

**CY 2018 CDER Drug and Biologic Calendar Year 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

**New Drug Application (NDA) Approvals:**

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	505(B)(2) APPROVAL	APPROVAL DATE
NDA 208612	BALCOLTRA	LEVONORGESTREL AND ETHINYL ESTRADIOL TABLETS AND FERROUS BISGLYCINATE TABLETS	AVION PHARMACEUTICALS LLC	S	Y	1/9/2018
NDA 208744		TIGECYCLINE	ACCORD HEALTHCARE INC USA	S	Y	1/18/2018
NDA 205493 (2)		LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS	MICRO LABS LTD INDIA	S		1/25/2018
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	Y	1/26/2018
NDA 209260		ATROPINE SULFATE	FRESENIUS KABI USA LLC	S	Y	1/26/2018
NDA 210428		METOPROLOL SUCCINATE EXTENDED-RELEASE	SUN PHARMA INDUSTRIES LTD	S	Y	1/26/2018
NDA 210251	BIKTARVY	BICTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INC	P		2/7/2018
NDA 202158	RADIOGENIX SYSTEM	SODIUM PERTECHNETATE TC99M INJECTION USP	NORTHSTAR MEDICAL RADIOISOTOPES LLC	S	Y	2/8/2018
NDA 208912	DEXYCU	DEXAMETHASONE	ICON BIOSCIENCE INC	S	Y	2/9/2018
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 209410	OSMOLEX ER	AMANTADINE	OSMOTICA PHARMACEUTICAL	S	Y	2/16/2018
NDA 210563	IMBRUVICA	IBRUTINIB	PHARMACYCLICS LLC	P,O		2/16/2018
NDA 209764 (1)	LUSDUNA	INSULIN GLARGINE INJECTION	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	S		2/22/2018
NDA 205389 (2)		EFAVIRENZ TABLETS	MICRO LABS LTD INDIA	S		2/23/2018
NDA 208653	APADAZ	ACETAMINOPHEN AND BENZHYDROCODONE	KEMPHARM INC	P	Y	2/23/2018
NDA 210850 (1)		SINCALIDE	MAIA PHARMACEUTICALS INC	P		2/23/2018
NDA 207962	ZTLIDO	LIDOCAINE TOPICAL SYSTEM	SCILEX PHARMACEUTICALS	S	Y	2/28/2018
NDA 210661 (1)		PEMETREXED	APOTEX INC	S	Y	3/28/2018
NDA 209299	TAVALISSE	FOSTAMATINIB	RIGEL PHARMACEUTICALS INC	S,O		4/17/2018
NDA 210493	AKYNZEO	FOSNETUPITAN AND PALONOSETRON	HELSINN HEALTHCARE SA	S		4/19/2018
NDA 204441	JYNARQUE	TOLVAPTAN	OTSUKA PHARMACEUTICAL CO LTD	P,O		4/23/2018
NDA 208085		HYDROCODONE BITARTRATE AND GUAIFENESIN	ECI PHARMACEUTICALS LLC	S	Y	4/25/2018
NDA 209381	PLENVU	POLYETHYLENE GLYCOL (PEG) 3350, SODIUM ASCORBATE, SODIUM SULFATE, ASCORBIC ACID, SODIUM CHLORIDE AND POTASSIUM CHLORIDE	SALIX PHARMACEUTICALS INC	S	Y	5/4/2018
NDA 209229	LUCEMYRA	LOFEXIDINE	US WORLDMEDS LLC	P		5/16/2018
NDA 207078	LOKELMA	SODIUM ZIRCONIUM CYCLOSILICATE	ASTRAZENECA PHARMACEUTICALS LP	S		5/18/2018
NDA 210238	DOPTELET	AVATROMBOPAG	AKARX INC	P,O		5/21/2018
NDA 210308	YONSA	ABIRATERONE ACETATE	SUN PHARMA GLOBAL FZE	S	Y	5/22/2018
NDA 210115	PROGRAF GRANULES	TACROLIMUS FOR ORAL SUSPENSION	ASTELLAS PHARMA US INC	S,O		5/24/2018
NDA 210566		HALOBETASOL PROPIONATE FOAM	THERAPEUTICS INC	S		5/24/2018
NDA 208564	IMVEXXY	ESTRADIOL VAGINAL INSERTS	THERAPEUTICSMD INC	S	Y	5/29/2018
NDA 207924	OLUMIANT	BARICITINIB	ELI LILLY AND CO	S		5/31/2018
NDA 210045	CONSENSI	AMLODIPINE AND CELECOXIB	KITOV PHARMACEUTICALS LTD	S	Y	5/31/2018
NDA 210867		MOXIDECTIN	MEDICINES DEVELOPMENT FOR GLOBAL HEALTH	P,O		6/13/2018
NDA 209844	LYMEPAK	DOXYCYCLINE HYCLATE TABLETS	CHARTWELL PHARMA NDA B2 HOLDINGS	S	Y	6/15/2018
NDA 022517	NOCDURNA	DESMOPRESSIN ACETATE	FERRING PHARMACEUTICALS INC	S		6/21/2018
NDA 207987	ABLYSINOL	DEHYDRATED ALCOHOL	BELCHER PHARMACEUTICALS LLC	S,O	Y	6/21/2018
NDA 210303	ZEMDRI	PLAZOMICIN	ACHAOGEN INC	P		6/25/2018

