

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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; Program Will Not Be Implemented

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to inform companies that the Direct-to-Consumer (DTC) television advertisement user fee program will not commence because the necessary user fees for the program were not "provided in advance in appropriations Acts" as required by the Food and Drug Administration Amendments Act of 2007 (FDAAA) and the previously issued notice establishing user fee rates for the program for fiscal year (FY) 2008 is being withdrawn.

FOR FURTHER INFORMATION CONTACT: Wayne Amchin, 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.

SUPPLEMENTARY INFORMATION: On September 27, 2007, the President signed into law FDAAA (Public Law 110-85). Title I of FDAAA reauthorized the Prescription Drug User Fee Act for FYs 2008 to 2012. In addition, Title I created new section 736A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379h-1), which authorized a new and separate user fee program

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for the advisory review of DTC prescription drug television advertisements. The DTC user fee program would have been available to companies interested in voluntarily submitting to FDA for advisory review a DTC television advertisement, as defined in section 736A(h)(4) of the act. FDAAA provided, however, that if FDA fails to receive at least \$11,250,000 in advisory review fees and operating reserve fees combined by 120 days after the legislation is enacted (i.e., by January 25, 2008), the program shall not commence (section 736A(f)(1) of the act). FDAAA also provided that the fees authorized for the DTC program “shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts.” (section 736A(g)(1) of the act).

On December 26, 2007, the President signed the Consolidated Appropriations Act, 2008 (Public Law 110–161). The law does not appropriate user fee funds for the voluntary review of DTC television advertisements. As a result, under section 736A(g)(1) of the act, FDA does not have the authority to collect and spend user fees for this purpose. Furthermore, as noted previously, section 736A(f)(1) of the act provides that if FDA has not collected at least \$11,250,000 in advisory review fees and operating reserve fees combined by 120 days after the legislation is enacted (i.e., by January 25, 2008), the program shall not commence. Therefore, no invoices will be sent. Advertisements voluntarily submitted for FDA review will be reviewed in as timely a manner as resources permit. In addition, FDA is withdrawing the previously issued **Federal Register** notice establishing the user fee rates for this program for FY 2008 (72 FR 70334, December 11, 2007).

Dated: 1/10/08
January 10, 2008.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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