



Drug Information

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Paragraph IV Patent Certifications As of August 1, 2003

The Agency is making available, on a trial basis, a list of drug products for which an Abbreviated New Drug Application (ANDA) has been received by the Office of Generic Drugs (OGD) containing a "Paragraph IV" patent certification. This list includes the name of the drug product, dosage form, strength (subject of Paragraph IV certification), and reference listed drug (RLD). The Agency will not disclose when the ANDA was received by the Office of Generic Drugs or the identity of the applicant. This information will be updated on a monthly basis and will be as current as the last update. This information should be used for reference only. The Agency will make every effort to ensure the accuracy of the information disclosed in this list. However, any discrepancies or disparities should be discussed with the Regulatory Support Branch at 301-827-5862, before making any decisions based on this information. **Additions to this month's list are in red.**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD
Acetaminophen	Extended-release Tablet	650 mg	Tylenol
Acetaminophen/ Aspirin/ Caffeine	Tablet	250 mg/ 250 mg/ 65 mg	Excedrin (migraine)
Acetaminophen and Tramadol Hydrochloride	Tablet	325 mg/ 37.5 mg	Ultracet
Acyclovir Sodium	Injection	50 mg/mL, 10 mL and 20 mL vials	Zovirax
Albuterol Sulfate	Oral Syrup	2 mg(base)/ 5 mL	Ventolin
Albuterol Sulfate	Extended-release Tablets	4 mg and 8 mg	Volmax
Alendronate Sodium	Tablets	5 mg, 10 mg, 35 mg, 40 mg and 70 mg	Fosamax
Alprazolam	Tablets	0.25 mg, 0.5 mg, 1 mg and 2 mg	Xanax
Amlodipine Besylate	Tablets	2.5 mg, 5 mg and	Norvasc

		10 mg	
Atenolol	Tablets	25 mg, 50 mg and 100 mg	Tenormin
Atenolol/ Chlorthalidone	Tablets	50 mg/ 25 mg and 100 mg/ 25 mg	Tenoretic
Atorvastatin Calcium	Tablets	10 mg, 20 mg, 40 mg and 80 mg	Lipitor
Betaxolol	Ophthalmic Solution	0.5%(base)	Betoptic
Brimonidine Tartrate	Ophthalmic Solution	0.2%	Alphagan
Bupropion Hydrochloride	Extended-release Tablet	150 mg	Zyban
Bupropion Hydrochloride	Extended-release Tablets	100 mg, 150 mg and 200 mg	Wellbutrin SR
Bupropion Hydrochloride	Tablets	75 mg and 100 mg	Wellbutrin
Bupirone Hydrochloride	Tablets	5 mg, 7.5 mg, 10 mg, 15 mg and 30 mg	Buspar
Butorphanol Tartrate	Nasal Spray	10 mg/mL	Stadol NS
Calcitonin-Salmon	Nasal Spray	200 IU/ spray	Miacalcin
Calcitriol	Injection	1 mcg/mL and 2 mcg/mL, 1 mL vials	Calcijex
Captopril	Tablets	12.5 mg, 25 mg, 50 mg, and 100 mg	Capoten
Carbamazepine	Extended-release Tablet	200 mg and 400 mg	Tegretol XR
Carbamazepine	Extended-release Capsule	300 mg	Carbatrol
Carbidopa/ Levodopa	Extended-release Tablets	25 mg/ 100 mg and 50 mg/ 200 mg	Sinemet CR

Carboplatin	For Injection	50 mg/vial, 150 mg/vial and 450 mg/vial	Paraplatin
Carboplatin	Injection	50 mg/vial, 150 mg/vial and 450 mg/vial	Paraplatin
Carisoprodol/ Aspirin	Tablet	200 mg/ 325 mg	Soma Compound
Carisoprodol/ Aspirin/Codeine	Tablet	200 mg/ 325 mg/ 16 mg	Soma Compound with Codeine
Carvedilol	Tablets	3.125 mg, 6.25 mg, 12.5 mg and 25 mg	Coreg
Chlorhexidine Gluconate	Scrub brush/sponge	4%	Hibiclens
Ciprofloxacin Hydrochloride	Tablets	100 mg, 250 mg, 500 mg and 750 mg	Cipro
Cisplatin	Injection	1 mg/mL, 10 mL, 50 mL, 100 mL and 200 mL vials	Platinol-AQ
Cisplatin	For Injection	10 mg/vial and 50 mg/vial	Platinol
Clonidine Hydrochloride	Transdermal System	0.1 mg/day, 0.2 mg/day, and 0.3 mg/day	Catapres-TTS
Clopidogrel Bisulfate	Tablet	75 mg	Plavix
Cyclobenzaprine Hydrochloride	Tablet	10 mg	Flexeril
Cyclophosphamide	For Injection	100 mg/vial, 200 mg/vial, 500 mg/vial, 1 g/vial and 2 g/vial	Cytosan
Desmopressin Acetate	Injection	4 mcg/mL, 1 mL and 10 mL vials	DDAVP
Desmopressin Acetate	Nasal Solution (nasal spray)	0.01%	DDAVP

