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 the meeting of the Psychopharmacologic Drugs Advisory Committee. The meeting was announced in the **Federal Register** of July 20, 2006 (71 FR 41220). The amendment is being made to reflect a change in the *Date and Time* and *Agenda* portion of the notice. The *Agenda* scheduled for September 7, 2006, has been cancelled. The *Agenda* portion scheduled for September 8, 2006, has been moved to September 7, 2006. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Cicely Reese, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *cicely.reese@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512544.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 20, 2006, FDA announced that a meeting of the Psychopharmacologic Drugs Advisory Committee would be held on September 7, 2006, to discuss new drug application (NDA) 21–999, paliperidone extended-release (ER) tablets, Janssen, L.P./ Johnson & Johnson Pharmaceutical Research and Development, L.L.C., proposed indication for treatment of schizophrenia and on September 8, 2006, to discuss NDA 21–992, desvenlafaxine succinate (DVS 233), ER tablets, Wyeth Pharmaceuticals, proposed indication for treatment of major depressive disorder. On page 41220, in the first column, the Date and Time portion of the meeting is amended to read as follows:

Date and Time: The meeting will be held on September 7, 2006, from 8 a.m. to 5 p.m.

On page 41220, second column, the *Agenda* portion of the meeting is amended to read as follows:

Agenda: On September 7, 2006, the committee will discuss new drug application (NDA) 21–992, desvenlafaxine succinate (DVS 233), extended-release tablets, Wyeth Pharmaceuticals, proposed indication for treatment of major depressive disorder (MDD).

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: August 8, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–13502 Filed 8–16–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0301]

Draft Guidance for Industry; Animal Drug User Fees: Fees Exceed Costs Waivers and Reductions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (#183) entitled ''Animal Drug User Fees: Fees Exceed Costs Waivers and Reductions.'' The draft guidance explains the procedures FDA expects to use to evaluate waiver requests under the fees exceed costs waiver provision of the Animal Drug User Fee Act of 2003.

DATES: Submit written or electronic comments on the draft guidance by October 31, 2006 to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http:// www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dave Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *david.newkirk@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Animal Drug User Fee Act of 2003 (ADUFA) (Public Law 108–130) amended the Federal Food, Drug, and Cosmetic Act (the act) and requires that FDA assess and collect user fees for certain applications, products, establishments, and sponsors. It also requires the agency to grant a waiver from, or a reduction of, those fees in certain circumstances.

The draft guidance explains the procedures FDA expects to use to evaluate waiver requests under the fees exceed costs waiver provision of ADUFA. These procedures may be modified in the future as FDA gains more experience with waiver requests.

To qualify for waiver consideration for fees due on or after October 1, 2004, a written request for a fees exceed costs waiver or reduction must be submitted no later than 180 days after the fee is due (section 740(i) of the act (21 U.S.C. 379j–12(i))).

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's Good Guidance Practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the topic. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative approaches may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in Guidance for Industry #170. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and have been approved under OMB Control No. 0910–0540.

IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of

electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the full title of the draft guidance document and the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on the Internet site, select Docket No. 2006D–0301, ''Animal Drug User Fees; Fees Exceeds Costs Waivers and Reductions'' and follow the directions. A copy of this document may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: August 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–13507 Filed 8–16–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the NIH Office of Portfolio Analysis and Strategic Initiatives (OPASI) Council of Councils (Council).

The Council will consult with, and provide advice and recommendations to the Director NIH, the Director, OPASI, and the individual Institute and Center (IC) Directors on potential trans-NIH initiatives at the conceptual stage. The Council's advice and recommendations will assist the IC Directors in identifying trans-NIH initiatives to be pursued for further development.

Duration of this committee is two years from the date the Charter is filed.

Dated: August 8, 2006.

Elias Zerhouni,

Director, National Institutes of Health.

[FR Doc. 06–6966 Filed 8–16–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Director's Consumer Liaison Group.

Date: October 25, 2006.

Time: 7:30 a.m. to 6 p.m.

Agenda: (1) Meeting with NCI Acting Director; (2) Updates on NCI Programs; (3) Update on NCI Budget and Legislation; Report from NCI Listens and Learns Working Group and DCLG Summit Working Group; (4) Public Comment; (5) Action Items and Conclusion.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Barbara Guest, Executive Secretary, Office of Liaison Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Blvd., Room 2202, Rockville, MD 20892–8324, 301–496–0307, *guestb@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/dclg/dclg.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS).

Dated: August 8, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–6963 Filed 8–16–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6), as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board.

Open: September 6, 2006, 8:30 a.m. to 4:15 p.m.

Agenda: Program reports and presentations; Business of the Board.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

Name of Committee: National Cancer Advisory Board.

Closed: September 6, 2006, 4:15 p.m. to 5:15 p.m.

Agenda: Review of grant applications.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

Name of Committee: National Cancer Advisory Board.

Open: September 7, 2006, 8 a.m. to 12 p.m.

Agenda: Program reports and presentations; Business of the Board.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

Any interested person may file written comments with the committee by forwarding