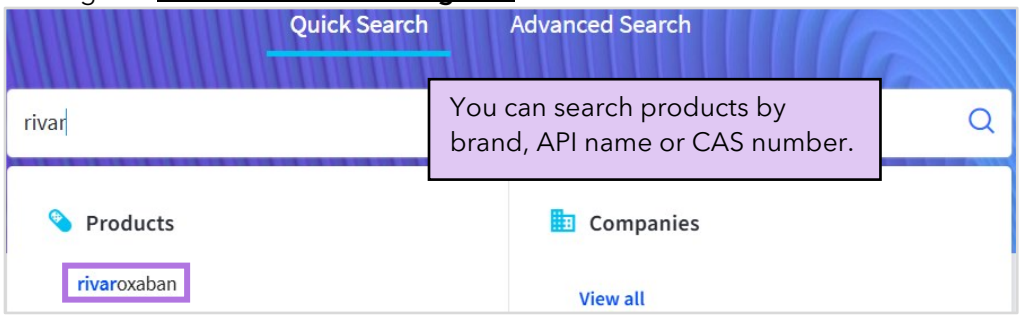
Identify product approvals in different Countries

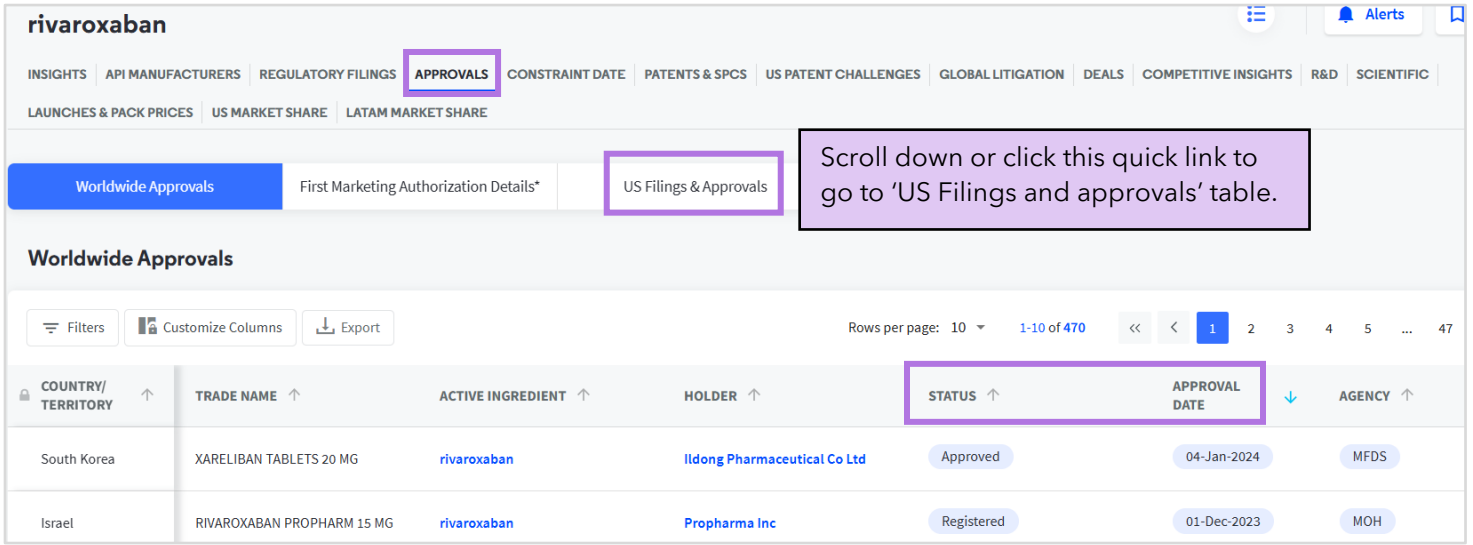
This guide explains how to identify product approvals in different authorities worldwide. The 'Approval' tab in product records helps you understand Marketing Authorization Holders (MAH) and approval dates in different markets as well as the status of NDA, ANDA, BLA and ABLA applications in the US.

Example: Analyze NDA and ANDA filings and approvals of Rivaroxaban in the USA. Which dose forms are included? How many are approved? Is there any dose form/strength with no patent challenges? Who are the filers?

