

[CDER Home](#)[About CDER](#)[Drug Information](#)[Regulatory Guidance](#)[CDER Calendar](#)[Specific Audiences](#)[CDER Archives](#)

Search

GO

powered by

Paragraph IV Patent Certifications As of September 5, 2005

Below is 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), reference listed drug (RLD), **and the date on which the first substantially complete generic drug application was submitted to the Agency (on a prospective basis beginning 3/2/04)**. The Agency will not disclose the identity of the applicant. This information will be updated on a **bi-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.

Any additions from the preceding list will be highlighted in red. (Note: New additions are not always received.)

- [FDA News: FDA announces measure to improve generic drug access](#)
- [Docket # 2000P-1556 Policy regarding ANDA holder confidentiality](#)

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Acarbose	Tablets	25 mg, 50 mg and 100 mg	Precose	3/22/2005
Acetaminophen	Extended-release Tablets	650 mg	Tylenol	
Acetaminophen/ Aspirin/ Caffeine	Tablets	250 mg/250 mg/ 65 mg	Excedrin (migraine)	
Acetaminophen and Tramadol Hydrochloride	Tablets	325 mg/ 37.5 mg	Ultracet	
Acyclovir Sodium	Injection	50 mg/mL, 10 mL and 20 mL vials	Zovirax	
Adenosine	Injection	3 mg/mL, 20 mL and 30 mL	Adenoscan	4/18/2005

		vials		
Albuterol Sulfate	Oral Syrup	2 mg(base)/ 5 mL	Ventolin	
Albuterol Sulfate	Extended-release Tablets	4 mg and 8 mg	Volmax	
Albuterol Sulfate/ Ipratropium Bromide	Inhalation Solution	0.083%/ 0.017%	Duoneb	
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	
Amifostine	For Injection	500 mg/vial	Ethyol	4/16/2004
Amlodipine Besylate	Tablets	2.5 mg, 5 mg and 10 mg	Norvasc	
Amlodipine Besylate and Benazepril Hydrochloride	Capsules	2.5 mg/10 mg, 5 mg/10 mg, 5 mg/20 mg and 10 mg/20 mg	Lotrel	6/9/2004
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 Tablets	150 mg and 300 mg	Wellbutrin XL	9/21/2004
Bupropion Hydrochloride	Extended-release Tablets	150 mg	Zyban	
Bupropion Hydrochloride	Extended-release Tablets	100 mg, 150 mg and 200 mg	Wellbutrin SR	
Bupropion Hydrochloride	Tablets	75 mg and 100	Wellbutrin	

		mg		
Buspirone 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	
Calcium Acetate	Capsules	EQ 169 mg calcium	PhosLo	5/31/2005
Calcium Carbonate/ Famotadine/ Magnesium Hydroxide	Chewable Tablets	800 mg/ 10 mg/ 165 mg (OTC)	Pepcid Complete	11/1/2004
Captopril	Tablets	12.5 mg, 25 mg, 50 mg, and 100 mg	Capoten	
Carbamazepine	Extended-release Tablets	200 mg and 400 mg	Tegretol XR	
Carbamazepine	Extended-release Capsules	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	Tablets	200 mg/ 325 mg	Soma Compound	
Carisoprodol/ Aspirin/Codeine	Tablets	200 mg/ 325 mg/ 16 mg	Soma Compound with Codeine	
Carvedilol	Tablets	3.125 mg, 6.25	Coreg	

		mg, 12.5 mg and 25 mg		
Celecoxib	Capsules	100 mg, 200 mg and 400 mg	Celebrex	
Cetirizine Hydrochloride and Pseudoephedrine	Extended-release Tablets	5 mg/120 mg	Zyrtec-D	6/2/2004
Cetirizine Hydrochloride	Chewable Tablets	5 mg and 10 mg	Zyrtec	3/25/2005
Chlorhexidine Gluconate	Scrub brush/sponge	4%	Hibiclens	
Hydrocodone Polistirex and Chlorpheniramine Polistirex	Extended-release Capsules	8 mg/10 mg and 4 mg/5 mg	Tussionex	9/10/2004
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	Tablets	75 mg	Plavix	
Clobetasol Propionate	Topical Foam	0.05%	Olux	6/27/2005
Conjugated Estrogens	Tablets	0.3 mg and 0.625 mg	Premarin	
Cyclobenzaprine Hydrochloride	Tablets	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	DDAVP	

		vials		
Desmopressin Acetate	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	
Dexmethylphenidate Hydrochloride	Tablets	5 mg and 10 mg	Focalin	5/27/2004
Dexmethylphenidate Hydrochloride	Tablets	2.5 mg	Focalin	7/27/2004
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	
Diazepam	Rectal Gel	2.5 mg/0.5 mL, 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL and 20 mg/4 mL	Diastat	3/23/2004
Didanosine	Delayed-release Capsules	200 mg, 250 mg and 400 mg	Videx EC	6/1/2004
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, 360 mg and 420 mg	Tiazac	
Diltiazem Hydrochloride	Extended-release Capsules	120 mg, 180 mg, 240 mg and 300 mg	Cardizem CD	
Diltiazem Hydrochloride	Extended-release	60 mg, 90 mg and 120 mg	Cardizem SR	

