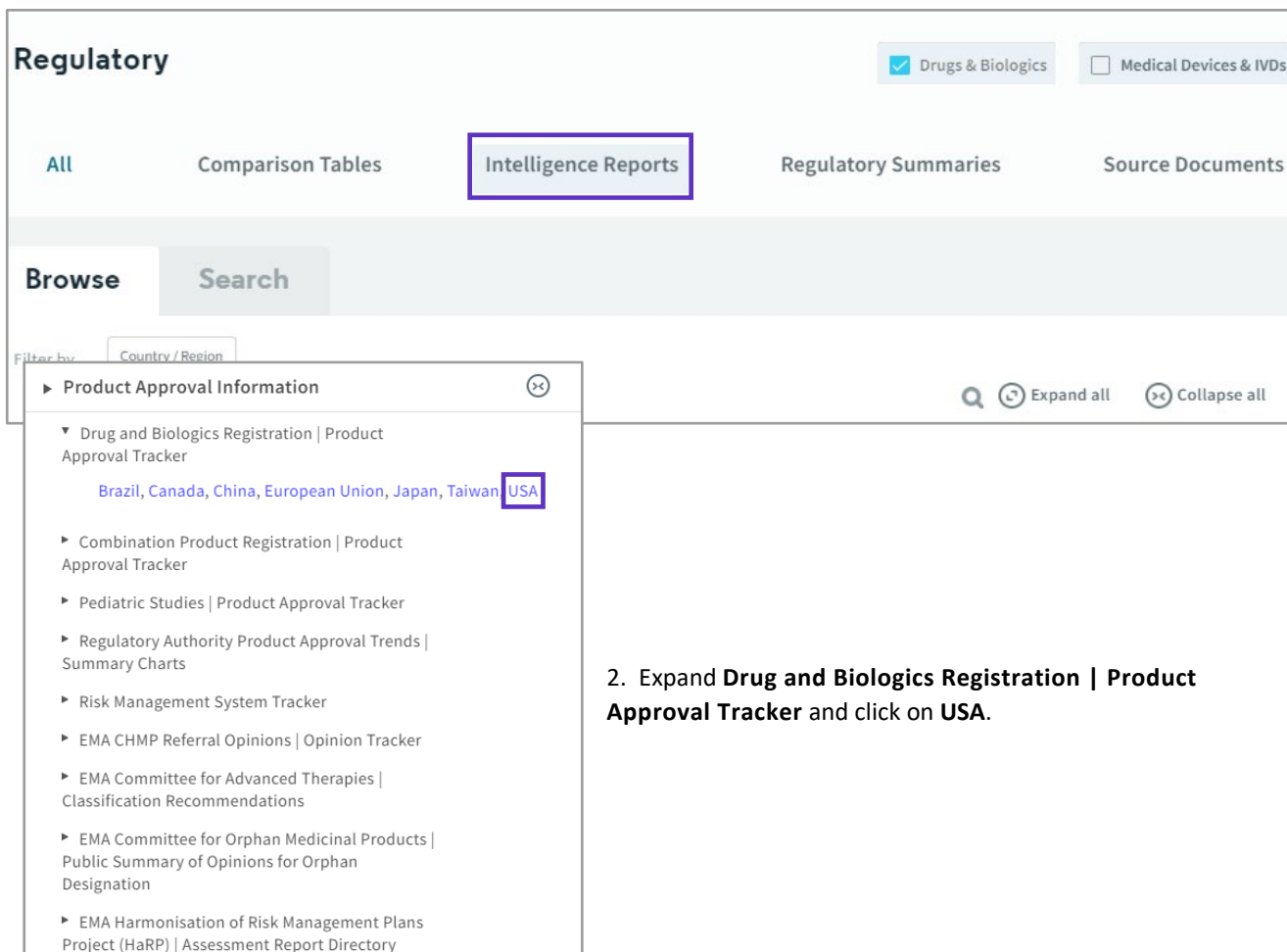


Regulatory Intelligence: US New Drug and Biologics License Applications

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.

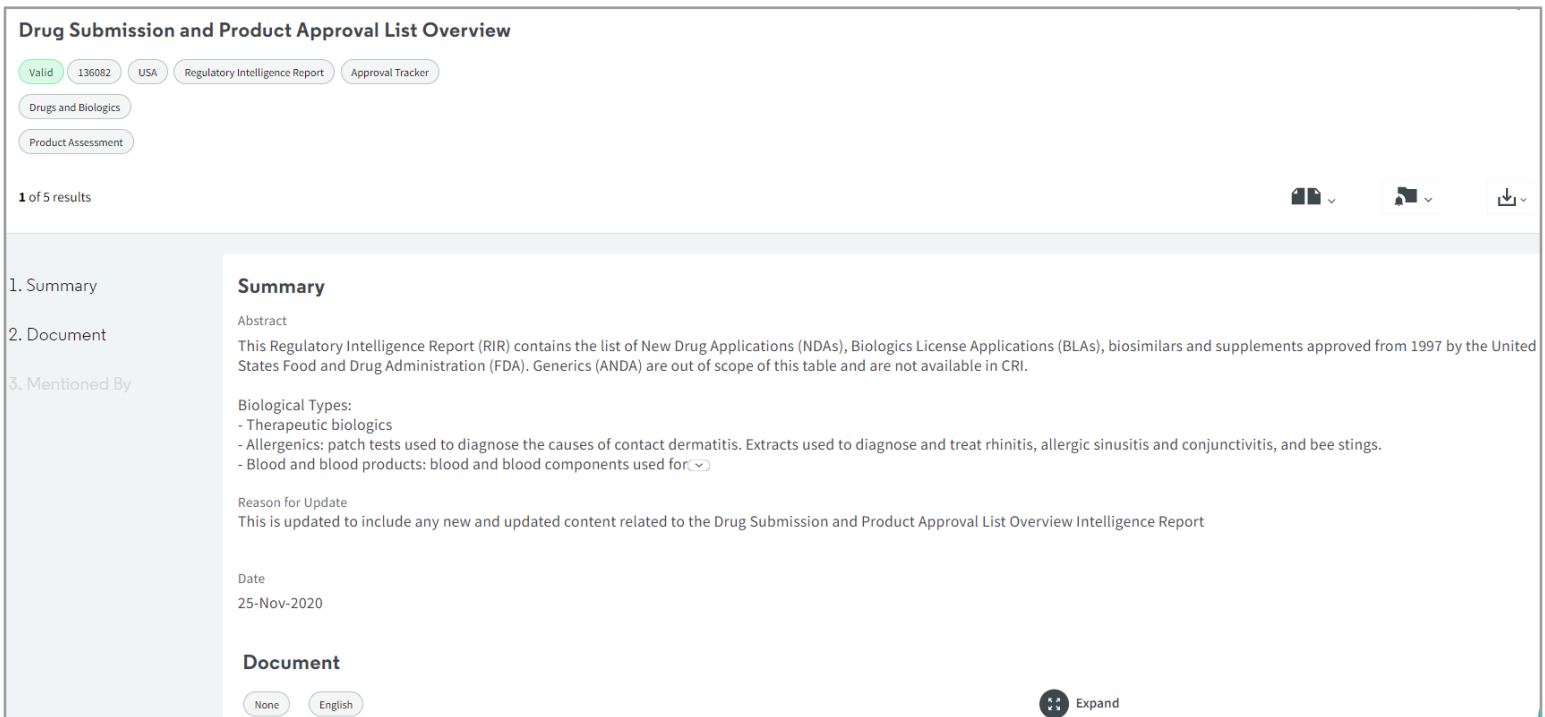
1. On the Cortellis Regulatory home page click **Intelligence Reports** and scroll down to **Product Approval Information**.



The screenshot shows the Cortellis Regulatory Intelligence website. At the top, there are navigation tabs: 'All', 'Comparison Tables', 'Intelligence Reports' (highlighted with a purple box), 'Regulatory Summaries', and 'Source Documents'. Below these are 'Browse' and 'Search' buttons. A 'Filter by' dropdown is open, showing 'Country / Region' with a list of regions: 'Brazil, Canada, China, European Union, Japan, Taiwan, USA' (where 'USA' is highlighted with a purple box). To the right of the dropdown are 'Expand all' and 'Collapse all' buttons.

2. Expand **Drug and Biologics Registration | Product Approval Tracker** 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.



Drug Submission and Product Approval List Overview

Valid 136082 USA Regulatory Intelligence Report Approval Tracker

Drugs and Biologics

Product Assessment

1 of 5 results

1. Summary

2. Document

3. Mentioned By

Summary

Abstract

This Regulatory Intelligence Report (RIR) contains the list of New Drug Applications (NDAs), Biologics License Applications (BLAs), biosimilars and supplements approved from 1997 by the United States Food and Drug Administration (FDA). Generics (ANDA) are out of scope of this table and are not available in CRI.

Biological Types:

- Therapeutic biologics
- Allergens: patch tests used to diagnose the causes of contact dermatitis. Extracts used to diagnose and treat rhinitis, allergic sinusitis and conjunctivitis, and bee stings.
- Blood and blood products: blood and blood components used for

Reason for Update

This is updated to include any new and updated content related to the Drug Submission and Product Approval List Overview Intelligence Report

Date

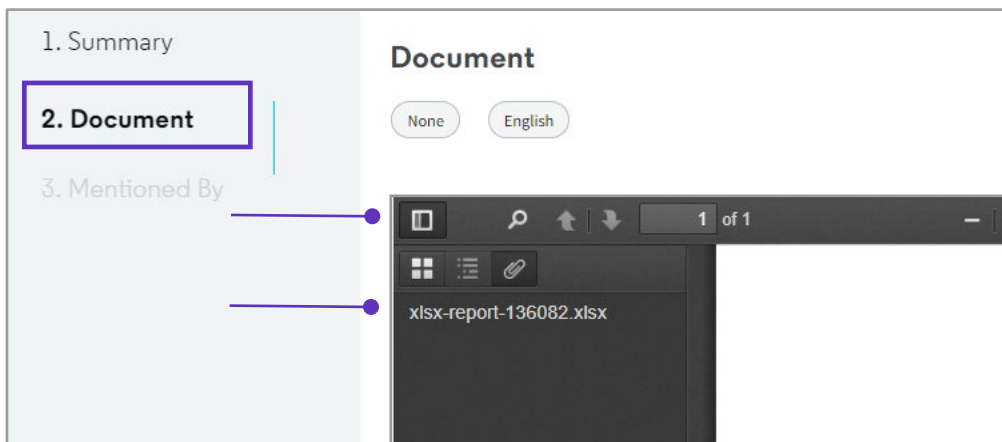
25-Nov-2020

Document

None English

Expand

4. To open the **Excel version** of the document for easy sorting and filtering, 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.



