

Volume 2 Sample
Table of Contents, Preface, Claim Types Definition
10 Pages of Companies
10 Pages of Products in Order by Their Next Upcoming Patent Expiration

Orange Book CompanionTM

The Premium Patent & Exclusivity Addendum
for the FDA Orange Book

2002 Edition

Volume 2 Companies & Expirations

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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
Volume 22, Supplement 5 of the Orange Book.

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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

NDA applicants starting with "A"

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

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CALCIJEX (Injectable) (CALCITRIOL)

NDA No.: 018874 Prod. No.: 001 RX (0.001MG/ML); 002 RX (0.002MG/ML)

Patents	Expiration	Patented Use
Pat. No. 6051567 Low oxygen content compositions of 1.alpha., 25-dihydroxycholecalciferol Claim Types: Formulation	FEB 02,2020 *PED	
Pat. No. 6265392 Low oxygen content compositions of 1.alpha., 25-dihydroxycholecalciferol Claim Types: Formulation	FEB 02,2020 *PED	
Pat. No. 6274169 Low oxygen content compositions of 1.alpha., 25-dihydroxycholecalciferol Claim Types: Process	FEB 02,2020 *PED	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: M - Miscellaneous	May 16,2005 PED	M-14: Additional clinical trial information added to pediatric use subsection

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CORLOPAM (Injectable) (FENOLDOPAM MESYLATE)

NDA No.: 019922 Prod. No.: 001 RX (EQ 10MG BASE/ML)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	SEP 23,2002	

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DEPACON (Injectable) (VALPROATE SODIUM)

NDA No.: 020593 Prod. No.: 001 RX (EQ 100MG BASE/ML)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: D - New Dosing Schedule	JAN 24,2005	D-72: Information regarding increased rate of infusion for DEPACON

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DEPAKOTE (Capsule, Delayed Rel Pellets) (DIVALPROEX SODIUM)

NDA No.: 019680 Prod. No.: 001 RX (EQ 125MG VALPROIC ACID)

Patents	Expiration	Patented Use
Pat. No. 4988731 Sodium hydrogen divalproate oligomer Claim Types: Composition	JAN 29,2008	
Pat. No. 5212326 Sodium hydrogen divalproate oligomer Claim Types: Composition	JAN 29,2008	

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DEPAKOTE (Tablet, Delayed Release) (DIVALPROEX SODIUM)

NDA No.: 018723 Prod. No.: 001 RX (EQ 250MG VALPROIC ACID); 002 RX (EQ 500MG VALPROIC ACID); 003 RX (EQ 125MG VALPROIC ACID)

Patents	Expiration	Patented Use
Pat. No. 4988731 Sodium hydrogen divalproate oligomer Claim Types: Composition	JAN 29,2008	
Pat. No. 5212326 Sodium hydrogen divalproate oligomer Claim Types: Composition	JAN 29,2008	

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DEPAKOTE CP (Tablet, Delayed Release) (DIVALPROEX SODIUM)

NDA No.: 019794 Prod. No.: 001 DISC (EQ 250MG BASE); 002 DISC (EQ 500MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4988731 Sodium hydrogen divalproate oligomer Claim Types: Composition	JAN 29,2008	
Pat. No. 5212326 Sodium hydrogen divalproate oligomer Claim Types: Composition	JAN 29,2008	

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DEPAKOTE ER (Tablet, Extended Release) (DIVALPROEX SODIUM)

NDA No.: 021168 Prod. No.: 001 RX (EQ 500MG VALPROIC ACID)

Patents	Expiration	Patented Use
Pat. No. 4913906 Novel controlled release dosage form of valproic acid Claim Types: Formulation; Process	APR 03,2007	
Pat. No. 4988731 Sodium hydrogen divalproate oligomer Claim Types: Composition	JAN 29,2008	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NP - New product	AUG 04,2003	

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HYTRIN (Capsule) (TERAZOSIN HYDROCHLORIDE)

NDA No.: 020347 Prod. No.: 001 RX (EQ 1MG BASE); 002 RX (EQ 2MG BASE); 003 RX (EQ 5MG BASE); 004 RX (EQ 10MG BASE)

Patents	Expiration	Patented Use
Pat. No. 5212176 R(+)-terazosin Claim Types: Compound; Composition; Method of use	JUN 29,2010	
Pat. No. 5294615 Terazosin polymorph and pharmaceutical composition Claim Types: New polymorph, salt or hydrate; Composition; Method of use	APR 29,2013	U-165: Treatment of symptomatic benign prostatic hyperplasia
Pat. No. 5294615 Terazosin polymorph and pharmaceutical composition Claim Types: New polymorph, salt or hydrate; Composition; Method of use	APR 29,2013	U-3: Treatment of hypertension
Pat. No. 5412095 Terazosin monohydrochloride and processes and intermediate for its production Claim Types: New polymorph, salt or hydrate	APR 29,2013	

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HYTRIN (Tablet) (TERAZOSIN HYDROCHLORIDE)

NDA No.: 019057 Prod. No.: 001 RX (EQ 1MG BASE); 002 RX (EQ 2MG BASE); 003 RX (EQ 5MG BASE); 004 RX (EQ 10MG BASE)

Patents	Expiration	Patented Use
Pat. No. 5212176 R(+)-terazosin Claim Types: Compound; Composition; Method of use	JUN 29,2010	
Pat. No. 5294615 Terazosin polymorph and pharmaceutical composition Claim Types: New polymorph, salt or hydrate; Composition; Method of use	APR 29,2013	U-165: Treatment of symptomatic benign prostatic hyperplasia
Pat. No. 5294615 Terazosin polymorph and pharmaceutical composition Claim Types: New polymorph, salt or hydrate; Composition; Method of use	APR 29,2013	U-3: Treatment of hypertension
Pat. No. 5412095 Terazosin monohydrochloride and processes and intermediate for its production Claim Types: New polymorph, salt or hydrate	APR 29,2013	

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KALETRA (Capsule) (LOPINAVIR; RITONAVIR)
NDA No.: 021226 Prod. No.: 001 RX (133.3MG;33.3MG)

Patents	Expiration	Patented Use
Pat. No. 5541206 Retroviral protease inhibiting compounds Claim Types: Compound; Composition; Method of use	JUL 30,2013	U-348: Method of use for inhibiting HIV infection
Pat. No. 5635523 Retroviral protease inhibiting compounds Claim Types: Method of use	JUN 30,2014	U-352: Inhibiting HIV infection by administering ritonavir in combination with a reverse transcriptase inhibitor
Pat. No. 5648497 Retroviral protease inhibiting compounds Claim Types: Compound	JUL 15,2014	
Pat. No. 5674882 Retroviral protease inhibiting compounds Claim Types: Method of use	OCT 07,2014	U-344: Method for inhibiting HIV infection by administering ritonavir in combination with another HIV protease inhibitor
Pat. No. 5846987 Retroviral protease inhibiting compounds Claim Types: Composition; Use of compound to prepare a composition	DEC 29,2012	U-350: Preparation of a pharmaceutical composition for concomitant admin with a reverse transcriptase inhibitor
Pat. No. 5886036 Retroviral protease inhibiting compounds Claim Types: Composition	DEC 29,2012	U-345: Ritonavir and another HIV protease inhibitor for concomitant administration for the treatment of an HIV infection
Pat. No. 5914332 Retroviral protease inhibiting compounds Claim Types: Compound; Composition; Method of use	DEC 13,2015	U-351: Inhibiting protease with lopinavir and inhibiting an HIV infection with lopinavir
Pat. No. 6037157 Method for improving pharmacokinetics Claim Types: Method of use	JUN 26,2016	U-346: Method for inhibiting cytochrome p450 monooxygenase with ritonavir and a method for improving the pharmacokinetics of a drug that is metabolized by cytochrome P450 monooxygenase by admin the drug and RITONAVIR
Pat. No. 6232333 Pharmaceutical composition Claim Types: Formulation	NOV 07,2017	
Pat. No. 6284767 Retroviral protease inhibiting compounds Claim Types: Composition; Method of use	FEB 14,2016	U-401: Use of lopinavir in combination with reverse transcriptase inhibitors for treating HIV infection and in combo with other HIV protease inhibitors
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NC - New combination	SEP 15,2003	

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KALETRA (Solution) (LOPINAVIR; RITONAVIR)
NDA No.: 021251 Prod. No.: 001 RX (80MG/ML;20MG/ML)

Patents	Expiration	Patented Use
Pat. No. 5541206 Retroviral protease inhibiting compounds Claim Types: Compound; Composition; Method of use	JUL 30,2013	U-348: Method of use for inhibiting HIV infection
Pat. No. 5635523 Retroviral protease inhibiting compounds Claim Types: Method of use	JUN 03,2014	U-352: Inhibiting HIV infection by administering ritonavir in combination with a reverse transcriptase inhibitor
Pat. No. 5648497 Retroviral protease inhibiting compounds Claim Types: Compound	JUL 15,2014	
Pat. No. 5674882 Retroviral protease inhibiting compounds Claim Types: Method of use	OCT 07,2014	U-344: Method for inhibiting HIV infection by administering ritonavir in combination with another HIV protease inhibitor
Pat. No. 5846987 Retroviral protease inhibiting compounds Claim Types: Composition; Use of compound to prepare a composition	DEC 29,2012	U-350: Preparation of a pharmaceutical composition for concomitant admin with a reverse transcriptase inhibitor
Pat. No. 5886036 Retroviral protease inhibiting compounds Claim Types: Composition	DEC 29,2012	U-345: Ritonavir and another HIV protease inhibitor for concomitant administration for the treatment of an HIV infection
Pat. No. 5914332 Retroviral protease inhibiting compounds Claim Types: Compound; Composition; Method of use	DEC 13,2005	U-351: Inhibiting protease with lopinavir and inhibiting an HIV infection with lopinavir

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Pat. No. 6037157 Method for improving pharmacokinetics Claim Types: Method of use	JUN 26,2016	U-346: Method for inhibiting cytochrome p450 monooxygenase with ritonavir and a method for improving the pharmacokinetics of a drug that is metabolized by cytochrome P450 monooxygenase by admin the drug and RITONAVIR
Pat. No. 6284767 Retroviral protease inhibiting compounds Claim Types: Composition; Method of use	FEB 14,2016	U-401: Use of lopinavir in combination with reverse transcriptase inhibitors for treating HIV infection and in combo with other HIV protease inhibitors
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NC - New combination	SEP 15,2003	

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MAVIK (Tablet) (TRANDOLAPRIL)

NDA No.: 020528 Prod. No.: 001 RX (1MG); 002 RX (2MG); 003 RX (4MG)

Patents	Expiration	Patented Use
Pat. No. 4933361 Derivatives of bicyclic aminoacids agents containing these compounds and their use Claim Types: Compound; Composition; Method of use	JUN 12,2007	
Pat. No. 5744496 Method of treating cardiac insufficiency using angiotensin-converting enzyme inhibitors Claim Types: Method of use	APR 28,2015	U-229: Cardiac insufficiency (congestive heart failure)

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MERIDIA (Capsule) (SIBUTRAMINE HYDROCHLORIDE)

NDA No.: 020632 Prod. No.: 001 RX (5MG); 002 RX (10MG); 003 RX (15MG)

Patents	Expiration	Patented Use
Pat. No. 4746680 Therapeutic agents Claim Types: Compound; Composition; Method of use	JUN 11,2007	
Pat. No. 4929629 Therapeutic compound Claim Types: Compound; Composition; Method of use	MAY 29,2007	
Pat. No. 5436272 Treatment of obesity Claim Types: Method of use	JUL 25,2012	U-439: Treatment of obesity
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: D - New Dosing Schedule	FEB 16,2004	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
Exclusivity Code: M - Miscellaneous	FEB 16,2004	M-9: Addition to the clinical studies section of the labeling of text and two tables containing information for the prescribing physician on blood pressure, heart rate, and heart rate variability
Exclusivity Code: NCE - New chemical entity	NOV 22,2002	

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MIVACRON (Injectable) (MIVACURIUM CHLORIDE)

NDA No.: 020098 Prod. No.: 001 RX (EQ 2MG BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 4761418 Novel compounds Claim Types: Compound; Composition; Method of use	JAN 22,2006	

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MIVACRON IN DEXTROSE 5% IN PLASTIC CONTAINER (Injectable) (MIVACURIUM CHLORIDE)

NDA No.: 020098 Prod. No.: 002 RX (EQ 0.5MG BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 4761418 Novel compounds Claim Types: Compound; Composition; Method of use	JAN 22,2006	

ABBOTT

NIMBEX (Injectable) (CISATRACURIUM BESYLATE)
NDA No.: 020551 Prod. No.: 001 RX (EQ 2MG BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 5453510 Neuromuscular blocking agents Claim Types: Formulation; Method of use	SEP 26,2012	U-127: Method of producing neuromuscular blockade

ABBOTT

NIMBEX PRESERVATIVE FREE (Injectable) (CISATRACURIUM BESYLATE)
NDA No.: 020551 Prod. No.: 002 RX (EQ 10MG BASE/ML); 003 RX (EQ 2MG BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 5453510 Neuromuscular blocking agents Claim Types: Formulation; Method of use	SEP 26,2012	U-127: Method of producing neuromuscular blockade

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NORVIR (Capsule) (RITONAVIR)
NDA No.: 020680 Prod. No.: 001 RX (100MG)

Patents	Expiration	Patented Use
Pat. No. 5541206 Retroviral protease inhibiting compounds Claim Types: Compound; Composition; Method of use	JUL 30,2013	U-140: Use of NORVIR to inhibit HIV protease or to inhibit an HIV infection
Pat. No. 5635523 Retroviral protease inhibiting compounds Claim Types: Method of use	JUN 03,2014	U-190: Use of ritonavir in combination with any reverse transcriptase inhibitor
Pat. No. 5648497 Retroviral protease inhibiting compounds Claim Types: Compound	JUL 15,2014	
Pat. No. 5846987 Retroviral protease inhibiting compounds Claim Types: Composition; Use of compound to prepare a composition	DEC 29,2012	U-190: Use of ritonavir in combination with any reverse transcriptase inhibitor
Pat. No. 5948436 Pharmaceutical composition Claim Types: Formulation	SEP 13,2013	

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NORVIR (Capsule) (RITONAVIR)
NDA No.: 020945 Prod. No.: 001 RX (100MG)

Patents	Expiration	Patented Use
Pat. No. 5541206 Retroviral protease inhibiting compounds Claim Types: Compound; Composition; Method of use	JUL 30,2013	U-348: Method of use for inhibiting HIV infection
Pat. No. 5635523 Retroviral protease inhibiting compounds Claim Types: Method of use	JUN 03,2014	U-347: Method of use in combination with reverse transcriptase inhibitors
Pat. No. 5648497 Retroviral protease inhibiting compounds Claim Types: Compound	JUL 15,2014	
Pat. No. 5846987 Retroviral protease inhibiting compounds Claim Types: Composition; Use of compound to prepare a composition	DEC 29,2012	U-347: Method of use in combination with reverse transcriptase inhibitors
Pat. No. 6232333 Pharmaceutical composition Claim Types: Formulation	NOV 07,2017	

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NORVIR (Solution) (RITONAVIR)
NDA No.: 020659 Prod. No.: 001 RX (80MG/ML)

Patents	Expiration	Patented Use
Pat. No. 5484801 Pharmaceutical composition for inhibiting HIV protease Claim Types: Formulation	JAN 28,2014	
Pat. No. 5541206 Retroviral protease inhibiting compounds Claim Types: Compound; Composition; Method of use	JUL 30,2013	U-140: Use of NORVIR to inhibit HIV protease or to inhibit an HIV infection

Continued on next page

Pat. No. 5635523 Retroviral protease inhibiting compounds Claim Types: Method of use	JUN 03,2014	U-190: Use of ritonavir in combination with any reverse transcriptase inhibitor
Pat. No. 5648497 Retroviral protease inhibiting compounds Claim Types: Compound	JUL 15,2014	
Pat. No. 5674882 Retroviral protease inhibiting compounds Claim Types: Method of use	OCT 07,2014	
Pat. No. 5846987 Retroviral protease inhibiting compounds Claim Types: Composition; Use of compound to prepare a composition	DEC 29,2012	U-190: Use of ritonavir in combination with any reverse transcriptase inhibitor
Pat. No. 5886036 Retroviral protease inhibiting compounds Claim Types: Composition	DEC 29,2012	
Pat. No. 6037157 Method for improving pharmacokinetics Claim Types: Method of use	JUN 26,2016	

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NUROMAX (Injectable) (DOXACURIUM CHLORIDE)
NDA No.: 019946 Prod. No.: 001 RX (EQ 1MG BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 4701460 Long duration neuromuscular blocking agents Claim Types: Compound; Method of use; Composition	MAR 06,2005	

ABBOTT

PRECEDEX (Injectable) (DEXMEDETOMIDINE)
NDA No.: 021038 Prod. No.: 001 RX (EQ 100UGM BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 4910214 Optical isomer of an imidazole derivative medetomidine as an alpha-2-receptor agonist Claim Types: Compound; Method of use	JUL 15,2008	U-421: Use for sedation
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	DEC 17,2004	

ABBOTT

TARKA (Tablet, Extended Release) (TRANDOLAPRIL; VERAPAMIL HYDROCHLORIDE)
NDA No.: 020591 Prod. No.: 002 RX (2MG;180MG); 002 RX (4MG;240MG); 003 RX (1MG;240MG); 004 RX (2MG;240MG)

Patents	Expiration	Patented Use
Pat. No. 4933361 Derivatives of bicyclic aminoacids agents containing these compounds and their use Claim Types: Compound; Composition; Method of use	JUN 12,2007	
Pat. No. 5721244 Combination of angiotensin-converting enzyme inhibitors with calcium antagonists as well as their use in drugs Claim Types: Composition; Method of use	FEB 24,2015	

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TRICOR (MICRONIZED) (Capsule) (FENOFIBRATE)
NDA No.: 019304 Prod. No.: 002 RX (67MG); 003 RX (134MG); 004 RX (200MG)

Patents	Expiration	Patented Use
Pat. No. 4895726 Novel dosage form of fenofibrate Claim Types: Formulation; Method of use Process	JAN 19,2009	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: I - New Indication	APR 24,2003	I-298: Treatment of patients with Frederickson Type IIa and IIb hyperlipoproteinemia

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TRICOR (Tablet) (FENOFIBRATE)

NDA No.: 021203 Prod. No.: 001 RX (54MG); 003 RX (160MG)

Patents	Expiration	Patented Use
Pat. No. 4895726 Novel dosage form of fenofibrate Claim Types: Formulation; Method of use Process	JAN 19,2009	
Pat. No. 6074670 Fenofibrate pharmaceutical composition having high bioavailability and method for preparing it Claim Types: Formulation	JAN 09,2018	
Pat. No. 6277405 Fenofibrate pharmaceutical composition having high bioavailability and method for preparing it Claim Types: Formulation	JAN 09,2018	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: I - New Indication	APR 24,2003	I-298: Treatment of patients with Frederickson Type IIa and IIb hyperlipoproteinemia

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ULTANE (Liquid) (SEVOFLURANE)

NDA No.: 020478 Prod. No.: 001 RX (100%)

Patents	Expiration	Patented Use
Pat. No. 5990176 Fluoroether compositions and methods for inhibiting their degradation in the presence of a Lewis acid Claim Types: Formulation; Method of improving a formulation	JUL 27,2017 *PED	
Pat. No. 6074668 Container for an inhalation anesthetic Claim Types: Drug in a container	JUL 09,2018 *PED	
Pat. No. 6288127 Fluoroether compositions and methods for inhibiting their degradation in the presence of a Lewis acid Claim Types: Formulation; Method of improving a formulation	JUL 27,2017 *PED	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: M - Miscellaneous	MAR 30,2004	M-17: Information regarding use of ULTANE in pediatric patients with congenital heart disease

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ULTIVA (Injectable) (REMIFENTANIL HYDROCHLORIDE)

NDA No.: 020630 Prod. No.: 001 RX (EQ 1MG BASE/VIAL)

Patents	Expiration	Patented Use
Pat. No. 5019583 N-phenyl-N-(4-piperidiny)amides useful as analgesics Claim Types: Compound; Composition; Method of use	AUG 15,2009 *PED	
Pat. No. 5466700 Anesthetic use of N-phenyl-N-(4-piperidiny)amides Claim Types: Method of use	MAR 01,2014 *PED	U-156: Method of providing anesthesia
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NPP - New patient population	Apr 15,2003 PED	
Exclusivity Code: NCE - New chemical entity	JAN 12,2002 PED	

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ULTIVA (Injectable) (REMIFENTANIL HYDROCHLORIDE)

NDA No.: 020630 Prod. No.: 002 RX (EQ 2MG BASE/VIAL)

Patents	Expiration	Patented Use
Pat. No. 5019583 N-phenyl-N-(4-piperidiny)amides useful as analgesics Claim Types: Compound; Composition; Method of use	AUG 15,2009 *PED	

Continued on next page

Pat. No. 5466700 Anesthetic use of N-phenyl-N-(4-piperidinyl)amides Claim Types: Method of use	AUG 30,2013	U-156: Method of providing anesthesia
Pat. No. 5466700 Anesthetic use of N-phenyl-N-(4-piperidinyl)amides Claim Types: Method of use	MAR 01,2014 *PED	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NPP - New patient population	Apr 15,2003 PED	
Exclusivity Code: NCE - New chemical entity	JAN 12,2002 PED	

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ULTIVA (Injectable) (REMIFENTANIL HYDROCHLORIDE)
NDA No.: 020630 Prod. No.: 003 RX (EQ 5MG BASE/VIAL)

Patents	Expiration	Patented Use
Pat. No. 5019583 N-phenyl-N-(4-piperidinyl)amides useful as analgesics Claim Types: Compound; Composition; Method of use	AUG 15,2009 *PED	
Pat. No. 5466700 Anesthetic use of N-phenyl-N-(4-piperidinyl)amides Claim Types: Method of use	MAR 01,2014 *PED	U-156: Method of providing anesthesia
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NPP - New patient population	Apr 15,2003 PED	
Exclusivity Code: NCE - New chemical entity	JAN 12,2002 PED	

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VICOPROFEN (Tablet) (HYDROCODONE BITARTRATE; IBUPROFEN)
NDA No.: 020716 Prod. No.: 001 RX (7.5MG;200MG)

Patents	Expiration	Patented Use
Pat. No. 4587252 Hydrocodone/ibuprofen pharmaceutical compositions and method Claim Types: Method of use; Composition	DEC 18,2004	U-55: Treatment of pain
Pat. No. 6348216 Ibuprofen and narcotic analgesic compositions Claim Types: Formulation	JUN 10,2017	

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ZEMPLAR (Injectable) (PARICALCITOL)
NDA No.: 020819 Prod. No.: 001 RX (0.005MG/ML)

Patents	Expiration	Patented Use
Pat. No. 5246925 19-nor-vitamin D compounds for use in treating hyperparathyroidism Claim Types: Method of use	APR 17,2012	U-314: Method for treating hyperparathyroidism which comprises suppressing parathyroid activity
Pat. No. 5587497 19-nor-vitamin D compounds Claim Types: Compound	DEC 24,2013	
Pat. No. 6136799 Cosolvent formulations Claim Types: Formulation; Process	APR 08,2018	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	APR 17,2003	

ABBOTT

ZYFLO (Tablet) (ZILEUTON)

NDA No.: 020471 Prod. No.: 001 RX (300MG); 003 RX (600MG)

Patents	Expiration	Patented Use
Pat. No. 4873259 Indole, benzofuran, benzothiophene containing lipoxigenase inhibiting compounds Claim Types: Compound; Composition; Method of use	DEC 10,2010	U-168: Method of inhibiting lipoxigenase activity in a mammal which is the mode of action in the treatment of asthma

ACTELION

TRACLEER (Tablet) (BOSENTAN)

NDA No.: 021290 Prod. No.: 001 RX (62.5MG); 002 RX (125MG)

Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	NOV 20,2006	
Exclusivity Code ODE: Orphan Drug	NOV 20,2008	Treatment of pulmonary arterial hypertension.

ADV MAGNETICS

FERIDEX I.V. (Injectable) (FERUMOXIDES)

NDA No.: 020416 Prod. No.: 001 RX (EQ 11.2MG IRON/ML)

Patents	Expiration	Patented Use
Pat. No. 4770183 Biologically degradable superparamagnetic particles for use as nuclear magnetic resonance imaging agents Claim Types: Method of use	SEP 13,2005	U-145: Biologically degradable superparamagnetic particles for use as nuclear magnetic resonance imaging agents
Pat. No. 4827945 Biologically degradable superparamagnetic materials for use in clinical applications Claim Types: Diagnostic or surgical method; Method of use	MAY 09,2006	U-144: Biologically degradable superparamagnetic materials for use in clinical applications
Pat. No. 4951675 Biodegradable superparamagnetic metal oxides as contrast agents for MR imaging Claim Types: Diagnostic or surgical method	AUG 28,2007	U-143: Biodegradable superparamagnetic metal oxides as contrast agents for mr imaging
Pat. No. 5055288 Vascular magnetic imaging method and agent comprising biodegradeable superparamagnetic metal oxides Claim Types: Composition	OCT 08,2008	
Pat. No. 5102652 Low molecular weight carbohydrates as additives to stabilize metal oxide compositions Claim Types: Formulation; Diagnostic or surgical method; Method of use; Process	FEB 06,2009	
Pat. No. 5219554 Hydrated biodegradable superparamagnetic metal oxides Claim Types: Composition	JUN 15,2010	
Pat. No. 5248492 Low molecular weight carbohydrates as additives to stabilize metal oxide compositions Claim Types: Formulation; Diagnostic or surgical method; Method of use; Method of improving a formulation	SEP 28,2010	

ADV MAGNETICS

GASTROMARK (Suspension) (FERUMOXSIL)

NDA No.: 020410 Prod. No.: 001 RX (EQ 0.175MG IRON/ML)

Patents	Expiration	Patented Use
Pat. No. 4695392 Magnetic particles for use in separations Claim Types: Composition	SEP 22,2004	
Pat. No. 4695393 Magnetic particles for use in separations Claim Types: Process	SEP 22,2004	
Pat. No. 4770183 Biologically degradable superparamagnetic particles for use as nuclear magnetic resonance imaging agents Claim Types: Method of use	SEP 13,2005	U-169: Methods of using the compound/drug product as a contrast agent in magnetic resonance imaging

Continued on next page

Pat. No. 4827945 Biologically degradable superparamagnetic materials for use in clinical applications Claim Types: Diagnostic or surgical method; Method of use	MAY 09,2006	U-170: Method of obtaining an mr image using the composition/drug product as a contrast agent
Pat. No. 4951675 Biodegradable superparamagnetic metal oxides as contrast agents for MR imaging Claim Types: Diagnostic or surgical method	SEP 13,2005	U-169: Methods of using the compound/drug product as a contrast agent in magnetic resonance imaging
Pat. No. 5055288 Vascular magnetic imaging method and agent comprising biodegradable superparamagnetic metal oxides Claim Types: Composition	OCT 08,2008	
Pat. No. 5069216 Silanized biodegradable super paramagnetic metal oxides as contrast agents for imaging the gastrointestinal tract Claim Types: Diagnostic or surgical method	MAY 09,2006	U-171: Methods of using the compound/drug product as an oral contrast agent in magnetic resonance imaging of the gastrointestinal tract
Pat. No. 5219554 Hydrated biodegradable superparamagnetic metal oxides Claim Types: Composition	JUN 15,2010	

AGOURON

RESCRIPTOR (Tablet) (DELAVIRDINE MESYLATE)
NDA No.: 020705 Prod. No.: 001 RX (100MG)

Patents	Expiration	Patented Use
Pat. No. 5563142 Diaromatic substituted compounds as anti-HIV-1 agents Claim Types: Compound	OCT 08,2013	
Pat. No. 6177101 Delavirdine high strength tablet formulation Claim Types: Formulation	JUN 11,2018	
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: NCE - New chemical entity	APR 04,2002	

AGOURON

VIRACEPT (For Suspension) (NELFINAVIR MESYLATE)
NDA No.: 020778 Prod. No.: 001 RX (EQ 50MG BASE/SCOOPFUL)

Patents	Expiration	Patented Use
Pat. No. 5484926 HIV protease inhibitors Claim Types: Compound	OCT 07,2013	
Pat. No. 5952343 HIV protease inhibitors Claim Types: Compound; Composition; Method of use	OCT 07,2013	U-257: Treatment of HIV infection
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: D - New Dosing Schedule	NOV 24,2002	D-52: Alternate dosing regimen of 1250mg twice daily
Exclusivity Code: NCE - New chemical entity	MAR 14,2002	

AGOURON

VIRACEPT (Tablet) (NELFINAVIR MESYLATE)
NDA No.: 020779 Prod. No.: 001 RX (EQ 250MG BASE)

Patents	Expiration	Patented Use
Pat. No. 5484926 HIV protease inhibitors Claim Types: Compound	OCT 07,2013	
Pat. No. 5952343 HIV protease inhibitors Claim Types: Compound; Composition; Method of use	OCT 07,2013	U-257: Treatment of HIV infection
Exclusivity	Expiration	Exclusivity Description
Exclusivity Code: D - New Dosing Schedule	NOV 24,2002	D-52: Alternate dosing regimen of 1250mg twice daily
Exclusivity Code: NCE - New chemical entity	MAR 14,2002	

Patent Expirations

Products whose first patent expiration is in 2002

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

MIFEPREX (Tablet) (MIFEPRISTONE)

NDA Applicant: POPULATION COUNCIL NDA No.: 020687 Prod. No.: 001 RX (200MG)

Patents	Expiration	Patented Use
Pat. No. 4386085 Novel steroids Claim Types: Compound; Composition; Method of use; Process	Jan 8, 2002	
Pat. No. 4447424 Steroid derivatives Claim Types: Composition; Method of use	Jan 8, 2002	
Pat. No. 4626531 Prostaglandins and antigestagens for induction of labor and for abortion Claim Types: Composition; Method of use	Oct 12, 2004	

PENTASA (Capsule, Extended Release) (MESALAMINE)

NDA Applicant: SHIRE LABS NDA No.: 020049 Prod. No.: 001 RX (250MG)

Patents	Expiration	Patented Use
Pat. No. 4496553 Pharmaceutical composition and method for the treatment of colitis ulcerosa and Crohn's disease by oral administration Claim Types: Method of use	Jan 29, 2002	U-78: Ulcerative colitis
Pat. No. 4980173 Pharmaceutical composition and method for the treatment of colitis ulcerosa and Crohn's disease by oral administration Claim Types: Process; Method of use	Jan 29, 2002	U-78: Ulcerative colitis

PENETREX (Tablet) (ENOXACIN)

NDA Applicant: AVENTIS NDA No.: 019616 Prod. No.: 004 RX (200MG); 005 RX (400MG)

Patents	Expiration	Patented Use
Pat. No. 4442101 Sesquihydrate of naphthyridine derivative, and process for the preparation thereof Claim Types: Compound; Composition; Method of use; Process	Feb 4, 2002	

TECHNESCAN HDP (Injectable) (TECHNETIUM TC-99M OXIDRONATE KIT)

NDA Applicant: MALLINCKRODT NDA No.: 018321 Prod. No.: 001 RX (N/A)

Patents	Expiration	Patented Use
Pat. No. 4497744 Gentisic acid salts as radiographic scanning agent stabilizers Claim Types: Compound	Feb 5, 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 7, 2002 *PED	

ESTRACE (Cream) (ESTRADIOL)

NDA Applicant: WARNER CHILCOTT NDA No.: 086069 Prod. No.: 001 RX (0.01%)

Patents	Expiration	Patented Use
Pat. No. 4436738 Stabilized estradiol cream composition Claim Types: Formulation	Mar 15, 2002	

ELOCON (Ointment) (MOMETASONE FUROATE)

NDA Applicant: SCHERING NDA No.: 019543 Prod. No.: 001 RX (0.1%)

Patents	Expiration	Patented Use
Pat. No. 4472393 3,20-Dioxo-1,4-pregnadiene-17.alpha.-ol 17-aromatic heterocycle carboxylates Claim Types: Compound; Composition; Method of use	Mar 18, 2002 *PED	

ELOCON (Cream) (MOMETASONE FUROATE)

NDA Applicant: SCHERING NDA No.: 019625 Prod. No.: 001 RX (0.1%)

Patents	Expiration	Patented Use
Pat. No. 4472393 3,20-Dioxo-1,4-pregnadiene-17.alpha.-ol 17-aromatic heterocycle carboxylates Claim Types: Compound; Composition; Method of use	Mar 18, 2002 *PED	
Pat. No. 4808610 Mometasone furoate anti-inflammatory cream composition using hexylene glycol Claim Types: Formulation	Apr 2, 2007 *PED	

ELOCON (Lotion) (MOMETASONE FUROATE)

NDA Applicant: SCHERING NDA No.: 019796 Prod. No.: 001 RX (0.1%)

Patents	Expiration	Patented Use
Pat. No. 4472393 3,20-Dioxo-1,4-pregnadiene-17.alpha.-ol 17-aromatic heterocycle carboxylates Claim Types: Compound; Composition; Method of use	Mar 18, 2002 *PED	
Pat. No. 4775529 Steroid lotion Claim Types: Formulation; Method of use	Nov 21, 2007 *PED	

NASONEX (Spray, Metered) (MOMETASONE FUROATE MONOHYDRATE)

NDA Applicant: SCHERING PLOUGH NDA No.: 020762 Prod. No.: 001 RX (EQ 0.05MG BASE/SPRAY)

Patents	Expiration	Patented Use
Pat. No. 4472393 3,20-Dioxo-1,4-pregnadiene-17.alpha.-ol 17-aromatic heterocycle carboxylates Claim Types: Compound; Composition; Method of use	Mar 18, 2002 *PED	
Pat. No. 5837699 Use of mometasone furoate for treating upper airway passage diseases Claim Types: Method of use; Formulation	Jul 27, 2014 *PED	
Pat. No. 6127353 Mometasone furoate monohydrate, process for making same and pharmaceutical compositions Claim Types: New polymorph, salt or hydrate; Composition; Formulation	Apr 3, 2018 *PED	

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 *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 5, 2009 *PED	U-75: Relief of ocular itching due to seasonal allergic conjunctivitis

AXID (Capsule) (NIZATIDINE)

NDA Applicant: LILLY NDA No.: 019508 Prod. No.: 001 RX (150MG); 002 RX (300MG)

Patents	Expiration	Patented Use
Pat. No. 4375547 N-Methyl-N'-2-([(2-dimethylaminomethyl)-4-thiazolyl]methylthio)ethyl 2-nitro-1,1-ethenediamine Claim Types: Compound	Apr 12, 2002	

AXID AR (Tablet) (NIZATIDINE)

NDA Applicant: WYETH CONS NDA No.: 020555 Prod. No.: 001 OTC (75MG)

Patents	Expiration	Patented Use
Pat. No. 4375547 N-Methyl-N'-2-([(2-dimethylaminomethyl)-4-thiazolyl]methylthio)ethyl 2-nitro-1,1-ethenediamine Claim Types: Compound	Apr 12, 2002	

GASTROCROM (Solution, Concentrate) (CROMOLYN SODIUM)

NDA Applicant: CELLTECH PHARMS NDA No.: 020479 Prod. No.: 001 RX (100MG/5ML)

Patents	Expiration	Patented Use
Pat. No. 4515805 Soluble sodium cromoglycate compositions Claim Types: Formulation; Process	May 7, 2002	U-130: Management of patients with mastocytosis

GEREF (Injectable) (SERMORELIN ACETATE)

NDA Applicant: SERONO NDA No.: 019863 Prod. No.: 001 RX (EQ 0.05MG BASE/AMP)

Patents	Expiration	Patented Use
Pat. No. 4517181 Mammalian PGRF Claim Types: Compound; Method of use; Composition	May 14, 2002	
Pat. No. 4703035 Human pancreatic GRF amidated fragments Claim Types: Compound; Composition; Method of use	Dec 28, 2004	

GEREF (Injectable) (SERMORELIN ACETATE)

NDA Applicant: SERONO NDA No.: 020443 Prod. No.: 001 RX (EQ 0.5MG BASE/VIAL); 002 RX (EQ 1MG BASE/VIAL)

Patents	Expiration	Patented Use
Pat. No. 4517181 Mammalian PGRF Claim Types: Compound; Method of use; Composition	May 14, 2002	
Pat. No. 4703035 Human pancreatic GRF amidated fragments Claim Types: Compound; Composition; Method of use	Dec 28, 2004	

IOPIDINE (Solution/Drops) (APRACLONIDINE HYDROCHLORIDE)

NDA Applicant: ALCON NDA No.: 020258 Prod. No.: 001 RX (EQ 0.5% BASE)

Patents	Expiration	Patented Use
Pat. No. 4517199 Method for lowering intraocular pressure using phenylimino-imidazoles Claim Types: Method of use	May 14, 2002	U-15: Method of lowering intraocular pressure

IOPIDINE (Solution/Drops) (APRACLONIDINE HYDROCHLORIDE)

NDA Applicant: ALCON NDA No.: 019779 Prod. No.: 001 RX (EQ 1% BASE)

Patents	Expiration	Patented Use
Pat. No. 4517199 Method for lowering intraocular pressure using phenylimino-imidazoles Claim Types: Method of use	May 14, 2002	U-15: Method of lowering intraocular pressure
Pat. No. 5212196 Control of post-surgical intraocular pressure using clonidine derivatives Claim Types: Method of use	May 18, 2010	U-15: Method of lowering intraocular pressure

PRIMACOR (Injectable) (MILRINONE LACTATE)

NDA Applicant: SANOFI SYNTHELABO NDA No.: 019436 Prod. No.: 001 RX (EQ 1MG BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 4313951 3-Substituted-6-(lower-alkyl)-5-(pyridinyl)-2(1H)-pyridinones, their cardiotonic use and intermediates therefor Claim Types: Compound; Composition; Method of use	May 26, 2002 *PED	

PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER (Injectable) (MILRINONE LACTATE)

NDA Applicant: SANOFI SYNTHELABO NDA No.: 020343 Prod. No.: 003 RX (EQ 20MG BASE/100ML) NDA No.: 020343 Prod. No.: 001 DISC (EQ 10MG BASE/100ML); 002 DISC (EQ 15MG BASE/100ML)

Patents	Expiration	Patented Use
Pat. No. 4313951 3-Substituted-6-(lower-alkyl)-5-(pyridinyl)-2(1H)-pyridinones, their cardiotonic use and intermediates therefor Claim Types: Compound; Composition; Method of use	May 26, 2002 *PED	

ZANTAC IN PLASTIC CONTAINER (Injectable) (RANITIDINE HYDROCHLORIDE)

NDA Applicant: GLAXOSMITHKLINE NDA No.: 019593 Prod. No.: 002 RX (EQ 1MG BASE/ML) NDA No.: 019593 Prod. No.: 001 DISC (EQ 50MG BASE/100ML)

Patents	Expiration	Patented Use
Pat. No. 4521431 Aminoalkyl furan derivative Claim Types: New polymorph, salt or hydrate; Composition; Method of use	Jun 4, 2002 *PED	U-121: Method of treating conditions mediated through histamine H2-receptors
Pat. No. 4585790 Pharmaceutical compositions Claim Types: Formulation	May 11, 2004 *PED	U-121: Method of treating conditions mediated through histamine H2-receptors

SHADE UVAGUARD (Lotion) (AVOBENZONE; OCTYL METHOXYCINNAMATE; OXYBENZONE)

NDA Applicant: SCHERING PLOUGH NDA No.: 020045 Prod. No.: 001 OTC (3%;7.5%;3%)

Patents	Expiration	Patented Use
Pat. No. 4387089 4-(1,1-Dimethylethyl)-4'-methoxydibenzoylmethane Claim Types: Compound; Composition; Formulation; Process;	Jun 7, 2002	
Pat. No. 4522807 Substantive topical compositions Claim Types: Formulation; Process	Jun 11, 2002	

PULMICORT (Powder, Metered) (BUDESONIDE)

NDA Applicant: ASTRAZENECA NDA No.: 020441 Prod. No.: 002 RX (0.16MG/INH) NDA No.: 020441 Prod. No.: 003 DISC (0.32MG/INH)

Patents	Expiration	Patented Use
Pat. No. 4524769 Dosage inhalator Claim Types: Device	Jun 25, 2002	
Pat. No. 4668218 Indicating means for a dosage dispensing device Claim Types: Device	Apr 11, 2006	
Pat. No. 4907583 Device in powder inhalators Claim Types: Device	Mar 13, 2007	

PRINIVIL (Tablet) (LISINAPRIL)

NDA Applicant: MERCK NDA No.: 019558 Prod. No.: 001 RX (5MG); 002 RX (10MG); 003 RX (20MG); 004 RX (40MG); 006 RX (2.5MG)

Patents	Expiration	Patented Use
Pat. No. 4374829 Aminoacid derivatives as antihypertensives Claim Types: Compound; Composition Method of use	Jun 29, 2002 *PED	

ZESTRIL (Tablet) (LISINOPRIL)

NDA Applicant: ASTRAZENECA NDA No.: 019777 Prod. No.: 001 RX (5MG); 002 RX (10MG); 003 RX (20MG); 004 RX (40MG); 005 RX (2.5MG); 006 RX (30MG)

Patents	Expiration	Patented Use
Pat. No. 4374829 Aminoacid derivatives as antihypertensives Claim Types: Compound; Composition Method of use	Jun 29, 2002 *PED	

PRINZIDE (Tablet) (HYDROCHLOROTHIAZIDE; LISINOPRIL)

NDA Applicant: MERCK NDA No.: 019778 Prod. No.: 001 RX (12.5MG;20MG); 002 RX (25MG;20MG); 003 RX (12.5MG;10MG)

Patents	Expiration	Patented Use
Pat. No. 4374829 Aminoacid derivatives as antihypertensives Claim Types: Compound; Composition Method of use	Jun 29, 2002 *PED	

ZESTORETIC (Tablet) (HYDROCHLOROTHIAZIDE; LISINOPRIL)

NDA Applicant: ASTRAZENECA NDA No.: 019888 Prod. No.: 001 RX (12.5MG;20MG); 002 RX (25MG;20MG); 003 RX (12.5MG;10MG)

Patents	Expiration	Patented Use
Pat. No. 4374829 Aminoacid derivatives as antihypertensives Claim Types: Compound; Composition Method of use	Jun 29, 2002 *PED	U-3: Treatment of hypertension

NAVELBINE (Injectable) (VINOELBINE TARTRATE)

NDA Applicant: GLAXOSMITHKLINE NDA No.: 020388 Prod. No.: 001 RX (EQ 10MG BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 4307100 Nor bis-indole compounds usable as medicaments Claim Types: Compound; Composition; Method of use	Jul 8, 2002	

CONCERTA (Tablet, Extended Release) (METHYLPHENIDATE HYDROCHLORIDE)

NDA Applicant: ALZA NDA No.: 021121 Prod. No.: 001 RX (18MG); 002 RX (36MG); 003 RX (54MG)

Patents	Expiration	Patented Use
Pat. No. 4519801 Osmotic device with wall comprising cellulose ether and permeability enhancer Claim Types: Device	Jul 12, 2002 *PED	
Pat. No. 4612008 Osmotic device with dual thermodynamic activity Claim Types: Device	Sep 16, 2003 *PED	
Pat. No. 4783337 Osmotic system comprising plurality of members for dispensing drug Claim Types: Device; Method of administration	Sep 16, 2003 *PED	
Pat. No. 5082668 Controlled-release system with constant pushing source Claim Types: Device	Sep 16, 2003 *PED	

EMLA (Cream) (LIDOCAINE; PRILOCAINE)

NDA Applicant: ASTRAZENECA NDA No.: 019941 Prod. No.: 001 RX (2.5%;2.5%)

Patents	Expiration	Patented Use
Pat. No. 4529601 Local anesthetic mixture for topical application and method for obtaining local anesthesia Claim Types: Formulation; Method of use	Jul 16, 2002	
Pat. No. 4562060 Local anesthetic mixture for topical application, process for its preparation, as well as method for obtaining local anesthesia Claim Types: Device; Method of use	Dec 31, 2002	

MAXZIDE (Tablet) (HYDROCHLOROTHIAZIDE; TRIAMTERENE)

NDA Applicant: MYLAN NDA No.: 019129 Prod. No.: 001 RX (50MG;75MG)

Patents	Expiration	Patented Use
Pat. No. 4444769 Antihypertensive diuretic combination composition and associated method Claim Types: Method of use; Composition	Jul 27, 2002	

MAXZIDE-25 (Tablet) (HYDROCHLOROTHIAZIDE; TRIAMTERENE)

NDA Applicant: MYLAN NDA No.: 019129 Prod. No.: 003 RX (25MG;37.5MG)

Patents	Expiration	Patented Use
Pat. No. 4444769 Antihypertensive diuretic combination composition and associated method Claim Types: Method of use; Composition	Jul 27, 2002	

SOMA COMPOUND (Tablet) (ASPIRIN; CARISOPRODOL)

NDA Applicant: WALLACE PHARMS NDA No.: 012365 Prod. No.: 005 RX (325MG;200MG)

Patents	Expiration	Patented Use
Pat. No. 4534973 Pharmaceutical compositions Claim Types: Composition; Method of use	Aug 13, 2002	

SOMA COMPOUND W/ CODEINE (Tablet) (ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE)

NDA Applicant: WALLACE PHARMS NDA No.: 012366 Prod. No.: 002 RX (325MG;200MG;16MG)

Patents	Expiration	Patented Use
Pat. No. 4534974 Pharmaceutical compositions with codeine Claim Types: Composition; Method of use	Aug 13, 2002	

REGLAN (Injectable) (METOCLOPRAMIDE HYDROCHLORIDE)

NDA Applicant: ROBINS AH NDA No.: 017862 Prod. No.: 001 RX (EQ 5MG BASE/ML) NDA No.: 017862 Prod. No.: 004 DISC (EQ 10MG BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 4536386 Method of controlling emesis caused by cisplatin in cancer chemotherapy Claim Types: Method of use	Aug 20, 2002	U-9: Control of emesis associated with any cancer chemotherapy agent

CARDIOGEN-82 (Injectable) (RUBIDIUM CHLORIDE RB-82)

NDA Applicant: BRACCO NDA No.: 019414 Prod. No.: 001 RX (N/A)

Patents	Expiration	Patented Use
Pat. No. 4400358 Method and adsorbant composition for .sup.82 Rb generation Claim Types: Formulation; Process; Device	Aug 23, 2002	

FLOLAN (Injectable) (EPOPROSTENOL SODIUM)

NDA Applicant: GLAXOSMITHKLINE NDA No.: 020444 Prod. No.: 001 RX (EQ 0.5MG BASE/VIAL); 002 RX (EQ 1.5MG BASE/VIAL)

Patents	Expiration	Patented Use
Pat. No. 4539333 Prostacyclin, methods of using and method of making Claim Types: Compound; Method of use; Process	Sep 3, 2002	
Pat. No. 4883812 Treatment of hypertension using prostacyclin Claim Types: Method of use	May 12, 2006	

XANAX (Tablet) (ALPRAZOLAM)

NDA Applicant: PHARMACIA AND UPJOHN NDA No.: 018276 Prod. No.: 001 RX (0.25MG); 002 RX (0.5MG); 003 RX (1MG); 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	U-46: Treatment of panic disorder

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	

NIMOTOP (Capsule) (NIMODIPINE)

NDA Applicant: BAYER NDA No.: 018869 Prod. No.: 001 RX (30MG)

Patents	Expiration	Patented Use
Pat. No. 4406906 Cerebral therapeutic agent and its use Claim Types: Method of use	Sep 27, 2002	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

PRILOSEC (Capsule, Delayed Rel Pellets) (OMEPRAZOLE)

NDA Applicant: ASTRAZENECA NDA No.: 019810 Prod. No.: 001 RX (20MG); 002 RX (40MG); 003 RX (10MG)

Patents	Expiration	Patented Use
Pat. No. 4508905 Substituted 2-(-benzimidazolyl)pyridines Claim Types: Compound	Oct 2, 2002 *PED	
Pat. No. 4636499 Sulphenamides Claim Types: Compound; Composition; Process; Method of use	Nov 30, 2005 *PED	
Pat. No. 4786505 Pharmaceutical preparation for oral use Claim Types: Formulation; Method of use; Process	Oct 20, 2007 *PED	
Pat. No. 4853230 Pharmaceutical formulations of acid labile substances for oral use Claim Types: Formulation; Process; Method of use	Oct 20, 2007 *PED	
Pat. No. 5093342 Use of omeprazole as an antimicrobial agent Claim Types: Method of use	Aug 2, 2010 *PED	
Pat. No. 5599794 Synergistic combination of a substance with gastric acid secretion inhibiting effect and an acid degradable antibiotic Claim Types: Composition; Method of administration	Aug 4, 2014 *PED	
Pat. No. 5629305 Synergistic combination of a substance with gastric acid secretion inhibiting effect and an acid degradable antibiotic Claim Types: Composition; Method of use	Aug 4, 2014 *PED	
Pat. No. 6147103 Omeprazole process and compositions thereof Claim Types: Formulation	Apr 9, 2019 *PED	
Pat. No. 6191148 Omerazole process and compositions thereof Claim Types: Formulation	Apr 9, 2019 *PED	
Pat. No. 6166213 Omeprazole process and compositions thereof Claim Types: Process; Product-by-process	Apr 19, 2019 *PED	
Pat. No. 6150380 Crystalline form of omeprazole Claim Types: New polymorph, salt or hydrate; Composition; Process	May 10, 2019 *PED	

SANDOSTATIN (Injectable) (OCTREOTIDE ACETATE)

NDA Applicant: NOVARTIS NDA No.: 019667 Prod. No.: 001 RX (EQ 0.05MG BASE/ML); 002 RX (EQ 0.1MG BASE/ML); 003 RX (EQ 0.5MG BASE/ML); 004 RX (EQ 0.2MG BASE/ML); 005 RX (EQ 1MG BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 4395403 Polypeptides, processes for their production, pharmaceutical compositions comprising said polypeptides and their use Claim Types: Compound; Composition; Method of use	Oct 21, 2002	
Pat. No. 5753618 Somatostatin analogue composition and use in treating breast cancer Claim Types: Formulation; Method of use	May 19, 2015	

OPTIRAY 320 (Injectable) (IOVERSOL)

NDA Applicant: MALLINCKRODT NDA No.: 019710 Prod. No.: 001 RX (68%)

Patents	Expiration	Patented Use
Pat. No. 4396598 Triiodoisophthalamide X-ray contrast agent Claim Types: Compound; Composition; Method of use	Oct 26, 2002	U-28: Cerebral, coronary, peripheral, visceral and renal arteriography, aortography and left ventriculography

OPTIRAY 240 (Injectable) (IOVERSOL)

NDA Applicant: MALLINCKRODT NDA No.: 019710 Prod. No.: 002 RX (51%)

Patents	Expiration	Patented Use
Pat. No. 4396598 Triiodoisophthalamide X-ray contrast agent Claim Types: Compound; Composition; Method of use	Oct 26, 2002	U-30: Cerebral angiography, and venography

OPTIRAY 160 (Injectable) (IOVERSOL)

NDA Applicant: MALLINCKRODT NDA No.: 019710 Prod. No.: 003 RX (34%)

Patents	Expiration	Patented Use
Pat. No. 4396598 Triiodoisophthalamide X-ray contrast agent Claim Types: Compound; Composition; Method of use	Oct 26, 2002	U-31: Intra-arterial digital subtraction angiography

OPTIRAY 300 (Injectable) (IOVERSOL)

NDA Applicant: MALLINCKRODT NDA No.: 019710 Prod. No.: 004 RX (64%)

Patents	Expiration	Patented Use
Pat. No. 4396598 Triiodoisophthalamide X-ray contrast agent Claim Types: Compound; Composition; Method of use	Oct 26, 2002	U-61: Cerebral and peripheral arteriography and CT imaging of the head

OPTIRAY 350 (Injectable) (IOVERSOL)

NDA Applicant: MALLINCKRODT NDA No.: 019710 Prod. No.: 005 RX (74%)

Patents	Expiration	Patented Use
Pat. No. 4396598 Triiodoisophthalamide X-ray contrast agent Claim Types: Compound; Composition; Method of use	Oct 26, 2002	U-62: Coronary arteriography, left ventriculography, CT imaging of the body, intravenous excretory urography, intravenous digital subtraction angiography and venography

BSS PLUS (Solution) (CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE)

NDA Applicant: ALCON NDA No.: 018469 Prod. No.: 001 RX (0.154MG/ML;0.92MG/ML;0.184MG/ML;0.2MG/ML;0.38MG/ML;2.1MG/ML;7.14MG/ML;0.42MG/ML)

Patents	Expiration	Patented Use
Pat. No. 4550022 Tissue irrigating solution Claim Types: Device	Oct 29, 2002	

LYOPHILIZED CYTOXAN (Injectable) (CYCLOPHOSPHAMIDE)

NDA Applicant: BRISTOL MYERS SQUIBB NDA No.: 012142 Prod. No.: 006 RX (100MG/VIAL); 007 RX (200MG/VIAL); 008 RX (500MG/VIAL); 009 RX (2GM/VIAL); 010 RX (1GM/VIAL)

Patents	Expiration	Patented Use
Pat. No. 4537883 Lyophilized cyclophosphamide Claim Types: Formulation	Nov 12, 2002	

SANDOSTATIN LAR (Injectable) (OCTREOTIDE ACETATE)

NDA Applicant: NOVARTIS NDA No.: 021008 Prod. No.: 001 RX (EQ 10MG BASE/VIAL); 002 RX (EQ 20MG BASE/VIAL); 003 RX (EQ 30MG BASE/VIAL)

Patents	Expiration	Patented Use
Pat. No. 4395403 Polypeptides, processes for their production, pharmaceutical compositions comprising said polypeptides and their use Claim Types: Compound; Composition; Method of use	Nov 21, 2002	U-269: Excess GH-secretion or gastro-intestinal disorders
Pat. No. 5538739 Sustained release formulations of water soluble peptides Claim Types: Formulation	Jul 23, 2013	U-269: Excess GH-secretion or gastro-intestinal disorders
Pat. No. 5639480 Sustained release formulations of water soluble peptides Claim Types: Formulation	Jun 17, 2014	U-269: Excess GH-secretion or gastro-intestinal disorders
Pat. No. 5688530 Sustained release formulations of water soluble peptides Claim Types: Method of use	Nov 18, 2014	U-269: Excess GH-secretion or gastro-intestinal disorders
Pat. No. 5922338 Polyol esters, their preparation and use in depot forms of pharmacologically active agents Claim Types: Composition	Jul 13, 2016	U-269: Excess GH-secretion or gastro-intestinal disorders
Pat. No. 5922682 Polyol esters, their preparation and use in depot forms of pharmacologically active agents Claim Types: Excipient; Formulation	Jul 13, 2016	U-269: Excess GH-secretion or gastro-intestinal disorders
Pat. No. 6395292 Sustained delivery of an active agent using an implantable system Claim Types: Device; Method of use; Method of administration; Process	Jan 30, 2017	U-269: Excess GH-secretion or gastro-intestinal disorders

MONOPRIL (Tablet) (FOSINOPRIL SODIUM)

NDA Applicant: BRISTOL MYERS SQUIBB NDA No.: 019915 Prod. No.: 002 RX (10MG); 003 RX (20MG); 004 RX (40MG)

Patents	Expiration	Patented Use
Pat. No. 4337201 Phosphinylalkanoyl substituted prolines Claim Types: Compound	Dec 4, 2002	
Pat. No. 5006344 Fosinopril tablet formulations Claim Types: Formulation	Jul 10, 2009	

MONOPRIL-HCT (Tablet) (FOSINOPRIL SODIUM; HYDROCHLOROTHIAZIDE)

NDA Applicant: BRISTOL MYERS SQUIBB NDA No.: 020286 Prod. No.: 001 RX (20MG;12.5MG); 002 RX (10MG;12.5MG)

Patents	Expiration	Patented Use
Pat. No. 4337201 Phosphinylalkanoyl substituted prolines Claim Types: Compound	Dec 4, 2002	
Pat. No. 5006344 Fosinopril tablet formulations Claim Types: Formulation	Jul 10, 2009	

ZANTAC (Injectable) (RANITIDINE HYDROCHLORIDE)

NDA Applicant: GLAXOSMITHKLINE NDA No.: 019090 Prod. No.: 001 RX (EQ 25MG BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 4521431 Aminoalkyl furan derivative Claim Types: New polymorph, salt or hydrate; Composition; Method of use	Dec 4, 2002 *PED	
Pat. No. 4585790 Pharmaceutical compositions Claim Types: Formulation	Nov 11, 2004 *PED	

ZANTAC (Syrup) (RANITIDINE HYDROCHLORIDE)

NDA Applicant: GLAXOSMITHKLINE NDA No.: 019675 Prod. No.: 001 RX (EQ 15MG BASE/ML)

Patents	Expiration	Patented Use
Pat. No. 4521431 Aminoalkyl furan derivative Claim Types: New polymorph, salt or hydrate; Composition; Method of use	Dec 4, 2002 *PED	
Pat. No. 4585790 Pharmaceutical compositions Claim Types: Formulation	Nov 11, 2004 *PED	
Pat. No. 5068249 Aqueous ranitidine compositions stabilized with ethanol Claim Types: Formulation	May 26, 2009 *PED	

ZANTAC 150 (Tablet) (RANITIDINE HYDROCHLORIDE)

NDA Applicant: GLAXOSMITHKLINE NDA No.: 018703 Prod. No.: 001 RX (EQ 150MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4521431 Aminoalkyl furan derivative Claim Types: New polymorph, salt or hydrate; Composition; Method of use	Dec 4, 2002 *PED	
Pat. No. 4880636 Film coated tablet of ranitidine HCl Claim Types: Formulation	Nov 13, 2008 *PED	

ZANTAC 300 (Tablet) (RANITIDINE HYDROCHLORIDE)

NDA Applicant: GLAXOSMITHKLINE NDA No.: 018703 Prod. No.: 002 RX (EQ 300MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4521431 Aminoalkyl furan derivative Claim Types: New polymorph, salt or hydrate; Composition; Method of use	Dec 4, 2002 *PED	
Pat. No. 4880636 Film coated tablet of ranitidine HCl Claim Types: Formulation	Nov 13, 2008 *PED	

ZANTAC 75 (Tablet) (RANITIDINE HYDROCHLORIDE)

NDA Applicant: WARNER LAMBERT NDA No.: 020520 Prod. No.: 001 OTC (EQ 75MG BASE)

Patents	Expiration	Patented Use
Pat. No. 4521431 Aminoalkyl furan derivative Claim Types: New polymorph, salt or hydrate; Composition; Method of use	Dec 4, 2002 *PED	
Pat. No. 4880636 Film coated tablet of ranitidine HCl Claim Types: Formulation	Nov 13, 2008 *PED	