

**CY 2020 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year Approvals
As of December 31, 2020**

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Selection Criteria:

User Response: Start Date: 1/1/2020 End Date: 12/31/2020

Sort Order: Approval Date

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
NDA 209637	3	New Indication	OZEMPIC (SEMAGLUTIDE)	NOVO NORDISK INC	S	1/16/2020
NDA 020427	21	New Patient Population	SABRIL (VIGABATRIN)	LUNDBECK PHARMACEUTICALS LLC	S	1/24/2020
NDA 022006	23	New Patient Population	SABRIL (VIGABATRIN)	LUNDBECK PHARMACEUTICALS LLC	S	1/24/2020
NDA 201699	12	New Patient Population	DIFICID (FIDAXOMICIN)	CUBIST PHARMACEUTICALS LLC	P	1/24/2020
NDA 204353	33	New Indication	INVOKAMET (CANAGLIFLOZIN AND METFORMIN HYDROCHLORIDE)	JANSSEN PHARMACEUTICALS INC	S	1/27/2020
NDA 205879	11	New Indication	INVOKAMET XR (CANAGLIFLOZIN AND METFORMIN HYDROCHLORIDE)	JANSSEN PHARMACEUTICALS INC	S	1/27/2020
NDA 020688	32	Rx To OTC Switch	PATADAY TWICE DAILY RELIEF (OLOPATADINE HYDROCHLORIDE)	NOVARTIS PHARMACEUTICALS CORP	S	2/14/2020
NDA 021545	22	Rx To OTC Switch	PATADAY ONCE DAILY RELIEF (OLOPATADINE HYDROCHLORIDE)	NOVARTIS PHARMACEUTICALS CORP	S	2/14/2020
NDA 022122	14	Rx To OTC Switch	VOLTAREN (DICLOFENAC SODIUM)	GLAXOSMITHKLINE CONSUMER HEALTHCARE	S	2/14/2020
NDA 208051	5	New Indication	NERLYNX (NERATINIB MALEATE)	PUMA BIOTECHNOLOGY INC	S	2/25/2020
NDA 210455	9	New Patient Population	SYM TUZA (DARUNAVIR, COBICISTAT, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE)	JANSSEN PRODUCTS LP	S	3/2/2020
NDA 022306	5	New Dosing Regimen	SOTALOL HYDROCHLORIDE	ALTATHERA PHARMACEUTICALS LLC	S	3/6/2020
NDA 205832	13	New Indication	OFEV (NINTEDANIB)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	3/9/2020
NDA 208341	14	New Patient Population	EPCLUSA (SOFOSBUVIR AND VELPATISVIR)	GILEAD SCIENCES INC	P	3/19/2020
NDA 207695	10	New Patient Population	EUCRISA (CRISABOROLE)	ANACOR PHARMACEUTICALS INC	P	3/23/2020
NDA 206321	11	New Indication	SAXENDA (LIRAGLUTIDE)	NOVO NORDISK INC	S	3/25/2020
NDA 210496	6	New Indication	BRAFTOVI [ENCORAFENIB (LGX818)]	ARRAY BIOPHARMA INC	P	4/8/2020
NDA 205437	8	New Indication	OTEZLA (APREMILAST)	AMGEN INC	S	4/10/2020
NDA 021427	52	New Patient Population	CYMBALTA (DULOXETINE HYDROCHLORIDE)	ELI LILLY AND CO	S	4/20/2020
NDA 205552	30	New Indication	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	P	4/21/2020
NDA 210563	6	New Indication	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	P	4/21/2020
NDA 203567	9	New Patient Population	JUBLIA (EFINACONAZOLE)	BAUSCH HEALTH AMERICAS INC	S	4/26/2020
NDA 208447	17	New Indication	ZEJULA (NIRAPARIB)	GLAXOSMITHKLINE LLC	P	4/29/2020
NDA 008085	71	New Indication	METHOTREXATE TABLETS	DAVA PHARMACEUTICALS INC	S	5/4/2020
NDA 202293	20	New Indication	FARXIGA (DAPAGLIFLOZIN)	ASTRAZENECA AB	P	5/5/2020
NDA 208558	13	New Indication	LYNPARZA (OLAPARIB)	ASTRAZENECA PHARMACEUTICALS LP	P	5/8/2020

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NDA 204026	23	New Indication	POMALYST (POMALIDOMIDE)	CELGENE CORP	P	5/14/2020
NDA 204026	24	New Indication	POMALYST (POMALIDOMIDE)	CELGENE CORP	P	5/14/2020
NDA 209115	4	New Indication	RUBRACA (RUCAPARIB)	CLOVIS ONCOLOGY INC	P	5/15/2020
NDA 208558	14	New Indication	LYNPARZA (OLAPARIB)	ASTRAZENECA PHARMACEUTICALS LP	P	5/19/2020
NDA 208772	8	New Indication	ALUNBRIG (BRIGATINIB)	ARIAD PHARMACEUTICALS INC	P	5/22/2020
NDA 050684	96	New Patient Population	ZOSYN (PIPERACILLIN AND TAZOBACTAM)	WYETH PHARMACEUTICALS LLC	S	5/26/2020
NDA 050750	43	New Patient Population	ZOSYN (PIPERACILLIN SODIUM AND TAZOBACTAM SODIUM) IN GALAXY CONTAINERS	WYETH PHARMACEUTICALS LLC	S	5/26/2020
NDA 204384	13	New Patient Population	SIRTURO (BEDAQUILINE)	JANSSEN RESEARCH AND DEVELOPMENT LLC	P	5/27/2020
NDA 022433	28	New Indication	BRILINTA (TICAGRELOR)	ASTRAZENECA PHARMACEUTICALS LP	S	5/28/2020
NDA 208143	11	New Indication	READI-CAT 2 AND READI-CAT 2 SMOOTHIE (BARIUM SULFATE)	BRACCO DIAGNOSTICS INC	S	5/29/2020
NDA 202324	11	New Indication	INLYTA (AXITINIB)	PF PRISM CV	P	6/4/2020
NDA 212819	2	New Indication	RECARBRIO (IMIPENEM/CILASTATIN/RELEBACTAM)	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	P	6/4/2020
NDA 204790	25	New Dosing Regimen	TIVICAY (DOLUTEGRAVIR)	VIIV HEALTHCARE CO	P	6/12/2020
NDA 205435	12	New Patient Population	SIVEXTRO (TEDIZOLID PHOSPHATE)	CUBIST PHARMACEUTICALS LLC	S	6/19/2020
NDA 205436	7	New Patient Population	SIVEXTRO (TEDIZOLID PHOSPHATE)	CUBIST PHARMACEUTICALS LLC	S	6/19/2020
NDA 212306	1	New Indication	SELINEXOR	KARYOPHARM THERAPEUTICS INC	P	6/22/2020
NDA 022000	19	New Indication	LIALDA (MESALAMINE)	TAKEDA PHARMACEUTICALS USA INC	S	6/26/2020
NDA 206276	5	Rx To OTC Switch	PATADAY ONCE DAILY RELIEF (OLOPATADINE HYDROCHLORIDE)	ALCON LABORATORIES INC	S	7/13/2020
NDA 203045	16	New Patient Population	ISENTRESS (RALTEGRAVIR)	MERCK SHARP AND DOHME CORP	S	7/14/2020
NDA 205786	8	New Patient Population	ISENTRESS (RALTEGRAVIR)	MERCK SHARP AND DOHME CORP	S	7/14/2020
NDA 208341	15	New Patient Population	EPCLUSA (SOFOSBUVIR AND VELPATISVIR)	GILEAD SCIENCES INC	S	7/14/2020
NDA 022395	19	New Indication	QUTENZA (CAPSAICIN)	AVERITAS PHARMA INC	S	7/17/2020
NDA 021882	33	Accelerated Approval Confirmatory Study	EXJADE (DEFERASIROX)	NOVARTIS PHARMACEUTICALS CORP	S	7/23/2020
NDA 206910	15	Accelerated Approval Confirmatory Study	JADENU (DEFERASIROX)	NOVARTIS PHARMACEUTICALS CORP	S	7/23/2020
NDA 207968	9	Accelerated Approval Confirmatory Study	JADENU SPRINKLE (DEFERASIROX)	NOVARTIS PHARMACEUTICALS CORP	S	7/23/2020
NDA 205395	16	New Patient Population	PREZCOBIX (COBICISTAT AND DARUNAVIR)	JANSSEN PRODUCTS LP	S	7/31/2020
NDA 206353	7	New Patient Population	EVOTAZ (ATAZANAVIR AND COBICISTAT)	BRISTOL MYERS SQUIBB CO	S	7/31/2020
NDA 210365	5	New Indication	EPIDIOLEX (CANNABIDIOL)	GW RESEARCH LTD	P	7/31/2020
NDA 210365	6	New Indication	EPIDIOLEX (CANNABIDIOL)	GW RESEARCH LTD	P	7/31/2020
NDA 211243	4	New Indication	SPRAVATO (ESKETAMINE)	JANSSEN PHARMACEUTICALS INC	S	7/31/2020
NDA 022372	13	New Patient Population	SUPREP BOWEL PREP KIT (SODIUM SULFATE, POTASSIUM SULFATE, AND MAGNESIUM SULFATE)	BRAINTREE LABORATORIES INC	S	8/5/2020
NDA 211994	6	New Patient Population	DOVATO (DOLUTEGRAVIR AND LAMIVUDINE)	VIIV HEALTHCARE CO	S	8/6/2020
NDA 021225	40	New Dosing Regimen	MIRENA (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM)	BAYER HEALTHCARE PHARMACEUTICALS INC	S	8/20/2020
NDA 202714	30	New Indication	KYPROLIS (CARFILZOMIB)	ONYX THERAPEUTICS INC A WHOLLY OWNED SUB OF AMGEN INC	S	8/20/2020
NDA 208183	2	New Patient Population	ULTRAVATE (HALOBETASOL PROPIONATE)	SUN PHARMACEUTICAL INDUSTRIES INC	S	8/27/2020
NDA 209449	5	New Dosing Regimen	NITYR (NITISINONE)	CYCLE PHARMACEUTICALS LTD	S	9/2/2020

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NDA 209482	10	New Indication	TRELEGY ELLIPTA (FLUTICASONE FUROATE, UMECLIDINIUM, AND VILANTEROL)	GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LTD ENGLAND	S	9/9/2020
NDA 021632	27	New Patient Population	ERAXIS (ANIDULAFUNGIN)	VICURON HOLDINGS LLC	S	9/22/2020
NDA 203214	26	New Patient Population	XELJANZ (TOFACITINIB)	PF PRISM CV	P	9/25/2020
NDA 209445	2	New Indication	FETROJA (CEFIDEROCOL)	SHIONOGI INC	P	9/25/2020
NDA 209115	8	New Indication	RUBRACA (RUCAPARIB)	CLOVIS ONCOLOGY INC	P	10/8/2020
NDA 208573	20	Accelerated Approval Confirmatory Study	VENCLEXTA (VENETOCLAX)	ABBVIE INC	P	10/16/2020
NDA 208573	21	Accelerated Approval Confirmatory Study	VENCLEXTA (VENETOCLAX)	ABBVIE INC	P	10/16/2020
NDA 202736	6	Rx To OTC Switch	SKLICE (IVERMECTIN)	ARBOR PHARMACEUTICALS LLC	S	10/27/2020
NDA 022128	19	New Patient Population	SELZENTRY (MARAVIROC)	VIIV HEALTHCARE CO	P	10/30/2020
NDA 208984	2	New Patient Population	SELZENTRY (MARAVIROC)	VIIV HEALTHCARE CO	P	10/30/2020
NDA 022025	19	New Indication	TOTECT (DEXRAZOXANE)	CLINIGEN INC	S	11/2/2020
NDA 022433	29	New Indication	BRILINTA (TICAGRELOR)	ASTRAZENECA PHARMACEUTICALS LP	P	11/5/2020
NDA 022253	46	New Indication	VIMPAT (LACOSAMIDE)	UCB INC	S	11/16/2020
NDA 022253	48	New Patient Population	VIMPAT (LACOSAMIDE)	UCB INC	S	11/16/2020
NDA 022254	36	New Indication	VIMPAT (LACOSAMIDE)	UCB INC	S	11/16/2020
NDA 022254	38	New Patient Population	VIMPAT (LACOSAMIDE)	UCB INC	S	11/16/2020
NDA 022255	27	New Indication	VIMPAT (LACOSAMIDE)	UCB INC	S	11/16/2020
NDA 022255	30	New Patient Population	VIMPAT (LACOSAMIDE)	UCB INC	S	11/16/2020
NDA 050779	27	New Dosing Regimen	CEFAZOLIN SODIUM	B BRAUN MEDICAL INC	S	11/23/2020
NDA 210854	4	New Indication	XOFLUZA (BALOXAVIR MARBOXIL)	GENENTECH INC	S	11/23/2020
NDA 207997	6	New Patient Population	RYDAPT (MIDOSTAURIN, PKC412)	NOVARTIS PHARMACEUTICALS CORP	P	11/24/2020
NDA 205677	7	New Indication	HETLIOZ (TASIMELTEON)	VANDA PHARMACEUTICALS INC	P	12/1/2020
NDA 206321	12	New Patient Population	SAXENDA (LIRAGLUTIDE)	NOVO NORDISK INC	S	12/4/2020
NDA 203469	34	New Indication	ICLUSIG (PONATINIB)	ARIAD PHARMACEUTICALS INC	P	12/18/2020
NDA 208065	21	New Indication	TAGRISO (OSIMERTINIB)	ASTRAZENECA PHARMACEUTICALS LP	P	12/18/2020
NDA 212306	5	New Indication	XPOVIO (SELINEXOR)	KARYOPHARM THERAPEUTICS INC	S	12/18/2020
NDA 020131	35	New Patient Population	PROHANCE (GADOTERIDOL) AND PROHANCE MULTIPACK (GADOTERIDOL)	BRACCO DIAGNOSTICS INC	S	12/19/2020
NDA 021489	14	New Patient Population	PROHANCE MULTIPACK (GADOTERIDOL)	BRACCO DIAGNOSTICS INC	S	12/19/2020

