transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

<table>
<thead>
<tr>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total responses</th>
<th>Average burden per response (in hours)</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse Faculty Loan Program—Program Specific Data Form</td>
<td>90</td>
<td>1</td>
<td>90</td>
<td>8</td>
<td>720</td>
</tr>
<tr>
<td>Nurse Faculty Loan Program—Annual Performance Report Financial Data Form</td>
<td>260</td>
<td>1</td>
<td>260</td>
<td>6</td>
<td>1,560</td>
</tr>
<tr>
<td>Total Burden</td>
<td>350</td>
<td></td>
<td>350</td>
<td></td>
<td>2,280</td>
</tr>
</tbody>
</table>

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.


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) 205–2082 (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 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.

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

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1 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.

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.
viro diagnostic for detection of 2019-nCoV to allow the Department to take preparedness measures based on information currently available about 2019-nCoV.

II. Determination by the Secretary of Health and Human Services

On February 4, 2020, pursuant to section 564 of the FD&C Act, I determined 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).

III. Declaration of the Secretary of Health and Human Services

Also on February 4, 2020, on the basis of my determination of 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 the novel (new) coronavirus (2019-nCoV), I declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV) pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of any EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the Federal Register as required under section 564 of the FD&C Act.

Alex M. Azar II,
Secretary.


DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, April 16, 2020, 6:00 p.m. The meeting is closed to the public.


Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) 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: National Institute of General Medical Sciences Special Emphasis Panel; Review the U01 Diversity Program Consortium—Dissemination and Translation Award applications.

Date: March 25, 2020.
Time: 8:30 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Embassy Suites—Chevy Chase Pavilion, Conference Room Chevy Chase Ballroom, 4300 Military Road NW, Washington, DC 20051.

Contact Person: Rebecca H. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18C, 45 Center Drive, Bethesda, MD 20892, (301) 594–2771, johnsonrh@nihms.nih.gov.

Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Cellular, Molecular and Integrative Reproduction Study Section, February 19, 2020, 8:00 a.m. to February 20, 2020, 5:00 p.m. at the Embassy Suites Alexandria Old Town, 1900 Diagonal Road, Alexandria, VA 22314, which was published in the Federal Register on January 27, 2020, 85 FR 4672.

The Contact Person for this meeting has been changed to Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Phone (301) 435–1053, email: riversae@csr.nih.gov. The meeting date and time remain the same. The meeting is closed to the public.