DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The Sixth Annual FDA–Orange County Regulatory Affairs (OCRA) Educational Conference ''FDA and OCRA: Understanding the Changing Landscape''

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing its sixth annual educational conference entitled ''FDA and OCRA: Understanding the Changing Landscape'' cosponsored with OCRA. The conference is intended to provide the drug, device and biologics industries with an opportunity to interact with FDA reviewers and compliance officers from FDA's centers and district offices, as well as other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the three medical product areas. Industry speakers, interactive questions and answer, and workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.

Date and Time: The meeting will be held on June 4 and 5, 2003, from 7:30 a.m. to 5 p.m.

Location: The meeting will be held at The Irvine Marriott, 18000 Von Karman Ave., Irvine, CA.

Contact: Ramlah Oma, Food and Drug Administration, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612, 949–798–7611, FAX 949–798–7656, or OCRA, Attention to detail (ATD), 111 East Avenida San Gabriel, San Clemente, CA 92672, 949–366–1056, FAX 949–366–1057, Web site: http://www.ocra-dg.org. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after the document publishes in the **Federal Register**.)

Registration and Meeting Information: See OCRA Web site at http://www.ocra-dg.org. Contact ATD at 949–366–1056.

Before May 20, 2003, registration fees are as follows: $425.00 for members, $500.00 for nonmembers, and $275.00 for FDA/government/full-time students with proper identification. After May 20, 2003, $495.00 for members, $575.00 for nonmembers, and $325.00 for FDA/government/full-time students with proper identification.

If you need special accommodations due to a disability, please contact Ramlah Oma at least 10 days in advance.

Dated: May 2, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–11651 Filed 5–8–03; 8:45 am]

BILLING CODE 4160–01–S

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 June 16, 2003, from 8 a.m. to 5 p.m.

Location: Marriott Washingtonian Center, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Jayne E. Peterson, 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, e-mail: petersonj@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: On June 16, 2003, the committee will discuss the white blood cell (WBC) monitoring schedule for patients being treated long-term with clozapine. Currently, the WBC monitoring schedule is weekly for the first 6 months of continuous therapy and biweekly thereafter. The committee will consider the question of whether the frequency of WBC monitoring can be diminished further following some period of biweekly monitoring. When available, background materials for this meeting will be posted 1-business day prior to the meeting on the FDA Web site at: www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2003 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 June 9, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 9, 2003, 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 Jayne Peterson 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: May 5, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–11649 Filed 5–8–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0528]

Risk Management; Public Workshop; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until May 30, 2003, the comment period for three concept papers entitled ''Premarketing Risk Assessment,'' ''Risk Management Programs,'' and ''Risk Assessment of Observational Data: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' The document that requested public input, review, and comments for the three concept papers was published in

the **Federal Register** of March 7, 2003 (68 FR 11120). The agency is taking this action in response to informal requests for an extension of the comment period.

DATES: Submit written or electronic comments on the concept papers by May 30, 2003.

ADDRESSES: Submit written requests for single copies of the concept paper(s) to Lee Lemley, Executive Operations Staff (HFD–006), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the concept papers.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail: *FDADockets@oc.fda.gov*, or on the Internet at *http://accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm*.

FOR FURTHER INFORMATION CONTACT: Lee Lemley, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6218, *lemleyl@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 7, 2003 (68 FR 11120), FDA published a document announcing a public workshop to discuss risk management activities for drug and biological products (excluding blood products other than plasma derivatives). The public workshop was held, as scheduled, on April 9, 10, and 11, 2003. To facilitate public input and discussion, FDA simultaneously had issued three concept papers for review and comment entitled: (1) ''Premarketing Risk Assessment,'' (2) ''Risk Management Programs,'' and (3) ''Risk Assessment of Observational Data: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' Interested persons were given until April 30, 2003, to submit written or electronic comments on the concept papers. In response to informal requests from interested persons for additional time to submit comments on the concept papers, FDA has decided to reopen the comment period until May 30, 2003.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the concept papers. You should annotate and organize your comments to identify the specific concept paper and issue to which the comments refer. Where possible, comments should reference line numbers in the concept papers. Two paper copies of any mailed comments are to be submitted, 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. The concept papers and received comments may be seen at the Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday.

III. Electronic Access

Electronic versions of the concept papers are available via the Internet at *http://www.fda.gov/cder/meeting/riskmanagement.htm*.

Dated: May 2, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–11497 Filed 5–8–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Advisory Board to the National Center for Toxicological Research; 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR).

General Function of the Committee: The Board advises the Director, NCTR, in establishing, implementing, and evaluating the research programs that assist the Commissioner of Food and Drugs in fulfilling his regulatory responsibilities. The Board provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

Date and Time: The meeting will be held on June 19, 2003, from 9 a.m. to 4:45 p.m. and on June 20, 2003, from 9 a.m. to 12:15 p.m.

Location: NCTR, Building #12, Conference Center, 3900 NCTR Dr., Jefferson, AR 72079.

Contact Person: Leonard M. Schechtman, NCTR (HFT–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12559. Please call the Information Line for up-to-date information on this meeting.

Agenda: The Board will be presented with a draft report on the evaluation of the Division of Biometry. The draft report is the product of a site visit team that conducted an onsite review of the Division in May. Division staffers will provide a preliminary response to the issues raised and recommendations made.

The establishment of a Pharmaceutical Safety Working Group and the background and history of two Expert Working Groups (EWG) will be discussed. A proposal to move oversight for the EWGs from the Center for Drug Evaluation and Research (CDER) to NCTR will also be reviewed. Representatives from CDER and industry will present perspectives on the proposed change in oversight. An earlier version of this proposal was discussed at the June 2001 and August 2002 meetings of the SAB. The Board will also receive updates on the activities of the Cardiotoxicity and Vascular Injury EWGs.

Procedure: On June 19, 2003, from 9 a.m. to 4:45 p.m., and June 20, 2003, from 9 a.m. to 11:45 a.m., the meeting is open to the public. 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 June 6, 2003. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m., on June 20, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 6, 2003, 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.

Closed Committee Deliberations: On June 20, 2003, from 11:45 a.m. to 12:15 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

Persons attending FDA's advisory committee meetings are advised that the