The FDA Commissioner's National Priority Voucher Pilot Program

Background

The FDA CNPV Pilot Program is being explored as a pathway to **dramatically reduce review times** for drug and biological product applications and manufacturing or efficacy supplements for products that align with critical U.S. national health priorities. The program is consistent with the FDA's mission and maintains the FDA's established safety and effectiveness approval standards, scientific rigor, and regulatory compliance requirements.

The Pilot Program is coordinated by the Office of the Chief Medical Officer within OC and currently involves CDER, CBER and OCE.

> The CNPV Pilot Program will prioritize the review of products of strategic national importance

Notable differences between the CNPV Pilot Program and other FDA priority review programs:

- **Ultra-fast timeline** – 1–2 months target vs. 6+ months
- **Nontransferable vouchers**
- **Enhanced presubmission requests** and rolling review
- **Multidisciplinary "tumor board-style" discussion** with senior leadership

Improvements will be made iteratively as the program progresses to ensure feasibility and scientific rigor.

Review Timeline Considerations

Review teams should note that all phases of the proposed review timeline for this pilot are targets that are intended to be flexible and may be adjusted as needed to ensure reviews of the highest scientific quality. **Review clock extensions may be granted by request and discussion with CNPV program leadership.**

Procedures

Voucher Selection Phase

Potential candidates are identified through internal nominations and external submissions and screened via collaboration between the Office of the Chief Medical Officer, Center Directors, Center Liaisons, and subject matter experts from review divisions. The following factors are considered:

- **Alignment with national priorities**
- **Anticipated public health impact**
- **Readiness indicators** (e.g., completeness of results)
- **Resource and timing considerations** raised by the relevant Center(s)
- **Known risks, uncertainties, or dependencies**

Importantly, receipt of a voucher does not impact the likelihood of approval.

Presubmission Phase

Sponsors may hold a presubmission meeting with review divisions to coordinate a mutually agreed upon presubmission timeline and to address review issues (e.g., CMC, inspection) in advance to **prevent delays**.

Sponsors are requested to submit the following at specified intervals:

- **CMC** – at least 60 days before final module submission
- **Proposed labeling** – same as above
- **Completed application package** – mutually agreed upon
- **Other presubmission requests** – as on the website

Application Review Phase

All CNPV applications are reviewed by the appropriate review teams in the relevant FDA center, **who will continue to develop independent recommendations based upon their own scientific analysis** and share these with a multidisciplinary tumor board-style panel (i.e., CNPV Review Council) for a collaborative discussion. The approval decision remains with the relevant center, using the center's normal processes.