

novel analytical methods—can increase product development speed, bolster supply chains, and prevent drug shortages. On June 8, 2023, FDA cosponsored and participated in a public workshop hosted by the Duke-Margolis Center for Health Policy on “Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches.” At this workshop, interested parties from industry shared feedback on their interactions with FDA’s CDER Emerging Technology Program (ETP) and CBER Advanced Technologies Team (CATT) to guide submissions from persons or organizations using innovative manufacturing technologies. Regulators, academic researchers, and industry representatives discussed the current barriers to using these technologies and shared ideas on how initiatives such as the newly created Advanced Manufacturing Technologies Designation Program (AMTDP) could alleviate these barriers. The workshop fulfilled a PDUFA VII commitment related to advancing utilization and implementation of innovative manufacturing, as well as section 506L(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356L(e)(1)), as amended by section 3213 of the Food and Drug Omnibus Reform Act of 2022 regarding the AMTDP.

Based on lessons learned from the Agency’s experience with submissions involving advanced manufacturing, the topics discussed during the June 8, 2023, workshop, and other public input, FDA developed the draft Strategy Document on Innovative Manufacturing Technologies, which outlines the specific activities FDA intends to undertake to facilitate the use of innovative manufacturing technologies. Specifically, under the draft strategic plan FDA intends to undertake the following activities: continue to enhance the ETP and CATT as a mechanism to support innovation; implement the AMTDP in a manner that reflects feedback on eligibility criteria; continue to identify opportunities for international harmonization in support of advanced manufacturing; support and utilize ongoing initiatives for advanced manufacturing to address potential barriers; and support training in advanced manufacturing for FDA assessment staff.

II. Requested Information and Comments

The draft Strategy Document on Innovative Manufacturing Technologies is available on FDA’s website for Completed PDUFA VII Deliverables (<https://www.fda.gov/industry/>

[prescription-drug-user-fee-amendments-completed-pdufa-vii-deliverables](https://www.fda.gov/industry/prescription-drug-user-fee-amendments-completed-pdufa-vii-deliverables)). Interested persons are invited to provide detailed comments on all aspects of the draft Strategy Document. FDA encourages interested parties to provide the specific rationale and basis for their comments, including any available supporting data and information.

Dated: September 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2023–0822]

Port Access Route Study: Approaches to the Port of Cape Canaveral and Vessel Transit Offshore Jacksonville, Daytona, and Canaveral, Florida

AGENCY: Coast Guard, DHS.

ACTION: Notice of public meeting.

SUMMARY: A meeting will be held on September 19, 2024, to support public interest in the Coast Guard’s Port Access Route Study (PARS) for the Approaches to the Port of Cape Canaveral and Vessel Transit Offshore Jacksonville, Daytona, and Canaveral, Florida. The Coast Guard will discuss the PARS notice of study that was published on April 17, 2024, and next steps for public engagement. This meeting is open to the public, and the Coast Guard invites those attending to bring additional comments that support the goals of the PARS.

Public Meeting: The meeting will be held at the Maritime Center (Commission Room), 445 Challenger Rd., Cape Canaveral, FL 32920 on Thursday, September 19, 2024, from 11 a.m. to 12:30 p.m., Eastern Daylight Time. Closer to the meeting date, guidance on how to join virtually will be published in the Local Notice to Mariners (LNM) for Coast Guard District Seven (D7) and the Sector Jacksonville Marine Safety Information Bulletin (MSIB). If the meeting date or time needs to be adjusted due to unforeseen circumstances, an updated date and time will be communicated via the LNM and MSIB. D7 LNMs can be accessed on the Coast Guard Navigation Center’s website at <https://www.navcen.uscg.gov/local-notices-to-mariners?district=7+0&subdistrict=n>. Sector Jacksonville MSIBs can be accessed on their Homeport page at

<https://homeport.uscg.mil/port-directory/jacksonville>.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of public meeting or the PARS notice of study, call or email Lieutenant Meredith Overstreet, Seventh Coast Guard District (dpw), U.S. Coast Guard; telephone 206–815–5857, email Meredith.D.Overstreet1@uscg.mil.

SUPPLEMENTARY INFORMATION: On April 17, 2024, the Coast Guard published a notice in the **Federal Register** announcing we were conducting a PARS to evaluate safe routes for vessel traffic transiting to and from the Port of Cape Canaveral and within the offshore waters of Jacksonville, Daytona, and Canaveral, Florida.¹ In the notice, we requested public comments on the PARS that closed on July 16, 2024. Additionally, we asked the public to inform us if they wanted a public meeting regarding the study area. We received two public comments requesting a public meeting.² We are scheduling a public meeting. The details on the meeting are located in the “Public Meeting” section of this document.

To access the original notice of study, refer to docket number USCG–2023–0822 in the **Federal Register** by utilizing the search box at <https://www.federalregister.gov/> or by following the direct link: <https://www.federalregister.gov/documents/2024/04/17/2024-08191/port-access-route-study-approaches-to-the-port-of-cape-canaveral-and-vessel-transit-offshore>.

This notice is published under the authority of 46 U.S.C. 70003(c)(1).

Dated: September 9, 2024.

Douglas M. Schofield,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

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¹ Coast Guard Notice of study; request for comments document titled, Port Access Route Study: “Approaches to the Port of Cape Canaveral and Vessel Transit Offshore Jacksonville, Daytona, and Canaveral, Florida” (89 FR 27435).

² These comments can be viewed on [regulations.gov](https://www.regulations.gov) at: [Regulations.gov](https://www.regulations.gov). Insert “USCG–2023–0822” in the “search box.” Click on the PARS Study Notice document. Then click on the tab “Document Comments.”