

CDER Breakthrough Therapy Designation Requests Received by Fiscal Year

Cohort: October 1, 2024 - September 30, 2025

Data as of December 31, 2024

Fiscal Year	Total Requests Received	Granted	Denied	Withdrawn
2025	38*	10	4	4

* Requests that are still pending a decision are included in the total requests received column.