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IASC Update

FDA Issues Final Guidance on SAER Reporting and Recordkeeping

July 14, 2009 – The U.S. Food and Drug Administration (FDA) announced in today's *Federal Register* that it has released its final "[Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act](#)" (the Act).

Under the Act, a "responsible person" (in the case of a dietary supplement, this is usually the marketer) has been required since December 2007 to submit to FDA within 15 days any serious adverse event report (SAER) it receives in association with its products. The document FDA released today contains guidance on such details as the minimum data elements that should be included in an SAER, as well as the recordkeeping requirements established under the Act. As with all agency-issued guidance, this document "does not create or confer any rights for or on any person and does not operate to bind FDA or the public," and states that the regulated trade "can use an alternative approach if such approach satisfies the requirements of the applicable statute and regulations."

The final guidance differs in several ways from the draft guidance FDA issued on this topic in October 2007. Changes include the following:

- ◆ The Act defines an SAER to include, among other things, "inpatient hospitalization." Concerns were expressed in written comments that the draft's description of inpatient hospitalization could be misinterpreted such that "the act of seeking treatment at a hospital emergency room for a minor adverse event could be erroneously considered to be a serious adverse event." It was also noted that the mandatory MedWatch Form 3500 provides additional information that would prevent any such confusion. The final guidance now provides an appendix which links to the MedWatch instructions, and so states that "emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes." This language clarifies that an emergency room visit does not necessarily and in and of itself constitute inpatient hospitalization.

- ◆ FDA's expressed position in the draft was that reports received in error for another manufacturer's product "should be promptly forwarded to that other responsible person." It was suggested in written comments that this language be revised both to acknowledge that there is no requirement under the Act to do anything with such a report, and to replace the words "should be promptly forwarded" with "the agency recommends that such reports be promptly forwarded." FDA incorporated these suggestions.
- ◆ The agency recommended in the draft that companies responsible for submitting SAERs "use trained health care practitioners to elicit information from reporters," and suggested that this be described as one of several options for obtaining such essential information. In the final guidance, FDA has revised the punctuation and language of this section to clarify that use of practitioners is just one of the means that can be used to achieve this purpose.
- ◆ The draft guidance would have exempted all but one responsible person from submitting an SAER to FDA if the report identified suspect products from more than one responsible person. FDA has revised the final guidance to clarify that all such persons have the same reporting requirement under the Act.
- ◆ Finally, written comments suggested that the agency, in addressing other information that might be submitted along with a MedWatch form, acknowledge that responsible persons are explicitly allowed to include "additional information" and "a statement ... that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event." The final guidance now states that it "does not provide an exhaustive list of all the documents or information that may be submitted with the report at the responsible person's option. "

"IASC is pleased to see suggestions from industry adopted by the agency," said Executive Director Devon Powell, "and the final guidance is a useful resource for responsible persons to comply with the SAER law."

The guidance can be accessed at

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm171383.htm>