CY 2017 CDER New Molecular Entity (NME) Drug & Original BLA 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 Molecular Entity Application (NME) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 208745	TRULANCE	PLECANATIDE	SYNERGY PHARMACEUTICALS INC	S	1/19/2017	FOR THE TREATMENT OF CHRONIC IDIOPATHIC CONSTIPATION (CIC) IN ADULTS
NDA 208325	PARSABIV	ETELCALCETIDE	KAI PHARMACEUTICALS INC A WHOLLY OWNED SUBSIDIARY OF AMGEN INC	S	2/7/2017	FOR THE USE OF PARSABIV (ETELCALCETIDE) INJECTION FOR SECONDARY HYPERPARATHYROIDISM (HPT) IN ADULT PATIENTS WITH CHRONIC KIDNEY DISEASE (CKD) ON HEMODIALYSIS
NDA 208684	EMFLAZA	DEFLAZACORT	MARATHON PHARMACEUTICALS LLC	P,O	2/9/2017	FOR THE TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY IN PATIENTS 5 YEARS OF AGE AND OLDER
NDA 208794	XERMELO	TELOTRISTAT ETHYL	LEXICON PHARMACEUTICALS INC	P,O	2/28/2017	FOR THE TREATMENT OF CARCINOID SYNDROME DIARRHEA IN COMBINATION WITH SOMATOSTATIN ANALOG (SSA) THERAPY IN ADULTS INADEQUATELY CONTROLLED BY SSA THERAPY
NDA 209092	KISQALI	RIBOCICLIB	NOVARTIS PHARMACEUTICALS CORP	P	3/13/2017	FOR THE TREATMENT OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR (HR)-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER
NDA 207145	XADAGO	SAFINAMIDE	NEWRON PHARMACEUTICALS US INC	S	3/21/2017	FOR ADJUNCTIVE TREATMENT TO LEVODOPA/CARBIDOPA IN PATIENTS WITH PARKINSON'S DISEASE EXPERIENCING "OFF" EPISODES.
NDA 208854	SYMPROIC	NALDEMEDINE	SHIONOGI INC	S	3/23/2017	FOR THE TREATMENT OF OPIOID-INDUCED CONSTIPATION (OIC) IN ADULT PATIENTS WITH CHRONIC NON-CANCER PAIN
NDA 208447	ZEJULA	NIRAPARIB	TESARO INC	P,O	3/27/2017	FOR THE MAINTENANCE TREATMENT OF ADULT PATIENTS WITH RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER WHO ARE IN A COMPLETE OR PARTIAL RESPONSE TO PLATINUM-BASED CHEMOTHERAPY
NDA 208082	AUSTEDO	DEUTETRABENAZINE	TEVA BRANDED PHARMACEUTICAL PRODUCTS R AND D INC	S,O	4/3/2017	FOR THE TREATMENT OF CHOREA ASSOCIATED WITH HUNTINGTON'S DISEASE
NDA 209241	INGREZZA	VALBENAZINE	NEUROCRINE BIOSCIENCES INC	P	4/11/2017	FOR THE TREATMENT OF TARDIVE DYSKINESIA

NDA 207997	RYDAPT	MIDOSTAURIN	NOVARTIS PHARMACEUTICALS CORP	P,O	4/28/2017	TREATMENT OF ADULT PATIENTS WITH NEWLY DIAGNOSED ACUTE MYELOID LEUKEMIA (AML) THAT IS FLT3 MUTATION-POSITIVE AS DETECTED BY AN FDA-APPROVED TEST, IN COMBINATION WITH STANDARD CYTARABINE AND DAUNORUBICIN INDUCTION AND CYTARABINE CONSOLIDATION
NDA 208743	TYMLOS	ABALOPARATIDE	RADIUS HEALTH INC	S	4/28/2017	FOR THE TREATMENT OF POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS AT HIGH RISK FOR FRACTURE
NDA 208772	ALUNBRIG	BRIGATINIB	ARIAD PHARMACEUTICALS INC	P,O	4/28/2017	FOR TREATMENT OF PATIENTS WITH ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHO HAVE PROGRESSED ON OR ARE INTOLERANT TO CRIZOTINIB
NDA 209176	RADICAVA	EDARAVONE	MITSUBISHI TANABE PHARMA CORP	S,O	5/5/2017	FOR THE TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS (ALS)
NDA 208610	BAXDELA	DELAFLOXACIN	MELINTA THERAPEUTICS INC	P	6/19/2017	FOR TREATMENT OF ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI)
NDA 208383	BEVYXXA	BETRIXABAN	PORTOLA PHARMACEUTICALS INC	P	6/23/2017	FOR THE PROPHYLAXIS OF VENOUS THROMBOEMBOLISM (VTE) IN ADULT PATIENTS HOSPITALIZED FOR AN ACUTE MEDICAL ILLNESS WHO ARE AT RISK FOR THROMBOEMBOLIC COMPLICATIONS DUE TO MODERATE OR SEVERE RESTRICTED MOBILITY AND OTHER RISK FACTORS FOR VTE
NDA 208051	NERLYNX	NERATINIB MALEATE	PUMA BIOTECHNOLOGY INC	S	7/17/2017	FOR EXTENDED ADJUVANT TREATMENT OF ADULT PATIENTS WITH EARLY STAGE HER2-OVEREXPRESSED/AMPLIFIED BREAST CANCER, TO FOLLOW ADJUVANT TRASTUZUMAB BASED THERAPY
NDA 209195	VOSEVI	SOFOSBUVIR, VELPATASVIR, AND VOXILAPREVIR	GILEAD SCIENCES INC	P	7/18/2017	VOSEVI IS INDICATED FOR THE TREATMENT OF ADULT PATIENTS WITH CHRONIC HEPATITIS C VIRUS (HCV)□ INFECTION WITHOUT CIRRHOSIS OR WITH COMPENSATED CIRRHOSIS WHO HAVE: □ -GENOTYPE 1, 2, 3, 4, 5 OR 6 INFECTION AND HAVE PREVIOUSLY BEEN TREATED WITH AN HCV REGIMEN CONTAINING AN NS5A INHIBITOR.□ -GENOTYPE 1A OR 3 INFECTION AND HAVE PREVIOUSLY BEEN TREATED WITH AN HCV□ REGIMEN CONTAINING SOFOSBUVIR WITHOUT AN NS5A INHIBITOR
NDA 209606	IDHIFA	ENASIDENIB	CELGENE CORP	P,O	8/1/2017	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY ACUTE MYELOID LEUKEMIA (AML) WITH AN ISOCITRATE DEHYDROGENASE-2 (IDH2) MUTATION AS DETECTED BY AN FDA-APPROVED TEST

NDA 209394	MAVYRET	GLECAPREVIR AND PIBRENTASVIR	ABBVIE INC	P	8/3/2017	FOR PATIENTS WITH CHRONIC HEPATITIS C VIRUS (HCV) GENOTYPE (GT) 1, 2, 3, 4, 5 OR 6 INFECTION WITHOUT CIRRHOSIS OR WITH COMPENSATED CIRRHOSIS; AND ALSO FOR PATIENTS WITH HCV GT1 INFECTION WHO PREVIOUSLY HAVE BEEN TREATED WITH A REGIMEN CONTAINING AN HCV NS5A INHIBITOR OR AN NS3/4A PROTEASE INHIBITOR, BUT NOT BOTH
NDA 209570		BENZNIDAZOLE	CHEMO RESEARCH SL	P,O	8/29/2017	FOR THE TREATMENT OF CHAGAS DISEASE (AMERICAN TRYPANOSOMIASIS), CAUSED BY TRYPANOSOMA CRUZI, IN PEDIATRIC PATIENTS 2 TO 12 YEARS OF AGE
NDA 209776	VABOMERE	MEROPENEM AND VABORBACTAM	REMPEX PHARMACEUTICALS A WHO	P	8/29/2017	FOR TREATMENT OF PATIENTS 18 YEARS OF AGE AND OLDER WITH COMPLICATED URINARY TRACT INFECTIONS (CUTI), INCLUDING PYELONEPHRITIS
NDA 209936	ALIQOPA	COPANLISIB	BAYER HEALTHCARE PHARMACEUTI	P,O	9/14/2017	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED FOLLICULAR LYMPHOMA (FL) WHO HAVE RECEIVED AT LEAST TWO PRIOR SYSTEMIC THERAPIES
NDA 209363	SOLOSEC	SECNIDAZOLE	LUPIN INC	P	9/15/2017	FOR THE TREATMENT OF BACTERIAL VAGINOSIS IN ADULT WOMEN
NDA 208716	VERZENIO	ABEMACICLIB	ELI LILLY AND CO	P	9/28/2017	IN COMBINATION WITH FULVESTRANT FOR THE TREATMENT OF WOMEN WITH HORMONE RECEPTOR (HR)-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER WITH DISEASE PROGRESSION FOLLOWING ENDOCRINE THERAPY; AND AS MONOTHERAPY FOR THE TREATMENT OF ADULT PATIENTS WITH HR-POSITIVE, HER2-NEGATIVE ADVANCED OR METASTATIC BREAST CANCER WITH DISEASE PROGRESSION FOLLOWING ENDOCRINE THERAPY AND PRIOR CHEMOTHERAPY IN THE METASTATIC SETTING
NDA 210259	CALQUENCE	ACALABRUTINIB	ASTRAZENECA UK LTD	P,O	10/31/2017	FOR THE TREATMENT OF ADULT PATIENTS WITH MANTLE CELL LYMPHOMA (MCL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY
NDA 207795	VYZULTA	LATANOPROSTENE BUNOD OPHTHALMIC SOLUTION	BAUSCH AND LOMB INC	S	11/2/2017	FOR REDUCTION OF INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN-ANGLE GLAUCOMA OR OCULAR HYPERTENSION
NDA 209939	PREVYMIS	LETERMOVIR	MERCK SHARP AND DOHME CORP	P,O	11/8/2017	FOR PROPHYLAXIS OF CYTOMEGALOVIRUS (CMV) INFECTION AND DISEASE IN ADULT CMVSEROPOSITIVE RECIPIENTS [R+] OF AN ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANT (HSCT)
NDA 209637	OZEMPIC	SEMAGLUTIDE	NOVO NORDISK INC	S	12/5/2017	AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS.
NDA 208945	XEPI	OZENOXACIN	FERRER INTERNACIONAL SA	S	12/11/2017	FOR THE TOPICAL TREATMENT OF IMPETIGO IN ADULTS, ADOLESCENTS AND CHILDREN 2 MONTHS AND OLDER
NDA 208254	RHOPRESSA	NETARSUDIL OPHTHALMIC SOLUTION	AERIE PHARMACEUTICALS INC	S	12/18/2017	FOR THE REDUCTION OF ELEVATED INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN-ANGLE GLAUCOMA OR OCULAR HYPERTENSION

NDA 209803	STEGLATRO	ERTUGLIFLOZIN	MERCK SHARP AND DOHME CORP	S	12/19/2017	AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS.
NDA 205598	MACRILEN	MACIMORELIN ACETATE	AETERNA ZENTARIS GMBH	S,O	12/20/2017	FOR THE DIAGNOSIS OF ADULT GROWTH HORMONE DEFICIENCY
NDA 209360	GIAPREZA	ANGIOTENSIN II	LA JOLLA PHARMACEUTICAL CO	P	12/21/2017	FOR INTRAVENOUS INFUSION TO INCREASE BLOOD PRESSURE IN ADULTS WITH SEPTIC OR OTHER DISTRIBUTIVE SHOCK

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
BLA 761032/0.0	SILIQ	BRODALUMAB	VALEANT PHARMACEUTICALS LUXEMBOU	S	2/15/2017	FOR THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS IN ADULT PATIENTS WHO ARCANDIDATES FOR SYSTEMIC THERAPY OR PHOTOTHERAPY AND HAVE FAILED TO RESPOND OR HAVE LOST RESPONSE TO OTHER SYSTEMIC THERAPIES
BLA 761049/0.0	BAVENCIO	AVELUMAB	EMD SERONO, INC.	P,O	3/23/2017	FOR THE TREATMENT OF ADULTS AND PEDIATRIC PATIENTS 12 YEARS AND OLDER WITH METASTATIC MERKEL CELL CARCINOMA
BLA 761053/0.0	OCREVUS	OCRELIZUMAB	GENENTECH, INC.	P	3/28/2017	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSING OR PRIMARY PROGRESSIVE FORMS OF MULTIPLE SCLEROSIS
BLA 761055/0.0	DUPIXENT	DUPILUMAB	REGENERON PHARMACEUTICALS, INC.	P	3/28/2017	FOR THE TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ATOPIC DERMATITIS WHOSE DISEASE IS NOT ADEQUATELY CONTROLLED WITH TOPICAL PRESCRIPTION THERAPIES OR WHEN THOSE THERAPIES ARE NOT ADVISABLE. DUPIXENT CAN BE USED WITH OR WITHOUT TOPICAL CORTICOSTEROIDS
BLA 761052/0.0	BRINEURA	CERLIPONASE ALFA	BIOMARIN PHARMACEUTICAL INC.	P,O	4/27/2017	INDICATED TO SLOW THE PROGRESSION OF LOSS OF AMBULATION IN SYMPTOMATIC PEDIATRIC PATIENTS 3 YEARS OF AGE AND OLDER WITH LATE INFANTILE NEURONAL CEROID LIPOFUSCINOSIS TYPE 2 (CLN2), ALSO KNOWN AS TRIPEPTIDYL PEPTIDASE 1 (TPP1) DEFICIENCY
BLA 761069/0.0	IMFINZI	DURVALUMAB	ASTRAZENECA UK LTD	P	5/1/2017	FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA WHO HAVE DISEASE PROGRESSION DURING OR FOLLOWING PLATINUM-CONTAINING CHEMOTHERAPY OR HAVE DISEASE PROGRESSION WITHIN 12 MONTHS OF NEOADJUVANT OR ADJUVANT TREATMENT WITH PLATINUM-CONTAINING CHEMOTHERAPY

BLA 761037/0.0	KEVZARA	SARILUMAB	SANOFI-AVENTIS U.S. LLC	S	5/22/2017	FOR ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS WHO HAVE HAD AN INADEQUATE RESPONSE OR INTOLERANCE TO ONE OR MORE DISEASE-MODIFYING ANTIRHEUMATIC DRUGS (DMARDS)
BLA 761061/0.0	TREMFYA	GUSELKUMAB	JANSSEN BIOTECH, INC.	P	7/13/2017	FOR THE TREATMENT OF ADULT PATIENTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS WHO ARE CANDIDATES FOR SYSTEMIC THERAPY OR PHOTOTHERAPY
BLA 761040/0.0	BESPONSA	INOTUZUMAB OZOGAMICIN	WYETH PHARMACEUTICALS INC.	P,O	8/17/2017	FOR THE TREATMENT OF ADULTS WITH RELAPSED OR REFRACTORY B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)
BLA 761070/0.0	FASENRA	BENRALIZUMAB	ASTRAZENECA AB	S	11/14/2017	FOR ADD-ON MAINTENANCE TREATMENT OF PATIENTS WITH SEVERE ASTHMA AGED 12 YEARS AND OLDER, AND WITH AN EOSINOPHILIC PHENOTYPE
BLA 761047/0.0	MEPSEVII	VESTRONIDASE ALFA-VJBK	ULTRAGENYX PHARAMCEUTICAL INC.	P,O	11/15/2017	FOR THE TREATMENT OF MUCOPOLYSACCHARIDOSIS TYPE VII (MPS VII, SLY SYNDROME)
BLA 761083/0.0	HEMLIBRA	EMICIZUMAB-KXWH	GENENTECH, INC.	P,O	11/16/2017	FOR ROUTINE PROPHYLAXIS TO PREVENT OR REDUCE THE FREQUENCY OF BLEEDING EPISODES IN ADULT AND PEDIATRIC PATIENTS WITH HEMOPHILIA A (CONGENITAL FACTOR VIII DEFICIENCY) WITH FACTOR VIII INHIBITORS

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).