NDA 210365	EPIDIOLEX	CANNABIDIOL	GW RESEARCH LTD	P,O		6/25/2018
NDA 210496	BRAFTOVI	ENCORAFENIB	ARRAY BIOPHARMA INC	S,O		6/27/2018
NDA 210498	MEKTOVI	BINIMETINIB	ARRAY BIOPHARMA INC	S,O		6/27/2018
NDA 210361	QBREXZA	GLYCOPYRRONIUM	DERMIRA INC	S	Y	6/28/2018
NDA 210793	NUPLAZID	PIMAVANSERIN	ACADIA PHARMACEUTICALS INC	S		6/28/2018
NDA 209830	ARISTADA INITIO	ARIPIRAZOLE LAUROXIL	ALKERMES INC	S	Y	6/29/2018
NDA 210326 (1)		FULVESTRANT	FRESENIUS KABI USA LLC	S	Y	6/29/2018
NDA 212319		ATROPINE	RAFA LABORATORIES LTD	P	Y	7/9/2018
NDA 209481		VANCOMYCIN HYDROCHLORIDE	MYLAN LABORATORIES LTD	S	Y	7/10/2018
NDA 210997	GLYRX-PF	GLYCOPYRROLATE	EXELA PHARMA SCIENCES LLC	S	Y	7/11/2018
NDA 208627	TPOXX	TECOVIRIMAT	SIGA TECHNOLOGIES INC	P,O		7/13/2018
NDA 208313	INFUGEM	GEMCITABINE IN 0.9% SODIUM CHLORIDE INJECTION	SUN PHARMACEUTICAL INDUSTRIES LTD	S	Y	7/16/2018
NDA 210455	SYM TUZA	DARUNAVIR, COBICISTAT, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	JANSSEN PRODUCTS LP	S		7/17/2018
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 208614		DOXERCALCIFEROL	HOSPIRA INC	S	Y	7/24/2018
NDA 210589	OMEGAVEN	FISH OIL TRIGLYCERIDES	FRESENIUS KABI USA LLC	P,O		7/27/2018
NDA 210655	PERSERIS	RISPERIDONE	INDIVIOR INC	S	Y	7/27/2018
NDA 208276	REMODULIN	TREPROSTINIL	UNITED THERAPEUTICS CORP	S,O		7/30/2018
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 211158		TIGECYCLINE	AMNEAL PHARMACEUTICALS LLC	S	Y	8/2/2018
NDA 211358	ORKAMBI	LUMACAFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS INC	P,O		8/7/2018
NDA 208288	SOLUPREP	2% CHLORHEXIDINE GLUCONATE AND 70% ISOPROPYL ALCOHOL	3M HEALTH CARE INFECTION PREVENTION DIV	S	Y	8/8/2018
NDA 209311	JORNAY PM	METHYLPHENIDATE HYDROCHLORIDE	IRONSHORE PHARMACEUTICALS AND DEVELOPMENT INC	S	Y	8/8/2018
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 209627	ANNOVERA	SEGESTERONE ACETATE AND ETHINYL ESTRADIOL VAGINAL SYSTEM	THERAPEUTICSMO INC	S	Y	8/10/2018
NDA 210922	ONPATTRO	PATISIRAN	ALNYLAM PHARMACEUTICALS INC	P,O		8/10/2018
NDA 205626		LAMIVUDINE, NEVIRAPINE AND ZIDOVUDINE	MICRO LABS LTD	S	Y	8/13/2018
NDA 210913	CEQUA	CYCLOSPORINE OPHTHALMIC SOLUTION	SUN PHARMA GLOBAL FZE	S	Y	8/14/2018
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 210565	INVELTYS	LOTEPREDNOL ETABONATE OPHTHALMIC SUSPENSION	KALA PHARMACEUTICALS INC	S	Y	8/22/2018
NDA 209353	ALTRENO	TRETINOIN	DOW PHARMACEUTICAL SCIENCES INC	S		8/23/2018
NDA 211109	XERAVA	ERAVACYCLINE	TETRAPHASE PHARMACEUTICALS INC	P		8/27/2018
NDA 205054	LUTRATE DEPOT	LEUPROLIDE ACETATE FOR DEPOT SUSPENSION	GP-PHARM SA	S	Y	8/28/2018
NDA 210806	PIFELTRO	DORAVIRINE	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	S		8/30/2018
NDA 210807	DELSTRIGO	DORAVIRINE, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	S	Y	8/30/2018
