

CY 2020 CDER Drug and Biologic Calendar Year Priority Approvals As of December 31, 2020

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

Selection Criteria:

User Response: Start Date: 1/1/2020 End Date: 12/31/2020

Sort Order: Approval Date

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
NDA 212608	AYVAKIT	AVAPRITINIB	BLUEPRINT MEDICINES CORP	P,O	1/9/2020
NDA 211723	TAZVERIK	TAZEMETOSTAT	EPIZYME INC	P,O	1/23/2020
NDA 213138	DIFICID	FIDAXOMICIN	CUBIST PHARMACEUTICALS LLC	P,O	1/24/2020
NDA 212728	NURTEC ODT	RIMEGEPANT	BIOHAVEN PHARMACEUTICAL HOLDING CO LTD	P	2/27/2020
NDA 213756	KOSELUGO	SELUMETINIB	ASTRAZENECA PHARMACEUTICALS LP	P,O	4/10/2020
NDA 211728	JELMYTO	MITOMYCIN	UROGEN PHARMA LTD	P,O	4/15/2020
NDA 213411	TUKYSA	TUCATINIB	SEATTLE GENETICS INC	P,O	4/17/2020
NDA 213736	PEMAZYRE	SELUMETINIB	INCYTE CORP	P,O	4/17/2020
NDA 213591	TABRECTA	CAPMATINIB	NOVARTIS PHARMACEUTICAL CORP	P,O	5/6/2020
NDA 213246	RETEVMO	SELPERCATINIB	LOXO ONCOLOGY INC	P,O	5/8/2020
NDA 213973	QINLOCK	RIPRETINIB	DECIPHERA PHARMACEUTICALS LLC	P,O	5/15/2020
NDA 209529	VESICARE LS	SOLIFENACIN SUCCINATE	ASTELLAS PHARMA US INC	P	5/26/2020
NDA 213036		ARTESUNATE	AMIVAS LLC	P,O	5/26/2020
NDA 212123	TAUVID	FLORTAUCIPIR F18 INJECTION	AVID RADIOPHARMACEUTICALS INC	P	5/28/2020
NDA 213170 (1)		ARTESUNATE	LA JOLLA PHARMACEUTICAL CO	P,O	5/29/2020
NDA 213983	TIVICAY PD	DOLUTEGRAVIR	VIIV HEALTHCARE CO	P	6/12/2020
NDA 213702	ZEPZELCA	LURBINECTEDIN	JAZZ PHARMACEUTICALS IRELAND LTD	P,O	6/15/2020
NDA 212102	FINTEPLA	FENFLURAMINE	ZOGENIX INC	P,O	6/25/2020
NDA 212950	RUKOBIA	FOSTEMSAVIR	VIIV HEALTHCARE CO	P	7/2/2020
NDA 212576	INQOVI	DECITABINE AND CEDAZURIDINE	OTSUKA PHARMACEUTICAL CO LTD	P,O	7/7/2020
NDA 212690	XYWAV	CALCIUM, MAGNESIUM, POTASSIUM, AND SODIUM OXYBATES	JAZZ PHARMACEUTICALS INC	P,O	7/21/2020
NDA 213464	LAMPIT	NIFURTIMOX	BAYER HEALTHCARE PHARMACEUTICALS INC	P,O	8/6/2020
NDA 213535	EVRYSDI	RISDIPLAM	GENENTECH INC	P,O	8/7/2020
NDA 212154	VILTEPSO	VILTOLARSEN	NIPPON SHINYAKU CO LTD	P,O	8/12/2020
NDA 214120	ONUREG	AZACITIDINE	CELGENE CORP	P,O	9/1/2020
NDA 213227	DETECTNET	COPPER CU 64 DOTATATE INJECTION	RADIOMEDIX INC	P,O	9/3/2020
NDA 213721	GAVRETO	PRALSETINIB	BLUEPRINT MEDICINES CORP	P,O	9/4/2020
NDA 213082	XELJANZ	TOFACITINIB	PFIZER INC	P	9/25/2020
NDA 214787	VEKLURY	REMDESIVIR	GILEAD SCIENCES INC	P	10/22/2020
NDA 214521 (2)		DOLUTEGRAVIR	MYLAN LABORATORIES LTD	P	11/19/2020
NDA 213969	ZOKINVY	LONAFARNIB	EIGER BIOPHARMACEUTICALS INC	P,O	11/20/2020
NDA 214103	OXLUMO	LUMASIRAN	ALNYLAM PHARMACEUTICALS INC	P,O	11/23/2020
NDA 213793	IMCIVREE	SETMELANOTIDE	RHYTHM PHARMACEUTICALS INC	P,O	11/25/2020
NDA 214517	HETLIOZ LQ	TASIMELTEON	VANDA PHARMACEUTICALS INC	P,O	12/1/2020
NDA 214621	ORGOVYX	RELUGOLIX	MYOVANT SCIENCES GMBH	P	12/18/2020

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761143	TEPEZZA	TEPROTUMUMAB-TRBW	HORIZON THERAPEUTICS IRELAND DAC	P,O	1/21/2020
BLA 761115	TRODELVY	SACITUZUMAB GOVITECAN-HZIY	IMMUNOMEDICS, INC.	P	4/22/2020
BLA 761163	MONJUVI	TAFASITAMAB-CXIX	MORPHOSYS US INC.	P,O	7/31/2020
BLA 761158	BLENREP	BELANTAMAB MAFODOTIN-BLMF	GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LTD. ENGLAND	P,O	8/5/2020
BLA 761169	INMAZEB	ATOLTIVIMAB, MAFTIVIMAB, AND ODESIVIMAB-EBGN	REGENERON PHARMACEUTICALS, INC.	P,O	10/14/2020
BLA 761171	DANYELZA	NAXITAMAB-GQGK	Y-MABS THERAPEUTICS, INC.	P,O	11/25/2020
BLA 761172	EBANGA	ANSUVIMAB-ZYKL	RIDGEBACK BIOTHERAPEUTICS	P,O	12/21/2020

(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).