

**Paragraph IV Patent Certifications
October 7, 2014**

| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|--------------------|---|--|---------------------------|
| Norelgestromin and Ethinyl Estradiol* | Transdermal System | 0.15 mg/0.02 mg per 24 hours | Ortho Evra | 3/22/2007 |
| Norethindrone Acetate/ Ethinyl Estradiol | Tablets | 1 mg/0.005 mg | Femhrt | |
| Norethindrone Acetate/ Ethinyl Estradiol | Tablets | 1 mg/ 0.02 mg, 1 mg/0.03 mg and 1 mg /0.035 mg | Estrostep Fe | |
| Norethindrone Acetate/ Ethinyl Estradiol | Tablets | 1 mg/0.02 mg, 1 mg/ 0.03 mg and 1 mg /0.035 mg | Estrostep 21 | |
| Norethindrone Acetate/ Ethinyl Estradiol and Ferrous Fumarate | Tablets | 1 mg/0.02 mg and 75 mg | Loestrin 24 Fe | 4/17/2006 |
| Norethindrone Acetate and Ethinyl Estradiol / Ethinyl Estradiol and Ferrous Fumarate | Tablets | 1 mg/0.01 mg, 0.01 mg and 75 mg | Lo Loestrin Fe | 4/29/2011 |
| Norethindrone and Ethinyl Estradiol and Ferrous Fumarate | Chewable Tablets | 0.4 mg/0.035 mg | Ovcon-35 Fe Femcon Fe NDA 21-490 | 4/27/2007 |
| Norethindrone and Ethinyl Estradiol and Ferrous Fumarate | Chewable Tablets | 0.8 mg/0.025 mg and 75 mg | Generess Fe | 8/5/2011 |
| Norethindrone/ Ethinyl Estradiol | Tablets | 0.5 mg/ 0.035 mg, 0.75 mg/ 0.035 mg and 1 mg /0.035 mg | Ortho-Novum 7/7/7, 21 and 28 day | |
| Norgestimate/ Ethinyl Estradiol | Tablets | 0.18 mg /0.025 mg, 0.215 mg /0.025 mg and 0.25 mg /0.025 mg | Ortho Tri- Cyclen Lo, 28 day | |
| Norgestimate/ Ethinyl Estradiol | Tablets | 0.18 mg /0.035 mg, 0.215 mg /0.035 mg and 0.25 mg /0.035 mg | Ortho Tri- Cyclen, 21 and 28 day | |

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| Nortriptyline Hydrochloride | Capsules | 10 mg, 25 mg, 50 mg and 75 mg | Pamelor | |
| Octreotide Acetate | Injection | 0.05 mg /mL, 0.1 mg /mL and 0.5 mg/mL, 1 mL vials | Sandostatin (Preservative-free) | |
| Octreotide Acetate | Injection | 0.2 mg/mL and 1 mg /mL, 5 mL vials | Sandostatin | |
| Octreotide Acetate | Injection | 0.05 mg/mL (base), 0.1 mg/mL (base) and 0.5 mg/mL (base) packaged in 1 mL pre-filled syringes (preservative-free) | SOctreotide Acetate Injection | 1/17/2008 |
| Ofloxacin | Otic Solution | 0.3% | Floxin | |
| Olanzapine | Tablets | 2.5 mg, 5 mg, 7.5 mg, 10 mg and 15 mg | Zyprexa | |
| Olanzapine | Tablets | 20 mg | Zyprexa | |
| Olanzapine | Orally Disintegrating Tablets | 5 mg, 10 mg, 15 mg and 20 mg | Zyprexa Zydis | |
| Olanzapine and Fluoxetine Hydrochloride | Capsules | 6 mg/25 mg, 12 mg/25 mg, 6 mg/50 mg and 12 mg/50 mg | Symbyax | 1/10/2005 |
| Olmesartan Medoxomil | Tablets | 5 mg, 20 mg and 40 mg | Benicar | 4/25/2006 |
| Olmesartan Medoxomil and Hydrochlorothiazide | Tablets | 20 mg/12.5 mg | Benicar HCT | 5/11/2007 |
| Olmesartan Medoxomil and Hydrochlorothiazide | Tablets | 40 mg/12.5 mg and 40 mg/25 mg | Benicar HCT | 2/15/2007 |
| Olopatadine Hydrochloride | Nasal Spray | 0.665 mg/ Spray | Patanase | 6/29/2009 |
| Olopatadine Hydrochloride | Ophthalmic Solution | 0.1% | Patanol | 7/17/2006 |
| Olopatadine Hydrochloride | Ophthalmic Solution | 0.2% | Pataday | 9/8/2008 |
| Omega-3-Acid Ethyl Esters | Capsules | 1 g | Lovaza | 11/10/2008 |

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| Omeprazole | Delayed-release Capsules | 10 mg, 20 mg and 40 mg | Prilosec | |
| Omeprazole and Sodium Bicarbonate | Capsules | 20 mg/1100 mg and 40 mg/1100 mg | Zegerid | 4/30/2007 |
| Omeprazole and Sodium Bicarbonate | Capsules | 20 mg/1100 mg | Zegerid OTC | 4/20/2010 |
| Omeprazole and Sodium Bicarbonate | Powder for Oral Suspension | 20mg/1680mg per packet | Zegerid | 11/13/2007 |
| Omeprazole and Sodium Bicarbonate | Powder for Oral Suspension | 40 mg/1680 mg per packet | Zegerid | 8/24/2007 |