NDA Efficacy Supplements Approved (SE8)

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
NDA 200677	6	Labeling Change With Clinical Data	SIGNIFOR (PASIREOTIDE)	RECORDATI RARE DISEASES INC	S	1/15/2020
NDA 204569	6	Labeling Change With Clinical Data	BELSOMRA (SUVOREXANT)	MERCK SHARP AND DOHME CORP	S	1/29/2020
NDA 022567	21	Labeling Change With Clinical Data	VIIBRYD (VILAZODONE HYDROCHLORIDE)	ALLERGAN SALES LLC	P	1/31/2020
NDA 208464	8	Labeling Change With Clinical Data	VEMLIDY (TENOFVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	2/4/2020
NDA 204063	23	Labeling Change With Clinical Data	TECFIDERA (DIMETHYL FUMARATE)	BIOGEN IDEC INC	S	2/5/2020
NDA 208051	6	Labeling Change With Clinical Data	NERLYNX (NERATINIB MALEATE)	PUMA BIOTECHNOLOGY INC	S	2/25/2020
NDA 211651	5	Labeling Change With Clinical Data	TALZENNA (TALAZOPARIB)	PFIZER INC	S	3/9/2020
NDA 202439	31	Labeling Change With Clinical Data	XARELTO (RIVAROXABAN)	JANSSEN PHARMACEUTICALS INC	S	3/10/2020
NDA 016269	56	Labeling Change With Clinical Data	MANNITOL	HOSPIRA INC	S	3/17/2020
NDA 201280	20	Labeling Change With Clinical Data	TRADJENTA (LINAGLIPTIN)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	3/30/2020
NDA 201281	24	Labeling Change With Clinical Data	JENTADUETO (LINAGLIPTIN AND METFORMIN HYDROCHLORIDE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	3/30/2020
NDA 206073	21	Labeling Change With Clinical Data	GLYXAMBI (EMPAGLIFLOZIN AND LINAGLIPTIN)	BOEHRINGER INGELHEIM	S	3/30/2020

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NDA 208026	12	Labeling Change With Clinical Data	JENTADUETO XR (LINAGLIPTIN AND METFORMIN HYDROCHLORIDE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	3/30/2020
NDA 208716	4	Labeling Change With Clinical Data	VERZENIO (ABEMACICLIB)	ELI LILLY AND CO	S	3/30/2020
NDA 209394	10	Labeling Change With Clinical Data	MAVYRET (GLECAPREVIR AND PIBRENTASVIR)	ABBVIE INC	S	4/10/2020
NDA 207078	3	Labeling Change With Clinical Data	LOKELMA (SODIUM ZIRCONIUM CYCLOSILICATE)	ASTRAZENECA PHARMACEUTICALS LP	S	4/24/2020
NDA 209310	3	Labeling Change With Clinical Data	SINUVA (MOMETASONE FUROATE)	INTERSECT ENT INC	S	4/28/2020
NDA 019603	40	Labeling Change With Clinical Data	MANNITOL	ICU MEDICAL INC	S	4/29/2020
NDA 021344	41	Labeling Change With Clinical Data	FASLODEX (FULVESTRANT)	ASTRAZENECA PHARMACEUTICALS LP	S	5/13/2020
NDA 208065	16	Labeling Change With Clinical Data	TAGRISSO (OSIMERTINIB)	ASTRAZENECA PHARMACEUTICALS LP	S	5/23/2020
NDA 208700	10	Labeling Change With Clinical Data	LUTATHERA (177 LU-DOTA0-TYR3-OCTREOTATE)	ADVANCED ACCELERATOR APPLICATIONS USA INC	S	5/28/2020
NDA 022225	6	Labeling Change With Clinical Data	BRIDION (SUGAMMADEX)	ORGANON USA INC A SUB OF MERCK AND CO INC	S	6/9/2020
NDA 209531	10	Labeling Change With Clinical Data	SPINRAZA (NUSINERSEN)	BIOGEN INC	S	6/16/2020
NDA 209092	5	Labeling Change With Clinical Data	KISQALI (RIBOCICLIB)	NOVARTIS PHARMACEUTICALS CORP	S	7/6/2020
NDA 209935	8	Labeling Change With Clinical Data	KISQALI FEMARA CO-PACK (LETROZOLE AND RIBOCICLIB)	NOVARTIS PHARMACEUTICALS CORP	S	7/6/2020
NDA 022145	42	Labeling Change With Clinical Data	ISENTRESS (RALTEGRAVIR)	MERCK SHARP AND DOHME CORP	S	7/14/2020
NDA 210192	7	Labeling Change With Clinical Data	JULUCA (DOLUTEGRAVIR AND RILPIVIRINE)	VIIV HEALTHCARE CO	S	7/14/2020
NDA 022087	9	Labeling Change With Clinical Data	VECTICAL (CALCITRIOL)	GALDERMA LABORATORIES LP	S	7/17/2020
NDA 021344	42	Labeling Change With Clinical Data	FASLODEX (FULVESTRANT)	ASTRAZENECA PHARMACEUTICALS LP	S	7/28/2020
NDA 208051	7	Labeling Change With Clinical Data	NERLYNX (NERATINIB MALEATE)	PUMA BIOTECHNOLOGY INC	S	7/29/2020
NDA 211994	7	Labeling Change With Clinical Data	DOVATO (DOLUTEGRAVIR AND LAMIVUDINE)	VIIV HEALTHCARE CO	S	8/6/2020
NDA 204042	34	Labeling Change With Clinical Data	INVOKANA (CANAGLIFLOZIN)	JANSSEN PHARMACEUTICALS INC	S	8/18/2020
NDA 204353	39	Labeling Change With Clinical Data	INVOKAMET (CANAGLIFLOZIN AND METFORMIN HYDROCHLORIDE)	JANSSEN PHARMACEUTICALS INC	S	8/18/2020
NDA 205879	17	Labeling Change With Clinical Data	INVOKAMET XR (CANAGLIFLOZIN AND METFORMIN HYDROCHLORIDE)	JANSSEN PHARMACEUTICALS INC	S	8/18/2020
NDA 208464	10	Labeling Change With Clinical Data	VEMLIDY (TENOFIVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	8/18/2020
NDA 208464	11	Labeling Change With Clinical Data	VEMLIDY (TENOFIVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	8/18/2020
NDA 202811	16	Labeling Change With Clinical Data	LINZESS (LINACLOTIDE)	ALLERGAN SALES LLC	S	9/22/2020
NDA 203188	33	Labeling Change With Clinical Data	KALYDECO (IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	9/24/2020
NDA 207925	11	Labeling Change With Clinical Data	KALYDECO (IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	9/24/2020
NDA 021196	32	Labeling Change With Clinical Data	XYREM (SODIUM OXYBATE)	JAZZ PHARMACEUTICALS	S	9/25/2020
NDA 019414	21	Labeling Change With Clinical Data	CARDIOGEN-82 GENERATOR (RUBIDIUM RB 82)	BRACCO DIAGNOSTICS INC	S	10/15/2020
NDA 207589	10	Labeling Change With Clinical Data	ENSTILAR (CALCIPOTRIENE AND BETAMETHASONE DIPROPIONATE)	LEO PHARMA AS	S	10/16/2020
NDA 207356	3	Labeling Change With Clinical Data	ARIKAYCE (AMIKACIN)	INSMED INC	S	10/19/2020
NDA 211651	6	Labeling Change With Clinical Data	TALZENNA (TALAZOPARIB)	PFIZER INC	S	10/22/2020
NDA 203415	16	Labeling Change With Clinical Data	XTANDI (ENZALUTAMIDE)	ASTELLAS PHARMA US INC	P	10/23/2020
NDA 212614	4	Labeling Change With Clinical Data	TRIJARDY XR (EMPAGLIFLOZIN, LINAGLIPTIN, AND METFORMIN HYDROCHLORIDE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	10/30/2020

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NDA 204447	20	Labeling Change With Clinical Data	TRINTELLIX (VORTIOXETINE)	TAKEDA PHARMACEUTICALS USA INC	S	11/13/2020
NDA 021318	54	Labeling Change With Clinical Data	FORTEO (TERIPARATIDE)	ELI LILLY AND CO	S	11/16/2020
NDA 204026	27	Labeling Change With Clinical Data	POMALYST (POMALIDOMIDE)	CELGENE CORP	P	11/20/2020
NDA 210951	4	Labeling Change With Clinical Data	ERLEADA (APALUTAMIDE)	JANSSEN BIOTECH INC	P	11/20/2020
NDA 210854	10	Labeling Change With Clinical Data	XOFLUZA (BALOXAVIR MARBOXIL)	GENENTECH INC	S	11/23/2020
NDA 209606	4	Labeling Change With Clinical Data	IDHIFA (ENASIDENIB)	CELGENE CORP	P	11/24/2020
NDA 020246	60	Labeling Change With Clinical Data	DEPO-PROVERA (MEDROXYPROGESTERONE ACETATE)	PHARMACIA AND UPJOHN CO	S	12/4/2020
NDA 020246	62	Labeling Change With Clinical Data	DEPO-PROVERA (MEDROXYPROGESTERONE ACETATE)	PHARMACIA AND UPJOHN CO	S	12/4/2020
NDA 021583	33	Labeling Change With Clinical Data	DEPO-SUBQ PROVERA 104 (MEDROXYPROGESTERONE ACETATE)	PHARMACIA AND UPJOHN SUB PFIZER INC	S	12/4/2020
NDA 021583	34	Labeling Change With Clinical Data	DEPO-SUBQ PROVERA 104 (MEDROXYPROGESTERONE ACETATE)	PHARMACIA AND UPJOHN SUB PFIZER INC	S	12/4/2020
NDA 021995	47	Labeling Change With Clinical Data	JANUVIA (SITAGLIPTIN PHOSPHATE)	MERCK SHARP AND DOHME CORP	P	12/4/2020
NDA 022044	48	Labeling Change With Clinical Data	JANUMET (METFORMIN HYDROCHLORIDE AND SITAGLIPTIN PHOSPHATE)	MERCK SHARP AND DOHME CORP	P	12/4/2020
NDA 202270	22	Labeling Change With Clinical Data	JANUMET XR (METFORMIN HYDROCHLORIDE AND SITAGLIPTIN PHOSPHATE)	MERCK SHARP AND DOHME CORP	P	12/4/2020
NDA 208558	16	Labeling Change With Clinical Data	LYNPARZA (OLAPARIB)	ASTRAZENECA PHARMACEUTICALS LP	P	12/7/2020
NDA 208065	18	Labeling Change With Clinical Data	TAGRISSO (OSIMERTINIB)	ASTRAZENECA PHARMACEUTICALS LP	S	12/9/2020
NDA 201023	24	Labeling Change With Clinical Data	JEVTANA (CABAZITAXEL)	SANOVI AVENTIS US LLC	P	12/18/2020
NDA 205552	32	Labeling Change With Clinical Data	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	S	12/18/2020
NDA 210563	9	Labeling Change With Clinical Data	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	S	12/18/2020
NDA 203188	34	Labeling Change With Clinical Data	KALYDECO (IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	12/21/2020
NDA 207925	13	Labeling Change With Clinical Data	KALYDECO (IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	12/21/2020
NDA 210491	7	Labeling Change With Clinical Data	SYMDEKO (IVACAFTOR AND TEZACAFTOR)	VERTEX PHARMACEUTICALS INC	P	12/21/2020
NDA 212273	2	Labeling Change With Clinical Data	TRIKAFTA (ELEXACAFTOR/TEZACAFTOR/IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	12/21/2020

BLA Efficacy Supplements Approved

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE	PROPER NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
BLA 125514	66	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	1/8/2020
BLA 125409	124	Labeling Change With Clinical Data	PERJETA (PERTUZUMAB)	GENENTECH, INC.	S	1/16/2020
BLA 761072	6	Efficacy	IXIFI (INFLIXIMAB)	PFIZER IRELAND PHARMACEUTICALS	S	1/16/2020
BLA 125370	68	Labeling Change With Clinical Data	BENLYSTA (BELIMUMAB)	HUMAN GENOME SCIENCES, INC.	S	1/17/2020
BLA 761089	2	Manufacturing Change With Clinical Data		TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.	S	1/27/2020
BLA 125504	31	New Dosing Regimen	COSENTYX (SECUKINUMAB)	NOVARTIS PHARMACEUTICALS CORPORATION	S	1/29/2020
BLA 125469	33	New Indication	TRULICITY (DULAGLUTIDE)	ELI LILLY AND COMPANY	S	2/21/2020
BLA 125377	108	New Indication	YERVOY (IPILIMUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	3/10/2020
BLA 125554	78	New Indication	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	3/10/2020
BLA 020898	65	Labeling Change With Clinical Data	THYROGEN (THYROTROPIN ALFA)	GENZYME CORPORATION	S	3/12/2020
BLA 125521	20	New Patient Population	TALTZ (IXEKIZUMAB)	ELI LILLY AND COMPANY	P	3/26/2020

