

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2017-21482 Filed 10-4-17; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (BSC, NCEH/ATSDR)

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting for the Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (BSC, NCEH/ATSDR). This meeting is open to the public, limited in the room by 60 people and 75 lines over the phone. The public is also welcome to listen to the meeting by 1-888-790-2009, passcode: 7865774, with 75 lines. The deadline for notification of attendance is November 10, 2017. The public comment period is scheduled on Wednesday, November 15, 2017 from 2:00 p.m. until 2:15 p.m.; and from 3:25 p.m. until 3:40 p.m. EST, and on Thursday, November 16, 2017 from 10:10 a.m. until 10:25 a.m. EST. Individuals wishing to make a comment during Public Comment period, please email your name, organization, and phone number by November 6, 2017 to William Cibulas at [wic1@cdc.gov](mailto:wic1@cdc.gov).

**DATES:** The meeting will be held on November 15, 2017, 8:30 a.m. to 4:30 p.m., EST and November 16, 2017, 8:30 a.m. to noon, EST.

**ADDRESSES:** CDC, 4770 Buford Hwy., Atlanta, Georgia 30341, Building 107, Room 1A or by phone: 1-888-790-2009

**FOR FURTHER INFORMATION CONTACT:** Shirley Little, Program Analyst, NCEH/ATSDR, CDC, 4770 Buford Hwy., Mail Stop F-45, Atlanta, Georgia 30341, telephone (770) 488-0577; [snl7@cdc.gov](mailto:snl7@cdc.gov).

#### SUPPLEMENTARY INFORMATION:

*Purpose:* The Secretary, Department of Health and Human Services (HHS) and by delegation, the Director, CDC

and Administrator, NCEH/ATSDR, are authorized under Section 301 (42 U.S.C. 241) and Section 311 (42 U.S.C. 243) of the Public Health Service Act, as amended, to: (1) Conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments; (2) assist states and their political subdivisions in the prevention of infectious diseases and other preventable conditions and in the promotion of health and wellbeing; and (3) train state and local personnel in health work. The BSC, NCEH/ATSDR provides advice and guidance to the Secretary, HHS; the Director, CDC and Administrator, ATSDR; and the Director, NCEH/ATSDR, regarding program goals, objectives, strategies, and priorities in fulfillment of the agency's mission to protect and promote people's health. The board provides advice and guidance that will assist NCEH/ATSDR in ensuring scientific quality, timeliness, utility, and dissemination of results. The board also provides guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents and to fulfill its mission in protecting America's health.

*Matters To Be Considered:* The agenda will include discussions on NCEH/ATSDR Director Updates; Noise-Induced Hearing Loss; NCEH/ATSDR Program Responses to BSC Guidance and Action Items; CDC's Hurricane Season Response; Lead Poisoning Prevention Program Updates; Flint Registry; Revision of blood lead level reference value (status); Discussion of Legislative Requirements of new Lead Exposure Poisoning Federal Advisory Committee; Amyotrophic Lateral Sclerosis (ALS) Program Update; Environmental Health Tracking Program update; updates from the National Institute of Environmental Health Sciences, the National Institute for Occupational Safety and Health, the U.S. Department of Energy and the U.S. Environmental Protection Agency. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2017-21422 Filed 10-4-17; 8:45 am]

**BILLING CODE 4163-19-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Mine Safety and Health Research Advisory Committee (MSHRAC)

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), announces the following meeting for the Mine Safety and Health Research Advisory Committee (MSHRAC). This meeting is open to the public, limited only by the limited only by the space available. The meeting room accommodates approximately 50 people. If you wish to attend in person or by phone, please contact Marie Chovanec by email at [MChovanec@cdc.gov](mailto:MChovanec@cdc.gov) or by phone at least 5 business days in advance of the meeting.

**DATES:** The meeting will be held on November 15, 2017, 8:00 a.m.-3:00 p.m., Mountain Time.

**ADDRESSES:** Sheraton Denver West Hotel, 360 Union Boulevard, Lakewood, CO 80228 or call 412-386-5302.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey H. Welsh, Designated Federal Officer, MSHRAC, NIOSH, CDC, 626 Cochran Mill Road, Pittsburgh, PA 15236, telephone 412-386-4040, fax 412-386-6614.

#### SUPPLEMENTARY INFORMATION:

*Purpose:* This committee is charged with providing advice to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NIOSH, on priorities in mine safety and health research, including grants and contracts for such research, 30 U.S.C. 812(b)(2), Section 102(b)(2).

*Matters To Be Considered:* The meeting will focus on mining safety and health research projects and outcomes, including built-in-place refuge alternatives, explosion protection, domestic and international

collaborations, fatigue management systems, mitigating dynamic failure in western underground coal mines, mining strategic planning, and mining innovations research initiative. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-E-2479]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; KOVALTRY

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for KOVALTRY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

**DATES:** Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by December 4, 2017. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by April 3, 2018. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be

considered. Electronic comments must be submitted on or before December 4, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of December 4, 2017.

Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2016-E-2479 for "Determination of Regulatory Review Period for Purposes of Patent Extension; KOVALTRY." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be