

**CDER New Molecular Entity (NME) Drug and New Biologic Approvals for Calendar Year 2008**

**Updated through November 30, 2008**

**NME New Drug Application (NDA) Approvals:**

Application Type	Application Number	Proprietary Name	Established Name	Applicant	Review Classification	Approval Date	Indications
N	022187	INTELENCE	ETRAVIRINE	TIBOTEC	P	18-Jan-08	PROVIDES IN COMBINATION WITH OTHER ANTIRETROVIRAL AGENTS FOR THE THE TREATMENT OF HIV-1 INFECTION IN TREATMENT-EXPERIENCED ADULT PATIENTS, WHO HAVE EVIDENCE OF VIRAL REPLICATION AND HIV-1 STRAINS RESISTANT TO A NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR (NNRTI) AND OTHER ANTIRETROVIRAL AGENTS.
N	021992	PRISTIQ	DESVENLAFAXINE SUCCINATE	WYETH	S	29-Feb-08	PROVIDES TREATMENT OF MAJOR DEPRESSIVE DISORDER.
N	022249	TREANDA	BENDAMUSTINE HYDROCHLORIDE	CEPHALON	P	20-Mar-08	PROVIDES FOR THE TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA (CLL).
N	022161	LEXISCAN	REGADENOSON	CV THERAPEUTICS	S	10-Apr-08	PROVIDES FOR THE USE AS A PHARMACOLOGIC STRESS AGENT FOR RADIONUCLIDE MYOCARDIAL PERFUSION IMAGING 0.4 MG/5 ML (0.08MG/ML).
N	021964	RELISTOR	METHYLNALTREXONE BROMIDE	PROGENICS	S	24-Apr-08	PROVIDES FOR THE TREATMENT OF OPIOID-INDUCED CONSTIPATION IN PATIENTS WITH ADVANCED ILLNESS WHO ARE RECEIVING PALLIATIVE CARE, WHEN RESPONSE TO LAXATIVE THERAPY HAS NOT BEEN SUFFICIENT.
N	021775	ENTEREG	ALVIMOPAN	ADOLOR	S	20-May-08	PROVIDES TREATMENT OF FOR THE ACCELERATION OF TIME TO GASTROINTESTINAL RECOVERY FOLLOWING PARTIAL LARGE OR SMALL BOWEL RESECTION SURGERY WITH PRIMARY ANASTOMOSIS.
N	022212	DUREZOL	DIFLUPREDNATE	SIRION	P	23-Jun-08	PROVIDES TREATMENT OF INFLAMMATION AND PAIN ASSOCIATED WITH OCULAR SURGERY.
N	022090	EOVIST INJECTION	GADOXETATE DISODIUM	BAYER	S	03-Jul-08	PROVIDES TREATMENT FOR USE IN MAGNETIC RESONANCE IMAGING (MRI) OF THE LIVER IN ADULT PATIENTS TO PROVIDE CONTRAST IN THE T1 WEIGHTED IMAGES TO AID IN THE DETECTION AND CHARACTERIZATION OF FOCAL LIVER PATHOLOGIES IN PRE-SURGICAL EVALUATION.
N	022156	CLEVIPREX	CLEVIDIPINE BUTYRATE	MEDICINES COMPANY	S	01-Aug-08	REDUCES BLOOD PRESSURE WHEN USE OF ORAL THERAPY IS NOT FEASIBLE.
N	021894	XENAZINE	TETRABENAZINE	PRESTWICK	P	15-Aug-08	PROVIDES TREATMENT FOR THE CHOREA OF HUNTINGTON'S DISEASE.
N	022290	ADRE VIEW	IOBENUANE I 123 INJECTION	GE HEALTHCARE	P	19-Sep-08	PROVIDES FOR THE DETECTION OF PRIMARY OR METASTATIC PHEOCHROMOCYTOMAS.

N	022206	RAPAFLO	SILODOSIN	WATSON LABS	S	08-Oct-08	PROVIDES TREATMENT OF THE SIGNS AND SYMPTOMS OF BENIGN PROSTHETIC HYPERPLASIA
N	022253	VIMPAT TABLETS	LACOSAMIDE	SCHWARZ BIOSCIENCES	S	28-Oct-08	PROVIDES ADJUNCTIVE THERAPY TREATMENT OF PARTIAL ONSET SEIZERS IN PTS WITH EPILEPSY.
N	022030	TOVIAZ	FESOTERODINE FUMARATE	PFIZER	S	31-Oct-08	PROVIDES FOR THE TREATMENT OF OVERACTIVE BLADDER.
N	021911	BANZEL ORAL TABS	RUFINAMIDE 100/200/400MG TABLETS	EISAI	S	14-Nov-08	PROVIDES FOR THE TREATMENT OF SEIZURES ASSOCIATED WITH LENNOX-GASTAUT SYNDROME
N	022291	PROMACTA	ELTROMBOPAG OLAMINE	GLAXOSMITHKLINE	P	20-Nov-08	PROVIDES FOR THE TREATMENT OF SHORT TERM IDIOPATHIC THROMBOCYTOPAENIC PUPURA (ITP)
N	022304	TAPENTADOL	TAPENTADOL	ORTHO MCNEIL JANSSEN	S	20-Nov-08	PROVIDES FOR THE TREATMENT OF MODERATE TO SEVERE ACUTE PAIN

**Biologic License Application (BLA) Approvals:**

BLA Number	Proprietary Name	Proper Name	Applicant	Review Classification	Approval Date	Indication
125249	ARCALYST	RILONACEPT	REGENERON	P,O	27-Feb-08	PROVIDES TREATMENT FOR CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS).
125160	CIMZIA	CERTOLIZUMAB PEGOL	UCB	S	22-Apr-08	PROVIDES FOR THE TREATMENT OF REDUCING THE SIGNS AND SYMPTOMS OF CROHN'S DISEASE AND MAINTAINING CLINICAL RESPONSE IN ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE DISEASE WHO HAVE AN INADEQUATE RESPONSE TO CONVENTIONAL THERAPY.
125268	NPLATE	ROMIPLOSTIM	AMGEN	P	22-Aug-08	PROVIDES TREATMENT FOR IDIOPATHIC (IMMUNE) THROMBOCYTOPENIC PURPURA.

**THERAPEUTIC POTENTIALS:**

P - PRIORITY REVIEW - SIGNIFICANT IMPROVEMENT COMPARED TO MARKETED PRODUCTS, IN THE TREATMENT, DIAGNOSIS, OR PREVENTION OF A DISEASE.

S - STANDARD REVIEW - THE DRUG APPEARS TO HAVE THERAPEUTIC QUALITIES SIMILAR TO THOSE OF ONE OR MORE ALREADY MARKETED DRUGS.

O - ORPHAN DESIGNATION- PURSUANT TO SECTION 526 OF THE ORPHAN DRUG ACT (PUBLIC LAW 97-414 AS AMENDED).