

CY 2012 CDER Fast Track Calendar Year Approvals*

Data as of 12-31-2012

Total of 20 Approvals

Appl Type Number	Submission Type and Number	Propriety Name	Established Name	Applicant	Approval Date	Use
BLA 125327	ORIG - 1	VORAXAZE	GLUCARPIDASE	BTG INTERNATIONAL INC.	17-Jan-2012	Treatment of toxic (> 1 micromole per liter) plasma methotrexate concentrations in patients with delayed methotrexate clearance due to impaired renal function
NDA 202324	ORIG - 1	INLYTA	AXITINIB	PF PRISM CV	27-Jan-2012	Treatment of advanced renal cell carcinoma after failure of one prior systemic therapy
NDA 203188	ORIG - 1	KALYDECO	IVACAFTOR	VERTEX PHARMACEUTICALS INC	31-Jan-2012	Treatment of cystic fibrosis in patients age 6 years and older who have a G551D mutation in the CFTR gene
NDA 022222	ORIG - 1	ULTRESA	PANCRELIPASE	FOREST LABORATORIES LLC	01-Mar-2012	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions
NDA 022542	ORIG - 1	VIKACE	PANCRELIPASE	FOREST LABORATORIES LLC	01-Mar-2012	Treatment of exocrine pancreatic insufficiency in adults due to chronic pancreatitis or pancreatotomy
NDA 021746	ORIG - 1	SURFAXIN	LUCINACTANT	WINDTREE THERAPEUTICS INC	06-Mar-2012	Prevention of respiratory distress syndrome in premature infants
NDA 022458	ORIG - 1	ELELYSO	TALIGLUCERASE ALFA	PFIZER INC	01-May-2012	Use as a long-term enzyme replacement therapy in patients with Type 1 Gaucher disease
NDA 022175	ORIG - 1	PERTZYE	PANCRELIPASE	DIGESTIVE CARE INC	17-May-2012	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions
NDA 021752	SUPPL - 30	TRUVADA	EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	16-Jul-2012	In combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk
NDA 202714	ORIG - 1	KYPROLIS	CARFILZOMIB	ONYX THERAPEUTICS INC A WHOLLY OWNED SUB OF AMGEN INC	20-Jul-2012	Treatment of patients with multiple myeloma who have received at least two prior therapies including bortezomib and an immunomodulatory agent and have demonstrated disease progression on or within 60 days of completion of the last therapy
NDA 203100	ORIG - 1	STRIBILD	COBICISTAT, ELVITEGRAVIR, EMTRICITABINE, AND TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	27-Aug-2012	Treatment of HIV-1 infection in treatment-naive adult patients
NDA 203415	ORIG - 1	XTANDI	ENZALUTAMIDE	ASTELLAS PHARMA US INC	31-Aug-2012	Treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel
NDA 203085	ORIG - 1	STIVARGA	REGORAFENIB	BAYER HEALTHCARE PHARMACEUTICALS INC	27-Sep-2012	Treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy
NDA 203585	ORIG - 1	SYNRIBO	OMACETAXINE MEPEUSUCCINATE	TEVA PHARMACEUTICALS INTERNATIONAL GMBH	26-Oct-2012	Treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKI)
NDA 203756	ORIG - 1	COMETRIQ	CABOZANTINIB	EXELIXIS INC	29-Nov-2012	Treatment of patients with progressive, metastatic medullary thyroid cancer (MTC)
BLA 125349	ORIG - 1		RAXIBACUMAB	EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC	14-Dec-2012	Treatment of 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 203469	ORIG - 1	ICLUSIG	PONATINIB	ARIAD PHARMACEUTICALS INC	14-Dec-2012	Treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) that is resistant or intolerant to prior tyrosine kinase inhibitor therapy
NDA 202155	ORIG - 1	ELIQUIS	APIXABAN	BRISTOL MYERS SQUIBB CO	28-Dec-2012	To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation
NDA 204384	ORIG - 1	SIRTURO	BEDAQUILINE	JANSSEN RESEARCH AND DEVELOPMENT LLC	28-Dec-2012	Treatment of adults (≥ 18 years) with pulmonary multi-drug resistant tuberculosis (MDR-TB) as part of a combination therapy regimen
NDA 202292	ORIG - 1	MYTESI	CROFELEMER	NAPO PHARMACEUTICALS INC	31-Dec-2012	Treatment of symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy

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