

3. Demonstrate the availability of adequately trained personnel to support the activities required under this cooperative agreement and agency commitment and support for this project including the development of the RRT.

4. Provide a detailed description of the current food regulatory program including types of inspections performed, and types and numbers of food establishments in the State inventory. Provide an indication of how many of each of these facilities would be covered each year under this agreement.

5. Provide a properly detailed budget (one for each of 3 years) that is intended to develop the RRT and enhance the food protection program in the State. Included will be the previous and current years State funding for the program including program staffing and costs.

6. Demonstrate the ability to satisfy the reporting requirements outlined in section VI.3.A of the full RFA notice.

7. Provide current funding level certification for their food safety program from State funding appropriations.

8. Outline detailed methodology for program assessment improvement or program development to accomplish the work.

9. Provide justification for hiring new staff, hiring qualifications, their training needs and any new equipment.

10. It is noted that the grantee should provide a clearly detailed description on how the State food program will follow procedures for notifying FDA of violative facilities for enforcement under FDA jurisdiction.

C. Dates

The application receipt date is August 15, 2008.

VI. Agency Contacts:

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into two areas: Scientific/research, and financial or grants management issues:

A. Scientific/Research Contacts

Jennifer Gabb, Project Officer, Division of Federal-State Relations (HFC-150), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, rm. 12-07, Rockville, MD 20857, telephone: 301-827-2899, e-mail: Jennifer.gabb@fda.hhs.gov or access the Internet at <http://www.fda.gov/ora/fedState/default.htm>.

B. Financial or Grants Management Contacts

Gladys M. Bohler, Grants Management Specialist, Division of Acquisition Support and Grants, Food and Drug Administration, 5630 Fishers Lane, rm. 2105, Rockville, MD 20857, telephone: 301-827-7168, e-mail: gladys.melendez@fda.hhs.gov.

Dated: June 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-14735 Filed 6-27-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0352]

Prescription Drug User Fee Act IV Information Technology Plan

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the information technology (IT) Plan entitled "Prescription Drug User Fee Act (PDUFA) IV Information Technology Plan" to achieve the objectives defined in the PDUFA Performance Goals. This plan is intended to provide regulated industry and other stakeholders with information on FDA's vision and plan for improving the automation of business processes and maintaining information systems that support the review process of human drug applications.

DATES: Submit written or electronic comments on the plan at any time. These comments will be considered as the agency makes annual adjustments to the plan each fiscal year.

ADDRESSES: Submit written requests for single copies of the IT plan to the Office of the Chief Information Officer (HFA-080), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the IT plan to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the plan.

FOR FURTHER INFORMATION CONTACT:

Suzanne Mitri, Office of the Chief Information Officer, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-255-6700.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the IT plan entitled "Prescription Drug User Fee Act (PDUFA) IV Information Technology Plan." This plan is intended to provide regulated industry and other stakeholders with information on FDA's vision and plan for improving the automation of business processes and maintaining information systems that support the process for the review of human drug applications to achieve the objectives defined in section XIV, Information Technology Goals, of the PDUFA Performance Goals (<http://www.fda.gov/oc/pdufa4/pdufa4goals.html>).

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007, which includes the reauthorization and expansion of PDUFA. The reauthorization of PDUFA will significantly broaden and upgrade the agency's drug safety program, increase resources for review of television drug advertising, and facilitate more efficient development of safe and effective new medications for the American public. The reauthorization also includes IT Goals that are divided into four subsections: Objectives, Communications and Technical Interactions, Standards and IT Plan, and Metrics and Measures. In addition, there are IT Goals associated with the upgrade of the agency's drug safety program in section VIII, Enhancement and Modernization of the FDA Drug Safety System of the PDUFA Performance Goals.

The objectives of the PDUFA IV IT Goals are to move FDA towards the long-term goal of an automated standards-based information technology environment for the exchange, review, and management of information supporting the process for the review of human drug applications throughout the product life cycle. As part of this process, FDA has developed and will periodically update the 5-year IT plan.

II. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic

comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: June 23, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-14744 Filed 6-27-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Mental Health Special Emphasis Panel; Fellowships and Dissertation Grants II.

Date: July 23, 2008.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Marina Broitman, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center,

6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892-9608, 301-402-8152, mbroitma@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: June 23, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-14695 Filed 6-27-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Mental Health Special Emphasis Panel; Community Based Participatory Research.

Date: July 16, 2008.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Aileen Schulte, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892-9608, 301-443-1225, aschulte@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: June 23, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-14697 Filed 6-27-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 General Medical Sciences Special Emphasis Panel; NRSA Institutional Research Training.

Date: July 22, 2008.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Brian R Pike, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892, 301-594-3907, pikbr@mail.nih.gov.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Short Courses in Integrative and Organ Systems Pharmacology.

Date: July 23, 2008.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Lisa Dunbar, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, 301-594-2849, dunbarl@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88,