

CY 2024 CDER Drug and Biologic Calendar Year Approvals

As of December 31, 2024

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

Selection Criteria:

User Response: Start Date: 1/1/2024 End Date: 12/31/2024

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 217424	ZELSUVMI	BERDAZIMER	LNHC INC	S	1/5/2024	
NDA 212427 (2)		DOLUTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	HETERO LABS LTD UNIT III	S	1/18/2024	Y
NDA 213976	EOHILIA	BUDESONIDE ORAL SUSPENSION	TAKEDA PHARMACEUTICALS USA INC	P,O	2/9/2024	Y
NDA 215040	LEGUBETI	ACETYLCYSTEINE	GALEPHAR PHARMACEUTICAL RESEARCH INC	S	2/13/2024	Y
NDA 217933	AURLUMYN	ILOPROST	EICOS SCIENCES INC	P,O	2/13/2024	Y
NDA 217512		PANTOPRAZOLE SODIUM IN 0.9% SODIUM CHLORIDE INJECTION	BAXTER HEALTHCARE CORP	S	2/14/2024	Y
NDA 218328 (1)	SEHIPPIY	VORTIOXETINE	SEASONS BIOTECHNOLOGY (TAIZHOU) CO LTD	S	2/16/2024	Y
NDA 216165	EXBLIFEP	CEFEPIME AND ENMETAZOACTAM	ALLECRA THERAPEUTICS SAS	P	2/22/2024	Y
NDA 218158		CLOBETASOL PROPIONATE	EYENOVIA INC	S	3/4/2024	Y
NDA 217439	TALZENNA	TALAZOPARIB	PFIZER INC	S	3/7/2024	
NDA 217785	REZDIFFRA	RESMETIROM	MADRIGAL PHARMACEUTICALS INC	P	3/14/2024	
NDA 219016	EDURANT PED	RILPIVIRINE	JANSSEN PRODUCTS LP	P	3/15/2024	
NDA 217686	TRYVIO	APROCITENTAN	IDORSIA PHARMACEUTICALS LTD	S	3/19/2024	
NDA 217865	DUVYZAT	GIVINOSTAT	ITALFARMACO SPA	P,O	3/21/2024	
NDA 213509 (2)		EFAVIRENZ, EMTRICITABINE AND TENOFOVIR ALAFENAMIDE	MYLAN LABORATORIES LTD	S	3/22/2024	Y
NDA 218490	OPSYNVI	MACITENTAN AND TADALAFIL	ACTELION PHARMACEUTICALS US INC	S,O	3/22/2024	Y
NDA 215192	VAFSEO	VADADUSTAT	AKEBIA THERAPEUTICS INC	S	3/27/2024	
NDA 214835	RISVAN	RISPERIDONE	LABORATORIOS FARMACEUTICOS ROVI SA	S	3/29/2024	Y
NDA 218037	VOYDEYA	DANICOPAN	ALEXION PHARMACEUTICALS INC	S,O	3/29/2024	
NDA 218275	ZEVTERA	CEFTOBIPROLE MEDOCARIL SODIUM	BASILEA PHARMACEUTICA INTERNATIONAL LTD ALLSCHWIL	P	4/3/2024	
NDA 218160	RETEVMO	SELPERCATINIB	LOXO ONCOLOGY A WHOLLY OWNED SUB OF ELI LILLY AND COMPANY	S,O	4/10/2024	
NDA 218591	ENTRESTO SPRINKLE	SACUBITRIL AND VALSARTAN	NOVARTIS PHARMACEUTICALS CORP	S	4/12/2024	
NDA 214511	LUMISIGHT	PEGULICIANINE	LUMICELL INC	P	4/17/2024	
NDA 215487	REZENOPY	NALOXONE HYDROCHLORIDE	SUMMIT BIOSCIENCES LLC	S	4/19/2024	Y
NDA 218424	LUMIFY	BAUSCH AND LOMB INC	BAUSCH AND LOMB INC	S	4/19/2024	Y
NDA 217700	OJEMDA	TOVORAFENIB	DAY ONE BIOPHARMACEUTICALS INC	P,O	4/23/2024	
NDA 218033	OJEMDA	TOVORAFENIB	DAY ONE BIOPHARMACEUTICALS INC	P,O	4/23/2024	
NDA 216483	PIVYA	PIVMCILLINAM	UTILITY THERAPEUTICS LTD	P	4/24/2024	Y
NDA 218466	VIJOICE	ALPELISIB	NOVARTIS PHARMACEUTICALS CORP	S,O	4/24/2024	
NDA 218347	RINVOQ LQ	UPADACITINIB	ABBVIE INC	S,O	4/26/2024	
NDA 218623	LIBERVANT	DIAZEPAM	AQUESTIVE THERAPEUTICS INC	S,O	4/26/2024	Y
NDA 218709	XOLREMDI	MAVORIXAFOR	X4 PHARMACEUTICALS INC	P,O	4/26/2024	
NDA 218390	INGREZZA SPRINKLE	VALBENZAZINE	NEUROCRINE BIOSCIENCES INC	S,O	4/30/2024	
NDA 216482	MYHIBBIN	MYCOPHENOLATE MOFETIL	AZURITY PHARMACEUTICALS INC	S	5/1/2024	Y

NDA 217645	ONYDA XR	CLONIDINE HYDROCHLORIDE	TRIS PHARMA INC	S	5/24/2024	Y
NDA 218771	TERIPARATIDE	TERIPARATIDE INJECTION	ALMAJECT INC	S	6/4/2024	Y
NDA 217779	RYTELO	IMETELSTAT	GERON CORP	S,O	6/6/2024	
NDA 218860	IQRVVO	ELAFIBRANOR	IPSEN BIOPHARMACEUTICALS INC	P,O	6/10/2024	
NDA 217684	VIGAFYDE	VIGABATRIN	PYROS PHARMACEUTICALS INC	S,O	6/17/2024	Y
NDA 217347	SOFDRA	SOPPIRONIUM	BOTANIX SB INC	S	6/18/2024	
NDA 216984	TEPYLUTE	THIOTEPA	SHORLA PHARMA LTD	S	6/25/2024	Y
NDA 217389	OHTUVAYRE	VERONA PHARMA INC	VERONA PHARMA INC	S	6/26/2024	
NDA 210661		PEMETREXED	AVYXA HOLDINGS LLC	S	6/28/2024	Y
NDA 218527	CHEWTADZY	TADALAFIL	B BETTER LLC	S	6/28/2024	Y
NDA 216778	ZITUVIMET	SITAGLIPTIN AND METFORMIN HYDROCHLORIDE	ZYDUS LIFESCIENCES GLOBAL FZE	S	7/18/2024	Y
NDA 216655	OPIPZA	ARIPIPRAZOLE	XIAMEN LP PHARMACUETICAL CO LTD	S	7/22/2024	Y
NDA 218718	FEMLYV	NORETHINDRONEACETATE AND ETHINYL ESTRADIOL	MILLICENT PUERTO RICO LLC	S	7/22/2024	Y
NDA 217900	LEQSELVI	DEURUXOLITINIB PHOSPHATE	SUN PHARMACEUTICAL INDUSTRIES INC	S	7/25/2024	
NDA 218754 (1)		APREPITANT	AZURITY PHARMACEUTICALS INC	S	7/25/2024	Y
NDA 216352	ERZOFRI	PALIPERIDONE PALMITATE	LUYE INNOMIND PHARMA (SHIJIAZHANG) CO LTD	S	7/26/2024	Y
NDA 218343		POTASSIUM PHOSPHATE	AMNEAL EU LTD	S	7/26/2024	Y
NDA 218549	ZUNVEYL	BENZGALANTAMINE	ALPHA COGNITION INC	S	7/26/2024	Y
NDA 218139	TEZRULY	TERAZOSIN	NOVITIUM PHARMA LLC	S	7/29/2024	Y
NDA 218784	VORANIGO	VORASIDENIB	SERVIER PHARMACEUTICALS LLC	P,O	8/6/2024	
NDA 217186	CREXONT	CARBIDOPA AND LEVODOPA	IMPAX LABORATORIES LLC	S	8/7/2024	Y
NDA 218590	ZURNAI	NALMEFENE HYDROCHLORIDE	PURDUE PHARMA LP	P	8/7/2024	Y
NDA 214697	NEFFY	EPINEPHRINE	ARS PHARMACEUTICALS OPERATIONS INC	S	8/9/2024	Y
NDA 216490	YORVIPATH	PALOPEGTERIPARATIDE	ASCENDIS PHARMA BONE DISEASES AS	P,O	8/9/2024	
NDA 217899	LIVDELZI	SELADELPAR	GILEAD SCIENCES INC	P,O	8/14/2024	
NDA 213005 (1)	YUTREPIA	TREPROSTINIL	LIQUIDIA TECHNOLOGIES INC	S	8/16/2024	Y
NDA 219008	LAZCLUZE	LAZERTINIB	JANSSEN BIOTECH INC	P	8/19/2024	
NDA 212782	BORTEZOMIB		SHILPA MEDICARE LTD	S	8/26/2024	Y
NDA 219104	PREVYMIS	LETERMOVIR	MERCK SHARP AND DOHME LLC	P,O	8/30/2024	Y
NDA 214927	MIPLYFFA	ARIMOCLOMOL	ZEVRA DENMARK AS	P,O	9/20/2024	
NDA 219132	AQNEURSA	LEVACETYLLEUCINE	INTRABIO INC	P,O	9/24/2024	
NDA 216158	COBENFY	XANOMELINE AND TROSPIUM CHLORIDE	BRISTOL-MYERS SQUIBB CO	S	9/26/2024	Y
NDA 213224	BYNFEZIA PEN	OCTREOTIDE ACETATE	SUN PHARMACEUTICAL INDUSTRIES LTD	S	9/27/2024	Y
NDA 215168	FLYRCADO	FLURPIRIDAZ (F18)	GE HEALTHCARE INC	S	9/27/2024	
NDA 217604		PYRIDOSTIGMINE BROMIDE	AMNEAL PHARMACEUTICALS LLC	S	10/4/2024	Y
NDA 219249	ITOVEBI	INAVOLISIB	GENENTECH INC	P	10/10/2024	
NDA 216962	VYALEV	FOSCARBIDOPA AND FOSLEVODOPA	ABBVIE INC	S,O	10/16/2024	Y
NDA 217294 (1)	LASIX ONYU	FUROSEMIDE INJECTION	SQ INNOVATION INC	S	10/18/2024	Y
NDA 218711	BEIZRAY	DOCETAXEL	ZHUHAI BEIHAI BIOTECH CO LTD	S	10/23/2024	Y
NDA 213972	ORLYNVAH	SULOPENEM ETZADROXIL AND PROBENECID	ITERUM THERAPEUTICS US LTD	P	10/25/2024	Y
NDA 215425 (1)		EPINEPHRINE	FRESENIUS KABI USA LLC	S	10/30/2024	Y
NDA 219015	EMROSI	MINOCYCLINE HYDROCHLORIDE	JOURNEY MEDICAL CORP	S	11/1/2024	Y
NDA 219293	DANZITEN	NILOTINIB	AZURITY PHARMACEUTICALS INC	S	11/7/2024	Y
NDA 218944	REVUFORJ	REVUMENIB	SYNDAX PHARMACEUTICALS INC	P,O	11/15/2024	
NDA 217630		DAPTOMYCIN	MAIA PHARMACEUTICALS INC	S	11/21/2024	Y
NDA 216540	ATTRUBY	ACORAMIDIS	BRIDGEBIO PHARMA INC	S,O	11/22/2024	
NDA 217202	RAPIBLYK	LANDIOLOL	AOP ORPHAN PHARMACEUTICALS AG	S	11/22/2024	Y
NDA 219097	IMKELDI	IMATINIB	SHORLA ONCOLOGY	S	11/22/2024	Y

