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

solicits comments on a proposed information collection titled ''The Real Cost Campaign Outcomes Evaluation Study: Cohort 3.''

DATES: Submit either electronic or written comments on the collection of information by September 26, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 26, 2022. 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–0862 for ''The Real Cost Campaign Outcomes Evaluation Study: Cohort 3.'' 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.

The Real Cost Campaign Outcomes Evaluation Study: Cohort 3

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, the FDA Center for Tobacco Products (CTP) 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. Complementary

evaluation studies, including the ''Evaluation of FDA's Public Education Campaign on Teen Tobacco (ExPECTT),'' were designed and implemented to measure awareness of and exposure to ''The Real Cost'' paid media campaign among youth ages 12–17 in targeted areas of the United States.

The first cohort (ExPECTT: Cohort 1) assessed the campaign's impact on outcome variables of interest from November 2013 to November 2016. The second cohort (ExPECTT: Cohort 2) has been assessing the campaign's impact on outcome variables of interest from June 2018 and will run through August 2022. To continue assessing the impact of ''The Real Cost'' campaign, FDA will implement The Real Cost Campaign Outcomes Evaluation Study: Cohort 3. The study will consist of four waves of data collection, including the baseline survey and three followup (FU) surveys. Online surveys with youth ages 11–20 will be conducted at baseline.

Online surveys of youth will be conducted in the United States to measure the effectiveness of FDA's ''The Real Cost'' campaign. The purpose of FDA's The Real Cost Campaign Outcomes Evaluation Study: Cohort 3 is to provide credible evidence that changes in key outcomes can be attributed to exposure to the campaign. The strength of the attribution is determined by the ability of the evaluation approach to rule out alternative explanations for observed changes in key outcomes. Attributing effects to a campaign require using multiple, complementary methods that build a case that exposure to the campaign leads to changes in key outcomes. For a national campaign evaluation, FDA can improve attribution by carefully assessing potential confounders. To improve attribution, we intend to measure variation in both potential campaign exposure (*e.g.,* market-level delivery) and self-reported campaign exposure to media advertising.

The goal of The Real Cost Campaign Outcomes Evaluation Study: Cohort 3 is to determine whether future waves of ''The Real Cost'' public education campaign will influence any of the following key outcomes:

- Awareness of campaign messages
- Specific beliefs targeted by messages (message-targeted beliefs)
- Psychosocial predictors or precursors of tobacco use behavior
  - Health and addiction risk perceptions
  - Perceived loss of control or threat to freedom expected from tobacco use
  - Anticipated guilt, shame, and regret from tobacco use
  - Perceptions of prevalence, approval, and popularity of tobacco use
  - Pro-health changes in normative beliefs about tobacco product use
  - Tobacco use susceptibility
  - Intention or willingness to use tobacco
  - Intention to quit and/or reduce daily consumption

In support of the provisions of the Tobacco Control Act (Pub. L. 11–31) that require FDA to protect the public health and to reduce tobacco use by minors, FDA requests OMB approval to collect information to evaluate CTP's public education campaign ''The Real Cost'' through the Evaluation Study: Cohort 3.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Respondent/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Parent Recruitment Study Materials—Main: Baseline & Followup 2 Replenishment	545,000	1	545,000	0.17 (10 mins)	92,650
Parent Screener—Main: Baseline & Followup 2 Replenishment	272,500	1	272,500	0.08 (5 mins)	21,800
Household Roster—Main: Baseline & Followup 2 Replenishment	5,500	1	5,500	0.08 (5 mins)	440
CATI Screener—Main: Baseline & Followup 2 Replenishment	2,000	1	2,000	0.08 (5 mins)	160
Parent Permission—Main: Baseline & Followup 1,2,3	21,600	1	21,600	0.08 (5 mins)	1,728
Youth Assent—Main: Baseline & Followup 1,2,3	21,600	1	21,600	0.08 (5 mins)	1,728
Youth Survey—Main: Baseline & Followup 1,2,3	21,600	1	21,600	0.50 (30 mins)	10,800
Youth Screener—Supplemental	5,000	1	5,000	0.08 (5 mins)	400
Youth Assent—Supplemental: Baseline & Followup 1,2,3	4,428	1	4,428	0.08 (5 mins)	355
Youth Survey—Supplemental: Baseline & Followup 1,2,3	4,428	1	4,428	0.50 (30 mins)	2,214
Total					132,275

