

Release Notes for June 4, 2020

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

Product Key Insights

Therapeutic Area

EphMRA Anatomical Classifications updated for 2020.

API Manufacturers / APIs

Issued GMP Certificates and Facility Inspections

Country/Territory	Regulatory Agency	Last Update Date
Brazil	ANVISA	June 1, 2020
India	CDSCO	May 18, 2020
Mexico	COFEPRIS	January 2020

Import and Manufacturing Registrations

Regulatory Agency	Content	Last Update Date
US FDA	Import - US FDA Import Refusal Reports for Active Pharmaceutical Ingredients	April 2020
India CDSCO	India CDSCO bulk drugs	May 2014
China CFDA	Import Registrations - China CFDA	August 25, 2017

US FDA Information

US FDA supported information (GDUFA Fee Payment Date and Facility Registration Date) for 2020.

US FDA Inspection Date was updated as of October 29, 2019.

US FDA Warning Letters was last updated [June 1, 2020](#).

Regulatory Filings

Regulatory Filing	Source	Last Update Date
US DMFs	US FDA	March 31, 2020
US DMF Completeness Assessment Review	US FDA	May 22, 2020
European Certificates of Suitability	EU EDQM	May 28, 2020
JP DMFs	Japanese PMDA	April 30, 2020
KR DMFs	Korea FDA	March 26, 2020

Approvals

Approvals	Source	Last Update Date
First Marketing Authorization Details	EMA, Country Specific SPCs	May 26, 2020
US Filings & Approvals	US FDA	May 15, 2020
US Filings & Approvals – Tentative	US FDA	May 12, 2020
WW Approvals	Australia TGA	May 2019
	Brazil ANVISA	September 2019
	China NMPA	August 2019
	Canada HC	May 2019
	Israel MOH	September 2019
	Italy AIFA	January 2018
	Japan MHLW	June 2019
	Mexico COFEPRIS	March 2018
	Saudi Arabia SFDA	November 201
	South Korea MFDS	March 2017
	Turkey TITCK	December 2015

