CDER New Molecular Entity (NME) & New BLA Calendar Year Approvals

As of December 31, 2012

Selection Criteria:
User Response: Start Date: 1/1/2012 End Date: 12/31/2012

Sort Order: Approval Date

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 202833	PICATO	INGENOL MEBUTATE	LEO PHARMA AS	S	1/23/2012	FOR ACTINIC KERATOSES ON THE TRUNK AND EXTREMITIES
NDA 202324	INLYTA	AXITINIB	PFIZER INC	S	1/27/2012	FOR THE TREATMENT OF ADVANCED RENAL CELL CARCINOMA AFTER FAILURE OF ONE PRIOR SYSTEMIC THERAPY
NDA 203388	ERIVEDGE	VISMODEGIB	GENENTECH INC	P	1/30/2012	FOR THE TREATMENT OF ADULTS WITH METASTATIC BASAL CELL CARCINOMA, OR WITH LOCALLY ADVANCED BASAL CELL CARCINOMA THAT HAS RECURRED FOLLOWING SURGERY OR WHO ARE NOT CANDIDATES FOR SURGERY, AND WHO ARE NOT CANDIDATES FOR RADIATION
NDA 203188	KALYDECO	IVACAFTOR	VERTEX PHARMACEUTICALS INC	P,O	1/31/2012	FOR THE TREATMENT OF CYSTIC FIBROSIS IN PATIENTS AGE 6 YEARS AND OLDER WHO HAVE A G551D MUTATION IN THE CFTR GENE
NDA 202514	ZIOPTAN	TAFLUPROST OPHTHALMIC SOLUTION	MERCK SHARP AND DOHME CORP	S	2/10/2012	PROVIDES FOR THE REDUCTION OF ELEVATED INTRAOCULAR PRESSURE (IOP) IN PATIENTS WITH OPEN-ANGLE GLAUCOMA OR OCULAR HYPERTENSION
NDA 021746	SURFAXIN	LUCINACTANT	DISCOVERY LABORATORIES INC	S	3/6/2012	FOR THE PREVENTION OF RESPIRATORY DISTRESS SYNDROME IN PREMATURE INFANTS
NDA 202799	OMONTYS	PEGINESATIDE	AFFYMAX INC	S	3/27/2012	FOR THE TREATMENT OF ANEMIA DUE TO CHRONIC KIDNEY DISEASE (CKD) IN ADULT PATIENTS ON DIALYSIS
NDA 202008	AMYVID	FLORBETAPIR F 18	AVID RADIOPHARMACEUTICALS INC	P	4/6/2012	FOR USE AS A RADIOACTIVE DIAGNOSTIC AGENT FOR POSITRON EMISSION TOMOGRAPHY (PET) IMAGING OF THE BRAIN TO ESTIMATE B-AMYLOID NEURITIC PLAQUE DENSITY IN ADULT PATIENTS WITH COGNITIVE IMPAIRMENT WHO ARE BEING EVALUATED FOR ALZHEIMER'S DISEASE (AD) AND OTHER CAUSES OF COGNITIVE DECLINE
NDA 202276	STENDRA	AVANAFIL	VIVUS INC	S	4/27/2012	FOR THE TREATMENT OF ERECTILE DYSFUNCTION (ED)
NDA 022458	ELELYSO	TALIGLUCERASE ALFA	PFIZER INC	S,O	5/1/2012	FOR USE AS LONG-TERM ENZYME REPLACEMENT THERAPY IN PATIENTS WITH TYPE 1 GAUCHER DISEASE
NDA 022529	BELVIQ	LORCASERIN HYDROCHLORIDE	ARENA PHARMACEUTICALS INC	S	6/27/2012	PROVIDES FOR THE USE AS AN ADJUNCT TO REDUCED-CALORIE DIET AND INCREASED PHYSICAL ACTIVITY FOR CHRONIC WEIGHT MANAGEMENT IN ADULT PATIENTS WITH A BODY MASS INDEX GREATER THAN OR EQUAL TO 30 KG/M2 (OBESE), OR ADULT PATIENTS WITH A BODY MASS INDEX GREATER THAN OR EQUAL TO 27 KG/M2 (OVERWEIGHT) IN THE PRESENCE OF AT LEAST ONE WEIGHT-RELATED COMORBID CONDITION
NDA 202611	MYRBETRIQ	MIRABEGRON	ASTELLAS PHARMA GLOBAL DEVELOPMENT INC	S	6/28/2012	PROVIDES FOR THE TREATMENT OF OVERACTIVE BLADDER

NDA 202535	PREPOPIK	SODIUM PICOSULFATE/ MAGNESIUM OXIDE/ CITRIC ACID	FERRING PHARMACEUTICALS AS	S	7/16/2012	PROVIDES FOR CLEANSING OF THE COLON AS A PREPARATION FOR COLONOSCOPY IN ADULTS
NDA 202714	KYPROLIS	CARFILZOMIB	ONYX PHARMACEUTICALS INC	S,O	7/20/2012	PROVIDES FOR THE TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA WHO HAVE RECEIVED AT LEAST TWO PRIOR THERAPIES INCLUDING BORTEZOMIB AND AN IMMUNOMODULATORY AGENT AND HAVE DEMONSTRATED DISEASE PROGRESSION ON OR WITHIN 60 DAYS OF COMPLETION OF THE LAST THERAPY
NDA 202450	TUDORZA PRESSAIR	ACLIDINIUM BROMIDE	FOREST LABORATORIES INC	S	7/23/2012	PROVIDES FOR THE LONG-TERM MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA
NDA 203100	STRIBILD	ELVITEGRAVIR/ COBICISTAT/ EMTRICITABINE/ TENOFOVIR DISOPROXIL FUMARATE	GILEAD SCIENCES INC	S	8/27/2012	PROVIDES FOR THE USE OF FIXED-DOSE COMBINATION TABLET FOR THE TREATMENT OF HIV-1 INFECTION IN TREATMENT-NAIVE ADULT PATIENTS
NDA 202811	LINZESS	LINACLOTIDE	FOREST LABORATORIES INC	S	8/30/2012	PROVIDES FOR THE TREATMENT OF IRRITABLE BOWEL SYNDROME WITH CONSTIPATION AND CHRONIC IDIOPATHIC CONSTIPATION
NDA 203415	XTANDI	ENZALUTAMIDE	MEDIVATION INC	P	8/31/2012	PROVIDES FOR THE TREATMENT OF PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER WHO HAVE PREVIOUSLY RECEIVED DOCETAXEL
NDA 203341		BOSUTINIB	WYETH PHARMACEUTICALS INC	S,O	9/4/2012	PROVIDES FOR THE TREATMENT OF ADULT PATIENTS WITH CHRONIC, ACCELERATED, OR BLAST PHASE PH+ CHRONIC MYELOGENOUS LEUKEMIA (CML) WITH RESISTANCE, OR INTOLERANCE TO PRIOR THERAPY
NDA 202992	AUBAGIO	TERIFLUNOMIDE	SANOFI AVENTIS US LLC	S	9/12/2012	PROVIDES FOR THE TREATMENT OF RELAPSING FORMS OF MULTIPLE SCLEROSIS
NDA 203155		CHOLINE C 11	MAYO CLINIC PET RADIOCHEMISTRY FACILITY	P	9/12/2012	FOR POSITRON EMISSION TOMOGRAPHY (PET) IMAGING OF PATIENTS WITH SUSPECTED PROSTATE CANCER RECURRENCE AND NON-INFORMATIVE BONE SCINTIGRAPHY, COMPUTERIZED TOMOGRAPHY (CT) OR MAGNETIC RESONANCE IMAGING (MRI)
NDA 203085	STIVARGA	REGORAFENIB	BAYER HEALTHCARE PHARMACEUTICALS INC	P	9/27/2012	FOR THE TREATMENT OF PATIENTS WITH METASTATIC COLORECTAL CANCER (CRC) WHO HAVE BEEN PREVIOUSLY TREATED WITH FLUOROPYRIMIDINE-, OXALIPLATIN- AND IRINOTECAN-BASED CHEMOTHERAPY, AN ANTI-VEGF THERAPY, AND, IF KRAS WILD TYPE, AN ANTI-EGFR THERAPY
NDA 202834	FYCOMPA	PERAMPANEL	EISAI INC	S	10/22/2012	INDICATED AS ADJUNCTIVE THERAPY FOR THE TREATMENT OF PARTIAL-ONSET SEIZURES WITH OR WITHOUT SECONDARILY GENERALIZED SEIZURES IN PATIENTS WITH EPILEPSY AGED 12 YEARS AND OLDER
NDA 203585	SYNRIBO	OMACETAXINE MEPESUCCINATE	IVAX INTERNATIONAL GMBH	S,O	10/26/2012	INDICATED FOR THE TREATMENT OF ADULT PATIENTS WITH CHRONIC OR ACCELERATED PHASE CHRONIC MYELOID LEUKEMIA (CML) WITH RESISTANCE AND/OR INTOLERANCE TO TWO OR MORE TYROSINE KINASE INHIBITORS (TKI)

NDA 203214	XELJANZ	TOFACITINIB	PFIZER INC	S	11/6/2012	INDICATED FOR THE TREATMENT OF ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS WHO HAVE HAD AN INADEQUATE RESPONSE OR INTOLERANCE TO METHOTREXATE; MAY BE USED AS MONOTHERAPY OR IN COMBINATION WITH METHOTREXATE OR OTHER NONBIOLOGIC DISEASE-MODIFYING ANTIRHEUMATIC DRUGS (DMARDS)
NDA 203756	COMETRIQ	CABOZANTINIB	EXELIXIS INC	P,O	11/29/2012	INDICATED FOR THE TREATMENT OF PATIENTS WITH PROGRESSIVE, METASTATIC MEDULLARY THYROID CANCER (MTC)
NDA 200677	SIGNIFOR	PASIREOTIDE DIASPARTATE	NOVARTIS PHARMACEUTICALS CORP	S,O	12/14/2012	INDICATED FOR THE TREATMENT OF ADULT PATIENTS WITH CUSHING'S DISEASE FOR WHOM PITUITARY SURGERY IS NOT AN OPTION OR HAS NOT BEEN CURATIVE
NDA 203469	ICLUSIG	PONATINIB	ARIAD PHARMACEUTICALS INC	P,O	12/14/2012	INDICATED FOR THE TREATMENT OF ADULT PATIENTS WITH CHRONIC PHASE, ACCELERATED PHASE, OR BLAST PHASE CHRONIC MYELOID LEUKEMIA (CML) THAT IS RESISTANT OR INTOLERANT TO PRIOR TYROSINE KINASE INHIBITOR THERAPY OR PHILADELPHIA CHROMOSOME POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA (PH+ALL) THAT IS RESISTANT OR INTOLERANT TO PRIOR TYROSINE KINASE INHIBITOR THERAPY
NDA 203441	GATTEX	TEDUGLUTIDE	NPS PHARMACEUTICALS INC	S,O	12/21/2012	INDICATED FOR THE TREATMENT OF ADULT PATIENTS WITH SHORT BOWEL SYNDROME (SBS) WHO ARE DEPENDENT ON PARENTERAL SUPPORT
NDA 203858	JUXTAPID	LOMITAPIDE	AEGERION PHARMACEUTICALS INC	S,O	12/21/2012	INDICATED AS AN ADJUNCT TO A LOW-FAT DIET AND OTHER LIPID-LOWERING TREATMENTS, INCLUDING LDL APHERESIS WHERE AVAILABLE, TO REDUCE LOW-DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C), TOTAL CHOLESTEROL (TC), APOLIPOPROTEIN B (APO B), AND NON-HIGHDENSITY LIPOPROTEIN CHOLESTEROL (NON-HDL-C) IN PATIENTS WITH HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HOFH)
NDA 202155	ELIQUIS	APIXABAN	BRISTOL MYERS SQUIBB CO PHARMACEUTICAL RESEARCH INSTITUTE	P	12/28/2012	INDICATED TO REDUCE THE RISK OF STROKE AND SYSTEMIC EMBOLISM IN PATIENTS WITH NONVALVULAR ATRIAL FIBRILLATION
NDA 204384	SIRTURO	BEDAQUILINE	JANSSEN THERAPEUTICS DIV JANSSEN PRODUCTS LP	P,O	12/28/2012	INDICATED AS PART OF COMBINATION THERAPY IN ADULTS (≥ 18 YEARS) WITH PULMONARY MULTI-DRUG RESISTANT TUBERCULOSIS (MDR-TB)
NDA 202292	FULYZAQ	CROFELEMER	SALIX PHARMACEUTICALS INC	P	12/31/2012	INDICATED FOR THE SYMPTOMATIC RELIEF OF NON-INFECTIOUS DIARRHEA IN ADULT PATIENTS WITH HIV/AIDS ON ANTI-RETROVIRAL THERAPY

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION

L 125327/0.0	VORAXAZE	GLUCARPIDASE	BTG INTERNATIONAL INC.	P,O	1/17/2012	INDICATED FOR THE TREATMENT OF TOXIC (>1 MICROMOLE PER LITER) PLASMA METHOTREXATE CONCENTRATIONS IN PATIENTS WITH DELAYED METHOTREXATE CLEARANCE DUE TO IMPAIRED RENAL FUNCTION. GLUCARPIDASE IS NOT INDICATED FOR USE IN PATIENTS WHO EXHIBIT THE EXPECTED CLEARANCE OF METHOTREXATE (PLASMA METHOTREXATE CONCENTRATIONS WITHIN 2 STANDARD DEVIATIONS OF THE MEAN METHOTREXATE EXCRETION CURVE SPECIFIC FOR THE DOSE OF METHOTREXATE ADMINISTERED) OR THOSE WITH NORMAL OR MILDLY IMPAIRED RENAL FUNCTION BECAUSE OF THE POTENTIAL RISK OF SUBTHERAPY
L 125409/0.0	PERJETA	PERTUZUMAB	GENENTECH, INC.	P	6/8/2012	INDICATED FOR USE IN COMBINATION WITH TRASTUZUMAB AND DOCETAXEL FOR THE TREATMENT OF PATIENTS WITH HER2-POSITIVE METASTATIC BREAST CANCER WHO HAVE NOT RECEIVED PRIOR ANTI-HER2 THERAPY OR CHEMOTHERAPY FOR METASTATIC DISEASE
L 125418/0.0	ZALTRAP	ZIV-AFLIBERCEPT	SANOFI-AVENTIS U.S. LLC	P	8/3/2012	IN COMBINATION WITH 5-FLOUROURACIL, LEUCOVORIN, IRINOTECAN-(FOLFIRI), IS INDICATED FOR PATIENTS WITH METASTATIC COLORECTAL CANCER (MCRC) THAT IS RESISTANT TO OR HAS PROGRESSED FOLLOWING AN OXALIPLATIN-CONTAINING REGIMEN
L 125294/0.0	NEUTROVAL	FILGRASTIM	SICOR BIOTECH UAB	S	8/29/2012	INDICATED FOR THE REDUCTION IN THE DURATION OF SEVERE NEUTROPENIA IN PATIENTS WITH NON-MYELOID MALIGNANCIES RECEIVING MYELOSUPPRESSIVE ANTI-CANCER DRUGS ASSOCIATED WITH A CLINICALLY SIGNIFICANT INCIDENCE OF FEBRILE NEUTROPENIA
L 125422/0.0	JETREA	OCRIPLASMIN	THROMBOGENICS INC.	P	10/17/2012	INDICATED FOR THE TREATMENT OF SYMPTOMATIC VITREOMACULAR ADHESION
L 125349/0.0		RAXIBACUMAB	HUMAN GENOME SCIENCES INC	P,O	12/14/2012	INDICATED FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS WITH INHALATIONAL ANTHRAX DUE TO BACILLUS ANTHRACIS IN COMBINATION WITH APPROPRIATE ANTIBACTERIAL DRUGS, AND FOR PROPHYLAXIS OF INHALATIONAL ANTHRAX WHEN ALTERNATIVE THERAPIES ARE NOT AVAILABLE OR ARE NOT APPROPRIATE

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).