Performance Report. OGM uses this data to ensure grantees are proceeding in a satisfactory manner in meeting the approved goals and objectives of the project and if funding should be continued for another budget period.

OMB grants policy requires grantees to report on performance. Specific citations are contained in 45 CFR part 75 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.

Respondents: All ACF discretionary grantees. State governments, Native American Tribal governments, Native American Tribal Organizations, local governments, universities, and nonprofits with or without 501(c)(3) status with the IRS.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
ACF–OGM–SF–PPR–B	6,000	2	1	12,000

Estimated Total Annual Burden Hours: 12,000.

Authority: 45 CFR part 75.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–15940 Filed 7–25–22; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0863]

Agency Information Collection Activities; Proposed Collection; Comment Request; Monthly Monitoring Study

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 a notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed information collection entitled ''Monthly Monitoring Study.''

DATES: Either electronic or written comments on the collection of information must be submitted by September 26, 2022.

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 26, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2022–N–0863 for the ''Monthly Monitoring Study'' 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: 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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Monthly Monitoring Study

OMB Control Number 0910–NEW

This information collection supports the development and implementation of FDA public education campaigns related to tobacco use. To reduce the public health burden of tobacco use in the United States and educate the public—especially young people—about the dangers of tobacco use, FDA's Center for Tobacco Products is developing and implementing multiple public education campaigns.

FDA launched ''The Real Cost'' in February 2014, seeking to reduce tobacco use among at-risk youth ages 12–17 in the United States who are open to smoking cigarettes and/or using electronic nicotine delivery systems (ENDS) products, or have already experimented with cigarettes and/or ENDS products. Given the rapidly evolving tobacco landscape in the United States, frequent and nimble data collection strategies are needed to keep pace and provide relevant information to FDA to inform its tobacco prevention media campaign development about changes in tobacco use and emerging products among youth and young adults.

In an effort to inform specified recommendations around ''The Real Cost'' and FDA's other public education programs to reduce tobacco-related death and disease, more research is needed to understand the trends in use and perceptions of novel and emerging tobacco products, as well as awareness and preferences related to emerging tobacco products and specific brands and device types so that the FDA can develop new media campaign messages that resonate with youth and young adults. The purpose of the Monthly Monitoring Study is to collect primary data from youth and young adults, ages 15 to 24 years old, in the United States to monitor perceptions and use of emerging and novel tobacco products and emerging trends in brand and device awareness and use.

The study will be conducted using web-based surveys that are self-administered on personal computers or web enabled mobile devices. The study will use an online survey to collect data from up to 27,000 youth and young adults ages 15 to 24 years to monitor perceptions about and trends in use of ENDS and other emerging tobacco products. Participants will be recruited through social media advertisements. To achieve the required pace of data collection, the study will not contact parents of youth under 18 years old for parental permission and will obtain a waiver of parental permission from the institutional review board. The study will include questions about marijuana use to allow the study team to differentiate between use of current and emerging tobacco products and marijuana, which can be used in tobacco products such as ENDS and little cigar/cigarillos. The survey will take approximately 20 minutes to complete per participant. This survey will ask participants to provide feedback on tobacco use and quitting behavior, as well as brand and device preferences, tobacco information sources, peer influence and perceptions, and marijuana use.

The aim of the Monthly Monitoring Study is to answer the following questions:

- What are the trends in brand and device use for ENDS products and other emerging tobacco products among youth and young adults ages 15 to 24 years in the United States? What are their perceptions of these products?
- How is respondent tobacco use affected by environmental factors, including peer influence and other external factors such as COVID–19?
- What are the primary sources of new product information and where are these products purchased/acquired?
- What are the primary sources of health information for ENDS and other emerging tobacco products?

