

**Paragraph IV Patent Certifications
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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Gabapentin	Oral Solution	250 mg/5 mL	Neurontin	
Gabapentin	Tablets	100 mg, 300 mg and 400 mg	Neurontin	
Gabapentin	Tablets	600 mg and 800 mg	Neurontin	
Galantamine Hydrobromide	Extended-release Capsules	8 mg	Razadyne ER	3/2/2006
Galantamine Hydrobromide	Extended-release Capsules	16 mg and 24 mg	Razadyne ER	3/11/2006
Galantamine Hydrobromide	Tablets	4 mg, 8 mg and 12 mg	Razadyne	2/28/2005
Ganciclovir Sodium	Capsules	250 mg and 500 mg	Cytovene	
Gatifloxacin	Injection	10 mg/mL, 20 mL and 40 mL vials	Tequin	11/24/2004
Gatifloxacin	Ophthalmic Solution	0.3 %	Zymar	7/19/2007
Gatifloxacin	Tablets	200 mg and 400 mg	Tequin	
Gatifloxacin in Dextrose 5% in Plastic Container	Injection	2 mg/mL, 100 mL and 200 mL containers (plastic)	Tequin	12/13/2004
Gemcitabine	For Injection	200 mg/vial	Gemzar	11/1/2005
Gemcitabine	For Injection	1g/vial	Gemzar	11/14/2005
Gemcitabine	For Injection	2 g/vial	Gemzar	8/24/2007
Gemifloxacin Mesylate	Tablets	320 mg	Factive	3/4/2008
Glatiramer Acetate	Injection	20 mg/mL, 1mL pre-filled syringe	Copaxane	12/27/2007
Glimepiride and Rosiglitazone Maleate	Tablets	1 mg/4 mg, 2 mg/4 mg and 4 mg/4 mg	Avandaryl	12/22/2006
Glimepiride and Rosiglitazone Maleate	Tablets	8 mg/2 mg and 8 mg/4 mg	Avandaryl	5/30/2008
Glipizide	Extended-release Tablets	2.5 mg, 5 mg and 10 mg	Glucotrol XL	
Glyburide	Tablets	1.5 mg, 3 mg, 4.5 mg and 6 mg	Glynase	
Glyburide/ Metformin Hydrochloride	Tablets	1.25mg/250 mg, 2.5 mg/500 mg and 5 mg/500 mg	Glucovance	
Glycopyrrolate	Tablets	1.5 mg	Robinul Forte	5/6/2009

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Granisetron Hydrochloride	Injection	0.1 mg/mL, 1 mL single dose vial	Kytril	3/8/2007
Granisetron Hydrochloride	Injection	1 mg/mL, 1 mL vials	Kytril	6/1/2004
Granisetron Hydrochloride	Injection	1 mg/mL, 4 mL multi-dose vials	Kytril	7/19/2004
Guaifenesin *	Extended-release Tablets	600 mg and 1.2 gm	Mucinex	6/9/2006
Guaifenesin and Dextromethorphan	Extended-release Tablets	600 mg/30 mg and 1200 mg/60 mg	Mucinex DM	12/17/2008
Guaifenesin and Pseudoephedrine Hydrochloride	Extended-release Tablets	600 mg/60 mg and 1200 mg/120 mg	Mucinex-D	12/29/2008
Guanfacine Hydrochloride	Extended-release Tablets	1 mg, 2 mg, 3 mg and 4 mg	Intuniv	12/29/2009
Hydrocodone Bitartrate and Ibuprofen	Tablets	2.5 mg/200 mg	Vicoprofen	2/24/2006
Hydrocodone Bitartrate and Ibuprofen	Tablets	5 mg/200 mg	Vicoprofen	5/27/2005
Hydrocodone Bitartrate and Ibuprofen	Tablets	7.5 mg/200 mg	Vicoprofen	
Hydrocodone Bitartrate and Ibuprofen	Tablets	10 mg/200 mg	Vicoprofen	
Ibandronate Sodium	Injection	1 mg/mL, 3 mL Vial	Boniva	8/31/2007
Ibandronate Sodium	Tablets	2.5 mg and 150 mg	Boniva	5/16/2007
Ibuprofen	Oral Drops	40 mg/mL	Children's Motrin Drops	
Ibuprofen	Oral Suspension	50 mg/1.25 mL	Concentrated Motrin Infant Drops	6/29/2007
Ibuprofen	Oral Suspension	100 mg/5 mL (Rx)	Motrin	
Ibuprofen	Oral Suspension	100 mg/5 mL (OTC)	Children's Motrin	
Ibuprofen	Chewable Tablets	50 mg and 100 mg	Children's Motrin, Junior Strength Motrin	
Ibuprofen and Pseudoephedrine Hydrochloride	Oral Suspension	100 mg/ 15 mg per 5 mL	Children's Motrin Cold	
Ibuprofen and Pseudoephedrine Hydrochloride	Tablets	200 mg/30 mg	Advil Cold and Sinus	

