

**Paragraph IV Patent Certifications
December 16, 2014**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Nicotine	Transdermal System	7 mg/24 hrs, 14 mg/24 hrs, and 21 mg/24 hrs	Nicoderm CQ	5/30/2014
Nicotine Polacrilex	Troche/Lozenge	2 mg and 4 mg	Commit	
Nifedipine	Capsules	10 mg and 20 mg	Procardia	
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Adalat CC	
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Procardia XL	
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	
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

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

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

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

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

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Pamidronate Disodium	For Injection	30 mg/vial, 60 mg/vial and 90 mg/vial	Aredia	
Pamidronate Disodium	Injection	30 mg/vial, 60 mg/vial and 90 mg/vial	Aredia	
Pantoprazole Sodium	For Injection	40 mg/vial	Prontonix IV	4/7/2005
Pantoprazole Sodium	Delayed-release Tablets	20 mg and 40 mg	Protonix	2/2/2004
Paricalcitol	Injection	0.002 mg per mL in 1 mL vial and 0.005 mg per mL in 1 mL and 2 mL vials	Zemplar	11/28/2008
Paricalcitol	Capsules	1 mcg and 2 mcg	Zemplar	10/14/2008
Paricalcitol	Capsules	4 mcg	Zemplar	8/25/2008
Paroxetine Hydrochloride	Capsules	10 mg and 20 mg	Paxil	
Paroxetine Hydrochloride	Oral Suspension	10 mg/5 mL	Paxil	2/10/2005
Paroxetine Hydrochloride	Tablets	10 mg, 20 mg, 30 mg and 40 mg	Paxil	
Paroxetine Hydrochloride	Extended-release Tablets	25 mg	Paxil CR	9/9/2005
Paroxetine Hydrochloride	Extended-release Tablets	37.5 mg	Paxil CR	5/19/2009
Paroxetine	Capsules	7.5 mg	Brisdelle	4/7/2014
Pemetrexed Disodium	For Injection	100 mg/vial	Alimta	7/1/2008
Pemetrexed Disodium	For Injection	500 mg/vial	Alimta	2/4/2008
Pemetrexed Disodium	For Injection	1000 mg/vial	Alimta	6/27/2012
Pergolide Mesylate	Tablets	0.05 mg, 0.25 mg and 1 mg	Permax	
Perindopril Erbumine	Tablets	2 mg, 4 mg and 8 mg	Aceon	6/6/2006
Phentermine Hydrochloride	Orally Disintegrating Tablets	15 mg and 30 mg	Suprenza	10/19/2012
Phentermine Hydrochloride	Orally Disintegrating Tablets	37.5 mg	Suprenza	3/22/2013
Phentermine Hydrochloride and Topiramate	Extended-release Capsules	3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg, 15 mg/92 mg	Qsymia	7/18/2013

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Pioglitazone Hydrochloride	Tablets	15 mg, 30 mg and 45 mg	Actos	
Pioglitazone Hydrochloride and Glimepiride	Tablets	30 mg/2 mg and 30 mg/4 mg	Duetact	12/22/2009
Pioglitazone Hydrochloride and Metformin	Extended-release Tablets	15 mg/1000 mg and 30 mg/1000	Actoplus Met XR	9/23/2011
Pioglitazone Hydrochloride and Metformin Hydrochloride	Tablets	15 mg/500 mg and 15 mg/850 mg	Actoplus Met	3/6/2008
Piperacillin Sodium and Tazobactam Sodium	For Injection	2.25 g/vial, 3.375 g/vial, 4.5 g/vial	Zosyn	PIV received prior to 2/5/2009
Piperacillin Sodium and Tazobactam Sodium	For Injection	12 g/1.5 g per vial (pharmacy bulk)	Zosyn	12/6/2011
Pitavastatin Calcium	Tablets	1 mg, 2 mg, and 4 mg	Livalo	8/5/2013
Plerixafor	Injection	24 mg/1.2 mL vials (20	Mozobil	12/17/2012
Polyethylene Glycol 3350	Powder for Oral Solution	17g/Scoopful	Miralax	
Polyethylene Glycol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride and Bisacodyl	For Oral Solution and Delayed-release Tablet	210 g, 5.6 g, 0.74 g, 2.86 g and 5 mg (1 Tablet Regimen)	Halflytely and Bisacodyl	7/30/2010
Polyethylene Glycol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride and Bisacodyl	For Oral Solution and Delayed-release Tablets	210 g, 5.6 g, 0.74 g, 2.86 g and 5 mg (2 Tablet Regimen)	Halflytely and Bisacodyl	1/28/2008
Polyethylene Glycol 3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate	For Oral Solution	100 g, 7.5 g, 2.691 g, 1.015 g, 5.9 g and 4.7 g per pouch	Moviprep	11/27/2007
Posaconazole	Oral Suspension	40 mg/mL	Noxafil	2/28/2011
Potassium Chloride	Extended-release Capsules	8 mEq and 10 mEq	Micro K	
Potassium Chloride	Extended-release Tablets	10 mEq and 20 mEq	K-Dur	
Pralatrexate	Injection	20 mg/mL and 40 mg/2 mL	Folotyn	9/24/2013

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Pramipexole Dihydrochloride	Tablets	0.125 mg, 0.5 mg, 1 mg and 1.5 mg	Mirapex	6/24/2005
Pramipexole Dihydrochloride	Tablets	0.25 mg	Mirapex	5/27/2005
Pramipexole Dihydrochloride	Tablets	0.75 mg	Mirapex	7/31/2008
Pramipexole Dihydrochloride	Extended-release Tablets	0.375 mg, 0.75 mg, 1.5 mg, 3 mg and 4.5 mg	Mirapex ER	6/1/2010
Pramipexole Dihydrochloride	Extended-release Tablets	2.25 mg and 3.75 mg	Mirapex ER	7/26/2011
Prasugrel Hydrochloride	Tablets	5 mg and 10 mg	Effient	7/10/2013
Pravastatin Sodium	Tablets	10 mg, 20 mg, 40 mg and 80 mg	Pravachol	
Pravastatin Sodium	Tablets	30 mg	Pravachol	6/1/2005
Prazosin Hydrochloride	Capsules	1 mg, 2 mg and 5 mg	Minipress	
Prednisolone Sodium Phosphate	Oral Solution	5 mg(base)/ 5 mL and 15 mg (base)/ 5 mL	Pediapred	
Prednisolone Sodium Phosphate	Orally Disintegrating Tablets	10 mg, 15 mg and 30 mg	Orapred	7/22/2010
Prednisone	Delayed-release Tablets	1 mg, 2 mg, and 5 mg	Rayos	11/26/2012
Pregabalin	Capsules	25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg	Lyrica	12/30/2008
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

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Quetiapine Fumarate	Extended-release Tablets	150 mg	Seroquel XR	11/17/2008
Quetiapine Fumarate	Extended-release Tablets	200 mg and 300 mg	Seroquel XR	6/12/2008
Quetiapine Fumarate	Extended-release Tablets	50 mg	Seroquel XR	10/17/2008
Quetiapine Fumarate	Tablets	25 mg	Seroquel	8/12/2005
Quetiapine Fumarate	Tablets	50 mg, 150 mg and 400 mg	Seroquel	2/12/2007
Quetiapine Fumarate	Tablets	100 mg, 200 mg and 300 mg	Seroquel	2/21/2006
Quinapril Hydrochloride	Tablets	5 mg, 10 mg, 20 mg and 40 mg	Accupril	
Quinapril Hydrochloride/ Hydrochlorothiazide	Tablets	10 mg/12.5 mg, 20 mg/12.5 mg and 20mg/25 mg	Accuretic	
Rabeprazole Sodium	Delayed-release Tablets	20 mg	Aciphex	
Regadenoson	Injection	0.08 mg/mL, 5 mL vial	Lexiscan	4/10/2012
Raltegravir	Tablets	400 mg	Isentress	10/12/2011
Raloxifene Hydrochloride	Tablets	60 mg	Evista	
Ramelteon	Tablets	8 mg	Rozerem	7/22/2009
Ramipril	Capsules	1.25 mg, 2.5 mg, 5 mg and 10 mg	Altace	
Ranitidine	Capsules	150 mg and 300 mg	Zantac	
Ranitidine	Injection	25 mg/mL, 2 mL and 6 mL and 40 mL vials	Zantac	
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

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Ribavirin	Capsules	200 mg	Rebetol	
Ribavirin	for Inhalation Solution	6 gm/vial	Virazole	5/22/2014
Risedronate Sodium	Tablets	5 mg, 30 mg and 35 mg	Actonel	4/23/2004
Risedronate Sodium*	Tablets	75 mg	Actonel	9/10/2007
Risedronate Sodium	Tablets	150 mg	Actonel	8/12/2008
Risedronate Sodium	Delayed-release Tablets	35 mg	Atelvia	6/9/2011
Risedronate Sodium with Calcium Carbonate *	Tablets	35 mg; 500 mg	Actonel with Calcium	12/18/2007
Risperidone	Oral Solution	1 mg/mL	Risperdal	
Risperidone	Tablets	0.25 mg, 1 mg, 2 mg, 3 mg and 4 mg	Risperdal	
Risperidone	Orally Disintegrating Tablets	0.25 mg	Risperdal	4/11/2005
Risperidone	Orally Disintegrating Tablets	0.5 mg, 1 mg and 2 mg	Risperdal	
Risperidone	Orally Disintegrating Tablets	3 mg and 4 mg	Risperdal	3/23/2005
Ritonavir	Tablets	100 mg	Norvir	12/21/2010
Ritonavir	Capsules	100 mg	Norvir	10/31/2012
Rivastigmine Tartrate	Capsules	1.5 mg, 3 mg, 4.5 mg and 6 mg	Exelon	4/21/2004
Rivastigmine Tartrate	Oral Solution	2 mg/mL	Exelon	11/5/2004
Rivastigmine	Transdermal System Extended-release	4.6 mg/24 hr and 9.5 mg/24 hr	Exelon	4/27/2011
Rivastigmine	Transdermal System Extended-release	13.3 mg/24 hr	Exelon	1/22/2013
Rizatriptan Benzoate	Tablets	5 mg and 10 mg	Maxalt	9/2/2004
Rizatriptan Benzoate	Orally Disintegrating Tablets	5 mg and 10 mg	Maxalt-MLT	2/17/2006
Rofecoxib	Tablets	12.5 mg, 25 mg and 50 mg	Vioxx	
Romidepsin	Injection	10 mg/vial	Istodax	11/5/2013
Ropinirole Hydrochloride	Extended-release Tablets	2 mg	Requip XL	10/14/2008
Ropinirole Hydrochloride	Extended-release Tablets	4 mg	Requip XL	10/31/2008

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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
Rotigotine	Extended-release Transdermal Film	1 mg/24 hr, 2 mg/24 hr, 3 mg/24 hr, 4 mg/24 hr, 6 mg/24 hr, and 8 mg/24 hr	Neupro	11/26/2013
Rufinamide	Tablets	100 mg, 200 mg and 400 mg	Banzel	11/14/2012
Rufinamide	Oral Suspension	40 mg/mL	Banzel	6/16/2014
Sapropterin Dihydrochloride	Tablets	100 mg	Kuvan	5/30/2014
Saxagliptin Hydrochloride	Tablets	2.5 mg and 5 mg	Onglyza	7/31/2013

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Saxagliptin Hydrochloride and Metformin Hydrochloride	Extended-release Tablets	5 mg/500 mg, 2.5 mg/1000 mg, and 5 mg/1000 mg	Kombiglyze XR	7/31/2013
Sertraline Hydrochloride	Oral Concentrate	20 mg/mL	Zoloft	
Sertraline Hydrochloride	Tablets	25 mg, 50 mg and 100 mg	Zoloft	
Sertraline Hydrochloride	Tablets	150 mg and 200 mg	Zoloft	11/9/2005
Sevelamer Carbonate	Powder for Oral Suspension	0.8 g/packet and 2.4 g/packet	Renvela	12/30/2009
Sevelamer Carbonate	Tablets	800 mg	Renvela	12/4/2008
Sevelamer Hydrochloride	Tablets	400 mg and 800 mg	Renagel	5/22/2008
Sevoflurane	Inhalation	100%, 250 mL	Ultane	
Sibutramine Hydrochloride	Capsules	10 mg and 15 mg	Meridia	8/14/2009
Sildenafil Citrate	Tablets	25 mg and 50 mg	Viagra	11/19/2004
Sildenafil Citrate	Tablets	100 mg	Viagra	10/25/2004
Silodosin	Capsules	4 mg and 8 mg	Rapaflo	10/9/2012
Silver Sulfadiazine	Cream	1%	Silvadene	
Simvastatin	Tablets	5 mg, 10 mg, 20 mg, 40 mg and 80 mg	Zocor	
Sirolimus	Tablets	0.5 mg	Rapamune	8/25/2010
Sirolimus	Tablets	1 mg and 2 mg	Rapamune	12/17/2009
Sodium Phosphate Monobasic Monohydrate and Sodium Phosphate Dibasic Anhydrous, USP	Tablets	1.102 g and 0.398 g	Osmoprep	4/9/2008
Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate	Oral Solution	17.5 g/3.13 g/1.6 g	Suprep Bowel Prep Kit	11/8/2010
Sodium Oxybate	Oral Solution	500 mg/mL	Xyrem	7/8/2010

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Solifenacin Succinate	Tablets	5 mg and 10 mg	Vesicare	4/8/2009
Sitagliptin Phosphate	Tablets	25 mg, 50 mg and 100 mg	Januvia	10/18/2010
Sitagliptin Phosphate and Metformin Hydrochloride	Tablets	50 mg/500 mg and 50 mg/1000 mg	Janumet	10/18/2010
Sitagliptin Phosphate and Metformin Hydrochloride	Extended-release Tablets	50 mg/500 mg and 50 mg/1000 mg	Janumet XR	3/16/2012
Sitagliptin Phosphate and Metformin Hydrochloride	Extended-release Tablets	100 mg/1000 mg	Janumet XR	10/22/2012
Sitagliptin Phosphate and Simvastatin	Tablets	100 mg/10 mg and 100 mg/40 mg	Juvisync	6/19/2012
Sitagliptin Phosphate and Simvastatin	Tablets	100 mg/20 mg	Juvisync	6/25/2012
Sitagliptin Phosphate and Simvastatin	Tablets	50 mg/10 mg, 50 mg/20 mg,	Juvisync	11/6/2012
Sorafenib Tosylate NEW	Tablets	200 mg	Nexavar	2/28/2014
Sumatriptan Succinate	Injection	6 mg/0.5 mL, 0.5 mL vials	Imitrex	10/25/2004
Sumatriptan Succinate*	Injection	6 mg/0.5 mL, 0.5 mL (prefilled syringes)	Imitrex	5/9/2006
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

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Tacrolimus	Extended-release Capsules	0.5 mg, 1 mg, and 5 mg	Astagraf XL	9/24/2013
Tadalafil	Tablets	2.5 mg	Cialis	10/14/2008
Tadalafil	Tablets	5 mg, 10 mg and 20 mg	Cialis	11/21/2007
Tadalafil	Tablets	20 mg	Adcirca	10/15/2009
Tamoxifen Citrate	Tablets	10 mg and 20 mg	Nolvadex	
Tamsulosin Hydrochloride	Capsules	0.4 mg	Flomax	12/20/2004
Tapentadol Hydrochloride	Tablets	50 mg, 75 mg, and 100 mg	Nucynta	11/20/2012
Tapentadol Hydrochloride	Extended-release Tablets	50 mg, 100 mg, 150 mg, 200 mg, and 250 mg	Nucynta ER	11/20/2012
Tapentadol	Oral Solution	20 mg/mL	Nucynta	12/20/2013
Telmisartan	Tablets	20 mg, 40 mg and 80 mg	Micardis	12/26/2006
Telmisartan and Hydrochlorothiazide	Tablets	80 mg/12.5 mg and 40 mg/12.5 mg	Micardis HCT	12/31/2008
Temazepam	Capsules	7.5 mg	Restoril	11/01/2006
Temozolomide	Capsules	5 mg, 20 mg, 100 mg, and 250 mg	Temodar	3/20/2007
Temozolomide	Capsules	140 mg and 180 mg	Temodar	3/24/2008
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	

