

CY 2021 CDER Fast Track Calendar Year Approvals*

Data as of 12-31-2021

Total of 39 Approvals

Appl Type Number	Submission Type and Number	Propriety Name	Established Name	Applicant	Approval Date	Use
NDA 214377	ORIG - 1	VERQUVO	VERICIGUAT	MERCK SHARP AND DOHME CORP	19-Jan-2021	To reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%
NDA 212887	ORIG - 1	VOCABRIA	CABOTEGRAVIR TABLETS	VIIV HEALTHCARE CO	21-Jan-2021	In combination with Edurant (rilpivirine) 25 mg tablet for the short-term treatment of HIV1 infection in adults who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine (release injectable suspension)
NDA 212888	ORIG - 1	CABENUVA	CABOTEGRAVIR AND RILPIVIRINE - EXTENDED RELEASE INJECTABLE SUSPENSION	VIIV HEALTHCARE CO	21-Jan-2021	Treatment of HIV-1 infection in adults to replace their current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine

NDA 213716	ORIG - 1	LUPKYNIS	VOCLOSPORIN	AURINIA PHARMACEUTICALS INC	22-Jan-2021	In combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis
NDA 213026	ORIG - 1	AMONDYS 45	CASIMERSEN	SAREPTA THERAPEUTICS INC	25-Feb-2021	Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping
BLA 761115	SUPPL - 9	TRODELVY	SACITUZUMAB GOVITECAN-HZIY	IMMUNOMEDICS INC	13-Apr-2021	Treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed deathligand 1 (PD-L1) inhibitor
NDA 021825	SUPPL - 8	FERRIPROX	DEFERIPRONE	CHIESI USA INC	30-Apr-2021	Treatment of patients with transfusional iron overload due to sickle cell disease or other anemias
NDA 202293	SUPPL - 24	FARXIGA	DAPAGLIFLOZIN	ASTRAZENECA AB	30-Apr-2021	To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression
NDA 208030	SUPPL - 5	FERRIPROX	DEFERIPRONE ORAL SOLUTION	CHIESI USA INC	30-Apr-2021	Treatment of patients with transfusional iron overload due to sickle cell disease or other anemias

NDA 212269	SUPPL - 1	FERRIPROX	DEFERIPRONE TABLETS	CHIESI USA INC	30-Apr-2021	Treatment of patients with transfusional iron overload due to sickle cell disease or other anemias
NDA 211988	ORIG - 1	ZYNRELEF	BUPIVACAINE AND MELOXICAM	HERON THERAPEUTICS INC	12-May-2021	For soft tissue or periarticular instillation use to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty
NDA 215014	ORIG - 1	EMPAVELI	PEGCETACOPLAN	APELLIS PHARMACEUTICALS INC	14-May-2021	Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH)
NDA 214622	ORIG - 1	TRUSELTIQ	INFIGRATINIB	QED THERAPEUTICS INC	28-May-2021	Treatment of adult patients with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangement as detected by an FDA approved test
NDA 214665	ORIG - 1	LUMAKRAS	SOTORASIB	AMGEN INC	28-May-2021	Treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy
NDA 214900	ORIG - 1	BREXAFEMME	IBREXAFUNGERP	SCYNEXIS INC	01-Jun-2021	Treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis
NDA 214460	ORIG - 1	TEMBEXA ORAL SUSPENSION	BRINCIDOFOVIR	CHIMERIX INC	04-Jun-2021	Treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates

NDA 214461	ORIG - 1	TEMBEXA TABLETS	BRINCIDOFOVIR	CHIMERIX INC	04-Jun-2021	Treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates
BLA 761178	ORIG - 1	ADUHELM	ADUCANUMAB-AVWA	BIOGEN INC	07-Jun-2021	Treatment of Alzheimer's disease
BLA 761179	ORIG - 1	RYLAZE	ASPARAGINASE ERWINIA CHRYSANTHEMI (RECOMBINANT)- RYWN	JAZZ PHARMACEUTICALS IRELAND LIMITED	30-Jun-2021	Treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to E. coli-derived asparaginase
NDA 215341	ORIG - 1	KERENDIA	FINERENONE	BAYER HEALTHCARE PHARMACEUTICALS INC	09-Jul-2021	To reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D)
NDA 215498	ORIG - 1	BYLVAY	ODEVIXIBAT	ALBIREO AB	20-Jul-2021	Treatment of pruritus in patients 3 months of age and older, with progressive familial intrahepatic cholestasis (PFIC)
BLA 761123	ORIG - 1	SAPHNELO	ANIFROLUMAB	ASTRAZENECA AB	30-Jul-2021	Treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), receiving standard therapy
BLA 761194	ORIG - 1	NEXVIAZYME	AVALGLUCOSIDASE ALFA	GENZYME CORPORATION	06-Aug-2021	Treatment of patients 1 year of age and older with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency)
NDA 212690	SUPPL - 6	XYWAV	CALCIUM, MAGNESIUM, POTASSIUM, AND SODIUM OXYBATES	JAZZ PHARMACEUTICALS INC	12-Aug-2021	Treatment of Idiopathic Hypersomnia (IH)

