

**CY 2020 CDER Drug and Biologic Calendar Year 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

New Drug Application (NDA) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	505(B)(2) APPROVAL	APPROVAL DATE
NDA 212608	AYVAKIT	AVAPRITINIB	BLUEPRINT MEDICINES CORP	P,O		1/9/2020
NDA 209575	NUMBRINO	COCAINE HYDROCHLORIDE	CODY LABORATORIES INC A WHOLLY OWNED SUBSIDIARY OF LANNETT CO INC	S	Y	1/10/2020
NDA 211635	VALTOCO	DIAZEPAM	NEURELIS INC	S,O	Y	1/10/2020
NDA 208171	MONOFER	FERRIC DERISOMALTOSE	PHARMACOSMOS AS	S		1/16/2020
NDA 211723	TAZVERIK	TAZEMETOSTAT	EPIZYME INC	P,O		1/23/2020
NDA 213138	DIFICID	FIDAXOMICIN	CUBIST PHARMACEUTICALS LLC	P,O		1/24/2020
NDA 212614	TRIJARDY XR	EMPAGLIFLOZIN, LINAGLIPTIN, AND METFORMIN HYDROCHLORIDE	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S		1/27/2020
NDA 213224	BYNEFEZIA PEN	OCTREOTIDE ACETATE	SUN PHARMACEUTICAL INDUSTRIES LTD	S	Y	1/28/2020
NDA 211281	PIZENSY	LACTITOL	BRAINTREE LABORATORIES INC	S	Y	2/12/2020
NDA 204017	TWIRLA	ETHINYL ESTRADIOL AND LEVONORGESTREL	AGILE THERAPEUTICS INC	S	Y	2/14/2020
NDA 213491	PROCYSBI	CYSTEAMINE BITARTRATE	HORIZON PHARMA USA INC	S,O	Y	2/14/2020
NDA 210583	ANJESO	MELOXICAM	BAUDAX BIO INC	S	Y	2/20/2020
NDA 211616	NEXLETOL	BEMPEDOIC ACID	ESPERION THERAPEUTICS INC	S		2/21/2020
NDA 209510	BARHEMSYS	AMISULPRIDE	ACACIA PHARMA LTD	S	Y	2/26/2020
NDA 211617	NEXLIZET	BEMPEDOIC ACID AND EZETIMIBE	ESPERION THERAPEUTICS INC	S	Y	2/26/2020
NDA 212728	NURTEC ODT	RIMEGEPANT	BIOHAVEN PHARMACEUTICAL HOLDING CO LTD	P		2/27/2020
NDA 211733	ADVIL DUAL ACTION WITH ACETAMINOPHEN	IBUPROFEN 125 MG/ACETAMINOPHEN 250 MG	PFIZER INC	S	Y	2/28/2020
NDA 211911	DURYSTA	BIMATOPROST IMPLANT	ALLERGAN INC	S		3/4/2020
NDA 212801	ISTURISA	OSILODROSTAT	RECORDATI RARE DISEASES INC	S,O		3/6/2020
NDA 211039		FLUORESCHEIN SODIUM AND BENOXINATE HYDROCHLORIDE OPHTHALMIC SOLUTION	BAUSCH HEALTH IRELAND LTD	S	Y	3/9/2020
NDA 208574		ROMIDEPSIN	TEVA PHARMACEUTICALS USA INC	S	Y	3/13/2020
NDA 209899	ZEPOSIA	OZANIMOD	CELGENE INTERNATIONAL II SARL	S		3/25/2020
NDA 212860	TRIFERIC AVNU	FERRIC PYROPHOSPHATE CITRATE	ROCKWELL MEDICAL INC	S		3/27/2020
NDA 209405		LEVONORGESTREL/ETHINYL ESTRADIOL	EXELTIS USA INC	S	Y	3/30/2020
NDA 213756	KOSELUGO	SELUMETINIB	ASTRAZENECA PHARMACEUTICALS LP	P,O		4/10/2020
NDA 211912 (2)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	CELLTRION INC	S	Y	4/13/2020
NDA 211728	JELMYTO	MITOMYCIN	UROGEN PHARMA LTD	P,O	Y	4/15/2020
NDA 213407	EMERPHED	EPHEDRINE SULFATE	NEXUS PHARMACEUTICALS INC	S	Y	4/17/2020
NDA 213411	TUKYSA	TUCATINIB	SEATTLE GENETICS INC	P,O		4/17/2020
NDA 213736	PEMAZYRE	SELUMETINIB	INCYTE CORP	P,O		4/17/2020
NDA 212489	ONGENTYS	OPICAPONE	NEUROCRINE BIOSCIENCES INC	S		4/24/2020
NDA 201110	MILPROSA	PROGESTERONE	FERRING PHARMACEUTICALS INC	S	Y	4/29/2020
NDA 213150	FENSOLVI	LEUPROLIDE ACETATE	TOLMAR INTERNATIONAL LTD	S	Y	5/1/2020
NDA 212157	ELYXYB	CELECOXIB	DR REDDYS LABORATORIES LTD	S	Y	5/5/2020
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 208297 (1)		PEMETREXED	DR REDDYS LABORATORIES LTD	S	Y	5/14/2020
NDA 213973	QINLOCK	RIPRETINIB	DECIPHERA PHARMACEUTICALS LLC	P,O		5/15/2020
NDA 212269	FERRIPROX	DEFERIPRONE	CHIESI USA INC	S,O		5/19/2020
NDA 213691	IMPEKLO	CLOBETASOL PROPIONATE	MYLAN PHARMACEUTICALS INC	S	Y	5/19/2020
NDA 212155	CERIANNA	18F-FLUOROESTRADIOL	ZIONEXA US CORP	S	Y	5/20/2020
NDA 210875	KYNMOBI	APOMORPHINE	SUNOVION PHARMACEUTICALS INC	S	Y	5/21/2020
NDA 208352	PHEXXI	LACTIC ACID, CITRIC ACID, AND POTASSIUM BITARTRATE	EVOFEM INC	S	Y	5/22/2020
NDA 209529	VESICARE LS	SOLIFENACIN SUCCINATE	ASTELLAS PHARMA US INC	P		5/26/2020

NDA 213036		ARTESUNATE	AMIVAS LLC	P,O	Y	5/26/2020
NDA 212123	TAUVID	FLORTAUCIPIR F18 INJECTION	AVID RADIOPHARMACEUTICALS INC	P		5/28/2020
NDA 213690	ZILXI	MINOCYCLINE	FOAMIX PHARMACEUTICALS INC	S	Y	5/28/2020
NDA 213170 (1)		ARTESUNATE	LA JOLLA PHARMACEUTICAL CO	P,O	Y	5/29/2020
NDA 213388	ORIAHNN	ELAGOLIX, ESTRADIOL AND NORETHINDRONE ACETATE CAPSULES; ELAGOLIX CAPSULES	ABBVIE INC	S	Y	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 209388	GIMOTI	METOCLOPRAMIDE	EVOKE PHARMA INC	S	Y	6/19/2020
NDA 212102	FINTEPLA	FENFLURAMINE	ZOGENIX INC	P,O	Y	6/25/2020
NDA 208232	MYCAPSSA	OCTREOTIDE	CHIASMA INC	S,O	Y	6/26/2020
NDA 213687	DOJOLVI	TRHEPTANOIN	ULTRAGENYX PHARMACEUTICAL INC	S,O	Y	6/30/2020
NDA 209376		TRALEMENT	AMERICAN REGENT INC	S	Y	7/2/2020
NDA 212209 (1)		BENDAMUSTINE HYDROCHLORIDE	SLAYBACK PHARMA LLC	S	Y	7/2/2020
NDA 212295	BYFAVO	REMIMAZOLAM	ACACIA PHARMA LTD	S		7/2/2020
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 212520	OPNEEQ	OXYMETAZOLINE HYDROCHLORIDE	RVL PHARMACEUTICALS INC	S	Y	7/8/2020
NDA 213422	WYNZORA	CALCIPTRIENE AND BETAMETHASONE DIPROPIONATE	MC2 THERAPEUTICS LTD	S	Y	7/20/2020
NDA 212690	XYWAV	CALCIUM, MAGNESIUM, POTASSIUM, AND SODIUM OXYBATES	JAZZ PHARMACEUTICALS INC	P,O		7/21/2020
NDA 212122	BREZTRI AEROSPHERE	BUDESONIDE, GLYCOPYRROLATE, AND FORMOTEROL FUMARATE	ASTRAZENECA AB	S	Y	7/23/2020
NDA 206966	XEGLYZE	ABAMETAPIR	DR REDDYS LABORATORIES SA	S		7/24/2020
NDA 212501		CYCLOPHOSPHAMIDE	INGENUS PHARMACEUTICALS LLC	S	Y	7/30/2020
NDA 213674	XTANDI	ENZALUTAMIDE	ASTELLAS PHARMA US INC	S		8/4/2020
NDA 213464	LAMPIT	NIFURTIMOX	BAYER HEALTHCARE PHARMACEUTICALS INC	P,O	Y	8/6/2020
NDA 210730	OLINVYK	OLICERIDINE	TREVENA INC	S		8/7/2020
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 211302	CYSTADROPS	CYSTEAMINE	RECORDATI RARE DISEASES INC	S	Y	8/19/2020
NDA 208419		PEMETREXED	ACTAVIS LLC AN INDIRECT WHOLLY OWNED SUB OF TEVA PHARMACEUTICALS USA INC	S	Y	8/21/2020
NDA 214121		METHOTREXATE	ACCORD HEALTHCARE INC	S	Y	8/24/2020
NDA 213433	WINLEVI	CLASCOTERONE	CASSIOPEA SPA	S		8/26/2020
NDA 209511	XARACOLL	BUPIVACAINE HCI	INNOCOLL PHARMACEUTICALS	S	Y	8/28/2020
NDA 214044	QDOLO	TRAMADOL HYDROCHLORIDE	ATHENA BIOSCIENCE LLC	S	Y	9/1/2020
NDA 214120	ONUREG	AZACITIDINE	CELGENE CORP	P,O		9/1/2020
NDA 213227	DETECTNET	COPPER CU 64 DOTATATE INJECTION	RADIOMEDIX INC	P,O	Y	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 213876	ALKINDI SPRINKLE	HYDROCORTISONE	ETON PHARMACEUTICALS INC	S,O	Y	9/29/2020
NDA 214652		ATROPINE SULFATE INJECTION	ACCORD HEALTHCARE INC	S	Y	9/29/2020
NDA 213556 (2)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE	SHANGHAI DESANO BIO-PHARMACEUTICALS CO LTD	S	Y	10/6/2020
NDA 213994		EPHEDRINE SULFATE	ENDO VENTURES LTD	S	Y	10/16/2020
NDA 214278		ESOMEPRAZOLE	DEXCEL PHARMA TECHNOLOGIES LTD	S	Y	10/20/2020
NDA 214787	VEKLURY	REMDESIVIR	GILEAD SCIENCES INC	P		10/22/2020
NDA 210933		LOTEPREDNOL ETABONATE	KALA PHARMACEUTICALS INC	S	Y	10/26/2020
NDA 202049	BRONCHITOL	MANNITOL	CHIESI USA INC	S,O	Y	10/30/2020
NDA 210864	SESQUIENT	FOSPHENYTOIN SODIUM	SEDOR PHARMACEUTICALS LLC	S	Y	11/5/2020
NDA 213330		LABETALOL HYDROCHLORIDE	HIKMA PHARMACEUTICALS INTERNATIONAL LTD	S	Y	11/9/2020
NDA 213135	SUTAB	SODIUM SULAFATE, MAGNESIUM SULFATE, POTASSIUM CHLORIDE	BRAINTREE LABORATORIES INC	S,O	Y	11/10/2020
NDA 214521 (2)		DOLUTEGRAVIR	MYLAN LABORATORIES LTD	P	Y	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 214410	XOFLUZA	BALOXAVIR MARBOXIL	GENENTECH INC	S		11/23/2020
NDA 212125 (1)		MICAFUNGIN SODIUM	TEVA PHARMACEUTICALS USA	S	Y	11/25/2020
NDA 213793	IMCIVREE	SETMELANOTIDE	RHYTHM PHARMACEUTICALS INC	P,O		11/25/2020
NDA 214047	THYQUIDITY	EVOTHYROXINE SODIUM	EMP LEVO US BV	S	Y	11/30/2020

NDA 212642		PSMA-11 GA 68	UNIV CALIFORNIA LOS ANGELES	S	Y	12/1/2020
NDA 212643		PSMA-11 GA 69	UNIV OF CALIFORNIA SAN FRANCISCO	S	Y	12/1/2020
NDA 214517	HETLIOZ LQ	TASIMELTEON	VANDA PHARMACEUTICALS INC	P,O		12/1/2020
NDA 214094	ORLADEYO	BEROTRALSTAT	BIOCRYSST PHARMACEUTICALS INC	S,O		12/3/2020
NDA 213681 (2)		DOLUTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	LAURUS LABS LTD	S	Y	12/4/2020
NDA 208088 (1)	TIANDO	TESTOSTERONE UNDECANOATE	LIPOCINE INC	S	Y	12/8/2020
NDA 213189	KLISYRI	TIRBANIBULIN	ALMIRALL LLC	S		12/14/2020
NDA 214621	ORGOVYX	RELUGOLIX	MYOVANT SCIENCES GMBH	P		12/18/2020
NDA 213006	GEMTESA	VIBEGRON	UROVANT SCIENCES GMBH	S		12/23/2020

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 209472	PEMFEXY	PEMETREXED INJECTION	EAGLE PHARMACEUTICALS INC	S	2/8/2020	10/26/2017, 10/9/2019
NDA 210296	BAFIERTAM	MONOMETHYL FUMARATE	BANNER LIFE SCIENCES LLC	S	4/28/2020	11/16/2018
NDA 212593	VASOPRESSIN	AMERICAN REGENT INC	AMERICAN REGENT INC	S	8/3/2020	1/28/2020

Biologic License Application (BLA) Approvals:

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 761119	VYEPTI	EPTINEZUMAB-JJMR	LUNDBECK SEATTLE BIOPHARMACEUTICALS, INC.	S	2/21/2020
BLA 761113	SARCLISA	ISATUXIMAB-IRFC	SANOVI-AVENTIS U.S. LLC	S,O	3/2/2020
BLA 210089	PULMOTECH MAA	TECHNETIUM TC 99M ALBUMIN AGGREGATED INJECTION	CIS BIO INTERNATIONAL	S	3/20/2020
BLA 761115	TRODELVY	SACITUZUMAB GOVITECAN-HZIY	IMMUNOMEDICS, INC.	P	4/22/2020
BLA 761145	DARZALEX FASPRO	DARATUMUMAB AND HYALURONIDASE-FIHJ	JANSSEN BIOTECH, INC.	S,O	5/1/2020
BLA 210605	SEMGLEE	INSULIN GLARGINE	MYLAN PHARMACEUTICALS, INC.	S	6/11/2020
BLA 761142	UPLIZNA	INEBILIZUMAB-CDON	VIELA BIO	S,O	6/11/2020
BLA 761109	LYUMJEV	INSULIN LISPRO-AABC	ELI LILLY AND COMPANY	S	6/15/2020
BLA 761170	PHESGO	PERTUZUMAB, TRASTUZUMAB, AND HYALURONIDASE-ZZXF	GENENTECH, INC.	S	6/29/2020
BLA 761146	QWO	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM-AAES	ENDO GLOBAL AESTHETICS LTD.	S	7/6/2020
BLA 761163	MONJUVI	TAFASITAMAB-CXIX	MORPHOSYS US INC.	P,O	7/31/2020
BLA 761158	BLNREP	BELANTAMAB MAFODOTIN-BLMF	GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LTD. ENGLAND	P,O	8/5/2020
BLA 761149	ENSPRYNG	SATRALIZUMAB-MWGE	GENENTECH, INC.	S,O	8/14/2020
BLA 761156	SOGROYA	SOMAPACITAN-BECO	NOVO NORDISK INC.	S	8/28/2020
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 761150	MARGENZA	MARGETUXIMAB-CMKB	MACROGENICS INC.	S	12/16/2020
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.

the 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).