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Ibuprofen Potassium and Pseudoephedrine Hydrochloride	Capsules	200 mg/30 mg	Advil Cold and Sinus	12/27/2004
Ifosfamide	For Injection	1 g/vial and 3 g/vial	Ifex	
Ifosfamide	Injection	50 mg/mL, 20 mL vials and 60 mL vials	Ifex	
Ifosfamide/ Mesna	For Injection/ Injection Kit	1 g/vial; 100 mg/mL, 10 mL vials and 3 g/vial; 100 mg/mL, 10 mL vials	Ifex/ Mesnex Kit	
Ifosfamide/ Mesna	Injection/ Injection Kit	50 mg/mL, 20 mL and 60 mL vials; 100 mg/mL, 10 mL vial	Ifex/ Mesnex Kit	
Imatinib Mesylate	Tablets	100 mg and 400 mg	Gleevec	3/12/2007
Imiquimod	Cream	5%	Aldara	10/17/2006
Indomethacin	Extended-release Capsules	75 mg	Indocin SR	
Irbesartan	Tablets	75 mg, 150 mg and 300 mg	Avapro	5/25/2004
Irbesartan and Hydrochlorothiazide	Tablets	150 mg/12.5 mg and 300 mg/12.5 mg	Avalide	11/10/2004
Irbesartan and Hydrochlorothiazide	Tablets	300 mg/25 mg	Avalide	6/6/2006
Irinotecan Hydrochloride	Injection	20 mg/mL, 2 mL and 5 mL vials	Camptosar	7/26/2004
Itraconazole	Capsules	100 mg	Sporanox	
Ketoconazole NEW!	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	0.5%	Acular	
Ketorolac Tromethamine	Ophthalmic Solution	0.4%	Acular LS	1/28/2005
Ketorolac Tromethamine	Tablets	10 mg	Toradol	
Ketotifen Fumarate	Ophthalmic Solution	0.025%	Zaditor	12/23/2004
Lactulose	Oral Syrup	10 g/15 mL	Cephulac	
Lactulose	Oral Syrup	10 g/15 mL	Chronulac	
Lamivudine	Tablets	100 mg	Epivir-HBV	10/31/2007
Lamivudine	Tablets	150 mg and 300 mg	Epivir	10/16/2007

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Lamivudine and Zidovudine	Tablets	150 mg/300 mg	Combivir	6/26/2007
Lamotrigine	Tablets	25 mg, 100 mg, 150 mg and 200 mg	Lamictal	
Lamotrigine	Chewable Tablets	2 mg, 5 mg and 25 mg	Lamictal CD	
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
Latanoprost	Ophthalmic Solution	0.005%	Xalatan	
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
Levetiracetam	Tablets	250 mg, 500 mg and 750 mg	Keppra	
Levetiracetam	Tablets	1000 mg	Keppra	1/24/2007
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	
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

