made on a space available basis at the Bethesda Marriott Pooks Hill (see *Location*).

Registration: You are encouraged to register at your earliest convenience.

A registration fee will be charged to help defray the costs of rental of the meeting spaces, meals and snacks provided, and to cover travel costs incurred by invited speakers, and other costs. The cost of registration is as follows:

One-Day Rates:
Government: $475
Academic: $795
Industry: $895
Two-Day Rates:
Government: $875
Academic: $1,495
Industry: $1,695

Registration fees will be waived for invited speakers and members of the working group. If you need special accommodations due to a disability, please contact Margaret Bogie or Cathleen Michaloski (see *Contact*) at least 7 days in advance of the meeting.

Registration Instructions: For further details on how to register for the public meeting, contact Margaret Bogie or Cathleen Michaloski (see *Contact*).

SUPPLEMENTARY INFORMATION: Insomnia is a common disorder in the United States, yet it remains relatively poorly understood. Questions remain, for example, about the definition of insomnia and the classification of patients with the disorder. A better understanding of insomnia should help lead to safer and more effective treatment. A number of medications have been approved for insomnia, and many experimental medications are currently in development. New concerns have arisen about the most appropriate way to evaluate both the safety and the efficacy of medications for insomnia, particularly given that they may differ in important characteristics, including both pharmacodynamic and pharmacokinetic properties.

DNP and PERI plan for the first day of the meeting to center on issues of efficacy, including the evolving definition of insomnia, the classification of patients with this disorder, and the measurement of clinically relevant outcomes, including the choice of endpoints, subjective versus objective assessments, and duration of effect. The second day of the meeting will center on safety issues of hypnotic drugs, including the nature and prevalence of adverse events (AEs) related to the use of hypnotic drugs and evaluation of these AEs with a concentration on psychovigilance testing and driving-related tests.

Additional information on the conference, program, and registration procedures is available on the Internet at *http://peri.org/course_details.cfm?course=2072*. FDA has verified the PERI Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.

Dated: April 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8285 Filed 4–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0013]

Statement of Organizations, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has reorganized the Center for Drug Evaluation and Research (CDER), Office of Surveillance and Epidemiology (OSE). This reorganization includes the organizations and their substructure components as listed in this document. This reorganization includes the establishment of six Staffs: Executive Operations and Strategic Planning Staff, Regulatory Science Staff, Regulatory Affairs Staff, Program Management and Analysis Staff, Project Management Staff, and Technical Information Staff. It will also include Office of Medication Error Prevention and Risk Management (OMEPRM) and Office of Pharmacovigilance and Epidemiology (OPE) under OSE. OMEPRM will consist of the Division of Risk Management and the Division of Medication Error Prevention and Analysis. OPE will consist of the Division of Epidemiology I and Division of Epidemiology II and the Division of Pharmacovigilance I and Division of Pharmacovigilance II. Also included are the abolishment of Business Process Improvement Staff, Regulatory Policy Staff, and Review Management Staff within OSE Immediate Office.

FOR FURTHER INFORMATION CONTACT: Karen Koenick, Center for Drug Evaluation and Research (HFD–063), Food and Drug Administration, 11919 Rockville Pike, rm. 324, Rockville, MD 20852, 301–796–4422.

I. Summary

The Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970; 60 FR 56605, November 9, 1995; 64 FR 36361, July 6, 1999; and 72 FR 50112, August 30, 2007) is amended to reflect the restructuring of CDER, FDA as follows.

II. Organization

CDER is headed by the Director, and includes the following organizational unit:

Office of Surveillance and Epidemiology

1. Provides leadership, direction, planning, budgeting, management, and supervision of Divisions and Staffs; and premarketing and postmarketing risk assessment program operations.
2. Develops and maintains international and national contact with regulators.
3. Develops, coordinates, and implements postmarket risk assessment policy, guidance, and interpretations.
4. Initiates regulation development and enhancement.
5. Coordinates and implements policies and initiatives, including information management initiatives across the Agency.

Regulatory Science Staff

1. Provides leadership, direction, and coordination for OSE regulatory research activities.
2. Develops and manages relationships with outside scientific groups that interface with OSE scientists on a variety of projects that relate to OSE's drug safety mission. These outside groups include academic organizations, private organizations, and other Federal Agencies.
3. Coordinates the access to large databases for pharmacoepidemiologic and pharmacovigilance studies, as well as to the outside scientists with drug safety expertise to collaborate with CDER.
4. Develops regulatory research programs that will support OSE as a whole, including risk management, pharmacovigilance, and medication error detection and prevention; in addition to epidemiology.

