

disabilities programs, only the PADD program requires an SGP. Following the required public input for the coming fiscal year, the P&As submit the final version of this SGP to the Administration on Developmental Disabilities (ADD). ADD will aggregate the information in the SGPs into a

national profile of programmatic emphasis for P&A Systems in the coming year. This aggregation will provide ADD with a tool for monitoring of the public input requirement. Furthermore, it will provide an overview of program direction, and permit ADD to track accomplishments

against goals/targets, permitting the formulation of technical assistance and compliance with the Government Performance and Results Act of 1993.

*Respondents:* State and Tribal Governments.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
P&A SGP .....	57	1	44	2,508

*Estimated Total Annual Burden Hours:* 2,508.

#### Additional Information

Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. *E-mail address:* [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

#### OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project; *Fax:* 202-395-7245, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: July 7, 2009.

**Janean Chambers,**

*Reports Clearance Officer.*

[FR Doc. E9-16317 Filed 7-9-09; 8:45 am]

**BILLING CODE 4184-01-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. 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 General Medical Sciences Special Emphasis Panel, NIH Pathway to Independence Awards.

*Date:* July 27-28, 2009.

*Time:* 7 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Double Tree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Meredith D. Temple-O'Connor, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12C, Bethesda, MD 20892, 301-594-2772, [templeocm@mail.nih.gov](mailto:templeocm@mail.nih.gov).

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel, Faculty Recruitment—ARRA Funds.

*Date:* July 28-29, 2009.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Double Tree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Rebecca H. Johnson, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18, Bethesda, MD 20892, 301-594-2771, [johnsonrh@nigms.nih.gov](mailto:johnsonrh@nigms.nih.gov).

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel, Faculty Recruitment—ARRA Funds.

*Date:* July 28-29, 2009.

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*Contact Person:* Meredith D. Temple-O'Connor, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12C, Bethesda, MD 20892, 301-594-2772, [templeocm@mail.nih.gov](mailto:templeocm@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, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: July 1, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-16068 Filed 7-9-09; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0295]

#### Providing Effective Information to Consumers About Prescription Drug Risks and Benefits; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER), in collaboration with FDA's Office of the Commissioner (OC), is announcing a public workshop entitled "Providing Effective Information to Consumers About Prescription Drug Risks and Benefits." This public workshop is intended to explore potential approaches that will result in written

prescription drug information for consumers that is comprehensible, accurate, and easy to access.

**DATES:** The public workshop will be held on September 24 and 25, 2009, from 8 a.m. to 5:30 p.m. Written or electronic comments on the posted information or on the workshop must be submitted to the docket by November 25, 2009.

**ADDRESSES:** The public workshop will be held at the Hilton Washington DC/ North Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in the brackets in the heading of this document. A transcript of plenary sessions will be available for review at the Division of Dockets Management and on the Internet at <http://www.regulations.gov> approximately 30 days after the workshop.

**FOR FURTHER INFORMATION CONTACT:**

Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6178, Silver Spring, MD 20993, 301-796-3519, e-mail: [mary.gross@fda.hhs.gov](mailto:mary.gross@fda.hhs.gov); or Marsha Holloman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6173, Silver Spring, MD 20993, 301-796-0731, e-mail: [marsha.holloman@fda.hhs.gov](mailto:marsha.holloman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In order to make informed decisions about health care, patients need to have easy access to up-to-date and accurate information about the risks and benefits of the prescription drugs they take. Currently, consumers are receiving multiple pieces of written information with their prescription drugs from the pharmacy, information that is developed and distributed through various sources. Over the years, FDA has undertaken a number of initiatives in an effort to ensure that consumers receive useful written information when they obtain their prescription medicines from the pharmacy. The following is a short description of both required and voluntary patient labeling.

Since 1968, FDA regulations have required that patient package inserts (PPIs), written specifically for patients, be distributed to patients when certain prescription drugs, or classes of prescription drugs are dispensed (§ 310.501 (21 CFR 310.501) and

§ 310.515 (21 CFR 310.515)). PPIs for estrogens (§ 310.515) and oral contraceptives (§ 310.501) are FDA-approved and are considered part of the product labeling. They must be given to the patient when the product is dispensed. Other PPIs are submitted to FDA voluntarily by manufacturers and approved by FDA, but their distribution is not mandated by regulation. For example, many PPIs have been submitted to the agency for review in response to the FDA draft guidance entitled "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements" issued in April 2001. Under the Food and Drug Administration Amendments Act (FDAAA), FDA can require a PPI as part of a risk evaluation and mitigation strategy (REMS).

Medication Guides are patient labeling (21 CFR part 208) and accompany those drugs deemed by the agency to have serious and significant risks. Medication Guides address issues that are specific to particular drugs or in some cases, drug classes, and they contain FDA-approved information that can help patients avoid serious adverse reactions. Medication Guides are developed by manufacturers and reviewed by FDA and they are required to be distributed by pharmacies with each prescription. In the **Federal Register** of August 24, 1995 (60 FR 44182), FDA published a proposed rule entitled "Prescription Drug Product Labeling: Medication Guide Requirements." In the **Federal Register** of December 1, 1998 (63 FR 66378), the final rule with the same title was published. On June 12 and 13, 2007, a public meeting entitled "Use of Medication Guides to Distribute Drug Risk Information to Patients" was held. The public testified that the Medication Guide distribution process needed improvement including providing a means for electronic printing, waiving certain format requirements and ensuring that a complete list of Medication Guides were posted in a central location on the Web. Some expressed the view that Medication Guides should be shorter and easier to read. Finally, comments indicated that the sources of patient information should be consolidated into a single document.

In September 2007, Congress amended the Federal Food, Drug, and Cosmetic Act and included Medication Guides as one potential element of a REMS. FDA may require a sponsor to develop a REMS if it determines a REMS is necessary to ensure that the benefits of a drug outweigh the risks. Between September 2007 when FDAAA

was enacted and May 31, 2009, FDA has approved 50 REMS with Medication Guides, including 43 REMS that consisted only of a Medication Guide and a timetable for assessment of the REMS. The use of Medication Guides as part of REMS, particularly as part of REMS that affect whole classes of drugs, has provided further impetus to evaluate different approaches to providing the type of prescription drug information that is normally provided in a Medication Guide to consumers.

Consumer Medication Information (CMI) is based on Public Law 104-180. Under Public Law 104-180, prescription drug information is developed and distributed by the private sector and the development of this information is voluntary. Public Law 104-180 adopted certain goals and timeframes consistent with FDA's proposed rule (60 FR 44182) which were:

- By the year 2000, 75 percent of people receiving new prescriptions would receive "useful" patient information with their prescriptions; and
- By the year 2006, 95 percent of people receiving new prescriptions would receive "useful" written patient information with their prescriptions.

FDA was charged with evaluating the private sector's progress in meeting these goals and to establish guidelines for usefulness criteria. By passing this legislation, FDA was also enjoined from further rulemaking that would require patient information for all prescription drugs, so long as these goals were met within specified timeframes.

CMI has failed to meet the statutory goals based on two independent evaluations performed in 2001 and 2008. In the 2001 evaluation, 89 percent of patients received some form of information, with 50 percent of this information determined to be useful. On July 6, 2006, FDA issued a guidance entitled "Useful Written Consumer Medication Information (CMI)." The second CMI evaluation, conducted in 2008, found that patients received information 94 percent of the time, but only 75 percent of that information was deemed useful, missing the goal set out in Public Law 104-180 that 95 percent of consumers would receive useful prescription drug information by 2006.

With a CMI effort that does not meet Congressional goals and reports indicating that many patients may not be understanding (or even receiving) Medication Guides from the pharmacy, FDA is reexamining the current process whereby prescription drug information is developed and disseminated to patients.

By September 21, 2009, FDA will post the following information:

- Workshop agenda;
- FDA Issues Paper that describes past history, current challenges, and possible approaches to improve the current system;
- A series of prototypes that explore different written approaches to conveying prescription drug information to consumers; and
- A list of FDA speakers, invited workshop participants, and meeting registrants.

