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ALERTS

Food, Drug & Device Law Alert - FDA Releases Draft Guidance On Distribution Of Scientific And Medical Publications On Unapproved Uses

March 4, 2014 | Atlanta | Chicago | Columbus | Delaware | Elkhart | Fort Wayne | Grand Rapids | Indianapolis | Los Angeles | Minneapolis | South Bend

The FDA recently released a draft guidance titled, “Distribution of Scientific and Medical Publications on Unapproved Uses – Recommended Practices.” This draft Guidance revises FDA’s 2009 guidance on good reprint practices on distribution of scientific and medical reference texts and clinical practice guidelines (CPGs) that include or may include information on unapproved uses of drugs or medical devices. This draft guidance provides recommendations for scientific journal articles, scientific or medical reference texts, and CPGs in separate sections, tailored to each type of publication. The draft Guidance establishes a “safe harbor” in that, as long as manufacturers distribute scientific or medical publications as recommended in the draft guidance, FDA states that it will not use such distribution as evidence of the manufacturer’s intent that the product be used for an unapproved new use (i.e., off-label promotion).

For each of the different types of publications, the draft guidance includes a number of limitations on their distribution if the manufacturer does not want FDA to consider the distribution as evidence of off-label promotion. For example, in the case of journal articles, some of the limitations include that the articles *should*:

- Be peer-reviewed and published in accordance with the peer-review procedures of the publisher.
- Be in the form of an unabridged reprint or copy of an article.
- Contain information that describes and addresses adequate and well-controlled clinical investigations that are considered scientifically sound by experts with scientific training and experience to evaluate the safety or effectiveness of the drug or device.
- Be disseminated with the approved labeling or, in the case of a medical device reviewed under section 510(k), labeling for the indications in the product’s cleared indications for use statement, for each of the manufacturer’s products that is included in the distributed article.
- Be disseminated with a comprehensive bibliography, when such information exists, of publications discussing adequate and well-controlled clinical studies published in scientific journals, medical journals, or scientific texts about the use of the drug or medical device covered by the information disseminated.

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- Be disseminated with a representative publication, when such information exists, that reaches contrary or different conclusions regarding the unapproved use—especially when the conclusions of articles to be disseminated have been specifically called into question by another publication.

- Be distributed separately from the delivery of information that is promotional in nature.

There are a comparable number of limitations on the distribution of medical reference texts and CPGs, and additional limitations where only part of a reference text (such as a chapter) or CPG is distributed.

For all three categories of publication, the draft guidance also includes the negative limitations that the literature *should not*:

- Be false or misleading.

- Contain information recommending or suggesting use of the product that makes the product dangerous to health when used in the manner suggested.

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