PEER REVIEWED

Modernising FDA Review: *National Priority Vouchers and the First Year of Implementation*

A year ago, the US Food and Drug Administration (FDA) launched a new "ultra-fast" review programme intended to dramatically shorten review times for drug and biological product applications, as well as for manufacturing or efficacy supplements. The initiative aligns with the agency's broader effort to improve approval efficiency and modernise regulatory frameworks to address emerging public health needs. With several actions already taken since launch, the FDA plans to publicly review the programme in early June.

Announced in June 2025 by then-FDA Commissioner Marty Makary, MD, MPH, the Commissioner's National Priority Voucher (CNPV) Pilot Program employs a "tumour board–style" review model to accelerate the evaluation and review of products aligned with one of five critical US national health priorities:

- **Public Health Crisis Response:** Products addressing urgent or emerging threats or significant population impact.
- **Innovative Breakthrough Therapies:** Transformative treatments with novel mechanisms that fundamentally change disease management.
- **Large Unmet Medical Needs:** Therapies for conditions where existing treatments inadequately address patient outcomes.
- **Onshoring and Supply Chain Resilience:** Efforts that strengthen domestic capacity, reduce foreign dependencies and improve national security.
- **Affordability:** Approaches that improve overall value through reduced costs to the healthcare system or expand access to important products.[1]

Makary noted that although the FDA has long led global medical innovation, "that leader status has been in jeopardy" and described the CNPV Pilot Program as a step toward modernising the agency's regulatory processes.[2] The pilot programme aims to 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.

Core Elements of the Programme

Coordinated by the Office of the Chief Medical Officer (OCMO) within the Office of the Commissioner, the pilot programme involves the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Oncology Center of Excellence (OCE).[3]

To participate, companies must submit a statement of interest identifying the relevant national health priority and briefly describe how their programme aligns with it. Requested information includes:

- The targeted disease or condition
- The potential impact of the drug
- The current stage of development (with clinical data highlights, as relevant)
- The unique aspects of the approach
- The specific issues for which enhanced communication with the FDA would facilitate development[4]

Potential participants may also be identified through internal nominations. In either case, factors considered in the voucher selection phase include alignment with national priorities, anticipated public health impact, readiness indicators (e.g., completeness of results), resource and timing considerations, and known risks, uncertainties, or dependencies.[3]

As part of the programme, the FDA established the CNPV Review Council, which provides recommendations to the delegated official (e.g., the deputy chief medical officer) on voucher selection and to the relevant center director to inform the center director's approvability recommendation for the portions of the application reviewed by the council.

Makary likened the council's multidisciplinary structure to clinical tumour boards, where experts jointly evaluate complex evidence. While the council informs review, final approval decisions remain within the FDA centers and follow the usual FDA processes. Criteria for voucher selection are outlined in the agency's *FDA Staff Manual Guides* issued in January 2026.[5]

Companies selected for the pilot programme receive a voucher entitling them to benefits including enhanced communications and rolling review to support a shortened review timeline. As described in the FDA's *Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics* (May 2014), rolling review allows the agency to evaluate portions of an application as they are submitted.[6] According to the agency's CNPV Pilot Program submission webpage (updated July 22, 2025),[4] the FDA will award a limited number of vouchers on a rolling basis.

The February 2026 Town Hall slides posted on the CNPV landing page note that the pilot programme includes an approximately 60-day presubmission period, followed by an abbreviated filing period of 14–21 days and an application review period of 30–60 days.[1,7] During presubmission, sponsors may meet with review divisions to establish a mutually agreed-upon timeline and address review issues (e.g., chemistry, manufacturing, and controls [CMC] and inspection) in advance to prevent delays.[3]

How the Pilot Compares

Complementing the FDA's established expedited programmes – including Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review – the CNPV Pilot Program targets products of national significance, combining expedited review with intensified regulatory engagement. Key differentiators of the CNPV Pilot

Program are its ultra-rapid review pathway and the nontransferability of its vouchers. By contrast, the FDA's Priority Review Voucher (PRV) programme awards transferable vouchers to sponsors who obtain approval for certain qualifying applications (e.g., treatments for tropical diseases, rare pediatric diseases, or material threat medical countermeasures).[8]

PRV recipients may use the voucher for a future human drug application submitted to the FDA or transfer it to another party. A redeemed PRV entitles the holder to obtain priority review (a 6-month review clock)[9] for a future application that would not otherwise qualify, upon payment of the annual PRV user fee announced in the *Federal Register*.[8]

The FDA noted in the Town Hall overview that the CNPV Pilot Program builds on elements from the OCE's Real-Time Oncology Review (RTOR) and the Split Real Time Application Review (STAR) pilot programme. Both the RTOR and STAR programmes shift review activities earlier in the process to shorten overall time to approval without altering statutory review clocks.[10,11] Each programme permits the FDA to begin evaluating portions of an application before the traditional complete submission milestone, enabling reviewers to identify issues sooner, reduce back-and-forth communication later in the cycle, and streamline the path to a final decision.

