

**CY 2017 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year Approvals  
As of December 31, 2017**

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**User Response: Start Date: 1/1/2017 End Date: 12/31/2017**

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APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE or SUBMISSION CLASS CODE	ESTABLISHED NAME	APPLICANT	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (MONTHS)
NDA 208036	2	New Dosing Regimen		BRACCO DIAGNOSTICS INC	S	3/3/2016	1/3/2017	10.1
NDA 022117	21	New Dosing Regimen		FOREST LABORATORIES LLC	S	3/18/2016	1/13/2017	9.9
NDA 022161	13	Manufacturing Change With Clinical Data		ASTELLAS PHARMA US INC	S	3/17/2016	1/17/2017	10.1
NDA 205552	16	New Indication		PHARMACYCLICS LLC	P	9/23/2016	1/18/2017	3.8
NDA 208411	1	Manufacturing Change With Clinical Data		ADAPT PHARMA OPERATIONS LTD	S	3/25/2016	1/24/2017	10.0
NDA 202811	10	New Dosing Regimen		FOREST LABORATORIES LLC	S	3/25/2016	1/25/2017	10.1
NDA 021929	13	New Patient Population		ASTRAZENECA PHARMACEUTICALS LP	U	7/28/2016	1/27/2017	6.0
NDA 200603	26	New Patient Population		SUNOVION PHARMACEUTICALS INC	P	7/29/2016	1/27/2017	6.0
NDA 200603	27	New Patient Population		SUNOVION PHARMACEUTICALS INC	P	8/1/2016	1/27/2017	5.9
NDA 203100	25	New Patient Population		GILEAD SCIENCES INC	P	7/28/2016	1/27/2017	6.0
NDA 203188	22	New Dosing Regimen		VERTEX PHARMACEUTICALS INC	S	4/8/2016	2/8/2017	10.1
NDA 207925	3	New Dosing Regimen		VERTEX PHARMACEUTICALS INC	S	4/8/2016	2/8/2017	10.1
NDA 021936	7	New Patient Population		BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P	8/15/2016	2/15/2017	6.0
NDA 021880	49	New Indication		CELGENE CORP	P	8/24/2016	2/22/2017	6.0
NDA 207931	6	New Patient Population		ABBVIE INC	S	4/27/2016	2/24/2017	10.0
NDA 020450	3	New Patient Population		PARKE DAVIS A SUBSIDIARY OF PFZIER INC	S	9/1/2016	3/1/2017	6.0
NDA 208143	2	New Indication		BRACCO DIAGNOSTICS INC	S	5/4/2016	3/1/2017	9.9
NDA 205122	3	New Indication		UPSHER-SMITH LABORATORIES INC	S	1/31/2017	3/29/2017	1.9
NDA 205122	5	New Patient Population		UPSHER-SMITH LABORATORIES INC	S	5/31/2016	3/29/2017	9.9
NDA 207103	4	New Indication		PFIZER INC	P	10/27/2016	3/31/2017	5.1
NDA 020351	44	New Indication		GE HEALTHCARE INC	P	10/5/2016	4/5/2017	6.0
NDA 020808	25	New Indication		GE HEALTHCARE INC	P	10/5/2016	4/5/2017	6.0
NDA 201635	11	New Indication		SUPERNUS PHARMACEUTICALS INC	S	2/10/2017	4/5/2017	1.8
NDA 201635	17	New Indication		SUPERNUS PHARMACEUTICALS INC	S	10/27/2016	4/5/2017	5.3
NDA 204671	6	New Patient Population		GILEAD SCIENCES INC	P	10/27/2016	4/7/2017	5.3
NDA 205834	17	New Patient Population		GILEAD SCIENCES INC	P	10/7/2016	4/7/2017	6.0
NDA 203085	7	New Indication		BAYER HEALTHCARE PHARMACEUTICALS INC	P	10/31/2016	4/27/2017	5.9
NDA 205637	7	New Dosing Regimen		BIODELIVERY SCIENCES INTERNATIONAL INC	S	11/2/2016	4/27/2017	5.8
NDA 022113	1	New Indication		PFIZER INC	S	6/30/2016	4/28/2017	9.9
NDA 203284	5	New Patient Population		HORIZON THERAPEUTICS INC	S	6/28/2016	4/28/2017	10.0
NDA 207997	Orig - 1	New Indication		NOVARTIS PHARMACEUTICALS CORP		8/29/2016	4/28/2017	8.0

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NDA 203188	19	New Indication		VERTEX PHARMACEUTICALS INC	P	1/23/2017	5/17/2017	3.7
NDA 207925	1	New Indication		VERTEX PHARMACEUTICALS INC	P	1/23/2017	5/17/2017	3.7
NDA 021567	40	New Dosing Regimen		BRISTOL-MYERS SQUIBB CO	S	9/30/2016	5/23/2017	7.7
NDA 021688	23	New Indication		AMGEN INC	S	12/2/2016	5/23/2017	5.7
NDA 206352	5	New Dosing Regimen		BRISTOL-MYERS SQUIBB CO	S	9/30/2016	5/23/2017	7.7
NDA 022145	36	New Dosing Regimen		MERCK SHARP AND DOHME CORP	S	7/27/2016	5/26/2017	10.0
NDA 203045	13	New Dosing Regimen		MERCK SHARP AND DOHME CORP	S	10/24/2016	5/26/2017	7.0
NDA 205786	4	New Dosing Regimen		MERCK SHARP AND DOHME CORP	S	10/24/2016	5/26/2017	7.0
NDA 207533	4	New Dosing Regimen		ALKERMES INC	S	8/5/2016	6/5/2017	10.0
NDA 202806	6	New Indication		NOVARTIS PHARMACEUTICALS CORP	P	9/22/2016	6/22/2017	9.0
NDA 204114	5	New Indication		NOVARTIS PHARMACEUTICALS CORP	P	9/22/2016	6/22/2017	9.0
NDA 022511	19	New Patient Population		HORIZON PHARMA USA INC	S	6/7/2016	7/6/2017	13.0
NDA 208143	4	New Dosing Regimen		BRACCO DIAGNOSTICS INC	S	9/8/2016	7/7/2017	9.9
NDA 202834	12	New Patient Population		EISAI INC	S	9/26/2016	7/26/2017	10.0
NDA 208277	1	New Patient Population		EISAI INC	S	9/26/2016	7/26/2017	10.0
NDA 202971	10	New Indication		OTSUKA PHARMACEUTICAL CO LTD	S	9/28/2016	7/27/2017	9.9
NDA 208341	1	New Patient Population		GILEAD SCIENCES INC	S	10/3/2016	8/1/2017	9.9
NDA 205552	17	New Indication		PHARMACYCLICS LLC	P	2/2/2017	8/2/2017	6.0
NDA 206162	7	Accelerated Approval Confirmatory Study		ASTRAZENECA PHARMACEUTICALS LP	U	5/17/2017	8/17/2017	3.0
NDA 021344	34	New Indication		ASTRAZENECA PHARMACEUTICALS LP	S	10/28/2016	8/25/2017	9.9
NDA 022341	27	New Indication		NOVO NORDISK INC	S	10/25/2016	8/25/2017	10.0
NDA 021232	20			SWEDISH ORPHAN BIOVITRUM AB PUBL	S	11/1/2016	9/1/2017	10.0
NDA 021572	57	New Patient Population		CUBIST PHARMACEUTICALS LLC	P	3/2/2017	9/1/2017	6.0
NDA 206356	3			SWEDISH ORPHAN BIOVITRUM AB PUBL	S	11/1/2016	9/1/2017	10.0
NDA 022416	9	New Patient Population	ESLICARPAZEPINE ACETATE (SEP-0002093)	SUNOVION PHARMACEUTICALS INC	P	3/13/2017	9/13/2017	6.0
NDA 205836	3	New Patient Population		UCB INC	S	11/14/2016	9/14/2017	10.0
NDA 205837	3	New Patient Population		UCB INC	S	11/14/2016	9/14/2017	10.0
NDA 205838	2	New Patient Population		UCB INC	S	11/14/2016	9/14/2017	10.0
NDA 022074	17	New Indication		IPSEN PHARMA	S	8/15/2016	9/15/2017	13.0
NDA 206426	4	New Patient Population		BIOCRIST PHARMACEUTICALS INC	P	3/24/2017	9/20/2017	5.9
NDA 207561	14	New Patient Population		GILEAD SCIENCES INC	P	4/3/2017	9/25/2017	5.8
NDA 208215	5	New Patient Population		GILEAD SCIENCES INC	P	4/11/2017	9/28/2017	5.6
NDA 021983	23	New Patient Population		MERIDIAN MEDICAL TECHNOLOGIES INC	S	12/7/2016	10/6/2017	10.0
NDA 021306	27	New Patient Population		PURDUE PHARMA LP	S	12/15/2016	10/13/2017	9.9
NDA 022387	15	New Dosing Regimen		UNITED THERAPEUTICS CORP	S	12/19/2016	10/19/2017	10.0
NDA 022406	24	New Dosing Regimen		JANSSEN PHARMACEUTICALS INC	P	4/28/2017	10/27/2017	6.0
NDA 022253	39	New Patient Population	LACOSAMIDE	UCB INC	S	1/3/2017	11/3/2017	10.0
NDA 022254	30	New Patient Population		UCB INC	S	1/3/2017	11/3/2017	10.0
NDA 022255	22	New Patient Population		UCB INC	S	1/3/2017	11/3/2017	10.0

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NDA 202429	16	New Indication		HOFFMANN-LA ROCHE INC	P	6/7/2017	11/6/2017	5.0
NDA 205874	13	New Indication		KERYX BIOPHARMACEUTICALS INC	S	1/6/2017	11/6/2017	10.0
NDA 208434	3	New Indication		HOFFMANN-LA ROCHE INC	P	5/31/2017	11/6/2017	5.2
NDA 021986	20	New Patient Population		BRISTOL-MYERS SQUIBB CO	P	5/9/2017	11/9/2017	6.0
NDA 021344	35	New Indication		ASTRAZENECA PHARMACEUTICALS LP	P	7/28/2017	11/14/2017	3.6
NDA 021938	33	New Indication		CP PHARMACEUTICALS INTERNATIONAL CV	S	3/17/2017	11/16/2017	8.0
NDA 201739	8	New Patient Population		KALEO INC	P	5/19/2017	11/17/2017	6.0
NDA 204790	14	New Indication		VIIV HEALTHCARE CO	S	8/4/2017	11/21/2017	3.6
NDA 205551	11	New Patient Population		VIIV HEALTHCARE CO	P	5/31/2017	11/21/2017	5.7
NDA 022145	37	New Patient Population		MERCK SHARP AND DOHME CORP	P	6/9/2017	11/22/2017	5.5
NDA 203045	14	New Patient Population		MERCK SHARP AND DOHME CORP	P	6/9/2017	11/22/2017	5.5
NDA 205786	6	New Patient Population		MERCK SHARP AND DOHME CORP	P	5/25/2017	11/22/2017	6.0
NDA 203214	17	New Indication		PF PRISM CV	S	2/22/2017	12/14/2017	9.7
NDA 208246	3	New Indication		PFIZER INC	S	2/22/2017	12/14/2017	9.7
NDA 203341	9	New Indication		PF PRISM CV	P	6/26/2017	12/19/2017	5.8
NDA 208692	2	New Indication		EXELIXIS INC	P	8/15/2017	12/19/2017	4.1
NDA 022264	15	Comparative Efficacy Claim		JANSSEN PHARMACEUTICALS INC	S	6/20/2017	12/20/2017	6.0
NDA 205552	20	New Dosing Regimen		PHARMACYCLICS LLC	P	8/2/2017	12/20/2017	4.6
NDA 208573	3	New Dosing Regimen		ABBVIE INC	P	6/28/2017	12/20/2017	5.8
NDA 205755	10	New Dosing Regimen		NOVARTIS PHARMACEUTICALS CORP	S	2/21/2017	12/21/2017	10.0
NDA 022068	26	New Dosing Regimen		NOVARTIS PHARMACEUTICALS CORP	U	7/13/2017	12/22/2017	5.3
NDA 018511	28	New Indication		JUBILANT DRAXIMAGE INC	S	2/27/2017	12/26/2017	9.9

