



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-2366]

Commissioner's National Priority Voucher (CNPV) Pilot Program; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public hearing related to the Commissioner's National Priority Voucher (CNPV) Pilot Program, which is designed to significantly reduce review times for qualifying new drug applications (NDAs), biologics license applications (BLAs), and manufacturing or efficacy supplements through enhanced regulatory engagement and streamlined review procedures. The CNPV Pilot Program is intended to expedite approvals for products that align with critical U.S. national health priorities while maintaining FDA's rigorous scientific and regulatory standards. We are holding this public hearing to obtain feedback and perspectives regarding the CNPV Pilot Program, including feedback on the eligibility criteria, voucher selection processes, sponsor responsibilities, FDA review procedures, and program implementation.

DATES: The public hearing will be held with an in-person and virtual option (i.e., hybrid) on June 12, 2026, from 1:00 p.m. to 4:00 p.m. Eastern Time. Meeting registration, including requests for participation in the public hearing, can be found at the following website:

<https://www.fda.gov/news-events/commissioners-national-priority-voucher-cnpv-pilot-program-public-hearing-06122026>. All requests for participation, including for those who wish to present during the public hearing, must be received by 11:59 p.m., May 1, 2026, through the meeting registration page. Questions about meeting registration and participation should be sent to CommissionerVoucher@fda.hhs.gov, and include the title of this notice: "Commissioner's

National Priority Voucher (CNPV) Pilot Program; Public Hearing; Request for Comments”).

See the **SUPPLEMENTARY INFORMATION** section for attendance and registration information.

Either electronic or written comments on this public hearing will be accepted after the public hearing until June 29, 2026. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: *Location:* The public hearing will be held at the White Oak Great Room, 10903 New Hampshire Ave., Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For security and parking information, please refer to <https://www.fda.gov/about-fda/visitor-information/public-meeting-information> and <https://www.fda.gov/about-fda/visitor-information/visitor-parking-and-campus-map>.

Additional details, such as any changes to the time of the public hearing and registration information, will be posted at <https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program>. The online web conference meeting link can be accessed at <https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program> on the day of the meeting.

All written requests for participation in the pilot program must be received by May 1, 2026 (email to: CommissionerVoucher@fda.hhs.gov).

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 June 29, 2026. 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-2026-N-2366 for "Commissioner's National Priority Voucher (CNPV) Pilot Program; Public Hearing; 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: Mallika Mundkur, Deputy Chief Medical Officer, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8800, CommissionerVoucher@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 17, 2025, FDA Commissioner Makary announced the launch of the Commissioner's National Priority Voucher (CNPV) Pilot Program, which is designed to significantly reduce review times for qualifying new drug applications (NDAs), biologics license applications (BLAs), and manufacturing or efficacy supplements from the standard 10-12 months to a target of 1-2 months through enhanced regulatory engagement and streamlined review procedures to address critical public health needs by providing an ultra-fast review pathway for drug and biological products of strategic national importance. The program is intended to expedite approvals for products that align with critical U.S. national health priorities -- including public health crisis response, innovative breakthrough therapies, large unmet medical needs, onshoring and supply chain resilience initiatives, and affordability improvements -- while maintaining FDA's rigorous scientific and regulatory standards.

FDA's authority for the CNPV Pilot Program stems from its general authority to implement the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 et seq.) and the Public Health Service Act (PHS Act) (42 U.S.C. 201 et seq.). This program is consistent with FDA's mission to promote and protect the public health, including with respect to the review of applications submitted for approval of drugs under section 505 of the FD&C Act (21 U.S.C. 355) or biological products under section 351 of the PHS Act (42 U.S.C. 262).

The CNPV Pilot Program provides a nontransferable "voucher" to recipients that grants expedited FDA review of a single application with enhanced regulatory engagement for a product aligned with the FDA Commissioner's national public health priorities. Key features of the program include:

- Expedited pre-filing period and target of 1-2 months from filing to action (versus 4-10 months filing-to-action for many other expedited programs).

- Nontransferable vouchers: Cannot be sold or used for a different application, unlike traditional priority review vouchers.
- Enhanced presubmission engagement: Facilitates earlier correction of issues (e.g., chemistry, manufacturing, and controls (CMC) and inspection) that can lead to review cycle extensions.
- Multidisciplinary review approach: “Tumor board style” discussion with senior leadership through the CNPV Review Council meeting.

The CNPV Pilot Program complements existing expedited programs (e.g., Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review) by addressing products of strategic national importance with enhanced review speed and regulatory engagement.

At the time of this notice, the CNPV Pilot Program involves FDA’s Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Oncology Center of Excellence (OCE). The program is coordinated by the Deputy Chief Medical Officer within the Office of the Commissioner.

As a pilot program, processes and procedures may be revised based on the circumstances of specific applications and will be improved and refined iteratively as the CNPV Pilot Program progresses.

II. Notice of Hearing Under Part 15

FDA will hold a public hearing consistent with part 15 (21 CFR part 15) to provide the opportunity for the public to present information and views on the CNPV Pilot Program. The hearing will be conducted by a presiding officer, who will be accompanied by FDA panelists, including subject matter experts from the Office of the Commissioner, CDER, CBER, and OCE. As provided in § 15.30(f) (21 CFR 15.30(f)), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members can pose questions; they can question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA’s policy

and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under 21 CFR 10.205, representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as provided in § 15.30(b) (see also Transcripts). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

III. Topics for Discussion at the Public Hearing

FDA is interested in the public's views, information, and any supporting data on the CNPV Pilot Program, including the following topics:

- Eligible Applications/Scope, including any comments on:
 - The five identified national priority areas (public health crisis response, innovative breakthrough therapies, large unmet medical needs, onshoring and supply chain resilience initiatives, and affordability improvements).
 - The types of applications eligible (NDAs, BLAs, manufacturing or efficacy supplements) and the exclusion of medical device applications (although combination products that include a device component but have a drug or biological product primary mode of action are eligible for inclusion).
 - Potential changes to the scope of the program, such as modifying priorities, expanding or limiting eligibility to certain applications, product types or development stages.
- The Voucher Selection Process, as outlined in the FDA *Staff Manual Guide on Commissioner's National Priority Voucher Review Council*,¹ including any comments on:

¹ FDA [Internet]. SMG 2010.23. FDA Staff Manual Guides (SMG), Volume III – General Administration FDA Councils and Committees. Commissioner's National Priority Voucher Review Council. Available from: <https://www.fda.gov/media/190099/download?attachment> (Accessed March 6, 2026).

