

**CY 2022 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year 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

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
NDA 208215	20	New Patient Population	DESCOVY (EMTRICITABINE AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	P	1/7/2022
NDA 211675	4	New Indication	RINVOQ (UPADACITINIB)	ABBVIE INC	P	1/14/2022
NDA 214787	10	New Dosing Regimen	VEKLURY (REMDESIVIR)	GILEAD SCIENCES INC	P	1/21/2022
NDA 209363	14	New Patient Population	SOLOSEC (SECNIDAZOLE)	LUPIN INC	S	1/26/2022
NDA 209363	16	New Patient Population	SOLOSEC (SECNIDAZOLE)	LUPIN INC	S	1/26/2022
NDA 210806	7	New Patient Population	PIFELTRO (DORAVIRINE)	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	P	1/27/2022
NDA 210807	8	New Patient Population	DELSTRIGO (DORAVIRINE, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE)	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	P	1/27/2022
NDA 020825	63	New Patient Population	GEODON (ZIPRASIDONE HYDROCHLORIDE)	VIATRIS SPECIALTY LLC	S	1/28/2022
NDA 212888	1	New Dosing Regimen	INJECTABLE SUSPENSION; RILPIVIRINE EXTENDED RELEASE INJECTABLE SUSPENSION)	VIIV HEALTHCARE CO	S	1/31/2022
NDA 205649	16	New Indication	XIGDUO XR (DAPAGLIFLOZIN AND METFORMIN)	ASTRAZENECA AB	S	2/3/2022
NDA 204629	33	New Indication	JARDIANCE (EMPAGLIFLOZIN)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	2/24/2022
NDA 214121	1	New Patient Population	METHOTREXATE	ACCORD HEALTHCARE INC	S	3/10/2022
NDA 208558	23	New Indication	LYNPARZA (OLAPARIB)	ASTRAZENECA PHARMACEUTICALS LP	P	3/11/2022
NDA 211675	7	New Indication	RINVOQ (UPADACITINIB)	ABBVIE INC	P	3/16/2022
NDA 207648	5	New Patient Population	SMOFLIPID (FISH OIL, MEDIUM CHAIN TRIGLYCERIDES, OLIVE OIL, AND SOYBEAN OIL)	FRESENIUS KABI USA LLC	P	3/22/2022
NDA 212888	3	New Dosing Regimen	INJECTABLE SUSPENSION; RILPIVIRINE EXTENDED RELEASE INJECTABLE SUSPENSION)	VIIV HEALTHCARE CO	S	3/23/2022
NDA 212102	3	New Indication	FINTEPLA (FENFLURAMINE HYDROCHLORIDE)	ZOGENIX INC	P	3/25/2022
NDA 209637	9	New Dosing Regimen	OZEMPIC (SEMAGLUTIDE)	NOVO NORDISK INC	S	3/28/2022
NDA 202022	17	New Patient Population	EDURANT (RILPIVIRINE HYDROCHLORIDE)	JANSSEN PRODUCTS LP	P	3/29/2022
NDA 202022	18	New Patient Population	EDURANT (RILPIVIRINE HYDROCHLORIDE)	JANSSEN PRODUCTS LP	P	3/29/2022
NDA 212887	5	New Patient Population	VOCABRIA (CABOTEGRAVIR)	VIIV HEALTHCARE CO	P	3/29/2022
NDA 212887	6	New Patient Population	VOCABRIA (CABOTEGRAVIR)	VIIV HEALTHCARE CO	P	3/29/2022
NDA 212888	5	New Patient Population	CABENUVA (CABOTEGRAVIR EXTENDED RELEASE INJECTABLE SUSPENSION; RILPIVIRINE EXTENDED RELEASE INJECTABLE SUSPENSION)	VIIV HEALTHCARE CO	P	3/29/2022

**CY 2022 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year 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

NDA 212888	6	New Patient Population	CABENUVA (CABOTEGRAVIR EXTENDED RELEASE INJECTABLE SUSPENSION; RILPIVIRINE EXTENDED RELEASE INJECTABLE SUSPENSION)	VIIV HEALTHCARE CO	P	3/29/2022
NDA 205551	28	New Patient Population	TRIUMEQ (ABACAVIR, DOLUTEGRAVIR, AND LAMIVUDINE)	VIIV HEALTHCARE CO	P	3/30/2022
NDA 205649	17	New Indication	XIGDUO XR (DAPAGLIFLOZIN AND METFORMIN)	ASTRAZENECA AB	S	4/11/2022
NDA 021116	23		THYRO-TABS (LEVOTHYROXINE SODIUM)	ALVOGEN INC	S	4/14/2022
NDA 019732	45	New Indication	LUPRON DEPOT (LEUPROLIDE ACETATE)	ABBVIE ENDOCRINE INC	S	4/18/2022
NDA 020517	43	New Indication	LUPRON DEPOT (LEUPROLIDE ACETATE)	ABBVIE ENDOCRINE INC	S	4/18/2022
NDA 206829	11	New Patient Population	ZERBAXA (CEFTOLOZANE SULFATE AND TAZOBACTAM SODIUM)	CUBIST PHARMACEUTICALS LLC	S	4/21/2022
NDA 206829	12	New Patient Population	ZERBAXA (CEFTOLOZANE SULFATE AND TAZOBACTAM SODIUM)	CUBIST PHARMACEUTICALS LLC	S	4/21/2022
NDA 214787	11	New Patient Population	VEKLURY (REMDESIVIR)	GILEAD SCIENCES INC	P	4/25/2022
NDA 211964	3	New Patient Population	QELBREE (VILOXAZINE)	SUPERNUS PHARMACEUTICALS INC	S	4/29/2022
NDA 022023	21	New Dosing Regimen	EMEND (FOSAPREPITANT)	MERCK SHARP AND DOHME CORP	S	5/2/2022
NDA 207924	6	New Indication	OLUMIANT (BARICITINIB)	ELI LILLY AND CO	P	5/10/2022
NDA 208627	7	New Patient Population	TPOXX (TECOVIRIMAT)	SIGA TECHNOLOGIES INC	S	5/18/2022
NDA 050794	34	New Indication	AZACITIDINE	CELGENE CORP	P	5/20/2022
NDA 211192	9	New Indication	TIBSOVO (IVOSIDENIB)	SERVIER PHARMACEUTICALS LLC	P	5/25/2022
NDA 213535	5	New Patient Population	EVRYSDI (RISDIPLAM)	GENENTECH INC	P	5/27/2022
NDA 050722	49	New Patient Population	CELLCEPT (MYCOPHENOLATE MOFETIL)	ROCHE PALO ALTO LLC	S	6/6/2022
NDA 050722	51	New Patient Population	CELLCEPT (MYCOPHENOLATE MOFETIL)	ROCHE PALO ALTO LLC	S	6/6/2022
NDA 050723	49	New Patient Population	CELLCEPT (MYCOPHENOLATE MOFETIL)	ROCHE PALO ALTO LLC	S	6/6/2022
NDA 050723	51	New Patient Population	CELLCEPT (MYCOPHENOLATE MOFETIL)	ROCHE PALO ALTO LLC	S	6/6/2022
NDA 050758	47	New Patient Population	CELLCEPT (MYCOPHENOLATE MOFETIL)	ROCHE PALO ALTO LLC	S	6/6/2022
NDA 050758	49	New Patient Population	CELLCEPT (MYCOPHENOLATE MOFETIL)	ROCHE PALO ALTO LLC	S	6/6/2022
NDA 050759	54	New Patient Population	CELLCEPT (MYCOPHENOLATE MOFETIL)	ROCHE PALO ALTO LLC	S	6/6/2022
NDA 050759	56	New Patient Population	CELLCEPT (MYCOPHENOLATE MOFETIL)	ROCHE PALO ALTO LLC	S	6/6/2022
NDA 209115	11	New Indication	RUBRACA (RUCAPARIB)	CLOVIS ONCOLOGY INC	P	6/10/2022

**CY 2022 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year 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

NDA 207924	7	New Indication	OLUMIANT (BARICITINIB)	ELI LILLY AND CO	P	6/13/2022
NDA 211371	7	New Patient Population	ZULRESSO (BREXANOLONE)	SAGE THERAPEUTICS INC	P	6/16/2022
NDA 213793	1	New Indication	IMCIVREE (SETMELANOTIDE)	RHYTHM PHARMACEUTICALS INC	P	6/16/2022
NDA 202806	22	New Indication	TAFINLAR (DABRAFENIB)	NOVARTIS PHARMACEUTICALS CORP	P	6/22/2022
NDA 204114	24	New Indication	MEKINIST (TRAMETINIB)	NOVARTIS PHARMACEUTICALS CORP	P	6/22/2022
NDA 022580	21	New Indication	QSYMIA (PHENTERMINE AND TOPIRAMATE)	VIVUS INC	S	6/24/2022
NDA 202714	34	New Dosing Regimen	KYPROLIS (CARFILZOMIB)	ONYX THERAPEUTICS INC A WHOLLY OWNED SUB OF AMGEN INC	S	6/30/2022
NDA 202570	33	New Indication	XALKORI (CRIZOTINIB)	PF PRISM CV	P	7/14/2022
NDA 206709	3	New Indication	DIACOMIT (STIRIPENTOL)	BIOCODEX SA	S	7/14/2022
NDA 207223	3	New Indication	DIACOMIT (STIRIPENTOL)	BIOCODEX SA	S	7/14/2022
NDA 021673	27	Accelerated Approval Confirmatory Study	CLOLAR (CLOFARABINE)	GENZYME CORP	S	7/18/2022
NDA 215309	1	New Indication	OPZELURA (RUXOLITINIB)	INCYTE CORP	P	7/18/2022
NDA 021137	5		LEVOLET	GENUS LIFE SCIENCES INC	S	8/5/2022
NDA 212099	2	New Indication	NUBEQA (DAROLUTAMIDE)	BAYER HEALTHCARE PHARMACEUTICALS INC	P	8/5/2022
NDA 214846	2	New Indication	MYFEMBREE (RELUGOLIX, ESTRADIOL, NORETHINDRONE ACETATE)	MYOVANT SCIENCES GMBH	S	8/5/2022
NDA 213591	4	Accelerated Approval Confirmatory Study	TABRECTA (CAPMATINIB)	NOVARTIS PHARMACEUTICAL CORP	P	8/10/2022
NDA 210854	5	New Patient Population	XOFLUZA (BALOXAVIR MARBOXIL)	GENENTECH INC	S	8/11/2022
NDA 210854	9	New Indication	XOFLUZA (BALOXAVIR MARBOXIL)	GENENTECH INC	S	8/11/2022
NDA 205552	36	New Patient Population	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	P	8/24/2022
NDA 210563	12	New Patient Population	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	P	8/24/2022
NDA 208558	26	New Indication	LYNPARZA (OLAPARIB)	ASTRAZENECA PHARMACEUTICALS LP	P	8/26/2022
NDA 213736	2	New Indication	PEMAZYRE (PEMIGATINIB)	INCYTE CORP	P	8/26/2022
NDA 215341	1		KERENDIA (FINERENONE)	BAYER HEALTHCARE PHARMACEUTICALS INC	S	9/1/2022
NDA 211358	4	New Patient Population	ORKAMBI (LUMACAFTOR/IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	9/2/2022
NDA 213246	7	Accelerated Approval Confirmatory Study	RETEVMO (SELPERCATINIB)	LOXO ONCOLOGY INC A WHOLLY OWNED SUB OF ELI LILLY AND CO	S	9/21/2022

**CY 2022 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year 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

NDA 213246	8	New Indication	RETEVMO (SELPERCATINIB)	LOXO ONCOLOGY INC A WHOLLY OWNED SUB OF ELI LILLY AND CO	P	9/21/2022
NDA 208078	8	New Patient Population	FIRDAPSE (AMIFAMPRIDINE PHOSPHATE)	CATALYST PHARMACEUTICALS INC	P	9/29/2022
NDA 214103	3	New Indication	OXLUMO (LUMASIRAN)	ALNYLAM PHARMACEUTICALS INC	S	10/6/2022
NDA 211810	9	New Dosing Regimen	TURALIO (PEXIDARTINIB)	DAIICHI SANKYO INC	S	10/14/2022
NDA 208464	14	New Patient Population	VEMLIDY (TENOFIVIR ALAFENAMIDE)	GILEAD SCIENCES INC	P	10/17/2022
NDA 211675	10	New Indication	RINVOQ (UPADACITINIB)	ABBVIE INC	S	10/21/2022
NDA 206192	5	New Indication	COTELLIC (COBIMETINIB)	GENENTECH INC	P	10/28/2022
NDA 022454	10	New Indication	DATSCAN ([123I]-IOFLUPANE)	GE HEALTHCARE INC	S	11/1/2022
NDA 206229	12	New Indication	LILETTA (LEVONORGESTREL)	MEDICINES360	S	11/10/2022
NDA 208419	2	New Indication	PEMETREXED	ACTAVIS LLC AN INDIRECT WHOLLY OWNED SUB OF TEVA PHARMACEUTICALS USA INC	S	11/22/2022
NDA 208419	3	New Indication	PEMETREXED	ACTAVIS LLC AN INDIRECT WHOLLY OWNED SUB OF TEVA PHARMACEUTICALS USA INC	S	11/22/2022
NDA 208419	4	New Indication	PEMETREXED	ACTAVIS LLC AN INDIRECT WHOLLY OWNED SUB OF TEVA PHARMACEUTICALS USA INC	S	11/22/2022
NDA 214900	2	New Indication	BREXAFEMME (IBREXAFUNGERP)	SCYNEXIS INC	P	11/30/2022
NDA 209191	3	New Indication	BORTEZOMIB	HOSPIRA INC	S	12/9/2022
NDA 207103	15	New Patient Population	IBRANCE (PALBOCICLIB)	PFIZER INC	S	12/13/2022
NDA 212436	3	New Patient Population	IBRANCE (PALBOCICLIB)	PFIZER INC	S	12/13/2022
NDA 020896	44	New Indication	XELODA (CAPECITABINE)	HOFFMANN LA ROCHE INC	S	12/14/2022
NDA 020896	45	New Indication	XELODA (CAPECITABINE)	HOFFMANN LA ROCHE INC	S	12/14/2022
NDA 020896	46	New Indication	XELODA (CAPECITABINE)	HOFFMANN LA ROCHE INC	S	12/14/2022
NDA 020896	47	New Indication	XELODA (CAPECITABINE)	HOFFMANN LA ROCHE INC	S	12/14/2022
NDA 020896	48	New Indication	XELODA (CAPECITABINE)	HOFFMANN LA ROCHE INC	S	12/14/2022
NDA 020896	49	New Indication	XELODA (CAPECITABINE)	HOFFMANN LA ROCHE INC	S	12/14/2022
NDA 020896	50	New Indication	XELODA (CAPECITABINE)	HOFFMANN LA ROCHE INC	S	12/14/2022
NDA 020896	51	New Indication	XELODA (CAPECITABINE)	HOFFMANN LA ROCHE INC	S	12/14/2022
NDA 209472	5	New Indication	PEMFEXY (PEMETREXED)	EAGLE PHARMACEUTICALS INC	S	12/14/2022

**CY 2022 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year 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

NDA 204370	9	New Indication	VRAYLAR (CARIPRAZINE)	ABBVIE INC	S	12/16/2022
NDA 214907	2	New Indication	CYTALUX (PAFOLACIANINE SODIUM)	ON TARGET LABORATORIES INC	P	12/16/2022
NDA 208743	13	New Indication	TYMLOS (ABALOPARATIDE)	RADIUS HEALTH INC	S	12/19/2022
NDA 206494	11	New Dosing Regimen	AVYCAZ (AVIBACTAM AND CEFTAZIDIME)	ALLERGAN SALES LLC	P	12/20/2022
NDA 215256	5	New Patient Population	WEGOVY (SEMAGLUTIDE)	NOVO NORDISK INC	P	12/23/2022

NDA Efficacy Supplements Approved (SE8)

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
NDA 207561	29	Labeling Change With Clinical Data	GENVOYA (ELVITEGRAVIR, COBICISTAT, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	P	1/7/2022
NDA 020505	62	Labeling Change With Clinical Data	TOPAMAX (TOPIRAMATE)	JANSSEN PHARMACEUTICALS INC	S	1/13/2022
NDA 020844	53	Labeling Change With Clinical Data	TOPAMAX (TOPIRAMATE)	JANSSEN PHARMACEUTICALS INC	S	1/13/2022
NDA 211994	12	Labeling Change With Clinical Data	DOVATO (DOLUTEGRAVIR AND LAMIVUDINE)	VIIV HEALTHCARE CO	S	1/20/2022
NDA 211994	13	Labeling Change With Clinical Data	DOVATO (DOLUTEGRAVIR AND LAMIVUDINE)	VIIV HEALTHCARE CO	S	1/20/2022
NDA 212950	2	Labeling Change With Clinical Data	RUKOBIA (FOSTEMSAVIR)	VIIV HEALTHCARE CO	S	1/24/2022
NDA 202806	19	Labeling Change With Clinical Data	TAFINLAR (DABRAFENIB)	NOVARTIS PHARMACEUTICALS CORP	S	1/28/2022
NDA 204114	19	Labeling Change With Clinical Data	MEKINIST (TRAMETINIB)	NOVARTIS PHARMACEUTICALS CORP	S	1/28/2022
NDA 202022	16	Labeling Change With Clinical Data	EDURANT (RILPIVIRINE HYDROCHLORIDE)	JANSSEN PRODUCTS LP	S	1/31/2022
NDA 208558	21	Labeling Change With Clinical Data	LYNPARZA (OLAPARIB)	ASTRAZENECA PHARMACEUTICALS LP	S	1/31/2022
NDA 212887	1	Labeling Change With Clinical Data	VOCABRIA (CABOTEGRAVIR)	VIIV HEALTHCARE CO	S	1/31/2022
NDA 212887	2	Labeling Change With Clinical Data	VOCABRIA (CABOTEGRAVIR)	VIIV HEALTHCARE CO	S	2/7/2022
NDA 212888	2	Labeling Change With Clinical Data	CABENUVA (CABOTEGRAVIR EXTENDED RELEASE INJECTABLE SUSPENSION; RILPIVIRINE EXTENDED RELEASE INJECTABLE SUSPENSION)	VIIV HEALTHCARE CO	S	2/7/2022
NDA 203469	35	Labeling Change With Clinical Data	ICLUSIG (PONATINIB)	TAKEDA PHARMACEUTICALS USA INC	S	2/15/2022
NDA 208772	13	Labeling Change With Clinical Data	ALUNBRIG (BRIGATINIB)	TAKEDA PHARMACEUTICALS USA INC	S	2/28/2022
NDA 209884	7	Labeling Change With Clinical Data	MAYZENT (SIPONIMOD)	NOVARTIS PHARMACEUTICALS CORP	S	3/1/2022
NDA 212887	3	Labeling Change With Clinical Data	VOCABRIA (CABOTEGRAVIR)	VIIV HEALTHCARE CO	S	3/23/2022
NDA 201292	17	Labeling Change With Clinical Data	GILOTRIF (AFATINIB)	BOEHRINGER INGELHEIM	P	4/7/2022

**CY 2022 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year 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

NDA 212728	9	Labeling Change With Clinical Data	NURTEC ODT (RIMEGEPANT)	BIOHAVEN PHARMACEUTICAL IRELAND DESIGNATED ACTIVITY CO	S	4/11/2022
NDA 208341	19	Labeling Change With Clinical Data	EPCLUSA (SOFOSBUVIR AND VELPATISVIR)	GILEAD SCIENCES INC	S	4/27/2022
NDA 214187	1	Labeling Change With Clinical Data	EPCLUSA (SOFOSBUVIR AND VELPATISVIR)	GILEAD SCIENCES INC	S	4/27/2022
NDA 208462	12	Labeling Change With Clinical Data	NINLARO (IXAZOMIB)	TAKEDA PHARMACEUTICALS USA INC	S	4/28/2022
NDA 211675	3	Labeling Change With Clinical Data	RINVOQ (UPADACITINIB)	ABBVIE INC	S	4/29/2022
NDA 022433	34	Labeling Change With Clinical Data	BRILINTA (TICAGRELOR)	ASTRAZENECA PHARMACEUTICALS LP	P	5/9/2022
NDA 202806	23	Labeling Change With Clinical Data	TAFINLAR (DABRAFENIB)	NOVARTIS PHARMACEUTICALS CORP	S	5/27/2022
NDA 204114	23	Labeling Change With Clinical Data	MEKINIST (TRAMETINIB)	NOVARTIS PHARMACEUTICALS CORP	S	5/27/2022
NDA 213535	3	Labeling Change With Clinical Data	EVRYSDI (RISDIPLAM)	GENENTECH INC	S	5/27/2022
NDA 208700	19	Labeling Change With Clinical Data	LUTATHERA (LUTETIUM LU 177 DOTATATE)	ADVANCED ACCELERATOR APPLICATIONS USA INC	S	6/13/2022
NDA 208692	14	Labeling Change With Clinical Data	CABOMETYX (CABOZANTINIB)	EXELIXIS INC	S	7/14/2022
NDA 206192	4	Labeling Change With Clinical Data	COTELLIC (COBIMETINIB)	GENENTECH INC	P	7/28/2022
NDA 021225	43	Labeling Change With Clinical Data	MIRENA (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM)	BAYER HEALTHCARE PHARMACEUTICALS INC	S	8/12/2022
NDA 205552	37	Labeling Change With Clinical Data	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	S	8/24/2022
NDA 205552	38	Labeling Change With Clinical Data	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	P	8/24/2022
NDA 210563	13	Labeling Change With Clinical Data	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	P	8/24/2022
NDA 210563	14	Labeling Change With Clinical Data	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	P	8/24/2022
NDA 021462	55	Labeling Change With Clinical Data	ALIMTA (PEMETREXED)	ELI LILLY AND CO	S	8/31/2022
NDA 203415	19	Labeling Change With Clinical Data	XTANDI (ENZALUTAMIDE)	ASTELLAS PHARMA US INC	S	9/9/2022
NDA 213674	6	Labeling Change With Clinical Data	XTANDI (ENZALUTAMIDE)	ASTELLAS PHARMA US INC	S	9/9/2022
NDA 201532	23	Labeling Change With Clinical Data	HALAVEN (ERIBULIN MESYLATE)	EISAI INC	P	9/13/2022
NDA 202324	14	Labeling Change With Clinical Data	INLYTA (AXITINIB)	PF PRISM CV	S	9/22/2022
NDA 210875	6	Labeling Change With Clinical Data	KYNMOBI (APOMORPHINE)	SUNOVION PHARMACEUTICALS INC	S	9/22/2022
NDA 209401	11	Labeling Change With Clinical Data	VYXEOS (CYTARABINE AND DAUNORUBICIN)	CELATOR PHARMACEUTICALS INC	S	9/27/2022
NDA 209092	13	Labeling Change With Clinical Data	KISQALI (RIBOCICLIB)	NOVARTIS PHARMACEUTICALS CORP	S	10/3/2022
NDA 209935	21	Labeling Change With Clinical Data	KISQALI FEMARA CO-PACK (LETROZOLE AND RIBOCICLIB)	NOVARTIS PHARMACEUTICALS CORP	S	10/3/2022
NDA 211810	8	Labeling Change With Clinical Data	TURALIO (PEXIDARTINIB)	DAIICHI SANKYO INC	S	10/6/2022
NDA 215358	1	Labeling Change With Clinical Data	SCEMBLIX (ASCIMINIB)	NOVARTIS PHARMACEUTICALS CORP	P	10/12/2022
NDA 210251	15	Labeling Change With Clinical Data	BIKTARVY (BICTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	10/14/2022

**CY 2022 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year 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

NDA 202276	20	Labeling Change With Clinical Data	AVANAFIL	METUCHEN PHARMACEUTICALS LLC	S	10/18/2022
NDA 214018	2	Labeling Change With Clinical Data	NULIBRY (FOSDENOPTERIN)	SENTYNL THERAPEUTICS INC	S	10/27/2022
NDA 212526	7	Labeling Change With Clinical Data	PIQRAY (ALPELISIB)	NOVARTIS PHARMACEUTICALS CORP	S	11/22/2022
NDA 208447	25	Labeling Change With Clinical Data	ZEJULA (NIRAPARIB)	GLAXOSMITHKLINE LLC	S	12/8/2022
NDA 210655	10	Labeling Change With Clinical Data	PERSERIS (RISPERIDONE)	INDIVIOR INC	S	12/15/2022
NDA 021038	28	Labeling Change With Clinical Data	PRECEDEX (DEXMEDETOMIDINE HYDROCHLORIDE)	HOSPIRA INC A PFIZER CO	S	12/16/2022
NDA 202192	27	Labeling Change With Clinical Data	JAKAFI (RUXOLITINIB PHOSPHATE)	INCYTE CORP	P	12/19/2022
NDA 209115	13	Labeling Change With Clinical Data	RUBRACA (RUCAPARIB)	CLOVIS ONCOLOGY INC	P	12/21/2022

BLA Efficacy Supplements Approved

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE	PROPER NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
BLA 761105	14	EFFICACY	SKYRIZI (RISANKIZUMAB-RZAA)	ABBVIE INC.	S	1/21/2022
BLA 125514	95	EFFICACY	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	2/4/2022
BLA 125486	29	EFFICACY	GAZYVA (OBINUTUZUMAB)	GENENTECH, INC.	S	2/14/2022
BLA 125276	134	EFFICACY	ACTEMRA (TOCILIZUMAB)	GENENTECH, INC.	S	2/28/2022
BLA 125554	112	EFFICACY	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	3/4/2022
BLA 761036	41	EFFICACY	DARZALEX (DARATUMUMAB)	JANSSEN BIOTECH, INC.	S	3/4/2022
BLA 125514	110	EFFICACY	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	3/21/2022
BLA 761035	15	EFFICACY	EMPLICITI (ELOTUZUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	3/22/2022
BLA 761108	23	EFFICACY	ULTOMIRIS (RAVLIZUMAB-CWVZ)	ALEXION PHARMACEUTICALS, INC.	P	4/27/2022
BLA 125521	23	EFFICACY	TALTZ (IXEKIZUMAB)	ELI LILLY AND COMPANY	S	5/4/2022
BLA 761139	17	EFFICACY		DAIICHI SANKYO, INC.	P	5/4/2022
BLA 761139	20	EFFICACY		DAIICHI SANKYO, INC.	P	5/4/2022
BLA 125377	124	EFFICACY	YERVOY (IPILIMUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	5/11/2022
BLA 125554	108	EFFICACY	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	5/11/2022
BLA 125514	123	EFFICACY	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	5/20/2022
BLA 761055	40	EFFICACY	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	P	5/20/2022
BLA 125377	122	EFFICACY	YERVOY (IPILIMUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	5/27/2022
BLA 125554	105	EFFICACY	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	5/27/2022
BLA 125554	106	EFFICACY	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	5/27/2022
BLA 761125	8	EFFICACY	BEOVU (BROLUCIZUMAB-DBLL)	NOVARTIS PHARMACEUTICALS CORPORATION	S	5/27/2022
BLA 761140	1	EFFICACY	RIABNI (RITUXIMAB-ARRX)	AMGEN, INC.	S	6/3/2022
BLA 761055	42	EFFICACY	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	P	6/7/2022
BLA 761105	16	EFFICACY	SKYRIZI (RISANKIZUMAB-RZAA)	ABBVIE INC.	P	6/16/2022
BLA 761059	4	EFFICACY		SAMSUNG BIOEPIS CO., LTD.	S	6/17/2022
BLA 203314	20	EFFICACY	TRESIBA (INSULIN DEGLUDEC)	NOVO NORDISK INC.	S	7/1/2022
BLA 125293	104	EFFICACY	KRYSTEXXA (PEGLOTICASE)	HORIZON THERAPEUTICS IRELAND DAC	P	7/7/2022
BLA 125554	114	EFFICACY	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	7/14/2022
BLA 761154	2	EFFICACY	HULIO (ADALIMUMAB-FKJP)	MYLAN PHARMACEUTICALS INC.	S	7/14/2022
BLA 761049	13	EFFICACY	BAVENCIO (AVELUMAB)	EMD SERONO, INC.	S	7/15/2022
BLA 761071	10	EFFICACY	HYRIMOZ (ADALIMUMAB-ADAZ)	SANDOZ INC.	S	7/18/2022

**CY 2022 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year 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