| Omeprazole Magnesium | Delayed-release Capsules | 20 mg | Prilosec OTC | 3/19/2007 |
| Ondansetron Hydrochloride | Injection | 2 mg/mL, 2 mL vials (Preservative-free) | Zofran | |
| Ondansetron Hydrochloride | Injection | 2 mg/mL, 20 mL vials | Zofran | |
| Ondansetron Hydrochloride | Injection | 0.64 mg/mL, 50 mL container (plastic) | Zofran in Plastic Container | |
| Ondansetron Hydrochloride | Oral Solution | 4 mg/5 mL | Zofran | 12/20/2004 |
| Ondansetron Hydrochloride | Orally Disintegrating Tablets | 4 mg and 8 mg | Zofran ODT | |
| Ondansetron Hydrochloride | Tablets | 4 mg, 8 mg, 16 mg and 24 mg | Zofran | |
| Orlistat | Capsules | 60 mg | Alli | 9/8/2010 |
| Oseltamivir Phosphate | Capsules | 30 mg and 45 mg | Tamiflu | 8/2/2011 |
| Oseltamivir Phosphate | Capsules | 75 mg | Tamiflu | 11/15/2010 |
| Oxaliplatin | For Injection | 50 mg/vial and 100 mg/vial | Eloxatin | 2/9/2007 |
| Oxaliplatin | Injection | 5 mg/mL, 10 mL and 20 mL vials | Eloxatin | 2/9/2007 |
| Oxaliplatin | Injection | 5 mg/mL, 40 mL vials | Eloxatin | 7/16/2007 |
| Oxandrolone | Tablets | 2.5 mg and 10 mg | Oxandrin | 6/19/2006 |
| Oxazepam | Capsules | 10 mg, 15 mg and 30 mg | Serax | |
| Oxcarbazepine | Tablets | 150 mg, 300 mg and 600 mg | Trileptal | 5/5/2006 |
| Oxcarbazepine | Oral Suspension | 300 mg/5 mL | Trileptal | 12/26/2006 |
| Oxcarbazepine | Extended-release Tablets | 600 mg | Oxtellar XR | 3/20/2013 |

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| Oxcarbazepine | Extended-release Tablets | 150 mg and 300 mg | Oxtellar XR | 4/12/2013 |
| Oxybutynin | Transdermal System Extended-release | 3.9 mg/24 hrs | Oxytrol | 8/19/2008 |
| Oxybutynin Chloride | Extended-release Tablets | 5 mg, 10 mg and 15 mg | Ditropan XL | |
| Oxycodone | Extended-release Tablets | 10 mg, 20 mg, 40 mg, 80 mg and 160 mg | Oxycontin (NDA 020553) | |
| Oxycodone Hydrochloride | Extended-release Tablets | 15 mg | Oxycontin (NDA 020553) | 2/15/2007 |
| Oxycodone Hydrochloride | Extended-release Tablets | 30 mg and 60 mg | Oxycontin (NDA 020553) | 1/3/2007 |
| Oxycodone Hydrochloride | Extended-release Tablets | 10 mg | Oxycontin (NDA 022272) | 10/25/2010 |
| Oxycodone Hydrochloride | Extended-release Tablets | 15 mg | Oxycontin (NDA 022272) | 10/28/2010 |
| Oxycodone Hydrochloride | Extended-release Tablets | 20 mg | Oxycontin (NDA 022272) | 10/29/2010 |
| Oxycodone Hydrochloride | Extended-release Tablets | 30 mg, 60 mg and 80 mg | Oxycontin (NDA 022272) | 10/18/2010 |
| Oxycodone Hydrochloride | Extended-release Tablets | 40 mg | Oxycontin (NDA 022272) | 10/4/2010 |
| Oxycodone Hydrochloride | Tablets | 5 mg and 7.5 mg | Oxecta | 2/7/2012 |
| Oxymorphone Hydrochloride | Extended-release Tablets | 5 mg, 10 mg, 20 mg and 40 mg | Opana ER | 11/23/2007 |
| Oxymorphone Hydrochloride | Extended-release Tablets | 7.5 mg and 15 mg | Opana ER | 5/29/2008 |
| Oxymorphone Hydrochloride | Extended-release Tablets | 30 mg | Opana ER | 6/12/2008 |
| Oxymorphone Hydrochloride | Extended-release Tablets | 7.5 mg, 10 mg, and 15 mg | Opana ER (NDA 201655) | 3/23/2012 |
| Oxymorphone Hydrochloride | Extended-release Tablets | 5 mg | Opana ER (NDA 201655) | 3/26/2012 |
| Oxymorphone Hydrochloride | Extended-release Tablets | 20 mg, 30 mg, 40 mg | Opana ER (NDA 201655) | 4/3/2012 |
| Paclitaxel | Injection | 6 mg/mL, 5 mL, 16.7 mL, 25 mL, 33.3 mL and 50 mL vials | Taxol | |
| Palonosetron Hydrochloride | Injection | 0.05 mg/mL, 1.5 mL and 5 mL | Aloxi | 5/27/2011 |

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| Pamidronate Disodium | For Injection | 30 mg/vial, 60 mg/vial and 90 mg/vial | Aredia | |
| Pamidronate Disodium | Injection | 30 mg/vial, 60 mg/vial and 90 mg/vial | Aredia | |
| Pantoprazole Sodium | For Injection | 40 mg/vial | Prontonix IV | 4/7/2005 |