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Levothyroxine Sodium	Tablets	0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.1 mg, 0.112 mg, 0.125 mg, 0.150 mg, 0.175 mg, 0.2 mg and 0.3 mg	Levoxyl	
Lidocaine	Topical Patch	5%	Lidoderm	11/13/2009
Linezolid	Injection	2 mg/mL, 100 mL bag	Zyvox	12/29/2009
Linezolid	Injection	2 mg/mL, 300 mL bag	Zyvox	9/1/2009
Linezolid	Oral Suspension	100 mg/5 mL	Zyvox	8/3/2009
Linezolid	Tablets	600 mg	Zyvox	12/21/2005
Loperamide Hydrochloride and Simethicone	Chewable Tablets	2 mg/125 mg	Imodium Advanced	
Loperamide Hydrochloride and Simethicone	Tablets	2 mg/125 mg	Imodium Advanced	12/29/2004
Lopinavir and Ritonavir	Tablets	100 mg/25 mg and 200 mg/50 mg	Kaletra	12/23/2008
Loratadine	Syrup	1 mg/mL	Claritin	
Loratadine	Tablets	10 mg	Claritin	
Loratadine	Orally Disintegrating Tablets	10 mg	Claritin RediTabs	
Loratadine/ Pseudoephedrine	Extended-release Tablets	5 mg/120 mg	Claritin D-12 hour	
Loratadine/ Pseudoephedrine	Extended-release Tablets	10 mg/240 mg	Claritin D-24 hour	
Losartan Potassium	Tablets	25 mg, 50 mg, and 100 mg	Cozaar	
Losartan Potassium and Hydrochlorothiazide	Tablets	50 mg/12.5 mg and 100 mg/25 mg	Hyzaar	5/24/2004
Losartan Potassium and Hydrochlorothiazide	Tablets	100 mg/12.5 mg	Hyzaar	4/4/2006
Lovastatin and Niacin	Extended-release Tablets	20 mg/500 mg	Advicor	9/22/2008
Lovastatin and Niacin	Extended-release Tablets	20 mg/750 mg	Advicor	12/17/2008
Lovastatin and Niacin	Extended-release Tablets	20 mg/1000 mg	Advicor	5/22/2008
Lovastatin and Niacin	Extended-release Tablets	40 mg/1000 mg	Advicor	11/19/2009
Mefloquine Hydrochloride	Tablets	250 mg	Lariam	

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Megestrol Acetate	Oral Suspension	40 mg/mL	Megace	
Meloxicam	Oral Suspension	7.5 mg/5 mL	Mobic	12/17/2009
Memantine Hydrochloride	Tablets	5 mg and 10 mg	Namenda	10/16/2007
Mesalamine	Delayed-release Tablets	400 mg	Asacol	6/22/2007
Metaxalone	Tablets	400 mg	Skelaxin	
Metaxalone	Tablets	800 mg	Skelaxin	11/4/2004
Metformin Hydrochloride	Extended-release Tablets	500 mg	Glucophage XR	
Metformin Hydrochloride	Extended-release Tablets	750 mg	Glucophage XR	
Metformin Hydrochloride	Extended-release Tablets	500 mg and 1000 mg	Fortamet	10/14/2008
Metformin Hydrochloride	Extended-release Tablets	500 mg and 1000 mg	Glumetza	7/27/2009
Methylphenidate Hydrochloride	Extended-release Capsules	10 mg	Ritalin LA	5/21/2007
Methylphenidate Hydrochloride	Extended-release Capsules	10 mg, 20 mg and 30 mg	Metadate CD	5/13/2005
Methylphenidate Hydrochloride	Extended-release Capsules	20 mg, 30 mg and 40 mg	Ritalin LA	8/21/06
Methylphenidate Hydrochloride	Extended-release Capsules	40 mg	Metadate CD	3/15/2007
Methylphenidate Hydrochloride	Extended-release Tablets	18 mg, 27 mg, 36 mg and 54 mg	Concerta	7/19/2005
Metoclopramide Hydrochloride	Injection	5 mg/mL, 2 mL, 10 mL, 20 mL and 30 mL vials	Reglan	
Metoprolol Succinate	Extended-release Tablets	25 mg, 50 mg, 100 mg and 200 mg	Toprol XL	
Metronidazole	Vaginal Gel	0.75%	MetroGel-Vaginal	9/2/2004
Metronidazole	Topical Gel	1%	Metrogel	10/21/2008
Miconazole Nitrate	Vaginal Cream and Suppository	2% and 1.2 g	Monistat 1 Combination Pack	12/5/2007
Minocycline Hydrochloride	Extended-release Tablet	45 mg, 90 mg and 135 mg	Solodyn	PIV received prior to 2/5/2009
Minocycline Hydrochloride	Extended-release Tablet	65 mg and 115 mg	Solodyn	11/19/2009
Minoxidil	Topical Aerosol Foam	5%	Men's Rogaine	4/6/2009

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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
Moxifloxacin Hydrochloride	Ophthalmic Solution/Drops	0.5%	Vigamox	12/22/2005
Moxifloxacin Hydrochloride	Tablets	400 mg	Avelox	
Mycophenolic Acid	Delayed-release Tablets	180 mg	Myfortic	6/4/2009
Mycophenolic Acid	Delayed-release Tablets	360 mg	Myfortic	2/2/2009
Nabumetone	Tablets	500 mg and 750 mg	Relafen	
Naproxen Sodium	Extended-release Tablets	375 mg (base) and 500 mg (base)	Naprelan	
Naproxen Sodium and Sumatriptan Succinate	Tablets	500 mg/85 mg	Alphapharm	7/23/2008
Nateglinide	Tablets	60 mg and 120 mg	Starlix	12/22/2004

