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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
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
Alprazolam	Orally Disintegrating Tablets	0.25 mg, 0.5 mg, 1 mg and 2 mg	Niravam	12/27/2005

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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
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

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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
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	
Azelastine Hydrochloride	Nasal Spray	0.125 mg base/spray	Astelin	11/14/2005

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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
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
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
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	Tablets	75 mg and 100 mg	Wellbutrin	
Buspirone Hydrochloride	Tablets	5 mg, 7.5 mg, 10 mg, 15 mg and 30 mg	Buspar	
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

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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
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

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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
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	

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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	12/6/2010
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
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/Packet and 3.75 g/Packet	Welchol	4/9/2010

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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	
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
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	

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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
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

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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 Sodium	Topical Gel	3%	Solaraze	12/16/2009
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, 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
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

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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
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
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
Duloxetine Hydrochloride	Delayed-release Capsules	20 mg, 30 mg and 60 mg	Cymbalta	8/4/2008
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

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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
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; 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
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	
Famotidine	Tablets	20 mg and 40 mg	Pepcid	
Famotidine	Tablets (Chewable)	10 mg (OTC)	Pepcid AC (chewable)	
Felodipine	Extended-release Tablets	2.5 mg, 5 mg and 10 mg	Plendil ER	

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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	
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	

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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
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

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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	
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

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Granisetron Hydrochloride	Injection	0.1 mg/mL, 1 mL single dose vial	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
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	

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Ibuprofen	Chewable Tablets	50 mg and 100 mg	Children's Motrin, Junior Strength Motrin	
Ibupofen 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	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	
Ifosfamide/ Mesna	Injection/ Injection Kit	50 mg/mL, 20 mL and 60 mL vials; 100 mg/mL, 10 mL vial	Ifex/ Mesnex Kit	
Imatinib Mesylate	Tablets	100 mg and 400 mg	Gleevec	3/12/2007
Imiquimod	Cream	5%	Aldara	10/17/2006
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
Itraconazole	Capsules	100 mg	Sporanox	
Ketoconazole	Foam	2%	Extina	7/30/2009

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Ketoprofen	Capsules	25 mg, 50 mg and 75 mg	Orudis	
Ketorolac Tromethamine	Injection	15 mg/mL and 30 mg/mL	Toradol	
Ketorolac Tromethamine	Opthalmic 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
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

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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
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

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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
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
Metaxalone	Tablets	400 mg	Skelaxin	

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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	
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
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

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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	
Nitroglycerin	Transdermal System	0.1 mg/hr, 0.2 mg/hr, 0.3 mg/hr, 0.4	Nitro-dur	
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
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
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
Oxycodone Hydrochloride **NEW**	Tablets	5 mg and 7.5 mg	Oxecta	2/8/2012
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 vials	Aloxi	5/27/2011
Pamidronate Disodium	For Injection	30 mg/vial, 60 mg/vial and 90 mg/vial	Aredia	

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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
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 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
Polyethylene Glycol 3350	Powder for Oral Solution	17g/Scoopful	Miralax	

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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 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
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

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Pregabalin	Capsules	25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg	Lyrica	12/30/2008
Pregablin	Oral Solution	20 mg/mL	Lyrica	5/19/2010
Propafenone	Extended-release Capsules	325 mg	Rythmol SR	11/07/2006
Propafenone Hydrochloride	Extended-release Capsules	225 mg and 425 mg	Rythmol SR	10/11/2006
Propofol	Injection	10 mg/mL ; 20 mL, 50 mL and 100 mL vials and 20 mL syringe	Diprivan	
Propranolol Hydrochloride	Extended-release Capsules	60 mg, 80 mg, 120 mg and 160 mg	Inderal LA	
Quetiapine Fumarate	Extended-release Tablets	400 mg	Seroquel XR	6/18/2008
Quetiapine Fumarate	Extended-release Tablets	150 mg	Seroquel XR	11/17/2008
Quetiapine Fumarate	Extended-release Tablets	200 mg and 300 mg	Seroquel XR	6/12/2008
Quetiapine Fumarate	Extended-release Tablets	50 mg	Seroquel XR	10/17/2008
Quetiapine Fumarate	Tablets	25 mg	Seroquel	8/12/2005
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 **NEW**	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	Altace	

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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	
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
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 Patch	4/27/2011
Rizatriptan Benzoate	Tablets	5 mg and 10 mg	Maxalt	9/2/2004

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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
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	

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
Silver Sulfadiazine	Cream	1%	Silvadene	
Simvastatin	Tablets	5 mg, 10 mg, 20 mg, 40 mg and 80 mg	Zocor	
Sirolimus	Tablets	0.5 mg	Rapamune	8/25/2010
Sirolimus	Tablets	1 mg and 2 mg	Rapamune	12/17/2009
Sodium Phosphate Monobasic Monohydrate and Sodium PhosphateDibasic 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
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
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	

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Tamsulosin Hydrochloride	Capsules	0.4 mg	Flomax	12/20/2004
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 **NEW**	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
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	
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

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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	
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

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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 mg, 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				