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DATES: Approval is withdrawn as of May 26, 2022.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

amended, notice is hereby given of the following meeting.

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 Center for Complementary and Integrative Health Special Emphasis Panel; Exploratory Clinical Trials of Mind and Body Interventions (MB).

Date: June 21–22, 2022.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Complementary and Integrative, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sushmita Purkayastha, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, NCCIH/NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892–5475, *sushmita.purkayastha@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: May 23, 2022.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–11340 Filed 5–25–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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 Institute of Child Health and Human Development Initial Review Group Reproduction, Andrology, and Gynecology Study Section.

Date: June 28, 2022.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2125D, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Jagpreet Singh Nanda, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2125D, Bethesda, MD 20892 (301) 451–4454, *jagpreet.nanda@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS).

Dated: May 23, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–11334 Filed 5–25–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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 Eye Institute Special Emphasis Panel; NEI RFA: Age-related Macular Degeneration (AMD) Integrative Biology Initiative: Discovery of AMD Pathobiology using Patient-Derived Induced Pluripotent Stem Cell-derived Retinal Pigment Epithelium.

Date: May 26, 2022.

Time: 10:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jennifer C. Schiltz, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20892, 240–276–5864, *jennifer.schiltz@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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: May 22, 2022.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–11335 Filed 5–25–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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 Eye Institute Special Emphasis Panel; NEI RFA: Ocular Surface Innervation from Cell Types to Circuit Functions (U01).

Date: June 8, 2022.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ashley Fortress, Ph.D., Designated Federal Official Division of Extramural Activities, National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20892, (301) 827–8613, *ashley.fortress@nih.gov.*