



May 24, 2023

Melissa Bar Hoover, Ph.D., RAC
Senior Regulatory Affairs Manager
Becton, Dickinson and Company
7 Loveton Circle,
Sparks, MD 21152-0999

Re: Revocation of EUA220453

Dear Dr. Bar Hoover:

This letter is in response to the request from Becton, Dickinson and Company (“BD”), in a letter received May 22, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System issued on December 23, 2022. BD has decided not to manufacture or sell these kits moving forward and requested that the EUA be withdrawn. FDA understands that, as of the date of this letter, no VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System reagents were distributed in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because BD has requested that FDA withdraw the EUA for the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System, FDA has determined that it is appropriate, to protect the public health or safety, to revoke this authorization. Accordingly, FDA hereby revokes EUA220453 for the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the VIASURE Monkeypox virus Real Time PCR Reagents for BD MAX System is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

//s//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Dated: October 4, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-22390 Filed 10-6-23; 8:45 am]

BILLING CODE 4164-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

**National Institute on Drug Abuse;
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: National Institute on Drug Abuse Special Emphasis Panel; Implementing Comprehensive HIV Services in Syringe Service Program Settings.

Date: November 17, 2023.

Time: 12:00 to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Trinh T. Tran, Ph.D., Scientific Review Officer, Scientific Review Branch, Office of Extramural Policy, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892 (301) 827-5843, trinh.tran@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS).

Dated: October 3, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-22361 Filed 10-6-23; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2023-0292]

National Chemical Transportation Safety Advisory Committee; November 2023 Meetings

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The National Chemical Transportation Safety Advisory Committee (Committee) will conduct a series of meetings over three days in League City, TX, to discuss matters relating to the safe and secure marine transportation of hazardous materials. The subcommittee meetings will also be available by videoconference for those unable to attend in person, however the full committee meeting will be held in person only. All meetings will be open to the public.

DATES:

Meetings: National Chemical Transportation Safety Advisory Committee subcommittees will meet on Tuesday, November 28 and Wednesday, November 29, 2023, from 9 a.m. to 5 p.m. Central Standard Time (CST) each day. The full Committee will meet on Thursday, November 30, 2023, from 9 a.m. until 5 p.m. CST. Please note these meetings may close early if the Committee has completed its business.

Comments and supporting documents: To ensure your comments are reviewed by Committee members before the meeting, submit your written comments no later than November 15, 2023.

ADDRESSES: The meeting will be held at INEOS Oligomers USA, 2600 South Shore Boulevard, Suite 400, League City, TX 77573.

Pre-Registration Information: Pre-registration is required for in-person access to the meeting or to attend the subcommittee meetings by videoconference. Public attendees will be required to pre-register no later than noon, Eastern Standard Time, on November 15, 2023, to be admitted to the meeting. In-person attendance may be capped due to limited space in the meeting venue, and registration will be on a first-come-first-served basis. To pre-register, contact Lieutenant Ethan Beard at Ethan.T.Beard@uscg.mil. You will be asked to provide your name, telephone number, email, company, or group with which you are affiliated, and whether you wish to attend virtually or in person; if a foreign national, also provide your country of citizenship, passport country, country of residence, place of birth, passport number, and passport expiration date.

The National Chemical Transportation Safety Advisory Committee is committed to ensuring all participants have equal access regardless of disability status. If you require reasonable accommodation due to a disability to fully participate, please email Lieutenant Ethan Beard at Ethan.T.Beard@uscg.mil or call at 202-372-1419 as soon as possible.

Instructions: You are free to submit comments at any time, including orally at the meeting as time permits, but if you want Committee members to review your comment before the meeting, please submit your comments no later than November 15, 2023. We are particularly interested in comments on the topics in the "Agenda" section below. We encourage you to submit comments through the Federal Decision Making Portal at <https://www.regulations.gov/docket/USCG-2023-0292>. If your material cannot be submitted using <https://www.regulations.gov>, contact the individual in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. You must include the docket number USCG-2023-0292. We do not redact personal information from comments which are posted at <https://www.regulations.gov>, so any personal information provided in a comment posted will be viewable by

the public. You may wish to review the Privacy and Security Notice found via a link on the homepage of <https://www.regulations.gov>, and DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). If you encounter technical difficulties with comment submission, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Docket Search: Documents mentioned in this notice as being available in the docket, and all public comments, will be in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign-up for email alerts, you will be notified when comments are posted.

FOR FURTHER INFORMATION CONTACT: Lieutenant Ethan T. Beard, Alternate Designated Federal Officer of the National Chemical Transportation Safety Advisory Committee, telephone 202-372-1419, or email Ethan.T.Beard@uscg.mil.

SUPPLEMENTARY INFORMATION: Notice of the meeting of the National Chemical Transportation Safety Advisory Committee is in compliance with the *Federal Advisory Committee Act*, (Pub. L. 117-286, 5. U.S.C., ch. 10). The Committee is authorized by section 601 of the *Frank LoBiondo Coast Guard Authorization Act of 2018* (Pub. L. 115-282, 132 Stat. 4192) and is codified in 46 U.S.C. 15101. The Committee operates under the provisions of the *Federal Advisory Committee Act* and 46 U.S.C. 15109. The Committee provides advice and recommendations to the Secretary of Homeland Security through the Commandant of the U.S. Coast Guard on matters related to the safe and secure marine transportation of hazardous materials.

Agenda

Tuesday, November 28, 2023

Two subcommittees will meet to discuss the following task statements:

9:00 a.m.–12:00 p.m. CST

(1) *Task Statement 21-01:* Recommendations on Loading Limits of Gas Carriers and USCG Supplement to International Hazardous Zone Requirements.

1:30 p.m.–5:00 p.m. CST

(2) *Task Statement 22-01:* Recommendations to Support Reductions to Emissions and Environmental Impacts Associated with Marine Transport of Chemicals,