

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Irbesartan	Tablets	75 mg, 150 mg and 300 mg	Avapro	5/25/2004
Irbesartan and Hydrochlorothiazide	Tablets	150 mg/12.5 mg and 300	Avalide	11/10/2004
Irbesartan and Hydrochlorothiazide	Tablets	300 mg/25 mg	Avalide	6/6/2006
Irinotecan Hydrochloride	Injection	20 mg/mL, 2 mL and 5 mL vials	Camptosar	7/26/2004
Isotretinoin	Capsules	30 mg and 40 mg	Absorica	12/31/2012
Isotretinoin	Capsules	20 mg	Absorica	1/7/2013
Isotretinoin	Capsules	10 mg	Absorica	6/19/2013
Itraconazole	Capsules	100 mg	Sporanox	
Itraconazole	Oral Solution	10 mg/mL	Sporanox	5/3/2013
Ixabepilon	Injection	15 mg/vial and 45 mg/vial, single-use vials	Ixempra Kit	4/16/2012
Ketoconazole	Foam	2%	Extina	7/30/2009
Ketoprofen	Capsules	25 mg, 50 mg and 75 mg	Orudis	
Ketorolac Tromethamine	Injection	15 mg/mL and 30 mg/mL	Toradol	
Ketorolac Tromethamine	Ophthalmic Solution	0.45%	Acuvail	8/24/2011
Ketorolac Tromethamine	Ophthalmic Solution	0.4%	Acular LS	1/28/2005
Ketorolac Tromethamine	Tablets	10 mg	Toradol	
Ketorolac Tromethamine*	Nasal Spray	15.75 mg/spray	Sprix	3/12/2012
Ketotifen Fumarate	Ophthalmic Solution	0.025%	Zaditor	12/23/2004
Lacosamide	Oral Solution	10 mg/mL	Vimpat	10/29/2012
Lacosamide	Tablets	50 mg, 100 mg, 150 mg, and	Vimpat	10/29/2012
Lactulose	Oral Syrup	10 g/15 mL	Cephulac	
Lactulose	Oral Syrup	10 g/15 mL	Chronulac	
Lamivudine*	Tablets	100 mg	Epivir-HBV	10/31/2007
Lamivudine	Tablets	150 mg and 300 mg	Epivir	10/16/2007
Lamivudine and Zidovudine	Tablets	150 mg/300 mg	Combivir	6/26/2007

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Lamivudine	Oral Solution	10 mg/mL	Epivir	11/22/2011
Lamotrigine	Tablets	25 mg, 100 mg, 150 mg and 200 mg	Lamictal	
Lamotrigine	Chewable Tablets	2 mg, 5 mg and 25 mg	Lamictal CD	
Lamotrigine	Orally Disintegrating Tablets	25 mg, 50 mg, 100 mg, and 200 mg	Lamictal ODT	12/21/2009
Lamotrigine	Extended-release Tablets	25 mg, 50 mg, 100 mg, 200 mg, 250 mg, and 300 mg	Lamictal XR	2/12/2014
Lansoprazole	Delayed-release Pellets/Capsules	15 mg and 30 mg	Prevacid	12/05/2005
Lansoprazole	Delayed-release Orally Disintegrating Tablets	15 mg and 30 mg	Prevacid	12/27/2006
Lanthanum Carbonate	Chewable Tablet	500 mg, 750 mg and 1000 mg	Fosrenol	10/27/2008
Lanthanum Carbonate s	Oral Powder	750 mg and 1000 mg	Fosrenol	11/25/2015
Lapatinib Ditosylate	Tablets	250 mg	Tykerb	3/14/2011
Latanoprost	Ophthalmic Solution	0.005%	Xalatan	
Lenalidomide	Capsules	5 mg, 10 mg and 15 mg	Revlimid	8/30/2010
Lenalidomide	Capsules	25 mg	Revlimid	7/12/2010
Letrozole	Tablets	2.5 mg	Femara	3/2/2006
Leuprolide Acetate	Injection (depot)	7.5 mg/vial	Lupron Depot	
Levalbuterol Hydrochloride	Inhalation Solution	0.0103%, 0.021% and 0.042%	Xopenex	6/20/2005
Levalbuterol Hydrochloride	Inhalation Solution	0.25% □	Xopenex	5/23/2006
Levalbuterol Tartrate	Inhalation Aerosol	0.045 mg/actuation	Xopenex	2/27/2012
Levetiracetam	Tablets	250 mg, 500 mg and 750 mg	Keppra	
Levetiracetam	Tablets	1000 mg	Keppra	1/24/2007
Levetiracetam	Extended-release Tablets	500 mg and 750 mg	Keppra XR	1/7/2011
Levetiracetam*	Extended-release Tablets	1000 mg	Keppra XR	1/7/2011

**Paragraph IV Patent Certifications
February 10, 2016**

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Levocetirizine Dihydrochloride	Oral Solution	0.5 mg/mL	Xyzal	1/14/2009
Levocetirizine Dihydrochloride	Tablets	5 mg	Xyzal	12/17/2007
Levofloxacin	Injection	5 mg/mL; 50 mL, 100 mL and 150 mL vials	Levaquin in Dextrose 5% in Plastic Container	
Levofloxacin	Injection	25 mg/mL	Levaquin	
Levofloxacin	Ophthalmic Solution	0.5%	Quixin	
Levofloxacin	Oral Solution	25 mg/mL	Levaquin	7/30/2009
Levofloxacin	Tablets	250 mg, 500 mg and 750 mg	Levaquin	
Levoleucovorin Calcium	Injection	10 mg/mL, 17.5 mL vial and 25 mL vial	Fusilev	10/26/2011
Levoleucovorin Calcium	Injection	50 mg/vial	Fusilev	12/19/2013
Levonorgestrel and Ethinyl Estradiol	Tablets	0.09 mg/0.02 mg	Lybrel	10/5/2007
Levonorgestrel and Ethinyl Estradiol	Tablets	0.15 mg/0.03 mg	Seasonale	3/29/2004
Levonorgestrel; Ethinyl Estradiol; Ethinyl Estradiol	Tablets	0.1 mg/0.02 mg and 0.01 mg	LoSeasonique	11/16/2009
Levonorgestrel; Ethinyl Estradiol; Ethinyl Estradiol	Tablets	0.15 mg/0.03 mg/0.01 mg	Seasonique	1/22/2008
Levonorgestrel; Ethinyl Estradiol; Ethinyl Estradiol	Tablets	0.15 mg/0.02 mg, 0.15 mg/0.025 mg,	Quartette	7/10/2013
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	
Levothyroxine Sodium	for Injection	100 mcg/vial and 500 mcg/vial	Levothyroxine Sodium	4/14/2015
Levothyroxine Sodium	for Injection	200 mcg/vial	Levothyroxine Sodium	5/1/2015
Lidocaine	Topical Patch	5%	Lidoderm	11/13/2009
Linagliptin	Tablets	5 mg	Tradjenta	5/4/2015

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Linagliptin and Metformin Hydrochloride	Tablets	2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg	Jentadueto	5/4/2015
Linezolid	Injection	2 mg/mL, 100 mL bag	Zyvox	12/29/2009
Linezolid	Injection	2 mg/mL, 300 mL bag	Zyvox	9/1/2009
Linezolid	Oral Suspension	100 mg/5 mL	Zyvox	8/3/2009
Linezolid	Tablets	600 mg	Zyvox	12/21/2005
Lisdexamfetamine Dimesylate	Capsules	20 mg, 30 mg, 40 mg, 50 mg, 60 mg and 70 mg	Vyvanse	2/23/2011
Loperamide Hydrochloride and Simethicone	Chewable Tablets	2 mg/125 mg	Imodium Advanced	
Loperamide Hydrochloride and Simethicone	Tablets	2 mg/125 mg	Imodium Advanced	12/29/2004
Lopinavir and Ritonavir	Tablets	100 mg/25 mg and 200 mg/50 mg	Kaletra	12/23/2008
Lopinavir and Ritonavir	Oral Solution	80 mg/20 mg per mL	Kaletra	6/19/2014
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

