Patent Listing Disputes

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Established Drug Product Name	NDA Number	NDA Holder	Strength(s)	Relevant U.S. Patent Number(s)	Type of Patent Claim	Original Use Code (if applicable)	Due Date for NDA Holder Response	NDA Holder Response Date	Dispute Outcome
bosutinib monohydrate	203341	PF PRISM CV	EQ 100MG BASE EQ 400MG BASE EQ 500MG BASE	11103497	Method of Use	U-3216: A METHOD FOR TREATING A BCRABL POSITIVE LEUKEMIA IN A SUBJECT THAT IS RESISTANT TO IMATINIB COMPRISING ADMINISTERING TO THE SUBJECT A THERAPEUTICALLY EFFECTIVE AMOUNT OF BOSUTINIB, WHEREIN THE SUBJECT HAS A MUTATION IN THE BCRABL PROTEIN AT 949T>C U-3217: A METHOD FOR TREATING A BCRABL POSITIVE LEUKEMIA IN A SUBJECT THAT IS RESISTANT TO IMATINIB COMPRISING ADMINISTERING TO THE SUBJECT A THERAPEUTICALLY EFFECTIVE AMOUNT OF BOSUTINIB, WHEREIN THE SUBJECT HAS A MUTATION IN THE BCRABL PROTEIN AT F317L	11/25/2026	Pending	Pending
rasagiline mesylate	021641	Teva Neuroscience Inc	EQ 0.5MG BASE EQ 1MG BASE	7572834	Disputes Not Related to Use Code	N/A	11/7/2026	10/22/2026	Patent Listing Updated
fluticasone furoate	022051	Haleon US Holdings	0.0275MG/SPRAY	8147461	Disputes Not Related to Use Code	N/A	9/24/2026	9/24/2026	Patent Listing Updated
bempedoic acid	211616	Esperion Theraps Inc	180MG	11744816	Method of Use	U-3883: A METHOD OF LOWERING LDL-C OR REDUCING THE RISK OF CARDIOVASCULAR DISEASE IN PATIENTS WITH FAMILIAL HYPERCHOLESTEROLEMIA USING 180 MG BEMPEDOIC ACID AND 10 MG EZETIMIBE	4/9/2026	4/9/2026	No Orange Book Changes
brexanolone	211371	Sage Therapeutics Inc	100MG/20ML (5MG/ML)	7635773 , 8410077, 9200088, 9750822, 10117951, 10322139	Disputes Not Related to Use Code	N/A	3/22/2026	5/11/2026	No Orange Book Changes
brexanolone	211371	Sage Therapeutics Inc	100MG/20ML (5MG/ML)	10251894, 10940156	Method of Use	U-2550: METHOD OF TREATING POSTPARTUM DEPRESSION	3/22/2026	5/11/2026	No Orange Book Changes
mirabegron	202611	Astellas	25MG 50MG	10842780, 11707451, 12097189	Method of Use	U-3670: ADMINISTRATION OF AN EXTENDED RELEASE TABLET FOR THE TREATMENT OF NEUROGENIC DETRUSOR OVERACTIVITY (NDO) IN PEDIATRIC PATIENTS AGED 3 YEARS AND OLDER AND WEIGHING 35 KG OR MORE	12/26/2025	12/18/2025	No Orange Book Changes
amlodipine besylate; celecoxib	210045	Purple Biotech	EQ 2.5MG BASE; 200MG EQ 5MG BASE; 200MG EQ 10MG BASE; 200MG	10925835, 9662315, 9408837	Method of Use	U-2410: TREATMENT OF ADULT PATIENTS FOR WHOM TREATMENT WITH BOTH AMLODIPINE FOR HYPERTENSION AND CELECOXIB FOR OSTEOARTHRITIS ARE APPROPRIATE	10/30/2025	10/27/2025	Patent Listing Updated
amlodipine besylate; celecoxib	210045	Purple Biotech	EQ 2.5MG BASE; 200MG EQ 5MG BASE; 200MG EQ 10MG BASE; 200MG	10945960, 9662315	Disputes Not Related to Use Code	N/A	10/30/2025	10/27/2025	Patent Listing Updated
glucagon	210134	Amphastar Pharms Inc	3MG	10894133	Disputes Not Related to Use Code	N/A	6/26/2025	6/12/2025	Patent Listing Updated
beclomethasone dipropionate	207921	Norton Waterford	0.04MG/INH 0.08MG/INH	9408837	Disputes Not Related to Use Code	N/A	6/22/2025	6/25/2025	No Orange Book Changes
glycopyrrolate	207923	Novartis	15.6MCG/INH	8182838	Disputes Not Related to Use Code	N/A	6/22/2025	6/20/2025	No Orange Book Changes
glycopyrrolate; indacaterol maleate	207930	Novartis	15.6MCG/INH; 27.5MCG/INH	8182838	Disputes Not Related to Use Code	N/A	6/22/2025	6/20/2025	No Orange Book Changes
