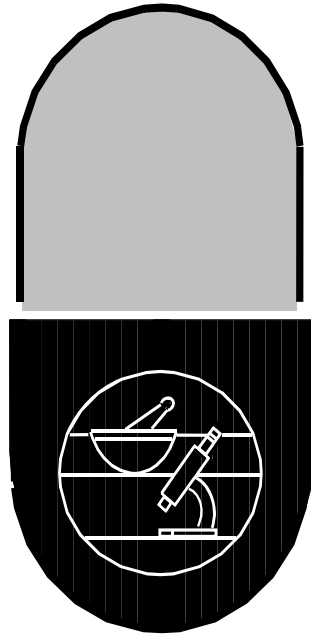


**CUMULATIVE  
SUPPLEMENT 04**  
April 2010



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**30<sup>th</sup> EDITION**

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

2010

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

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**30<sup>th</sup> EDITION**

**Cumulative Supplement 04**

**April 2010**

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**APPROVED DRUG PRODUCTS  
with  
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**30<sup>th</sup> EDITION**

**CUMULATIVE SUPPLEMENT 04  
April 2010**

**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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 30th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 30th 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  
7500 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>
ASCENT PEDIATRICS INC (ASCENT PEDS)	SHIONOGI PHARMA INC (SHIONOGI PHARMA)
GOLDLINE LABORATORIES INC (GOLDLINE)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)
HLR TECHNOLOGY (HLR)	HOFFMANN LA ROCHE INC (HOFFMANN LA ROCHE)
IVAX PHARMACEUTICALS INC (IVAX PHARMS)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)
MEDICIS PHARMACEUTICAL CORP (MEDICIS)	SHIONOGI PHARMA INC (SHIONOGI PHARMA)
MINRAD INC (MINRAD)	PIRAMAL CRITICAL CARE INC (PIRAMAL CRITICAL)

PROCTER AND GAMBLE CO (PROCTER AND GAMBLE)	WARNER CHILCOTT CO LLC (WARNER CHILCOTT)
PROCTER AND GAMBLE CO PHARMACEUTICALS INC SUB PROCTER AND GAMBLE CO (PROCTER AND GAMBLE)	WARNER CHILCOTT CO LLC (WARNER CHILCOTT)
SCIELE PHARMA INC (SCIELE PHARMA INC)	SHIONOGI PHARMA INC (SHIONOGI PHARMA)
TEVA PHARMACEUTICALS USA (TEVA PHARMS)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)
ZENITH GOLDLINE LABORATORIES INC (ZENITH GOLDLINE)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)
ZENITH GOLDLINE PHARMACEUTICALS (ZENITH GOLDLINE)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)
ZENITH GOLDLINE PHARMACEUTICALS INC (ZENITH GOLDLINE)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)

#### 1.4 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>.

## 1.5 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 2008) 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 2009</u>	<u>MAR 2010</u>	<u>JUN 2010</u>	<u>SEPT 2010</u>	<u>DEC 2010</u>
DRUG PRODUCTS LISTED	13065	13216			
SINGLE SOURCE	2460	2474			
	(18.8%)	(18.7%)			
MULTISOURCE	10516	10653			
	(80.5%)	(80.6%)			
THERAPEUTICALLY	10367	10502			
EQUIVALENT	(79.3%)	(79.5%)			
NOT THERAPEUTICALLY	149	151			
EQUIVALENT	(1.1%)	(1.1%)			
EXCEPTIONS <sup>1</sup>	89	89			
	(0.7%)	(0.7%)			
NEW MOLECULAR ENTITIES					
APPROVED	3	5			
NUMBER OF APPLICANTS	718	727			

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

## 1.6 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 - 30TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2010

1-1

ACETAMINOPHEN; BUTALBITAL

TABLET; ORAL

BUTAPAP

AA MIKART 325MG;50MG A089987 001 Oct 26, 1992 Feb CTEC

PHRENILIN

AA + VALEANT 325MG;50MG A087811 001 Jun 19, 1985 Feb CTEC

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

+ NEXGEN PHARMA 300MG;50MG;40MG A040885 001 Nov 16, 2009 Feb CRLD

AA WEST WARD 500MG;50MG;40MG A040261 001 Oct 28, 1998 Feb CTEC

ESGIC-PLUS

AA + MIKART 500MG;50MG;40MG A040085 001 Mar 28, 1996 Feb CTEC

TABLET; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

AA CONCORD LABS NJ 325MG;50MG;40MG A040864 001 Dec 01, 2008 Feb CTEC

AA 500MG;50MG;40MG A040883 001 Dec 23, 2008 Feb CTEC

AA MALLINCKRODT 325MG;50MG;40MG A087804 001 Jan 24, 1985 Feb CTEC

AA MIKART 325MG;50MG;40MG A089175 001 Jan 21, 1987 Feb CTEC

AA VINTAGE PHARMS 325MG;50MG;40MG A040511 001 Aug 27, 2003 Feb CTEC

AA 500MG;50MG;40MG A040513 001 Aug 25, 2003 Feb CTEC

AA WATSON LABS 500MG;50MG;40MG A040267 001 Jul 30, 1998 Feb CTEC

AA WEST WARD 325MG;50MG;40MG A089718 001 Jun 12, 1995 Feb CTEC

AA 500MG;50MG;40MG A040336 001 Aug 18, 1999 Feb CTEC

ESGIC-PLUS

AA + MIKART 500MG;50MG;40MG A089451 001 May 23, 1988 Feb CTEC

FIORICET

AA + WATSON PHARMS 325MG;50MG;40MG A088616 001 Nov 09, 1984 Feb CTEC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

+ MIKART 300MG/15ML;10MG/15ML A040881 001 Feb 25, 2010 Feb NEWA

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

ACETAMINOPHEN AND PENTAZOCINE HYDROCHLORIDE

AB + WATSON LABS 650MG;EQ 25MG BASE A074699 001 Mar 24, 2000 Feb CRLD

TALACEN

@ SANOFI AVENTIS US 650MG;EQ 25MG BASE N018458 001 Sep 23, 1982 Feb DISC

ACITRETIN

CAPSULE; ORAL

SORIATANE

STIEFEL LABS INC 17.5MG N019821 003 Aug 06, 2009 Jan NEWA

22.5MG N019821 004 Aug 06, 2009 Jan NEWA

ACYCLOVIR

CAPSULE; ORAL

ACYCLOVIR

>D> AB IVAX SUB TEVA PHARMS 200MG A074674 001 Apr 22, 1997 Apr DISC

>A> @ 200MG A074674 001 Apr 22, 1997 Apr DISC

CAPSULE; ORAL

## ACYCLOVIR

AB	MYLAN	200MG	A074727 001	Apr 22, 1997	Mar	CMFD
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TABLET; ORAL

## ACYCLOVIR

>D>	AB	IVAX SUB TEVA PHARMS	400MG	A074836 001	Apr 22, 1997	Apr	DISC
>A>		@	400MG	A074836 001	Apr 22, 1997	Apr	DISC
>D>	AB		800MG	A074836 002	Apr 22, 1997	Apr	DISC
>A>		@	800MG	A074836 002	Apr 22, 1997	Apr	DISC
	AB	MYLAN	400MG	A075211 001	Sep 28, 1998	Mar	CMFD
	AB		800MG	A075211 002	Sep 28, 1998	Mar	CMFD

ADAPALENE

## LOTION; TOPICAL

## DIFFERIN

+	GALDERMA R AND D	0.1%	N022502 001	Mar 17, 2010	Mar	NEWA
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ALBUTEROL SULFATE

## SOLUTION; INHALATION

## ALBUTEROL SULFATE

AN	APOTEX INC	EQ 0.021% BASE	A078623 001	Apr 05, 2010	Mar	NEWA
AN		EQ 0.042% BASE	A078623 002	Apr 05, 2010	Mar	NEWA
AN	NEPHRON	EQ 0.021% BASE	A076355 002	Mar 31, 2010	Mar	NEWA

ALENDRONATE SODIUM

## TABLET; ORAL

## ALENDRONATE SODIUM

AB	CADISTA PHARMS	EQ 5MG BASE	A090557 001	Feb 18, 2010	Jan	NEWA
AB		EQ 10MG BASE	A090557 002	Feb 18, 2010	Jan	NEWA
AB		EQ 35MG BASE	A090557 003	Feb 18, 2010	Jan	NEWA
AB		EQ 70MG BASE	A090557 004	Feb 18, 2010	Jan	NEWA

ALPRAZOLAM

## TABLET, ORALLY DISINTEGRATING; ORAL

## ALPRAZOLAM

AB	ACTAVIS ELIZABETH	0.25MG	A078561 001	Mar 16, 2010	Feb	NEWA
AB		0.5MG	A078561 002	Mar 16, 2010	Feb	NEWA
AB		1MG	A078561 003	Mar 16, 2010	Feb	NEWA
AB		2MG	A078561 004	Mar 16, 2010	Feb	NEWA

AMLODIPINE BESYLATE

## TABLET; ORAL

## AMLODIPINE BESYLATE

AB	VINTAGE	EQ 2.5MG BASE	A078414 001	Apr 07, 2010	Mar	NEWA
AB		EQ 5MG BASE	A078414 002	Apr 07, 2010	Mar	NEWA
AB		EQ 10MG BASE	A078414 003	Apr 07, 2010	Mar	NEWA
AB	WORLD GEN	EQ 2.5MG BASE	A077516 001	Jul 11, 2007	Mar	CAHN
AB		EQ 5MG BASE	A077516 002	Jul 11, 2007	Mar	CAHN
AB		EQ 10MG BASE	A077516 003	Jul 11, 2007	Mar	CAHN

AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

## CAPSULE; ORAL

## AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE

AB	DR REDDYS LABS INC	EQ 2.5MG BASE;10MG	A077183 001	Apr 15, 2010	Mar	NEWA
AB		EQ 5MG BASE;10MG	A077183 002	Apr 15, 2010	Mar	NEWA
AB		EQ 5MG BASE;20MG	A077183 003	Apr 15, 2010	Mar	NEWA

CAPSULE; ORALAMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE

AB	DR REDDYS LABS INC	EQ 10MG BASE;20MG	A077183 004	Apr 15, 2010	Mar	NEWA
AB	LUPIN PHARMS	EQ 2.5MG BASE;10MG	A078466 001	Feb 05, 2010	Jan	NEWA
AB		EQ 5MG BASE;10MG	A078466 002	Feb 05, 2010	Jan	NEWA
AB		EQ 5MG BASE;20MG	A078466 003	Feb 05, 2010	Jan	NEWA
AB		EQ 10MG BASE;20MG	A078466 004	Feb 05, 2010	Jan	NEWA

AMOXICILLINFOR SUSPENSION; ORALTRIMOX

@	APOTHECON	50MG/ML	A061886 001		Feb	DISC
@		125MG/5ML	A061886 002		Feb	DISC
@		125MG/5ML	A062885 001	Mar 08, 1988	Feb	DISC
@		250MG/5ML	A061886 003		Feb	DISC
@		250MG/5ML	A062885 002	Mar 08, 1988	Feb	DISC

AMOXICILLIN; CLAVULANATE POTASSIUMFOR SUSPENSION; ORALAUGMENTIN '125'

AB	GLAXOSMITHKLINE	125MG/5ML;EQ 31.25MG BASE/5ML	N050575 001	Aug 06, 1984	Feb	CMFD
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AUGMENTIN '250'

AB	GLAXOSMITHKLINE	250MG/5ML;EQ 62.5MG BASE/5ML	N050575 002	Aug 06, 1984	Feb	CMFD
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TABLET; ORALAUGMENTIN '250'

AB	GLAXOSMITHKLINE	250MG;EQ 125MG BASE	N050564 001	Aug 06, 1984	Feb	CMFD
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AUGMENTIN '500'

AB	GLAXOSMITHKLINE	500MG;EQ 125MG BASE	N050564 002	Aug 06, 1984	Feb	CMFD
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AUGMENTIN '875'

AB	GLAXOSMITHKLINE	875MG;EQ 125MG BASE	N050720 001	Feb 13, 1996	Feb	CMFD
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TABLET, EXTENDED RELEASE; ORALAMOXICILLIN AND CLAVULANATE POTASSIUM

>A>	AB	SANDOZ	1GM;EQ 62.5MG BASE	A090227 001	Apr 21, 2010	Apr	NEWA
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AUGMENTIN XR

AB	GLAXOSMITHKLINE	1GM;EQ 62.5MG BASE	N050785 001	Sep 25, 2002	Feb	CMFD
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AMPHOTERICIN BINJECTABLE, LIPID COMPLEX; INJECTIONABELCET

+	SIGMA TAU	5MG/ML	N050724 001	Nov 20, 1995	Feb	CAHN
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AMPICILLIN SODIUM; SULBACTAM SODIUMINJECTABLE; INJECTIONAMPICILLIN AND SULBACTAM

AP	BIONICHE PHARMA	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A065316 001	Jun 29, 2007	Mar	CAHN
----	-----------------	--	-------------	--------------	-----	------

AP		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A065316 002	Jun 29, 2007	Mar	CAHN
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ARMODAFINILTABLET; ORALNUVIGIL

@	CEPHALON	100MG	N021875 002	Mar 26, 2009	Feb	DISC
---	----------	-------	-------------	--------------	-----	------

@		200MG	N021875 005	Mar 26, 2009	Feb	DISC
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ARTEMETHER; LUMEFANTRINE

TABLET; ORAL

COARTEM

+	NOVARTIS	20MG;120MG	N022268 001	Apr 07, 2009	Mar	CRLD
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ARTICAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE

INJECTABLE; INJECTION

ARTICAINE HYDROCHLORIDE WITH EPINEPHRINE

PIERREL

4%;EQ 0.009MG BASE/1.8ML (EQ  
0.005MG BASE/ML)

N022466 001 Feb 26, 2010 Feb NEWA

+		4%;EQ 0.018MG BASE/1.8ML (EQ 0.01MG BASE/ML)	N022466 002	Feb 26, 2010	Feb	NEWA
---	--	---	-------------	--------------	-----	------

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

FIORINAL

AA	+	WATSON PHARMS	325MG;50MG;40MG	N017534 005	Apr 16, 1986	Feb	CTEC
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LANORINAL

AA		LANNETT	325MG;50MG;40MG	A086996 002	Oct 11, 1985	Feb	CTEC
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TABLET; ORAL

BUTALBITAL, ASPIRIN AND CAFFEINE

AA		ACTAVIS ELIZABETH	325MG;50MG;40MG	A086710 002	Aug 23, 1983	Feb	CTEC
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AA	+	WEST WARD	325MG;50MG;40MG	A086162 002	Feb 16, 1984	Feb	CTEC
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ASPIRIN; METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL AND ASPIRIN

>D>	AB	+	IVAX SUB TEVA PHARMS	325MG;400MG	A087211 001	Dec 22, 1982	Apr	DISC
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>A>		@		325MG;400MG	A087211 001	Dec 22, 1982	Apr	DISC
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>D>	AB		STEVENS J	325MG;400MG	A081145 001	Jan 31, 1995	Apr	CRLD
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>A>		+		325MG;400MG	A081145 001	Jan 31, 1995	Apr	CRLD
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ATOVAQUONE; PROGUANIL HYDROCHLORIDE

TABLET; ORAL

MALARONE PEDIATRIC

>D>		+	GLAXOSMITHKLINE	62.5MG;25MG	N021078 002	Jul 14, 2000	Apr	CRLD
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>A>				62.5MG;25MG	N021078 002	Jul 14, 2000	Apr	CRLD
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AZELASTINE HYDROCHLORIDE

SPRAY, METERED; NASAL

ASTELIN

AB	+	MEDA PHARMS	EQ 0.125MG BASE/SPRAY	N020114 001	Nov 01, 1996	Jan	CTEC
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AZELASTINE HYDROCHLORIDE

AB		APOTEX INC	EQ 0.125MG BASE/SPRAY	A077954 001	Apr 30, 2009	Jan	CMFD
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AZITHROMYCIN

INJECTABLE; INJECTION

AZITHROMYCIN

AP		GENERAMEDIX	EQ 500MG BASE/VIAL	A065501 001	Nov 09, 2009	Mar	CAHN
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AP		GLAND PHARMA LTD	EQ 500MG BASE/VIAL	A065501 001	Nov 09, 2009	Feb	CAHN
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AZTREONAM

FOR SOLUTION; INHALATION

CAYSTON

+	GILEAD	75MG/VIAL	N050814 001	Feb 22, 2010	Feb	NEWA
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BACLOFEN

TABLET; ORAL

BACLOFEN

AB	MATRIX LABS LTD	10MG	A090334 001	Feb 18, 2010	Jan	NEWA
AB		20MG	A090334 002	Feb 18, 2010	Jan	NEWA

TABLET, ORALLY DISINTEGRATING; ORAL

KEMSTRO

@ SCHWARZ PHARMA

10MG

N021589 001 Oct 30, 2003 Jan DISC

@

20MG

N021589 002 Oct 30, 2003 Jan DISC

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION

QVAR 40

+ TEVA BRANDED PHARM

0.04MG/INH

N020911 002 Sep 15, 2000 Feb CAHN

QVAR 80

+ TEVA BRANDED PHARM

0.08MG/INH

N020911 001 Sep 15, 2000 Feb CAHN

BENAZEPRIL HYDROCHLORIDE

TABLET; ORAL

BENAZEPRIL HYDROCHLORIDE

AB HUAHAI US INC

5MG

A076118 001 Feb 11, 2004 Mar CAHN

AB

10MG

A076118 002 Feb 11, 2004 Mar CAHN

AB

20MG

A076118 003 Feb 11, 2004 Mar CAHN

AB

40MG

A076118 004 Feb 11, 2004 Mar CAHN

BENZTROPINE MESYLATE

INJECTABLE; INJECTION

BENZTROPINE MESYLATE

AP PHARMAFORCE

1MG/ML

A091152 001 Mar 29, 2010 Mar NEWA

TABLET; ORAL

BENZTROPINE MESYLATE

AA INVAGEN PHARMS

0.5MG

A090294 001 Mar 29, 2010 Mar NEWA

AA

1MG

A090294 002 Mar 29, 2010 Mar NEWA

AA

2MG

A090294 003 Mar 29, 2010 Mar NEWA

AA + LANNETT

0.5MG

A088877 001 Apr 11, 1985 Feb CAHN

AA +

1MG

A088894 001 Apr 11, 1985 Feb CAHN

AA +

2MG

A088895 001 Apr 11, 1985 Feb CAHN

BETAMETHASONE ACETATE; BETAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

BETAMETHASONE ACETATE AND BETAMETHASONE SODIUM PHOSPHATE

AB LUITPOLD

3MG/ML; EQ 3MG BASE/ML

A090747 001 Jul 31, 2009 Mar CAHN

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

BETAXOLOL HYDROCHLORIDE

AT AKORN

EQ 0.5% BASE

A075386 001 Jun 30, 2000 Jan CTNA

AT NOVEX

EQ 0.5% BASE

A075446 001 Sep 28, 2000 Jan CTNA

AT WOCKHARDT

EQ 0.5% BASE

A078694 001 Nov 16, 2009 Jan CAIN

TABLET; ORAL

BETAXOLOL HYDROCHLORIDE

AB MIKAH PHARMA

10MG

A075541 001 Oct 22, 1999 Feb CAHN

AB +

20MG

A075541 002 Oct 22, 1999 Feb CAHN

BETHANECHOL CHLORIDE

TABLET; ORAL

BETHANECHOL CHLORIDE

>A>	AA	EMCURE USA	5MG	A091256 001	May 04, 2010	Apr	NEWA
>A>	AA		10MG	A091256 002	May 04, 2010	Apr	NEWA
>A>	AA		25MG	A091256 003	May 04, 2010	Apr	NEWA
>A>	AA		50MG	A091256 004	May 04, 2010	Apr	NEWA

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE

INJECTABLE; INJECTION

BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE

AP	+	HOSPIRA	0.5%;0.005MG/ML	A071168 001	Jun 16, 1988	Mar	CTEC
AP			0.5%;0.005MG/ML	A071170 001	Jun 16, 1988	Mar	CMFD

BUPRENORPHINE HYDROCHLORIDE

TABLET; SUBLINGUAL

BUPRENORPHINE HYDROCHLORIDE

>A>	AB	BARR	EQ 2MG BASE	A090360 001	May 07, 2010	Apr	NEWA
>A>	AB		EQ 8MG BASE	A090360 002	May 07, 2010	Apr	NEWA

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

BUPROPION HYDROCHLORIDE

	AB1	MYLAN	100MG	A090325 001	Apr 08, 2010	Mar	NEWA
	AB1		150MG	A090325 002	Apr 08, 2010	Mar	NEWA
>A>	AB2		150MG	A090941 001	May 03, 2010	Apr	NEWA
	AB1		200MG	A090325 003	Apr 08, 2010	Mar	NEWA
	AB1	SUN PHARMA GLOBAL	100MG	A078866 001	Apr 06, 2010	Mar	NEWA
	AB1		150MG	A078866 002	Apr 06, 2010	Mar	NEWA
	AB1		200MG	A078866 003	Apr 06, 2010	Mar	NEWA

