

Based on FDA data, we estimate that 1,480 respondents will submit 2,960 new establishment registrations annually. Based on the number of registered establishments in our database, we estimate 10,000 registrants will provide 10,000 annual reviews and updates of registration information (including expedited updates) or reviews and certifications that no changes have occurred. The estimates include the registration of establishments for both domestic and foreign manufacturers, repackers, relabelers, and drug product salvagers, and registration information submitted by anyone acting as an authorized agent for an establishment that manufactures, repacks, relabels, or salvages drugs. The estimates include an additional 80 positron emission tomography (PET) drug producers who are not exempt from registration and approximately 30 manufacturers of plasma derivatives.

We estimate that it will take 1 hour for registrants to submit initial registration information electronically for each new establishment. We also estimate that it will take approximately 30 minutes for each annual review and update of registration information (including any expedited updates) or each review and certification that no changes have occurred. The burden hour estimates above are based on our familiarity with the amount of time it takes registrants to input registration information electronically since June 2009. The estimates are an average of the time it would take to register a domestic or foreign establishment and an average of the time it would take to review registration information and update several registration items in the database or review registration information and only certify that no changes have occurred.

Based on the number of drugs listed annually since June 2009, we estimate that approximately 1,713 registrants will report 12,469 new listings annually (including the information submitted to obtain a labeler code and to reserve an NDC for future use).

Based on the number of drugs in our listing database and the current number of changes to listing information submitted, we estimate 5,300 registrants will each report 20 reviews and updates (including the information submitted to revise an NDC) for a total of 106,000 annually.

The estimates for the number of drug listings include both domestic and foreign listings, listings submitted by registrants for products sold under their own names as well as products intended for private label distribution, and information submitted related to an

NDC and to obtain a labeler code. The estimate for the number of drugs subject to the listing requirements includes PET drugs and approximately 30 plasma derivatives. The estimates for the number of June and December reviews and updates of listing information include the number of changes to drug characteristics pertaining to the drug product code to obtain a new NDC and the reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii) (21 CFR 314.81(b)(3)(iii)).

Based on our familiarity with the time required to input listing information electronically since June 2009, we estimate that it will take registrants 1 hour and 30 minutes to submit information electronically for each drug they list for the first time (for both foreign and domestic registrant listings). These estimates are an average of the time it will take manufacturers, repackers, relabelers, and drug product salvagers, with drug product salvagers taking considerably less time than manufacturers. The estimates include the time for submitting the content of labeling and other labeling in electronic format. (For drugs subject to an approved marketing application, the electronic submission of the content of labeling under § 314.50(l)(1)(i) is approved under OMB control number 0910-0001.) We also estimate that it will take 45 minutes for each June and December review and update. These estimates represent the average amount of time to review and update listing information or to review and certify that no changes have occurred. The estimates include the time for submitting any labeling for each drug, changes to the drug's characteristics submitted for a new NDC, and reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii).

In 2009, to help respondents transition to the current electronic reporting requirements, FDA issued the guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing." The document provides guidance to industry on the statutory requirement to submit electronically drug establishment registration and drug listing information. The guidance describes the types of information to include for purposes of drug establishment registration and drug listing and how to prepare and submit the information in an electronic format (Structured Product Labeling (SPL) files) that FDA can process, review, and archive. The burden attributed to the guidance includes the preparation of an SOP for

creating and uploading the SPL file. Although most firms will already have prepared an SOP for the electronic submission of drug establishment registration and drug listing information, each year additional firms will need to create an SOP. As reflected in table 2, FDA estimates that approximately 1,000 firms will expend 40 hours to prepare, review, and approve an SOP, for a total of 40,000 hours annually.

Cumulatively, the information collection reflects a decrease of 3,295 in both annual responses and burden hours. This adjustment results from eliminating burden previously attributable to guidance recommendations for creating drug establishment registration and drug listing files for electronic submission. Because electronic registration and listing is now mandatory, we believe respondents have since developed and implemented SOPs consistent with meeting the technical format specifications set forth in the regulations and we no longer attribute burden to this activity.

Dated: November 5, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-24440 Filed 11-7-18; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2012-N-0253]**

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) 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 December 10, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of

Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–0230. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Postmarketing Adverse Drug and Biological Product Experience Reporting and Recordkeeping**

*OMB Control Number 0910–0230—Revision*

Sections 201, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 352, 355, and 371) (FD&C Act) 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. We have issued regulations at §§ 310.305 and 314.80 (21 CFR 310.305 and 314.80) to implement reporting and recordkeeping requirements that enable us to take necessary action to protect the public health from adverse drug experiences.

All applicants who have received marketing approval of drug products are required to report serious, unexpected adverse drug experiences (15-day “Alert reports”), as well as follow-up reports (§ 314.80(c)(1)). This includes reports of all foreign or domestic adverse experiences as well as those based on information from applicable scientific literature and certain reports from postmarketing studies. Section 314.80(c)(1)(iii) pertains to such reports submitted 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, expected 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(j), 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 follow-up reports (§ 310.305(c)). Section 310.305(c)(5) pertains to the submission of follow-up 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.

Section 760 of the Act (21 U.S.C. 379aa), also provides for mandatory safety reporting for over-the-counter (OTC) human drug products not subject to applications approved under section 505 of the Act (new drug applications or abbreviated new drug applications). These requirements apply to all OTC drug products marketed without an approved application, including those marketed under the OTC Drug Monograph Review process (whether or not subject to a final monograph), those marketed outside the monograph system, and including those that have been discontinued from marketing but for which a report of an adverse event was received. Under 21 CFR part 329.100 respondents must submit section 760 reports in an electronic format.

To assist respondents with implementation of section 760 we developed the guidance document entitled “Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application.” The guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) of the FD&C Act (21 U.S.C. 379aa(b)(1)), including follow-up reports under 760(c)(2) of the FD&C Act (21 U.S.C. 379aa(c)(2)), and how to submit these reports.

Section 760(e) of the FD&C Act (21 U.S.C. 379aa(e)) also requires that responsible persons maintain records of nonprescription adverse event reports, whether or not the event is serious, for a period of 6 years. The guidance recommends that respondents maintain records of efforts to obtain the minimum

data elements for a report of a serious adverse drug event and any follow-up reports. The information collection associated with the guidance is currently approved under OMB Control No. 0910–0636, however we are now consolidating it into this collection.

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 a variety of sources, including reports 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 us 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.

In the **Federal Register** of July 11, 2018 (83 FR 32132) we published a 60-day notice requesting public comment on the proposed collection of information approved under OMB Control No. 0910–0230. One comment from an anonymous source referred us to attachments that were not successfully transmitted. We are therefore unable to address this comment. In the **Federal Register** of August 15, 2018 (83 FR 40520) we published a 60-day notice requesting public comment on the collection of information approved under OMB Control No 0910–0636. No comments were received.

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

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1 2</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
310.305(c)(5) .....	3	1	3	1	3
314.80(c)(1)(iii) .....	5	1	5	1	5
314.80(c)(2) .....	810	17.19	13,923.90	60	835,434
Reports of serious adverse drug events (21 U.S.C. 379aa(b) and (c)) .....	283	687.099	194,449	6	1,166,694
<b>Total</b> .....					<b>2,002,136</b>

<sup>1</sup> 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 0910–0645.

<sup>2</sup> The capital costs or operating and maintenance costs associated with this collection of information are approximately \$25,000 annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1 2</sup>

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
310.305(g) .....	25	1	25	16	400
314.80(j) .....	352	1,870	658,240	16	10,531,840
Recordkeeping (21 U.S.C. 379aa(e)(1)) .....	300	885.6667	265,700	8	2,125,600
<b>Total</b> .....					<b>12,657,840</b>

<sup>1</sup> There are no capital costs or operating costs associated with this collection of information.

<sup>2</sup> There are maintenance costs of approximately \$22,000 annually.

Based on submissions received we have increased our burden estimate for reporting under part 314.80(c)(2) and recordkeeping under part 314.80(j). Additionally, and as previously stated, we are consolidating burden associated with reporting and recordkeeping under section 760 of the FD&C Act. Based on our records, we received 194,449 total annual reports from approximately 283 respondents for nonprescription drugs marketed without an approved application. We estimate each submission takes approximately 6 hours to prepare and submit. We estimate that there are 265,700 records per year maintained by approximately 300 respondents, and that it takes 8 hours to maintain each record.

Dated: November 2, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–24442 Filed 11–7–18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Drug Abuse; 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 552b(c)(4) and 552b(c)(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:* National Institute on Drug Abuse Special Emphasis Panel; R13 Conference Grant Review.

*Date:* November 14, 2018.

*Time:* 12:00 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4228, MSC 9550, Bethesda, MD 20892, 301–827–5842, [ramadanir@mail.nih.gov](mailto:ramadanir@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute on Drug Abuse Special Emphasis Panel; Multi-site Clinical Trials.

*Date:* November 16, 2018.

*Time:* 12:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4228, MSC 9550, Bethesda, MD 20892, 301–827–5842, [ramadanir@mail.nih.gov](mailto:ramadanir@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 2, 2018.

**Natasha M. Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018–24470 Filed 11–7–18; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; 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