| Pantoprazole Sodium | Delayed-release Tablets | 20 mg and 40 mg | Protonix | 2/2/2004 |
| Paricalcitol | Injection | 0.002 mg per mL in 1 mL vial and 0.005 mg per mL in 1 mL and 2 mL vials | Zemplar | 11/28/2008 |
| Paricalcitol | Capsules | 1 mcg and 2 mcg | Zemplar | 10/14/2008 |
| Paricalcitol | Capsules | 4 mcg | Zemplar | 8/25/2008 |
| Paroxetine Hydrochloride | Capsules | 10 mg and 20 mg | Paxil | |
| Paroxetine Hydrochloride | Oral Suspension | 10 mg/5 mL | Paxil | 2/10/2005 |
| Paroxetine Hydrochloride | Tablets | 10 mg, 20 mg, 30 mg and 40 mg | Paxil | |
| Paroxetine Hydrochloride | Extended-release Tablets | 25 mg | Paxil CR | 9/9/2005 |
| Paroxetine Hydrochloride | Extended-release Tablets | 37.5 mg | Paxil CR | 5/19/2009 |
| Pemetrexed Disodium | For Injection | 100 mg/vial | Alimta | 7/1/2008 |
| Pemetrexed Disodium | For Injection | 500 mg/vial | Alimta | 2/4/2008 |
| Pemetrexed Disodium | For Injection | 1000 mg/vial | Alimta | 6/27/2012 |
| Pergolide Mesylate | Tablets | 0.05 mg, 0.25 mg and 1 mg | Permax | |
| Perindopril Erbumine | Tablets | 2 mg, 4 mg and 8 mg | Aceon | 6/6/2006 |
| Phentermine Hydrochloride | Orally Disintegrating Tablets | 15 mg and 30 mg | Suprenza | 10/19/2012 |
| Phentermine Hydrochloride | Orally Disintegrating Tablets | 37.5 mg | Suprenza | 3/22/2013 |
| Phentermine Hydrochloride and Topiramate | Extended-release Capsules | 3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg, 15 mg/92 mg | Qsymia | 7/18/2013 |
| Pioglitazone Hydrochloride | Tablets | 15 mg, 30 mg and 45 mg | Actos | |

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| Pioglitazone Hydrochloride and Glimepiride | Tablets | 30 mg/2 mg and 30 mg/4 mg | Duetact | 12/22/2009 |
| Pioglitazone Hydrochloride and Metformin | Extended-release Tablets | 15 mg/1000 mg and 30 mg/1000 | Actoplus Met XR | 9/23/2011 |
| Pioglitazone Hydrochloride and Metformin Hydrochloride | Tablets | 15 mg/500 mg and 15 mg/850 mg | Actoplus Met | 3/6/2008 |
| Piperacillin Sodium and Tazobactam Sodium | For Injection | 2.25 g/vial, 3.375 g/vial, 4.5 g/vial | Zosyn | PIV received prior to 2/5/2009 |
| Piperacillin Sodium and Tazobactam Sodium | For Injection | 12 g/1.5 g per vial (pharmacy bulk) | Zosyn | 12/6/2011 |
| Pitavastatin Calcium | Tablets | 1 mg, 2 mg, and 4 mg | Livalo | 8/5/2013 |
| Plerixafor | Injection | 24 mg/1.2 mL vials (20 | Mozobil | 12/17/2012 |
| Polyethylene Glycol 3350 | Powder for Oral Solution | 17g/Scoopful | Miralax | |
| Polyethylene Glycol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride and Bisacodyl | For Oral Solution and Delayed-release Tablet | 210 g, 5.6 g, 0.74 g, 2.86 g and 5 mg (1 Tablet Regimen) | Halflytely and Bisacodyl | 7/30/2010 |
| Polyethylene Glycol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride and Bisacodyl | For Oral Solution and Delayed-release Tablets | 210 g, 5.6 g, 0.74 g, 2.86 g and 5 mg (2 Tablet Regimen) | Halflytely and Bisacodyl | 1/28/2008 |
| Polyethylene Glycol 3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate | For Oral Solution | 100 g, 7.5 g, 2.691 g, 1.015 g, 5.9 g and 4.7 g per pouch | Moviprep | 11/27/2007 |
| Posaconazole | Oral Suspension | 40 mg/mL | Noxafil | 2/28/2011 |
| Potassium Chloride | Extended-release Capsules | 8 mEq and 10 mEq | Micro K | |
| Potassium Chloride | Extended-release Tablets | 10 mEq and 20 mEq | K-Dur | |
| Pralatrexate | Injection | 20 mg/mL and 40 mg/2 mL | Folotyn | 9/24/2013 |
| Pramipexole Dihydrochloride | Tablets | 0.125 mg, 0.5 mg, 1 mg and 1.5 mg | Mirapex | 6/24/2005 |
| Pramipexole Dihydrochloride | Tablets | 0.25 mg | Mirapex | 5/27/2005 |
| Pramipexole Dihydrochloride | Tablets | 0.75 mg | Mirapex | 7/31/2008 |

