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. 6200, 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 or biological 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 drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 drug 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 drug product, DAYBUE (trofinetide). DAYBUE is indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older. Subsequent to this approval, the USPTO received a patent term restoration application for DAYBUE (U.S. Patent No. 9,212,204) from Acadia Pharmaceuticals Inc., and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated January 24, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of DAYBUE 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 DAYBUE is 5,106 days. Of this time, 4,864 days occurred during the testing phase of the regulatory review period, while 242 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* March 19, 2009. The applicant claims December 20, 2012, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 19, 2009, which was 30 days after FDA receipt of an earlier IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* July 12, 2022. FDA has verified the applicant's claim that the new drug application (NDA) for DAYBUE (NDA 217026) was initially submitted on July 12, 2022.

3. *The date the application was approved:* March 10, 2023. FDA has verified the applicant's claim that NDA 217026 was approved on March 10, 2023.

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 application for patent extension, this applicant seeks 1,443 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: September 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21941 Filed 9–24–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2381]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Recall Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 25, 2024.

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 0910–0432. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Medical Device Recall Authority

OMB Control Number 0910–0432—Extension

This collection of information helps to implement section 518(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360h(e)) and regulations in part 810 (21 CFR part 810) which set forth mandatory medical device recall authority provisions. Section 518(e) of the FD&C Act provides FDA with the authority to issue an order requiring an appropriate person, including manufacturers, importers, distributors, and retailers of a device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious, adverse health consequences or death, to: (1) Immediately cease distribution of such device and (2) immediately notify health professionals and device-user facilities of the order and to instruct such professionals and facilities to cease use of such device.

The person named in the order will have an opportunity for a regulatory hearing or to provide a written request to FDA asking that the order be modified, vacated, or amended. FDA may later amend the order to require a mandatory recall of the device. FDA currently allows for these requests, along with other reports and records concerning mandatory recalls, to be submitted to the Agency using electronic methods including email and FDA's eSubmitter program (*https://www.fda.gov/industry/fda-esubmitter*).

FDA issued part 810 to implement the provisions of section 518 of the FD&C Act. The information collected under the mandatory recall authority provisions is used by FDA to implement mandatory recalls.

Description of Respondents: Respondents for this collection of information are firms, including medical device manufacturers, importers, distributors, and retailers, that have been issued a cease distribution and notification order or mandatory recall order in accordance with the provisions under part 810, during the timeframe(s) specified in the order.

In the **Federal Register** of June 5, 2024 (89 FR 48174), 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]

Collection activity—21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of information to FDA about device distribution and remedial actions to be taken, as specified in the order—810.10(d)	2	1	2	8	16
Submission of a written request for regulatory hearing—810.11(a)	1	1	1	8	8
Submission of a written request to FDA asking that the order be modified or vacated—810.12(a–b)	1	1	1	8	8
Submission of a strategy for compliance with cease distribution and notification or mandatory recall order—810.14	2	1	2	16	32
Submission of periodic status reports to FDA to enable the Agency to assess progress in compliance with the order—810.16(a–b)	2	12	24	40	960
Submission of a written request to FDA to certify compliance with and terminate the order—810.17(a)	2	1	2	8	16
Total Hours					1,040

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Collection activity—21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Documentation of communications to appropriate person(s)—810.15(b)	2	1	2	8	16

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Collection activity—21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual responses	Average burden per disclosure	Total hours
Communications to appropriate person(s) concerning a cease distribution and notification or mandatory recall order—810.15(a)–(c)	2	1	2	12	24
Follow up communications to appropriate person(s) who fail to respond to the initial communication—810.15(d)	2	1	2	4	8

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Collection activity—21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual responses	Average burden per disclosure	Total hours
Notifications provided by recipients of communications to appropriate consignees—810.15(e)	10	1	10	1	10
Total					42

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

The burden per response, burden per recordkeeping, and burden per disclosure estimates are based on FDA's recent experience with voluntary recalls under 21 CFR part 7. Based on an analysis of cease distribution and notification and mandatory recall order activity over the last 3 years, FDA expects no more than two of such actions per year as a conservative estimate.

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: September 19, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21904 Filed 9–24–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–E–2829]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ELUCIREM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug 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 25, 2024. 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 24, 2025. 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. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 25, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2023–E–2829 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ELUCIREM.'' 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