

**Patent Listing Disputes**  
Current through April 10, 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        |
|--|------------|-----------------------|---|--|----------------------------------|--|----------------------------------|--------------------------|------------------------|
| bempedoic acid                               | 211616     | Esperion Theraps Inc  | 180MG   | 11,744,816   | 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                         | Pending                  | Pending                |
| 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                        | Pending                  | Pending                |
| brexanolone                                  | 211371     | Sage Therapeutics Inc | 100MG/20ML (5MG/ML)   | 10251894, 10940156   | Method of Use                    | U-2550: METHOD OF TREATING POSTPARTUM DEPRESSION   | 3/22/2026                        | Pending                  | Pending                |
| mirabegron                                   | 202611     | Astellas              | 25MG<br>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<br>EQ 5MG BASE; 200MG<br>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<br>EQ 5MG BASE; 200MG<br>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<br>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<br>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 propionate                       | 208798     | Teva Pharm            | 0.055MG/INH (Prod 001)<br>0.113MG/INH (Prod 002)<br>0.232MG/INH (Prod 003)<br>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 propionate                       | 208798     | Teva Pharm            | 0.055MG/INH (Prod 004)<br>0.113MG/INH (Prod 005)<br>0.232MG/INH (Prod 006)<br>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)<br>0.113MG/INH; EQ 0.014MG BASE/INH (Prod 002)<br>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)<br>0.113MG/INH; EQ 0.014MG BASE/INH (Prod 005)<br>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     | Viatrix               | 0.3MG/DELIVERY<br>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,<br>10MG; 500MG, 10MG; 1GM   | 10973836, 11903955   | Disputes Not Related to Use Code | N/A  | 9/20/2024                        | 9/18/2024                | No Orange Book Changes |
| 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 |
| acridinium 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 |
| acridinium 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 |
| umecidinium 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 |

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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        |
|---|------------|----------------------|---|--|----------------------------------|-----------------------------------|----------------------------------|--------------------------|------------------------|
| fluticasone furoate; vilanterol trifenate                       | 204275     | Glaxo Grp Ltd        | 0.1MG/INH; EQ 0.025MG BASE/INH<br>0.2MG/INH; EQ 0.025MG BASE/INH<br>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 trifenate                      | 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 trifenate | 209482     | Glaxosmithkline      | 0.1MG/INH; EQ 0.0625MG BASE/INH; EQ 0.025MG BASE/INH<br>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<br>0.08MG/INH  | 22509, 10022510, 10086156, 10695512 11865247, 118967   | 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)<br>2MG/3ML (0.68MG/ML)<br>4MG/3ML (1.34MG/ML)<br>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 propionate  | 208798     | Teva Pharm           | 0.055MG/INH (Prod 001)<br>0.113MG/INH (Prod 002)<br>0.232MG/INH (Prod 003)<br>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 propionate  | 208798     | Teva Pharm           | 0.055MG/INH (Prod 004)<br>0.113MG/INH (Prod 005)<br>0.232MG/INH (Prod 006)<br>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)<br>0.113MG/INH; EQ 0.014MG BASE/INH (Prod 002)<br>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)<br>0.113MG/INH; EQ 0.014MG BASE/INH (Prod 005)<br>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 |
| 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<br>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 |

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|---|------------|------------------------------|--|---|----------------------------------|--|----------------------------------|--------------------------|------------------------|
| 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%<br>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%<br>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<br>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<br>2MG<br>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<br>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<br>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<br>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<br>14MG<br>21MG<br>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<br>0.15MG<br>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 |
| 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<br>5MG/ 1000MG<br>10MG/ 500MG<br>10MG/ 1000MG<br>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 |

**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        |
|-------------------------------|------------|----------------------|---|--|----------------------------------|---|----------------------------------|--------------------------|------------------------|
| 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<br>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,<br>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<br>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<br>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;<br>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 |
| pifedipone                    | 208780     | Genentech Inc        | 267MG<br>534MG<br>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,<br>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,<br>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<br>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 |
| 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<br>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<br>1GM                                    | 8323692  | Disputes Not Related to Use Code | N/A   | 3/10/2018                        | 2/21/2018                | Patent Listing Updated |

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|-------------------------------|------------|----------------------|----------------------------------|--|----------------------------------|---|----------------------------------|--------------------------|------------------------|
| dapagliflozin                 | 202293     | Astrazeneca AB       | 5MG<br>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<br>400MG<br>600MG<br>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<br>110MG<br>150MG           | 7866474  | Disputes Not Related to Use Code | N/A   | 9/7/2017                         | 9/1/2017                 | Patent Listing Updated |
| dapagliflozin                 | 202293     | Astrazeneca AB       | 5MG<br>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<br>110MG<br>150MG           | 9034822  | Disputes Not Related to Use Code | N/A   | 5/28/2017                        | 5/26/2017                | No Orange Book Changes |