

FDA Issues Draft Guidance Document on Good Reprint Practices

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On February 15, 2008, the FDA released a draft guidance document for drug and medical device manufacturers on good reprint practices to be used when informing medical professionals about unapproved new uses of drugs or devices. Guidance documents do not create new duties, but do express agency recommendations. A public comment period on the draft guidance will be open for 60 days commencing from 02/15/08.

The draft guidance document pertains to manufacturers, a term which FDA indicates as including sponsors, licensed distributors, and marketers of drugs and medical devices. The guidance applies to the unrequested dissemination of information about off-label uses, and does not apply to unsolicited requests for information.

Because promotion of off-label uses is not permissible, the guidance serves to direct appropriate communications from manufacturers about those uses. Disseminated journal articles that address off-label uses should not be written or edited by (or at the behest of) the manufacturer, nor in the form of a supplement funded by the manufacturer. Articles should come from peer-reviewed sources, overseen by editorial boards with expertise in the subject area of interest and independent of the publisher. Articles should not be false or misleading, nor provide information that poses a risk to public health. Articles should address controlled clinical investigations or significant non-clinical research.

Only unabridged article reprints should be sent, and not merely abstracts. Reprints should not contain highlighting or summaries by the manufacturer, and (if reprints lack it) should be accompanied by a bibliography of any additional research articles addressing the off-label use. If contrary conclusions have been reached in other research reports, the manufacturer should also include a reprint of such a report. Promotional materials should not be physically attached to reprints. Reprints may be distributed at medical conferences, but should not be distributed in promotional exhibit areas.

A statement should be fastened to reprints that the uses are not FDA approved or cleared. Manufacturer's and author's interests in the drug or device, and study funding sources, should also be expressed. If the manufacturer is aware of risks not discussed in the reprint, those should be stated. The approved labeling of the drug or device should also be supplied.

Text of the draft guidance document: <http://www.fda.gov/oc/op/goodreprint.html>.

To submit comments: <http://www.regulations.gov>.

Enter the following Docket number under Comments or Submissions:

Docket No. FDA-2008-D-0053

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