

**CDER BIOSIMILAR BIOLOGIC INDs WITH ACTIVITY \***

**CALENDAR YEAR 2022**

| <b>Calendar Year</b> | <b>Commercial</b> | <b>Research</b> | <b>Total</b> |
|----------------------|-------------------|-----------------|--------------|
| <b>2022</b>          | 81                | 1               | 82           |

\* 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.