Syner·G

What You Should Know About the FDA's New CNPV Pilot Program

Fast-tracking therapies that strengthen U.S. health security

What Is the CNPV Program?

A first-of-its-kind FDA pilot designed to **dramatically accelerate review times**—from the typical 6+ months down to **1–2 months**—for products that address **critical national health priorities.**

The program maintains **full FDA safety, efficacy, and scientific standards** while removing procedural delays that slow access to high-impact therapies.

Why the CNPV Program Matters

- **Strengthens U.S. drug supply chain** by prioritizing domestic manufacturing of essential medicines.
- **Accelerates access** to breakthrough therapies in cancer, diabetes, infertility, sensory loss, addiction treatment, and more.
- **Improves affordability** by reducing development and review burdens for manufacturers.
- **Uses multidisciplinary, tumor-board–style review** to ensure scientific rigor even on fast timelines.
- **Voucher-based model** provides accelerated review but is **non-transferable**, ensuring only true priority products benefit.

How It Works

01 Voucher Selection

Products are nominated internally or submitted externally, then evaluated based on:

- Alignment with U.S. national health priorities
- Public health impact
- Readiness of clinical and manufacturing data
- Resource/timing feasibility
- Known risks or dependencies

Note: Receiving a voucher does not increase chances of approval—only the speed of review.

02 Presubmission Phase

Sponsors collaborate with FDA to eliminate bottlenecks before filing:

- CMC packages due **60+ days before** final submission
- Early labeling reviews
- Rolling submissions to prevent review delays

03 Accelerated Review

- Applications undergo the FDA's full scientific assessment
- Senior leadership participates in multidisciplinary discussions
- Review timelines remain flexible to maintain scientific quality
- Some approvals have occurred in **as little as 55 days**

The First Wave of Prioritized Products

2026

The FDA has designated multiple high-value therapies across critical public health needs and multiple key approvals as of March 2026.

Strengthening U.S. Supply & Essential Medicines

- **Augmentin XR** – Rebuilding domestic antibiotic manufacturing ✓ APPROVED
- **Ketamine** – Ensuring U.S. supply of a critical anesthesia drug

Transformational Therapies for Chronic & Rare Conditions

- **Pergoveris** – Infertility
- **Teplizumab** – Type 1 diabetes
- **Bitopertin** – Porphyria
- **Wegovy HD** - semaglutide injection for weight loss and long-term maintenance of weight loss ✓ APPROVED

Oncology Breakthroughs

- **Hernexeos (zongertinib)** – Lung cancer ✓ APPROVED
- **Tec-Dara (teclistamab + daratumumab)** – Relapsed/refractory multiple myeloma ✓ APPROVED just 55 days after filing
- **RMC-6236** – Pancreatic cancer
- **Sacituzumab Tirumotecan** – TROP2-directed ADC

Addressing Addiction, Sensory Loss & More

- **Cytisinicline** – Nicotine vaping addiction
- **DB-OTO** – Genetic therapy for deafness
- **Cenegermin-bkbj** – Vision restoration
- **Enlicitide decanoate** – Oral PCSK9 inhibitor for cholesterol management

Why This Pilot Signals a Major Shift

The CNPV program represents a new regulatory model—one where:

Critical medicines get **rapid, coordinated, senior-level attention**

Sponsors collaborate earlier and more deeply with FDA

National health security becomes a central driver of regulatory priority

For patients, providers, manufacturers, and policymakers, CNPV marks a **modernized, mission-focused FDA** aiming to get the right products to the public—faster and more reliably than ever before.

Ready to Evaluate Your Fit for the CNPV Program?

Connect with Syner-G today for a complimentary consultation.

Let's determine whether this accelerated pathway can advance your program—and how to position your asset for maximum impact, speed, and success.

References:

https://www.fda.gov/news-events/press-announcements/fda-grants-third-approval-under-national-priority-voucher-program

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