4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2489]

Onshoring Manufacturing of Drugs and Biological Products; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the establishment of a docket to solicit public comments on issues related to accelerating the establishment of new pharmaceutical manufacturing facilities in the United States. FDA is also announcing the following public meeting entitled "Onshoring Manufacturing of Drugs and Biological Products." At this meeting, FDA will present a draft framework that seeks to facilitate onshoring of pharmaceutical manufacturing. Participants will then engage in a guided discussion regarding the proposed framework, its strengths, weaknesses, and opportunities. The group will also discuss additional considerations that may help overcome current challenges faced by industry to onshoring the manufacturing of pharmaceuticals, including active pharmaceutical ingredients (APIs) and finished drug and biological products, and ideas and options within the bounds of FDA's statutory authority that could facilitate such onshoring of manufacturing.

DATES: The hybrid public meeting will be held on September 30, 2025, from 9:00 a.m. to 4:00 p.m. Eastern Time and will take place in person and virtually. Either electronic or written comments on this public meeting must be submitted by October 30, 2025. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held in person at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD

20993-0002 and virtually using Microsoft Teams. Participants must be REAL ID compliant to access federal facilities. For additional information regarding REAL ID, refer to https://www.dhs.gov/real-id/real-id-faqs. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to https://www.fda.gov/about-fda/visitor-information.

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 on October 30, 2025. 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-2025-N-2489 for "Onshoring Manufacturing of Drugs and Biological Products; Public Meeting; Request for Comments." 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: Maya Thompson, Office of External Affairs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5335, Silver Spring, MD, 20993-0001, 301-837-7398, PublicEngagement@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A resilient supply chain for medical products, and specifically, pharmaceuticals (i.e., drugs and biological products), is critical for the safety and security of the United States. The globalization of pharmaceutical production over the past several decades complicates these challenges.

Until the 2000s, pharmaceutical manufacturing was largely a domestic enterprise. In the last several decades, however, such manufacturing has increasingly moved offshore. Today, more than half of the pharmaceuticals distributed in the U.S. are manufactured overseas. As of June 2025, approximately 53% of brand drug products and 69% of generic drug products have at least one manufacturer outside of the United States. Additionally, as of 2025, 9% of API (Type II) Drug Master File (DMF) holders are in the United States, 22% are in China, and 44% are in India.

To help bolster pharmaceutical supply chain resiliency in the U.S., on May 5, 2025, the President issued Executive Order (EO) 14293, "Regulatory Relief to Promote Domestic Production of Critical Medicines." EO 14293 sets forth a policy intended to streamline the regulation of manufacturing pharmaceutical products to facilitate the restoration of a robust domestic pharmaceutical manufacturing base. EO 14293 directs FDA to review existing regulations and guidance that pertain to the development of domestic pharmaceutical manufacturing and take steps to "eliminate any duplicative or unnecessary requirements…; maximize the timeliness and predictability of agency review; and streamline and accelerate the development of domestic pharmaceutical manufacturing."

In response to EO 14293, FDA has developed a proposal, "FDA PreCheck," to accelerate the establishment of high priority new pharmaceutical manufacturing facilities in the U.S. and strengthen the domestic pharmaceutical supply chain. Specifically, the proposal consists of a two-phase approach: (1) Facility Readiness Phase, and (2) Application Submission Phase.

Phase 1: Facility Readiness Phase

The following elements of the Facility Readiness Phase are intended to help enable early facility engagement and support:

Pre-operational Review:

- Enables manufacturers to seek FDA feedback, as applicable, at critical facility development stages including facility design, pre-construction, construction/equipment installation and qualification, and pre-production phases.
- Provides manufacturers insight into whether their planned facility and manufacturing operations as designed are likely to comply with Current Good Manufacturing Practice (CGMP) requirements.

Manufacturing Facility Information Provided via Type V DMF:

- Offers industry an opportunity to provide FDA with a comprehensive master file that contains facility-specific information including, for example, site operations

layout and description found in a Site Master File, Pharmaceutical Quality System elements, and Quality Management Maturity practices.

- Helps FDA to provide timely feedback on consistency and effectiveness of quality procedures to reduce the risk of CGMP deficiencies that could compromise product quality, patient safety, and application approval.
- Serves as a living document that is updated throughout the facility lifecycle that, as appropriate, can be incorporated by reference into a drug application, and can be leveraged to streamline facility assessments during application reviews.

