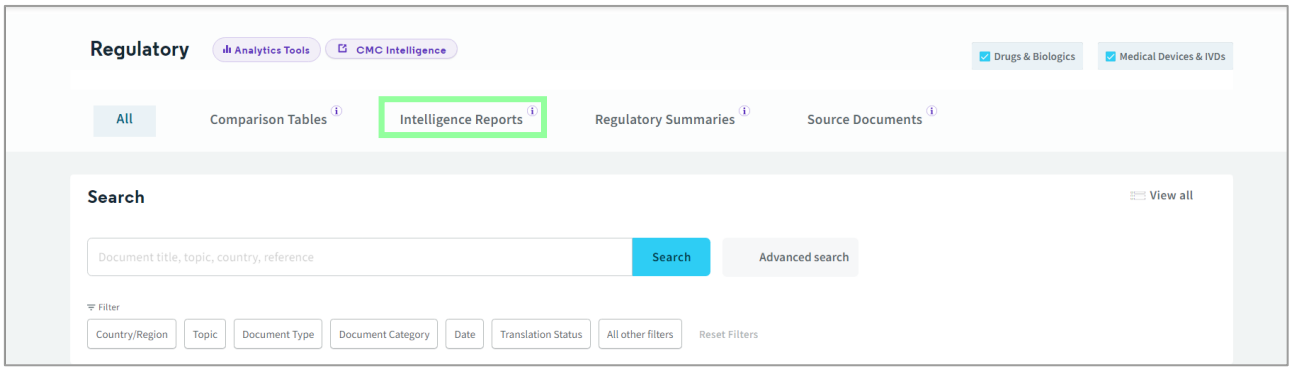
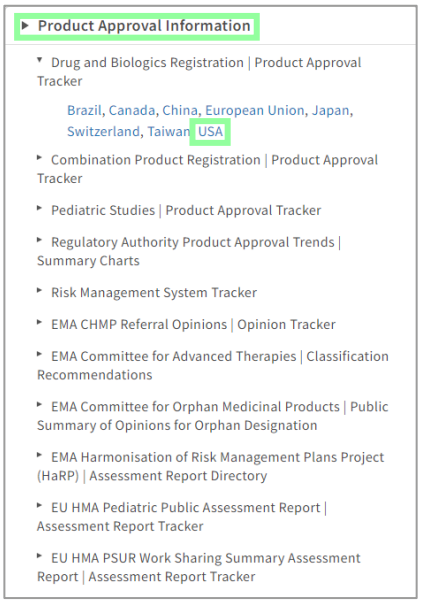
Maximizing US Approval Tracker

Do you need to compare existing and emerging competitor products approved in the US? Do you want to find out which products were approved in your field of interest? With Cortellis Regulatory Intelligence you can quickly access a list of US New Drugs Applications (NDAs) and Biologics License Applications (BLAs) and biosimilars approved from 1997 by the FDA, compiled into a single Excel table. The table also includes efficacy supplements.

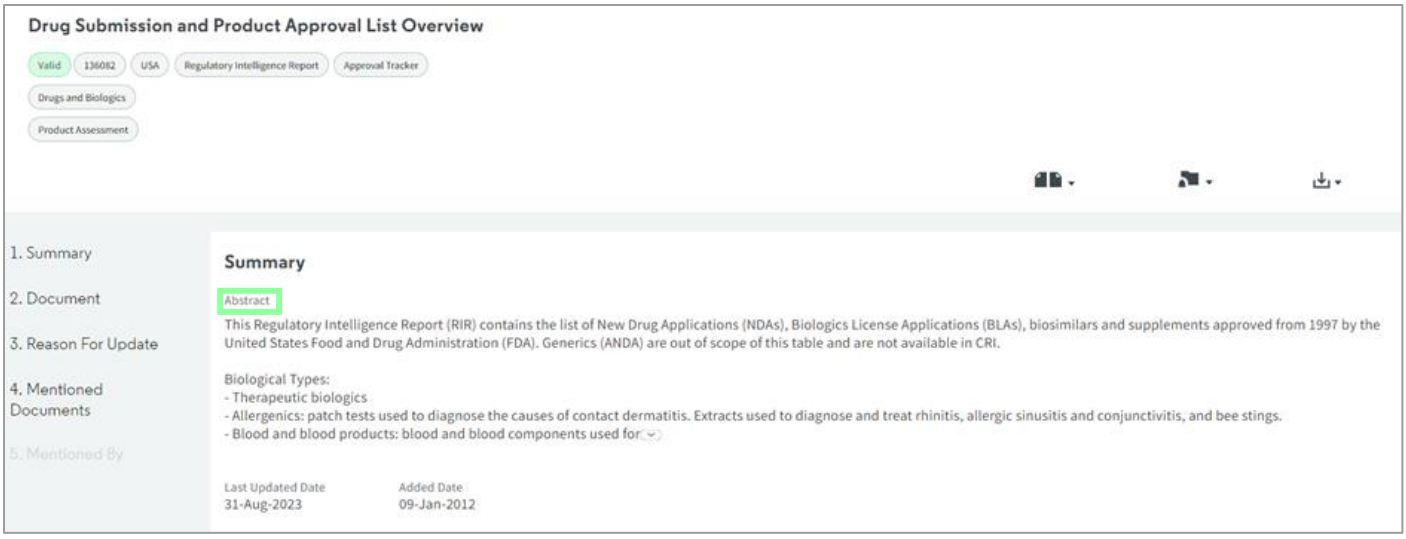
1. On the Cortellis Regulatory home page click **Intelligence Reports** tab and scroll down to **Product Approval Information**.



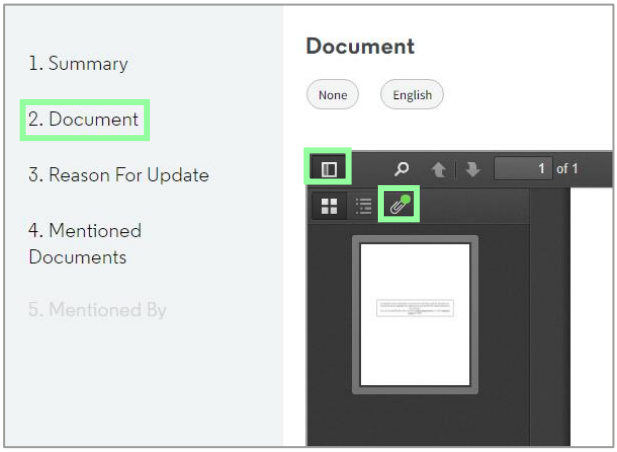
2. Expand **Product Approval Information** and click on **USA**.



3. The **Abstract** under the **Summary** provides information on the scope of the document, when it was last updated and more.



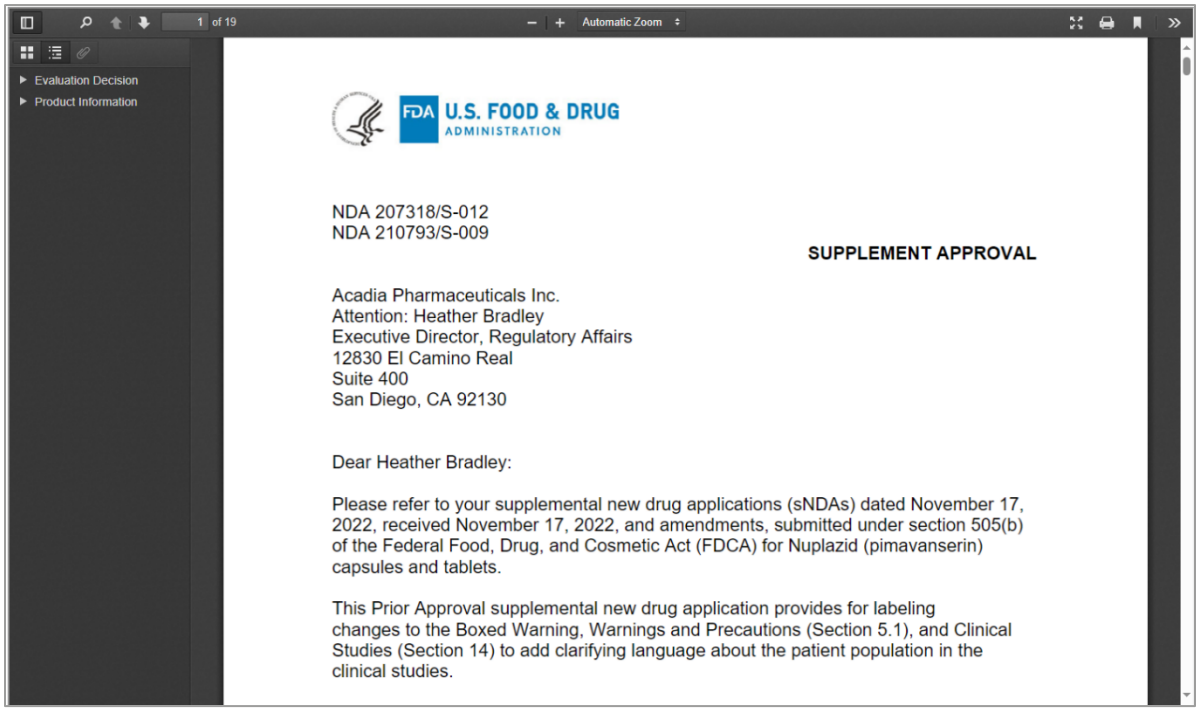
4. To open the Excel version of the document for easy sorting and filtering, click "**Download Excel**" button, or click **Document**, then the **Toggle Side Bar icon** in the upper left-hand corner of the PDF. Click the **Paperclip icon** that appears to open the attached Excel spreadsheet.



5. Filter the table as desired. Scroll to the right and click the hyperlinks under column **AH**, Link to Product Approval Document, to open the **NDAs** and **BLAs**.

	A	B	C	D	E	F	G	H	AH
1	**Name**	**Active Ingredient(s)**	**Application/Submission Type**	**Application Number**	**Active Substance Status**	**FDA Biological Type**	**FDA Chemical Type**	**Product Type**	**Link to Product Approval Document**
2	NUPLAZID	pimavanserin	sNDA	207318/012; 210793/009	Known active substance ; New active substance	Not applicable	New dosage form ; New molecular entity (NME)	Drugs & Biologics	371355 371354
3	FINTEPLA	fenfluramine	sNDA	212102/007	Known active substance	Not applicable	New dosage form	Drugs & Biologics	371354
4	FINTEPLA	fenfluramine	sNDA	212102/008	Known active substance	Not applicable	New dosage form	Drugs & Biologics	371353

6. In Cortellis, all parts of the FDA review are compiled into **one single PDF file**, including the approval letter, labeling and all reviews.



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