2013 CDER Fast Track Calendar Year Approvals*

Data as of 12-31-2013
Total of 14 Approvals

Appl Type Number	Submission Type and Number	Propriety Name	Established Name	Applicant	Approval Date	Use
NDA 203284	ORIG - 1	RAVICTI	GLYCEROL PHENYLBUTYRATE	HORIZON THERAPEUTICS LLC	01-Feb-2013	Nitrogen-binding adjunctive therapy for chronic management of adult and pediatric patients ≥2 years of age with urea cycle disorders (UCDs) that cannot be managed by dietary protein restriction and/or amino acid supplementation alone
NDA 204026	ORIG - 1	POMALYST	POMALIDOMIDE	CELGENE CORP	08-Feb-2013	Treatment of patients with multiple myeloma who have rece ived at least two prior therapiesincluding lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy
BLA 125427	ORIG - 1	KADCYLA	TRASTUZUMAB EMTANSINE	GENENTECH, INC.	22-Feb-2013	Treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination.
NDA 204369	ORIG - 1	STIVARGA	REGORAFENIB	BAYER HEALTHCARE PHARMACEUTICALS INC	25-Feb-2013	Treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.
NDA 203340	ORIG - 1	NYMALIZE	NIMODIPINE	PHARMACEUTICALS LLC	10-May-2013	Treatment of subarachnoid hemorrhage
NDA 203971	ORIG - 1	XOFIGO	RADIUM-223 DICHLORIDE	BAYER HEALTHCARE PHARMACEUTICALS INC	15-May-2013	Treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease
NDA 202806	ORIG - 1	TAFINLAR	DABRAFENIB	NOVARTIS PHARMACEUTICALS CORP	29-May-2013	Treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test
NDA 204114	ORIG - 1	MEKINIST	TRAMETINIB	NOVARTIS PHARMACEUTICALS CORP	29-May-2013	Treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test
NDA 022407	ORIG - 1	VIBATIV	TELAVANCIN	THERAVANCE BIOPHARMA ANTIBIOTICS INC	21-Jun-2013	Treatment of hospital acquired bacterial pneumonia/ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of Staphylococcus aureus (including methicillin-susceptible and -resistant isolates) when alternative treatments are not suitable
NDA 201292	ORIG - 1	GILOTRIF	AFATINIB	BOEHRINGER INGELHEIM	12-Jul-2013	Treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test
NDA 204790	ORIG - 1	TIVICAY	DOLUTEGRAVIR	VIIV HEALTHCARE CO	12-Aug-2013	In combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and children aged 12 years and older and weighing at least 40
NDA 205552	ORIG - 1	IMBRUVICA	IBRUTINIB	PHARMACYCLICS LLC	13-Nov-2013	Treatment of patients with Mantle Cell lymphoma (MCL)

NDA 205123	ORIG - 1	OLYSIO	SIMEPREVIR	JANSSEN PRODUCTS LP	22-Nov-2013	Treatment of chronic hepatitis C (CHC) infection, as a component of a combination antiviral treatment regimen
NDA 204671	ORIG - 1	SOVALDI	SOFOSBUVIR	GILEAD SCIENCES INC	06-Dec-2013	Component of a combination antiviral regimen for the treatment of chronic hepatitis C infection

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