**Paragraph IV Patent Certifications
February 10, 2016**

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Lubiprostone	Capsules	8 mcg and 24 mcg	Amitiza	8/20/2012
Lurasidone Hydrochloride	Tablets	20 mg, 40 mg, 60 mg, 80 mg, and 120 mg	Latuda	10/28/2014
Malathion	Topical Lotion	0.50%	Ovide	3/16/2011
Maraviroc	Tablets	150 mg and 300 mg	Selzentry	8/8/2011
Mefloquine Hydrochloride	Tablets	250 mg	Lariam	
Megestrol Acetate	Oral Suspension	40 mg/mL	Megace	
Megestrol Acetate	Oral Suspension	125 mg/mL	Megace ES	4/27/2011
Meloxicam	Oral Suspension	7.5 mg/5 mL	Mobic	12/17/2009
Memantine Hydrochloride	Tablets	5 mg and 10 mg	Namenda	10/16/2007
Memantine Hydrochloride	Extended-release Capsules	7 mg, 14 mg, 21 mg, and 28 mg	Namenda XR	6/10/2013
Memantine Hydrochloride Extended-release and Donepezil Hydrochloride	Capsules	14 mg/10 mg and 28 mg/10 mg	Namzaric	5/18/2015
Mesalamine*	Delayed-release Tablets	400 mg	Asacol	6/22/2007
Mesalamine	Delayed-release Tablets	800 mg	Asacol HD	7/13/2011
Mesalamine	Delayed-release Tablets	1.2 g	Lialda	12/16/2009
Mesalamine	Extended-release Capsules	0.375 g	Apriso	4/3/2012
Mesalamine	Suppository	1000 mg	Canasa	5/24/2013
Mesalamine	Delayed-release Capsules	400 mg	Delzicol	6/17/2014
Metaxalone	Tablets	400 mg	Skelaxin	
Metaxalone	Tablets	800 mg	Skelaxin	11/4/2004
Metformin Hydrochloride	Extended-release Tablets	500 mg	Glucophage XR	
Metformin Hydrochloride	Extended-release Tablets	750 mg	Glucophage XR	

**Paragraph IV Patent Certifications
February 10, 2016**

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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
Methylnaltrexone Bromide	Injection	12 mg/0.6 mL	Relistor	7/22/2015
Methylnaltrexone Bromide	Injection	8 mg/0.4 mL	Relistor	9/8/2015
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
Methylphenidate Hydrochloride	Extended-release Oral Suspension	5 mg/mL	Quillivant XR	8/2/2013
Metoclopramide Hydrochloride	Injection	5 mg/mL, 2 mL, 10 mL, 20 mL and 30 mL vials	Reglan	
Metoclopramide Hydrochloride	Orally Disintegrating Tablets	5 mg and 10 mg	Metozolv ODT	8/24/2010
Metoprolol Succinate	Extended-release Tablets	25 mg, 50 mg, □ 100 mg and □ 200 mg	Toprol XL	
Metronidazole	Vaginal Gel	0.75%	MetroGel-Vaginal	9/2/2004
Metronidazole	Topical Gel	1%	Metrogel	10/21/2008
Micafungin Sodium	For Injection	50 mg/vial and 100 mg/vial	Mycamine	6/16/2014

**Paragraph IV Patent Certifications
February 10, 2016**

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Miconazole Nitrate	Vaginal Cream and Suppository	2% and 1.2 g	Monistat 1 Combination Pack	12/5/2007
Milnacipran Hydrochloride	Tablets	12.5 mg, 25 mg, 50 mg, and 100 mg	Savella	1/14/2013
Minocycline Hydrochloride	Extended-release Tablet	45 mg, 90 mg and 135 mg	Solodyn	PIV received prior to 2/5/2009
Minocycline Hydrochloride	Extended-release Tablet	55 mg	Solodyn	12/2/2010
Minocycline Hydrochloride	Extended-release Tablet	65 mg and 115 mg	Solodyn	11/19/2009
Minocycline Hydrochloride	Extended-release Tablet	80 mg	Solodyn	10/27/2010
Minocycline Hydrochloride	Extended-release Tablet	105 mg	Solodyn	12/13/2010
Minoxidil	Topical Aerosol Foam	5%	Men's Rogaine	4/6/2009
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

**Paragraph IV Patent Certifications
February 10, 2016**

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Morphine Sulfate and Naltrexone Hydrochloride	Extended-release Capsules	100 mg/4 mg	Embeda	5/3/2010
Morphine Sulfate and Naltrexone Hydrochloride	Extended-release Capsules	60 mg/2.4 mg	Embeda	5/25/2010
Morphine Sulfate and Naltrexone Hydrochloride	Extended-release Capsules	30 mg/1.2 mg, 50 mg/2 mg and 80 mg/3.2 mg	Embeda	5/28/2010
Moxifloxacin Hydrochloride*	Ophthalmic Solution/Drops	0.5%	Vigamox	12/22/2005
Moxifloxacin Hydrochloride	Ophthalmic Solution	0.5%	Moxeza	2/29/2012
Moxifloxacin Hydrochloride	Tablets	400 mg	Avelox	
Moxifloxacin Hydrochloride	Injection	1.6 mg/mL	Avelox in Sodium Chloride 0.8% in plastic container	2/7/2014
Mycophenolic Acid	Delayed-release Tablets	180 mg	Myfortic	6/3/2009
Mycophenolic Acid	Delayed-release Tablets	360 mg	Myfortic	2/2/2009
Mycophenolic Mofetil	For Oral Suspension	200 mg/mL	Cellcept	3/25/2011
Nabumetone	Tablets	500 mg and 750 mg	Relafen	
Naftifine Hydrochloride	Gel	2%	Naftin Gel	2/27/2015
Naltrexone Hydrochloride and Bupropion Hydrochloride	Extended-release Tablets	8 mg/90 mg	Contrave	3/12/2015
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

**Paragraph IV Patent Certifications
February 10, 2016**

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Nefazodone Hydrochloride	Tablets	50 mg, 100 mg, 150 mg 200 mg and 250 mg	Serzone	
Nepafenac	Ophthalmic Suspension	0.3%	Ilevro	12/21/2015
Nevirapine	Extended-release Tablets	400 mg	Viramune XR	6/21/2013
Niacin	Extended-release Tablets	500 mg, 750 mg and 1000 mg	Niaspan	
Niacin and Simvastatin	Extended-release Tablets	500 mg/20 mg	Simcor	2/12/2010
Niacin and Simvastatin	Extended-release Tablets	750 mg/20 mg	Simcor	2/17/2010
Niacin and Simvastatin	Extended-release Tablets	1000 mg/20 mg	Simcor	9/17/2009
Niacin and Simvastatin	Extended-release Tablets	1000 mg/40 mg	Simcor	2/4/2011
Niacin and Simvastatin	Extended-release Tablets	500 mg/40 mg	Simcor	2/9/2011
Nicardipine Hydrochloride	Injection	2.5 mg/mL, 10 mL Ampoules	Cardene	12/27/2006
Nicardipine Hydrochloride	Injection	0.1 mg/mL, 200 mL and 0.2mg/mL, 200 mL	Cardene in 0.86% Sodium Chloride in plastic container and Cardene 0.83% Sodium Chloride in plastic container	1/9/2013
Nicotine	Transdermal System	7 mg/day, 14 mg/day and 21 mg/day	Habitrol	
Nicotine	Transdermal System	7 mg/24 hrs, 14 mg/24 hrs, and 21 mg/24 hrs	Nicoderm CQ	5/30/2014
Nicotine Polacrilex	Troche/Lozenge	2 mg and 4 mg	Commit	
Nicotine Polacrilex	Gum	2 mg	Nicorette	1/22/2013
Nicotine Polacrilex	Gum	4 mg	Nicorette	1/22/2013

