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

also describes the additional specific human subject protection requirements for emergency research. Elsewhere in this issue of the **Federal Register**, FDA is announcing a public hearing on emergency research conducted without informed consent under FDA regulations.

DATES: Submit written or electronic comments on the draft guidance by October 30, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit phone requests to 800–835–4709 or 301–827–1800. Submit written comments on the draft guidance 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: Carolyn Hommel, Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION:

I. Background

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 was developed to assist IRBs, clinical investigators, and sponsors in the development and conduct of emergency research, that is, research in emergency settings when an exception from the informed consent requirements is requested under FDA's emergency research regulation. Further, the draft guidance describes the additional specific human subject protection requirements for emergency research, such as community consultation and public disclosure activities, the need for the concurrence of a licensed physician, use of data monitoring committees, use of independent IRBs, and the documentation of efforts to contact a subject's legally authorized representative or family member regarding the subject's participation in the study.

In addition to the draft guidance, FDA is holding a public hearing on emergency research conducted without informed consent under FDA regulations. The public hearing is designed to solicit the views of individuals and groups affected by challenges encountered in the conduct of emergency research in the absence of informed consent, including patient advocacy groups, individuals who have participated in clinical trials, IRB members, sponsors, clinical investigators, medical societies, ethicists, and other interested parties. FDA will consider comments and suggestions received at the hearing together with any comments received on the draft guidance to determine whether the current framework is adequate for the ethical conduct of emergency research, or whether modifications would be appropriate.

Under the regulations in 21 CFR 50.24, and the conforming amendments contained in 21 CFR parts 56, 312, 314, 601, 812, and 814, an exception may be requested from the requirement to obtain informed consent from each subject, or the subject's legally authorized representative, prior to enrollment in a clinical investigation. The narrow exception applies to emergency research for which, among other things, the following conditions exist: (1) An investigational new drug application (IND) or investigational device exemption application (IDE) is required; (2) that involves human subjects who have a life-threatening medical condition (for which available treatments are unproven or unsatisfactory); (3) that involves subjects who because of their medical condition (e.g., unconsciousness) cannot give informed consent; and (4) where, to be effective, the intervention must be administered before informed consent from the subjects' legally authorized representative is feasible. Studies involving an exception from the general requirement of informed consent may proceed only after a sponsor has received prior written permission from FDA, and the IRB has found and documented that specific conditions have been met.

This 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 exception from informed consent requirements for emergency research. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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). The collections of information in part 56 (21 CFR part 56) have been approved under OMB control number 0910–0130, the collections of information in part 312 (21 CFR part 312) have been approved under OMB control number 0910–0014, and the collections of information in part 812 (21 CFR part 812) have been approved under OMB control number 0910–0078. Modifications to these approved information collection requirements are underway or will be made at the time that each information collection is renewed. The agency believes that this is appropriate because this guidance has only a minor impact on these existing collections of information.

III. Comments

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 docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: August 21, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–14262 Filed 8–25–06; 8:45 am]

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