

Patent Listing Disputes

Current through June 10, 2022

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)	Revised Use Code (if applicable)	Due Date for NDA Holder Response	NDA Holder Response Date	Dispute Outcome
baricitinib	207924	Eli Lilly Co	1mg 2mg 4mg	9089574 and 11045474	Disputes Not Related to Use Code	N/A	N/A	6/7/2022	Pending	Pending
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	N/A	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	N/A	5/26/2022	Pending	Pending
fostamatinib disodium	209299	Rigel Pharmaceuticals Inc	100 mg 150 mg	8263122, 8652492	Disputes Not Related to Use Code	N/A	N/A	4/8/2022	4/5/2022	No Orange Book Changes
famotidine; ibuprofen	22519	Horizon Medicines LLC	26.6mg; 800mg	8067033	Disputes Not Related to Use Code	N/A	N/A	3/12/2022	2/22/2022	Patent Listing Updated
metaxalone	013217	King Pharms	800 mg	7122566	Disputes Not Related to Use Code	N/A	N/A	12/17/2021	12/3/2021	No Orange Book Changes
epinephrine	205029	Belcher	1mg/mL	10004700 and 10039728	Disputes Not Related to Use Code	N/A	N/A	7/24/2021	Pending	Pending
memantine hydrochloride	22525	Allergan Sales LLC	7 mg 14 mg 21 mg 28 mg	8168209, 8173708, 8283379, 8329752, 8362085 and 8598233	Disputes Not Related to Use Code	N/A	N/A	5/28/2021	5/28/2021	Patent Listing Updated
epinephrine	201739	Kaleo Inc	0.1 mg 0.15 mg 0.3 mg	10824938	Disputes Not Related to Use Code	N/A	N/A	2/28/2021	2/3/2021	Patent Listing Updated
netarsudil and latanoprost	208259	Aerie Pharms Inc	0.02%/0.005%	10654844	Disputes Not Related to Use Code	N/A	N/A	11/18/2020	10/30/2020	Patent Listing Updated
netarsudil	208254	Aerie Pharms Inc	0.02%	10654844	Disputes Not Related to Use Code	N/A	N/A	11/18/2020	10/30/2020	Patent Listing Updated
cangrelor	204958	Chiesi	50 mg/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)	U-2979: Method comprising IV administration of cangrelor before PCI then continuous infusion for at least 2 hours or the duration of PCI and, during or after continuous infusion, administration of a loading dose of ticagrelor, or an equivalent method	11/8/2020	11/3/2020	Patent Listing Updated
dapagliflozin and metform HCl	205649	AstraZeneca	5mg/500mg 5mg/1000mg 10mg/500mg 10mg/1000mg 2.5mg/1000mg	6515117	Disputes Not Related to Use Code	N/A	N/A	10/29/2020	10/1/2020	Patent Listing Updated
cangrelor	204958	Chiesi	50 mg/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	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)	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)	N/A	6/15/2020	6/10/2020	No Orange Book Changes

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paliperidone palmitate	022264	Janssen Pharms	39 mg/0.25 mL, 78 mg/0.5 mL, 117 mg/0.75 mL, 156 mg/mL	9439906	Method of Use	U-543: Treatment of Schizophrenia	U-2757: Dosing regimen for the treatment of schizophrenia in adults by administering two loading doses of paliperidone palmitate followed by maintenance dose(s)	3/21/2020	3/20/2020	Patent Listing Updated
paliperidone palmitate	022264	Janssen Pharms	39 mg/0.25 mL, 78 mg/0.5 mL, 117 mg/0.75 mL, 156 mg/mL	9439906	Method of Use	U-1901: Treatment of Schizoaffective Disorder as a Monotherapy and as an adjunct to mood stabilizers or antidepressants	U-2758: Dosing regimen for the treatment of schizoaffective disorder in adults as a monotherapy and as an adjunct to mood stabilizers or antidepressants by administering two loading doses of paliperidone palmitate followed by maintenance dose(s)	3/21/2020	3/20/2020	Patent Listing Updated
glatiramer acetate	020622	Teva Pharms USA	40mg/ml	8232250, 8399413, 8969302, 9155776, and 9402874	Disputes Not Related to Use Code	N/A	N/A	2/15/2020	2/6/2020	Patent Listing Updated
empagliflozin and 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	N/A	1/18/2020	1/17/2020	Patent Listing Updated
empagliflozin	204629	Boehringer Ingelheim	10 mg, 25 mg	10406172	Method of Use	U-1652: Method of Treating Type 2 Diabetes Mellitus by administering Linagliptin in combination with empagliflozin and metformin	N/A	1/18/2020	1/17/2020	Patent Listing Updated
sodium oxybate	021196	Jazz Pharms	500 mg/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	N/A	10/30/2019	10/29/2019	No Orange Book Changes
sodium oxybate	021196	Jazz Pharms	500 mg/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	N/A	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	N/A	10/30/2019	10/29/2019	No Orange Book Changes
abaterone acetate	202379	Janssen Biotech	250 mg, 500 mg	8822438	Disputes Not Related to Use Code	N/A	N/A	9/22/2019	9/19/2019	Patent Listing Updated
sodium oxybate	021196	Jazz Pharms	500 mg/mL	7668730, 7765106, 7765107, 7895059, 8457988, 8589182	Disputes Not Related to Use Code	N/A	N/A	9/22/2019	9/19/2019	Patent Listing Updated
ramelteon	021782	Takeda Pharms USA	8 mg	10098866	Disputes Not Related to Use Code	N/A	N/A	7/18/2019	7/11/2019	No Orange Book Changes
fexofenadine hydrochloride	201373	Sanofi Aventis US	30 mg/5 mL	8933097	Disputes Not Related to Use Code	N/A	N/A	6/15/2019	6/12/2019	Patent Listing Updated

