Dated: January 3, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–675 Filed 1–15–08; 8:45 am]

BILLING CODE 4160–01–S

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; 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(FDAAA) and the previously issued notice establishing user fee rates for the program for fiscal year (FY) 2008 is being withdrawn.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 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: January 10, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–740 Filed 1–15–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Psychopharmacologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of December 19, 2007 (72 FR 71923). The amendment is being made to reflect changes in the *Location, Contact Person, and Procedure* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *diem.ngo@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), code 3014512544. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 19, 2007, FDA announced that a meeting of the Psychopharmacologic Drugs Advisory Committee would be held on February 6, 2008.

On page 71923, in the third column, the *Location* portion of the document is changed to read as follows:

Location: Crowne Plaza/Silver Spring, Kennedy Ballrooms, 8777 Georgia Ave., Silver Spring, MD. The hotel telephone number is 301–589–0800.

On page 71923, in the third column, the first sentence of the *Contact Person* portion of the document is changed to read as follows:

Contact Person: Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *diem.ngo@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512544.

On page 71924, in the first column, the first paragraph of the *Procedure* portion of the document is changed to read as follows:

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 18, 2008. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 10, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons