requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for the submissions of investigational new drug applications, including clinical trial design and study protocols, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to the submissions of new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to the submissions of biologics license applications have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the 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: August 29, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19060 Filed 9–1–23; 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: Faculty Loan Repayment Program OMB No. 0915–0150—Revision

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

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 November 6, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 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 Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Faculty Loan Repayment Program OMB No. 0915–0150—Revision

Abstract: HRSA administers the Faculty Loan Repayment Program (FLRP). FLRP provides health professionals from disadvantaged backgrounds based on environmental and/or economic factors the opportunity to enter into a contract with the Department of Health and Human Services 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 that the applicant comes from an economically or environmentally disadvantaged background who 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). The sole change in this version of the ICR from previous ICR versions is that there is an increase in the estimated burden hours related to an increased number of respondents/applicants to the FLRP.

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.

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	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Eligible Applications	215	1	215	1.00	215.00

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Institution/Loan Repayment Employment Form	*215	1	215	1.00	215.00
Authorization to Release Information Form	215	1	215	.25	53.75
Disadvantaged Background Form	215	1	215	.20	43.00
Total	860				526.75

*Respondents for this form is the institution on behalf of the applicant.

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. 2023–19054 Filed 9–1–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) hereby gives notice that the National Vaccine Advisory Committee (NVAC) will hold an in-person meeting. The meeting will be open to the public and public comment will be heard during the meeting.

DATES: The meeting will be held September 21–22, 2023. The confirmed meeting times and agenda will be posted on the NVAC website at *http://www.hhs.gov/nvpo/nvac/meetings/index.html* as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted online at: *http://www.hhs.gov/nvpo/nvac/meetings/index.html* at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting in person or participate in public comment. Please register at *http://www.hhs.gov/nvpo/nvac/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, Office of Infectious Disease and HIV/AIDS Policy, U.S. Department of Health and Human Services, Tower Building, Room, 1101 Wootton Parkway, Rockville, MD 20852. Email: *nvac@hhs.gov.* Phone: 202–795–7697.

SUPPLEMENTARY INFORMATION: Pursuant to section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of HHS was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

During this meeting, NVAC will hear presentations to support the recent charges on innovation and safety from Admiral Rachel L. Levine, MD, the Assistant Secretary for Health and Director of the National Vaccine Program. NVAC will also hear presentations on the actions and strategies taken to better address the unique vaccination needs of people with disabilities, respiratory disease prevention plans for the upcoming fall season, and updates on climate change vaccines. Please note that agenda items are subject to change, as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: *http://www.hhs.gov/nvpo/nvac/index.html.*

Members of the public will have the opportunity to provide comment at the NVAC meeting during the public comment period designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Members of the public may also submit written comments. Written comments should not exceed three pages in length. Individuals planning to submit comments should email their written comments or their request to provide a comment during the meeting to *nvac@hhs.gov* at least five business days prior to the meeting.

Dated: August 7, 2023.

Ann Aikin,

Acting Designated Federal Official, Office of the Assistant Secretary for Health.

[FR Doc. 2023–18994 Filed 9–1–23; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Ivana Frech, Ph.D. (formerly Ivana De Domenico) (Respondent), former Assistant Professor, Department of Internal Medicine, University of Utah (UU) School of Medicine. Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grants R01 DK070947, R01 DK090257, and R01 DK030534, National Institute of General Medical Sciences (NIGMS), NIH, grant P50 GM082545, National Institute of Allergy and Infectious Diseases (NIAID), NIH, grant R01 AI051174, and National Heart, Lung, and Blood Institute (NHLBI), NIH, grant R01 HL026922. The administrative actions, including debarment for a period of three (3) years, were implemented beginning on August 21, 2023, and are detailed below.