Drug Databases (http://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Postmarket Requirements and Commitments

Revise Search (index.cfm) | New Search (index.cfm?resetfields=1)

You searched for: Both CBER and CDER; Paxlovid; Delayed; Neither

«« « 1 of 1 » »»

Applicant:	PFIZER INC
Product:	Paxlovid (nirmatrelvir and ritonavir)
NDA/BLA Number:	217188
NDA/BLA Approval Date:	05/25/2023
Annual Report Due Date: (must be submitted within 60 days of this date)	05/25/2026
Annual Report Received:	07/22/2025

Requirement/Commitment Number: 2

Required Under:	Pediatric Research Equity Act
Original Projected Completion Date:	11/30/2028
Description:	PMR 4392-2: Conduct a study to evaluate the safety, tolerability, pharmacokinetics, and treatment response of PAXLOVID in pediatric subjects 2 to less than 6 years of age, with mild-to-moderate coronavirus disease 2019 (COVID-19).
Current Status:	Delayed
Explanation of Status:	Original Final Report Due Date: 10/31/2025; Deferral Extension granted per FDA letter dated 06/13/2025. The study completion milestone was also revised.

Requirement/Commitment Number: 8

Required Under:	N/A
Original Projected Completion Date:	12/31/2024

Description:	PMC 4392-8: Submit the final study report with datasets for the ongoing trial, “A Phase 1, Open-Label Study To Evaluate The Pharmacokinetics, Safety, And Tolerability Of Orally Administered Nirmatrelvir/Ritonavir In Pregnant Women With Mild-To-Moderate COVID-19” (Study C4671035; NCT05386472).
Current Status:	Delayed
Explanation of Status:	The trial completion and final report milestones were missed.Acknowledge Revised PMC Milestones letter was issued on 11/20/2024.

You searched for: Both CBER and CDER; Paxlovid; Delayed; Neither

«« « 1 of 1 » »»

Revise Search (index.cfm) | **New Search (index.cfm?resetfields=1)**

Page Last Updated: 08/09/2013