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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC Town Hall Meeting on Laboratory Biosafety—Use of Laboratory Instruments

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces a meeting regarding biosafety and laboratory instrumentation.

DATES: The meeting will be held on Friday, June 24, 2022, from 10 a.m. to 3:30 p.m., EDT.

ADDRESSES: This meeting is open to the public through a virtual format, limited only by the webcast lines available. Registration is not required. Visit the CDC Safe Labs website for the meeting webcast at <https://www.cdc.gov/safelabs/biosafety-townhall.html>.

FOR FURTHER INFORMATION CONTACT:

Nancy E. Cornish M.D., Center for Surveillance, Epidemiology and Laboratory Services, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24-3, Atlanta, Georgia 30329-4018; Phone: (404)498-2720; Email: dlsbiosafety@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The purpose of this meeting is to provide an overview and discussion on laboratory biosafety when using laboratory instruments to test human and biologic specimens. Meeting topics are listed in the “Matters to be Considered” section of this notice.

Matters to be Considered: The agenda will include presentations and discussions on four topic areas: (1) instrument design and incorporating biosafety; (2) perceived risks to laboratory personnel and impact on testing; (3) independent assessment of risks and instrument design; and (4) a discussion of potential areas of collaboration to address issues discussed during the meeting. There will be prepared presentations, discussions among presenters and panelists, and a period for questions and

public comments. Agenda items are subject to change as priorities dictate.

Background: CDC’s Division of Laboratory Systems is hosting the town hall meeting in collaboration with clinical and public health laboratory partners, and instrument manufacturers to address clinical laboratory biosafety. The recent publication *Clinical Laboratory Biosafety Gaps: Lessons Learned from Past Outbreaks Reveal a Path to a Safer Future* (Cornish NE. et. al. *Clinical Laboratory Biosafety Gaps: Lessons Learned from Past Outbreaks Reveal a Path to a Safer Future*. *Clin Microbiol Rev.* July 2021, Vol. 34/3 e00126-18) discussed critical gaps in clinical laboratory biosafety, including issues related to the use and disinfection of laboratory instruments. The discussion and feedback generated during the meeting will assist in evaluating current biosafety guidance and identify opportunities for improvement in clinical laboratory biosafety and use of laboratory instrumentation. This meeting is a listening session. Participants may provide individual advice or perspectives. CDC is not seeking consensus advice or recommendations from participants.

Dated: June 14, 2022.

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0030]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and

to allow 60 days for public comment in response to the notice. This notice solicits comments on electronic reporting for outsourcing facilities.

DATES: Submit either electronic or written comments on the collection of information by August 16, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 16, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”