

**Paragraph IV Patent Certifications
August 19, 2014**

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

**Paragraph IV Patent Certifications
August 19, 2014**

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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 Zydys	
Olanzapine and Fluoxetine Hydrochloride	Capsules	6 mg/25 mg, 12 mg/25 mg, 6 mg/50 mg and 12 mg/50 mg	Symbyax	1/10/2005
Olmesartan Medoxomil	Tablets	5 mg, 20 mg and 40 mg	Benicar	4/25/2006
Olmesartan Medoxomil and Hydrochlorothiazide	Tablets	20 mg/12.5 mg	Benicar HCT	5/11/2007
Olmesartan Medoxomil and Hydrochlorothiazide	Tablets	40 mg/12.5 mg and 40 mg/25 mg	Benicar HCT	2/15/2007
Olopatadine Hydrochloride	Nasal Spray	0.665 mg/ Spray	Patanase	6/29/2009
Olopatadine Hydrochloride	Ophthalmic Solution	0.1%	Patanol	7/17/2006
Olopatadine Hydrochloride	Ophthalmic Solution	0.2%	Pataday	9/8/2008
Omega-3-Acid Ethyl Esters	Capsules	1 g	Lovaza	11/10/2008
Omeprazole	Delayed-release Capsules	10 mg, 20 mg and 40 mg	Prilosec	
Omeprazole and Sodium Bicarbonate	Capsules	20 mg/1100 mg and 40 mg/1100 mg	Zegerid	4/30/2007
Omeprazole and Sodium Bicarbonate	Capsules	20 mg/1100 mg	Zegerid OTC	4/20/2010
Omeprazole and Sodium Bicarbonate	Powder for Oral Suspension	20mg/1680mg per packet	Zegerid	11/13/2007
Omeprazole and Sodium Bicarbonate	Powder for Oral Suspension	40 mg/1680 mg per packet	Zegerid	8/24/2007

**Paragraph IV Patent Certifications
August 19, 2014**

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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
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

**Paragraph IV Patent Certifications
August 19, 2014**

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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,	Taxol	
Palonosetron Hydrochloride	Injection	0.05 mg/mL, 1.5 mL and 5 mL vials	Aloxi	5/27/2011
Pamidronate Disodium	For Injection	30 mg/vial, 60 mg/vial and 90 mg/vial	Aredia	
Pamidronate Disodium	Injection	30 mg/vial, 60 mg/vial and 90 mg/vial	Aredia	
Pantoprazole Sodium	For Injection	40 mg/vial	Prontonix IV	4/7/2005
Pantoprazole Sodium	Delayed-release Tablets	20 mg and 40 mg	Protonix	2/2/2004
Paricalcitol	Injection	0.002 mg per mL in 1 mL vial and 0.005 mg per mL in 1 mL and 2 mL vials	Zemplar	11/28/2008

**Paragraph IV Patent Certifications
August 19, 2014**

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Paricalcitol	Capsules	1 mcg and 2 mcg	Zemplar	10/14/2008
Paricalcitol	Capsules	4 mcg	Zemplar	8/25/2008
Paroxetine Hydrochloride	Capsules	10 mg and 20 mg	Paxil	
Paroxetine Hydrochloride	Oral Suspension	10 mg/5 mL	Paxil	2/10/2005
Paroxetine Hydrochloride	Tablets	10 mg, 20 mg, 30 mg and 40 mg	Paxil	
Paroxetine Hydrochloride	Extended-release Tablets	25 mg	Paxil CR	9/9/2005
Paroxetine Hydrochloride	Extended-release Tablets	37.5 mg	Paxil CR	5/19/2009
Pemetrexed Disodium	For Injection	100 mg/vial	Alimta	7/1/2008
Pemetrexed Disodium	For Injection	500 mg/vial	Alimta	2/4/2008
Pemetrexed Disodium	For Injection	1000 mg/vial	Alimta	6/27/2012
Pergolide Mesylate	Tablets	0.05 mg, 0.25 mg and 1 mg	Permax	
Perindopril Erbumine	Tablets	2 mg, 4 mg and 8 mg	Aceon	6/6/2006
Phentermine Hydrochloride	Orally Disintegrating Tablets	15 mg and 30 mg	Suprenza	10/19/2012
Phentermine Hydrochloride	Orally Disintegrating Tablets	37.5 mg	Suprenza	3/22/2013
Phentermine Hydrochloride and Topiramate	Extended-release Capsules	3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg, 15 mg/92 mg	Qsymia	7/18/2013
Pioglitazone Hydrochloride	Tablets	15 mg, 30 mg and 45 mg	Actos	
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
Pitavastatin Calcium	Tablets	1 mg, 2 mg, and 4 mg	Livalo	8/5/2013

