

Guest Article

FDA Finalizes Guidance on Distribution of Reprints:

Agency clarifies when
manufacturers may hand
out scientific journal articles

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PMN81-03

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This article is part of the January 2009 issue of *Pharma Marketing News*.

For other articles in this issue, see:

<http://www.news.pharma-mkting.com/PMNissueJan09archive.htm>

Published by:
VirSci Corporation
PO Box 760
Newtown, PA 18940
infovirsci@virsci.com



Pharmaceutical and medical device manufacturers now have a clearer picture of when they can appropriately distribute valid scientific and medical information to healthcare providers about off-label or investigational uses of their products.

On January 12, the 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 U.S.* (see <http://tinyurl.com/2tzebt>). The guidance provides the agency's current thinking about the distribution of journal articles and reprints.

"It's good for the industry that they have some final guidance," says Erin Reilly Lewis, Esq., counsel with Baker and Daniels in Indianapolis. "A manufacturer, if called to the mat on it, can say, I looked at the final guidance you issued, FDA, and I believe I followed it for X, Y, and Z reasons."

Requirements in the guidance

According to the guidance, a scientific or medical journal article that is distributed should be:

- Published by an organization with an editorial board that uses independent experts and has a public policy of full disclosure of any conflict of interest or biases
- Peer-reviewed and published in accordance with the organization's peer-review procedures
- Generally available in bookstores or other independent distribution channels

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

- Written, edited, excerpted, or published specifically for, or at the request of, a pharmaceutical or medical device manufacturer
- Edited or significantly influenced by a pharmaceutical or medical device manufacturer or any individuals having a financial relationship with the manufacturer
- In the form of a special supplement or publication funded in whole or in part by the manufacturer

In addition, articles must not be false or misleading or pose a significant risk to the public health, if relied upon.

Appropriate information

The guidance allows companies to distribute information in scientific or medical journal articles

or reference publications that address scientifically sound clinical investigations including historically controlled studies, pharmacokinetic and pharmacodynamic studies, and meta-analyses that test a specific clinical hypothesis.

The FDA also clarifies the types of publications that are appropriate for distribution. According to the guidance, publications or articles that are not appropriate include:

- Letters to the editor
- Abstracts of a publication
- Reports of Phase 1 trials in healthy subjects
- Reference publications that contain little or no substantive discussion of the relevant investigation or data

"The FDA broke down the information into the types of reprints and articles and reference publications and then the manner in which that information should be disseminated," says Bruce Armon, Esq., vice-office managing partner for Saul Ewing's Philadelphia office. "The FDA provided some useful information. I think they have tried to provide some clarity in terms of how a company could follow this guidance document and continue its business operations."

Off-label promotion still prohibited

The new guidance does not permit companies to promote products for off-label uses, says Howard Dorfman, Esq., counsel for Ropes and Gray in New York.

"The guidance ... poses very real requirements on the part of manufacturers in relation to the appropriate way they can disseminate valid and reliable scientific information that the medical profession requires in order to help healthcare providers to understand the most up-to-date state of medical knowledge relating to determining appropriate therapeutic options for their patients," Dorfman says.

Off-label promotion remains an area of focus for the Department of Justice (DOJ) and the Office of Inspector General. How the guidance will affect investigations into allegations of off-label marketing is unknown.

"At the moment, we really don't have a clear idea of how the Justice Department is going to view the final guidance with regard to investigations of alleged off-label promotion in the industry, even though the FDA Guidance does not relate to off-label promotional activities and is totally different," Dorfman says.

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Companies have to look at internal processes and procedures to determine whether they are distributing legitimate scientific information or engaging in unlawful off-label promotion, Lewis says.

"I think they need to, if possible, step back and say, 'I need to make sure the information I am putting out there is permitted under the final guidance,'" Lewis says.

Financial disclosures

The guidance provides some increased transparency regarding financial relationships between authors and industry. Companies must disclose if any author associated with an article has a financial interest in the product or manufacturer discussed. In addition, companies must disclose the nature of the affiliation and the amount of the financial interest.

"It's really an effort to make sure that if somebody is an author, anyone who is reading and potentially relying on that author's findings has the ability to know what relationships that author may or may not have," Armon says.

Industry need for guidance

The final guidance helps fill the gap created when certain provisions of the Food and Drug Modernization Act (FDAMA) sunset in 2006. The FDA released a draft version of the guidance in February 2008.

For some period of time, the industry found itself in a state of limbo, says Dorfman. The guidance provides clear direction to them. Implementing the guidance in its final form will allow companies to "do the right thing" when disseminating information that is critical to healthcare providers.

Although the guidance does not carry the force of law, it represents the FDA's current thinking, says Armon.

"Certainly even though it is only guidance ...companies would be well served by heeding the FDA's recommendations and reviewing and updating their company policies," Armon says.

The lack of guidance may have kept companies from distributing any reprints at all, notwithstanding the fact that the reprints were of the type covered in the guidance, Dorfman says. Until release of a guidance in final form, companies were cautious about distributing any information because they weren't sure about the FDA's position as to what information they were permitted to distribute and under what procedure. The guidance gives manufacturers an opportunity to evaluate whether

they want to disseminate medical articles and also provides them with a clear idea of what they can and cannot distribute.

"There is a more defined line which manufacturers and companies can look at and figure out, 'how can I make this work for me and how can I make this work for my company,'" says Lewis.

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