SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for small business entities entitled ''Toll-Free Number Labeling and Related Requirements for Over-the-Counter and Prescription Drugs Marketed With Approved Applications; Small Entity Compliance Guide.''

This guidance summarizes the final rule published in the **Federal Register** of October 28, 2008 (73 FR 63886), which requires the labeling of each human drug product for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include: (1) The toll-free number maintained by FDA for the purpose of receiving reports of adverse events regarding drugs and (2) a statement that the number is to be used for reporting purposes only, and not to receive medical advice. The final rule requires that the toll-free number and reporting information be:

- Included in all FDA-approved Medication Guides for products approved under section 505,
- Provided to patients by authorized dispensers or pharmacies with each prescription drug product approved under section 505, and
- Included in the labeling of certain over-the-counter drugs approved under section 505.

FDA has previously issued a guidance for industry entitled ''Medication Guides—Adding a Toll-Free Number for Reporting Adverse Events'' (June 2009) to assist new drug application holders with revising FDA-approved Medication Guides to comply with the first of these requirements. This guidance is intended to assist small businesses and others with implementing the two other requirements in the final rule: Distribution of the toll-free number information to patients with each prescription (or refill) and adding the toll-free number information to the labeling of certain OTC drugs.

FDA is issuing this small entity compliance guide as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on side effects statement requirements as set forth in the final rule. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14632 Filed 6–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 materials, 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 Neurological Disorders and Stroke Special Emphasis Panel; Center Core Grants.

Date: June 28, 2012.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Churchill Hotel, 1914 Connecticut Avenue NW., Washington, DC 20009.

Contact Person: Richard D. Crosland, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892, 301–594–0635, *Rc218u@nih.gov.*

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

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: June 8, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–14605 Filed 6–14–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: AIDS and Related Research Integrated Review Group; AIDS-associated Opportunistic Infections and Cancer Study Section.

Date: July 10, 2012.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Eduardo A Montalvo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435–1168, *montalve@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Oral Biology and Craniofacial Development.

Date: July 10, 2012.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Rajiv Kumar, Ph.D., Chief, MOSS IRG, Center for Scientific Review,