

**CY 2023 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year Approvals
As of December 31, 2023**

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Selection Criteria:
User Response: Start Date: 1/1/2023 End Date: 12/31/2023
Sort Order: Approval Date

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
NDA 213217	7	New Indication	BRUKINSA (ZANUBRUTINIB)	BEIGENE USA INC	S	1/19/2023
NDA 213411	4	New Indication	TUKYSA (TUCATINIB)	SEAGEN INC	P	1/19/2023
NDA 208288	4	Manufacturing Change With Clinical Data	SOLUPREP S (CHLORHEXIDINE GLUCONATE AND ISOPROPYL ALCOHOL)	3M HEALTH CARE INFECTION PREVENTION DIV	S	1/20/2023
NDA 021845	25	New Indication	REVATIO (SILDENAFIL CITRATE)	VIATRIS SPECIALTY LLC	S	1/31/2023
NDA 206111	33	New Indication	SYNJARDY (EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	2/6/2023
NDA 208658	21	New Indication	SYNJARDY XR (EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	2/6/2023
NDA 207131 (1)	9	New Patient Population	CEFAZOLIN	BAXTER HEALTHCARE CORP	S	2/15/2023
NDA 020438	8	Manufacturing Change With Clinical Data	VESANOID (TRETINOIN)	CHEPLAPHARM ARZNEIMITTEL GMBH	P	2/21/2023
NDA 213645	1	New Dosing Regimen	DAPZURA RT (DAPTOMYCIN)	BAXTER HEALTHCARE CORP	S	2/27/2023
NDA 205054	4	New Indication	LUTRATE DEPOT (LEUPROLIDE ACETATE)	INVAGEN PHARMACEUTICALS INC	S	2/28/2023
NDA 208716	10	New Indication	VERZENIO (ABEMACICLIB)	ELI LILLY AND CO	S	3/3/2023
NDA 208716	11	New Indication	VERZENIO (ABEMACICLIB)	ELI LILLY AND CO	S	3/3/2023
NDA 214032	1	New Patient Population	ILLUCCIX (KIT FOR THE PREPARATION OF GA-68 PSMA-11)	TELIX PHARMACEUTICALS US INC	S	3/15/2023
NDA 202806	25	New Patient Population	TAFINLAR (DABRAFENIB)	NOVARTIS PHARMACEUTICALS CORP	P	3/16/2023
NDA 204114	25	New Patient Population	MEKINIST (TRAMETINIB)	NOVARTIS PHARMACEUTICALS CORP	P	3/16/2023
NDA 214028	2	New Dosing Regimen	VUIITY (PILOCARPINE HYDROCHLORIDE, 1.25% OPHTHALMIC SOLUTION)	ABBVIE INC	S	3/28/2023
NDA 208411	6	Rx To OTC Switch	NARCAN (NALOXONE HYDROCHLORIDE)	EMERGENT OPERATIONS IRELAND LTD	P	3/29/2023
NDA 207695	12	New Dosing Regimen	EUCRISA (CRISABOROLE)	ANACOR PHARMACEUTICALS INC	S	4/3/2023
NDA 020263	53	New Dosing Regimen	LUPRON DEPOT PED (LEUPROLIDE ACETATE)	ABBVIE ENDOCRINE INC	S	4/14/2023
NDA 215206	4	New Indication	QULIPTA (ATOGEPAANT)	ABBVIE INC	S	4/17/2023
NDA 022253	50	New Dosing Regimen	VIMPAT (LACOSAMIDE)	UCB INC	S	4/28/2023
NDA 022254	40	New Dosing Regimen	VIMPAT (LACOSAMIDE)	UCB INC	S	4/28/2023
NDA 022255	32	New Dosing Regimen	VIMPAT (LACOSAMIDE)	UCB INC	S	4/28/2023
NDA 207925	16	New Indication	KALYDECO (IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	5/3/2023
NDA 202293	26	New Indication	FARXIGA (DAPAGLIFLOZIN)	ASTRAZENECA AB	S	5/8/2023
NDA 205422	9	New Indication	REXULTI (BREPPIRAZOLE)	OTSUKA PHARMACEUTICAL CO LTD	P	5/10/2023
NDA 022348	24	New Patient Population	CALDOLOR (IBUPROFEN)	CUMBERLAND PHARMACEUTICALS INC	S	5/11/2023
NDA 021323	55	New Patient Population	LEXAPRO (ESCITALOPRAM OXALATE)	ABBVIE INC	S	5/12/2023
NDA 021365	39	New Patient Population	LEXAPRO (ESCITALOPRAM OXALATE)	ABBVIE INC	S	5/12/2023
NDA 204275	22	New Patient Population	BREO ELLIPTA (FLUTICASON FUROATE AND VILANTEROL)	GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE	P	5/12/2023
NDA 211675	15	New Indication	RINVOQ (UPADACITINIB)	ABBVIE INC	S	5/18/2023
NDA 212608	13	New Indication	AYYAKIT (AVAPRITINIB)	BLUEPRINT MEDICINES CORP	P	5/22/2023
NDA 020220	54	New Indication	ULTRAVIST (IOPROMIDE)	BAYER HEALTHCARE PHARMACEUTICALS INC	S	5/25/2023
NDA 021425	36	New Indication	ULTRAVIST (IOPROMIDE)	BAYER HEALTHCARE PHARMACEUTICALS INC	S	5/25/2023
NDA 203565	20	New Indication	INJECTAFER (FERRIC CARBOXYMALTOSE)	AMERICAN REGENT INC	S	5/31/2023
NDA 208558	25	New Indication	LYNPARZA (OLAPARIB)	ASTRAZENECA PHARMACEUTICALS LP	P	5/31/2023
NDA 213464	5	Accelerated Approval Confirmatory Study	LAMPIT (NIFURTIMOX)	BAYER HEALTHCARE PHARMACEUTICALS INC	S	6/2/2023
NDA 209939	12	New Patient Population	PREVYMIS (LETTERMOVIR)	MERCK SHARP AND DOHME LLC A SUB OF MERCK AND CO INC	P	6/5/2023
NDA 209940	11	New Patient Population	PREVYMIS (LETTERMOVIR)	MERCK SHARP AND DOHME LLC A SUB OF MERCK AND CO INC	P	6/5/2023
NDA 211580	6	New Indication	SPY AGENT GREEN (INDOCYANINE GREEN)	NOVADAQ TECHNOLOGIES ULC	S	6/5/2023
NDA 202811	21	New Indication	LINZESS (LINACLOTIDE)	ABBVIE INC	P	6/12/2023
NDA 215498	3	New Indication	BYLVAY (ODEVIXIBAT)	ALBIREO AB	P	6/13/2023
NDA 215413	2	New Patient Population	TRIUMEQ PD (ABACAVIR, DOLUTEGRAVIR, AND LAMIVUDINE)	VIIV HEALTHCARE CO	P	6/15/2023
NDA 204629	42	New Patient Population	JARDIANCE (EMPAGLIFLOZIN)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	6/20/2023
NDA 206111	38	New Patient Population	SYNJARDY (EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	6/20/2023

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NDA 211651	10	New Indication	TALZENNA (TALAZOPARIB)	PFIZER INC	P	6/20/2023
NDA 206229	13	New Indication	LILETTA (LEVONORGESTREL)	MEDICINES360	S	6/29/2023
NDA 022304	24	New Patient Population	NUCYNTA (TAPENTADOL)	COLLEGIUM PHARMACEUTICAL INC	P	7/3/2023
NDA 203794	10	New Patient Population	NUCYNTA (TAPENTADOL)	COLLEGIUM PHARMACEUTICAL INC	P	7/3/2023
NDA 017031	41	Rx To OTC Switch	OPILL (NORGESTREL)	LABORATOIRE HRA PHARMA	S	7/13/2023
NDA 021343	48	New Indication	ELIGARD (LEUPROLIDE ACETATE)	TOLMAR INC	S	7/20/2023
NDA 021379	50	New Indication	ELIGARD (LEUPROLIDE ACETATE)	TOLMAR INC	S	7/20/2023
NDA 021488	45	New Indication	ELIGARD (LEUPROLIDE ACETATE)	TOLMAR INC	S	7/20/2023
NDA 021731	47	New Indication	ELIGARD (LEUPROLIDE ACETATE)	TOLMAR INC	S	7/20/2023
NDA 215256	7	New Dosing Regimen	WEGOVY (SEMAGLUTIDE)	NOVO NORDISK INC	S	7/21/2023
NDA 207981	12	New Indication	LONSURF (TIPIRACIL HYDROCHLORIDE AND TRIFLURIDINE)	TAIHO ONCOLOGY INC	P	8/2/2023
NDA 209939	11	New Dosing Regimen	PREVYMIS (LETTERMOVIR)	MERCK SHARP AND DOHME LLC A SUB OF MERCK AND CO INC	S	8/2/2023
NDA 209940	10	New Dosing Regimen	PREVYMIS (LETTERMOVIR)	MERCK SHARP AND DOHME LLC A SUB OF MERCK AND CO INC	S	8/2/2023
NDA 208647	7	New Indication	EZALLOR (ROSUVASTATIN)	SUN PHARMACEUTICAL INDUSTRIES LTD	S	8/4/2023
NDA 208647	8	New Indication	EZALLOR (ROSUVASTATIN)	SUN PHARMACEUTICAL INDUSTRIES LTD	S	8/4/2023
NDA 208647	9	New Indication	EZALLOR (ROSUVASTATIN)	SUN PHARMACEUTICAL INDUSTRIES LTD	S	8/4/2023
NDA 208647	10	New Indication	EZALLOR (ROSUVASTATIN)	SUN PHARMACEUTICAL INDUSTRIES LTD	S	8/4/2023
NDA 208647	11	New Indication	EZALLOR (ROSUVASTATIN)	SUN PHARMACEUTICAL INDUSTRIES LTD	S	8/4/2023
NDA 209241	26		INGREZZA (VALBENAZINE)	NEUROCRINE BIOSCIENCES INC	S	8/18/2023
NDA 202806	27	New Indication	TAFINLAR (DABRAFENIB)	NOVARTIS PHARMACEUTICALS CORP	P	8/31/2023
NDA 204114	29	New Indication	MEKINIST (TRAMETINIB)	NOVARTIS PHARMACEUTICALS CORP	P	8/31/2023
NDA 202570	36	New Dosing Regimen	XALKORI (CRIZOTINIB)	PF PRISM CV	S	9/7/2023
NDA 021029	36	New Indication	TEMODAR (TEMOZOLOMIDE)	MERCK SHARP AND DOHME CORP	S	9/14/2023
NDA 021029	37	New Indication	TEMODAR (TEMOZOLOMIDE)	MERCK SHARP AND DOHME CORP	S	9/14/2023
NDA 021029	38	New Indication	TEMODAR (TEMOZOLOMIDE)	MERCK SHARP AND DOHME CORP	S	9/14/2023
NDA 022277	17	New Indication	TEMODAR (TEMOZOLOMIDE)	MERCK SHARP AND DOHME CORP	S	9/14/2023
NDA 022277	18	New Indication	TEMODAR (TEMOZOLOMIDE)	MERCK SHARP AND DOHME CORP	S	9/14/2023
NDA 022277	19	New Indication	TEMODAR (TEMOZOLOMIDE)	MERCK SHARP AND DOHME CORP	S	9/14/2023
NDA 204629	40	New Indication	JARDIANCE (EMPAGLIFLOZIN)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	9/21/2023
NDA 203341	25	New Indication	BOSULIF (BOSUTINIB)	PF PRISM CV	P	9/26/2023
NDA 205739	38	New Patient Population	VELTASSA (PATIROMER)	VIFOR PHARMA INC	S	10/2/2023
NDA 215985	2	New Patient Population	ROFLUMILAST	ARCUTIS BIOTHERAPEUTICS INC	S	10/5/2023
NDA 210496	14	New Indication	BRAFTOVI (ENCORAFENIB)	ARRAY BIOPHARMA INC	S	10/11/2023
NDA 210498	9	New Indication	MEKTOVI (BINIMETINIB)	ARRAY BIOPHARMA INC	S	10/11/2023
NDA 212725	9	New Patient Population	ROZLYTREK (ENTRECTINIB)	GENENTECH INC	P	10/20/2023
NDA 214938	2	New Patient Population	VOXZOGO (VOSORITIDE)	BIOMARIN PHARMACEUTICAL INC	S	10/20/2023
NDA 211192	11	New Indication	TIBSOVO (IVOSIDENIB)	SERVIER PHARMACEUTICALS LLC	P	10/24/2023
NDA 022496	44	New Indication	EXPAREL (BUPIVACAINE)	PACIRA PHARMACEUTICALS INC	S	11/9/2023
NDA 203415	22	New Indication	XTANDI (ENZALUTAMIDE)	ASTELLAS PHARMA US INC	P	11/16/2023
NDA 213674	10	New Indication	XTANDI (ENZALUTAMIDE)	ASTELLAS PHARMA US INC	P	11/16/2023
NDA 216059	1	New Indication	JAYPIRCA (PIRTOBRUTINIB)	LOXO ONCOLOGY INC	P	12/1/2023
NDA 207500	15	New Patient Population	CRESEMBA (ISAVUCONAZONIUM SULFATE)	ASTELLAS PHARMA US INC	P	12/8/2023
NDA 207501	13	New Patient Population	CRESEMBA (ISAVUCONAZONIUM SULFATE)	ASTELLAS PHARMA US INC	P	12/8/2023
NDA 215383	6	New Indication	WELIREG (BELZUTIFAN)	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	P	12/14/2023

NDA Efficacy Supplements Approved (SE8)

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NDA 210922	12	Labeling Change With Clinical Data	ONPATTRO (PATISIRAN)	ALNYLAM PHARMACEUTICALS INC	S	1/13/2023
NDA 211994	14	Labeling Change With Clinical Data	DOVATO (DOLUTEGRAVIR AND LAMIVUDINE)	VIIV HEALTHCARE CO	S	1/25/2023
NDA 214846	5	Labeling Change With Clinical Data	MYFEMBREE (RELUGOLIX, ESTRADIOL, NORETHINDRONE ACETATE)	MYOVANT SCIENCES GMBH	S	1/27/2023

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NDA 215014	2	Labeling Change With Clinical Data	EMPAVELI (PEGCETACOPLAN)	APELLIS PHARMACEUTICALS INC	S	2/8/2023
NDA 213871	1	Labeling Change With Clinical Data	CIBINQO (ABROCITINIB)	PFIZER INC	P	2/9/2023
NDA 204063	29	Labeling Change With Clinical Data	TECFIDERA (DIMETHYL FUMARATE)	BIOGEN INC	S	2/10/2023
NDA 211855	9	Labeling Change With Clinical Data	VUMERITY (DIOXIMEL FUMARATE)	BIOGEN INC	S	2/10/2023
NDA 205625	9	Labeling Change With Clinical Data	ARNUITY ELLIPTA (FLUTICASONE FUROATE)	GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LTD ENGLAND	S	3/1/2023
NDA 022473	16	Labeling Change With Clinical Data	REVATIO (SILDENAFIL CITRATE)	VIATRIS SPECIALTY LLC	S	3/3/2023
NDA 203109	16	Labeling Change With Clinical Data	REVATIO (SILDENAFIL CITRATE)	VIATRIS SPECIALTY LLC	S	3/3/2023
NDA 214662	4	Labeling Change With Clinical Data	LIVMARLI (MARALIXIBAT)	MIRUM PHARMACEUTICALS INC	P	3/13/2023
NDA 204168	10	Labeling Change With Clinical Data	FETZIMA (LEVOMILNACIPRAN)	ABBVIE INC	S	3/24/2023
NDA 212028	8	Labeling Change With Clinical Data	DAYVIGO (LEMBOREXANT)	EISAI INC	S	4/20/2023
NDA 208447	27	Labeling Change With Clinical Data	ZEJULA (NIRAPARIB)	GLAXOSMITHKLINE LLC	S	4/26/2023
NDA 205552	40	Labeling Change With Clinical Data	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	S	5/18/2023
NDA 210563	17	Labeling Change With Clinical Data	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	S	5/18/2023
NDA 205551	31	Labeling Change With Clinical Data	TRIUMEQ (ABACAVIR, DOLUTEGRAVIR, AND LAMIVUDINE)	VIIV HEALTHCARE CO	P	6/15/2023
NDA 214998	1	Labeling Change With Clinical Data	CAMZYOS (MAVACAMTEN)	BRISTOL MYERS SQUIBB CO	S	6/15/2023
NDA 201280	27	Labeling Change With Clinical Data	TRADJENTA (LINAGLIPTIN)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	6/20/2023
NDA 201281	35	Labeling Change With Clinical Data	JENTADUETO (LINAGLIPTIN AND METFORMIN HYDROCHLORIDE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	6/20/2023
NDA 208026	24	Labeling Change With Clinical Data	JENTADUETO XR (LINAGLIPTIN AND METFORMIN HYDROCHLORIDE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	6/20/2023
NDA 208658	26	Labeling Change With Clinical Data	SYNJARDY XR (EMPAGLIFLOZIN AND METFORMIN HYDROCHLORIDE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	6/20/2023