**Paragraph IV Patent Certifications
August 19, 2014**

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Plerixafor	Injection	24 mg/1.2 mL vials (20 mg/mL)	Mozobil	12/17/2012
Polyethylene Glycol 3350	Powder for Oral Solution	17g/Scoopful	Miralax	
Polyethylene Glycol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride and Bisacodyl	For Oral Solution and Delayed-release Tablet	210 g, 5.6 g, 0.74 g, 2.86 g and 5 mg (1 Tablet Regimen)	Halflytely and Bisacodyl	7/30/2010
Polyethylene Glycol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride and Bisacodyl	For Oral Solution and Delayed-release Tablets	210 g, 5.6 g, 0.74 g, 2.86 g and 5 mg (2 Tablet)	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	
Pralatrexate	Injection	20 mg/mL and 40 mg/2 mL	Folotyn	9/24/2013
Pramipexole Dihydrochloride	Tablets	0.125 mg, 0.5 mg, 1 mg and 1.5 mg	Mirapex	6/24/2005
Pramipexole Dihydrochloride	Tablets	0.25 mg	Mirapex	5/27/2005
Pramipexole Dihydrochloride	Tablets	0.75 mg	Mirapex	7/31/2008
Pramipexole Dihydrochloride	Extended-release Tablets	0.375 mg, 0.75 mg, 1.5 mg, 3 mg and 4.5 mg	Mirapex ER	6/1/2010
Pramipexole Dihydrochloride	Extended-release Tablets	2.25 mg and 3.75 mg	Mirapex ER	7/26/2011
Prasugrel Hydrochloride	Tablets	5 mg and 10 mg	Effient	7/10/2013
Pravastatin Sodium	Tablets	10 mg, 20 mg, 40 mg and 80 mg	Pravachol	
Pravastatin Sodium	Tablets	30 mg	Pravachol	6/1/2005
Prazosin Hydrochloride	Capsules	1 mg, 2 mg and 5 mg	Minipress	

**Paragraph IV Patent Certifications
August 19, 2014**

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Prednisolone Sodium Phosphate	Oral Solution	5 mg(base)/ 5 mL and 15 mg (base)/ 5 mL	Pediapred	
Prednisolone Sodium Phosphate	Orally Disintegrating Tablets	10 mg, 15 mg and 30 mg	Orapred	7/22/2010
Prednisone	Delayed-release Tablets	1 mg, 2 mg, and 5 mg	Rayos	11/26/2012
Pregabalin	Capsules	25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg	Lyrica	12/30/2008
Pregablin	Oral Solution	20 mg/mL	Lyrica	5/19/2010
Propafenone	Extended-release Capsules	325 mg	Rythmol SR	11/07/2006
Propafenone Hydrochloride	Extended-release Capsules	225 mg and 425 mg	Rythmol SR	10/11/2006
Propofol	Injection	10 mg/mL ; 20 mL, 50 mL and 100 mL vials and 20 mL syringe	Diprivan	
Propranolol Hydrochloride	Extended-release Capsules	60 mg, 80 mg, 120 mg and 160 mg	Inderal LA	
Quetiapine Fumarate	Extended-release Tablets	400 mg	Seroquel XR	6/18/2008
Quetiapine Fumarate	Extended-release Tablets	150 mg	Seroquel XR	11/17/2008
Quetiapine Fumarate	Extended-release Tablets	200 mg and 300 mg	Seroquel XR	6/12/2008
Quetiapine Fumarate	Extended-release Tablets	50 mg	Seroquel XR	10/17/2008
Quetiapine Fumarate	Tablets	25 mg	Seroquel	8/12/2005
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	

**Paragraph IV Patent Certifications
August 19, 2014**

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

**Paragraph IV Patent Certifications
August 19, 2014**

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

**Paragraph IV Patent Certifications
August 19, 2014**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
Saxagliptin Hydrochloride	Tablets	2.5 mg and 5 mg	Onglyza	7/31/2013
Saxagliptin Hydrochloride and Metformin Hydrochloride	Extended-release Tablets	5 mg/500 mg, 2.5 mg/1000 mg, and 5 mg/1000 mg	Kombiglyze XR	7/31/2013
Sertraline Hydrochloride	Oral Concentrate	20 mg/mL	Zoloft	
Sertraline Hydrochloride	Tablets	25 mg, 50 mg and 100 mg	Zoloft	
Sertraline Hydrochloride	Tablets	150 mg and 200 mg	Zoloft	11/9/2005
Sevelamer Carbonate	Powder for Oral Suspension	0.8 g/packet and 2.4 g/packet	Renvela	12/30/2009
Sevelamer Carbonate	Tablets	800 mg	Renvela	12/4/2008
Sevelamer Hydrochloride	Tablets	400 mg and 800 mg	Renagel	5/22/2008
Sevoflurane	Inhalation	100%, 250 mL	Ultane	
Sibutramine Hydrochloride	Capsules	10 mg and 15 mg	Meridia	8/14/2009
Sildenafil Citrate	Tablets	25 mg and 50 mg	Viagra	11/19/2004
Sildenafil Citrate	Tablets	100 mg	Viagra	10/25/2004
Silodosin	Capsules	4 mg and 8 mg	Rapaflo	10/9/2012
Silver Sulfadiazine	Cream	1%	Silvadene	

**Paragraph IV Patent Certifications
August 19, 2014**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Simvastatin	Tablets	5 mg, 10 mg, 20 mg, 40 mg and 80 mg	Zocor	
Sirolimus	Tablets	0.5 mg	Rapamune	8/25/2010
Sirolimus	Tablets	1 mg and 2 mg	Rapamune	12/17/2009
Sodium Phosphate Monobasic Monohydrate and Sodium Phosphate Dibasic Anhydrous, USP	Tablets	1.102 g and 0.398 g	Osmoprep	4/9/2008
Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate	Oral Solution	17.5 g/3.13 g/1.6 g	Suprep Bowel Prep Kit	11/8/2010
Sodium Oxybate	Oral Solution	500 mg/mL	Xyrem	7/8/2010
Solifenacin Succinate	Tablets	5 mg and 10 mg	Vesicare	4/8/2009
Sitagliptin Phosphate	Tablets	25 mg, 50 mg and 100 mg	Januvia	10/18/2010
Sitagliptin Phosphate and Metformin Hydrochloride	Tablets	50 mg/500 mg and 50 mg/1000 mg	Janumet	10/18/2010
Sitagliptin Phosphate and Metformin Hydrochloride	Extended-release Tablets	50 mg/500 mg and 50 mg/1000 mg	Janumet XR	3/16/2012
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	Juvisync	6/19/2012
Sitagliptin Phosphate and Simvastatin	Tablets	100 mg/20 mg	Juvisync	6/25/2012
Sitagliptin Phosphate and Simvastatin	Tablets	50 mg/10 mg, 50 mg/20 mg, and 50 mg/40	Juvisync	11/6/2012
Sumatriptan Succinate	Injection	6 mg/0.5 mL, 0.5 mL vials	Imitrex	10/25/2004
Sumatriptan Succinate*	Injection	6 mg/0.5 mL, 0.5 mL (prefilled syringes)	Imitrex	5/9/2006

**Paragraph IV Patent Certifications
August 19, 2014**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Sumatriptan Succinate	Tablets	25 mg, 50 mg and 100 mg	Imitrex	
Sunitinib Malate	Capsules	12.5 mg, 25 mg, 37.5 mg and 50 mg	Sutent	1/26/2010
Tacrolimus	Ointment	0.03%	Protopic	11/22/2010
Tacrolimus	Ointment	0.10%	Protopic	9/9/2010
Tacrolimus NEW	Extended-release Capsules	0.5 mg, 1 mg, and 5 mg	Astagraf XL	11/15/2013
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

**Paragraph IV Patent Certifications
August 19, 2014**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Tenofovir Disoproxil Fumarate	Tablets	300 mg	Viread	1/26/2010
Tenofovir Disoproxil Fumarate	Tablets	150 mg, 200 mg, and 250 mg	Viread	5/17/2012
Terazosin Hydrochloride	Capsules	1 mg, 2 mg, 5 mg and 10 mg	Hytrin	
Terazosin Hydrochloride	Tablets	1 mg, 2 mg, 5 mg and 10 mg	Hytrin	
Terbinafine Hydrochloride	Tablets	250 mg	Lamisil	
Terfenadine	Tablets	60 mg	Seldane	
Testosterone	Gel	1%	Androgel	
Testosterone	Gel	1%	Testim	8/21/2008
Testosterone	Gel Metered-dose Pump	1%	Androgel	12/19/2008
Testosterone	Gel	1.62%	Androgel	4/6/2012
Testosterone	Gel	10 mg/actuation	Fortesta	8/14/2012
Testosterone	Topical Solution	30 mg/1.5 mL	Axiron	1/29/2013
Thalidomide	Capsules	50 mg and 100 mg	Thalomid	12/18/2006
Thalidomide	Capsules	200 mg	Thalomid	9/25/2006
Tiagabine Hydrochloride	Tablets	2 mg and 4 mg	Gabitril	2/1/2005
Ticlopidine Hydrochloride	Tablets	250 mg	Ticlid	
Tigecycline	For Injection	50 mg per vial	Tygacil	6/15/2009
Timolol Maleate	Ophthalmic Solution	0.25% and 0.5%	Timoptic	
Timolol Maleate	Ophthalmic Solution	0.5%	Istalol	10/19/2012
Tizanidine Hydrochloride	Capsules	2 mg, 4 mg and 6 mg	Zanaflex	8/10/2007
Tobramycin	Inhalation Solution	300 mg/5 mL	Tobi	6/29/2009
Tolterodine Tartrate	Extended-release Capsules	2 mg and 4 mg	Detrol LA	7/30/2007
Tolterodine Tartrate*	Tablets	1 mg and 2 mg	Detrol	
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

