

CY 2024 CDER Fast Track Calendar Year Approvals*

Data as of 9-30-2024

Total of 21 Approvals

Appl Type Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	Use
NDA 216165	ORIG - 1	EXBLIFEP	CEFEPIME AND ENMETAZOACTAM	ALLECRA THERAPEUTICS SAS	22-Feb-2024	Treatment of patients 18 years and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Proteus mirabilis, and Enterobacter cloacae complex
NDA 213217	SUPPL - 11	BRUKINSA	ZANUBRUTINIB	BEIGENE USA INC	07-Mar-2024	Treatment of adult patients with relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy
NDA 217785	ORIG - 1	REZDIFFRA	RESMETIROM	MADRIGAL PHARMACEUTICALS INC	14-Mar-2024	In conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis)
NDA 217865	ORIG - 1	DUVYZAT	GIVINOSTAT	ITALFARMACO SPA	21-Mar-2024	Treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older
NDA 218275	ORIG - 1	ZEVTERA	CEFTOBIPROLE MEDOCARIL SODIUM	BASILEA PHARMACEUTICA INTERNATIONAL LTD ALLSCHWIL	03-Apr-2024	Treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following gram-positive and gram-negative microorganisms: Staphylococcus aureus (methicillin-susceptible and methicillin-resistant isolates), Streptococcus pyogenes, and Klebsiella pneumoniae
NDA 214511	ORIG - 1	LUMISIGHT	PEGULICIANINE	LUMICELL INC	17-Apr-2024	For fluorescence imaging in adults with breast cancer as an adjunct for the intraoperative detection of cancerous tissue within the resection cavity following removal of the primary specimen during lumpectomy surgery

BLA 761336	ORIG - 1	ANKTIVA	NOGAPENDEKIN ALFA INBAKICEPT-PMLN	ALTOR BIOSCIENCE LLC	22-Apr-2024	Indicated with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors
NDA 218623	ORIG - 1	LIBERVANT	DIAZEPAM	AQUESTIVE THERAPEUTICS	26-Apr-2024	Treatment of intermittent, stereotypical episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age
NDA 218709	ORIG - 1	XOLREMDI	MAVORIXAFOR	X4 PHARMACEUTICALS INC	26-Apr-2024	Treatment of patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes
NDA 217779	ORIG - 1	RYTELO	IMETELSTAT	GERON CORP	06-Jun-2024	Treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA)
NDA 218213	SUPPL - 1	AUGTYRO	REPOTRECTINIB	BRISTOL MYERS SQUIBB CO	13-Jun-2024	Treatment of adult and pediatric patients 12 years of age and older with solid tumors that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory alternative therapy
NDA 211150	SUPPL - 5	WAKIX	PITOLISANT	HARMONY BIOSCIENCES LLC	21-Jun-2024	Treatment of excessive daytime sleepiness in patients 6 years of age and older with narcolepsy
BLA 761248	ORIG - 1	KISUNLA	DONANEMAB-AZBT	ELI LILLY AND COMPANY	02-Jul-2024	Treatment of Alzheimer's disease
NDA 217900	ORIG - 1	LEQSELVI	DEURUXOLITINIB	SUN PHARMACEUTICAL INDUSTRIES INC	25-Jul-2024	Treatment of adults with severe alopecia areata
NDA 218784	ORIG - 1	VORANIGO	VORASIDENIB	SERVIER PHARMACEUTICALS LLC	06-Aug-2024	Treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation, following surgery including biopsy, sub-total resection, or gross total resection

NDA 218590	ORIG - 1	ZURNAI	NALMEFENE	PURDUE PHARMA LP	07-Aug-2024	Emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression
NDA 214697	ORIG - 1	NEFFY	EPINEPHRINE	ARS PHARMACEUTICALS OPERATIONS INC	09-Aug-2024	Emergency treatment of type I allergic reactions, including anaphylaxis, in adults and pediatric patients who weigh 30 kg or greater
BLA 761411	ORIG - 1	NIKTIMVO	AXATILIMAB-CSFR	INCYTE CORPORATION	14-Aug-2024	Treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg
BLA 761306	ORIG - 1	EBGLYSS	LEBRIKIZUMAB-LBKZ	ELI LILLY AND COMPANY	13-Sep-2024	Treatment of moderate to severe atopic dermatitis
NDA 214927	ORIG - 1	MIPLYFFA	ARIMOCLOMOL	ZEVRA DENMARK A/S	20-Sep-2024	In combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients 2 years of age and older
NDA 219132	ORIG - 1	AQNEURSA	LEVACETYLLEUCINE	INTRABIO INC	24-Sep-2024	The treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥15 kg

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