

of communication, to a Public Safety Answering Point (PSAP) for the purpose of requesting emergency services.

As part of implementing section 506 of RAY BAUM'S Act, on August 1, 2019, the Commission adopted a *Report and Order (2019 Order)*, set forth rules requiring Fixed Telephony providers and MLTS providers to ensure that dispatchable location is conveyed with 911 calls.

The Commission's 2019 Order adopted §§ 9.8(a) and 9.16(b)(3)(i), (ii), and (iii) to facilitate the provision of automated dispatchable location. For Fixed Telephony and in fixed Multi-line Telephone Systems (MLTS) environments, respective providers must provide automated dispatchable location with 911 calls. For on-premises, non-fixed devices associated with an MLTS, the MLTS operator or manager must provide automated dispatchable location to the appropriate PSAP when technically feasible; otherwise they must provide either dispatchable location based on end-user manual update, or alternative location information. For off-premises MLTS calls to 911, the MLTS operator or manager must provide (1) dispatchable location, if technically feasible, or, otherwise, either (2) manually-updated dispatchable location, or (3) enhanced location information, which may be coordinate-based, consisting of the best available location that can be obtained from any available technology or combination of technologies at reasonable cost. The requirements adopted in the 2019 Order account for variance in the feasibility of providing dispatchable location for non-fixed MLTS 911 calls, and the means available to provide it. The information collection requirements associated with these rules will ensure that Fixed Telephony and MLTS providers have the means to provide 911 callers' locations to PSAPs, thus reducing response times for emergency services.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023-24648 Filed 11-7-23; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreements to

the Secretary by email at Secretary@fmc.gov, or by mail, Federal Maritime Commission, 800 North Capitol Street, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. Copies of agreements are available through the Commission's website (www.fmc.gov) or by contacting the Office of Agreements at (202) 523-5793 or tradeanalysis@fmc.gov.

Agreement No.: 2011175-007.

Agreement Name: Port of NY/NJ Sustainable Services Agreement.

Parties: APM Terminals Elizabeth, LLC; Port Liberty Bayonne LLC; Maher Terminals LLC; Port Liberty New York LLC; Port Newark Container Terminal LLC; Red Hook Container Terminal, LLC.

Filing Party: Carol Lambos; The Lambos Firm LLP.

Synopsis: The Amendment reflects the name changes of member companies GCT Bayonne LP and GCT New York LP to Port Liberty Bayonne LLC and Port Liberty LLC respectively.

Proposed Effective Date: 10/27/2023.

Location: <https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/8136>.

Dated: November 3, 2023.

Carl Savoy,

Federal Register Alternate Liaison Officer.

[FR Doc. 2023-24677 Filed 11-7-23; 8:45 am]

BILLING CODE 6730-02-P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Notice of Board Meeting

DATES: November 14, 2023 at 10 a.m. EST

ADDRESSES: Telephonic. Dial-in (listen only) information: Number: 1-202-599-1426; Code: 675 746 624#; or via web: https://teams.microsoft.com/l/meetup-join/19%3ameeting_OTIxOTM4MzAtYTUyOC00NzNkLWFkMTUtZGQ3ODVhZTY0OGQx%40thread.v2/0?context=%7b%22Tid%22%3a%22f6323b7-e3fd-4f35-b43d-1a7afae5910d%22%2c%22Oid%22%3a%2241d6f4d1-9772-4b51-a10d-cf72f842224a%22%7d.

FOR FURTHER INFORMATION CONTACT: Kimberly Weaver, Director, Office of External Affairs, (202) 942-1640.

SUPPLEMENTARY INFORMATION:

Board Meeting Agenda

Open Session

1. Approval of the October 24, 2023, Board Meeting Minutes
2. Monthly Reports
 - (a) Participant Report
 - (b) Investment Report
 - (c) Legislative Report
3. Quarterly Reports
 - (d) Metrics
4. Internal Audit Update
5. Participant Survey Report
6. OPR Annual Report
7. TSP Investment Option Benchmark Study

Closed Session

8. Information covered under 5 U.S.C. 552b (c)(6) and (c)(10).

Authority: 5 U.S.C. 552b (e)(1).