NDA 211675	17	Labeling Change With Clinical Data	RINVOQ (UPADACITINIB)	ABBVIE INC	S	6/22/2023
NDA 214787	19	Labeling Change With Clinical Data	VEKLURY (REMDESIVIR)	GILEAD SCIENCES INC	P	7/13/2023
NDA 021343	47	Labeling Change With Clinical Data	ELIGARD (LEUPROLIDE ACETATE)	TOLMAR INC	S	7/20/2023
NDA 021379	49	Labeling Change With Clinical Data	ELIGARD (LEUPROLIDE ACETATE)	TOLMAR INC	S	7/20/2023
NDA 021488	44	Labeling Change With Clinical Data	ELIGARD (LEUPROLIDE ACETATE)	TOLMAR INC	S	7/20/2023
NDA 021731	44	Labeling Change With Clinical Data	ELIGARD (LEUPROLIDE ACETATE)	TOLMAR INC	S	7/20/2023
NDA 205437	12	Labeling Change With Clinical Data	OTEZLA (APREMILAST)	AMGEN INC	S	7/20/2023
NDA 022271	15	Labeling Change With Clinical Data	NESINA (ALOGLIPTIN)	TAKEDA PHARMACEUTICALS USA INC	S	7/27/2023
NDA 203414	16	Labeling Change With Clinical Data	KAZANO (ALOGLIPTIN AND METFORMIN HYDROCHLORIDE)	TAKEDA PHARMACEUTICALS USA INC	S	7/27/2023
NDA 213721	9	Labeling Change With Clinical Data	GAVRETO (PRALSETINIB)	GENENTECH INC	S	8/9/2023
NDA 204447	26	Labeling Change With Clinical Data	TRINTELLIX (VORTIOXETINE)	TAKEDA PHARMACEUTICALS USA INC	P	8/23/2023
NDA 207103	17	Labeling Change With Clinical Data	IBRANCE (PALBOCICLIB)	PFIZER INC	S	9/6/2023
NDA 212436	5	Labeling Change With Clinical Data	IBRANCE (PALBOCICLIB)	PFIZER INC	S	9/6/2023

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NDA 207318	12	Labeling Change With Clinical Data	NUPLAZID (PIMAVANSERIN)	ACADIA PHARMACEUTICALS INC	S	9/15/2023
NDA 210793	9	Labeling Change With Clinical Data	NUPLAZID (PIMAVANSERIN)	ACADIA PHARMACEUTICALS INC	S	9/15/2023
NDA 213535	11	Labeling Change With Clinical Data	EVRYSDI (RISDIPLAM)	GENENTECH INC	S	10/3/2023
NDA 206316	19	Labeling Change With Clinical Data	SAVAYSA (EDOXABAN)	DAIICHI SANKYO INC	S	10/18/2023
NDA 210365	20	Labeling Change With Clinical Data	EPIDIOLEX (CANNABIDIOL)	JAZZ PHARMACEUTICALS RESEARCH UK LTD	S	10/20/2023
NDA 022425	30	Labeling Change With Clinical Data	MULTAQ (DRONEDARONE HYDROCHLORIDE)	SANOFI AVENTIS US LLC	S	10/23/2023
NDA 206947	28	Labeling Change With Clinical Data	LENVIMA (LENVATINIB MESYLATE)	EISAI INC	S	10/23/2023
NDA 208558	28	Labeling Change With Clinical Data	LYNPARZA (OLAPARIB)	ASTRAZENECA PHARMACEUTICALS LP	S	11/6/2023
NDA 211939	4	Labeling Change With Clinical Data	BONSITY (TERIPARATIDE)	ALVOGEN INC	S	11/16/2023
NDA 216338	1	Labeling Change With Clinical Data	PACLITAXEL	TEVA PHARMACEUTICALS INC	S	11/21/2023
NDA 213871	4	Labeling Change With Clinical Data	CIBINQO (ABROCITINIB)	PFIZER INC	S	12/14/2023
NDA 210951	14	Labeling Change With Clinical Data	ERLEADA (APALUTAMIDE)	JANSSEN BIOTECH INC	S	12/19/2023
NDA 215935	3	Labeling Change With Clinical Data	TARPEYO (BUDESONIDE)	CALLIDITAS THERAPEUTICS AB	P	12/20/2023
NDA 213217	9	Labeling Change With Clinical Data	BRUKINSA (ZANUBRUTINIB)	BEIGENE USA INC	S	12/21/2023