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Testosterone	Gel	1%	Testim	8/21/2008
Testosterone	Gel	1% (pump)	Androgel	12/19/2008
Testosterone	Gel	1.62% (pump)	Androgel	4/6/2012
Testosterone	Gel	1.62% (1.25 g and 2.5 g packets)	Androgel	6/19/2013
Testosterone	Gel	10 mg/actuation	Fortesta	8/14/2012
Testosterone	Topical Solution	30 mg/1.5 mL	Axiron	1/29/2013
Testosterone Undecanoate	Injection	250 mg/mL	Aveed	6/11/2014
Thalidomide	Capsules	50 mg and 100 mg	Thalomid	12/18/2006
Thalidomide	Capsules	200 mg	Thalomid	9/25/2006
Thalidomide NEW	Capsules	150 mg	Thalomid	2/3/2014
Tiagabine Hydrochloride	Tablets	2 mg and 4 mg	Gabitril	2/1/2005
Ticlopidine Hydrochloride	Tablets	250 mg	Ticlid	
Tigecycline	For Injection	50 mg per vial	Tygacil	6/15/2009
Timolol Maleate	Ophthalmic Solution	0.25% and 0.5%	Timoptic	
Timolol Maleate	Ophthalmic Solution	0.5%	Istalol	10/19/2012
Tizanidine Hydrochloride	Capsules	2 mg, 4 mg and 6 mg	Zanaflex	8/10/2007
Tobramycin	Inhalation Solution	300 mg/5 mL	Tobi	6/29/2009
Tolterodine Tartrate	Extended-release Capsules	2 mg and 4 mg	Detrol LA	7/30/2007
Tolterodine Tartrate*	Tablets	1 mg and 2 mg	Detrol	
Tolvaptan	Tablets	15 mg and 30 mg	Samsca	9/23/2013
Topiramate	Capsules	15 mg and 25 mg	Topamax Sprinkle	9/7/2005
Topiramate	Tablets	25 mg, 100 mg and 200 mg	Topamax	12/26/2001
Topiramate	Tablets	50 mg	Topamax	9/8/2005
Topiramate	Extended-release Capsules	200 mg	Trokendi XR	4/3/2014

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Topiramate	Extended-release Capsules	25 mg, 50 mg, and 100 mg	Trokendi XR	5/12/2014
Torseamide	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
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	

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Trospium Chloride	Extended-release Capsules	60 mg	Sanctura XR	3/2/2009
Ulipristal Acetate	Tablets	30 mg	Ella	8/13/2014
Unoprostone Isopropyl NEW	Ophthalmic Solution	0.15%	Rescula	5/12/2014
Valacyclovir Hydrochloride	Tablets	500 mg and 1000 mg	Valtrex	
Valganciclovir Hydrochloride	for Oral Solution	50 mg/mL	Valcyte	3/21/2011
Valganciclovir Hydrochloride	Tablets	450 mg	Valcyte	12/27/2005
Valsartan	Tablets	40 mg, 80 mg, □ 160 mg and 320 mg	Diovan	12/28/2004
Valsartan and Hydrochlorothiazide	Tablets	80 mg/12.5 mg, 160 mg/12.5 mg and 160 mg/25 mg	Diovan HCT	12/2/2005
Valsartan and Hydrochlorothiazide	Tablets	320 mg/12.5 mg and 320 mg/25 mg	Diovan HCT	2/7/2007
Vardenafil Hydrochloride	Tablets	2.5 mg	Levitra	9/4/2009
Vardenafil Hydrochloride	Tablets	5 mg and 10 mg	Levitra	7/10/2009
Vardenafil Hydrochloride	Tablets	20 mg	Levitra	3/5/2009
Vardenafil Hydrochloride	Orally Disintegrating Tablets	10 mg	Staxyn	12/22/2011
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

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