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Nifedipine	Capsules	10 mg and 20 mg	Procardia	
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Adalat CC	
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Procardia XL	
Nilotinib	Capsules	150 mg and 200 mg	Tasigna	11/8/2013
Nitric Oxide	for Inhalation	100 ppm and 800 ppm	INOMax	5/20/2014
Nisoldipine	Extended-release Tablets	8.5 mg and 17 mg	Sular	3/2/2009
Nisoldipine	Extended-release Tablets	20 mg and 30 mg	Sular	11/7/2007
Nisoldipine	Extended-release Tablets	25.5 mg and 34 mg	Sular	11/28/2008
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	

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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 Acetate and Ethinyl Estradiol and Ferrous Fumarate	Chewable Tablets	1 mg/0.02 mg and 75 mg	Minastrin 24 Fe	4/23/2014
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	

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Olopatadine Hydrochloride	Ophthalmic Solution	0.7%	Pazeo	9/10/2015
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
Omeprazole Magnesium	Delayed-release Tablets	20 mg	Prilosec OTC	3/30/2012
Omeprazole	Delayed-release Tablets	20 mg	Omeprazole	6/3/2015
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
Oseltamivir Phosphate	for Oral Suspension	6 mg/mL	Tamiflu	6/18/2015

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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	
Oxybutynin Chloride	Gel	10%	Gelnique	6/19/2014
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

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Oxycodone Hydrochloride and Acetaminophen	Extended-release Tablets	7.5 mg/325 mg	Xartemis XR	4/3/2014
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
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

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
Phenylephrine and Ketorolac	Injection	1%/0.3%	Omidria	5/29/2015
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
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	

**Paragraph IV Patent Certifications
February 10, 2016**

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)	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
Posaconazole	Delayed-release Tablets	100 mg	Noxafil	6/16/2014
Posaconazole	Injection	18 mg/mL, 16.7 mL vials	Noxafil	11/24/2015
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
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
February 10, 2016**

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
Remifentanyl Hydrochloride	for Injection	1 mg/vial, 2 mg/vial and 5 mg/vial	Ultiva	12/27/2013
Repaglinide	Tablets	0.5 mg*, 1 mg and 2 mg	Prandin	2/10/2005
Repaglinide and Metformin Hydrochloride*	Tablets	1 mg/500 mg and 2 mg/500 mg	Prandimet	4/9/2009
Ribavirin	Capsules	200 mg	Rebetol	
Ribavirin	for Inhalation Solution	6 gm/vial	Virazole	5/22/2014
Risedronate Sodium	Tablets	5 mg, 30 mg and 35 mg	Actonel	4/23/2004
Risedronate Sodium*	Tablets	75 mg	Actonel	9/10/2007
Risedronate Sodium	Tablets	150 mg	Actonel	8/12/2008
Risedronate Sodium	Delayed-release Tablets	35 mg	Atelvia	6/9/2011
Risedronate Sodium with Calcium Carbonate *	Tablets	35 mg; 500 mg	Actonel with Calcium	12/18/2007
Risperidone	Oral Solution	1 mg/mL	Risperdal	

