procurement-service-contract-inventories. GSA has posted its FY 2016 and FY 2017 inventory analyses and its planned analyses of FY 2018 and FY 2019 actions at the following location: *http://www.gsa.gov/gsasci.*

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2020–19297 Filed 8–31–20; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1064]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Petitions for Exemption From Preemption

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: Submit written comments (including recommendations) on the collection of information by October 1, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0277. 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.*

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.

State Petitions for Exemption From Preemption—21 CFR 100.1(d)

OMB Control Number 0910–0277—Extension

Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343–1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard-of-identity requirements. Section 100.1(d) (21 CFR 100.1(d)) sets forth the information a State is required to submit in such a petition. The information required under § 100.1(d) enables FDA to determine whether the State food labeling or standard-of-identity requirement satisfies the criteria of section 403A(b) of the FD&C Act for granting exemption from Federal preemption.

Description of Respondents: The respondents to this collection of information are State and local governments who regulate food labeling and standards of identity.

In the **Federal Register** of May 22, 2020 (85 FR 31190), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information 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
100.1(d)	1	1	1	40	40

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

The reporting burden for § 100.1(d) is minimal because petitions for exemption from preemption are seldom submitted by States. In the last 3 years, we have received one new petition for exemption from preemption; therefore, we estimate that one or fewer petitions will be submitted annually.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–19256 Filed 8–31–20; 8:45 am]

BILLING CODE 4164–01–Ps

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0231]

Agency Information Collection Activities: Proposed Collection; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

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 proposed extension of the collection of information concerning requirements relating to FDA's Adverse Experience Reporting System (FAERS) for licensed biological products, and general records associated with the manufacture and distribution of biological products.

DATES: Submit either electronic or written comments on the collection of information by November 2, 2020.

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 November 2, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 2, 2020. 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 identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–N–0231 for ''Adverse Experience Reporting for Licensed Biological Products; and General Records.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–45, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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.

Adverse Experience Reporting For Licensed Biological Products; and General Records—21 CFR Part 600

OMB Control Number 0910–0308—Extension

Under the Public Health Service Act (42 U.S.C. 262), FDA may only approve a biologics license application for a biological product that is safe, pure, and potent. When a biological product is approved and enters the market, the product is introduced to a larger patient population in settings different from clinical trials. New information generated during the postmarketing period offers further insight into the benefits and risks of the product, and evaluation of this information is important to ensure its safe use. FDA issued the Adverse Experience Reporting (AER) requirements in part 600 (21 CFR part 600) to enable FDA to take actions necessary for the protection of the public health in response to reports of adverse experiences related to licensed biological products. The primary purpose of FDA's FAERS is to identify potentially serious safety problems with licensed biological products. Although premarket testing discloses a general safety profile of a biological product's comparatively

common adverse effects, the larger and more diverse patient populations exposed to the licensed biological product provides the opportunity to collect information on rare, latent, and long-term effects. In addition, production and/or distribution problems have contaminated biological products in the past. AER reports are obtained from a variety of sources, including manufacturers, patients, physicians, foreign regulatory agencies, and clinical investigators. Identification of new and unexpected safety issues through the analysis of the data in FAERS contributes directly to increased public health protection. For example, evaluation of these safety issues enables FDA to take focused regulatory action. Such action may include, but is not limited to, important changes to the product's labeling (such as adding a new warning), coordination with manufacturers to ensure adequate corrective action is taken, and removal of a biological product from the market when necessary.

Section 600.80(c)(1) requires licensed manufacturers or any person whose name appears on the label of a licensed biological product to report each adverse experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days of initial receipt of the information by the licensed manufacturer. These reports are known as postmarketing 15-day Alert reports. This section also requires licensed manufacturers to submit any followup reports within 15 calendar days of receipt of new information or as requested by FDA, and if additional information is not obtainable, to maintain records of the unsuccessful steps taken to seek additional information. In addition, this section requires that a person who submits an adverse action report to the licensed manufacturer, rather than to FDA, maintain a record of this action. Section 600.80(e) requires licensed manufacturers to submit a 15-day Alert report for an adverse experience obtained from a postmarketing clinical study only if the licensed manufacturer concludes that there is a reasonable possibility that the product caused the adverse experience. Section 600.80(c)(2) requires licensed manufacturers to report each adverse experience not reported in a postmarketing 15-day Alert report at quarterly intervals, for 3 years from the date of issuance of the biologics license, and then at annual intervals. The majority of these periodic reports are submitted annually, since a large percentage of currently licensed biological products have been licensed longer than 3 years. Section 600.80(k) requires licensed manufacturers to maintain for a period of 10 years records of all adverse experiences known to the licensed manufacturer, including raw data and any correspondence relating to the adverse experiences. Section 600.81 requires licensed manufacturers to submit, at an interval of every 6 months, information about the quantity of the product distributed under the biologics license, including the quantity distributed to distributors. These distribution reports provide FDA with important information about products distributed under biologics licenses, including the quantity, certain lot numbers, labeled date of expiration, the fill lot numbers for the total number of dosage units of each strength or potency distributed (*e.g.,* 50,000 per 10-milliliter vials), and date of release. FDA may require the licensed manufacturer to submit distribution reports under this section at times other than every 6 months. Under § 600.82(a), an applicant of a biological product or blood and blood component must notify FDA of a permanent discontinuance of manufacture or an interruption in manufacturing or disruption in supply, as applicable. Under §§ 600.80(h)(2) and 600.81(b)(2), a licensed manufacturer may request a temporary waiver for the requirements under §§ 600.80(h)(1) and 600.80(b)(1), respectively. Requests for waivers must be submitted in accordance with § 600.90. Under § 600.90, a licensed manufacturer may submit a waiver request for any requirements that apply to the licensed manufacturer under §§ 600.80 and 600.81. A waiver request submitted under § 600.90 must include supporting documentation.

Manufacturers of biological products for human use must keep records of each step in the manufacture and distribution of a product, including any recalls. These recordkeeping requirements serve preventative and remedial purposes by establishing accountability and traceability in the manufacture and distribution of products. These requirements also enable FDA to perform meaningful inspections. Section 600.12 requires, among other things, that records be made concurrently with the performance of each step in the manufacture and distribution of products. These records must be retained for no less than 5 years after the records of manufacture have been completed or 6 months after the latest expiration date for the individual product, whichever represents a later date. In addition, under § 600.12, manufacturers must maintain records relating to the sterilization of equipment and supplies, animal necropsy records, and records in cases of divided manufacturing responsibility with respect to a product. Under § 600.12(b)(2), manufacturers are also required to maintain complete records pertaining to the recall from distribution of any product. Furthermore, § 610.18(b) (21 CFR 610.18(b)) requires, in part, that the results of all periodic tests for verification of cultures and determination of freedom from extraneous organisms be recorded and retained. The recordkeeping requirements for 21 CFR 610.12(g), 610.13(a)(2), 610.18(d), 680.2(f) and 680.3(f) are approved under OMB control number 0910–0139.

Respondents to this collection of information include manufacturers of biological products (including blood and blood components) and any person whose name appears on the label of a licensed biological product. In table 1, the number of respondents is based on the estimated number of manufacturers that are subject to those regulations or that submitted the required information to the Center for Biologics Evaluation and Research and Center for Drugs Evaluation and Research, FDA, in fiscal year (FY) 2019. Based on information obtained from the FDA's database system, there were 103 manufacturers of biological products. This number excludes those manufacturers who produce Whole Blood, components of Whole Blood, or in-vitro diagnostic licensed products, because of the exemption under § 600.80(m). The total annual responses are based on the number of submissions received by FDA in FY 2019. There were an estimated 169,334 15-day Alert reports, 184,265 periodic reports, and 789 lot distribution reports submitted to FDA. The number of 15-day Alert reports for postmarketing studies under § 600.80(e) is included in the total number of 15-day Alert reports. FDA received 63 requests from 40 manufacturers for waivers under § 600.90 (including §§ 600.80(h)(2) and 600.81(b)(2)), of which 61 were granted. The hours per response are based on FDA experience. The burden hours required to complete the MedWatch Form (Form FDA 3500A) for § 600.80(c)(1), (e), and (f) are reported under OMB control number 0910–0291.

FDA estimates the burden of this collection of information 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 (in hours)	Total hours
600.80(c)(1), 600.80(d), 600.80(e); postmarketing 15-day Alert Reports	103	1,644.02	169,334	1	169,334
600.82; notification of discontinuance or interruption in manufacturing	21	1.67	35	2	70
600.80(c)(2) periodic adverse experience reports	103	1,788.98	184,265	28	5,159,420
600.81; distribution reports	117	6.744	789	1	789
600.80(h)(2), 600.81(b)(2), 600.90; waiver requests	40	1.575	63	1	63
Total					5,329,676

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

In table 2 the number of respondents is based on the number of manufacturers subject to those regulations. Based on information obtained from FDA's database system, there were 212 licensed manufacturers of biological products in FY 2019. However, the number of recordkeepers listed for § 600.12(a) through (e), excluding (b)(2), is estimated to be 109. This number excludes manufacturers of blood and blood components because their burden hours for recordkeeping have been reported under § 606.160 in OMB control number 0910–0116. The total annual records is based on the annual average of lots released in FY 2019 (6,670), number of recalls made (735), and total number of adverse experience reports received (305,951) in FY 2019. The hours per record are based on FDA experience.

FDA estimates the burden of this recordkeeping as follows:

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper (in hours)	Total hours
600.12 [2]; maintenance of Records	109	61.19	6,670	32	213,440
600.12(b)(2); recall records	212	3,467	735	24	17,640
600.80(c)(1) & 600.80(k); AER records	103	3,433	353,599	1	353,599
Total					584,679

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The recordkeeping requirements in § 610.18(b) are included in the estimate for § 600.12.

The burden for this information collection has changed since the last OMB approval. The reporting and recordkeeping burden has increased mostly due to an increase in the number of AER reports submitted to FDA and the associated recordkeeping with these reports.

Dated: August 26, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–19239 Filed 8–31–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–E–1918; FDA–2019–E–1934; and FDA–2019–E–1942]

Determination of Regulatory Review Period for Purposes of Patent Extension; LUMOXITI

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for LUMOXITI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by November 2, 2020. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 1, 2021. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 November 2, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 2, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery