

# **APPROVED DRUG PRODUCTS**

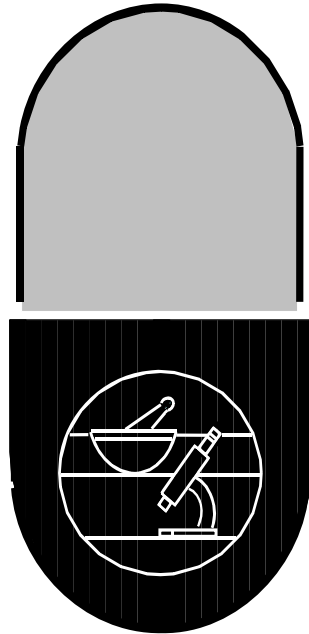
## **With Therapeutic Equivalence Evaluations**



**The "Orange Book"**

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**CUMULATIVE  
SUPPLEMENT 05  
May 2007**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**27<sup>th</sup> EDITION**

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

2007

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

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**27<sup>th</sup> EDITION**

**Cumulative Supplement 05**

**May 2007**

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**27<sup>th</sup> EDITION**

**CUMULATIVE SUPPLEMENT 05  
May 2007**

**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, 27th 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 26th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 27th 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@cder.fda.gov](mailto:drugproducts@cder.fda.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>
BERLEX INC (BERLEX)	BAYER HEALTHCARE PHARMACEUTICALS INC (BAYER HLTHC)
BIONICHE PHARMA (BIONICHE PHARMA)	BIONICHE PHARMA USA LLC (BIONICHE PHARMA)
BIONICHE PHARMA (CANADA) LTD (BIONICHE (CANADA))	BIONICHE PHARMA USA LLC (BIONICHE PHARMA)
BIONICHE PHARMA USA INC (BIONICHE PHARM USA)	BIONICHE PHARMA USA LLC (BIONICHE PHARMA)
MAYNE PHARMA USA INC (MAYNE PHARMA USA)	HOSPIRA INC (HOSPIRA)
QLT USA INC (QLT USA)	TOLMAR INC (TOLMAR)
KOS LIFE SCIENCES INC	ABBOTT LABORATORIES

#### 1.4 AVAILABILITY OF THE EDITION

Since 1997, the Electronic Orange Book Query (EOBQ) <http://www.fda.gov/cder/ob/default.htm>, 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 Annual Edition. 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://www.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/cder/rxotcdpl/pdplarchive.htm>

There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at <http://www.fda.gov/cder/orange/obreadme.htm>. The drug product text files are provided in eobzip.exe and 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 2004) 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 2006</u>	<u>MAR 2007</u>	<u>JUN 2007</u>	<u>SEPT 2007</u>
DRUG PRODUCTS LISTED	11896	12063	12157	
SINGLE SOURCE	2471	2471	2476	
	(20.8%)	(20.5%)	(20.4%)	
MULTISOURCE	9336	9503	9592	
	(78.5%)	(78.8%)	(78.9%)	
THERAPEUTICALLY	9139	9320	9410	
EQUIVALENT	(76.8%)	(77.3%)	(77.4%)	
NOT THERAPEUTICALLY	197	183	182	
EQUIVALENT	(1.7%)	(1.5%)	(1.5%)	
EXCEPTIONS <sup>1</sup>	89	89	89	
	(0.7%)	(0.7%)	(0.7%)	
NEW MOLECULAR ENTITIES				
APPROVED	10	4	6	
NUMBER OF APPLICANTS	666	675	675	

<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 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 - 27TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2007

1-1

ABARELIX

INJECTABLE; INTRAMUSCULAR

PLENAXIS

@ SPECIALITY EUROPEAN 100MG/VIAL

N21320 001 Nov 25, 2003 Feb CAHN

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

AA BOCA PHARMA 356.4MG;30MG;16MG

N40688 001 Apr 03, 2007 Mar NEWA

AA + MIKART 356.4MG;30MG;16MG

N40109 001 Aug 26, 1997 Mar CTEC

TABLET; ORAL

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

AA BOCA PHARMA 712.8MG;60MG;32MG

N40701 001 Apr 03, 2007 Mar NEWA

AA + MIKART 712.8MG;60MG;32MG

N40316 001 Apr 28, 1999 Feb CTEC

AA WEST WARD 712.8MG;60MG;32MG

N40637 001 Sep 22, 2006 Feb CTEC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA INTERPHARM 500MG;10MG

N40813 001 Feb 23, 2007 Feb NEWA

>D> AA UCB INC 500MG;10MG

N40210 001 Aug 13, 1997 May DISC

>A> @ 500MG;10MG

N40210 001 Aug 13, 1997 May DISC

>D> AA 650MG;7.5MG

N40134 001 Nov 21, 1996 May DISC

>A> @ 650MG;7.5MG

N40134 001 Nov 21, 1996 May DISC

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

AB WOCKHARDT 325MG;50MG

N77677 001 Mar 16, 2007 Mar NEWA

AB 650MG;100MG

N77677 002 Mar 16, 2007 Mar NEWA

ACETAZOLAMIDE

CAPSULE, EXTENDED RELEASE; ORAL

DIAMOX

>D> @ DURAMED PHARMS BARR 500MG

N12945 001 May CMFD

>A> + 500MG

N12945 001 May CMFD

ALBUTEROL

AEROSOL, METERED; INHALATION

ALBUTEROL

+ ARMSTRONG PHARMS 0.09MG/INH

N72273 001 Aug 14, 1996 Mar CRLD

@ IVAX PHARMS 0.09MG/INH

N73272 001 Dec 28, 1995 Mar DISC

VENTOLIN

@ GLAXOSMITHKLINE 0.09MG/INH

N18473 001 Mar DISC

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

AN APOTEX INC EQ 0.083% BASE

N75717 001 Feb 02, 2007 Jan NEWA

>D> AN ROXANE EQ 0.083% BASE

N75129 001 Feb 13, 2001 May DISC

>A> @ EQ 0.083% BASE

N75129 001 Feb 13, 2001 May DISC

## TABLET, EXTENDED RELEASE; ORAL

## ALBUTEROL SULFATE

AB	MYLAN	EQ 4MG BASE	N78092 002	Jan 29, 2007	Jan	NEWA
AB		EQ 8MG BASE	N78092 001	Jan 29, 2007	Jan	NEWA
VOSPIRE ER						
AB	DAVA PHARMS INC	EQ 4MG BASE	N76130 002	Sep 26, 2002	Jan	CTEC
AB	+	EQ 8MG BASE	N76130 003	Sep 26, 2002	Jan	CTEC

ALENDRONATE SODIUM; CHOLECALCIFEROL

## TABLET; ORAL

## FOSAMAX PLUS D

	MERCK	EQ 70MG BASE;2,800 IU	N21762 001	Apr 07, 2005	Apr	CRLD
+		EQ 70MG BASE;5,600 IU	N21762 002	Apr 26, 2007	Apr	NEWA

ALISKIREN HEMIFUMARATE

## TABLET; ORAL

## TEKTURNA

	NOVARTIS	EQ 150MG BASE	N21985 001	Mar 05, 2007	Mar	NEWA
+		EQ 300MG BASE	N21985 002	Mar 05, 2007	Mar	NEWA

ALLOPURINOL SODIUM

## INJECTABLE; INJECTION

## ALOPRIM

>A>	AP	+	BIONICHE PHARMA	EQ 500MG BASE/VIAL	N20298 001	May 17, 1996	May	CAHN
>D>	AP	+	NABI	EQ 500MG BASE/VIAL	N20298 001	May 17, 1996	May	CAHN

ALPRAZOLAM

## TABLET; ORAL

## ALPRAZOLAM

AB	APOTEX INC	0.25MG	N77741 001	Jan 19, 2007	Jan	NEWA
AB		0.5MG	N77741 002	Jan 19, 2007	Jan	NEWA
AB		1MG	N77741 003	Jan 19, 2007	Jan	NEWA
AB		2MG	N77741 004	Jan 19, 2007	Jan	NEWA
AB	DAVA INTL INC	0.25MG	N74174 001	Oct 19, 1993	Mar	CMFD
	@	0.25MG	N74174 001	Oct 19, 1993	Feb	CAHN
AB		0.5MG	N74174 002	Oct 19, 1993	Mar	CMFD
	@	0.5MG	N74174 002	Oct 19, 1993	Feb	CAHN
AB		1MG	N74174 003	Oct 19, 1993	Mar	CMFD
	@	1MG	N74174 003	Oct 19, 1993	Feb	CAHN
AB		2MG	N74174 004	Oct 19, 1993	Mar	CMFD
	@	2MG	N74174 004	Oct 19, 1993	Feb	CAHN

## TABLET, EXTENDED RELEASE; ORAL

## ALPRAZOLAM

AB	ACTAVIS ELIZABETH	0.5MG	N78056 001	Feb 13, 2007	Jan	NEWA	
AB		1MG	N78056 002	Feb 13, 2007	Jan	NEWA	
AB		2MG	N78056 003	Feb 13, 2007	Jan	NEWA	
AB		3MG	N78056 004	Feb 13, 2007	Jan	NEWA	
AB	COREPHARMA	0.5MG	N77996 001	Jan 31, 2007	Jan	NEWA	
AB		1MG	N77996 002	Jan 31, 2007	Jan	NEWA	
AB		2MG	N77996 003	Jan 31, 2007	Jan	NEWA	
AB		3MG	N77996 004	Jan 31, 2007	Jan	NEWA	
>A>	AB	IMPAX LABS	0.5MG	N77968 004	May 24, 2007	May	NEWA
>A>	AB		1MG	N77968 003	May 24, 2007	May	NEWA
>A>	AB		2MG	N77968 002	May 24, 2007	May	NEWA
>A>	AB		3MG	N77968 001	May 24, 2007	May	NEWA
AB	TEVA PHARMS	0.5MG	N77979 001	Feb 28, 2007	Feb	NEWA	

## TABLET, EXTENDED RELEASE; ORAL

## ALPRAZOLAM

AB	TEVA PHARMS	1MG	N77979 002	Feb 28, 2007	Feb	NEWA
AB		2MG	N77979 003	Feb 28, 2007	Feb	NEWA
AB		3MG	N77979 004	Feb 28, 2007	Feb	NEWA

## TABLET, ORALLY DISINTEGRATING; ORAL

## NIRAVAM

+	SCHWARZ PHARMA	1MG	N21726 003	Jan 19, 2005	Jan	CRLD
		2MG	N21726 004	Jan 19, 2005	Jan	CRLD

ALPROSTADIL

## INJECTABLE; INJECTION

## CAVERJECT IMPULSE

	PHARMACIA AND UPJOHN	0.01MG/VIAL	N21212 001	Jun 11, 2002	Apr	CTNA
		0.02MG/VIAL	N21212 002	Jun 11, 2002	Apr	CTNA

AMINO ACIDS

## INJECTABLE; INJECTION

## NOVAMINE 11.4%

+	HOSPIRA	11.4% (11.4GM/100ML)	N17957 003	Aug 09, 1982	Jan	CRLD
	NOVAMINE 15%					
+	HOSPIRA	15% (15GM/100ML)	N17957 004	Nov 28, 1986	Jan	CRLD

AMIODARONE HYDROCHLORIDE

## INJECTABLE; INJECTION

## CORDARONE

>D>						
>D>	AP	+	WYETH PHARMS INC	50MG/ML	N20377 001	Aug 03, 1995 May DISC
>A>		@		50MG/ML	N20377 001	Aug 03, 1995 May DISC

AMLODIPINE BESYLATE

## TABLET; ORAL

## AMLODIPINE BESYLATE

>A>	AB	APOTEX	EQ 2.5MG BASE	N76719 001	May 23, 2007	May	NEWA
>A>	AB		EQ 5MG BASE	N76719 002	May 23, 2007	May	NEWA
>A>	AB		EQ 10MG BASE	N76719 003	May 23, 2007	May	NEWA

AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

## CAPSULE; ORAL

## AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE

>A>	AB	TEVA PHARMS	EQ 2.5MG BASE;10MG	N77179 001	May 18, 2007	May	NEWA
>A>	AB		EQ 5MG BASE;10MG	N77179 002	May 18, 2007	May	NEWA
>A>	AB		EQ 5MG BASE;20MG	N77179 003	May 18, 2007	May	NEWA
>A>	AB		EQ 10MG BASE;20MG	N77179 004	May 18, 2007	May	NEWA
		LOTREL					
>D>		NOVARTIS	EQ 2.5MG BASE;10MG	N20364 002	Mar 03, 1995	May	CFTG
>A>	AB		EQ 2.5MG BASE;10MG	N20364 002	Mar 03, 1995	May	CFTG
>D>			EQ 5MG BASE;10MG	N20364 003	Mar 03, 1995	May	CFTG
>A>	AB		EQ 5MG BASE;10MG	N20364 003	Mar 03, 1995	May	CFTG
>D>			EQ 5MG BASE;20MG	N20364 004	Mar 03, 1995	May	CFTG
>A>	AB		EQ 5MG BASE;20MG	N20364 004	Mar 03, 1995	May	CFTG
>D>			EQ 10MG BASE;20MG	N20364 005	Jun 20, 2002	May	CFTG
>A>	AB		EQ 10MG BASE;20MG	N20364 005	Jun 20, 2002	May	CFTG

AMOXICILLIN

## CAPSULE; ORAL

## AMOXICILLIN

AB	HIKMA PHARMS	250MG	N65291 001	Feb 05, 2007	Jan	NEWA
AB		500MG	N65291 002	Feb 05, 2007	Jan	NEWA
>D>	TRIMOX					
>D>	AB	APOTHECON	250MG	N61885 001	May	DISC
>A>	@	250MG	N61885 001		May	DISC
>D>	AB	500MG	N61885 002		May	DISC
>A>	@	500MG	N61885 002		May	DISC

## FOR SUSPENSION; ORAL

## AMOXICILLIN

AB	SANDOZ	125MG/5ML	N65387 001	Mar 26, 2007	Mar	NEWA
AB		200MG/5ML	N65378 001	Mar 26, 2007	Mar	NEWA
AB		250MG/5ML	N65387 002	Mar 26, 2007	Mar	NEWA
AB		400MG/5ML	N65378 002	Mar 26, 2007	Mar	NEWA

## TABLET, FOR SUSPENSION; ORAL

## AMOXICILLIN

AB	AUROBINDO PHARMA	200MG	N65324 001	Jan 17, 2007	Jan	NEWA
AB		400MG	N65324 002	Jan 17, 2007	Jan	NEWA
	DISPERMOX					
AB	RANBAXY	200MG	N65080 002	Aug 11, 2003	Jan	CTEC
AB	+	400MG	N65080 001	Aug 11, 2003	Jan	CTEC

AMOXICILLIN; CLAVULANATE POTASSIUM

## FOR SUSPENSION; ORAL

## AMOXICILLIN AND CLAVULANATE POTASSIUM

AB	RANBAXY	600MG/5ML;EQ 42.9MG BASE/5ML	N65207 002	Jan 30, 2007	Jan	NEWA	
	AUGMENTIN ES-600						
AB	+	SMITHKLINE BEECHAM	600MG/5ML;EQ 42.9MG BASE/5ML	N50755 001	Jun 22, 2001	Mar	CAHN

ARIPIPIRAZOLE

## SOLUTION; ORAL

## ABILIFY

+	OTSUKA PHARM	1MG/ML	N21713 001	Dec 10, 2004	Apr	CAHN
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## TABLET; ORAL

## ABILIFY

	OTSUKA	15MG	N21436 002	Nov 15, 2002	Feb	CRLD
		30MG	N21436 004	Nov 15, 2002	Feb	CRLD

## TABLET, ORALLY DISINTEGRATING; ORAL

## ABILIFY

+	OTSUKA	10MG	N21729 002	Jun 07, 2006	Feb	CRLD
		30MG	N21729 005	Jun 07, 2006	Feb	CRLD

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

## TABLET; ORAL

## NORGESIC

AB	GRACEWAY	385MG;30MG;25MG	N13416 003	Oct 27, 1982	Jan	CAHN	
	NORGESIC FORTE						
AB	+	GRACEWAY	770MG;60MG;50MG	N13416 004	Oct 27, 1982	Jan	CAHN

AZACITIDINE

>A>	INJECTABLE; IV-SC						
>A>	VIDAZA						
>A>	+ PHARMION	100MG/VIAL		N50794 001	May 19, 2004	May	CDFR
>D>	INJECTABLE; SUBCUTANEOUS						
>D>	VIDAZA						
>D>	+ PHARMION	100MG/VIAL		N50794 001	May 19, 2004	May	CDFR

AZATHIOPRINE

	TABLET; ORAL						
	AZATHIOPRINE						
AB	ZYDUS PHARMS USA	50MG		N77621 001	Mar 15, 2007	Mar	NEWA

AZITHROMYCIN

	INJECTABLE; INJECTION						
	AZITHROMYCIN						
AP	PLIVA HRVATSKA DOO	EQ 500MG BASE/VIAL		N65265 001	Jan 18, 2007	Jan	NEWA
>D>	AP + SICOR PHARMS	EQ 500MG BASE/VIAL		N50809 001	Dec 19, 2006	May	CAHN
>D>	+	EQ 2.5GM BASE/VIAL		N50809 002	Dec 19, 2006	May	CAHN
>A>	AP + TEVA PARENTERAL	EQ 500MG BASE/VIAL		N50809 001	Dec 19, 2006	May	CAHN
>A>	+	EQ 2.5GM BASE/VIAL		N50809 002	Dec 19, 2006	May	CAHN
	SOLUTION/DROPS; OPHTHALMIC						
	AZASITE						
>D>	+ INSITE VISION	1%		N50810 001	Apr 27, 2007	May	CAHN
	+	1%		N50810 001	Apr 27, 2007	Apr	NEWA
>A>	+ INSPIRE	1%		N50810 001	Apr 27, 2007	May	CAHN
	TABLET; ORAL						
	AZITHROMYCIN						
>A>	AB MYLAN	EQ 250MG BASE		N65365 001	May 30, 2007	May	NEWA
>A>	AB	EQ 500MG BASE		N65366 001	May 30, 2007	May	NEWA

BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

	OINTMENT; OPHTHALMIC						
	CORTISPORIN						
	@ MONARCH PHARMS	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM		N50416 002		Feb	DISC
	NEOMYCIN AND POLYMYXIN B SULFATES, BACITRACIN ZINC AND HYDROCORTISONE						
	+ BAUSCH AND LOMB	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM		N64068 001	Oct 30, 1995	Feb	CTEC

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

	OINTMENT; OPHTHALMIC						
	NEOSPORIN						
	@ MONARCH PHARMS	400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM		N50417 001		Feb	DISC

BACITRACIN ZINC; POLYMYXIN B SULFATE

	OINTMENT; OPHTHALMIC						
	POLYSPORIN						
	@ MONARCH PHARMS	500 UNITS/GM;10,000 UNITS/GM		N61229 001		Feb	DISC

BECLOMETHASONE DIPROPIONATE

	AEROSOL, METERED; INHALATION						
	QVAR 40						
	+ IVAX RES	0.04MG/INH		N20911 002	Sep 15, 2000	Mar	CAHN

## AEROSOL, METERED; INHALATION

QVAR 80

+	IVAX RES	0.08MG/INH	N20911 001	Sep 15, 2000	Mar	CAHN
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BENDROFLUMETHIAZIDE; NADOLOL

TABLET; ORAL

CORZIDE

AB	KING PHARMS	5MG;40MG	N18647 001	May 25, 1983	Mar	CFTG
AB	+	5MG;80MG	N18647 002	May 25, 1983	Mar	CFTG

NADOLOL AND BENDROFLUMETHIAZIDE

AB	IMPAX LABS	5MG;40MG	N77833 001	Mar 30, 2007	Mar	NEWA
AB		5MG;80MG	N77833 002	Mar 30, 2007	Mar	NEWA

BENZONATATE

CAPSULE; ORAL

BENZONATATE

AA	THE PHARMA NETWORK	100MG	N40627 001	Mar 30, 2007	Mar	NEWA
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BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE

GEL; TOPICAL

BENZACLIN

@ SANOFI AVENTIS US 5%;EQ 1% BASE

N50756 002	Apr 20, 2007	Apr	DISC
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BENZPHETAMINE HYDROCHLORIDE

TABLET; ORAL

BENZPHETAMINE HYDROCHLORIDE

AA	TEDOR PHARM	50MG	N40747 001	Mar 30, 2007	Mar	NEWA
AA	TYCO HLTHCARE	50MG	N40773 001	Apr 25, 2007	Apr	NEWA

BETAINE HYDROCHLORIDE

FOR SOLUTION; ORAL

CYSTADANE

+ RARE DIS 1GM/SCOOPFUL

N20576 001	Oct 25, 1996	Apr	CAHN
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BETAMETHASONE DIPROPIONATE

LOTION, AUGMENTED; TOPICAL

BETAMETHASONE DIPROPIONATE

>A>	AB	ALTANA	EQ 0.05% BASE	N77111 001	May 21, 2007	May	NEWA
>A>	AB	TARO	EQ 0.05% BASE	N77477 001	May 21, 2007	May	NEWA

DIPROLENE

>D>	+	SCHERING	EQ 0.05% BASE	N19716 001	Aug 01, 1988	May	CFTG
>A>	AB	+	EQ 0.05% BASE	N19716 001	Aug 01, 1988	May	CFTG

>D> BISKALCITRATE; METRONIDAZOLE; TETRACYCLINE

&gt;D&gt; CAPSULE; ORAL

&gt;D&gt; PYLERA

>D>	+	AXCAN SCANDIPHARM	140MG;125MG;125MG	N50786 001	Sep 28, 2006	May	CAIN
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>A> BISMUTH SUBCITRATE POTASSIUM; METRONIDAZOLE; TETRACYCLINE

&gt;A&gt; CAPSULE; ORAL

&gt;A&gt; PYLERA

>A>	+	AXCAN SCANDIPHARM	140MG;125MG;125MG	N50786 001	Sep 28, 2006	May	CAIN
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BUDESONIDE

POWDER, METERED; INHALATION

PULMICORT FLEXHALER

	ASTRAZENECA	0.08MG/INH	N21949 001	Jul 12, 2006	Feb	CTNA
+		0.16MG/INH	N21949 002	Jul 12, 2006	Feb	CTNA

BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE

SPRAY, METERED; INHALATION

SYMBICORT

+	ASTRAZENECA	0.08MG/INH;0.045MG/INH	N21929 001	Jul 21, 2006	Jan	CAIN
+		0.16MG/INH;0.045MG/INH	N21929 002	Jul 21, 2006	Jan	CAIN

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

SENSORCAINE

>A>	AP	ABRAXIS BIOSCIENCE	0.25%	N18304 001		May	CAHN
>A>	AP		0.25%	N70552 001	May 21, 1986	May	CAHN
>A>	AP		0.5%	N18304 002		May	CAHN
>A>	AP		0.5%	N70553 001	May 21, 1986	May	CAHN
>A>	AP		0.75%	N18304 003		May	CAHN
>A>	AP		0.75%	N70554 001	May 21, 1986	May	CAHN
>D>	AP	ASTRAZENECA	0.25%	N18304 001		May	CAHN
>D>	AP		0.25%	N70552 001	May 21, 1986	May	CAHN
>D>	AP		0.5%	N18304 002		May	CAHN
>D>	AP		0.5%	N70553 001	May 21, 1986	May	CAHN
>D>	AP		0.75%	N18304 003		May	CAHN
>D>	AP		0.75%	N70554 001	May 21, 1986	May	CAHN

INJECTABLE; SPINAL

SENSORCAINE

>A>	AP	ABRAXIS BIOSCIENCE	0.75%	N71202 001	Apr 15, 1987	May	CAHN
>D>	AP	ASTRAZENECA	0.75%	N71202 001	Apr 15, 1987	May	CAHN

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE

INJECTABLE; INJECTION

SENSORCAINE

>A>	AP	ABRAXIS BIOSCIENCE	0.25%;0.0091MG/ML	N70966 001	Oct 13, 1987	May	CAHN
>A>	AP		0.25%;0.0091MG/ML	N70967 001	Oct 13, 1987	May	CAHN
>A>	AP		0.5%;0.0091MG/ML	N18304 004	Sep 02, 1983	May	CAHN
>A>	AP		0.5%;0.0091MG/ML	N70968 001	Oct 13, 1987	May	CAHN
>A>	AP		0.75%;0.0091MG/ML	N18304 005	Sep 02, 1983	May	CAHN
>D>	AP	ASTRAZENECA	0.25%;0.0091MG/ML	N70966 001	Oct 13, 1987	May	CAHN
>D>	AP		0.25%;0.0091MG/ML	N70967 001	Oct 13, 1987	May	CAHN
>D>	AP		0.5%;0.0091MG/ML	N18304 004	Sep 02, 1983	May	CAHN
>D>	AP		0.5%;0.0091MG/ML	N70968 001	Oct 13, 1987	May	CAHN
>D>	AP		0.75%;0.0091MG/ML	N18304 005	Sep 02, 1983	May	CAHN

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

BUPRENORPHINE HYDROCHLORIDE

AP	PHARMAFORCE	EQ 0.3MG BASE/ML	N78331 001	Mar 27, 2007	Mar	NEWA
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CABERGOLINE

TABLET; ORAL

CABERGOLINE

AB	IVAX PHARMS INC	0.5MG	N77750 001	Mar 07, 2007	Feb	NEWA
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CAFFEINE CITRATE

SOLUTION; INTRAVENOUS

CAFFEINE CITRATE

>A>	AP	LUITPOLD	EQ 30MG BASE/3ML (EQ 10MG BASE/ML)	N77906 001	May 15, 2007	May	NEWA
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CARBIDOPA; ENTACAPONE; LEVODOPA

TABLET; ORAL

STALEVO 50

+ ORION PHARMA INC 12.5MG;200MG;50MG

N21485 001	Jun 11, 2003	Apr	CRLD
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CARBOPLATIN

INJECTABLE; IV (INFUSION)

CARBOPLATIN

AP	GENERAMEDIX	EQ 50MG/5ML (10MG/ML)	N77998 001	Apr 24, 2007	Apr	NEWA
AP		EQ 150MG/ML (10MG/ML)	N77998 002	Apr 24, 2007	Apr	NEWA
AP		EQ 450MG/45ML (10MG/ML)	N77998 003	Apr 24, 2007	Apr	NEWA
AP	SICOR PHARMS	EQ 50MG/5ML (10MG/ML)	N77389 001	Mar 30, 2007	Mar	NEWA
AP		EQ 150MG/15ML (10MG/ML)	N77389 002	Mar 30, 2007	Mar	NEWA
AP		EQ 450MG/45ML (10MG/ML)	N77389 003	Mar 30, 2007	Mar	NEWA
AP	WATSON LABS	EQ 50MG/5ML (10MG/ML)	N77861 001	Jan 18, 2007	Jan	NEWA
AP		EQ 150MG/15ML (10MG/ML)	N77861 002	Jan 18, 2007	Jan	NEWA
AP		EQ 450MG/45ML (10MG/ML)	N77861 003	Jan 18, 2007	Jan	NEWA
AP		EQ 600MG/60ML (10MG/ML)	N77861 004	Jan 18, 2007	Jan	NEWA

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

AA	SUN PHARM INDS LTD	350MG	N40755 001	Feb 27, 2007	Feb	NEWA
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CEFACLOR

CAPSULE; ORAL

CEFACLOR

	@ CEPH INTL	EQ 250MG BASE	N62205 001		Apr	DISC	
	@	EQ 500MG BASE	N62205 002		Apr	DISC	
AB	HIKMA	EQ 250MG BASE	N65350 001	Apr 03, 2007	Mar	NEWA	
AB		EQ 500MG BASE	N65350 002	Apr 03, 2007	Mar	NEWA	
>D>	AB	TEVA	EQ 250MG BASE	N64145 001	Jun 24, 1996	May	DISC
>A>	@	EQ 250MG BASE	N64145 001	Jun 24, 1996	May	DISC	
>D>	AB		EQ 500MG BASE	N64145 002	Jun 24, 1996	May	DISC
>A>	@	EQ 500MG BASE	N64145 002	Jun 24, 1996	May	DISC	

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

CEFADROXIL

>D>	AB	AUROBINDO PHARMA	500MG	N65352 001	Jan 25, 2007	May	CPOT
>A>	AB		EQ 500MG BASE	N65352 001	Jan 25, 2007	May	CPOT
	AB		500MG	N65352 001	Jan 25, 2007	Jan	NEWA
>A>	AB	LUPIN	EQ 500MG BASE	N65392 001	May 29, 2007	May	NEWA

CEFAZOLIN SODIUM

INJECTABLE; INJECTION  
CEFAZOLIN SODIUM

>A> AP SANDOZ EQ 1GM BASE/VIAL N65345 001 May 09, 2007 May NEWA

CEFDINIR

CAPSULE; ORAL

CEFDINIR

AB SANDOZ 300MG N65330 001 Apr 06, 2007 Mar NEWA

>A> AB TEVA PHARMS 300MG N65368 001 May 09, 2007 May NEWA

FOR SUSPENSION; ORAL

CEFDINIR

AB LUPIN 250MG/5ML N65259 002 May 07, 2007 Apr NEWA

AB SANDOZ 125MG/5ML N65337 001 Apr 06, 2007 Mar NEWA

AB 250MG/5ML N65337 002 Apr 06, 2007 Mar NEWA

AB TEVA PHARMS 125MG/5ML N65332 001 May 04, 2007 Apr NEWA

AB 250MG/5ML N65332 002 May 04, 2007 Apr NEWA

OMNICEF

AB + ABBOTT 250MG/5ML N50749 002 Jul 29, 2004 Mar CFTG

CEFIXIME

SUSPENSION; ORAL

CEFIXIME

LUPIN PHARMS 200MG/5ML N65355 001 Apr 10, 2007 Mar NEWA

SUPRAX

LUPIN PHARMS 100MG/5ML N65129 001 Feb 23, 2004 Apr CRLD

+ 200MG/5ML N65355 001 Apr 10, 2007 Apr CRLD

CEFPROZIL

FOR SUSPENSION; ORAL

CEFPROZIL

AB AUROBINDO PHARMA 125MG/5ML N65381 001 Jan 30, 2007 Jan NEWA

AB 250MG/5ML N65381 002 Jan 30, 2007 Jan NEWA

TABLET; ORAL

CEFPROZIL

>A> AB AUROBINDO PHARMA LTD 250MG N65340 001 May 24, 2007 May NEWA

>A> AB 500MG N65340 002 May 24, 2007 May NEWA

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION

CEFIZOX

@ ASTELLAS EQ 1GM BASE/VIAL N50560 002 Sep 15, 1983 Feb DISC

+ EQ 1GM BASE/VIAL N63294 002 Mar 31, 1994 Feb CRLD

CEFTRIAZONE SODIUM

INJECTABLE; IM-IV

CEFTRIAZONE

AP CEPHAZONE PHARMA EQ 250MG BASE/VIAL N65294 001 Mar 26, 2007 Mar NEWA

AP EQ 500MG BASE/VIAL N65294 002 Mar 26, 2007 Mar NEWA

AP EQ 1GM BASE/VIAL N65294 003 Mar 26, 2007 Mar NEWA

AP EQ 2GM BASE/VIAL N65294 004 Mar 26, 2007 Mar NEWA

AP HANFORD GC EQ 1GM BASE/VIAL N65268 001 Feb 28, 2007 Feb NEWA

AP EQ 2GM BASE/VIAL N65268 002 Feb 28, 2007 Feb NEWA

AP SICOR PHARMS EQ 250MG BASE/VIAL N65227 001 Mar 15, 2007 Mar NEWA

## INJECTABLE; IM-IV

## CEFTRIAXONE

AP	SICOR PHARMS	EQ 500MG BASE/VIAL	N65227 002	Mar 15, 2007	Mar	NEWA
AP		EQ 1GM BASE/VIAL	N65227 003	Mar 15, 2007	Mar	NEWA
AP		EQ 2GM BASE/VIAL	N65227 004	Mar 15, 2007	Mar	NEWA
AP	TEVA	EQ 1GM BASE/VIAL	N65262 001	Jun 29, 2006	Apr	CTNA
AP		EQ 2GM BASE/VIAL	N65262 002	Jun 29, 2006	Apr	CTNA
AP	WOCKHARDT	EQ 250MG BASE/VIAL	N65391 001	Apr 12, 2007	Apr	NEWA
AP		EQ 500MG BASE/VIAL	N65391 002	Apr 12, 2007	Apr	NEWA
AP		EQ 2GM BASE/VIAL	N65391 003	Apr 12, 2007	Apr	NEWA

## INJECTABLE; INJECTION

## CEFTRIAXONE

AP	HANFORD GC	EQ 10GM BASE/VIAL	N65269 001	Feb 28, 2007	Feb	NEWA
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CELECOXIB

## CAPSULE; ORAL

## CELEBREX

## GD SEARLE

50MG

N20998 004 Dec 15, 2006 Jan NEWA

CEPHALEXIN

## FOR SUSPENSION; ORAL

## CEPHALEXIN

>D>	+	CEPH INTL	EQ 100MG BASE/ML	N62117 001		May	DISC
>A>	@		EQ 100MG BASE/ML	N62117 001		May	DISC
>D>	AB	TEVA	EQ 125MG BASE/5ML	N62767 001	Jun 16, 1987	May	DISC
>A>	@		EQ 125MG BASE/5ML	N62767 001	Jun 16, 1987	May	DISC
>D>	AB		EQ 250MG BASE/5ML	N62768 001	Jun 16, 1987	May	DISC
>A>	@		EQ 250MG BASE/5ML	N62768 001	Jun 16, 1987	May	DISC

>D> CEPHRADINE

## &gt;D&gt; CAPSULE; ORAL

## &gt;D&gt; CEPHRADINE

>D>		TEVA	250MG	N62683 001	Jan 09, 1987	May	DISC
>A>	@		250MG	N62683 001	Jan 09, 1987	May	DISC
>D>	+		500MG	N62683 002	Jan 09, 1987	May	DISC
>A>	@		500MG	N62683 002	Jan 09, 1987	May	DISC
>D>		FOR SUSPENSION; ORAL					
>D>		ANSPOR					
>D>	AB	GLAXOSMITHKLINE	125MG/5ML	N61866 001		May	DISC
>A>	@		125MG/5ML	N61866 001		May	DISC
>D>	AB		250MG/5ML	N61866 002		May	DISC
>A>	@		250MG/5ML	N61866 002		May	DISC
>D>		CEPHRADINE					
>D>	AB	TEVA	125MG/5ML	N62693 001	Jan 09, 1987	May	DISC
>A>	@		125MG/5ML	N62693 001	Jan 09, 1987	May	DISC
>D>	AB		250MG/5ML	N62693 002	Jan 09, 1987	May	DISC
>A>	@		250MG/5ML	N62693 002	Jan 09, 1987	May	DISC
>D>		VELOSEF '125'					
>D>	AB	+ APOTHECON	125MG/5ML	N61763 001		May	DISC
>A>	@		125MG/5ML	N61763 001		May	DISC
>D>		VELOSEF '250'					
>D>	AB	+ APOTHECON	250MG/5ML	N61763 002		May	DISC
>A>	@		250MG/5ML	N61763 002		May	DISC

CHLORAMPHENICOL SODIUM SUCCINATE

INJECTABLE; INJECTION

CHLORAMPHENICOL SODIUM SUCCINATE

+	ABRAXIS PHARM	EQ 1GM BASE/VIAL	N62365 001	Aug 25, 1982	Feb	CRLD
	CHLOROMYCETIN					
	@ PARKEDALE	EQ 1GM BASE/VIAL	N50155 001		Feb	DISC

CHLOROTHIAZIDE

SUSPENSION; ORAL

DIURIL

+	SALIX PHARMS	250MG/5ML	N11870 001		Feb	CAHN
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CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL

CODEPREX

	@ UCB INC	EQ 4MG MALEATE/5ML;EQ 20MG BASE/5ML	N21369 001	Jun 21, 2004	Mar	DISC
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CIPROFLOXACIN HYDROCHLORIDE

TABLET; ORAL

CIPROFLOXACIN

AB	AUROBINDO PHARMA	EQ 250MG BASE	N77859 001	Apr 26, 2007	Apr	NEWA
AB		EQ 500MG BASE	N77859 002	Apr 26, 2007	Apr	NEWA
AB		EQ 750MG BASE	N77859 003	Apr 26, 2007	Apr	NEWA

CIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

CIPRO XR

AB	+	BAYER PHARMS	212.6MG;EQ 287.5MG BASE	N21473 001	Dec 13, 2002	Mar	CFTG
AB	+		425.2MG;EQ 574.9MG BASE	N21473 002	Aug 28, 2003	Mar	CFTG
		CIPROFLOXACIN EXTENDED RELEASE					
AB		DR REDDYS LABS LTD	425.2MG;EQ 574.9MG BASE	N77701 001	Mar 26, 2007	Mar	NEWA
AB		MYLAN	212.6MG;EQ 287.5MG BASE	N78183 001	Mar 22, 2007	Mar	NEWA
AB			425.2MG;EQ 574.9MG BASE	N78183 002	Mar 22, 2007	Mar	NEWA

CISPLATIN

INJECTABLE; INJECTION

CISPLATIN

	@ BEDFORD	10MG/VIAL	N74713 001	Nov 14, 2000	Mar	DISC
	@	50MG/VIAL	N74713 002	Nov 14, 2000	Mar	DISC

PLATINOL

+	BRISTOL MYERS	10MG/VIAL	N18057 001		Mar	CTEC
+		50MG/VIAL	N18057 002		Mar	CTEC

CITALOPRAM HYDROBROMIDE

CAPSULE; ORAL

CITALOPRAM HYDROBROMIDE

	ALPHAPHARM	EQ 10MG BASE	N77668 001	Feb 28, 2007	Feb	NEWA
		EQ 20MG BASE	N77668 002	Feb 28, 2007	Feb	NEWA
+		EQ 40MG BASE	N77668 003	Feb 28, 2007	Feb	NEWA

TABLET; ORAL

CITALOPRAM HYDROBROMIDE

>D>	AB	ROXANE	EQ 10MG BASE	N77041 001	Nov 23, 2004	May	DISC
>A>		@	EQ 10MG BASE	N77041 001	Nov 23, 2004	May	DISC
>D>	AB		EQ 20MG BASE	N77041 002	Nov 23, 2004	May	DISC

## TABLET; ORAL

## CITALOPRAM HYDROBROMIDE

>A>	@ ROXANE	EQ 20MG BASE	N77041 002	Nov 23, 2004	May	DISC
AB	TORRENT PHARMS	EQ 10MG BASE	N78216 001	Mar 27, 2007	Mar	NEWA
AB		EQ 20MG BASE	N78216 002	Mar 27, 2007	Mar	NEWA
AB		EQ 40MG BASE	N78216 003	Mar 27, 2007	Mar	NEWA

CLINDAMYCIN PHOSPHATE

## INJECTABLE; INJECTION

## CLINDAMYCIN PHOSPHATE

AP	ABRAXIS PHARM	EQ 150MG BASE/ML	N65346 001	Mar 29, 2007	Mar	NEWA
>A>	AP	EQ 150MG BASE/ML	N65347 001	May 09, 2007	May	NEWA

CLOBETASOL PROPIONATE

## AEROSOL, FOAM; TOPICAL

## OLUX E

## + CONNETICS

0.05%

N22013 001 Jan 12, 2007 Jan NEWA

## SOLUTION; TOPICAL

## CLOBETASOL PROPIONATE

AT ALTANA

0.05%

N75391 001 Feb 08, 1999 Feb CMFD

CLOCORTOLONE PIVALATE

## CREAM; TOPICAL

## CLODERM

&gt;A&gt; + CORIA

0.1%

N17765 001

May CAHN

&gt;D&gt; + HEALTHPOINT

0.1%

N17765 001

May CAHN

CLONIDINE HYDROCHLORIDE

## TABLET; ORAL

## CLONIDINE HYDROCHLORIDE

AB VINTAGE

0.1MG

N77901 001 Mar 09, 2007 Feb NEWA

AB

0.2MG

N77901 002 Mar 09, 2007 Feb NEWA

AB

0.3MG

N77901 003 Mar 09, 2007 Feb NEWA

CLOZAPINE

## TABLET, ORALLY DISINTEGRATING; ORAL

## FAZACLO ODT

&gt;A&gt; AVANIR PHARMS

12.5MG

N21590 004 May 30, 2007 May NEWA

CORTISONE ACETATE

## INJECTABLE; INJECTION

## CORTISONE ACETATE

@ PHARMACIA AND UPJOHN

25MG/ML

N08126 002

Apr DISC

## TABLET; ORAL

## CORTISONE ACETATE

@ PHARMACIA AND UPJOHN

5MG

N08126 003

Apr DISC

@

10MG

N08126 004

Apr DISC

@

25MG

N08126 001

Apr DISC

+ WEST WARD

25MG

N80776 002

Apr CRLD

CROMOLYN SODIUM

## SOLUTION; INHALATION

## CROMOLYN SODIUM

&gt;D&gt; AN ROXANE

10MG/ML

N75175 001 Sep 30, 1999 May DISC

&gt;A&gt; @

10MG/ML

N75175 001 Sep 30, 1999 May DISC

CYCLOBENZAPRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

AMRIX

	ECR	15MG	N21777 001	Feb 01, 2007	Feb	NEWA
+		30MG	N21777 002	Feb 01, 2007	Feb	NEWA

TABLET; ORAL

CYCLOBENZAPRINE HYDROCHLORIDE

AB	VINTAGE PHARMS	5MG	N77797 001	Feb 28, 2007	Feb	NEWA
AB		10MG	N77797 002	Feb 28, 2007	Feb	NEWA

DALTEPARIN SODIUM

&gt;D&gt; INJECTABLE; INJECTION

&gt;D&gt; FRAGMIN

>D>	+	PHARMACIA AND UPJOHN	2,500 IU/0.2ML	N20287 001	Dec 22, 1994	May	CDFR
>D>	+		5,000 IU/0.2ML	N20287 003	Mar 18, 1996	May	CDFR
>D>	+		7,500 IU/0.3ML	N20287 005	Apr 04, 2002	May	CDFR
>D>	+		10,000 IU/ML	N20287 004	Jan 30, 1998	May	CDFR
>D>	+		95,000IU/9.5ML(10,000IU/ML)	N20287 007	Apr 04, 2002	May	CDFR
>D>	+		95,000IU/3.8ML(25,000IU/ML)	N20287 006	Apr 04, 2002	May	CDFR

&gt;A&gt; INJECTABLE; SUBCUTANEOUS

&gt;A&gt; FRAGMIN

>A>	+	PHARMACIA AND UPJOHN	2,500IU/0.2ML (12,500IU/ML)	N20287 001	Dec 22, 1994	May	CDFR
>A>	+		5,000IU/0.2ML (25,000IU/ML)	N20287 003	Mar 18, 1996	May	CDFR
>A>	+		7,500IU/0.3ML (25,000IU/ML)	N20287 005	Apr 04, 2002	May	CDFR
>A>	+		10,000IU/ML (10,000IU/ML)	N20287 004	Jan 30, 1998	May	CDFR
>A>	+		10,000IU/0.4ML (25,000IU/ML)	N20287 002	May 01, 2007	May	NEWA
>A>	+		12,500IU/0.5ML (25,000IU/ML)	N20287 009	May 01, 2007	May	NEWA
>A>	+		15,000IU/0.6ML (25,000IU/ML)	N20287 010	May 01, 2007	May	NEWA
>A>	+		18,000IU/0.72ML (25,000IU/ML)	N20287 011	May 01, 2007	May	NEWA
>A>	+		95,000IU/9.5ML(10,000IU/ML)	N20287 007	Apr 04, 2002	May	CDFR
>A>	+		95,000IU/3.8ML(25,000IU/ML)	N20287 006	Apr 04, 2002	May	CDFR

DANAZOL

CAPSULE; ORAL

DANAZOL

AB	BARR	50MG	N74582 003	May 29, 1998	Apr	CTEC
AB		100MG	N74582 002	May 29, 1998	Apr	CTEC
AB	LANNETT	50MG	N78214 001	Apr 19, 2007	Apr	NEWA
AB		100MG	N78214 002	Apr 19, 2007	Apr	NEWA

DAPSONE

GEL; TOPICAL

ACZONE

>A>	@	QLT USA	5%	N21794 001	Jul 07, 2005	May	CAHN
>D>	@	TOLMAR	5%	N21794 001	Jul 07, 2005	May	CAHN

DEFEROXAMINE MESYLATE

INJECTABLE; INJECTION

DEFEROXAMINE MESYLATE

>A>	AP	BEDFORD	500MG/VIAL	N78086 001	May 30, 2007	May	NEWA
>A>	AP		2GM/VIAL	N78086 002	May 30, 2007	May	NEWA

DEMECLOCYCLINE HYDROCHLORIDE

	TABLET; ORAL						
	DECLOMYCIN						
	@ STIEFEL	75MG		N50261 001		Mar	CAHN
AB		150MG		N50261 002		Mar	CAHN
AB	+	300MG		N50261 003		Mar	CAHN

DESIPRAMINE HYDROCHLORIDE

	TABLET; ORAL						
	DESIPRAMINE HYDROCHLORIDE						
AB	ACTAVIS TOTOWA	10MG		N74430 001	Feb 09, 1996	Mar	CAHN
AB		25MG		N71601 001	Jun 05, 1987	Mar	CAHN
AB		75MG		N71602 001	Oct 05, 1987	Mar	CAHN
AB		100MG		N71766 001	Oct 05, 1987	Mar	CAHN
AB		150MG		N74430 002	Feb 09, 1996	Mar	CAHN
AB	AMIDE PHARM	50MG		N71588 001	Jun 05, 1987	Mar	CAHN

DESMOPRESSIN ACETATE

	SPRAY, METERED; NASAL						
	STIMATE						
	+ CSL BEHRING	0.15MG/SPRAY		N20355 001	Mar 07, 1994	Apr	CAHN

DESONIDE

	CREAM; TOPICAL						
>A>	DESONIDE						
>A>	AB + PERRIGO NEW YORK	0.05%		N17010 001		May	CTNA
>D>	TRIDESILON						
>D>	AB + PERRIGO NEW YORK	0.05%		N17010 001		May	CTNA
	OINTMENT; TOPICAL						
>A>	DESONIDE						
>A>	AB + PERRIGO NEW YORK	0.05%		N17426 001		May	CTNA
>D>	TRIDESILON						
>D>	AB + PERRIGO NEW YORK	0.05%		N17426 001		May	CTNA

DEXMETHYLPHENIDATE HYDROCHLORIDE

	TABLET; ORAL						
	DEXMETHYLPHENIDATE HYDROCHLORIDE						
AB	TEVA PHARMS	2.5MG		N77107 003	Jan 29, 2007	Jan	NEWA
AB		5MG		N77107 001	Jan 29, 2007	Jan	NEWA
AB		10MG		N77107 002	Jan 29, 2007	Jan	NEWA
	FOCALIN						
AB	NOVARTIS	2.5MG		N21278 001	Nov 13, 2001	Jan	CFTG
AB		5MG		N21278 002	Nov 13, 2001	Jan	CFTG
AB	+	10MG		N21278 003	Nov 13, 2001	Jan	CFTG

DEXTROAMPHETAMINE SULFATE

	TABLET; ORAL						
	DEXEDRINE						
	@ GLAXOSMITHKLINE	5MG		N84935 001		Feb	DISC
	DEXTROSTAT						
AA	+	SHIRE	5MG	N84051 001		Mar	CAHN
AA	+		10MG	N84051 002		Mar	CAHN



DIAZOXIDE

	SUSPENSION; ORAL				
	PROGLYCEM				
>D>	+	BAKER NORTON	50MG/ML	N17453 001	May CAHN
>A>	+	IVAX RES	50MG/ML	N17453 001	May CAHN

DICLOFENAC EPOLAMINE

	PATCH; TOPICAL				
	FLECTOR				
	+	INST BIOCHEM	1.3%	N21234 001	Jan 31, 2007 Jan NEWA

DIDANOSINE

	FOR SOLUTION; ORAL				
	DIDANOSINE				
AA		AUROBINDO PHARMA	10MG/ML	N78112 001	Mar 08, 2007 Feb NEWA
	VIDEX				
AA	+	BRISTOL MYERS SQUIBB	10MG/ML	N20156 001	Oct 09, 1991 Feb CFTG

DIFLORASONE DIACETATE

	OINTMENT; TOPICAL				
	FLORONE				
>D>		@ PHARMACIA AND UPJOHN	0.05%	N17994 001	May CTNA
>D>					
>A>		PSORCON E			
>A>		@ PHARMACIA AND UPJOHN	0.05%	N17994 001	May CTNA

DIMYRISTOYL LECITHIN; PERFLEXANE

	INJECTABLE; INTRAVENOUS				
	IMAGENT				
		@ IMCOR PHARMS CO	0.92MG/VIAL;0.092MG/VIAL	N21191 001	May 31, 2002 Feb CAHN

DIPHENHYDRAMINE HYDROCHLORIDE

	INJECTABLE; INJECTION				
	BENADRYL				
		@ MCNEIL CONS	10MG/ML	N06146 001	Mar CAHN
AP	+		50MG/ML	N06146 002	Mar CAHN
	BENADRYL PRESERVATIVE FREE				
AP	+	MCNEIL CONS	50MG/ML	N09486 001	Mar CAHN

DIPYRIDAMOLE

	TABLET; ORAL				
	DIPYRIDAMOLE				
AB		MURTY PHARMS	25MG	N40733 001	Feb 13, 2007 Jan NEWA
AB			50MG	N40733 002	Feb 13, 2007 Jan NEWA
AB			75MG	N40733 003	Feb 13, 2007 Jan NEWA

DOXORUBICIN HYDROCHLORIDE

	INJECTABLE; INJECTION				
	DOXORUBICIN HYDROCHLORIDE				
AP	+	BEDFORD	10MG/VIAL	N62921 001	Mar 17, 1989 Apr CRLD
AP	+		20MG/VIAL	N62921 002	Mar 17, 1989 Apr CRLD
AP	+		50MG/VIAL	N62921 003	Mar 17, 1989 Apr CRLD
	RUBEX				
		@ BRISTOL MYERS SQUIBB	10MG/VIAL	N62926 001	Apr 13, 1989 Mar DISC
		@	50MG/VIAL	N62926 002	Apr 13, 1989 Mar DISC

## INJECTABLE; INJECTION

RUBEX

@ BRISTOL MYERS SQUIBB 100MG/VIAL

N62926 003 Apr 13, 1989 Mar DISC

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE

AB RANBAXY EQ 75MG BASE

N65053 003 Sep 10, 2003 Jan CTEC

MONODOX

AB OCLASSEN EQ 75MG BASE

N50641 003 Oct 18, 2006 Jan NEWA

ECONAZOLE NITRATE

CREAM; TOPICAL

ECONAZOLE NITRATE

&gt;D&gt; AB HEALTHPOINT 1%

N76574 001 Dec 17, 2004 May CAHN

&gt;A&gt; AB PRASCO 1%

N76574 001 Dec 17, 2004 May CAHN

EDETATE CALCIUM DISODIUM

INJECTABLE; INJECTION

CALCIUM DISODIUM VERSENATE

+ GRACEWAY 200MG/ML

N08922 001 Jan CAHN

TABLET; ORAL

CALCIUM DISODIUM VERSENATE

@ GRACEWAY 500MG

N08922 002 Jan CAHN

ENALAPRILAT

INJECTABLE; INJECTION

ENALAPRILAT

AP + BEDFORD 1.25MG/ML

N75634 001 Aug 22, 2000 Mar CRLD

VASOTEC

&gt;D&gt; @ BIOVAIL LABS INTL 1.25MG/ML

N19309 001 Feb 09, 1988 May CMFD

&gt;A&gt; AP + 1.25MG/ML

N19309 001 Feb 09, 1988 May CMFD

@ 1.25MG/ML

N19309 001 Feb 09, 1988 Mar DISC

EPIRUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ELLENC

AP + PFIZER INC 2MG/ML (200MG/100ML)

N50778 001 Sep 15, 1999 Apr CFTG

AP 2MG/ML (50MG/25ML)

N50778 002 Sep 15, 1999 Apr CFTG

EPIRUBICIN HYDROCHLORIDE

HOSPIRA 2MG/ML (150MG/75ML)

N65343 003 Apr 19, 2007 Apr NEWA

2MG/ML (10MG/5ML)

N65343 001 Apr 19, 2007 Apr NEWA

AP 2MG/ML (50MG/25ML)

N65343 002 Apr 19, 2007 Apr NEWA

AP 2MG/ML (200MG/100ML)

N65343 004 Apr 19, 2007 Apr NEWA

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL

ERGOMAR

+ ROSEDALE THERAPEUTIC 2MG

N87693 001 Feb 24, 1983 Jan CAHN

ERYTHROMYCIN

OINTMENT; TOPICAL

AKNE-MYCIN

&gt;A&gt; + CORIA 2%

N50584 001 Jan 10, 1985 May CAHN

&gt;D&gt; + HEALTHPOINT 2%

N50584 001 Jan 10, 1985 May CAHN

SWAB; TOPICAL

>D>		C-SOLVE-2							
>D>	AT	IVAX PHARMS	2%	N62751	001	Jul 30,	1993	May	DISC
>A>		@	2%	N62751	001	Jul 30,	1993	May	DISC
>D>		ERYCETFE							
>D>	AT	+ J AND J	2%	N50594	001	Feb 15,	1985	May	DISC
>A>		@	2%	N50594	001	Feb 15,	1985	May	DISC
		ERYTHROMYCIN							
>D>	AT	ALTANA	2%	N65320	001	Jul 25,	2006	May	CRLD
>A>	AT	+	2%	N65320	001	Jul 25,	2006	May	CRLD
>D>	AT	STIEFEL	2%	N64126	001	Jul 03,	1996	May	CRLD
>A>	AT	+	2%	N64126	001	Jul 03,	1996	May	CRLD
>D>	AT		2%	N64128	001	Jul 03,	1996	May	DISC
>A>		@	2%	N64128	001	Jul 03,	1996	May	DISC

ESTAZOLAM

## TABLET; ORAL

## ESTAZOLAM

>D>	AB	TEVA	2MG	N74921	002	Jul 10,	1997	May	CRLD
>A>	AB	+	2MG	N74921	002	Jul 10,	1997	May	CRLD
		PROSOM							
		@ ABBOTT	1MG	N19080	001	Dec 26,	1990	Apr	DISC
		@	2MG	N19080	002	Dec 26,	1990	Apr	DISC

ESTRADIOL

## GEL, METERED; TRANSDERMAL

## ELESTRIN

BX	+	BRADLEY PHARMS	0.06%	N21813	001	Dec 15,	2006	Jan	CAHN
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## TABLET; ORAL

## ESTRADIOL

@	HERITAGE PHARMS INC	0.5MG	N40275	001	Dec 29,	1998	Feb	CAHN
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@		1MG	N40275	002	Dec 29,	1998	Feb	CAHN
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@		2MG	N40275	003	Dec 29,	1998	Feb	CAHN
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ESTROGENS, CONJUGATED SYNTHETIC B

## TABLET; ORAL

## ENJUVIA

DURAMED		0.9MG	N21443	005	Apr 27,	2007	Apr	NEWA
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ETHINYL ESTRADIOL; LEVONORGESTREL

## TABLET; ORAL

## LYBREL

>A>									
>A>	+	WYETH PHARMS INC	0.02MG;0.09MG	N21864	001	May 22,	2007	May	NEWA

## TABLET; ORAL-28

## LEVONORGESTREL AND ETHINYL ESTRADIOL

AB1	+	WATSON LABS	0.02MG;0.1MG	N76625	001	Nov 18,	2004	Apr	CRLD
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ETHINYL ESTRADIOL; NORETHINDRONE

## TABLET, CHEWABLE; ORAL-28

## OVCON-35 FE

+	WARNER CHILCOTT	0.035MG;0.4MG	N21490	001	Nov 14,	2003	Jan	CTNA
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ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL-21		MICROGESTIN 1.5/30							
AB	WATSON LABS	0.03MG;1.5MG		N75548	002	Jul 30, 2003	Jan	NEWA	
TABLET; ORAL-28		MICROGESTIN 1/20							
AB	WATSON LABS	0.02MG;1MG		N75647	002	Jul 30, 2003	Jan	NEWA	
TABLET; ORAL-28		NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE							
AB	TEVA PHARMS	0.02MG;1MG		N77077	001	May 20, 2005	Apr	CAHN	
AB		0.03MG;1.5MG		N77075	001	Apr 28, 2005	Apr	CAHN	

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET; ORAL-28		PREVIFEM							
AB	TEVA PHARMS	0.035MG;0.25MG		N76334	001	Jan 09, 2004	Apr	CAHN	
TABLET; ORAL-28		TRI-PREVIFEM							
AB	TEVA PHARMS	0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG		N76335	001	Mar 26, 2004	Apr	CAHN	
AB		0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG		N76335	001	Mar 26, 2004	Apr	CAHN	
AB		0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG		N76335	001	Mar 26, 2004	Apr	CAHN	

ETODOLAC

## CAPSULE; ORAL

## ETODOLAC

@	AAIPHARMA LLC	300MG		N74929	001	Jan 30, 1998	Apr	DISC	
@	GENPHARM	200MG		N75071	001	Sep 30, 1998	Apr	DISC	
@		300MG		N75071	002	Sep 30, 1998	Apr	DISC	
@	MYLAN	200MG		N74932	001	May 16, 1997	Apr	DISC	
@		300MG		N74932	002	May 16, 1997	Apr	DISC	
@	SANDOZ	200MG		N74840	001	Aug 29, 1997	Apr	DISC	
@		200MG		N74942	001	Sep 30, 1997	Apr	DISC	
@		300MG		N74840	002	Aug 29, 1997	Apr	DISC	
@		300MG		N74942	002	Sep 30, 1997	Apr	DISC	
@	TEVA	200MG		N75126	001	Sep 16, 1999	Apr	DISC	
@	WATSON LABS	200MG		N74844	001	Dec 23, 1997	Apr	DISC	
@		300MG		N74844	002	Dec 23, 1997	Apr	DISC	

## TABLET; ORAL

## ETODOLAC

@	AAIPHARMA LLC	400MG		N74927	001	Oct 30, 1997	Apr	DISC	
@	GENPHARM	400MG		N75012	001	Sep 30, 1998	Apr	DISC	
@		500MG		N75012	002	Sep 30, 1998	Apr	DISC	
@	IVAX PHARMS	400MG		N74883	001	Feb 28, 1997	Apr	DISC	
@		500MG		N74883	002	Nov 20, 1998	Apr	DISC	
@	RANBAXY	400MG		N75226	001	Nov 24, 1998	Apr	DISC	
@		500MG		N75226	002	Nov 24, 1998	Apr	DISC	
@	SANDOZ	400MG		N74839	001	Jul 11, 1997	Apr	DISC	
@		400MG		N74846	001	Feb 28, 1997	Apr	DISC	
@	TEVA	400MG		N74847	001	Apr 23, 1999	Apr	DISC	
@		500MG		N74847	002	Apr 23, 1999	Apr	DISC	
@	WATSON LABS	400MG		N74892	001	Apr 16, 1997	Apr	DISC	
@		400MG		N75069	001	Apr 16, 1998	Apr	DISC	
@		500MG		N74892	002	Oct 29, 1998	Apr	DISC	

## TABLET, EXTENDED RELEASE; ORAL

## ETODOLAC

@	ANDRX PHARMS	400MG	N75829 001	Nov 30, 2001	Apr	DISC
@		500MG	N75829 002	Nov 30, 2001	Apr	DISC
@	SANDOZ	400MG	N75943 001	Jul 26, 2002	Apr	DISC
@		500MG	N75943 002	Jul 26, 2002	Apr	DISC
@		600MG	N75943 003	Jul 26, 2002	Apr	DISC

FAMOTIDINE

## FOR SUSPENSION; ORAL

## PEPCID

+	SALIX PHARMS	40MG/5ML	N19527 001	Feb 02, 1987	Feb	CAHN
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FENOFIBRATE

## TABLET; ORAL

## TRIGLIDE

	SKYEPHARMA AG	50MG	N21350 001	May 07, 2005	Jan	CAHN
BX		160MG	N21350 002	May 07, 2005	Jan	CAHN

FENOLDOPAM MESYLATE

## INJECTABLE; INJECTION

## FENOLDOPAM MESYLATE

AP	SICOR PHARMS	EQ 10MG BASE/ML	N77826 001	Mar 07, 2007	Feb	NEWA
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FENTANYL

## FILM, EXTENDED RELEASE; TRANSDERMAL

## DURAGESIC-12

AB	ALZA	12.5UGM/HR	N19813 005	Feb 04, 2005	Jan	CFTG
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## FENTANYL-100

AB	LAVIPHARM LABS	100UGM/HR	N77051 004	Aug 04, 2006	Jan	CTNA
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AB	MYLAN TECHNOLOGIES	100UGM/HR	N76258 004	Jan 28, 2005	Jan	CTNA
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## FENTANYL-12

AB	MYLAN TECHNOLOGIES	12.5UGM/HR	N76258 005	Jan 23, 2007	Jan	NEWA
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## FENTANYL-25

AB	LAVIPHARM LABS	25UGM/HR	N77051 001	Aug 04, 2006	Jan	CTNA
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AB	MYLAN TECHNOLOGIES	25UGM/HR	N76258 001	Jan 28, 2005	Jan	CTNA
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## FENTANYL-50

AB	LAVIPHARM LABS	50UGM/HR	N77051 002	Aug 04, 2006	Jan	CTNA
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AB	MYLAN TECHNOLOGIES	50UGM/HR	N76258 002	Jan 28, 2005	Jan	CTNA
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## FENTANYL-75

AB	LAVIPHARM LABS	75UGM/HR	N77051 003	Aug 04, 2006	Jan	CTNA
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AB	MYLAN TECHNOLOGIES	75UGM/HR	N76258 003	Jan 28, 2005	Jan	CTNA
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FENTANYL CITRATE

## TABLET; BUCCAL

## FENTORA

## CEPHALON

		EQ 0.3MG BASE	N21947 006	Mar 02, 2007	Mar	NEWA
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FEXOFENADINE HYDROCHLORIDE

## TABLET; ORAL

## FEXOFENADINE HYDROCHLORIDE

AB	MYLAN	180MG	N77081 001	Apr 16, 2007	Apr	NEWA
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FINASTERIDE

TABLET; ORAL

FINASTERIDE

AB	ACTAVIS TOTOWA	5MG	N77914 001	Mar 28, 2007	Mar	NEWA
AB	DR REDDYS LABS LTD	5MG	N76437 001	Feb 28, 2007	Feb	NEWA

FLECAINIDE ACETATE

TABLET; ORAL

TAMBOCOR

AB	GRACEWAY	50MG	N18830 004	Aug 23, 1988	Jan	CAHN
AB		100MG	N18830 001	Oct 31, 1985	Jan	CAHN
AB	+	150MG	N18830 003	Jun 03, 1988	Jan	CAHN
	@	200MG	N18830 002	Oct 31, 1985	Jan	CAHN

FLUDARABINE PHOSPHATE

INJECTABLE; INJECTION

FLUDARABINE PHOSPHATE

AP	MAYNE PHARMA USA	50MG/VIAL	N77790 001	Apr 06, 2007	Mar	NEWA
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FLUOROURACIL

INJECTABLE; INJECTION

FLUOROURACIL

	@ ABRAXIS PHARM	50MG/ML	N40291 001	Mar 24, 1999	Apr	DISC	
	@	50MG/ML	N40379 001	Nov 15, 2000	Apr	DISC	
AP	+	500MG/10ML (50MG/ML)	N40279 002	Sep 30, 1998	Apr	NEWA	
AP	+	1GM/20ML (50MG/ML)	N40279 001	Sep 30, 1998	Apr	CPOT	
AP	+	2.5GM/50ML (50MG/ML)	N40278 001	Sep 30, 1998	Apr	CPOT	
AP	+	5GM/100ML (50MG/ML)	N40278 002	Sep 30, 1998	Apr	NEWA	
AP	+	GENERAMEDIX	500MG/10ML (50MG/ML)	N40743 002	Apr 26, 2007	Apr	NEWA
AP	+	1GM/20ML (50MG/ML)	N40743 001	Apr 26, 2007	Apr	NEWA	
AP	+	2.5GM/50ML (50MG/ML)	N40798 002	Apr 26, 2007	Apr	NEWA	
AP	+	5GM/100ML (50MG/ML)	N40798 001	Apr 26, 2007	Apr	NEWA	
AP	+	SICOR PHARMS	500MG/10ML (50MG/ML)	N40333 001	Jan 27, 2000	Apr	CPOT
AP	+	2.5GM/50ML (50MG/ML)	N40334 001	Feb 25, 2000	Apr	CPOT	
AP	+	5GM/100ML (50MG/ML)	N40334 002	Feb 25, 2000	Apr	NEWA	
AP	+	VALEANT	500MG/10ML (50MG/ML)	N12209 001		Apr	CPOT

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL

FLUOXETINE

>A>	AB	MYLAN	EQ 40MG BASE	N75207 003	May 25, 2007	May	NEWA
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SOLUTION; ORAL

FLUOXETINE HYDROCHLORIDE

AA	SILARX	EQ 20MG BASE/5ML	N77849 001	Feb 09, 2007	Jan	NEWA
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FLUOXETINE HYDROCHLORIDE; OLANZAPINE

CAPSULE; ORAL

SYMBYAX

LILLY

EQ 25MG BASE;EQ 3MG BASE

N21520 001	Apr 09, 2007	Apr	NEWA
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FLUPHENAZINE DECANOATE

INJECTABLE; INJECTION

FLUPHENAZINE DECANOATE

AO	+	BEDFORD	25MG/ML	N74531 001	Aug 30, 1996	Jan	CRLD
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## INJECTABLE; INJECTION

PROLIXIN DECANOATE

@ BRISTOL MYERS SQUIBB 25MG/ML

N16727 001

Jan DISC

FLUPHENAZINE HYDROCHLORIDE

## INJECTABLE; INJECTION

FLUPHENAZINE HYDROCHLORIDE

+ ABRAXIS PHARM 2.5MG/ML

N89556 001 Apr 16, 1987 Jan CRLD

PROLIXIN

@ APOTHECON 2.5MG/ML

N11751 005

Jan DISC

## TABLET; ORAL

FLUPHENAZINE HYDROCHLORIDE

AB + MYLAN 10MG

N89804 001 Aug 12, 1988 Feb CRLD

PROLIXIN

@ APOTHECON 1MG

N11751 004

Jan DISC

@ 2.5MG

N11751 001

Jan DISC

@ 5MG

N11751 003

Jan DISC

@ 10MG

N11751 002

Jan DISC

FLURBIPROFEN

## TABLET; ORAL

FLURBIPROFEN

AB THERAGEN 100MG

N74560 002 May 16, 1997 Apr CAHN

FLUTICASONE FUROATE

## SPRAY, METERED; NASAL

VERAMYST

+ GLAXOSMITHKLINE 0.0275MG/INH

N22051 001 Apr 27, 2007 Apr NEWA

FOLIC ACID

## INJECTABLE; INJECTION

FOLIC ACID

+ ABRAXIS PHARM 5MG/ML

N89202 001 Feb 18, 1986 Jan CTEC

@ BEN VENUE 5MG/ML

N81066 001 Dec 29, 1993 Jan DISC

FOLLITROPIN ALFA/BETA

## INJECTABLE; SUBCUTANEOUS

GONAL-F

@ EMD SERONO 37.5 IU/VIAL

N20378 003 May 25, 2000 Mar CAHN

@ 37.5 IU/VIAL

N21765 001 Mar 25, 2004 Mar CAHN

@ 75 IU/VIAL

N20378 001 Sep 29, 1997 Mar CAHN

@ 150 IU/VIAL

N20378 002 Sep 29, 1997 Mar CAHN

@ 150 IU/VIAL

N21765 003 Mar 25, 2004 Mar CAHN

+ 450 IU/VIAL

N20378 005 Mar 26, 2004 Mar CAHN

@ 1,050 IU/VIAL

N20378 004 Feb 28, 2001 Mar CAHN

GONAL-F RFF

+ EMD SERONO 75 IU/VIAL

N21765 002 Mar 25, 2004 Mar CAHN

FORMOTEROL FUMARATE

## POWDER; INHALATION

FORADIL CERTIHALER

+ NOVARTIS 0.0085MG/INH

N21592 001 Dec 15, 2006 Jan CRLD

&gt;A&gt; SOLUTION; INHALATION

&gt;A&gt; PERFOROMIST

&gt;A&gt; + DEY LP 0.02MG/2ML

N22007 001 May 11, 2007 May NEWA

FUROSEMIDE

INJECTABLE; INJECTION  
FUROSEMIDE

AP		WOCKHARDT	10MG/ML	N77941 001	Mar 22, 2007	Mar	NEWA
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GABAPENTIN

CAPSULE; ORAL  
GABAPENTIN

>A>	AB	WATSON LABS	100MG	N75485 003	May 11, 2007	May	NEWA
>A>	AB		300MG	N75485 002	May 11, 2007	May	NEWA
>A>	AB		400MG	N75485 001	May 11, 2007	May	NEWA

TABLET; ORAL  
GABAPENTIN

AB	+	IVAX PHARMS	800MG	N76017 005	Apr 29, 2005	Feb	CRLD
AB		PFIZER PHARMS	800MG	N20882 002	Oct 09, 1998	Feb	CRLD

GEMFIBROZIL

TABLET; ORAL  
GEMFIBROZIL

>A>	AB	IMPAX PHARMS	600MG	N78207 001	Jun 01, 2007	May	NEWA
	AB	PERRIGO R AND D	600MG	N78012 001	Mar 26, 2007	Mar	NEWA

GLIPIZIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL  
GLIPIZIDE AND METFORMIN HYDROCHLORIDE

AB		MYLAN	2.5MG;250MG	N78083 001	Apr 12, 2007	Apr	NEWA
AB			2.5MG;500MG	N78083 002	Apr 12, 2007	Apr	NEWA
AB			5MG;500MG	N78083 003	Apr 12, 2007	Apr	NEWA

HALOBETASOL PROPIONATE

CREAM; TOPICAL  
HALOBETASOL PROPIONATE

AB		G AND W LABS	0.05%	N78162 001	Apr 24, 2007	Apr	NEWA
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HEPARIN SODIUM

INJECTABLE; INJECTION  
HEPARIN SODIUM

@	ABRAXIS PHARM	1,000 UNITS/ML	N17979 001		Mar	DISC
@		10,000 UNITS/ML	N17979 002		Mar	DISC
@	WATSON LABS	1,000 UNITS/ML	N17064 002		Feb	CAHN
@		2,500 UNITS/ML	N17064 015		Feb	CAHN
@		3,000 UNITS/ML	N17064 016		Feb	CAHN
@		4,000 UNITS/ML	N17064 017		Feb	CAHN
@		5,000 UNITS/ML	N17064 003		Feb	CAHN
@		6,000 UNITS/ML	N17064 018		Feb	CAHN
@		7,500 UNITS/ML	N17064 019		Feb	CAHN
@		10,000 UNITS/ML	N17064 004		Feb	CAHN
@		20,000 UNITS/ML	N17064 005		Feb	CAHN
@		40,000 UNITS/ML	N17064 006		Feb	CAHN



HISTRELIN ACETATE

	IMPLANT; SUBCUTANEOUS						
>A>	SUPPRELIN LA						
>A>	+ INDEVUS	50MG	N22058	001	May 03, 2007	May	NEWA
	VANTAS						
	+ INDEVUS	50MG	N21732	001	Oct 12, 2004	Apr	CAHN

HYDRALAZINE HYDROCHLORIDE

	TABLET; ORAL						
	HYDRALAZINE HYDROCHLORIDE						
	@ HERITAGE PHARMS INC	25MG	N86243	001		Feb	CAHN
	@	50MG	N86242	002		Feb	CAHN

HYDROCHLOROTHIAZIDE

	TABLET; ORAL						
	HYDROCHLOROTHIAZIDE						
AB	ACTAVIS ELIZABETH	12.5MG	N40707	001	Feb 27, 2007	Feb	NEWA
AB	CARACO	25MG	N40810	001	Mar 27, 2007	Mar	NEWA
AB		50MG	N40810	002	Mar 27, 2007	Mar	NEWA
AB	EXCELLIUM	25MG	N40702	001	Mar 16, 2007	Mar	NEWA
AB		50MG	N40702	002	Mar 16, 2007	Mar	NEWA
AB	HERITAGE PHARMS INC	25MG	N85181	001		Feb	CAHN
AB		50MG	N85182	001		Feb	CAHN
AB	MYLAN	12.5MG	N40770	001	Jan 23, 2007	Feb	CTEC
		12.5MG	N40770	001	Jan 23, 2007	Jan	NEWA
AB		25MG	N40735	002	Jan 23, 2007	Jan	NEWA
AB		50MG	N40735	003	Jan 23, 2007	Jan	NEWA

HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDE

	TABLET; ORAL						
	MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE						
AB	TEVA	12.5MG;7.5MG	N76980	001	Mar 07, 2007	Feb	NEWA
AB		12.5MG;15MG	N76980	003	Mar 07, 2007	Feb	NEWA
AB		25MG;15MG	N76980	002	Mar 07, 2007	Feb	NEWA
	UNIRETIC						
AB	SCHWARZ PHARMA	12.5MG;7.5MG	N20729	001	Jun 27, 1997	Feb	CFTG
AB		12.5MG;15MG	N20729	003	Feb 14, 2002	Feb	CFTG
AB	+	25MG;15MG	N20729	002	Jun 27, 1997	Feb	CFTG

HYDROCODONE BITARTRATE; IBUPROFEN

	TABLET; ORAL						
	HYDROCODONE BITARTRATE AND IBUPROFEN						
AB	INTERPHARM	5MG;200MG	N76642	002	Mar 18, 2004	Apr	CRLD

HYDROCORTISONE

	TABLET; ORAL						
	CORTEF						
AB	PHARMACIA AND UPJOHN	5MG	N08697	003		Mar	CFTG
AB		10MG	N08697	001		Mar	CFTG
		10MG	N08697	001		Feb	CMFD
AB	+	20MG	N08697	002		Mar	CTEC
	HYDROCORTISONE						
AB	STIEFEL	5MG	N40646	001	Mar 30, 2007	Mar	NEWA
AB		10MG	N40646	002	Mar 30, 2007	Mar	NEWA

	TABLET; ORAL							
	HYDROCORTISONE							
AB	STIEFEL	20MG	N40646	003	Mar 30, 2007	Mar	NEWA	
	<u>HYDROCORTISONE BUTYRATE</u>							
>A>	LOTION; TOPICAL							
>A>	LOCOID							
>A>	+	FERNDAL LABS	0.1%	N22076	001	May 18, 2007	May	NEWA
	<u>HYDROMORPHONE HYDROCHLORIDE</u>							
	INJECTABLE; INJECTION							
	HYDROMORPHONE HYDROCHLORIDE							
AP	BARR	10MG/ML	N76444	001	Apr 25, 2003	Apr	CAHN	
	@	WATSON LABS	10MG/ML	N74317	001	Aug 23, 1995	Feb	DISC
	<u>HYDROXYZINE HYDROCHLORIDE</u>							
	INJECTABLE; INJECTION							
	HYDROXYZINE HYDROCHLORIDE							
	@	HOSPIRA	25MG/ML	N87416	001		Feb	DISC
	@		50MG/ML	N87546	001		Feb	DISC
	@	WATSON LABS	50MG/ML	N85779	001		Feb	DISC
	TABLET; ORAL							
	HYDROXYZINE HYDROCHLORIDE							
AB	KVK-TECH INC	10MG	N40786	001	Mar 20, 2007	Mar	NEWA	
AB		25MG	N40787	001	Mar 20, 2007	Mar	NEWA	
AB		50MG	N40788	001	Mar 20, 2007	Mar	NEWA	
	<u>IDARUBICIN HYDROCHLORIDE</u>							
	INJECTABLE; INJECTION							
	IDARUBICIN HYDROCHLORIDE							
>A>	AP	BEDFORD LABS	1MG/ML	N65288	001	May 15, 2007	May	NEWA
	<u>IFOSFAMIDE</u>							
	INJECTABLE; INJECTION							
	IFOSFAMIDE							
	+	SICOR PHARMS	1GM/20ML (50MG/ML)	N76657	001	Apr 04, 2007	Mar	NEWA
	+		3GM/60ML (50MG/ML)	N76657	002	Apr 04, 2007	Mar	NEWA
	<u>ILOPROST</u>							
	SOLUTION; INHALATION							
	VENTAVIS							
	+	ACTELION	10UGM/ML (10UGM/ML)	N21779	002	Dec 08, 2005	Jan	CAHN
	+		20UGM/2ML (10UGM/ML)	N21779	001	Dec 29, 2004	Jan	CAHN
	+	ACTELION PHARM	10UGM/ML (10UGM/ML)	N21779	002	Dec 08, 2005	Feb	CAHN
	+		20UGM/2ML (10UGM/ML)	N21779	001	Dec 29, 2004	Feb	CAHN
	<u>IMIQUIMOD</u>							
	CREAM; TOPICAL							
	ALDARA							
	+	GRACEWAY	5%	N20723	001	Feb 27, 1997	Jan	CAHN
	<u>INDIUM IN-111 CHLORIDE</u>							
	INJECTABLE; INJECTION							
	INDICLOR							
>D>	+	AMERSHAM	2mCi/0.2ML	N19862	001	Dec 29, 1992	May	CAHN

## INJECTABLE; INJECTION

## INDICLOR

>A>	+	GE HEALTHCARE	2mCi/0.2ML	N19862 001	Dec 29, 1992	May	CAHN
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INDOMETHACIN

## CAPSULE; ORAL

## INDOMETHACIN

	@	HERITAGE PHARMS INC	25MG	N18851 001	May 18, 1984	Feb	CAHN
	@		50MG	N18851 002	May 18, 1984	Feb	CAHN
AB		MYLAN	25MG	N18858 001	Apr 20, 1984	Feb	CTEC
	@		50MG	N18858 002	Apr 20, 1984	Mar	DISC
AB	+		50MG	N70624 001	Sep 04, 1985	Mar	CRLD
AB		SANDOZ	25MG	N70673 001	Apr 29, 1987	Feb	CMFD
AB			50MG	N70674 001	Apr 29, 1987	Feb	CMFD

INSULIN GLULISINE RECOMBINANT

>A>			INJECTABLE; IV (INFUSION)-SC				
>A>			APIDRA				
>A>	+	SANOFI AVENTIS US	1000 UNITS/10ML (100 UNITS/ML)	N21629 001	Apr 16, 2004	May	CDFR
>A>	+		300 UNITS/3ML (100 UNITS/ML)	N21629 002	Dec 20, 2005	May	CDFR
>D>			INJECTABLE; SUBCUTANEOUS				
>D>			APIDRA				
>D>	+	SANOFI AVENTIS US	1000 UNITS/10ML (100 UNITS/ML)	N21629 001	Apr 16, 2004	May	CDFR
>D>	+		300 UNITS/3ML (100 UNITS/ML)	N21629 002	Dec 20, 2005	May	CDFR

IRON SUCROSE

## INJECTABLE; INTRAVENOUS

## VENOFER

## @ LUITPOLD

EQ 50MG BASE/2.5ML(EQ 20MG  
BASE/ML)

N21135 002 Mar 20, 2005 Feb DISC

## @

EQ 75MG BASE/3.75ML(EQ 20MG  
BASE/ML)

N21135 003 Mar 29, 2005 Feb DISC

EQ 200MG BASE/10ML(EQ 20MG  
BASE/ML)

N21135 004 Feb 09, 2007 Feb NEWA

ISOSORBIDE DINITRATE

## TABLET; ORAL

## ISOSORBIDE DINITRATE

AB		WEST WARD	30MG	N40591 001	Jan 10, 2007	Jan	NEWA
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KETOPROFEN

## CAPSULE; ORAL

## KETOPROFEN

AB		HERITAGE PHARMS INC	25MG	N74014 001	Jan 29, 1993	Feb	CAHN
AB			50MG	N74014 002	Jan 29, 1993	Feb	CAHN
AB			75MG	N74014 003	Jan 29, 1993	Feb	CAHN

KETOROLAC TROMETHAMINE

## INJECTABLE; INJECTION

## KETOROLAC TROMETHAMINE

	@	AMPHASTAR PHARM	15MG/ML	N76209 001	Jul 21, 2004	Mar	DISC
	@		30MG/ML	N76209 002	Jul 21, 2004	Mar	DISC
	@	APOTEX INC	30MG/ML	N75626 001	Jul 24, 2001	Mar	DISC
	@		30MG/ML	N77201 001	Oct 14, 2005	Mar	DISC
	@	GLAND PHARMA LTD	15MG/ML	N76722 001	Jul 27, 2004	Mar	DISC
	@		30MG/ML	N76722 002	Jul 27, 2004	Mar	DISC
AP		WOCKHARDT	15MG/ML	N77942 001	Mar 27, 2007	Mar	NEWA

