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DATES: Approval is withdrawn as of May 26, 2022.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