TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN 1

<table>
<thead>
<tr>
<th>Guidance recommendations</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>Meeting Requests:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CDER</td>
<td>1,319</td>
<td>2.31</td>
<td>3,058</td>
<td>10</td>
<td>30,580</td>
</tr>
<tr>
<td>CBER</td>
<td>301</td>
<td>1.21</td>
<td>363</td>
<td>10</td>
<td>3,630</td>
</tr>
<tr>
<td>Subtotal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>34,210</td>
</tr>
<tr>
<td>Information Packages:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CDER</td>
<td>1,149</td>
<td>2.19</td>
<td>2,522</td>
<td>18</td>
<td>45,396</td>
</tr>
<tr>
<td>CBER</td>
<td>187</td>
<td>1.12</td>
<td>210</td>
<td>18</td>
<td>3,780</td>
</tr>
<tr>
<td>Subtotal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>49,176</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>83,386</td>
</tr>
</tbody>
</table>

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

Our estimated burden for the information collection reflects an overall increase since the previous OMB approval. We attribute this adjustment to an increase in the number of meeting requests and information packages received over the last few years.

Based on Agency data, we estimate 1,319 sponsors and applicants (respondents) request 3,058 formal meetings with CDER annually, and 301 respondents request 363 formal meetings with CBER annually regarding the development and review of a PDUFA product. The hours per response, which is the estimated number of hours that a respondent spends preparing the information to be submitted with a meeting request in accordance with the guidance, is estimated to be 10 hours. We expect it takes this amount of time to gather and copy brief statements about the product as well as a description of the purpose and details of the meeting.

Also consistent with Agency data, we estimate 1,149 respondents submitted 2,522 information packages to CDER annually, and 187 respondents submitted 210 information packages to CBER annually, prior to a formal meeting regarding the development and review of a PDUFA product. We estimate 18 hours is needed to prepare the information package in accordance with the guidance.

Dated: July 5, 2018.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2018–14800 Filed 7–10–18; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2012–N–0253]
Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Adverse Drug and Biological Product Experience Reporting and Recordkeeping
AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA’s postmarketing adverse drug experience reporting and recordkeeping requirements.

DATES: Submit either electronic or written comments on the collection of information by September 10, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 10, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of September 10, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions
Submit electronic comments in the following way:
• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:
• Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and
and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRASStaff@fda.hhs.gov.

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.

Postmarketing Adverse Drug and Biological Product Experience Reporting and Recordkeeping

OMB Control Number 0910–0230—Extension

Sections 201, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 352, 355, and 371) require that marketed drugs be safe and effective. To monitor the safety and efficacy of drugs that are on the market, FDA must be promptly informed of adverse experiences associated with the use of marketed drugs. FDA issued regulations at §§ 310.305 and 314.80 (21 CFR 310.305 and 314.80) to implement reporting and recordkeeping requirements on the drug industry that would enable FDA to take the action necessary to protect the public health from adverse drug experiences.

All applicants who have received marketing approval of drug products are required to report to FDA serious, unexpected adverse drug experiences (15-day “Alert reports”), as well as followup reports (§ 314.80(c)(1)). This includes reports of all foreign or domestic adverse experiences as well as adverse drug experiences reported to the FDA by nonapplicants.

Under § 314.80(c)(2), applicants must provide periodic reports of adverse drug experiences. A periodic report includes, for the reporting interval, reports of serious, unexpected adverse drug experiences and all nonserious adverse drug experiences and an index of these reports, a narrative summary and analysis of adverse drug experiences, an analysis of the 15-day “Alert reports” submitted during the reporting interval, and a history of actions taken because of adverse drug experiences. Under § 314.80(i), applicants must keep for 10 years records of all adverse drug experience reports known to the applicant.

For marketed prescription drug products without approved new drug applications or abbreviated new drug applications, manufacturers, packers, and distributors are required to report to FDA serious, unexpected adverse drug experiences as well as followup reports (§ 310.305(c)). Section 310.305(c)(5) pertains to the submission of followup reports to reports forwarded to the manufacturers, packers, and distributors by FDA. Under § 310.305(g), each manufacturer, packer, and distributor shall maintain for 10 years records of all adverse drug experiences required to be reported.

The primary purpose of FDA’s adverse drug experience reporting system is to enable identification of signals for potentially serious safety problems with marketed drugs. Although premarket testing discloses a general safety profile of a new drug’s comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed drug provide the opportunity to collect information on rare, latent, and long-term effects. Signals are obtained from patients, treating physicians, foreign regulatory agencies, and clinical investigators. Information derived from the adverse drug experience reporting system contributes directly to increased...
public health protection because the information enables FDA to make important changes to the product’s labeling (such as adding a new warning), to make decisions about risk evaluation and mitigation strategies or the need for postmarketing studies or clinical trials, and when necessary, to initiate removal of a drug from the market.

Respondents to this collection of information are manufacturers, packers, distributors, and applicants. The following estimates are based on FDA’s knowledge of adverse drug experience reporting, including the time needed to prepare the reports and the number of reports submitted to the Agency.

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

**TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN 1**

<table>
<thead>
<tr>
<th>21 CFR section</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>310.305(c)(5)</td>
<td></td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>314.80(c)(1)(ii)</td>
<td></td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>314.80(c)(2)</td>
<td></td>
<td>810</td>
<td>17.19</td>
<td>60</td>
<td>835,434</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>835,442</td>
</tr>
</tbody>
</table>

1 The reporting burden for § 310.305(c)(1), (2), and (3), and § 314.80(c)(1)(i) and (ii) is covered under OMB control number 0910–0291.

**TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN 1**

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>310.305(g)</td>
<td></td>
<td>25</td>
<td>1</td>
<td>25</td>
<td>16</td>
</tr>
<tr>
<td>314.80(j)</td>
<td></td>
<td>352</td>
<td>1,870</td>
<td>658,240</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10,532,240</td>
</tr>
</tbody>
</table>

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

The burden associated with table 2 has increased due to the electronic Safety Reporting Rule that mandated sponsors to submit ALL reports electronically by September 2016. Prior to this date, FDA did not enter all individual report data in document tracking systems or count some types of paper-based nonexempted reports (i.e., those describing adverse events that are both nonserious and previously labeled). With required electronic reporting of all reports and each report counted separately, the total number of records and required recordkeeping also increased.


Leslie Kux,
Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2018–N–1917]

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on August 3, 2018, from 8 a.m. to 5 p.m.

ADDRESS: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408553.htm.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–1917. The docket will close on August 2, 2018. Submit either electronic or written comments on this public meeting by August 2, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 2, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of August 2, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before July 25, 2018, will be provided to the committees. Comments received after that date will be taken into