This public workshop is intended to explore potential approaches that will result in written prescription drug information that is comprehensible, accurate, and more easily accessible to consumers. The purpose of this public workshop is to assemble stakeholder groups to determine appropriate steps towards improving the content, format, distribution, and evaluation of patient information.

**Registration:** To register for the meeting either: (1) Mail your registration information to one of the contact persons (see **FOR FURTHER INFORMATION CONTACT**) or (2) e-mail your registration information to [PatientInfoPublicWkshp@fda.hhs.gov](mailto:PatientInfoPublicWkshp@fda.hhs.gov). Registration information should include registrant name, company or organization, address, phone number, and e-address. Registration requests should be received by August 17, 2009. Registration is free. Seats are limited. FDA may limit the numbers of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted for participation in the workshop. Onsite registration on the day of the meeting will be based on space availability on the day of the event starting at 7:30 a.m. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop at <http://www.fda.gov/Drugs/NewsEvents/ucm168106.htm>. If you need special accommodations due to a disability, please contact Mary Gross or Marsha Holloman (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Dated: July 2, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9-16335 Filed 7-9-09; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Drug Abuse; 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 on Drug Abuse Special Emphasis Panel, NIDA ARRA Go Applications on Genetics, Harmonizing Phenotypes and Envirotypes, Epigenetics and Pharmacogenomics.

**Date:** July 16, 2009.

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

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

**Place:** Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

**Contact Person:** Gerald L. McLaughlin, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Blvd., Bethesda, MD 20892-8401, 301-402-6626, [gm145a@nih.gov](mailto:gm145a@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

**Name of Committee:** National Institute on Drug Abuse Special Emphasis Panel, ARRA GO Criminal Justice Grant Application Review.

**Date:** July 23, 2009.

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

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

**Place:** Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

**Contact Person:** Gerald L. McLaughlin, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Blvd., Bethesda, MD 20892-8401, 301-402-6626, [gm145a@nih.gov](mailto:gm145a@nih.gov).

**Name of Committee:** National Institute on Drug Abuse Special Emphasis Panel, ARRA GO CTN-Based Grant Application Review.

**Date:** July 27, 2009.

**Time:** 9 a.m. to 5 p.m.

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

**Place:** National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852.

**Contact Person:** Mark R. Green, PhD, Deputy Director, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892-8401, (301) 435-1431, [mgreen1@nida.nih.gov](mailto:mgreen1@nida.nih.gov).

**Name of Committee:** National Institute on Drug Abuse Special Emphasis Panel, ARRA GO Small Molecule and Vaccine Medications.

**Date:** July 28, 2009.

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

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

**Place:** Sofitel Washington DC, Lafayette Hotel, 806 15th Street, NW., Washington, DC 20005.

**Contact Person:** Jose F Ruiz, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, 6101 Executive Blvd., Rm. 213, MSC 8401, Bethesda, MD 20892, 301-451-3086, [ruizjf@nida.nih.gov](mailto:ruizjf@nida.nih.gov).

**Name of Committee:** National Institute on Drug Abuse Special Emphasis Panel, NIDA Conference Grant Application Review.

**Date:** July 30, 2009.

**Time:** 10 a.m. to 1 p.m.

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

**Place:** National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

**Contact Person:** Mark R. Green, PhD, Deputy Director, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892-8401, (301)435-1431, [mgreen1@nida.nih.gov](mailto:mgreen1@nida.nih.gov).

**Name of Committee:** National Institute on Drug Abuse Special Emphasis Panel, ARRA Grand Opportunities: Prevention Infrastructure.

**Date:** August 4, 2009.

**Time:** 9 a.m. to 5 p.m.

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

**Place:** The Dupont Hotel, 1500 New Hampshire Avenue, NW., Washington, DC 20036.

**Contact Person:** Nadine Rogers, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892-8401, 301-402-2105, [rogersn2@nida.nih.gov](mailto:rogersn2@nida.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 91279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: July 1, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-16067 Filed 7-9-09; 8:45 am]

**BILLING CODE 4140-01-M**