## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2026–N–7232]**

## FDA's Strategy Document on Facilitating Chemistry, Manufacturing, and Controls Readiness for Products With Accelerated Clinical Development

**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 Facilitating Chemistry, Manufacturing, and Controls Readiness for Products With Accelerated Clinical Development (Strategy Document), which outlines actions FDA has taken and the Agency's plans for fiscal years 2026–2027 to facilitate chemistry, manufacturing, and controls (CMC) readiness for products with accelerated clinical development timelines. 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 its capability to facilitate CMC development for sponsors of CDER- and CBER-regulated drugs and biologics intended to diagnose, treat, or prevent a serious disease or condition where there is an unmet medical need. The actions described in the Strategy Document are based on lessons learned from FDA's experience with submissions for products on accelerated clinical development timelines as well as other public input.

**DATES:** The announcement of the strategy document is published in the **Federal Register** on July 23, 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–2026–N–7232 for ''FDA's Strategy Document on Facilitating Chemistry, Manufacturing, and Controls Readiness for Products With Accelerated Clinical Development.'' 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:** Tanya Clayton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4506, Silver Spring, MD 20993–0002, 301–796–0871, or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Products with accelerated clinical development activities often face challenges in expediting chemistry, manufacturing, and controls (CMC) development activities to align with the accelerated clinical timelines. Overcoming such CMC challenges often requires additional interaction with FDA during product development and the use of science- and risk-based regulatory approaches so that the clinical benefits of earlier patient access to these products can be realized. Since April 2023, FDA has implemented a CMC Development and Readiness Pilot (CDRP) to facilitate expedited CMC development of CDER- or CBER-regulated products under an IND application and on an accelerated clinical timeframe. In addition, on September 10, 2025, FDA cosponsored a public workshop hosted by the Duke-Margolis Center for Health Policy titled ''Lessons Learned from the CDRP Program.'' Regulators and industry representatives discussed the current barriers to expedited CMC readiness, and shared ideas on how practices like those employed in the pilot could alleviate these barriers. The pilot and the workshop fulfilled PDUFA VII commitments related to facilitating CMC

readiness for products with accelerated clinical development.

Based on lessons learned from the Agency's experience with submissions involving accelerated clinical development, especially those through the pilot, the discussions during the September 10, 2025, workshop, and other public input, this Strategy Document outlines the specific activities FDA has undertaken or intends to undertake to facilitate CMC development for products with accelerated clinical development timelines. These include: continuing to provide opportunities for enhanced communication and the application of risk-based, scientific, and regulatory strategies to sponsors with a Breakthrough Therapy, Fast-Track, or Regenerative Medicine Advanced Therapy Designation; and providing regulatory flexibilities as described in CDER's existing MAPP 5015.13 and CBER's newly published flexibilities for cell and gene therapies (see the announcement at link: *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/flexible-requirements-cell-and-gene-therapies-advance-innovation* and the guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/chemistry-manufacturing-and-controls-flexibilities-developing-human-cellular-and-gene-therapy*).

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

- Chemistry, Manufacturing, and Controls Development and Readiness Pilot (CDRP) Program, available at: *https://www.fda.gov/drugs/pharmaceutical-quality-resources/chemistry-manufacturing-and-controls-development-and-readiness-pilot-cdrp-program*.

**Grace R. Graham,**

*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–2026–N–0008]**

### Advisory Committee; Peripheral and Central Nervous System Drugs Advisory Committee; Termination and Reestablishment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; termination and reestablishment of Federal advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the termination and reestablishment of the Peripheral and Central Nervous System Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Peripheral and Central Nervous System Drugs Advisory Committee was terminated on June 4, 2026, because its charter was not renewed on or before that expiration date. The Commissioner has determined that it is in the public interest to reestablish the Peripheral and Central Nervous System Drugs Advisory Committee for 2 years from the date it is reestablished.

**DATES:** Authority for the Peripheral and Central Nervous System Drugs Advisory Committee will reestablish on July 30, 2026.

**FOR FURTHER INFORMATION CONTACT:** Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3215, Silver Spring, MD 20993–0002, (301) 796–8220, *ACOMSSubmissions@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Pursuant to 21 CFR 14.55(b); 21 CFR 14.40(b) and 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the termination and reestablishment of the Peripheral and Central Nervous System Drugs Advisory Committee (the Committee). The Committee was terminated on June 4, 2026, because its charter was not renewed on or before that expiration date while administrative review remained pending. It is now being reestablished after receiving concurrence from GSA. The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises and informs the Commissioner or designee(s) about the existing and relevant evidence concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of neurologic diseases. The Committee may consider the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of at least six voting members including the Chair. Subject to legal and regulatory requirements, members and the Chair are selected by and serve at the discretion of the Commissioner or designee. Each member, including the Chair, will be selected from among authorities knowledgeable in the fields of neurology, pediatric neurology, epidemiology, statistics, and related specialties.

Members will be invited to serve for terms of up to four years, or for less time at the discretion of the Commissioner or designee. Non-Federal members of this committee will serve either as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios.

In addition to the voting members, the Commissioner or designee may identify consumer and/or industry representatives to join the Committee (or serve as alternate representatives) as non-voting representative member(s), via a process consistent with legal and regulatory requirements. Individuals currently employed at FDA-regulated companies, such as pharmaceutical and medical device manufacturers, shall not be selected to serve as members of the Committee unless this Committee is expected to address issues for which inclusion of an industry representative is required by statute. If this Committee includes an industry representative, the Commissioner or designee will determine whether to invite them to participate in meetings on a case-by-case basis, according to applicable legal and regulatory requirements.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees to serve temporarily as voting members and to designate Special Government Employees to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking.

A quorum for the Committee is a majority of the current voting members present at the time, provided that FDA may specify a quorum that is less than a majority of the current voting members because of the size of the