2018 CDER Fast Track Calendar Year Approvals*

Data as of 12/31/2018 Total of 33 Approvals

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date*	Use
NDA 208910	ORIGINAL-1	FIRVANQ	VANCOMYCIN HYDROCHLORIDE	RXM THERAPEUTICS LLC	26-Jan-2018	Treatment of Clostridium difficile-associated diarrhea
NDA 208700	ORIGINAL-1	LUTATHERA	^{177}Lu-DOTA^{0}-Tyr^{3}-OCTREOTATE	ADVANCED ACCELERATOR APPLICATIONS USA INC	26-Jan-2018	Treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults
NDA 208255	ORIGINAL-1	SYMFI LO	EFAVIRENZ, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	MYLAN PHARMACEUTICALS INC	5-Feb-2018	Treatment of HIV-1 infection in adult and pediatric patients weighing at least 35 kg
NDA 210491	ORIGINAL-1	SYMDEKO	TEZACAFTOR/ IVACAFTOR	VERTEX PHARMACEUTICALS INC	12-Feb-2018	Treatment of patients with cystic fibrosis (CF) aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence
NDA 210951	ORIGINAL-1	ERLEADA	APALUTAMIDE	JANSSEN BIOTECH INC	14-Feb-2018	Treatment of patients with high risk non-metastatic castration resistant prostate cancer
NDA 208855	ORIGINAL-1	VERZENIO	ABEMACICLIB	ELI LILLY AND CO	26-Feb-2018	In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer
BLA 761065	ORIGINAL-1	TROGARZO	IBALIZUMAB-UIYK	THERATECHNOLOGIES INC	6-Mar-2018	Treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen
BLA 761068	ORIGINAL-1	CRYSVITA	BUROSUMAB-TWZA	ULTRAGENYX PHARAMCEUTICAL INC	17-Apr-2018	Treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age and older
NDA 209229	ORIGINAL-1	LUCEMYRA	LOFEXIDINE	US WORLDMEDS LLC	16-May-2018	Mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults
BLA 761079	ORIGINAL-1	PALYNZIQ	PEGVALIASE-PQPZ	BIOMARIN PHARMACEUTICAL INC	24-May-2018	To reduce blood phenylalanine concentrations in adult patients with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management
NDA 210365	ORIGINAL-1	EPIDIOLEX	CANNABIDIOL	GW RESEARCH, LTD	25-Jun-2018	Treatment of seizures associated with Dravet syndrome in patients two years of age and older
NDA 208627	ORIGINAL-1	TPOXX	TECOVIRIMAT	SIGA TECHNOLOGIES INC	13-Jul-2018	Treatment of patients with human smallpox disease caused by variola virus
NDA 211192	ORIGINAL-1	TIBSOVO	IVOSIDENIB	AGIOS PHARMACEUTICALS INC	20-Jul-2018	Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1(IDH1) mutation as detected by an FDA-approved test
NDA 210589	ORIGINAL-1	OMEGAVEN	FISH OIL TRIGLYCERIDES	FRESENIUS KABI USA LLC	27-Jul-2018	A source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis (PNAC)
NDA 209607	ORIGINAL-1	AZEDRA	IOBENGUANE I 131	PROGENICS PHARMACEUTICALS INC	30-Jul-2018	Treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy
NDA 210923	ORIGINAL-1	MULPLETA	LUSUTROMBOPAG	SHIONOGI INC	31-Jul-2018	Treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure
NDA 211358	ORIGINAL-1	ORKAMBI	LUMACAFTOR/ IVACAFTOR	VERTEX PHARMACEUTICALS INC	7-Aug-2018	Treatment of cystic fibrosis (CF) in patients 2 years and older, homozygous for the F508del-cystic fibrosis transmembrane conductance regulator (CFTR) mutation in the CFTR gene
NDA 210607	ORIGINAL-1	ARAKODA	TAFENOQUINE	60 DEGREES PHARMACEUTICALS LLC	8-Aug-2018	For the prophylaxis of malaria in patients 18 years and older
NDA 210922	ORIGINAL-1	ONPATTRO	PATISIRAN	ALNYLAM PHARMACEUTICALS INC	10-Aug-2018	Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
NDA 208623	ORIGINAL-1	GALAFOLD	MIGALASTAT	AMICUS THERAPEUTICS U.S INC	10-Aug-2018	Treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data
BLA 761094	ORIGINAL-1	OXERVATE	CENEGERMIN-BKBJ	DOMPE FARMACEUTICI S.P.A.	22-Aug-2018	Treatment of neurotrophic keratitis
BLA 761090	ORIGINAL-1	TAKHZYRO	LANADELUMAB-FLYO	DYAX CORP	23-Aug-2018	Prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older
NDA 211109	ORIGINAL-1	XERAVA	ERAVACYCLINE	TETRAPHASE PHARMACEUTICALS INC	27-Aug-2018	Treatment of complicated intra-abdominal infections in patients 18 years of age and older
BLA 761104	ORIGINAL-1	LUMOXITI	MOXETUMOMAB PASUDOTOX-TDFK	ASTRAZENECA AB	13-Sep-2018	Treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA)
NDA 211155	ORIGINAL-1	COPIKTRA	DUVELISIB	VERASTEM INC	24-Sep-2018	Treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies
NDA 211155	ORIGINAL-2	COPIKTRA	DUVELISIB	VERASTEM INC	24-Sep-2018	Treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies
NDA 207356	ORIGINAL-1	ARIKAYCE	AMIKACIN LIPOSOME INHALATION SUSPENSION	INSMED INC	28-Sep-2018	Treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy for use in adults who have limited or no alternative treatment options
NDA 209816	ORIGINAL-1	NUZYRA	OMADACYCLINE	PARATEK PHARMACEURICALS INC	2-Oct-2018	Treatment of Community-Acquired Bacterial Pneumonia (CABP) and Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in adults due to the designated susceptible bacteria
NDA 209817	ORIGINAL-1	NUZYRA	OMADACYCLINE	PARATEK PHARMACEURICALS INC	2-Oct-2018	Treatment of Community-Acquired Bacterial Pneumonia (CABP) and Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in adults due to the designated susceptible bacteria
BLA 761092	ORIGINAL-1	REVCOVI	ELAPEGADEMASE-LVLR	LEADIANT BIOSCIENCES INC	5-Oct-2018	Treatment of Adenosine Deaminase-Severe Combined Immunodeficiency (ADA-SCID)
NDA 211172	ORIGINAL-1	TEGSEDI	INOTERSEN	AKCEA THERAPEUTICS INC	5-Oct-2018	Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults
NDA 210910	ORIGINAL-1	AEMCOLO	RIFAMYCIN	COSMO TECHNOLOGIES LTD	16-Nov-2018	Treatment of travelers' diarrhea caused by noninvasive strains of Escherichia coli in adults

NDA 211349	ORIGINAL-1	XOSPATA	GILTERITINIB	ASTELLAS PHARMA US INC	28-Nov-2018	Treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test

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