

CY 2019 CDER Drug and Biologic Calendar Year Priority Approvals As of December 31, 2019

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

Selection Criteria:

User Response: Start Date: 1/1/2019 End Date: 12/31/2019

Sort Order: Approval Date

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
NDA 208711	EGATEN	TRICLABENDAZOLE	NOVARTIS PHARMACEUTICALS CORP	P,O	2/13/2019
NDA 211962		VANCOMYCIN INJECTION	XELLIA PHARMACEUTICALS APS	P	2/15/2019
NDA 211243	SPRAVATO	ESKETAMINE	JANSSEN PHARMACEUTICALS INC	P	3/5/2019
NDA 210649		EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS,	MACLEODS PHARMACEUTICALS LTD	P	3/15/2019
NDA 211371	ZULRESSO	BREXANOLONE	SAGE THERAPEUTICS INC	P	3/19/2019
NDA 210796 (2)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE TABLETS	MACLEODS PHARMACEUTICALS LTD	P	3/25/2019
NDA 209884	MAYZENT	SIPONIMOD	NOVARTIS PHARMACEUTICALS CORP	P	3/26/2019
NDA 211994	DOVATO	DOLUTEGRAVIR AND LAMIVUDINE	VIIV HEALTHCARE CO	P	4/8/2019
NDA 212018	BALVERSA	ERDAFITINIB	JANSSEN BIOTECH INC	P	4/12/2019
NDA 210660	ELCYS	CYSTEINE HYDROCHLORIDE INJECTION	EXELA PHARMA SCIENCES LLC	P	4/16/2019
NDA 209964	CORLANOR	IVABRADINE	AMGEN INC	P,O	4/22/2019
NDA 209379		SELENIOS ACID INJECTION	AMERICAN REGENT INC	P	4/30/2019
NDA 211996	VYNDAQUEL	TAFAMIDIS MEGLUMINE	FOLDRIX PHARMACEUTICALS INC SUB PFIZER INC	P,O	5/3/2019
NDA 209321	RUZURGI	AMIFAMPRIDINE	JACOBUS PHARMACEUTICAL CO INC	P,O	5/6/2019
NDA 212526	PIQRAY	ALPELISIB	NOVARTIS PHARMACEUTICALS CORP	P	5/24/2019
NDA 212306		SELINEXOR	KARYOPHARM THERAPEUTICS INC	P,O	7/3/2019
NDA 212819	RECARBRIO	IMIPENEM, CILASTATIN,AND RELEBACTAM	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	P	7/16/2019
NDA 212099	NUBEQA	DAROLUTAMIDE	BAYER HEALTHCARE PHARMACEUTICALS INC	P	7/30/2019
NDA 211810	TURALIO	PEXIDARTINIB	DAIICHI SANKYO INC	P,O	8/2/2019
NDA 211150	WAKIX	PITOLISANT	HARMONY BIOSCIENCES LLC	P,O	8/14/2019
NDA 212862		PRETOMANID	THE GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT	P,O	8/14/2019
NDA 212725	ROZLYTREK	ENTRECTINIB	GENENTECH INC	P,O	8/15/2019
NDA 211675	RINVOQ	UPADACITINIB	ABBVIE INC	P	8/16/2019
NDA 212327	INREBIC	FEDRATINIB	IMPACT BIOMEDICINES INC A WHOLLY OWNED SUB OF CELGENE CORP	P,O	8/16/2019
NDA 211672	XENLETA	LEFAMULIN	NABRIVA THERAPEUTICS IRELAND DAC	P	8/19/2019
NDA 211673	XENLETA	LEFAMULIN	NABRIVA THERAPEUTICS IRELAND DAC	P	8/19/2019
NDA 212477	HARVONI	LEDIPASVIR	GILEAD SCIENCES INC	P,O	8/28/2019
NDA 212480	SOVALDI	SOFOSBUVIR	GILEAD SCIENCES INC	P,O	8/28/2019
NDA 212121		POTASSIUM PHOSPHATES INJECTION, USP, PHOSPHORUS 3 MMOL/ML AND POTASSIUM 4.7 MEQ/ML	CMP DEVELOPMENT LLC	P	9/19/2019
NDA 213051	RYBELSUS	SEMAGLUTIDE	NOVO NORDISK INC	P	9/20/2019

NDA 210797	SCENESSE	AFAMELANOTIDE	CLINUVEL INC	P,O	10/8/2019
NDA 212273	TRIKAFTA	ELEXACAFTOR, TEZACAFTOR AND IVACAFTOR TABLETS; IVACAFTOR TABLETS	VERTEX PHARMACEUTICALS INC	P,O	10/21/2019
NDA 213004	TALICIA	OMEPRAZOLE MAGNESIUM, AMOXICILLIN AND RIFABUTIN	REDHILL BIOPHARMA LTD	P	11/1/2019
NDA 209445	FETROJA	CEFIDEROCOL	SHIONOGI INC	P	11/14/2019
NDA 213217	BRUKINSA	ZANUBRUTINIB	BEIGENE USA INC	P,O	11/14/2019
NDA 212194	GIVLAARI	GIVOSIRAN	ALNYLAM PHARMACEUTICALS INC	P,O	11/20/2019
NDA 213137	OXBRYTA	VOXELOTOR	GLOBAL BLOOD THERAPEUTICS INC	P,O	11/25/2019
NDA 212832		POTASSIUM PHOSPHATES	FRESENIUS KABI USA LLC	P	11/26/2019
NDA 211970	VYONDYS 53	GOLODIRSEN	SAREPTA THERAPEUTICS INC	P,O	12/12/2019
NDA 212535	NOURESS	CYSTEINE HYDROCHLORIDE INJECTION	AVADEL LEGACY PHARMACEUTICALS LLC	P	12/13/2019
NDA 209569	TISSUEBLUE	BRILLIANT BLUE G OPHTHALMIC SOLUTION	DUTCH OPHTHALMIC RESEARCH CENTER INTERNATIONAL BV	P,O	12/20/2019

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761112	CABLIVI	CAPLACIZUMAB-YHDP	ABLYNX NV	P,O	2/6/2019
BLA 761121	POLIVY	POLATUZUMAB VEDOTIN-PIIQ	GENENTECH, INC.	P,O	6/10/2019
BLA 761125	BEOVU	BROLUCIZUMAB-DBLL	NOVARTIS PHARMACEUTICALS CORPORATION	P	10/7/2019
BLA 761136	REBLOZYL	LUSPATERCEPT – AAMT	CELGENE CORPORATION	P,O	11/8/2019
BLA 761128	ADAKVEO	CRIZANLIZUMAB-TMCA	NOVARTIS PHARMACEUTICALS CORPORATION	P,O	11/15/2019
BLA 761137	PADCEV	ENFORTUMAB VEDOTIN-EJFV	ASTELLAS PHARMA US, INC.	P	12/18/2019
BLA 761139	ENHERTU	FAM-TRASTUZUMAB DERUXTECAN-NXKI	DAIICHI SANKYO, INC.	P	12/20/2019

(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).