## INJECTABLE; INJECTION

## KETOROLAC TROMETHAMINE

AP	WOCKHARDT	30MG/ML	N77942 002	Mar 27, 2007	Mar	NEWA
AP		30MG/ML	N77943 001	Mar 27, 2007	Mar	NEWA

LAPATINIB DITOSYLATE

## TABLET; ORAL

## TYKERB

+	GLAXOSMITHKLINE	EQ 250MG BASE	N22059 001	Mar 13, 2007	Mar	NEWA
+	SMITHKLINE BEECHAM	EQ 250MG BASE	N22059 001	Mar 13, 2007	Apr	CAHN

LEUCOVORIN CALCIUM

## INJECTABLE; INJECTION

## LEUCOVORIN CALCIUM

>D>	AP	PHARMACHEMIE	EQ 350MG BASE/VIAL	N40262 001	Dec 15, 1999	May	DISC
>A>		@	EQ 350MG BASE/VIAL	N40262 001	Dec 15, 1999	May	DISC
>D>	AP	PHARMACHEMIE USA	EQ 50MG BASE/VIAL	N89628 001	Apr 17, 1997	May	DISC
>A>		@	EQ 50MG BASE/VIAL	N89628 001	Apr 17, 1997	May	DISC

## TABLET; ORAL

## LEUCOVORIN CALCIUM

@	PHARMACHEMIE	EQ 5MG BASE	N73099 001	Mar 28, 1997	Jan	DISC
@		EQ 25MG BASE	N73101 001	Mar 28, 1997	Jan	DISC

LEUPROLIDE ACETATE

## INJECTABLE; SUBCUTANEOUS

## ELIGARD

+	SANOFI AVENTIS US	7.5MG/VIAL	N21343 001	Jan 23, 2002	Jan	CAHN
+		22.5MG/VIAL	N21379 001	Jul 24, 2002	Jan	CAHN
+		30MG/VIAL	N21488 001	Feb 13, 2003	Jan	CAHN
+		45MG/VIAL	N21731 001	Dec 14, 2004	Jan	CAHN

LEVOCARNITINE

## SOLUTION; ORAL

## CARNITOR SF

AA	SIGMA TAU	1GM/10ML	N19257 002	Mar 28, 2007	Mar	NEWA
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>A> LEVOCETIRIZINE DIHYDROCHLORIDE

## &gt;A&gt; TABLET; ORAL

## &gt;A&gt; XYZAL

>A>	+	UCB INC	5MG	N22064 001	May 25, 2007	May	NEWA
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LIDOCAINE

## PATCH; TOPICAL

## LIDOCAINE

+	NOVEN	46.1MG/PATCH	N20575 002	May 21, 1996	Jan	CDFR
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LIDOCAINE HYDROCHLORIDE

## SOLUTION; ORAL

## LIDOCAINE HYDROCHLORIDE VISCOUS

AT	VINTAGE	2%	N40708 001	Feb 27, 2007	Feb	NEWA
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## SOLUTION; TOPICAL

## LIDOCAINE HYDROCHLORIDE

AT	VINTAGE	4%	N40710 001	Feb 27, 2007	Feb	NEWA
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LIDOCAINE; TETRACAINE

CREAM; TOPICAL

LIDOCAINE AND TETRACAINE

+	GALDERMA LABS LP	7%;7%	N21717 001	Jun 29, 2006	Apr	CAHN
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LIOTHYRONINE SODIUM

INJECTABLE; INJECTION

TRIOSTAT

AP	+	KING PHARMS	EQ 0.01MG BASE/ML	N20105 001	Dec 31, 1991	Apr	CAHN
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LISDEXAMFETAMINE DIMESYLATE

CAPSULE; ORAL

VYVANSE

>D>		NEW RIVER	30MG	N21977 001	Feb 23, 2007	May	CAHN
			30MG	N21977 001	Feb 23, 2007	Feb	NEWA
>D>			50MG	N21977 002	Feb 23, 2007	May	CAHN
			50MG	N21977 002	Feb 23, 2007	Feb	NEWA
>D>	+		70MG	N21977 003	Feb 23, 2007	May	CAHN
	+		70MG	N21977 003	Feb 23, 2007	Feb	NEWA
>A>		NEW RIVER PHARMS	30MG	N21977 001	Feb 23, 2007	May	CAHN
>A>			50MG	N21977 002	Feb 23, 2007	May	CAHN
>A>	+		70MG	N21977 003	Feb 23, 2007	May	CAHN

LISINAPRIL

TABLET; ORAL

LISINAPRIL

AB		WOCKHARDT	2.5MG	N78402 001	Apr 19, 2007	Apr	NEWA
AB			5MG	N78402 002	Apr 19, 2007	Apr	NEWA
AB			10MG	N78402 003	Apr 19, 2007	Apr	NEWA
AB			20MG	N78402 004	Apr 19, 2007	Apr	NEWA
AB			30MG	N78402 005	Apr 19, 2007	Apr	NEWA
AB			40MG	N78402 006	Apr 19, 2007	Apr	NEWA

LOVASTATIN

TABLET; ORAL

LOVASTATIN

AB		APOTEX INC	10MG	N77748 001	Feb 28, 2007	Feb	NEWA
AB			20MG	N77748 002	Feb 28, 2007	Feb	NEWA
AB			40MG	N77748 003	Feb 28, 2007	Feb	NEWA

TABLET, EXTENDED RELEASE; ORAL

ALTOPREV

@	ANDRX LABS LLC	10MG	N21316 001	Jun 26, 2002	Feb	DISC
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LOVASTATIN; NIACIN

TABLET, EXTENDED RELEASE; ORAL

ADVICOR

+	ABBOTT	20MG;500MG	N21249 001	Dec 17, 2001	Mar	CAHN
+		20MG;750MG	N21249 002	Dec 17, 2001	Mar	CAHN
+		20MG;1GM	N21249 003	Dec 17, 2001	Mar	CAHN
+		40MG;1GM	N21249 004	Apr 27, 2006	Mar	CAHN

MAFENIDE ACETATE

CREAM; TOPICAL

SULFAMYLON

>D>	+	MYLAN BERTEK	EQ 85MG BASE/GM	N16763 001		May	CAHN
>A>	+	UDL LABS	EQ 85MG BASE/GM	N16763 001		May	CAHN

FOR SOLUTION; TOPICAL

SULFAMYLON

>D>	+	MYLAN BERTEK	5%	N19832 003	Jun 05, 1998	May	CAHN
>A>	+	UDL LABS	5%	N19832 003	Jun 05, 1998	May	CAHN

MAGNESIUM SULFATE

INJECTABLE; INJECTION

MAGNESIUM SULFATE IN PLASTIC CONTAINER

HOSPIRA

			2GM/50ML (40MG/ML)	N20309 003	Jan 26, 2007	Jan	NEWA
	+		4GM/100ML (40MG/ML)	N20309 001	Jun 24, 1994	Jan	CPOT
	+		4GM/50ML (80MG/ML)	N20309 002	Jun 24, 1994	Jan	CPOT

MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

POLOCAINE

>A>	AP	ABRAXIS BIOSCIENCE	1%	N89407 001	Dec 01, 1986	May	CAHN
>A>	AP		2%	N89410 001	Dec 01, 1986	May	CAHN
>D>	AP	ASTRAZENECA	1%	N89407 001	Dec 01, 1986	May	CAHN
>D>	AP		2%	N89410 001	Dec 01, 1986	May	CAHN

POLOCAINE-MPF

>A>	AP	ABRAXIS BIOSCIENCE	1%	N89406 001	Dec 01, 1986	May	CAHN
>A>	AP		1.5%	N89408 001	Dec 01, 1986	May	CAHN
>A>	AP		2%	N89409 001	Dec 01, 1986	May	CAHN
>D>	AP	ASTRAZENECA	1%	N89406 001	Dec 01, 1986	May	CAHN
>D>	AP		1.5%	N89408 001	Dec 01, 1986	May	CAHN
>D>	AP		2%	N89409 001	Dec 01, 1986	May	CAHN

MERCAPTOPYRINE

TABLET; ORAL

MERCAPTOPYRINE

>A>	AB	MYLAN	50MG	N40594 001	Jul 01, 2005	May	CAIN
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MERCAPTOPYRINE ANHYDROUS

TABLET; ORAL

MERCAPTOPYRINE

>D>	AB	MYLAN	50MG	N40594 001	Jul 01, 2005	May	CAIN
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MESALAMINE

TABLET, DELAYED RELEASE; ORAL

LIALDA

	+	SHIRE	1.2GM	N22000 001	Jan 16, 2007	Jan	NEWA
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METFORMIN HYDROCHLORIDE

TABLET; ORAL

METFORMIN HYDROCHLORIDE

AB		TORRENT PHARMS	500MG	N77711 001	Jan 24, 2007	Jan	NEWA
AB			850MG	N77711 002	Jan 24, 2007	Jan	NEWA
AB			1GM	N77711 003	Jan 24, 2007	Jan	NEWA

>A> METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE

&gt;A&gt; TABLET; ORAL

&gt;A&gt; ACTOPLUS MET

&gt;A&gt; TAKEDA GLOBAL 500MG;EQ 15MG BASE N21842 001 Aug 29, 2005 May CAIN

&gt;A&gt; + 850MG;EQ 15MG BASE N21842 002 Aug 29, 2005 May CAIN

METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE

TABLET; ORAL

JANUMET

MERCCK

500MG;EQ 50MG BASE

N22044 001 Mar 30, 2007 Mar NEWA

+

1GM;EQ 50MG BASE

N22044 002 Mar 30, 2007 Mar NEWA

>D> METFORMIN; PIOGLITAZONE HYDROCHLORIDE

&gt;D&gt; TABLET; ORAL

&gt;D&gt; ACTOPLUS MET

&gt;D&gt; TAKEDA GLOBAL 500MG;EQ 15MG BASE N21842 001 Aug 29, 2005 May CAIN

&gt;D&gt; + 850MG;EQ 15MG BASE N21842 002 Aug 29, 2005 May CAIN

METHADONE HYDROCHLORIDE

TABLET; ORAL

METHADONE HYDROCHLORIDE

&gt;D&gt; AA ROXANE 5MG N88108 001 Mar 08, 1983 May DISC

&gt;A&gt; @ 5MG N88108 001 Mar 08, 1983 May DISC

&gt;D&gt; AA 10MG N88109 001 Mar 08, 1983 May DISC

&gt;A&gt; @ 10MG N88109 001 Mar 08, 1983 May DISC

&gt;D&gt; AA 40MG N74081 001 Apr 28, 1995 May DISC

&gt;A&gt; @ 40MG N74081 001 Apr 28, 1995 May DISC

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE LPF

@ HOSPIRA

EQ 25MG BASE/ML

N11719 007 Mar 31, 1982 Apr CAHN

METHOTREXATE PRESERVATIVE FREE

@ HOSPIRA

EQ 20MG BASE/2ML (10 MG/ML)

N11719 014 Apr 13, 2005 Apr CAHN

@

EQ 500MG BASE/20ML (25 MG/ML)

N11719 013 Apr 13, 2005 Apr CAHN

@

EQ 2.5GM BASE/100ML (25 MG/ML)

N11719 011 Apr 13, 2005 Apr CAHN

METHOTREXATE SODIUM

AP + ABRAXIS PHARM

EQ 50MG BASE/2ML (25MG/ML)

N40263 001 Feb 26, 1999 Apr CTNA

AP +

EQ 250MG BASE/10ML (25MG/ML)

N40263 002 Feb 26, 1999 Apr CTNA

@ HOSPIRA

EQ 2.5MG BASE/ML

N11719 004 Apr CAHN

@

EQ 20MG BASE/VIAL

N11719 001 Apr CAHN

@

EQ 25MG BASE/ML

N11719 005 Apr CAHN

@

EQ 50MG BASE/VIAL

N11719 003 Apr CAHN

AP +

EQ 50MG BASE/2ML (25 MG/ML)

N11719 010 Dec 15, 2004 Apr CTNA

@

EQ 100MG BASE/VIAL

N11719 006 Apr CAHN

METHOTREXATE SODIUM PRESERVATIVE FREE

AP + BEDFORD

EQ 50MG BASE/2ML (25MG/ML)

N89340 001 Sep 16, 1986 Apr CTNA

AP +

EQ 250MG BASE/10ML (25MG/ML)

N89343 001 Sep 16, 1986 Apr CTEC

AP + GENERAMEDIX

EQ 50MG BASE/2ML (25MG/ML)

N40767 001 Apr 30, 2007 Apr NEWA

AP +

EQ 250MG BASE/10ML (25MG/ML)

N40768 001 Apr 30, 2007 Apr NEWA

AP +

EQ 1GM BASE/40ML (25MG/ML)

N40716 001 Apr 30, 2007 Apr NEWA

@ HOSPIRA

EQ 1GM BASE/VIAL

N11719 009 Apr 07, 1988 Apr CAHN

AP +

EQ 1GM BASE/40ML (25MG/ML)

N11719 012 Apr 13, 2005 Apr CAHN

METHYLPHENIDATE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

METADATE CD

>D>	BX	+	UCB INC	30MG	N21259 002	Jun 19, 2003	May	CRLD
>A>	BX			30MG	N21259 002	Jun 19, 2003	May	CRLD

TABLET, EXTENDED RELEASE; ORAL

CONCERTA

			ALZA	18MG	N21121 001	Aug 01, 2000	Apr	CAHN
				27MG	N21121 004	Apr 01, 2002	Apr	CAHN
				36MG	N21121 002	Aug 01, 2000	Apr	CAHN
		+		54MG	N21121 003	Dec 08, 2000	Apr	CAHN
			JOHNSON AND JOHNSON	18MG	N21121 001	Aug 01, 2000	Feb	CAHN
				27MG	N21121 004	Apr 01, 2002	Feb	CAHN
				36MG	N21121 002	Aug 01, 2000	Feb	CAHN
		+		54MG	N21121 003	Dec 08, 2000	Feb	CAHN

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

METHYLPREDNISOLONE SODIUM SUCCINATE

AP			BEDFORD LABS	EQ 40MG BASE/VIAL	N40662 001	Feb 21, 2007	Feb	NEWA
AP				EQ 125MG BASE/VIAL	N40641 002	Feb 21, 2007	Feb	NEWA
AP				EQ 500MG BASE/VIAL	N40641 003	Feb 21, 2007	Feb	NEWA
AP				EQ 500MG BASE/VIAL	N40709 001	Feb 21, 2007	Feb	NEWA
AP				EQ 1GM BASE/VIAL	N40641 004	Feb 21, 2007	Feb	NEWA
AP				EQ 1GM BASE/VIAL	N40709 002	Feb 21, 2007	Feb	NEWA

METOLAZONE

TABLET; ORAL

METOLAZONE

>D>	AB		ROXANE	10MG	N76482 002	Apr 29, 2004	May	DISC
>A>			@	10MG	N76482 002	Apr 29, 2004	May	DISC

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL

METOPROLOL SUCCINATE

>A>	AB		KV PHARM	EQ 100MG TARTRATE	N76640 002	May 18, 2007	May	NEWA
>A>	AB			EQ 200MG TARTRATE	N76640 001	May 18, 2007	May	NEWA
>A>	AB		SANDOZ	EQ 50MG TARTRATE	N76969 002	May 18, 2007	May	NEWA
			TOPROL-XL					
>D>		+	ASTRAZENECA	EQ 50MG TARTRATE	N19962 001	Jan 10, 1992	May	CFTG
>A>	AB	+		EQ 50MG TARTRATE	N19962 001	Jan 10, 1992	May	CFTG
>D>				EQ 100MG TARTRATE	N19962 002	Jan 10, 1992	May	CFTG
>A>	AB			EQ 100MG TARTRATE	N19962 002	Jan 10, 1992	May	CFTG
>D>		+		EQ 200MG TARTRATE	N19962 003	Jan 10, 1992	May	CFTG
>A>	AB	+		EQ 200MG TARTRATE	N19962 003	Jan 10, 1992	May	CFTG

METOPROLOL TARTRATE

INJECTABLE; INJECTION

METOPROLOL TARTRATE

>A>	AP		HIKMA FARMACEUTICA	1MG/ML	N77761 001	May 30, 2007	May	NEWA
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METRONIDAZOLE

GEL; VAGINAL

METROGEL-VAGINAL

AB	+	GRACEWAY	0.75%	N20208 001	Aug 17, 1992	Jan	CAHN
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MEXILETINE HYDROCHLORIDE

CAPSULE; ORAL

MEXILETINE HYDROCHLORIDE

AB	+	TEVA	250MG	N74377 003	May 16, 1995	Apr	CRLD
		MEXITIL					
		@ BOEHRINGER INGELHEIM	150MG	N18873 002	Dec 30, 1985	Apr	DISC
		@	200MG	N18873 003	Dec 30, 1985	Apr	DISC
		@	250MG	N18873 004	Dec 30, 1985	Apr	DISC

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

MIDAZOLAM HYDROCHLORIDE

AP	+	HOSPIRA	EQ 1MG BASE/ML	N75293 001	Jun 20, 2000	Apr	CRLD
AP		TAYLOR	EQ 1MG BASE/ML	N75494 001	Jun 30, 2000	Feb	CAHN
AP			EQ 5MG BASE/ML	N75494 002	Jun 30, 2000	Feb	CAHN
		MIDAZOLAM HYDROCHLORIDE PRESERVATIVE FREE					
AP	+	HOSPIRA	EQ 1MG BASE/ML	N75857 001	Jul 22, 2002	Feb	CTNA
AP	+		EQ 5MG BASE/ML	N75857 002	Jul 22, 2002	Feb	CTNA

MITOMYCIN

INJECTABLE; INJECTION

MITOZYTREX

	+	SUPERGEN	5MG/VIAL	N50763 001	Nov 14, 2002	Jan	CTNA
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MITOXANTRONE HYDROCHLORIDE

INJECTABLE; INJECTION

NOVANTRONE

AP	+	EMD SERONO	EQ 20MG BASE/10ML (2MG/ML)	N19297 001	Dec 23, 1987	Mar	CAHN
AP	+		EQ 25MG BASE/12.5ML (2MG/ML)	N19297 002	Dec 23, 1987	Mar	CAHN
AP	+		EQ 30MG BASE/15ML (2MG/ML)	N19297 003	Dec 23, 1987	Mar	CAHN

MOMETASONE FUROATE

CREAM; TOPICAL

MOMETASONE FUROATE

AB		TOLMAR	0.1%	N76591 001	Apr 18, 2007	Apr	NEWA
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MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

AVINZA

BX		KING PHARMS	30MG	N21260 001	Mar 20, 2002	Mar	CAHN
BX			60MG	N21260 002	Mar 20, 2002	Mar	CAHN
			90MG	N21260 003	Mar 20, 2002	Mar	CAHN
	+		120MG	N21260 004	Mar 20, 2002	Mar	CAHN
		KADIAN					
		ALPHARMA BRANDED	10MG	N20616 008	Apr 20, 2007	Apr	NEWA
			20MG	N20616 001	Jul 03, 1996	Apr	CAHN
BX			30MG	N20616 004	Mar 09, 2001	Apr	CAHN
			50MG	N20616 002	Jul 03, 1996	Apr	CAHN
BX			60MG	N20616 005	Mar 09, 2001	Apr	CAHN

## CAPSULE, EXTENDED RELEASE; ORAL

## KADIAN

	ALPHARMA BRANDED	80MG	N20616 006	Oct 27, 2006	Apr	CAHN
+		100MG	N20616 003	Jul 03, 1996	Apr	CAHN
		200MG	N20616 007	Feb 27, 2007	Apr	CAHN
	ALPHARMA US PHARMS	200MG	N20616 007	Feb 27, 2007	Feb	NEWA

## INJECTABLE; INJECTION

## ASTRAMORPH PF

>A>	AP	ABRAXIS BIOSCIENCE	0.5MG/ML	N71050 001	Oct 07, 1986	May	CAHN
>A>	AP		0.5MG/ML	N71051 001	Oct 07, 1986	May	CAHN
>A>	AP		1MG/ML	N71052 001	Oct 07, 1986	May	CAHN
>A>	AP		1MG/ML	N71053 001	Oct 07, 1986	May	CAHN
>D>	AP	ASTRAZENECA	0.5MG/ML	N71050 001	Oct 07, 1986	May	CAHN
>D>	AP		0.5MG/ML	N71051 001	Oct 07, 1986	May	CAHN
>D>	AP		1MG/ML	N71052 001	Oct 07, 1986	May	CAHN
>D>	AP		1MG/ML	N71053 001	Oct 07, 1986	May	CAHN

NALBUPHINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## NALBUPHINE HYDROCHLORIDE

AP		BARR	10MG/ML	N74471 001	Mar 19, 1998	Apr	CAHN
AP			20MG/ML	N74471 002	Mar 19, 1998	Apr	CAHN
AP	+	HOSPIRA	10MG/ML	N70914 001	Feb 03, 1989	Feb	CRLD
AP	+		10MG/ML	N70915 001	Feb 03, 1989	Feb	CRLD
AP	+		20MG/ML	N70916 001	Feb 03, 1989	Feb	CRLD
AP	+		20MG/ML	N70918 001	Feb 03, 1989	Feb	CRLD
		NUBAIN					
	@	ENDO PHARMS	10MG/ML	N18024 001		Feb	DISC
	@		20MG/ML	N18024 002	May 27, 1982	Feb	DISC

NAPROXEN

## TABLET; ORAL

## NAPROXEN

AB		GLENMARK PHARMS INC	250MG	N78250 001	Mar 28, 2007	Mar	NEWA
AB			375MG	N78250 002	Mar 28, 2007	Mar	NEWA
AB			500MG	N78250 003	Mar 28, 2007	Mar	NEWA

NAPROXEN SODIUM

## TABLET; ORAL

## NAPROXEN SODIUM

AB		GLENMARK PHARMS	EQ 250MG BASE	N78314 001	Apr 27, 2007	Apr	NEWA
AB			EQ 500MG BASE	N78314 002	Apr 27, 2007	Apr	NEWA
AB		INTERPHARM	EQ 250MG BASE	N78432 001	Apr 25, 2007	Apr	NEWA
AB			EQ 500MG BASE	N78432 002	Apr 25, 2007	Apr	NEWA

NELFINAVIR MESYLATE

## POWDER; ORAL

## VIRACEPT

+		AGOURON	EQ 50MG BASE/SCOOPFUL	N20778 001	Mar 14, 1997	Mar	CDFR
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NEOMYCIN SULFATE

## TABLET; ORAL

## NEOMYCIN SULFATE

AA	+	TEVA	500MG	N60304 001		Apr	CTEC
AA		X GEN PHARMS	500MG	N65220 001	Jul 28, 2006	Apr	CTEC

NESIRITIDE RECOMBINANT

FOR SOLUTION; INTRAVENOUS

NATRECOR

+	ALZA CORP	1.5MG/VIAL	N20920 001	Aug 10, 2001	Jan	CAHN
+	SCIOS	1.5MG/VIAL	N20920 001	Aug 10, 2001	Feb	CAHN

NIACIN

TABLET, EXTENDED RELEASE; ORAL

NIASPAN

@	ABBOTT	375MG	N20381 001	Jul 28, 1997	Mar	CAHN
		500MG	N20381 002	Jul 28, 1997	Apr	CRLD
+		500MG	N20381 002	Jul 28, 1997	Mar	CAHN
+		750MG	N20381 003	Jul 28, 1997	Mar	CAHN
+		1GM	N20381 004	Jul 28, 1997	Mar	CAHN
	NIASPAN TITRATION STARTER PACK					
@	ABBOTT	375MG;500MG;750MG	N20381 005	Jul 28, 1997	Mar	CAHN

NIMODIPINE

CAPSULE; ORAL

NIMODIPINE

AB	BARR	30MG	N77811 001	May 02, 2007	Apr	NEWA
AB	SUN PHARM INDS INC	30MG	N77067 001	Apr 17, 2007	Apr	NEWA
	NIMOTOP					
AB	+ BAYER PHARMS	30MG	N18869 001	Dec 28, 1988	Apr	CFTG

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL

MINITRAN

AB1	GRACEWAY	0.1MG/HR	N89771 001	Aug 30, 1996	Jan	CAHN
AB1		0.2MG/HR	N89772 001	Aug 30, 1996	Jan	CAHN
AB1		0.4MG/HR	N89773 001	Aug 30, 1996	Jan	CAHN
AB1		0.6MG/HR	N89774 001	Aug 30, 1996	Jan	CAHN

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ONDANSETRON HYDROCHLORIDE

AP	HOSPIRA	EQ 2MG BASE/ML	N77840 001	Jan 19, 2007	Jan	NEWA
AP	PLIVA	EQ 2MG BASE/ML	N77582 001	Dec 26, 2006	Mar	CAHN
AP	SPECTRUM PHARMS	EQ 2MG BASE/ML	N78180 001	Mar 26, 2007	Mar	NEWA
	ONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER					
AP	HOSPIRA	EQ 0.64MG BASE/ML	N77348 001	Feb 01, 2007	Jan	NEWA
AP	MAYNE PHARMA USA	EQ 0.64MG BASE/ML	N76978 001	Feb 26, 2007	Feb	NEWA
	ONDANSETRON HYDROCHLORIDE PRESERVATIVE FREE					
AP	PLIVA	EQ 2MG BASE/ML	N77387 001	Dec 26, 2006	Mar	CAHN
	ZOFRAN AND DEXTROSE IN PLASTIC CONTAINER					
AP	+ GLAXOSMITHKLINE	EQ 0.64MG BASE/ML	N20403 001	Jan 31, 1995	Jan	CTNA

ORPHENADRINE CITRATE

INJECTABLE; INJECTION

NORFLEX

AP	+ GRACEWAY	30MG/ML	N13055 001		Jan	CAHN
	TABLET, EXTENDED RELEASE; ORAL					
	NORFLEX					
	@ GRACEWAY	100MG	N12157 001		Jan	CAHN

## TABLET, EXTENDED RELEASE; ORAL

## ORPHENADRINE CITRATE

AB	ACTAVIS TOTOWA	100MG	N40284 001	Jun 19, 1998	Mar	CAHN
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OXANDROLONE

## TABLET; ORAL

## OXANDROLONE

AB	UPSHER SMITH	10MG	N78033 001	Mar 22, 2007	Mar	NEWA
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OXYBUTYNIN CHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## OXYBUTYNIN CHLORIDE

>A>	AB	IMPAX PHARMS	5MG	N76745 002	May 09, 2007	May	NEWA
>A>	AB		10MG	N76745 003	May 09, 2007	May	NEWA
>A>	AB	MYLAN	15MG	N78293 001	May 10, 2007	May	NEWA

OXYCODONE HYDROCHLORIDE

## TABLET; ORAL

## OXYCODONE HYDROCHLORIDE

AB	KV PHARM	5MG	N77290 001	Dec 08, 2005	Mar	CTEC
AB	TYCO HLTHCARE	5MG	N78206 001	Mar 19, 2007	Mar	NEWA
AB	VINTAGE PHARMS	15MG	N77712 001	Jan 31, 2007	Jan	NEWA
AB		30MG	N77712 002	Jan 31, 2007	Jan	NEWA

