

**CY 2023 CDER Drug and Biologic Calendar Year Priority Approvals
As of December 31, 2023**

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

Selection Criteria:

User Response: Start Date: 1/1/2023 End Date: 12/31/2023

Sort Order: Approval Date

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
NDA 216059	JAYPIRCA	PIRTOBRUTINIB	LOXO ONCOLOGY INC	P,O	1/27/2023
NDA 217639	ORSERDU	ELACESTRANT	STEMLINE THERAPEUTICS INC	P	1/27/2023
NDA 216403	FILSPARI	SPARSENTAN	TRAVERE THERAPEUTICS INC	P,O	2/17/2023
NDA 217171	SYFOVRE	PEGCETACOPLAN	APELLIS PHARMACEUTICALS INC	P	2/17/2023
NDA 216718	SKYCLARYS	OMAVELOXOLONE	REATA PHARMACEUTICALS INC	P,O	2/28/2023
NDA 217026	DAYBUE	TROFINETIDE	ACADIA PHARMACEUTICALS INC	P,O	3/10/2023
NDA 217513	MEKINIST	TRAMETINIB	NOVARTIS PHARMACEUTICALS CORP	P,O	3/16/2023
NDA 217514	TAFINLAR	DABRAFENIB	NOVARTIS PHARMACEUTICALS CORP	P,O	3/16/2023
NDA 217417	REZZAYO	REZAFUNGIN	CIDARA THERAPEUTICS INC	P,O	3/22/2023
NDA 217759	JOENJA	LENIOLISIB PHOSPHATE	PHARMING TECHNOLOGIES BV	P,O	3/24/2023
NDA 215887	QALSODY (TOFERSEN)	TOFERSEN	BIOGEN MA INC	P,O	4/25/2023
NDA 217660	TRIKAFTA	ELEXACAFTOR/TEZACAFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS INC	P,O	4/26/2023
NDA 215319 (2)		DOLUTEGRAVIR	LAURUS GENERICS INC	P	4/28/2023
NDA 216578	VEOZAH	FEZOLINETANT	ASTELLAS PHARMA US INC	P	5/12/2023
NDA 217470	OPVEE	NALMEFENE HYDROCHLORIDE	INDIVIOR INC	P	5/22/2023
NDA 210136	BRIXADI	BUPRENORPHINE HYDROCHLORIDE	BRAEBURN INC	P	5/23/2023
NDA 216974	XACDURO	SULBACTAM FOR INJECTION; DURLOBACTAM FOR INJECTION	ENTASIS THERAPEUTICS INC	P	5/23/2023
NDA 217188	PAXLOVID	NIRMATRELVIR AND RITONAVIR	PFIZER INC	P	5/25/2023
NDA 215727	LODOCO	COLCHICINE	AGEPHA PHARMA FZ LLC	P	6/16/2023
NDA 216993	VANFLYTA	QUIZARTINIB	DAIICHI SANKYO INC	P,O	7/20/2023
NDA 217722	RIVIVE	NALOXONE HYDROCHLORIDE	HARM REDUCTION THERAPEUTICS INC	P	7/28/2023
NDA 217225	IZERVAY	AVACINCAPTAD PEGOL	IVERIC BIO INC	P	8/4/2023
NDA 217369	ZURZUVAE	ZURANOLONE	SAGE THERAPEUTICS INC	P	8/4/2023
NDA 216793	AKEEGA	NIRAPARIB AND ABIRATERONE ACETATE	JANSSEN BIOTECH INC	P	8/11/2023
NDA 217070		ABACAVIR, DOLUTEGRAVIR AND LAMIVUDINE TABLET FOR ORAL SUSPENSION	AUROBINDO PHARMA LTD	P	8/14/2023
NDA 215559	SOHONOS	PALOVAROTENE	IPSEN BIOPHARMACEUTICALS INC	P,O	8/16/2023
NDA 218193		ABACAVIR, DOLUTEGRAVIR AND LAMIVUDINE	MYLAN LABORATORIES LTD	P	8/16/2023
NDA 217729	BOSULIF	BOSUTINIB	PF PRISM CV	P,O	9/26/2023
NDA 218550	ROZLYTREK	ENTRECTINIB	GENENTECH INC	P,O	10/20/2023
NDA 217564	FRUZAQLA	FRUQUINTINIB	TAKEDA PHARMACEUTICALS USA INC	P	11/8/2023
NDA 217806	ZEPBOUND	TIRZEPATIDE	ELI LILLY AND CO	P	11/8/2023
NDA 214520	DEFENCATH	TAUROLIDINE AND HEPARIN CATHETER LOCK SOLUTION	CORMEDIX INC	P	11/15/2023
NDA 218213	AUGTYRO	REPOTRECTINIB	BRISTOL MYERS SQUIBB CO	P,O	11/15/2023
NDA 218197	TRUQAP	CAPIVASERTIB	ASTRAZENECA PHARMACEUTICALS LP	P	11/16/2023
NDA 217677	OGSIVEO	NIROGACESTAT	SPRINGWORKS THERAPEUTICS INC	P,O	11/27/2023
NDA 218276	FABHALTA	IPTACOPAN	NOVARTIS PHARMACEUTICALS CORP	P,O	12/5/2023
NDA 215500	IWILFIN	EFLORNITHINE	USWM LLC	P,O	12/13/2023
NDA 215064	FILSUVEZ	BIRCH TRITERPENES	CHIESI FARMACEUTICI SPA	P,O	12/18/2023
NDA 209847 (2)		DARUNAVIR AND RITONAVIR	MYLAN LABORATORIES LTD	P	12/22/2023

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761269	LEQEMBI	LECANEMAB-IRMB	EISAI, INCORPORATED	P	1/6/2023
BLA 761278	LAMZEDE	VELMANASE ALFA-TYCV	CHIESI FARMACEUTICI S.P.A.	P,O	2/16/2023
BLA 761334	ZYNYZ	RETIFANLIMAB-DLWR	INCYTE CORPORATION	P,O	3/22/2023
BLA 761161	ELFABRIO	PEGUNIGALSIDASE ALFA-IWXJ	CHIESI FARMACEUTICI S.P.A.	P	5/9/2023
BLA 761324	EPKINLY	EPCORITAMAB-BYSP	GENMAB US, INC.	P	5/19/2023
BLA 761309	COLUMVI	GLOFITAMAB-GXBM	GENENTECH, INC.	P	6/15/2023
BLA 761304	VYVGART HYTRULO	EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC	ARGENX BV	P,O	6/20/2023
BLA 761286	RYSTIGGO	ROZANOLIXIZUMAB-NOLI	UCB, INC.	P,O	6/26/2023
BLA 761342	TALVEY	TALQUETAMAB-TGVS	JANSSEN BIOTECH, INC.	P,O	8/9/2023
BLA 761345	ELREXFIO	ELRANATAMAB-BCMM	PFIZER INC.	P,O	8/14/2023
BLA 761339	VEOPOZ	POZELIMAB-BBFG	REGENERON PHARMACEUTICALS, INC.	P,O	8/18/2023
BLA 761355	EYLEA HD	AFLIBERCEPT	REGENERON PHARMACEUTICALS, INC.	P	8/18/2023
BLA 761240	LOQTORZI (TORIPALIMAB-TPZI)	COHERUS BIOSCIENCES, INC.	COHERUS BIOSCIENCES, INC.	P,O	10/27/2023

(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).