FDA Issues Guidance on Direct-To-Consumer Television Advertisements

Draft Guidance Outlines Requirements for Pre-Dissemination Review

This week, the Food and Drug Administration ("FDA") issued a draft guidance document describing how it intends to implement the review of certain direct-to-consumer prescription drug television advertisements ("TV ads") prior to dissemination.[1] This draft guidance outlines FDA's implementation of the review authority granted under the Food and Drug Administration Amendments Act of 2007 ("FDAAA") that created section 503B of the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 USC 353(b)). Under FDAAA, FDA is authorized to require the submission of any TV ad for a drug at least 45 days prior to the ad's dissemination. FDA can then require the drug's sponsor to make changes to the ad or include additional information. Using a risk-based approach, FDA's draft guidance proposes several categories of prescription drugs that would be subject to this pre-dissemination review. Additionally, FDA details the review submission process, including the information drug sponsors would be required to provide.

Categories of TV Ads Subject to Review

The draft guidance sets out six categories of TV ads that require pre-dissemination review:

- Category 1: the initial TV ad for i) any prescription drug, or ii) any new or expanded approved indication of a prescription drug;
- Category 2: all TV ads for a prescription drug subject to a risk evaluation management strategy ("REMS") with elements to ensure safe use of the drug;
- Category 3: all TV ads for a Schedule II controlled substance (*e.g.*, those drugs with a high risk for abuse, such as amphetamines);
- Category 4: the first TV ad for any prescription drug after a safety labeling update that affects the boxed warning, contraindications, or warnings and precautions sections of the drug's labeling;
- Category 5: the first TV ad for a prescription drug after the drug's sponsor has received an enforcement letter that either cites a TV ad or causes the cancellation of a TV ad due to issues similar to those cited in an enforcement letter; and
- Category 6: any TV ad FDA identifies as subject to pre-dissemination review.

Some of these categories are consistent with industry expectations regarding pre-submission review, but the last undefined "catch-all" category could greatly expand FDA's reach into this area.

Notification by FDA

The draft guidance also provides information about how sponsors would be notified of any pre-dissemination review requirements. FDA would notify sponsors through either written correspondence (including application approvals, labeling approvals, and enforcement letters) or publication in the Federal Register, depending on the category and whether the drug is currently approved:

[1] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM295554.pdf

	Currently Approved Drugs	Drugs Approved in Future
Category 1	Federal Register Notice	Written Correspondence – approval letter
Category 2	Federal Register Notice	No specific notice, but Operation of Law – REMS with elements of safe use
Category 3	Federal Register Notice	No specific notice, but Operation of Law – Schedule II controlled substance
Category 4	Written Correspondence	Written Correspondence – letter approving labeling update
Category 5	Written Correspondence	Written Correspondence – enforcement letter (Warning or untitled)
Category 6	Written Correspondence	Written Correspondence

If a sponsor is creating a TV ad for a prescription drug that meets one of these categories, but the sponsor has not received written notification, FDA **recommends** that the sponsor nonetheless should submit the TV ad for review.

The draft guidance also provides information on the required contents of the review submission package, which includes an annotated storyboard and a video of the ad, if available.

Timing and Enforcement

Along with the proposed framework, the draft guidance provides information about the timing of review and the penalties for failing to submit an ad for pre-dissemination review. Under section 503B of the FDCA, sponsors must submit TV ads for review at least 45 days prior to dissemination of the TV ad. If FDA is unable to review the TV ad within the 45 day period, the sponsor will be notified and must decide whether to wait for FDA's comments or to disseminate the TV ad. If the sponsor decides to disseminate the TV ad, the FDA review process will end, but the sponsor is taking the risk that FDA may find the TV ad in violation of the FDCA and initiate an enforcement action.

The draft guidance also outlines the various consequences of violating the section 503B review requirements. If a TV ad falls into one of the six mandatory categories and the sponsor fails to submit the TV ad for review or disseminates the TV ad prior to the completion of FDA review, the sponsor has committed a prohibited act under the FDCA and may face criminal penalties. Additionally, if the TV ad is false or misleading, the sponsor may be required to pay civil monetary penalties. Dissemination of a TV ad without incorporating FDA comments related to certain safety issues or approval requirements also is a prohibited act under the FDCA and may expose the sponsor to the risk of injunction and criminal penalties.

For more information, please contact a member of Ropes & Gray's FDA regulatory team or your regular Ropes & Gray attorney.