entities. Reclassification of the device from class III to class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this reclassification action, if finalized, will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

XIII. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this document by August 13, 2001. Two copies of any comment 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–13302 Filed 5–25–01; 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 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 (the Commissioner) in fulfilling 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 11, 2001, 1 p.m. to 5:30 p.m., and June 12, 2001, 8:30 a.m. to 1 p.m.

Location: NCTR, Bldg. #12, Conference Center, Jefferson, AR.

Contact: 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 progress reports on the implementation of recommendations made by the board at its last meeting on NCTR's research programs in endocrine disrupter knowledge base and microbiology. The NCTR director will provide a center update and a discussion of future research directions. A proposal will be made to the board that it consider establishing a subcommittee on scientific opportunities to improve regulatory science through collaboration with external stakeholders. A report will be provided to the board on the activities of an existing subcommittee with a similar focus (Advisory Committee for Pharmaceutical Science, Nonclinical Studies Subcommittee) NCTR division directors will discuss the accomplishments and future directions for their divisions.

Procedure: On June 11, 2001, from 1 p.m. to 5:30 p.m., and June 12, 2001, from 8:30 a.m. to 12 noon, 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 May 18, 2001. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on June 12, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 18, 2001, 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 12, 2001, from 12 noon to 1 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.

The Commissioner approves the scheduling of meetings at locations outside the Washington, DC area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 22, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–13378 Filed 5–25–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection: Comment Request; a Study of Motivations and Deterrents to Blood Donation in the United States

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: A Study of Motivations and Deterrents to Blood Donation in the United States. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* There are serious blood shortages in the U.S. and the situation is predicted to worsen unless corrective measures are initiated. Through a randomized, anonymous mail survey of individuals who have donated blood at one of the five blood centers participating in the NHLBI Retrovirus Donor Study (REDS), this study will examine the personal, or