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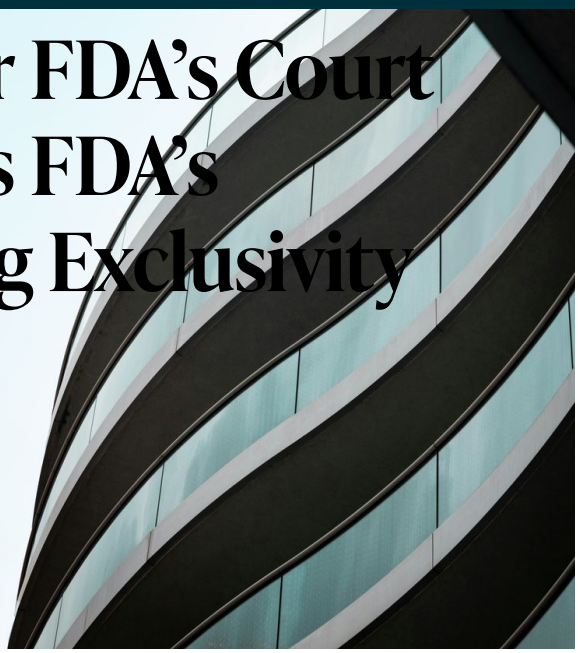
Oliver Twisted Again: After FDA's Court Losses, Congress Approves FDA's Standards on Orphan Drug Exclusivity



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Last week, Congress enacted the Consolidated Appropriations Act of 2026. This legislation narrows the scope of the statutory protection for drugs for rare diseases and conditions under the Orphan Drug Act, 21 U.S. Code § 360cc. The Orphan Drug Act provides a 7-year period of market exclusivity for drugs designed to treat certain rare diseases or conditions, i.e., diseases or conditions impacting fewer than 200,000 patients in the United States. Accordingly, the Orphan Drug Act creates an incentive for pharmaceutical companies to develop treatments for rare diseases that might otherwise be ignored.

FDA has traditionally tied orphan-drug exclusivity to only the use or indication for which the drug product was approved. In *Catalyst Pharms., Inc. v. Becerra*, however, the 11th Circuit held that orphan-drug exclusivity applies to the *entire disease or condition*, regardless of the scope of the drug product's approved use or indication. 14 F.4th 1299 (11th Cir. 2021). FDA agreed to comply with the court's order with respect to the particular drugs at issue in *Catalyst* but announced its intention "to continue to apply its regulations tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved to matters beyond the scope of that order." Clarification of Orphan-Drug Exclusivity Following *Catalyst Pharms., Inc. v. Becerra*; Notification, 88 Fed. Reg. 4086 (Jan. 24, 2023) (codified at 21 C.F.R. § 316).

Congress's recent legislation amends the statute to override the 11th Circuit's holding, bringing the Orphan Drug Act in line with FDA's longstanding approach. Congress replaced the

statute's language of "same disease or condition" with the new language of "same approved use or indication within such rare disease or condition."

> **. . . the Secretary may not approve another application under section 355 of this title [e.g., an NDA or ANDA] or issue another license under section 262 of title 42 [e.g., a BLA or aBLA] for the same drug for the ~~same disease or condition~~ *same approved use or indication within such rare disease or condition* for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of the approval of the approved application or the issuance of the license.**

21 U.S.C. § 360cc(a)(2) as amended by the Consolidated Appropriations Act of 2026 (emphasis added).

The newly narrowed scope of the Orphan Drug Act is notable for pharmaceutical companies seeking to market generic drugs. Regulatory exclusivity is a powerful tool for brand companies, but the Consolidated Appropriations Act of 2026 may open the door for generic companies seeking approval for uses or indications that differ from those of the original orphan drug. Although this likely will not change FDA's approach, generic companies may no longer need to consider the possibility of a *Catalyst*-style suit.

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