

**Xenobiotic and Nutrient Disposition and Action Study Section.**

*Date:* October 6, 2010.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Patricia Greenwel, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2172, MSC 7818, Bethesda, MD 20892. 301-435-1169. [greenwel@csr.nih.gov](mailto:greenwel@csr.nih.gov).

*Name of Committee:* Cardiovascular and Respiratory Sciences Integrated Review Group, Myocardial Ischemia and Metabolism Study Section.

*Date:* October 6–7, 2010.

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

*Agenda:* To review and evaluate grant applications.

*Place:* The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

*Contact Person:* Joseph Thomas Peterson, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892. 301-443-8130. [petersonjt@csr.nih.gov](mailto:petersonjt@csr.nih.gov).

*Name of Committee:* Bioengineering Sciences & Technologies Integrated Review Group, Gene and Drug Delivery Systems Study Section.

*Date:* October 6–7, 2010.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

*Contact Person:* Amy L Rubinstein, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5152, MSC 7844, Bethesda, MD 20892. 301-408-9754. [rubinsteinal@csr.nih.gov](mailto:rubinsteinal@csr.nih.gov).

*Name of Committee:* Cell Biology Integrated Review Group, Molecular and Integrative Signal Transduction Study Section.

*Date:* October 6–7, 2010.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Sir Francis Drake Hotel, 450 Powell Street at Sutter, San Francisco, CA 94102.

*Contact Person:* Raya Mandler, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5134, MSC 7840, Bethesda, MD 20892. (301) 402-8228. [rayam@csr.nih.gov](mailto:rayam@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Small Business: Neuroscience Education.

*Date:* October 6–7, 2010.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting.)

*Contact Person:* Jonathan Arias, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892. 301-435-2406. [ariasj@csr.nih.gov](mailto:ariasj@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 23, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Molecular Genetics B Study Section, October 3, 2010, 7 p.m. to October 4, 2010, 8 a.m., The Fairmont Hotel, 950 Mason Street, San Francisco, CA 94108 which was published in the **Federal Register** on August 19, 2010, 75 FR 51277–51278.

The meeting will be held October 4, 2010, 7 p.m. to October 5, 2010, 6 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: August 19, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0437]

#### Development and Distribution of Patient Medication Information for Prescription Drugs; Public Hearing

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

**ACTION:** Notice of public hearing; request for comment.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a 2-day public hearing to obtain input on a new framework for development and distribution of patient medication information (PMI) to be provided to patients who are prescribed drug products. Under the current system, patients may receive several different

types of information, developed by different sources that may be duplicative, incomplete, or difficult to read and understand. FDA has determined that the current system is not adequate to ensure that patients receive the essential medication information that is needed to use the drug safely. Based on recommendations from FDA's Risk Communication Advisory Committee (RCAC) and other stakeholder input, FDA sees merit in adopting use of a single document that is standardized with respect to content and format. The purpose of this hearing is to solicit public input on processes and procedures for standardizing PMI using a quality system approach for monitoring development and distribution of PMI.

**DATES:** The public hearing will be held on September 27 and 28, 2010, from 8:30 a.m. to 4:30 p.m. Registration requests and requests to present at the public hearing should be received by September 13, 2010 (see section III of this document for details). Electronic or written comments will be accepted after the public hearing until October 29, 2010 (see section V of this document for details).

**ADDRESSES:** The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20993. To register for the public hearing, email your registration information to [PMIpublicmeeting@fda.hhs.gov](mailto:PMIpublicmeeting@fda.hhs.gov). See section III of this document for registration details. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Denise Hinton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6348, Silver Spring, MD 20993, 301-796-1090, FAX: 301-847-3529, email: [PMIpublicmeeting@fda.hhs.gov](mailto:PMIpublicmeeting@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Ensuring that patients who are prescribed medical products have access to quality information about those products is an important component of medical product safety. Currently, patients receive multiple types of written prescription drug information in varying formats, which