



**CDER Drug and Biologic Calendar Year Approvals
As of December 31, 2011**

Last Refresh Date: 3/9/2012

Selection Criteria:

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

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 200748 (2) | LAMIVUDINE AND ZIDOVUDINE TABLETS, 30 MG/60 MG | LAMIVUDINE AND ZIDOVUDINE TABLETS, 30 MG/60 MG | MATRIX LABORATORIES LTD | S | Y | 1/5/2011 |
| NDA 022344 (2) | LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS, 300 MG/300 MG | LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS, 300 MG/300 MG | AUROBINDO PHARMA LTD | S | Y | 1/7/2011 |
| NDA 022510 | ABSTRAL | FENTANYL | PROSTRAKAN INC | S | Y | 1/7/2011 |
| NDA 022485 (1) | ARGATROBAN INJECTION (IN SODIUM CHLORIDE) | ARGATROBAN INJECTION (IN SODIUM CHLORIDE) | SANDOZ INC | S | Y | 1/13/2011 |
| NDA 022454 | DATSCAN | IOFLUPANE I-123 INJECTION | GE HEALTHCARE INC | P | | 1/14/2011 |
| NDA 201444 | NITHIODOTE | SODIUM NITRITE INJECTION USP AND SODIUM THIOSULFATE INJECTION USP FOR INTRAVENOUS INFUSION | HOPE PHARMACEUTICALS | P,O | Y | 1/14/2011 |
| NDA 022408 | NATROBA | SPINOSAD | PARAPRO PHARMACEUTICALS LLC | S | | 1/18/2011 |
| NDA 022567 | VIIBRYD | VILAZODONE HYDROCHLORIDE | FOREST LABORATORIES INC | S | | 1/21/2011 |
| NDA 201373 | CHILDREN'S ALLEGRA® ALLERGY AND CHILDREN'S ALLEGRA® HIVES | FEXOFENADINE HCL | SANOFI AVENTIS US LLC | S | | 1/24/2011 |
| NDA 022494 | SODIUM FLUORIDE F-17 | SODIUM FLUORIDE F-18 | NATIONAL INSTITUTES HEALTH NATIONAL CANCER INSTITUTE DIV CANCER TREATMENT AND DIAGNOSIS | P | Y | 1/26/2011 |
| NDA 022544 | GRALISE | GABAPENTIN | DEPOMED INC | S | Y | 1/28/2011 |
| NDA 200582 | TOPOTECAN INJ | TOPOTECAN INJ | HOSPIRA INC | S | Y | 2/2/2011 |
| NDA 021945 | MAKENA | HYDROXYPREGESTERONE CAPROATE | KV PHARMACEUTICAL CO | P,O | Y | 2/3/2011 |
| NDA 050824 | OMEPRAZOLE DELAYED-RELEASE CAPSULES, 20MG, AMOXICILLIN CAPSULES 500MG, AND CLARITHROMYCIN TABLETS, 500MG | OMEPRAZOLE DELAYED-RELEASE CAPSULES, 20MG, AMOXICILLIN CAPSULES 500MG, AND CLARITHROMYCIN TABLETS, 500MG | GASTROENTERO LOGIC LLC | S | Y | 2/8/2011 |
| NDA 201743 (1) | ARGATROBAN INJECTION (IN DEXTROSE) | ARGATROBAN INJECTION (IN DEXTROSE) | SANDOZ INC | S | Y | 2/10/2011 |
| NDA 200732 | ZIDOVUDINE TABLETS, 100MG | ZIDOVUDINE TABLETS, 100MG | MATRIX LABORATORIES LTD | S | Y | 2/23/2011 |
| NDA 200199 | TOPOTECAN INJECTION | TOPOTECAN INJECTION | SANDOZ INC | S | Y | 2/25/2011 |
| NDA 200403 (1) | HYDROMORPHONE HYDROCHLORIDE INJECTION 1,2, AND 4 MG/ML | HYDROMORPHONE HYDROCHLORIDE INJECTION 1,2, AND 4 MG/ML | HOSPIRA INC | S | Y | 2/25/2011 |
| NDA 200796 | EDARBI | AZILSARTAN MEDOXOMIL | TAKEDA PHARMACEUTICALS NORTH AMERICA INC | S | | 2/25/2011 |
| NDA 022522 | ROFLUMILAST | ROFLUMILAST | FOREST RESEARCH INSTITUTE INC | S | | 2/28/2011 |
| NDA 201367 | BANZEL | RUFINAMIDE | EISAI INC | S,O | | 3/3/2011 |
| NDA 022547 (2) | ABACAVIR SULFATE TABS FOR ORAL SUSPENSION (60MG) | ABACAVIR SULFATE TABS FOR ORAL SUSPENSION (60MG) | CIPLA LTD | S | Y | 3/4/2011 |
| NDA 200623 (2) | LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS | LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS | CIPLA LTD | S | Y | 3/4/2011 |
| NDA 201277 | GADAVIST | GADOBUTROL | BAYER HEALTHCARE PHARMACEUTICALS INC | S | | 3/14/2011 |
| NDA 201153 | ZYCLARA | IMIQUIMOD | GRACEWAY PHARMACEUTICALS LLC | S | | 3/24/2011 |
| NDA 201152 | VIRAMUNE® XR™ | NEVIRAPINE | BOEHRINGER INGELHEIM PHARMACEUTICALS INC | S | | 3/25/2011 |
| NDA 022399 | HORIZANT | GABAPENTIN ENACARBIL | GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE | S | Y | 4/6/2011 |
| NDA 022405 | VMOCATE | VANDETANIB | IPR PHARMACEUTICALS INC | P,O | | 4/6/2011 |
| NDA 200738 | LOTEMAX | LOTEPREDNOL ETABONATE OPHTHALMIC OINTMENT | BAUSCH AND LOMB INC | S | | 4/15/2011 |
| NDA 022581 | PHOSLYRA | CALCIUM ACETATE | FRESENIUS MEDICAL CARE NORTH AMERICA | S,O | | 4/18/2011 |
| NDA 022519 | DUEXIS | IBUPROFEN AND FAMOTIDINE | HORIZON PHARMA INC | S | Y | 4/23/2011 |
| NDA 202379 | ZYTIGA | ABIRATERONE ACETATE | CENTOCOR ORTHO BIOTECH INC | P | | 4/28/2011 |
| NDA 022309 | ANDROGEL | TESTOSTERONE GEL | ABBOTT PRODUCTS INC | S | Y | 4/29/2011 |
| NDA 201280 | TRADJENTA | LINAGLIPTIN | BOEHRINGER INGELHEIM PHARMACEUTICALS INC | S | | 5/2/2011 |
| NDA 202007 (2) | ABACAVIR SULFATE AND LAMIVUDINE TABLETS | ABACAVIR SULFATE AND LAMIVUDINE TABLETS | CIPLA LTD | P | Y | 5/12/2011 |
| NDA 202258 | VICTRELIS™ | BOCEPREVIR | SCHERING CORP | P | | 5/13/2011 |
| NDA 202022 | EDURANT™ | RILPIVIRINE | TIBOTEC INC | S | | 5/20/2011 |
| NDA 201917 | INCIVEK™ | TELAPREVIR | VERTEX PHARMACEUTICALS INC | P | | 5/23/2011 |
| NDA 201699 | DIFICID | FIDAXOMICIN | OPTIMER PHARMACEUTICALS INC | P | | 5/27/2011 |
| NDA 022439 | ZUTRIPRO® | HYDROCODONE, CHLORPHENIRAMINE, AND PSEUDOEPHEDRINE | CYPRESS PHARMACEUTICAL INC | S | Y | 6/8/2011 |
| NDA 022442 | REZIRA® | HYDROCODONE AND PSEUDOEPHEDRINE | CYPRESS PHARMACEUTICAL INC | S | Y | 6/8/2011 |
| NDA 201195 | DOCETAXEL INJECTION | DOCETAXEL INJECTION | ACCORD HEALTHCARE INC | S | Y | 6/8/2011 |
| NDA 022345 | POTIGA | EZOGABINE | GLAXOSMITHKLINE | S | | 6/10/2011 |
| NDA 050823 | CEFTAZIDIME FOR INJECTION, USP AND DEXTROSE INJECTION, USP IN THE DUPLEX CONTAINER | CEFTAZIDIME FOR INJECTION, USP AND DEXTROSE INJECTION, USP IN THE DUPLEX CONTAINER | B BRAUN MEDICAL INC | S | Y | 6/13/2011 |
| NDA 202088 | SUPRENZA | PHENTERMINE HYDROCHLORIDE | CITIUS PHARMACEUTICALS LLC | S | Y | 6/13/2011 |
| NDA 202080 | OXECTA | OXYCODONE HCL | KING PHARMACEUTICALS RESEARCH DEVELOPMENT INC | P | Y | 6/17/2011 |
| NDA 021359 | RECTIV | NITROGLYCERIN | PROSTRAKAN INC | P | Y | 6/21/2011 |

