

**CY 2017 CDER Drug and Biologic Calendar Year Approvals
As of December 31, 2017**

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

Selection Criteria:

User Response: Start Date: 1/1/2017 End Date: 12/31/2017

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 208603	ARYMO ER	MORPHINE SULFATE	EGALET CORP	S	Y	1/9/2017
NDA 208780	ESBRIET	PIRFENIDONE	GENENTECH INC	S,O		1/11/2017
NDA 207975	VANTRELA ER	HYDROCODONE BITARTRATE	TEVA BRANDED PHARMACEUTICAL PRODUCTS R AND D INC	S		1/17/2017
NDA 208552	RHOFADE	OXYMETAZOLINE HYDROCHLORIDE	ALLERGAN INC	S		1/18/2017
NDA 208745	TRULANCE	PLECANATIDE	SYNERGY PHARMACEUTICALS INC	S		1/19/2017
NDA 208264	TEPADINA	THIOTEPA	ADIENNE SA	S,O	Y	1/26/2017
NDA 208798	ARMONAIR RESPICLICK	FLUTICASONE PROPIONATE	TEVA PHARMACEUTICAL INDUSTRIES LTD	S	Y	1/27/2017
NDA 208799	AIRDUO RESPICLICK	FLUTICASONE PROPIONATE/SALMETEROL	TEVA PHARMACEUTICAL INDUSTRIES LTD	S	Y	1/27/2017
NDA 208943	CORPHEDRA	EPHEDRINE SULFATE	PAR STERILE PRODUCTS LLC	S	Y	1/27/2017
NDA 208510	VYVANSE	LISDEXAMFETAMINE DIMESYLATE	SHIRE DEVELOPMENT LLC	S		1/28/2017
NDA 209089	XYZAL ALLERGY 24HR	LEVOCETIRIZINE DIHYDROCHLORIDE	SANOFI-AVENTIS US LLC	S	Y	1/31/2017
NDA 209090	XYZAL ALLERGY 24HR	LEVOCETIRIZINE DIHYDROCHLORIDE	SANOFI-AVENTIS US LLC	S	Y	1/31/2017
NDA 208325	PARSABIV	ETELCALCETIDE	KAI PHARMACEUTICALS INC A WHOLLY OWNED SUBSIDIARY OF AMGEN INC	S		2/7/2017
NDA 208684	EMFLAZA	DEFLAZACORT	MARATHON PHARMACEUTICALS LLC	P,O	Y	2/9/2017
NDA 208685	EMFLAZA	DEFLAZACORT	MARATHON PHARMACEUTICALS LLC	P,O	Y	2/9/2017
NDA 209347		GANCICLOVIR	EXELA PHARMA SCIENCES LLC	S	Y	2/17/2017
NDA 209091	QTERN	DAPAGLIFLOZIN AND SAXAGLIPTIN	ASTRAZENECA AB	S		2/27/2017
NDA 208794	XERMEL0	TELOTRISTAT ETHYL	LEXICON PHARMACEUTICALS INC	P,O		2/28/2017
NDA 208609		EPHEDRINE SULFATE	AKORN INC	S	Y	3/1/2017
NDA 208715 (1)		CABAZITAXEL	SANDOZ INC	S	Y	3/2/2017
NDA 201656	NOCTIVA	DESMOPRESSIN	SERENITY PHARMACEUTICALS LLC	S	Y	3/3/2017
NDA 209387	NIPRIDE RTU	SODIUM NITROPRUSSIDE	EXELA PHARMA SCIENCES LLC	S	Y	3/8/2017
NDA 208255 (2)		EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE	MYLAN PHARMACEUTICALS INC	P	Y	3/10/2017
NDA 209092	KISQALI	RIBOCICLIB	NOVARTIS PHARMACEUTICALS CORP	P		3/13/2017
NDA 207145	XADAGO	SAFINAMIDE	NEWRON PHARMACEUTICALS US INC	S		3/21/2017
NDA 208854	SYMPROIC	NALDEMEDINE	SHIONOGI INC	S		3/23/2017
NDA 208447	ZEJULA	NIRAPARIB	TESARO INC	P,O		3/27/2017
NDA 208082	AUSTEDO	DEUTETRABENAZINE	TEVA BRANDED PHARMACEUTICAL PRODUCTS R AND D INC	S,O	Y	4/3/2017
NDA 208775 (2)		ABACAVIR AND LAMIVUDINE	CIPLA LTD	S	Y	4/6/2017
NDA 209241	INGREZZA	VALBENAZINE	NEUROCRINE BIOSCIENCES INC	P		4/11/2017
NDA 208083		CLINDAMYCIN	BAXTER HEALTHCARE CORP	S	Y	4/20/2017
NDA 209777	ROXYBOND	OXYCODONE HYDROCHLORIDE	INSPIRION DELIVERY SCIENCES LLC	P	Y	4/20/2017
NDA 208400	XATMEP	METHOTREXATE	SILVERGATE PHARMACEUTICALS INC	S,O	Y	4/25/2017
NDA 208400	XATMEP	METHOTREXATE	SILVERGATE PHARMACEUTICALS INC	S,O	Y	4/25/2017
NDA 209191 (1)		BORTEZOMIB	HOSPIRA INC	S	Y	4/26/2017
NDA 209259 (1)	XYROSA	DOXYCYCLINE	SUN PHARMACEUTICAL INDUSTRIES LTD	S	Y	4/26/2017
NDA 207997	RYDAPT	MIDOSTAURIN	NOVARTIS PHARMACEUTICALS CORP	P,O		4/28/2017
NDA 208743	TYMLOS	ABALOPARATIDE	RADIUS HEALTH INC	S		4/28/2017
NDA 208772	ALUNBRIG	BRIGATINIB	ARIAD PHARMACEUTICALS INC	P,O		4/28/2017
NDA 205555	STERITALC	TALC	NOVATECH SA	S,O	Y	5/1/2017
NDA 209935	KISQALI FEMARA CO-PACK	RIBOCICLIB , LETROZOLE	NOVARTIS PHARMACEUTICALS CORP	S		5/4/2017

