacturers would be required to:

- employ qualified employees and supervisors;
- design and construct their physical plant in a manner that protects dietary supplements (and their ingredients) from becoming contaminated during manufacturing, packaging and holding;
- use equipment and utensils that are of appropriate design, construction and workmanship for the intended use;

- establish and use a quality control unit and master manufacturing and batch production records;
- hold and distribute materials used to manufacture, package and label dietary supplements, ingredients and finished products under appropriate temperature, humidity, light and sanitation conditions so that their quality is not affected;
- keep a written record of each consumer complaint related to product quality or good manufacturing practices; and
- retain written records for three years beyond the date of manufacture of the last batch of dietary ingredients or supplements.

In addition, manufacturers would be legally obligated to evaluate the purity, identity, quality, strength, and composition of the ingredients contained in supplements, and to display accurate information on the product label.

The FDA would have the power to oversee the construction of manufacturers' plants, establish quality control procedures, and send inspectors into plants to test raw ingredients and finished products. It would also have the authority to remove products that are contaminated, contain the wrong substances, or have too much (or too little) of an ingredient.

The proposed GMPs would apply to all firms that manufacture, package, or hold dietary supplements or ingredients, including firms that test, label, distribute, or oversee the quality of supplements. These regulations would apply to both foreign and domestic firms.

A company's size would determine how soon it must meet with the FDA's standards. According to the administration, there are approximately 1,000 dietary supplement makers in the U.S. Large supplement manufacturers would have to comply with the rules as soon as they go into effect, but smaller companies could have up to three years to implement the guidelines.

Trade Groups Sound Off

The FDA's announcement was welcomed by consumer groups and some members of the dietary supplement industry.

"The responsible manufacturers are happy to comply," remarked John Hathcock, an executive with the Council for Responsible Nutrition, which represents approximately 80 supplement makers that already follow voluntary quality standards. He added that some manufacturers "cloud our whole industry, and we're glad to see federal action to force them to ... get in line or get out of business."[3]

"We think this will provide consumers with a lot more confidence in the products they are taking," added Donna Edenhart, a spokesperson for the Consumer Healthcare Products Association.[4]

Still, some critics have wondered why the FDA took nine years to propose new supplement guidelines. Language written into DSHEA gave the administration the authority to create and enforce manufacturing standards, but until this March, it had never issued specific regulations on what companies had to do to comply, nor had it indicated it would enforce such regulations.

In an article in the *New York Times*, Robin Gellman, a spokesperson for the American Herbal Products Association, said she was "sorry it (the proposal) took so long," but added, "It's irresponsible for the FDA to insinuate that supplements aren't regulated. It's not like it's the Wild West out there and this is day one of regulations."[5]

Exactly what effect will have on the Oriental medicine profession is unclear. Under DSHEA, herbal remedies fall under the same category as dietary supplements, which means herbal medicine suppliers will also have to comply with the new regulations. Additionally, the construction of new plants and the implementation of new procedures could lead to increased costs for consumers and health care providers in the short term.

Overall, however, the guidelines should be considered a positive benefit to the profession for a number of reasons. With stricter manufacturing practices in place, acupuncturists will be able to trust that the supplements they use and recommend contain the same ingredients listed on the product label, which could lead to better treatment outcomes and increased quality of care. Mandatory testing procedures could also influence some companies to conduct more research into herbal remedies. Perhaps most important, the new procedures would be a boon to patients. Ensuring high standards of quality would translate to safer products, leading to fewer adverse reactions due to a supplement being too potent, mislabeled, or otherwise contaminated.

Comments Are Welcome

The complete FDA proposal - all 547 pages - can be found online at www.fda.gov/OHRMS/DOCKETS/98fr/96n-0417npr0001-01.pdf. The proposal will be subject to public comment for 90 days, with a final set of regulations scheduled for delivery early next year. As the proposal was published in the Federal Register on March 13, comments must be submitted by June 11. Comments may be mailed to: Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852, or sent electronically at www.fda.gov/dockets/ecomments.

References

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