**Paragraph IV Patent Certifications
August 19, 2014**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Topiramate NEW	Extended-release Capsules	200 mg	Trokendi XR	4/3/2014
Torsemide	Tablets	5 mg, 10 mg, 20 mg, and 100 mg	Demadex	
Tramadol Hydrochloride	Tablets	50 mg	Ultram	
Tramadol Hydrochloride	Extended-release Tablets	100 mg	Ultram ER	1/8/2007
Tramadol Hydrochloride	Extended-release Tablets	200 mg	Ultram ER	3/28/2007
Tramadol Hydrochloride	Extended-release Tablets	300 mg	Ultram ER	9/25/2007
Tramadol Hydrochloride	Extended-release Tablets	100 mg, 200 mg and 300 mg	Ryzolt	6/18/2009
Trandolapril	Tablets	1 mg, 2 mg and 4 mg	Mavik	10/4/2004
Trandolapril and Verapamil Hydrochloride	Extended-release Tablets	2 mg/180 mg and 2 mg/240 mg	Tarka	11/9/2007
Trandolapril and Verapamil Hydrochloride	Extended-release Tablets	1 mg/240 mg	Tarka	2/20/2008
Trandolapril and Verapamil Hydrochloride	Extended-release Tablets	4 mg/ 240 mg	Tarka	7/24/2007
Tranexamic Acid	Tablets	650 mg	Lysteda	5/24/2011
Travoprost	Ophthalmic Solution	0.004%	Travatan	11/28/2008
Travoprost (Preserved)	Ophthalmic Solution	0.004%	Travatan Z	2/19/2009
Trazodone Hydrochloride	Tablets	150 mg	Desyrel	
Trazodone Hydrochloride	Extended-release Tablets	150 mg and 300 mg	Oleptro	10/18/2010
Treprostinil Sodium	Injection	10 mg/mL, 20 mL vial	Remodulin	12/2/2011
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	

**Paragraph IV Patent Certifications
August 19, 2014**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Tropium Chloride	Extended-release Capsules	60 mg	Sanctura XR	3/2/2009
Valacyclovir Hydrochloride	Tablets	500 mg and 1000 mg	Valtrex	
Valganciclovir Hydrochloride	for Oral Solution	50 mg/mL	Valcyte	3/21/2011
Valganciclovir Hydrochloride	Tablets	450 mg	Valcyte	12/27/2005
Valsartan	Tablets	40 mg, 80 mg, 160 mg and 320 mg	Diovan	12/28/2004
Valsartan and Hydrochlorothiazide	Tablets	80 mg/12.5 mg, 160 mg/12.5 mg and 160 mg/25 mg	Diovan HCT	12/2/2005
Valsartan and Hydrochlorothiazide	Tablets	320 mg/12.5 mg and 320 mg/25 mg	Diovan HCT	2/7/2007
Vardenafil Hydrochloride	Tablets	2.5 mg	Levitra	9/4/2009
Vardenafil Hydrochloride	Tablets	5 mg and 10 mg	Levitra	7/10/2009
Vardenafil Hydrochloride	Tablets	20 mg	Levitra	3/5/2009
Vardenafil Hydrochloride	Orally Disintegrating Tablets	10 mg	Staxyn	12/22/2011
Varenicline Tartrate	Tablets	0.5 mg and 1 mg	Chantix	5/10/2010
Vecuronium Bromide	For Injection	10 mg/vial and 20 mg/vial	Norcuron	
Venlafaxine Hydrochloride	Extended-release Capsules	37.5 mg, 75 mg and 150 mg	Effexor XR	
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	

**Paragraph IV Patent Certifications
August 19, 2014**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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