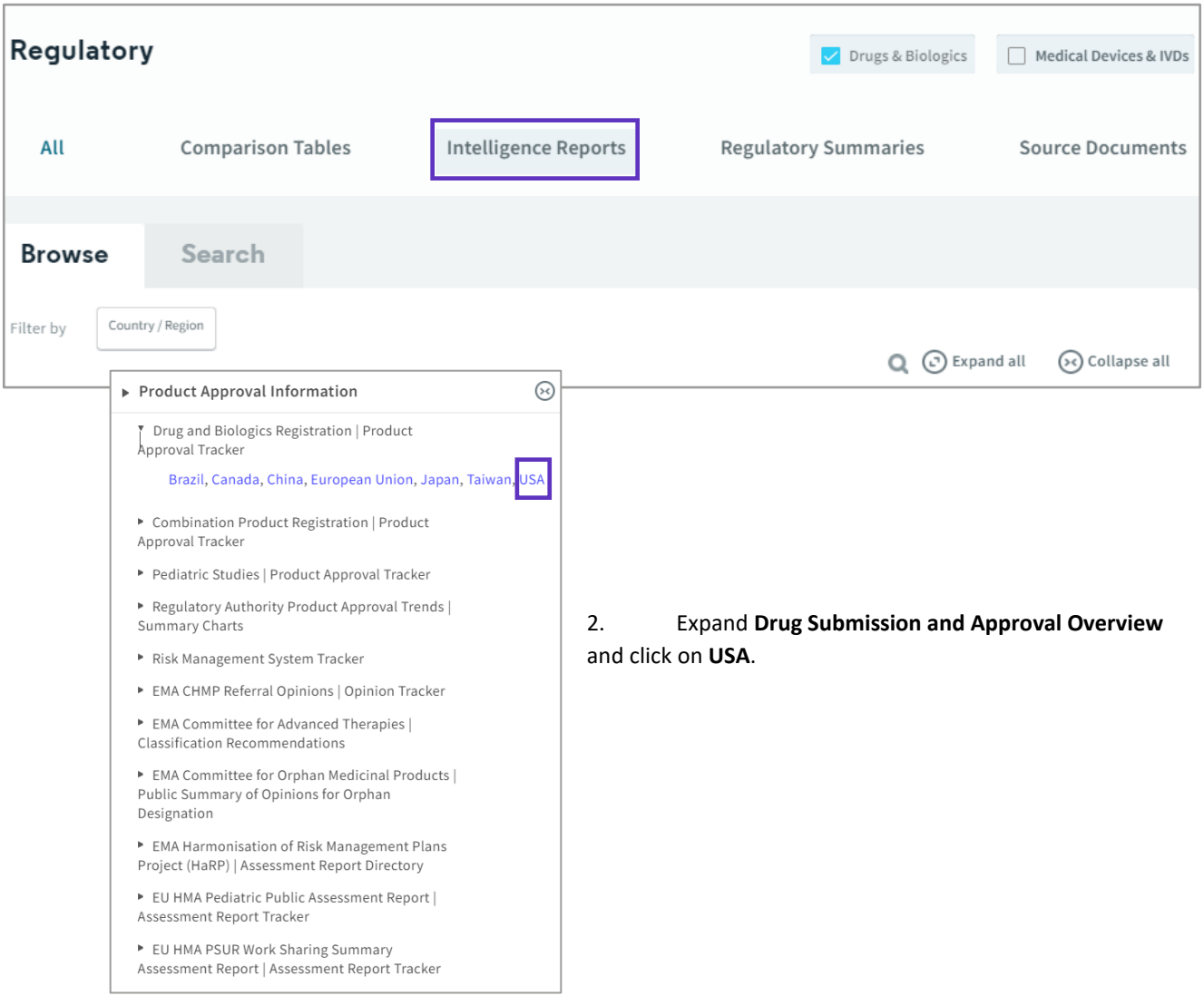
Maximizing the US Approval Tracker

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?

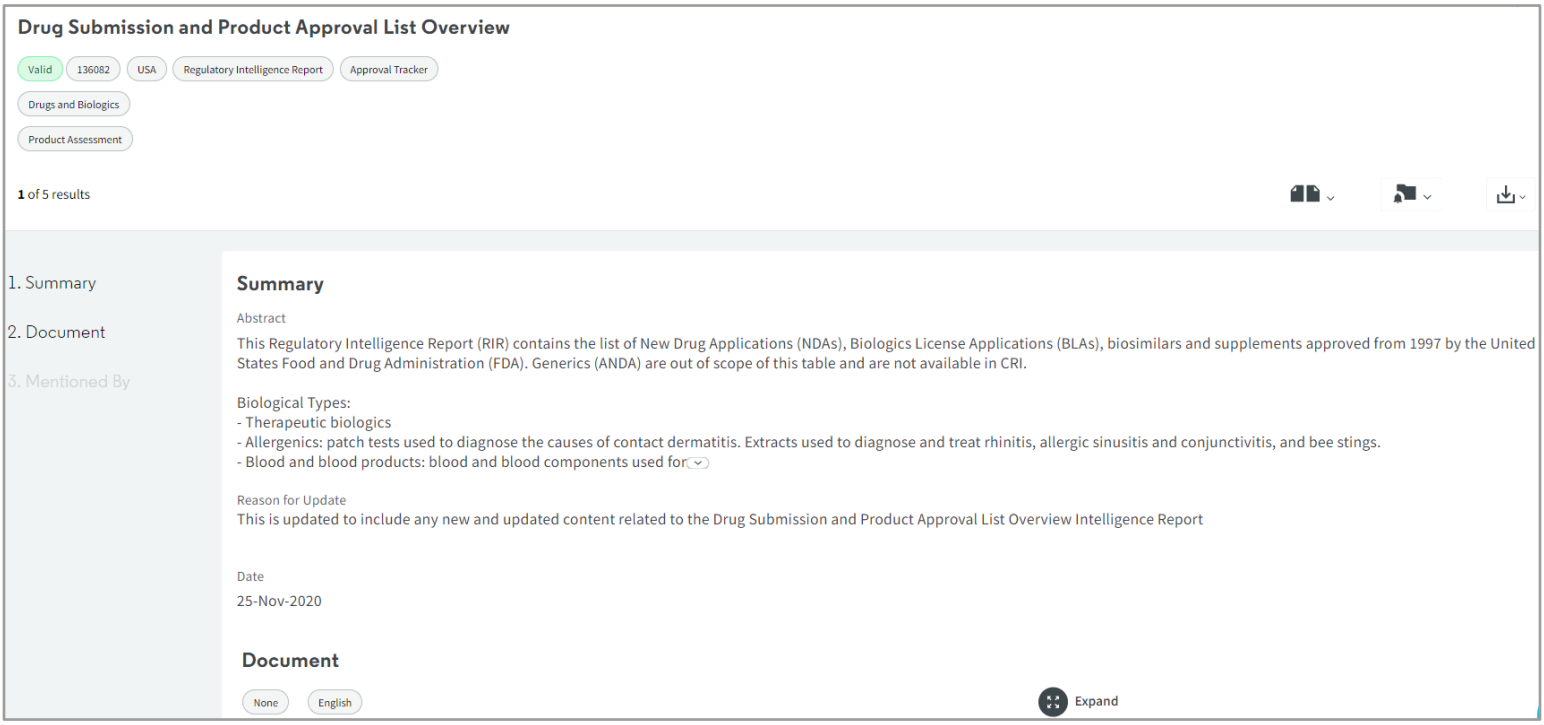
With *Cortellis Regulatory Intelligence* you can quickly access a list of **US New Drugs Applications (NDAs) and Biologics License Applications (BLAs) and biosimilars approved from 1997 by the FDA, compiled into a single Excel table.** The table also includes efficacy supplements.

