

CY 2022 CDER Drug and Biologic Calendar Year Approvals

As of December 31, 2022

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

Selection Criteria:

User Response: Start Date: 1/1/2022 End Date: 12/31/2022

Sort Order: Approval Date

New Drug Application (NDA) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	505(B)(2) APPROVAL
NDA 214985	QUVIVIQ	DARIDOREXANT	IDORSIA PHARMACEUTICALS LTD	S	1/7/2022	
NDA 211746	RYALTRIS	OLOPATADINE HYDROCHLORIDE AND MOMETASONE FUROATE	GLENMARK SPECIALTY SA	S	1/13/2022	Y
NDA 213871	CIBINQO	ABROCITINIB	PFIZER INC	P	1/14/2022	
NDA 214581		HYDROXYCHLOROQUINE SULFATE	NOVITIUM PHARMA LLC	S	1/14/2022	Y
NDA 213645	DAPZURA RT	DAPTOMYCIN	BAXTER HEALTHCARE CORP	S	1/25/2022	Y
NDA 213696 (2)		DOLUTEGRAVIR, LAMIVUDINE AND TENOFOVIR ALAFENAMIDE TABLETS	LAURUS LABS LTD	S	1/25/2022	Y
NDA 215428		CITALOPRAM	ALMATICA PHARMA INC	S	1/31/2022	Y
NDA 215602	FLEQSUVY	BACLOFEN	AZURITY PHARMACEUTICALS INC	S	2/4/2022	Y
NDA 216196	PYRUKYND (MITAPIVAT)	MITAPIVAT	AGIOS PHARMACEUTICALS INC	P,O	2/17/2022	
NDA 214993	NEPHROSCAN	TECHNETIUM TC99M SUCCIMER	THERAGNOSTICS INC	P,O	2/18/2022	Y
NDA 214439	NORLIQVA	AMLODIPINE	CMP DEVELOPMENT LLC	S	2/24/2022	Y
NDA 022388	ACUVUE THERAVISION WITH KETOTIFEN	ETAFILCON A LENS WITH KETOTIFEN	JOHNSON AND JOHNSON VISION CARE INC	S	2/25/2022	Y
NDA 208712	VONJO	PACRITINIB	CTI BIOPHARMA CORP	P,O	2/28/2022	
NDA 215457		NALOXONE	KALEO INC	P	2/28/2022	Y
NDA 216018	ASPRUZYO	RANOLAZINE	SUN PHARMA INDUSTRIES LTD	S	2/28/2022	Y
NDA 212304	ADLARITY	DONEPEZIL HYDROCHLORIDE	CORIUM INC	S	3/11/2022	Y
NDA 213581		ATROPINE SULFATE OPHTHALMIC SOLUTION	PARAGON BIOTECK INC	S	3/15/2022	Y
NDA 215712	NASONEX 24HR ALLERGY	MOMETASONE FUROATE	PERRIGO PHARMA INTERNATIONAL DAC	S	3/17/2022	
NDA 215904	ZTALMY	GANAXOLONE	MARINUS PHARMACEUTICALS INC	P,O	3/18/2022	
NDA 213478	HYFTOR	SIROLIMUS	NOBELPHARMA CO LTD	P,O	3/22/2022	Y
NDA 215401	XELSTRYM	DEXTROAMPHETAMINE	NOVEN PHARMACEUTICALS INC	S	3/22/2022	Y
NDA 215833	PLUVICTO	LUTETIUM (177LU) VIPIVOTIDE TETRAXETAN	ADVANCED ACCELERATOR APPLICATIONS USA INC A NOVARTIS CO	P	3/23/2022	
NDA 215841	LOCAMETZ	GALLIUM (68GA) GOZETOTIDE	ADVANCED ACCELERATOR APPLICATIONS USA INC A NOVARTIS CO	S	3/23/2022	Y
NDA 208088	TLANDO	TESTOSTERONE UNDECANOATE	ANTARES PHARMA INC	S	3/28/2022	Y
NDA 212527 (2)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFOVIR ALAFENAMIDE TABLETS	CIPLA LTD	S	3/30/2022	
NDA 215413		ABACAVIR, DOLUTEGRAVIR, AND LAMIVUDINE	VIIV HEALTHCARE CO	P	3/30/2022	
NDA 215039	VIJOICE	ALPELISIB	NOVARTIS PHARMACEUTICALS CORP	P,O	4/5/2022	
NDA 215390	IGALMI	DEXMEDETOMIDINE	BIOXCEL THERAPEUTICS INC	S	4/5/2022	Y
NDA 214919		GLYCOPYRROLATE	FRESENIUS KABI USA LLC	S	4/21/2022	Y
NDA 214510	EPSOLAY	BENZOYL PEROXIDE	GALDERMA LABORATORIES LP	S	4/22/2022	Y
NDA 215888	VIVJOA	OTESECONAZOLE	MYCOVIA PHARMACEUTICALS INC	P	4/26/2022	
NDA 214998	CAMZYOS	MAVACAMTEN	MYOKARDIA INC	S,O	4/28/2022	
NDA 215760	CUVRIOR	TRIENTINE TETRAHYDROCHLORIDE	ORPHALAN SA	S,O	4/28/2022	Y

NDA 215809	ERMEZA	LEVOTHYROXINE SODIUM	MYLAN PHARMACEUTICALS INC A VIATRIS CO	S	4/29/2022	Y
NDA 215152	VOQUEZNA TRIPLE PAK	VONOPRAZAN, AMOXICILLIN, AND CLARITHROMYCIN	PHATHOM PHARMACEUTICALS INC	P	5/3/2022	Y
NDA 215153	VOQUEZNA DUAL PAK	VONOPRAZAN AND AMOXICILLIN	PHATHOM PHARMACEUTICALS INC	P	5/3/2022	Y
NDA 215446	RADICAVA ORS	EDARAVONE	MITSUBISHI TANABE PHARMA CORP	P,O	5/12/2022	
NDA 215866	MOUNJARO	TIRZEPATIDE	ELI LILLY AND CO	P	5/13/2022	
NDA 215000		CARMUSTINE	ACCORD HEALTHCARE INC	S	5/16/2022	
NDA 214408 (1)		PEMETREXED	ACCORD HEALTHCARE INC	S	5/17/2022	
NDA 214518	TPOXX	TECOVIRIMAT	SIGA TECHNOLOGIES INC	S,O	5/18/2022	
NDA 214324	TYVASO DPI	TREPROSTINIL	UNITED THERAPEUTICS CORP	P,O	5/23/2022	
NDA 215272	VTAMA	TAPINAROF	DERMAVANT SCIENCES INC	S	5/23/2022	
NDA 216318		TESTOSTERONE CYPIONATE	SLAYBACK PHARMA LLC	S	6/2/2022	Y
NDA 206968		ACETAMINOPHEN	HIKMA PHARMACEUTICALS USA INC	S	6/3/2022	Y
NDA 215515	AMVUTTRA	VUTRISIRAN	ALNYLAM PHARMACEUTICALS INC	S,O	6/13/2022	
NDA 214522	TADLIQ	TADALAFIL	CMP DEVELOPMENT LLC	S	6/17/2022	Y
NDA 216513	PHEBURANE	SODIUM PHENYL BUTYRATE	MEDUNIK CANADA INC	S,O	6/17/2022	Y
NDA 216117	RELEXII	METHYLPHENIDATE HYDROCHLORIDE)	OSMOTICA PHARMACEUTICAL US LLC	S	6/23/2022	Y
NDA 215429	VENBYSI XR	VENLAFAXINE BESYLATE	ALMATICA PHARMA LLC	S	6/29/2022	Y
NDA 216285		DROSPIRENONE	EXELTIS USA INC	S	6/29/2022	
NDA 216264	BLUDIGO	INDIGOTINDISULFONATE SODIUM	PROVEPHARM SAS	S	7/8/2022	Y
NDA 216078 (1)		BENDAMUSTINE HYDROCHLORIDE	CELERITY PHARMACEUTICALS LLC	S	7/14/2022	Y
NDA 214273	ZONISADE	ZONISAMIDE	AZURITY PHARMACEUTICALS INC	S	7/15/2022	Y
NDA 216338 (1)		PACLITAXEL	TEVA PHARMACEUTICALS INC	S	7/15/2022	Y
NDA 214755 (1)	LUMRYZ	SODIUM OXYBATE	AVADEL CNS PHARMACEUTICALS LLC	S,O	7/18/2022	Y
NDA 215868		MIDAZOLAM	EXELA PHARMA SCIENCES LLC	S	7/20/2022	Y
NDA 213953	KYZATREX	TESTOSTERONE UNDECANOATE	MARIUS PHARMACEUTICALS LLC	S	7/27/2022	Y
NDA 215331		BORTEZOMIB	MAIA PHARMACEUTICALS INC	S	7/27/2022	Y
NDA 215985	ZORYVE	ROFLUMILAST	ARCUTIS BIOTHERAPEUTICS INC	S	7/29/2022	
NDA 216387	CALQUENCE	ACALABRUTINIB MALEATE	ASTRAZENECA UK LTD	S,O	8/3/2022	
NDA 216359		MIDAZOLAM	RAFA LABORATORIES LTD	P	8/8/2022	Y
NDA 211363		EPINEPHRINE	INTERNATIONAL MEDICATION SYSTEMS LTD	S	8/15/2022	Y
NDA 215430	AUVELITY	DEXTROMETHORPHAN HYDROBROMIDE AND BUPROPION HYDROCHLORIDE	AXSOME THERAPEUTICS INC	P	8/18/2022	Y
NDA 217003	IMBRUVICA	IBRUTINIB	PHARMACYCLICS LLC	P,O	8/24/2022	
NDA 212641 (1)	LIBERVANT	DIAZEPAM	AQUESTIVE THERAPEUTICS INC	S,O	8/30/2022	Y
NDA 213593	KONVOMEF	OMEPRAZOLE AND BICARBONATE	AZURITY PHARMACEUTICALS INC	S	8/30/2022	Y
NDA 214958	SOTYKTU	DEUCRAVACITINIB	BRISTOL MYERS SQUIBB CO	S	9/9/2022	
NDA 022231	TERLIVAZ	TERLIPRESSIN	MALLINCKRODT PHARMACEUTICALS IRELAND LTD	P,O	9/14/2022	
NDA 215700		NOREPINEPHRINE BITARTRATE	INFORLIFE SA	S	9/15/2022	Y
NDA 216457	APONVIE	APREPITANT	HERON THERAPEUTICS INC	S	9/16/2022	Y
NDA 212937	PEDMARK	SODIUM THIOSULFATE	FENNEC PHARMACEUTICALS INC	P,O	9/20/2022	Y
NDA 216986	ELUCIREM	GADOPICLENOL	GUERBET	P	9/21/2022	
NDA 215092	OMLONTI	OMIDENEPAG ISOPROPYL	SANTEN INC	S	9/22/2022	
NDA 216227	IHEEZO	CHLOROPROCAINE HYDROCHLORIDE	SINETICA SA	S	9/27/2022	Y
NDA 216660	RELYVRIO	SODIUM PHENYL BUTYRATE AND TAURURSODIOL	AMLYX PHARMACEUTICALS INC	P,O	9/29/2022	
NDA 214801	LYTGOBI	FUTIBATINIB	TAIHO ONCOLOGY INC	P,O	9/30/2022	
NDA 216774 (1)	ALVAIZ (ELTROMBOPAG CHOLINE)	ELTROMBOPAG CHOLINE	TEVA PHARMACEUTICALS INC	S	10/3/2022	Y
NDA 214628		NOREPINEPHRINE	NEVAKAR INJECTABLES INC	S	10/6/2022	Y
NDA 209988	FUROSCIX INFUSOR	FUROSEMIDE	SCPHARMACEUTICALS INC	S	10/7/2022	Y
NDA 216109		CEFAZOLIN	HIKMA PHARMACEUTICALS USA INC	S	10/7/2022	Y

NDA 215910	SEZABY (PHENOBARBITAL)	PHENOBARBITAL	SUN PHARMACEUTICAL INDUSTRIES INC	P,O	11/17/2022	Y
NDA 215813		DOCETAXEL	MERIDIAN LABORATORIES INC	S	11/22/2022	Y
NDA 212479	JYLAMVO (METHOTREXATE)	METHOTREXATE	THERAKIND LTD	S	11/29/2022	Y
NDA 215814	REZLIDHIA (OLUTASIDENIB)	OLUTASIDENIB	RIGEL PHARMACEUTICALS INC	S,O	12/1/2022	
NDA 215033		BENDAMUSTINE HYDROCHLORIDE	APOTEX INC	S	12/7/2022	Y
NDA 216340	KRAZATI	ADAGRASIB	MIRATI THERAPEUTICS INC	S,O	12/12/2022	
NDA 216472	IYUZEH	LATANOPROST	THEA PHARMA INC	S	12/13/2022	Y
NDA 216078		BENDAMUSTINE HYDROCHLORIDE	BAXTER HEALTHCARE CORP	S	12/15/2022	Y
NDA 214860	OLPRUVA	SODIUM PHENYL BUTYRATE	ACER THERAPEUTICS INC	S	12/22/2022	Y
NDA 215973	SUNLENCA	LENACAPAVIR	GILEAD SCIENCES INC	P	12/22/2022	
NDA 215974	SUNLENCA	LENACAPAVIR	GILEAD SCIENCES INC	P	12/22/2022	
NDA 214375	XENOVIEV	HYPERPOLARIZED 129-XE	POLAREAN INC	S	12/23/2022	Y

