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Client Alert

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FDA Finalizes Guidance on Good Reprint Practices

On January 12, 2009, the United States Food and Drug Administration ("FDA") finalized its *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* ("GRP Guidance"). While not legally binding, the GRP Guidance provides the agency's current thinking about the distribution of journal articles and reprints by drug or medical device manufacturers and representatives and differs only slightly from the draft guidance FDA released for comment in February, 2008. We summarize the agency's most significant recommendations below; any substantive change from the 2008 draft guidance has been **bolded**.

Types of Reprints/Articles/Reference Publications

Under the GRP Guidance, a scientific or medical journal article must be published by an organization that has an editorial board consisting of experts in the subject area of the article. The organization should adhere to a policy of full disclosure of any conflict of interest or bias of any author, contributor, or editor associated with the article. The article must be peer-reviewed and published in accordance with sound scientific principles. The distribution of special supplements or publications that have been funded by one or more of the manufacturers of a product mentioned in the publication is prohibited. Further, a scientific or medical reference publication that is distributed generally should be available in bookstores or other independent distribution channels where medical textbooks or periodicals are sold. The reference publication should not be written, edited, excerpted, or published specifically for, or at the request of, a drug or device manufacturer; it should also not be edited or significantly influenced by a drug or device manufacturer or any individuals having a financial relationship with the manufacturer.

The information contained in such publications must address adequate and well-controlled clinical investigations that are considered scientifically sound by experts with sufficient training to evaluate the safety or effectiveness of the drug or device. **The referenced clinical investigations can include historically controlled studies, pharmacokinetic (PK) and pharmacodynamic (PD) studies, and meta-analyses if they are testing a specific clinical hypothesis.** The information cannot be false or misleading, such as an article or reference text that is inconsistent with the weight of credible evidence derived from adequate and well-controlled clinical studies. An article should

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not have been withdrawn by the author, disclaimed by the journal, or derived from a clinical investigation FDA found to be inadequate or not well-controlled. The information also must not present a significant risk to the public health, "**if relied upon**."

Examples of publications that would not be considered consistent with the GRP Guidance include (1) letters to the editor, (2) abstracts of a publication, (3) reports of Phase 1 trials in healthy subjects, or (4) reference publications that contain little or no substantive discussion of the relevant investigation or data.

Manner in Which to Disseminate Scientific and Medical Information

The GRP Guidance states that drug and medical device manufacturers may disseminate scientific and medical information, so long as the information distributed is:

- in the form of an unabridged reprint, copy of an article, or reference publication;
- not marked, highlighted, summarized, or characterized by the manufacturer in any way (**except to provide the accompanying disclosures discussed in this section**);
- accompanied by the approved labeling for the drug or medical device;
- accompanied, **when such information exists**, by a comprehensive bibliography of publications discussing adequate and well-controlled clinical studies published in a medical journal or medical or scientific text that have been previously published about the use of the drug or medical device covered by the information disseminated (unless the information already includes such a bibliography);
- disseminated with a representative publication, **when such information exists**, that reaches contrary or different conclusions regarding the unapproved use; **especially** those in cases where the conclusions of articles or texts to be disseminated have been specifically called into question by another article(s) or text(s); and
- distributed separately from information that is promotional in nature.

Under the GRP Guidance, a journal reprint and reference publication should be accompanied by a prominently displayed and permanently affixed statement disclosing:

- that the uses described in the information have not been approved or cleared by FDA, as applicable to the described drug or medical device;
- the manufacturer's interest in the drug or medical device that is the subject of the journal reprint or reference text;
- any author known to the manufacturer as having a financial interest in the product or manufacturer or who is receiving compensation from the manufacturer, **along with the affiliation of the author, to the extent known by the manufacturer, and the nature and amount of any financial interest of the author or compensation received by the author from the manufacturer**;
- any person known to the manufacturer who has provided funding for the study, if applicable; and

- any significant risks or safety concerns known to the manufacturer concerning the unapproved use that are not discussed in the journal article or reference text.

FDA does not intend to consider the distribution of such medical and scientific information that is done according to the recommendations in the GRP Guidance as establishing intent that the product be used for an unapproved new use. FDA adds, however, that, "**if a manufacturer engages in other conduct that unlawfully promotes an unapproved use of a medical product – whether or not the manufacturer also engages in conduct in conformance with the recommendations in this guidance – such other conduct may result in enforcement action**."

Please feel free to contact us if you have any questions about this bulletin.