

**CY 2025 CDER Drug and Biologic Calendar Year Approvals
As of December 31, 2025**

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

Selection Criteria:

User Response: Start Date: 1/1/2025 End Date: 12/31/2025

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 219122	BRYNOVIN	SITAGLIPTIN	AZURITY PHARMACEUTICALS INC	S	1/16/2025	Y
NDA 216469 (1)	MYINFLA	COLCHICINE	COLOMBA THERAPEUTICS INC	S	1/17/2025	Y
NDA 214759	GRAFAPEX	TREOSULFAN	MEDEXUS PHARMA INC	S,O	1/21/2025	
NDA 219141	INZIRQO	HYDROCHLOROTHIAZIDE	NOVITIUM PHARMA LLC	S	1/28/2025	Y
NDA 215431	SYMBRAVO	MELOXICAM AND RIZATRIPTAN	AXSOME THERAPEUTICS INC	S	1/30/2025	Y
NDA 219209	JOURNAVX	SUZETRIGINE	VERTEX PHARMACEUTICALS INC	P	1/30/2025	
NDA 214056	ONAPGO	A POMORPHINE HYDROCHLORIDE	MDD US OPERATIONS LLC A SUB OF SUPERNUS PHARMACEUTICALS INC	S,O	2/3/2025	
NDA 217906	EMBLAVEO	AZTREONAM AND AVIBACTAM	ABBVIE INC	P	2/7/2025	Y
NDA 219285	EVRYSDI	RISDIPLAM	GENENTECH INC	S,O	2/11/2025	
NDA 219379	GOMEKLI	MIRDAMETINIB	SPRINGWORKS THERAPEUTICS INC	P,O	2/11/2025	
NDA 219389	GOMEKLI	MIRDAMETINIB	SPRINGWORKS THERAPEUTICS INC	P,O	2/11/2025	
NDA 219304	ROMVIMZA	VIMSELTINIB	DECIPHERA PHARMACEUTICALS LLC	P	2/14/2025	
NDA 218922	NILCEYA	NILOTINIB	CIPLA LTD	S	2/19/2025	Y
NDA 218038		DILTIAZEM HYDROCHLORIDE	HQ SPECIALTY PHARMA CORP	S	2/21/2025	Y
NDA 219488	CTEXTLI	CHENODIOL	MIRUM PHARMACEUTICALS INC	P,O	2/21/2025	Y
NDA 218201	MIUDELLA	COPPER INTRAUTERINE SYSTEM	SEBELA WOMENS HEALTH INC	S	2/24/2025	Y
NDA 218475		EPINEPHRINE	BAXTER HEALTHCARE CORP	S	2/28/2025	Y
NDA 212205 (2)	DOLUTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	DOLUTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE	CIPLA LTD	S	3/13/2025	
NDA 218772	ARBLI	LOSARTAN POTASSIUM	SCIENTURE LLC	S	3/13/2025	
NDA 218647	HEMICLOR	CHLOROTHALIDONE	PRM PHARMA LLC	S	3/17/2025	Y
NDA 219592	GOZELLIX	KIT FOR THE PREPARATION OF GALLIUM GA 68 GOZETOTIDE	TELIX INNOVATIONS SA	S	3/20/2025	Y
NDA 218230	BLUJEP A	GEPOTIDACIN	GLAXOSMITHKLINE LLC	P	3/25/2025	
NDA 216665	VYKAT XR	DIAZOXIDE CHOLINE	SOLENO THERAPEUTICS INC	P,O	3/26/2025	Y
NDA 219019	QFITLIA	FITUSIRAN	GENZYME CORP	S,O	3/28/2025	
NDA 219208	VANRAFIA	ATRASENTAN	NOVARTIS PHARMACEUTICALS CORP	S	4/2/2025	
NDA 206056		PIPERACILLIN AND TAZOBACTAM	B BRAUN MEDICAL INC	S	4/3/2025	Y
NDA 219617 (1)		TRABECTEDIN	EVER VALINJECT GMBH	S	4/9/2025	Y
NDA 219373	LOPRESSOR	METOPROLOL TARTRATE	RUBICON RESEARCH LTD	S	4/10/2025	Y
NDA 219485	LIVMARLI	MARALIXIBAT	MIRUM PHARMACEUTICALS INC	S,O	4/10/2025	
NDA 211448	MEZO FY	ARIPIRAZOLE	CMG PHARMACEUTICAL CO LTD	S	4/15/2025	Y
NDA 220073	ELIQUIS SPRINKLE	APIXABAN	BRISTOL MYERS SQUIBB CO	P	4/17/2025	
NDA 217593	QAMZOVA	MELOXICAM	NANJING DELOVA BIOTECH CO LTD	S	4/22/2025	Y
NDA 217901	ATZUMI	DIHYDROERGOTAMINE	SATSUMA PHARMACEUTICALS INC	S	4/30/2025	Y
NDA 219616	AVMAPKI FAKZYNJA CO-PACK	AVUTOMETINIB CAPSULES, 0.8 MG; DEFACTINIB TABLETS, 200 MG)	VERASTEM INC	P,O	5/8/2025	
NDA 215400	BREKIYA	DIHYDROERGOTAMINE MESYLATE	AMNEAL PHARMACEUTICALS LLC	S	5/14/2025	Y
NDA 217062 (1)	AUSUSVAR	RIVAROXABAN	AUSON PHARMACEUTICALS INC	S	5/20/2025	Y
NDA 213005	YUTREPIA	TREPROSTINIL	LIQUIDIA TECHNOLOGIES INC	S	5/23/2025	Y
NDA 217370	TRYPTYR	ACOLTREM ON	ALCON LABORATORIES INC	S	5/28/2025	
NDA 218980	KHINDIVI	HYDROCORTISONE	ETON PHARMACEUTICALS INC	S	5/28/2025	Y
NDA 216830		PHENYLEPHRINE HYDROCHLORIDE INJECTION	DR REDDYS LABORATORIES SA	S	5/30/2025	Y
NDA 218395	XIFYRM	MELOXICAM	AZURITY PHARMACEUTICALS INC	S	6/5/2025	Y
NDA 219423	WIDAPLIK	TELMISARTAN, AMLODIPINE, AND INDAPAMIDE	GEORGE MEDICINES PTY LTD	S	6/5/2025	Y
NDA 217472	ROCURONIUM BROMIDE INJECTION	ROCURONIUM BROMIDE	FRESENIUS KABI USA LLC	S	6/9/2025	Y
NDA 218785	BRUKINSA	ZANUBRUTINIB	BEONE MEDICINES USA INC	S,O	6/10/2025	
NDA 219713	IBTROZI	TALETRECTINIB	NUVATION BIO INC	P,O	6/11/2025	
NDA 215793	ZUSDURI	MITOMYCIN	UROGEN PHARMA LTD	S	6/12/2025	Y

NDA 219847	ARYNTA	LISDEXAMFETAMINE DIMESYLATE	AZURITY PHARMACEUTICALS INC	S	6/16/2025	Y
NDA 220018	YEZTUGO	LENACAPAVIR	GILEAD SCIENCES INC	P	6/18/2025	
NDA 220020	YEZTUGO	LENACAPAVIR	GILEAD SCIENCES INC	P	6/18/2025	
NDA 219920	AVGEMSI	GEMCITABINE	AVYXA HOLDINGS LLC	S	6/27/2025	Y
NDA 219839	ZEGFROVY	SUNVOZERTINIB	DIZAL (JIANGSU) PHARMACEUTICAL CO LTD	P	7/2/2025	
NDA 219014		BENDAMUSTINE	DR REDDYS LABORATORIES LTD	S	7/3/2025	
NDA 219301	EKTERLY	SEBETRALSTAT	KALVISTA PHARMACEUTICALS LTD	S,O	7/3/2025	
NDA 219935		FAMOTIDINE	SAGENT PHARMACEUTICALS	S	7/16/2025	
NDA 219155	ANZUPGO	DELGOCITINIB	LEO PHARMA AS	S	7/23/2025	
NDA 219757	VOSTALLY	RAMIPRIL	ROSEMONT PHARMACEUTICALS INC	S	7/23/2025	
NDA 219531	SDAMLO	AMLODIPINE	BRILLIAN PHARMA INC	S	7/24/2025	
NDA 219696	DOPTELET SPRINKLE	AVATROMBOPAG	AKARX INC	S,O	7/24/2025	
NDA 219666	SEPHIENCE	SEPIAPTERIN	PTC THERAPEUTICS INC	S,O	7/28/2025	
NDA 211759	VYSCOXA	CELECOXIB	CARWIN PHARMACEUTICAL ASSOCIATES LLC	S	7/29/2025	
NDA 219843	ATMEKSI	METHOCARBAMOL	ROSEMONT PHARMACEUTICALS INC	S	7/30/2025	
NDA 218585	VIZZ	ACECLIDINE	LENZ THERAPEUTICS INC	S	7/31/2025	
NDA 219840	E-Z-DISK	BIARIUM SULFATE	BRACCO DIAGNOSTICS INC	S	8/1/2025	
NDA 219876	MODEYSO	DORDAVIPRONE	CHIMERIX INC	P,O	8/6/2025	
NDA 219042	HERNEXEOS	ZONGERTINIB	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	8/8/2025	
NDA 219921	KYXATA	CARBOPLATIN	AVYXA HOLDINGS LLC	S	8/8/2025	
NDA 217673	BRINSUPRI	BRENSOCATIB	INSMED INC	P	8/12/2025	
NDA 218643	CYKLX	ARTICAINE HYDROCHLORIDE	AMERICAN GENOMICS LLC	S	8/15/2025	
NDA 219428	TONMYA	CYCLOBENZAPRINE	TONIX PHARMACEUTICALS INC	S	8/15/2025	
NDA 219407	DAWNZERA	DONIDALORSEN	IONIS PHARMACEUTICALS INC	S,O	8/21/2025	
NDA 219745	CAMCEVI ETM	LEUPROLIDE	FORESEE PHARMACEUTICALS CO LTD	S	8/25/2025	
NDA 218698	LOPRESSOR	METOPROLOL TARTRATE	XTM CONSULTING LLC	S	8/28/2025	
NDA 210745	OTEZLA XR	APREMILAST	AMGEN INC	S,O	8/29/2025	
NDA 219130	ESCITALOPRAM	ESCITALOPRAM	ALMATICA PHARMA LLC	S	8/29/2025	
NDA 219685	WAYRILZ	RILZABRUTINIB	GENZYME CORP	S,O	8/29/2025	
NDA 217307	ZOLYMBUS	BIMATOPROST	THEA PHARMA INC	S	9/9/2025	Y
NDA 219683	INLEXZO	GEMCITABINE	JANSSEN BIOTECH INC	P	9/9/2025	Y
NDA 219943	KOSELUGO	SELUMETINIB	ASTRAZENECA PHARMACEUTICALS LP	P,O	9/10/2025	
NDA 219500	ENBUMYST	BUMETANIDE	CORSTASIS THERAPEUTICS INC	S	9/12/2025	Y
NDA 218879	SUBVENITE	LAMOTRIGINE	OWP PHARMACEUTICALS INC	S	9/16/2025	Y
NDA 215244	FORZINITY	ELAMPRETIDE	STEALTH BIOTHERAPEUTICS INC	P,O	9/19/2025	
NDA 215029	BONDLIDO	LIDOCAINE	MEDRX USA INC	S	9/24/2025	Y
NDA 218881	INLURIYO	IMLUNESTRANT	ELI LILLY AND CO	S	9/25/2025	
NDA 219070	PALSONIFY	PALTUSOTINE	CRINETICS PHARMACEUTICALS INC	S,O	9/25/2025	
NDA 217628	CLOTIC	CLOTRIMAZOLE	CARWIN PHARMACEUTICAL ASSOCIATES LLC	P,O	9/26/2025	Y
NDA 218436	RHAPSIDO	REMIBRUTINIB	NOVARTIS PHARMACEUTICALS CORP	P	9/30/2025	
NDA 217294	LASIX ONYU (FUROSEMIDE INJECTION)	FUROSEMIDE INJECTION)	SQ INNOVATION INC	S	10/7/2025	Y
NDA 218764	JASCAYD	NERANDOMILAST	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P,O	10/7/2025	
NDA 219868	FERABRIGHT	FERUMOXYTOL	COVIS PHARMA GMBH	S,O	10/16/2025	
NDA 219910	EPIOXA AND EPIOXA HD	RIBOFLAVIN 5'-PHOSPHATE	GLAUKOS CORP	S,O	10/17/2025	Y
NDA 212271	CONTEPO	FOSFOMYCIN	MEITHEAL PHARMACEUTICALS INC	P	10/22/2025	Y
NDA 214988		DEHYDRATED ALCOHOL	ROYAL PHARMACEUTICALS LLC	S,O	10/23/2025	Y
NDA 220256	JAVADIN	CLONIDINE HYDROCHLORIDE	AZURITY PHARMACEUTICALS INC	S	10/23/2025	Y
NDA 219108		ROCURONIUM BROMIDE INJECTION 10MG/ML IN 5ML LUER LOCK SYRINGE	B BRAUN MEDICAL INC	S	10/24/2025	Y
NDA 219469	LYNKUET	ELINZANETANT	BAYER HEALTHCARE PHARMACEUTICALS INC	S	10/24/2025	
NDA 220258 (1)	RESNIBEN	CABOZANTINIB	AZURITY PHARMACEUTICALS INC	S	10/24/2025	Y
NDA 219792	KYGEVVI	DOXECITINE AND DOXRIBTIMINE	UCB INC	P,O	11/3/2025	Y
NDA 220305	KOMZIFTI	ZIFTOMENIB	KURA ONCOLOGY INC	P,O	11/13/2025	
NDA 219947	REDEMPLO	PLOZASIRAN	ARROWHEAD PHARMACEUTICALS INC	S,O	11/18/2025	
NDA 219972	HYRNUO	SEVABERTINIB	BAYER HEALTHCARE PHARMACEUTICALS INC	P,O	11/19/2025	
NDA 219660 (1)		RUXOLITINIB MESYLATE	APOTEX INC	S	11/21/2025	Y
NDA 219776	ORLADEYO	BEROTRALSTAT	BIOCRYST PHARMACEUTICALS INC	P,O	12/11/2025	
NDA 219884	DAYBUE	TROFINETIDE	ACADIA PHARMACEUTICALS INC	S,O	12/11/2025	
NDA 218571	CARDAMYST	ETRIPAMIL	MILESTONE PHARMACEUTICALS USA INC	S	12/12/2025	
NDA 219491	NUZOLVENCE	ZOLIFLODACIN	ENTASIS THERAPEUTICS INC	P	12/12/2025	
NDA 210858	VYBRIQUE		IBSA INSTITUT BIOCHIMIQUE SA	S	12/16/2025	Y
NDA 219083	MYQORZO	AFICAMTEN	CYTOKINETICS INC	S,O	12/19/2025	

NDA 217338		NAPROXEN SODIUM/DEXTROMETHORPHAN HBR/GUAIFENESIN	RB HEALTH US LLC	S	12/22/2025	Y
NDA 218316	WEGOVY	SEMAGLUTIDE	NOVO NORDISK INC	S	12/22/2025	
NDA 220152	NEREUS	TRADIPITANT	VANDA PHARMACEUTICALS INC	S	12/30/2025	

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 215425		EPINEPHRINE	FRESENIUS KABI USA LLC	S	3/13/2025	10/30/2024

Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761394	DATROWAY	DATOPOTAMAB DERUXTECAN-DLNK	DAIICHI SANKYO, INC.	S	1/17/2025
BLA 761258		PENPULIMAB-KCQX	AKESO BIOPHARMA CO., LTD.	S,O	4/23/2025
BLA 761430	IMAAVY	NIPOCALIMAB-AAHU	JANSSEN BIOTECH, INC.	P,O	4/29/2025
BLA 761384	EMRELIS	TELISOTUZUMAB VEDOTIN-TLLV	ABBVIE INC.	P	5/14/2025
BLA 761432	ENFLONSIA	CLESROVIMAB-CFOR	MERCK SHARP & DOHME LLC	P	6/9/2025
BLA 761367	ANDEMBRY	GARADACIMAB-GXII	CSL BEHRING LLC	S,O	6/16/2025
BLA 761464	DATROWAY	DATOPOTAMAB DERUXTECAN-DLNK	DAIICHI SANKYO, INC.	P	6/23/2025
BLA 761400	LYNOZYFIC	LINVOSELTAMAB-GCPT	REGENERON PHARMACEUTICALS, INC.	P,O	7/2/2025
BLA 761375	LEQEMBI IQLIK	LECANEMAB-IRMB	EISAI, INCORPORATED	S	8/29/2025
BLA 761467	KEYTRUDA QLEX	PEMBROLIZUMAB AND BERAHYALURONIDASE ALFA-PMPH	MERCK SHARP & DOHME LLC	P	9/19/2025
BLA 761440	BLENREP	BELANTAMAB MAFODOTIN-BLMF	GLAXOSMITHKLINE LLC	S,O	10/23/2025
BLA 761434	VOYXACT	SIBEPRENIMAB-SZSI	OTSUKA PHARMACEUTICAL COMPANY, LTD.	P	11/25/2025
BLA 761427	LEROCHOL	LERODALCIBEP-LIGA	LIB THERAPEUTICS, INC.	S	12/12/2025
BLA 761458	EXDENSUR	DEPEMOKIMAB-ULAA	GLAXOSMITHKLINE LLC	S	12/16/2025
BLA 761433	RYBREVANT FASPRO	AMIVANTAMAB AND HYALURONIDASE- LPUJ	JANSSEN BIOTECH, INC.	P	12/17/2025
BLA 761152	YARTEMLA	NARSOPLIMAB-WUUG	OMEROS CORPORATION	P,O	12/23/2025

(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).