

CY 2023 CDER Drug and Biologic Calendar Year Approvals As of December 31, 2023

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

Selection Criteria:

User Response: Start Date: 1/1/2023 End Date: 12/31/2023

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 214070	AIRSUPRA	ALBUTEROL AND BUDESONIDE	ASTRAZENECA PHARMACEUTICALS LP	S	1/10/2023	Y
NDA 212849	RYKINDO	RISPERIDONE	SHANDONG LUYE PHARMACEUTICAL CO LTD	S	1/13/2023	Y
NDA 214544 (2)		DOLUTEGRAVIR, EMTRICITABINE AND TENOFOVIR ALAFENAMIDE	LUPIN LTD	S	1/19/2023	Y
NDA 210274		VANCOMYCIN HYDROCHLORIDE FOR INJECTION	ZHEJIANG NOVUS PHARMACEUTICALS CO LTD	S	1/20/2023	Y
NDA 214373	BRENZAVVY	BEXAGLIFLOZIN	THERACOSBIO LLC	S	1/20/2023	
NDA 216059	JAYPIRCA	PIRTOBRUTINIB	LOXO ONCOLOGY INC	P,O	1/27/2023	
NDA 217639	ORSERDU	ELACESTRANT	STEMLINE THERAPEUTICS INC	P	1/27/2023	
NDA 216820		KIT FOR THE PREPARATION OF TECHNETIUM TC 99M MERTIATIDE	JUBILANT DRAXIMAGE INC	S	1/30/2023	Y
NDA 217415		DAPTOMYCIN FOR INJECTION, 350MG/VIAL AND 500 MG/VIAL	XELLIA PHARMACEUTICALS APS	S	1/30/2023	Y
NDA 213260	ATORVALIQ	ATORVASTATIN	CMP DEVELOPMENT LLC	S	2/1/2023	Y
NDA 216951	JESDUVROQ	DAPRODUSTAT	GLAXOSMITHKLINE INTELLECTUAL PROPERTY NO 2 LTD ENGLAND	S	2/1/2023	
NDA 215870	FENTANYL CITRATE	FENTANYL CITRATE	EXELA PHARMA SCIENCES LLC	S	2/8/2023	Y
NDA 216354	AUSTEDO XR	DEUTETRABENAZINE	TEVA NEUROSCIENCE INC	S,O	2/17/2023	Y
NDA 216403	FILSPARI	SPARSENTAN	TRAVERE THERAPEUTICS INC	P,O	2/17/2023	
NDA 217171	SYFOVRE	PEGCETACOPLAN	APELLIS PHARMACEUTICALS INC	P	2/17/2023	
NDA 216903	PREVDUO	NEOSTIGMINE METHYLSULFATE AND GLYCOPYRROLATE	SLAYBACK PHARMA LLC	S	2/23/2023	Y
NDA 216718	SKYCLARYS	OMAVELOXOLONE	REATA PHARMACEUTICALS INC	P,O	2/28/2023	
NDA 209471	COMBOGESIC	ACETAMINOPHEN AND IBUPROFEN	AFT PHARMACEUTICALS LTD	S	3/1/2023	Y
NDA 208969	REXTOVY	ZAVEGEPANT	AMPHASTAR PHARMACEUTICALS INC	S	3/7/2023	Y
NDA 216386	ZAVZPRET	NALOXONE HYDROCHLORIDE	PFIZER INC	S	3/9/2023	
NDA 217026	DAYBUE	TROFINETIDE	ACADIA PHARMACEUTICALS INC	P,O	3/10/2023	
NDA 217513	MEKINIST	TRAMETINIB	NOVARTIS PHARMACEUTICALS CORP	P,O	3/16/2023	
NDA 217514	TAFINLAR	DABRAFENIB	NOVARTIS PHARMACEUTICALS CORP	P,O	3/16/2023	
NDA 217417	REZZAYO	REZAFUNGIN	CIDARA THERAPEUTICS INC	P,O	3/22/2023	
NDA 217759	JOENJA	LENIOLISIB PHOSPHATE	PHARMING TECHNOLOGIES BV	P,O	3/24/2023	
NDA 205394	RIZAFILM	RIZATRIPTAN	INTELGENX CORP	S	4/14/2023	Y
NDA 215875	ADRENALIN	EPINEPHRINE IN SODIUM CHLORIDE	PAR STERILE PRODUCTS LLC	S	4/21/2023	Y
NDA 215887	QALSODY	TOFERSEN	BIOGEN MA INC	P,O	4/25/2023	
NDA 214876	ZEJULA	NIRAPARIB	GLAXOSMITHKLINE LLC	S,O	4/26/2023	
NDA 217660	TRIKAFTA	ELEXACAFTOR/TEZACAFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS INC	P,O	4/26/2023	
NDA 217006	ABILIFY ASIMTUFII	ARIPIPRAZOLE	OTSUKA PHARMACEUTICAL CO LTD	S	4/27/2023	
NDA 213586	UZEDY	RISPERIDONE	TEVA NEUROSCIENCE INC	S	4/28/2023	Y
NDA 214952	LIQREV	SILDENAFIL	CMP DEVELOPMENT LLC	S	4/28/2023	Y

