DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science; 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: Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science.

General Function of the Subcommittee: To provide advice and recommendations to the Committee for Pharmaceutical Science on FDA's regulatory issues.

Date and Time: The meeting will be held on October 18, 2006, from 8:30 a.m. to 5:30 p.m. and on October 19, 2006, from 8:30 a.m. to 1 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Mimi Phan, 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: 301–827–6801, e-mail: *mimi.phan@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in Washington, DC area), code 3014512539. 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 ''Advisory Committee for Pharmaceutical Science (ACPS).'' (Click on the year 2006 and scroll down to ACPS meetings.)

Agenda: On October 18, 2006, the subcommittee will: (1) Receive an update on previous Clinical Pharmacology Subcommittee meeting recommendations and an introduction to three new topics of this meeting; (2) discuss and provide comments on the first new topic: The scope and strength of evidence to support the inclusion of pharmacogenetic information on Cytochrome P2D6 polymorphisms in a revision of the label for tamoxifen to improve the benefit/risk of the drug; and (3) discuss and provide comments on the second new topic: evaluation of transporter-based drug interactions. On October 19, 2006, the subcommittee will consider the third new topic: The impact of using prior knowledge on drug development and regulatory decisions. Prior knowledge of disease change over time and covariates, placebo variation and drug effects can be used to make better decisions and design more informative clinical trials. Examples will be used to demonstrate these principles.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person on or before October 3, 2006. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 11:45 a.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentation should notify the contact person 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 on or before October 3, 2006.

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 Mimi Phan 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: August 23, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–14296 Filed 8–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Psychopharmacologic Drugs Advisory Committee scheduled for September 7, 2006, is cancelled. This amended meeting was announced in the **Federal Register** of August 17, 2006 (71 FR 47502).

FOR FURTHER INFORMATION CONTACT: Cicely Reese, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, 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. Please call the Information Line for up-to-date information on this meeting.

Dated: August 23, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–14293 Filed 8–28–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0331]

Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research.'' This draft guidance, when finalized, is intended to assist Institutional Review Boards (IRBs), clinical investigators, and sponsors in the development and conduct of emergency research.The draft guidance