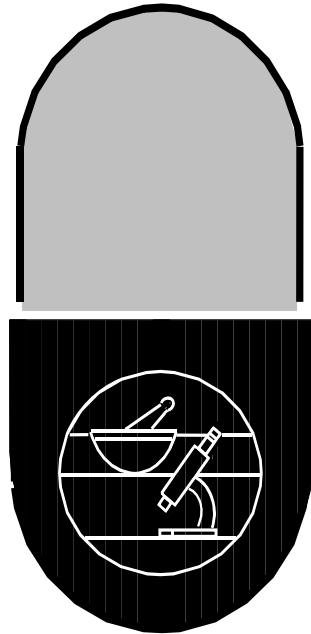


**CUMULATIVE  
SUPPLEMENT 2  
February 2012**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**32nd EDITION**

**Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Generic Drugs**

2012

Prepared By  
Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration

**APPROVED DRUG PRODUCTS  
with  
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**32<sup>nd</sup> EDITION**

**Cumulative Supplement 2**

**February 2012**

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**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**32nd EDITION**

**CUMULATIVE SUPPLEMENT 2  
February 2012**

**1.0 INTRODUCTION**

**1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT**

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 30th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; over-the-counter (OTC) drug products that require approved applications as a condition of marketing; drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research; and products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to mark to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement. Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision.

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case, the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Products that have never been marketed, are for exportation, are for military use, or have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 32nd Edition List will then be added to the "Discontinued Drug Product List" appearing in the 33rd Edition. The current Edition Section 2., How To Use The Drug Product Lists, describes the layout and usage of the List.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >A>. The Patent and Exclusivity List new additions are indicated by the symbol >A> to the left of Patent Number or Exclusivity Code. The >A> symbol is then dropped in subsequent Cumulative Supplements for that item.

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >D> (DELETE) to the left of the line. The information line with the >D> symbol is dropped in subsequent Cumulative Supplements for that item.

The Patent and Exclusivity List is arranged in alphabetical order by active ingredient name(s) and trade name. The trade name will follow the active ingredient name separated by a dash symbol. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Drug substance and drug product patents are indicated as such with DS or DP in the Patent codes column. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms, Section B, in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Refer to Section 1.3 for internet access to the most current list of Patent and Exclusivity terms.

## 1.2 CUMULATIVE SUPPLEMENT CONTENT

Since February 2005, we have been providing daily Electronic Orange Book (EOB) product information for new generic drug approvals. Daily generic updates provide the consumer with the current list of approved generic products which is important for substitution purposes. Previously, a first-time-generic product approved early in the month would not be published in the Cumulative Supplement (CS) for several weeks.

The CS monthly update publish goal is by the end of the following month's second work week (e.g., November's supplement will be updated by the end of the second full work week in December).

Currently, the monthly PDF CS includes:

- Generic product ANDA (Abbreviated New Drug Approval) approvals as of the date of publication.
- All product changes received and processed as of the date of publication.
  - Refer to CS Section 1.8 Cumulative Supplement Legend for types of changes
  - Discontinued products will be processed as of the date of publication. There will be circumstances where a product is discontinued in one month, however, it will be reported in a different month's CS. For example, the Orange Book Staff received a letter November 7 that the product has been discontinued from manufacturing and marketing. The Orange Book subsequently publishes the October CS on November 14. The product will show in the October CS that it is discontinued even though the date of discontinuance is the day that the Orange Book Staff receives notification (November 7).
- New Drug Application (NDA) approvals (20,000 and 50,000 series) appear in the CS month they were approved.

- Patent information, also updated daily in the EOB, is current to the date of publication.
- Exclusivity information is updated monthly and current to the date of publication.

Every effort is made to ensure the Cumulative Supplement is current and accurate. Applicant holders are requested to inform the FDA Orange Book Staff (OBS) of any changes or corrections. The OBS can be contacted by email at [drugproducts@fda.hhs.gov](mailto:drugproducts@fda.hhs.gov). Send Changes by FAX: 240-276-8974; mail to:

FDA/CDER Orange Book Staff  
Office of Generic Drugs, HFD-610  
7620 Standish Place  
Rockville, MD 20855-2773

### 1.3 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section. The Electronic Orange Book Query, updated monthly, will contain the most current applicant holder name.

<u>FORMER APPLICANT NAME</u> <u>(FORMER ABBREVIATED NAME)</u>	<u>NEW APPLICANT NAME</u> <u>(NEW ABBREVIATED NAME)</u>
ALCON UNIVERSAL LTD (ALCON UNIVERSAL)	ALCON PHARMACEUTICALS LTD (ALCON PHARMS LTD)
OVATION PHARMACEUTICALS INC (OVATION PHARMS)	OAK PHARMACEUTICALS INC (OAK PHARMS)

### 1.4 LEVOTHYROXINE SODIUM

Because there are multiple reference listed drugs of levothyroxine sodium tablets and some reference listed drugs' sponsors have conducted studies to establish their drugs' therapeutic equivalence to other reference listed drugs, FDA has determined that its usual practice of assigning two or three character TE codes may be potentially confusing and inadequate for these drug products. Accordingly, FDA provides the following explanation and chart of therapeutic equivalence evaluations for levothyroxine sodium drug products.

Levothyroxine Sodium (Mylan ANDA 76187) and Levo-T (Alara NDA 21342) tablets have been determined to be therapeutically equivalent to corresponding strengths of Unithroid (Jerome Stevens NDA 021210) tablets. Levo-T (Alara NDA 021342), Levothyroxine Sodium (Mylan ANDA 76187), Unithroid (Jerome Stevens NDA 021210), and Levothyroxine Sodium (Merck KGAA ANDA 76752) tablets have been determined to be therapeutically equivalent to corresponding strengths of Synthroid (Abbott NDA 021402) tablets.

Levo-T (Alara NDA 021342), Unithroid (Jerome Stevens NDA 021210), Levothyroxine Sodium (Mylan ANDA 076187), and Levothyroxine Sodium (Merck KGAA ANDA 76752) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levoxyl (King Pharms NDA 021301) tablets.

Levothyroxine Sodium (Mylan ANDA 76187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levotheroid (Lloyd NDA 021116) tablets.

The chart outlines TE codes for all 0.025mg products. Other product strengths may be similar. Therapeutic equivalence has been established between products that have the same AB+number TE code. More than one TE code may apply to some products. One common TE code indicates therapeutic equivalence between products.

Trade Name	Applicant	Potency	TE Code	Appl No	Product No
UNITHROID	STEVENS J	0.025MG	AB1	21210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB1	76187	001
LEVOXYL	KING PHARMS	0.025MG	AB1	21301	001
SYNTHROID	ABBOTT	0.025MG	AB1	21402	001
LEVO-T	ALARA PHARM	0.025MG	AB1	21342	001
SYNTHROID	ABBOTT	0.025MG	AB2	21402	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB2	76187	001
LEVO-T	ALARA PHARM	0.025MG	AB2	21342	001
UNITHROID	STEVENS J	0.025MG	AB2	21210	001
LEVOTHYROXINE SODIUM	MERCK KGAA	0.025MG	AB2	76752	001
LEVOXYL	KUNG PHARMS	0.025MG	AB3	21301	001
LEVO-T	ALARA PHARM	0.025MG	AB3	21342	001
UNITHROID	STEVENS J	0.025MG	AB3	21210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB3	76187	001
LEVOTHYROXINE SODIUM	MERCK KGAA	0.025MG	AB3	76752	001
LEVOTHEROID	LLOYD	0.025MG	AB4	21116	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB4	76187	001

## 1.5 AVAILABILITY OF THE EDITION

Since 1997, the Electronic Orange Book Query (EOBQ) <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>, has been available on the internet and has become the updated-every-month Orange Book. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder, applicant number or patent number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product.

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements have been provided in downloadable Portable Document Format (PDF) at the EOB home page by clicking on Publications. The PDF annual and cumulative supplements duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

The downloaded Annual Edition and Cumulative Supplements are also available in a paper version (Approved Drug Products with Therapeutic Equivalence Evaluations, ADP) from the U.S. Government Printing Office: <http://bookstore.gpo.gov>; toll free 866-512-1800.

There are historical lists of Orange Book cumulative supplement product monthly changes at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm>. There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm129689.htm>. The drug product text files are provided in eobzip.zip format. The files are updated concurrently with the monthly cumulative supplements. The annual Orange Book Edition Appendices A, B, and C in PDF format are updated quarterly.

Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the FDA Forms List, <http://www.fda.gov/opacom/morechoices/fdaforms/default.html>.

The current listing of the Orphan Product Designations and Approvals is available at <http://www.fda.gov/orphan/designat/list.htm>.

## 1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

### DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 2011) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

### DEFINITIONS

#### Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

#### New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use



in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST  
COUNTS CUMULATIVE BY QUARTER

<u>CATEGORIES COUNTED</u>	<u>DEC 2011</u>	<u>MAR 2012</u>	<u>JUN 2012</u>	<u>SEPT 2012</u>	<u>DEC 2012</u>
DRUG PRODUCTS LISTED	14480				
SINGLE SOURCE	2451				
	(16.9%)				
MULTISOURCE	11953				
	(82.5%)				
THERAPEUTICALLY EQUIVALENT	11792				
	(81.4%)				
NOT THERAPEUTICALLY EQUIVALENT	161				
	(1.1%)				
EXCEPTIONS <sup>1</sup>	76				
	(0.5%)				
NEW MOLECULAR ENTITIES APPROVED	6				
NUMBER OF APPLICANTS	810				

<sup>1</sup>Amino acid-containing products of varying composition (see Introduction, page xx of the List).

## 1.7 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The application number preceded by "N" is a New Drug Application (NDA or innovator). The application number preceded by an "A" is an Abbreviated New Drug Application (ANDA or generic). The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

New ingredient(s), new dosage form; route(s), new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA. Following months will display the same information without the >A>.

Changes to currently listed products will list two records. The deleted product record will be preceded by >D>. The product record change addition being made will be preceded by >A>. Following months will display only the >A> record without the >A>. All changes that occur to the product through the Annual year will be listed. The change month and change code will document the change.

The change code and description:

NEWA	New drug product approval usually in the supplement month.
CAHN	Applicant holder firm name has changed.
CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.

CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMS1	Change. Miscellaneous addition to list.
CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.

PRESCRIPTION DRUG PRODUCT LIST - 32ND EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2012

1-1

ACARBOSE

TABLET; ORAL

ACARBOSE

AB	EMCURE PHARMS LTD	25MG	A202271 001	Feb 07, 2012	Jan	NEWA
AB		50MG	A202271 002	Feb 07, 2012	Jan	NEWA
AB		100MG	A202271 003	Feb 07, 2012	Jan	NEWA

ACETAMINOPHEN; CODEINE PHOSPHATE

SOLUTION; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

AA	+ PHARM ASSOC	120MG/5ML;12MG/5ML	A087508 001		Jan	CRLD
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SUSPENSION; ORAL

CAPITAL AND CODEINE

	+ VALEANT	120MG/5ML;12MG/5ML	A086024 001		Jan	CTEC
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ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA	VISTAPHARM	325MG/15ML;7.5MG/15ML	A200343 001	Jan 25, 2012	Jan	NEWA
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ADAPALENE

CREAM; TOPICAL

ADAPALENE

AB	FOUGERA PHARMS	0.1%	A090824 001	Jun 30, 2010	Jan	CAHN
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ADENOSINE

INJECTABLE; INJECTION

ADENOSINE

	@ TEVA PARENTERAL	3MG/ML	A076564 001	Jun 16, 2004	Jan	DISC
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ALCLOMETASONE DIPROPIONATE

CREAM; TOPICAL

ALCLOMETASONE DIPROPIONATE

AB	FOUGERA PHARMS	0.05%	A076973 001	Jul 12, 2005	Jan	CAHN
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OINTMENT; TOPICAL

ALCLOMETASONE DIPROPIONATE

AB	FOUGERA PHARMS	0.05%	A076884 001	Jul 18, 2005	Jan	CAHN
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ALFUZOSIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

ALFUZOSIN HYDROCHLORIDE

AB	INVAGEN PHARMS	10MG	A090284 001	Jan 17, 2012	Jan	NEWA
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ALPRAZOLAM

TABLET, ORALLY DISINTEGRATING; ORAL

NIRAVAM

AB	UCB INC	0.25MG	N021726 001	Jan 19, 2005	Jan	CAHN
AB		0.5MG	N021726 002	Jan 19, 2005	Jan	CAHN
AB	+	1MG	N021726 003	Jan 19, 2005	Jan	CAHN
AB		2MG	N021726 004	Jan 19, 2005	Jan	CAHN

ALVIMOPAN

CAPSULE; ORAL

ENTEREG

>D>	+	ADOLOR	12MG	N021775 001	May 20, 2008	Feb	CAHN
>A>	+	CUBIST PHARMS	12MG	N021775 001	May 20, 2008	Feb	CAHN

AMCINONIDE

CREAM; TOPICAL

AMCINONIDE

AB	+	FOUGERA PHARMS	0.1%	A076065 001	May 15, 2003	Jan	CAHN
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LOTION; TOPICAL

AMCINONIDE

	+	FOUGERA PHARMS	0.1%	A076329 001	Nov 06, 2002	Jan	CAHN
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OINTMENT; TOPICAL

AMCINONIDE

AB	+	FOUGERA PHARMS	0.1%	A076096 001	Nov 19, 2002	Jan	CAHN
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AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION

AMIODARONE HYDROCHLORIDE

	@	TEVA PARENTERAL	50MG/ML	A076163 001	Sep 05, 2003	Jan	DISC
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AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

CHLORDIAZEPOXIDE AND AMITRIPTYLINE HYDROCHLORIDE

>D>	AB	MYLAN	EQ 12.5MG BASE;5MG	A071297 002	Dec 10, 1986	Feb	CTEC
>D>	AB		EQ 25MG BASE;10MG	A071297 001	Dec 10, 1986	Feb	CRLD
>A>		MYLAN PHARMS INC	EQ 12.5MG BASE;5MG	A071297 002	Dec 10, 1986	Feb	CTEC
>A>	+		EQ 25MG BASE;10MG	A071297 001	Dec 10, 1986	Feb	CRLD
>D>		LIMBITROL					
>D>	AB	VALEANT PHARM INTL	EQ 12.5MG BASE;5MG	N016949 001		Feb	DISC
>A>		@	EQ 12.5MG BASE;5MG	N016949 001		Feb	DISC
>D>		LIMBITROL DS					
>D>	AB	VALEANT PHARM INTL	EQ 25MG BASE;10MG	N016949 002		Feb	DISC
>A>		@	EQ 25MG BASE;10MG	N016949 002		Feb	DISC

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

AB		AUROBINDO PHARMA LTD	250MG;EQ 125MG BASE	A091569 001	Jan 20, 2012	Jan	NEWA
AB			500MG;EQ 125MG BASE	A091569 002	Jan 20, 2012	Jan	NEWA
AB			875MG;EQ 125MG BASE	A091568 001	Jan 20, 2012	Jan	NEWA

ANAGRELIDE HYDROCHLORIDE

CAPSULE; ORAL

AGRYLIN

AB		SHIRE LLC	EQ 0.5MG BASE	N020333 001	Mar 14, 1997	Jan	CAHN
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ARGATROBAN

INJECTABLE; INJECTION

ACOVA

AP	+	PFIZER	250MG/2.5ML (100MG/ML)	N020883 001	Jun 30, 2000	Jan	CTNA
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ARGATROBAN

AP		HIKMA PHARM CO LTD	250MG/2.5ML (100MG/ML)	N203049 001	Jan 05, 2012	Jan	NEWA
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ASCORBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE

FOR SOLUTION; ORAL

ASCORBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE

AA		NOVEL LABS INC	4.7GM;100GM;1.015GM;5.9MG;2.691GM ;7.5GM	A090145 001	Jan 25, 2012	Jan	NEWA
		MOVIPREP					
AA	+	SALIX PHARMS	4.7GM;100GM;1.015GM;5.9MG;2.691GM ;7.5GM	N021881 001	Aug 02, 2006	Jan	CFTG

ASPIRIN; CARISOPRODOL

TABLET; ORAL

CARISOPRODOL AND ASPIRIN

>D>	AB	ACTAVIS TOTOWA	325MG;200MG	A040252 001	Dec 10, 1997	Feb	CAHN
>A>	AB	PROSAM LABS	325MG;200MG	A040252 001	Dec 10, 1997	Feb	CAHN

ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE

TABLET; ORAL

CARISOPRODOL, ASPIRIN AND CODEINE PHOSPHATE

>D>	AB	ACTAVIS TOTOWA	325MG;200MG;16MG	A040283 001	Dec 29, 1998	Feb	CAHN
>A>	AB	PROSAM LABS	325MG;200MG;16MG	A040283 001	Dec 29, 1998	Feb	CAHN

ATRACURIUM BESYLATE

INJECTABLE; INJECTION

ATRACURIUM BESYLATE

>D>	+	BEDFORD	10MG/ML	A074901 001	Jul 18, 1997	Feb	CTEC
>A>	AP	+	10MG/ML	A074901 001	Jul 18, 1997	Feb	CTEC
>A>	AP	SAGENT PHARMS	10MG/ML	A091489 001	Feb 17, 2012	Feb	NEWA
		ATRACURIUM BESYLATE PRESERVATIVE FREE					
>D>	+	BEDFORD	10MG/ML	A074900 001	Jul 18, 1997	Feb	CTEC
>A>	AP	+	10MG/ML	A074900 001	Jul 18, 1997	Feb	CTEC
>A>	AP	SAGENT PHARMS	10MG/ML	A091488 001	Feb 17, 2012	Feb	NEWA

AXITINIB

TABLET; ORAL

INLYTA

		PFIZER	1MG	N202324 001	Jan 27, 2012	Jan	NEWA
		+	5MG	N202324 002	Jan 27, 2012	Jan	NEWA

