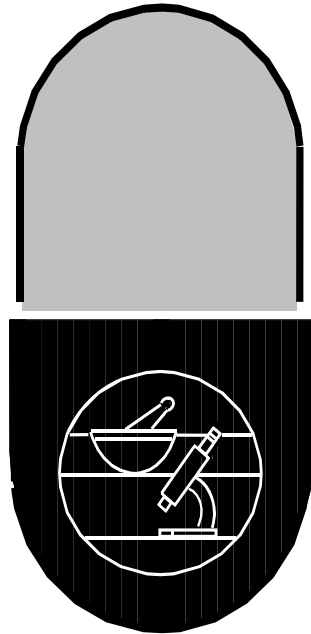


**CUMULATIVE  
SUPPLEMENT 2  
February 2011**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**31<sup>st</sup> EDITION**

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

2011

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

**APPROVED DRUG PRODUCTS  
with  
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**31<sup>st</sup> EDITION**

**Cumulative Supplement 2**

**February 2011**

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**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**31<sup>st</sup> EDITION**

**CUMULATIVE SUPPLEMENT 2  
February 2011**

**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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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  
7620 Standish Place  
Rockville, MD 20855-2773

### 1.3 APPLICANT NAME CHANGES

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

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

FORMER APPLICANT NAME <u>(FORMER ABBREVIATED NAME)</u>	NEW APPLICANT NAME <u>(NEW ABBREVIATED NAME)</u>
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### 1.4 LEVOTHYROXINE SODIUM

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

Levothyroxine Sodium (Mylan ANDA 76187) and Levo-T (Alara NDA 21342) tablets have been determined to be therapeutically equivalent to corresponding strengths of Unithroid (Jerome Stevens NDA 021210) tablets.

Levo-T (Alara NDA 021342), Levothyroxine Sodium (Mylan ANDA 76187), Unithroid (Jerome Stevens NDA 021210), and Levothyroxine Sodium (Merck KGAA ANDA 76752) tablets have been determined to be therapeutically

equivalent to corresponding strengths of Synthroid (Abbott NDA 021402) tablets.

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

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

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

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

## 1.5 AVAILABILITY OF THE EDITION

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

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements have been provided in downloadable Portable Document Format (PDF) at the EOB home page by clicking on Publications. The PDF annual and cumulative supplements duplicate previous paper

versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

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

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

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

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

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

### DESCRIPTION OF REPORT

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

The baseline column (Dec 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 2010</u>	<u>MAR 2011</u>	<u>JUN 2011</u>	<u>SEPT 2011</u>	<u>DEC 2011</u>
DRUG PRODUCTS LISTED	13838				
SINGLE SOURCE	2482				
	(17.9%)				
MULTISOURCE	11267				
	(81.4%)				
THERAPEUTICALLY EQUIVALENT	11107				
	(80.3%)				
NOT THERAPEUTICALLY EQUIVALENT	160				
	(1.2%)				
EXCEPTIONS <sup>1</sup>	89				
	(0.6%)				
NEW MOLECULAR ENTITIES APPROVED	8				
NUMBER OF APPLICANTS	752				

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

### 1.7 CUMULATIVE SUPPLEMENT LEGEND

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

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

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

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

The change code and description:

NEWA	New drug product approval usually in the supplement month.
CAHN	Applicant holder firm name has changed.
CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.
CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMS1	Change. Miscellaneous addition to list.

CMS2 Change. Miscellaneous deletion from list.  
CPOT Change. Potency amount/unit.  
CRLD Change. Reference Listed Drug.  
CTEC Change. Therapeutic Equivalence Code.  
CTNA Change. Trade Name.  
DISC Discontinued. The Rx or OTC listed product is not  
being marketed and will be moved to the discontinued  
section in the next edition.

PRESCRIPTION DRUG PRODUCT LIST - 31ST EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2011

1-1

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

AA	WRASER PHARMS LLC	356.4MG;30MG;16MG	A040688	001	Apr 03, 2007	Jan	CAHN
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ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>D>	AB	BOCA PHARMA	300MG;5MG	A090415	001	Jan 24, 2011	Feb	CTEC
>A>	AA		300MG;5MG	A090415	001	Jan 24, 2011	Feb	CTEC
	AB		300MG;5MG	A090415	001	Jan 24, 2011	Jan	NEWA
>D>	AB		300MG;7.5MG	A090415	002	Jan 24, 2011	Feb	CTEC
>A>	AA		300MG;7.5MG	A090415	002	Jan 24, 2011	Feb	CTEC
	AB		300MG;7.5MG	A090415	002	Jan 24, 2011	Jan	NEWA
>D>	AB		300MG;10MG	A090415	003	Jan 24, 2011	Feb	CTEC
>A>	AA		300MG;10MG	A090415	003	Jan 24, 2011	Feb	CTEC
	AB		300MG;10MG	A090415	003	Jan 24, 2011	Jan	NEWA
>D>		MIKART	300MG;5MG	A040658	001	Jan 19, 2006	Feb	CTEC
>A>	AA		300MG;5MG	A040658	001	Jan 19, 2006	Feb	CTEC
>D>		+	300MG;7.5MG	A040556	002	Mar 24, 2006	Feb	CTEC
>A>	AA	+	300MG;7.5MG	A040556	002	Mar 24, 2006	Feb	CTEC
>D>		+	300MG;10MG	A040556	001	Jun 23, 2004	Feb	CTEC
>A>	AA	+	300MG;10MG	A040556	001	Jun 23, 2004	Feb	CTEC
		LORTAB						
AA	UCB INC		500MG;5MG	A087722	001	Jul 09, 1982	Jan	CAHN

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

DARVOCET-N 100

@	XANODYNE PHARM	650MG;100MG	N017122	002		Jan	DISC
---	----------------	-------------	---------	-----	--	-----	------

DARVOCET-N 50

@	XANODYNE PHARM	325MG;50MG	N017122	001		Jan	DISC
---	----------------	------------	---------	-----	--	-----	------

ACYCLOVIR

CAPSULE; ORAL

ACYCLOVIR

>D>	AB	GENPHARM	200MG	A074977	001	Apr 13, 1998	Feb	CAHN
>A>	AB	MYLAN	200MG	A074977	001	Apr 13, 1998	Feb	CAHN

TABLET; ORAL

ACYCLOVIR

>D>	AB	GENPHARM	400MG	A074976	001	Apr 13, 1998	Feb	CAHN
>D>	AB		800MG	A074976	002	Apr 13, 1998	Feb	CAHN
>A>	AB	MYLAN	400MG	A074976	001	Apr 13, 1998	Feb	CAHN
>A>	AB		800MG	A074976	002	Apr 13, 1998	Feb	CAHN

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ACYCLOVIR SODIUM

>D>	AP	HOSPIRA	EQ 50MG BASE/ML	A075065	001	Feb 25, 1999	Feb	DISC
>A>		@	EQ 50MG BASE/ML	A075065	001	Feb 25, 1999	Feb	DISC

ALENDRONATE SODIUM

TABLET; ORAL

ALENDRONATE SODIUM

>D>	AB	GENPHARM ULC	EQ 35MG BASE	A078638 001	Aug 04, 2008	Feb	CAHN
>D>	AB		EQ 70MG BASE	A078638 002	Aug 04, 2008	Feb	CAHN
>A>	AB	MYLAN	EQ 35MG BASE	A078638 001	Aug 04, 2008	Feb	CAHN
>A>	AB		EQ 70MG BASE	A078638 002	Aug 04, 2008	Feb	CAHN

ALLOPURINOL

TABLET; ORAL

ALLOPURINOL

>A>	AB	IPCA LABS LTD	100MG	A090637 001	Mar 16, 2011	Feb	NEWA
>A>	AB		300MG	A090637 002	Mar 16, 2011	Feb	NEWA

AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

CAPSULE; ORAL

LOTREL

AB		NOVARTIS	EQ 5MG BASE;40MG	N020364 007	Apr 11, 2006	Jan	CFTG
AB	+		EQ 10MG BASE;40MG	N020364 006	Apr 11, 2006	Jan	CFTG

AMOXICILLIN

>D>		CAPSULE; ORAL					
>D>		AMOXICILLIN					
>D>		@ AM ANTIBIOTICS	250MG	A062058 001		Feb	CDFR
>A>	AB		250MG	A062058 001		Feb	CDFR
>D>		@	500MG	A062058 002		Feb	CDFR
>A>	AB		500MG	A062058 002		Feb	CDFR

>A> AMOXICILLIN; CLARITHROMYCIN; OMEPRAZOLE

>A>		CAPSULE, TABLET, CAPSULE, DELAYED RELEASE; ORAL					
>A>		OMEPRAZOLE AND CLARITHROMYCIN AND AMOXICILLIN					
>A>	+	DAVA PHARMS INC	500MG,N/A,N/A;N/A,500MG,N/A;N/A,N/A,20MG	N050824 001	Feb 08, 2011	Feb	NEWA

ANASTROZOLE

TABLET; ORAL

ANASTROZOLE

>A>	AB	SANTOS BIOTECH	1MG	A078944 001	Jun 28, 2010	Feb	CAHN
>D>	AB	STASON PHARMS	1MG	A078944 001	Jun 28, 2010	Feb	CAHN

ASPIRIN; CARISOPRODOL

TABLET; ORAL

CARISOPRODOL AND ASPIRIN

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

ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE

TABLET; ORAL

CARISOPRODOL, ASPIRIN AND CODEINE PHOSPHATE

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

ASPIRIN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL

>A>		OXYCODONE AND ASPIRIN							
>A>	AA	COASTAL PHARMS	325MG;4.8355MG	A091670	001	Mar 16, 2011	Feb	NEWA	
		PERCODAN							
>D>	+	ENDO PHARMS	325MG;4.8355MG	N007337	007	Aug 05, 2005	Feb	CFTG	
>A>	AA	+	325MG;4.8355MG	N007337	007	Aug 05, 2005	Feb	CFTG	

ATENOLOL

TABLET; ORAL

ATENOLOL

>D>	AB	GENPHARM	25MG	A074126	003	Aug 26, 1998	Feb	CAHN	
>D>	AB		50MG	A074126	001	Mar 23, 1994	Feb	CAHN	
>D>	AB		100MG	A074126	002	Mar 23, 1994	Feb	CAHN	
>A>	AB	MYLAN	25MG	A074126	003	Aug 26, 1998	Feb	CAHN	
>A>	AB		50MG	A074126	001	Mar 23, 1994	Feb	CAHN	
>A>	AB		100MG	A074126	002	Mar 23, 1994	Feb	CAHN	

ATOVAQUONE; PROGUANIL HYDROCHLORIDE

TABLET; ORAL

ATOVAQUONE AND PROGUANIL HYDROCHLORIDE

	AB	GLENMARK GENERICS	250MG;100MG	A091211	001	Jan 12, 2011	Jan	NEWA	
		MALARONE							
	AB	+	GLAXOSMITHKLINE	250MG;100MG	N021078	001	Jul 14, 2000	Jan	CFTG

AZILSARTAN MEDOXOMIL

>A>		TABLET; ORAL							
>A>		EDARBI							
>A>		TAKEDA PHARMS	40MG	N200796	001	Feb 25, 2011	Feb	NEWA	
>A>		+	80MG	N200796	002	Feb 25, 2011	Feb	NEWA	

BACITRACIN

OINTMENT; OPHTHALMIC

BACITRACIN

>A>	+	FERA PHARMS	500 UNITS/GM	A061212	001		Feb	CAHN	
>D>	+	NYCOMED US	500 UNITS/GM	A061212	001		Feb	CAHN	
	+		500 UNITS/GM	A061212	001		Jan	CAHN	

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC

>A>	AT	FERA PHARMS	400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A060764	002		Feb	CAHN	
>D>	AT	NYCOMED US	400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A060764	002		Feb	CAHN	
	AT		400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A060764	002		Jan	CAHN	

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

BACITRACIN ZINC AND POLYMYXIN B SULFATE

>A>	AT	FERA PHARMS	500 UNITS/GM;10,000 UNITS/GM	A065022	001	Feb 27, 2002	Feb	CAHN	
>D>	AT	NYCOMED US	500 UNITS/GM;10,000 UNITS/GM	A065022	001	Feb 27, 2002	Feb	CAHN	
	AT		500 UNITS/GM;10,000 UNITS/GM	A065022	001	Feb 27, 2002	Jan	CAHN	

BACITRACIN; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

## OINTMENT; OPHTHALMIC

## BACITRACIN-NEOMYCIN-POLYMYXIN W/ HYDROCORTISONE ACETATE

>A>	+	FERA PHARMS	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A062166 002		Feb	CAHN
>D>	+	NYCOMED US	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A062166 002		Feb	CAHN
	+		400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A062166 002		Jan	CAHN

BACLOFEN

## INJECTABLE; INTRATHECAL

## GABLOFEN

>D>		CNS THERAP	0.05MG/ML	N022462 001	Nov 19, 2010	Feb	CTEC
>D>			0.5MG/ML	N022462 002	Nov 19, 2010	Feb	CTEC
>D>			2MG/ML	N022462 003	Nov 19, 2010	Feb	CTEC
>A>	AP	CNS THERAPS INC	0.05MG/ML	N022462 001	Nov 19, 2010	Feb	CTEC
>A>	AP		0.5MG/ML	N022462 002	Nov 19, 2010	Feb	CTEC
>A>	AP		2MG/ML	N022462 003	Nov 19, 2010	Feb	CTEC

## LIORESAL

>D>	+	MEDTRONIC	0.05MG/ML	N020075 003	Nov 07, 1996	Feb	CTEC
>A>	AP	+	0.05MG/ML	N020075 003	Nov 07, 1996	Feb	CTEC
>D>	+		0.5MG/ML	N020075 001	Jun 17, 1992	Feb	CTEC
>A>	AP	+	0.5MG/ML	N020075 001	Jun 17, 1992	Feb	CTEC
>D>	+		2MG/ML	N020075 002	Jun 17, 1992	Feb	CTEC
>A>	AP	+	2MG/ML	N020075 002	Jun 17, 1992	Feb	CTEC

## TABLET; ORAL

## BACLOFEN

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

BENAZEPRIL HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

## TABLET; ORAL

## BENAZEPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

>D>	AB	GENPHARM	5MG;6.25MG	A076612 001	Feb 11, 2004	Feb	CAHN
>D>	AB		10MG;12.5MG	A076612 002	Feb 11, 2004	Feb	CAHN
>D>	AB		20MG;12.5MG	A076612 003	Feb 11, 2004	Feb	CAHN
>D>	AB		20MG;25MG	A076612 004	Feb 11, 2004	Feb	CAHN
>A>	AB	MYLAN	5MG;6.25MG	A076612 001	Feb 11, 2004	Feb	CAHN
>A>	AB		10MG;12.5MG	A076612 002	Feb 11, 2004	Feb	CAHN
>A>	AB		20MG;12.5MG	A076612 003	Feb 11, 2004	Feb	CAHN
>A>	AB		20MG;25MG	A076612 004	Feb 11, 2004	Feb	CAHN

BENZTROPINE MESYLATE

## INJECTABLE; INJECTION

## BENZTROPINE MESYLATE

>A>	AP	LUITPOLD	1MG/ML	A091152 001	Mar 29, 2010	Feb	CAHN
>D>	AP	PHARMAFORCE	1MG/ML	A091152 001	Mar 29, 2010	Feb	CAHN

CARBAMAZEPINE

## TABLET, CHEWABLE; ORAL

## CARBAMAZEPINE

## @ JUBILANT CADISTA

100MG

A071940 001 Feb 01, 1988 Jan CAHN

CARBIDOPA; LEVODOPA

TABLET; ORAL

SINEMET

AB	MERCK SHARP DOHME	10MG;100MG	N017555 001		Jan	CAHN
AB		25MG;100MG	N017555 003		Jan	CAHN
AB	+	25MG;250MG	N017555 002		Jan	CAHN

TABLET, EXTENDED RELEASE; ORAL

SINEMET CR

AB	MERCK SHARP DOHME	25MG;100MG	N019856 002	Dec 24, 1992	Jan	CAHN
AB	+	50MG;200MG	N019856 001	May 30, 1991	Jan	CAHN

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

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

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

AP	HOSPIRA INC	EQ 500MG BASE/VIAL	A065226 001	Apr 21, 2005	Jan	CAHN
AP		EQ 1GM BASE/VIAL	A065226 002	Apr 21, 2005	Jan	CAHN
AP		EQ 1GM BASE/VIAL	A065244 001	Aug 12, 2005	Jan	CAHN
AP		EQ 10GM BASE/VIAL	A065247 001	Aug 12, 2005	Jan	CAHN

CEFEPIME HYDROCHLORIDE

INJECTABLE; INJECTION

CEFEPIME HYDROCHLORIDE

AP	HOSPIRA INC	EQ 500MG BASE/VIAL	A065369 001	Jun 18, 2007	Jan	CAHN
AP		EQ 1GM BASE/VIAL	A065369 002	Jun 18, 2007	Jan	CAHN
AP		EQ 2GM BASE/VIAL	A065369 003	Jun 18, 2007	Jan	CAHN

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

CEFOTAXIME SODIUM

AP	HOSPIRA INC	EQ 500MG BASE/VIAL	A065290 001	Aug 11, 2006	Jan	CAHN
AP		EQ 1GM BASE/VIAL	A065290 002	Aug 11, 2006	Jan	CAHN
AP		EQ 1GM BASE/VIAL	A065293 001	Aug 10, 2006	Jan	CAHN
AP		EQ 2GM BASE/VIAL	A065290 003	Aug 11, 2006	Jan	CAHN
AP		EQ 2GM BASE/VIAL	A065293 002	Aug 10, 2006	Jan	CAHN
AP		EQ 10GM BASE/VIAL	A065292 001	Aug 10, 2006	Jan	CAHN

CEFOXITIN SODIUM

INJECTABLE; INJECTION

CEFOXITIN

AP	HOSPIRA INC	EQ 1GM BASE/VIAL	A065313 001	Jan 23, 2006	Jan	CAHN
AP		EQ 2GM BASE/VIAL	A065313 002	Jan 23, 2006	Jan	CAHN
AP		EQ 10GM BASE/VIAL	A065312 001	Feb 13, 2006	Jan	CAHN

CEFPODOXIME PROXETIL

TABLET; ORAL

CEFPODOXIME PROXETIL

AB	+	SANDOZ	EQ 200MG BASE	A065462 002	May 28, 2008	Jan	CRLD
		VANTIN					
		@ PHARMACIA AND UPJOHN	EQ 100MG BASE	N050674 001	Aug 07, 1992	Jan	DISC

## TABLET; ORAL

## VANTIN

@ PHARMACIA AND UPJOHN	EQ 200MG BASE	N050674 002	Aug 07, 1992	Jan	DISC
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CEFTRIAZONE SODIUM

## INJECTABLE; IM-IV

## CEFTRIAZONE

AP	HOSPIRA INC	EQ 250MG BASE/VIAL	A065230 001	Aug 02, 2005	Jan	CAHN
AP		EQ 500MG BASE/VIAL	A065230 002	Aug 02, 2005	Jan	CAHN
AP		EQ 1GM BASE/VIAL	A065230 003	Aug 02, 2005	Jan	CAHN
AP		EQ 2GM BASE/VIAL	A065230 004	Aug 02, 2005	Jan	CAHN

## INJECTABLE; INJECTION

## CEFTRIAZONE

AP	HOSPIRA INC	EQ 1GM BASE/VIAL	A065231 001	Aug 02, 2005	Jan	CAHN
AP		EQ 2GM BASE/VIAL	A065231 002	Aug 02, 2005	Jan	CAHN
AP		EQ 10GM BASE/VIAL	A065232 001	Aug 02, 2005	Jan	CAHN
AP	+ SANDOZ	EQ 10GM BASE/VIAL	A065168 001	May 17, 2005	Jan	CRLD

CEFUROXIME SODIUM

## INJECTABLE; IM-IV

## CEFUROXIME SODIUM

AP	HOSPIRA INC	EQ 750MG BASE/VIAL	A065483 001	Oct 15, 2008	Jan	CAHN
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## INJECTABLE; INJECTION

## CEFUROXIME SODIUM

AP	HOSPIRA INC	EQ 1.5GM BASE/VIAL	A065503 001	Oct 15, 2008	Jan	CAHN
AP		EQ 1.5GM BASE/VIAL	A065483 002	Oct 15, 2008	Jan	CAHN
AP		EQ 7.5GM BASE/VIAL	A065484 001	Oct 15, 2008	Jan	CAHN

CEPHALEXIN

## FOR SUSPENSION; ORAL

## CEPHALEXIN

	@ ACS DOBFAR	EQ 100MG BASE/ML	A062117 001		Jan	CAHN
AB		EQ 125MG BASE/5ML	A062117 002		Jan	CAHN
AB	+	EQ 250MG BASE/5ML	A062117 003		Jan	CAHN

CHLORHEXIDINE GLUCONATE

## SOLUTION; DENTAL

## CHLORHEXIDINE GLUCONATE

>D>	AT	ACTAVIS MID ATLANTIC	0.12%	A074291 001	Dec 28, 1995	Feb	CAHN
>A>	AT	LYNE	0.12%	A074291 001	Dec 28, 1995	Feb	CAHN

CHLOROQUINE PHOSPHATE

## TABLET; ORAL

## CHLOROQUINE PHOSPHATE

AA	NATCO PHARMA LTD	EQ 150MG BASE	A091621 001	Jan 21, 2011	Jan	NEWA
AA		EQ 300MG BASE	A090612 001	Jan 21, 2011	Jan	NEWA

CICLOPIROX

## SHAMPOO; TOPICAL

## CICLOPIROX

>A>	AT	TARO	1%	A090269 001	Feb 23, 2011	Feb	NEWA
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CLONIDINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## CLONIDINE HYDROCHLORIDE

AP	WEST WARD	1MG/10ML (0.1MG/ML)	A200300 001	Jan 26, 2011	Jan	NEWA
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## INJECTABLE; INJECTION

## CLONIDINE HYDROCHLORIDE

AP	WEST WARD	5MG/10ML (0.5MG/ML)	A200300	002	Jan 26, 2011	Jan	NEWA
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CYCLOBENZAPRINE HYDROCHLORIDE

## TABLET; ORAL

## CYCLOBENZAPRINE HYDROCHLORIDE

>D>	AB	ACTAVIS TOTOWA	5MG	A077291	001	Feb 03, 2006	Feb	CAHN
>D>	AB		10MG	A077209	001	Oct 04, 2005	Feb	CAHN
	AB	JUBILANT CADISTA	5MG	A077563	001	Apr 19, 2006	Jan	CAHN
	AB		10MG	A077563	002	Apr 19, 2006	Jan	CAHN
>A>	AB	KVK TECH	5MG	A078048	001	Feb 28, 2011	Feb	NEWA
>A>	AB		10MG	A078048	002	Feb 28, 2011	Feb	NEWA
>A>	AB	PROSAM LABS	5MG	A077291	001	Feb 03, 2006	Feb	CAHN
>A>	AB		10MG	A077209	001	Oct 04, 2005	Feb	CAHN

DESLORATADINE

## TABLET; ORAL

## DESLORATADINE

>A>	AB	DR REDDYS LABS LTD	5MG	A078365	001	Mar 08, 2011	Feb	NEWA
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DESOGESTREL; ETHINYL ESTRADIOL

## TABLET; ORAL-28

## EMOQUETTE

>A>	AB	VINTAGE	0.15MG;0.03MG	A076675	001	Feb 25, 2011	Feb	NEWA
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DESOXIMETASONE

## GEL; TOPICAL

## DESOXIMETASONE

>A>	AB	VERSAPHARM	0.05%	A090727	001	Mar 10, 2011	Feb	NEWA
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DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

## OINTMENT; OPHTHALMIC

## NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

>A>	AT	FERA PHARMS	0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A062938	001	Jul 31, 1989	Feb	CAHN
>D>	AT	NYCOMED US	0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A062938	001	Jul 31, 1989	Feb	CAHN
	AT		0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	A062938	001	Jul 31, 1989	Jan	CAHN

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

## SYRUP; ORAL

## PROMETHAZINE HYDROCHLORIDE AND DEXTROMETHORPHAN HYDROBROMIDE

AA	AMNEAL PHARMS	15MG/5ML;6.25MG/5ML	A090575	001	Feb 08, 2011	Jan	NEWA
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DIPYRIDAMOLE

## TABLET; ORAL

## DIPYRIDAMOLE

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

DIVALPROEX SODIUM

TABLET, DELAYED RELEASE; ORAL

DIVALPROEX SODIUM

>A>	AB	WATSON LABS FLORIDA	EQ 500MG BASE VALPROIC ACID	A079080 001	Feb 25, 2011	Feb	NEWA
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DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE

	AB	IMPAX LABS INC	EQ 150MG BASE	A200065 001	Feb 17, 2011	Jan	NEWA	
	AB	MYLAN	40MG	A090855 001	Jul 01, 2010	Jan	CDFR	
>D>	AB	+	PAR PHARM	EQ 150MG BASE	A065055 003	Jul 15, 2005	Feb	CTEC
>A>	AB	+		EQ 150MG BASE	A065055 003	Jul 15, 2005	Feb	CTEC
	AB	+		EQ 150MG BASE	A065055 003	Jul 15, 2005	Jan	CTEC

ENOXAPARIN SODIUM

&gt;A&gt; INJECTABLE; INTRAVENOUS, SUBCUTANEOUS

&gt;A&gt; LOVENOX

>A>		SANOFI AVENTIS US	300MG/3ML (100MG/ML)	N020164 009	Jan 23, 2003	Feb	CDFR
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&gt;D&gt; INJECTABLE; SUBCUTANEOUS

&gt;D&gt; LOVENOX

>D>		SANOFI AVENTIS US	300MG/3ML (100MG/ML)	N020164 009	Jan 23, 2003	Feb	CDFR
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EPINASTINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

ELESTAT

>D>	+	ALLERGAN	0.05%	N021565 001	Oct 16, 2003	Feb	CFTG
>A>	AT	+		N021565 001	Oct 16, 2003	Feb	CFTG
>A>		EPINASTINE HYDROCHLORIDE					
>A>	AT	CYPRESS PHARM	0.05%	A090870 001	Mar 14, 2011	Feb	NEWA

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL

ERYTHROMYCIN

	AB	ARBOR PHARMS INC	250MG	A062746 001	Dec 22, 1986	Jan	CAHN
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OINTMENT; OPHTHALMIC

ERYTHROMYCIN

>A>	AT	+	FERA PHARMS	0.5%	A062447 001	Sep 26, 1983	Feb	CAHN
>D>	AT	+	NYCOMED US	0.5%	A062447 001	Sep 26, 1983	Feb	CAHN
	AT	+		0.5%	A062447 001	Sep 26, 1983	Jan	CAHN

SOLUTION; TOPICAL

ERYDERM

	@	ARBOR PHARMS INC	2%	A062290 001		Jan	CAHN
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TABLET; ORAL

ERYTHROMYCIN

		ARBOR PHARMS INC	250MG	A061621 001		Jan	CAHN
	+		500MG	A061621 002		Jan	CAHN

TABLET, COATED PARTICLES; ORAL

PCE

		ARBOR PHARMS INC	333MG	N050611 001	Sep 09, 1986	Jan	CAHN
	+		500MG	N050611 002	Aug 22, 1990	Jan	CAHN

TABLET, DELAYED RELEASE; ORAL

E-MYCIN

	@	ARBOR PHARMS INC	250MG	A060272 001		Jan	CAHN
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	@		333MG	A060272 002		Jan	CAHN
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## TABLET, DELAYED RELEASE; ORAL

## ERY-TAB

+	ARBOR PHARMS INC	250MG	A062298 001		Jan	CAHN
+		333MG	A062298 003	Mar 29, 1982	Jan	CAHN
+		500MG	A062298 002		Jan	CAHN

ERYTHROMYCIN ETHYLSUCCINATE

## GRANULE; ORAL

## E.E.S.

AB	ARBOR PHARMS INC	EQ 200MG BASE/5ML	N050207 001		Jan	CAHN
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## ERYPED

AB	ARBOR PHARMS INC	EQ 200MG BASE/5ML	N050207 003	Mar 30, 1987	Jan	CAHN
+		EQ 400MG BASE/5ML	N050207 002		Jan	CAHN

## SUSPENSION; ORAL

## E.E.S. 200

AB	ARBOR PHARMS INC	EQ 200MG BASE/5ML	A061639 001		Jan	CAHN
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## E.E.S. 400

AB	+	ARBOR PHARMS INC	EQ 400MG BASE/5ML	A061639 002		Jan	CAHN
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## PEDIAMYCIN

AB	ARBOR PHARMS INC	EQ 200MG BASE/5ML	A062304 001		Jan	CAHN
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## PEDIAMYCIN 400

AB	ARBOR PHARMS INC	EQ 400MG BASE/5ML	A062304 002		Jan	CAHN
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## TABLET; ORAL

## E.E.S. 400

BX	+	@ ARBOR PHARMS INC	EQ 400MG BASE	A061905 001		Jan	CAHN
			EQ 400MG BASE	A061905 002	Aug 12, 1982	Jan	CAHN

## ERYTHROMYCIN ETHYLSUCCINATE

BX	+	ARBOR PHARMS INC	EQ 400MG BASE	A061904 001		Jan	CAHN
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## TABLET, CHEWABLE; ORAL

## E.E.S.

		@ ARBOR PHARMS INC	EQ 200MG BASE	N050297 002		Jan	CAHN
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## ERYPED

		@ ARBOR PHARMS INC	EQ 200MG BASE	N050297 003	Jul 05, 1988	Jan	CAHN
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ERYTHROMYCIN STEARATE

## TABLET; ORAL

## ERYTHROCIN STEARATE

		@ ARBOR PHARMS INC	EQ 125MG BASE	A060359 002		Jan	CAHN
			EQ 250MG BASE	A060359 001		Jan	CAHN
	+		EQ 500MG BASE	A060359 003		Jan	CAHN

ETHINYL ESTRADIOL; NORETHINDRONE

## TABLET, CHEWABLE; ORAL

## NORETHINDRONE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

+	WARNER CHILCOTT	0.025MG;0.8MG	N022573 001	Dec 22, 2010	Jan	CRLD
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ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

## TABLET; ORAL-28

## GILDESS FE 1.5/30

AB	VINTAGE	0.03MG;1.5MG	A077075 001	Apr 28, 2005	Jan	CTNA
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## GILDESS FE 1/20

AB	VINTAGE	0.02MG;1MG	A077077 001	May 20, 2005	Jan	CTNA
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ETHINYL ESTRADIOL; NORGESTIMATE

TABLET; ORAL-28

NORGESTIMATE AND ETHINYL ESTRADIOL

>A>	AB	WATSON LABS	0.025MG,0.025MG,0.025MG;0.18MG,0.215MG,0.25MG	A090479	001	Mar 09, 2011	Feb	NEWA
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ETODOLAC

CAPSULE; ORAL

ETODOLAC

>D>		@ GENPHARM	200MG	A075071	001	Sep 30, 1998	Feb	CAHN
>D>		@	300MG	A075071	002	Sep 30, 1998	Feb	CAHN
>A>		@ MYLAN	200MG	A075071	001	Sep 30, 1998	Feb	CAHN
>A>		@	300MG	A075071	002	Sep 30, 1998	Feb	CAHN

TABLET; ORAL

ETODOLAC

>D>		@ GENPHARM	400MG	A075012	001	Sep 30, 1998	Feb	CAHN
>D>		@	500MG	A075012	002	Sep 30, 1998	Feb	CAHN
>A>		@ MYLAN	400MG	A075012	001	Sep 30, 1998	Feb	CAHN
>A>		@	500MG	A075012	002	Sep 30, 1998	Feb	CAHN

ETRAVIRINE

TABLET; ORAL

INTELENCE

TIBOTEC

+

100MG

200MG

N022187 001 Jan 18, 2008 Jan CRLD

N022187 002 Dec 22, 2010 Jan NEWA

FAMOTIDINE

INJECTABLE; INJECTION

PEPCID

@ MERCK

10MG/ML

N019510 001 Nov 04, 1986 Jan DISC

PEPCID PRESERVATIVE FREE

@ MERCK

10MG/ML

N019510 004 Nov 04, 1986 Jan DISC

PEPCID PRESERVATIVE FREE IN PLASTIC CONTAINER

@ MERCK

0.4MG/ML

N020249 001 Feb 18, 1994 Jan DISC

TABLET; ORAL

FAMOTIDINE

>D>	AB	GENPHARM	20MG	A075457	001	Apr 18, 2001	Feb	CAHN
>D>	AB		40MG	A075457	002	Apr 18, 2001	Feb	CAHN
>A>	AB	MYLAN	20MG	A075457	001	Apr 18, 2001	Feb	CAHN
>A>	AB		40MG	A075457	002	Apr 18, 2001	Feb	CAHN

FENOFIBRATE

TABLET; ORAL

FENOGLIDE

>D>		SHIONOGI PHARMA	40MG	N022118	001	Aug 10, 2007	Feb	CAHN
>D>		+	120MG	N022118	002	Aug 10, 2007	Feb	CAHN
>A>		SHORE THERAP	40MG	N022118	001	Aug 10, 2007	Feb	CAHN
>A>		+	120MG	N022118	002	Aug 10, 2007	Feb	CAHN

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL

FENTANYL-100

AB		MALLINCKRODT INC	100MCG/HR	A077154	004	Feb 09, 2011	Jan	NEWA
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FENTANYL-25

AB		MALLINCKRODT INC	25MCG/HR	A077154	001	Feb 09, 2011	Jan	NEWA
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FILM, EXTENDED RELEASE; TRANSDERMAL

	FENTANYL-50							
AB	MALLINCKRODT INC	50MCG/HR	A077154	002	Feb 09, 2011	Jan	NEWA	
	FENTANYL-75							
AB	MALLINCKRODT INC	75MCG/HR	A077154	003	Feb 09, 2011	Jan	NEWA	

