

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]

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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]

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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

intrinsic reasons for choosing to donate blood, as well as external reasons for choosing to donate blood. Donors who do not initially respond to the mail survey will be given the opportunity to complete the survey on a secured website. Comparisons will be made between one-time donors and repeat donors will be premise that repeat donors may have a stronger altruistic impetus for donating than donors who donate less frequently. Donors will be asked about the donation experience, the context in which he/she first donated blood, and questions addressing accessibility to donate. Using the Self-Report Altruism Scale, respondents will rate themselves based on other personal behaviors that are considered to exhibit social responsibility and/or altruism. Additionally, the study will examine possible barriers to donation, such as inconvenience, discomfort, and confidentiality, among donors who have

not donated recently. With the majority of the blood supply coming from committed, repeat donors, information regarding why an individual decides to donate, and more importantly, what motivates them to come back, will provide valuable insight on possible strategies to encourage increased donation frequency among the current blood donor population. It is also important to gain perspective on why only 50% of first time donors return to donate again. Without successful recruitment of new regular donors it is impossible to sustain the blood supply and availability. Assessment of possible barriers to donation will provide areas for focusing improvement in the blood donation process. Blood availability continues to be one of the most serious problems facing the healthcare industry and was recently compounded by new Food and Drug Administration regulations regarding deferring donors who had traveled to or lived in the

United Kingdom for a cumulative period of 6 months between 1980 and 1996. Data from this survey will provide a valuable perspective for devising strategies to increase blood donation the U.S. These data will be invaluable to NHLBI, FDA, and other government agencies in helping formulate policy for ensuring Americans that safe blood is available when needed. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Adult Blood Donors. The annual reporting burden is as follows: *Estimated Number of Respondents:* 30,000; *Estimated Number of Respondents per Respondent:* 1; *Average Burden Hours Per Response:* 0.25; and *Estimated Total Annual Burden Hours Requested:* 7,500. The annualized cost to respondents is estimated at: \$112,500 (based on \$15 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of respondents per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adult Blood Donors	30,000	1	0.25	7,500

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriated automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before July 30, 2001.

FOR FURTHER INFORMATION CONTRACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. George J. Nemo, Group Leader, Transfusion Medicine,

Scientific Research Group, Division of Blood Diseases and Resources, NHLBI, NIH, Two Rockledge Center, Suite 10042, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892-7950, or call (301) 435-0075, or e-mail your request to: nemog@nih.gov.

Dated: May 17, 2001.

Donald Christoferson,
Executive Officer, NHLBI.
[FR Doc. 01-13344 Filed 5-25-01; 8:45 am]
BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage

for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Ocular Therapeutic Agent Delivery Devices And Methods

Michael R. Robinson (NEI), Karl G. Csaky (NEI), Peng Yuan (NEI), Cynthia Sung (EM), Robert B. Nussenblatt (NEI), Janine A. Smith (NEI)

Serial No. 09/808,149, filed Mar. 15, 2001

Licensing Contact: Dale Berkley; 301/496-7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is directed to ocular implant devices for the delivery of therapeutic agents to the eye in a controlled and sustained manner. Implants suitable for either subconjunctival or intravitreal placement are the subject of the invention. These implants permit