SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Applications for Food and Drug Administration Approval To Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs—OMB Control Number 0910–0646—Extension

In the Federal Register of July 28, 2009 (74 FR 37163), FDA published a final rule that required, under §314.81(b)(2)(ii)(B) (21 CFR 314.81(b)(2)(ii)(B)), the holder of a new drug application (NDA) to notify the Agency if an authorized generic drug is marketed by clearly including this information in annual reports in an easily accessible place and by sending a copy of the relevant portion of the annual reports to a central contact point. We took this action as part of our implementation of the Food and Drug Administration Amendments Act (Public Law 110–85), which requires that FDA publish a list of all authorized generic drugs included in an annual report after January 1, 1999, and that the Agency update the list quarterly. We initially published this list on June 27, 2006, on the Internet and notified relevant Federal Agencies that the list was published, and we will continue to update it.

Based on the number of annual reports the Agency currently receives under §314.81(b)(2) containing authorized generic drug information, we estimate that we will receive approximately 500 annual reports containing the required information on authorized generic drugs. Based on the number of sponsors that currently submit these annual reports, we estimate that approximately 70 sponsors will submit these 500 annual reports. We estimate that each sponsor will need approximately 30 minutes to include the required information on authorized generic drugs in each annual report.

We also estimate that we will receive authorized generic drug information on first marketed generics in approximately 20 annual reports from approximately 20 sponsors, and that each sponsor will need approximately 1 hour to include the required information in each annual report.

We also estimate that we will receive a copy of that portion of each annual report containing the authorized generic drug information for approximately 500 annual reports from approximately 70 sponsors, and that each sponsor will need approximately 3 minutes to submit a copy of that portion of each annual report containing the authorized generic drug information.

FDA estimates the burden of this collection of information is as follows:

<table>
<thead>
<tr>
<th>21 CFR 314.81(b)(2)(ii)(B)</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submission of authorized generic drug information in each annual report.</td>
<td>70</td>
<td>7</td>
<td>490</td>
<td>0.5 (30 minutes)</td>
<td>245</td>
</tr>
<tr>
<td>Submission of authorized generic drug information on first marketed generics in an annual report.</td>
<td>20</td>
<td>1</td>
<td>20</td>
<td>1</td>
<td>20</td>
</tr>
<tr>
<td>Submission of a copy of that portion of each annual report containing authorized generic drug information.</td>
<td>70</td>
<td>7</td>
<td>490</td>
<td>0.05 (3 minutes)</td>
<td>25</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>290</td>
</tr>
</tbody>
</table>

† There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 6, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FR Doc. 2013–11277 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–01–P

Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anesthetic and Analgesic Drug Products Advisory Committee.

General Function of the Committee: To provide advice and
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Reports Clearance Officer at (301) 443–1904.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: Develop and Implement UCARE4LIFE Message Library (OMB No. 0915–xxxx)—New

Abstract: HRSA HIV/AIDS Bureau (HAB) will develop and implement the UCARE4LIFE message library project aimed at increasing HIV primary care retention rates for racial and ethnic minority youth aged 15 to 24 living with HIV/AIDS. The primary aims are: (1) to develop, test, and maintain a text message library, which addresses topics of HIV disease management, e.g. appointment keeping, retention in care, and medication adherence rates; and (2) to develop, implement, conduct, and evaluate a pilot study of delivering text messages to targeted youth receiving care at Ryan White grantee sites and other clinical sites. HRSA awarded a two-year contract to the Research Triangle Institute (RTI) International to conduct the UCARE4Life project. The UCARE4Life project is supported by the Department of Health and Human

DEVELOPMENT OF THE UCARE4LIFE MESSAGE LIBRARY

The UCARE4Life Project is a two-year (2013–2014) initiative to develop, test, and disseminate an evidence-based text message program to help improve the care retention of HIV-infected adolescents and young adults. The text messages will be tailored for use among racial and ethnic minority youth and are targeted at those who are either newly diagnosed or are already receiving care through Ryan White grantees.

The content of the messages will focus on key clinical and social outcomes, including appointment keeping, retention in care, and medication adherence. The messages will also contain links to relevant online resources. The overall goal of the UCARE4Life project is to improve the health outcomes of HIV-infected adolescents and young adults, particularly those who are from racial and ethnic minority groups.

In order to develop an effective message library, HRSA will conduct a needs assessment to identify the most relevant topics and messages for adolescent and young adult audiences. This will involve reviewing existing literature, consulting with experts, and conducting focus groups with target audiences. Based on the results of this assessment, HRSA will develop a set of messages that are culturally responsive and that reflect the specific needs of the target population.

The message library will be tested and refined through a pilot study involving Ryan White grantees. The project will provide technical assistance to grantees to help them implement the messages and track their impact. The results of the pilot study will be used to refine the messages further, ensuring that they are effective and sustainable.

Finally, HRSA will conduct a follow-up evaluation to assess the impact of the messages on care retention rates and other key outcomes. This evaluation will provide evidence of the project’s effectiveness and will help to inform future rounds of funding for the UCARE4Life initiative.