# Clarivate

# **Content Release Notes for April 18, 2024**

Dates in **blue** for those content sets that have been updated in this release.

#### **Product Key Insights**

#### **Sales and API Consumption**

IQVIA regional sales data for fourth quarter 2023.

IQVIA regional API consumption data for fourth quarter 2023.

#### **Therapeutic Area**

EphMRA Anatomical Classifications were last updated in 2023.

### **API Manufacturers / APIs**

#### **Issued GMP Certificates and Facility Inspections**

Country/Territory	Regulatory Agency	Last Update Date
Brazil	ANVISA	April 15, 2024
India	CDSCO	February 02, 2024
Mexico	COFEPRIS	October 16, 2023

#### Import and Manufacturing Registrations

Regulatory Agency	Content	Last Update Date
US FDA	Import - US FDA Import Refusal Reports for Active Pharmaceutical Ingredients	March 2024

#### **US FDA Information**

US FDA supported information (GDUFA Fee Payment Date and Facility Registration Date) for 2024.

US FDA Inspection Dates were updated as of December 2023.

US FDA Warning Letters were last updated April 15, 2024.

#### Launches & Pack Prices

IQVIA launched drug information for fourth quarter 2023.

US Label Information as of March 31, 2024.



# **Regulatory Filings**

Regulatory Filing	Source	Last Update Date
US DMFs	US FDA	December 31, 2023
US DMF Completeness Assessment Review	US FDA	April 12, 2024
European Certificates of Suitability	EU EDQM	April 11, 2024
JP DMFs	Japanese PMDA	March 15, 2024
KR DMFs	Korea FDA	January 29, 2024
CN DMFs	China NMPA	March 11, 2024

# Approvals

Approvals	Source	Last Update Date
First Marketing Authorization Details	EMA, Country Specific SPCs	March 21, 2024
US Filings & Approvals	US FDA	April 10, 2024
US Filings & Approvals – Tentative	US FDA	April 12, 2024
WW Approvals	Brazil ANVISA	On hold
	China NMPA	August 2019
	Canada HC	January 2024
	Israel MOH	January 2024
	Italy AIFA	October 2023
	Japan MHLW	March 2024
	Mexico COFEPRIS	September 2023
	Saudi Arabia SFDA	On hold
	South Korea MFDS	July 2023
	Turkey TITCK	February 2024



## **US Market Share**

Merative - US Market Share data was last updated February 2024.

#### LATAM Market Share

Latin America market share data was last updated February 2024.

# **Global Pricing Trends**

Global Pricing Innovations - Global Pricing Trends data was last updated March 2024.