

NIDCD, NIH, Executive Plaza South, Room 400C, 6120 Executive Blvd., Bethesda, MD 20892-7180, 301-496-8693, [jordanc@nidcd.nih.gov](mailto:jordanc@nidcd.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles, will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://www.nidcd.nih.gov/about/groups/ndcdac/>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: August 4, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-19092 Filed 8-10-09; 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; ARRA Funds—ZGM1—GDB-0—FR.

*Date:* August 18, 2009.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, Room 3AN18, 45 Center

Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Margaret J. Weidman, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18B, Bethesda, MD 20892, 301-594-3663.

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.

(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: August 4, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-19089 Filed 8-10-09; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

*Date:* September 16, 2009.

*Open:* 8:30 a.m. to 12 p.m.

*Agenda:* To discuss administrative details relating to the Council's business and special Reports.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

*Closed:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

*Contact Person:* Susana Serrate-Sztein, MD, Director, Division of Skin and Rheumatic Diseases, NIAMS/NIH, 6701 Democracy Blvd., Suite 800, Bethesda, MD 20892-4872, (301) 594-5032. [szteins@mail.nih.gov](mailto:szteins@mail.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: August 4, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-19219 Filed 8-10-09; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2009-N-0335]

**Review of Post-Inspection Responses**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a program to support public health protection by facilitating the timely issuance of warning letters. The program establishes a timeframe for the submission and agency review of post-inspection responses to inspectional

observations that are communicated to a firm through issuance of a form FDA 483, list of inspectional observations.

**DATES:** The program will begin on September 15, 2009.

**FOR FURTHER INFORMATION CONTACT:**

Karen Stutsman, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-632-6860.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA issues a form FDA 483, Inspectional Observations, upon completion of an inspection, to notify an inspected establishment's top management of objectionable conditions relating to products and/or processes, or other violations of the Federal Food, Drug, and Cosmetic Act and related acts, that were observed during the inspection.

The FDA 483 form includes this preprinted instruction: "This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations; and do not represent a final agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address [on the form]."

When FDA determines, based on the inspection, that the establishment is in violation of the Federal Food, Drug, and Cosmetic Act or another statute that we enforce, we may issue a warning letter. Warning letters are issued only for significant violations that may lead to enforcement action if they are not promptly and adequately corrected. The decision to issue a warning letter is made by senior officials within FDA, often including the product center, after a thorough review of all of the relevant facts.

It is not uncommon for an inspected establishment to respond in writing to observations made on an FDA 483 to describe completed or ongoing corrective actions or to promise future corrections. In fact, some inspected establishments submit multiple responses to FDA, sometimes over many months. Delayed and multiple responses to an FDA 483 have resulted in delays in the issuance of warning letters while these responses are reviewed and addressed. FDA's timely

issuance of a warning letter should help to achieve prompt voluntary compliance and is therefore in the public interest.

While FDA considers corrective actions, and other factors, in determining whether to issue a warning letter, ongoing or promised corrective actions generally do not preclude the issuance of a warning letter. A warning letter is an important means of notifying regulated industry of violations and achieving prompt voluntary correction. Warning letters serve to ensure that the seriousness and scope of the violations are understood by top management of the inspected establishment, and that the appropriate resources are allocated to fully correct the violations and to prevent their recurrence. FDA is initiating a program to establish a timeframe for the submission of such post-inspection responses to FDA 483 inspectional observations for FDA's consideration in deciding whether to issue a warning letter. Under the program (described in more detail later in this document), the agency will not ordinarily delay the issuance of a warning letter in order to review a response to an FDA 483 that is received more than 15 business days after the FDA 483 was issued.

The purpose of this program is to optimize resource utilization, facilitate the timely issuance of warning letters, and promote prompt correction of violations. FDA will use the information from the program to determine whether to make the program permanent. FDA will conduct an assessment of the program after approximately 18 months.

**II. Program Description**

Under the program, before issuing a warning letter, FDA will generally allow firms 15 business days to provide a response to FDA 483 observations. If we receive a response to FDA 483 observations within 15 business days after the FDA 483 was issued, we plan to conduct a detailed review of the response before determining whether to issue a warning letter. If we issue a warning letter after reviewing a firm's timely response, the warning letter will recognize receipt of the response and reply as to the apparent adequacy of the firm's corrective actions set forth in the response. Additional correspondence from FDA may be issued with regard to the response, if needed.

If we receive a response to FDA 483 observations more than 15 business days after the FDA 483 was issued, we do not plan to routinely include a response on the apparent adequacy of the firm's corrective actions in the warning letter. Rather, we plan to evaluate the response along with any

other written material provided as the direct response to the warning letter (a firm's response to a warning letter may reference any of the firm's earlier responses).

Note that FDA, at its discretion, may issue Warning Letters at any time, independent of receiving a response; and that firms are expected to implement needed corrections to conform to the requirements of the Federal Food, Drug, and Cosmetic Act and associated regulations regardless of whether they respond in writing to FDA or whether such a response is reviewed by FDA.

After the 18-month time period, FDA will evaluate this program and decide whether to continue it with or without adjustments.

Dated: August 4, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9-19107 Filed 8-10-09; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

[Docket ID FEMA-2009-0001]

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice; 60-day notice and request for comments; revision of a currently approved information collection; OMB No. 1660-0099; FEMA Form 646-0, Citizen Corps Individual Registration.

**SUMMARY:** The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this Notice seeks comments concerning the online registration process for Citizen Corps Individual Registration.

**DATES:** Comments must be submitted on or before October 13, 2009.

**ADDRESSES:** To avoid duplicate submissions to the docket, please use only one of the following means to submit comments: