

Agency is reviewing recommendations made at the meeting.

On the morning of May 21, 2025, the Committee discussed new drug application (NDA) 215793, for UGN-102 (mitomycin) intravesical solution, submitted by UroGen Pharma, Inc. The proposed indication (use) is for the treatment of adult patients with low-grade intermediate risk non-muscle invasive bladder cancer (LG-IR-NMIBC). The issues the Committee discussed focused on whether randomized trials should be required in the future to assess the effectiveness of therapies in LG-IR-NMIBC given the uncertainty regarding interpretation of study results. The Committee was split with a slight majority voting that the overall benefit-risk of UGN-102 was not favorable in patients with recurrent LG-IR-NMIBC (5 Noes and 4 Yeses). Agency Action: The Agency is reviewing recommendations made at the meeting.

On the afternoon of May 21, 2025, the Committee discussed supplemental new drug application (sNDA) 211651/S-013, for TALZENNA (talazoparib) capsules, submitted by Pfizer Inc. The proposed indication (use) is in combination with enzalutamide for the treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC). The issues the Committee discussed focused on whether efficacy should be formally evaluated in a biomarker-negative population when the biomarker is predictive of response and the prevalence of the biomarker-negative group is high. The Committee members were in unanimous agreement (8 Noes, and 0 Yeses) that the results from the TALAPRO-2 trial were not sufficient to conclude a favorable benefit-risk profile for adding talazoparib to enzalutamide in patients with non-HRRm mCRPC. Agency Action: The Agency is reviewing recommendations made at the meeting.

On July 17, 2025, the Committee discussed BLA 761440, belantamab mafodotin submitted by GlaxoSmithKline LLC, for the treatment of adults with multiple myeloma in combination with bortezomib and dexamethasone in patients who have received at least one prior line of therapy; and in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide. The majority of Committee members (5 Noes, 3 Yeses) agreed that the overall benefit-risk of belantamab mafodotin in combination with bortezomib and dexamethasone was not favorable at the proposed dosage in the proposed patient

population. The Committee was nearly in unanimous agreement (7 Noes, 1 Yes) that the overall benefit-risk of belantamab mafodotin in combination with pomalidomide and dexamethasone was not favorable at the proposed dosage in the proposed patient population. Agency Action: The Agency is reviewing recommendations made at the meeting.

7. Explanation of why the committee/subcommittee is essential to the conduct of agency business.

Reasons for Continuation: The committee plays a critical role in enabling FDA to meet the requirements of sections 505(n)(1) and (s)(1) of the Federal Food, Drug, and Cosmetic Act by providing expert scientific advice and recommendations. Without the Oncologic Drugs Advisory Committee, FDA's ability to obtain external expert input on issues related to the approval and regulation of the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer would be significantly limited.

In conclusion, this public interest determination documents that renewing the committee is in the public interest, essential to the conduct of agency business, and that the information to be obtained is not already available through another advisory committee or source within the Federal Government.

This notice is issued under the Federal Advisory Committee Act as amended (5 U.S.C. 1001 *et seq.*). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Faculty Loan Repayment Program, OMB No. 0906-0082—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 20, 2026.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 13N82, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Samantha Miller, the HRSA Information Collection Clearance Officer, at (301) 443-9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Faculty Loan Repayment Program OMB No. 0906-0082—Revision.

Abstract: HRSA administers the Faculty Loan Repayment Program (FLRP). FLRP provides health professionals from disadvantaged backgrounds, defined as a geographic and/or economic vulnerability, the opportunity to enter into a contract with HHS to receive repayment of qualifying educational loans in exchange for a minimum of 2 years of service as a full-time or part-time faculty member at an eligible health professions school. The applicant completes and submits an electronic application that identifies for the Secretary of Health and Human Services (Secretary) that the applicant comes from an economically or geographically vulnerable background, has a contract with an eligible health professions school to serve as a full-time or part-time faculty member for a minimum of 2 years, and has qualifying outstanding educational loans. In addition, for each undergraduate and/or graduate loan for which repayment is sought, the applicant is required to submit loan documentation verifying the establishment of the educational loan(s) and lender account statements, promissory notes including the original date, and current balance of the outstanding educational loan(s).

This revised ICR contains two new forms. The first is the Employer's Agreement to Loan Repayment Match/Request for a Waiver of the Loan Repayment Match form, which is

needed to ensure applicant eligibility and school compliance with the statute. The second is the Semi-annual In-Service Verification form, which is sent to current participants and the institution twice each year to confirm their employment status. The addition of these forms and an increased number of respondents/applicants to the FLRP will increase the estimated burden hours.

This proposed ICR also contains updated terminology with respect to Disadvantaged Background and accompanying definitions by updating the following:

- Changing form title to “Certification Regarding Vulnerable Background,”
- Replacing “disadvantaged” with “vulnerable” throughout the form, and
- Replacing “environmentally disadvantaged” with “geographically vulnerable.”