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Nefazodone Hydrochloride	Tablets	50 mg, 100 mg, 150 mg, 200 mg and 250 mg	Serzone	
Niacin	Extended-release Tablets	500 mg, 750 mg and 1000 mg	Niaspan	
Niacin and Simvastatin	Extended-release Tablets	500 mg/20 mg	Simcor	2/12/2010
Niacin and Simvastatin DATE CORRECTION!	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
Nicardipine Hydrochloride	Injection	2.5 mg/mL, 10 mL Ampoules	Cardene	12/27/2006
Nicotine	Transdermal System	7 mg/day, 14 mg/day and 21 mg/day	Habitrol	
Nicotine Polacrilex	Troche/Lozenge	2 mg and 4 mg	Commit	
Nifedipine	Capsules	10 mg and 20 mg	Procardia	
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Adalat CC	
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Procardia XL	
Nisoldipine	Extended-release Tablets	8.5 mg and 17 mg	Sular	3/2/2009
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	

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Nizatidine	Capsules	150 mg and 300 mg	Axid	
Nizatidine	Oral Solution	15 mg/mL	Axid	5/14/2008
Norelgestromin and Ethinyl Estradiol	Transdermal System	0.15 mg/0.02 mg per 24 hours	Ortho Evra	3/22/2007
Norethindrone Acetate/ Ethinyl Estradiol	Tablets	1 mg/0.005 mg	Femhrt	
Norethindrone Acetate/ Ethinyl Estradiol	Tablets	1 mg/ 0.02 mg, 1 mg/0.03 mg and 1 mg /0.035 mg	Estrostep Fe	
Norethindrone Acetate/ Ethinyl Estradiol	Tablets	1 mg/0.02 mg, 1 mg/ 0.03 mg and 1 mg /0.035 mg	Estrostep 21	
Norethindrone Acetate/ Ethinyl Estradiol and Ferrous Fumarate	Tablets	1 mg/0.02 mg and 75 mg	Loestrin 24 Fe	4/17/2006
Norethindrone 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/ 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)	

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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 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
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	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

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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	
Oxaliplatin	Injection	5 mg/mL, 10 mL and 20 mL vials	Eloxatin	2/9/2007
Oxaliplatin	For Injection	50 mg/vial and 100 mg/vial	Eloxatin	2/9/2007
Oxaliplatin	Injection	200 mg/40 mL	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
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	
Oxycodone Hydrochloride	Extended-release Tablets	15 mg	Oxycontin	2/15/2007
Oxycodone Hydrochloride	Extended-release Tablets	30 mg and 60 mg	Oxycontin	1/3/2007
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

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Oxymorphone Hydrochloride	Extended-release Tablets	30 mg	Opana ER	6/12/2008
Paclitaxel	Injection	6 mg/mL, 5 mL, 16.7 mL, 25 mL, 33.3 mL and 50 mL vials	Taxol	
Pamidronate Disodium	For Injection	30 mg/vial, 60 mg/vial and 90 mg/vial	Aredia	
Pamidronate Disodium	Injection	30 mg/vial, 60 mg/vial and 90 mg/vial	Aredia	
Pantoprazole Sodium	For Injection	40 mg/vial	Prontonix IV	4/7/2005
Pantoprazole Sodium	Delayed-release Tablets	20 mg and 40 mg	Protonix	2/2/2004
Paricalcitol	Injection	0.002 mg per mL in 1 mL vial and 0.005 mg per mL in 1 mL and 2 mL vials	Zemplar	11/28/2008
Paricalcitol	Capsules	1 mcg and 2 mcg	Zemplar	10/14/2008
Paricalcitol	Capsules	4 mcg	Zemplar	8/25/2008
Paroxetine Hydrochloride	Capsules	10 mg and 20 mg	Paxil	
Paroxetine Hydrochloride	Oral Suspension	10 mg/5 mL	Paxil	2/10/2005
Paroxetine Hydrochloride	Tablets	10 mg, 20 mg, 30 mg and 40 mg	Paxil	
Paroxetine Hydrochloride	Extended-release Tablets	25 mg	Paxil CR	9/9/2005
Paroxetine Hydrochloride	Extended-release Tablets	37.5 mg	Paxil CR	5/19/2009
Pemetrexed Disodium	For Injection	100 mg/vial	Alimta	7/1/2008
Pemetrexed Disodium	For Injection	500 mg/vial	Alimta	2/4/2008
Pergolide Mesylate	Tablets	0.05 mg, 0.25 mg and 1 mg	Permax	
Perindopril Erbumine	Tablets	2 mg, 4 mg and 8 mg	Aceon	6/6/2006
Pioglitazone Hydrochloride	Tablets	15 mg, 30 mg and 45 mg	Actos	
Pioglitazone Hydrochloride and Glimepiride	Tablets	30 mg/2 mg and 30 mg/4 mg	Duetact	12/22/2009
Pioglitazone Hydrochloride and Metformin Hydrochloride	Tablets	15 mg/500 mg and 15 mg/850 mg	Actoplus Met	3/6/2008

