DIVISION OF BUSINESS ANALYSIS AND REPORTING
OFFICE OF BUSINESS INFORMATICS

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

As of December 31, 2011

Last Refresh Date: 1/6/2012

Selection Criteria:
User Response: Start Date: 1/1/2011 End Date: 12/31/2011

Sort Order: Approval Date

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 022454	DATSCAN	IOFLUPANE 1-123 INJECTION	GE HEALTHCARE INC	P	1/14/2011	INDICATED FOR STRIATAL DOPAMINE TRANSPORTER VISUALIZATION USING SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY (SPECT) BRAIN IMAGING TO ASSIST IN THE EVALUATION OF ADULT PATIENTS WITH SUSPECTED PARKINSONIAN SYNDROMES (PS)
NDA 022408	NATROBA	SPINOSAD	PARAPRO PHARMACEUTICALS LLC	S	1/18/2011	INDICATED FOR THE TREATMENT OF HEAD LICE AND NITS FOR PATIENTS AGED 4 YEARS AND ABOVE.
NDA 022567	VIIBRYD	VILAZODONE HYDROCHLORIDE	TROVIS PHARMACEUTICALS LLC	S	1/21/2011	INDICATED FOR THE TREATMENT OF MAJOR DEPRESSIVE DISORDER
NDA 200796	EDARBI	AZILSARTAN MEDOXOMIL	TAKEDA PHARMACEUTICALS NORTH AMERICA INC	S	2/25/2011	INDICATED FOR THE TREATMENT OF HYPERTENSION
NDA 022522	DALIRESP TABLETS, 500 MCG	ROFLUMILAST	FOREST RESEARCH INSTITUTE INC	S	2/28/2011	INDICATED AS A TREATMENT TO REDUCE THE RISK OF COPD EXACERBATIONS IN PATIENTS WITH SEVERE COPD ASSOCIATED WITH CHRONIC BRONCHITIS AND A HISTORY OF EXACERBATIONS
NDA 201277	GADAVIST	GADOBUTROL	BAYER HEALTHCARE PHARMACEUTICALS INC	S	3/14/2011	INDICATED FOR INTRAVENOUS USE IN DIAGNOSTIC MRI IN ADULTS AND CHILDREN (2 YEARS OF AGE AND OLDER) TO DETECT AND VISUALIZE AREAS WITH DISRUPTED BLOOD BRAIN BARRIER (BBB) AND/OR ABNORMAL VASCULARITY OF THE CENTRAL NERVOUS SYSTEM.
NDA 022405	VANDETANIB	VANDETANIB	IPR PHARMACEUTICALS INC	P,O	4/6/2011	TREATMENT OF SYMPTOMATIC OR PROGRESSIVE MEDULLARY THYROID CANCER IN PATIENTS WITH UNRESECTABLE LOCALLY ADVANCED OR METASTATIC DISEASE.
NDA 022399	HORIZANT	GABAPENTIN ENACARBIL	GLAXO GROUP LTD DBA GLAXOSMITHKLINE	S	4/6/2011	TREATMENT OF MODERATE TO SEVERE PRIMARY RESTLESS LEGS SYNDROME (RLS) IN ADULTS.
NDA 202379	ZYTIGA	ABIRATERONE ACETATE	CENTOCOR ORTHO BIOTECH INC	P	4/28/2011	FOR USE IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER WHO HAVE RECEIVED PRIOR CHEMOTHERAPY CONTAINING DOXETAXEL
NDA 201280	TRADJENTA	LINAGLIPTIN	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	5/2/2011	PROVIDES FOR THE USE OF TRADJENTA (LINAGLIPTIN) TABLETS AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS
NDA 202022	EDURANT™	RILPIVIRINE	TIBOTEC INC	S	5/20/2011	PROVIDES FOR THE USE OF EDURANT™ (RILPIVIRINE) TABLETS IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE TREATMENT OF HIV-1 INFECTION IN TREATMENTNAÏVE ADULT PATIENTS
NDA 202258	VICTRELIS™	BOCEPREVIR	SCHERING CORP	P	5/13/2011	PROVIDES FOR THE USE OF VICTRELIS™ (BOCEPREVIR) 200 MG CAPSULES FOR THE TREATMENT OF CHRONIC HEPATITIS C (CHC) GENOTYPE 1 INFECTION, IN COMBINATION WITH PEGINTERFERON ALFA AND RIBAVIRIN, IN ADULT PATIENTS, 18 YEARS OF AGE AND OLDER, WITH COMPENSATED LIVER
NDA 201917	INCIVEK™	TELAPREVIR	VERTEX PHARMACEUTICALS INC	P	5/23/2011	PROVIDES FOR THE USE OF INCIVEK™ (TELAPREVIR) IN COMBINATION WITH PEGINTERFERON ALFA AND RIBAVIRIN, FOR THE TREATMENT OF GENOTYPE 1 CHRONIC HEPATITIS C (CHC) IN ADULT PATIENTS WITH COMPENSATED LIVER DISEASE, INCLUDING CIRRHOSIS, WHO ARE TREATMENT-NAÏVE OR
NDA 201699	DIFICID	FIDAXOMICIN	OPTIMER PHARMACEUTICALS INC	P	5/27/2011	PROVIDES FOR THE USE OF DIFICID (FIDAXOMICIN) TABLET FOR THE TREATMENT OF CLOSTRIDIUM DIFFICILE-ASSOCIATED DIARRHEA IN ADULTS (≥ 18 YEARS OF AGE).
NDA 022345	POTIGA	EZOGABINE	GLAXOSMITHKLINE	S	6/10/2011	PROVIDES FOR THE USE OF POTIGA AS ADJUNCTIVE TREATMENT FOR ADULT PATIENTS WITH PARTIAL-ONSET SEIZURES WITH OR WITHOUT SECONDARY GENERALIZATION
NDA 022383	ARCAPTA NEOHALER	INDACATEROL MALEATE INHALATION POWDER	NOVARTIS PHARMACEUTICALS CORP	S	7/1/2011	PROVIDES FOR THE LONG-TERM, ONCE-DAILY MAINTENANCE BRONCHODILATOR TREATMENT OF AIRFLOW OBSTRUCTION IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCHITIS AND/OR EMPHYSEMA
NDA 022406	XARELTO	RIVAROXABAN	JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC	S	7/1/2011	PROVIDES FOR THE PROPHYLAXIS OF DEEP YEIN THROMBOSIS AND PULMONARY EMBOLISM IN PATIENTS UNDERGOING HIP REPLACEMENT SURGERY OR KNEE REPLACEMENT SURGERY.
NDA 022433	BRILINTA	TICAGRELOR	ASTRAZENECA LP	S	7/20/2011	PROVIDES TO REDUCE THE RATE OF THROMBOTIC CARDIOVASCULAR EVENTS IN PATIENTS WITH ACUTE CORONARY SYNDROME (ACS) (UNSTABLE ANGINA, NON-ST ELEVATION MYOCARDIAL INFARCTION, OR ST ELEVATION MYOCARDIAL INFARCTION)

NDA 202429	ZELBORAF	VEMURAFENIB	HOFFMANN LA ROCHE INC	P,O	8/17/2011	PROVIDES FOR THE TREATMENT OF UNRESECTABLE OR METASTATIC MELANOMA WITH THE BRAFV600E MUTATION AS DETECTED BY AN FDA-APPROVED TEST.
NDA 022150	FIRAZYR	ICATIBANT ACETATE	SHIRE ORPHAN THERAPIES INC	P,O	8/25/2011	PROVIDES FOR THE TREATMENT OF ACUTE ATTACKS OF HEREDITARY ANGIOEDEMA IN ADULTS 18 YEARS OF AGE AND OLDER
NDA 202570	XALKORI	CRIZOTINIB	PFIZER INC	P,O	8/26/2011	PROVIDES FOR THE TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) THAT IS ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE AS DETECTED BY AN FDA APPROVED TEST
NDA 021825	FERRIPROX	DEFERIPRONE	APOPHARMA INC	S,O	10/14/2011	PROVIDES FOR THE TREATMENT OF PATIENTS WITH TRANSFUSIONAL IRON OVERLOAD DUE TO THALASSEMIA SYNDROMES WHEN CURRENT CHELATION THERAPY IS INADEQUATE
NDA 202067	ONFI	CLOBAZAM	LUNDBECK INC	S,O	10/21/2011	PROVIDES ADJUNCTIVE TREATMENT OF SEIZURES ASSOCIATED WITH LENNOX-GASTAUT SYNDROME (LGS) IN PATIENTS 2 YEARS OF AGE OR ORDER
NDA 202192	JAKAFI	RUXOLITINIB	INCYTE CORP	P,O	11/16/2011	PROVIDES FOR THE TREATMENT OF PATIENTS WITH INTERMEDIATE OR HIGH-RISK MYELOFIBROSIS, INCLUDING PRIMARY MYELOFIBROSIS, POST-POLYCYTHEMIA VERA MYELOFIBROSIS AND POST-ESSENTIAL THROMBOCYTHEMIA MYELOFIBROSIS.

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
L 125370/0.0	BENLYSTA	BELIMUMAB	HUMAN GENOME SCIENCES, INC.	P	3/9/2011	TREATMENT OF ADULT PATIENTS WITH ACTIVE, AUTOANTIBODY-POSITIVE, SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) WHO ARE RECEIVING STANDARD THERAPY
L 125377/0.0	YERVOY	IPILIMUMAB	BRISTOL-MYERS SQUIBB COMPANY	P,O	3/25/2011	TREATMENT OF UNRESECTABLE OR METASTATIC MELANOMA
L 125288/0.0	NULOJIX	BELATACEPT	BRISTOL-MYERS SQUIBB COMPANY	S,O	6/15/2011	PROPHYLAXIS OF ORGAN REJECTION IN ADULT PATIENTS RECEIVING A KIDNEY TRANSPLANT
L 125388/0.0	ADCETRIS	BRENTUXIMAB VEDOTIN	SEATTLE GENETICS, INC.	P,O	8/19/2011	TREATMENT OF PATIENTS WITH HODGKIN LYMPHOMA AFTER FAILURE OF AUTOLOGOUS STEM CELL TRANSPLANT (ASCT) OR AFTER FAILURE OF AT LEAST TWO PRIOR MULTI-AGENT CHEMOTHERAPY REGIMENS IN PATIENTS WHO ARE NOT ASCT CANDIDATES
L 125359/0.0	ERWINAZE	ASPARAGINASE ERWINIA CHRYSANTHEMI	EUSA PHARMA (USA) INC..	P,O	11/18/2011	FOR THE TREATMENT OF PATIENTS WITH ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) WHO HAVE DEVELOPED HYPERSENSITIVITY TO E.COLI-DERIVED ASPARAGINASE.
L 125387/0.0	EYLEA	AFLIBERCEPT	REGENERON PHARMACEUTICALS, INC.	P	11/18/2011	FOR THE TREATMENT OF NEOVASCULAR "WET" AGE-RELATED MACULAR DEGENERATION (AMD).

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).