	Capsules			
Diltiazem Hydrochloride	Extended-release Tablets	420 mg	Cardizem LA	4/25/2005
Divalproex Sodium	Delayed-release Tablets	125 mg, 250 mg and 500 mg	Depakote	
Divalproex Sodium	Extended-release Tablets	250 mg	Depakote ER	5/3/2004
Divalproex Sodium	Extended-release Tablets	500 mg	Depakote ER	2/8/2005
Donepezil Hydrochloride	Tablets	5 mg and 10 mg	Aricept	
Doxazosin Mesylate	Tablets	1 mg, 2 mg, 4 mg and 8 mg	Cardura	
Drospirenone and Ethinyl Estradiol	Tablets	3.0 mg/0.03 mg	Yasmin	1/7/2005
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	
Estradiol; Estradiol and Norgestimate	Tablets	1 mg; 1 mg and 0.09 mg	Prefest	
Etodolac	Extended-	400 mg, 500	Lodine XL	

	release Tablets	mg and 600 mg		
Famciclovir	Tablets	125 mg, 250 mg and 500 mg	Famvir	12/28/2004
Famotidine	Tablets	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	Tablets (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	
Fentanyl Citrate	Lozenges	0.4 mg	Actiq	10/6/2004
Fentanyl Citrate	Lozenges	0.2 mg	Actiq	10/29/2004
Fentanyl Citrate	Lozenges	0.8 mg, 1.2 mg and 1.6 mg	Actiq	11/22/2004
Fentanyl Citrate	Lozenges	0.6 mg	Actiq	12/20/2004
Fexofenadine Hydrochloride	Capsules	60 mg	Allegra	
Fexofenadine Hydrochloride	Tablets	30 mg, 60 mg and 180 mg	Allegra	

Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride	Extended-release Tablets	60 mg/120 mg	Allegra-D	
Finasteride	Tablets	5 mg	Proscar	
Finasteride	Tablets	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 Capsules	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	

Galantamine Hydrobromide	Tablets	4 mg, 8 mg and 12 mg	Reminyl	2/28/2005
Ganciclovir Sodium	Capsules	250 mg and 500 mg	Cytovene	
Gatifloxacin	Tablets	200 mg and 400 mg	Tequin	
Gatifloxacin	Injection	10 mg/mL, 20 mL and 40 mL vials	Tequin	11/24/2004
Gatifloxacin in Dextrose 5% in Plastic Container	Injection	2 mg/mL, 100 mL and 200 mL containers (plastic)	Tequin	12/13/2004
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	
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
Hydrocodone Bitartrate and Ibuprofen	Tablets	7.5 mg/200 mg	Vicoprofen	
Hydrocodone Bitartrate and Ibuprofen	Tablets	10 mg/200 mg	Vicoprofen	5/27/2005
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	Tablets	200 mg/30 mg	Advil Cold and Sinus	
Ibuprofen Potassium and Pseudoephedrine Hydrochloride	Capsules	200 mg/30 mg	Advil Cold and Sinus	12/27/2004
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 mg/mL, 10 mL vial	Ifex/ Mesnex Kit	
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
Irinotecan Hydrochloride	Injection	20 mg/mL, 2 mL and 5 mL vials	Camptosar	7/26/2004
Itraconazole	Capsules	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	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	
Lamotrigine	Tablets	25 mg, 100 mg, 150 mg and 200 mg	Lamictal	
Lamotrigine	Chewable Tablets	2 mg, 5 mg and 25 mg	Lamictal CD	
Latanoprost	Ophthalmic Solution	0.005%	Xalatan	
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
Levetiracetam	Tablets	250 mg, 500 mg and 750 mg	Keppra	
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	
Levofloxacin	Ophthalmic Solution	0.5%	Quixin	
Levonorgestrel and Ethinyl Estradiol	Tablets	0.15 mg/0.03 mg	Seasonale	3/29/2004
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	Chewable Tablets	2 mg/125 mg	Imodium Advanced	
Loperamide HCl and Simethicone	Tablets	2 mg/125 mg	Imodium Advanced	12/29/2004
Loratadine	Tablets	10 mg	Claritin	
Loratadine	Syrup	1 mg/mL	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
Mefloquine Hydrochloride	Tablets	250 mg	Lariam	
Megestrol Acetate	Oral Suspension	40 mg/mL	Megace	
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	
Methylphenidate Hydrochloride	Extended-release Capsules	10 mg, 20 mg and 30 mg	Methadate CD	5/13/2005
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
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	Provigil	