In support of the provisions of the Family Smoking Prevention and Tobacco Control Act that require FDA to protect the public health and to reduce tobacco use by minors, FDA requests OMB approval to collect data for the Monthly Monitoring Study.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED REPORTING BURDEN [1]

Type of respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Youth Screener	27,000	1	27,000	0.04167 (2.5 minutes)	1,125
Youth Assent	13,500	1	13,500	0.04167 (2.5 minutes)	563
Youth Online Survey	13,500	1	13,500	0.3333 (20 minutes)	4,500
Young Adult Screener	27,000	1	27,000	0.04167 (2.5 minutes)	1,125
Young Adult Consent	13,500	1	13,500	0.04167 (2.5 minutes)	563

TABLE 1—ESTIMATED REPORTING BURDEN [1]—Continued

Type of respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Young Adult Online Survey	13,500	1	13,500	0.3333 (20 minutes)	4,500
Total					12,376

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

We expect the screening process (2.5 minutes per response) to yield a 2 to 1 ratio of eligible participants. We will need to screen approximately 54,000 potential participants (27,000 youth and 27,000 young adults) over the study period. Participants determined to be eligible through the screener will complete a youth assent or young adult consent (2.5 minutes per response) and the online survey (20 minutes per response).

Over the course of the study period, we intend to survey approximately 1,500 youth ages 15–17, and young adults ages 18–24, every 1 to 2 months. The survey will be repeated with a new cross-sectional sample approximately every month or every other month over a period of 18 months. We will obtain a final sample size of 27,000 youth and young adults (13,500 youth and 13,500 young adults) over the course of the study period. Respondents will be allowed to complete an additional, cross-sectional survey after 6 months.

Dated: July 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15955 Filed 7–25–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1729]

Revocation of Emergency Use of a Drug During the COVID–19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Gilead Sciences, Inc. (Gilead) for VEKLURY (remdesivir). FDA revoked the Authorization on April 25, 2022, under the Federal Food, Drug, and Cosmetic Act (FD&C Act) given the approval of a supplemental new drug application (NDA) for VEKLURY, which expanded the approved indication to cover the authorized population. The revocation, which includes an explanation of the reasons for the revocation, is reprinted in this document.

DATES: The Authorization is revoked as of April 25, 2022.

ADDRESSES: Submit written requests for single copies of the Authorization and/or revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On May 1, 2020, FDA issued an Authorization (EUA 046) to Gilead for remdesivir, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on September 11, 2020 (85 FR 56231), as required by section 564(h)(1) of the FD&C Act. Subsequent amendments to the Authorization on August 28, 2020, October 1, 2020, October 16, 2020, October 22, 2020, and January 21, 2022, were made available on FDA's website.

II. EUA Criteria for Issuance No Longer Met

Under section 564(g)(2) of the FD&C Act, the Secretary of HHS may revoke an EUA if, among other things, the criteria for issuance are no longer met. On April 25, 2022, FDA revoked the EUA for VEKLURY because the criteria for issuance were no longer met. Under section 564(c)(3) of the FD&C Act, an EUA may be issued only if FDA concludes there is no adequate, approved,[1] and available alternative to the product for diagnosing, preventing, or treating the disease or condition. On April 25, 2022, FDA approved a supplemental NDA to NDA 214787 for VEKLURY, which expanded the approved indication to the following:

> Veklury is a severe acute respiratory syndrome coronavirus 2 (SARS-CoV–2) nucleotide analog RNA polymerase inhibitor indicated for the treatment of coronavirus disease 2019 (COVID–19) in adults and pediatric patients (28 days of age and older and weighing at least 3 kg) with positive results of direct SARS-CoV–2 viral testing, who are:
> - Hospitalized, or
> - Not Hospitalized and have mild-to-moderate COVID–19 and are at high risk for progression to severe COVID–19, including hospitalization or death.

FDA has concluded that VEKLURY approved under NDA 214787 is an adequate, approved, and available alternative to the VEKLURY available for emergency use for the treatment of COVID–19 for purposes of section 564(c)(3) of the FD&C Act. Accordingly, FDA revoked EUA 046 for emergency use of VEKLURY, pursuant to section 564(g)(2) of the FD&C Act.

III. Electronic Access

[1] In the context of section 564, the term ''approved'' refers to a product that is approved, licensed, or cleared under section 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), or 360(e)) or section 351 of the Public Health Service Act (42 U.S.C. 262). See section 564(a)(2) of the FD&C Act.