CY 2024 CDER New Molecular Entity (NME) Drug & Original BLA 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 Molecular Entity Application (NME) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 217424	ZELSUVMI	BERDAZIMER	LNHC INC	S	1/5/2024	FOR THE TOPICAL TREATMENT OF MOLLUSCUM CONTAGIOSUM (MC) IN ADULTS AND PEDIATRIC PATIENTS 1
NDA 216165	EXBLIFEP	CEFEPIME AND ENMETAZOBACTAM	ALLECRA THERAPEUTICS SAS	P	2/22/2024	FOR TREATMENT OF PATIENTS 18 YEARS AND OLDER WITH COMPLICATED URINARY TRACT INFECTIONS (CUTI) INCLUDING PYELONEPHRITIS CAUSED BY THE FOLLOWING SUSCEPTIBLE MICROORGANISMS: ESCHERICHIA COLI, KLEBSIELLA PNEUMONIAE, PSEUDOMONAS AERUGINOSA, PROTEUS MIRABILIS, AND ENTEROBACTER CLOACAE COMPLEX
NDA 217785	REZDIFFRA	RESMETIROM	MADRIGAL PHARMACEUTICALS INC	P	3/14/2024	INDICATED IN CONJUNCTION WITH DIET AND EXERCISE FOR THE TREATMENT OF ADULTS WITH NONCIRRHOTIC NONALCOHOLIC STEATOHEPATITIS (NASH) WITH MODERATE TO ADVANCED LIVER FIBROSIS (CONSISTENT WITH STAGES F2 TO F3 FIBROSIS)
NDA 217686	TRYVIO	APROCITENTAN	IDORSIA PHARMACEUTICALS LTD	S	3/19/2024	FOR THE TREATMENT OF HYPERTENSION IN COMBINATION WITH OTHER ANTIHYPERTENSIVE DRUGS, TO LOWER BLOOD PRESSURE IN ADULT PATIENTS WHO ARE NOT ADEQUATELY CONTROLLED ON OTHER DRUGS
NDA 217865	DUVYZAT	GIVINOSTAT	ITALFARMACO SPA	P,O	3/21/2024	FOR THE TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY (DMD) IN PATIENTS 6 YEARS OF AGE AND OLDER
NDA 215192	VAFSEO	VADADUSTAT	AKEBIA THERAPEUTICS INC	S	3/27/2024	FOR THE TREATMENT OF ANEMIA DUE TO CHRONIC KIDNEY DISEASE (CKD) IN ADULTS WHO HAVE BEEN RECEIVING DIALYSIS FOR AT LEAST THREE MONTHS
NDA 218037	VOYDEYA	DANICOPAN	ALEXION PHARMACEUTICALS INC	S,O	3/29/2024	INDICATED AS ADD-ON THERAPY TO RAVULIZUMAB OR ECULIZUMAB FOR THE TREATMENT OF EXTRAVASCULAR HEMOLYSIS (EVH) IN ADULTS WITH PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH).
NDA 218275	ZEVTERA	CEFTOBIPROLE MEDOCARIL SODIUM	BASILEA PHARMACEUTICA INTERNATIONAL LTD ALLSCHWIL	P	4/3/2024	FOR THE TREATMENT OF STAPHYLOCOCCUS AUREUS BACTEREMIA (SAB), INCLUDING THOSE WITH RIGHT-SIDED ENDOCARDITIS, ACUTE BACTERIAL SKIN AND SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI) AND COMMUNITY ACQUIRED BACTERIAL PNEUMONIA (CABP)
NDA 214511	LUMISIGHT	PEGULICIANINE	LUMICELL INC	P	4/17/2024	FOR FLUORESCENCE IMAGING IN ADULTS WITH BREAST CANCER AS AN ADJUNCT FOR THE INTRAOPERATIVE DETECTION OF CANCEROUS TISSUE WITHIN THE RESECTION CAVITY FOLLOWING REMOVAL OF THE PRIMARY SPECIMEN DURING LUMPECTOMY SURGERY.
NDA 217700	OJEMDA	TOVORAFENIB	DAY ONE BIOPHARMACEUTICALS INC	P,O	4/23/2024	FOR THE TREATMENT OF PATIENTS 6 MONTHS OF AGE AND OLDER WITH RELAPSED OR REFRACTORY PEDIATRIC LOW-GRADE GLIOMA (LGG) HARBORING A BRAF FUSION OR REARRANGEMENT, OR BRAF V600 MUTATION.
NDA 218709	XOLREMDI	MAVORIXAFOR	X4 PHARMACEUTICALS INC	P,O	4/26/2024	FOR PATIENTS 12 YEARS OF AGE AND OLDER WITH WHIM SYNDROME (WARTS, HYPOGAMMAGLOBULINEMIA, INFECTIONS AND MYELOKATHEXIS) TO INCREASE THE NUMBER OF CIRCULATING MATURE NEUTROPHILS AND LYMPHOCYTES.

NDA 217779	RYTELO	IMETELSTAT	GERON CORP	S,O	6/6/2024	FOR THE TREATMENT OF ADULT PATIENTS WITH LOW- TO INTERMEDIATE-1 RISK MYELODYSPLASTIC SYNDROMES (MDS) WITH TRANSFUSION-DEPENDENT ANEMIA REQUIRING 4 OR MORE RED BLOOD CELL UNITS OVER 8 WEEKS WHO HAVE NOT RESPONDED TO OR HAVE LOST RESPONSE TO OR ARE INELIGIBLE FOR ERYTHROPOIESIS-STIMULATING AGENTS (ESA)
NDA 218860	IQIRVO	ELAFIBRANOR	IPSEN BIOPHARMACEUTICALS INC	P,O	6/10/2024	FOR THE TREATMENT OF PRIMARY BILIARY CHOLANGITIS (PBC) IN COMBINATION WITH URSODEOXYCHOLIC ACID (UDCA) IN ADULTS WHO HAVE AN INADEQUATE RESPONSE TO UDCA, OR AS MONOTHERAPY IN PATIENTS UNABLE TO TOLERATE UDCA.
NDA 217347	SOFDRA	SOFPIRONIUM	BOTANIX SB INC	S	6/18/2024	FOR THE TREATMENT OF PRIMARY AXILLARY HYPERHIDROSIS IN ADULT AND PEDIATRIC PATIENTS 9 YEARS OF AGE AND OLDER
NDA 217389	OHTUVAYRE	ENSIFENTRINE	VERONA PHARMA INC	S	6/26/2024	MAINTENANCE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN ADULT PATIENTS
NDA 217900	LEQSELVI	DEURUXOLITINIB	PHOSPHATE	S	7/25/2024	FOR THE TREATMENT OF ADULTS WITH SEVERE ALOPECIA AREATA.
NDA 218784	VORANIGO	VORASIDENIB	SERVIER PHARMACEUTICALS LLC	P,O	8/6/2024	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 12 YEARS AND OLDER WITH GRADE 2 ASTROCYTOMA OR OLIGODENDROGLIOMA WITH A SUSCEPTIBLE IDH1 OR IDH2 MUTATION FOLLOWING SURGERY INCLUDING BIOPSY, SUB-TOTAL RESECTION, OR GROSS TOTAL RESECTION.
NDA 216490	YORVIPATH	PALOPEGTERIPARATIDE	ASCENDIS PHARMA BONE DISEASES AS	P,O	8/9/2024	FOR THE TREATMENT OF HYPOPARATHYROIDISM IN ADULTS.
NDA 217899	LIVDELZI	SELADELPAR	GILEAD SCIENCES INC	P,O	8/14/2024	FOR THE TREATMENT OF PRIMARY BILIARY CHOLANGITIS (PBC) IN COMBINATION WITH URSODEOXYCHOLIC ACID (UDCA) IN ADULTS WHO HAVE AN INADEQUATE RESPONSE TO UDCA, OR AS MONOTHERAPY IN PATIENTS UNABLE TO TOLERATE UDCA.
NDA 219008	LAZCLUZE	LAZERTINIB	JANSSEN BIOTECH INC	P	8/19/2024	LAZERTINIB IN COMBINATION WITH AMIVANTAMAB-VMJW FOR FIRST-LINE TREATMENT OF ADULT PATIENTS WITH LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WITH EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) EXON 19 DELETIONS OR EXON 21 L858R SUBSTITUTION MUTATIONS, AS DETECTED BY AN FDA-APPROVED TEST.
NDA 214927	MIPLYFFA	ARIMOCLOMOL	ZEVRA DENMARK AS	P,O	9/20/2024	FOR THE USE OF MIPLYFFA (ARIMOCLOMOL) CAPSULES IN COMBINATION WITH MIGLUSTAT FOR THE TREATMENT OF NEUROLOGICAL MANIFESTATIONS OF NIEMANN-PICK DISEASE TYPE C (NPC) IN ADULTS AND PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER.
NDA 219132	AQNEURSA	LEVACETYLLEUCINE	INTRABIO INC	P,O	9/24/2024	FOR THE TREATMENT OF NEUROLOGICAL MANIFESTATIONS OF NIEMANN-PICK DISEASE TYPE C (NPC) IN ADULTS AND PEDIATRIC PATIENTS WEIGHING =15 KG.
NDA 216158	COBENFY	XANOMELINE AND TROSPIUM CHLORIDE	BRISTOL-MYERS SQUIBB CO	S	9/26/2024	FOR THE TREATMENT OF SCHIZOPHRENIA IN ADULTS
NDA 215168	FLYRCADO	FLURPIRIDAZ F 18	GE HEALTHCARE INC	S	9/27/2024	INDICATED FOR POSITRON EMISSION TOMOGRAPHY (PET) MYOCARDIAL PERFUSION IMAGING (MPI) UNDER REST OR STRESS (PHARMACOLOGIC OR EXERCISE) IN ADULT PATIENTS WITH KNOWN OR SUSPECTED CORONARY ARTERY DISEASE (CAD) TO EVALUATE FOR MYOCARDIAL ISCHEMIA AND INFARCTION.

NDA 219249	ITOVEBI	INAVOLISIB	GENENTECH INC	P	10/10/2024	FOR THE USE OF INAVOLISIB IN COMBINATION WITH PALBOCICLIB AND FULVESTRANT FOR THE TREATMENT OF ADULTS WITH ENDOCRINE-RESISTANT, PIK3CA-MUTATED, HORMONE RECEPTOR (HR)-POSITIVE, HUMAN EPIDERMAL GROWTH-FACTOR RECEPTOR 2 (HER2)-NEGATIVE, LOCALLY ADVANCED OR METASTATIC BREAST CANCER, AS DETECTED BY AN FDA-APPROVED TEST, FOLLOWING RECURRENCE ON OR AFTER COMPLETING ADJUVANT ENDOCRINE THERAPY.
NDA 213972	ORLYNVAH	SULOPENEM ETZADROXIL AND PROBENECID)	ITERUM THERAPEUTICS US LTD	P	10/25/2024	FOR THE TREATMENT OF UNCOMPLICATED URINARY TRACT INFECTIONS (UUTI) CAUSED BY THE DESIGNATED MICROORGANISMS ESCHERICHIA COLI, KLEBSIELLA PNEUMONIAE, OR PROTEUS MIRABILIS IN ADULT WOMEN WHO HAVE LIMITED OR NO ALTERNATIVE ORAL ANTIBACTERIAL TREATMENT OPTIONS.
NDA 218944	REVUFORJ	REVUMENIB	SYNDAX PHARMACEUTICALS INC	P,O	11/15/2024	FOR THE TREATMENT OF RELAPSED OR REFRACTORY ACUTE LEUKEMIA WITH A LYSINE METHYLTRANSFERASE 2A GENE (KMT2A) TRANSLOCATION IN ADULT AND PEDIATRIC PATIENTS 1 YEAR AND OLDER.
NDA 216540	ATTRUBY	ACORAMIDIS	BRIDGEBIO PHARMA INC	S,O	11/22/2024	FOR THE TREATMENT OF THE CARDIOMYOPATHY OF WILD-TYPE OR VARIANT TRANSTHYRETIN-MEDIATED AMYLOIDOSIS (ATTR-CM) IN ADULTS TO REDUCE CARDIOVASCULAR DEATH AND CARDIOVASCULAR-RELATED HOSPITALIZATION
NDA 217202	RAPIBLYK	LANDIOLOL	AOP ORPHAN PHARMACEUTICALS AG	S	11/22/2024	FOR THE SHORT-TERM REDUCTION OF VENTRICULAR RATE IN ADULTS WITH SUPRAVENTRICULAR TACHYCARDIA INCLUDING ATRIAL FIBRILLATION AND ATRIAL FLUTTER.
NDA 216016	IOMERVU	IOMEPROL	BRACCO DIAGNOSTICS INC	S	11/27/2024	INTRA-ARTERIAL PROCEDURES-• CEREBRAL ARTERIOGRAPHY, INCLUDING INTRA-ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY (IADSA), IN ADULTS AND PEDIATRIC PATIENTS • VISCERAL AND PERIPHERAL ARTERIOGRAPHY AND AORTOGRAPHY, INCLUDING IA-DSA, IN ADULTS AND PEDIATRIC PATIENTS • CORONARY ARTERIOGRAPHY AND CARDIAC VENTRICULOGRAPHY IN ADULTS • RADIOGRAPHIC EVALUATION OF CARDIAC CHAMBERS AND RELATED ARTERIES IN PEDIATRIC PATIENTS.INTRAVENOUS PROCEDURES • COMPUTED TOMOGRAPHY (CT) OF THE HEAD AND BODY IN ADULTS AND PEDIATRIC PATIENTS • CT ANGIOGRAPHY OF INTRACRANIAL,
NDA 218808	CRENESSITY	CRINECERFONT	NEUROCRINE BIOSCIENCES INC	P,O	12/13/2024	AS ADJUNCTIVE TREATMENT TO GLUCOCORTICOID REPLACEMENT TO CONTROL ANDROGENS IN ADULTS AND PEDIATRIC PATIENTS 4 YEARS OF AGE AND OLDER WITH CLASSIC CONGENITAL ADRENAL HYPERPLASIA (CAH).
NDA 218171	ENSACOVE	ENSARTINIB	XCOVERY HOLDINGS INC	S	12/18/2024	TREATMENT OF ADULT PATIENTS WITH ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE LOCALLY ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHO HAVE NOT PREVIOUSLY RECEIVED AN ALK-INHIBITOR
NDA 218614	TRYNGOLZA	OLEZARSEN	IONIS PHARMACEUTICALS INC	P,O	12/19/2024	AS AN ADJUNCT TO DIET TO REDUCE TRIGLYCERIDES IN ADULTS WITH FAMILIAL CHYLOMICRONEMIA SYNDROME
NDA 218730	ALYFTREK	VANZACAFTOR, TEZACAFTOR, AND DEUTIVACAFTOR	VERTEX PHARMACEUTICALS INC	P,O	12/20/2024	TREATMENT OF CYSTIC FIBROSIS (CF) IN PATIENTS 6 YEARS OF AGE AND OLDER WHO HAVE AT LEAST ONE F508DEL MUTATION OR ANOTHER RESPONSIVE MUTATION IN THE CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) GENE.

New Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
BLA 761225	LETYBO	LETIBOTULINUMTOXINA-WLBG	HUGEL INC.	S	2/29/2024	FOR THE TEMPORARY IMPROVEMENT IN THE APPEARANCE OF MODERATE TO SEVERE GLABELLAR LINES ASSOCIATED WITH CORRUGATOR AND/OR PROCERUS MUSCLE ACTIVITY IN ADULT PATIENTS
BLA 761363	WINREVAIR	SOTATERCEPT-CSRK	MERCK SHARP & DOHME LLC	P,O	3/26/2024	ARTERIAL HYPERTENSION (PAH, WHO GROUP 1) TO INCREASE EXERCISE CAPACITY, IMPROVE WHO FUNCTIONAL CLASS (FC) AND REDUCE THE RISK OF CLINICAL WORSENING EVENTS.
BLA 761359	ENTYVIO AND ENTYVIO PEN	VEDOLIZUMAB	TAKEDA PHARMACEUTICALS U.S.A., INC.	S	4/18/2024	FOR THE TREATMENT OF ADULTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE
BLA 761336	ANKTIVA	NOGAPENDEKIN ALFA INBAKICEPT-PMLN	ALTOR BIOSCIENCE, LLC, AN INDIRECT WHOLLY-OWNED SUBSIDIARY OF IMMUNITYBIO, INC.	S	4/22/2024	INDICATED WITH BACILLUS CALMETTE-GUÉRIN (BCG) FOR THE TREATMENT OF ADULT PATIENTS WITH BCG-UNRESPONSIVE NONMUSCLE INVASIVE BLADDER CANCER (NMIBC) WITH CARCINOMA IN SITU (CIS) WITH OR WITHOUT PAPILLARY TUMORS.
BLA 761344	IMDELLTRA	TARLATAMAB-DLLE	AMGEN INC.	P,O	5/16/2024	FOR THE TREATMENT OF ADULT PATIENTS WITH EXTENSIVE STAGE SMALL CELL LUNG CANCER (ES-SCLC) WITH DISEASE PROGRESSION ON OR AFTER PLATINUM-BASED CHEMOTHERAPY
BLA 761388	PIASKY	CROVALIMAB-AKKZ	GENENTECH, INC.	S,O	6/20/2024	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 13 YEARS AND OLDER WITH PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH) AND BODY WEIGHT OF AT LEAST 40 KG.
BLA 761248	KISUNLA	DONANEMAB-AZBT	ELI LILLY AND COMPANY	P	7/2/2024	FOR THE TREATMENT OF EARLY SYMPTOMATIC ALZHEIMER'S DISEASE
BLA 761390	NEMLUVIO	NEMOLIZUMAB-ILTO	GALDERMA LABORATORIES, L.P.	P	8/12/2024	FOR THE TREATMENT OF PRURIGO NODULARIS
BLA 761411	NIKTIMVO	AXATILIMAB-CSFR	INCYTE CORPORATION	P,O	8/14/2024	FOR THE TREATMENT OF CHRONIC GRAFT-VERSUS-HOST DISEASE (CGVHD) AFTER FAILURE OF AT LEAST TWO PRIOR LINES OF SYSTEMIC THERAPY IN ADULT AND PEDIATRIC PATIENTS WEIGHING AT LEAST 40 KG
BLA 761306	EBGLYSS	LEBRIKIZUMAB-LBKZ	ELI LILLY AND COMPANY	S	9/13/2024	FOR THE TREATMENT OF ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER WHO WEIGH AT LEAST 40KG WITH MODERATE-TO-SEVERE ATOPIC DERMATITIS WHOSE DISEASE IS NOT ADEQUATELY CONTROLLED WITH TOPICAL PRESCRIPTION THERAPIES OR WHEN THOSE THERAPIES ARE NOT ADVISABLE.
BLA 761369	HYMPAVZI	MARSTACIMAB-HNCQ	PFIZER INC.	S,O	10/11/2024	HYMPAVZI IS A TISSUE FACTOR PATHWAY INHIBITOR (TFPI) ANTAGONIST INDICATED FOR ROUTINE PROPHYLAXIS TO PREVENT OR REDUCE THE FREQUENCY OF BLEEDING EPISODES IN ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER WITH HEMOPHILIA A (CONGENITAL FACTOR VIII DEFICIENCY) WITHOUT FACTOR VIII INHIBITORS, OR HEMOPHILIA B (CONGENITAL FACTOR IX DEFICIENCY) WITHOUT FACTOR IX INHIBITORS.

BLA 761365	VYLOY	ZOLBETUXIMAB-CLZB	ASTELLAS PHARMA US, INC.	P,O	10/18/2024	VYLOY IS A CLAUDIN 18.2-DIRECTED CYTOLYTIC ANTIBODY AND IS INDICATED IN COMBINATION WITH FLUOROPYRIMIDINE- AND PLATINUM-CONTAINING CHEMOTHERAPY FOR THE FIRST-LINE TREATMENT OF ADULTS WITH LOCALLY ADVANCED UNRESECTABLE OR METASTATIC HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 (HER2)-NEGATIVE GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA WHOSE TUMORS ARE CLAUDIN (CLDN) 18.2 POSITIVE AS DETERMINED BY AN FDA-APPROVED TEST.
BLA 761416	ZIIHERA	ZANIDATAMAB-HRII	JAZZ PHARMACEUTICALS IRELAND LIMITED	P,O	11/20/2024	FOR THE TREATMENT OF ADULTS WITH PREVIOUSLY TREATED, UNRESECTABLE OR METASTATIC HER2-POSITIVE (IHC3+) BILIARY TRACT CANCER AS DETECTED BY AN FDA APPROVED TEST
BLA 761352	BIZENGRI	ZENOCUTUZUMAB-ZBCO	MERUS NV	P,O	12/4/2024	FOR THE TREATMENT OF: ADULTS WITH ADVANCED, UNRESECTABLE OR METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) HARBORING A NEUREGULIN 1 (NRG1) GENE FUSION WITH DISEASE PROGRESSION ON OR AFTER PRIOR SYSTEMIC THERAPY. AND ADULTS WITH ADVANCED, UNRESECTABLE OR METASTATIC PANCREATIC ADENOCARCINOMA HARBORING A NEUREGULIN 1 (NRG1) GENE FUSION WITH DISEASE PROGRESSION ON OR AFTER PRIOR SYSTEMIC THERAPY.
BLA 761297	UNLOXCYT	COSIBELIMAB-IPDL	CHECKPOINT THERAPEUTICS, INC.	S	12/13/2024	FOR THE TREATMENT OF ADULTS WITH METASTATIC CUTANEOUS SQUAMOUS CELL CARCINOMA (MCSCC) OR LOCALLY ADVANCED CSCC (LACSCC) WHO ARE NOT CANDIDATES FOR CURATIVE SURGERY OR CURATIVE RADIATION.
BLA 761315	ALHEMO	CONCIZUMAB-MTCI	NOVO NORDISK INC.	P,O	12/20/2024	ROUTINE PROPHYLAXIS TO PREVENT OR REDUCE THE FREQUENCY OF BLEEDING EPISODES IN ADULT AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER WITH HEMOPHILIA A (CONGENITAL FACTOR VIII DEFICIENCY) WITH FVIII INHIBITORS OR HEMOPHILIA B (CONGENITAL FACTOR IX DEFICIENCY) WITH FIX INHIBITORS.

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).