and the plan for analyzing the states' needs assessment and baseline family, staff and program data that will be the focus of the report. Agenda items are subject to change as priorities dictate.

Public Comments: Members of the public may submit written comments that will be distributed to Committee members prior to the meeting. Written comments must be received by Monday, September 9, 2013 for consideration. Comments can be submitted to T'Pring Westbrook at *Tpring.Westbrook@acf.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Any person interested in obtaining other information relevant to joining the webinar can contact Carolyn Swaney at *Carolyn.Swaney@icfi.com.*

SUPPLEMENTARY INFORMATION: The Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation is authorized by subsection 511(g)(1) of Title V of the Social Security Act (42 U.S.C. 701 et seq.) as amended by section 2951 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (Affordable Care Act). The purpose of the Committee is to advise the Secretary of Health and Human Services on the design, plan, progress, and findings of the evaluation required for the home visiting program under the Affordable Care Act. More specifically, the Committee is to review, and make recommendations on, the design and plan for this evaluation; maintain and advise the Secretary regarding the progress of the evaluation; and comment, if the Committee so desires, on the report submitted to Congress under subsection 511(g)(3) of Title V.

The Department of Health and Human Services has contracted with MDRC, formerly known as Manpower Demonstration Research Corporation, a nonprofit, nonpartisan education and social policy research organization, to conduct the evaluation of the MIECHV program.

As specified in the legislation, the evaluation will provide a state-by-state analysis of the needs assessments and the States' actions in response to the assessments. Additionally, as specified in the legislation, the evaluation will provide an assessment of: (a) The effect of early childhood home visiting programs on outcomes for parents, children, and communities with respect to domains specified in the Affordable Care Act (such as maternal and child health status, school readiness, and domestic violence, among others); (b) the effectiveness of such programs on different populations, including the extent to which the ability to improve participant outcomes varies across programs and populations; and (c) the potential for the activities conducted under such programs, if scaled broadly, to enhance health care practices, eliminate health disparities, improve health care system quality, and reduce costs.

Naomi Goldstein,

Director, Office of Planning, Research, and Evaluation, ACF.

Rebecca Slifkin,

Director, Office of Planning, Analysis and Evaluation, HRSA.

[FR Doc. 2013–20725 Filed 8–27–13; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0918]

The Applicability of Good Laboratory Practice in Premarket Device Submissions: Questions and Answers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''The Applicability of Good Laboratory Practice in Premarket Device Submissions: Questions & Answers.'' This draft guidance answers commonly asked questions about the applicability of good laboratory practice (GLP) to nonclinical laboratory studies conducted in support of research and marketing applications for medical devices. This draft guidance is not final nor is it in effect at this time.

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 November 26, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''The Applicability of Good Laboratory Practice in Premarket Device Submissions: Questions & Answers'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration (CDRH), 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002; or Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Victoria Hampshire, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1218, Silver Spring, MD 20993–0002, 301–796–6375; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued the GLP regulations in response to public concerns that several important studies supporting the safety of FDA-regulated products were seriously flawed due to poor research practices and laboratory misconduct. The GLP regulations apply to nonclinical laboratory studies supporting the safety of FDA-regulated products (21 CFR 58.1). The draft guidance provides clarification on GLP terminology, the types of medical device research or marketing applications that are subject to the GLP regulation, and, if applicable, the types of information related to GLP that should be provided to FDA.

II. Significance of Guidance

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 good laboratory practices. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive ''The Applicability of Good Laboratory Practice in Premarket Device Submissions: Questions & Answers,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1779 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

The draft guidance refers to currently 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 part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231.

V. 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.*

Dated: August 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20916 Filed 8–27–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0007]

Prescription Drug User Fee Rates for Fiscal Year 2014; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Prescription Drug User Fee Rates for Fiscal Year 2014'' that appeared in the **Federal Register** of August 2, 2013 (78 FR 46980). The document announced the Fiscal Year 2014 fee rates for the Prescription Drug User Fee Act. The document was published with four errors. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: David Miller, Office of Financial Management (HFA–100), Food and Drug Administration, 1350 Piccard Dr., PI50, Rm. 210J, Rockville, MD 20850, 301–796–7103.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, August 2, 2013, in FR Doc. 2013–18624, on pages 46981 and 46982 the following corrections are made:

1. On page 46981, in the second column, in the second sentence of the second paragraph under I. Background, ''$718,699,000'' is corrected to read ''$718,669,000''.

2. On page 46981, in the third column, in the first sentence of the first paragraph under II. Fee Revenue Amount for 2014, ''$718,699,000'' is corrected to read ''$718,669,000''.

3. On page 46981, in the third column, in the first sentence of the first paragraph under *A. FY 2014 Statutory Fee Revenue Adjustments for Inflation,* ''$718,699,000'' is corrected to read ''$718,669,000''.

4. On page 46982, in the first column, in the first sentence of the first paragraph under *B. FY 2014 Statutory Fee Revenue Adjustments for Workload,* ''$718,699,000'' is corrected to read ''$718,669,000''.

Dated: *August 22, 2013.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20958 Filed 8–27–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Palliative Care: Conversations Matter Evaluation

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Nursing Research (NINR), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June, 14, 2013, page 35942 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer. To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Adrienne Burroughs, Health Communications Specialist, Office of Communications and Public Liaison, NINR, NIH, Building 31, Room 5B10, 31 Center Drive, Bethesda, MD 20892, or call non-toll-free number (301) 496–0256, or Email your request, including your address to: *adrienne.burroughs@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Palliative Care: Conversations Matter Evaluation, -0925-New—National Institute of Nursing Research (NINR), National Institutes of Health (NIH).

Need and Use of Information Collection: NINR developed *Palliative Care: Conversations Matter,* a pediatric palliative care campaign to address the communications challenges faced by health care providers who recommend