Regulatory Affairs Staff

1. Responsible for the coordination and implementation of regulatory policies by staff within OSE by coordinating the development and upkeep of guidances, MAPPs, and standard operating procedures, answering regulatory questions, managing the process for waivers of

postmarketing safety reporting requirements and citizen petition responses, and being involved in the development of safety regulations.

2. Provides leadership on initiatives related to the Medical Dictionary for Regulatory Activities (MedDRA).

Executive Operations & Strategic Planning Staff

1. Creates and maintains professional and skills training programs for OSE personnel.

2. Plans and tracks goals and objectives of all OSE Offices and Divisions.

3. Evaluates OSE work products and communications using quality control technology.

4. Interacts with Executive Secretariat, Press Office, and etc.

Technical Information Staff

1. Provides coordination, development and assessment of policies, procedures, and best practices related to OSE data and information system management within OSE.

2. Provides representation for OSE on Center and Agency best practices boards associated with staff responsibilities.

3. Represents OSE in Center and Agency boards or workgroups that address business process improvements and information technology related to postmarket drug safety.

4. Ensures that OSE's informatics systems (*e.g.,* Adverse Event Reporting System, Phonetic Orthographic Computer Analysis, and Phonetic Orthographic Computer Analysis) serve OSE's needs.

Program Management and Analysis Staff

1. Provides leadership, direction, planning, budgeting, management, and supervision of programs related to the OSE office administration and contracts management.

2. Provides guidance and support services to the OSE on all aspects of administrative, budget, and facilities management and provides service and support on human resource, personnel operations services, and recruitment activities.

3. Provides management, tracking and facilitation of projects related to office administration and contracts management within OSE.

4. Provides coordination, development, and assessment of policies, procedures, and best practices related to OSE office administration and contract management within OSE.

5. Provides representation for OSE on center and Agency best practices boards associated with staff responsibilities.

Project Management Staff

1. Provides leadership, direction, planning, management, and supervision of programs related to drug safety reviews and staff.

2. Provides management, tracking, and facilitation of projects related to drug safety reviews within OSE.

3. Provides coordination, development, and assessment of policies and procedures related to drug safety reviews, review templates, and other best practices related to drug safety reviews within OSE.

4. Provides representation for OSE on Center best practices associated with staff responsibilities.

Office of Medication Error Prevention and Risk Management

1. Directs and supports the Divisions of Medication Error Prevention and Analysis and Risk Management.

2. Leads OSE review of proposed and implemented Risk Minimization Action Plans (RiskMAPs)/Risk Evaluation and Mitigation Strategies (REMS).

3. Coordinates risk communication components of drug safety risk management programs.

4. Coordinates reviews of proposed proprietary trade names for their potential to result in sound-alike or look-alike medication errors.

5. Performs root-cause analyses of postmarketing medication error reports.

Division of Medication Error Prevention and Analysis

1. Plans, directs, and provides information technology support to the OSE.

2. Develops and maintains necessary software, processes, procedures, training, and security or databases available to OSE.

3. Acts as focal point for all hardware, software, and other information systems issues.

4. In conjunction with the OSE programs, evaluates extant information resources for utility and value to the OSE missions. Arranges for necessary accesses, training, and other needs related to effective use of those resources.

5. Develops and maintains the OSE Center for Drug Evaluation and Research Network (CDERNET) Web pages and works with other Agency programs to develop and maintain Internet pages related to office programs.

6. Serves as the primary OSE contact for World Health Organization (WHO) searches, Freedom of Information (FOI) and National Technical Information Services (NTIS) issues, and for database searches.

7. Reviews proposed proprietary trade names for their potential to result in sound-alike or look-alike medication errors.

8. Analyzes and performs root-cause analyses of postmarketing medication error reports.

9. Develops and implements internal MAPPs and guidance on medication error and patient safety initiatives.

Division of Risk Management

1. Plans and directs all risk management activities in the OSE.

2. Provides risk management expertise to OSE and the center.

3. Reviews all proposed Risk Minimization Action Plans (RiskMAPs) or Risk Management Plans (RMPs) for conformance with FDA's standards.

4. Conducts postmarketing monitoring of all products with approved RiskMAPs.

5. Conducts evaluations of the performance of RiskMAPs.

6. In conjunction with Office of New Drugs (OND), conducts premarketing risk assessments for some products.

7. Helps develop and maintain the Agency's OSE CDERNET RiskMAP Web pages and works with other Agency programs to develop and maintain RiskMAP Internet pages.

8. Develops and implements internal MAPPs and guidance on risk management initiatives.

Office of Pharmacovigilance and Epidemiology

1. Directs and supports the Divisions of Pharmacovigilance and Epidemiology.

2. Evaluates the safety of marketed drugs.

3. Reviews adverse event reports with OND.

4. Collaborates with other offices to recommend appropriate actions.

5. Provides recommendations on risk management programs and REMS.

6. Coordinates the review and analysis of epidemiologic study protocols and results of epidemiologic studies submitted by industry, from the literature or other sources that are related to the postmarketing safety of drugs.

