SHEPPARD MULLIN
SHEPPARD MULLIN RICHTER & HAMPTON LLP
FDA Law Update BLOG
Current Issues Affecting FDA-Regulated Companies

FDA Law Update

Posted at 1:42 PM on September 15, 2009 by Sheppard Mullin

OTC Drug and Dietary Supplement Labeling: Adverse Event Reporting Information

Recently, FDA issued its final guidance on the requirements for OTC drugs and dietary supplement labeling to include contact information for consumer reporting of a serious adverse event. This guidance builds upon requirements that were passed into law in the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 ("the Act").

The issues that FDA's final guidance address are: (1) the contact information to be provided for consumers to report a serious adverse event; and (2) the placement of an introductory statement before that contact information.

With respect to the first issue, Section 502(x) of the Act requires the label of an OTC drug (marketed in the United States without an approved application) to include "a domestic address or domestic phone number through which a responsible person (i.e. the manufacturer, packer, distributor, or retailer identified on the drug label) . . . may receive a report of a serious adverse event" associated with taking or using the product. FDA specifies that this must include the responsible person's full U.S. mailing address including either the street address or P.O. Box, and the city state, and zip code. Further, if one chooses to provide a domestic telephone number rather than a domestic address for adverse event reporting, FDA specifies that the phone number must include the area code (e.g. a toll-free area code 800 or similar area code or a local area code).

With respect to the second issue, FDA states that a prefatory statement is recommended though not explicitly required. In the guidance, FDA also provides suggestions for the specific wording and placement of such an introductory statement. For example, for OTC drug product labeling that provides a domestic telephone number, FDA explains that one can include a clarifying statement such as "You may report serious side effects to [insert phone number]," either under any of the following sections of the labeling the "Questions or Questions or comments," "Other Information," or "Drug Facts." FDA recommends a similar prefatory statement for OTC drug products labeling that includes a domestic address rather than a telephone number. Regardless of whether a prefatory statement is included, FDA states that the domestic address should be included either under the "Other Information" section or outside of the "Drug Facts" section where the label identifies the manufacturer's place of business.

In addition, FDA notes that one can provide on the product label an e-mail address or URL to which reports can be made. However, the domestic phone number or domestic address must still also be provided.

FDA's final guidance sets forth its intention to exercise enforcement for the new labeling requirements through **September 30, 2010**.

Authored by:

Arianna B. Chernove
(202) 772-5361
achernove@sheppardmullin.com

and

Deborah M. Shelton
(202) 772-5351
dshelton@sheppardmullin.com