NDA 207315 (2)		LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE	HETERO LABS LTD UNIT III	S	Y	5/5/2017
NDA 209176	RADICAVA	EDARAVONE	MITSUBISHI TANABE PHARMA CORP	S,O		5/5/2017
NDA 209269	MINOLIRA	MINOCYCLINE HYDROCHLORIDE	DR REDDYS LABORATORIES LTD	S	Y	5/8/2017
NDA 207968	JADENU SPRINKLE	DEFERASIROX	NOVARTIS PHARMACEUTICALS CORP	S,O		5/18/2017
NDA 208694	ZERVIAE	CETIRIZINE OPHTHALMIC SOLUTION	NICOX OPHTHALMICS INC	P	Y	5/30/2017
NDA 208630	GLEOLAN	AMINOLEVULINIC ACID HYDROCHLORIDE	NX DEVELOPMENT CORP	P,O	Y	6/6/2017
NDA 209512	NORVIR	RITONAVIR	ABBVIE INC	P,O		6/7/2017
NDA 207534	SYMJEPI	EPINEPHRINE INJECTION	ADAMIS PHARMACEUTICALS CORP	S	Y	6/15/2017
NDA 208418		CALCIUM GLUCONATE	FRESENIUS KABI USA LLC	S	Y	6/15/2017
NDA 205489	COTEMPLA XR-ODT	METHYLPHENIDATE	NEOS THERAPEUTICS INC	S	Y	6/19/2017
NDA 208610	BAXDELA	DELAFLOXACIN	MELINTA THERAPEUTICS INC	P		6/19/2017
NDA 208611	BAXDELA	DELAFLOXACIN	MELINTA THERAPEUTICS INC	P		6/19/2017
NDA 022063	MYDAYIS	MIXED SALTS OF A SINGLE-ENTITY AMPHETAMINE PRODUCT	SHIRE DEVELOPMENT LLC	S		6/20/2017
NDA 208383	BEVYXXA	BETRIXABAN	PORTOLA PHARMACEUTICALS INC	P		6/23/2017
NDA 208956	TRIPTODUR	TRIPTORELIN	ARBOR PHARMACEUTICALS LLC	S,O		6/29/2017
NDA 209463		PANTOPRAZOLE SODIUM	EXELA PHARMA SCIENCES LLC	S	Y	6/30/2017
NDA 209400		OMEPRAZOLE	DEXCEL PHARMA TECHNOLOGIES LTD	S	Y	7/5/2017
NDA 208587	ENDARI	L-GLUTAMINE	EMMAUS MEDICAL INC	S,O	Y	7/7/2017
NDA 208379	ZYPITAMAG	PITAVASTATIN	ZYDUS PHARMACEUTICALS USA INC	S	Y	7/14/2017
NDA 208051	NERLYNX	NERATINIB MALEATE	PUMA BIOTECHNOLOGY INC	S		7/17/2017
NDA 209195	VOSEVI	SOFOSBUVIR, VELPATASVIR, AND VOXILAPREVIR	GILEAD SCIENCES INC	P		7/18/2017
NDA 208722 (1)	LUSDUNA	INSULIN GLARGINE	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	S	Y	7/19/2017
NDA 209449		NITISINONE	CYCLE PHARMACEUTICALS LTD	S	Y	7/26/2017
NDA 209606	IDHIFA	ENASIDENIB	CELGENE CORP	P,O		8/1/2017
NDA 209670 (2)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	MYLAN LABORATORIES LTD	P	Y	8/2/2017
NDA 207921	QVAR REDHALER	BECLOMETHASONE DIPROPIONATE	NORTON WATERFORD LTD	S	Y	8/3/2017
NDA 209394	MAVYRET	GLECAPREVIR AND PIBRENTASVIR	ABBVIE INC	P		8/3/2017
NDA 209401	VYXEOS	DAUNORUBICIN AND CYTARABINE	CELATOR PHARMACEUTICALS INC	P,O	Y	8/3/2017
NDA 209604		GEMCITABINE	ACCORD HEALTHCARE INC	S	Y	8/3/2017
NDA 209478	CAROSPIR	SPIRONOLACTONE	CMP DEVELOPMENT LLC	S,O	Y	8/4/2017
NDA 209875	NIKITA	PITAVASTATIN	LUPIN LTD	S	Y	8/4/2017
NDA 208558	LYNPARZA	OLAPARIB	ASTRAZENECA PHARMACEUTICALS LP	P		8/17/2017
NDA 208870	DRAX EXAMETAZIME	KIT FOR THE PREPARATION OF TC99M EXAMETAZIME FOR LEUKOCYTE LABELING	JUBILANT DRAXIMAGE INC	S	Y	8/17/2017
NDA 209203	DUZALLO	LESINURAD/ALLOPURINOL	IRONWOOD PHARMACEUTICALS INC	S	Y	8/18/2017
NDA 209618 (2)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	AUROBINDO PHARMA LTD	P	Y	8/18/2017
NDA 208944	GOCOVRI	AMANTADINE EXTENDED-RELEASE	ADAMAS PHARMA LLC	S,O	Y	8/24/2017
NDA 209570		BENZNIDAZOLE	CHEMO RESEARCH SL	P,O	Y	8/29/2017
NDA 209776	VABOMERE	MEROPENEM AND VABORBACTAM	REMPEX PHARMACEUTICALS A WHOLLY OWNED SUB OF THE MEDICINES CO	P	Y	8/29/2017
NDA 209279	TRACLEER	BOSENTAN	ACTELION PHARMACEUTICALS LTD	S,O		9/5/2017
NDA 208385		DAPTOMYCIN	SAGENT PHARMACEUTICALS INC	S	Y	9/12/2017
NDA 209936	ALIQOPA	COPANLISIB	BAYER HEALTHCARE PHARMACEUTICALS INC	P,O		9/14/2017
NDA 204325	ADZENYS ER	AMPHETAMINE	NEOS THERAPEUTICS INC	S	Y	9/15/2017
NDA 209363	SOLOSEC	SECNIDAZOLE	LUPIN INC	P		9/15/2017
NDA 209022	XHANCE	FLUTICASONE PROPIONATE	OPTNOSE US INC	S	Y	9/18/2017
NDA 209482	TRELEGY ELLIPTA	FLUTICASONE FUROATE 100 MCG, UMECLIDINIUM 62.5 MCG, AND VILANTEROL 25 MCG	GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LTD ENGLAND	S		9/18/2017
NDA 208791	CLOTOTEKAL	CHLOROPROCAINE HCL	SINTETICA SA	S	Y	9/26/2017
NDA 208716	VERZENIO	ABEMACICLIB	ELI LILLY AND CO	P		9/28/2017
NDA 208751	FIASP	INSULIN ASPART INJECTION	NOVO NORDISK INC	S		9/29/2017

NDA 209112	ASCOR	ASCORBIC ACID	MCGUFF PHARMACEUTICALS INC	S,O	Y	10/2/2017
NDA 208845	ZILRETTA	TRIAMCINOLONE ACETONIDE EXTENDED-RELEASE INJECTABLE SUSPENSION	FLEXION THERAPEUTICS INC	S	Y	10/6/2017
NDA 209501	LYRICA	PREGABALIN	PFIZER INC	S		10/11/2017
NDA 210064 (1)		FOSAPREPITANT	TEVA PHARMACEUTICALS USA	S	Y	10/12/2017
NDA 209210	BYDUREON BCISE	EXENATIDE EXTENDED-RELEASE	ASTRAZENECA AB	S		10/20/2017
NDA 209949		DAPTOMYCIN	XELLIA PHARMACEUTICALS APS	S	Y	10/20/2017
NDA 208399	VARUBI	ROLAPITANT	TESARO INC	S		10/25/2017
NDA 209472 (1)	PEMFEXY	PEMETREXED INJECTION	EAGLE PHARMACEUTICALS INC	S	Y	10/26/2017
NDA 206451 (2)		ATAZANAVIR AND RITONAVIR	CIPLA LTD	P	Y	10/27/2017
NDA 210259	CALQUENCE	ACALABRUTINIB	ASTRAZENECA UK LTD	P,O		10/31/2017
NDA 207795	VYZULTA	LATANOPROSTENE BUNOD OPHTHALMIC SOLUTION	BAUSCH AND LOMB INC	S		11/2/2017
NDA 209939	PREVYMIS	LETERMOVIR	MERCK SHARP AND DOHME CORP	P,O		11/8/2017
NDA 209940	PREVYMIS	LETERMOVIR	MERCK SHARP AND DOHME CORP	P,O		11/8/2017
NDA 209296	CINVANTI	APREPITANT	HERON THERAPEUTICS INC	S	Y	11/9/2017
NDA 207202	ABILIFY MYCITE	ARIPIPIRAZOLE	OTSUKA PHARMACEUTICAL CO LTD	S		11/13/2017
NDA 210709	TEKTURNA	ALISKIREN	NODEN PHARMA DAC	P		11/14/2017
NDA 210192	JULUCA	DOLUTEGRAVIR AND RILPIVIRINE	VIIV HEALTHCARE CO	P		11/21/2017
NDA 208656 (2)		ABACAVIR	MICRO LABS LTD INDIA	S	Y	11/28/2017
NDA 209483	IMPOYZ	CLOBETASOL PROPIONATE	ENCORE DERMATOLOGY INC	S		11/28/2017
NDA 209589	CLENPIQ	SODIUM PICOSULFATE, MAGNESIUM OXIDE, AND ANHYDROUS CITRIC ACID	FERRING PHARMACEUTICALS INC	S	Y	11/28/2017
NDA 209359 (1)		EPINEPHRINE	HOSPIRA INC	S	Y	11/29/2017
NDA 209819	SUBLOCADE	BUPRENORPHINE	INDIVIOR INC	P,O	Y	11/30/2017
NDA 208437	LONHALA MAGNAIR	GLYCOPYRRROLATE	SUNOVION RESPIRATORY DEVELOPMENT INC	S	Y	12/5/2017
NDA 209637	OZEMPIC	SEMAGLUTIDE	NOVO NORDISK INC	S		12/5/2017
NDA 209310	SINUVA	MOMETASONE FUROATE	INTERSECT ENT INC	S	Y	12/8/2017
NDA 208945	XEPI	OZENOXACIN	FERRER INTERNACIONAL SA	S		12/11/2017
NDA 208582	ALTAFLUOR BENOX	FLUORESCEIN SODIUM AND BENOXINATE HYDROCHLORIDE OPHTHALMIC SOLUTION	ALTAIRE PHARMACEUTICALS INC	P	Y	12/14/2017
NDA 209305	ESKATA	HYDROGEN PEROXIDE	ACLARIS THERAPEUTICS INC	S	Y	12/14/2017
NDA 209963	GOPRELTO	COCAINE HYDROCHLORIDE NASAL SOLUTION, 4%	GENUS LIFE SCIENCES INC	S	Y	12/14/2017
NDA 208254	RHOPRESSA	NETARSUDIL OPHTHALMIC SOLUTION	AERIE PHARMACEUTICALS INC	S		12/18/2017
NDA 209803	STEGLATRO	ERTUGLIFLOZIN	MERCK SHARP AND DOHME CORP	S		12/19/2017
NDA 209805	STEGLUJAN	ERTUGLIFLOZIN AND SITAGLIPTIN	MERCK SHARP AND DOHME CORP	S		12/19/2017
NDA 209806	SEGLUROMET	ERTUGLIFLOZIN AND METFORMIN HYDROCHLORIDE	MERCK SHARP AND DOHME CORP	S	Y	12/19/2017
NDA 205598	MACRILEN	MACIMORELIN ACETATE	AETERNA ZENTARIS GMBH	S,O		12/20/2017
NDA 208374		BIVALIRUDIN IN 0.9% SODIUM CHLORIDE, 250 MG/50 ML AND 500 MG/100 ML	CELERITY PHARMACEUTICALS LLC	S	Y	12/21/2017
NDA 208843	SIKLOS	HYDROXYUREA	ADDMEDICA SAS	P,O	Y	12/21/2017
NDA 209360	GIAPREZA	ANGIOTENSIN II	LA JOLLA PHARMACEUTICAL CO	P		12/21/2017
NDA 208144	LUMIFY	BRIMONIDINE TARTRATE	BAUSCH AND LOMB INC	S	Y	12/22/2017

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 022018		LAMIVUDINE/ZIDOVUDINE	PHARMACARE LTD	P	8/23/2006	3/17/2017
NDA 208562		VORICONAZOLE	XELLIA PHARMACEUTICALS APS	S	5/24/206	3/9/2017
NDA 204119 (2)		EFAVIRENZ, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	HETERO LABS LTD UNIT III	P		11/8/2012, 6/30/2017
NDA 205004		BORTEZOMIB	FRESENIUS KABI USA LLC	S	11/6/2017	11/17/2015
NDA 208109		PALONOSETRON HYDROCHLORIDE	FRESENIUS KABI USA LLC	S	11/21/2017	7/29/2016
NDA 209139	PREXXARTAN	VALSARTAN	CARMEL BIOSCIENCES INC	S	12/19/2017	10/30/2017
NDA 209196	ADMELOG	INSULIN LISPRO INJECTION	SANOFI-AVENTIS US LLC	S	12/11/2017	9/1/2017

Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761032/0.0	SILIQ	BRODALUMAB	VALEANT PHARMACEUTICALS LUXEMBOURG S.A.R.L. (VPL)	S	2/15/2017
BLA 761049/0.0	BAVENCIO	AVELUMAB	EMD SERONO, INC.	P,O	3/23/2017
BLA 761053/0.0	OCREVUS	OCRELIZUMAB	GENENTECH, INC.	P	3/28/2017
BLA 761055/0.0	DUPIXENT	DUPILUMAB	REGENERON PHARMACEUTICALS, INC.	P	3/28/2017
BLA 761052/0.0	BRINEURA	CERLIPONASE ALFA	BIOMARIN PHARMACEUTICAL INC.	P,O	4/27/2017
BLA 761069/0.0	IMFINZI	DURVALUMAB	ASTRAZENECA UK LTD	P	5/1/2017
BLA 761037/0.0	KEVZARA	SARILUMAB	SANOFI-AVENTIS U.S. LLC	S	5/22/2017
BLA 761064/0.0	RITUXAN HYCELA	RITUXIMAB AND HYALURONIDASE HUMA	GENENTECH, INC.	S,O	6/22/2017
BLA 761061/0.0	TREMFYA	GUSELKUMAB	JANSSEN BIOTECH, INC.	P	7/13/2017
BLA 761043/0.0	BENLYSTA	BELIMUMAB	HUMAN GENOME SCIENCES, INC.	S	7/20/2017
BLA 761040/0.0	BESPONSA	INOTUZUMAB OZOGAMICIN	WYETH PHARMACEUTICALS INC.	P,O	8/17/2017
BLA 761060/0.0	MYLOTARG	GEMTUZUMAB OZOGAMICIN	WYETH PHARMACEUTICALS INC.	S,O	9/1/2017
BLA 761060/0.0	MYLOTARG	GEMTUZUMAB OZOGAMICIN	WYETH PHARMACEUTICALS INC.	S,O	9/1/2017
BLA 761070/0.0	FASENRA	BENRALIZUMAB	ASTRAZENECA AB	S	11/14/2017
BLA 761047/0.0	MEPSEVII	VESTRONIDASE ALFA-VJBK	ULTRAGENYX PHARAMCEUTICAL INC.	P,O	11/15/2017
BLA 761083/0.0	HEMLIBRA	EMICIZUMAB-KXWH	GENENTECH, INC.	P,O	11/16/2017

(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).