DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 2004N–0330]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric 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 joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee. This meeting was announced in the **Federal Register** of August 4, 2004 (69 FR 47157). The amendment is being made to reflect changes in the *Addresses* and *Procedure* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Anuja Patel, 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: *patelA@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.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 4, 2004, FDA announced that a joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee would be held on September 13 and 14, 2004. On page 47157, in the third column, the *Addresses* and on

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page 47158, in the second column, the *Procedure* portions are amended to read as follows:

Addresses: Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments.* Select ''2004N–0330—Suicidality in Clinical Trials for Antidepressant Drugs in Pediatric Patients'' and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments received by August 23, 2004, will be provided to the committee before the meeting. Comments received after August 23, 2004, will be reviewed by FDA's decision makers.

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 Division of Dockets Management as stated in the *Addresses* section of this document. Oral presentations from the public will be scheduled between approximately 2 p.m. to 6 p.m. on September 13, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before 4:30 p.m. on August 27, 2004, 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. Docket ''2004N–0330—Suicidality in Clinical Trials for Antidepressant Drugs in Pediatric Patients'' will remain open for public submissions until July 29, 2005.

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

Dated: August 13, 2004
August 13, 2004.

William K. Hubbard,
Associate Commissioner for Policy and Planning.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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