information. Two comments were received but neither responded to any of the four information collection topics solicited and are therefore not addressed by the Agency.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 511.1(b)(4) | 263 | 5.30 | 1,395 | 1 | 1,395 |
| 511.1(b)(5) | 263 | .26 | 69 | 8 | 552 |
| 511.1(b)(6) | 263 | .01 | 2 | 1 | 2 |
| 511.1(b)(8)(ii) | 263 | .06 | 15 | 2 | 30 |
| 511.1(b)(9) | 263 | .06 | 15 | 8 | 120 |
| Total | | | | | 2,099 |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| 511.1(a)(3) | 263 | 2.07 | 545 | 1 | 545 |
| 511.1(b)(3) | 263 | 5.30 | 1,395 | 1 | 1,395 |
| 511.1(b)(7)(ii) | 263 | 5.30 | 1,395 | 3.5 | 4,882.5 |
| 511.1(b)(8)(i) | 263 | 5.30 | 1,395 | 3.5 | 4,882.5 |
| Total | | | | | 11,705 |

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

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on informal Agency communication with industry. Based on the number of sponsors subject to animal drug user fees, FDA estimates that there are 263 respondents. We use this estimate consistently throughout the table and calculate the ''annual frequency per respondent'' by dividing the total annual responses by number of respondents. Additional information needed to make a final calculation of the total burden hours (*i.e.,* the number of respondents, the number of recordkeepers, the number of NCIEs received, etc.) is derived from Agency records.

Dated: *June 17, 2015.*

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–15320 Filed 6–22–15; 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 Experience Reporting and Recordkeeping Biological Products

**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 July 22, 2015.

**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.* 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:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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 Experience Reporting

*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. In order to know whether drugs that are not safe and effective are on the market, FDA must be promptly informed of adverse experiences associated with the use of marketed drugs. In order to help ensure this, FDA issued regulations at §§ 310.305 and 314.80 (21 CFR 310.305 and 314.80) to impose 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 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 non-applicants.

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(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 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(f), 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 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 FDA to make important changes to the product's labeling (such as adding a new warning), decisions about risk evaluation and mitigation strategies or the need for postmarket studies or clinical trials, and when necessary, to initiate removal of a drug from the market.

In the **Federal Register** of March 12, 2015 (80 FR 13009), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

| 21 CFR section | No. of respondents | No. 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) | 724 | 19.33 | 13,996 | 60 | 839,760 |
| Total | | | | | 839,768 |

[1] The reporting burden for § 310.305(c)(1), (c)(2), and (c)(3), and § 314.80(c)(1)(i) and (c)(1)(ii) is covered under OMB Control No. 0910–0291.
[2] 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 [1] [2]

| 21 CFR section | No. of recordkeepers | No. of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| 310.305(f) | 25 | 1 | 25 | 16 | 400 |
| 314.80(i) | 724 | 508 | 367,959 | 16 | 5,887,344 |
| Total | | | | | 5,887,744 |

[1] There are no capital costs or operating costs associated with this collection of information.
[2] There are maintenance costs of approximately $22,000 annually.

Dated: June 17, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–15319 Filed 6–22–15; 8:45 am]

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