eligible organization or its plan. Eligible organizations are required to self-certify that they are eligible for this accommodation and provide a copy of such self-certification to their third party administrators. The final rules also set forth processes and standards to fund the payments for the contraceptive services that are provided for participants and beneficiaries in self-insured plans of eligible organizations under the accommodation described previously, through an adjustment in the FFE user fee payable by an issuer participating in an FFE.

CMS will use the data collections from participating issuers and third party administrators to verify the total dollar amount for such payments for contraceptive services provided under this accommodation for the purpose of determining a participating issuer's user fee adjustment. The attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) will help ensure that the user fee adjustment is being utilized to provide contraceptive services for the self-insured plans in accordance with the previously noted accommodation. *Form Number:* CMS–10492 (OMB control number: 0938–1285); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 861; *Total Annual Responses:* 861; *Total Annual Hours:* 12,930. (For policy questions regarding this collection contact Jacqueline Wilson at *jacqueline.wilson1@cms.hhs.gov.*)

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–11301 Filed 5–25–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Sexual Risk Avoidance Education National Evaluation: Nationwide Study of the National Descriptive Study (New Collection)

AGENCY: Office of Planning, Research and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), proposes survey and focus group data collection activities for the Sexual Risk Avoidance Education National Evaluation (SRAENE) Nationwide Study (NWS) of the National Descriptive Study.

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

SUPPLEMENTARY INFORMATION:

Description: OPRE/ACF/HHS proposes to conduct the NWS, a sub-study under the National Descriptive Study (NDS) of the SRAENE, to learn about Sexual Risk Avoidance Education (SRAE) program implementation experiences and outcomes of the SRAE grant program. The NWS builds on the Early Implementation Study, the first sub-study of the NDS, which was designed to tell the story about SRAE grant program plans (OMB Control #0970–0530). The NWS, which supports Congress's reauthorization in February 2018 of title V, section 510 of the Social Security Act (Pub. L. 115–123) and extended by the Coronavirus Aid, Relief, and Economic Security (CARES) ACT of 2020 (Pub. L. 116–136), will use a mixed-methods approach of surveys and focus groups to tell the story of the SRAE grant program, collecting detailed information on grantee program implementation experiences from grant recipients, SRAE program providers and facilitators, and youth program recipients. The NWS will also make use of extant data from grant-recipient performance measures on program outputs and outcomes. Combined with data on program implementation, the NWS will examine associations between implementation, outputs, and outcomes. The survey and focus group data are key to fully understanding program implementation experiences from all levels that bring the SRAE programs to youth-from grant administrators to program supervisors to the facilitators who interact directly with the youth themselves.

The study is being undertaken by ACF and its contractor Mathematica. The study research questions driving the need for data collection are as follows:

1. What are grant recipients' and providers' experiences with delivering SRAE curricular content? What are youth's experiences with receiving the SRAE curricular content?

2. How did grant recipients and providers interpret, understand, and address the A to F topics in the SRAE legislation?

3. Are some features of implementation more strongly associated with youth outcomes than others?

4. What provider characteristics are associated with a greater number of youth served and with youth outcomes?

To support these efforts, ACF proposes the following data collection activities: (1) A web-based survey of all grant recipient Directors who are not also providers, (2) a web-based survey of all SRAE program providers, (3) a web-based survey of all SRAE program facilitators, and (4) in-person (or virtual if necessary) focus groups with youth recipients of SRAE programming across five geographic regions of the United States.

Respondents: Respondents to the surveys will be SRAE program grant Directors, SRAE program providers, and SRAE program facilitators. Focus group participants will be youth recipients of SRAE programming. The focus group participants will be recruited from middle and high school across five U.S. Geographic regions: West, Midwest, Southwest, Southeast, and Northeast.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
(1) NWS Grantee Survey	40	1	.17	7
(2) NWS Provider Survey	500	1	.75	375
(3) NWS Facilitator Survey	1,600	1	.5	800
(4)SRAE Program Youth Focus Group Discussion Guide	200	1	.75	150

Estimated Total Annual Burden Hours: 1,332.

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: The Title V Competitive SRAE Program was authorized and funded by 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 the CARES Act of 2020 (Pub. L. 116–136).

See *https://www.ssa.gov/OP_Home/ssact/title05/0510.htm.*

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–11364 Filed 5–25–22; 8:45 am]

BILLING CODE 4184–83–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0850]

Gilead Sciences, Inc.; Withdrawal of Approval of Indications for Relapsed Follicular Lymphoma and Relapsed Small Lymphocytic Lymphoma for ZYDELIG (Idelalisib) Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it is withdrawing approval of the indications for relapsed follicular lymphoma and relapsed small lymphocytic lymphoma for ZYDELIG (idelalisib) Tablets, approved under new drug application (NDA) 205858, held by Gilead Sciences, Inc., 333 Lakeside Dr., Foster City, CA 94404 (Gilead). Gilead voluntarily requested that the Agency withdraw approval of these indications and waived its opportunity for a hearing.

DATES: Approval is withdrawn as of May 26, 2022.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On July 23, 2014, FDA approved NDA 205858 for ZYDELIG (idelalisib) Tablets for the treatment of patients with relapsed follicular B-cell non-Hodgkin lymphoma in patients who have received at least two prior systemic therapies (the follicular lymphoma indication). On that same day, FDA also approved NDA 205858 for ZYDELIG (idelalisib) Tablets for the treatment of patients with relapsed small lymphocytic lymphoma in patients who have received at least two prior systemic therapies (the SLL indication). FDA approved both the follicular lymphoma indication and the SLL indication under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. As a condition of accelerated approval of ZYDELIG (idelalisib) Tablets for the follicular lymphoma indication and the SLL indication, the applicant was required to conduct postmarketing trials to verify the clinical benefit of idelalisib for the follicular lymphoma and SLL indications.

On November 22, 2021, FDA met with Gilead to discuss the status of ZYDELIG (idelalisib) Tablet's accelerated approval for the follicular lymphoma indication and the SLL indication, including the continued need for postmarketing trials intended to verify clinical benefit in follicular lymphoma and small lymphocytic lymphoma. FDA raised withdrawal of approval during this discussion, explaining its intent to consult the Oncologic Drugs Advisory Committee (ODAC) on whether FDA should pursue withdrawal of the follicular lymphoma indication and the SLL indication. Subsequently, on December 17, 2021, following further communication with Gilead, FDA advised Gilead that voluntary withdrawal of approval for these indications would be appropriate under § 314.150(d) (21 CFR 314.150(d)). On January 10, 2022, Gilead submitted a letter requesting withdrawal of the follicular lymphoma indication and the SLL indication for ZYDELIG (idelalisib) Tablets and waiving its opportunity for a hearing. Gilead subsequently clarified, on February 23, 2022, that they were requesting the Agency withdraw approval of the follicular lymphoma indication and the SLL indication pursuant to § 314.150(d).

Therefore, under § 314.150(d), approvals of the follicular lymphoma indication and the SLL indication for ZYDELIG (idelalisib) Tablets are withdrawn as of May 26, 2022. Withdrawal of approval of these indications does not affect any other approved indication for ZYDELIG (idelalisib) Tablets.

Dated: May 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–11277 Filed 5–25–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as