The Dietary Supplement and Nonprescription Drug Consumer Protection Act

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The Dietary Supplement and Nonprescription Drug Consumer Protection Act (P.L. 109-462) was signed into law on 12/22/06 and became effective on 12/22/07. The law applies to dietary supplements, defined as a vitamin, herb or other botanical, amino acid, supplement, concentrate, metabolite, constituent, extract, or any combination of the above intended for ingestion.

The law requires the manufacturer, packer, or distributor (as the "responsible person" listed on the product label) to provide to the Food and Drug Administration (FDA) with reports of serious adverse events for dietary supplements marketed within the U.S. If a retailer's name is on the label, they are a distributor responsible for filing such reports. However, if the retailer also has an agreement with the manufacturer or packer to transfer that responsibility, then the retailer need only alert the responsible person when the retailer receives a report of a serious adverse event. If the retailer's name is not on the label, the retailer should forward reports of serious adverse events to the responsible person.

A serious adverse event is defined as resulting in death, life-threatening experience, inpatient hospitalization, persistent or significant disability, congenital anomaly or birth defect, or one which requires medical intervention to prevent such outcomes.

A serious adverse event report must have five data elements: an identifiable injured person; an identifiable initial reporter; identity and contact information for the responsible person; identity of the suspect dietary supplement; and identity of the serious adverse event. A report of a serious adverse event technically has not been received by a responsible person until all the data elements have been gathered.

The responsible person then has 15 business days to submit a report by mail to the FDA, using MedWatch Form 3500A. Do not use MedWatch Form 3500, which is reserved for voluntary reports. A copy of the label must be included with Form 3500A. The injured person should not be identified by name on Form 3500A. Any new medical information subsequently received by the responsible person must be forwarded to FDA within 15 business days, accompanied by a copy of the previously submitted Form 3500A.

Submission of Form3500A does not constitute admission of causal or contributory connection between the product and the adverse event. It would be prudent for the responsible person to include a statement to that effect on Form 3500A.

Records of serious adverse events - and also non-serious adverse events - must be maintained for at least 6 years. They may be inspected by the FDA. Maintain records of Form 3500A submissions, new medical information and reports of same to FDA, and communications with the initial reporter and other persons who provided information.

To access FDA Form 3500A: http://www.fda.gov/medwatch/how.htm
To access the FDA Draft Guidance document: http://www.cfsan.fda.gov/~dms/dsaergui.html

About The Author:
Dr. Kailin, senior consultant for Convergent Medical Systems, Inc., is widely regarded as the leading authority on CAM-related federal regulations. He is the author of ***Quality In Complementary & Alternative Medicine*** (2006, CMS Press). Dr. Kailin consults on quality improvement and regulatory issues, and for integrative medicine programs.
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