



Client Alert

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TV Review Program Not Commencing

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On January 16, 2008, FDA announced that the Direct-to-Consumer ("DTC") television advertisement user fee program for prescription drugs will not commence because FDA did not receive funding for the program. The user fee program, established by the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), would have allowed companies to pay a user fee to receive an advisory review by FDA of DTC prescription drug television advertisements.

The FDAAA provided that the new DTC user fee program could only commence if FDA received a minimum combined total of \$11.25 million from advisory review fees and operating reserve fees within 120 days of the FDAAA's enactment. The Act also provided that user fees could be collected only to the extent and in the amount provided in advance by appropriations acts.

On December 26, 2007, President Bush signed into law the Consolidated Appropriations Act, 2008. Among other things, the law provides appropriations to FDA for necessary agency expenses, such as salaries. The Appropriations Act did not allocate user fee funds for the new DTC user fee program. Therefore, FDA does not have the authority to collect and spend DTC television advertisement user fees, and invoices to those companies which expressed their intent to participate in the program will not be sent.

Television advertisements voluntarily submitted for FDA review will be reviewed as agency resources permit. The program could be restarted if Congress appropriates the required funding for the 2009 fiscal year.

Please feel free to contact us if you have any questions or require additional information.

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