DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0390]

User Fee Program for Advisory Review of Direct-to-Consumer Television Advertisements for Prescription Drug and Biological Products; Request for Notification of Participation and Number of Advertisements for Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to explain the new direct-to-consumer (DTC) user fee program (DTC user fee program) established by the Food and Drug Administration Amendments Act of 2007 (FDAAA) and, as required by the new law, to ask companies to notify FDA within 30 calendar days if they intend to participate in the DTC user fee program during fiscal year (FY) 2008 and, if they do plan to participate, to identify the number of DTC television advertisements for prescription drug and biological products they plan to submit for advisory review during FY 2008. The information gathered in response to this notice will be used to establish the FY 2008 fee that will be charged for each FY 2008 advisory review submission to FDA and to fund the operating reserve established under FDAAA.

DATES: Submit written responses by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written responses by overnight courier service to Wayne Amchin, Project Manager, Division of Drug Marketing, Advertising, and

Communications (DDMAC), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1477, Silver Spring, MD 20993–0002. For companies that use Federal Express or DHL for overnight courier service, the courier will be able to deliver packages directly to DDMAC's office. Other courier services will need to call 301–796–1200 to request that the DDMAC project manager meet the courier at the security desk for package pickup. In addition, fax a copy of your response to 301–796–9878 or e-mail a copy to *dtcp@fda.hhs.gov*.

FOR FURTHER INFORMATION CONTACT: For questions about the DTC user fee program, contact Wayne Amchin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1477, Silver Spring, MD 20993–0002, 301–796–1200, FAX: 301–796–9878, e-mail: *dtcp@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

On September 27, 2007, the President signed into law FDAAA (Public Law 110–85). Title I of this statute reauthorized the Prescription Drug User Fee Act (PDUFA) for FYs 2008 to 2012. In addition, Title I also created new section 736A of the Federal Food, Drug, and Cosmetic Act (the act), which authorizes 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 a required fee for that review. FDA has agreed to use the

resources collected under this program to meet certain performance goals set forth in an enclosure to letters dated September 27, 2007, from the Secretary of Health and Human Services (the Secretary) to the Chairmen and Ranking Minority Members of the Senate Committee on Health, Education, Labor, and Pensions and the House of Representatives Committee on Energy and Commerce. The letters are posted at *http://www.fda.gov/cder/pdufa*.

FDA is issuing this **Federal Register** notice to explain the new program and to ask companies to notify FDA by [*insert date 30 days after date of publication in the* **Federal Register**]: (1) If they intend to participate in the FY 2008 DTC user fee program and (2) if they do plan to participate, to identify the number of DTC television advertisements they plan to submit for advisory review during FY 2008 to DDMAC in the Center for Drug Evaluation and Research or the Advertising and Promotional Labeling Branch in the Center for Biologics Evaluation and Research. The information gathered in response to this notice will be used to establish the fees that will be charged for each advisory review submission to FDA during FY 2008 and to create an operating reserve.

II. Background

FDA's prescription drug advertising regulations give companies the option of submitting proposed television advertisements to FDA for advisory review before publicly disseminating them. In this way, companies can benefit from FDA's advice on whether or not the advertisements are accurate, balanced, and adequately supported. The submission of advertisements for advisory review gives sponsors the opportunity to address any problems before the advertisements are shown to the public and can improve the quality of the advertisements. Companies have recognized the benefits of this advisory

review mechanism, and between 2000 and 2006, FDA received an average of approximately 150 television advertisements for advisory review each year. Recognizing the value of this review, the Pharmaceutical Research and Manufacturers of America (PhRMA) recently stated in its voluntary guiding principles on DTC advertising (see ''PhRMA Guiding Principles; Direct to Consumer Advertisements About Prescription Medicines'' at *http://www.phrma.org/files/DTCGuidingprinciples.pdf*) that companies should submit all new DTC television advertisements to FDA before broadcasting them. In addition, FDAAA provides that FDA may require the submission of drug television advertisements for review before dissemination. However, this provision does not take effect until 180 days after FDAAA's enactment, and does not affect this user fee program, which only applies to voluntary submissions for advisory review.

