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]

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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