

## 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FDA is announcing the availability of a draft guidance for industry entitled "Over-the-Counter Sunscreens: Safety and Effectiveness Data." This draft guidance addresses FDA's current thinking regarding the safety and effectiveness data needed to determine whether a nonprescription sunscreen active ingredient or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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Over-the-Counter Sunscreens: Safety and Effectiveness Data; Draft Guidance for Industry; Availability."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.*

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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](mailto: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](mailto: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.*

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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.*

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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