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BLA 103628	5263	Labeling Change With Clinical Data	AVONEX (INTERFERON BETA-1A)	BIOGEN INC.	S	3/27/2020
BLA 125486	25	Labeling Change With Clinical Data	GAZYVA [OBINUTUZUMAB (GA101, RO5072759)]	GENENTECH, INC.	P	3/27/2020
BLA 125499	18	Labeling Change With Clinical Data	PLEGRIDY (PEGYLATED INTERFERON BETA-1A)	BIOGEN INC.	S	3/27/2020
BLA 761069	18	New Indication	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	P	3/27/2020
BLA 125514	59	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	4/28/2020
BLA 125514	60	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	4/28/2020
BLA 125514	61	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	4/28/2020
BLA 125514	62	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	4/28/2020
BLA 125514	63	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	4/28/2020
BLA 125514	64	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	4/28/2020
BLA 125514	69	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	4/28/2020
BLA 125514	76	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	4/28/2020
BLA 125514	77	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	4/28/2020
BLA 125514	78	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	4/28/2020
BLA 125514	79	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	4/28/2020
BLA 125514	80	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	4/28/2020
BLA 125514	81	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	4/28/2020
BLA 125514	82	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	4/28/2020
BLA 125514	83	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	4/28/2020
BLA 125377	109	New Indication	YERVOY (IPILIMUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	5/15/2020
BLA 125554	80	New Indication	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	5/15/2020
BLA 761034	27	New Indication	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	5/18/2020
BLA 103780	5203	Labeling Change With Clinical Data	REBIF (INTERFERON BETA-1A)	EMD SERONO, INC.	S	5/26/2020
BLA 125377	110	New Indication	YERVOY (IPILIMUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	5/26/2020
BLA 125554	82	New Indication	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	5/26/2020
BLA 761055	20	New Patient Population	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	P	5/26/2020
BLA 761103	3	Labeling Change With Clinical Data	RUXIENCE (RITUXIMAB-PVVR)	PFIZER, INC.	S	5/26/2020
BLA 125085	332	New Indication	AVASTIN (BEVACIZUMAB)	GENENTECH, INC.	P	5/29/2020
BLA 125477	34	New Indication	CYRAMZA (RAMUCIRUMAB)	ELI LILLY AND COMPANY	S	5/29/2020
BLA 125521	19	New Indication	TALTZ (IXEKIZUMAB)	ELI LILLY AND COMPANY	S	5/29/2020
BLA 761034	25	New Indication	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	5/29/2020
BLA 125320	203	Labeling Change With Clinical Data	PROLIA (DENOSUMAB)	AMGEN, INC.	S	6/9/2020
BLA 125320	203	Labeling Change With Clinical Data	XGEVA (DENOSUMAB)	AMGEN, INC.	S	6/9/2020
BLA 125554	81	New Indication	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	6/10/2020
BLA 761042	12	New Patient Population	ERELZI (ETANERCEPT-SZZS)	SANDOZ INC.	U	6/11/2020
BLA 125513	18	Labeling Change With Clinical Data	STRENSIQ (ASFOTASE ALFA)	ALEXION PHARMACEUTICALS, INC.	S	6/12/2020
BLA 125319	97	New Patient Population	ILARIS	NOVARTIS PHARMACEUTICALS CORPORATION	P	6/16/2020
BLA 125319	97	New Patient Population	ILARIS (CANAKINUMAB)	NOVARTIS PHARMACEUTICALS CORPORATION	P	6/16/2020
BLA 125504	35	New Indication	COSENTYX (SECUKINUMAB)	NOVARTIS PHARMACEUTICALS CORPORATION	P	6/16/2020
BLA 125514	71	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	6/16/2020
BLA 125514	90	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	6/16/2020
BLA 761060	4	New Patient Population	MYLOTARG (GEMTUZUMAB OZOGAMICIN)	WYETH PHARMACEUTICALS LLC	P	6/16/2020
BLA 761055	17	Labeling Change With Clinical Data	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	S	6/18/2020
BLA 761068	5	New Indication	CRYSVITA (BUROSUMAB-1WZA) (KRN23; UX023; RECOMBINANT HUMAN IGG1 MONOCLONAL ANTIBODY TO FIBROBLAST GROWTH FACTOR 23 [FGF23])	KYOWA KIRIN, INC.	P	6/18/2020
BLA 761068	5	New Indication	HUMAN IGG1 MONOCLONAL ANTIBODY TO FIBROBLAST GROWTH FACTOR 23 [FGF23]	KYOWA KIRIN, INC.	P	6/18/2020
BLA 125514	68	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	6/24/2020