NDA 204629	SUPPL - 26	JARDIANCE	EMPAGLIFLOZIN	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	18-Aug-2021	To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure and reduced ejection fraction
NDA 202439	SUPPL - 35	XARELTO	RIVAROXABAN	JANSSEN PHARMACEUTICALS INC	23-Aug-2021	In combination with aspirin, to reduce the risk of major thromboticvascular events (myocardial infarction, ischemic stroke, acute limb ischemia, and major amputation of a vascular etiology) in patients with PAD, including patients who have recently undergone a lower extremity revascularization procedure due to symptomatic PAD
NDA 211192	SUPPL - 8	TIBSOVO	IVOSIDENIB	PHARMACEUTICALS LLC	25-Aug-2021	Treatment of adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an IDH1 mutation as detected by an FDA-approved test
NDA 213895	ORIG - 1	NA	VANCOMYCIN	XELLIA PHARMACEUTICALS APS	26-Aug-2021	Treatment of: <ul style="list-style-type: none"> • Clostridioides difficile-associated diarrhea • Enterocolitis caused by Staphylococcus aureus (including methicillin-resistant strains) •Septicemia • Infective Endocarditis • Skin and Skin Structure Infections • Bone Infections • Lower Respiratory Tract Infections
NDA 213217	SUPPL - 4	BRUKINSA	ZANUBRUTINIB	BEIGENE USA INC	31-Aug-2021	Treatment of adult patients with Waldenström's macroglobulinemia (WM)

NDA 213217	SUPPL - 5	BRUKINSA	ZANUBRUTINIB	BEIGENE USA INC	14-Sep-2021	Treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen
NDA 215310	ORIG - 1	EXKIVITY	MOBOCERTINIB	TAKEDA PHARMACEUTICALS USA INC	15-Sep-2021	Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy
BLA 761197	ORIG - 1	SUSVIMO	RANIBIZUMAB	GENENTEC INC	22-Oct-2021	Treatment of patients with Neovascular (wet) Age-related Macular Degeneration (AMD)
NDA 215358	ORIG - 1	SCEMBLIX	ASCIMINIB	NOVARTIS PHARMACEUTICALS CORP	29-Oct-2021	Treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs)
NDA 215358	ORIG - 2	SCEMBLIX	ASCIMINIB	NOVARTIS PHARMACEUTICALS CORP	29-Oct-2021	Treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) with the T315I mutation
NDA 213312	ORIG - 1	FYARRO	SIROLIMUS PROTEIN- BOUND PARTICLES	AADI BIOSCIENCE INC	22-Nov-2021	Treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa)
NDA 214907	ORIG - 1	CYTALUX	PAFOLACIANINE SODIUM	ON TARGET LABORATORIES INC	29-Nov-2021	As an optical imaging agent for use in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions

NDA 215650	ORIG - 1	XACIATO	CLINDAMYCIN PHOSPHATE	DARE BIOSCIENCE INC	07-Dec-2021	Treatment of bacterial vaginosis in female patients 12 years of age and older
BLA 761195	ORIG - 1	VYVGART	EFGARTIGIMOD ALFA	ARGENX BV	17-Dec-2021	Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti- acetylcholine receptor (AChR) antibody positive
NDA 215499	ORIG - 1	APRETUDE	CABOTEGRAVIR	VIIV HEALTHCARE CO	21-Dec-2021	HIV-1 pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and pediatric patients 12 to less than 18 years of age weighing at least 35 kg

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