

Drugs

Under Patent

2009

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

foi

Drugs Under Patent 2009

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

foi

Published by:

FOI Services, Inc.

704 Quince Orchard Road • Suite 275
Gaithersburg MD 20878-1770, U.S.A.

Phone: 301-975-9400

Fax: 301-975-0702

EMail: infofoi@foiservices.com

International Standard Book Number: 1-880626-30-6

Printed in the United States of America

Copyright © 2009 by FOI Services, Inc.

All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means (electronic, mechanical, photocopying, recording, or otherwise) without the publisher's written permission in each instance.

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 2008. 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.

Sample
Page

Table of Contents

1 Company Index	1
<p>This main index is the only index containing all of the fields: Company Name • Generic Name • Trade Name • Dosage Form • Patent Date • Exclusivity Code • Exclusivity Date • NDA Number • Approval Date • Patent Number • Patent Use Code • Discontinuation Indicator</p>	
2 Trade Name Index	123
Trade Name • Generic Name • Company Name	
3 Generic Name Index	147
Generic Name • Company Name	
4 Date Index	161
Patent Expiration Date • Company Name • Generic Name • Patent Number	
5 Dosage Form Index	229
Dosage Form • Generic Name • Company Name • Expiration Date & Code	
6 Exclusivity Code Index	243
Exclusivity Code • Exclusivity Description • Generic Name • Company Name • Expiration Date	
7 Patent Number Index	257
Patent Number • Generic Name • Company Name	
8 NDA Number Index	307
NDA Number • Generic Name • Company Name	
9 Discontinued Drugs	323
Company Name • Generic Name	
Appendices	
A Patent Use Codes	327
B Marketing Exclusivity Codes	339
C Discrepancies in Patent Dates	349

Sample
Page

Section 1 – Company Index

Section 1 lists drugs under patent alphabetically by company name. This is the main index in this book, and the only index containing all of the information for each product. Within each company, individual drugs are listed alphabetically by generic name. The company name has been standardized for each reference; if the company or product you are seeking does not appear, be sure to check the listing for the parent company. Company names that denote names of people are alphabetized by surname (e.g. Eli Lilly will be found under “L”).

Recent mergers in the pharmaceutical industry have yielded many new names. Generally, the current company name is used, but it is always prudent to check the precedent name(s).

Please note that blank fields indicate that the data are not applicable or do not appear on FDA's master list of approved drug products.

Sample Record

1	Amylin				
2	Exenatide Synthetic 300ugm/1.2ml (250ugm/ml)				
3	Byetta		NDA No: 021773		Approved: 04/28/05
4	Subcutaneous – Injectable			5	6
	Patent: 5424286	05/24/13	PatUse: U-653		
	Patent: 5424286	12/01/16	PatUse: U-653		
	Patent: 6858576	01/06/17	PatUse: U-656		
	Patent: 6872700	01/14/20	PatUse: U-654		
	Patent: 6902744	01/14/20	PatUse: DP		
	Patent: 6956026	01/07/18	PatUse: U-687		
	Patent: 7297761	10/15/17	PatUse: DP		
				Mkt Excl: I-520	12/22/09
				Mkt Excl: NCE	04/28/10
7					

- Key:**
- 1 Company Name
 - 2 Drug generic name(s) and strength
 - 3 Drug trade name — if no trade name, then generic name repeated
 - 4 Route of administration & dosage form
 - 5 NDA (FDA New Drug Application) number
 - 6 Approval date in the format mm/dd/yy.
 - 7 Patent & Marketing Exclusivity Information. Indicated in order are:
 - Patent Number & Patent Expiration Date
 - Patent Use Code (see page 327 for decoding)
 - Marketing Exclusivity Code & Expiration Date (see page 339 for decoding)

When applicable, some records also have an indicator that the NDA has been discontinued.

Sample
Page

3M

Albuterol Sulfate eq .09mg base/1inh

Proventil-HFA	NDA No: 020503	Approved: 08/15/96
Inhalation – Aerosol, Metered		
Patent: 5225183	07/06/10	
Patent: 5439670	07/06/10	
Patent: 5605674	02/25/14	
Patent: 5695743	07/06/10	PatUse: U-491
Patent: 5695743	07/06/10	
Patent: 5766573	06/16/15	
Patent: 6352684	11/28/09	

Alcohol 61%; Chlorhexidine Gluconate 1%

Avagard	NDA No: 021074	Approved: 06/07/01
Topical – Solution		
Patent: 5897031	06/21/16	

Iodine Povacrylex eq 0.7% Iodine; Isopropyl Alcohol 74% (6ml)

Duraprep	NDA No: 021586	Approved: 09/29/06
Topical – Sponge		
	Mkt Excl: NC	09/29/09

Iodine Povacrylex eq 0.7% Iodine; Isopropyl Alcohol 74% (26ml)

Duraprep	NDA No: 021586	Approved: 09/29/06
Topical – Sponge		
	Mkt Excl: NC	09/29/09

Abbott Laboratories

Calcitriol 0.001mg/ml

Calcijex	NDA No: 018874	Approved: 09/25/86
Injection – Injectable		
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

Calcijex	NDA No: 018874	Approved: 09/25/86
Injection – Injectable		
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

Omnicef	NDA No: 050749	Approved: 12/04/97
Oral – Powder for Reconstitution		
Patent: 4935507	12/04/11	PatUse: DS

Cefdinir 250mg/5ml

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

Cefdinir 300mg

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

Choline Fenofibrate eq 135mg Fenofibric Acid

Trilipex	NDA No: 022224	Approved: 12/15/08
Oral – Capsule, Delayed Release		
Patent: 7259186	01/07/25	PatUse: DS

Choline Fenofibrate eq 45mg Fenofibric Acid

Trilipex	NDA No: 022224	Approved: 12/15/08
Oral – Capsule, Delayed Release		
Patent: 7259186	01/07/25	PatUse: DS

Cisatracurium Besylate eq 2mg base/1ml

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

Cisatracurium Besylate eq 2mg base/1ml

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

Cisatracurium Besylate eq 10mg base/1ml

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

Clarithromycin 500mg

Biaxin XL	NDA No: 050775	Approved: 03/03/00
Oral – Tablet, Extended Release		
Patent: 6010718	04/11/17	PatUse: DP U-924
Patent: 6552616	07/15/17	

Divalproex Sodium eq 125mg Valproic Acid

Depakote	NDA No: 018723	Approved: 10/26/84
Oral – Tablet, Delayed Release		
Patent: 4988731	01/29/08	
Patent: 4988731*PED	07/29/08	
Patent: 5212326	01/29/08	
Patent: 5212326*PED	07/29/08	

Divalproex Sodium eq 125mg Valproic Acid

Depakote	NDA No: 019680	Approved: 09/12/89
Oral – Capsule, Delayed Rel Pellets		
Patent: 4988731	01/29/08	
Patent: 4988731*PED	07/29/08	
Patent: 5212326	01/29/08	
Patent: 5212326*PED	07/29/08	
	Mkt Excl: M-34	03/24/11
	Mkt Excl: PED	09/24/11

Divalproex Sodium eq 250mg base

Depakote CP	NDA No: 019794	Approved: 07/11/90
Oral – Tablet, Delayed Release		
Patent: 4988731	01/29/08	
Patent: 4988731*PED	07/29/08	
Patent: 5212326	01/29/08	
Patent: 5212326*PED	07/29/08	

Divalproex Sodium eq 250mg Valproic Acid

Depakote	NDA No: 018723	Approved: 03/10/83
Oral – Tablet, Delayed Release		
Patent: 4988731	01/29/08	
Patent: 4988731*PED	07/29/08	
Patent: 5212326	01/29/08	
Patent: 5212326*PED	07/29/08	

Divalproex Sodium eq 250mg Valproic Acid

Depakote ER	NDA No: 021168	Approved: 05/31/02
Oral – Tablet, Extended Release		
Patent: 4913906	04/03/07	
Patent: 4913906*PED	10/03/07	
Patent: 4988731	01/29/08	
Patent: 4988731*PED	07/29/08	
Patent: 5212326	01/29/08	PatUse: DS DP
Patent: 5212326*PED	07/29/08	
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: DS DP
Patent: 6528090*PED	06/18/19	
Patent: 6528091	12/18/18	
Patent: 6528091*PED	06/18/19	
Patent: 6713086	12/18/18	PatUse: DS 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
	Mkt Excl: PED	06/06/09

Divalproex Sodium eq 500mg base

Depakote CP	NDA No: 019794	Approved: 07/11/90
Oral – Tablet, Delayed Release		
Patent: 4988731	01/29/08	
Patent: 4988731*PED	07/29/08	
Patent: 5212326	01/29/08	
Patent: 5212326*PED	07/29/08	

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.

Abilify		
Aripiprazole 10mg	Otsuka	
Aripiprazole 15mg	Otsuka	
Aripiprazole 1mg/ml	Otsuka	
Aripiprazole 20mg	Otsuka	
Aripiprazole 2mg	Otsuka	
Aripiprazole 30mg	Otsuka	
Aripiprazole 5mg	Otsuka	
Aripiprazole 9.75mg/1.3ml (7.5mg/ml)	Otsuka	
Abraxane		
Paclitaxel 100mg/vial	Abraxis	
Abreva		
Docosanol 10%	GlaxoSmithKline	
Accolate		
Zafirlukast 10mg	AstraZeneca	
Zafirlukast 20mg	AstraZeneca	
Accretropin		
Somatropin Recombinant 5mg/ml	Cangene	
AccuNeb		
Albuterol Sulfate eq 0.021mg base/inh	Dey Laboratories	
Albuterol Sulfate eq 0.042mg base/inh	Dey Laboratories	
Accupril		
Quinapril Hydrochloride eq 10mg base	Pfizer	
Quinapril Hydrochloride eq 20mg base	Pfizer	
Quinapril Hydrochloride eq 40mg base	Pfizer	
Quinapril Hydrochloride eq 5mg base	Pfizer	
Aceon		
Perindopril Erbumine 2mg	Solvay	
Perindopril Erbumine 4mg	Solvay	
Perindopril Erbumine 8mg	Solvay	
Acetadote		
Acetylcysteine 6gm/30ml (200mg/ml)	Cumberland Pharmaceuticals	
Aciphex		
Rabeprazole Sodium 10mg	Eisai	
Rabeprazole Sodium 20 mg	Eisai	
Acova		
Argatroban 100mg/ml	Pfizer	
Actiq		
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	
Activella		
Estradiol 0.5mg; Norethindrone Acetate 0.1mg	Novo Nordisk	
Actonel		
Risedronate Sodium 150mg	Procter & Gamble	
Risedronate Sodium 30 mg	Procter & Gamble	
Risedronate Sodium 35mg	Procter & Gamble	
Risedronate Sodium 5mg	Procter & Gamble	
Risedronate Sodium 75mg	Procter & Gamble	
Actonel with Calcium (Copackaged)		
Calcium Carbonate eq 500mg base; Risedronate Sodium 35mg	Procter & Gamble	
Actos		
Pioglitazone Hydrochloride eq 15mg base	Takeda	
Pioglitazone Hydrochloride eq 30mg base	Takeda	
Pioglitazone Hydrochloride eq 45mg base	Takeda	
Acular		
Ketorolac Tromethamine 0.5%	Allergan Pharmaceuticals	
Acular LS		
Ketorolac Tromethamine 0.4%	Allergan Pharmaceuticals	
AcuTect		
Technetium Tc-99m Apcitide N/A	CIS Bio	
Azone		
Dapsone 5%	Allergan Pharmaceuticals	
ACTOplus Met		
Metformin Hydrochloride 500mg; Pioglitazone Hydrochloride eq 15mg base	Takeda	
Metformin Hydrochloride 850mg; Pioglitazone Hydrochloride eq 15mg base	Takeda	
Adalat CC		
Nifedipine 30mg	Bayer	
Nifedipine 60mg	Bayer	
Nifedipine 90mg	Bayer	
Adderall 10		
Dextroamphetamine Saccharate 2.5mg; Amphetamine Aspartate 2.5mg;		
Dextroamphetamine Sulfate 2.5mg; Amphetamine Sulfate 2.5mg	Duramed Pharmaceuticals	
Adderall 12.5		
Amphetamine Aspartate 3.125mg; Amphetamine Sulfate 3.125mg; Dextroamphetamine Saccharate 3.125mg; Dextroamphetamine Sulfate 3.125mg	Duramed Pharmaceuticals	
Adderall 15		
Amphetamine Aspartate 3.75mg; Amphetamine Sulfate 3.75mg; Dextroamphetamine Saccharate 3.75mg; Dextroamphetamine Sulfate 3.75mg	Duramed Pharmaceuticals	
Adderall 20		
Dextroamphetamine Saccharate 5mg; Amphetamine Aspartate 5mg;		
Dextroamphetamine Sulfate 5mg; Amphetamine Sulfate 5mg	Duramed Pharmaceuticals	
Adderall 30		
Dextroamphetamine Saccharate 7.5mg; Amphetamine Aspartate 7.5mg;		
Dextroamphetamine Sulfate 7.5mg; Amphetamine Sulfate 7.5mg	Duramed Pharmaceuticals	
Adderall 5		
Dextroamphetamine Saccharate 1.25mg; Amphetamine Aspartate 1.25mg;		
Dextroamphetamine Sulfate 1.25mg; Amphetamine Sulfate 1.25mg	Duramed Pharmaceuticals	
Adderall 7.5		
Amphetamine Aspartate 1.875mg; Amphetamine Sulfate 1.875mg; Dextroamphetamine Saccharate 1.875mg; Dextroamphetamine Sulfate 1.875mg	Duramed Pharmaceuticals	
Adderall XR 5		
Amphetamine Aspartate 1.25mg; Amphetamine Sulfate 1.25mg;		
Dextroamphetamine Saccharate 1.25mg; Dextroamphetamine Sulfate 1.25mg	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	GlaxoSmithKline	Ambrisentan 5mg	Gilead Sciences
Abacavir Sulfate eq 300mg base	GlaxoSmithKline	Amifostine 375mg/vial	MedImmune Oncology
Abacavir Sulfate eq 300mg base; Lamivudine 150mg; Zidovudine 300mg	GlaxoSmithKline	Amifostine 500mg/1 vial	MedImmune Oncology
Abacavir Sulfate eq 600mg base; Lamivudine 300mg	GlaxoSmithKline	Aminolevulinic Acid Hydrochloride 20%	DUSA Pharmaceuticals
Abarelix 100mg/vial	Specialty European Pharma	Amiodarone Hydrochloride 200mg	Dey Laboratories
Acamprosate Calcium 333mg	Forest Laboratories	Amlexanox 5%	Uluru
Acarbose 100mg	Bayer	Amlodipine Besylate eq 10mg base	Synthon
Acarbose 25mg	Bayer	Amlodipine Besylate eq 10mg base; Atorvastatin Calcium eq 10mg base	Pfizer
Acarbose 50mg	Bayer	Amlodipine Besylate eq 10mg base; Benazepril Hydrochloride 40mg	Novartis
Acetaminophen 325mg; Tramadol Hydrochloride 37.5mg	Ortho McNeil	Amlodipine Besylate eq 10mg base; Enalapril Hydrochloride 20mg	Novartis
Acetaminophen 500mg; Clemastine Fumarate eq 0.25mg base; Pseudoephedrine Hydrochloride 30mg	Novartis	Amlodipine Besylate eq 10mg base; Olmesartan Medoxomil 20mg	Daichi Pharm.
Acetaminophen; Aspirin; Caffeine 250 mg; 250 mg; 65 mg	Novartis	Amlodipine Besylate eq 10mg base; Olmesartan Medoxomil 40mg	Daichi Pharm.
Acetylcholine Chloride 20mg/vial	Novartis	Amlodipine Besylate eq 10mg base; Valsartan 160mg	Novartis
Acetylcysteine 6gm/30ml (200mg/ml)	Cumberland Pharmaceuticals	Amlodipine Besylate eq 10mg base; Valsartan 320mg	Novartis
Adapalene	Galderma Laboratories	Amlodipine Besylate eq 2.5mg base	Synthon
Adapalene .1%	Galderma Laboratories	Amlodipine Besylate eq 2.5mg base; Atorvastatin Calcium eq 10mg base	Pfizer
Adapalene 0.3%	Galderma Laboratories	Amlodipine Besylate eq 2.5mg base; Atorvastatin Calcium eq 20mg base	Pfizer
Adefovir Dipivoxil 10mg	Gilead Sciences	Amlodipine Besylate eq 2.5mg base; Atorvastatin Calcium eq 40mg base	Pfizer
Adenosine 3mg/1ml	Astellas	Amlodipine Besylate eq 5mg base	Synthon
Alatrofloxacin Mesylate eq 300mg base/vial	Pfizer	Amlodipine Besylate eq 5mg base; Atorvastatin Calcium eq 10mg base	Pfizer
Alatrofloxacin Mesylate eq 5mg base/1ml	Pfizer	Amlodipine Besylate eq 5mg base; Atorvastatin Calcium eq 20mg base	Pfizer
Albumin Human .5ml	GE Healthcare	Amlodipine Besylate eq 5mg base; Atorvastatin Calcium eq 40mg base	Pfizer
Albuterol Sulfate eq .09mg base/1inh	3M	Amlodipine Besylate eq 5mg base; Atorvastatin Calcium eq 80mg base	Pfizer
Albuterol Sulfate eq 0.021mg base/inh	Dey Laboratories	Amlodipine Besylate eq 5mg base; Benazepril Hydrochloride 40mg	Novartis
Albuterol Sulfate eq 0.042mg base/inh	Dey Laboratories	Amlodipine Besylate eq 5mg base; Olmesartan Medoxomil 40mg	Daichi Pharm.
Albuterol Sulfate eq 0.09mg base/inh	GlaxoSmithKline	Amlodipine Besylate eq 5mg base; Olmesartan Medoxomil 20mg	Daichi Pharm.
Albuterol Sulfate eq 0.09mg base/inh	Teva Pharmaceuticals	Amlodipine Besylate eq 5mg base; Valsartan 160mg	Novartis
Alcohol 61%; Chlorhexidine Gluconate 1%	3M	Amlodipine Besylate eq 5mg base; Valsartan 320mg	Novartis
Alendronate Sodium eq 10mg base	Merck	Ammonia, N-13 30mci-300mci/8ml (3.75-37.5mci/ml)	Feinstein Institute for Medical Research
Alendronate Sodium eq 35mg base	Merck	Amoxicillin 1gm; Clavulanate Potassium eq 62.5mg base	GlaxoSmithKline
Alendronate Sodium eq 40mg base	Merck	Amoxicillin 775mg	MiddleBrook Pharmaceuticals
Alendronate Sodium eq 5mg base	Merck	Amphetamine Aspartate 1.25mg; Amphetamine Sulfate 1.25mg;	
Alendronate Sodium eq 70mg base	Merck	Dextroamphetamine Saccharate 1.25mg; Dextroamphetamine Sulfate 1.25mg	Shire Laboratories
Alendronate Sodium eq 70mg base/75ml	Merck	Amphetamine Aspartate 1.875mg; Amphetamine Sulfate 1.875mg;	
Alendronate Sodium eq 70mg base; Cholecalciferol 2,800 iu	Merck	Dextroamphetamine Saccharate 1.875mg; Dextroamphetamine Sulfate 1.875mg	Duramed Pharmaceuticals
Alendronate Sodium eq 70mg base; Cholecalciferol 5,600 iu	Merck	Amphetamine Aspartate 2.5mg; Amphetamine Sulfate 2.5mg;	
Alfuzosin Hydrochloride 10mg	Sanofi	Dextroamphetamine Saccharate 2.5mg; Dextroamphetamine Sulfate 2.5mg	Shire Laboratories
Alikiren Hemifumarate eq 150mg base	Novartis	Amphetamine Aspartate 3.125mg; Amphetamine Sulfate 3.125mg;	
Alikiren Hemifumarate eq 150mg base; Hydrochlorothiazide 25mg	Novartis	Dextroamphetamine Saccharate 3.125mg; Dextroamphetamine Sulfate 3.125mg	Duramed Pharmaceuticals
Alikiren Hemifumarate eq 150mg base; Hydrochlorothiazide 12.5mg	Novartis	Amphetamine Aspartate 3.75mg; Amphetamine Sulfate 3.75mg;	
Alikiren Hemifumarate eq 300mg base	Novartis	Dextroamphetamine Saccharate 3.75mg; Dextroamphetamine Sulfate 3.75mg	Duramed Pharmaceuticals
Alikiren Hemifumarate eq 300mg base; Hydrochlorothiazide 25mg	Novartis	Amphetamine Aspartate 3.75mg; Amphetamine Sulfate 3.75mg;	
Alikiren Hemifumarate eq 300mg base; Hydrochlorothiazide 12.5mg	Novartis	Dextroamphetamine Saccharate 3.75mg; Dextroamphetamine Sulfate 3.75mg	Shire Laboratories
Allitretinoin eq 0.1% base	Eisai	Amphetamine Aspartate 5mg; Amphetamine Sulfate 5mg;	
Almotriptan Malate eq 12.5mg base	Ortho McNeil	Dextroamphetamine Saccharate 5mg; Dextroamphetamine Sulfate 5mg	Shire Laboratories
Almotriptan Malate eq 6.25mg base	Ortho McNeil	Amphetamine Aspartate 6.25mg; Amphetamine Sulfate 6.25mg;	
Alosetron Hydrochloride eq 0.5mg base	Prometheus Laboratories	Dextroamphetamine Saccharate 6.25mg; Dextroamphetamine Sulfate 6.25mg	Shire Laboratories
Alosetron Hydrochloride eq 1mg base	Prometheus Laboratories	Amphetamine Aspartate 7.5mg; Amphetamine Sulfate 7.5mg;	
Alprazolam 0.25mg	Schwarz	Dextroamphetamine Saccharate 7.5mg; Dextroamphetamine Sulfate 7.5mg	Shire Laboratories
Alprazolam 0.5mg	Schwarz	Amphotericin B 50mg/1 vial	Astellas
Alprazolam 1mg	Schwarz	Amprenavir 150mg	GlaxoSmithKline
Alprazolam 2mg	Schwarz	Amprenavir 15mg/ml	GlaxoSmithKline
Alprostadil .005mg/1 vial	Pfizer	Amprenavir 50mg	GlaxoSmithKline
Alprostadil .01mg/1 vial	Pfizer	Anastrozole 1mg	AstraZeneca
Alprostadil .02mg/1 vial	Pfizer	Anidulafungin 100mg/vial	Vicuron
Alprostadil .04mg/1 vial	Pfizer		
Alprostadil .125mg	Vivus		
Alprostadil .25mg	Vivus		
Alprostadil .5mg	Vivus		
Alprostadil 0.01mg/vial	Pfizer		
Alprostadil 0.02mg/vial	Pfizer		
Alprostadil 1mg	Vivus		
Alvimopan 12mg	Adolor		
Ambrisentan 10mg	Gilead Sciences		

01/14/09

4943639*PED	UCB Pharma	Levetiracetam 100mg/ml
4943639*PED	UCB Pharma	Levetiracetam 1gm
4943639*PED	UCB Pharma	Levetiracetam 250mg
4943639*PED	UCB Pharma	Levetiracetam 500mg
4943639*PED	UCB Pharma	Levetiracetam 500mg/5ml (100mg/ml)
4943639*PED	UCB Pharma	Levetiracetam 750mg
5081154	AstraZeneca	Metoprolol Succinate eq 100mg Tartrate
5081154	AstraZeneca	Metoprolol Succinate eq 200mg Tartrate
5081154	AstraZeneca	Metoprolol Succinate eq 25mg Tartrate
5081154	AstraZeneca	Metoprolol Succinate eq 50mg Tartrate

01/17/09

5006530	Bayer	Cerivastatin Sodium .05mg
5006530	Bayer	Cerivastatin Sodium .1mg
5006530	Bayer	Cerivastatin Sodium .2mg
5006530	Bayer	Cerivastatin Sodium .3mg
5006530	Bayer	Cerivastatin Sodium 0.4 mg
5006530	Bayer	Cerivastatin Sodium 0.8mg

01/19/09

4895726	Abbott Laboratories	Fenofibrate 134mg
4895726	Abbott Laboratories	Fenofibrate 160mg
4895726	Abbott Laboratories	Fenofibrate 200mg
4895726	Abbott Laboratories	Fenofibrate 54mg
4895726	Abbott Laboratories	Fenofibrate 67mg

01/21/09

5082668	Searle Pharmaceuticals	Verapamil Hydrochloride 180mg
5082668	Searle Pharmaceuticals	Verapamil Hydrochloride 240mg

01/22/09

4602017*PED	GlaxoSmithKline	Lamotrigine 100mg
4602017*PED	GlaxoSmithKline	Lamotrigine 150mg
4602017*PED	GlaxoSmithKline	Lamotrigine 200mg
4602017*PED	GlaxoSmithKline	Lamotrigine 250mg
4602017*PED	GlaxoSmithKline	Lamotrigine 25mg
4602017*PED	GlaxoSmithKline	Lamotrigine 2mg
4602017*PED	GlaxoSmithKline	Lamotrigine 50mg
4602017*PED	GlaxoSmithKline	Lamotrigine 5mg

01/24/09

4910225	ISTA Pharmaceuticals	Bromfenac Sodium 0.09%
---------	----------------------	------------------------

01/27/09

4639436	Pfizer	Miglitol 100mg
4639436	Pfizer	Miglitol 25mg
4639436	Pfizer	Miglitol 50mg

02/06/09

5037845*PED	GlaxoSmithKline	Sumatriptan 10mg/1 Spray
5037845*PED	GlaxoSmithKline	Sumatriptan 20mg/1 Spray
5037845*PED	GlaxoSmithKline	Sumatriptan 5mg/1 Spray
5037845*PED	GlaxoSmithKline	Sumatriptan Succinate eq 100mg base
5037845*PED	GlaxoSmithKline	Sumatriptan Succinate eq 25mg base
5037845*PED	GlaxoSmithKline	Sumatriptan Succinate eq 4mg base/0.5ml (8mg/ml)
5037845*PED	GlaxoSmithKline	Sumatriptan Succinate eq 50mg base
5037845*PED	GlaxoSmithKline	Sumatriptan Succinate eq 6mg base/0.5ml
5037845*PED	GlaxoSmithKline	Sumatriptan Succinate eq 6mg base/0.5ml (12mg/ml)

5102652	AMAG Pharmaceuticals	Ferumoxides eq 11.2mg Iron/1ml
---------	----------------------	--------------------------------

02/08/09

5047407	GlaxoSmithKline	Lamivudine 5mg/ml
7119202	GlaxoSmithKline	Abacavir Sulfate eq 300mg base; Lamivudine 150mg; Zidovudine 300mg
7119202	GlaxoSmithKline	Abacavir Sulfate eq 600mg base; Lamivudine 300mg
7119202	GlaxoSmithKline	Lamivudine 100mg
7119202	GlaxoSmithKline	Lamivudine 10mg/1ml
7119202	GlaxoSmithKline	Lamivudine 150mg
7119202	GlaxoSmithKline	Lamivudine 150mg; Zidovudine 300mg
7119202	GlaxoSmithKline	Lamivudine 300mg
7119202	GlaxoSmithKline	Lamivudine 5mg/ml

02/13/09

4927855*PED	Cephalon	Armodafinil 150mg
4927855*PED	Cephalon	Armodafinil 250mg
4927855*PED	Cephalon	Armodafinil 50mg

02/15/09

5019583	Bioniche Pharma	Remifentanil Hydrochloride eq 1mg base/1 vial
5019583	Bioniche Pharma	Remifentanil Hydrochloride eq 2mg base/1 vial
5019583	Bioniche Pharma	Remifentanil Hydrochloride eq 5mg base/1 vial

02/18/09

5089509	Allergan Pharmaceuticals	Tazarotene .05%
5089509	Allergan Pharmaceuticals	Tazarotene .1%

02/25/09

5091169	GE Healthcare	Mangafodipir Trisodium 37.9mg/1ml
---------	---------------	-----------------------------------

03/01/09

5002953*PED	SB Pharmco	Metformin Hydrochloride 1gm; Rosiglitazone Maleate eq 4mg base Metformin Hydrochloride 1gm; Rosiglitazone Maleate eq 2mg base Metformin Hydrochloride 500mg; Rosiglitazone Maleate eq 4mg base Metformin Hydrochloride 500mg; Rosiglitazone Maleate eq 2mg base Metformin Hydrochloride 500mg; Rosiglitazone Maleate eq 1mg base Rosiglitazone Maleate eq 2mg base Rosiglitazone Maleate eq 4mg base Rosiglitazone Maleate eq 8mg base
5002953*PED	SB Pharmco	
5002953*PED	SB Pharmco	
5002953*PED	SB Pharmco	
5002953*PED	SB Pharmco	
5002953*PED	SB Pharmco	
5002953*PED	SB Pharmco	
5002953*PED	SB Pharmco	

03/03/09

5045321*PED	Takeda	Lansoprazole 15mg
5045321*PED	Takeda	Lansoprazole 15mg/packet
5045321*PED	Takeda	Lansoprazole 30mg
5045321*PED	Takeda	Lansoprazole 30mg/packet
5093132*PED	Takeda	Lansoprazole 15mg
5093132*PED	Takeda	Lansoprazole 15mg/packet
5093132*PED	Takeda	Lansoprazole 30mg
5093132*PED	Takeda	Lansoprazole 30mg/packet
5433959*PED	Takeda	Lansoprazole 15mg
5433959*PED	Takeda	Lansoprazole 15mg/packet
5433959*PED	Takeda	Lansoprazole 30mg
5433959*PED	Takeda	Lansoprazole 30mg/packet

03/14/09

6143769	Novo Nordisk	Repaglinide 1mg
6143769	Novo Nordisk	Repaglinide 2mg
RE37035	Novo Nordisk	Metformin Hydrochloride 500mg; Repaglinide 1mg
RE37035	Novo Nordisk	Metformin Hydrochloride 500mg; Repaglinide 2mg
RE37035	Novo Nordisk	Repaglinide .5mg
RE37035	Novo Nordisk	Repaglinide 1mg
RE37035	Novo Nordisk	Repaglinide 2mg

03/15/09

4863931*PED	Schering	Desloratadine 5mg
4863931*PED	Schering	Loratadine 10mg
4863931*PED	Schering	Loratadine 10mg; Pseudoephedrine Sulfate 240mg
4863931*PED	Schering	Loratadine 1mg/1ml
4863931*PED	Schering	Loratadine 5mg; Pseudoephedrine Sulfate 120mg

03/17/09

5096885	Genentech	Somatropin, Biosynthetic 10mg/1 vial
5096885	Genentech	Somatropin, Biosynthetic 5mg/vial
5589180	Teikoku Pharma	Lidocaine 5%
5709869	Teikoku Pharma	Lidocaine 5%

03/24/09

6143769	Novo Nordisk	Repaglinide .5mg
---------	--------------	------------------

03/26/09

4513006*PED	Ortho McNeil	Topiramate 100mg
4513006*PED	Ortho McNeil	Topiramate 15mg
4513006*PED	Ortho McNeil	Topiramate 200mg
4513006*PED	Ortho McNeil	Topiramate 25mg
4513006*PED	Ortho McNeil	Topiramate 300mg
4513006*PED	Ortho McNeil	Topiramate 400mg
4513006*PED	Ortho McNeil	Topiramate 50mg

03/27/09

4911932	Barrier	Miconazole Nitrate 0.25%; Petrolatum, White 81.35%; Zinc Oxide 15%
---------	---------	---

04/01/09

4636505*PED	AstraZeneca	Bicalutamide 50mg
5053432*PED	GlaxoSmithKline	Atovaquone 250mg
5053432*PED	GlaxoSmithKline	Atovaquone 250mg; Proguanil Hydrochloride 100mg
5053432*PED	GlaxoSmithKline	Atovaquone 62.5mg; Proguanil Hydrochloride 25mg
5053432*PED	GlaxoSmithKline	Atovaquone 750mg/5ml

04/04/09

5035899	Eisai	Rabeprazole Sodium 10mg
5035899	Eisai	Rabeprazole Sodium 20 mg

04/06/09

4980171	Sanofi	Tiludronate Disodium eq 200mg 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%	Connetics
Clobetasol Propionate 0.05%	Connetics
Desonide 0.05%	Connetics
Minoxidil 5%	Johnson & Johnson

Aerosol, Metered

Albuterol Sulfate eq .09mg base/1inh	3M
Albuterol Sulfate eq 0.09mg base/1inh	GlaxoSmithKline
Albuterol Sulfate eq 0.09mg base/1inh	Teva Pharmaceuticals
Beclomethasone Dipropionate 0.04mg/inh	Teva Pharmaceuticals
Beclomethasone Dipropionate 0.08mg/inh	Teva Pharmaceuticals
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 .018mg/1inh;	
Albuterol Sulfate eq .09mg base/1inh	Boehringer Ingelheim
Ipratropium Bromide 0.021mg/inh	Boehringer Ingelheim
Levalbuterol Tartrate eq 0.045mg base/inh	Sepracor
Salmeterol Xinafoate eq .021mg base/1inh	GlaxoSmithKline

Capsule

Alvimopan 12mg	Adolor
Amlodipine Besylate eq 10mg base; Benazepril Hydrochloride 40mg	Novartis
Amlodipine Besylate eq 10mg base; Enazepril Hydrochloride 20mg	Novartis
Amlodipine Besylate eq 5mg base; Benazepril Hydrochloride 40mg	Novartis
Amprenavir 150mg	GlaxoSmithKline
Amprenavir 50mg	GlaxoSmithKline
Aprepitant 125mg	Merck
Aprepitant 40mg	Merck
Aprepitant 80mg	Merck
Atazanavir Sulfate 150mg base	Bristol-Myers
Atazanavir Sulfate 200mg base	Bristol-Myers
Atazanavir Sulfate eq 100mg 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
Benazepril Hydrochloride 10mg; Amlodipine Besylate eq 5mg base	Novartis
Benazepril Hydrochloride 10mg; Amlodipine Besylate eq 2.5mg base	Novartis
Benazepril Hydrochloride 20mg; Amlodipine Besylate eq 5mg base	Novartis
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 30mg base	Daiichi Pharmaceutical
Colesevelam Hydrochloride 375mg	Sankyo USA
Cyclosporine 100mg	Novartis
Cyclosporine 25mg	Novartis
Cyclosporine 50mg	Novartis
Dofetilide 0.125mg	Pfizer
Dofetilide 0.25mg	Pfizer
Dofetilide 0.5mg	Pfizer
Doxercalciferol	Genzyme
Doxercalciferol 0.5ugm	Genzyme
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 134mg	Abbott Laboratories
Fenofibrate 150mg	Cipher
Fenofibrate 200mg	Abbott Laboratories
Fenofibrate 43mg	Oscient Pharmaceuticals
Fenofibrate 50mg	Cipher
Fenofibrate 67mg	Abbott Laboratories
Fexofenadine Hydrochloride 60mg	Aventis Pharmaceuticals
Fluoxetine Hydrochloride 10mg base	Eli Lilly
Fluoxetine Hydrochloride 20mg base	Eli Lilly
Fluoxetine Hydrochloride eq 25mg base; Olanzapine eq 12mg base	Eli Lilly
Fluoxetine Hydrochloride eq 25mg base; Olanzapine eq 6mg base	Eli Lilly
Fluoxetine Hydrochloride eq 25mg base; Olanzapine eq 3mg base	Eli Lilly
Fluoxetine Hydrochloride eq 50mg base; Olanzapine eq 12mg base	Eli Lilly
Fluoxetine Hydrochloride eq 50mg base; Olanzapine eq 6mg 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	Banner Pharmacaps
Ibuprofen eq 200mg Free Acid; Pseudoephedrine Hydrochloride 30mg	Wyeth
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 400mg base	Merck
Isosorbide Dinitrate 40 mg	Merck
Itraconazole 100mg	Ortho McNeil
Lenalidomide 10mg	Celgene
Lenalidomide 15mg	Celgene
Lenalidomide 25mg	Celgene
Lenalidomide 5mg	Celgene
Lisdexamfetamine Dimesylate 20mg	New River Pharmaceuticals
Lisdexamfetamine Dimesylate 30mg	New River Pharmaceuticals
Lisdexamfetamine Dimesylate 40mg	New River Pharmaceuticals
Lisdexamfetamine Dimesylate 50mg	New River Pharmaceuticals
Lisdexamfetamine Dimesylate 60mg	New River Pharmaceuticals
Lisdexamfetamine Dimesylate 70mg	New River Pharmaceuticals
Lopinavir 133.3mg; Ritonavir 33.3mg	Abbott Laboratories
Lubiprostone 24ugm	Sucampo
Lubiprostone 8ugm	Sucampo
Miglustat 100mg	Actelion Pharmaceuticals

Section 6 — Exclusivity Code Index

Section 6, the Exclusivity Code Index, presents drugs under patent which have marketing exclusivity expiring from January 1, 2009 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 2009 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-102 New Dosing Schedule: New Dosing Regimen of One Spray Twice Daily for Seasonal Allergic Rhinitis in Patients 12 Years of Age and Older

Azelastine Hydrochloride eq .125mg base/1 Spray Meda Pharmaceuticals – 02/17/09

D-103 New Dosing Schedule: New Dosing Recommendation for the Treatment of Recurrent Genital Herpes in Immunocompetent Patients, Specifically a Reduction in Course of Therapy from Famciclovir 125mg Twice-a-Day for 5 Days to 1000mg Twice-a-Day for 1 Day.

Famciclovir 125mg Novartis – 07/28/09
Famciclovir 250mg Novartis – 07/28/09
Famciclovir 500mg Novartis – 07/28/09

D-104 New Dosing Schedule: 0.5mg/0.1mg for the Treatment of Moderate to Severe Vasomotor Symptoms Associated with Menopause in Women Who Have a Uterus

Estradiol 0.5mg; Norethindrone Acetate 0.1mg Novo Nordisk – 12/29/09
Estradiol 0.5mg; Norethindrone Acetate 0.1mg Novo Nordisk – 12/28/09

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 influenzae*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae* for Community-Acquired Pneumonia

Gemifloxacin Mesylate eq 320 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 (5mg/1ml) Ortho McNeil – 09/14/10
Levofloxacin eq 500mg/100ml (5mg/1ml) Ortho McNeil – 09/14/10
Levofloxacin eq 500mg/20ml (25mg/ml) Ortho McNeil – 09/14/10
Levofloxacin eq 750mg/150ml (5mg/ml) Ortho McNeil – 09/14/10
Levofloxacin eq 750mg/30ml (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

I-235 New Indication: Prevention of Exercise-Induced Bronchospasm in Patients 12 Years of Age and Older

Albuterol Sulfate eq 0.09mg base/inh Teva Pharmaceuticals – 02/03/09

Section 7 – Patent Number Index

Section 7, the Patent Number Index, presents a listing of drugs under patent arranged by patent number. Use this section when only a patent number is known, or to find all of the drug products covered by a particular patent.

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

4234571	Nafarelin Acetate eq .2mg base/1 Spray	Searle Pharmaceuticals	Amlodipine Besylate eq 5mg base;	
4513006*PED	Topiramate 100mg	Ortho McNeil	Atorvastatin Calcium eq 10mg base	Pfizer
	Topiramate 15mg	Ortho McNeil	Amlodipine Besylate eq 5mg base;	
	Topiramate 200mg	Ortho McNeil	Atorvastatin Calcium eq 80mg base	Pfizer
	Topiramate 25mg	Ortho McNeil	Amlodipine Besylate eq 5mg base;	
	Topiramate 300mg	Ortho McNeil	Atorvastatin Calcium eq 40mg base	Pfizer
	Topiramate 400mg	Ortho McNeil	Atorvastatin Calcium eq 10mg base	Pfizer
	Topiramate 50mg	Ortho McNeil	Atorvastatin Calcium eq 20mg base	Pfizer
4598089	Orlistat 120mg	Hoffmann-La Roche	Atorvastatin Calcium eq 40mg base	Pfizer
	Orlistat 60mg	GlaxoSmithKline	Atorvastatin Calcium eq 80mg base	Pfizer
4598089*PED	Orlistat 120mg	Hoffmann-La Roche	4687777	Glimepiride 2mg; Pioglitazone Hydrochloride 30mg
4602017*PED	Lamotrigine 100mg	GlaxoSmithKline	Glimepiride 4mg; Pioglitazone Hydrochloride 30mg	Takeda
	Lamotrigine 150mg	GlaxoSmithKline	Metformin Hydrochloride 500mg;	
	Lamotrigine 200mg	GlaxoSmithKline	Pioglitazone Hydrochloride eq 15mg base	Takeda
	Lamotrigine 250mg	GlaxoSmithKline	Metformin Hydrochloride 850mg;	
	Lamotrigine 25mg	GlaxoSmithKline	Pioglitazone Hydrochloride eq 15mg base	Takeda
	Lamotrigine 2mg	GlaxoSmithKline	Pioglitazone Hydrochloride eq 15mg base	Takeda
	Lamotrigine 50mg	GlaxoSmithKline	Pioglitazone Hydrochloride eq 30mg base	Takeda
	Lamotrigine 5mg	GlaxoSmithKline	Pioglitazone Hydrochloride eq 45mg base	Takeda
4628098	Lansoprazole 15mg	Takeda	4689338	Imiquimod 5%
	Lansoprazole 15mg/packet	Takeda	4689338*PED	Imiquimod 5%
	Lansoprazole 30mg	Takeda	4696949	Toremifene Citrate eq 60mg base
	Lansoprazole 30mg/packet	Takeda	4703063	Tamsulosin Hydrochloride .4mg
4628098*PED	Lansoprazole 15mg	Takeda	4717720	Adapalene
	Lansoprazole 15mg/packet	Takeda		Adapalene .1%
	Lansoprazole 30mg	Takeda		Adapalene 0.3%
	Lansoprazole 30mg/packet	Takeda	4745177	Desirudin Recombinant 15mg/vial
4634697	Ceftibuten Dihydrate eq 180mg base/5ml	Sciele Pharma	4753935	Mycophenolate Mofetil 200mg/ml
	Ceftibuten Dihydrate eq 400mg base	Sciele Pharma		Mycophenolate Mofetil 250mg
	Ceftibuten Dihydrate eq 90mg base/5ml	Sciele Pharma		Mycophenolate Mofetil 500mg
4636505*PED	Bicalutamide 50mg	AstraZeneca		Mycophenolate Mofetil Hydrochloride 500mg/vial
4639436	Miglitol 100mg	Pfizer	4758479	Pantoprazole Sodium eq 20mg base
	Miglitol 25mg	Pfizer	4758579	Pantoprazole Sodium eq 20mg base
	Miglitol 50mg	Pfizer		Pantoprazole Sodium eq 40mg base
4661491	Alfuzosin Hydrochloride 10mg	Sanofi		Pantoprazole Sodium eq 40mg base/vial
4681893	Amlodipine Besylate eq 10mg base;		4761237	Calcium Chloride 25.7mg/100ml; Icodextrin 7.5gm/100ml;
	Atorvastatin Calcium eq 10mg base	Pfizer		Magnesium Chloride 5.08mg/100ml;
	Amlodipine Besylate eq 2.5mg base;			Sodium Chloride 535mg/100ml; Sodium Lactate 448mg/100ml
	Atorvastatin Calcium eq 40mg base	Pfizer	4795751	Sparfloxacin 200mg
	Amlodipine Besylate eq 2.5mg base;		4801577	Ganirelix Acetate eq 250 ugm base/ 0.5 ml
	Atorvastatin Calcium eq 10mg base	Pfizer	4808614	Gemcitabine Hydrochloride eq 1gm base/1 vial /vial
	Amlodipine Besylate eq 2.5mg base;			Gemcitabine Hydrochloride eq 200mg base/1 vial /vial
	Atorvastatin Calcium eq 20mg base	Pfizer	4808614*PED	Gemcitabine Hydrochloride eq 1gm base/1 vial /vial
	Amlodipine Besylate eq 5mg base;			Gemcitabine Hydrochloride eq 200mg base/1 vial /vial
	Atorvastatin Calcium eq 10mg base	Pfizer	4808616	Exemestane 25mg
	Amlodipine Besylate eq 5mg base;		4812561	Ceftibuten Dihydrate eq 180mg base/5ml
	Atorvastatin Calcium eq 20mg base	Pfizer		Ceftibuten Dihydrate eq 400mg base
	Amlodipine Besylate eq 5mg base;			Ceftibuten Dihydrate eq 90mg base/5ml
	Atorvastatin Calcium eq 40mg base	Pfizer	4814470	Docetaxel eq 40mg base/1ml
	Atorvastatin Calcium eq 10mg base	Pfizer	4830010	Urea, C-13 125mg/1 vial
	Atorvastatin Calcium eq 20mg base	Pfizer		Urea, C-13 eq 75mg/Pouche
	Atorvastatin Calcium eq 40mg base	Pfizer	4831031	Ziprasidone Hydrochloride eq 10mg base/ml
	Atorvastatin Calcium eq 80mg base	Pfizer		Ziprasidone Hydrochloride eq 20mg base
4681893*PED	Amlodipine Besylate eq 10mg base;			Ziprasidone Hydrochloride eq 40mg base
	Atorvastatin Calcium eq 10mg base	Pfizer		Ziprasidone Hydrochloride eq 60mg base
	Amlodipine Besylate eq 2.5mg base;			Ziprasidone Hydrochloride eq 80mg base
	Atorvastatin Calcium eq 20mg base	Pfizer		Ziprasidone Mesylate eq 20mg base/ml
	Amlodipine Besylate eq 2.5mg base;		4839342	Cyclosporine 0.05%
	Atorvastatin Calcium eq 10mg base	Pfizer	4839350	Cefditoren Pivoxil 200mg
	Amlodipine Besylate eq 2.5mg base;			Cefditoren Pivoxil 400mg
	Atorvastatin Calcium eq 40mg base	Pfizer	4845075	Methoxsalen 0.02mg/ml
	Amlodipine Besylate eq 5mg base;		4847265	Clopidogrel Bisulfate eq 75mg base
	Atorvastatin Calcium eq 20mg base	Pfizer	4855290	Cevimeline Hydrochloride 30mg base

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.

004782	Estrogens, Conjugated 0.3mg	Wyeth	018658	Dextromethorphan Polistirex eq 30mg HBr/5ml	Adams Respiratory
	Estrogens, Conjugated 0.625mg	Wyeth	018705	Nitroglycerin 0.4mg/Spray	G. Pohl Boskamp
	Estrogens, Conjugated 0.9mg	Wyeth	018731	Buspirone Hydrochloride 10mg	Bristol-Myers
	Estrogens, Conjugated 1.25mg	Wyeth		Buspirone Hydrochloride 15mg	Bristol-Myers
	Estrogens, Conjugated 2.5mg	Wyeth		Buspirone Hydrochloride 30mg	Bristol-Myers
008809	Ascorbic Acid 20mg/ml; Biotin 0.006mg/ml; Cyanocobalamin 0.05ugm/ml; Dexpanthenol 1.5mg/ml; Ergocalciferol 0.0005mg/ml; Folic Acid 0.06mg/ml; Niacinamide 4mg/ml; Pyridoxine Hydrochloride 0.6mg/ml; Riboflavin Phosphate Sodium 0.36mg/ml; Thiamine Hydrochloride 0.6mg/ml; Vitamin A 0.1mg/ml; Vitamin E 1mg/ml	Mayne Pharma	018859	Ribavirin 6gm/vial	Valeant Pharmaceuticals
010402	Estrogens, Conjugated 25mg/vial	Wyeth	018874	Calcitriol 0.001mg/ml	Abbott Laboratories
010971	Estrogens, Conjugated 0.45mg; Meprobamate 400mg	Wyeth		Calcitriol 0.002mg/ml	Abbott Laboratories
	Meprobamate 200mg; Estrogens, Conjugated 0.45mg	Wyeth	018936	Fluoxetine Hydrochloride 10mg base	Eli Lilly
011522	Amphetamine Aspartate 1.875mg; Amphetamine Sulfate 1.875mg; Dextroamphetamine Saccharate 1.875mg; Dextroamphetamine Sulfate 1.875mg	Duramed Pharmaceuticals		Fluoxetine Hydrochloride 20mg base	Eli Lilly
	Amphetamine Aspartate 3.125mg; Amphetamine Sulfate 3.125mg; Dextroamphetamine Saccharate 3.125mg; Dextroamphetamine Sulfate 3.125mg	Duramed Pharmaceuticals	018938	Desmopressin Acetate .015mg/1ml	Aventis Pharmaceuticals
	Amphetamine Aspartate 3.75mg; Amphetamine Sulfate 3.75mg; Dextroamphetamine Saccharate 3.75mg; Dextroamphetamine Sulfate 3.75mg	Duramed Pharmaceuticals		Desmopressin Acetate 0.004mg/ml	Aventis Pharmaceuticals
	Dextroamphetamine Saccharate 1.25mg; Amphetamine Aspartate 1.25mg; Dextroamphetamine Sulfate 1.25mg; Amphetamine Sulfate 1.25mg	Duramed Pharmaceuticals	019034	Hydromorphone Hydrochloride 10mg/ml	Purdue Pharma
	Dextroamphetamine Saccharate 2.5mg; Amphetamine Aspartate 2.5mg; Dextroamphetamine Sulfate 2.5mg; Amphetamine Sulfate 2.5mg	Duramed Pharmaceuticals		Hydromorphone Hydrochloride 250mg/1 vial	Purdue Pharma
	Dextroamphetamine Saccharate 5mg; Amphetamine Aspartate 5mg; Dextroamphetamine Sulfate 5mg; Amphetamine Sulfate 5mg	Duramed Pharmaceuticals	019057	Terazosin Hydrochloride eq 10mg base	Abbott Laboratories
	Dextroamphetamine Saccharate 7.5mg; Amphetamine Aspartate 7.5mg; Dextroamphetamine Sulfate 7.5mg; Amphetamine Sulfate 7.5mg	Duramed Pharmaceuticals		Terazosin Hydrochloride eq 1mg base	Abbott Laboratories
011792	Carisoprodol 250mg	Meda Pharmaceuticals		Terazosin Hydrochloride eq 2mg base	Abbott Laboratories
012827	Glycopyrrolate 1mg	Sciele Pharma		Terazosin Hydrochloride eq 5mg base	Abbott Laboratories
	Glycopyrrolate 2mg	Sciele Pharma	019304	Fenofibrate 134mg	Abbott Laboratories
013217	Metaxalone 400mg	King Pharmaceuticals		Fenofibrate 200mg	Abbott Laboratories
	Metaxalone 800mg	Carrick Laboratories		Fenofibrate 67mg	Abbott Laboratories
	Metaxalone 800mg	King Pharmaceuticals	019385	Pergolide Mesylate eq 0.05mg base	Valeant Pharmaceuticals
013718	Oxandrolone 10mg	Savient Pharmaceuticals		Pergolide Mesylate eq 0.25mg base	Valeant Pharmaceuticals
	Oxandrolone 2.5mg	Savient Pharmaceuticals		Pergolide Mesylate eq 1mg base	Valeant Pharmaceuticals
017697	Sincalide 0.005mg/vial	Bracco Diagnostics	019386	Esmolol Hydrochloride 2gm/100ml	Baxter
017922	Desmopressin Acetate .1mg/1ml	Aventis Pharmaceuticals		Esmolol Hydrochloride 10mg/ml	Baxter
	Desmopressin Acetate 0.01%	Aventis Pharmaceuticals		Esmolol Hydrochloride 1gm/100ml	Baxter
018057	Cisplatin 0.5mg/ml	Bristol-Myers		Esmolol Hydrochloride 20mg/ml	Baxter
	Cisplatin 10mg/vial	Bristol-Myers	019415	Urofollitropin 150iu/1amp	Serono
	Cisplatin 1mg/ml	Bristol-Myers		Urofollitropin 75iu/amp	Serono
	Cisplatin 50mg/vial	Bristol-Myers	019452	Fluocinolone Acetonide 0.01%	Hill Dermaceuticals
018163	Temazepam 7.5mg	Tyco Healthcare	019537	Ciprofloxacin Hydrochloride eq 100mg base	Bayer
018343	Captopril 100mg	Par Pharmaceutical		Ciprofloxacin Hydrochloride eq 250mg base	Bayer
	Captopril 12.5mg	Par Pharmaceutical		Ciprofloxacin Hydrochloride eq 500mg base	Bayer
	Captopril 150mg	Par Pharmaceutical	019596	Gadopentetate Dimeglumine 469.01mg/ml	Berlex Laboratories
	Captopril 25mg	Par Pharmaceutical	019627	Propofol 10mg/ml	Abraxis
	Captopril 37.5mg	Par Pharmaceutical	019640	Somatropin, Biosynthetic 12mg/vial	Eli Lilly
	Captopril 50mg	Par Pharmaceutical		Somatropin, Biosynthetic 24mg/vial	Eli Lilly
	Captopril 75mg	Par Pharmaceutical		Somatropin, Biosynthetic 5mg/vial	Eli Lilly
018644	Bupropion Hydrochloride 100mg	GlaxoSmithKline		Somatropin, Biosynthetic 6mg/vial	Eli Lilly
	Bupropion Hydrochloride 50mg	GlaxoSmithKline	019651	Mesalamine 400mg	Procter & Gamble
	Bupropion Hydrochloride 75mg	GlaxoSmithKline	019658	Loratadine 10mg	Schering
018651	Dronabinol 10mg	Unimed	019667	Octreotide Acetate eq .05mg base/1ml	Novartis
	Dronabinol 2.5mg	Unimed		Octreotide Acetate eq .1mg base/1ml	Novartis
	Dronabinol 5mg	Unimed		Octreotide Acetate eq .2mg base/1ml	Novartis
				Octreotide Acetate eq .5mg base/1ml	Novartis
				Octreotide Acetate eq 1mg base/ml	Novartis
			019670	Loratadine 5mg; Pseudoephedrine Sulfate 120mg	Schering
			019675	Ranitidine Hydrochloride eq 15mg base/ml	GlaxoSmithKline
			019680	Divalproex Sodium eq 125mg Valproic Acid	Abbott Laboratories
			019684	Nifedipine 30mg	Pfizer
				Nifedipine 60mg	Pfizer
				Nifedipine 90mg	Pfizer
			019700	Ketorolac Tromethamine 0.5%	Allergan Pharmaceuticals
			019721	Somatropin, Biosynthetic 4mg/1 vial	Novo Nordisk
				Somatropin, Biosynthetic 8mg/1 vial	Novo Nordisk
			019726	Goserelin Acetate eq 3.6mg base	AstraZeneca
			019732	Leuprolide Acetate 7.5mg/vial	Abbott Laboratories
			019734	Nicardipine Hydrochloride 25mg/10ml (2.5mg/ml)	EKR Therapeutics
			019762	Testosterone 4mg/24hr	Alza
				Testosterone 6mg/24hr	Alza

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

Fenofibrate 134mg
Fenofibrate 160mg
Fenofibrate 200mg
Fenofibrate 54mg
Fenofibrate 67mg
Leuprolide Acetate 3.75mg/1 vial; Leuprolide Acetate 7.5mg/1 vial
Leuprolide Acetate 7.5mg/1 vial; Leuprolide Acetate 7.5mg/1 vial
Niacin 375mg
Niacin 750mg
Ritonavir 100mg

Alcon Laboratories

Betaxolol Hydrochloride eq .25% base/1ml; Pilocarpine Hydrochloride 1.75%/1ml
Levobetaxolol Hydrochloride eq 0.5% base

Allergan Pharmaceuticals

Brimonidine Tartrate .2%/1ml

Alza

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

AndRx

Lovastatin 10mg

AstraZeneca

Budesonide 0.064mg/inh
Hydrochlorothiazide 12.5mg; Metoprolol Succinate eq 25mg Tartrate
Hydrochlorothiazide 12.5mg; Metoprolol Succinate eq 100mg Tartrate
Hydrochlorothiazide 12.5mg; Metoprolol Succinate eq 50mg Tartrate
Quetiapine Fumarate eq 150mg base

Aventis Pharmaceuticals

Desmopressin Acetate .015mg/1ml
Desmopressin Acetate .1mg/1ml
Enoxaparin Sodium 90mg/0.6ml
Fexofenadine Hydrochloride 60mg

Azur Pharma

Clozapine 50mg

Bayer

Cerivastatin Sodium .05mg
Cerivastatin Sodium .1mg
Cerivastatin Sodium .2mg
Cerivastatin Sodium .3mg
Cerivastatin Sodium 0.4 mg
Cerivastatin Sodium 0.8mg

Biovail Laboratories

Diltiazem Hydrochloride 120mg
Diltiazem Hydrochloride 180mg
Tramadol Hydrochloride 50mg

Boehringer Ingelheim

Pramipexole Dihydrochloride 1.25mg

Bracco Diagnostics

Technetium Tc-99m Teboroxime Kit

Braintree

Bisacodyl 5mg; Polyethylene Glycol 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
Cisplatin 0.5mg/ml
Didanosine 100mg
Didanosine 150mg
Didanosine 200mg
Didanosine 25mg
Didanosine 50mg
Efavirenz 300mg
Etoposide Phosphate eq 1gm base/vial
Etoposide Phosphate eq 500mg base/vial
Gatifloxacin 200mg
Gatifloxacin 200mg/100ml (2mg/ml)
Gatifloxacin 200mg/5ml
Gatifloxacin 400mg
Gatifloxacin 400mg/200ml (2mg/ml)
Gatifloxacin 400mg/40ml (10mg/ml)
Gatifloxacin 400mg/40ml
Nefazodone Hydrochloride 100mg
Nefazodone Hydrochloride 150mg
Nefazodone Hydrochloride 200mg
Nefazodone Hydrochloride 250mg
Nefazodone Hydrochloride 300mg
Nefazodone Hydrochloride 50mg
Stavudine 100mg
Stavudine 37.5mg
Stavudine 50mg
Stavudine 75mg

Carrick Laboratories

Metaxalone 800mg

Cephalon

Armodafinil 100mg
Tiagabine Hydrochloride 20mg

ChiRhoClin

Secretin Synthetic Porcine 16ugm/vial

CIS Bio

Technetium Tc-99m Apcitide N/A

Critical Therapeutics

Zileuton 300mg

Cubist Pharmaceuticals

Daptomycin 250mg/vial

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/m² or 175mg/m² 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 Convert 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 Ziban 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/m² Followed by Cisplatin at a Dose of 75mg/m² 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> |
|---|---|

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	03/01/09 Metformin Hydrochloride 1gm;	
	12/10/10 Zileuton 300mg	Critical Therapeutics	Rosiglitazone Maleate eq 2mg base	SB Pharmco
	12/10/10 Zileuton 600mg	Critical Therapeutics	03/01/09 Metformin Hydrochloride 500mg;	
4886812	10/08/10 Pramipexole Dihydrochloride .05mg	Boehringer Ingelheim	Rosiglitazone Maleate eq 4mg base	SB Pharmco
	10/08/10 Pramipexole Dihydrochloride .125mg	Boehringer Ingelheim	03/01/09 Metformin Hydrochloride 500mg;	
	10/08/10 Pramipexole Dihydrochloride .25mg	Boehringer Ingelheim	Rosiglitazone Maleate eq 2mg base	SB Pharmco
	10/08/10 Pramipexole Dihydrochloride 0.75mg	Boehringer Ingelheim	03/01/09 Metformin Hydrochloride 500mg;	
	10/08/10 Pramipexole Dihydrochloride 1.25mg	Boehringer Ingelheim	Rosiglitazone Maleate eq 1mg base	SB Pharmco
	10/08/10 Pramipexole Dihydrochloride 1.5mg	Boehringer Ingelheim	03/01/09 Rosiglitazone Maleate eq 2mg base	SB Pharmco
	10/08/10 Pramipexole Dihydrochloride 1mg	Boehringer Ingelheim	03/01/09 Rosiglitazone Maleate eq 4mg base	SB Pharmco
	03/25/11 Pramipexole Dihydrochloride .05mg	Boehringer Ingelheim	03/01/09 Rosiglitazone Maleate eq 8mg base	SB Pharmco
	03/25/11 Pramipexole Dihydrochloride .125mg	Boehringer Ingelheim	03/17/12 Glimepiride 1mg; Rosiglitazone Maleate 4mg	SB Pharmco
	03/25/11 Pramipexole Dihydrochloride .25mg	Boehringer Ingelheim	03/17/12 Glimepiride 2mg; Rosiglitazone Maleate 4mg	SB Pharmco
	03/25/11 Pramipexole Dihydrochloride 1.25mg	Boehringer Ingelheim	03/17/12 Glimepiride 2mg; Rosiglitazone Maleate 8mg	SB Pharmco
	03/25/11 Pramipexole Dihydrochloride 1.5mg	Boehringer Ingelheim	03/17/12 Glimepiride 4mg; Rosiglitazone Maleate 4mg	SB Pharmco
	03/25/11 Pramipexole Dihydrochloride 1mg	Boehringer Ingelheim	03/17/12 Glimepiride 4mg; Rosiglitazone Maleate 8mg	SB Pharmco
4927855*PED	02/13/09 Armodafinil 150mg	Cephalon	03/17/12 Metformin Hydrochloride 1gm;	
	02/13/09 Armodafinil 250mg	Cephalon	Rosiglitazone Maleate eq 2mg base	SB Pharmco
	02/13/09 Armodafinil 50mg	Cephalon	03/17/12 Metformin Hydrochloride 1gm;	
	11/22/09 Armodafinil 150mg	Cephalon	Rosiglitazone Maleate eq 4mg base	SB Pharmco
	11/22/09 Armodafinil 250mg	Cephalon	03/17/12 Metformin Hydrochloride 500mg;	
	11/22/09 Armodafinil 50mg	Cephalon	Rosiglitazone Maleate eq 2mg base	SB Pharmco
4981874*PED	02/15/10 Atovaquone 250mg	GlaxoSmithKline	03/17/12 Metformin Hydrochloride 500mg;	
	02/15/10 Atovaquone 750mg/5ml	GlaxoSmithKline	Rosiglitazone Maleate eq 4mg base	SB Pharmco
4990517	06/30/09 Moxifloxacin Hydrochloride 0.5%	Alcon Laboratories	03/17/12 Metformin Hydrochloride 500mg;	
	06/30/09 Moxifloxacin Hydrochloride 160mg/100ml	Bayer	Rosiglitazone Maleate eq 1mg base	SB Pharmco
	06/30/09 Moxifloxacin Hydrochloride eq 400mg base	Bayer	03/17/12 Rosiglitazone Maleate eq 2mg base	SB Pharmco
	12/08/11 Moxifloxacin Hydrochloride 0.5%	Alcon Laboratories	03/17/12 Rosiglitazone Maleate eq 4mg base	SB Pharmco
	12/08/11 Moxifloxacin Hydrochloride 160mg/100ml	Bayer	03/17/12 Rosiglitazone Maleate eq 8mg base	SB Pharmco
	12/08/11 Moxifloxacin Hydrochloride eq 400mg base	Bayer		
4990517*PED	12/30/09 Moxifloxacin Hydrochloride 0.5%	Alcon Laboratories		
	06/08/12 Moxifloxacin Hydrochloride 0.5%	Alcon Laboratories		
5002953*PED	03/01/09 Metformin Hydrochloride 1gm;			
	Rosiglitazone Maleate eq 4mg base	SB Pharmco		

Order Form

**Yes! Please send me _____ copies of
Drugs Under Patent • 2009 at \$199⁰⁰ for the first copy.**

Additional Copies are \$149⁰⁰ each.

Add \$6.95 shipping within the U.S. & Canada for any quantity;

\$19.95 air shipping per book elsewhere.

Add 6% tax for orders delivered in Maryland.

1 • Ship To

Name: _____

Firm: _____

Address*: _____

Telephone: _____

Email: _____

**Street address is required for UPS delivery.*

2 • Method of Payment

Check Enclosed

FOI Services Account Number _____

VISA MasterCard American Express

Card Number: _____

Expiration Date: _____

3 • Your Signature

Signature: _____

4 • Send Your Order

By Mail: FOI Services, Inc.
704 Quince Orchard Road • Suite 275
Gaithersburg MD 20878-1770 USA

Phone: 301-975-9400

Fax: 301-975-0702

EMail: infofoi@foiservices.com

Or order on the web at www.foiservices.com

The logo for FOI Services, Inc. features the lowercase letters "foi" in a bold, green, serif font. The letters are slightly italicized and have a classic, elegant appearance.