

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0469]

Establishment of Fiscal Year 2008 User Fee Rates for Advisory Review of Direct-to-Consumer Television Advertisements for Prescription Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice, as required by the Food and Drug Administration Amendments Act of 2007 (FDAAA), to establish the fiscal year (FY) 2008 fees that will be charged for each FY 2008 advisory review submission to FDA and to fund the operating reserve established under FDAAA. The Federal Food, Drug, and Cosmetic Act (the act), as amended by FDAAA, authorizes FDA to collect user fees for certain direct-to-consumer (DTC) television advertisements submitted to FDA for advisory review.

ADDRESSES: Information about the DTC television user fee program is available on the Internet at http://www.fda.gov/cder/ddmac/user_fees/default.htm.

FOR FURTHER INFORMATION CONTACT: *For questions about rates, invoices, or payments:* Ashley Linkous, Office of Regulatory Policy (HFD-7), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

For questions about where or how to submit proposed DTC television advertisements for advisory review, what to include in your submission, the

status of pending DTC television advertisements submitted for advisory review, or your remaining balance of advisory reviews under the DTC television user fee program: Wayne Amchin, Division of Drug Marketing, Advertising, and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1454, Silver Spring, MD 20993-0002, 301-796-1200, FAX: 301-796-9878, e-mail dtcp@fda.hhs.gov.

For questions about submissions to the Advertising and Promotional Labeling Branch (APLB) in the Center for Biologics Evaluation and Review (CBER): Ele Ibarra-Pratt, Advertising and Promotional Labeling Branch, Center for Biologics Evaluation and Research (HFM-602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6331.

SUPPLEMENTARY INFORMATION:

I. Introduction

On September 27, 2007, the President signed into law FDAAA (Public Law 110-85). Section 104 of this statute created new section 736A of the act, which in addition to reauthorizing the Prescription Drug User Fee Act (PDUFA) for FYs 2008-2012, also authorized a new and separate user fee program for the advisory review of DTC prescription drug television advertisements.

Participation in the program is voluntary. Sponsors can decide, at their own discretion, whether to seek FDA advisory review of DTC prescription drug television advertisements in advance of publicly broadcasting them. However, under the new law, if a sponsor decides to seek FDA advisory review of a DTC television advertisement, the sponsor must pay all applicable fees for that review under the DTC television user fee program.

In the **Federal Register** of October 25, 2007 (72 FR 60677), FDA issued a participation notice asking companies: (1) To notify FDA by November 26, 2007, if they intend to participate in the DTC television user fee program during FY 2008 and (2) if they do plan to participate, to identify the number of DTC television advertisements for prescription drug and biological products they plan to submit to CDER or CBER for advisory review during FY 2008. The information gathered in response to the participation notice is the basis for the fees this notice establishes that will be charged for each FY 2008 advisory review submission to FDA and to fund the operating reserve established under FDAAA.

II. Establishing the Advisory Review Fee and Operating Reserves

A. Basis for the Fee

The advisory review fee for FY 2008 will be \$41,390 for each proposed television advertisement voluntarily submitted for advisory review. The fee is based on the number of advertisements identified by all companies in response to the participation notice. The advisory review fees in FY 2008 are set at a level to generate target revenues of \$6.25 million in the first year of the program. Individual fees have been determined by dividing the target revenue, established in the statute, by 151 (the number of television advertisements all companies have indicated in response to the participation notice that they intend to submit during FY 2008 for advisory review).

A participant who does not pay the fees on time as specified in the billing instructions included with the invoice will be assessed a fee of \$62,085 because the statute establishes a 50 percent penalty for fees not paid on time. A participant who submits more advertisements for advisory review in FY 2008 than it has told FDA it plans to submit in response to the participation

notice will be assessed for each additional submission a fee that is 50 percent greater than the established individual fee. A participant who intends to submit additional advertisements should notify Wayne Amchin (see **FOR FURTHER INFORMATION CONTACT**).

The target revenue figures will be adjusted annually for inflation and workload on a compounded basis in subsequent years. In each subsequent year of the program, FDA will issue a new notice of participation by June 1 of that year and a second notice by August 1 establishing the fees.

B. Operating Reserves

To establish operating reserves for the program, in the first year of their participation in the program, participants will be assessed a one-time participation fee that will be based on the number of submissions the participant identifies for that year. In this way, FDA will collect revenues of \$6.25 million to be placed in reserve from which funds can be drawn if target revenues fluctuate downward in subsequent years. For companies who responded by November 26, 2007 (the date given in the participation notice), the operating reserve fee for each participant in FY 2008 will be an amount equal to the total amount assessed that company for the annual advisory review fees for FY 2008. For companies who responded to the participation notice by November 26, 2007, but do not pay the assessed operating reserve fee within the time period specified in the invoice, the operating reserve fee will be 50 percent higher than what they would have owed had they paid on time. For participants who join the program late in FY 2008 (i.e., those who did not notify FDA of their intent to participate by November 26, 2007), the operating reserve fee will be 50 percent higher than what they would have owed had they both notified FDA and paid on time.