**NDA Efficacy Supplements Approved (SE8)**

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NDA 022117	20	Labeling Change With Clinical Data		FOREST LABORATORIES LLC	S	3/14/2016	1/13/2017	10.0
NDA 020453	7	Labeling Change With Clinical Data		FOUGERA PHARMACEUTICALS INC	S	5/3/2016	1/25/2017	8.8
NDA 206494	3	Labeling Change With Clinical Data		CEREXA INC	U	7/28/2016	1/26/2017	6.0
NDA 022450	10	Labeling Change With Clinical Data		MALLINCKRODT IP	P	4/29/2016	1/27/2017	9.0
NDA 206353	3	Labeling Change With Clinical Data		BRISTOL-MYERS SQUIBB CO	S	3/28/2016	1/27/2017	10.0
NDA 204042	18	Labeling Change With Clinical Data		JANSSEN PHARMACEUTICALS INC	S	4/4/2016	2/1/2017	10.0

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NDA 204353	14	Labeling Change With Clinical Data	JANSSEN PHARMACEUTICALS INC	S	4/4/2016	2/1/2017	10.0
NDA 022410	23	Labeling Change With Clinical Data	INDIVIOR INC	S	7/1/2015	2/13/2017	19.5
NDA 207561	4	Labeling Change With Clinical Data	GILEAD SCIENCES INC	S	4/29/2016	2/15/2017	9.6
NDA 207561	5	Labeling Change With Clinical Data	GILEAD SCIENCES INC	S	4/29/2016	2/15/2017	9.6
NDA 022350	18	Labeling Change With Clinical Data	ASTRAZENECA AB	S	4/27/2016	2/27/2017	10.1
NDA 200678	18	Labeling Change With Clinical Data	ASTRAZENECA AB	S	4/27/2016	2/27/2017	10.1
NDA 204447	9	Labeling Change With Clinical Data	TAKEDA PHARMACEUTICALS USA INC	S	5/10/2016	3/10/2017	10.0
NDA 021264	14	Labeling Change With Clinical Data	US WORLDMEDS LLC	S	5/19/2016	3/16/2017	9.9
NDA 022008	9	Labeling Change With Clinical Data	GLAXOSMITHKLINE LLC	S	2/26/2016	3/23/2017	12.9
NDA 021572	55	Labeling Change With Clinical Data	CUBIST PHARMACEUTICALS LLC	P	6/30/2016	3/29/2017	8.9
NDA 208065	6	Labeling Change With Clinical Data	ASTRAZENECA PHARMACEUTICALS LP	P	9/30/2016	3/30/2017	6.0
NDA 208036	5	Labeling Change With Clinical Data	BRACCO DIAGNOSTICS INC	S	6/8/2016	4/7/2017	10.0
NDA 203341	7	Labeling Change With Clinical Data	PF PRISM CV	S	6/28/2016	4/13/2017	9.5
NDA 206321	4	Labeling Change With Clinical Data	NOVO NORDISK INC	S	6/27/2016	4/26/2017	10.0
NDA 202570	19	Labeling Change With Clinical Data	PF PRISM CV	S	6/28/2016	4/28/2017	10.0
NDA 204275	12	Labeling Change With Clinical Data	GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE	S	7/15/2016	5/15/2017	10.0
NDA 201023	20	Labeling Change With Clinical Data	SANOFI-AVENTIS US LLC	P	11/21/2016	5/17/2017	5.8
NDA 205755	9	Labeling Change With Clinical Data	NOVARTIS PHARMACEUTICALS CORP	P	11/28/2016	5/26/2017	5.9
NDA 050795	24	Labeling Change With Clinical Data	MAYNE PHARMA INTERNATIONAL PTY LTD	S	8/3/2016	5/31/2017	9.9
NDA 021225	38	Labeling Change With Clinical Data	BAYER HEALTHCARE PHARMACEUTICALS INC	S	8/10/2016	6/8/2017	9.9
NDA 020702	67	Labeling Change With Clinical Data	PFIZER INC	S	8/26/2016	6/23/2017	9.9
NDA 203415	11	Labeling Change With Clinical Data	ASTELLAS PHARMA US INC	S	1/24/2017	7/24/2017	6.0

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NDA 203188	26	Labeling Change With Clinical Data		VERTEX PHARMACEUTICALS INC	U	6/2/2017	7/31/2017	1.9
NDA 207925	5	Labeling Change With Clinical Data		VERTEX PHARMACEUTICALS INC	U	6/2/2017	7/31/2017	1.9
NDA 200179	4	Labeling Change With Clinical Data		BAYER HEALTHCARE PHARMACEUTICALS INC	U	10/21/2016	8/2/2017	9.4
NDA 206229	4	Labeling Change With Clinical Data		MEDICINES360	S	10/3/2016	8/3/2017	10.0
NDA 208143	5	Labeling Change With Clinical Data		BRACCO DIAGNOSTICS INC	S	10/5/2016	8/4/2017	10.0
NDA 021856	11	Labeling Change With Clinical Data		TAKEDA PHARMACEUTICALS USA INC	S	10/20/2016	8/15/2017	9.8
NDA 207561	11	Labeling Change With Clinical Data		GILEAD SCIENCES INC	S	11/10/2016	8/15/2017	9.1
NDA 208351	2	Labeling Change With Clinical Data		GILEAD SCIENCES INC	S	10/31/2016	8/21/2017	9.7
NDA 208351	3	Labeling Change With Clinical Data		GILEAD SCIENCES INC	S	10/31/2016	8/21/2017	9.7
NDA 203214	14	Labeling Change With Clinical Data		PF PRISM CV	S	10/27/2016	8/22/2017	9.8
NDA 208246	1	Labeling Change With Clinical Data		PFIZER INC	S	1/13/2017	8/22/2017	7.3
NDA 204781	1	Labeling Change With Clinical Data		GUERBET LLC	S	10/27/2016	8/25/2017	9.9
NDA 022522	8	Labeling Change With Clinical Data		ASTRAZENECA PHARMACEUTICALS LP	U	3/15/2017	8/31/2017	5.6
NDA 021929	41	Labeling Change With Clinical Data		ASTRAZENECA PHARMACEUTICALS LP	S	11/18/2016	9/11/2017	9.8
NDA 202429	14	Labeling Change With Clinical Data		HOFFMANN-LA ROCHE INC	S	4/27/2017	9/13/2017	4.6
NDA 201023	19	Labeling Change With Clinical Data		SANOFI-AVENTIS US LLC	S	11/14/2016	9/14/2017	10.0
NDA 021880	51	Labeling Change With Clinical Data		CELGENE CORP	P	3/31/2017	9/15/2017	5.5
NDA 205266	4	Labeling Change With Clinical Data		SUN PHARMA GLOBAL FZE	S	11/18/2016	9/18/2017	10.0
NDA 022453	10	Labeling Change With Clinical Data	TOPOTECAN	TEVA PHARMACEUTICALS USA	S	11/21/2016	9/20/2017	10.0
NDA 022334	39	Labeling Change With Clinical Data		NOVARTIS PHARMACEUTICALS CORP	S	1/13/2017	9/26/2017	8.4
NDA 022472	11	Labeling Change With Clinical Data		MANNKIND CORP	S	11/30/2016	9/29/2017	10.0
NDA 202192	14	Labeling Change With Clinical Data		INCYTE CORP	S	12/15/2016	10/10/2017	9.8

