

Sample of Volume 1
Table of Contents, Preface and Claim Types
10 Pages of Trade Names
10 Pages of Generic Names
A Page from the Index of Compounds in Multi-Ingredient Products

Orange Book CompanionTM

The Premium Patent & Exclusivity Addendum
for the FDA Orange Book

2002 Edition

Volume 1

**Tradenames &
Generic Names**

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This is dedicated to my loving wife, Margo, and
my wonderful children, Lauren and Tara,
who have never stopped supporting my
dreams.

The information contained in this edition was derived from
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Preface

Welcome to the inaugural edition of the *Orange Book Companion*. We created this reference since we know that online services, such as our OrangeBookPatents.com, cannot always substitute for having a good reference volume close at hand to page through.

How does the *Orange Book Companion* differ from the “Patent and Exclusivity Addendum” of the hardcopy Orange Book?

We have four sections of information that have drug information arranged in different ways: alphabetical by tradename, generic name, and NDA applicant, and chronologically by the next-to-expire patent for each product.

In each section, the term by which it is arranged is displayed in large, bold type. So it is easy to find the product that you are interested in.

For each patent, the title and a summary of the types of claims is displayed.

Each Use Code and Exclusivity Code is followed by its full description, so there is no need to find the description in a separate list.

For most Orphan Drugs, we include the Orphan Indication. These Orphan Indications are not found anywhere in the Orange Book.

In Volume 1, we have an index of all the active compounds that are part of multi-ingredient products. In this way, you can easily find a multi-ingredient product even if you know the name of only one of its active compounds.

We hope that having all of this information in one place will save you valuable time when you need the patent and exclusivity situation for a drug.

Explanation of Claim Types

The claims of each patent in the Orange Book have been examined, and we have provided our opinion of the category that a claim should fall into. As we went through the patents, we kept adding new categories, finally arriving at the following nineteen:

Compound	Just the chemical, usually delineated by its structure
Composition	One or more active ingredients and a pharmaceutically acceptable carrier
Formulation	Any combination of one or more active ingredients where something in addition to the presence of the active ingredients and the carrier is specified. This can be a specific excipient, or it can be the ratio of two active ingredients, or it can be any other claim limitation that we feel distinguishes the claim from a composition claim.
Method of use	A method of using the active ingredient to treat a disease
Process	Method of making something. E.g., method of making the active ingredient; method of making a dosage form; method of preparing a formulation
Product-by-process	Anything where a product (including an intermediate or excipient) is described by its method of preparation
Device	Anything with “parts,” e.g., walls, chambers, etc., such as an osmotic pump dosage form. It of course also includes more traditional devices, such as spray pumps, syringes, etc.
Kit	Mainly defined in the claim, itself, e.g., “a kit comprising . . .”
Intermediate	A chemical used to make another chemical. DNA is an intermediate when the final product is a protein or polypeptide.
Method of administration	A way of getting the drug into the patient
Excipient	An inactive part of a dosage form
Packaging or device material	Material from which the packaging or device is constructed
Diagnostic or surgical method	Self-explanatory
Method of improving a formulation	E.g., “a method of improving the stability of formulations containing compound X.”
Drug in a container	E.g., “an article of manufacture comprising drug X in a container”
New polymorph, salt or hydrate	A new form of a previously approved compound
Method of improving a treatment	E.g., “a method of reducing the side effects due to the administration of drug X”
Functional tablet design	Tablets that are easy to break into equal-size pieces
Ornamental appearance of a device	A design patent

Tradenames starting with "A"

Patents whose numbers are in italics have been extended under 35 USC 156.

ABELCET (Injectable, Lipid Complex) (AMPHOTERICIN B)

NDA Applicant: ELAN PHARMS NDA No.: 050724 Prod. No.: 001 RX (5MG/ML)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code ODE: Orphan Drug	OCT 18,2003	Treatment of invasive fungal infections.

ABREVA (Cream) (DOCOSANOL)

NDA Applicant: GLAXOSMITHKLINE NDA No.: 020941 Prod. No.: 001 OTC (10%)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	JUL 25,2005	

ACCOLATE (Tablet) (ZAFIRLUKAST)

NDA Applicant: ASTRAZENECA NDA No.: 020547 Prod. No.: 001 RX (20MG)

Patents	Expiration	Patented Use
Pat. No. 4859692 Heterocyclic amide derivatives and pharmaceutical use Claim Types: Compound; Composition; Method of use	SEP 26,2010	
Pat. No. 5294636 Crystalline form of indole derivative and pharmaceutical method thereof Claim Types: New polymorph, salt or hydrate; Composition; Method of use	DEC 11,2011	
Pat. No. 5319097 Pharmaceutical agents Claim Types: New polymorph, salt or hydrate; Composition; Process	DEC 11,2011	
Pat. No. 5482963 Pharmaceutical agents useful as leukotriene antagonists Claim Types: Composition; Method of use	JAN 09,2013	
Pat. No. 5583152 Method for treating vasospastic cardiovascular diseases heterocyclic amide derivatives Claim Types: Method of use	SEP 26,2010	
Pat. No. 5612367 Method of enhancing bioavailability of pharmaceutical agents Claim Types: Method of improving a formulation	MAR 18,2014	U-189: Enhancement of the bioavailability of the drug substance
Pat. No. 6143775 Process for preparing pharmaceutical composition containing a heterocyclic amide Claim Types: New polymorph, salt or hydrate	DEC 11,2011	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: I - New Indication	SEP 17,2002	I-328: Prophylaxis and chronic treatment of asthma in patients 5-6 years of age

ACCOLATE (Tablet) (ZAFIRLUKAST)

NDA Applicant: ASTRAZENECA NDA No.: 020547 Prod. No.: 003 RX (10MG)

Patents	Expiration	Patented Use
Pat. No. 4859692 Heterocyclic amide derivatives and pharmaceutical use Claim Types: Compound; Composition; Method of use	SEP 26,2010	

Continued on next page

Pat. No. 5294636 Crystalline form of indole derivative and pharmaceutical method thereof Claim Types: New polymorph, salt or hydrate; Composition; Method of use	DEC 11,2011	
Pat. No. 5319097 Pharmaceutical agents Claim Types: New polymorph, salt or hydrate; Composition; Process	DEC 11,2011	
Pat. No. 5482963 Pharmaceutical agents useful as leukotriene antagonists Claim Types: Composition; Method of use	JAN 09,2013	
Pat. No. 5583152 Method for treating vasospastic cardiovascular diseases heterocyclic amide derivatives Claim Types: Method of use	SEP 26,2010	
Pat. No. 5612367 Method of enhancing bioavailability of pharmaceutical agents Claim Types: Method of improving a formulation	MAR 18,2014	U-189: Enhancement of the bioavailability of the drug substance
Pat. No. 6143775 Process for preparing pharmaceutical composition containing a heterocyclic amide Claim Types: New polymorph, salt or hydrate	DEC 11,2011	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: I - New Indication	SEP 17,2002	I-328: Prophylaxis and chronic treatment of asthma in patients 5-6 years of age
Exclusivity Code: NS - New strength	SEP 17,2002	

ACCUNEB (Solution) (ALBUTEROL SULFATE)

NDA Applicant: DEY NDA No.: 020949 Prod. No.: 001 RX (EQ 0.042% BASE); 002 RX (EQ 0.021% BASE)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NP - New product	APR 30,2004	

ACCUPRIL (Tablet) (QUINAPRIL HYDROCHLORIDE)

NDA Applicant: PARKE DAVIS NDA No.: 019885 Prod. No.: 001 RX (EQ 5MG BASE); 002 RX (EQ 10MG BASE); 003 RX (EQ 20MG BASE); 004 RX (EQ 40MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4344949 Substituted acyl derivatives of 1,2,3,4-tetrahydroisoquinoline-3-carboxylic acids Claim Types: Compound; Composition; Method of use	APR 03,2003 *PED	U-3: Treatment of hypertension
Pat. No. 4743450 Stabilized compositions Claim Types: Formulation; Process	AUG 24,2007 *PED	
Pat. No. 5684016 Method of treating cardiac insufficiency Claim Types: Method of use	MAY 04,2015 *PED	U-210: Method of treating congestive heart failure
Pat. No. 5747504 Method of treating cardiac insufficiency using angiotensin-converting enzyme inhibitors Claim Types: Method of use	OCT 10,2005 *PED	U-210: Method of treating congestive heart failure

ACCURETIC (Tablet) (HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE)

NDA Applicant: PARKE DAVIS NDA No.: 020125 Prod. No.: 001 RX (12.5MG;EQ 10MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4344949 Substituted acyl derivatives of 1,2,3,4-tetrahydroisoquinoline-3-carboxylic acids Claim Types: Compound; Composition; Method of use	APR 03,2003 *PED	U-3: Treatment of hypertension
Pat. No. 4743450 Stabilized compositions Claim Types: Formulation; Process	AUG 24,2007 *PED	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NC - New combination	Jun 28,2003 PED	

ACCURETIC (Tablet) (HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE)

NDA Applicant: PARKE DAVIS NDA No.: 020125 Prod. No.: 002 RX (12.5MG;EQ 20MG BASE); 003 RX (25MG;EQ 20MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4344949 Substituted acyl derivatives of 1,2,3,4-tetrahydroisoquinoline-3-carboxylic acids Claim Types: Compound; Composition; Method of use	APR 03,2003 *PED	U-3: Treatment of hypertension
Pat. No. 4743450 Stabilized compositions Claim Types: Formulation; Process	AUG 24,2007 *PED	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NC - New combination	DEC 28,2002	

ACCUTANE (Capsule) (ISOTRETINOIN)

NDA Applicant: HLR NDA No.: 018662 Prod. No.: 002 RX (10MG); 003 RX (40MG); 004 RX (20MG)

Patents	Expiration	Patented Use
Pat. No. 4464394 Compositions and methods for using 13-cis vitamin A acid compounds Claim Types: Composition Method of use	FEB 07,2002 *PED	

ACEON (Tablet) (PERINDOPRIL ERBUMINE)

NDA Applicant: SOLVAY PHARMA NDA No.: 020184 Prod. No.: 001 RX (2MG); 002 RX (4MG); 003 RX (8MG)

Patents	Expiration	Patented Use
Pat. No. 4508729 Substituted iminodiacids, their preparation and pharmaceutical compositions containing them Claim Types: Compound; Composition; Method of use	AUG 21,2006	

ACIPHEX (Tablet, Delayed Release) (RABEPRAZOLE SODIUM)

NDA Applicant: EISAI MEDCL RES NDA No.: 020973 Prod. No.: 002 RX (20MG)

Patents	Expiration	Patented Use
Pat. No. 5035899 Peroral preparation of acid-unstable compound Claim Types: Formulation	APR 04,2009	U-385: Treatment of peptic ulcers
Pat. No. 5045552 Pyridine derivatives having anti-ulcerative activity Claim Types: Compound; Composition; Method of use	SEP 03,2008	U-385: Treatment of peptic ulcers
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: I - New Indication	FEB 12,2005	I-346: Treatment of symptomatic gastro esophageal reflux disease (GERD)
Exclusivity Code: NCE - New chemical entity	AUG 19,2004	

ACTINEX (Cream) (MASOPROCOL)

NDA Applicant: UNIV AZ CANCER CTR NDA No.: 019940 Prod. No.: 001 RX (10%)

Patents	Expiration	Patented Use
Pat. No. 4695590 Method for retarding aging Claim Types: Method of use; Composition	APR 17,2008	
Pat. No. 5008294 Methods of treating tumors with compositions of catecholic butanes Claim Types: Method of use	APR 15,2008	U-68: Treatment of actinic keratosis

ACTIQ (Troche/Lozenge) (FENTANYL CITRATE)

NDA Applicant: ANESTA NDA No.: 020747 Prod. No.: 001 RX (EQ 0.2MG BASE); 002 RX (EQ 0.4MG BASE); 003 RX (EQ 0.6MG BASE); 004 RX (EQ 0.8MG BASE); 005 RX (EQ 1.2MG BASE); 006 RX (EQ 1.6MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4671953 Methods and compositions for noninvasive administration of sedatives, analgesics, and anesthetics Claim Types: <input type="checkbox"/> Method of administration; Formulation	MAY 01,2005	U-253: Oral transmucosal use

ACTIVELE (Tablet) (ESTRADIOL; NORETHINDRONE ACETATE)

NDA Applicant: NOVO NORDISK NDA No.: 020907 Prod. No.: 001 RX (1MG;0.5MG)

Patents	Expiration	Patented Use
Pat. No. RE36247 Method of hormonal treatment for menopausal or post-menopausal disorders involving continuous administration of progestogens and estrogens Claim Types: Method of use; Formulation	MAY 02,2006	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: I - New Indication	APR 11,2003	I-295: Prevention of postmenopausal osteoporosis for women with an intact uterus

ACTONEL (Tablet) (RISEDRONATE SODIUM)

NDA Applicant: PROCTER AND GAMBLE NDA No.: 020835 Prod. No.: 001 RX (30MG); 002 RX (5MG)

Patents	Expiration	Patented Use
Pat. No. 5583122 Pharmaceutical compositions containing geminal diphosphonates Claim Types: Compound; Composition; Method of use	DEC 10,2013	U-222: Method of treating Paget's disease using ACTONEL
Pat. No. 6096342 Dosage forms of risedronate Claim Types: Formulation	MAR 12,2017	
Pat. No. 6165513 Film-coated tablet for improved upper gastrointestinal tract safety Claim Types: Formulation	JUN 10,2018	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: D - New Dosing Schedule	MAY 17,2005	D-73: Once a week dosing for the treatment of postmenopausal osteoporosis
Exclusivity Code: D - New Dosing Schedule	MAY 17,2005	D-74: Once a week dosing for the prevention of postmenopausal osteoporosis
Exclusivity Code: I - New Indication	APR 14,2003	I-290: Treatment of corticosteroid-induced osteoporosis
Exclusivity Code: I - New Indication	APR 14,2003	I-291: Prevention of postmenopausal osteoporosis
Exclusivity Code: I - New Indication	APR 14,2003	I-292: Treatment of postmenopausal osteoporosis
Exclusivity Code: I - New Indication	APR 14,2003	I-293: Treatment of corticosteroid-induced osteoporosis
Exclusivity Code: NCE - New chemical entity	MAR 27,2003	

ACTOS (Tablet) (PIOGLITAZONE HYDROCHLORIDE)

NDA Applicant: TAKEDA PHARMS NA NDA No.: 021073 Prod. No.: 001 RX (EQ 15MG BASE); 002 RX (EQ 30MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4687777 Thiazolidinedione derivatives, useful as antidiabetic agents Claim Types: Compound; Composition	JAN 17,2006	
Pat. No. 5965584 Pharmaceutical composition Claim Types: Composition; Method of use	JUN 19,2016	U-417: Combination use of AD-4833 with a biguanide
Pat. No. 6150383 Pharmaceutical composition Claim Types: Method of use	JUN 19,2016	U-418: A method of treating lipid metabolism disorders by administering a chemical compound having a particular formula (which includes pioglitazone) in combination with an insulin secretion enhancer

Pat. No. 6150384 Pharmaceutical composition Claim Types: Method of use	JUN 19,2016	U-419: A method of treating lipid metabolism disorders by administering an insulin sensitivity enhancer (including pioglitazone) in combination with a biguanide
Pat. No. 6166042 Pharmaceutical composition Claim Types: Method of use	JUN 19,2016	U-414: A method of treating glycometabolism disorders by administering an insulin sensitivity enhancer (including pioglitazone) in combination with a biguanide
Pat. No. 6166043 Pharmaceutical composition Claim Types: Method of use	JUN 19,2016	U-415: A method for reducing the amount of active components administered to a diabetic patient by administering an insulin sensitivity enhancer (including pioglitazone) in combination with a biguanide as said active components
Pat. No. 6172090 Pharmaceutical composition Claim Types: Method of use	JUN 19,2016	U-416: A method for reducing side effects of active components administered to a diabetic patient by administering an insulin sensitivity enhancer (including pioglitazone) in combination with a biguanide as said active components
Pat. No. 6211205 Pharmaceutical composition Claim Types: Method of improving a treatment	JUN 19,2016	U-410: Method of reducing amount of respective active components administered to a diabetic patient by administering a chemical compound having a particular formula (including pioglitazone) in combination with an insulin secretion enhancer
Pat. No. 6271243 Pharmaceutical composition Claim Types: Method of improving a treatment	JUN 19,2016	U-411: Method of reducing the side effects of active components administered to a diabetic patient by administering a chemical compound having a particular formula (which includes pioglitazone) in combination with an insulin preparation
Pat. No. 6303640 Pharmaceutical composition Claim Types: Method of improving a treatment	AUG 09,2016	U-425: Method of reducing side effects of active components admin to a diabetic by admin a chemical compound having formula (inclpioglitazone) in combination with an insulin secretion enhancer
Pat. No. 6329404 Pharmaceutical composition Claim Types: Composition; Method of use	JUN 19,2016	U-430: Method of treating a diabetic by administering an insulin sensitizer in combination with an insulin secretion enhancer, and a drug product comprising an insulin sensitizer and an insulin secretion enhancer
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	JUL 15,2004	

ACTOS (Tablet) (PIOGLITAZONE HYDROCHLORIDE)

NDA Applicant: TAKEDA PHARMS NA NDA No.: 021073 Prod. No.: 003 RX (EQ 45MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4687777 Thiazolidinedione derivatives, useful as antidiabetic agents Claim Types: Compound; Composition	JAN 17,2006	
Pat. No. 5965584 Pharmaceutical composition Claim Types: Composition; Method of use	JUN 19,2016	U-417: Combination use of AD-4833 with a biguanide
Pat. No. 6150383 Pharmaceutical composition Claim Types: Method of use	JUN 19,2016	U-418: A method of treating lipid metabolism disorders by administering a chemical compound having a particular formula (which includes pioglitazone) in combination with an insulin secretion enhancer
Pat. No. 6150384 Pharmaceutical composition Claim Types: Method of use	JUN 19,2016	
Pat. No. 6166042 Pharmaceutical composition Claim Types: Method of use	JUN 19,2016	U-414: A method of treating glycometabolism disorders by administering an insulin sensitivity enhancer (including pioglitazone) in combination with a biguanide
Pat. No. 6166043 Pharmaceutical composition Claim Types: Method of use	JUN 19,2016	U-415: A method for reducing the amount of active components administered to a diabetic patient by administering an insulin sensitivity enhancer (including pioglitazone) in combination with a biguanide as said active components

Continued on next page

Pat. No. 6172090 Pharmaceutical composition Claim Types: Method of use	JUN 19,2016	U-416: A method for reducing side effects of active components administered to a diabetic patient by administering an insulin sensitivity enhancer (including pioglitazone) in combination with a biguanide as said active components
Pat. No. 6211205 Pharmaceutical composition Claim Types: Method of improving a treatment	JUN 19,2016	U-410: Method of reducing amount of respective active components administered to a diabetic patient by administering a chemical compound having a particular formula (including pioglitazone) in combination with an insulin secretion enhancer
Pat. No. 6271243 Pharmaceutical composition Claim Types: Method of improving a treatment	JUN 19,2016	U-411: Method of reducing the side effects of active components administered to a diabetic patient by administering a chemical compound having a particular formula (which includes pioglitazone) in combination with an insulin preparation
Pat. No. 6303640 Pharmaceutical composition Claim Types: Method of improving a treatment	AUG 09,2016	U-425: Method of reducing side effects of active components admin to a diabetic by admin a chemical compound having formula (inclpioglitazone) in combination with an insulin secretion enhancer
Pat. No. 6329404 Pharmaceutical composition Claim Types: Composition; Method of use	JUN 19,2016	U-430: Method of treating a diabetic by administering an insulin sensitizer in combination with an insulin secretion enhancer, and a drug product comprising an insulin sensitizer and an insulin secretion enhancer
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	JUL 15,2004	

ACULAR (Solution/Drops) (KETOROLAC TROMETHAMINE)

NDA Applicant: ALLERGAN NDA No.: 019700 Prod. No.: 001 RX (0.5%)

Patents	Expiration	Patented Use
Pat. No. 4454151 Use of pyrrolo pyrroles in treatment of ophthalmic diseases Claim Types: Composition; Method of use	MAR 22,2002	U-75: Relief of ocular itching due to seasonal allergic conjunctivitis
Pat. No. 4454151 Use of pyrrolo pyrroles in treatment of ophthalmic diseases Claim Types: Composition; Method of use	SEP 22,2002 *PED	U-75: Relief of ocular itching due to seasonal allergic conjunctivitis
Pat. No. 5110493 Ophthalmic NSAID formulations containing a quaternary ammonium preservative and a nonionic surfactant Claim Types: Formulation; Excipient	NOV 05,2009 *PED	U-75: Relief of ocular itching due to seasonal allergic conjunctivitis
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: M - Miscellaneous	FEB 08,2005	M-16: Change in wording of the pediatric section of the package insert

ACULAR PRESERVATIVE FREE (Solution/Drops) (KETOROLAC TROMETHAMINE)

NDA Applicant: ALLERGAN NDA No.: 020811 Prod. No.: 001 RX (0.5%)

Patents	Expiration	Patented Use
Pat. No. 4454151 Use of pyrrolo pyrroles in treatment of ophthalmic diseases Claim Types: Composition; Method of use	SEP 22,2002 *PED	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: M - Miscellaneous	FEB 08,2005	M-16: Change in wording of the pediatric section of the package insert

ACUTECT (Injectable) (TECHNETIUM TC-99M APCITIDE)

NDA Applicant: DIATIDE RES LABS NDA No.: 020887 Prod. No.: 001 RX (N/A)

Patents	Expiration	Patented Use
Pat. No. 5443815 Technetium-99m labeled peptides for imaging Claim Types: Composition; Kit; Process	AUG 22,2012	

Pat. No. 5508020 Technetium-99M labeled peptides for imaging Claim Types: Composition	APR 16,2013	
Pat. No. 5645815 Radiolabeled compounds for thrombus imaging Claim Types: Intermediate; Kit; Diagnostic or surgical method	JUL 08,2014	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	SEP 14,2003	

ADALAT CC (Tablet, Extended Release) (NIFEDIPINE)

NDA Applicant: BAYER NDA No.: 020198 Prod. No.: 001 RX (30MG); 002 RX (60MG); 003 RX (90MG)

Patents	Expiration	Patented Use
Pat. No. 4892741 Press coated DHP tablets Claim Types: Formulation; Process	JUN 08,2008	
Pat. No. 5264446 Solid medicament formulations containing nifedipine, and processes for their preparation Claim Types: Formulation; Method of use	NOV 23,2010	

ADDERALL XR 10 (Capsule, Extended Release) (AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE)

NDA Applicant: SHIRE LABS NDA No.: 021303 Prod. No.: 001 RX (2.5MG;2.5MG;2.5MG;2.5MG)

Patents	Expiration	Patented Use
Pat. No. 6322819 Oral pulsed dose drug delivery system Claim Types: Formulation	NOV 27,2018	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NDF - New dosage form	OCT 11,2004	

ADDERALL XR 20 (Capsule, Extended Release) (AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE)

NDA Applicant: SHIRE LABS NDA No.: 021303 Prod. No.: 002 RX (5MG;5MG;5MG;5MG)

Patents	Expiration	Patented Use
Pat. No. 6322819 Oral pulsed dose drug delivery system Claim Types: Formulation	NOV 27,2018	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NDF - New dosage form	OCT 11,2004	

ADDERALL XR 30 (Capsule, Extended Release) (AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE)

NDA Applicant: SHIRE LABS NDA No.: 021303 Prod. No.: 003 RX (7.5MG;7.5MG;7.5MG;7.5MG)

Patents	Expiration	Patented Use
Pat. No. 6322819 Oral pulsed dose drug delivery system Claim Types: Formulation	NOV 27,2018	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NDF - New dosage form	OCT 11,2004	

ADENOCARD (Injectable) (ADENOSINE)

NDA Applicant: FUJISAWA HLTHCARE NDA No.: 019937 Prod. No.: 002 RX (3MG/ML)

Patents	Expiration	Patented Use
Pat. No. 4673563 Adenosine in the treatment of supraventricular tachycardia Claim Types: Method of use	JUN 16,2004	U-38: Treatment of paroxysmal supraventricular tachycardia

ADENOSCAN (Injectable) (ADENOSINE)

NDA Applicant: FUJISAWA HLTHCARE NDA No.: 020059 Prod. No.: 001 RX (3MG/ML)

Patents	Expiration	Patented Use
Pat. No. 5070877 Novel method of myocardial imaging Claim Types: Diagnostic or surgical method	MAY 18,2009	U-116: Method of myocardial imaging
Pat. No. 5731296 Selective vasodilation by continuous adenosine infusion Claim Types: Method of use	MAR 24,2015	U-221: Selective vasodilation by continuous adenosine infusion

ADVAIR DISKUS 100/50 (Powder) (FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE)

NDA Applicant: GLAXOSMITHKLINE NDA No.: 021077 Prod. No.: 001 RX (0.1MG/INH;EQ 0.05MG BASE/INH)

Patents	Expiration	Patented Use
Pat. No. 4335121 Androstane carbothioates Claim Types: Compound; Composition; Method of use	NOV 14,2003	
Pat. No. 4992474 Phenethanolamine derivatives Claim Types: Compound; Composition; Method of use	FEB 12,2008	U-211: Use in patients with reversible airway obstruction
Pat. No. 5126375 Phenethanolamine derivatives Claim Types: Compound; Composition	FEB 12,2008	
Pat. No. 5225445 Phenethanolamine derivatives having .beta..sub.2 -adrenoreceptor selective stimulant action Claim Types: Method of use	FEB 12,2008	U-211: Use in patients with reversible airway obstruction
Pat. No. 5270305 Medicaments Claim Types: Composition; Method of use	SEP 07,2010	U-387: Treatment of patients with respiratory disorders
Pat. No. 5290815 Treatment of inflammation and allergy Claim Types: Method of use	MAR 01,2011	U-386: Treatment of patients suffering from a late asthmatic reaction or late phase asthma
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NC - New combination	AUG 24,2003	

ADVAIR DISKUS 250/50 (Powder) (FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE)

NDA Applicant: GLAXOSMITHKLINE NDA No.: 021077 Prod. No.: 002 RX (0.25MG/INH;EQ 0.05MG BASE/INH)

Patents	Expiration	Patented Use
Pat. No. 4335121 Androstane carbothioates Claim Types: Compound; Composition; Method of use	NOV 14,2003	
Pat. No. 4992474 Phenethanolamine derivatives Claim Types: Compound; Composition; Method of use	FEB 12,2008	U-211: Use in patients with reversible airway obstruction
Pat. No. 5126375 Phenethanolamine derivatives Claim Types: Compound; Composition	FEB 12,2008	
Pat. No. 5225445 Phenethanolamine derivatives having .beta..sub.2 -adrenoreceptor selective stimulant action Claim Types: Method of use	FEB 12,2008	U-211: Use in patients with reversible airway obstruction
Pat. No. 5270305 Medicaments Claim Types: Composition; Method of use	SEP 07,2010	U-387: Treatment of patients with respiratory disorders
Pat. No. 5290815 Treatment of inflammation and allergy Claim Types: Method of use	MAR 01,2011	U-386: Treatment of patients suffering from a late asthmatic reaction or late phase asthma
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NC - New combination	AUG 24,2003	

ADVAIR DISKUS 500/50 (Powder) (FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE)

NDA Applicant: GLAXOSMITHKLINE NDA No.: 021077 Prod. No.: 003 RX (0.5MG/INH;EQ 0.05MG BASE/INH)

Patents	Expiration	Patented Use
Pat. No. 4335121 Androstane carbothioates Claim Types: Compound; Composition; Method of use	NOV 14,2003	

Pat. No. 4992474 Phenethanolamine derivatives Claim Types: Compound; Composition; Method of use	FEB 12,2008	U-211: Use in patients with reversible airway obstruction
Pat. No. 5126375 Phenethanolamine derivatives Claim Types: Compound; Composition	FEB 12,2008	
Pat. No. 5225445 Phenethanolamine derivatives having .beta..sub.2 -adrenoreceptor selective stimulant action Claim Types: Method of use	FEB 12,2008	U-211: Use in patients with reversible airway obstruction
Pat. No. 5270305 Medicaments Claim Types: Composition; Method of use	SEP 07,2010	U-387: Treatment of patients with respiratory disorders
Pat. No. 5290815 Treatment of inflammation and allergy Claim Types: Method of use	MAR 01,2011	U-386: Treatment of patients suffering from a late asthmatic reaction or late phase asthma
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NC - New combination	AUG 24,2003	

ADVICOR (Tablet, Extended Release) (LOVASTATIN; NIACIN)

NDA Applicant: KOS **NDA No.:** 021249 **Prod. No.:** 001 RX (20MG;500MG); 002 RX (20MG;750MG); 003 RX (20MG;1GM)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NC - New combination	DEC 17,2004	

ADVIL COLD AND SINUS (Tablet) (IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE)

NDA Applicant: WYETH CONS **NDA No.:** 019771 **Prod. No.:** 001 OTC (200MG;30MG)

Patents	Expiration	Patented Use
Pat. No. 4552899 Cough/cold mixtures comprising non-steroidal anti-inflammatory drugs Claim Types: Composition; Method of use	OCT 09,2004 *PED	

ADVIL MIGRAINE LIQUI-GELS (Capsule) (IBUPROFEN POTASSIUM)

NDA Applicant: WYETH CONS **NDA No.:** 020402 **Prod. No.:** 002 OTC (200MG)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NP - New product	MAR 16,2003	

AEROBID (Aerosol, Metered) (FLUNISOLIDE)

NDA Applicant: SYNTEX (USA) INC LLC **NDA No.:** 018340 **Prod. No.:** 001 RX (0.25MG/INH)

Patents	Expiration	Patented Use
Pat. No. 4933168 Stable, crystalline flunisolide Claim Types: Compound; Formulation; Method of use	JUN 12,2007	

AGENERASE (Capsule) (AMPRENAVIR)

NDA Applicant: GLAXOSMITHKLINE **NDA No.:** 021007 **Prod. No.:** 001 DISC (50MG)

Patents	Expiration	Patented Use
Pat. No. 5585397 Sulfonamide inhibitors of aspartyl protease Claim Types: Compound; Composition	DEC 17,2013	
Pat. No. 5646180 Treatment of the CNS effects of HIV Claim Types: Method of use	JUL 08,2014	U-257: Treatment of HIV infection
Pat. No. 5723490 THF-containing sulfonamide inhibitors of aspartyl protease Claim Types: Composition; Method of use	MAR 03,2013	U-257: Treatment of HIV infection
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	APR 15,2004	

AGENERASE (Capsule) (AMPRENAVIR)

NDA Applicant: GLAXOSMITHKLINE NDA No.: 021007 Prod. No.: 002 DISC (150MG)

Patents	Expiration	Patented Use
Pat. No. 5585397 Sulfonamide inhibitors of aspartyl protease Claim Types: Compound; Composition	DEC 17,2013	
Pat. No. 5646180 Treatment of the CNS effects of HIV Claim Types: Method of use	JUL 08,2014	U-257: Treatment of HIV infection
Pat. No. 5723490 THF-containing sulfonamide inhibitors of aspartyl protease Claim Types: Composition; Method of use	MAR 03,2015	U-257: Treatment of HIV infection
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	APR 15,2004	

AGENERASE (Solution) (AMPRENAVIR)

NDA Applicant: GLAXOSMITHKLINE NDA No.: 021039 Prod. No.: 001 DISC (15MG/ML)

Patents	Expiration	Patented Use
Pat. No. 5585397 Sulfonamide inhibitors of aspartyl protease Claim Types: Compound; Composition	DEC 17,2013	
Pat. No. 5646180 Treatment of the CNS effects of HIV Claim Types: Method of use	JUL 08,2014	U-257: Treatment of HIV infection
Pat. No. 5723490 THF-containing sulfonamide inhibitors of aspartyl protease Claim Types: Composition; Method of use	MAR 03,2015	U-257: Treatment of HIV infection
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	APR 15,2004	

AGGRASTAT (Injectable) (TIROFIBAN HYDROCHLORIDE)

NDA Applicant: MERCK NDA No.: 020912 Prod. No.: 001 RX (EQ 0.25MG BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 5292756 Novel sulfonamide fibrinogen receptor antagonists Claim Types: Compound; Method of use	MAY 14,2012	U-230: Prevention of acute cardiac ischemic events
Pat. No. 5658929 Sulfonamide fibrinogen receptor antagonists Claim Types: Compound	MAR 08,2011	
Pat. No. 5733919 Compositions for inhibiting platelet aggregation Claim Types: Formulation	OCT 23,2016	
Pat. No. 5880136 Sulfonamide fibrinogen receptor antagonists Claim Types: Method of use	SEP 27,2010	U-254: Use of AGGRASTAT in combination with HEPARIN
Pat. No. 5965581 Compositions for inhibiting platelet aggregation Claim Types: Formulation; Product-by-process; Method of use	OCT 23,2016	
Pat. No. 5972967 Compositions for inhibiting platelet aggregation Claim Types: Formulation; Method of use; Product-by-process	OCT 23,2016	
Pat. No. 5978698 Angioplasty procedure using nonionic contrast media Claim Types: Method of use	OCT 08,2017	
Pat. No. 6136794 Platelet aggregation inhibition using low molecular weight heparin in combination with a GP IIb/IIIa antagonist Claim Types: Method of use	JAN 29,2019	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	MAY 14,2003	

Generic names starting with "A"

Patents whose numbers are in italics have been extended under 35 USC 156.

ABACAVIR SULFATE (ZIAGEN (Solution))

NDA Applicant: GLAXOSMITHKLINE NDA No.: 020978 Prod. No.: 001 RX (EQ 20MG BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 5034394 Therapeutic nucleosides Claim Types: Compound; Composition	DEC 26,2009 *PED	
Pat. No. 5089500 Therapeutic nucleosides Claim Types: Method of use	JUN 26,2009	U-248: Treatment of HIV
Pat. No. 5089500 Therapeutic nucleosides Claim Types: Method of use	DEC 26,2009 *PED	
Pat. No. 6294540 Carbocyclic nucleoside hemisulfate and its use in treating viral infections Claim Types: Composition; Method of use	NOV 14,2018 *PED	U-65: Method of treatment of a patient infected with HIV
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	Jun 17,2004 PED	

ABACAVIR SULFATE (ZIAGEN (Tablet))

NDA Applicant: GLAXOSMITHKLINE NDA No.: 020977 Prod. No.: 001 RX (EQ 300MG BASE)

Patents	Expiration	Patented Use
Pat. No. 5034394 Therapeutic nucleosides Claim Types: Compound; Composition	JUN 26,2009	
Pat. No. 5034394 Therapeutic nucleosides Claim Types: Compound; Composition	DEC 26,2009 *PED	
Pat. No. 5089500 Therapeutic nucleosides Claim Types: Method of use	JUN 26,2009	U-248: Treatment of HIV
Pat. No. 5089500 Therapeutic nucleosides Claim Types: Method of use	DEC 26,2009 *PED	
Pat. No. 6294540 Carbocyclic nucleoside hemisulfate and its use in treating viral infections Claim Types: Composition; Method of use	NOV 14,2018 *PED	U-65: Method of treatment of a patient infected with HIV
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	Jun 17,2004 PED	

ABACAVIR SULFATE; LAMIVUDINE; ZIDOVUDINE (TRIZIVIR (Tablet))

NDA Applicant: GLAXOSMITHKLINE NDA No.: 021205 Prod. No.: 001 RX (EQ 300MG BASE;150MG;300MG)

Patents	Expiration	Patented Use
Pat. No. 4724232 Treatment of human viral infections Claim Types: Method of use	SEP 17,2005	
Pat. No. 4818538 Treatment of human viral infections Claim Types: Composition	SEP 17,2005	
Pat. No. 4828838 Treatment of human viral infection Claim Types: Composition	SEP 17,2005	
Pat. No. 4833130 Treatment of human viral infections Claim Types: Method of use	SEP 17,2005	
Pat. No. 4837208 Treatment of human viral infections Claim Types: Method of use	SEP 17,2005	

Continued on next page

Pat. No. 5034394 Therapeutic nucleosides Claim Types: Compound; Composition	DEC 26,2009 *PED	
Pat. No. 5047407 2-substituted-5-substituted-1,3-oxathiolanes with antiviral properties Claim Types: Compound; Composition	MAY 17,2010 *PED	
Pat. No. 5089500 Therapeutic nucleosides Claim Types: Method of use	DEC 26,2009 *PED	U-248: Treatment of HIV
Pat. No. 5905082 Crystalline oxathiolane derivatives Claim Types: Composition; Method of use	NOV 18,2016 *PED	
Pat. No. 6180639 1,3-oxathiolane nucleoside analogues Claim Types: Method of use; Formulation	JUL 30,2018 *PED	U-248: Treatment of HIV
Pat. No. 6294540 Carbocyclic nucleoside hemisulfate and its use in treating viral infections Claim Types: Composition; Method of use	NOV 14,2018 *PED	U-65: Method of treatment of a patient infected with HIV
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	Jun 17,2004 PED	

ACARBOSE (PRECOSE (Tablet))

NDA Applicant: BAYER NDA No.: 020482 Prod. No.: 001 RX (50MG); 002 RX (100MG); 004 RX (25MG)

Patents	Expiration	Patented Use
Pat. No. 4904769 Highly pure acarbose Claim Types: Formulation; Process	FEB 27,2007	

ACETAMINOPHEN (TYLENOL (Tablet, Extended Release))

NDA Applicant: MCNEIL CONS SPECLT NDA No.: 019872 Prod. No.: 001 OTC (650MG)

Patents	Expiration	Patented Use
Pat. No. 4820522 Oral sustained release acetaminophen formulation and process Claim Types: Formulation; Process	JUL 27,2007	
Pat. No. 4968509 Oral sustained release acetaminophen formulation and process Claim Types: Formulation; Process	NOV 06,2007	
Pat. No. 5004613 Oral sustained release pharmaceutical formulation and process Claim Types: Formulation; Process	JUL 27,2007	

ACETAMINOPHEN; ASPIRIN; CAFFEINE (EXCEDRIN (MIGRAINE) (Tablet))

NDA Applicant: BRISTOL MYERS NDA No.: 020802 Prod. No.: 001 OTC (250MG;250MG;65MG)

Patents	Expiration	Patented Use
Pat. No. 4943565 Analgesic tablet of aspirin and caffeine containing low-substituted hydroxypropyl cellulose Claim Types: Formulation	JUL 24,2007	
Pat. No. 5972916 Compositions containing the nonprescription combination of acetaminophen, aspirin and caffeine to alleviate the pain and symptoms of migraine Claim Types: Method of use	JUL 14,2017	U-296: Treating migraine pain and one or more of a cluster of symptoms characteristic of a migraine attack symptoms being selected from photophobia, phonophobia, nausea and functional disability

ACETAMINOPHEN; CLEMASTINE FUMARATE; PSEUDOEPHEDRINE HYDROCHLORIDE (TAVIST ALLERGY/SINUS/HEADACHE (Tablet))

NDA Applicant: NOVARTIS NDA No.: 021082 Prod. No.: 001 OTC (500MG;EQ 0.25MG BASE;30MG)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NC - New combination	MAR 01,2004	

ACETAMINOPHEN; TRAMADOL HYDROCHLORIDE (ULTRACET (Tablet))

NDA Applicant: JOHNSON RW NDA No.: 021123 Prod. No.: 001 RX (325MG;37.5MG)

Patents	Expiration	Patented Use
Pat. No. 5336691 Composition comprising a tramadol material and acetaminophen and its use Claim Types: Composition; Method of use	AUG 09,2011	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NC - New combination	AUG 15,2004	

ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE (SEMPREX-D (Capsule))

NDA Applicant: CELLTECH PHARMS NDA No.: 019806 Prod. No.: 001 RX (8MG;60MG)

Patents	Expiration	Patented Use
Pat. No. 4501893 3-[6-[3-Pyrrolidino-1-(4-tolyl)prop-1-enyl]-2-pyridyl]acrylic acid and pharmaceutically acceptable salts thereof Claim Types: Compound	FEB 01,2003	
Pat. No. 4650807 Antihistaminic compositions and methods containing pyridine derivatives Claim Types: Composition; Method of use	MAR 26,2008	U-93: Use as an antihistamine/ decongestant

ADAPALENE (DIFFERIN (Cream))

NDA Applicant: GALDERMA LABS LP NDA No.: 020748 Prod. No.: 001 RX (0.1%)

Patents	Expiration	Patented Use
Pat. No. 4717720 Benzonaphthalene derivatives and compositions Claim Types: Compound; Composition	MAY 31,2010	
Pat. No. RE34440 Benzonaphthalene derivatives, a process for their preparation and their use in therapeutic and cosmetic compositions Claim Types: Method of use; Composition	MAY 31,2010	U-275: Method of use of the drug substance
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NDF - New dosage form	MAY 26,2003	

ADAPALENE (DIFFERIN (Gel))

NDA Applicant: GALDERMA LABS LP NDA No.: 020380 Prod. No.: 001 RX (0.1%)

Patents	Expiration	Patented Use
Pat. No. 4717720 Benzonaphthalene derivatives and compositions Claim Types: Compound; Composition	MAY 31,2010	
Pat. No. RE34440 Benzonaphthalene derivatives, a process for their preparation and their use in therapeutic and cosmetic compositions Claim Types: Method of use; Composition	MAY 31,2010	U-275: Method of use of the drug substance

ADAPALENE (DIFFERIN (Solution))

NDA Applicant: GALDERMA LABS LP NDA No.: 020338 Prod. No.: 001 RX (0.1%)

Patents	Expiration	Patented Use
Pat. No. 4717720 Benzonaphthalene derivatives and compositions Claim Types: Compound; Composition	MAY 31,2010	
Pat. No. RE34440 Benzonaphthalene derivatives, a process for their preparation and their use in therapeutic and cosmetic compositions Claim Types: Method of use; Composition	MAR 31,2010	U-275: Method of use of the drug substance

ADENOSINE (ADENOCARD (Injectable))

NDA Applicant: FUJISAWA HLTHCARE NDA No.: 019937 Prod. No.: 002 RX (3MG/ML)

Patents	Expiration	Patented Use
Pat. No. 4673563 Adenosine in the treatment of supraventricular tachycardia Claim Types: Method of use	JUN 16,2004	U-38: Treatment of paroxysmal supraventricular tachycardia

ADENOSINE (ADENOSCAN (Injectable))

NDA Applicant: FUJISAWA HLTHCARE NDA No.: 020059 Prod. No.: 001 RX (3MG/ML)

Patents	Expiration	Patented Use
Pat. No. 5070877 Novel method of myocardial imaging Claim Types: Diagnostic or surgical method	MAY 18,2009	U-116: Method of myocardial imaging
Pat. No. 5731296 Selective vasodilation by continuous adenosine infusion Claim Types: Method of use	MAR 24,2015	U-221: Selective vasodilation by continuous adenosine infusion

ALATROFLOXACIN MESYLATE (TROVAN PRESERVATIVE FREE (Injectable))

NDA Applicant: PFIZER NDA No.: 020760 Prod. No.: 001 RX (EQ 200MG BASE/VIAL); 002 RX (EQ 300MG BASE/VIAL)

Patents	Expiration	Patented Use
Pat. No. 5164402 Azabicyclo quinolone and naphthyridinone carboxylic acids Claim Types: Compound; Composition; Method of use	NOV 17,2009	U-282: Method of treating bacterial infections
Pat. No. 5763454 Crystal form of anhydrous 7-(1.alpha.,5.alpha.,6.alpha.-6-amino-3-azabicyclo[3.1.0]hex-3-yl)-6-fluoro-1-(2,4-difluorophenyl)-1,4-dihydro-4-oxo-1,8 naphthyridine-3-carboxylic acid, methanessulfonic acid salt Claim Types: New polymorph, salt or hydrate; Composition; Method of use	JUN 15,2015	U-282: Method of treating bacterial infections
Pat. No. 6080756 Polymorphs of the prodrug 6-N-(L-ALA-L-ALA)-trovafloxacin Claim Types: New polymorph, salt or hydrate; Method of use; Composition	JUL 05,2016	
Pat. No. 6194429 Alatrofloxacin parenteral compositions Claim Types: Compound; Formulation; Process; Composition; Method of use	JUL 23,2018	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	DEC 18,2002	

ALBENDAZOLE (ALBENZA (Tablet))

NDA Applicant: GLAXOSMITHKLINE NDA No.: 020666 Prod. No.: 001 RX (200MG)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code ODE: Orphan Drug	JUN 11,2003	Treatment of hydatid disease (cystic echinococcosis due to E. granulosus larvae or alveolar echinococcosis due to E. multilocularis larvae).
Exclusivity Code ODE: Orphan Drug	JUN 11,2003	Treatment of neurocysticercosis due to Taenia solium as: 1) chemotherapy of parenchymal, subarachnoidal and racemose (cysts in spinal fluid) neurocysticercosis in symptomatic cases and 2) prophylaxis of epilepsy and other sequelae in asymptomatic neurocyst

ALBUTEROL SULFATE (ACCUNEB (Solution))

NDA Applicant: DEY NDA No.: 020949 Prod. No.: 001 RX (EQ 0.042% BASE); 002 RX (EQ 0.021% BASE)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NP - New product	APR 30,2004	

ALBUTEROL SULFATE (PROVENTIL (Syrup))

NDA Applicant: SCHERING NDA No.: 018062 Prod. No.: 001 RX (EQ 2MG BASE/5ML)

Patents	Expiration	Patented Use
Pat. No. 4499108 Stable pleasant-tasting albuterol sulfate pharmaceutical formulations Claim Types: Formulation	JUN 08,2003	

ALBUTEROL SULFATE (PROVENTIL-HFA (Aerosol, Metered))

NDA Applicant: 3M NDA No.: 020503 Prod. No.: 001 RX (EQ 0.09MG BASE/INH)

Patents	Expiration	Patented Use
Pat. No. 5225183 Medicinal aerosol formulations Claim Types: Formulation	JUL 06,2010	
Pat. No. 5439670 Medicinal aerosol formulations Claim Types: Formulation	JUL 06,2010	
Pat. No. 5605674 Medicinal aerosol formulations Claim Types: Formulation	FEB 25,2014	
Pat. No. 5766573 Medicinal aerosol formulations Claim Types: Method of administration	JUN 16,2015	
Pat. No. 6352684 CRC-free medicinal aerosol formulations of 1,1,1,2-tetrafluoroethane (134A) with polar adjuvant Claim Types: Formulation	NOV 28,2009	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: I - New Indication	JUN 02,2002	I-262: Treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise induced bronchospasm in children ages 4-12

ALBUTEROL SULFATE (VENTOLIN (Syrup))

NDA Applicant: GLAXOSMITHKLINE NDA No.: 019621 Prod. No.: 001 DISC (EQ 2MG BASE/5ML)

Patents	Expiration	Patented Use
Pat. No. 4594359 Pharmaceutical compositions Claim Types: Formulation	JUN 10,2003	

ALBUTEROL SULFATE (VENTOLIN HFA (Aerosol, Metered))

NDA Applicant: GLAXOSMITHKLINE NDA No.: 020983 Prod. No.: 001 RX (EQ 0.09MG BASE/INH)

Patents	Expiration	Patented Use
Pat. No. 6251368 Pharmaceutical aerosol formulation containing a particulate medicament, a propellant and substantially free of a surfactant Claim Types: Formulation	DEC 04,2012	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: I - New Indication	JUN 02,2002	I-262: Treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise induced bronchospasm in children ages 4-12

ALBUTEROL SULFATE (VOLMAX (Tablet, Extended Release))

NDA Applicant: MURO NDA No.: 019604 Prod. No.: 001 RX (EQ 8MG BASE); 002 RX (EQ 4MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4751071 Composition comprising salbutamol Claim Types: Formulation	JUN 14,2005	
Pat. No. 4777049 Constant release system with pulsed release Claim Types: Device; Method of administration	OCT 11,2005	
Pat. No. 4851229 Composition comprising a therapeutic agent and a modulating agent Claim Types: Formulation	JUN 14,2005	

ALBUTEROL SULFATE; IPRATROPIUM BROMIDE (COMBIVENT (Aerosol, Metered))

NDA Applicant: BOEHRINGER INGELHEIM NDA No.: 020291 Prod. No.: 001 RX (EQ 0.09MG BASE/INH;0.018MG/INH)

Patents	Expiration	Patented Use
Pat. No. 5603918 Aerosol composition of a salt of ipratropium and a salt of albuterol Claim Types: Formulation; Process	JUN 09,2015	

ALBUTEROL SULFATE; IPRATROPIUM BROMIDE (DUONEB (Solution))

NDA Applicant: DEY NDA No.: 020950 Prod. No.: 001 RX (EQ 0.083% BASE;0.017%)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NP - New product	MAR 21,2004	

ALCOHOL; CHLORHEXIDINE GLUCONATE (AVAGARD (Solution))

NDA Applicant: 3M NDA No.: 021074 Prod. No.: 001 OTC (61%;1%)

Patents	Expiration	Patented Use
Pat. No. 5897031 Dispenser for antimicrobial liquids Claim Types: Device; Method of using a device	JUN 21,2016	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NC - New combination	JUN 07,2004	

ALENDRONATE SODIUM (FOSAMAX (Tablet))

NDA Applicant: MERCK NDA No.: 020560 Prod. No.: 001 RX (EQ 10MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4621077 Pharmacologically active biphosphonates, process for the preparation thereof and pharmaceutical compositions therefrom Claim Types: Method of use	AUG 06,2007	U-114: Use for inhibiting bone resorption
Pat. No. 5358941 Dry mix formulation for bisphosphonic acids with lactose Claim Types: Formulation	DEC 02,2012	
Pat. No. 5681590 Dry mix formulation for bisphosphonic acids Claim Types: Formulation; Process	DEC 02,2012	
Pat. No. 5804570 Method of lessening the risk of non-vertebral bone fractures Claim Types: Method of use	FEB 17,2015	
Pat. No. 5849726 Anhydrous alendronate monosodium salt formulations Claim Types: Composition; Method of use	JUN 06,2015	
Pat. No. 6008207 Anhydrous alendronate monosodium salt formulations Claim Types: Method of use	JUN 06,2015	U-303: Method of use patent-product approved for treatment of osteoporosis, Paget's disease, prevention and treatment of glucocorticoid-induced osteoporosis
Pat. No. 6090410 Dry mix formulation for bisphosphonic acids Claim Types: Formulation	DEC 02,2012	
Pat. No. 6194004 Dry mix formulation for bisphosphonic acids Claim Types: Formulation	DEC 02,2012	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: I - New Indication	JUN 16,2002	I-272: Treatment of glucocorticoid-induced osteoporosis in men and women receiving glucocorticoids in a daily dose equivalent to 7.5mg or greater of prednisone and who have low bone mineral density
Exclusivity Code: I - New Indication	SEP 29,2003	I-309: Increase bone mass in men with osteoporosis
Exclusivity Code: M - Miscellaneous	NOV 24,2002	M-3: Addition of efficacy and safety information in which FOSAMAX was used concomitantly with estrogen alone or with estrogen plus progestin

ALENDRONATE SODIUM (FOSAMAX (Tablet))

NDA Applicant: MERCK NDA No.: 020560 Prod. No.: 002 RX (EQ 40MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4621077 Pharmacologically active biphosphonates, process for the preparation thereof and pharmaceutical compositions therefrom Claim Types: Method of use	AUG 06,2007	U-114: Use for inhibiting bone resorption
Pat. No. 5358941 Dry mix formulation for bisphosphonic acids with lactose Claim Types: Formulation	DEC 02,2012	
Pat. No. 5681590 Dry mix formulation for bisphosphonic acids Claim Types: Formulation; Process	DEC 02,2012	
Pat. No. 5849726 Anhydrous alendronate monosodium salt formulations Claim Types: Composition; Method of use	JUN 06,2015	
Pat. No. 6008207 Anhydrous alendronate monosodium salt formulations Claim Types: Method of use	JUN 06,2015	U-303: Method of use patent-product approved for treatment of osteoporosis, Paget's disease, prevention and treatment of glucocorticoid-induced osteoporosis
Pat. No. 6090410 Dry mix formulation for bisphosphonic acids Claim Types: Formulation	DEC 02,2012	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: I - New Indication	JUN 16,2002	I-272: Treatment of glucocorticoid-induced osteoporosis in men and women receiving glucocorticoids in a daily dose equivalent to 7.5mg or greater of prednisone and who have low bone mineral density
Exclusivity Code: M - Miscellaneous	NOV 24,2002	M-3: Addition of efficacy and safety information in which FOSAMAX was used concomitantly with estrogen alone or with estrogen plus progestin

ALENDRONATE SODIUM (FOSAMAX (Tablet))

NDA Applicant: MERCK NDA No.: 020560 Prod. No.: 003 RX (EQ 5MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4621077 Pharmacologically active biphosphonates, process for the preparation thereof and pharmaceutical compositions therefrom Claim Types: Method of use	AUG 06,2007	U-114: Use for inhibiting bone resorption
Pat. No. 5358941 Dry mix formulation for bisphosphonic acids with lactose Claim Types: Formulation	DEC 02,2012	
Pat. No. 5681590 Dry mix formulation for bisphosphonic acids Claim Types: Formulation; Process	DEC 02,2012	
Pat. No. 5804570 Method of lessening the risk of non-vertebral bone fractures Claim Types: Method of use	FEB 17,2015	
Pat. No. 5849726 Anhydrous alendronate monosodium salt formulations Claim Types: Composition; Method of use	JUN 06,2015	
Pat. No. 6008207 Anhydrous alendronate monosodium salt formulations Claim Types: Method of use	JUN 06,2015	U-303: Method of use patent-product approved for treatment of osteoporosis, Paget's disease, prevention and treatment of glucocorticoid-induced osteoporosis
Pat. No. 6090410 Dry mix formulation for bisphosphonic acids Claim Types: Formulation	DEC 02,2012	

Continued on next page

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: I - New Indication	JUN 16,2002	I-272: Treatment of glucocorticoid-induced osteoporosis in men and women receiving glucocorticoids in a daily dose equivalent to 7.5mg or greater of prednisone and who have low bone mineral density
Exclusivity Code: M - Miscellaneous	NOV 24,2002	M-3: Addition of efficacy and safety information in which FOSAMAX was used concomitantly with estrogen alone or with estrogen plus progestin

ALENDRONATE SODIUM (FOSAMAX (Tablet))

NDA Applicant: MERCK NDA No.: 020560 Prod. No.: 004 RX (EQ 35MG BASE); 005 RX (EQ 70MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4621077 Pharmacologically active biphosphonates, process for the preparation thereof and pharmaceutical compositions therefrom Claim Types: Method of use	AUG 06,2007	U-114: Use for inhibiting bone resorption
Pat. No. 5358941 Dry mix formulation for bisphosphonic acids with lactose Claim Types: Formulation	DEC 02,2012	
Pat. No. 5681590 Dry mix formulation for bisphosphonic acids Claim Types: Formulation; Process	DEC 02,2012	
Pat. No. 5804570 Method of lessening the risk of non-vertebral bone fractures Claim Types: Method of use	FEB 17,2015	
Pat. No. 5849726 Anhydrous alendronate monosodium salt formulations Claim Types: Composition; Method of use	JUN 06,2015	
Pat. No. 5994329 Method for inhibiting bone resorption Claim Types: Method of use; Kit	JUL 17,2018	
Pat. No. 6008207 Anhydrous alendronate monosodium salt formulations Claim Types: Method of use	JUN 06,2015	
Pat. No. 6015801 Method for inhibiting bone resorption Claim Types: Method of use	JUL 17,2018	U-353: Prevention and treatment of osteoporosis
Pat. No. 6090410 Dry mix formulation for bisphosphonic acids Claim Types: Formulation	DEC 02,2012	
Pat. No. 6225294 Method for inhibiting bone resorption Claim Types: Kit	JUL 17,2018	

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: D - New Dosing Schedule	OCT 20,2003	D-61: Once weekly dosing for the treatment of postmenopausal osteoporosis
Exclusivity Code: D - New Dosing Schedule	OCT 20,2003	D-62: Once weekly dosing for the prevention of postmenopausal osteoporosis
Exclusivity Code: NS - New strength	OCT 20,2003	

ALITRETINOIN (PANRETIN (Gel))

NDA Applicant: LIGAND NDA No.: 020886 Prod. No.: 001 RX (EQ 0.1% BASE)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	FEB 02,2004	
Exclusivity Code ODE: Orphan Drug	FEB 02,2006	Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.

ALLOPURINOL SODIUM (ALOPRIM (Injectable))

NDA Applicant: CATALYTICA PHARMS NDA No.: 020298 Prod. No.: 001 RX (EQ 500MG BASE/VIAL)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code ODE: Orphan Drug	MAY 17,2003	

ALMOTRIPTAN MALATE (AXERT (Tablet))

NDA Applicant: PHARMACIA AND UPJOHN NDA No.: 021001 Prod. No.: 001 RX (EQ 6.25MG BASE); 002 RX (EQ 12.5MG BASE)

Patents	Expiration	Patented Use
Pat. No. 5565447 Indole derivatives Claim Types: Compound; Method of use	MAR 27,2014	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	MAY 07,2006	

ALOSETRON HYDROCHLORIDE (LOTRONEX (Tablet))

NDA Applicant: GLAXOSMITHKLINE NDA No.: 021107 Prod. No.: 001 RX (EQ 1MG BASE)

Patents	Expiration	Patented Use
Pat. No. 5360800 Tetrahydro-1H-pyrido[4,3-b]indol-1-one derivatives Claim Types: Compound; Composition; Method of use	FEB 02,2010	
Pat. No. 6284770 Medicaments for the treatment of non-constipated female irritable bowel syndrome Claim Types: Method of use	OCT 05,2018	U-405: Method of use of LOTRONEX
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	FEB 09,2005	

ALPRAZOLAM (XANAX (Tablet))

NDA Applicant: PHARMACIA AND UPJOHN NDA No.: 018276 Prod. No.: 001 RX (0.25MG); 002 RX (0.5MG); 003 RX (1MG)

Patents	Expiration	Patented Use
Pat. No. 4508726 Treatment of panic disorders with alprazolam Claim Types: Method of use	SEP 16,2002	U-46: Treatment of panic disorder

ALPRAZOLAM (XANAX (Tablet))

NDA Applicant: PHARMACIA AND UPJOHN NDA No.: 018276 Prod. No.: 004 RX (2MG)

Patents	Expiration	Patented Use
Pat. No. 4508726 Treatment of panic disorders with alprazolam Claim Types: Method of use	SEP 16,2002	U-46: Treatment of panic disorder
Pat. No. 5061494 Tri-scored drug tablet Claim Types: Functional tablet design	OCT 29,2008	

ALPROSTADIL (CAVERJECT (Injectable))

NDA Applicant: PHARMACIA AND UPJOHN NDA No.: 020379 Prod. No.: 001 RX (0.01MG/VIAL); 002 RX (0.02MG/VIAL); 003 RX (0.005MG/VIAL); 004 RX (0.04MG/VIAL)

Patents	Expiration	Patented Use
Pat. No. 5741523 Stabilized prostaglandin E1 Claim Types: Product-by-process	APR 21,2015	

ALPROSTADIL (MUSE (Suppository))

NDA Applicant: VIVUS NDA No.: 020700 Prod. No.: 001 RX (0.125MG); 002 RX (0.25MG); 003 RX (0.5MG); 004 RX (1MG)

Patents	Expiration	Patented Use
Pat. No. 4801587 Impotence ointment Claim Types: Method of use	JAN 31,2007	U-155: Treatment of erectile dysfunction
Pat. No. 5242391 Urethral insert for treatment of erectile dysfunction Claim Types: Device	SEP 07,2010	U-155: Treatment of erectile dysfunction
Pat. No. 5474535 Dosage and inserter for treatment of erectile dysfunction Claim Types: Device	DEC 12,2012	U-155: Treatment of erectile dysfunction

AMIFOSTINE (ETHYOL (Injectable))

NDA Applicant: MEDIMMUNE ONCOLOGY NDA No.: 020221 Prod. No.: 001 RX (500MG/VIAL)

Patents	Expiration	Patented Use
Pat. No. 5424471 Crystalline amifostine compositions and methods of the preparation and use of same Claim Types: Product-by-process; Process	JUL 31,2012	
Pat. No. 5591731 Crystalline amifostine compositions Claim Types: Composition	JUL 31,2012	
Pat. No. 5994409 Methods for treatment of neuro--and nephro--disorders and therapeutic toxicities using aminothiol compounds Claim Types: Method of use	DEC 08,2017	U-305: Methods for using the drug product
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: I - New Indication	JUN 24,2002	I-283: To reduce the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer, where the radiation port includes a substantial portion of the parotid glands
Exclusivity Code ODE: Orphan Drug	DEC 08,2002	For use as a chemoprotective agent for cisplatin in the treatment of advanced ovarian carcinoma.
Exclusivity Code ODE: Orphan Drug	JUN 24,2006	Reduction of the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer.

AMIFOSTINE (ETHYOL (Injectable))

NDA Applicant: MEDIMMUNE ONCOLOGY NDA No.: 020221 Prod. No.: 002 RX (375MG/VIAL)

Patents	Expiration	Patented Use
Pat. No. 5242471 Coupling capillary gas chromatography to traditional liquid chromatography detectors Claim Types:	JUL 31,2012	
Pat. No. 5591731 Crystalline amifostine compositions Claim Types: Composition	JUL 31,2012	
Pat. No. 5994409 Methods for treatment of neuro--and nephro--disorders and therapeutic toxicities using aminothiol compounds Claim Types: Method of use	DEC 08,2017	U-305: Methods for using the drug product
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: I - New Indication	JUN 24,2002	I-283: To reduce the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer, where the radiation port includes a substantial portion of the parotid glands
Exclusivity Code ODE: Orphan Drug	DEC 08,2002	For use as a chemoprotective agent for cisplatin in the treatment of advanced ovarian carcinoma.
Exclusivity Code ODE: Orphan Drug	JUN 24,2006	Reduction of the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer.

Sample of the Index of Compounds in
Multi-Ingredient Products

Active Ingredients Starting with P

PERFLUOROPOLYMETHYLISOPROPYL ETHER = PERFLUOROPOLYMETHYLISOPROPYL ETHER; POLYTETRAFLUOROETHYLENE	PSEUDOEPHEDRINE HYDROCHLORIDE = ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE
PILOCARPINE HYDROCHLORIDE = BETAXOLOL HYDROCHLORIDE; PILOCARPINE HYDROCHLORIDE	PSEUDOEPHEDRINE HYDROCHLORIDE = BROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE
POLYTETRAFLUOROETHYLENE = PERFLUOROPOLYMETHYLISOPROPYL ETHER; POLYTETRAFLUOROETHYLENE	PSEUDOEPHEDRINE HYDROCHLORIDE = FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE
POTASSIUM CHLORIDE = CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE	PSEUDOEPHEDRINE HYDROCHLORIDE = IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE
POTASSIUM CHLORIDE = CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	PSEUDOEPHEDRINE HYDROCHLORIDE = NAPROXEN SODIUM; PSEUDOEPHEDRINE HYDROCHLORIDE
PRILOCAINE = LIDOCAINE; PRILOCAINE	PSEUDOEPHEDRINE SULFATE = LORATADINE; PSEUDOEPHEDRINE SULFATE
PROGUANIL HYDROCHLORIDE = ATOVAQUONE; PROGUANIL HYDROCHLORIDE	
PSEUDOEPHEDRINE HYDROCHLORIDE = ACETAMINOPHEN; CLEMASTINE FUMARATE; PSEUDOEPHEDRINE HYDROCHLORIDE	

Active Ingredients Starting with Q

QUINAPRIL HYDROCHLORIDE = HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE	
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Active Ingredients Starting with R

RITONAVIR = LOPINAVIR; RITONAVIR	
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Active Ingredients Starting with S

SALMETEROL XINAFOATE = FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	SODIUM PHOSPHATE = CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE
SIMETHICONE = LOPERAMIDE HYDROCHLORIDE; SIMETHICONE	SODIUM PHOSPHATE, DIBASIC, ANHYDROUS = SODIUM PHOSPHATE, DIBASIC, ANHYDROUS; SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE
SODIUM BICARBONATE = CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE	SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE = CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE
SODIUM BICARBONATE = CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE = SODIUM PHOSPHATE, DIBASIC, ANHYDROUS; SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE
SODIUM CHLORIDE = CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE	
SODIUM CHLORIDE = CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	