Achievements and Current Status

Completed in two months, the first review decision under the CNPV Pilot Program was issued in December 2025 for Augmentin XR (amoxicillin-clavulanate potassium) from USAntibiotics.[12] Originally approved by the FDA in 2002, Augmentin XR is indicated for the treatment of community-acquired pneumonia and acute bacterial sinusitis in adults and pediatric patients.

According to the sponsor, Augmentin XR had been off the US market since August 2011, when the previous manufacturer ceased production.[13] The sponsor indicated that the FDA had confirmed in October 2024 that the drug had not been withdrawn for safety or effectiveness reasons. Based on available information, the December 2025 action appears to have been a manufacturing-focused re-approval rather than a new NDA or labeling supplement. Because Drugs@FDA posts only original applications, efficacy supplements, and labeling supplements, this CMC-based action does not appear in the public database (see sidebar below).

> The FDA updates its Drugs@FDA database with information from original NDAs/BLAs, efficacy supplements, and labeling supplements, as described on the *Drugs@FDA Frequently Asked Questions* webpage.[14] Under 21 CFR 314.70, many post-approval manufacturing changes – such as facility or supply chain changes – are submitted as Changes Being Effected in 30 Days (CBE 30), CBE, or annual reportable supplements, categories that generally do not require labeling updates.[15]

In announcing the approval, the FDA noted that essential medicines such as amoxicillin and Augmentin XR "have experienced documented shortages... highlighting the critical need for stable domestic manufacturing capacity to protect public health."[12] The agency stated that the Augmentin XR application demonstrated "clear alignment" with the CNPV programme's national health priorities by strengthening the US drug supply chain and addressing antibiotic shortages.

By May 2026, the agency had awarded vouchers for 21 products and granted seven approvals, including two notable programme firsts. On April 1, the FDA approved the first new molecular entity (NME) under the programme, Foundayo (orforglipron) from Eli Lilly and Company. In the press release announcing the approval, the FDA noted that this was also the fastest approval of an NME since 2002.[16] The second notable first under the pilot was the April 23 approval of Otarmeni (lunsotogene parvec-cwha) from Regeneron Pharmaceuticals, Inc., representing first-ever dual adeno-associated virus (AAV) vector-based gene therapy for the treatment of a type of genetic hearing loss.[17] All of these awards and approvals are summarised in Tables 1 and 2; the dates of these entries are drawn from FDA press announcements published between 2025 and 2026.

On June 4, 2026, the FDA will host a public meeting to solicit feedback and perspectives on the CNPV Pilot Program, including topics such as the eligibility criteria, voucher selection processes, sponsor responsibilities, FDA review procedures, and overall programme implementation.[18] Written comments may be submitted through June 29, 2026.

REFERENCES

1. FDA. Commissioner's National Priority Voucher (CNPV) Pilot Program. Updated April 28, 2026. Accessed May 26, 2026. https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program
2. FDA. Commissioner's National Priority Vouchers. YouTube. Published

Date of Voucher Award	Product	Indication/Use
October 16, 2025	Pergoveris	Infertility
	Teplizumab	Type I diabetes
	Cytisinicline	Nicotine vaping addiction
	DB-OTO	Deafness
	Cenegermin-bkbj	Blindness
	RMC-6236	Pancreatic cancer
	Bitopertin	Porphyria
	Ketamine	Domestic manufacturing of a critical drug for general anesthesia
	Augmentin XR	Domestic manufacturing of a common antibiotic
November 6, 2025	Zongertinib	HER2 lung cancer
	Bedaquiline	Drug-resistant tuberculosis in young children
	Dostarlimab	Rectal cancer
	Casgevy	Sickle cell disease
	Orforglipron	Obesity and related conditions
	Wegovy	
December 15, 2025	Teclistamab + daratumumab	Relapsed/refractory multiple myeloma
December 19, 2025	Enlicitide decanoate	Lowering LDL cholesterol
	Sacituzumab tirumotecan	Not specified in FDA announcement
April 24, 2026	Psilocybin	Treatment-resistant depression
	Psilocybin	Major depressive disorder
	Methylone	Post-traumatic stress disorder (PTSD)
		+ indicates combination therapy

Table 1. Products Awarded Vouchers Under the CNPV Pilot Program

Date of Approval	Time Since Filing	Product	Indication
December 9, 2025	60 days	Augmentin XR (amoxicillin-clavulanate potassium)	Treatment of community-acquired pneumonia and acute bacterial sinusitis in adults and pediatric patients
February 26, 2026	44 days	Hernexeos (zongertinib)	Treatment of adults with unresectable or metastatic non-squamous non–small cell lung cancer (NSCLC) whose tumours have HER2 (ERBB2) tyrosine kinase domain activating mutations as detected by an FDA-authorised test
March 5, 2026	55 days	Tec-Dara (teclistamab-cqyv + daratumumab hyaluronidase-fihj)	Treatment of adults with relapsed or refractory multiple myeloma who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent
March 19, 2026	54 days	Wegovy (semaglutide)	Addition of a new higher dose (7.2 mg) for weight loss and long-term weight maintenance
April 1, 2026	50 days	Foundayo (orforglipron)	In combination with a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition
April 23, 2026	61 days	Otarmeni (lunsotogene parvec-cwha)	Treatment of pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (any frequency >90 dB HL) associated with molecularly confirmed biallelic variants in the *OTOF* gene, preserved outer hair cell function, and no prior cochlear implant in the same ear
May 8, 2026	42 days	Bizengri (zenocutuzumab-zbco)	Treatment of adults with advanced, unresectable, or metastatic cholangiocarcinoma harboring a neuregulin 1 (*NRG1*) gene fusion with disease progression on or after prior systemic therapy
			+ indicates combination therapy

