

**CDER Drug and Biologic Approvals for Calendar Year 2008**

**Updated through November 30, 2008**

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

| Application Type | Application Number | Proprietary Name  | Established Name              | Applicant   | Chemical Type | Review Classification | 505B2 FLAG | Approval Date |
|------------------|--------------------|-------------------|-------------------------------|-------------|---------------|-----------------------|------------|---------------|
| N                | 021658             | ALVESCO           | CICLESONIDE                   | NYCOMED     | 3             | S                     | Y          | 10-Jan-08     |
| N                | 022067             | FLO-PRED          | PREDNISOLONE ACETATE          | TARO        | 3             | S                     | Y          | 17-Jan-08     |
| N                | 022187             | INTELENCE         | ETRAVIRINE                    | TIBOTEC     | 1             | P                     |            | 18-Jan-08     |
| N                | 022107             | TEKTRUNA HCT      | ALISKIREN/HYDROCHLOROTHIAZIDE | NOVARTIS    | 4             | S                     |            | 18-Jan-08     |
| N                | 021538             | ACCRETROPIN       | SOMATROPIN                    | CHESAPEAKE  | 5             | S                     | Y          | 23-Jan-08     |
| N                | 050813             | MOXATAG           | AMOXICILLIN                   | MIDDLEBROOK | 3             | S                     | Y          | 23-Jan-08     |
| N                | 022023             | EMEND             | FOSAPREPITANT DIMEGLUMINE     | MERCK & CO  | 2             | S                     | Y          | 25-Jan-08     |
| N                | 022157             | XYZAL             | LEVOCETIRZINE DIHYDROCHLORIDE | UCB, INC.   | 3             | S                     |            | 28-Jan-08     |
| N                | 022078             | SIMCOR            | NIACIN/SIMVASTATIN            | ABBOTT      | 4             | S                     | Y          | 15-Feb-08     |
| N                | 022029             | SALONPAS          | METHYL SALICYLATE & MENTHOL   | HISAMITSU   | 3,4           | S                     | Y          | 20-Feb-08     |
| N                | 022028             | COSYNTROPIN       | COSYNTROPIN                   | SANDOZ      | 5             | S                     |            | 21-Feb-08     |
| N                | 022101             | NEXIUM            | ESOMEPRAZOLE MAGNESIUM        | ASTRAZENECA | 3             | S                     |            | 27-Feb-08     |
| N                | 022033             | LUVOX CR          | FLUVOXAMINE MALEATE           | SOLVAY      | 3             | S                     | Y          | 28-Feb-08     |
| N                | 021992             | PRISTIQ           | DESVENLAFAXINE SUCCINATE      | WYETH       | 1             | S                     |            | 29-Feb-08     |
| N                | 020140             | ISOVORIN          | LEUCOVORIN CALCIUM            | SPECTRUM    | 5             | S,O                   |            | 07-Mar-08     |
| N                | 022195             | MORPHINE SULPHATE | MORPHINE SULPHATE             | ROXANE      | 7             | S                     | Y          | 17-Mar-08     |
| N                | 022207             | MORPHINE SULFATE  | MORPHINE SULFATE              | ROXANE      | 7             | S                     | Y          | 17-Mar-08     |
| N                | 022056             | PRIOSEC           | OMEPRAZOLE                    | ASTRAZENECA | 3             | S                     |            | 20-Mar-08     |
| N                | 022249             | TREANDA           | BENDAMUSTINE HYDROCHLORIDE    | CEPHALON    | 1             | P,O                   | Y          | 20-Mar-08     |