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BLA 125514	92	New Dosing Regimen	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	6/24/2020
BLA 761097	5	Labeling Change With Clinical Data	LIBTAYO (CEMIPLIMAB-RWLC)	REGENERON PHARMACEUTICALS, INC.	S	6/25/2020
BLA 125514	84	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	6/29/2020
BLA 761036	26	Labeling Change With Clinical Data	DARZALEX (DARATUMUMAB)	JANSSEN BIOTECH, INC.	S	6/29/2020
BLA 761049	9	New Indication	BAVENCIO (AVELUMAB)	EMD SERONO, INC.	P	6/30/2020
BLA 103000	5315	New Patient Population	BOTOX AND BOTOX COSMETIC (ONABOTULINUMTOXINA)	ALLERGAN, INC.	S	7/8/2020
BLA 125274	118	New Patient Population	DYSPORE (ABOBOTULINUMTOXINA)	IPSEN BIOPHARM LIMITED	S	7/8/2020
BLA 761061	7	New Patient Population	TREMFYA (GUSELKUMAB)	JANSSEN BIOTECH, INC.	S	7/13/2020
BLA 125261	150	New Patient Population	STELARA (USTEKINUMAB)	JANSSEN BIOTECH, INC.	S	7/29/2020
BLA 761034	28	New Indication	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	7/30/2020
BLA 125360	78	New Patient Population	XEOMIN (INCOBOTULINUMTOXINA)	MERZ PHARMACEUTICALS GMBH C/O MERZ PHARMACEUTICALS LLC	S	8/18/2020
BLA 125326	70	New Indication	ARZERRA (OFATUMUMAB)	NOVARTIS PHARMACEUTICALS CORPORATION	P	8/20/2020
BLA 761036	29	Labeling Change With Clinical Data	DARZALEX (DARATUMUMAB)	JANSSEN BIOTECH, INC.	S	8/20/2020
BLA 103705	5460	Labeling Change With Clinical Data	RITUXAN (RITUXIMAB)	GENENTECH, INC.	S	8/28/2020
BLA 125469	36	New Dosing Regimen	TRULICITY (DULAGLUTIDE)	ELI LILLY AND COMPANY	S	9/3/2020
BLA 125377	112	Labeling Change With Clinical Data	YERVOY (IPILIMUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	9/18/2020
BLA 125554	84	Labeling Change With Clinical Data	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	9/18/2020
BLA 125554	85	Labeling Change With Clinical Data	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	9/18/2020
BLA 125370	71	Labeling Change With Clinical Data	BENLYSTA (BELIMUMAB)	HUMAN GENOME SCIENCES, INC.	S	9/24/2020
BLA 125526	17	New Indication	NUCALA (MEPOLIZUMAB)	GLAXOSMITHKLINE LLC	P	9/25/2020
BLA 125433	30	New Patient Population	SIMPONI ARIA (GOLIMUMAB)	JANSSEN BIOTECH, INC.	S	9/29/2020
BLA 125433	31	New Patient Population	SIMPONI ARIA (GOLIMUMAB)	JANSSEN BIOTECH, INC.	S	9/29/2020
BLA 761034	29	Labeling Change With Clinical Data	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	9/30/2020
BLA 125377	115	New Indication	YERVOY (IPILIMUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	10/2/2020
BLA 125514	70	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	10/2/2020
BLA 125554	89	New Indication	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	10/2/2020
BLA 761079	5	Labeling Change With Clinical Data	PALYNZIQ (PEGVALIASE-PQPZ)	BIOMARIN PHARMACEUTICAL INC.	S	10/6/2020
BLA 761079	6	New Dosing Regimen	PALYNZIQ (PEGVALIASE-PQPZ)	BIOMARIN PHARMACEUTICAL INC.	S	10/6/2020
BLA 761079	7	New Dosing Regimen	PALYNZIQ (PEGVALIASE-PQPZ)	BIOMARIN PHARMACEUTICAL INC.	S	10/6/2020
BLA 761108	5	Manufacturing Change With Clinical Data	ULTOMIRIS (RAVULIZUMAB-CWVZ) INJECTION	ALEXION PHARMACEUTICALS, INC.	S	10/9/2020
BLA 125514	85	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	10/14/2020
BLA 125514	88	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	11/13/2020
BLA 761069	23	New Dosing Regimen	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	P	11/18/2020
BLA 761069	24	New Dosing Regimen	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	P	11/18/2020
BLA 103976	5235	New Indication	XOLAIR (OMALIZUMAB)	GENENTECH, INC.	S	11/30/2020
BLA 761053	22	New Dosing Regimen	OCREVUS (OCRELIZUMAB)	GENENTECH, INC.	S	12/14/2020
BLA 125057	419	New Dosing Regimen	HUMIRA (ADALIMUMAB)	ABBVIE INC.	S	12/16/2020
BLA 125370	73	New Indication	BENLYSTA (BELIMUMAB)	HUMAN GENOME SCIENCES, INC.	U	12/16/2020
BLA 761043	13	New Indication	BENLYSTA (BELIMUMAB)	HUMAN GENOME SCIENCES, INC.	U	12/16/2020
BLA 103950	5189	New Indication	KINERET (ANAKINRA)	SWEDISH ORPHAN BIOVITRUM AB (PUBL)	P	12/18/2020
BLA 125249	47	Labeling Change With Clinical Data	ARCALYST (RILONACEPT)	KINIKA PHARMACEUTICALS GMBH	P	12/18/2020
BLA 125360	86	New Patient Population	XEOMIN (INCOBOTULINUMTOXINA)	MERZ PHARMACEUTICALS GMBH C/O MERZ PHARMACEUTICALS LLC	P	12/18/2020
BLA 761034	31	Labeling Change With Clinical Data	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	S	12/18/2020

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BLA 761034	32	Labeling Change With Clinical Data	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	S	12/18/2020
BLA 761047	5	Labeling Change With Clinical Data	MEPSEVII (VESTRONIDASE ALFA-VJBK)	ULTRAGENYX PHARMACEUTICAL INC.	S	12/23/2020