

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.*

[FR Doc. 2010-26933 Filed 10-22-10; 8:45 am]

**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.*

[FR Doc. 2010-26937 Filed 10-22-10; 8:45 am]

**BILLING CODE 4140-01-P**

## 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

development toolkit containing new scientific and technical methods was needed to improve the efficiency of drug development. Too often, attention to a needed DDT is delayed until the time when the registration study protocols are under development and the available DDTs are inadequate. Innovative and improved DDTs are among the methods that can help streamline the drug development process, improve the chances for clinical trial success, and yield more information about the treatment and/or disease. DDTs include, but are not limited to biomarkers and patient reported outcome instruments. This draft guidance describes a formal process that CDER will use in working with sponsors of these tools to guide them as they refine the tools and rigorously evaluate them for use in the regulatory process.

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 the qualification process for DDTs. 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 found in FDA regulations. These collections of information 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 in 21 CFR 312.30, 21 CFR 314.50(d)(5), and 21 CFR 314.126(b)(6) have been approved under OMB control numbers 0910–0001 and 0910–0014.

## III. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

## IV. Electronic Access

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

Dated: October 19, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–26927 Filed 10–22–10; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel; Kochanek T32.

*Date:* November 16, 2010.

*Time:* 1:30 p.m. to 2:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Peter Zelazowski, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child, Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–7510, 301–435–6902, [peter.zelazowski@nih.gov](mailto:peter.zelazowski@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 19, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010–26874 Filed 10–22–10; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel; Cornelia de Lange Syndrome.

*Date:* November 15, 2010.

*Time:* 2 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Neelakanta Ravindranath, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01G, Bethesda, MD 20892, 301–435–6889, [ravindr@nih.gov](mailto:ravindr@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 19, 2010.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010–26875 Filed 10–22–10; 8:45 am]

**BILLING CODE 4140–01–P**