

**CY 2021 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year Approvals
As of December 31, 2021**

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Sort Order: Approval Date

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
NDA 202570	30	New Indication	XALKORI (CRIZOTINIB)	PF PRISM CV	P	1/14/2021
NDA 207958	19	New Indication	LEVETIRACETAM	APRECIA PHARMACEUTICALS LLC	S	1/19/2021
NDA 202022	14	New Dosing Regimen	EDURANT (RILPIVIRINE HYDROCHLORIDE)	JANSSEN PRODUCTS LP	P	1/21/2021
NDA 022562	8	New Indication	CARBAGLU (N-CARBAMYL-L-GLUTAMIC ACID)	RECORDATI RARE DISEASES INC	P	1/22/2021
NDA 022562	9	New Indication	CARBAGLU (N-CARBAMYL-L-GLUTAMIC ACID)	RECORDATI RARE DISEASES INC	P	1/22/2021
NDA 208692	10	New Indication	CABOMETYX (CABOZANTINIB)	EXELIXIS INC	P	1/22/2021
NDA 206426	7	New Patient Population	RAPIVAB (PERAMIVIR)	BIOCRIST PHARMACEUTICALS INC	P	1/28/2021
NDA 207131	6	New Dosing Regimen	CEFAZOLIN	BAXTER HEALTHCARE CORP	S	2/1/2021
NDA 208944	4	New Indication	GOCOVRI (AMANTADINE)	ADAMAS PHARMA LLC	S	2/1/2021
NDA 213176	2	New Indication	UMBRALISIB	TG THERAPEUTICS INC	P	2/5/2021
NDA 210251	7	New Patient Population	BIKTARVY (BICTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	2/5/2021
NDA 209949 (1)	6	New Patient Population	DAPTOMYCIN	XELLIA PHARMACEUTICALS APS	S	2/12/2021
NDA 205551	25	New Patient Population	TRIUMEQ (ABACAVIR, DOLUTEGRAVIR, AND LAMIVUDINE)	VIIV HEALTHCARE CO	S	3/1/2021
NDA 211994	10	New Patient Population	DOVATO (DOLUTEGRAVIR AND LAMIVUDINE)	VIIV HEALTHCARE CO	S	3/1/2021
NDA 210868	4	Accelerated Approval Confirm	LORBRENA [LORLATINIB (PF-06463922)]	PFIZER INC	P	3/3/2021
NDA 212909	1	Manufacturing Change With C	CBIORPHEN (PHENYLEPHRINE HYDROCHLORIDE)	ETON PHARMACEUTICALS	S	3/11/2021
NDA 022496	35	New Indication	EXPAREL (BUPIVACAINE)	PACIRA PHARMACEUTICALS INC	S	3/22/2021
NDA 202611	17	New Indication	MYRBETRIQ (MIRABEGRON)	ASTELLAS PHARMA GLOBAL DEVELOPMENT INC	P	3/25/2021
NDA 011719	131	New Indication	METHOTREXATE SODIUM	HOSPIRA INC	S	3/29/2021
NDA 209401	6	New Indication	VYXEOS (CYTARABINE AND DAUNORUBICIN)	CELATOR PHARMACEUTICALS INC	P	3/30/2021
NDA 022387	17	New Indication	TYVASO (TREPASTINIL)	UNITED THERAPEUTICS CORP	S	3/31/2021
NDA 209191	2	New Indication	BORTEZOMIB	HOSPIRA INC	S	4/14/2021
NDA 209905	1	New Patient Population	EVEKEO (AMPHETAMINE SULFATE) IMMEDIATE RELEASE ORALLY DISINTEGRATING TABLET	ARBOR PHARMACEUTICALS LLC	S	4/16/2021
NDA 209241	20	New Dosing Regimen	INGREZZA (VALBENAZINE)	NEUROCRINE BIOSCIENCES INC	S	4/23/2021
NDA 022408	10	New Indication	NATROBA (SPINOSAD)	PARAPRO LLC	S	4/28/2021
NDA 203565	14	New Dosing Regimen	INJECTAFER (FERRIC CARBOXYMALTOSIDE)	AMERICAN REGENT INC	S	4/28/2021
NDA 202515	25	New Dosing Regimen	MORPHINE SULFATE	HOSPIRA INC	S	4/29/2021
NDA 021825	8	Accelerated Approval Confirm	FERRIPROX (DEFERIPRONE)	CHIESI USA INC	S	4/30/2021

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NDA 202293	24	New Indication	FARXIGA (DAPAGLIFLOZIN)	ASTRAZENECA AB	P	4/30/2021
NDA 208030	5	Accelerated Approval Confirm	FERRIPROX (DEFERIPRONE)	CHIESI USA INC	S	4/30/2021
NDA 212269	1	Accelerated Approval Confirm	FERRIPROX (DEFERIPRONE)	CHIESI USA INC	S	4/30/2021
NDA 209949	6	New Patient Population	DAPTOMYCIN	XELLIA PHARMACEUTICALS APS	S	5/5/2021
NDA 209949	7	New Patient Population	DAPTOMYCIN	XELLIA PHARMACEUTICALS APS	S	5/5/2021
NDA 203341	20	Accelerated Approval Confirm	BOSULIF (BOSUTINIB MONOHYDRATE)	PF PRISM CV	P	5/14/2021
NDA 202207	12	New Patient Population	LYMPHOSEEK (TECHNETIUM TC 99M TILMANOCEPT)	CARDINAL HEALTH 414 LLC CARDINAL HEALTH NUCLEAR PHARMACY SERVICES	S	5/19/2021
NDA 022202	13	New Patient Population	ZIPSOR (DICLOFENAC POTASSIUM)	ASSERTIO THERAPEUTICS INC	S	5/25/2021
NDA 209816	11	New Dosing Regimen	NUZYRA (OMADACYCLINE)	PARATEK PHARMACEUTICALS INC	S	5/27/2021
NDA 209817	10	New Dosing Regimen	NUZYRA (OMADACYCLINE)	PARATEK PHARMACEUTICALS INC	S	5/27/2021
NDA 209899	1	New Indication	ZEPOSIA (OZANIMOD)	CELGENE INTERNATIONAL II SARL	P	5/27/2021
NDA 212728	6	New Indication	NURTEC ODT (RIMEGEPANT)	BIOHAVEN PHARMACEUTICAL IRELAND DESIGNATED ACTIVITY CO	S	5/27/2021
NDA 211962	9	New Patient Population	VANCOMYCIN	XELLIA PHARMACEUTICALS APS	S	5/28/2021
NDA 205053	12	New Patient Population	NOXAFIL (POSACONAZOLE)	MERCK SHARP AND DOHME CORP	S	5/31/2021
NDA 205596	12	New Patient Population	NOXAFIL (POSACONAZOLE)	MERCK SHARP AND DOHME CORP	S	5/31/2021
NDA 022195	10	Pediatric	MORPHINE SULFATE	HIKMA PHARMACEUTICALS USA INC	S	6/2/2021
NDA 022207	5	Pediatric	MORPHINE SULFATE	HIKMA PHARMACEUTICALS USA INC	S	6/2/2021
NDA 212273	4	Manufacturing Change With C	TRIKAFTA (ELEXACAFTOR/TEZACAFTOR/IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	6/8/2021
NDA 209394	13	New Patient Population	MAVYRET (GLECAPREVIR AND PIBRENTASVIR)	ABBVIE INC	P	6/10/2021
NDA 212608	6	New Indication	AYVAKIT (AVAPRITINIB)	BLUEPRINT MEDICINES CORP	P	6/16/2021
NDA 212608	7	New Indication	AYVAKIT (AVAPRITINIB)	BLUEPRINT MEDICINES CORP	P	6/16/2021
NDA 022030	19	New Patient Population	TOVIAZ (FESOTERODINE FUMARATE)	PFIZER INC	P	6/17/2021
NDA 205053	11	New Indication	NOXAFIL (POSACONAZOLE)	MERCK SHARP AND DOHME CORP	S	6/17/2021
NDA 205596	13	New Indication	NOXAFIL (POSACONAZOLE)	MERCK SHARP AND DOHME CORP	S	6/17/2021
NDA 022512	41	New Patient Population	PRADAXA (DABIGATRAN ETEXILATE MESYLATE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	6/21/2021
NDA 210872	1	Manufacturing Change With C	ISOPROPYL ALCOHOL	ZUREX PHARMA	S	6/24/2021
NDA 208051	9	New Dosing Regimen	NERLYNX (NERATINIB MALEATE)	PUMA BIOTECHNOLOGY INC	S	6/28/2021
NDA 209363	12	New Indication	SOLOSEC (SECNIDAZOLE)	LUPIN INC	S	6/30/2021
NDA 208798	8	New Patient Population	ARMONAIR RESPICLICK (FLUTICASONE PROPIONATE)	TEVA PHARMACEUTICAL INDUSTRIES LTD	P	7/9/2021
NDA 050708	53	New Indication	PROGRAF (TACROLIMUS)	ASTELLAS PHARMA US INC	P	7/16/2021
NDA 050709	45	New Indication	PROGRAF (TACROLIMUS)	ASTELLAS PHARMA US INC	P	7/16/2021

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NDA 210115	5	New Indication	PROGRAF GRANULES (TACROLIMUS)	ASTELLAS PHARMA US INC	P	7/16/2021
NDA 200534	10	New Dosing Regimen	OXYCODONE HYDROCHLORIDE	GENUS LIFE SCIENCES INC	S	7/21/2021
NDA 200535	17	New Dosing Regimen	OXYCODONE HYDROCHLORIDE	GENUS LIFE SCIENCES INC	S	7/21/2021
NDA 201194	9	New Dosing Regimen	OXYCODONE HYDROCHLORIDE	VISTAPHARM INC	S	7/21/2021
NDA 206947	20	New Indication	LENVIMA (LENVATINIB MESYLATE)	EISAI INC	P	7/21/2021
NDA 021883	10	New Patient Population	DALVANCE (DALBAVANCIN)	ALLERGAN SALES LLC	S	7/22/2021
NDA 022200	31	New Indication	BYDUREON (EXENATIDE)	ASTRAZENECA AB	P	7/22/2021
NDA 209210	17	New Indication	BYDUREON BCISE (EXENATIDE)	ASTRAZENECA AB	P	7/22/2021
NDA 212516	2	New Indication	DRIZALMA SPRINKLE (DULOXETINE)	SUN PHARMA GLOBAL FZE	S	7/23/2021
NDA 206947	19	New Indication	LENVIMA (LENVATINIB MESYLATE)	EISAI INC	P	8/10/2021
NDA 212690	6	New Indication	XYWAV (CALCIUM, MAGNESIUM, POTASSIUM, AND SODIUM)	JAZZ PHARMACEUTICALS INC	P	8/12/2021
NDA 204629	26	New Indication	JARDIANCE (EMPAGLIFLOZIN)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	8/18/2021
NDA 202439	35	New Indication	XARELTO (RIVAROXABAN)	JANSSEN PHARMACEUTICALS INC	S	8/23/2021
NDA 211192	8	New Indication	TIBSOVO (IVOSIDENIB)	SERVIER PHARMACEUTICALS LLC	P	8/25/2021
NDA 205836	9	New Patient Population	BRIVIACT (BRIVARACETAM)	UCB INC	S	8/27/2021
NDA 205837	7	New Patient Population	BRIVIACT (BRIVARACETAM)	UCB INC	S	8/27/2021
NDA 205838	6	New Patient Population	BRIVIACT (BRIVARACETAM)	UCB INC	S	8/27/2021
NDA 207946	10	New Dosing Regimen	INVEGA TRINZA (PALIPERIDONE) AND INVEGA HAFYER	JANSSEN PHARMACEUTICALS INC	S	8/30/2021
NDA 213217	4	New Indication	BRUKINSA (ZANUBRUTINIB)	BEIGENE USA INC	S	8/31/2021
NDA 213217	5	New Indication	BRUKINSA (ZANUBRUTINIB)	BEIGENE USA INC	P	9/14/2021
NDA 208692	12	New Indication	CABOMETYX (CABOZANTINIB)	EXELIXIS INC	P	9/17/2021
NDA 205004	3	New Dosing Regimen	BORTEZOMIB	FRESENIUS KABI USA LLC	S	9/20/2021
NDA 202192	23	New Indication	JAKAFI (RUXOLITINIB PHOSPHATE)	INCYTE CORP	P	9/22/2021
NDA 022068	35	New Patient Population	TASIGNA (NILOTINIB)	NOVARTIS PHARMACEUTICALS CORP	P	9/23/2021

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NDA 204141	9	New Patient Population	TOPICORT (DESOXIMETASONE)	TARO PHARMACEUTICALS INC	S	10/7/2021
NDA 208742	7	New Indication	DEXTENZA (DEXAMETHASONE)	OCULAR THERAPEUTIX INC	S	10/7/2021
NDA 210251	14	New Patient Population	BIKTARVY (BICTEGRAVIR, EMTRICITABINE, AND TENOF	GILEAD SCIENCES INC	P	10/7/2021
NDA 208716	6	New Indication	VERZENIO (ABEMACICLIB)	ELI LILLY AND CO	S	10/12/2021
NDA 208716	7	New Patient Population	VERZENIO (ABEMACICLIB)	ELI LILLY AND CO	S	10/12/2021
NDA 208716	8	New Patient Population	VERZENIO (ABEMACICLIB)	ELI LILLY AND CO	S	10/12/2021
NDA 022253	49	New Patient Population	VIMPAT (LACOSAMIDE)	UCB INC	S	10/14/2021
NDA 022254	39	New Patient Population	VIMPAT (LACOSAMIDE)	UCB INC	S	10/14/2021
NDA 022255	31	New Patient Population	VIMPAT (LACOSAMIDE)	UCB INC	S	10/14/2021
NDA 203565	16	New Patient Population	INJECTAFER (FERRIC CARBOXYMALTOSE)	AMERICAN REGENT INC	S	11/19/2021
NDA 208627	6	New Dosing Regimen	TPOXX (TECOVIRIMAT)	SIGA TECHNOLOGIES INC	S	11/23/2021
NDA 202714	33	New Indication	KYPROLIS (CARFILZOMIB)	ONYX THERAPEUTICS INC A WHOLLY OWNED SUB OF AMG	S	11/30/2021
NDA 208843	3	New Patient Population	SIKLOS (HYDROXYUREA)	ADDMEDICA SAS	S	12/7/2021
NDA 211988	5	New Indication	ZYNRELEF (BUPIVACAINE AND MELOXICAM)	HERON THERAPEUTICS INC	S	12/8/2021
NDA 208261	7	New Patient Population	ZEPATIER (ELBASVIR AND GRAZOPREVR)	MERCK SHARP AND DOHME CORP	S	12/9/2021
NDA 021652	29	New Patient Population	EPZICOM (ABACAVIR AND LAMIVUDINE)	VIIV HEALTHCARE CO	S	12/10/2021
NDA 022134	8	Rx To OTC Switch	LASTACFT (ALCAFTADINE)	ALLERGAN INC	S	12/10/2021
NDA 209092	8	New Patient Population	KISQALI (RIBOCICLIB)	NOVARTIS PHARMACEUTICALS CORP	S	12/10/2021
NDA 209935	14	New Patient Population	KISQALI FEMARA CO-PACK (LETROZOLE AND RIBOCICI	NOVARTIS PHARMACEUTICALS CORP	S	12/10/2021
NDA 021116	21	Efficacy	THYRO-TABS (LEVOTHYROXINE SODIUM)	ALVOGEN INC	S	12/13/2021
NDA 203214	28	New Indication	XELJANZ (TOFACITINIB)	PF PRISM CV	S	12/14/2021
NDA 208246	13	New Indication	XELJANZ XR (TOFACITINIB)	PFIZER INC	S	12/14/2021
NDA 211675	2	New Indication	RINVOQ (UPADACITINIB)	ABBVIE INC	S	12/14/2021
NDA 021137	2	Comparative Efficacy Claim	LEVOLET	GENUS LIFE SCIENCES INC	S	12/17/2021
NDA 021137	3	Efficacy	LEVOLET	GENUS LIFE SCIENCES INC	S	12/17/2021
NDA 021137	4	Efficacy	LEVOLET	GENUS LIFE SCIENCES INC	S	12/17/2021
NDA 209500	5	New Indication	CAPLYTA (LUMATEPERONE)	INTRA-CELLULAR THERAPIES INC	S	12/17/2021
NDA 209500	6	New Indication	CAPLYTA (LUMATEPERONE)	INTRA-CELLULAR THERAPIES INC	S	12/17/2021
NDA 213137	6	New Indication	OXBRYTA (VOXELOTOR)	GLOBAL BLOOD THERAPEUTICS INC	P	12/17/2021
NDA 205437	11	New Indication	OTEZLA (APREMILAST)	AMGEN INC	S	12/20/2021
NDA 212887	4	New Indication	VOCABRIA (CABOTEGRAVIR)	VIIV HEALTHCARE CO	P	12/20/2021

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NDA 205422	7	New Indication	REXULTI (BREXPIPIRAZOLE)	OTSUKA PHARMACEUTICAL CO LTD	P	12/27/2021
NDA 210132	6	New Indication	BIJUVA (ESTRADIOL AND PROGESTERONE)	THERAPEUTICSMD INC	S	12/28/2021

NDA Efficacy Supplements Approved (SE8)

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
NDA 212099	1	Labeling Change With Clinical Data	NUBEQA (DAROLUTAMIDE)	BAYER HEALTHCARE PHARMACEUTICALS INC	P	1/7/2021
NDA 022225	7	Labeling Change With Clinical Data	BRIDION (SUGAMMADEX)	ORGANON USA INC A SUB OF MERCK AND CO INC	S	1/22/2021
NDA 204447	21	Labeling Change With Clinical Data	TRINTELLIX (VORTIOXETINE)	TAKEDA PHARMACEUTICALS USA INC	P	1/22/2021
NDA 207947	8	Labeling Change With Clinical Data	UPTRAVI (SELEXIPAG)	ACTELION PHARMACEUTICALS US INC	S	1/30/2021
NDA 210450	4	Labeling Change With Clinical Data	ORILISSA	ABBVIE INC	S	2/1/2021
NDA 210450	5	Labeling Change With Clinical Data	ORILISSA	ABBVIE INC	S	2/1/2021
NDA 210450	6	Labeling Change With Clinical Data	ORILISSA	ABBVIE INC	S	2/1/2021
NDA 207620	18	Labeling Change With Clinical Data	ENTRESTO (SACUBITRIL AND VALSARTAN)	NOVARTIS PHARMACEUTICALS CORP	S	2/16/2021
NDA 210251	8	Labeling Change With Clinical Data	BIKTARVY (BICTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	2/24/2021
NDA 208558	19	Labeling Change With Clinical Data	LYNPARZA (OLAPARIB)	ASTRAZENECA PHARMACEUTICALS LP	S	3/11/2021
NDA 210861	4	Labeling Change With Clinical Data	VITRAKVI (LAROTRECTINIB)	BAYER HEALTHCARE PHARMACEUTICALS INC	S	3/25/2021
NDA 211710	4	Labeling Change With Clinical Data	VITRAKVI (LAROTRECTINIB)	BAYER HEALTHCARE PHARMACEUTICALS INC	S	3/25/2021
NDA 207962	5	Labeling Change With Clinical Data	ZTLIDO (LIDOCAINE HCL TOPICAL SYSTEM)	SCILEX PHARMACEUTICALS INC	S	4/8/2021
NDA 021283	58	Labeling Change With Clinical Data	DIOVAN (VALSARTAN)	NOVARTIS PHARMACEUTICALS CORP	S	4/19/2021
NDA 202992	13	Labeling Change With Clinical Data	AUBAGIO (TERIFLUNOMIDE)	SANOVI AVENTIS US LLC	S	4/30/2021
NDA 210326	1	Labeling Change With Clinical Data	FULVESTRANT	FRESENIUS KABI USA LLC	S	5/12/2021
NDA 208341	17	Labeling Change With Clinical Data	EPCLUSA (SOFOSBUVIR AND VELPATISVIR)	GILEAD SCIENCES INC	P	6/10/2021
NDA 022474	11	Labeling Change With Clinical Data	ELLA (ULIPRISTAL ACETATE)	LABORATOIRE HRA PHARMA	S	6/24/2021
NDA 208082	9	Labeling Change With Clinical Data	AUSTEDO (DEUTETRABENAZINE)	TEVA BRANDED PHARMACEUTICAL PRODUCTS R AND D INC	P	6/24/2021
NDA 022225	8	Labeling Change With Clinical Data	BRIDION (SUGAMMADEX)	ORGANON USA INC A SUB OF MERCK AND CO INC	S	6/25/2021
NDA 212038	2	Labeling Change With Clinical Data	ADHANSIA XR	PURDUE PHARMA LP	S	6/28/2021
NDA 204790	28	Labeling Change With Clinical Data	TIVICAY (DOLUTEGRAVIR)	VIIV HEALTHCARE CO	S	7/9/2021
NDA 208799	21	Labeling Change With Clinical Data	AIRDUO RESPICLICK/AIRDUO DIGIHALER (FLUTICASONE PROPIONATE AND SALMETEROL XINAFOATE)	TEVA PHARMACEUTICAL INDUSTRIES LTD	S	7/9/2021
NDA 210192	11	Labeling Change With Clinical Data	JULUCA (DOLUTEGRAVIR AND RILPIVIRINE)	VIIV HEALTHCARE CO	S	7/9/2021
NDA 213983	2	Labeling Change With Clinical Data	TIVICAY PD (DOLUTEGRAVIR)	VIIV HEALTHCARE CO	S	7/9/2021
NDA 021977	46	Labeling Change With Clinical Data	VYVANSE (LISDEXAMFETAMINE DIMESYLATE)	TAKEDA PHARMACEUTICALS USA INC	P	7/29/2021
NDA 208510	3	Labeling Change With Clinical Data	VYVANSE (LISDEXAMFETAMINE DIMESYLATE)	TAKEDA PHARMACEUTICALS USA INC	P	7/29/2021
NDA 022393	17	Labeling Change With Clinical Data	ISTODAX (ROMIDEPSIN)	CELGENE CORP	S	7/30/2021
NDA 021225	42	Labeling Change With Clinical Data	MIRENA (LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM)	BAYER HEALTHCARE PHARMACEUTICALS INC	S	8/11/2021
NDA 210566	3	Labeling Change With Clinical Data	LEXETTE (HALOBETASOL PROPIONATE)	MAYNE PHARMA LLC	S	8/18/2021
NDA 021938	39	Labeling Change With Clinical Data	SUTENT (SUNITINIB MALATE)	CP PHARMACEUTICALS INTERNATIONAL CV	S	8/30/2021

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NDA 210951	6	Labeling Change With Clinical Data	ERLEADA (APALUTAMIDE)	JANSSEN BIOTECH INC	S	9/7/2021
NDA 211651	7	Labeling Change With Clinical Data	TALZENNA (TALAZOPARIB)	PFIZER INC	S	9/9/2021
NDA 209803	4	Labeling Change With Clinical Data	STEGLATRO (ERTUGLIFLOZIN)	MERCK SHARP AND DOHME CORP	S	9/17/2021
NDA 209805	8	Labeling Change With Clinical Data	STEGLUJAN (ERTUGLIFLOZIN AND SITAGLIPTIN)	MERCK SHARP AND DOHME CORP	S	9/17/2021
