

**CDER Drug and Biologic 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

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

| APPLICATION NUMBER | PROPRIETARY NAME | ESTABLISHED NAME   | APPLICANT  | REVIEW CLASSIFICATION | 505(B)(2) APPROVAL | APPROVAL DATE |
|--------------------|------------------|--|--|-----------------------|--------------------|---------------|
| NDA 202788         | SUBSYS           | FENTANYL   | INSYS THERAPEUTICS INC                           | S                     | Y                  | 1/4/2012      |
| NDA 203049         |                  | ARGATROBAN   | HIKMA PHARM CO LTD                               | S                     | Y                  | 1/5/2012      |
| NDA 202832         |                  | SODIUM CHLORIDE  | MEDEFIL INC                                      | S                     | Y                  | 1/6/2012      |
| NDA 022312         |                  | DOCETAXEL  | APOTEX INC                                       | S                     | Y                  | 1/11/2012     |
| NDA 201194         |                  | OXYCODONE HYDROCHLORIDE  | VISTAPHARM INC                                   | S                     | Y                  | 1/12/2012     |
| NDA 022577         | VIREAD           | TENOFOVIR DISOPROXIL FUMARATE  | GILEAD SCIENCES INC                              | P,O                   |                    | 1/18/2012     |
| NDA 202129         | ZETONNA          | CICLESONIDE  | NYCOMED GMBH                                     | S                     |                    | 1/20/2012     |
| NDA 202833         | PICATO           | INGENOL MEBUTATE   | LEO PHARMA AS                                    | S                     |                    | 1/23/2012     |
| NDA 022200         | BYDUREON         | EXENATIDE  | AMYLIN PHARMACEUTICALS INC                       | S                     |                    | 1/27/2012     |
| NDA 202324         | INLYTA           | AXITINIB   | PFIZER INC                                       | S                     |                    | 1/27/2012     |
| NDA 201281         | JENTADUETO       | LINAGLIPTIN/ METFORMIN   | BOEHRINGER INGELHEIM PHARMACEUTICALS INC         | S                     | Y                  | 1/30/2012     |
| NDA 203388         | ERIVEDGE         | VISMODEGIB   | GENENTECH INC                                    | P                     |                    | 1/30/2012     |
| NDA 202381 (2)     |                  | ABACAVIR SULFATE/ LAMIVUDINE   | MYLAN LABORATORIES LTD                           | S                     | Y                  | 1/31/2012     |
| NDA 203188         | KALYDECO         | IVACAFTOR  | VERTEX PHARMACEUTICALS INC                       | P,O                   |                    | 1/31/2012     |
| NDA 202667         | COSOPT           | DORZOLAMIDE HYDROCHLORIDE/ TIMOLOL MALEATE                             | MERCK SHARP AND DOHME CORP                       | S                     |                    | 2/1/2012      |
| NDA 202270         | JANUMET          | SITAGLIPTIN/ METFORMIN HYDROCHLORIDE                                   | MERCK SHARP AND DOHME CORP                       | S                     |                    | 2/2/2012      |
| NDA 022205         | GIAZO            | BALSALAZIDE DISODIUM   | SALIX PHARMACEUTICALS INC                        | S                     |                    | 2/3/2012      |
| NDA 022572         | MITOSOL          | MITOMYCIN  | MOBIUS THERAPEUTICS LLC                          | P,O                   | Y                  | 2/7/2012      |
| NDA 202736         | SKLICE           | IVERMECTIN   | SANOFI TOPAZ INC                                 | S                     |                    | 2/7/2012      |
| NDA 202589 (2)     |                  | LAMIVUDINE/ NEVIRAPINE/ ZIDOVUDINE                                     | MACLEODS PHARMACEUTICALS LTD                     | S                     | Y                  | 2/8/2012      |
| NDA 202514         | ZIOPTAN          | TAFLUPROST OPHTHALMIC SOLUTION   | MERCK SHARP AND DOHME CORP                       | S                     |                    | 2/10/2012     |
| NDA 202763         |                  | TESTOSTERONE   | TEVA PHARMACEUTICALS USA                         | S                     | Y                  | 2/14/2012     |
| NDA 203922         |                  | SODIUM NITRITE   | HOPE PHARMACEUTICALS                             | S,O                   | Y                  | 2/14/2012     |
| NDA 203923         |                  | SODIUM THIOSULFATE   | HOPE PHARMACEUTICALS                             | S,O                   | Y                  | 2/14/2012     |
| NDA 202107         | KORLYM           | MIFEPRISTONE   | CORCEPT THERAPEUTICS INC                         | S,O                   | Y                  | 2/17/2012     |
| NDA 022222         | ULTRESA          | PANCRELIPASE   | APTALIS PHARMA US INC                            | P                     | Y                  | 3/1/2012      |
| NDA 022542         | VIOKACE          | PANCRELIPASE   | APTALIS PHARMA US INC                            | S                     | Y                  | 3/1/2012      |
| NDA 021746         | SURFAXIN         | LUCINACTANT  | DISCOVERY LABORATORIES INC                       | S                     | Y                  | 3/8/2012      |
| NDA 202344         | BINOSTO          | ALENDRONATE SODIUM   | EFFRX PHARMACEUTICALS SA                         | S                     | Y                  | 3/12/2012     |
| NDA 202813         | QNASL            | BECLOMETHASONE DIPROPIONATE  | TEVA BRANDED PHARMACEUTICAL PRODUCTS R AND D INC | S                     | Y                  | 3/23/2012     |
| NDA 202799         | OMONTYS          | PEGINESATIDE   | AFFYMAX INC                                      | S                     |                    | 3/27/2012     |
| NDA 202008         | AMVYD            | FLORBETAPIR F 18   | AVID RADIOPHARMACEUTICALS INC                    | P                     |                    | 4/6/2012      |
| NDA 202276         | STENDRA          | AVANAFIL   | VIVUS INC  | S                     |                    | 4/27/2012     |
| NDA 202212 (2)     |                  | NEVIRAPINE   | CIPLA LTD  | S                     | Y                  | 4/30/2012     |
| NDA 022458         | ELELYSO          | TALIGLUCERASE ALFA   | PFIZER INC                                       | S,O                   |                    | 5/1/2012      |
| NDA 202236         | DYMISTA          | AZELASTINE HYDROCHLORIDE/ FLUTICASONE PROPIONATE                       | MEDA PHARMACEUTICALS                             | S                     | Y                  | 5/1/2012      |
| NDA 202428         | FABIOR           | TAZAROTENE   | STIEFEL LABORATORIES INC                         | S                     |                    | 5/11/2012     |
| NDA 022175         | PERTZYE          | PANCRELIPASE   | DIGESTIVE CARE INC                               | S                     | Y                  | 5/17/2012     |
| NDA 021951         | ABSORICA         | ISOTRETINOIN   | CIPHER PHARMACEUTICALS LTD                       | S                     | Y                  | 5/25/2012     |
| NDA 203195         | SUPRAX           | CEFIXIME   | LUPIN LTD  | S                     | Y                  | 6/1/2012      |
| NDA 201803         | ADVIL            | SODIUM IBUPROFEN   | PFIZER CONSUMER HEALTHCARE                       | S                     | Y                  | 6/12/2012     |
| NDA 202814 (2)     |                  | LAMIVUDINE/ ZIDOVUDINE   | CIPLA LTD  | S                     | Y                  | 6/15/2012     |
| NDA 201635 (1)     | TROKENDI         | TOPIRAMATE   | SUPERNUS PHARMACEUTICALS INC                     | S                     | Y                  | 6/25/2012     |
| NDA 022529         | BELVIQ           | LORCASERIN HYDROCHLORIDE   | ARENA PHARMACEUTICALS INC                        | S                     |                    | 6/27/2012     |
| NDA 202611         | MYRBETRIQ        | MIRABEGRON   | ASTELLAS PHARMA GLOBAL DEVELOPMENT INC           | S                     |                    | 6/28/2012     |
| NDA 201922         | XIMINO           | MINOCYCLINE HYDROCHLORIDE  | RANBAXY LABORATORIES LTD                         | S                     | Y                  | 7/11/2012     |
| NDA 202535         | PREPOPIK         | SODIUM PICOSULFATE/ MAGNESIUM OXIDE/ CITRIC ACID                       | FERRING PHARMACEUTICALS AS                       | S                     | Y                  | 7/16/2012     |
| NDA 022580         | QSYMIA           | PHENTERMINE/ TOPIRAMATE  | VIVUS INC  | S                     | Y                  | 7/17/2012     |
| NDA 202714         | KYPROLIS         | CARFILZOMIB  | ONYX PHARMACEUTICALS INC                         | S,O                   |                    | 7/20/2012     |
| NDA 202450         | TUDORZA PRESSAIR | ACLDINIUM BROMIDE  | FOREST LABORATORIES INC                          | S                     |                    | 7/23/2012     |
| NDA 202020         | RAYOS            | PREDNISONE   | HORIZON PHARMA INC                               | S                     | Y                  | 7/26/2012     |
| NDA 202057         | VASCEPA          | ICOSAPENT ETHYL  | AMARIN PHARMA INC                                | S                     | Y                  | 7/26/2012     |
| NDA 202497         | MARQIBO          | VINCRISTINE SULFATE  | TALON THERAPEUTICS INC                           | S                     | Y                  | 8/9/2012      |
| NDA 203100         | STRIBILD         | ELVITEGRAVIR/ COBICISTAT/ EMTRICITABINE/ TENOFOVIR DISOPROXIL FUMARATE | GILEAD SCIENCES INC                              | S                     |                    | 8/27/2012     |
| NDA 203985         | AFINITOR DISPERZ | EVEROLIMUS   | NOVARTIS PHARMACEUTICAL CORP                     | P,O                   |                    | 8/29/2012     |
| NDA 202811         | LINZESS          | LINACLOTIDE  | FOREST LABORATORIES INC                          | S                     |                    | 8/30/2012     |
| NDA 203109         | REVATIO          | SILDENAFIL   | PFIZER INC                                       | P,O                   |                    | 8/30/2012     |
| NDA 203415         | XTANDI           | ENZALUTAMIDE   | MEDIVATION INC                                   | P                     |                    | 8/31/2012     |
| NDA 203341         |                  | BOSUTINIB  | WYETH PHARMACEUTICALS INC                        | S,O                   |                    | 9/4/2012      |
| NDA 202992         | AUBAGIO          | TERIFLUNOMIDE  | SANOFI AVENTIS US LLC                            | S                     |                    | 9/12/2012     |

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|----------------|------------|---|--|-----|---|------------|
| NDA 203155     |            | CHOLINE C 11  | MAYO CLINIC PET RADIOCHEMISTRY FACILITY                      | P   | Y | 9/12/2012  |
| NDA 202685 (2) |            | LAMIVUDINE/ NEVIRAPINE/<br>ZIDOVUDINE                     | STRIDES ARCOLAB LTD  | S   | Y | 9/21/2012  |
| NDA 202100     | QUILLIVANT | METHYLPHENIDATE<br>HYDROCHLORIDE                          | NEXTWAVE PHARMACEUTICALS INC                                 | S   | Y | 9/27/2012  |
| NDA 203085     | STIVARGA   | REGORAFENIB   | BAYER HEALTHCARE PHARMACEUTICALS INC                         | P   |   | 9/27/2012  |
| NDA 202872     | LOTEMAX    | LOTEPREDNOL ETABONATE                                     | BAUSCH AND LOMB INC  | S   |   | 9/28/2012  |
| NDA 200740     | CYSTARAN   | CYSTEAMINE  | SIGMA TAU PHARMACEUTICALS INC                                | P,O | Y | 10/2/2012  |
| NDA 201820     | BETHKIS    | TOBRAMYCIN  | CORNERSTONE THERAPEUTICS INC                                 | S   | Y | 10/12/2012 |
| NDA 203794     | NUCYNTA    | TAPENTADOL  | JANSSEN PHARMACEUTICALS INC                                  | S   |   | 10/15/2012 |
| NDA 203076 (2) |            | LAMIVUDINE/ NEVIRAPINE/<br>ZIDOVUDINE                     | CIPLA LTD  | S   | Y | 10/16/2012 |
| NDA 203491     |            | NEPAFENAC   | ALCON RESEARCH LTD   | S   |   | 10/16/2012 |
| NDA 202810     | OXTELLAR   | OXCARBAZEPINE   | SUPERNUS PHARMACEUTICALS INC                                 | S   | Y | 10/19/2012 |
| NDA 202834     | FYCOMPA    | PERAMPANEL  | EISAI INC  | S   |   | 10/22/2012 |
| NDA 203585     | SYNRIBO    | OMACETAXINE<br>MEPESUCCINATE                              | IVAX INTERNATIONAL GMBH                                      | S,O |   | 10/26/2012 |
| NDA 203752     | MINIVELLE  | ESTRADIOL   | NOVEN PHARMACEUTICALS INC                                    | S   |   | 10/29/2012 |
| NDA 203050 (1) |            | PALONOSETRON<br>HYDROCHLORIDE                             | DR REDDYS LABORATORIES LTD                                   | S   | Y | 11/2/2012  |
| NDA 203214     | XELJANZ    | TOFACITINIB   | PFIZER INC   | S   |   | 11/6/2012  |
| NDA 203283 (2) |            | LAMIVUDINE/ TENOFOVIR<br>DISOPROXIL FUMARATE              | MACLEODS PHARMACEUTICALS LTD                                 | S   | Y | 11/8/2012  |
| NDA 204119 (2) |            | EFAVIRENZ/ LAMIVUDINE/<br>TENFOVIR DISOPROXIL<br>FUMARATE | HETERO LABS LTD  | P   | Y | 11/8/2012  |
| NDA 203231 (1) |            | ZOLEDRONIC ACID   | ACS DOBFAR INFO SA   | S   | Y | 11/9/2012  |
| NDA 203756     | COMETRIQ   | CABOZANTINIB  | EXELIXIS INC   | P,O |   | 11/29/2012 |
| NDA 204200     | ADRENALIN  | EPINEPHRINE   | JHP PHARMACEUTICALS LLC                                      | S   | Y | 12/7/2012  |
| NDA 200677     | SIGNIFOR   | PASIREOTIDE DIASPARTATE                                   | NOVARTIS PHARMACEUTICALS CORP                                | S,O |   | 12/14/2012 |
| NDA 203469     | ICLUSIG    | PONATINIB   | ARIAD PHARMACEUTICALS INC                                    | P,O |   | 12/14/2012 |
| NDA 203696     | LUPANETA   | LEUPROLIDE ACETATE/<br>NORETHINDRONE ACETATE              | ABBOTT ENDOCRINE INC   | S   |   | 12/14/2012 |
| NDA 203993     | ONFI       | CLOBAZAM  | LUNDBECK LLC   | S,O |   | 12/14/2012 |
| NDA 022453     |            | TOPOTECAN   | TEVA PHARMACEUTICALS USA                                     | S   | Y | 12/20/2012 |
| NDA 203826     |            | PHENYLEPHRINE<br>HYDROCHLORIDE                            | WEST WARD PHARMACEUTICAL CORP                                | S   | Y | 12/20/2012 |
| NDA 022549     | ADASUVE    | LOXAPINE  | ALEXZA PHARMACEUTICALS INC                                   | S   | Y | 12/21/2012 |
| NDA 203441     | GATTTEX    | TEDUGLUTIDE   | NPS PHARMACEUTICALS INC                                      | S,O |   | 12/21/2012 |
| NDA 203858     | JUXTAPID   | LOMITAPIDE  | AEGERION PHARMACEUTICALS INC                                 | S,O |   | 12/21/2012 |
| NDA 204150 (1) |            | DESVENLAFAXINE  | ALEMBIC PHARMACEUTICALS LTD                                  | S   | Y | 12/21/2012 |
| NDA 202155     | ELIQUIS    | APIXABAN  | BRISTOL MYERS SQUIBB CO PHARMACEUTICAL RESEARCH<br>INSTITUTE | P   |   | 12/28/2012 |
| NDA 204384     | SIRTURO    | BEDAQUILINE   | JANSSEN THERAPEUTICS DIV JANSSEN PRODUCTS LP                 | P,O |   | 12/28/2012 |
| NDA 202292     | FULYZAQ    | CROFELEMER  | SALIX PHARMACEUTICALS INC                                    | P   |   | 12/31/2012 |

