



IASC Update

FDA Issues Final Guidance on SAER Labeling

Labels must have either domestic phone number or three-line address by Sept. 30, 2010

September 1, 2009 – The U.S. Food and Drug Administration (FDA) in today's *Federal Register* announced the publication of its final "[Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act](#)" (the Act).

Since December 2007, a "responsible person" (in the case of a dietary supplement, this is usually the marketer) has been required to submit to FDA within 15 days any serious adverse event report (SAER) it receives in association with its products. The document released today provides guidance related to labeling requirements of the Act and announces the agency's intent to exercise enforcement discretion with respect to those new labeling requirements until Sept. 30, 2010.

Under the Act, a dietary supplement label must bear either a domestic phone number or domestic address for adverse event reporting. FDA's final guidance states that a conforming phone number must include the area code (and clarifies with an example that a toll-free number is acceptable), and that a conforming domestic address must include a street address or P.O. box, along with the city, state and zip code. Current labeling rules require identification of only the city, state, and zip code, as long as the firm's street address is listed in a current telephone directory or other city directory.

FDA's final guidance also states that a label may include an email address or Web site to which reports may be made, so long as the domestic phone number or domestic address is also present on the label.

Finally, FDA maintains in the final draft document a *recommendation* that "the label also bear a clear, prominent statement informing consumers that they may report serious adverse events to the domestic address or domestic phone number on the label." In language new to the guidance, FDA indicates that this *recommended* signal statement may contain additional information, noting "the

responsible person can also clarify that a doctor should be called for medical advice.” The guidance provides the following multi-purpose label statement as an example: “You should call your doctor for medical advice about serious adverse events. To report a serious adverse event or obtain product information, contact...”

The International Aloe Science Council (IASC) notes that the agency also states in the guidance that the law “does not require a label to include anything other than a domestic address or domestic phone number for the responsible person.” Further, as FDA establishes at the beginning of the document: “FDA’s guidance documents, including this document, do not establish legally enforceable responsibilities.”

“IASC expresses its appreciation for the extended period of enforcement discretion and encourages its members to promptly review labels for inclusion of a domestic phone number or address,” said Executive Director Devon Powell. “Additionally, companies may want to consider the limits of their actual legal responsibility when determining whether to adopt FDA’s recommendation for use of signal language.”

The FDA guidance document is online at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm179018.htm>.