As FDA's DTC advisory review workload has grown, FDA's ability to keep pace with the demands for reviews has decreased, and the time it takes to review DTC materials submitted for advisory review, including television advertisements, has been increasing. The lack of timely, predictable FDA review times for DTC television advertisements has hindered companies' ability to accurately set timeframes for their marketing campaigns and has discouraged companies from taking advantage of the DTC advisory review process.

III. DTC User Fee Program

The DTC user fee program is available to companies interested in voluntarily submitting to FDA for advisory review a DTC television advertisement for any product that qualifies as a ''prescription drug product,'' as defined in 21 U.S.C. 379g(3). Under this program, a company that chooses

to submit a DTC television advertisement for advisory review will be assessed two types of fees: (1) A fee for each proposed DTC television advertisement submitted for advisory review prior to its initial public dissemination (''advisory review fee'') and (2) a fee paid during the company's first year of participation in the program to establish a reserve fund (''operating reserve fee'').

The decision to seek an advisory review from FDA remains voluntary. However, FDA will not accept for review any prescription drug DTC television advertisements voluntarily submitted by a company for advisory review unless the company has paid both fees.

The payment of an advisory review fee under new section 736A of the act entitles a company to submit for advisory review by FDA one proposed predissemination DTC television advertisement, and one resubmission of the same proposed DTC television advertisement, after receipt of FDA advisory comments on the initial submission. It should be noted that fees will not be assessed for advertisements required to be submitted to FDA prior to initial public dissemination, such as advertisements for accelerated approval drugs (21 CFR 314.550 and 314.640 (subparts H and I)), biologics (21 CFR 601.45 and 601.94 (subparts E and H)), and submissions required by the Secretary under section 901 of FDAAA (as it amends the act to add section 503B, ''Prereview of Television Advertisements''), unless the sponsor voluntarily designates the required submission as a submission for advisory review under this program. Fees also will not be assessed for advisory reviews of advertising or promotional material other than DTC television advertisements (e.g., print advertisements or promotional labeling).

The user fees associated with this program are structured to provide incentives for companies to join the program in FY 2008 and to pay all fees on time, as this will give FDA the funding it needs to hire sufficient staff to review the identified number of advisory submissions in FY 2008. FDA will recruit staff to conduct reviews based upon the expected number of submissions for FY 2008 that are identified in response to this participation notice. Fees for FY 2008 must be paid in a timely manner to allow FDA to actually obtain these staffing resources to conduct timely reviews and meet performance metrics during this year. In addition, the program contains incentives for timely participation and payment. Participants who do not pay their fees on time or who join the program late in a fiscal year must pay individual fees that are 50 percent greater than the established individual fees for participants who both join the program and pay on time.

IV. Establishing the Advisory Review Fee

A. Process

Congress directed FDA to issue a **Federal Register** notice, not later than 30 days after enactment of FDAAA, asking companies to indicate whether they intend to participate in the DTC user fee program by voluntarily submitting for FDA advisory review DTC television advertisements for prescription drugs during FY 2008. Companies that indicate they intend to participate must specify the number of advertisements they intend to submit in FY 2008. Once companies have responded to this notice, FDA will issue another **Federal Register** notice establishing the fee for each advisory review submission for FY 2008.

B. Basis for the Fee

The fee will be based on the number of advertisements identified in response to this participation notice. The advisory review fees in FY 2008 will be set at a level to generate target revenues of $6.25 million in the first year of the program. Individual fees will be determined by dividing the target revenue, established in the statute, by the number of proposed television advertisements that all companies have indicated (in response to the participation notice) that they intend to submit during FY 2008. For example, if companies indicate that they intend to submit 150 total advertisements, the fee for each advisory review submission will be $41,667 ($6.25 million divided by 150). The statute limits this fee to no more than $83,000 per submission for FY 2008. This limitation is one of several provisions in the statute that help ensure individual sponsors will not individually bear a disproportionate share of the cost of the program. The target revenue figures will be adjusted annually for inflation and workload in subsequent years. In each subsequent fiscal year of the program, FDA will issue a new request for notice of participation by June 1 of the previous fiscal year and a second notice by August 1 of the previous fiscal year establishing the fees for the fiscal year beginning October 1.

