Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2025–10900 Filed 6–13–25; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #: 0970–0536]

Proposed Information Collection Activity; Sexual Risk Avoidance Education Program Performance Analysis Study

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE) and the Family and Youth Services Bureau (FYSB) in the Administration for Children and Families (ACF) requests approval for a revision to a currently approved information collection activity as part of the Sexual Risk Avoidance Education (SRAE) Program Performance Analysis Study (PAS) (Office of Management and Budget (OMB) #: 0970–0536; expiration date December 31, 2025). The goal of the study is to collect, analyze and report on performance measures data for the SRAE program. The purpose of the request is to continue the ongoing data collection and submission of the performance measures by SRAE grant recipients, which includes revisions to the current performance measures. We are proposing revisions to the current performance measures to address feedback from grant recipients to simplify and clarify participant surveys and to ensure the measures meet FYSB data needs.

DATES: *Comments due* August 15, 2025. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects 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 their programs' 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.

We are proposing revisions to the current performance measures to address feedback from grant recipients to simplify and clarify participant surveys, and to ensure the measures meet FYSB data needs. The changes are expected to reduce the burden for completing the participant entry survey from eight minutes to seven minutes per response.

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 burden (in hours)	Annual burden (in hours)
(1) Participant Entry Survey:					
GDSRAE participants	185,401	1	0.1167	21,636	7,212
SSRAE participants	684,593	1	0.1167	79,892	26,631
CSRAE participants	54,914	1	0.1167	6,408	2,136
(2) Participant Exit Survey:					
GDSRAE participants	148,321	1	0.1667	24,725	8,242
SSRAE participants	547,674	1	0.1667	91,297	30,432
CSRAE participants	43,931	1	0.1667	7,323	2,441
(3) Performance reporting data entry form: grant recipients:					
GDSRAE grant recipients	108	6	16	10,368	3,456
SSRAE grant recipients	38	6	16	3,648	1,216
CSRAE grant recipients	44	6	16	4,224	1,408
(4) Performance reporting data entry form: subrecipients:					
GDSRAE subrecipients	151	6	13	11,778	3,926
SSRAE subrecipients	266	6	13	20,748	6,916
CSRAE subrecipients	73	6	13	5,694	1,898
Estimated Total and Annual Burden Hours				287,741	95,914

Estimated Total Annual Burden Hours: 95,914.

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. 710(b)(6).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–10857 Filed 6–13–25; 8:45 am]

BILLING CODE 4184–83–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–0439]

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

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 RIVFLOZA 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 August 15, 2025. 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 December 15, 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 August 15, 2025. 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–2024–E–0439 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; RIVFLOZA.'' 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: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

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