beclomethasone dipropionate	020911	Teva Branded Pharm	0.08MG/INH 0.04MG/INH	10022509, 10022510, 10086156, 10695512	Disputes Not Related to Use Code	N/A	6/22/2025	6/25/2025	No Orange Book Changes
albuterol sulfate	021457	Teva Branded Pharm	EQ 0.09MG BASE/INH	10022509, 10022510, 10086156, 10695512	Disputes Not Related to Use Code	N/A	6/22/2025	6/25/2025	No Orange Book Changes
albuterol sulfate	205636	Teva Branded Pharm	EQ 0.09MG BASE/INH (Prod 001)	8651103, 8978966, 9216260, 9463288, 9731087, 10022510, 10124131, 10765820	Disputes Not Related to Use Code	N/A	6/22/2025	6/25/2025	No Orange Book Changes
albuterol sulfate	205636	Teva Branded Pharm	EQ 0.09MG BASE/INH (Prod 002)	8651103, 8978966, 9216260, 9463288, 9731087, 9782550, 9782551, 10022510, 10124131, 10569034, 10765820, 11000653, 11266796, 11351317, 11357935, 11439777 and 11464923	Disputes Not Related to Use Code	N/A	6/22/2025	6/25/2025	No Orange Book Changes
fluticasone proprionate	208798	Teva Pharm	0.055MG/INH (Prod 001) 0.113MG/INH (Prod 002) 0.232MG/INH (Prod 003) 0.03MG/INH (Prod 007)	8651103, 8714149, 8978966, 9216260, 9463288, 9731087, 10022510, 10124131, and 10765820	Disputes Not Related to Use Code	N/A	6/22/2025	6/25/2025	No Orange Book Changes
fluticasone proprionate	208798	Teva Pharm	0.055MG/INH (Prod 004) 0.113MG/INH (Prod 005) 0.232MG/INH (Prod 006) 0.03MG/INH (Prod 008)	8651103, 8714149, 8978966, 9216260, 9463288, 9731087, 9782550, 9782551, 10022510, 10124131, 10569034, 10765820, 11000653, 11266796, 11351317, 11357935, 11439777, and 11464923	Disputes Not Related to Use Code	N/A	6/22/2025	6/25/2025	No Orange Book Changes
fluticasone propionate; salmeterol xinafoate	208799	Teva Pharm	0.055MG/INH; EQ 0.014MG BASE/INH (Prod 001) 0.113MG/INH; EQ 0.014MG BASE/INH (Prod 002) 0.232MG/INH; EQ 0.014MG BASE/INH (Prod 003)	8651103, 8714149, 8978966, 9216260, 9463288, 9731087, 10022510, 10124131, and 10765820	Disputes Not Related to Use Code	N/A	6/22/2025	6/25/2025	No Orange Book Changes
fluticasone propionate; salmeterol xinafoate	208799	Teva Pharm	0.055MG/INH; EQ 0.014MG BASE/INH (Prod 004) 0.113MG/INH; EQ 0.014MG BASE/INH (Prod 005) 0.232MG/INH; EQ 0.014MG BASE/INH (Prod 006)	8651103, 8714149, 8978966, 9216260, 9463288, 9731087, 9782550, 9782551, 10022510, 10124131, 10569034, 10765820, 11000653, 11266796, 11351317, 11357935, 11439777, and 11464923	Disputes Not Related to Use Code	N/A	6/22/2025	6/25/2025	No Orange Book Changes
epinephrine	019430	Viatris	0.3MG/DELIVERY 0.15MG/DELIVERY	7449012, 7794432, 8048035, 9586010	Disputes Not Related to Use Code	N/A	6/22/2025	6/20/2025	No Orange Book Changes
cabozantinib s-malate	208692	Exelixis Inc.	EQ 20MG BASE, EQ 40MG BASE, EQ 60MG BASE	8877776	Method of Use	U-3225: TREATMENT OF DIFFERENTIATED THYROID CANCER THAT HAS PROGRESSED FOLLOWING PRIOR VEGFR-TARGETED THERAPY	3/20/2025	3/7/2025	No Orange Book Changes
nitric oxide	202860	Vero Biotech Inc	800PPM	7560076, 7618594, 8607785, 8821801, 8944049, 9522249, 9701538, 10213572, 10737051, 10926054, 11103669, 11291793, 11511252	Disputes Not Related to Use Code	N/A	2/12/2025	2/12/2025	No Orange Book Changes
nitric oxide	202860	Vero Biotech Inc	800PPM	7947227, 8057742, 8226916, 8609028, 9604028, 9956373, 10124142, 10814092, 11383059, 11554241, 11672938	Method of Use	U-3037: A METHOD OF DELIVERING NITRIC OXIDE TO A PATIENT; U-2793: A METHOD FOR DELIVERING NITRIC OXIDE TO A PATIENT WITH PULMONARY HYPERTENSION OR HYPOXIA	2/12/2025	2/12/2025	No Orange Book Changes