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Risperidone	Tablets	0.25 mg, 1 mg, 2 mg, 3 mg and 4 mg	Risperdal	
Risperidone	Orally Disintegrating Tablets	0.25 mg	Risperdal	4/11/2005
Risperidone	Orally Disintegrating Tablets	0.5 mg, 1 mg and 2 mg	Risperdal	
Risperidone	Orally Disintegrating Tablets	3 mg and 4 mg	Risperdal	3/23/2005
Ritonavir	Tablets	100 mg	Norvir	12/21/2010
Ritonavir	Capsules	100 mg	Norvir	10/31/2012
Rivastigmine Tartrate	Capsules	1.5 mg, 3 mg, 4.5 mg and 6 mg	Exelon	4/21/2004
Rivastigmine Tartrate	Oral Solution	2 mg/mL	Exelon	11/5/2004
Rivastigmine	Transdermal System Extended-release	4.6 mg/24 hr and 9.5 mg/24 hr	Exelon	4/27/2011
Rivastigmine	Transdermal System Extended-release	13.3 mg/24 hr	Exelon	1/22/2013
Rivaroxaban	Tablets	10 mg, 15 mg, and 20 mg	Xarelto	7/1/2015
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	
Roflumilast	Tablets	500 mcg	Daliresp	3/2/2015
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

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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	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	6/5/2014
Sapropterin Dihydrochloride	Powder for Oral Solution	100 mg per packet	Kuvan	11/9/2015
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	

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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 Picosulfate, Magnesium Oxide and Anhydrous Citric Acid	Oral Solution	10 mg, 3.5 g, and 12 g	Prepopik	5/21/2014
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

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Sitagliptin Phosphate and Metformin Hydrochloride	Tablets	50 mg/500 mg and 50 mg/1000 mg	Janumet	10/18/2010
Sitagliptin Phosphate and Metformin Hydrochloride	Extended-release Tablets	50 mg/500 mg and 50 mg/1000 mg	Janumet XR	3/16/2012
Sitagliptin Phosphate and Metformin Hydrochloride	Extended-release Tablets	100 mg/1000 mg	Janumet XR	10/22/2012
Sitagliptin Phosphate and Simvastatin	Tablets	100 mg/10 mg and 100 mg/40 mg	Juvisync	6/19/2012
Sitagliptin Phosphate and Simvastatin	Tablets	100 mg/20 mg	Juvisync	6/25/2012
Sitagliptin Phosphate and Simvastatin	Tablets	50 mg/10 mg, 50 mg/20 mg, and 50 mg/40 mg	Juvisync	11/6/2012
Sorafenib Tosylate	Tablets	200 mg	Nexavar	2/28/2014
Sumatriptan Succinate	Injection	6 mg/0.5 mL, 0.5 mL vials	Imitrex	10/25/2004
Sumatriptan Succinate*	Injection	6 mg/0.5 mL, 0.5 mL (prefilled syringes)	Imitrex	5/9/2006
Sumatriptan Succinate	Tablets	25 mg, 50 mg and 100 mg	Imitrex	
Sunitinib Malate	Capsules	12.5 mg, 25 mg, 37.5 mg and 50 mg	Sutent	1/26/2010
Tacrolimus	Ointment	0.03%	Protopic	11/22/2010
Tacrolimus	Ointment	0.10%	Protopic	9/9/2010
Tacrolimus	Extended-release Capsules	0.5 mg, 1 mg, and 5 mg	Astagraf XL	9/24/2013
Tadalafil	Tablets	2.5 mg	Cialis	10/14/2008
Tadalafil	Tablets	5 mg, 10 mg and 20 mg	Cialis	11/21/2007
Tadalafil	Tablets	20 mg	Adcirca	10/15/2009
Tamoxifen Citrate	Tablets	10 mg and 20 mg	Nolvadex	
Tamsulosin Hydrochloride	Capsules	0.4 mg	Flomax	12/20/2004

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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	
Teriparatide	Injection	250 mcg/mL, 2.4 mL prefilled Pen	Forteo	7/27/2015
Testosterone	Gel	1%	Androgel	
Testosterone	Gel	1%	Testim	8/21/2008
Testosterone	Gel	1% (pump)	Androgel	12/19/2008
Testosterone	Gel	1.62% (pump)	Androgel	4/6/2012

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Testosterone	Gel	1.62% (1.25 g and 2.5 g packets)	Androgel	6/19/2013
Testosterone	Gel	10 mg/actuation	Fortesta	8/14/2012
Testosterone	Topical Solution	30 mg/1.5 mL	Axiron	1/29/2013
Testosterone Undecanoate	Injection	250 mg/mL	Aveed	6/11/2014
Thalidomide	Capsules	50 mg and 100 mg	Thalomid	12/18/2006
Thalidomide	Capsules	200 mg	Thalomid	9/25/2006
Thalidomide	Capsules	150 mg	Thalomid	2/3/2014
Tiagabine Hydrochloride	Tablets	2 mg and 4 mg	Gabitril	2/1/2005
Tiagabine Hydrochloride	Tablets	12 mg and 16 mg	Gabitril	1/24/2014
Ticagrelor	Tablets	90 mg	Brilinta	7/20/2015
Ticagrelor	Tablets	60 mg	Brilinta	9/30/2015
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

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Topiramate	Tablets	25 mg, 100 mg and 200 mg	Topamax	12/26/2001
Topiramate	Tablets	50 mg	Topamax	9/8/2005
Topiramate	Extended-release Capsules	200 mg	Trokendi XR	4/3/2014
Topiramate	Extended-release Capsules	25 mg, 50 mg, and 100 mg	Trokendi XR	5/12/2014
Torseמידe	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
Treprostinil Sodium	Inhalation Solution	0.6 mg/mL, 2.9 mL ampules	Tyvaso	4/13/2015
Tretinoin	Cream	0.025%, 0.05% and 0.1%	Retin-A	
Tretinoin	Gel	0.025%	Retin-A	

**Paragraph IV Patent Certifications
February 10, 2016**

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Tretinoin	Gel	0.04%	Retin-A Micro	12/20/2010
Tretinoin	Gel	0.1%	Retin-A Micro	7/8/2010
Triamcinolone Acetonide	Nasal Spray	0.055 mg/Spray	Nasacort AQ	12/29/2005
Triamterene/ Hydrochlorothiazide	Tablets	37.5 mg/25 mg and 75 mg/50 mg	Maxzide	
Trospium Chloride	Extended-release Capsules	60 mg	Sanctura XR	3/2/2009
Ulipristal Acetate	Tablets	30 mg	Ella	8/13/2014
Unoprostone Isopropyl	Ophthalmic Solution	0.15%	Rescula	5/12/2014
Valacyclovir Hydrochloride	Tablets	500 mg and 1000 mg	Valtrex	
Valganciclovir Hydrochloride	for Oral Solution	50 mg/mL	Valcyte	3/21/2011
Valganciclovir Hydrochloride	Tablets	450 mg	Valcyte	12/27/2005
Valsartan	Tablets	40 mg, 80 mg, □ 160 mg and 320 mg	Diovan	12/28/2004
Valsartan and Hydrochlorothiazide	Tablets	80 mg/12.5 mg, 160 mg/12.5 mg and 160 mg/25 mg	Diovan HCT	12/2/2005
Valsartan and Hydrochlorothiazide	Tablets	320 mg/12.5 mg and 320 mg/25 mg	Diovan HCT	2/7/2007
Vardenafil Hydrochloride	Tablets	2.5 mg	Levitra	9/4/2009
Vardenafil Hydrochloride	Tablets	5 mg and 10 mg	Levitra	7/10/2009
Vardenafil Hydrochloride	Tablets	20 mg	Levitra	3/5/2009
Vardenafil Hydrochloride	Orally Disintegrating Tablets	10 mg	Staxyn	12/22/2011
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

**Paragraph IV Patent Certifications
February 10, 2016**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
Vilazodone Hydrochloride	Tablets	10 mg, 20 mg, and 40 mg	VIIBRYD	1/21/2015
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

Paragraph IV Patent Certifications
February 10, 2016

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Zolpidem Tartrate	Sublingual Tablets	1.75 mg and 3.5 mg	Intermezzo	4/10/2012

* ANDA withdrawn or exclusivity relinquished