FENTANYL CITRATE

## TABLET; SUBLINGUAL

## ABSTRAL

	PROSTRAKAN INC	EQ 0.1MG BASE	N022510	001	Jan 07, 2011	Jan	NEWA	
		EQ 0.2MG BASE	N022510	002	Jan 07, 2011	Jan	NEWA	
		EQ 0.3MG BASE	N022510	003	Jan 07, 2011	Jan	NEWA	
+		EQ 0.4MG BASE	N022510	004	Jan 07, 2011	Jan	NEWA	
		EQ 0.6MG BASE	N022510	005	Jan 07, 2011	Jan	NEWA	
		EQ 0.8MG BASE	N022510	006	Jan 07, 2011	Jan	NEWA	

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

## FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

	DR REDDYS LABS LTD	180MG;240MG	A079043	001	Mar 17, 2010	Jan	CTEC	
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FLUCONAZOLE

## TABLET; ORAL

## FLUCONAZOLE

>A>	AB	AMNEAL PHARM	50MG	A078423	001	Mar 07, 2011	Feb	NEWA
>A>	AB		100MG	A078423	002	Mar 07, 2011	Feb	NEWA
>A>	AB		150MG	A078423	003	Mar 07, 2011	Feb	NEWA
>A>	AB		200MG	A078423	004	Mar 07, 2011	Feb	NEWA
>D>	AB	GENPHARM	50MG	A076042	001	Jul 29, 2004	Feb	CAHN
>D>	AB		100MG	A076042	002	Jul 29, 2004	Feb	CAHN
>D>	AB		150MG	A076042	003	Jul 29, 2004	Feb	CAHN
>D>	AB		200MG	A076042	004	Jul 29, 2004	Feb	CAHN
>A>	AB	MYLAN	50MG	A076042	001	Jul 29, 2004	Feb	CAHN
>A>	AB		100MG	A076042	002	Jul 29, 2004	Feb	CAHN
>A>	AB		150MG	A076042	003	Jul 29, 2004	Feb	CAHN
>A>	AB		200MG	A076042	004	Jul 29, 2004	Feb	CAHN

FLUDARABINE PHOSPHATE

## TABLET; ORAL

## OFORTA

	@ SANOFI AVENTIS US	10MG	N022273	001	Dec 18, 2008	Jan	DISC	
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FLUDEOXYGLUCOSE F-18

## INJECTABLE; INTRAVENOUS

## FLUDEOXYGLUCOSE F18

>D>	+	FEINSTEIN	20-200mCi/ML	N021870	001	Aug 19, 2005	Feb	CTEC
>A>	AP	+	20-200mCi/ML	N021870	001	Aug 19, 2005	Feb	CTEC
>A>	AP	PETNET	20-200mCi/ML	A079086	001	Feb 25, 2011	Feb	NEWA

FLUTAMIDE

## CAPSULE; ORAL

## FLUTAMIDE

>D>	AB	GENPHARM	125MG	A076224	001	May 09, 2003	Feb	CAHN
>A>	AB	MYLAN	125MG	A076224	001	May 09, 2003	Feb	CAHN

FLUVOXAMINE MALEATE

TABLET; ORAL

FLUVOXAMINE MALEATE

>D>	@ GENPHARM	50MG	A075950 001	Oct 15, 2001	Feb	CAHN
>D>	@	100MG	A075950 002	Oct 15, 2001	Feb	CAHN
>A>	@ MYLAN	50MG	A075950 001	Oct 15, 2001	Feb	CAHN
>A>	@	100MG	A075950 002	Oct 15, 2001	Feb	CAHN

FOLIC ACID

TABLET; ORAL

FOLIC ACID

AA	JUBILANT CADISTA	1MG	A040514 001	Jun 14, 2005	Jan	CAHN
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GABAPENTIN

CAPSULE; ORAL

GABAPENTIN

AB	MATRIX LABS LTD	100MG	A090158 001	Feb 14, 2011	Jan	NEWA
AB		300MG	A090158 002	Feb 14, 2011	Jan	NEWA
AB		400MG	A090158 003	Feb 14, 2011	Jan	NEWA

SOLUTION; ORAL

GABAPENTIN

>A>	AA	HI TECH PHARMA	250MG/5ML	A078974 001	Feb 18, 2011	Feb	NEWA
>D>	+	PARKE DAVIS	250MG/5ML	N021129 001	Mar 02, 2000	Feb	CFTG
>A>	AA	+	250MG/5ML	N021129 001	Mar 02, 2000	Feb	CFTG

TABLET; ORAL

GABAPENTIN

AB	ZYDUS PHARMS USA INC	600MG	A078926 001	Feb 11, 2011	Jan	NEWA	
AB		800MG	A078926 002	Feb 11, 2011	Jan	NEWA	
BX	+	ABBOTT PRODS	300MG	N022544 001	Jan 28, 2011	Jan	NEWA
BX	+		600MG	N022544 002	Jan 28, 2011	Jan	NEWA

GALANTAMINE HYDROBROMIDE

CAPSULE, EXTENDED RELEASE; ORAL

GALANTAMINE HYDROBROMIDE

AB	MYLAN	EQ 8MG BASE	A090900 001	Jan 24, 2011	Jan	NEWA
AB		EQ 16MG BASE	A090900 002	Jan 24, 2011	Jan	NEWA
AB		EQ 24MG BASE	A090900 003	Jan 24, 2011	Jan	NEWA
AB	SUN PHARMA GLOBAL	EQ 8MG BASE	A090178 001	Feb 02, 2011	Jan	NEWA
AB		EQ 16MG BASE	A090178 002	Feb 02, 2011	Jan	NEWA
AB		EQ 24MG BASE	A090178 003	Feb 02, 2011	Jan	NEWA

TABLET; ORAL

GALANTAMINE HYDROBROMIDE

AB	ZYDUS PHARMS USA INC	EQ 4MG BASE	A078898 001	Feb 17, 2011	Jan	NEWA
AB		EQ 8MG BASE	A078898 002	Feb 17, 2011	Jan	NEWA
AB		EQ 12MG BASE	A078898 003	Feb 17, 2011	Jan	NEWA

GEMCITABINE HYDROCHLORIDE

INJECTABLE; INJECTION

GEMCITABINE

>D>		HOSPIRA INC	EQ 2GM BASE/VIAL	A079183 001	Nov 15, 2010	Feb	CRLD
>A>	+		EQ 2GM BASE/VIAL	A079183 001	Nov 15, 2010	Feb	CRLD
AP		TEVA PARENTERAL	EQ 200MG BASE/VIAL	A077983 002	Jan 25, 2011	Jan	NEWA

## INJECTABLE; INJECTION

## GEMCITABINE HYDROCHLORIDE

AP		TEVA PARENTERAL	EQ 1GM BASE/VIAL	A077983 001	Jan 25, 2011	Jan	NEWA
GEMZAR							
AP	+	LILLY	EQ 200MG BASE/VIAL	N020509 001	May 15, 1996	Jan	CFTG
AP	+		EQ 1GM BASE/VIAL	N020509 002	May 15, 1996	Jan	CFTG

GEMFIBROZIL

## TABLET; ORAL

## GEMFIBROZIL

>A>	AB	BLU CARIBE	600MG	A078012 001	Mar 26, 2007	Feb	CAHN
>D>	AB	PERRIGO R AND D	600MG	A078012 001	Mar 26, 2007	Feb	CAHN

GENTAMICIN SULFATE

## OINTMENT; OPHTHALMIC

## GENTAMICIN SULFATE

>A>	AT	FERA PHARMS	EQ 0.3% BASE	A065024 001	Jul 30, 2004	Feb	CAHN
>D>	AT	NYCOMED US	EQ 0.3% BASE	A065024 001	Jul 30, 2004	Feb	CAHN
	AT		EQ 0.3% BASE	A065024 001	Jul 30, 2004	Jan	CAHN

## SOLUTION/DROPS; OPHTHALMIC

## GENTAMICIN SULFATE

>D>	AT	ALTANA	EQ 0.3% BASE	A065121 001	Jan 30, 2004	Feb	CAHN
>A>	AT	FERA PHARMS	EQ 0.3% BASE	A065121 001	Jan 30, 2004	Feb	CAHN

GLIMEPIRIDE

## TABLET; ORAL

## GLIMEPIRIDE

>D>	AB	GENPHARM	1MG	A077486 001	Feb 10, 2006	Feb	CAHN
>D>	AB		2MG	A077486 002	Feb 10, 2006	Feb	CAHN
>D>	AB		4MG	A077486 003	Feb 10, 2006	Feb	CAHN
>A>	AB	MYLAN	1MG	A077486 001	Feb 10, 2006	Feb	CAHN
>A>	AB		2MG	A077486 002	Feb 10, 2006	Feb	CAHN
>A>	AB		4MG	A077486 003	Feb 10, 2006	Feb	CAHN

GLIPIZIDE; METFORMIN HYDROCHLORIDE

## TABLET; ORAL

## GLIPIZIDE AND METFORMIN HYDROCHLORIDE

AB		ZYDUS PHARMS USA INC	2.5MG;250MG	A078905 001	Jan 31, 2011	Jan	NEWA
AB			2.5MG;500MG	A078905 002	Jan 31, 2011	Jan	NEWA
AB			5MG;500MG	A078905 003	Jan 31, 2011	Jan	NEWA

GLYBURIDE

## TABLET; ORAL

## GLYBURIDE

>A>	AB	INDICUS PHARMA	1.25MG	A090937 001	Feb 28, 2011	Feb	NEWA
>A>	AB		2.5MG	A090937 002	Feb 28, 2011	Feb	NEWA
>A>	AB		5MG	A090937 003	Feb 28, 2011	Feb	NEWA

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

## TABLET; ORAL

## FULVICIN P/G

## @ ELORAC

## @

## FULVICIN P/G 165

## @ ELORAC

125MG

250MG

165MG

A061996 001

A061996 002

A061996 003

Jan CAHN

Jan CAHN

Apr 06, 1982 Jan CAHN

## TABLET; ORAL

FULVICIN P/G 330

@ ELORAC

330MG

A061996 004 Apr 06, 1982 Jan CAHN

HYDROCHLOROTHIAZIDE

## CAPSULE; ORAL

HYDROCHLOROTHIAZIDE

AB JUBILANT CADISTA 12.5MG

A078391 001 Feb 11, 2008 Jan CAHN

## TABLET; ORAL

HYDROCHLOROTHIAZIDE

AB JUBILANT CADISTA 25MG

A040809 001 Sep 04, 2007 Jan CAHN

AB 50MG

A040809 002 Sep 04, 2007 Jan CAHN

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

## TABLET; ORAL

LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

AB WATSON LABS 12.5MG;50MG

A200180 001 Jan 12, 2011 Jan NEWA

AB 12.5MG;100MG

A200180 002 Jan 12, 2011 Jan NEWA

AB 25MG;100MG

A200180 003 Jan 12, 2011 Jan NEWA

HYDROMORPHONE HYDROCHLORIDE

## TABLET; ORAL

HYDROMORPHONE HYDROCHLORIDE

&gt;A&gt; AB ELITE LABS 8MG

A076723 001 Oct 18, 2005 Feb CAHN

&gt;D&gt; AB MIKAH PHARMA 8MG

A076723 001 Oct 18, 2005 Feb CAHN

HYDROXYAMPHETAMINE HYDROBROMIDE

## SOLUTION/DROPS; OPHTHALMIC

PAREDRIINE

@ PHARMICS

1%

N000004 004 Jan CAHN

>A> HYDROXYPROGESTERONE CAPROATE

## &gt;A&gt; SOLUTION; INTRAMUSCULAR

&gt;A&gt; MAKENA

&gt;A&gt; + KV PHARM 1250MG/5ML (250MG/ML)

