

(Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Times and Dates:

8:00 a.m.–5:00 p.m., June 13, 2013 (Closed)

8:00 a.m.–5:00 p.m., June 14, 2013 (Closed)

Place: Embassy Suites, 1900 Diagonal Road, Alexandria, Virginia 22314, Telephone: (703) 684-5900, Fax: (703) 684-0653.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects, which will lead to improvements in the delivery of occupational safety and health services, and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters To Be Discussed: The meeting will convene to address matters related to the conduct of Study Section business and for the study section to consider safety and occupational health-related grant applications. These portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, Centers for Disease Control and Prevention, pursuant to Section 10(d) Public Law 92-463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Price Connor, Ph.D., NIOSH Health Scientist, CDC, 2400 Executive Parkway, Mailstop E-20, Atlanta, Georgia 30345, Telephone: (404) 498-2511, Fax: (404) 498-2571.

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. 2013-09873 Filed 4-25-13; 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:

Time and Date: 9:00 a.m.–5:00 p.m. Eastern Time, May 21, 2013.

Place: Cincinnati Airport Marriott, 2395 Progress Drive, Hebron, Kentucky 41018, Telephone (859) 334-4611, Fax (859) 334-4619.

Status: Open to the public, but without a public comment period. To access by conference call dial the following information 1 (866) 659-0537, Participant Pass Code 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, 2013.

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 to be Discussed: The agenda for the Subcommittee meeting includes: dose reconstruction program quality management and assurance activities, including: current findings from NIOSH internal dose reconstruction blind reviews; and discussion of dose reconstruction cases under review (sets 8-9, and Savannah River Site, Rocky Flats Plant, and Los Alamos National Laboratory cases from sets 10-13).

The agenda is subject to change as priorities dictate.

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

Contact Person for More Information: Theodore M. Katz, M.P.A., Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road, NE., Mailstop E-20, Atlanta, Georgia 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.

Elaine L. Baker,

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

[FR Doc. 2013-09877 Filed 4-25-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS-685, CMS-10436, CMS-10452, CMS-10180 and CMS-R-199]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden

estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease (ESRD) Network Semi-Annual Cost Report Forms and Supporting Regulations in 42 CFR section 405.2110 and 42 CFR 405.2112; *Use:* Section 1881(c) of the Social Security Act establishes End Stage Renal Disease (ESRD) Network contracts. The regulations found at 42 CFR 405.2110 and 405.2112 designated 18 ESRD Networks which are funded by renewable contracts. These contracts are on 3-year cycles. To better administer the program, CMS is requiring contractors to submit semi-annual cost reports. The purpose of the cost reports is to enable the ESRD Networks to report costs in a standardized manner. This will allow CMS to review, compare and project ESRD Network costs during the life of the contract. Since the last collection, the survey instrument has been revised. The burden has not changed. *Form Number:* CMS-685 (OMB#: 0938-0657); *Frequency:* Reporting—Semi-annually; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 18; *Total Annual Responses:* 36; *Total Annual Hours:* 108. (For policy questions regarding this collection contact Benjamin Bernstein at 410-786-6570. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Evaluation of the Multi-Payer Advanced Primary Care Practice Demonstration; *Use:* On September 16, 2009, the Department of Health and Human Services announced the establishment of the Multi-Payer Advanced Primary Care Practice (MAPCP) Demonstration, under which Medicare joined Medicaid and private insurers as a payer participant in state-sponsored initiatives to promote the principles that characterize advanced primary care, often referred to as the "patient-centered medical home" (PCMH). The CMS selected eight states to participate in this demonstration: Maine, Vermont, Rhode Island, New

York, Pennsylvania, North Carolina, Michigan, and Minnesota. These states vary on a number of important dimensions, such as features of their public (Medicaid) and private insurance markets, delivery system, prior experience with medical home initiatives, and nature of their state-sponsored multi-payer initiative.

CMS is conducting an evaluation of the demonstration to assess the effects of advanced primary care practice when supported by Medicare, Medicaid, and private health plans. As part of this evaluation, qualitative and quantitative data will be collected and analyzed to answer research questions focused on: (1) State initiative features and implementation, including various payment models; (2) practice characteristics, particularly medical home transformation; and (3) outcomes, including access to and coordination of care, clinical quality of care and patient safety, beneficiary experience with care, patterns of utilization, Medicare and Medicaid expenditures, and budget neutrality.

Subsequent to the publication of the 60-day **Federal Register** notice (May 31, 2012; 77 FR 32118), the interview protocols have been revised by adding, revising and/or deleting questions. Also, there have been protocols added to the information collection request. *Form Number:* CMS-10436 (OCN: 0938-New); *Frequency:* Yearly; *Affected Public:* Individuals and households; *Number of Respondents:* 472; *Total Annual Responses:* 472; *Total Annual Hours:* 478 (For policy questions regarding this collection contact Suzanne Goodwin at 410-786-0226. For all other issues call 410-786-1326.)

