

Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

**Agenda:** On May 19, 2011, the committee will discuss the findings of the Action to Control Cardiovascular Risk in Diabetes-Lipid (ACCORD Lipid) trial as they relate to the efficacy and safety of the approved new drug application (NDA) 22224, TRILIPIX (fenofibric acid) delayed release capsules, manufactured by Abbott Laboratories.

TRILIPIX (fenofibric acid), an active form of fenofibrate, is indicated for use in combination with a 3-hydroxy-3-methyl-glutaryl-coenzyme A reductase inhibitor, commonly referred to as a "statin", to lower high levels of serum triglycerides and raise low levels of high-density lipoprotein cholesterol in patients with mixed dyslipidemia and coronary heart disease (CHD) or CHD risk equivalent who are on optimal statin therapy to achieve their low-density lipoprotein cholesterol goal.

The ACCORD Lipid study was a randomized, double-blind, placebo-controlled add-on trial, which is the kind of clinical trial designed to provide data with strong measures of accuracy and reliability. The ACCORD Lipid study evaluated the efficacy and safety of adding fenofibrate therapy to treatment with the statin, simvastatin in subjects with type 2 diabetes mellitus. The results of the ACCORD Lipid trial indicated that there was no statistically significant difference in the proportion of clinical trial subjects treated with simvastatin plus placebo versus simvastatin plus fenofibrate who experienced a major adverse cardiac event. In a prespecified subgroup analysis from the ACCORD Lipid trial, there was an increase in the proportion of female trial subjects treated with simvastatin plus fenofibrate versus simvastatin plus placebo who experienced a major adverse cardiac event. The clinical significance of this finding is unclear.

An additional safety concern associated with the use of fenofibrate

plus simvastatin, or any other statin, is muscle toxicity.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

**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 on or before May 12, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before May 5, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 6, 2011.

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 Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

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

Dated: April 21, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-10003 Filed 4-25-11; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; DEM Fellowships.

**Date:** June 15-16, 2011.

**Time:** 6 p.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Crowne Plaza Washington National Airport, 1489 Jefferson Davis Hwy, Arlington, VA 22202.

**Contact Person:** Michael W. Edwards, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 750, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8886, [edwardsm@extra.niddk.nih.gov](mailto:edwardsm@extra.niddk.nih.gov).

**Name of Committee:** National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Fellowships in Digestive Diseases and Nutrition

**Date:** June 22, 2011.

**Time:** 8:30 a.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Georgetown Suites, 1000 29th Street, NW, Washington, DC 20007

**Contact Person:** Thomas A. Tatham, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 760, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-3993, [tatham@mail.nih.gov](mailto:tatham@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition

Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: April 20, 2011.

**Anna P. Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-10008 Filed 4-25-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; NIBIB K awards review (1022/10).

*Date:* June 24, 2011.

*Time:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Democracy Two Plaza, 6707 Democracy Boulevard, Suite #242, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Manana Sukhareva, PhD, Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Suite 959, Bethesda, MD 20892, 301-451-3397, [sukharem@mail.nih.gov](mailto:sukharem@mail.nih.gov).

Dated: April 20, 2011.

**Anna P. Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-10009 Filed 4-25-11; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Transportation Security Administration

[Docket No. TSA-2006-24191]

#### Intent To Request Renewal From OMB of One Current Public Collection of Information: Transportation Worker Identification Credential (TWIC) Program

**AGENCY:** Transportation Security Administration, DHS.

**ACTION:** 60 Day Notice.

**SUMMARY:** The Transportation Security Administration (TSA) invites public comment on one currently approved information collection requirement, Office of Management and Budget (OMB) control number 1652-0047, abstracted below that we will submit to OMB for renewal in compliance with the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. OMB approved the collection of information for six months and TSA now seeks the maximum three-year approval. The collection involves the submission of identifying and other information by individuals applying for a TWIC and a customer satisfaction survey.

**DATES:** Send your comments by June 27, 2011.

**ADDRESSES:** Comments may be e-mailed to [TSAPRA@dhs.gov](mailto:TSAPRA@dhs.gov) or delivered to the TSA PRA Officer, Office of Information Technology (OIT), TSA-11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598-6011.

**FOR FURTHER INFORMATION CONTACT:** Joanna Johnson at the above address, or by telephone (571) 227-3651.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at <http://www.reginfo.gov>. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

#### Information Collection Requirement

*OMB Control Number 1652-0047; Transportation Worker Identification Credential (TWIC) Program.* TSA developed the Transportation Worker Identification Credential (TWIC) program to mitigate threats and vulnerabilities in the national transportation system. TWIC is a common credential for all personnel requiring unescorted access to secure areas of facilities and vessels regulated under the Maritime Transportation Security Act (MTSA) and all mariners holding U. S. Coast Guard credentials. Before issuing an individual a TWIC, TSA performs a security threat assessment, which requires TSA to collect certain personal information such as name, address, and date of birth. Applicants are also required to provide fingerprints and undergo a criminal history records check.

The program implements authorities set forth in the Aviation and Transportation Security Act (ATSA) (Pub. L. 107-71; Nov. 19, 2002; sec. 106), the Maritime Transportation Security Act of 2002 (MTSA) (Pub. L. 107-295; Nov. 25, 2002; sec. 102), and the Safe, Accountable, Flexible, Efficient Transportation Equity Act—A Legacy for Users (SAFETEA-LU) (Pub. L. 109-59; Aug. 10, 2005; sec. 7105), codified at 49 U.S.C. 5103a(g). TSA and the U. S. Coast Guard (Coast Guard) issued a joint notice of proposed rulemaking (NPRM) on May 22, 2006, 71 FR 29396. After consideration of public comments on the NPRM, TSA issued a joint final rule with the Coast Guard on January 25, 2007 (72 FR 3492), applicable to the maritime transportation sector that would require this information collection.

TSA collects data from applicants during an optional pre-enrollment step or during the enrollment session at an enrollment center. TSA will use the information collected to conduct a security threat assessment, which includes: (1) A criminal history records check; (2) a check of intelligence databases; and (3) an immigration status check. TSA invites all TWIC applicants to complete an optional survey to gather information on the applicants' overall customer satisfaction with the