

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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Certifier A. Corbin

Science Advisory Board to the National Center for Toxicological Research;

Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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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.

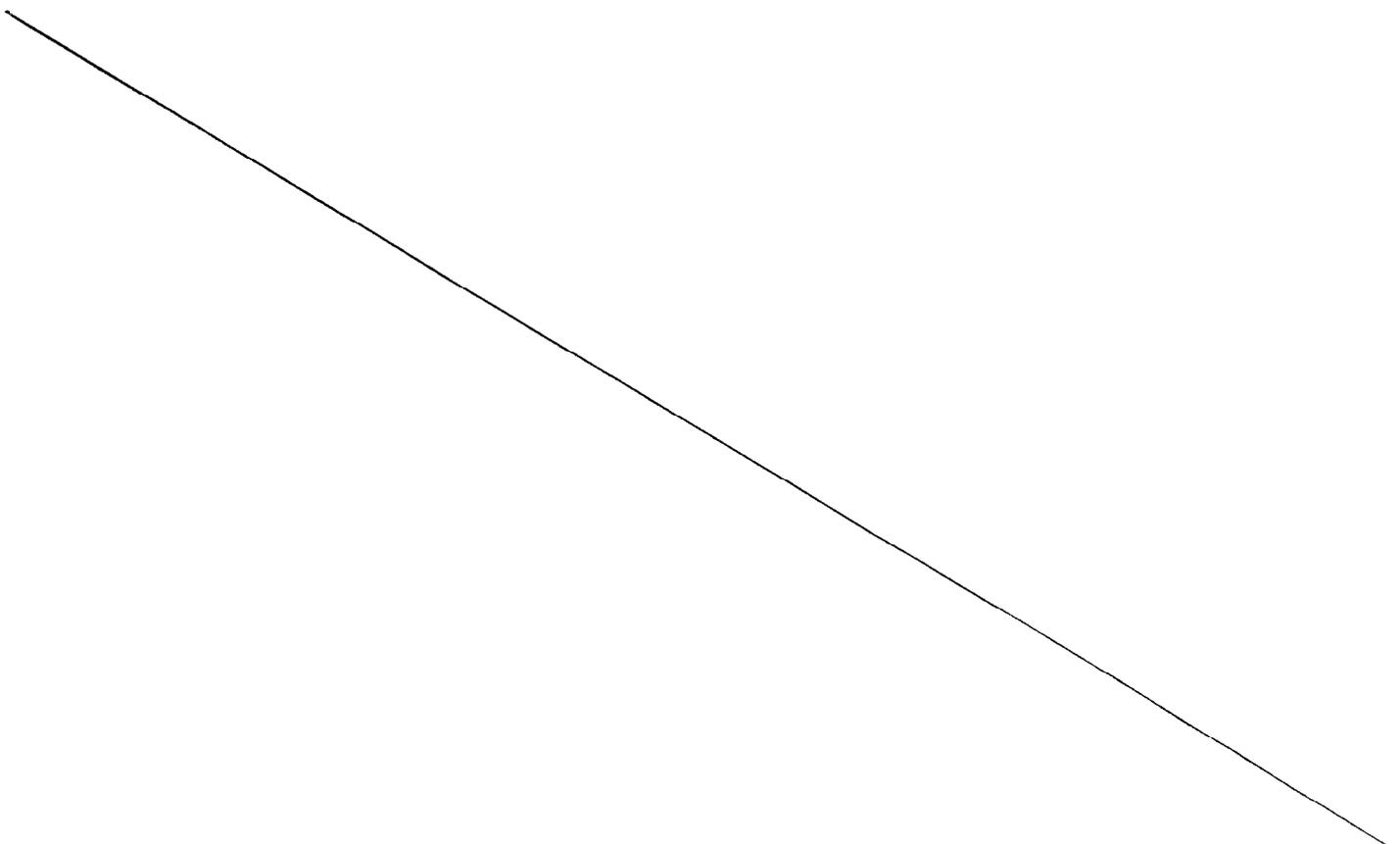
*Procedure:* On June 19, 2003, from 9 a.m. to 4:45 p.m., and June 20, 2003, from 9 a.m. to 11:45 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact 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 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 Leonard M. Schechtman at least 14 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: 5/3/03  
May 3, 2003.



Peter J. Pitts,  
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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