DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee; 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: Psychopharmacologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 4, 2002, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, the Ballroom, Two Montgomery Village Ave., Gaithersburg, MD, 301–948–8900.

Contact Person: Sandra Titus, 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, or e-mail Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12544. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider supplemental new drug application S–047, Clozaril, (clozapine, Novartis Pharmaceuticals Corp.) proposed for the treatment of suicidality in patients with schizophrenia or schizoaffective disorder. The purpose of this meeting is to discuss the findings and regulatory implications for the InterSePT Study, a study that compared clozapine and olanzapine on the outcome of emergent suicidal behavior and thinking in schizophrenic and schizoaffective patients who were judged to be at risk of suicide. Background material for this meeting will be posted no later than 24 hours before the meeting at the Psychopharmacologic Drugs Advisory Committee Docket site: http://www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2002 and scroll down to Psychopharmacologic Drugs Advisory Committee.)

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 contact person by October 24, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 24, 2002, 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.

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 Sandra Titus 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: October 10, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–26616 Filed 10–17–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0350]

Draft Guidance for Industry on Handling and Retention of Bioavailability and Bioequivalence Testing Samples; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until December 17, 2002, the comment period for the draft guidance for industry entitled ''Handling and Retention of Bioavailability and Bioequivalence Testing Samples.'' This draft guidance is intended to clarify how to distribute test articles and reference standards to testing facilities, how to randomly select reserve samples, and how to retain reserve samples. FDA published a notice of availability of the draft guidance in the **Federal Register** of August 21, 2002 (67 FR 54219). The agency is taking this action in response to a request for an extension of the comment period and to allow interested parties additional time to submit comments.

DATES: Submit written or electronic comments on the draft guidance by December 17, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, 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 written comments on the draft guidance to the Dockets Management Branch (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: Martin Yau, Center for Drug Evaluation and Research (HFD–45), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5458.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 21, 2002 (67 FR 54219), FDA announced the availability of a draft guidance for industry entitled ''Handling and Retention of Bioavailability and Bioequivalence Testing Samples.'' The draft guidance had a 30-day comment period. The draft guidance clarifies the responsibilities of the involved parties for retention of samples used in bioavailability and bioequivalence studies. It includes recommendations for sampling techniques and responsibilities in various study settings.

In a letter dated September 20, 2002, FDA received a request from an interested party to extend the comment period. The party indicated that issues of importance to the pharmaceutical industry had been raised that warrant further discussion before filing comments. In response to this request, and to provide all interested persons additional time to comment on this draft guidance, FDA is reopening the comment period for 60 days.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: October 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–26475 Filed 10–17–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0428]

Draft ''Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components'' dated October 2002. The draft guidance document recognizes the ''Circular of Information for the Use of Human Blood and Blood Components'' (the circular) dated July 2002 as acceptable for use by manufacturers of blood and blood components intended for transfusion. The circular will assist those manufacturers in complying with the labeling requirements under FDA regulations.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by December 17, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance and the Circular to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The documents may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components'' dated October 2002. The draft guidance document recognizes that the circular dated July 2002 meets the labeling requirements in § 606.122 (21 CFR 606.122), and therefore is acceptable for use by manufacturers of blood and blood components intended for transfusion that are subject to U.S. statutes and regulations.

The requirements under § 606.122 specify that an instruction circular must be available for distribution with blood and blood components intended for transfusion, and that the information in the instruction circular must include adequate instructions for use. The circular will assist manufacturers of blood and blood components intended for transfusion in complying with the labeling requirements under § 606.122. The circular was prepared jointly by the American Association of Blood Banks, America's Blood Centers and the American National Red Cross. A copy of the circular is in the draft guidance document.

This draft guidance document is being issued in accordance with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance document represents the agency's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document and the circular at either http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm. The circular may also be obtained at www.aabb.org.

Dated: October 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–26612 Filed 10–17–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0005]

Guidance for Industry on Labeling Over-the-Counter Human Drug Products—Updating Labeling in Reference Listed Drugs and Abbreviated New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Labeling OTC Human Drug