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]

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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.

An electronic version of this document and the full text of the Authorization and revocation are available on the internet from *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization* and *https://www.regulations.gov/.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g) of the FD&C Act are met, FDA has revoked the EUA for Gilead's VEKLURY (remdesivir). The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

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U.S. FOOD & DRUG ADMINISTRATION

April 25, 2022

Gilead Sciences, Inc.
Attention: Madelyn Low, MBS
Manager, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

RE: Emergency Use Authorization 046

Dear Ms. Low:

This letter is to notify you of the revocation of the Emergency Use Authorization (EUA 046) for emergency use of Gilead Sciences, Inc.'s ("Gilead") Veklury (remdesivir), issued initially on May 1, 2020, and amended on August 28, 2020, October 1, 2020, October 16, 2020, October 22, 2020, and January 21, 2022.

The authorization of a drug for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revised or revoked when the criteria under section 564(b)(1) of the Act no longer exist, the criteria under section 564(c) of the Act for issuance of such authorization are no longer met, or other circumstances make such revision or revocation appropriate to protect the public health or safety.

FDA has determined that the criteria for issuance of such authorization under section 564(c) of the Act are no longer met. Under section 564(c)(3) of the 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, the Agency approved a supplemental New Drug Application (NDA) to NDA 214787, which expanded the approved indication to the following:

> *Vekhury 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.*

Page 2 – Ms. Low, Gilead Sciences, Inc.

Based on this approval, FDA has concluded that NDA 214787 for Veklury is an adequate, approved[1], and available alternative to Veklury available for emergency use, for the treatment of COVID-19 for purposes of section 564(c)(3) of the Act.

Accordingly, FDA revokes EUA 046 for emergency use of Veklury, pursuant to section 564(g)(2) of the Act. As of the date of this letter, the Veklury that was authorized by FDA for emergency use under EUA 046 is no longer authorized by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

[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 Act or section 351 of the Public Health Service Act. See section 564(a)(2) of the Act.

Dated: July 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15956 Filed 7–25–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0862]

Agency Information Collection Activities; Proposed Collection; Comment Request; The Real Cost Campaign Outcomes Evaluation Study: Cohort 3

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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