

CY 2024 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement 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

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
NDA 204630	21	Accelerated Approval Confirmatory Study	PROVAYBLUE (METHYLENE BLUE)	PROVEPHARM SAS	S	1/8/2024
NDA 212526	9	New Indication	PIQRAY (ALPELISIB)	NOVARTIS PHARMACEUTICALS CORP	P	1/18/2024
NDA 212018	8	Accelerated Approval Confirmatory Study	BALVERSA (ERDAFITINIB)	JANSSEN BIOTECH INC	P	1/19/2024
NDA 212018	9	New Indication	BALVERSA (ERDAFITINIB)	JANSSEN BIOTECH INC	P	1/19/2024
NDA 211988	13	New Indication	ZYNRELEF (BUPIVACAINE AND MELOXICAM)	HERON THERAPEUTICS INC	S	1/23/2024
NDA 206494	12	New Patient Population	AVYCAZ (AVIBACTAM AND CEFTAZIDIME)	ALLERGAN SALES LLC	P	1/26/2024
NDA 207131	9	New Patient Population	CEFAZOLIN	BAXTER HEALTHCARE CORP	S	2/1/2024
NDA 207793	16	New Indication	ONIVYDE (IRINOTECAN LIPOSOME)	IPSEN BIOPHARMACEUTICALS INC	S	2/13/2024
NDA 214096	3	Accelerated Approval Confirmatory Study	TEPMETKO (TEPOTINIB)	EMD SERONO INC	S	2/15/2024
NDA 208065	30	New Indication	TAGRISSO (OSIMERTINIB)	ASTRAZENECA PHARMACEUTICALS LP	P	2/16/2024
NDA 210251	18	New Indication	BIKTARVY (BICTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	2/23/2024
NDA 214787	26	New Patient Population	VEKLURY (REMDESIVIR)	GILEAD SCIENCES INC	P	2/28/2024
NDA 210854	20	New Patient Population	XOFLUZA (BALOXAVIR MARBOXIL)	GENENTECH INC	S	3/1/2024
NDA 214410	6	New Patient Population	XOFLUZA (BALOXAVIR MARBOXIL)	GENENTECH INC	S	3/1/2024
NDA 213217	11	New Indication	BRUKINSA (ZANUBRUTINIB)	BEIGENE USA INC	S	3/7/2024
NDA 215256	11	New Indication	WEGOVY (SEMAGLUTIDE)	NOVO NORDISK INC	P	3/8/2024
NDA 214662	5	New Indication	LIVMARLI (MARALIXIBAT)	MIRUM PHARMACEUTICALS INC	S	3/13/2024
NDA 202022	20	New Patient Population	EDURANT (RILPIVIRINEE)	JANSSEN PRODUCTS LP	P	3/15/2024
NDA 202022	22	New Patient Population	EDURANT (RILPIVIRINEE)	JANSSEN PRODUCTS LP	P	3/15/2024
NDA 209022	19	New Indication	XHANCE (FLUTICASON PROPIONATE)	OPTINOSE US INC	S	3/15/2024
NDA 203469	37	New Indication	ICLUSIG (PONATINIB)	TAKEDA PHARMACEUTICALS USA INC	P	3/19/2024
NDA 211616	12	New Indication	NEXLETOL (BEMPEDOIC ACID)	ESPERION THERAPEUTICS INC	S	3/22/2024
NDA 211616	13	New Indication	NEXLETOL (BEMPEDOIC ACID)	ESPERION THERAPEUTICS INC	S	3/22/2024
NDA 211617	16	New Indication	NEXLIZET (BEMPEDOIC ACID AND EZETIMIBE)	ESPERION THERAPEUTICS INC	S	3/22/2024
NDA 211617	17	New Indication	NEXLIZET (BEMPEDOIC ACID AND EZETIMIBE)	ESPERION THERAPEUTICS INC	S	3/22/2024
NDA 208464	16	New Patient Population	VEMLIDY (TENFOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	P	3/27/2024
NDA 022192	23	New Indication	FANAPT (ILOPERIDONE)	VANDA PHARMACEUTICALS INC	S	4/2/2024
NDA 206947	30	Manufacturing Change With Clinical Data	LENVIMA (LENVATINIB MESYLATE)	EISAI INC	P	4/3/2024
NDA 211994	18	New Patient Population	DOVATO (DOLUTEGRAVIR AND LAMIVUDINE)	VIIV HEALTHCARE CO	S	4/5/2024
NDA 211994	19	New Patient Population	DOVATO (DOLUTEGRAVIR AND LAMIVUDINE)	VIIV HEALTHCARE CO	S	4/5/2024
NDA 208434	15	New Indication	ALECENSA (ALECTINIB)	HOFFMANN LA ROCHE INC	P	4/18/2024
NDA 208700	31	New Patient Population	LUTATHERA (LUTETIUM LU 177 DOTATATE)	ADVANCED ACCELERATOR APPLICATIONS USA INC	P	4/23/2024
NDA 204508	22	New Patient Population	CLINOLIPID (LIPID EMULSION)	BAXTER HEALTHCARE CORP	S	4/24/2024
NDA 215039	2	New Route Of Administration	VIJOICE (ALPELISIB)	NOVARTIS PHARMACEUTICALS CORP	S	4/24/2024
NDA 205437	13	New Indication	OTEZLA (APREMILAST)	AMGEN INC	P	4/25/2024
NDA 211675	21	New Patient Population	RINVOQ (UPADACITINIB)	ABBVIE INC	S	4/26/2024
NDA 211675	22	New Patient Population	RINVOQ (UPADACITINIB)	ABBVIE INC	S	4/26/2024
NDA 214846	7	New Dosing Regimen	MYFEMBREE (RELUGOLIX, ESTRADIOL, NORETHINDRONE ACETATE)	SUMITOMO PHARMA AMERICA INC	S	4/30/2024

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NDA 213246	12	New Indication	RETEVMO (SELPERCATINIB)	LOXO ONCOLOGY INC A WHOLLY OWNED SUB OF ELI LILLY AND CO	P	5/29/2024
NDA 208078	12	New Dosing Regimen	FIRDAPSE (AMIFAMPRIDINE PHOSPHATE)	CATALYST PHARMACEUTICALS INC	S	5/30/2024
NDA 207131	10	New Dosing Regimen	CEFAZOLIN	BAXTER HEALTHCARE CORP	S	5/31/2024
NDA 213189	5	New Dosing Regimen	KLISYRI (TIRBANIBULIN)	ALMIRALL LLC	S	6/7/2024
NDA 216185	1	New Indication	MOTPOLY XR (LACOSAMIDE)	AUCTA PHARMACEUTICALS INC	S	6/7/2024
NDA 202293	31	New Patient Population	FARXIGA (DAPAGLIFLOZIN)	ASTRAZENECA AB	P	6/12/2024
NDA 205649	22	New Patient Population	XIGDUO XR (DAPAGLIFLOZIN AND METFORMIN)	ASTRAZENECA AB	P	6/12/2024
NDA 213246	9	New Indication	RETEVMO (SELPERCATINIB)	LOXO ONCOLOGY INC A WHOLLY OWNED SUB OF ELI LILLY AND CO	S	6/12/2024
NDA 218213	1	New Indication	AUGTYRO (REPOTRECTINIB)	BRISTOL MYERS SQUIBB CO	P	6/13/2024
NDA 022304	28	New Indication	NUCYNTA (TAPENTADOL)	COLLEGIUM PHARMACEUTICAL INC	P	6/14/2024
NDA 200533	29	New Patient Population	NUCYNTA ER (TAPENTADOL)	COLLEGIUM PHARMACEUTICAL INC	P	6/14/2024
NDA 203794	13	New Patient Population	NUCYNTA (TAPENTADOL)	COLLEGIUM PHARMACEUTICAL INC	P	6/14/2024
NDA 204384	19	Accelerated Approval Confirmatory Study	SIRTURO (BEDAQUILINE)	JANSSEN RESEARCH AND DEVELOPMENT LLC	S	6/21/2024
NDA 211150	5	New Patient Population	WAKIX (PITOLISANT)	HARMONY BIOSCIENCES LLC	P	6/21/2024
NDA 211150	6	New Patient Population	WAKIX (PITOLISANT)	HARMONY BIOSCIENCES LLC	P	6/21/2024
NDA 216340	5	New Indication	KRAZATI (ADAGRASIB)	MIRATI THERAPEUTICS INC	P	6/21/2024
NDA 205109	9	New Patient Population	VELPHORO (SUCROFERRIC OXYHYDROXIDE)	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	S	7/1/2024
NDA 215985	7	New Indication	ROFLUMILAST	ARCUTIS BIOTHERAPEUTICS INC	S	7/9/2024
NDA 209092	19	New Indication	KISQALI (RIBOCICLIB)	NOVARTIS PHARMACEUTICALS CORP	S	7/22/2024
NDA 214662	10	New Patient Population	LIVMARLI (MARALIXIBAT)	MIRUM PHARMACEUTICALS INC	S	7/24/2024
NDA 218276	1	New Indication	FABHALTA (IPTACOPAN)	NOVARTIS PHARMACEUTICALS CORP	P	8/7/2024
NDA 209988	1	New Indication	FUROSCIX INFUSOR (FUROSEMIDE)	SCPHARMACEUTICALS INC	S	8/9/2024
NDA 020988	70	New Patient Population	PROTONIX IV (PANTOPRAZOLE SODIUM)	WYETH PHARMACEUTICALS LLC	S	8/12/2024
NDA 050779	34	New Patient Population	CEFAZOLIN SODIUM	B BRAUN MEDICAL INC	S	8/26/2024
NDA 209939	13	New Patient Population	PREVMIS (LETTERMOVIR)	MERCK SHARP AND DOHME LLC A SUB OF MERCK AND CO INC	P	8/30/2024
NDA 209939	16	New Patient Population	PREVMIS (LETTERMOVIR)	MERCK SHARP AND DOHME LLC A SUB OF MERCK AND CO INC	P	8/30/2024
NDA 209940	12	New Patient Population	PREVMIS (LETTERMOVIR)	MERCK SHARP AND DOHME LLC A SUB OF MERCK AND CO INC	P	8/30/2024
NDA 209940	16	New Patient Population	PREVMIS (LETTERMOVIR)	MERCK SHARP AND DOHME LLC A SUB OF MERCK AND CO INC	P	8/30/2024
NDA 216403	3	New Indication	FILSPARI (SPARSENTAN)	TRAVERE THERAPEUTICS INC	P	9/5/2024
NDA 215395	7	New Indication	LANREOTIDE ACETATE	INVAGEN PHARMACEUTICALS INC	S	9/16/2024
NDA 209092	18	New Indication	KISQALI (RIBOCICLIB)	NOVARTIS PHARMACEUTICALS CORP	P	9/17/2024
NDA 209935	27	New Indication	KISQALI FEMARA CO-PACK (LETROZOLE AND RIBOCICLIB)	NOVARTIS PHARMACEUTICALS CORP	S	9/17/2024
NDA 208065	33	New Indication	TAGRISSO (OSMERTINIB)	ASTRAZENECA PHARMACEUTICALS LP	P	9/25/2024
NDA 213246	13	Accelerated Approval Confirmatory Study	RETEVMO (SELPERCATINIB)	LOXO ONCOLOGY INC A WHOLLY OWNED SUB OF ELI LILLY AND CO	P	9/27/2024
NDA 218160	2	Accelerated Approval Confirmatory Study	RETEVMO (SELPERCATINIB)	LOXO ONCOLOGY A WHOLLY OWNED SUB OF ELI LILLY AND CO	P	9/27/2024
NDA 208081	28	New Dosing Regimen	AMELUZ (5-AMINOLEVULINIC ACID HYDROCHLORIDE)	BIOFRONTERA BIOSCIENCE GMBH	S	10/4/2024
NDA 020287	80	New Patient Population	FRAGMIN (DALTEPARIN SODIUM)	PFIZER INC	S	10/15/2024
NDA 214755	6	New Patient Population	LUMRYZ (SODIUM OXYBATE)	AVADEL CNS PHARMACEUTICALS LLC	S	10/16/2024
NDA 212479	2	New Patient Population	JYLAMVO (METHOTREXATE)	SHORLA PHARMA LTD	S	10/23/2024
NDA 212479	3	New Patient Population	JYLAMVO (METHOTREXATE)	SHORLA PHARMA LTD	S	10/23/2024
NDA 215358	8	New Indication	SCEMBLIX (ASCIMINIB)	NOVARTIS PHARMACEUTICALS CORP	P	10/29/2024
NDA 215358	9	New Indication	SCEMBLIX (ASCIMINIB)	NOVARTIS PHARMACEUTICALS CORP	P	10/29/2024

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NDA 208716	17	New Indication	VERZENIO (ABEMACICLIB)	ELI LILLY AND CO	S	11/13/2024
NDA 022137	15	New Indication	FLUDARABINE PHOSPHATE	SANDOZ INC	S	11/19/2024
NDA 212862	8	New Dosing Regimen	PRETOMANID	MYLAN IRELAND LTD	S	11/22/2024
NDA 021539	19	New Dosing Regimen	ACETADOTE (ACETYLCYSTEINE)	CUMBERLAND PHARMACEUTICALS INC	S	11/26/2024
NDA 215256	15	New Dosing Regimen	WEGOVY (SEMAGLUTIDE)	NOVO NORDISK INC	S	11/27/2024
NDA 011525	39	New Indication	CARDIO-GREEN (INDOCYANINE GREEN)	RENEW PHARMACEUTICALS LTD	S	12/5/2024
NDA 213051	20	New Dosing Regimen	RYBELSUS (SEMAGLUTIDE)	NOVO NORDISK INC	S	12/9/2024
NDA 022225	14	New Patient Population	BRIDION (SUGAMMADEX)	MERCK SHARP AND DOHME LLC A SUB OF MERCK AND CO INC	P	12/12/2024
NDA 215272	2	New Dosing Regimen	VTAMA (TAPINAROF)	DERMAVANT SCIENCES INC	S	12/12/2024
NDA 204042	43	New Patient Population	INVOKANA (CANAGLIFLOZIN)	JANSSEN PHARMACEUTICALS INC	P	12/18/2024
NDA 204353	46	New Patient Population	INVOKAMET (CANAGLIFLOZIN AND METFORMIN HYDROCHLORIDE)	JANSSEN PHARMACEUTICALS INC	P	12/18/2024
NDA 205879	23	New Patient Population	INVOKAMET XR (CANAGLIFLOZIN AND METFORMIN HYDROCHLORIDE)	JANSSEN PHARMACEUTICALS INC	P	12/18/2024
NDA 211635	10	New Patient Population	VALTOCO (DIAZEPAM)	NEURELIS INC	S	12/18/2024
NDA 213006	11	New Indication	GEMTESA (VIBEGRON)	UROVANT SCIENCES GMBH	S	12/18/2024
NDA 216109	3	New Dosing Regimen	CEFAZOLIN FOR INJECTION	HIKMA PHARMACEUTICALS USA INC	S	12/18/2024
NDA 205649	23	New Indication	XIGDUO XR (DAPAGLIFLOZIN AND METFORMIN)	ASTRAZENECA AB	S	12/20/2024
NDA 210496	17	New Indication	BRAFTOVI (ENCORAFENIB)	ARRAY BIOPHARMA INC	P	12/20/2024
NDA 213793	7	New Indication	IMCIVREE (SETMELANOTIDE)	RHYTHM PHARMACEUTICALS INC	P	12/20/2024
NDA 217806	13	New Indication	ZEPBOUND (TIRZEPATIDE) INJECTION, AND ZEPBOUND KWIKPEN (TIRZEPATIDE) INJECTION	ELI LILLY AND CO	P	12/20/2024
NDA 021345	52	New Patient Population	ARIXTRA (FONDAPARINUX SODIUM)	MYLAN IRELAND LTD	S	12/23/2024

NDA Efficacy Supplements Approved (SE8)

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
NDA 213756	4	Labeling Change With Clinical Data	KOSELUGO (SELUMETINIB)	ASTRAZENECA PHARMACEUTICALS LP	S	1/24/2024
NDA 208065	29	Labeling Change With Clinical Data	TAGRISKO (OSIMERTINIB)	ASTRAZENECA PHARMACEUTICALS LP	S	1/31/2024
NDA 210942	2	Labeling Change With Clinical Data	GLOPERBA (COLCHICINE)	SCILEX PHARMACEUTICALS INC	S	2/29/2024
NDA 021064	33	Labeling Change With Clinical Data	DEFINITY (PERFLUTREN LIPID MICROSPHERE)	LANTHEUS MEDICAL IMAGING INC	S	3/1/2024
NDA 022405	22	Labeling Change With Clinical Data	CAPRELSA (VANDETANIB)	GENZYME CORP	S	3/7/2024
NDA 022433	35	Labeling Change With Clinical Data	BRILINTA (TICAGRELOR)	ASTRAZENECA PHARMACEUTICALS LP	S	3/22/2024
NDA 208464	17	Labeling Change With Clinical Data	VEMLIDY (TENOFIVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	3/27/2024
NDA 207620	25	Labeling Change With Clinical Data	ENTRESTO (SACUBITRIL AND VALSARTAN)	NOVARTIS PHARMACEUTICALS CORP	S	4/12/2024
NDA 210251	19	Labeling Change With Clinical Data	BIKTARVY (BICTEGRIVIR, EMTRICITABINE, AND TENOFIVIR ALAFENAMIDE)	GILEAD SCIENCES INC	P	4/24/2024
NDA 213716	4	Labeling Change With Clinical Data	LUPKYNIS (VOCLOSPORIN)	AURINIA PHARMACEUTICALS INC	S	4/29/2024

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NDA 205422	11	Labeling Change With Clinical Data	REXULTI (BREXPIRAZOLE)	OTSUKA PHARMACEUTICAL CO LTD	P	5/7/2024
NDA 206947	31	Labeling Change With Clinical Data	LENVIMA (LENVATINIB MESYLATE)	EISAI INC	S	6/7/2024
NDA 218160	1	Labeling Change With Clinical Data	RETEVMO (SELPERCATINIB)	LOXO ONCOLOGY A WHOLLY OWNED SUB OF ELI LILLY AND COMPANY	S	6/12/2024
NDA 018680	74	Labeling Change With Clinical Data	PARAGARD (COPPER T MODEL 380A)	COOPERSURGICAL INC	S	6/28/2024
NDA 210942	2	Labeling Change With Clinical Data	GLOPERBA (COLCHICINE)	SCILEX PHARMACEUTICALS INC	S	7/8/2024
NDA 215358	7	Labeling Change With Clinical Data	SCEMBLIX (ASCIMINIB)	NOVARTIS PHARMACEUTICALS CORP	S	8/7/2024
NDA 213072	4	Labeling Change With Clinical Data	ROSZET (ROSUVASTATIN AND EZETIMIBE)	ALTHERA PHARMACEUTICALS LLC	S	8/26/2024
NDA 210942	2	Labeling Change With Clinical Data	GLOPERBA (COLCHICINE)	SCILEX PHARMACEUTICALS INC	S	8/28/2024
NDA 209899	11	Labeling Change With Clinical Data	ZEPOSIA (OZANIMOD)	BRISTOL MYERS SQUIBB CO	S	8/30/2024
NDA 210496	16	Labeling Change With Clinical Data	BRAFTOVI (ENCORAFENIB)	ARRAY BIOPHARMA INC	S	9/12/2024
NDA 210498	10	Labeling Change With Clinical Data	MEKTOVI (BINIMETINIB)	ARRAY BIOPHARMA INC	S	9/12/2024
NDA 022580	25	Labeling Change With Clinical Data	QSYMIA (PHENTERMINE AND TOPIRAMATE)	VIVUS LLC	S	9/13/2024
NDA 213535	13	Labeling Change With Clinical Data	EVRYSDI (RISDIPLAM)	GENENTECH INC	S	9/17/2024
NDA 212887	9	Labeling Change With Clinical Data	VOCABRIA (CABOTEGRAVIR)	VIIV HEALTHCARE CO	P	9/20/2024
NDA 212887	10	Labeling Change With Clinical Data	VOCABRIA (CABOTEGRAVIR)	VIIV HEALTHCARE CO	S	9/20/2024
NDA 212888	15	Labeling Change With Clinical Data	CABENUVA (CABOTEGRAVIR EXTENDED RELEASE INJECTABLE SUSPENSION; RILPIVIRINE EXTENDED RELEASE INJECTABLE SUSPENSION)	VIIV HEALTHCARE CO	P	9/20/2024
NDA 215499	8	Labeling Change With Clinical Data	APRETUDE (CABOTEGRAVIR)	VIIV HEALTHCARE CO	S	9/20/2024
NDA 213246	11	Labeling Change With Clinical Data	RETEVMO (SELPERCATINIB)	LOXO ONCOLOGY INC A WHOLLY OWNED SUB OF ELI LILLY AND CO	S	9/27/2024
NDA 218160	3	Labeling Change With Clinical Data	RETEVMO (SELPERCATINIB)	LOXO ONCOLOGY A WHOLLY OWNED SUB OF ELI LILLY AND CO	S	9/27/2024
NDA 214985	10	Labeling Change With Clinical Data	QUVIVIQ (DARIDOREXANT)	IDORSIA PHARMACEUTICALS LTD	S	9/30/2024
NDA 214985	11	Labeling Change With Clinical Data	QUVIVIQ (DARIDOREXANT)	IDORSIA PHARMACEUTICALS LTD	S	9/30/2024
NDA 217026	1	Labeling Change With Clinical Data	DAYBUE (TROFINETIDE)	ACADIA PHARMACEUTICALS INC	S	9/30/2024
NDA 022350	26	Labeling Change With Clinical Data	ONGLYZA (SAXAGLIPTIN)	ASTRAZENECA AB	S	10/11/2024
NDA 200678	28	Labeling Change With Clinical Data	KOMBIGLYZE XR (METFORMIN HYDROCHLORIDE AND SAXAGLIPTIN)	ASTRAZENECA AB	S	10/11/2024
NDA 214621	6	Labeling Change With Clinical Data	ORGOVYX (RELUGOLIX)	SUMITOMO PHARMA SWITZERLAND GMBH	S	10/18/2024
NDA 217806	6	Labeling Change With Clinical Data	ZEPBOUND (TIRZEPATIDE) INJECTION, AND ZEPBOUND KWIKPEN (TIRZEPATIDE) INJECTION	ELI LILLY AND CO	S	10/18/2024

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NDA 215973	6	Labeling Change With Clinical Data	SUNLENCA (LENACAPAVIR)	GILEAD SCIENCES INC	S	11/25/2024
NDA 215974	8	Labeling Change With Clinical Data	SUNLENCA (LENACAPAVIR)	GILEAD SCIENCES INC	S	11/25/2024
NDA 206038	18	Labeling Change With Clinical Data	ORKAMBI (IVACAFTOR AND LUMACAFTOR)	VERTEX PHARMACEUTICALS INC	P	12/13/2024
NDA 211358	6	Labeling Change With Clinical Data	ORKAMBI (LUMACAFTOR/IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	12/13/2024
NDA 210854	21	Labeling Change With Clinical Data	XOFLUZA (BALOXAVIR MARBOXIL)	GENENTECH INC	S	12/19/2024
NDA 214410	7	Labeling Change With Clinical Data	XOFLUZA (BALOXAVIR MARBOXIL)	GENENTECH INC	S	12/19/2024
NDA 212273	12	Labeling Change With Clinical Data	TRIKAFTA (ELEXACAFTOR/TEZACAFTOR/IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	12/20/2024
NDA 216718	8	Labeling Change With Clinical Data	SKYCLARYS (OMAVELOXOLONE)	REATA PHARMACEUTICALS INC A WHOLLY OWNED SUB OF BIOGEN	S	12/20/2024
NDA 217660	3	Labeling Change With Clinical Data	TRIKAFTA (ELEXACAFTOR/TEZACAFTOR/IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	12/20/2024
NDA 019414	34	Labeling Change With Clinical Data	CARDIOGEN-82 GENERATOR (RUBIDIUM RB 82)	BRACCO DIAGNOSTICS INC	P	12/23/2024

BLA Efficacy Supplements Approved

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE	PROPER NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
BLA 125514	147	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	P	1/12/2024
BLA 761055	55	Labeling Change With Clinical Data	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	S	1/12/2024
BLA 125514	124	Accelerated Approval Confirmatory Study	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	1/25/2024
BLA 761055	57	New Patient Population	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	P	1/25/2024
BLA 125554	122	Manufacturing Change With Clinical Data	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	1/26/2024
BLA 761139	26	Labeling Change With Clinical Data		DAIICHI SANKYO, INC.	S	2/15/2024
BLA 103976	5245	New Indication	XOLAIR (OMALIZUMAB)	GENENTECH, INC.	P	2/16/2024
BLA 761291	3	New Dosing Regimen	TECVAYLI (TECLISTAMAB-CQYV)	JANSSSEN BIOTECH, INC.	S	2/20/2024
BLA 761210	3	New Indication	RYBREVAANT (AMIVANTAMAB-VMJW)	JANSSSEN BIOTECH, INC.	P	3/1/2024
BLA 125320	213	Labeling Change With Clinical Data	PROLIA (DENOSUMAB)	AMGEN INC.	S	3/5/2024
BLA 125320	213	Labeling Change With Clinical Data	XGEVA AND PROLIA (DENOSUMAB)	AMGEN INC.	S	3/5/2024
BLA 125320	213	Labeling Change With Clinical Data	XGEVA (DENOSUMAB)	AMGEN INC.	S	3/5/2024
BLA 125554	125	Labeling Change With Clinical Data	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	3/6/2024
BLA 761040	3	New Indication	BESPONSA (INOTUZUMAB OZOGAMICIN)	WYETH PHARMACEUTICALS LLC	P	3/6/2024
BLA 125559	39	New Indication	PRALUENT (ALIROCUMAB)	REGENERON PHARMACEUTICALS, INC.	S	3/8/2024
BLA 021839	31	Labeling Change With Clinical Data	INCRELEX (MECASERMIN)	IPSEN BIOPHARMACEUTICALS, INC.	S	3/15/2024

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BLA 761244	3	New Indication	SPEVIGO (SPESOLIMAB-SBZO)	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	S	3/18/2024
BLA 761108	26	New Indication	ULTOMIRIS (RAVULIZUMAB-CWVZ)	ALEXION PHARMACEUTICALS, INC.	S	3/22/2024
BLA 761310	5	Labeling Change With Clinical Data	ELAHERE (MIRVETUXIMAB SORAVTANSINE-GYNX)	IMMUNOGEN, INC.	P	3/22/2024
BLA 761067	18	Labeling Change With Clinical Data	ILUMYA (TILDRAKIZUMAB-ASMN)	SUN PHARMACEUTICAL INDUSTRIES LIMITED	S	4/3/2024
BLA 761070	20	New Patient Population	FASENRA (BENRALIZUMAB)	ASTRAZENECA AB	S	4/5/2024
BLA 761097	23	Labeling Change With Clinical Data	LIBTAYO (CEMPIIMAB-RWLC)	REGENERON PHARMACEUTICALS, INC.	S	4/5/2024
BLA 761139	28	New Indication		DAIICHI SANKYO, INC.	P	4/5/2024
BLA 761208	7	Labeling Change With Clinical Data	TIVDAK (TISOTUMAB VEDOTIN-TFTV)	SEAGEN INC.	P	4/29/2024
BLA 125164	89	New Patient Population	MIRCERA (METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA)	VIFOR (INTERNATIONAL) INC.	S	4/30/2024
BLA 761058	26	Manufacturing Change With Clinical Data	CYLTEZO (ADALIMUMAB-ADBIM)	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	S	4/30/2024
BLA 761058	26	Manufacturing Change With Clinical Data	CYLTEZO PEN (ADALIMUMAB-ADBIM)	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	S	4/30/2024
BLA 761043	27	New Patient Population	BENLYSTA (BELIMUMAB)	GLAXOSMITHKLINE LLC	S	5/16/2024
BLA 125514	154	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	6/7/2024
BLA 761037	15	New Indication	KEVZARA (SARILUMAB)	SANOFI-AVENTIS U.S. LLC	S	6/10/2024
BLA 761180	6	New Indication	ADBRY (TRALOKINUMAB-LDRM)	LEO PHARMA A/S	S	6/12/2024
BLA 125557	28	New Indication	BLINCYTO (BLINATUMOMAB)	AMGEN INC.	P	6/14/2024
BLA 761069	45	New Indication	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	S	6/14/2024
BLA 125514	155	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	P	6/17/2024
BLA 103792	5354	Labeling Change With Clinical Data	HERCEPTIN (TRASTUZUMAB)	GENENTECH, INC.	S	6/18/2024
BLA 761105	29	New Indication	SKYRIZI (RISANKIZUMAB-RZAA)	ABBVIE INC.	S	6/18/2024
BLA 761106	10	Labeling Change With Clinical Data	HERCEPTIN HYLECTA (TRASTUZUMAB AND HYALURONIDASE-OYSK)	GENENTECH, INC.	S	6/18/2024
BLA 761262	7	New Indication	SKYRIZI (RISANKIZUMAB-RZAA)	ABBVIE INC.	S	6/18/2024
BLA 761304	5	New Indication	VYVGART HYTRULO (EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC)	ARGENX BV	P	6/21/2024
BLA 761128	6	Labeling Change With Clinical Data	ADAKVEO (CRIZANLIZUMAB-TMCA)	NOVARTIS PHARMACEUTICALS CORPORATION	S	6/26/2024
BLA 761324	3	New Indication	EPKINLY (EPCORITAMAB-BYSP)	GENMAB US, INC.	P	6/26/2024
BLA 125360	99	New Indication	XEOMIN (INCOBOTULINUMTOXINA)	MERZ PHARMACEUTICALS GMBH C/O MERZ PHARMACEUTICALS LLC	S	7/5/2024
BLA 761052	14	New Patient Population	BRINEURA (CERLIPONASE ALFA)	BIOMARIN PHARMACEUTICAL INC.	S	7/24/2024
BLA 761145	25	New Indication	DARZALEX FASPRO (DARATUMUMAB AND HYALURONIDASE-FIHJ)	JANSSEN BIOTECH, INC.	P	7/30/2024
BLA 761036	50	Labeling Change With Clinical Data	DARZALEX (DARATUMUMAB)	JANSSEN BIOTECH, INC.	S	7/31/2024
BLA 761174	9	New Indication	JEMPERLI (DOSTARLIMAB-GXLY)	GLAXOSMITHKLINE LLC	P	8/1/2024
BLA 125514	157	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	8/7/2024
BLA 761195	4	Labeling Change With Clinical Data	VYVGART (EFGARTIGIMOD ALFA)	ARGENX BV	S	8/8/2024
BLA 761304	3	Labeling Change With Clinical Data	VYVGART HYTRULO (EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC)	ARGENX BV	S	8/8/2024

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BLA 761069	43	New Indication	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	S	8/15/2024
BLA 761192	10	New Indication	NEXOBRID (ANACAULASE-BCDB)	VERICEL CORPORATION	S	8/15/2024
BLA 761192	10	New Indication	NEXOBRID (CONCENTRATE OF PROTEOLYTIC ENZYMES ENRICHED IN BROMELAIN-BCDB)	VERICEL CORPORATION	S	8/15/2024
BLA 761192	10	New Indication	NEXOBRID (DEBRASE)	VERICEL CORPORATION	S	8/15/2024
BLA 761210	5	New Indication	RYBREVANT (AMIVANTAMAB-VMJW)	JANSSEN BIOTECH, INC.	P	8/19/2024
BLA 761024	19	Labeling Change With Clinical Data	AMJEVITA (ADALIMUMAB-ATTO)	AMGEN INC.	S	8/20/2024
BLA 761328	5	Labeling Change With Clinical Data	BEYFORTUS (NIRSEVIMAB-ALIP)	ASTRAZENECA AB	S	8/22/2024
BLA 761061	21	New Indication	TREMFYA (GUSELKUMAB)	JANSSEN BIOTECH, INC.	P	9/11/2024
BLA 761061	21	New Indication	TREMFYA (GUSELKUMAB) INJECTION AND TREMFYA PEN (GUSELKUMAB) INJECTION	JANSSEN BIOTECH, INC.	P	9/11/2024
BLA 761061	21	New Indication	TREMFYA PEN (GUSELKUMAB) INJECTION	JANSSEN BIOTECH, INC.	P	9/11/2024
BLA 761055	66	New Patient Population	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	P	9/12/2024
BLA 125160	275	Labeling Change With Clinical Data	CIMZIA (CERTOLIZUMAB PEGOL)	UCB, INC.	S	9/13/2024
BLA 125514	161	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	P	9/17/2024
BLA 761070	21	New Indication	FASENRA (BENRALIZUMAB)	ASTRAZENECA AB	S	9/17/2024
BLA 761210	4	New Indication	RYBREVANT (AMIVANTAMAB-VMJW)	JANSSEN BIOTECH, INC.	S	9/19/2024
BLA 125276	144	Labeling Change With Clinical Data	ACTEMRA (TOCILIZUMAB)	GENENTECH, INC.	S	9/20/2024
BLA 125472	56	Labeling Change With Clinical Data	ACTEMRA (TOCILIZUMAB)	GENENTECH, INC.	S	9/20/2024
BLA 761113	14	New Indication	SARCLISA (ISATUXIMAB-IRFC)	SANOFI-AVENTIS U.S. LLC	P	9/20/2024
BLA 761151	5	New Indication	BIMZELX (BIMEKIZUMAB)	UCB, INC.	S	9/20/2024
BLA 761151	6	New Indication	BIMZELX (BIMEKIZUMAB)	UCB, INC.	S	9/20/2024
BLA 761151	7	New Indication	BIMZELX (BIMEKIZUMAB)	UCB, INC.	S	9/20/2024
BLA 761055	64	Labeling Change With Clinical Data	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	P	9/27/2024
BLA 125554	127	New Indication	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	10/3/2024
BLA 761049	19	Labeling Change With Clinical Data	BAVENCIO (AVELUMAB)	EMD SERONO, INC.	S	10/11/2024
BLA 761151	9	Labeling Change With Clinical Data	BIMZELX (BIMEKIZUMAB)	UCB, INC.	S	10/11/2024
BLA 103000	5331	New Indication	BOTOX AND BOTOX COSMETIC (ONABOTULINUMTOXINA)	ABBVIE INC.	S	10/18/2024
BLA 761113	11	Labeling Change With Clinical Data	SARCLISA (ISATUXIMAB-IRFC)	SANOFI-AVENTIS U.S. LLC	S	10/25/2024
BLA 761113	12	Labeling Change With Clinical Data	SARCLISA (ISATUXIMAB-IRFC)	SANOFI-AVENTIS U.S. LLC	S	10/25/2024
BLA 761151	10	New Indication	BIMZELX (BIMEKIZUMAB)	UCB, INC.	S	11/19/2024
BLA 761115	58	New Indication	TRODELVY (SACITUZUMAB GOVITECAN-HZIY)	GILEAD SCIENCES, INC.	P	11/22/2024
BLA 761170	7	Labeling Change With Clinical Data	PHESGO (PERTUZUMAB, TRASTUZUMAB, AND HYALURONIDASE-ZZXF)	GENENTECH, INC.	S	11/22/2024
BLA 761263	5	Labeling Change With Clinical Data	LUNSUMIO (MOSUNETUZUMAB-AXGB)	GENENTECH, INC.	S	11/22/2024
BLA 761291	9	Labeling Change With Clinical Data	TECVAYLI (TECLISTAMAB-CQYV)	JANSSEN BIOTECH, INC.	S	11/22/2024
BLA 761069	49	New Indication	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	P	12/4/2024

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BLA 125514	162	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	12/11/2024
BLA 761285	1	Manufacturing Change With Clinical Data	WEZLANA (USTEKINUMAB-AUUB)	AMGEN INC.	S	12/26/2024