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

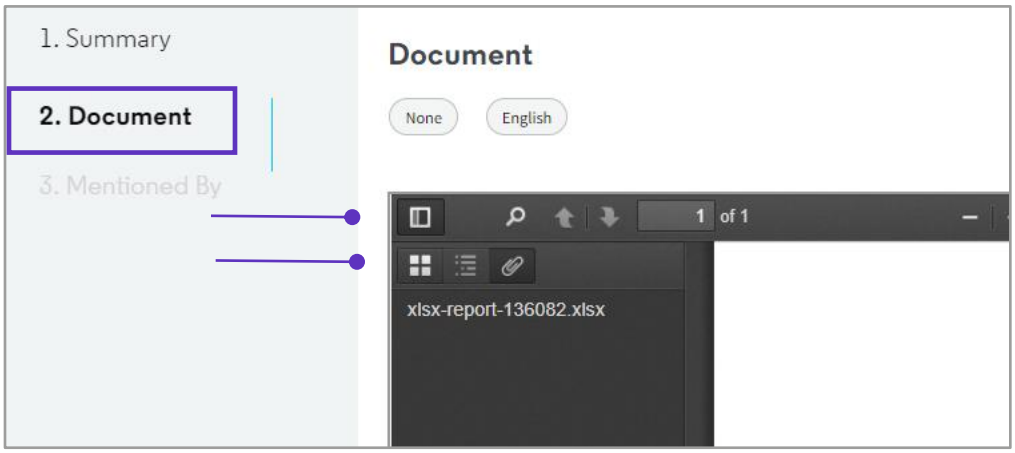


2. Expand **Drug Submission and Approval Overview** and click on **USA**.

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



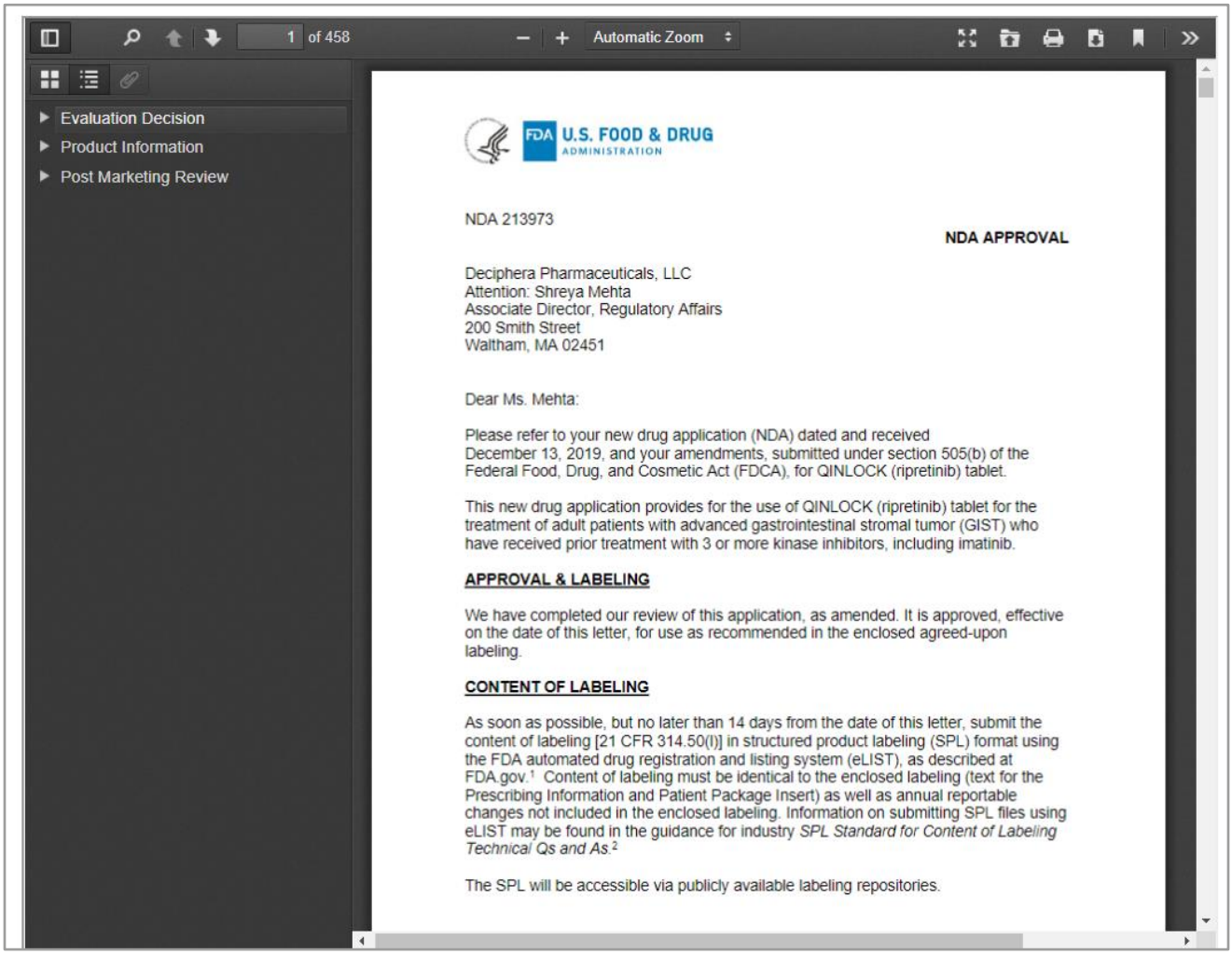
4. To open the **Excel version** of the document for easy sorting and filtering, click “Download Excel” or click **Document**, then the **Toggle Side Bar icon** in the upper left hand corner of the PDF. Next click the **Paperclip icon** that appears to open the attached Excel spreadsheet.



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

Name	Active Ingredient(s)	Application/Submission Type	FDA Supplement Type	Link to Product
OMECLAMOX-PAK	amoxicillin ; clarithromycin ; omeprazole	sNDA	Non-efficacy supplement	305341
AFINITOR ; AFINITOR DISPERZ	everolimus	sNDA	Non-efficacy supplement	305325
DENGVAXIA	dengue tetravalent vaccine live	sBLA	Non-efficacy supplement	305311
BENLYSTA	belimumab	sBLA	Efficacy-labeling change with clinical data	305308
FEMARA ; KISQALI	letrozole ; ribociclib	sNDA	Non-efficacy supplement	305231
KISQALI	ribociclib	sNDA	Non-efficacy supplement	305230
TEPEZZA	teprotumumab-trbw	BLA	Original approval	305219
DG GEL CARDS	blood grouping reagent anti-A (murine monoclonal)	sBLA	Non-efficacy supplement	305211

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.**