TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Azelastine hydrochloride; Fluticasone propionate.
Baloxavir marboxil.
Cabozantinib S-malate (multiple reference listed drugs).
Doxepin hydrochloride.
Fluticasone furoate.
Fluticasone propionate.
Formoterol fumarate.
Formoterol fumarate; Mometasone furoate.
Glycopyrrolate.
Glycopyrrolate; Indacaterol maleate.
Indacaterol maleate.
Ivacaftor.
Lidocaine.
Lithium carbonate (multiple reference listed drugs).
Mometasone furoate.
Paliperidone palmitate.
Rasagiline mesylate.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–10710 Filed 5–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Substance Use Disorder Treatment and Recovery Loan Repayment Program and the Pediatric Specialty Loan Repayment Program

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than June 20, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Substance Use Disorder Treatment and Recovery Loan Repayment Program and the Pediatric Specialty Loan Repayment Program, OMB No. 0906–0058—Revision

Abstract: The Consolidated Appropriations Act, 2023 included $40,000,000 for the Substance Use Disorder Treatment and Recovery (STAR) Loan Repayment Program (LRP). This funding will allow HRSA to provide the repayment of education loans for individuals working in a full-time substance use disorder treatment job that involves direct patient care in either a Health Professional Shortage Area (HPSA) designated for Mental Health, or a county where the average drug overdose death rate exceeds the national average. The Further Consolidated Appropriations Act, 2022 and the Consolidated Appropriations Act, 2023 included $5,000,000 and $10,000,000, respectively, for HRSA to award eligible individuals through the Pediatric Specialty LRP. This funding will allow HRSA to provide the repayment of education loans to pediatric medical subspecialist, pediatric surgical specialist, and child and adolescent mental and behavioral health care providers working full-time in or serving a HPSA, medically underserved area (MUA), or medically underserved population (MUP). This information collection request adds the Pediatric Specialty LRP and relevant forms.

The Department of Health and Human Services agrees to make payment of up to $250,000 for the repayment of eligible educational loans in return for 6 years of service obligation through the STAR LRP, and up to $100,000 in return for 3 years of service obligation through the Pediatric Specialty LRP. The forms used by the STAR LRP and the Pediatric Specialty LRP include the following: the LRP Application, the Authorization for Disclosure of Loan Information form, the Privacy Act Release Authorization form, and the electronic Employment Verification form, if applicable. The forms collect information needed for selecting participants and repaying eligible educational loans.

Eligible disciplines for the STAR LRP and the Pediatric Specialty LRP include, but are not limited to physicians, psychologists, psychiatric nurses, marriage and facility therapists, social workers, counselors, and substance use disorder counselors. Additional providers that are exclusively eligible for the Pediatric Specialty LRP include pediatric medical subspecialty, pediatric surgical specialty, and child and adolescent mental and behavioral health care providers.

Eligible facilities or sites for the STAR LRP and Pediatric Specialty LRP programs include, but are not limited to: School-Based Clinics, Community Health Centers, Inpatient Programs/Rehabilitation Centers, Federally Qualified Health Centers, Centers for Medicare & Medicaid Services-approved Critical Access Hospitals, American Indian Health Facilities (Indian Health Service Facilities, Tribally-Operated 638 Health Programs, and Urban Indian Health Programs), inpatient

rehabilitation centers, and psychiatric facilities. STAR LRP facilities must be located in a mental health HPSA or a county where the average drug overdose death rate exceeds the national average. Pediatric Specialty LRP sites must provide pediatric medical subspecialty care, pediatric surgical specialty care, or child and adolescent mental and behavioral health care in or to a HPSA, MUA, or MUP. HRSA will approve and activate sites for the Pediatric Specialty LRP if:

(1) The facility is already approved for the National Health Service Corps, Nurse Corps, or STAR LRP and located in or serves a HPSA, MUA, or MUP; or

(2) During the Pediatric Specialty LRP application cycle, the facility submits to HRSA the site type and the point of contact(s) to *PS_LRP_Sites@hrsa.gov*.

HRSA will review and approve new facilities during the respective application cycle for the STAR LRP and the Pediatric Specialty LRP. New facilities must submit to HRSA the facility type and the recruitment contact(s). HRSA will use the information collected to determine eligibility of the facility for the assignment of health professionals and to verify the need for clinicians. Note: Despite the similarity in the titles, the STAR LRP is not the existing National Health Service Corps Substance Use Disorder LRP (OMB #0915–0127), which is authorized under Title III of the Public Health Service Act. The STAR LRP is authorized under Title VII of the Public Health Service Act and has different service requirements, loan repayment protocols, and authorized employment facilities.

