the subject of NDA 021400, held by Bayer HealthCare Pharmaceuticals, Inc., and initially approved on August 19, 2003. Levitra is a phosphodiesterase 5 inhibitor indicated for the treatment of erectile dysfunction.

In letters dated September 26, 2019, September 24, 2020, and September 20, 2021, Bayer HealthCare Pharmaceuticals, Inc. notified FDA that Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg and 20 mg, respectively, were being discontinued, and FDA moved the drug products to the ''Discontinued Drug Product List'' section of the Orange Book.

Respira Therapeutics, Inc. submitted a citizen petition dated August 29, 2022 (Docket No. FDA–2022–P–2060), under 21 CFR 10.30, requesting that the Agency determine whether Levitra (vardenafil hydrochloride) oral tablets, 20 mg, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 5 mg and 10 mg strengths, those strengths have also been discontinued. On our own initiative, we have also determined whether those strengths were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg, and 20 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg, and 20 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list Levitra (vardenafil hydrochloride) oral tablets, 5 mg, 10 mg, and 20 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to these drug products. Additional ANDAs for these drug products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09365 Filed 5–2–23; 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; Application and Other Forms Used by the National Health Service Corps Scholarship Program, the NHSC Students to Service Loan Repayment Program, and the Native Hawaiian Health Scholarship 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 2, 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 Acting HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call 301–594–4394.

SUPPLEMENTARY INFORMATION: *Information Collection Request Title:* Application and Other Forms Used by the National Health Service Corps (NHSC) Scholarship Program (SP), the NHSC Students to Service Loan Repayment Program (S2S LRP), and the Native Hawaiian Health Scholarship Program (NHHSP), OMB No. 0915–0146-Revision.

Abstract: Administered by HRSA's Bureau of Health Workforce, the NHSC SP, NHSC S2S LRP, and the NHHSP provide scholarships or loan repayment to qualified students who are pursuing primary care health professions education and training. In return, students agree to provide primary health care services in underserved communities located in federally designated Health Professional Shortage Areas once they are fully trained and licensed health professionals. Awards are made to applicants who demonstrate the greatest potential for successful completion of their education and training as well as commitment to provide primary health care services to communities of greatest need. The information from program applications, forms, and supporting documentation is used to select the best qualified candidates for these competitive awards, and to monitor program participants' enrollment in school, postgraduate training, and compliance with program requirements.

Although some program forms vary from program to program (see program-specific burden charts below), required forms generally include: a program application, academic and non-academic letters of recommendation, the authorization to release information, and the acceptance/verification of good academic standing report. The NHHSP is not seeking to change or add any forms or documentation.

A 60-day notice published in the **Federal Register** on February 14, 2023, 88 FR 9525–26. There were no public comments.

Need and Proposed Use of the Information: The NHSC SP, S2S LRP, and NHHSP applications, forms, and supporting documentation are used to collect necessary information from applicants and schools that enable HRSA to make selection determinations for the competitive awards and monitor compliance (via training programs and sites) with program requirements.

Likely Respondents: Qualified students who are pursuing education and training in primary care health professions and are interested in working in health professional shortage areas and schools at which such students are enrolled.

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

NHSC Scholarship Program Application

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NHSC Scholarship Program Application	2,575	1	2,575	2.00	5150.00
Letters of Recommendation	2,575	2	5,150	1.00	5150.00
Authorization to Release Information	2,575	1	2,575	.10	257.50
Acceptance/Verification of Good Standing Report	2,575	1	2,575	.25	643.75
Verification of Disadvantaged Background Status	615	1	615	.25	153.75
Total	*2,575		13,490		11,355.00

*Certain documents are submitted by a subset of respondents consistent with program requirements.

NHSC Awardees/Schools/Post Graduate Training Programs/Sites

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Data Collection Worksheet	400	1	400	1.00	400
Post Graduate Training Verification Form	100	1	100	.50	50
Enrollment Verification Form	600	2	1,200	.50	600
Total	*600		1,700		1,050

*Please note that the same group of respondents may complete each form as necessary.

NHSC Students to Service Loan Repayment Program Application

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NHSC Students to Service Loan Repayment Program Application	284	1	284	2.00	568.00
Letters of Recommendation	284	1	284	2.00	568.00
Authorization to Release Information	284	1	284	.10	28.40
Acceptance/Verification of Good Standing Report	284	1	284	.25	71.00
Verification of Disadvantaged Background Status	84	1	84	.25	21.00
Total	*284		1,220		1,256.40

*Certain documents are submitted by a subset of respondents consistent with program requirements.

Native Hawaiian Health Scholarship Program Application

Form name	Number of respondents	Number of responses per respondent	Total Responses	Average burden per response (in hours)	Total burden hours
Native Hawaiian Health Scholarship Program Application	310	1.00	310	2.00	620.00
Letters of Recommendation	310	2.00	620	.25	155.00
Authorization to Release Information	310	1.00	310	.25	77.50
Acceptance/Verification of Good Standing Report	40	1.00	40	.25	10.00
Scholar Enrollment Verification Form	40	7.50	300	.50	150.00
Change in Program Curriculum Form	40	2.00	80	.25	20.00
NHHSP Graduation Documentation Form	40	1.00	40	.25	10.00
Total	*310		1,700		1,042.50

*Certain documents are submitted by a subset of respondents consistent with program requirements.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–09356 Filed 5–2–23; 8:45 am]

