

CY 2022 CDER Fast Track Calendar Year Approvals*

Data as of 06-30-2022

Total of 11 Approvals

Appl Type Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	Use
NDA 216196	ORIG - 1	PYRUKYND	MITAPIVAT	AGIOS PHARMACEUTICALS INC	17-Feb-2022	Treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency
NDA 208712	ORIG - 1	VONJO	PACRITINIB	CTI BIOPHARMA CORP	28-Feb-2022	Treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below $50 \times 10^9/L$
BLA 761234	ORIG - 1	OPDUALAG	NIVOLUMAB AND RELATLIMAB-RMBW	BRISTOL-MYERS SQUIBB CO	18-Mar-2022	Treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma
NDA 213478	ORIG - 1	HYFTOR	SIROLIMUS	NOBELPHARMA CO LTD	22-Mar-2022	Treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older
NDA 215390	ORIG - 1	IGALMI	DEXMEDETOMIDINE	BIOXCEL THERAPEUTICS INC	05-Apr-2022	Acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults
NDA 215888	ORIG - 1	VIVJOA	OTESECONAZOLE	MYCOVIA PHARMACEUTICALS INC	26-Apr-2022	To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential
NDA 215152	ORIG - 1	VOQUEZNA TRIPLE PAK	VONOPRAZAN, AMOXICILLIN, AND CLARITHROMYCIN	PHATHOM PHARMACEUTICALS INC	03-May-2022	Treatment of Helicobacter pylori (H. pylori) infection in adults
NDA 215153	ORIG - 1	VOQUEZNA DUAL PAK	VONOPRAZAN AND AMOXICILLIN	PHATHOM PHARMACEUTICALS INC	03-May-2022	Treatment of Helicobacter pylori (H. pylori) infection in adults
NDA 215446	ORIG - 1	RADICAVA ORS	EDARAVONE	MITSUBISHI TANABE PHARMA CORP	12-May-2022	Treatment of amyotrophic lateral sclerosis
NDA 214518	ORIG - 1	TPOXX	TECOVIRIMAT	SIGA TECHNOLOGIES INC	18-May-2022	Treatment of human smallpox disease caused by variola virus in adults and pediatric patients weighing at least 3 kg
NDA 215515	ORIG - 1	AMVUTTRA	VUTRISIRAN	ALNYLAM PHARMACEUTICALS INC	13-Jun-2022	Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults

*NOTE: Approvals with Fast Track granted because the drug was qualified as a PEPFAR drug are excluded.