

**CY 2021 CDER Drug and Biologic Calendar Year 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

New Drug Application (NDA) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	505(B)(2) APPROVAL	APPROVAL DATE
NDA 208746 (1)		PEMETREXED	HOSPIRA INC	S	Y	1/8/2021
NDA 206610		ACETAMINOPHEN	MYLAN LABORATORIES LTD	S	Y	1/15/2021
NDA 214313	NOREPINEPHRINE BITARTRATE IN 5% DEXTROSE	NOREPINEPHRINE BITARTRATE	BAXTER HEALTHCARE CORP	S	Y	1/15/2021
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 204803	POSIMIR	BUPIVACAINE	DURECT CORP	S	Y	2/1/2021
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 204957		ACETAMINOPHEN	B BRAUN MEDICAL INC	S	Y	2/18/2021
NDA 214218 (1)		PEMETREXED	HOSPIRA INC	S		2/23/2021
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 212994	AZSTARYS	SERDEXMETHYLPHENIDATE AND DEXMETHYLPHENIDATE	COMMAVE THERAPEUTICS SA	S	Y	3/2/2021
NDA 212904	FOTIVDA	TIVOZANIB	AVEO PHARMACEUTICALS INC	S		3/10/2021
NDA 214155	KIMYRSA	ORITAVANCIN	MELINTA THERAPEUTICS LLC	S		3/12/2021
NDA 214566 (2)		DOLUTEGRAVIR	MACLEODS PHARMACEUTICALS LTD	P		3/16/2021
NDA 213498	PONVORY	PONESIMOD	JANSSSEN PHARMACEUTICALS INC	S		3/18/2021
NDA 211844		MIDAZOLAM	INFORLIFE SA	S	Y	3/22/2021
NDA 214231	ZEGALOGUE	DASIGLUCAGON	ZEALAND PHARMA AS	S		3/22/2021
NDA 213072	ROSZET	ROSUVASTATIN AND EZETIMIBE	ALThERA PHARMACEUTICALS LLC	S	Y	3/23/2021
NDA 213801	MYRBETRIQ GRANULES	MIRABEGRON EXTENDED-RELEASE FOR ORAL SUSPENSION	ASTELLAS PHARMA GLOBAL DEVELOPMENT INC	P		3/25/2021
NDA 211964	QELBREE	VILOXAZINE	SUPERNUS PHARMACEUTICALS INC	S		4/2/2021
NDA 214154	NEXTSTELLIS	DROSPIRENONE AND ESTETROL TABLETS	MAYNE PHARMA LLC	S	Y	4/15/2021
NDA 212045	KLOXXADO	NALOXONE HCL	HIKMA PHARMACEUTICALS USA INC	S	Y	4/29/2021
NDA 214657 (1)	PEMETREXED		SANDOZ INC	S	Y	5/6/2021
NDA 211988	ZYNRELEF	BUPIVACAINE AND MELOXICAM	HERON THERAPEUTICS INC	P	Y	5/12/2021
NDA 215014	EMPAVELI	PEGCETACOPLAN	APELLIS PHARMACEUTICALS INC	P,O		5/14/2021
NDA 214253	LEVOTHYROXINE SODIUM		CUSTOPHARM INC	S	Y	5/17/2021
NDA 211488	CAMCEVI	LEUPROLIDE	FORESEE PHARMACEUTICALS CO LTD	S	Y	5/25/2021
NDA 214793	PYLARIFY	PIFLUFOLASTAT F-18	PROGENICS PHARMACEUTICALS INC	P		5/26/2021
NDA 214846	MYFEMBREE	RELUGOLIX 40 MG, ESTRADIOL 1 MG, AND NORETHINDRONE ACETATE 0.5 MG	MYOVANT SCIENCES GMBH	S	Y	5/26/2021
NDA 213378	LYBALVI	OLANZAPINE AND SAMIDORPHAN	ALKERMES INC	S	Y	5/28/2021
NDA 214622	TRUSELTIQ	INFIGRATINIB	QED THERAPEUTICS INC	P,O		5/28/2021
NDA 214665	LUMAKRAS	SOTORASIB	AMGEN INC	P,O		5/28/2021
NDA 214770	NOXAFIL	POSACONAZOLE	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	S		5/31/2021
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 215025		SODIUM PHENYLACETATE AND SODIUM BENZOATE	MAIA PHARMACEUTICALS INC	S	Y	6/10/2021
NDA 215110	MAVYRET	GLECAPREVIR AND PIBRENTASVIR	ABBVIE INC	P,O		6/10/2021
NDA 213218	SOAANZ	TORSEMIDE	SARFEZ PHARMACEUTICALS INC	S	Y	6/14/2021
NDA 213536	REZIPRES	EPHEDRINE HYDROCHLORIDE	ETON PHARMACEUTICALS INC	S	Y	6/14/2021
NDA 212156		MICAFUNGIN	PAR STERILE PRODUCTS LLC	S	Y	6/16/2021
