

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]

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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

internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; FEB2023 Cycle 43 NExT SEP Committee Meeting.

Date: April 27, 2023.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To evaluate the NCI Experimental Therapeutics Program Portfolio.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Room 3A44, Bethesda, Maryland 20892 (WebEx Meeting).

Contact Persons: Barbara Mroczkowski, Ph.D., Executive Secretary, Discovery Experimental Therapeutics Program, National Cancer Institute, NIH, 31 Center Drive, Room 3A44, Bethesda, Maryland 20817, 301-496-4291, mroczkowskib@mail.nih.gov.

Toby Hecht, Ph.D., Executive Secretary, Development Experimental Therapeutics Program, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 3W110, Rockville, Maryland 20850, 240-276-5683, toby.hecht2@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 15, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-05604 Filed 3-17-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA)

Advisory Committee for Women's Services (ACWS); Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of a meeting of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Advisory Committee for Women's Services (ACWS) on April 25, 2023.

The meeting will include discussions on assessing SAMHSA's current strategies, including the mental health and substance use needs of the women and girls population. Additionally, the ACWS will be addressing priorities regarding the impact of COVID-19 on the behavioral health needs of women and children and directions around behavioral health services and access for women and children.

The meeting is open to the public and will be held at 5600 Fishers Lane, Rockville, Maryland 20857. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions should be forwarded to the contact person by April 15, 2023. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations are encouraged to notify the contact person on or before April 15, 2023. Up to five minutes will be allotted for each presentation as time allows.

The meeting may be accessed via telephone or web meeting. To obtain the call-in number and access code, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register on-line at <https://snacregister.samhsa.gov>, or communicate with SAMHSA's Designated Federal Officer, Ms. Valerie Kolick.

Substantive meeting information and a roster of ACWS members may be obtained either by accessing the SAMHSA Committees' Web, <https://www.samhsa.gov/about-us/advisory-councils/acws>, or by contacting Ms. Kolick.

Committee Name: Substance Abuse and Mental Health Services Administration Advisory Committee for Women's Services (ACWS).

Date/Time/Type: Tuesday, April 25, 2023, from: 9 a.m. to 4:30 p.m. EDT (OPEN).

Place: SAMHSA, 5600 Fishers Lane, Rockville, MD 20857.

Contact: Valerie Kolick, Designated Federal Officer, SAMHSA's Advisory Committee for Women's Services, 5600 Fishers Lane, Rockville, MD 20857, Telephone: (240) 276-1738, Email: Valerie.kolick@samhsa.hhs.gov.

Dated: March 13, 2023.

Carlos Castillo,

CAPT, USPHS, Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 2023-05568 Filed 3-17-23; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Meeting of the Substance Abuse and Mental Health Services Administration, Center for Mental Health Services National Advisory Council

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: Pursuant to Public Law 92-463, notice is hereby given of the meeting on April 25, 2023, of the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services National Advisory Council (CMHS NAC).

The meeting is open to the public and will include consideration of the meeting minutes from the August 18, 2022, SAMHSA, CMHS NAC meeting; updates from the CMHS Director; a discussion from SAMHSA's Assistant Secretary; a discussion on Certified Community Behavioral Health Clinic; a discussion on School Based Mental Health Services; a discussion on Mental Health Block Grant; a discussion on Black Youth Suicide Prevention Activities; and a discussion on CMHS/SAMHSA Response to Disasters.

The meeting will be held at SAMHSA, 5600 Fishers Lane, 5N54, Rockville, MD 20857. Attendance by the public will be limited to space available and will be limited to the open sessions of the meeting. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Council. Presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making public comment must notify the contact person, Pamela Foote, CMHS NAC Designated Federal Officer (DFO) on or before April 14, 2023. Up to three minutes will be allotted for each public comment as time permits. Written comments received in advance of the meeting will be considered for inclusion in the official record.

The open meeting session may also be accessed virtually. Please register on-line at <https://snacregister.samhsa.gov>, to attend on either on site or virtually, submit written or brief oral comments, or request special accommodations for persons with disabilities. To communicate with the CMHS NAC DFO please see the contact information below. Meeting information and a roster of Council members may be obtained by accessing the SAMHSA Committee