and submission for each suffix does not provide a basis by which the estimate was calculated or whether it is broadly applicable. We find this figure rather high and retain our original estimate of 6 hours. The latter figure is based on our familiarity with the average amount of time required by similar submissions to FDA. At the same time, the comment also suggested that we failed to adequately account for the time spent on creating proposed suffixes. In consideration, therefore, we have revised our estimate upward to account for burden associated with creating and submitting up to 10 proposed suffixes for designation, as reflected in table 1.

FDA estimates the information collection burden as follows:

**Description of Respondents:**
Respondents to the collection are sponsors of biological product applications.

**TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN**

<table>
<thead>
<tr>
<th>Activity</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>Information for the Proposed Proper Name for Biological Products Submitted Under Section 351(a) of the PHS Act</td>
<td>20</td>
<td>2</td>
<td>40</td>
<td>420</td>
<td>16,800</td>
</tr>
<tr>
<td>Information for the Proposed Proper Name for Biosimilar Products and Interchangeable Products Submitted Under Section 351(k) of the PHS Act</td>
<td>3</td>
<td>2</td>
<td>6</td>
<td>420</td>
<td>2,520</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>19,320</td>
</tr>
</tbody>
</table>

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

The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information for the submission of a biologics license application (BLA) and changes (supplements) to an approved application under 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information for the submission of a BLA under section 351(k) of the PHS Act (biosimilar products and interchangeable products) have been approved under OMB control number 0910–0719.

Dated: May 26, 2016.

Leslie Kux,
Associate Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT:
Please send requests for information to Dawn Smith, Bureau of Health Workforce, HRSA, in one of two ways: (1) Send a request to the following address: Dawn Smith, Bureau of Health Workforce, Health Resources and Services Administration, Room 14N70B, 5600 Fishers Lane, Rockville, Maryland 20857; or (2) send an email to dsmith3@hrsa.gov.

**SUPPLEMENTARY INFORMATION:**
Further information regarding the NACNHSC, including the roster of members and past meeting summaries, is available at: http://nhsc.hrsa.gov/corpsexperience/aboutus/nationaladvisorycouncil/meetingssummaries/index.html.

Members of the public and interested parties may request to participate in the meeting by contacting Dawn Smith via email at dsmith3@hrsa.gov to obtain access information. Access will be granted on a first come, first served basis. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed above at least 10 days prior to the meeting.

Public participants may submit written statements in advance of the scheduled meeting. If you would like to provide oral public comment during the meeting, please register with Dawn Smith. Public comment will be limited to 3 minutes per speaker. Statements and comments can be addressed to Dawn Smith by emailing her at dsmith@hrsa.gov.

In addition, please be advised that committee members are given copies of all written statements submitted from the public. Any further public
participation will be solely at the discretion of the Chair, with approval of the Designated Federal Official. Registration through the designated contact for the public comment session is required.

Jason E. Bennett,
Director, Division of the Executive Secretariat.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

Date: June 12–14, 2016.

Time: 6:00 p.m. to 11:30 a.m.

Agenda: To review and evaluate personal qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Contact Person: Lyle Furr, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20852 (Telephone Conference Call).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel—Research Support Services for NIDA AIDS Program (1209).

Date: June 21, 2016.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Lyle Furr, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550, (301) 435–1439, lj33c.nih.gov.

Proposed Collection: Methodological Studies for the Population Assessment of Tobacco and Health (PATH) Study (NIDA)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, 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 March 11, 2016, pages 12913–12914 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.

Direct Comments to OMB: 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.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project, contact: Dr. Kevin F. Conway, Deputy Director, Division of Epidemiology, Services, and Prevention Research, NIDA, NIH, 6001 Executive Boulevard, Room 5185, Rockville, MD 20852; or call non-toll-free number (301) 443–8755 or Email your request, including your address to: PATHprojectofficer@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Methodological Studies for the Population Assessment of Tobacco and Health (PATH) Study (NIDA), 0925–0675, expiration date 5/31/2016—Reinstatement Without Change—NIDA, NIH, in partnership.