C. Additional Submissions

If, in response to this notice, a participant notifies FDA that it plans to submit a certain number of advertisements for FY 2008 and then exceeds that number of advertisements, the participant will be assessed a fee for each additional submission. The fee will be 50 percent greater than the established individual fee. In addition, a participant who does not pay the fees for which it is billed within the timeframe specified by the Secretary once the fees are

set for FY 2008 will be assessed a penalty that is 50 percent greater than the established individual fee.

D. Year-to-Year Carry Overs

If a company identifies and pays for more advisory reviews than it submits in a given fiscal year, the company may carry over one paid submission for advisory review to the next fiscal year. This means that a submission for advisory review for which the fee was paid in 1 fiscal year can be submitted for advisory review in the following fiscal year. Companies cannot carry over more than one such submission to the next fiscal year; for unused submissions over and above the one available for carryover, the paid user fee will not be refunded, waived, exempted, or reduced. However, resubmissions are not subject to a fiscal year limitation. For example, a company can submit an advertisement for advisory review in fiscal year 2008 and resubmit a revised version of that same advertisement for advisory review in fiscal year 2009, at no additional cost.

E. 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 anticipated submissions the participant identifies for that year. In this way, FDA will collect additional 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 responding by [*insert date 30 days after date of publication in the* **Federal Register**], the operating reserve fee for each participant in FY 2008 will be an amount equal to the total amount that company is charged for its annual advisory review fees for FY 2008. For companies who respond by

[*insert date 30 days after date of publication in the* **Federal Register**], but do not pay the assessed operating reserve fee within the timeframe specified by the Secretary, their 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 do not notify FDA of their intent to participate until after [*insert date 30 days after date of publication in the* **Federal Register**], 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 to 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 fiscal year they join 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.

F. Effect of Inadequate Funding

The statute provides that if FDA fails to receive sufficient funding from companies within 120 days after enactment of FDAAA, 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 that paid.

G. FDA Commitment

The fees will be used to fund approximately 27 additional staff for predissemination advisory review of DTC television advertisements. These additional resources will enable FDA to provide more timely reviews of DTC television advertisements. FDA has committed to phased-in performance metrics. For example, assuming 150 submissions in FY 2008, FDA will review and provide advisory comments to the sponsor within 45 days on 50 percent of the 150 original submissions. In addition, FDA is committed to reviewing 50 percent of resubmissions within 30 days. The performance metrics will be phased in over the 5 years of the program, with each year including more stringent performance goals.

V. Request for Notice of Participation

FDA is asking companies that intend to submit advertisements to FDA for advisory review in FY 2008 to notify FDA by [*insert date 30 days after date of publication in the* **Federal Register**] of: (1) Their intent to submit advertisements for advisory review and (2) the number of DTC television advertisements they plan to submit for advisory review during FY 2008.

Notification of participation without specifying the number of DTC television advertisements to be submitted in FY 2008 will be considered an incomplete notification, and subsequent notification of intent to submit advertisements after [*insert date 30 days after date of publication in the* **Federal Register**] would be treated as late.

The agency requests that all companies submit their written responses within 30 calendar days (see **DATES**) by overnight courier service to Wayne

Amchin (see **ADDRESSES**) and fax or e-mail a copy of their response (see **ADDRESSES**).

A. What Should Those Wishing To Participate Submit in Their Written Notification?

The following information should be included in a company's DTC television advertisement written notification:

- A statement that they will submit DTC television advertisements to FDA for advisory review during FY 2008,
- The number of proposed DTC television advertisements they will submit for advisory review under the DTC user fee program in FY 2008, and
- The name, title, billing address, and contact information (phone, e-mail, fax) of the company representative who will be the primary person for FDA to contact concerning the company's participation in the program.

B. What Does Written Notification to FDA Mean?

Each company's written notification to FDA of the number of DTC television advertisements it intends to submit for advisory review in FY 2008 is a legally binding commitment by that company to pay the FY 2008 advisory review fee for each submission (see section 736A(a)(1)(D)(ii) of the act). Each person who is assessed an advisory review fee is also required to pay an operating reserve fee for those submissions (a one-time fee in the first year of participation to fund the operating reserve) (see section 736A(a)(2) of the act). FDA will send invoices to each company for all submissions identified in response to this notice, and the advisory review fee and the operating reserve fee for all these submissions are due and payable on the date specified in the invoices. FDA will also assign each participant a series of unique user fee ID numbers to correspond with the number of advisory reviews that the

participant identified in response to this notice. For example, a company identifying 10 advisory reviews will receive 10 unique user fee ID numbers in its invoice. Each submission of a DTC television advertisement for FDA advisory review will be identified with a user fee ID number to show that the fee has been paid. A company's request for advisory review will be considered incomplete and submissions will not be accepted for review until all fees owed by the company for all advisory reviews and the operating reserve fee have been paid (see section 736A(e) of the act).

C. Can a Company Transfer or Sell its Remaining Balance of User Fee Credits to Another Company?

For each advisory review fee paid by a person for a fiscal year, section 736A(a)(1)(F)(i) of the act provides that the person is entitled to acceptance for advisory review of one DTC advertisement and acceptance of one resubmission for advisory review of the same advertisement. Section 736A(a)(1)(F)(i) of the act further provides that the advertisement shall be submitted for review in the fiscal year for which the fee was assessed, except that a person may carry over not more than one paid advisory review submission to the next fiscal year. FDA will administratively keep track of these submissions as advisory review credits. Each credit for an advisory review will expire at the end of the fiscal year for which the user fees were paid, except that one unused credit can be carried over from the fiscal year in which it was purchased to the next fiscal year. Advisory review credits are not transferable, except to a successor in interest (see section 736A(a)(1)(F)(iv) of the act). If unexpired credits are transferred to a successor in interest, the successor company and former owner should notify FDA to ensure that future billing of the successor company reflects prior contributions to the DTC user

fee program reserve fund and the unexpired credit balance. Evidence of a successor in interest could include a copy of the documentation required under 21 CFR 314.72. Please contact Wayne Amchin (see **FOR INFORMATION CONTACT**) concerning successor in interest issues.

Successors in interest with an unexpired credit balance should also be aware of the following:

- One unused credit can be carried over from the fiscal year in which it was purchased to the next fiscal year.
- In responding to the annual **Federal Register** notice for company participation, the successor company must indicate its intent to use the unexpired carryover credit in the upcoming fiscal year.

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

FDA intends to issue guidance to industry explaining how to submit DTC advisory review packages for review under the DTC 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 user fee program performance clock. FDA will issue a **Federal Register** notice to announce the availability of this guidance.

E. 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 DTC television advertisement submitted for advisory review in FY 2008

is subject to the previously discussed fees under this program. FDA recognizes that, because of 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. However, the voluntary submission of a DTC television advertisement for FDA advisory review on or after October 1, 2007, but before [*insert date 30 days after date of publication in the* **Federal Register**] will be considered by FDA as notification that the company who submitted the advertisement wishes to participate in the program and agrees to pay the advisory review fee and operating reserve fee for each such submission in a timely manner once the fees for FY 2008 are established and the company is invoiced. Companies who submit DTC television advertisements for advisory review in this period should respond to this participation notice, and include any such submissions in their count of the total number of advisory submissions they intend to submit in FY 2008. FDA will also 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 companies who do agree, FDA will begin its advisory review of a complete submission of a DTC television advertisement for advisory review on the date that it receives written confirmation of the company's commitment to pay the fees associated with the submission in a timely manner once the company is invoiced.

For information on how FDA will treat DTC television advertisement advisory review submissions not identified in response to this notice that are

submitted after [*insert date 30 days after date of publication in the* **Federal Register**], see sections IV.C ''Additional Submissions'' and IV.E ''Operating Reserves'' of this document.

Dated: October 19, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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

BILLING CODE 4160–01–S