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FDA Announces Commissioner's National Priority Voucher Program to Accelerate Drug Application Review Process and Support National Priorities

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On June 17, 2025, the U.S. Food and Drug Administration (FDA) announced the Commissioner's National Priority Voucher (CNPV) program, a new program that aims to speed up drug application review for companies aligned with U.S. national priorities. In terms of qualifying for the program, the key differentiator between this program and other "priority" review programs is that the application must support increased domestic drug manufacturing—presumably meaning that the applicant commits to manufacture the drug in the United States. The key benefit is that drug developers can redeem the vouchers to accelerate their application review time from 10-12 months to one to two months after a sponsor's final drug application submission. The program includes enhanced communication with the sponsor and will utilize a team-based review process, in which a multidisciplinary team of FDA experts, who will prereview clinical information, gather for a one-day "tumor board style" meeting. While some of the review work is envisioned to be "front loaded" before the actual application is submitted, it is still the case that a two-month review window would be a radical acceleration of the review timeline compared to standard review times.

In the first year, a limited number of vouchers will be given to the companies aligned with the following national priorities: addressing a health crisis in the United States, delivering innovative cures for Americans, meeting unmet public health needs, or increasing domestic drug manufacturing as a national security issue. To qualify, companies must submit the chemistry, manufacturing, and controls (CMC) portion of the application and the draft labeling at least 60 days before the final submission. Companies must also respond promptly to FDA inquiries during CNPV review. Additionally, the vouchers can be directed towards

specific investigational drugs or undesignated drugs, allowing companies to use the program for a new drug at its discretion, within two years following receipt from the FDA.

Another core distinction between this program and other priority review programs is that those other programs have generally been enacted by Congress whereas CNPV is being initiated solely by FDA. Because the key benefits of the program are administrative—interactive benefits during the review process and an accelerated review time goal—FDA likely determined that additional statutory or regulatory authority was not needed; however, Congress might choose to codify the program in statute at some point in the future. Moreover, it can be expected that this program will feature prominently in Prescription Drug User Fee Amendments ("PDUFA") user fee negotiations that are expected to begin later this year.

FDA intends to provide additional information about the application process in the near future.

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