DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel, Member Conflict: AARR.

Date: April 23–24, 2010.

Time: 9 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: Robert Freund, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3200, MSC 7848, Bethesda, MD 20892, 301–435–1050. *freundr@csr.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.

(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: April 6, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–8246 Filed 4–9–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0168]

Developing Guidance on Naming, Labeling, and Packaging Practices to Reduce Medication Errors; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled "Developing Guidance on Naming, Labeling, and Packaging Practices to Reduce Medication Errors." The purpose of the public workshop is to initiate constructive dialogue and information sharing among regulators, researchers, the pharmaceutical industry, health care organizations, health care professionals, and others from the general public about the design of drug and therapeutic biologic container labels, carton labeling, and product packaging, and practices to develop proprietary names to reduce medication errors. The input from this workshop will be used to develop draft guidance for industry on practices for naming, labeling, and packaging of drugs and biologics to reduce the potential for medication errors. FDA is also opening a public docket to receive comments on this topic to assist in the development of draft guidance.

DATES AND TIME: The public workshop will be held on Thursday and Friday, June 24 and 25, 2010, from 8:30 a.m. to 5 p.m. each day. Register to make a presentation at the workshop by May 25, 2010. See section IV of this document for information on how to attend or present at the meeting. Submit written or electronic comments to the docket by July 23, 2010, to receive consideration.

ADDRESSES: The public workshop will be held at the Marriott Residence Inn at 7335 Wisconsin Ave., Bethesda, MD 20814. Submit electronic requests to register and make a presentation to *GNLP.meeting@fda.hhs.gov*. Submit written requests to register and make a presentation to Colleen O'Malley (see **FOR FURTHER INFORMATION CONTACT**).

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Colleen O'Malley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4305, Silver Spring, MD 20993, 301–796–1786, FAX: 301–796–9832, email: *colleen.omalley@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In title I of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85), Congress reauthorized and expanded the Prescription Drug User Fee Act program for fiscal years (FYs) 2008 through 2012 (PDUFA IV). As part of the performance goals and procedures set forth in an enclosure to the letter from the Secretary of the Health and Human Services referred to in section 101(c) of FDAAA, FDA committed to certain performance goals and procedures. (See *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm*). In that letter, FDA stated that it would use fees collected under PDUFA to implement various measures to reduce medication errors related to look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose designations, and error-prone label and packaging designs. Among these measures, FDA agreed that by the end of FY 2010, after public consultation with academia, industry, and others from the general public, the agency would publish a draft guidance describing practices for naming, labeling, and packaging drugs and biologics to reduce medication errors.

II. Workshop Objectives and Issues for Discussion

This workshop represents the first step in meeting the PDUFA goal described previously and is intended to provide valuable information to assist the agency in developing draft guidance for industry on practices to reduce medication errors. The workshop will not discuss the ongoing FDA pilot program to evaluate proposed proprietary name submissions. Persons seeking more information on the pilot program should refer to the FDA concept paper entitled "PDUFA Pilot Project Proprietary Name Review" at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidance/ucm072229.pdf* and the **Federal Register** notice entitled "Pilot Program to Evaluate Proposed Proprietary Name Submissions; Procedures to Register for Participation and Submit Data" (74 FR 50806, October 1, 2009) announcing procedures for participation in the voluntary pilot program.

The workshop objectives are as follows: (1) Initiate constructive dialogue and information sharing among regulators, researchers, the pharmaceutical industry, health care organizations, health care professionals, and others from the general public about the design of drug and therapeutic biologic container labels, carton labeling, and product packaging, and practices in developing proprietary