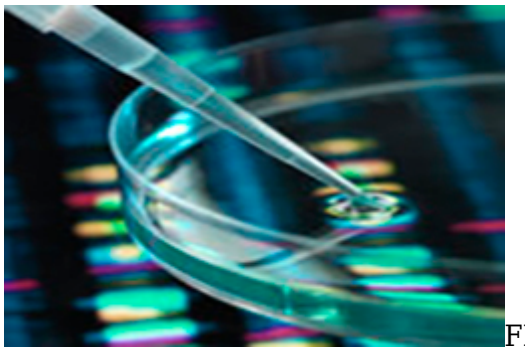
Move Fast: FDA is Accepting Submissions for the Pilot Program Class for FDA Commissioner's National Priority Voucher Program



FDA is now accepting submissions to the Commissioner's National Priority Voucher (CNPV) pilot program, and with only five vouchers to be awarded as part of the initial year of the program, the competition is anticipated to be fierce. It has been a little over a month since the FDA **announced** the CNPV pilot program, and the FDA has now provided additional information to help interested companies through the process and criteria for applying for these vouchers.

On June 17, 2025, the FDA announced that through the CNPV program, selected sponsors will receive non-transferable vouchers that can be redeemed for expedited review of their drug or biologic product candidates. The FDA touts the CNPV program as a "novel" priority program that "shortens [the agency's] review time from approximately 10-12 months to 1-2 months following a sponsor's final drug application submission." The vouchers awarded through the program can be applied to drug or biologic product candidates in any area of medicine and will focus on companies that are aligned with the following national priorities:

1. Addressing a health crisis in the US,
2. Delivering more innovative cures for the American people,
3. Increasing affordability,
4. Addressing unmet public health needs, and
5. Increasing domestic drug manufacturing as a national security issue.

In an update posted July 22, 2025, the FDA provided **examples** of each of the national priorities that could make a company or its drug candidate eligible for a CNPV voucher. Of notable interest to the rare disease community, FDA's example for addressing a large unmet medical need specifically includes condition(s) that available therapies do not adequately diagnose or treat, "including drugs to treat or prevent rare diseases."

Here are four things to know about the CNPV program, based on the information the FDA has provided thus far:

- **Participation Process**: Interested and eligible companies should submit a statement of interest to FDA through the **CNPV Program Submission** page. Interested companies can submit a maximum of one statement of interest each, although the FDA has indicated that vouchers can be granted for review of a specific drug or as an undesignated voucher, allowing a company to use the voucher for review of an application for a drug "at the company's discretion subject to consistency with the program's objectives." The FDA will select

companies based on the submitted statement of interest for "possible acceptance" into the pilot program. These statements are short—just 350 words or fewer—and should discuss one national priority the drug development program addresses and any specific issue(s) for which the company may be seeking enhanced communications with FDA to facilitate program development. If the program addresses more than one national priority, companies should identify the primary national priority in their statement of interest.

- **Submission and Review Process**: The CNPV program submissions will be evaluated by a senior, multi-disciplinary committee of experts, led by FDA's Office of Chief Medical and Scientific Officer, and the committee will pre-review the submitted statements of interest and convene for a 1-day "tumor board style" meeting. The Commissioner's **YouTube announcement** for the program explains that such meetings allows experts "to consider hard questions in light of all the latest clinical evidence," and the CNPV committee plans to utilize a similar approach. Companies must be prepared to respond promptly to any FDA inquiries about their submission. FDA is accepting statements of interest on a rolling basis, and although there is not a specific deadline for submissions, we recommend that interested companies act with urgency in order to get considered for the initial pilot program class.
- **CNPV Voucher Benefits**: As **highlighted** by FDA, a CNPV voucher entitles the company holding it to enhanced communications and rolling review to allow for a shortened review time. The FDA plans to provide a limited number of vouchers to companies aligned with US national priorities. A non-transferable voucher issued by the FDA could either be directed at a specific product or awarded to a company as an "undesignated voucher" that the company could use for a new drug at its discretion and consistent with the CNPV program's objectives. The FDA has published a frequently asked questions document, "**FAQs: Commissioner's National Priority Voucher Program**," and notes that this page will be updated regularly as questions arise.
- **Alignment with President Trump's Executive Order**: Among the national priorities that the CNPV program seeks to advance is the goal to increase affordability of drugs and biologics, and that goal is a direct focus of President Trump's May 12, 2025, **Executive Order** on drug pricing, signaling the Administration's goal of "equalizing" prices among the United States and other developed countries throughout the world. Among other directives, the Executive Order directs FDA to contemplate approaches that may involve pricing (for example, examining whether case-by-case importation of products would be appropriate if manufacturers do not lower their prices or whether there may be some sort of action with respect to the product's approval). *See **Goodwin Alert** on the Most Favored Nation Drug Pricing Executive Order*. Companies are paying attention. In just the last couple weeks, two large drug makers have announced direct-to-consumer programs to offer a low-cost option to patients.