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

BUSPAR

@ BRISTOL MYERS SQUIBB 10MG

N018731 002 Sep 29, 1986 Mar DISC

@ 15MG

N018731 003 Apr 22, 1996 Feb DISC

BUSPIRONE HYDROCHLORIDE

AB + IVAX SUB TEVA PHARMS 15MG

A075385 003 Mar 01, 2002 Mar CRLD

AB TEVA 30MG

A075022 004 Mar 25, 2004 Mar CRLD

AB + 30MG

A075022 004 Mar 25, 2004 Feb CRLD

CABERGOLINE

TABLET; ORAL

CABERGOLINE

AB IMPAX LABS INC 0.5MG

A077843 001 Jul 03, 2007 Mar CAHN

CAFFEINE CITRATE

SOLUTION; ORAL

CAFFEINE CITRATE

>A>	AA	PADDOCK LABS	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	A077304 001	Sep 21, 2006	Apr	CAHN
>D>	AA	PHARMAFORCE	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	A077304 001	Sep 21, 2006	Apr	CAHN

CALCIPOTRIENE

OINTMENT; TOPICAL

CALCIPOTRIENE

+ GLENMARK GENERICS 0.005% A090633 001 Mar 24, 2010 Mar NEWA

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE

SOLUTION; IRRIGATION

BALANCED SALT

AT B BRAUN 0.48MG/ML;0.3MG/ML;0.75MG/ML;3.9MG/ML;6.4MG/ML;1.7MG/ML A091387 001 Feb 03, 2010 Jan NEWA

CAPTOPRIL

TABLET; ORAL

CAPTOPRIL

>A>	AB	HUAHAI US INC	12.5MG	A074477 001	Feb 13, 1996	Apr	CAHN
>A>	AB		25MG	A074477 002	Feb 13, 1996	Apr	CAHN
>A>	AB		50MG	A074477 003	Feb 13, 1996	Apr	CAHN
>A>	AB		100MG	A074477 004	Feb 13, 1996	Apr	CAHN
>D>	AB	KALI LABS	12.5MG	A074477 001	Feb 13, 1996	Apr	CAHN
>D>	AB		25MG	A074477 002	Feb 13, 1996	Apr	CAHN
>D>	AB		50MG	A074477 003	Feb 13, 1996	Apr	CAHN
>D>	AB		100MG	A074477 004	Feb 13, 1996	Apr	CAHN

CAPTOPRIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL

CAPTOPRIL AND HYDROCHLOROTHIAZIDE

>D>	AB	IVAX SUB TEVA PHARMS	25MG;15MG	A075055 001	Jun 18, 1998	Apr	DISC
>A>		@	25MG;15MG	A075055 001	Jun 18, 1998	Apr	DISC
>D>	AB		25MG;25MG	A075055 002	Jun 18, 1998	Apr	DISC
>A>		@	25MG;25MG	A075055 002	Jun 18, 1998	Apr	DISC
>D>	AB		50MG;15MG	A075055 004	Jun 18, 1998	Apr	DISC
>A>		@	50MG;15MG	A075055 004	Jun 18, 1998	Apr	DISC
>D>	AB		50MG;25MG	A075055 003	Jun 18, 1998	Apr	DISC
>A>		@	50MG;25MG	A075055 003	Jun 18, 1998	Apr	DISC

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

>D>	AB	INWOOD LABS	200MG	A070231 001	Aug 14, 1986	Apr	DISC
>A>		@	200MG	A070231 001	Aug 14, 1986	Apr	DISC

CARBIDOPA

TABLET; ORAL

LODOSYN

>A>		+ ATON	25MG	N017830 001		Apr	CAHN
>D>		+ BRISTOL MYERS SQUIBB	25MG	N017830 001		Apr	CAHN

CARBINOXAMINE MALEATE

SOLUTION; ORAL

CARBINOXAMINE MALEATE

>A>	AA	CYPRESS PHARM	4MG/5ML	A090418 001	May 04, 2010	Apr	NEWA
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TABLET; ORAL

CARBINOXAMINE MALEATE

AA		INVAGEN PHARMS	4MG	A090435 001	Apr 15, 2010	Mar	NEWA
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CARBOPLATIN

INJECTABLE; IV (INFUSION)

CARBOPLATIN

AP	BIONICHE PHARMA USA	50MG/5ML (10MG/ML)	A077998 001	Apr 24, 2007	Mar	CAHN
AP		150MG/15ML (10MG/ML)	A077998 002	Apr 24, 2007	Mar	CAHN
AP		450MG/45ML (10MG/ML)	A077998 003	Apr 24, 2007	Mar	CAHN

CARGLUMIC ACID

TABLET; ORAL

CARBAGLU

+	ORPHAN EUROPE	200MG	N022562 001	Mar 18, 2010	Mar	NEWA
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CARVEDILOL PHOSPHATE

CAPSULE, EXTENDED RELEASE; ORAL

COREG CR

+	SB PHARMCO	40MG	N022012 003	Oct 20, 2006	Feb	CRLD
		80MG	N022012 004	Oct 20, 2006	Feb	CRLD

CEFACLOR

TABLET, EXTENDED RELEASE; ORAL

CEFACLOR

AB	+ WORLD GEN	EQ 500MG BASE	A065057 001	Jan 05, 2001	Mar	CAHN
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CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

CEFADROXIL

AB	+ TEVA PHARMS	EQ 500MG BASE	A065282 001	Jan 20, 2006	Mar	CRLD
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FOR SUSPENSION; ORAL

CEFADROXIL

AB	+ LUPIN	EQ 500MG BASE/5ML	A065396 002	Feb 21, 2008	Jan	CRLD
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DURICEF

@	WARNER CHILCOTT	EQ 250MG BASE/5ML	N050527 003		Jan	DISC
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@		EQ 500MG BASE/5ML	N050527 001		Jan	DISC
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CEFOTAXIME SODIUM

INJECTABLE; INJECTION

CEFOTAXIME SODIUM

AP	CEPHAZONE PHARMA	EQ 10GM BASE/VIAL	A065348 001	Jan 25, 2010	Jan	NEWA
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CEFOXITIN SODIUM

INJECTABLE; INJECTION

CEFOXITIN

AP	HIKMA FARMACEUTICA	EQ 1GM BASE/VIAL	A065238 001	Mar 12, 2010	Feb	NEWA
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AP		EQ 2GM BASE/VIAL	A065238 002	Mar 12, 2010	Feb	NEWA
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AP		EQ 10GM BASE/VIAL	A065239 001	Mar 02, 2010	Feb	NEWA
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CEFPROZIL

FOR SUSPENSION; ORAL

CEFPROZIL

AB	+ LUPIN	250MG/5ML	A065261 002	Dec 19, 2005	Feb	CTEC
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TABLET; ORAL

CEFPROZIL

AB	+ LUPIN	500MG	A065276 002	Dec 08, 2005	Feb	CRLD
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CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN

>D>	AB	IVAX SUB TEVA PHARMS	EQ 250MG BASE	A061969 001		Apr	DISC
>A>		@	EQ 250MG BASE	A061969 001		Apr	DISC
>D>	AB		EQ 500MG BASE	A061969 002		Apr	DISC
>A>		@	EQ 500MG BASE	A061969 002		Apr	DISC

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CETIRIZINE HYDROCHLORIDE

AA		ACTAVIS MID ATLANTIC	5MG/5ML	A078617 001	Feb 02, 2010	Jan	NEWA
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CHLOROQUINE PHOSPHATE

TABLET; ORAL

CHLOROQUINE PHOSPHATE

>A>	AA	IPCA LABS LTD	EQ 300MG BASE	A090249 001	Dec 03, 2009	Apr	CAHN
>D>	AA	OHM LABS	EQ 300MG BASE	A090249 001	Dec 03, 2009	Apr	CAHN

CICLOPIROX

SHAMPOO; TOPICAL

CICLOPIROX

AT		PERRIGO	1%	A078594 001	Feb 16, 2010	Jan	NEWA
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SOLUTION; TOPICAL

CICLOPIROX

AT		VERSAPHARM	8%	A078975 001	Feb 17, 2010	Jan	NEWA
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CILOSTAZOL

TABLET; ORAL

CILOSTAZOL

>D>	AB	IVAX SUB TEVA PHARMS	100MG	A077020 002	Mar 01, 2005	Apr	DISC
>A>		@	100MG	A077020 002	Mar 01, 2005	Apr	DISC

CIPROFLOXACIN HYDROCHLORIDE

TABLET; ORAL

CIPRO

AB	+	BAYER HLTHCARE	EQ 500MG BASE	N019537 003	Oct 22, 1987	Feb	CRLD
AB			EQ 750MG BASE	N019537 004	Oct 22, 1987	Feb	CRLD

CLARITHROMYCIN

TABLET; ORAL

CLARITHROMYCIN

>D>	AB	IVAX SUB TEVA PHARMS	250MG	A065137 001	May 31, 2005	Apr	DISC
>A>		@	250MG	A065137 001	May 31, 2005	Apr	DISC
>D>	AB		500MG	A065137 002	May 31, 2005	Apr	DISC
>A>		@	500MG	A065137 002	May 31, 2005	Apr	DISC

CLINDAMYCIN PHOSPHATE

AEROSOL, FOAM; TOPICAL

CLINDAMYCIN PHOSPHATE

AT		COBREK PHARMS	1%	A090785 001	Mar 31, 2010	Mar	NEWA
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EVOCLIN

AT	+	STIEFEL LABS INC	1%	N050801 001	Oct 22, 2004	Mar	CFTG
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## CREAM; VAGINAL

	CLINDAMYCIN PHOSPHATE							
AB	NYCOMED US	EQ 2% BASE		A065139 001	Dec 27, 2004	Mar	CAHN	

CLOBETASOL PROPIONATE

## OINTMENT; TOPICAL

	CLOBETASOL PROPIONATE							
AB	NYCOMED US	0.05%		A074407 001	Feb 23, 1996	Mar	CAHN	

CLONIDINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## DURACLON

AP	BIONICHE PHARMA USA	1 MG/10 ML (0.1 MG/ML)		N020615 001	Oct 02, 1996	Mar	CAHN	
AP	+	5 MG/10 ML (0.5 MG/ML)		N020615 002	Apr 27, 1999	Mar	CAHN	

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

## SYRUP; ORAL

## PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE

AA	SUN PHARM INDS INC	10MG/5ML;6.25MG/5ML		A090180 001	Mar 17, 2010	Mar	NEWA	
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COLCHICINE; PROBENECID

## TABLET; ORAL

## PROBENECID AND COLCHICINE

>D>	BP	IVAX SUB TEVA PHARMS	0.5MG;500MG	A083734 001		Apr	DISC	
>A>		@	0.5MG;500MG	A083734 001		Apr	DISC	

COSYNTROPIN

## INJECTABLE; INJECTION

## COSYNTROPIN

AP	BIONICHE PHARMA	0.25MG/VIAL		A090574 001	Dec 17, 2009	Mar	CAHN	
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CROMOLYN SODIUM

## CONCENTRATE; ORAL

## CROMOLYN SODIUM

>D>	AA	GENERA PHARMS	100MG/5ML	A090954 001	Dec 18, 2009	Apr	DISC	
>A>		@	100MG/5ML	A090954 001	Dec 18, 2009	Apr	DISC	

## GASTROCROM

>D>	AA	+	AZUR PHARMA	100MG/5ML	N020479 001	Feb 29, 1996	Apr	CTEC
>A>		+		100MG/5ML	N020479 001	Feb 29, 1996	Apr	CTEC

CYANOCOBALAMIN

## SPRAY, METERED; NASAL

## CALOMIST

## @ FLEMING

25MCG/SPRAY

N022102 001	Jul 27, 2007	Jan	DISC
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CYCLOPHOSPHAMIDE

## INJECTABLE; INJECTION

## CYTOXAN

AP	+	BAXTER HLTHCARE	500MG/VIAL	N012142 003		Feb	CMFD	
AP	+		1GM/VIAL	N012142 004	Aug 30, 1982	Feb	CMFD	
AP	+		2GM/VIAL	N012142 005	Aug 30, 1982	Feb	CMFD	

## LYOPHILIZED CYTOXAN

## @ BAXTER HLTHCARE

100MG/VIAL

N012142 006	Dec 05, 1985	Feb	DISC
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## @

200MG/VIAL

N012142 007	Dec 10, 1985	Feb	DISC
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## @

500MG/VIAL

N012142 008	Jan 04, 1984	Feb	DISC
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## @

1GM/VIAL

N012142 010	Sep 24, 1985	Feb	DISC
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INJECTABLE; INJECTION  
LYOPHILIZED CYTOXAN  
@ BAXTER HLTHCARE

2GM/VIAL

N012142 009 Dec 10, 1984 Feb DISC

CYTARABINE

INJECTABLE; INJECTION  
CYTARABINE

>D>	AP	HOSPIRA	20MG/ML	A071868 001	Jun 04, 1990	Apr	CRLD
>A>	AP	+	20MG/ML	A071868 001	Jun 04, 1990	Apr	CRLD
	AP	+	20MG/ML	A072168 001	Aug 31, 1990	Mar	CRLD

DACTINOMYCIN

INJECTABLE; INJECTION  
COSMEGEN

AP	+	LUNDBECK INC	0.5MG/VIAL	N050682 001		Mar	CFTG
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DACTINOMYCIN

AP		BEDFORD	0.5MG/VIAL	A090304 001	Mar 16, 2010	Mar	NEWA
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DALFAMPRIDINE

TABLET, EXTENDED RELEASE; ORAL  
AMPYRA

+	ACORDA	10MG	N022250 001	Jan 22, 2010	Jan	NEWA
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DES Loratadine

TABLET; ORAL  
CLARINEX

AB	+	SCHERING PLOUGH	5MG	N021165 001	Dec 21, 2001	Jan	CFTG
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DES Loratadine

AB		ORCHID HLTHCARE	5MG	A078357 001	Feb 19, 2010	Jan	NEWA
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DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL  
STIMATE (NEEDS NO REFRIGERATION)

@	CSL BEHRING	1.5MG/SPRAY	N020355 002	Oct 24, 2007	Jan	DISC
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DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28  
MIRCETTE

>D>	AB	+	DURAMED	0.15MG,N/A;0.02MG,0.01MG	N020713 001	Apr 22, 1998	Apr	CAHN
>D>	AB	+		0.15MG,N/A;0.02MG,0.01MG	N020713 001	Apr 22, 1998	Apr	CAHN
>D>	AB	+		0.15MG,N/A;0.02MG,0.01MG	N020713 001	Apr 22, 1998	Apr	CAHN
>D>	AB	+		0.15MG,N/A;0.02MG,0.01MG	N020713 001	Apr 22, 1998	Apr	CAHN
>A>	AB	+	TEVA WOMENS	0.15MG,N/A;0.02MG,0.01MG	N020713 001	Apr 22, 1998	Apr	CAHN
>A>	AB	+		0.15MG,N/A;0.02MG,0.01MG	N020713 001	Apr 22, 1998	Apr	CAHN
>A>	AB	+		0.15MG,N/A;0.02MG,0.01MG	N020713 001	Apr 22, 1998	Apr	CAHN
>A>	AB	+		0.15MG,N/A;0.02MG,0.01MG	N020713 001	Apr 22, 1998	Apr	CAHN

DEXLANSOPRAZOLE

CAPSULE, DELAYED RELEASE; ORAL  
DEXILANT

		TAKEDA PHARMS	30MG	N022287 001	Jan 30, 2009	Mar	CTNA
		+	60MG	N022287 002	Jan 30, 2009	Mar	CTNA

DEXMEDETOMIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

PRECEDEX

+	HOSPIRA	EQ 100MCG BASE/ML (EQ100MCG BASE/ML)	N021038 001	Dec 17, 1999	Jan	CAIN
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DIAZOXIDE

CAPSULE; ORAL

PROGLYCEM

@ TEVA BRANDED PHARM

50MG

N017425 001

Feb CAHN

@

100MG

N017425 002

Feb CAHN

DICLOFENAC POTASSIUM

FOR SOLUTION; ORAL

CAMBIA

+	NAUTILUS NEUROSCIENC	50MG	N022165 001	Jun 17, 2009	Mar	CAHN
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TABLET; ORAL

DICLOFENAC POTASSIUM

@ SANDOZ

50MG

A075582 001 Feb 23, 2001 Jan DISC

&gt;D&gt; AB

WATSON LABS

50MG

A075152 001 Nov 27, 1998 Apr DISC

&gt;A&gt;

@

50MG

A075152 001 Nov 27, 1998 Apr DISC

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL

DICLOFENAC SODIUM

&gt;D&gt; AB

NOSTRUM LABS

50MG

A074986 001 Feb 26, 1999 Apr DISC

&gt;A&gt;

@

50MG

A074986 001 Feb 26, 1999 Apr DISC

&gt;D&gt; AB

@

75MG

A074986 002 Feb 26, 1999 Apr DISC

&gt;A&gt;

@

75MG

A074986 002 Feb 26, 1999 Apr DISC

DIDANOSINE

CAPSULE, DELAYED REL PELLETS; ORAL

DIDANOSINE

AB MATRIX LABS LTD

125MG

A090788 001 Apr 08, 2010 Mar NEWA

AB

@

200MG

A090788 002 Apr 08, 2010 Mar NEWA

AB

@

250MG

A090788 003 Apr 08, 2010 Mar NEWA

AB

@

400MG

A090788 004 Apr 08, 2010 Mar NEWA

DIFLORASONE DIACETATE

CREAM; TOPICAL

DIFLORASONE DIACETATE

AB1 + ALTANA

0.05%

A075187 001 Mar 30, 1998 Mar CRLD

PSORCON

@ SANOFI AVENTIS US

0.05%

N020205 001 Nov 20, 1992 Feb DISC

DILTIAZEM HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

CARDIZEM LA

AB BIOVAIL LABS INTL

120MG

N021392 001 Feb 06, 2003 Feb CFTG

AB

@

180MG

N021392 002 Feb 06, 2003 Feb CFTG

AB

@

240MG

N021392 003 Feb 06, 2003 Feb CFTG

AB

@

300MG

N021392 004 Feb 06, 2003 Feb CFTG

AB

@

360MG

N021392 005 Feb 06, 2003 Feb CFTG

AB

+

420MG

N021392 006 Feb 06, 2003 Feb CFTG

TABLET, EXTENDED RELEASE; ORALDILTIAZEM HYDROCHLORIDE

AB	WATSON LABS FLORIDA	120MG	A077686 006	Mar 15, 2010	Feb	NEWA
AB		180MG	A077686 005	Mar 15, 2010	Feb	NEWA
AB		240MG	A077686 004	Mar 15, 2010	Feb	NEWA
AB		300MG	A077686 003	Mar 15, 2010	Feb	NEWA
AB		360MG	A077686 002	Mar 15, 2010	Feb	NEWA
AB		420MG	A077686 001	Mar 15, 2010	Feb	NEWA

DOXAZOSIN MESYLATETABLET; ORALDOXAZOSIN MESYLATE

>D>	AB	IVAX SUB TEVA PHARMS	EQ 1MG BASE	A075453 001	Oct 18, 2000	Apr	DISC
>A>		@	EQ 1MG BASE	A075453 001	Oct 18, 2000	Apr	DISC
>D>	AB		EQ 2MG BASE	A075453 002	Oct 18, 2000	Apr	DISC
>A>		@	EQ 2MG BASE	A075453 002	Oct 18, 2000	Apr	DISC
>D>	AB		EQ 4MG BASE	A075453 003	Oct 18, 2000	Apr	DISC
>A>		@	EQ 4MG BASE	A075453 003	Oct 18, 2000	Apr	DISC
>D>	AB		EQ 8MG BASE	A075453 004	Oct 18, 2000	Apr	DISC
>A>		@	EQ 8MG BASE	A075453 004	Oct 18, 2000	Apr	DISC

DOXEPIN HYDROCHLORIDETABLET; ORALSILENORSOMAXON

			EQ 3MG BASE	N022036 001	Mar 17, 2010	Mar	NEWA
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+			EQ 6MG BASE	N022036 002	Mar 17, 2010	Mar	NEWA
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DOXYCYCLINE HYCLATETABLET; ORALDOXYCYCLINE HYCLATE

>A>		@ LARKEN LABS	EQ 20MG BASE	A065287 001	Feb 28, 2006	Apr	CAHN
>D>		@ PAR PHARM	EQ 20MG BASE	A065287 001	Feb 28, 2006	Apr	CAHN

ELTROMBOPAG OLAMINETABLET; ORALPROMACTAGLAXOSMITHKLINE

			EQ 75MG ACID	N022291 003	Sep 08, 2009	Mar	NEWA
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ENALAPRIL MALEATETABLET; ORALENALAPRIL MALEATE

>D>	AB	GENPHARM	2.5MG	A075472 001	Aug 22, 2000	Apr	CAHN
>D>	AB		5MG	A075472 002	Aug 22, 2000	Apr	CAHN
>D>	AB		10MG	A075472 003	Aug 22, 2000	Apr	CAHN
>D>	AB		20MG	A075472 004	Aug 22, 2000	Apr	CAHN
>A>	AB	MYLAN	2.5MG	A075472 001	Aug 22, 2000	Apr	CAHN
>A>	AB		5MG	A075472 002	Aug 22, 2000	Apr	CAHN
>A>	AB		10MG	A075472 003	Aug 22, 2000	Apr	CAHN
>A>	AB		20MG	A075472 004	Aug 22, 2000	Apr	CAHN

ENALAPRIL MALEATE; FELODIPINETABLET, EXTENDED RELEASE; ORALLEXXEL@ ASTRAZENECA

			5MG;5MG	N020668 001	Dec 27, 1996	Mar	DISC
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EPINEPHRINE

## INJECTABLE; IM-SC

## ADRENACLICK

>D>	+	SHIONOGI PHARMA	EQ 0.15MG /DELIVERY	N020800 003	Nov 25, 2009	Apr	CTEC
>A>	BX	+	EQ 0.15MG /DELIVERY	N020800 003	Nov 25, 2009	Apr	CTEC
		+	EQ 0.15MG /DELIVERY	N020800 003	Nov 25, 2009	Mar	NEWA
>D>	+		EQ 0.3MG /DELIVERY	N020800 004	Nov 25, 2009	Apr	CTEC
>A>	BX	+	EQ 0.3MG /DELIVERY	N020800 004	Nov 25, 2009	Apr	CTEC
		+	EQ 0.3MG /DELIVERY	N020800 004	Nov 25, 2009	Mar	NEWA

## &gt;A&gt; EPIPEN

>A>	BX	+	MERIDIAN MEDCL TECHN	0.3MG/DELIVERY	N019430 001	Dec 22, 1987	Apr	CDFR
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## &gt;A&gt; EPIPEN JR.

