

**CY 2015 CDER New Molecular Entity (NME) Drug & Original BLA Calendar Year Approvals
As of December 31, 2015**

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

Selection Criteria:

User Response: Start Date: 1/1/2015 End Date: 12/31/2015

Sort Order: Approval Date

New Molecular Entity Application (NME) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 206316	SAVAYSA	EDOXABAN TOSYLATE	DAIICHI SANKYO INC	S	1/8/2015	REDUCE THE RISK OF STROKE AND SYSTEMIC EMBOLISM IN PATIENTS WITH NONVALVULAR ATRIAL FIBRILLATION
NDA 207103	IBRANCE	PALBOCICLIB	PFIZER INC	P	2/3/2015	FOR THE TREATMENT OF POSTMENOPAUSAL WOMEN WITH ESTROGEN RECEPTOR (ER)-POSITIVE, HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE ADVANCED BREAST CANCER AS INITIAL ENDOCRINE-BASED THERAPY FOR THEIR METASTATIC DISEASE
NDA 206947	LENVIMA	LENVATINIB	EISAI INC	P,O	2/13/2015	FOR THE TREATMENT OF PATIENTS WITH LOCALLY RECURRENT OR METASTATIC, PROGRESSIVE, RADIOACTIVE IODINEREFRACTORY DIFFERENTIATED THYROID CANCER
NDA 205353	FARYDAK	PANOBINOSTAT	NOVARTIS PHARMACEUTICALS CORP	P,O	2/23/2015	FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA (MM), WHO HAVE RECEIVED AT LEAST 2 PRIOR REGIMENS, INCLUDING BORTEZOMIB AND AN IMMUNOMODULATORY AGENT
NDA 206494	AVYCAZ	CEFTAZIDIME-AVIBACTAM	CEREXA INC	P	2/25/2015	FOR COMPLICATED URINARY TRACT INFECTIONS (CUTI) INCLUDING PYELONEPHRITIS AND COMPLICATED INTRA-ABDOMINAL INFECTIONS (CIAI)
NDA 207500	CRESEMBA	ISAVUCONAZONIUM SULFATE	ASTELLAS PHARMA US INC	P,O	3/6/2015	FOR THE TREATMENT OF INVASIVE ASPERGILLOSIS AND INVASIVE MUCORMYCOSIS
NDA 205750	CHOLBAM	CHOLIC ACID	ASKLEPION PHARMACEUTICALS LLC	P,O	3/17/2015	FOR THE TREATMENT OF BILE ACID SYNTHESIS DISORDERS DUE TO SINGLE ENZYME DEFECTS AND AS ADJUNCTIVE TREATMENT OF PEROXISOMAL DISORDERS INCLUDING ZELLWEGER SPECTRUM DISORDERS IN PATIENTS WHO EXHIBIT MANIFESTATIONS OF LIVER DISEASE, STEATORRHEA OR COMPLICATIONS FROM DECREASED FAT SOLUBLE VITAMIN ABSORPTION

NDA 206143	CORLANOR	IVABRADINE	AMGEN INC	P	4/15/2015	TO REDUCE THE RISK OF HOSPITALIZATION FOR WORSENING HEART FAILURE IN PATIENTS WITH STABLE, SYMPTOMATIC CHRONIC HEART FAILURE WITH LEFT VENTRICULAR EJECTION FRACTION \leq 35%, WHO ARE IN SINUS RHYTHM WITH RESTING HEART RATE \geq 70 BEATS PER MINUTE AND EITHER ARE ON MAXIMALLY TOLERATED DOSES OF BETA-BLOCKERS OR HAVE A CONTRAINDICATION TO BETA-BLOCKER
NDA 206333	KYBELLA	DEOXYCHOLIC ACID	KYTHERA BIOPHARMACEUTICALS INC	S	4/29/2015	FOR IMPROVEMENT IN THE APPEARANCE OF MODERATE TO SEVERE CONVEXITY OR FULLNESS ASSOCIATED WITH SUBMENTAL FAT IN ADULTS
NDA 206940	VIBERZI	ELUXADOLINE	FURIEX PHARMACEUTICALS INC	P	5/27/2015	FOR THE TREATMENT OF IRRITABLE BOWEL SYNDROME WITH DIARRHEA
NDA 204958	KENGREAL	CANGRELOR	THE MEDICINES CO	S	6/22/2015	AS AN ADJUNCT TO PERCUTANEOUS CORONARY INTERVENTION (PCI) TO REDUCE THE RISK OF PERIPROCEDURAL MYOCARDIAL INFARCTION (MI), REPEAT CORONARY REVASCULARIZATION, AND STENT THROMBOSIS (ST) IN PATIENTS WHO HAVE NOT BEEN TREATED WITH A P2Y12 PLATELET INHIBITOR AND ARE NOT BEING GIVEN A GLYCOPROTEIN IIB/IIIA INHIBITOR
NDA 206038	ORKAMBI	LUMACAFOTOR/IVACAFOTOR	VERTEX PHARMACEUTICALS INC	P,O	7/2/2015	FOR THE TREATMENT OF CYSTIC FIBROSIS (CF) IN PATIENTS AGE 12 YEARS AND OLDER WHO ARE HOMOZYGOUS FOR THE F508DEL MUTATION IN THE CFTR GENE
NDA 207620	ENTRESTO	SACUBITRIL/VALSARTAN	NOVARTIS PHARMACEUTICALS CORP	P	7/7/2015	TO REDUCE THE RISK OF CARDIOVASCULAR DEATH AND HOSPITALIZATION FOR HEART FAILURE IN PATIENTS WITH CHRONIC HEART FAILURE (NYHA CLASS II-IV) AND REDUCED EJECTION FRACTION
NDA 205422	REXULTI	BREXPIPIRAZOLE	OTSUKA PHARMACEUTICAL CO LTD	S	7/10/2015	ADJUNCTIVE TREATMENT OF MAJOR DEPRESSIVE DISORDER
NDA 205266	ODOMZO	SONIDEGIB	NOVARTIS PHARMACEUTICALS CORP	S	7/24/2015	WITH LOCALLY ADVANCED BASAL CELL CARCINOMA (BCC) THAT HAS RECURRENT FOLLOWING SURGERY OR RADIATION THERAPY OR THOSE WHO ARE NOT CANDIDATES FOR SURGERY OR
NDA 206843	DAKLINZA	DACLATASVIR	BRISTOL-MYERS SQUIBB CO	P	7/24/2015	HEPATITIS C VIRUS, GENOTYPE 3 INFECTION

NDA 022526	ADDYI	FLIBANSERIN	SPROUT PHARMACEUTICALS INC	S	8/18/2015	FOR THE 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 WITHIN THE RELATIONSHIP, OR THE EFFECTS OF A MEDICATION OR OTHER DRUG SUBSTANCE
NDA 206500	VARUBI	ROLAPITANT	TESARO INC	S	9/1/2015	FOR PREVENTION OF DELAYED NAUSEA AND VOMITING ASSOCIATED WITH INITIAL AND REPEAT COURSES OF EMETOGENIC CANCER CHEMOTHERAPY, INCLUDING, BUT NOT LIMITED TO, HIGHLY EMETOGENIC CHEMOTHERAPY
NDA 208169	XURIDEN	URIDINE TRIACETATE	WELLSTAT THERAPEUTICS CORP	P,O	9/4/2015	FOR THE TREATMENT OF HEREDITARY OROTIC ACIDURIA
NDA 204370	VRAYLAR	CARIPRAZINE	FOREST RESEARCH INSTITUTE INC	S	9/17/2015	EPISODES ASSOCIATED WITH BIPOLAR I DISORDER
NDA 207981	LONSURF	TRIFLURIDINE AND TIPIRACIL	TAIHO ONCOLOGY INC	S	9/22/2015	FOR THE TREATMENT OF PATIENTS WITH METASTATIC COLORECTAL CANCER WHO HAVE BEEN PREVIOUSLY TREATED WITH FLUOROPYRIMIDINE-OXALIPLATIN-AND IRINOTECAN-BASED CHEMOTHERAPY, AN ANTI-VEGF BIOLOGICAL THERAPY, AND IF RAS WILD-TYPE, AN ANTI-EGFR THERAPY
NDA 203314	TRESIBA	INSULIN DEGLUDEC INJECTION	NOVO NORDISK INC	S	9/25/2015	TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH DIABETES MELLITUS
NDA 207533	ARISTADA	ARIPIRAZOLE LAUROXIL	ALKERMES INC	S	10/5/2015	FOR THE TREATMENT OF SCHIZOPHRENIA
NDA 205739	VELTASSA	PATIROMER	RELYPSA INC	S	10/21/2015	FOR THE TREATMENT OF HYPERKALEMIA
NDA 207953	YONDELIS	TRABECTEDIN	JANSSEN PRODUCTS LP	P,O	10/23/2015	FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC LIPOSARCOMA OR LEIOMYOSARCOMA WHO RECEIVED A PRIOR ANTHRACYCLINE-CONTAINING REGIMEN
NDA 207561	GENVOYA	ELVITEGRAVIR, COBICISTAT, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INC	S	11/5/2015	FOR TREATMENT OF HIV-1 INFECTION IN ADULTS AND PEDIATRIC PATIENTS 12 YEARS OF AGE OR OLDER 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 6 MONTHS WITH NO HISTORY OF TREATMENT FAILURE AND NO KNOWN SUBSTITUTIONS ASSOCIATED WITH RESISTANCE TO THE INDIVIDUAL COMPONENTS OF GENVOYA

NDA 206192	COTELLIC	COBIMETINIB	GENENTECH INC	P,O	11/10/2015	FOR THE TREATMENT, OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA WITH BRAF V600E OR V600K MUTATION, IN COMBINATION WITH VEMURAFENIB. COTELLIC IS NOT INDICATED FOR TREATMENT OF PATIENTS WITH WILD-TYPE BRAF MELANOMA
NDA 208065	TAGRISO	OSIMERTINIB	ASTRAZENECA PHARMACEUTICALS LP	P,O	11/13/2015	FOR THE TREATMENT OF PATIENTS WITH METASTATIC EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) T790M MUTATION-POSITIVE-NON-SMALL-CELL LUNG CANCER (NSCLC), AS DETECTED BY AN FDAAPPROVED TEST, WHO HAVE PROGRESSED ON OR AFTER EGFR TKI THERAPY
NDA 208462	NINLARO	IXAZOMIB	MILLENNIUM PHARMACEUTICALS INC	P,O	11/20/2015	FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST ONE PRIOR THERAPY
NDA 208434	ALECENSA	ALECTINIB	HOFFMANN-LA ROCHE INC	P,O	12/11/2015	FOR THE 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 022225	BRIDION	SUGAMMADEX	ORGANON USA INC A SUBSIDIARY OF MERCK AND CO INC	P	12/15/2015	FOR THE REVERSAL OF NEUROMUSCULAR BLOCKADE INDUCED BY ROCURONIUM BROMIDE AND VECURONIUM BROMIDE IN ADULTS UNDERGOING SURGERY
NDA 207947	UPTRAVI	SELEXIPAG	ACTELION PHARMACEUTICALS LTD	S,O	12/21/2015	FOR TREATMENT OF PULMONARY ARTERIAL HYPERTENSION (PAH, WHO GROUP I) TO REDUCE THE RISKS OF DISEASE PROGRESSION AND HOSPITALIZATION FOR PAH
NDA 207988	ZURAMPIC	LESINURAD	ARDEA BIOSCIENCES INC	S	12/22/2015	FOR THE TREATMENT OF HYPERURICEMIA ASSOCIATED WITH GOUT IN PATIENTS WHO HAVE NOT ACHIEVED TARGET SERUM URIC ACID LEVELS WITH A XANTHINE OXIDASE INHIBITOR ALONE

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
BLA 125504/0.0	COSENTYX	SECUKINUMAB	NOVARTIS PHARMACEUTICALS CORPORA	S	1/21/2015	FOR THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS IN ADULT PATIENTS WHO ARE CANDIDATES FOR SYSTEMIC THERAPY OR PHOTOTHERAPY

BLA 125511/0.0	NATPARA	PARATHYROID HORMONE	NPS PHARMACEUTICALS	S,O	1/23/2015	INDICATED AS AN ADJUNCT TO CALCIUM AND VITAMIN D TO CONTROL HYPOCALCEMIA IN PATIENTS WITH HYPOPARATHYROIDISM
BLA 125516/0.0	UNITUXIN	DINUTUXIMAB	UNITED THERAPEUTICS CORPORATION	P,O	3/10/2015	FOR THE TREATMENT OF PEDIATRIC PATIENTS WITH HIGH-RISK NEUROBLASTOMA WHO ACHIEVE AT LEAST A PARTIAL RESPONSE TO PRIOR FIRST-LINE MULTIAGENT,MULTIMODALITY THERAPY
BLA 125559/0.0	PRALUENT	ALIROCUMAB	SANOFI-AVENTIS U.S. LLC	P	7/24/2015	AS AN ADJUNCT TO DIET AND MAXIMALLY TOLERATED STATIN THERAPY FOR THE TREATMENT OF ADULTS WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA OR CLINICAL ATHEROSCLEROTIC CARDIOVASCULAR DISEASE, WHO REQUIRE ADDITIONAL LOWERING OF LDL-C
BLA 125522/0.0	REPATHA	EVOLOCUMAB	AMGEN, INC.	S,O	8/27/2015	INDICATED AS AN ADJUNCT TO DIET AND MAXIMALLY TOLERATED STATIN THERAPY FOR THE TREATMENT OF ADULTS WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA OR CLINICAL ATHEROSCLEROTIC CARDIOVASCULAR DISEASE, WHO REQUIRE ADDITIONAL LOWERING OF LDL-C. REPATHA IS ALSO INDICATED AS AN ADJUNCT TO DIET AND OTHER LDL-LOWERING THERAPIES (E.G., STATINS, EZETIMIBE, LDL APHERESIS) IN PATIENTS WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH) WHO REQUIRE ADDITIONAL LOWERING OF LDL-C. THIS APPLICATION ONLY INCLUDES A 420 MG ONCE MONTHLY DOSING REGIMEN FOR THE HOFH INDICATION
BLA 761025/0.0	PRAXBIND	IDARUCIZUMAB	BOEHRINGER INGELHEIM PHARMACEUTIC	P	10/16/2015	INDICATED IN PATIENTS TREATED WITH PRADAXA® WHEN REVERSAL OF THE ANTICOAGULANT EFFECTS OF DABIGATRAN IS NEEDED FOR EMERGENCY SURGERY/URGENT PROCEDURES AND IN LIFE-THREATENING OR UNCONTROLLED BLEEDING
BLA 125513/0.0	STRENSIQ	ASFOTASE ALFA	ALEXION PHARMACEUTICALS, INC.	P,O	10/23/2015	FOR THE TREATMENT OF PATIENTS WITH PERINATAL/INFANTILE- AND JUVENILE-ONSET HYPOPHOSPHATASIA (HPP)
BLA 125526/0.0	NUCALA	MEPOLIZUMAB	GLAXOSMITHKLINE LLC	S	11/4/2015	INDICATED FOR THE ADD-ON MAINTENANCE TREATMENT OF PATIENTS WITH SEVERE ASTHMA AGED 12 YEARS AND OLDER, AND WITH AN EOSINOPHILIC PHENOTYPE

BLA 761036/0.0	DARZALEX	DARATUMUMAB	JANSSEN BIOTECH, INC.	P,O	11/16/2015	INDICATED FOR TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST 3 PRIOR LINES OF THERAPY INCLUDING A PROTEASOME INHIBITOR AND AN IMMUNOMODULATORY AGENT OR ARE DOUBLE REFRACTORY TO A PROTEASOME INHIBITOR AND AN
BLA 125547/0.0	PORTRAZZA	NECITUMUMAB	ELI LILLY AND COMPANY	S	11/24/2015	IS INDICATED, IN COMBINATION WITH GEMCITABINE AND CISPLATIN, FOR FIRST-LINE TREATMENT OF PATIENTS WITH METASTATIC, SQUAMOUS, NON-SMALL CELL LUNG CANCER. PORTRAZZA IS NOT INDICATED FOR TREATMENT OF NON-SQUAMOUS, NON-SMALL CELL LUNG CANCER
BLA 761035/0.0	EMPLICITI	ELOTUZUMAB	BRISTOL-MYERS SQUIBB COMPANY	P,O	11/30/2015	INDICATED IN COMBINATION WITH LENALIDOMIDE AND DEXAMETHASONE FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED ONE TO THREE PRIOR THERAPIES
BLA 125561/0.0	KANUMA	SEBELIPASE ALFA	SYNAGEVA BIOPHARMA CORP	P,O	12/8/2015	INDICATED FOR THE TREATMENT OF PATIENTS WITH A DIAGNOSIS OF LYSOSOMAL ACID LIPASE (LAL) DEFICIENCY

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).