

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on formal meetings between FDA and sponsors or applicants of PDUFA products.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This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction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

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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.

## ANNUAL BURDEN ESTIMATES

Instrument	Total/Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Discussion Guide for use with state TANF directors .....	10	1	1.5	15
Discussion Guide for use with local TANF directors .....	5	1	1.5	8
Discussion Guide for use with local TANF front-line staff .....	15	1	1	15
Discussion Guide for use with community-based organizations .....	5	1	1	5
Discussion Guide for use with client focus groups .....	112	1	1.5	168
Discussion guide for use with client interviews .....	25	1	1	25

*Estimated Total Annual Burden Hours: 236.*

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Karl Koerper,**

*OPRE Reports Clearance Officer.*

[FR Doc. 2015-05522 Filed 3-10-15; 8:45 am]

**BILLING CODE 4184-73-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Applications for New Awards; National Institute on Disability, Independent Living, and Rehabilitation Research—Advanced Rehabilitation Research Training Program

**AGENCY:** Administration for Community Living, Department of Health and Human Services.

**ACTION:** Notice.

#### Overview Information

National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)—Advanced

#### Rehabilitation Research Training (ARRT) Program.

Notice inviting applications for new awards for fiscal year (FY) 2015.

Catalog of Federal Domestic Assistance (CFDA) Numbers: 84.133P-1, 84.133P-3, and 84-133P-4.

**Note:** This notice invites applications for three separate competitions. See the chart in the *Award Information* section of this notice for funding and other key information for each of the three competitions.

#### DATES:

*Applications Available:* March 11, 2015.

**Note:** On July 22, 2014, President Obama signed the Workforce Innovation Opportunity Act (WIOA). WIOA was effective immediately. One provision of WIOA transferred the National Institute on Disability and Rehabilitation Research (NIDRR) from the Department of Education to the Administration for Community Living (ACL) in the Department of Health and Human Services. In addition, NIDRR's name was changed to the Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR). For FY 2015, all NIDILRR priority notices will be published as ACL notices, and ACL will make all NIDILRR awards. During this transition period, however, NIDILRR will continue to review grant applications using Department of Education tools. NIDILRR will post previously-approved application kits to [grants.gov](http://grants.gov), and NIDILRR applications submitted to [grants.gov](http://grants.gov) will be forwarded to the Department of Education's G-5 system for peer review. We are using Department of Education application kits and peer review systems during this transition year in order to provide for a smooth and orderly process for our applicants.

*Date of Pre-Application Meeting:* April 1, 2015.

*Deadline for Transmittal of Applications:* May 11, 2015.

#### Full Text of Announcement

##### I. Funding Opportunity Description

*Purpose of Program:* The purpose of the Disability and Rehabilitation Research Projects and Centers Program is to plan and conduct research, demonstration projects, training, and related activities, including international activities, to develop

methods, procedures, and rehabilitation technology. The Program's activities are designed to maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities, and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

#### Advanced Rehabilitation Research Training Program

The purpose of NIDILRR's ARRT program, which is funded through the Disability and Rehabilitation Research Projects and Centers Program, is to provide advanced research training and experience to individuals with doctorates, or similar advanced degrees, who have clinical or other relevant experience. ARRT projects train rehabilitation researchers, including researchers with disabilities, with particular attention to research areas that support the implementation and objectives of the Rehabilitation Act, and that improve the effectiveness of services authorized under the Rehabilitation Act.

Additional information on the ARRT program can be found at: [www.ed.gov/rschstat/research/pubs/res-program.html#ARRT](http://www.ed.gov/rschstat/research/pubs/res-program.html#ARRT).

*Priority:* There is one priority for the three competitions, which will each address one of NIDILRR's major domains of individual well-being: (a) Community living and participation, (b) employment, or (c) health and function. This priority is from the notice of final priority for this program, published in the **Federal Register** on June 11, 2013 (78 FR 34901).

*Absolute Priority:* For FY 2015 and any subsequent year in which we make awards from the list of unfunded applicants from these competitions, this priority is an absolute priority for each of the three competitions. Under 45 CFR part 75 we consider only applications that meet this program priority.

This priority is: