

**CY 2025 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year 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**

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
NDA 210259	11	New Indication	CALQUENCE (ACALABRUTINIB)	ASTRAZENECA UK LTD	P	1/16/2025
NDA 214665	9	New Indication	LUMAKRAS (SOTORASIB)	AMGEN INC	P	1/16/2025
NDA 216387	5	New Indication	CALQUENCE (ACALABRUTINIB MALEATE)	ASTRAZENECA UK LTD	P	1/16/2025
NDA 211243	16	New Indication	SPRAVATO (ESKETAMINE)	JANSSEN PHARMACEUTICALS INC	P	1/17/2025
NDA 208843	5	New Patient Population	SIKLOS (HYDROXYUREA)	THERAVIA PHARMA	S	1/22/2025
NDA 209637	25	New Indication	OZEMPIC (SEMAGLUTIDE)	NOVO NORDISK INC	S	1/28/2025
NDA 217188	8	New Patient Population	PAXLOVID (NIRMATRELVIR AND RITONAVIR)	PFIZER INC	P	1/31/2025
NDA 210867	6	New Patient Population	MOXIDECTIN	MEDICINES DEVELOPMENT FOR GLOBAL HEALTH LTD	P	2/7/2025
NDA 208351	14	New Patient Population	ODEFSEY (EMTRICITABINE, RILPIVIRINE, AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	2/19/2025
NDA 208351	15	New Patient Population	ODEFSEY (EMTRICITABINE, RILPIVIRINE, AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	2/19/2025
NDA 214697	1	New Patient Population	NEFFY (EPINEPHRINE)	ARS PHARMACEUTICALS OPERATIONS INC	P	3/5/2025
NDA 209988	3	New Indication	FUROSCIX INFUSOR (FUROSEMIDE)	SCPHARMACEUTICALS INC	S	3/6/2025
NDA 206111	45	New Indication	SYNJARDY (EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	3/7/2025
NDA 208658	32	New Indication	SYNJARDY XR (EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	3/7/2025
NDA 212097	12	New Indication	GVOKE VIALDX (GLUCAGON) INJECTION	XERIS PHARMACEUTICALS INC	S	3/14/2025
NDA 210134	4	New Patient Population	BAQSIMI (GLUCAGON)	AMPHASTAR PHARMACEUTICALS INC	P	3/17/2025
NDA 215515	6	New Indication	AMVUTTRA (VUTRISIRAN)	ALNYLAM PHARMACEUTICALS INC	P	3/20/2025
NDA 218276	4	New Indication	FABHALTA (IPTACOPAN)	NOVARTIS PHARMACEUTICALS CORP	P	3/20/2025
NDA 205395	28	New Patient Population	PREZCOBIX (COBICISTAT AND DARUNAVIR)	JANSSEN PRODUCTS LP	S	3/21/2025
NDA 208692	17	New Indication	CABOMETYX (CABOZANTINIB)	EXELIXIS INC	S	3/26/2025
NDA 202971	18	New Dosing Regimen	ABILIFY MAINTENA (ARIPIRAZOLE)	OTSUKA PHARMACEUTICAL CO LTD	S	3/28/2025
NDA 215833	21	New Indication	PLUVICTO (LUTETIUM (177LU) VIPIVOTIDE TETRAXETAN)	NOVARTIS PHARMACEUTICALS CORP	S	3/28/2025
NDA 217006	1	New Dosing Regimen	ABILIFY ASIMTUFII (ARIPIRAZOLE)	OTSUKA PHARMACEUTICAL CO LTD	S	3/28/2025
NDA 205435	16	New Patient Population	SIVEXTRO (TEDIZOLID PHOSPHATE)	CUBIST PHARMACEUTICALS LLC	S	4/4/2025
NDA 205436	13	New Patient Population	SIVEXTRO (TEDIZOLID PHOSPHATE)	CUBIST PHARMACEUTICALS LLC	S	4/4/2025
NDA 208742	13	New Patient Population	DEXTENZA (DEXAMETHASONE)	OCULAR THERAPEUTIX INC	S	4/7/2025
NDA 211635	10	New Patient Population	VALTOCO (DIAZEPAM)	NEURELIS INC	S	4/15/2025
NDA 212801	3	New Indication	ISTURISA (OSILODROSTAT)	RECORDATI RARE DISEASES INC	S	4/15/2025
NDA 215383	11	New Patient Population	WELIREG (BELZUTIFAN)	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	S	4/15/2025
NDA 203050	3	New Patient Population	POSFREA (PALONOSETRON)	AVYXA HOLDINGS LLC	S	4/16/2025
NDA 202155	39	New Patient Population	ELIQUIS (APIXABAN)	BRISTOL MYERS SQUIBB CO	P	4/17/2025
NDA 202155	40	New Dosing Regimen	ELIQUIS (APIXABAN)	BRISTOL MYERS SQUIBB CO	P	4/17/2025
NDA 214998	10	New Dosing Regimen	CAMZYOS (MAVACAMTEN)	BRISTOL MYERS SQUIBB CO	S	4/17/2025
NDA 211675	25	New Indication	RINVOQ (UPADACITINIB)	ABBVIE INC	S	4/28/2025
NDA 020899	25	New Indication	OPTISON (PERFLUTREN PROTEIN TYPE A MICROSPHERE)	GE HEALTHCARE INC	S	5/9/2025
NDA 217242	5	New Indication	ZORYVE (ROFLUMILAST)	ARCUTIS BIOTHERAPEUTICS INC	S	5/22/2025
NDA 214410	8	New Dosing Regimen	XOFLUZA (BALOXAVIR MARBOXIL)	GENENTECH INC	S	5/30/2025
NDA 212099	8	New Indication	NUBEQA (DAROLUTAMIDE)	BAYER HEALTHCARE PHARMACEUTICALS INC	S	6/3/2025
NDA 209394	19	New Indication	MAVYRET (GLECAPREVIR AND PIBRENTASVIR)	ABBVIE INC	P	6/10/2025
NDA 209449	18	New Indication	NITYR (NITISINONE) AND HARLIKU (NITISINONE)	CYCLE PHARMACEUTICALS LTD	P	6/10/2025

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NDA 215110	5	New Indication	MAVYRET (GLECAPREVIR AND PIBRENTASVIR)	ABBVIE INC	P	6/10/2025
NDA 211651	13	New Indication	TALZENNA (TALAZOPARIB)	PFIZER INC	P	6/12/2025
NDA 217439	3	New Indication	TALZENNA (TALAZOPARIB)	PFIZER INC	P	6/12/2025
NDA 203094	17	New Patient Population	TYBOST (COBICISTAT)	GILEAD SCIENCES INC	S	6/20/2025
NDA 203094	18	New Patient Population	TYBOST (COBICISTAT)	GILEAD SCIENCES INC	S	6/20/2025
NDA 208215	23	New Patient Population	DESCOVY (EMTRICITABINE AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	6/20/2025
NDA 207958	27	New Route Of Administration	LEVETIRACETAM	APRECIA PHARMACEUTICALS LLC	S	6/27/2025
NDA 211962	17	New Patient Population	TYZAVAN (VANCOMYCIN)	HIKMA PHARMACEUTICALS USA INC	S	6/27/2025
NDA 212801	4	New Dosing Regimen	ISTURISA (OSILODROSTAT)	RECORDATI RARE DISEASES INC	S	7/3/2025
NDA 215341	9	New Indication	KERENDIA (FINERENONE)	BAYER HEALTHCARE PHARMACEUTICALS INC	P	7/11/2025
NDA 017558	68	New Indication	ROBINUL (GLYCOPYRROLATE)	HIKMA PHARMACEUTICALS USA INC	S	7/16/2025
NDA 210997	8	New Patient Population	GLYRX-PF (GLYCOPYRROLATE)	EXELA PHARMA SCIENCES LLC	S	7/16/2025
NDA 214919	2	New Patient Population	GLYCOPYRROLATE	FRESENIUS KABI USA LLC	S	7/16/2025
NDA 022306	8	New Dosing Regimen	SOTALOL HYDROCHLORIDE	ALTATHERA PHARMACEUTICALS LLC	S	7/23/2025
NDA 205437	14	New Patient Population	OTEZLA (APREMILAST)	AMGEN INC	S	7/23/2025
NDA 210238	10	New Indication	DOPTELET (AVATROMBOPAG)	AKARX INC	S	7/24/2025
NDA 204384	20	New Patient Population	SIRTURO (BEDAQUILINE)	JANSSEN RESEARCH AND DEVELOPMENT LLC	P	7/28/2025
NDA 215014	11	New Indication	EMPAVELI (PEGCETACOPLAN)	APELLIS PHARMACEUTICALS INC	P	7/28/2025
NDA 210251	23	New Patient Population	BIKTARVY (BICTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	7/30/2025
NDA 214012	16	New Indication	LEQVIO (INCLISIRAN)	NOVARTIS PHARMACEUTICALS CORP	S	7/31/2025
NDA 216099	5	New Indication	PHYRAGO (DASATINIB)	HANDA THERAPEUTICS LLC	S	8/1/2025
NDA 215256	24	New Indication	WEGOVY (SEMAGLUTIDE)	NOVO NORDISK INC	P	8/15/2025
NDA 212045	5	Manufacturing Change With Clinical Data	KLOXXADO (NALOXONE HCL)	HIKMA PHARMACEUTICALS USA INC	S	8/25/2025
NDA 217700	2	New Patient Population	OJEMDA (TOVORAFENIB)	DAY ONE BIOPHARMACEUTICALS INC	S	8/27/2025
NDA 218033	2	New Patient Population	OJEMDA (TOVORAFENIB)	DAY ONE BIOPHARMACEUTICALS INC	S	8/27/2025
NDA 217684	2	New Route Of Administration	VIGAFYDE (VIGABATRIN)	PYROS PHARMACEUTICALS INC	S	9/3/2025
NDA 213756	5	New Indication	KOSELUGO (SELUMETINIB)	ASTRAZENECA PHARMACEUTICALS LP	P	9/10/2025
NDA 215309	7	New Patient Population	OPZELURA (RUXOLITINIB)	INCYTE CORP	S	9/18/2025
NDA 213702	11	New Indication	ZEPZELCA (LURBINECTEDIN)	JAZZ PHARMACEUTICALS IRELAND LTD	P	10/2/2025
NDA 210661	4	New Indication	AXTLE (PEMETREXED) FOR INJECTION	AVYXA HOLDINGS LLC	S	10/3/2025
NDA 215985	12	New Patient Population	ROFLUMILAST	ARCUTIS BIOTHERAPEUTICS INC	S	10/4/2025
NDA 018735	75	New Indication	ISOVUE (IOPAMIDOL)	BRACCO DIAGNOSTICS INC	S	10/10/2025
NDA 213586	8	New Indication	UZEDY (RISPERIDONE)	TEVA NEUROSCIENCE INC	S	10/10/2025
NDA 214860	7	New Indication	OLPRUVA (SODIUM PHENYL BUTYRATE)	ACER THERAPEUTICS INC	S	10/10/2025
NDA 203214	39	New Indication	XELJANZ (TOFACITINIB)	PF PRISM CV	S	10/16/2025
NDA 213082	11	New Indication	TOFACITINIB	PFIZER INC	S	10/16/2025
NDA 215904	11	New Dosing Regimen	ZTALMY (GANAXOLONE)	MARINUS PHARMACEUTICALS INC	S	10/16/2025
NDA 213051	24	New Indication	RYBELSUS (SEMAGLUTIDE) TABLETS	NOVO NORDISK INC	S	10/17/2025
NDA 218944	3	New Indication	REVUFORJ (REVUMENIB)	SYNDAX PHARMACEUTICALS INC	P	10/24/2025
NDA 202811	22	New Patient Population	LINZESS (LINACLOTIDE)	ABBVIE INC	P	11/4/2025
NDA 209500	16	New Indication	CAPLYTA (LUMATEPERONE)	INTRA-CELLULAR THERAPIES INC	S	11/5/2025
NDA 213756	6	New Indication	KOSELUGO (SELUMETINIB)	ASTRAZENECA PHARMACEUTICALS LP	S	11/19/2025
NDA 215390	2	New Indication	IGALMI (DEXMEDETOMIDINE)	BIOXCEL THERAPEUTICS INC	S	11/19/2025
NDA 211616	24	New Indication	NEXLETOL (BEMPEDOIC ACID)	ESPERION THERAPEUTICS INC	S	11/21/2025
NDA 211617	29	New Indication	NEXLIZET (BEMPEDOIC ACID AND EZETIMIBE)	ESPERION THERAPEUTICS INC	S	11/21/2025

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NDA 215256	23	New Indication	SEMAGLUTIDE	NOVO NORDISK INC	S	11/21/2025
NDA 216059	5	New Indication	JAYPIRCA (PIRTOBRUTINIB)	LOXO ONCOLOGY INC	S	12/2/2025
NDA 212819	8	New Patient Population	RECARBRIO (IMIPENEM/CILASTATIN/RELEBACTAM)	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	S	12/9/2025
NDA 218230	1	New Indication	BLUJEP A (GEPOTIDACIN)	GLAXOSMITHKLINE LLC	P	12/11/2025
NDA 216793	1	New Indication	AKEEGA (NIRAPARIB AND ABIRATERONE ACETATE)	JANSSEN BIOTECH INC	P	12/12/2025
NDA 022526	13	New Indication	ADDYII (FLIBANSERIN)	SPROUT PHARMACEUTICALS INC	P	12/13/2025
NDA 209115	14	Accelerated Approval Confirmatory Study	RUBRACA (RUCAPARIB)	PHARMAAND GMBH	S	12/17/2025
NDA 209115	15	New Patient Population	RUBRACA (RUCAPARIB)	PHARMAAND GMBH	S	12/17/2025
NDA 204370	14	New Dosing Regimen	VRAYLAR (CARIPRAZINE)	ABBVIE INC	S	12/18/2025
NDA 204370	15	New Patient Population	VRAYLAR (CARIPRAZINE)	ABBVIE INC	P	12/18/2025
NDA 204370	16	New Patient Population	VRAYLAR (CARIPRAZINE)	ABBVIE INC	P	12/18/2025
NDA 204370	17	New Patient Population	VRAYLAR (CARIPRAZINE)	ABBVIE INC	P	12/18/2025
NDA 212320	19	New Patient Population	ACCRUFER (FERRIC MALTOL)	SHIELD TX UK LTD	P	12/19/2025
NDA 215866	39	New Patient Population	MOUNJARO (TIRZEPATIDE) INJECTION, AND MOUNJARO KWIKPEN (TIRZEPATIDE) INJECTION	ELI LILLY AND CO	P	12/19/2025
NDA 209988	4	New Patient Population	FUROSCIX INFUSOR (FUROSEMIDE)	SCPHARMACEUTICALS INC	S	12/22/2025
NDA 216196	3	New Indication	PYRUKYND (MITAPIVAT) TABLET, AND AQVESME (MITAPIVAT) TABLETS	AGIOS PHARMACEUTICALS INC	S	12/23/2025

**NDA Efficacy Supplements Approved (SE8)**

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
NDA 206947	33	Labeling Change With Clinical Data	LENVIMA (LENVATINIB MESYLATE)	EISAI INC	P	1/29/2025
NDA 217225	1	Labeling Change With Clinical Data	IZERVAY (AVACINCAPTAD PEGOL)	ASTELLAS PHARMA US INC	S	2/12/2025
NDA 203214	38	Labeling Change With Clinical Data	XELJANZ (TOFACITINIB)	PF PRISM CV	S	2/21/2025
NDA 208246	25	Labeling Change With Clinical Data	XELJANZ XR (TOFACITINIB)	PFIZER INC	S	2/21/2025
NDA 209819	31	Labeling Change With Clinical Data	SUBLOCADE (BUPRENORPHINE)	INDIVIOR INC	P	2/21/2025
NDA 213082	10	Labeling Change With Clinical Data	TOFACITINIB	PFIZER INC	S	2/21/2025
NDA 204410	29	Labeling Change With Clinical Data	OPSUMIT (MACITENTAN)	ACTELION PHARMACEUTICALS US INC	P	2/28/2025
NDA 202806	33	Labeling Change With Clinical Data	TAFINLAR (DABRAFENIB)	NOVARTIS PHARMACEUTICALS CORP	S	3/7/2025
NDA 204114	34	Labeling Change With Clinical Data	MEKINIST (TRAMETINIB)	NOVARTIS PHARMACEUTICALS CORP	S	3/7/2025
NDA 217513	5	Labeling Change With Clinical Data	MEKINIST (TRAMETINIB)	NOVARTIS PHARMACEUTICALS CORP	S	3/7/2025
NDA 217514	6	Labeling Change With Clinical Data	TAFINLAR (DABRAFENIB)	NOVARTIS PHARMACEUTICALS CORP	S	3/7/2025
NDA 210496	18	Labeling Change With Clinical Data	BRAFTOVI (ENCORAFENIB)	ARRAY BIOPHARMA INC	S	3/12/2025

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NDA 210498	11	Labeling Change With Clinical Data	MEKTOVI (BINIMETINIB)	ARRAY BIOPHARMA INC	S	3/12/2025
NDA 215559	2	Labeling Change With Clinical Data	SOHONOS (PALOVAROTENE)	IPSEN BIOPHARMACEUTICALS INC	S	3/13/2025
NDA 215842	2	Labeling Change With Clinical Data	RIVFLOZA (NEDOSIRAN)	NOVO NORDISK INC	S	3/27/2025
NDA 215842	2	Labeling Change With Clinical Data	RIVFLOZA (NEDOSIRAN)	NOVO NORDISK INC	S	3/27/2025
NDA 210861	12	Labeling Change With Clinical Data	VITRAKVI (LAROTRECTINIB)	BAYER HEALTHCARE PHARMACEUTICALS INC	S	4/9/2025
NDA 211710	10	Labeling Change With Clinical Data	VITRAKVI (LAROTRECTINIB)	BAYER HEALTHCARE PHARMACEUTICALS INC	S	4/9/2025
NDA 215383	10	Labeling Change With Clinical Data	WELIREG (BELZUTIFAN)	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	S	4/15/2025
NDA 207103	20	Labeling Change With Clinical Data	IBRANCE (PALBOCICLIB)	PFIZER INC	S	4/23/2025
NDA 212436	8	Labeling Change With Clinical Data	IBRANCE (PALBOCICLIB)	PFIZER INC	S	4/23/2025
NDA 205422	14	Labeling Change With Clinical Data	REXULTI (BREPPIRAZOLE)	OTSUKA PHARMACEUTICAL CO LTD	S	5/9/2025
NDA 215383	12	Labeling Change With Clinical Data	WELIREG (BELZUTIFAN)	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	P	5/14/2025
NDA 020263	56	Labeling Change With Clinical Data	LUPRON DEPOT PED (LEUPROLIDE ACETATE)	ABBVIE ENDOCRINE INC	S	5/22/2025
NDA 202714	36	Labeling Change With Clinical Data	KYPROLIS (CARFILZOMIB)	ONYX PHARMACEUTICALS INC A WHOLLY OWNED SUB OF AMGEN INC	P	5/22/2025
NDA 203188	41	Labeling Change With Clinical Data	KALYDECO (IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	5/22/2025
NDA 207925	19	Labeling Change With Clinical Data	KALYDECO (IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	5/22/2025
NDA 210854	23	Labeling Change With Clinical Data	XOFLUZA (BALOXAVIR MARBOXIL)	GENENTECH INC	S	5/30/2025
NDA 214375	1	Labeling Change With Clinical Data	XENOVIEW (HYPERPOLARIZED 129-XE)	POLAREAN INC	S	5/30/2025
NDA 020862	33	Labeling Change With Clinical Data	HECTOROL (DOXERCALCIFEROL)	SANOFI GENZYME	S	6/11/2025
NDA 214876	3	Labeling Change With Clinical Data	ZEJULA (NIRAPARIB)	GLAXOSMITHKLINE LLC	S	6/18/2025
NDA 208215	25	Labeling Change With Clinical Data	DESCOVY (EMTRICITABINE AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	6/20/2025
NDA 202008	46	Labeling Change With Clinical Data	AMYVID ([18F]-FLORBETAPIR)	AVID RADIOPHARMACEUTICALS INC	S	6/23/2025
NDA 203137	24	Labeling Change With Clinical Data	VIZAMYL ([18F]-FLUTEMETAMOL)	GE HEALTHCARE INC	S	6/23/2025
NDA 204677	24	Labeling Change With Clinical Data	NEURACEQ ([18F]-FLORBETABEN)	LIFE MOLECULAR IMAGING LTD	U	6/23/2025
NDA 210166	4	Labeling Change With Clinical Data	MOTTEGRITY (PRUCALOPRIDE SUCCINATE)	TAKEDA PHARMACEUTICALS USA INC	S	7/10/2025
NDA 219008	2	Labeling Change With Clinical Data	LAZCLUZE (LAZERTINIB)	JANSSEN BIOTECH INC	S	8/14/2025
NDA 216403	5	Labeling Change With Clinical Data	FILSPARI (SPARSENTAN)	TRAVERE THERAPEUTICS INC	S	8/27/2025

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NDA 208692	18	Labeling Change With Clinical Data	CABOMETYX (CABOZANTINIB)	EXELIXIS INC	S	9/10/2025
NDA 214070	1	Labeling Change With Clinical Data	AIRSUPRA (ALBUTEROL AND BUDESONIDE)	ASTRAZENECA PHARMACEUTICALS LP	S	9/15/2025
NDA 207103	23	Labeling Change With Clinical Data	IBRANCE (PALBOCICLIB)	PFIZER INC	S	9/16/2025
NDA 212436	11	Labeling Change With Clinical Data	IBRANCE (PALBOCICLIB)	PFIZER INC	S	9/16/2025
NDA 203469	38	Labeling Change With Clinical Data	ICLUSIG (PONATINIB)	TAKEDA PHARMACEUTICALS USA INC	S	10/10/2025
NDA 211675	28	Labeling Change With Clinical Data	RINVOQ (UPADACITINIB)	ABBVIE INC	S	10/10/2025
NDA 213246	15	Labeling Change With Clinical Data	RETEVMO (SELPERCATINIB)	ELI LILLY AND CO	P	11/20/2025
NDA 218160	6	Labeling Change With Clinical Data	RETEVMO (SELPERCATINIB)	ELI LILLY AND CO	P	11/20/2025
NDA 215596	7	Labeling Change With Clinical Data	LIVTENCITY (MARIBAVIR)	TAKEDA PHARMACEUTICALS USA INC	S	11/21/2025
NDA 215358	12	Labeling Change With Clinical Data	SCEMBLIX (ASCIMINIB)	NOVARTIS PHARMACEUTICALS CORP	S	11/25/2025
NDA 215498	5	Labeling Change With Clinical Data	BYLVAY (ODEVIXIBAT)	IPSEN BIOPHARMACEUTICALS INC	S	12/19/2025

**BLA Efficacy Supplements Approved**

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE	PROPER NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
BLA 761279	2	New Indication	OMVOH (MIRIKIZUMAB-MRKZ)	ELI LILLY AND COMPANY	S	1/15/2025
BLA 761279	3	Labeling Change With Clinical Data	OMVOH (MIRIKIZUMAB-MRKZ)	ELI LILLY AND COMPANY	S	1/15/2025
BLA 125147	213	New Indication	VECTIBIX (PANITUMUMAB)	AMGEN INC.	P	1/16/2025
BLA 761036	51	Labeling Change With Clinical Data	DARZALEX (DARATUMUMAB)	JANSSEN BIOTECH, INC.	S	1/23/2025
BLA 761269	5	New Indication	LEQEMBI (LECANEMAB-IRMB)	EISAI, INCORPORATED	S	1/24/2025
BLA 125477	48	Labeling Change With Clinical Data	CYRAMZA (RAMUCIRUMAB)	ELI LILLY AND COMPANY	S	1/27/2025
BLA 761139	32	New Indication		DAIICHI SANKYO, INC.	P	1/27/2025
BLA 125377	132	New Dosing Regimen	YERVOY (IPILIMUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	1/28/2025
BLA 125514	172	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	P	1/28/2025
BLA 761197	6	New Indication	SUSVIMO (RANIBIZUMAB)	GENENTECH, INC.	S	2/3/2025
BLA 125388	108	New Indication	ADCETRIS (BRENTUXIMAB VEDOTIN)	SEAGEN INC.	S	2/11/2025
BLA 103909	5197	New Indication	TNKASE (TENECTEPLASE)	GENENTECH, INC.	S	2/28/2025
BLA 125166	448	New Patient Population	SOLIRIS (ECULIZUMAB)	ALEXION PHARMACEUTICALS, INC.	P	2/28/2025
BLA 761069	51	Labeling Change With Clinical Data	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	S	2/28/2025
BLA 125514	170	Accelerated Approval Confirmatory Study	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	3/19/2025
BLA 761061	24	New Indication	TREMFYA (GUSELKUMAB)	JANSSEN BIOTECH, INC.	P	3/20/2025

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BLA 761061	24	New Indication	TREMFYA (GUSELKUMAB) INJECTION AND TREMFYA PEN (GUSELKUMAB) INJECTION	JANSSEN BIOTECH, INC.	P	3/20/2025
BLA 761061	24	New Indication	TREMFYA PEN (GUSELKUMAB) INJECTION	JANSSEN BIOTECH, INC.	P	3/20/2025
BLA 761069	50	New Indication	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	P	3/28/2025
BLA 761142	3	New Indication	UPLIZNA (INEBILIZUMAB)	HORIZON THERAPEUTICS IRELAND DAC	P	4/3/2025
BLA 125477	49	Labeling Change With Clinical Data	CYRAMZA (RAMUCIRUMAB)	ELI LILLY AND COMPANY	P	4/7/2025
BLA 125377	135	Accelerated Approval Confirmatory Study	YERVOY (IPILIMUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	4/8/2025
BLA 125554	132	Accelerated Approval Confirmatory Study	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	4/8/2025
BLA 761036	54	Labeling Change With Clinical Data	DARZALEX (DARATUMUMAB)	JANSSEN BIOTECH, INC.	S	4/10/2025
BLA 761304	8	New Dosing Regimen	VYVGART HYTRULO (EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC)	ARGENX BV	S	4/10/2025
BLA 125377	133	Accelerated Approval Confirmatory Study	YERVOY (IPILIMUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	4/11/2025
BLA 125554	129	Accelerated Approval Confirmatory Study	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	4/11/2025
BLA 761055	51	New Patient Population	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	S	4/17/2025
BLA 125514	174	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MSD INTERNATIONAL BUSINESS GMBH	S	4/21/2025
BLA 761232	2	New Dosing Regimen	TEVIMBRA (TISLELIZUMAB-JSGR)	BEONE MEDICINES USA, INC.	S	4/22/2025
BLA 761232	3	New Dosing Regimen	TEVIMBRA (TISLELIZUMAB-JSGR)	BEONE MEDICINES USA, INC.	S	4/22/2025
BLA 761232	5	New Dosing Regimen	TEVIMBRA (TISLELIZUMAB-JSGR)	BEONE MEDICINES USA, INC.	S	4/22/2025
BLA 761232	6	New Dosing Regimen	TEVIMBRA (TISLELIZUMAB-JSGR)	BEONE MEDICINES USA, INC.	S	4/22/2025
BLA 761232	11	New Dosing Regimen	TEVIMBRA (TISLELIZUMAB-JSGR)	BEONE MEDICINES USA, INC.	S	4/22/2025
BLA 761232	12	New Dosing Regimen	TEVIMBRA (TISLELIZUMAB-JSGR)	BEONE MEDICINES USA, INC.	S	4/22/2025
BLA 125427	121	Labeling Change With Clinical Data	KADCYLA (ADO-TRASTUZUMAB EMTANSINE)	GENENTECH, INC.	S	5/14/2025
BLA 761334	4	New Indication	ZYNYZ (RETIFANLIMAB-DLWR)	INCYTE CORPORATION	P	5/15/2025
BLA 761197	7	New Indication	SUSVIMO (RANIBIZUMAB)	GENENTECH, INC.	S	5/21/2025
BLA 125320	219	Labeling Change With Clinical Data	PROLIA (DENOSUMAB)	AMGEN INC.	S	5/22/2025
BLA 125320	219	Labeling Change With Clinical Data	XGEVA AND PROLIA (DENOSUMAB)	AMGEN INC.	S	5/22/2025
BLA 125320	219	Labeling Change With Clinical Data	XGEVA (DENOSUMAB)	AMGEN INC.	S	5/22/2025
BLA 125514	182	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MSD INTERNATIONAL BUSINESS GMBH	P	5/22/2025
BLA 125526	7	Labeling Change With Clinical Data	NUCALA (MEPOLIZUMAB)	GLAXOSMITHKLINE LLC	S	5/22/2025
BLA 125377	136	New Indication	YERVOY (IPILIMUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	5/23/2025
BLA 125554	133	New Indication	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	5/23/2025
BLA 761244	4	New Patient Population	SPEVIGO (SPESOLIMAB-SBZO)	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	S	5/28/2025
BLA 125514	173	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MSD INTERNATIONAL BUSINESS GMBH	S	6/3/2025
BLA 125514	183	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MSD INTERNATIONAL BUSINESS GMBH	S	6/6/2025
BLA 761365	3	Labeling Change With Clinical Data	VYLOY (ZOLBETUXIMAB-CLZB)	ASTELLAS PHARMA US, INC.	S	6/6/2025

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BLA 125514	180	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MSD INTERNATIONAL BUSINESS GMBH	P	6/12/2025
BLA 761055	70		DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	P	6/18/2025
BLA 761163	13	New Indication	MONJUVI (TAFASITAMAB-CXIX)	INCYTE CORPORATION	P	6/18/2025
BLA 761043	34	Labeling Change With Clinical Data	BENLYSTA (BELIMUMAB)	GLAXOSMITHKLINE LLC	S	6/20/2025
BLA 761107	18	New Indication	GAMIFANT (EMAPALUMAB-LZSG)	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	P	6/27/2025
BLA 761248	4	New Dosing Regimen	KISUNLA (DONANEMAB-AZBT)	ELI LILLY AND COMPANY	P	7/1/2025
BLA 761345	3	New Dosing Regimen	ELREXFIO (ELRANATAMAB-BCMM)	PFIZER INC.	S	7/10/2025
BLA 125514	178	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MSD INTERNATIONAL BUSINESS GMBH	S	7/24/2025
BLA 761177	8	New Patient Population	SKYTROFA (LONAPEG SOMATROPIN-TCGD)	ASCENDIS PHARMA ENDOCRINOLOGY DIVISION A/S	S	7/25/2025
BLA 761089	31	New Patient Population	AJOVY (FREMANEZUMAB-VFRM)	TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.	P	8/5/2025
BLA 125276	149	Labeling Change With Clinical Data	ACTEMRA (TOCILIZUMAB)	GENENTECH, INC.	S	8/8/2025
BLA 761210	9	Labeling Change With Clinical Data	RYBREVANT (AMIVANTAMAB-VMJW)	JANSSEN BIOTECH, INC.	S	8/14/2025
BLA 761119	10	Manufacturing Change With Clinical Data	VYEPTI (EPTINEZUMAB-JJMR)	LUNDBECK SEATTLE BIOPHARMACEUTICALS, INC.	S	8/18/2025
BLA 761105	39	Manufacturing Change With Clinical Data	SKYRIZI (RISANKIZUMAB-RZAA)	ABBVIE INC.	S	9/3/2025
BLA 761262	11	Manufacturing Change With Clinical Data	SKYRIZI (RISANKIZUMAB-RZAA)	ABBVIE INC.	S	9/3/2025
BLA 761061	26	New Indication	TREMFYA (GUSELKUMAB)	JANSSEN BIOTECH, INC.	S	9/19/2025
BLA 761181	2	New Patient Population		REGENERON PHARMACEUTICALS, INC.	P	9/25/2025
BLA 761061	28	New Patient Population	TREMFYA (GUSELKUMAB)	JANSSEN BIOTECH, INC.	S	9/26/2025
BLA 761061	29	New Indication	TREMFYA (GUSELKUMAB)	JANSSEN BIOTECH, INC.	S	9/26/2025
BLA 761034	58	New Indication	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	10/2/2025
BLA 761347	3	New Indication	TECENTRIQ HYBREZA (ATEZOLIZUMAB AND HYALURONIDASE-TQJS)	GENENTECH, INC.	P	10/2/2025
BLA 125289	157	New Indication	SIMPONI (GOLIMUMAB)	JANSSEN BIOTECH, INC.	S	10/7/2025
BLA 125289	157	New Indication	SIMPONI (GOLIMUMAB) INJECTION	JANSSEN BIOTECH, INC.	S	10/7/2025
BLA 761097	30	New Indication	LIBTAYO (CEMPIIMAB-RWLC)	REGENERON PHARMACEUTICALS, INC.	P	10/8/2025
BLA 125559	47	New Indication	PRALUENT (ALIROCUMAB)	REGENERON PHARMACEUTICALS, INC.	S	10/9/2025
BLA 125486	37	New Indication	GAZYVA (OBINUTUZUMAB)	GENENTECH, INC.	S	10/17/2025
BLA 125486	38	Labeling Change With Clinical Data	GAZYVA (OBINUTUZUMAB)	GENENTECH, INC.	S	10/17/2025
BLA 761195	12	Labeling Change With Clinical Data	VYVGART (EFGARTIGIMOD ALFA)	ARGENX BV	S	10/17/2025
BLA 761224	6	New Indication	TEZSPIRE (TEZPELUMAB-EKKO)	ASTRAZENECA AB	S	10/17/2025
BLA 761304	10	Labeling Change With Clinical Data	VYVGART HYTRULO (EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC)	ARGENX BV	S	10/17/2025
BLA 761328	12	Labeling Change With Clinical Data	BEYFORTUS (NIRSEVIMAB-ALIP)	SANOVI PASTEUR INC.	S	10/20/2025
BLA 761119	11	Labeling Change With Clinical Data	VYEPTI (EPTINEZUMAB-JJMR)	LUNDBECK SEATTLE BIOPHARMACEUTICALS, INC.	S	10/22/2025
BLA 761363	7	Labeling Change With Clinical Data	WINREVAIR (SOTATERCEPT-CSRK)	MERCK SHARP & DOHME LLC	P	10/24/2025
BLA 761381	1	New Indication	OPDIVO QVANTIG (NIVOLUMAB HYALURONIDASE)	BRISTOL-MYERS SQUIBB COMPANY	S	10/27/2025
BLA 761381	1	New Indication	OPDIVO QVANTIG (NIVOLUMAB HYALURONIDASE-NVHY)	BRISTOL-MYERS SQUIBB COMPANY	S	10/27/2025
BLA 761381	2	New Indication	OPDIVO QVANTIG (NIVOLUMAB HYALURONIDASE)	BRISTOL-MYERS SQUIBB COMPANY	S	10/27/2025

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BLA 761381	2	New Indication	OPDIVO QVANTIG (NIVOLUMAB HYALURONIDASE-NVHY)	BRISTOL-MYERS SQUIBB COMPANY	S	10/27/2025
BLA 761097	32	Labeling Change With Clinical Data	LIBTAYO (CEMPLIMAB-RWLC)	REGENERON PHARMACEUTICALS, INC.	P	10/29/2025
BLA 761145	29	New Indication	DARZALEX FASPRO (DARATUMUMAB AND HYALURONIDASE-FIHJ)	JANSSEN BIOTECH, INC.	S	11/6/2025
BLA 761324	9	Accelerated Approval Confirmatory Study	EPKINLY (EPCORITAMAB-BYSP)	GENMAB US, INC.	P	11/18/2025
BLA 761145	32	Accelerated Approval Confirmatory Study	DARZALEX FASPRO (DARATUMUMAB AND HYALURONIDASE-FIHJ)	JANSSEN BIOTECH, INC.	S	11/19/2025
BLA 761344	1		IMDELLTRA (TARLATAMAB-DLLE)	AMGEN INC.	P	11/19/2025
BLA 761355	10	New Indication	EYLEA HD (AFLIBERCEPT)	REGENERON PHARMACEUTICALS, INC.	P	11/19/2025
BLA 125514	188	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MSD INTERNATIONAL BUSINESS GMBH	P	11/21/2025
BLA 761137	32	New Indication	PADCEV (ENFORTUMAB VEDOTIN-EJFV)	ASTELLAS PHARMA US, INC.	P	11/21/2025
BLA 761297	1	Labeling Change With Clinical Data	UNLOXCYT (COSIBELIMAB-IPDL)	CHECKPOINT THERAPEUTICS, INC.	S	11/21/2025
BLA 761467	1	New Indication	KEYTRUDA QLEX (PEMBROLIZUMAB AND BERAHYALURONIDASE ALFA-PMMPH) INJECTION	MERCK SHARP & DOHME LLC	P	11/21/2025
BLA 761347	4	New Dosing Regimen	TECENTRIQ HYBREZA (ATEZOLIZUMAB AND HYALURONIDASE-TQJS)	GENENTECH, INC.	P	11/24/2025
BLA 761381	5	New Patient Population	OPDIVO QVANTIG (NIVOLUMAB HYALURONIDASE)	BRISTOL-MYERS SQUIBB COMPANY	S	11/24/2025
BLA 761381	5	New Patient Population	OPDIVO QVANTIG (NIVOLUMAB HYALURONIDASE-NVHY)	BRISTOL-MYERS SQUIBB COMPANY	S	11/24/2025
BLA 761069	52	New Indication	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	P	11/25/2025
BLA 761232	9	New Dosing Regimen	TEVIMBRA (TISLELIZUMAB-JSGR)	BEONE MEDICINES USA, INC.	S	12/9/2025
BLA 761232	10	New Dosing Regimen	TEVIMBRA (TISLELIZUMAB-JSGR)	BEONE MEDICINES USA, INC.	S	12/9/2025
BLA 761232	13	New Dosing Regimen	TEVIMBRA (TISLELIZUMAB-JSGR)	BEONE MEDICINES USA, INC.	S	12/9/2025
BLA 761142	4	New Indication	UPLIZNA (INEBILIZUMAB)	HORIZON THERAPEUTICS IRELAND DAC	S	12/11/2025
BLA 761067	24	Labeling Change With Clinical Data	ILUMYA (TILDRAKIZUMAB-ASMN)	SUN PHARMACEUTICAL INDUSTRIES LIMITED	S	12/12/2025
BLA 761139	38	New Indication		DAIICHI SANKYO, INC.	P	12/15/2025
BLA 761334	5	Accelerated Approval Confirmatory Study	ZYNYZ (RETIFANLIMAB-DLWR)	INCYTE CORPORATION	S	12/17/2025
BLA 761263	6	New Indication	LUNSUMIO (MOSUNETUZUMAB-AXGB)	GENENTECH, INC.	S	12/19/2025
BLA 761263	6	New Indication	LUNSUMIO (MOSUNETUZUMAB-AXGB) INJECTION AND LUNSUMIO VELO (MOSUNETUZUMAB-AXGB) INJECTION	GENENTECH, INC.	S	12/19/2025
BLA 761112	18	New Patient Population	CABLIVI (CAPLACIZUMAB-YHDP)	ABLYNX NV	P	12/23/2025