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Persons interested in obtaining a copy of the draft guidance may do so by using the Internet.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The draft guidance refers to currently approved collections of information found in FDA regulations.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

and provide palliative care to pediatric populations. NINR is launching this effort to increase the use of palliative care for children living with serious illness or life-limiting conditions. The *Palliative Care: Conversations Matter* evaluation will assess the information and materials being disseminated as part of the official campaign. Survey findings will help (1) Determine if the campaign is effective, relevant, and useful to health care providers who recommend and provide palliative care to pediatric populations; (2) to better understand the information needs of health care providers to inform future campaign efforts; and (3) examine how effective the campaign materials are in starting and continuing a pediatric palliative care conversation and addressing the communications needs of health care providers around this topic.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 200.

Estimated Annualized Burden Hours

TABLE A–12–1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Number of respondents	Frequency of response	Average time per response (in hours)	Total burden hours
Physicians	150	2	20/60	100
Nurses	150	2	20/60	100
Total	300			200

* The average time for completing one of the surveys is 20 minutes; this includes reading the consent form on page 1 of the survey.

Dated: August 19, 2013.

Amanda Greene,

NINR PRA Liaison, Science Evaluation Officer, NINR, NIH.

[FR Doc. 2013–21005 Filed 8–27–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Use of Exenatide for the Treatment of Neurodegenerative Diseases

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to Peptron, Inc., a company having a place of business in Daejeon, South Korea, to practice the inventions embodied in U.S. Provisional Patent Application No. 60/309,076, filed July 31, 2001, entitled ''Long-Acting Insulinotropic Peptides and Uses Thereof'' (HHS Ref. No. E–049–2001/0–US–01); U.S. Patent No. 7,576,050, issued August 18, 2009, entitled ''GLP–1 Exendin–4 Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–US–03); U.S. Patent No. 8,278,272, issued October 2, 2012, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–US–14); U.S. Patent Application No. 13/594,313, filed August 24, 2012, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–US–21); PCT Patent Application No. PCT/US2002/024141, filed July 30, 2002, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–PCT–02); Australian Patent No. 2002317599, issued July 17, 2008, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–AU–04); Australian Patent No. 2008202893, issued April 26, 2012, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–AU–10); Australian Patent Application No. 2012202081, filed April 11, 2012, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–AU–20); Canadian Patent Application No. 2455963, filed January 29, 2004, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–CA–05); European Patent No. 1411968, issued September 17, 2008, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–EP–06) and validated in Germany (HHS Ref. No. E–049–2001/0–DE–11), France (HHS Ref. No. E–049–2001/0–FR–12), and Great Britain (HHS Ref. No. E–049–2001/0–GB–13); European Patent No. 2022505, issued December 14, 2011, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–EP–09) and validated in Germany (HHS Ref. No. E–049–2001/0–DE–17), France (HHS Ref. No. E–049–2001/0–FR–18), and Great Britain (HHS Ref. No. E–049–2001/0–GB–19); European Patent Application No. 10177860.3, filed September 21, 2010, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–EP–16); Indian Patent Application No. 0488/DELNP/2004, filed February 27, 2004, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–IN–07); Japanese Patent Application No. 2003–517083, filed February 2, 2004, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–JP–08); Japanese Patent Application No. 2009–262568, filed November 18, 2009, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–JP–15; and Japanese Patent Application No. 2013–007743, filed January 18, 2013, entitled ''GLP–1, Exendin–4, Peptide Analogs and Uses Thereof'' (HHS Ref. No. E–049–2001/0–JP–22). The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Exclusive Patent License may be worldwide, and the field of use may be limited to ''Methods of using exenatide for the treatment of neurodegenerative disease in humans.''

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before September 27, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application(s), inquiries, comments, and other materials relating to the contemplated Exclusive Patent License should be directed to: Tara L. Kirby, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4426; Facsimile: