

- HTAC Subcommittee Updates
- Open Discussion Period

Public Participation: The meeting is open to the public. Individuals who would like to attend and/or to make oral statements during the public comment period must register no later than 5:00 p.m. on Wednesday, April 15, 2015, by email at HTAC@nrel.gov. Entry to the meeting room will be restricted to those who have confirmed their attendance in advance. Please provide your name, organization, citizenship, and contact information. Anyone attending the meeting will be required to present government-issued identification. Those wishing to make a public comment are required to register. The public comment period will take place between 8:30 a.m. and 9:00 a.m. on April 21, 2015. Time allotted per speaker will depend on the number who wish to speak but will not exceed five minutes. Those not able to attend the meeting or have insufficient time to address the committee are invited to send a written statement by email to HTAC@nrel.gov.

Minutes: The minutes of the meeting will be available within 45 days for public review at http://hydrogen.energy.gov/advisory_htac.html.

Issued in Washington, DC in March 4, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015-05531 Filed 3-10-15; 8:45 am]

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FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Notice

March 9, 2015.

TIME AND DATE: 10:00 a.m., Tuesday, March 17, 2015

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW., Washington, DC 20004 (enter from F Street entrance)

STATUS: Open

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Pocahontas Coal Co., LLC v. Secretary of Labor*, Docket No. WEVA 2014-202-R; and *Pocahontas Coal Co., LLC v. Secretary of Labor*, Docket Nos. WEVA 2014-642-R, et al. (Issues include whether the Administrative Law Judges erred in ruling that they lacked jurisdiction to review a Notice of Pattern of Violations and a Notice of Safeguard, respectively.)

Any person attending this meeting who requires special accessibility

features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

FOR FURTHER INFORMATION CONTACT:

Emogene Johnson (202) 434-9935/(202) 708-9300 for TDD Relay/1-800-877-8339 for toll free.

Sarah Stewart,

Deputy General Counsel.

[FR Doc. 2015-05633 Filed 3-9-15; 4:15 pm]

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FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Notice

March 9, 2015.

TIME AND DATE: 11:00 a.m., Tuesday, March 17, 2015.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW., Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Secretary of Labor v. Paramont Coal Company Virginia, LLC*, Docket Nos. VA 2010-369-R, et al. (Issues include whether the Administrative Law Judge erred in ruling that a particular violation of the standard governing conveyor belt alignment was not "significant and substantial.").

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

FOR FURTHER INFORMATION CONTACT:

Emogene Johnson (202) 434-9935/(202) 708-9300 for TDD Relay/1-800-877-8339 for toll free.

Sarah Stewart,

Deputy General Counsel.

[FR Doc. 2015-05637 Filed 3-9-15; 4:15 pm]

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FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Notice: Cancellation of Meeting Notice

March 6, 2015.

The following Commission meeting has been cancelled. No earlier announcement of the cancellation was possible.

TIME AND DATE: 10:00 a.m., Thursday, March 5, 2015

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW., Washington, DC 20004 (enter from F Street entrance)

STATUS: Open

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Pocahontas Coal Co., LLC v. Secretary of Labor*, Docket No. WEVA 2014-202-R; and *Pocahontas Coal Co., LLC v. Secretary of Labor*, Docket Nos. WEVA 2014-642-R, et al. (Issues include whether the Administrative Law Judges erred in ruling that they lacked jurisdiction to review a Notice of Pattern of Violations and a Notice of Safeguard, respectively.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFO:

Emogene Johnson (202) 434-9935/(202) 708-9300 for TDD Relay/1-800-877-8339 for toll free.

Emogene Johnson,

Administrative Assistant.