dapagliflozin; metformin hydrochloride	205649	Astrazeneca AB	5MG; 500MG, 5MG; 1GM, 10MG; 500MG, 10MG; 1GM	10973836, 11903955	Disputes Not Related to Use Code	N/A	9/20/2024	9/18/2024	No Orange Book Changes

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glucagon	210134	Amphastar Pharms Inc	3MG	10894133	Disputes Not Related to Use Code	N/A	6/8/2024	6/6/2024	No Orange Book Changes
exenatide synthetic	022200	Astrazeneca AB	2MG	8216180, 8439864, 8690837, 8721615, 8758292, 8827963, 8998876, 9320853	Disputes Not Related to Use Code	N/A	6/8/2024	6/7/2024	No Orange Book Changes
olodaterol hydrochloride	203108	Boehringer Ingelheim	EQ 0.0025MG BASE/INH	7284474, 7396341, 7837235, 7896264, 9027967	Disputes Not Related to Use Code	N/A	6/8/2024	6/7/2024	No Orange Book Changes
olodaterol hydrochloride; tiotropium bromide	206756	Boehringer Ingelheim	EQ 0.0025MG BASE/INH; EQ 0.0025MG BASE/INH	7284474, 7396341, 7837235, 7896264, 9027967	Disputes Not Related to Use Code	N/A	6/8/2024	6/7/2024	No Orange Book Changes
aclidinium bromide	202450	Covis	0.4MG/INH	8051851	Disputes Not Related to Use Code	N/A	6/8/2024	6/6/2024	No Orange Book Changes
aclidinium bromide; formoterol fumarate	210595	Covis	0.4MG/INH; 0.012MG/INH	8051851	Disputes Not Related to Use Code	N/A	6/8/2024	6/6/2024	No Orange Book Changes
umeclidinium bromide	205382	Glaxo Grp England	EQ 0.0625MG BASE/INH	8746242, 9333310, 8201556	Disputes Not Related to Use Code	N/A	6/8/2024	6/5/2024	No Orange Book Changes
fluticasone furoate; vilanterol trifenatate	204275	Glaxo Grp Ltd	0.1MG/INH; EQ 0.025MG BASE/INH 0.2MG/INH; EQ 0.025MG BASE/INH 0.05MG/INH; EQ 0.025MG BASE/INH	8161968, 9333310	Disputes Not Related to Use Code	N/A	6/8/2024	6/5/2024	No Orange Book Changes
umeclidinium bromide; vilanterol trifenatate	203975	Glaxosmithkline	EQ 0.0625MG BASE/INH; EQ 0.025MG BASE/INH	8161968, 8534281, 8746242, 9333310	Disputes Not Related to Use Code	N/A	6/8/2024	6/5/2024	No Orange Book Changes
fluticasone furoate; umeclidinium bromide; vilanterol trifenatate	209482	Glaxosmithkline	0.1MG/INH; EQ 0.0625MG BASE/INH; EQ 0.025MG BASE/INH 0.2MG/INH; EQ 0.0625MG BASE/INH; EQ 0.025MG BASE/INH	8161968, 9333310	Disputes Not Related to Use Code	N/A	6/8/2024	6/5/2024	No Orange Book Changes
beclomethasone dipropionate	207921	Norton Waterford	0.04MG/INH 0.08MG/INH	0022509, 10022510, 10086156, 10695512 11865247, 1189675	Disputes Not Related to Use Code	N/A	6/8/2024	6/3/2024	No Orange Book Changes
glycopyrrolate	207923	Novartis	15.6MCG/INH	8182838	Disputes Not Related to Use Code	N/A	6/8/2024	6/5/2024	No Orange Book Changes
glycopyrrolate; indacaterol maleate	207930	Novartis	15.6MCG/INH; 27.5MCG/INH	8182838	Disputes Not Related to Use Code	N/A	6/8/2024	6/5/2024	No Orange Book Changes
liraglutide	206321	Novo	18MG/3ML (6MG/ML)	7762994, 8684969, 8920383, 9108002, 9132239, 9457154, 9616180, 9687611, 9775953, 9861757, 10220155, 10357616, 10376652, 11097063, 11311679, 11446443, RE46363	Disputes Not Related to Use Code	N/A	6/8/2024	6/10/2024	No Orange Book Changes
semaglutide	209637	Novo	2MG/1.5ML (1.34MG/ML) 2MG/3ML (0.68MG/ML) 4MG/3ML (1.34MG/ML) 8MG/3ML (2.68MG/ML)	7762994, 8684969, 8920383, 9108002, 9132239, 9457154, 9616180, 9687611, 9775953, 9861757, 10220155, 10357616, 10376652, 11097063, 11311679, 11446443, RE46363	Disputes Not Related to Use Code	N/A	6/8/2024	6/10/2024	No Orange Book Changes
liraglutide	022341	Novo Nordisk Inc	18MG/3ML (6MG/ML)	7762994, 9265893	Disputes Not Related to Use Code	N/A	6/8/2024	6/10/2024	No Orange Book Changes
fluticasone proprionate	208798	Teva Pharm	0.055MG/INH (Prod 001) 0.113MG/INH (Prod 002) 0.232MG/INH (Prod 003) 0.03MG/INH (Prod 007)	8651103, 8714149, 8978966, 9216260, 9463288, 9731087, 10022510, 10124131, 10561808, 10765820	Disputes Not Related to Use Code	N/A	6/8/2024	6/4/2024	No Orange Book Changes
fluticasone proprionate	208798	Teva Pharm	0.055MG/INH (Prod 004) 0.113MG/INH (Prod 005) 0.232MG/INH (Prod 006) 0.03MG/INH (Prod 008)	8651103, 8714149, 8978966, 9216260, 9463288, 9731087, 9782550, 9782551, 10022510, 10124131, 10561808, 10569034, 10765820, 11000653, 11266796, 11351317, 11357935, 11439777, 11464923	Disputes Not Related to Use Code	N/A	6/8/2024	6/4/2024	No Orange Book Changes
fluticasone propionate; salmeterol xinafoate	208799	Teva Pharm	0.055MG/INH; EQ 0.014MG BASE/INH (Prod 001) 0.113MG/INH; EQ 0.014MG BASE/INH (Prod 002) 0.232MG/INH; EQ 0.014MG BASE/INH (Prod 003)	8651103, 8714149, 8978966, 9216260, 9463288, 9731087, 10022510, 10124131, 10561808, 10765820	Disputes Not Related to Use Code	N/A	6/8/2024	6/4/2024	No Orange Book Changes
fluticasone propionate; salmeterol xinafoate	208799	Teva Pharm	0.055MG/INH; EQ 0.014MG BASE/INH (Prod 004) 0.113MG/INH; EQ 0.014MG BASE/INH (Prod 005) 0.232MG/INH; EQ 0.014MG BASE/INH (Prod 006)	8651103, 8714149, 8978966, 9216260, 9463288, 9731087, 9782550, 9782551, 10022510, 10124131, 10561808, 10569034, 10765820, 11000653, 11266796, 11351317, 11357935, 11439777, 11464923	Disputes Not Related to Use Code	N/A	6/8/2024	6/4/2024	No Orange Book Changes
cyclosporine	050790	Abbvie	0.05%	8292129, 8561859, 9669974, 9676525	Disputes Not Related to Use Code	N/A	12/16/2023	12/14/2023	No Orange Book Changes
budesonide; formoterol fumarate dihydrate	021929	Astrazeneca	0.08MG/INH; 0.0045MG/INH	7587988, 8387615, 8528545, 8616196, 8875699	Disputes Not Related to Use Code	N/A	12/16/2023	12/14/2023	No Orange Book Changes
tiotropium bromide	021395	Boehringer Ingelheim	EQ 0.018MG BASE/INH	7694676, 9010323	Disputes Not Related to Use Code	N/A	12/16/2023	12/15/2023	No Orange Book Changes
ipratropium bromide	021527	Boehringer Ingelheim	0.021MG/INH	8474447	Disputes Not Related to Use Code	N/A	12/16/2023	12/15/2023	No Orange Book Changes
albuterol sulfate; ipratropium bromide	021747	Boehringer Ingelheim	EQ 0.1MG BASE/INH; 0.02MG/INH	7284474, 7396341, 7837235, 7896264, 8733341, 9027967	Disputes Not Related to Use Code	N/A	12/16/2023	12/15/2023	No Orange Book Changes
tiotropium bromide	021936	Boehringer Ingelheim	EQ 0.00125MG BASE/INH	7284474, 7396341, 7837235, 7896264, 8733341, 9027967	Disputes Not Related to Use Code	N/A	12/16/2023	12/15/2023	No Orange Book Changes
fluticasone propionate; salmeterol xinafoate	021254	Glaxo Grp Ltd	0.115MG/INH; EQ 0.021MG BASE/INH	7500444	Disputes Not Related to Use Code	N/A	12/16/2023	12/15/2023	Patent Listing Updated
fluticasone propionate	021433	Glaxo Grp Ltd	0.044MG/INH	7500444	Disputes Not Related to Use Code	N/A	12/16/2023	12/15/2023	Patent Listing Updated

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albuterol sulfate	020983	Glaxosmithkline	EQ 0.09MG BASE/INH	7500444	Disputes Not Related to Use Code	N/A	12/16/2023	12/15/2023	Patent Listing Updated