>A>	BX	+	MERIDIAN MEDCL TECHN	0.15MG/DELIVERY	N019430 002	Dec 22, 1987	Apr	CDFR
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## TWINJECT 0.15

>D>	+	SHIONOGI PHARMA	EQ 0.15MG /DELIVERY	N020800 002	May 28, 2004	Apr	CTEC
>A>	BX	+	EQ 0.15MG /DELIVERY	N020800 002	May 28, 2004	Apr	CTEC
		+	EQ 0.15MG /DELIVERY	N020800 002	May 28, 2004	Jan	CAHN

## TWINJECT 0.3

>D>	+	SHIONOGI PHARMA	EQ 0.3MG /DELIVERY	N020800 001	May 30, 2003	Apr	CTEC
>A>	BX	+	EQ 0.3MG /DELIVERY	N020800 001	May 30, 2003	Apr	CTEC
		+	EQ 0.3MG /DELIVERY	N020800 001	May 30, 2003	Jan	CAHN

## &gt;D&gt; INJECTABLE; INTRAMUSCULAR

## &gt;D&gt; EPIPEN

>D>	+	MERIDIAN MEDCL TECHN	0.3MG/DELIVERY	N019430 001	Dec 22, 1987	Apr	CDFR
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## &gt;D&gt; EPIPEN JR.

>D>	+	MERIDIAN MEDCL TECHN	0.15MG/DELIVERY	N019430 002	Dec 22, 1987	Apr	CDFR
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EPIRUBICIN HYDROCHLORIDE

## INJECTABLE; INJECTION

## EPIRUBICIN HYDROCHLORIDE

AP		BIONICHE PHARMA USA	50MG/25ML (2MG/ML)	A065371 001	Nov 28, 2007	Mar	CAHN
AP			200MG/100ML (2MG/ML)	A065371 002	Nov 28, 2007	Mar	CAHN
AP		X GEN PHARMS	50MG/25ML (2MG/ML)	A090075 001	Mar 25, 2010	Mar	NEWA
AP			200MG/100ML (2MG/ML)	A090075 002	Mar 25, 2010	Mar	NEWA

ERYTHROMYCIN

## OINTMENT; OPHTHALMIC

## ERYTHROMYCIN

>D>		@ AKORN	0.5%	A064030 001	Jul 18, 1996	Apr	CMFD
>A>	AT		0.5%	A064030 001	Jul 18, 1996	Apr	CMFD

ESOMEPRAZOLE MAGNESIUM; NAPROXEN

## &gt;A&gt; TABLET, DELAYED RELEASE; ORAL

## &gt;A&gt; VIMOVO

>A>		POZEN	EQ 20MG BASE;375MG	N022511 002	Apr 30, 2010	Apr	NEWA
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>A>	+		EQ 20MG BASE;500MG	N022511 001	Apr 30, 2010	Apr	NEWA
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ESTRADIOL VALERATE

## INJECTABLE; INJECTION

## ESTRADIOL VALERATE

AO		PHARMAFORCE	20MG/ML	A090920 001	Jan 19, 2010	Jan	NEWA
AO			40MG/ML	A090920 002	Jan 19, 2010	Jan	NEWA

ESTROGENS, CONJUGATED SYNTHETIC A

TABLET; ORAL

CENESTIN

>D>	DURAMED	0.3MG	N020992 001	Jun 21, 2002	Apr	CAHN
>D>		0.45MG	N020992 005	Feb 05, 2004	Apr	CAHN
>D>		0.625MG	N020992 002	Mar 24, 1999	Apr	CAHN
>D>		0.9MG	N020992 003	Mar 24, 1999	Apr	CAHN
>D>	+	1.25MG	N020992 004	Mar 13, 2000	Apr	CAHN
>A>	TEVA WOMENS	0.3MG	N020992 001	Jun 21, 2002	Apr	CAHN
>A>		0.45MG	N020992 005	Feb 05, 2004	Apr	CAHN
>A>		0.625MG	N020992 002	Mar 24, 1999	Apr	CAHN
>A>		0.9MG	N020992 003	Mar 24, 1999	Apr	CAHN
>A>	+	1.25MG	N020992 004	Mar 13, 2000	Apr	CAHN

ESTROGENS, CONJUGATED SYNTHETIC B

TABLET; ORAL

ENJUVIA

>D>	DURAMED	0.3MG	N021443 001	Dec 20, 2004	Apr	CAHN
>D>		0.45MG	N021443 002	Dec 20, 2004	Apr	CAHN
>D>		0.625MG	N021443 003	May 10, 2004	Apr	CAHN
>D>		0.9MG	N021443 005	Apr 27, 2007	Apr	CAHN
>D>	+	1.25MG	N021443 004	May 10, 2004	Apr	CAHN
>A>	TEVA WOMENS	0.3MG	N021443 001	Dec 20, 2004	Apr	CAHN
>A>		0.45MG	N021443 002	Dec 20, 2004	Apr	CAHN
>A>		0.625MG	N021443 003	May 10, 2004	Apr	CAHN
>A>		0.9MG	N021443 005	Apr 27, 2007	Apr	CAHN
>A>	+	1.25MG	N021443 004	May 10, 2004	Apr	CAHN

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

NORETHINDRONE AND ETHINYL ESTRADIOL

WATSON LABS

0.035MG;0.4MG

A078379 001 Feb 23, 2010 Feb NEWA

TABLET; ORAL-28

NORETHINDRONE AND ETHINYL ESTRADIOL

AB WATSON LABS

0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG

A076393 001 Feb 04, 2010 Jan NEWA

AB WATSON LABS

0.035MG;0.4MG

A078323 001 Feb 04, 2010 Jan NEWA

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

AB WATSON LABS

0.02MG;1MG

A078267 001 Sep 01, 2009 Jan CDFR

TABLET; ORAL-28

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL

AB WATSON LABS

0.02MG,0.03MG,0.035MG;1MG,1MG,1MG

A076629 001 Mar 18, 2010 Mar NEWA

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

AB VINTAGE

0.02MG;1MG

A077077 001 May 20, 2005 Feb CAHN

AB VINTAGE

0.03MG;1.5MG

A077075 001 Apr 28, 2005 Feb CAHN

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET; ORAL-28

PREVIFEM

AB VINTAGE

0.035MG;0.25MG

A076334 001 Jan 09, 2004 Feb CAHN



## TABLET; ORAL-28

## TRI-PREVIFEM

AB	VINTAGE	0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A076335 001	Mar 26, 2004	Feb	CAHN
AB		0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A076335 001	Mar 26, 2004	Feb	CAHN
AB		0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A076335 001	Mar 26, 2004	Feb	CAHN
AB		0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A076335 001	Mar 26, 2004	Feb	CAHN
AB		0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A076335 001	Mar 26, 2004	Feb	CAHN
AB		0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A076335 001	Mar 26, 2004	Feb	CAHN
AB		0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A076335 001	Mar 26, 2004	Feb	CAHN
AB		0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A076335 001	Mar 26, 2004	Feb	CAHN
AB		0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A076335 001	Mar 26, 2004	Feb	CAHN

EVEROLIMUS

## TABLET; ORAL

>A>	ZORTRESS					
>A>	NOVARTIS	0.25MG	N021560 001	Apr 20, 2010	Apr	NEWA
>A>		0.5MG	N021560 002	Apr 20, 2010	Apr	NEWA
>A>	+	0.75MG	N021560 003	Apr 20, 2010	Apr	NEWA

FAMOTIDINE

## INJECTABLE; INJECTION

## FAMOTIDINE

AP	+	BAXTER HLTHCARE	10MG/ML	A075488 001	Apr 16, 2001	Feb	CRLD
AP	+		10MG/ML	A075799 001	Apr 30, 2002	Feb	CRLD
		FAMOTIDINE PRESERVATIVE FREE					
AP	+	BAXTER HLTHCARE	10MG/ML	A075486 001	Apr 16, 2001	Feb	CRLD
AP	+		10MG/ML	A075789 001	Apr 30, 2002	Feb	CRLD
		FAMOTIDINE PRESERVATIVE FREE IN PLASTIC CONTAINER					
AP	+	BAXTER HLTHCARE	0.4MG/ML	A075591 001	May 10, 2001	Feb	CRLD

## TABLET, ORALLY DISINTEGRATING; ORAL

## FLUXID

@	SCHWARZ PHARMA	20MG	N021712 001	Sep 24, 2004	Jan	DISC
@		40MG	N021712 002	Sep 24, 2004	Jan	DISC

FENOFIBRATE

## CAPSULE; ORAL

## ANTARA (MICRONIZED)

	LUPIN ATLANTIS	43MG	N021695 001	Nov 30, 2004	Jan	CAHN
@		87MG	N021695 002	Nov 30, 2004	Jan	CAHN
+		130MG	N021695 003	Nov 30, 2004	Jan	CAHN

## TABLET; ORAL

## FENOGLIDE

	SHIONOGI PHARMA	40MG	N022118 001	Aug 10, 2007	Jan	CAHN
+		120MG	N022118 002	Aug 10, 2007	Jan	CAHN

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## ALLEGRA D 24 HOUR

AB	+	SANOFI AVENTIS US	180MG;240MG	N021704 001	Oct 19, 2004	Mar	CFTG
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## TABLET, EXTENDED RELEASE; ORAL

## FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

AB	DR REDDYS LABS LTD	180MG;240MG	A079043 001	Mar 17, 2010	Mar	NEWA
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FINASTERIDE

## TABLET; ORAL

## FINASTERIDE

AB	ACCORD HLTHCARE INC	5MG	A090121 001	Feb 23, 2010	Feb	NEWA
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FLUCONAZOLE

## INJECTABLE; INJECTION

## FLUCONAZOLE IN SODIUM CHLORIDE 0.9%

	BEDFORD	100MG/50ML (2MG/ML)	A076087 002	Sep 26, 2008	Jan	CTNA
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## FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

@	HOSPIRA	200MG/100ML (2MG/ML)	A076617 001	Jul 29, 2004	Feb	DISC
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@		400MG/200ML (2MG/ML)	A076617 002	Jul 29, 2004	Feb	DISC
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FLUNISOLIDE

## AEROSOL, METERED; INHALATION

## AEROSPAN HFA

+	ACTON PHARMS	EQ 78MCG BASE/INH	N021247 001	Jan 27, 2006	Feb	CAHN
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## SPRAY, METERED; NASAL

## NASAREL

AB	+	TEVA BRANDED PHARM	0.029MG/SPRAY	N020409 001	Mar 08, 1995	Feb	CAHN
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FLUOROURACIL

## CREAM; TOPICAL

## FLUOROURACIL

AB	TARO	5%	A090368 001	Mar 05, 2010	Feb	NEWA
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## INJECTABLE; INJECTION

## FLUOROURACIL

AP	+	BIONICHE PHARMA	500MG/10ML (50MG/ML)	A040743 002	Apr 26, 2007	Mar	CAHN
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AP	+		1GM/20ML (50MG/ML)	A040743 001	Apr 26, 2007	Mar	CAHN
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AP	+		2.5GM/50ML (50MG/ML)	A040798 002	Apr 26, 2007	Mar	CAHN
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AP	+		5GM/100ML (50MG/ML)	A040798 001	Apr 26, 2007	Mar	CAHN
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FLUOXETINE HYDROCHLORIDE

## CAPSULE, DELAYED REL PELLETS; ORAL

## FLUOXETINE HYDROCHLORIDE

AB	BARR	EQ 90MG BASE	A076237 001	Mar 24, 2010	Mar	NEWA
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AB	DR REDDYS LABS LTD	EQ 90MG BASE	A078572 001	Mar 22, 2010	Mar	NEWA
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## PROZAC WEEKLY

AB	+	LILLY	EQ 90MG BASE	N021235 001	Feb 26, 2001	Mar	CFTG
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## SOLUTION; ORAL

## FLUOXETINE HYDROCHLORIDE

AA	LANNETT	EQ 20MG BASE/5ML	A076458 001	May 14, 2004	Feb	CAHN
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FOLIC ACID

## TABLET; ORAL

## FOLIC ACID

AA	+	PHARMAX	1MG	A040625 001	Jul 21, 2005	Jan	CRLD
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AA	+	WATSON LABS	1MG	A080680 001		Jan	CMFD
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FOMEPIZOLE

INJECTABLE; INJECTION

FOMEPIZOLE

AP	BIONICHE PHARMA USA	1.5GM/1.5ML (1GM/ML)	A079033 001	Apr 07, 2009	Mar	CAHN
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FORMOTEROL FUMARATE

SOLUTION; INHALATION

PERFORMIST

>D>	+	DEY LP	0.02MG/2ML	N022007 001	May 11, 2007	Apr	CAHN
>A>	+	DEY PHARMA	0.02MG/2ML	N022007 001	May 11, 2007	Apr	CAHN

FOSPHENYTOIN SODIUM

INJECTABLE; INJECTION

FOSPHENYTOIN SODIUM

AP	PHARMAFORCE	EQ 50MG PHENYTOIN NA/ML	A078277 001	Aug 06, 2007	Feb	CAHN
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GADOVERSETAMIDE

INJECTABLE; INJECTION

OPTIMARK IN PLASTIC CONTAINER

	+	MALLINCKRODT	9927MG/30ML (330.9MG/ML)	N020976 001	Dec 08, 1999	Mar	CPOT
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GANCICLOVIR SODIUM

INJECTABLE; INJECTION

CYTOVENE

	+	ROCHE PALO	EQ 500MG BASE/VIAL	N019661 001	Jun 23, 1989	Mar	CMFD
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GANCICLOVIR SODIUM

@ BEDFORD

			EQ 500MG BASE/VIAL	A076222 001	Jul 16, 2003	Mar	DISC
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GEMFIBROZIL

TABLET; ORAL

GEMFIBROZIL

AB	DAVA PHARMS INC	600MG	A074270 001	Sep 27, 1993	Mar	CMFD
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GLIMEPIRIDE

TABLET; ORAL

GLIMEPIRIDE

>A>	AB	WATSON LABS FLORIDA	1MG	A076995 001	Apr 27, 2010	Apr	NEWA
>A>	AB		2MG	A076995 002	Apr 27, 2010	Apr	NEWA
>A>	AB		4MG	A076995 003	Apr 27, 2010	Apr	NEWA

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLYBURIDE AND METFORMIN HYDROCHLORIDE

@ TEVA

		1.25MG; 250MG	A076821 001	Jan 27, 2005	Jan	DISC
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@

		2.5MG; 500MG	A076821 002	Jan 27, 2005	Jan	DISC
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@

		5MG; 500MG	A076821 003	Jan 27, 2005	Jan	DISC
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GLYCOPYRROLATE

TABLET; ORAL

ROBINUL

AA	+	SHIONOGI PHARMA	1MG	N012827 001		Jan	CAHN
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ROBINUL FORTE

AA	+	SHIONOGI PHARMA	2MG	N012827 002		Jan	CAHN
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GRANISETRON HYDROCHLORIDE

INJECTABLE; INJECTION

GRANISETRON HYDROCHLORIDE

AP	SAGENT STRIDES	EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML)	A091136 001	Apr 09, 2010	Mar	NEWA
AP		EQ 1MG BASE/ML (EQ 1MG BASE/ML)	A091136 002	Apr 09, 2010	Mar	NEWA
AP		EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	A091137 002	Apr 09, 2010	Mar	NEWA

GRISEOFULVIN, MICROCRYSTALLINE

TABLET; ORAL

FULVICIN-U/F

	@ ELORAC	250MG	A060569 002		Feb	CAHN
	@	500MG	A060569 001		Feb	CAHN

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

GUANFACINE HYDROCHLORIDE

AB	MIKAH PHARMA	EQ 1MG BASE	A074673 001	Feb 28, 1997	Feb	CAHN
AB		EQ 2MG BASE	A074673 002	Feb 28, 1997	Feb	CAHN

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALDOL

	@ ORTHO MCNEIL JANSSEN	EQ 5MG BASE/ML	N015923 001		Feb	DISC
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HALOPERIDOL

AP	+ TEVA PARENTERAL	EQ 5MG BASE/ML	A076035 001	Aug 29, 2001	Feb	CRLD
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HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HYDROCHLORIDE

AA	HERITAGE PHARMS INC	10MG	A086242 001	Feb 04, 2010	Jan	NEWA
AA		100MG	A086242 004	Feb 04, 2010	Jan	NEWA
AA	ZYDUS PHARMS USA	10MG	A040858 001	Feb 26, 2010	Feb	NEWA
AA		25MG	A040858 002	Feb 26, 2010	Feb	NEWA
AA		50MG	A040858 003	Feb 26, 2010	Feb	NEWA
AA		100MG	A040858 004	Feb 26, 2010	Feb	NEWA

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDROCHLOROTHIAZIDE

AB	UNICHEM	12.5MG	A090510 001	Jan 19, 2010	Jan	NEWA
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HYDROCHLOROTHIAZIDE; LISINAPRIL

TABLET; ORAL

LISINAPRIL AND HYDROCHLOROTHIAZIDE

	@ TEVA	12.5MG;10MG	A075869 001	Jul 01, 2002	Jan	DISC
	@	12.5MG;20MG	A075869 002	Jul 01, 2002	Jan	DISC
	@	25MG;20MG	A075869 003	Jul 01, 2002	Jan	DISC

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

TABLET; ORAL

HYZAAR

AB	MERCK	12.5MG;50MG	N020387 001	Apr 28, 1995	Mar	CFTG
AB		12.5MG;100MG	N020387 003	Oct 20, 2005	Mar	CFTG
AB	+	25MG;100MG	N020387 002	Nov 10, 1998	Mar	CFTG

## TABLET; ORAL

## LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

AB	MYLAN	12.5MG;100MG	A091652 002	Apr 06, 2010	Mar	NEWA
AB	ROXANE	12.5MG;100MG	A077732 001	Apr 06, 2010	Mar	NEWA
AB	TEVA PHARMS	12.5MG;50MG	A077157 001	Apr 06, 2010	Mar	NEWA
AB		12.5MG;100MG	A077157 002	Apr 06, 2010	Mar	NEWA
AB		25MG;100MG	A077157 003	Apr 06, 2010	Mar	NEWA
AB	TORRENT PHARMS	12.5MG;100MG	A090528 003	Apr 06, 2010	Mar	NEWA

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE

## TABLET; ORAL

## METOPROLOL TARTRATE AND HYDROCHLOROTHIAZIDE

>D>	AB	+	MYLAN	25MG;100MG	A076792 002	Aug 20, 2004	Apr	CRLD
>A>	AB			25MG;100MG	A076792 002	Aug 20, 2004	Apr	CRLD
	AB	+		25MG;100MG	A076792 002	Aug 20, 2004	Jan	CRLD
				50MG;100MG	A076792 003	Aug 20, 2004	Jan	CTEC

HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDE

## TABLET; ORAL

## MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

AB	GLENMARK PHARMS	12.5MG;7.5MG	A090718 001	Mar 17, 2010	Mar	NEWA
AB		12.5MG;15MG	A090718 002	Mar 17, 2010	Mar	NEWA
AB		25MG;15MG	A090718 003	Mar 17, 2010	Mar	NEWA

HYDROCORTISONE

## CREAM; TOPICAL

## HYDROCORTISONE

AT	+	FOUGERA	1%	A080693 003		Feb	CRLD
AT	+		2.5%	A089414 001	Dec 16, 1986	Feb	CRLD
		HYTONE					
	@	SANOFI AVENTIS US	1%	A080472 003		Feb	DISC
	@		2.5%	A080472 004		Feb	DISC

## LOTION; TOPICAL

## HYTONE

## @ SANOFI AVENTIS US

@

	@	SANOFI AVENTIS US	1%	A080473 003		Feb	DISC
	@		2.5%	A080473 004	Nov 30, 1982	Feb	DISC

HYDROMORPHONE HYDROCHLORIDE

## INJECTABLE; INJECTION

## HYDROMORPHONE HYDROCHLORIDE

>A>	AP	AKORN	10MG/ML	A078228 001	Apr 14, 2010	Apr	NEWA
>A>	AP		10MG/ML	A078228 001	Apr 14, 2010	Apr	NEWA
	AP		10MG/ML	A078228 001	Apr 14, 2010	Mar	NEWA
	AP		10MG/ML	A078261 001	Apr 14, 2010	Mar	NEWA

## TABLET, EXTENDED RELEASE; ORAL

## EXALGO

## MALLINCKRODT INC

			8MG	N021217 001	Mar 01, 2010	Mar	NEWA
			12MG	N021217 002	Mar 01, 2010	Mar	NEWA
	+		16MG	N021217 003	Mar 01, 2010	Mar	NEWA

HYDROXYZINE PAMOATE

## CAPSULE; ORAL

## HYDROXYZINE PAMOATE

>D>	AB	IVAX SUB TEVA PHARMS	EQ 25MG HCL	A087761 001	Mar 05, 1982	Apr	DISC
>A>		@	EQ 25MG HCL	A087761 001	Mar 05, 1982	Apr	DISC
>D>	AB		EQ 50MG HCL	A087760 001	Mar 05, 1982	Apr	DISC

## CAPSULE; ORAL

## HYDROXYZINE PAMOATE

>A>	@ IVAX SUB TEVA PHARMS	EQ 50MG HCL	A087760 001	Mar 05, 1982	Apr	DISC
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IBUPROFEN

## TABLET; ORAL

## IBUPROFEN

AB	CONTRACT PHARMACAL	400MG	A071267 001	Oct 15, 1986	Jan	CAHN
AB		600MG	A071268 001	Oct 15, 1986	Jan	CAHN
AB		800MG	A072300 001	Jul 01, 1988	Jan	CAHN

IBUTILIDE FUMARATE

## INJECTABLE; INJECTION

## IBUTILIDE FUMARATE

AP	BIONICHE PHARMA USA	0.1MG/ML	A090924 001	Jan 11, 2010	Mar	CAHN
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IFOSFAMIDE

## INJECTABLE; INJECTION

## IFEX

AP	BAXTER HLTHCARE	1GM/VIAL	N019763 001	Dec 30, 1988	Feb	CMFD
AP		3GM/VIAL	N019763 002	Dec 30, 1988	Feb	CMFD

## IFOSFAMIDE

AP	+	APP PHARMS	1GM/VIAL	A076078 001	May 28, 2002	Feb	CTEC
AP	+		1GM/VIAL	A076078 001	May 28, 2002	Feb	CTEC
	+		1GM/VIAL	A076078 001	May 28, 2002	Jan	CTEC
	+		1GM/VIAL	A076078 001	May 28, 2002	Jan	CTEC
AP			1GM/20ML (50MG/ML)	A090181 001	Sep 22, 2009	Jan	CPOT
AP	+		3GM/VIAL	A076078 002	May 28, 2002	Feb	CTEC
AP	+		3GM/VIAL	A076078 002	May 28, 2002	Feb	CTEC
	+		3GM/VIAL	A076078 002	May 28, 2002	Jan	CTEC
	+		3GM/VIAL	A076078 002	May 28, 2002	Jan	CTEC
AP			3GM/60ML (50MG/ML)	A090181 002	Sep 22, 2009	Jan	CPOT
AP	+	TEVA PARENTERAL	1GM/20ML (50MG/ML)	A076657 001	Apr 04, 2007	Jan	CTEC
AP	+		3GM/60ML (50MG/ML)	A076657 002	Apr 04, 2007	Jan	CTEC

IFOSFAMIDE; MESNA

## INJECTABLE; INJECTION

## IFEX/MESNEX KIT

## @ BAXTER HLTHCARE

1GM/VIAL;100MG/ML

N019763 003 Oct 10, 1992 Feb DISC

## @

3GM/VIAL;100MG/ML

N019763 004 Oct 10, 1992 Feb DISC

IMIPRAMINE HYDROCHLORIDE

## TABLET; ORAL

## IMIPRAMINE HYDROCHLORIDE

AB	LUPIN LTD	10MG	A090443 001	Mar 11, 2010	Feb	NEWA
AB		25MG	A090442 001	Mar 11, 2010	Feb	NEWA
AB		50MG	A090441 001	Mar 11, 2010	Feb	NEWA

IMIPRAMINE PAMOATE

## CAPSULE; ORAL

## IMIPRAMINE PAMOATE

>A>							
>A>	AB	LUPIN LTD	EQ 75MG HCL	A090444 001	Apr 16, 2010	Apr	NEWA
>A>	AB		EQ 100MG HCL	A090444 002	Apr 16, 2010	Apr	NEWA
>A>	AB		EQ 125MG HCL	A090444 003	Apr 16, 2010	Apr	NEWA
>A>	AB		EQ 150MG HCL	A090444 004	Apr 16, 2010	Apr	NEWA
>A>	AB	ROXANE	EQ 75MG HCL	A091099 001	Apr 16, 2010	Apr	NEWA

CAPSULE; ORAL

>A>		IMIPRAMINE PAMOATE						
>A>	AB	ROXANE	EQ 100MG HCL	A091099 002	Apr 16, 2010	Apr	NEWA	
>A>	AB		EQ 125MG HCL	A091099 003	Apr 16, 2010	Apr	NEWA	
>A>	AB		EQ 150MG HCL	A091099 004	Apr 16, 2010	Apr	NEWA	
		TOFRANIL-PM						
>D>	+	TYCO HLTHCARE	EQ 75MG HCL	N017090 001		Apr	CFTG	
>A>	AB	+	EQ 75MG HCL	N017090 001		Apr	CFTG	
>D>			EQ 100MG HCL	N017090 004		Apr	CFTG	
>A>	AB		EQ 100MG HCL	N017090 004		Apr	CFTG	
>D>			EQ 125MG HCL	N017090 003		Apr	CFTG	
>A>	AB		EQ 125MG HCL	N017090 003		Apr	CFTG	
>D>			EQ 150MG HCL	N017090 002		Apr	CFTG	
>A>	AB		EQ 150MG HCL	N017090 002		Apr	CFTG	

IMIQUIMOD

## CREAM; TOPICAL

		ALDARA						
AB	+	GRACEWAY	5%	N020723 001	Feb 27, 1997	Feb	CFTG	
		IMIQUIMOD						
AB		NYCOMED US	5%	A078548 001	Feb 25, 2010	Feb	NEWA	
		ZYCLARA						
	+	GRACEWAY	3.75%	N022483 001	Mar 25, 2010	Mar	NEWA	

INAMRINONE LACTATE

## INJECTABLE; INJECTION

## AMRINONE LACTATE

		@ BAXTER HLTHCARE CORP	EQ 5MG BASE/ML	A075542 001	May 10, 2000	Feb	DISC	
	+	BEDFORD	EQ 5MG BASE/ML	A075513 001	May 09, 2000	Feb	CTEC	

INDOMETHACIN

## INJECTABLE; INJECTION

## INDOMETHACIN

	+	APP PHARMS	EQ 1MG BASE/VIAL	N022536 001	Mar 17, 2010	Mar	NEWA	
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IRINOTECAN HYDROCHLORIDE

## INJECTABLE; INJECTION

## IRINOTECAN HYDROCHLORIDE

>A>	AP	DR REDDYS LABS LTD	40MG/2ML (20MG/ML)	A078953 001	Apr 15, 2010	Apr	NEWA	
>A>	AP		100MG/5ML (20MG/ML)	A078953 002	Apr 15, 2010	Apr	NEWA	
		@ SANDOZ	40MG/2ML (20MG/ML)	A077994 001	Feb 27, 2008	Mar	DISC	
		@	100MG/5ML (20MG/ML)	A077994 002	Feb 27, 2008	Mar	DISC	

ISOSORBIDE DINITRATE

## TABLET, EXTENDED RELEASE; ORAL

## ISOSORBIDE DINITRATE

AB	+	CARACO	40MG	A040009 001	Dec 30, 1998	Mar	CAHN	
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ITRACONAZOLE

## TABLET; ORAL

## ITRACONAZOLE

>A>	+	STIEFEL LABS INC	200MG	N022484 001	Apr 29, 2010	Apr	NEWA	
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LABETALOL HYDROCHLORIDE

INJECTABLE; INJECTION

LABETALOL HYDROCHLORIDE

AP	SAGENT STRIDES	5MG/ML	A079134 001	Feb 03, 2010	Jan	NEWA
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TABLET; ORAL

TRANDATE

AB	+ PROMETHEUS LABS	200MG	N018716 002	Aug 01, 1984	Feb	CRLD
>D>	AB	300MG	N018716 003	Aug 01, 1984	Apr	DISC
>A>	@	300MG	N018716 003	Aug 01, 1984	Apr	DISC
AB		300MG	N018716 003	Aug 01, 1984	Feb	CRLD

LACOSAMIDE

&gt;A&gt; SOLUTION; ORAL

&gt;A&gt; VIMPAT

>A>	+ SCHWARZ BIOSCIENCES	10MG/ML	N022255 001	Apr 20, 2010	Apr	NEWA
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LAMOTRIGINE

TABLET, EXTENDED RELEASE; ORAL

LAMICTAL XR

>A>	SMITHKLINE BEECHAM	300MG	N022115 005	Apr 14, 2010	Apr	NEWA
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LANSOPRAZOLE

CAPSULE, DELAYED RELEASE; ORAL

LANSOPRAZOLE

>A>	AB SANDOZ	15MG	A090331 001	Apr 23, 2010	Apr	NEWA
>A>	AB	30MG	A090331 002	Apr 23, 2010	Apr	NEWA

LENALIDOMIDE

CAPSULE; ORAL

REVLIMID

+ CELGENE	5MG	N021880 001	Dec 27, 2005	Jan	CRLD
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LEUPROLIDE ACETATE

INJECTABLE; INJECTION

LEUPROLIDE ACETATE

>D>	AP BEDFORD LABS	1MG/0.2ML	A074728 001	Aug 04, 1998	Apr	CAHN
>A>	AP OAKWOOD LABS	1MG/0.2ML	A074728 001	Aug 04, 1998	Apr	CAHN

LEVETIRACETAM

SOLUTION; ORAL

LEVETIRACETAM

AA	WOCKHARDT	100MG/ML	A090028 001	Mar 03, 2010	Feb	NEWA
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TABLET; ORAL

LEVETIRACETAM

AB	TARO	250MG	A078960 004	Feb 01, 2010	Jan	NEWA
AB		500MG	A078960 003	Feb 01, 2010	Jan	NEWA
AB		750MG	A078960 002	Feb 01, 2010	Jan	NEWA
AB		1GM	A078960 001	Feb 01, 2010	Jan	NEWA

LEVONORGESTREL

TABLET; ORAL

LEVONORGESTREL

>D>	AB WATSON LABS	0.75MG	A078665 001	Aug 28, 2009	Apr	CRLD
>A>	AB +	0.75MG	A078665 001	Aug 28, 2009	Apr	CRLD



LEVOTHYROXINE SODIUM

CAPSULE; ORAL

TIROSINT

INST BIOCHIMIQUE	0.013MG	N022121 001	Aug 01, 2007	Feb	CMFD
	0.025MG	N021924 002	Oct 13, 2006	Feb	CMFD
	0.05MG	N021924 003	Oct 13, 2006	Feb	CMFD
	0.075MG	N021924 004	Oct 13, 2006	Feb	CMFD
	0.088MG	N021924 010	Oct 02, 2009	Feb	NEWA
	0.1MG	N021924 005	Oct 13, 2006	Feb	CMFD
	0.112MG	N021924 008	Oct 02, 2009	Feb	NEWA
	0.125MG	N021924 006	Oct 13, 2006	Feb	CMFD
	0.137MG	N021924 009	Oct 02, 2009	Feb	NEWA
	0.15MG	N021924 007	Oct 13, 2006	Feb	CMFD

LIDOCAINE; PRILOCAINE

CREAM; TOPICAL

LIDOCAINE AND PRILOCAINE

AB	NYCOMED US	2.5%;2.5%	A076453 001	Aug 18, 2003	Mar	CAHN
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LIRAGLUTIDE RECOMBINANT

SOLUTION; SUBCUTANEOUS

VICTOZA

+	NOVO NORDISK INC	18MG/3ML (6MG/ML)	N022341 001	Jan 25, 2010	Jan	NEWA
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LISINAPRIL

TABLET; ORAL

LISINAPRIL

@	TEVA	2.5MG	A075783 001	Jul 01, 2002	Jan	DISC
@		5MG	A075783 002	Jul 01, 2002	Jan	DISC
@		10MG	A075783 003	Jul 01, 2002	Jan	DISC
@		20MG	A075783 004	Jul 01, 2002	Jan	DISC
@		30MG	A075783 005	Jul 01, 2002	Jan	DISC
@		40MG	A075783 006	Jul 01, 2002	Jan	DISC

LITHIUM CARBONATE

CAPSULE; ORAL

ESKALITH

@	NOVEN THERAP	300MG	N016860 001		Jan	DISC
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LOSARTAN POTASSIUM

TABLET; ORAL

COZAAR

AB	MERCK	25MG	N020386 001	Apr 14, 1995	Mar	CFTG
AB		50MG	N020386 002	Apr 14, 1995	Mar	CFTG
AB	+	100MG	N020386 003	Oct 13, 1998	Mar	CFTG

LOSARTAN POTASSIUM

AB	TEVA	25MG	A076958 001	Apr 06, 2010	Mar	NEWA
AB		50MG	A076958 002	Apr 06, 2010	Mar	NEWA
AB		100MG	A076958 003	Apr 06, 2010	Mar	NEWA

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

ANTIVERT

AA	+	PFIZER	50MG	N010721 001	Jan 20, 1982	Jan	CMFD
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## TABLET, CHEWABLE; ORAL

ANTIVERT

@ PFIZER

25MG

N010721 005

Jan DISC

MEFLOQUINE HYDROCHLORIDE

TABLET; ORAL

MEFLOQUINE HYDROCHLORIDE

&gt;A&gt; AB

WEST WARD

250MG

A077699 001 Apr 21, 2010 Apr NEWA

MELPHALAN HYDROCHLORIDE

INJECTABLE; INJECTION

MELPHALAN HYDROCHLORIDE

AP

BIONICHE PHARMA USA

EQ 50MG BASE/VIAL

A090299 001 Oct 27, 2009 Mar CAHN

MEMANTINE HYDROCHLORIDE

TABLET; ORAL

&gt;D&gt;

MEMANTINE

&gt;A&gt;

@ SUN PHARM INDS (IN)

5MG

A090058 001 May 05, 2010 Apr DISC

&gt;A&gt;

@

10MG

A090058 002 May 05, 2010 Apr DISC

&gt;D&gt;

MEMANTINE HYDROCHLORIDE

&gt;D&gt;

AB

DR REDDYS LABS LTD

5MG

A090048 001 Apr 14, 2010 Apr DISC

&gt;A&gt;

@

5MG

A090048 001 Apr 14, 2010 Apr DISC

AB

5MG

A090048 001 Apr 14, 2010 Mar NEWA

&gt;D&gt;

AB

10MG

10MG

A090048 002 Apr 14, 2010 Apr DISC

&gt;A&gt;

@

10MG

A090048 002 Apr 14, 2010 Apr DISC

AB

10MG

A090048 002 Apr 14, 2010 Mar NEWA

NAMENDA

&gt;D&gt;

AB

FOREST LABS

5MG

N021487 001 Oct 16, 2003 Apr CTEC

&gt;A&gt;

5MG

N021487 001 Oct 16, 2003 Apr CTEC

AB

5MG

N021487 001 Oct 16, 2003 Mar CFTG

&gt;D&gt;

AB

+

10MG

10MG

N021487 002 Oct 16, 2003 Apr CTEC

&gt;A&gt;

+

10MG

10MG

N021487 002 Oct 16, 2003 Apr CTEC

AB

+

10MG

10MG

N021487 002 Oct 16, 2003 Mar CFTG

MEPERIDINE HYDROCHLORIDE

SYRUP; ORAL

MEPERIDINE HYDROCHLORIDE

+

ROXANE

50MG/5ML

A088744 001 Jan 30, 1985 Feb CRLD

TABLET; ORAL

DEMEROL

@ SANOFI AVENTIS US

50MG

N005010 001

Feb DISC

MEPERIDINE HYDROCHLORIDE

AA

MIKAH PHARMA

50MG

A040331 001 May 28, 1999 Feb CAHN

AA

100MG

A040331 002 May 28, 1999 Feb CAHN

MESALAMINE

TABLET, DELAYED RELEASE; ORAL

ASACOL

+

WARNER CHILCOTT INC

400MG

N019651 001 Jan 31, 1992 Feb CAHN

ASACOL HD

+

WARNER CHILCOTT INC

800MG

N021830 001 May 29, 2008 Feb CAHN

MESNA

INJECTABLE; INTRAVENOUS

MESNA

AP

SAGENT STRIDES

100MG/ML

A090913 001 Apr 13, 2010 Mar NEWA

METAXALONE

TABLET; ORAL

METAXALONE

AB		SANDOZ	800MG	A040445 001	Mar 31, 2010	Mar	NEWA
AB	+	KING PHARMS	800MG	N013217 003	Aug 30, 2002	Mar	CFTG

METFORMIN HYDROCHLORIDE

TABLET; ORAL

METFORMIN HYDROCHLORIDE

>A>	AB		GRANULES INDIA	500MG	A090564 001	Apr 22, 2010	Apr	NEWA
>A>	AB			850MG	A090564 002	Apr 22, 2010	Apr	NEWA
>A>	AB			1GM	A090564 003	Apr 22, 2010	Apr	NEWA
		@	IPCA LABS LTD	500MG	A078422 001	Aug 06, 2007	Mar	DISC
		@		850MG	A078422 002	Aug 06, 2007	Mar	DISC
		@		1GM	A078422 003	Aug 06, 2007	Mar	DISC
>D>	AB		IVAX SUB TEVA PHARMS	500MG	A075975 001	Jan 24, 2002	Apr	DISC
>A>		@		500MG	A075975 001	Jan 24, 2002	Apr	DISC
>D>	AB			625MG	A075972 005	Jan 24, 2002	Apr	CTEC
>A>				625MG	A075972 005	Jan 24, 2002	Apr	CTEC
>D>	AB			625MG	A075975 004	Jan 24, 2002	Apr	DISC
>A>		@		625MG	A075975 004	Jan 24, 2002	Apr	DISC
>D>	AB			750MG	A075972 004	Jan 24, 2002	Apr	CTEC
>A>				750MG	A075972 004	Jan 24, 2002	Apr	CTEC
>D>	AB			750MG	A075975 005	Jan 24, 2002	Apr	DISC
>A>		@		750MG	A075975 005	Jan 24, 2002	Apr	DISC
>D>	AB			850MG	A075975 002	Jan 24, 2002	Apr	DISC
>A>		@		850MG	A075975 002	Jan 24, 2002	Apr	DISC
>D>	AB			1GM	A075975 003	Jan 24, 2002	Apr	DISC
>A>		@		1GM	A075975 003	Jan 24, 2002	Apr	DISC

TABLET, EXTENDED RELEASE; ORAL

METFORMIN HYDROCHLORIDE

>D>	AB		IVAX SUB TEVA PHARMS	500MG	A076545 001	Dec 01, 2003	Apr	DISC
>A>		@		500MG	A076545 001	Dec 01, 2003	Apr	DISC
AB			TORRENT PHARMS	750MG	A079226 001	Feb 18, 2010	Jan	NEWA

METHADONE HYDROCHLORIDE

INJECTABLE; INJECTION

DOLOPHINE HYDROCHLORIDE

+	BIONICHE PHARMA	10MG/ML	N021624 001			Mar	CAHN
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METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL

DESOXYN

>D>	+	LUNDBECK INC	5MG	N005378 002		Apr	CTEC	
>A>	AA	+		N005378 002		Apr	CTEC	
>A>			METHAMPHETAMINE HYDROCHLORIDE					
>A>	AA		COASTAL PHARMS	5MG	A091189 001	Apr 21, 2010	Apr	NEWA

METHENAMINE HIPPURATE

TABLET; ORAL

UREX

AB		CNTY LINE PHARMS	1GM	N016151 001		Feb	CAHN
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METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE SODIUM PRESERVATIVE FREE

AP	+	BIONICHE PHARMA	EQ 50MG BASE/2ML (EQ 25MG BASE/ML)	A040767 001	Apr 30, 2007	Mar	CAHN
AP	+	BIONICHE PHARMA USA	EQ 250MG BASE/10ML (EQ 25MG BASE/ML)	A040768 001	Apr 30, 2007	Mar	CAHN
AP	+		EQ 1GM BASE/40ML (EQ 25MG BASE/ML)	A040716 001	Apr 30, 2007	Mar	CAHN

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HYDROCHLORIDE

		@ HOSPIRA	EQ 5MG BASE/ML	A074147 001	Aug 02, 1996	Feb	DISC
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TABLET; ORAL

METOCLOPRAMIDE HYDROCHLORIDE

		@ SANDOZ	EQ 10MG BASE	A074478 002	Oct 05, 1995	Jan	DISC
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		@ WATSON LABS	EQ 10MG BASE	A070511 001	Jan 22, 1986	Jan	DISC
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METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL

METOPROLOL SUCCINATE

>A>	AB	WATSON LABS FLORIDA	EQ 100MG TARTRATE	A077298 001	Apr 15, 2010	Apr	NEWA
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>A>	AB		EQ 200MG TARTRATE	A077298 002	Apr 15, 2010	Apr	NEWA
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METOPROLOL TARTRATE

INJECTABLE; INJECTION

METOPROLOL TARTRATE

>A>	AP	SAGENT STRIDES	1MG/ML	A090317 001	Apr 19, 2010	Apr	NEWA
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METRONIDAZOLE

TABLET; ORAL

METRONIDAZOLE

>D>	AB	IVAX SUB TEVA PHARMS	250MG	N018517 001		Apr	DISC
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>A>		@	250MG	N018517 001		Apr	DISC
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>D>	AB		500MG	N018517 002	May 05, 1982	Apr	DISC
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>A>		@	500MG	N018517 002	May 05, 1982	Apr	DISC
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		@ WORLD GEN	250MG	A070040 001	Jan 29, 1985	Mar	CAHN
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TABLET, EXTENDED RELEASE; ORAL

FLAGYL ER

>D>		+ GD SEARLE LLC	750MG	N020868 001	Nov 26, 1997	Apr	CFTG
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>A>	AB		750MG	N020868 001	Nov 26, 1997	Apr	CFTG
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>A>		METRONIDAZOLE					
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>A>	AB	ALEMBIC LTD	750MG	A090222 001	May 05, 2010	Apr	NEWA
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MICONAZOLE

>A>		TABLET; BUCCAL					
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>A>		ORAVIG					
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>A>		+ BIOALLIANCE PHARMA	50MG	N022404 001	Apr 16, 2010	Apr	NEWA
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MILRINONE LACTATE

INJECTABLE; INJECTION

MILRINONE LACTATE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	+	BAXTER HLTHCARE	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	A075834 001	May 28, 2002	Feb	CTEC
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AP	+		EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	A075834 002	May 28, 2002	Feb	CRLD
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INJECTABLE; INJECTIONMILRINONE LACTATE IN PLASTIC CONTAINER

AP	HIKMA FARMACEUTICA	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	A090038 001	Jan 21, 2010	Jan	NEWA
AP		EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	A090038 002	Jan 21, 2010	Jan	NEWA
	<u>PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER</u>					
	@ SANOFI AVENTIS US	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	N020343 003	Aug 09, 1994	Feb	DISC
	@	EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	N020343 004	Aug 09, 1994	Feb	DISC

MITOXANTRONE HYDROCHLORIDEINJECTABLE; INJECTIONMITOXANTRONE HYDROCHLORIDE

AP	BIONICHE PHARMA USA	EQ 20MG BASE/10ML (EQ 2MG BASE/ML)	A078980 001	Apr 13, 2009	Mar	CAHN
AP		EQ 30MG BASE/15ML (EQ 2MG BASE/ML)	A078980 002	Apr 13, 2009	Mar	CAHN

MOEXIPRIL HYDROCHLORIDETABLET; ORALMOEXIPRIL HYDROCHLORIDE

AB	GLENMARK GENERICS	7.5MG	A090416 001	Mar 30, 2010	Mar	NEWA
AB		15MG	A090416 002	Mar 30, 2010	Mar	NEWA

MORPHINE SULFATESOLUTION; ORALMORPHINE SULFATE

	ROXANE	20MG/5ML	N022195 002	Mar 17, 2008	Jan	CRLD
+		100MG/5ML	N022195 003	Jan 25, 2010	Jan	NEWA

TABLET, EXTENDED RELEASE; ORALMORPHINE SULFATE

	@ PURDUE PHARMA LP	15MG	A074862 001	Jul 07, 1998	Feb	CAHN
	@	30MG	A074862 002	Jul 07, 1998	Feb	CAHN
	@	60MG	A074862 003	Jul 07, 1998	Feb	CAHN
	@	100MG	A074769 001	Jul 02, 1998	Feb	CAHN
	@	200MG	A074769 002	Jul 02, 1998	Feb	CAHN

NALIDIXIC ACIDTABLET; ORALNEGGRAM

	@ SANOFI AVENTIS US	250MG	N014214 002		Feb	DISC
	@	500MG	N014214 004		Feb	DISC
	@	1GM	N014214 005		Feb	DISC

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDETABLET; ORALPENTAZOCINE AND NALOXONE HYDROCHLORIDES

AB	+	WATSON LABS	EQ 0.5MG BASE;EQ 50MG BASE	A074736 001	Jan 21, 1997	Feb	CRLD
		TALWIN NX					
	@	SANOFI AVENTIS US	EQ 0.5MG BASE;EQ 50MG BASE	N018733 001	Dec 16, 1982	Feb	DISC

NEFAZODONE HYDROCHLORIDETABLET; ORALNEFAZODONE HYDROCHLORIDE

>D>	AB	IVAX SUB TEVA PHARMS	50MG	A075763 001	Sep 16, 2003	Apr	DISC
>A>	@		50MG	A075763 001	Sep 16, 2003	Apr	DISC

TABLET; ORAL

## NEFAZODONE HYDROCHLORIDE

>D>	AB	IVAX SUB TEVA PHARMS	100MG	A075763 002	Sep 16, 2003	Apr	DISC
>A>		@	100MG	A075763 002	Sep 16, 2003	Apr	DISC
>D>	AB		150MG	A075763 003	Sep 16, 2003	Apr	DISC
>A>		@	150MG	A075763 003	Sep 16, 2003	Apr	DISC
>D>	AB		200MG	A075763 004	Sep 16, 2003	Apr	DISC
>A>		@	200MG	A075763 004	Sep 16, 2003	Apr	DISC
>D>	AB		250MG	A075763 005	Sep 16, 2003	Apr	DISC
>A>		@	250MG	A075763 005	Sep 16, 2003	Apr	DISC

NEOMYCIN SULFATE

## TABLET; ORAL

## NEOMYCIN SULFATE

AA		OMAN PHARM PRODUCTS	500MG	A065468 001	Mar 29, 2010	Mar	NEWA
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NICARDIPINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## NICARDIPINE HYDROCHLORIDE

AP		BIONICHE PHARMA USA	25MG/10ML (2.5MG/ML)	A090664 001	Nov 17, 2009	Mar	CAHN
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NIFEDIPINE

## CAPSULE; ORAL

## NIFEDIPINE

AB		INTERGEL PHARM	10MG	A072781 001	Jul 30, 1993	Mar	CAHN
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NISOLDIPINE

## TABLET, EXTENDED RELEASE; ORAL

## SULAR

+		SHIONOGI PHARMA	8.5MG	N020356 008	Jan 02, 2008	Jan	CAHN
		@	10MG	N020356 001	Feb 02, 1995	Jan	CAHN
+			17MG	N020356 007	Jan 02, 2008	Jan	CAHN
		@	20MG	N020356 002	Feb 02, 1995	Jan	CAHN
			25.5MG	N020356 006	Jan 02, 2008	Jan	CAHN
		@	30MG	N020356 003	Feb 02, 1995	Jan	CAHN
+			34MG	N020356 005	Jan 02, 2008	Jan	CAHN
		@	40MG	N020356 004	Feb 02, 1995	Jan	CAHN

NITROFURANTOIN

## SUSPENSION; ORAL

## FURADANTIN

+		SHIONOGI PHARMA	25MG/5ML	N009175 001		Jan	CAHN
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NITROGLYCERIN

## AEROSOL; SUBLINGUAL

## NITROLINGUAL

		@ POHL BOSKAMP	0.4MG/SPRAY	N018705 001	Oct 31, 1985	Mar	CAHN
		@ SHIONOGI PHARMA	0.4MG/SPRAY	N018705 001	Oct 31, 1985	Jan	CAHN

## SPRAY, METERED; SUBLINGUAL

## NITROLINGUAL PUMPSPRAY

+		POHL BOSKAMP	0.4MG/SPRAY	N018705 002	Jan 10, 1997	Mar	CAHN
+		SHIONOGI PHARMA	0.4MG/SPRAY	N018705 002	Jan 10, 1997	Jan	CAHN

NORETHINDRONE

TABLET; ORAL-28  
HEATHER

>A> AB1 GLENMARK GENERICS 0.35MG A090454 001 Apr 23, 2010 Apr NEWA

OFLOXACIN

TABLET; ORAL  
OFLOXACIN

@ LARKEN LABS

200MG

A076093 001 Sep 02, 2003 Jan CAHN

@

300MG

A076093 002 Sep 02, 2003 Jan CAHN

@

400MG

A076093 003 Sep 02, 2003 Jan CAHN

ONDANSETRON

TABLET, ORALLY DISINTEGRATING; ORAL  
ONDANSETRON

AB AUROBINDO PHARMA

4MG

A090469 001 Apr 12, 2010 Mar NEWA

AB

8MG

A090469 002 Apr 12, 2010 Mar NEWA

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ONDANSETRON HYDROCHLORIDE

>A> AP EMCURE PHARMS EQ 2MG BASE/ML A090424 001 Apr 16, 2010 Apr NEWA

AP LANNETT

EQ 2MG BASE/ML

A090116 001 Apr 14, 2010 Mar NEWA

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL

ORPHENADRINE CITRATE

AB GAVIS PHARMS

100MG

A040284 001 Jun 19, 1998 Feb CAHN

OXALIPLATIN

>D> INJECTABLE; INJECTION

>D> OXALIPLATIN

>D> AP + HOSPIRA INC 50MG/VIAL A078815 001 Sep 30, 2009 Apr CDFR

AP + 50MG/VIAL A078815 001 Sep 30, 2009 Jan CRLD

>D> AP + 100MG/VIAL A078815 002 Sep 30, 2009 Apr CDFR

AP + 100MG/VIAL A078815 002 Sep 30, 2009 Jan CRLD

>A> INJECTABLE; IV (INFUSION)

>A> OXALIPLATIN

>A> AP + HOSPIRA INC 50MG/VIAL A078815 001 Sep 30, 2009 Apr CDFR

>A> AP + 100MG/VIAL A078815 002 Sep 30, 2009 Apr CDFR

OXCARBAZEPINE

TABLET; ORAL

OXCARBAZEPINE

AB CADISTA PHARMS

150MG

A090239 001 Jan 25, 2010 Jan NEWA

AB 300MG A090239 002 Jan 25, 2010 Jan NEWA

AB 600MG A090239 003 Jan 25, 2010 Jan NEWA

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

>D> OXYCODONE HYDROCHLORIDE

>D> AB MALLINCKRODT 10MG A077822 001 Jul 24, 2008 Apr DISC

>A> @ 10MG A077822 001 Jul 24, 2008 Apr DISC

>D> AB 20MG A077822 002 Jul 24, 2008 Apr DISC

>A> @ 20MG A077822 002 Jul 24, 2008 Apr DISC

## TABLET, EXTENDED RELEASE; ORAL

>D>		OXYCODONE HYDROCHLORIDE							
>D>	AB	MALLINCKRODT	40MG	A077822	003	Jul 24, 2008	Apr	DISC	
>A>		@	40MG	A077822	003	Jul 24, 2008	Apr	DISC	
>D>	AB		80MG	A077822	004	Jul 24, 2008	Apr	DISC	
>A>		@	80MG	A077822	004	Jul 24, 2008	Apr	DISC	
		OXYCONTIN							
>D>	AB	PURDUE PHARMA LP	10MG	N020553	001	Dec 12, 1995	Apr	CTEC	
>D>	AB		10MG	N020553	001	Dec 12, 1995	Apr	CTEC	
>A>			10MG	N020553	001	Dec 12, 1995	Apr	CTEC	
>A>			10MG	N020553	001	Dec 12, 1995	Apr	CTEC	
>D>	AB		20MG	N020553	002	Dec 12, 1995	Apr	CTEC	
>D>	AB		20MG	N020553	002	Dec 12, 1995	Apr	CTEC	
>A>			20MG	N020553	002	Dec 12, 1995	Apr	CTEC	
>A>			20MG	N020553	002	Dec 12, 1995	Apr	CTEC	
>D>	AB	+	40MG	N020553	003	Dec 12, 1995	Apr	CTEC	
>D>	AB	+	40MG	N020553	003	Dec 12, 1995	Apr	CTEC	
>A>		+	40MG	N020553	003	Dec 12, 1995	Apr	CTEC	
>A>		+	40MG	N020553	003	Dec 12, 1995	Apr	CTEC	
>D>	AB		80MG	N020553	004	Jan 06, 1997	Apr	CTEC	
>D>	AB		80MG	N020553	004	Jan 06, 1997	Apr	CTEC	
>A>			80MG	N020553	004	Jan 06, 1997	Apr	CTEC	
>A>			80MG	N020553	004	Jan 06, 1997	Apr	CTEC	

PACLITAXEL

## INJECTABLE; INJECTION

## PACLITAXEL

>D>	AP	PLIVA LACHEMA	6MG/ML	A077413	001	Mar 12, 2008	Apr	DISC	
>A>		@	6MG/ML	A077413	001	Mar 12, 2008	Apr	DISC	

PALIPERIDONE PALMITATE

## SUSPENSION, EXTENDED RELEASE; INTRAMUSCULAR

## INVEGA SUSTENNA

+	JOHNSON AND JOHNSON	234MG/1.5ML (156MG/ML)		N022264	005	Jul 31, 2009	Jan	CRLD	
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PAMIDRONATE DISODIUM

## INJECTABLE; INJECTION

## PAMIDRONATE DISODIUM

AP	MN PHARMS	30MG/VIAL		A078300	001	Mar 10, 2009	Feb	CAHN	
AP		90MG/VIAL		A078300	002	Mar 10, 2009	Feb	CAHN	

PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

## CAPSULE, DELAYED RELEASE; ORAL

## CREON

## ABBOTT PRODS

		30,000USP UNITS;6,000USP UNITS;19,000USP UNITS		N020725	001	Apr 30, 2009	Mar	CAHN	
		60,000USP UNITS;12,000USP UNITS;38,000USP UNITS		N020725	002	Apr 30, 2009	Mar	CAHN	
+		120,000USP UNITS;24,000USP UNITS;76,000USP UNITS		N020725	003	Apr 30, 2009	Mar	CAHN	

## &gt;A&gt; PANCREAZE

>A>	ORTHO MCNEIL JANSSEN	17,500USP/ UNITS;4,200USP/ UNITS;10,000USP/ UNITS		N022523	001	Apr 12, 2010	Apr	NEWA	
>A>		43,750USP/ UNITS;10,500USP/ UNITS;25,000USP/ UNITS		N022523	002	Apr 12, 2010	Apr	NEWA	
>A>		70,000USP/ UNITS;16,800USP/ UNITS;40,000USP/ UNITS		N022523	004	Apr 12, 2010	Apr	NEWA	
>A>	+	61,000USP/ UNITS;21,000USP/ UNITS;37,000USP/ UNITS		N022523	003	Apr 12, 2010	Apr	NEWA	



PEGADEMASE BOVINE

INJECTABLE; INJECTION

ADAGEN

+	SIGMA TAU	250 UNITS/ML	N019818 001	Mar 21, 1990	Feb	CAHN
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PERINDOPRIL ERBUMINE

TABLET; ORAL

PERINDOPRIL ERBUMINE

AB	LUPIN LTD	2MG	A078263 001	Jan 27, 2010	Jan	NEWA
AB		4MG	A078263 002	Jan 27, 2010	Jan	NEWA
AB		8MG	A078263 003	Jan 27, 2010	Jan	NEWA

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE; ORAL

BONTRIL

BC	VALEANT	105MG	A088021 001	Sep 21, 1982	Feb	CAHN
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PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HYDROCHLORIDE

AA	BARR	15MG	A090591 001	Mar 18, 2010	Mar	NEWA
AA		30MG	A090591 002	Mar 18, 2010	Mar	NEWA

POLIDOCANOL

SOLUTION; INTRAVENOUS

ASCLERA

	CHEMISCH FBRK KRSSLR	10MG/2ML (5MG/ML)	N021201 001	Mar 30, 2010	Mar	NEWA
+		20MG/2ML (10MG/ML)	N021201 002	Mar 30, 2010	Mar	NEWA

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

FOR SOLUTION; ORAL

LAX-LYTE WITH FLAVOR PACKS

AA	PADDOCK	420GM/BOT;1.48GM/BOT;5.72GM/BOT;1.2GM/BOT	A079232 001	Feb 25, 2010	Feb	NEWA
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PEG-3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE

AA	MYLAN	420GM/BOT;1.48GM/BOT;5.72GM/BOT;1.2GM/BOT	A090409 001	Apr 02, 2010	Mar	NEWA
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POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE ANHYDROUS

FOR SOLUTION; ORAL

PEG 3350 AND ELECTROLYTES

AA	MYLAN	236GM;2.97GM;6.74GM;5.86GM;22.74GM	A090928 001	Jan 28, 2010	Jan	NEWA
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POLYETHYLENE GLYCOL 3350 AND ELECTROLYTES

AA	PADDOCK LABS	240GM/BOT;2.98GM/BOT;6.72GM/BOT;5.84GM/BOT;22.72GM/BOT	A090712 001	Feb 25, 2010	Feb	NEWA
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POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

