10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: March 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05641 Filed 3–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Security Assistant Deputy Secretary of National Security Statement of Delegation of Authority

Notice is hereby given that I have delegated to the Assistant Deputy Secretary for National Security within the Office of the Secretary (OS), Immediate Office of the Secretary (IOS), Office of National Security (ONS), the authorities vested in me as the Secretary of Health and Human Services for managing the Controlled Unclassified Information Program under Executive Order 13556, now and hereafter.

This authority may be redelegated, but only within ONS. Exercise of this authority shall be in accordance with established policies, procedures, guidelines, and regulations as prescribed by the E.O. 13556 and 32 CFR part 2002 ''Controlled Unclassified Information.''

This delegation of authority is effective immediately upon signature.

Dated: March 15, 2023.

Xavier Becerra,

Secretary.

[FR Doc. 2023–05637 Filed 3–17–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

COVID–19 Emergency Use Authorization Declaration

ACTION: Notice of amendment.

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 March 15, 2023, the Secretary amended the February 4, 2020 determination made pursuant to section 564 of the FD&C Act and determined pursuant to his authority under section 564(b)(1)(C) 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 biological agent, namely the novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV, or SARS–CoV–2).

DATES: The section 564(b)(1)(C) determination that was originally issued on February 4, 2020, is amended as of March 15, 2023.

FOR FURTHER INFORMATION CONTACT: Paige Ezernack: 202–260–0365, *paige.ezernack@hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an EUA authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, an unlicensed biological product, or an unapproved animal drug; or (2) an unapproved use of an approved drug, approved or cleared device, licensed biological product, or conditionally approved animal drug. 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 CBRN 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 issue a declaration(s) that circumstances exist that justify the issuance of an EUA(s), at which point the FDA Commissioner may issue an EUA(s) for certain products if the criteria for issuance under section 564 of the FD&C Act are met. The section 564 declaration(s) terminate only when the Secretary of HHS determines that the termination requirements of section 564(b)(2)(A) of the FD&C Act are met. Additionally, section 564(b)(3) provides that the Secretary shall provide advance notice, by publication in the **Federal Register**, that a declaration(s) under section 564 will be terminated.

II. Determination by the Secretary of Health and Human Services

On February 4, 2020, pursuant to his authority under section 564 of the FD&C Act, the Secretary of HHS determined that the circumstances in section 564(b)(1) exist because ''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).'' 85 FR 7316.

It is now well established that SARS–CoV–2 is constantly evolving and continues to be an ongoing challenge. As of January 30, 2023, SARS–CoV–2 has led to over 753 million cases of COVID–19, including 6.8 million deaths worldwide. This is due, in part, to variations in the virus that may allow it to spread more easily or make it resistant to treatments or decreased vaccine effectiveness. There is also a risk that eventually a variant will emerge that will escape the protection provided by the current generation of vaccines against severe disease. For example, the SARS–CoV–2 Omicron variant has continued to evolve into sublineages with additional mutations in the spike glycoprotein and the

receptor binding domain. Evolution of the virus also raises similar concerns about the continued efficacy of certain categories of therapeutics, such as monoclonal antibodies. The distribution of Omicron sublineages varies at different points in time in different regions of the world. The large number of mutations in the Omicron variant sublineages and the ongoing evolution of the virus remain a concern for potential evasion of vaccine immunity.

In light of this, I have now amended the February 4, 2020 determination to recognize the fact 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 biological agent, namely the novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV, or SARS–CoV–2). (Emphasis added). If the current conditions change such that there is no longer a ''public health emergency'' within the meaning of section 564, the section 564(b)(1)(C) determination would remain in place because I have determined that there is also a ''significant potential for a public health emergency'' under that section. This avoids the need to issue a new determination under section 564 when there is no longer a ''public health emergency,'' but there is still a ''significant potential for a public health emergency'' involving SARS–CoV–2.

The four previously-issued section 564 declarations that refer to the February 4, 2020 determination have not been terminated by the Secretary because, among other things, the circumstances described in section 564(b)(1) continue to exist—*i.e.,* COVID–19, a disease attributable to SARS–CoV–2, continues to present 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. Consistent with section 564(f), the currently-in-effect Emergency Use Authorizations (EUAs) issued under those section 564 declarations remain in effect until the earlier of the termination of relevant section 564 declarations under section 564(b), or revocation of the EUAs. Therefore, these EUAs continue in effect.

III. Declarations of the Secretary of Health and Human Services; EUAs Issued Under the Declarations

Based on the February 4, 2020 determination, in February and March 2020, the Secretary of HHS, pursuant to section 564 of the FD&C Act and subject to the terms of any authorization issued under that section, declared that circumstances exist justifying the authorization of emergency use of: (1) in vitro diagnostics for detection and/or diagnosis of this novel coronavirus, 85 FR 7316; (2) personal respiratory protective devices, 85 FR 13907; (3) other medical devices including alternative products used as medical devices, 85 FR 17335; and (4) drugs and biological products, 85 FR 18250.

These section 564 declarations continue in effect. Specifically, under section 564(b)(2)(A), a declaration made under section 564 will not terminate unless the Secretary determines that ''the circumstances described in [section 564(b)(1)] have ceased to exist,'' or there is ''a change in the approval status of the [authorized] product such that the circumstances described in subsection (a)(2) have ceased to exist.'' Section 564(b)(2)(A) of the FD&C Act. The first basis for termination is not met because the circumstances described in section 564(b)(1) have not ceased to exist; to the contrary, as described above, I have determined that the circumstances described in section 564(b)(1)(C) continue to exist. The second basis for termination is not met because each declaration covers many products, or emergency uses of products, at least some of which remain ''unapproved'' within the meaning of section 564(a)(2).

Consistent with section 564(f), the EUAs issued under these declarations remain in effect until the earlier of the termination of relevant section 564 declarations or revocation of the EUAs. Accordingly, the currently-in-effect EUAs issued under the section 564 determination/declarations for COVID–19 also continue in effect.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–05609 Filed 3–17–23; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Care Quality Across the Lifespan.

Date: March 28, 2023.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mary Kate Baker, DRPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–5117, *katie.baker2@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 15, 2023.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–05631 Filed 3–17–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 meetings 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 purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to