## ROXICODONE

AB	+	XANODYNE PHARMS INC	15MG	N21011 001	Aug 31, 2000	Feb	CAHN
AB			30MG	N21011 002	Aug 31, 2000	Feb	CAHN

## TABLET, EXTENDED RELEASE; ORAL

## OXYCONTIN

>D>		PURDUE PHARMA LP	15MG	N20553 006	Sep 18, 2006	May	DISC
>A>		@	15MG	N20553 006	Sep 18, 2006	May	DISC
>D>			30MG	N20553 007	Sep 18, 2006	May	DISC
>A>		@	30MG	N20553 007	Sep 18, 2006	May	DISC
>D>			60MG	N20553 008	Sep 18, 2006	May	DISC
>A>		@	60MG	N20553 008	Sep 18, 2006	May	DISC

PAROXETINE HYDROCHLORIDE

## TABLET; ORAL

## PAROXETINE HYDROCHLORIDE

AB	ZYDUS PHARMS USA	EQ 10MG BASE	N77584 001	Mar 07, 2007	Feb	NEWA
AB		EQ 20MG BASE	N77584 002	Mar 07, 2007	Feb	NEWA
AB		EQ 30MG BASE	N77584 003	Mar 07, 2007	Feb	NEWA
AB		EQ 40MG BASE	N77584 004	Mar 07, 2007	Feb	NEWA

PENTOSTATIN

## INJECTABLE; INJECTION

## NIPENT

+	HOSPIRA INC	10MG/VIAL	N20122 001	Oct 11, 1991	Mar	CAHN
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PENTOXIFYLLINE

## TABLET, EXTENDED RELEASE; ORAL

## PENTOXIFYLLINE

AB	HERITAGE PHARMS INC	400MG	N74877 001	Jul 08, 1997	Feb	CAHN
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PERGOLIDE MESYLATE

TABLET; ORAL

PERGOLIDE MESYLATE

	@	IVAX PHARMS	EQ 0.05MG BASE	N76094 001	Sep 04, 2003	Mar	DISC
	@		EQ 0.25MG BASE	N76094 002	Sep 04, 2003	Mar	DISC
	@		EQ 1MG BASE	N76094 003	Sep 04, 2003	Mar	DISC
	@	PAR PHARM	EQ 0.05MG BASE	N76061 001	Nov 27, 2002	Mar	DISC
	@		EQ 0.25MG BASE	N76061 002	Nov 27, 2002	Mar	DISC
	@		EQ 1MG BASE	N76061 003	Nov 27, 2002	Mar	DISC
		PERMAX					
	@	VALEANT PHARM INTL	EQ 0.05MG BASE	N19385 001	Dec 30, 1988	Mar	DISC
AB			EQ 0.05MG BASE	N19385 001	Dec 30, 1988	Jan	CAHN
	@		EQ 0.25MG BASE	N19385 002	Dec 30, 1988	Mar	DISC
AB	+		EQ 0.25MG BASE	N19385 002	Dec 30, 1988	Jan	CAHN
	@		EQ 1MG BASE	N19385 003	Dec 30, 1988	Mar	DISC
AB			EQ 1MG BASE	N19385 003	Dec 30, 1988	Jan	CAHN

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HYDROCHLORIDE

AA	+	SANDOZ	30MG	N87190 001		Feb	CRLD
AA		TG UNITED INC	30MG	N40083 001	Mar 07, 1997	Feb	CAHN

PILOCARPINE HYDROCHLORIDE

TABLET; ORAL

PILOCARPINE HYDROCHLORIDE

AB		ROXANE	7.5MG	N76963 002	Feb 27, 2007	Feb	NEWA
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PIPERACILLIN SODIUM

INJECTABLE; INJECTION

PIPERACILLIN

	+	ISTITUTO BIOCHIMICO	EQ 2GM BASE/VIAL	N65114 001	Nov 14, 2003	Feb	CAHN
	+		EQ 3GM BASE/VIAL	N65114 002	Nov 14, 2003	Feb	CAHN
	+		EQ 4GM BASE/VIAL	N65114 003	Nov 14, 2003	Feb	CAHN
	+		EQ 40GM BASE/VIAL	N65157 001	Jul 12, 2004	Feb	CAHN

PIRBUTEROL ACETATE

AEROSOL, METERED; INHALATION

MAXAIR

	@	GRACEWAY	EQ 0.2MG BASE/INH	N19009 001	Dec 30, 1986	Jan	CAHN
	+		EQ 0.2MG BASE/INH	N20014 001	Nov 30, 1992	Jan	CAHN

POLYETHYLENE GLYCOL 3350

FOR SOLUTION; ORAL

POLYETHYLENE GLYCOL 3350

	AA	ANABOLIC LABS	17GM/SCOOPFUL	N77706 001	Sep 27, 2006	Jan	CAHN
>D>	AA	COASTAL PHARMS	17GM/SCOOPFUL	N77893 001	May 26, 2006	May	CAHN
>A>	AA	PADDOCK	17GM/SCOOPFUL	N77893 001	May 26, 2006	May	CAHN

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS

FOR SUSPENSION; ORAL

GO-EVAC

>A>	AA	BOCA PHARMA	236GM/BOT;2.97GM/BOT;6.74GM/BOT;5.86GM/BOT;22.74GM/BOT	N73433 001	Apr 28, 1992	May	CAHN
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## FOR SUSPENSION; ORAL

## GO-EVAC

>D>	AA	COPLEY PHARM	236GM/BOT;2.97GM/BOT;6.74GM/BOT;5.86GM/BOT;22.74GM/BOT	N73433 001	Apr 28, 1992	May	CAHN
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PRAVASTATIN SODIUM

## TABLET; ORAL

## PRAVACHOL

AB	+	BRISTOL MYERS SQUIBB	80MG	N19898 008	Dec 18, 2001	Apr	CFTG
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## PRAVASTATIN SODIUM

>A>	AB	GLENMARK PHARMS	10MG	N77987 001	May 11, 2007	May	NEWA
>A>	AB		20MG	N77987 002	May 11, 2007	May	NEWA
>A>	AB		40MG	N77987 003	May 11, 2007	May	NEWA
	AB	RANBAXY	10MG	N76445 001	Apr 23, 2007	Apr	NEWA
	AB		20MG	N76445 002	Apr 23, 2007	Apr	NEWA
	AB		40MG	N76445 003	Apr 23, 2007	Apr	NEWA
	AB		80MG	N76445 004	Apr 23, 2007	Apr	NEWA

PREDNICARBATE

## OINTMENT; TOPICAL

## DERMATOP

AB	+	SANOFI AVENTIS US	0.1%	N19568 001	Sep 23, 1991	Feb	CFTG
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## PREDNICARBATE

AB		ALTANA	0.1%	N77236 001	Mar 09, 2007	Feb	NEWA
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PROCAINAMIDE HYDROCHLORIDE

## CAPSULE; ORAL

## PROCAINAMIDE HYDROCHLORIDE

	@	IVAX PHARMS	250MG	N84604 001		Jan	DISC
	@		375MG	N84595 001		Jan	DISC
	@		500MG	N84606 001		Jan	DISC
	@	WATSON LABS	250MG	N83287 001		Jan	DISC
	@		375MG	N84403 001		Jan	DISC
	@		500MG	N84280 001		Jan	DISC

## PRONESTYL

	@	APOTHECON	250MG	N07335 001		Jan	DISC
	@		375MG	N07335 004		Jan	DISC
	@		500MG	N07335 003		Jan	DISC

## TABLET, EXTENDED RELEASE; ORAL

## PRONESTYL-SR

	@	APOTHECON	500MG	N87361 001		Jan	DISC
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PROCHLORPERAZINE

## SUPPOSITORY; RECTAL

## COMPAZINE

	@	GLAXOSMITHKLINE	25MG	N11127 002		Feb	DISC
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## PROCHLORPERAZINE

AB	+	G AND W LABS	25MG	N40058 001	Nov 24, 1993	Feb	CRLD
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PROCHLORPERAZINE EDISYLATE

## INJECTABLE; INJECTION

## COMPAZINE

	@	GLAXOSMITHKLINE	EQ 5MG BASE/ML	N10742 002		Feb	DISC
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## PROCHLORPERAZINE

	@	BAXTER HLTHCARE	EQ 5MG BASE/ML	N87759 001	Oct 01, 1982	Feb	DISC
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## INJECTABLE; INJECTION

## PROCHLORPERAZINE EDISYLATE

AP	+	BAXTER HLTHCARE	EQ 5MG BASE/ML	N89903 001	Aug 29, 1989	Feb	CRLD
		@ HOSPIRA	EQ 5MG BASE/ML	N89703 001	Apr 07, 1988	Feb	DISC
		@ WATSON LABS	EQ 5MG BASE/ML	N89530 001	Jul 08, 1987	Feb	DISC

PROCHLORPERAZINE MALEATE

## CAPSULE, EXTENDED RELEASE; ORAL

## COMPAZINE

		@ GLAXOSMITHKLINE	EQ 15MG BASE	N21019 002	Oct 06, 1999	Jan	DISC
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## TABLET; ORAL

## COMPAZINE

		@ GLAXOSMITHKLINE	EQ 5MG BASE	N10571 001		Feb	DISC
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		@	EQ 10MG BASE	N10571 002		Feb	DISC
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		@	EQ 25MG BASE	N10571 003		Feb	DISC
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## PROCHLORPERAZINE MALEATE

AB	+	SANDOZ	EQ 10MG BASE	N40101 002	Jul 19, 1996	Feb	CRLD
		@	EQ 25MG BASE	N40101 003	Jul 19, 1996	Feb	DISC

PROMETHAZINE HYDROCHLORIDE

## SYRUP; ORAL

## PROMETHAZINE HYDROCHLORIDE

AA		TARO	6.25MG/5ML	N40718 001	Apr 04, 2007	Mar	NEWA
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## TABLET; ORAL

## PROMETHAZINE HYDROCHLORIDE

AB		KVK-TECH INC	12.5MG	N40712 002	May 04, 2007	Apr	NEWA
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PROPOXYPHENE HYDROCHLORIDE

## CAPSULE; ORAL

## DOLENE

		@ HERITAGE PHARMS INC	65MG	N80530 001		Feb	CAHN
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PROPRANOLOL HYDROCHLORIDE

## CAPSULE, EXTENDED RELEASE; ORAL

## INDERAL LA

AB		WYETH PHARMS INC	60MG	N18553 004	Mar 18, 1987	Jan	CTEC
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AB			80MG	N18553 002	Apr 19, 1983	Jan	CTEC
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AB			120MG	N18553 003	Apr 19, 1983	Jan	CTEC
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AB	+		160MG	N18553 001	Apr 19, 1983	Jan	CTEC
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## PROPRANOLOL HYDROCHLORIDE

AB		MYLAN	60MG	N78022 001	Feb 15, 2007	Feb	NEWA
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AB			80MG	N78022 002	Feb 15, 2007	Feb	NEWA
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AB			120MG	N78022 003	Feb 15, 2007	Feb	NEWA
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AB			160MG	N78022 004	Feb 15, 2007	Feb	NEWA
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AB		PAR PHARM	60MG	N78065 001	Jan 26, 2007	Jan	NEWA
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AB			80MG	N78065 002	Jan 26, 2007	Jan	NEWA
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AB			120MG	N78065 003	Jan 26, 2007	Jan	NEWA
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AB			160MG	N78065 004	Jan 26, 2007	Jan	NEWA
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## &gt;D&gt; CONCENTRATE; ORAL

## &gt;D&gt; PROPRANOLOL HYDROCHLORIDE INTENSOL

>D>	+	ROXANE	80MG/ML	N71388 001	May 15, 1987	May	DISC
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>A>		@	80MG/ML	N71388 001	May 15, 1987	May	DISC
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## TABLET; ORAL

## INDERAL

		@ WYETH PHARMS INC	10MG	N16418 001		Jan	DISC
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		@	20MG	N16418 003		Jan	DISC
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PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION  
 PYRIDOXINE HYDROCHLORIDE

+	ABRAXIS PHARM	100MG/ML	N80618 001		Jan	CRLD
	@ WATSON LABS	100MG/ML	N80572 001		Jan	DISC

QUETIAPINE FUMARATE

>A>	TABLET, EXTENDED RELEASE; ORAL					
>A>	SEROQUEL XR					
>A>	ASTRAZENECA	50MG	N22047 001	May 17, 2007	May	NEWA
>A>		200MG	N22047 002	May 17, 2007	May	NEWA
>A>		300MG	N22047 003	May 17, 2007	May	NEWA
>A>	+	400MG	N22047 004	May 17, 2007	May	NEWA

QUINIDINE SULFATE

TABLET; ORAL  
 QUINIDINE SULFATE

	@ WATSON LABS	200MG	N83288 001		Mar	DISC
	@	300MG	N85583 001		Apr	DISC

RABEPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL  
 ACIPHEX

AB	+	EISAI MEDCL RES	20MG	N20973 002	Aug 19, 1999	Feb	CFTG
AB		RABEPRAZOLE SODIUM					
		TEVA	20MG	N76822 001	Feb 21, 2007	Feb	NEWA

RAMIPRIL

CAPSULE; ORAL  
 ALTACE

	KING PHARMS	1.25MG	N19901 001	Jan 28, 1991	Jan	CTEC
		2.5MG	N19901 002	Jan 28, 1991	Jan	CTEC
		5MG	N19901 003	Jan 28, 1991	Jan	CTEC
	+	10MG	N19901 004	Jan 28, 1991	Jan	CTEC
	RAMIPRIL					
	@ COBALT	1.25MG	N76549 001	Oct 24, 2005	Jan	DISC
	@	2.5MG	N76549 002	Oct 24, 2005	Jan	DISC
	@	5MG	N76549 003	Oct 24, 2005	Jan	DISC
	@	10MG	N76549 004	Oct 24, 2005	Jan	DISC

TABLET; ORAL

ALTACE

	COBALT	1.25MG	N22021 001	Feb 27, 2007	Feb	NEWA
		2.5MG	N22021 002	Feb 27, 2007	Feb	NEWA
		5MG	N22021 003	Feb 27, 2007	Feb	NEWA
	+	10MG	N22021 004	Feb 27, 2007	Feb	NEWA
	KING PHARMS	1.25MG	N22021 001	Feb 27, 2007	Apr	CAHN
		2.5MG	N22021 002	Feb 27, 2007	Apr	CAHN
		5MG	N22021 003	Feb 27, 2007	Apr	CAHN
	+	10MG	N22021 004	Feb 27, 2007	Apr	CAHN

RANITIDINE HYDROCHLORIDE

SYRUP; ORAL

RANITIDINE HYDROCHLORIDE

AA	ALPHARMA US PHARMS	EQ 15MG BASE/ML	N76124 001	Feb 21, 2007	Feb	NEWA
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SYRUP; ORAL

ZANTAC

AA	+	GLAXOSMITHKLINE	EQ 15MG BASE/ML	N19675	001	Dec 30, 1988	Feb	CFTG
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RETAPAMULIN

OINTMENT; TOPICAL

ALTABAX

	+	GLAXO GRP LTD	1%	N22055	001	Apr 12, 2007	Apr	NEWA
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RIBAVIRIN

TABLET; ORAL

RIBAVIRIN

AB		THREE RIVERS PHARMS	400MG	N77456	002	Dec 05, 2005	Mar	CTEC
AB	+		600MG	N77456	003	Dec 05, 2005	Mar	CTEC
AB		ZYDUS PHARMS USA	400MG	N77094	002	Mar 16, 2007	Mar	NEWA
AB			600MG	N77094	003	Mar 16, 2007	Mar	NEWA

RISEDRONATE SODIUM

TABLET; ORAL

ACTONEL

	+	PROCTER AND GAMBLE	75MG	N20835	004	Apr 16, 2007	Apr	NEWA
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RISPERIDONE

INJECTABLE; INTRAMUSCULAR

RISPERDAL CONSTA

JANSSEN PHARMA 12.5MG/VIAL

N21346	004	Apr 12, 2007	Apr	NEWA
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>A> ROTIGOTINE

&gt;A&gt; FILM, EXTENDED RELEASE; TRANSDERMAL

&gt;A&gt; NEUPRO

>A>		SCHWARZ BIOSCIENCES	2MG/24HR	N21829	001	May 09, 2007	May	NEWA
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>A>			4MG/24HR	N21829	002	May 09, 2007	May	NEWA
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>A>	+		6MG/24HR	N21829	003	May 09, 2007	May	NEWA
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SERMORELIN ACETATE

INJECTABLE; INJECTION

GEREF

	+	EMD SERONO	EQ 0.05MG BASE/AMP	N19863	001	Dec 28, 1990	Feb	CAHN
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	@		EQ 0.5MG BASE/VIAL	N20443	001	Sep 26, 1997	Feb	CAHN
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	@		EQ 1MG BASE/VIAL	N20443	002	Sep 26, 1997	Feb	CAHN
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SERTRALINE HYDROCHLORIDE

CONCENTRATE; ORAL

SERTRALINE HYDROCHLORIDE

AA		RANBAXY	EQ 20MG BASE/ML	N78053	001	Feb 05, 2007	Feb	CTEC
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AB			EQ 20MG BASE/ML	N78053	001	Feb 05, 2007	Jan	NEWA
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AA		ROXANE	EQ 20MG BASE/ML	N76934	001	Jun 30, 2006	Feb	CTEC
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ZOLOFT

AA	+	PFIZER	EQ 20MG BASE/ML	N20990	001	Dec 07, 1999	Feb	CTEC
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TABLET; ORAL

SERTRALINE HYDROCHLORIDE

AB		ACTAVIS ELIZABETH	EQ 25MG BASE	N77345	001	Feb 06, 2007	Jan	NEWA
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AB			EQ 50MG BASE	N77345	002	Feb 06, 2007	Jan	NEWA
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AB			EQ 100MG BASE	N77345	003	Feb 06, 2007	Jan	NEWA
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AB		APOTEX INC	EQ 25MG BASE	N76882	001	Feb 06, 2007	Jan	NEWA
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## TABLET; ORAL

## SERTRALINE HYDROCHLORIDE

AB	APOTEX INC	EQ 50MG BASE	N76882 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N76882 003	Feb 06, 2007	Jan	NEWA
AB	AUROBINDO PHARMA	EQ 25MG BASE	N77206 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77206 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77206 003	Feb 06, 2007	Jan	NEWA
AB	COBALT	EQ 25MG BASE	N77663 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77663 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77663 003	Feb 06, 2007	Jan	NEWA
AB	DR REDDYS LABS LTD	EQ 25MG BASE	N76442 001	Apr 30, 2007	Apr	NEWA
AB		EQ 50MG BASE	N76442 002	Apr 30, 2007	Apr	NEWA
AB		EQ 100MG BASE	N76442 003	Apr 30, 2007	Apr	NEWA
AB	GENPHARM	EQ 25MG BASE	N76540 001	Mar 20, 2007	Mar	NEWA
AB		EQ 50MG BASE	N76540 002	Mar 20, 2007	Mar	NEWA
AB		EQ 100MG BASE	N76540 003	Mar 20, 2007	Mar	NEWA
AB	INVAGEN PHARMS	EQ 25MG BASE	N77397 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77397 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77397 003	Feb 06, 2007	Jan	NEWA
AB	LUPIN	EQ 25MG BASE	N77670 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77670 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77670 003	Feb 06, 2007	Jan	NEWA
AB	MUTUAL PHARM	EQ 25MG BASE	N77818 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77818 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77818 003	Feb 06, 2007	Jan	NEWA
AB	MYLAN	EQ 25MG BASE	N76671 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N76671 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N76671 003	Feb 06, 2007	Jan	NEWA
AB	PLIVA HRVATSKA DOO	EQ 25MG BASE	N77299 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77299 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77299 003	Feb 06, 2007	Jan	NEWA
AB	RANBAXY	EQ 25MG BASE	N77977 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77977 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77977 003	Feb 06, 2007	Jan	NEWA
		EQ 150MG BASE	N77977 004	Feb 06, 2007	Jan	NEWA
		EQ 200MG BASE	N77977 005	Feb 06, 2007	Jan	NEWA
AB	ROXANE	EQ 25MG BASE	N76881 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N76881 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N76881 003	Feb 06, 2007	Jan	NEWA
AB	SANDOZ	EQ 25MG BASE	N77713 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77713 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77713 003	Feb 06, 2007	Jan	NEWA
AB	SUN PHARM INDS (IN)	EQ 25MG BASE	N78108 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N78108 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N78108 003	Feb 06, 2007	Jan	NEWA
AB	TORRENT PHARMS	EQ 25MG BASE	N77765 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77765 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77765 003	Feb 06, 2007	Jan	NEWA
AB	WATSON LABS	EQ 25MG BASE	N77162 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77162 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77162 003	Feb 06, 2007	Jan	NEWA
AB	ZYDUS PHARMS USA	EQ 25MG BASE	N77106 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77106 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77106 003	Feb 06, 2007	Jan	NEWA

SEVOFLURANELIQUID; INHALATION  
SOJOURN

AN MINRAD 100% N77867 001 May 02, 2007 Apr NEWA

SIMVASTATINTABLET; ORAL  
SIMVASTATIN

>A>	AB	LUPIN	10MG	N78103 001	May 11, 2007	May	NEWA
>A>	AB		20MG	N78103 002	May 11, 2007	May	NEWA
>A>	AB		40MG	N78103 003	May 11, 2007	May	NEWA
>A>	AB		80MG	N78103 004	May 11, 2007	May	NEWA

SODIUM CHLORIDEINJECTABLE; INJECTION  
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP FRESENIUS MEDCL 900MG/100ML N78177 001 Apr 12, 2007 Apr NEWA

SODIUM LACTATEINJECTABLE; INJECTION  
SODIUM LACTATE IN PLASTIC CONTAINER

+ HOSPIRA 5MEQ/ML N18947 001 Sep 05, 1984 Feb CRLD

SOMATROPIN RECOMBINANTINJECTABLE; INJECTION  
SAIZEN

BX	EMD SERONO	4MG/VIAL	N19764 005	Jan 16, 2007	Feb	CAHN
BX		5MG/VIAL	N19764 002	Oct 08, 1996	Feb	CAHN
	@	6MG/VIAL	N19764 001	Oct 08, 1996	Feb	CAHN
	+	8.8MG/VIAL	N19764 003	Aug 29, 2000	Feb	CAHN
BX	SERONO	4MG/VIAL	N19764 005	Jan 16, 2007	Jan	NEWA
	SEROSTIM					
BX	EMD SERONO	4MG/VIAL	N20604 003	Jul 25, 1997	Feb	CAHN
BX		5MG/VIAL	N20604 002	Aug 23, 1996	Feb	CAHN
BX		6MG/VIAL	N20604 001	Aug 23, 1996	Feb	CAHN
	@	8.8MG/VIAL	N20604 004	Sep 06, 2001	Feb	CAHN
	VALTROPIN					
BX	LG LIFE	5MG/VIAL	N21905 001	Apr 19, 2007	Apr	NEWA
	INJECTABLE; SUBCUTANEOUS					
	SEROSTIM LQ					
	@ EMD SERONO	6MG/0.5ML	N20604 005	Feb 11, 2005	Feb	CAHN

SOTALOL HYDROCHLORIDETABLET; ORAL  
SOTALOL HYDROCHLORIDE

AB2	MYLAN	80MG	N77616 001	Feb 07, 2007	Jan	NEWA
AB2		120MG	N77616 002	Feb 07, 2007	Jan	NEWA
AB2		160MG	N77616 003	Feb 07, 2007	Jan	NEWA

SULFAMETHOXAZOLE; TRIMETHOPRIMINJECTABLE; INJECTION  
BACTRIM

@ MUTUAL PHARM 80MG/ML; 16MG/ML N18374 001 Feb DISC

## SUSPENSION; ORAL

	BACTRIM PEDIATRIC							
	@ MUTUAL PHARM	200MG/5ML;40MG/5ML	N17560	002			Feb	DISC
	SEPTRA							
	@ MONARCH PHARMS	200MG/5ML;40MG/5ML	N17598	001			Feb	DISC
	SEPTRA GRAPE							
	@ MONARCH PHARMS	200MG/5ML;40MG/5ML	N17598	002	Feb 12, 1986	Feb	Feb	DISC
	SULFAMETHOXAZOLE AND TRIMETHOPRIM							
	@ TEVA	200MG/5ML;40MG/5ML	N18812	001	Jan 28, 1983	Feb	Feb	DISC
	@	200MG/5ML;40MG/5ML	N18812	002	Jun 10, 1983	Feb	Feb	DISC
AB	+ TEVA PHARMS	200MG/5ML;40MG/5ML	N77612	001	Nov 13, 2006	Feb	Feb	CRLD
AB	VINTAGE	200MG/5ML;40MG/5ML	N77785	001	Jan 24, 2007	Jan	Jan	NEWA
	SULFATRIM							
	@ ACTAVIS MID ATLANTIC	200MG/5ML;40MG/5ML	N18615	002	Jan 07, 1983	Mar	Mar	DISC

## TABLET; ORAL

	SULFAMETHOXAZOLE AND TRIMETHOPRIM							
AB	VINTAGE	400MG;80MG	N78060	002	Jan 25, 2007	Jan	Jan	NEWA
AB		800MG;160MG	N78060	001	Jan 25, 2007	Jan	Jan	NEWA

SULFANILAMIDE

## CREAM; VAGINAL

## AVC

	+ AZUR PHARMA	15%	N06530	003	Jan 27, 1987	Apr	Apr	CAHN
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## SUPPOSITORY; VAGINAL

## AVC

	@ AZUR PHARMA	1.05GM	N06530	004	Jan 27, 1987	Apr	Apr	CAHN
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SULFASALAZINE

## TABLET; ORAL

## SULFASALAZINE

	@ HERITAGE PHARMS INC	500MG	N80197	001			Feb	CAHN
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SULINDAC

## TABLET; ORAL

## SULINDAC

	@ HERITAGE PHARMS INC	150MG	N73262	002	Sep 06, 1991	Feb	Feb	CAHN
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	@	200MG	N73262	001	Sep 06, 1991	Feb	Feb	CAHN
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TADALAFIL

## TABLET; ORAL

## CIALIS

	LILLY	5MG	N21368	001	Nov 21, 2003	Apr	Apr	CAHN
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		10MG	N21368	002	Nov 21, 2003	Apr	Apr	CAHN
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	+	20MG	N21368	003	Nov 21, 2003	Apr	Apr	CAHN
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TAMOXIFEN CITRATE

## TABLET; ORAL

## NOLVADEX

	@ ASTRAZENECA	EQ 10MG BASE	N17970	001			Mar	DISC
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	@	EQ 20MG BASE	N17970	002	Mar 21, 1994	Mar	Mar	DISC
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## TAMOXIFEN CITRATE

>D>	AB	PHARMACHEMIE	EQ 20MG BASE	N74858	001	Feb 20, 2003	May	CRLD
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>A>	AB	+ TEVA PHARMS	EQ 20MG BASE	N74858	001	Feb 20, 2003	May	CRLD
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TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION

DRAXIMAGE MDP-10

AP	+	DRAXIMAGE	N/A	N18035 001		Jan	CTNA
		DRAXIMAGE MDP-25					
	+	DRAXIMAGE	N/A	N18035 002	Feb 27, 2004	Jan	NEWA

TECHNETIUM TC-99M SESTAMIBI KIT

INJECTABLE; INJECTION

MIRALUMA

>D>							
>D>	+	BRISTOL MYERS SQUIBB	N/A	N19785 003	May 23, 1997	May	DISC
>A>	@		N/A	N19785 003	May 23, 1997	May	DISC

TEGASEROD MALEATE

TABLET; ORAL

ZELNORM

@ NOVARTIS

EQ 2MG BASE

N21200 001 Jul 24, 2002 Mar DISC

@

EQ 6MG BASE

N21200 002 Jul 24, 2002 Mar DISC

TEMSIROLIMUS

SOLUTION; INTRAVENOUS

TORISEL

>A>	+	WYETH PHARMS INC	25MG/ML (25MG/ML)	N22088 001	May 30, 2007	May	NEWA
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TERBUTALINE SULFATE

TABLET; ORAL

BRETHINE

@ AAIPHARMA LLC

2.5MG

N17849 001 Apr DISC

@

5MG

N17849 002 Apr DISC

TERCONAZOLE

SUPPOSITORY; VAGINAL

TERCONAZOLE

AB		TARO	80MG	N77553 001	Mar 09, 2007	Feb	NEWA
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TESTOSTERONE

GEL; TRANSDERMAL

TESTOSTERONE

>A>	AB	PAR PHARM	1%	N76744 001	May 23, 2007	May	NEWA
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TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

ACHROMYCIN V

@ HERITAGE PHARMS INC 250MG

N50278 003 Apr CAHN

@ 500MG

N50278 001 Apr CAHN

FIBER, EXTENDED RELEASE; PERIODONTAL

ACTISITE

>D>		@ ALZA	12.7MG/FIBER	N50653 001	Mar 25, 1994	May	CAHN
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>A>		@ ON SITE	12.7MG/FIBER	N50653 001	Mar 25, 1994	May	CAHN
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THALIDOMIDE

CAPSULE; ORAL

THALOMID

CELGENE 150MG

N20785 004 Jan 10, 2007 Jan NEWA

THEOPHYLLINE

TABLET; ORAL

QUIBRON-T

@ MONARCH PHARMS 300MG N88656 001 Aug 22, 1985 Feb DISC

THEOLAIR

+ GRACEWAY 125MG N86399 001 Mar CAHN

+ 250MG N86399 002 Mar CAHN

TABLET, EXTENDED RELEASE; ORAL

QUIBRON-T/SR

@ MONARCH PHARMS 300MG N87563 001 Jun 21, 1983 Feb DISC

THIORIDAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

&gt;D&gt; THIORIDAZINE HYDROCHLORIDE INTENSOL

&gt;D&gt; AA ROXANE 30MG/ML N88941 001 Dec 16, 1985 May DISC

&gt;A&gt; @ 30MG/ML N88941 001 Dec 16, 1985 May DISC

&gt;D&gt; AA 100MG/ML N88942 001 Dec 16, 1985 May DISC

&gt;A&gt; @ 100MG/ML N88942 001 Dec 16, 1985 May DISC

TOLCAPONE

TABLET; ORAL

TASMAR

VALEANT PHARM INTL 100MG N20697 001 Jan 29, 1998 Jan CAHN

+ 200MG N20697 002 Jan 29, 1998 Jan CAHN

TRAMADOL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

ULTRAM ER

+ BIOVAIL LABS INTL 100MG N21692 001 Sep 08, 2005 Apr CRLD

100MG N21692 001 Sep 08, 2005 Feb CTNA

200MG N21692 002 Sep 08, 2005 Feb CTNA

300MG N21692 003 Sep 08, 2005 Apr CRLD

+ 300MG N21692 003 Sep 08, 2005 Feb CTNA

TRANDOLAPRIL; VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

TARKA

&gt;D&gt; + ABBOTT 1MG;240MG N20591 003 Oct 22, 1996 May CRLD

&gt;A&gt; 1MG;240MG N20591 003 Oct 22, 1996 May CRLD

&gt;D&gt; + 2MG;180MG N20591 001 Oct 22, 1996 May CRLD

&gt;A&gt; 2MG;180MG N20591 001 Oct 22, 1996 May CRLD

&gt;D&gt; + 2MG;240MG N20591 004 Oct 22, 1996 May CRLD

&gt;A&gt; 2MG;240MG N20591 004 Oct 22, 1996 May CRLD

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HYDROCHLORIDE

AB APOTEX 50MG N71258 001 Mar 25, 1987 Mar CAHN

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

KENALOG

@ APOTHECON 0.5% N83943 001 Mar DISC

## CREAM; TOPICAL

## TRIAMCINOLONE ACETONIDE

AT	+	ALTANA	0.5%	N85692 002		Apr	CRLD
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VALACYCLOVIR HYDROCHLORIDE

## TABLET; ORAL

## VALACYCLOVIR HYDROCHLORIDE

AB		RANBAXY	EQ 500MG BASE	N76588 001	Jan 31, 2007	Jan	NEWA
AB			EQ 1GM BASE	N76588 002	Jan 31, 2007	Jan	NEWA
		VALTREX					
AB		GLAXOSMITHKLINE	EQ 500MG BASE	N20487 001	Jun 23, 1995	Jan	CFTG
AB	+		EQ 1GM BASE	N20487 002	Jun 23, 1995	Jan	CFTG

VALRUBICIN

## SOLUTION; INTRAVESICAL

## VALSTAR PRESERVATIVE FREE

	+	INDEVUS PHARMS	40MG/ML	N20892 001	Sep 25, 1998	Apr	CAHN
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VERAPAMIL HYDROCHLORIDE

## CAPSULE, EXTENDED RELEASE; ORAL

## VERELAN

>D>	AB	+	ELAN DRUG	120MG	N19614 001	May 29, 1990	May	CRLD
>A>	AB			120MG	N19614 001	May 29, 1990	May	CRLD
>D>	AB	+		180MG	N19614 003	Jan 09, 1992	May	CRLD
>A>	AB			180MG	N19614 003	Jan 09, 1992	May	CRLD
>D>	AB	+		240MG	N19614 002	May 29, 1990	May	CRLD
>A>	AB			240MG	N19614 002	May 29, 1990	May	CRLD

## INJECTABLE; INJECTION

## ISOPTIN

	@	FSC	2.5MG/ML	N18485 001		Feb	DISC
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## VERAPAMIL HYDROCHLORIDE

	@	LUITPOLD	2.5MG/ML	N70225 001	Nov 12, 1985	Feb	DISC
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AP	+		2.5MG/ML	N70617 001	Nov 12, 1985	Feb	CRLD
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## TABLET; ORAL

## CALAN

AB	+	GD SEARLE LLC	120MG	N18817 002	Sep 10, 1984	Feb	CRLD
		ISOPTIN					
	@	FSC	40MG	N18593 003	Nov 23, 1987	Feb	DISC
	@		80MG	N18593 001	Mar 08, 1982	Feb	DISC
	@		120MG	N18593 002	Mar 08, 1982	Feb	DISC
		VERAPAMIL HYDROCHLORIDE					
	@	HERITAGE PHARMS INC	80MG	N71880 001	Apr 05, 1988	Feb	CAHN
	@		120MG	N71881 001	Apr 05, 1988	Feb	CAHN

ZICONOTIDE

## INJECTABLE; INTRATHECAL

## PRIALT

>D>	+	ELAN PHARMS	100UGM/1ML(100MG/ML)	N21060 002	Dec 28, 2004	May	CPOT
>A>	+		100UGM/1ML(100UGM/ML)	N21060 002	Dec 28, 2004	May	CPOT
>D>	+		500UGM/20ML(25MG/ML)	N21060 001	Dec 28, 2004	May	CPOT
>D>	+		500UGM/5ML(100MG/ML)	N21060 004	Dec 28, 2004	May	CPOT
>A>	+		500UGM/20ML(25UGM/ML)	N21060 001	Dec 28, 2004	May	CPOT
>A>	+		500UGM/5ML(100UGM/ML)	N21060 004	Dec 28, 2004	May	CPOT

ZIDOVUDINECAPSULE; ORAL  
ZIDOVUDINE

>A>	AB	CIPLA LTD	100MG	N78349 001	May 23, 2007	May	NEWA
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ZILEUTON

TABLET, EXTENDED RELEASE; ORAL

>A>		ZYFLO CR					
>A>	+	CRITICAL	600MG	N22052 001	May 30, 2007	May	NEWA

ZOLEDRONIC ACIDINJECTABLE; IV (INFUSION)  
RECLAST

+	NOVARTIS	EQ 5MG BASE/100ML	N21817 001	Apr 16, 2007	Apr	NEWA
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ZOLPIDEM TARTRATE

TABLET; ORAL

AMBIEN

AB		SANOFI AVENTIS US	5MG	N19908 001	Dec 16, 1992	Apr	CFTG
AB	+		10MG	N19908 002	Dec 16, 1992	Apr	CFTG

ZOLPIDEM TARTRATE

AB		APOTEX INC	5MG	N77884 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N77884 002	Apr 23, 2007	Apr	NEWA
AB		AUROBINDO PHARMA	5MG	N78413 001	May 04, 2007	Apr	NEWA
AB			10MG	N78413 002	May 04, 2007	Apr	NEWA
AB		CARACO	5MG	N77359 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N77359 002	Apr 23, 2007	Apr	NEWA
AB		CARLSBAD	5MG	N77990 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N77990 002	Apr 23, 2007	Apr	NEWA
AB		DR REDDYS LABS LTD	5MG	N77985 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N77985 002	Apr 23, 2007	Apr	NEWA
AB		GENPHARM	5MG	N78016 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N78016 002	Apr 23, 2007	Apr	NEWA
AB		LEK PHARMS DD	5MG	N77322 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N77322 002	Apr 23, 2007	Apr	NEWA
AB		MUTUAL PHARMA	5MG	N77288 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N77288 002	Apr 23, 2007	Apr	NEWA
AB		MYLAN	5MG	N76578 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N76578 002	Apr 23, 2007	Apr	NEWA
AB		PAR PHARM	5MG	N76062 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N76062 002	Apr 23, 2007	Apr	NEWA
AB		RANBAXY	5MG	N78055 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N78055 002	Apr 23, 2007	Apr	NEWA
AB		ROXANE	5MG	N77214 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N77214 002	Apr 23, 2007	Apr	NEWA
AB		SYNTHON PHARMS	5MG	N77540 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N77540 002	Apr 23, 2007	Apr	NEWA
AB		TEVA	5MG	N76410 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N76410 002	Apr 23, 2007	Apr	NEWA
AB		WATSON LABS	5MG	N77773 001	Apr 23, 2007	Apr	NEWA
AB			10MG	N77773 002	Apr 23, 2007	Apr	NEWA
>A>	AB	WOCKHARDT	5MG	N78426 001	May 15, 2007	May	NEWA
>A>	AB		10MG	N78426 002	May 15, 2007	May	NEWA



## TABLET, ORALLY DISINTEGRATING; ORAL

## TOVALT ODT

	BIOVAIL LABS INTL	5MG	N21412 001	Apr 25, 2007	Apr	NEWA
+		10MG	N21412 002	Apr 25, 2007	Apr	NEWA

ZONISAMIDE

## CAPSULE; ORAL

## ZONISAMIDE

AB	COREPHARMA	25MG	N77876 001	Feb 21, 2007	Feb	NEWA
AB		50MG	N77876 002	Feb 21, 2007	Feb	NEWA
AB		100MG	N77876 003	Feb 21, 2007	Feb	NEWA

OTC DRUG PRODUCT LIST - 27TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2007

2-1

BROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

EFIDAC 24 PSEUDOEPHEDRINE HYDROCHLORIDE/BROMPHENIRAMINE MALEATE

>D>	+	ALZA	16MG;240MG	N19672 001	Mar 29, 1996	May	DISC
>A>		@	16MG;240MG	N19672 001	Mar 29, 1996	May	DISC

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SPONGE; TOPICAL

CHLORAPREP ONE-STEP

+	ENTURIA INC	2%;70% (10.5ML)	N20832 004	Aug 20, 2003	Jan	CAHN
+		2%;70% (3ML)	N20832 001	Jul 14, 2000	Jan	CAHN
+		2%;70% (26ML)	N20832 006	Nov 21, 2006	Jan	CAHN

CHLORAPREP ONE-STEP FREPP

+	ENTURIA INC	2%;70% (1.5ML)	N20832 003	Apr 26, 2002	Jan	CAHN
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CHLORAPREP WITH TINT

+	ENTURIA INC	2%;70% (3ML)	N20832 007	Oct 10, 2006	Feb	NEWA
+		2%;70% (26ML)	N20832 002	May 03, 2005	Jan	CAHN
+		2%;70% (10.5ML)	N20832 005	Apr 03, 2006	Jan	CAHN

SWAB; TOPICAL

CHLORAPREP ONE-STEP SEPP

+	ENTURIA INC	2%;70% (0.67ML)	N21555 001	Oct 07, 2002	Jan	CAHN
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CHLORAPREP SINGLE SWABSTICK

+	ENTURIA INC	2%;70% (1.75ML)	N21555 002	May 10, 2005	Jan	CAHN
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DIPHENHYDRAMINE HYDROCHLORIDE; IBUPROFEN

CAPSULE; ORAL

ADVIL PM

+	WYETH CONS	25MG;EQ 200MG FREE ACID AND POTASSIUM SALT	N21393 001	Dec 21, 2005	Apr	CAIN
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DOXYLAMINE SUCCINATE

TABLET; ORAL

UNISOM

+	CHATTEM	25MG	N18066 001		Feb	CAHN
+	MCNEIL CONS	25MG	N18066 001		Jan	CAHN

FAMOTIDINE

TABLET, CHEWABLE; ORAL

FAMOTIDINE

+	PERRIGO	10MG	N75715 001	Aug 22, 2003	Mar	CRLD
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PEPCID AC

@	MERCK	10MG	N20801 001	Sep 24, 1998	Mar	DISC
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GUAIFENESIN

TABLET, EXTENDED RELEASE; ORAL

HUMIBID

+	ADAMS RESP THERAP	1.2GM	N21282 002	Dec 18, 2002	Apr	CTNA
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IBUPROFEN

CAPSULE; ORAL

ADVIL LIQUI-GELS

+	WYETH CONS	EQ 200MG FREE ACID AND POTASSIUM SALT	N20402 001	Apr 20, 1995	Jan	CAIN
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## CAPSULE; ORAL

ADVIL MIGRAINE LIQUI-GELS

+	WYETH CONS	EQ 200MG FREE ACID AND POTASSIUM SALT	N20402 002	Mar 16, 2000	Jan	CAIN
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IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

## CAPSULE; ORAL

ADVIL COLD AND SINUS

+	WYETH CONS	EQ 200MG FREE ACID AND POTASSIUM SALT;30MG	N21374 001	May 30, 2002	Apr	CAIN
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KETOTIFEN FUMARATE

## SOLUTION/DROPS; OPHTHALMIC

ALAWAY

+	BAUSCH AND LOMB	EQ 0.025% BASE	N21996 001	Dec 01, 2006	Jan	CAHN
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LOPERAMIDE HYDROCHLORIDE

## TABLET, CHEWABLE; ORAL

IMODIUM A-D EZ CHEWS

+	MCNEIL	2MG	N20448 001	Jul 24, 1997	Jan	CTNA
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LORATADINE

## TABLET, ORALLY DISINTEGRATING; ORAL

LORATADINE REDIDOSE

RANBAXY

10MG

N77153 001	Apr 11, 2007	Apr	NEWA
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NICOTINE POLACRILEX

## GUM, CHEWING; BUCCAL

NICOTINE POLACRILEX

>A>	PERRIGO R AND D	EQ 2MG BASE	N78547 001	May 24, 2007	May	NEWA
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>A>		EQ 4MG BASE	N78546 001	May 24, 2007	May	NEWA
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NONOXYNOL-9

## SPONGE; VAGINAL

TODAY

+	ALLENDAL PHARMS	1GM	N18683 001	Apr 01, 1983	Feb	CMFD
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ORLISTAT

## CAPSULE; ORAL

ALLI

+	GLAXOSMITHKLINE CONS	60MG	N21887 001	Feb 07, 2007	Feb	NEWA
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PSEUDOEPHEDRINE HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

>D>	EFIDAC 24 PSEUDOEPHEDRINE HYDROCHLORIDE					
>D>	+	ALZA	240MG	N20021 002	Dec 15, 1992	May CTNA

## SUDAFED 12 HOUR

+	MCNEIL CONS	120MG	N73585 001	Oct 31, 1991	Mar	CAHN
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>A>	SUDAFED 24 HOUR					
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>A>	+	ALZA	240MG	N20021 002	Dec 15, 1992	May CTNA
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RANITIDINE HYDROCHLORIDE

## TABLET, EFFERVESCENT; ORAL

ZANTAC 75

@ BOEHRINGER INGELHEIM EQ 75MG BASE

N20745 001	Feb 26, 1998	Feb	CAHN
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## TABLET; ORAL

ZANTAC 150

+ BOEHRINGER INGELHEIM EQ 150MG BASE

N21698 001 Aug 31, 2004 Jan CAHN

ZANTAC 75

BOEHRINGER INGELHEIM EQ 75MG BASE

N20520 001 Dec 19, 1995 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 05 MAY 2007**

NO MAY 2007 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 MAY 2007 ADDITIONS

# PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

See report footnotes for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ABACAVIR SULFATE; LAMIVUDINE - EPZICOM</u>					
021652 001	>A> 7119202	Feb 08, 2009	DS		
	>A> 7119202*PED	Aug 08, 2009			
<u>ABACAVIR SULFATE; LAMIVUDINE; ZIDOVUDINE - TRIZIVIR</u>					
021205 001	>A> 7119202	Feb 08, 2009	DS		
	>A> 7119202*PED	Aug 08, 2009			
<u>ACARBOSE - PRECOSE</u>					
020482 001	4904769	Sep 06, 2009			
<u>ACARBOSE - PRECOSE</u>					
020482 002	4904769	Sep 06, 2009			
<u>ACARBOSE - PRECOSE</u>					
020482 004	4904769	Sep 06, 2009			
<u>ALBUTEROL SULFATE - VENTOLIN HFA</u>					
020983 001	6558651	Dec 19, 2016	DP		
	6743413	Jun 01, 2021	DP	U-716	
<u>ALENDRONATE SODIUM; CHOLECALCIFEROL - FOSAMAX PLUS D</u>					
021762 001				>A> M-51	Dec 21, 2008
<u>ALENDRONATE SODIUM; CHOLECALCIFEROL - FOSAMAX PLUS D</u>					
021762 002				>A> D-107	Apr 26, 2010
				>A> M-51	Dec 21, 2008
				>A> NC	Apr 07, 2008
<u>ALFUZOSIN HYDROCHLORIDE - UROXATRAL</u>					
021287 001	4661491	Jan 18, 2011		U-706	
<u>ALISKIREN HEMIFUMARATE - TEKTURNA</u>					
021985 001	5559111	Apr 04, 2015	DS DP	U-3 NCE	Mar 05, 2012
<u>ALISKIREN HEMIFUMARATE - TEKTURNA</u>					
021985 002	5559111	Apr 04, 2015	DS DP	U-3 NCE	Mar 05, 2012
<u>ANIDULAFUNGIN - ERAXIS</u>					
021632 001	7198796	Jun 13, 2022	DP		
<u>ANIDULAFUNGIN - ERAXIS</u>					
021632 002	5965525	Oct 12, 2016	DS DP	U-540	
	6384013	Mar 19, 2012	DS		
	6743777	Mar 19, 2012		DP U-540	
	6960564	Apr 12, 2021		DP U-540	
	7198796	Jun 13, 2022		DP	
<u>ARFORMOTEROL TARTRATE - BROVANA</u>					
021912 001	5795564	Apr 03, 2012		U-793	
	6068833	Apr 03, 2012		U-793	
	6589508	Apr 03, 2012		U-793	
	6866839	Apr 03, 2012		U-793	
<u>ASCORBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE - MOVIPREP</u>					
021881 001	7169381	Sep 01, 2024	DS DP		
<u>ATORVASTATIN CALCIUM - LIPITOR</u>					
020702 001				I-523	Mar 02, 2010
<u>ATORVASTATIN CALCIUM - LIPITOR</u>					
020702 002				I-523	Mar 02, 2010
<u>ATORVASTATIN CALCIUM - LIPITOR</u>					
020702 003				I-523	Mar 02, 2010
<u>ATORVASTATIN CALCIUM - LIPITOR</u>					
020702 004				I-523	Mar 02, 2010
<u>AVOBENZONE; ECAMSULE; OCTOCRYLENE - CAPITAL SOLEIL 15</u>					
021501 001				NC	Jul 21, 2009
				NP	Oct 02, 2009
<u>AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE - ANTHELIOS 20</u>					
021471 001				NC	Oct 05, 2009



**PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY LIST**

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>BALSALAZIDE DISODIUM - COLAZAL</u>					
020610 001				ODE PED	Dec 20, 2013 Jun 20, 2014
<u>BORTEZOMIB - VELCADE</u>					
021602 001	5780454	May 03, 2017	DP		
<u>BOSENTAN - TRACLEER</u>					
021290 001				M-64	Feb 15, 2010
<u>BOSENTAN - TRACLEER</u>					
021290 002				M-64	Feb 15, 2010
<u>BUDESONIDE - PULMICORT RESPULES</u>					
020929 001	6899099	Dec 23, 2018		U-529	
<u>BUDESONIDE - PULMICORT RESPULES</u>					
020929 002	6899099	Dec 23, 2018		U-529	
<u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>					
021929 001	6641800	Sep 23, 2012	DP		
<u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u>					
021929 002	6641800	Sep 23, 2012	DP		
<u>BUPROPION HYDROCHLORIDE - BUPROPION HYDROCHLORIDE</u>					
077284 002				PC	Jun 12, 2007
<u>BUPROPION HYDROCHLORIDE - BUPROPION HYDROCHLORIDE</u>					
077415 002				PC	Jun 12, 2007
<u>CARVEDILOL - COREG</u>					
020297 001				M-61 PED	Feb 23, 2010 Aug 23, 2010
<u>CARVEDILOL - COREG</u>					
020297 002				M-61 PED	Feb 23, 2010 Aug 23, 2010
<u>CARVEDILOL - COREG</u>					
020297 003				M-61 PED	Feb 23, 2010 Aug 23, 2010
<u>CARVEDILOL - COREG</u>					
020297 004				M-61 PED	Feb 23, 2010 Aug 23, 2010
<u>CELECOXIB - CELEBREX</u>					
020998 004	5466823	Nov 30, 2013	DS	I-466	Jul 29, 2008
	5466823*PED	May 30, 2014		NPP	Dec 15, 2009
	5563165	Nov 30, 2013	DP	PED	Jun 15, 2010
	5563165*PED	May 30, 2014		PED	Jan 29, 2009
	5760068	Jun 02, 2015		U-672	
	5760068*PED	Dec 02, 2015			
<u>CETRORELIX - CETROTIDE</u>					
021197 001	5198533	Oct 24, 2010	DS DP		
<u>CETRORELIX - CETROTIDE</u>					
021197 002	5198533	Oct 24, 2010	DS DP		
<u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - CHLORAPREP ONE-STEP</u>					
020832 006	6991394	Jan 31, 2024	DP		
<u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - CHLORAPREP WITH TINT</u>					
020832 002	6991394	Jan 31, 2024	DP		
<u>CICLESONIDE - OMNARIS</u>					
022004 001	5482934	Jan 09, 2013	DS DP	U-557	
	6767901	Oct 21, 2020		DP	
	6939559	Apr 21, 2019		DP	
<u>CLOBETASOL PROPIONATE - OLUX E</u>					
022013 001	6730288	Sep 08, 2019	DP	NP	Jan 12, 2010
	7029659	Sep 08, 2019	DP		

**PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY LIST**

See report footnotes for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>CLOZAPINE - FAZACLO ODT</u>					
021590 001	5178878	Jan 12, 2010	DP		
<u>CLOZAPINE - FAZACLO ODT</u>					
021590 002	5178878	Jan 12, 2010	DP		
<u>CLOZAPINE - FAZACLO ODT</u>					
021590 003	5178878	Jan 12, 2010	DP		
<u>COLESTIPOL HYDROCHLORIDE - COLESTIPOL HYDROCHLORIDE</u>					
077510 001				PC	Jun 12, 2007
<u>CONIVAPTAN HYDROCHLORIDE - VAPRISOL</u>					
021697 001				I-526	Feb 28, 2010
<u>CYCLOBENZAPRINE HYDROCHLORIDE - AMRIX</u>					
021777 001				NDF	Feb 01, 2010
<u>CYCLOBENZAPRINE HYDROCHLORIDE - AMRIX</u>					
021777 002				NDF	Feb 01, 2010
<u>CYTARABINE - DEPOCYT</u>					
021041 001	5455044	May 14, 2013		U-806	
	5723147	Mar 03, 2015	DP	U-806	
	5962016	Jan 31, 2017	DP	U-806	
	6071534	Feb 18, 2008	DP		
	7198801	Jun 25, 2022	DP		
<u>DALTEPARIN SODIUM - FRAGMIN</u>					
020287 001				>A> I-534	May 01, 2010
<u>DALTEPARIN SODIUM - FRAGMIN</u>					
020287 002				>A> I-534	May 01, 2010
<u>DALTEPARIN SODIUM - FRAGMIN</u>					
020287 003				>A> I-534	May 01, 2010
<u>DALTEPARIN SODIUM - FRAGMIN</u>					
020287 004				>A> I-534	May 01, 2010
<u>DALTEPARIN SODIUM - FRAGMIN</u>					
020287 005				>A> I-534	May 01, 2010
<u>DALTEPARIN SODIUM - FRAGMIN</u>					
020287 006				>A> I-534	May 01, 2010
<u>DALTEPARIN SODIUM - FRAGMIN</u>					
020287 007				>A> I-534	May 01, 2010
<u>DASATINIB - SPRYCEL</u>					
021986 001	7153856	Apr 28, 2020		U-780	
<u>DASATINIB - SPRYCEL</u>					
021986 002	7153856	Apr 28, 2020		U-780	
<u>DASATINIB - SPRYCEL</u>					
021986 003	7153856	Apr 28, 2020		U-780	
<u>DECITABINE - DACOGEN</u>					
021790 001				ODE	May 02, 2013
<u>DESLORATADINE - CLARINEX</u>					
021165 001	>A> 7211582	Dec 30, 2014		U-809	
	>A> 7211582*PED	Jun 30, 2015			
<u>DESLORATADINE - CLARINEX</u>					
021300 001	>A> 7211582	Dec 30, 2014		U-809	
	>A> 7211582*PED	Jun 30, 2015			
<u>DESLORATADINE - CLARINEX</u>					
021312 001	>A> 7211582	Dec 30, 2014		U-809	
	>A> 7211582*PED	Jun 30, 2015			
<u>DESLORATADINE - CLARINEX</u>					
021312 002	>A> 7211582	Dec 30, 2014		U-809	
	>A> 7211582*PED	Jun 30, 2015			