KLOR-CON

>D>	+	UPSHER SMITH	8MEQ	N019123 001	Apr 17, 1986	Apr	CTEC
>A>	BC	+	8MEQ	N019123 001	Apr 17, 1986	Apr	CTEC

POTASSIUM CITRATE

TABLET, EXTENDED RELEASE; ORAL

UROCIT-K

MISSION PHARMA 15MEQ N019071 003 Dec 30, 2009 Feb NEWA

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET; ORAL

MIRAPEX

AB BOEHRINGER INGELHEIM 0.75MG N020667 007 Jul 30, 2007 Mar CFTG

PRAMIPEXOLE DIHYDROCHLORIDE

AB MYLAN 0.75MG A090764 001 Apr 09, 2010 Mar NEWA

TABLET, EXTENDED RELEASE; ORAL

MIRAPEX ER

BOEHRINGER INGELHEIM 0.375MG N022421 001 Feb 19, 2010 Feb NEWA

0.75MG N022421 002 Feb 19, 2010 Feb NEWA

1.5MG N022421 003 Feb 19, 2010 Feb NEWA

3MG N022421 004 Feb 19, 2010 Feb NEWA

+ 4.5MG N022421 005 Feb 19, 2010 Feb NEWA

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HYDROCHLORIDE

@ WATSON LABS EQ 1MG BASE A072352 001 May 16, 1989 Jan DISC

@ EQ 2MG BASE A072333 001 May 16, 1989 Jan DISC

PREDNISOLONE

SYRUP; ORAL

PREDNISOLONE

&gt;D&gt; AA IVAX SUB TEVA PHARMS 15MG/5ML A040287 001 May 28, 1999 Apr DISC

&gt;A&gt; @ 15MG/5ML A040287 001 May 28, 1999 Apr DISC

PREDNISONE

TABLET; ORAL

PREDNISONE

AB CONTRACT PHARMACAL 5MG A080209 001 Jan CAHN

PREGABALIN

SOLUTION; ORAL

LYRICA

+ PFIZER 20MG/ML N022488 001 Jan 04, 2010 Jan NEWA

PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

PROCAINE HYDROCHLORIDE

@ WATSON LABS 1% A080658 001 Jan DISC

PROCHLORPERAZINE MALEATE

TABLET; ORAL

PROCHLORPERAZINE MALEATE

@ DURAMED PHARMS BARR EQ 5MG BASE A040207 001 May 01, 1997 Jan DISC

@ EQ 10MG BASE A040207 002 May 01, 1997 Jan DISC

PROCOMP

AB CADISTA PHARMS EQ 5MG BASE A040268 001 Feb 27, 1998 Jan CTNA

AB EQ 10MG BASE A040268 002 Feb 27, 1998 Jan CTNA

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HYDROCHLORIDE

@	PAR PHARM	65MG	A080269 001		Jan	DISC
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PROTRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

PROTRIPTYLINE HYDROCHLORIDE

>A>	AB	SIGMAPHARM LABS LLC	5MG	A090462 001	May 03, 2010	Apr	NEWA
>A>	AB		10MG	A090462 002	May 03, 2010	Apr	NEWA

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

@	CONTRACT PHARMACAL	200MG	A083808 001		Jan	CAHN
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RIFAXIMIN

TABLET; ORAL

XIFAXAN

	SALIX PHARMS	550MG	N021361 002	Mar 24, 2010	Mar	NEWA
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RISPERIDONE

INJECTABLE; INTRAMUSCULAR

RISPERDAL CONSTA

+	ORTHO MCNEIL JANSSEN	25MG/VIAL	N021346 001	Oct 29, 2003	Jan	CRLD
		50MG/VIAL	N021346 003	Oct 29, 2003	Jan	CRLD

TABLET; ORAL

RISPERIDONE

@	SYNTHON PHARMS	0.25MG	A078187 001	Oct 22, 2009	Feb	DISC
@		0.5MG	A078187 002	Oct 22, 2009	Feb	DISC
@		1MG	A078187 003	Oct 22, 2009	Feb	DISC
@		2MG	A078187 004	Oct 22, 2009	Feb	DISC
@		3MG	A078187 005	Oct 22, 2009	Feb	DISC
@		4MG	A078187 006	Oct 22, 2009	Feb	DISC

RITONAVIR

TABLET; ORAL

RITONAVIR

+	ABBOTT LABS	100MG	N022417 001	Feb 10, 2010	Feb	NEWA
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RIVASTIGMINE TARTRATE

CAPSULE; ORAL

EXELON

AB	NOVARTIS	EQ 6MG BASE	N020823 006	Apr 21, 2000	Feb	CRLD
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ROCURONIUM BROMIDE

INJECTABLE; INJECTION

ROCURONIUM BROMIDE

AP	BIONICHE PHARMA USA	50MG/5ML (10MG/ML)	A079199 001	Nov 26, 2008	Mar	CAHN
AP		100MG/10ML (10MG/ML)	A079199 002	Nov 26, 2008	Mar	CAHN

ROPINIROLE HYDROCHLORIDE

TABLET; ORAL

ROPINIROLE HYDROCHLORIDE

AB	ALEMBIC LTD	EQ 0.25MG BASE	A090429 001	Mar 24, 2010	Mar	NEWA
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## TABLET; ORAL

ROPINIROLE HYDROCHLORIDE

AB	ALEMBIC LTD	EQ 0.5MG BASE	A090429 002	Mar 24, 2010	Mar	NEWA
AB		EQ 1MG BASE	A090429 003	Mar 24, 2010	Mar	NEWA
AB		EQ 2MG BASE	A090429 004	Mar 24, 2010	Mar	NEWA
AB		EQ 3MG BASE	A090429 005	Mar 24, 2010	Mar	NEWA
AB		EQ 4MG BASE	A090429 006	Mar 24, 2010	Mar	NEWA
AB		EQ 5MG BASE	A090429 007	Mar 24, 2010	Mar	NEWA
AB	GLENMARK GENERICS	EQ 0.25MG BASE	A090135 001	Feb 25, 2010	Feb	NEWA
AB		EQ 0.5MG BASE	A090135 002	Feb 25, 2010	Feb	NEWA
AB		EQ 1MG BASE	A090135 003	Feb 25, 2010	Feb	NEWA
AB		EQ 2MG BASE	A090135 004	Feb 25, 2010	Feb	NEWA
AB		EQ 3MG BASE	A090135 005	Feb 25, 2010	Feb	NEWA
AB		EQ 4MG BASE	A090135 006	Feb 25, 2010	Feb	NEWA
AB		EQ 5MG BASE	A090135 007	Feb 25, 2010	Feb	NEWA

SELEGILINE HYDROCHLORIDE

## TABLET; ORAL

SELEGILINE HYDROCHLORIDE

AB	MYLAN	5MG	A074866 001	Nov 26, 1997	Mar	CAHN
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SODIUM BICARBONATE

## INJECTABLE; INJECTION

SODIUM BICARBONATE

+	HOSPIRA	0.9MEQ/ML	A077394 001	Nov 09, 2005	Feb	CRLD
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SOMATROPIN RECOMBINANT

## INJECTABLE; INJECTION

NORDITROPIN FLEXPRO

BX	NOVO NORDISK INC	5MG/1.5ML	N021148 008	Mar 01, 2010	Mar	NEWA
BX		10MG/1.5ML	N021148 009	Mar 01, 2010	Mar	NEWA
		15MG/1.5ML	N021148 010	Mar 01, 2010	Mar	NEWA

STAVUDINE

## CAPSULE; ORAL

STAVUDINE

AB	MYLAN	15MG	A079069 001	Dec 29, 2008	Feb	CAHN
AB		20MG	A079069 002	Dec 29, 2008	Feb	CAHN
AB		30MG	A079069 003	Dec 29, 2008	Feb	CAHN
AB		40MG	A079069 004	Dec 29, 2008	Feb	CAHN

SUCRALFATE

## TABLET; ORAL

SUCRALFATE

AB	NOSTRUM LABS	1GM	A074415 001	Jun 08, 1998	Mar	CAHN
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SULFAMETHOXAZOLE; TRIMETHOPRIM

## TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB	AUROBINDO PHARMA	400MG;80MG	A090624 001	Feb 16, 2010	Jan	NEWA
AB		800MG;160MG	A090624 002	Feb 16, 2010	Jan	NEWA

>D> SULFISOXAZOLE

## &gt;D&gt; TABLET; ORAL

>D> SULFISOXAZOLE

>D>	+	IVAX SUB TEVA PHARMS	500MG	A080142 001		Apr DISC
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>D> TABLET; ORAL  
 >D> SULFISOXAZOLE  
 >A> @ IVAX SUB TEVA PHARMS 500MG A080142 001 Apr DISC

TAMSULOSIN HYDROCHLORIDE

CAPSULE; ORAL  
 FLOMAX  
 AB + BOEHRINGER INGELHEIM 0.4MG N020579 001 Apr 15, 1997 Feb CFTG  
 TAMSULOSIN HYDROCHLORIDE  
 AB IMPAX LABS 0.4MG A090377 001 Mar 02, 2010 Feb NEWA  
 >A> AB MYLAN 0.4MG A090408 001 Apr 27, 2010 Apr NEWA  
 >A> AB SANDOZ 0.4MG A078015 001 Apr 27, 2010 Apr NEWA  
 >A> AB SYNTHON PHARMS 0.4MG A078801 001 Apr 27, 2010 Apr NEWA  
 >A> AB TEVA PHARMS 0.4MG A077630 001 Apr 27, 2010 Apr NEWA  
 >A> AB WOCKHARDT 0.4MG A078938 001 Apr 27, 2010 Apr NEWA  
 >A> AB ZYDUS PHARMS USA INC 0.4MG A078225 001 Apr 27, 2010 Apr NEWA

TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR

SOLUTION; INJECTION, ORAL  
 TECHNELITE  
 + LANTHEUS MEDCL 0.0083-2.7 CI/GENERATOR N017771 001 Feb CRLD  
 ULTRA-TECHNEKOW FM  
 + MALLINCKRODT 0.25-3 CI/GENERATOR N017243 002 Feb CRLD

TEMOZOLOMIDE

CAPSULE; ORAL  
 TEMODAR  
 AB SCHERING 5MG N021029 001 Aug 11, 1999 Feb CFTG  
 AB 20MG N021029 002 Aug 11, 1999 Feb CFTG  
 AB 100MG N021029 003 Aug 11, 1999 Feb CFTG  
 AB 140MG N021029 005 Oct 19, 2006 Feb CFTG  
 AB 180MG N021029 006 Oct 19, 2006 Feb CFTG  
 AB + 250MG N021029 004 Aug 11, 1999 Feb CFTG  
 TEMOZOLOMIDE  
 AB BARR 5MG A078879 001 Mar 01, 2010 Feb NEWA  
 AB 20MG A078879 002 Mar 01, 2010 Feb NEWA  
 AB 100MG A078879 003 Mar 01, 2010 Feb NEWA  
 AB 140MG A078879 005 Mar 01, 2010 Feb NEWA  
 AB 180MG A078879 006 Mar 01, 2010 Feb NEWA  
 AB 250MG A078879 004 Mar 01, 2010 Feb NEWA

TERCONAZOLE

CREAM; VAGINAL  
 TERCONAZOLE  
 BX + NYCOMED US 0.8% N021735 001 Oct 01, 2004 Jan CAHN

THEOPHYLLINE

ELIXIR; ORAL  
 ELIXOPHYLLIN  
 + CARACO 80MG/15ML A085186 001 Mar CAHN  
 TABLET, EXTENDED RELEASE; ORAL  
 THEOCHRON  
 AB CARACO 100MG A088320 001 Feb 21, 1985 Mar CAHN  
 AB 200MG A088321 001 Feb 21, 1985 Mar CAHN  
 AB 300MG A087400 002 Jan 11, 1983 Mar CAHN

TINZAPARIN SODIUM

INJECTABLE; INJECTION

INNOHEP

+	LEO PHARMA AS	20,000 IU/ML	N020484 001	Jul 14, 2000	Feb	CAHN
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TOLMETIN SODIUM

TABLET; ORAL

TOLMETIN SODIUM

>D>	AB	IVAX SUB TEVA PHARMS	EQ 600MG BASE	A074399 001	Mar 28, 1996	Apr	DISC
>A>		@	EQ 600MG BASE	A074399 001	Mar 28, 1996	Apr	DISC

TOPIRAMATE

TABLET; ORAL

TOPIRAMATE

@	PLIVA HRVATSKA DOO	25MG	A077905 001	Mar 30, 2009	Jan	DISC
@		50MG	A077905 002	Mar 30, 2009	Jan	DISC
@		100MG	A077905 003	Mar 30, 2009	Jan	DISC
@		200MG	A077905 004	Mar 30, 2009	Jan	DISC

TORSEMIDE

INJECTABLE; INJECTION

TORSEMIDE

>D>	+	BEDFORD LABS	20MG/2ML (10MG/ML)	A078007 001	Jun 11, 2008	Apr	CTEC
>A>	AP	+	20MG/2ML (10MG/ML)	A078007 001	Jun 11, 2008	Apr	CTEC
>D>	+		50MG/5ML (10MG/ML)	A078007 002	Jun 11, 2008	Apr	CTEC
>A>	AP	+	50MG/5ML (10MG/ML)	A078007 002	Jun 11, 2008	Apr	CTEC
>A>	AP	PHARMAFORCE	20MG/2ML (10MG/ML)	A090656 001	Apr 21, 2010	Apr	NEWA
>A>	AP		50MG/5ML (10MG/ML)	A090656 002	Apr 21, 2010	Apr	NEWA

TRAMADOL HYDROCHLORIDE

TABLET, ORALLY DISINTEGRATING; ORAL

TRAMADOL HYDROCHLORIDE

+	VICTORY PHARMA	50MG	N021693 001	May 05, 2005	Mar	CMFD
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TRANDOLAPRIL

TABLET; ORAL

TRANDOLAPRIL

AB	EPIC PHARMA	1MG	A078508 003	Jun 18, 2008	Feb	CAHN
AB		2MG	A078508 001	Jun 18, 2008	Feb	CAHN
AB		4MG	A078508 002	Jun 18, 2008	Feb	CAHN

TRANDOLAPRIL; VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

TARKA

>D>	+	ABBOTT	4MG;240MG	N020591 002	Oct 22, 1996	Apr	CFTG
>A>	AB	+	4MG;240MG	N020591 002	Oct 22, 1996	Apr	CFTG
>A>		TRANDOLAPRIL AND VERAPAMIL HYDROCHLORIDE					
>A>	AB	GLENMARK GENERICS	4MG;240MG	A079135 003	May 05, 2010	Apr	NEWA

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HYDROCHLORIDE

AB	VINTAGE	50MG	A072192 001	Feb 02, 1989	Feb	CAHN
AB		100MG	A072193 001	Feb 02, 1989	Feb	CAHN

## TABLET, EXTENDED RELEASE; ORAL

## OLEPTRO

	LABOPHARM	150MG	N022411 001	Feb 02, 2010	Feb	NEWA
+		300MG	N022411 002	Feb 02, 2010	Feb	NEWA

TRETINOIN

## CAPSULE; ORAL

## TRETINOIN

+	BARR	10MG	A077684 001	Jun 22, 2007	Feb	CRLD
	VESANOID					
	@ ROCHE	10MG	N020438 001	Nov 22, 1995	Feb	DISC

## CREAM; TOPICAL

## TRETINOIN

+	TRIAx PHARMS LLC	0.0375%	A090098 001	Mar 22, 2010	Mar	NEWA
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TRIPTORELIN PAMOATE

## INJECTABLE; INTRAMUSCULAR

## TRELSTAR

+	WATSON LABS	EQ 22.5MG BASE/VIAL	N022437 001	Mar 10, 2010	Mar	NEWA
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UNOPROSTONE ISOPROPYL

## SOLUTION/DROPS; OPHTHALMIC

## RESCULA

## @ SUCAMPO PHARMS

0.15%

N021214 001	Aug 03, 2000	Jan	DISC
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UREA, C-14

## CAPSULE; ORAL

## PYTEST

+	AVENT	1uCi	N020617 001	May 09, 1997	Feb	CAHN
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## PYTEST KIT

+	AVENT	1uCi	N020617 002	May 09, 1997	Feb	CAHN
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URSODIOL

## CAPSULE; ORAL

## URSODIOL

AB	MIKAH PHARMA	300MG	A075517 001	Mar 14, 2000	Feb	CAHN
AB	MYLAN	300MG	A090530 001	Feb 17, 2010	Jan	NEWA

VALPROATE SODIUM

## INJECTABLE; INJECTION

## VALPROATE SODIUM

AP	HIKMA FARMACEUTICA	EQ 100MG BASE/ML	A078523 001	Feb 17, 2010	Jan	NEWA
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VANCOMYCIN HYDROCHLORIDE

## INJECTABLE; INJECTION

## VANCOMYCIN HYDROCHLORIDE

AP	BIONICHE PHARMA USA	EQ 500MG BASE/VIAL	A065401 001	Jun 30, 2008	Mar	CAHN	
AP		EQ 1GM BASE/VIAL	A065401 002	Jun 30, 2008	Mar	CAHN	
>A>	AP	SANDOZ	EQ 500MG BASE/VIAL	A090250 001	Apr 27, 2010	Apr	NEWA
>A>	AP		EQ 1GM BASE/VIAL	A090250 002	Apr 27, 2010	Apr	NEWA

VECURONIUM BROMIDE

## INJECTABLE; INJECTION

## VECURONIUM BROMIDE

AP	MUSTAFA NEVZAT	10MG/VIAL	A078274 001	Dec 29, 2008	Mar	CAHN
AP		20MG/VIAL	A078274 002	Dec 29, 2008	Mar	CAHN

VELAGLUCERASE ALFA

INJECTABLE; IV (INFUSION)

VPRIV

SHIRE HUMAN GENETIC 400 UNITS/VIAL N022575 001 Feb 26, 2010 Feb NEWA

POWDER; IV (INFUSION)

VPRIV

+ SHIRE HUMAN GENETIC 200 UNITS/VIAL N022575 002 Feb 26, 2010 Feb NEWA

VENLAFAXINE HYDROCHLORIDE

TABLET; ORAL

VENLAFAXINE HYDROCHLORIDE

AB	AUROBINDO PHARMA	EQ 25MG BASE	A090555 001	Apr 07, 2010	Mar	NEWA
AB		EQ 37.5MG BASE	A090555 002	Apr 07, 2010	Mar	NEWA
AB		EQ 50MG BASE	A090555 003	Apr 07, 2010	Mar	NEWA
AB		EQ 75MG BASE	A090555 004	Apr 07, 2010	Mar	NEWA
AB		EQ 100MG BASE	A090555 005	Apr 07, 2010	Mar	NEWA
>A>	INTERPHARM	EQ 25MG BASE	A079098 001	May 11, 2010	Apr	NEWA
>A>		EQ 37.5MG BASE	A079098 002	May 11, 2010	Apr	NEWA
>A>		EQ 50MG BASE	A079098 003	May 11, 2010	Apr	NEWA
>A>		EQ 75MG BASE	A079098 004	May 11, 2010	Apr	NEWA
>A>		EQ 100MG BASE	A079098 005	May 11, 2010	Apr	NEWA

VORICONAZOLE

TABLET; ORAL

VFEND

>D>	PFIZER	50MG	N021266 001	May 24, 2002	Apr	CFTG
>A>	AB	50MG	N021266 001	May 24, 2002	Apr	CFTG
>D>	+	200MG	N021266 002	May 24, 2002	Apr	CFTG
>A>	AB +	200MG	N021266 002	May 24, 2002	Apr	CFTG
>A>	VORICONAZOLE					
>A>	MATRIX LABS LTD	50MG	A090547 001	Apr 22, 2010	Apr	NEWA
>A>	AB	200MG	A090547 002	Apr 22, 2010	Apr	NEWA

ZIDOVUDINE

INJECTABLE; INJECTION

RETROVIR

>D>	+	VIIV HLTHCARE	10MG/ML	N019951 001	Feb 02, 1990	Apr	CFTG
>A>	AP +		10MG/ML	N019951 001	Feb 02, 1990	Apr	CFTG
>A>	ZIDOVUDINE						
>A>	PHARMAFORCE	10MG/ML	A091457 001	May 06, 2010	Apr	NEWA	

ZOLPIDEM TARTRATE

TABLET; ORAL

ZOLPIDEM TARTRATE

@ WORLD GEN

@

5MG

10MG

A076062 001 Apr 23, 2007 Mar CAHN

A076062 002 Apr 23, 2007 Mar CAHN



OTC DRUG PRODUCT LIST - 30TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2010

