

**Paragraph IV Patent Certifications
January 7, 2015**

| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|--------------------------|-------------------------------------|-----------------------|---------------------------|
| Abacavir Sulfate | Tablets | 300 mg | Ziagen | 1/28/2009 |
| Abacavir Sulfate and Lamivudine | Tablets | 600 mg/300 mg | Epzicom | 9/27/2007 |
| Abacavir Sulfate, Lamivudine and Zidovudine | Tablets | 300 mg/150 mg/300 mg | Trizivir | 3/22/2011 |
| Acarbose | Tablets | 25 mg, 50 mg and 100 mg | Precose | 3/22/2005 |
| Acetylcysteine | Injection | 200 mg/mL, 30 mL vials | Acetadote | 4/4/2012 |
| Acetaminophen | Injection | 1000 mg/100 mL (10 mg/mL) | Ofirmev | 4/7/2011 |
| Acetaminophen | Extended-release Tablets | 650 mg | Tylenol | |
| Acetaminophen and Tramadol Hydrochloride | Tablets | 325 mg/ 37.5 mg | Ultracet | |
| Acetaminophen/ Aspirin/ Caffeine | Tablets | 250 mg/250 mg/□ 65 mg | Excedrin □ (migraine) | |
| Acyclovir Sodium | Injection | 50 mg/mL, 10 mL and 20 mL vials | Zovirax | |
| Adapalene | Topical Gel | 0.30% | Differin | 9/15/2009 |
| Adapalene and Benzoyl Peroxide | Gel | 0.1%/2.5% | Epiduo | 12/30/2011 |
| Adefovir Dipivoxil | Tablets | 10 mg | Hepsera | 6/8/2010 |
| Adenosine | Injection | 3 mg/mL, 20 mL and 30 mL vials | Adenoscan | 4/16/2005 |
| Albuterol Sulfate | Oral Syrup | 2 mg(base)/□ 5 mL | Ventolin | |
| Albuterol Sulfate | Extended-release Tablets | 4 mg and 8 mg | Volmax | |
| Albuterol Sulfate | Inhalation Solution | 0.021% and 0.042% | Accuneb | 10/19/2005 |
| Albuterol Sulfate/ Ipratropium Bromide | Inhalation Solution | 0.083%/ 0.017% | Duoneb | |
| Albuterol Sulfate | Inhalation Aerosol | 0.09 mg base per actuation | Pro-Air HFA | 5/18/2012 |
| Alcaftadine | Ophthalmic Solution | 0.25% | Lastacaft | 7/30/2014 |
| Alendronate Sodium* | Oral Solution | 70 mg/75 mL | Fosamax | 9/7/2007 |
| Alendronate Sodium | Tablets | 5 mg, 10 mg, 35 mg, 40 mg and 70 mg | Fosamax | |
| Alendronate Sodium and Cholecalciferol | Tablets | 70 mg/2800 IU and 70 mg/5600 IU | Fosamax Plus D | 11/20/2007 |

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| Alfuzosin Hydrochloride | Extended-release Tablets | 10 mg | Uroxatral | 6/12/2007 |
| Aliskiren Hemifumarate | Tablets | 150 mg and 300 mg | Tekturna | 12/13/2013 |
| Aliskiren Hemifumarate and Hydrochlorothiazide | Tablets | 150 mg/12.5 mg, 150 mg/25 mg, 300 mg/12.5 mg, 300 mg/25 mg | Tekturna HCT | 3/7/2014 |
| Almotriptan Malate | Tablets | 6.25 mg and 12.5 mg | Axert | 12/8/2005 □ |
| Alosetron Hydrochloride | Tablets | 0.5 mg and 1 mg | Lotronex | 12/2/2010 |
| Alprazolam | Orally Disintegrating Tablets | 0.25 mg, 0.5 mg, 1 mg and 2 mg | Niravam | 12/27/2005 |
| Alprazolam | Tablets | 0.25 mg, 0.5 mg, 1 mg and 2 mg | Xanax | |
| Amifostine | For Injection | 500 mg/vial | Ethylol | 4/16/2004 |
| Amlodipine Besylate | Tablets | 2.5 mg, 5 mg and 10 mg | Norvasc | |
| Amlodipine Besylate and Atorvastatin Calcium | Tablets | 2.5 mg/10 mg, 2.5 mg/20 mg and 10 mg/40 mg | Caduet | 9/17/2009 |
| Amlodipine Besylate and Atorvastatin Calcium | Tablets | 2.5 mg/40 mg | Caduet | 9/17/2009 |
| Amlodipine Besylate and Atorvastatin Calcium* | Tablets | 5 mg/10 mg, 5 mg/20 mg, 5 mg/40 mg, 10 mg/10 mg, 10 mg/20 mg and 10 mg/80 mg | Caduet | 12/29/2006 |
| Amlodipine Besylate and Atorvastatin Calcium | Tablets | 5 mg/80 mg | Caduet | 4/7/2009 |
| Amlodipine Besylate and Benazepril Hydrochloride | Capsules | 2.5 mg/10 mg, 5 mg/10 mg, 5 mg/20 mg and 10 mg/20 mg | Lotrel | 6/9/2004 |
| Amlodipine Besylate and Benazepril Hydrochloride | Capsules | 5 mg/40 mg and 10 mg/40 mg | Lotrel | 11/17/2006 |
| Amlodipine Besylate and Olmesartan Medoxomil | Tablets | 5 mg/20 mg and 10 mg/40 mg | Azor | 2/11/2008 |
| Amlodipine Besylate and Olmesartan Medoxomil | Tablets | 10 mg/20 mg and 5 mg/40 mg | Azor | 3/31/2008 |

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| Amlodipine Besylate and Valsartan | Tablets | 5 mg/160 mg | Exforge | 10/22/2007 |
| Amlodipine Besylate and Valsartan | Tablets | 5 mg/320 mg | Exforge | 11/26/2007 |
| Amlodipine Besylate and Valsartan | Tablets | 10 mg/160 mg | Exforge | 10/1/2007 |
| Amlodipine Besylate and Valsartan | Tablets | 10 mg/320 mg | Exforge | 11/9/2007 |
| Amlodipine, Hydrochlorothiazide and Valsartan! | Tablets | 5 mg/12.5 mg/160 mg, 5 mg/25 mg/160 mg, 10 mg/25 mg/160 mg and 10 mg/25 mg/320 mg | Exforge HCT | 9/14/2009 |
| Amlodipine, Hydrochlorothiazide and Valsartan! | Tablets | 10 mg/12.5 mg/160 mg | Exforge HCT | 10/22/2009 |
| Amoxicillin and Clavulanate Potassium | Extended-release Tablets | 1000 mg/62.5 mg | Augmentin XR | 1/21/2009 |
| Aprepitant | Capsule | 40 mg, 80 mg and 125 mg | Emend | 11/3/2008 |
| Arformoterol Tartrate | Inhalation Solution | Eq. 0.015 mg base/2 mL | Brovana | 10/1/2009 |
| Argatroban | Injection | 100 mg/mL, 2.5 mL vials | Argatroban | 9/24/2007 |
| Argatroban in Sodium Chloride | Injection | 1 mg/mL, 50 mL vials | Argatroban | 12/16/2011 |
| Aripiprazole | Oral Solution | 1 mg/mL | Abilify | 12/20/2007 |
| Aripiprazole | Tablets | 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg | Abilify | 11/15/2006 |
| Aripiprazole | Orally Disintegrating Tablets | 10 mg, 15 mg, 20 mg and 30 mg | Abilify | 11/15/2006 |
| Armodafinil | Tablets | 50 mg, 150 mg and 250 mg | Nuvigil | 7/24/2009 |
| Armodafinil | Tablets | 100 mg | Nuvigil | 9/8/2009 |
| Armodafinil | Tablets | 200 mg | Nuvigil | 9/3/2009 |
| Asenapine Maleate | Sublingual Tablets | 5 mg and 10 mg | Saphris | 8/13/2013 |
| Aspirin and Dipyridamole | Extended-release Capsules | 25 mg and 200 mg | Aggrenox | 2/1/2007 |
| Atazanavir Sulfate | Capsules | 100 mg and 150 mg | Reyataz | 3/19/2010 |
| Atazanavir Sulfate | Capsules | 200 mg | Reyataz | 2/16/2010 |
| Atazanavir Sulfate | Capsules | 300 mg | Reyataz | 7/20/2009 |

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| Atenolol | Tablets | 25 mg, 50 mg and 100 mg | Tenormin | |
| Atenolol/ Chlorthalidone | Tablets | 50 mg/25 mg and 100 mg/25 mg | Tenoretic | |
| Atovaquone* | Oral Suspension | 750 mg/5 mL | Mepron | 10/20/2009 |
| Atovaquone and Proguanil Hydrochloride | Tablets | 62.5 mg/25 mg | Malarone | 9/14/2010 |
| Atovaquone and Proguanil Hydrochloride | Tablets | 250 mg/100 mg | Malarone | 4/3/2009 |
| Atomoxetine Hydrochloride | Capsules | 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg | Strattera | 5/29/2007 |
| Atorvastatin Calcium | Tablets | 10 mg, 20 mg, 40 mg and 80 mg | Lipitor | |
| Azelaic Acid | Gel | 15% | Finacea | 7/27/2012 |
| Azelastine Hydrochloride | Nasal Spray | 0.125 mg base/spray | Astelin | 11/14/2005 |
| Azelastine Hydrochloride | Nasal Spray | 205.5 mcg/spray | Astepro | 12/15/2011 |
| Azelastine Hydrochloride | Ophthalmic Solution | 0.05% | Optivar | 12/13/2006 |
| Azelastine Hydrochloride and Fluticasone Propionate | Nasal Spray | 137 mcg/50 mcg per spray | Dymista | 6/13/2014 |
| Azithromycin | for Injection | 500 mg/vial | Zithromax | 6/17/2011 |
| Azithromycin | Ophthalmic Solution | 1% | Azasite | 3/3/2011 |
| Balsalazide Disodium | Tablets | 1.1 g | Giazo | 11/5/2013 |
| Bendamustine Hydrochloride | Injection | 25 mg/vial and 100 mg/vial | Treanda | 6/4/2013 |
| Bepotastine Besilate | Ophthalmic Solution | 1.5% | Bepreve | 9/9/2013 |
| Betamethasone Valerate | Foam | 0.12% | Luxiq | 8/10/2007 |
| Betaxolol | Ophthalmic Solution | 0.5%(base) | Betoptic | |
| Bexarotene | Capsules | 75 mg | Targretin | 6/6/2011 |
| Bimatoprost | Ophthalmic Solution | 0.01% | Lumigan | 4/5/2011 |
| Bimatoprost | Ophthalmic Solution | 0.03% | Lumigan | 12/22/2008 |
| Bimatoprost | Topical Solution | 0.03% | Latisse | 5/3/2010 |
| Bivalirudin | For Injection | 250 mg/vial | Angiomax | 9/1/2009 |
| Bortezomib* | For Injection | 3.5 mg/vial | Velcade | 11/20/2008 |
| Brimonidine Tartrate | Ophthalmic Solution | 0.1% | Alphagan P | 12/20/2006 |
| Brimonidine Tartrate | Ophthalmic Solution | 0.15% | Alphagan P | 11/03/2006 |
| Brimonidine Tartrate | Ophthalmic Solution | 0.2% | Alphagan | |

