

Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007." The draft guidance, when finalized, will assist the industry in complying with the Reportable Food Registry requirements prescribed by the Food and Drug Administration Amendments Act of 2007 (FDAAA). FDA is also announcing a further delay in the implementation of the Reportable Food Registry (the Registry) of FDAAA until September 8, 2009, to consider any comments received on the draft guidance and through the agency's planned outreach initiatives, and to allow for further testing of the electronic portal for reportable foods.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on the draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by July 27, 2009.

**ADDRESSES:** Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written requests for single copies of the draft guidance to the Office of Food Defense, Communication and Emergency Response, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Faye Feldstein, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2428.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance entitled "Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007." The draft guidance is intended to assist those parties responsible for complying with the Reportable Food Registry requirements prescribed by FDAAA.

FDA is issuing this draft guidance as a level 1 draft guidance consistent with

FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### **II. Notice of Further Delay in Implementation**

On September 27, 2007, the President signed FDAAA into law (Public Law 110-85). Section 1005 of FDAAA amends the Federal Food, Drug, and Cosmetic Act (the act) by creating a new section 417 (21 U.S.C. 350f), among other things. Section 417 of the act requires the Secretary of Health and Human Services to establish within FDA a Reportable Food Registry (the Registry); the Registry is to be established not later than 1 year after the date of enactment (i.e., by September 27, 2008).

To further the development of the Registry, section 417 of the act requires FDA to establish, also within 1 year after the date of enactment (i.e., by September 27, 2008), an electronic portal (the Reportable Food electronic portal) by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials.

FDA made the decision that the most efficient and cost effective means to implement the requirements of section 417 of the act relating to the Registry was to utilize the business enterprise system currently under development within the agency: the MedWatch<sup>Plus</sup> Portal. This would permit the agency to establish an electronic portal through which instances of reportable food may be submitted to the agency. However, FDA recognized that the MedWatch<sup>Plus</sup> Portal would not be implemented in time to meet the September 27, 2008, deadline for establishing the Reportable Food electronic portal and therefore announced that it was delaying its implementation until spring 2009 (73 FR 30405; May 27, 2008).

The agency now expects the system to be operational on September 8, 2009, and is therefore announcing that the implementation of the requirements of section 417 of the act will be further delayed until September 8, 2009.

In the interim, FDA strongly encourages persons to continue to report instances of adulterated food through existing mechanisms, such as notifying the relevant FDA District office, until such time as the Registry and its

associated electronic portal are fully implemented.

##### **III. Paperwork Reduction Act of 1995**

This draft guidance document contains a collection of information that requires clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. FDA intends to submit the collection of information to OMB in the near future for emergency processing. At that time, the agency will publish a notice in the **Federal Register** soliciting comments on the collection of information.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in question 28 of the guidance have been approved under OMB control no. 0910-0249.

##### **IV. 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.

##### **V. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/default.htm> or <http://www.regulations.gov>.

Dated: June 5, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9-13614 Filed 6-10-09; 8:45 am]

**BILLING CODE 4160-01-S**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Centers for Disease Control and Prevention**

##### **Draft Guideline for Prevention of Catheter-Associated Urinary Tract Infections 2008 [Correction]**

The notice "Draft Guideline for Prevention of Catheter-Associated Urinary Tract Infections 2008," was published in the **Federal Register** on June 3rd, 2009, (Vol. 74 FR No. 105).

This notice is corrected as follows: On page 26704 first column, under **SUMMARY**, the Web site should read: <http://wwwn.cdc.gov/publiccomments/>.

Dated: June 4, 2009.

**James D. Seligman,**

*Chief Information Officer, Centers for Disease Control and Prevention.*

[FR Doc. E9-13694 Filed 6-10-09; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; Notice of Closed Meeting

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 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 General Medical Sciences; Initial Review Group Minority Programs Review, Subcommittee B.

*Date:* July 9-10, 2009.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 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 3AN18C, Bethesda, MD 20892. 301-594-2771. [Johnsonrh@nigms.nih.gov](mailto:Johnsonrh@nigms.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, National Institutes of Health, HHS)

Dated: June 4, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-13757 Filed 6-10-09; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; Notice of Closed Meeting

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 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 General Medical Sciences Special Emphasis Panel; MBRS SCORE.

*Date:* July 9, 2009.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, Room 3AN12, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call)

*Contact Person:* Arthur L. Zachary, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN-12, Bethesda, MD 20892, (301) 594-2886, [zacharya@nigms.nih.gov](mailto:zacharya@nigms.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, National Institutes of Health, HHS)

Dated: June 4, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-13758 Filed 6-10-09; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, Coordinating Center for Health Promotion (BSC, CCHP)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

*Time and Date:* 8:30 a.m.-5 p.m., July 1, 2009.

*Place:* CDC, 1825 Century Boulevard, NE., Room 1042, Atlanta, Georgia 30345.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

*Purpose:* This BSC is charged with providing advice and guidance to the Secretary of Health and Human Services, the Director of CDC, and the Director of CCHP concerning strategies and goals for the programs and research within the National Center on Birth Defects and Developmental Disabilities and the National Center for Chronic Disease Prevention and Health Promotion.

*Matters To Be Discussed:* The agenda will include a review and discussion of charges to the BSC Work Groups. The Work Group projects include strategic planning and procedures for future external peer review of programs in the National Center on Birth Defects and Developmental Disabilities, and the National Center for Chronic Disease Prevention and Health Promotion. The BSC will also discuss results of its review of the National Center for Chronic Disease Prevention and Health Promotion as an organizational unit at CDC.

*Providing Oral or Written Comments:* It is the policy of the BSC, CCHP to provide a brief period for oral public comments. In general, each individual or group requesting to make an oral presentation will be limited to a total time of five minutes if time permits.

*Contact Person for Additional Information:* Karen Steinberg, PhD, Senior Science Officer, Coordinating Center for Health Promotion, CDC, 4770 Buford Highway, NE., Mailstop E-70, Atlanta, Georgia 30341; telephone (404) 498-6700; fax (404) 498-6880; or via e-mail at [Karen.Steinberg@cdc.hhs.gov](mailto:Karen.Steinberg@cdc.hhs.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 4, 2009.

**Lorenzo Falgiano,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E9-13692 Filed 6-10-09; 8:45 am]

**BILLING CODE 4163-18-P**