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<u>DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR</u>					
021802 004	5837284	Dec 04, 2015	DP		
	5908850	Dec 04, 2015		U-678	
	6228398	Nov 01, 2019	DP	U-676	
	6528530	Dec 04, 2015	DP		
	6635284	Dec 04, 2015	DP	U-677	
	6730325	Nov 01, 2019	DP	U-676	
<u>DICLOFENAC EPOLAMINE - FLECTOR</u>					
021234 001	4948805	Nov 09, 2007	DS		NE Jan 31, 2010
	5607690	Apr 13, 2014	DP		NDF Jan 31, 2010
<u>DONEPEZIL HYDROCHLORIDE - ARICEPT</u>					
020690 001				I-529	Oct 13, 2009
<u>DONEPEZIL HYDROCHLORIDE - ARICEPT</u>					
020690 002				I-529	Oct 13, 2009
<u>DONEPEZIL HYDROCHLORIDE - ARICEPT</u>					
021719 001				I-529	Oct 13, 2009
<u>DONEPEZIL HYDROCHLORIDE - ARICEPT ODT</u>					
021720 001				I-529	Oct 13, 2009
<u>DONEPEZIL HYDROCHLORIDE - ARICEPT ODT</u>					
021720 002				I-529	Oct 13, 2009
<u>DROSPIRENONE; ETHINYL ESTRADIOL - YAZ</u>					
021676 001	7163931	Dec 20, 2021		U-1	I-522 Jan 26, 2010
<u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>					
021427 001	5023269	Jun 11, 2013	DS DP	U-795	I-524 Feb 23, 2010
	5023269	Jun 11, 2013	DS DP	U-799	
	5023269	Jun 11, 2013	DS DP	U-797	
	5023269	Jun 11, 2013	DS DP	U-796	
	5023269	Jun 11, 2013	DS DP	U-605	
<u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>					
021427 002	5023269	Jun 11, 2013	DS DP	U-797	I-524 Feb 23, 2010
	5023269	Jun 11, 2013	DS DP	U-799	
	5023269	Jun 11, 2013	DS DP	U-796	
	5023269	Jun 11, 2013	DS DP	U-795	
	5023269	Jun 11, 2013	DS DP	U-605	
<u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>					
021427 004	5023269	Jun 11, 2013	DS DP	U-795	I-524 Feb 23, 2010
	5023269	Jun 11, 2013	DS DP	U-797	
	5023269	Jun 11, 2013	DS DP	U-799	
	5023269	Jun 11, 2013	DS DP	U-796	
	5023269	Jun 11, 2013	DS DP	U-605	
<u>DUTASTERIDE - AVODART</u>					
021319 001	5565467	Nov 20, 2015	DS DP		
<u>EFAVIRENZ; EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE - ATRIPLA</u>					
021937 001	6639071	Feb 14, 2018	DS		NCE PED Jul 02, 2008 Jan 02, 2009
<u>EMTRICITABINE - EMTRIVA</u>					
021500 001	5210085	May 11, 2010		U-257	
	5814639	Sep 29, 2015	DS DP		
	5914331	Sep 29, 2015	DS		
<u>ENOXAPARIN SODIUM - LOVENOX</u>					
020164 009				>A>	I-533 May 16, 2010
<u>ENOXAPARIN SODIUM - LOVENOX (PRESERVATIVE FREE)</u>					
020164 001				>A>	I-533 May 16, 2010
<u>ENOXAPARIN SODIUM - LOVENOX (PRESERVATIVE FREE)</u>					
020164 002				>A>	I-533 May 16, 2010
<u>ENOXAPARIN SODIUM - LOVENOX (PRESERVATIVE FREE)</u>					
020164 003				>A>	I-533 May 16, 2010

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<u>ENOXAPARIN SODIUM - LOVENOX (PRESERVATIVE FREE)</u>							
020164 004						>A> I-533	May 16, 2010
<u>ENOXAPARIN SODIUM - LOVENOX (PRESERVATIVE FREE)</u>							
020164 005						>A> I-533	May 16, 2010
<u>ENOXAPARIN SODIUM - LOVENOX (PRESERVATIVE FREE)</u>							
020164 006						>A> I-533	May 16, 2010
<u>ENOXAPARIN SODIUM - LOVENOX (PRESERVATIVE FREE)</u>							
020164 007						>A> I-533	May 16, 2010
<u>ENOXAPARIN SODIUM - LOVENOX (PRESERVATIVE FREE)</u>							
020164 008						>A> I-533	May 16, 2010
<u>ENTECAVIR - BARACLUDE</u>							
021798 001	5908638	Jul 26, 2015		DP			
<u>EPLERENONE - INSPRA</u>							
021437 001	4559332	Aug 11, 2007	DS	DP	U-537		
	7157101	Dec 08, 2019		DP	U-664		
<u>EPLERENONE - INSPRA</u>							
021437 002	4559332	Aug 11, 2007	DS	DP	U-537		
	7157101	Dec 08, 2019		DP	U-664		
<u>EPLERENONE - INSPRA</u>							
021437 003	4559332	Aug 11, 2007	DS	DP	U-537		
	7157101	Dec 08, 2019		DP	U-664		
<u>ERTAPENEM SODIUM - INVANZ</u>							
021337 001	5478820	Nov 21, 2015	DS	DP	U-160		
	5478820*PED	May 21, 2016					
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>							
021153 001	4738974	Sep 01, 2007	DS	DP	U-635		
	4738974	Sep 01, 2007	DS	DP	U-770		
	4738974	Sep 01, 2007	DS	DP	U-373		
	4738974*PED	Mar 01, 2008			U-373		
	4853230	Sep 01, 2007		DP	U-729		
	4853230	Sep 01, 2007		DP	U-770		
	4853230	Sep 01, 2007		DP	U-373		
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>							
021153 002	4738974	Sep 01, 2007	DS	DP	U-770		
	4738974	Sep 01, 2007	DS	DP	U-635		
	4738974	Sep 01, 2007	DS	DP	U-373		
	4738974*PED	Mar 01, 2008			U-373		
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>							
021957 001	4738974	Sep 01, 2007	DS	DP	U-773		
	4738974	Sep 01, 2007	DS	DP	U-729		
	4783974*PED	Mar 01, 2008					
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>							
021957 002	4738974	Sep 01, 2007	DS	DP	U-773		
	4738974	Sep 01, 2007	DS	DP	U-729		
	4783974*PED	Mar 01, 2008					
<u>ESTRADIOL - ELESTRIN</u>							
021813 001	7198801	Jun 25, 2022		DP			
<u>ESTRADIOL; NORETHINDRONE ACETATE - ACTIVELLA</u>							
020907 002						D-104	Dec 28, 2009
						I-525	Dec 29, 2009
<u>ESTROGENS, CONJUGATED SYNTHETIC A - CENESTIN</u>							
020992 001	5908638	Jul 26, 2015		DP			
<u>ESTROGENS, CONJUGATED SYNTHETIC B - ENJUVIA</u>							
021443 001						I-528	Apr 23, 2010
<u>ETHINYL ESTRADIOL; LEVONORGESTREL - LYBREL</u>							
021864 001						>A> NP	May 22, 2010

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<u>FENTANYL CITRATE - ACTIQ</u>					
020747 001				M-63	Feb 06, 2010
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 002				M-63	Feb 06, 2010
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 003				M-63	Feb 06, 2010
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 004				M-63	Feb 06, 2010
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 005				M-63	Feb 06, 2010
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 006				M-63	Feb 06, 2010
<u>FENTANYL CITRATE - FENTORA</u>					
021947 006				NDF	Sep 25, 2009
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>					
021520 001	>A> 5229382	Apr 23, 2011	DS DP	>A> NC	Dec 24, 2006
	>A> 5229382*PED	Oct 23, 2011		>A> PED	Jun 24, 2007
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>					
021520 002	5229382	Apr 23, 2011	DS DP	NC	Dec 24, 2006
	5229382*PED	Oct 23, 2011		PED	Jun 24, 2007
	5945416	Mar 24, 2017	DS DP		
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>					
021520 003	5229382	Apr 23, 2011	DS DP	NC	Dec 24, 2006
	5229382*PED	Oct 23, 2011		PED	Jun 24, 2007
	5945416	Mar 24, 2017	DS DP		
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>					
021520 004	5229382	Apr 23, 2011	DS DP	NC	Dec 24, 2006
	5229382*PED	Oct 23, 2011		PED	Jun 24, 2007
	5945416	Mar 24, 2017	DS DP		
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>					
021520 005	5229382	Apr 23, 2011	DS DP	NC	Dec 24, 2006
	5229382*PED	Oct 23, 2011		PED	Jun 24, 2007
	5945416	Mar 24, 2017	DS DP		
<u>FLUTICASON FUROATE - VERAMYST</u>					
022051 001	>A> 6858596	Aug 03, 2021	DP	U-808	
	>A> 7101866	Aug 03, 2021	DS DP	U-808	
<u>FORMOTEROL FUMARATE - FORADIL CERTIHALER</u>					
021592 001	6182655	Dec 05, 2016	DP	NP	Dec 15, 2009
	6645466	Nov 10, 2019	DP		
<u>FORMOTEROL FUMARATE - PERFOROMIST</u>					
022007 001				>A> NP	May 11, 2010
<u>GALANTAMINE HYDROBROMIDE - RAZADYNE ER</u>					
021615 001	7160559	Dec 20, 2019	DP		
<u>GALANTAMINE HYDROBROMIDE - RAZADYNE ER</u>					
021615 002	7160559	Dec 20, 2019	DP		
<u>GALANTAMINE HYDROBROMIDE - RAZADYNE ER</u>					
021615 003	7160559	Dec 20, 2019	DP		
<u>GEMIFLOXACIN MESYLATE - FACTIVE</u>					
021158 001				>A> D-106	May 01, 2010
<u>HISTRELIN ACETATE - SUPPRELIN LA</u>					
022058 001				>A> NP	May 03, 2010
<u>HYDROCHLOROTHIAZIDE; VALSARTAN - DIOVAN HCT</u>					
020818 004	5399578	Mar 21, 2012	DS DP	U-3	
	6294197	Jun 18, 2017	DP	U-3	

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<u>HYDROCHLOROTHIAZIDE; VALSARTAN - DIOVAN HCT</u>					
020818 005	5399578	Mar 21, 2012	DS DP U-3		
	6294197	Jun 18, 2017	DP U-3		
<u>HYDROCORTISONE BUTYRATE - LOCOID</u>					
022076 001				>A> NDF	May 18, 2010
<u>HYDROXOCOBALAMIN - CYANOKIT</u>					
022041 002	5834448	Nov 14, 2016	DP U-789	ODE	Dec 15, 2013
<u>IBANDRONATE SODIUM - BONIVA</u>					
021455 001	4927814	Jul 09, 2008	DS DP U-700		
	4927814	Jul 09, 2008	DS DP U-642		
<u>IBANDRONATE SODIUM - BONIVA</u>					
021455 002	4927814	Jul 09, 2008	DS DP U-700		
	4927814	Jul 09, 2008	DS DP U-642		
	7192938	May 06, 2023		U-798	
<u>IBUPROFEN LYSINE - NEOPROFEN</u>					
021903 001	6342530	Nov 14, 2020	DS DP U-794		
	6344479	Mar 20, 2021	DS DP U-794		
<u>IMATINIB MESYLATE - GLEEVEC</u>					
021335 001	6958335	Dec 19, 2021		U-791	
	6958335*PED	Jun 19, 2022			
<u>IMATINIB MESYLATE - GLEEVEC</u>					
021335 002	6958335	Dec 19, 2021		U-791	
	6958335*PED	Jun 19, 2022			
<u>IMATINIB MESYLATE - GLEEVEC</u>					
021588 001	6958335	Dec 19, 2021		U-791	
	6958335*PED	Jun 19, 2022			
<u>IMATINIB MESYLATE - GLEEVEC</u>					
021588 002	6958335	Dec 19, 2021		U-791	
	6958335*PED	Jun 19, 2022			
<u>IRON SUCROSE - VENOFER</u>					
021135 004				I-474 I-459	Oct 17, 2008 Jun 17, 2008
<u>KETOCONAZOLE - XOLEGEL</u>					
021946 001	7179475	Dec 04, 2018	DP U-792		
<u>LAMIVUDINE - EPIVIR</u>					
020564 001	>A> 7119202	Feb 08, 2009	DS		
	>A> 7119202*PED	Aug 08, 2009			
<u>LAMIVUDINE - EPIVIR</u>					
020564 003	>A> 7119202	Feb 08, 2009	DS		
	>A> 7119202*PED	Aug 08, 2009			
<u>LAMIVUDINE - EPIVIR</u>					
020596 001	>A> 7119202	Feb 08, 2009	DS		
	>A> 7119202*PED	Aug 08, 2009			
<u>LAMIVUDINE - EPIVIR-HBV</u>					
021003 001	>A> 7119202	Feb 08, 2009	DS		
	>A> 7119202*PED	Aug 08, 2008			
<u>LAMIVUDINE - EPIVIR-HBV</u>					
021004 001	>A> 7119202	Feb 08, 2009	DS		
	>A> 7119202*PED	Aug 08, 2009			
<u>LAMIVUDINE; ZIDOVUDINE - COMBIVIR</u>					
020857 001	>A> 7119202	Feb 08, 2009	DS		
	>A> 7119202*PED	Aug 08, 2009			
<u>LAMOTRIGINE - LAMICTAL</u>					
020241 001	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010

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<u>LAMOTRIGINE - LAMICTAL</u>					
020241 002	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
<u>LAMOTRIGINE - LAMICTAL</u>					
020241 003	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
<u>LAMOTRIGINE - LAMICTAL</u>					
020241 004	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
<u>LAMOTRIGINE - LAMICTAL</u>					
020241 005	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
<u>LAMOTRIGINE - LAMICTAL</u>					
020241 006	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
<u>LAMOTRIGINE - LAMICTAL CD</u>					
020764 001	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
	5698226	Jan 29, 2012			
	5698226*PED	Jul 29, 2012			
<u>LAMOTRIGINE - LAMICTAL CD</u>					
020764 002	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
	5698226	Jan 29, 2012			
	5698226*PED	Jul 29, 2012			
<u>LAMOTRIGINE - LAMICTAL CD</u>					
020764 003	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
	5698226	Jan 29, 2012			
	5698226*PED	Jul 29, 2012			
<u>LAMOTRIGINE - LAMICTAL CD</u>					
020764 004	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
	5698226	Jan 29, 2012			
	5698226*PED	Jul 29, 2012			
<u>LAPATINIB DITOSYLATE - TYKERB</u>					
022059 001	6391874	Jul 11, 2017	DS DP	U-800	NCE
	6713485	Jan 08, 2019	DS DP	U-800	Mar 13, 2012
	6727256	Jan 08, 2019	DS DP	U-800	
	6828320	Jul 11, 2017		U-800	
	7157466	Nov 19, 2021	DS DP		
<u>LATANOPROST - XALATAN</u>					
020597 001	7163959	Jun 19, 2010	DS		
<u>LENALIDOMIDE - REVLIMID</u>					
021880 001	7189740	Apr 11, 2023		U-769	
<u>LENALIDOMIDE - REVLIMID</u>					
021880 002	7189740	Apr 11, 2023		U-769	
<u>LENALIDOMIDE - REVLIMID</u>					
021880 003	7189740	Apr 11, 2023		U-769	
<u>LENALIDOMIDE - REVLIMID</u>					
021880 004	7189740	Apr 11, 2023		U-769	

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<u>LEUPROLIDE ACETATE - ELIGARD</u>					
021343 001	6395293	Sep 28, 2013	DP U-801		
	6565874	Oct 28, 2018	DP U-801		
	6626870	Mar 27, 2020	DP		
	6773714	Oct 28, 2018	DP U-801		
	RE37950	Oct 03, 2008	DP U-801		
<u>LEUPROLIDE ACETATE - ELIGARD</u>					
021379 001	6395293	Sep 28, 2013	DP		
	6565874	Oct 28, 2018	DP U-801		
	6626870	Mar 27, 2020	DP		
	6773714	Oct 28, 2018	DP U-801		
	RE37950	Oct 03, 2008	DP U-801		
<u>LEUPROLIDE ACETATE - ELIGARD</u>					
021488 001	6395293	Sep 28, 2013	DP		
	6565874	Oct 28, 2018	DP U-801		
	6626870	Mar 27, 2020	DP		
	6773714	Oct 28, 2018	DP U-801		
	RE37950	Oct 03, 2008	DP U-801		
<u>LEVETIRACETAM - KEPPRA</u>					
021035 001				I-527	Mar 19, 2010
<u>LEVETIRACETAM - KEPPRA</u>					
021035 002				I-527	Mar 19, 2010
<u>LEVETIRACETAM - KEPPRA</u>					
021035 003				I-527	Mar 19, 2010
<u>LEVETIRACETAM - KEPPRA</u>					
021035 004				I-527	Mar 19, 2010
<u>LEVETIRACETAM - KEPPRA</u>					
021505 001				I-527	Mar 19, 2010
<u>LEVOCETIRIZINE DIHYDROCHLORIDE - XYZAL</u>					
022064 001				>A> NP	May 25, 2010
<u>LEVOFLOXACIN - LEVAQUIN</u>					
020634 001	5053407	Dec 20, 2010		D-100	Aug 04, 2008
	5053407*PED	Jun 20, 2011		D-83	Oct 23, 2006
				PED	Feb 04, 2009
				PED	Apr 23, 2007
<u>LEVOFLOXACIN - LEVAQUIN</u>					
020634 002	5053407	Dec 20, 2010		D-100	Aug 04, 2008
	5053407*PED	Jun 20, 2011		D-83	Oct 23, 2006
				PED	Feb 04, 2009
				PED	Apr 23, 2007
<u>LEVOFLOXACIN - LEVAQUIN</u>					
020634 003	5053407	Dec 20, 2010		D-100	Aug 04, 2008
	5053407*PED	Jun 20, 2011		D-83	Oct 23, 2006
				PED	Apr 23, 2007
				PED	Feb 04, 2009
<u>LEVOFLOXACIN - LEVAQUIN</u>					
020635 001	5053407	Dec 20, 2010		D-100	Aug 04, 2008
	5053407*PED	Jun 20, 2011		D-83	Oct 23, 2006
				PED	Feb 04, 2009
				PED	Apr 23, 2007
<u>LEVOFLOXACIN - LEVAQUIN</u>					
020635 004	5053407	Dec 20, 2010		D-100	Aug 04, 2008
	5053407*PED	Jun 20, 2011		D-83	Oct 23, 2006
				PED	Apr 23, 2007
				PED	Feb 04, 2009
<u>LEVOFLOXACIN - LEVAQUIN</u>					
021721 001	5053407	Dec 20, 2010	DS	U-36	Aug 04, 2008
	5053407*PED	Jun 20, 2011			Feb 04, 2009
	6806256	Feb 26, 2022	DP		
	6806256*PED	Aug 26, 2022			



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<u>LEVOFLOXACIN - LEVAQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER</u>					
020635 002	5053407	Dec 20, 2010		D-100	Aug 04, 2008
	5053407*PED	Jun 20, 2011		D-83 PED PED	Oct 23, 2006 Feb 04, 2009 Apr 23, 2007
<u>LEVOFLOXACIN - LEVAQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER</u>					
020635 003	5053407	Dec 20, 2010		D-100	Aug 04, 2008
	5053407*PED	Jun 20, 2011		D-83 PED PED	Oct 23, 2006 Feb 04, 2009 Apr 23, 2007
<u>LEVOFLOXACIN - LEVAQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER</u>					
020635 005	5053407	Dec 20, 2010		D-100	Aug 04, 2008
	5053407*PED	Jun 20, 2011		D-83 PED PED	Oct 23, 2006 Apr 23, 2007 Feb 04, 2009
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>					
021977 001	7105486	Jun 29, 2023	U-727	NCE	Feb 23, 2012
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>					
021977 002	7105486	Jun 29, 2023	U-727	NCE	Feb 23, 2012
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>					
021977 003	7105486	Jun 29, 2023	U-727	NCE	Feb 23, 2012
<u>LOPERAMIDE HYDROCHLORIDE - IMODIUM A-D EZ CHEWS</u>					
020448 001	5489436	Feb 06, 2013	DP		
	6814978	Aug 26, 2021	DP		
<u>LOPINAVIR; RITONAVIR - KALETRA</u>					
021251 001	5914332	Dec 13, 2015	U-351		
<u>LOPINAVIR; RITONAVIR - KALETRA</u>					
021906 001	7148359	Jul 19, 2019	DP		
<u>MESALAMINE - LIALDA</u>					
022000 001	6773720	Jun 08, 2020	DP	NP	Jan 16, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 001				M-62	Jan 31, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 002				M-62	Jan 31, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 003				M-62	Jan 31, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 004				M-62	Jan 31, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 005				M-62	Jan 31, 2010
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>					
022044 001	6303661	Apr 24, 2017	U-802	NC	Mar 30, 2010
	6699871	Jul 26, 2022	DS DP	U-802	Oct 16, 2011
	6890898	Feb 02, 2019		U-803	
	7078381	Feb 02, 2019		U-803	
	7125873	Jul 26, 2022	DP	U-803	
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>					
022044 002	6303661	Apr 24, 2017	U-802	NC	Mar 30, 2010
	6699871	Jul 26, 2022	DS DP	U-802	Oct 16, 2011
	6890898	Feb 02, 2019		U-803	
	7078381	Feb 02, 2019		U-803	
	7125873	Jul 26, 2022	DP	U-803	
<u>METHYL AMINOLEVULINATE HYDROCHLORIDE - METVIXIA</u>					
021415 001	6034267	Mar 08, 2016	U-804		
<u>MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE - VUSION</u>					
021026 001	4911932	Mar 27, 2008	DP	U-718	

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<u>MONTELUKAST SODIUM - SINGULAIR</u>					
020829 002	>A> 5565473	Feb 03, 2012	DS DP	U-675	I-530 Apr 13, 2010
	>A> 5565473	Feb 03, 2012	DS DP	U-807	
	>A> 5565473	Feb 03, 2012	DS DP	U-228	
<u>MONTELUKAST SODIUM - SINGULAIR</u>					
020830 001	>A> 5565473	Feb 03, 2012	DS DP	U-675	I-530 Apr 13, 2010
	>A> 5565473	Feb 03, 2012	DS DP	U-807	
	>A> 5565473	Feb 03, 2012	DS DP	U-228	
<u>MONTELUKAST SODIUM - SINGULAIR</u>					
020830 002	>A> 5565473	Feb 03, 2012	DS DP	U-807	I-530 Apr 13, 2010
	>A> 5565473	Feb 03, 2012	DS DP	U-675	
	>A> 5565473	Feb 03, 2012	DS DP	U-228	
<u>MONTELUKAST SODIUM - SINGULAIR</u>					
021409 001	>A> 5565473	Feb 03, 2012	DS DP	U-807	I-530 Apr 13, 2010
	>A> 5565473	Feb 03, 2012	DS DP	U-675	
<u>MORPHINE SULFATE - KADIAN</u>					
020616 006	5202128	Apr 13, 2010		DP	
	5378474	Mar 23, 2010		DP	
<u>MORPHINE SULFATE - KADIAN</u>					
020616 007	5202128	Apr 13, 2010		DP	
	5378474	Mar 23, 2010		DP	
<u>MORPHINE SULFATE - KADIAN</u>					
020616 008	5202128	Apr 13, 2010			
<u>MOXIFLOXACIN HYDROCHLORIDE - VIGAMOX</u>					
021598 001	6716830	Sep 29, 2019		DP	
<u>OLANZAPINE - ZYPREXA</u>					
020592 001	5229382	Apr 23, 2011	DS DP	U-149	I-417 Jan 14, 2007
	5229382	Apr 23, 2011	DS DP	U-547	PED Jul 14, 2007
	5229382*PED	Oct 23, 2011			
	>A> 5605897	Feb 25, 2014		U-176	
	>A> 5605897*PED	Aug 25, 2014			
	>A> 5627178	Apr 23, 2011		U-364	
	>A> 5627178*PED	Oct 23, 2011			
	>A> 5736541	Mar 24, 2015		U-307	
	>A> 5736541*PED	Sep 24, 2015			
	>A> 5817655	Apr 23, 2011		U-364	
	>A> 5817655*PED	Oct 23, 2011			
	>A> 5817656	Apr 23, 2011		U-360	
	>A> 5817656*PED	Oct 23, 2011			
	>A> 5817657	Apr 23, 2011		U-363	
	>A> 5817657*PED	Oct 23, 2011			
	>A> 5919485	Mar 24, 2015		U-308	
	>A> 5919485*PED	Sep 24, 2015			
	>A> 6251895	Sep 23, 2017			
	>A> 6251895*PED	Mar 23, 2018			

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<u>OLANZAPINE - ZYPREXA</u>					
020592 002	5229382	Apr 23, 2011	DS DP	U-547	I-417
	5229382	Apr 23, 2011	DS DP	U-149	PED
	5229382*PED	Oct 23, 2011			
	>A> 5605897	Feb 25, 2014		U-176	
	>A> 5605897*PED	Aug 25, 2014			
	>A> 5627178	Apr 23, 2011		U-364	
	>A> 5627178*PED	Oct 23, 2011			
	>A> 5736541	Mar 24, 2015		U-307	
	>A> 5736541*PED	Sep 24, 2015			
	>A> 5817655	Apr 23, 2011		U-364	
	>A> 5817655*PED	Oct 23, 2011			
	>A> 5817656	Apr 23, 2011		U-360	
	>A> 5817656*PED	Oct 23, 2011			
	>A> 5817657	Apr 23, 2011		U-363	
	>A> 5817657*PED	Oct 23, 2011			
	>A> 5919485	Mar 24, 2015		U-308	
	>A> 5919485*PED	Sep 24, 2015			
	>A> 6251895	Sep 23, 2017			
	>A> 6251895*PED	Mar 23, 2018			
<u>OLANZAPINE - ZYPREXA</u>					
020592 003	5229382	Apr 23, 2011	DS DP	U-547	I-417
	5229382	Apr 23, 2011	DS DP	U-149	PED
	5229382*PED	Oct 23, 2011			
	>A> 5605897	Feb 25, 2014		U-176	
	>A> 5605897*PED	Aug 25, 2014			
	>A> 5627178	Apr 23, 2011		U-364	
	>A> 5627178*PED	Oct 23, 2011			
	>A> 5736541	Mar 24, 2015		U-307	
	>A> 5736541*PED	Sep 24, 2015			
	>A> 5817655	Apr 23, 2011		U-364	
	>A> 5817655*PED	Oct 23, 2011			
	>A> 5817656	Apr 23, 2011		U-360	
	>A> 5817656*PED	Oct 23, 2011			
	>A> 5817657	Apr 23, 2011		U-363	
	>A> 5817657*PED	Oct 23, 2011			
	>A> 5919485	Mar 24, 2015		U-308	
	>A> 5919485*PED	Sep 24, 2015			
	>A> 6251895	Sep 23, 2017			
	>A> 6251895*PED	Mar 23, 2018			

