FDA RELEASES DRAFT GUIDANCE ON REPRINT PRACTICES FOR DISSEMINATION OF ARTICLES ON DRUGS OR MEDICAL DEVICES

The Food and Drug Administration (FDA) recently announced the availability of a draft guidance for industry entitled “Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved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.” This Client Alert summarizes the major provisions of the guidance.

Prohibition on Marketing Drugs and Devices for Unapproved Uses

The Food, Drug, and Cosmetic Act and the FDA’s implementing regulations prohibit manufacturers from promoting or advertising a drug or device for any use that the FDA has not approved as safe and effective or cleared through a substantial equivalence determination. An approved drug or device that is marketed for a use that has not been approved or cleared by the FDA is considered adulterated and misbranded with respect to that use. Beginning in 1997, Section 401 of the Food and Drug Administration Modernization Act (FDAMA) created a safe harbor in which the dissemination to healthcare professionals of journal articles or reference publications discussing unapproved uses of approved drugs and cleared or approved devices would not be considered evidence of the manufacturer’s intent to promote the product for an unapproved or uncleared new use. However, few manufacturers took advantage of the safe harbor because of the rigorous requirements of FDAMA, including the need for various submissions to the FDA.

Sunset of FDAMA Safe Harbor

FDAMA Section 401 ceased to be effective on September 30, 2006, and the implementing regulations are no longer applicable. However, the FDA’s legal authority to determine whether distribution of medical or scientific information constitutes promotion of an unapproved or uncleared new use, or whether such activities cause a product to be misbranded and adulterated, has not changed. In recognition of the public-health value of healthcare professionals’ receiving truthful and non-misleading scientific and medical information, the FDA is now providing recommendations concerning “Good Reprint Practices” for the dissemination of medical journal articles and medical or scientific reference publications on unapproved uses of drugs and medical devices. This draft guidance fills the gap left by the sunset of FDAMA Section 401 and reflects the agency’s current thinking with respect to the dissemination of such materials.

Good Reprint Practices

Broadly, the guidance addresses the following topics:

A. the types of reprints, articles, and reference publications that may be distributed by manufacturers; and

B. the manner in which scientific and medical information should be disseminated.

Types of Reprints/Articles/Reference Publications

A scientific or medical journal article that is distributed should:

- be published by an organization with an independent editorial board that employs experts in the field and has a publicly stated disclosure policy regarding conflicts of interest;
- be peer-reviewed; and
- not be a special supplement or publication funded by the manufacturer.

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

- be primarily distributed by a drug or device manufacturer; or
- be written, edited, or published by or for a drug or device manufacturer or individuals having a financial relationship with a manufacturer.

The information contained in such scientific or medical journal articles or reference publications should address adequate and well-controlled clinical investigations that are considered scientifically sound by experts and must not:

- be false or misleading, or
- pose a significant risk to the public health.
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Manner in which Scientific and Medical Information Should Be Disseminated

Scientific or medical information that is distributed should:

• be in the form of an unabridged reprint, copy of an article, or reference publication;
• not be marked, highlighted, summarized, or characterized by the manufacturer;
• be accompanied by the approved labeling for the product;
• be accompanied by a comprehensive bibliography of relevant publications;
• where applicable, be disseminated with a representative publication that reaches contrary conclusions regarding the unapproved use; and
• be distributed separately from information that is promotional in nature.

The journal reprint or reference publication should be accompanied by a prominently displayed and permanently affixed statement disclosing:

• that the uses described have not been approved or cleared by the FDA;
• the manufacturer’s interest in the subject drug or device;
• any author having a financial interest in the product or manufacturer;
• any person known to the manufacturer who has provided funding for the study; and
• any known significant risks or safety concerns with respect to the unapproved use.

If manufacturers adhere to these Good Reprint Practices, the FDA does not intend to use the distribution of such medical and scientific information as evidence of intent by the manufacturer to promote the product for an unapproved or uncleared use.

The draft guidance is available on the FDA’s website at http://www.fda.gov/oc/goodreprint.html, or upon written request to the agency. Comments are due by April 21, 2008.

For more information on this topic, please contact David Hoffmeister, Farah Gerdes, or Jon Nygaard of Wilson Sonsini Goodrich & Rosati’s drug and device regulatory practice.