NDA 213872	ASTEPRO ALLERGY	AZELASTINE HYDROCHLORIDE	BAYER HEALTHCARE LLC	S		6/17/2021
NDA 210282		DAPTOMYCIN	HOSPIRA INC	S	Y	6/21/2021
NDA 214358	PRADAXA	DABIGATRAN ETEXILATE MESYLATE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P		6/21/2021
NDA 214965	VERKAZIA	CYCLOSPORINE	SANTEN INC	S,O	Y	6/23/2021
NDA 212303 (1)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	LUPIN LTD	S	Y	6/25/2021
NDA 211875 (1)	PACLITAXEL	HBT LABS INC	S			6/30/2021
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 214902	TWYNEO	TRETINOIN AND BENZOYL PEROXIDE	SOL-GEL TECHNOLOGIES LTD	S	Y	7/26/2021
NDA 214275	UPTRAVI	SELEXIPAG	ACTELION PHARMACEUTICALS US INC	S,O		7/29/2021
NDA 215383	WELIREG	BELZUTIFAN	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	P,O		8/13/2021
NDA 215143		SUCCINYLCOLINE CHLORIDE	HIKMA PHARMACEUTICALS USA INC	S	Y	8/20/2021
NDA 215441 (1)		BORTEZOMIB	INTAS PHARMACEUTICALS LTD	S		8/20/2021
NDA 214916	KORSUVA	DIFELIKEFALIN	CARA THERAPEUTICS INC	P		8/23/2021
NDA 210735		CYCLOPHOSPHAMIDE	EUGIA PHARMA SPECIALITIES LTD	S	Y	8/25/2021
NDA 213895		VANCOMYCIN	XELLIA PHARMACEUTICALS APS	P	Y	8/26/2021
NDA 214826	LOREEV XR	LORAZEPAM	ALMATICA PHARMA LLC	S	Y	8/27/2021
NDA 211566 (1)		SITAGLIPTIN	ZYDUS WORLDWIDE DMCC	S	Y	9/2/2021
NDA 213436	TRUDHESA	DIHYDROERGOTAMINE MESYLATE	IMPEL NEUROPHARMA	S	Y	9/2/2021
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	ATOGEANT	ABBVIE INC	P		9/28/2021
NDA 214662	LIVMARLI	MARALIXIBAT	MIRUM PHARMACEUTICALS INC	P,O		9/29/2021
NDA 215133		SERTRALINE HYDROCHLORIDE	ALMATICA PHARMA LLC	S	Y	10/4/2021
NDA 214487	TAVNEOS	AVACOPAN	CHEMOCENTRYX INC	S,O		10/7/2021
NDA 212854	ZIMHI	NALOXONE HYDROCHLORIDE	ADAMIS PHARMACEUTICALS CORP	S	Y	10/15/2021
NDA 213426	SEGLENTIS	CELECOXIB AND TRAMADOL HYDROCHLORIDE	KOWA PHARMACEUTICALS AMERICA INC	S	Y	10/15/2021
NDA 213978	TYRVAYA	VARENICLINE SOLUTION	OYSTER POINT PHARMA INC	S	Y	10/15/2021
NDA 211950	XIPERE	TRIAMCINOLONE ACETONIDE	BAUSCH AND LOMB INC	S	Y	10/22/2021
NDA 214028	VUITY	PILOCARPINE HYDROCHLORIDE	ABBVIE INC	S	Y	10/28/2021
NDA 215252		DILTIAZEM HYDROCHLORIDE	EXELA PHARMA SCIENCES LLC	S		10/28/2021
NDA 215358	SCEMBLIX	ASCIMINIB	NOVARTIS PHARMACEUTICALS CORP	P,O		10/29/2021
NDA 210526	DYANAVEL XR	AMPHETAMINE	TRIS PHARMA INC	S	Y	11/4/2021
NDA 213005 (1)	YUTREPIA	TREPROSTINIL	LIQUIDIA TECHNOLOGIES	S	Y	11/4/2021
NDA 214679	EPRONTIA	TOPIRAMATE	AZURITY PHARMACEUTICALS INC	S	Y	11/5/2021
NDA 214869	DHIVY	CARBIDOPA AND LEVODOPA	AVION PHARMACEUTICALS LLC	S	Y	11/12/2021
NDA 215668 (1)		BENDAMUSTINE HYDROCHLORIDE	DR REDDYS LABORATORIES LTD	S	Y	11/12/2021
NDA 214938	VOXZOGO	VOSORITIDE	BIOMARIN PHARMACEUTICAL INC	P,O		11/19/2021
NDA 213312	FYARRO	SIROLIMUS PROTEIN-BOUND PARTICLES	AADI BIOSCIENCE INC	P,O	Y	11/22/2021
NDA 215422	LYVISPAH	BACLOFEN	SAOL THERAPEUTICS RESEARCH LTD	S	Y	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	Y	12/7/2021
NDA 215423	ENTADFI	TADALAFIL AND FINASTERIDE	VERU INC	S	Y	12/9/2021
NDA 215935	TARPEYO	BUDESONIDE	CALLIDITAS THERAPEUTICS AB	P,O	Y	12/15/2021

