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FDA Draft Guidance Establishes 45-Day Review Period for Certain Direct-to-Consumer TV Advertisements

On March 13, 2012, the Food and Drug Administration (FDA) published a draft guidance for industry to address direct-to-consumer (DTC) television promotions of prescription drugs and biologics.[1] The draft guidance, entitled *Direct-to-Consumer Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program*, seeks to implement the Food and Drug Administration Amendments Act of 2007 (FDAAA), which gives the FDA authority to require television advertisements be submitted for agency review at least 45 days prior to airing.[2] Comments and suggestions on the draft guidance may be submitted to the FDA through May 14, 2012.

The draft guidance addresses, among other things, which categories of television advertisements will be subject to pre-dissemination review and what materials should be submitted in the pre-dissemination review package.

Categories for Pre-Dissemination Review

To assure agency resources are directed at those advertisements that pose the highest risk to the public health or have the greatest impact, the FDA has identified six categories of television advertisements that will be subject to pre-dissemination review at least 45 days prior to publication.

Specifically, the proposed categories for pre-dissemination review include the following:

- Category 1—The initial television advertisement for (i) any prescription drug; or (ii) a new or expanded indication for a prescription drug, where the FDA can offer guidance on, among other things, the major statement (i.e., the presentation of risk information in a broadcast ad) and the presentation of the product's indications.
- Category—All television advertisements for a prescription drug requiring a Risk Evaluation and Mitigation Strategy with elements to assure safe use.
- Category 3—All television advertisements for a Schedule II controlled substance.

1 77 *Fed. Reg.* 14811.
2 See 21 U.S.C. § 353b.The draft guidance is available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM295554.pdf.

- Category 4—The initial television advertisement of a prescription drug after a safety labeling update to the product's approved prescribing information, such as that affecting the Boxed Warning (if applicable), the Contraindications, or the Warnings & Precautions sections of the labeling.
- Category 5—The initial television advertisement for a prescription drug after the sponsor's receipt of an enforcement letter for the product, which cites a television advertisement or requires the discontinuation of a television advertisement for the product.
- Category 6—Any television advertisement otherwise deemed to be subject to pre-dissemination review.

To ensure that sponsors are aware of the pre-dissemination review requirement, the FDA intends to include notice in the agency's approval letters (i.e., new drug application, supplement, or labeling update), enforcement letters, and other correspondence. The agency will also publish a notice in the *Federal Register* to notify sponsors of the pre-dissemination review requirements.

The Pre-Dissemination Review Package

The FDA notes that a sponsor must provide one pre-dissemination review package for each proposed television advertisement and that other draft promotional labeling, unrelated to the advertisement, should not be included. The draft guidance outlines those documents that the agency wants to review and should receive to provide a meaningful review of any DTC television advertising. The recommendations for content include:

- A cover letter with the following:
  a) Sponsor contact information;
  b) A subject line stating "Pre-Dissemination Review Package for a Proposed TV Ad Subject to 503B of the FD&C Act [Federal Food, Drug, and Cosmetic Act]" with the proprietary/trade name and dosage form of the product;
  c) New Drug Application number or Submission Tracking Number;
  d) Name of the proposed television advertisement; and
  e) List of contents, with the number of copies of each item, for pre-dissemination review package;
- Annotated storyboard of the proposed television advertisement, showing references to support each claim;
- Current, approved prescribing information and patient labeling or medication guide (if applicable), with annotations cross-referenced to the storyboard; and
- Other appropriate documentation, including additional annotated references, verification of certain elements in the advertisement, or a video of the television advertisement.

The FDA's 45-day time frame for review does not begin until the pre-dissemination review package is considered complete. If the FDA is unable to provide comments within this 45-day period, the sponsor may notify the agency that it intends to air the advertisement prior to receiving comments, and the agency will discontinue its review. However, the sponsor remains at risk for enforcement action if the advertisement is subsequently found in violation of the law.

In addition, the draft guidance highlights that not submitting a television advertisement for pre-dissemination review as required (or revising a draft advertisement following pre-dissemination review to add new claims, concepts, or creative themes and not resubmitting to the FDA), disseminating an advertisement before the 45-day review period ends, or failing to incorporate the FDA's comments for the television advertisement (e.g., serious risk disclosures) is a prohibited activity, subject to legal action, criminal penalties, and civil monetary penalties.[3]

3 See 21 U.S.C. § 331(kk).