



FDA Renews Focus on Drug Repurposing with New RFI

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On May 12, 2026, the Food and Drug Administration (FDA) published a notice in the *Federal Register* requesting comment on the agency's efforts related to drug repurposing to help address unmet medical needs. In this request for information (RFI), FDA is seeking input to identify potential new uses for FDA-approved drugs—such as a new indication or a new population—to help accelerate the availability of treatments for unmet medical needs. Stakeholders are encouraged to submit priority disease areas and potential candidates for drug repurposing, particularly in cases where there is a lack of commercial incentive to pursue labeling changes or a significant unmet need.

FDA is focusing on drugs that meet the following criteria for new use: (1) there is scientific evidence to support the effectiveness of the drug for the new use; (2) the dosage forms and/or route of administration for the new use are the same as for an approved indication and (3) there is a comparable safety profile for patient populations for the new use and approved applications. FDA specifically seeks input on the following topics:

- **Priority areas.** Whether the FDA's proposed priority disease areas—including metabolic, neurodegenerative, men's and women's health, substance use and rare diseases—appropriately reflect unmet medical needs that could benefit from drug repurposing.
- **Candidates for drug repurposing.** Which candidates for drug repurposing show the greatest potential to effectively treat specific medical conditions.
- **Approaches to identifying candidates for drug repurposing.** What innovative approaches could be used to identify new candidates for drug repurposing, including specific methods or opportunities to facilitate this process.

- **Barriers and opportunities.** Barriers to drug repurposing, both in the absence of commercial incentives and in the clinical use of approved drugs for unapproved indications, and recommendations on how the Agency can address these challenges and improve data collection on real-world use.

Drug repurposing has been recognized as a tool for potentially improving public health in several contexts. The *Make Our Children Healthy Again Strategy Report*, released in September 2025, explicitly directed the National Institutes of Health (NIH) and FDA to strengthen the use of repurposed drugs for the treatment of chronic disease, while harmonizing authorization processes through collaborative clinical trial designs to achieve FDA approval. FDA's Oncology Center of Excellence leads Project Renewal, an initiative aimed at updating labeling information for certain older oncology drugs to ensure information is clinically meaningful and scientifically up to date.

Congress has also been active on drug repurposing policy issues in recent years. In 2020, the Making Objective Drug Evidence Revisions for New (MODERN) Labeling Act was signed into law as part of the Consolidated Appropriations Act, 2021 (P.L. 116-260), which outlined a process to update generic drug labeling in cases where there is new scientific evidence available pertaining to new or existing conditions of use that is not reflected in the approved labeling; the approved labeling does not reflect current legal and regulatory requirements for content or format; or there is a relevant accepted use in clinical practice that is not reflected in the approved labeling, and updating the approved labeling would benefit the public health. The MODERN Act also explicitly outlined a mechanism for public input in identifying drugs with repurposing potential and FDA's recent RFI builds on these legislative efforts. Congress more recently reaffirmed its support for exploring drug repurposing in pediatric research through the Mikaela Naylor Give Kids a Chance Act, signed into law in February 2026 as part of the Consolidated Appropriations Act, 2026 (P.L. 119-75). The bill reauthorized parts of the Best Pharmaceuticals for Children Act, specifically the NIH program that prioritizes and sponsors clinical trials of off-patent drug products for further study in children.

The notice establishes a public docket, and FDA invites interested parties, including clinical and public health communities, patients and researchers to submit comments by June 11, 2026. Given the bipartisan congressional work and the administration's focus on advancing drug repurposing, the RFI presents a timely opportunity to submit public comment, and it might also inform the upcoming Prescription Drug User Fee Act (PDUFA) and Generic Drug User Fee

Act (GDUFA) reauthorizations as lawmakers may seek to consider these issues further and build on their previous legislative efforts on this front.

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