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cyclosporine	050790	Allergan	0.05%	9669974, 9676525	Disputes Not Related to Use Code	N/A	N/A	4/26/2019	4/19/2019	No Orange Book Changes
nateglinide	021204	Novartis	60 mg, 120 mg	6559188, 6878749	Disputes Not Related to Use Code	N/A	N/A	1/25/2019	1/22/2019	Patent Listing Updated
avibactam sodium; ceftazidime	206494	Allergan Sales LLC	EQ 0.5 gm base; 2 gm/vial	8969566	Disputes Not Related to Use Code	N/A	N/A	1/6/2019	1/7/2019	No Orange Book Changes
trosipium chloride	022103	Allergan	60 mg	7410978, 7759359, 7763635, 7781448, 7781449	Disputes Not Related to Use Code	N/A	N/A	11/18/2018	10/31/2018	Patent Listing Updated
metformin hydrochloride	021748	Santarus Inc	500 mg, 1 gm	6723340	Disputes Not Related to Use Code	N/A	N/A	8/25/2018	8/23/2018	No Orange Book Changes
pirfenidone	208780	Genentech Inc	267 mg, 534 mg, 801 mg	8383150	Disputes Not Related to Use Code	N/A	N/A	8/23/2018	8/24/2018	Patent Listing Updated
empagliflozin and linagliptin	206073	Boehringer Ingelheim	10 mg; 5 mg, 25 mg; 5 mg	8673927	Method of Use	U-1772: Method of treating type 2 diabetes mellitus by administering linagliptin in combination with empagliflozin	None	8/9/2018	8/10/2018	No Orange Book Changes
empagliflozin and linagliptin	206073	Boehringer Ingelheim	10 mg; 5 mg, 25 mg; 5 mg	9173859	Method of Use	U-1652: Method of treating type 2 diabetes mellitus by administering linagliptin in combination with empagliflozin and metformin	None	8/9/2018	8/10/2018	No Orange Book Changes
tadalafil	022332	Eli Lilly Co	20 mg	6821975, 7182958	Disputes Not Related to Use Code	N/A	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	N/A	6/20/2018	6/7/2018	No Orange Book Changes
metformin hydrochloride	021748	Santarus Inc	500 mg, 1 gm	6488962	Disputes Not Related to Use Code	N/A	N/A	6/17/2018	6/19/2018	Patent Listing Updated
metaxalone	013217	King Pharms	880 mg	7122566	Disputes Not Related to Use Code	N/A	N/A	6/7/2018	6/6/2018	No Orange Book Changes
colchicine	204820	Hikma Intl Pharms	0.6 mg	8927607, 9399036, 9555029, 9675613, 9789108	Method of Use	U-1020: Method of using colchicine for the prophylaxis of gout flares	None	5/12/2018	5/10/2018	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	U-2263: Modified dosing regimen for the management of moderate to severe pain with adjunctive opioid analgesics	4/4/2018	4/4/2018	Patent Listing Updated
acetaminophen	022450	Mallinckrodt IP	1 gm/100 mL (10 mg/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	U-2261: Modified dosing regimen for the management of mild to moderate pain or management of moderate to severe pain as an adjunct to opioid analgesics U-2262: Modified dosing regimen for the reduction of fever	4/4/2018	4/4/2018	Patent Listing Updated
dimethyl fumarate	204063	Biogen Idec Inc	120 mg, 240 mg	7320999, 8759393	Disputes Not Related to Use Code	N/A	N/A	4/4/2018	3/30/2018	No Orange Book Changes

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tofacitinib citrate	208246	Pfizer Inc	EQ 11 mg base	RE41783	Disputes Not Related to Use Code	N/A	N/A	3/13/2018	3/8/2018	No Orange Book Changes
metformin hydrochloride	021748	Santarus Inc	500 mg, 1 gm	8323692	Disputes Not Related to Use Code	N/A	N/A	3/10/2018	2/21/2018	Patent Listing Updated
dapagliflozin propanediol	202293	Astrazeneca AB	5 mg, 10 mg	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	N/A	1/11/2018	1/5/2018	Patent Listing Updated
eslicarbazepine acetate	022416	Sunovion Pharms Inc	200 mg, 400 mg, 600 mg, 800 mg	9750747	Method of Use	U-2041: Treatment of partial-onset seizures	None	12/8/2017	12/5/2017	No Orange Book Changes
dabigatran etexilate mesylate	022512	Boehringer Ingelheim	75 mg, 110 mg, 150 mg	7866474	Disputes Not Related to Use Code	N/A	N/A	9/7/2017	9/1/2017	Patent Listing Updated
dapagliflozin propanediol	202293	Astrazeneca AB	5 mg, 10 mg	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	None	9/6/2017	9/5/2017	No Orange Book Changes
metaxalone	013217	King Pharms	800 mg	7122566	Disputes Not Related to Use Code	N/A	N/A	6/25/2017	6/23/2017	No Orange Book Changes
dabigatran etexilate mesylate	022512	Boehringer Ingelheim	75 mg, 110 mg, 150 mg	9034822	Disputes Not Related to Use Code	N/A	N/A	5/28/2017	5/26/2017	No Orange Book Changes