NDA 215319 (2)		DOLUTEGRAVIR	LAURUS GENERICS INC	P	4/28/2023	Y
NDA 216185	MOTPOLY XR	LACOSAMIDE	AUCTA PHARMACEUTICALS INC	S	5/4/2023	Y
NDA 215352	MYDCOMBI	TROPICAMIDE AND PHENYLEPHRINE	EYENOVIA INC	S	5/5/2023	Y
NDA 211413		CEFAZOLIN	HQ SPECIALTY PHARMA CORP	S	5/8/2023	Y
NDA 215721		ZOLPIDEM TARTRATE	ALMATICA PHARMA INC	S	5/9/2023	Y
NDA 216578	VEOZAH	FEZOLINETANT	ASTELLAS PHARMA US INC	P	5/12/2023	
NDA 216675	MIEBO	PERFLUOROHEXYLOCTANE	BAUSCH AND LOMB INC	S	5/18/2023	
NDA 215179		PEMETREXED	SHILPA MEDICARE LTD	S	5/22/2023	Y
NDA 217470	OPVEE	NALMEFENE HYDROCHLORIDE	INDIVIOR INC	P	5/22/2023	Y
NDA 210136	BRIXAD	BUPRENORPHINE HYDROCHLORIDE	BRAEBURN INC	P	5/23/2023	Y
NDA 216974	XACDURO	SULBACTAM FOR INJECTION; DURLOBACTAM FOR INJECTION) CO- PACKAGED	ENTASIS THERAPEUTICS INC	P	5/23/2023	Y
NDA 216023	POSLUMA	FLOTUFOLASTAT F 18	BLUE EARTH DIAGNOSTICS LTD	S	5/25/2023	
NDA 217188	PAXLOVID	NIRMATRELVIR AND RITONAVIR	PFIZER INC	P	5/25/2023	
NDA 215448 (2)		DOLUTEGRAVIR, EMTRICITABINE AND TENOFIVIR ALAFENAMIDE	AUROBINDO PHARMA LTD	S	5/26/2023	Y
NDA 216203	INPEFA	SOTAGLIFLOZIN	LEXICON PHARMACEUTICALS INC	S	5/26/2023	
NDA 217469	VEVYE	CYCLOSPORINE	NOVALIQ GMBH	S	5/30/2023	Y
NDA 210852		CYCLOPHOSPHAMIDE	DR REDDYS LABORATORIES LTD	S	6/7/2023	Y
NDA 215344		POLYETHYLENE GLYCOL 3350, SODIUM SULFATE, POTASSIUM CHLORIDE, MAGNESIUM SULFATE, AND SODIUM CHLORIDE	BRAINTREE LABORATORIES INC	S	6/15/2023	
NDA 215727	LODOCO	COLCHICINE	AGEPHA PHARMA FZ LLC	P	6/16/2023	Y
NDA 215830	LITFULO	RITLECITINIB	PFIZER INC	S	6/23/2023	
NDA 217651		CYCLOPHOSPHAMIDE	NEVAKAR INJECTABLES INC	S	6/27/2023	Y
NDA 211868		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFIVIR DISOPROXIL FUMARATE	EMCURE PHARMACEUTICALS LTD	S	7/12/2023	Y
NDA 215187		DOLUTEGRAVIR, LAMIVUDINE AND TENOFIVIR ALAFENAMIDE	LUPIN LTD	S	7/18/2023	Y
NDA 216993	VANFLYTA	QUIZARTINIB	DAIICHI SANKYO INC	P,O	7/20/2023	
NDA 212905	YCANTH	CANTHARIDIN	VERRICA PHARMACEUTICALS INC	S	7/21/2023	
NDA 217603	XDEMVY	LOTILANER	TARSUS PHARMACEUTICALS INC	S	7/24/2023	
NDA 215212		MEROPENEM	HQ SPECIALTY PHARMA CORP	S	7/26/2023	Y
NDA 217722	RIVIVE	NALOXONE HYDROCHLORIDE	HARM REDUCTION THERAPEUTICS INC	P	7/28/2023	Y
NDA 217225	IZERVAY	AVACINCAPTAD PEGOL	IVERIC BIO INC	P	8/4/2023	
NDA 217369	ZURZUVAE	ZURANOLONE	SAGE THERAPEUTICS INC	P	8/4/2023	
NDA 216793	AKEEGA	NIRAPARIB AND ABIRATERONE ACETATE	JANSSEN BIOTECH INC	P	8/11/2023	
NDA 201848	HEPZATO	MELPHALAN HYDROCHLORIDE	DEL CATH SYSTEMS INC	S,O	8/14/2023	Y
NDA 217070		ABACAVIR, DOLUTEGRAVIR AND LAMIVUDINE TABLET FOR ORAL SUSPENSION	AUROBINDO PHARMA LTD	P	8/14/2023	Y
NDA 215559	SOHONOS	PALOVAROTENE	IPSEN BIOPHARMACEUTICALS INC	P,O	8/16/2023	
NDA 218193		ABACAVIR, DOLUTEGRAVIR AND LAMIVUDINE	MYLAN LABORATORIES LTD	P	8/16/2023	Y
NDA 217110		MELPHALAN HYDROCHLORIDE INJECTION	APOTEX INC	S	8/18/2023	Y
NDA 216686	FOCINVEZ	FOSAPREPITANT INJECTION	SPES PHARMACEUTICALS INC	S	8/22/2023	Y
NDA 217581	XALKORI	CRIZOTINIB	PF PRISM CV	S,O	9/7/2023	
NDA 217159	APHEXDA	MOTIXAFORTIDE	BIOLINERX LTD	S,O	9/8/2023	
NDA 217150		CYCLOPHOSPHAMIDE INJECTION	SANDOZ INC	S	9/12/2023	Y
NDA 217016		DOLUTEGRAVIR, LAMIVUDINE AND TENOFIVIR DISOPROXIL FUMARATE TABLETS, 50 MG/300 MG/300 MG	STRIDES PHARMA GLOBAL PTE LTD	S	9/14/2023	Y