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NDA 022200	25	Labeling Change With Clinical Data		ASTRAZENECA AB	S	12/22/2016	10/20/2017	9.9
NDA 202293	12	Labeling Change With Clinical Data		ASTRAZENECA AB	S	12/22/2016	10/20/2017	9.9
NDA 208090	4	Labeling Change With Clinical Data		COLLEGIUM PHARMACEUTICAL INC	S	10/4/2016	11/6/2017	13.1
NDA 204370	2	Labeling Change With Clinical Data		ALLERGAN SALES LLC	S	1/12/2017	11/9/2017	9.9
NDA 207561	13	Labeling Change With Clinical Data		GILEAD SCIENCES INC	S	2/28/2017	11/22/2017	8.8
NDA 205388	6	Labeling Change With Clinical Data		OMEROS CORP	P	6/9/2017	12/8/2017	6.0
NDA 208603 (1)	1	Labeling Change With Clinical Data		EGALET CORP	S	2/21/2017	12/14/2017	9.7
NDA 021077	56	Labeling Change With Clinical Data		GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE	S	10/3/2016	12/20/2017	14.6
NDA 021077	57	Labeling Change With Clinical Data		GLAXO GROUP LTD ENGLAND DBA GLAXOSMITHKLINE	S	10/3/2016	12/20/2017	14.6
NDA 021929	42	Labeling Change With Clinical Data		ASTRAZENECA PHARMACEUTICALS LP	S	2/28/2017	12/20/2017	9.7
NDA 022518	22	Labeling Change With Clinical Data		MERCK SHARP AND DOHME CORP	S	7/31/2017	12/20/2017	4.7
NDA 021923	18	Labeling Change With Clinical Data		BAYER HEALTHCARE PHARMACEUTICALS INC	S	8/22/2017	12/22/2017	4.0
NDA 203389	20	Labeling Change With Clinical Data		HORIZON PHARMA USA INC	U	6/29/2017	12/22/2017	5.8

**BLA Efficacy Supplements Approved**

APPL NUMBER	SUBM TYPE & NUMBER	SUPPLEMENT TYPE	PROPER NAME	APPLICANT	PRIORITY REVIEW	RECEIPT DATE	APPROVAL DATE	TOTAL APPROVAL TIME (MONTHS)
BLA 125156	111	EFFICACY		GENENTECH, INC.	P	7/11/2016	1/5/2017	5.9
BLA 125469	7	EFFICACY		ELI LILLY AND COMPANY	S	3/28/2016	1/27/2017	10.0
BLA 125469	8	EFFICACY		ELI LILLY AND COMPANY	S	3/28/2016	1/27/2017	10.0
BLA 125554	24	EFFICACY		BRISTOL-MYERS SQUIBB COMPANY	P	9/2/2016	2/2/2017	5.0
BLA 125514	15	EFFICACY		MERCK SHARP & DOHME CORP.	P	9/15/2016	3/14/2017	5.9
BLA 125057	399	EFFICACY		ABBVIE INC.	S	6/3/2016	3/27/2017	9.8
BLA 125118	211	EFFICACY		BRISTOL-MYERS SQUIBB COMPANY	P	9/30/2016	3/30/2017	6.0
BLA 103000	5296	BOTOX® AND BOTOX® COSMETIC (ONABOTULINUMTOXINA)		ALLERGAN, INC.	S	6/8/2016	4/4/2017	9.9

