

CY 2018 CDER New Molecular Entity (NME) Drug & Original BLA 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 Molecular Entity Application (NME) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 208700	LUTATHERA	LUTETIUM LU 177 DOTATATE	ADVANCED ACCELERATOR APPLICATIONS USA INC	P,O	1/26/2018	FOR THE TREATMENT OF SOMATOSTATIN RECEPTOR POSITIVE GEP-NETS INCLUDING FOREGUT, MIDGUT, AND HINDGUT NEUROENDOCRINE TUMORS IN ADULTS
NDA 210251	BIKTARVY	BICTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INC	P	2/7/2018	FOR THE TREATMENT OF HIV-1 INFECTION IN ADULTS WHO HAVE NO ANTIRETROVIRAL TREATMENT HISTORY OR TO REPLACE THE CURRENT ANTIRETROVIRAL REGIMEN IN THOSE WHO ARE VIROLOGICALLY SUPPRESSED (HIV-1 RNA LESS THAN 50 COPIES PER ML) ON A STABLE ANTIRETROVIRAL REGIMEN FOR AT LEAST 3 MONTHS WITH NO HISTORY OF TREATMENT FAILURE AND NO KNOWN SUBSTITUTIONS ASSOCIATED WITH RESISTANCE TO THE INDIVIDUAL COMPONENTS OF BIKTARVY
NDA 210491	SYMDEKO	TEZACAFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS INC	P,O	2/12/2018	FOR THE TREATMENT OF PATIENTS WITH CYSTIC FIBROSIS (CF) AGED 12 YEARS AND OLDER WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION OR WHO HAVE AT LEAST ONE MUTATION IN THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) GENE THAT IS RESPONSIVE TO TEZACAFTOR/IVACAFTOR BASED ON IN VITRO DATA AND/OR CLINICAL EVIDENCE
NDA 210951	ERLEADA	APALUTAMIDE	JANSSEN BIOTECH INC	P	2/14/2018	FOR PATIENTS WITH NONMETASTATIC CASTRATION-RESISTANT PROSTATE CANCER
NDA 209299	TAVALISSE	FOSTAMATINIB	RIGEL PHARMACEUTICALS INC	S,O	4/17/2018	FOR THE TREATMENT OF THROMBOCYTOPENIA IN ADULT PATIENTS WITH CHRONI IMMUNE THROMBOCYTOPENIA (ITP) WHO HAVE HAD AN INSUFFICIENT RESPONSE TO A PREVIOUS TREATMENT
NDA 210493	AKYNZEO	FOSNETUPITANT AND PALONOSETRON	HELSINN HEALTHCARE SA	S	4/19/2018	FOR PREVENTION OF ACUTE AND DELAYED NAUSEA AND VOMITING ASSOCIATED WITH INITIAL AND REPEAT COURSES OF HIGHLY EMETOGENIC CANCER CHEMOTHERAPY
NDA 209229	LUCEMYRA	LOFEXIDINE	US WORLDMEDS LLC	P	5/16/2018	FOR THE MITIGATION OF OPIOID WITHDRAWAL SYMPTOMS TO FACILITATE ABRUPT OPIOID DISCONTINUATION IN ADULTS
NDA 207078	LOKELMA	CYCLOSILICATE	ASTRAZENECA PHARMACEUTICALS LP	S	5/18/2018	FOR THE TREATMENT OF HYPERKALEMIA
NDA 210238	DOPTELET	AVATROMBOPAG	AKARX INC	P,O	5/21/2018	FOR TREATMENT OF THROMBOCYTOPENIA IN ADULT PATIENTS WITH CHRONIC LIVER DISEASE WHO ARE SCHEDULED TO UNDERGO A PROCEDURE
NDA 207924	OLUMIANT	BARICITINIB	ELI LILLY AND CO	S	5/31/2018	FOR THE TREATMENT OF ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS WHO HAVE HAD AN INADEQUATE RESPONSE TO ONE OR MORE TUMOR NECROSIS FACTOR (TNF) ANTAGONIST THERAPIES

NDA 210867		MOXIDECTIN	MEDICINES DEVELOPMENT FOR GLOBAL HEALTH	P,O	6/13/2018	FOR THE TREATMENT OF ONCHOCERCIASIS DUE TO ONCHOCERCA VOLVULUS IN PATIENTS AGED 12 YEARS AND OLDER
NDA 210303	ZEMDRI	PLAZOMICIN	ACHAOGEN INC	P	6/25/2018	TREATMENT OF COMPLICATED URINARY TRACT INFECTIONS (CUTI), INCLUDING PYELONEPHRITIS, CAUSED BY THE FOLLOWING SUSCEPTIBLE MICROORGANISMS: ESCHERICHIA COLI, KLEBSIELLA PNEUMONIAE, PROTEUS MIRABILIS, AND ENTEROBACTER CLOACAE, IN PATIENTS 18 YEARS OF AGE AND OLDER
NDA 210365	EPIDIOLEX	CANNABIDIOL	GW RESEARCH LTD	P,O	6/25/2018	FOR THE TREATMENT OF SEIZURES ASSOCIATED WITH LENNOX-GASTAUT SYNDROME OR DRAVET SYNDROME IN PATIENTS TWO YEARS OF AGE AND OLDER.
NDA 210496	BRAFTOVI	ENCORAFENIB	ARRAY BIOPHARMA INC	S,O	6/27/2018	FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH A BRAF V600E OR V600K MUTATION, AS DETECTED BY AN FDA-APPROVED TEST
NDA 210498	MEKTOVI	BINIMETINIB	ARRAY BIOPHARMA INC	S,O	6/27/2018	IN COMBINATION WITH ENCORAFENIB, FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH A BRAF V600E OR V600K MUTATION, AS DETECTED BY AN FDA-APPROVED TEST
NDA 208627	TPOXX	TECOVIRIMAT	SIGA TECHNOLOGIES INC	P,O	7/13/2018	FOR THE TREATMENT OF PATIENTS WITH HUMAN SMALLPOX DISEASE CAUSED BY VARIOLA VIRUS
NDA 210795	KRINTAFEL	TAFENOQUINE	GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LTD ENGLAND	P,O	7/20/2018	FOR THE RADICAL CURE (PREVENTION OF RELAPSE) OF PLASMODIUM VIVAX MALARIA IN PATIENTS AGED 16 YEARS AND OLDER WHO ARE RECEIVING APPROPRIATE ANTIMALARIAL THERAPY FOR ACUTE P. VIVAX INFECTION
NDA 211192	TIBSOVO	IVOSIDENIB	AGIOS PHARMACEUTICALS INC	P,O	7/20/2018	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY ACUTE MYELOID LEUKEMIA (AML) WITH A SUSCEPTIBLE ISOCITRATE DEHYDROGENASE-1 (IDH1) MUTATION AS DETECTED BY AN FDA-APPROVED TEST
NDA 210450	ORLISSA	ELAGOLIX SODIUM	ABBVIE INC	P	7/23/2018	FOR THE MANAGEMENT OF MODERATE TO SEVERE PAIN ASSOCIATED WITH ENDOMETRIOSIS
NDA 210589	OMEGAVEN	FISH OIL TRIGLYCERIDES	FRESENIUS KABI USA LLC	P,O	7/27/2018	INJECTABLE EMULSION INDICATED AS A SOURCE OF CALORIES AND FATTY ACIDS IN PEDIATRIC PATIENTS WITH PARENTERAL NUTRITION-ASSOCIATED CHOLESTASIS
NDA 210923	MULPLETA	LUSUTROMBOPAG	SHIONOGI INC	P	7/31/2018	FOR THE TREATMENT OF THROMBOCYTOPENIA IN ADULT PATIENTS WITH CHRONIC LIVER DISEASE (CLD) WHO ARE SCHEDULED TO UNDERGO A PROCEDURE
NDA 208623	GALAFOLD	MIGALASTAT	AMICUS THERAPEUTICS US INC	P,O	8/10/2018	FOR THE TREATMENT OF ADULTS WITH A CONFIRMED DIAGNOSIS OF FABRY DISEASE AND AN AMENABLE GALACTOSIDASE ALPHA GENE (GLA) VARIANT BASED ON IN VITRO ASSAY DATA
NDA 209627	ANNOVERA	ETHINYL ESTRADIOL VAGINAL SYSTEM	THERAPEUTICSMD INC	S	8/10/2018	FOR PREVENTION OF PREGNANCY IN FEMALES OF REPRODUCTIVE POTENTIAL
NDA 210922	ONPATTRO	PATISIRAN	ALNYLAM PHARMACEUTICALS INC	P,O	8/10/2018	FOR THE TREATMENT OF THE POLYNEUROPATHY OF HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS IN ADULTS

NDA 206709	DIACOMIT	STIRIPENTOL	BIOCODEX SA	P,O	8/20/2018	FOR THE TREATMENT OF SEIZURES ASSOCIATED WITH DRAVET SYNDROME (DS) IN PATIENTS 2 YEARS OF AGE AND OLDER TAKING CLOBAZAM
