

Authority: Social Security Act Title V 511 [42 U.S.C. 711]. As amended by Section 6101 of the Consolidated Appropriations Act, 2023 (Public Law 117–328).

Mary B. Jones,
ACF/OPRE Certifying Officer.
[FR Doc. 2023–15075 Filed 7–14–23; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Title V State Sexual Risk Avoidance Education (Office of Management and Budget #0970–0551)

AGENCY: Family and Youth Services Bureau, Administration for Children and Families, United States Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Family and Youth Services Bureau (FYSB) within the Administration on Children, Youth and Families (ACYF) is accepting mandatory

formula grant applications and state plans from states and territories for the development of and implementation for Title V State Sexual Risk Avoidance Education (SRAE) Program. The Title V State SRAE Notice of Funding Opportunity (NOFO) sets forth the application requirements for recipients. This request is to extend Office of Management and Budget (OMB) approval of the request for information. No changes are proposed.

DATES: *Comments due within 60 days of publication.* 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 infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:
Description: The Title V SRAE Program has mandatory, formula allotments for state and territories to apply. The application process is for states and territories to submit and for ACYF/FYSB to collect an application,

state plan, and semi-annual performance progress reports.
Purpose and Use of the Information Collection: The application and state plans will offer information about the proposed state project and it will be used as the primary basis to determine whether or not the project meets the minimum requirements of the NOFO for the grant award. The Performance Progress Reports are collected semi-annually and will inform the monitoring of the grantees’ program design, program evaluation, management improvement, service quality and compliance with agreed upon goals. ACYF/FYSB will use the information to assure effective service delivery for program participants. Finally, the data from this collection will be used to report outcomes and efficiencies and will provide valuable information to policy makers and key stakeholders in the development of program and research efforts.

Respondents: Thirty-eight states and nine Territories, to include, District of Columbia, Puerto Rico, Virgin Islands, Guam, American Samoa, Northern Mariana Islands, the Federated States of Micronesia, the Marshall Islands, and Palau.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Applications	47	1	24	1,128
State Plans	47	1	40	1,880
Performance Progress Reports	47	2	16	1,504

Estimated Total Annual Burden Hours: 4,512.

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: Section 510 of the Social Security Act (42 U.S.C. 710), as amended by Section 50502 of the

Bipartisan Budget Act of 2018 (Pub. L. 115–123) and extended by Division CC, Title III, Section 303 of the Consolidated Appropriations Act, 2022 (Public Law 117–103).

Mary B. Jones,
ACF/OPRE Certifying Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2607]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that ELEVIDYS (delandistrogene moxeparovec-rokl), manufactured by Sarepta Therapeutics, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that ELEVIDYS, manufactured by Sarepta Therapeutics, Inc., meets the criteria for a priority review voucher.

ELEVIDYS is indicated for treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with confirmed mutation in the DMD gene.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs>. For further information about ELEVIDYS, go to the Center for Biologics Evaluation and Research's Approved Cellular and Gene Therapy Products website at <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>.

Dated: July 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-2562]

Agency Information Collection Activities; Proposed Collection; Comment Request; Temporary Marketing Permit Applications

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 reporting requirements contained in existing FDA regulations governing temporary marketing permit applications.

DATES: Either electronic or written comments on the collection of information must be submitted by September 15, 2023.

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 September 15, 2023. 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-N-2562 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Temporary Marketing Permit Applications." 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601