BLA Efficacy Supplements Approved

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE	PROPER NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
BLA 125274	123	Labeling Change With Clinical Data	DYSPORT (ABOBOTULINUMTOXINA)	IPSEN BIOPHARM LIMITED	S	1/12/2023
BLA 761036	44	Labeling Change With Clinical Data	DARZALEX (DARATUMUMAB)	JANSSEN BIOTECH, INC.	S	1/19/2023
BLA 125476	48	Manufacturing Change With Clinical Data	ENTYVIO (VEDOLIZUMAB)	TAKEDA PHARMACEUTICALS U.S.A., INC.	S	1/25/2023
BLA 761164	3	New Indication	ENJAYMO (SUTIMLIMAB-JOME)	BIOVERATIV THERAPEUTICS, INC.	P	1/25/2023
BLA 125514	128	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	1/26/2023
BLA 761235	1	Labeling Change With Clinical Data	VABYSMO (FARICIMAB-SVOA)	GENENTECH, INC.	S	1/27/2023
BLA 761224	1	Manufacturing Change With Clinical Data	TEZSPIRE (TEZPELUMAB-EKKO)	ASTRAZENECA AB	S	2/1/2023
BLA 761090	10	Labeling Change With Clinical Data	TAKHZYRO (LANADELUMAB-FLYO)	TAKEDA PHARMACEUTICALS U.S.A., INC.	P	2/3/2023
BLA 761115	35	New Indication	TRODELVY (SACITUZUMAB GOVITECAN-HZIY)	GILEAD SCIENCES, INC.	P	2/3/2023
BLA 125387	75	New Indication	EYLEA (AFLIBERCEPT)	REGENERON PHARMACEUTICALS, INC.	P	2/8/2023
BLA 761178	7	Labeling Change With Clinical Data	ADUHELM (ADUCANUMAB-AVWA)	BIOGEN INC.	S	2/8/2023
BLA 761174	3	New Indication	JEMPERLI (DOSTARLIMAB-GXLY)	GLAXOSMITHKLINE LLC	S	2/9/2023
BLA 761174	4	New Indication	JEMPERLI (DOSTARLIMAB-GXLY)	GLAXOSMITHKLINE LLC	S	2/9/2023
BLA 125377	129	New Patient Population	YERVOY (IPILIMUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	2/15/2023
BLA 125554	117	New Patient Population	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	2/15/2023
BLA 125554	118	New Patient Population	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	2/15/2023
BLA 125554	119	New Patient Population	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	2/15/2023
BLA 761043	22	Labeling Change With Clinical Data	BENLYSTA (BELIMUMAB)	GLAXOSMITHKLINE LLC	S	2/15/2023