|   |        |                                     |  |                          |   |   |   |           |
|---|--------|-------------------------------------|--|--------------------------|---|---|---|-----------|
| N | 022009 | ANTHELIOS 40                        | AVOBENZENE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE      | L'OREAL                  | 5 | S |   | 31-Mar-08 |
| N | 022161 | LEXISCAN                            | REGADENOSON  | CV THERAPEUTICS          | 1 | S |   | 10-Apr-08 |
| N | 021926 | TREXIMET                            | SUMATRITAM; NAPROXEN SODIUM                              | POZEN                    | 4 | S | Y | 15-Apr-08 |
| N | 021861 | PATANASE                            | OLOPATADINE HYDROCHLORIDE                                | ALCON                    | 3 | S | Y | 15-Apr-08 |
| N | 022108 | APLENZIN                            | BUPROPION HYDROBROMIDE                                   | BIOVAIL LABS             | 2 | S | Y | 23-Apr-08 |
| N | 021964 | RELISTOR                            | METHYLNALTREXONE BROMIDE                                 | PROGENICS                | 1 | S |   | 24-Apr-08 |
| N | 021795 | MINIRIN                             | DESMOPRESSIN ACETATE                                     | FERRING                  | 5 | S | Y | 08-May-08 |
| N | 022185 | TACLONEX SCALP                      | CALCIPOTRIENE; BETAMETHASONE DIPROPIONATE                | LEO PHARM PRODUCTS       | 3 | S | Y | 09-May-08 |
| N | 022159 | ORAVERSE                            | PHENTOLAMINE MESYLATE                                    | NOVALAR                  | 3 | S | Y | 09-May-08 |
| N | 021775 | ENTEREG                             | ALVIMOPAN  | ADOLOR                   | 1 | S | Y | 20-May-08 |
| N | 022104 | VENLAFAXINE HYDROCHLORIDE           | VENLAFAXINE HYDROCHLORIDE                                | OSMOTICA                 | 3 | S | Y | 20-May-08 |
| N | 021830 | ASACOL                              | MESALAMINE   | PROCTOR AND GAMBLE       | 3 | S | Y | 29-May-08 |
| N | 022008 | REQUIP XL                           | ROPINIROLE   | SMITHKLINE BEECHAM       | 3 | S |   | 13-Jun-08 |
| N | 021952 | CLARITIN LIQUI-GELS                 | LORATADINE   | SCHERING-PLOUGH          | 3 | S |   | 16-Jun-08 |
| N | 022220 | TRIVARIA                            | TRIAMCINOLONE ACETONIDE                                  | ALLERGAN                 | 3 | S | Y | 16-Jun-08 |
| N | 021822 | APTIVUS                             | TIPRANAVIR   | BOEHRINGER INGELHEIM     | 3 | P | Y | 23-Jun-08 |
| N | 022212 | DUREZOL                             | DIFLUPREDNATE  | SIRION                   | 1 | P |   | 23-Jun-08 |
| N | 022292 | APTIVUS                             | TIPRANAVIR   | BOEHRINGER INGELHEIM     | 3 | P | Y | 23-Jun-08 |
| N | 022386 | PRANDIMET                           | REPAGLINIDE/METFORMIN HYDROCHLORIDE                      | NOVO NORDISK             | 4 | S | Y | 23-Jun-08 |
| N | 022260 | EPOPROSTENOL SODIUM                 | EPOPROSTENOL SODIUM                                      | GENERAMEDIX              | 5 | S |   | 27-Jun-08 |
| N | 022090 | EOVIST INJECTION                    | GADOXETATE DISODIUM                                      | BAYER                    | 1 | S | Y | 03-Jul-08 |
| N | 022193 | NAVSTEL                             | OPHTHALMIC SOLUTION; HYPROMELLOSE; DEXTROSE; GLUTATHIONE | ALCON                    | 3 | S | Y | 24-Jul-08 |
| N | 022276 | NICARDIPINE HYDROCHLORIDE INJECTION | NICARDINE  | TEVA PARENTERAL          | 5 | S | Y | 24-Jul-08 |
| N | 022152 | STAVZOR                             | VALPROIC ACID  | BANNER MEDICINES COMPANY | 3 | S | Y | 29-Jul-08 |
| N | 022156 | CLEVIPREX                           | CLEVIDIPINE BUTYRATE                                     | BANNER MEDICINES COMPANY | 1 | S | Y | 01-Aug-08 |
| N | 050817 | CEFEPIME INJECTION                  | CEFEPIME INJECTION                                       | BAXTER                   | 3 | S |   | 05-Aug-08 |