- FDA's practice of accepting internal nominations by FDA review divisions and external statements of interest submitted by sponsors and applicants.
- FDA's requested format for brief statements of interest submitted by sponsors and applicants.
- Factors considered in voucher selection, including alignment with national priorities, anticipated public health impact, readiness indicators, resource and timing considerations, and known risks or uncertainties.
- Other aspects of selection.
- The Enhanced Regulatory Engagement Requirements for sponsors and applicants accepting CNPV vouchers, including any comments on:
 - The expectation for rapid response to FDA information requests (typically within 24-48 hours).
 - Availability for ad hoc meetings with FDA staff during business hours.
 - Facilitation of FDA inspections to verify regulatory compliance.
 - Submission of complete application packages within mutually agreed timeframes.
 - Labeling negotiations ideally limited to maximum two rounds.
 - FDA is interested in the feasibility of these requirements for sponsors, particularly smaller companies.
- The Presubmission and Rolling Submissions Requirements, including any comments on:
 - Presubmission informational meetings with review divisions to review the expectations and coordinate submissions timeline.
 - Rolling submission of CMC information and of proposed labeling at least 60 days before final module submission.
 - The recommended presubmission process including:

- Limiting the number of manufacturing facilities to no more than 2-3 per submission with justification for any additional sites.
 - Submission of all available data related to the application (e.g., raw data, toxicology data, nonclinical data, clinical and safety data, and any completed application components) and submission of the information described in Standardized Format for Electronic Submission of NDA and BLA Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for CDER Submissions to facilitate inspection planning for clinical investigators, sponsors, and contract research organizations.
- The CNPV Review Timeline and Process², including any comments on:
 - The target review timeline of 1-2 months after the complete application submission filing action.
 - The proposed filing review timeline of 14-21 days after receipt of the final application component submission.
 - The flexibility built into the review timeline, including the ability for review divisions to request review clock extensions to ensure reviews of the highest scientific quality.
 - The relationship between CNPV Pilot Program target timelines and PDUFA goal dates.
 - The use of optional tools (e.g., review templates, AI tools) to facilitate review or tracking of applications.

² FDA[Internet]. The Commissioner's National Priority Voucher (CNPV) Pilot Program. CDER, CBER, OCE Town Hall. February 3, 2026. Office of the Chief Medical Officer, Office of the Commissioner. Available from <https://www.fda.gov/media/190927/download?attachment> (Accessed March 6, 2026).

- The CNPV Review Council, as outlined in the FDA *Staff Manual Guide on Commissioner's National Priority Voucher Review Council*¹, including any comments on:
 - The role of the CNPV Review Council in providing recommendations to the relevant Center Director regarding application approvability with respect to the part(s) of the application presented to the Council for consideration.
 - The “tumor board style” meeting format, including application presentation, discussion, primary review team recommendation, Council vote, and Center Director recommendation.
- The Sponsor Responsibilities and Expectations, including any comments on the following processes/procedures:
 - FDA’s request for written acknowledgment and confirmation of sponsor or applicant’s agreement to participate within two weeks of voucher issuance.
 - FDA’s clarity of communication regarding the fact that a voucher does not guarantee approval or a 1-2 month timeframe.
 - FDA’s expectation that the intent to redeem voucher should ideally be acknowledged within 2 weeks of official issuance date.
 - FDA’s expectation that sponsors submit complete application within 2 years of official voucher issuance date.
 - FDA’s request for sponsors to share public announcements related to the CNPV Pilot Program with FDA prior to release.
- The Program Evaluation and Future Directions, including any comments on
 - Metrics or outcomes FDA should consider in evaluating the program’s success.
 - What the Agency should consider for continuing, modifying, or expanding the program based on pilot results.

- Other topics, issues, or concerns related to the CNPV Pilot Program that stakeholders wish to address, such as suggestions for improving the program design, implementation, or communication, and potential unintended consequences of the program and how they might be mitigated.

IV. Participating in Public Hearing

Registration: To register to attend or participate in the free public hearing, please visit the following website: <https://www.fda.gov/news-events/commissioners-national-priority-voucher-cnpv-pilot-program-public-hearing-06122026>.

Registration will open on April 1, 2026. Live closed captioning will be provided during the public hearing. Additional information on requests for special accommodations due to a disability will be provided during registration.

Written Notice of Participation: During online registration you may indicate if you wish to present information and views at the hearing (oral statements without slides). FDA will do its best to accommodate requests to make public presentations. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will notify participants ahead of the hearing. All written requests for participation must be received by May 1, 2026, 11:59 p.m. Eastern Time (email to: CommissionerVoucher@fda.hhs.gov). No commercial or promotional material will be permitted to be presented or distributed at the public hearing.

Transcripts: Please be advised that as soon as a transcript of the public hearing is available, it will be accessible at <https://www.regulations.gov>. Once available, the transcript may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at <https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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