

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on formal meetings between FDA and sponsors or applicants of PDUFA products.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This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction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.

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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.

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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.