



READY FOR PRIMETIME? FDA'S PROPOSED GUIDANCE ON PRE-SCREENING OF DTC TV DRUG ADS

by

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Direct to Consumer (DTC) Television advertisements have generated considerable public and regulatory attention over the years. The Food and Drug Administration Amendments Act of 2007 gives the U.S. Food and Drug Administration (FDA) the authority to require sponsors to submit “any television advertisement” for a drug at least 45 days before dissemination. On March 12, 2012, FDA described how it intends to exercise this authority in a long-awaited draft guidance. The guidance identifies the categories of TV advertisements that will be subject to pre-dissemination review; describes how the agency will notify sponsors that submission of a particular advertisement is required; details the required components of a pre-dissemination submission package; and provides information regarding the potential penalties associated with non-compliance.

FDA proposes to require pre-dissemination review for six types of “high risk and high impact” television advertisements:

- The initial TV advertisement for any prescription drug or the initial TV advertisement for a new or expanded approved indication for any prescription drug.
- All TV advertisements for prescription drugs subject to a Risk Evaluation and Mitigation Strategy (REMS) with elements to ensure safe use.
- All TV advertisements for Schedule II controlled substances.
- The first TV advertisement for a prescription drug following a safety labeling update that affects the Boxed Warning, Contraindications, Warnings & Precautions section of its labeling.
- The first TV advertisement for a prescription drug following the receipt by the sponsor of an enforcement letter for that product that either cites a TV advertisement or causes a TV advertisement to be discontinued because the TV advertisement contained violations similar to the ones cited in the enforcement letter.
- Any TV advertisement that FDA otherwise identifies to be subject to the pre-dissemination review provision.

FDA proposes to notify sponsors of the requirement to submit an advertisement for pre-dissemination review via written correspondence (e.g., approval letter) or notice in the *Federal Register*, depending on the reason for which pre-dissemination review is required and/or the date on which the drug received marketing approval. However, it is important to note that if a sponsor is developing a TV advertisement that falls into one of the six above-referenced categories, though FDA has not notified the

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sponsor that pre-dissemination review is required, the agency recommends that the sponsor nonetheless submit the advertisement for pre-dissemination review.

When submitting a pre-dissemination review package to FDA, sponsors should include a cover letter, an annotated storyboard of the advertisement (which illustrates which reference(s) support the claim(s) made in the advertisement), and a copy of the most current FDA-approved prescribing information (annotated to include cross-references to the storyboard). The review package should also contain the following items (if any of the following apply): annotated references to support product claims not contained in the package insert; spokesperson verification; verification that the translation of a non-U.S. TV advertisement is accurate; annotated references to support disease or epidemiology information; and a video of the TV advertisement (if available). In the event that FDA receives an incomplete review package, the agency will inform the sponsor that its submission package is incomplete, describe the reason(s) that the package is incomplete, and request that the sponsor submit a complete package. Sponsors should carefully review the required elements of a pre-dissemination package. Although the package generally consists of the same information as is currently required for submissions to the agency's advisory review process for television advertisements, there are certain differences, particularly with respect to the number of copies required of a particular item.

The failure to submit an advertisement as required, the dissemination of an advertisement before FDA has provided comments, and/or the dissemination of an advertisement prior to the end of the 45-day review period may result in enjoinder, criminal penalties and, if the advertisement is false or misleading, civil monetary penalties (CMPs). FDA has indicated that it will consider the sponsor's refusal to comply with the submission requirement if it issues an enforcement letter and/or imposes CMPs.

Except for the disclosure of a serious risk listed in the labeling and/or the inclusion of the date of the product's approval for up to two years post-approval, sponsors are not required to comply with the agency's suggestions; however, FDA cautions that failure to do so may result in more severe enforcement action if the advertisement is later deemed to be violative.

If the agency does not respond to the sponsor's submission within 45 days, a sponsor will not be subject to legal consequences merely because it decides to run the advertisement without waiting for the agency's comments. Once an advertisement is disseminated, however, FDA may take enforcement action against the sponsor insofar as it determines that the advertisement violates the Federal Food, Drug and Cosmetic Act (FDCA) and/or its implementing regulations.

A critical unanswered question raised by the guidance is how quickly FDA will be able to provide sponsors with meaningful feedback to a pre-dissemination submission. Although the agency's goal is to respond within 45 days of receiving a complete submission, the draft guidance acknowledges that, in some cases, it may take the agency longer to respond. In these cases, a sponsor may be put in the unenviable position of choosing to wait to begin marketing until FDA responds, or moving ahead with commercializing its product and subjecting itself to traditional enforcement actions for disseminating a false or misleading advertisement.

In addition, despite its attempt to limit the application of the guidance to "high risk and high impact" advertisements, the draft guidance would, as a practical matter, subject virtually every type of DTC TV advertisement for drugs to pre-dissemination review by FDA. As such, pharmaceutical manufacturers should consider modifying their standard operating procedures to allow for the submission of television advertisements to FDA prior to their airing. Failure to do so may otherwise expose manufacturers to additional liability. While the draft guidance is not binding, it represents FDA's current thinking on pre-dissemination review for DTC advertisements.