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February 18, 2026 • Updates

New FDA Drug Reforms: Congress Extends Voucher Incentive, Clarifies Orphan Exclusivity and Provides Greater Transparency for Q1/Q2 Generic Approvals

Key Takeaways

- In legislation enacted on Feb. 3, 2026, Congress reauthorized the rare pediatric disease priority review voucher program, clarified the scope of orphan drug exclusivity (ODE) and mandated increased transparency in FDA's Q1/Q2 determinations for certain generic drugs.
- Companies with rare pediatric disease development programs and potential investors in those programs should evaluate how priority review voucher eligibility could impact financial strategy.
- Those developing orphan drugs or potential competing products should consider reevaluating current portfolios, as well as exclusivity and litigation risk analyses.
- Generic manufacturers should monitor for FDA guidance on Q1/Q2 determinations and other updates on the agency's implementation of new transparency requirements, while innovators should revise their strategic planning to account for the potential of facing generic applicants at an earlier point in time.

The Consolidated Appropriations Act, 2026, enacted on Feb. 3 (the 2026 Act) includes several FDA reforms that affect drug development incentives and competitive dynamics. These include measures renewing FDA's authority to award rare pediatric disease priority review vouchers (PRVs), addressing uncertainty around the scope of ODE and increasing transparency around FDA's qualitative and quantitative sameness (Q1/Q2) determinations with the goal of speeding up the generic drug approval process.

Extending the Rare Pediatric Disease Priority Review Voucher Program

The 2026 Act reauthorizes the rare pediatric disease PRV program,[1] which Congress had previously allowed to sunset for products not designated for rare pediatric diseases by December 20, 2024. Under this program, if FDA approves a sponsor's qualifying drug or biological product application for a rare pediatric disease, the sponsor receives a voucher, which can then be redeemed to obtain priority review of a different product.[2] Vouchers

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may be sold or transferred and have historically commanded significant market value, often selling for prices between $100 and $200 million. This makes PRV eligibility a potentially important consideration in financing or partnering strategies.

Unless Congress acts again to extend authority for the program, FDA will be unable to award PRVs for products approved after September 30, 2029. Companies planning to request a PRV should consult FDA's draft guidance on the program and seek counsel on timing and eligibility questions to avoid a misstep that could reduce the chance of receiving a PRV down the road.

Clarifying the Scope of Orphan Drug Exclusivity

The 2026 Act also made a change to resolve uncertainty around the scope of ODE—a powerful regulatory exclusivity that blocks approval of certain competing products to incentivize drug development for rare diseases. Before the recent amendments, once FDA approved an application for a drug (including a biologic) that had received orphan designation for a rare disease or condition, the statute prevented FDA from approving another sponsor's application for "the same drug ***for the same disease or condition***" until seven years after the orphan drug's approval.[3] Often, the "disease or condition" for which a product originally receives orphan drug designation is broader than the specific indication for which the product is ultimately approved, and FDA had long interpreted this statutory language to mean that ODE only blocks approval of another product for the same approved use or indication.[4] But in *Catalyst Pharmaceuticals, Inc. (Catalyst) v. Becerra*, the U.S. Court of Appeals for the Eleventh Circuit found that the statutory language foreclosed FDA's interpretation and held that the ODE for Catalyst's drug barred approval of another company's drug for all indications falling within the orphan-designated disease.[5] Although FDA indicated that it would continue to apply its existing interpretation and regulations outside the scope of the Court's order, the *Catalyst* decision created uncertainty and prompted additional litigation.

The 2026 Act appears to settle this uncertainty in favor of FDA's position—providing that ODE only blocks approval of "the same drug ***for the same approved use or indication within [the orphan designated] rare disease or condition[.]***"[6] Congress also specified that the amendment applies to all orphan designated drugs, regardless of when they receive designation or FDA approval. This clarification may affect lifecycle planning, indication strategy and litigation risk assessments for both innovator and follow-on sponsors, and companies should consider whether existing exclusivity analyses or pipeline positioning warrant reevaluation.

Q1/Q2 Transparency for Generic Applicants

A reform to promote generic competition also made it into the 2026 Act.

For certain generic drugs (typically, topicals, parenterals and the like), FDA requires the abbreviated new drug application (ANDA) applicant to show that its product is Q1/Q2 to the reference listed drug (RLD).[7] The agency also recommends that applicants demonstrate Q1/Q2 sameness in some product-specific guidances. To be Q1/Q2, the ANDA product must have the same inactive ingredient(s) at concentrations within +/- 5% of the RLD. Historically, FDA did not confirm specific RLD inactive ingredient quantities but would generally inform an applicant whether a proposed formulation was (or was not) Q1/Q2, without providing details as to which ingredients in what amounts failed to meet Q1/Q2 sameness. Therefore, generic applicants often had to rely on numerous controlled correspondence requests to identify a proposed formulation that satisfied Q1/Q2 expectations, which could be time consuming for many products.

Under the 2026 Act, FDA must now, upon an applicant's request, confirm that a proposed

generic is Q1/Q2 to the RLD or identify the specific inactive ingredient(s) that differ and disclose the extent of any quantitative deviation. The amendments specifically authorize FDA to disclose this information in response to a request, or on its own initiative, without violating protections for trade secret information regarding the RLD. In addition, FDA will generally be bound to its determinations that a generic drug is Q1/Q2, subject to limited exceptions to account for changes to the RLD and agency errors. We anticipate that these changes will reduce uncertainty and development timelines for certain ANDA applicants.

The 2026 Act requires FDA to issue draft or updated guidance on Q1/Q2 determinations for public comment by March 3, 2027.[8]

Strategic Considerations Going Forward

The provisions of the 2026 Act discussed in this alert make targeted but meaningful adjustments to FDA's authorities. As FDA implements these changes, stakeholders should remain attentive to how evolving regulatory interpretation may shape development planning, exclusivity expectations and business strategies.

[1] Section 6604 of the 2026 Act.

[2] 21 U.S.C. § 360ff.

[3] 21 U.S.C. § 360cc(a) (emphasis added).

[4] 21 C.F.R. §§ 316.3(b)(12), 316.31(a)-(b).

[5] *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299, 1308 (11th Cir. 2021).

[6] Section 6605 of the 2026 Act (emphasis added).

[7] *See* 21 C.F.R. § 314.94(a)(9).

[8] Section 6703 of the 2026 Act.