

CY 2021 CDER Drug and Biologic Calendar Year Priority Approvals As of December 31, 2021

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

Selection Criteria:

User Response: Start Date: 1/1/2021 End Date: 12/31/2021

Sort Order: Approval Date

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
NDA 214377	VERQUVO	VERICIGUAT	MERCK SHARP AND DOHME CORP	P	1/19/2021
NDA 212887	VOCABRIA	CABOTEGRAVIR	VIIV HEALTHCARE CO	P	1/21/2021
NDA 212888	CABENUVA	CABOTEGRAVIR EXTENDED RELEASE INJECTABLE SUSPENSION; RILPIVIRINE EXTENDED RELEASE INJECTABLE SUSPENSION	VIIV HEALTHCARE CO	P	1/21/2021
NDA 213716	LUPKYNIS	VOCLOSPORIN	AURINIA PHARMACEUTICALS INC	P	1/22/2021
NDA 214096	TEPMETKO	TEPOTINIB	EMD SERONO INC	P,O	2/3/2021
NDA 213176	UKONIQ	UMBRALISIB	TG THERAPEUTICS INC	P,O	2/5/2021
NDA 214200	COSELA	TRILACICLIB	G1 THERAPEUTICS INC	P	2/12/2021
NDA 213026	AMONDYS 45	CASIMERSON	SAREPTA THERAPEUTICS INC	P,O	2/25/2021
NDA 214018	NULIBRY	FOSDENOPTERIN	ORIGIN BIOSCIENCES INC	P,O	2/26/2021
NDA 214383	PEPAXTO	MELPHALAN FLUFENAMIDE	ONCOPEPTIDES AB	P,O	2/26/2021
NDA 214566 (2)		DOLUTEGRAVIR	MACLEODS PHARMACEUTICALS LTD	P	3/16/2021
NDA 213801	MYRBETRIQ GRANULES	MIRABEGRON EXTENDED-RELEASE FOR ORAL SUSPENSION	ASTELLAS PHARMA GLOBAL DEVELOPMENT INC	P	3/25/2021
NDA 211988	ZYNRELEF	BUPIVACAINE AND MELOXICAM	HERON THERAPEUTICS INC	P	5/12/2021
NDA 215014	EMPAVELI	PEGCETACOPLAN	APELLIS PHARMACEUTICALS INC	P,O	5/14/2021
NDA 214793	PYLARIFY	PIFLUFOLASTAT F-18	PROGENICS PHARMACEUTICALS INC	P	5/26/2021
NDA 214622	TRUSELTIQ	INFIGRATINIB	QED THERAPEUTICS INC	P,O	5/28/2021
NDA 214665	LUMAKRAS	SOTORASIB	AMGEN INC	P,O	5/28/2021
NDA 214900	BREXAFEMME	IBREXAFUNGERP	SCYNEXIS INC	P	6/1/2021
NDA 214460	TEMBEXA	BRINCIDOFOVIR	CHIMERIX INC	P,O	6/4/2021
NDA 214461	TEMBEXA	BRINCIDOFOVIR	CHIMERIX INC	P,O	6/4/2021
NDA 215256	WEGOVY	SEMAGLUTIDE	NOVO NORDISK INC	P	6/4/2021
NDA 214187	EPCLUSA	SOFOSBUVIR AND VELPATISVIR	GILEAD SCIENCES INC	P,O	6/10/2021
NDA 215110	MAVYRET	GLECAPREVIR AND PIBRENTASVIR	ABBVIE INC	P,O	6/10/2021
NDA 214358	PRADAXA	DABIGATRAN ETEXILATE MESYLATE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	6/21/2021
NDA 215341	KERENDIA	FINERENONE	BAYER HEALTHCARE PHARMACEUTICALS INC	P	7/9/2021
NDA 214429		FEXINIDAZOLE	SANOFI AVENTIS US LLC	P,O	7/16/2021
NDA 214783	REZUROCK	BELUMOSUDIL	KADMON PHARMACEUTICALS LLC	P,O	7/16/2021
NDA 215498	BYLVAY	ODEVIXIBAT	ALBIREO AB	P,O	7/20/2021
NDA 215383	WELIREG	BELZUTIFAN	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	P,O	8/13/2021
NDA 214916	KORSUVA	DIFELIKEFALIN	CARA THERAPEUTICS INC	P	8/23/2021
NDA 213895		VANCOMYCIN	XELLIA PHARMACEUTICALS APS	P	8/26/2021
NDA 215310	EXKIVITY	MOBOCERTINIB	TAKEDA PHARMACEUTICALS USA INC	P,O	9/15/2021
NDA 215309	OPZELURA	RUXOLITINIB	INCYTE CORP	P	9/21/2021
NDA 215206	QULIPTA	ATOGEPAANT	ABBVIE INC	P	9/28/2021
NDA 214662	LIVMARLI	MARALIXIBAT	MIRUM PHARMACEUTICALS INC	P,O	9/29/2021
NDA 215358	SCEMBLIX	ASCIMINIB	NOVARTIS PHARMACEUTICALS CORP	P,O	10/29/2021