|   |         |                                 |  |                      |   |     |   |           |
|---|---------|---------------------------------|--|----------------------|---|-----|---|-----------|
| N | 022186  | AK-FLUOR                        | FLUORESCHEIN INJECTION                   | AKORN                | 3 | S   |   | 08-Aug-08 |
| N | 022234* | DOCETAXEL INJECTION             | DOCETAXEL INJECTION                      | HOSPIRA INC          | 5 | S   |   | 11-Aug-08 |
| N | 021894  | XENAZINE                        | TETRABENAZINE                            | PRESTWICK            | 1 | P,O | Y | 15-Aug-08 |
| N | 022233  | ALOXI                           | PALONOSETRAN HYDROCHLORIDE               | HELSINN              | 3 | S   | Y | 22-Aug-08 |
| N | 021810  | NOVOLOG MIX 50/50               | BIPHASIC INSULIN ASPART 50/50            | NOVO NORDISK         | 3 | S   | Y | 26-Aug-08 |
| N | 022198  | SANCUSO                         | GRAINSETRON TRANSDERMAL SYSTEM/GRANISETR | STRAKAN              | 2 | S   | Y | 12-Sep-08 |
| N | 022285  | KEPPRA EXTENDED RELEASE TABLETS | LEVETIRACETAM                            | UCB INC              | 3 | S   | Y | 12-Sep-08 |
| N | 022290  | ADRE VIEW                       | IOBENUANE I 123 INJECTION                | GE HEALTHCARE        | 1 | P,O | Y | 19-Sep-08 |
| N | 022221  | AKTEN                           | LIDOCAINE HYDROCHLORIDE                  | AKORN                | 5 | S   |   | 07-Oct-08 |
| N | 022206  | RAPAFLO                         | SILODOSIN                                | WATSON LABS          | 1 | S   | Y | 08-Oct-08 |
| N | 022203  | ASTEPRO NASAL SPRAY             | AZELASTINE HYDROCHLORIDE                 | MEDPOINTE            | 5 | S   |   | 15-Oct-08 |
| N | 022226* | PANTOPRAZOLE SODIUM             | PANTOPRAZOLE SODIUM                      | TEVA PARENTERAL      | 5 | S   |   | 20-Oct-08 |
| N | 050819  | ACANYA                          | CLINDAMYCIN PHOSPHATE ALUCEN             | DOW PHARMACEUTICAL   | 5 | S   |   | 23-Oct-08 |
| N | 022262  | LO SEASONIQUE                   | LEVONORGESTREL / ETHINYL ESTRADIOL       | DURAMED              | 3 | S   | Y | 24-Oct-08 |
| N | 022253  | VIMPAT TABLETS                  | LACOSAMIDE                               | SCHWARZ BIOSCIENCES  | 1 | S   | Y | 28-Oct-08 |
| N | 022254  | VIMPAT INJECTION                | LACOSAMIDE                               | SCHWARZ BIOSCIENCES  | 3 | S   | Y | 28-Oct-08 |
| N | 022030  | TOVIAZ                          | FESOTERODINE FUMARATE                    | PFIZER               | 1 | S   |   | 31-Oct-08 |
| N | 022301  | APRISO                          | MESALAMINE                               | SALIX                | 3 | S   |   | 31-Oct-08 |
| N | 021911  | BANZEL ORAL TABS                | RUFINAMIDE TABLETS                       | EISAI                | 1 | S   | Y | 14-Nov-08 |
| N | 022291  | PROMACTA                        | ELTROMBOPAG OLAMINE                      | GLAXOSMITHKLINE      | 1 | P   | Y | 20-Nov-08 |
| N | 022304  | TAPENTADOL                      | TAPENTADOL                               | ORTHO MCNEIL JANSSEN | 1 | S   | Y | 20-Nov-08 |
| N | 021788  | CENESTIN                        | CENESTIN VAGINAL CREAM                   | DURAMED              | 3 | S   | Y | 28-Nov-08 |