2-1

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

AUROBINDO PHARMA 5MG/5ML A090750 002 Feb 02, 2010 Jan NEWA

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

AUROBINDO PHARMA 5MG/5ML A090750 001 Feb 02, 2010 Jan NEWA

TABLET; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

AMNEAL PHARMS NY 5MG A078780 001 Jan 21, 2010 Jan NEWA

10MG A078780 004 Jan 21, 2010 Jan NEWA

TORRENT PHARMS LLC 5MG A079191 001 Apr 15, 2010 Mar NEWA

10MG A079191 004 Apr 15, 2010 Mar NEWA

CETIRIZINE HYDROCHLORIDE HIVES RELIEF

AMNEAL PHARMS NY 5MG A078780 003 Jan 21, 2010 Jan NEWA

10MG A078780 002 Jan 21, 2010 Jan NEWA

TORRENT PHARMS LLC 5MG A079191 003 Apr 15, 2010 Mar NEWA

10MG A079191 002 Apr 15, 2010 Mar NEWA

CIMETIDINE

TABLET; ORAL

CIMETIDINE

CONTRACT PHARMACAL 200MG A074961 001 Jun 19, 1998 Jan CAHN

200MG A074963 001 Jun 19, 1998 Jan CAHN

FAMOTIDINE

TABLET, CHEWABLE; ORAL

FAMOTIDINE

>D> + PERRIGO 10MG A075715 001 Aug 22, 2003 Apr CRLD

>A> 10MG A075715 001 Aug 22, 2003 Apr CRLD

PEPCID AC

>D> MERCK 20MG N020801 002 Dec 17, 2007 Apr CRLD

>A> + 20MG N020801 002 Dec 17, 2007 Apr CRLD

IBUPROFEN

CAPSULE; ORAL

IBUPROFEN

+ CONTRACT PHARMACAL 200MG A074782 001 Jul 06, 1998 Jan CAHN

TABLET; ORAL

IBUPROFEN

CONTRACT PHARMACAL 200MG A071732 001 Sep 10, 1987 Jan CAHN

200MG A071735 001 Sep 10, 1987 Jan CAHN

200MG A072299 001 Jul 01, 1988 Jan CAHN

200MG A073691 001 Feb 25, 1994 Jan CAHN

PROFEN

CONTRACT PHARMACAL 200MG A071265 001 Oct 15, 1986 Jan CAHN

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL

IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE

CONTRACT PHARMACAL 200MG;30MG A075588 001 Apr 08, 2002 Jan CAHN

LEVONORGESTREL

TABLET; ORAL

LEVONORGESTREL

>D>	WATSON LABS	0.75MG	A078665 001	Aug 28, 2009	Apr	CRLD
>A>	+	0.75MG	A078665 001	Aug 28, 2009	Apr	CRLD

LOPERAMIDE HYDROCHLORIDE

TABLET; ORAL

LOPERAMIDE HYDROCHLORIDE

CONTRACT PHARMACAL 2MG

A073254 001 Jul 30, 1993 Jan CAHN

LORATADINE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

CLARITIN-D

+ SCHERING PLOUGH 5MG;120MG

N019670 002 Nov 27, 2002 Mar CMFD

LORATADINE AND PSEUDOEPHEDRINE SULFATE

IMPAX LABS 5MG;120MG

A076050 001 Jan 30, 2003 Mar CRLD

MICONAZOLE NITRATE

CREAM; VAGINAL

MICONAZOLE NITRATE

PERRIGO R AND D 4%

A091366 001 Jan 15, 2010 Jan NEWA

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC

VISINE-A

+ JOHNSON AND JOHNSON 0.025%;0.3%

N020485 001 Jan 31, 1996 Jan CRLD

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

SUDAFED 24 HOUR

+ MCNEIL CONS 240MG

N020021 002 Dec 15, 1992 Feb CAHN

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE HYDROCHLORIDE

CONTRACT PHARMACAL EQ 75MG BASE

A075094 001 Jun 21, 1999 Jan CAHN

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

**CUMULATIVE SUPPLEMENT NUMBER 04 APRIL 2010**

NO APRIL 2010 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 APRIL 2010 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2010

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 - DIFFERIN</u>						
N022502 001					NDF	Mar 17, 2013
<u>ALENDRONATE SODIUM - FOSAMAX</u>						
N021575 001	5994329	Jul 17, 2018		Y		
	6015801	Jul 17, 2018		Y		
	6225294	Jul 17, 2018		Y		
<u>ALISKIREN HEMIFUMARATE; VALSARTAN - VALTURNA</u>						
N022217 001					NCE	Mar 05, 2012
<u>ALISKIREN HEMIFUMARATE; VALSARTAN - VALTURNA</u>						
N022217 002					NCE	Mar 05, 2012
<u>AMINOLEVULINIC ACID HYDROCHLORIDE - LEVULAN</u>						
N020965 001					M-82	Mar 12, 2013
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 10</u>						
N021303 001	RE41148	Oct 21, 2018	DP			
	RE41148*PED	Apr 21, 2019				
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 15</u>						
N021303 006	RE41148	Oct 21, 2018	DP			
	RE41148*PED	Apr 21, 2019				
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 20</u>						
N021303 002	RE41148	Oct 21, 2018	DP			
	RE41148*PED	Apr 21, 2019				
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 25</u>						
N021303 004	RE41148	Oct 21, 2018	DP			
	RE41148*PED	Apr 21, 2019				
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 30</u>						
N021303 003	RE41148	Oct 21, 2018	DP			
	RE41148*PED	Apr 21, 2019				
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 5</u>						
N021303 005	RE41148	Oct 21, 2018	DP			
	RE41148*PED	Apr 21, 2019				
<u>APREPITANT - EMEND</u>						
N021549 001					M-82	Mar 19, 2013
<u>APREPITANT - EMEND</u>						
N021549 002					M-82	Mar 19, 2013
<u>APREPITANT - EMEND</u>						
N021549 003					M-82	Mar 19, 2013
<u>ASCORBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE - MOVIPREP</u>						
N021881 001	7658914	Sep 01, 2024	DS DP			

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2010

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>AZTREONAM - CAYSTON</u>						
N050814 001	7208141	Dec 20, 2021	DP U-1031			
	7214364	Dec 20, 2021	DP			
	7427633	Dec 20, 2021	DP U-1031			
<u>BALSALAZIDE DISODIUM - COLAZAL</u>						
N020610 001	7452872	Aug 24, 2026	U-141			
	7452872*PED	Feb 24, 2027				
	7625884	Aug 24, 2026	U-141			
	7625884*PED	Feb 24, 2027				
<u>BEXAROTENE - TARGRETIN</u>						
N021055 001	7655699	Apr 22, 2012	DS DP U-509			
<u>BEXAROTENE - TARGRETIN</u>						
N021056 001	7655699	Apr 22, 2012	DS DP U-510			
<u>BIVALIRUDIN - ANGIOMAX</u>						
N020873 001	5196404	May 23, 2010	DS DP U-1040			
	5196404*PED	Nov 23, 2010				
<u>BUDESONIDE - RHINOCORT</u>						
N020746 001	6686346	Apr 29, 2017	DP U-557	Y		
	6686346*PED	Oct 29, 2017				
	6986904	Apr 29, 2017	DP U-699	Y		
	6986904*PED	Oct 29, 2017				
<u>BUDESONIDE - RHINOCORT</u>						
N020746 002	6686346	Apr 29, 2017	DP U-557			
	6686346*PED	Oct 29, 2017				
	6986904	Apr 29, 2017	DP U-699			
	6986904*PED	Oct 29, 2017				
<u>BUPROPION HYDROBROMIDE - APLENZIN</u>						
N022108 001	7645802	Jun 27, 2026	DP			
	7649019	Jun 27, 2026	DP			
	7662407	Jun 27, 2026	DP			
	7671094	Jun 27, 2026	DP			
<u>BUPROPION HYDROBROMIDE - APLENZIN</u>						
N022108 002	7645802	Jun 27, 2026	DP			
	7649019	Jun 27, 2026	DP			
	7662407	Jun 27, 2026	DP			
	7671094	Jun 27, 2026	DP			
<u>BUPROPION HYDROBROMIDE - APLENZIN</u>						
N022108 003	7645802	Jun 27, 2026	DP			
	7649019	Jun 27, 2026	DP			
	7662407	Jun 27, 2026	DP			
	7671094	Jun 27, 2026	DP			
<u>CAPSAICIN - QUTENZA</u>						
N022395 001					ODE	Nov 16, 2016
<u>CARGLUMIC ACID - CARBAGLU</u>						
N022562 001					NCE	Mar 18, 2015

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2010

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>CEFTIBUTEN DIHYDRATE - CEDAX</u>						
N050686 001	5599557	Feb 04, 2014	DP U-578			
	5599557	Feb 04, 2014	DP U-282			
<u>CEFTIBUTEN DIHYDRATE - CEDAX</u>						
N050686 002	5599557	Feb 04, 2014	DP U-578			
	5599557	Feb 04, 2014	DP U-282			
<u>CLINDAMYCIN PHOSPHATE - CLINDAMYCIN PHOSPHATE</u>						
A090785 001					>A> PC	Sep 27, 2010
<u>CLINDAMYCIN PHOSPHATE; TRETINOIN - ZIANA</u>						
N050802 001	RE41134	Feb 24, 2015	DP U-1033			
<u>CLOBETASOL PROPIONATE - CLOBEX</u>						
N021644 001	>A> 7700081	Jan 03, 2022	U-1044			
<u>CLOFARABINE - CLOLAR</u>						
N021673 001	>A> 5661136	Jan 14, 2018	U-626			
	>A> 5661136*PED	Jul 14, 2018				
<u>CLONIDINE HYDROCHLORIDE - JENLOGA</u>						
N022331 001	5869100	Oct 13, 2013	DP			
<u>COLESEVELAM HYDROCHLORIDE - WELCHOL</u>						
N022362 001	5607669	Jun 10, 2014	U-757			
	5607669*PED	Dec 10, 2014				
	5679717	Apr 29, 2014	U-757			
	5679717*PED	Oct 29, 2014				
	5693675	Dec 02, 2014	DS			
	5693675*PED	Jun 02, 2015				
	5917007	Apr 29, 2014	DS U-757			
	5917007*PED	Oct 29, 2014				
	5919832	Apr 29, 2014	DS			
	5919832*PED	Oct 29, 2014				
	6066678	Apr 29, 2014	DS U-757			
	6066678*PED	Oct 29, 2014				
	6433026	Apr 29, 2014	DS			
	6433026*PED	Oct 29, 2014				
	6784254	Apr 29, 2014	DS DP			
	6784254*PED	Oct 29, 2014				
	7101960	Apr 29, 2014	DS DP U-757			
	7101960*PED	Oct 29, 2014				
	7229613	Apr 17, 2022	U-493			
	7229613*PED	Oct 17, 2022				



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<u>COLESEVELAM HYDROCHLORIDE - WELCHOL</u>							
N022362 002	5607669	Jun	10, 2014	U-757			
	5607669*PED	Dec	10, 2014				
	5679717	Apr	29, 2014	U-757			
	5679717*PED	Oct	29, 2014				
	5693675	Dec	02, 2014	DS			
	5693675*PED	Jun	02, 2015				
	5917007	Apr	29, 2014	DS U-757			
	5917007*PED	Oct	29, 2014				
	5919832	Apr	29, 2014	DS			
	5919832*PED	Oct	29, 2014				
	6066678	Apr	29, 2014	DS U-757			
	6066678*PED	Oct	29, 2014				
	6433026	Apr	29, 2014	DS			
	6433026*PED	Oct	29, 2014				
	6784254	Apr	29, 2014	DS DP			
	6784254*PED	Oct	29, 2014				
	7101960	Apr	29, 2014	DS DP U-757			
	7101960*PED	Oct	29, 2014				
	7229613	Apr	17, 2022	U-493			
	7229613*PED	Oct	17, 2022				
<u>DALFAMPRIDINE - AMPYRA</u>							
N022250 001	5370879	Dec	06, 2011	DP		NCE	Jan 22, 2015
	5540938	Jul	30, 2013	U-1030		ODE	Jan 22, 2017
<u>DECITABINE - DACOGEN</u>							
N021790 001						D-123	Mar 11, 2013
<u>DICLOFENAC POTASSIUM - CAMBIA</u>							
N022165 001	7482377	May	15, 2017	DS DP U-436		NDF	Jun 17, 2012
<u>DICLOFENAC POTASSIUM - ZIPSOR</u>							
N022202 001	6365180	Jul	15, 2019	DP U-980			
	7662858	Feb	24, 2029	U-1035			
<u>DOCETAXEL - TAXOTERE</u>							
N020449 001	4814470	May	14, 2010	DS DP		I-543	Sep 28, 2010
	4814470*PED	Nov	14, 2010			I-542	Sep 28, 2010
	5438072	Nov	22, 2013	DP		PED	Mar 28, 2011
	5438072*PED	May	22, 2014				
	5698582	Jul	03, 2012	DP			
	5698582*PED	Jan	03, 2013				
	5714512	Jul	03, 2012	DP			
	5714512*PED	Jan	03, 2013				
	5750561	Jul	03, 2012	DP			
	5750561*PED	Jan	03, 2013				

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<u>DOXEPIN HYDROCHLORIDE - SILENOR</u>						
N022036 001	5502047	Mar 22, 2013	U-620		>A> NP	Mar 17, 2013
	5585115	Jan 09, 2015	DP			
	5725884	Sep 30, 2016	DP			
	5866166	Jun 10, 2016	DP			
	5948438	Jun 04, 2017	DP			
	6103219	Dec 17, 2017	DP			
	6106865	Nov 12, 2019	DP			
	6211229	Feb 17, 2020	U-620			
<u>DOXEPIN HYDROCHLORIDE - SILENOR</u>						
N022036 002	5502047	Mar 22, 2013	U-620		>A> NP	Mar 17, 2013
	5585115	Jan 09, 2015	DP			
	5725884	Sep 30, 2016	DP			
	5866166	Jun 10, 2016	DP			
	5948438	Jun 04, 2017	DP			
	6103219	Dec 17, 2017	DP			
	6106865	Nov 12, 2019	DP			
	6211229	Feb 17, 2020	U-620			
<u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>						
N021427 003	5023269	Jun 11, 2013	DS DP U-799			
	5023269	Jun 11, 2013	DS DP U-797			
	5023269	Jun 11, 2013	DS DP U-795			
	5508276	Jul 18, 2014	DP			
<u>ELTROMBOPAG OLAMINE - PROMACTA</u>						
N022291 003	6280959	Oct 30, 2018	DS DP U-930		NCE	Nov 20, 2013
	7160870	Dec 08, 2021	DS DP U-930		ODE	Nov 20, 2015
	7332481	May 24, 2021	U-930			
	7452874	May 24, 2021	DS DP			
	7473686	May 24, 2021	DS DP U-930			
	7547719	Mar 04, 2024	DS DP U-930			
<u>EPINEPHRINE - ADRENALIN</u>						
N020800 003	5665071	May 27, 2013	DP			
<u>EPINEPHRINE - ADRENALIN</u>						
N020800 004	5665071	May 27, 2013	DP			
<u>ERLOTINIB HYDROCHLORIDE - TARCEVA</u>						
N021743 001					>A> I-624	Apr 16, 2013
<u>ERLOTINIB HYDROCHLORIDE - TARCEVA</u>						
N021743 002					>A> I-624	Apr 16, 2013
<u>ERLOTINIB HYDROCHLORIDE - TARCEVA</u>						
N021743 003					>A> I-624	Apr 16, 2013
<u>ESOMEPRAZOLE MAGNESIUM; NAPROXEN - VIMOVO</u>						
N022511 001					>A> NC	Apr 30, 2013
<u>ESOMEPRAZOLE MAGNESIUM; NAPROXEN - VIMOVO</u>						
N022511 002					>A> NC	Apr 30, 2013
<u>ESTRADIOL ACETATE - FEMTRACE</u>						
N021633 001	7572779	Mar 02, 2024	U-904			

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<u>ESTRADIOL ACETATE - FEMTRACE</u>						
N021633 002	7572779	Mar 02, 2024	U-904			
<u>ESTRADIOL ACETATE - FEMTRACE</u>						
N021633 003	7572779	Mar 02, 2024	U-904			
<u>ETHINYL ESTRADIOL; LEVONORGESTREL - SEASONIQUE</u>						
N021840 001	7615545	Jun 15, 2023	U-1			
<u>EVEROLIMUS - ZORTRESS</u>						
N021560 001					>A> NCE	Mar 30, 2014
<u>EVEROLIMUS - ZORTRESS</u>						
N021560 002					>A> NCE	Mar 30, 2014
<u>EVEROLIMUS - ZORTRESS</u>						
N021560 003					>A> NCE	Mar 30, 2014
<u>EZETIMIBE - ZETIA</u>						
N021445 001	7612058	Jan 25, 2022	U-1027			
	7612058*PED	Jul 25, 2022				
<u>FENOFIBRATE - FENOGLIDE</u>						
N022118 001	7658944	Dec 09, 2024	DP			
<u>FENOFIBRATE - FENOGLIDE</u>						
N022118 002	7658944	Dec 09, 2024	DP			
<u>FEXOFENADINE HYDROCHLORIDE - ALLEGRA</u>						
N020872 001	7662835	May 18, 2014	U-139			
	7662835*PED	Nov 18, 2014				
	7666881	May 18, 2014	U-139			
	7666881*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE - ALLEGRA</u>						
N020872 002	7662835	May 18, 2014	U-139			
	7662835*PED	Nov 18, 2014				
	7666881	May 18, 2014	U-139			
	7666881*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE - ALLEGRA</u>						
N020872 004	7662835	May 18, 2014	U-139			
	7662835*PED	Nov 18, 2014				
	7666881	May 18, 2014	U-139			
	7666881*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE - ALLEGRA</u>						
N021909 001	7662835	May 18, 2014	U-139			
	7662835*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - ALLEGRA D 24 HOUR</u>						
N021704 001	7662835	May 18, 2014	U-139			
	7662835*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - ALLEGRA-D 12 HOUR</u>						
N020786 001	7662835	May 18, 2014	U-139			
	7662835*PED	Nov 18, 2014				
	7666881	May 18, 2014	U-139			
	7666881*PED	Nov 18, 2014				

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<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
N021357 001					NPP	Mar 17, 2013
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
N021357 002					NPP	Mar 17, 2013
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
N021357 003					NPP	Mar 17, 2013
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
N021357 004					NPP	Mar 17, 2013
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u>						
N020387 001	5608075****	Mar 04, 2009		Y		
	5608075*PED	Sep 04, 2009				
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u>						
N020387 002	5608075****	Mar 04, 2009		Y		
	5608075*PED	Sep 04, 2009				
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE</u>						
A077157 001					PC	Oct 03, 2010
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE</u>						
A077157 003					PC	Oct 03, 2010
<u>HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL - BENICAR HCT</u>						
N021532 002	6878703	Nov 19, 2021	U-3	Y		
<u>HYDROMORPHONE HYDROCHLORIDE - EXALGO</u>						
N021217 001	>A> 5702725	Jul 07, 2014	DP U-1043		NDF	Mar 01, 2013
	>A> 5914131	Jul 07, 2014	DP U-1043			
<u>HYDROMORPHONE HYDROCHLORIDE - EXALGO</u>						
N021217 002	>A> 5702725	Jul 07, 2014	DP U-1043		NDF	Mar 01, 2013
	>A> 5914131	Jul 07, 2014	DP U-1043			
<u>HYDROMORPHONE HYDROCHLORIDE - EXALGO</u>						
N021217 003	>A> 5702725	Jul 07, 2014	DP U-1043		NDF	Mar 01, 2013
	>A> 5914131	Jul 07, 2014	DP U-1043			
<u>IMIQUIMOD - IMIQUIMOD</u>						
A078548 001					PC	Aug 24, 2010
<u>IMIQUIMOD - ZYCLARA</u>						
N022483 001					NP	Mar 25, 2013
<u>INSULIN GLULISINE RECOMBINANT - APIDRA</u>						
N021629 001	>A> 7696162	Mar 22, 2022	DP U-471			
<u>INSULIN GLULISINE RECOMBINANT - APIDRA</u>						
N021629 002	>A> 7696162	Mar 22, 2022	DP U-471			
<u>INSULIN GLULISINE RECOMBINANT - APIDRA SOLOSTAR</u>						
N021629 003	6221633	Jun 18, 2018	DS DP U-471			
	6960561	Jan 25, 2023	DP U-471			
	7452860	Mar 22, 2022	DP			
	>A> 7696162	Mar 22, 2022	DP U-471			
<u>ITRACONAZOLE - ITRACONAZOLE</u>						
N022484 001					>A> NP	Apr 28, 2013

