

considered by FDA and the Quality Expert Working Group.

The draft guidance provides guidance on the development, implementation, operation, and lifecycle management of CM.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on "Q13 Continuous Manufacturing of Drug Substances and Drug Products."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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at 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/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: October 8, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the COVID–19 Health Equity Task Force

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As required by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the COVID–19 Health Equity Task Force (Task Force) will hold a virtual meeting on October 28, 2021. The purpose of this meeting is to present and vote on the Task Force Final Report with recommended Implementation Plan and Accountability Plan for mitigating inequities caused or exacerbated by the COVID–19 pandemic and for preventing such inequities in the future. This meeting is open to the public and will be live-streamed at www.hhs.gov/live. Information about the meeting will be posted on the HHS Office of Minority Health website: www.minorityhealth.hhs.gov/healthequitytaskforce/ prior to the meeting.

DATES: The Task Force meeting will be held on Thursday, October 28, 2021, from 1 p.m. to approximately 4 p.m. ET (date and time are tentative and subject to change). The confirmed time and agenda will be posted on the COVID–19 Health Equity Task Force web page: www.minorityhealth.hhs.gov/healthequitytaskforce/ when this information becomes available.

FOR FURTHER INFORMATION CONTACT: Samuel Wu, Designated Federal Officer for the Task Force; Office of Minority Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Suite 100, Rockville, Maryland 20852. Phone: 240–453–6173; email: COVID19HETF@hhs.gov.

SUPPLEMENTARY INFORMATION:

Background: The COVID–19 Health Equity Task Force (Task Force) was established by Executive Order 13995, dated January 21, 2021. The Task Force is tasked with providing specific recommendations to the President, through the Coordinator of the COVID–19 Response and Counselor to the President (COVID–19 Response Coordinator), for mitigating the health inequities caused or exacerbated by the COVID–19 pandemic and for preventing such inequities in the future. The Task Force shall submit a final report to the COVID–19 Response Coordinator

addressing any ongoing health inequities faced by COVID–19 survivors that may merit a public health response, describing the factors that contributed to disparities in COVID–19 outcomes, and recommending actions to combat such disparities in future pandemic responses.

The meeting is open to the public and will be live-streamed at www.hhs.gov/live. No registration is required. A public comment session will be held during the meeting. Pre-registration is required to provide public comment during the meeting. To pre-register, please send an email to COVID19HETF@hhs.gov and include your name, title, and organization by close of business on Friday, October 22, 2021. Comments will be limited to no more than three minutes per speaker and should be pertinent to the meeting discussion. Individuals are encouraged to provide a written statement of any public comment(s) for accurate minute-taking purposes. If you decide you would like to provide public comment but do not pre-register, you may submit your written statement by emailing COVID19HETF@hhs.gov no later than close of business on Thursday, November 4, 2021. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact: COVID19HETF@hhs.gov and reference this meeting. Requests for special accommodations should be made at least 10 business days prior to the meeting.

Dated: October 7, 2021.

Samuel Wu,

Designated Federal Officer, COVID–19 Health Equity Task Force.

[FR Doc. 2021–22330 Filed 10–13–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public.