



## FDA Announces Public Hearing and Opportunity to Comment on National Priority Voucher Pilot Program

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On March 20, 2026, the Food and Drug Administration (FDA) **announced** the agency will hold a public hearing on the Commissioner's National Priority Voucher (CNPV) Pilot Program, with a *Federal Register* notice soliciting public comment and scheduling a public hearing for June 12, 2026. As previously noted **here** and **here**, the program was announced in June 2025 for the purpose of providing select sponsors with a nontransferable voucher for enhanced engagement with FDA and expedited review for drugs and biologics supporting one or more critical national health priorities, while maintaining adherence to the law's rigorous safety and effectiveness standards. The national health priorities include public health crisis response, innovative breakthrough therapies, large unmet medical needs, onshoring and supply chain resilience initiatives, and affordability improvements. To date, FDA has issued 18 Commissioner's National Priority vouchers and approved four products to receive these vouchers, including two oncology drugs 44 and 55 days after filing.

The topics included for discussion at the upcoming public hearing include the pilot program's scope and five identified national priority areas, voucher selection process, enhanced regulatory engagement requirements for sponsors and applicants, pre-submission and rolling submission requirements, CNPV timeline and process, CNPV Review Council, sponsor responsibilities and expectations, and program evaluation and future directions. Requests to speak at the June 12 public hearing, which will be held at FDA's White Oak Headquarters with both an in-person and virtual option, are due by May 1. Written comments will be accepted through June 27, 2026. The FDA panelists will include subject matter experts from the Office

of the Commissioner, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Oncology Center of Excellence, as well as a presiding officer.

The CNPV program continues to garner attention and questions, including from policymakers in Congress. The agency soliciting public input on the CNPV program marks an inflection point for the pilot program and may lead to further refinement and adjustments to it as informed by the public hearing and comments, and as the agency continues to gain more experience with the program. Regardless, interested parties will be watching for any additional announcements related to the CNPV program, and it is also a policy issue to watch as the reauthorization of the Prescription Drug User Fee Act (PDUFA VIII) moves forward given Capitol Hill's interest in the pilot program.

## Categories



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