

CY 2024 CDER Drug and Biologic Calendar Year Priority 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

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
NDA 213976	EOHILIA	BUDESONIDE ORAL SUSPENSION	TAKEDA PHARMACEUTICALS USA INC	P,O	2/9/2024
NDA 217933	AURLUMYN	ILOPROST	EICOS SCIENCES INC	P,O	2/13/2024
NDA 216165	EXBLIFEP	CEFEPIME AND ENMETAZOBACTAM	ALLECRA THERAPEUTICS SAS	P	2/22/2024
NDA 217785	REZDIFFRA	RESMETIROM	MADRIGAL PHARMACEUTICALS INC	P	3/14/2024
NDA 219016	EDURANT PED	RILPIVIRINE	JANSSSEN PRODUCTS LP	P	3/15/2024
NDA 217865	DUVYZAT	GIVINOSTAT	ITALFARMACO SPA	P,O	3/21/2024
NDA 218275	ZEVTERA	CEFTOBIPROLE MEDOCARIL SODIUM	BASILEA PHARMACEUTICA INTERNATIONAL LTD ALLSCHWIL	P	4/3/2024
NDA 216593	XROMI	HYDROXYUREA	NOVA LABORATORIES LTD	P,O	4/4/2024
NDA 214511	LUMISIGHT	PEGULICIANINE	LUMICELL INC	P	4/17/2024
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	PIVMECILLINAM	UTILITY THERAPEUTICS LTD	P	4/24/2024
NDA 218709	XOLREMDI	MAVORIXAFOR	X4 PHARMACEUTICALS INC	P,O	4/26/2024
NDA 218860	IQIRVO	ELAFIBRANOR	IPSEN BIOPHARMACEUTICALS INC	P,O	6/10/2024
NDA 218784	VORANIGO	VORASIDENIB	SERVIER PHARMACEUTICALS LLC	P,O	8/6/2024
NDA 218590	ZURNAL	NALMEFENE HYDROCHLORIDE	PURDUE PHARMA LP	P	8/7/2024
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 219008	LAZCLUZE	LAZERTINIB	JANSSSEN BIOTECH INC	P	8/19/2024
NDA 219104	PREVYMIS	LETREMOVIR	MERCK SHARP AND DOHME LLC	P,O	8/30/2024
NDA 214927	MIPLYFFA	ARIMOCLOMOL	ZEVRA DENMARK AS	P,O	9/20/2024
NDA 219132	AQNEURSA	LEVACETYLLEUCINE	INTRABIO INC	P,O	9/24/2024
NDA 219249	ITOVEBI	INAVOLISIB	GENENTECH INC	P	10/10/2024
NDA 213972	ORLYNVAH	SULOPENEM ETZADROXIL AND PROBENECID	ITERUM THERAPEUTICS US LTD	P	10/25/2024
NDA 218944	REVUFORJ	REVUMENIB	SYNDAX PHARMACEUTICALS INC	P,O	11/15/2024
NDA 218808	CRENESSITY	CRINECERFONT	NEUROCRINE BIOSCIENCES INC	P,O	12/13/2024
NDA 218820	CRENESSITY	CRINECERFONT	NEUROCRINE BIOSCIENCES INC	P,O	12/13/2024
NDA 218614	TRYNGOLZA	OLEZARSEN	IONIS PHARMACEUTICALS INC	P,O	12/19/2024
NDA 218730	ALYFTREK	VANZACAFTOR, TEZACAFTOR, AND DEUTIVACAFTOR	VERTEX PHARMACEUTICALS INC	P,O	12/20/2024

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761363	WINREVAIR	SOTATERCEPT-CSRK	MERCK SHARP & DOHME LLC	P,O	3/26/2024
BLA 761344	IMDELLTRA	TARLATAMAB-DLLE	AMGEN INC.	P,O	5/16/2024
BLA 761248	KISUNLA	DONANEMAB-AZBT	ELI LILLY AND COMPANY	P	7/2/2024
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 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	BIZENGRİ	ZENOCUTUZUMAB-ZBCO	MERUS NV	P,O	12/4/2024
BLA 761315	ALHEMO	CONCIZUMAB-MTCl	NOVO NORDISK INC.	P,O	12/20/2024

(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).