NDA 211109	XERAVA	ERAVACYCLINE	TETRAPHASE PHARMACEUTICALS INC	P	8/27/2018	FOR THE TREATMENT OF COMPLICATED INTRA-ABDOMINAL INFECTIONS IN PATIENTS 18 YEARS OF AGE AND OLDER
NDA 210806	PIFELTRO	DORAVIRINE	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	S	8/30/2018	FOR THE TREATMENT OF HIV-1 INFECTION IN ADULT PATIENTS WITH NO PRIOR ANTIRETROVIRAL TREATMENT HISTORY
NDA 211155	COPIKTRA	DUVELISIB	VERASTEM INC	P,O	9/24/2018	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY FOLLICULAR LYMPHOMA (FL) AFTER AT LEAST TWO PRIOR SYSTEMIC THERAPIES
NDA 211288	VIZIMPRO	DACOMITINIB	PFIZER INC	P,O	9/27/2018	FOR THE FIRST-LINE TREATMENT OF PATIENTS WITH METASTATIC NON-SMALL-CELL LUNG CANCER (NSCLC) WITH EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 19 DELETION OR EXON 21 L858R SUBSTITUTION MUTATIONS AS DETECTED BY AN FDA-APPROVED TEST
NDA 209521	SEYSARA	SARECYCLINE	ALMIRALL LLC	S	10/1/2018	FOR THE TREATMENT OF INFLAMMATORY LESIONS OF NON-NODULAR MODERATE TO SEVERE ACNE VULGARIS IN PATIENTS 9 YEARS OF AGE AND OLDER
NDA 209817	NUZYRA	OMADACYCLINE	PARATEK PHARMACEUTICALS INC	P	10/2/2018	FOR THE TREATMENT OF COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP) AND ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI) IN ADULTS DUE TO THE DESIGNATED SUSCEPTIBLE BACTERIA
NDA 211172	TEGSEDI	INOTERSEN	AKCEA THERAPEUTICS INC	P,O	10/5/2018	FOR THE TREATMENT OF THE POLYNEUROPATHY OF HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS IN ADULTS
NDA 211651	TALZENNA	TALAZOPARIB	PFIZER INC	P	10/16/2018	FOR THE TREATMENT OF ADULT PATIENTS WITH DELETERIOUS OR SUSPECTED DELETERIOUS GERMLINE BREAST CANCER SUSCEPTIBILITY GENE (BRCA)-MUTATED (GBRCAM) HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER
NDA 210854	XOFLUZA	BALOXAVIR MARBOXIL	GENENTECH INC	P	10/24/2018	FOR THE TREATMENT OF ACUTE UNCOMPLICATED INFLUENZA IN PATIENTS 12 YEARS OF AGE AND OLDER WHO HAVE BEEN SYMPTOMATIC FOR NO MORE THAN 48 HOURS
NDA 210868	LORBRENA	LORLATINIB	PFIZER INC	P,O	11/2/2018	FOR THE TREATMENT OF PATIENTS WITH ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHOSE DISEASE HAS PROGRESSED ON: • CRIZOTINIB AND AT LEAST ONE OTHER ALK INHIBITOR FOR METASTATIC DISEASE; OR • ALECTINIB AS THE FIRST ALK INHIBITOR THERAPY FOR METASTATIC DISEASE; OR • CERITINIB AS THE FIRST ALK INHIBITOR THERAPY FOR METASTATIC DISEASE
NDA 210598	YUPELRI	REVEFENACIN	MYLAN IRELAND LTD	S	11/9/2018	FOR THE MAINTENANCE TREATMENT OF PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)
NDA 210910	AEMCOLO	RIFAMYCIN	COSMO TECHNOLOGIES LTD	P	11/16/2018	FOR THE TREATMENT OF TRAVELERS' DIARRHEA CAUSED BY NONINVASIVE STRAINS OF ESCHERICHIA COLI IN ADULTS

NDA 210656	DAURISMO	GLASDEGIB	PFIZER INC	P,O	11/21/2018	FOR THE TREATMENT OF NEWLY-DIAGNOSED ACUTE MYELOID LEUKEMIA (AML) IN ADULT PATIENTS WHO ARE > 75 YEARS OLD OR WHO HAVE COMORBIDITIES THAT PRECLUDE USE OF INTENSIVE INDUCTION CHEMOTHERAPY
NDA 210861	VITRAKVI	LAROTRECTINIB	LOXO ONCOLOGY INC	P,O	11/26/2018	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS WITH SOLID TUMORS THAT HAVE A NEUROTROPHIC RECEPTOR TYROSINE KINASE (NTRK) GENE FUSION WITHOUT A KNOWN ACQUIRED RESISTANCE MUTATION; ARE METASTATIC OR WHERE SURGICAL RESECTION IS LIKELY TO RESULT IN SEVERE MORBIDITY; AND HAVE NO SATISFACTORY ALTERNATIVE TREATMENTS OR THAT HAVE PROGRESSED FOLLOWING TREATMENT
NDA 208078	FIRDAPSE	AMIFAMPRIDINE	CATALYST PHARMACEUTICALS INC	P,O	11/28/2018	FOR THE TREATMENT OF LAMBERT-EATON MYASTHENIC SYNDROME (LEMS) IN ADULTS
NDA 211349	XOSPATA	GILTERITINIB	ASTELLAS PHARMA US INC	P,O	11/28/2018	FOR THE TREATMENT OF ADULT PATIENTS WHO HAVE RELAPSED OR REFRACTORY ACUTE MYELOID LEUKEMIA (AML) WITH A FMS-LIKE TYROSINE KINASE 3 (FLT3) MUTATION AS DETECTED BY AN FDA-APPROVED TEST
NDA 210166	MOTEGRITY	PRUCALOPRIDE	SHIRE DEVELOPMENT LLC	S	12/14/2018	FOR CHRONIC IDIOPATHIC CONSTIPATION

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
BLA 761065	TROGARZO	IBALIZUMAB - UIYK	THERATECHNOLOGIES INC.	P,O	3/6/2018	FOR THE TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) INFECTION IN HEAVILY TREATMENT-EXPERIENCED ADULTS WITH MULTIDRUG RESISTANT HIV-1 INFECTION FAILING THEIR CURRENT ANTIRETROVIRAL REGIMEN
BLA 761067	ILUMYA	TILDRAKIZUMAB - ASMN	MERCK SHARP & DOHME CORP.	S	3/20/2018	FOR THE TREATMENT OF ADULTS WITH MODERATE-TO-SEVERE PLAQUE PSORIASIS WHO ARE CANDIDATES FOR SYSTEMIC THERAPY OR PHOTOTHERAPY
BLA 761068	CRYSVITA	BUROSUMAB-TWZA	ULTRAGENYX PHARAMCEUTICAL INC.	P,O	4/17/2018	FOR THE TREATMENT OF XLINKED HYPOPHOSPHATEMIA (XLH) IN ADULT AND PEDIATRIC PATIENTS 1 YEAR OF AGE AND OLDER
BLA 761077	AIMOVIG	ERENUMAB-AOOE	AMGEN, INC.	S	5/17/2018	FOR THE PREVENTIVE TREATMENT OF MIGRAINE IN ADULTS
BLA 761079	PALYNZIQ	PEGVALIASE-PQPZ	BIOMARIN PHARMACEUTICAL INC.	P,O	5/24/2018	INDICATED TO REDUCE BLOOD PHENYLALANINE CONCENTRATIONS IN ADULT PATIENTS WITH PHENYLKETONURIA (PKU) WHO HAVE UNCONTROLLED BLOOD PHENYLALANINE CONCENTRATIONS GREATER THAN 600 MICROMOL/L ON EXISTING MANAGEMENT
BLA 761051	POTELIGEO	MOGAMULIZUMAB-KPKC	KYOWA KIRIN, INC.	P,O	8/8/2018	FOR THE TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY MYCOSIS FUNGOIDES (MF) OR SÉZARY SYNDROME (SS) AFTER AT LEAST ONE PRIOR SYSTEMIC THERAPY
BLA 761094	OXERVATE	CENEGERMIN-BKBJ	DOMPE FARMACEUTICI S.P.A.	P,O	8/22/2018	FOR TREATMENT OF NEUROTROPHIC KERATITIS
BLA 761090	TAKHZYRO	LANADELUMAB-FLYO	DYAX CORP.	P,O	8/23/2018	FOR PROPHYLAXIS TO PREVENT ATTACKS OF HEREDITARY ANGIOEDEMA (HAE) IN PATIENTS 12 YEARS AND OLDER

BLA 761104	LUMOXITI	MOXETUMOMAB PASUDOTOX-TD	ASTRAZENECA AB	P,O	9/13/2018	FOR TREATMENT OF ADULT PATIENTS WITH RELAPSED OR REFRACTORY HAIRY CELL LEUKEMIA (HCL) WHO RECEIVED AT LEAST TWO PRIOR SYSTEMIC THERAPIES, INCLUDING TREATMENT WITH A PURINE NUCLEOSIDE ANALOG (PNA)
BLA 761089	AJOVY	FREMANEZUMAB-VFRM	TEVA BRANDED PHARMACEUTICAL PRODU	P	9/14/2018	FOR THE PREVENTIVE TREATMENT OF MIGRAINE IN ADULTS.
BLA 761063	EMGALITY	GALCANEZUMAB-GNLM	ELI LILLY AND COMPANY	S	9/27/2018	FOR THE PREVENTIVE TREATMENT OF MIGRAINE IN ADULTS
BLA 761097	LIBTAYO	CEMPLIMAB-RWLC	REGENERON PHARMACEUTICALS, INC.	P	9/28/2018	FOR THE TREATMENT OF PATIENTS WITH METASTATIC CUTANEOUS SQUAMOUS CELL CARCINOMA (CSCC) OR LOCALLY ADVANCED CSCC WHO ARE NOT CANDIDATES FOR CURATIVE SURGERY OR CURATIVE RADIATION
BLA 761092	REVCОВI	ELAPEGADEMASE-LVLR	LEADIANT BIOSCIENCES, INC.	P,O	10/5/2018	FOR TREATMENT OF ADENOSINE DEAMINASE-SEVERE COMBINED IMMUNODEFICIENCY (ADA-SCID)
BLA 761107	GAMIFANT	EMAPALUMAB-LZSG	NOVIMMUNE SA	P,O	11/20/2018	FOR THE TREATMENT OF ADULT AND PEDIATRIC (NEWBORN AND OLDER) PATIENTS WITH PRIMARY HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (HLH) WITH REFRACTORY, RECURRENT OR PROGRESSIVE DISEASE OR INTOLERANCE WITH CONVENTIONAL HLH THERAPY
BLA 761102	ASPARLAS	CALASPARGASE PEGOL-MKNL	SERVIER PHARMACEUTICALS LLC	S,O	12/20/2018	FOR THE TREATMENT OF ACUTE LYMPHOBLASTIC LEUKEMIA IN PEDIATRIC AND YOUNG ADULT PATIENTS AGE 1 MONTH TO 21 YEARS
BLA 761108	ULTOMIRIS	RAVULIZUMAB-CWVZ	ALEXION PHARMACEUTICALS, INC.	P,O	12/21/2018	FOR THE TREATMENT OF ADULT PATIENTS WITH PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH)
BLA 761116	ELZONRIS	TAGRAXOFUSP-ERZS	STEMLINE THERAPEUTICS INC	P,O	12/21/2018	FOR THE TREATMENT OF BLASTIC PLASMACYTOID DENDRITIC CELL NEOPLASM (BPDCN) IN ADULTS AND IN PEDIATRIC PATIENTS 2 YEARS AND OLDER

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).**