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New Fees for FDA Advisory Review of DTC Television Ads

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA), which amended the Federal Food, Drug, and Cosmetic Act (FFDCA) to include provisions regarding prescription drug television advertisements.

- **Immediate Effect.** Advisory review fees apply to all advertisements submitted for advisory review as of October 1, 2007
- **Civil Penalties for False or Misleading DTC TV Advertisements.** In determining the amount of a civil penalty FDA may impose under the new legislation for dissemination of a false or misleading DTC television advertisement, the agency may consider whether the advertisement was submitted for advisory review. Civil penalties can be up to \$250,000 for the first violation in any 3-year period and up to \$500,000 for each subsequent violation in the 3-year period. FDA may not assess any civil penalty if the entity submitted the advertisement to FDA and incorporated each comment received from the agency.
- **Change in Review Comments.** FDA may retract or modify prior comments it has provided to an advertisement submitted for advisory review based on new information or changed circumstances so long as the agency provides written notice of these new views and a reasonable time for modification or correction prior to seeking any civil penalty.
- **Required Notification.** In response to an annual notice published by FDA in the Federal Register, companies must notify the agency of the number of DTC television advertisements they intend to submit for advisory review in the next fiscal year (an advisory fee is not assessed if pre-approval of promotional materials is required, e.g., for accelerated approval products). For fiscal year 2008, FDA is required to publish the notice by October 29, 2007, and notifications will be due within 30 days of publication of the notice. For subsequent years, FDA will publish the notice by June 1 and notification will be due within 30 days.
- **Accuracy is Key.** Notification of the number of DTC advertisements the entity intends to submit for advisory review is considered a legally binding commitment to pay advisory review fees for that number of submissions. For each advisory review submission in excess of the notified number the fee goes up by 50% and only one paid advisory review may be carried



over to the next fiscal year. The legislation provides for no refunds, waivers, exemptions or reductions, and the right to advisory review is not transferable, except to a successor in interest.

- Calculation of the Advisory Review Fees. The annual advisory review fee will be established based on the number of advertisements identified in the notifications in order to generate fee revenue of \$6,250,000 for each of fiscal years 2008 through 2012, as adjusted for inflation and changes in workload. The legislation provides that the advisory review fee for fiscal year 2008 may not be more than \$83,000 per submission. FDA will establish the advisory review fee for the upcoming fiscal year on or before August 1 (for fiscal year 2008, not later than December 27, 2007). Each advisory review fee covers the submission of one DTC advertisement for advisory review and one resubmission of the same advertisement (a resubmission may not introduce significant new concepts or creative themes).
- Operating Reserve Fee. In its first fiscal year of participation in the advisory review program, each entity must also pay a one-time operating reserve fee. The operating reserve fee for each participant is calculated by multiplying the number of advertisements identified in its first year notification by the advisory review fee amount for that fiscal year. Thus, for the first year of participation, a company must essentially pay double the advisory review fee for each submission identified in its notification. The operating reserve fee is due by November 1 of the first year of participation (for fiscal year 2008, the payment is due by January 25, 2008).
- Operating Reserve Fee Penalty. If in the first fiscal year of an entity's participation in the advisory review program the entity submits any advertisements in excess of the notified number, it must pay an operating reserve fee for each of the excess submissions in the amount of 150% of the regular advisory review fee, in addition to the excess submission advisory fee. Thus, for each excess submission in the first year of participation, the advisory review fee plus the operating reserve fee will equal 300% of the regular advisory review fee. This fee is due 20 days before submission of the advertisement.
- Operating Reserve Fees and Reserve Fee Penalties Applicable Only to Entity's First Year of Participation. Operating reserve fees and reserve fee penalties are due only during an entity's first year of participation, even if the entity's usage of the program increases in subsequent years. Thus, if an entity anticipates the possibility of making one advisory review submission in fiscal 2008, but predicts that it will make more than one submission in fiscal 2009, it may be advantageous to identify one



submission in the 2008 notification, pay the 2008 advisory review fee and operating reserve fee based on one submission, and, if this submission is not made during fiscal 2008, carry over the advisory fee to 2009 (limit of one advisory-fee-carryover, see above).

- Performance Goals. FDA has issued “Performance Goals and Procedures for Advisory Review of Direct-to-Consumer Television Advertising Fiscal Years 2008 Through 2012.” See <http://www.fda.gov/oc/pdufa4/pdufa4goals.html>. FDA will review and provide comments on 75 of the first 150 advisory review submissions in fiscal year 2008 within 45 days (50% of 150) and 37 resubmissions within 30 days (50% of 75). For each subsequent year, the percentage of reviews of the first 150 submissions that will meet each goal increases by 10% up to 90% in 2012.
- Survival of the Advisory Review Fee Program. If FDA does not receive at least \$11,250,000 in combined advisory review and operating reserve fees by January 26, 2008, the program will not be initiated and all collected fees will be refunded. In addition, in later fiscal years, if on November 1 the combination of operating reserves, annual fee revenues from that fiscal year, and unobligated fee revenues from prior fiscal years falls below \$9,000,000, adjusted for inflation, the advisory review fee program will terminate and FDA will refund unused fees and operating reserves after termination of the program.
- Required review. The FDAAA also provides FDA with the authority to *require* prior agency review of selected drug television advertisements and to recommend changes necessary to “protect the consumer good and well-being,” make the advertisement consistent with prescribing information for the product, and, if appropriate, address the efficacy of the product as it relates to specific population groups, including the elderly, children, and racial and ethnic minorities. This provision is not currently limited to prescription drug advertisements and therefore, without correction, would appear to be able to be used by FDA to require prior review of over-the-counter (OTC) drug television advertisements.
- Clear and conspicuous major statement. DTC television or radio advertisements that state the name of the drug and its conditions of use must present the major statement relating to side effects and contraindications “in a clear, conspicuous, and neutral manner.” FDA is required to promulgate regulations by March 2010 establishing standards for determining whether a major statement meets these requirements.
- Adverse event reporting statement in print ads. Print DTC advertisements must include the following statement in conspicuous text: “You are



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encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088." This requirement does not currently apply to DTC television advertisements, but the Secretary, in consultation with the Advisory Committee on Risk Communication, must conduct a study by March 2008 to determine if this statement is appropriate for television advertisements as well and, if appropriate, promulgate regulations requiring this statement in television advertisements.