1. Summary

2. Document

3. Mentioned By

Document

None English

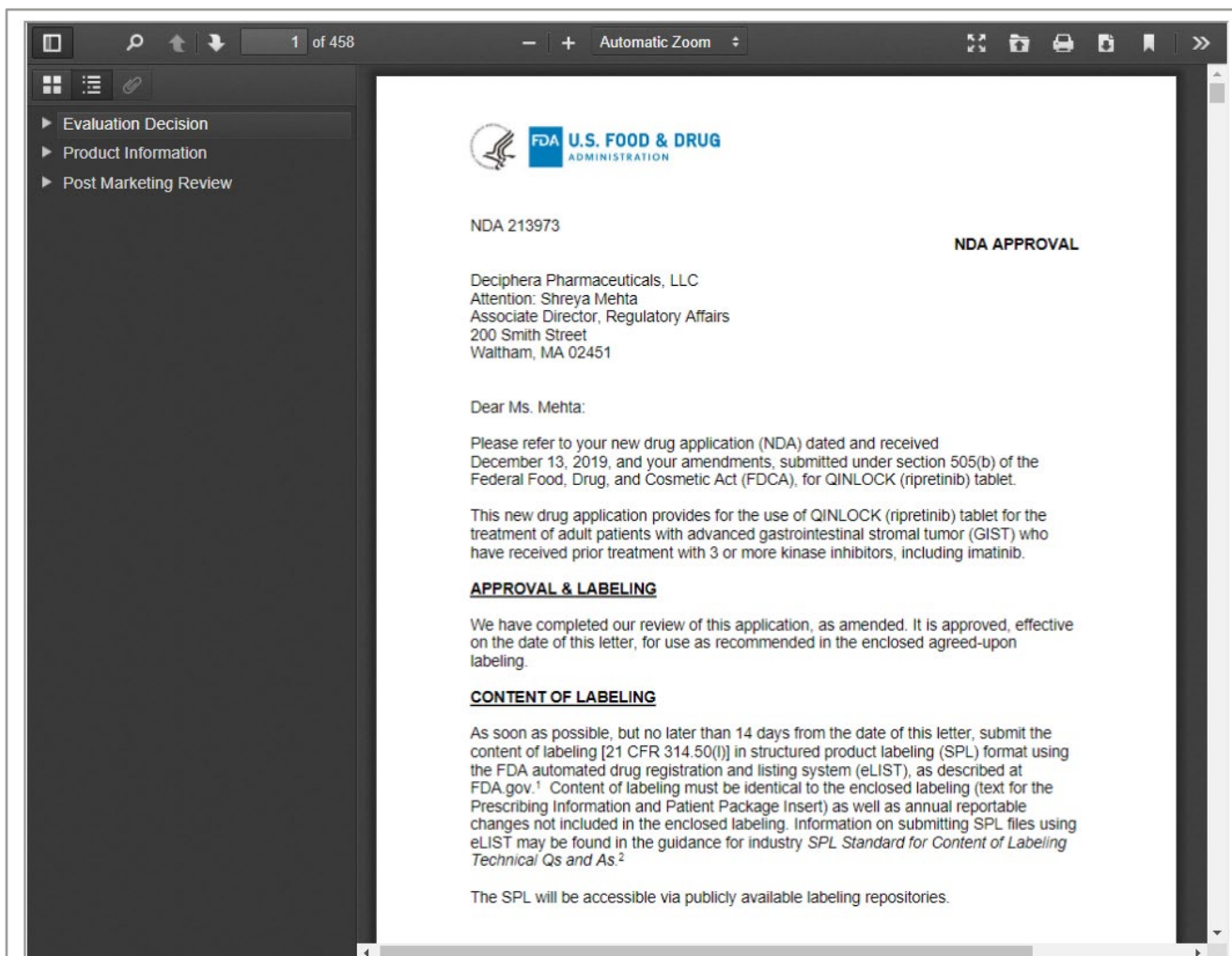
1 of 1

xlsx-report-136082.xlsx

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
DENGVAIXIA	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.



1 of 458 Automatic Zoom

FDA U.S. FOOD & DRUG ADMINISTRATION

NDA 213973 **NDA APPROVAL**

Deciphera Pharmaceuticals, LLC
 Attention: Shreya Mehta
 Associate Director, Regulatory Affairs
 200 Smith Street
 Waltham, MA 02451

Dear Ms. Mehta:

Please refer to your new drug application (NDA) dated and received December 13, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), for QINLOCK (ripretinib) tablet.

This new drug application provides for the use of QINLOCK (ripretinib) tablet for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Patient Package Insert) as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible via publicly available labeling repositories.

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