

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](mailto: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