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and the previously issued notice establishing user fee rates for the program for fiscal year (FY) 2008 is being withdrawn.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

regarding their request to speak by January 11, 2008.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 10, 2008.

**Randall W. Lutter,**

*Assistant Commissioner for Policy.*

[FR Doc. E8–726 Filed 1–15–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; Comment Request; Quality of Life Outcomes in Neurological Disorders

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Neurological Disorders and Stroke (NINDS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 24, 2007, page number 54269 and allowed 60 days for public comment. One public comment was received; also received were one request for the data collection plans and proposed instruments and a request for information on a related Web site. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Proposed Collection: Title:* Quality of Life Outcomes in Neurological Disorders; *Type of Information Collection Request:* New; *Form Number:* NA; *Need and Use of Information Collection:* In order to improve outcome measurement in clinical trials of neurological conditions, NINDS is developing a health-related quality of life (HRQL) measurement system for major neurological diseases that affect the United States population. This measurement system must be consistent enough across the selected conditions to allow for cross-disease comparison, and yet flexible enough to capture condition-specific HRQL issues. The primary end users of this measurement system will be clinical trialists and other clinical neurology researchers; however the measurement system will also be appropriate for clinical practice. The proposed information collection will support psychometric testing of HRQL item banks and testing of Spanish translation of the final questionnaires. *Frequency of Response:* Once; *Affected Public:* Individuals; *Type of Respondent:* Adults and children. The annual reporting burden is shown in the following table. There are no Capital Costs, Operating Costs or Maintenance Costs to report.

| Type of respondents | Number of respondents | Frequency of response | Average time per response | Annual hour burden |
|---|---|---|---|---|
| Adults | 6,000 | 1 | 0.5 | 3,000 |
| Children | 3,000 | 1 | 0.5 | 1,500 |
| Totals | 9,000 | | | 4,500 |

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Claudia Moy, Program Director, Clinical Trials Group, NINDS, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 2214, Bethesda, MD 20892, or call non-toll-free number 301–496–2789 or e-mail your request, including your address to: <*moyc@ninds.nih.gov*>.

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: December 20, 2007.

**Joellen Austin Harper,**

*Executive Officer, NINDS, National Institutes of Health.*

[FR Doc. E8–606 Filed 1–15–08; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Child Health and Human Development; Longitudinal Investigation of Fertility and the Environment Study

**SUMMARY:** In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval. This is a request for renewal of an information collection request that was approved (OMB Clearance 0925–0543) following publication in the **Federal Register** on January 9, 2004, page 1589 and December 2, 2004, page 70153.

*Proposed Collection: Title:* Longitudinal Investigation of Fertility and the Environment Study. *Type of*