2017 CDER Fast Track Calendar Year Approvals*

Data as of 12/31/2017

Total of 26 Approvals

Appl Type Number	Submission Type and Number	Propriety Name	Established Name	Applicant	Approval Date	Use
NDA 208603	ORIG - 1	ARYMO ER	MORPHINE SULFATE	EGALET US INC	09-Jan-2017	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate
NDA 208264	ORIG - 1	TEPADINA	THIOTEPA	ADIENNE SA	26-Jan-2017	To reduce the risk of graft rejection when used in conjunction with high-dose busulfan and cyclophosphamide as a preparative regimen for allogeneic hematopoietic progenitor (stem) cell transplantation (HSCT) for pediatric patients with class 3 beta-thalassemia
NDA 208684	ORIG - 1	EMFLAZA	DEFLAZACORT TABLET	MARATHON PHARMACEUTICALS LLC	09-Feb-2017	Treatment of Duchenne muscular dystrophy in patients 5 years of age or older
NDA 208685	ORIG - 1	EMFLAZA	DEFLAZACORT SUSPENSION	MARATHON PHARMACEUTICALS LLC	09-Feb-2017	Treatment of Duchenne muscular dystrophy in patients 5 years of age or older
NDA 208794	ORIG - 1	XERMELO	TELOTRISTAT ETHYL	LEXICON PHARMACEUTICALS INC	28-Feb-2017	Treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy
BLA 761049	ORIG - 1	BAVENCIO	AVELUMAB	EMD SERONO INC	23-Mar-2017	Treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma
NDA 208447	ORIG - 1	ZEJULA	NIRAPARIB	TESARO INC	27-Mar-2017	Treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy
BLA 761053	ORIG - 1	OCREVUS	OCRELIZUMAB	GENENTECH INC	28-Mar-2017	Treatment of adult patients with primary progressive forms of multiple sclerosis
NDA 209241	ORIG - 1	INGREZZA	VALBENAZINE	NEUROCRINE BIOSCIENCES INC	11-Apr-2017	Treatment of tardive dyskinesia
NDA 203085	SUPPL - 7	STIVARGA	REGORAFENIB	BAYER HEALTHCARE PHARMACEUTICALS INC	27-Apr-2017	Treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib

NDA 207997	ORIG - 1	RYDAPT	MIDOSTAURIN	NOVARTIS PHARMACEUTICALS CORP	28-Apr-2017	Treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)
NDA 208630	ORIG - 1	GLEOLAN	AMINOLEVULINIC ACID HYDROCHLORIDE	NX DEVELOPMENT CORP	06-Jun-2017	As an optical imaging agent indicated in patients with glioma (suspected World Health Organization Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery
NDA 208610	ORIG - 1	BAXDELA	DELAFLOXACIN TABLET	MELINTA THERAPEUTICS INC	19-Jun-2017	Treatment of acute bacterial skin and skin structure infections (ABSSSI)
NDA 208611	ORIG - 1	BAXDELA	DELAFLOXACIN INJECTION	MELINTA SUBSIDIARY CORP	19-Jun-2017	Treatment of acute bacterial skin and skin structure infections (ABSSSI)
NDA 208383	ORIG - 1	BEVYXXA	BETRIXABAN	PORTOLA PHARMACEUTICALS INC	23-Jun-2017	Prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE
NDA 209606	ORIG - 1	IDHIFA	ENASIDENIB	CELGENE CORP	01-Aug-2017	Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test
NDA 209394	ORIG - 1	MAVYRET	GLECAPREVIR AND PIBRENTASVIR	ABBVIE INC	03-Aug-2017	Treatment of chronic hepatitis C virus (HCV) genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis; and also for patients with HCV GT1 infection who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both
NDA 209401	ORIG - 1	VYXEOS	CYTARABINE AND DAUNORUBICIN	CELATOR PHARMACEUTICALS INC	3-AUG-2017	Treatment of patients with newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC)

NDA 208558	ORIG - 1	LYNPARZA	OLAPARIB	ASTRAZENECA PHARMACEUTICALS LP	17-AUG-2017	Treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy; and treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.
NDA 209776	ORIG - 1	VABOMERE	MEROPENEM AND VABORBACTAM	REMPEX PHARMACEUTICALS INC	29-Aug-2017	Treatment of patients 18 years of age and older with complicated Urinary Tract Infections (cUTI), including pyelonephritis
NDA 209936	ORIG - 1	ALIQOPA	COPANLISIB HYDROCHLORIDE	BAYER HEALTHCARE PHARMACEUTICALS INC	14-Sep-2017	Treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.
NDA 209363	ORIG - 1	SOLOSEC	SECNIDAZOLE	SYMBIOMIX THERAPEUTICS LLC	15-Sep-2017	Treatment of bacterial vaginosis in adult women.
NDA 208716	ORIG - 1	VERZENIO	ABEMACICLIB	ELI LILLY AND CO	28-Sep-2017	Treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
NDA 209939	ORIG - 1	PREVYMIS	LETERMOVIR	MERCK SHARP AND DOHME CORP	08-Nov-2017	Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMVseropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
BLA 761047	ORIG - 1	MEPSEVII	VESTRONIDASE ALFA-VJBK	ULTRAGENYX PHARMACEUTICAL INC	15-Nov-2017	Treatment of Mucopolysaccharidosis type VII (MPS VII, Sly syndrome)
NDA 209819	ORIG - 1	SUBLOCADE	BUPRENORPHINE	INDIVIOR INC	30-Nov-2017	Treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days

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