N021945 001 Feb 03, 2011 Feb NEWA

ILOPERIDONE

## TABLET; ORAL

FANAPT

NOVARTIS

2MG

N022192 002 May 06, 2009 Jan CAHN

4MG

N022192 003 May 06, 2009 Jan CAHN

6MG

N022192 004 May 06, 2009 Jan CAHN

8MG

N022192 005 May 06, 2009 Jan CAHN

10MG

N022192 006 May 06, 2009 Jan CAHN

IMIQUIMOD

## CREAM; TOPICAL

IMIQUIMOD

&gt;A&gt; AB TOLMAR 5%

A091044 001 Feb 28, 2011 Feb NEWA

INDOMETHACIN

## CAPSULE, EXTENDED RELEASE; ORAL

INDOMETHACIN

AB + SANDOZ 75MG

A074464 001 May 28, 1998 Jan CTNA



IOFLUPANE I-123

SOLUTION; INTRAVENOUS

DATSCAN

+	GE HLTHCARE INC	5MCI/2.5ML (2MCI/ML)	N022454	001	Jan 14, 2011	Jan	NEWA
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IOPAMIDOL

INJECTABLE; INJECTION

IOPAMIDOL-200

>D>	AP	HOSPIRA	41%	A074898	001	Dec 30, 1997	Feb	DISC
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>A>		@	41%	A074898	001	Dec 30, 1997	Feb	DISC
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>D>		IOPAMIDOL-200 IN PLASTIC CONTAINER						
-----	--	------------------------------------	--	--	--	--	--	--

>D>	AP	HOSPIRA	41%	A074636	001	Dec 30, 1997	Feb	DISC
-----	----	---------	-----	---------	-----	--------------	-----	------

>A>		@	41%	A074636	001	Dec 30, 1997	Feb	DISC
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IOPAMIDOL-250

>D>	AP	HOSPIRA	51%	A074898	002	Dec 30, 1997	Feb	DISC
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>A>		@	51%	A074898	002	Dec 30, 1997	Feb	DISC
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>D>		IOPAMIDOL-250 IN PLASTIC CONTAINER						
-----	--	------------------------------------	--	--	--	--	--	--

>D>	AP	HOSPIRA	51%	A074636	002	Dec 30, 1997	Feb	DISC
-----	----	---------	-----	---------	-----	--------------	-----	------

>A>		@	51%	A074636	002	Dec 30, 1997	Feb	DISC
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IOPAMIDOL-300

>D>	AP	HOSPIRA	61%	A074898	003	Dec 30, 1997	Feb	DISC
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>A>		@	61%	A074898	003	Dec 30, 1997	Feb	DISC
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>D>		IOPAMIDOL-300 IN PLASTIC CONTAINER						
-----	--	------------------------------------	--	--	--	--	--	--

>D>	AP	HOSPIRA	61%	A074636	003	Dec 30, 1997	Feb	DISC
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>A>		@	61%	A074636	003	Dec 30, 1997	Feb	DISC
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IOPAMIDOL-370

>D>	AP	HOSPIRA	76%	A074898	004	Dec 30, 1997	Feb	DISC
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>A>		@	76%	A074898	004	Dec 30, 1997	Feb	DISC
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>D>		IOPAMIDOL-370 IN PLASTIC CONTAINER						
-----	--	------------------------------------	--	--	--	--	--	--

>D>	AP	HOSPIRA	76%	A074636	004	Dec 30, 1997	Feb	DISC
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>A>		@	76%	A074636	004	Dec 30, 1997	Feb	DISC
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ISRADIPINE

CAPSULE; ORAL

ISRADIPINE

>D>	AB	ACTAVIS TOTOWA	2.5MG	A077169	001	Apr 24, 2006	Feb	CAHN
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>D>	AB		5MG	A077169	002	Apr 24, 2006	Feb	CAHN
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>A>	AB	MIKAH PHARMA	2.5MG	A077169	001	Apr 24, 2006	Feb	CAHN
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>A>	AB		5MG	A077169	002	Apr 24, 2006	Feb	CAHN
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LAMOTRIGINE

TABLET; ORAL

LAMOTRIGINE

AB	ALEMBIC LTD	25MG	A090607	001	Jan 13, 2011	Jan	NEWA
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AB		100MG	A090607	002	Jan 13, 2011	Jan	NEWA
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AB		150MG	A090607	003	Jan 13, 2011	Jan	NEWA
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AB		200MG	A090607	004	Jan 13, 2011	Jan	NEWA
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TABLET, CHEWABLE; ORAL

LAMOTRIGINE

>A>	AB	JUBILANT LIFE	5MG	A200220	001	Feb 28, 2011	Feb	NEWA
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>A>	AB		25MG	A200220	002	Feb 28, 2011	Feb	NEWA
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LEVETIRACETAM

TABLET; ORAL

LEVETIRACETAM

AB	ACCORD HLTHCARE	250MG	A090843 001	Feb 14, 2011	Jan	NEWA
AB		500MG	A090843 002	Feb 14, 2011	Jan	NEWA
AB		750MG	A090843 003	Feb 14, 2011	Jan	NEWA
AB		1GM	A090843 004	Feb 14, 2011	Jan	NEWA

LEVOCETIRIZINE DIHYDROCHLORIDE

TABLET; ORAL

LEVOCETIRIZINE DIHYDROCHLORIDE

>A>	AB	DR REDDYS LABS LTD	5MG	A090392 001	Feb 24, 2011	Feb	NEWA
>A>	AB	GLENMARK GENERICS	5MG	A090385 001	Feb 24, 2011	Feb	NEWA

LEVOFLOXACIN

SOLUTION/DROPS; OPHTHALMIC

LEVOFLOXACIN

AT	HI TECH PHARMA	0.5%	A076826 001	Feb 10, 2011	Jan	NEWA
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LEVONORGESTREL

TABLET; ORAL

PLAN B

>D>		@ DURAMED	0.75MG	N021045 001	Jul 28, 1999	Feb	CAHN
>D>	AB	+	0.75MG	N021045 002	Aug 24, 2006	Feb	CAHN
>A>	AB	+ TEVA WOMENS	0.75MG	N021045 002	Aug 24, 2006	Feb	CAHN
>A>		@	0.75MG	N021045 001	Jul 28, 1999	Feb	CAHN

LEVOTHYROXINE SODIUM\*\*

\*\*Refer to Annual Edition Preface Section 1.8 Levothyroxine Sodium for amplifying information

TABLET; ORAL

LEVO-T

>D>	AB2, AB3	ALARA PHARM	0.025MG	N021342 001	Mar 01, 2002	Feb	CTEC
>A>	AB1, AB2, AB3		0.025MG	N021342 001	Mar 01, 2002	Feb	CTEC
>D>	AB2, AB3		0.05MG	N021342 002	Mar 01, 2002	Feb	CTEC
>A>	AB1, AB2, AB3		0.05MG	N021342 002	Mar 01, 2002	Feb	CTEC
>D>	AB2, AB3		0.075MG	N021342 003	Mar 01, 2002	Feb	CTEC
>A>	AB1, AB2, AB3		0.075MG	N021342 003	Mar 01, 2002	Feb	CTEC
>D>	AB2, AB3		0.088MG	N021342 004	Mar 01, 2002	Feb	CTEC
>A>	AB1, AB2, AB3		0.088MG	N021342 004	Mar 01, 2002	Feb	CTEC
>D>	AB2, AB3		0.1MG	N021342 005	Mar 01, 2002	Feb	CTEC
>A>	AB1, AB2, AB3		0.1MG	N021342 005	Mar 01, 2002	Feb	CTEC
>D>	AB2, AB3		0.112MG	N021342 006	Mar 01, 2002	Feb	CTEC
>A>	AB1, AB2, AB3		0.112MG	N021342 006	Mar 01, 2002	Feb	CTEC

## TABLET; ORAL

## LEVO-T

>D>	AB2, AB3	ALARA PHARM	0.125MG	N021342 007	Mar 01, 2002	Feb	CTEC
>A>	AB1, AB2, AB3		0.125MG	N021342 007	Mar 01, 2002	Feb	CTEC
>D>	AB2, AB3		0.137MG	N021342 012	Dec 08, 2003	Feb	CTEC
>A>	AB1, AB2, AB3		0.137MG	N021342 012	Dec 08, 2003	Feb	CTEC
>D>	AB2, AB3		0.15MG	N021342 008	Mar 01, 2002	Feb	CTEC
>A>	AB1, AB2, AB3		0.15MG	N021342 008	Mar 01, 2002	Feb	CTEC
>D>	AB2, AB3		0.175MG	N021342 009	Mar 01, 2002	Feb	CTEC
>A>	AB1, AB2, AB3		0.175MG	N021342 009	Mar 01, 2002	Feb	CTEC
>D>	AB2, AB3		0.2MG	N021342 010	Mar 01, 2002	Feb	CTEC
>A>	AB1, AB2, AB3		0.2MG	N021342 010	Mar 01, 2002	Feb	CTEC
>D>	AB2, + AB3		0.3MG	N021342 011	Mar 01, 2002	Feb	CTEC
>A>	AB1, + AB2, AB3		0.3MG	N021342 011	Mar 01, 2002	Feb	CTEC

LITHIUM CARBONATE

## TABLET, EXTENDED RELEASE; ORAL

## LITHIUM CARBONATE

AB		GLENMARK GENERICS	450MG	A091616 001	Feb 14, 2011	Jan	NEWA
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LOSARTAN POTASSIUM

## TABLET; ORAL

## LOSARTAN POTASSIUM

AB		MYLAN	25MG	A091590 001	Oct 06, 2010	Jan	NEWA
AB			50MG	A091590 002	Oct 06, 2010	Jan	NEWA
AB			100MG	A091590 003	Oct 06, 2010	Jan	NEWA

MECLIZINE HYDROCHLORIDE

## TABLET; ORAL

## MECLIZINE HYDROCHLORIDE

>A>	AA	AMNEAL PHARMS	12.5MG	A201451 001	Feb 23, 2011	Feb	NEWA
>A>	AA		25MG	A201451 002	Feb 23, 2011	Feb	NEWA
>A>	AA		50MG	A201451 003	Feb 23, 2011	Feb	NEWA
	AA	JUBILANT CADISTA	12.5MG	A040659 001	Jun 04, 2010	Jan	CAHN
	AA		25MG	A040659 002	Jun 04, 2010	Jan	CAHN

MELOXICAM

## TABLET; ORAL

## MELOXICAM

>D>	AB	GENPHARM	7.5MG	A077934 001	Jul 20, 2006	Feb	CAHN
>D>	AB		15MG	A077934 002	Jul 20, 2006	Feb	CAHN
>A>	AB	MYLAN	7.5MG	A077934 001	Jul 20, 2006	Feb	CAHN
>A>	AB		15MG	A077934 002	Jul 20, 2006	Feb	CAHN

METFORMIN HYDROCHLORIDE

TABLET; ORAL

METFORMIN HYDROCHLORIDE

>D>	AB	GENPHARM	500MG	A075973 001	Jan 25, 2002	Feb	CAHN
>D>	AB		850MG	A075973 002	Jan 25, 2002	Feb	CAHN
>D>	AB		1GM	A075973 003	Jan 25, 2002	Feb	CAHN
>A>	AB	MYLAN	500MG	A075973 001	Jan 25, 2002	Feb	CAHN
>A>	AB		850MG	A075973 002	Jan 25, 2002	Feb	CAHN
>A>	AB		1GM	A075973 003	Jan 25, 2002	Feb	CAHN

METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE

TABLET; ORAL

ACTOPLUS MET

>D>		TAKEDA GLOBAL	500MG;EQ 15MG BASE	N021842 001	Aug 29, 2005	Feb	CFTG
>A>	AB		500MG;EQ 15MG BASE	N021842 001	Aug 29, 2005	Feb	CFTG
>D>		+	850MG;EQ 15MG BASE	N021842 002	Aug 29, 2005	Feb	CFTG
>A>	AB	+	850MG;EQ 15MG BASE	N021842 002	Aug 29, 2005	Feb	CFTG
>A>		PIOGLITAZONE HYDROCHLORIDE AND METFORMIN HYDROCHLORIDE					
>A>	AB	MYLAN	500MG;EQ 15MG BASE	A090406 001	Feb 25, 2011	Feb	NEWA
>A>	AB		850MG;EQ 15MG BASE	A090406 002	Feb 25, 2011	Feb	NEWA

METHYLPREDNISOLONE

TABLET; ORAL

METHYLPREDNISOLONE

	AB	JUBILANT CADISTA	4MG	A040189 001	Oct 31, 1997	Jan	CAHN
	AB		8MG	A040189 002	Oct 31, 1997	Jan	CAHN
	AB		16MG	A040189 003	Jul 20, 2007	Jan	CAHN
	AB		32MG	A040189 004	Jul 20, 2007	Jan	CAHN

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

A-METHAPRED

>D>	AP	HOSPIRA	EQ 500MG BASE/VIAL	A089173 001	Aug 18, 1987	Feb	DISC
>A>		@	EQ 500MG BASE/VIAL	A089173 001	Aug 18, 1987	Feb	DISC
>D>	AP		EQ 1GM BASE/VIAL	A089174 001	Aug 18, 1987	Feb	DISC
>A>		@	EQ 1GM BASE/VIAL	A089174 001	Aug 18, 1987	Feb	DISC

METRONIDAZOLE

GEL; TOPICAL

METRONIDAZOLE

	AB	G AND W LABS INC	0.75%	A078178 001	Jan 19, 2011	Jan	NEWA
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MICAFUNGIN SODIUM

INJECTABLE; IV (INFUSION)

MYCAMINE

		+	ASTELLAS	100MG/VIAL	N021506 003	Jun 27, 2006	Jan	CRLD
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MILRINONE LACTATE

INJECTABLE; INJECTION

MILRINONE LACTATE

>D>	AP	HOSPIRA	EQ 1MG BASE/ML	A075884 001	May 28, 2002	Feb	DISC
>A>		@	EQ 1MG BASE/ML	A075884 001	May 28, 2002	Feb	DISC

MIRTAZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL

MIRTAZAPINE

AB	ACTAVIS ELIZABETH	15MG	A077959 001	Feb 14, 2011	Jan	NEWA
AB		30MG	A077959 002	Feb 14, 2011	Jan	NEWA
AB		45MG	A077959 003	Feb 14, 2011	Jan	NEWA

MUPIROCIN CALCIUM

CREAM; TOPICAL

BACTROBAN

+	GLAXOSMITHKLINE	EQ 2% BASE	N050746 001	Dec 11, 1997	Jan	CDFR
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NABUMETONE

TABLET; ORAL

NABUMETONE

AB	LUPIN LTD	500MG	A090445 001	Jan 12, 2011	Jan	NEWA
AB		750MG	A090445 002	Jan 12, 2011	Jan	NEWA

NALTREXONE HYDROCHLORIDE

TABLET; ORAL

NALTREXONE HYDROCHLORIDE

>A>	AB	ELITE LABS	50MG	A075274 001	May 26, 1999	Feb	CAHN
>D>	AB	MIKAH PHARMA	50MG	A075274 001	May 26, 1999	Feb	CAHN

NAPROXEN

TABLET; ORAL

NAPROXEN

AB	MARKSANS PHARMA	250MG	A091416 001	Feb 14, 2011	Jan	NEWA
AB		375MG	A091416 002	Feb 14, 2011	Jan	NEWA
AB		500MG	A091416 003	Feb 14, 2011	Jan	NEWA

NARATRIPTAN

TABLET; ORAL

NARATRIPTAN

AB	SUN PHARM INDS LTD	EQ 2.5MG BASE	A091552 001	Feb 14, 2011	Jan	NEWA
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NARATRIPTAN HYDROCHLORIDE

TABLET; ORAL

NARATRIPTAN

>A>	AB	INDICUS PHARMA	EQ 1MG BASE	A200502 001	Feb 28, 2011	Feb	NEWA
>A>	AB		EQ 2.5MG BASE	A200502 002	Feb 28, 2011	Feb	NEWA

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL

NISOLDIPINE

AB	MYLAN	8.5MG	A091001 001	Jan 26, 2011	Jan	NEWA
AB		17MG	A091001 002	Jan 26, 2011	Jan	NEWA
AB		25.5MG	A091001 003	Jan 26, 2011	Jan	NEWA
AB		34MG	A091001 004	Jan 26, 2011	Jan	NEWA

SULAR

AB	+	SHIONOGI PHARMA	8.5MG	N020356 008	Jan 02, 2008	Jan	CFTG
AB	+		17MG	N020356 007	Jan 02, 2008	Jan	CFTG
AB			25.5MG	N020356 006	Jan 02, 2008	Jan	CFTG
AB	+		34MG	N020356 005	Jan 02, 2008	Jan	CFTG

NIZATIDINE

CAPSULE; ORAL

NIZATIDINE

>D>	AB	GENPHARM	150MG	A075934 001	Jul 09, 2002	Feb	CAHN
>D>	AB		300MG	A075934 002	Jul 09, 2002	Feb	CAHN
>A>	AB	MYLAN	150MG	A075934 001	Jul 09, 2002	Feb	CAHN
>A>	AB		300MG	A075934 002	Jul 09, 2002	Feb	CAHN

NYSTATIN

SUSPENSION; ORAL

NYSTATIN

>A>	AA	VISTAPHARM	100,000 UNITS/ML	A065422 001	Mar 07, 2011	Feb	NEWA
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OCTREOTIDE ACETATE

INJECTABLE; INJECTION

OCTREOTIDE ACETATE (PRESERVATIVE FREE)

AP		BIONICHE PHARMA USA	EQ 0.05MG BASE/ML	A079198 001	Feb 10, 2011	Jan	NEWA
AP			EQ 0.1MG BASE/ML	A079198 002	Feb 10, 2011	Jan	NEWA
AP			EQ 0.5MG BASE/ML	A079198 003	Feb 10, 2011	Jan	NEWA

ONDANSETRON

TABLET, ORALLY DISINTEGRATING; ORAL

ONDANSETRON

>A>	AB	RANBAXY	4MG	A078602 001	Feb 24, 2011	Feb	NEWA
>A>	AB		8MG	A078602 002	Feb 24, 2011	Feb	NEWA

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ONDANSETRON HYDROCHLORIDE

AP		TEVA	EQ 2MG BASE/ML	A076876 001	Nov 22, 2006	Jan	CMFD
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SOLUTION; ORAL

ONDANSETRON HYDROCHLORIDE

AA		AMNEAL PHARMS	EQ 4MG BASE/5ML	A091483 001	Jan 31, 2011	Jan	NEWA
AA		SILARX	EQ 4MG BASE/5ML	A091342 001	Jan 27, 2011	Jan	NEWA

OXALIPLATIN

INJECTABLE; IV (INFUSION)

OXALIPLATIN

AP		SANDOZ	50MG/10ML (5MG/ML)	A078817 001	Jan 24, 2011	Jan	NEWA
AP			100MG/20ML (5MG/ML)	A078817 002	Jan 24, 2011	Jan	NEWA

OXAPROZIN

TABLET; ORAL

OXAPROZIN

>D>	AB	GENPHARM	600MG	A075847 001	Feb 28, 2001	Feb	CAHN
>A>	AB	MYLAN	600MG	A075847 001	Feb 28, 2001	Feb	CAHN

OXYCODONE HYDROCHLORIDE

TABLET; ORAL

OXYCODONE HYDROCHLORIDE

>A>	AB	COASTAL PHARMS	5MG	A091313 001	Feb 18, 2011	Feb	NEWA
>A>	AB		15MG	A091313 002	Feb 18, 2011	Feb	NEWA
>A>	AB		30MG	A091313 003	Feb 18, 2011	Feb	NEWA
>A>	AB	RHODES PHARMS	5MG	A091490 001	Mar 09, 2011	Feb	NEWA
>A>	AB		10MG	A091490 002	Mar 09, 2011	Feb	NEWA

## TABLET; ORAL

## OXYCODONE HYDROCHLORIDE

>A>	AB	RHODES PHARMS	15MG	A091490 003	Mar 09, 2011	Feb	NEWA
>A>	AB		20MG	A091490 004	Mar 09, 2011	Feb	NEWA
>A>	AB		30MG	A091490 005	Mar 09, 2011	Feb	NEWA

OXYMORPHONE HYDROCHLORIDE

## TABLET; ORAL

## OXYMORPHONE HYDROCHLORIDE

AB	TEVA		5MG	A091443 002	Feb 15, 2011	Jan	NEWA
AB			10MG	A091443 001	Feb 15, 2011	Jan	NEWA

## TABLET, EXTENDED RELEASE; ORAL

## OPANA ER

>D>	AB	ENDO PHARMS	7.5MG	N021610 005	Feb 29, 2008	Feb	DISC
>A>	@		7.5MG	N021610 005	Feb 29, 2008	Feb	DISC
>D>	AB		15MG	N021610 006	Feb 29, 2008	Feb	DISC
>A>	@		15MG	N021610 006	Feb 29, 2008	Feb	DISC

PANTOPRAZOLE SODIUM

## TABLET, DELAYED RELEASE; ORAL

## PANTOPRAZOLE SODIUM

AB	ACTAVIS TOTOWA		EQ 20MG BASE	A090797 001	Feb 07, 2011	Jan	NEWA
AB			EQ 40MG BASE	A090797 002	Feb 07, 2011	Jan	NEWA
AB	DR REDDYS LABS LTD		EQ 20MG BASE	A077619 001	Jan 19, 2011	Jan	NEWA
AB			EQ 40MG BASE	A077619 002	Jan 19, 2011	Jan	NEWA
AB	KUDCO IRELAND		EQ 20MG BASE	A078281 001	Jan 20, 2011	Jan	NEWA
AB			EQ 40MG BASE	A078281 002	Jan 20, 2011	Jan	NEWA
AB	MATRIX LABS LTD		EQ 20MG BASE	A090970 001	Jan 19, 2011	Jan	NEWA
AB			EQ 40MG BASE	A090970 002	Jan 19, 2011	Jan	NEWA
AB	TORRENT PHARMS		EQ 20MG BASE	A090074 001	Jan 19, 2011	Jan	NEWA
AB			EQ 40MG BASE	A090074 002	Jan 19, 2011	Jan	NEWA
AB	WOCKHARDT		EQ 20MG BASE	A091231 001	Jan 19, 2011	Jan	NEWA
AB			EQ 40MG BASE	A091231 002	Jan 19, 2011	Jan	NEWA

PHENTERMINE HYDROCHLORIDE

## TABLET; ORAL

## PHENTERMINE HYDROCHLORIDE

AA	EPIC PHARMA LLC		37.5MG	A200272 001	Jan 31, 2011	Jan	NEWA
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PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

## INJECTABLE; INJECTION

## PIPERACILLIN AND TAZOBACTAM

AP	HOSPIRA INC		EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	A065386 001	Sep 15, 2009	Jan	CAHN
AP			EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	A065386 002	Sep 15, 2009	Jan	CAHN
AP			EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	A065386 003	Sep 15, 2009	Jan	CAHN
AP			EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	A065446 001	Sep 15, 2009	Jan	CAHN

