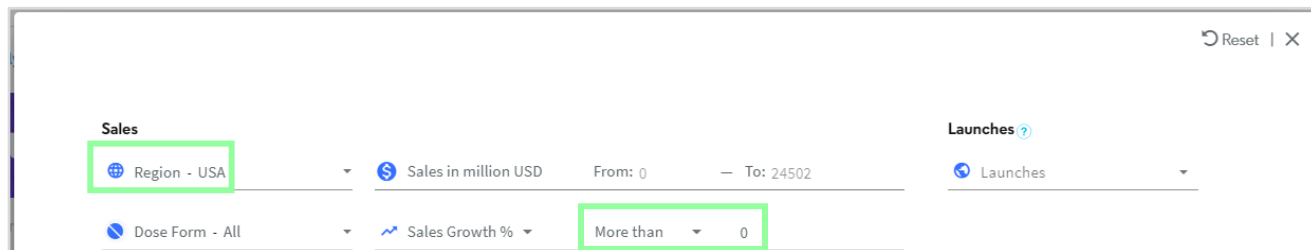# NCE-1 date and when to file ANDAs

Orange book exclusivities including New Chemical Entity (NCE) are viewable in product records in *Cortellis Product Intelligence*. These exclusivities can be searched using the *Product Selector Tool* to identify products for your portfolios with certain NCE-1 dates and combined with other criteria, for example, by sales volume, dose form, and other fields.

This guide uses the following example: *identify products formulated as capsules with growing sales in the USA and losing NCE exclusivity after January 1st of 2024*. These products are expected to have Abbreviated New Drug Applications (ANDAs) filed for the first time in 2023 (the NCE minus 1 date). The first applicant to file a substantially complete ANDA containing a paragraph IV certification to a listed patent will be eligible for a 180-day period of exclusivity under the Hatch-Waxman Act in the USA.
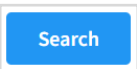
1. Once in *Product Selector Tool*, select 'USA' from the *Sales region* and add 'zero' to *Sales growth % More than*, as shown next. This finds products with any amount of sales growth in the USA.
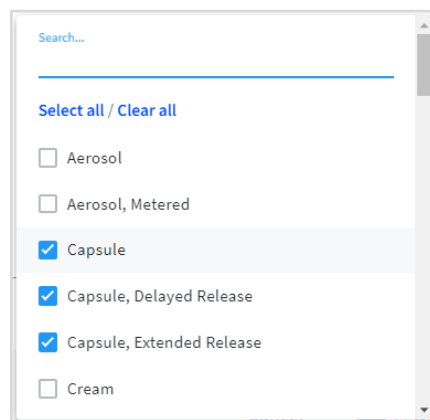

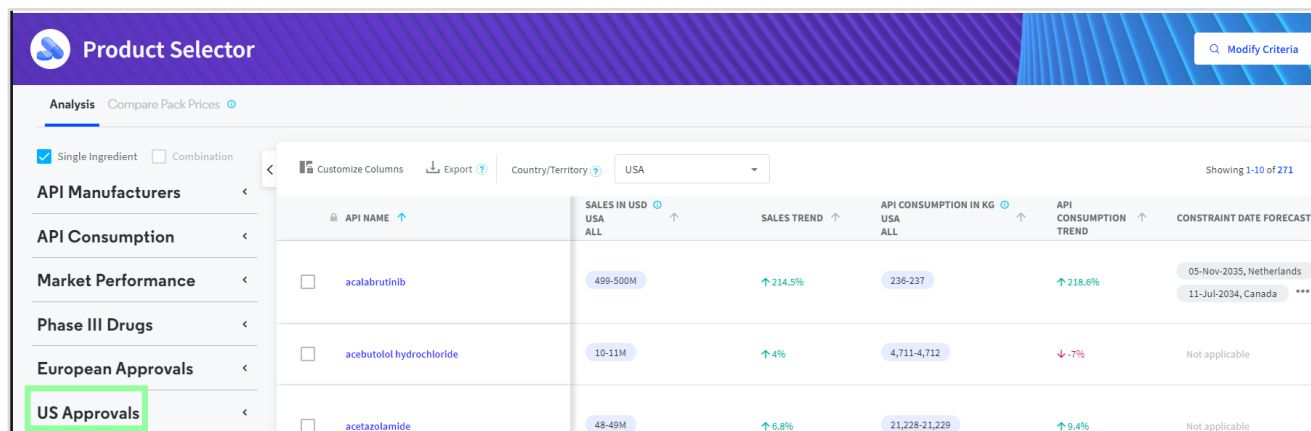2. Click 'Dose Form' under *Product Specification*.

3. Select different forms of 'Capsule' available from the drop-down menu.

4. Click **Search** to retrieve results.

5. Results table is displayed next showing API names, sales trends, dose form/strength and other details.
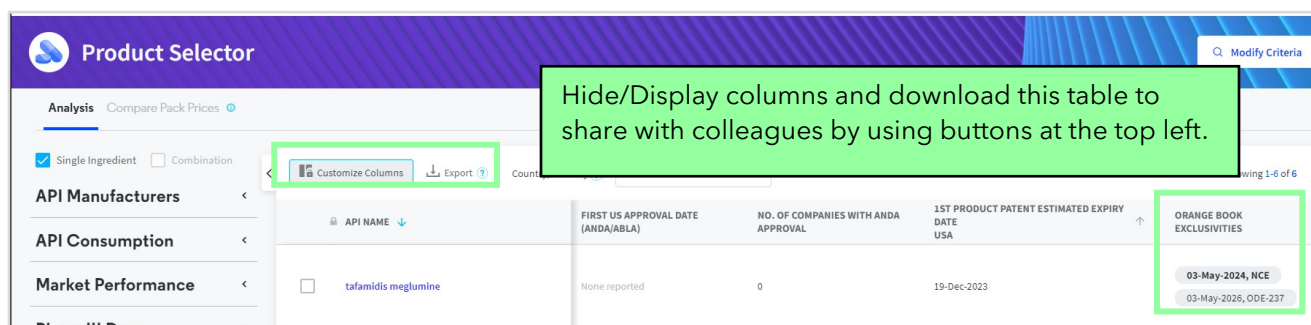
6. Click 'US Approvals' on the left and scroll down to view *Orange Book Exclusivities*. Select 'NCE' and add 'January 1st of 2024' to *Expiry Date*.

7. Results table is updated with products formulated as capsules with growing sales in the USA and losing NCE exclusivity after January 1st of 2024. Scroll to the right to display *Orange Book Exclusivity* column.

8. To learn more, click *Tafamidis meglumine* to navigate to API record. Once in *Approvals* page, scroll down to *US Patents & Exclusivities associated with Approvals* table and evaluate further.

NCE-1 date is 3rd May 2023, the earliest date when the first ANDA filings are expected for *Tafamidis* and *Tafamidis meglumine.*

For more information contact Customer Service at **LS Product Support**