

**CY 2015 CDER Drug and Biologic Calendar Year Approvals
As of December 31, 2015**

This report reflects the data shown as it is identified in the database.

Selection Criteria:

User Response: Start Date: 1/1/2015 End Date: 12/31/2015

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 203312 | RYTARY | CARBIDOPA AND LEVODOPA EXTENDED-RELEASE CAPSULES | IMPAX LABORATORIES INC | S | Y | 1/7/2015 |
| NDA 203629 | | NEOSTIGMINE METHYLSULFATE | FRESENIUS KABI USA LLC | S | Y | 1/8/2015 |
| NDA 206316 | SAVAYSA | EDOXABAN TOSYLATE | DAIICHI SANKYO INC | S | | 1/8/2015 |
| NDA 206316 | SAVAYSA | EDOXABAN TOSYLATE | DAIICHI SANKYO INC | S | | 1/8/2015 |
| NDA 203952 | DUOPA | CARBIDOPA AND LEVODOPA | ABBVIE INC | S,O | Y | 1/9/2015 |
| NDA 207026 | PHOXILLUM | BK4/2.5 AND B22K4/0 | GAMBRO RENAL PRODUCTS | S,O | | 1/13/2015 |
| NDA 207926 | | PHENYLEPHRINE HYDROCHLORIDE | AKORN INC | S | Y | 1/15/2015 |
| NDA 205003 | PRESTALIA | PERINDOPRIL ARGININE AND AMLODIPINE | SYMLMED PHARMACEUTICALS LLC | S | Y | 1/21/2015 |
| NDA 206317 | TRIFERIC | FERRIC PYROPHOSPHATE CITRATE | ROCKWELL MEDICAL INC | S | | 1/23/2015 |
| NDA 205395 | PREZCOBIX | DARUNAVIR AND COBICISTAT | JANSSEN PRODUCTS LP | S | | 1/29/2015 |
| NDA 206353 | EVOTAZ | ATAZANAVIR AND COBICISTAT | BRISTOL-MYERS SQUIBB CO | S | | 1/29/2015 |
| NDA 206073 | GLYXAMBI | EMPAGLIFLOZIN AND LINAGLIPTIN | BOEHRINGER INGELHEIM | S | | 1/30/2015 |
| NDA 206276 | PAZEO | OLOPATADINE HYDROCHLORIDE | ALCON RESEARCH LTD | P | | 1/30/2015 |
| NDA 207103 | IBRANCE | PALBOCICLIB | PFIZER INC | P | | 2/3/2015 |
| NDA 206510 | DUTREBIS | LAMIVUDINE AND RALTEGRAVIR | MERCK SHARP AND DOHME CORP | S | Y | 2/6/2015 |
| NDA 206947 | LENVIMA | LENAVATINIB | EISAI INC | P,O | | 2/13/2015 |
| NDA 205353 | FARYDAK | PANOBINOSTAT | NOVARTIS PHARMACEUTICALS CORP | P,O | | 2/23/2015 |
| NDA 206494 | AVYCAZ | CEFTAZIDIME-AVIBACTAM | CEREXA INC | P | Y | 2/25/2015 |
| NDA 206538 | TOUJEO | INSULIN GLARGINE | SANOFI US SERVICES INC | S | | 2/25/2015 |
| NDA 206229 | LILETTA | LEVONORGESTREL | MEDICINES360 | S | Y | 2/26/2015 |
| NDA 207500 | CRESEMBA | ISAVUCONAZONIUM SULFATE | ASTELLAS PHARMA US INC | P,O | | 3/6/2015 |
| NDA 207501 | CRESEMBA | ISAVUCONAZONIUM SULFATE | ASTELLAS PHARMA US INC | P,O | | 3/6/2015 |
| NDA 205750 | CHOLBAM | CHOLIC ACID | ASKLEPION PHARMACEUTICALS LLC | P,O | Y | 3/17/2015 |
| NDA 207925 | KALYDECO | IVACAFTOR | VERTEX PHARMACEUTICALS INC | P,O | | 3/17/2015 |
| NDA 201811 | | ARGATROBAN | FRESENIUS KABI USA LLC | S | Y | 3/23/2015 |
| NDA 205383 | ORALTAG | IOHEXOL | INTERPHARMA PRAHA AS | S | Y | 3/26/2015 |
| NDA 205040 (2) | | RITONAVIR TABLETS 25MG AND RITONAVIR TABLETS 50MG | CIPLA LTD | P | Y | 3/29/2015 |
| NDA 206910 | JADENU | DEFERASIROX | NOVARTIS PHARMACEUTICALS CORP | S | | 3/30/2015 |
| NDA 205572 | | MOXIFLOXACIN | FRESENIUS KABI USA LLC | S | Y | 4/3/2015 |
| NDA 206143 | CORLANOR | IVABRADINE | AMGEN INC | P | | 4/15/2015 |
| NDA 205831 | APTENSIO | METHYLPHENIDATE HYDROCHLORIDE | RHODES PHARMACEUTICALS LP | S | Y | 4/17/2015 |
| NDA 206333 | KYBELLA | DEOXYCHOLIC ACID | KYTHERA BIOPHARMACEUTICALS INC | S | | 4/29/2015 |
| NDA 202106 | | MEROPENEM | B BRAUN MEDICAL INC | S | Y | 4/30/2015 |
| NDA 207768 | TUZISTRA | CODEINE POLISTIREX AND CHLORPHENIRAMINE POLISTIREX | VERNALIS R AND D LTD | S | Y | 4/30/2015 |
| NDA 201849 | | GLUCAGON | FRESENIUS KABI USA LLC | S | Y | 5/8/2015 |
| NDA 022279 | HYCOFENIX | HYDROCODONE/GUAIFENESIN/PSEUDOEPHEDRINE | MIKART INC | S | Y | 5/14/2015 |

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| NDA 022424 | FLOWTUSS | HYDROCODONE BITARTRATE AND GUAIFENESIN | MIKART INC | S | Y | 5/14/2015 |
| NDA 207946 | INVEGA TRINZA | PALIPERIDONE PALMITATE | JANSSEN PHARMACEUTICALS INC | P | | 5/18/2015 |
| NDA 205425 (2) | | LOPINAVIR AND RITONAVIR | CIPLA LTD | P | Y | 5/21/2015 |
| NDA 206756 | STIOLTO RESPIMAT | TIOTROPIUM BROMIDE AND OLODATEROL | BOEHRINGER INGELHEIM PHARMACEUTICALS INC | S | | 5/21/2015 |
| NDA 205747 | HUMALOG | INSULIN LISPRO | ELI LILLY AND CO | S | | 5/26/2015 |
| NDA 206940 | VIBERZI | ELUXADOLINE | FURIEX PHARMACEUTICALS INC | P | | 5/27/2015 |
| NDA 022503 | | METAXALONE | COREPHARMA LLC | S | Y | 6/1/2015 |
| NDA 207844 | ALBENZA | ALBENDAZOLE | AMEDRA PHARMACEUTICALS LLC | S,O | | 6/11/2015 |
| NDA 204958 | KENGREAL | CANGRELOR | THE MEDICINES CO | S | | 6/22/2015 |
| NDA 206323 | | CODEINE PHOSPHATE AND CHLORPHENIRAMINE MALEATE | SPRIASO LLC | S | Y | 6/22/2015 |
| NDA 207949 (1) | | CABAZITAXEL | ACCORD HEALTHCARE INC | S | Y | 6/25/2015 |
| NDA 206038 | ORKAMBI | LUMACAFTOR/IVACAFTOR | VERTEX PHARMACEUTICALS INC | P,O | | 7/2/2015 |
| NDA 207620 | ENTRESTO | SACUBITRIL/VALSARTAN | NOVARTIS PHARMACEUTICALS CORP | P | | 7/7/2015 |
| NDA 205422 | REXULTI | BREXPIPIRAZOLE | OTSUKA PHARMACEUTICAL CO LTD | S | | 7/10/2015 |
| NDA 205422 | REXULTI | BREXPIPIRAZOLE | OTSUKA PHARMACEUTICAL CO LTD | S | | 7/10/2015 |
| NDA 206995 | IRESSA | GEFITINIB | ASTRAZENECA UK LTD | S,O | | 7/13/2015 |
| NDA 207917 | EPIDUO FORTE | ADAPALENE AND BENZOYL PEROXIDE | GALDERMA LABORATORIES INC | S | Y | 7/15/2015 |
| NDA 205266 | ODOMZO | SONIDEGB | NOVARTIS PHARMACEUTICALS CORP | S | | 7/24/2015 |
| NDA 206843 | DAKLINZA | DACLATASVIR | BRISTOL-MYERS SQUIBB CO | P | | 7/24/2015 |
| NDA 207931 | TECHNIVIE | OMBITASVIR, PARITAPREVIR, AND RITONAVIR | ABBVIE INC | P | | 7/24/2015 |
| NDA 207071 | FINACEA | AZELAIC ACID | BAYER HEALTHCARE PHARMACEUTICALS INC | S | | 7/29/2015 |
| NDA 207958 | SPRITAM | LEVETIRACETAM | APRECIA PHARMACEUTICALS CO | S | Y | 7/31/2015 |
| NDA 207131 | | CEFAZOLIN INJECTION | CELERITY PHARMACEUTICALS LLC | S | Y | 8/7/2015 |
| NDA 022526 | ADDYI | FLIBANSERIN | SPROUT PHARMACEUTICALS INC | S | | 8/18/2015 |
| NDA 207970 (1) | | CABAZITAXEL | ACTAVIS LLC | S | Y | 8/19/2015 |
| NDA 208019 | | POTASSIUM CHLORIDE | PHARMA RESEARCH SOFTWARE SOLUTION LLC | S | Y | 8/19/2015 |
| NDA 207027 | PROMACTA | ELTROMBOPAG | NOVARTIS PHARMACEUTICALS CORP | P,O | | 8/24/2015 |
| NDA 206111 | SYNJARDY | EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE | BOEHRINGER INGELHEIM PHARMACEUTICALS INC | S | Y | 8/26/2015 |
| NDA 206500 | VARUBI | ROLAPITANT | TESARO INC | S | | 9/1/2015 |
| NDA 200671 | DURLAZA | ASPIRIN | NEW HAVEN PHARMACEUTICALS INC | S | Y | 9/4/2015 |
| NDA 208169 | XURIDEN | URIDINE TRIACETATE | WELLSTAT THERAPEUTICS CORP | P,O | Y | 9/4/2015 |
| NDA 208030 | FERRIPROX | DEFERIPRONE | AOPHARMA INC | S,O | | 9/9/2015 |
| NDA 204370 | VRAYLAR | CARIPRAZINE | FOREST RESEARCH INSTITUTE INC | S | | 9/17/2015 |
| NDA 204370 | VRAYLAR | CARIPRAZINE | FOREST RESEARCH INSTITUTE INC | S | | 9/17/2015 |
| NDA 022259 | TOLAK | FLUOROURACIL | HILL DERMACEUTICALS INC | S | Y | 9/18/2015 |
| NDA 207981 | LONSURF | TRIFLURIDINE AND TIPIRACIL | TAIHO ONCOLOGY INC | S | | 9/22/2015 |
| NDA 203313 | RYZODEG | INSULIN DEGLUDEC AND INSULIN ASPART INJECTION | NOVO NORDISK INC | S | | 9/25/2015 |
| NDA 203314 | TRESIBA | INSULIN DEGLUDEC INJECTION | NOVO NORDISK INC | S | | 9/25/2015 |
| NDA 206544 | MORPHABOND | MORPHINE SULFATE | INSPIRION DELIVERY TECHNOLOGIES LLC | S | Y | 10/2/2015 |
| NDA 207533 | ARISTADA | ARIPIPIRAZOLE LAUROXIL | ALKERMES INC | S | Y | 10/5/2015 |
| NDA 207589 | ENSTILAR | CALCIPOTRIENE AND BETAMETHASONE DIPROPIONATE | LEO PHARMA AS | S | | 10/16/2015 |
| NDA 208147 | DYANAVEL XR | AMPHETAMINE | TRIS PHARMA INC | S | Y | 10/19/2015 |
| NDA 205739 | VELTASSA | PATROMER | RELYPSA INC | S | | 10/21/2015 |
| NDA 206628 | | DEXMEDETOMIDINE HYDROCHLORIDE | HQ SPECIALTY PHARMA CORP | S | Y | 10/21/2015 |
| NDA 207233 | VIVLODEX | MELoxicAM | IROKO PHARMACEUTICALS LLC | S | Y | 10/22/2015 |
| NDA 207793 | ONIVYDE | IRINOTECAN LIPOSOME INJECTION | MERRIMACK PHARMACEUTICALS INC | P,O | Y | 10/22/2015 |
| NDA 207932 | BELBUCA | BUPRENORPHINE | ENDO PHARMACEUTICALS INC | S | Y | 10/23/2015 |
| NDA 207953 | YONDELIS | TRABECTEDIN | JANSSEN PRODUCTS LP | P,O | | 10/23/2015 |

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| NDA 204767 | | ACETAMINOPHEN INJECTION | FRESENIUS KABI USA LLC | S | Y | 10/28/2015 |
| NDA 207923 | SEEBRI NEOHALER | GLYCOPYRROLATE | NOVARTIS PHARMACEUTICALS CORP | S | | 10/29/2015 |
| NDA 207930 | UTIBRON NEOHALER | INDACATEROL/GLYCOPYRROLATE | NOVARTIS PHARMACEUTICALS CORP | S | | 10/29/2015 |
| NDA 207561 | GENVOYA | ELVITEGRAVIR, COBICISTAT, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE | GILEAD SCIENCES INC | S | | 11/5/2015 |
| NDA 208090 (1) | XTAMPZA ER | OXYCODONE | COLLEGIUM PHARMACEUTICAL INC | S | Y | 11/6/2015 |
| NDA 208183 | ULTRAVATE | HALOBETASOL PROPIONATE | FERNDALE LABORATORIES INC | S | | 11/6/2015 |
| NDA 206192 | COTELLIC | COBIMETINIB | GENENTECH INC | P,O | | 11/10/2015 |
| NDA 207369 (2) | | ABACAVIR AND LAMIVUDINE TABLETS | HETERO LABS LTD UNIT V | S | | 11/13/2015 |
| NDA 208065 | TAGRISSO | OSIMERTINIB | ASTRAZENECA PHARMACEUTICALS LP | P,O | | 11/13/2015 |
| NDA 205004 (1) | | BORTEZOMIB | FRESENIUS KABI USA LLC | S | Y | 11/17/2015 |
| NDA 208411 | NARCAN NASAL SPRAY | NALOXONE HYDROCHLORIDE | ADAPT PHARMA INC | P | Y | 11/18/2015 |
| NDA 206110 (1) | | CASPOFUNGIN ACETATE | FRESENIUS KABI USA LLC | S | Y | 11/20/2015 |
| NDA 208462 | NINLARO | IXAZOMIB | MILLENNIUM PHARMACEUTICALS INC | P,O | | 11/20/2015 |
| NDA 207920 | NEXIUM 24HR | ESOMEPRAZOLE | ASTRAZENECA LP | S | | 11/23/2015 |
| NDA 205645 (1) | | TIGECYCLINE | FRESENIUS KABI USA LLC | S | Y | 11/25/2015 |
| NDA 207960 | QUILLICHEW ER | METHYLPHENIDATE HYDROCHLORIDE | PFIZER INC | S | Y | 12/4/2015 |
| NDA 208194 | BENDEKA | BENDAMUSTINE HYDROCHLORIDE | EAGLE PHARMACEUTICALS INC | S,O | Y | 12/7/2015 |
| NDA 207986 | OTIPRIO | 6% CIPROFLOXACIN OTIC SUSPENSION | OTONOMY INC | S | Y | 12/10/2015 |
| NDA 208159 | VISTOGARD | URIDINE TRIACETATE | WELLSTAT THERAPEUTICS CORP | P,O | | 12/11/2015 |
| NDA 208434 | ALECENSA | ALECTINIB | HOFFMANN-LA ROCHE INC | P,O | | 12/11/2015 |
| NDA 022225 | BRIDION | SUGAMMADEX | ORGANON USA INC A SUBSIDIARY OF MERCK AND CO INC | P | | 12/15/2015 |
| NDA 207865 | EMEND | APREPITANT | MERCK SHARP AND DOHME CORP A SUBSIDIARY OF MERCK AND CO INC | P | | 12/17/2015 |
| NDA 207947 | UPTRAVI | SELEXIPAG | ACTELION PHARMACEUTICALS LTD | S,O | | 12/21/2015 |
| NDA 205934 | | DOCETAXEL INJECTION | TEIKOKU PHARMA USA INC | S | Y | 12/22/2015 |
| NDA 207988 | ZURAMPIC | LESINURAD | ARDEA BIOSCIENCES INC | S | | 12/22/2015 |