		200 mg		
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	Topical Solution (Cream)	0.1%	Elocon	
Mometasone Furoate	Topical Solution (Lotion)	0.1%	Elocon	6/10/2004
Moxifloxacin Hydrochloride	Tablets	400 mg	Avelox	
Nabumetone	Tablets	500 mg and 750 mg	Relafen	
Naproxen Sodium	Extended-release Tablets	375 mg (base) and 500 mg (base)	Naprelan	
Nateglinide	Tablets	60 mg and 120 mg	Starlix	12/22/2004
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	
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	
Nitrofurantoin Monohydrate/Macrocrystals	Capsules	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	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	
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	
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	
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	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
Omeprazole	Delayed-release Capsules	10 mg, 20 mg and 40 mg	Prilosec	
Ondansetron Hydrochloride	Oral Solution	4 mg/5 mL	Zofran	12/20/2004
Ondansetron Hydrochloride	Tablets	4 mg, 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 mL vials (Preservative-free)	Zofran	
Ondansetron Hydrochloride	Injection	0.64 mg/mL, 50 mL container (plastic)	Zofran in Plastic Container	
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-	10 mg, 20 mg,	Oxycontin	

	release Tablets	40 mg, 80 mg and 160 mg		
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	Delayed-release Tablets	20 mg and 40 mg	Protonix	2/02/2004
Pantoprazole Sodium	For Injection	40 mg/vial	Prontonix IV	4/7/2005
Paroxetine Hydrochloride	Tablets	10 mg, 20 mg, 30 mg and 40 mg	Paxil	
Paroxetine Hydrochloride	Capsules	10 mg and 20 mg	Paxil	
Paroxetine Hydrochloride	Oral Suspension	10 mg/5 mL	Paxil	2/10/2005
Pergolide Mesylate	Tablets	0.05 mg, 0.25 mg and 1 mg	Permax	
Pioglitazone Hydrochloride	Tablets	15 mg, 30 mg and 45 mg	Actos	
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	
Pramipexole Dihydrochloride	Tablets	0.25 mg	Mirapex	5/27/2005
Pramipexole Dihydrochloride	Tablets	0.125 mg, 0.5 mg, 1 mg and 1.5 mg	Mirapex	6/24/2005

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	
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 20mg/25 mg	Accuretic	
Rabeprazole Sodium	Delayed-release Tablets	20 mg	Aciphex	
Raloxifene Hydrochloride	Tablets	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	Zantac	

		300 mg		
Ranitidine	Oral Solution	15 mg/mL	Zantac	3/22/2005
Repaglinide	Tablets	0.5 mg, 1 mg and 2 mg	Prandin	2/10/2005
Ribavirin	Capsules	200 mg	Rebetol	
Risedronate Sodium	Tablets	5 mg, 30 mg and 35 mg	Actonel	4/23/2004
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	0.5 mg, 1 mg and 2 mg	Risperdal	
Risperidone	Orally Disintegrating Tablets	0.25 mg	Risperdal	6/27/2005
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
Rofecoxib	Tablets	12.5 mg, 25 mg and 50 mg	Vioxx	
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	2/4/5005
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
Sertraline Hydrochloride	Tablets	25 mg, 50 mg	Zoloft	

		and 100 mg		
Sertraline Hydrochloride	Oral Concentrate	20 mg/mL	Zoloft	
Sevoflurane	Inhalation	100%, 250 mL	Ultane	
Sildenafil Citrate	Tablets	100 mg	Viagra	10/25/2004
Sildenafil Citrate	Tablets	25 mg and 50 mg	Viagra	11/19/2004
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	
Sumatriptan Succinate	Injection	6 mg/0.5 mL, 0.5 mL vials	Imitrex	10/25/2004
Tamoxifen Citrate	Tablets	10 mg and 20 mg	Nolvadex	
Tamsulosin Hydrochloride	Capsules	0.4 mg	Flomax	12/20/2004
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	
Tiagabine Hydrochloride	Tablets	2 mg and 4 mg	Gabitril	2/1/2005
Ticlopidine Hydrochloride	Tablets	250 mg	Ticlid	
Timolol Maleate	Ophthalmic Solution	0.25% and 0.5%	Timoptic	
Tolterodine Tartrate	Tablets	1 mg and 2 mg	Detrol	
Topiramate	Tablets	25 mg, 100 mg and 200 mg	Topamax	12/26/2001
Toremide	Tablets	5 mg, 10 mg, 20 mg, and 100 mg	Demadex	
Tramadol Hydrochloride	Tablets	50 mg	Ultram	
Trandolapril	Tablets	1 mg, 2 mg	Mavik	10/4/2004

		and 4 mg		
Trazodone Hydrochloride	Tablets	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	
Valsartan	Tablets	40 mg, 80 mg, 160 mg and 320 mg	Diovan	12/28/2004
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 Tablets	180 mg	Isoptin SR	
Verapamil Hydrochloride	Extended- release Tablets	240 mg	Covera HS	
Vincristine Sulfate	Injection	1 mg/mL, 1 mL, 2 mL and 5 mL vials	Oncovin	
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

[↑ Back to Top](#) [↩ Back to OGD](#)

Date created: February 16, 2005, updated September 13, 2005

[CDER Home Page](#) | [CDER Site Info](#) | [Contact CDER](#) | <http://web.archive.org/web/20050914144022/http://www.fda.gov/cder/whatsnew.htm>
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#) | [HHS Home Page](#)

