

CY 2018 CDER Drug and Biologic Calendar Year Priority Approvals As of December 31, 2018

This report reflects the data shown as it is identified in the database.

Selection Criteria:

User Response: Start Date: 1/1/2018 End Date: 12/31/2018

Sort Order: Approval Date

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
NDA 208700	LUTATHERA	LUTETIUM LU 177 DOTATATE	ADVANCED ACCELERATOR APPLICATIONS USA INC	P,O	1/26/2018
NDA 208910	FIRVANQ	VANCOMYCIN HYDROCHLORIDE	RXMTM THERAPEUTICS LLC A WHOLLY OWNED SUB OF CUTISPHARMA INC	P	1/26/2018
NDA 210251	BIKTARVY	BICTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INC	P	2/7/2018
NDA 210237 (2)		DOLUTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE TABLETS	MYLAN LABORATORIES LTD	P	2/9/2018
NDA 210491	SYMDEKO	TEZACAFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS INC	P,O	2/12/2018
NDA 210951	ERLEADA	APALUTAMIDE	JANSSEN BIOTECH INC	P	2/14/2018
NDA 210563	IMBRUVICA	IBRUTINIB	PHARMACYCLICS LLC	P,O	2/16/2018
NDA 208653	APADAZ	ACETAMINOPHEN AND BENZHYDROCODONE	KEMPHARM INC	P	2/23/2018
NDA 210850 (1)		SINCALIDE	MAIA PHARMACEUTICALS INC	P	2/23/2018
NDA 204441	JYNARQUE	TOLVAPTAN	OTSUKA PHARMACEUTICAL CO LTD	P,O	4/23/2018
NDA 209229	LUCEMYRA	LOFEXIDINE	US WORLDMEDS LLC	P	5/16/2018
NDA 210238	DOPTELET	AVATROMBOPAG	AKARX INC	P,O	5/21/2018
NDA 210867		MOXIDECTIN	MEDICINES DEVELOPMENT FOR GLOBAL HEALTH	P,O	6/13/2018
NDA 210303	ZEMDRI	PLAZOMICIN	ACHAOGEN INC	P	6/25/2018
NDA 210365	EPIDIOLEX	CANNABIDIOL	GW RESEARCH LTD	P,O	6/25/2018
NDA 212319		ATROPINE	RAFA LABORATORIES LTD	P	7/9/2018
NDA 208627	TPOXX	TECOVIRIMAT	SIGA TECHNOLOGIES INC	P,O	7/13/2018
NDA 210795	KRINTAFEL	TAFENOQUINE	GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LTD ENGLAND	P,O	7/20/2018
NDA 211192	TIBSOVO	IVOSIDENIB	AGIOS PHARMACEUTICALS INC	P,O	7/20/2018
NDA 210450	ORILISSA	ELAGOLIX SODIUM	ABBVIE INC	P	7/23/2018
NDA 210589	OMEGAVEN	FISH OIL TRIGLYCERIDES	FRESENIUS KABI USA LLC	P,O	7/27/2018
NDA 209607	AZEDRA	IOBENGUANE I 131	PROGENICS PHARMACEUTICALS INC	P,O	7/30/2018
NDA 210923	MULPLETA	LUSUTROMBOPAG	SHIONOGI INC	P	7/31/2018
NDA 211358	ORKAMBI	LUMACAFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS INC	P,O	8/7/2018
NDA 210607	ARAKODA	TAFENOQUINE	60 DEGREES PHARMACEUTICALS LLC	P	8/8/2018
NDA 210880 (2)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	HETERO LABS LTD UNIT III	P	8/8/2018
NDA 208623	GALAFOLD	MIGALASTAT	AMICUS THERAPEUTICS US INC	P,O	8/10/2018
NDA 210922	ONPATTRO	PATISIRAN	ALNYLAM PHARMACEUTICALS INC	P,O	8/10/2018

NDA 210540 (2)		LOPINAVIR AND RITONAVIR	MYLAN LABORATORIES LTD	P	8/16/2018
NDA 206709	DIACOMIT	STIRIPENTOL	BIOCODEX SA	P,O	8/20/2018
NDA 207223	DIACOMIT	STIRIPENTOL	BIOCODEX SA	P,O	8/20/2018
NDA 211109	XERAVA	ERAVACYCLINE	TETRAPHASE PHARMACEUTICALS INC	P	8/27/2018
NDA 211155	COPIKTRA	DUVELISIB	VERASTEM INC	P,O	9/24/2018
NDA 211288	VIZIMPRO	DACOMITINIB	PFIZER INC	P,O	9/27/2018
NDA 207356	ARIKAYCE	AMIKACIN LIPOSOME INHALATION SUSPENSION	INSMED INC	P,O	9/28/2018
NDA 209816	NUZYRA	OMADACYCLINE	PARATEK PHARMACEUTICALS INC	P	10/2/2018
NDA 209817	NUZYRA	OMADACYCLINE	PARATEK PHARMACEUTICALS INC	P	10/2/2018
NDA 211172	TEGSEDI	INOTERSEN	AKCEA THERAPEUTICS INC	P,O	10/5/2018
NDA 211651	TALZENNA	TALAZOPARIB	PFIZER INC	P	10/16/2018
NDA 210854	XOFLUZA	BALOXAVIR MARBOXIL	GENENTECH INC	P	10/24/2018
NDA 210868	LORBRENA	LORLATINIB	PFIZER INC	P,O	11/2/2018
NDA 210910	AEMCOLO	RIFAMYCIN	COSMO TECHNOLOGIES LTD	P	11/16/2018
NDA 210656	DAURISMO	GLASDEGIB	PFIZER INC	P,O	11/21/2018
NDA 210861	VITRAKVI	LAROTRECTINIB	LOXO ONCOLOGY INC	P,O	11/26/2018
NDA 211710	VITRAKVI	LAROTRECTINIB	LOXO ONCOLOGY INC	P,O	11/26/2018
NDA 208078	FIRDAPSE	AMIFAMPRIDINE	CATALYST PHARMACEUTICALS INC	P,O	11/28/2018
NDA 211349	XOSPATA	GILTERITINIB	ASTELLAS PHARMA US INC	P,O	11/28/2018
NDA 210136 (1)	BRIXADI	BUPRENORPHINE	BRAEBURN PHARMACEUTICALS INC	P	12/21/2018

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761065	TROGARZO	IBALIZUMAB - UIYK	THERATECHNOLOGIES INC.	P,O	3/6/2018
BLA 761068	CRYSVITA	BUROSUMAB-TWZA	ULTRAGENYX PHARAMCEUTICAL INC.	P,O	4/17/2018
BLA 761079	PALYNZIQ	PEGVALIASE-PQPZ	BIOMARIN PHARMACEUTICAL INC.	P,O	5/24/2018
BLA 761051	POTELIGEO	MOGAMULIZUMAB-KPKC	KYOWA KIRIN, INC.	P,O	8/8/2018
BLA 761094	OXERVATE	CENEGERMIN-BKBJ	DOMPE FARMACEUTICI S.P.A.	P,O	8/22/2018
BLA 761090	TAKHZYRO	LANADELUMAB-FLYO	DYAX CORP.	P,O	8/23/2018
BLA 761104	LUMOXITI	MOXETUMOMAB PASUDOTOX-TDFK	ASTRAZENECA AB	P,O	9/13/2018
BLA 761089	AJOVY	FREMANEZUMAB-VFRM	TEVA BRANDED PHARMACEUTICAL PRODUCTS R&	P	9/14/2018
BLA 761097	LIBTAYO	CEMIPLIMAB-RWLC	REGENERON PHARMACEUTICALS, INC.	P	9/28/2018
BLA 761092	REVCovi	ELAPEGADEMASE-LVLR	LEADIANT BIOSCIENCES, INC.	P,O	10/5/2018
BLA 761107	GAMIFANT	EMAPALUMAB-LZSG	NOVIMMUNE SA	P,O	11/20/2018
BLA 761108	ULTOMIRIS	RAVULIZUMAB-CWVZ	ALEXION PHARMACEUTICALS, INC.	P,O	12/21/2018
BLA 761116	ELZONRIS	TAGRAXOFUSP-ERZS	STEMLINE THERAPEUTICS INC	P,O	12/21/2018

(1) Application has been tentatively approved.

(2) Application has been tentatively approved or approved under PEPFAR.

Review Classification:

P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.

O - Orphan Designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).