Table 2. Products Approved Under the CNPV Pilot Program

June 17, 2025. Accessed May 26, 2026. https://www.youtube.com/watch?v=CzMG6_hOB5w

3. FDA The FDA Commissioner's National Priority Voucher Pilot Program [Fact Sheet]. Published 2025. Accessed May 26, 2026. https://www.fda.gov/media/190896/download
4. FDA. Commissioner's National Priority Voucher (CNPV) Pilot Program Submission. Updated July 22, 2025. Accessed May 26, 2026. https://www.fda.gov/industry/commissioners-national-priority-voucher-cnpv-pilot-program/commissioners-national-priority-voucher-cnpv-pilot-program-submission
5. FDA. FDA Staff Manual Guides (SMG), Volume III – General Administration: FDA Councils and Committees, Commissioner's National Priority Voucher Review Council (SMG 2010.23). Effective January 15, 2026. Accessed May 26, 2026. https://www.fda.gov/media/190099/download
6. FDA. Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics. Published May 2014. Accessed May 26, 2026. https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf
7. FDA. The Commissioner's National Priority Voucher (CNPV) Pilot Program: CDER, CBER, OCE Town Hall Pilot Program Overview [Slide Deck]. Dated February 3, 2026. Accessed May 26, 2026. https://www.fda.gov/media/190927/download
8. FDA. Fee Rate for Using a Priority Review Voucher in Fiscal Year 2026. Federal Register. September 18, 2025; 90(179):45041–45044. Docket No. FDA–2025–N–3406. Accessed May 26, 2026. https://www.govinfo.gov/content/pkg/FR-2025-09-18/pdf/2025-18075.pdf
9. FDA. Priority Review. Updated January 4, 2018. Accessed May 26, 2026. https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review
10. FDA. Guidance for Industry: Real-Time Oncology Review (RTOR). Published November 2023. Accessed May 26, 2026. https://www.fda.gov/media/173641/download
11. FDA. Split Real Time Application Review (STAR). Updated January 13, 2026. Accessed May 26, 2026. https://www.fda.gov/drugs/development-resources/split-real-time-application-review-star
12. FDA. First Approval in Commissioner's National Priority Voucher Pilot Program Strengthens Domestic Antibiotic Manufacturing Capacity. Updated December 10, 2025. Accessed May 26, 2026. https://www.fda.gov/news-events/press-announcements/first-approval-commissioners-national-priority-voucher-pilot-program-strengthens-domestic-antibiotic
13. USAntibiotics. FDA Approves USAntibiotics' Augmentin XR in Historic First for Expedited Review Program. Published December 11, 2025. Accessed May 26, 2026. https://us-antibiotics.com/2025/12/11/fda-approves-usantibiotics-augmentin-xr-in-historic-first-for-expedited-review-program/
14. FDA. Drugs@FDA Frequently Asked Questions. Accessed May 26, 2026. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=faq.page
15. FDA. 21 CFR § 314.70 – Supplements and other changes to an approved NDA. Updated May 21, 2026. Accessed May 26, 2026. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-314/subpart-B/section-314.70#p-314.70(c)(6)
16. FDA. FDA Approves First New Molecular Entity Under National Priority Voucher Program. Published April 1, 2026. Accessed May 26, 2026. https://www.fda.gov/news-events/press-announcements/fda-approves-first-new-molecular-entity-under-national-priority-voucher-program
17. FDA. FDA Approves First-Ever Gene Therapy for Treatment of Genetic Hearing Loss Under National Priority Voucher Program. Published April 23, 2026. Accessed May 26, 2026. https://www.fda.gov/news-events/press-announcements/fda-approves-first-ever-gene-therapy-treatment-genetic-hearing-loss-under-national-priority-voucher
18. FDA. Commissioner's National Priority Voucher (CNPV) Pilot Program Public Hearing. Published April 1, 2026. Accessed May 26, 2026. https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/commissioners-national-priority-voucher-cnpv-pilot-program-public-hearing-06042026#Meeting

Deborah Komlos

Deborah Komlos, MS, is a former Principal Content Writer/Editor for the Cortellis suite of life science intelligence solutions at Clarivate, where she covered FDA advisory committee meetings, workshops, and product approvals. Her other previous positions have included writing and editing for magazines, newspapers, online venues, and scientific journals.