2017 CDER Fast Track Calendar Year Approvals*

Data as of 12/31/2017 Total of 26 Approvals

Number Number Number Name Established Name Applicant Number Nu		Submission					
MARATHON NDA 208695 ORIG - 1 EMFLAZA NDA 208695 ORIG - 1 EMFLAZA NDA 208794 ORIG - 1 BAVENCIO BELA 761049 ORIG - 1 ZEJULA NDA 208447 ORIG - 1 INGREZZA NDA 208447 ORIG - 1 ZEJULA NDA 208447 ORIG - 1 INGREZZA NDA 2		71		Fatablish ad Nama	A !! (Approval	
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TIDITECTOR OF THE TENTE OF THE	NDA 203085	SUPPL - 7	STIVARGA	REGORAFENIB	INC	27-Apr-2017	treated with sorafenib

NDA 207997	ORIG - 1	RYDAPT	MIDOSTAURIN	NOVARTIS PHARMACEUTICALS CORP	28-Apr-2017	Treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)
NDA 208630	ORIG - 1	GLEOLAN	AMINOLEVULINIC ACID HYDROCHLORIDE	NX DEVELOPMENT CORP	06-Jun-2017	As an optical imaging agent indicated in patients with glioma (suspected World Health Organization Grades III or IV on preoperative imaging) as an adjunct for the visualization of malignant tissue during surgery
NDA 208610	ORIG - 1	BAXDELA	DELAFLOXACIN TABLET	MELINTA THERAPEUTICS INC	19-Jun-2017	Treatment of acute bacterial skin and skin structure infections (ABSSSI)
NDA 208611	ORIG - 1	BAXDELA	DELAFLOXACIN INJECTION	MELINTA SUBSIDIARY CORP	19-Jun-2017	Treatment of acute bacterial skin and skin structure infections (ABSSSI)
NDA 208383	ORIG - 1	BEVYXXA	BETRIXABAN	PORTOLA PHARMACEUTICALS INC	23-Jun-2017	Prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE
NDA 209606	ORIG - 1	IDHIFA	ENASIDENIB	CELGENE CORP	01-Aug-2017	Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test
NDA 209394	ORIG - 1	MAVYRET	GLECAPREVIR AND PIBRENTASVIR	ABBVIE INC	03-Aug-2017	Treatment of chronic hepatitis C virus (HCV) genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis; and also for patients with HCV GT1 infection who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both
NDA 209401	ORIG - 1	VYXEOS	CYTARABINE AND DAUNORUBICIN	CELATOR PHARMACEUTICALS INC	3-AUG-2017	Treatment of patients with newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC)

						Treatment of adult patients with recurrent
						epithelial ovarian, fallopian tube or primary
						peritoneal cancer, who are in a complete or
						partial response to platinum-based
						chemotherapy; and treatment of adult patients
				4 OTD 4 75 N 5 O 4		with deleterious or suspected deleterious
				ASTRAZENECA		germline BRCA-mutated (gBRCAm) advanced
NDA 200550	ODIC 4	1 VAID 4 D 7 4	OL A DA DID	PHARMACEUTICALS LP	47 4110 2047	ovarian cancer who have been treated with
NDA 208558	ORIG - 1	LYNPARZA	OLAPARIB	<u> </u>	17-AUG-2017	three or more prior lines of chemotherapy.
			MEROPENEM	REMPEX		Treatment of patients 18 years of age and older
NDA 000770	0010 4	\/ADOMEDE	AND	PHARMACEUTICALS	00 4 0047	with complicated Urinary Tract Infections
NDA 209776	ORIG - 1	VABOMERE	VABORBACTAM	INC	29-Aug-2017	(cUTI), including pyelonephritis
			000044114010	BAYER HEALTHCARE		Treatment of adult patients with relapsed
	0010 4	41.10004	COPANLISIB	PHARMACEUTICALS		follicular lymphoma (FL) who have received at
NDA 209936	ORIG - 1	ALIQOPA	HYDROCHLORIDE	INC	14-Sep-2017	least two prior systemic therapies.
	0010 4	0010050	050111547015	SYMBIOMIX	45.0 0045	Treatment of bacterial vaginosis in adult
NDA 209363	ORIG - 1	SOLOSEC	SECNIDAZOLE	THERAPEUTICS LLC	15-Sep-2017	women.
						Treatment of adult patients with HR-positive,
						HER2-negative advanced or metastatic breast
						cancer with disease progression following
_						endocrine therapy and prior chemotherapy in
NDA 208716	ORIG - 1	VERZENIO	ABEMACICLIB	ELI LILLY AND CO	28-Sep-2017	the metastatic setting
						Prophylaxis of cytomegalovirus (CMV) infection
						and disease in adult CMVseropositive
				MERCK SHARP AND		recipients [R+] of an allogeneic hematopoietic
NDA 209939	ORIG - 1	PREVYMIS	LETERMOVIR	DOHME CORP	08-Nov-2017	stem cell transplant (HSCT)
				ULTRAGENYX		
			VESTRONIDASE	PHARMACEUTICAL		Treatment of Mucopolysaccharidosis type VII
BLA 761047	ORIG - 1	MEPSEVII	ALFA-VJBK	INC	15-Nov-2017	(MPS VII, Sly syndrome)
						Treatment of moderate to severe opioid use
						disorder in patients who have initiated
						treatment with a transmucosal buprenorphine-
						containing product, followed by dose
NDA 209819	ORIG - 1	SUBLOCADE	BUPRENORPHINE	INDIVIOR INC	30-Nov-2017	adjustment for a minimum of 7 days

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