

CDER Breakthrough Therapy Designation Requests Received by Fiscal Year

Cohort: October 1, 2023 - September 30, 2024

Data as of September 30, 2024

Fiscal Year	Total Requests Received	Granted	Denied	Withdrawn
2024	134*	52	51	11

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