

**CY 2019 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year Approvals  
As of December 31, 2019**

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**Selection Criteria:**

**User Response: Start Date: 1/1/2019 End Date: 12/31/2019**

**Sort Order: Approval Date**

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
NDA 022534	7	New Indication	DOCETAXEL	SUN PHARMA GLOBAL FZE	S	1/8/2019
NDA 208692	3	New Indication	CABOMETYX (CABOZANTINIB)	EXELIXIS INC	S	1/14/2019
NDA 203388	12	New Dosing Regimen	ERIVEDGE (VISMODEGIB)	GENENTECH INC	S	1/18/2019
NDA 203505	15	New Indication	OSPHENA (OSPEMIFENE)	DUCHESNAY INC	S	1/25/2019
NDA 021266	39	New Patient Population	VFEND (VORICONAZOLE)	PF PRISM CV	P	1/29/2019
NDA 021267	50	New Patient Population	VFEND (VORICONAZOLE)	PF PRISM CV	P	1/29/2019
NDA 021630	29	New Patient Population	VFEND (VORICONAZOLE)	PF PRISM CV	P	1/29/2019
NDA 204200	9	New Indication	ADRENALIN (EPINEPHRINE)	PAR STERILE PRODUCTS LLC	S	1/29/2019
NDA 204640	9	New Indication	ADRENALIN (EPINEPHRINE)	PAR STERILE PRODUCTS LLC	S	1/29/2019
NDA 021462	53	New Indication	ALIMTA (PEMETREXED)	ELI LILLY AND CO	S	1/30/2019
NDA 208583	2	New Indication	XULTOPHY 100/3.6 (INSULIN DEGLUDEC AND LIRAGLUTIDE)	NOVO NORDISK INC	S	2/1/2019
NDA 208583	3	New Indication	XULTOPHY 100/3.6 (INSULIN DEGLUDEC AND LIRAGLUTIDE)	NOVO NORDISK INC	S	2/1/2019
NDA 208464	7	New Patient Population	VEMLIDY (TENOFIVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	2/4/2019
NDA 208147	5	New Patient Population	DYANAVAL XR (AMPHETAMINE)	TRIS PHARMA INC	S	2/5/2019
NDA 209935	2	New Indication	KISQALI FEMARA CO-PACK (LETROZOLE AND RIBOCICLIB)	NOVARTIS PHARMACEUTICALS CORP	P	2/13/2019
NDA 207981	8	New Indication	LONSURF (TIPIRACIL HYDROCHLORIDE AND TRIFLURIDINE)	TAIHO ONCOLOGY INC	P	2/22/2019
NDA 208583	8	New Indication	XULTOPHY 100/3.6 (INSULIN DEGLUDEC AND LIRAGLUTIDE)	NOVO NORDISK INC	S	2/27/2019
NDA 208583	10	New Indication	XULTOPHY 100/3.6 (INSULIN DEGLUDEC AND LIRAGLUTIDE)	NOVO NORDISK INC	S	2/27/2019
NDA 208583	11	New Indication	XULTOPHY 100/3.6 (INSULIN DEGLUDEC AND LIRAGLUTIDE)	NOVO NORDISK INC	S	2/27/2019
NDA 208673	7	New Indication	SOLIQUA (INSULIN GLARGINE AND LIXISENATIDE)	SANOVI AVENTIS US LLC	S	2/27/2019
NDA 017874	43	Manufacturing Change With Clinical Data	TRANSDERM SCOP (SCOPOLAMINE)	GLAXOSMITHKLINE CONSUMER HEALTH	S	3/1/2019
NDA 021234	16	New Patient Population	FLECTOR (DICLOFENAC EPOLAMINE)	INSTITUT BIOCHIMIQUE SA	S	3/1/2019
NDA 021344	37	New Indication	FASLODEX (FULVESTRANT)	ASTRAZENECA PHARMACEUTICALS LP	P	3/11/2019
NDA 206494	5	New Indication	AVYCAZ (AVIBACTAM AND CEFTAZIDIME)	ALLERGAN SALES LLC	P	3/14/2019
NDA 206494	6	New Indication	AVYCAZ (AVIBACTAM AND CEFTAZIDIME)	ALLERGAN SALES LLC	P	3/14/2019
NDA 021200	15	New Indication	ZELNORM (TEGASEROD MALEATE)	US WORLDMEDS LLC	S	3/29/2019
NDA 203188	29	New Patient Population	KALYDECO (IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	4/29/2019
NDA 209394	6	New Patient Population	MAVYRET (GLECAPREVIR AND PIBRENTASVIR)	ABBVIE INC	P	4/30/2019

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NDA 209091	2	New Indication	QTERN (SAXAGLIPTIN AND DAPAGLIFLOZIN)	ASTRAZENECA AB	S	5/2/2019
NDA 211192	1	New Indication	TIBSOVO (IVOSIDENIB)	AGIOS PHARMACEUTICALS INC	P	5/2/2019
NDA 208573	13	New Indication	VENCLEXTA (VENETOCLAX)	ABBVIE INC	P	5/15/2019
NDA 022363	15	New Patient Population	LIVALO (PITAVASTATIN)	KOWA CO LTD	P	5/16/2019
NDA 203441	13	New Patient Population	GATTEX (TEDUGLUTIDE)	NPS PHARMACEUTICALS INC	P	5/16/2019
NDA 021446	36	New Patient Population	PREGABALIN	PF PRISM CV	P	5/23/2019
NDA 022488	14	New Patient Population	LYRICA (PREGABALIN)	PF PRISM CV	P	5/23/2019
NDA 202192	17	New Indication	JAKAFI (RUXOLITINIB PHOSPHATE)	INCYTE CORP	P	5/24/2019
NDA 204370	6	New Indication	VRAYLAR (CARIPRAZINE)	ALLERGAN SALES LLC	S	5/24/2019
NDA 210496	3	New Dosing Regimen	BRAFTOVI [ENCORAFENIB (LGX818)]	ARRAY BIOPHARMA INC	S	5/24/2019
NDA 021880	57	New Indication	REVLIMID (LENALIDOMIDE)	CELGENE CORP	P	5/28/2019
NDA 206829	8	New Indication	ZERBAXA (CEFTOLOZANE SULFATE AND TAZOBACTAM SODIUM)	CUBIST PHARMACEUTICALS LLC	P	6/3/2019
NDA 208684	3	New Patient Population	EMFLAZA (DEFLAZACORT)	PTC THERAPEUTICS INC	P	6/7/2019
NDA 208685	3	New Patient Population	EMFLAZA (DEFLAZACORT)	PTC THERAPEUTICS INC	P	6/7/2019
NDA 205831	5		APTENSIO XR (METHYLPHENIDATE HYDROCHLORIDE)	RHODES PHARMACEUTICALS LP	P	6/14/2019
NDA 022341	31	New Patient Population	VICTOZA (LIRAGLUTIDE)	NOVO NORDISK INC	P	6/17/2019
NDA 210251	5	New Patient Population	BIKTARVY (BICTEGRAVIR, EMTRICITABINE, AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	P	6/18/2019
NDA 208742	1	New Indication	DEXTENZA (DEXAMETHASONE INSERT)	OCULAR THERAPEUTIX INC	S	6/20/2019
NDA 210238	1	New Indication	DOPTELET (AVATROMBOPAG)	AKARX INC	S	6/26/2019
NDA 208558	9	New Indication	LYNPARZA (OLAPARIB)	ASTRAZENECA PHARMACEUTICALS LP	S	7/1/2019
NDA 201277	17	New Indication	GADAVIST (GADOBUTROL)	BAYER HEALTHCARE PHARMACEUTICALS INC	S	7/12/2019
NDA 205437	7	New Indication	OTEZLA (APREMILAST)	CELGENE CORP	S	7/19/2019
NDA 021825	4	New Dosing Regimen	FERRIPROX (DEFERIPRONE)	APOPHARMA INC	S	7/25/2019
NDA 207589	5	New Patient Population	ENSTILAR (CALCIPOTRIENE AND BETAMETHASONE DIPROPIONATE)	LEO PHARMA AS	P	7/30/2019
NDA 021877	10	Accelerated Approval Confirmatory Study	ARRANON (NELARABINE)	NOVARTIS PHARMACEUTICALS CORP	S	7/31/2019
NDA 209589	5	New Patient Population	CLENPIQ (CITRIC ACID, MAGNESIUM OXIDE, AND SODIUM PICOSULFATE)	FERRING PHARMACEUTICALS INC	S	8/8/2019
NDA 204384	10	New Patient Population	SIRTURO (BEDAQUILINE)	JANSSEN RESEARCH AND DEVELOPMENT LLC	S	8/9/2019
NDA 203094	13	New Patient Population	TYBOST (COBICISTAT)	GILEAD SCIENCES INC	P	8/22/2019
NDA 204671	14	New Patient Population	SOVALDI (SOFOSBUVIR)	GILEAD SCIENCES INC	P	8/28/2019
NDA 205834	29	New Patient Population	HARVONI (LEDIPASVIR AND SOFOSBUVIR)	GILEAD SCIENCES INC	P	8/28/2019
NDA 205832	12	New Indication	OFEV (NINTEDANIB)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	9/6/2019
NDA 201849	5	New Indication	GLUCAGON	FRESENIUS KABI USA LLC	S	9/9/2019
NDA 207154	4	New Patient Population	ACZONE (DAPSONE)	ALMIRALL LLC	P	9/10/2019
NDA 200327	22	New Patient Population	TEFLARO (CEFTAROLINE FOSAMIL)	ALLERGAN SALES LLC	S	9/13/2019

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NDA 206947	11	New Indication	LENVIMA (LENVATINIB MESYLATE)	EISAI INC	P	9/17/2019
NDA 210806	2	New Patient Population	PIFELTRO (DORAVIRINE)	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	S	9/19/2019
NDA 210807	2	New Patient Population	DELSTRIGO (DORAVIRINE, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE)	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	S	9/19/2019
NDA 209394	8	New Dosing Regimen	MAVYRET (GLECAPREVIR AND PIBRENTASVIR)	ABBVIE INC	P	9/26/2019
NDA 204042	32	New Indication	INVOKANA (CANAGLIFLOZIN)	JANSSEN PHARMACEUTICALS INC	P	9/27/2019
NDA 203094	14	New Patient Population	TYBOST (COBICISTAT)	GILEAD SCIENCES INC	P	10/3/2019
NDA 208215	12	New Indication	DESCOVY (EMTRICITABINE AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	P	10/3/2019
NDA 207924	1	New Dosing Regimen	OLUMIANT (BARICITINIB)	ELI LILLY AND CO	S	10/8/2019
NDA 022406	33	New Indication	XARELTO (RIVAROXABAN)	JANSSEN PHARMACEUTICALS INC	S	10/11/2019
NDA 210854	1	New Patient Population	XOFLUZA (BALOXAVIR MARBOXIL)	GENENTECH INC	S	10/16/2019
NDA 202293	18	New Indication	FARXIGA (DAPAGLIFLOZIN)	ASTRAZENECA AB	S	10/18/2019
NDA 203496	11	New Indication	ORENITRAM	UNITED THERAPEUTICS CORP	S	10/18/2019
NDA 205649	11	New Indication	XIGDUO XR (DAPAGLIFLOZIN AND METFORMIN)	ASTRAZENECA AB	S	10/18/2019
NDA 208751	8	New Indication	FIASP (INSULIN ASPART)	NOVO NORDISK INC	S	10/21/2019
NDA 209296	4	New Dosing Regimen	CINVANTI (APREPITANT)	HERON THERAPEUTICS INC	S	10/21/2019
NDA 208447	14	New Indication	ZEJULA (NIRAPARIB)	GLAXOSMITHKLINE LLC	P	10/23/2019
NDA 208610	7	New Indication	BAXDELA (DELAFLXACIN MEGLUMINE)	MELINTA SUBSIDIARY CORP	P	10/24/2019
NDA 208611	6	New Indication	BAXDELA (DELAFLXACIN MEGLUMINE)	MELINTA SUBSIDIARY CORP	P	10/24/2019
NDA 206229	8	New Indication	LILETTA (LEVONORGESTREL)	MEDICINES360	S	10/25/2019
NDA 022563	7	New Patient Population	SORILUX (CALCIPOTRIENE)	MAYNE PHARMA LLC	S	11/5/2019
NDA 203684	5	New Patient Population	LUMASON (SULFUR HEXAFLUORIDE LIPID-TYPE A MICROSPHERES)	BRACCO DIAGNOSTICS INC	S	11/13/2019
NDA 205834	28	New Patient Population	HARVONI (LEDIPASVIR AND SOFOSBUVIR)	GILEAD SCIENCES INC	S	11/15/2019
NDA 208341	12	New Patient Population	EPCLUSA (SOFOSBUVIR AND VELPATISVIR)	GILEAD SCIENCES INC	S	11/15/2019
NDA 209195	3	New Patient Population	VOSEVI (SOFOSBUVIR, VELPATASVIR, AND VOXILAPREVIR)	GILEAD SCIENCES INC	S	11/15/2019
NDA 212477	2	New Patient Population	HARVONI (LEDIPASVIR AND SOFOSBUVIR)	GILEAD SCIENCES INC	S	11/15/2019
NDA 210259	6	New Indication	CALQUENCE (ACALABRUTINIB)	ASTRAZENECA UK LTD	P	11/21/2019
NDA 210259	7	New Indication	CALQUENCE (ACALABRUTINIB)	ASTRAZENECA UK LTD	P	11/21/2019
NDA 206538	12	New Patient Population	TOUJEO (INSULIN GLARGINE)	SANOFI AVENTIS US LLC	S	11/26/2019
NDA 208215	11	New Patient Population	DESCOVY (EMTRICITABINE AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	12/3/2019
NDA 208351	10	New Patient Population	ODEFSEY (EMTRICITABINE, RILPIVIRINE, AND TENOFOVIR ALAFENAMIDE)	GILEAD SCIENCES INC	S	12/3/2019
NDA 022038	6	New Dosing Regimen	DIVIGEL (ESTRADIOL)	VERTICAL PHARMACEUTICALS LLC	S	12/12/2019
NDA 208246	9	New Indication	XELJANZ XR (TOFACITINIB)	PFIZER INC	S	12/12/2019
NDA 202057	35	New Indication	VASCEPA (ICOSAPENT ETHYL)	AMARIN PHARMACEUTICALS IRELAND LTD	P	12/13/2019
NDA 203415	15	New Indication	XTANDI (ENZALUTAMIDE)	ASTELLAS PHARMA US INC	P	12/16/2019
NDA 208751	10	New Patient Population	FIASP (INSULIN ASPART)	NOVO NORDISK INC	S	12/19/2019
NDA 208751	11	New Indication	FIASP (INSULIN ASPART)	NOVO NORDISK INC	S	12/19/2019
NDA 021506	23	New Patient Population	MYCAMINE (MICA FUNGIN SODIUM)	ASTELLAS PHARMA US INC	P	12/20/2019
NDA 208558	10	New Indication	LYNPARZA (OLAPARIB)	ASTRAZENECA PHARMACEUTICALS LP	P	12/27/2019

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APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
NDA 022253	41	Labeling Change With Clinical Data	VIMPAT (LACOSAMIDE)	UCB INC	S	1/9/2019
NDA 022254	32	Labeling Change With Clinical Data	VIMPAT (LACOSAMIDE)	UCB INC	S	1/9/2019
NDA 022255	23	Labeling Change With Clinical Data	VIMPAT (LACOSAMIDE)	UCB INC	S	1/9/2019
NDA 210496	1	Labeling Change With Clinical Data	BRAFTOVI [ENCORAFENIB (LGX818)]	ARRAY BIOPHARMA INC	S	1/23/2019
NDA 210498	1	Labeling Change With Clinical Data	MEKTOVI [BINIMETINIB (MEK161, ARRY-438162)]	ARRAY BIOPHARMA INC	S	1/23/2019
NDA 205552	26	Labeling Change With Clinical Data	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	P	1/25/2019
NDA 210563	2	Labeling Change With Clinical Data	IMBRUVICA (IBRUTINIB)	PHARMACYCLICS LLC	P	1/25/2019
NDA 022200	28	Labeling Change With Clinical Data	BYDUREON (EXENATIDE)	ASTRAZENECA AB	S	2/15/2019
NDA 209210	1	Labeling Change With Clinical Data	EXENATIDE	ASTRAZENECA AB	S	2/15/2019
NDA 021856	13	Labeling Change With Clinical Data	ULORIC (FEBUXOSTAT)	TAKEDA PHARMACEUTICALS USA INC	S	2/21/2019
NDA 021928	48	Labeling Change With Clinical Data	CHANTIX (VARENICLINE TARTRATE)	PF PRISM CV	P	2/22/2019
NDA 202293	15	Labeling Change With Clinical Data	FARXIGA (DAPAGLIFLOZIN)	ASTRAZENECA AB	S	2/22/2019
NDA 205649	9	Labeling Change With Clinical Data	XIGDUO XR (DAPAGLIFLOZIN AND METFORMIN)	ASTRAZENECA AB	S	2/22/2019
NDA 209296	3	Labeling Change With Clinical Data	CINVANTI (APREPITANT)	HERON THERAPEUTICS INC	S	2/26/2019
NDA 205435	10	Labeling Change With Clinical Data	SIVEXTRO (TEDIZOLID PHOSPHATE)	CUBIST PHARMACEUTICALS LLC	S	3/6/2019
NDA 205436	5	Labeling Change With Clinical Data	SIVEXTRO (TEDIZOLID PHOSPHATE)	CUBIST PHARMACEUTICALS LLC	S	3/6/2019
NDA 022416	11	Labeling Change With Clinical Data	APTiom (ESLICARBAZEPINE ACETATE)	SUNOVION PHARMACEUTICALS INC	S	3/15/2019
NDA 021976	53	Labeling Change With Clinical Data	PREZISTA (DARUNAVIR)	JANSSEN PRODUCTS LP	S	3/21/2019
NDA 202895	24	Labeling Change With Clinical Data	PREZISTA (DARUNAVIR)	JANSSEN PRODUCTS LP	S	3/21/2019
NDA 202450	12	Labeling Change With Clinical Data	TUDORZA PRESSAIR (ACLIDINIUM BROMIDE)	CIRCASSIA LTD	S	3/29/2019
NDA 022433	23	Labeling Change With Clinical Data	BRILINTA (TICAGRELOR)	ASTRAZENECA PHARMACEUTICALS LP	S	4/3/2019
NDA 207103	8	Labeling Change With Clinical Data	IBRANCE (PALBOCICLIB)	PFIZER INC	S	4/4/2019
NDA 021602	44	Labeling Change With Clinical Data	VELCADE (BORTEZOMIB)	MILLENNIUM PHARMACEUTICALS INC	S	4/25/2019
NDA 207925	8	Labeling Change With Clinical Data	KALYDECO (IVACAFTOR)	VERTEX PHARMACEUTICALS INC	P	4/29/2019
NDA 208036	10	Labeling Change With Clinical Data	E-Z-CAT DRY (BARIUM SULFATE)	BRACCO DIAGNOSTICS INC	S	4/30/2019
NDA 022563	6	Labeling Change With Clinical Data	SORILUX (CALCIPOTRIENE)	MAYNE PHARMA LLC	S	5/6/2019
NDA 021938	36	Labeling Change With Clinical Data	SUTENT (SUNITINIB MALATE)	CP PHARMACEUTICALS INTERNATIONAL CV	P	5/7/2019
NDA 020287	72	Labeling Change With Clinical Data	FRAGMIN (DALTEPARIN SODIUM)	PFIZER INC	P	5/16/2019

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NDA 021882	31	Labeling Change With Clinical Data	EXJADE (DEFERASIROX)	NOVARTIS PHARMACEUTICALS CORP	P	5/24/2019
NDA 206910	14	Labeling Change With Clinical Data	JADENU (DEFERASIROX)	NOVARTIS PHARMACEUTICALS CORP	P	5/24/2019
NDA 207968	8	Labeling Change With Clinical Data	JADENU SPRINKLE (DEFERASIROX)	NOVARTIS PHARMACEUTICALS CORP	P	5/24/2019
NDA 211349	1	Labeling Change With Clinical Data	XOSPATA (GILTERITINIB)	ASTELLAS PHARMA US INC	P	5/29/2019
NDA 202379	28	Labeling Change With Clinical Data	ZYTIGA (ABIRATERONE ACETATE)	JANSSEN BIOTECH INC	S	6/3/2019
NDA 203975	10	Labeling Change With Clinical Data	ANORO ELLIPTA (UMECLIDINIUM AND VILANTEROL)	GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LTD ENGLAND	S	6/6/2019
NDA 205382	10	Labeling Change With Clinical Data	INCRUSE ELLIPTA	GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LTD ENGLAND	S	6/6/2019
NDA 208223	5	Labeling Change With Clinical Data	ZEMBRACE DUOCLIQ (SUMATRIPTAN SUCCINATE)	DR REDDYS LABORATORIES LTD	S	6/10/2019
NDA 210491	3	Labeling Change With Clinical Data	SYMDEKO (IVACAFTOR AND TEZACAFTOR)	VERTEX PHARMACEUTICALS INC	P	6/21/2019
NDA 010721	63	Labeling Change With Clinical Data	ANTIVERT (MECLIZINE HYDROCHLORIDE)	CASPER PHARMA LLC	S	6/28/2019
NDA 201280	18	Labeling Change With Clinical Data	TRADJENTA (LINAGLIPTIN)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	7/3/2019
NDA 201281	22	Labeling Change With Clinical Data	JENTADUETO (LINAGLIPTIN AND METFORMIN HYDROCHLORIDE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	7/3/2019
NDA 206073	17	Labeling Change With Clinical Data	GLYXAMBI (EMPAGLIFLOZIN AND LINAGLIPTIN)	BOEHRINGER INGELHEIM	S	7/3/2019
NDA 208026	8	Labeling Change With Clinical Data	JENTADUETO XR (LINAGLIPTIN AND METFORMIN HYDROCHLORIDE)	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	7/3/2019
NDA 021882	30	Labeling Change With Clinical Data	EXJADE (DEFERASIROX)	NOVARTIS PHARMACEUTICALS CORP	S	7/24/2019
NDA 202992	6	Labeling Change With Clinical Data	AUBAGIO (TERIFLUNOMIDE)	SANOFI AVENTIS US LLC	S	7/24/2019
NDA 022185	27	Labeling Change With Clinical Data	TACLONEX (CALCIPOTRIENE AND BETAMETHASONE DIPROPIONATE)	LEO PHARMA AS	S	7/25/2019
NDA 207968	7	Labeling Change With Clinical Data	JADENU SPRINKLE (DEFERASIROX)	NOVARTIS PHARMACEUTICALS CORP	S	7/25/2019
NDA 209210	2	Labeling Change With Clinical Data	EXENATIDE	ASTRAZENECA AB	S	7/25/2019
NDA 209210	3	Labeling Change With Clinical Data	EXENATIDE	ASTRAZENECA AB	S	7/25/2019
NDA 209210	4	Labeling Change With Clinical Data	EXENATIDE	ASTRAZENECA AB	S	7/25/2019
NDA 209210	5	Labeling Change With Clinical Data	EXENATIDE	ASTRAZENECA AB	S	7/25/2019
NDA 209210	6	Labeling Change With Clinical Data	EXENATIDE	ASTRAZENECA AB	S	7/25/2019
NDA 209210	7	Labeling Change With Clinical Data	EXENATIDE	ASTRAZENECA AB	S	7/25/2019
NDA 206910	12	Labeling Change With Clinical Data	JADENU (DEFERASIROX)	NOVARTIS PHARMACEUTICALS CORP	S	7/26/2019
NDA 021087	71	Labeling Change With Clinical Data	TAMIFLU (OSELTAMIVIR PHOSPHATE)	HOFFMANN LA ROCHE INC	S	8/2/2019
NDA 021246	54	Labeling Change With Clinical Data	TAMIFLU (OSELTAMIVIR PHOSPHATE)	HOFFMANN LA ROCHE INC	S	8/2/2019
NDA 208583	12	Labeling Change With Clinical Data	XULTOPHY 100/3.6 (INSULIN DEGLUDEC AND LIRAGLUTIDE)	NOVO NORDISK INC	S	8/8/2019
NDA 206316	15	Labeling Change With Clinical Data	SAVAYSA (EDOXABAN TOSYLATE)	DAIICHI SANKYO INC	S	8/9/2019

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NDA 021995	45	Labeling Change With Clinical Data	JANUVIA (SITAGLIPTIN PHOSPHATE)	MERCK SHARP AND DOHME CORP	S	8/12/2019
NDA 022044	46	Labeling Change With Clinical Data	JANUMET (METFORMIN HYDROCHLORIDE AND SITAGLIPTIN PHOSPHATE)	MERCK SHARP AND DOHME CORP	S	8/12/2019
NDA 022518	26	Labeling Change With Clinical Data	DULERA (FORMOTEROL FUMARATE AND MOMETASONE FUROATE)	MERCK SHARP AND DOHME CORP	P	8/12/2019
NDA 202270	19	Labeling Change With Clinical Data	JANUMET XR (METFORMIN HYDROCHLORIDE AND SITAGLIPTIN PHOSPHATE)	MERCK SHARP AND DOHME CORP	S	8/12/2019
NDA 205641	10	Labeling Change With Clinical Data	ASMANEX HFA (MOMETASONE FUROATE)	MERCK SHARP AND DOHME CORP	S	8/12/2019
NDA 207103	11	Labeling Change With Clinical Data	IBRANCE (PALBOCICLIB)	PFIZER INC	S	9/9/2019
NDA 022063	1	Labeling Change With Clinical Data	MYDAYIS (MIXED SALTS OF A SINGLE-ENTITY AMPHETAMINE)	SHIRE DEVELOPMENT LLC	P	9/13/2019
NDA 210951	1	Labeling Change With Clinical Data	ERLEADA (APALUTAMIDE)	JANSSEN BIOTECH INC	P	9/17/2019
NDA 020006	28	Labeling Change With Clinical Data	MANNITOL	B BRAUN MEDICAL INC	S	9/24/2019
NDA 211651	2	Labeling Change With Clinical Data	TALZENNA (TALAZOPARIB)	PFIZER INC	S	9/24/2019
NDA 209394	7	Labeling Change With Clinical Data	MAVYRET (GLECAPREVIR AND PIBRENTASVIR)	ABBVIE INC	S	9/26/2019
NDA 207620	13	Labeling Change With Clinical Data	ENTRESTO (SACUBITRIL AND VALSARTAN)	NOVARTIS PHARMACEUTICALS CORP	P	10/1/2019
NDA 208051	4	Labeling Change With Clinical Data	NERLYNX (NERATINIB MALEATE)	PUMA BIOTECHNOLOGY INC	S	10/1/2019
NDA 207620	13	Labeling Change With Clinical Data	ENTRESTO (SACUBITRIL AND VALSARTAN)	NOVARTIS PHARMACEUTICALS CORP	P	10/1/2019
NDA 208051	4	Labeling Change With Clinical Data	NERLYNX (NERATINIB MALEATE)	PUMA BIOTECHNOLOGY INC	S	10/1/2019
NDA 203284	11	Labeling Change With Clinical Data	RAVICTI (GLYCEROL PHENYL BUTYRATE)	HORIZON THERAPEUTICS LLC	S	10/4/2019
NDA 202806	12	Labeling Change With Clinical Data	TAFINLAR (DABRAFENIB)	NOVARTIS PHARMACEUTICALS CORP	S	10/6/2019
NDA 204114	12	Labeling Change With Clinical Data	MEKINIST (TRAMETINIB)	NOVARTIS PHARMACEUTICALS CORP	S	10/6/2019
NDA 204168	6	Labeling Change With Clinical Data	FETZIMA (LEVOMILNACIPRAN)	ALLERGAN SALES LLC	S	10/7/2019
NDA 210806	3	Labeling Change With Clinical Data	PIFELTRO (DORAVIRINE)	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	S	10/10/2019
NDA 210807	3	Labeling Change With Clinical Data	DELSTRIGO (DORAVIRINE, LAMIVUDINE, AND TENOFOVIR DISOPROXIL FUMARATE)	MERCK SHARP AND DOHME CORP A SUB OF MERCK AND CO INC	S	10/10/2019
NDA 209589	6	Labeling Change With Clinical Data	CLENPIQ (CITRIC ACID, MAGNESIUM OXIDE, AND SODIUM PICOSULFATE)	FERRING PHARMACEUTICALS INC	S	10/18/2019
NDA 021035	102	Labeling Change With Clinical Data	KEPPRA (LEVETIRACETAM)	UCB INC	S	10/23/2019
NDA 021505	42	Labeling Change With Clinical Data	KEPPRA (LEVETIRACETAM)	UCB INC	S	10/23/2019
NDA 021872	28	Labeling Change With Clinical Data	KEPPRA (LEVETIRACETAM)	UCB INC	S	10/23/2019
NDA 022285	28	Labeling Change With Clinical Data	KEPPRA XR (LEVETIRACETAM)	UCB INC	S	10/23/2019
NDA 021611	16	Labeling Change With Clinical Data	OPANA (OXYMORPHONE HYDROCHLORIDE)	ENDO PHARMACEUTICALS INC	S	10/25/2019
NDA 019193	21	Labeling Change With Clinical Data	PROVOCHOLINE (METHACHOLINE CHLORIDE)	METHAPHARM INC	S	11/8/2019
NDA 021344	38	Labeling Change With Clinical Data	FASLODEX (FULVESTRANT)	ASTRAZENECA PHARMACEUTICALS LP	S	11/21/2019

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NDA 011366	33	Labeling Change With Clinical Data	KEYEYIS (DICHLORPHENAMIDE)	STRONGBRIDGE US INC	S	11/22/2019
NDA 208169	3	Labeling Change With Clinical Data	XURIDEN (URIDINE TRIACETATE)	WELLSTAT THERAPEUTICS CORP	S	12/2/2019
NDA 209080	1	Labeling Change With Clinical Data	TIGLUTIK (RILUZOLE)	ITALFARMACO SPA	S	12/13/2019
NDA 208845	7	Labeling Change With Clinical Data	ZILRETTA (TRIAMCINOLONE ACETONIDE)	FLEXION THERAPEUTICS INC	S	12/23/2019

**BLA Efficacy Supplements Approved**

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE	PROPER NAME	APPLICANT	PRIORITY REVIEW	APPROVAL DATE
BLA 103411	5196	Labeling Change With Clinical Data	ONCASPAR (PEGASPARGASE)	BAXALTA US INC.	S	1/3/2019
BLA 125469	23	Labeling Change With Clinical Data	TRULICITY (DULAGLUTIDE)	ELI LILLY AND COMPANY	S	1/15/2019
BLA 103705	5454	Labeling Change With Clinical Data	RITUXAN (RITUXIMAB)	GENENTECH, INC.	S	1/25/2019
BLA 761061	1	Manufacturing Change With Clinical Data	TREMFYA (GUSELKUMAB)	JANSSEN BIOTECH, INC.	S	1/29/2019
BLA 103951	5378	Labeling Change With Clinical Data	ARANESP (DARBEPOETIN ALPHA)	AMGEN, INC.	P	1/30/2019
BLA 761036	16	New Dosing Regimen	DARZALEX (DARATUMUMAB)	JANSSEN BIOTECH, INC.	S	2/8/2019
BLA 125514	40	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	S	2/15/2019
BLA 125554	42	Accelerated Approval Confirmatory Study	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	P	3/7/2019
BLA 761034	18	New Indication	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	3/8/2019
BLA 761055	12	New Patient Population	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	P	3/11/2019
BLA 761077	1	Manufacturing Change With Clinical Data	AIMOVIG (ERENUMAB-AOOE)	AMGEN, INC.	S	3/11/2019
BLA 761034	19	New Indication	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	P	3/18/2019
BLA 125160	237		CIMZIA (CERTOLIZUMAB PEGOL)	UCB, INC.	S	3/28/2019
BLA 125276	120	Labeling Change With Clinical Data	ACTEMRA (TOCILIZUMAB)	GENENTECH, INC.	S	4/11/2019
BLA 125276	121	Labeling Change With Clinical Data	ACTEMRA (TOCILIZUMAB)	GENENTECH, INC.	S	4/11/2019
BLA 125514	47	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	4/11/2019
BLA 125554	70	New Dosing Regimen	OPDIVO (NIVOLUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	4/18/2019
BLA 125514	54	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	4/19/2019
BLA 125370	64	New Indication	BENLYSTA (BELIMUMAB)	HUMAN GENOME SCIENCES, INC.	P	4/26/2019
BLA 125559	19	New Indication	PRALUENT (ALIROCUMAB)	SANOFI-AVENTIS U.S. LLC	S	4/26/2019
BLA 125559	20	Labeling Change With Clinical Data	PRALUENT (ALIROCUMAB)	SANOFI-AVENTIS U.S. LLC	S	4/26/2019
BLA 125427	105	Manufacturing Change With Clinical Data	KADCYLA (ADO-TRASTUZUMAB EMTANSINE)	GENENTECH, INC.	P	5/3/2019
BLA 761034	13	New Dosing Regimen	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	S	5/6/2019
BLA 761034	14	New Dosing Regimen	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	S	5/6/2019
BLA 125360	74	New Indication	XEOMIN (INCOBOTULINUMTOXINA)	MERZ PHARMACEUTICALS GMBH C/O MERZ PHARMACEUTICALS LLC	S	5/10/2019
BLA 125477	29	New Indication	CYRAMZA (RAMUCIRUMAB)	ELI LILLY AND COMPANY	S	5/10/2019
BLA 125387	61	New Indication	EYLEA (AFLIBERCEPT)	REGENERON PHARMACEUTICALS, INC.	S	5/13/2019

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BLA 761049	6	New Indication	BAVENCIO (AVELUMAB)	EMD SERONO, INC.	P	5/14/2019
BLA 761091	2	New Indication	HERZUMA (TRASTUZUMAB)	CELLTRION	S	5/16/2019
BLA 761088	1	Labeling Change With Clinical Data	TRUXIMA (RITUXIMAB)	CELLTRION	S	5/23/2019
BLA 761088	2	Labeling Change With Clinical Data	TRUXIMA (RITUXIMAB)	CELLTRION	S	5/23/2019
BLA 761063	3	New Indication	EMGALITY (GALCANEZUMAB)	ELI LILLY AND COMPANY	P	6/4/2019
BLA 125514	52	Accelerated Approval Confirmatory Study	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	6/10/2019
BLA 125514	53	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	6/17/2019
BLA 125544	9	Labeling Change With Clinical Data	INFLECTRA (INFLIXIMAB-DYYB)	CELLTRION	S	6/18/2019
BLA 103000	5309	New Indication	BOTOX AND BOTOX COSMETIC (ONABOTULINUMTOXINA)	ALLERGAN, INC.	P	6/20/2019
BLA 761028	4	Accelerated Approval Confirmatory Study	MVASI (BEVACIZUMAB-AWWB)	AMGEN, INC.	S	6/24/2019
BLA 761054	9	Labeling Change With Clinical Data	RENFLEXIS (INFLIXIMAB-ABDA)	SAMSUNG BIOEPIS CO., LTD.	S	6/26/2019
BLA 761055	14	New Indication	DUPIXENT (DUPILUMAB)	REGENERON PHARMACEUTICALS, INC.	P	6/26/2019
BLA 125166	431	New Indication	SOLIRIS (ECULIZUMAB)	ALEXION PHARMACEUTICALS, INC.	P	6/27/2019
BLA 761036	20	Labeling Change With Clinical Data	DARZALEX (DARATUMUMAB)	JANSSEN BIOTECH, INC.	P	6/27/2019
BLA 761069	13	Labeling Change With Clinical Data	IMFINZI (DURVALUMAB)	ASTRAZENECA UK LTD	S	7/19/2019
BLA 125514	55	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	7/30/2019
BLA 125514	56	New Indication	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	7/30/2019
BLA 103846	5190	New Indication	MYOBLOC (RIMABOTULINUMTOXINB)	SOLSTICE NEUROSCIENCES, LLC	S	8/20/2019
BLA 125521	16	New Indication	TALTZ (IXEKIZUMAB)	ELI LILLY AND COMPANY	S	8/23/2019
BLA 125526	12	New Patient Population	NUCALA (MEPOLIZUMAB)	GLAXOSMITHKLINE LLC	S	9/12/2019
BLA 761122	3	New Patient Population	NUCALA (MEPOLIZUMAB (SB240563))	GLAXOSMITHKLINE LLC	S	9/12/2019
BLA 125514	65	Labeling Change With Clinical Data	KEYTRUDA (PEMBROLIZUMAB)	MERCK SHARP & DOHME CORP.	P	9/17/2019
BLA 125274	115	New Indication	DYSPORT (ABOBOTULINUMTOXINA)	IPSEN BIOPHARM LIMITED	P	9/25/2019
BLA 761036	24	New Patient Population	DARZALEX (DARATUMUMAB)	JANSSEN BIOTECH, INC.	P	9/26/2019
BLA 103705	5457	New Indication	RITUXAN (RITUXIMAB)	GENENTECH, INC.	P	9/27/2019
BLA 761068	3	Labeling Change With Clinical Data	CRYSVITA	KYOWA KIRIN, INC.	S	9/27/2019
BLA 761068	4	Labeling Change With Clinical Data	CRYSVITA	KYOWA KIRIN, INC.	P	9/27/2019
BLA 761070	5	Manufacturing Change With Clinical Data	FASENRA (BENRALIZUMAB)	ASTRAZENECA AB	S	10/3/2019
BLA 125268	164	New Patient Population	NPLATE (ROMIPLOSTIM)	AMGEN, INC.	S	10/17/2019
BLA 103000	5310	New Indication	BOTOX AND BOTOX COSMETIC (ONABOTULINUMTOXINA)	ALLERGAN, INC.	S	10/18/2019
BLA 761042	10	New Indication	ERELZI (ETANERCEPT-SZS)	SANDOZ INC.	S	10/18/2019
BLA 761044	3	New Indication	STELARA (USTEKINUMAB)	JANSSEN BIOTECH, INC.	S	10/18/2019
BLA 761108	1	New Indication	ULTOMIRIS (RAVULIZUMAB-CWVZ) INJECTION	ALEXION PHARMACEUTICALS, INC.	P	10/18/2019
BLA 761035	10	Labeling Change With Clinical Data	EMPLICITI (ELOTUZUMAB)	BRISTOL-MYERS SQUIBB COMPANY	S	10/28/2019
BLA 761061	4	Labeling Change With Clinical Data	TREMFYA (GUSELKUMAB)	JANSSEN BIOTECH, INC.	S	11/22/2019
BLA 761034	21	New Indication	TECENTRIQ (ATEZOLIZUMAB)	GENENTECH, INC.	S	12/3/2019
BLA 761088	5	New Indication	TRUXIMA (RITUXIMAB)	CELLTRION	S	12/18/2019
BLA 761088	6	New Indication	TRUXIMA (RITUXIMAB)	CELLTRION	S	12/18/2019