

Upcoming CGT Exclusivity Products & Cos. Targeting them (2025-2028)

OCT 18, 2024



Executive Summary :

Historically, the FD&C Act has provided an **incentive and potential reward** to the first applicant that, among other things, filed a substantially complete ANDA containing a Paragraph IV certification to a listed patent in the FDA's Orange Book.

The FDA Reauthorization Act of 2017 has created a **new type of 180-day exclusivity**, different from 180-day patent challenge exclusivity, for the **first approved applicant** of a drug with a **CGT designation** for which there were **no unexpired patents or exclusivities** listed in the Orange Book at the **time of original** submission of the ANDA. This new 180-day exclusivity, under CGT exclusivity is intended to incentivize competition for drugs that are not protected by patents or exclusivities and for which there is inadequate generic competition.

This report forecasts the **upcoming eligible CGT exclusivity** drugs between **2025-2028** and **generic manufacturers** targeting those drugs. The report is prepared from our **GenUS database**.

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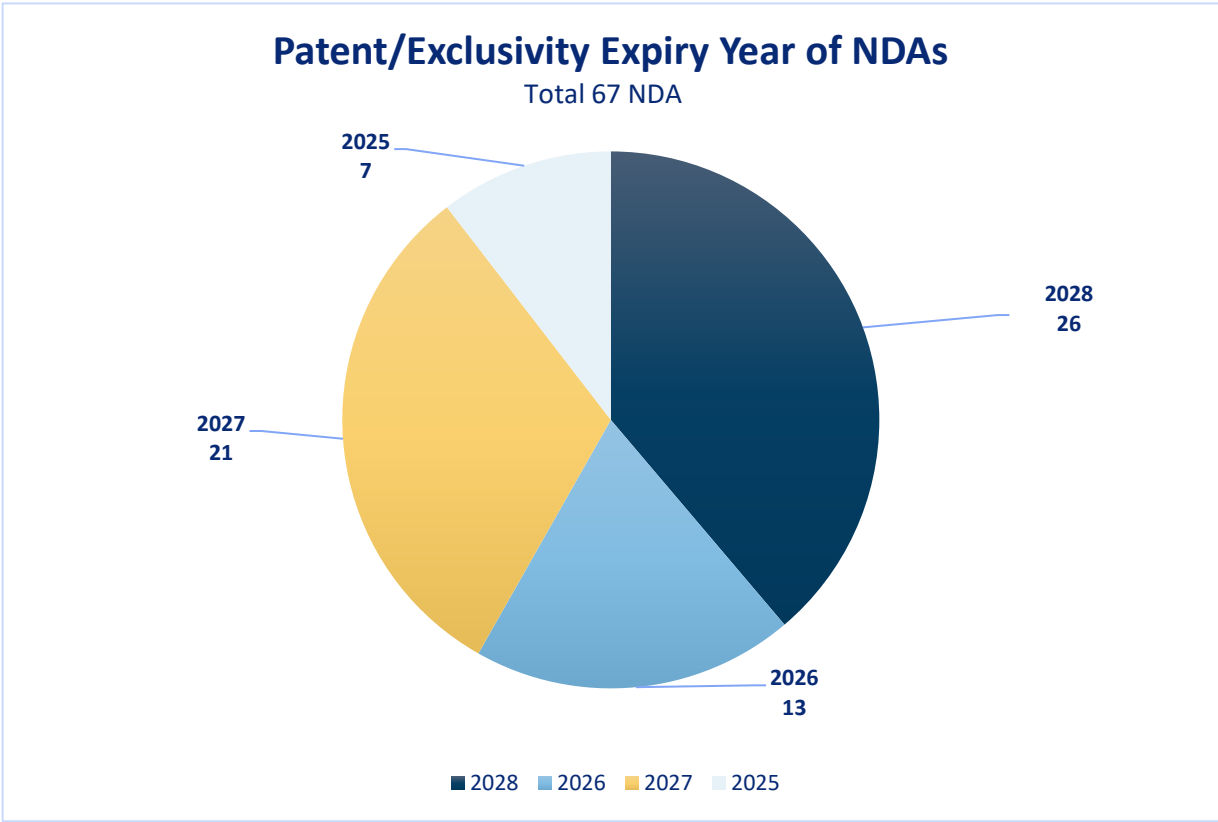
Products and Generic Manufacturers covered in this report:

- NDA products with **last patent expiry** ranging between **Jan 01, 2025 – Dec 31, 2028** with their key drug **exclusivities** either already expired or is likely to expire by Dec 2028.
- Generic manufacturers targeting these drugs are those ANDA developers who are conducting or have already conducted **BA/BE trials in India**. BA/BE trials conducted **outside India are not captured in this report**.
- **Contract Research Organizations (CROs)** conducting BA/BE trials for client companies are also included in this list.
- Among the eligible list, **NDA approved under 505(b)(2) are excluded**.

Report discusses different classifications of “**67 CGT Exclusivity eligible NDAs**” based on:

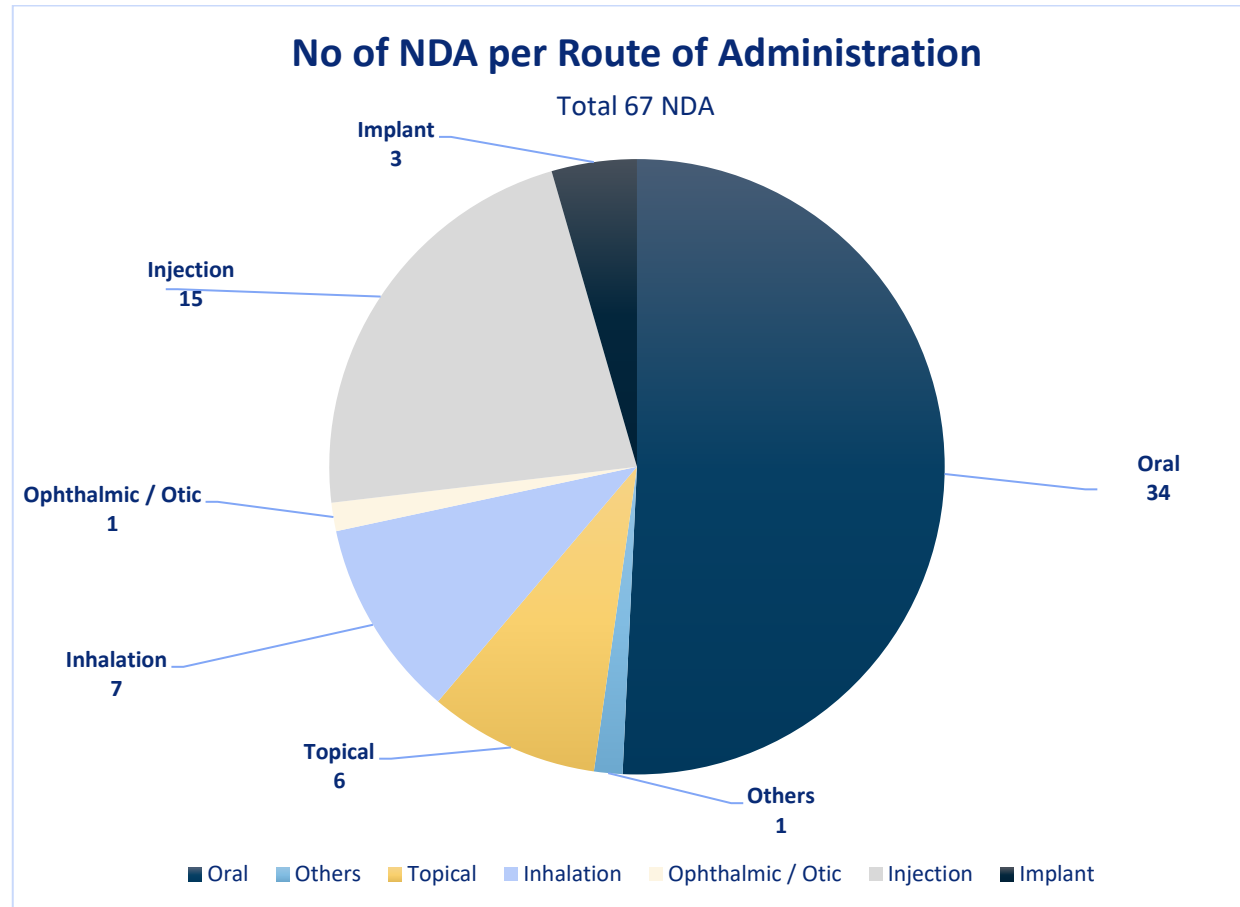
- 1) Year wise loss of exclusivity
- 2) Route of Administration
- 3) Drug Complexity
- 4) Marketing Status
- 5) Eligible CGTs facing competition from approved 505(b)(2) drugs
- 6) Generics Targeting Upcoming CGT Exclusivities
 - a. Product wise
 - b. Company wise

Breakup - Year wise Loss of Exclusivity



Source – Research Delta Advisors

Breakup – Route of Administration

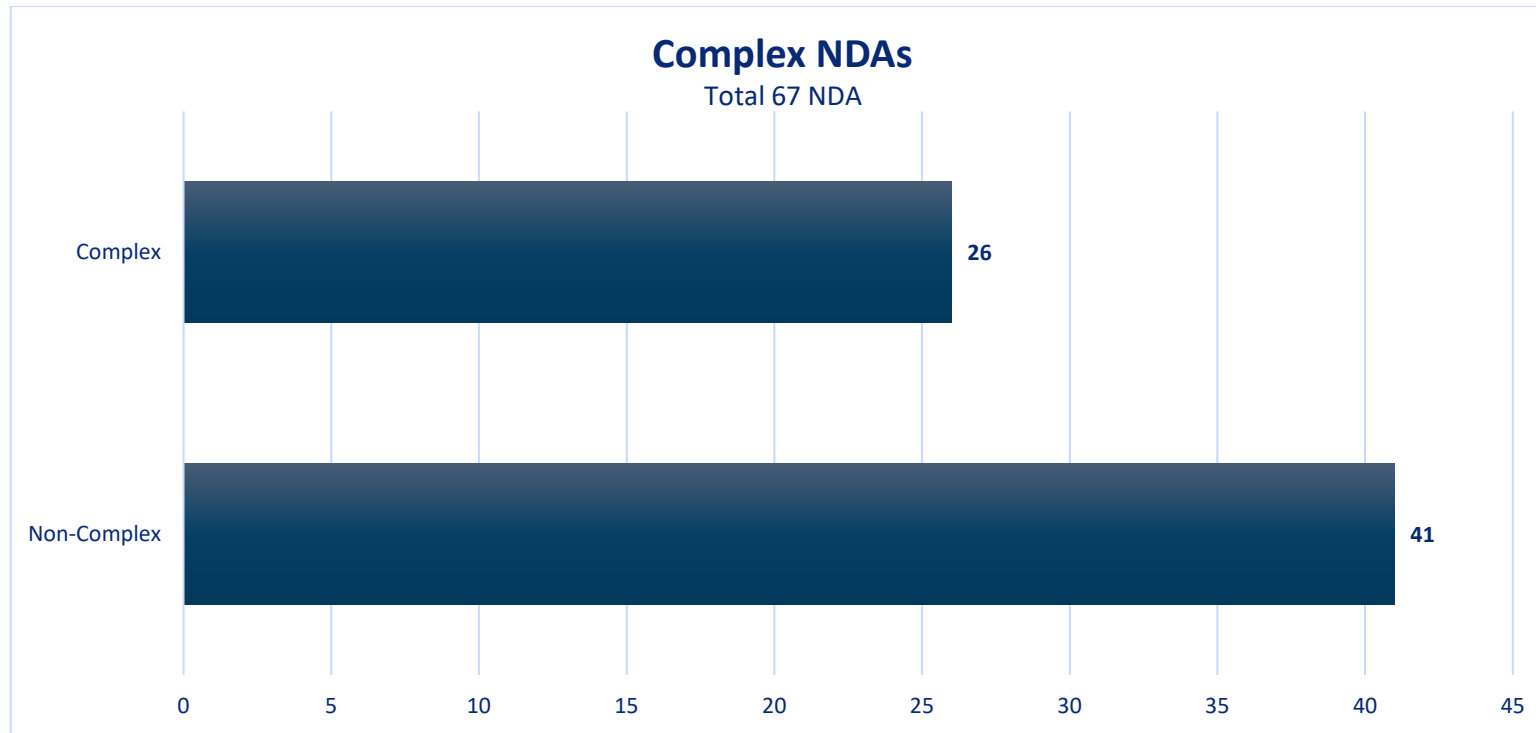


Source – Research Delta Advisors

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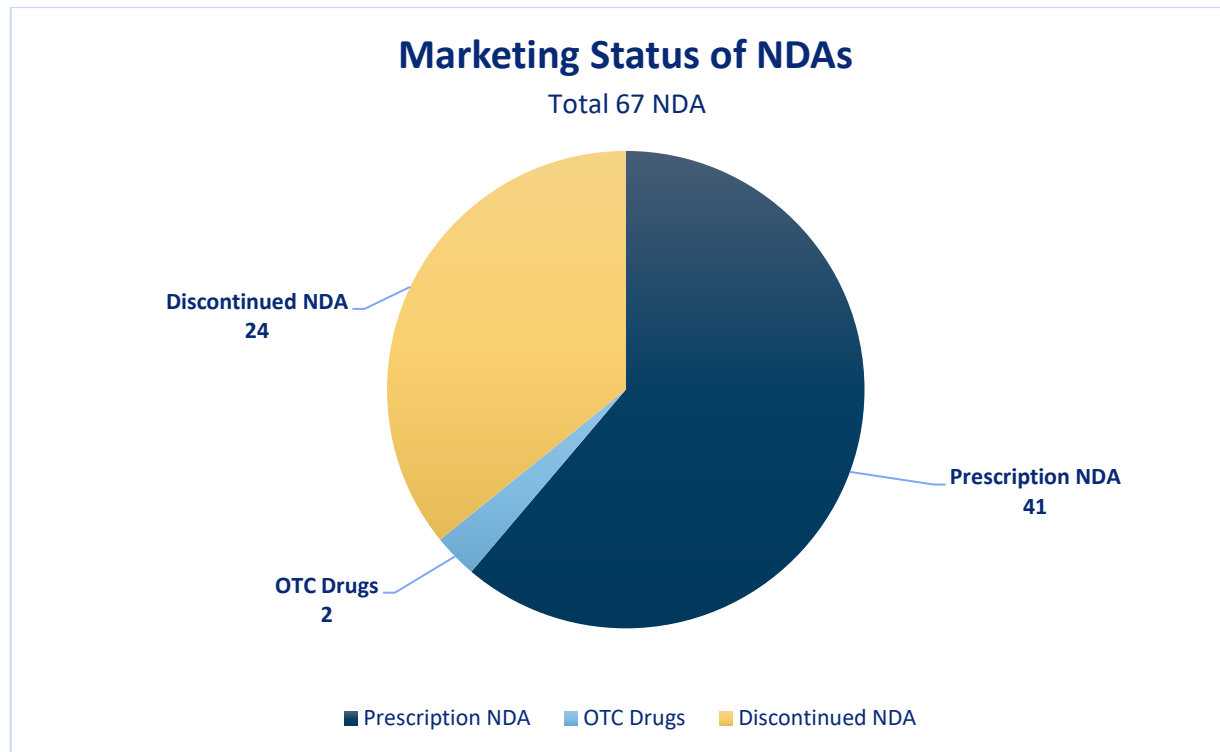
Breakup – Drug Complexity



Source – Research Delta Advisors

Breakup - Marketing Status

More than 60% of the NDAs are still available in the market.



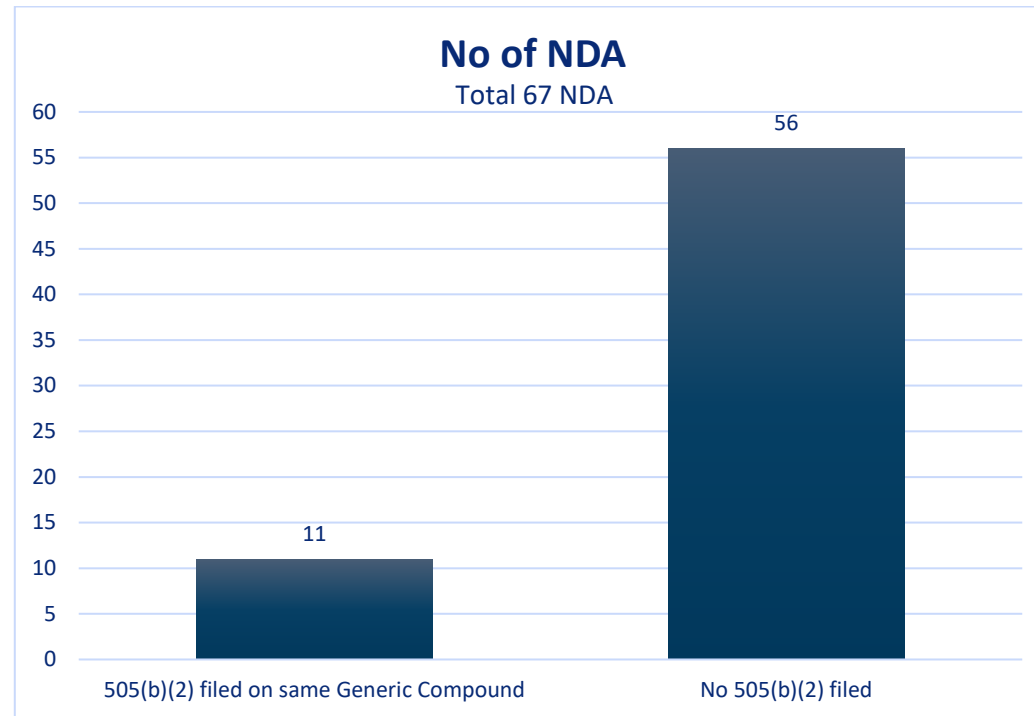
Source – Research Delta Advisors

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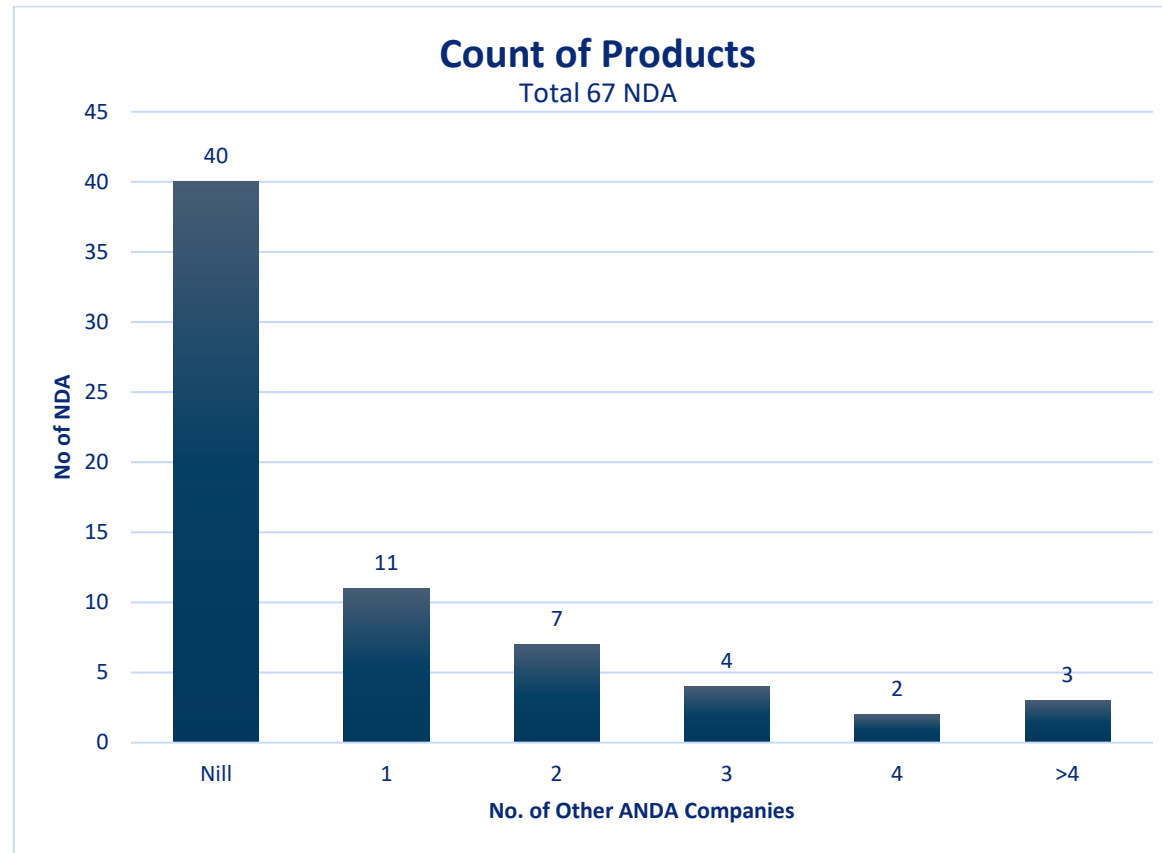
Eligible CGTs facing competition from approved 505(b)(2) drugs

Only 11 CGTs are already witnessing competition from 505(b)(2) as same compounds.