NDA 214938	VOXZOGO	VOSORITIDE	BIOMARIN PHARMACEUTICAL INC	P,O	11/19/2021
NDA 213312	FYARRO	SIROLIMUS PROTEIN-BOUND PARTICLES	AADI BIOSCIENCE INC	P,O	11/22/2021
NDA 215596	LIVTENCITY	MARIBAVIR	TAKEDA PHARMACEUTICALS USA INC	P,O	11/23/2021
NDA 214907	CYTALUX	PAFOLACIANINE SODIUM	ON TARGET LABORATORIES INC	P,O	11/29/2021
NDA 215650	XACIATO	CLINDAMYCIN PHOSPHATE	DARE BIOSCIENCE INC	P	12/7/2021
NDA 215935	TARPEYO	BUDESONIDE	CALLIDITAS THERAPEUTICS AB	P,O	12/15/2021
NDA 216157	OXBRYTA	VOXELOTOR	GLOBAL BLOOD THERAPEUTICS INC	P,O	12/17/2021
NDA 215499	APRETUDE	CABOTEGRAVIR	VIIV HEALTHCARE CO	P	12/20/2021
NDA 215859	XARELTO	RIVAROXABAN	JANSSEN PHARMACEUTICALS INC	P	12/20/2021

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761181	EVKEEZA	EVINACUMAB-DGNB	REGENERON PHARMACEUTICALS, INC.	P,O	2/11/2021
BLA 761174	JEMPERLI	DOSTARLIMAB-GXLY	GLAXOSMITHKLINE LLC	P	4/22/2021
BLA 761196	ZYNLONTA	LONCASTUXIMAB TESIRINE-LPYL	ADC THERAPEUTICS SA	P,O	4/23/2021
BLA 761210	RYBREVANT	AMIVANTAMAB-VMJW	JANSSEN BIOTECH, INC.	P	5/21/2021
BLA 761178	ADUHELM	ADUCANUMAB-AVWA	BIOGEN INC.	P	6/7/2021
BLA 761194	NEXVIAZYME	AVALGLUCOSIDASE ALFA-NGPT	GENZYME CORPORATION	P,O	8/6/2021
BLA 761223	JEMPERLI	DOSTARLIMAB-GXLY	GLAXOSMITHKLINE LLC	P	8/17/2021
BLA 761208	TIVDAK	TISOTUMAB VEDOTIN-TFTV	SEAGEN INC.	P	9/20/2021
BLA 761197	SUSVIMO	RANIBIZUMAB	GENENTECH, INC.	P	10/22/2021
BLA 761224	TEZSPIRE	TEZEPELUMAB-EKKO	ASTRAZENECA AB	P	12/17/2021

(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).