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.

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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