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| Pramipexole Dihydrochloride | Extended-release Tablets | 0.375 mg, 0.75 mg, 1.5 mg, 3 mg and 4.5 mg | Mirapex ER | 6/1/2010 |
| Pramipexole Dihydrochloride | Extended-release Tablets | 2.25 mg and 3.75 mg | Mirapex ER | 7/26/2011 |
| Prasugrel Hydrochloride | Tablets | 5 mg and 10 mg | Effient | 7/10/2013 |
| Pravastatin Sodium | Tablets | 10 mg, 20 mg, 40 mg and 80 mg | Pravachol | |
| Pravastatin Sodium | Tablets | 30 mg | Pravachol | 6/1/2005 |
| Prazosin Hydrochloride | Capsules | 1 mg, 2 mg and 5 mg | Minipress | |
| Prednisolone Sodium Phosphate | Oral Solution | 5 mg(base)/ 5 mL and 15 mg (base)/ 5 mL | Pediapred | |
| Prednisolone Sodium Phosphate | Orally Disintegrating Tablets | 10 mg, 15 mg and 30 mg | Orapred | 7/22/2010 |
| Prednisone | Delayed-release Tablets | 1 mg, 2 mg, and 5 mg | Rayos | 11/26/2012 |
| Pregabalin | Capsules | 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg | Lyrica | 12/30/2008 |
| Pregablin | Oral Solution | 20 mg/mL | Lyrica | 5/19/2010 |
| Propafenone | Extended-release Capsules | 325 mg | Rythmol SR | 11/07/2006 |
| Propafenone Hydrochloride | Extended-release Capsules | 225 mg and 425 mg | Rythmol SR | 10/11/2006 |
| Propofol | Injection | 10 mg/mL ; 20 mL, 50 mL and 100 mL vials and 20 mL syringe | Diprivan | |
| Propranolol Hydrochloride | Extended-release Capsules | 60 mg, 80 mg, 120 mg and 160 mg | Inderal LA | |
| Quetiapine Fumarate | Extended-release Tablets | 400 mg | Seroquel XR | 6/18/2008 |
| Quetiapine Fumarate | Extended-release Tablets | 150 mg | Seroquel XR | 11/17/2008 |
| Quetiapine Fumarate | Extended-release Tablets | 200 mg and 300 mg | Seroquel XR | 6/12/2008 |
| Quetiapine Fumarate | Extended-release Tablets | 50 mg | Seroquel XR | 10/17/2008 |
| Quetiapine Fumarate | Tablets | 25 mg | Seroquel | 8/12/2005 |

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| Quetiapine Fumarate | Tablets | 50 mg, 150 mg and 400 mg | Seroquel | 2/12/2007 |
| Quetiapine Fumarate | Tablets | 100 mg, 200 mg and 300 mg | Seroquel | 2/21/2006 |
| Quinapril Hydrochloride | Tablets | 5 mg, 10 mg, 20 mg and 40 mg | Accupril | |
| Quinapril Hydrochloride/ Hydrochlorothiazide | Tablets | 10 mg/12.5 mg, 20 mg/12.5 mg and 20mg/25 mg | Accuretic | |
| Rabeprazole Sodium | Delayed-release Tablets | 20 mg | Aciphex | |
| Regadenoson | Injection | 0.08 mg/mL, 5 mL vial | Lexiscan | 4/10/2012 |
| Raltegravir | Tablets | 400 mg | Isentress | 10/12/2011 |
| Raloxifene Hydrochloride | Tablets | 60 mg | Evista | |
| Ramelteon | Tablets | 8 mg | Rozerem | 7/22/2009 |
| Ramipril | Capsules | 1.25 mg, 2.5 mg, 5 mg and 10 mg | Altace | |
| Ranitidine | Capsules | 150 mg and 300 mg | Zantac | |
| Ranitidine | Injection | 25 mg/mL, 2 mL and 6 mL and 40 mL vials | Zantac | |
| Ranitidine | Oral Solution | 15 mg/mL | Zantac | |
| Ranitidine | Tablets | 75 mg, 150 mg and 300 mg | Zantac | |
| Ranitidine Hydrochloride | Tablets | 150 mg | Zantac 150 (NDA 21698/Product 002) | 10/30/2007 |
| Ranolazine | Extended-release | 500 mg and 1000 mg | Renexa | 5/17/2010 |
| Rasagiline Mesylate | Tablets | 0.5 mg and 1 mg | Azilect | 5/17/2010 |
| Repaglinide | Tablets | 0.5 mg*, 1 mg and 2 mg | Prandin | 2/10/2005 |
| Repaglinide and Metformin Hydrochloride* | Tablets | 1 mg/500 mg and 2 mg/500 mg | Prandimet | 4/9/2009 |
| Ribavirin | Capsules | 200 mg | Rebetol | |
| Risedronate Sodium | Tablets | 5 mg, 30 mg and 35 mg | Actonel | 4/23/2004 |
| Risedronate Sodium* | Tablets | 75 mg | Actonel | 9/10/2007 |
| Risedronate Sodium | Tablets | 150 mg | Actonel | 8/12/2008 |
| Risedronate Sodium | Delayed-release Tablets | 35 mg | Atelvia | 6/9/2011 |

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| Risedronate Sodium with Calcium Carbonate * | Tablets | 35 mg; 500 mg | Actonel with Calcium | 12/18/2007 |
| Risperidone | Oral Solution | 1 mg/mL | Risperdal | |
| Risperidone | Tablets | 0.25 mg, 1 mg, 2 mg, 3 mg and 4 mg | Risperdal | |
| Risperidone | Orally Disintegrating Tablets | 0.25 mg | Risperdal | 4/11/2005 |
| Risperidone | Orally Disintegrating Tablets | 0.5 mg, 1 mg and 2 mg | Risperdal | |
| Risperidone | Orally Disintegrating Tablets | 3 mg and 4 mg | Risperdal | 3/23/2005 |
| Ritonavir | Tablets | 100 mg | Norvir | 12/21/2010 |
| Ritonavir | Capsules | 100 mg | Norvir | 10/31/2012 |
| Rivastigmine Tartrate | Capsules | 1.5 mg, 3 mg, 4.5 mg and 6 mg | Exelon | 4/21/2004 |
| Rivastigmine Tartrate | Oral Solution | 2 mg/mL | Exelon | 11/5/2004 |
| Rivastigmine | Transdermal System Extended-release | 4.6 mg/24 hr and 9.5 mg/24 hr | Exelon | 4/27/2011 |
| Rivastigmine | Transdermal System Extended-release | 13.3 mg/24 hr | Exelon | 1/22/2013 |
| Rizatriptan Benzoate | Tablets | 5 mg and 10 mg | Maxalt | 9/2/2004 |
| Rizatriptan Benzoate | Orally Disintegrating Tablets | 5 mg and 10 mg | Maxalt-MLT | 2/17/2006 |
| Rofecoxib | Tablets | 12.5 mg, 25 mg and 50 mg | Vioxx | |
| Romidepsin | Injection | 10 mg/vial | Istodax | 11/5/2013 |
| Ropinirole Hydrochloride | Extended-release Tablets | 2 mg | Requip XL | 10/14/2008 |
| Ropinirole Hydrochloride | Extended-release Tablets | 4 mg | Requip XL | 10/31/2008 |
| Ropinirole Hydrochloride | Extended-release Tablets | 6 mg | Requip XL | 7/14/2009 |
| Ropinirole Hydrochloride | Extended-release Tablets | 8 mg | Requip XL | 11/3/2008 |
| Ropinirole Hydrochloride | Tablets | 0.25 mg, 0.5 mg, 1 mg and 2 mg | Requip | 12/22/2004 |
| Ropinirole Hydrochloride | Tablets | 3 mg, 4 mg and 5 mg | Requip | 2/4/2005 |
| Ropinirole Hydrochloride* | Extended-release Tablets | 3 mg | Requip XL | 1/8/2009 |

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| Ropinirole Hydrochloride | Extended-release Tablets | 12 mg | Requip XL | 2/5/2009 |
| Ropivacaine Hydrochloride | Injection | 2 mg/mL, 5 mg/mL and 10 mg/mL, 20 mL, 30 mL and 20 mL vials | Naropin | 11/13/2006 |
| Rosiglitazone Maleate | Tablets | 2 mg, 4 mg and 8 mg | Avandia | |
| Rosiglitazone Maleate and Metformin Hydrochloride | Tablets | 1 mg/ 500 mg, 2 mg/ 500mg, 4 mg/ 500 mg, 2 mg/ 1000 mg and 4 mg/ 1000 mg | Avandamet | 10/22/2004 |
| Rosuvastatin Calcium | Tablets | 5 mg, 10 mg, 20 mg and 40 mg | Crestor | 8/13/2007 |
| Rotigotine | Extended-release Transdermal Film | 1 mg/24 hr, 2 mg/24 hr, 3 mg/24 hr, 4 mg/24 hr, 6 mg/24 hr, and 8 mg/24 hr | Neupro | 11/26/2013 |
| Rufinamide | Tablets | 100 mg, 200 mg and 400 mg | Banzel | 11/14/2012 |
| Sapropterin Dihydrochloride | Tablets | 100 mg | Kuvan | 5/30/2014 |
| Saxagliptin Hydrochloride | Tablets | 2.5 mg and 5 mg | Onglyza | 7/31/2013 |
| Saxagliptin Hydrochloride and Metformin Hydrochloride | Extended-release Tablets | 5 mg/500 mg, 2.5 mg/1000 mg, and 5 mg/1000 mg | Kombiglyze XR | 7/31/2013 |
| Sertraline Hydrochloride | Oral Concentrate | 20 mg/mL | Zoloft | |
| Sertraline Hydrochloride | Tablets | 25 mg, 50 mg and 100 mg | Zoloft | |
| Sertraline Hydrochloride | Tablets | 150 mg and 200 mg | Zoloft | 11/9/2005 |

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|--|----------------------------|-------------------------------------|-----------------------|---------------------------|
| Sevelamer Carbonate | Powder for Oral Suspension | 0.8 g/packet and 2.4 g/packet | Renvela | 12/30/2009 |
| Sevelamer Carbonate | Tablets | 800 mg | Renvela | 12/4/2008 |
| Sevelamer Hydrochloride | Tablets | 400 mg and 800 mg | Renagel | 5/22/2008 |
| Sevoflurane | Inhalation | 100%, 250 mL | Ultane | |
| Sibutramine Hydrochloride | Capsules | 10 mg and 15 mg | Meridia | 8/14/2009 |
| Sildenafil Citrate | Tablets | 25 mg and 50 mg | Viagra | 11/19/2004 |
| Sildenafil Citrate | Tablets | 100 mg | Viagra | 10/25/2004 |
| Silodosin | Capsules | 4 mg and 8 mg | Rapaflo | 10/9/2012 |
| Silver Sulfadiazine | Cream | 1% | Silvadene | |
| Simvastatin | Tablets | 5 mg, 10 mg, 20 mg, 40 mg and 80 mg | Zocor | |
| Sirolimus | Tablets | 0.5 mg | Rapamune | 8/25/2010 |
| Sirolimus | Tablets | 1 mg and 2 mg | Rapamune | 12/17/2009 |
| Sodium Phosphate Monobasic Monohydrate and Sodium Phosphate Dibasic Anhydrous, USP | Tablets | 1.102 g and 0.398 g | Osmoprep | 4/9/2008 |
| Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate | Oral Solution | 17.5 g/3.13 g/1.6 g | Suprep Bowel Prep Kit | 11/8/2010 |
| Sodium Oxybate | Oral Solution | 500 mg/mL | Xyrem | 7/8/2010 |
| Solifenacin Succinate | Tablets | 5 mg and 10 mg | Vesicare | 4/8/2009 |
| Sitagliptin Phosphate | Tablets | 25 mg, 50 mg and 100 mg | Januvia | 10/18/2010 |
| Sitagliptin Phosphate and Metformin Hydrochloride | Tablets | 50 mg/500 mg and 50 mg/1000 mg | Janumet | 10/18/2010 |
| Sitagliptin Phosphate and Metformin Hydrochloride | Extended-release Tablets | 50 mg/500 mg and 50 mg/1000 mg | Janumet XR | 3/16/2012 |

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|---|---------------------------|---|-------------|---------------------------|
| Sitagliptin Phosphate and Metformin Hydrochloride | Extended-release Tablets | 100 mg/1000 mg | Janumet XR | 10/22/2012 |
| Sitagliptin Phosphate and Simvastatin | Tablets | 100 mg/10 mg and 100 mg/40 mg | Juvisync | 6/19/2012 |
| Sitagliptin Phosphate and Simvastatin | Tablets | 100 mg/20 mg | Juvisync | 6/25/2012 |
| Sitagliptin Phosphate and Simvastatin | Tablets | 50 mg/10 mg, 50 mg/20 mg, | Juvisync | 11/6/2012 |
| Sumatriptan Succinate | Injection | 6 mg/0.5 mL, 0.5 mL vials | Imitrex | 10/25/2004 |
| Sumatriptan Succinate* | Injection | 6 mg/0.5 mL, 0.5 mL (prefilled syringes) | Imitrex | 5/9/2006 |
| Sumatriptan Succinate | Tablets | 25 mg, 50 mg and 100 mg | Imitrex | |
| Sunitinib Malate | Capsules | 12.5 mg, 25 mg, 37.5 mg and 50 mg | Sutent | 1/26/2010 |
| Tacrolimus | Ointment | 0.03% | Protopic | 11/22/2010 |
| Tacrolimus | Ointment | 0.10% | Protopic | 9/9/2010 |
| Tacrolimus | Extended-release Capsules | 0.5 mg, 1 mg, and 5 mg | Astagraf XL | 9/24/2013 |
| Tadalafil | Tablets | 2.5 mg | Cialis | 10/14/2008 |
| Tadalafil | Tablets | 5 mg, 10 mg and 20 mg | Cialis | 11/21/2007 |
| Tadalafil | Tablets | 20 mg | Adcirca | 10/15/2009 |
| Tamoxifen Citrate | Tablets | 10 mg and 20 mg | Nolvadex | |
| Tamsulosin Hydrochloride | Capsules | 0.4 mg | Flomax | 12/20/2004 |
| Tapentadol Hydrochloride | Tablets | 50 mg, 75 mg, and 100 mg | Nucynta | 11/20/2012 |
| Tapentadol Hydrochloride | Extended-release Tablets | 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg | Nucynta ER | 11/20/2012 |
| Tapentadol | Oral Solution | 20 mg/mL | Nucynta | 12/20/2013 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|-------------------------------------|-----------------------|---------------------------------|--------------|---------------------------|
| Telmisartan | Tablets | 20 mg, 40 mg and 80 mg | Micardis | 12/26/2006 |
| Telmisartan and Hydrochlorothiazide | Tablets | 80 mg/12.5 mg and 40 mg/12.5 mg | Micardis HCT | 12/31/2008 |
| Temazepam | Capsules | 7.5 mg | Restoril | 11/01/2006 |
| Temozolomide | Capsules | 5 mg, 20 mg, 100 mg, and 250 mg | Temodar | 3/20/2007 |
| Temozolomide | Capsules | 140 mg and 180 mg | Temodar | 3/24/2008 |
| Temsirolimus | Injection | 25 mg/mL, 1.8 mL vial | Torisel | 5/25/2011 |
| Tenofovir Disoproxil Fumarate | Tablets | 300 mg | Viread | 1/26/2010 |
| Tenofovir Disoproxil Fumarate | Tablets | 150 mg, 200 mg, and 250 mg | Viread | 5/17/2012 |
| Terazosin Hydrochloride | Capsules | 1 mg, 2 mg, 5 mg and 10 mg | Hytrin | |