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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 Tablets	210 g, 5.6 g, 0.74 g, 2.86 g and 5 mg	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
Potassium Chloride	Extended-release Capsules	8 mEq and 10 mEq	Micro K	
Potassium Chloride	Extended-release Tablets	10 mEq and 20 mEq	K-Dur	
Pramipexole Dihydrochloride	Tablets	0.125 mg, 0.5 mg, 1 mg and 1.5 mg	Mirapex	6/24/2005
Pramipexole Dihydrochloride	Tablets	0.25 mg	Mirapex	5/27/2005
Pramipexole Dihydrochloride	Tablets	0.75 mg	Mirapex	7/31/2008
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	
Pregabalin	Capsules	25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg	Lyrica	12/30/2008
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	

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Propranolol Hydrochloride	Extended-release Capsules	60 mg, 80 mg, 120 mg and 160 mg	Inderal LA	
Quetiapine Fumarate	Tablets	25 mg	Seroquel	8/12/2005
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	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
Quetiapine Fumarate	Tablets	200 mg and 300 mg	Seroquel XR	6/12/2008
Quetiapine Fumarate	Extended-release Tablets	50 mg	Seroquel XR	10/17/2008
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	
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
Repaglinide	Tablets	0.5 mg, 1 mg and 2 mg	Prandin	2/10/2005

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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 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
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
Rizatriptan Benzoate	Tablets	5 mg and 10 mg	Maxalt	9/2/2004
Rizatriptan Benzoate	Orally Disintegrating Tablets	5 mg and 10 mg	Maxalt-MLT	2/17/2006
Rofecoxib	Tablets	12.5 mg, 25 mg and 50 mg	Vioxx	
Ropinirole Hydrochloride	Extended-release Tablets	2 mg	Requip XL	10/14/2008
Ropinirole Hydrochloride	Extended-release Tablets	4 mg	Requip XL	10/31/2008
Ropinirole Hydrochloride	Extended-release Tablets	6 mg	Requip XL	7/14/2009
Ropinirole Hydrochloride	Extended-release Tablets	8 mg	Requip XL	11/3/2008
Ropinirole Hydrochloride	Tablets	0.25 mg, 0.5 mg, 1 mg and 2 mg	Requip	12/22/2004
Ropinirole Hydrochloride	Tablets	3 mg, 4 mg and 5 mg	Requip	2/4/2005
Ropinirole Hydrochloride	Extended-release Tablets	3 mg	Requip XL	1/8/2009
Ropinirole Hydrochloride	Extended-release Tablets	12 mg	Requip XL	2/5/2009

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Ropivacaine Hydrochloride	Injection	2 mg/mL, 5 mg/mL and 10 mg/mL, 20 mL, 30 mL and 20 mL vials	Naropin	11/13/2006
Rosiglitazone Maleate	Tablets	2 mg, 4 mg and 8 mg	Avandia	
Rosiglitazone Maleate and Metformin Hydrochloride	Tablets	1 mg/ 500 mg, 2 mg/ 500mg, 4 mg/ 500 mg, 2 mg/ 1000 mg and 4 mg/ 1000 mg	Avandamet	10/22/2004
Rosuvastatin Calcium	Tablets	5 mg, 10 mg, 20 mg and 40 mg	Crestor	8/13/2007
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	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
Silver Sulfadiazine	Cream	1%	Silvadene	
Simvastatin	Tablets	5 mg, 10 mg, 20 mg, 40 mg and 80 mg	Zocor	
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
Solifenacin Succinate	Tablets	5 mg and 10 mg	Vesicare	4/8/2009
Sumatriptan Succinate	Injection	6 mg/0.5 mL, 0.5 mL vials	Imitrex	10/25/2004

