

CDER BIOSIMILAR BIOLOGIC INDs WITH ACTIVITY *

CALENDAR YEAR 2025 (January 1, 2025 to December 31, 2025)

Data as of 31 December 2025

Calendar Year	Commercial	Research	Total
2025	85	2	87

* Excludes Drug and Non-Biosimilar Biologic INDs, Expanded Access INDs, and Unknown INDs.
Unknown refers to INDs that have not yet been designated as Commercial or Research.