BACLOFEN

TABLET; ORAL

BACLOFEN

>D>	AB	ACTAVIS TOTOWA	10MG	A077089 001	Oct 31, 2007	Feb	CAHN
>D>	AB		20MG	A077088 001	Oct 31, 2007	Feb	CAHN
>A>	AB	PROSAM LABS	10MG	A077089 001	Oct 31, 2007	Feb	CAHN
>A>	AB		20MG	A077088 001	Oct 31, 2007	Feb	CAHN

TABLET, ORALLY DISINTEGRATING; ORAL

KEMSTRO

		@ UCB INC	10MG	N021589 001	Oct 30, 2003	Jan	CAHN
		@	20MG	N021589 002	Oct 30, 2003	Jan	CAHN

BALSALAZIDE DISODIUM

>A>		TABLET; ORAL					
>A>		GIAZO					
>A>	+	SALIX PHARMS	1.1GM	N022205 001	Feb 03, 2012	Feb	NEWA

BENZOYL PEROXIDE; ERYTHROMYCIN

GEL; TOPICAL

BENZAMYCIN

AB	+	VALEANT INTL	5%;3%	N050557	001	Oct 26, 1984	Jan	CAHN
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BENZPHETAMINE HYDROCHLORIDE

TABLET; ORAL

BENZPHETAMINE HYDROCHLORIDE

AA		EMCURE PHARMS LTD	50MG	A202061	001	Jan 27, 2012	Jan	NEWA
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BENZTROPINE MESYLATE

INJECTABLE; INJECTION

COGENTIN

>D>	AP	+	LUNDBECK INC	1MG/ML	N012015	001		Feb	CAHN
>A>	AP	+	OAK PHARMS AKORN	1MG/ML	N012015	001		Feb	CAHN

TABLET; ORAL

BENZTROPINE MESYLATE

>D>		@	ACTAVIS TOTOWA	0.5MG	A040699	001	Feb 14, 2008	Feb	CMFD
>D>		@		1MG	A040705	001	Feb 14, 2008	Feb	CMFD
>D>		@		2MG	A040706	001	Feb 14, 2008	Feb	CMFD
		@	LANNETT HOLDINGS INC	0.5MG	A088877	001	Apr 11, 1985	Jan	DISC
		@		1MG	A088894	001	Apr 11, 1985	Jan	DISC
		@		2MG	A088895	001	Apr 11, 1985	Jan	DISC
>A>	AA		PROSAM LABS	0.5MG	A040699	001	Feb 14, 2008	Feb	CMFD
>A>	AA			1MG	A040705	001	Feb 14, 2008	Feb	CMFD
>A>	AA			2MG	A040706	001	Feb 14, 2008	Feb	CMFD
	AA	+	USL PHARMA	0.5MG	A040103	001	Dec 12, 1996	Jan	CRLD
	AA	+		1MG	A040103	002	Dec 12, 1996	Jan	CRLD
	AA	+		2MG	A040103	003	Dec 12, 1996	Jan	CRLD

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

BETAMETHASONE DIPROPIONATE

AB	+	FOUGERA PHARMS	EQ 0.05% BASE	N019137	001	Jun 26, 1984	Jan	CAHN
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CREAM, AUGMENTED; TOPICAL

BETAMETHASONE DIPROPIONATE

AB		FOUGERA PHARMS	EQ 0.05% BASE	A076215	001	Dec 09, 2003	Jan	CAHN
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GEL, AUGMENTED; TOPICAL

BETAMETHASONE DIPROPIONATE

AB	+	FOUGERA PHARMS	EQ 0.05% BASE	A075276	001	May 13, 2003	Jan	CAHN
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LOTION, AUGMENTED; TOPICAL

BETAMETHASONE DIPROPIONATE

AB		FOUGERA PHARMS	EQ 0.05% BASE	A077111	001	May 21, 2007	Jan	CAHN
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OINTMENT, AUGMENTED; TOPICAL

BETAMETHASONE DIPROPIONATE

AB		FOUGERA PHARMS	EQ 0.05% BASE	A075373	001	Jun 22, 1999	Jan	CAHN
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BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE

CREAM; TOPICAL

CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE

AB		FOUGERA PHARMS	EQ 0.05% BASE;1%	A075502	001	Jun 05, 2001	Jan	CAHN
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LOTION; TOPICAL

CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE

AB		FOUGERA PHARMS	EQ 0.05% BASE;1%	A076516	001	Jun 16, 2005	Jan	CAHN
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## LOTION; TOPICAL

## LOTRISONE

>A>	AB	+	SCHERING CORP	EQ 0.05% BASE;1%	N020010	001	Dec 08, 2000	Feb	CAHN
>D>	AB	+	SCHERING PLOUGH RES	EQ 0.05% BASE;1%	N020010	001	Dec 08, 2000	Feb	CAHN

BETAMETHASONE VALERATE

## AEROSOL, FOAM; TOPICAL

## LUXIQ

	+	STIEFEL	EQ 0.12% BASE	N020934	001	Feb 28, 1999	Jan	CAHN
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BISOPROLOL FUMARATE

## TABLET; ORAL

## ZEBETA

AB		TEVA WOMENS	5MG	N019982	002	Jul 31, 1992	Jan	CAHN
AB	+		10MG	N019982	001	Jul 31, 1992	Jan	CAHN

BORTEZOMIB

## INJECTABLE; INTRAVENOUS, SUBCUTANEOUS

## VELCADE

	+	MILLENNIUM PHARMS	3.5MG/VIAL	N021602	001	May 13, 2003	Jan	CDFR
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BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE

## AEROSOL, METERED; INHALATION

## SYMBICORT

	+	ASTRAZENECA	0.08MG/INH;0.0045MG/INH	N021929	001	Jul 21, 2006	Jan	CDFR
	+		0.16MG/INH;0.0045MG/INH	N021929	002	Jul 21, 2006	Jan	CDFR

BUSPIRONE HYDROCHLORIDE

## TABLET; ORAL

## BUSPIRONE HYDROCHLORIDE

>D>		@	ACTAVIS TOTOWA	5MG	A075388	001	May 09, 2002	Feb	CMFD
>D>		@		10MG	A075388	002	May 09, 2002	Feb	CMFD
>D>		@		15MG	A075388	003	May 09, 2002	Feb	CMFD
>D>		@		30MG	A078302	001	Dec 17, 2007	Feb	CMFD
>A>	AB		PROSAM LABS	5MG	A075388	001	May 09, 2002	Feb	CMFD
>A>	AB			10MG	A075388	002	May 09, 2002	Feb	CMFD
>A>	AB			15MG	A075388	003	May 09, 2002	Feb	CMFD
>A>	AB			30MG	A078302	001	Dec 17, 2007	Feb	CMFD

CAFFEINE CITRATE

## SOLUTION; INTRAVENOUS

## CAFCIT

AP	+	BEDFORD LABS	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	N020793	001	Sep 21, 1999	Jan	CAHN
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## SOLUTION; ORAL

## CAFCIT

AA	+	BEDFORD LABS	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	N020793	002	Apr 12, 2000	Jan	CAHN
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CALCIPOTRIENE

## SOLUTION; TOPICAL

## CALCIPOTRIENE

AT		FOUGERA PHARMS	0.005%	A078305	001	May 06, 2008	Jan	CAHN
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CARBIDOPA; LEVODOPA

TABLET, ORALLY DISINTEGRATING; ORAL

PARCOPA

AB	UCB INC	10MG;100MG	A076699 001	Aug 27, 2004	Jan	CAHN
AB		25MG;100MG	A076699 002	Aug 27, 2004	Jan	CAHN
AB	+	25MG;250MG	A076699 003	Aug 27, 2004	Jan	CAHN

CARBOPLATIN

INJECTABLE; INJECTION

PARAPLATIN

>D>	@	BRISTOL MYERS SQUIBB	50MG/VIAL	N019880 001	Mar 03, 1989	Feb	CAHN
>D>	@		150MG/VIAL	N019880 002	Mar 03, 1989	Feb	CAHN
>D>	@		450MG/VIAL	N019880 003	Mar 03, 1989	Feb	CAHN
>A>	@	CORDEN PHARMA	50MG/VIAL	N019880 001	Mar 03, 1989	Feb	CAHN
>A>	@		150MG/VIAL	N019880 002	Mar 03, 1989	Feb	CAHN
>A>	@		450MG/VIAL	N019880 003	Mar 03, 1989	Feb	CAHN

INJECTABLE; IV (INFUSION)

CARBOPLATIN

AP	ACTAVIS TOTOWA	50MG/5ML (10MG/ML)	A078732 001	Feb 06, 2012	Jan	NEWA
AP		150MG/15ML (10MG/ML)	A078732 002	Feb 06, 2012	Jan	NEWA
AP		450MG/45ML (10MG/ML)	A078732 003	Feb 06, 2012	Jan	NEWA
AP		600MG/60ML (10MG/ML)	A078732 004	Feb 06, 2012	Jan	NEWA

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

>D>	AA	ACTAVIS TOTOWA	350MG	A040188 001	Mar 07, 1997	Feb	CAHN
>A>	AA	PROSAM LABS	350MG	A040188 001	Mar 07, 1997	Feb	CAHN

CEFACLOR

FOR SUSPENSION; ORAL

CEFACLOR

>D>	+	RANBAXY	EQ 125MG BASE/5ML	A064166 001	Oct 02, 1997	Feb	CTEC
>A>	AB	+	EQ 125MG BASE/5ML	A064166 001	Oct 02, 1997	Feb	CTEC
>D>	+		EQ 187MG BASE/5ML	A064165 001	Oct 02, 1997	Feb	CTEC
>A>	AB	+	EQ 187MG BASE/5ML	A064165 001	Oct 02, 1997	Feb	CTEC
>D>	+		EQ 250MG BASE/5ML	A064164 001	Oct 02, 1997	Feb	CTEC
>A>	AB	+	EQ 250MG BASE/5ML	A064164 001	Oct 02, 1997	Feb	CTEC
>D>	+		EQ 375MG BASE/5ML	A064155 001	Oct 02, 1997	Feb	CTEC
>A>	AB	+	EQ 375MG BASE/5ML	A064155 001	Oct 02, 1997	Feb	CTEC
>A>	AB	YUNG SHIN PHARM	EQ 125MG BASE/5ML	A065412 001	Feb 17, 2012	Feb	NEWA
>A>	AB		EQ 187MG BASE/5ML	A065412 002	Feb 17, 2012	Feb	NEWA
>A>	AB		EQ 250MG BASE/5ML	A065412 003	Feb 17, 2012	Feb	NEWA
>A>	AB		EQ 375MG BASE/5ML	A065412 004	Feb 17, 2012	Feb	NEWA

CEFPROZIL

FOR SUSPENSION; ORAL

CEFPROZIL

>A>	AB	APOTEX INC	125MG/5ML	A065351 001	Feb 29, 2012	Feb	NEWA
>A>	AB		250MG/5ML	A065351 002	Feb 29, 2012	Feb	NEWA

TABLET; ORAL

CEFZIL

>D>	@	BRISTOL MYERS SQUIBB	250MG	N050664 001	Dec 23, 1991	Feb	CAHN
>D>	@		500MG	N050664 002	Dec 23, 1991	Feb	CAHN
>A>	@	CORDEN PHARMA	250MG	N050664 001	Dec 23, 1991	Feb	CAHN



## TABLET; ORAL

CEFZIL

>A>	@	CORDEN PHARMA	500MG	N050664	002	Dec 23, 1991	Feb	CAHN
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CICLESONIDE

AEROSOL, METERED; NASAL

ZETONNA

	+	NYCOMED GMBH	0.037MG/INH	N202129	001	Jan 20, 2012	Jan	NEWA
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CICLOPIROX

CREAM; TOPICAL

CICLOPIROX

AB		FOUGERA PHARMS	0.77%	A076435	001	Dec 29, 2004	Jan	CAHN
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GEL; TOPICAL

CICLOPIROX

AB		FOUGERA PHARMS	0.77%	A077896	001	Jun 10, 2008	Jan	CAHN
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>A>	AB	GLENMARK GENERICS	0.77%	A091595	001	Feb 29, 2012	Feb	NEWA
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SHAMPOO; TOPICAL

CICLOPIROX

AT		FOUGERA PHARMS	1%	A090146	001	May 25, 2010	Jan	CAHN
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SOLUTION; TOPICAL

CICLOPIROX

>A>	AT	MYLAN PHARMS INC	8%	A078567	001	Sep 18, 2007	Feb	CAHN
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>D>	AT	SYNERX PHARMA	8%	A078567	001	Sep 18, 2007	Feb	CAHN
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SUSPENSION; TOPICAL

CICLOPIROX

AB		FOUGERA PHARMS	0.77%	A076422	001	Aug 06, 2004	Jan	CAHN
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CIPROFLOXACIN

INJECTABLE; INJECTION

CIPROFLOXACIN

	@	TEVA PARENTERAL	400MG/40ML (10MG/ML)	A077782	002	Aug 28, 2006	Jan	DISC
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CIPROFLOXACIN HYDROCHLORIDE

TABLET; ORAL

CIPROFLOXACIN HYDROCHLORIDE

	@	PLIVA	EQ 100MG BASE	A076426	001	Jun 15, 2005	Jan	DISC
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	@		EQ 250MG BASE	A076426	002	Jun 15, 2005	Jan	DISC
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	@		EQ 500MG BASE	A076426	003	Jun 15, 2005	Jan	DISC
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	@		EQ 750MG BASE	A076426	004	Jun 15, 2005	Jan	DISC
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CISATRACURIUM BESYLATE

INJECTABLE; INJECTION

CISATRACURIUM BESYLATE

AP		SANDOZ INC	EQ 2MG BASE/ML	A200159	001	Feb 03, 2012	Jan	NEWA
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CISATRACURIUM BESYLATE PRESERVATIVE FREE

AP		SANDOZ INC	EQ 2MG BASE/ML	A200154	001	Feb 03, 2012	Jan	NEWA
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AP			EQ 10MG BASE/ML	A200154	002	Feb 03, 2012	Jan	NEWA
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NIMBEX

AP	+	ABBOTT	EQ 2MG BASE/ML	N020551	001	Dec 15, 1995	Jan	CFTG
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NIMBEX PRESERVATIVE FREE

AP	+	ABBOTT	EQ 2MG BASE/ML	N020551	003	Dec 15, 1995	Jan	CFTG
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AP	+		EQ 10MG BASE/ML	N020551	002	Dec 15, 1995	Jan	CFTG
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CLINDAMYCIN PHOSPHATE

	CREAM; VAGINAL								
	CLINDAMYCIN PHOSPHATE								
AB	FOUGERA PHARMS	EQ 2% BASE	A065139	001	Dec 27, 2004	Jan	CAHN		
	GEL; TOPICAL								
	CLINDAMYCIN PHOSPHATE								
AB	FOUGERA PHARMS	EQ 1% BASE	A064160	001	Jan 28, 2000	Jan	CAHN		
	LOTION; TOPICAL								
	CLINDAMYCIN PHOSPHATE								
AB	FOUGERA PHARMS	EQ 1% BASE	A065067	001	Jan 31, 2002	Jan	CAHN		
	SOLUTION; TOPICAL								
	CLINDAMYCIN PHOSPHATE								
AT	FOUGERA PHARMS	EQ 1% BASE	A065254	001	Feb 14, 2006	Jan	CAHN		

CLOBETASOL PROPIONATE

	CREAM; TOPICAL								
	CLOBETASOL PROPIONATE (EMOLLIENT)								
AB2	FOUGERA PHARMS	0.05%	A075430	001	May 26, 1999	Jan	CAHN		
	TEMOVATE								
AB1	+ FOUGERA PHARMS	0.05%	N019322	001	Dec 27, 1985	Jan	CAHN		
	GEL; TOPICAL								
	CLOBETASOL PROPIONATE								
AB	FOUGERA PHARMS	0.05%	A075368	001	Feb 15, 2000	Jan	CAHN		
	TEMOVATE								
AB	+ FOUGERA PHARMS	0.05%	N020337	001	Apr 29, 1994	Jan	CAHN		
	OINTMENT; TOPICAL								
	CLOBETASOL PROPIONATE								
AB	FOUGERA PHARMS	0.05%	A074407	001	Feb 23, 1996	Jan	CAHN		
	TEMOVATE								
AB	+ FOUGERA PHARMS	0.05%	N019323	001	Dec 27, 1985	Jan	CAHN		
	SOLUTION; TOPICAL								
	CLOBETASOL PROPIONATE								
AT	FOUGERA PHARMS	0.05%	A075391	001	Feb 08, 1999	Jan	CAHN		
	TEMOVATE								
AT	+ FOUGERA PHARMS	0.05%	N019966	001	Feb 22, 1990	Jan	CAHN		

CLONIDINE HYDROCHLORIDE

	INJECTABLE; INJECTION								
	DURACLON								
>D>	AP	BIONICHE PHARMA USA	1 MG/10 ML (0.1 MG/ML)	N020615	001	Oct 02, 1996	Feb	CAHN	
>D>	AP	+	5 MG/10 ML (0.5 MG/ML)	N020615	002	Apr 27, 1999	Feb	CAHN	
>A>	AP	MYLAN INSTITUTIONAL	1 MG/10 ML (0.1 MG/ML)	N020615	001	Oct 02, 1996	Feb	CAHN	
>A>	AP	+	5 MG/10 ML (0.5 MG/ML)	N020615	002	Apr 27, 1999	Feb	CAHN	

CLOTRIMAZOLE

	CREAM; TOPICAL								
	CLOTRIMAZOLE								
AB	FOUGERA PHARMS	1%	A078338	001	Sep 02, 2008	Jan	CAHN		

CYCLOBENZAPRINE HYDROCHLORIDE

	TABLET; ORAL								
	CYCLOBENZAPRINE HYDROCHLORIDE								
>D>	AB	ACTAVIS TOTOWA	5MG	A077291	001	Feb 03, 2006	Feb	CAHN	
>D>	AB		10MG	A077209	001	Oct 04, 2005	Feb	CAHN	
>A>	AB	PROSAM LABS	5MG	A077291	001	Feb 03, 2006	Feb	CAHN	

