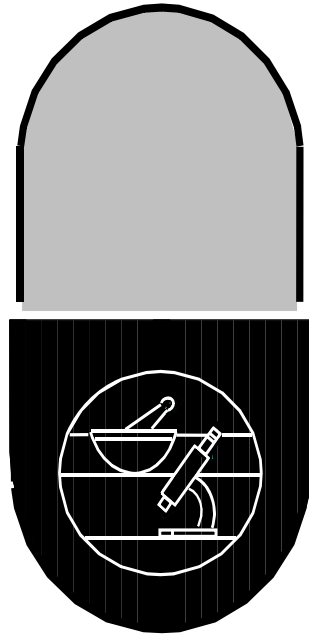


**CUMULATIVE  
SUPPLEMENT 03  
March 2010**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

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

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

2010

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

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

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

**Cumulative Supplement 03**

**March 2010**

**CONTENTS**

	<i>PAGE</i>
1.0 INTRODUCTION .....	iii
1.1 How to use the Cumulative Supplement .....	iii
1.2 Cumulative Supplement Content.....	iv
1.3 Applicant Name Changes.....	v
1.4 Availability of the Edition .....	vi
1.5 Report of Counts for the Prescription Drug Product List .....	vii
1.6 Cumulative Supplement Legend .....	vii
DRUG PRODUCT LISTS	
Prescription Drug Product List .....	1-1
OTC Drug Product List .....	2-1
Drug Products with Approval under Section 505 of the Act	
Administered by the Center for Biologics Evaluation and Research List.....	3-1
Orphan Product Designations and Approvals List .....	4-1
Drug Products Which Must Demonstrate in vivo Bioavailability	
Only if Product Fails to Achieve Adequate Dissolution .....	5-1
PATENT AND EXCLUSIVITY INFORMATION ADDENDUM	
A. Patent and Exclusivity Lists .....	A-1
B. Patent and Exclusivity Terms .....	B-1

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

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

**CUMULATIVE SUPPLEMENT 03  
March 2010**

**1.0 INTRODUCTION**

**1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT**

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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

Products that have never been marketed, are for exportation, are for military use, or have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 30th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 31st Edition. The current Edition Section 2., How To Use The Drug Product Lists, describes the layout and usage of the List.

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

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

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

## 1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

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

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

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

FDA/CDER Orange Book Staff  
Office of Generic Drugs, HFD-610  
7500 Standish Place  
Rockville, MD 20855-2773

### 1.3 APPLICANT NAME CHANGES

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

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

<u>FORMER APPLICANT NAME</u> <u>(FORMER ABBREVIATED NAME)</u>	<u>NEW APPLICANT NAME</u> <u>(NEW ABBREVIATED NAME)</u>
ASCENT PEDIATRICS INC (ASCENT PEDS)	SHIONOGI PHARMA INC (SHIONOGI PHARMA)
GOLDLINE LABORATORIES INC (GOLDLINE)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)
HLR TECHNOLOGY (HLR)	HOFFMANN LA ROCHE INC (HOFFMANN LA ROCHE)
IVAX PHARMACEUTICALS INC (IVAX PHARMS)	IVAX PHARMACEUTICALS INC SUB TEVA PHARMACEUTICALS USA (IVAX SUB TEVA PHARMS)
MEDICIS PHARMACEUTICAL CORP (MEDICIS)	SHIONOGI PHARMA INC (SHIONOGI PHARMA)
PROCTER AND GAMBLE CO (PROCTER AND GAMBLE)	WARNER CHILCOTT CO LLC (WARNER CHILCOTT)

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

#### 1.4 AVAILABILITY OF THE EDITION

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

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

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

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

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

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

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

### DESCRIPTION OF REPORT

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

The baseline column (Dec 2008) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

### DEFINITIONS

#### Drug Product

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

#### New Molecular Entity

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

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

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

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

## 1.6 CUMULATIVE SUPPLEMENT LEGEND

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

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The application



number preceded by "N" is a New Drug Application (NDA or innovator). The application number preceded by an "A" is an Abbreviated New Drug Application (ANDA or generic). The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

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

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

The change code and description:

NEWA	New drug product approval usually in the supplement month.
CAHN	Applicant holder firm name has changed.
CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.
CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMS1	Change. Miscellaneous addition to list.
CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.

PRESCRIPTION DRUG PRODUCT LIST - 30TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

1-1

ACETAMINOPHEN; BUTALBITAL

TABLET; ORAL  
 BUTAPAP  
 AA MIKART 325MG;50MG A089987 001 Oct 26, 1992 Feb CTEC  
 PHRENILIN  
 AA + VALEANT 325MG;50MG A087811 001 Jun 19, 1985 Feb CTEC

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL  
 BUTALBITAL, ACETAMINOPHEN AND CAFFEINE  
 + NEXGEN PHARMA 300MG;50MG;40MG A040885 001 Nov 16, 2009 Feb CRLD  
 AA WEST WARD 500MG;50MG;40MG A040261 001 Oct 28, 1998 Feb CTEC  
 ESGIC-PLUS  
 AA + MIKART 500MG;50MG;40MG A040085 001 Mar 28, 1996 Feb CTEC  
 TABLET; ORAL  
 BUTALBITAL, ACETAMINOPHEN AND CAFFEINE  
 AA CONCORD LABS NJ 325MG;50MG;40MG A040864 001 Dec 01, 2008 Feb CTEC  
 AA 500MG;50MG;40MG A040883 001 Dec 23, 2008 Feb CTEC  
 AA MALLINCKRODT 325MG;50MG;40MG A087804 001 Jan 24, 1985 Feb CTEC  
 AA MIKART 325MG;50MG;40MG A089175 001 Jan 21, 1987 Feb CTEC  
 AA VINTAGE PHARMS 325MG;50MG;40MG A040511 001 Aug 27, 2003 Feb CTEC  
 AA 500MG;50MG;40MG A040513 001 Aug 25, 2003 Feb CTEC  
 AA WATSON LABS 500MG;50MG;40MG A040267 001 Jul 30, 1998 Feb CTEC  
 AA WEST WARD 325MG;50MG;40MG A089718 001 Jun 12, 1995 Feb CTEC  
 AA 500MG;50MG;40MG A040336 001 Aug 18, 1999 Feb CTEC  
 ESGIC-PLUS  
 AA + MIKART 500MG;50MG;40MG A089451 001 May 23, 1988 Feb CTEC  
 FIORICET  
 AA + WATSON PHARMS 325MG;50MG;40MG A088616 001 Nov 09, 1984 Feb CTEC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION; ORAL  
 HYDROCODONE BITARTRATE AND ACETAMINOPHEN  
 + MIKART 300MG/15ML;10MG/15ML A040881 001 Feb 25, 2010 Feb NEWA

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL  
 ACETAMINOPHEN AND PENTAZOCINE HYDROCHLORIDE  
 AB + WATSON LABS 650MG;EQ 25MG BASE A074699 001 Mar 24, 2000 Feb CRLD  
 TALACEN  
 @ SANOFI AVENTIS US 650MG;EQ 25MG BASE N018458 001 Sep 23, 1982 Feb DISC

ACITRETIN

CAPSULE; ORAL  
 SORIATANE  
 STIEFEL LABS INC 17.5MG N019821 003 Aug 06, 2009 Jan NEWA  
 22.5MG N019821 004 Aug 06, 2009 Jan NEWA

ACYCLOVIR

CAPSULE; ORAL  
 ACYCLOVIR  
 >D> @ MYLAN 200MG A074727 001 Apr 22, 1997 Mar CMFD  
 >A> AB 200MG A074727 001 Apr 22, 1997 Mar CMFD

## TABLET; ORAL

## ACYCLOVIR

>D>		@ MYLAN	400MG	A075211 001	Sep 28, 1998	Mar	CMFD
>A>	AB		400MG	A075211 001	Sep 28, 1998	Mar	CMFD
>D>		@	800MG	A075211 002	Sep 28, 1998	Mar	CMFD
>A>	AB		800MG	A075211 002	Sep 28, 1998	Mar	CMFD

ADAPALENE

>A>		LOTION; TOPICAL					
>A>		DIFFERIN					
>A>		+ GALDERMA R AND D	0.1%	N022502 001	Mar 17, 2010	Mar	NEWA

ALBUTEROL SULFATE

## SOLUTION; INHALATION

## ALBUTEROL SULFATE

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

ALENDRONATE SODIUM

## TABLET; ORAL

## ALENDRONATE SODIUM

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

ALPRAZOLAM

## TABLET, ORALLY DISINTEGRATING; ORAL

## ALPRAZOLAM

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

AMLODIPINE BESYLATE

## TABLET; ORAL

## AMLODIPINE BESYLATE

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

AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

## CAPSULE; ORAL

## AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE

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

CAPSULE; ORAL

AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE

AB	LUPIN PHARMS	EQ 5MG BASE;10MG	A078466 002	Feb 05, 2010	Jan	NEWA
AB		EQ 5MG BASE;20MG	A078466 003	Feb 05, 2010	Jan	NEWA
AB		EQ 10MG BASE;20MG	A078466 004	Feb 05, 2010	Jan	NEWA

AMOXICILLIN

FOR SUSPENSION; ORAL

TRIMOX

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

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AUGMENTIN '125'

AB	GLAXOSMITHKLINE	125MG/5ML;EQ 31.25MG BASE/5ML	N050575 001	Aug 06, 1984	Feb	CMFD
AB	GLAXOSMITHKLINE	250MG/5ML;EQ 62.5MG BASE/5ML	N050575 002	Aug 06, 1984	Feb	CMFD

TABLET; ORAL

AUGMENTIN '250'

AB	GLAXOSMITHKLINE	250MG;EQ 125MG BASE	N050564 001	Aug 06, 1984	Feb	CMFD
AB	GLAXOSMITHKLINE	500MG;EQ 125MG BASE	N050564 002	Aug 06, 1984	Feb	CMFD
AB	GLAXOSMITHKLINE	875MG;EQ 125MG BASE	N050720 001	Feb 13, 1996	Feb	CMFD

TABLET, EXTENDED RELEASE; ORAL

AUGMENTIN XR

AB	GLAXOSMITHKLINE	1GM;EQ 62.5MG BASE	N050785 001	Sep 25, 2002	Feb	CMFD
----	-----------------	--------------------	-------------	--------------	-----	------

AMPHOTERICIN B

INJECTABLE, LIPID COMPLEX; INJECTION

ABELCET

+	SIGMA TAU	5MG/ML	N050724 001	Nov 20, 1995	Feb	CAHN
---	-----------	--------	-------------	--------------	-----	------

AMPICILLIN SODIUM; SULBACTAM SODIUM

INJECTABLE; INJECTION

AMPICILLIN AND SULBACTAM

>A>	AP	BIONICHE PHARMA	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A065316 001	Jun 29, 2007	Mar	CAHN
>A>	AP		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A065316 002	Jun 29, 2007	Mar	CAHN
>D>	AP	GENERAMEDIX	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	A065316 001	Jun 29, 2007	Mar	CAHN
>D>	AP		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	A065316 002	Jun 29, 2007	Mar	CAHN

ARMODAFINIL

TABLET; ORAL

NUVIGIL

@	CEPHALON	100MG	N021875 002	Mar 26, 2009	Feb	DISC
@		200MG	N021875 005	Mar 26, 2009	Feb	DISC

ARTEMETHER; LUMEFANTRINE

TABLET; ORAL

COARTEM

>D>		NOVARTIS	20MG;120MG	N022268 001	Apr 07, 2009	Mar	CRLD
>A>	+		20MG;120MG	N022268 001	Apr 07, 2009	Mar	CRLD

ARTICAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE

INJECTABLE; INJECTION

ARTICAINE HYDROCHLORIDE WITH EPINEPHRINE

PIERREL

			4%;EQ 0.009MG BASE/1.8ML (EQ 0.005MG BASE/ML)	N022466 001	Feb 26, 2010	Feb	NEWA
	+		4%;EQ 0.018MG BASE/1.8ML (EQ 0.01MG BASE/ML)	N022466 002	Feb 26, 2010	Feb	NEWA

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

FIORINAL

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

LANORINAL

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

TABLET; ORAL

BUTALBITAL, ASPIRIN AND CAFFEINE

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

AZELASTINE HYDROCHLORIDE

SPRAY, METERED; NASAL

ASTELIN

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

AZELASTINE HYDROCHLORIDE

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

AZITHROMYCIN

INJECTABLE; INJECTION

AZITHROMYCIN

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

AZTREONAM

FOR SOLUTION; INHALATION

CAYSTON

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

BACLOFEN

TABLET; ORAL

BACLOFEN

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

TABLET, ORALLY DISINTEGRATING; ORAL

KEMSTRO

@ SCHWARZ PHARMA

@

			10MG	N021589 001	Oct 30, 2003	Jan	DISC
			20MG	N021589 002	Oct 30, 2003	Jan	DISC

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION

QVAR 40

+ TEVA BRANDED PHARM 0.04MG/INH N020911 002 Sep 15, 2000 Feb CAHN

QVAR 80

+ TEVA BRANDED PHARM 0.08MG/INH N020911 001 Sep 15, 2000 Feb CAHN

BENZAEPRIIL HYDROCHLORIDE

TABLET; ORAL

BENZAEPRIIL HYDROCHLORIDE

>A>	AB	HUAHAI US INC	5MG	A076118 001	Feb 11, 2004	Mar	CAHN
>A>	AB		10MG	A076118 002	Feb 11, 2004	Mar	CAHN
>A>	AB		20MG	A076118 003	Feb 11, 2004	Mar	CAHN
>A>	AB		40MG	A076118 004	Feb 11, 2004	Mar	CAHN
>D>	AB	KV PHARM	5MG	A076118 001	Feb 11, 2004	Mar	CAHN
>D>	AB		10MG	A076118 002	Feb 11, 2004	Mar	CAHN
>D>	AB		20MG	A076118 003	Feb 11, 2004	Mar	CAHN
>D>	AB		40MG	A076118 004	Feb 11, 2004	Mar	CAHN

BENZTROPINE MESYLATE

INJECTABLE; INJECTION

BENZTROPINE MESYLATE

&gt;A&gt; AP PHARMAFORCE 1MG/ML A091152 001 Mar 29, 2010 Mar NEWA

TABLET; ORAL

BENZTROPINE MESYLATE

>A>	AA	INVAGEN PHARMS	0.5MG	A090294 001	Mar 29, 2010	Mar	NEWA
>A>	AA		1MG	A090294 002	Mar 29, 2010	Mar	NEWA
>A>	AA		2MG	A090294 003	Mar 29, 2010	Mar	NEWA
	AA	+ LANNETT	0.5MG	A088877 001	Apr 11, 1985	Feb	CAHN
	AA	+	1MG	A088894 001	Apr 11, 1985	Feb	CAHN
	AA	+	2MG	A088895 001	Apr 11, 1985	Feb	CAHN

BETAMETHASONE ACETATE; BETAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

BETAMETHASONE ACETATE AND BETAMETHASONE SODIUM PHOSPHATE

>A>	AB	LUITPOLD	3MG/ML;EQ 3MG BASE/ML	A090747 001	Jul 31, 2009	Mar	CAHN
>D>	AB	PHARMAFORCE	3MG/ML;EQ 3MG BASE/ML	A090747 001	Jul 31, 2009	Mar	CAHN

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

BETAXOLOL HYDROCHLORIDE

AT	AKORN		EQ 0.5% BASE	A075386 001	Jun 30, 2000	Jan	CTNA
AT	NOVEX		EQ 0.5% BASE	A075446 001	Sep 28, 2000	Jan	CTNA
AT	WOCKHARDT		EQ 0.5% BASE	A078694 001	Nov 16, 2009	Jan	CAIN

TABLET; ORAL

BETAXOLOL HYDROCHLORIDE

AB	MIKAH PHARMA		10MG	A075541 001	Oct 22, 1999	Feb	CAHN
AB	+		20MG	A075541 002	Oct 22, 1999	Feb	CAHN

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE

INJECTABLE; INJECTION

BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE

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

INJECTABLE; INJECTIONBUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE

>A>	AP	HOSPIRA	0.5%;0.005MG/ML	A071170	001	Jun 16, 1988	Mar	CMFD
-----	----	---------	-----------------	---------	-----	--------------	-----	------

BUPROPION HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

BUPROPION HYDROCHLORIDE

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

BUSPIRONE HYDROCHLORIDE

## TABLET; ORAL

BUSPAR

>D>	AB	BRISTOL MYERS SQUIBB	10MG	N018731	002	Sep 29, 1986	Mar	DISC
>A>		@	10MG	N018731	002	Sep 29, 1986	Mar	DISC
		@	15MG	N018731	003	Apr 22, 1996	Feb	DISC

BUSPIRONE HYDROCHLORIDE

>D>	AB	IVAX SUB TEVA PHARMS	15MG	A075385	003	Mar 01, 2002	Mar	CRLD	
>A>	AB	+	15MG	A075385	003	Mar 01, 2002	Mar	CRLD	
>D>	AB	+	TEVA	30MG	A075022	004	Mar 25, 2004	Mar	CRLD
>A>	AB		30MG	A075022	004	Mar 25, 2004	Mar	CRLD	
	AB	+	30MG	A075022	004	Mar 25, 2004	Feb	CRLD	

CABERGOLINE

## TABLET; ORAL

CABERGOLINE

>A>	AB	IMPAX LABS INC	0.5MG	A077843	001	Jul 03, 2007	Mar	CAHN
>D>	AB	WATSON LABS	0.5MG	A077843	001	Jul 03, 2007	Mar	CAHN

CALCIPOTRIENE

>A>		OINTMENT; TOPICAL							
>A>		CALCIPOTRIENE							
>A>		+	GLENMARK GENERICS	0.005%	A090633	001	Mar 24, 2010	Mar	NEWA

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

## SOLUTION; IRRIGATION

BALANCED SALT

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

CARBINOXAMINE MALEATE

## TABLET; ORAL

CARBINOXAMINE MALEATE

>A>	AA	INVAGEN PHARMS	4MG	A090435	001	Apr 15, 2010	Mar	NEWA
-----	----	----------------	-----	---------	-----	--------------	-----	------

CARBOPLATIN

## INJECTABLE; IV (INFUSION)

CARBOPLATIN

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

## INJECTABLE; IV (INFUSION)

## CARBOPLATIN

>D>	AP	GENERAMEDIX	50MG/5ML (10MG/ML)	A077998 001	Apr 24, 2007	Mar	CAHN
>D>	AP		150MG/15ML (10MG/ML)	A077998 002	Apr 24, 2007	Mar	CAHN
>D>	AP		450MG/45ML (10MG/ML)	A077998 003	Apr 24, 2007	Mar	CAHN

>A> CARGLUMIC ACID

&gt;A&gt; TABLET; ORAL

&gt;A&gt; CARBAGLU

>A>	+	ORPHAN EUROPE	200MG	N022562 001	Mar 18, 2010	Mar	NEWA
-----	---	---------------	-------	-------------	--------------	-----	------

CARVEDILOL PHOSPHATE

CAPSULE, EXTENDED RELEASE; ORAL

COREG CR

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

CEFACTOR

TABLET, EXTENDED RELEASE; ORAL

CEFACTOR

>D>	AB	+	PAR PHARM	EQ 500MG BASE	A065057 001	Jan 05, 2001	Mar	CAHN
>A>	AB	+	WORLD GEN	EQ 500MG BASE	A065057 001	Jan 05, 2001	Mar	CAHN

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

CEFADROXIL

>D>	AB		TEVA PHARMS	EQ 500MG BASE	A065282 001	Jan 20, 2006	Mar	CRLD
>A>	AB	+		EQ 500MG BASE	A065282 001	Jan 20, 2006	Mar	CRLD

FOR SUSPENSION; ORAL

CEFADROXIL

AB	+	LUPIN	EQ 500MG BASE/5ML	A065396 002	Feb 21, 2008	Jan	CRLD
		DURICEF					
		@ WARNER CHILCOTT	EQ 250MG BASE/5ML	N050527 003		Jan	DISC
		@	EQ 500MG BASE/5ML	N050527 001		Jan	DISC

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

CEFOTAXIME SODIUM

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

CEFOXITIN SODIUM

INJECTABLE; INJECTION

CEFOXITIN

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

CEFPROZIL

FOR SUSPENSION; ORAL

CEFPROZIL

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

TABLET; ORAL

CEFPROZIL

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



CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CETIRIZINE HYDROCHLORIDE

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

CICLOPIROX

SHAMPOO; TOPICAL

CICLOPIROX

AT		PERRIGO	1%	A078594	001	Feb 16, 2010	Jan	NEWA
----	--	---------	----	---------	-----	--------------	-----	------

SOLUTION; TOPICAL

CICLOPIROX

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

CIPROFLOXACIN HYDROCHLORIDE

TABLET; ORAL

CIPRO

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

AB			EQ 750MG BASE	N019537	004	Oct 22, 1987	Feb	CRLD
----	--	--	---------------	---------	-----	--------------	-----	------

CLINDAMYCIN PHOSPHATE

AEROSOL, FOAM; TOPICAL

CLINDAMYCIN PHOSPHATE

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

EVOCLIN

>D>	+	STIEFEL LABS INC	1%	N050801	001	Oct 22, 2004	Mar	CFTG
-----	---	------------------	----	---------	-----	--------------	-----	------

>A>	AT	+	1%	N050801	001	Oct 22, 2004	Mar	CFTG
-----	----	---	----	---------	-----	--------------	-----	------

CREAM; VAGINAL

CLINDAMYCIN PHOSPHATE

>D>	AB	ALTANA PHARMA	EQ 2% BASE	A065139	001	Dec 27, 2004	Mar	CAHN
-----	----	---------------	------------	---------	-----	--------------	-----	------

>A>	AB	NYCOMED US	EQ 2% BASE	A065139	001	Dec 27, 2004	Mar	CAHN
-----	----	------------	------------	---------	-----	--------------	-----	------

CLOBETASOL PROPIONATE

OINTMENT; TOPICAL

CLOBETASOL PROPIONATE

>D>	AB	FOUGERA	0.05%	A074407	001	Feb 23, 1996	Mar	CAHN
-----	----	---------	-------	---------	-----	--------------	-----	------

>A>	AB	NYCOMED US	0.05%	A074407	001	Feb 23, 1996	Mar	CAHN
-----	----	------------	-------	---------	-----	--------------	-----	------

CLONIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

DURACLON

>A>	AP	BIONICHE PHARMA USA	1 MG/10 ML (0.1 MG/ML)	N020615	001	Oct 02, 1996	Mar	CAHN
-----	----	---------------------	------------------------	---------	-----	--------------	-----	------

>A>	AP	+	5 MG/10 ML (0.5 MG/ML)	N020615	002	Apr 27, 1999	Mar	CAHN
-----	----	---	------------------------	---------	-----	--------------	-----	------

>D>	AP	XANODYNE PHARM	1 MG/10 ML (0.1 MG/ML)	N020615	001	Oct 02, 1996	Mar	CAHN
-----	----	----------------	------------------------	---------	-----	--------------	-----	------

>D>	AP	+	5 MG/10 ML (0.5 MG/ML)	N020615	002	Apr 27, 1999	Mar	CAHN
-----	----	---	------------------------	---------	-----	--------------	-----	------

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE

>A>	AA	SUN PHARM INDS INC	10MG/5ML;6.25MG/5ML	A090180	001	Mar 17, 2010	Mar	NEWA
-----	----	--------------------	---------------------	---------	-----	--------------	-----	------

COSYNTROPIN

INJECTABLE; INJECTION

COSYNTROPIN

>A>	AP	BIONICHE PHARMA	0.25MG/VIAL	A090574	001	Dec 17, 2009	Mar	CAHN
-----	----	-----------------	-------------	---------	-----	--------------	-----	------

>D>	AP	GENERAMEDIX	0.25MG/VIAL	A090574	001	Dec 17, 2009	Mar	CAHN
-----	----	-------------	-------------	---------	-----	--------------	-----	------

CYANOCOBALAMIN

SPRAY, METERED; NASAL

CALOMIST

@ FLEMING	25MCG/SPRAY	N022102 001	Jul 27, 2007	Jan	DISC
-----------	-------------	-------------	--------------	-----	------

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION

CYTOXAN

AP +	BAXTER HLTHCARE	500MG/VIAL	N012142 003		Feb	CMFD
AP +		1GM/VIAL	N012142 004	Aug 30, 1982	Feb	CMFD
AP +		2GM/VIAL	N012142 005	Aug 30, 1982	Feb	CMFD
	LYOPHILIZED CYTOXAN					
@	BAXTER HLTHCARE	100MG/VIAL	N012142 006	Dec 05, 1985	Feb	DISC
@		200MG/VIAL	N012142 007	Dec 10, 1985	Feb	DISC
@		500MG/VIAL	N012142 008	Jan 04, 1984	Feb	DISC
@		1GM/VIAL	N012142 010	Sep 24, 1985	Feb	DISC
@		2GM/VIAL	N012142 009	Dec 10, 1984	Feb	DISC

CYTARABINE

INJECTABLE; INJECTION

CYTARABINE

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

DACTINOMYCIN

INJECTABLE; INJECTION

COSMEGEN

>D>	+ LUNDBECK INC	0.5MG/VIAL	N050682 001		Mar	CFTG
>A>	AP +	0.5MG/VIAL	N050682 001		Mar	CFTG
>A>	DACTINOMYCIN					
>A>	AP BEDFORD	0.5MG/VIAL	A090304 001	Mar 16, 2010	Mar	NEWA

DALFAMPRIDINE

TABLET, EXTENDED RELEASE; ORAL

AMPYRA

+ ACORDA	10MG	N022250 001	Jan 22, 2010	Jan	NEWA
----------	------	-------------	--------------	-----	------

DES Loratadine

TABLET; ORAL

CLARINEX

AB +	SCHERING PLOUGH	5MG	N021165 001	Dec 21, 2001	Jan	CFTG
AB	ORCHID HLTHCARE	5MG	A078357 001	Feb 19, 2010	Jan	NEWA

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

STIMATE (NEEDS NO REFRIGERATION)

@ CSL BEHRING	1.5MG/SPRAY	N020355 002	Oct 24, 2007	Jan	DISC
---------------	-------------	-------------	--------------	-----	------

DEXLANSOPRAZOLE

CAPSULE, DELAYED RELEASE; ORAL

DEXILANT

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

## CAPSULE, DELAYED RELEASE; ORAL

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

DEXMEDETOMIDINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## PRECEDEX

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

DIAZOXIDE

## CAPSULE; ORAL

## PROGLYCEM

@	TEVA BRANDED PHARM	50MG	N017425	001		Feb	CAHN		
@		100MG	N017425	002		Feb	CAHN		

DICLOFENAC POTASSIUM

## FOR SOLUTION; ORAL

## CAMBIA

>D>	+	KOWA PHARMS	50MG	N022165	001	Jun 17, 2009	Mar	CAHN	
>A>	+	NAUTILUS NEUROSCIENC	50MG	N022165	001	Jun 17, 2009	Mar	CAHN	

## TABLET; ORAL

## DICLOFENAC POTASSIUM

@	SANDOZ	50MG	A075582	001	Feb 23, 2001	Jan	DISC		
---	--------	------	---------	-----	--------------	-----	------	--	--

DIDANOSINE

## CAPSULE, DELAYED REL PELLETS; ORAL

## DIDANOSINE

>A>	AB	MATRIX LABS LTD	125MG	A090788	001	Apr 08, 2010	Mar	NEWA	
>A>	AB		200MG	A090788	002	Apr 08, 2010	Mar	NEWA	
>A>	AB		250MG	A090788	003	Apr 08, 2010	Mar	NEWA	
>A>	AB		400MG	A090788	004	Apr 08, 2010	Mar	NEWA	

DIFLORASONE DIACETATE

## CREAM; TOPICAL

## DIFLORASONE DIACETATE

>D>	AB1	ALTANA	0.05%	A075187	001	Mar 30, 1998	Mar	CRLD	
>A>	AB1	+	0.05%	A075187	001	Mar 30, 1998	Mar	CRLD	
		PSORCON							
	@	SANOFI AVENTIS US	0.05%	N020205	001	Nov 20, 1992	Feb	DISC	

DILTIAZEM HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## CARDIZEM LA

AB	BIOVAIL LABS INTL	120MG	N021392	001	Feb 06, 2003	Feb	CFTG		
AB		180MG	N021392	002	Feb 06, 2003	Feb	CFTG		
AB		240MG	N021392	003	Feb 06, 2003	Feb	CFTG		
AB		300MG	N021392	004	Feb 06, 2003	Feb	CFTG		
AB		360MG	N021392	005	Feb 06, 2003	Feb	CFTG		
AB	+	420MG	N021392	006	Feb 06, 2003	Feb	CFTG		

## DILTIAZEM HYDROCHLORIDE

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

## TABLET, EXTENDED RELEASE; ORAL

## DILTIAZEM HYDROCHLORIDE

AB	WATSON LABS FLORIDA	360MG	A077686 002	Mar 15, 2010	Feb	NEWA
AB		420MG	A077686 001	Mar 15, 2010	Feb	NEWA

DOXEPIN HYDROCHLORIDE

&gt;A&gt; TABLET; ORAL

&gt;A&gt; SILENOR

>A>	SOMAXON	EQ 3MG BASE	N022036 001	Mar 17, 2010	Mar	NEWA
-----	---------	-------------	-------------	--------------	-----	------

>A>	+	EQ 6MG BASE	N022036 002	Mar 17, 2010	Mar	NEWA
-----	---	-------------	-------------	--------------	-----	------

ELTROMBOPAG OLAMINE

TABLET; ORAL

## PROMACTA

>A>	GLAXOSMITHKLINE	EQ 75MG ACID	N022291 003	Sep 08, 2009	Mar	NEWA
-----	-----------------	--------------	-------------	--------------	-----	------

>D> ENALAPRIL MALEATE; FELODIPINE

&gt;D&gt; TABLET, EXTENDED RELEASE; ORAL

&gt;D&gt; LEXXEL

>D>	+	ASTRAZENECA	5MG;5MG	N020668 001	Dec 27, 1996	Mar	DISC
-----	---	-------------	---------	-------------	--------------	-----	------

>A>	@	5MG;5MG	N020668 001	Dec 27, 1996	Mar	DISC
-----	---	---------	-------------	--------------	-----	------

EPINEPHRINE

INJECTABLE; IM-SC

&gt;A&gt; ADRENACLICK

>A>	+	SHIONOGI PHARMA	EQ 0.15MG /DELIVERY	N020800 003	Nov 25, 2009	Mar	NEWA
-----	---	-----------------	---------------------	-------------	--------------	-----	------

>A>	+		EQ 0.3MG /DELIVERY	N020800 004	Nov 25, 2009	Mar	NEWA
-----	---	--	--------------------	-------------	--------------	-----	------

TWINJECT 0.15

+ SHIONOGI PHARMA EQ 0.15MG /DELIVERY

N020800 002	May 28, 2004	Jan	CAHN
-------------	--------------	-----	------

TWINJECT 0.3

+ SHIONOGI PHARMA EQ 0.3MG /DELIVERY

N020800 001	May 30, 2003	Jan	CAHN
-------------	--------------	-----	------

EPIRUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

## EPIRUBICIN HYDROCHLORIDE

>A>	AP	BIONICHE PHARMA USA	50MG/25ML (2MG/ML)	A065371 001	Nov 28, 2007	Mar	CAHN
-----	----	---------------------	--------------------	-------------	--------------	-----	------

>A>	AP		200MG/100ML (2MG/ML)	A065371 002	Nov 28, 2007	Mar	CAHN
-----	----	--	----------------------	-------------	--------------	-----	------

>D>	AP	GENERAMEDIX	50MG/25ML (2MG/ML)	A065371 001	Nov 28, 2007	Mar	CAHN
-----	----	-------------	--------------------	-------------	--------------	-----	------

>D>	AP		200MG/100ML (2MG/ML)	A065371 002	Nov 28, 2007	Mar	CAHN
-----	----	--	----------------------	-------------	--------------	-----	------

>A>	AP	X GEN PHARMS	50MG/25ML (2MG/ML)	A090075 001	Mar 25, 2010	Mar	NEWA
-----	----	--------------	--------------------	-------------	--------------	-----	------

>A>	AP		200MG/100ML (2MG/ML)	A090075 002	Mar 25, 2010	Mar	NEWA
-----	----	--	----------------------	-------------	--------------	-----	------

ESTRADIOL VALERATE

INJECTABLE; INJECTION

## ESTRADIOL VALERATE

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

AO		40MG/ML	A090920 002	Jan 19, 2010	Jan	NEWA
----	--	---------	-------------	--------------	-----	------

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

## NORETHINDRONE AND ETHINYL ESTRADIOL

WATSON LABS 0.035MG;0.4MG

A078379 001	Feb 23, 2010	Feb	NEWA
-------------	--------------	-----	------

TABLET; ORAL-28

## NORETHINDRONE AND ETHINYL ESTRADIOL

AB	WATSON LABS	0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG	A076393 001	Feb 04, 2010	Jan	NEWA
----	-------------	--	-------------	--------------	-----	------

## TABLET; ORAL-28

	NORETHINDRONE AND ETHINYL ESTRADIOL								
AB	WATSON LABS	0.035MG;0.4MG	A078323	001	Feb 04, 2010	Jan	NEWA		

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

## TABLET; ORAL

	NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE								
AB	WATSON LABS	0.02MG;1MG	A078267	001	Sep 01, 2009	Jan	CDFR		

## TABLET; ORAL-28

	NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL								
>A>	AB	WATSON LABS	0.02MG,0.03MG,0.035MG;1MG,1MG,1MG	A076629	001	Mar 18, 2010	Mar	NEWA	
	NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE								
	AB	VINTAGE	0.02MG;1MG	A077077	001	May 20, 2005	Feb	CAHN	
	AB		0.03MG;1.5MG	A077075	001	Apr 28, 2005	Feb	CAHN	

ETHINYL ESTRADIOL; NORGESTIMATE

## TABLET; ORAL-28

	PREVIFEM								
AB	VINTAGE	0.035MG;0.25MG	A076334	001	Jan 09, 2004	Feb	CAHN		
	TRI-PREVIFEM								
AB	VINTAGE	0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A076335	001	Mar 26, 2004	Feb	CAHN		

FAMOTIDINE

## INJECTABLE; INJECTION

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

## TABLET, ORALLY DISINTEGRATING; ORAL

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

FENOFIBRATE

## CAPSULE; ORAL

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

## TABLET; ORAL

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

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

	ALLEGRA D 24 HOUR								
>D>	+	SANOFI AVENTIS US	180MG;240MG	N021704	001	Oct 19, 2004	Mar	CFTG	
>A>	AB	+	180MG;240MG	N021704	001	Oct 19, 2004	Mar	CFTG	
	FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE								
>A>	AB	DR REDDYS LABS LTD	180MG;240MG	A079043	001	Mar 17, 2010	Mar	NEWA	

FINASTERIDE

TABLET; ORAL

FINASTERIDE

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

FLUCONAZOLE

INJECTABLE; INJECTION

FLUCONAZOLE IN SODIUM CHLORIDE 0.9%

BEDFORD

100MG/50ML (2MG/ML)

A076087 002 Sep 26, 2008 Jan CTNA

FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

@ HOSPIRA

200MG/100ML (2MG/ML)

A076617 001 Jul 29, 2004 Feb DISC

@

400MG/200ML (2MG/ML)

A076617 002 Jul 29, 2004 Feb DISC

FLUNISOLIDE

AEROSOL, METERED; INHALATION

AEROSPAN HFA

+ ACTON PHARMS

EQ 78MCG BASE/INH

N021247 001 Jan 27, 2006 Feb CAHN

SPRAY, METERED; NASAL

NASAREL

AB +

TEVA BRANDED PHARM

0.029MG/SPRAY

N020409 001 Mar 08, 1995 Feb CAHN

FLUOROURACIL

CREAM; TOPICAL

FLUOROURACIL

AB

TARO

5%

A090368 001 Mar 05, 2010 Feb NEWA

INJECTABLE; INJECTION

FLUOROURACIL

&gt;A&gt;

AP

+ BIONICHE PHARMA

500MG/10ML (50MG/ML)

A040743 002 Apr 26, 2007 Mar CAHN

&gt;A&gt;

AP

+

1GM/20ML (50MG/ML)

A040743 001 Apr 26, 2007 Mar CAHN

&gt;A&gt;

AP

+

2.5GM/50ML (50MG/ML)

A040798 002 Apr 26, 2007 Mar CAHN

&gt;A&gt;

AP

+

5GM/100ML (50MG/ML)

A040798 001 Apr 26, 2007 Mar CAHN

&gt;D&gt;

AP

+ GENERAMEDIX

500MG/10ML (50MG/ML)

A040743 002 Apr 26, 2007 Mar CAHN

&gt;D&gt;

AP

+

1GM/20ML (50MG/ML)

A040743 001 Apr 26, 2007 Mar CAHN

&gt;D&gt;

AP

+

2.5GM/50ML (50MG/ML)

A040798 002 Apr 26, 2007 Mar CAHN

&gt;D&gt;

AP

+

5GM/100ML (50MG/ML)

A040798 001 Apr 26, 2007 Mar CAHN

FLUOXETINE HYDROCHLORIDE

CAPSULE, DELAYED REL PELLETS; ORAL

FLUOXETINE HYDROCHLORIDE

&gt;A&gt;

AB

BARR

EQ 90MG BASE

A076237 001 Mar 24, 2010 Mar NEWA

&gt;A&gt;

AB

DR REDDYS LABS LTD

EQ 90MG BASE

A078572 001 Mar 22, 2010 Mar NEWA

PROZAC WEEKLY

&gt;D&gt;

+

LILLY

EQ 90MG BASE

N021235 001 Feb 26, 2001 Mar CFTG

&gt;A&gt;

AB

+

EQ 90MG BASE

N021235 001 Feb 26, 2001 Mar CFTG

SOLUTION; ORAL

FLUOXETINE HYDROCHLORIDE

AA

LANNETT

EQ 20MG BASE/5ML

A076458 001 May 14, 2004 Feb CAHN

FOLIC ACID

TABLET; ORAL

FOLIC ACID

AA

+ PHARMAX

1MG

A040625 001 Jul 21, 2005 Jan CRLD

AA

+ WATSON LABS

1MG

A080680 001 Jan CMFD

FOMEPIZOLE

INJECTABLE; INJECTION

FOMEPIZOLE

>A>	AP	BIONICHE PHARMA USA	1.5GM/1.5ML (1GM/ML)	A079033 001	Apr 07, 2009	Mar	CAHN
>D>	AP	GENERAMEDIX	1.5GM/1.5ML (1GM/ML)	A079033 001	Apr 07, 2009	Mar	CAHN

FOSPHENYTOIN SODIUM

INJECTABLE; INJECTION

FOSPHENYTOIN SODIUM

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

GADOVERSETAMIDE

INJECTABLE; INJECTION

OPTIMARK IN PLASTIC CONTAINER

>D>	+	MALLINCKRODT	1654.5MG/5ML (330.9MG/ML)	N020976 001	Dec 08, 1999	Mar	CPOT
>A>	+		9927MG/30ML (330.9MG/ML)	N020976 001	Dec 08, 1999	Mar	CPOT

GANCICLOVIR SODIUM

INJECTABLE; INJECTION

CYTOVENE

>D>		@ ROCHE PALO	EQ 500MG BASE/VIAL	N019661 001	Jun 23, 1989	Mar	CMFD
>A>	+		EQ 500MG BASE/VIAL	N019661 001	Jun 23, 1989	Mar	CMFD
>D>		GANCICLOVIR SODIUM					
>D>		BEDFORD	EQ 500MG BASE/VIAL	A076222 001	Jul 16, 2003	Mar	DISC
>A>		@	EQ 500MG BASE/VIAL	A076222 001	Jul 16, 2003	Mar	DISC

GEMFIBROZIL

TABLET; ORAL

GEMFIBROZIL

>D>		@ DAVA PHARMS INC	600MG	A074270 001	Sep 27, 1993	Mar	CMFD
>A>	AB		600MG	A074270 001	Sep 27, 1993	Mar	CMFD

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLYBURIDE AND METFORMIN HYDROCHLORIDE

		@ TEVA	1.25MG;250MG	A076821 001	Jan 27, 2005	Jan	DISC
		@	2.5MG;500MG	A076821 002	Jan 27, 2005	Jan	DISC
		@	5MG;500MG	A076821 003	Jan 27, 2005	Jan	DISC

GLYCOPYRROLATE

TABLET; ORAL

ROBINUL

AA	+	SHIONOGI PHARMA	1MG	N012827 001		Jan	CAHN
		ROBINUL FORTE					
AA	+	SHIONOGI PHARMA	2MG	N012827 002		Jan	CAHN

GRANISETRON HYDROCHLORIDE

INJECTABLE; INJECTION

GRANISETRON HYDROCHLORIDE

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

GRISEOFULVIN, MICROCRYSTALLINE

TABLET; ORAL

FULVICIN-U/F

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

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

GUANFACINE HYDROCHLORIDE

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

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALDOL

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

HALOPERIDOL

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

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HYDROCHLORIDE

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

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDROCHLOROTHIAZIDE

AB	UNICHEM	12.5MG	A090510	001	Jan 19, 2010	Jan	NEWA
----	---------	--------	---------	-----	--------------	-----	------

HYDROCHLOROTHIAZIDE; LISINAPRIL

TABLET; ORAL

LISINAPRIL AND HYDROCHLOROTHIAZIDE

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

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

TABLET; ORAL

HYZAAR

>D>	MERCK	12.5MG;50MG	N020387	001	Apr 28, 1995	Mar	CFTG	
>A>	AB	12.5MG;50MG	N020387	001	Apr 28, 1995	Mar	CFTG	
>D>		12.5MG;100MG	N020387	003	Oct 20, 2005	Mar	CFTG	
>A>	AB	12.5MG;100MG	N020387	003	Oct 20, 2005	Mar	CFTG	
>D>	+	25MG;100MG	N020387	002	Nov 10, 1998	Mar	CFTG	
>A>	AB	25MG;100MG	N020387	002	Nov 10, 1998	Mar	CFTG	
>A>	LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE							
>A>	AB	MYLAN	12.5MG;100MG	A091652	002	Apr 06, 2010	Mar	NEWA
>A>	AB	ROXANE	12.5MG;100MG	A077732	001	Apr 06, 2010	Mar	NEWA
>A>	AB	TEVA PHARMS	12.5MG;50MG	A077157	001	Apr 06, 2010	Mar	NEWA
>A>	AB		12.5MG;100MG	A077157	002	Apr 06, 2010	Mar	NEWA



TABLET; ORAL

>A>		LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE					
>A>	AB	TEVA PHARMS	25MG;100MG	A077157	003	Apr 06, 2010	Mar NEWA
>A>	AB	TORRENT PHARMS	12.5MG;100MG	A090528	003	Apr 06, 2010	Mar NEWA

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATETABLET; ORAL

		METOPROLOL TARTRATE AND HYDROCHLOROTHIAZIDE					
AB	+	MYLAN	25MG;100MG	A076792	002	Aug 20, 2004	Jan CRLD
			50MG;100MG	A076792	003	Aug 20, 2004	Jan CTEC

HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDETABLET; ORAL

		MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE					
>A>	AB	GLENMARK PHARMS	12.5MG;7.5MG	A090718	001	Mar 17, 2010	Mar NEWA
>A>	AB		12.5MG;15MG	A090718	002	Mar 17, 2010	Mar NEWA
>A>	AB		25MG;15MG	A090718	003	Mar 17, 2010	Mar NEWA

HYDROCORTISONECREAM; TOPICAL

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

LOTION; TOPICAL

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

HYDROMORPHONE HYDROCHLORIDEINJECTABLE; INJECTION

		HYDROMORPHONE HYDROCHLORIDE					
>A>	AP	AKORN	10MG/ML	A078228	001	Apr 14, 2010	Mar NEWA
>A>	AP		10MG/ML	A078261	001	Apr 14, 2010	Mar NEWA
>A>		TABLET, EXTENDED RELEASE; ORAL					
>A>		EXALGO					
>A>		MALLINCKRODT INC	8MG	N021217	001	Mar 01, 2010	Mar NEWA
>A>			12MG	N021217	002	Mar 01, 2010	Mar NEWA
>A>			16MG	N021217	003	Mar 01, 2010	Mar NEWA

IBUPROFENTABLET; ORAL

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

IBUTILIDE FUMARATEINJECTABLE; INJECTION

		IBUTILIDE FUMARATE					
>A>	AP	BIONICHE PHARMA USA	0.1MG/ML	A090924	001	Jan 11, 2010	Mar CAHN
>D>	AP	GENERAMEDIX	0.1MG/ML	A090924	001	Jan 11, 2010	Mar CAHN

IFOSFAMIDE

## INJECTABLE; INJECTION

## IFEX

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

## IFOSFAMIDE

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

IFOSFAMIDE; MESNA

## INJECTABLE; INJECTION

## IFEX/MESNEX KIT

## @ BAXTER HLTHCARE

1GM/VIAL;100MG/ML

N019763 003 Oct 10, 1992 Feb DISC

## @

3GM/VIAL;100MG/ML

N019763 004 Oct 10, 1992 Feb DISC

IMIPRAMINE HYDROCHLORIDE

## TABLET; ORAL

## IMIPRAMINE HYDROCHLORIDE

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

IMIQUIMOD

## CREAM; TOPICAL

## ALDARA

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

INAMRINONE LACTATE

## INJECTABLE; INJECTION

## AMRINONE LACTATE

## @ BAXTER HLTHCARE CORP

EQ 5MG BASE/ML

A075542 001 May 10, 2000 Feb DISC

## +

EQ 5MG BASE/ML

A075513 001 May 09, 2000 Feb CTEC

INDOMETHACIN

## INJECTABLE; INJECTION

## INDOMETHACIN

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

IRINOTECAN HYDROCHLORIDE

## INJECTABLE; INJECTION

## IRINOTECAN HYDROCHLORIDE

>D>	AP	SANDOZ	40MG/2ML (20MG/ML)	A077994 001	Feb 27, 2008	Mar	DISC
>A>		@	40MG/2ML (20MG/ML)	A077994 001	Feb 27, 2008	Mar	DISC
>D>	AP		100MG/5ML (20MG/ML)	A077994 002	Feb 27, 2008	Mar	DISC
>A>		@	100MG/5ML (20MG/ML)	A077994 002	Feb 27, 2008	Mar	DISC

ISOSORBIDE DINITRATE

TABLET, EXTENDED RELEASE; ORAL

ISOSORBIDE DINITRATE

>A>	AB	+	CARACO	40MG	A040009	001	Dec 30, 1998	Mar	CAHN
>D>	AB	+	INWOOD LABS	40MG	A040009	001	Dec 30, 1998	Mar	CAHN

LABETALOL HYDROCHLORIDE

INJECTABLE; INJECTION

LABETALOL HYDROCHLORIDE

AP			SAGENT STRIDES	5MG/ML	A079134	001	Feb 03, 2010	Jan	NEWA
----	--	--	----------------	--------	---------	-----	--------------	-----	------

TABLET; ORAL

TRANDATE

AB	+		PROMETHEUS LABS	200MG	N018716	002	Aug 01, 1984	Feb	CRLD
AB				300MG	N018716	003	Aug 01, 1984	Feb	CRLD

LENALIDOMIDE

CAPSULE; ORAL

REVLIMID

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

LEVETIRACETAM

SOLUTION; ORAL

LEVETIRACETAM

AA			WOCKHARDT	100MG/ML	A090028	001	Mar 03, 2010	Feb	NEWA
----	--	--	-----------	----------	---------	-----	--------------	-----	------

TABLET; ORAL

LEVETIRACETAM

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

LEVOTHYROXINE SODIUM

CAPSULE; ORAL

TIROSINT

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

LIDOCAINE; PRILOCAINE

CREAM; TOPICAL

LIDOCAINE AND PRILOCAINE

>D>	AB		ALTANA	2.5%;2.5%	A076453	001	Aug 18, 2003	Mar	CAHN
>A>	AB		NYCOMED US	2.5%;2.5%	A076453	001	Aug 18, 2003	Mar	CAHN

LIRAGLUTIDE RECOMBINANT

SOLUTION; SUBCUTANEOUS

VICTOZA

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

LISINOPRIL

TABLET; ORAL

LISINOPRIL

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

LITHIUM CARBONATE

CAPSULE; ORAL

ESKALITH

@	NOVEN THERAP	300MG	N016860 001		Jan	DISC
---	--------------	-------	-------------	--	-----	------

LOSARTAN POTASSIUM

TABLET; ORAL

COZAAR

>D>		MERCK	25MG	N020386 001	Apr 14, 1995	Mar	CFTG
>A>	AB		25MG	N020386 001	Apr 14, 1995	Mar	CFTG
>D>			50MG	N020386 002	Apr 14, 1995	Mar	CFTG
>A>	AB		50MG	N020386 002	Apr 14, 1995	Mar	CFTG
>D>		+	100MG	N020386 003	Oct 13, 1998	Mar	CFTG
>A>	AB	+	100MG	N020386 003	Oct 13, 1998	Mar	CFTG
>A>		LOSARTAN POTASSIUM					
>A>	AB	TEVA	25MG	A076958 001	Apr 06, 2010	Mar	NEWA
>A>	AB		50MG	A076958 002	Apr 06, 2010	Mar	NEWA
>A>	AB		100MG	A076958 003	Apr 06, 2010	Mar	NEWA

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

ANTIVERT

AA	+	PFIZER	50MG	N010721 001	Jan 20, 1982	Jan	CMFD
----	---	--------	------	-------------	--------------	-----	------

TABLET, CHEWABLE; ORAL

ANTIVERT

@	PFIZER	25MG	N010721 005		Jan	DISC
---	--------	------	-------------	--	-----	------

MELPHALAN HYDROCHLORIDE

INJECTABLE; INJECTION

MELPHALAN HYDROCHLORIDE

>A>	AP	BIONICHE PHARMA USA	EQ 50MG BASE/VIAL	A090299 001	Oct 27, 2009	Mar	CAHN
>D>	AP	GENERAMEDIX	EQ 50MG BASE/VIAL	A090299 001	Oct 27, 2009	Mar	CAHN

MEMANTINE HYDROCHLORIDE

TABLET; ORAL

MEMANTINE HYDROCHLORIDE

>A>	AB	DR REDDYS LABS LTD	5MG	A090048 001	Apr 14, 2010	Mar	NEWA
>A>	AB		10MG	A090048 002	Apr 14, 2010	Mar	NEWA
>D>		NAMENDA					
>D>		FOREST LABS	5MG	N021487 001	Oct 16, 2003	Mar	CFTG
>A>	AB		5MG	N021487 001	Oct 16, 2003	Mar	CFTG
>D>		+	10MG	N021487 002	Oct 16, 2003	Mar	CFTG
>A>	AB	+	10MG	N021487 002	Oct 16, 2003	Mar	CFTG

MEPERIDINE HYDROCHLORIDE

SYRUP; ORAL

MEPERIDINE HYDROCHLORIDE

+ ROXANE 50MG/5ML A088744 001 Jan 30, 1985 Feb CRLD

TABLET; ORAL

DEMEROL

@ SANOFI AVENTIS US 50MG N005010 001 Feb DISC

MEPERIDINE HYDROCHLORIDE

AA MIKAH PHARMA 50MG A040331 001 May 28, 1999 Feb CAHN

AA 100MG A040331 002 May 28, 1999 Feb CAHN

MESALAMINE

TABLET, DELAYED RELEASE; ORAL

ASACOL

+ WARNER CHILCOTT INC 400MG N019651 001 Jan 31, 1992 Feb CAHN

ASACOL HD

+ WARNER CHILCOTT INC 800MG N021830 001 May 29, 2008 Feb CAHN

MESNA

INJECTABLE; INTRAVENOUS

MESNA

&gt;A&gt; AP SAGENT STRIDES 100MG/ML A090913 001 Apr 13, 2010 Mar NEWA

METAXALONE

TABLET; ORAL

&gt;A&gt; METAXALONE

&gt;A&gt; AB SANDOZ 800MG A040445 001 Mar 31, 2010 Mar NEWA

SKELAXIN

&gt;D&gt; + KING PHARMS 800MG N013217 003 Aug 30, 2002 Mar CFTG

&gt;A&gt; AB + 800MG N013217 003 Aug 30, 2002 Mar CFTG

METFORMIN HYDROCHLORIDE

TABLET; ORAL

&gt;D&gt; METFORMIN HYDROCHLORIDE

&gt;D&gt; AB IPCA LABS LTD 500MG A078422 001 Aug 06, 2007 Mar DISC

&gt;A&gt; @ 500MG A078422 001 Aug 06, 2007 Mar DISC

&gt;D&gt; AB 850MG A078422 002 Aug 06, 2007 Mar DISC

&gt;A&gt; @ 850MG A078422 002 Aug 06, 2007 Mar DISC

&gt;D&gt; AB 1GM A078422 003 Aug 06, 2007 Mar DISC

&gt;A&gt; @ 1GM A078422 003 Aug 06, 2007 Mar DISC

TABLET, EXTENDED RELEASE; ORAL

METFORMIN HYDROCHLORIDE

AB TORRENT PHARMS 750MG A079226 001 Feb 18, 2010 Jan NEWA

METHADONE HYDROCHLORIDE

INJECTABLE; INJECTION

DOLOPHINE HYDROCHLORIDE

&gt;A&gt; + BIONICHE PHARMA 10MG/ML N021624 001 Mar CAHN

&gt;D&gt; + XANODYNE PHARM 10MG/ML N021624 001 Mar CAHN

METHENAMINE HIPPURATE

TABLET; ORAL

UREX

AB CNTY LINE PHARMS 1GM N016151 001 Feb CAHN

METHOTREXATE SODIUM

## INJECTABLE; INJECTION

## METHOTREXATE SODIUM PRESERVATIVE FREE

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

METOCLOPRAMIDE HYDROCHLORIDE

## INJECTABLE; INJECTION

## METOCLOPRAMIDE HYDROCHLORIDE

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

## TABLET; ORAL

## METOCLOPRAMIDE HYDROCHLORIDE

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

METRONIDAZOLE

## TABLET; ORAL

## METRONIDAZOLE

>D>			@ PAR PHARM	250MG	A070040 001	Jan 29, 1985	Mar	CAHN
>A>			@ WORLD GEN	250MG	A070040 001	Jan 29, 1985	Mar	CAHN

MILRINONE LACTATE

## INJECTABLE; INJECTION

## MILRINONE LACTATE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	+	BAXTER HLTHCARE	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	A075834 001	May 28, 2002	Feb	CTEC
----	---	-----------------	--	-------------	--------------	-----	------

AP	+		EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	A075834 002	May 28, 2002	Feb	CRLD
----	---	--	--	-------------	--------------	-----	------

## MILRINONE LACTATE IN PLASTIC CONTAINER

AP		HIKMA FARMACEUTICA	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	A090038 001	Jan 21, 2010	Jan	NEWA
----	--	--------------------	--	-------------	--------------	-----	------

AP			EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	A090038 002	Jan 21, 2010	Jan	NEWA
----	--	--	--	-------------	--------------	-----	------

## PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER

		@ SANOFI AVENTIS US	EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)	N020343 003	Aug 09, 1994	Feb	DISC
--	--	---------------------	--	-------------	--------------	-----	------

		@	EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)	N020343 004	Aug 09, 1994	Feb	DISC
--	--	---	--	-------------	--------------	-----	------

MITOXANTRONE HYDROCHLORIDE

## INJECTABLE; INJECTION

## MITOXANTRONE HYDROCHLORIDE

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

MOEXIPRIL HYDROCHLORIDE

TABLET; ORAL

MOEXIPRIL HYDROCHLORIDE

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

MORPHINE SULFATE

SOLUTION; ORAL

MORPHINE SULFATE

ROXANE

20MG/5ML

N022195 002 Mar 17, 2008 Jan CRLD

+

100MG/5ML

N022195 003 Jan 25, 2010 Jan NEWA

TABLET, EXTENDED RELEASE; ORAL

MORPHINE SULFATE

@ PURDUE PHARMA LP

15MG

A074862 001 Jul 07, 1998 Feb CAHN

@

30MG

A074862 002 Jul 07, 1998 Feb CAHN

@

60MG

A074862 003 Jul 07, 1998 Feb CAHN

@

100MG

A074769 001 Jul 02, 1998 Feb CAHN

@

200MG

A074769 002 Jul 02, 1998 Feb CAHN

NALIDIXIC ACID

TABLET; ORAL

NEGGRAM

@ SANOFI AVENTIS US

250MG

N014214 002

Feb DISC

@

500MG

N014214 004

Feb DISC

@

1GM

N014214 005

Feb DISC

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

PENTAZOCINE AND NALOXONE HYDROCHLORIDES

AB + WATSON LABS EQ 0.5MG BASE;EQ 50MG BASE

A074736 001 Jan 21, 1997 Feb CRLD

TALWIN NX

@ SANOFI AVENTIS US EQ 0.5MG BASE;EQ 50MG BASE

N018733 001 Dec 16, 1982 Feb DISC

NEOMYCIN SULFATE

TABLET; ORAL

NEOMYCIN SULFATE

>A>	AA	OMAN PHARM PRODUCTS	500MG	A065468 001	Mar 29, 2010	Mar	NEWA
-----	----	---------------------	-------	-------------	--------------	-----	------

