

CDER BIOSIMILAR BIOLOGIC INDs WITH ACTIVITY *

CALENDAR YEAR 2023 (January 1, 2023 to December 31, 2023)

Data as of 31 January 2025

Calendar Year	Commercial	Research	Total
2023	83	1	84

* Excludes Drug and Non-Biosimilar Biologic INDs, Expanded Access INDs, and Unknown INDs. Unknown refers to those INDs where the designation of Commercial or Research had not been made at the end of the calendar year.