

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Over-the-Counter Sunscreens: Safety and Effectiveness Data." This draft guidance addresses FDA's current thinking regarding the safety and effectiveness data needed to determine whether a nonprescription sunscreen active ingredient or combination of active ingredients evaluated under the SIA is GRASE and not misbranded when used under specified conditions. The guidance also addresses FDA's current thinking about an approach to safety-related final formulation testing that it anticipates adopting in the future.

FDA is issuing this guidance in partial implementation of the SIA (Pub. L. 113-195), enacted November 26, 2014, which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Among other things, the SIA established new procedures and review time lines for FDA to determine whether a nonprescription sunscreen active ingredient or combination of active ingredients is GRASE and not misbranded when used under the conditions specified in a final sunscreen order (GRASE determination) (21 U.S.C. 360fff-1, -2, and -3). The SIA also directed FDA to issue four guidances on various topics, including this guidance (21 U.S.C. 360ffff-4). Many of the safety topics addressed in this guidance were discussed at a public Nonprescription Drug Advisory Committee meeting held September 4 and 5, 2014 (<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/NonprescriptionDrugsAdvisoryCommittee/ucm380890.htm>).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Over-the-Counter Sunscreens: Safety and Effectiveness Data; Draft Guidance for Industry; Availability." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance contains collections of information that are exempt from the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). Section 586D(a)(1)(C) of the FD&C Act (21 U.S.C. 360fff-4(a)(1)(C)) as amended by the SIA states that the PRA shall not apply to collections of information

made for purposes of guidance under that subsection.

III. Electronic Access

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

Dated: November 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-29636 Filed 11-20-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting Notice for the President's Advisory Council on Faith-Based and Neighborhood Partnerships

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the President's Advisory Council on Faith-based and Neighborhood Partnerships announces the following webinar:

Name: President's Advisory Council on Faith-based and Neighborhood Partnerships Council Meetings.

Time and Date: Wednesday, December 9th, 2015 3:00 p.m.-4:30 p.m. (EST).

Public Webinar: The meeting will be available to the public through a webinar system. Register to participate in the conference call on Wednesday, December 9th at the Web site <https://attendee.gotowebinar.com/register/831474153301651458>.

Status: Open to the public, limited only by space available. Conference call limited only by lines available.

Purpose: The Council brings together leaders and experts in fields related to the work of faith-based and neighborhood organizations in order to: Identify best practices and successful modes of delivering social services; evaluate the need for improvements in the implementation and coordination of public policies relating to faith-based and other neighborhood organizations; and make recommendations for changes in policies, programs, and practices. The charge for this Council focuses on steps the government should take to reduce poverty and inequality and create opportunity for all, including changes in policies, programs, and practices that affect the delivery of services by faith-based and community organizations and the needs of low-income and other underserved persons.

Contact Person for Additional Information: Please contact Ben O'Dell

for any additional information about the President's Advisory Council meeting at partnerships@hhs.gov.

Agenda: Opening and Welcome from the Chairperson and Executive Director for the President's Advisory Council for Faith-based and Neighborhood Partnership; Updates for three working groups; Deliberation of recommendations (if necessary); Conclusion from Chairperson and Executive Director.

Public Comment: There will be an opportunity for public comment at the end of the meeting. Comments and questions can be sent in advance to partnerships@hhs.gov.

Dated: November 17, 2015.

Ben O'Dell,

Associate Director for Center for Faith-based and Neighborhood Partnerships at U.S. Department of Health and Human Services.

[FR Doc. 2015-29826 Filed 11-20-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Heart, Lung, and Blood Institute Special Emphasis Panel, December 7, 2015, 8:00 a.m. through December 8, 2015, 5:00 p.m., The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD, 20854 which was published in the **Federal Register** on November 12, 2015, 2015-28656.

Dr. Joyce's December 7-8, 2015 ZHL1 meeting has been rescheduled to January 4-5, 2016, at 8:00 a.m. The meeting is closed to the public.

Dated: November 17, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-29735 Filed 11-20-15; 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; Member Conflict: Transporters and Receptors.

Date: December 10, 2015.

Time: 1:00 p.m. to 2:30 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: Richard D Crosland, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, 301-435-1220, crosland@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Molecular Neurodevelopment and Injury.

Date: December 11, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213-9887, hamelinc@csr.nih.gov.

(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: November 17, 2015.

Sylvia Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-29732 Filed 11-20-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments; Amended Notice

SUMMARY: This notice amends **Federal Register** notice 80 FR 61831, published October 14, 2015, announcing the National Toxicology Program (NTP)

Board of Scientific Counselors (BSC) meeting and requesting comments. The deadline for written public comment submission has been changed to January 8, 2016. Persons submitting comments for the BSC meeting are encouraged to send them by November 30, 2015, to facilitate review by the BSC and NTP staff prior to the meeting. NTP is extending the written public comment period beyond the BSC meeting to provide additional opportunity for the public to comment on two draft concepts, Mountaintop Removal Mining: Impacts on Health in the Surrounding Community and Systematic Review on Fluoride and Developmental Toxicity. All other information in the original notice has not changed. Information about the meeting and registration is available at <http://ntp.niehs.nih.gov/go/165>.

DATES: Meeting: December 1-2, 2015; it begins at 8:00 a.m. Eastern Standard Time (EST) on December 1 and at 10:00 a.m. on December 2 and continues each day until adjournment. Written Public Comment Submission: Deadline is January 8, 2016.

Dated: November 17, 2015.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2015-29734 Filed 11-20-15; 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; Member Conflict: AIDS and AIDS Related Research.

Date: December 8, 2015.

Time: 1:00 p.m. to 4:00 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: Barna Dey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, Bethesda, MD 20892, 301-451-2796, bdey@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR13-061: Tuberculosis and HIV Co-Infections.

Date: December 8, 2015.

Time: 12:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

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: AIDS and AIDS Related Research.

Date: December 9, 2015.

Time: 1:00 p.m. to 5:00 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: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301-435-1050, freundr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: December 10, 2015.

Time: 12:00 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: 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; Multidisciplinary Studies of HIV/AIDS and Aging.

Date: December 11, 2015.

Time: 11:00 a.m. to 5:00 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, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301-435-1050, freundr@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;