fluticasone furoate	205625	Glaxosmithkline	0.1MG/INH	8113199, 8161968, 8534281, 8746242	Disputes Not Related to Use Code	N/A	12/16/2023	12/15/2023	Patent Listing Updated
epinephrine	020800	Impax	EQ 0.15MG/ DELIVERY	7905352, 10166334	Disputes Not Related to Use Code	N/A	12/16/2023	11/21/2023	Patent Listing Updated
epinephrine	201739	Kaleo Inc	EQ 0.15MG/ DELIVERY	7731686, 7731690, 7749194, 8016788, 8920377, 8926594, 9238108, 10960155	Disputes Not Related to Use Code	N/A	12/16/2023	12/6/2023	Patent Listing Updated
epinephrine	019430	Mylan Specialty LP	0.15MG/DELIVERY 0.3MG/DELIVERY	7449012, 7794432, 8048035, 9586010	Disputes Not Related to Use Code	N/A	12/16/2023	12/15/2023	No Orange Book Changes
beclomethasone dipropionate	207921	Norton Waterford	0.04MG/INH	8132712, 10022509, 10022510, 10086156, 10561808, 10695512, 11395889	Disputes Not Related to Use Code	N/A	12/16/2023	1/5/2024	No Orange Book Changes
beclomethasone dipropionate	020911	Teva Branded Pharm	0.04MG/INH	9463289, 9808587, 10022509, 10022510, 10086156, 10561808, 10695512, 11395889	Disputes Not Related to Use Code	N/A	12/16/2023	1/5/2024	No Orange Book Changes
albuterol Sulfate	021457	Teva Branded Pharm	EQ 0.09MG BASE/INH	8132712, 9463289, 9808587, 10022509, 10022510, 10086156, 10561808, 10695512, 11395889	Disputes Not Related to Use Code	N/A	12/16/2023	1/5/2024	No Orange Book Changes
albuterol Sulfate	205636	Teva Branded Pharm	EQ 0.09MG BASE/INH	8651103, 8978966, 9216260, 9463288, 9731087, 9782550, 9782551, 10022510, 10124131, 10561808, 10569034, 10765820, 11000653, 11266796, 11351317, 11357935, 11439777, 11464923	Disputes Not Related to Use Code	N/A	12/16/2023	1/5/2024	No Orange Book Changes
betamethasone dipropionate; calcipotriene	213422	MC2	0.064% 0.005%	11638711	Disputes Not Related to Use Code	N/A	9/8/2023	8/29/2023	Patent Listing Updated
adapalene; benzoyl peroxide	022320	Galderma Labs LP	0.1% 2.5%	8445543	Disputes Not Related to Use Code	N/A	8/12/2023	7/21/2023	Patent Listing Updated
isavuconazonium sulfate	207500	Astellas	74.5MG	10812238	Disputes Not Related to Use Code	N/A	7/23/2023	6/29/2023	Patent Listing Updated
propofol	019627	Fresenius Kabi USA	10MG/ML	8476010	Disputes Not Related to Use Code	N/A	4/21/2023	4/21/2023	No Orange Book Changes
phentolamine mesylate	022159	Septodont Holding	0.4MG/1.7ML	7229630, 7575757	Disputes Not Related to Use Code	N/A	1/21/2023	1/13/2023	Patent Listing Updated
epinephrine	205029	BPI Labs LLC	1MG/ML	9283197	Disputes Not Related to Use Code	N/A	12/9/2022	12/1/2022	No Orange Book Changes
amifampridine phosphate	208078	Catalyst Pharmaceuticals Inc	10MG	10636088	Disputes Not Related to Use Code	N/A	11/16/2022	11/8/2022	No Orange Book Changes
pitolisant hydrochloride	211150	Harmony Biosciences LLC	4.45MG 17.8MG	8486947	Method of Use	U-1102: Method of treating cataplexy in patients with narcolepsy	8/7/2022	8/4/2022	No Orange Book Changes
ganaxolone	215904	Marinus Pharmaceuticals Inc	50MG/ML	8022054	Disputes Not Related to Use Code	N/A	7/30/2022	7/19/2022	Patent Listing Updated
baricitinib	207924	Eli Lilly Co	1MG 2MG 4MG	9089574, 11045474	Disputes Not Related to Use Code	N/A	6/7/2022	6/24/2022	No Orange Book Changes
tipiracil hydrochloride; trifluridine	207981	Taiho Oncology Inc	6.14MG; 15MG 8.19MG; 20MG	10960004	Method of Use	U-2642: Method of treating cancer by detecting a creatinine clearance of a patient and administering Lonsurf	5/28/2022	5/24/2022	No Orange Book Changes
