

2016 CDER Fast Track Calendar Year Approvals*

Data as of 12/31/2016

Total of 12 Approvals

Appl Type Number	Submission Type and Number	Propriety Name	Established Name	Applicant	Approval Date	Use
BLA 125509	ORIG - 1	ANTHIM	OBILTOXAXIMAB	ELUSYS THERAPEUTICS	18-Mar-2016	Treatment of adult and pediatric patients with inhalational anthrax due to Bacillus anthracis in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate
NDA 208114	ORIG - 1	DEFITELIO	DEFIBROTIDE SODIUM	JAZZ PHARMACEUTICALS	30-Mar-2016	Treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome (SOS), with renal or pulmonary dysfunction following hematopoietic stem cell transplantation (HSCT)
NDA 208692	ORIG - 1	CABOMETYX	CABOZANTINIB	EXELIXIS	APR-25-2016	Treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy
NDA 208090	ORIG - 1	XTAMPZA ER	OXYCODONE	COLLEGIUM PHARMACEUTICAL	26-Apr-2016	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate
NDA 207999	ORIG - 1	OCALIVA	OBETICHOLIC ACID	INTERCEPT PHARMACEUTICALS	27-May-2016	Treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA
NDA 208341	ORIG - 1	EPCLUSA	SOFOSBUVIR AND VELPATASVIR	GILEAD SCIENCES	28-Jun-2016	Treatment of adult patients with chronic hepatitis C virus (HCV) genotypes 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
NDA 206488	ORIG - 1	EXONDYS 51	ETEPLIRSEN	SAREPTA THERAPEUTICS	19-Sep-2016	Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping
NDA 206038	SUPPL - 5	ORKAMBI	IVACAFTOR AND LUMACAFTOR	VERTEX PHARMACEUTICALS	28-Sep-2016	Expands the indication to include 6-11 year old cystic fibrosis patients who are homozygous for the F508del mutation in the CFTR gene
BLA 761038	ORIG - 1	LARTRUVO	OLARATUMAB	ELI LILLY AND COMPANY	19-Oct-2016	in combination with doxorubicin , for the treatment of adult patients with soft tissue sarcoma (STS) with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery
BLA 761046	ORIG - 1	ZINPLAVA	BEZLOTOXUMAB	MERCK SHARP & DOHME CORP	21-Oct-2016	To reduce recurrence of Clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence.
BLA 761036	SUPPL - 4	DARZALEX	DARATUMUMAB	JANSSEN BIOTECH	21-Nov-2016	In combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma
NDA 209531	ORIG - 1	SPINRAZA	NUSINERSEN	BIOGEN	23-Dec-2016	Treatment of spinal muscular atrophy in pediatric and adult patients

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