

CDER Breakthrough Therapy Designations Withdrawn after Granting or Rescinded by Fiscal Year

Cohort: July 9, 2012 - September 30, 2024

Data as of December 31, 2024

Fiscal Year	Withdrawn After Granting	Rescinded
2024	0	2
2023	2	5
2022	1	3
2021	1	6
2020	2	11
2019	1	5
2018	2	4
2017	2	3
2016	0	2
2015	0	4
2014	2	0
2013	0	0
2012	0	0
Total	13	45

*The Food and Drug Administration Safety and Innovation Act, enacted on July 9, 2012, provided for breakthrough therapy designation.