

international scale in a pilot program starting in January 2014. The international partners for the MDSAP pilot, Therapeutic Goods Administration of Australia, Brazil's Agência Nacional de Vigilância Sanitária, Health Canada, FDA, and Japan's Ministry of Health, Labour and Welfare and Pharmaceuticals and Medical Devices Agency, are official observers and active participants in the pilot program's Regulatory Authority Council and subject matter expert groups.

The mission of the participants in the MDSAP International Coalition is to jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers. The development of the MDSAP includes the use of third party auditors, much like some current regulatory audit programs, as well as regulatory inspectorates. Recognizing the increasingly global nature and number of medical device manufacturers, the use of third party auditors in addition to regulatory authority inspectorates, allows greater coverage in auditing manufacturers as opposed to relying solely on the government resources of individual countries. The government resources can then be focused on high risk or problematic medical devices, manufacturers that are not in compliance with the regulations, and oversight of the third party auditing organizations. The MDSAP Pilot is intended to allow MDSAP-recognized auditing organizations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulatory authorities participating in the pilot.

The regulatory authorities involved in the pilot will base their recognition and assessment process on the following final IMDRF MDSAP documents:

- IMDRF MDSAP WG N3—“Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition;”
- IMDRF MDSAP WG N4—“Competence and Training Requirements for Auditing Organizations;”
- IMDRF MDSAP WG N5—“Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations;” and
- IMDRF MDSAP WG N6—“Regulatory Authority Assessor Competency and Training Requirements.”

Each of these documents was proposed in draft by the IMDRF and comments were solicited. IMDRF is in the process of revising these documents based on comments received. The IMDRF MDSAP Working Group has submitted the four proposed final documents for the IMDRF Management Committee meeting in Brussels on November 12 to 14, 2013.

The proposed drafts for each document are not available during the revision process. When final, these documents will be available on the IMDRF Web site (see <http://www.imdrf.org/>).

In addition, the MDSAP International Coalition has also developed several documents in order to implement the pilot. As documents are finalized by the MDSAP International Coalition Regulatory Authority Council, the documents will be posted on FDA's Web site.

The MDSAP audit process was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the requirements of medical devices. FDA will accept the MDSAP audit reports as a substitute for routine Agency inspections. Inspections conducted “For Cause” or “Compliance Followup” by FDA will not be affected by this program. Moreover, this MDSAP Pilot would not apply to any necessary preapproval or postapproval inspections for Premarket Approval (PMA) applications or to decisions under section 513(f)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(5)) concerning the classification of a device.

III. Electronic Access

Additional information on the IMDRF MDSAP can be found at: <http://www.imdrf.org/> and at <http://www.fda.gov/MedicalDevices/>.

V. Comments

Interested persons may submit either electronic comments regarding the MDSAP International Coalition Pilot Program to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

Dated: November 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–27358 Filed 11–14–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1038]

Over-the-Counter Ophthalmic Drug Products—Emergency Use Eyewash Products; Rescheduling of Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; rescheduling of public hearing.

SUMMARY: The Food and Drug Administration (FDA) is rescheduling a December 4, 2013, public hearing to obtain information on the formulation, manufacturing, and labeling of currently marketed over-the-counter (OTC) emergency use eyewash products, announced in the **Federal Register** of Wednesday, September 18, 2013. Based on a request received by the Agency, we are rescheduling the public hearing to March 7, 2014, and updating the related procedural dates that appeared in the September 18, 2013, notice.

DATES: The public hearing will be held on March 7, 2014, from 9 a.m. to 5 p.m. Submit electronic or written requests to make oral presentations and comments by February 14, 2014. If you wish to attend the hearing or make an oral presentation during the hearing, you must register by submitting an electronic request to CDEREYEWASHMEETING@fda.hhs.gov by close of business on February 14, 2014. For those unable to attend in person, FDA will provide a Webcast to the meeting; additional information about the Webcast location will be posted on the Web page at <http://www.fda.gov/Drugs/NewsEvents/ucm356526.htm> prior to March 7, 2014. Electronic or written comments will be accepted after the hearing until June 6, 2014.

FOR FURTHER INFORMATION CONTACT: Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301–796–3519, FAX: 301–847–8753, mary.gross@fda.hhs.gov; or Elaine Abraham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire

Ave., Silver Spring, MD 20903, 301-796-0843, FAX: 301-796-9899, elaine.abraham@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 18, 2013 (78 FR 57397), FDA announced that it would hold a public hearing on December 4, 2013, to obtain information on the formulation, manufacturing, and labeling of currently marketed OTC emergency use eyewash products. Based on a request received by the Agency, we are rescheduling the public hearing to March 7, 2014. Because we are rescheduling the hearing, we are also rescheduling the procedural dates (see **DATES**) that appeared in the September 18, 2013, notice. For additional information about the purpose and scope of the hearing, see the September 18, 2013, notice available on FDA's Web site at <http://www.fda.gov/Drugs/NewsEvents/ucm356526.htm>.

Dated: November 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-27359 Filed 11-14-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

The meeting will be open to the public, 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.

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: December 5-6, 2013.

Time: December 05, 2013, 9:00 a.m. to 5:00 p.m.

Agenda: NIH Director's report; ACD Working Group Implementation Team reports, NIH updates, and other business of the Committee.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Time: December 06, 2013, 9:00 a.m. to 12:00 p.m.

Agenda: ACD Working Group Implementation Team reports, NIH updates, and other business of the Committee.

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 103, Bethesda, MD 20892, 301-496-4272, woodgs@od.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://acd.od.nih.gov>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: November 8, 2013.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-27348 Filed 11-14-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel, NIAID Resource Related Research Projects (R24).

Date: December 11, 2013.

Time: 11:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Sujata Vijh, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301-594-0985, vijhs@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 8, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-27350 Filed 11-14-13; 8:45 am]

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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: Center for Scientific Review Special Emphasis Panel; Musculoskeletal Diseases.

Date: December 6, 2013.

Time: 2:00 p.m. to 4:30 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: Yanming Bi, Ph.D., Scientific Review Officer, Center for