These changes are needed to align the form with the Administration’s priority of reinforcing programs that direct resources to areas of greatest need to improve health outcomes. The FLRP statute defines eligible individuals as coming from “disadvantaged backgrounds” (42 U.S.C. 293b(a)) but does not define the term. HRSA’s use of “vulnerable background” operationalizes the statutory term by identifying individuals whose geographic or economic circumstances inhibited their ability to obtain the knowledge, skills, and abilities required to enroll in and graduate from an eligible health professions school. This approach remains consistent with the statute’s intent while incorporating more current terminology. These updates were made throughout the form to improve consistency and help ensure that applicants and reviewers

understand the criteria using current terminology.

FLRP will define “vulnerable background” as “coming from a geographically vulnerable background or an economically vulnerable background that has inhibited the individual from obtaining the knowledge, skills, and abilities required to enroll in and graduate from an eligible health professions school.”

Examples of indicators that an individual comes from a geographically vulnerable background include, but are not limited to:

- Individuals who graduated from a high school with low average SAT/ACT scores or below average state test results.
- Individuals from a school district where 50 percent or less of graduates go to college.
- Individuals raised in households where language barriers affected education access.
- Individuals from a high school where at least 30 percent of enrolled students are eligible for free or reduced-price lunch.
- Individuals who are the first generation in their family to attend college.

An individual from an economically vulnerable background is defined as someone who:

- Comes from a low-income family. Low-income family is defined as a family that has an annual income below the 200 percent of HHS’s poverty guidelines;
- Is eligible for a Pell Grant; and/or
- Comes from a family that receives public assistance (e.g., Temporary Assistance to Needy Families, Supplemental Nutrition Assistance Program, Medicaid, public housing).

The Secretary defines a ‘low-income family’ for programs included in Titles III, VII, and VIII of the Public Health Service Act as having an annual income that does not exceed 200 percent of HHS’s poverty guidelines, which are based on the U.S. Census Bureau’s low-income threshold. This threshold is simplified to facilitate the determination of financial eligibility for some federal programs and further adjusted by the Secretary based on the Consumer Price Index. Family is defined as a group of two or more individuals related by birth, marriage, or adoption who live together, or an individual who is not living with any relatives.

Need and Proposed Use of the Information: The information collected will be used to evaluate applicants’ eligibility to participate in the FLRP and to monitor FLRP related activities and compliance with program requirements.

Likely Respondents: FLRP applicants and institutions providing employment to the applicants.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Completed by	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Eligible Applications	Applicant	225	1	225	1.00	225.00
Institution/Loan Repayment Employment Form.	Institution, on behalf of applicant.	225	1	225	1.00	225.00
Authorization to Release Information Form.	Applicant	225	1	225	0.25	56.25
Certification Regarding Vulnerable Background Form.	Applicant	225	1	225	0.20	45.00
Employer’s Agreement to Loan Repayment Match/Request for a Waiver of the Loan Repayment Match Form.	Institution, on behalf of applicant.	225	1	225	1.00	225.00
Participant Semi-Annual In Service Verification Form.	Institution, Participant.	150	2	300	0.50	150.00

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Completed by	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Total		*600		1,425		926.25

* The total number of unique respondents is estimated to be 600, consisting of 225 applicants and 225 institutions completing forms on behalf of the applicant. Additionally, an estimated 75 participants receiving the loan repayment and 75 institutions verifying service will complete the semi-annual In-Service Verification Form.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Training: Research Education Programs in the Behavioral, Health, and Population Sciences (R25).

Date: September 24, 2026.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: David Erik Pollio, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1006F, Bethesda, MD 20892, (301) 594–4002, polliode@csr.nih.gov.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; Immune Mechanisms of Hypersensitivity and Allergy Study Section.

Date: October 20–21, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Deanna C Bublit, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–4005, deanna.bublit@nih.gov.

Name of Committee: Cell Biology Integrated Review Group; Maximizing Investigators' Research Award C Study Section.

Date: October 20–21, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Ezgi Kunttas-Tatli, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–7047, ezgi.kunttas-tatli@nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Basic Mechanisms of Diabetes and Metabolism Study Section.

Date: October 22–23, 2026.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Victoria Martinez Virador, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–4703, victoria.virador@nih.gov.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Imaging and Bioengineering Technology for Visual Systems Study Section.

Date: October 26–27, 2026.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Susan Gillmor, Ph.D., Scientific Review Officer, National Institutes

of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 240–762–3076, susan.gillmor@nih.gov.

Name of Committee: Cell Biology Integrated Review Group; Cellular Signaling and Regulatory Systems Study Section.

Date: October 26–27, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Jimok Kim, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive Bethesda, MD 20892, (301) 827–6918, jimok.kim@nih.gov.

Name of Committee: Applied Therapeutics for Cancer Integrated Review Group; Drug Discovery and Molecular Pharmacology C Study Section.

Date: October 27–28, 2026.

Time: 8:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Alireza S Alavi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–4108, ali.alavi@nih.gov.

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Imaging Technology for Neuroscience Study Section.

Date: October 27–28, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Rachel A. Kane, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 496–0221, kanera@csr.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biomaterials and Biointerfaces Study Section.

Date: October 27–28, 2026.

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

Agenda: To review and evaluate grant applications.