| Terazosin Hydrochloride | Tablets | 1 mg, 2 mg, 5 mg and 10 mg | Hytrin | |
| Terbinafine Hydrochloride | Tablets | 250 mg | Lamisil | |
| Terfenadine | Tablets | 60 mg | Seldane | |
| Testosterone | Gel | 1% | Androgel | |
| Testosterone | Gel | 1% | Testim | 8/21/2008 |
| Testosterone | Gel Metered-dose Pump | 1% | Androgel | 12/19/2008 |
| Testosterone | Gel | 1.62% | Androgel | 4/6/2012 |
| Testosterone | Gel | 10 mg/actuation | Fortesta | 8/14/2012 |
| Testosterone | Topical Solution | 30 mg/1.5 mL | Axiron | 1/29/2013 |
| Testosterone Undecanoate | Injection | 250 mg/mL | Aveed | 6/11/2014 |
| Thalidomide | Capsules | 50 mg and 100 mg | Thalomid | 12/18/2006 |
| Thalidomide | Capsules | 200 mg | Thalomid | 9/25/2006 |
| Tiagabine Hydrochloride | Tablets | 2 mg and 4 mg | Gabitril | 2/1/2005 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|---------------------------|--------------------------------|------------------|---------------------------|
| Ticlopidine Hydrochloride | Tablets | 250 mg | Ticlid | |
| Tigecycline | For Injection | 50 mg per vial | Tygacil | 6/15/2009 |
| Timolol Maleate | Ophthalmic Solution | 0.25% and 0.5% | Timoptic | |
| Timolol Maleate | Ophthalmic Solution | 0.5% | Istalol | 10/19/2012 |
| Tizanidine Hydrochloride | Capsules | 2 mg, 4 mg and 6 mg | Zanaflex | 8/10/2007 |
| Tobramycin | Inhalation Solution | 300 mg/5 mL | Tobi | 6/29/2009 |
| Tolterodine Tartrate | Extended-release Capsules | 2 mg and 4 mg | Detrol LA | 7/30/2007 |
| Tolterodine Tartrate* | Tablets | 1 mg and 2 mg | Detrol | |
| Tolvaptan | Tablets | 15 mg and 30 mg | Samsca | 9/23/2013 |
| Topiramate | Capsules | 15 mg and 25 mg | Topamax Sprinkle | 9/7/2005 |
| Topiramate | Tablets | 25 mg, 100 mg and 200 mg | Topamax | 12/26/2001 |
| Topiramate | Tablets | 50 mg | Topamax | 9/8/2005 |
| Topiramate | Extended-release Capsules | 200 mg | Trokendi XR | 4/3/2014 |
| Torseמידe | Tablets | 5 mg, 10 mg, 20 mg, and 100 mg | Demadex | |
| Tramadol Hydrochloride | Tablets | 50 mg | Ultram | |
| Tramadol Hydrochloride | Extended-release Tablets | 100 mg | Ultram ER | 1/8/2007 |
| Tramadol Hydrochloride | Extended-release Tablets | 200 mg | Ultram ER | 3/28/2007 |
| Tramadol Hydrochloride | Extended-release Tablets | 300 mg | Ultram ER | 9/25/2007 |
| Tramadol Hydrochloride | Extended-release Tablets | 100 mg, 200 mg and 300 mg | Ryzolt | 6/18/2009 |
| Trandolapril | Tablets | 1 mg, 2 mg and 4 mg | Mavik | 10/4/2004 |
| Trandolapril and Verapamil Hydrochloride | Extended-release Tablets | 2 mg/180 mg and 2 mg/240 mg | Tarka | 11/9/2007 |
| Trandolapril and Verapamil Hydrochloride | Extended-release Tablets | 1 mg/240 mg | Tarka | 2/20/2008 |
| Trandolapril and Verapamil Hydrochloride | Extended-release Tablets | 4 mg/ 240 mg | Tarka | 7/24/2007 |
| Tranexamic Acid | Tablets | 650 mg | Lysteda | 5/24/2011 |
| Travoprost | Ophthalmic Solution | 0.004% | Travatan | 11/28/2008 |
| Travoprost (Preserved) | Ophthalmic Solution | 0.004% | Travatan Z | 2/19/2009 |
| Trazodone Hydrochloride | Tablets | 150 mg | Desyrel | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--------------------------------------|-------------------------------|--|---------------|---------------------------|
| Trazodone Hydrochloride | Extended-release Tablets | 150 mg and 300 mg | Oleptro | 10/18/2010 |
| Treprostinil Sodium | Injection | 10 mg/mL, 20 mL vial | Remodulin | 12/2/2011 |
| Treprostinil Sodium | Injection | 1 mg/mL, 2.5 mg/mL, and 5 mg/mL, 20 mL vial | Remodulin | 12/7/2012 |
| Tretinoin | Cream | 0.025%, 0.05% and 0.1% | Retin-A | |
| Tretinoin | Gel | 0.025% | Retin-A | |
| Tretinoin | Gel | 0.04% | Retin-A Micro | 12/20/2010 |
| Tretinoin | Gel | 0.1% | Retin-A Micro | 7/8/2010 |
