

CY 2016 CDER Drug and Biologic Calendar Year Priority 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

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
NDA 208261	ZEPATIER	ELBASVIR/GRAZOPREVIK	MERCK SHARP AND DOHME CORP	P	1/28/2016
NDA 208351	ODEFSEY	EMTRICITABINE, RILPIVIRINE, AND TENOFOVIR ALAFENAMIDE	GILEAD SCIENCES INC	P	3/1/2016
NDA 208114	DEFITELIO	DEFIBROTIDE SODIUM	GENTIUM SPA	P,O	3/30/2016
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	4/15/2016
NDA 208692	CABOMETYX	CABOZANTINIB	EXELIXIS INC	P	4/25/2016
NDA 207318	NUPLAZID	PIMAVANSERIN	ACADIA PHARMACEUTICALS INC	P	4/29/2016
NDA 204442	PROBUPHINE	BUPRENORPHINE HYDROCHLORIDE	BRAEBURN PHARMACEUTICALS INC	P	5/26/2016
NDA 207999	OCALIVA	OBETICHOLIC ACID	INTERCEPT PHARMACEUTICALS INC	P,O	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	6/1/2016
NDA 208341	EPCLUSA	SOFOSBUVIR AND VELPATASVIR	GILEAD SCIENCES INC	P	6/28/2016
NDA 208073	XIIDRA	LIFITEGRAST OPHTHALMIC SOLUTION	SHIRE DEVELOPMENT LLC	P	7/11/2016
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	7/15/2016
NDA 206488	EXONDYS 51	ETEPLIRSEN	SAREPTA THERAPEUTICS INC	P,O	9/19/2016
NDA 208398	VERMOX	CHEWABLE (MEBENDAZOLE CHEWABLE TABLETS),	JANSSEN PHARMACEUTICALS INC	P,O	10/19/2016
NDA 209862	EVZIO	NALOXONE HYDROCHLORIDE INJECTION	KALEO INC	P	10/19/2016
NDA 208984	SELZENTRY	MARAVIROC	VIIV HEALTHCARE CO	P	11/4/2016
NDA 208673	SOLIQUA™ (INSULIN GLARGINE AND LIXISENATIDE)	100/33 (INSULIN GLARGINE AND LIXISENATIDE INJECTION)	SANOFI-AVENTIS US LLC	P	11/21/2016
NDA 209115	RUBRACA	RUCAPARIB	CLOVIS ONCOLOGY INC	P,O	12/19/2016
NDA 209531	SPINRAZA	NUSINERSEN	BIOGEN IDEC INC	P,O	12/23/2016

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761034/0.0	TECENTRIQ	ATEZOLIZUMAB	GENENTECH, INC.	P	5/18/2016
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
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(1) Application has been tentatively approved.

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

Review Classification:

P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.

O - Orphan Designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).