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

Main Data Collection

The main data collection will include a baseline survey and three FU surveys. The recruitment sample for the main data collection is youth ages 11–17. We intend to replenish the longitudinal sample at FU2 to obtain 6,000 youth respondents to maintain at least 4,800 respondents at each wave. We expect the screening process to yield a 100:1 ratio of eligible responding households. We estimate that we will mail 400,000 recruitment/study material packages (10 minutes per response) in order to receive at least 200,000 completed screeners (5 minutes per response) by adults within households. Households completing the screener by mail will be contacted to complete a computer-assisted telephone interview (CATI) where an interviewer will determine eligibility and obtain parental permission (5 minutes per response). For households identified as eligible for the study during the screening process (*i.e.,* the presence of one or more youth ages 11 to 17), we will ask the parent/guardian to list all eligible youth in their households for study selection, a process called rostering (5 minutes per response). We estimate from the 200,000 completed screeners, we will recruit 6,000 eligible youth from the 4,000 eligible households.

Baseline

At baseline, we plan to collect data from approximately 6,000 youth respondents from the 4,000 eligible households identified through screening. More than one eligible youth

per household may be recruited for the study. These 6,000 youth respondents are estimated to provide baseline assent (5 minutes per response) and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study. We estimate that we will lose approximately 20 percent of the original baseline sample at each FU wave.

Followup 1

We estimate that we will retain 80 percent of the sample from baseline and collect data from 4,800 respondents (5 minutes per response) at FU1. These 4,800 youth respondents are estimated to provide assent (5 minutes per response) for FU1 and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study. We do not intend to replenish the sample at FU1.

Followup 2

We estimate that we will retain 80 percent of the sample from FU1 resulting in 3,840 respondents at FU2. To replenish the longitudinal sample at FU2, we will send additional ''baseline'' screeners to new households. We intend to send recruitment/study material packages to an additional 145,000 households (10 minutes per response) to receive an estimated 72,500 completed screeners (5 minutes per response). For households identified as eligible for the study during the screening process (*i.e.,* the presence of 1 or more youth ages 11 to 17), we will ask the parent/guardian to list all eligible youth in their households for study selection, a process called rostering (5 minutes per response). Households completing the screener by mail will be contacted to complete a CATI where an interviewer will determine eligibility and obtain parental permission (5 minutes per response). From these completed screeners, we estimate that we will obtain data from an additional 2,160 youth within approximately 1,500 households. Replenishing the sample will allow us to obtain 6,000 youth respondents at FU2 (3,840 from the original sample, and 2,160 from the replenishment sample) and maintain a minimum study sample of 4,800 respondent at all study waves. These 6,000 youth respondents are estimated to provide assent (5 minutes per response) for FU2 and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study.

Followup 3

We estimate that we will retain 80 percent of the sample from FU2 and collect data from 4,800 respondents at FU3. We do not intend to replenish the sample at FU3. These 4,800 youth respondents are estimated to provide assent (5 minutes per response) for FU2 and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study.

Supplemental Data Collection

In addition to the main data collection, we intend to collect data from subpopulations shown to be at higher risk of initiating use of cigarettes and ENDS products, such as youth who identify as LGBTQ+ and youth who have a mental health disorder. Data collection will consist of online self-administered surveys of participants recruited through social media advertisements. The recruitment sample for this data collection will be youth ages 14 to 20 who meet the subpopulation criteria. We intend to collect data at baseline from 1,500 respondents. We anticipate that we will need to screen 5,000 respondents (5 minutes per response) to obtain a baseline sample of 1,500 respondents who meet the subpopulation criteria. At baseline, we plan to collect data from approximately 1,500 respondents identified as eligible through screening. These 1,500 youth respondents are estimated to provide assent (5 minutes per response) and complete the survey (30 minutes per response). We estimate that we will lose approximately 20 percent of the original baseline sample at each FU wave; therefore, estimating 1,200 respondents at FU1, 960 respondents at FU2, and 768 respondents at FU3. For the FU samples, youth will provide assent (5 minutes per response) and complete the survey (30 minutes per response).

Dated: July 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15954 Filed 7–25–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Human Genome Research.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Human Genome Research.

Date: August 1, 2022.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rudy O. Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100 Bethesda, MD 20892, (301) 402–0838, *pozzattr@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Information is also available on the Institute's/Center's home page: *http://www.genome.gov/council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: July 20, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–15908 Filed 7–25–22; 8:45 am]

BILLING CODE 4140–01–P