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BLA 103000	5297	BOTOX® AND BOTOX® COSMETIC (ONABOTULINUMTOXINA)		ALLERGAN, INC.	S	6/8/2016	4/4/2017	9.9
BLA 103000	5298	BOTOX® AND BOTOX® COSMETIC (ONABOTULINUMTOXINA)		ALLERGAN, INC.	S	6/8/2016	4/4/2017	9.9
BLA 125156	114	LUCENTIS® (RANIBIZUMAB)		GENENTECH, INC.	P	10/18/2016	4/15/2017	5.9
BLA 761034	1	TECENTRIQ™ (ATEZOLIZUMAB)		GENENTECH, INC.	P	10/31/2016	4/17/2017	5.5
BLA 125559	1	PRALUENT® (ALIROCUMAB)		SANOFI-AVENTIS U.S. LLC	S	3/24/2016	4/24/2017	13.0
BLA 125554	31	OPDIVO® (NIVOLUMAB)		BRISTOL-MYERS SQUIBB COMPANY	P	12/9/2016	4/25/2017	4.5
BLA 761078	Orig - 1	BAVENCIO	AVELUMAB	EMD SERONO, INC.	P	12/27/2016	5/9/2017	4.4
BLA 125514	16	KEYTRUDA® (PEMBROLIZUMAB)		MERCK SHARP & DOHME CORP.	P	11/10/2016	5/10/2017	6.0
BLA 761035	5	EMPLICITI™ (ELOTUZUMAB)		BRISTOL-MYERS SQUIBB COMPANY	S	7/18/2016	5/11/2017	9.8
BLA 125514	13	KEYTRUDA® (PEMBROLIZUMAB)		MERCK SHARP & DOHME CORP.	S	8/12/2016	5/17/2017	9.1
BLA 125514	17	KEYTRUDA® (PEMBROLIZUMAB)		MERCK SHARP & DOHME CORP.	P	12/14/2016	5/18/2017	5.1
BLA 125514	18	KEYTRUDA® (PEMBROLIZUMAB)		MERCK SHARP & DOHME CORP.	P	12/14/2016	5/18/2017	5.1
BLA 125472	24	ACTEMRA® (TOCILIZUMAB)		GENENTECH, INC.	P	11/22/2016	5/22/2017	6.0
BLA 125514	14	KEYTRUDA® (PEMBROLIZUMAB)		MERCK SHARP & DOHME CORP.	P	9/8/2016	5/23/2017	8.4
BLA 103471	5189	BETASERON® (INTERFERON BETA-1B)		BAYER HEALTHCARE PHARMACEUTICALS INC.	S	7/29/2016	5/26/2017	9.9
BLA 125320	181	PROLIA® (DENOSUMAB)		AMGEN, INC.	S	7/29/2016	5/26/2017	9.9
BLA 761029	1	ZIINBRYTA™ (DACLIZUMAB)	Daclizumab High Yield Process (DAC HYP)	BIOGEN INC.	S	7/29/2016	5/26/2017	9.9
BLA 125274	109	DYSPORT® (ABOBOTULINUMTOXINA)		IPSEN BIOPHARM LIMITED	S	8/15/2016	6/14/2017	10.0
BLA 761036	5	DARZALEX® (DARATUMUMAB)		JANSSEN BIOTECH, INC.	S	8/17/2016	6/16/2017	10.0
BLA 125289	133	SIMPONI® (GOLIMUMAB)		JANSSEN BIOTECH, INC.	S	8/22/2016	6/22/2017	10.0
BLA 125147	207	VECTIBIX® (PANITUMUMAB)		AMGEN, INC.	S	8/29/2016	6/29/2017	10.0
BLA 125118	209	ORENCIA® (ABATACEPT [BMS- 188667])		BRISTOL-MYERS SQUIBB COMPANY	S	8/31/2016	6/30/2017	10.0
BLA 125557	8	BLINCYTO® (BLINATUMOMAB)		AMGEN, INC.	P	2/14/2017	7/11/2017	4.8
BLA 125377	87	YERVOY® (IPILIMUMAB)		BRISTOL-MYERS SQUIBB COMPANY	S	1/23/2017	7/21/2017	5.9
BLA 125554	34	OPDIVO® (NIVOLUMAB)		BRISTOL-MYERS SQUIBB COMPANY	P	2/2/2017	7/31/2017	5.9
BLA 125276	114	ACTEMRA® (TOCILIZUMAB)		GENENTECH, INC.	P	6/1/2017	8/30/2017	3.0

