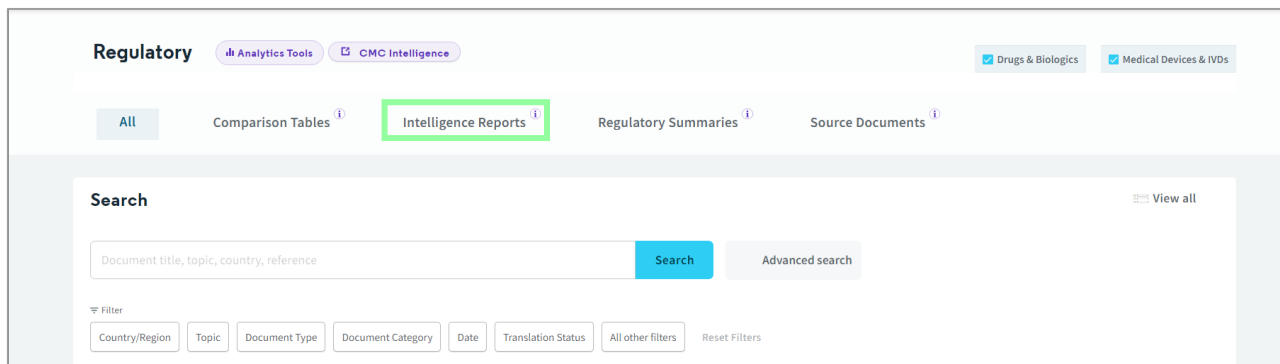


# Maximizing US Approval Tracker

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**.



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



**Product Approval Information**

- Drug and Biologics Registration | Product Approval Tracker
  - [Brazil, Canada, China, European Union, Japan, Switzerland, Taiwan, \*\*USA\*\*](#)
- Combination Product Registration | Product Approval Tracker
- Pediatric Studies | Product Approval Tracker
- Regulatory Authority Product Approval Trends | Summary Charts
- Risk Management System Tracker
- EMA CHMP Referral Opinions | Opinion Tracker
- EMA Committee for Advanced Therapies | Classification Recommendations
- EMA Committee for Orphan Medicinal Products | Public Summary of Opinions for Orphan Designation
- EMA Harmonisation of Risk Management Plans Project (HaRP) | Assessment Report Directory
- EU HMA Pediatric Public Assessment Report | Assessment Report Tracker
- EU HMA PSUR Work Sharing Summary Assessment Report | Assessment Report Tracker

3. The **Abstract** under the **Summary** provides information on 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. Summary
2. Document
3. Reason For Update
4. Mentioned Documents
5. Mentioned By

#### Summary

Abstract

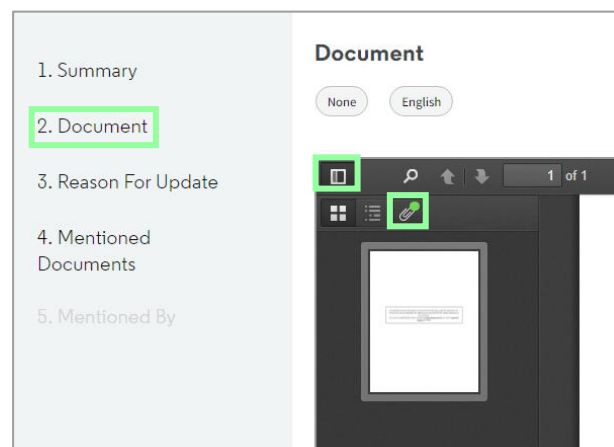
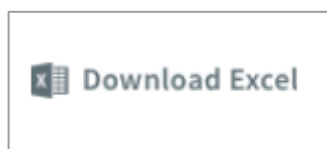
This Regulatory Intelligence Report (RIR) contains the list of New Drug Applications (NDAs), Biologics License Applications (BLAs), biosimilars and supplements approved from 1997 by the United States Food and Drug Administration (FDA). Generics (ANDA) are out of scope of this table and are not available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