If a company is selected as one of the five pilot participants in the initial year of the CNPV program, the FDA states that the "voucher process must be commenced within two years" after receipt of the CNPV, although we note that the current information provided by the Agency does not expressly state whether an NDA or BLA must be submitted within two years. Since the voucher can be applied to a product "at any stage of development," we anticipate that this two-year timeframe may be an area where FDA will provide more clarity as it selects sponsors for the program.

We encourage interested stakeholders to reach out to a member of the Goodwin **Life Sciences Regulatory and Compliance** team for further questions or assistance with submitting a statement of interest for the CNPV program.

FDA's Push for "Radical Transparency": Key Takeaways from the Agency's Publication of Complete Response Letters

On July 10, 2025, the U.S. Food and Drug Administration (FDA) **announced** publication of over 200 complete response letters (CRLs) issued in response to applications submitted to FDA for approval of drugs or biologics between 2020 and 2024. The FDA has described this move as a step toward the Agency's "broader initiatives to modernize and increase transparency."

CRLs are formal communications sent to applicants when the FDA has completed its review of an application but determined that it cannot approve the application in its current form. Until now, the Agency has only made CRLs available as part of larger approval package files on the Drugs@FDA online database (i.e., after product approval). While the CRLs released this week continue to be limited to approved products—and have been redacted to remove trade secrets and confidential commercial information—the FDA has, for the first time, provided these documents in a central database on **openFDA**. A few key highlights:

- While many of these CRLs have already been disclosed as part of the "Other Action Letters" section of publicly posted drug approval packages, some have not.
- There are multiple CRLs for supplemental New Drug Applications (sNDAs) that had not yet been disclosed, reflecting the fact that approval packages for sNDAs are not consistently posted in the same manner as original NDA approvals.
- Some of these CRLs were issued for products approved before 2020, suggesting that the CRL database scope may exceed the time frame identified in the FDA's announcement.
- At least one CRL has been posted for a product approved as recently as June 2025. For this product, no other portions of the approval package (beyond the label and approval letter) have yet been posted on Drugs@FDA.

Notably, the FDA's announcement references a 2015 analysis conducted by FDA researchers, which found that sponsor disclosures of CRLs did not consistently provide full detail regarding the Agency's specific concerns. The FDA's highlighting of this finding, coupled with the Agency's statement that it plans to publish additional CRLs from its archives, warrants attention from sponsors, especially public company sponsors.

Sponsor disclosures regarding CRLs are always closely scrutinized, and the FDA's move to (1)

centralize and regularly release CRLs, and (2) publish additional CRLs (e.g., those for sNDAs, or very recently approved products) is likely to invite further scrutiny—by investors, analysts, competitors, and patient communities. Sponsors should prepare disclosures around receipt of a CRL with the expectation that the CRL itself will become public upon approval of an application. Even where a product is ultimately approved, third parties may make comparisons between a sponsor's characterization of a CRL and the later-posted CRL itself.

According to the FDA, publication of CRLs is just one step in the Agency's broader transparency push. Our team will continue to monitor the frequency and scope of additional releases, as well as any opportunities for interested stakeholders to provide comments or feedback to FDA on its plans.