#### New Drug Application (NDA) Approvals with Prior Tentative Approval(s):

| APPLICATION<br>NUMBER | PROPRIETARY NAME | ESTABLISHED NAME | APPLICANT       | REVIEW<br>CLASSIFICATION | APPROVAL<br>DATE | TENTATIVE<br>APPROVAL DATE |
|-----------------------|------------------|------------------|-----------------|--------------------------|------------------|----------------------------|
| NDA 201739            | AUVI-Q           | EPINEPHRINE      | INTELLIJECT INC | S                        | 8/10/2012        | 7/29/2011                  |

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

| BLA NUMBER   | PROPRIETARY NAME | PROPER NAME     | APPLICANT                 | REVIEW<br>CLASSIFICATION | APPROVAL<br>DATE |
|--------------|------------------|-----------------|---------------------------|--------------------------|------------------|
| L 125327/0.0 | VORAXAZE         | GLUCARPIDASE    | BTG INTERNATIONAL INC.    | P,O                      | 1/17/2012        |
| L 125409/0.0 | PERJETA          | PERTUZUMAB      | GENENTECH, INC.           | P                        | 6/8/2012         |
| L 125418/0.0 | ZALTRAP          | ZIV-AFLIBERCEPT | SANOFI-AVENTIS U.S. LLC   | P                        | 8/3/2012         |
| L 125294/0.0 | NEUTROVAL        | FILGRASTIM      | SICOR BIOTECH UAB         | S                        | 8/29/2012        |
| L 125422/0.0 | JETREA           | OCRIPLASMIN     | THROMBOGENICS INC.        | P                        | 10/17/2012       |
| L 125349/0.0 |                  | RAXIBACUMAB     | HUMAN GENOME SCIENCES INC | P,O                      | 12/14/2012       |

(1) Application has been tentatively approved.

(2) Application has been tentatively approved or approved under PEPFAR.

Tentative Approval (TA) is an action given to an application for a drug that meets all the requirements for approval; however, it may not be legally marketed in the U.S. until the market exclusivity and/or patent term of the listed drug upon which the application relies, has expired.

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).