Last Updated Date 31-Aug-2023
Added Date 09-Jan-2012

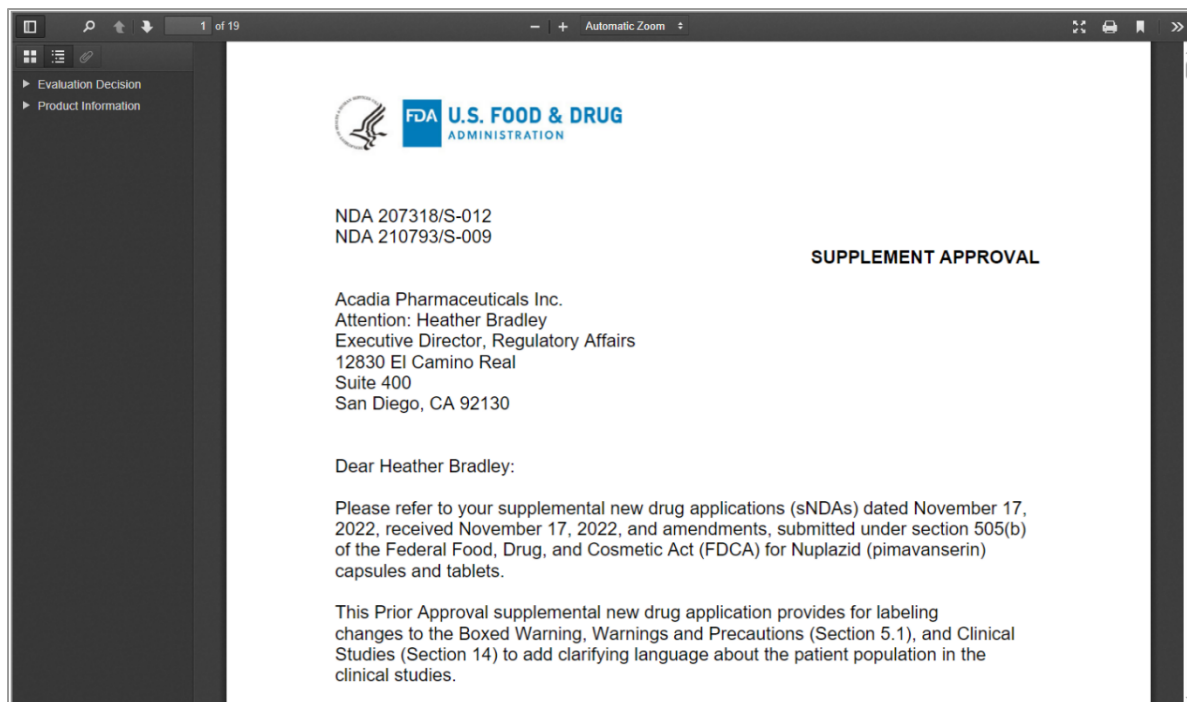
4. To open the Excel version of the document for easy sorting and filtering, click **“Download Excel”** button, or click **Document**, then the **Toggle Side Bar icon** in the upper left-hand corner of the PDF. Click the **Paperclip icon** that appears to open the attached Excel spreadsheet.



- Filter the table as desired. Scroll to the right and click the hyperlinks under column **AH**, Link to Product Approval Document, to open the **NDA**s and **BLA**s.

	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
	NUPLAZID	pimavanserin	sNDA	207318/012; 210793/009	Known active substance ; New active substance	Not applicable	New dosage form ; New molecular entity (NME)	Drugs & Biologics	<a href="#">271355</a>
2	FINTEPLA	fenfluramine	sNDA	212102/007	Known active substance	Not applicable	New dosage form	Drugs & Biologics	<a href="#">271354</a>
3	FINTEPLA	fenfluramine	sNDA	212102/008	Known active substance	Not applicable	New dosage form	Drugs & Biologics	<a href="#">271353</a>
4									

- 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**.