tipiracil hydrochloride; trifluridine	207981	Taiho Oncology Inc	6.14MG; 15MG 8.19MG; 20MG	10456399	Method of Use	U-2642: Method of treating cancer by detecting a creatinine clearance of a patient and administering Lonsurf	5/26/2022	5/24/2022	No Orange Book Changes
fostamatinib disodium	209299	Rigel Pharmaceuticals Inc	100MG 150MG	8263122, 8652492	Disputes Not Related to Use Code	N/A	4/8/2022	4/5/2022	No Orange Book Changes
famotidine; ibuprofen	022519	Horizon Medicines LLC	26.6MG; 800MG	8067033	Disputes Not Related to Use Code	N/A	3/12/2022	2/22/2022	Patent Listing Updated
metaxalone	013217	King Pharms	800MG	7122566	Disputes Not Related to Use Code	N/A	12/17/2021	12/3/2021	No Orange Book Changes
epinephrine	205029	Belcher	1MG/ML	10004700, 10039728	Disputes Not Related to Use Code	N/A	7/24/2021	12/14/2022	No Orange Book Changes
memantine hydrochloride	022525	Allergan Sales LLC	7MG 14MG 21MG 28MG	8168209, 8173708, 8283379, 8329752, 8362085, 8598233	Disputes Not Related to Use Code	N/A	5/28/2021	5/28/2021	Patent Listing Updated
epinephrine	201739	Kaleo Inc	0.1MG 0.15MG 0.3MG	10824938	Disputes Not Related to Use Code	N/A	2/28/2021	2/3/2021	Patent Listing Updated
netarsudil dimesylate	208254	Aerie Pharms Inc	0.02%	10654844	Disputes Not Related to Use Code	N/A	11/18/2020	10/30/2020	Patent Listing Updated

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Established Drug Product Name	NDA Number	NDA Holder	Strength(s)	Relevant U.S. Patent Number(s)	Type of Patent Claim	Original Use Code (if applicable)	Due Date for NDA Holder Response	NDA Holder Response Date	Dispute Outcome
latanoprost; netarsudil dimesylate	208259	Aerie Pharms Inc	0.02%/0.005%	10654844	Disputes Not Related to Use Code	N/A	11/18/2020	10/30/2020	Patent Listing Updated
cangrelor	204958	Chiesi	50MG/VIAL	8680052	Method of Use	U-2869: IV Administration of cangrelor before PCI and continuous infusion for at least 2 hours or the duration of the PCI and, during or after the continuous infusion, administration of a loading dose of ticagrelor or an equivalent therapy (per labeling)	11/8/2020	11/3/2020	Patent Listing Updated
dapagliflozin; metformin hydrochloride	205649	Astrazeneca	5MG/ 500MG 5MG/ 1000MG 10MG/ 500MG 10MG/ 1000MG 2.5MG/1000MG	6515117	Disputes Not Related to Use Code	N/A	10/29/2020	10/1/2020	Patent Listing Updated
cangrelor	204958	Chiesi	50MG/VIAL	8680052	Method of Use	U-1715: P2Y12 Platelet Inhibitor for use as adjunct to percutaneous coronary intervention to reduce risk of various diseases/conditions in patients not treated with a P2Y12 platelet inhibitor and not given a glycoprotein IIb/IIIA inhibitor	8/9/2020	8/7/2020	Patent Listing Updated
fingolimod hydrochloride	022527	Novartis	EQ 0.5MG BASE	9187405	Method of Use	U-2613: Treatment of Relapsing-Remitting Sclerosis (MS)	6/15/2020	6/10/2020	No Orange Book Changes
paliperidone palmitate	022264	Janssen Pharms	39MG/0.25ML, 78MG/0.5ML, 117MG/0.75ML, 156MG/ML	9439906	Method of Use	U-543: Treatment of Schizophrenia	3/21/2020	3/20/2020	Patent Listing Updated
paliperidone palmitate	022264	Janssen Pharms	39MG/0.25ML, 78MG/0.5ML, 117MG/0.75ML, 156MG/ML	9439906	Method of Use	U-1901: Treatment of Schizoaffective Disorder as a Monotherapy and as an adjunct to mood stabilizers or antidepressants	3/21/2020	3/20/2020	Patent Listing Updated
