

**CY 2016 CDER Drug and Biologic Calendar Year Approvals
As of December 31, 2016**

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

Selection Criteria:

User Response: Start Date: 1/1/2016 End Date: 12/31/2016

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 208036	E-Z-HD	BARIUM SULFATE	BRACCO DIAGNOSTICS INC	S	Y	1/11/2016
NDA 208143	READI-CAT 2 AND READI-CAT 2 SMOOTHIE	BARIUM SULFATE	BRACCO DIAGNOSTICS INC	S	Y	1/15/2016
NDA 208056	DEXILANT SOLUTAB	DEXLANSOPRAZOLE DELAYED-RELEASE ORALLY DISINTEGRATING TABLET	TAKEDA PHARMACEUTICALS USA INC	S		1/26/2016
NDA 204326	ADZENYS XR-ODT	AMPHETAMINE EXTENDED-RELEASE ORALLY DISINTEGRATING TABLETS	NEOS THERAPEUTICS	S	Y	1/27/2016
NDA 206099	ONZETRA XSAIL	SUMATRIPTAN	AVANIR PHARMACEUTICALS	S	Y	1/27/2016
NDA 208286 (1)	ZENAVOD	DOXYCYCLINE	DR REDDYS LABORATORIES INC	S		1/27/2016
NDA 208223	ZEMBRACE SYMTOUCH	SUMATRIPTAN	DR REDDYS LABORATORIES LTD	S	Y	1/28/2016
NDA 208261	ZEPATIER	ELBASVIR/GRAZOPREVIR	MERCK SHARP AND DOHME CORP	P		1/28/2016
NDA 207916	CETYLEV	ACETYLCYSTEINE	ARBOR PHARMACEUTICALS LLC	S,O	Y	1/29/2016
NDA 207174		PARICALCITOL	ACCORD HEALTHCARE INC	S	Y	2/4/2016
NDA 208079	SERNIVO	BETAMETHASONE DIPROPIONATE	PROMIUS PHARMA LLC	S	Y	2/5/2016
NDA 205836	BRIVIACT	BRIVARACETAM	UCB INC	S		2/18/2016
NDA 205837	BRIVIACT	BRIVARACETAM	UCB INC	S		2/18/2016
NDA 205838	BRIVIACT	BRIVARACETAM	UCB INC	S		2/18/2016
NDA 208246	XELJANZ	TOFACITINIB	PFIZER INC	S		2/23/2016
NDA 207154	ACZONE	DAPSONE	ALLERGAN INC	S		2/24/2016
NDA 208135	STERI-UNIT	TETRACAINE HYDROCHLORIDE OPHTHALMIC SOLUTION	ALCON RESEARCH LTD	S	Y	2/29/2016
NDA 208351	ODEFSEY	EMTRICITABINE, RILPIVIRINE, AND TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INC	P		3/1/2016
NDA 207155	EVOMELA	CAPTISOL-ENABLED MELPHALAN HCL FOR INJECTION	SPECTRUM PHARMACEUTICALS INC	S,O	Y	3/10/2016
NDA 207155	EVOMELA	CAPTISOL-ENABLED MELPHALAN HCL FOR INJECTION	SPECTRUM PHARMACEUTICALS INC	S	Y	3/10/2016
NDA 208114	DEFITELIO	DEFIBROTIDE SODIUM	GENTIUM SPA	P,O		3/30/2016
NDA 208215	DESCOVY	EMTRICITABINE AND TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INC	S		4/4/2016
NDA 204630	PROVAYBLUE	METHYLENE BLUE	PROVEPHARM SAS	S,O	Y	4/8/2016
NDA 206911	BROMSITE	BROMFENAC OPHTHALMIC SOLUTION	INSITE VISION INC	S	Y	4/8/2016
NDA 208573	VENCLEXTA	VENETOCLAX	ABBVIE INC	P,O		4/11/2016

NDA 203324	PHOTREXA VISCOUS, PHOTREXA	PHOTREXA VISCOUS (RIBOFLAVIN 5'-PHOSPHATE IN 20% DEXTRAN OPHTHALMIC SOLUTION) 0.146%, PHOTREXA (RIBOFLAVIN 5'-PHOSPHATE OPHTHALMIC SOLUTION) 0.146%	AVEDRO INC	P,O	Y	4/15/2016
NDA 206679		SIMVASTATIN	ROSEMONT PHARMACEUTICALS LTD	S	Y	4/21/2016
NDA 206356	ORFADIN	NITISINONE	SWEDISH ORPHAN BIOVITRUM SOBI	S,O		4/22/2016
NDA 208294	BEVESPI AEROSPHERE	GLYCOPYRROLATE AND FORMOTEROL FUMARATE	PEARL THERAPEUTICS INC	S	Y	4/25/2016
NDA 208551	TRIFERIC	FERRIC PYROPHOSPHATE CITRATE	ROCKWELL MEDICAL INC	S		4/25/2016
NDA 208692	CABOMETYX	CABOZANTINIB	EXELIXIS INC	P		4/25/2016
NDA 208253	ACTICLATE CAP	DOXYCYCLINE HYCLATE	AQUA PHARMACEUTICALS	S	Y	4/26/2016
NDA 207318	NUPLAZID	PIMAVANSERIN	ACADIA PHARMACEUTICALS INC	P		4/29/2016
NDA 208216		AZACITIDINE	ACTAVIS LLC	S	Y	4/29/2016
NDA 208251	OTOVEL	CIPROFLOXACIN 0.3% AND FLUOCINOLONE ACETONIDE 0.025%	LABORATORIOS SALVAT SA	S	Y	4/29/2016
NDA 208277	FYCOMPA	PERAMPANEL	EISAI INC	S		4/29/2016
NDA 208289	AKOVAZ	EPHEDRINE SULFATE	FLAMEL IRELAND LIMITED	S	Y	4/29/2016
NDA 208081	AMELUZ	AMINOLEVULINIC ACID HYDROCHLORIDE	BIOFRONTERA BIOSCIENCE GMBH	S		5/10/2016
NDA 208562 (1)		VORICONAZOLE	XELLIA PHARMACEUTICALS APS	S	Y	5/24/2016
NDA 204442	PROBUPHINE	BUPRENORPHINE HYDROCHLORIDE	BRAEBURN PHARMACEUTICALS INC	P	Y	5/26/2016
NDA 207999	OCALIVA	OBETICHOLIC ACID	INTERCEPT PHARMACEUTICALS INC	P,O		5/27/2016
NDA 208026	JENTADUETO XR	LINAGLIPTIN AND METFORMIN HYDROCHLORIDE EXTENDED-RELEASE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S		5/27/2016
NDA 208054	AXUMIN	FLUCICLOVINE F18	BLUE EARTH DIAGNOSTICS LTD	P		5/27/2016
NDA 208547	NETSPOT	KIT FOR THE PREPARATION OF GALLIUM GA 68 DOTATATE INJECTION	ADVANCED ACCELERATOR APPLICATIONS USA INC	P,O	Y	6/1/2016
NDA 206302	BYVALSON	NEBIVOLOL/VALSARTAN	FOREST LABORATORIES LLC	S	Y	6/3/2016
NDA 208025		LANSOPRAZOLE DELAYED-RELEASE, ORALLY-DISINTEGRATING TABLETS	DEXCEL PHARMA TECHNOLOGIES LTD	S	Y	6/7/2016
NDA 208424	GONITRO	NITROGLYCERIN	G POHL BOSKAMP GMBH AND CO KG	S		6/8/2016
NDA 208010	RAYALDEE	CALCIFEDIOL	OPKO IRELAND GLOBAL HOLDINGS LTD	S		6/17/2016
NDA 208341	EPCLUSA	SOFOSBUVIR AND VELPATASVIR	GILEAD SCIENCES INC	P		6/28/2016
NDA 208032	KOVANAZE	TETRACAINE HCL AND OXYMETAZOLINE HCL	ST RENATUS LLC	S	Y	6/29/2016
NDA 205525	SYNDROS	DRONABINOL	INSYS DEVELOPMENT CO INC	S	Y	7/1/2016
NDA 208073	XIIDRA	LIFITEGRAST OPHTHALMIC SOLUTION	SHIRE DEVELOPMENT LLC	P		7/11/2016
NDA 207648	SMOFLIPID	LIPID INJECTABLE EMULSION	FRESENIUS KABI USA LLC	S		7/13/2016
NDA 203324	PHOTREXA VISCOUS, PHOTREXA	PHOTREXA VISCOUS (RIBOFLAVIN 5'-PHOSPHATE IN 20% DEXTRAN OPHTHALMIC SOLUTION) 0.146%, PHOTREXA (RIBOFLAVIN 5'-PHOSPHATE OPHTHALMIC SOLUTION) 0.146%	AVEDRO INC	P,O		7/15/2016
NDA 208524	BELVIQ XR	LORCASERIN HYDROCHLORIDE	EISAI INC	S		7/15/2016
NDA 208271	RELISTOR	METHYLNALTREXONE BROMIDE	SALIX PHARMACEUTICALS INC	S		7/19/2016
NDA 208624	VIEKIRA XR	DASABUVIR, OMBITASVIR, PARITAPREVIR, AND RITONAVIR	ABBVIE INC	S		7/22/2016
NDA 208471	ADLYXIN	LIXISENATIDE	SANOFI-AVENTIS US LLC	S		7/27/2016

NDA 208109 (1)		PALONOSETRON INJECTION	FRESENIUS KABI USA LLC	S	Y	7/29/2016
NDA 208401	QBRELIS	LISINAPRIL	SILVERGATE PHARMACEUTICALS INC	S	Y	7/29/2016
NDA 022445	SUSTOL	GRANISETRON	HERON THERAPEUTICS INC	S	Y	8/9/2016
NDA 207621	TROXYCA ER	OXYCODONE HYDROCHLORIDE AND NALTREXONE HYDROCHLORIDE	PFIZER INC	S	Y	8/19/2016
NDA 205103	YOSPRALA	ASPIRIN 81 MG/OMEPRAZOLE 40 MG, AND ASPIRIN 325 MG/OMEPRAZOLE 40 MG	ARALEZ PHARMACEUTICALS TRADING DAC	S	Y	9/14/2016
NDA 208224	KYLEENA	LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM	BAYER HEALTHCARE PHARMACEUTICALS INC	S		9/16/2016
NDA 206488	EXONDYS 51	ETEPLIRSEN	SAREPTA THERAPEUTICS INC	P,O		9/19/2016
NDA 205879	INVOKAMET XR	CANAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDED RELEASE	JANSSEN PHARMACEUTICALS INC	S		9/20/2016
NDA 208686	EPANED	ENALAPRIL MALEATE	SILVERGATE PHARMACEUTICALS INC	S,O	Y	9/20/2016
NDA 208723		LEVOLEUCOVORIN	ACTAVIS LLC	S,O	Y	9/29/2016
NDA 202153	RUBY-FILL	RUBIDIUM RB-82 GENERATOR 85-115MCI	JUBILANT DRAXIMAGE INC	S	Y	9/30/2016
NDA 206030	CARNEXIV	CARBAMAZEPINE	LUNDBECK PHARMACEUTICALS LLC	S,O	Y	10/7/2016
NDA 208844	VARIBAR PUDDING	BARIUM SULFATE PASTE, 40% (W/V)	BRACCO DIAGNOSTICS INC	S	Y	10/14/2016
NDA 208398	VERMOX	CHEWABLE (MEBENDAZOLE CHEWABLE TABLETS),	JANSSEN PHARMACEUTICALS INC	P,O	Y	10/19/2016
NDA 209862	EVZIO	NALOXONE HYDROCHLORIDE INJECTION	KALEO INC	P	Y	10/19/2016
NDA 208645 (1)		BORTEZOMIB INJECTION	ACTAVIS LLC	S	Y	10/20/2016
NDA 208984	SELZENTRY	MARAVIROC	VIIV HEALTHCARE CO	P		11/4/2016
NDA 209661	BONJESTA	DOXYLAMINE SUCCINATE AND PYRIDOXINE HYDROCHLORIDE	DUCHESNAY INC	S		11/7/2016
NDA 208464	VEMLIDY	TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INC	S		11/10/2016
NDA 208470	INTRAROSA	PRASTERONE	ENDOCEUTICS INC	S	Y	11/16/2016
NDA 208583	XULTOPHY	100/3.6 (INSULIN DEGLUDEC AND LIRAGLUTIDE INJECTION)	NOVO NORDISK INC	S		11/21/2016
NDA 208673	SOLIQUA™ (INSULIN GLARGINE AND LIXISENATIDE)	100/33 (INSULIN GLARGINE AND LIXISENATIDE INJECTION)	SANOFI-AVENTIS US LLC	P		11/21/2016
NDA 208151	ISOPTO ATROPINE	ATROPINE SULFATE OPHTHALMIC SOLUTION	NOVARTIS PHARMACEUTICALS CORP	S	Y	12/1/2016
NDA 208658	SYNJARDY XR	EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE EXTENDEDRELEASE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S		12/9/2016
NDA 207695	EUCRISA	CRISABOROLE	ANACOR PHARMACEUTICALS INC	S		12/14/2016
NDA 206977	TIROSINT-SOL	LEVOTHYROXINE SODIUM ORAL SOLUTION	IBSA INSTITUT BIOCHIMIQUE SA	S	Y	12/15/2016
NDA 209115	RUBRACA	RUCAPEPARIB	CLOVIS ONCOLOGY INC	P,O		12/19/2016
NDA 209531	SPINRAZA	NUSINERSEN	BIOGEN IDEC INC	P,O		12/23/2016