NDA 209080	TIGLUTIK	RILUZOLE	ITALFARMACO SPA	S,O	Y	9/5/2018
NDA 208042	CASSIPA	BUPRENORPHINE AND NALOXONE	TEVA PHARMACEUTICALS USA INC	S	Y	9/7/2018
NDA 206185	XELPROS	LATANOPROST	SUN PHARMA GLOBAL FZE	S	Y	9/12/2018
NDA 209566	SEIZALAM	MIDAZOLAM INJECTION	MERIDIAN MEDICAL TECHNOLOGIES INC	S,O	Y	9/14/2018
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	Y	9/28/2018
NDA 209863	XYOSTED	TESTOSTERONE ENANTHATE	ANTARES PHARMA INC	S	Y	9/28/2018
NDA 209521	SEYSARA	SARECYCLINE	ALMIRALL LLC	S		10/1/2018
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 210331	YUTIQ	FLUOCINOLONE ACETONIDE INTRAVITREAL IMPLANT	EYEPOINT PHARMACEUTICALS INC	S		10/12/2018
NDA 211651	TALZENNA	TALAZOPARIB	PFIZER INC	P		10/16/2018
NDA 211210	QMIIZ ODT	MELOXICAM	TERSERA THERAPEUTICS LLC	S	Y	10/19/2018
NDA 211226	KHAPZORY	LEVOLEUCOVORIN	SPECTRUM PHARMACEUTICALS INC	S	Y	10/19/2018
NDA 210854	XOFLUZA	BALOXAVIR MARBOXIL	GENENTECH INC	P		10/24/2018
NDA 210132	BUJVA	ESTRADIOL AND PROGESTERONE	THERAPEUTICSMO INC	S	Y	10/28/2018
NDA 210906		CALCIUM GLUCONATE	HQ SPECIALTY PHARMA CORP	S	Y	10/29/2018
NDA 209128	DSUVIA	SUFENTANIL SUBLINGUAL TABLET	ACELRX PHARMACEUTICALS INC	S	Y	11/2/2018
NDA 210868	LORBRENA	LORLATINIB	PFIZER INC	P,O		11/2/2018
NDA 205920	PRIMATENE MIST	EPINEPHRINE	ARMSTRONG PHARMACEUTICALS INC	S	Y	11/7/2018
NDA 210598	YUPELRI	REVEFENACIN	MYLAN IRELAND LTD	S		11/9/2018
NDA 210296 (1)	BAFIERTAM	MONOMETHYL FUMARATE	BANNER LIFE SCIENCES LLC	S		11/16/2018
NDA 210910	AEMCOLO	RIFAMYCIN	COSMO TECHNOLOGIES LTD	P	Y	11/16/2018
NDA 211284	TEMIXYS	LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE	CELLTRION INC	S	Y	11/16/2018
NDA 207964	READYPREP CHG	CHLORHEXIDINE GLUCONATE	MEDLINE INDUSTRIES INC	S	Y	11/20/2018
NDA 210656	DAURISMO	GLASDEGIB	PFIZER INC	P,O		11/21/2018
NDA 211580	SPY AGENT GREEN	INDOCYANINE GREEN FOR INJECTION (USP)	NOVADAQ TECHNOLOGIES ULC	S	Y	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 209552		ARGATROBAN	AUROBINDO PHARMA LTD	S	Y	11/27/2018
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 208742	DEXTENZA	DEXAMETHASONE OPHTHALMIC INSERT	OCULAR THERAPEUTIX INC	S	Y	11/30/2018
NDA 208901	TOLSURA	ITRACONAZOLE CAPSULES	MAYNE PHARMA INTERNATIONAL PTY LTD	S	Y	12/11/2018
NDA 210166	MOTTEGRITY	PRUCALOPRIDE	SHIRE DEVELOPMENT LLC	S		12/14/2018
NDA 208647	EZALLOR	ROSUVASTATIN	SUN PHARMA GLOBAL FZE	S	Y	12/18/2018
NDA 206976	LICART	DICLOFENAC EPOLAMINE	INSTITUT BIOCHIMIQUE SA	S	Y	12/19/2018
NDA 204417	ELEPSIA XR	LEVETIRACETAM	SUN PHARMA GLOBAL FZE	S	Y	12/20/2018
NDA 209184	INBRUA	LEVODOPA INHALATION POWDER	ACORDA THERAPEUTICS INC	S	Y	12/21/2018
NDA 210136 (1)	BRIXADI	BUPRENORPHINE	BRAEBURN PHARMACEUTICALS INC	P	Y	12/21/2018

**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 207970		CABAZITAXEL	ACTAVIS LLC AN INDIRECT WHOLLY-OWNED SUB OF TEVA PHARMACEUTICALS USA INC	S		8/19/2015, 1/17/2018
NDA 208255	SYMFI LO	EFAVIRENZ, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	MYLAN PHARMACEUTICALS INC	P	2/5/2018	3/10/2017
NDA 022141		LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE	MYLAN LABORATORIES LTD	P	2/28/2018	9/12/2008
NDA 022142	SYMFI	EFAVIRENZ, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	MYLAN LABORATORIES LTD	P	3/22/2018	9/3/2009
NDA 022344		LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE	AUROBINDO PHARMA LTD	S	5/15/2018	1/7/2011
NDA 205580		BENDAMUSTINE HYDROCHLORIDE	EAGLE PHARMACEUTICALS INC	S,O	5/15/2018	7/2/2014, 3/30/2018
NDA 209191		BORTEZOMIB	HOSPIRA INC	S	7/12/2018	4/26/2017
NDA 022343		EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE	AUROBINDO PHARMA LTD	S	8/15/2018	6/26/2013
NDA 210833	SYMPAZAN	CLOBAZAM	AQUESTIVE THERAPEUTICS	S	11/1/2018	8/31/2018
NDA 209355	BRYHALI	HALOBETASOL PROPIONATE	DOW PHARMACEUTICAL SCIENCES INC	S	11/6/2018	10/5/2018

**Biologic License Application (BLA) Approvals:**

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761065	TROGARZO	IBALIZUMAB - UIYK	THERATECHNOLOGIES INC.	P,O	3/6/2018
BLA 761067	ILUMYA	TILDRAKIZUMAB - ASMN	MERCK SHARP & DOHME CORP.	S	3/20/2018
BLA 761068	CRYSVITA	BUROSUMAB-TWZA	ULTRAGENYX PHARMACEUTICAL INC.	P,O	4/17/2018
BLA 761077	AIMOVIG	ERENUMAB-AOOE	AMGEN, INC.	S	5/17/2018
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	CENERGERMIN-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&D, INC.	P	9/14/2018
BLA 761063	EMGALITY	GALCANEZUMAB-GNLM	ELI LILLY AND COMPANY	S	9/27/2018
BLA 761097	LIBTAYO	CEMPLIMAB-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 761102	ASPARLAS	CALASPARGASE PEGOL-MKNL	SERVIER PHARMACEUTICALS LLC	S,O	12/20/2018
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.

Tentative Approval (TA) is an action given to an application for a drug that meets all the requirements for approval; however, it may not be legally marketed in the U.S. until the 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).