glatiramer acetate	020622	Teva Pharms USA	40MG/ML	8232250, 8399413, 8969302, 9155776, 9402874	Disputes Not Related to Use Code	N/A	2/15/2020	2/6/2020	Patent Listing Updated
empagliflozin	204629	Boehringer Ingelheim	10MG 25MG	10406172	Method of Use	U-1652: Method of Treating Type 2 Diabetes Mellitus by administering Linagliptin in combination with empagliflozin and metformin	1/18/2020	1/17/2020	Patent Listing Updated
empagliflozin; linagliptin	206073	Boehringer Ingelheim	10MG; 5MG, 25MG; 5MG	10406172	Method of Use	U-1652: Method of Treating Type 2 Diabetes Mellitus by administering Linagliptin in combination with empagliflozin and metformin	1/18/2020	1/17/2020	Patent Listing Updated
sodium oxybate	021196	Jazz Pharms	500MG/ML	10213400	Method of Use	U-2499: Method of reducing adverse effects in patients suffering from excessive daytime sleepiness and/or cataplexy in narcolepsy who are concomitantly administered sodium oxybate and divalproex sodium	10/30/2019	10/29/2019	No Orange Book Changes
sodium oxybate	021196	Jazz Pharms	500MG/ML	8772306, 9050302, 9486426	Method of Use	U-1532: Method of treating excessive daytime sleepiness and/or cataplexy in narcolepsy patients with sodium oxybate when divalproex sodium is concomitantly administered	10/30/2019	10/29/2019	No Orange Book Changes
sodium oxybate	021196	Jazz Pharms	500 MG/ML	8731963	Method of Use	U-1110: Method of treating a patient with a prescription drug using a computer database in a computer system for distribution	10/30/2019	10/29/2019	No Orange Book Changes
abiraterone acetate	202379	Janssen Biotech	250MG 500MG	8822438	Disputes Not Related to Use Code	N/A	9/22/2019	9/19/2019	Patent Listing Updated
sodium oxybate	021196	Jazz Pharms	500MG/ML	7668730, 7765106, 7765107, 7895059, 8457988, 8589182	Disputes Not Related to Use Code	N/A	9/22/2019	9/19/2019	Patent Listing Updated
ramelteon	021782	Takeda Pharms USA	8MG	10098866	Disputes Not Related to Use Code	N/A	7/18/2019	7/11/2019	No Orange Book Changes
fexofenadine hydrochloride	201373	Sanofi Aventis US	30MG/5ML	8933097	Disputes Not Related to Use Code	N/A	6/15/2019	6/12/2019	Patent Listing Updated
cyclosporine	050790	Allergan	0.05%	9669974, 9676525	Disputes Not Related to Use Code	N/A	4/26/2019	4/19/2019	No Orange Book Changes
nateglinide	021204	Novartis	60MG 120MG	6559188, 6878749	Disputes Not Related to Use Code	N/A	1/25/2019	1/22/2019	Patent Listing Updated
avibactam sodium; ceftazidime	206494	Allergan Sales LLC	EQ 0.5GM BASE; 2 GM/VIAL	8969566	Disputes Not Related to Use Code	N/A	1/6/2019	1/7/2019	No Orange Book Changes
trospium chloride	022103	Allergan	60MG	7410978, 7759359, 7763635, 7781448, 7781449	Disputes Not Related to Use Code	N/A	11/18/2018	10/31/2018	Patent Listing Updated
metformin hydrochloride	021748	Santarus Inc	500MG, 1GM	6723340	Disputes Not Related to Use Code	N/A	8/25/2018	8/23/2018	No Orange Book Changes
pirfenidone	208780	Genentech Inc	267MG 534MG 801MG	8383150	Disputes Not Related to Use Code	N/A	8/23/2018	8/24/2018	Patent Listing Updated
empagliflozin; linagliptin	206073	Boehringer Ingelheim	10MG; 5MG, 25MG; 5MG	8673927	Method of Use	U-1772: Method of treating type 2 diabetes mellitus by administering linagliptin in combination with empagliflozin	8/9/2018	8/10/2018	No Orange Book Changes
empagliflozin; linagliptin	206073	Boehringer Ingelheim	10MG; 5MG, 25MG; 5MG	9173859	Method of Use	U-1652: Method of treating type 2 diabetes mellitus by administering linagliptin in combination with empagliflozin and metformin	8/9/2018	8/10/2018	No Orange Book Changes
