

**CY 2019 CDER Drug and Biologic Calendar Year 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

New Drug Application (NDA) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	505(B)(2) APPROVAL	APPROVAL DATE
NDA 210884	TOSYMRA	SUMATRIPTAN	DR REDDYS LABORATORIES INC	S	Y	1/25/2019
NDA 211530 (1)		BENDAMUSTINE	HOSPIRA A PFIZER CO	S	Y	1/29/2019
NDA 209905	EVEKEO ODT	AMPHETAMINE SULFATE	ARBOR PHARMACEUTICALS LLC	S	Y	1/30/2019
NDA 210942	GLOPERBA	COLCHICINE	ROMEG THERAPEUTICS LLC	S	Y	1/30/2019
NDA 210787 (2)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE TABLETS	LAURUS LABS LTD	S	Y	2/1/2019
NDA 208711	EGATEN	TRICLABENDAZOLE	NOVARTIS PHARMACEUTICALS CORP	P,O		2/13/2019
NDA 211962		VANCOMYCIN INJECTION	XELLIA PHARMACEUTICALS APS	P	Y	2/15/2019
NDA 208219	LOTEMAX SM	LOTEPREDNOL ETABONATE OPHTHALMIC GEL	BAUSCH AND LOMB INC	S		2/22/2019
NDA 212038	ADHANSIA XR	METHYLPHENIDATE HYDROCHLORIDE	PURDUE PHARMA LP	S	Y	2/27/2019
NDA 212035 (1)		ARGATROBAN	ACCORD HEALTHCARE INC	S	Y	2/28/2019
NDA 211243	SPRAVATO	ESKETAMINE	JANSSEN PHARMACEUTICALS INC	P		3/5/2019
NDA 208259	ROCKLATAN	NETARSUDIL AND LATANOPROST OPHTHALMIC SOLUTION	AERIE PHARMACEUTICALS INC	S	Y	3/12/2019
NDA 210821		TETRACAINE HYDROCHLORIDE	PARAGON BIOTECK INC	S	Y	3/12/2019
NDA 210649		EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS,	MACLEODS PHARMACEUTICALS LTD	P	Y	3/15/2019
NDA 211225	ZYKADIA	CERITINIB	NOVARTIS PHARMACEUTICALS CORP	S,O		3/18/2019
NDA 211371	ZULRESSO	BREXANOLONE	SAGE THERAPEUTICS INC	P		3/19/2019
NDA 211230	SUNOSI	SOLRIAMFETOL	JAZZ PHARMACEUTICALS IRELAND LTD	S,O		3/20/2019
NDA 210796 (2)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE TABLETS	MACLEODS PHARMACEUTICALS LTD	P	Y	3/25/2019
NDA 209884	MAYZENT	SIPONIMOD	NOVARTIS PHARMACEUTICALS CORP	P		3/26/2019
NDA 206089	JATENZO	TESTOSTERONE UNDECANOATE	CLARUS THERAPEUTICS INC	S	Y	3/27/2019
NDA 022561	MAVENCLAD	CLADRIBINE	EMD SERONO INC	S		3/29/2019
NDA 202408	AVACLYR	ACYCLOVIR OPHTHALMIC OINTMENT	FERA PHARMACEUTICALS LLC	S,O	Y	3/29/2019
NDA 210595	DUAKLIR PRESSAIR	ACLIDINIUM BROMIDE/FORMOTEROL FUMARATE DIHYDRATE INHALATION POWDER	ASTRAZENECA PHARMACEUTICALS LP	S		3/29/2019
NDA 210895	WELCHOL	COLESEVELAM HCL	DAIICHI SANKYO INC	S		4/3/2019
NDA 211994	DOVATO	DOLUTEGRAVIR AND LAMIVUDINE	VIIV HEALTHCARE CO	P		4/8/2019
NDA 210632		LEVOTHYROXINE SODIUM INJECTION	FRESENIUS KABI USA LLC	S	Y	4/11/2019
NDA 212018	BALVERSA	ERDAFITINIB	JANSSEN BIOTECH INC	P		4/12/2019
NDA 212020		TRANEXAMIC ACID	EXELA PHARMA SCIENCES LLC	S	Y	4/15/2019
NDA 210660	ELCYS	CYSTEINE HYDROCHLORIDE INJECTION	EXELA PHARMA SCIENCES LLC	P	Y	4/16/2019
NDA 209964	CORLANOR	IVABRADINE	AMGEN INC	P,O		4/22/2019
NDA 209354	DUOBRII	HALOBETASOL PROPIONATE AND TAZAROTENE	BAUSCH HEALTH AMERICAS INC	S		4/25/2019
NDA 210872	ZURAGARD	ISOPROPYL ALCOHOL	ZUREX PHARMA	S	Y	4/26/2019
NDA 209379		SELENIOS ACID INJECTION	AMERICAN REGENT INC	P	Y	4/30/2019

NDA 210874	QTERNMET XR	DAPAGLIFLOZIN, SAXAGLIPTIN, AND METFORMIN HYDROCHLORIDE	ASTRAZENECA AB	S		5/2/2019
NDA 211996	VYNDAQUEL	TAFAMIDIS MEGLUMINE	FOLDRX PHARMACEUTICALS INC SUB PFIZER INC	P,O		5/3/2019
NDA 212161	VYNDAMAX	TAFAMIDIS	FOLDRX PHARMACEUTICALS INC SUB PFIZER INC	S,O		5/3/2019
NDA 209321	RUZURGI	AMIFAMPRIDINE	JACOBUS PHARMACEUTICAL CO INC	P,O		5/6/2019
NDA 211321	NAYZILAM	MIDAZOLAM	UCB INC	S,O	Y	5/17/2019
NDA 211367	SLYND	DROSPIRENONE	EXELTIS USA INC	S	Y	5/23/2019
NDA 212526	PIQRAY	ALPELISIB	NOVARTIS PHARMACEUTICALS CORP	P		5/24/2019
NDA 208157	MYXREDLIN	INSULIN HUMAN IN SODIUM CHLORIDE INJECTION	BAXTER HEALTHCARE CORP	S	Y	6/20/2019
NDA 210557	VYLEESI	BREMELANOTIDE	AMAG PHARMACEUTICALS INC	S		6/21/2019
NDA 211843	THIOLA EC	TIOPRONIN	MISSION PHARMACAL CO	S,O	Y	6/28/2019
NDA 212306	XPOVIO	SELINEXOR	KARYOPHARM THERAPEUTICS INC	P,O		7/3/2019
NDA 211340		AMLODIPINE BENZOATE	SILVERGATE PHARMACEUTICALS INC	S	Y	7/8/2019
NDA 212819	RECARBRIO	IMIPENEM, CILASTATIN,AND RELEBACTAM	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	P		7/16/2019
NDA 209377		ZINC SULFATE	AMERICAN REGENT INC	S	Y	7/18/2019
NDA 212516	DRIZALMA SPRINKLE	DULOXETINE DELAYED-RELEASE CAPSULES	SUN PHARMA GLOBAL FZE	S	Y	7/19/2019
NDA 210134	BAQSIMI	GLUCAGON	ELI LILLY AND CO	S		7/24/2019
NDA 211215	ANGIOMAX RTU	BIVALIRUDIN	MAIA PHARMACEUTICALS INC	S	Y	7/25/2019
NDA 212320	ACCRUFER	FERRIC MALTOL	SHIELD TX UK LTD	S	Y	7/25/2019
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 210063		FULVESTRANT	TEVA PHARMACEUTICALS USA INC	S	Y	8/19/2019
NDA 210828		GA-68-DOTATOC	UNIV IOWA HOSPS AND CLINICS PET IMAGING CENTER	S,O	Y	8/21/2019
NDA 022075	NOURIANZ	ISTRADEFYLLINE	KYOWA KIRIN INC	S		8/27/2019
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 212595	RIOMET ER	METFORMIN HYDROCHLORIDE FOR EXTENDED-RELEASE ORAL SUSPENSION)	SUN PHARMACEUTICAL INDUSTRIES LTD	S	Y	8/29/2019
NDA 212097	GVOKE (GLUCAGON)	GLUCAGON	XERIS PHARMACEUTICALS INC	S	Y	9/10/2019
NDA 210865 (2)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFOVIR ALAFENAMIDE	MYLAN LABORATORIES LTD	S	Y	9/11/2019
NDA 211801	IBSRELA	TENAPANOR	ARDELYX INC	S		9/12/2019
NDA 208193	OZOBAX	BACLOFEN	METACEL PHARMACEUTICALS LLC	S,O	Y	9/18/2019
NDA 212121		POTASSIUM PHOSPHATES INJECTION, USP, PHOSPHORUS 3 MMOL/ML AND POTASSIUM 4.7 MEQ/ML	CMP DEVELOPMENT LLC	P	Y	9/19/2019
NDA 213051	RYBELSUS	SEMAGLUTIDE	NOVO NORDISK INC	P		9/20/2019
NDA 211379	DEXAMETHASONE	DEXAMETHASONE	DEXCEL PHARMA TECHNOLOGIES LTD	S,O	Y	10/3/2019
NDA 206927		BORTEZOMIB	DR REDDYS LABORATORIES LTD	S	Y	10/4/2019
NDA 211415	QUZYTIR	CETIRIZINE HYDROCHLORIDE	JDP THERAPEUTICS LLC	S	Y	10/4/2019
NDA 211527	AKLIEF	TRIFAROTENE	GALDERMA RESEARCH AND DEVELOPMENT INC	S		10/4/2019
NDA 211939	BONSITY	TERIPARATIDE	ALVOGEN MALTA OPERATIONS LTD	S	Y	10/4/2019
NDA 210797	SCENESSE	AFAMELANOTIDE	CLINUVEL INC	P,O		10/8/2019
NDA 200655		[F-18] FLUORODOPA (FDOPA)	FEINSTEIN INSTITUTE MEDICAL RESEARCH	S	Y	10/10/2019

