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Persons interested in obtaining a copy of the draft guidance may do so by using the Internet.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 dsnicca@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The draft guidance refers to currently approved collections of information found in FDA regulations.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


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., P150, 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 National Institutes of Health, Office of Management and Budget, Office of Financial Management, 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.


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