update report [5]; or a periodic benefit–risk evaluation report.[6]

Non-expedited ICSRs can be submitted on paper or electronically. When submitted electronically, the non-expedited ICSRs should be submitted in XML format. This is because FDA is currently able to process electronic submissions of non-expedited ICSRs only in XML, prepared according to International Conference on Harmonisation (ICH) standards for database-to-database transmission of information.[7] When submitted in this compatible electronic format, non-expedited ICSRs can be downloaded into the FDA Adverse Event Reporting System (FAERS) database through the Electronic Submission Gateway.

We have become aware that some firms have submitted non-expedited ICSRs to the electronic Common Technical Document (eCTD) in a portable document file (pdf) format together with the descriptive portion of the periodic safety report.

FDA does not have a systematic method to identify non-expedited ICSRs that are submitted to the eCTD in pdf format together with the descriptive portion of the periodic safety report. In addition, non-expedited ICSRs submitted to the eCTD in pdf format cannot be downloaded into the FAERS database. Lack of access to non-expedited ICSRs in FAERS hinders FDA's ability to monitor product safety and public health. Furthermore, submission in pdf format prevents public access to the non-expedited ICSRs through FAERS.[8]

FDA is issuing this guidance as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the submission of non-expedited ICSRs in an electronic format supported by FDA. 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.

[5] FDA allows firms with approved waivers (under 21 CFR 314.90 and 600.90) to use the ICH E2C Periodic Safety Update Report format when submitting the descriptive portion of periodic safety reports.

[6] FDA allows firms with approved waivers (under 21 CFR 314.90 and 600.90) to use the ICH E2C(R2) Periodic Benefit-Risk Evaluation Report format when submitting the descriptive portion of periodic safety reports.

[7] See FAERS Electronic Submissions at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115894.htm.*

[8] FAERS data are available to the public as quarterly data files or by written Freedom of Information request to FDA. See *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082193.htm.*

II. 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.*

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations 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 in § 314.80 have been approved under OMB control number 0910–0230. The collections of information in § 600.80 have been approved under OMB control number 0910–0308.

IV. Electronic Access

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

Dated: July 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–17747 Filed 7–23–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Third Annual Food and Drug Administration Health Professional Organizations Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of conference.

The Food and Drug Administration (FDA) is announcing a conference for representatives of Health Professional Organizations. Topics on the agenda include FDA Updates, an overview of FDA's Network of Experts (public/private partnerships), and a FDA Town Hall. The FDA Town Hall will feature FDA senior executives including Jeffrey Shuren, M.D., J.D., Director of the Center for Devices and Radiological Health; Douglas C. Throckmorton, M.D., Deputy Director for Regulatory Programs of the Center for Drug Evaluation and Research; and Michael R. Taylor, Deputy Commissioner for Foods and Veterinary Medicine.

Date and Time: The conference will be held on October 24, 2013, from 8 a.m. to 12 noon.

Location: The conference will be held at the White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact: Brenda Rose, Office of Special Health Issues, 10903 New Hampshire Ave., Silver Spring, MD 20993, *Brenda.Rose@fda.hhs.gov,* 301–796–8460.

Registration: Register at *http://www.cvent.com/d/hcqym9/1Q.* Please include the name and title of the person attending, the name of the organization, and email address. There is no registration fee for this conference. Early registration is suggested because space is limited.

SUPPLEMENTARY INFORMATION: The aim of the conference is to further the public health mission of the FDA through training, collaboration, and structured discussion between health professional organizations and FDA staff. The Office of Health and Constituent Affairs serves as a liaison between the FDA Centers and the public on matters that involve medical product safety.

Please indicate during your registration a question of greatest interest to you for the FDA Town Hall.

If you need special accommodations due to a disability, please contact Brenda Rose at *Brenda.Rose@fda.hhs.gov* at least 7 days in advance of the conference.

Dated: July 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–17769 Filed 7–23–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Sickle Cell Disease Treatment Demonstration Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for Class Deviation for Non-Competitive Extension: Sickle Cell Disease Treatment Demonstration Program (U1E) Awards to Three Currently Funded Grantees.

SUMMARY: HRSA currently has nine programs that are funded through competitive grant awards under the Sickle Cell Disease Treatment Demonstration Program. Three of these awards will end on August 31, 2013, prior to the end of the other six awards. HRSA intends to implement a non-competitive extension of the project period for the three grants that will end in 2013. This will allow improved data gathering from each of the grantees in the program, which will be used in a report for Congress that is mandated by the legislation authorizing the grant. In addition, the program will benefit from cost savings realized from having the program completed in a consolidated funding cycle.

SUPPLEMENTARY INFORMATION:

Intended Recipients of the Award: The three incumbent grantees of record (listed below).

Amount of the Non-Competitive Awards: Up to $390,000 per grantee.

CFDA Number: 93.365.

Period of Supplemental Funding: 9/1/2013–8/30/2014.

Authority: Section 712(c) of the American Jobs Creation Act of 2004, Pub. L. 108–357.

Justification: The Sickle Cell Disease Treatment Demonstration Program provides grants to evaluate the use of strategies in improving sickle cell care. The extension will allow the Maternal and Child Health Bureau to fully assess the impact of the program by allowing data to be gathered on the health outcomes and impact of the Sickle Cell Disease Treatment Demonstration Program from all grantees on the same timeline and in a standard format. Currently, three grantees are scheduled to end prior to the end of the other grantees, leaving a period in which data would not be gathered from these sites. Data gathered from each of the grantees in the program will be used in a report for Congress that is mandated by the legislation authorizing the grant. In addition, the program will benefit from cost savings realized from having the program completed in a consolidated funding cycle.

FOR FURTHER INFORMATION CONTACT: Edward Donnell Ivy, M.D., M.P.H, Genetic Services Branch, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18A–19, Rockville, MD 20857; 301.443.9775; *eivy@hrsa.gov.*

MATERNAL AND CHILD HEALTH BUREAU SELECTED PROGRAMS EXTENSIONS WITH FUNDING

Grantee/organization name	Grant No.	State	Project start date	Project end date	Revised project end date	FY 2012 Appropriation	FY 2013 Appropriation
Children's Hospital & Research Center.	U1EMC16492	CA	9/1/2009	8/31/2013	8/30/2014	$390,000	$390,000
University of Colorado at Denver.	U1EMC16490	CO	9/1/2009	8/31/2013	8/30/2014	390,000	390,000
Newark Beth Israel Medical Center.	U1EMC16491	NJ	9/1/2009	8/31/2013	8/30/2014	390,000	390,000

Dated: July 17, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–17720 Filed 7–23–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the Council of Councils.

The meeting will be held via teleconference and is open to the public as indicated below. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of 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: Council of Councils.

Open: August 15, 2013, 1:00 p.m. to 1:40 p.m.

Agenda: Establishment of Chimpanzee Research Use Panel and Discussion. Vote on Establishment of the Panel. NIH Director's Early Independence Awards.

Place: National Institutes of Health, Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

Dial in number: 1–888–790–1964.

Participant Passcode: 9121608.

Closed: August 15, 2013, 1:45 p.m. to 2:15 p.m.

Agenda: Review of Grant Applications.

Contact Person: Robin Kawazoe, Executive Secretary, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, Building 1, Room 260, Bethesda, MD 20892, *kawazoer@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Information is also available on the Council of Council's home page at *http://dpcpsi.nih.gov/council/where* an agenda and proposals to be discussed will be posted before the meeting date.