

## CY 2022 CDER Drug and Biologic Calendar Year Priority Approvals As of December 31, 2022

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

**Selection Criteria:**

**User Response: Start Date: 1/1/2022 End Date: 12/31/2022**

**Sort Order: Approval Date**

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
NDA 213871	CIBINQO	ABROCITINIB	PFIZER INC	P	1/14/2022
NDA 216196	PYRUKYND (MITAPIVAT)	MITAPIVAT	AGIOS PHARMACEUTICALS INC	P,O	2/17/2022
NDA 214993	NEPHROSCAN	TECHNETIUM TC99M SUCCIMER	THERAGNOSTICS INC	P,O	2/18/2022
NDA 208712	VONJO	PACRITINIB	CTI BIOPHARMA CORP	P,O	2/28/2022
NDA 215457		NALOXONE	KALEO INC	P	2/28/2022
NDA 215904	ZTALMY	GANAXOLONE	MARINUS PHARMACEUTICALS INC	P,O	3/18/2022
NDA 213478	HYFTOR	SIROLIMUS	NOBELPHARMA CO LTD	P,O	3/22/2022
NDA 215833	PLUVICTO	LUTETIUM (177LU) VIPIVOTIDE TETRAKETAN	ADVANCED ACCELERATOR APPLICATIONS USA INC A NOVARTIS CO	P	3/23/2022
NDA 215413	TRIUMEQ PD	ABACAVIR, DOLUTEGRAVIR, AND LAMIVUDINE	VIIV HEALTHCARE CO	P	3/30/2022
NDA 215039	VIJOICE	ALPELISIB	NOVARTIS PHARMACEUTICALS CORP	P,O	4/5/2022
NDA 215888	VIVJOA	OTESECONAZOLE	MYCOVIA PHARMACEUTICALS INC	P	4/26/2022
NDA 215152	VOQUEZNA TRIPLE PAK	VONOPRAZAN, AMOXICILLIN, AND CLARITHROMYCIN	PHATHOM PHARMACEUTICALS INC	P	5/3/2022
NDA 215153	VOQUEZNA DUAL PAK	VONOPRAZAN AND AMOXICILLIN	PHATHOM PHARMACEUTICALS INC	P	5/3/2022
NDA 215446	RADICAVA ORS	EDARAVONE	MITSUBISHI TANABE PHARMA CORP	P,O	5/12/2022
NDA 215866	MOUNJARO	TIRZEPATIDE	ELI LILLY AND CO	P	5/13/2022
NDA 214324	TYVASO DPI	TREPROSTINIL	UNITED THERAPEUTICS CORP	P,O	5/23/2022
NDA 216359		MIDAZOLAM	RAFA LABORATORIES LTD	P	8/8/2022
NDA 215430	AUVELITY	DEXTROMETHORPHAN HYDROBROMIDE AND BUPROPION HYDROCHLORIDE	AXSOME THERAPEUTICS INC	P	8/18/2022
NDA 217003	IMBRUVICA	IBRUTINIB	PHARMACYCLICS LLC	P,O	8/24/2022
NDA 022231	TERLIVAZ	TERLIPRESSIN	MALLINCKRODT PHARMACEUTICALS IRELAND LTD	P,O	9/14/2022
NDA 212937	PEDMARK	SODIUM THIOSULFATE	FENNEC PHARMACEUTICALS INC	P,O	9/20/2022
NDA 216986	ELUCIREM	GADOPICLENOL	GUERBET	P	9/21/2022
NDA 216660	RELYVRIO	SODIUM PHENYL BUTYRATE AND TAURURSODIOL	AMLYX PHARMACEUTICALS INC	P,O	9/29/2022
NDA 214801	LYTGOBI	FUTIBATINIB	TAIHO ONCOLOGY INC	P,O	9/30/2022
NDA 215910	SEZABY (PHENOBARBITAL)	PHENOBARBITAL	SUN PHARMACEUTICAL INDUSTRIES INC	P,O	11/17/2022
NDA 215973	SUNLENCA	LENACAPAVIR	GILEAD SCIENCES INC	P	12/22/2022
NDA 215974	SUNLENCA	LENACAPAVIR	GILEAD SCIENCES INC	P	12/22/2022

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE
BLA 761228	KIMMTRAK	TEBENTAFUSP-TEBN	IMMUNOCORE LIMITED	P,O	1/25/2022
BLA 761235	VABYSMO	FARICIMAB-SVOA	GENENTECH, INC.	P	1/28/2022

BLA 761164	ENJAYMO	SUTIMLIMAB-JOME	BIOVERATIV THERAPEUTICS, INC.	P,O	2/4/2022
BLA 761234	OPDUALAG	NIVOLUMAB AND RELATLIMAB-RMBW	BRISTOL-MYERS SQUIBB COMPANY	P,O	3/18/2022
BLA 761262	SKYRIZI	RISANKIZUMAB-RZAA	ABBVIE INC.	P,O	6/16/2022
BLA 761261	XENPOZYME	OLIPUDASE ALFA-RPCP	GENZYME CORPORATION	P,O	8/31/2022
BLA 761244	SPEVIGO	SPESOLIMAB-SBZO	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	P,O	9/1/2022
BLA 761289	IMJUDO	TREMELIMUMAB-ACTL	ASTRAZENECA AB	P,O	10/21/2022
BLA 761291	TECVAYLI	TECLISTAMAB-CQYV	JANSEN BIOTECH, INC.	P,O	10/25/2022
BLA 761310	ELAHERE	MIRVETUXIMAB SORAVTANSINE-GYNX	IMMUNOGEN, INC.	P,O	11/14/2022
BLA 761183	TZIELD	TEPLIZUMAB-MZWV	PROVENTION BIO, INC.	P	11/17/2022
BLA 761263	LUNSUMIO	MOSUNETUZUMAB-AXGB	GENENTECH, INC.	P,O	12/22/2022

(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).