FDA Initiates New DTC User Fee Program

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On October 25, 2007, the Food and Drug Administration (FDA) published a Federal Register notice initiating the new prescription drug user fee program for direct-to-consumer (DTC) television advertisements created by the Food and Drug Administration Amendments Act of 2007 (FDAAA). The notice requests pharmaceutical companies that intend to submit one or more DTC television advertisements to FDA for advisory review during fiscal year 2008 (October 1, 2007, through September 30, 2008) to notify the Agency of (1) the company's intent to participate in the program; and (2) the specific number of such advertisements that will be submitted. Companies will have until late November 2007 to provide this information to FDA.[i]

Estimates should be as accurate as possible because a company's response to the Federal Register notice is considered to be a "legally binding commitment" to pay the required user fee for the number of television advertisements identified in the response. FDA will invoice participating companies, and payment will be due by the date specified by FDA in the invoice (but in no event later than January 25, 2008). Payment will be considered "late"--and subject to substantial late fees--if not paid in full by the "late fee" date specified by FDA. FDA will not accept an advertisement for advisory review unless all required DTC user fees have been paid or, for fiscal year 2008, the company has committed to pay the fee prior to invoicing.

Description of the New DTC User Fee Program

The FDAAA creates a new, standalone prescription drug user fee for companies seeking FDA advisory reviews of DTC television advertisements. In return, FDA has committed to review submitted advertisements within 45 days (30 days for resubmissions) to ensure a timely and predictable advisory review process. The new program seeks to generate revenues of approximately $6.25 million per year to allow FDA to hire approximately 27 new employees to meet these performance goals.

Fees are required ***only*** if a company voluntarily requests advisory review of a DTC television advertisement prior to dissemination. Fees are ***not*** required for: (1) the dissemination of DTC television ads ***without*** advisory review; (2) DTC television ads that are subject to mandatory pre-review (such as pursuant to new section 503B added by the FDAAA) unless the company voluntarily requests advisory review; or (3) advisory reviews of other types of advertisements or promotional

material (e.g., print advertisements or promotional labeling).

There are two types of fees under the new program: advisory review fees and operating reserve fees.

Advisory Review Fees: An advisory review fee must be paid for each DTC television advertisement voluntarily submitted to FDA for advisory review. FDA will not review a television advertisement without the payment of the fee. The fee amount will depend on the total number of submissions each year but likely will range between $40,000 and $60,000 per submission. To facilitate planning, the fee cannot increase more than 50% from one year to the next.

The advisory review fee will be set at the beginning of each fiscal year, although the fee for fiscal year 2008 is not required to be set until December 26, 2007, because of delays in enacting the FDAAA. Under the program, companies must inform FDA by July 1 (extended until November 26 this year) of the number of DTC television advertisements they plan to submit to FDA for advisory review in the upcoming fiscal year. FDA will then set the fee by dividing the target annual revenue by the number of expected submissions industry-wide. For example, if companies collectively indicate that they will submit 150 advertisements for advisory review in fiscal year 2008, the fee per submission would be $41,667 ($6,250,000 divided by 150).

Advisory review fees must be paid at the beginning of the fiscal year (October 1) for all planned submissions. Payment of a fee entitles the sponsor to FDA advisory review of one original submission during the relevant fiscal year and one resubmission in any fiscal year. In addition, sponsors can carry over one paid advisory review to the next fiscal year. The right to an advisory review is not transferable, and fees are non-refundable so long as the program is in operation.

If a company wishes to submit more DTC television advertisements than were identified at the beginning of the fiscal year, it may do so, but the required fee will be higher. In this way, companies receive a substantial discount for paying early. Likewise, if payment for identified submissions is more than one month late (November 1), a substantial late fee (50%) is imposed.

Operating Reserve Fee: In addition to the advisory review fee, companies are subject to an operating reserve fee in the first fiscal year in which they participate in the program. This fee is designed to provide FDA with reserves that can be used to sustain the program if advisory review fees collected in one fiscal year do not meet expected revenue targets. The operating reserve will be established at no less than $6.25 million.

The amount of a company's operating reserve fee will be equal to the amount of the company's total advisory review fee for the relevant fiscal year. For example, if a company notifies FDA it will submit four DTC television advertisements for advisory review in fiscal year 2008, and the advisory review fee is established at $40,000 per submission, the company's one-time operating reserve fee will be $160,000 ($40,000 x 4 submissions).

Review Metrics

In return for DTC user fees, FDA has committed to review and provide comments on original

submissions within 45 days and on resubmissions within 30 days. This is a substantial reduction in the current review times. As with all PDUFA goals, these review times will be implemented on a staggered basis, i.e., 50% to 90% over five years.

Inadequate Funding

The DTC user fee program will be terminated if there is inadequate funding in any fiscal year, including the first year. In fiscal year 2008, if FDA has not received $11.25 million in combined advisory review fees and operating reserve fees (i.e., 90% of target revenues) by January 25, 2008, the program will not commence and all fees will be refunded. In fiscal years 2009 through 2012, if the combination of the operating reserve, collected advisory review fees and unobligated fee revenues from prior fiscal years falls below $9 million (adjusted for inflation), the program shall cease to exist, and FDA will shut down the program and refund all remaining funds.

To Participate or Not

- Participation is voluntary, but FDA will not provide advisory reviews of DTC television advertisements without payment of all required fees.
- Under the program, FDA's advisory reviews should be more timely and predictable.
- If an advertisement is submitted to FDA prior to dissemination and incorporates each of FDA's comments, FDA cannot assess civil money penalties (CMPs) against the advertisement, and if FDA changes its position, it will give companies reasonable time to make necessary changes.
- In determining the size of any CMP, FDA can consider whether the person submitted the advertisement for review under the DTC user fee program.

Recommendations

- Immediately begin the process of forecasting your company's expected use of the FDA advisory review process in fiscal year 2008. Information must be submitted to FDA by November 26, 2007. Substantial late fees may apply if this deadline is missed.
- Ensure that estimates include planned television advertising across all product categories. Television advertisements that are overlooked and not included in the response to FDA's Federal Register notice may be subject to late fees.
- Ensure that estimates are as accurate as possible. Estimates that are too low could result in substantial late fees. Estimates that are too high could result in the forfeiture of advisory review fees, since paid fees will not be refunded.
- Remember that companies may "carry over" one paid advisory review to the next fiscal year without penalty. When forecasting, it thus may be beneficial to err slightly on the high side rather than the low side.
- Remember that the amount of the advisory review fee will not be set at the time companies are required to submit their notifications to FDA. However, fees are expected to range between $40,000 and $60,000 per advisory review (based upon historical trends). In no event can the fee for fiscal year 2008 exceed $83,000 per television advertisement. These expected and maximum fee amounts should help facilitate the budgeting process for user

fees.

- If any of your company's advertisements are required to be submitted to FDA prior to dissemination, include such advertisements in your notice to FDA only if you plan to voluntarily request advisory comments on those advertisements.
- When budgeting, remember that both an advisory review fee and an operating reserve fee will be due in the first fiscal year the company participates in the program.
- Ensure that processes are in place to facilitate the prompt payment of advisory review fees and operating reserve fees. If payment is delayed for administrative or other reasons, steep "late fees" may apply.

[i] Companies must provide the information to FDA no later than 30 days after the date of publication. Since this date (November 24, 2007) falls on a weekend, FDA should allow submissions until the following Monday, November 26, 2007.