BILLING CODE 4165–15–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 Johnny J. He, Ph.D. (Respondent), who is a Professor, Department of Microbiology and Immunology, Rosalind Franklin University of Medicine and Science (RFUMS). Respondent engaged in research misconduct in research reported in grant applications submitted for U.S. Public Health Service (PHS) funds, specifically U01 DA056010–01 and DP1 DA056160–01 submitted to the National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), R01 AG078019–01 submitted to the National Institute on Aging (NIA), NIH, and R35 NS127233–01 submitted to the National Institute of Neurological Disorders and Stroke (NINDS), NIH. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on April 17, 2023, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Sheila Garrity, JD, MPH, MBA, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Johnny J. He, Ph.D., Rosalind Franklin University of Medicine and Science: Based on the report of an investigation conducted by RFUMS, an admission by Respondent, and analysis conducted by ORI in its oversight review, ORI found that Johnny J. He, Ph.D., Professor, Department of Microbiology and Immunology, RFUMS, engaged in research misconduct in research reported in grant applications submitted for PHS funds, specifically U01 DA056010–01 and DP1 DA056160–01 submitted to NIDA, NIH, R01 AG078019–01 submitted to NIA, NIH, and R35 NS127233–01 submitted to NINDS, NIH.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying, fabricating, and plagiarizing experimental data and text that described the research from one (1) preprint and four (4) published papers and represented the data and/or ideas as his own under different experimental conditions in four (4) NIH grant applications and in one research record. The falsified, fabricated, and plagiarized research data and text appeared in the following NIH grant applications:

- NIA, NIH, grant R01 AG078019–01, ''iTat mice to model HIV-impaired neurogenesis and accelerated aging,'' submitted on September 7, 2021
- NIDA, NIH, grant U01 DA056010–01, ''Single cell and spatial transcriptomic changes of cocaine use in the iTat HAND model,'' submitted on July 20, 2021
- NIDA, NIH, grant DP1 DA056160–01, ''Targeting epigenetic changes to understand and treat CUD in people living with HAND,'' submitted on August 13, 2021
- NINDS, NIH, grant R35 NS127233–01, ''HIV-associated neurocognitive disorder: from mechanisms to therapeutics,'' submitted on July 13, 2021

The sources of the plagiarized images and text were:

- *Clin Transl Med.* 2017 June 8;6(1):20. doi: 10.1186/s40169–017–0150–9 (hereafter referred to as ''*Clin Trans Med* 2017'')
- *Sci Adv.* 2019 October 16;5(10):eaax1532. doi: 10.1126/sciadv.aax1532 (hereafter referred to as ''*Sci Adv* 2019'')
- *BioRxiv.* March 5, 2020. doi:10.1101/2020.02.29.970558v2 (hereafter referred to as ''*BioRxiv* 2020''). *BioRxiv* 2020 is a preprint version of *Nature.* 2021 October 6;598(7879):103–110. doi: 10.1038/s41586–021–03500–8
- *Biosci Biotechnol Biochem.* 2020 May;84(5):919–926. doi:10.1080/09168451.2020.1714420 (hereafter referred to as ''*BBB* 2020'')
- *Front Oncol.* 2021 January 19;10:607349. doi: 10.3389/fonc.2020.607349 (hereafter referred to as ''*Front Onc* 2021'')

Specifically, ORI found that Respondent knowingly, intentionally, or recklessly:

- falsified, fabricated, and plagiarized research data and the text that described the research by:

—using Figures 1A and 1B of *BBB* 2020, representing wild-type and APP23 mice at 6 and 24 months, as the Respondent's own data in Figures 5A and 5B of U01 DA056010–01 and Figures 7A and 7B of R01 AG78019–01, representing wild-type and iTat mice at 6 and 12 months

—using Figures 3c and 3d of *BioRxiv* 2020, representing results in 60 days old *Snap25–IRES2–Cre* mice crossed to *Ai14* mice, as the Respondent's own data in Figure 6 of U01 DA056010–01 and Figure 8 of R01 AG078019–01, representing results in 12-weeks old iTat mice

—using, cropping, and splicing Figures 5g–5i of *BioRxiv* 2020, representing cell type transcription factors networks signature of the regulatory genome in neurons isolated from the brains of *Snap25–IRES2–Cre* mice crossed to *Ai14* mice, as the Respondent's own data in one research record intended for use in preparing figures for incorporation in U01 DA056010–01, representing spatiotemporal atlas of gene regulatory networks and biological pathways in the brain during neurogenesis and aging altered by Tat expression and HIV infection

- fabricated and plagiarized research data and text that described the research by:

—using Figure 3 of *Front Onc* 2021 as the Respondent's own data in Figure 8 of U01 DA056010–01 and Figure 10 of R01 AG078019–01

- plagiarized text by:

—using a paragraph from *Sci Adv* 2019 as the Respondent's own text describing cocaine use disorder in the section titled ''The problem description and a new therapeutic strategy for CUD in people living with HAND'' of DP1 DA056160–01

—using a paragraph from *Clin Trans Med* 2017 as the Respondent's own text describing single cell sequencing in Specific Aim 2 of both U01 DA056010–01 and R01 AG078019–01

Dr. He entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed to the following:

(1) Respondent will have his research supervised for a period of three (3) years beginning on April 17, 2023 (the ''Supervision Period''). Prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity in PHS-supported research, Respondent will submit a plan for supervision of Respondent's duties to ORI for approval. The supervision plan must be designed to ensure the integrity of Respondent's research. Respondent will not participate in any PHS-supported research until such a supervision plan is approved by ORI. Respondent will comply with the agreed-upon supervision plan.