Desmopressin Acetate	Tablets	0.1 mg and 0.2 mg	DDAVP
Desogestrel; Ethinyl Estradiol Tablets	Tablets	0.15mg/ 0.02 mg and 0.01 mg	Mircette
Dexrazoxane	For Injection	250 mg/vial	Zinecard
Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate	Extended-release Capsules	5 mg, 10 mg, 15 mg, 20 mg, 25 mg and 30 mg	Adderall XR
Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate	Tablets	7.5 mg, 12.5 mg and 15 mg	Adderall
Diazepam	Tablets	2 mg, 5 mg and 10 mg	Valium
Diltiazem Hydrochloride	Extended-release Capsules	120 mg, 180 mg and 240 mg	Dilacor XR
Diltiazem Hydrochloride	Extended-release Capsules	120 mg, 180 mg, 240 mg, 300 mg and 360 mg	Tiazac
Diltiazem Hydrochloride	Extended-release Capsules	120 mg, 180 mg, 240 mg and 300 mg	Cardizem CD
Diltiazem Hydrochloride	Extended-release Capsules	60 mg, 90 mg and 120 mg	Cardizem SR
Divalproex Sodium	Delayed-release Tablets	125 mg, 250 mg and 500 mg	Depakote
Doxazosin Mesylate	Tablets	1 mg, 2 mg, 4 mg and 8 mg	Cardura
Enalapril Maleate	Tablets	2.5 mg, 5 mg, 10 mg and 20 mg	Vasotec
Enoxaparin Sodium	Injection	100 mg/mL, 0.3 mL, 0.4 mL, 0.6 mL, 0.8 mL and 1 mL prefilled syringes 150 mg/mL, 0.6 mL, 0.8 mL and 1 mL prefilled syringes	Lovenox

Escitalopram Oxalate	Tablets	5 mg, 10 mg and 20 mg	Lexapro
Esmolol Hydrochloride	Injection	10 mg/mL, 10 mL vial	Brevibloc
Estradiol	Transdermal System	0.05 mg/day and 0.1 mg/day	Climara
Etodolac	Extended-release Tablets	400 mg, 500 mg and 600 mg	Lodine XL
Famotidine	Tablet	10 mg (OTC)	Pepcid AC
Famotidine	Tablets	20 mg and 40 mg	Pepcid
Famotidine	Injection	10 mg/mL, 4 mL and 20 mL vials; preserved	Pepcid
Famotidine	Injection	10 mg/mL, 50 mL vial, pharmacy bulk package; unpreserved	Pepcid
Famotidine	Injection	10 mg/mL, 2 mL vials; unpreserved	Pepcid
Famotidine	Tablet (Chewable)	10 mg (OTC)	Pepcid AC (chewable)
Felodipine	Extended-release Tablets	2.5 mg, 5 mg and 10 mg	Plendil ER
Fenofibrate	Capsules	67 mg, 134 mg and 200 mg	Tricor
Fenofibrate	Tablets	54 mg, 107 mg and 160 mg	Tricor
Fentanyl	Transdermal Extended-release Film	0.6 mg/ 24 hr, 1.2 mg/ 24 hr, 1.8 mg/ 24 hr and 2.4 mg/ 24 hr	Duragesic
Fexofenadine Hydrochloride	Capsule	60 mg	Allegra
Fexofenadine Hydrochloride	Tablets	30 mg, 60 mg and	Allegra

		180 mg	
Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride	Extended-release Tablet	60 mg/ 120 mg	Allegra-D
Finasteride	Tablet	5 mg	Proscar
Finasteride	Tablet	1 mg	Propecia
Flecainide Acetate	Tablets	50 mg, 100 mg and 150 mg	Tambocor
Fluconazole	Tablets	50 mg, 100 mg, 150 mg and 200 mg	Diflucan
Fluconazole	For Oral Suspension	50 mg/5 mL and 200 mg/ 5 mL	Diflucan for Oral Suspension
Flunisolide	Nasal Solution	0.025%	Nasalide
Fluocinonide	Ointment	0.05%	Lidex
Fluoxetine Hydrochloride	Tablets	10 mg and 20 mg	Prozac
Fluoxetine Hydrochloride	Capsules	10 mg, 20 mg and 40 mg	Prozac
Fluoxetine Hydrochloride	Delayed-release Capsule	90 mg	Prozac Weekly
Fluoxetine Hydrochloride	Oral Solution	20 mg (base)/ 5 mL	Prozac
Fluoxetine Hydrochloride	Capsules	10 mg and 20 mg	Sarafem
Flutamide	Capsule	125 mg	Eulexin
Fosinopril Sodium	Tablets	10 mg, 20 mg and 40 mg	Monopril
Fosinopril Sodium and Hydrochlorothiazide	Tablets	10 mg/ 12.5 mg and 20 mg/ 12.5 mg	Monopril HCT
Gabapentin	Capsules	100 mg, 300 mg and 400 mg	Neurontin
Gabapentin	Tablets	600 mg and 800 mg	Neurontin
Gabapentin	Oral Solution	250 mg/ 5 mL	Neurontin

Ganciclovir Sodium	Capsules	250 mg and 500 mg	Cytovene
Glipizide	Extended-release Tablet	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
Hydrocodone Bitartrate and Ibuprofen	Tablet	7.5 mg/ 200 mg	Vicoprofen
Ibuprofen	Chewable Tablets	50 mg and 100 mg	Children's Motrin, Junior Strength Motrin
Ibuprofen	Oral Suspension	100 mg/ 5 mL (Rx)	Motrin
Ibuprofen	Oral Suspension	100 mg/ 5 mL (OTC)	Children's Motrin
Ibuprofen	Oral Drops	40 mg/mL	Children's Motrin Drops
Ibuprofen and Pseudoephedrine Hydrochloride	Tablet	200 mg/ 30 mg	Advil Cold and Sinus
Ibuprofen and Pseudoephedrine Hydrochloride	Oral Suspension	100 mg/ 15 mg per 5 mL	Children's Motrin Cold
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	Ifex/ Mesnex Kit

		mg/mL, 10 mL vial	
Indomethacin	Extended-release Capsule	75 mg	Indocin SR
Itraconazole	Capsule	100 mg	Sporanox
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	Tablet	10 mg	Toradol
Lactulose	Oral Syrup	10 g/15 mL	Cephulac
Lactulose	Oral Syrup	10 g/15 mL	Chronulac
Lamotrigine	Tablets	25 mg, 100 mg, 150 mg and 200 mg	Lamictal
Lamotrigine	Chewable Tablets	5 mg and 25 mg	Lamictal CD
Latanoprost	Ophthalmic Solution	0.005%	Xalatan
Leuprolide Acetate	Injection (depot)	7.5 mg/vial	Lupron Depot
Levofloxacin	Tablets	250 mg, 500 mg and 750 mg	Levaquin
Levofloxacin	Injection	25 mg/mL	Levaquin
Levofloxacin	Injection	5 mg/mL; 50 mL, 100 mL and 150 mL vials	Levaquin in Dextrose 5% in Plastic Container
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
Loperamide HCl and Simethicone	Tablet	2 mg/ 125 mg	Imodium Advanced
Loratadine	Tablet	10 mg	Claritin

Loratadine	Oral Syrup	1 mg/mL	Claritin
Loratadine	Orally Disintegrating Tablet	10 mg	Claritin RediTabs
Loratadine/ Pseudoephedrine	Extended-release Tablet	5 mg/ 120 mg	Claritin D- 12 hour
Loratadine/ Pseudoephedrine	Extended-release Tablet	10 mg/ 240 mg	Claritin D-24 hour
Mefloquine Hydrochloride	Tablet	250 mg	Lariam
Megestrol Acetate	Oral Suspension	40 mg/mL	Megace
Metaxalone	Tablet	400 mg	Skelaxin
Metformin Hydrochloride	Extended-release Tablet	500 mg	Glucophage XR
Metoclopramide Hydrochloride	Injection	5 mg/mL, 2 mL, 10 mL, 20 mL and 30 mL vials	Reglan
Metoprolol Succinate	Extended-release Tablet	200 mg	Toprol XL
Mirtazapine	Tablets	7.5 mg, 15 mg, 30 mg, and 45 mg	Remeron
Mirtazapine	Orally Disintegrating Tablets	15 mg and 30 mg	Remeron SolTab
Modafinil	Tablets	100 mg and 200 mg	Provigil
Moexipril Hydrochloride	Tablets	7.5 mg and 15 mg	Univasc
Mometasone Furoate	Cream	0.1%	Elocon
Nabumetone	Tablets	500 mg and 750 mg	Relafen
Naproxen Sodium	Extended-release Tablets	375 mg (base) and 500 mg (base)	Naprelan
Nefazodone HCl	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

