


Dated: March 7, 2018.

Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. FDA–2014–D–1837]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Transfer of a Premarket Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 12, 2018.

ADDRESSES: To ensure that comments on the proposed collection of information are 510(k) holders and parties claiming to be 510(k) holders.

In the Federal Register of December 22, 2014 (79 FR 76331), FDA published a 60-day notice requesting public comment on the proposed collection of information. While FDA received comments on the draft guidance document, none were related to the information collection.

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

<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>Voluntary reporting of transfer of 510(k) clearance on FDA’s Unified Registration and Listing System (URLS) (outside of annual listing reporting requirement)</td>
<td>4,080</td>
<td>1</td>
<td>4,080</td>
<td>0.25</td>
<td>1,020</td>
</tr>
<tr>
<td>Submission of 510(k) transfer documentation when more than one party lists the same 510(k)</td>
<td>2,033</td>
<td>1</td>
<td>2,033</td>
<td>4</td>
<td>8,132</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>9,152</td>
</tr>
</tbody>
</table>

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

FDA estimates that 78 percent of 510(k)s are listed outside of the annual registration cycle based on numbers in the FURLS database from fiscal year 2009 through fiscal year 2014. Fiscal year 2008 was left out of this cohort as it was the first year that registrants were required to report the 510(k) number on their listings and, therefore, an unusually high number of listings were created. An average of 5,231 510(k)s have been listed each year since 2008.

For further Information Contact:
Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867. PRAsstaff@fda.hhs.gov.
Because listing outside of the annual requirement is voluntary, FDA estimates that annually 78 percent of 510(k)s will continue to be listed outside of the annual requirement. FDA estimates that 4,080 510(k)s may be listed outside of the annual registration cycle. FDA estimates that it will take approximately 15 minutes for each listing, for a total reporting burden of 1,020 hours.

FDA estimates it will have 2,033 instances of more than one party claiming to be a 510(k) holder for a specific device as part of annual registration and listing. FDA reached this estimate by identifying the number of unique 510(k) device listings entered in FURLS between fiscal years 2009 and 2014 that conflict with a listing already entered by another party (5,304), dividing that number by the number of years (6), and multiplying by the average number of parties claiming to be the 510(k) holder when there is a conflict in the current FURLS database (2.3). The draft guidance identifies potential documentation a party could submit to FDA to establish the transfer of a 510(k) clearance. FDA estimates it will take a party approximately 4 hours to locate and submit information to establish the transfer of the 510(k) clearance, resulting in 8,132 burden hours for those 2,033 parties claiming to be 510(k) holders. FDA reached this estimate based on its expectation of the amount of time it will take a party to locate the information, copy it, and submit a copy to FDA.

The burden estimate does not include the maintenance of records used to document transferring a premarket notification (510(k)) clearance. Based on available information, FDA believes that the maintenance of these records is a usual and customary part of normal business activities. For example, in the ordinary course of business, supporting documents should be kept to verify asset information for calculating the annual depreciation or calculating gain or loss on sale of an asset on a business’s tax return. Therefore, this recordkeeping requirement creates no additional paperwork burden.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 807 (registration and listing) are approved under OMB control number 0910–0625; the collections of information in 21 CFR part 807 subpart E (premarket notification submission) have been approved under OMB control number 0910–0120, and collections of information in 21 CFR part 807 subpart D (premarket notification submission) have been approved under OMB control number 0910–0617.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Advisory Committee on Research on Women’s Health.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

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

Name of Committee: Advisory Committee

Closed: April 17, 2018, 2:30 p.m. to 4:45 p.m.

Agenda: To evaluate the Sex/Gender

Open: April 18, 2018, 9:00 a.m. to 1:30 p.m.

Agenda: Opening Remarks, Director’s

Report, NIH Legislative Update, Strategic

Place: National Institutes of Health,

Planning Update, and Scientific Presentations.

Building 31, 6th Floor, Conference Room 10,

31 Center Drive, Bethesda, MD 20892.

Contact Person: Elizabeth Spencer, R.N.,

[FR Doc. 2018–04955 Filed 3–12–18; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Dated: March 6, 2018.

Michelle Trout, Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552(b)(4) and 552(b)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning