FDA Issues Final Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles

January 22, 2009

On January 13, 2009, the FDA issued its final guidance for industry on good reprint practices for the distribution of medical journal articles. The guidance provides a safe harbor provision from the intent requirements for the distribution of a drug and/or product for an unapproved new use. The guidance has several stringent requirements, including that "a scientific or medical journal article that is to be distributed:

- Be published by an organization that has an editorial board that uses experts who have demonstrated expertise in the subject of the article under review by the organization and who are independent of the organization to review and objectively select, reject, or provide comments about proposed articles; and that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors, contributors, or editors associated with the journal or organization;
- Be peer-reviewed and published in accordance with the peer-review procedures of the organization; and
- Not be in the form of a special supplement or publication that has been funded in whole or in part by one or more of the manufacturers of the product that is the subject of the article.

A scientific or medical reference publication that is distributed should not be:

- Primarily distributed by a drug or device manufacturer, but should be generally available in bookstores or other independent distribution channels (*e.g.*subscription, Internet) where medical textbooks or periodicals are sold;
- Written, edited, excerpted, or published specifically for, or at the request of, a drug or device manufacturer; or
- Edited or significantly influenced by a drug or device manufacturer or any individuals having a financial relationship with the manufacturer."

Guidance for Industry, Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices U.S., January 2009.

In addition, the article may not be false or misleading or pose a significant risk to the public health if relied upon. The guidance includes examples of publications that are not covered, including letters to the editor, abstracts, reports of Phase I trials in healthy subjects and reference publications containing little or no substantive discussion. In addition, the guidance contains stringent requirements on how scientific or medical information may be disseminated, including:

- Distributing an unabridged reprint;
- Document may not be marked or highlighted;
- The approved labeling must accompany the document;
- A comprehensive bibliography of publications discussing the drug advice must be included;
- If contrary or different conclusions regarding the unapproved use have been reached in other publications, they must be included; and
- No promotional information may be included with the publication.

Finally, the guidance contains certain requirements regarding disclosures that must be included with the reprint.

For Further Information

If you have questions concerning this guidance or would like more information, please contact Frederick R. Ball, any of the other health law lawyers in the Pharmaceutical & Biotechnology industry group or the attorney in the firm with whom you are regularly in contact.