## TABLET; ORAL

## CYCLOBENZAPRINE HYDROCHLORIDE

>A>	AB	PROSAM LABS	10MG	A077209	001	Oct 04, 2005	Feb	CAHN
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CYTARABINE

## INJECTABLE; INJECTION

## CYTARABINE

AP		ONCO THERAPIES LTD	100MG/ML	A201784	001	Jan 30, 2012	Jan	NEWA
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DARUNAVIR ETHANOLATE

## SUSPENSION; ORAL

## PREZISTA

>A>	+	JANSSEN PRODS	EQ 100MG BASE/ML	N202895	001	Dec 16, 2011	Feb	CAHN
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>D>	+	TIBOTEC	EQ 100MG BASE/ML	N202895	001	Dec 16, 2011	Feb	CAHN
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## TABLET; ORAL

## PREZISTA

>A>		JANSSEN PRODS	EQ 75MG BASE	N021976	004	Dec 18, 2008	Feb	CAHN
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>A>			EQ 150MG BASE	N021976	005	Dec 18, 2008	Feb	CAHN
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>A>	@		EQ 300MG BASE	N021976	001	Jun 23, 2006	Feb	CAHN
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>A>			EQ 400MG BASE	N021976	003	Oct 21, 2008	Feb	CAHN
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>A>	+		EQ 600MG BASE	N021976	002	Feb 25, 2008	Feb	CAHN
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>D>		TIBOTEC	EQ 75MG BASE	N021976	004	Dec 18, 2008	Feb	CAHN
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>D>			EQ 150MG BASE	N021976	005	Dec 18, 2008	Feb	CAHN
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>D>	@		EQ 300MG BASE	N021976	001	Jun 23, 2006	Feb	CAHN
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>D>			EQ 400MG BASE	N021976	003	Oct 21, 2008	Feb	CAHN
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>D>	+		EQ 600MG BASE	N021976	002	Feb 25, 2008	Feb	CAHN
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DESLORATADINE

## TABLET; ORAL

## DESLORATADINE

AB		MYLAN PHARMS INC	5MG	A078351	001	Feb 10, 2012	Jan	NEWA
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DESONIDE

## LOTION; TOPICAL

## DESONIDE

AB		FOUGERA PHARMS	0.05%	A075860	001	Mar 19, 2002	Jan	CAHN
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## OINTMENT; TOPICAL

## DESONIDE

AB		FOUGERA PHARMS	0.05%	A075751	001	Mar 12, 2001	Jan	CAHN
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DESOXIMETASONE

## CREAM; TOPICAL

## DESOXIMETASONE

AB		FOUGERA PHARMS	0.25%	A078369	001	Jun 29, 2010	Jan	CAHN
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DEXAMETHASONE SODIUM PHOSPHATE

## INJECTABLE; INJECTION

## DEXAMETHASONE SODIUM PHOSPHATE

>D>	AP	APP PHARMS	EQ 10MG PHOSPHATE/ML	A040572	001	Apr 22, 2005	Feb	CRLD
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>A>	AP	+	APP PHARMS LLC	EQ 10MG PHOSPHATE/ML	A040572	001	Apr 22, 2005	Feb	CRLD
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DIFLORASONE DIACETATE

## CREAM; TOPICAL

## DIFLORASONE DIACETATE

BX	+	FOUGERA PHARMS	0.05%	A076263	001	Dec 20, 2002	Jan	CAHN
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AB1	+		0.05%	A075187	001	Mar 30, 1998	Jan	CAHN
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## OINTMENT; TOPICAL

## DIFLORASONE DIACETATE

AB	FOUGERA PHARMS	0.05%	A075374	001	Apr 27, 1999	Jan	CAHN
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DIFLUNISAL

## TABLET; ORAL

## DIFLUNISAL

>A>	AB	EMCURE PHARMS USA	500MG	A202845	001	Mar 08, 2012	Feb	NEWA
>D>		+ TEVA	500MG	A073673	001	Jul 31, 1992	Feb	CTEC
>A>	AB	+	500MG	A073673	001	Jul 31, 1992	Feb	CTEC

DILTIAZEM HYDROCHLORIDE

## INJECTABLE; INJECTION

## DILTIAZEM HYDROCHLORIDE

	@ TEVA PARENTERAL	5MG/ML	A074894	001	Aug 26, 1997	Jan	DISC
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DIPYRIDAMOLE

## INJECTABLE; INJECTION

## DIPYRIDAMOLE

	@ TEVA PARENTERAL	5MG/ML	A074952	001	Nov 26, 1997	Jan	DISC
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## TABLET; ORAL

## DIPYRIDAMOLE

>D>	AB	ACTAVIS TOTOWA	25MG	A040542	001	Apr 21, 2006	Feb	CAHN
>D>	AB		50MG	A040542	002	Apr 21, 2006	Feb	CAHN
>D>	AB		75MG	A040542	003	Apr 21, 2006	Feb	CAHN
>A>	AB	PROSAM LABS	25MG	A040542	001	Apr 21, 2006	Feb	CAHN
>A>	AB		50MG	A040542	002	Apr 21, 2006	Feb	CAHN
>A>	AB		75MG	A040542	003	Apr 21, 2006	Feb	CAHN

DIVALPROEX SODIUM

## TABLET, EXTENDED RELEASE; ORAL

## DIVALPROEX SODIUM

>A>	AB	DR REDDYS LABS LTD	EQ 250MG VALPROIC ACID	A090161	001	Mar 15, 2012	Feb	NEWA
>A>	AB	REDDYS	EQ 500MG VALPROIC ACID	A090070	001	Mar 12, 2012	Feb	NEWA

DOCETAXEL

## INJECTABLE; INJECTION

## DOCETAXEL

AP	ACCORD HLTHCARE	20MG/0.5ML (40MG/ML)	N201195	001	Jun 08, 2011	Jan	CTEC
AP		80MG/2ML (40MG/ML)	N201195	002	Jun 08, 2011	Jan	CTEC
AP	APOTEX INC	20MG/0.5ML (40MG/ML)	N022312	001	Jan 11, 2012	Jan	NEWA
AP		80MG/2ML (40MG/ML)	N022312	002	Jan 11, 2012	Jan	NEWA

DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE

## SOLUTION/DROPS; OPHTHALMIC

## COSOPT PF

>A>		+ MERCK SHARP DOHME	EQ 2% BASE;EQ 0.5% BASE	N202667	001	Feb 01, 2012	Feb	NEWA
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DOXAZOSIN MESYLATE

## TABLET; ORAL

## DOXAZOSIN MESYLATE

>D>	AB	NESHER PHARMS	EQ 1MG BASE	A075609	001	Oct 18, 2000	Feb	DISC
>A>		@	EQ 1MG BASE	A075609	001	Oct 18, 2000	Feb	DISC
>D>	AB		EQ 2MG BASE	A075609	002	Oct 18, 2000	Feb	DISC
>A>		@	EQ 2MG BASE	A075609	002	Oct 18, 2000	Feb	DISC
>D>	AB		EQ 4MG BASE	A075609	003	Oct 18, 2000	Feb	DISC

TABLET; ORAL

## DOXAZOSIN MESYLATE

>A>		@ NESHER PHARMS	EQ 4MG BASE	A075609 003	Oct 18, 2000	Feb	DISC
>D>	AB		EQ 8MG BASE	A075609 004	Oct 18, 2000	Feb	DISC
>A>		@	EQ 8MG BASE	A075609 004	Oct 18, 2000	Feb	DISC

DOXEPIN HYDROCHLORIDE

## CREAM; TOPICAL

## ZONALON

	+	FOUGERA PHARMS	5%	N020126 001	Apr 01, 1994	Jan	CAHN
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DOXORUBICIN HYDROCHLORIDE

## INJECTABLE; INJECTION

## DOXORUBICIN HYDROCHLORIDE

AP		ONCO THERAPIES LTD	2MG/ML	A200901 001	Feb 14, 2012	Jan	NEWA
AP		SUN PHARM INDS	2MG/ML	A091418 001	Feb 15, 2012	Jan	NEWA

## INJECTABLE, LIPOSOMAL; INJECTION

## DOXIL

	+	JANSSEN R AND D	20MG/10ML (2MG/ML)	N050718 001	Nov 17, 1995	Jan	CAHN
	+		50MG/25ML (2MG/ML)	N050718 002	Jun 13, 2000	Jan	CAHN

DOXYCYCLINE HYCLATE

## TABLET, DELAYED RELEASE; ORAL

## DORYX

AB	+	MAYNE PHARMA	EQ 150MG BASE	N050795 003	Jun 20, 2008	Jan	CTEC
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## DOXYCYCLINE HYCLATE

AB		MYLAN PHARMS INC	EQ 150MG BASE	A091052 001	Feb 08, 2012	Jan	NEWA
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DROSPIRENONE; ETHINYL ESTRADIOL

## TABLET; ORAL

## ANGELIQ

>A>		BAYER HLTHCARE	0.25MG;0.5MG	N021355 001	Feb 29, 2012	Feb	NEWA
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ECONAZOLE NITRATE

## CREAM; TOPICAL

## ECONAZOLE NITRATE

AB	+	FOUGERA PHARMS	1%	A076075 001	Nov 26, 2002	Jan	CAHN
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ENALAPRIL MALEATE

## TABLET; ORAL

## ENALAPRIL MALEATE

>D>	AB	SANDOZ	2.5MG	A075621 001	Aug 22, 2000	Feb	DISC
>D>	AB		5MG	A075621 002	Aug 22, 2000	Feb	DISC
>D>	AB		10MG	A075621 003	Aug 22, 2000	Feb	DISC
>D>	AB		20MG	A075621 004	Aug 22, 2000	Feb	DISC
>A>		@ SANDOZ INC	2.5MG	A075621 001	Aug 22, 2000	Feb	DISC
		@	2.5MG	A075496 001	Aug 22, 2000	Jan	DISC
>A>		@	5MG	A075621 002	Aug 22, 2000	Feb	DISC
		@	5MG	A075496 002	Aug 22, 2000	Jan	DISC
>A>		@	10MG	A075621 003	Aug 22, 2000	Feb	DISC
		@	10MG	A075459 001	Aug 22, 2000	Jan	DISC
>A>		@	20MG	A075621 004	Aug 22, 2000	Feb	DISC
		@	20MG	A075459 002	Aug 22, 2000	Jan	DISC

ERYTHROMYCIN

GEL; TOPICAL

ERYTHROMYCIN

AT	FOUGERA PHARMS	2%	A064184	001	Sep 30, 1997	Jan	CAHN
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SOLUTION; TOPICAL

C-SOLVE-2

AT	FOUGERA PHARMS	2%	A062468	001	Jul 03, 1985	Jan	CMFD
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SWAB; TOPICAL

ERYTHROMYCIN

AT	+ FOUGERA PHARMS	2%	A065320	001	Jul 25, 2006	Jan	CAHN
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ESCITALOPRAM OXALATE

SOLUTION; ORAL

ESCITALOPRAM OXALATE

>A>	AA	AMNEAL PHARMS	EQ 5MG BASE/5ML	A202227	001	Mar 14, 2012	Feb	NEWA
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LEXAPRO

>D>	+ FOREST LABS	EQ 5MG BASE/5ML	N021365	001	Nov 27, 2002	Feb	CFTG
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>A>	AA	+	EQ 5MG BASE/5ML	N021365	001	Nov 27, 2002	Feb	CFTG
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TABLET; ORAL

ESCITALOPRAM OXALATE

>A>	AB	IVAX SUB TEVA PHARMS	EQ 5MG BASE	A076765	001	Mar 14, 2012	Feb	NEWA
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>A>	AB		EQ 10MG BASE	A076765	002	Mar 14, 2012	Feb	NEWA
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>A>	AB		EQ 20MG BASE	A076765	003	Mar 14, 2012	Feb	NEWA
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LEXAPRO

>D>	FOREST LABS	EQ 5MG BASE	N021323	001	Aug 14, 2002	Feb	CFTG
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>A>	AB		EQ 5MG BASE	N021323	001	Aug 14, 2002	Feb	CFTG
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>D>		EQ 10MG BASE	N021323	002	Aug 14, 2002	Feb	CFTG
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>A>	AB		EQ 10MG BASE	N021323	002	Aug 14, 2002	Feb	CFTG
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>D>	+	EQ 20MG BASE	N021323	003	Aug 14, 2002	Feb	CFTG
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>A>	AB	+	EQ 20MG BASE	N021323	003	Aug 14, 2002	Feb	CFTG
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ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL

ESTRADIOL AND NORETHINDRONE ACETATE

>A>	AB	TEVA PHARMS USA	0.5MG;0.1MG	A200747	001	Mar 08, 2012	Feb	NEWA
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ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-28

MARLISSA

>A>	AB	GLENMARK GENERICS	0.03MG;0.15MG	A091452	001	Feb 29, 2012	Feb	NEWA
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ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28

ALYACEN 1/35

AB	GLENMARK GENERICS	0.035MG;1MG	A091634	001	Jan 19, 2012	Jan	NEWA
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ALYACEN 7/7/7

AB	GLENMARK GENERICS	0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG	A091636	001	Jan 19, 2012	Jan	NEWA
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ETODOLAC

TABLET; ORAL

ETODOLAC

>D>	@ ACTAVIS ELIZABETH	400MG	A074819	001	Feb 28, 1997	Feb	CMFD
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>D>	@	500MG	A074819	002	Apr 28, 1998	Feb	CMFD
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>A>	AB	PROSAM LABS	400MG	A074819	001	Feb 28, 1997	Feb	CMFD
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## TABLET; ORAL

## ETODOLAC

>A>	AB	PROSAM LABS	500MG	A074819 002	Apr 28, 1998	Feb	CMFD
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ETOPOSIDE

## CAPSULE; ORAL

## VEPESID

>D>	@	BRISTOL MYERS SQUIBB	50MG	N019557 001	Dec 30, 1986	Feb	CAHN
>D>	@		100MG	N019557 002	Dec 30, 1986	Feb	CAHN
>A>	@	CORDEN PHARMA	50MG	N019557 001	Dec 30, 1986	Feb	CAHN
>A>	@		100MG	N019557 002	Dec 30, 1986	Feb	CAHN

## INJECTABLE; INJECTION

## VEPESID

>D>	@	BRISTOL MYERS SQUIBB	20MG/ML	N018768 001	Nov 10, 1983	Feb	CAHN
>A>	@	CORDEN PHARMA	20MG/ML	N018768 001	Nov 10, 1983	Feb	CAHN

ETRAVIRINE

## TABLET; ORAL

## INTELENCE

>A>		JANSSEN R AND D	100MG	N022187 001	Jan 18, 2008	Feb	CAHN
>A>	+		200MG	N022187 002	Dec 22, 2010	Feb	CAHN
>D>		TIBOTEC	100MG	N022187 001	Jan 18, 2008	Feb	CAHN
>D>	+		200MG	N022187 002	Dec 22, 2010	Feb	CAHN

EXENATIDE SYNTHETIC

## FOR SUSPENSION, EXTENDED RELEASE; SUBCUTANEOUS

## BYDUREON

	+	AMYLIN	2MG/VIAL	N022200 001	Jan 27, 2012	Jan	NEWA
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EZETIMIBE

## TABLET; ORAL

## ZETIA

>A>	+	MSD INTL GMBH	10MG	N021445 001	Oct 25, 2002	Feb	CAHN
>D>	+	MSP SINGAPORE	10MG	N021445 001	Oct 25, 2002	Feb	CAHN
	+		10MG	N021445 001	Oct 25, 2002	Jan	CAHN

EZETIMIBE; SIMVASTATIN

## TABLET; ORAL

## VYTORIN

		MSD INTL	10MG;10MG	N021687 001	Jul 23, 2004	Jan	CAHN
			10MG;20MG	N021687 002	Jul 23, 2004	Jan	CAHN
			10MG;40MG	N021687 003	Jul 23, 2004	Jan	CAHN
	+		10MG;80MG	N021687 004	Jul 23, 2004	Jan	CAHN

FAMCICLOVIR

## TABLET; ORAL

## FAMCICLOVIR

AB		MACLEODS PHARMS LTD	125MG	A201022 001	Jan 12, 2012	Jan	NEWA
AB			250MG	A201022 002	Jan 12, 2012	Jan	NEWA
AB			500MG	A201022 003	Jan 12, 2012	Jan	NEWA

FAMOTIDINE

## TABLET; ORAL

## PEPCID

AB		MARATHON PHARMS	20MG	N019462 001	Oct 15, 1986	Jan	CAHN
AB	+		40MG	N019462 002	Oct 15, 1986	Jan	CAHN

## TABLET, ORALLY DISINTEGRATING; ORAL

## FLUXID

@	UCB INC	20MG	N021712	001	Sep 24, 2004	Jan	CAHN
@		40MG	N021712	002	Sep 24, 2004	Jan	CAHN

FENOFIBRATE

## CAPSULE; ORAL

## ANTARA (MICRONIZED)

>D>		LUPIN ATLANTIS	43MG	N021695	001	Nov 30, 2004	Feb	CFTG
>A>	AB		43MG	N021695	001	Nov 30, 2004	Feb	CFTG
>D>		+	130MG	N021695	003	Nov 30, 2004	Feb	CFTG
>A>	AB	+	130MG	N021695	003	Nov 30, 2004	Feb	CFTG

## FENOFIBRATE (MICRONIZED)

>A>	AB	DR REDDYS LABS SA	43MG	A090859	001	Mar 01, 2012	Feb	NEWA
>A>	AB		130MG	A090859	002	Mar 01, 2012	Feb	NEWA

FENTANYL

## SPRAY; SUBLINGUAL

## SUBSYS

		INSYS THERAP	0.1MCG	N202788	001	Jan 04, 2012	Jan	NEWA
			0.2MCG	N202788	002	Jan 04, 2012	Jan	NEWA
		+	0.4MCG	N202788	003	Jan 04, 2012	Jan	NEWA
			0.6MCG	N202788	004	Jan 04, 2012	Jan	NEWA
			0.8MCG	N202788	005	Jan 04, 2012	Jan	NEWA

FENTANYL CITRATE

## SPRAY, METERED; NASAL

## LAZANDA

		ARCHIMEDES	EQ 0.1MG BASE	N022569	001	Jun 30, 2011	Jan	CPOT
		+	EQ 0.4MG BASE	N022569	002	Jun 30, 2011	Jan	CPOT

## TROCHE/LOZENGE; TRANSMUCOSAL

## FENTANYL CITRATE

>D>	AB	BARR	EQ 0.2MG BASE	A077312	001	Oct 30, 2009	Feb	CAHN
>D>	AB		EQ 0.4MG BASE	A077312	002	Oct 30, 2009	Feb	CAHN
>D>	AB		EQ 0.6MG BASE	A077312	003	Oct 30, 2009	Feb	CAHN
>D>	AB		EQ 0.8MG BASE	A077312	004	Oct 30, 2009	Feb	CAHN
>D>	AB		EQ 1.2MG BASE	A077312	005	Oct 30, 2009	Feb	CAHN
>D>	AB		EQ 1.6MG BASE	A077312	006	Oct 30, 2009	Feb	CAHN
>A>	AB	PAR PHARM	EQ 0.2MG BASE	A077312	001	Oct 30, 2009	Feb	CAHN
>A>	AB		EQ 0.4MG BASE	A077312	002	Oct 30, 2009	Feb	CAHN
>A>	AB		EQ 0.6MG BASE	A077312	003	Oct 30, 2009	Feb	CAHN
>A>	AB		EQ 0.8MG BASE	A077312	004	Oct 30, 2009	Feb	CAHN
>A>	AB		EQ 1.2MG BASE	A077312	005	Oct 30, 2009	Feb	CAHN
>A>	AB		EQ 1.6MG BASE	A077312	006	Oct 30, 2009	Feb	CAHN

FLUCONAZOLE

## INJECTABLE; INJECTION

## FLUCONAZOLE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP		HIKMA FARMACEUTICA	200MG/100ML (2MG/ML)	A078764	001	Jan 30, 2012	Jan	NEWA
AP			400MG/200ML (2MG/ML)	A078764	002	Jan 30, 2012	Jan	NEWA

## FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP		HIKMA FARMACEUTICA	200MG/100ML (2MG/ML)	A078698	001	Jan 30, 2012	Jan	NEWA
AP			400MG/200ML (2MG/ML)	A078698	002	Jan 30, 2012	Jan	NEWA

## TABLET; ORAL

## FLUCONAZOLE

>D>	BX	PLIVA	50MG	A076424	001	Jul 29, 2004	Feb	DISC
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TABLET; ORAL

## FLUCONAZOLE

>A>	@ PLIVA	50MG	A076424 001	Jul 29, 2004	Feb	DISC
>D>	BX	100MG	A076424 002	Jul 29, 2004	Feb	DISC
>A>	@	100MG	A076424 002	Jul 29, 2004	Feb	DISC
>D>	BX	150MG	A076424 003	Jul 29, 2004	Feb	DISC
>A>	@	150MG	A076424 003	Jul 29, 2004	Feb	DISC
>D>	BX	200MG	A076424 004	Jul 29, 2004	Feb	DISC
>A>	@	200MG	A076424 004	Jul 29, 2004	Feb	DISC

FLUMAZENIL

## INJECTABLE; INJECTION

## FLUMAZENIL

@ TEVA PARENTERAL

0.5MG/5ML (0.1MG/ML)

A076589 002 Oct 12, 2004 Jan DISC

@

1MG/10ML (0.1MG/ML)

A076589 001 Oct 12, 2004 Jan DISC

FLUOCINOLONE ACETONIDE

## OIL/DROPS; OTIC

## FLUOCINOLONE ACETONIDE

AT IDENTI PHARMS INC

0.01%

A091306 001 Oct 17, 2011 Jan CPOT

FLUOCINONIDE

## CREAM; TOPICAL

## FLUOCINONIDE EMULSIFIED BASE

AB2 FOUGERA PHARMS

0.05%

A076586 001 Jun 23, 2004 Jan CAHN

## OINTMENT; TOPICAL

## FLUOCINONIDE

AB FOUGERA PHARMS

0.05%

A074905 001 Aug 26, 1997 Jan CAHN

FLUOROURACIL

## CREAM; TOPICAL

## FLUOROPLEX

+ AQUA PHARMS

1%

N016988 001 Jan CAHN

FLUTICASONE PROPIONATE

## CREAM; TOPICAL

## CUTIVATE

AB + FOUGERA PHARMS

0.05%

N019958 001 Dec 18, 1990 Jan CAHN

## FLUTICASONE PROPIONATE

AB FOUGERA PHARMS

0.05%

A076451 001 May 14, 2004 Jan CAHN

## OINTMENT; TOPICAL

## FLUTICASONE PROPIONATE

AB FOUGERA PHARMS

0.005%

A076300 001 May 14, 2004 Jan CAHN

GLYCOPYRROLATE

## TABLET; ORAL

## GLYCOPYRROLATE

&gt;A&gt; AA

NEXGEN PHARMA

1.5MG

A091522 001 Mar 12, 2012 Feb NEWA

GRISEOFULVIN, MICROCRYSTALLINE

## SUSPENSION; ORAL

## GRIFULVIN V

&gt;D&gt; AB

+ ORTHONEUTROGENA

125MG/5ML

A062483 001 Jan 26, 1984 Feb CAHN

&gt;A&gt; AB

+ VALEANT PHARM NORTH

125MG/5ML

A062483 001 Jan 26, 1984 Feb CAHN

HALOBETASOL PROPIONATE

CREAM; TOPICAL

HALOBETASOL PROPIONATE

AB	FOUGERA PHARMS	0.05%	A077001 001	Dec 16, 2004	Jan	CAHN
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OINTMENT; TOPICAL

HALOBETASOL PROPIONATE

AB	FOUGERA PHARMS	0.05%	A076903 001	Dec 16, 2004	Jan	CAHN
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HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDROCHLOROTHIAZIDE

AB	LANNETT HOLDINGS INC	12.5MG	A091662 001	Jan 27, 2012	Jan	NEWA
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HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET; ORAL

AVALIDE

>D>	SANOFI AVENTIS	12.5MG;300MG	N020758 003	Aug 31, 1998	Feb	CRLD
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>A>	+	12.5MG;300MG	N020758 003	Aug 31, 1998	Feb	CRLD
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HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

TABLET; ORAL

LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

>A>	AB	ALEMBIC LTD	12.5MG;50MG	A091617 001	Feb 17, 2012	Feb	NEWA
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>A>	AB		12.5MG;100MG	A091617 002	Feb 17, 2012	Feb	NEWA
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>A>	AB		25MG;100MG	A091617 003	Feb 17, 2012	Feb	NEWA
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HYDROCHLOROTHIAZIDE; METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL

DUTOPROL

	ASTRAZENECA	12.5MG;EQ 25MG TARTRATE	N021956 001	Aug 28, 2006	Jan	CMFD
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		12.5MG;EQ 50MG TARTRATE	N021956 002	Aug 28, 2006	Jan	CMFD
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		12.5MG;EQ 100MG TARTRATE	N021956 003	Aug 28, 2006	Jan	CMFD
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HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE

TABLET; ORAL

METOPROLOL TARTRATE AND HYDROCHLOROTHIAZIDE

AB	MYLAN	50MG;100MG	A076792 003	Aug 20, 2004	Jan	CTEC
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AB	SUN PHARM INDS	25MG;50MG	A090654 001	Jan 19, 2012	Jan	NEWA
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AB		25MG;100MG	A090654 002	Jan 19, 2012	Jan	NEWA
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AB		50MG;100MG	A090654 003	Jan 19, 2012	Jan	NEWA
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HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDE

TABLET; ORAL

MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

@	PADDOCK LLC	12.5MG;7.5MG	A090096 001	Sep 25, 2008	Jan	DISC
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@		12.5MG;15MG	A090096 002	Sep 25, 2008	Jan	DISC
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@		25MG;15MG	A090096 003	Sep 25, 2008	Jan	DISC
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HYDROCORTISONE

LOTION; TOPICAL

HYDROCORTISONE

AT	+	FOUGERA PHARMS	2.5%	A040351 001	Jul 25, 2000	Jan	CAHN
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OINTMENT; TOPICAL

HYDROCORTISONE

AT	+	FOUGERA PHARMS	1%	A080692 001		Jan	CAHN
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HYDROCORTISONE ACETATE; UREA

CREAM; TOPICAL

CARMOL HC

AT	FOUGERA PHARMS	1%;10%	A080505 001	Jan	CAHN
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HYDROCORTISONE VALERATE

OINTMENT; TOPICAL

HYDROCORTISONE VALERATE

AB	FOUGERA PHARMS	0.2%	A075085 001	Jul 31, 2001	Jan CAHN
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HYDROFLUMETHIAZIDE

TABLET; ORAL

SALURON

AB	+ SHIRE LLC	50MG	N011949 001	Jan	CAHN
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HYDROXYZINE HYDROCHLORIDE

SYRUP; ORAL

HYDROXYZINE HYDROCHLORIDE

>D>	@ ACTAVIS MID ATLANTIC	10MG/5ML	A086880 001	Feb	CAHN
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>A>	@ STI PHARMA LLC	10MG/5ML	A086880 001	Feb	CAHN
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IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HYDROCHLORIDE

>D>	@ ACTAVIS TOTOWA	10MG	A040753 001	Feb 28, 2008	Feb CMFD
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>D>	@	25MG	A040752 001	Feb 28, 2008	Feb CMFD
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>D>	@	50MG	A040751 001	Feb 28, 2008	Feb CMFD
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>A>	AB PROSAM LABS	10MG	A040753 001	Feb 28, 2008	Feb CMFD
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>A>	AB	25MG	A040752 001	Feb 28, 2008	Feb CMFD
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>A>	AB	50MG	A040751 001	Feb 28, 2008	Feb CMFD
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IMIQUIMOD

CREAM; TOPICAL

IMIQUIMOD

AB	FOUGERA PHARMS	5%	A078548 001	Feb 25, 2010	Jan CAHN
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>A>	AB GLENMARK GENERICS	5%	A201994 001	Mar 06, 2012	Feb NEWA
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INGENOL MEBUTATE

GEL; TOPICAL

PICATO

LEO PHARMA AS 0.015%

N202833 001	Jan 23, 2012	Jan NEWA
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+ 0.05%

N202833 002	Jan 23, 2012	Jan NEWA
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IRINOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION

IRINOTECAN HYDROCHLORIDE

AP	EMCURE PHARMS LTD	40MG/2ML (20MG/ML)	A200771 001	Feb 14, 2012	Jan NEWA
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AP		100MG/5ML (20MG/ML)	A200771 002	Feb 14, 2012	Jan NEWA
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ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL

ISOSORBIDE MONONITRATE

@ SKYEPHARMA AG 60MG

A075166 001	Oct 07, 1999	Jan DISC
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ISOTRETINOIN

CAPSULE; ORAL

MYORISAN

AB	DOUGLAS PHARMS	10MG	A076485 001	Jan 19, 2012	Jan	NEWA
AB		20MG	A076485 002	Jan 19, 2012	Jan	NEWA
AB		40MG	A076485 003	Jan 19, 2012	Jan	NEWA

IVACAFTOR

TABLET; ORAL

KALYDECO

+	VERTEX PHARMS	150MG	N203188 001	Jan 31, 2012	Jan	NEWA
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IVERMECTIN

&gt;A&gt; LOTION; TOPICAL

&gt;A&gt; SKLICE

>A>	+	SANOFI PASTEUR	0.5%	N202736 001	Feb 07, 2012	Feb	NEWA
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KETOCONAZOLE

CREAM; TOPICAL

KETOCONAZOLE

AB	FOUGERA PHARMS	2%	A076294 001	Apr 28, 2004	Jan	CAHN
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LACTULOSE

SOLUTION; ORAL

LACTULOSE

AA	FRESENIUS KABI	10GM/15ML	A090503 001	Jan 25, 2012	Jan	NEWA
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SOLUTION; ORAL, RECTAL

LACTULOSE

AA	FRESENIUS KABI	10GM/15ML	A090502 001	Jan 25, 2012	Jan	NEWA
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LANTHANUM CARBONATE

TABLET, CHEWABLE; ORAL

FOSRENOL

>D>	@ SHIRE	EQ 250MG BASE	N021468 001	Oct 26, 2004	Feb	CAHN
>D>		EQ 500MG BASE	N021468 002	Oct 26, 2004	Feb	CAHN
>D>		EQ 750MG BASE	N021468 003	Nov 23, 2005	Feb	CAHN
>D>	+	EQ 1GM BASE	N021468 004	Nov 23, 2005	Feb	CAHN
>A>	@ SHIRE LLC	EQ 250MG BASE	N021468 001	Oct 26, 2004	Feb	CAHN
>A>		EQ 500MG BASE	N021468 002	Oct 26, 2004	Feb	CAHN
>A>		EQ 750MG BASE	N021468 003	Nov 23, 2005	Feb	CAHN
>A>	+	EQ 1GM BASE	N021468 004	Nov 23, 2005	Feb	CAHN

LEVETIRACETAM

INJECTABLE; IV (INFUSION)

LEVETIRACETAM

AP	PHARMAFORCE	500MG/5ML (100MG/ML)	A202143 001	Jan 31, 2012	Jan	NEWA
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SOLUTION; ORAL

LEVETIRACETAM

>A>	AA	HI-TECH PHARMACAL	100MG/ML	A090601 001	Feb 28, 2012	Feb	NEWA
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LEVOFLOXACIN

TABLET; ORAL

LEVOFLOXACIN

AB	ORCHID HLTHCARE	250MG	A202200 001	Jan 30, 2012	Jan	NEWA
AB		500MG	A202200 002	Jan 30, 2012	Jan	NEWA

## TABLET; ORAL

	LEVOFLOXACIN								
AB	ORCHID HLTHCARE	750MG	A202200	003	Jan 30, 2012	Jan	NEWA		

LIDOCAINE; PRILOCAINE

## CREAM; TOPICAL

	LIDOCAINE AND PRILOCAINE								
AB	FOUGERA PHARMS	2.5%;2.5%	A076453	001	Aug 18, 2003	Jan	CAHN		

LINAGLIPTIN; METFORMIN HYDROCHLORIDE

## TABLET; ORAL

## JENTADUETO

	BOEHRINGER INGELHEIM	2.5MG;500MG	N201281	001	Jan 30, 2012	Jan	NEWA		
		2.5MG;850MG	N201281	002	Jan 30, 2012	Jan	NEWA		
	+	2.5MG;1GM	N201281	003	Jan 30, 2012	Jan	NEWA		

LORAZEPAM

## CONCENTRATE; ORAL

## LORAZEPAM

AA	HI-TECH PHARMA CO	2MG/ML	A200169	001	Jan 30, 2012	Jan	NEWA		
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MAGNESIUM SULFATE

## INJECTABLE; INJECTION

## MAGNESIUM SULFATE IN PLASTIC CONTAINER

	HOSPIRA	20GM/500ML (40MG/ML)	N020309	004	Jan 18, 1995	Jan	NEWA		
		40GM/1000ML(40MG/ML)	N020309	005	Jan 18, 1995	Jan	NEWA		

MALATHION

## LOTION; TOPICAL

## MALATHION

>A>	AT	MYLAN PHARMS INC	0.5%	A078743	001	Mar 06, 2009	Feb	CAHN	
>D>	AT	SYNERX PHARMA	0.5%	A078743	001	Mar 06, 2009	Feb	CAHN	

MEMANTINE HYDROCHLORIDE

## TABLET; ORAL

## MEMANTINE HYDROCHLORIDE

>A>	AB	ORCHID HLTHCARE	5MG	A090044	001	Mar 12, 2012	Feb	NEWA	
>A>	AB		10MG	A090044	002	Mar 12, 2012	Feb	NEWA	
		NAMENDA							
>D>		FOREST LABS	5MG	N021487	001	Oct 16, 2003	Feb	CTEC	
>A>	AB		5MG	N021487	001	Oct 16, 2003	Feb	CTEC	
>D>		+	10MG	N021487	002	Oct 16, 2003	Feb	CTEC	
>A>	AB	+	10MG	N021487	002	Oct 16, 2003	Feb	CTEC	

MESALAMINE

## SUPPOSITORY; RECTAL

## ROWASA

	@ MEDA PHARMS	500MG	N019919	001	Dec 18, 1990	Jan	CAHN		
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MESNA

## INJECTABLE; INTRAVENOUS

## MESNA

>A>	AP	MYLAN INSTITUTIONAL	100MG/ML	A076488	001	Mar 08, 2012	Feb	NEWA	
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METFORMIN HYDROCHLORIDE

TABLET; ORAL

METFORMIN HYDROCHLORIDE

>A>	AB	MARKSANS PHARMA	500MG	A090888 001	Mar 12, 2012	Feb	NEWA
>A>	AB		850MG	A090888 002	Mar 12, 2012	Feb	NEWA
>A>	AB		1GM	A090888 003	Mar 12, 2012	Feb	NEWA

TABLET, EXTENDED RELEASE; ORAL

METFORMIN HYDROCHLORIDE

AB1		INVENTIA HLTHCARE	500MG	A201991 001	Jan 18, 2012	Jan	NEWA
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METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE

>A>							
>A>		JANUMET XR					
>A>		MERCK SHARP DOHME	500MG;EQ 50MG BASE	N202270 001	Feb 02, 2012	Feb	NEWA
>A>			1GM;EQ 50MG BASE	N202270 002	Feb 02, 2012	Feb	NEWA
>A>	+		1GM;EQ 100MG BASE	N202270 003	Feb 02, 2012	Feb	NEWA

METHIMAZOLE

TABLET; ORAL

METHIMAZOLE

>A>	AB	BOCA PHARMA	5MG	A202068 001	Mar 07, 2012	Feb	NEWA
>A>	AB		10MG	A202068 002	Mar 07, 2012	Feb	NEWA

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE PRESERVATIVE FREE

AP		APP PHARMS LLC	EQ 1GM BASE/VIAL	A040266 001	Feb 26, 1999	Jan	CMFD
>A>	AP	PHARMACHEMIE BV	EQ 100MG BASE/4ML (EQ 25MG BASE/ML)	A200171 001	Feb 27, 2012	Feb	NEWA

METHOTREXATE SODIUM

>D>	+	BEDFORD	EQ 100MG BASE/4ML (EQ 25MG BASE/ML)	A089341 001	Sep 16, 1986	Feb	CTEC
>A>	AP	+	EQ 100MG BASE/4ML (EQ 25MG BASE/ML)	A089341 001	Sep 16, 1986	Feb	CTEC

METHOTREXATE SODIUM PRESERVATIVE FREE

>D>	AP	+	BIONICHE PHARMA	EQ 50MG BASE/2ML (EQ 25MG BASE/ML)	A040767 001	Apr 30, 2007	Feb	CAHN
>A>	AP	+	MYLAN INSTITUTIONAL	EQ 50MG BASE/2ML (EQ 25MG BASE/ML)	A040767 001	Apr 30, 2007	Feb	CAHN

METHYLPHENIDATE HYDROCHLORIDE

TABLET; ORAL

METHYLPHENIDATE HYDROCHLORIDE

>A>	AB	SUN PHARM INDS INC	5MG	A090710 001	Mar 15, 2012	Feb	NEWA
>A>	AB		10MG	A090710 002	Mar 15, 2012	Feb	NEWA
>A>	AB		20MG	A090710 003	Mar 15, 2012	Feb	NEWA

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HYDROCHLORIDE

		@ TEVA PARENTERAL	EQ 5MG BASE/ML	A073135 001	Nov 27, 1991	Jan	DISC
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METRONIDAZOLE

CREAM; TOPICAL

METRONIDAZOLE

AB		FOUGERA PHARMS	0.75%	A076408 001	May 28, 2004	Jan	CAHN
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## GEL; TOPICAL

	METRONIDAZOLE								
AB	FOUGERA PHARMS	0.75%		A077018	001	Jun 06, 2006	Jan	CAHN	

## LOTION; TOPICAL

	METRONIDAZOLE								
AB	FOUGERA PHARMS	0.75%		A077197	001	May 24, 2006	Jan	CAHN	

MIDAZOLAM HYDROCHLORIDE

## INJECTABLE; INJECTION

## MIDAZOLAM HYDROCHLORIDE

>A>	AP	GLAND PHARMA LTD	EQ 1MG BASE/ML	A090696	001	Feb 29, 2012	Feb	NEWA	
	AP		EQ 5MG BASE/ML	A090850	001	Jan 25, 2012	Jan	NEWA	

MIDODRINE HYDROCHLORIDE

## TABLET; ORAL

## PROAMATINE

AB	SHIRE LLC	2.5MG		N019815	001	Sep 06, 1996	Jan	CAHN	
AB	+	5MG		N019815	002	Sep 06, 1996	Jan	CAHN	
AB		10MG		N019815	003	Mar 20, 2002	Jan	CAHN	

MIFEPRISTONE

## TABLET; ORAL

>A>		KORLYM							
>A>	+	CORCEPT THERAP	300MG	N202107	001	Feb 17, 2012	Feb	NEWA	

MITOMYCIN

>A>		FOR SOLUTION; TOPICAL							
>A>		MITOSOL							
>A>	+	MOBIUS THERAP	0.2MG/VIAL	N022572	001	Feb 07, 2012	Feb	NEWA	

MOMETASONE FUROATE

## CREAM; TOPICAL

## MOMETASONE FUROATE

AB	FOUGERA PHARMS	0.1%		A076171	001	Apr 08, 2005	Jan	CAHN	
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## LOTION; TOPICAL

## MOMETASONE FUROATE

AB	FOUGERA PHARMS	0.1%		A075919	001	Nov 29, 2007	Jan	CAHN	
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## OINTMENT; TOPICAL

## MOMETASONE FUROATE

AB	FOUGERA PHARMS	0.1%		A077061	001	Mar 28, 2005	Jan	CAHN	
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MUPIROCIN

## OINTMENT; TOPICAL

## MUPIROCIN

AB	FOUGERA PHARMS	2%		A065192	001	Nov 30, 2005	Jan	CAHN	
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NABUMETONE

## TABLET; ORAL

## NABUMETONE

>D>	@	ACTAVIS ELIZABETH	500MG	A079093	001	Feb 27, 2009	Feb	CMFD	
>D>	@		750MG	A079093	002	Feb 27, 2009	Feb	CMFD	
>A>	AB	PROSAM LABS	500MG	A079093	001	Feb 27, 2009	Feb	CMFD	
>A>	AB		750MG	A079093	002	Feb 27, 2009	Feb	CMFD	

NAFTIFINE HYDROCHLORIDE

CREAM; TOPICAL

NAFTIN

	+	MERZ PHARMS	2%	N019599 002	Jan 13, 2012	Jan	NEWA
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NALTREXONE HYDROCHLORIDE

TABLET; ORAL

NALTREXONE HYDROCHLORIDE

>A>	AB	SUN PHARMA GLOBAL	50MG	A090356 001	Feb 24, 2012	Feb	NEWA
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NITROGLYCERIN

OINTMENT; INTRA-ANAL

RECTIV

	+	APTALIS PHARMA	0.4%	N021359 001	Jun 21, 2011	Jan	CAHN
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NYSTATIN

CREAM; TOPICAL

NYSTATIN

AT		FOUGERA PHARMS	100,000 UNITS/GM	A062129 001		Jan	CAHN
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OINTMENT; TOPICAL

NYSTATIN

AT	+	FOUGERA PHARMS	100,000 UNITS/GM	A062124 002	Sep 23, 1982	Jan	CAHN
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OLANZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL

OLANZAPINE

AB		BARR LABS INC	5MG	A077243 001	Jan 30, 2012	Jan	NEWA
AB			10MG	A077243 002	Jan 30, 2012	Jan	NEWA
AB			15MG	A077243 003	Jan 30, 2012	Jan	NEWA
AB			20MG	A077243 004	Jan 30, 2012	Jan	NEWA
>A>	AB	SUN PHARM INDS	5MG	A090881 001	Feb 28, 2012	Feb	NEWA
>A>	AB		10MG	A090881 002	Feb 28, 2012	Feb	NEWA
>A>	AB		15MG	A090881 003	Feb 28, 2012	Feb	NEWA
>A>	AB		20MG	A090881 004	Feb 28, 2012	Feb	NEWA

OSELTAMIVIR PHOSPHATE

FOR SUSPENSION; ORAL

TAMIFLU

	+	ROCHE	EQ 6MG BASE/ML	N021246 002	Mar 21, 2011	Jan	CRLD
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OXICONAZOLE NITRATE

CREAM; TOPICAL

OXISTAT

	+	FOUGERA PHARMS	EQ 1% BASE	N019828 001	Dec 30, 1988	Jan	CAHN
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OXYBUTYNIN

GEL, METERED; TRANSDERMAL

ANTUROL

>D>	+	ANTARES PHARMA INC	3%	N202513 001	Dec 07, 2011	Feb	CAHN
>A>	+	WATSON LABS INC	3%	N202513 001	Dec 07, 2011	Feb	CAHN

OXYCODONE HYDROCHLORIDE

SOLUTION; ORAL

OXYCODONE HYDROCHLORIDE

	+	VISTAPHARM	5MG/5ML	N201194 001	Jan 12, 2012	Jan	NEWA
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OXYTOCIN

INJECTABLE; INJECTION

OXYTOCIN

@	TEVA PARENTERAL	10USP UNITS/ML (10USP UNITS/ML)	A077453 001	Jan 24, 2008	Jan	DISC
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PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

CAPSULE, DELAYED RELEASE; ORAL

CREON

>A>	ABBOTT LABS	30,000USP UNITS;6,000USP UNITS;19,000USP UNITS	N020725 001	Apr 30, 2009	Feb	CAHN
>A>		60,000USP UNITS;12,000USP UNITS;38,000USP UNITS	N020725 002	Apr 30, 2009	Feb	CAHN
>A>	+	120,000USP UNITS;24,000USP UNITS;76,000USP UNITS	N020725 003	Apr 30, 2009	Feb	CAHN
>D>	ABBOTT PRODS	30,000USP UNITS;6,000USP UNITS;19,000USP UNITS	N020725 001	Apr 30, 2009	Feb	CAHN
>D>		60,000USP UNITS;12,000USP UNITS;38,000USP UNITS	N020725 002	Apr 30, 2009	Feb	CAHN
>D>	+	120,000USP UNITS;24,000USP UNITS;76,000USP UNITS	N020725 003	Apr 30, 2009	Feb	CAHN

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL

PANTOPRAZOLE SODIUM

AB	MACLEODS PHARMS LTD	EQ 20MG BASE	A200821 001	Feb 16, 2012	Jan	NEWA
AB		EQ 40MG BASE	A200821 002	Feb 16, 2012	Jan	NEWA

PAROXETINE HYDROCHLORIDE

TABLET; ORAL

PAROXETINE HYDROCHLORIDE

>D>	@	ACTAVIS ELIZABETH	EQ 10MG BASE	A076968 001	Jun 21, 2010	Feb	CMFD
>A>	AB		EQ 10MG BASE	A076968 001	Jun 21, 2010	Feb	CMFD
>D>	@		EQ 20MG BASE	A076968 002	Jun 21, 2010	Feb	CMFD
>A>	AB		EQ 20MG BASE	A076968 002	Jun 21, 2010	Feb	CMFD
>D>	@		EQ 30MG BASE	A076968 003	Jun 21, 2010	Feb	CMFD
>A>	AB		EQ 30MG BASE	A076968 003	Jun 21, 2010	Feb	CMFD
>D>	@		EQ 40MG BASE	A076968 004	Jun 21, 2010	Feb	CMFD
>A>	AB		EQ 40MG BASE	A076968 004	Jun 21, 2010	Feb	CMFD

PENTOBARBITAL SODIUM

INJECTABLE; INJECTION

NEMBUTAL SODIUM

>D>	+	LUNDBECK INC	50MG/ML	A083246 001		Feb	CAHN
>A>	+	OAK PHARMS	50MG/ML	A083246 001		Feb	CAHN

PERINDOPRIL ERBUMINE

TABLET; ORAL

ACEON

AB	XOMA	2MG	N020184 001	Dec 30, 1993	Jan	CAHN
AB		4MG	N020184 002	Dec 30, 1993	Jan	CAHN
AB	+	8MG	N020184 003	Dec 30, 1993	Jan	CAHN

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HYDROCHLORIDE

>A>	AA	LANNETT	15MG	A087022 002	Jan 20, 2012	Feb	NEWA
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## TABLET; ORAL

## PHENTERMINE HYDROCHLORIDE

>D>	+	SANDOZ	30MG	A088605 001	Sep 28, 1987	Feb	DISC
>A>		@ SANDOZ INC	30MG	A088605 001	Sep 28, 1987	Feb	DISC

PHENTERMINE RESIN COMPLEX

## CAPSULE, EXTENDED RELEASE; ORAL

## PHENTERMINE RESIN COMPLEX

+	LANNETT HOLDINGS INC	EQ 15MG BASE	A040872 001	Jul 28, 2011	Jan	CRLD
+		EQ 30MG BASE	A040872 002	Jul 28, 2011	Jan	CRLD

PHYTONADIONE

## INJECTABLE; INJECTION

## PHYTONADIONE

>D>	BP	INTL MEDICATION	1MG/0.5ML	A083722 001		Feb	CRLD
>A>	BP	+	1MG/0.5ML	A083722 001		Feb	CRLD

POTASSIUM CITRATE

## FOR SOLUTION; ORAL

## POTASSIUM CITRATE

>A>		@ NOVA K	10MEQ/PACKET	N019647 002	Oct 13, 1988	Feb	CAHN
>A>		@	20MEQ/PACKET	N019647 001	Oct 13, 1988	Feb	CAHN
>D>		@ UNIV TX SW MEDCTR	10MEQ/PACKET	N019647 002	Oct 13, 1988	Feb	CAHN
>D>		@	20MEQ/PACKET	N019647 001	Oct 13, 1988	Feb	CAHN

PREDNICARBATE

## CREAM; TOPICAL

## PREDNICARBATE

AB		FOUGERA PHARMS	0.1%	A077287 001	Sep 19, 2006	Jan	CAHN
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## OINTMENT; TOPICAL

## PREDNICARBATE

AB		FOUGERA PHARMS	0.1%	A077236 001	Mar 09, 2007	Jan	CAHN
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PREGABALIN

## CAPSULE; ORAL

## LYRICA

	PF PRISM	25MG	N021446 001	Dec 30, 2004	Jan	CAHN
		50MG	N021446 002	Dec 30, 2004	Jan	CAHN
		75MG	N021446 003	Dec 30, 2004	Jan	CAHN
		100MG	N021446 004	Dec 30, 2004	Jan	CAHN
		150MG	N021446 005	Dec 30, 2004	Jan	CAHN
		200MG	N021446 006	Dec 30, 2004	Jan	CAHN
		225MG	N021446 007	Dec 30, 2004	Jan	CAHN
	+	300MG	N021446 008	Dec 30, 2004	Jan	CAHN

## SOLUTION; ORAL

## LYRICA

+	PF PRISM	20MG/ML	N022488 001	Jan 04, 2010	Jan	CAHN
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PROGESTERONE

## CAPSULE; ORAL

## PROGESTERONE

>A>		TEVA PHARMS	100MG	A202121 001	Feb 29, 2012	Feb	NEWA
>A>	AB		200MG	A202121 002	Feb 29, 2012	Feb	NEWA
		PROMETRIUM					
>D>		ABBOTT LABS	100MG	N019781 001	May 14, 1998	Feb	CFTG
>A>	AB		100MG	N019781 001	May 14, 1998	Feb	CFTG

## CAPSULE; ORAL

## PROMETRIUM

>D>	+	ABBOTT LABS	200MG	N019781 002	Oct 15, 1999	Feb	CFTG
>A>	AB	+	200MG	N019781 002	Oct 15, 1999	Feb	CFTG

RAMIPRIL

## TABLET; ORAL

## ALTACE

@ KING PFIZER

1.25MG

N022021 001 Feb 27, 2007 Jan DISC

@

2.5MG

N022021 002 Feb 27, 2007 Jan DISC

@

5MG

N022021 003 Feb 27, 2007 Jan DISC

@

10MG

N022021 004 Feb 27, 2007 Jan DISC

RIFAMPIN

## CAPSULE; ORAL

## RIMACTANE

>D>		@ PROSAM LABS	300MG	N050429 001		Feb	CMFD
>A>	AB		300MG	N050429 001		Feb	CMFD

RILPIVIRINE HYDROCHLORIDE

## TABLET; ORAL

## EDURANT

>A>	+	JANSSEN PRODS	EQ 25MG BASE	N202022 001	May 20, 2011	Feb	CAHN
>D>	+	TIBOTEC	EQ 25MG BASE	N202022 001	May 20, 2011	Feb	CAHN

RISPERIDONE

## TABLET; ORAL

## RISPERIDONE

>D>		@ ACTAVIS TOTOWA	0.25MG	A078071 001	Jun 17, 2009	Feb	CMFD
>D>		@	0.5MG	A078071 002	Jun 17, 2009	Feb	CMFD
>D>		@	1MG	A078071 003	Jun 17, 2009	Feb	CMFD
>D>		@	2MG	A078071 004	Jun 17, 2009	Feb	CMFD
>D>		@	3MG	A078071 005	Jun 17, 2009	Feb	CMFD
>D>		@	4MG	A078071 006	Jun 17, 2009	Feb	CMFD
>A>	AB	PROSAM LABS	0.25MG	A078071 001	Jun 17, 2009	Feb	CMFD
>A>	AB		0.5MG	A078071 002	Jun 17, 2009	Feb	CMFD
>A>	AB		1MG	A078071 003	Jun 17, 2009	Feb	CMFD
>A>	AB		2MG	A078071 004	Jun 17, 2009	Feb	CMFD
>A>	AB		3MG	A078071 005	Jun 17, 2009	Feb	CMFD
>A>	AB		4MG	A078071 006	Jun 17, 2009	Feb	CMFD

## TABLET, ORALLY DISINTEGRATING; ORAL

## RISPERIDONE

>A>	AB	TEVA	0.5MG	A076908 001	Mar 12, 2012	Feb	NEWA
>A>	AB		1MG	A076908 002	Mar 12, 2012	Feb	NEWA
>A>	AB		2MG	A076908 003	Mar 12, 2012	Feb	NEWA

ROPINIROLE HYDROCHLORIDE

## TABLET; ORAL

## ROPINIROLE HYDROCHLORIDE

AB		APOTEX	EQ 0.25MG BASE	A079165 001	Feb 07, 2012	Jan	NEWA
AB			EQ 0.5MG BASE	A079165 002	Feb 07, 2012	Jan	NEWA
AB			EQ 1MG BASE	A079165 003	Feb 07, 2012	Jan	NEWA
AB			EQ 2MG BASE	A079165 004	Feb 07, 2012	Jan	NEWA
AB			EQ 3MG BASE	A079165 005	Feb 07, 2012	Jan	NEWA
AB			EQ 4MG BASE	A079165 006	Feb 07, 2012	Jan	NEWA
AB			EQ 5MG BASE	A079165 007	Feb 07, 2012	Jan	NEWA

SERTACONAZOLE NITRATE

CREAM; TOPICAL

ERTACZO

+ VALEANT INTL 2% N021385 001 Dec 10, 2003 Jan CAHN

SERTRALINE HYDROCHLORIDE

TABLET; ORAL

SERTRALINE HYDROCHLORIDE

>D>	@	ACTAVIS TOTOWA	EQ 25MG BASE	A078175 001	Jul 21, 2010	Feb	CMFD
>D>	@		EQ 50MG BASE	A078175 002	Jul 21, 2010	Feb	CMFD
>D>	@		EQ 100MG BASE	A078175 003	Jul 21, 2010	Feb	CMFD
>A>	AB	PROSAM LABS	EQ 25MG BASE	A078175 001	Jul 21, 2010	Feb	CMFD
>A>	AB		EQ 50MG BASE	A078175 002	Jul 21, 2010	Feb	CMFD
>A>	AB		EQ 100MG BASE	A078175 003	Jul 21, 2010	Feb	CMFD

SIMVASTATIN

TABLET; ORAL

SIMVASTATIN

>D>	@	ACTAVIS TOTOWA	5MG	A078735 001	Aug 30, 2010	Feb	CMFD
>D>	@		10MG	A078735 002	Aug 30, 2010	Feb	CMFD
>D>	@		20MG	A078735 003	Aug 30, 2010	Feb	CMFD
>D>	@		40MG	A078735 004	Aug 30, 2010	Feb	CMFD
>D>	@		80MG	A078735 005	Aug 30, 2010	Feb	CMFD
>A>	AB	PROSAM LABS	5MG	A078735 001	Aug 30, 2010	Feb	CMFD
>A>	AB		10MG	A078735 002	Aug 30, 2010	Feb	CMFD
>A>	AB		20MG	A078735 003	Aug 30, 2010	Feb	CMFD
>A>	AB		40MG	A078735 004	Aug 30, 2010	Feb	CMFD
>A>	AB		80MG	A078735 005	Aug 30, 2010	Feb	CMFD

SODIUM BICARBONATE; TARTARIC ACID

GRANULE, EFFERVESCENT; ORAL

BAROS

@ MALLINCKRODT INC 460MG/GM;420MG/GM N018509 001 Aug 07, 1985 Jan CAHN

SODIUM CHLORIDE

INJECTABLE; INJECTION

SODIUM CHLORIDE 0.9%

AP		HIKMA (MAPLE)	9MG/ML	A201850 001	Jan 20, 2012	Jan	NEWA
		SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER					
		MEDEFIL	9MG/ML	N202832 001	Jan 06, 2012	Jan	NEWA

SODIUM IODIDE I-131

CAPSULE; ORAL

SODIUM IODIDE I-131

>D>		DRAXIMAGE	9-100mCi	N021305 006	May 19, 2005	Feb	CAHN
>A>		JUBILANT DRAXIMAGE	9-100mCi	N021305 006	May 19, 2005	Feb	CAHN
		@	2-200mCi	N021305 004	Nov 18, 2004	Jan	DISC

SOLUTION; ORAL

HICON

>D>	+	DRAXIMAGE	1-500mCi/0.5ML	N021305 003	Jan 24, 2003	Feb	DISC
>D>	+		1-250mCi/0.25ML	N021305 002	Jan 24, 2003	Feb	DISC
>D>	+		1-1000mCi/ML	N021305 005	Apr 04, 2006	Feb	DISC
>A>	@	JUBILANT DRAXIMAGE	1-250mCi/0.25ML	N021305 002	Jan 24, 2003	Feb	DISC
>A>	@		1-1000mCi/ML	N021305 005	Apr 04, 2006	Feb	DISC
>A>	@		1-500mCi/0.5ML	N021305 003	Jan 24, 2003	Feb	DISC

		SOLUTION; ORAL							
		HICON							
		+ JUBILANT DRAXIMAGE	250-1000mCi			N021305	007	Dec 05, 2011	Jan NEWA
>A>		<u>SODIUM NITRITE</u>							
>A>		SOLUTION; INTRAVENOUS							
>A>		SODIUM NITRITE							
>A>		+ HOPE PHARMS	300MG/10ML (30MG/ML)			N203922	001	Feb 14, 2012	Feb NEWA
>A>		<u>SODIUM THIOSULFATE</u>							
>A>		SOLUTION; INTRAVENOUS							
>A>		SODIUM THIOSULFATE							
>A>		+ HOPE PHARMS	12.5GM/50ML (250MG/ML)			N203923	001	Feb 14, 2012	Feb NEWA
		<u>SULFACETAMIDE SODIUM</u>							
		LOTION; TOPICAL							
		SULFACETAMIDE SODIUM							
AB		FOUGERA PHARMS	10%			A077015	001	Nov 17, 2006	Jan CAHN
>A>		<u>TAFLUPROST</u>							
>A>		SOLUTION/DROPS; OPHTHALMIC							
>A>		ZIOPTAN							
>A>		+ MERCK SHARP DOHME	0.0015%			N202514	001	Feb 10, 2012	Feb NEWA
		<u>TENOFOVIR DISOPROXIL FUMARATE</u>							
		POWDER; ORAL							
		VIREAD							
		+ GILEAD SCIENCES INC	40MG/SCOOPFUL			N022577	001	Jan 18, 2012	Jan NEWA
		<u>TERBUTALINE SULFATE</u>							
		INJECTABLE; INJECTION							
		TERBUTALINE SULFATE							
		@ TEVA PARENTERAL	1MG/ML			A076853	001	Jul 20, 2004	Jan DISC
		<u>TERCONAZOLE</u>							
		CREAM; VAGINAL							
		TERCONAZOLE							
AB		FOUGERA PHARMS	0.4%			A076712	001	Feb 18, 2005	Jan CAHN
		SUPPOSITORY; VAGINAL							
		TERCONAZOLE							
AB		FOUGERA PHARMS	80MG			A076850	001	Jul 12, 2006	Jan CAHN
		<u>TESTOSTERONE</u>							
		GEL; TRANSDERMAL							
		ANDROGEL							
>D>		ABBOTT LABS	1% (2.5GM/PACKET)			N021015	001	Feb 28, 2000	Feb CPOT
>D>	BX	+	1% (5GM/PACKET)			N021015	002	Feb 28, 2000	Feb CPOT
>A>			1% (25MG/2.5GM PACKET)			N021015	001	Feb 28, 2000	Feb CPOT
>A>	BX	+	1% (50MG/5GM PACKET)			N021015	002	Feb 28, 2000	Feb CPOT
		TESTIM							
>D>	BX	+	AUXILIUM PHARMS	1% (5GM/PACKET)		N021454	001	Oct 31, 2002	Feb CPOT
>A>	BX	+		1% (50MG/5GM PACKET)		N021454	001	Oct 31, 2002	Feb CPOT
>A>		TESTOSTERONE							
>A>		TEVA PHARMS	25MG/2.5GM PACKET			N202763	001	Feb 14, 2012	Feb NEWA
>A>			50MG/5GM PACKET			N202763	002	Feb 14, 2012	Feb NEWA

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION  
TESTOSTERONE CYPIONATE

>A>	AO	MYLAN INSTITUTIONAL	200MG/ML	A040652 001	Dec 11, 2006	Feb	CAHN
>D>	AO	SYNERX PHARMA	200MG/ML	A040652 001	Dec 11, 2006	Feb	CAHN

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION  
TESTOSTERONE ENANTHATE

>A>	AO	MYLAN INSTITUTIONAL	200MG/ML	A040647 001	Oct 05, 2009	Feb	CAHN
>D>	AO	SYNERX PHARMA	200MG/ML	A040647 001	Oct 05, 2009	Feb	CAHN

TETRAHYDROZOLINE HYDROCHLORIDE

SOLUTION; NASAL  
TYZINE

+	FOUGERA PHARMS	0.05%	A086576 002			Jan	CAHN
		0.1%	A086576 001			Jan	CAHN

SPRAY; NASAL  
TYZINE

+	FOUGERA PHARMS	0.1%	A086576 003			Jan	CAHN
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TIAGABINE HYDROCHLORIDE

TABLET; ORAL  
GABITRIL

@	CEPHALON	6MG	N020646 006	Nov 29, 2005	Jan	DISC
@		8MG	N020646 007	Nov 29, 2005	Jan	DISC
@		10MG	N020646 008	Nov 29, 2005	Jan	DISC

TIZANIDINE HYDROCHLORIDE

CAPSULE; ORAL  
TIZANIDINE HYDROCHLORIDE

AB	APOTEX INC	EQ 2MG BASE	A078868 001	Feb 03, 2012	Jan	NEWA
AB		EQ 4MG BASE	A078868 002	Feb 03, 2012	Jan	NEWA
AB		EQ 6MG BASE	A078868 003	Feb 03, 2012	Jan	NEWA
	ZANAFLEX					
AB	ACORDA	EQ 2MG BASE	N021447 001	Aug 29, 2002	Jan	CFTG
AB		EQ 4MG BASE	N021447 002	Aug 29, 2002	Jan	CFTG
AB	+	EQ 6MG BASE	N021447 003	Aug 29, 2002	Jan	CFTG

TABLET; ORAL  
TIZANIDINE HYDROCHLORIDE

>D>	@	ACTAVIS TOTOWA	EQ 2MG BASE	A076281 001	Oct 20, 2003	Feb	CMFD
>D>	@		EQ 4MG BASE	A076281 002	Oct 20, 2003	Feb	CMFD
>A>	AB	PROSAM LABS	EQ 2MG BASE	A076281 001	Oct 20, 2003	Feb	CMFD
>A>	AB		EQ 4MG BASE	A076281 002	Oct 20, 2003	Feb	CMFD
>A>	AB	SANDOZ INC	EQ 2MG BASE	A076280 001	Nov 26, 2002	Feb	NEWA

TRANEXAMIC ACID

INJECTABLE; INJECTION  
TRANEXAMIC ACID

>A>	AP	NEXUS PHARMS	100MG/ML	A091596 001	Mar 02, 2012	Feb	NEWA
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TRANLYCYPROMINE SULFATE

TABLET; ORAL  
PARNATE

AB	+	COVIS PHARMA	EQ 10MG BASE	N012342 003	Aug 16, 1985	Jan	CAHN
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TRETINOIN

CREAM; TOPICAL		RENOVA							
	+	VALEANT INTL	0.02%	N021108	001	Aug 31, 2000	Jan	CAHN	
AB2	+		0.05%	N019963	001	Dec 29, 1995	Jan	CAHN	
RETIN-A									
AB	+	VALEANT INTL	0.025%	N019049	001	Sep 16, 1988	Jan	CAHN	
AB1	+		0.05%	N017522	001		Jan	CAHN	
AB	+		0.1%	N017340	001		Jan	CAHN	
GEL; TOPICAL		RETIN-A							
AB	+	VALEANT INTL	0.01%	N017955	001		Jan	CAHN	
AB	+		0.025%	N017579	002		Jan	CAHN	
SOLUTION; TOPICAL		RETIN-A							
AT	+	VALEANT INTL	0.05%	N016921	001		Jan	CAHN	
SWAB; TOPICAL		RETIN-A							
		@ VALEANT INTL	0.05%	N016921	002		Jan	CAHN	

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL		TRIAMCINOLONE ACETONIDE							
AT		FOUGERA PHARMS	0.025%	A085692	001		Jan	CAHN	
AT			0.1%	A085692	003		Jan	CAHN	
AT	+		0.5%	A085692	002		Jan	CAHN	
LOTION; TOPICAL		TRIAMCINOLONE ACETONIDE							
AT		FOUGERA PHARMS	0.025%	A040467	001	Apr 21, 2003	Jan	CAHN	
AT			0.1%	A040467	002	Apr 21, 2003	Jan	CAHN	
OINTMENT; TOPICAL		TRIAMCINOLONE ACETONIDE							
AT		FOUGERA PHARMS	0.025%	A085691	001		Jan	CAHN	
AT			0.1%	A085691	003		Jan	CAHN	
AT			0.5%	A085691	002		Jan	CAHN	

VANDETANIB

TABLET; ORAL		CAPRELSA							
>A>		IPR PHARMS INC	100MG	N022405	001	Apr 06, 2011	Feb	CTNA	
>A>	+		300MG	N022405	002	Apr 06, 2011	Feb	CTNA	
VANDETANIB									
>D>		IPR PHARMS INC	100MG	N022405	001	Apr 06, 2011	Feb	CTNA	
>D>	+		300MG	N022405	002	Apr 06, 2011	Feb	CTNA	

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL		CALAN SR							
>A>	AB	+	PFIZER	120MG	N019152	003	Mar 06, 1991	Feb	CTNA
>A>	AB	+		180MG	N019152	002	Dec 15, 1989	Feb	CTNA
>A>	AB	+		240MG	N019152	001	Dec 16, 1986	Feb	CTNA
ISOPTIN SR									
>D>	AB	+	PFIZER	120MG	N019152	003	Mar 06, 1991	Feb	CTNA
>D>	AB	+		180MG	N019152	002	Dec 15, 1989	Feb	CTNA
>D>	AB	+		240MG	N019152	001	Dec 16, 1986	Feb	CTNA

VISMODEGIB

CAPSULE; ORAL

ERIVEDGE

+	GENENTECH	150MG	N203388	001	Jan 30, 2012	Jan	NEWA
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ZIPRASIDONE HYDROCHLORIDE

CAPSULE; ORAL

GEODON

>D>	+	PFIZER	EQ 20MG BASE	N020825	001	Feb 05, 2001	Feb	CFTG
>A>	AB	+	EQ 20MG BASE	N020825	001	Feb 05, 2001	Feb	CFTG
>D>			EQ 40MG BASE	N020825	002	Feb 05, 2001	Feb	CFTG
>A>	AB		EQ 40MG BASE	N020825	002	Feb 05, 2001	Feb	CFTG
>D>			EQ 60MG BASE	N020825	003	Feb 05, 2001	Feb	CFTG
>A>	AB		EQ 60MG BASE	N020825	003	Feb 05, 2001	Feb	CFTG
>D>			EQ 80MG BASE	N020825	004	Feb 05, 2001	Feb	CFTG
>A>	AB		EQ 80MG BASE	N020825	004	Feb 05, 2001	Feb	CFTG
>A>		ZIPRASIDONE HYDROCHLORIDE						
>A>	AB	APOTEX CORP	EQ 20MG BASE	A077561	001	Mar 02, 2012	Feb	NEWA
>A>	AB		EQ 40MG BASE	A077561	002	Mar 02, 2012	Feb	NEWA
>A>	AB		EQ 60MG BASE	A077561	003	Mar 02, 2012	Feb	NEWA
>A>	AB		EQ 80MG BASE	A077561	004	Mar 02, 2012	Feb	NEWA
>A>	AB	DR REDDYS LABS INC	EQ 20MG BASE	A077565	001	Mar 02, 2012	Feb	NEWA
>A>	AB		EQ 40MG BASE	A077565	002	Mar 02, 2012	Feb	NEWA
>A>	AB		EQ 60MG BASE	A077565	003	Mar 02, 2012	Feb	NEWA
>A>	AB		EQ 80MG BASE	A077565	004	Mar 02, 2012	Feb	NEWA
>A>	AB	LUPIN PHARMS	EQ 20MG BASE	A077560	001	Mar 02, 2012	Feb	NEWA
>A>	AB		EQ 40MG BASE	A077560	002	Mar 02, 2012	Feb	NEWA
>A>	AB		EQ 60MG BASE	A077560	003	Mar 02, 2012	Feb	NEWA
>A>	AB		EQ 80MG BASE	A077560	004	Mar 02, 2012	Feb	NEWA



OTC DRUG PRODUCT LIST - 32ND EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2012

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DIPHENHYDRAMINE HYDROCHLORIDE; IBUPROFEN

CAPSULE; ORAL

IBUPROFEN AND DIPHENHYDRAMINE HYDROCHLORIDE

>A> STRIDES ARCOLAB LTD 25MG;EQ 200MG FREE ACID AND POTASSIUM SALT A200888 001 Mar 05, 2012 Feb NEWA

FEXOFENADINE HYDROCHLORIDE

TABLET; ORAL

CHILDREN'S FEXOFENADINE HYDROCHLORIDE ALLERGY

SUN PHARM INDS 30MG A091567 002 Feb 06, 2012 Jan NEWA

WOCKHARDT LTD 30MG A079112 002 Feb 08, 2012 Jan NEWA

CHILDREN'S FEXOFENADINE HYDROCHLORIDE HIVES

SUN PHARM INDS 30MG A091567 001 Feb 06, 2012 Jan NEWA

WOCKHARDT LTD 30MG A079112 001 Feb 08, 2012 Jan NEWA

FEXOFENADINE HYDROCHLORIDE ALLERGY

SUN PHARM INDS 60MG A091567 004 Feb 06, 2012 Jan NEWA

180MG A091567 006 Feb 06, 2012 Jan NEWA

WOCKHARDT LTD 60MG A079112 004 Feb 08, 2012 Jan NEWA

180MG A079112 006 Feb 08, 2012 Jan NEWA

FEXOFENADINE HYDROCHLORIDE HIVES

SUN PHARM INDS 60MG A091567 003 Feb 06, 2012 Jan NEWA

180MG A091567 005 Feb 06, 2012 Jan NEWA

WOCKHARDT LTD 60MG A079112 003 Feb 08, 2012 Jan NEWA

180MG A079112 005 Feb 08, 2012 Jan NEWA

IBUPROFEN

CAPSULE; ORAL

IBUPROFEN

ACCUCAPS INDS EQ 200MG FREE ACID AND POTASSIUM SALT A077338 001 Jul 10, 2009 Jan CAHN

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE HYDROCHLORIDE

>A> SHASUN CHEMS EQ 75MG BASE A201745 001 Feb 29, 2012 Feb NEWA

**DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT  
ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST**

**CUMULATIVE SUPPLEMENT NUMBER 02 FEBRUARY 2012**

NO FEBRUARY 2012 APPROVALS

## ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The list of List of Orphan Designations and Approvals is available at:

<http://www.fda.gov/orphan/designat/list.htm>

**DRUG PRODUCTS WHICH MUST DEMONSTRATE *IN VIVO* BIOAVAILABILITY  
ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION**

NO FEBRUARY 2012 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2012

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ADAPALENE; BENZOYL PEROXIDE - EPIDUO</u>						
N022320 001	>A> 8105618	Dec 23, 2022	U-1078			
<u>ALBUTEROL SULFATE - PROAIR HFA</u>						
N021457 001	>A> 6446627	Dec 18, 2017	DP			
<u>ALVIMOPAN - ENTEREG</u>						
N021775 001	>A> 8112290	Jul 31, 2030	U-1225			
<u>AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u>						
N022314 001	8101599	May 16, 2023	DP			
<u>AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u>						
N022314 002	8101599	May 16, 2023	DP			
<u>AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u>						
N022314 003	8101599	May 16, 2023	DP			
<u>AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u>						
N022314 004	8101599	May 16, 2023	DP			
<u>AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u>						
N022314 005	8101599	May 16, 2023	DP			
<u>ARFORMOTEROL TARTRATE - BROVANA</u>						
N021912 001	8110706	Nov 09, 2021	DP			
<u>ATOVAQUONE; PROGUANIL HYDROCHLORIDE - ATOVAQUONE AND PROGUANIL HYDROCHLORIDE</u>						
A091211 001					PC	Mar 13, 2012
<u>AXITINIB - INLYTA</u>						
N202324 001	>A> 6534524	Jun 30, 2020	DS DP		NCE	Jan 27, 2017
	>A> 7141581	Jun 30, 2020	U-1220			
<u>AXITINIB - INLYTA</u>						
N202324 002	>A> 6534524	Jun 30, 2020	DS DP		NCE	Jan 27, 2017
	>A> 7141581	Jun 30, 2020	U-1220			
<u>AZILSARTAN KAMEDOXOMIL; CHLORTHALIDONE - EDARBYCLOR</u>						
N202331 001	5583141	Dec 10, 2013	DS DP U-3			
	5736555	Jun 25, 2012	DS DP U-3			
	7157584	May 22, 2025	DS			
	7572920	Jan 07, 2025	DP U-3			
<u>AZILSARTAN KAMEDOXOMIL; CHLORTHALIDONE - EDARBYCLOR</u>						
N202331 002	5583141	Dec 10, 2013	DS DP U-3			
	5736555	Jun 25, 2012	DS DP U-3			
	7157584	May 22, 2025	DS			
	7572920	Jan 07, 2025	DP U-3			
<u>BALSALAZIDE DISODIUM - GIAZO</u>						
N022205 001	>A> 6197341	Mar 13, 2018	DP U-1229		>A> NDF	Feb 03, 2015
	>A> 7452872	Aug 24, 2026	U-1229			
	>A> 7625884	Aug 24, 2026	U-1229			

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2012

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>BIMATOPROST - LATISSE</u>						
N022369 001	8101161	May 25, 2024	DP U-1219			
	8101161	May 25, 2024	DP U-1218			
	8101161	May 25, 2024	DP U-1217			
<u>BORTEZOMIB - VELCADE</u>						
N021602 001					NR	Jan 23, 2015
<u>BUPIVACAINE - EXPAREL</u>						
N022496 001	>A> 6132766	Nov 16, 2013	DP			
<u>BUPIVACAINE - EXPAREL</u>						
N022496 002	>A> 6132766	Nov 16, 2013	DP			
<u>CARVEDILOL PHOSPHATE - COREG CR</u>						
N022012 001	>A> 8101209	Sep 11, 2025	DP			
	>A> 8101209*PED	Mar 11, 2026				
<u>CARVEDILOL PHOSPHATE - COREG CR</u>						
N022012 002	>A> 8101209	Sep 11, 2025	DP			
	>A> 8101209*PED	Mar 11, 2026				
<u>CARVEDILOL PHOSPHATE - COREG CR</u>						
N022012 003	>A> 8101209	Sep 11, 2025	DP			
	>A> 8101209*PED	Mar 11, 2026				
<u>CARVEDILOL PHOSPHATE - COREG CR</u>						
N022012 004	>A> 8101209	Sep 11, 2025	DP			
	>A> 8101209*PED	Mar 11, 2026				
<u>CICLESONIDE - ZETONNA</u>						
N202129 001	5482934	Oct 24, 2017	DS DP U-1002		NP	Jan 20, 2015
	5605674	Feb 25, 2014	DP			
	5683677	Nov 04, 2014	DP			
	5775321	Jul 07, 2015	DP			
	6006745	Dec 28, 2016	DP			
	6036942	Apr 30, 2013	DP			
	6120752	May 13, 2018	DP			
	6264923	May 13, 2018	DP			
<u>COLCHICINE - COLCRYS</u>						
N022352 001	7964648	Oct 06, 2028	U-1161			
	8097655	Oct 06, 2028	U-1020			
<u>DAPTOMYCIN - CUBICIN</u>						
N021572 002	>A> 8129342	Nov 28, 2020	DS DP			

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2012

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N021976 001	5843946*PED	Jun 01, 2016				
	6037157	Jun 26, 2016	U-935			
	6037157	Jun 26, 2016	U-1209			
	6037157*PED	Dec 26, 2016				
	6335460	Aug 25, 2012	DS DP U-935			
	6335460	Aug 25, 2012	DS DP U-903			
	6335460	Aug 25, 2012	DS DP U-744			
	6335460	Aug 25, 2012	DS DP U-1209			
	6335460*PED	Feb 25, 2013				
	6703403	Jun 26, 2016	U-935			
	6703403	Jun 26, 2016	U-1209			
	6703403*PED	Dec 26, 2016				
	7470506	Jun 23, 2019	U-935			
	7470506	Jun 23, 2019	U-1209			
	7470506*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N021976 002	5843946*PED	Jun 01, 2016				
	6037157	Jun 26, 2016	U-935			
	6037157	Jun 26, 2016	U-1209			
	6037157*PED	Dec 26, 2016				
	6335460	Aug 25, 2012	DS DP U-935			
	6335460	Aug 25, 2012	DS DP U-903			
	6335460	Aug 25, 2012	DS DP U-744			
	6335460	Aug 25, 2012	DS DP U-1209			
	6335460*PED	Feb 25, 2013				
	6703403	Jun 26, 2016	U-935			
	6703403	Jun 26, 2016	U-1209			
	6703403*PED	Dec 26, 2016				
	7470506	Jun 23, 2019	U-935			
	7470506	Jun 23, 2019	U-1209			
	7470506*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N021976 003	5843946*PED	Jun 01, 2016				
	6037157	Jun 26, 2016	U-935			
	6037157	Jun 26, 2016	U-1209			
	6037157*PED	Dec 26, 2016				
	6335460	Aug 25, 2012	DS DP U-935			
	6335460	Aug 25, 2012	DS DP U-903			
	6335460	Aug 25, 2012	DS DP U-744			
	6335460	Aug 25, 2012	DS DP U-1209			
	6335460*PED	Feb 25, 2013				
	6703403	Jun 26, 2016	U-935			
	6703403	Jun 26, 2016	U-1209			
	6703403*PED	Dec 26, 2016				
	7470506	Jun 23, 2019	U-935			
	7470506	Jun 23, 2019	U-1209			
	7470506*PED	Dec 23, 2019				

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N021976 004	5843946*PED	Jun 01, 2016				
	6037157	Jun 26, 2016	U-935			
	6037157	Jun 26, 2016	U-1209			
	6037157*PED	Dec 26, 2016				
	6335460	Aug 25, 2012	DS DP U-935			
	6335460	Aug 25, 2012	DS DP U-903			
	6335460	Aug 25, 2012	DS DP U-744			
	6335460	Aug 25, 2012	DS DP U-1209			
	6335460*PED	Feb 25, 2013				
	6703403	Jun 26, 2016	U-935			
	6703403	Jun 26, 2016	U-1209			
	6703403*PED	Dec 26, 2016				
	7470506	Jun 23, 2019	U-935			
	7470506	Jun 23, 2019	U-1209			
	7470506*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N021976 005	5843946*PED	Jun 01, 2016				
	6037157	Jun 26, 2016	U-935			
	6037157	Jun 26, 2016	U-1209			
	6037157*PED	Dec 26, 2016				
	6335460	Aug 25, 2012	DS DP U-935			
	6335460	Aug 25, 2012	DS DP U-903			
	6335460	Aug 25, 2012	DS DP U-744			
	6335460	Aug 25, 2012	DS DP U-1209			
	6335460*PED	Feb 25, 2013				
	6703403	Jun 26, 2016	U-935			
	6703403	Jun 26, 2016	U-1209			
	6703403*PED	Dec 26, 2016				
	7470506	Jun 23, 2019	U-935			
	7470506	Jun 23, 2019	U-1209			
	7470506*PED	Dec 23, 2019				
<u>DARUNAVIR ETHANOLATE - PREZISTA</u>						
N202895 001	5843946	Dec 01, 2015	DP U-1209			
	5843946*PED	Jun 01, 2016				
	6037157	Jun 26, 2016	U-1209			
	6037157*PED	Dec 26, 2016				
	6248775	Aug 13, 2014	DS			
	6248775*PED	Feb 13, 2015				
	6335460	Aug 25, 2012	DS DP U-1209			
	6335460*PED	Feb 25, 2013				
	6703403	Jun 26, 2016	U-1209			
	6703403*PED	Dec 26, 2016				
	7470506	Jun 23, 2019	U-1209			
	7470506*PED	Dec 23, 2019				
	7700645	Dec 26, 2026	DS DP			
	7700645*PED	Jun 26, 2027				
	RE42889	Oct 19, 2016	DP			
	RE42889*PED	Apr 19, 2017				



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<u>DEXAMETHASONE - OZURDEX</u>						
N022315 001	8088407	Oct 20, 2020	DP U-1205			
<u>DEXLANSOPRAZOLE - DEXILANT</u>						
N022287 001	>A> 8105626	Sep 27, 2026	DP			
	>A> 8105626*PED	Mar 27, 2027				
<u>DEXLANSOPRAZOLE - DEXILANT</u>						
N022287 002	>A> 8105626	Sep 27, 2026	DP			
	>A> 8105626*PED	Mar 27, 2027				
<u>DICLOFENAC POTASSIUM - CAMBIA</u>						
N022165 001	8097651	Jun 16, 2026	DS DP U-436			
<u>DICLOFENAC POTASSIUM - ZIPSOR</u>						
N022202 001	8110606	Feb 24, 2029	U-980			
<u>DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE - COSOPT PF</u>						
N202667 001					>A> NP	Feb 01, 2015
<u>DROSPIRENONE; ETHINYL ESTRADIOL - ANGELIQ</u>						
N021355 001					>A> NS	Mar 01, 2015
<u>EPROSARTAN MESYLATE - EPROSARTAN MESYLATE</u>						
A202012 001					PC	Jun 17, 2012
<u>EPROSARTAN MESYLATE - EPROSARTAN MESYLATE</u>						
A202012 002					PC	Jun 17, 2012
<u>ERIBULIN MESYLATE - HALAVEN</u>						
N201532 001	8097648	Jan 22, 2021	U-1096			
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>						
N021957 001	5877192	May 27, 2014	U-773			
	5877192	May 27, 2014	U-729			
	5877192	May 27, 2014	U-1207			
	5877192*PED	Nov 27, 2014				
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>						
N021957 002	5877192	May 27, 2014	U-773			
	5877192	May 27, 2014	U-729			
	5877192	May 27, 2014	U-1207			
	5877192*PED	Nov 27, 2014				
<u>EXENATIDE SYNTHETIC - BYDUREON</u>						
N022200 001	>A> 5424286	Dec 01, 2016	U-1108		NP	Jan 27, 2015
	>A> 6479065	Aug 10, 2020	DP			
	>A> 6495164	May 25, 2020	DP			
	>A> 6667061	May 25, 2020	DP			
	>A> 6824822	Oct 09, 2022	DP			
	>A> 6858576	Jan 06, 2017	U-656			
	>A> 6872700	Jan 14, 2020	U-654			
	>A> 6956026	Jan 07, 2018	U-687			
	>A> 7223440	Aug 31, 2021	DP			
	>A> 7456254	Jun 30, 2025	DP U-1223			
	>A> 7563871	Apr 15, 2024	DP			
	>A> 7612176	Apr 13, 2025	DP U-1223			
	>A> 7741269	Jan 07, 2018	U-1224			

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<u>EXENATIDE SYNTHETIC - BYETTA</u>						
N021773	001				>A> M-111	Oct 19, 2014
<u>EXENATIDE SYNTHETIC - BYETTA</u>						
N021773	002				>A> M-111	Oct 19, 2014
<u>EZETIMIBE - ZETIA</u>						
N021445	001				M-109	Jan 24, 2015
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
N021687	001				M-109	Jan 24, 2015
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
N021687	002				M-109	Jan 24, 2015
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
N021687	003				M-109	Jan 24, 2015
<u>EZETIMIBE; SIMVASTATIN - VYTORIN</u>						
N021687	004				M-109	Jan 24, 2015
<u>FAMCICLOVIR - FAMVIR</u>						
N020363	001				>A> M-112	Feb 09, 2015
<u>FAMCICLOVIR - FAMVIR</u>						
N020363	002				>A> M-112	Feb 09, 2015
<u>FAMCICLOVIR - FAMVIR</u>						
N020363	003				>A> M-112	Feb 09, 2015
<u>FENTANYL - SUBSYS</u>						
N202788	001				NP	Jan 04, 2015
<u>FENTANYL - SUBSYS</u>						
N202788	002				NP	Jan 04, 2015
<u>FENTANYL - SUBSYS</u>						
N202788	003				NP	Jan 04, 2015
<u>FENTANYL - SUBSYS</u>						
N202788	004				NP	Jan 04, 2015
<u>FENTANYL - SUBSYS</u>						
N202788	005				NP	Jan 04, 2015
<u>FENTANYL CITRATE - FENTORA</u>						
N021947	001	8092832	Dec 30, 2024	DP		
<u>FENTANYL CITRATE - FENTORA</u>						
N021947	002	8092832	Dec 30, 2024	DP		
	>A>	8119158	Dec 30, 2024	DP		
<u>FENTANYL CITRATE - FENTORA</u>						
N021947	003	8092832	Dec 30, 2024	DP		
	>A>	8119158	Dec 30, 2024	DP		
<u>FENTANYL CITRATE - FENTORA</u>						
N021947	004	8092832	Dec 30, 2024	DP		
	>A>	8119158	Dec 30, 2024	DP		
<u>FENTANYL CITRATE - FENTORA</u>						
N021947	005	8092832	Dec 30, 2024	DP		
	>A>	8119158	Dec 30, 2024	DP		

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<u>FESOTERODINE FUMARATE - TOVIAZ</u>						
N022030 001	8088398	Jun 07, 2027	DP U-913			
<u>FESOTERODINE FUMARATE - TOVIAZ</u>						
N022030 002	8088398	Jun 07, 2027	DP U-913			
<u>FLUNISOLIDE - AEROSPAN HFA</u>						
N021247 001	>A> 5776433	Jul 07, 2015	DP			
	>A> 5980867	Jul 06, 2018	DP			
<u>GABAPENTIN ENACARBIL - HORIZANT</u>						
N022399 001	>A> 8114909	Apr 11, 2026		U-1231		
<u>GABAPENTIN ENACARBIL - HORIZANT</u>						
N022399 002	>A> 8114909	Apr 11, 2026		U-1231		
<u>GLYCOPYRROLATE - CUVPOSA</u>						
N022571 001					>A> ODE	Jul 28, 2017
<u>IMATINIB MESYLATE - GLEEVEC</u>						
N021588 001					ODE	Dec 19, 2015
<u>IMATINIB MESYLATE - GLEEVEC</u>						
N021588 002					ODE	Dec 19, 2015
<u>INGENOL MEBUTATE - PICATO</u>						
N202833 001	>A> 6432452	Aug 19, 2018	DS U-68		NCE	Jan 23, 2017
	>A> 6844013	Aug 19, 2018	DS DP U-1221			
	>A> 7410656	Aug 19, 2018	DS U-1222			
<u>INGENOL MEBUTATE - PICATO</u>						
N202833 002	>A> 6432452	Aug 19, 2018	DS U-68		NCE	Jan 23, 2017
	>A> 6844013	Aug 19, 2018	DS DP U-1221			
	>A> 7410656	Aug 19, 2018	DS U-1222			
<u>IVACAFTOR - KALYDECO</u>						
N203188 001	>A> 7495103	May 20, 2027	DS DP		NCE >A> ODE	Jan 31, 2017 Jan 31, 2019
<u>IVERMECTIN - SKLICE</u>						
N202736 001	>A> 6103248	May 22, 2018	DP		>A> NP	Feb 07, 2015
<u>IXABEPILONE - IXEMPRA KIT</u>						
N022065 001	RE41911	Sep 28, 2020	DS DP U-961			
	RE41911*PED	Mar 28, 2021				
<u>IXABEPILONE - IXEMPRA KIT</u>						
N022065 002	RE41911	Sep 28, 2020	DS DP U-961			
	RE41911*PED	Mar 28, 2021				
<u>KETOCONAZOLE - EXTINA</u>						
N021738 001	8026238	Oct 19, 2018	DP U-1213			
<u>LAMIVUDINE; ZIDOVUDINE - LAMIVUDINE AND ZIDOVUDINE</u>						
A079081 001					PC	May 15, 2012

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<u>LENALIDOMIDE - REVLIMID</u>						
N021880 001	5635517	Oct 04, 2019	DS			U-1211
	6045501	Aug 28, 2018				U-1210
	6281230	Jul 24, 2016				U-1212
	6315720	Oct 23, 2020				U-1210
	6555554	Jul 24, 2016	DP			U-1211
	6561976	Aug 28, 2018				U-1210
	6561977	Oct 23, 2020				U-1210
	6755784	Oct 23, 2020				U-1210
	6908432	Aug 28, 2018				U-1210
	7189740	Apr 11, 2023				U-1215
	7465800	Apr 27, 2027	DS DP			
	7968569	Oct 07, 2023				U-1216
<u>LENALIDOMIDE - REVLIMID</u>						
N021880 002	5635517	Oct 04, 2019	DS			U-1211
	6045501	Aug 28, 2018				U-1210
	6281230	Jul 24, 2016				U-1212
	6315720	Oct 23, 2020				U-1210
	6555554	Jul 24, 2016	DP			U-1211
	6561976	Aug 28, 2018				U-1210
	6561977	Oct 23, 2020				U-1210
	6755784	Oct 23, 2020				U-1210
	6908432	Aug 28, 2018				U-1210
	7189740	Apr 11, 2023				U-1215
	7465800	Apr 27, 2027	DS DP			
	7968569	Oct 07, 2023				U-1216
<u>LENALIDOMIDE - REVLIMID</u>						
N021880 003	5635517	Oct 04, 2019	DS			U-1211
	6045501	Aug 28, 2018				U-1210
	6281230	Jul 24, 2016				U-1212
	6315720	Oct 23, 2020				U-1210
	6555554	Jul 24, 2016	DP			U-1211
	6561976	Aug 28, 2018				U-1210
	6561977	Oct 23, 2020				U-1210
	6755784	Oct 23, 2020				U-1210
	6908432	Aug 28, 2018				U-1210
	7189740	Apr 11, 2023				U-1215
	7465800	Apr 27, 2027	DS DP			
	7855217	Nov 24, 2024	DS DP			
	7968569	Oct 07, 2023				U-1216

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<u>LENALIDOMIDE - REVLIMID</u>						
N021880 004	5635517	Oct 04, 2019	DS U-1211			
	6045501	Aug 28, 2018	U-1210			
	6281230	Jul 24, 2016	U-1212			
	6315720	Oct 23, 2020	U-1210			
	6555554	Jul 24, 2016	DP U-1211			
	6561976	Aug 28, 2018	U-1210			
	6561977	Oct 23, 2020	U-1210			
	6755784	Oct 23, 2020	U-1210			
	6908432	Aug 28, 2018	U-1210			
	7189740	Apr 11, 2023	U-1215			
	7465800	Apr 27, 2027	DS DP			
	7968569	Oct 07, 2023	U-1216			
<u>LENALIDOMIDE - REVLIMID</u>						
N021880 005	5635517	Oct 04, 2019	DS U-1211			
	6045501	Aug 28, 2018	U-1210			
	6281230	Jul 24, 2016	U-1212			
	6315720	Oct 23, 2020	U-1210			
	6555554	Jul 24, 2016	DP U-1211			
	6561976	Aug 28, 2018	U-1210			
	6561977	Oct 23, 2020	U-1210			
	6755784	Oct 23, 2020	U-1210			
	6908432	Aug 28, 2018	U-1210			
	7119106	Jul 24, 2016	DP			
	7189740	Apr 11, 2023	U-1215			
	7465800	Apr 27, 2027	DS DP			
	7855217	Nov 24, 2024	DS DP			
	7968569	Oct 07, 2023	U-1216			
<u>LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO</u>						
N201281 001	>A> 6303661	Apr 24, 2017	U-802		NCE	May 02, 2016
	>A> 6890898	Feb 02, 2019	U-1039		NC	Jan 30, 2015
	>A> 7078381	Feb 02, 2019	U-1039			
	>A> 7407955	Aug 12, 2023	DS DP			
	>A> 7459428	Feb 02, 2019	U-1039			
<u>LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO</u>						
N201281 002	>A> 6303661	Apr 24, 2017	U-802		NCE	May 02, 2016
	>A> 6890898	Feb 02, 2019	U-1039		NC	Jan 30, 2015
	>A> 7078381	Feb 02, 2019	U-1039			
	>A> 7407955	Aug 12, 2023	DS DP			
	>A> 7459428	Feb 02, 2019	U-1039			
<u>LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO</u>						
N201281 003	>A> 6303661	Apr 24, 2017	U-802		NCE	May 02, 2016
	>A> 6890898	Feb 02, 2019	U-1039		NC	Jan 30, 2015
	>A> 7078381	Feb 02, 2019	U-1039			
	>A> 7407955	Aug 12, 2023	DS DP			
	>A> 7459428	Feb 02, 2019	U-1039			
<u>LIRAGLUTIDE RECOMBINANT - VICTOZA</u>						
N022341 001	>A> 8114833	Aug 13, 2025	DP			

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<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 001	7662788	Feb 24, 2023	U-727		I-645	Jan 31, 2015
	7713936	Feb 24, 2023	U-727			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 002	7662788	Feb 24, 2023	U-727		I-645	Jan 31, 2015
	7713936	Feb 24, 2023	U-727			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 003	7662788	Feb 24, 2023	U-727		I-645	Jan 31, 2015
	7713936	Feb 24, 2023	U-727			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 004	7662788	Feb 24, 2023	U-727		I-645	Jan 31, 2015
	>A> 7671030	Feb 24, 2023	DP U-727			
	>A> 7674774	Mar 18, 2023	DP U-842			
	>A> 7678771	Mar 25, 2023	DP U-842			
	>A> 7687467	Apr 08, 2023	DP U-842			
	7713936	Feb 24, 2023	U-727			
	>A> 7718619	Feb 24, 2023	DP U-842			
	>A> 7723305	Feb 24, 2023	DP U-842			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 005	7662788	Feb 24, 2023	U-727		I-645	Jan 31, 2015
	7713936	Feb 24, 2023	U-727			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 006	7662788	Feb 24, 2023	U-727		I-645	Jan 31, 2015
	7713936	Feb 24, 2023	U-727			
<u>LUBIPROSTONE - AMITIZA</u>						
N021908 001	8097649	Oct 16, 2020	DP			
	8097653	Nov 14, 2022	U-1214			
	8114890	Sep 05, 2020	DP			
<u>LUBIPROSTONE - AMITIZA</u>						
N021908 002	8097649	Oct 16, 2020	DP			
	8114890	Sep 05, 2020	DP			
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET XR</u>						
N202270 001	>A> 6303661	Apr 24, 2017	U-1227			
	>A> 6340475	Sep 19, 2016	DP			
	>A> 6635280	Sep 19, 2016	DP			
	>A> 6699871	Jul 26, 2022	DS DP U-1227			
	>A> 6890898	Feb 02, 2019	U-1228			
	>A> 7078381	Feb 02, 2019	U-1227			
	>A> 7125873	Jul 26, 2022	DP U-1227			
	>A> 7326708	Apr 11, 2026	DS DP U-1227			
	>A> 7459428	Feb 02, 2019	U-1227			

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<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET XR</u>						
N202270 002	>A> 6303661	Apr 24, 2017	U-1227			
	>A> 6340475	Sep 19, 2016	DP			
	>A> 6635280	Sep 19, 2016	DP			
	>A> 6699871	Jul 26, 2022	DS DP U-1227			
	>A> 6890898	Feb 02, 2019	U-1228			
	>A> 7078381	Feb 02, 2019	U-1227			
	>A> 7125873	Jul 26, 2022	DP U-1227			
	>A> 7326708	Apr 11, 2026	DS DP U-1227			
	>A> 7459428	Feb 02, 2019	U-1227			
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET XR</u>						
N202270 003	>A> 6303661	Apr 24, 2017	U-1227			
	>A> 6340475	Sep 19, 2016	DP			
	>A> 6635280	Sep 19, 2016	DP			
	>A> 6699871	Jul 26, 2022	DS DP U-1227			
	>A> 6890898	Feb 02, 2019	U-1228			
	>A> 7078381	Feb 02, 2019	U-1227			
	>A> 7125873	Jul 26, 2022	DP U-1227			
	>A> 7326708	Apr 11, 2026	DS DP U-1227			
	>A> 7459428	Feb 02, 2019	U-1227			
<u>METHYLPHENIDATE HYDROCHLORIDE - METHYLPHENIDATE HYDROCHLORIDE</u>						
A078458 001					>A> PC	Jul 01, 2012
<u>METHYLPHENIDATE HYDROCHLORIDE - METHYLPHENIDATE HYDROCHLORIDE</u>						
A078458 002					>A> PC	Jul 01, 2012
<u>METHYLPHENIDATE HYDROCHLORIDE - METHYLPHENIDATE HYDROCHLORIDE</u>						
A078458 003					>A> PC	Jul 01, 2012
<u>MICONAZOLE - ORAVIG</u>						
N022404 001	>A> 7651698	Sep 11, 2022	U-1051			
<u>MIFEPRISTONE - KORLYM</u>						
N202107 001					>A> NP	Feb 17, 2015
<u>MITOMYCIN - MITOSOL</u>						
N022572 001					>A> ODE	Feb 07, 2019
<u>NAFTIFINE HYDROCHLORIDE - NAFTIN</u>						
N019599 002					NS	Jan 13, 2015
<u>NICOTINE - NICODERM CQ</u>						
N020165 004	>A> 8075911	May 22, 2021	DP			
<u>NICOTINE - NICODERM CQ</u>						
N020165 005	>A> 8075911	May 22, 2021	DP			
<u>NICOTINE - NICODERM CQ</u>						
N020165 006	>A> 8075911	May 22, 2021	DP			

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<u>NITRIC OXIDE - INOMAX</u>						
N020845 002	>A> 5558083	Nov 22, 2013	DP U-1226			
	>A> 5558083*PED	May 22, 2014				
	>A> 5732693	Dec 13, 2016	DP U-1230			
	>A> 5732693*PED	Jun 13, 2017				
	>A> 5752504	Dec 13, 2016	DP U-1230			
	>A> 5752504*PED	Jun 13, 2017				
<u>NITRIC OXIDE - INOMAX</u>						
N020845 003	>A> 5558083	Nov 22, 2013	DP U-1226			
	>A> 5558083*PED	May 22, 2014				
	>A> 5732693	Dec 13, 2016	DP U-1230			
	>A> 5732693*PED	Jun 13, 2017				
	>A> 5752504	Dec 13, 2016	DP U-1230			
	>A> 5752504*PED	Jun 13, 2017				
<u>OXCARBAZEPINE - TRILEPTAL</u>						
N021285 001	>A> 8119148	Dec 19, 2020	DP U-724			
	>A> 8119148*PED	Jun 19, 2021				
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N022272 001	8114383	Oct 10, 2024	DP			
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N022272 002	8114383	Oct 10, 2024	DP			
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N022272 003	8114383	Oct 10, 2024	DP			
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N022272 004	8114383	Oct 10, 2024	DP			
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N022272 005	8114383	Oct 10, 2024	DP			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N201655 001	>A> 8114383	Aug 08, 2024	DP			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N201655 002	>A> 8114383	Aug 08, 2024	DP			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N201655 003	>A> 8114383	Aug 08, 2024	DP			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N201655 004	>A> 8114383	Aug 08, 2024	DP			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N201655 005	>A> 8114383	Aug 08, 2024	DP			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N201655 006	>A> 8114383	Aug 08, 2024	DP			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N201655 007	>A> 8114383	Aug 08, 2024	DP			
<u>PAZOPANIB HYDROCHLORIDE - VOTRIENT</u>						
N022465 001	>A> 8114885	Dec 19, 2021	DS DP			



## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2012

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>PAZOPANIB HYDROCHLORIDE - VOTRIENT</u>						
N022465 002	>A> 8114885	Dec 19, 2021	DS DP			
<u>RALTEGRAVIR POTASSIUM - ISENTRESS</u>						
N203045 001	7169780	Oct 03, 2023	DS DP			
	7217713	Oct 21, 2022			U-257	
	7435734	Oct 21, 2022			U-257	
	7754731	Mar 11, 2029	DS DP		U-257	
<u>RALTEGRAVIR POTASSIUM - ISENTRESS</u>						
N203045 002	7169780	Oct 03, 2023	DS DP			
	7217713	Oct 21, 2022			U-257	
	7435734	Oct 21, 2022			U-257	
	7754731	Mar 11, 2029	DS DP		U-257	
<u>REGADENOSON - LEXISCAN</u>						
N022161 001	>A> 8106029	Jun 22, 2019			U-1042	
	>A> 8106183	Feb 02, 2027	DS			
<u>RILPIVIRINE HYDROCHLORIDE - EDURANT</u>						
N202022 001	8080551	Apr 11, 2023	DS DP			
	>A> 8101629	Aug 09, 2022			DP	
<u>SILDENAFIL CITRATE - REVATIO</u>						
N021845 001	5250534	Mar 27, 2012	DS DP		I-598	May 07, 2012
	5250534*PED	Sep 27, 2012			PED	Nov 07, 2012
<u>SILDENAFIL CITRATE - REVATIO</u>						
N022473 001	5250534	Mar 27, 2012	DS DP		NDF	Nov 20, 2012
	5250534*PED	Sep 27, 2012			PED	May 20, 2013
<u>SILDENAFIL CITRATE - VIAGRA</u>						
N020895 001	5250534	Mar 27, 2012				
	5250534*PED	Sep 27, 2012				
	6469012	Oct 22, 2019			U-155	
	6469012*PED	Apr 22, 2020				
<u>SILDENAFIL CITRATE - VIAGRA</u>						
N020895 002	5250534	Mar 27, 2012				
	5250534*PED	Sep 27, 2012				
	6469012	Oct 22, 2019			U-155	
	6469012*PED	Apr 22, 2020				
<u>SILDENAFIL CITRATE - VIAGRA</u>						
N020895 003	5250534	Mar 27, 2012				
	5250534*PED	Sep 27, 2012				
	6469012	Oct 22, 2019			U-155	
	6469012*PED	Apr 22, 2020				
<u>SODIUM NITRITE - SODIUM NITRITE</u>						
N203922 001					>A> ODE	Jan 14, 2018
<u>SODIUM THIOSULFATE - SODIUM THIOSULFATE</u>						
N203923 001					>A> ODE	Jan 14, 2018
<u>SUMATRIPTAN SUCCINATE - SUMAVEL DOSEPRO</u>						
N022239 001	>A> 8118771	Aug 10, 2023	DP			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>T AFLUPROST - ZIOPTAN</u>						
N202514 001	>A> 5886035	Dec 18, 2017	DS DP U-778		>A> NCE	Feb 10, 2017
<u>T APENTADOL HYDROCHLORIDE - NUCYNTA ER</u>						
N200533 001	>A> 8114383	Oct 10, 2024	DP			
<u>T APENTADOL HYDROCHLORIDE - NUCYNTA ER</u>						
N200533 002	>A> 8114383	Oct 10, 2024	DP			
<u>T APENTADOL HYDROCHLORIDE - NUCYNTA ER</u>						
N200533 003	>A> 8114383	Oct 10, 2024	DP			
<u>T APENTADOL HYDROCHLORIDE - NUCYNTA ER</u>						
N200533 004	>A> 8114383	Oct 10, 2024	DP			
<u>T APENTADOL HYDROCHLORIDE - NUCYNTA ER</u>						
N200533 005	>A> 8114383	Oct 10, 2024	DP			
<u>T ELAVANCIN HYDROCHLORIDE - VIBATIV</u>						
N022110 001	>A> 8101575	May 01, 2021	DP			
<u>T ELAVANCIN HYDROCHLORIDE - VIBATIV</u>						
N022110 002	>A> 8101575	May 01, 2021	DP			
<u>T ELBIVUDINE - TYZEKA</u>						
N022154 001	7858594	Sep 11, 2023	DS DP U-999			
<u>T EMSIROLIMUS - TORISEL</u>						
N022088 001	>A> 5362718	Apr 18, 2014	DS DP		>A> M-92	Jul 09, 2013
	>A> 5362718*PED	Oct 18, 2014			>A> M-91	Apr 26, 2013
	>A> 8026276	Jan 20, 2026	DP		>A> NCE	May 30, 2012
	>A> 8026276*PED	Jul 20, 2026			>A> ODE	May 30, 2014
					>A> PED	Nov 30, 2014
					>A> PED	Jan 09, 2014
					>A> PED	Oct 26, 2013
					>A> PED	Nov 30, 2012
<u>T ENOFOVIR DISOPROXIL FUMARATE - VIREAD</u>						
N021356 001					NPP	Jan 18, 2015
					PED	Jul 18, 2015

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>TENOFOVIR DISOPROXIL FUMARATE - VIREAD</u>						
N022577 001	5922695	Jul 25, 2017	DS U-250		NDF	Jan 18, 2015
	5922695	Jul 25, 2017	DS U-256		PED	Jul 18, 2015
	5922695	Jul 25, 2017	DS U-999			
	5922695	Jul 25, 2017	DS U-248			
	5922695*PED	Jan 25, 2018				
	5935946	Jul 25, 2017	DP U-999	Y		
	5935946	Jul 25, 2017	DP U-248	Y		
	5935946	Jul 25, 2017	DP U-250	Y		
	5935946	Jul 25, 2017	DP U-256	Y		
	5935946*PED	Jan 25, 2018				
	5977089	Jul 25, 2017	DS DP U-250			
	5977089	Jul 25, 2017	DS DP U-256			
	5977089	Jul 25, 2017	DS DP U-999			
	5977089	Jul 25, 2017	DS DP U-248			
	5977089*PED	Jan 25, 2018				
	6043230	Jul 25, 2017	U-248			
	6043230	Jul 25, 2017	U-250			
	6043230	Jul 25, 2017	U-256			
	6043230	Jul 25, 2017	U-999			
	6043230*PED	Jan 25, 2018				
<u>TESTOSTERONE - TESTOSTERONE</u>						
N202763 001					>A> NP	Feb 14, 2015
<u>TRAMADOL HYDROCHLORIDE - TRAMADOL HYDROCHLORIDE</u>						
A091607 001					PC	Jun 27, 2012
<u>TRAMADOL HYDROCHLORIDE - TRAMADOL HYDROCHLORIDE</u>						
A091607 002					PC	Jun 27, 2012
<u>TRAMADOL HYDROCHLORIDE - TRAMADOL HYDROCHLORIDE</u>						
A091607 003					PC	Jun 27, 2012
<u>VISMODEGIB - ERIVEDGE</u>						
N203388 001					NCE	Jan 30, 2017
<u>VORINOSTAT - ZOLINZA</u>						
N021991 001	8093295	May 16, 2026	DP			
	8101663	Mar 04, 2023	U-892			

## Footnote:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. They may not be flagged with respect to other claims which may apply.

## PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 31<sup>st</sup> Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

The current complete list of patent terms is available at <http://www.accessdata.fda.gov/scripts/cder/ob/docs/pattermsall.cfm>

The current complete list of patent terms is available at <http://www.accessdata.fda.gov/scripts/cder/ob/docs/excltermsall.cfm>