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| Brimonidine Tartrate and Timolol Maleate | Ophthalmic Solution | 0.2%/0.5% | Combigan | 11/21/2008 |
| Bromfenac Sodium | Ophthalmic Solution | 0.07% | Prolensa | 7/26/2013 |
| Budesonide | Enteric Coated Capsules | 3 mg | Entocort EC | 2/1/2008 |
| Budesonide | Nasal Spray | 0.032 mg (32 mcg)/spray | Rhinocort | 5/14/2007 |
| Budesonide | Inhalation Suspension | 0.25 mg/2 mL and 0.5 mg/2 mL | Pulmicort Respules | 9/15/2005 |
| Budesonide | Inhalation Suspension | 1 mg/2 mL | Pulmicort Respules | 5/28/2010 |
| Budesonide NEW | Extended-release Tablets | 9 mg | Uceris | 3/11/2013 |
| Buprenorphine Hydrochloride and Naloxone Hydrochloride | Sublingual Film | 2 mg/0.5 mg and 8 mg/2 mg | Suboxone | 10/15/2012 |
| Buprenorphine Hydrochloride and Naloxone Hydrochloride | Sublingual Film | 4 mg/1 mg | Suboxone | 5/14/2013 |
| Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate | Sublingual Tablets | 1.4 mg/0.36 mg and 5.7 mg/1.4 mg | Zubsolv | 10/22/2013 |
| Buprenorphine | Transdermal System | 5 mcg/hr, 10 mcg/hr, and 20 mcg/hr | Butrans | 6/6/2013 |
| Bupropion Hydrobromide | Extended-release Tablets | 174 mg | Aplenzin | 9/28/2009 |
| Bupropion Hydrobromide | Extended-release Tablets | 348 mg | Aplenzin | 9/24/2009 |
| Bupropion Hydrobromide | Extended-release Tablets | 522 mg | Aplenzin | 12/24/2009 |
| Bupropion Hydrochloride | Extended-release Tablets | 100 mg, 150 mg and 200 mg | Wellbutrin SR | |
| Bupropion Hydrochloride | Extended-release Tablets | 150 mg | Zyban | |
| Bupropion Hydrochloride | Extended-release Tablets | 150 mg and 300 mg | Wellbutrin XL | 9/21/2004 |
| Bupropion Hydrochloride | Extended-release Tablets | 450 mg | Forfivo XL | 2/28/2013 |
| Bupropion Hydrochloride | Tablets | 75 mg and 100 mg | Wellbutrin | |

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| Buspirone Hydrochloride | Tablets | 5 mg, 7.5 mg, 10 mg, 15 mg and 30 mg | Buspar | |
| Busulfan | Injection | 6 mg/mL | Busulfex | 12/26/2012 |
| Butoconazole Nitrate | Vaginal Cream | 2% | Gynazole-1 | 12/23/2009 |
| Butorphanol Tartrate | Nasal Spray | 10 mg/mL | Stadol NS | |
| Cabazitaxel | Injection | 60 mg/1.5 mL | Jevtana | 6/17/2014 |
| Calcipotriene | Topical Cream | 0.005% | Dovonex | 12/2/2009 |
| Calcipotriene | Topical Solution | 0.005% | Dovonex | 5/19/2006 |
| Calcipotriene and Betamethasone Dipropionate | Ointment | 0.005%/0.064% | Taclonex | 3/31/2010 |
| Calcitonin-Salmon | Nasal Spray | 200 IU/spray | Miacalcin | |
| Calcitonin-Salmon (Recombinant) | Nasal Spray | 200 IU/spray | Fortical | 3/29/2006 |
| Calcitriol | Injection | 1 mcg/mL and 2 mcg/mL, 1 mL vials | Calcijex | |
| Calcium Acetate | Capsules | EQ 169 mg calcium | PhosLo | 5/31/2005 |
| Calcium Acetate | Oral Solution | 667 mg/5 mL | Phoslyra | 12/5/2013 |
| Calcium Carbonate/ Famotadine/ Magnesium Hydroxide | Chewable Tablets | 800 mg/ 10 mg/ 165 mg (OTC) | Pepcid Complete | 11/1/2004 |
| Candesartan Cilexetil | Tablets | 4 mg, 8 mg, 16 mg and 32 mg | Atacand | 12/22/2006 |
| Candesartan Cilexetil and Hydrochlorothiazide | Tablets | 16 mg/12.5 mg and 32 mg/12.5 mg | Atacand HCT | 6/25/2008 |
| Candesartan Cilexetil and Hydrochlorothiazide | Tablets | 32 mg/25 mg | Atacand HCT | 3/6/2009 |
| Capecitabine | Tablets | 150 mg and 500 mg | Xeloda | 11/10/2008 |
| Captopril | Tablets | 12.5 mg, 25 mg, 50 mg, and 100 mg | Capoten | |
| Carbamazepine | Extended-release Capsules | 100 mg and 200 mg | Carbatrol | 2/2/2006 |
| Carbamazepine | Extended-release Capsules | 200 mg and 300 mg | Equetro | 8/21/2007 |

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| Carbamazepine | Extended-release Capsules | 100 mg | Equetro | 5/23/2014 |
| Carbamazepine | Extended-release Capsules | 300 mg | Carbatrol | |
| Carbamazepine | Extended-release Tablets | 100 mg | Tegretol-XR | 12/30/2005 |
| Carbamazepine | Extended-release Tablets | 200 mg and 400 mg | Tegretol-XR | |
| Carbidopa, Levodopa and Entacapone | Tablets | 12.5 mg, 50 mg and 200 mg | Stalevo 50 | 8/5/2008 |
| Carbidopa, Levodopa and Entacapone | Tablets | 18.75 mg/75 mg/200 mg and 31.25 mg/125 mg/200 mg | Stalevo 75 and Stalevo 125 | 5/19/2009 |
| Carbidopa, Levodopa and Entacapone | Tablets | 25/100/200 mg and 37.5/150/200 mg | Stalevo 100 and Stalevo 150 | 6/29/2007 |
| Carbidopa, Levodopa and Entacapone | Tablets | 50 mg/200 mg/200 mg | Stalevo 200 | 8/28/2008 |
| Carbidopa/ Levodopa | Extended-release Tablets | 25 mg/100 mg and 50 mg/200 mg | Sinemet CR | |
| Carboplatin | For Injection | 50 mg/vial, 150 mg/vial and 450 mg/vial | Paraplatin | |
| Carboplatin | Injection | 50 mg/vial, 150 mg/vial and 450 mg/vial | Paraplatin | |
| Carisoprodol/ Aspirin | Tablets | 200 mg/ 325 mg | Soma Compound | |
| Carisoprodol/ Aspirin/ Codeine | Tablets | 200 mg/ 325 mg/ 16 mg | Soma Compound with Codeine | |
| Carvedilol | Tablets | 3.125 mg, 6.25 mg, 12.5 mg and 25 mg | Coreg | |
| Carvedilol Phosphate | Extended-release Capsules | 10 mg and 20 mg | Coreg CR | 3/18/2008 |
| Carvedilol Phosphate | Extended-release Capsules | 40 mg | Coreg CR | 12/21/2007 |
| Carvedilol Phosphate | Extended-release Capsules | 80 mg | Coreg CR | 11/19/2007 |
| Caspofungin Acetate | For Injection | 50 mg/vial and 70 mg/vial | Cancidas | 6/26/2009 |
| Ceftaroline Fosamil | For Injection | 400 mg/vial and 600 mg/vial | Teflaro | 10/29/2014 |

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| Celecoxib* | Capsules | 50 mg | Celebrex | 3/21/2008 |
| Celecoxib | Capsules | 100 mg, 200 mg and 400 mg | Celebrex | |
| Cetirizine Hydrochloride | Syrup | 5 mg/5 mL | Zyrtec | 3/19/2007 |
| Cetirizine Hydrochloride | Chewable Tablets | 5 mg and 10 mg | Zyrtec | 3/25/2005 |
| Cetirizine Hydrochloride and Pseudoephedrine | Extended-release Tablets | 5 mg/120 mg | Zyrtec-D | 6/2/2004 |
| Cevimeline Hydrochloride | Capsules | 30 mg | Evoxac | 2/27/2009 |
| Chlorhexidine Gluconate | Scrub brush/sponge | 4% | Hibiclens | |
| Chlorpheniramine Polistirex and Hydrocodone Polistirex | Extended-release Capsules | 8 mg/10 mg and 4 mg/5 mg | Tussionex | 9/10/2004 |
| Ciclesonide | Nasal Spray | 50 mcg | Omnaris | 2/13/2012 |
| Ciclopirox | Gel | 0.77% | Loprox | 5/10/2006 |
| Cinacalcet Hydrochloride | Tablets | 30 mg, 60 mg and 90 mg | Sensipar | 3/10/2008 |
| Ciprofloxacin | Oral Suspension | 250 mg/5 mL and 500 mg/ 5 mL | Cipro | 10/16/2009 |
| Ciprofloxacin Hydrochloride | Tablets | 100 mg, 250 mg, 500 mg and 750 mg | Cipro | |
| Cisatracurium Besylate (multi-dose) | Injection | 2 mg/mL, 10 mL vial | Nimbex | 8/12/2009 |
| Cisatracurium Besylate (preserve free) | Injection | 2 mg/mL, 5 mL vial and 10 mg/mL, 20 mL vial | Nimbex | 8/4/2009 |
| Cisplatin | Injection | 1 mg/mL, 10 mL, 50 mL, 100 mL and 200 mL vials | Platinol-AQ | |
| Cisplatin | For Injection | 10 mg/vial and 50 mg/vial | Platinol | |
| Clarithromycin | Extended-release Tablets | 500 mg | Biaxin XL | PIV received prior to 2/5/2009 |
| Clindamycin Phosphate | Foam | 1% | Evoclin | PIV received prior to 2/5/2009 |
| Clindamycin Phosphate and Benzoyl Peroxide | Gel | 1% / 5% | Duac | 12/11/2008 |
| Clindamycin Phosphate and Tretinoin | Gel | 1.2%/0.025% | Ziana | 12/17/2010 |
| Clindamycin Phosphate and Benzoyl Peroxide | Gel | 1.2%/2.5% | Acanya | 12/20/2012 |

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| Clobetasol Propionate | Emulsion Foam | 0.05% | Olux-E | 2/25/2010 |
| Clobetasol Propionate | Topical Foam | 0.05% | Olux | 6/27/2005 |
| Clobetasol Propionate | Lotion | 0.05% | Clobex | 3/27/2006 |
| Clobetasol Propionate | Spray | 0.05% | Clobex | 9/29/2008 |
| Clobetasol Propionate | Topical Shampoo | 0.05% | Clobex | 1/9/2008 |
| Clofarabine | Injection | 1 mg/mL, 20 mL vial | Clolar | 2/23/2012 |
| Clonidine Hydrochloride | Extended-release Tablets | 0.1 mg and 0.2 mg | Jenloga | 3/4/2011 |
| Clonidine Hydrochloride | Extended-release Tablets | 0.1 mg and 0.2 mg | Kapvay | 3/4/2011 |
| Clonidine Hydrochloride | Transdermal System | 0.1 mg/day, 0.2 mg/day, and 0.3 mg/day | Catapres-TTS | |
| Clopidogrel Bisulfate | Tablets | 75 mg | Plavix | |
| Clopidogrel Bisulfate | Tablets | 300 mg | Plavix | 3/4/2009 |
| Clozapine | Orally Disintegrating Tablets | 12.5 mg | Fazaclo | 6/5/2008 |
| Clozapine | Orally Disintegrating Tablets | 25 mg and 100 mg | Fazaclo | 4/28/2008 |
| Clozapine | Orally Disintegrating Tablets | 150 mg | Fazaclo | 4/8/2011 |
| Clozapine | Orally Disintegrating Tablets | 200 mg | Fazaclo | 4/18/2011 |
| Colchicine | Tablets | 0.6 mg | Colcrys | 12/23/2011 |
| Colesevelam Hydrochloride | Powder for Oral Suspension | 1.875 g/Package and 3.75 | Welchol | 4/9/2010 |
| Colesevelam Hydrochloride | Tablets | 625 mg | Welchol | 7/1/2009 |
| Colestipol Hydrochloride | Tablets | 1 g | Colestid | 8/23/2005 |
| Conjugated Estrogen (Synthetic A) | Tablets | 0.3 mg, 0.45 mg and 0.9 mg | Cenestin | 3/19/2009 |
| Conjugated Estrogen (Synthetic A) | Tablets | 1.25 mg | Cenestin | 11/3/2008 |
| Conjugated Estrogen (Synthetic A) | Tablets | 0.625 mg | Cenestin | 3/2/2009 |
| Conjugated Estrogens | Tablets | 0.3 mg and 0.625 mg | Premarin | |
| Cyclobenzaprine Hydrochloride | Tablets | 10 mg | Flexeril | |
| Cyclobenzaprine Hydrochloride | Extended-release Capsule | 15 mg and 30 mg | Amrix | 8/11/2008 |
| Cyclophosphamide | For Injection | 100 mg/vial, 200 mg/vial, 500 mg/vial, 1 g/vial and 2 g/vial | Cytoxan | |

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| Dabigatran Etexilate Mesylate | Capsules | eq. to 75 mg base and 150 mg base | Pradaxa | 10/20/2014 |
| Dalfampridine | Extended-release Tablets | 10 mg | Ampyra | 1/22/2014 |
| Daptomycin | For Injection | 500 mg/vial | Cubicin | 11/19/2008 |
| Darifenacin Hydrobromide | Extended-release Tablets | 7.5 mg and 15 mg | Enablex | 12/22/2008 |
| Darunavir Ethanolate | Tablets | 75 mg, 150 mg, 300 mg, 400 mg and 600 mg | Prezista | 6/23/2010 |
| Darunavir Ethanolate | Tablets | 800 mg | Prezista | 5/14/2013 |
| Dasatinib | Tablets | 80 mg and 140 mg | Sprycel | 6/17/2011 |
| Dasatinib | Tablets | 20 mg, 50 mg, 70 mg and 100 mg | Sprycel | 6/28/2010 |
| Deferasirox | Tablets | 125 mg, 250 mg, and 500 mg | Exjade | 10/28/2011 |
| Desflurane | Inhalation | 99.9% | Suprane | 9/11/2008 |
| Desloratadine | Tablets | 5 mg | Clarinet | 6/21/2006 |
| Desloratadine | Orally Disintegrating Tablets | 2.5 mg and 5 mg | Clarinet | 6/21/2006 |
| Desloratadine | Oral Solution | 0.5 mg/mL | Clarinet Syrup | 5/8/2008 |
| Desloratadine and Pseudoephedrine Sulfate | Extended-release Tablets | 2.5 mg/120 mg | Clarinet-D 24 Hour | 6/1/2007 |
| Desloratadine and Pseudoephedrine Sulfate | Extended-release Tablets | 5 mg/240 mg | Clarinet-D 24 Hour | 6/21/2006 |
| Desmopressin Acetate | Injection | 4 mcg/mL, 1 mL and 10 mL vials | DDAVP | |
| Desmopressin Acetate | Nasal Spray | 0.01% | DDAVP | |
| Desmopressin Acetate | Tablets | 0.1 mg and 0.2 mg | DDAVP | |
| Desogestrel; Ethinyl Estradiol Tablets | Tablets | 0.15mg/ 0.02 mg and 0.01 mg | Mircette | |
| Desonide | Gel | 0.05% | Desonate | 12/1/2010 |
| Desoximetasone | Topical Spray | 0.25% | Topicort | 12/18/2013 |
| Desvenlafaxine Succinate | Extended-release Tablets | 50 mg and 100 mg | Pristiq | 2/29/2012 |

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| Dexlansoprazole | Delayed-release Capsules | 30 mg | Dexilant | 11/30/2010 |
| Dexlansoprazole | Delayed-release Capsules | 60 mg | Dexilant | 8/25/2010 |
| Dexmedetomidine | Injection | 100 mcg/mL | Precedex | 4/8/2009 |
| Dexmedetomidine | Injection | 4 mcg/mL, 50 mL and 100 mL vials | Precedex | 12/26/2013 |
| Dexmethylphenidate Hydrochloride | Tablets | 2.5 mg | Focalin | 7/27/2004 |
| Dexmethylphenidate Hydrochloride | Tablets | 5 mg and 10 mg | Focalin | 5/27/2004 |
| Dexmethylphenidate Hydrochloride | Extended-release Capsules | 15 mg | Focalin XR | 5/14/2007 |
| Dexmethylphenidate Hydrochloride | Extended-release Capsules | 5 mg, 10 mg and 20 mg | Focalin XR | 3/30/2007 |
| Dexmethylphenidate Hydrochloride | Extended-release Capsules | 30 mg | Focalin XR | 12/15/2010 |
| Dexmethylphenidate Hydrochloride | Extended-release Capsules | 40 mg | Focalin XR | 12/20/2010 |
| Dexmethylphenidate | Extended-release Capsules | 35 mg | Focalin XR | 9/29/2011 |
| Dexmethylphenidate | Extended-release Capsules | 25 mg | Focalin XR | 9/30/2011 |
| Dexrazoxane | For Injection | 250 mg/vial | Zinecard | |
| Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate | Extended-release Capsules | 5 mg, 10 mg, 15 mg, 20 mg, 25 mg and 30 mg | Adderall XR | |
| Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate | Tablets | 5 mg, 10 mg, 20 mg, 30 mg | Adderall | 11/18/2009 |
| Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate | Tablets | 7.5 mg, 12.5 mg and 15 mg | Adderall | |
| Dextromethorphan Polistirex | Extended-release Suspension | 30 mg/5 mL | Delsym | 1/12/2009 |
| Dextromethorphan Hydrobromide and Quinidine Sulfate | Capsules | 20 mg/10 mg | Nuedexta | 3/7/2011 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|------------------------------------|---------------------------|---|-----------------|---------------------------|
| Diazepam | Tablets | 2 mg, 5 mg and 10 mg | Valium | |
| Diazepam | Rectal Gel | 2.5 mg/0.5 mL, 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL and 20 mg/4 mL | Diastat | 3/23/2004 |
| Diazepam | Rectal Gel | 5 mg/mL, 4mL pre-filled syringe | Diastat Acudial | 12/8/2008 |
| Diazepam | Rectal Gel | 5 mg/mL, 2mL pre-filled syringe | Diastat Acudial | 12/23/2008 |
| Diclofenac Potassium | Oral Solution (Sachet) | 50 mg | Cambia | 1/24/2011 |
| Diclofenac Potassium | Capsules | 25 mg | Zipsor | 11/14/2012 |
| Diclofenac Sodium | Topical Gel | 3% | Solaraze | 12/16/2009 |
| Diclofenac Sodium | Topical Solution | 1.5% | Pennsaid | 7/11/2012 |
| Diclofenac Sodium | Topical Solution | 2.0% | Pennsaid | 6/3/2014 |
| Diclofenac | Capsules | 18 mg and 35 mg | Zorvolex | 6/6/2014 |
| Diclofenac Sodium and Misoprostol* | Delayed-release Tablets | 50 mg/0.2 mg | Arthrotec | 6/29/2009 |
| Diclofenac Sodium and Misoprostol* | Delayed-release Tablets | 75 mg/0.2 mg | Arthrotec | 11/28/2008 |
| Didanosine | Delayed-release Capsules | 200 mg, 250 mg and 400 mg | Videx EC | 6/1/2004 |
| Diltiazem Hydrochloride | Extended-release Capsules | 60 mg, 90 mg and 120 mg | Cardizem SR | |
| Diltiazem Hydrochloride | Extended-release Capsules | 120 mg, 180 mg and 240 mg | Dilacor XR | |
| Diltiazem Hydrochloride | Extended-release Capsules | 120 mg, 180 mg, 240 mg, 300 mg and 360 mg | Cardizem CD | |
| Diltiazem Hydrochloride | Extended-release Capsules | 120 mg, 180 mg, 240 mg, 300 mg, 360 mg and 420 mg | Tiazac | |
| Diltiazem Hydrochloride | Extended-release Tablets | 120 mg, 180 mg, 240 mg, 300 mg and 360 mg | Cardizem LA | 8/30/2005 |
| Diltiazem Hydrochloride | Extended-release Tablets | 420 mg | Cardizem LA | 4/25/2005 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|-------------------------------|---------------------------------|-------------|--------------------------------|
| Difluprednate | Ophthalmic Emulsion | 0.05% | Durezol | 5/1/2014 |
| Divalproex Sodium | Delayed-release Tablets | 125 mg, 250 mg and 500 mg | Depakote | |
| Divalproex Sodium* | Extended-release Tablets | 250 mg | Depakote ER | 5/3/2004 |
| Divalproex Sodium | Extended-release Tablets | 500 mg | Depakote ER | 2/8/2005 |
| Docetaxel | Injection | 40 mg/mL, 0.5 mL and 2 mL vials | Taxotere | 6/30/2009 |
| Dofetilide | Capsules | 0.125 mg, 0.25 mg, and 0.5 mg | Tikosyn | 5/1/2014 |
| Donepezil Hydrochloride | Tablets | 5 mg and 10 mg | Aricept | |
| Donepezil Hydrochloride | Orally Disintegrating Tablets | 5 mg and 10 mg | Aricept ODT | 6/30/2010 |
| Donepezil Hydrochloride | Tablets | 23 mg | Aricept | 7/9/2013 |
| Doripenem | Injection | 250 mg/vial and 500 mg/vial | Doribax | 10/12/2011 |
| Dorzolamide Hydrochloride | Ophthalmic Solution | 2% | Trusopt | 10/11/2005 |
| Dorzolamide Hydrochloride and Timolol Maleate | Ophthalmic Solution | 2%/0.5% | Cosopt | 10/11/2005 |
| Doxazosin Mesylate | Tablets | 1 mg, 2 mg, 4 mg and 8 mg | Cardura | |
| Doxepin Hydrochloride | Tablets | 3 mg and 6 mg | Silenor | 9/16/2010 |
| Doxercalciferol | Capsules | 1 mcg | Hectorol | 2/12/2010 |
| Doxercalciferol | Capsules | 0.5 mcg and 2.5 mcg | Hectorol | 3/25/2009 |
| Doxercalciferol* | Injection | 2 mcg/mL, 2 mL ampules | Hectorol | 10/15/2007 |
| Doxercalciferol* | Injection | 2 mcg/mL, 1 mL in 2 mL vial | Hectorol | 12/28/2011 |
| Doxycycline | Delayed-release Capsules | 40 mg | Oracea | 12/11/2008 |
| Doxycycline Hyclate | Delayed-release Tablets | 75 mg and 100 mg | Doryx | PIV received prior to 2/5/2009 |
| Doxycycline Hyclate | Delayed-release Tablets | 150 mg | Doryx | 12/19/2008 |
| Doxylamine Succinate and Pyridoxine Hydrochloride | Delayed-release Tablets | 10 mg/10 mg | Diclegis | 8/1/2013 |
| Dronedarone Hydrochloride | Tablets | 400 mg | Multaq | 7/1/2013 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|--------------------------|------------------------------------|------------|---------------------------|
| Drospirenone and Estradiol | Tablets | 0.5 mg/1 mg | Angeliq | 12/26/2007 |
| Drospirenone and Ethinyl Estradiol | Tablets | 3 mg/0.02 mg | Yaz | 9/29/2006 |
| Drospirenone and Ethinyl Estradiol | Tablets | 3 mg/0.03 mg | Yasmin | 1/7/2005 |
| Drospirenone and Ethinyl Estradiol and Levomefolate Calcium and Levomefolate Calcium | Tablets | 3 mg/0.03 mg/0.451 mg and 0.451 mg | Safyral | 9/28/2012 |
| Drospirenone and Ethinyl Estradiol and Levomefolate Calcium and Levomefolate Calcium | Tablets | 3 mg/0.02 mg/0.451 mg and 0.451 mg | Beyaz | 11/13/2012 |
| Duloxetine Hydrochloride | Delayed-release Capsules | 20 mg, 30 mg and 60 mg | Cymbalta | 8/4/2008 |
| Duloxetine Hydrochloride | Delayed-release Capsules | 40 mg | Cymbalta | 5/10/2012 |
| Dutasteride | Capsules | 0.5 mg | Avodart | 10/29/2007 |
| Dutasteride and Tamsulosin Hydrochloride | Capsules | 0.5 mg/0.4 mg | Jalyn | 10/26/2010 |
| Efavirenz | Tablets | 600 mg | Sustiva | 4/9/2009 |
| Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate | Tablets | 600 mg/200 mg/300 mg | Atripla | 12/29/2008 |
| Eletriptan Hydrobromide | Tablets | 20 mg and 40 mg | Relpax | 3/29/2010 |
| Eltrombopag Olamine | Tablets | 50 mg and 75 mg | Promacta | 1/7/2014 |
| Eltrombopag Olamine | Tablets | 12.5 mg and 25 mg | Promacta | 2/4/2014 |
| Emtricitabine and Tenofovir Disoproxil Fumarate | Tablets | 200 mg/300 mg | Truvada | 9/26/2008 |
| Enalapril Maleate | Tablets | 2.5 mg, 5 mg, 10 mg and 20 mg | Vasotec | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--------------------------|---------------------------|---|-----------------------|---------------------------|
| Enoxaparin Sodium | Injection | 100 mg/mL, 0.3 mL, 0.4 mL, 0.6 mL, 0.8 mL and 1 mL prefilled syringes | Lovenox | |
| Enoxaparin Sodium | Injection | 150 mg/mL, 0.6 mL, 0.8 mL and 1 mL prefilled syringes | Lovenox | |
| Enoxaparin Sodium | Injection | 100 mg/mL, 3 mL vials | Lovenox | 12/7/2006 |
| Entacapone | Tablets | 200 mg | Comtan | 4/11/2007 |
| Entecavir | Tablets | 0.5 mg and 1 mg | Baraclude | 6/14/2010 |
| Epinastine Hydrochloride | Ophthalmic Solution | 0.05% | Elestat | 10/14/2008 |
| Epinephrine | Injection (Auto-injector) | 0.15 mg/0.3 mL and 0.3 mg/0.3 mL | Epipen and Epipen Jr. | 7/20/2009 |
| Eplerenone | Tablets | 25 mg and 50 mg | Inspra | 9/27/2006 |
| Eptifibatide | Injection | 0.75 mg/mL, 100 mL vial | Integrilin | 6/5/2009 |
| Eptifibatide | Injection | 2 mg/mL, 10 mL vial | Integrilin | 9/30/2008 |
| Eptifibatide | Injection | 2 mg/mL, 100 mL vial | Integrilin | 12/18/2008 |
| Eprosartan Mesylate | Tablets | 400 mg and 600 mg | Teveten | 5/10/2010 |
| Erlotinib Hydrochloride | Tablets | 25 mg, 100 mg and 150 mg | Tarceva | 11/18/2008 |
| Ertapenem | Injection | 1 g/vial | Invanz | 12/21/2012 |
| Escitalopram Oxalate | Capsules | 5 mg | Lexapro | 8/17/2005 |
| Escitalopram Oxalate | Capsules | 10 mg and 20 mg | Lexapro | 3/30/2005 |
| Escitalopram Oxalate | Tablets | 5 mg, 10 mg and 20 mg | Lexapro | |
| Esmolol Hydrochloride | Injection | 10 mg/mL, 10 mL vial | Brevibloc | |
| Esmolol Hydrochloride | Injection | 10 mg/mL, 250 mL infusion bags and 20 mg/mL, 100 mL infusion bags | Brevibloc | 1/31/2014 |
| Esomeprazole Magnesium | Delayed-release Capsules | 20 mg and 40 mg | Nexium | 8/5/2005 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---------------------------------------|--------------------------|--|--------------|---------------------------|
| Esomeprazole Magnesium | Delayed-release Capsules | 20 mg | Nexium (OTC) | 4/24/2014 |
| Esomeprazole Sodium | For Injection | 20 mg/vial and 40 mg/vial | Nexium IV | 11/23/2009 |
| Estradiol | Transdermal System | 0.025 mg/day, 0.0375 mg/day, 0.05 mg/days, 0.075 mg/day and 0.1 mg/day | Vivelle Dot | 4/27/2010 |
| Estradiol | Transdermal System | 0.0375 mg/day and 0.06 mg/day | Climara | |
| Estradiol | Transdermal System | 0.05 mg/day and 0.1 mg/day | Climara | 9/12/2005 |
| Estradiol | Vaginal Tablets | 10 mcg | Vagifem | 1/2/2013 |
| Estradiol; Estradiol and Norgestimate | Tablets | 1 mg; 1 mg and 0.09 mg | Prefest | |
| Estradiol Valerate and Dienogest | Tablets | 3 mg; 2 mg/2 mg; 2 mg/3 mg and 1 mg | Natazia | 10/22/2010 |
| Eszopiclone | Tablets | 1 mg, 2 mg and 3 mg | Lunesta | 12/15/2008 |
| Ethinyl Estradiol and Etonogestrel | Vaginal Ring | 0.015 mg/24 hour and 0.12 | Nuvaring | 6/17/2013 |
| Etodolac | Extended-release Tablets | 400 mg, 500 mg and 600 mg | Lodine XL | |
| Everolimus | Tablets | 0.25 mg, 0.5 mg, and 0.75 mg | Zortress | 9/30/2013 |
| Everolimus | Tablets | 10 mg | Afinitor | 6/18/2014 |
| Exenatide | Injection | 250 mg/mL, 1.2 mL and 2.4 mL prefilled syringe | Byetta | 6/11/2014 |
| Ezetimibe | Tablets | 10 mg | Zetia | 10/25/2006 |
| Ezetimibe and Simvastatin | Tablets | 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg | Vytorin | 7/27/2009 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---------------------|---|--|----------------------|---------------------------|
| Famciclovir | Tablets | 125 mg, 250 mg and 500 mg | Famvir | 12/28/2004 |
| Famotidine | Injection | 10 mg/mL, 2 mL vials; unpreserved | Pepcid | |
| Famotidine | Injection | 10 mg/mL, 4 mL and 20 mL vials; preserved | Pepcid | |
| Famotidine | Injection | 10 mg/mL, 50 mL vial, pharmacy bulk package; unpreserved | Pepcid | |
| Famotidine | Tablets | 10 mg (OTC) | Pepcid AC | |
| Famotidine | Tablets | 20 mg and 40 mg | Pepcid | |
| Famotidine | Tablets (Chewable) | 10 mg (OTC) | Pepcid AC (chewable) | |
| Febuxostat | Tablets | 40 mg and 80 mg | Uloric | 2/13/2013 |
| Felodipine | Extended-release Tablets | 2.5 mg, 5 mg and 10 mg | Plendil ER | |
| Fenofibrate | Tablets | 40 mg and 120 mg | Fenoglide | 3/17/2010 |
| Fenofibrate | Capsules | 43 mg and 130 mg | Antara | 9/15/2008 |
| Fenofibrate Choline | Delayed-release Capsules | 45 mg | Trilipix | 9/2/2009 |
| Fenofibrate Choline | Delayed-release Capsules | 135 mg | Trilipix | 9/1/2009 |
| Fenofibrate | Capsules | 67 mg, 134 mg and 200 mg | Tricor | |
| Fenofibrate | Tablets | 48 mg | Tricor | 7/1/2008 |
| Fenofibrate | Tablets | 54 mg, 107 mg and 160 mg | Tricor | |
| Fenofibrate | Tablets | 145 mg | Tricor | 10/19/2007 |
| Fentanyl | Transdermal Extended-release Film | 0.6 mg/24 hr, 1.2 mg/ 24 hr, 1.8 mg/ 24 hr and 2.4 mg/ 24 hr | Duragesic | |
| Fentanyl Citrate | Buccal Tablets | 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.6 mg and 0.8 mg | Fentora | 11/13/2007 |
| Fentanyl Citrate | Lozenges | 0.2 mg | Actiq | 10/29/2004 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|--------------------------|---|------------------------------|---------------------------|
| Fentanyl Citrate | Lozenges | 0.4 mg | Actiq | 10/6/2004 |
| Fentanyl Citrate | Lozenges | 0.6 mg | Actiq | 12/20/2004 |
| Fentanyl Citrate | Lozenges | 0.8 mg, 1.2 mg and 1.6 mg | Actiq | 11/22/2004 |
| Fentanyl Citrate NEW | Sublingual Tablets | 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.6 mg and 0.8 mg | Abstral | 6/19/2014 |
| Fesoterodine Fumarate | Extended-release Tablets | 4 mg and 8 mg | Toviaz | 10/31/2012 |
| Fexofenadine Hydrochloride | Oral Suspension | 30 mg/5 mL | Allegra | 1/25/2010 |
| Fexofenadine Hydrochloride | Capsules | 60 mg | Allegra | |
| Fexofenadine Hydrochloride | Tablets | 30 mg, 60 mg and 180 mg | Allegra | |
| Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride | Extended-release Tablets | 60 mg/120 mg | Allegra-D | |
| Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride | Extended-release Tablets | 180 mg/240 mg | Allegra-D 24 Hour | 6/6/2007 |
| Finasteride | Tablets | 1 mg | Propecia | |
| Finasteride | Tablets | 5 mg | Proscar | |
| Fingolimod | Capsules | 0.5 mg | Gilenya | 9/22/2014 |
| Flecainide Acetate | Tablets | 50 mg, 100 mg and 150 mg | Tambocor | |
| Fluconazole | For Oral Suspension | 50 mg/5 mL and 200 mg/5 mL | Diflucan for Oral Suspension | |
| Fluconazole | Tablets | 50 mg, 100 mg, 150 mg and 200 mg | Diflucan | |
| Flunisolide | Nasal Solution | 0.025% | Nasalide | |
| Fluocinonide | Cream | 0.1% | Vanos | 1/31/2008 |
| Fluocinonide | Ointment | 0.05% | Lidex | |
| Fluorouracil | Cream | 0.5% | Carac | 7/29/2011 |
| Fluoxetine Hydrochloride | Tablets | 10 mg and 20 mg | Prozac | |
| Fluoxetine Hydrochloride | Capsules | 10 mg, 20 mg and 40 mg | Prozac | |
| Fluoxetine Hydrochloride | Delayed-release Capsules | 90 mg | Prozac Weekly | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|---------------------------|---------------------------------|--------------|---------------------------|
| Fluoxetine Hydrochloride | Oral Solution | 20 mg (base)/5 mL | Prozac | |
| Fluoxetine Hydrochloride | Capsules | 10 mg and 20 mg | Sarafem | |
| Flutamide | Capsules | 125 mg | Eulexin | |
| Fluticasone Furoate | Nasal Spray | 27.5 mcg | Veramyst | 7/15/2011 |
| Fluticasone Propionate | Lotion | 0.05% | Cutivate | 7/28/2008 |
| Fluvastatin | Capsules | 20 mg and 40 mg | Lescol | 6/4/2008 |
| Fluvastatin Sodium | Extended-release Tablets | 80 mg | Lescol XL | 3/15/2007 |
| Fluvoxamine Maleate | Extended-release Capsules | 100 mg | Luvox CR | 4/20/2009 |
| Fluvoxamine Maleate | Extended-release Capsules | 150 mg | Luvox CR | 4/13/2009 |
| Formoterol Fumarate | Inhalation Solution | 0.02 mg/2 mL | Perforomist | 1/21/2009 |
| Fosamprenavir Calcium | Tablets | 700 mg | Lexiva | 1/18/2012 |
| Fosaprepitant Dimeglumine | Injection | 115 mg/vial | Emend | 1/25/2012 |
| Fosaprepitant Dimeglumine | Injection | 150 mg/vial | Emend | 1/25/2012 |
| Fosinopril Sodium | Tablets | 10 mg, 20 mg and 40 mg | Monopril | |
| Fosinopril Sodium and Hydrochlorothiazide | Tablets | 10 mg/12.5 mg and 20 mg/12.5 mg | Monopril HCT | |
| Frovatriptan Succinate | Tablets | 2.5 mg | Frova | 3/9/2011 |
| Fulvestrant | Injection | 50 mg/mL, 2.5 mL and 5 mL | Faslodex | 10/1/2009 |
| Gabapentin | Capsules | 100 mg, 300 mg and 400 mg | Neurontin | |
| Gabapentin | Oral Solution | 250 mg/5 mL | Neurontin | |
| Gabapentin | Tablets | 300 mg and 600 mg | Gralise | 10/31/2011 |
| Gabapentin | Tablets | 100 mg, 300 mg and 400 mg | Neurontin | |
| Gabapentin | Tablets | 600 mg and 800 mg | Neurontin | |
| Galantamine Hydrobromide | Extended-release Capsules | 8 mg | Razadyne ER | 3/2/2006 |
| Galantamine Hydrobromide | Extended-release Capsules | 16 mg and 24 mg | Razadyne ER | 3/11/2006 |
| Galantamine Hydrobromide | Tablets | 4 mg, 8 mg and 12 mg | Razadyne | 2/28/2005 |
| Ganciclovir Sodium | Capsules | 250 mg and 500 mg | Cytovene | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|--------------------------|---|-------------------|---------------------------|
| Ganirelix Acetate | Injection | 250 mcg/0.5 mL, 1 mL PFS | Ganirelix Acetate | 3/30/2012 |
| Gatifloxacin | Injection | 10 mg/mL, 20 mL and 40 mL vials | Tequin | 11/24/2004 |
| Gatifloxacin | Ophthalmic Solution | 0.3 % | Zymar | 7/19/2007 |
| Gatifloxacin | Ophthalmic Solution | 0.5 % | Zymaxid | 12/7/2010 |
| Gatifloxacin | Tablets | 200 mg and 400 mg | Tequin | |
| Gatifloxacin in Dextrose 5% in Plastic Container | Injection | 2 mg/mL, 100 mL and 200 mL containers (plastic) | Tequin | 12/13/2004 |
| Gemcitabine | For Injection | 200 mg/vial | Gemzar | 11/1/2005 |
| Gemcitabine | For Injection | 1g/vial | Gemzar | 11/14/2005 |
| Gemcitabine | For Injection | 2 g/vial | Gemzar | 8/24/2007 |
| Gemifloxacin Mesylate | Tablets | 320 mg | Factive | 3/4/2008 |
| Glatiramer Acetate | Injection | 20 mg/mL, 1mL pre-filled syringe | Copaxone | 12/27/2007 |
| Glatiramer Acetate | Injection | 40 mg/mL, 1 mL pre-filled syringe | Copaxone | 2/26/2014 |
| Glimepiride and Rosiglitazone Maleate | Tablets | 1 mg/4 mg, 2 mg/4 mg and 4 mg/4 mg | Avandaryl | 12/22/2006 |
| Glimepiride and Rosiglitazone Maleate | Tablets | 8 mg/2 mg and 8 mg/4 mg | Avandaryl | 5/30/2008 |
| Glipizide | Extended-release Tablets | 2.5 mg, 5 mg and 10 mg | Glucotrol XL | |
| Glyburide | Tablets | 1.5 mg, 3 mg, 4.5 mg and 6 mg | Glynase | |
| Glyburide/ Metformin Hydrochloride | Tablets | 1.25mg/250 mg, 2.5 mg/500 mg and 5 mg/500 mg | Glucovance | |
| Glycerol Phenylbutyrate | Oral Liquid | 1.1 g/mL | Ravicti | 11/19/2013 |
| Glycopyrrolate | Tablets | 1 mg | Robinul | 8/14/2009 |
| Glycopyrrolate | Tablets | 1.5 mg | Robinul Forte | 5/6/2009 |
| Glycopyrrolate | Tablets | 2 mg | Robinul Forte | 10/12/2010 |
| Glycopyrrolate | Oral Solution | 1 mg/5 mL | Cuvposa | 6/20/2012 |
| Granisetron Hydrochloride | Injection | 0.1 mg/mL, 1 mL single dose vial | Kytril | 3/8/2007 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|---------------------------|--|------------------|---------------------------|
| Granisetron Hydrochloride | Injection | 1 mg/mL, 1 mL vials | Kytril | 6/1/2004 |
| Granisetron Hydrochloride | Injection | 1 mg/mL, 4 mL multi-dose vials | Kytril | 7/19/2004 |
| Guaifenesin * | Extended-release Tablets | 600 mg and 1.2 gm | Mucinex | 6/9/2006 |
| Guaifenesin and Dextromethorphan | Extended-release Tablets | 600 mg/30 mg and 1200 mg/60 mg | Mucinex DM | 12/17/2008 |
| Guaifenesin and Pseudoephedrine Hydrochloride | Extended-release Tablets | 600 mg/60 mg and 1200 mg/120 mg | Mucinex-D | 12/29/2008 |
| Guanfacine Hydrochloride | Extended-release Tablets | 1 mg, 2 mg, 3 mg and 4 mg | Intuniv | 12/29/2009 |
| Hydrocodone Bitartrate | Extended-release Capsules | 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg | Zohydro ER | 2/26/2014 |
| Hydrocodone Bitartrate and Ibuprofen | Tablets | 2.5 mg/200 mg | Vicoprofen | 2/24/2006 |
| Hydrocodone Bitartrate and Ibuprofen | Tablets | 5 mg/200 mg | Vicoprofen | 5/27/2005 |
| Hydrocodone Bitartrate and Ibuprofen | Tablets | 7.5 mg/200 mg | Vicoprofen | |
| Hydrocodone Bitartrate and Ibuprofen | Tablets | 10 mg/200 mg | Vicoprofen | |
| Hydrocortisone Butyrate | Cream | 0.10% | Locoid Lipocream | 6/28/2010 |
| Hydromorphone Hydrochloride | Extended-release Tablets | 8 mg and 12 mg | Exlago | 9/2/2010 |
| Hydromorphone Hydrochloride | Extended-release Tablets | 16 mg | Exlago | 8/2/2010 |
| Hydromorphone Hydrochloride | Oral Solution | 5 mg/5mL | Dilaudid | 2/25/2011 |
| Hydromorphone Hydrochloride | Injection | 10 mg/mL | Dilaudid-HP | 11/4/2011 |
| Hydromorphone Hydrochloride | Injection | 2 mg/mL | Dilaudid | 6/22/2011 |
| Hydromorphone Hydrochloride | Tablets | 2 mg, 4 mg, and 8 mg | Dilaudid | 8/5/2013 |
| Ibandronate Sodium* | Injection | 1 mg/mL, 3 mL Vial | Boniva | 8/31/2007 |
| Ibandronate Sodium | Tablets | 2.5 mg and 150 mg | Boniva | 5/16/2007 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|------------------------------|---|---|---------------------------|
| Ibuprofen | Oral Drops | 40 mg/mL | Children's Motrin Drops | |
| Ibuprofen | Oral Suspension | 50 mg/1.25 mL | Concentrated Motrin Infant Drops | 6/29/2007 |
| Ibuprofen | Oral Suspension | 100 mg/5 mL (Rx) | Motrin | |
| Ibuprofen | Oral Suspension | 100 mg/5 mL (OTC) | Children's Motrin | |
| Ibuprofen | Chewable Tablets | 50 mg and 100 mg | Children's Motrin, Junior Strength Motrin | |
| Ibuprofen Lysine | Injection | 10 mg/mL, 2 mL vials | Neoprofen | 10/1/2010 |
| Ibuprofen and Famotidine | Tablets | 800 mg/26.6 mg | Duexis | 12/6/2011 |
| Ibuprofen and Pseudoephedrine Hydrochloride | Oral Suspension | 100 mg/ 15 mg per 5 mL | Children's Motrin Cold | |
| Ibuprofen and Pseudoephedrine Hydrochloride | Tablets | 200 mg/30 mg | Advil Cold and Sinus | |
| Ibuprofen Potassium and Pseudoephedrine Hydrochloride | Capsules | 200 mg/30 mg | Advil Cold and Sinus | 12/27/2004 |
| Icosapent Ethyl | Capsules | 1 g | Vascepa | 1/15/2013 |
| Ifosfamide | For Injection | 1 g/vial and 3 g/vial | Ifex | |
| Ifosfamide | Injection | 50 mg/mL, 20 mL vials and 60 mL vials | Ifex | |
| Ifosfamide/ Mesna | For Injection/ Injection Kit | 1 g/vial; 100 mg/mL, 10 mL vials and 3 g/vial; 100 mg/mL, 10 mL vials | Ifex/ Mesnex Kit | |
| Ifosfamide/ Mesna | Injection/ Injection Kit | 50 mg/mL, 20 mL and 60 mL vials; 100 mg/mL, 10 mL vial | Ifex/ Mesnex Kit | |
| Iloperidone | Tablets | 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, & 12 mg | Fanapt | 5/6/2013 |

**Paragraph IV Patent Certifications
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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|------------------------------------|---------------------------|---|-------------|---------------------------|
| Imatinib Mesylate | Tablets | 100 mg and 400 mg | Gleevec | 3/12/2007 |
| Imatinib Mesylate | Capsules | 400 mg | Gleevec | 1/24/2014 |
| Imiquimod | Cream | 5% | Aldara | 10/17/2006 |
| Imiquimod | Cream | 2.5% | Zyclara | 6/17/2014 |
| Imiquimod | Cream | 3.75% | Zyclara | 8/8/2012 |
| Indomethacin | Extended-release Capsules | 75 mg | Indocin SR | |
| Irbesartan | Tablets | 75 mg, 150 mg and 300 mg | Avapro | 5/25/2004 |
| Irbesartan and Hydrochlorothiazide | Tablets | 150 mg/12.5 mg and 300 | Avalide | 11/10/2004 |
| Irbesartan and Hydrochlorothiazide | Tablets | 300 mg/25 mg | Avalide | 6/6/2006 |
| Irinotecan Hydrochloride | Injection | 20 mg/mL, 2 mL and 5 mL vials | Camptosar | 7/26/2004 |
| Isotretinoin | Capsules | 30 mg and 40 mg | Absorica | 12/31/2012 |
| Isotretinoin | Capsules | 20 mg | Absorica | 1/7/2013 |
| Isotretinoin | Capsules | 10 mg | Absorica | 6/19/2013 |
| Itraconazole | Capsules | 100 mg | Sporanox | |
| Itraconazole | Oral Solution | 10 mg/mL | Sporanox | 5/3/2013 |
| Ixabepilon | Injection | 15 mg/vial and 45 mg/vial, single-use vials | Ixempra Kit | 4/16/2012 |
| Ketoconazole | Foam | 2% | Extina | 7/30/2009 |
| Ketoprofen | Capsules | 25 mg, 50 mg and 75 mg | Orudis | |
| Ketorolac Tromethamine | Injection | 15 mg/mL and 30 mg/mL | Toradol | |
| Ketorolac Tromethamine | Ophthalmic Solution | 0.45% | Acuvail | 8/24/2011 |
| Ketorolac Tromethamine | Ophthalmic Solution | 0.4% | Acular LS | 1/28/2005 |
| Ketorolac Tromethamine | Tablets | 10 mg | Toradol | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---------------------------|---|--|--------------|---------------------------|
| Ketorolac Tromethamine | Nasal Spray | 15.75 mg/spray | Sprix | 3/12/2012 |
| Ketotifen Fumarate | Ophthalmic Solution | 0.025% | Zaditor | 12/23/2004 |
| Lacosamide | Oral Solution | 10 mg/mL | Vimpat | 10/29/2012 |
| Lacosamide | Tablets | 50 mg, 100 mg, 150 mg, and | Vimpat | 10/29/2012 |
| Lactulose | Oral Syrup | 10 g/15 mL | Cephulac | |
| Lactulose | Oral Syrup | 10 g/15 mL | Chronulac | |
| Lamivudine* | Tablets | 100 mg | Epivir-HBV | 10/31/2007 |
| Lamivudine | Tablets | 150 mg and 300 mg | Epivir | 10/16/2007 |
| Lamivudine and Zidovudine | Tablets | 150 mg/300 mg | Combivir | 6/26/2007 |
| Lamivudine | Oral Solution | 10 mg/mL | Epivir | 11/22/2011 |
| Lamotrigine | Tablets | 25 mg, 100 mg, 150 mg and 200 mg | Lamictal | |
| Lamotrigine | Chewable Tablets | 2 mg, 5 mg and 25 mg | Lamictal CD | |
| Lamotrigine | Orally Disintegrating Tablets | 25 mg, 50 mg, 100 mg, and 200 mg | Lamictal ODT | 12/21/2009 |
| Lamotrigine | Extended-release Tablets | 25 mg, 50 mg, 100 mg, 200 mg, 250 mg, and 300 mg | Lamictal XR | 2/12/2014 |
| Lansoprazole | Delayed-release Pellets/Capsules | 15 mg and 30 mg | Prevacid | 12/05/2005 |
| Lansoprazole | Delayed-release Orally Disintegrating Tablets | 15 mg and 30 mg | Prevacid | 12/27/2006 |
| Lanthanum Carbonate | Chewable Tablet | 500 mg, 750 mg and 1000 mg | Fosrenol | 10/27/2008 |
| Lapatinib Ditosylate | Tablets | 250 mg | Tykerb | 3/14/2011 |
| Latanoprost | Ophthalmic Solution | 0.005% | Xalatan | |
| Lenalidomide | Capsules | 5 mg, 10 mg and 15 mg | Revlimid | 8/30/2010 |
| Lenalidomide | Capsules | 25 mg | Revlimid | 7/12/2010 |
| Letrozole | Tablets | 2.5 mg | Femara | 3/2/2006 |
| Leuprolide Acetate | Injection (depot) | 7.5 mg/vial | Lupron Depot | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|-----------------------------|---|---|---------------------------|
| Levalbuterol Hydrochloride | Inhalation Solution | 0.0103%, 0.021% and 0.042% | Xopenex | 6/20/2005 |
| Levalbuterol Hydrochloride | Inhalation Solution | 0.25% □ | Xopenex | 5/23/2006 |
| Levalbuterol Tartrate | Inhalation Aerosol | 0.045 mg/actuation | Xopenex | 2/27/2012 |
| Levetiracetam | Tablets | 250 mg, 500 mg and 750 mg | Keppra | |
| Levetiracetam | Tablets | 1000 mg | Keppra | 1/24/2007 |
| Levetiracetam | Extended-release Tablets | 500 mg and 750 mg | Keppra XR | 1/7/2011 |
| Levetiracetam | Extended-release Tablets | 1000 mg | Keppra XR | 1/7/2011 |
| Levocetirizine Dihydrochloride | Oral Solution | 0.5 mg/mL | Xyzal | 1/14/2009 |
| Levocetirizine Dihydrochloride | Tablets | 5 mg | Xyzal | 12/17/2007 |
| Levofloxacin | Injection | 5 mg/mL; 50 mL, 100 mL and 150 mL vials | Levaquin in Dextrose 5% in Plastic Container | |
| Levofloxacin | Injection | 25 mg/mL | Levaquin | |
| Levofloxacin | Ophthalmic Solution | 0.5% | Quixin | |
| Levofloxacin | Oral Solution | 25 mg/mL | Levaquin | 7/30/2009 |
| Levofloxacin | Tablets | 250 mg, 500 mg and 750 mg | Levaquin | |
| Levoleucovorin Calcium | Injection | 10 mg/mL, 17.5 mL vial and 25 mL vial | Fusilev | 10/26/2011 |
| Levoleucovorin Calcium | Injection | 50 mg/vial | Fusilev | 12/19/2013 |
| Levonorgestrel and Ethinyl Estradiol | Tablets | 0.09 mg/0.02 mg | Lybrel | 10/5/2007 |
| Levonorgestrel and Ethinyl Estradiol | Tablets | 0.15 mg/0.03 mg | Seasonale | 3/29/2004 |
| Levonorgestrel; Ethinyl Estradiol; Ethinyl Estradiol | Tablets | 0.1 mg/0.02 mg and 0.01 mg | LoSeasonique | 11/16/2009 |
| Levonorgestrel; Ethinyl Estradiol; Ethinyl Estradiol | Tablets | 0.15 mg/0.03 mg/0.01 mg | Seasonique | 1/22/2008 |
| Levonorgestrel; Ethinyl Estradiol; Ethinyl Estradiol | Tablets | 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, | Quartette | 7/10/2013 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|-------------------------------|---|--------------------|---------------------------|
| Levothyroxine Sodium | Tablets | 0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.1 mg, 0.112 mg, 0.125 mg, 0.150 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.375 mg, 0.4 mg, 0.5 mg, 0.75 mg, 1 mg, 1.25 mg, 1.5 mg, 2 mg, 2.5 mg, 3 mg, 3.75 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 37.5 mg, 40 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 300 mg, 400 mg, 600 mg, 800 mg, 1000 mg | Levoxyl | |
| Lidocaine | Topical Patch | 5% | Lidoderm | 11/13/2009 |
| Linezolid | Injection | 2 mg/mL, 100 mL bag | Zyvox | 12/29/2009 |
| Linezolid | Injection | 2 mg/mL, 300 mL bag | Zyvox | 9/1/2009 |
| Linezolid | Oral Suspension | 100 mg/5 mL | Zyvox | 8/3/2009 |
| Linezolid | Tablets | 600 mg | Zyvox | 12/21/2005 |
| Lisdexamfetamine Dimesylate | Capsules | 20 mg, 30 mg, 40 mg, 50 mg, 60 mg and 70 mg | Vyvanse | 2/23/2011 |
| Loperamide Hydrochloride and Simethicone | Chewable Tablets | 2 mg/125 mg | Imodium Advanced | |
| Loperamide Hydrochloride and Simethicone | Tablets | 2 mg/125 mg | Imodium Advanced | 12/29/2004 |
| Lopinavir and Ritonavir | Tablets | 100 mg/25 mg and 200 mg/50 mg | Kaletra | 12/23/2008 |
| Loratadine | Syrup | 1 mg/mL | Claritin | |
| Loratadine | Tablets | 10 mg | Claritin | |
| Loratadine | Orally Disintegrating Tablets | 10 mg | Claritin RediTabs | |
| Loratadine/Pseudoephedrine | Extended-release Tablets | 5 mg/120 mg | Claritin D-12 hour | |
| Loratadine/Pseudoephedrine | Extended-release Tablets | 10 mg/240 mg | Claritin D-24 hour | |
| Losartan Potassium | Tablets | 25 mg, 50 mg, and 100 mg | Cozaar | |
| Losartan Potassium and Hydrochlorothiazide | Tablets | 50 mg/12.5 mg and 100 mg/25 mg | Hyzaar | 5/24/2004 |
| Losartan Potassium and Hydrochlorothiazide | Tablets | 100 mg/12.5 mg | Hyzaar | 4/4/2006 |
| Lovastatin and Niacin | Extended-release Tablets | 20 mg/500 mg | Advicor | 9/22/2008 |
| Lovastatin and Niacin | Extended-release Tablets | 20 mg/750 mg | Advicor | 12/17/2008 |
| Lovastatin and Niacin | Extended-release Tablets | 20 mg/1000 mg | Advicor | 5/22/2008 |
| Lovastatin and Niacin | Extended-release Tablets | 40 mg/1000 mg | Advicor | 11/19/2009 |
| Lubiprostone | Capsules | 8 mcg and 24 mcg | Amitiza | 8/20/2012 |

**Paragraph IV Patent Certifications
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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--------------------------------|---------------------------|--|---------------|---------------------------|
| Lurasidone Hydrochloride | Tablets | 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg | Latuda | 10/28/2014 |
| Malathion | Topical Lotion | 0.50% | Ovide | 3/16/2011 |
| Maraviroc | Tablets | 150 mg and 300 mg | Selzentry | 8/8/2011 |
| Mefloquine Hydrochloride | Tablets | 250 mg | Lariam | |
| Megestrol Acetate | Oral Suspension | 40 mg/mL | Megace | |
| Megestrol Acetate | Oral Suspension | 125 mg/mL | Megace ES | 4/27/2011 |
| Meloxicam | Oral Suspension | 7.5 mg/5 mL | Mobic | 12/17/2009 |
| Memantine Hydrochloride | Tablets | 5 mg and 10 mg | Namenda | 10/16/2007 |
| Memantine Hydrochloride | Extended-release Capsules | 7 mg, 14 mg, 21 mg, and 28 mg | Namenda XR | 6/10/2013 |
| Mesalamine* | Delayed-release Tablets | 400 mg | Asacol | 6/22/2007 |
| Mesalamine | Delayed-release Tablets | 800 mg | Asacol HD | 7/13/2011 |
| Mesalamine | Delayed-release Tablets | 1.2 g | Lialda | 12/16/2009 |
| Mesalamine | Extended-release Capsules | 0.375 g | Apriso | 4/3/2012 |
| Mesalamine | Suppository | 1000 mg | Canasa | 5/24/2013 |
| Metaxalone | Tablets | 400 mg | Skelaxin | |
| Metaxalone | Tablets | 800 mg | Skelaxin | 11/4/2004 |
| Metformin Hydrochloride | Extended-release Tablets | 500 mg | Glucophage XR | |
| Metformin Hydrochloride | Extended-release Tablets | 750 mg | Glucophage XR | |
| Metformin Hydrochloride | Extended-release Tablets | 500 mg and 1000 mg | Fortamet | 10/14/2008 |
| Metformin Hydrochloride | Extended-release Tablets | 500 mg and 1000 mg | Glumetza | 7/27/2009 |
| Methylphenidate Hydrochloride* | Extended-release Capsules | 10 mg | Ritalin LA | 5/21/2007 |
| Methylphenidate Hydrochloride | Extended-release Capsules | 10 mg, 20 mg and 30 mg | Metadate CD | 5/13/2005 |
| Methylphenidate Hydrochloride | Extended-release Capsules | 20 mg, 30 mg and 40 mg | Ritalin LA | 8/21/06 |
| Methylphenidate Hydrochloride | Extended-release Capsules | 40 mg | Metadate CD | 3/15/2007 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|-------------------------------|----------------------------------|---|-----------------------------|--------------------------------|
| Methylphenidate Hydrochloride | Extended-release Tablets | 18 mg*, 27 mg, 36 mg and 54 mg | Concerta | 7/19/2005 |
| Methylphenidate Hydrochloride | Oral Solution | 5 mg/5 mL and 10 mg/5 mL | Methylin | 4/13/2010 |
| Methylphenidate | Transdermal System | 10 mg/9 hrs, 15 mg/9 hrs, 20 mg/9 hrs and 30 mg/9 hrs | Daytrana | 4/13/2011 |
| Methylphenidate Hydrochloride | Extended-release Oral Suspension | 5 mg/mL | Quillivant XR | 8/2/2013 |
| Metoclopramide Hydrochloride | Injection | 5 mg/mL, 2 mL, 10 mL, 20 mL and 30 mL vials | Reglan | |
| Metoclopramide Hydrochloride | Orally Disintegrating Tablets | 5 mg and 10 mg | Metozolv ODT | 8/24/2010 |
| Metoprolol Succinate | Extended-release Tablets | 25 mg, 50 mg, □ 100 mg and □ 200 mg | Toprol XL | |
| Metronidazole | Vaginal Gel | 0.75% | MetroGel-Vaginal | 9/2/2004 |
| Metronidazole | Topical Gel | 1% | Metrogel | 10/21/2008 |
| Micafungin Sodium | For Injection | 50 mg/vial and 100 mg/vial | Mycamine | 6/16/2014 |
| Miconazole Nitrate | Vaginal Cream and Suppository | 2% and 1.2 g | Monistat 1 Combination Pack | 12/5/2007 |
| Milnacipran Hydrochloride | Tablets | 12.5 mg, 25 mg, 50 mg, and 100 mg | Savella | 1/14/2013 |
| Minocycline Hydrochloride | Extended-release Tablet | 45 mg, 90 mg and 135 mg | Solodyn | PIV received prior to 2/5/2009 |
| Minocycline Hydrochloride | Extended-release Tablet | 55 mg | Solodyn | 12/2/2010 |
| Minocycline Hydrochloride | Extended-release Tablet | 65 mg and 115 mg | Solodyn | 11/19/2009 |
| Minocycline Hydrochloride | Extended-release Tablet | 80 mg | Solodyn | 10/27/2010 |
| Minocycline Hydrochloride | Extended-release Tablet | 105 mg | Solodyn | 12/13/2010 |
| Minoxidil | Topical Aerosol Foam | 5% | Men's Rogaine | 4/6/2009 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|-------------------------------|--|---|---------------------------|
| Mirtazapine | Tablets | 7.5 mg, 15 mg, 30 mg, and 45 mg | Remeron | |
| Mirtazapine | Orally Disintegrating Tablets | 15 mg, 30 mg and 45 mg | Remeron SolTab | |
| Modafinil | Tablets | 100 mg and 200 mg | Provigil | |
| Moexipril Hydrochloride | Tablets | 7.5 mg and 15 mg | Univasc | |
| Moexipril Hydrochloride and Hydrochlorothiazide | Tablets | 7.5mg/12.5mg □ 15 mg/25 mg and 15 mg/12.5 mg | Uniretic | 1/15/2004 |
| Mometasone Furoate | Nasal Spray | 50 mcg/ Spray | Nasonex | 8/7/2009 |
| Mometasone Furoate | Topical Solution (Cream) | 0.1% | Elocon | |
| Mometasone Furoate | Topical Solution (Lotion) | 0.1% | Elocon | 6/10/2004 |
| Montelukast | Tablets | 10 mg | Singulair | 2/20/2007 |
| Montelukast Sodium | Chewable Tablets | 4 mg and 5 mg | Singulair | 12/26/2006 |
| Montelukast Sodium | Oral Granules | 4 mg | Singular Granules | 10/17/2008 |
| Morphine Sulfate | Extended-release Capsules | 30 mg, 60 mg, 90 mg and 120 mg | Avinza | 6/4/2007 |
| Morphine Sulfate* | Extended-release Capsules | 45 mg and 75 mg | Avinza | 7/30/2009 |
| Morphine Sulfate and Naltrexone Hydrochloride | Extended-release Capsules | 100 mg/4 mg | Embeda | 5/3/2010 |
| Morphine Sulfate and Naltrexone Hydrochloride | Extended-release Capsules | 60 mg/2.4 mg | Embeda | 5/25/2010 |
| Morphine Sulfate and Naltrexone Hydrochloride | Extended-release Capsules | 30 mg/1.2 mg, 50 mg/2 mg and 80 mg/3.2 mg | Embeda | 5/28/2010 |
| Moxifloxacin Hydrochloride | Ophthalmic Solution/Drops | 0.5% | Vigamox | 12/22/2005 |
| Moxifloxacin Hydrochloride | Ophthalmic Solution | 0.5% | Moxeza | 2/29/2012 |
| Moxifloxacin Hydrochloride | Tablets | 400 mg | Avelox | |
| Moxifloxacin Hydrochloride | Injection | 1.6 mg/mL | Avelox in Sodium Chloride 0.8% in plastic container | 2/7/2014 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|--------------------------|---|-------------|---------------------------|
| Mycophenolic Acid | Delayed-release Tablets | 180 mg | Myfortic | 6/3/2009 |
| Mycophenolic Acid | Delayed-release Tablets | 360 mg | Myfortic | 2/2/2009 |
| Mycophenolic Mofetil | For Oral Suspension | 200 mg/mL | Cellcept | 3/25/2011 |
| Nabumetone | Tablets | 500 mg and 750 mg | Relafen | |
| Naproxen Sodium | Extended-release Tablets | 375 mg (base) and 500 mg (base) | Naprelan | |
| Naproxen and Esomeprazole Magnesium | Delayed-release Tablets | 375 mg/20 mg and 500 mg/20 mg | Vimovo | 11/5/2010 |
| Naproxen Sodium and Sumatriptan Succinate | Tablets | 500 mg/85 mg | Treximet | 7/23/2008 |
| Nateglinide | Tablets | 60 mg and 120 mg | Starlix | 12/22/2004 |
| Nebivolol Hydrochloride | Tablets | 2.5 mg, 5 mg, 10 mg, and 20 mg | Bystolic | 12/19/2011 |
| Nefazodone Hydrochloride | Tablets | 50 mg, 100 mg, 150 mg 200 mg and 250 mg | Serzone | |
| Nevirapine | Extended-release Tablets | 400 mg | Viramune XR | 6/21/2013 |
| Niacin | Extended-release Tablets | 500 mg, 750 mg and 1000 mg | Niaspan | |
| Niacin and Simvastatin | Extended-release Tablets | 500 mg/20 mg | Simcor | 2/12/2010 |
| Niacin and Simvastatin | Extended-release Tablets | 750 mg/20 mg | Simcor | 2/17/2010 |
| Niacin and Simvastatin | Extended-release Tablets | 1000 mg/20 mg | Simcor | 9/17/2009 |
| Niacin and Simvastatin | Extended-release Tablets | 1000 mg/40 mg | Simcor | 2/4/2011 |
| Niacin and Simvastatin | Extended-release Tablets | 500 mg/40 mg | Simcor | 2/9/2011 |
| Nicardipine Hydrochloride | Injection | 2.5 mg/mL, 10 mL Ampoules | Cardene | 12/27/2006 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---------------------------|--------------------------|---|--|---------------------------|
| Nicardipine Hydrochloride | Injection | 0.1 mg/mL, 200 mL and 0.2mg/mL, 200 mL | Cardene in 0.86% Sodium Chloride in plastic container and Cardene 0.83% Sodium Chloride in plastic container | 1/9/2013 |
| Nicotine | Transdermal System | 7 mg/day, 14 mg/day and 21 mg/day | Habitrol | |
| Nicotine | Transdermal System | 7 mg/24 hrs, 14 mg/24 hrs, and 21 mg/24 hrs | Nicoderm CQ | 5/30/2014 |
| Nicotine Polacrilex | Troche/Lozenge | 2 mg and 4 mg | Commit | |
| Nifedipine | Capsules | 10 mg and 20 mg | Procardia | |
| Nifedipine | Extended-release Tablets | 30 mg, 60 mg and 90 mg | Adalat CC | |
| Nifedipine | Extended-release Tablets | 30 mg, 60 mg and 90 mg | Procardia XL | |
| Nilotinib NEW | Capsules | 150 mg and 200 mg | Tasigna | 1/29/2013 |
| Nitric Oxide NEW | for Inhalation | 100 ppm and 800 ppm | INOmax | 5/20/2014 |
| Nisoldipine | Extended-release Tablets | 8.5 mg and 17 mg | Sular | 3/2/2009 |
| Nisoldipine | Extended-release Tablets | 20 mg and 30 mg | Sular | 11/7/2007 |
| Nisoldipine | Extended-release Tablets | 25.5 mg and 34 mg | Sular | 11/28/2008 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|--------------------------|---|---------------------------|---------------------------|
| Nisoldipine | Extended-release Tablets | 40 mg | Sular | 6/11/2007 |
| Nitrofurantoin Monohydrate/ Macrocrystals | Capsules | 75 mg/25 mg | Macrobid | |
| Nitroglycerin* | Sublingual Tablets | 0.3 mg, 0.4 mg, and 0.6 mg | Nitrostat | 10/19/2005 |
| Nitroglycerin | Transdermal System | 0.1 mg/hr | Transderm- Nitro | |
| Nitroglycerin | Transdermal System | 0.1 mg/hr, 0.2 mg/hr, 0.3 mg/hr, 0.4 mg/hr, 0.6 mg/hr and 0.8 mg/hr | Nitro-dur | |
| Nitroglycerin | Sublingual Spray | 400 mcg/spray, 4.9 g and 12 g bottles | Nitrolingual Pumpspray | 4/17/2012 |
| Nizatidine | Capsules | 150 mg and 300 mg | Axid | |
| Nizatidine | Oral Solution | 15 mg/mL | Axid | 5/14/2008 |
| 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 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|--------------------|---|--|---------------------------|
| 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 | |
| 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 | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|-------------------------------|---|-----------------------------|---------------------------|
| 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 |
| 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 | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---------------------------|-------------------------------------|---------------------------------------|------------------------|---------------------------|
| 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 |
| 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 |

**Paragraph IV Patent Certifications
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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|----------------------------|--------------------------|---|-----------------------|---------------------------|
| 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 |
| 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 |
| Paroxetine | Capsules | 7.5 mg | Brisdelle | 4/7/2014 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|--|--|--------------------------|--------------------------------|
| 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 | |
| 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 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|---|--|--------------------------|---------------------------|
| 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 |
| 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 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|---------------------------|--|-------------|---------------------------|
| 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 |
| 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 | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|-------------------------------------|------------------------------------|------------------------------------|---------------------------|
| 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 | |
| Ribavirin | for Inhalation Solution | 6 gm/vial | Virazole | 5/22/2014 |
| 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 |
| 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 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|-------------------------------|--|------------|---------------------------|
| 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 |
| 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 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|-----------------------------------|--|---------------|---------------------------|
| 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 |
| Rufinamide | Oral Suspension | 40 mg/mL | Banzel | 6/16/2014 |
| 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 |
| 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 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|--------------------------|--|-----------------------|---------------------------|
| 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 |
| 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 |
| Sorafenib Tosylate | Tablets | 200 mg | Nexavar | 2/28/2014 |
| 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 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|-------------------------------------|---------------------------|---|--------------|---------------------------|
| 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 |
| 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 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|-------------------------------|---------------------|----------------------------------|------------|---------------------------|
| 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 | 1% (pump) | Androgel | 12/19/2008 |
| Testosterone | Gel | 1.62% (pump) | Androgel | 4/6/2012 |
| Testosterone | Gel | 1.62% (1.25 g and 2.5 g packets) | Androgel | 6/19/2013 |
| 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 |
| Thalidomide | Capsules | 150 mg | Thalomid | 2/3/2014 |
| Tiagabine Hydrochloride | Tablets | 2 mg and 4 mg | Gabitril | 2/1/2005 |
| 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 |

**Paragraph IV Patent Certifications
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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|---------------------------|--------------------------------|------------------|---------------------------|
| 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 |
| Topiramate | Extended-release Capsules | 25 mg, 50 mg, and 100 mg | Trokendi XR | 5/12/2014 |
| Torsemide | 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 | |
| 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 |

**Paragraph IV Patent Certifications
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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|-------------------------------------|-------------------------------|--|---------------|---------------------------|
| 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 |
| Ulipristal Acetate | Tablets | 30 mg | Ella | 8/13/2014 |
| Unoprostone Isopropyl | Ophthalmic Solution | 0.15% | Rescula | 5/12/2014 |
| 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 |

**Paragraph IV Patent Certifications
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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---------------------------|---------------------------|---|---------------------------|---------------------------|
| Varenicline Tartrate | Tablets | 0.5 mg and 1 mg | Chantix | 5/10/2010 |
| 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 |

**Paragraph IV Patent Certifications
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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|-------------------|--------------------------|--------------------|------------|---------------------------|
| Zolpidem Tartrate | Extended-release Tablets | 12.5 mg | Ambien CR | 1/19/2006 |
| 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 | | | | |