

validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2015.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters for Discussion: The agenda for the Advisory Board meeting includes: NIOSH Program Update; Department of Labor Program Update; Department of Energy Program Update; SEC Issues Work Group Report on "Sufficient Accuracy"/Co-Worker Dose Modeling; SEC Petitions Update; an update on SEC and Site Profile work for the Area IV of the Santa Susana Field Laboratory (Ventura County, CA); and Board Work Session.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted to the contact person below well in advance of the meeting. Any written comments received will be provided at the meeting in accordance with the redaction policy provided below.

Policy on Redaction of Board Meeting Transcripts (Public Comment): (1) If a person making a comment gives his or her personal information, no attempt will be made to redact the name; however, NIOSH will redact other personally identifiable information, such as contact information, social security numbers, case numbers, etc., of the commenter.

(2) If an individual in making a statement reveals personal information (e.g., medical or employment

information) about themselves that information will not usually be redacted. The NIOSH Freedom of Information Act (FOIA) coordinator will, however, review such revelations in accordance with the Federal Advisory Committee Act and if deemed appropriate, will redact such information.

(3) If a commenter reveals personal information concerning a living third party, that information will be reviewed by the NIOSH FOIA coordinator, and upon determination, if deemed appropriated, such information will be redacted, unless the disclosure is made by the third party's authorized representative under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) program.

(4) In general, information concerning a deceased third party may be disclosed; however, such information will be redacted if (a) the disclosure is made by an individual other than the survivor claimant, a parent, spouse, or child, or the authorized representative of the deceased third party; (b) if it is unclear whether the third party is living or deceased; or (c) the information is unrelated or irrelevant to the purpose of the disclosure.

The Board will take reasonable steps to ensure that individuals making public comment are aware of the fact that their comments (including their name, if provided) will appear in a transcript of the meeting posted on a public Web site. Such reasonable steps include: (a) A statement read at the start of each public comment period stating that transcripts will be posted and names of speakers will not be redacted; (b) A printed copy of the statement mentioned in (a) above will be displayed on the table where individuals sign up to make public comments; (c) A statement such as outlined in (a) above will also appear with the agenda for a Board Meeting when it is posted on the NIOSH Web site; (d) A statement such as in (a) above will appear in the **Federal Register** Notice that announces Board and Subcommittee meetings.

Contact Person for More Information: Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road NE., MS E-20, Atlanta, Georgia 30333, telephone: (513) 533-6800, toll free: 1-800-CDC-INFO, email: dcas@cdc.gov.

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 the Centers for Disease Control and Prevention and

the Agency for Toxic Substances and Disease Registry.

Claudette Grant,

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

[FR Doc. 2014-23855 Filed 10-6-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee for Dose Reconstruction Reviews (SDRR), Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting for the aforementioned subcommittee:

Date and Time: October 29, 2014, EST, 10:30 a.m.-5:00 p.m.

Place: Audio Conference Call via FTS Conferencing.

Status: Open to the public, but without a public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the teleconference at the USA toll-free, dial-in number, 1-866-659-0537 and the passcode is 9933701.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3,

2001, renewed at appropriate intervals, and will expire on August 3, 2015.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

Matters for Discussion: The agenda for the Subcommittee meeting includes the following dose reconstruction program quality management and assurance activities: Discussion of current findings from NIOSH and Advisory Board dose reconstruction blind reviews; discussion of dose reconstruction cases under review (cases involving Hanford, Mound Plant, Y-12, Oak Ridge National Laboratory, Lawrence Livermore National Laboratory, Pacific Proving Grounds, Hooker Electrochemical, Simonds Saw and Steel, Bethlehem Steel, Weldon Spring, W.R. Grace, Westinghouse, International Minerals and Chemical (IMC) Corporation, Koppers Company, Bridgeport Brass, Uranium Mill in Monticello, General Steel Industries, and DuPont Deepwater Works); and preparation of the Advisory Board's next report to the Secretary, HHS, summarizing the results of completed dose reconstruction reviews.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road NE., Mailstop E-20, Atlanta GA 30333, Telephone (513)533-6800, Toll Free 1(800)CDC-INFO, Email ocas@cdc.gov.

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.

Claudette Grant,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices (ACIP)

In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announce the following meeting of the aforementioned committee.

Times and Dates:

8:00 a.m.–5:45 p.m., EDT, October 29, 2014
8:00 a.m.–1:15 p.m., EDT, October 30, 2014

Place: Centers for Disease Control and Prevention, Tom Harkin Global Communications Center, 1600 Clifton Road NE., Building 19, Kent "Oz" Nelson Auditorium, Atlanta, Georgia 30333.

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

Purpose: The committee is charged with advising the Director, CDC, on the appropriate use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. Further, under provisions of the Affordable Care Act, at section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been adopted by the Director of the Centers for Disease Control and Prevention must be covered by applicable health plans.

Matters for Discussion: The agenda will include discussions on: General recommendations; human papillomavirus vaccines; influenza; novel influenza vaccines; tetanus, diphtheria, and acellular pertussis vaccine (Tdap); meningococcal vaccines; child/adolescent immunization schedule; adult immunization schedule; immunization safety; hepatitis vaccines; typhoid vaccines; and vaccine supply. Recommendation votes are scheduled for general recommendations, child/adolescent immunization schedule, adult immunization schedule and typhoid vaccines. Time will be available for public comment.

Agenda items are subject to change as priorities dictate. **Contact Person for More Information:** Stephanie Thomas, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road NE., MS-A27, Atlanta, Georgia 30333, telephone 404/639-8836; Email ACIP@CDC.GOV

Meeting is Webcast live via the World Wide Web; for instructions and more information on ACIP please visit the ACIP Web site: <http://www.cdc.gov/vaccines/acip/index.html>.

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.

Claudette Grant,

Acting 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-2014-N-0386]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Orphan Drugs; Common European Medicines Agency/ Food and Drug Administration Application Form for Orphan Medicinal Product Designation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by November 6, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0167. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.