

NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods and strategies applicable to the needs of U.S. Federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about ICCVAM and NICEATM can be found on the NICEATM-ICCVAM Web site (<http://iccvam.niehs.nih.gov>).

SACATM was established in response to the ICCVAM Authorization Act [Section 285l-3(d)] and is composed of scientists from the public and private sectors. SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. SACATM

provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at <http://ntp.niehs.nih.gov/go/167>.

Dated: April 18, 2011.

John R. Bucher,
Associate Director, National Toxicology Program.

[FR Doc. 2011-10020 Filed 4-25-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: State Plan for the Temporary Assistance of Needy Families (TANF).

OMB No. 0970-0145.

Description: The State plan is a mandatory statement submitted to the Secretary of the Department of Health and Human Services by the State. It consists of an outline specifying how the State's TANF program will be administered and operated and certain required certifications by the State's Chief Executive Officer. It is used to provide the public with information about the program.

Authority to require States to submit a State TANF plan is contained in section 402 of the Social Security Act, as amended by Public Law 104-193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. States are required to submit new plans periodically (*i.e.*, within a 27-month period).

We are proposing to continue the information collection without change.

Respondents: The 50 States of the United States, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Title Amendments | 18 | 1 | 3 | 54 |
| State Plan | 18 | 1 | 30 | 540 |

Estimated Total Annual Burden Hours: 594.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,
Reports Clearance Officer.

[FR Doc. 2011-9956 Filed 4-25-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Endocrinologic and Metabolic 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: Endocrinologic and Metabolic 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 May 19, 2011, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/ Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel telephone number is 301-589-5200.

Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX 301-847-8533, e-mail: EDMAC@fda.hhs.gov, or FDA Advisory

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]

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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.

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.

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