3. *Type of Information Collection Request:* New collection; *Title of Information Collection:* CMS Enterprise Identity Management System; *Use:* The Enterprise Identity Management (EIDM) solution will provide an enterprise-wide solution that will also support CMS' senior management goal to improve the Provider and Health Information Exchange experience by providing an enterprise-wide set of credentials and single sign-on capability for multiple CMS applications. In order to prove the identity of an individual requesting electronic access to CMS protected information or services, CMS will collect a core set of attributes about that individual. These core attributes will be used to:

1. Provide the identity proofing service sufficient data to establish that the individual's identity is provable to a NIST assurance level;

2. Store the approval information returned by the identity proofing service;

3. Provide CMS with additional data for multi-factor identification (personal questions and answers);

4. Provide the user a single sign-on, federated CMS EIDM ID and Password;

5. Authenticate the user; and

6. Authorize the user for application access.

The information collected will be gathered and used solely by CMS and approved contractor(s) and state health insurance exchanges. Information confidentiality will conform to HIPAA and FISMA requirements. Respondents may also access CMS Terms of Service and CMS Privacy Statement on the Web. *Form Numbers:* CMS-10452 (OCN: 0938-New); *Frequency:* Reporting—On occasion; *Affected Public:* Individuals and households; *Number of Annual Respondents:* 26,000,000; *Total Annual Responses:* 26,000,000; *Total Annual Hours:* 8,666,667. (For policy questions regarding this collection contact Robert Burger at 410-786-2125. For all other issues call 410-786-1326.)

4. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Children's Health Insurance Program (CHIP) Report on Payables and Receivables; *Use:* Collection of Children's Health Insurance Program (CHIP) data and the calculation of the CHIP Incurred But Not Reported (IBNR) estimate are pertinent to CMS' financial audit. The Chief Financial Officer auditors have reported the lack of an estimate for CHIP IBNR payables and receivables as a reportable condition in the FY 2005 audit of CMS's financial statements. It is essential that CMS collect the necessary data from State agencies in FY 2006, so that CMS continues to receive an unqualified audit opinion on its financial statements. Program expenditures for the CHIP have increased since its inception; as such, CHIP receivables and payables may materially impact the financial statements. The CHIP Report on Payables and Receivables will provide the information needed to calculate the CHIP IBNR; *Form Number:* CMS-10180 (OCN: 0938-0988); *Frequency:* Reporting—Annually; *Affected Public:* State, Local or Tribal governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 392. (For policy questions regarding this collection contact Michele Myers at 410-786-7911. For all other issues call 410-786-1326.)

5. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Medicaid Report on Payables and Receivables; *Use:* The Chief Financial Officers (CFO) Act of 1990, as amended by the Government Management Reform Act (GMRA) of 1994, requires government agencies to produce auditable financial statements. Because the Centers for Medicare & Medicaid Services (CMS) fulfills its mission through its contractors and the States; these entities are the primary source of information for the financial statements. There are three basic categories of data: Expenses, payables, and receivables. The CMS-64 is used to collect data on Medicaid expenses. The CMS-R-199 collects Medicaid payable and receivable accounting data from the States. *Form Number:* CMS-R-199 (OCN: 0938-0697); *Frequency:* Reporting—Annually; *Affected Public:* State, Local or Tribal governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 336. (For policy questions regarding this collection contact Michele Myers at 410-786-7911. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *May 28, 2013*. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, Email: OIRA_submission@omb.eop.gov.

Dated: April 23, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0800]

Guidance for Industry on Regulatory Classification of Pharmaceutical Co-Crystals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Regulatory Classification of Pharmaceutical Co-Crystals.” This guidance provides applicants of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) with the Center for Drug Evaluation and Research’s (CDER’s) current thinking on the appropriate regulatory classification of pharmaceutical co-crystal solid-state forms. This guidance also provides information about the data the applicant should submit to support the appropriate classification of a co-crystal, as well as the regulatory implications of the classification.

The recommendations in this guidance apply to materials that the Agency has not previously evaluated and determined to be pharmaceutical co-crystals. The recommendations do not apply to materials that the Agency has previously designated as salts, complexes, or other non-co-crystalline forms.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, 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 guidance document.

Submit electronic comments on the 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:

Andre Raw, Center for Drug Evaluation and Research, Food and Drug Administration, Metro Park North II,

7500 Standish Pl., Rockville, MD 20855, 240-276-8500; or Richard Lostritto, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 21, rm. 1626, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-1900.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Regulatory Classification of Pharmaceutical Co-Crystals.” This guidance provides applicants of NDAs and ANDAs with CDER’s current thinking on the appropriate regulatory classification of pharmaceutical co-crystal solid-state forms. This guidance also provides information about the data the applicant should submit to support the appropriate classification of a co-crystal, as well as the regulatory implications of the classification.

On December 2, 2011 (76 FR 75551), FDA announced the availability of the draft version of this guidance. The public comment period closed on March 1, 2012. A number of comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes. Any changes to the guidance were minor and made to clarify statements in the draft guidance.

Co-crystals are solids that are crystalline materials composed of two or more molecules in the same crystal lattice. These solid-state forms, composed of an active pharmaceutical ingredient (API) with a neutral guest compound (also referred to as a conformer), have been the focus of significant interest in drug product development. Pharmaceutical co-crystals have opened the opportunity for engineering solid-state forms designed to have tailored properties to enhance drug product bioavailability and stability, as well as enhance processability of the solid material inputs in drug product manufacture. Pharmaceutical co-crystals are of interest because they offer the advantage of generating a diverse array of solid-state forms from APIs that lack ionizable functional groups needed for salt formation.

Traditionally, solid-state polymorphic forms of an API are classified as either crystalline, amorphous, or solvate and hydrate forms, and applicable regulatory schemes for these solid-state polymorphic forms are well-defined. Co-crystals, however, are distinguishable from these traditional pharmaceutical solid-state forms. Unlike