



IASC Member Update

FDA Extends AER Label Compliance Deadline By One Year

December 17, 2008 – The Food and Drug Administration (FDA) will not begin enforcing labeling requirements related to the reporting of adverse events until Jan. 1, 2010, the agency announces in a notice published in the Dec. 11 Federal Register.

The notice announces that two draft guidance documents released by FDA in January – one for dietary supplements and one for nonprescription drugs – and described as “intended to assist ... industry” in complying with purported labeling requirements of the Dietary Supplement and Nonprescription Drug Consumer Protection Act (“the AER bill”) have been revised to extend the enforcement date deadline “because the agency is still in the process of finalizing the guidance[s].”

A link to the revised guidance for the dietary supplement industry is here:

<http://www.cfsan.fda.gov/~dms/dsaergu3.html>

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