approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *https://www.regulations.gov.*

Dated: February 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02421 Filed 2–6–20; 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: Nurse Faculty Loan Program—Program Specific Data Form and Annual Performance Report Financial Data Form, OMB No. 0915–0314—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 April 7, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, 14N136B, 5600 Fishers Lane, Rockville, MD 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

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

Information Collection Request Title: Nurse Faculty Loan Program—Program Specific Data Form and Annual Performance Report Financial Data Form OMB No. 0915–0314—Revision.

Abstract: This clearance request is for approval of both the Nurse Faculty Loan Program (NFLP) Program Specific Data Form and the Annual Performance Report (APR) Financial Data Form. The APR Financial Data Form is currently approved under OMB Approval No. 0915–0314 and the Program Specific Data Form is currently approved under OMB Approval No. 0915–0378, both with the expiration date of July 31, 2020. For program efficiency, HRSA is combining these previously separate ICRs under OMB No. 0915–0314 and will be discontinuing OMB No. 0915–0378.

Need and Proposed Use of the Information: Section 846A of the Public Health Service Act provides the Secretary of HHS with the authority to enter into an agreement with schools of nursing for the establishment and operation of a student loan fund to increase the number of qualified nurse faculty.

Under the agreement, HRSA makes awards to the school for the NFLP loan fund, which schools must maintain in a distinct account. The school of nursing makes loans from the NFLP account to students enrolled full-time or, at the discretion of the Secretary, part-time, in a master's or doctoral nursing education program that will prepare them to become qualified nursing faculty. Following graduation from the NFLP-lending school, loan recipients may receive up to 85 percent NFLP loan cancellation over a 4-year period in exchange for service as full-time faculty at a school of nursing. The NFLP-lending school collects any portion of the loan that it has not cancelled and any loans that go into repayment due to default and deposits these monies into the NFLP loan fund to make additional NFLP loans.

The NFLP Program Specific Data Form is a required electronic attachment within the NFLP application materials. The data provided in the form is essential for the formula-based criteria used to determine the award amount to the applicant schools. The form collects application-related data from applicants such as the amount requested, number of students the school will fund, tuition information, and projected unused loan fund balance. Approval of the NFLP Program Specific Data Form allows HRSA to continue to capture data to generate the formula-based awards for the NFLP program. This data collection assists HRSA in streamlining the application submission process, enabling an efficient award determination process, and facilitating reporting on the use of funds and analysis of program outcomes.

The NFLP–APR Financial Data Form is an online form that exists in the HRSA Electronic Handbooks Performance Report module. The NFLP–APR Financial Data Form collects outcome and financial data to capture the NFLP loan fund account activity related to financial receivables, disbursements, and borrower account data related to employment status, loan cancellation, loan repayment, and collections. Participating schools provide HHS with current and cumulative information on: (1) NFLP loan funds received, (2) number and amount of NFLP loans made, (3) number and amount of loans cancelled, (4) number and amount of loans in repayment, (5) loan default rate percent, (6) number of NFLP graduates employed as nurse faculty, and (7) other related loan fund costs and activities.

The school of nursing must keep records of all NFLP loan fund transactions. HRSA uses the NFLP–APR Financial Data Form to monitor grantee performance by collecting information related to the NFLP loan fund operations and financial activities for a specified reporting period (July 1 through June 30 of the academic year). Participating schools are required to complete and submit the NFLP–APR Financial Data Form annually.

The data provided in the form is essential for HRSA to monitor the school's use of NFLP funds in accordance with the statute and program guidelines. Approval of the NFLP–APR Financial Data Form extension will allow HRSA to continue to monitor program performance and program outcome.

Likely Respondents: Participating NFLP schools and applicants to the NFLP program.

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
Nurse Faculty Loan Program—Program Specific Data Form	90	1	90	8	720
Nurse Faculty Loan Program—Annual Performance Report Financial Data Form	260	1	260	6	1,560
Total Burden	350		350		2,280

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. 2020–02408 Filed 2–6–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Determination of Public Health Emergency

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On February 4, 2020, the Secretary determined pursuant to his authority under section 564 of the FD&C Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of this novel coronavirus (2019-nCoV) pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination and declaration took effect February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, M.D., MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 564 of the FD&C Act, 21 U.S.C. 360bbb–3, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act [1] sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.[2]

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

The determination of a public health emergency, and the declaration that circumstances exist justifying emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV) by the Secretary of HHS, as described below, enable the FDA Commissioner to issue EUAs for certain in vitro diagnostics for emergency use under section 564 of the FD&C Act. The Centers for Disease Control and Prevention (CDC) requested that the FDA issue an EUA for its in

[1] 42 U.S.C. 247d–6b.

[2] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Public Law 113–5, the Secretary may make determination of a public health emergency, or a significant potential for a public health emergency, under section 564 of the FD&C Act. The Secretary is no longer required to make a determination of a public health emergency in accordance with section 319 of the PHS Act, 42 U.S.C. 247d to support a determination or declaration made under section 564 of the FD&C Act.