BLA 761071	12	EFFICACY	HYRIMOZ (ADALIMUMAB-ADAZ)	SANDOZ INC.	S	7/18/2022
BLA 761108	21	EFFICACY	ULTOMIRIS (RAVULIZUMAB-CWVZ)	ALEXION PHARMACEUTICALS, INC.	S	7/22/2022
BLA 125370	78	EFFICACY	BENLYSTA (BELIMUMAB)	GLAXOSMITHKLINE LLC	P	7/26/2022
BLA 761024	10	EFFICACY	AMJEVITA (ADALIMUMAB-ATTO)	AMGEN, INC.	S	7/28/2022
BLA 125261	161	EFFICACY	STELARA (USTEKINUMAB)	JANSSSEN BIOTECH, INC.	S	7/29/2022
BLA 761118	6	EFFICACY	ABRILADA (ADALIMUMAB-AFZB)	PFIZER INC.	S	7/29/2022
BLA 761139	22	EFFICACY	ENHERTU (FAM-TRASTUZUMAB DERUXTECAN-NXKI)	DAIICHI SANKYO, INC.	P	8/5/2022
BLA 761139	21	EFFICACY	ENHERTU (FAM-TRASTUZUMAB DERUXTECAN-NXKI)	DAIICHI SANKYO, INC.	P	8/11/2022
BLA 761059	5	EFFICACY	HADLIMA (ADALIMUMAB-BWWD)	SAMSUNG BIOEPIS CO., LTD.	S	8/15/2022
BLA 761069	35	EFFICACY	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	P	9/2/2022
BLA 761105	18	EFFICACY	SKYRIZI (RISANKIZUMAB-RZAA)	ABBVIE INC.	S	9/23/2022
BLA 761055	44	EFFICACY	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	P	9/28/2022
BLA 761065	13	EFFICACY	TROGARZO (IBALIZUMAB-UIYK)	THERATECHNOLOGIES INC.	S	10/3/2022
BLA 761077	15	EFFICACY	AIMOVIG (ERENUMAB-AOOE)	AMGEN INC.	S	10/3/2022
BLA 761109	4	EFFICACY	LYUMJEV (INSULIN LISPRO-AABC)	ELI LILLY AND COMPANY	S	10/14/2022
BLA 761069	36	EFFICACY	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	P	10/21/2022
BLA 761116	5	EFFICACY	ELZONRIS (TAGRAXOFUSP-ERZS)	STEMLINE THERAPEUTICS, INC.	S	10/27/2022
BLA 761139	24	EFFICACY		DAIICHI SANKYO, INC.	P	11/4/2022
BLA 761210	2	EFFICACY	RYBREVAANT (AMIVANTAMAB-VMJW)	JANSSSEN BIOTECH, INC.	S	11/4/2022
BLA 761097	14	EFFICACY	LIBTAYO (CEMIPLIMAB-RWLC)	REGENERON PHARMACEUTICALS, INC.	S	11/8/2022
BLA 125388	106	EFFICACY	ADCETRIS (BRENTUXIMAB VEDOTIN)	SEAGEN INC.	P	11/10/2022
BLA 761042	18	EFFICACY	ERELZI (ETANERCEPT-SZS)	SANDOZ INC.	S	11/10/2022
BLA 761069	33	EFFICACY	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	S	11/10/2022
BLA 125469	51	EFFICACY	TRULICITY (DULAGLUTIDE)	ELI LILLY AND COMPANY	P	11/17/2022
BLA 761179	1	EFFICACY		JAZZ PHARMACEUTICALS IRELAND LIMITED	S	11/18/2022
BLA 761039	14	EFFICACY	UDENYCA (PEGFILGRASTIM-CBQV)	COHERUS BIOSCIENCES, INC.	S	11/28/2022
BLA 761034	50	EFFICACY	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	12/2/2022
BLA 761034	47	EFFICACY	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	12/9/2022
BLA 125514	127	EFFICACY	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	12/16/2022
BLA 761067	14	EFFICACY	ILUMYA (TILDRAKIZUMAB-ASMN)	SUN PHARMA GLOBAL FZE	S	12/19/2022
BLA 125276	138	EFFICACY	ACTEMRA (TOCILIZUMAB)	GENENTECH, INC.	P	12/21/2022
BLA 125160	305	EFFICACY	CIMZIA (CERTOLIZUMAB PEGOL)	UCB, INC.	S	12/22/2022