NICARDIPINE HYDROCHLORIDE

INJECTABLE; INJECTION

NICARDIPINE HYDROCHLORIDE

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

>D>	AP	GENERAMEDIX	25MG/10ML (2.5MG/ML)	A090664 001	Nov 17, 2009	Mar	CAHN
-----	----	-------------	----------------------	-------------	--------------	-----	------

NIFEDIPINE

CAPSULE; ORAL

NIFEDIPINE

>A>	AB	INTERGEL PHARM	10MG	A072781 001	Jul 30, 1993	Mar	CAHN
-----	----	----------------	------	-------------	--------------	-----	------

>D>	AB	INVERNESS MEDCL	10MG	A072781 001	Jul 30, 1993	Mar	CAHN
-----	----	-----------------	------	-------------	--------------	-----	------

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL

SULAR

+ SHIONOGI PHARMA

8.5MG

N020356 008 Jan 02, 2008 Jan CAHN

@

10MG

N020356 001 Feb 02, 1995 Jan CAHN

## TABLET, EXTENDED RELEASE; ORAL

## SULAR

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

NITROFURANTOIN

## SUSPENSION; ORAL

## FURADANTIN

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

NITROGLYCERIN

## AEROSOL; SUBLINGUAL

## NITROLINGUAL

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

## SPRAY, METERED; SUBLINGUAL

## NITROLINGUAL PUMPSPRAY

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

OFLOXACIN

## TABLET; ORAL

## OFLOXACIN

@	LARKEN LABS	200MG	A076093 001	Sep 02, 2003	Jan	CAHN
@		300MG	A076093 002	Sep 02, 2003	Jan	CAHN
@		400MG	A076093 003	Sep 02, 2003	Jan	CAHN

ONDANSETRON

## TABLET, ORALLY DISINTEGRATING; ORAL

## ONDANSETRON

>A>	AB	AUROBINDO PHARMA	4MG	A090469 001	Apr 12, 2010	Mar	NEWA
>A>	AB		8MG	A090469 002	Apr 12, 2010	Mar	NEWA

ONDANSETRON HYDROCHLORIDE

## INJECTABLE; INJECTION

## ONDANSETRON HYDROCHLORIDE

>A>	AP	LANNETT	EQ 2MG BASE/ML	A090116 001	Apr 14, 2010	Mar	NEWA
-----	----	---------	----------------	-------------	--------------	-----	------

ORPHENADRINE CITRATE

## TABLET, EXTENDED RELEASE; ORAL

## ORPHENADRINE CITRATE

AB		GAVIS PHARMS	100MG	A040284 001	Jun 19, 1998	Feb	CAHN
----	--	--------------	-------	-------------	--------------	-----	------

OXALIPLATIN

## INJECTABLE; INJECTION

## OXALIPLATIN

AP	+	HOSPIRA INC	50MG/VIAL	A078815 001	Sep 30, 2009	Jan	CRLD
AP	+		100MG/VIAL	A078815 002	Sep 30, 2009	Jan	CRLD



OXCARBAZEPINE

TABLET; ORAL

OXCARBAZEPINE

AB	CADISTA PHARMS	150MG	A090239 001	Jan 25, 2010	Jan	NEWA
AB		300MG	A090239 002	Jan 25, 2010	Jan	NEWA
AB		600MG	A090239 003	Jan 25, 2010	Jan	NEWA

PALIPERIDONE PALMITATE

SUSPENSION, EXTENDED RELEASE; INTRAMUSCULAR

INVEGA SUSTENNA

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

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION

PAMIDRONATE DISODIUM

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

PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

CAPSULE, DELAYED RELEASE; ORAL

CREON

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

PEGADEMASE BOVINE

INJECTABLE; INJECTION

ADAGEN

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

PERINDOPRIL ERBUMINE

TABLET; ORAL

PERINDOPRIL ERBUMINE

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

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE; ORAL

BONTRIL

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

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HYDROCHLORIDE

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

>A> POLIDOCANOL  
 >A> SOLUTION; INTRAVENOUS  
 >A> ASCLERA  
 >A> CHEMISCH FBRK KRSSLR 10MG/2ML (5MG/ML) N021201 001 Mar 30, 2010 Mar NEWA  
 >A> + 20MG/2ML (10MG/ML) N021201 002 Mar 30, 2010 Mar NEWA

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

FOR SOLUTION; ORAL

LAX-LYTE WITH FLAVOR PACKS

AA PADDOCK 420GM/BOT;1.48GM/BOT;5.72GM/BOT;1 A079232 001 Feb 25, 2010 Feb NEWA  
 1.2GM/BOT  
 >A> PEG-3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE  
 >A> AA MYLAN 420GM/BOT;1.48GM/BOT;5.72GM/BOT;1 A090409 001 Apr 02, 2010 Mar NEWA  
 1.2GM/BOT

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

FOR SOLUTION; ORAL

PEG 3350 AND ELECTROLYTES

AA MYLAN 236GM;2.97GM;6.74GM;5.86GM;22.74G A090928 001 Jan 28, 2010 Jan NEWA  
 M  
 POLYETHYLENE GLYCOL 3350 AND ELECTROLYTES  
 AA PADDOCK LABS 240GM/BOT;2.98GM/BOT;6.72GM/BOT;5 A090712 001 Feb 25, 2010 Feb NEWA  
 .84GM/BOT;22.72GM/BOT

POTASSIUM CITRATE

TABLET, EXTENDED RELEASE; ORAL

UROCIT-K

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

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET; ORAL

MIRAPEX

>D> BOEHRINGER INGELHEIM 0.75MG N020667 007 Jul 30, 2007 Mar CFTG  
 >A> AB 0.75MG N020667 007 Jul 30, 2007 Mar CFTG  
 >A> PRAMIPEXOLE DIHYDROCHLORIDE  
 >A> AB MYLAN 0.75MG A090764 001 Apr 09, 2010 Mar NEWA

TABLET, EXTENDED RELEASE; ORAL

MIRAPEX ER

BOEHRINGER INGELHEIM 0.375MG N022421 001 Feb 19, 2010 Feb NEWA  
 0.75MG N022421 002 Feb 19, 2010 Feb NEWA  
 1.5MG N022421 003 Feb 19, 2010 Feb NEWA  
 3MG N022421 004 Feb 19, 2010 Feb NEWA  
 + 4.5MG N022421 005 Feb 19, 2010 Feb NEWA

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HYDROCHLORIDE

@ WATSON LABS EQ 1MG BASE A072352 001 May 16, 1989 Jan DISC  
 @ EQ 2MG BASE A072333 001 May 16, 1989 Jan DISC

PREDNISONE

TABLET; ORAL

PREDNISONE

AB CONTRACT PHARMACAL 5MG A080209 001 Jan CAHN

PREGABALIN

SOLUTION; ORAL

LYRICA

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

PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

PROCAINE HYDROCHLORIDE

@	WATSON LABS	1%	A080658	001		Jan	DISC
---	-------------	----	---------	-----	--	-----	------

PROCHLORPERAZINE MALEATE

TABLET; ORAL

PROCHLORPERAZINE MALEATE

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

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

PROCOMP

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

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

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HYDROCHLORIDE

@	PAR PHARM	65MG	A080269	001		Jan	DISC
---	-----------	------	---------	-----	--	-----	------

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

@	CONTRACT PHARMACAL	200MG	A083808	001		Jan	CAHN
---	--------------------	-------	---------	-----	--	-----	------

RIFAXIMIN

TABLET; ORAL

XIFAXAN

>A>	SALIX PHARMS	550MG	N021361	002	Mar 24, 2010	Mar	NEWA
-----	--------------	-------	---------	-----	--------------	-----	------

RISPERIDONE

INJECTABLE; INTRAMUSCULAR

RISPERDAL CONSTA

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

		50MG/VIAL	N021346	003	Oct 29, 2003	Jan	CRLD
--	--	-----------	---------	-----	--------------	-----	------

TABLET; ORAL

RISPERIDONE

@	SYNTHON PHARMS	0.25MG	A078187	001	Oct 22, 2009	Feb	DISC
---	----------------	--------	---------	-----	--------------	-----	------

@		0.5MG	A078187	002	Oct 22, 2009	Feb	DISC
---	--	-------	---------	-----	--------------	-----	------

@		1MG	A078187	003	Oct 22, 2009	Feb	DISC
---	--	-----	---------	-----	--------------	-----	------

@		2MG	A078187	004	Oct 22, 2009	Feb	DISC
---	--	-----	---------	-----	--------------	-----	------

@		3MG	A078187	005	Oct 22, 2009	Feb	DISC
---	--	-----	---------	-----	--------------	-----	------

@		4MG	A078187	006	Oct 22, 2009	Feb	DISC
---	--	-----	---------	-----	--------------	-----	------

RITONAVIR

TABLET; ORAL

RITONAVIR

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

RIVASTIGMINE TARTRATE

CAPSULE; ORAL

EXELON

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

ROCURONIUM BROMIDE

INJECTABLE; INJECTION

ROCURONIUM BROMIDE

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

ROPINIROLE HYDROCHLORIDE

TABLET; ORAL

ROPINIROLE HYDROCHLORIDE

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

SELEGILINE HYDROCHLORIDE

TABLET; ORAL

SELEGILINE HYDROCHLORIDE

>D>	AB	ALPHAPHARM	5MG	A074866 001	Nov 26, 1997	Mar	CAHN
>A>	AB	MYLAN	5MG	A074866 001	Nov 26, 1997	Mar	CAHN

SODIUM BICARBONATE

INJECTABLE; INJECTION

SODIUM BICARBONATE

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

SOMATROPIN RECOMBINANT

INJECTABLE; INJECTION

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

STAVUDINE

CAPSULE; ORAL

STAVUDINE

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

CAPSULE; ORAL

## STAVUDINE

AB	MYLAN	40MG	A079069 004	Dec 29, 2008	Feb	CAHN
----	-------	------	-------------	--------------	-----	------

SUCRALFATE

## TABLET; ORAL

## SUCRALFATE

>A>	AB	NOSTRUM LABS	1GM	A074415 001	Jun 08, 1998	Mar	CAHN
>D>	AB	RATIOPHARM	1GM	A074415 001	Jun 08, 1998	Mar	CAHN

SULFAMETHOXAZOLE; TRIMETHOPRIM

## TABLET; ORAL

## SULFAMETHOXAZOLE AND TRIMETHOPRIM

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

TAMSULOSIN HYDROCHLORIDE

## CAPSULE; ORAL

## FLOMAX

AB	+	BOEHRINGER INGELHEIM	0.4MG	N020579 001	Apr 15, 1997	Feb	CFTG
AB		TAMSULOSIN HYDROCHLORIDE		A090377 001	Mar 02, 2010	Feb	NEWA

TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR

## SOLUTION; INJECTION, ORAL

## TECHNELITE

+	LANTHEUS MEDCL	0.0083-2.7 CI/GENERATOR	N017771 001		Feb	CRLD
+	MALLINCKRODT	0.25-3 CI/GENERATOR	N017243 002		Feb	CRLD

TEMOZOLOMIDE

## CAPSULE; ORAL

## TEMODAR

AB	SCHERING	5MG	N021029 001	Aug 11, 1999	Feb	CFTG
AB		20MG	N021029 002	Aug 11, 1999	Feb	CFTG
AB		100MG	N021029 003	Aug 11, 1999	Feb	CFTG
AB		140MG	N021029 005	Oct 19, 2006	Feb	CFTG
AB		180MG	N021029 006	Oct 19, 2006	Feb	CFTG
AB	+	250MG	N021029 004	Aug 11, 1999	Feb	CFTG

## TEMOZOLOMIDE

AB	BARR	5MG	A078879 001	Mar 01, 2010	Feb	NEWA
AB		20MG	A078879 002	Mar 01, 2010	Feb	NEWA
AB		100MG	A078879 003	Mar 01, 2010	Feb	NEWA
AB		140MG	A078879 005	Mar 01, 2010	Feb	NEWA
AB		180MG	A078879 006	Mar 01, 2010	Feb	NEWA
AB		250MG	A078879 004	Mar 01, 2010	Feb	NEWA

TERCONAZOLE

## CREAM; VAGINAL

## TERCONAZOLE

BX	+	NYCOMED US	0.8%	N021735 001	Oct 01, 2004	Jan	CAHN
----	---	------------	------	-------------	--------------	-----	------

THEOPHYLLINE

## ELIXIR; ORAL

## ELIXOPHYLLIN

>A>	+	CARACO	80MG/15ML	A085186 001		Mar	CAHN
-----	---	--------	-----------	-------------	--	-----	------

## ELIXIR; ORAL

## ELIXOPHYLLIN

>D>	+	FOREST LABS	80MG/15ML	A085186 001		Mar	CAHN
-----	---	-------------	-----------	-------------	--	-----	------

## TABLET, EXTENDED RELEASE; ORAL

## THEOCHRON

>A>	AB	CARACO	100MG	A088320 001	Feb 21, 1985	Mar	CAHN
>A>	AB		200MG	A088321 001	Feb 21, 1985	Mar	CAHN
>A>	AB		300MG	A087400 002	Jan 11, 1983	Mar	CAHN
>D>	AB	INWOOD LABS	100MG	A088320 001	Feb 21, 1985	Mar	CAHN
>D>	AB		200MG	A088321 001	Feb 21, 1985	Mar	CAHN
>D>	AB		300MG	A087400 002	Jan 11, 1983	Mar	CAHN