\*= DOCETAXEL INJECTION AND PANTOPRAZOLE SODIUM HAVE BEEN TENTATIVELY APPROVED

**New Drug Application (NDA) Tentative Approvals under the President's Emergency Plan for AIDS Relief (PEPFAR):**

| Application Number | Proprietary Name                        | Established Name                        | Applicant       | Chemical Type | Review Classification | 505B2 FLAG | Approval Date |
|--------------------|---|---|-----------------|---------------|-----------------------|------------|---------------|
| 021837             | STAVUDINE; LAMIVUDINE; NEVIRAPINE       | STAVUDINE; LAMIVUDINE; NEVIRAPINE       | STRIDES         | 4             | P                     |            | 20-Mar-08     |
| 022177             | STAVUDINE; LAMIVUDINE; NEVIRAPINE       | STAVUDINE; LAMIVUDINE; NEVIRAPINE       | STRIDES         | 4             | P                     | Y          | 20-Mar-08     |
| 022167             | LAMIVUDINE; STAVUDINE                   | LAMIVUDINE; STAVUDINE                   | CIPLA LIMITED   | 3             | P                     | Y          | 19-Jun-08     |
| 022141             | TENOFAVIR DISOPROXYL FURMATE/LAMIVUDINE | TENOFAVIR DISOPROXYL FURMATE/LAMIVUDINE | MATRIX LABS     | 4             | P                     | Y          | 12-Sep-08     |
| 022293             | ABACAVIR SULFATE                        | ABACAVIR SULFATE                        | AUROBINDO       | 3             | P                     |            | 12-Sep-08     |
| 022061             | LANIVUDINE; ZIDOVUDINE; NEVIRAP         | LANIVUDINE; ZIDOVUDINE; NEVIRAP         | MATRIX LABS LTD | 3             | S                     | Y          | 21-Oct-08     |

N021837 stavudine 40mg/lamivudine 150mg/nevirapine 200mg Tablets was tentatively approved on 03/20/2008 under PEPFAR

N022177 stavudine 30mg/lamivudine 150mg/nevirapine 200mg Tablets was tentatively approved on 03/20/2008 under PEPFAR.

N022167 lamivudine 30mg/stavudine 6mg Tablets was tentatively approved on 06/19/2008 under PEPFAR.

N022141 tenofovir disoproxyl furmate/lamivudine was tentatively approved on 09/12/2008 under PEPFAR.

N022293 acacavir sulfate 60mg tablets was tentatively approved on 09/12/2008 under PEPFAR.

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

| BLA Number | Proprietary Name | Proper Name              | Applicant | Review Classification | Approval Date |
|------------|------------------|--------------------------|-----------|-----------------------|---------------|
| 125249     | ARCALYST         | RILONACEPT               | REGENERON | P,O                   | 27-Feb-08     |
| 125160     | CIMZIA           | CERTOLIZUMAB PEGOL       | UCB       | S                     | 22-Apr-08     |
| 125196     | PEGPAK           | PEGINTERFERON; RIBAVIRIN | SCHERING  | S                     | 13-Jun-08     |
| 125268     | NPLATE           | ROMIPLOSTIM              | AMGEN     | P                     | 22-Aug-08     |

**NDA Chemical Type:**

- 1 - New molecular entity
- 2 - New ester, new salt, or other noncovalent derivative
- 3 - New dosage form
- 4 - New combination
- 5 - New formulation or new manufacturer
- 7 - Drug already marketed, but without an approved NDA
- 8 - OTC switch

**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).