

## CY 2025 CDER Drug and Biologic Calendar Year Priority 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**

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
NDA 219209	JOURNAVX	SUZETRIGINE	VERTEX PHARMACEUTICALS INC	P	1/30/2025
NDA 217906	EMBLAVEO	AZTREONAM AND AVIBACTAM	ABBVIE INC	P	2/7/2025
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 219488	CTEXLI	CHENODIOL	MIRUM PHARMACEUTICALS INC	P,O	2/21/2025
NDA 218230	BLUJEP	GEPOTIDACIN	GLAXOSMITHKLINE LLC	P	3/25/2025
NDA 216665	VYKAT XR	DIAZOXIDE CHOLINE	SOLENO THERAPEUTICS INC	P,O	3/26/2025
NDA 220073	ELIQUIS SPRINKLE	APIXABAN	BRISTOL MYERS SQUIBB CO	P	4/17/2025
NDA 219616	AVMAPKI FAKZYNJA CO-PACK	AVUTOMETINIB CAPSULES, 0.8 MG; DEFACTINIB TABLETS, 200 MG)	VERASTEM INC	P,O	5/8/2025
NDA 219713	IBTROZI	TALETRECTINIB	NUVATION BIO INC	P,O	6/11/2025
NDA 220018	YEZTUGO	LENACAPAVIR	GILEAD SCIENCES INC	P	6/18/2025
NDA 220020	YEZTUGO	LENACAPAVIR	GILEAD SCIENCES INC	P	6/18/2025
NDA 219839	ZEGFROVY	SUNVOZERTINIB	DIZAL (JIANGSU) PHARMACEUTICAL CO LTD	P	7/2/2025
NDA 219876	MODEYSO	DORDAVIPRONE	CHIMERIX INC	P,O	8/6/2025
NDA 219042	HERNEXEOS	ZONGERTINIB	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	8/8/2025
NDA 217673	BRINSUPRI	BRENSOCATIB	INSMED INC	P	8/12/2025
NDA 219683	INLEXZO	GEMCITABINE	JANSSEN BIOTECH INC	P	9/9/2025
NDA 219943	KOSELUGO	SELUMETINIB	ASTRAZENECA PHARMACEUTICALS LP	P,O	9/10/2025
NDA 215244	FORZINITY	ELAMIPRETIDE	STEALTH BIOTHERAPEUTICS INC	P,O	9/19/2025
NDA 217628	CLOTIC	CLOTTRIMAZOLE	CARWIN PHARMACEUTICAL ASSOCIATES LLC	P,O	9/26/2025
NDA 218436	RHAPSIDO	REMIBRUTINIB	NOVARTIS PHARMACEUTICALS CORP	P	9/30/2025
NDA 218764	JASCAYD	NERANDOMILAST	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P,O	10/7/2025
NDA 212271	CONTEPO	FOSFOMYCIN	MEITHEAL PHARMACEUTICALS INC	P	10/22/2025
NDA 219792	KYGEVVI	DOXECITINE AND DOXRIBTIMINE	UCB INC	P,O	11/3/2025
NDA 220305	KOMZIFTI	ZIFTOMENIB	KURA ONCOLOGY INC	P,O	11/13/2025
NDA 219972	HYRNUO	SEVABERTINIB	BAYER HEALTHCARE PHARMACEUTICALS INC	P,O	11/19/2025
NDA 219776	ORLADEYO	BEROTRALSTAT	BIOCRYST PHARMACEUTICALS INC	P,O	12/11/2025
NDA 219491	NUZOLVECE	ZOLIFLODACIN	ENTASIS THERAPEUTICS INC	P	12/12/2025

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
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	ENFLONIA	CLESROVIMAB-CFOR	MERCK SHARP & DOHME LLC	P	6/9/2025
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 761467	KEYTRUDA QLEX	PEMBROLIZUMAB AND BERAHYALURONIDASE ALFA-PMPH	MERCK SHARP & DOHME LLC	P	9/19/2025
BLA 761434	VOYXACT	SIBEPRENIMAB-SZSI	OTSUKA PHARMACEUTICAL COMPANY, LTD.	P	11/25/2025
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.

Review Classification:

P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.

O - Orphan Designation - Pursuant to Section 526 of the Orphan Drug Act (Public Law 97-414 as amended).