Dated: November 2, 2023.

Dharmesh Vashee,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2023-24642 Filed 11-7-23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-0823]

Real-Time Oncology Review; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Real-Time Oncology Review (RTOR)." The purpose of this guidance is to provide recommendations to applicants on the process for submission of selected new drug applications (NDAs) and biologics license applications (BLAs) with oncology indications for review under RTOR. This guidance finalizes the draft guidance of the same title issued on July 22, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on November 8, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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."

Instructions: All submissions received must include the Docket No. FDA-2022-D-0823 for "Real-Time Oncology Review (RTOR)." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information

redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of

Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: R. Angelo De Claro, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2173, Silver Spring, MD 20993, 301-796-4415; or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Real-

Time Oncology Review (RTOR)." The purpose of this guidance is to provide recommendations to applicants on the process for submission of selected NDAs and BLAs with oncology indications for review under RTOR.

The FDA Oncology Center of Excellence, in collaboration with the Office of Oncologic Diseases, commenced RTOR in February 2018 to facilitate earlier submission of topline results (*i.e.*, efficacy and safety results from clinical studies before the study report is completed) and datasets, after database lock, to support an earlier start to the FDA application review. The intent of RTOR is to provide FDA reviewers earlier access to data, to identify data quality and potential review issues, and to potentially enable early feedback to the applicant, which can allow for a more streamlined and efficient review process. RTOR also involves early engagement with the applicant to discuss the submission timelines for RTOR components and the full application submission. RTOR does not alter the review performance goals and timelines associated with the applications, including as described in the Prescription Drug User Fee Amendments. Participation by the applicant is voluntary and acceptance into RTOR does not guarantee or influence approval of the application, which is subject to the same statutory and regulatory requirements for approval as applications that are not included in RTOR.

This guidance finalizes the draft guidance entitled "Real-Time Oncology Review (RTOR)" issued on July 22, 2022 (87 FR 43870). FDA considered comments received on the draft guidance as the guidance was finalized. The final guidance includes (1) clarification of terminologies used in the guidance, (2) clarification on the submission process, and (3) additional changes to align the guidance with the RTOR website.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Real-Time Oncology Review (RTOR)." 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 (44 U.S.C. 3501–3521). 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; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

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/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: November 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–24712 Filed 11–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (Parent R13 Clinical Trial Not Allowed).

Date: December 5–7, 2023.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of

Health, 5601 Fishers Lane, Room 3E71, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Lee G. Klinkenberg, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71, Rockville, MD 20852, 301–761–7749, lee.klinkenberg@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 2, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24634 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session can be accessed from the Fogarty International Center website (<https://www.fic.nih.gov/About/Advisory/Pages/default.aspx>).

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: Fogarty International Center Advisory Board.

Date: February 5–6, 2024.

Closed: February 5, 2024, 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate the second level of grant applications.

Place: Fogarty International Center, National Institutes of Health, Lawton Chiles International House (Stone House), 16 Center Drive, Conference Room Bethesda, MD 20892.

Open: February 6, 2024, 9:00 a.m. to 3:00 p.m.

Agenda: Update and discussion of current and planned Fogarty International Center activities.

Place: Fogarty International Center, National Institutes of Health, Lawton Chiles International House (Stone House), 16 Center Drive, Conference Room Bethesda, MD 20892 (Virtual Meeting).

Meeting Access: <https://www.fic.nih.gov/About/Advisory/Pages/default.aspx>.

Contact Person: Kristen Weymouth, Executive Secretary, Fogarty International Center, 31 Center Drive, Room B2C02, Bethesda, MD 20892, 301–495–1415, kristen.weymouth@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Persons listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at <https://www.nih.gov/about-nih/visitor-information/campusaccess-security> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://www.fic.nih.gov/About/Advisory/Pages/default.aspx>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship Awards Program, National Institutes of Health, HHS)

Dated: November 2, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–24627 Filed 11–7–23; 8:45 am]

BILLING CODE 4140–01–P