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 212209 (1)	VIVIMUSTA	BENDAMUSTINE HYDROCHLORIDE	SLAYBACK PHARMA LLC	S		7/2/2020, 3/16/2022 8/26/22
NDA 209191		BORTEZOMIB	HOSPIRA INC	S	5/2/2022	12/17/2021
NDA 214657		PEMETREXED	SANDOZ INC	S	5/26/2022	5/06/2021
NDA 208746		PEMETREXED	HOSPIRA INC A PFIZER CO	S	6/10/2022	1/08/2021
NDA 214218		PEMETREXED	HOSPIRA INC	S	6/22/2022	2/23/2021
NDA 215441		BORTEZOMIB	ACCORD HEALTHCARE INC	S	7/26/2022	8/20/2021
NDA 211875		PACLITAXEL	HBT LABS INC	S	7/27/2022	6/30/2021
NDA 210850		SINCALIDE	MAIA PHARMACEUTICALS INC	P	11/22/2022	2/23/2018
NDA 214962	TASCENSO ODT	FINGOLIMOD	CYCLE PHARMACEUTICALS LTD	S	12/9/2022	10/18/2021
NDA 211530		BENDAMUSTINE	HOSPIRA INC	S	12/15/2022	1/29/2019

Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761228	KIMMTRAK	TEBENTAFUSP-TEBN	IMMUNOCORE LIMITED	P,O	1/25/2022
BLA 761235	VABYSMO	FARICIMAB-SVOA	GENENTECH, INC.	P	1/28/2022
BLA 761164	ENJAYMO	SUTIMLIMAB-JOME	BIOVERATIV THERAPEUTICS, INC.	P,O	2/4/2022
BLA 761234	OPDUALAG	NIVOLUMAB AND RELATLIMAB-RMBW	BRISTOL-MYERS SQUIBB COMPANY	P,O	3/18/2022
BLA 761262	SKYRIZI	RISANKIZUMAB-RZAA	ABBVIE INC.	P,O	6/16/2022
BLA 761261	XENPOZYME	OLIPUDASE ALFA-RPCP	GENZYME CORPORATION	P,O	8/31/2022
BLA 761244	SPEVIGO	SPESOLIMAB-SBZO	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	P,O	9/1/2022
BLA 761127	DAXXIFY	DAXIBOTULINUMTOIXNA-LANM	REVANCE THERAPEUTICS, INC.	S	9/7/2022
BLA 761148	ROLVEDON	EFLAPEGRASIM-XNST	SPECTRUM PHARMACEUTICALS, INC.	S	9/9/2022
BLA 761289	IMJUDO	TREMELIMUMAB-ACTL	ASTRAZENECA AB	P,O	10/21/2022
BLA 761291	TECVAYLI	TECLISTAMAB-CQYV	JANSSEN BIOTECH, INC.	P,O	10/25/2022
BLA 761310	ELAHERE	MIRVETUXIMAB SORAVTANSINE-GYNX	IMMUNOGEN, INC.	P,O	11/14/2022
BLA 761183	TZIELD	TEPLIZUMAB-MZWV	PROVENTION BIO, INC.	P	11/17/2022
BLA 761263	LUNSUMIO	MOSUNETUZUMAB-AXGB	GENENTECH, INC.	P,O	12/22/2022
BLA 761192	NEXOBRID	ANACAULASE-BCDB	MEDIWOUND, LTD.	S,O	12/28/2022
BLA 761238	BRIUMVI	UBLITUXIMAB-XIY	TG THERAPEUTICS, INC.	S	12/28/2022

(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).