NDA 211280	REYVOW	LASMITAN	ELI LILLY AND CO	S	Y	10/11/2019
NDA 212268	SECUADO	ASENAPINE	HISAMITSU PHARMACEUTICAL CO INC	S	Y	10/11/2019
NDA 212379	AMZEEQ	MINOCYCLINE	FOAMIX PHARMACEUTICALS INC	S	Y	10/18/2019
NDA 212273	TRIKAFTA	ELEXACAFTOR, TEZACAFTOR AND IVACAFTOR TABLETS; IVACAFTOR TABLETS	VERTEX PHARMACEUTICALS INC	P,O		10/21/2019
NDA 212909	BIORPHEN	PHENYLEPHRINE HYDROCHLORIDE	ETON PHARMACEUTICALS	S	Y	10/21/2019
NDA 212436	IBRANCE	PALBOCICLIB	PFIZER INC	S		11/1/2019
NDA 213004	TALICIA	OMEPRAZOLE MAGNESIUM, AMOXICILLIN AND RIFABUTIN	REDHILL BIOPHARMA LTD	P	Y	11/1/2019
NDA 209359		EPINEPHRINE	HOSPIRA INC	S		11/5/2019
NDA 211913	ABSORICA LD	ISOTRETINOIN	SUN PHARMACEUTICAL INDUSTRIES LTD	S	Y	11/5/2019
NDA 212279	EXEM FOAM	AIR POLYMER-TYPE A	GISKIT BV	S	Y	11/7/2019
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 212839	XCOPRI	CENOBAMATE	SK LIFE SCIENCE INC	S		11/21/2019
NDA 207937 (1)		CABAZITAXEL	FRESENIUS KABI USA LLC	S	Y	11/22/2019
NDA 212640	EXSERVAN	RILUZOLE	AQUESTIVE THERAPEUTICS	S,O	Y	11/22/2019
NDA 213137	OXBRYTA	VOXELOTOR	GLOBAL BLOOD THERAPEUTICS INC	P,O		11/25/2019
NDA 212832		POTASSIUM PHOSPHATES	FRESENIUS KABI USA LLC	P	Y	11/26/2019
NDA 210737	REDITREX	METHOTREXATE	CUMBERLAND PHARMACEUTICALS INC	S		11/27/2019
NDA 211970	VYONDYS 53	GOLODIRSEN	SAREPTA THERAPEUTICS INC	P,O		12/12/2019
NDA 212535	NOURESS	CYSTEINE HYDROCHLORIDE INJECTION	AVADEL LEGACY PHARMACEUTICALS LLC	P	Y	12/13/2019
NDA 211882	ARALZO	TAZAROTENE	BAUSCH HEALTH AMERICAS INC	S	Y	12/18/2019
NDA 212895	CONJUPRI	LEVAMLODIPINE MALEATE	CSPC OUYI PHARMACEUTICAL CO LTD	S	Y	12/19/2019
NDA 202860	GENOSYL	NITRIC OXIDE	VERO BIOTECH	S,O	Y	12/20/2019
NDA 209500	CAPLYTA	LUMATEPERONE	INTRA-CELLULAR THERAPIES INC	S		12/20/2019
NDA 209569	TISSUEBLUE	BRILLIANT BLUE G OPHTHALMIC SOLUTION	DUTCH OPHTHALMIC RESEARCH CENTER INTERNATIONAL BV	P,O	Y	12/20/2019
NDA 212028	DAYVIGO	LEMBOREXANT	EISAI INC	S		12/20/2019
NDA 211765	UBREVLY	UBROGEPANT	ALLERGAN SALES LLC	S		12/23/2019

