were needed, or existing regulations required revision because they were not well-suited for medical gases. One area where new regulations were established was CGMP.

Prior to implementation of the final rule, medical gas manufacturers were subject to the general drug CGMP regulations for finished pharmaceutical under parts 210 and 211, but these regulations did not account for differences in how medical gases are manufactured compared to other drugs. Notably, medical gases are generally manufactured in a closed, sealed pressurized system; are not expected to expire or degrade under ordinary storage conditions; and are contained in cylinders that are reused many times. In addition, medical gas manufacturing involves entities downstream of the original gas manufacturer who further manufacture, process, pack, or hold medical gases. Mix-ups or the accidental use of rejected or quarantined product generally pose more of a risk to patient safety than does contamination.

Because of these differences, certain requirements in the general CGMP regulations under parts 210 and 211 were unnecessary to assure the safety, identity, strength, quality, and purity of medical gases (*e.g.,* distributing oldest stock first, use of filters, and certain requirements for controlling microbial contamination). FDA addressed these differences in the June 2017 draft guidance for industry.

However, those recommendations will no longer be applicable with the implementation of the final rule. As of December 18, 2025, medical gas manufacturers are subject to medical gas-specific CGMP regulations under part 213 (21 CFR part 213) rather than the general CGMP regulations under parts 210 and 211 (note, conforming amendments to CGMP regulations for combination products are effective February 2, 2026). The guidance announced in this notice explains how medical gas manufacturers can comply with part 213, and includes among its recommendations clarification on the following:

- Ensuring the reliability of a supplier's capabilities
- Protecting against container closure leaks
- Appropriate cleaning and maintenance of buildings, facilities, and equipment used in medical gas manufacture
- Prevention of labeling and product mix-ups
- Circumstances requiring stability testing, expiration testing, or both
- Handling of returned and salvaged medical gases

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Medical Gases—Current Good Manufacturing Practice.'' 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

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 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 11 relating to electronic records and electronic signatures have been approved under OMB control number 0910–0303. The collections of information in 21 CFR part 213 relating to current good manufacturing practice requirements for medical gases, including 21 CFR 213.22(d), which states that quality unit activities (such as quality agreements with suppliers) and procedures should be in writing, have been approved under OMB control number 0910–0906.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2024–N–3945]

FDA's Strategy Document on Innovative Manufacturing Technologies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the publication of FDA's Strategy Document on Innovative Manufacturing Technologies (Strategy Document), which outlines specific actions FDA has taken and the Agency's plans for 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. The actions described in the Strategy Document are based on lessons learned from FDA's experiences with submissions involving advanced manufacturing technologies as well as public input.

DATES: The announcement of the strategy document is published in the **Federal Register** on January 30, 2026.

ADDRESSES: You may submit either electronic or written comments 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 2024–N–3945 for ''FDA's Strategy Document on Innovative Manufacturing Technologies.'' 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.

- *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 docket number, Date, or access the information at: *https://www.gpo.gov/fdsys/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. 4226, Silver Spring, MD 20993, 301–796–4226, *Elisa.Nickum@fda.hhs.gov,* or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Innovative manufacturing technologies—including but not limited to continuous manufacturing, distributed manufacturing, modern aseptic manufacturing equipment and processes, and novel analytical methods—can increase product development speed, bolster supply chains, improve drug quality, and prevent drug shortages. On June 8, 2023, FDA supported 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 the FDA's Center for Drug Evaluation and Research (CDER) Emerging Technology Program (ETP) and Center for Biologics Evaluation and Research (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 intent of this workshop was to fulfill 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, 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, including public comments received in response to the draft strategy document announced in the **Federal Register** on September 12, 2024 (89 FR 74279), FDA developed the Strategy Document. The Strategy Document outlines the specific activities FDA has undertaken or intends to undertake to facilitate the use of innovative manufacturing technologies, including: continuing to enhance the ETP and CATT as a mechanism to support innovation; implementing the AMTDP in a manner that incorporates feedback on eligibility criteria; continuing to identify opportunities for international harmonization of regulatory expectations in support of further adoption of advanced manufacturing; supporting and utilizing ongoing initiatives for advanced manufacturing to address potential barriers; and supporting training in advanced manufacturing for FDA regulatory staff.

The Strategy Document will be made available on the following FDA web pages:

- CDER's Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) Initiative, available at: *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cders-framework-regulatory-advanced-manufacturing-evaluation-frame-initiative.*
- CDER Emerging Technology Program (ETP), available at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/emerging-technology-program-etp.*
- CBER Advanced Technologies Program, available at *https://www.fda.gov/vaccines-blood-biologics/industry-biologics/cber-advanced-technologies-program.*

Authority: 21 U.S.C. 379g–h2. This document is being published to fufill a commitment in the Prescription Drug User Fee Act (PDUFA) Reauthorization Performance Goals and Procedures Fiscal Years 2023–2027 (PDUFA VII).

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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