

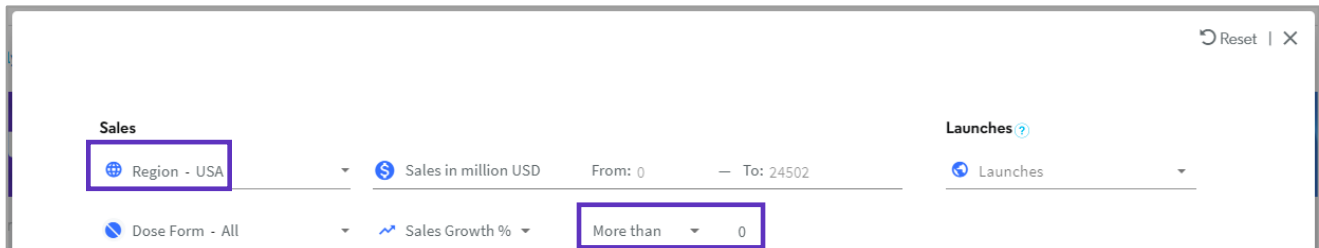
Cortellis Generics Intelligence

NCE-1 date and when to file ANDAs

Orange book exclusivities including New Chemical Entity (NCE) are viewable in product records in *Cortellis Generics 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.

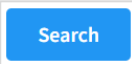
1. Once in *Product Selector Tool*, select 'USA' from the *Sales region* and add 'zero' to *Sales growth % More than*, as shown next. This finds products with any amount of sales growth in the USA.

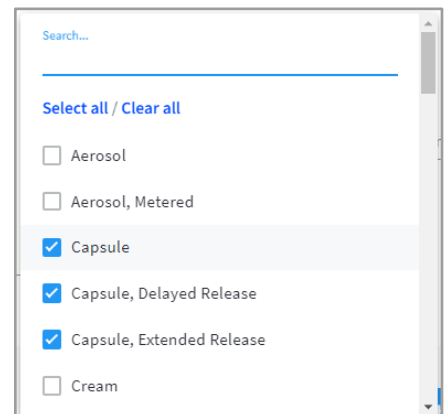


2. Click 'Dose Form' under *Product Specification*.



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

4. Click  to retrieve results.



5. Results table is displayed next showing API names, sales trends, dose form/strength and other details.

API NAME	SALES IN USD USA ALL	SALES TREND	API CONSUMPTION IN KG USA ALL	API CONSUMPTION TREND	CONSTRAINT DATE FORECAST
<input type="checkbox"/> acalabrutinib	499-500M	↑ 214.5%	236-237	↑ 218.6%	05-Nov-2025, Netherlands 11-Jul-2034, Canada ***
<input type="checkbox"/> acebutolol hydrochloride	10-11M	↑ 4%	4,711-4,712	↓ -7%	Not applicable
<input type="checkbox"/> acetazolamide	48-49M	↑ 6.8%	21,228-21,229	↑ 9.4%	Not applicable

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*.

Orange Book Patent Expiry Date

From To

Orange Book Exclusions

Type - NCE - NEW CHEMI...

Expiry Date

To

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.

Hide/Display columns and download this table to share with colleagues by using buttons at the top left.

API NAME	FIRST US APPROVAL DATE (ANDA/ABLA)	NO. OF COMPANIES WITH ANDA APPROVAL	1ST PRODUCT PATENT ESTIMATED EXPIRY DATE USA	ORANGE BOOK EXCLUSIVITIES
<input type="checkbox"/> tafamidis meglumine	None reported	0	19-Dec-2023	03-May-2024, NCE 03-May-2026, ODE-237

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.

US Patents & Exclusivities Associated with Approvals

Filters: Filing/Approval Number, Dose Form, Publication Number, Exclusivity Type

Customize Columns, Export

ACTIVE INGREDIENT	TRADE NAME	FILING/APPROVAL NUMBER	APPROVAL HOLDER	PUBLICATION NUMBER	PATENT TYPE	ORANGE BOOK PATENT EXPIRY DATE	EXCLUSIVITY TYPE	EXCLUSIVITY EXPIRY DATE
tafamidis	VYNDAMAX	212161-001	FoldRx Pharmaceuticals Inc	None reported	None reported	None reported	NCE	03-May-2024
tafamidis meglumine	VYNDAQEL	211996-001	FoldRx Pharmaceuticals Inc	None reported	None reported	None reported	NCE	03-May-2024

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**