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<u>OLANZAPINE - ZYPREXA</u>					
020592 004	5229382	Apr 23, 2011	DS DP	U-547	I-417
	5229382	Apr 23, 2011	DS DP	U-149	PED
	5229382*PED	Oct 23, 2011			
	>A> 5605897	Feb 25, 2014		U-176	
	>A> 5605897*PED	Aug 25, 2014			
	>A> 5627178	Apr 23, 2011		U-364	
	>A> 5627178*PED	Oct 23, 2011			
	>A> 5736541	Mar 24, 2015		U-307	
	>A> 5736541*PED	Sep 24, 2015			
	>A> 5817655	Apr 23, 2011		U-364	
	>A> 5817655*PED	Oct 23, 2011			
	>A> 5817656	Apr 23, 2011		U-360	
	>A> 5817656*PED	Oct 23, 2011			
	>A> 5817657	Apr 23, 2011		U-363	
	>A> 5817657*PED	Oct 23, 2011			
	>A> 5919485	Mar 24, 2015		U-308	
	>A> 5919485*PED	Sep 24, 2015			
	>A> 6251895	Sep 23, 2017			
	>A> 6251895*PED	Mar 23, 2018			
<u>OLANZAPINE - ZYPREXA</u>					
020592 005	5229382	Apr 23, 2011	DS DP	U-149	I-417
	5229382	Apr 23, 2011	DS DP	U-547	PED
	5229382*PED	Oct 23, 2011			
	>A> 5605897	Feb 25, 2014		U-176	
	>A> 5605897*PED	Aug 25, 2014			
	>A> 5627178	Apr 23, 2011		U-364	
	>A> 5627178*PED	Oct 23, 2011			
	>A> 5736541	Mar 24, 2015		U-307	
	>A> 5736541*PED	Sep 24, 2015			
	>A> 5817655	Apr 23, 2011		U-364	
	>A> 5817655*PED	Oct 23, 2011			
	>A> 5817656	Apr 23, 2011		U-360	
	>A> 5817656*PED	Oct 23, 2011			
	>A> 5817657	Apr 23, 2011		U-363	
	>A> 5817657*PED	Oct 23, 2011			
	>A> 5919485	Mar 24, 2015		U-308	
	>A> 5919485*PED	Sep 24, 2015			
	>A> 6251895	Sep 23, 2017			
	>A> 6251895*PED	Mar 23, 2018			

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<u>OLANZAPINE - ZYPREXA</u>					
020592 006	5229382	Apr 23, 2011	DS DP	U-547	I-417 Jan 14, 2007
	5229382	Apr 23, 2011	DS DP	U-149	PED Jul 14, 2007
	5229382*PED	Oct 23, 2011			
	>A> 5605897	Feb 25, 2014		U-176	
	>A> 5605897*PED	Aug 25, 2014			
	>A> 5627178	Apr 23, 2011		U-364	
	>A> 5627178*PED	Oct 23, 2011			
	>A> 5736541	Mar 24, 2015		U-307	
	>A> 5736541*PED	Sep 24, 2015			
	>A> 5817655	Apr 23, 2011		U-364	
	>A> 5817655*PED	Oct 23, 2011			
	>A> 5817656	Apr 23, 2011		U-360	
	>A> 5817656*PED	Oct 23, 2011			
	>A> 5817657	Apr 23, 2011		U-363	
	>A> 5817657*PED	Oct 23, 2011			
	>A> 5919485	Mar 24, 2015		U-308	
	>A> 5919485*PED	Sep 24, 2015			
	>A> 6251895	Sep 23, 2017			
	>A> 6251895*PED	Mar 23, 2018			
<u>OLANZAPINE - ZYPREXA</u>					
021253 001	5229382	Apr 23, 2011	DS DP	U-571	NP Mar 29, 2007
	5229382*PED	Oct 23, 2011			NDF Mar 29, 2007
					PED Sep 29, 2007
					PED Sep 29, 2007
<u>OLANZAPINE - ZYPREXA ZYDIS</u>					
021086 001	5229382	Apr 23, 2011		U-324	I-400 Jul 10, 2006
	5229382*PED	Oct 23, 2011			I-417 Jan 14, 2007
					PED Jan 10, 2007
					PED Jul 14, 2007
<u>OLANZAPINE - ZYPREXA ZYDIS</u>					
021086 002	5229382	Apr 23, 2011		U-324	I-400 Jul 10, 2006
	5229382*PED	Oct 23, 2011			I-417 Jan 14, 2007
					PED Jan 10, 2007
					PED Jul 14, 2007
<u>OLANZAPINE - ZYPREXA ZYDIS</u>					
021086 003	5229382	Apr 23, 2011		U-324	I-400 Jul 10, 2006
	5229382*PED	Oct 23, 2011			I-417 Jan 14, 2007
					PED Jan 10, 2007
					PED Jul 14, 2007
<u>OLANZAPINE - ZYPREXA ZYDIS</u>					
021086 004	5229382	Apr 23, 2011		U-324	I-400 Jul 10, 2006
	5229382*PED	Oct 23, 2011			I-417 Jan 14, 2007
					PED Jan 10, 2007
					PED Jul 14, 2007
<u>ONDANSETRON - ONDANSETRON</u>					
076506 001					PC Jun 24, 2007
<u>ONDANSETRON - ONDANSETRON</u>					
076506 002					PC Jun 24, 2007
<u>ONDANSETRON HYDROCHLORIDE - ONDANSETRON HYDROCHLORIDE</u>					
076183 001					PC Jun 24, 2007
<u>ONDANSETRON HYDROCHLORIDE - ONDANSETRON HYDROCHLORIDE</u>					
076183 002					PC Jun 24, 2007
<u>ONDANSETRON HYDROCHLORIDE - ONDANSETRON HYDROCHLORIDE</u>					
076183 003					PC Jun 24, 2007
<u>ORLISTAT - ALLI</u>					
021887 001	4598089	Jun 18, 2009	DS DP		NP Feb 07, 2010
	6004996	Jan 06, 2018		DP	

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<u>OXALIPLATIN - ELOXATIN</u>					
021492 001				M-61 PED	Jan 10, 2010 Jul 10, 2010
<u>OXALIPLATIN - ELOXATIN</u>					
021492 002				M-61 PED	Jan 10, 2010 Jul 10, 2010
<u>OXALIPLATIN - ELOXATIN</u>					
021759 001	5420319	Aug 09, 2016	DS		
	5420319*PED	Feb 09, 2017			
<u>OXALIPLATIN - ELOXATIN</u>					
021759 002	5420319	Aug 09, 2016	DS		
	5420319*PED	Feb 09, 2017			
<u>OXALIPLATIN - ELOXATIN</u>					
021759 003	5290961	Jan 12, 2013	DS		
	5290961*PED	Jul 12, 2013			
	5338874	Apr 07, 2013	DS		
	5338874*PED	Oct 07, 2013			
	5420319	Aug 09, 2016	DS		
	5420319*PED	Feb 09, 2017			
	5716988	Aug 07, 2015		DP	
	5716988*PED	Feb 07, 2016			
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021014 001	7037525	Feb 12, 2018		U-724	
	7037525*PED	Aug 12, 2018			
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021014 002	7037525	Feb 12, 2018		U-724	
	7037525*PED	Aug 12, 2018			
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021014 003	7037525	Feb 12, 2018		U-724	
	7037525*PED	Aug 12, 2018			
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021285 001	>A> 7037525*PED	Aug 12, 2018			
<u>OXYBUTYNIN - OXYTROL</u>					
021351 002	7179483	Apr 26, 2020	DS	DP	U-318
<u>PALIPERIDONE - INVEGA</u>					
021999 001	5158952	Oct 27, 2009	DP	U-90	>A> I-531 Apr 27, 2010
<u>PALIPERIDONE - INVEGA</u>					
021999 002	5158952	Oct 27, 2009	DP	U-90	>A> I-531 Apr 27, 2010
<u>PALIPERIDONE - INVEGA</u>					
021999 003	5158952	Oct 27, 2009	DP	U-90	>A> I-531 Apr 27, 2010
<u>PALIPERIDONE - INVEGA</u>					
021999 004	5158952	Oct 27, 2009	DP	U-90	>A> I-531 Apr 27, 2010
<u>PALONOSETRON HYDROCHLORIDE - ALOXI</u>					
021372 001	>A> 5202333	Apr 13, 2015	DS	DP	U-528
<u>PAROXETINE HYDROCHLORIDE - PAROXETINE HYDROCHLORIDE</u>					
077395 001				PC	Jun 10, 2007
<u>PAROXETINE HYDROCHLORIDE - PAXIL CR</u>					
020936 001	5789449	Jan 06, 2009		U-788	
	5789449*PED	Jul 06, 2009			
<u>PAROXETINE HYDROCHLORIDE - PAXIL CR</u>					
020936 002	5789449	Jan 06, 2009		U-788	
	5789449*PED	Jul 06, 2009			
<u>PAROXETINE HYDROCHLORIDE - PAXIL CR</u>					
020936 003	5789449	Jan 06, 2009		U-788	
	5789449*PED	Jul 06, 2009			

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<u>PEMETREXED DISODIUM - ALIMTA</u>					
021462 001	5344932	Jul 24, 2016	DS DP		
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>					
022047 001				>A> NDF	May 17, 2010
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>					
022047 002				>A> NDF	May 17, 2010
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>					
022047 003				>A> NDF	May 17, 2010
<u>QUETIAPINE FUMARATE - SEROQUEL XR</u>					
022047 004				>A> NDF	May 17, 2010
<u>RAMIPRIL - ALTACE</u>					
019901 001	5061722	Oct 29, 2008			
<u>RAMIPRIL - ALTACE</u>					
019901 002	5061722	Oct 29, 2008			
<u>RAMIPRIL - ALTACE</u>					
019901 003	5061722	Oct 29, 2008			
<u>RAMIPRIL - ALTACE</u>					
019901 004	5061722	Oct 29, 2008			
<u>RAMIPRIL - ALTACE</u>					
022021 001	5061722	Oct 29, 2008	DS DP	U-185	
	5403856	Apr 04, 2012		U-71	
<u>RAMIPRIL - ALTACE</u>					
022021 002	5061722	Oct 29, 2008	DS DP	U-185	
	5403856	Apr 04, 2012		U-71	
<u>RAMIPRIL - ALTACE</u>					
022021 003	5061722	Oct 29, 2008	DS DP	U-185	
	5403856	Apr 04, 2012		U-71	
<u>RAMIPRIL - ALTACE</u>					
022021 004	5061722	Oct 29, 2008	DS DP	U-185	
	5403856	Apr 04, 2012		U-71	
<u>RANITIDINE HYDROCHLORIDE - RANITIDINE HYDROCHLORIDE</u>					
076124 001				PC	Sep 15, 2007
<u>RETAPAMULIN - ALTABAX</u>					
022055 001	>A> RE39128	Oct 27, 2018	DS DP	U-805	NCE Apr 12, 2012
<u>RISEDRONATE SODIUM - ACTONEL</u>					
020835 004	>A> 5583122	Dec 10, 2013	DS DP	U-353	D-105 Apr 16, 2010
	>A> 6096342	Nov 22, 2011	DP	U-353	M-52 Jan 24, 2009
	>A> 6165513	Jun 10, 2018	DP		
<u>RISPERIDONE - RISPERDAL</u>					
020272 001	4804663	Dec 29, 2007		U-90	I-509 Oct 06, 2009
	4804663*PED	Jun 29, 2008			I-413 Dec 04, 2006
					I-412 Dec 04, 2006
					PED Jun 04, 2007
					PED Jun 04, 2007
					PED Apr 06, 2010
<u>RISPERIDONE - RISPERDAL</u>					
020272 002	4804663	Dec 29, 2007		U-90	I-509 Oct 06, 2009
	4804663*PED	Jun 29, 2008			I-413 Dec 04, 2006
					I-412 Dec 04, 2006
					PED Jun 04, 2007
					PED Jun 04, 2007
					PED Apr 06, 2010

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<u>RISPERIDONE - RISPERDAL</u>							
020272 003	4804663	Dec 29, 2007	U-90			I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008				I-413	Dec 04, 2006
						I-412	Dec 04, 2006
						PED	Jun 04, 2007
						PED	Jun 04, 2007
						PED	Apr 06, 2010
<u>RISPERIDONE - RISPERDAL</u>							
020272 004	4804663	Dec 29, 2007	U-90			I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008				I-413	Dec 04, 2006
						I-412	Dec 04, 2006
						PED	Jun 04, 2007
						PED	Jun 04, 2007
						PED	Apr 06, 2010
<u>RISPERIDONE - RISPERDAL</u>							
020272 005	4804663	Dec 29, 2007	U-90			I-413	Dec 04, 2006
	4804663*PED	Jun 29, 2008				I-412	Dec 04, 2006
						PED	Jun 04, 2007
						PED	Jun 04, 2007
<u>RISPERIDONE - RISPERDAL</u>							
020272 007	4804663	Dec 29, 2007	U-90			I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008				I-413	Dec 04, 2006
						I-412	Dec 04, 2006
						PED	Jun 04, 2007
						PED	Jun 04, 2007
						PED	Apr 06, 2010
<u>RISPERIDONE - RISPERDAL</u>							
020272 008	4804663	Dec 29, 2007	U-90			I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008				I-413	Dec 04, 2006
						I-412	Dec 04, 2006
						PED	Jun 04, 2007
						PED	Jun 04, 2007
						PED	Apr 06, 2010
<u>RISPERIDONE - RISPERDAL</u>							
020588 001	4804663	Dec 29, 2007	U-90			I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008				I-413	Dec 04, 2006
	5453425	Jul 11, 2014				I-412	Dec 04, 2006
	5453425*PED	Jan 11, 2015				PED	Apr 06, 2010
	5616587	Jul 11, 2014				PED	Jun 04, 2007
	5616587*PED	Jan 11, 2015				PED	Jun 04, 2007
	RE39181	Jul 11, 2014	DP				
	RE39181*PED	Jan 11, 2015					
<u>RISPERIDONE - RISPERDAL</u>							
021444 001	4804663	Dec 29, 2007	DS	DP	U-516	I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008				I-413	Dec 04, 2006
	5648093	Jul 15, 2014		DP		I-412	Dec 04, 2006
	5648093*PED	Jan 15, 2015				PED	Jun 04, 2007
	6224905	Jun 10, 2017		DP		PED	Jun 04, 2007
	6244905*PED	Dec 10, 2017				PED	Apr 06, 2010
<u>RISPERIDONE - RISPERDAL</u>							
021444 002	4804663	Dec 29, 2007	DS	DP	U-516	I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008				I-413	Dec 04, 2006
	5648093	Jul 15, 2014		DP		I-412	Dec 04, 2006
	5648093*PED	Jan 15, 2015				PED	Jun 04, 2007
	6224905	Jun 10, 2017		DP		PED	Jun 04, 2007
	6244905*PED	Dec 10, 2017				PED	Apr 06, 2010



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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>RISPERIDONE - RISPERDAL</u>					
021444 003	4804663	Dec 29, 2007	DS DP	U-516	I-509 Oct 06, 2009
	4804663*PED	Jun 29, 2008			I-413 Dec 04, 2006
	5648093	Jul 15, 2014	DP		I-412 Dec 04, 2006
	5648093*PED	Jan 15, 2015			PED Apr 06, 2010
	6224905	Jun 10, 2017	DP		PED Jun 04, 2007
	6244905*PED	Dec 10, 2017			PED Jun 04, 2007
<u>RISPERIDONE - RISPERDAL</u>					
021444 004	4804663	Dec 29, 2007	DS DP	U-516	I-509 Oct 06, 2009
	4804663	Dec 29, 2007	DS DP	U-543	I-413 Dec 04, 2006
	4804663*PED	Jun 29, 2008			I-412 Dec 04, 2006
	5648093	Jul 15, 2014	DP		PED Jun 04, 2007
	5648093*PED	Jan 15, 2015			PED Jun 04, 2007
	6224905	Jun 10, 2017	DP		PED Apr 06, 2010
	6244905*PED	Dec 10, 2017			
<u>RISPERIDONE - RISPERDAL</u>					
021444 005	4804663	Dec 29, 2007	DS DP	U-516	I-509 Oct 06, 2009
	4804663	Dec 29, 2007	DS DP	U-543	I-413 Dec 04, 2006
	4804663*PED	Jun 29, 2008			I-412 Dec 04, 2006
	5648093	Jul 15, 2014	DP		PED Jun 04, 2007
	5648093*PED	Jan 15, 2015			PED Jun 04, 2007
	6224905	Jun 10, 2017	DP		PED Apr 06, 2010
	6244905*PED	Dec 10, 2017			
<u>RISPERIDONE - RISPERDAL CONSTA</u>					
021346 001	4804663	Dec 29, 2007			NDF Oct 29, 2006
	4804663*PED	Jun 29, 2008			PED Apr 29, 2007
	5688801	Nov 18, 2014			
	5688801*PED	May 18, 2015			
	5770231	Nov 19, 2013			
	5770231*PED	May 19, 2014			
	5792477	May 02, 2017			
	5792477*PED	Nov 02, 2017			
	5916598	May 02, 2017			
	5916598*PED	Nov 02, 2017			
	5965168	Nov 19, 2013			
	5965168*PED	May 19, 2014			
	6110503	May 02, 2017			
	6110503*PED	Nov 02, 2017			
	6110921	Nov 19, 2013			
	6110921*PED	May 19, 2014			
	6194006	Dec 30, 2018			
	6194006*PED	Jun 30, 2019			
	6264987	May 19, 2020			
	6264987*PED	Nov 19, 2020			
	6368632	Nov 19, 2013		U-543	
	6368632*PED	May 19, 2014			
	6379703	Dec 30, 2018	DP		
	6379703*PED	Jun 30, 2019			
	6379704	May 19, 2020	DP		
	6379704*PED	Nov 19, 2020			
	6403114	May 02, 2017			
	6403114*PED	Nov 02, 2017			
	6534092	May 19, 2020	DP		
	6534092*PED	Nov 19, 2020			
	>A> 6596316	Dec 30, 2018	DP		
	>A> 6596316*PED	Jun 30, 2019			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>RISPERIDONE - RISPERDAL CONSTA</u>					
021346 002	4804663	Dec 29, 2007		NDF	Oct 29, 2006
	4804663*PED	Jun 29, 2008		PED	Apr 29, 2007
	5688801	Nov 18, 2014			
	5688801*PED	May 18, 2015			
	5770231	Nov 19, 2013			
	5770231*PED	May 19, 2014			
	5792477	May 02, 2017			
	5792477*PED	Nov 02, 2017			
	5916598	May 02, 2017			
	5916598*PED	Nov 02, 2017			
	5965168	Nov 19, 2013			
	5965168*PED	May 19, 2014			
	6110503	May 02, 2017			
	6110503*PED	Nov 02, 2017			
	6110921	Nov 19, 2013			
	6110921*PED	May 19, 2014			
	6194006	Dec 30, 2018			
	6194006*PED	Jun 30, 2019			
	6264987	May 19, 2020			
	6264987*PED	Nov 19, 2020			
	6368632	Nov 19, 2013		U-543	
	6368632*PED	May 19, 2014			
	6379703	Dec 30, 2018	DP		
	6379703*PED	Jun 30, 2019			
	6379704	May 19, 2020	DP		
	6379704*PED	Nov 19, 2020			
	6403114	May 02, 2017			
	6403114*PED	Nov 02, 2017			
	6534092	May 19, 2020	DP		
	6534092*PED	Nov 19, 2020			
	>A> 6596316	Dec 30, 2018	DP		
	>A> 6596316*PED	Jun 30, 2019			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>RISPERIDONE - RISPERDAL CONSTA</u>					
021346 003	4804663	Dec 29, 2007		NDF	Oct 29, 2006
	4804663*PED	Jun 29, 2008		PED	Apr 29, 2007
	5688801	Nov 18, 2014			
	5688801*PED	May 18, 2015			
	5770231	Nov 19, 2013			
	5770231*PED	May 19, 2014			
	5792477	May 02, 2017			
	5792477*PED	Nov 02, 2017			
	5916598	May 02, 2017			
	5916598*PED	Nov 02, 2017			
	5965168	Nov 19, 2013			
	5965168*PED	May 19, 2014			
	6110503	May 02, 2017			
	6110503*PED	Nov 02, 2017			
	6110921	Nov 19, 2013			
	6110921*PED	May 19, 2014			
	6194006	Dec 30, 2018			
	6194006*PED	Jun 30, 2019			
	6264987	May 19, 2020			
	6264987*PED	Nov 19, 2020			
	6368632	Nov 19, 2013		U-543	
	6368632*PED	May 19, 2014			
	6379703	Dec 30, 2018	DP		
	6379703*PED	Jun 30, 2019			
	6379704	May 19, 2020	DP		
	6379704*PED	Nov 19, 2020			
	6403114	May 02, 2017			
	6403114*PED	Nov 02, 2017			
	6534092	May 19, 2020	DP		
	6534092*PED	Nov 19, 2020			
	>A> 6596316	Dec 30, 2018	DP		
	>A> 6596316*PED	Jun 30, 2019			
<u>RISPERIDONE - RISPERDAL CONSTA</u>					
021346 004	>A> 4804663	Dec 29, 2007	DS DP	U-543	
	>A> 4804663*PED	Jun 29, 2008			
	>A> 5688801	Nov 18, 2014		U-543	
	>A> 5688801*PED	May 18, 2015			
	>A> 5770231	Nov 19, 2013	DP		
	>A> 5770231*PED	May 19, 2014			
	>A> 5792477	May 02, 2017	DP		
	>A> 5792477*PED	Nov 02, 2017			
	>A> 5916598	May 02, 2017	DP		
	>A> 5916598*PED	Nov 02, 2017			
	>A> 5965168	Nov 19, 2013	DP		
	>A> 5965168*PED	May 19, 2014			
	>A> 6110503	May 02, 2017	DP		
	>A> 6110503*PED	Nov 02, 2017			
	>A> 6110921	Nov 19, 2013		U-543	
	>A> 6110921*PED	May 19, 2014			
	>A> 6194006	Dec 30, 2018	DP		
	>A> 6194006*PED	Jun 30, 2019			
	>A> 6368632	Nov 19, 2013		U-543	
	>A> 6368632*PED	May 19, 2014			
	>A> 6379703	Dec 30, 2018	DP		
	>A> 6379703*PED	Jun 30, 2019			
	>A> 6403114	May 02, 2017	DP		
	>A> 6403114*PED	Nov 02, 2017			
	>A> 6596316	Dec 30, 2018	DP		
	>A> 6596316*PED	Jun 30, 2019			

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<u>ROTIGOTINE - NEUPRO</u>					
021829 001				>A> NCE	May 09, 2012
<u>ROTIGOTINE - NEUPRO</u>					
021829 002				>A> NCE	May 09, 2012
<u>ROTIGOTINE - NEUPRO</u>					
021829 003				>A> NCE	May 09, 2012
<u>SELEGILINE - EMSAM</u>					
021336 001	7150881	Jun 12, 2018	DS DP		
<u>SELEGILINE - EMSAM</u>					
021336 002	7150881	Jun 12, 2018	DS DP		
<u>SELEGILINE - EMSAM</u>					
021336 003	7150881	Jun 12, 2018	DS DP		
<u>SOMATROPIN RECOMBINANT - SAIZEN</u>					
019764 005				I-440	Aug 26, 2007
<u>SOMATROPIN RECOMBINANT - VALTROPIN</u>					
021905 001				>A> NP	Apr 19, 2010
<u>TADALAFIL - CIALIS</u>					
021368 001	5859006	Nov 21, 2017	DS DP		
	7182958	Apr 26, 2020	DP	U-155	
<u>TADALAFIL - CIALIS</u>					
021368 002	5859006	Nov 21, 2017	DS DP		
	7182958	Apr 26, 2020	DP	U-155	
<u>TADALAFIL - CIALIS</u>					
021368 003	5859006	Nov 21, 2017	DS DP		
	7182958	Apr 26, 2020	DP	U-155	
<u>TEMSIROLIMUS - TORISEL</u>					
022088 001				>A> NCE	May 30, 2012
<u>TERIPARATIDE RECOMBINANT HUMAN - FORTEO</u>					
021318 001	7163684	Aug 19, 2019		U-790	
<u>THALIDOMIDE - THALOMID</u>					
020785 004	5629327	May 13, 2014		U-731	
	6045501	Aug 28, 2018		U-731	
	6235756	Mar 01, 2013		U-731	
	6315720	Oct 23, 2020		U-731	
	6561976	Aug 28, 2018		U-731	
	6561977	Oct 23, 2020		U-731	
	6755784	Oct 23, 2020		U-731	
	6869399	Oct 23, 2020		U-731	
	6908432	Aug 28, 2018		U-731	
	7141018	Oct 23, 2020		U-731	
<u>TIMOLOL MALEATE - TIMOLOL MALEATE</u>					
020963 001	6174524	Mar 26, 2019			
	6174524*PED	Sep 26, 2019			
<u>TIMOLOL MALEATE - TIMOLOL MALEATE</u>					
020963 002	6174524	Mar 26, 2019			
	6174524*PED	Sep 26, 2019			
<u>TINIDAZOLE - TINDAMAX</u>					
021618 001				>A> I-532	May 21, 2010
<u>TINIDAZOLE - TINDAMAX</u>					
021618 002				>A> I-532	May 21, 2010
<u>ZIPRASIDONE HYDROCHLORIDE - GEODON</u>					
021483 001	7175855	May 18, 2020	DP		
<u>ZOLEDRONIC ACID - RECLAST</u>					
021817 001				NP	Apr 16, 2010

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<u>ZOLPIDEM TARTRATE - AMBIEN</u>					
019908	001			M-54 PED	Mar 29, 2010 Sep 29, 2010
<u>ZOLPIDEM TARTRATE - AMBIEN</u>					
019908	002			M-54 PED	Mar 29, 2010 Sep 29, 2010

Footnotes:

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 submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor:  
 DS = Drug Substance claim  
 DP = Drug Product claim  
 U and number = Method of Use claim (may be multiple). Specific Method of use claims are listed at <http://www.fda.gov/cder/orange/patex.htm>
3. 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.
4. \*PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with \*PED as was done prior to August 18, 2003. Patents with \*PED added after August 18, 2003 will not contain any information relative to the patent itself other than the \*PED extension. Information related specifically to the patent will be conveyed on the original patent only.
5. \*\*\* U.S. Patent Nos. RE 36481 and RE 36520 were relisted for Zocor (NDA 19-766) pursuant to the decision and related order in *Ranbaxy Labs. v. Leavitt*, No. 05-1838 (D.D.C. April 30, 2006). The '481 and '520 patents remained listed in Approved Drug Products with Therapeutic Equivalence Evaluations until any applicable periods of exclusivity pursuant to section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act were triggered and run. For additional information on this matter, please refer to Docket Nos. 2005P-0008 and 2005P-0046. Patents were subsequently delisted in the December 2006 Orange Book update as the exclusivity periods have triggered and run to expiration.

## 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, 27<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>

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