Nicotine	Transdermal System	7 mg/day, 14 mg/day and 21 mg/day	Habitrol
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
Nitrofurantoin Monohydrate/Macrocrystals	Capsule	75 mg/25 mg	Macrobid
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
Nizatidine	Capsules	150 mg and 300 mg	Axid
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
Norethindrone Acetate/Ethinyl Estradiol	Tablet	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
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
Ofloxacin	Otic Solution	0.3%	Floxin
Olanzapine	Tablets	2.5 mg, 5 mg, 7.5 mg, 10 mg and 15 mg	Zyprexa
Olanzapine	Tablet	20 mg	Zyprexa
Olanzapine	Orally Disintegrating Tablets	5 mg, 10 mg, 15 mg and 20 mg	Zyprexa Zydis
Omeprazole	Delayed- release Capsules	10 mg, 20 mg and 40 mg	Prilosec
Ondansetron Hydrochloride	Tablets	4mg, 8 mg, 16 mg and 24 mg	Zofran
Ondansetron Hydrochloride	Orally Disintegrating Tablets	4 mg and 8 mg	Zofran ODT
Ondansetron Hydrochloride	Injection	2 mg/mL, 20 mL Vials	Zofran
Ondansetron Hydrochloride	Injection	2 mg/mL, 2 mLVials (Preservative- free)	Zofran
Oxazepam	Capsules	10 mg, 15 mg and 30 mg	Serax
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
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
Paroxetine Hydrochloride	Tablets	10 mg, 20 mg, 30 mg and 40 mg	Paxil
Paroxetine Hydrochloride	Capsules	10 mg and 20 mg	Paxil
Pergolide Mesylate	Tablets	0.05 mg, 0.25 mg and 1 mg	Permax
Polyethylene Glycol 3350	Powder for Oral Solution	17g/Scoopful	Miralax
Potassium Chloride	Extended-release Tablets	10 mEq and 20 mEq	K-Dur
Potassium Chloride	Extended-release Capsules	8 mEq and 10 mEq	Micro K
Pravastatin Sodium	Tablets	10 mg, 20 mg, 40 mg and 80 mg	Pravachol
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
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
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 20 mg/ 25 mg	Accuretic
Raloxifene Hydrochloride	Tablet	60 mg	Evista
Ramipril	Capsules	1.25 mg, 2.5 mg, 5 mg and 10 mg	Altace
Ranitidine	Injection	25 mg/mL, 2 mL and 6 mL and 40 mL vials	Zantac
Ranitidine	Tablets	75 mg, 150 mg and 300 mg	Zantac
Ranitidine	Capsules	150 mg and 300 mg	Zantac
Ranitidine	Oral Solution	15 mg/mL	Zantac
Risperidone	Oral Solution	1 mg/mL	Risperdal
Ribavirin	Capsule	200 mg	Rebetol
Rofecoxib	Tablets	12.5 mg, 25 mg and 50 mg	Vioxx
Rosiglitazone Maleate	Tablets	2 mg, 4 mg and 8 mg	Avandia
Sertraline Hydrochloride	Tablets	25 mg, 50 mg and 100 mg	Zoloft
Sevoflurane	Inhalation	100%, 250 mL	Ultane
Silver Sulfadiazine	Cream	1%	Silvadene
Simvastatin	Tablets	5 mg, 10 mg, 20 mg, 40 mg and 80 mg	Zocor

Sumatriptan Succinate	Tablets	25 mg, 50 mg and 100 mg	Imitrex
Tamoxifen Citrate	Tablets	10 mg and 20 mg	Nolvadex
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	Tablet	250 mg	Lamisil
Terfenadine	Tablet	60 mg	Seldane
Testosterone	Gel	1%	Androgel
Ticlopidine Hydrochloride	Tablet	250 mg	Ticlid
Timolol Maleate	Ophthalmic Solution	0.25% and 0.5%	Timoptic
Torsemide	Tablets	5 mg, 10 mg, 20 mg, and 100 mg	Demadex
Tramadol Hydrochloride	Tablet	50 mg	Ultram
Trazodone Hydrochloride	Tablet	150 mg	Desyrel
Tretinoin	Cream	0.025%, 0.05% and 0.1%	Retin-A
Tretinoin	Gel	0.025%	Retin-A
Triamterene/ Hydrochlorothiazide	Tablets	37.5 mg/ 25 mg and 75 mg/ 50 mg	Maxzide
Valacyclovir Hydrochloride	Tablets	500 mg and 1 g	Valtrex
Venlafaxine Hydrochloride	Extended-release Capsules	37.5 mg, 75 mg and 150 mg	Effexor XR
Vecuronium Bromide	For Injection	10 mg/vial and 20 mg/vial	Norcuron
Verapamil Hydrochloride	Extended-release Capsules	120 mg, 180 mg and 240 mg	Verelan SR
Verapamil Hydrochloride	Extended-release Tablet	180 mg	Isoptin SR

Vincristine Sulfate	Injection	1 mg/mL, 1 mL, 2 mL and 5 mL vials	Oncovin
Zidovudine	Capsule	100 mg	Retrovir



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