PIROXICAM

## CAPSULE; ORAL

## PIROXICAM

>D>	@	GENPHARM	10MG	A074043 001	Sep 22, 1992	Feb	CAHN
>D>	@		20MG	A074043 002	Sep 22, 1992	Feb	CAHN
>A>	@	MYLAN	10MG	A074043 001	Sep 22, 1992	Feb	CAHN

## CAPSULE; ORAL

PIROXICAM

>A>	@ MYLAN	20MG	A074043 002	Sep 22, 1992	Feb	CAHN
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PREDNISONE

TABLET; ORAL

PREDNISONE

AB	JUBILANT CADISTA	1MG	A040611 001	Jun 06, 2005	Jan	CAHN
AB		5MG	A040362 002	Aug 29, 2001	Jan	CAHN
AB		10MG	A040362 001	Aug 29, 2001	Jan	CAHN
AB		20MG	A040362 003	Jun 29, 2005	Jan	CAHN

PROCHLORPERAZINE MALEATE

TABLET; ORAL

PROCOMP

AB	JUBILANT CADISTA	EQ 5MG BASE	A040268 001	Feb 27, 1998	Jan	CAHN
AB		EQ 10MG BASE	A040268 002	Feb 27, 1998	Jan	CAHN

PROPANTHELINE BROMIDE

TABLET; ORAL

PROPANTHELINE BROMIDE

+	ROXANE	15MG	A080927 002		Jan	CMFD
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PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

DARVON

@	XANODYNE PHARM	65MG	N010997 003		Jan	DISC
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PROPOXYPHENE HYDROCHLORIDE

@	WEST WARD	65MG	A083501 001		Jan	DISC
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PROPOXYPHENE NAPSYLATE

TABLET; ORAL

DARVON-N

@	XANODYNE PHARM	100MG	N016862 002		Jan	DISC
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QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

QUINAPRIL HYDROCHLORIDE

>D>	AB	GENPHARM	EQ 5MG BASE	A076036 001	Jan 28, 2005	Feb	CAHN
>D>	AB		EQ 10MG BASE	A076036 002	Jan 28, 2005	Feb	CAHN
>D>	AB		EQ 20MG BASE	A076036 003	Jan 28, 2005	Feb	CAHN
>D>	AB		EQ 40MG BASE	A076036 004	Jan 28, 2005	Feb	CAHN
>A>	AB	MYLAN	EQ 5MG BASE	A076036 001	Jan 28, 2005	Feb	CAHN
>A>	AB		EQ 10MG BASE	A076036 002	Jan 28, 2005	Feb	CAHN
>A>	AB		EQ 20MG BASE	A076036 003	Jan 28, 2005	Feb	CAHN
>A>	AB		EQ 40MG BASE	A076036 004	Jan 28, 2005	Feb	CAHN

RANITIDINE HYDROCHLORIDE

CAPSULE; ORAL

RANITIDINE HYDROCHLORIDE

>D>	@	GENPHARM	EQ 150MG BASE	A075564 001	Oct 27, 2000	Feb	CAHN
>D>	@		EQ 300MG BASE	A075564 002	Oct 27, 2000	Feb	CAHN
>A>	@	MYLAN	EQ 150MG BASE	A075564 001	Oct 27, 2000	Feb	CAHN
>A>	@		EQ 300MG BASE	A075564 002	Oct 27, 2000	Feb	CAHN



TABLET; ORALRANITIDINE HYDROCHLORIDE

>D>	AB	GENPHARM	EQ 150MG BASE	A074023 001	Aug 22, 1997	Feb	CAHN
>D>	AB		EQ 300MG BASE	A074023 002	Aug 22, 1997	Feb	CAHN
>A>	AB	MYLAN	EQ 150MG BASE	A074023 001	Aug 22, 1997	Feb	CAHN
>A>	AB		EQ 300MG BASE	A074023 002	Aug 22, 1997	Feb	CAHN

RIFAXIMINTABLET; ORALXIFAXAN

>D>		SALIX PHARMS	550MG	N022554 001	Mar 24, 2010	Feb	CRLD
>A>		+	550MG	N022554 001	Mar 24, 2010	Feb	CRLD

RISPERIDONESOLUTION; ORALRISPERIDONE

AA		TARO	1MG/ML	A090347 001	Feb 07, 2011	Jan	NEWA
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TABLET; ORALRISPERIDONE

>D>	AB	RATIOPHARM	0.25MG	A077784 001	Jun 08, 2010	Feb	DISC
>A>		@	0.25MG	A077784 001	Jun 08, 2010	Feb	DISC
>D>	AB		0.5MG	A077784 002	Jun 08, 2010	Feb	DISC
>A>		@	0.5MG	A077784 002	Jun 08, 2010	Feb	DISC
>D>	AB		1MG	A077784 003	Jun 08, 2010	Feb	DISC
>A>		@	1MG	A077784 003	Jun 08, 2010	Feb	DISC
>D>	AB		2MG	A077784 004	Jun 08, 2010	Feb	DISC
>A>		@	2MG	A077784 004	Jun 08, 2010	Feb	DISC
>D>	AB		3MG	A077784 005	Jun 08, 2010	Feb	DISC
>A>		@	3MG	A077784 005	Jun 08, 2010	Feb	DISC
>D>	AB		4MG	A077784 006	Jun 08, 2010	Feb	DISC
>A>		@	4MG	A077784 006	Jun 08, 2010	Feb	DISC

ROCURONIUM BROMIDEINJECTABLE; INJECTIONROCURONIUM BROMIDE

AP		SAGENT STRIDES	50MG/5ML (10MG/ML)	A091458 001	Jul 28, 2010	Jan	CAHN
AP			100MG/10ML (10MG/ML)	A091458 002	Jul 28, 2010	Jan	CAHN

>A> ROFLUMILAST>A> TABLET; ORAL>A> DALIRESP

>A>		+	FOREST RES INST INC	500MCG	N022522 001	Feb 28, 2011	Feb	NEWA
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SECOBARBITAL SODIUMCAPSULE; ORALSECONAL SODIUM

		+	MARATHON PHARMS	50MG	A086101 001	Oct 03, 1983	Jan	CAHN
		+		100MG	A086101 002	Oct 03, 1983	Jan	CAHN

SERTRALINE HYDROCHLORIDETABLET; ORALSERTRALINE HYDROCHLORIDE

>D>	AB	GENPHARM	EQ 25MG BASE	A076540 001	Mar 20, 2007	Feb	CAHN
>D>	AB		EQ 50MG BASE	A076540 002	Mar 20, 2007	Feb	CAHN
>D>	AB		EQ 100MG BASE	A076540 003	Mar 20, 2007	Feb	CAHN
>A>	AB	MYLAN	EQ 25MG BASE	A076540 001	Mar 20, 2007	Feb	CAHN

## TABLET; ORAL

## SERTRALINE HYDROCHLORIDE

>A>	AB	MYLAN	EQ 50MG BASE	A076540 002	Mar 20, 2007	Feb	CAHN
>A>	AB		EQ 100MG BASE	A076540 003	Mar 20, 2007	Feb	CAHN

SODIUM FLUORIDE F-18

## INJECTABLE; INTRAVENOUS

## SODIUM FLUORIDE F 18

+	NIH NCI DCTD	10-200mCi/ML	N022494 001	Jan 26, 2011	Jan	NEWA
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SODIUM NITRITE; SODIUM THIOSULFATE

## SOLUTION, SOLUTION; INTRAVENOUS, INTRAVENOUS

>A>		NITHIODOTE					
>A>	+	HOPE PHARMS	300MG/10ML(30MG/ML),N/A;N/A,12.5GM/50ML(250MG/ML)	N201444 001	Jan 14, 2011	Feb	CTNA
>D>		SODIUM NITRITE					
>D>	+	HOPE PHARMS	300MG/10ML(30MG/ML),N/A;N/A,12.5GM/50ML(250MG/ML)	N201444 001	Jan 14, 2011	Feb	CTNA
	+		300MG/10ML(30MG/ML),N/A;N/A,12.5GM/50ML(250MG/ML)	N201444 001	Jan 14, 2011	Jan	NEWA

SPINOSAD

## SUSPENSION; TOPICAL

## NATROBA

+	PARAPRO PHARMS	0.9%	N022408 001	Jan 18, 2011	Jan	NEWA
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TERAZOSIN HYDROCHLORIDE

## CAPSULE; ORAL

## TERAZOSIN HYDROCHLORIDE

AB		JUBILANT CADISTA	EQ 1MG BASE	A075317 001	Dec 20, 2004	Jan	CAHN
AB			EQ 2MG BASE	A075317 002	Dec 20, 2004	Jan	CAHN
AB			EQ 5MG BASE	A075317 003	Dec 20, 2004	Jan	CAHN
AB			EQ 10MG BASE	A075317 004	Dec 20, 2004	Jan	CAHN

TERBINAFINE HYDROCHLORIDE

## TABLET; ORAL

## TERBINAFINE HYDROCHLORIDE

>D>	AB	GENPHARM	EQ 250MG BASE	A077136 001	Jul 02, 2007	Feb	CAHN
>A>	AB	MYLAN	EQ 250MG BASE	A077136 001	Jul 02, 2007	Feb	CAHN
>D>	AB	ROXANE	EQ 250MG BASE	A077223 001	Jul 02, 2007	Feb	DISC
>A>		@	EQ 250MG BASE	A077223 001	Jul 02, 2007	Feb	DISC

TERBUTALINE SULFATE

## TABLET; ORAL

## TERBUTALINE SULFATE

AB	+	IMPAX LABS	5MG	A075877 002	Jun 26, 2001	Jan	CRLD
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TICLOPIDINE HYDROCHLORIDE

## TABLET; ORAL

## TICLOPIDINE HYDROCHLORIDE

>D>	AB	GENPHARM	250MG	A075161 001	Sep 13, 1999	Feb	CAHN
>A>	AB	MYLAN	250MG	A075161 001	Sep 13, 1999	Feb	CAHN

TOPOTECAN HYDROCHLORIDE

## INJECTABLE; INJECTION

## TOPOTECAN HYDROCHLORIDE

>A>	AP	DR REDDYS LABS LTD	EQ 4MG BASE/VIAL	A201191 001	Mar 09, 2011	Feb	NEWA
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## INJECTABLE; INJECTION

## TOPOTECAN HYDROCHLORIDE

AP	SAGENT PHARMS	EQ 4MG BASE/VIAL	A091284 001	Jan 26, 2011	Jan	NEWA
>A>	SOLUTION; INTRAVENOUS					
>A>	TOPOTECAN					
>A>	AP	HOSPIRA INC	EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	N200582 001	Feb 02, 2011	Feb NEWA
>A>		SANDOZ	EQ 1MG BASE/ML (EQ 1MG BASE/ML)	N200199 001	Feb 25, 2011	Feb NEWA
>A>			EQ 3MG BASE/3ML (EQ 1MG BASE/ML)	N200199 002	Feb 25, 2011	Feb NEWA
>A>	AP	+	EQ 4MG BASE/4ML (EQ 1MG BASE/ML)	N200199 003	Feb 25, 2011	Feb NEWA

TRAMADOL HYDROCHLORIDE

## TABLET; ORAL

## TRAMADOL HYDROCHLORIDE

AB	ZYDUS PHARMS USA INC	50MG	A090404 001	Jan 31, 2011	Jan	NEWA
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TRIMETHOBENZAMIDE HYDROCHLORIDE