NDA 216873	OJJAARA	MOMELOTINIB	GLAXOSMITHKLINE LLC	S,O	9/15/2023	
NDA 021164	EXXUA	GEPIRONE	FABRE KRAMER PHARMACEUTICALS INC	S	9/22/2023	
NDA 216755	LIKMEZ	METRONIDAZOLE	SAPTALIS PHARMACEUTICALS LLC	S	9/22/2023	Y
NDA 217064	RYZUMVI	PHENTOLAMINE	OCUPHIRE PHARMA INC	S	9/25/2023	Y
NDA 217729	BOSULIF	BOSUTINIB	PF PRISM CV	P,O	9/26/2023	
NDA 215211	OPFOLDA	MIGLUSTAT	AMICUS THERAPEUTICS US LLC	S,O	9/28/2023	
NDA 022335		TECHNETIUM TC 99M CARBON	CYCLOMEDICA AUSTRALIA PTY LTD	S	9/29/2023	Y
NDA 215842	RIVFLOZA	NEDOSIRAN	NOVO NORDISK INC	S,O	9/29/2023	
NDA 216142		MICAFUNGIN IN 0.9% SODIUM CHLORIDE	BAXTER HEALTHCARE CORP	S	9/29/2023	Y
NDA 217569		VASOPRESSIN IN 0.9% SODIUM CHLORIDE INJECTION	BAXTER HEALTHCARE CORP	S	9/29/2023	Y
NDA 213681 (2)	DOLUTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	DOLUTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	LAURUS LABS LTD	S	10/12/2023	Y
NDA 216956	VELSIPITY	ETRASIMOD	PFIZER INC	S	10/12/2023	
NDA 213931	XPHOZAH	TENAPANOR HYDROCHLORIDE	ARDELIX INC	S	10/17/2023	
NDA 215320	COMBOGESIC IV	ACETAMINOPHEN AND IBUPROFEN	HIKMA PHARMACEUTICALS USA INC	S	10/17/2023	Y
NDA 216834	ZILBRYSQ	ZILUCOPLAN	UCB INC	S,O	10/17/2023	
NDA 217836	QLOSI	PILOCARPINE HYDROCHLORIDE	ORASIS PHARMACEUTICALS LTD	S	10/17/2023	
NDA 211566	ZITUVIO	SITAGLIPTIN	ZYDUS WORLDWIDE DMCC	S	10/18/2023	Y
NDA 216632	CABTREO	CLINDAMYCIN PHOSPHATE, BENZOYL PEROXIDE, AND ADAPALENE	BAUSCH HEALTH US LLC	S	10/20/2023	Y
NDA 217927	COXANTO	OXAPROZIN	SOLUBIOMIX LLC	S	10/20/2023	Y
NDA 218550	ROZLYTREK	ENTRECTINIB	GENENTECH INC	P,O	10/20/2023	
NDA 215239	AGAMREE	VAMOROLONE	CATALYST PHARMACEUTICALS INC	S,O	10/26/2023	
NDA 215151	VOQUEZNA	VONOPRAZAN	PHATHOM PHARMACEUTICALS INC	S	11/1/2023	
NDA 216743	ZITUVIMET	SITAGLIPTIN AND METFORMIN HYDROCHLORIDE	ZYDUS WORLDWIDE DMCC	S	11/3/2023	Y
NDA 217564	FRUZAQLA	FRUQUINTINIB	TAKEDA PHARMACEUTICALS USA INC	P	11/8/2023	
NDA 217806	ZEPBOUND	TIRZEPATIDE	ELI LILLY AND CO	P	11/8/2023	
NDA 214520	DEFENCATH	TAUROLIDINE AND HEPARIN CATHETER LOCK SOLUTION	CORMEDIX INC	P	11/15/2023	
NDA 218213	AUGTYRO	REPOTRECTINIB	BRISTOL MYERS SQUIBB CO	P,O	11/15/2023	
NDA 218197	TRUQAP	CAPIVASERTIB	ASTRAZENECA PHARMACEUTICALS LP	P	11/16/2023	
NDA 217677	OGSIVEO	NIROGACESTAT	SPRINGWORKS THERAPEUTICS INC	P,O	11/27/2023	
NDA 216774	ALVAIZ	ELTROMBOPAG TABLETS	TEVA PHARMACEUTICALS INC	S	11/29/2023	Y
NDA 218276	FABHALTA	IPTACOPAN	NOVARTIS PHARMACEUTICALS CORP	P,O	12/5/2023	
NDA 215500	IWILFIN	EFLORNITHINE	USWM LLC	P,O	12/13/2023	Y
NDA 218010	IDOSE TR	TRAVOPROST	GLAUKOS CORP	S	12/13/2023	Y
NDA 217812		HYDROMORPHONE HYDROCHLORIDE INJECTION, 2 MG/ML	HIKMA PHARMACEUTICALS USA INC	S	12/14/2023	Y
NDA 217242	ZORYVE	ROFLUMILAST	ARCUTIS BIOTHERAPEUTICS INC	S	12/15/2023	
NDA 215064	FILSUVEZ	BIRCH TRITERPENES	CHIESI FARMACEUTICI SPA	P,O	12/18/2023	
NDA 217388	WAINUA	EPLONTERSEN	ASTRAZENECA AB	S,O	12/21/2023	
NDA 204311		ABACAVIR AND LAMIVUDINE	MYLAN LABORATORIES LTD	S	12/22/2023	Y
NDA 209847 (2)		DARUNAVIR AND RITONAVIR	MYLAN LABORATORIES LTD	P	12/22/2023	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 208715		CABAZITAXEL	SANDOZ INC	S	1/5/2023	3/2/2017
NDA 216338		PACLITAXEL	TEVA PHARMACEUTICALS INC	S	5/11/2023	2/6/2023
NDA 214755	LUMRYZ	SODIUM OXYBATE	AVADEL CNS PHARMACEUTICALS LLC	S	5/1/2023	7/18/2022