NDA 215019	DARTISLA ODT	GLYCOPYRROLATE	EDENBRIDGE PHARMACEUTICALS LLC	S	Y	12/16/2021
NDA 214032	ILLUCCIX	KIT FOR THE PREPARATION OF GA-68 PSMA-11	TELIX PHARMACEUTICALS US INC	S	Y	12/17/2021
NDA 215395		LANREOTIDE ACETATE	INVAGEN PHARMACEUTICALS INC	S	Y	12/17/2021
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	RIVAROXYBAN	JANSSEN PHARMACEUTICALS INC	P		12/20/2021
NDA 214012	LEQVIO	INCLISIRAN	NOVARTIS PHARMACEUTICALS CORP	S		12/22/2021
NDA 214133	RECORLEV	LEVOKETOCONAZOLE	STRONGBRIDGE DUBLIN LTD	S,O	Y	12/30/2021

New Drug Application (NDA) Approvals with Prior Tentative Approval(s):

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	TENTATIVE APPROVAL DATE
NDA 212035		ARGATROBAN	ACCORD HEALTHCARE INC	S	6/7/2021	2/28/2019
NDA 212125		MICAFUNGIN SODIUM	TEVA PHARMACEUTICALS USA INC	S	7/30/2021	11/25/2020
NDA 209191		BORTEZOMIB	HOSPIRA INC	S		12/17/2021, 4/26/2017
NDA 214962	TASCENSO ODT	FINGOLIMOD	HANDA NEUROSCIENCE LLC	S	12/23/2021	10/18/2021
NDA 207949		CABAZITAXEL	ACCORD HEALTHCARE INC	S	12/29/2021	6/25/2015

Biologic License Application (BLA) Approvals:

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 761179	RYLAZE	ASPARAGINASE ERWINIA CHRYSANTHEMI (RECOMBINANT)-RYWN	JAZZ PHARMACEUTICALS IRELAND LIMITED	S,O	6/30/2021
BLA 761123	SAPHNELO	ANIFROLUMAB-FNIA	ASTRAZENECA AB	S	7/30/2021
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 761177	SKYTROFA	LONAPEG SOMATROPIN-TCGD	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S	S,O	8/25/2021
BLA 761208	TIVDAK	TISOTUMAB VEDOTIN-TFTV	SEAGEN INC.	P	9/20/2021
BLA 761197	SUSVIMO	RANIBIZUMAB	GENENTECH, INC.	P	10/22/2021
BLA 761166	BESREMI	ROPEGINTERFERON-ALFA-2B-NJFT	PHARMAESSENTIA CORPORATION	S,O	11/12/2021
BLA 761195	VYVGART	EFGARTIGIMOD ALFA-FCAB	ARGENX BV	S,O	12/17/2021
BLA 761224	TEZSPIRE	TEZPELUMAB-EKKO	ASTRAZENECA AB	P	12/17/2021
BLA 761180	ADBRY	TRALOKINUMAB-LDRM	LEO PHARMA A/S	S	12/27/2021

(1) Application has been tentatively approved.

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

market exclusivity and/or patent term of the listed drug upon which the application relies, has expired.

Review Classification:

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

S - Standard Review - Products that do not qualify for priority review.

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