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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
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
Telmisartan and Hydrochlorothiazide	Tablets	80 mg/25 mg	Micardis HCT	2/27/2009
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
Terazosin Hydrochloride	Capsules	1 mg, 2 mg, 5 mg and 10 mg	Hytrin	
Terazosin Hydrochloride	Tablets	1 mg, 2 mg, 5 mg and 10 mg	Hytrin	
Terbinafine Hydrochloride	Tablets	250 mg	Lamisil	
Terfenadine	Tablets	60 mg	Seldane	
Testosterone	Gel	1%	Androgel	
Testosterone	Gel	1%	Testim	8/21/2008
Testosterone	Gel Metered-dose Pump	1%	Androgel	12/19/2008
Thalidomide	Capsules	50 mg and 100 mg	Thalomid	12/18/2006
Thalidomide	Capsules	200 mg	Thalomid	9/25/2006
Tiagabine Hydrochloride	Tablets	2 mg and 4 mg	Gabitril	2/1/2005
Ticlopidine Hydrochloride	Tablets	250 mg	Ticlid	
Tigecycline	For Injection	50 mg per vial	Tygacil	6/15/2009
Timolol Maleate	Ophthalmic Solution	0.25% and 0.5%	Timoptic	
Tizanidine Hydrochloride	Capsules	2 mg, 4 mg and 6 mg	Zanaflex	8/10/2007

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Tobramycin	Inhalation Solution	300 mg/5 mL	Tobi	6/29/2009
Tolterodine Tartrate	Extended-release Capsules	2 mg and 4 mg	Detrol LA	7/30/2007
Tolterodine Tartrate	Tablets	1 mg and 2 mg	Detrol	
Topiramate	Capsules	15 mg and 25 mg	Topamax Sprinkle	9/7/2005
Topiramate	Tablets	25 mg, 100 mg and 200 mg	Topamax	12/26/2001
Topiramate	Tablets	50 mg	Topamax	9/8/2005
Torsemide	Tablets	5 mg, 10 mg, 20 mg, and 100 mg	Demadex	
Tramadol Hydrochloride	Tablets	50 mg	Ultram	
Tramadol Hydrochloride	Extended-release Tablets	100 mg	Ultram ER	1/8/2007
Tramadol Hydrochloride	Extended-release Tablets	200 mg	Ultram ER	3/28/2007
Tramadol Hydrochloride	Extended-release Tablets	300 mg	Ultram ER	9/25/2007
Tramadol Hydrochloride	Extended-release Tablets	100 mg, 200 mg and 300 mg	Ryzolt	6/18/2009
Trandolapril	Tablets	1 mg, 2 mg and 4 mg	Mavik	10/4/2004
Trandolapril and Verapamil Hydrochloride	Extended-release Tablets	2 mg/180 mg and 2 mg/240 mg	Tarka	11/9/2007
Trandolapril and Verapamil Hydrochloride	Extended-release Tablets	1 mg/240 mg	Tarka	2/20/2008
Trandolapril and Verapamil Hydrochloride	Extended-release Tablets	4 mg/ 240 mg	Tarka	7/24/2007
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	
Tretinoin	Cream	0.025%, 0.05% and 0.1%	Retin-A	
Tretinoin	Gel	0.025%	Retin-A	
Triamcinolone Acetonide	Nasal Spray	0.055 mg/Spray	Nasacort AQ	12/29/2005
Triamterene/ Hydrochlorothiazide	Tablets	37.5 mg/25 mg and 75 mg/50 mg	Maxzide	
Trospium Chloride	Extended-release Capsules	60 mg	Sanctura XR	3/2/2009
Valacyclovir Hydrochloride	Tablets	500 mg and 1000 mg	Valtrex	

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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
Verapamil Hydrochloride	Extended-release Capsules	100 mg and 200 mg	Verelan PM	7/20/2006
Verapamil Hydrochloride	Extended-release Capsules	120 mg, 180 mg and 240 mg	Verelan SR	
Verapamil Hydrochloride	Extended-release Tablets	180 mg	Isoptin SR	
Verapamil Hydrochloride	Extended-release Tablets	240 mg	Covera HS	
Verapamil Hydrochloride	Extended-release Capsules	300 mg	Verelan PM	5/19/2006
Vincristine Sulfate	Injection	1 mg/mL, 1 mL, 2 mL and 5 mL vials	Oncovin	
Voriconazole	For Injection	200 mg/vial	Vfend	9/12/2008
Voriconazole	Tablets	50 mg and 200 mg	Vfend	4/14/2008

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DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
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
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
* ANDA withdrawn				