Source – Research Delta Advisors

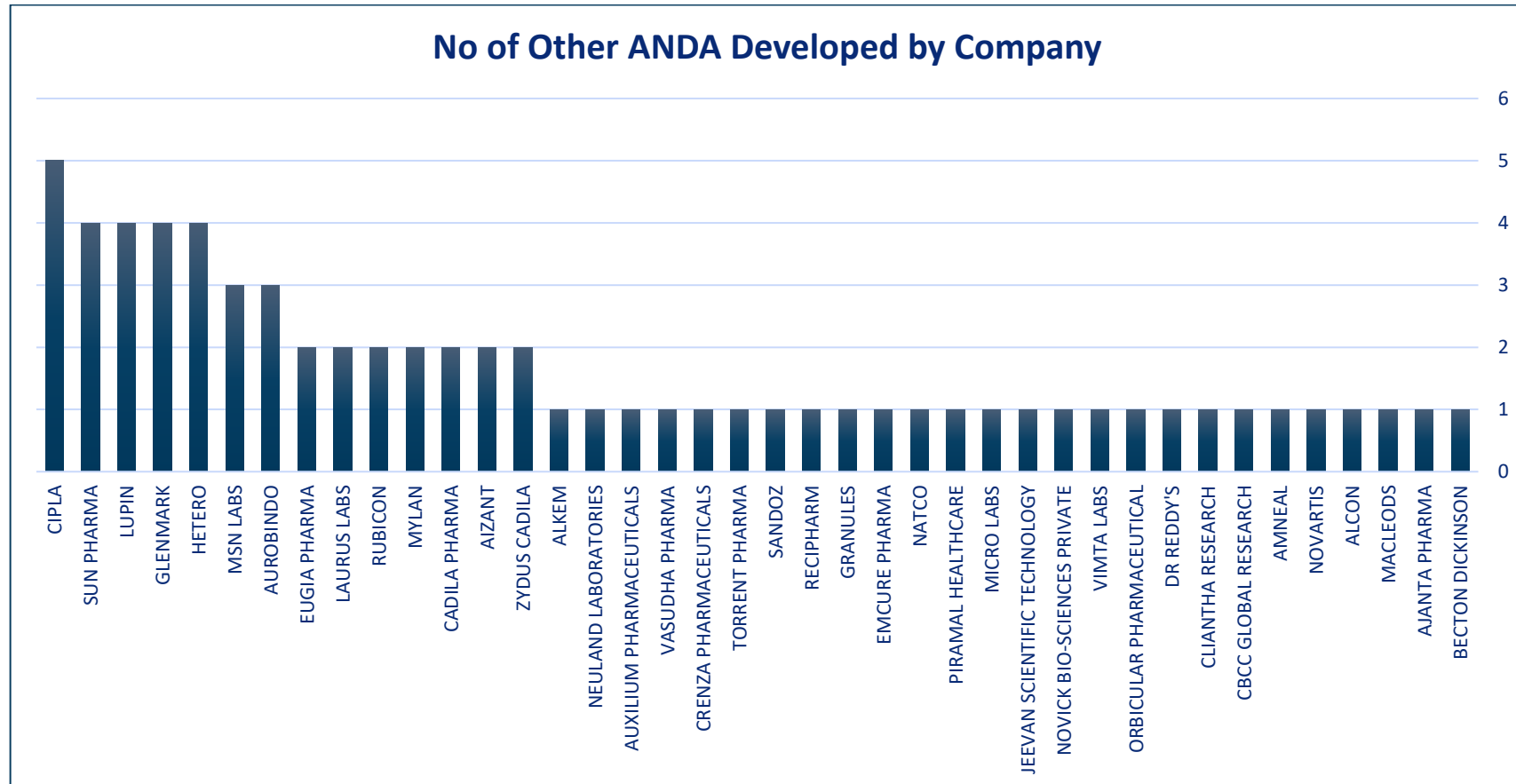
Generics Targeting Upcoming CGT Exclusivities - Product wise



Source – Research Delta Advisors

Generics Targeting Upcoming CGT Exclusivities - Company wise

Cipla has targeted the most product compared to other developers



Source – Research Delta Advisors

List of NDA eligible for CGT Exclusivity

| Sr No. | Brand Name | Generic Name | Dosage & Route of Administration | Complexity | Other Anda Developers | Last Patent Expiry | Any Blocking Exclusivity |
|--------|---|--------------|----------------------------------|------------|-----------------------|--------------------|--------------------------|
| 1 | Doral 15mg, 7.5mg | Quazepam | Tablet, Oral | None | Hetero | 03-Jun-2028 | - |
| 2 | <div style="text-align: center; padding: 100px;"> <p>Premium Content</p> </div> | | | | | | |
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|--------|-----------------|--------------|----------------------------------|------------|-----------------------|--------------------|--------------------------|
| 62 | Premium Content | | | | | | |
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Red Colour – Discontinued NDA

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