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]

BILLING CODE 4140–01–P

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

names to reduce medication errors; (2) share current FDA experience regarding the evaluation of labels, packaging, and proprietary names; and (3) obtain input on developing consistent review criteria for FDA to use in evaluating container labels, carton labeling, and product packaging submitted to the agency. FDA will use information from the workshop to help develop a draft guidance for manufacturers and distributors for creating product names and designing product labels and packaging to reduce medication errors.

Four panel discussions will focus on areas in which the agency requests input.

Panel 1 will focus on characteristics of container label and carton labeling design as they relate to reducing the risk of medication errors. Topics with respect to container label and carton labeling design include content, format, type of label, layout, use of color, use of graphics, and costs associated with designing labels.

Panel 1 will address the following questions:

1. What does FDA need to consider to ensure that the container labels and carton labeling designs are safe and reduce the risk of medication errors?

2. What are the challenges in designing container label and carton labeling to reduce the risk of medication errors?

3. What are some strategies for addressing these design challenges without compromising safety?

Panel 2 will focus on characteristics related to study design, conduct and interpretation of human factors analysis, Failure Mode and Effects Analysis (FMEA), usability studies, and other studies specifically focused on evaluating the safety of container label and carton labeling designs to reduce the risk of medication errors. Topics include methodology, selection of participants and subjects, collection of data, analysis of data, costs and time to conduct such studies, and interpretation of study findings.

Panel 2 will address the following questions:

1. What are the strengths and limitations of performing such studies?

2. Are there other types of studies and analyses that provide useful information about the medication error risks associated with the container label or carton labeling design?

3. How can FDA ensure that the study design accurately captures and assesses potential medication error risks that should be considered in our evaluation of the container labels and carton labeling?

Panel 3 will focus on characteristics of the manufacturers' packaging used for medications as they relate to the safe use of the medicine from a medication errors perspective. Topics include medication error considerations when designing a container-closure system for a medication, drug-device combination packaging, studies and analyses to evaluate the safety of product packaging design, and costs associated with designing product packaging.

Panel 3 will address the following questions:

1. What information does FDA need to consider to ensure that the manufacturers' packaging design is safe and reduces the risk for medication errors?

2. What are the challenges in designing manufacturers' packaging to reduce the risk of medication errors?

3. What are some strategies for addressing these challenges without compromising safety?

4. How can FDA ensure that the study design accurately captures and assesses potential medication error risks that should be considered in our evaluation of a proposed manufacturers' packaging design for a particular medication?

5. Are there other types of studies and analyses that provide useful information about the medication error risks associated with the manufacturers' packaging design?

Panel 4 will focus on recommended practices in developing proprietary names as they relate to reducing medication errors. Topics include choosing a nomenclature strategy for new products containing the same active ingredient as marketed products; selection and application of modifiers to proprietary names; and medication error potential from use of the same proprietary name as a component of the proprietary names for multiple products containing different active ingredients; U.S. Adopted Names (USAN) Council Stems; medical abbreviations; encoding dosage forms or dosing intervals; and including the established name or ingredients within the proprietary name.

Panel 4 will address the following questions:

1. What are the challenges in developing a proprietary name from a safety perspective to prevent medication errors?

2. What are some strategies for addressing these challenges without compromising safety?

3. When products are developed containing the same ingredient as a marketed product, how can risks associated with a given nomenclature strategy for the proposed product be evaluated, minimized, and mitigated (e.g., use of a modifier "Proprietary XL" versus the use of an alternate proprietary name)?

III. Comments

Regardless of attendance at the public workshop, interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). 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.

IV. Attendance and Registration

There is no fee to attend the workshop, and attendees who do not wish to make a formal presentation do not need to register. Seating will be on a first-come, first-served basis.

If you would like to make an oral presentation to the panelists during the meeting, you must register by mail or email (see **ADDRESSES**) and provide an abstract of your presentation by 5 p.m. on May 25, 2010. You must also provide your name, title, business affiliation (if applicable), address, telephone and fax numbers, and e-mail address. Identify the panel number and question number(s) you will address in your presentation.

FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Persons registered to make a formal presentation should check in before the workshop. Ample time will be allowed during the scheduled agenda for attendees who have not registered to ask questions of the panelists. In addition, we strongly encourage written comments to the docket.

If you need special accommodations because of disability, please contact Colleen O'Malley (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the workshop.

V. Transcripts

Please be advised that as soon as a transcript of the workshop is available, it will accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management

(see **ADDRESSES**). A transcript will also be made available in either hard copy or on a CD–ROM upon submission of a Freedom of Information request. Written requests are to be sent to Freedom of Information (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: March 31, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–8233 Filed 4–9–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2010–0020]

Homeland Security Science and Technology Advisory Committee

AGENCY: Science and Technology Directorate, DHS.

ACTION: Committee Management; notice of closed Federal Advisory Committee meeting

SUMMARY: The Homeland Security Science and Technology Advisory Committee will meet April 20–22, 2010 at the National Biodefense Analysis and Countermeasures Center, 110 Thomas Johnson Drive, Suite 400, Frederick, MD. This meeting will be closed to the public.

DATES: The Homeland Security Science and Technology Advisory Committee will meet April 20, 2010 from 8:30 a.m. to 5 p.m., April 21, 2010 from 9 a.m. to 5 p.m. and on April 22, 2010 from 9:30 a.m. to 1 p.m.

ADDRESSES: The meeting will be held at the National Biodefense Analysis and Countermeasures Center, 110 Thomas Johnson Drive, Suite 400, Frederick, MD 21702. Requests to have written material distributed to each member of the committee prior to the meeting should reach the contact person at the address below by Friday, April 16, 2010. Send written material to Ms. Tiwanda Burse, Science and Technology Directorate, Department of Homeland Security, 245 Murray Lane, Bldg. 410, Washington, DC 20528. Comments must be identified by DHS–2010–0020 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *E-mail: HSSTAC@dhs.gov*. Include the docket number in the subject line of the message.
- *Fax:* 202–254–6173.
- *Mail:* Ms. Tiwanda Burse, Science and Technology Directorate, Department of Homeland Security, 245 Murray Lane, Bldg. 410, Washington, DC 20528.

Instructions: All submissions received must include the words "Department of Homeland Security" and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov*, including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the (committee name), go to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Ms. Tiwanda Burse, Science and Technology Directorate, Department of Homeland Security, 245 Murray Lane, Bldg. 410, Washington, DC 20528, 202–254–6877.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463).

At this meeting, the Committee will receive sensitive and classified (Secret-level) briefings and presentations regarding relationships between Science & Technology and selected National Biodefense Analysis and Countermeasures related topics, which are matters relevant to homeland security.

Basis for Closure: In accordance with Section 10(d) of the Federal Advisory Committee Act, it has been determined that the Homeland Security Science and Technology Advisory Committee meeting concerns sensitive Homeland Security information and classified matters within the meaning of 5 U.S.C. 552b(c)(1) and (c)(9)(B) which, if prematurely disclosed, would significantly jeopardize national security and frustrate implementation of proposed agency actions and that, accordingly, this meeting will be closed to the public.

Dated: April 2, 2010.

Tara O'Toole,

Under Secretary for Science and Technology.

[FR Doc. 2010–8203 Filed 4–9–10; 8:45 am]

BILLING CODE 9110–9F–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3311–EM; Docket ID FEMA–2010–0002]

Rhode Island; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Rhode Island (FEMA–3311–EM), dated March 30, 2010, and related determinations.

DATES: *Effective Date:* March 30, 2010.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated March 30, 2010, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of Rhode Island resulting from severe storms and flooding beginning on March 12, 2010, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* ("the Stafford Act"). Therefore, I declare that such an emergency exists in the State of Rhode Island.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program. This assistance excludes regular time costs for subgrantees' regular employees. In addition, you are authorized to provide such other forms of assistance under Title V of the Stafford Act as you may deem appropriate.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Craig A. Gilbert, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.