

national and State statistics on public and private residential services for individuals with intellectual and developmental disabilities, including disaggregation of data related to specific demographic groups. The project will conduct analyses that describe the movement of individuals with intellectual and developmental disabilities from institutional to community settings. Project staff will also participate in collaborative efforts with ADD and other data collection projects to review and report on unmet needs in data collection, analyses, and reporting activities that would promote the self-determination, independence, productivity, and integration and inclusion of people with intellectual and developmental disabilities in all facets of community life.

*Contact for Further Information:*

Ophelia McLain, Supervisory Program Specialist, Administration on Developmental Disabilities, 370 L'Enfant Promenade, SW., Mail Stop: HHH-405D, Washington, DC 20447. Telephone: 202-690-7025 E-mail: [ophelia.mclain@acf.hhs.gov](mailto:ophelia.mclain@acf.hhs.gov).

Dated: October 14, 2010.

**Sharon Lewis,**

*Commissioner, Administration on Developmental Disabilities.*

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**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Dental and Craniofacial Research; Interagency Pain Research Coordinating Committee; Call for Nominations

The Department of Health and Human Services has created the Interagency Pain Research Coordinating Committee and is seeking nominations for this committee. As specified in Public Law 111-148 ("Patient Protection and Affordable Care Act") the Committee will: (a) Develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain; (b) identify critical gaps in basic and clinical research on the symptoms and causes of pain; (c) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort; (d) make recommendations on how best to disseminate information on pain care;

and (e) make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.

Membership on the committee will include six (6) non-Federal members from among scientists, physicians, and other health professionals and six (6) non-Federal members of the general public who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions. Members will serve overlapping three year terms. It is anticipated that the committee will meet at least once a year.

The Department strives to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS Federal advisory committees and, therefore, the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the Committee. Appointment to this committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Nominations are due by COB November 26, 2010, and should be sent to Amy Adams, PhD, NIDCR/NIH, 31 Center Drive, Room 5B55, MSC-2190, Bethesda MD 20892-2190, [adamsamy@mail.nih.gov](mailto:adamsamy@mail.nih.gov) by either USPS mail or e-mail. Nominations should include contact information and a current curriculum vitae or resume.

Dated: October 18, 2010.

**Amy Adams,**

*National Institute of Dental and Craniofacial Research, National Institutes of Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0529]

#### Draft Guidance for Industry on Qualification Process for Drug Development Tools; 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 "Qualification Process for Drug Development Tools." This draft guidance describes the qualification process for drug development tools (DDTs) intended for potential use, over time, in multiple drug development programs. The draft guidance provides a framework for interactions between the Center for Drug Evaluation and Research (CDER) and DDT sponsors to support work towards qualification of an identified DDT and creates a mechanism for formal review of data by CDER to qualify the DDT and ensure that the evaluation is comprehensive and reliable.

**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 January 24, 2011.

**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, 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 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:** Shaniece Gathers, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4555, Silver Spring, MD 20993-0002, 301-796-2600.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Qualification Process for Drug Development Tools." In March 2006, FDA issued the "Critical Path Opportunities Report" and the "Critical Path Opportunities List." In these reports, FDA described six key areas along the critical path to improved therapies, and a list of specific opportunities for advancement within these topic areas. The opportunities report noted that a new product