

# Drugs

## Under Patent

2010

The comprehensive guide  
to FDA-Approved pharmaceuticals  
covered under patent  
and marketing exclusivity.

*foi*

# Drugs

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The comprehensive guide to  
FDA-Approved pharmaceuticals  
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All information included in **Drugs Under Patent** was derived directly from FDA's computer listing of approved drug products. Therefore, the publisher of this book cannot accept responsibility for errors or omissions in the listings. This book should be regarded only as a guide to patent and exclusivity expirations; further verification of these data should be done before accepting this information as correct.

## Introduction

This book indexes drugs that qualify under the Drug Price Competition and Patent Term Restoration Act (the 1984 Waxman-Hatch Act) for periods of exclusivity, during which abbreviated new drug applications may not generally be submitted or made effective. Drugs qualifying for Orphan Drug Exclusivity are also listed here.

Applications qualifying for periods of exclusivity are:

(1) A new drug application approved after September 24, 1984 for a drug product whose active ingredients have never been approved before. No subsequent ANDA may be submitted for five years from approval; the exception is that an ANDA can be submitted after four years if it contains a certification that the patent is invalid or will not be infringed.

(2) A new drug application approved after September 24, 1984 that includes reports of new clinical investigations that were sponsored by the applicant and were essential to approval. These ANDAs may be made effective three years after the approval of the original application. If an applicant has exclusivity for a new use or indication, this does not preclude the approval of an ANDA for indications not covered by exclusivity.

(3) A supplement to an NDA containing a previously approved active ingredient approved after September 24, 1984, that contains new clinical investigations essential to approval. The approval of a subsequent application for a change approved in the supplement may not be made effective for three years after the approval of the original supplement.

The 1984 amendments do not apply to antibiotic products.

Patent information is also included here. The patents that FDA regards as claiming these drug patents are:

- Patents that claim the active ingredient(s)
- Drug product patents, which include formulation/composition patents
- Use patents for a particular approved indication or method of using the product.

Please note that the Uruguay Round Agreements Act (URAA, also known as GATT) extended the term of patents issued on or after June 8, 1995 from 17 years from date of issue to 20 years from date of filing.

**Drugs Under Patent** provides complete listings of pharmaceuticals affected by the 1984 Act, offering index points by company name, drug trade and generic names, expiration date, dosage form, exclusivity code, patent number, market status and NDA number.

All data used to prepare **Drugs Under Patent** were obtained from the Food & Drug Administration's listing of approved drug products as of December 2009. Therefore, the publisher of this book cannot accept responsibility for errors or omissions in the listings. This book should be regarded only as a guide to patent and exclusivity expirations; further verification of these data should be done before accepting this information as correct.

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## 3M

**Albuterol Sulfate eq 0.09mg base/inh**

<b>Proventil-HFA</b>	<b>NDA No: 020503</b>	<b>Approved: 08/15/96</b>
<b>Inhalation – Aerosol, Metered</b>		
Patent: 5225183	07/06/10	
Patent: 5439670	07/06/10	
Patent: 5605674	02/25/14	
Patent: 5695743	07/06/10	PatUse: U-491
Patent: 5766573	06/16/15	

**Alcohol 61%; Chlorhexidine Gluconate 1%**

<b>Avagard</b>	<b>NDA No: 021074</b>	<b>Approved: 06/07/01</b>
<b>Topical – Solution</b>		
Patent: 5897031	06/21/16	
Patent: 6090395	06/22/15	PatUse: DP
Patent: 6534069	06/22/15	PatUse: DP
Patent: 6623744	06/23/15	PatUse: U-1008
Patent: 7081246	08/03/16	PatUse: DP
Patent: 7566460	06/22/15	PatUse: DP U-1008

## Abbott Laboratories

**Calcitriol 0.001mg/ml**

<b>Calcijex</b>	<b>NDA No: 018874</b>	<b>Approved: 09/25/86</b>
<b>Injection – Injectable</b>		
Patent: 6051567	08/02/19	
Patent: 6051567*PED	02/02/20	
Patent: 6265392	08/02/19	
Patent: 6265392*PED	02/02/20	
Patent: 6274169	08/02/19	
Patent: 6274169*PED	02/02/20	

**Calcitriol 0.002mg/ml**

<b>Calcijex</b>	<b>NDA No: 018874</b>	<b>Approved: 09/25/86</b>
<b>Injection – Injectable</b>		
Patent: 6051567	08/02/19	
Patent: 6051567*PED	02/02/20	
Patent: 6265392	08/02/19	
Patent: 6265392*PED	02/02/20	
Patent: 6274169	08/02/19	
Patent: 6274169*PED	02/02/20	

**Cefdinir 125mg/5ml**

<b>Omnicef</b>	<b>NDA No: 050749</b>	<b>Approved: 12/04/97</b>
<b>Oral – for Suspension</b>		
Patent: 4935507	12/04/11	PatUse: DS

**Cefdinir 250mg/5ml**

<b>Omnicef</b>	<b>NDA No: 050749</b>	<b>Approved: 07/29/04</b>
<b>Oral – for Suspension</b>		
Patent: 4935507	12/04/11	PatUse: DS

**Cefdinir 300mg**

<b>Omnicef</b>	<b>NDA No: 050739</b>	<b>Approved: 12/04/97</b>
<b>Oral – Capsule</b>		
Patent: 4935507	12/04/11	PatUse: DS

**Choline Fenofibrate eq 135mg Fenofibric Acid**

<b>Trilipix</b>	<b>NDA No: 022224</b>	<b>Approved: 12/15/08</b>
<b>Oral – Capsule, Delayed Release</b>		
Patent: 7259186	01/07/25	PatUse: DS Mkt Excl: NP 12/15/11

**Choline Fenofibrate eq 45mg Fenofibric Acid**

<b>Trilipix</b>	<b>NDA No: 022224</b>	<b>Approved: 12/15/08</b>
<b>Oral – Capsule, Delayed Release</b>		
Patent: 7259186	01/07/25	PatUse: DS Mkt Excl: NP 12/15/11

**Cisatracurium Besylate eq 10mg base/ml**

<b>Nimbex Preservative Free</b>	<b>NDA No: 020551</b>	<b>Approved: 12/15/95</b>
<b>Injection – Injectable</b>		
Patent: 5453510	09/26/12	PatUse: U-127

**Cisatracurium Besylate eq 2mg base/ml**

<b>Nimbex</b>	<b>NDA No: 020551</b>	<b>Approved: 12/15/95</b>
<b>Injection – Injectable</b>		
Patent: 5453510	09/26/12	PatUse: U-127

**Cisatracurium Besylate eq 2mg base/ml**

<b>Nimbex Preservative Free</b>	<b>NDA No: 020551</b>	<b>Approved: 12/15/95</b>
<b>Injection – Injectable</b>		
Patent: 5453510	09/26/12	PatUse: U-127

**Clarithromycin 500mg**

<b>Biaxin XL</b>	<b>NDA No: 050775</b>	<b>Approved: 03/03/00</b>
<b>Oral – Tablet, Extended Release</b>		
Patent: 6010718	04/11/17	PatUse: DP U-924
Patent: 6551616	07/15/17	PatUse: U-924

**Divalproex Sodium eq 125mg Valproic Acid**

<b>Depakote</b>	<b>NDA No: 019680</b>	<b>Approved: 09/12/89</b>
<b>Oral – Capsule, Delayed Rel Pellets</b>		
		Mkt Excl: M-34 03/24/11
		Mkt Excl: PED 09/24/11

**Divalproex Sodium eq 250mg Valproic Acid**

<b>Depakote ER</b>	<b>NDA No: 021168</b>	<b>Approved: 05/31/02</b>
<b>Oral – Tablet, Extended Release</b>		
Patent: 6511678	12/18/18	
Patent: 6511678*PED	06/18/19	
Patent: 6528090	12/18/18	PatUse: DP
Patent: 6528090*PED	06/18/19	
Patent: 6713086	12/18/18	PatUse: DP U-579
Patent: 6713086*PED	06/18/19	
Patent: 6720004	12/18/18	PatUse: DP
Patent: 6720004*PED	06/18/19	
		Mkt Excl: M-34 03/24/11
		Mkt Excl: PED 09/24/11

**Divalproex Sodium eq 500mg Valproic Acid**

<b>Depakote ER</b>	<b>NDA No: 021168</b>	<b>Approved: 08/04/00</b>
<b>Oral – Tablet, Extended Release</b>		
Patent: 6419953	12/18/18	
Patent: 6419953*PED	06/18/19	
Patent: 6511678	12/18/18	
Patent: 6511678*PED	06/18/19	
Patent: 6528090	12/18/18	PatUse: DP
Patent: 6528090*PED	06/18/19	
Patent: 6528091	12/18/18	PatUse: U-106
Patent: 6528091*PED	06/18/19	
Patent: 6713086	12/18/18	PatUse: DP U-579
Patent: 6713086*PED	06/18/19	
Patent: 6720004	12/18/18	PatUse: DP
Patent: 6720004*PED	06/18/19	
		Mkt Excl: M-34 03/24/11
		Mkt Excl: PED 09/24/11

**Eprosartan Mesylate eq 300mg base**

<b>Teveten</b>	<b>NDA No: 020738</b>	<b>Approved: 12/22/97</b>
<b>Oral – Tablet</b>		
Patent: 5185351	02/09/10	PatUse: U-3
Patent: 5656650	08/12/14	PatUse: U-3
		<b>Discontinued</b>

**Eprosartan Mesylate eq 400mg base**

<b>Teveten</b>	<b>NDA No: 020738</b>	<b>Approved: 12/22/97</b>
<b>Oral – Tablet</b>		
Patent: 5185351	02/09/10	PatUse: U-3
Patent: 5656650	08/12/14	PatUse: U-3

**Eprosartan Mesylate eq 600mg base**

<b>Teveten</b>	<b>NDA No: 020738</b>	<b>Approved: 05/27/99</b>
<b>Oral – Tablet</b>		
Patent: 5185351	02/09/10	PatUse: U-3
Patent: 5656650	08/12/14	PatUse: U-3

**Eprosartan Mesylate 600mg; Hydrochlorothiazide 12.5mg**

<b>Teveten HCT</b>	<b>NDA No: 021268</b>	<b>Approved: 11/01/01</b>
<b>Oral – Tablet</b>		
Patent: 5185351	02/09/10	PatUse: U-3
Patent: 5656650	08/12/14	PatUse: U-3

**Eprosartan Mesylate 600mg; Hydrochlorothiazide 25mg**

<b>Teveten HCT</b>	<b>NDA No: 021268</b>	<b>Approved: 11/01/01</b>
<b>Oral – Tablet</b>		
Patent: 5185351	02/09/10	PatUse: U-3
Patent: 5656650	08/12/14	PatUse: U-3

## Section 2 – Trade Name Index

Section 2 presents a listing of drugs under patent arranged alphabetically by product trade name. Please note that trade names have not been established for all drug products.

Each listing contains the trade name, generic name and manufacturer. For more detailed information about a particular drug, note the product's manufacturer and generic name for lookup in Section 1, the Company Index, which contains full information about each drug.

<b>Abilify</b>			
Aripiprazole 10mg	Otsuka		
Aripiprazole 15mg	Otsuka		
Aripiprazole 1mg/ml	Otsuka		
Aripiprazole 20mg	Otsuka		
Aripiprazole 2mg	Otsuka		
Aripiprazole 30mg	Otsuka		
Aripiprazole 30mg	Otsuka		
Aripiprazole 5mg	Otsuka		
Aripiprazole 9.75mg/1.3ml (7.5mg/ml)	Otsuka		
<b>Ablavar</b>			
Gadofosveset Trisodium 2440mg/10ml (244mg/ml)	Lantheus Medical		
Gadofosveset Trisodium 3660mg/15ml (244mg/ml)	Lantheus Medical		
<b>Abraxane</b>			
Paclitaxel 100mg/vial	Abraxis		
<b>Abreva</b>			
Docosanol 10%	GlaxoSmithKline		
<b>Acanya</b>			
Benzoyl Peroxide 2.5%; Clindamycin Phosphate 1.2%	Dow Chemical		
<b>Accolate</b>			
Zafirlukast 10mg	AstraZeneca		
Zafirlukast 20mg	AstraZeneca		
<b>Accretropin</b>			
Somatropin Recombinant 5mg/ml (5mg/ml)	Cangene		
<b>AccuNeb</b>			
Albuterol Sulfate eq 0.021% base	Dey Laboratories		
Albuterol Sulfate eq 0.042% base	Dey Laboratories		
<b>Accupril</b>			
Quinapril Hydrochloride eq 10mg base	Pfizer		
Quinapril Hydrochloride eq 20mg base	Pfizer		
Quinapril Hydrochloride eq 40mg base	Pfizer		
Quinapril Hydrochloride eq 5mg base	Pfizer		
<b>Acetadote</b>			
Acetylcysteine 6gm/30ml (200mg/ml)	Cumberland Pharmaceuticals		
<b>Aciphex</b>			
Rabeprazole Sodium 10mg	Eisai		
Rabeprazole Sodium 20mg	Eisai		
<b>Actiq</b>			
Fentanyl Citrate eq 0.2mg base	Cephalon		
Fentanyl Citrate eq 0.4mg base	Cephalon		
Fentanyl Citrate eq 0.6mg base	Cephalon		
Fentanyl Citrate eq 0.8mg base	Cephalon		
Fentanyl Citrate eq 1.2mg base	Cephalon		
Fentanyl Citrate eq 1.6mg base	Cephalon		
<b>Actonel</b>			
Risedronate Sodium 150mg	Procter & Gamble		
Risedronate Sodium 30mg	Procter & Gamble		
Risedronate Sodium 35mg	Procter & Gamble		
Risedronate Sodium 5mg	Procter & Gamble		
Risedronate Sodium 75mg	Procter & Gamble		
<b>Actonel with Calcium (Copackaged)</b>			
Calcium Carbonate eq 500mg base; Risedronate Sodium 35mg	Procter & Gamble		
<b>Actos</b>			
Pioglitazone Hydrochloride eq 15mg base	Takeda		
Pioglitazone Hydrochloride eq 30mg base	Takeda		
Pioglitazone Hydrochloride eq 45mg base	Takeda		
<b>AcuTect</b>			
Technetium Tc-99m Apcitide		CIS Bio	
<b>Acuvail</b>			
Ketorolac Tromethamine 0.45%		Allergan Pharmaceuticals	
<b>Acyclovir and Hydrocortisone</b>			
Acyclovir 5%; Hydrocortisone 1%		Medivir	
<b>Aczone</b>			
Dapsone 5%		Allergan Pharmaceuticals	
<b>ACTOplus Met</b>			
Metformin Hydrochloride 500mg; Pioglitazone Hydrochloride eq 15mg base		Takeda	
Metformin Hydrochloride 850mg; Pioglitazone Hydrochloride eq 15mg base		Takeda	
<b>ACTOplus Met XR</b>			
Metformin Hydrochloride 1gm; Pioglitazone Hydrochloride eq 15mg base		Takeda	
Metformin Hydrochloride 1gm; Pioglitazone Hydrochloride eq 30mg base		Takeda	
<b>Adalat CC</b>			
Nifedipine 30mg		Bayer	
Nifedipine 60mg		Bayer	
Nifedipine 90mg		Bayer	
<b>Adcirca</b>			
Tadalafil 20mg		Eli Lilly	
<b>Adderall 10</b>			
Amphetamine Aspartate 2.5mg; Amphetamine Sulfate 2.5mg;			
Dextroamphetamine Saccharate 2.5mg;			
Dextroamphetamine Sulfate 2.5mg		Duramed Pharmaceuticals	
<b>Adderall 12.5</b>			
Amphetamine Aspartate 3.125mg; Amphetamine Sulfate 3.125mg; Dextroamphetamine Saccharate 3.125mg;			
Dextroamphetamine Sulfate 3.125mg		Duramed Pharmaceuticals	
<b>Adderall 15</b>			
Amphetamine Aspartate 3.75mg; Amphetamine Sulfate 3.75mg;			
Dextroamphetamine Saccharate 3.75mg;			
Dextroamphetamine Sulfate 3.75mg		Duramed Pharmaceuticals	
<b>Adderall 20</b>			
Amphetamine Aspartate 5mg; Amphetamine Sulfate 5mg;			
Dextroamphetamine Saccharate 5mg;			
Dextroamphetamine Sulfate 5mg		Duramed Pharmaceuticals	
<b>Adderall 30</b>			
Amphetamine Aspartate 7.5mg; Amphetamine Sulfate 7.5mg;			
Dextroamphetamine Saccharate 7.5mg;			
Dextroamphetamine Sulfate 7.5mg		Duramed Pharmaceuticals	
<b>Adderall 5</b>			
Amphetamine Aspartate 1.25mg; Amphetamine Sulfate 1.25mg;			
Dextroamphetamine Saccharate 1.25mg;			
Dextroamphetamine Sulfate 1.25mg		Duramed Pharmaceuticals	
<b>Adderall 7.5</b>			
Amphetamine Aspartate 1.875mg; Amphetamine Sulfate 1.875mg; Dextroamphetamine Saccharate 1.875mg;			
Dextroamphetamine Sulfate 1.875mg		Duramed Pharmaceuticals	
<b>Adderall XR 10</b>			
Amphetamine Aspartate 2.5mg; Amphetamine Sulfate 2.5mg;			
Dextroamphetamine Saccharate 2.5mg;			
Dextroamphetamine Sulfate 2.5mg		Shire Laboratories	
<b>Adderall XR 15</b>			
Amphetamine Aspartate 3.75mg; Amphetamine Sulfate 3.75mg;			
Dextroamphetamine Saccharate 3.75mg;			
Dextroamphetamine Sulfate 3.75mg		Shire Laboratories	

## Section 3 – Generic Name Index

Section 3 presents a listing of drugs under patent arranged alphabetically by generic name. Use this index to identify the manufacturer(s) of a product; detailed information for each drug is presented in Section 1, the Company Index. Combination drug products are listed alphabetically by component.

Abacavir Sulfate eq 20mg base/ml	Viiv Healthcare	Amnirolevalinic Acid Hydrochloride 20%	DUSA Pharmaceuticals
Abacavir Sulfate eq 300mg base	Viiv Healthcare	Amiodarone Hydrochloride 50mg/ml	Prism Pharms
Abacavir Sulfate eq 300mg base; Lamivudine 150mg; Zidovudine 300mg	Viiv Healthcare	Amlexanox 5%	Uluru
Abacavir Sulfate eq 600mg base; Lamivudine 300mg	Viiv Healthcare	Amlodipine 10mg; Hydrochlorothiazide 12.5mg; Valsartan 160mg	Novartis
Abarelix 100mg/vial	Specialty European Pharma	Amlodipine 10mg; Hydrochlorothiazide 25mg; Valsartan 160mg	Novartis
Acetaminophen 250mg; Aspirin 250 mg; Caffeine 65mg	Novartis	Amlodipine 10mg; Hydrochlorothiazide 25mg; Valsartan 320mg	Novartis
Acetaminophen 325mg; Tramadol Hydrochloride 37.5mg	Ortho McNeil	Amlodipine 5mg; Hydrochlorothiazide 25mg; Valsartan 160mg	Novartis
Acetylcholine Chloride 20mg/vial	Novartis	Amlodipine Besylate eq 10mg base	Synthon
Acetylcysteine 6gm/30ml (200mg/ml)	Cumberland Pharmaceuticals	Amlodipine Besylate eq 10mg base; Atorvastatin Calcium eq 10mg base	Pfizer
Acyclovir 5%; Hydrocortisone 1%	Medivir	Amlodipine Besylate eq 10mg base; Atorvastatin Calcium eq 20mg base	Pfizer
Adapalene .1%; Benzoyl Peroxide 2.5%	Galderma Laboratories	Amlodipine Besylate eq 10mg base; Atorvastatin Calcium eq 40mg base	Pfizer
Adapalene 0.1%	Galderma Laboratories	Amlodipine Besylate eq 10mg base; Atorvastatin Calcium eq 80mg base	Pfizer
Adapalene 0.3%	Galderma Laboratories	Amlodipine Besylate eq 2.5mg base	Synthon
Adefovir Dipivoxil 10mg	Gilead Sciences	Amlodipine Besylate eq 2.5mg base; Atorvastatin Calcium eq 10mg base	Pfizer
Adenosine 3mg/ml	Astellas	Amlodipine Besylate eq 2.5mg base; Atorvastatin Calcium eq 20mg base	Pfizer
Alatrofloxacin Mesylate eq 200mg base/vial	Pfizer	Amlodipine Besylate eq 2.5mg base; Atorvastatin Calcium eq 40mg base	Pfizer
Alatrofloxacin Mesylate eq 300mg base/vial	Pfizer	Amlodipine Besylate eq 2.5mg base; Atorvastatin Calcium eq 80mg base	Pfizer
Albumin Human 10mg/ml	GE Healthcare	Amlodipine Besylate eq 5mg base	Synthon
Albuterol Sulfate eq 0.021% base	Dey Laboratories	Amlodipine Besylate eq 5mg base; Atorvastatin Calcium eq 10mg base	Pfizer
Albuterol Sulfate eq 0.042% base	Dey Laboratories	Amlodipine Besylate eq 5mg base; Atorvastatin Calcium eq 20mg base	Pfizer
Albuterol Sulfate eq 0.083% base; Ipratropium Bromide 0.017%	Dey Laboratories	Amlodipine Besylate eq 5mg base; Atorvastatin Calcium eq 40mg base	Pfizer
Albuterol Sulfate eq 0.09mg base/inh	3M	Amlodipine Besylate eq 5mg base; Atorvastatin Calcium eq 80mg base	Pfizer
Albuterol Sulfate eq 0.09mg base/inh	GlaxoSmithKline	Amlodipine Besylate eq 5mg base; Benazepril Hydrochloride 10mg	Novartis
Albuterol Sulfate eq 0.09mg base/inh	Teva	Amlodipine Besylate eq 5mg base; Benazepril Hydrochloride 20mg	Novartis
Albuterol Sulfate; Ipratropium Bromide eq 0.09mg base/inh;0.018mg/inh	Boehringer Ingelheim	Amlodipine Besylate eq 5mg base; Olmesartan Medoxomil 20mg	Daiichi Pharmaceutical
Alcohol 61%; Chlorhexidine Gluconate 1%	3M	Amlodipine Besylate eq 5mg base; Olmesartan Medoxomil 40mg	Daiichi Pharmaceutical
Alendronate Sodium eq 10mg base	Merck	Amlodipine Besylate eq 5mg base; Telmisartan 40mg	Boehringer Ingelheim
Alendronate Sodium eq 35mg base	Merck	Amlodipine Besylate eq 5mg base; Telmisartan 80mg	Boehringer Ingelheim
Alendronate Sodium eq 40mg base	Merck	Amlodipine Besylate eq 5mg base; Valsartan 160mg	Novartis
Alendronate Sodium eq 5mg base	Merck	Amlodipine Besylate eq 5mg base; Valsartan 320mg	Novartis
Alendronate Sodium eq 70mg base	Merck	Ammonia, N-13 30mci-300mci/8ml (3.75-37.5mci/ml)	Feinstein Institute for Medical Research
Alendronate Sodium eq 70mg base/75ml	Merck	Amoxicillin 1gm; Clavulanate Potassium eq 62.5mg base	GlaxoSmithKline
Alendronate Sodium eq 70mg base; Cholecalciferol 2,800 iu	Merck	Amoxicillin 500mg; Clarithromycin 500mg; Lansoprazole 30mg	Takeda
Alendronate Sodium eq 70mg base; Cholecalciferol 5,600 iu	Merck	Amoxicillin 775mg	MiddleBrook Pharmaceuticals
Alfuzosin Hydrochloride 10mg	Sanofi	Amphetamine Aspartate 1.25mg; Amphetamine Sulfate 1.25mg; Dextroamphetamine Saccharate 1.25mg;	
Alikiren Hemifumarate 300mg base; Valsartan 320mg	Novartis	Dextroamphetamine Sulfate 1.25mg	Duramed Pharmaceuticals
Alikiren Hemifumarate eq 150mg base	Novartis	Amphetamine Aspartate 1.25mg; Amphetamine Sulfate 1.25mg; Dextroamphetamine Saccharate 1.25mg;	
Alikiren Hemifumarate eq 150mg base; Hydrochlorothiazide 12.5mg	Novartis	Dextroamphetamine Sulfate 1.25mg	Shire Laboratories
Alikiren Hemifumarate eq 150mg base; Hydrochlorothiazide 25mg	Novartis	Amphetamine Aspartate 1.875mg; Amphetamine Sulfate 1.875mg; Dextroamphetamine Saccharate 1.875mg;	
Alikiren Hemifumarate eq 150mg base; Valsartan 160mg	Novartis	Dextroamphetamine Sulfate 1.875mg	Duramed Pharmaceuticals
Alikiren Hemifumarate eq 300mg base	Novartis	Amphetamine Aspartate 2.5mg; Amphetamine Sulfate 2.5mg; Dextroamphetamine Saccharate 2.5mg;	
Alikiren Hemifumarate eq 300mg base; Hydrochlorothiazide 12.5mg	Novartis	Dextroamphetamine Sulfate 2.5mg	Duramed Pharmaceuticals
Allitretinoin eq 0.1% base	Eisai	Amphetamine Aspartate 2.5mg; Amphetamine Sulfate 2.5mg; Dextroamphetamine Saccharate 2.5mg;	
Almotriptan Malate eq 12.5mg base	Ortho McNeil	Dextroamphetamine Sulfate 2.5mg	Duramed Pharmaceuticals
Almotriptan Malate eq 6.25mg base	Ortho McNeil	Amphetamine Aspartate 2.5mg; Amphetamine Sulfate 2.5mg; Dextroamphetamine Saccharate 2.5mg;	
Alosetron Hydrochloride eq 0.5mg base	Prometheus Laboratories	Dextroamphetamine Sulfate 2.5mg	Shire Laboratories
Alosetron Hydrochloride eq 1mg base	Prometheus Laboratories	Amphetamine Aspartate 3.125mg; Amphetamine Sulfate 3.125mg; Dextroamphetamine Saccharate 3.125mg;	
Alprazolam 0.25mg	Schwarz	Dextroamphetamine Sulfate 3.125mg	Duramed Pharmaceuticals
Alprazolam 0.5mg	Schwarz	Amphetamine Aspartate 3.75mg; Amphetamine Sulfate 3.75mg; Dextroamphetamine Saccharate 3.75mg;	
Alprazolam 1mg	Schwarz	Dextroamphetamine Sulfate 3.75mg	Duramed Pharmaceuticals
Alprazolam 2mg	Schwarz	Amphetamine Aspartate 3.75mg; Amphetamine Sulfate 3.75mg; Dextroamphetamine Saccharate 3.75mg;	
Alprostadil 0.005mg/vial	Pfizer	Dextroamphetamine Sulfate 3.75mg	Duramed Pharmaceuticals
Alprostadil 0.01mg/vial	Pfizer	Amphetamine Aspartate 3.75mg; Amphetamine Sulfate 3.75mg; Dextroamphetamine Saccharate 3.75mg;	
Alprostadil 0.02mg/vial	Pfizer	Dextroamphetamine Sulfate 3.75mg	Duramed Pharmaceuticals
Alprostadil 0.04mg/vial	Pfizer	Amphetamine Aspartate 3.75mg; Amphetamine Sulfate 3.75mg; Dextroamphetamine Saccharate 3.75mg;	
Alprostadil 0.125mg	Vivus	Dextroamphetamine Sulfate 3.75mg	Shire Laboratories
Alprostadil 0.25mg	Vivus	Amphetamine Aspartate 5mg; Amphetamine Sulfate 5mg; Dextroamphetamine Saccharate 5mg;	
Alprostadil 0.5mg	Vivus	Dextroamphetamine Sulfate 5mg	Duramed Pharmaceuticals
Alprostadil 1mg	Vivus	Amphetamine Aspartate 5mg; Amphetamine Sulfate 5mg; Dextroamphetamine Saccharate 5mg;	
Alvimopan 12mg	Adolor	Dextroamphetamine Sulfate 5mg	Shire Laboratories
Ambrisentan 10mg	Gilead Sciences	Amphetamine Aspartate 5mg; Amphetamine Sulfate 5mg; Dextroamphetamine Saccharate 5mg;	
Ambrisentan 5mg	Gilead Sciences	Dextroamphetamine Sulfate 5mg	Shire Laboratories
Amifostine 375mg/vial	MedImmune Oncology		
Amifostine 500mg/vial	MedImmune Oncology		

## Section 4 – Date Index

Section 4, the Date Index, organizes drugs under patent by date of patent expiration from January 1, 2010 forward. In addition, the manufacturer, generic name and patent number for each drug are indicated. Please refer to Section 1, the Company Index, for complete information on each drug product.

### A Note Regarding Patent Date Discrepancies

There are records in this book in which a single patent number is connected with more than one patent expiration date. These discrepancies are in the official FDA data used to prepare this reference.

There are three main reasons for these discrepancies:

- FDA has the authority to extend patents for various reasons, including time spent in reviewing NDA applications, extensions for pediatric indications, and other situations. FDA does not report these extensions to the Patent & Trademark Office (PTO), which maintains U.S. patent records, so one cannot use PTO data to verify the expiry date differences.
- Harmonization of GATT and U.S. patent regulations required changing the patent expiration dates of many U.S. drug patents. FDA did not always enter these changes across its databases.
- FDA keying errors may account for a substantial number of these discrepancies, particularly those dates that are only one day apart or precisely ten years apart. This is a result of ongoing data integrity problems at the FDA.

FDA maintains that the online reference *Approved Drug Products with Therapeutic Equivalence Evaluation*, historically known as the "Orange Book," is the reference of record for patent expiry dates. However, the same discrepancies exist there. Therefore, the publisher of *Drugs Under Patent* has no effective way of determining the correct patent expiration dates to correct the discrepancies.

Patent challenges and requests for definitive patent information should be addressed to FDA's Division of Data Management & Services of the Center for Drug Evaluation & Research, which will research the data and provide an answer.

**Appendix C, beginning on page 343, lists the discrepancies in patent expiry dates in this book.**

#### 01/05/10

5760090	Sepracor	Levalbuterol Hydrochloride eq 0.0103% base	5178878	Azur Pharma	Clozapine 25mg
5760090	Sepracor	Levalbuterol Hydrochloride eq 0.021% base	5178878	Azur Pharma	Clozapine 50mg
5760090	Sepracor	Levalbuterol Hydrochloride eq 0.042% base	5178878	Organon	Mirtazapine 15mg
5760090	Sepracor	Levalbuterol Hydrochloride eq 0.25% base	5178878	Organon	Mirtazapine 30mg
5760090	Sepracor	Levalbuterol Tartrate eq 0.045mg base/inh	5178878	Organon	Mirtazapine 45mg
5844002	Sepracor	Levalbuterol Hydrochloride eq 0.0103% base	5178878	Sanofi	Fexofenadine Hydrochloride 30mg
5844002	Sepracor	Levalbuterol Hydrochloride eq 0.021% base	5178878	Schering	Desloratadine 2.5mg
5844002	Sepracor	Levalbuterol Hydrochloride eq 0.042% base	5178878	Schering	Desloratadine 5mg
5844002	Sepracor	Levalbuterol Hydrochloride eq 0.25% base	5178878	Sciele Pharma	Prednisolone Sodium Phosphate eq 10mg base
5844002	Sepracor	Levalbuterol Tartrate eq 0.045mg base/inh	5178878	Sciele Pharma	Prednisolone Sodium Phosphate eq 15mg base
6083993	Sepracor	Levalbuterol Hydrochloride eq 0.0103% base	5178878	Sciele Pharma	Prednisolone Sodium Phosphate eq 30mg base
6083993	Sepracor	Levalbuterol Hydrochloride eq 0.021% base	<b>01/19/10</b>		
6083993	Sepracor	Levalbuterol Hydrochloride eq 0.042% base	5180668	Bayer	Lepirudin Recombinant 50mg/vial
6083993	Sepracor	Levalbuterol Hydrochloride eq 0.25% base	5180715	Ortho McNeil	Pentosan Polysulfate Sodium 100mg
6083993	Sepracor	Levalbuterol Tartrate eq 0.045mg base/inh	<b>01/23/10</b>		
			5134127	Pfizer	Voriconazole 200mg/vial
			5134127	Pfizer	Ziprasidone Mesylate eq 20mg base/ml
			5134127	Prism Pharms	Amiodarone Hydrochloride 50mg/ml
			5376645	Pfizer	Voriconazole 200mg/vial
			5376645	Pfizer	Ziprasidone Mesylate eq 20mg base/ml
			5376645	Prism Pharms	Amiodarone Hydrochloride 50mg/ml
			<b>01/30/10</b>		
			4876248	Sanofi	Tiludronate Disodium eq 200mg base

#### 01/10/10

5006344*PED	Bristol-Myers	Fosinopril Sodium 10mg
5006344*PED	Bristol-Myers	Fosinopril Sodium 10mg; Hydrochlorothiazide 12.5mg
5006344*PED	Bristol-Myers	Fosinopril Sodium 20mg
5006344*PED	Bristol-Myers	Fosinopril Sodium 20mg; Hydrochlorothiazide 12.5mg
5006344*PED	Bristol-Myers	Fosinopril Sodium 40mg

#### 01/12/10

5178878	Azur Pharma	Clozapine 100mg
5178878	Azur Pharma	Clozapine 12.5mg

**02/01/10**

7402588	Gilead Sciences	Efavirenz 600mg; Emtricitabine 200mg; Tenofovir Disoproxil Fumarate 300mg
7402588	Gilead Sciences	Emtricitabine 200mg
7402588	Gilead Sciences	Emtricitabine 200mg; Tenofovir Disoproxil Fumarate 300mg

**02/04/10**

4795751	Mylan Pharmaceuticals	Sparfloxacin 200mg
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**02/09/10**

5045302	GE Healthcare	Technetium Tc-99m Tetrofosmin Kit
5185351	Abbott Laboratories	Eprosartan Mesylate 600mg; Hydrochlorothiazide 12.5mg
5185351	Abbott Laboratories	Eprosartan Mesylate 600mg; Hydrochlorothiazide 25mg
5185351	Abbott Laboratories	Eprosartan Mesylate eq 300mg base
5185351	Abbott Laboratories	Eprosartan Mesylate eq 400mg base
5185351	Abbott Laboratories	Eprosartan Mesylate eq 600mg base

**02/11/10**

5138069*PED	Merck	Hydrochlorothiazide 12.5mg; Losartan Potassium 50mg
5138069*PED	Merck	Hydrochlorothiazide 12.5mg; Losartan Potassium 100mg
5138069*PED	Merck	Hydrochlorothiazide 25mg; Losartan Potassium 100mg
5138069*PED	Merck	Losartan Potassium 100mg
5138069*PED	Merck	Losartan Potassium 25mg
5138069*PED	Merck	Losartan Potassium 50mg

**02/12/10**

5013743	Takeda	Amoxicillin 500mg; Clarithromycin 500mg; Lansoprazole 30mg
5013743	Takeda	Lansoprazole 15mg
5013743	Takeda	Lansoprazole 15mg/packet
5013743	Takeda	Lansoprazole 30mg
5013743	Takeda	Lansoprazole 30mg/packet
RE37872	Pfizer	Insulin Recombinant Human 1mg/inh
RE37872	Pfizer	Insulin Recombinant Human 3mg/inh
RE38385	Pfizer	Insulin Recombinant Human 1mg/inh
RE38385	Pfizer	Insulin Recombinant Human 3mg/inh

**02/15/10**

4981874*PED	GlaxoSmithKline	Atovaquone 250mg
4981874*PED	GlaxoSmithKline	Atovaquone 750mg/5ml

**02/16/10**

5186938	Key Pharmaceuticals	Nitroglycerin 0.1mg/hr
5186938	Key Pharmaceuticals	Nitroglycerin 0.2mg/hr
5186938	Key Pharmaceuticals	Nitroglycerin 0.3mg/hr
5186938	Key Pharmaceuticals	Nitroglycerin 0.4mg/hr
5186938	Key Pharmaceuticals	Nitroglycerin 0.6mg/hr
5186938	Key Pharmaceuticals	Nitroglycerin 0.8mg/hr
7511014	Novartis	Cyclosporine 100mg
7511014	Novartis	Cyclosporine 25mg
7511014	Novartis	Cyclosporine 50mg

**02/22/10**

5028432	GlaxoSmithKline	Ranitidine Hydrochloride eq 150mg base
5028432	GlaxoSmithKline	Ranitidine Hydrochloride eq 300mg base

**02/25/10**

4689338*PED	Graceway Pharmaceuticals	Imiquimod 5%
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**03/09/10**

5192535	Inspire Pharmaceuticals	Azithromycin 1%
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**03/19/10**

5470567	Stiefel GSK	Mequinol 2%; Tretinoin 0.01%
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**03/23/10**

5196205	Axcan Pharma	Bismuth Subcitrate Potassium 140mg; Metronidazole 125mg; Tetracycline 125mg
5196404	The Medicines Company	Bivalirudin 250mg/vial
5378474	Activis	Morphine Sulfate 100mg
5378474	Activis	Morphine Sulfate 10mg
5378474	Activis	Morphine Sulfate 200mg
5378474	Activis	Morphine Sulfate 20mg
5378474	Activis	Morphine Sulfate 30mg
5378474	Activis	Morphine Sulfate 50mg
5378474	Activis	Morphine Sulfate 60mg
5378474	Activis	Morphine Sulfate 80mg
5378474	Alpharma	Morphine Sulfate 100mg; Naltrexone Hydrochloride 4mg
5378474	Alpharma	Morphine Sulfate 20mg; Naltrexone Hydrochloride 0.8mg
5378474	Alpharma	Morphine Sulfate 30mg; Naltrexone Hydrochloride 1.2mg
5378474	Alpharma	Morphine Sulfate 50mg; Naltrexone Hydrochloride 2mg
5378474	Alpharma	Morphine Sulfate 60mg; Naltrexone Hydrochloride 2.4mg
5378474	Alpharma	Morphine Sulfate 80mg; Naltrexone Hydrochloride 3.2mg
5476669	Axcan Pharma	Bismuth Subcitrate Potassium 140mg; Metronidazole 125mg; Tetracycline 125mg

**03/24/10**

4681893*PED	Pfizer	Amlodipine Besylate eq 10mg base; Atorvastatin Calcium eq 40mg base
4681893*PED	Pfizer	Amlodipine Besylate eq 10mg base; Atorvastatin Calcium eq 10mg base
4681893*PED	Pfizer	Amlodipine Besylate eq 10mg base; Atorvastatin Calcium eq 20mg base
4681893*PED	Pfizer	Amlodipine Besylate eq 10mg base; Atorvastatin Calcium eq 80mg base
4681893*PED	Pfizer	Amlodipine Besylate eq 2.5mg base; Atorvastatin Calcium eq 20mg base
4681893*PED	Pfizer	Amlodipine Besylate eq 2.5mg base; Atorvastatin Calcium eq 10mg base
4681893*PED	Pfizer	Amlodipine Besylate eq 2.5mg base; Atorvastatin Calcium eq 40mg base
4681893*PED	Pfizer	Amlodipine Besylate eq 5mg base; Atorvastatin Calcium eq 40mg base
4681893*PED	Pfizer	Amlodipine Besylate eq 5mg base; Atorvastatin Calcium eq 20mg base
4681893*PED	Pfizer	Amlodipine Besylate eq 10mg base; Atorvastatin Calcium eq 10mg base
4681893*PED	Pfizer	Amlodipine Besylate eq 10mg base; Atorvastatin Calcium eq 20mg base
4681893*PED	Pfizer	Amlodipine Besylate eq 40mg base; Atorvastatin Calcium eq 40mg base
4681893*PED	Pfizer	Amlodipine Besylate eq 40mg base; Atorvastatin Calcium eq 80mg base

**03/30/10**

5198226	EKR Therapeutics	Nicardipine Hydrochloride 30mg
5198226	EKR Therapeutics	Nicardipine Hydrochloride 45mg
5198226	EKR Therapeutics	Nicardipine Hydrochloride 60mg

**04/06/10**

5153197*PED	Merck	Hydrochlorothiazide 12.5mg; Losartan Potassium 50mg
5153197*PED	Merck	Hydrochlorothiazide 12.5mg; Losartan Potassium 100mg
5153197*PED	Merck	Hydrochlorothiazide 25mg; Losartan Potassium 100mg
5153197*PED	Merck	Losartan Potassium 100mg
5153197*PED	Merck	Losartan Potassium 25mg
5153197*PED	Merck	Losartan Potassium 50mg
5200509	Insmed	Mecasermin Rinfabate Recombinant 36mg/0.6ml

**04/12/10**

5092843	Meridian Medical	Atropine 2.1mg/0.7ml; Pralidoxime Chloride 600mg/2ml
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**04/13/10**

5202128	Activis	Morphine Sulfate 100mg
5202128	Activis	Morphine Sulfate 10mg
5202128	Activis	Morphine Sulfate 200mg
5202128	Activis	Morphine Sulfate 20mg
5202128	Activis	Morphine Sulfate 30mg
5202128	Activis	Morphine Sulfate 50mg
5202128	Activis	Morphine Sulfate 60mg
5202128	Activis	Morphine Sulfate 80mg
5202128	Alpharma	Morphine Sulfate 100mg; Naltrexone Hydrochloride 4mg
5202128	Alpharma	Morphine Sulfate 20mg; Naltrexone Hydrochloride 0.8mg
5202128	Alpharma	Morphine Sulfate 30mg; Naltrexone Hydrochloride 1.2mg
5202128	Alpharma	Morphine Sulfate 50mg; Naltrexone Hydrochloride 2mg
5202128	Alpharma	Morphine Sulfate 60mg; Naltrexone Hydrochloride 2.4mg
5202128	Alpharma	Morphine Sulfate 80mg; Naltrexone Hydrochloride 3.2mg

**04/22/10**

4927855	Cephalon	Armodafinil 100mg
4927855	Cephalon	Armodafinil 150mg
4927855	Cephalon	Armodafinil 200mg
4927855	Cephalon	Armodafinil 250mg
4927855	Cephalon	Armodafinil 50mg

**04/25/10**

5773020	Vivus	Alprostadil 0.125mg
5773020	Vivus	Alprostadil 0.25mg
5773020	Vivus	Alprostadil 0.5mg
5773020	Vivus	Alprostadil 1mg

**04/27/10**

4703063*PED	Boehringer Ingelheim	Tamsulosin Hydrochloride 0.4mg
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**05/02/10**

4962128*PED	Pfizer	Sertraline Hydrochloride eq 100mg base
4962128*PED	Pfizer	Sertraline Hydrochloride eq 150mg base
4962128*PED	Pfizer	Sertraline Hydrochloride eq 200mg base
4962128*PED	Pfizer	Sertraline Hydrochloride eq 25mg base
4962128*PED	Pfizer	Sertraline Hydrochloride eq 50mg base

## Section 5 – Dosage Form Index

Section 5 presents a listing of drugs under patent grouped by dosage form. For each drug, the generic name and company name are included.

Refer to Section 1, the Company Index, for complete information on each drug product.

### Aerosol, Foam

Betamethasone Valerate eq 0.12% base	Connetics
Clindamycin Phosphate 1%	Stiefel GSK
Clobetasol Propionate 0.05%	Connetics
Clobetasol Propionate 0.05%	Stiefel GSK
Desonide 0.05%	Stiefel GSK
Ketoconazole 2%	Stiefel GSK
Minoxidil 5%	Johnson & Johnson

### Aerosol, Metered

Albuterol Sulfate eq 0.09mg base/inh	3M
Albuterol Sulfate eq 0.09mg base/inh	GlaxoSmithKline
Albuterol Sulfate eq 0.09mg base/inh	Teva
Albuterol Sulfate; Ipratropium Bromide eq 0.09mg base/inh;0.018mg/inh	Boehringer Ingelheim
Beclomethasone Dipropionate 0.04mg/inh	Teva
Beclomethasone Dipropionate 0.08mg/inh	Teva
Ciclesonide 0.08mg/inh	Nycomed
Ciclesonide 0.16mg/inh	Nycomed
Fluticasone Propionate 0.044mg/inh	GlaxoSmithKline
Fluticasone Propionate 0.045mg/inh;	
Salmeterol Xinafoate eq 0.021mg base/inh	GlaxoSmithKline
Fluticasone Propionate 0.115mg/inh;	
Salmeterol Xinafoate eq 0.021mg base/inh	GlaxoSmithKline
Fluticasone Propionate 0.11mg/inh	GlaxoSmithKline
Fluticasone Propionate 0.22mg/inh	GlaxoSmithKline
Fluticasone Propionate 0.23mg/inh;	
Salmeterol Xinafoate eq 0.021mg base/inh	GlaxoSmithKline
Ipratropium Bromide 0.021mg/inh	Boehringer Ingelheim
Levalbuterol Tartrate eq 0.045mg base/inh	Sepracor
Nitroglycerin 0.4mg/Spray	Akrimax Pharmaceuticals

### Capsule

Alvimopan 12mg	Adolor
Amlodipine Besylate eq 10mg base; Benazepril Hydrochloride 40mg	Novartis
Amlodipine Besylate eq 10mg base; Benazepril Hydrochloride 20mg	Novartis
Amlodipine Besylate eq 2.5mg base; Benazepril Hydrochloride 10mg	Novartis
Amlodipine Besylate eq 5mg base; Benazepril Hydrochloride 20mg	Novartis
Amlodipine Besylate eq 5mg base; Benazepril Hydrochloride 10mg	Novartis
Amlodipine Besylate eq 5mg base; Benazepril Hydrochloride 20mg	Novartis
Amprenavir 150mg	GlaxoSmithKline
Amprenavir 50mg	GlaxoSmithKline
Aprepitant 125mg	Merck
Aprepitant 40mg	Merck
Aprepitant 80mg	Merck
Atazanavir Sulfate eq 100mg base	Bristol-Myers
Atazanavir Sulfate eq 150mg base	Bristol-Myers
Atazanavir Sulfate eq 200mg base	Bristol-Myers
Atazanavir Sulfate eq 300mg base	Bristol-Myers
Atomoxetine Hydrochloride 100mg	Eli Lilly
Atomoxetine Hydrochloride 10mg	Eli Lilly
Atomoxetine Hydrochloride 18mg	Eli Lilly
Atomoxetine Hydrochloride 25mg	Eli Lilly
Atomoxetine Hydrochloride 40mg	Eli Lilly
Atomoxetine Hydrochloride 5mg	Eli Lilly
Atomoxetine Hydrochloride 60mg	Eli Lilly
Atomoxetine Hydrochloride 80mg	Eli Lilly
Bexarotene 75mg	Eisai
Bismuth Subcitrate Potassium 140mg; Metronidazole 125mg;	
Tetracycline 125mg	Axcan Pharma
Budesonide 3mg	AstraZeneca
Calcium Acetate eq 169mg Calcium	Fresenius
Cefdinir 300mg	Abbott Laboratories
Ceftibuten Dihydrate eq 400mg base	Sciele Pharma

Celecoxib 100mg	Searle Pharmaceuticals
Celecoxib 200mg	Searle Pharmaceuticals
Celecoxib 400mg	Searle Pharmaceuticals
Celecoxib 50mg	Searle Pharmaceuticals
Cevimeline Hydrochloride eq 30mg base	Daiichi Pharmaceutical
Colesevelam Hydrochloride 375mg	Daiichi Pharmaceutical
Cyclosporine 100mg	Novartis
Cyclosporine 25mg	Novartis
Cyclosporine 50mg	Novartis
Diclofenac Potassium 25mg	Xanodyne Pharmaceuticals
Dofetilide 0.125mg	Pfizer
Dofetilide 0.25mg	Pfizer
Dofetilide 0.5mg	Pfizer
Doxercalciferol 0.5ugm	Genzyme
Doxercalciferol 1ugm	Genzyme
Doxercalciferol 2.5ugm	Genzyme
Doxycycline 40mg	Galderma Laboratories
Dronabinol 10mg	Unimed
Dronabinol 2.5mg	Unimed
Dronabinol 5mg	Unimed
Dutasteride 0.5mg	GlaxoSmithKline
Efavirenz 100mg	Bristol-Myers
Efavirenz 200mg	Bristol-Myers
Efavirenz 50mg	Bristol-Myers
Emtricitabine 200mg	Gilead Sciences
Fenofibrate 100mg	Cipher
Fenofibrate 130mg	Oscient Pharmaceuticals
Fenofibrate 150mg	Cipher
Fenofibrate 43mg	Oscient Pharmaceuticals
Fenofibrate 50mg	Cipher
Fexofenadine Hydrochloride 60mg	Sanofi
Fluoxetine Hydrochloride eq 10mg base	Eli Lilly
Fluoxetine Hydrochloride eq 20mg base	Eli Lilly
Fluoxetine Hydrochloride eq 25mg base; Olanzapine eq 3mg base	Eli Lilly
Fluoxetine Hydrochloride eq 25mg base; Olanzapine eq 6mg base	Eli Lilly
Fluoxetine Hydrochloride eq 25mg base; Olanzapine eq 12mg base	Eli Lilly
Fluoxetine Hydrochloride eq 40mg base	Eli Lilly
Fluoxetine Hydrochloride eq 50mg base; Olanzapine eq 6mg base	Eli Lilly
Fluoxetine Hydrochloride eq 50mg base; Olanzapine eq 12mg base	Eli Lilly
Fluvastatin Sodium eq 20mg base	Novartis
Fluvastatin Sodium eq 40mg base	Novartis
Gabapentin 100mg	Pfizer
Gabapentin 300mg	Pfizer
Gabapentin 400mg	Pfizer
Ibuprofen 200mg	Banner Pharmacaps
Imatinib Mesylate eq 100mg base	Novartis
Imatinib Mesylate eq 50mg base	Novartis
Indinavir Sulfate eq 100mg base	Merck
Indinavir Sulfate eq 200mg base	Merck
Indinavir Sulfate eq 333mg base	Merck
Indinavir Sulfate eq 400mg base	Merck
Itraconazole 100mg	Ortho McNeil
Lenalidomide 10mg	Celgene
Lenalidomide 15mg	Celgene
Lenalidomide 25mg	Celgene
Lenalidomide 5mg	Celgene
Lisdexamfetamine Dimesylate 20mg	Shire Laboratories
Lisdexamfetamine Dimesylate 30mg	Shire Laboratories
Lisdexamfetamine Dimesylate 40mg	Shire Laboratories
Lisdexamfetamine Dimesylate 50mg	Shire Laboratories
Lisdexamfetamine Dimesylate 60mg	Shire Laboratories
Lisdexamfetamine Dimesylate 70mg	Shire Laboratories
Lopinavir 133.3mg; Ritonavir 33.3mg	Abbott Laboratories
Lubiprostone 24ugm	Sucampo

## Section 6 — Exclusivity Code Index

Section 6, the Exclusivity Code Index, presents drugs under patent which have marketing exclusivity expiring from January 1, 2010 forward under the terms of the Waxman-Hatch Act. These drugs are grouped by exclusivity code, with a description of each code. Drugs with marketing exclusivity expiring before 2010 are not listed here, but may be included in Section 1, the Company Index. For a complete list of exclusivity codes, see Appendix B.

For each drug, the generic name, company name and marketing exclusivity expiration date are included. Duplicate entries indicate different dosage forms for the same drug; please refer to Section 1, the Company Index, for complete information about each drug product.

### D-105 New Dosing Schedule: Use of Actonel 75 mg Two Consecutive Days per Month for the Prevention and Treatment of Postmenopausal Osteoporosis

Risedronate Sodium 75mg Procter & Gamble – 04/16/10

### D-106 New Dosing Schedule: Five Day Treatment of Selected Susceptible Strains of Streptococcus Pneumoniae, Haemophilus Influenza, Mycoplasma Pneumoniae, and Chlamydia Pneumoniae for Community-Acquired Pneumonia

Gemifloxacin Mesylate eq 320mg base Oscient Pharmaceuticals – 05/01/10

### D-107 New Dosing Schedule: Provides for the Combination Tablet of 70mg Alendronate and 5600 Iu of Vitamin D3 for the Treatment of Osteoporosis in Postmenopausal Women and to Increase Bone Mass in Men with Osteoporosis

Alendronate Sodium eq 70mg base; Cholecalciferol 5,600 Iu Merck – 04/26/10

### D-108 New Dosing Schedule: Treatment of Complicated Urinary Tract Infection and Acute Pyelonephritis with Levaquin 750mg Once Daily for Five Days

Levofloxacin 250mg Ortho McNeil – 09/14/10  
 Levofloxacin 250mg/10ml Ortho McNeil – 09/14/10  
 Levofloxacin 500mg Ortho McNeil – 09/14/10  
 Levofloxacin 750mg Ortho McNeil – 09/14/10  
 Levofloxacin eq 250mg/50ml (eq 5mg/ml) Ortho McNeil – 09/14/10  
 Levofloxacin eq 500mg/100ml (eq 5mg/ml) Ortho McNeil – 09/14/10  
 Levofloxacin eq 500mg/20ml (eq 25mg/ml) Ortho McNeil – 09/14/10  
 Levofloxacin eq 750mg/150ml (eq 5mg/ml) Ortho McNeil – 09/14/10  
 Levofloxacin eq 750mg/30ml (eq 25mg/ml) Ortho McNeil – 09/14/10

### D-109 New Dosing Schedule: Provide for the Use of a Lower Dose for the Treatment of Adults with Chronic Phase Chronic Myeloid Leukemia (CML) with Resistance or Intolerance to Prior Therapy Including Imatinib Mesylate

Dasatinib 100mg Bristol-Myers – 11/06/10  
 Dasatinib 20mg Bristol-Myers – 11/06/10  
 Dasatinib 50mg Bristol-Myers – 11/06/10  
 Dasatinib 70mg Bristol-Myers – 11/06/10

### D-110 New Dosing Schedule: Treatment of Schizophrenia in Adolescents Aged 13-17

Aripiprazole 10mg Otsuka – 10/29/10  
 Aripiprazole 15mg Otsuka – 10/29/10  
 Aripiprazole 1mg/ml Otsuka – 10/29/10  
 Aripiprazole 20mg Otsuka – 10/29/10  
 Aripiprazole 2mg Otsuka – 10/29/10  
 Aripiprazole 30mg Otsuka – 10/29/10  
 Aripiprazole 5mg Otsuka – 10/29/10  
 Aripiprazole 9.75mg/1.3ml (7.5mg/ml) Otsuka – 10/29/10

### D-111 New Dosing Schedule: Provides for Once Daily Use of Cialis, 2.5 mg and 5 mg, for the Treatment of Erectile Dysfunction

Tadalafil 2.5mg Eli Lilly – 01/07/11  
 Tadalafil 5mg Eli Lilly – 01/07/11

### D-112 New Dosing Schedule: Provides for Pediatric Pump Use

Insulin Aspart Recombinant 100 units/ml Novo Nordisk – 03/14/11

### D-113 New Dosing Schedule: Once Daily Dosing Regimen for Patients Who Become Constipated on Twice Daily Regimen

Alosetron Hydrochloride eq 0.5mg base Prometheus Laboratories – 04/01/11  
 Alosetron Hydrochloride eq 1mg base Prometheus Laboratories – 04/01/11

### D-114 New Dosing Schedule: New Dosing Recommendations for Use of Sirolimus in Combination with Cyclosporine for the Prophylaxis of Rejection in High-Risk Renal Transplant Recipients

Sirolimus 1mg Wyeth – 01/30/10  
 Sirolimus 1mg/ml Wyeth – 01/30/10  
 Sirolimus 2mg Wyeth – 01/30/10

### D-115 New Dosing Schedule: Starting Dose of 15mg/Day for Monotherapy in Acute Treatment of Bipolar Disorder, Manic or Mixed

Aripiprazole 10mg Otsuka – 05/06/11  
 Aripiprazole 15mg Otsuka – 05/06/11  
 Aripiprazole 1mg/ml Otsuka – 05/06/11  
 Aripiprazole 20mg Otsuka – 05/06/11  
 Aripiprazole 2mg Otsuka – 05/06/11  
 Aripiprazole 30mg Otsuka – 05/06/11  
 Aripiprazole 5mg Otsuka – 05/06/11  
 Aripiprazole 9.75mg/1.3ml (7.5mg/ml) Otsuka – 05/06/11

### D-116 New Dosing Schedule: Alternative Dosing Regimen Atazanavir Sulfate Co-Administered with Ritonavir for the Treatment of HIV-1 Infection in Treatment Naive Patients

Atazanavir Sulfate eq 100mg base Bristol-Myers – 09/30/11  
 Atazanavir Sulfate eq 150mg base Bristol-Myers – 09/30/11  
 Atazanavir Sulfate eq 200mg base Bristol-Myers – 09/30/11  
 Atazanavir Sulfate eq 300mg base Bristol-Myers – 09/30/11

### D-117 New Dosing Schedule: 50 mg Tablet for Initiation of Dose Titration for Bipolar Disorder

Quetiapine Fumarate eq 150mg base AstraZeneca – 10/08/11  
 Quetiapine Fumarate eq 200mg base AstraZeneca – 10/08/11  
 Quetiapine Fumarate eq 300mg base AstraZeneca – 10/08/11  
 Quetiapine Fumarate eq 400mg base AstraZeneca – 10/08/11  
 Quetiapine Fumarate eq 50mg base AstraZeneca – 10/08/11

### D-118 New Dosing Schedule: Two 400mg Tablets Once Daily, Co-Administered with 100mg Ritonavir

Darunavir Ethanolate eq 400mg base Centocor Ortho – 10/21/11

### D-119 New Dosing Schedule: Dosing Recommendations for HIV Infected Pediatric Patients 6 to Less Than 18 Years of Age

Darunavir Ethanolate eq 150mg base Centocor Ortho – 12/18/11  
 Darunavir Ethanolate eq 300mg base Centocor Ortho – 12/18/11  
 Darunavir Ethanolate eq 400mg base Centocor Ortho – 12/18/11  
 Darunavir Ethanolate eq 600mg base Centocor Ortho – 12/18/11  
 Darunavir Ethanolate eq 75mg base Centocor Ortho – 12/18/11



## Section 8 – NDA Number Index

Section 8, the NDA Number Index, presents a listing of drugs under patent arranged by NDA (FDA-assigned New Drug Application) number. Use this section when only an NDA number is known, or to find all of the drugs under patent covered by a particular NDA.

Each listing contains the NDA number, generic name and manufacturer of the drug. Please refer to Section 1, the Company Index, for complete information about each drug product.

<b>008809</b>	Ascorbic Acid; Biotin; Cyanocobalamin; Dexpantenol; Ergocalciferol; Folic Acid; Niacinamide; Pyridoxine Hydrochloride; Riboflavin Phosphate Sodium; Thiamine Hydrochloride; Vitamin A; Vitamin E 20mg/ml; 0.006mg/ml; 0.05ugm/ml; 1.5mg/ml; 0.0005mg/ml; 0.06mg/ml;	Hospira	<b>019034</b>	Hydromorphone Hydrochloride 10mg/ml Hydromorphone Hydrochloride 250mg/vial	Purdue Purdue
<b>010971</b>	Estrogens, Conjugated 0.45mg; Meprobamate 200mg	Wyeth	<b>019057</b>	Terazosin Hydrochloride eq 10mg base Terazosin Hydrochloride eq 1mg base Terazosin Hydrochloride eq 2mg base Terazosin Hydrochloride eq 5mg base	Abbott Laboratories Abbott Laboratories Abbott Laboratories Abbott Laboratories
<b>011522</b>	Estrogens, Conjugated 0.45mg; Meprobamate 400mg	Wyeth	<b>019386</b>	Esmolol Hydrochloride 10mg/ml Esmolol Hydrochloride 1gm/100ml Esmolol Hydrochloride 20mg/ml Esmolol Hydrochloride 2gm/100ml	Baxter Baxter Baxter Baxter
	Amphetamine Aspartate 1.25mg; Amphetamine Sulfate 1.25mg;		<b>019415</b>	Urofollitropin 150 iu/amp Urofollitropin 75 iu/amp	Serono Serono
	Dextroamphetamine Saccharate 1.25mg;	Duramed Pharmaceuticals	<b>019430</b>	Epinephrine 0.15mg/Delivery Epinephrine 0.3mg/Delivery	Meridian Medical Meridian Medical
	Amphetamine Aspartate 1.875mg; Amphetamine Sulfate 1.875mg;		<b>019452</b>	Fluocinolone Acetonide 0.01%	Hill Dermaceuticals
	Dextroamphetamine Saccharate 1.875mg;		<b>019537</b>	Ciprofloxacin Hydrochloride eq 100mg base Ciprofloxacin Hydrochloride eq 250mg base Ciprofloxacin Hydrochloride eq 500mg base Ciprofloxacin Hydrochloride eq 750mg base	Bayer Bayer Bayer Bayer
	Dextroamphetamine Sulfate 1.875mg	Duramed Pharmaceuticals	<b>019596</b>	Gadopentetate Dimeglumine 469.01mg/ml	Bayer
	Amphetamine Aspartate 2.5mg; Amphetamine Sulfate 2.5mg;		<b>019627</b>	Propofol 10mg/ml	APP Pharmaceuticals
	Dextroamphetamine Saccharate 2.5mg;		<b>019640</b>	Somatropin Recombinant 12mg/vial Somatropin Recombinant 24mg/vial Somatropin Recombinant 2mg/vial Somatropin Recombinant 5mg/vial Somatropin Recombinant 6mg/vial	Eli Lilly Eli Lilly Eli Lilly Eli Lilly Eli Lilly
	Dextroamphetamine Sulfate 2.5mg	Duramed Pharmaceuticals	<b>019651</b>	Mesalamine 400mg	Procter & Gamble
	Amphetamine Aspartate 3.125mg; Amphetamine Sulfate 3.125mg;		<b>019667</b>	Octreotide Acetate eq 0.05mg base/ml Octreotide Acetate eq 0.1mg base/ml Octreotide Acetate eq 0.2mg base/ml Octreotide Acetate eq 0.5mg base/ml Octreotide Acetate eq 1mg base/ml	Novartis Novartis Novartis Novartis Novartis
	Dextroamphetamine Saccharate 3.125mg;		<b>019680</b>	Divalproex Sodium eq 125mg Valproic Acid	Abbott Laboratories
	Dextroamphetamine Sulfate 3.125mg	Duramed Pharmaceuticals	<b>019684</b>	Nifedipine 30mg Nifedipine 60mg Nifedipine 90mg	Pfizer Pfizer Pfizer
	Amphetamine Aspartate 3.75mg; Amphetamine Sulfate 3.75mg;		<b>019726</b>	Goserelin Acetate eq 3.6mg base	AstraZeneca
	Dextroamphetamine Saccharate 3.75mg;		<b>019732</b>	Leuprolide Acetate 7.5mg/vial	Abbott Laboratories
	Dextroamphetamine Sulfate 3.75mg	Duramed Pharmaceuticals	<b>019734</b>	Nicardipine Hydrochloride 20mg/200ml (0.1mg/ml) Nicardipine Hydrochloride 40mg/200ml (0.2mg/ml)	EKR Therapeutics EKR Therapeutics
	Amphetamine Aspartate 5mg; Amphetamine Sulfate 5mg;		<b>019762</b>	Testosterone 4mg/24hr Testosterone 6mg/24hr	Alza Alza
	Dextroamphetamine Saccharate 5mg;		<b>019764</b>	Somatropin Recombinant 5mg/vial Somatropin Recombinant 8.8mg/vial	Serono Serono
	Dextroamphetamine Sulfate 5mg	Duramed Pharmaceuticals	<b>019779</b>	Apraclonidine Hydrochloride eq 1% base	Alcon Laboratories
	Amphetamine Aspartate 7.5mg; Amphetamine Sulfate 7.5mg;		<b>019785</b>	Technetium Tc-99m Sestamibi Kit	Lantheus Medical
	Dextroamphetamine Saccharate 7.5mg;		<b>019810</b>	Omeprazole 10mg Omeprazole 20mg Omeprazole 40mg	AstraZeneca AstraZeneca AstraZeneca
	Dextroamphetamine Sulfate 7.5mg	Duramed Pharmaceuticals	<b>019839</b>	Sertraline Hydrochloride eq 100mg base Sertraline Hydrochloride eq 150mg base Sertraline Hydrochloride eq 200mg base Sertraline Hydrochloride eq 25mg base Sertraline Hydrochloride eq 50mg base	Pfizer Pfizer Pfizer Pfizer Pfizer
<b>011792</b>	Carisoprodol 250mg	Meda Pharmaceuticals	<b>019842</b>	Ibuprofen 100mg/5ml	McNeil Consumer
<b>012827</b>	Glycopyrrolate 1mg Glycopyrrolate 2mg	Sciele Pharma Sciele Pharma	<b>019845</b>	Betaxolol Hydrochloride eq 0.25% base	Alcon Laboratories
<b>013217</b>	Metaxalone 400mg Metaxalone 800mg	King Pharmaceuticals King Pharmaceuticals	<b>019881</b>	Butoconazole Nitrate 2%	KV Pharmaceutical
<b>013718</b>	Oxandrolone 10mg Oxandrolone 2.5mg	Savient Pharmaceuticals Savient Pharmaceuticals	<b>019885</b>	Quinapril Hydrochloride eq 10mg base Quinapril Hydrochloride eq 20mg base Quinapril Hydrochloride eq 40mg base Quinapril Hydrochloride eq 5mg base	Pfizer Pfizer Pfizer Pfizer
<b>017697</b>	Sincalide 0.005mg/vial	Bracco Diagnostics	<b>019891</b>	Hydromorphone Hydrochloride 5mg/5ml	Purdue
<b>017922</b>	Desmopressin Acetate 0.01% Desmopressin Acetate 0.01mg/Spray	Sanofi Sanofi			
<b>018163</b>	Temazepam 7.5mg	Tyco Healthcare			
<b>018343</b>	Captopril 100mg Captopril 12.5mg Captopril 150mg Captopril 25mg Captopril 37.5mg Captopril 50mg Captopril 75mg	Par Pharmaceutical Par Pharmaceutical Par Pharmaceutical Par Pharmaceutical Par Pharmaceutical Par Pharmaceutical Par Pharmaceutical			
<b>018613</b>	Malathion 0.5%	Taro Pharmaceuticals			
<b>018651</b>	Dronabinol 10mg Dronabinol 2.5mg Dronabinol 5mg	Unimed Unimed Unimed			
<b>018658</b>	Dextromethorphan Polistirex eq 30mg HBr/5ml	Reckitt Benckiser			
<b>018705</b>	Nitroglycerin 0.4mg/Spray	G. Pohl Boskamp			
<b>018708</b>	Quazepam 15mg Quazepam 7.5mg	Questcor Questcor			
<b>018859</b>	Ribavirin 6gm/vial	Valeant Pharmaceuticals			
<b>018874</b>	Calcitriol 0.001mg/ml Calcitriol 0.002mg/ml	Abbott Laboratories Abbott Laboratories			
<b>018936</b>	Fluoxetine Hydrochloride eq 10mg base Fluoxetine Hydrochloride eq 20mg base Fluoxetine Hydrochloride eq 40mg base	Eli Lilly Eli Lilly Eli Lilly			
<b>018938</b>	Desmopressin Acetate 0.004mg/ml Desmopressin Acetate 0.015mg/ml	Sanofi Sanofi			

## Section 9 – Discontinued Drugs

This index lists patented drugs whose marketing has been discontinued. Arranged alphabetically by manufacturer, each entry indicates the generic drug name. Additional information about each discontinued product is available in Section 1, the Company Index.

Before presuming a particular patented product is off the market entirely, it is essential to refer to the Company Index to determine if the same product is available in a different strength, dosage form, etc.

### Abbott Laboratories

Eprosartan Mesylate eq 300mg base  
Fenofibrate 160mg  
Fenofibrate 54mg  
Leuprolide Acetate 3.75mg/vial,7.5mg/vial  
Leuprolide Acetate 7.5mg/vial,7.5mg/vial  
Niacin 375mg  
Niacin 375mg;500mg;750mg  
Ritonavir 100mg

### Alaven

Metoclopramide Hydrochloride eq 10mg base  
Metoclopramide Hydrochloride eq 5mg base

### Alcon Laboratories

Betaxolol Hydrochloride eq 0.25% base; Pilocarpine Hydrochloride 1.75%  
Levobetaxolol Hydrochloride eq 0.5% base

### Alza

Fentanyl Hydrochloride 10.8ugm  
Testosterone 4mg/24hr  
Testosterone 5mg/24hr  
Testosterone 6mg/24hr

### AndRx

Lovastatin 10mg

### Anesiva

Lidocaine Hydrochloride 0.5mg

### Astellas

Conivaptan Hydrochloride 20mg/4ml (5mg/ml)

### AstraZeneca

Budesonide 0.064mg/inh  
Quetiapine Fumarate eq 150mg base

### Azur Pharma

Clozapine 50mg

### Bayer

Cerivastatin Sodium 0.05mg  
Cerivastatin Sodium 0.1mg  
Cerivastatin Sodium 0.2mg  
Cerivastatin Sodium 0.3mg  
Cerivastatin Sodium 0.4mg  
Cerivastatin Sodium 0.8mg

### Biovail Laboratories

Diltiazem Hydrochloride 120mg  
Diltiazem Hydrochloride 180mg  
Diltiazem Hydrochloride 240mg  
Diltiazem Hydrochloride 300mg

### Boehringer Ingelheim

Pramipexole Dihydrochloride 1.25mg

### Bracco Diagnostics

Technetium Tc-99m Teboroxime Kit

### Braintree

Bisacodyl 5mg.; Polyethylene Glycol 3350 210gm; Potassium Chloride 0.74gm;  
Sodium Bicarbonate 2.86gm; Sodium Chloride 5.6gm

### Bristol-Myers

Aspirin 325mg; Pravastatin Sodium 20mg  
Aspirin 325mg; Pravastatin Sodium 40mg  
Aspirin 325mg; Pravastatin Sodium 80mg  
Aspirin 81mg; Pravastatin Sodium 20mg  
Aspirin 81mg; Pravastatin Sodium 40mg  
Aspirin 81mg; Pravastatin Sodium 80mg  
Didanosine 100mg  
Didanosine 150mg  
Didanosine 200mg  
Didanosine 25mg  
Didanosine 50mg  
Efavirenz 100mg  
Efavirenz 300mg  
Etoposide Phosphate eq 1gm base/vial  
Etoposide Phosphate eq 500mg base/vial  
Fosinopril Sodium 10mg; Hydrochlorothiazide 12.5mg  
Fosinopril Sodium 20mg; Hydrochlorothiazide 12.5mg  
Stavudine 100mg  
Stavudine 37.5mg  
Stavudine 50mg  
Stavudine 75mg

### Cangene

Somatropin Recombinant 5mg/ml (5mg/ml)

### Cephalon

Tiagabine Hydrochloride 20mg

### CIS Bio

Technetium Tc-99m Apcitide

### Critical Therapeutics

Zileuton 300mg

### Cubist Pharmaceuticals

Daptomycin 250mg/vial

### Daichi Pharmaceutical

Colesevelam Hydrochloride 375mg

### Duramed Pharmaceuticals

Ethinyl Estradiol 0.05mg; Levonorgestrel 0.25mg

### Eisai

Rabeprazole Sodium 10mg  
Rufinamide 100mg

### Elan Pharmaceutical

Ziconotide 200ugm/2ml (100mg/ml)

### Falcon Pharmaceuticals

Diclofenac Sodium 0.1%

### Fresenius

Calcium Acetate eq 169mg Calcium

Sample  
Page

## Appendix A

### Patent Use Codes

The following list provides the descriptions of each of the Patent Use codes appearing in Section 1, the Company Index:

U-1	Prevention of Pregnancy	U-35X	A Process for Inhibiting the Secretion of Prolactin in Mammals
U-2	Treatment or Prophylaxis of Angina Pectoris and Arrhythmia	U-36	Methods of Treating Bacterial Illnesses
U-3	Treatment of Hypertension	U-36X	A Process for Treating a Patient Suffering from Parkinson's Syndrome and in Need of Treatment
U-4X	Treatment or Prophylaxis	U-37X	Method for Cholesterol Lowering
U-5	Method of Producing Bronchodilation	U-38X	Treatment of Humans Suffering from Undesired Urotoxic Side Effects Caused by Cytostatically Active Alkylating Agents
U-5X	Treatment of Hypertension	U-39	Angina Pectoris
U-6	Method of Producing Sympathomimetic Effects	U-39X	Method of Combating Pathologically Reduced Cerebral Functions and Performance Weaknesses, Cerebral Insufficiency and Disorders in Cerebral Circulation and Metabolism in Warm-Blooded Mammals
U-6X	Treating Mammals Suffering [from] Anxiety	U-40X	Method of Effecting Coronary Vascular Dilation in Humans and Animals
U-7	Increasing Cardiac Contractility	U-41X	Method for Treating Prostatic Carcinoma Comprising Administering Flutamide
U-7X	Providing Prevention and Treatment of Emesis and Nausea in Mammals	U-42	Adjuvant Treatment in Combination with Fluorouracil After Surgical Resection in Patients with Dukes' Stage C Colon Cancer
U-8	Acute Myocardial Infarction	U-42X	Method for Treating Prostate Adenocarcinoma Comprising Administering an Antiandrogen Including Flutamide and an LHRH Agonist
U-8X	Reducing Intravascular Pressure in Mammals	U-43	Management of Chronic Pain in Patients Requiring Opioid Analgesic
U-9	Control of Emesis Associated with any Cancer Chemotherapy Agent	U-43X	Reducing Cholesterol in Cholelithiasis Patients
U-10X	Method of Producing Sympathomimetic Effects	U-44	Relief of Nausea and Vomiting
U-11	Treatment of Prophylaxis or Cardiac Disorders	U-44X	Reducing Cholesterol Gallstones and/or Fragments Thereof
U-11X	Increasing Cardiac Contractility	U-45	Treatment of Inflammation and Analgesia
U-12	Method of Treating a Human Suffering from Depression	U-45X	Dissolving Cholesterol and Gallstones and/or Fragments Thereof
U-13	A Method for Treating Anxiety in a Human Subject in Need of Such Treatment	U-46	Treatment of Panic Disorder
U-13X	Control of Emesis Associated with any Cancer Chemotherapy Agent	U-46X	Cerebral, Coronary, Peripheral, Visceral and Renal Arteriography, Aortography and Left Ventriculography
U-14	Adjunctive Therapy for the Prevention and Treatment of Hyperammonemia in the Chronic Management of Patients with Urea Cycle Enzymopathies	U-47	Stimulation of the Release of Growth Hormone
U-14X	Treatment of Stress-Induced Depression	U-47X	CT Imaging of the Head and Body, and Intravenous Excretory Urography
U-15	Method of Lowering Intraocular Pressure	U-48	Analgesia
U-15X	Diagnostic Method for Distinguishing Between Hypothalamic Malfunctions or Lesions in Humans	U-48X	Cerebral Angiography, and Venography
U-16X	Treatment of Prophylaxis of Cardiac Disorders	U-49	Symptomatic Cancer-Related Hypercalcemia
U-17X	Method for Treatment of Herpetic Infections	U-49X	Intra-Arterial Digital Subtraction Angiography
U-18	Method for Inhibiting Gastric Secretion in Animals	U-50	Use in Treating Inflammatory Diseases
U-18X	Method for Treating [a] Human Suffering from Depression	U-50X	Palliative Treatment of Patients with Ovarian Carcinoma Recurrent After Prior Chemotherapy, Including Patients Who Have Been Previously Treated with Cisplatin
U-19	Treatment of Inflammation	U-51	Blood Pool Imaging, Including Cardiac First Pass and Gated Equilibrium Imaging and for Detection of Sites of Gastrointestinal Bleeding
U-20	A Process for Treating a Patient Suffering from Parkinson's Syndrome and in Need of Treatment	U-51X	Treating Viral Infections in a Mammal
U-21	Treatment of Humans Suffering Undesired Urotoxic Side Effects Caused by Cytostatically Active Alkylating Agents	U-52	Treatment of Adult and Pediatric Patients (Over Six Months of Age) with Advanced HIV Infection
U-22	Method of Combatting Pathologically Reduced Cerebral Functions and Performance Weaknesses, Cerebral Insufficiency and Disorders in Cerebral Circulation and Metabolism in Warm-Blooded Animals	U-52X	Treating Viral Infections in a Warm Blooded Animal
U-23	Method for Treating Prostatic Carcinoma Comprising Administering Flutamide	U-53	Hypercalcemia of Malignancy
U-24	Method for Treating Prostate Adenocarcinoma Comprising Administering an Antiandrogen Including Flutamide and an LHRH Agonist	U-53X	Treating Cytomegalovirus in a Human with an Injectible Composition
U-24X	Adjunctive Therapy for the Prevention and Treatment of Hyperammonemia in the Chronic Management of Patients with Urea Cycle Enzymopathies	U-54	Reversal Agent or Antagonist of Nondepolarizing Neuromuscular Blocking Agents
U-25	Reducing Cholesterol in Cholelithiasis Patients	U-54X	Methods of Treating Bacterial Illnesses
U-25X	Method of Lowering Intraocular Pressure	U-55	Treatment of Pain
U-26	Reducing Cholesterol Gallstones and/or Fragments Thereof	U-56	Aid to Smoking Cessation
U-26X	Method of Treating Animals Suffering from an Appetite Disorder	U-56X	Treatment of Paroxysmal Supraventricular Tachycardia
U-27	Dissolving Cholesterol Gallstones and/or Fragments Thereof	U-57	Ophthalmic Use of Norfloxacin
U-28	Cerebral, Coronary, Peripheral, Visceral and Renal Arteriography, Aortography and Left Ventriculography	U-57X	Angina Pectoris
U-28X	Method for Improving Memory in Mammals	U-58	Method of Treating Inflammatory Intestinal Diseases
U-29	CT Imaging of the Head and Body, and Intravenous Excretory Urography	U-58X	Acute Myocardial Infarction
U-29X	Method for Treating Amnesia	U-59	Method of Treating Hypercholesterolemia
U-30	Cerebral Angiography, and Venography	U-59X	Method of Treatment of Burns
U-31	Intra-Arterial Digital Subtraction Angiography	U-60	Nasal Administration of Butorphanol
U-31X	Use in Lung Scanning Procedures	U-61	Cerebral and Peripheral Arteriography and CT Imaging of the Head
U-32	Palliative Treatment of Patients with Ovarian Carcinoma Recurrent After Prior Chemotherapy, Including Patients Who Have Been Previously Treated with Cisplatin	U-62	Coronary Arteriography, Left Ventriculography, CT Imaging of the Body, Intravenous Excretory Urography, Intravenous Digital Subtraction Angiography and Venography
U-32X	Treatment of Ventricular and Supraventricular Arrhythmias	U-63	Isoprenaline Antagonism on the Heart Rate or Blood Pressure
U-33	Treating Viral Infections in a Mammal	U-64	Treatment of Viral Infections
U-33X	Method for Inhibiting Gastric Secretion in Mammals	U-65	Method of Treatment of Patients Infected with HIV
U-34	Treating Viral Infections in a Warm-Blooded Animal		
U-34X	Treatment of Inflammation		
U-35	Treating Cytomegalovirus in a Human with an Injectible Composition		

## Appendix B

### Marketing Exclusivity Codes

The following list provides the descriptions of each of the Marketing Exclusivity codes appearing in Section 1, the Company Index and Section 6, the Marketing Exclusivity Index:

#### D New Dosing Schedules

- |   |   |
|---|---|
| <p>D-1 Once a Day Application</p> <p>D-2 Once Daily Dosing</p> <p>D-3 Seven Days/Seven Days/Seven Days Dosing Schedule</p> <p>D-4 Seven Days/Fourteen Days Dosing Schedule</p> <p>D-5 Ten Days/Eleven Days Dosing Schedule</p> <p>D-6 Seven Days/Nine Days/Five Days Dosing Schedule</p> <p>D-7 BID Dosing</p> <p>D-8 Intravenous, Epidural and Intrathecal Dosing</p> <p>D-9 Narcotic Overdose in Adults</p> <p>D-10 Narcotic Overdose in Children</p> <p>D-11 Postoperative Narcotic Depression in Children</p> <p>D-12 Bedtime Dosing of 800mg for Treatment of Active Duodenal Ulcer</p> <p>D-13 Increased Maximum Daily Dosage Recommendation</p> <p>D-14 Bedtime Dosing of 800mg for Treatment of Active Benign Gastric Ulcer</p> <p>D-15 Single Daily Dose of 25mg/37.5mg</p> <p>D-16 Continuous Intravenous Infusion</p> <p>D-17 400mg Every 12 Hours for Three Days for Uncomplicated Urinary Tract Infections</p> <p>D-18 Lower Recommended Starting Dose Guidelines</p> <p>D-19 Bolus Dosing Guidelines</p> <p>D-20 Single 32mg Dose</p> <p>D-21 Alternative Dosage of 300mg Once Daily After the Evening Meal</p> <p>D-22 Reduction in Infusion Time from 24 to 4 Hours for the 60mg Dose</p> <p>D-23 Increase Maximum Dose and Variations in the Dosing Regimen</p> <p>D-24 For Ovarian Cancer the Recommended Regimen Is 135mg/m<sup>2</sup> or 175mg/m<sup>2</sup> Intravenously Over Three Hours Every Three Weeks</p> <p>D-25 Additional Dosage Regimen Equal to Half of the Original Dosing Regimen</p> <p>D-26 Once Weekly Application</p> <p>D-27 BID Dosing in Patients 12 Years of Age and Older for Prevention of Nausea and Vomiting Associated with Moderately Emetogenic Cancer Chemotherapy</p> <p>D-28 Use of Isovue-370 in Excretory Urography at Equivalent Grams of Iodine to the Currently Approved Isovue-250 and Isovue-300</p> <p>D-29 Increase of Cumulative Dose to 0.3mmol/kg for MRI of the CNS in Adults</p> <p>D-30 5000 IU Dose for Prophylaxis Against Deep Vein Thrombosis</p> <p>D-31 Change in Recommended Total Daily Dose to 80mg (40mg BID)</p> <p>D-32 Removal of the Restrictions Limiting Treatment to Two Consecutive Weeks and to Small Areas</p> <p>D-33 Once Daily Dosing for Plaque Psoriasis</p> <p>D-34 Every Four Months Dosage Regimen</p> <p>D-35 For a One Week Dosing Period for Interdigital Tinea Pedis</p> <p>D-36 For a Single 2mg Dose as an Alternative to the 1mg Dose Give Twice Daily</p> <p>D-37 Dosing Regimen for Administration Either Once Daily (QD) or Twice Daily (BID)</p> <p>D-38 Continuous Infusion as an Alternate Method of Administration</p> <p>D-39 Change in Time to Take the Drug Prior to a Meal to Prevent Meal-Induced Heartburn Symptoms from "...1/2-1 Hour Before Eating..." to "...Right Before Eating or Up to 60 Minutes Before Consuming..."</p> <p>D-40 Once-a-day Dosing Regimen</p> <p>D-41 Drug May Be Dosed Right Before a Meal or any Time Up to 30 Min Before Eating or Drinking Food and Beverages That Would Be Expected to Cause Symptoms</p> <p>D-42 Ten Day Dosing Regimen for Triple Therapy, Prevacid in Combination with Clarithromycin and Amoxicillin, for the Eradication of <i>H. pylori</i> in Patients with Duodenal Ulcer Disease</p> <p>D-43 Initiation of Treatment with 900mg/Day by Deletion of the Requirement to Titrate to 900mg/Day Over a 3-day Period</p> <p>D-44 In a Clinical Trial, Fewer Discontinuations Due to Adverse Events, Especially Dizziness and Vertigo, Were Observed When Titrating the Dose in Increments of 50mg/Day Every Three Days Until an Effective Dose (Not Exceeding 400mg/Day) Was Reached</p> <p>D-45 Once Daily Dosing for Maintenance Only</p> <p>D-46 New Dosing Regimen of 80mg Daily</p> | <p>D-47 Take Drug "15 Minutes to 1 Hour" Prior to a Meal to Prevent Meal-Induced Heartburn</p> <p>D-48 Administration of Cisatracurium, a Neuromuscular Blocking Agent at Doses of 3 and 4x the ED95 of Cisatracurium Following Induction with Thiopental</p> <p>D-49 Pediatric Dosing Guidelines</p> <p>D-50 Information for Use of Corvert in Post-Cardiac Surgery Patients</p> <p>D-51 Optional Starting Dose of 40mg Daily</p> <p>D-52 Alternate Dosing Regimen of 1250mg Twice Daily</p> <p>D-53 Use in Pediatric Patients from 1 Month to 16 Years of Age</p> <p>D-54 Use of Zylan for Maintenance Therapy. Treatment Up to 6 Months Was Shown Efficacious</p> <p>D-55 Addition of a Higher Dose of Nutropin for Pubertal Patients (Pubertal Dose Less Than or Equal to 0/7mg/kg/Week)</p> <p>D-56 Addition of Postprandial Dosing</p> <p>D-57 3-hour Infusion of Taxol Given Every Three Weeks at a Dose of 175mg/m<sup>2</sup> Followed by Cisplatin at a Dose of 75mg/m<sup>2</sup> for the First-Line Treatment of Advanced Ovarian Cancer</p> <p>D-58 Change in Dosing Interval to Once-Daily Administration</p> <p>D-59 Reduction of Elevated LDL-C in a New, Higher Strength Tablet, 0.8mg, and for Extension of the Dosage Range to 0.8mg Daily</p> <p>D-60 Addition of a Post-Operative Dosing Regimen</p> <p>D-61 Once Weekly Dosing for the Treatment of Postmenopausal Osteoporosis</p> <p>D-62 Once Weekly Dosing for the Prevention of Postmenopausal Osteoporosis</p> <p>D-63 To Allow a Titration Dosing Regimen Using a 25mg Dose</p> <p>D-64 Increasing Dosage for Nerve Block Anesthesia Using Naropin 7.5mg/ml and for Extending the Duration of Treatment for Postoperative Analgesia Using Naropin 2mg/ml</p> <p>D-65 Change Dosing and Administration to Indicate Maintenance of Weight Loss Over an 18 Month Period thus Extending the Use of This Drug from One to Two Years</p> <p>D-66 Dosing Recommendations for Patients Undergoing PCI</p> <p>D-67 Shorter Treatment Course of Three Days in the Treatment of Recurrent Episodes of Genital Herpes</p> <p>D-68 Change of Administration Rate for Infusion of Aredia for Treatment of Moderate and Severe Hypercalcemia of Malignancy from 24 Hours to 2 Hours Up to But Not including 24 Hours</p> <p>D-69 Shortened Dosing Regimen to 5 Days for the Treatment of Acute Exacerbation of Chronic Bronchitis</p> <p>D-70 80mg Once Daily Dosing Regimen</p> <p>D-71 Eight Week Dosing Regimen</p> <p>D-72 Information Regarding Increased Rate of Infusion for Depacon</p> <p>D-73 Once a Week Dosing for the Treatment of Postmenopausal Osteoporosis</p> <p>D-74 Once a Week Dosing for the Prevention of Postmenopausal Osteoporosis</p> <p>D-75 Intermittent Dosing Regimen, Starting Daily Dose 14 Days Prior to the Anticipated Onset of Menstruation through the First Full Day of Menses and Repeating with Each New Cycle</p> <p>D-76 For Use on an "As Needed" or PRN Basis for the Management of Nasal Symptoms in Patients for Whom the Drug Is Indicated</p> <p>D-77 Addition of 20mg and 40mg Daily as Optional Starting Doses with 40mg Intended for Patients Who Require a Large Reduction in LDL-C (More Than 45%)</p> <p>D-78 Use of Flexeril 5mg for the Relief of Muscle Spasm Associated with Acute, Painful, Musculoskeletal Conditions</p> <p>D-79 New Lower Starting Dose for Treatment of Moderate to Severe Vasomotor Symptoms and/or Moderate to Severe Symptoms of Vulvar and Vaginal Atrophy Associated with the Menopause</p> <p>D-80 Change of Dosing Schedule for Lantus from Once Daily at Bedtime to Flexible Daily Dosing</p> <p>D-81 New Lower Starting Dose for the Prevention of Postmenopausal Osteoporosis</p> <p>D-82 Use of Premarin 0.3 mg and 0.45 mg for the Prevention of Postmenopausal Osteoporosis</p> <p>D-83 750 mg, Once Daily for 5 Days for Community Acquired Pneumonia (CAP)</p> |
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## Appendix C

### Patent Date Discrepancies

This appendix details the records in this book in which a single patent number is connected with more than one patent expiration date. These discrepancies are in the official FDA data used to prepare this reference.

There are three main reasons for these discrepancies:

- FDA has the authority to extend patents for various reasons, including time spent in reviewing NDA applications, extensions for pediatric indications, and other situations. FDA does not report these extensions to the Patent & Trademark Office (PTO), which maintains U.S. patent records, so one cannot use PTO data to verify the expiry date differences.
- Harmonization of GATT and U.S. patent regulations required changing the patent expiration dates of many U.S. drug patents. FDA did not always enter these changes across their databases.
- FDA keying errors may account for a substantial number of these discrepancies, particularly those dates that are only one day apart or precisely ten years apart. This is a result of ongoing data integrity problems at the FDA.

FDA maintains that the online database *Approved Drug Products with Therapeutic Equivalence Evaluation*, historically known as the "Orange Book," is the reference of record for patent expiry dates. However, many of the same discrepancies exist there. Unfortunately, the publisher of *Drugs Under Patent* has no effective way, utilizing other data sources, of determining the correct patent expiration dates to correct the discrepancies.

Patent challenges and requests for definitive patent information should be addressed to FDA's Division of Data Management & Services of the Center for Drug Evaluation & Research, which will research the data and provide an answer.

4873259	12/09/10 Zileuton 600mg	Critical Therapeutics	5719147	06/29/12 Aprepitant 125mg	Merck	
	12/10/10 Zileuton 300mg	Critical Therapeutics		06/29/12 Aprepitant 40mg	Merck	
	12/10/10 Zileuton 600mg	Critical Therapeutics		04/17/15 Aprepitant 80mg	Merck	
5075114	05/23/10 Calcium Carbonate 800mg; Famotidine 10mg; Magnesium Hydroxide 165mg	Merck	5866538	06/19/17 Insulin Aspart Protamine Recombinant 70 units/ml; Insulin Aspart Recombinant 30 units/ml	Novo Nordisk	
	05/23/10 Famotidine 20mg	Merck		06/20/17 Insulin Aspart Protamine Recombinant 50 units/ml; Insulin Aspart Recombinant 50 units/ml	Novo Nordisk	
	10/23/10 Famotidine 10mg	Merck		06/20/17 Insulin Aspart Recombinant 100 units/ml	Novo Nordisk	
5177080	01/26/11 Cerivastatin Sodium 0.8mg	Bayer	5866581	06/20/17 Insulin Detemir Recombinant 100 units/ml	Novo Nordisk	
	11/26/11 Cerivastatin Sodium 0.05mg	Bayer		09/04/14 Penciclovir Sodium 1%	Novartis	
	11/26/11 Cerivastatin Sodium 0.1mg	Bayer		10/04/14 Famciclovir 125mg	Novartis	
	11/26/11 Cerivastatin Sodium 0.2mg	Bayer		10/04/14 Famciclovir 250mg	Novartis	
	11/26/11 Cerivastatin Sodium 0.3mg	Bayer		10/04/14 Famciclovir 500mg	Novartis	
	11/26/11 Cerivastatin Sodium 0.4mg	Bayer		5919832	04/29/14 Colesevelam Hydrochloride 1.875gm/packet	Daiichi Pharmaceutical
5326570	07/05/11 Carbamazepine 100mg	Shire Laboratories	04/29/14 Colesevelam Hydrochloride 3.75gm/packet		Daiichi Pharmaceutical	
	07/05/11 Carbamazepine 200mg	Shire Laboratories	04/29/14 Colesevelam Hydrochloride 625mg		Daiichi Pharmaceutical	
	07/05/11 Carbamazepine 300mg	Shire Laboratories	06/10/14 Colesevelam Hydrochloride 375mg	Daiichi Pharmaceutical		
	07/23/11 Carbamazepine 100mg	Validus Pharmaceuticals	5919832*PED 10/29/14 Colesevelam Hydrochloride 625mg	Daiichi Pharmaceutical		
	07/23/11 Carbamazepine 200mg	Validus Pharmaceuticals	12/10/14 Colesevelam Hydrochloride 375mg	Daiichi Pharmaceutical		
5424286	07/23/11 Carbamazepine 300mg	Validus Pharmaceuticals	6008207*PED	06/06/15 Alendronate Sodium eq 40mg base	Merck	
	05/24/13 Exenatide Synthetic 600ugm/2.4ml (250ugm/ml)	Amylin		12/06/15 Alendronate Sodium eq 10mg base	Merck	
5464632	12/01/16 Exenatide Synthetic 300ugm/1.2ml (250ugm/ml)	Amylin	12/06/15 Alendronate Sodium eq 35mg base	Merck		
	11/07/12 Lansoprazole 15mg	Takeda	12/06/15 Alendronate Sodium eq 5mg base	Merck		
	11/07/12 Lansoprazole 30mg	Takeda	12/06/15 Alendronate Sodium eq 70mg base	Merck		
5559111	03/22/13 Tramadol Hydrochloride 50mg	Victory Pharma	6020353	09/08/14 Nitazoxanide 100mg/5ml	Romark	
	04/04/15 Aliskiren Hemifumarate eq 150mg base; Hydrochlorothiazide 25mg	Novartis		09/18/14 Nitazoxanide 500mg	Romark	
	04/04/15 Aliskiren Hemifumarate eq 150mg base; Hydrochlorothiazide 12.5mg	Novartis	6037353	03/14/17 Fexofenadine Hydrochloride 180mg	Sanofi	
	04/04/15 Aliskiren Hemifumarate eq 300mg base; Hydrochlorothiazide 12.5mg	Novartis		03/14/17 Fexofenadine Hydrochloride 30mg	Sanofi	
	07/21/18 Aliskiren Hemifumarate 300mg base; Valsartan 320mg	Novartis		03/14/17 Fexofenadine Hydrochloride 30mg/5ml	Sanofi	
	07/21/18 Aliskiren Hemifumarate eq 150mg base	Novartis		03/14/17 Fexofenadine Hydrochloride 60mg	Sanofi	
	07/21/18 Aliskiren Hemifumarate eq 150mg base; Valsartan 160mg	Novartis		03/14/17 Fexofenadine Hydrochloride 60mg; Pseudoephedrine Hydrochloride 120mg	Sanofi	
	07/21/18 Aliskiren Hemifumarate eq 300mg base	Novartis		03/17/17 Fexofenadine Hydrochloride 180mg; Pseudoephedrine Hydrochloride 240mg	Sanofi	
	5578621	07/21/18 Aliskiren Hemifumarate eq 300mg base		Novartis		
		11/26/13 Nitazoxanide 500mg		Romark		
	09/08/14 Nitazoxanide 100mg/5ml	Romark				

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