New Drug Application (NDA) Approvals with Prior Tentative Approval(s):

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	TENTATIVE APPROVAL DATE
NDA 211929	ORTIKOS	BUDESONIDE	SUN PHARMA GLOBAL FZE	S	6/13/2019	1/30/2019, 4/18/2019
NDA 210326		FULVESTRANT	FRESENIUS KABI USA LLC	S	5/20/2019	6/29/2018
NDA 210064		FOSAPREPITANT	TEVA PHARMACEUTICALS USA	S	9/5/2019	10/12/2017
NDA 209472	PEMFEXY	PEMETREXED INJECTION	EAGLE PHARMACEUTICALS INC	S		10/26/2017 , 10/9/2019
NDA 211855	VUMERITY	DIROXIMEL FUMARATE	BIOGEN	S	10/29/2019	10/11/2019
NDA 209359	ABBOJECT SYRINGE	EPINEPHRINE	HOSPIRA INC	S	11/5/2019	11/29/2017

Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761085	JEUVEAU	PRABOTULINUMTOXINA-XVFS	EVOLUS INC.	S	2/1/2019
BLA 761112	CABLIVI	CAPLACIZUMAB-YHDP	ABLYNX NV	P,O	2/6/2019
BLA 761106	HERCEPTIN HYLECTA	TRASTUZUMAB AND HYALURONIDASE-OYSK	GENENTECH, INC.	S	2/28/2019
BLA 761062	EVENITY	ROMOSOZUMAB-AQQG	AMGEN, INC.	S	4/9/2019
BLA 761105	SKYRIZI	RISANKIZUMAB-RZAA	ABBVIE INC.	S	4/23/2019
BLA 761122	NUCALA	MEPOLIZUMAB	GLAXOSMITHKLINE LLC	S	6/6/2019
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.
market exclusivity and/or patent term of the listed drug upon which the application relies, has expired.

Review Classification:

- P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.
- S - Standard Review - Products that do not qualify for priority review.
- O - Orphan Designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).