of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *OPREinfocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The purpose of the SRAE program is to educate youth on how to voluntarily refrain from nonmarital sexual activity and prevent other youth risk behaviors. Data will continue to be used to determine if the SRAE grant recipients are meeting performance benchmarks related to their program's mission and priorities.

The SRAE PAS collects performance measures data from SRAE grant recipients, program providers, and participants. The data include information on program structure, cost, and support for implementation; program attendance, reach, and dosage; the characteristics of youth involved in programming; youth sexual and other risky behavior prior to program participation; and youth sexual and other risky behavior intentions at program exit. The performance measures help the ACF program office and grant recipients to monitor and report on progress in implementing SRAE programs and inform technical assistance.

Some of the performance measures data come from youth participants through surveys SRAE grant recipients administer at program entry and exit. There are separate versions of the entry and exit surveys for middle school youth, which exclude some of the more sensitive items that are included in the versions for high school and older youth. There is also a shorter version of the entry survey for programs conducting impact studies, to reduce the burden on participants in those programs who are likely responding to other surveys as part of their impact study. Although there was a version of the exit survey for programs conducting impact studies in the past, it was removed through the previous OMB request, and youth in these programs now complete the same version of the exit survey as other youth.

ACF is currently working on future revisions to this information collection, which will be submitted to OMB for review and approval in 2025. Notices inviting public comment on those revisions will accompany that request, but comments received in response to this notice could also inform those revisions.

Respondents: General Departmental (GDSRAE), State (SSRAE), and Competitive (CSRAE) grant recipients, their subrecipients, and program participants.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total/ annual burden (in hours)
(1) Participant Entry Survey:				
GDSRAE participants	126,130	1	0.1333	16,813
SSRAE participants	317,633	1	0.1333	42,340
CSRAE participants	20,136	1	0.1333	2,684
(2) Participant Exit Survey:				
GDSRAE participants	100,904	1	0.1667	16,821
SSRAE participants	254,106	1	0.1667	42,360
CSRAE participants	16,109	1	0.1667	2,685
(3) Performance reporting data entry form: grant recipients:				
GDSRAE grant recipients	119	2	16	3,808
SSRAE grant recipients	39	2	16	1,248
CSRAE grant recipients	34	2	16	1,088
(4) Performance reporting data entry form: subrecipients:				
GDSRAE subrecipients	252	2	13	6,552
SSRAE subrecipients	426	2	13	11,076
CSRAE subrecipients	63	2	13	1,638

Estimated Total Annual Burden Hours: 149,113.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C 1310.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–20953 Filed 9–13–24; 8:45 am]

BILLING CODE 4184–73–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–3224, FDA–2023–E–3225, FDA–2023–E–3221, and FDA–2023–E–3223]

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

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 ORSERDU 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 a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by November 15, 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 17, 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 15, 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 Nos. FDA–2023–E–3224, FDA–2023–E–3225, FDA–2023–E–3221, and FDA–2023–E–3223 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ORSERDU.'' 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. 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, ORSERDU (elacestrant dihydrochloride). ORSERDU is indicated for treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast

cancer with disease progression following at least one line of endocrine therapy. Subsequent to this approval, the USPTO received patent term restoration applications for ORSERDU (U.S. Patent Nos. 7,612,114 and 8,399,520 filed by Eisai R&D Management Co., Ltd., and U.S. Patent Nos. 10,071,066 and 10,420,734, filed by Duke University), and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated January 30, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ORSERDU 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 ORSERDU is 2,965 days. Of this time, 2,740 days occurred during the testing phase of the regulatory review period, while 225 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:* December 17, 2014. FDA has verified the applicants' claims that the date the investigational new drug application became effective was on December 17, 2014.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* June 17, 2022. FDA has verified the applicants' claims that the new drug application (NDA) for ORSERDU (NDA 217639) was initially submitted on June 17, 2022.

3. *The date the application was approved:* January 27, 2023. FDA has verified the applicants' claims that NDA 217639 was approved on January 27, 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 the applications for patent extension, the applicants seek 724 days, 841 days, or 1,595 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 4, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20893 Filed 9–13–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1216]

Electronic Common Technical Document; Data Standards; Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Supporting Electronic Common Technical Document Version 4.0

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research are announcing support for Electronic Common Technical Document (eCTD) Version 4.0 (v4.0)-based electronic submissions.

DATES: Support for eCTDv4.0 electronic submissions begins September 16, 2024. FDA will also continue to support eCTDv3.2.2 electronic submissions. Submit either electronic or written comments at any time.

ADDRESSES: You may submit comments as follows:

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 ''Instruction.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–1216 for ''Electronic Common Technical Document; Data Standards; Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Supporting Electronic Common Technical Document Version 4.0.'' Received comments 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