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|----------------|---|--|---|-----|---|------------|
| NDA 201517 | MORPHINE SULFATE ORAL SOLUTION | MORPHINE SULFATE ORAL SOLUTION | LANNETT HOLDINGS INC | S | Y | 6/23/2011 |
| NDA 202231 | LEVOTHYROXINE SODIUM FOR INJECTION | LEVOTHYROXINE SODIUM FOR INJECTION | APP PHARMACEUTICALS | S | Y | 6/24/2011 |
| NDA 022434 | ARGATROBAN INJECTION | ARGATROBAN INJECTION | EAGLE PHARMACEUTICALS INC | S | Y | 6/29/2011 |
| NDA 201525 | DOCETAXEL INJECTION | DOCETAXEL INJECTION | SANDOZ INC | S | Y | 6/29/2011 |
| NDA 022569 | LAZANDA | FENTANYL | ARCHIMEDES DEVELOPMENT LTD | S | Y | 6/30/2011 |
| NDA 202245 | CODEINE SULFATE ORAL SOLUTION | CODEINE SULFATE ORAL SOLUTION | ROXANE LABORATORIES INC | S | Y | 6/30/2011 |
| NDA 022383 | ARCAPTA NEOHALER | INDACATEROL MALEATE INHALATION POWDER | NOVARTIS PHARMACEUTICALS CORP | S | | 7/1/2011 |
| NDA 022406 | XARELTO | RIVAROXABAN | JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC | S | | 7/1/2011 |
| NDA 022433 | BRILINTA | TICAGRELOR | ASTRAZENECA LP | S | | 7/20/2011 |
| NDA 201370 | HEPARIN SODIUM INJECTION | HEPARIN SODIUM INJECTION | PFIZER INC | S | Y | 7/21/2011 |
| NDA 201739 (1) | E-CUE | EPINEPHRINE | INTELLUJECT INC | S | Y | 7/29/2011 |
| NDA 200795 | GEMCITABINE INJECTION | GEMCITABINE INJECTION | HOSPIRA INC | S | Y | 8/4/2011 |
| NDA 202172 (1) | ROSUVASTATIN ZINC | ROSUVASTATIN ZINC | WATSON LABORATORIES INC | S | Y | 8/4/2011 |
| NDA 202123 | COMPLERA | EMTRICITABINE/RILPIVIRINE/TE NOFOVIR DISOPROXIL FUMARATE | GILEAD SCIENCES INC | P | | 8/10/2011 |
| NDA 202429 | ZELBORAF | VEMURAFENIB | HOFFMANN LA ROCHE INC | P,O | | 8/17/2011 |
| NDA 022150 | FIRAZZYR | ICATIBANT ACETATE | SHIRE ORPHAN THERAPIES INC | P,O | | 8/25/2011 |
| NDA 200533 | NUCYNTA ER | TAPENTADOL | ORTHO MCNEIL JANSSEN PHARMACEUTICALS INC | S | | 8/25/2011 |
| NDA 202570 | XALKORI | CRIZOTINIB | PFIZER INC | P,O | | 8/26/2011 |
| NDA 022305 | PUR-WASH | PURIFIED WATER | NIAGARA PHARMACEUTICALS INC | S | Y | 9/1/2011 |
| NDA 202171 (2) | LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE | LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE | MATRIX LABORATORIES LTD | S | Y | 9/8/2011 |
| NDA 201151 (2) | LAMIVUDINE AND ZIDOVUDINE | LAMIVUDINE AND ZIDOVUDINE | CIPLA LTD | S | Y | 9/22/2011 |
| NDA 202133 | FLUOXETINE | FLUOXETINE | EDGE MONT PHARMACEUTICALS LLC | S | | 10/6/2011 |
| NDA 021747 | COMBIVENT RESPIMAT | IPRATROPIUM BROMIDE AND ALBUTEROL | BOEHRINGER INGELHEIM PHARMACEUTICALS INC | S | Y | 10/7/2011 |
| NDA 202343 | JUVISYNC | SITAGLIPTIN AND SIMVASTATIN FIXED-DOSE COMBINATION TABLETS | MERCK SHARP AND DOHME CORP | S | | 10/7/2011 |
| NDA 021825 | FERRIPROX | DEFERIPRONE | APOPHARMA INC | S,O | | 10/14/2011 |
| NDA 202067 | ONFI | CLOBAZAM | LUNDBECK INC | S,O | | 10/21/2011 |
| NDA 022496 | EXPAREL | BUPIVACAINE LIPOSOME INJECTABLE SUSPENSION | PACIRA PHARMACEUTICALS INC | S | Y | 10/28/2011 |
| NDA 202439 | XARELTO | RIVAROXABAN | JANSSEN PHARMACEUTICALS INC | S | | 11/4/2011 |
| NDA 202543 | LEVETIRACETAM | LEVETIRACETAM | HQ SPECIALTY PHARMA LLC | S | Y | 11/9/2011 |
| NDA 022497 | FORFIVO XL | BUPROPION HYDROCHLORIDE | INTELGENX CORP | S | Y | 11/10/2011 |
| NDA 202515 | MORPHINE SULFATE | MORPHINE SULFATE | HOSPIRA INC | S | Y | 11/14/2011 |
| NDA 202192 | JAKAFI | RUXOLITINIB | INCYTE CORP | P,O | | 11/16/2011 |
| NDA 022282 (2) | ATAZANAVIR SULFATE AND RITONAVIR TABLETS | ATAZANAVIR SULFATE AND RITONAVIR TABLETS | MYLAN LABORATORIES LTD | P | Y | 11/18/2011 |
| NDA 202157 (2) | LAMIVUDINE, NEVIRAPINE AND ZIDOVUDINE TABLETS | LAMIVUDINE, NEVIRAPINE AND ZIDOVUDINE TABLETS | HETERO LABS LTD | S | Y | 11/18/2011 |
| NDA 022328 | INTERMEZZO | ZOLPIDEM TARTRATE | PURDUE PHARMA PRODUCTS LP | S | Y | 11/23/2011 |
| NDA 202513 | ANTUROL | OXYBUTYNYN | ANTARES PHARMA INC | S | Y | 12/7/2011 |
| NDA 201655 | OPANA ER | OXYMORPHONE HYDROCHLORIDE | ENDO PHARMACEUTICALS INC | P | | 12/9/2011 |
| NDA 202895 | PREZISTA | DARUNAVIR | TIBOTEC INC | P | | 12/16/2011 |
| NDA 202331 | EDARBYCLOR | AZILSARTAN MEDOXOMIL AND CHLORThALIDONE | TAKEDA PHARMACEUTICALS NORTH AMERICA INC | S | Y | 12/20/2011 |
| NDA 022113 | ADVIL ALLERGY AND CONGESTION RELIEF | IBUPROFEN/PHENYLEPHRINE HYDROCHLORIDE/CHLORPHENIRAMINE MALEATE | PFIZER CONSUMER HEALTHCARE | S | Y | 12/21/2011 |
| NDA 203045 | ISENTRESS | RALTEGRAVIR | MERCK SHARP AND DOHME CORP | P | | 12/21/2011 |

New Drug Application (NDA) Approvals with Prior Tentative Approvals:

| Application Number | Proprietary Name | Established Name | Applicant | Review Classification | Approval Date | Tentative Approval Date |
|--------------------|---|---|-----------------------|-----------------------|---------------|-------------------------|
| NDA 022234 | DOCETAXEL INJECTION | DOCETAXEL INJECTION | HOSPIRA INC | S | 3/8/2011 | 8/11/2008 |
| NDA 022534 | DOCEFREZ™ | DOCETAXEL | SUN PHARMA GLOBAL FZE | S | 5/3/2011 | 2/23/2010 |
| NDA 022485 | ARGATROBAN INJECTION (IN SODIUM CHLORIDE) | ARGATROBAN INJECTION (IN SODIUM CHLORIDE) | SANDOZ INC | S | 5/9/2011 | 1/13/2011 |
| NDA 201743 | ARGATROBAN INJECTION (IN DEXTROSE) | ARGATROBAN INJECTION (IN DEXTROSE) | SANDOZ INC | S | 5/9/2011 | 2/10/2011 |
| NDA 200403 | HYDROMORPHONE HYDROCHLORIDE INJECTION | HYDROMORPHONE HYDROCHLORIDE INJECTION | HOSPIRA INC | S | 12/1/2011 | 2/25/2011 |

Biologic License Application (BLA) Approvals:

| BLA NUMBER | PROPRIETARY NAME | PROPER NAME | APPLICANT | REVIEW CLASSIFICATION | APPROVAL DATE |
|--------------|------------------|-----------------------------------|---------------------------------|-----------------------|---------------|
| L 125370/0.0 | BENLYSTA | BELIMUMAB | HUMAN GENOME SCIENCES, INC. | P | 3/9/2011 |
| L 125377/0.0 | YERVOY | IPILIMUMAB | BRISTOL-MYERS SQUIBB COMPANY | P,O | 3/25/2011 |
| L 125288/0.0 | NULOJIX | BELATACEPT | BRISTOL-MYERS SQUIBB COMPANY | S,O | 6/15/2011 |
| L 125388/0.0 | ADCETRIS | BRENTUXIMAB VEDOTIN | SEATTLE GENETICS, INC. | P,O | 8/19/2011 |
| L 125359/0.0 | ERWINAZE | ASPARAGINASE ERWINIA CHRYSANTHEMI | EUSA PHARMA (USA) INC., | P,O | 11/18/2011 |
| L 125387/0.0 | EYLEA | AFLIBERCEPT | REGENERON PHARMACEUTICALS, INC. | P | 11/18/2011 |

(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).