Tougher Regulation Coming for Diet Supplements

BY NANCY WALSH
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LA JOLLA, CALIF. — The newly enacted Dietary Supplement and Nonprescription Drug Consumer Protection Act mandates for the first time the reporting of serious adverse events associated with dietary supplements and over-the-counter products.

The law, passed by Congress in December, is the first revision of the regulation of dietary supplements since the passage of the Dietary Supplement Health and Education Act (DSHEA) of 1994 , Peter Reinecke said at a symposium on natural supplements sponsored by the Scripps Center for Integrative Medicine.

DSHEA authorized the Food and Drug Administration (FDA) to seize adulterated or misbranded products and to remove from the market products that present significant or unreasonable risk of injury or illness or pose an imminent hazard to public health or safety. It made no provision for the same type of reporting of adverse events required for pharmaceutical drugs.

But when the new law goes into effect on December 22, 2007, all manufacturers, packers, and distributors of supplements will be required to report serious adverse events to the FDA within 15 business days through the MedWatch program.

Serious adverse events are defined as those that result in death, a life-threatening experience, inpatient hospitalization, persistent or significant disability or incapacity, or a congenital abnormality or birth defect; or that require, based on reasonable medical judgment, a medical or surgical intervention to prevent one of these outcomes.

If a consumer reports that he or she has experienced a serious adverse event, the manufacturer must report it— regardless of whether proof is provided, medical care was sought, or the company disagrees with the claim.

"The intent of the new law is clearly to err on the side of over-reporting to give the FDA the ability to spot trends that are out there, not to overanalyze any single event," said Mr. Reinecke, principal of Reinecke Strategic Solutions, Bethesda, Md.

The labeling of dietary supplements will be required to include an address or telephone number consumers can use to contact the manufacturer or other responsible party, should an adverse event occur. Any product without this information on the label will be considered misbranded, Mr. Reinecke said at the meeting, which was cosponsored by the University of California, San Diego.

Manufacturers, packers, and distributors will be required to maintain for 6 years all records relating to adverse- event reports. Falsification of records will be illegal, and could lead to an injunction or criminal penalties.

The recent change of leadership in Congress is likely to result in greater efforts to ensure the safety of supplements, particularly by implementing and making final the DSHEA provision that establishes good manufacturing practices governing the preparation, packing, and holding of these products, said Mr. Reinecke, who was one of the Capitol Hill staffers involved in writing DSHEA.

"The coming year also is likely to see the biggest effort in Washington in the 20-something years I've been there to get the FDA some much-needed resources. This will be difficult given the fiscal situation in which we find ourselves, but there is strong support for this in industry and consumer groups," he said. ■

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