DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic 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 the meeting of the Oncologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of October 14, 2005 (70 FR 60094). The amendment is being made to reflect changes in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Johanna Clifford, 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 or email: *cliffordj@cder.fda.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 14, 2005, FDA announced that a meeting of the Oncologic Drugs Advisory Committee will be held on November 8, 2005. On page 60094, beginning in the third column, and continuing on page 60095, the *Agenda* portion of the meeting is amended to read as follows:

Agenda: The committee will discuss new drug applications approved under 21 CFR 314.500 and 601.40 (subparts H and subpart E, respectively, accelerated approval regulations) in an open session to do the following: (1) Review the status of phase IV clinical studies; (2) identify difficulties associated with completion of phase IV commitments; and (3) provide advice to sponsors to assist in the planning and execution of postmarketing commitments of newly approved drugs. The committee will discuss phase IV commitments of: (1) New drug application (NDA) 50–718, DOXIL (doxorubicin hydrochloride liposome injection, Johnson and Johnson Pharmaceutical Research and Development, L.L.C.) for the treatment of acquired immune deficiency syndrome (AIDS) related Kaposi's sarcoma in patients with disease that has progressed on prior combination therapy or in patients who are intolerant to such therapy; (2) biologics license application (BLA) 103767/0, ONTAK (denileukin diftitox, Seragen Incorporated) for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the interleukin-2 receptor; (3) NDA 21–041, DEPOCYT (cytarabine liposome injection, SkyePharma Inc.) for the intrathecal treatment of lymphomatous meningitis; (4) NDA 21–156, CELEBREX (celecoxib capsules, Pfizer Inc.) for reducing the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP), as an adjunct to usual care (e.g., endoscopic surveillance, surgery); (5) NDA 21–174, MYLOTARG (gemtuzumab ozogamicin for injection, Wyeth Pharmaceuticals, Inc.) for the treatment of patients with CD33 positive acute myeloid leukemia in first relapse who are 60 years of age or older and who are not considered candidates for other cytotoxic chemotherapy; and (6) BLA 103948/0, CAMPATH (alemtuzumab, ILEX Pharmaceuticals, L.P.) for the treatment of B-cell chronic lymphocytic leukemia (B–CLL) in patients who have been treated with alkylating agents and who have failed fludarabine therapy.

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: October 21, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. 05–21493 Filed 10–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0410]

Prescription Drug User Fee Act; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of October 18, 2005 (70 FR 60536). The document announced a public meeting on the Prescription Drug User Fee Act (PDUFA). The document was published with typographical errors in the **DATES** and **FOR FURTHER INFORMATION CONTACT** sections of the document. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 05–20875, appearing on page 60536 in the **Federal Register** of Tuesday, October 18, 2005, the following corrections are made:

1. On page 60536, in the second column, the third sentence under **DATES** is corrected to read: ''You may register electronically at *CBERTrainingSuggestions @cber.fda.gov.''*

2. On page 60536, in the second column, in the **FOR FURTHER INFORMATION CONTACT** section, beginning in the fifth line, the telephone number ''301–827–2647'' is corrected to read ''301–827–5902''.

Dated: October 20, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21525 Filed 10–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Psychopharmacologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 2, 2005, from 8 a.m. to 5 p.m.

Location: Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD, 301–977–8900.

Contact Person: Cicely Reese, 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: *ReeseCi@cder.fda.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. The background material will

become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under the heading ''Psychopharmacologic Drugs Advisory Committee (PDAC).'' (Click on the year 2005 and scroll down to PDAC meetings.)

Agenda: The committee will discuss new drug application (NDA) 21–514, proposed trade name METHYPATCH (Methylphenidate) Tdp, (Methylphenidate Transdermal System), Noven Pharmaceuticals, proposed indication for the treatment of attention deficit hyperactivity disorder (ADHD).

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 by November 18, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 18, 2005, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Cicely Reese at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 21, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. 05–21524 Filed 10–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, U.S. Department of Homeland Security.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted the following information collection to the Office of Management and Budget (OMB) for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The submission describes the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort and resources used by respondents to respond) and cost, and includes the actual data collection instruments FEMA will use.

Title: State/Local/Tribal Hazard Mitigation Plans–Section 322 of the Disaster Mitigation Act of 2000.

OMB Number: 1660–0062.

Abstract: This collection is in accordance with our responsibilities under 44 CFR Part 201 Hazard Mitigation Planning, which requires FEMA's approval and determination of State, local and tribal eligibility for Stafford Act assistance.

Affected Public: State, local and Tribal governments.

Number of Respondents: 1,024 respondents.

Estimated Time per Respondent: The estimated response time for this collection varies depending on the level of government and the scope of the plan. Response time can be as short as 8 hours for a State's review of a local mitigation plan or as long as 2,080 hours for the actual development of a new mitigation plan. On average the collection takes approximately 545 hours.

Estimated Total Annual Burden Hours: 571,200 hours.

Frequency of Response: Once every three years with 3/5 year updates.

Comments: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs at OMB, Attention: Desk Officer for the Department of Homeland Security/FEMA, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503, or facsimile number (202) 395–7285. Comments must be submitted on or before November 28, 2005.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Chief, Records Management, FEMA at 500 C Street, SW., Room 316, Washington, DC 20472, facsimile number (202) 646–3347, or e-mail address *FEMA-Information-Collections@dhs.gov*.

Dated: October 21, 2005.

George S. Trotter,

Acting Branch Chief, Information Resources Management Branch, Information Technology Services Division.

[FR Doc. 05–21507 Filed 10–27–05; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, U.S. Department of Homeland Security.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed continuing information collection. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)), this notice seeks comments on the Exemption of State-Owned Properties Under Self-Insurance Plan.

SUPPLEMENTARY INFORMATION: 44 CFR part 75 establishes standards with respect to the Federal Insurance Administrator's (FIA) determinations, that a State's plan of self-insurance is adequate and satisfactory for the purposes of the Act, from the requirement of purchasing flood insurance coverage for State-owned structures and their contents in areas identified by the Administrator as A, AO, AH, A1–A30, AE, A99, M, V, VO, V1–V30 and E zones, in which the sale of insurance has been made available. It also establishes the procedures by