[FR Doc. 2015-05589 Filed 3-9-15; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 80 FR 14117-14119, dated January 9, 2015) is amended to establish the Western States Division and Spokane Mining Research Division, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows:

After the title and functional statement for the *World Trade Center Health Program (CCP), National*

Institute for Occupational Safety and Health (CC), insert the following:

Western States Division (CCQ). The Western States Division (WSD) conducts research and provides technical assistance for the prevention of work-related illness, injury, and death; these activities are predominately focused on, but not limited to, occupational safety and health (OS&H) problems in the Western U.S., including Alaska and Hawaii. WSD conducts specific activities that provide actionable evidence to reduce OS&H hazards. To accomplish its mission, WSD: (1) Conducts prevention research for at risk populations; (2) facilitates the development of OS&H programs in states and regions that have minimal or limited OS&H public health program capacity and state-supporting infrastructure; (3) serves as a multi-regional resource to provide outreach, expert advice, and technical assistance on OS&H priority issues, including the development, dissemination, and diffusion of NIOSH research products; (4) enhances and facilitates NIOSH initiatives and programs; and (5) responds to requests for technical assistance and conducts site evaluations to support Division programs and priorities and other NIOSH initiatives and programs, including evaluating exposures to hazardous chemical, biological, physical, and radioactive agents and recommending appropriate controls. Research includes the development of viable strategies to evaluate and prioritize hazards, communicate risk, provide evidence for prevention recommendations, and building state OS&H (capacity or activities) through surveillance data and stakeholder input. At risk populations include, but are not limited to, (a) high-risk industries such as oil and gas extraction, fishing, and aviation; (b) underserved groups such as American Indian/Alaska Native and immigrant and contingent workers; and (c) workers engaged in particularly hazardous activities such as hydraulic fracturing, wind and other renewable energy development, wild land firefighting; and water and air transportation.

After the title and functional statement for the *Office of Mine Safety and Health Research (CCM)*, *National Institute for Occupational Safety and Health (CC)*, insert the following:

Spokane Mining Research Division (CCMG). (1) Provides leadership for prevention of work-related illness, injury, and death in the extractive industries with an emphasis on the special needs of these industries in western United States; (2) develops numerical models and conducts laboratory and field investigations to better understand the causes of catastrophic failures in underground metal/nonmetal mines that may lead to multiple injuries and fatalities; (3) develops new design practices and tools, control technologies, and work practices to reduce the risk of these global and local ground failures in underground metal/nonmetal mines; (4) conducts numerical studies and field investigations to understand the problems of ventilating deep and multilevel underground mines, and develops improved design approaches and engineering

controls to reduce the concentration of toxic substances in the mine air; (5) conducts laboratory and field studies to help leverage and support the Institute's mining research program; (6) develops and recommends appropriate criteria for new standards, NIOSH policy, documents, or testimony related to health and safety in the extractive industries.

James Seligman,

Acting Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2015-05552 Filed 3-10-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1999-D-1315 (formerly 1999-D-0296)]

Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Prescription Drug User Fee Act Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Formal Meetings Between the FDA and Sponsors or Applicants of Prescription Drug User Fee Act (PDUFA) Products." This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of drug or biological products ("products"). This draft guidance revises the guidance for industry entitled "Formal Meetings Between the FDA and Sponsors or Applicants" published May 19, 2009. **DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 9, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128,

Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Rachel E. Hartford, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6312, Silver Spring, MD 20993-0002, 301-796-0319; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products." This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of products regulated by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research. This draft guidance does not apply to abbreviated new drug applications, applications for biosimilar biological products, or submissions for medical devices. For the purposes of this draft guidance, "formal meeting" includes any meeting that is requested by a sponsor or applicant following the request procedures provided in this guidance and includes meetings conducted in any format (*i.e.*, face to face, teleconference, videoconference, or written response).

This draft guidance discusses the principles of good meeting management practices and describes standardized procedures for requesting, preparing for, scheduling, conducting, and documenting such formal meetings. The general principles in this draft guidance may be extended to other nonapplication-related meetings with external constituents, insofar as this is possible.

This draft guidance revises the guidance for industry entitled "Formal Meetings Between the FDA and Sponsors or Applicants" published May 19, 2009. This draft guidance is being