The FDA Requires Adverse Event Reporting For Dietary Supplements And OTC Drugs

Effective Dec. 22, 2007, manufacturers or distributors of dietary supplements and non-prescription (over-the-counter) drug products will be required to report serious adverse events regarding their products under a new law passed in the waning days of the last Congress and signed by the President. The “Dietary Supplement and Nonprescription Drug Consumer Protection Act” amends the Federal Food, Drug and Cosmetic Act and also requires manufacturer or distributor contact information on the labels of these products.

Currently, manufacturers of prescription and some non-prescription drugs are required to report to the Food and Drug Administration (FDA) adverse events that result from the use of their drugs. No such requirements apply to dietary supplements, although some reports are voluntarily made. The new law will require "responsible persons" (typically manufacturers or distributors) to submit to the FDA "serious adverse event reports" (SAERs) received for finished OTC drug products and dietary supplements, along with a copy of the product's label.

A "serious adverse event" is an event that (A) results in death; a life-threatening experience; in-patient hospitalization; a persistent or significant disability or incapacity; or a congenital anomaly or birth defect; or (B) requires a medical or surgical intervention to prevent one of these outcomes.

Such reports must be submitted within 15 business days from the date of receipt of the information. New information concerning the adverse event that is received within one year of the initial report must also be submitted to the agency.

Nothing prevents the voluntary submission of adverse event reports (AERs) that do not rise to the level of being "serious.” However, in any case, records of all adverse events (whether serious or not) must be kept for six years for FDA review. Label changes needed, too.

Products labeled on or after Dec. 22, 2007, will need to include a domestic address or domestic phone number through which the responsible person can receive reports of adverse events. Products that do not include such information (including those imported from foreign manufacturers) will be deemed to be "misbranded" and subject to regulatory action by the FDA.

The law preempts any state or local requirements for reporting adverse events that are not identical to the federal requirements. In addition, the submission of an AER is specifically prohibited from being construed as an admission that the product involved caused or contributed to the adverse event.

The major dietary supplement and OTC drug trade associations strongly supported the legislation, since it is expected to increase consumer confidence in the safety of these products (and dietary supplements in particular) by providing the FDA with the means to monitor potential health risks associated with their use.

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