NDA 216099	PHYRAGO	DASATINIB	NANOCOPOEIA LLC	S,O	12/5/2023	5/18/2023
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Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761269	LEQEMBI	LECANEMAB-IRMB	EISAI, INCORPORATED	P	1/6/2023
BLA 761278	LAMZEDE	VELMANASE ALFA-TYCV	CHIESI FARMACEUTICI S.P.A.	P,O	2/16/2023
BLA 761334	ZYNYZ	RETIFANLIMAB-DLWR	INCYTE CORPORATION	P,O	3/22/2023
BLA 761161	ELFABRIO	PEGUNIGALSIDASE ALFA-IWXJ	CHIESI FARMACEUTICI S.P.A.	P	5/9/2023
BLA 761324	EPKINLY	EPCORITAMAB-BYSP	GENMAB US, INC.	P	5/19/2023
BLA 761309	COLUMVI	GLOFITAMAB-GXBM	GENENTECH, INC.	P	6/15/2023
BLA 761304	VYVGART HYTRULO	EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC	ARGENX BV	P,O	6/20/2023
BLA 761286	RYSTIGGO	ROZANOLIXIZUMAB-NOLI	UCB, INC.	P,O	6/26/2023
BLA 761184	NGENLA	SOMATROGON-GHLA	PFIZER IRELAND PHARMACEUTICALS	S,O	6/27/2023
BLA 761328	BEYFORTUS	NIRSEVIMAB-ALIP	ASTRAZENECA AB	S	7/17/2023
BLA 761342	TALVEY	TALQUETAMAB-TGVS	JANSSEN BIOTECH, INC.	P,O	8/9/2023
BLA 761345	ELREXFIO	ELRANATAMAB-BCMM	PFIZER INC.	P,O	8/14/2023
BLA 761339	VEOPOZ	POZELIMAB-BBFG	REGENERON PHARMACEUTICALS, INC.	P,O	8/18/2023
BLA 761355	EYLEA HD	AFLIBERCEPT	REGENERON PHARMACEUTICALS, INC.	P	8/18/2023
BLA 761133	ENTYVIO	VEDOLIZUMAB	TAKEDA PHARMACEUTICALS U.S.A., INC.	S	9/27/2023
BLA 761204	POMBILITI	CIPAGLUCOSIDASE ALFA-ATGA	AMICUS THERAPEUTICS US, LLC	S	9/28/2023
BLA 761349	COSENTYX (SECUKINUMAB)	NOVARTIS PHARMACEUTICALS CORPORAT	NOVARTIS PHARMACEUTICALS CORPORATION	S	10/6/2023
BLA 761151	BIMZELX (BIMEKIZUMAB)	UCB, INC.	UCB, INC.	S	10/17/2023
BLA 761358	ZYMFENTRA (INFLIXIMAB)	CELLTRION, INC.	CELLTRION, INC.	S	10/20/2023
BLA 761279	OMVOH (MIRIKIZUMAB-MRKZ)	ELI LILLY AND COMPANY	ELI LILLY AND COMPANY	S,O	10/26/2023
BLA 761240	LOQTORZI (TORIPALIMAB-TPZI)	COHERUS BIOSCIENCES, INC.	COHERUS BIOSCIENCES, INC.	P,O	10/27/2023
BLA 761134	RYZNEUTA	EFBEMALENOGRASTIM ALFA-VUXW	EVIVE BIOTECHNOLOGY SINGAPORE PTE. LTD.	S	11/16/2023

(1) Application has been tentatively approved.

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

Tentative Approval (TA) is an action given to an application for a drug that meets all the requirements for approval; however, it may not be legally marketed in the U.S. until 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).