2015 CDER Fast Track Calendar Year Approvals*

Data as of 12-31-2015/Revised 12-23-2021**

Total of 23 Approvals

Appl Type Number	Submission Type and Number	Propriety Name	Established Name	Applicant	Approval Date	Use
NDA 203952	ORIG - 1	DUOPA	CARBIDOPA AND LEVODOPA	ABBVIE INC	09-Jan-2015	Treatment of motor fluctuations in patients with advanced Parkinson's disease
NDA 206494	ORIG - 1	AVYCAZ	AVIBACTAM AND CEFTAZIDIME	ALLERGAN SALES LLC	25-Feb-2015	Treatment complicated urinary tract infections (cUTIs), including pyelonephritis and complicated intra-abdominal infections (cIAIs)
NDA 207925	ORIG - 1	KAYLDECO	IVACAFTOR	VERTEX PHARMACEUTICALS INC	3-Mar-2015	Treatment of cystic fibrosis patients 2 years and older who have one of the following mutations in CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R and R117H.
BLA 125527	ORIG - 1	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	04-Mar-2015	Treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy.
NDA 206143	ORIG - 1	CORLANOR	IVABRADINE	AMGEN INC	15-Apr-2015	To reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use
NDA 206940	ORIG - 1	VIBERZI	ELUXADOLINE	ALLERGAN HOLDINGS UNLTD CO	27-May-2015	Treatment of irritable bowel syndrome with diarrhea (IBS-D)
NDA 206038	ORIG - 1	ORKAMBI	IVACAFTOR AND LUMACAFTOR	VERTEX PHARMACEUTICALS INC	02-Jul-2015	Treatment of cystic fibrosis (CF) in patients age 12 years and older who are homozygous for the F508del mutation in the CFTR gene.
NDA 207620	ORIG - 1	ENTRESTO	SACUBITRIL AND VALSARTAN	NOVARTIS PHARMACEUTICALS CORP	07-Jul-2015	To reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction
NDA 206843	ORIG - 1	DAKLINZA	DACLATASVIR	BRISTOL MYERS SQUIBB CO	24-Jul-2015	In combination with sofosbuvir for the treatment of chronic hepatitis C virus, genotype 3 infection
NDA 207981	ORIG - 1	LONSURF	TIPIRACIL HYDROCHLORIDE AND TRIFLURIDINE	TAIHO ONCOLOGY INC	22-Sep-2015	Treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-oxaliplatin-and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy
BLA 125554**	Supp-5	OPDIVO	NIVOLUMAB	BRISTOL MYERS SQUIBB CO	09-Oct-2015	Treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC) with progression on or after platinum based chemotherapy
NDA 207793	ORIG - 1	ONIVYDE	IRINOTECAN LIPOSOME	IPSEN BIOPHARMACEUTICALS INC	22-Oct-2015	In combination with 5-fluorouracil and leucovorin, for the treatment of patients with metastatic adenocarcinoma of the pancreas that has progressed following gemcitabine-based therapy
BLA 125513	ORIG - 1	STRENSIQ	ASFOTASE ALFA	ALEXION PHARMACEUTICALS, INC.	23-Oct-2015	Treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP)
NDA 207561	ORIG - 1	GENVOYA	ELVITEGRAVIR, COBICISTAT, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INC	05-Nov-2015	Treatment of HIV-1 infection in adults and pediatric patients 12 years of age or older who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of GENVOYA
NDA 206192	ORIG - 1	COTELLIC	COBIMETINIB	GENENTECH INC	10-Nov-2015	Treatment, of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutation, in combination with vemurafenib. COTELLIC is not indicated for treatment of patients with wild-type BRAF melanoma
NDA 208065	ORIG - 1	TAGRISSO	OSIMERTINIB	ASTRAZENECA PHARMACEUTICALS LP	13-Nov-2015	Treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive-non-small-cell lung cancer (NSCLC), as detected by an FDA approved test, who have progressed on or after EGFR TKI therapy
BLA 761036	ORIG - 1	DARZALEX	DARATUMUMAB	JANSSEN BIOTECH, INC.	16-Nov-2015	Treatment of patients with multiple myeloma who have received at least 3 prior lines of therapy including a proteasome inhibitor and an immunomodulatory agent or are double refractory to a proteasome inhibitor and an immunomodulatory agent

NDA 208411	ORIG - 1	NARCAN	NALOXONE HYDROCHLORIDE	ADAPT PHARMA OPERATIONS LTD	18-Nov-2015	Emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression
BLA 125554**	SUPP-12	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	11-Nov-2015	Treatment of advanced renal cell carcinoma patients who have received prior antiangiogenic therapy
BLA 125547	ORIG - 1	PORTRAZZA	NECITUMUMAB	ELI LILLY AND COMPANY	24-Nov-2015	In combination with gemcitabine and cisplatin for first-line treatment of patients with metastatic, squamous, non-small cell lung cancer
BLA 125561	ORIG - 1	KANUMA	SEBELIPASE ALFA	ALEXION PHARMACEUTICALS, INC.	08-Dec-2015	Treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency
NDA 208159	ORIG - 1	VISTOGARD	URIDINE TRIACETATE	WELLSTAT THERAPEUTICS CORP	11-Dec-2015	Emergency treatment of adult and pediatric patients following a fluorouracil or capecitabine overdose regardless of the presence of symptoms, or who exhibit early-onset, severe or life-threatening toxicity affecting the cardiac or central nervous system, and/or early-onset, unusually severe adverse reactions (e.g., gastrointestinal toxicity and/or neutropenia) within 96 hours following the end of fluorouracil or capecitabine administration
NDA 207865	ORIG - 1	EMEND	APREPITANT	MERCK SHARP AND DOHME CORP	17-Dec-2015	Prevention of chemotherapy induced nausea and vomiting in patients ages 6 months of age and older

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