TINZAPARIN SODIUM

## INJECTABLE; INJECTION

## INNOHEP

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

TOPIRAMATE

## TABLET; ORAL

## TOPIRAMATE

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

TRAMADOL HYDROCHLORIDE

## TABLET, ORALLY DISINTEGRATING; ORAL

## TRAMADOL HYDROCHLORIDE

>D>	@	VICTORY PHARMA	50MG	N021693 001	May 05, 2005	Mar	CMFD
>A>	+		50MG	N021693 001	May 05, 2005	Mar	CMFD

TRANDOLAPRIL

## TABLET; ORAL

## TRANDOLAPRIL

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

TRAZODONE HYDROCHLORIDE

## TABLET; ORAL

## TRAZODONE HYDROCHLORIDE

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

## TABLET, EXTENDED RELEASE; ORAL

## OLEPTRO

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

TRETINOIN

## CAPSULE; ORAL

## TRETINOIN

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

CREAM; TOPICALTRETINOIN

>A>	+	TRIAx PHARMS LLC	0.0375%	A090098 001	Mar 22, 2010	Mar	NEWA
-----	---	------------------	---------	-------------	--------------	-----	------

TRIPTORELIN PAMOATEINJECTABLE; INTRAMUSCULARTRELSTAR

>A>	+	WATSON LABS	EQ 22.5MG BASE/VIAL	N022437 001	Mar 10, 2010	Mar	NEWA
-----	---	-------------	---------------------	-------------	--------------	-----	------

UNOPROSTONE ISOPROPYLSOLUTION/DROPS; OPHTHALMICRESCULA

@ SUCAMPO PHARMS

0.15%

N021214 001 Aug 03, 2000 Jan DISC

UREA, C-14CAPSULE; ORALPYTEST

+ AVENT

1uCi

N020617 001 May 09, 1997 Feb CAHN

PYTEST KIT

+ AVENT

1uCi

N020617 002 May 09, 1997 Feb CAHN

URSODIOLCAPSULE; ORALURSODIOL

AB MIKAH PHARMA

300MG

A075517 001 Mar 14, 2000 Feb CAHN

AB MYLAN

300MG

A090530 001 Feb 17, 2010 Jan NEWA

VALPROATE SODIUMINJECTABLE; INJECTIONVALPROATE SODIUM

AP HIKMA FARMACEUTICA

EQ 100MG BASE/ML

A078523 001 Feb 17, 2010 Jan NEWA

VANCOMYCIN HYDROCHLORIDEINJECTABLE; INJECTIONVANCOMYCIN HYDROCHLORIDE

>A>	AP	BIONICHE PHARMA USA	EQ 500MG BASE/VIAL	A065401 001	Jun 30, 2008	Mar	CAHN
-----	----	---------------------	--------------------	-------------	--------------	-----	------

>A>	AP		EQ 1GM BASE/VIAL	A065401 002	Jun 30, 2008	Mar	CAHN
-----	----	--	------------------	-------------	--------------	-----	------

>D>	AP	GENERAMEDIX	EQ 500MG BASE/VIAL	A065401 001	Jun 30, 2008	Mar	CAHN
-----	----	-------------	--------------------	-------------	--------------	-----	------

>D>	AP		EQ 1GM BASE/VIAL	A065401 002	Jun 30, 2008	Mar	CAHN
-----	----	--	------------------	-------------	--------------	-----	------

VECURONIUM BROMIDEINJECTABLE; INJECTIONVECURONIUM BROMIDE

>D>	AP	GENERAMEDIX	10MG/VIAL	A078274 001	Dec 29, 2008	Mar	CAHN
-----	----	-------------	-----------	-------------	--------------	-----	------

>D>	AP		20MG/VIAL	A078274 002	Dec 29, 2008	Mar	CAHN
-----	----	--	-----------	-------------	--------------	-----	------

>A>	AP	MUSTAFA NEVZAT	10MG/VIAL	A078274 001	Dec 29, 2008	Mar	CAHN
-----	----	----------------	-----------	-------------	--------------	-----	------

>A>	AP		20MG/VIAL	A078274 002	Dec 29, 2008	Mar	CAHN
-----	----	--	-----------	-------------	--------------	-----	------

VELAGLUCERASE ALFAINJECTABLE; IV (INFUSION)VPRIV

SHIRE HUMAN GENETIC

400 UNITS/VIAL

N022575 001 Feb 26, 2010 Feb NEWA

POWDER; IV (INFUSION)VPRIV

+ SHIRE HUMAN GENETIC

200 UNITS/VIAL

N022575 002 Feb 26, 2010 Feb NEWA

VENLAFAXINE HYDROCHLORIDE

TABLET; ORAL

VENLAFAXINE HYDROCHLORIDE

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

ZOLPIDEM TARTRATE

TABLET; ORAL

ZOLPIDEM TARTRATE

>D>	@	PAR PHARM	5MG	A076062 001	Apr 23, 2007	Mar	CAHN
>D>	@		10MG	A076062 002	Apr 23, 2007	Mar	CAHN
>A>	@	WORLD GEN	5MG	A076062 001	Apr 23, 2007	Mar	CAHN
>A>	@		10MG	A076062 002	Apr 23, 2007	Mar	CAHN



OTC DRUG PRODUCT LIST - 30TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

2-1

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

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

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

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

TABLET; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

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

10MG A078780 004 Jan 21, 2010 Jan NEWA

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

>A> 10MG A079191 004 Apr 15, 2010 Mar NEWA

CETIRIZINE HYDROCHLORIDE HIVES RELIEF

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

10MG A078780 002 Jan 21, 2010 Jan NEWA

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

>A> 10MG A079191 002 Apr 15, 2010 Mar NEWA

CIMETIDINE

TABLET; ORAL

CIMETIDINE

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

200MG A074963 001 Jun 19, 1998 Jan CAHN

IBUPROFEN

CAPSULE; ORAL

IBUPROFEN

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

TABLET; ORAL

IBUPROFEN

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

200MG A071735 001 Sep 10, 1987 Jan CAHN

200MG A072299 001 Jul 01, 1988 Jan CAHN

200MG A073691 001 Feb 25, 1994 Jan CAHN

PROFEN

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

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL

IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE

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

LOPERAMIDE HYDROCHLORIDE

TABLET; ORAL

LOPERAMIDE HYDROCHLORIDE

CONTRACT PHARMACAL 2MG A073254 001 Jul 30, 1993 Jan CAHN

LORATADINE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

CLARITIN-D

>D> @ SCHERING PLOUGH 5MG;120MG N019670 002 Nov 27, 2002 Mar CMFD

>A> + 5MG;120MG N019670 002 Nov 27, 2002 Mar CMFD

## TABLET, EXTENDED RELEASE; ORAL

## LORATADINE AND PSEUDOEPHEDRINE SULFATE

>D>	+	IMPAX LABS	5MG;120MG	A076050 001	Jan 30, 2003	Mar	CRLD
>A>			5MG;120MG	A076050 001	Jan 30, 2003	Mar	CRLD

MICONAZOLE NITRATE

## CREAM, SUPPOSITORY; TOPICAL, VAGINAL

## MONISTAT 1 COMBINATION PACK

>D>	+	JOHNSON AND JOHNSON	1.2GM,2%	N021308 001	Jun 29, 2001	Mar	CPOT
>A>	+		2%,1.2GM	N021308 001	Jun 29, 2001	Mar	CPOT

## CREAM; VAGINAL

## MICONAZOLE NITRATE

		PERRIGO R AND D	4%	A091366 001	Jan 15, 2010	Jan	NEWA
--	--	-----------------	----	-------------	--------------	-----	------

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

## SOLUTION/DROPS; OPHTHALMIC

## VISINE-A

	+	JOHNSON AND JOHNSON	0.025%;0.3%	N020485 001	Jan 31, 1996	Jan	CRLD
--	---	---------------------	-------------	-------------	--------------	-----	------

PSEUDOEPHEDRINE HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## SUDAFED 24 HOUR

	+	MCNEIL CONS	240MG	N020021 002	Dec 15, 1992	Feb	CAHN
--	---	-------------	-------	-------------	--------------	-----	------

RANITIDINE HYDROCHLORIDE

## TABLET; ORAL

## RANITIDINE HYDROCHLORIDE

		CONTRACT PHARMACAL	EQ 75MG BASE	A075094 001	Jun 21, 1999	Jan	CAHN
--	--	--------------------	--------------	-------------	--------------	-----	------

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

**CUMULATIVE SUPPLEMENT NUMBER 03 MARCH 2010**

NO MARCH 2010 APPROVALS

## ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

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

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

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

NO MARCH 2010 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>ADAPALENE - DIFFERIN</u>						
N022502	001				>A> NDF	Mar 17, 2013
<u>ALENDRONATE SODIUM - FOSAMAX</u>						
N021575	001	>A> 5994329	Jul 17, 2018		Y	
		>A> 6015801	Jul 17, 2018		Y	
		>A> 6225294	Jul 17, 2018		Y	
<u>ALISKIREN HEMIFUMARATE; VALSARTAN - VALTURNA</u>						
N022217	001				NCE	Mar 05, 2012
<u>ALISKIREN HEMIFUMARATE; VALSARTAN - VALTURNA</u>						
N022217	002				NCE	Mar 05, 2012
<u>AMINOLEVULINIC ACID HYDROCHLORIDE - LEVULAN</u>						
N020965	001				>A> M-82	Mar 12, 2013
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 10</u>						
N021303	001	>A> RE41148	Oct 21, 2018	DP		
		>A> RE41148*PED	Apr 21, 2019			
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 15</u>						
N021303	006	>A> RE41148	Oct 21, 2018	DP		
		>A> RE41148*PED	Apr 21, 2019			
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 20</u>						
N021303	002	>A> RE41148	Oct 21, 2018	DP		
		>A> RE41148*PED	Apr 21, 2019			
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 25</u>						
N021303	004	>A> RE41148	Oct 21, 2018	DP		
		>A> RE41148*PED	Apr 21, 2019			
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 30</u>						
N021303	003	>A> RE41148	Oct 21, 2018	DP		
		>A> RE41148*PED	Apr 21, 2019			
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 5</u>						
N021303	005	>A> RE41148	Oct 21, 2018	DP		
		>A> RE41148*PED	Apr 21, 2019			
<u>APREPITANT - EMEND</u>						
N021549	001				>A> M-82	Mar 19, 2013
<u>APREPITANT - EMEND</u>						
N021549	002				>A> M-82	Mar 19, 2013
<u>APREPITANT - EMEND</u>						
N021549	003				>A> M-82	Mar 19, 2013
<u>ASCORBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE - MOVIPREP</u>						
N021881	001	7658914	Sep 01, 2024	DS DP		

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>AZTREONAM - CAYSTON</u>						
N050814 001	7208141	Dec 20, 2021	DP U-1031			
	7214364	Dec 20, 2021	DP			
	7427633	Dec 20, 2021	DP U-1031			
<u>BALSALAZIDE DISODIUM - COLAZAL</u>						
N020610 001	7452872	Aug 24, 2026	U-141			
	7452872*PED	Feb 24, 2027				
	7625884	Aug 24, 2026	U-141			
	7625884*PED	Feb 24, 2027				
<u>BEXAROTENE - TARGRETIN</u>						
N021055 001	7655699	Apr 22, 2012	DS DP U-509			
<u>BEXAROTENE - TARGRETIN</u>						
N021056 001	7655699	Apr 22, 2012	DS DP U-510			
<u>BIVALIRUDIN - ANGIOMAX</u>						
N020873 001	>A> 5196404	May 23, 2010	DS DP U-1040			
	>A> 5196404*PED	Nov 23, 2010				
<u>BUDESONIDE - RHINOCORT</u>						
N020746 001	6686346	Apr 29, 2017	DP U-557	Y		
	6686346*PED	Oct 29, 2017				
	6986904	Apr 29, 2017	DP U-699	Y		
	6986904*PED	Oct 29, 2017				
<u>BUDESONIDE - RHINOCORT</u>						
N020746 002	6686346	Apr 29, 2017	DP U-557			
	6686346*PED	Oct 29, 2017				
	6986904	Apr 29, 2017	DP U-699			
	6986904*PED	Oct 29, 2017				
<u>BUPROPION HYDROBROMIDE - APLENZIN</u>						
N022108 001	7645802	Jun 27, 2026	DP			
	7649019	Jun 27, 2026	DP			
	7662407	Jun 27, 2026	DP			
	7671094	Jun 27, 2026	DP			
<u>BUPROPION HYDROBROMIDE - APLENZIN</u>						
N022108 002	7645802	Jun 27, 2026	DP			
	7649019	Jun 27, 2026	DP			
	7662407	Jun 27, 2026	DP			
	7671094	Jun 27, 2026	DP			
<u>BUPROPION HYDROBROMIDE - APLENZIN</u>						
N022108 003	7645802	Jun 27, 2026	DP			
	7649019	Jun 27, 2026	DP			
	7662407	Jun 27, 2026	DP			
	7671094	Jun 27, 2026	DP			
<u>CAPSAICIN - QUTENZA</u>						
N022395 001					ODE	Nov 16, 2016
<u>CARGLUMIC ACID - CARBAGLU</u>						
N022562 001					>A> NCE	Mar 18, 2015

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>CEFTIBUTEN DIHYDRATE - CEDAX</u>						
N050686 001	5599557	Feb 04, 2014	DP U-578			
	5599557	Feb 04, 2014	DP U-282			
<u>CEFTIBUTEN DIHYDRATE - CEDAX</u>						
N050686 002	5599557	Feb 04, 2014	DP U-578			
	5599557	Feb 04, 2014	DP U-282			
<u>CLINDAMYCIN PHOSPHATE; TRETINOIN - ZIANA</u>						
N050802 001	RE41134	Feb 24, 2015	DP U-1033			
<u>CLONIDINE HYDROCHLORIDE - JENLOGA</u>						
N022331 001	5869100	Oct 13, 2013	DP			
<u>COLESEVELAM HYDROCHLORIDE - WELCHOL</u>						
N022362 001	5607669	Jun 10, 2014	U-757			
	5607669*PED	Dec 10, 2014				
	5679717	Apr 29, 2014	U-757			
	5679717*PED	Oct 29, 2014				
	5693675	Dec 02, 2014	DS			
	5693675*PED	Jun 02, 2015				
	5917007	Apr 29, 2014	DS U-757			
	5917007*PED	Oct 29, 2014				
	5919832	Apr 29, 2014	DS			
	5919832*PED	Oct 29, 2014				
	6066678	Apr 29, 2014	DS U-757			
	6066678*PED	Oct 29, 2014				
	6433026	Apr 29, 2014	DS			
	6433026*PED	Oct 29, 2014				
	6784254	Apr 29, 2014	DS DP			
	6784254*PED	Oct 29, 2014				
	7101960	Apr 29, 2014	DS DP U-757			
	7101960*PED	Oct 29, 2014				
	7229613	Apr 17, 2022	U-493			
	7229613*PED	Oct 17, 2022				



## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE		PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>COLESEVELAM HYDROCHLORIDE - WELCHOL</u>							
N022362 002	5607669	Jun	10, 2014	U-757			
	5607669*PED	Dec	10, 2014				
	5679717	Apr	29, 2014	U-757			
	5679717*PED	Oct	29, 2014				
	5693675	Dec	02, 2014	DS			
	5693675*PED	Jun	02, 2015				
	5917007	Apr	29, 2014	DS U-757			
	5917007*PED	Oct	29, 2014				
	5919832	Apr	29, 2014	DS			
	5919832*PED	Oct	29, 2014				
	6066678	Apr	29, 2014	DS U-757			
	6066678*PED	Oct	29, 2014				
	6433026	Apr	29, 2014	DS			
	6433026*PED	Oct	29, 2014				
	6784254	Apr	29, 2014	DS DP			
	6784254*PED	Oct	29, 2014				
	7101960	Apr	29, 2014	DS DP U-757			
	7101960*PED	Oct	29, 2014				
	7229613	Apr	17, 2022	U-493			
	7229613*PED	Oct	17, 2022				
<u>DALFAMPRIDINE - AMPYRA</u>							
N022250 001	5370879	Dec	06, 2011	DP		NCE	Jan 22, 2015
	5540938	Jul	30, 2013	U-1030		ODE	Jan 22, 2017
<u>DECITABINE - DACOGEN</u>							
N021790 001						>A> D-123	Mar 11, 2013
<u>DICLOFENAC POTASSIUM - CAMBIA</u>							
N022165 001	>A> 7482377	May	15, 2017	DS DP U-436		NDF	Jun 17, 2012
<u>DICLOFENAC POTASSIUM - ZIPSOR</u>							
N022202 001	6365180	Jul	15, 2019	DP U-980			
	7662858	Feb	24, 2029	U-1035			
<u>DOCETAXEL - TAXOTERE</u>							
N020449 001	>A> 4814470	May	14, 2010	DS DP		>A> I-543	Sep 28, 2010
	>A> 4814470*PED	Nov	14, 2010			>A> I-542	Sep 28, 2010
	>A> 5438072	Nov	22, 2013	DP		>A> PED	Mar 28, 2011
	>A> 5438072*PED	May	22, 2014				
	>A> 5698582	Jul	03, 2012	DP			
	>A> 5698582*PED	Jan	03, 2013				
	>A> 5714512	Jul	03, 2012	DP			
	>A> 5714512*PED	Jan	03, 2013				
	>A> 5750561	Jul	03, 2012	DP			
	>A> 5750561*PED	Jan	03, 2013				

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>DOXEPIN HYDROCHLORIDE - SILENOR</u>						
N022036 001	>A> 5502047	Mar 22, 2013	U-620			
	>A> 5585115	Jan 09, 2015	DP			
	>A> 5725884	Sep 30, 2016	DP			
	>A> 5866166	Jun 10, 2016	DP			
	>A> 5948438	Jun 04, 2017	DP			
	>A> 6103219	Dec 17, 2017	DP			
	>A> 6106865	Nov 12, 2019	DP			
	>A> 6211229	Feb 17, 2020	U-620			
<u>DOXEPIN HYDROCHLORIDE - SILENOR</u>						
N022036 002	>A> 5502047	Mar 22, 2013	U-620			
	>A> 5585115	Jan 09, 2015	DP			
	>A> 5725884	Sep 30, 2016	DP			
	>A> 5866166	Jun 10, 2016	DP			
	>A> 5948438	Jun 04, 2017	DP			
	>A> 6103219	Dec 17, 2017	DP			
	>A> 6106865	Nov 12, 2019	DP			
	>A> 6211229	Feb 17, 2020	U-620			
<u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>						
N021427 003	5023269	Jun 11, 2013	DS DP U-799			
	5023269	Jun 11, 2013	DS DP U-797			
	5023269	Jun 11, 2013	DS DP U-795			
	5508276	Jul 18, 2014	DP			
<u>ELTROMBOPAG OLAMINE - PROMACTA</u>						
N022291 003	>A> 6280959	Oct 30, 2018	DS DP U-930		>A> NCE	Nov 20, 2013
	>A> 7160870	Dec 08, 2021	DS DP U-930		>A> ODE	Nov 20, 2015
	>A> 7332481	May 24, 2021	U-930			
	>A> 7452874	May 24, 2021	DS DP			
	>A> 7473686	May 24, 2021	DS DP U-930			
	>A> 7547719	Mar 04, 2024	DS DP U-930			
<u>EPINEPHRINE - ADRENALIN</u>						
N020800 003	>A> 5665071	May 27, 2013	DP			
<u>EPINEPHRINE - ADRENALIN</u>						
N020800 004	>A> 5665071	May 27, 2013	DP			
<u>ESTRADIOL ACETATE - FEMTRACE</u>						
N021633 001	>A> 7572779	Mar 02, 2024	U-904			
<u>ESTRADIOL ACETATE - FEMTRACE</u>						
N021633 002	>A> 7572779	Mar 02, 2024	U-904			
<u>ESTRADIOL ACETATE - FEMTRACE</u>						
N021633 003	>A> 7572779	Mar 02, 2024	U-904			
<u>ETHINYL ESTRADIOL; LEVONORGESTREL - SEASONIQUE</u>						
N021840 001	7615545	Jun 15, 2023	U-1			
<u>EZETIMIBE - ZETIA</u>						
N021445 001	7612058	Jan 25, 2022	U-1027			
	7612058*PED	Jul 25, 2022				

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>FENOFIBRATE - FENOGLIDE</u>						
N022118 001	7658944	Dec 09, 2024	DP			
<u>FENOFIBRATE - FENOGLIDE</u>						
N022118 002	7658944	Dec 09, 2024	DP			
<u>FEXOFENADINE HYDROCHLORIDE - ALLEGRA</u>						
N020872 001	>A> 7662835	May 18, 2014	U-139			
	>A> 7662835*PED	Nov 18, 2014				
	>A> 7666881	May 18, 2014	U-139			
	>A> 7666881*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE - ALLEGRA</u>						
N020872 002	>A> 7662835	May 18, 2014	U-139			
	>A> 7662835*PED	Nov 18, 2014				
	>A> 7666881	May 18, 2014	U-139			
	>A> 7666881*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE - ALLEGRA</u>						
N020872 004	>A> 7662835	May 18, 2014	U-139			
	>A> 7662835*PED	Nov 18, 2014				
	>A> 7666881	May 18, 2014	U-139			
	>A> 7666881*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE - ALLEGRA</u>						
N021909 001	>A> 7662835	May 18, 2014	U-139			
	>A> 7662835*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - ALLEGRA D 24 HOUR</u>						
N021704 001	>A> 7662835	May 18, 2014	U-139			
	>A> 7662835*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - ALLEGRA-D 12 HOUR</u>						
N020786 001	>A> 7662835	May 18, 2014	U-139			
	>A> 7662835*PED	Nov 18, 2014				
	>A> 7666881	May 18, 2014	U-139			
	>A> 7666881*PED	Nov 18, 2014				
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
N021357 001					>A> NPP	Mar 17, 2013
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
N021357 002					>A> NPP	Mar 17, 2013
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
N021357 003					>A> NPP	Mar 17, 2013
<u>GADOBENATE DIMEGLUMINE - MULTIHANCE</u>						
N021357 004					>A> NPP	Mar 17, 2013
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u>						
N020387 001	5608075****	Mar 04, 2014		Y		
	5608075*PED	Sep 04, 2014				
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u>						
N020387 002	5608075****	Mar 04, 2014		Y		
	5608075*PED	Sep 04, 2014				

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE</u>						
A077157	001				>A> PC	Oct 03, 2010
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE</u>						
A077157	003				>A> PC	Oct 03, 2010
<u>HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL - BENICAR HCT</u>						
N021532	002	6878703	Nov 19, 2021	U-3	Y	
<u>HYDROMORPHONE HYDROCHLORIDE - EXALGO</u>						
N021217	001				>A> NDF	Mar 01, 2013
<u>HYDROMORPHONE HYDROCHLORIDE - EXALGO</u>						
N021217	002				>A> NDF	Mar 01, 2013
<u>HYDROMORPHONE HYDROCHLORIDE - EXALGO</u>						
N021217	003				>A> NDF	Mar 01, 2013
<u>IMIQUIMOD - IMIQUIMOD</u>						
A078548	001				PC	Aug 24, 2010
<u>IMIQUIMOD - ZYCLARA</u>						
N022483	001				>A> NP	Mar 25, 2013
<u>INSULIN GLULISINE RECOMBINANT - APIDRA SOLOSTAR</u>						
N021629	003	6221633	Jun 18, 2018	DS DP U-471		
		6960561	Jan 25, 2023	DP U-471		
		7452860	Mar 22, 2022	DP		
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N022115	001				I-622 NDF PED	Jan 29, 2013 May 29, 2012 Nov 29, 2012
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N022115	002				I-622 NDF PED	Jan 29, 2013 May 29, 2012 Nov 29, 2012
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N022115	003				I-622 NDF PED	Jan 29, 2013 May 29, 2012 Nov 29, 2012
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N022115	004				I-622 NDF PED	Jan 29, 2013 May 29, 2012 Nov 29, 2012
<u>LAPATINIB DITOSYLATE - TYKERB</u>						
N022059	001	>A> 6713485	Sep 29, 2020	DS DP U-800	I-620	Jan 29, 2013
<u>LEVETIRACETAM - KEPBRA</u>						
N021872	001				I-563 PED	Mar 19, 2010 Sep 19, 2010
<u>LIRAGLUTIDE RECOMBINANT - VICTOZA</u>						
N022341	001	6268343	Aug 22, 2017	DS DP U-968	NCE	Jan 25, 2015
		6458924	Aug 22, 2017	DS DP U-968		
		7235627	Aug 22, 2017	DS DP		

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 001	7655630	Feb 24, 2023	DS		>A> M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP	U-727		
	7659254	Feb 24, 2023		U-1034		
	7662787	Feb 24, 2023	DS			
	>A> 7674774	Mar 18, 2023	DP	U-842		
	>A> 7678770	Mar 25, 2023		U-842		
	>A> 7678771	Mar 25, 2023	DP	U-842		
	>A> 7687466	Feb 24, 2023	DP			
	>A> 7687467	Apr 08, 2023	DP	U-842		
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 002	7655630	Feb 24, 2023	DS		>A> M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP	U-727		
	7659254	Feb 24, 2023		U-1034		
	7662787	Feb 24, 2023	DS			
	>A> 7674774	Mar 18, 2023	DP	U-842		
	>A> 7678770	Mar 25, 2023		U-842		
	>A> 7678771	Mar 25, 2023	DP	U-842		
	>A> 7687466	Feb 24, 2023	DP			
	>A> 7687467	Apr 08, 2023	DP	U-842		
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 003	7655630	Feb 24, 2023	DS		>A> M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP	U-727		
	7659254	Feb 24, 2023		U-1034		
	7662787	Feb 24, 2023	DS			
	>A> 7674774	Mar 18, 2023	DP	U-842		
	>A> 7678770	Mar 25, 2023		U-842		
	>A> 7678771	Mar 25, 2023	DP	U-842		
	>A> 7687466	Feb 24, 2023	DP			
	>A> 7687467	Apr 08, 2023	DP	U-842		
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 004	7655630	Feb 24, 2023	DS		>A> M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP	U-727		
	7659254	Feb 24, 2023		U-1034		
	7662787	Feb 24, 2023	DS			
	>A> 7678770	Mar 25, 2023		U-842		
	>A> 7687466	Feb 24, 2023	DP			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 005	7655630	Feb 24, 2023	DS		>A> M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP	U-727		
	7659254	Feb 24, 2023		U-1034		
	7662787	Feb 24, 2023	DS			
	>A> 7674774	Mar 18, 2023	DP	U-842		
	>A> 7678770	Mar 25, 2023		U-842		
	>A> 7678771	Mar 25, 2023	DP	U-842		
	>A> 7687466	Feb 24, 2023	DP			
	>A> 7687467	Apr 08, 2023	DP	U-842		

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 006	7655630	Feb 24, 2023	DS		>A> M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP U-727			
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	>A> 7674774	Mar 18, 2023	DP U-842			
	>A> 7678770	Mar 25, 2023	U-842			
	>A> 7678771	Mar 25, 2023	DP U-842			
	>A> 7687466	Feb 24, 2023	DP			
	>A> 7687467	Apr 08, 2023	DP U-842			
<u>LOSARTAN POTASSIUM - COZAAR</u>						
N020386 001	5608075****	Mar 04, 2014		Y		
	5608075*PED	Sep 04, 2014				
<u>LOSARTAN POTASSIUM - COZAAR</u>						
N020386 002	5608075****	Mar 04, 2014		Y		
	5608075*PED	Sep 04, 2014				
<u>LOSARTAN POTASSIUM - COZAAR</u>						
N020386 003	5608075****	Mar 04, 2014		Y		
	5608075*PED	Sep 04, 2014				
<u>LOSARTAN POTASSIUM - LOSARTAN POTASSIUM</u>						
A076958 001					>A> PC	Oct 03, 2010
<u>LOSARTAN POTASSIUM - LOSARTAN POTASSIUM</u>						
A076958 002					>A> PC	Oct 06, 2010
<u>LOSARTAN POTASSIUM - LOSARTAN POTASSIUM</u>						
A076958 003					>A> PC	Oct 03, 2010
<u>MESALAMINE - SFROWASA</u>						
N019618 002	7645801	Jul 24, 2027	DS DP			
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>						
N022044 001	>A> 6890898	Feb 02, 2019	U-803			
	>A> 6890898	Feb 02, 2019	U-1038			
	>A> 6890898	Feb 02, 2019	U-1036			
	>A> 7078381	Feb 02, 2019	U-803			
	>A> 7078381	Feb 02, 2019	U-1038			
	>A> 7078381	Feb 02, 2019	U-1036			
	>A> 7125873	Jul 26, 2022	DP U-803			
	>A> 7125873	Jul 26, 2022	DP U-1038			
	>A> 7125873	Jul 26, 2022	DP U-1036			
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>						
N022044 002	>A> 6890898	Feb 02, 2019	U-803			
	>A> 6890898	Feb 02, 2019	U-1038			
	>A> 6890898	Feb 02, 2019	U-1036			
	>A> 7078381	Feb 02, 2019	U-803			
	>A> 7078381	Feb 02, 2019	U-1038			
	>A> 7078381	Feb 02, 2019	U-1036			
	>A> 7125873	Jul 26, 2022	DP U-803			
	>A> 7125873	Jul 26, 2022	DP U-1038			
	>A> 7125873	Jul 26, 2022	DP U-1036			