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<u>LACOSAMIDE - VIMPAT</u>						
N022255	001				>A> NCE	Oct 28, 2013
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N022115	001				I-622 NDF PED	Jan 29, 2013 May 29, 2012 Nov 29, 2012
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N022115	002				I-622 NDF PED	Jan 29, 2013 May 29, 2012 Nov 29, 2012
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N022115	003				I-622 NDF PED	Jan 29, 2013 May 29, 2012 Nov 29, 2012
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N022115	004				I-622 NDF PED	Jan 29, 2013 May 29, 2012 Nov 29, 2012
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N022115	005				>A> I-622 >A> NDF >A> PED	Jan 29, 2013 May 29, 2012 Nov 29, 2012
<u>LAPATINIB DITOSYLATE - TYKERB</u>						
N022059	001	6713485	Sep 29, 2020	DS DP U-800	I-620	Jan 29, 2013
<u>LEVETIRACETAM - KEPPRA</u>						
N021872	001				I-563 PED	Mar 19, 2010 Sep 19, 2010
<u>LIRAGLUTIDE RECOMBINANT - VICTOZA</u>						
N022341	001	6268343	Aug 22, 2017	DS DP U-968	NCE	Jan 25, 2015
		6458924	Aug 22, 2017	DS DP U-968		
		7235627	Aug 22, 2017	DS DP		
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977	001	7655630	Feb 24, 2023	DS	M-82	Apr 05, 2013
		7659253	Feb 24, 2023	DS DP U-727		
		7659254	Feb 24, 2023	U-1034		
		7662787	Feb 24, 2023	DS		
	>A>	7671030	Feb 24, 2023	DP U-727		
	>A>	7671031	Feb 28, 2023	U-727		
		7674774	Mar 18, 2023	DP U-842		
		7678770	Mar 25, 2023	U-842		
		7678771	Mar 25, 2023	DP U-842		
		7687466	Feb 24, 2023	DP		
		7687467	Apr 08, 2023	DP U-842		

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<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 002	7655630	Feb 24, 2023	DS		M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP U-727			
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	>A> 7671030	Feb 24, 2023	DP U-727			
	>A> 7671031	Feb 28, 2023	U-727			
	7674774	Mar 18, 2023	DP U-842			
	7678770	Mar 25, 2023	U-842			
	7678771	Mar 25, 2023	DP U-842			
	7687466	Feb 24, 2023	DP			
	7687467	Apr 08, 2023	DP U-842			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 003	7655630	Feb 24, 2023	DS		M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP U-727			
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	>A> 7671030	Feb 24, 2023	DP U-727			
	>A> 7671031	Feb 28, 2023	U-727			
	7674774	Mar 18, 2023	DP U-842			
	7678770	Mar 25, 2023	U-842			
	7678771	Mar 25, 2023	DP U-842			
	7687466	Feb 24, 2023	DP			
	7687467	Apr 08, 2023	DP U-842			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 004	7655630	Feb 24, 2023	DS		M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP U-727			
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	>A> 7671031	Feb 28, 2023	U-727			
	7678770	Mar 25, 2023	U-842			
	7687466	Feb 24, 2023	DP			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 005	7655630	Feb 24, 2023	DS		M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP U-727			
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	>A> 7671030	Feb 24, 2023	DP U-727			
	>A> 7671031	Feb 28, 2023	U-727			
	7674774	Mar 18, 2023	DP U-842			
	7678770	Mar 25, 2023	U-842			
	7678771	Mar 25, 2023	DP U-842			
	7687466	Feb 24, 2023	DP			
	7687467	Apr 08, 2023	DP U-842			

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<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 006	7655630	Feb 24, 2023	DS		M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP U-727			
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	>A> 7671030	Feb 24, 2023	DP U-727			
	>A> 7671031	Feb 28, 2023	U-727			
	7674774	Mar 18, 2023	DP U-842			
	7678770	Mar 25, 2023	U-842			
	7678771	Mar 25, 2023	DP U-842			
	7687466	Feb 24, 2023	DP			
	7687467	Apr 08, 2023	DP U-842			
<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
N021251 001					>A> D-124	Apr 27, 2013
<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
N021906 001					>A> D-124	Apr 27, 2013
<u>LOPINAVIR; RITONAVIR - KALETRA</u>						
N021906 002					>A> D-124	Apr 27, 2013
<u>LOSARTAN POTASSIUM - COZAAR</u>						
N020386 001	5608075****	Mar 04, 2009		Y		
	5608075*PED	Sep 04, 2009				
<u>LOSARTAN POTASSIUM - COZAAR</u>						
N020386 002	5608075****	Mar 04, 2009		Y		
	5608075*PED	Sep 04, 2009				
<u>LOSARTAN POTASSIUM - COZAAR</u>						
N020386 003	5608075****	Mar 04, 2009		Y		
	5608075*PED	Sep 04, 2009				
<u>LOSARTAN POTASSIUM - LOSARTAN POTASSIUM</u>						
A076958 001					PC	Oct 03, 2010
<u>LOSARTAN POTASSIUM - LOSARTAN POTASSIUM</u>						
A076958 002					PC	Oct 06, 2010
<u>LOSARTAN POTASSIUM - LOSARTAN POTASSIUM</u>						
A076958 003					PC	Oct 03, 2010
<u>MESALAMINE - SFROWASA</u>						
N019618 002	7645801	Jul 24, 2027	DS DP			
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>						
N022044 001	6890898	Feb 02, 2019	U-803			
	6890898	Feb 02, 2019	U-1038			
	6890898	Feb 02, 2019	U-1036			
	7078381	Feb 02, 2019	U-803			
	7078381	Feb 02, 2019	U-1038			
	7078381	Feb 02, 2019	U-1036			
	7125873	Jul 26, 2022	DP U-803			
	7125873	Jul 26, 2022	DP U-1038			
	7125873	Jul 26, 2022	DP U-1036			

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<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>						
N022044 002	6890898	Feb 02, 2019	U-803			
	6890898	Feb 02, 2019	U-1038			
	6890898	Feb 02, 2019	U-1036			
	7078381	Feb 02, 2019	U-803			
	7078381	Feb 02, 2019	U-1038			
	7078381	Feb 02, 2019	U-1036			
	7125873	Jul 26, 2022	DP U-803			
	7125873	Jul 26, 2022	DP U-1038			
	7125873	Jul 26, 2022	DP U-1036			
<u>METHYLPHENIDATE HYDROCHLORIDE - METHYLIN</u>						
N021419 001	7691880	Oct 07, 2024	DP			
<u>METHYLPHENIDATE HYDROCHLORIDE - METHYLIN</u>						
N021419 002	7691880	Oct 07, 2024	DP			
<u>MICONAZOLE - ORAVIG</u>						
N022404 001					>A> NDF	Apr 16, 2013
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 001	7682633	Jun 19, 2027	U-443			
	7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 002	7682633	Jun 19, 2027	U-443			
	7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 003	7682633	Jun 19, 2027	U-443			
	7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 004	7682633	Jun 19, 2027	U-443			
	7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 005	7682633	Jun 19, 2027	U-443			
	7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 006	7682633	Jun 19, 2027	U-443			
	7682634	Jun 19, 2027	DP			
<u>MOXIFLOXACIN HYDROCHLORIDE - VIGAMOX</u>						
N021598 001	7671070	Sep 29, 2019	U-709			
	7671070*PED	Mar 29, 2020				
<u>NICARDIPINE HYDROCHLORIDE - CARDENE IN 0.83% SODIUM CHLORIDE IN PLASTIC CONTAINER</u>						
N019734 004	7659291	Apr 18, 2027	U-1029			
<u>NICARDIPINE HYDROCHLORIDE - CARDENE IN 0.86% SODIUM CHLORIDE IN PLASTIC CONTAINER</u>						
N019734 003	7659291	Apr 18, 2027	U-1029			
<u>NICARDIPINE HYDROCHLORIDE - CARDENE IN 4.8% DEXTROSE IN PLASTIC CONTAINER</u>						
N019734 002	7659291	Apr 18, 2027	U-1029			



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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>NICARDIPINE HYDROCHLORIDE - CARDENE IN 5.0% DEXTROSE IN PLASTIC CONTAINER</u>						
N019734 005	7659291	Apr 18, 2027	U-1029			
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
N021286 001					NPP PED	Feb 04, 2013 Aug 04, 2010
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
N021286 003					NPP PED	Feb 04, 2013 Aug 04, 2010
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
N021286 004					NPP PED	Feb 04, 2013 Aug 04, 2010
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021087 001					M-90	Feb 22, 2013
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021087 002					M-90	Feb 22, 2013
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021087 003					M-90	Feb 22, 2010
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021246 001					M-90	Feb 22, 2013
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553 001	7674799	Mar 30, 2025	DS			
	7674800	Mar 30, 2025	DS			
	7683072	Mar 30, 2025	DS			
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553 002	7674799	Mar 30, 2025	DS			
	7674800	Mar 30, 2025	DS			
	7683072	Mar 30, 2025	DS			
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553 003	7674799	Mar 30, 2025	DS			
	7674800	Mar 30, 2025	DS			
	7683072	Mar 30, 2025	DS			
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553 004	7674799	Mar 30, 2025	DS			
	7674800	Mar 30, 2025	DS			
	7683072	Mar 30, 2025	DS			
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553 005	>A> 7674800	Mar 30, 2025	DS			
	7683072	Mar 30, 2025	DS			
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553 006	7674799	Mar 30, 2025	DS			
	7674800	Mar 30, 2025	DS			
	7683072	Mar 30, 2025	DS			
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553 007	7674799	Mar 30, 2025	DS			
	7674800	Mar 30, 2025	DS			
	7683072	Mar 30, 2025	DS			

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<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553 008	7674799	Mar 30, 2025	DS			
	7674800	Mar 30, 2025	DS			
	7683072	Mar 30, 2025	DS			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610 001	7276250	Feb 04, 2023	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610 002	7276250	Feb 04, 2023	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610 003	7276250	Feb 04, 2023	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610 004	7276250	Feb 04, 2023	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610 005	7276250	Feb 04, 2023	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610 006	7276250	Feb 04, 2023	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610 007	7276250	Feb 04, 2023	DP U-826			
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - CREON</u>						
N020725 001					>A> I-625	Apr 30, 2013
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - CREON</u>						
N020725 002					>A> I-625	Apr 30, 2013
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - CREON</u>						
N020725 003					>A> I-625	Apr 30, 2013
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - PANCREAZE</u>						
N022523 001					>A> NCE	Apr 12, 2015
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - PANCREAZE</u>						
N022523 002					>A> NCE	Apr 12, 2015
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - PANCREAZE</u>						
N022523 003					>A> NCE	Apr 12, 2015
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - PANCREAZE</u>						
N022523 004					>A> NCE	Apr 12, 2015
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP</u>						
N022210 001	7658918	Feb 20, 2028	DP			
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP</u>						
N022210 002	7658918	Feb 20, 2028	DP			
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP</u>						
N022210 003	7658918	Feb 20, 2028	DP			
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP</u>						
N022210 004	7658918	Feb 20, 2028	DP			
<u>PANTOPRAZOLE SODIUM - PROTONIX</u>						
N022020 001	7544370	Jun 07, 2026	DP			
	7544370*PED	Dec 07, 2026				

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<u>PENCICLOVIR SODIUM - DENAVIR</u>						
N020629 001	5866581	Oct 04, 2014	U-501			
	6124304	Oct 04, 2014	U-501			
<u>POLIDOCANOL - ASCLERA</u>						
N021201 001					NCE	Mar 30, 2015
<u>POLIDOCANOL - ASCLERA</u>						
N021201 002					NCE	Mar 30, 2015
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 001	4886812	Oct 08, 2010	DS DP		I-623	Mar 19, 2013
	7695734	Apr 26, 2028	DP		NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 002	4886812	Oct 08, 2010	DS DP		I-623	Mar 19, 2013
	7695734	Apr 26, 2028	DP		NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 003	4886812	Oct 08, 2010	DS DP		I-623	Mar 19, 2013
	7695734	Apr 26, 2028	DP		NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 004	4886812	Oct 08, 2010	DS DP		I-623	Mar 19, 2013
	7695734	Apr 26, 2028	DP		NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 005	4886812	Oct 08, 2010	DS DP		I-623	Mar 19, 2013
	7695734	Apr 26, 2028	DP		NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724 001					PC	Jul 03, 2010
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724 002					PC	Jul 03, 2010
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724 003					PC	Jul 03, 2010
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724 004					PC	Jul 03, 2010
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724 005					PC	Jul 03, 2010
<u>PREGABALIN - LYRICA</u>						
N022488 001	5563175	Oct 08, 2013	U-661		I-535	Jun 21, 2010
	6001876	Dec 30, 2018	U-819			
	6001876	Dec 30, 2018	U-55			
	6197819	Dec 30, 2018	DS DP			
<u>REGADENOSON - LEXISCAN</u>						
N022161 001	7655636	Jun 22, 2019	U-869			
	7655637	Jun 22, 2019	DS DP	U-869		
	>A> 7683037	Jun 22, 2019	U-1042			
<u>RIFAXIMIN - XIFAXAN</u>						
N021361 002	7045620	Jun 19, 2024	DS		NP	Mar 24, 2013

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<u>RITONAVIR - RITONAVIR</u>						
N022417 001	5541206	Jul 30, 2013	DS DP U-688			
	5541206*PED	Jan 30, 2014				
	5635523	Jun 03, 2014	U-688			
	5635523*PED	Dec 03, 2014				
	5648497	Jul 15, 2014	DS			
	5648497*PED	Jan 15, 2015				
	5674882	Oct 07, 2014	U-688			
	5674882*PED	Apr 07, 2015				
	6037157	Jun 26, 2016	U-688			
	6037157*PED	Dec 26, 2016				
	6703403	Jun 26, 2016	U-688			
	6703403*PED	Dec 26, 2016				
	7148359	Jul 19, 2019	DP			
	7148359*PED	Jan 19, 2020				
	7364752	Nov 10, 2020	DP U-688			
	7364752*PED	May 10, 2021				
<u>ROMIDEPSIN - ISTODAX</u>						
N022393 001					ODE	Nov 05, 2016
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>						
N021366 002	7030152	Apr 02, 2018	U-1032		I-621	Feb 08, 2013
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>						
N021366 003	7030152	Apr 02, 2018	U-1032		I-621	Feb 08, 2013
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>						
N021366 004	7030152	Apr 02, 2018	U-1032		I-621	Feb 08, 2013
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>						
N021366 005	7030152	Apr 02, 2018	U-1032		I-621	Feb 08, 2013
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N021995 001	6890898	Feb 02, 2019	U-775			
	6890898	Feb 02, 2019	U-1039			
	6890898	Feb 02, 2019	U-1036			
	7078381	Feb 02, 2019	U-775			
	7078381	Feb 02, 2019	U-1038			
	7078381	Feb 02, 2019	U-1037			
	7078381	Feb 02, 2019	U-1036			
	7125873	Jul 26, 2022	U-775			
	7125873	Jul 26, 2022	U-1038			
	7125873	Jul 26, 2022	U-1037			
	7125873	Jul 26, 2022	U-1036			

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<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N021995 002	6890898	Feb 02, 2019	U-775			
	6890898	Feb 02, 2019	U-1039			
	6890898	Feb 02, 2019	U-1036			
	7078381	Feb 02, 2019	U-775			
	7078381	Feb 02, 2019	U-1038			
	7078381	Feb 02, 2019	U-1037			
	7078381	Feb 02, 2019	U-1036			
	7125873	Jul 26, 2022	U-775			
	7125873	Jul 26, 2022	U-1038			
	7125873	Jul 26, 2022	U-1037			
	7125873	Jul 26, 2022	U-1036			
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N021995 003	6890898	Feb 02, 2019	U-775			
	6890898	Feb 02, 2019	U-1039			
	6890898	Feb 02, 2019	U-1036			
	7078381	Feb 02, 2019	U-775			
	7078381	Feb 02, 2019	U-1038			
	7078381	Feb 02, 2019	U-1037			
	7078381	Feb 02, 2019	U-1036			
	7125873	Jul 26, 2022	U-775			
	7125873	Jul 26, 2022	U-1038			
	7125873	Jul 26, 2022	U-1037			
	7125873	Jul 26, 2022	U-1036			
<u>SODIUM OXYBATE - XYREM</u>						
N021196 001	7668730	Mar 07, 2024	U-1028			
<u>SODIUM PHOSPHATE, DIBASIC ANHYDROUS; SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE - OSMOPREP</u>						
N021892 001	7687075	Jun 22, 2028	DS DP			
<u>SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO</u>						
N021148 008	5849700	Dec 15, 2015	U-1041		I-572	Oct 31, 2011
	5849704	Dec 15, 2015	DP U-1041		I-551	Sep 20, 2010
					I-536	May 31, 2010
					ODE	May 31, 2014
<u>SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO</u>						
N021148 009	5849700	Dec 15, 2015	U-1041		I-572	Oct 31, 2011
	5849704	Dec 15, 2015	DP U-1041		I-551	Sep 20, 2010
					I-536	May 31, 2010
					ODE	May 31, 2014
<u>SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO</u>						
N021148 010	5849700	Dec 15, 2015	U-1041		I-572	Oct 31, 2011
	5849704	Dec 15, 2015	DP U-1041		I-551	Sep 20, 2010
					I-536	May 31, 2010
					ODE	May 31, 2014
<u>TELAVANCIN HYDROCHLORIDE - VIBATIV</u>						
N022110 001	>A> 7700550	May 01, 2021	U-282			
<u>TELAVANCIN HYDROCHLORIDE - VIBATIV</u>						
N022110 002	>A> 7700550	May 01, 2021	U-282			
<u>TEMSIROLIMUS - TORISEL</u>						
N022088 001					>A> M-91	Apr 26, 2013

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<u>TENOFOVIR DISOPROXIL FUMARATE - VIREAD</u>						
N021356	001				NPP	Mar 24, 2013
<u>TERBINAFINE - LAMISIL AT</u>						
N021958	001	5681849	Oct 28, 2014	DP		
		5681849*PED	Apr 28, 2015			
		5856355	May 18, 2012	DP U-540		
		5856355	May 18, 2012	DP U-504		
		5856355*PED	Nov 18, 2012			
<u>TIOTROPIUM BROMIDE MONOHYDRATE - SPIRIVA</u>						
N021395	001	7642268	Sep 24, 2021	DS DP		
<u>TOLTERODINE TARTRATE - DETROL</u>						
N020771	001	5559269	Nov 05, 2013	U-318	Y	
		5559269*PED	May 05, 2014			
<u>TOLTERODINE TARTRATE - DETROL</u>						
N020771	002	5559269	Nov 05, 2013	U-318	Y	
		5559269*PED	May 05, 2014			
<u>TRAZODONE HYDROCHLORIDE - OLEPTRO</u>						
N022411	001	6607748	Jun 29, 2020	DP	NDF	Feb 02, 2013
<u>TRAZODONE HYDROCHLORIDE - OLEPTRO</u>						
N022411	002	6607748	Jun 29, 2020	DP	NDF	Feb 02, 2013
<u>TRIPTORELIN PAMOATE - TRELSTAR</u>						
N022437	001	5776885	Jul 07, 2015	DP	NP	Mar 10, 2013
<u>VARDENAFIL HYDROCHLORIDE - LEVITRA</u>						
N021400	001	7696206	Oct 31, 2018	DS DP U-533		
<u>VARDENAFIL HYDROCHLORIDE - LEVITRA</u>						
N021400	002	7696206	Oct 31, 2018	DS DP U-533		
<u>VARDENAFIL HYDROCHLORIDE - LEVITRA</u>						
N021400	003	7696206	Oct 31, 2018	DS DP U-533		
<u>VARDENAFIL HYDROCHLORIDE - LEVITRA</u>						
N021400	004	7696206	Oct 31, 2018	DS DP U-533		
<u>VARENICLINE TARTRATE - CHANTIX</u>						
N021928	001	7265119	Aug 03, 2022	DS DP U-56		
<u>VARENICLINE TARTRATE - CHANTIX</u>						
N021928	002	7265119	Aug 03, 2022	DS DP U-56		
<u>VELAGLUCERASE ALFA - VPRIV</u>						
N022575	001				NCE	Feb 26, 2015
<u>VELAGLUCERASE ALFA - VPRIV</u>						
N022575	002				NCE	Feb 26, 2015
<u>VORINOSTAT - ZOLINZA</u>						
N021991	001	7652069	Mar 04, 2023	DS		

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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.
3. \*\*\*\* The expiration date for U.S. Patent No. 5,608,075 is March 4, 2009.

## 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, 29<sup>th</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>