CY 2019 CDER New Molecular Entity (NME) Drug & Original BLA 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 Molecular Entity Application (NME) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 208711	EGATEN	TRICLABENDAZOLE	NOVARTIS PHARMACEUTICALS CORP	P,O	2/13/2019	FOR THE TREATMENT OF FASCIOLIASIS IN PATIENTS 6 YEARS OF AGE AND OLDER
NDA 211371	ZULRESSO	BREXANOLONE	SAGE THERAPEUTICS INC	P	3/19/2019	FOR POSTPARTUM DEPRESSION
NDA 211230	SUNOSI	SOLRIAMFETOL	JAZZ PHARMACEUTICALS IRELAND LTD	S,O	3/20/2019	TO IMPROVE WAKEFULNESS IN ADULT PATIENTS WITH EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY TO IMPROVE WAKEFULNESS IN ADULT PATIENTS WITH EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH OBSTRUCTIVE SLEEP APNEA (OSA)
NDA 209884	MAYZENT	SIPONIMOD	NOVARTIS PHARMACEUTICALS CORP	P	3/26/2019	FOR THE TREATMENT OF RELAPSING FORMS OF MULTIPLE SCLEROSIS (MS), TO INCLUDE CLINICALLY ISOLATED SYNDROME, RELAPSINGREMITTING DISEASE, AND ACTIVE SECONDARY PROGRESSIVE DISEASE, IN ADULTS
NDA 212018	BALVERSA	ERDAFITINIB	JANSSEN BIOTECH INC	P	4/12/2019	TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA (MUC), THAT HAS: SUSCEPTIBLE FGFR3 OR FGFR2 GENETIC ALTERATIONS, AND PROGRESSED DURING OR FOLLOWING AT LEAST ONE LINE OF PRIOR PLATINUM-CONTAINING CHEMOTHERAPY, INCLUDING WITHIN 12 MONTHS OF NEOADJUVANT OR ADJUVANT PLATINUM-CONTAINING CHEMOTHERAPY.
NDA 211996	VYNDAQUEL	TAFAMIDIS MEGLUMINE	FOLDRX PHARMACEUTICALS INC SUB PFIZER INC	P,O	5/3/2019	FOR THE TREATMENT OF THE CARDIOMYOPATHY OF WILD TYPE OR HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS IN ADULTS TO REDUCE CARDIOVASCULAR MORTALITY AND CARDIOVASCULAR-RELATED HOSPITALIZATION
NDA 212526	PIQRAY	ALPELISIB	NOVARTIS PHARMACEUTICALS CORP	P	5/24/2019	FOR THE TREATMENT OF POSTMENOPAUSAL WOMEN, AND MEN, WITH HORMONE RECEPTOR (HR)-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE, PIK3CA-MUTATED, ADVANCED OR METASTATIC BREAST CANCER AS DETECTED BY AN FDA-APPROVED TEST FOLLOWING PROGRESSION ON OR AFTER AN ENDOCRINE-BASED REGIMEN
NDA 210557	VYLEESI	BREMELANOTIDE	AMAG PHARMACEUTICALS INC	S	6/21/2019	TREATMENT OF PREMENOPAUSAL WOMEN WITH ACQUIRED, GENERALIZED HYPOACTIVE SEXUAL DESIRE DISORDER (HSDD) AS CHARACTERIZED BY LOW SEXUAL DESIRE THAT CAUSES MARKED DISTRESS OR INTERPERSONAL DIFFICULTY AND IS NOT DUE TO: A CO-EXISTING MEDICAL OR PSYCHIATRIC CONDITION, PROBLEMS WITH THE RELATIONSHIP, OR THE EFFECTS OF A MEDICATION OR DRUG SUBSTANCE.
NDA 212306	XPOVIO	SELINEXOR	KARYOPHARM THERAPEUTICS INC	P,O	7/3/2019	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA (RRMM) WHO HAVE RECEIVED AT LEAST FOUR PRIOR THERAPIES AND WHOSE DISEASE IS REFRACTORY TO AT LEAST TWO PROTEASOME INHIBITORS, AT LEAST TWO IMMUNOMODULATORY AGENTS, AND AN ANTI-CD38 MONOCLONAL ANTIBODY

NDA 212819	RECARBRIO	IMIPENEM, CILASTATIN,AND RELEBACTAM	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	P	7/16/2019	FOR THE TREATMENT OF THE FOLLOWING INFECTIONS CAUSED BY CERTAIN SUSCEPTIBLE GRAM-NEGATIVE BACTERIA: □ COMPLICATED URINARY TRACT INFECTIONS (CUTI), INCLUDING PYELONEPHRITIS □ COMPLICATED INTRA-ABDOMINAL INFECTIONS (CIAI)
NDA 212320	ACCRUFER	FERRIC MALTOL	SHIELD TX UK LTD	S	7/25/2019	FOR THE TREATMENT OF IRON DEFICIENCY IN ADULTS
NDA 212099	NUBEQA	DAROLUTAMIDE	BAYER HEALTHCARE PHARMACEUTICALS INC	P	7/30/2019	FOR THE TREATMENT OF PATIENTS WITH NON-METASTATIC CASTRATION RESISTANT PROSTATE CANCER (NMCRPC)
NDA 211810	TURALIO	PEXIDARTINIB	DAIICHI SANKYO INC	P,O	8/2/2019	FOR THE TREATMENT OF ADULT PATIENTS WITH SYMPTOMATIC TENOSYNOVIAL GIANT CELL TUMOR (TGCT) ASSOCIATED WITH SEVERE MORBIDITY OR FUNCTIONAL LIMITATIONS AND NOT AMENABLE TO IMPROVEMENT WITH SURGERY
NDA 211150	WAKIX	PITOLISANT	HARMONY BIOSCIENCES LLC	P,O	8/14/2019	TREATMENT OF EXCESSIVE DAYTIME SLEEPINESS (EDS) IN ADULT PATIENTS WITH NARCOLEPSY.
NDA 212862		PRETOMANID	THE GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT	P,O	8/14/2019	FOR THE TREATMENT OF ADULTS WITH PULMONARY EXTENSIVELY DRUG RESISTANT (XDR),OR TREATMENT-INTOLERANT OR NONRESPONSIVE MULTIDRUG-RESISTANT (MDR) TUBERCULOSIS. APPROVAL OF THIS INDICATION IS BASED ON LIMITED CLINICAL SAFETY AND EFFICACY DATA. THIS DRUG IS INDICATED FOR USE IN A LIMITED AND SPECIFIC POPULATION OF PATIENTS
NDA 212725	ROZLYTREK	ENTRECTINIB	GENENTECH INC	P,O	8/15/2019	TREATMENT OF ADULT PATIENTS WITH METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE TUMORS ARE ROS1-POSITIVE
NDA 211675	RINVOQ	UPADACITINIB	ABBVIE INC	P	8/16/2019	TREATMENT OF ADULTS WITH MODERATELY TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS WHO HAVE HAD AN INADEQUATE RESPONSE OR INTOLERANCE TO METHOTREXATE
NDA 212327	INREBIC	FEDRATINIB	IMPACT BIOMEDICINES INC A WHOLLY OWNED SUB OF CELGENE CORP	P,O	8/16/2019	FOR THE TREATMENT OF ADULT PATIENTS WITH INTERMEDIATE-2 OR HIGH-RISK PRIMARY OR SECONDARY (POSTPOLYCYTHEMIA VERA OR POST-ESSENTIAL THROMBOCYTHEMIA) MYELOFIBROSIS (MF)
NDA 211672	XENLETA	LEFAMULIN	NABRIVA THERAPEUTICS IRELAND DAC	P	8/19/2019	FOR THE TREATMENT OF ADULTS WITH COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP) CAUSED BY SUSCEPTIBLE MICROORGANISMS.
NDA 210828		GA-68-DOTATOC	UNIV IOWA HOSPS AND CLINICS PET IMAGING CENTER	S,O	8/21/2019	FOR USE WITH POSITRON EMISSION TOMOGRAPHY (PET) FOR LOCALIZATION OF SOMATOSTATIN RECEPTOR POSITIVE NEUROENDOCRINE TUMORS (NETS) IN ADULT AND PEDIATRIC PATIENTS
NDA 022075	NOURIANZ	ISTRADEFYLLINE	KYOWA KIRIN INC	S	8/27/2019	ADJUNCTIVE TREATMENT TO LEVODOPA/CARBIDOPA IN ADULT PATIENTS WITH PARKINSON'S DISEASE (PD) EXPERIENCING "OFF" EPISODES
NDA 211801	IBSRELA	TENAPANOR	ARDELYX INC	S	9/12/2019	TREATMENT OF IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C) IN ADULTS
NDA 211527	AKLIEF	TRIFAROTENE	GALDERMA RESEARCH AND DEVELOPMENT INC	S	10/4/2019	FOR THE TOPICAL TREATMENT OF ACNE VULGARIS IN PATIENTS 9 YEARS OF AGE AND OLDER.
NDA 210797	SCENESSE	AFAMELANOTIDE	CLINUVEL INC	P,O	10/8/2019	TO INCREASE PAIN-FREE LIGHT EXPOSURE IN ADULT PATIENTS WITH A HISTORY OF PHOTOTOXIC REACTIONS FROM ERYTHROPOIETIC PROTOPORPHYRIA (EPP).
NDA 200655		[F-18] FLUORODOPA (FDOPA)	FEINSTEIN INSTITUTE MEDICAL RESEARCH	S	10/10/2019	IS A RADIOACTIVE DIAGNOSTIC AGENT INDICATED FOR USE IN POSITRON EMISSION TOMOGRAPHY (PET) TO VISUALIZE DOPAMINERGIC NERVE TERMINALS IN THE STRIATUM FOR THE EVALUATION OF ADULT PATIENTS WITH SUSPECTED PARKINSONIAN SYNDROMES (PS). FLUORODOPA F 18 PET IS AN ADJUNCT TO OTHER DIAGNOSTIC EVALUATIONS
NDA 211280	REYVOW	LASMIDITAN	ELI LILLY AND CO	S	10/11/2019	FOR THE ACUTE TREATMENT OF MIGRAINE WITH OR WITHOUT AURA IN ADULTS
NDA 212273	TRIKAFTA	TEZACAFTOR AND IVACAFTOR TABLETS; IVACAFTOR TABLETS	VERTEX PHARMACEUTICALS INC	P,O	10/21/2019	FOR THE TREATMENT OF CYSTIC FIBROSIS PATIENTS 12 YEARS AND OLDER WHO HAVE AT LEAST ONE F508DEL MUTATION IN THE CFTR GENE
NDA 212279	EXEM FOAM	AIR POLYMER-TYPE A	GISKIT BV	S	11/7/2019	AN ULTRASOUND CONTRAST AGENT INDICATED FOR SONOHYSTEROSALPINGOGRAPHY TO ASSESS FALLOPIAN TUBE PATENCY IN WOMEN WITH KNOWN OR SUSPECTED INFERTILITY

NDA 209445	FETROJA	CEFIDEROCOL	SHIONOGI INC	P	11/14/2019	FOR THE TREATMENT OF PATIENTS 18 YEARS OF AGE OR OLDER WHO HAVE LIMITED OR NO ALTERNATIVE TREATMENT OPTIONS FOR THE TREATMENT OF COMPLICATED URINARY TRACT INFECTIONS (CUTIS), INCLUDING PYELONEPHRITIS CAUSED BY THE FOLLOWING SUSCEPTIBLE GRAM-NEGATIVE MICROORGANISMS: ESCHERICHIA COLI, KLEBSIELLA PNEUMONIAE, PROTEUS MIRABILIS, PSEUDOMONAS AERUGINOSA, AND ENTEROBACTER CLOACAE COMPLEX
NDA 213217	BRUKINSA	ZANUBRUTINIB	BEIGENE USA INC	P,O	11/14/2019	FOR THE TREATMENT OF ADULT PATIENTS WITH MANTLE CELL LYMPHOMA (MCL) WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY
NDA 212194	GIVLAARI	GIVOSIRAN	ALNYLAM PHARMACEUTICALS INC	P,O	11/20/2019	FOR THE TREATMENT OF ADULTS WITH ACUTE HEPATIC PORPHYRIA (AHP)
NDA 212839	XCOPRI	CENOBAMATE	SK LIFE SCIENCE INC	S	11/21/2019	FOR THE TREATMENT OF PARTIAL-ONSET SEIZURES IN ADULT PATIENTS.
NDA 213137	OXBRYTA	VOXELOTOR	GLOBAL BLOOD THERAPEUTICS INC	P,O	11/25/2019	FOR THE TREATMENT OF SICKLE CELL DISEASE IN ADULTS AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER.
NDA 211970	VYONDYS 53	GOLODIRSEN	SAREPTA THERAPEUTICS INC	P,O	12/12/2019	TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY (DMD) IN PATIENTS WHO HAVE A CONFIRMED MUTATION OF THE DMD GENE THAT IS AMENABLE TO EXON 53 SKIPPING. THIS INDICATION IS APPROVED UNDER ACCELERATED APPROVAL BASED ON AN INCREASE IN DYSTROPHIN PRODUCTION IN SKELETAL MUSCLE OBSERVED IN PATIENTS TREATED WITH VYONDYS 53
NDA 209500	CAPLYTA	LUMATEPERONE	INTRA-CELLULAR THERAPIES INC	S	12/20/2019	FOR THE TREATMENT OF SCHIZOPHRENIA
NDA 209569	TISSUEBLUE	BRILLIANT BLUE G OPHTHALMIC SOLUTION	DUTCH OPHTHALMIC RESEARCH CENTER INTERNATIONAL BV	P,O	12/20/2019	FOR USE AS AN AID IN OPHTHALMIC SURGERY BY SELECTIVELY STAINING THE INTERNAL LIMITING MEMBRANE (ILM)
NDA 212028	DAYVIGO	LEMBOREXANT	EISAI INC	S	12/20/2019	TREATMENT OF ADULT PATIENTS WITH INSOMNIA, CHARACTERIZED BY DIFFICULTIES WITH SLEEP ONSET AND/OR SLEEP MAINTENANCE
NDA 211765	UBREVLY	UBROGEPANT	ALLERGAN SALES LLC	S	12/23/2019	ACUTE TREATMENT OF MIGRAINE WITH OR WITHOUT AURA IN ADULTS

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
BLA 761085	JEUVEAU	PRABOTULINUMTOXINA-XVFS	EVOLUS INC.	S	2/1/2019	FOR THE TEMPORARY IMPROVEMENT IN THE APPEARANCE OF MODERATE TO SEVERE GLABELLAR LINES ASSOCIATED WITH CORRUGATOR AND/OR PROCERUS MUSCLE ACTIVITY IN ADULT PATIENTS
BLA 761112	CABLIVI	CAPLACIZUMAB-YHDP	ABLYNX NV	P,O	2/6/2019	FOR THE TREATMENT OF ADULT PATIENTS WITH ACQUIRED THROMBOTIC THROMBOCYTOPENIC PURPURA (ATTP), IN COMBINATION WITH PLASMA EXCHANGE AND IMMUNOSUPPRESSIVE THERAPY
BLA 761062	EVENITY	ROMOSOZUMAB-AQQG	AMGEN, INC.	S	4/9/2019	FOR THE TREATMENT OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN AT HIGH RISK FOR FRACTURE, DEFINED AS A HISTO1Y OF OSTEOPOROTIC FRACTURE, OR MULTIPLE RISK FACTORS FOR FRACTURE; OR PATIENTS WHO HAVE FAILED OR AI·E INTOLERANT TO OTHER AVAILABLE OSTEOPOROSIS THERAPY
BLA 761105	SKYRIZI	RISANKIZUMAB-RZAA	ABBVIE INC.	S	4/23/2019	FOR THE TREATMENT OF MODERATE-TO-SEVERE PLAQUE PSORIASIS IN ADULTS WHO ARE CANDIDATES FOR SYSTEMIC THERAPY OR PHOTOTHERAPY
BLA 761121	POLIVY	POLATUZUMAB VEDOTIN-PIIQ	GENENTECH, INC.	P,O	6/10/2019	INDICATED IN COMBINATION WITH BENDAMUSTINE AND A RITUXIMAB PRODUCT FOR ADULT PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA (DLBCL), NOT OTHERWISE SPECIFIED, AFTER AT LEAST TWO PRIOR THERAPIES
BLA 761125	BEOVU	BROLUCIZUMAB-DBLL	NOVARTIS PHARMACEUTICALS COR	P	10/7/2019	FOR THE TREATMENT OF NEOVASCULAR AGE-RELATED MACULAR DEGENERATION

BLA 761136	REBLOZYL	LUSPATERCEPT – AAMT	CELGENE CORPORATION	P,O	11/8/2019	FOR THE TREATMENT OF ANEMIA IN ADULT PATIENTS WITH BETA THALASSEMIA WHO REQUIRE REGULAR RED BLOOD CELL (RBC) TRANSFUSIONS
BLA 761128	ADAKVEO	CRIZANLIZUMAB-TMCA	NOVARTIS PHARMACEUTICALS COR	P,O	11/15/2019	TO REDUCE THE FREQUENCY OF VASOOCCLUSIVE CRISES IN ADULTS AND PEDIATRIC PATIENTS AGED 16 YEARS AND OLDER WITH SICKLE CELL DISEASE
BLA 761137	PADCEV	ENFORTUMAB VEDOTIN-EJF	ASTELLAS PHARMA US, INC.	P	12/18/2019	FOR THE TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CANCER (MUC) WHO HAVE PREVIOUSLY RECEIVED A PROGRAMMED DEATH RECEPTOR-1 (PD-1) OR PROGRAMMED DEATH-LIGAND 1 (PD-L1) INHIBITOR, AND A PLATINUM-CONTAINING CHEMOTHERAPY IN THE NEOADJUVANT/ADJUVANT, LOCALLY ADVANCED OR METASTATIC SETTING
BLA 761139	ENHERTU	FAM-TRASTUZUMAB DERUXT	DAIICHI SANKYO, INC.	P	12/20/2019	FOR THE TREATMENT OF ADULT PATIENTS WITH UNRESECTABLE OR METASTATIC HER2-POSITIVE BREAST CANCER WHO HAVE RECEIVED TWO OR MORE PRIOR ANTI-HER2-BASED REGIMENS IN THE METASTATIC SETTING

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).