Need and Proposed Use of the Information: The need and purpose of this information collection is to obtain information that is used to assess an applicant's eligibility and qualifications for the STAR LRP and the Pediatric Specialty LRP, and to obtain information for eligible facilities or sites. Clinicians interested in participating in the STAR LRP or the Pediatric Specialty LRP must apply to the applicable program to participate. Additionally, health care facilities located in a high overdose death rate area or mental health HPSAs must submit the facility type and the site point(s) of contact(s) for HRSA to determine the facility's eligibility to participate in the STAR LRP. Similarly, sites located in or serving a HPSA, MUA, or MUP must submit the site type and the site point(s) of contact(s) for HRSA to determine the sites' eligibility to participate in the Pediatric Specialty LRP. The STAR LRP and the Pediatric Specialty LRP application asks for personal, professional, and financial information needed to determine the applicant's eligibility to participate in either of the programs. In addition, applicants must provide information regarding the loans for which repayment is being requested.

A 60-day notice published in the **Federal Register** on March 8, 2023, vol. 88, No. 45; pp. 14373–74. There were no public comments.

Likely Respondents: Licensed medical, mental, and behavioral health providers who are employed or seeking employment and are interested in serving underserved populations; and health care facilities or sites interested in participating in the STAR LRP and/or the Pediatric Specialty LRP and becoming an approved facility or site.

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 tables below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS FOR THE STAR LRP

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
STAR LRP Application	3,200	1	3,200	.50	1,600
Authorization for Disclosure of Loan Information Form	3,200	1	3,200	.50	1,600
Privacy Act Release Authorization Form	3,200	1	3,200	.50	1,600
Employment Verification Form	3,200	1	3,200	.50	1,600
Total	12,800		12,800		6,400

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS FOR THE PEDIATRIC SPECIALTY LRP

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Pediatric Specialty LRP Application	500	1	500	.50	250
Authorization for Disclosure of Loan Information Form	500	1	500	.50	250
Privacy Act Release Authorization Form	500	1	500	.50	250
Employment Verification Form	500	1	500	.50	250
Total	2,000		2,000		1,000

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–10692 Filed 5–18–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Given the capacity constraints of the venue, the public is strongly encouraged to attend virtually via NIH videocast. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/.*

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: Advisory Committee to the Director, National Institutes of Health.

Date: June 8, 2023.

Open: 9:00 a.m. to 4:45 p.m.

Agenda: Performing the Duties of the NIH Director's Report; NIH Public Access Plan; Cancer Moonshot; Addressing the Mental Health Crisis through Research; Addressing the Public Health Threat of Post-Acute Sequelae of SARS CoV–2 Infection (PASC)—NIH RECOVER Initiative: Briefing for the Advisory Council to the Director (ACD); The Foundation for the National Institutes of Health (FNIH); Other Business of the Committee.

Date: June 8, 2023.

Closed: 4:55 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Date: June 9, 2023.

Open: 9:00 a.m. to 3:00 p.m.

Agenda: HeLA Genome Data Access Working Group: Data Access Requests; NIH-wide Collaborative Initiative on Climate Change and Health; Clinical Trial Stewardship; Accessibility Update; Update from the ACD Working Group on Catalyzing the Development and Use of Novel Alternative Methods to Advance Biomedical Research; Update from the ACD Working Group on Re-envisioning NIH-Supported Postdoctoral Training; Other Business of the Committee.

Place: National Institutes of Health, Building 1, Wilson Hall, One Center Drive, Bethesda, MD 20892.

Contact Person: Cyndi Burrus-Shaw, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301–496–2433, *shawcy@od.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

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

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: May 15, 2023.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–10689 Filed 5–18–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; Notice of Closed Meeting

Pursuant to section 1009 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: NIDCR Special Grants Review Committee.

Date: June 29–30, 2023.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Thomas John O'Farrell, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Bethesda, MD 20892, 301–402–8559, *tom.ofarrell@nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: May 15, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–10656 Filed 5–18–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention's (CSAP) Drug Testing Advisory Board (DTAB) will convene via web conference on June 13, 2023, from 9:30 a.m. EST to 5:00 p.m. EST.