Phase 2: Application Submission Phase

The following element of the Application Submission Phase is intended to help facilitate enhanced and accelerated quality assessment:

Pre-application Meetings and Engagements:

- Provide applicants and their manufacturers the opportunity to give FDA advanced awareness of facility and manufacturing strategies for specific drugs in forthcoming applications, while enabling earlier assessment and inspection activities within the review cycle.
- Enable FDA to provide Chemistry, Manufacturing and Controls (CMC) feedback on anticipated data or logistical needs to support timely review and inspection processes.
- Allow FDA to accelerate quality element assessments for applications from new U.S. facilities through early facility engagement and frontloaded assessment activities.

FDA PreCheck aims to support faster establishment of new U.S. pharmaceutical manufacturing capacity through earlier regulatory input, enhanced engagement, and efficient CMC assessments. FDA PreCheck support will be commensurate with regulatory resources available to operationalize the effort.

II. Topics for Discussion at the Public Meeting

To facilitate discussion on enhancing domestic pharmaceutical manufacturing, FDA has developed a proposal to facilitate the establishment of new pharmaceutical manufacturing facilities in the U.S. to strengthen the domestic pharmaceutical supply chain. FDA is seeking input on the proposal, as well as other ideas to incentivize or strengthen pharmaceutical manufacturing in the U.S. In all cases, FDA encourages stakeholders to provide the specific rationale and basis for their comments, including any available supporting data and information. FDA will also post a planned agenda for the meeting on the FDA website at https://www.fda.gov/drugs/news-events-human-drugs/fda-public-meeting-onshoring-manufacturing-drugs-and-biological-products-09302025.

On the proposal, FDA is seeking specific input on the following:

1. What do you consider the most significant regulatory hurdle in establishing a new domestic pharmaceutical manufacturing facility?
2. Which element(s) described in the FDA PreCheck proposal are most likely to help the establishment of new US pharmaceutical manufacturing facilities?
3. Are there additional elements or implementation considerations that should be considered in the FDA PreCheck proposal?
4. Would your company be willing to provide information about manufacturing facilities relevant to FDA oversight (e.g., facility design relevant to CGMP compliance, quality systems, processes and controls, qualification or validation data) in advance of, or separate from, an application submission? What concerns might you have about sharing this information outside the context of a drug application?

FDA is also interested in participants' other ideas relevant to FDA authorities that may help incentivize or strengthen pharmaceutical manufacturing in the U.S.

III. Participating in the Public Meeting

Registration: This meeting is open to the public and attendance will be available in-person and virtually. When registering, please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Additionally, attendees are encouraged to provide additional details on the product types they intend to manufacture domestically, facility capabilities, and manufacturing experience within their companies, so the meeting will have a representative cross section of the drug manufacturing industry. With this information, FDA will prioritize limited space for in person participation to those registrants that best represent the breadth of domestic pharmaceutical manufacturers.

Registration is free and based on space availability, with priority for in-person participation given to registrants that, in FDA's view, represent higher priority areas for Domestic Manufacturing. Persons interested in attending this public meeting must register by September 2, 2025, 11:59 p.m. Eastern Time. Register to attend the public meeting in-person or virtually at this link: https://www.fda.gov/drugs/news-events-human-drugs/fda-public-meeting-onshoring-manufacturing-drugs-and-biological-products-09302025. Early registration is recommended because seating is limited. For this meeting, FDA is limiting the number of in-person participants per company/entity to facilitate a broad representation of the drug manufacturing industry. FDA will confirm registration for in-person participants based on the information requested above. Registrants that are not confirmed for in person participation may join the meeting virtually.

If you need special accommodations due to a disability, please contact Maya Thompson, Office of External Affairs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5335, Silver Spring, MD, 20993-0001, 301-837-7398, PublicEngagement@fda.hhs.gov no later than September 23, 2025.

Virtual Participation in the Public Meeting: The public will also have the option to participate through an online teleconferencing and/or video conferencing platform. This public

meeting will also be webcast. Virtual attendees will receive a confirmation email containing the website link after their registration has been submitted.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at FDA website at https://www.fda.gov/drugs/news-events-human-drugs/fda-public-meeting-onshoring-manufacturing-drugs-and-biological-products-09302025.

Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Notice of this meeting is given pursuant to 21 CFR 10.65.

Dated: August 5, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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