

CDER BIOSIMILAR BIOLOGIC INDs WITH ACTIVITY *
CALENDAR YEARS 2009 - 2013

Calendar Year	Commercial	Research	Total
2013	23	2	25
2012	14	2	16
2011	7	2	9
2010	0	1	1
2009	0	1**	1

* 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.

**Following the passage of the Biologics Price Competition and Innovation Act of 2009, the sponsor of this IND decided to pursue development of their proposed product as a biosimilar.