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>METHYLPHENIDATE HYDROCHLORIDE - METHYLIN</u>						
N021419 001	>A> 7691880	Oct 07, 2024	DP			
<u>METHYLPHENIDATE HYDROCHLORIDE - METHYLIN</u>						
N021419 002	>A> 7691880	Oct 07, 2024	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 001	>A> 7682633	Jun 19, 2027	U-443			
	>A> 7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 002	>A> 7682633	Jun 19, 2027	U-443			
	>A> 7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 003	>A> 7682633	Jun 19, 2027	U-443			
	>A> 7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 004	>A> 7682633	Jun 19, 2027	U-443			
	>A> 7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 005	>A> 7682633	Jun 19, 2027	U-443			
	>A> 7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 006	>A> 7682633	Jun 19, 2027	U-443			
	>A> 7682634	Jun 19, 2027	DP			
<u>MOXIFLOXACIN HYDROCHLORIDE - VIGAMOX</u>						
N021598 001	>A> 7671070	Sep 29, 2019	U-709			
	>A> 7671070*PED	Mar 29, 2020				
<u>NICARDIPINE HYDROCHLORIDE - CARDENE IN 0.83% SODIUM CHLORIDE IN PLASTIC CONTAINER</u>						
N019734 004	7659291	Apr 18, 2027	U-1029			
<u>NICARDIPINE HYDROCHLORIDE - CARDENE IN 0.86% SODIUM CHLORIDE IN PLASTIC CONTAINER</u>						
N019734 003	7659291	Apr 18, 2027	U-1029			
<u>NICARDIPINE HYDROCHLORIDE - CARDENE IN 4.8% DEXTROSE IN PLASTIC CONTAINER</u>						
N019734 002	7659291	Apr 18, 2027	U-1029			
<u>NICARDIPINE HYDROCHLORIDE - CARDENE IN 5.0% DEXTROSE IN PLASTIC CONTAINER</u>						
N019734 005	7659291	Apr 18, 2027	U-1029			
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
N021286 001				NPP PED		Feb 04, 2013 Aug 04, 2010
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
N021286 003				NPP PED		Feb 04, 2013 Aug 04, 2010
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
N021286 004				NPP PED		Feb 04, 2013 Aug 04, 2010
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021087 001				M-90		Feb 22, 2013

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021087	002				M-90	Feb 22, 2013
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021087	003				M-90	Feb 22, 2010
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021246	001				M-90	Feb 22, 2013
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	001	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	002	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	003	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	004	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	005	>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	006	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	007	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	008	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610	001	>A> 7276250	Feb 04, 2023	DP U-826		
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610	002	>A> 7276250	Feb 04, 2023	DP U-826		
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610	003	>A> 7276250	Feb 04, 2023	DP U-826		
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610	004	>A> 7276250	Feb 04, 2023	DP U-826		



## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610 005	>A> 7276250	Feb 04, 2023	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610 006	>A> 7276250	Feb 04, 2023	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610 007	>A> 7276250	Feb 04, 2023	DP U-826			
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP</u>						
N022210 001	7658918	Feb 20, 2028	DP			
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP</u>						
N022210 002	7658918	Feb 20, 2028	DP			
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP</u>						
N022210 003	7658918	Feb 20, 2028	DP			
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP</u>						
N022210 004	7658918	Feb 20, 2028	DP			
<u>PANTOPRAZOLE SODIUM - PROTONIX</u>						
N022020 001	7544370	Jun 07, 2026	DP			
	7544370*PED	Dec 07, 2026				
<u>PENCICLOVIR SODIUM - DENAVIR</u>						
N020629 001	>A> 5866581	Oct 04, 2014	U-501			
	>A> 6124304	Oct 04, 2014	U-501			
<u>POLIDOCANOL - ASCLERA</u>						
N021201 001					>A> NCE	Mar 30, 2015
<u>POLIDOCANOL - ASCLERA</u>						
N021201 002					>A> NCE	Mar 30, 2015
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 001	4886812	Oct 08, 2010	DS DP		>A> I-623	Mar 19, 2013
	>A> 7695734	Apr 26, 2028	DP		>A> NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 002	4886812	Oct 08, 2010	DS DP		>A> I-623	Mar 19, 2013
	>A> 7695734	Apr 26, 2028	DP		>A> NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 003	4886812	Oct 08, 2010	DS DP		>A> I-623	Mar 19, 2013
	>A> 7695734	Apr 26, 2028	DP		>A> NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 004	4886812	Oct 08, 2010	DS DP		>A> I-623	Mar 19, 2013
	>A> 7695734	Apr 26, 2028	DP		>A> NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 005	4886812	Oct 08, 2010	DS DP		>A> I-623	Mar 19, 2013
	>A> 7695734	Apr 26, 2028	DP		>A> NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724 001					PC	Jul 03, 2010
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724 002					PC	Jul 03, 2010

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724	003				PC	Jul 03, 2010
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724	004				PC	Jul 03, 2010
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724	005				PC	Jul 03, 2010
<u>PREGABALIN - LYRICA</u>						
N022488	001	5563175	Oct 08, 2013	U-661	I-535	Jun 21, 2010
		6001876	Dec 30, 2018	U-819		
		6001876	Dec 30, 2018	U-55		
		6197819	Dec 30, 2018	DS DP		
<u>REGADENOSON - LEXISCAN</u>						
N022161	001	7655636	Jun 22, 2019	U-869		
		7655637	Jun 22, 2019	DS DP U-869		
<u>RIFAXIMIN - XIFAXAN</u>						
N021361	002	>A> 7045620	Jun 19, 2024	DS	>A> NP	Mar 24, 2013
<u>RITONAVIR - RITONAVIR</u>						
N022417	001	5541206	Jul 30, 2013	DS DP U-688		
		5541206*PED	Jan 30, 2014			
		5635523	Jun 03, 2014	U-688		
		5635523*PED	Dec 03, 2014			
		5648497	Jul 15, 2014	DS		
		5648497*PED	Jan 15, 2015			
		5674882	Oct 07, 2014	U-688		
		5674882*PED	Apr 07, 2015			
		6037157	Jun 26, 2016	U-688		
		6037157*PED	Dec 26, 2016			
		6703403	Jun 26, 2016	U-688		
		6703403*PED	Dec 26, 2016			
		7148359	Jul 19, 2019	DP		
		7148359*PED	Jan 19, 2020			
		7364752	Nov 10, 2020	DP U-688		
		7364752*PED	May 10, 2021			
<u>ROMIDEPSIN - ISTODAX</u>						
N022393	001				ODE	Nov 05, 2016
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>						
N021366	002	7030152	Apr 02, 2018	U-1032	I-621	Feb 08, 2013
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>						
N021366	003	7030152	Apr 02, 2018	U-1032	I-621	Feb 08, 2013
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>						
N021366	004	7030152	Apr 02, 2018	U-1032	I-621	Feb 08, 2013
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>						
N021366	005	7030152	Apr 02, 2018	U-1032	I-621	Feb 08, 2013

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N021995 001	>A> 6890898	Feb 02, 2019	U-775			
	>A> 6890898	Feb 02, 2019	U-1039			
	>A> 6890898	Feb 02, 2019	U-1036			
	>A> 7078381	Feb 02, 2019	U-775			
	>A> 7078381	Feb 02, 2019	U-1038			
	>A> 7078381	Feb 02, 2019	U-1037			
	>A> 7078381	Feb 02, 2019	U-1036			
	>A> 7125873	Jul 26, 2022	U-775			
	>A> 7125873	Jul 26, 2022	U-1038			
	>A> 7125873	Jul 26, 2022	U-1037			
	>A> 7125873	Jul 26, 2022	U-1036			
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N021995 002	>A> 6890898	Feb 02, 2019	U-775			
	>A> 6890898	Feb 02, 2019	U-1039			
	>A> 6890898	Feb 02, 2019	U-1036			
	>A> 7078381	Feb 02, 2019	U-775			
	>A> 7078381	Feb 02, 2019	U-1038			
	>A> 7078381	Feb 02, 2019	U-1037			
	>A> 7078381	Feb 02, 2019	U-1036			
	>A> 7125873	Jul 26, 2022	U-775			
	>A> 7125873	Jul 26, 2022	U-1038			
	>A> 7125873	Jul 26, 2022	U-1037			
	>A> 7125873	Jul 26, 2022	U-1036			
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N021995 003	>A> 6890898	Feb 02, 2019	U-775			
	>A> 6890898	Feb 02, 2019	U-1039			
	>A> 6890898	Feb 02, 2019	U-1036			
	>A> 7078381	Feb 02, 2019	U-775			
	>A> 7078381	Feb 02, 2019	U-1038			
	>A> 7078381	Feb 02, 2019	U-1037			
	>A> 7078381	Feb 02, 2019	U-1036			
	>A> 7125873	Jul 26, 2022	U-775			
	>A> 7125873	Jul 26, 2022	U-1038			
	>A> 7125873	Jul 26, 2022	U-1037			
	>A> 7125873	Jul 26, 2022	U-1036			
<u>SODIUM OXYBATE - XYREM</u>						
N021196 001	7668730	Mar 07, 2024	U-1028			
<u>SODIUM PHOSPHATE, DIBASIC ANHYDROUS; SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE - OSMOPREP</u>						
N021892 001	>A> 7687075	Jun 22, 2028	DS DP			
<u>SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO</u>						
N021148 008	>A> 5849700	Dec 15, 2015	U-1041		>A> I-572	Oct 31, 2011
	>A> 5849704	Dec 15, 2015	DP U-1041		>A> I-551	Sep 20, 2010
					>A> I-536	May 31, 2010
					>A> ODE	May 31, 2014
<u>SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO</u>						
N021148 009	>A> 5849700	Dec 15, 2015	U-1041		>A> I-572	Oct 31, 2011
	>A> 5849704	Dec 15, 2015	DP U-1041		>A> I-551	Sep 20, 2010
					>A> I-536	May 31, 2010
					>A> ODE	May 31, 2010

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO</u>						
N021148 010	>A> 5849700	Dec 15, 2015	U-1041		>A> I-572	Oct 31, 2011
	>A> 5849704	Dec 15, 2015	DP U-1041		>A> I-551	Sep 20, 2010
					>A> I-536	May 31, 2010
					>A> ODE	May 31, 2014
<u>TENOFOVIR DISOPROXIL FUMARATE - VIREAD</u>						
N021356 001					>A> NPP	Mar 24, 2013
<u>TERBINAFINE - LAMISIL AT</u>						
N021958 001	>A> 5681849	Oct 28, 2014	DP			
	>A> 5681849*PED	Apr 28, 2015				
	>A> 5856355	May 18, 2012	DP U-540			
	>A> 5856355	May 18, 2012	DP U-504			
	>A> 5856355*PED	Nov 18, 2012				
<u>TIOTROPIUM BROMIDE MONOHYDRATE - SPIRIVA</u>						
N021395 001	7642268	Sep 24, 2021	DS DP			
<u>TOLTERODINE TARTRATE - DETROL</u>						
N020771 001	5559269	Nov 05, 2013	U-318	Y		
	5559269*PED	May 05, 2014				
<u>TOLTERODINE TARTRATE - DETROL</u>						
N020771 002	5559269	Nov 05, 2013	U-318	Y		
	5559269*PED	May 05, 2014				
<u>TRAZODONE HYDROCHLORIDE - OLEPTRO</u>						
N022411 001	6607748	Jun 29, 2020	DP		NDF	Feb 02, 2013
<u>TRAZODONE HYDROCHLORIDE - OLEPTRO</u>						
N022411 002	6607748	Jun 29, 2020	DP		NDF	Feb 02, 2013
<u>TRIPTORELIN PAMOATE - TRELSTAR</u>						
N022437 001	>A> 5776885	Jul 07, 2015	DP		>A> NP	Mar 10, 2013
<u>VARDENAFIL HYDROCHLORIDE - LEVITRA</u>						
N021400 001	>A> 7696206	Oct 31, 2018	DS DP U-533			
<u>VARDENAFIL HYDROCHLORIDE - LEVITRA</u>						
N021400 002	>A> 7696206	Oct 31, 2018	DS DP U-533			
<u>VARDENAFIL HYDROCHLORIDE - LEVITRA</u>						
N021400 003	>A> 7696206	Oct 31, 2018	DS DP U-533			
<u>VARDENAFIL HYDROCHLORIDE - LEVITRA</u>						
N021400 004	>A> 7696206	Oct 31, 2018	DS DP U-533			
<u>VARENICLINE TARTRATE - CHANTIX</u>						
N021928 001	>A> 7265119	Aug 03, 2022	DS DP U-56			
<u>VARENICLINE TARTRATE - CHANTIX</u>						
N021928 002	>A> 7265119	Aug 03, 2022	DS DP U-56			
<u>VELAGLUCERASE ALFA - VPRIV</u>						
N022575 001					NCE	Feb 26, 2015
<u>VELAGLUCERASE ALFA - VPRIV</u>						
N022575 002					NCE	Feb 26, 2015

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>VORINOSTAT - ZOLINZA</u>						
N021991 001	7652069	Mar 04, 2023	DS			

Footnote:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. They may not be flagged with respect to other claims which may apply.
3. \*\*\*\* The expiration date for U.S. Patent No. 5,608,075 is March 4, 2009.

## PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 29<sup>th</sup> Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

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