

**Paragraph IV Patent Certifications
January 6, 2014**

| 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 |
| 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 |
| 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 |
| Alfuzosin Hydrochloride | Extended-release Tablets | 10 mg | Uroxatral | 6/12/2007 |
| 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 |

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| 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 | Ethyol | 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 |
| 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 |

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| 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 |
| 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 |
| 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 |

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|--|-------------------------|---|--------------------|---------------------------|
| 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 |
| Azithromycin | for Injection | 500 mg/vial | Zithromax | 6/17/2011 |
| Azithromycin | Ophthalmic Solution | 1% | Azasite | 3/3/2011 |
| Bendamustine Hydrochloride NEW | Injection | 25 mg/vial and 100 mg/vial | Treanda | 6/4/2013 |
| Bepotastine Besilate NEW | 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 | |
| Brimonidine Tartrate and Timolol Maleate | Ophthalmic Solution | 0.2%/0.5% | Combigan | 11/21/2008 |
| Bromfenac Sodium NEW | 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 |
| Buprenorphine Hydrochloride and Naloxone Hydrochloride | Sublingual Film | 2 mg/0.5 mg and 8 mg/2 mg | Suboxone | 10/15/2012 |

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| 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 | |
| Buspirone Hydrochloride | Tablets | 5 mg, 7.5 mg, 10 mg, 15 mg and 30 mg | Buspar | |
| Busulfan | Injection | 6 mg/mL | Busulfex | 6/20/2013 |
| Butoconazole Nitrate | Vaginal Cream | 2% | Gynazole-1 | 12/23/2009 |
| Butorphanol Tartrate | Nasal Spray | 10 mg/mL | Stadol NS | |
| 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 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 |

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| 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 |
| 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 |

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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 | Cytosan | |
| 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 |

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| Darunavir Ethanolate | Tablets | 75 mg, 150 mg, 300 mg, 400 mg and 600 mg | Prezista | 6/23/2010 |
| 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 | Clarinex | 6/21/2006 |
| Desloratadine | Orally Disintegrating Tablets | 2.5 mg and 5 mg | Clarinex | 6/21/2006 |
| Desloratadine | Oral Solution | 0.5 mg/mL | Clarinex Syrup | 5/8/2008 |
| Desloratadine and Pseudoephedrine Sulfate | Extended-release Tablets | 2.5 mg/120 mg | Clarinex-D 24 Hour | 6/1/2007 |
| Desloratadine and Pseudoephedrine Sulfate | Extended-release Tablets | 5 mg/240 mg | Clarinex-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 |
| Desvenlafaxine Succinate | Extended-release Tablets | 50 mg and 100 mg | Pristiq | 2/29/2012 |
| 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 |
| 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 |

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| 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 |
| 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 |

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|---|-------------------------------|---|-------------|---------------------------|
| Diclofenac Sodium | Topical Solution | 1.5% | Pennsaid | 7/11/2012 |
| 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 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 |
| 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 |
| 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 | |

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

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|---------------------------|---|-----------------------|---------------------------|
| Eletriptan Hydrobromide | Tablets | 20 mg and 40 mg | Relpax | 3/29/2010 |
| 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 | |
| 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 | 6/20/2013 |
| 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 | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---------------------------------------|--------------------------|--|-------------|---------------------------|
| Esomeprazole Magnesium | Delayed-release Capsules | 20 mg and 40 mg | Nexium | 8/5/2005 |
| 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 | 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 mg/24 hour | Nuvaring | 6/17/2013 |
| Etodolac | Extended-release Tablets | 400 mg, 500 mg and 600 mg | Lodine XL | |
| 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 |
| 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 | |

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

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|---------------------------|-----------------------------------|------------------------------|---------------------------|
| 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 | |
| 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 | |
| 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 |
| Fulvestrant | Injection | 50 mg/mL, 2.5 mL and 5 mL syringe | Faslodex | 10/1/2009 |
| 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 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|---------------------------|---|-------------------|---------------------------|
| 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 | Monopril HCT | |
| Frovatriptan Succinate | Tablets | 2.5 mg | Frova | 3/9/2011 |
| 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 | |
| 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 | Copaxane | 12/27/2007 |
| 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 | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|--------------------------|--|---------------------|---------------------------|
| 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 | |
| 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 | Kytril | 3/8/2007 |
| 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 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 |

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

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|------------------------------------|---------------------------|--|------------------|---------------------------|
| Ifosfamide/ Mesna | Injection/ Injection Kit | 50 mg/mL, 20 mL and 60 mL vials; 100 mg/mL, 10 mL vial | Ifex/ Mesnex Kit | |
| lloperidone | Tablets | 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, & 12 mg | Fanapt | 5/6/2013 |
| Imatinib Mesylate | Tablets | 100 mg and 400 mg | Gleevec | 3/12/2007 |
| Imiquimod | Cream | 5% | Aldara | 10/17/2006 |
| 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 mg/12.5 mg | 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 |
| Itraconazole | Capsules | 100 mg | Sporanox | |
| Itraconazole | Oral Solution | 10 mg/mL | Sporanox | 5/3/2013 |
| Ixabepilon | Injection | 15 mg/vial and 45 mg/vial, | 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 | |
| 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 |

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

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|---------------------|--|--|---------------------------|
| 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 |
| 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 |
| 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 and 0.3 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 | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|-------------------------------|--------------------------------|--------------------|---------------------------|
| 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 |
| 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 NEW | Extended-release Capsules | 7 mg, 14 mg, 21 mg, and 28 mg | Namenda XR | 8/16/2013 |
| 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 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|-----------------------------------|----------------------------------|--|-----------------------------------|---------------------------|
| 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 |
| 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 |
| 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 |
| Miconazole Nitrate | Vaginal Cream and Suppository | 2% and 1.2 g | Monistat 1 Combination Pack | 12/5/2007 |

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

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

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|--------------------------|--|--|---------------------------|
| Nicardipine Hydrochloride | Injection | 2.5 mg/mL, 10 mL Ampoules | Cardene | 12/27/2006 |
| 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 | 6/20/2013 |
| Nicotine | Transdermal System | 7 mg/day, 14 mg/day and 21 mg/day | Habitrol | |
| 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 | |
| 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 |
| 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 | |

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

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

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

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

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|-------------------------------|---|--------------|---------------------------|
| Paclitaxel | Injection | 6 mg/mL, 5 mL, 16.7 mL, 25 mL, 33.3 mL and 50 mL | Taxol | |
| Palonosetron Hydrochloride | Injection | 0.05 mg/mL, 1.5 mL and 5 mL vials | 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 |
| 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 |
| 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 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|---|---|--------------------------|--------------------------------|
| Pioglitazone Hydrochloride and Metformin Hydrochloride | Extended-release Tablets | 15 mg/1000 mg and 30 mg/1000 mg | 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 |
| Plerixafor | Injection | 24 mg/1.2 mL vials (20 mg/mL) | Mozobil | 12/17/2012 |
| Polyethylene Glycol 3350 | Powder for Oral Solution | 17g/Scoopful | Miralax | |
| Polyethylene Glycol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride and Bisacodyl | For Oral Solution and Delayed-release Tablet | 210 g, 5.6 g, 0.74 g, 2.86 g and 5 mg (1 Tablet Regimen) | Halflytely and Bisacodyl | 7/30/2010 |
| Polyethylene Glycol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride and Bisacodyl | For Oral Solution and Delayed-release Tablets | 210 g, 5.6 g, 0.74 g, 2.86 g and 5 mg (2 Tablet Regimen) | Halflytely and Bisacodyl | 1/28/2008 |
| Polyethylene Glycol 3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate and Ascorbic Acid | 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 | |
| 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 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|-------------------------------|-------------------------------|--|-------------|---------------------------|
| Pramipexole Dihydrochloride | Extended-release Tablets | 2.25 mg and 3.75 mg | Mirapex ER | 7/26/2011 |
| 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 |
| Pregabalin | 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 | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|----------------------------|--|---|---------------------------|
| Quinapril Hydrochloride/ Hydrochlorothiazide | Tablets | 10 mg/12.5 mg, 20 mg/12.5 mg and 20mg/25 mg | Accuretic | |
| Rabeprazole Sodium | Delayed-release Tablets | 20 mg | Aciphex | |
| Regadenoson | Injection | 0.08 mg/mL, 5 mL vial | Lexiscan | 4/10/2012 |
| Raltegravir | Tablets | 400 mg | Isentress | 10/12/2011 |
| Raloxifene Hydrochloride | Tablets | 60 mg | Evista | |
| Ramelteon | Tablets | 8 mg | Rozerem | 7/22/2009 |
| Ramipril | Capsules | 1.25 mg, 2.5 mg, 5 mg and 10 mg | Altace | |
| Ranitidine | Capsules | 150 mg and 300 mg | Zantac | |
| Ranitidine | Injection | 25 mg/mL, 2 mL and 6 mL and 40 mL vials | Zantac | |
| Ranitidine | Oral Solution | 15 mg/mL | Zantac | |
| Ranitidine | Tablets | 75 mg, 150 mg and 300 mg | Zantac | |
| Ranitidine Hydrochloride | Tablets | 150 mg | Zantac 150 (NDA 21698/Product 002) | 10/30/2007 |
| Ranolazine | Extended-release | 500 mg and 1000 mg | Renexa | 5/17/2010 |
| Rasagiline Mesylate | Tablets | 0.5 mg and 1 mg | Azilect | 5/17/2010 |
| Repaglinide | Tablets | 0.5 mg*, 1 mg and 2 mg | Prandin | 2/10/2005 |
| Repaglinide and Metformin Hydrochloride* | Tablets | 1 mg/500 mg and 2 mg/500 mg | Prandimet | 4/9/2009 |
| Ribavirin | Capsules | 200 mg | Rebetol | |
| Risedronate Sodium | Tablets | 5 mg, 30 mg and 35 mg | Actonel | 4/23/2004 |
| Risedronate Sodium | Tablets | 75 mg | Actonel | 9/10/2007 |
| Risedronate Sodium | Tablets | 150 mg | Actonel | 8/12/2008 |
| Risedronate Sodium | Delayed-release Tablets | 35 mg | Atelvia | 6/9/2011 |
| Risedronate Sodium with Calcium Carbonate * | Tablets | 35 mg; 500 mg | Actonel with Calcium | 12/18/2007 |
| Risperidone | Oral Solution | 1 mg/mL | Risperdal | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---------------------------|-------------------------------------|------------------------------------|------------|---------------------------|
| Risperidone | Tablets | 0.25 mg, 1 mg, 2 mg, 3 mg and 4 mg | Risperdal | |
| Risperidone | Orally Disintegrating Tablets | 0.25 mg | Risperdal | 4/11/2005 |
| Risperidone | Orally Disintegrating Tablets | 0.5 mg, 1 mg and 2 mg | Risperdal | |
| Risperidone | Orally Disintegrating Tablets | 3 mg and 4 mg | Risperdal | 3/23/2005 |
| Ritonavir | Tablets | 100 mg | Norvir | 12/21/2010 |
| Ritonavir | Capsules | 100 mg | Norvir | 10/31/2012 |
| Rivastigmine Tartrate | Capsules | 1.5 mg, 3 mg, 4.5 mg and 6 mg | Exelon | 4/21/2004 |
| Rivastigmine Tartrate | Oral Solution | 2 mg/mL | Exelon | 11/5/2004 |
| Rivastigmine | Transdermal System Extended-release | 4.6 mg/24 hr and 9.5 mg/24 hr | Exelon | 4/27/2011 |
| Rivastigmine | Transdermal System Extended-release | 13.3 mg/24 hr | Exelon | 1/22/2013 |
| Rizatriptan Benzoate | Tablets | 5 mg and 10 mg | Maxalt | 9/2/2004 |
| Rizatriptan Benzoate | Orally Disintegrating Tablets | 5 mg and 10 mg | Maxalt-MLT | 2/17/2006 |
| Rofecoxib | Tablets | 12.5 mg, 25 mg and 50 mg | Vioxx | |
| 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 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---|----------------------------|--|------------|---------------------------|
| 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 |
| Rufinamide | Tablets | 100 mg, 200 mg and 400 mg | Banzel | 11/14/2012 |
| 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 |
| Sirolimus | Tablets | 1 mg and 2 mg | Rapamune | 12/17/2009 |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|--------------------------|---|-----------------------|---------------------------|
| 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, and 50 mg/40 mg | Juvisync | 11/6/2012 |
| Sumatriptan Succinate | Injection | 6 mg/0.5 mL, 0.5 mL vials | Imitrex | 10/25/2004 |
| Sumatriptan Succinate* | Injection | 6 mg/0.5 mL, 0.5 mL (prefilled syringes) | Imitrex | 5/9/2006 |
| Sumatriptan Succinate | Tablets | 25 mg, 50 mg and 100 mg | Imitrex | |
| Sunitinib Malate | Capsules | 12.5 mg, 25 mg, 37.5 mg and 50 mg | Sutent | 1/26/2010 |
| Tacrolimus | Ointment | 0.03% | Protopic | 11/22/2010 |
| Tacrolimus | Ointment | 0.10% | Protopic | 9/9/2010 |
| Tadalafil | Tablets | 2.5 mg | Cialis | 10/14/2008 |

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

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|--|---------------------------|--------------------------------|------------------|---------------------------|
| Thalidomide | Capsules | 50 mg and 100 mg | Thalomid | 12/18/2006 |
| Thalidomide | Capsules | 200 mg | Thalomid | 9/25/2006 |
| Tiagabine Hydrochloride | Tablets | 2 mg and 4 mg | Gabitril | 2/1/2005 |
| Ticlopidine Hydrochloride | Tablets | 250 mg | Ticlid | |
| Tigecycline | For Injection | 50 mg per vial | Tygacil | 6/15/2009 |
| Timolol Maleate | Ophthalmic Solution | 0.25% and 0.5% | Timoptic | |
| Timolol Maleate | Ophthalmic Solution | 0.5% | Istalol | 10/19/2012 |
| Tizanidine Hydrochloride | Capsules | 2 mg, 4 mg and 6 mg | Zanaflex | 8/10/2007 |
| Tobramycin | Inhalation Solution | 300 mg/5 mL | Tobi | 6/29/2009 |
| Tolterodine Tartrate | Extended-release Capsules | 2 mg and 4 mg | Detrol LA | 7/30/2007 |
| Tolterodine Tartrate* | Tablets | 1 mg and 2 mg | Detrol | |
| 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 |
| 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 |

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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 |
| Valacyclovir Hydrochloride | Tablets | 500 mg and 1000 mg | Valtrex | |
| Valganciclovir Hydrochloride | for Oral Solution | 50 mg/mL | Valcyte | 3/21/2011 |
| Valganciclovir Hydrochloride | Tablets | 450 mg | Valcyte | 12/27/2005 |
| Valsartan | Tablets | 40 mg, 80 mg, 160 mg and 320 mg | Diovan | 12/28/2004 |
| Valsartan and Hydrochlorothiazide | Tablets | 80 mg/12.5 mg, 160 mg/12.5 mg and 160 mg/25 mg | Diovan HCT | 12/2/2005 |
| Valsartan and Hydrochlorothiazide | Tablets | 320 mg/12.5 mg and 320 mg/25 mg | Diovan HCT | 2/7/2007 |
| Vardenafil Hydrochloride | Tablets | 2.5 mg | Levitra | 9/4/2009 |
| Vardenafil Hydrochloride | Tablets | 5 mg and 10 mg | Levitra | 7/10/2009 |
| Vardenafil Hydrochloride | Tablets | 20 mg | Levitra | 3/5/2009 |
| Vardenafil Hydrochloride | Orally Disintegrating Tablets | 10 mg | Staxyn | 12/22/2011 |
| Varenicline Tartrate | Tablets | 0.5 mg and 1 mg | Chantix | 5/10/2010 |
| 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 | |

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| DRUG NAME | DOSAGE FORM | STRENGTH | RLD | DATE OF SUBMISSION |
|---------------------------|---------------------------|---|---------------------------|---------------------------|
| 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 |
| Zolpidem Tartrate | Extended-release Tablets | 6.25 mg | Ambien CR | 2/24/2006 |
| Zolpidem Tartrate | Extended-release Tablets | 12.5 mg | Ambien CR | 1/19/2006 |
| 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 | | | | |