Although FDA has issued guidance on expanded access requests, including expanded access for individual patients, the Agency is aware that IRBs seek further clarity on this topic.

Under FDA regulations, there are three categories of expanded access: individual (also known as single) patient, including for emergency use; intermediate-size for intermediate-size patient populations; and ''treatment'' for larger populations. This guidance only applies to IRB review of individual patient expanded access submissions, as outlined in 21 CFR 312.310. The recommendations in this guidance are intended to provide additional clarity to assist IRBs in conducting efficient reviews of individual patient expanded access requests.

In the **Federal Register** of June 9, 2020 (85 FR 35311), FDA announced the availability of a guidance for IRBs and investigators entitled ''Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID–19 Public Health Emergency: Guidance for IRBs and Clinical Investigators'' (2020 COVID–19 guidance) to support public health efforts following a determination, under section 319 of the Public Health Service (PHS) Act (42 U.S.C. 247d), by the Secretary of Health and Human Services that a public health emergency existed related to Coronavirus Disease 2019 (COVID–19 public health emergency). The 2020 COVID–19 guidance focused on addressing the COVID–19 public health emergency and was intended to remain in effect only for the duration of the COVID–19 public health emergency. However, the 2020 COVID–19 guidance explained we expected the recommendations would assist the Agency more broadly in its continued efforts to facilitate access to drugs through expanded access for individual patients beyond the COVID–19 public health emergency and that FDA would replace the 2020 COVID–19 guidance with any appropriate changes based on comments received and the Agency's experience with implementation. FDA continues to believe that many of the recommendations set forth in the 2020 COVID–19 guidance are applicable outside the context of the COVID–19 public health emergency and are applicable to key factors and procedures IRBs should consider when reviewing individual patient expanded access submissions. In addition, in the **Federal Register** of March 13, 2023 (88 FR 15417), FDA listed the 2020 COVID–19 guidance as one of the guidances FDA was revising to continue in effect for 180 days after the COVID–19 PHE declaration issued under the PHS Act expired on May 11, 2023, during which time FDA planned to further revise those guidances. Consistent with what we said in the **Federal Register** of March 13, 2023, FDA is therefore issuing this revised final guidance, which supersedes the 2020 COVID–19 guidance. FDA revised the guidance to remove references to the COVID–19 public health emergency and made editorial changes to improve clarity. FDA also clarified recommendations on IRB procedures and factors to consider for individual patient expanded access submissions.

FDA is issuing this guidance for immediate implementation in accordance with our good guidance practices regulation (21 CFR 10.115(g)(3)) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate (see 21 CFR 10.115(g)(2) and section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i))). Specifically, we are not seeking prior comment because public health emergencies (PHEs) and the need to address individual patient expanded access submissions for patient access to investigational drugs for diagnosing, monitoring, or treating diseases or conditions related to PHEs may occur without notice and, as we have learned from experience during the COVID–19 PHE, may hinder physicians seeking to treat their patients in a timely manner. It is thus important to public health to provide recommendations regarding the key factors and procedures IRBs should consider when reviewing requests. Interested parties had an opportunity to comment on the recommendations in the 2020 COVID–19 guidance, and FDA considered those comments when revising the guidance. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with FDA's good guidance practices regulation (§ 10.115(g)(3)(D)).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on ''Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 and Form FDA 1571 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 relating to the protection of human subjects, informed consent, and IRBs have been approved under OMB control number 0910–0130. The collections of information in 21 CFR 312.300 through 312.320 relating to expanded access to investigational drugs for treatment use and Form FDA 3926 have been approved under OMB control number 0910–0814. The collections of information in 21 CFR part 11 relating to electronic records and signatures have been approved under OMB control number 0910–0303.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19501 Filed 9–8–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's Centers for Disease Control and Prevention (CDC)/HRSA Advisory Committee on HIV, Viral Hepatitis and

STD Prevention and Treatment (CHAC) has scheduled a public meeting. Information about CHAC and the meeting can be found on the CHAC website at *https://www.cdc.gov/faca/committees/chachspt.html* and the meeting website at *https://targethiv.org/ta-org/chac*.

DATES: Tuesday, October 24, 2023, 9 a.m. to 4 p.m. Eastern Time (ET); and Wednesday, October 25, 2023, 9 a.m. to 3 p.m. ET.

ADDRESSES: This meeting will be hybrid, held both virtually through Zoom and in person at 5600 Fishers Lane, Pavilion Rooms 5A02, 5A03, and 5A04, Rockville, Maryland 20857. Advance registration is required to attend. Please visit the meeting website to register. The in-person registration deadline is Monday, October 16, 2023, at 5 p.m. ET; registration for virtual attendance will remain open. Prior to the meeting, each individual registrant will receive a registration confirmation along with an access link to the virtual meeting location.

FOR FURTHER INFORMATION CONTACT: Shalonda Collins, Public Health Analyst, HIV/AIDS Bureau, HRSA, (301) 945–0835; *CHACAdvisoryComm@hrsa.gov*.

SUPPLEMENTARY INFORMATION: CHAC provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under Section 222 of the Public Health Service Act, 42 U.S.C. 217a.

The purpose of the CHAC is to advise the Secretary of HHS, CDC Director, and HRSA Administrator regarding objectives, strategies, policies, and priorities for the prevention and treatment of HIV, viral hepatitis, and other STDs, including surveillance, epidemiologic, behavioral, health services, and laboratory research, identification of policy issues related to professional eduction, patient healthcare delivery, and prevention services; agency policies regarding health care delivery, research and training; strategic issues influencing the ability of CDC and HRSA to fulfill their missions' programmatic efforts to prevent and treat HIV, viral hepatitis, and other STDs; and support to CDC and HRSA in their development of responses to emerging health needs related to these issues.

During the October 24–25, 2023, meeting, CHAC will discuss issues related to reducing barriers and improving outcomes in HIV and Hepatitis C co-infection, payment models for addressing social determinants of health, incorporating stigma reduction in HIV care and treatment, as well as other special presentations. Agenda items are subject to change as priorities dictate. Refer to the CHAC meeting information page for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may also submit written statements as further described below. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to CHAC should be sent via the meeting website at *https://targethiv.org/ta-org/chac*. Requests for oral comment must be received by October 17, 2023, at 5 p.m. ET to be considered. Written comments may be submitted to Shalonda Collins at the email address and/or phone number listed above prior to and up to 10 business days after the meeting. Visit the meeting information page for additional details: *https://targethiv.org/ta-org/chac*.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Shalonda Collins at the email address and/or phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–19542 Filed 9–8–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 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; Societal and Ethical Issues in Research.

Date: October 6, 2023.

Time: 10:00 a.m. to 9:00 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: Maria De Jesus Diaz Perez, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000G, Bethesda, MD 20892, (301) 496–4227, *diazperezm2@csr.nih.gov*.

(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: September 6, 2023.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–19506 Filed 9–8–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2748–23; DHS Docket No. USCIS–2014–004]

RIN 1615–ZB79

Extension and Redesignation of South Sudan for Temporary Protected Status

Correction

In Notice document 2023–19312 beginning on page 60971 in the issue of Wednesday, September 6, 2023, make the following correction:

On page 60976, in the first column, in the signature, in the first line ''Alejandro N. Mayorkas,Vienna'' should read ''Alejandro N. Mayorkas,''.

[FR Doc. C1–2023–19312 Filed 9–8–23; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0001]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Petition for Alien Fiancé(e)

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.