NDA 218637	RALDESY	TRAZODONE HYDROCHLORIDE	KAMAT PHARMATECH LLC	S	11/26/2024	Y
NDA 216016	IOMERVU	IOMEPROL	BRACCO DIAGNOSTICS INC	S	11/27/2024	Y
NDA 216017	IOMERVU	IOMEPROL	BRACCO DIAGNOSTICS INC	S	11/27/2024	Y
NDA 216190	ONTRALFY	TIZANIDINE	FIDELITY BIOPHARMA CO USA	S	12/12/2024	Y
NDA 218808	CRENESSITY	CRINECEFONT	NEUROCRINE BIOSCIENCES INC	P,O	12/13/2024	
NDA 218820	CRENESSITY	CRINECEFONT	NEUROCRINE BIOSCIENCES INC	P,O	12/13/2024	
NDA 218171	ENSACOVE	ENSARTINIB	XCOVERY HOLDINGS INC	S	12/18/2024	
NDA 218614	TRYNGOLZA	OLEZARSEN	IONIS PHARMACEUTICALS INC	P,O	12/19/2024	
NDA 209628 (2)		DOLUTEGRAVIR, LAMIVUDINE, AND TENOFVIR DISOPROXIL FUMARATE	CIPLA LTD	S	12/20/2024	
NDA 218730	ALYFTREK	VANZACAFITOR, TEZACAFITOR, AND DEUTIVACAFITOR	VERTEX PHARMACEUTICALS INC	P,O	12/20/2024	