1. Login to **Cortellis Product Intelligence** and search rivaroxaban.

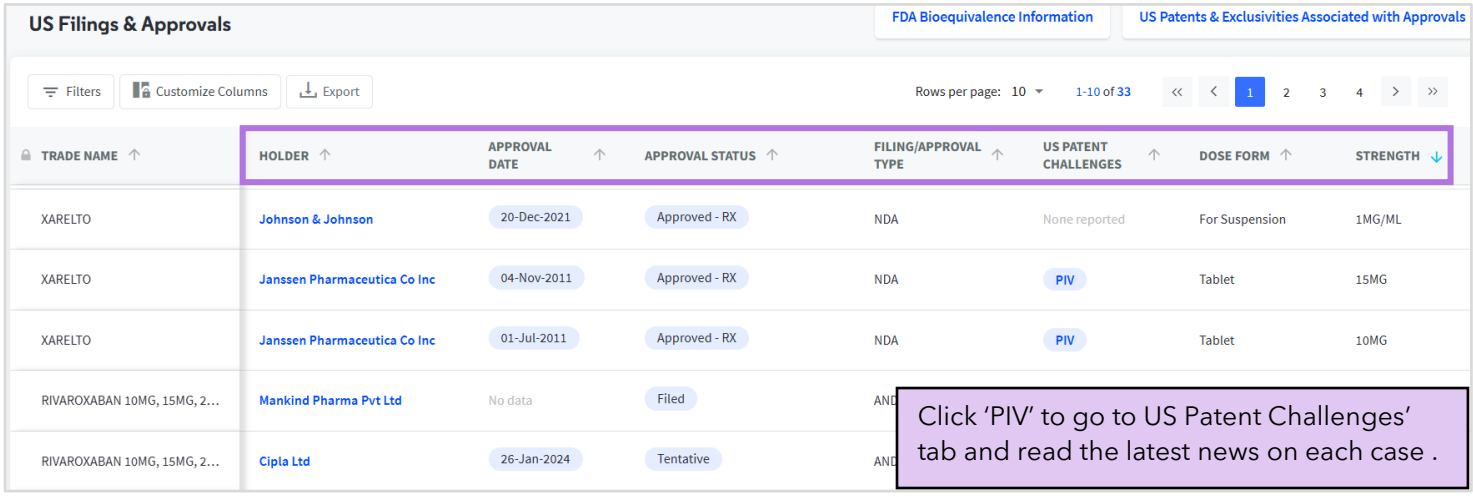


2. Go to 'Approvals' tab. The 'Worldwide Approvals' table displays MAH names, approval dates and other details from different authorities around the world.

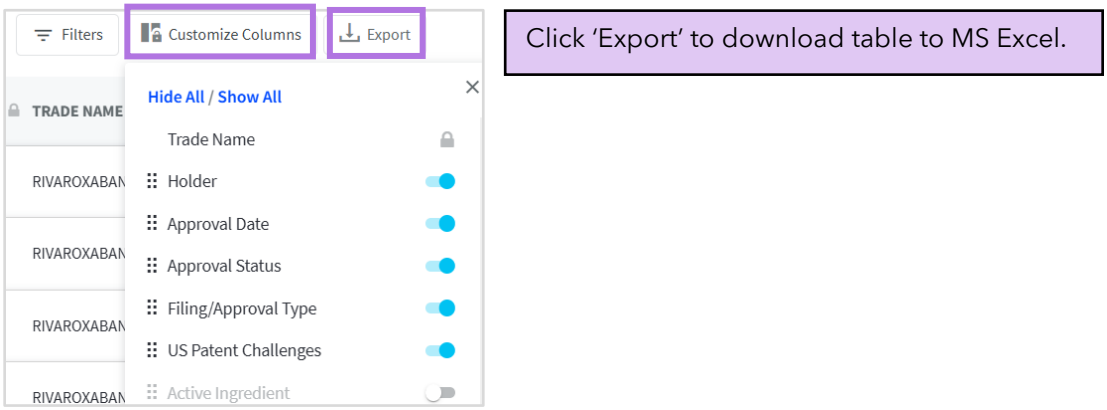


3. Scroll down to 'US Filings & Approvals' table to analyze NDA and ANDA applications, their holders, status, dates and more details, as shown next.

Scroll further to the right to find pediatric extension details when available.



4. Click 'Customize columns' to hide, show and reorder columns in your table.



As of Dec 2024:

- The only dose form to not have a PVI certification was suspension of 1mg/ml. All other dose forms did. Twenty-eight ANDAs have been filed from which only 15 are on 'Tentative' status.
- SPCs have been granted in Denmark and Malta. SPCs applications have been filed in 13 other countries in Europe. There are no applications for pediatric extensions.

It is highly recommended to set up email alerts* to monitor updates to this table. These alerts can be set up from the bell icon at the top right of the page.

** Alerts are only available to users with access to Cortellis Product Global and Premium Tier.

* Note: Country coverage includes Brazil ANVISA, EMA, China NMPA, Canada HC, Israel MOH, Italy AIFA, Japan MHLW, Mexico COFEPRIS, Saudi Arabia SFDA, South Korea MFDS and Turkey TITCK.

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