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

| APPLICATION NUMBER | PROPRIETARY NAME | ESTABLISHED NAME | APPLICANT | REVIEW CLASSIFICATION | APPROVAL DATE | TENTATIVE APPROVAL DATE |
|--------------------|-------------------|-------------------------------------|--|-----------------------|---------------|-------------------------|
| NDA 203797 | | DAPTOMYCIN | HOSPIRA INC | S | | 3/15/2013, 2/18/2015 |
| NDA 205636 | PROAIR RESPICLICK | ALBUTEROL SULFATE | TEVA BRANDED PHARMACEUTICAL PRODUCTS R AND D INC | S | 3/31/2015 | 3/5/2015 |
| NDA 206473 | | LINEZOLID | HOSPIRA INC | S | 6/18/2015 | 9/26/2014 |
| NDA 206406 | ENVARUS XR | TACROLIMUS EXTENDED-RELEASE TABLETS | VELOXIS PHARMACEUTICALS INC | S | 7/10/2015 | 10/30/2014 |
| NDA 205692 | BASAGLAR | INSULIN GLARGINE | ELI LILLY AND CO | S | 12/16/2015 | 8/18/2014 |
| NDA 204016 | | ZOLEDRONIC ACID | | S | 12/28/2015 | 7/3/2013 |

Biologic License Application (BLA) Approvals:

| BLA NUMBER | PROPRIETARY NAME | PROPER NAME | APPLICANT | REVIEW CLASSIFICATION | APPROVAL DATE |
|----------------|------------------|---------------------|--|-----------------------|---------------|
| BLA 125504/0.0 | COSENTYX | SECUKINUMAB | NOVARTIS PHARMACEUTICALS CORPORATION | S | 1/21/2015 |
| BLA 125511/0.0 | NATPARA | PARATHYROID HORMONE | NPS PHARMACEUTICALS | S,O | 1/23/2015 |
| BLA 125516/0.0 | UNITUXIN | DINUTUXIMAB | UNITED THERAPEUTICS CORPORATION | P,O | 3/10/2015 |
| BLA 125559/0.0 | PRALUENT | ALIROCUMAB | SANOFI-AVENTIS U.S. LLC | P | 7/24/2015 |
| BLA 125522/0.0 | REPATHA | EVOLOCUMAB | AMGEN, INC. | S,O | 8/27/2015 |
| BLA 761025/0.0 | PRAXBIND | IDARUCIZUMAB | BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. | P | 10/16/2015 |
| BLA 125513/0.0 | STRENSIQ | ASFOTASE ALFA | ALEXION PHARMACEUTICALS, INC. | P,O | 10/23/2015 |
| BLA 125526/0.0 | NUCALA | MEPOLIZUMAB | GLAXOSMITHKLINE LLC | S | 11/4/2015 |

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| BLA 761036/0.0 | DARZALEX | DARATUMUMAB | JANSSEN BIOTECH, INC. | P,O | 11/16/2015 |
| BLA 125547/0.0 | PORTRAZZA | NECITUMUMAB | ELI LILLY AND COMPANY | S | 11/24/2015 |
| BLA 761035/0.0 | EMPLICITI | ELOTUZUMAB | BRISTOL-MYERS SQUIBB COMPANY | P,O | 11/30/2015 |
| BLA 125561/0.0 | KANUMA | SEBELIPASE ALFA | SYNAGEVA BIOPHARMA CORP | P,O | 12/8/2015 |

(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).