increasing collaboration between public health ethics and public health law.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: For security reasons, members of the public interested in attending the meeting should contact Drue Barrett, Ph.D., Designated Federal Officer, ACD, CDC—ES, 1600 Clifton Road NE., M/S D–50, Atlanta, Georgia 30333. Telephone: (404) 639–4690. Email: *dbarrett@cdc.gov*. The deadline for notification of attendance is October 1, 2012.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 12, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–23192 Filed 9–19–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Title IV–E Plan for Foster Care, Adoption Assistance, and, optional, Guardianship Assistance Programs.

OMB No.: 0980–0141.

Description: A title IV–E plan is required by section 471, part IV–E of the Social Security Act (the Act) for each public child welfare agency requesting Federal funding for foster care, adoption assistance and guardianship assistance under the Act. Section 479B of the Act provides for an Indian tribe, tribal organization or tribal consortium (Tribe) to operate a title IV–E program in the same manner as a State with minimal exceptions. The Tribe must have an approved title IV–E Plan. The title IV–E plan provides assurances the programs will be administered in conformity with the specific requirements stipulated in title IV–E. The plan must include all applicable State or Tribal statutory, regulatory, or policy references and citations for each requirement as well as supporting documentation. A title IV–E agency may use the pre-print format prepared by the Children's Bureau of the Administration for Children and Families or a different format, on the condition that the format used includes all of the title IV–E plan requirements of the law.

Respondents: Title IV–E agencies administering or supervising the administration of the title IV–E programs.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title IV–E Plan	17	1	16	272

Estimated Total Annual Burden Hours: 272.

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: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@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*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–23120 Filed 9–19–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number 93.631]

Announcement of the Award of a Single-Source Program Expansion Supplement Grant to the University of Boston for the Institute for Community Inclusion (ICI) in Boston, MA

AGENCY: Administration on Developmental and Intellectual Disabilities (AIDD), ACF, HHS.

ACTION: Announcing the award a single-source program expansion supplement to the University of Massachusetts for the Institute for Community Inclusion in Boston, MA, to support the additional employment grants that will be awarded.

SUMMARY: The Administration for Children and Families (ACF), Administration on Developmental and Intellectual Disabilities (AIDD) announces the award of a grant in the amount of $300,000 to the University of Massachusetts for the Institute for Community Inclusion, Boston, MA.

DATES: The project period for the award is from September 30, 2012 to September 29, 2013.

FOR FURTHER INFORMATION CONTACT: Ophelia McLain, Supervisory Program Specialist, Administration on Intellectual and Developmental Disabilities, 370 L'Enfant Promenade SW., 2nd Floor East, Washington, DC 20447. Telephone: 202–690–7025; Email: *ophelia.mclain@acf.hhs.gov*.

SUPPLEMENTARY INFORMATION: In September 2011, the Administration on Developmental and Intellectual Disabilities (AIDD) awarded a grant to the ICI to serve as the training and technical assistance (T/TA) provider to recipients of Partnerships in Employment Systems Change grants, also awarded that same year. AIDD has expanding the Employment efforts by awarding two additional Partnerships in Employment Systems Change grants in

Fiscal Year 2012. Program expansion supplemental award funds will support T/TA efforts by the ICI in serving the two additional two grantees.

Statutory Authority: The statutory authority is the Developmental Disabilities Assistance and Bill of Rights Act of 2000, Section 161.

Jamie Kendall,

Deputy Commissioner, Administration on Intellectual and Developmental Disabilities.

[FR Doc. 2012–23244 Filed 9–19–12; 8:45 am]

BILLING CODE 4184–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369; (Formerly Docket No. 2007D–0168)]

Draft Guidance for Industry on Bioequivalence Recommendations for Pentosan Polysulfate Sodium Capsule; 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 ''Bioequivalence Recommendations for Pentosan Polysulfate Sodium.'' The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for pentosan polysulfate sodium capsule.

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 comments 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 November 19, 2012.

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: Geoffrey Wu, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9326.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311; FDA–2007–D–0433), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for pentosan polysulfate sodium capsule.

New drug application 020193 for Elmiron (pentosan polysulfate sodium) capsule was initially approved by FDA in September 1996. There are no approved ANDAs for this product. FDA is now issuing a draft guidance for industry on BE recommendations for generic pentosan polysulfate sodium capsule (Draft Pentosan Polysulfate Sodium Capsule BE Recommendations).

In March 2012, Janssen Pharmaceuticals, Inc. (Janssen), manufacturer of the reference listed drug (RLD), Elmiron, submitted (through its attorneys) a citizen petition requesting that FDA require that any ANDA referencing Elmiron meet certain conditions, including conditions related to demonstrating BE (Docket No. FDA–2012–P–0295). FDA is reviewing the issues raised in the petition. FDA will consider any comments on the Draft Pentosan Polysulfate Sodium Capsule BE Recommendations before responding to Janssen's citizen petition.

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 design of BE studies to support ANDAs for pentosan polysulfate sodium capsule. 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. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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.*

III. 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: September 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–23177 Filed 9–19–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 8, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability,