Requests for copies of the information collection proposal should be sent to Mr. Lucas at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: September 4, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–20650 Filed 9–11–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3945]

The Food and Drug Administration's Draft Strategy Document on Innovative Manufacturing Technologies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the publication of a draft Strategy Document for public comment outlining specific actions FDA will take during fiscal years 2023–2027 to facilitate the use of innovative manufacturing technologies. As part of the Prescription Drug User Fee Act (PDUFA) Reauthorization Performance Goals and Procedures Fiscal Years 2023–2027 (PDUFA VII), FDA committed to advance the use and implementation of innovative manufacturing. In connection with this effort, on June 8, 2023, FDA participated in a public workshop on the use of innovative manufacturing technologies for products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), including barriers to their adoption. FDA also committed to issuing this draft Strategy Document for public comment. The actions described in the draft Strategy Document are based on lessons learned from FDA's experiences with submissions involving advanced manufacturing technologies as well as feedback from the workshop and other public input.

DATES: Either electronic or written comments on the draft Strategy Document must be submitted by November 12, 2024.

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 November 12, 2024.Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–3945 for ''FDA's Strategy Document on Innovative Manufacturing Technologies.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Elisa A. Nickum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4521, Silver Spring, MD 20993, 301–796–4226, *Elisa.Nickum@fda.hhs.gov;* or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Innovative manufacturing technologies—including but not limited to continuous manufacturing, distributed manufacturing, modern aseptic manufacturing equipment, and

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*). 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.

[FR Doc. 2024–20665 Filed 9–11–24; 8:45 am]

BILLING CODE 4164–01–P

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.

[FR Doc. 2024–20746 Filed 9–11–24; 8:45 am]

BILLING CODE 9110–04–P

[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 at: *Regulations.gov.* Insert ''USCG–2023–0822'' in the ''search box.'' Click on the PARS Study Notice document. Then click on the tab ''Document Comments.''