tadalafil	022332	Eli Lilly Co	20MG	6821975, 7182958	Disputes Not Related to Use Code	N/A	7/27/2018	7/23/2018	Patent Listing Updated
ropivacaine hydrochloride	020533	Fresenius Kabi USA	200MG/100ML (2MG/ML), 400MG/200ML (2MG/ML)	7828787, 7857802, 8118802, 8162915	Disputes Not Related to Use Code	N/A	6/20/2018	6/7/2018	No Orange Book Changes
metformin hydrochloride	021748	Santarus Inc	500MG 1GM	6488962	Disputes Not Related to Use Code	N/A	6/17/2018	6/19/2018	Patent Listing Updated
metaxalone	013217	King Pharms	880MG	7122566	Disputes Not Related to Use Code	N/A	6/7/2018	6/6/2018	No Orange Book Changes

Patent Listing Disputes

Current through November 13, 2026

Established Drug Product Name	NDA Number	NDA Holder	Strength(s)	Relevant U.S. Patent Number(s)	Type of Patent Claim	Original Use Code (if applicable)	Due Date for NDA Holder Response	NDA Holder Response Date	Dispute Outcome
colchicine	204820	Hikma Intl Pharms	0.6MG	8927607, 9399036, 9555029, 9675613, 9789108	Method of Use	U-1020: Method of using colchicine for the prophylaxis of gout flares	5/12/2018	5/10/2018	No Orange Book Changes
dimethyl fumarate	204063	Biogen Idec Inc	120MG 240MG	7320999, 8759393	Disputes Not Related to Use Code	N/A	4/4/2018	3/30/2018	No Orange Book Changes
acetaminophen	022450	Mallinckrodt IP	1GM/100ML (10MG/ML)	9610265	Method of Use	U-2000: Management of moderate to severe pain as an adjunct to opioid analgesics	4/4/2018	4/4/2018	Patent Listing Updated
acetaminophen	022450	Mallinckrodt IP	1GM/100 ML (10MG/ML)	9399012	Method of Use	U-1882: Management of mild to moderate pain, management of moderate to severe pain as an adjunct to opioid analgesics, reduction in fever through analgesic and antipyretic activity	4/4/2018	4/4/2018	Patent Listing Updated
tofacitinib citrate	208246	Pfizer Inc	EQ 11MG BASE	RE41783	Disputes Not Related to Use Code	N/A	3/13/2018	3/8/2018	No Orange Book Changes
metformin hydrochloride	021748	Santarus Inc	500MG 1GM	8323692	Disputes Not Related to Use Code	N/A	3/10/2018	2/21/2018	Patent Listing Updated
dapagliflozin	202293	Astrazeneca AB	5MG 10MG	6479065, 6495164, 6667061, 6824822, 6872700, 6956026, 7223440, 7456254, 7563871, 7612176, 7741269, 8216180, 8329648, 8431685, 8439864, 8461105, 8690837, 8712615, 8758292, 8827963, 8906851, 8998876, 9238076, 9320853	Disputes Not Related to Use Code	N/A	1/11/2018	1/5/2018	Patent Listing Updated
eslicarbazepine acetate	022416	Sunovion Pharms Inc	200MG 400MG 600MG 800MG	9750747	Method of Use	U-2041: Treatment of partial-onset seizures	12/8/2017	12/5/2017	No Orange Book Changes
dabigatran etexilate mesylate	022512	Boehringer Ingelheim	75MG 110MG 150MG	7866474	Disputes Not Related to Use Code	N/A	9/7/2017	9/1/2017	Patent Listing Updated
dapagliflozin	202293	Astrazeneca AB	5MG 10MG	8685934	Method of Use	U-1522: Treatment of type 2 diabetes mellitus in a patient, wherein glycemic control (HbA1c < 7.0%) is not achievable using one or more of insulin, metformin, pioglitazone, or rosiglitazone	9/6/2017	9/5/2017	No Orange Book Changes
metaxalone	013217	King Pharms	800MG	7122566	Disputes Not Related to Use Code	N/A	6/25/2017	6/23/2017	No Orange Book Changes
dabigatran etexilate mesylate	022512	Boehringer Ingelheim	75MG 110MG 150MG	9034822	Disputes Not Related to Use Code	N/A	5/28/2017	5/26/2017	No Orange Book Changes