NDA 209806	6	Labeling Change With Clinical Data	SEGLUROMET (ERTUGLIFLOZIN AND METFORMIN HYDROCHLORIDE)	MERCK SHARP AND DOHME CORP	S	9/17/2021
NDA 208743	9	Labeling Change With Clinical Data	TYMLOS (ABALOPARATIDE)	RADIUS HEALTH INC	S	9/20/2021
NDA 022068	36	Labeling Change With Clinical Data	TASIGNA (NLOTINIB)	NOVARTIS PHARMACEUTICALS CORP	P	9/23/2021
NDA 208573	24	Labeling Change With Clinical Data	VENCLEXTA (VENETOCLAX)	ABBVIE INC	S	10/4/2021
NDA 022362	29	Labeling Change With Clinical Data	WELCHOL (COLESEVELAM HYDROCHLORIDE)	DAIICHI SANKYO INC	S	10/20/2021
NDA 208743	10	Labeling Change With Clinical Data	TYMLOS (ABALOPARATIDE)	RADIUS HEALTH INC	S	10/28/2021
NDA 021773	45	Labeling Change With Clinical Data	BYETTA (EXENATIDE)	ASTRAZENECA AB	S	11/4/2021
NDA 022348	21	Labeling Change With Clinical Data	CALDOLOR (IBUPROFEN)	CUMBERLAND PHARMACEUTICALS INC	S	11/19/2021
NDA 206947	21	Labeling Change With Clinical Data	LENVIMA (LENAVATINIB MESYLATE)	EISAI INC	S	12/19/2021
NDA 208743	10	Labeling Change With Clinical Data	TYMLOS (ABALOPARATIDE)	RADIUS HEALTH INC	S	12/22/2021
NDA 022334	50	Labeling Change With Clinical Data	AFINITOR (EVEROLIMUS)	NOVARTIS PHARMACEUTICALS CORP	S	12/30/2021

BLA Efficacy Supplements Approved

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE	PROPER NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
BLA 761145	1	New Indication	DARZALEX FASPRO (DARATUMUMAB AND HYALURONIDASE-FIHJ)	JANSSEN BIOTECH, INC.	S	1/11/2021
BLA 761139	11	New Indication		DAIICHI SANKYO, INC.	P	1/15/2021
BLA 761145	2	New Indication	DARZALEX FASPRO (DARATUMUMAB AND HYALURONIDASE-FIHJ)	JANSSEN BIOTECH, INC.	P	1/15/2021
BLA 125554	90	New Dosing Regimen	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	1/22/2021
BLA 125268	167	New Indication	NPLATE (ROMIPLOSTIM)	AMGEN, INC.	P	1/28/2021
BLA 125499	21	New Route Of Administration	PLEGRIDY (PEGYLATED INTERFERON BETA-1A)	BIOGEN INC.	S	1/29/2021
BLA 125433	32	Labeling Change With Clinical Data	SIMPONI ARIA (GOLIMUMAB)	JANSSEN BIOTECH, INC.	S	2/1/2021
BLA 103000	5318	New Patient Population	BOTOX AND BOTOX COSMETIC (ONABOTULINUMTOXINA)	ALLERGAN, INC.	S	2/9/2021
BLA 761097	8	New Indication	LIBTAYO (CEMPIPLIMAB-RWLC)	REGENERON PHARMACEUTICALS, INC.	P	2/9/2021
BLA 761097	9	New Indication	LIBTAYO (CEMPIPLIMAB-RWLC)	REGENERON PHARMACEUTICALS, INC.	P	2/9/2021
BLA 761099	4	New Indication	ZIRABEV (BEVACIZUMAB-BVZR)	PFIZER, INC.	S	2/9/2021
BLA 761034	33	New Dosing Regimen	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	2/17/2021
BLA 761034	34	New Dosing Regimen	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	2/17/2021
BLA 761034	35	New Dosing Regimen	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	2/17/2021
BLA 761034	36	New Dosing Regimen	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	2/17/2021
BLA 761034	37	New Dosing Regimen	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	2/17/2021
BLA 761034	38	New Dosing Regimen	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	2/17/2021
BLA 761069	29	New Indication	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	P	2/19/2021
BLA 761097	7	New Indication	LIBTAYO (CEMPIPLIMAB-RWLC)	REGENERON PHARMACEUTICALS, INC.	P	2/22/2021
BLA 125057	417	New Indication	HUMIRA (ADALIMUMAB)	ABBVIE INC.	S	2/24/2021
BLA 125472	44	New Indication	ACTEMRA (TOCILIZUMAB)	GENENTECH, INC.	P	3/4/2021
BLA 103979	5309	Accelerated Approval Confirmatory Study	FABRAZYME (AGALSIDASE BETA)	GENZYME CORPORATION	S	3/11/2021
BLA 125557	18	Labeling Change With Clinical Data	BLINCYTO (BLINATUMOMAB)	AMGEN, INC.	P	3/11/2021
BLA 125557	20	Labeling Change With Clinical Data	BLINCYTO (BLINATUMOMAB)	AMGEN, INC.	P	3/11/2021
BLA 125514	91	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	3/16/2021

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BLA 125514	93	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	3/16/2021
BLA 125249	49	New Indication	ARCALYST (RILONACEPT)	KINIKSA PHARMACEUTICALS (UK), LTD	P	3/18/2021
BLA 125514	96	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	3/22/2021
BLA 761113	3	New Indication	SARCLISA (ISATUXIMAB-IRFC)	SANOFI-AVENTIS U.S. LLC	S	3/31/2021
BLA 125559	29	New Indication	PRALUENT (ALIROCUMAB)	REGENERON PHARMACEUTICALS, INC.	S	4/1/2021
BLA 125084	277	New Indication	ERBITUX (CETUXIMAB)	ELI LILLY AND COMPANY	S	4/6/2021
BLA 125084	280	New Indication	ERBITUX (CETUXIMAB)	ELI LILLY AND COMPANY	S	4/6/2021
BLA 761115	5	Accelerated Approval Confirmatory Study	TRODELVY (SACITUZUMAB GOVITECAN-HZIY)	IMMUNOMEDICS, INC.	P	4/7/2021
BLA 761115	13	New Patient Population	TRODELVY (SACITUZUMAB GOVITECAN-HZIY)	IMMUNOMEDICS, INC.	P	4/7/2021
BLA 103976	5238	New Indication	XOLAIR (OMALIZUMAB)	GENENTECH, INC.	S	4/9/2021
BLA 761115	9	New Indication	TRODELVY (SACITUZUMAB GOVITECAN-HZIY)	IMMUNOMEDICS, INC.	P	4/13/2021
BLA 125554	91	New Indication	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	4/16/2021
BLA 761105	9	New Dosing Regimen	SKYRIZI (RISANKIZUMAB-RZAA)	ABBVIE INC.	S	4/26/2021
BLA 761105	10	Manufacturing Change With Clinical Data	SKYRIZI (RISANKIZUMAB-RZAA)	ABBVIE INC.	S	4/26/2021
BLA 125514	97	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	5/5/2021
BLA 125554	92	New Indication	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	5/20/2021
BLA 125377	121	Labeling Change With Clinical Data	YERVOY (IPILIMUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	5/25/2021
BLA 125504	43	New Indication	COSENTYX (SECUKINUMAB)	NOVARTIS PHARMACEUTICALS CORPORATION	S	5/28/2021
BLA 761108	12	New Patient Population	ULTOMIRIS (RAVULIZUMAB-CWVZ) INJECTION	ALEXION PHARMACEUTICALS, INC.	P	6/7/2021
BLA 761055	16	Manufacturing Change With Clinical Data	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	S	6/14/2021
BLA 125514	100	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	7/1/2021
BLA 761137	6	New Patient Population	PADCEV (ENFORTUMAB VEDOTIN-EJFV)	ASTELLAS PHARMA US, INC.	P	7/9/2021
BLA 761137	8	Accelerated Approval Confirmatory Study	PADCEV (ENFORTUMAB VEDOTIN-EJFV)	ASTELLAS PHARMA US, INC.	P	7/9/2021
BLA 761145	7	New Indication	DARZALEX FASPRO (DARATUMUMAB AND HYALURONIDASE-FIHJ)	JANSSEN BIOTECH, INC.	S	7/9/2021
BLA 125554	99	Labeling Change With Clinical Data	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	7/15/2021
BLA 125514	105	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	7/21/2021
BLA 125514	89	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	7/26/2021
BLA 125514	114	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	7/26/2021
BLA 103000	5320	Labeling Change With Clinical Data	BOTOX AND BOTOX COSMETIC (ONABOTULINUMTOXINA)	ALLERGAN, INC.	S	7/28/2021
BLA 125526	18	New Indication	NUCALA (MEPOLIZUMAB)	GLAXOSMITHKLINE LLC	S	7/29/2021
BLA 761122	6	New Indication	NUCALA (MEPOLIZUMAB)	GLAXOSMITHKLINE LLC	S	7/29/2021
BLA 208471	4	Labeling Change With Clinical Data	ADLYXIN (LIXISENATIDE)	SANOFI-AVENTIS U.S. LLC	S	7/30/2021
BLA 125514	102	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	8/10/2021
BLA 761109	3	Labeling Change With Clinical Data	LYUMJEV (INSULIN LISPRO-AABC)	ELI LILLY AND COMPANY	S	8/13/2021
BLA 125554	97	New Indication	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	8/19/2021
BLA 125514	117	Accelerated Approval Confirmatory Study	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	8/31/2021
BLA 125514	118	New Patient Population	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	8/31/2021
BLA 125084	279	New Indication	ERBITUX (CETUXIMAB)	ELI LILLY AND COMPANY	S	9/24/2021
BLA 125522	29	New Indication	REPATHA (EVOLOCUMAB)	AMGEN, INC.	S	9/24/2021
BLA 761034	44	New Indication	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	S	10/6/2021
BLA 125514	121	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	10/13/2021
BLA 125514	122	Accelerated Approval Confirmatory Study	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	10/13/2021
BLA 761034	42	New Indication	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	10/15/2021
BLA 761058	8	New Indication	CYLTEZO (ADALIMUMAB-ADBIM)	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	S	10/15/2021
BLA 761055	31	New Indication	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	S	10/20/2021
BLA 761028	8	New Indication	MVASI (BEVACIZUMAB-AWWB)	AMGEN, INC.	S	11/15/2021
BLA 761103	5	Labeling Change With Clinical Data	RUXIENCE (RITUXIMAB-PVVR)	PFIZER IRELAND PHARMACEUTICALS	S	11/15/2021
BLA 125514	113	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	11/17/2021
BLA 125561	13	New Dosing Regimen	KANUMA (SEBELIPASE ALFA)	ALEXION PHARMACEUTICALS, INC.	S	11/19/2021
BLA 761145	9	New Indication	DARZALEX FASPRO (DARATUMUMAB AND HYALURONIDASE-FIHJ)	JANSSEN BIOTECH, INC.	S	11/30/2021

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BLA 103705	5465	New Indication	RITUXAN (RITUXIMAB)	GENENTECH, INC.	P	12/2/2021
BLA 125514	112	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	12/3/2021
BLA 125118	240	New Indication	ORENCIA (ABATACEPT)	BRISTOL-MYERS SQUIBB COMPANY	P	12/15/2021
BLA 125514	120	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	12/17/2021
BLA 125504	50	New Indication	COSENTYX (SECUKINUMAB)	NOVARTIS PHARMACEUTICALS CORPORATION	P	12/22/2021
BLA 125504	51	New Indication	COSENTYX (SECUKINUMAB)	NOVARTIS PHARMACEUTICALS CORPORATION	P	12/22/2021