



June 18, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2026-N-2366 Commissioner's National Priority Voucher (CNPV) Pilot Program; Public Hearing; Request for Comments

Dear Sir/Madam:

The Biotechnology Innovation Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the public hearing related to the Agency's Commissioner's National Priority Voucher (CNPV) Pilot Program.

BIO is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO also organizes the BIO International Convention and a series of annual conferences that drive partnerships, investment, and progress within the sector. Learn more at bio.org.

Sincerely,

/s/

Annetta Beauregard
Senior Vice President
Science and Regulatory Affairs
Biotechnology Innovation Organization

/s/

Joe Franklin
Chief Legal and Policy Officer
Biotechnology Innovation Organization

General Comments

BIO appreciates FDA's efforts to evaluate novel strategies to bring biotechnology breakthroughs to patients more quickly, and the substantial work undertaken by FDA review staff to implement a new approach. For programs to effectively advance innovation, and hence patient access, it is imperative that sponsors and other stakeholders have a clear understanding of program structure (e.g., eligibility and selection criteria) along with transparent review processes and predictable timelines. Transparency regarding FDA's program structure and operations allows sponsors to plan development programs effectively and work with FDA toward the shared goal of accelerating patient access to novel therapies. Robust stakeholder input ensures alignment across programs, maximizes opportunities for patient access, and minimizes unintended consequences. Currently, however, the CNPV Pilot Program does not provide sufficient transparency or regulatory certainty to achieve these goals or encourage participation. For example, greater clarity around selection criteria could help sponsors determine whether to apply for a CNPV and, if so, for which products. Likewise, transparent CNPV review milestones and action dates would help sponsors ensure readiness for launch at approval. This is particularly important for reviews operating on compressed timelines where modest accelerations or shifts can meaningfully affect supply readiness if not anticipated.

Further, BIO strongly recommends that FDA clarify how it intends to ensure that the CNPV Pilot Program is implemented in a way that complies with FDA's statutory and regulatory authorities and user fee program commitments and does not disrupt procedures available to sponsors.¹ For example, FDA should clearly explain, through guidance², how the CNPV Pilot Program complies with FDA's application review standards and dispute resolution procedures. Providing this information to the public will promote transparency and confidence in the CNPV Pilot Program and any similar programs.

Finally, BIO encourages FDA to ensure that the CNPV Pilot Program does not detract from existing review capacity. As FDA evaluates the pilot and considers broader implementation, it will be important to assess the staffing and resources needed to sustain accelerated timelines without adversely affecting reviews outside the CNPV Pilot Program. Implementation of the CNPV Pilot Program should proactively consider the need to avoid disruptions to FDA's user fee program commitments.

Throughout this letter, BIO expands upon these themes, identifying areas where additional clarity, predictability, and transparency would support stakeholder participation and confidence in the CNPV Pilot Program. Specific comments are organized according to the nine areas on which FDA requested input. BIO looks forward to continued engagement as FDA reviews stakeholder feedback and iterates on future versions of the CNPV Pilot Program.

¹ FDA had stated, but has since deleted from the CNPV website, that the program is derived from FDA's "general authority to implement the [FDCA] and the [PHSA] consistent with its mission to promote and protect the public health, including with respect to review of applications submitted for approval for a drug under section 505 of the FDCA (21 U.S.C. § 355) or a biological product under section 351 of the PHSA (42 U.S.C. § 262)."

² See 21 C.F.R. § 10.115(e) (requiring that the Agency use guidance documents exclusivity to communicate new Agency policies and new regulatory approaches: "These GGP's must be followed whenever regulatory expectations that are not readily apparent from the statute or regulations are first communicated to a broad public audience.").

Specific Comments

Eligible Applications and Scope

FDA has described the CNPV Pilot Program as oriented toward five “national priority areas”: public health crisis response, innovative breakthrough therapies, large unmet medical needs, onshoring and supply chain resilience, and affordability.

In general, BIO suggests that FDA provide more detailed guidance with respect to these criteria, describing how the Agency interprets and applies these national priority areas, and how the Agency’s approach aligns with or deviates from existing FDA expedited programs and requirements. Greater specificity and transparency would increase stakeholder and public confidence in the CNPV Pilot Program.

Given that affordability has not previously been used as a criterion in FDA’s expedited review programs or other Agency decision-making, BIO strongly urges FDA to clearly explain how affordability considerations fall within the Agency’s remit, and how the Agency proposes to apply affordability-related considerations in the context of the CNPV Pilot Program. BIO has significant concerns that introducing affordability as a criterion may create the perception that CNPV Pilot Program decisions are influenced by factors outside FDA’s core public health mission and may exceed FDA’s mandate to review drugs for safety and effectiveness.³

BIO also notes that other eligibility criteria outside of the national priority areas appear to have evolved over the short life of the CNPV Pilot Program without clear notification or explanation. The lack of clear, proactive communication regarding significant updates to eligibility and scope has created uncertainty for sponsors and other stakeholders. For example, BIO is aware of changes such as the removal of the initial limitation of one application per company, the rescission of the limitation of participation to “U.S. companies,” the withdrawal of FDA’s suggestion that participation may not be well-suited for “complex” and/or “novel” products, the expansion to include drug-device combination products, and the acceptance of applications seeking review of manufacturing or efficacy supplements. These types of significant changes to eligibility criteria should be clearly announced and explained to support transparency and consistent understanding of the CNPV Pilot Program.

Overall, clearer communication and consistency regarding the eligibility and scope of the CNPV Pilot Program – and clear grounding in FDA’s statutory and regulatory framework – would provide critical transparency, help sponsors better assess whether their product candidates are appropriate for the CNPV Pilot Program, and support more informed stakeholder feedback.

Selection Process

Selection of applications for the CNPV Pilot Program should be implemented in a consistent, equitable, and transparent manner, whether decisions are made through the internal nomination process or external requests. BIO also recommends that participation in the CNPV Pilot Program be voluntary; if nominated by an FDA review team, the sponsor should have the option to decline participation without penalty. Likewise, the sponsor should be able to withdraw from the CNPV Pilot Program at any time without penalty.

BIO urges FDA to ensure transparency in how it defines and applies eligibility and selection criteria, and to provide guidance on selection criteria. Doing so will support participation and help ensure that the process is fair, evidence-based, and perceived as such. Transparency will also enable sponsors to better assess competitiveness and strengthen their applications. Similarly,

³ See 21 U.S.C. § 393(b)(2)(B)

BIO recommends that FDA clearly define the roles and responsibilities of Agency personnel in the selection and review processes, including clarifying the roles and responsibilities of the CNPV Review Council, the Deputy Chief Medical Officer, and any other delegated officials, relative to that of the review division.

Finally, BIO recommends that FDA establish and publish general timelines and next steps for the selection process, including expected timeframes from submission of a statement of interest or internal nomination to a selection determination. Predictability and consistency in implementation are essential for sponsors to plan regulatory strategies and submission timelines effectively, and clearly articulated milestones would strengthen the CNPV Pilot Program.

Enhanced Regulatory Engagement Requirements

BIO recognizes that the accelerated timelines envisioned by the CNPV Pilot Program are likely to involve heightened engagement between FDA and sponsors, including more rapid communications and greater availability of FDA staff and the sponsor for meetings. However, FDA should ensure that these requirements are workable across the full range of sponsors that may participate, and that they do not detract from applications outside of the CNPV Pilot Program.

BIO encourages additional clarity on how review and communication will be managed with the sponsor or confirmation that they will be consistent with the existing practices described in the PDUFA Desk Reference Guide and Good Review Management Principles and Practices (GRMPs) guidelines. It would also be helpful to clarify the types of interactions available under the CNPV Pilot Program, including informal calls, formal meetings, expected timelines for FDA and sponsor responses to questions.

Presubmission and Rolling Submissions Requirements

BIO supports the concept of presubmission engagement and rolling submissions as mechanisms to facilitate accelerated review timelines such as those envisioned by the CNPV Pilot Program. Early engagement between FDA and sponsors – including presubmission informational meetings and the rolling submission of CMC information at least 60 days before final module submission (or 120 days, for programs that include manufacturing sites outside of the U.S.) – can help identify and resolve potential issues before formal review begins.

BIO supports the goal of efficient labeling discussions. However, BIO notes that it may not be feasible to include proposed labeling in the presubmission package. Labeling often involves complex issues regarding indications, contraindications, warnings, precautions, and dosing that are not decided presubmission. While sponsors may be able to propose high-level or preliminary labeling information, clinical data are often needed to inform final proposed labeling. Expecting sponsors to include final proposed labeling prematurely may undermine the benefit of rolling submissions. BIO recommends that FDA consider the limitations on what types of data can feasibly be provided at the presubmission stage and calibrate expectations accordingly.

BIO recommends that FDA provide greater clarity around presubmission expectations. Although the Agency lists CMC and labeling information as required presubmission components, there also appear to be exceptions in some situations such as efficacy supplements. Presubmission expectations beyond CMC and draft labeling are also unclear. While FDA has recommended the submission of all available data in the presubmission package, including the BIMO package for pivotal studies, it is not clear how inclusion of these kinds of data and information presubmission will affect filing or review timing. For example, because BIMO packages typically require database lock and full data readout, additional clarity on these expectations would help reduce the risk of misalignment on timing and content. It would likewise be helpful for FDA to provide further clarity on the timing of inspections – including clinical site (BIMO), manufacturing facility, and sponsor

inspections – for original BLAs/NDAs and supplements under the CNPV Pilot Program, as well as clarity on whether FDA intends to rely on inspection tools, such as remote inspections or single-day inspections, or alternatives, such as remote regulatory assessments.

BIO also requests that FDA provide clarity regarding the presubmission process, including the expected content and format of presubmission packages, the types of interactions available (e.g., written feedback, teleconferences, in-person meetings), and the timelines for FDA responses during the presubmission period. BIO suggests that the Agency provide clarity around scenarios where review divisions may request extensions to better align overall timelines. Sponsors and the Agency will benefit from clear expectations in the presubmission phase and how this time can be the most productive.

Regarding FDA's recommendation that no more than 2 to 3 manufacturing facilities be included in a submission, BIO suggests that it is critical for FDA to retain flexibility to permit additional sites. For certain products – particularly cutting-edge biologics, cell and gene therapies, and other complex modalities – the manufacturing network may necessarily involve multiple facilities. BIO recommends that FDA evaluate the appropriateness of the number of manufacturing facilities listed on a case-by-case basis, taking into account the product type, the complexity of the manufacturing process, and the sponsor's justification for any additional sites. This regulatory flexibility will preserve the ability of products with complex supply chains to participate fully in the CNPV Pilot Program.

CNPV Review Timeline and Process

As noted in the general comments, BIO recommends that FDA provide clear, publicly accessible materials that explain how the CNPV Pilot Program differs from the traditional review process. Transparency around the review process and how the CNPV Pilot Program aligns with existing priority review pathways will enhance sponsor and public trust in the CNPV Pilot Program.

In addition, aligning how the CNPV Pilot Program is described with how it functions in practice may help reduce confusion and improve external understanding. Despite the term “voucher,” a CNPV is neither transferable nor sellable, and applies only to the specific product to which it is awarded. In practice, it operates more like a review designation or prioritization mechanism – comparable in concept (and in many of the criteria) to Priority Review or Breakthrough Therapy – rather than a traditional voucher. Clarifying this distinction could also help address misperceptions of preferential treatment or biased selection, without undermining the integrity of the pilot.

Furthermore, greater transparency in the review timeline would enhance predictability and facilitate sponsor planning. This includes, for example, clarification regarding when the review period begins (i.e., from the filing date), whether and how vouchers expire, when FDA considers the voucher process to be initiated, and any actions required prior to expiration, as applicable. BIO encourages FDA to consider an early-stage evaluation of CNPV applications to identify factors such as program complexity or use of surrogate endpoints that may require modifications to the overall approach or timeline. BIO also recommends that FDA clarify how participation in the CNPV Pilot Program interacts with other review pathways and initiatives, including whether applications selected for other expedited programs may also participate in the CNPV Pilot Program.

Finally, it is critical for FDA to reconcile its approach to the development of review documentation and the availability for public disclosure of any application- or review-related information with standard FDA review procedures and applicable requirements.

CNPV Review Council

BIO urges FDA to clearly define the role of the CNPV Review Council in all stages of the CNPV Pilot Program, from selection of applications to review and approval decisions. It is critical to have a defined governance and accountability structure that complies with applicable statutory and regulatory requirements and clearly delineates decision-making authority, roles and responsibilities, and signatory processes to ensure accountability at all levels.

BIO recommends that FDA clarify the Council's procedures to ensure that the review team's independent written scientific assessment remains the primary input into any given approval decision and is reflected in the administrative record, consistent with FDA's longstanding review practices. Similarly, should an Agency action conflict with the recommendation of the review team, BIO recommends that FDA include the deciding official's rationale as part of the administrative record, consistent with historical practice. Approval decisions and associated documentation should be published promptly to ensure transparency, consistent with FDA practice.

Finally, FDA must ensure and transparently confirm that review processes implemented through the CNPV Review Council – and any other aspects of the CNPV Pilot Program – do not adversely affect a sponsor's ability to pursue dispute resolution procedures as described in the statute and FDA regulations. Further, FDA should also clarify that the timelines for Formal Dispute Resolution specified in the PDUFA commitment letter will continue to apply to products submitted through the CNPV Pilot Program.

Sponsor Responsibilities and Expectations

BIO understands that the expedited nature of review under the CNPV Pilot Program will involve specific expectations for sponsors, but we encourage FDA to build flexibility into processes where appropriate to reflect the circumstances of particular sponsors, as well as differences in sponsor size, resources, and experience.

Program Evaluation and Future Directions

BIO offers several recommendations for how FDA should evaluate and evolve the CNPV Pilot Program over time, consistent with the design of the program as a pilot with a commitment to continuous improvement.

BIO encourages FDA to publicly share high-level learnings from the CNPV Pilot Program, including information such as review timelines, approval outcomes (including postmarketing commitments), and any observed impacts on non-CNPV review timelines. BIO also recommends sharing general insights into the factors most frequently associated with receipt of a CNPV, as well as common reasons for declining requests. Publicly reporting such information, as appropriate, will support transparency and enable FDA and stakeholders to assess whether the CNPV Pilot Program is achieving its intended goals.

BIO also recommends that FDA consider formal opportunities for stakeholder input as the CNPV Pilot Program progresses. This should include Agency guidance that describes the CNPV Pilot Program procedures, criteria, and expectations and explains how it is consistent with statutory and regulatory requirements and other FDA regulatory processes.⁴ Such a guidance document would be an important source of transparency and predictability. FDA also could facilitate periodic public workshops, listening sessions, or requests for comment that allow industry, patient groups, and other stakeholders to provide feedback on the CNPV Pilot Program implementation and suggest refinements. This public hearing is a welcome first step, and BIO encourages FDA to continue this type of engagement on an ongoing basis.

⁴ See footnote 2, *supra*, discussing the requirements of FDA's good guidance practice regulations.

Where appropriate, and in accordance with applicable statutory and regulatory requirements and FDA's PDUFA commitments, BIO also encourages FDA to explore ways to consider incorporating lessons learned from the CNPV Pilot Program into standard regulatory practice. Elements such as changes in presubmission management, rolling submissions, frequent and continuous interaction with FDA review teams, early submission of CMC information, and the appropriate use of technology will likely have broader applicability across FDA's review programs. FDA should continue to evaluate its experience from the CNPV Pilot Program and consider how relevant lessons may be applied more broadly across its review processes and operations.