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 202172		ROSUVASTATIN ZINC TABLETS	WATSON LABORATORIES INC	S		8/4/11 , 2/12/2016
NDA 203050		PALONOSETRON HYDROCHLORIDE	DR REDDYS LABORATORIES LTD	S	3/1/16	11/2/2012
NDA 205703		ESMOLOL HYDROCHLORIDE	HQ SPECIALTY PHARMA CORP	S	4/7/2016	4/14/2014
NDA 208090	XTAMPZA ER	OXYCODONE	COLLEGIUM PHARMACEUTICAL INC	S	4/26/2016	11/6/2015

NDA 207963		PALONOSETRON HYDROCHLORIDE	EXELA PHARMA SCIENCES LLC	S	8/22/2016	3/22/2016
NDA 205645		TIGECYCLINE FOR INJECTION	FRESENIUS KABI USA LLC	S	12/1/2016	11/25/2015
NDA 204553	COLPREP KIT	SODIUM SULFATE, POTASSIUM SULFATE AND MAGNESIUM SULFATE	GATOR PHARMACEUTICALS INC	S	12/27/2016	10/4/2013, 11/25/2015
NDA 206110		CASPOFUNGIN ACETATE FOR INJECTION	FRESENIUS KABI USA LLC	S	12/30/2016	11/20/2015

Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 125509/0.0	ANTHIM	OBILTOXAXIMAB	ELUSYS THERAPEUTICS, INC.	S,O	3/18/2016
BLA 125521/0.0	TALTZ	IXEKIZUMAB	ELI LILLY AND COMPANY	S	3/22/2016
BLA 761033/0.0	CINQAIR	RESLIZUMAB	TEVA RESPIRATORY, LLC	S	3/23/2016
BLA 761034/0.0	TECENTRIQ	ATEZOLIZUMAB	GENENTECH, INC.	P	5/18/2016
BLA 761029/0.0	ZINBRYTA	DACLIZUMAB	BIOGEN INC.	S	5/27/2016
BLA 761044/0.0	STELARA	USTEKINUMAB	JANSEN BIOTECH, INC.	S	9/23/2016
BLA 761038/0.0	LARTRUVO	OLARATUMAB	ELI LILLY AND COMPANY	P,O	10/19/2016
BLA 761046/0.0	ZINPLAVA	BEZLOTOXUMAB	MERCK SHARP & DOHME CORP.	P	10/21/2016

(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).