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

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 Nos. FDA–2019–E–1918; FDA–2019–E–1934; and FDA–2019–E–1942 For ''Determination of Regulatory Review Period for Purposes of Patent Extension; LUMOXITI.'' 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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product LUMOXITI (moxetumomab pasudotox-tdfk). LUMOXITI is indicated for the treatment of adult patients with relapsed or refractory hairy cell leukemia who received at least two prior systemic therapies, including treatment with a purine nucleoside analog. Subsequent to this approval, the USPTO received patent term restoration applications for LUMOXITI (U.S. Patent Nos. 8,809,502; 9,580,461; and 10,072,083) from the U.S. Department of Health and Human Services, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 21, 2019, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of LUMOXITI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for LUMOXITI is 4,320 days. Of this time, 4,092 days occurred during the testing phase of the regulatory review period, while 228 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i))*

became effective: November 17, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 17, 2006.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* January 29, 2018. FDA has verified the applicant's claim that the biologics license application (BLA) for LUMOXITI (BLA 761104) was initially submitted on January 29, 2018.

3. *The date the application was approved:* September 13, 2018. FDA has verified the applicant's claim that BLA 761104 was approved on September 13, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 159 days, 163 days, and 2 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 26, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–19214 Filed 8–31–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0906–0053—Extension]

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Coronavirus 2019 Data Report

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than November 2, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Coronavirus 2019 Data Report OMB No. 0915-0906–0053—Extension.

Abstract: This information collection request was previously approved by the Office of Management and Budget (OMB) on June 11, 2020, as an emergency clearance (OMB No.: 0906–0053). HRSA is currently undergoing the standard Paperwork Reduction Act process for normal OMB approval.

HRSA's Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low income people with HIV. Nearly two-thirds of clients (patients) live at or below 100 percent of the federal poverty level and approximately three-quarters of RWHAP clients are racial/ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of safety net providers who deliver high quality direct health care and support services to over half a million people with HIV—more than 50 percent of all people with diagnosed HIV in the United States.

FY 2020 Coronavirus Aid, Relief, and Economic Security Act

On March 27, 2020, the President signed into law the ''Coronavirus Aid, Relief, and Economic Security Act'' (CARES Act). The CARES Act appropriated $90 million to HRSA's RWHAP to prevent, prepare for, and respond to coronavirus disease 2019 (COVID–19). This funding supports 581 RWHAP recipients across the country, including city/county health departments, state health departments, health clinics, community-based organizations, and AIDS Education and Training Centers in their efforts to help prevent or minimize the impact of COVID–19 on RWHAP clients. The award provides RWHAP recipients the flexibility to meet evolving COVID–19 needs in their respective communities, including extending operational hours, increasing staffing hours, purchasing additional equipment, enhancing workforce training and capacity development, and providing critical services to people with HIV during this pandemic, such as home-delivered meals, emergency housing, and transportation.

HRSA identified a new data collection need to support HRSA's requirement to monitor and report quarterly to the Secretary of HHS the COVID–19 activities conducted with the CARES Act funding. The COVID–19 Data Report module will provide monthly reporting on the types of services provided and number of people served for the treatment or prevention of COVID–19 among RWHAP clients (and immediate household members in limited circumstances). This module will be required for all providers (regardless of whether they are recipients or subrecipients) who receive CARES Act RWHAP funding.

Need and Proposed Use of the Information: HRSA proposes that service providers who receive CARES Act RWHAP funding report aggregate information on the number of clients and immediate household members tested for COVID–19, the number of clients newly diagnosed (or presumed