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BLA 761216	1	Labeling Change With Clinical Data	YUSIMRY (ADALIMUMAB-AQVH)	COHERUS BIOSCIENCES, INC.	S	2/27/2023
BLA 761037	13	New Indication	KEVZARA (SARILUMAB)	SANOFI-AVENTIS U.S. LLC	P	2/28/2023
BLA 761039	13	Labeling Change With Clinical Data	UDENYCA ONBODY (PEGFILGRASTIM-CBQV)	COHERUS BIOSCIENCES, INC.	S	3/3/2023
BLA 761039	13	Labeling Change With Clinical Data	UDENYCA (PEGFILGRASTIM-CBQV)	COHERUS BIOSCIENCES, INC.	S	3/3/2023
BLA 761071	14	Labeling Change With Clinical Data	HYRIMOZ (ADALIMUMAB-ADAZ)	SANDOZ INC.	S	3/20/2023
BLA 761181	1	New Patient Population		REGENERON PHARMACEUTICALS, INC.	P	3/21/2023
BLA 761024	12	Labeling Change With Clinical Data	AMJEVITA (ADALIMUMAB-ATTO)	AMGEN INC.	S	3/22/2023
BLA 761058	13	New Indication	CYLTEZO (ADALIMUMAB-ADB)	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	S	3/22/2023
BLA 761058	13	New Indication	CYLTEZO PEN (ADALIMUMAB-ADB)	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	S	3/22/2023
BLA 125514	132	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	3/28/2023
BLA 125164	87	Labeling Change With Clinical Data	MIRCERA (METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA)	VIFOR (INTERNATIONAL) INC.	S	3/31/2023
BLA 125514	136	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	P	4/3/2023
BLA 761137	18	New Indication	PADCEV (ENFORTUMAB VEDOTIN-EJFV)	ASTELLAS PHARMA US, INC.	P	4/3/2023
BLA 761121	8	New Indication	POLIVY (POLATUZUMAB VEDOTIN (DCDS4501A OR RO5541077))	GENENTECH, INC.	S	4/19/2023
BLA 761097	15	Labeling Change With Clinical Data	LIBTAYO (CEMPLIMAB-RWLC)	REGENERON PHARMACEUTICALS, INC.	S	4/28/2023
BLA 761097	16	Accelerated Approval Confirmatory Study	LIBTAYO (CEMPLIMAB-RWLC)	REGENERON PHARMACEUTICALS, INC.	S	4/28/2023
BLA 761156	5	New Patient Population	SOGROYA (SOMAPACITAN-BECO)	NOVO NORDISK INC.	S	4/28/2023
BLA 125504	44	Manufacturing Change With Clinical Data	COSENTYX (SECUKINUMAB)	NOVARTIS PHARMACEUTICALS CORPORATION	S	5/11/2023
BLA 125504	44	Manufacturing Change With Clinical Data	COSENTYX UNOREADY PEN (SECUKINUMAB)	NOVARTIS PHARMACEUTICALS CORPORATION	S	5/11/2023
BLA 761058	16	Manufacturing Change With Clinical Data	CYLTEZO (ADALIMUMAB-ADB)	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	S	5/18/2023
BLA 761058	16	Manufacturing Change With Clinical Data	CYLTEZO PEN (ADALIMUMAB-ADB)	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	S	5/18/2023
BLA 761150	5	Labeling Change With Clinical Data	MARGENZA (MARGETUXIMAB-CMKB)	MACROGENICS INC.	S	5/25/2023
BLA 761046	12	New Patient Population	ZINPLAVA (BEZLOTOXUMAB)	MERCK SHARP & DOHME LLC	P	5/26/2023
BLA 125388	107	Labeling Change With Clinical Data	ADCETRIS (BRENTUXIMAB VEDOTIN)	SEAGEN INC.	S	6/14/2023
BLA 761118	9	New Indication	ABRILADA (ADALIMUMAB-AFZB)	PFIZER INC.	S	6/14/2023
BLA 125557	23	Accelerated Approval Confirmatory Study	BLINCYTO (BLINATUMOMAB)	AMGEN INC.	P	6/20/2023
BLA 125557	26	Labeling Change With Clinical Data	BLINCYTO (BLINATUMOMAB)	AMGEN INC.	P	6/20/2023
BLA 761059	6	New Indication	HADLIMA (ADALIMUMAB-BWWD)	SAMSUNG BIOEPIS CO., LTD.	S	6/26/2023
BLA 761058	18	New Indication	CYLTEZO (ADALIMUMAB-ADB)	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	S	6/30/2023
BLA 761058	18	New Indication	CYLTEZO PEN (ADALIMUMAB-ADB)	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	S	6/30/2023
BLA 761269	1	Accelerated Approval Confirm	LEQEMBI (LECANEMAB-IRMB)	EISAI, INCORPORATED	P	7/6/2023
BLA 761059	8	New Indication	HADLIMA (ADALIMUMAB-BWWD)	SAMSUNG BIOEPIS CO., LTD.	S	7/11/2023
BLA 021106	74	Labeling Change With Clinical Data	SOMAVERT (PEGVISOMANT)	PHARMACIA & UPJOHN COMPANY LLC	S	7/27/2023
BLA 761174	6	New Indication	JEMPERLI (DOSTARLIMAB-GXLY)	GLAXOSMITHKLINE LLC	P	7/31/2023
BLA 103000	5325	New Indication	BOTOX AND BOTOX COSMETIC (ONABOTULINUMTOXINA)	ALLERGAN, INC.	S	8/11/2023
BLA 761127	2	New Indication	DAXXIFY (DAXIBOTULINUMTOXINA-LANM)	REVANCE THERAPEUTICS, INC.	S	8/11/2023
BLA 125514	134	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	8/14/2023
BLA 125514	135	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	8/14/2023
BLA 761024	15	Manufacturing Change With Clinical Data	AMJEVITA (ADALIMUMAB-ATTO)	AMGEN INC.	S	8/14/2023
BLA 125319	107	New Indication	ILARIS (CANAKINUMAB)	NOVARTIS PHARMACEUTICALS CORPORATION	S	8/25/2023
BLA 761136	9	New Indication	REBLOZYL (LUSPATERCEPT-AAMT)	CELGENE CORPORATION, A BRISTOL-MYERS SQUIBB COMP	P	8/28/2023
BLA 761049	15	Accelerated Approval Confirm	BAVENCIO (AVELUMAB)	EMD SERONO, INC.	S	9/6/2023
BLA 761194	5	Labeling Change With Clinical Data		GENZYME CORPORATION	S	9/15/2023

**CY 2023 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year Approvals
As of December 31, 2023**

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

Selection Criteria:

User Response: Start Date: 1/1/2023 End Date: 12/31/2023

Sort Order: Approval Date

BLA 125514	138	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	10/12/2023
BLA 125554	121	New Indication	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	10/13/2023
BLA 125514	139	Labeling Change With Clinical	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	10/16/2023
BLA 103795	5595	New Indication	ENBREL (ETANERCEPT)	IMMUNEX CORPORATION	S	10/18/2023
BLA 125514	142	Labeling Change With Clinical	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	10/23/2023
BLA 761235	3	New Indication	VABYSMO (FARICIMAB-SVOA)	GENENTECH, INC.	S	10/26/2023
BLA 125118	250	New Indication	ORENCIA (ABATACEPT)	BRISTOL-MYERS SQUIBB COMPANY	S	10/30/2023
BLA 125504	63	New Indication	COSENTYX (SECUKINUMAB)	NOVARTIS PHARMACEUTICALS CORPORATION	S	10/31/2023
BLA 125504	63	New Indication	COSENTYX UNOREADY PEN (SECUKINUMAB)	NOVARTIS PHARMACEUTICALS CORPORATION	S	10/31/2023
BLA 125514	144	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	10/31/2023
BLA 125514	145	Labeling Change With Clinical	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	10/31/2023
BLA 761113	9	Labeling Change With Clinical	SARCLISA (ISATUXIMAB-IRFC)	SANOI-AVENTIS U.S. LLC	S	11/1/2023
BLA 125514	148	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	11/7/2023
BLA 125514	143	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	S	11/16/2023
BLA 761123	3	Labeling Change With Clinical	SAPHNELO (ANIFROLUMAB-FNIA)	ASTRAZENECA AB	S	12/1/2023
BLA 103964	5276	Labeling Change With Clinical	PEGASYS (PEGINTERFERON ALFA-2A)	PHARMAAND GMBH	S	12/11/2023
BLA 761180	1	New Patient Population	ADBRY (TRALOKINUMAB-LDRM)	LEO PHARMA A/S	S	12/14/2023
BLA 125514	151	New Patient Population	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	P	12/15/2023
BLA 125514	152	Accelerated Approval Confirm	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME LLC	P	12/15/2023
BLA 761137	24	New Patient Population	PADCEV (ENFORTUMAB VEDOTIN-EJFV)	ASTELLAS PHARMA US, INC.	P	12/15/2023
BLA 761137	25	Accelerated Approval Confirm	PADCEV (ENFORTUMAB VEDOTIN-EJFV)	ASTELLAS PHARMA US, INC.	P	12/15/2023