Companies who join the program in subsequent fiscal years (FYs 2009–2012) will be assessed an amount for the operating reserve fee that will be at least as much as the amount they would have been assessed if they had joined the program at the start of FY 2008. Specifically, in subsequent years, the operating reserve fee for new participants will be the higher of: (1) The total amount of advisory review fees for all of the new participant’s proposed DTC television advertisements in the year the participant joins the program or (2) the total amount of advisory review fees that would have been assessed in FY 2008 for that number of proposed DTC television advertisements. This statutory fee structure limits the incentive for companies to join the program late, which could prevent the program from receiving sufficient funding in the initial year and place a disproportionate share of the cost of the program on those participants who join the program in its initial year of operation.

C. Effect of Inadequate Funding

The statute provides that if FDA fails to receive sufficient funding from companies by January 25, 2008, the program will not commence. Sufficient funding consists of a combined total amount of at least \$11.25 million from advisory review fees and operating reserve fees. In the event that insufficient funding is received and the program does not commence, all collected fees will be refunded to the companies who paid.

III. Participating in the DTC Television User Fee Program

A. How Do Participating Companies Pay the User Fees for Advisory Review?

FDA will send invoices to each company for all submissions identified in response to the participation notice, and the advisory review fees and the operating reserve fees are due and payable on the date specified in the invoices. Participating companies should not send payment until after receipt

of the invoice. FDA will also assign each participant a series of unique user fee ID numbers to correspond with the number of advisory reviews that participants have identified in response to the participation notice. For example, a company that has identified 10 advisory reviews will receive 10 unique user fee ID numbers in its invoice. Companies should assign one of its unique user fee ID numbers to each submission of a DTC television advertisement for FDA advisory review and reference this number in the submission cover letter and outer package. FDA will track this unique user fee ID number against the invoice to ensure that all applicable fees have been paid and that the company has an available balance of advisory reviews for each submission received by the FDA. A company's advisory review submission will be considered incomplete and not accepted for review until all fees owed by the company for all advisory reviews and the operating reserve fee have been paid.

B. How Do I Send In DTC Television Advertisements for Advisory Review Under the DTC Television User Fee Program?

FDA intends to issue guidance for industry explaining how to submit proposed DTC television Advisory Review Request Packages for review by CDER and CBER under the DTC television user fee program. The guidance document will provide details on the contents, format, and procedures that FDA recommends be followed. The guidance will also explain how and where to submit advisory review packages to start the DTC television user fee program performance clock. FDA will issue a **Federal Register** notice to announce the availability of this guidance. Prior to availability of the guidance, for questions about where or how to submit proposed DTC television advertisements for advisory review, what to include in your submission, the status of pending

DTC television advertisements submitted for advisory review, or your remaining balance of advisory reviews under the DTC television user fee program, please contact Wayne Amchin (see **FOR FURTHER INFORMATION CONTACT**).

For questions about submissions to CBER (APLB), please contact Ele Ibarra-Pratt (see **FOR FURTHER INFORMATION CONTACT**).

C. What Happens if I Send In a DTC Television Advertisement for Advisory Review After October 1, 2007, but Before I'm Invoiced by FDA for My FY 2008 Fees?

The effective date for the assessment and collection of fees for DTC television advertisements under this program is October 1, 2007. Therefore, any proposed DTC television advertisement voluntarily submitted for advisory review in FY 2008 is subject to the fees established in this notice. FDA recognizes that, due to the timing of the enactment of FDAAA, the advisory review and operating reserve fees for FY 2008 were not established and billed before October 1, 2007, and that there will be a gap between the start of the fiscal year and the date that fees are due. FDA will contact companies who submit DTC television advertisements in this time period to request written confirmation from these companies of their commitment to pay these fees; if companies do not agree to make this commitment, FDA will request that they withdraw their submission(s), and such submissions will not be reviewed. For further information, contact Wayne Amchin (see **FOR FURTHER INFORMATION CONTACT**).

For information on how FDA will treat DTC television advertisement advisory review submissions not identified in response to the participation

notice that are submitted after the 30-calendar-day time period for responding to that notice has elapsed, see sections II.A “Basis for the Fee” and II.B “Operating Reserves” of this document.

Dated: December 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

BILLING CODE 4160-01-S