Division of Epidemiology I

1. Provides leadership, direction, planning, budgeting, management, and supervision of Division programs and staff.

2. Reviews and provides analyses of epidemiologic study protocols and results of epidemiologic studies submitted by industry, from the literature or other sources that are related to the postmarketing safety of drugs.

3. Provides development and assessment of methodologies and best practices for active and passive surveillance systems and for incorporating such data, when appropriate, into the review of the postmarketing safety of drugs.

4. Reviews and analyzes drug utilization information.

5. Performs epidemiologic research on drug safety issues.

6. Provides epidemiologic and drug utilization expertise to support medical review divisions in areas of responsibility, as well as, for Advisory Committee presentations and related documents.

7. Provides input on epidemiologic and drug utilization aspects of information for the public related to significant postmarketing safety information regarding drugs, biologics, devices, and foods.

8. Develops and implements internal MAPPs and guidance on epidemiologic and drug utilization initiatives.

Division of Epidemiology II

1. Provides leadership, direction, planning, budgeting, management, and supervision of Division programs and staff.

2. Reviews and analyzes epidemiologic study protocols and results of epidemiologic studies submitted by industry from the literature or other sources that are related to the postmarketing safety of drugs.

3. Provides for the development and assessment of methodologies and best practices for scientifically-sound observational studies related to postmarketing safety of drugs.

4. Reviews and analyzes drug utilization information.

5. Performs epidemiologic research on drug safety issues.

6. Provides epidemiologic and drug utilization expertise to support medical review divisions in areas of responsibility, as well as, for Advisory Committee presentations and related documents.

7. Provides input on epidemiologic and drug utilization aspects of information for the public related to significant postmarketing safety information regarding drugs, biologics, devices, and foods.

8. Develops and implements internal MAPPs and guidance on epidemiologic and drug utilization initiatives.

Division of Pharmacovigilance I

1. Provides leadership, direction, planning, budgeting, management, and supervision of Division programs and staff.

2. Reviews and provides analysis of adverse event reports from industry submissions and from reports submitted directly to FDA related to marketed drugs in order to detect safety signals and evaluate risk; and performs followup when such signals are detected.

3. Provides development and assessments of methodologies and best practices for scientifically-sound safety signal detection and drug risk evaluation related to the postmarketing safety of drugs.

4. Provides safety signal detection and drug risk evaluation support to medical review divisions in areas of responsibility, as well as, for Advisory Committee presentations.

5. Provides recommendations on safety signal detection and drug risk evaluation aspects of proposed and implemented RiskMAPs or RMPs.

6. Provides input on signal detection and drug risk evaluation included in information for the public related to significant safety information regarding drugs, biologics, devices, and foods.

7. Develops and implements internal MAPPs and guidance on safety signal detection and drug risk evaluation initiatives.

Division of Pharmacovigilance II

1. Provides leadership, direction, planning, budgeting, management, and supervision of Division programs and staff.

2. Reviews and provides analyses of adverse event reports from industry submissions and from reports submitted directly to FDA related to marketed drugs in order to detect safety signals and evaluate risk; performs followup when such signals are detected.

3. Provides development and assessment of methodologies and best practices for scientifically-sound safety signal detection and drug risk evaluation related to the postmarketing safety of drugs.

4. Provides safety signal detection and drug risk evaluation support to medical review divisions in areas of responsibility, as well as, for Advisory Committee presentations.

5. Provides recommendations on safety signal detection and drug risk evaluation aspects of proposed and implemented RiskMAPs or RMPs.

6. Provides input on signal detection and drug risk evaluation included in information for the public related to significant safety information regarding drugs, biologics, devices, and foods.

7. Develops and implements internal MAPPs and guidance on safety signal detection and drug risk evaluation initiatives.

III. Delegation of Authority

Pending further delegation, directives or orders by the Commissioner of the Food and Drugs or the Center Director, CDER, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

Dated: April 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8313 Filed 4–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 Environmental Health Sciences Special Emphasis Panel, Baseline Study For Arsenic Exposure.

Date: April 27, 2011.

Time: 1:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709, (Telephone Conference Call).

Contact Person: Sally Eckert-Tilotta, Ph.D., Scientific Review Administrator, Nat. Institute of Environmental Health Sciences, Office of Program Operations, Scientific Review Branch, P.O. Box 12233 MD EC–30, Research Triangle Park, NC 27709, (919) 541–1446, *eckertt1@niehs.nih.gov.*

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, Loan Repayment Program.

Date: May 2, 2011.

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

Agenda: To review and evaluate grant applications.