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 207970		CABAZITAXEL	ACTAVIS LLC AN INDIRECT WHOLLY OWNED SUB OF TEVA PHARMACEUTICALS USA INC	S	3/14/2024	8/19/2015, 1/17/2018
NDA 210661		PEMETREXED	AVYXA HOLDINGS LLC	S	6/28/2024	3/28/2018
NDA 217766		VASOPRESSIN	LONG GROVE PHARMACEUTICALS LLC	S	7/11/2024	4/30/2024
NDA 216593	XROMI	HYDROXYUREA	NOVA LABORATORIES LTD	P,O	12/23/2024	4/4/2024

Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761225	LETYBO	LETIBOTULINUMTOXINA-WLBG	HUGEL INC.	S	2/29/2024
BLA 761363	WINREVAIR	SOTATERCEPT-CSRK	MERCK SHARP & DOHME LLC	P,O	3/26/2024
BLA 761359	ENTYVIO AND ENTYVIO PEN	VEDOLIZUMAB	TAKEDA PHARMACEUTICALS U.S.A., INC.	S	4/18/2024
BLA 761336	ANKTIVA	NOGAPENDEKIN ALFA INBAKICEPT-PMLN	ALTOR BIOSCIENCE, LLC, AN INDIRECT WHOLLY- OWNED SUBSIDIARY OF IMMUNITYBIO, INC.	S	4/22/2024
BLA 761344	IMDELLTRA	TARLATAMAB-DLLE	AMGEN INC.	P,O	5/16/2024
BLA 761388	PIASKY	CROVALIMAB-AKKZ	GENENTECH, INC.	S,O	6/20/2024
BLA 761248	KISUNLA	DONANEMAB-AZBT	ELI LILLY AND COMPANY	P	7/2/2024
BLA 761312	LYMPHIR	DENILEUKIN	DIFTITOX-CXDL	S,O	8/7/2024
BLA 761390	NEMLUVIO	NEMOLIZUMAB-ILTO	GALDERMA LABORATORIES, L.P.	P	8/12/2024
BLA 761411	NIKTIMVO	AXATILIMAB-CSFR	INCYTE CORPORATION	P,O	8/14/2024
BLA 761347	TECENTRIQ HYBREZA	ATEZOLIZUMAB AND HYALURONIDASE- TQJS	GENENTECH, INC.	S	9/12/2024
BLA 761306	EBGLYSS	LEBRIKIZUMAB-LBKZ	ELI LILLY AND COMPANY	S	9/13/2024
BLA 761371	OCREVUS ZUNOVO	OCRELIZUMAB AND HYALURONIDASE- OCSQ	GENENTECH, INC.	S	9/13/2024
BLA 761369	HYMPAVZI	MARSTACIMAB-HNCQ	PFIZER INC.	S,O	10/11/2024
BLA 761365	VYLOY	ZOLBETUXIMAB-CLZB	ASTELLAS PHARMA US, INC.	P,O	10/18/2024
BLA 761416	ZIIHERA	ZANIDATAMAB-HRII	JAZZ PHARMACEUTICALS IRELAND LIMITED	P,O	11/20/2024
BLA 761352	BIZENGRI	ZENOCUTUZUMAB-ZBCO	MERUS NV	P,O	12/4/2024
BLA 761297	UNLOXCYT	COSIBELIMAB-IPDL	CHECKPOINT THERAPEUTICS, INC.	S	12/13/2024
BLA 761391	NEMLUVIO	NEMOLIZUMAB-ILTO	GALDERMA LABORATORIES, L.P.	S	12/13/2024
BLA 761315	ALHEMO	CONCIZUMAB-MTCI	NOVO NORDISK INC.	P,O	12/20/2024
BLA 761381	OPDIVO QVANTIG	NIVOLUMAB HYALURONIDASE-NVHY	BRISTOL-MYERS SQUIBB COMPANY	S	12/27/2024

(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).