| Triamcinolone Acetonide | Nasal Spray | 0.055 mg/Spray | Nasacort AQ | 12/29/2005 |
| Triamterene/ Hydrochlorothiazide | Tablets | 37.5 mg/25 mg and 75 mg/50 mg | Maxzide | |
| Trospium Chloride | Extended-release Capsules | 60 mg | Sanctura XR | 3/2/2009 |
| Valacyclovir Hydrochloride | Tablets | 500 mg and 1000 mg | Valtrex | |
| Valganciclovir Hydrochloride | for Oral Solution | 50 mg/mL | Valcyte | 3/21/2011 |
| Valganciclovir Hydrochloride | Tablets | 450 mg | Valcyte | 12/27/2005 |
| Valsartan | Tablets | 40 mg, 80 mg, □ 160 mg and 320 mg | Diovan | 12/28/2004 |
| Valsartan and Hydrochlorothiazide | Tablets | 80 mg/12.5 mg, 160 mg/12.5 mg and 160 mg/25 mg | Diovan HCT | 12/2/2005 |
| Valsartan and Hydrochlorothiazide | Tablets | 320 mg/12.5 mg and 320 mg/25 mg | Diovan HCT | 2/7/2007 |
| Vardenafil Hydrochloride | Tablets | 2.5 mg | Levitra | 9/4/2009 |
| Vardenafil Hydrochloride | Tablets | 5 mg and 10 mg | Levitra | 7/10/2009 |
| Vardenafil Hydrochloride | Tablets | 20 mg | Levitra | 3/5/2009 |
| Vardenafil Hydrochloride | Orally Disintegrating Tablets | 10 mg | Staxyn | 12/22/2011 |
| Varenicline Tartrate | Tablets | 0.5 mg and 1 mg | Chantix | 5/10/2010 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---------------------------|---------------------------|---|---------------------------|---------------------------|
| Vecuronium Bromide | For Injection | 10 mg/vial and 20 mg/vial | Norcuron | |
| Venlafaxine Hydrochloride | Extended-release Capsules | 37.5 mg, 75 mg and 150 mg | Effexor XR | |
| Venlafaxine Hydrochloride | Tablets | 25 mg, 37.5 mg, 50 mg, 75 mg and 100 mg | Effexor | 11/03/2005 |
| Venlafaxine Hydrochloride | Extended-release Tablets | 37.5 mg, 75 mg and 150 mg | Effexor XR | 5/3/2007 |
| Venlafaxine Hydrochloride | Extended-release Tablets | 37.5 mg, 75 mg and 150 mg | Venlafaxine Hydrochloride | 2/12/2009 |
| Venlafaxine Hydrochloride | Extended-release Tablets | 225 mg | Venlafaxine Hydrochloride | 1/10/2011 |
| Verapamil Hydrochloride | Extended-release Capsules | 100 mg and 200 mg | Verelan PM | 7/20/2006 |
| Verapamil Hydrochloride | Extended-release Capsules | 120 mg, 180 mg and 240 mg | Verelan SR | |
| Verapamil Hydrochloride | Extended-release Tablets | 180 mg | Isoptin SR | |
| Verapamil Hydrochloride | Extended-release Tablets | 240 mg | Covera HS | |
| Verapamil Hydrochloride | Extended-release Capsules | 300 mg | Verelan PM | 5/19/2006 |
| Vincristine Sulfate | Injection | 1 mg/mL, 1 mL, 2 mL and 5 mL vials | Oncovin | |
| Voriconazole | For Injection | 200 mg/vial | Vfend | 9/12/2008 |
| Voriconazole | Oral Suspension | 40 mg/mL | Vfend | 10/8/2010 |
| Voriconazole | Tablets | 50 mg and 200 mg | Vfend | 4/14/2008 |
| Zafirlukast | Tablets | 10 mg and 20 mg | Accolate | 2/29/2008 |
| Zaleplon | Capsules | 5 mg and 10 mg | Sonata | 6/21/2005 |
| Zidovudine | Capsules | 100 mg | Retrovir | |
| Ziprasidone Hydrochloride | Capsules | 20 mg, 40 mg, 60 mg and 80 mg | Geodon | 2/7/2005 |
| Zoledronic Acid* | Injection | 0.05 mg/mL, 100 mL vial | Reclast | 8/29/2008 |
| Zoledronic Acid* | Injection | 0.8 mg (base) /mL | Zometa | 6/11/2008 |
| Zoledronic Acid | Injection | 4 mg/100 mL, 100 mL vial | Zometa | 1/31/2012 |
| Zolmitriptan | Nasal Spray | 5 mg/spray | Zomig | 11/14/2013 |
| Zolpidem Tartrate | Extended-release Tablets | 6.25 mg | Ambien CR | 2/24/2006 |
| Zolpidem Tartrate | Extended-release Tablets | 12.5 mg | Ambien CR | 1/19/2006 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|-------------------|--------------------|--------------------|------------|---------------------------|
| Zolpidem Tartrate | Sublingual Tablets | 5 mg and 10 mg | Edluar | 4/29/2010 |
| Zolpidem Tartrate | Sublingual Tablets | 1.75 mg and 3.5 mg | Intermezzo | 4/10/2012 |
| * ANDA withdrawn | | | | |