

CY 2017 CDER Drug and Biologic Calendar Year Priority Approvals As of December 31, 2017

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

Selection Criteria:

User Response: Start Date: 1/1/2017 End Date: 12/31/2017

Sort Order: Approval Date

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
NDA 208684	EMFLAZA	DEFLAZACORT	MARATHON PHARMACEUTICALS LLC	P,O	2/9/2017
NDA 208685	EMFLAZA	DEFLAZACORT	MARATHON PHARMACEUTICALS LLC	P,O	2/9/2017
NDA 208794	XERMELO	TELOTRISTAT ETHYL	LEXICON PHARMACEUTICALS INC	P,O	2/28/2017
NDA 208255 (2)		EFAVIRENZ, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE	MYLAN PHARMACEUTICALS INC	P	3/10/2017
NDA 209092	KISQALI	RIBOCICLIB	NOVARTIS PHARMACEUTICALS CORP	P	3/13/2017
NDA 208447	ZEJULA	NIRAPARIB	TESARO INC	P,O	3/27/2017
NDA 209241	INGREZZA	VALBENAZINE	NEUROCRINE BIOSCIENCES INC	P	4/11/2017
NDA 209777	ROXYBOND	OXYCODONE HYDROCHLORIDE	INSPIRION DELIVERY SCIENCES LLC	P	4/20/2017
NDA 207997	RYDAPT	MIDOSTAURIN	NOVARTIS PHARMACEUTICALS CORP	P,O	4/28/2017
NDA 208772	ALUNBRIG	BRIGATINIB	ARIAD PHARMACEUTICALS INC	P,O	4/28/2017
NDA 208694	ZERVIAE	CETIRIZINE OPHTHALMIC SOLUTION	NICOX OPHTHALMICS INC	P	5/30/2017
NDA 208630	GLEOLAN	AMINOLEVULINIC ACID HYDROCHLORIDE	NX DEVELOPMENT CORP	P,O	6/6/2017
NDA 209512	NORVIR	RITONAVIR	ABBVIE INC	P,O	6/7/2017
NDA 208610	BAXDELA	DELAFLOXACIN	MELINTA THERAPEUTICS INC	P	6/19/2017
NDA 208611	BAXDELA	DELAFLOXACIN	MELINTA THERAPEUTICS INC	P	6/19/2017
NDA 208383	BEVYXXA	BETRIXABAN	PORTOLA PHARMACEUTICALS INC	P	6/23/2017
NDA 209195	VOSEVI	SOFOSBUVIR, VELPATASVIR, AND VOXILAPREVIR	GILEAD SCIENCES INC	P	7/18/2017
NDA 209606	IDHIFA	ENASIDENIB	CELGENE CORP	P,O	8/1/2017
NDA 209670 (2)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	MYLAN LABORATORIES LTD	P	8/2/2017
NDA 209394	MAVYRET	GLECAPREVIR AND PIBRENTASVIR	ABBVIE INC	P	8/3/2017
NDA 209401	VYXEOS	DAUNORUBICIN AND CYTARABINE	CELATOR PHARMACEUTICALS INC	P,O	8/3/2017
NDA 208558	LYNPARZA	OLAPARIB	ASTRAZENECA PHARMACEUTICALS LP	P	8/17/2017
NDA 209618 (2)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	AUROBINDO PHARMA LTD	P	8/18/2017
NDA 209570		BENZNIDAZOLE	CHEMO RESEARCH SL	P,O	8/29/2017
NDA 209776	VABOMERE	MEROPENEM AND VABORBACTAM	REMPEX PHARMACEUTICALS A WHOLLY OWNED SUB OF THE MEDICINES CO	P	8/29/2017
NDA 209936	ALIQOPA	COPANLISIB	BAYER HEALTHCARE PHARMACEUTICALS INC	P,O	9/14/2017
NDA 209363	SOLOSEC	SECNIDAZOLE	LUPIN INC	P	9/15/2017
NDA 208716	VERZENIO	ABEMACICLIB	ELI LILLY AND CO	P	9/28/2017
NDA 206451 (2)		ATAZANAVIR AND RITONAVIR	CIPLA LTD	P	10/27/2017
NDA 210259	CALQUENCE	ACALABRUTINIB	ASTRAZENECA UK LTD	P,O	10/31/2017
NDA 209939	PREVYMIS	LETERMOVIR	MERCK SHARP AND DOHME CORP	P,O	11/8/2017

NDA 209940	PREVYMIS	LETETMOVIR	MERCK SHARP AND DOHME CORP	P,O	11/8/2017
NDA 210709	TEKTRUNA	ALISKIREN	NODEN PHARMA DAC	P	11/14/2017
NDA 210192	JULUCA	DOLUTEGRAVIR AND RILPIVIRINE	VIIV HEALTHCARE CO	P	11/21/2017
NDA 209819	SUBLOCADE	BUPRENORPHINE	INDIVIOR INC	P,O	11/30/2017
NDA 208582	ALTAFLUOR BENOX	FLUORESCIEIN SODIUM AND BENOXINATE HYDROCHLORIDE OPHTHALMIC SOLUTION	ALTAIRE PHARMACEUTICALS INC	P	12/14/2017
NDA 208843	SIKLOS	HYDROXYUREA	ADDMEDICA SAS	P,O	12/21/2017
NDA 209360	GIAPREZA	ANGIOTENSIN II	LA JOLLA PHARMACEUTICAL CO	P	12/21/2017

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761049/0.0	BAVENCIO	AVELUMAB	EMD SERONO, INC.	P,O	3/23/2017
BLA 761053/0.0	OCREVUS	OCRELIZUMAB	GENENTECH, INC.	P	3/28/2017
BLA 761055/0.0	DUPIXENT	DUPILUMAB	REGENERON PHARMACEUTICALS, INC.	P	3/28/2017
BLA 761052/0.0	BRINEURA	CERLIPONASE ALFA	BIOMARIN PHARMACEUTICAL INC.	P,O	4/27/2017
BLA 761069/0.0	IMFINZI	DURVALUMAB	ASTRAZENECA UK LTD	P	5/1/2017
BLA 761061/0.0	TREMFYA	GUSELKUMAB	JANSSEN BIOTECH, INC.	P	7/13/2017
BLA 761040/0.0	BESPOUSA	INOTUZUMAB OZOGAMICIN	WYETH PHARMACEUTICALS INC.	P,O	8/17/2017
BLA 761047/0.0	MEPSEVII	VESTRONIDASE ALFA-VJBK	ULTRAGENYX PHARMACEUTICAL INC.	P,O	11/15/2017
BLA 761083/0.0	HEMLIBRA	EMICIZUMAB-KXWH	GENENTECH, INC.	P,O	11/16/2017

(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).