Responses: 30; *Total Annual Hours: 1,790.* (For policy questions regarding this collection contact: Beverly Boston at 410–786–4186.)

3. Title of Information Collection: Behavioral Health Clinic Quality Data Reporting; *Type of Information Collection Request:* Revision of an active collection of information request; *Use:* This Information Collection concerns the Behavioral Health Clinic Quality Data Reporting Template (hereinafter ''Reporting Template'' or ''Template''), developed in partnership with the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Assistant Secretary for Planning and Evaluation (ASPE) (collectively, ''the Agencies''). The Reporting Template is designed to collect quality measure data and to report at the clinic level. The Agencies developed the Template to provide states and clinics with a streamlined and structured tool to report quality measures data. The Reporting Template aims to eliminate the time required for states or clinics to develop their own reporting templates for quality measure data reporting and minimizes inconsistencies in reporting. Furthermore, the Reporting Template, with its accompanying instructions, support an innovative approach to improve behavioral health, a key focus of health care reform. *Form Number:* CMS–10398 (#48) (OMB control number: 0938–1148); *Frequency:* Annual; *Affected Public:* Private Sector (Businesses or other for profits and Not for profit institutions) and State, Local, or Tribal Governments; *Number of Respondents:* 429; *Total Annual Responses:* 1,009; *Total Annual Hours: 6,814.* (For policy questions regarding this collection contact: Beverly Boston at 410–786–4186.)

Dated: January 4, 2024.

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–00205 Filed 1–8–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

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 CASGEVY (exagamglogene autotemcel), manufactured by Vertex Pharmaceuticals, 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 CASGEVY (exagamglogene autotemcel), manufactured by Vertex Pharmaceuticals, Inc., meets the criteria for a priority review voucher.

CASGEVY (exagamglogene autotemcel) is indicated for treatment of sickle cell disease in patients 12 years of age and older with recurrent vaso-occlusive crises.

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 CASGEVY (exagamglogene autotemcel), 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: January 4, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–00263 Filed 1–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0987]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications

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 the collection of qualitative data on tobacco products and communications.

DATES: Either electronic or written comments on the collection of information must be submitted by March 11, 2024.

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 March 11, 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