**CY 2017 New Drug Application (NDA) & Biologic License Application (BLA) Efficacy Supplement Calendar Year Approvals  
As of December 31, 2017**

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

**Selection Criteria:**

**User Response: Start Date: 1/1/2017 End Date: 12/31/2017**

**Sort Order: Approval Date**

BLA 103795	5556	ENBREL® (ETANERCEPT)		AMGEN, INC.	S	11/14/2016	9/14/2017	10.0
BLA 125559	6	PRALUENT® (ALIROCUMAB)		SANOFI-AVENTIS U.S. LLC	S	11/21/2016	9/20/2017	10.0
BLA 125514	24	KEYTRUDA® (PEMBROLIZUMAB)		MERCK SHARP & DOHME CORP.	P	3/22/2017	9/22/2017	6.0
BLA 125554	41	OPDIVO® (NIVOLUMAB)		BRISTOL-MYERS SQUIBB COMPANY	P	3/24/2017	9/22/2017	6.0
BLA 103000	5303	BOTOX® AND BOTOX® COSMETIC (ONABOTULINUMTOXINA)		ALLERGAN, INC.	S	12/2/2016	10/2/2017	10.0
BLA 103964	5270	PEGASYS® (PEGINTERFERON ALFA-2A)		HOFFMANN-LA ROCHE INC.	S	12/15/2016	10/13/2017	9.9
BLA 125261	138	STELARA® (USTEKINUMAB)		JANSSEN BIOTECH, INC.	S	12/15/2016	10/13/2017	9.9
BLA 125377	86	YERVOY® (IPIILIMUMAB)		BRISTOL-MYERS SQUIBB COMPANY	S	12/22/2016	10/20/2017	9.9
BLA 125433	20	SIMPONI® ARIA™ (GOLIMUMAB)		JANSSEN BIOTECH, INC.	S	12/20/2016	10/20/2017	10.0
BLA 125433	21	SIMPONI® ARIA™ (GOLIMUMAB)		JANSSEN BIOTECH, INC.	S	12/20/2016	10/20/2017	10.0
BLA 125166	422	SOLIRIS® (ECULIZUMAB)		ALEXION PHARMACEUTICALS, INC.	S	12/23/2016	10/23/2017	10.0
BLA 125388	94	ADCETRIS® (BRENTUXIMAB VEDOTIN)		SEATTLE GENETICS, INC.	P	6/16/2017	11/9/2017	4.8
BLA 125486	17	GAZYVA® [OBINUTUZUMAB (GA101, RO5072759)]		GENENTECH, INC.	P	6/23/2017	11/16/2017	4.8
BLA 103795	5559	ENBREL® (ETANERCEPT)		AMGEN, INC.	S	1/23/2017	11/22/2017	10.0
BLA 125521	4	TALTZ™ (IXEKIZUMAB)		ELI LILLY AND COMPANY	S	2/2/2017	12/1/2017	9.9
BLA 125522	13	REPATHA™ (EVOLOCUMAB)		AMGEN, INC.	P	6/2/2017	12/1/2017	6.0
BLA 125522	14	REPATHA™ (EVOLOCUMAB)		AMGEN, INC.	S	6/2/2017	12/1/2017	6.0
BLA 125085	319	AVASTIN® (BEVACIZUMAB)		GENENTECH, INC.	S	2/1/2017	12/5/2017	10.1
BLA 125526	4	NUCALA® (MEPOLIZUMAB)		GLAXOSMITHKLINE LLC	P	6/28/2017	12/12/2017	5.5
BLA 125409	113	PERJETA® (PERTUZUMAB)		GENENTECH, INC.	S	2/28/2017	12/20/2017	9.7
BLA 125409	118	PERJETA® (PERTUZUMAB)		GENENTECH, INC.	P	7/28/2017	12/20/2017	4.8
BLA 125554	55	OPDIVO® (NIVOLUMAB)		BRISTOL-MYERS SQUIBB COMPANY	P	8/14/2017	12/20/2017	4.2