2019 CDER Fast Track Calendar Year Approvals*

Data as of 12/31/2019

Total of 29 Approvals

Appl Type Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	Use
BLA 761112	ORIG - 1	CABLIVI	CAPLACIZUMAB	ABLYNX NV	06-Feb-2019	Treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP) in combination with plasma exchange and immunosuppressive
NDA 208711	ORIG - 1	EGATEN	TRICLABENDAZOLE	NOVARTIS PHARMACEUTICALS CORP	13-Feb-2019	Treatment of fascioliasis in patients 6 years of age and older
NDA 211962	ORIG - 1	VANCOMYCIN	VANCOMYOCIN	XELLIA PHARMACEUTICALS APS	15-Feb-2019	Treatment of septicemia, infective endocarditis, skin and skin structure infections, bone infections, and lower
NDA 211243	ORIG - 1	SPRAVATO	ESKETAMINE	JANSSEN PHARMACEUTICALS INC	05-Mar-2019	Treatment of treatment-resistant major depression
NDA 210660	ORIG - 1	ELCYS	L-CYSTEINE HYDROCHLORIDE	EXELA PHARMA SCIENCES LLC	16-Apr-2019	To meet the nutritional requirements of newborn infants requiring total parenteral nutrition (TPN); and of adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN
NDA 209379	ORIG - 1	SELENIOUS ACID	SELENIOUS ACID	AMERICAN REGENT INC	30-Apr-2019	Treatment of adult and pediatric patients as a source of selenium for parental nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated
NDA 211996	ORIG - 1	VYNDAQUEL	TAFAMIDIS MEGLUMINE	FOLDRX PHARMACEUTICALS INC SUB PFIZER INC	03-May-2019	Treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization
NDA 209321	ORIG - 1	RUZURGI	AMIFAMPRIDINE (3,4-DIAMINOPYRIDINE)	JACOBUS PHARMACEUTICAL CO INC	06-May-2019	Treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 to less than 17 years of age

NDA 211321	ORIG - 1	NAYZILAM	MIDAZOLAM HYDROCHLORIDE	UCB INC	20-May-2019	Acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures)
NDA 206829	SUPPL - 8	ZERBAXA	CEFTOLOZANE AND TAZOBACTAM	CUBIST PHARMACEUTICALS LLC	03-Jun-2019	Treatment of Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia (HABP/VABP)
BLA 761063	SUPPL - 3	EMGALITY	GALCANEZUMAB	ELI LILLY AND COMPANY	04-Jun-2019	Treatment of episodic cluster headache in adults
NDA 212099	ORIG - 1	NUBEQA	DAROLUTAMIDE	BAYER HEALTHCARE PHARMACEUTICALS INC	30-Jul-2019	Treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC)
NDA 212306	ORIG - 1	XPOVIO	SELINEXOR	KARYOPHARM THERAPEUTICS INC	03-Jul-2019	In combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody
NDA 212819	ORIG - 1	RECARBRIO	IMIPENEM/CILASTATIN/RELEBACTAM	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	16-Jul-2019	Treatment of patients 18 years of age and older who have limited or no alternative treatment options for the treatment of the following infections caused by certain susceptible gram-negative bacteria:1) Complicated Urinary Tract Infections (cUTI), including pyelonephritis 2)Complicated Intra-abdominal Infections (cIAI)
NDA 211150	ORIG - 1	WAKIX	PITOLISANT	HARMONY BIOSCIENCES LLC	14-Aug-2019	Treatment of excessive daytime sleepiness in adult withpatients with narcolepsy
NDA 212862	ORIG - 1		PRETOMANID	MYLAN IRELAND LTD	14-Aug-2019	As part of a combination regimen with bedaquiline and linezolid, for the treatment of adults with pulmonary extensively drug resistant (XDR),or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis

NDA 211672	ORIG - 1	XENLETA Tablets	LEFAMULIN	NABRIVA THERAPEUTICS IRELAND DAC	19-Aug-2019	Treatment of adults with Community-Acquired Bacterial Pneumonia (CABP) caused by designated susceptible microorganisms
NDA 211673	ORIG - 1	XENLETA IV	LEFAMULIN	NABRIVA THERAPEUTICS IRELAND DAC	19-Aug-2019	Treatment of adults with Community-Acquired Bacterial Pneumonia (CABP) caused by designated susceptible microorganisms
BLA 761068	SUPPL - 4	CRYSVITA	BUROSUMAB-TWZA	KYOWA KIRIN, INC.	27-Sep-2019	Treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older
NDA 210797	ORIG - 1	SCENESSE	AFAMELANOTIDE	CLINUVEL INC	08-Oct-2019	To increase pain-free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP)
NDA 022406	SUPPL - 33	XARELTO	RIVAROXABAN	JANSSEN PHARMACEUTICALS INC	11-Oct-2019	Prophylaxis of venous thromboembolism in acutely ill medical patients at risk for thromboembolic complications not at high risk of bleeding
NDA 212273	ORIG - 1	TRIKAFTA	ELEXACAFTOR/TEZACAFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS INC	21-Oct-2019	Treatment of cystic fibrosis in patients 12 years and older who have at least one F508del mutation in the CFTR gene
NDA 213004	ORIG - 1	TALICIA	OMEPRAZOLE MAGNESIUM, AMOXICILLIN, RIFABUTIN	REDHILL BIOPHARMA LTD	11/1/2019	Treatment of Helicobacter pylori infection in adults
BLA 761136	ORIG - 1	REBLOZYL	LUSPATERCEPT-AAMT	CELGENE CORPORATION	08-Nov-2019	Treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions.

NDA 209445	ORIG - 1	FETROJA	CEFIDEROCOL	SHIONOGI INC	14-Nov-2019	Treatment of patients 18 years of age or older who have limited or no alternative treatment options for the treatment of complicated urinary tract infections (cUTIs),including pyelonephritis caused by the following susceptible Gram-negative microorganisms: Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, and Enterobacter cloacae complex
NDA 213137	ORIG - 1	OXBRYTA	VOXELOTOR	GLOBAL BLOOD THERAPEUTICS INC	25-Nov-2019	Treatment of sickle cell disease in adults and pediatric patients 12 years of age and older
NDA 211970	ORIG - 1	VYONDYS 53	GOLODIRSEN	SAREPTA THERAPEUTICS INC	12-Dec-2019	Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping
BLA 761139	ORIG - 1	ENHERTU	FAM-TRASTUZUMAB DERUXTECAN-NXKI	DAIICHI SANKYO, INC.	20-Dec-2019	Treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting
NDA 209500	ORIG - 1	CAPLYTA	LUMATEPERONE	INTRA-CELLULAR THERAPIES INC	20-Dec-2019	Treatment of Schizophrenia

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