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

updated in accordance with the Meeting Management Goals section of the PDUFA Reauthorization Performance Goals and Procedures, Fiscal Years 2013 through 2017. Significant changes from the 2009 guidance include:

- Addition of the written response meeting format for pre-investigational new drug application and Type C meetings
- Designation of a post-action meeting requested within 3 months after an FDA regulatory action other than approval as a Type A meeting
- Designation of a post-action meeting requested 3 or more months after an FDA regulatory action other than approval as a Type B meeting
- Designation of a meeting regarding risk evaluation and mitigation strategies or postmarketing requirements that occur outside the context of the review of a marketing application as a Type B meeting
- Inclusion of a meeting package in Type A meeting requests
- Designation of meetings to discuss the overall development program for products granted breakthrough therapy designation status as a Type B meeting

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 Agency's current thinking on formal meetings between FDA and sponsors or applicants of PDUFA products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information referred to in the guidance entitled ''Formal Meetings Between the FDA and Sponsors or Applicants'' have been approved under OMB control number 0910–0429. The collections of information for Form FDA 1571 and end-of-phase 2 meetings have been approved under OMB control number 0910–0014, and collections of information for Form FDA 356h have been approved under OMB control number 0910–0338.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: March 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05523 Filed 3–10–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Arthritis Advisory Committee: Notice of Postponement of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is postponing the meeting of the Arthritis Advisory Committee scheduled for March 17, 2015. The meeting was announced in the **Federal Register** of February 10, 2015 (80 FR 7480). The postponement is due to information requests pending with the sponsor of the application. A future meeting date will be announced in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Stephanie L. Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *AAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

Dated: March 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05527 Filed 3–10–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Temporary Assistance for Needy Families Two-Parent Study.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF) is proposing an information collection activity as part of the Temporary Assistance for Needy Families Two-Parent Study. Through this information collection, ACF seeks to gain an in-depth, systematic understanding of the characteristics of two-parent families participating in or eligible to receive TANF, the variety of services two-parent families receive through TANF, how state policies may affect participation in TANF among two-parent families, and how the beliefs of staff and eligible families affect two-parent families' participation in TANF.

The proposed information collection consists of semi-structured interviews with key State and local staff, community-based organization representatives, and adult members of two-parent TANF or likely eligible families on questions of TANF policies, service delivery, and program context, as well as focus groups with adult members of two-parent TANF or likely eligible families.

Respondents: State- and local-level TANF administrators and staff, representatives from community-based organizations, and adults from two-parent families on or likely eligible for TANF.