

2017 CDER Fast Track Calendar Year Approvals*

Data as of 12/31/2017

Total of 26 Approvals

| Appl Type Number | Submission Type and Number | Propriety Name | Established Name | Applicant | Approval Date | Use |
|------------------|----------------------------|----------------|-----------------------------------|--------------------------------------|---------------|--|
| NDA 208603 | ORIG - 1 | ARYMO ER | MORPHINE SULFATE | EGALET US INC | 09-Jan-2017 | Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate |
| NDA 208264 | ORIG - 1 | TEPADINA | THIOTEPA | ADIENNE SA | 26-Jan-2017 | To reduce the risk of graft rejection when used in conjunction with high-dose busulfan and cyclophosphamide as a preparative regimen for allogeneic hematopoietic progenitor (stem) cell transplantation (HSCT) for pediatric patients with class 3 beta-thalassemia |
| NDA 208684 | ORIG - 1 | EMFLAZA | DEFLAZACORT TABLET | MARATHON PHARMACEUTICALS LLC | 09-Feb-2017 | Treatment of Duchenne muscular dystrophy in patients 5 years of age or older |
| NDA 208685 | ORIG - 1 | EMFLAZA | DEFLAZACORT SUSPENSION | MARATHON PHARMACEUTICALS LLC | 09-Feb-2017 | Treatment of Duchenne muscular dystrophy in patients 5 years of age or older |
| NDA 208794 | ORIG - 1 | XERMELO | TELOTRISTAT ETHYL | LEXICON PHARMACEUTICALS INC | 28-Feb-2017 | Treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy |
| BLA 761049 | ORIG - 1 | BAVENCIO | AVELUMAB | EMD SERONO INC | 23-Mar-2017 | Treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma |
| NDA 208447 | ORIG - 1 | ZEJULA | NIRAPARIB | TESARO INC | 27-Mar-2017 | 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 |
| BLA 761053 | ORIG - 1 | OCREVUS | OCRELIZUMAB | GENENTECH INC | 28-Mar-2017 | Treatment of adult patients with relapsing or primary progressive forms of multiple sclerosis |
| NDA 209241 | ORIG - 1 | INGREZZA | VALBENZAZINE | NEUROCRINE BIOSCIENCES INC | 11-Apr-2017 | Treatment of tardive dyskinesia |
| NDA 203085 | SUPPL - 7 | STIVARGA | REGORAFENIB | BAYER HEALTHCARE PHARMACEUTICALS INC | 27-Apr-2017 | Treatment of patients with hepatocellular carcinoma (HCC) who have been previously 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 | DELAFLORACIN TABLET | MELINTA THERAPEUTICS INC | 19-Jun-2017 | Treatment of acute bacterial skin and skin structure infections (ABSSSI) |
| NDA 208611 | ORIG - 1 | BAXDELA | DELAFLORACIN 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 |

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| 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) |
| NDA 208558 | ORIG - 1 | LYNPARZA | OLAPARIB | ASTRAZENECA PHARMACEUTICALS LP | 17-AUG-2017 | 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 with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. |
| NDA 209776 | ORIG - 1 | VABOMERE | MEROPENEM AND VABORBACTAM | REMPLEX PHARMACEUTICALS INC | 29-Aug-2017 | Treatment of patients 18 years of age and older with complicated Urinary Tract Infections (cUTI), including pyelonephritis |
| NDA 209936 | ORIG - 1 | ALIQOPA | COPANLISIB HYDROCHLORIDE | BAYER HEALTHCARE PHARMACEUTICALS INC | 14-Sep-2017 | Treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies. |
| NDA 209363 | ORIG - 1 | SOLOSEC | SECNIDAZOLE | SYMBIOMIX THERAPEUTICS LLC | 15-Sep-2017 | Treatment of bacterial vaginosis in adult women. |
| NDA 208716 | ORIG - 1 | VERZENIO | ABEMACICLIB | ELI LILLY AND CO | 28-Sep-2017 | Treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting |
| NDA 209939 | ORIG - 1 | PREVMIS | LETERMOVIR | MERCK SHARP AND DOHME CORP ULTRAGENYX PHARMACEUTICAL INC | 08-Nov-2017 | Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMVseropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) |
| BLA 761047 | ORIG - 1 | MEPSEVII | VESTRONIDASE ALFA-VJBK | PHARMACEUTICAL INC | 15-Nov-2017 | Treatment of Mucopolysaccharidosis type VII (MPS VII, Sly syndrome) |
| NDA 209819 | ORIG - 1 | SUBLOCADE | BUPRENORPHINE | INDIVIOR INC | 30-Nov-2017 | Treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days |

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