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Persons interested in obtaining a copy of the draft guidance may do so by using the Internet.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 dsmicia@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The draft guidance refers to currently approved collections of information found in FDA regulations.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 0910–0078; and 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 812 have been approved under OMB control number 0910–0078.

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
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>
<thead>
<tr>
<th>Type of respondents</th>
<th>Number of respondents</th>
<th>Frequency of response</th>
<th>Average time per response (in hours)</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians</td>
<td>150</td>
<td>2</td>
<td>20/60</td>
<td>100</td>
</tr>
<tr>
<td>Nurses</td>
<td>150</td>
<td>2</td>
<td>20/60</td>
<td>100</td>
</tr>
<tr>
<td>Total</td>
<td>300</td>
<td></td>
<td></td>
<td>200</td>
</tr>
</tbody>
</table>

* 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.

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.


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: