

progress in implementing resource capacity planning and modernized time reporting. This meeting is intended to satisfy FDA's commitment to host an annual public meeting in the third quarter of each fiscal year beginning in FY 2019 and can be found in the Commitment Letters listed below (sections II.B.3 of PDUFA VI (p. 38), IV.B.3 of BsUFA II (p. 29), and VI.B.4 of GDUFA II (p.22)).

This public meeting is intended to meet performance commitments included in the respective Commitment Letters for PDUFA VI, BsUFA II, and GDUFA II. These user fee programs were reauthorized as part of the FDA Reauthorization Act of 2017 signed by the President on August 18, 2017. The complete set of performance goals for each program are available at:

- PDUFA VI program: <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>
- BsUFA II program: <https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf>
- GDUFA II program: <https://www.fda.gov/downloads/forindustry/userfees/genericdruguserfees/ucm525234.pdf>

Each of these user fee programs' Commitment Letters included a set of commitments related to financial management. These included commitments to publish a 5-year financial plan and update that plan annually, develop resource capacity planning capability and modernize time reporting practices, and have a third-party evaluation of resource management practices for these user fee programs. In addition, each user fee program includes a commitment to host a public meeting in the third quarter of each fiscal year, beginning in FY 2019, to discuss specific topics.

II. Topics for Discussion at the Public Meeting

This meeting will provide FDA the opportunity to update interested public stakeholders on topics related to the financial management of PDUFA VI, BsUFA II, and GDUFA II. These topics include the 5-year financial plans for each of these programs and FDA's progress towards implementing resource capacity planning and modernizing its time reporting approach.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: [https://fda.zoomgov.com/webinar/register/WN_](https://fda.zoomgov.com/webinar/register/WN_C5cXHj38R6WeNg1ZuqbKaA)

[C5cXHj38R6WeNg1ZuqbKaA](https://fda.zoomgov.com/webinar/register/WN_C5cXHj38R6WeNg1ZuqbKaA). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Persons interested in attending this public meeting must register by June 2, 2022, at 11:59 p.m. Eastern Time. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Monica Ellerbe at Monica.Ellerbe@fda.hhs.gov by June 2, 2022, at 11:59 p.m. Eastern Time.

Streaming Webcast of the Public Meeting: This public meeting will be a webcast. To register for the public meeting and obtain the webcast information, please visit the following website: https://fda.zoomgov.com/webinar/register/WN_C5cXHj38R6WeNg1ZuqbKaA.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: May 6, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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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 June 14, 2022.

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 virtually. Interested persons may present data, information, or views, orally or in writing, on issues pending

before the committee. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in sending written submissions or in making oral presentations should forward them to the contact person by 4:00 p.m. (EDT) May 27, 2022. Up to five minutes will be allotted for each presentation.

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://www.samhsa.gov/about-us/advisory-councils> 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, June 14, 2022, from: 12:30 p.m. to 4:30 p.m. EDT/(OPEN).

Place: SAMHSA, 5600 Fishers Lane, Rockville, MD 20857 (Virtual).

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: May 5, 2022.

Carlos Castillo,

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

[FR Doc. 2022-10158 Filed 5-11-22; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4634-DR; Docket ID FEMA-2022-0001]

Colorado; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Colorado (FEMA-4634-DR), dated December 31, 2021, and related determinations.