## INJECTABLE; INJECTION

## TRIMETHOBENZAMIDE HYDROCHLORIDE

>A>	AP	PHARMAFORCE	100MG/ML	A091330 001	Mar 08, 2011	Feb NEWA
>A>	AP	PHARMAFORCE	100MG/ML	A091329 001	Mar 08, 2011	Feb NEWA

TRIMIPRAMINE MALEATE

## CAPSULE; ORAL

## TRIMIPRAMINE MALEATE

>D>	AB	ACTAVIS TOTOWA	EQ 25MG BASE	A077361 001	Aug 02, 2006	Feb CAHN
>D>	AB		EQ 50MG BASE	A077361 002	Aug 02, 2006	Feb CAHN
>D>	AB		EQ 100MG BASE	A077361 003	Aug 02, 2006	Feb CAHN
>A>	AB	MIKAH PHARMA	EQ 25MG BASE	A077361 001	Aug 02, 2006	Feb CAHN
>A>	AB		EQ 50MG BASE	A077361 002	Aug 02, 2006	Feb CAHN
>A>	AB		EQ 100MG BASE	A077361 003	Aug 02, 2006	Feb CAHN

VALACYCLOVIR HYDROCHLORIDE

## TABLET; ORAL

## VALACYCLOVIR HYDROCHLORIDE

>A>	AB	ACTAVIS PHARMA	EQ 500MG BASE	A090370 001	Mar 16, 2011	Feb NEWA
>A>	AB		EQ 1GM BASE	A090370 002	Mar 16, 2011	Feb NEWA

VILAZODONE HYDROCHLORIDE

## TABLET; ORAL

## VILIBRYD

## TROVIS PHARMS

		10MG	N022567 001	Jan 21, 2011	Jan	NEWA
		20MG	N022567 002	Jan 21, 2011	Jan	NEWA
	+	40MG	N022567 003	Jan 21, 2011	Jan	NEWA

VINCRISTINE SULFATE

## INJECTABLE; INJECTION

## VINCRISTINE SULFATE

## @ APP PHARMS

1MG/ML

A076401 001 Oct 28, 2003 Jan DISC

ZIDOVUDINE

## INJECTABLE; INJECTION

## ZIDOVUDINE

>A>	AP	LUITPOLD	10MG/ML	A091457 001	May 06, 2010	Feb CAHN
>D>	AP	PHARMAFORCE	10MG/ML	A091457 001	May 06, 2010	Feb CAHN

## TABLET; ORAL

## ZIDOVUDINE

>A>		@ MATRIX LABS LTD	100MG		N200732 001	Feb 23, 2011	Feb	NEWA
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ZOLPIDEM TARTRATE

## TABLET; ORAL

## ZOLPIDEM TARTRATE

>D>	AB	GENPHARM	5MG		A078016 001	Apr 23, 2007	Feb	CAHN
>D>	AB		10MG		A078016 002	Apr 23, 2007	Feb	CAHN
>A>	AB	MYLAN	5MG		A078016 001	Apr 23, 2007	Feb	CAHN
>A>	AB		10MG		A078016 002	Apr 23, 2007	Feb	CAHN

OTC DRUG PRODUCT LIST - 31ST EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2011

2-1

FAMOTIDINE

TABLET; ORAL

FAMOTIDINE

>D>	GENPHARM	10MG	A075674	001	Dec 21, 2001	Feb	CAHN
>A>	MYLAN	10MG	A075674	001	Dec 21, 2001	Feb	CAHN

FEXOFENADINE HYDROCHLORIDE

SUSPENSION; ORAL

CHILDREN'S ALLEGRA ALLERGY

+	SANOFI AVENTIS US	30MG/5ML	N201373	001	Jan 24, 2011	Jan	NEWA
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CHILDREN'S ALLEGRA HIVES

+	SANOFI AVENTIS US	30MG/5ML	N201373	002	Jan 24, 2011	Jan	NEWA
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TABLET, ORALLY DISINTEGRATING; ORAL

CHILDREN'S ALLEGRA ALLERGY

+	SANOFI AVENTIS US	30MG	N021909	002	Jan 24, 2011	Jan	NEWA
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CHILDREN'S ALLEGRA HIVES

+	SANOFI AVENTIS US	30MG	N021909	003	Jan 24, 2011	Jan	NEWA
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TABLET; ORAL

ALLEGRA ALLERGY

	SANOFI AVENTIS US	60MG	N020872	007	Jan 24, 2011	Jan	NEWA
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+		180MG	N020872	010	Jan 24, 2011	Jan	NEWA
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ALLEGRA HIVES

	SANOFI AVENTIS US	60MG	N020872	008	Jan 24, 2011	Jan	NEWA
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+		180MG	N020872	009	Jan 24, 2011	Jan	NEWA
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CHILDREN'S ALLEGRA ALLERGY

	SANOFI AVENTIS US	30MG	N020872	005	Jan 24, 2011	Jan	NEWA
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CHILDREN'S ALLEGRA HIVES

	SANOFI AVENTIS US	30MG	N020872	006	Jan 24, 2011	Jan	NEWA
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FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

ALLEGRA-D 12 HOUR ALLERGY AND CONGESTION

+	SANOFI AVENTIS US	60MG;120MG	N020786	002	Jan 24, 2011	Jan	NEWA
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ALLEGRA-D 24 HOUR ALLERGY AND CONGESTION

+	SANOFI AVENTIS US	180MG;240MG	N021704	002	Jan 24, 2011	Jan	NEWA
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IBUPROFEN

TABLET; ORAL

IBUPROFEN

	MARKSANS PHARMA	200MG	A091237	001	Feb 08, 2011	Jan	NEWA
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		200MG	A091239	001	Feb 01, 2011	Jan	NEWA
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	MERRO PHARM	200MG	A070985	001	Oct 02, 1987	Jan	CAHN
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INSULIN SUSP ISOPHANE RECOMBINANT HUMAN

INJECTABLE; INJECTION

NOVOLIN N

+	NOVO NORDISK INC	100 UNITS/ML	N019959	001	Jul 01, 1991	Jan	CRLD
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LEVONORGESTREL

TABLET; ORAL

PLAN B

>D>	+	DURAMED	0.75MG	N021045	002	Aug 24, 2006	Feb	CAHN
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>A>	+	TEVA WOMENS	0.75MG	N021045	002	Aug 24, 2006	Feb	CAHN
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NAPROXEN SODIUM

TABLET; ORAL

NAPROXEN SODIUM

>A>	MARKSANS PHARMA	EQ 200MG BASE	A090545 001	Mar 16, 2011	Feb	NEWA
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RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE HYDROCHLORIDE

>D>	GENPHARM	EQ 75MG BASE	A075497 001	Jan 14, 2000	Feb	CAHN
>A>	MYLAN	EQ 75MG BASE	A075497 001	Jan 14, 2000	Feb	CAHN

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

**CUMULATIVE SUPPLEMENT NUMBER 2 FEBRUARY 2011**

NO FEBRUARY 2011 APPROVALS

## ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

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

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



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

NO FEBRUARY 2011 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2011

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>						
N021753 001	7868044	Mar 12, 2023	U-1078			
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO</u>						
N022545 001					NCE	Mar 05, 2012
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO</u>						
N022545 002					NCE	Mar 05, 2012
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO</u>						
N022545 003					NCE	Mar 05, 2012
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE - TEKAMLO</u>						
N022545 004					NCE	Mar 05, 2012
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>						
N200045 001	5559111	Jul 21, 2018	DS DP U-3		NCE	Mar 05, 2012
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>						
N200045 002	5559111	Jul 21, 2018	DS DP U-3		NCE	Mar 05, 2012
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>						
N200045 003	5559111	Jul 21, 2018	DS DP U-3		NCE	Mar 05, 2012
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>						
N200045 004	5559111	Jul 21, 2018	DS DP U-3		NCE	Mar 05, 2012
<u>ALISKIREN HEMIFUMARATE; AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE - AMTURNIDE</u>						
N200045 005	5559111	Jul 21, 2018	DS DP U-3		NCE	Mar 05, 2012
<u>ALVIMOPAN - ENTEREG</u>						
N021775 001	>A> 5250542	Mar 29, 2016	DS DP U-878			
<u>AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE - AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE</u>						
A078381 005					PC	Jul 02, 2011
<u>AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE - AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE</u>						
A078381 006					PC	Jul 02, 2011
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 10</u>						
N021303 001	>A> RE42096	Oct 21, 2018	DP			
	>A> RE42096*PED	Apr 21, 2019				
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 15</u>						
N021303 006	>A> RE42096	Oct 21, 2018	DP			
	>A> RE42096*PED	Apr 21, 2019				
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 20</u>						
N021303 002	>A> RE42096	Oct 21, 2018	DP			
	>A> RE42096*PED	Apr 21, 2019				
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 25</u>						
N021303 004	>A> RE42096	Oct 21, 2018	DP			
	>A> RE42096*PED	Apr 21, 2019				

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2011

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 30</u>						
N021303 003	>A> RE42096	Oct 21, 2018	DP			
	>A> RE42096*PED	Apr 21, 2019				
<u>AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE - ADDERALL XR 5</u>						
N021303 005	>A> RE42096	Oct 21, 2018	DP			
	>A> RE42096*PED	Apr 21, 2019				
<u>ARIPIPIRAZOLE - ABILIFY</u>						
N021436 001					>A> I-633	Feb 16, 2014
<u>ARIPIPIRAZOLE - ABILIFY</u>						
N021436 002					>A> I-633	Feb 16, 2014
<u>ARIPIPIRAZOLE - ABILIFY</u>						
N021436 003					>A> I-633	Feb 16, 2014
<u>ARIPIPIRAZOLE - ABILIFY</u>						
N021436 004					>A> I-633	Feb 16, 2014
<u>ARIPIPIRAZOLE - ABILIFY</u>						
N021436 005					>A> I-633	Feb 16, 2014
<u>ARIPIPIRAZOLE - ABILIFY</u>						
N021436 006					>A> I-633	Feb 16, 2014
<u>ARIPIPIRAZOLE - ABILIFY</u>						
N021713 001					>A> I-633	Feb 16, 2014
<u>ARIPIPIRAZOLE - ABILIFY</u>						
N021729 002					>A> I-633	Feb 16, 2014
<u>ARIPIPIRAZOLE - ABILIFY</u>						
N021729 003					>A> I-633	Feb 16, 2014
<u>ARIPIPIRAZOLE - ABILIFY</u>						
N021866 001					>A> I-633	Feb 16, 2014
<u>ATAZANAVIR SULFATE - REYATAZ</u>						
N021567 001					D-130	Feb 04, 2014
<u>ATAZANAVIR SULFATE - REYATAZ</u>						
N021567 002					D-130	Feb 04, 2014
<u>ATAZANAVIR SULFATE - REYATAZ</u>						
N021567 003					D-130	Feb 04, 2014
<u>ATAZANAVIR SULFATE - REYATAZ</u>						
N021567 004					D-130	Feb 04, 2014
<u>AZILSARTAN MEDOXOMIL - EDARBI</u>						
N200796 001	>A> 5583141	Dec 10, 2013	DS DP U-3		>A> NCE	Feb 25, 2016
	>A> 5736555	Jun 25, 2012	DS DP U-3			
	>A> 5958961	Jun 06, 2014	DP U-3			
	>A> 7157584	May 22, 2025	DS			
	>A> 7572920	Jan 07, 2025	DP U-3			

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2011

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>AZILSARTAN MEDOXOMIL - EDARBI</u>						
N200796 002	>A> 5583141	Dec 10, 2013	DS DP U-3		>A> NCE	Feb 25, 2016
	>A> 5736555	Jun 25, 2012	DS DP U-3			
	>A> 5958961	Jun 06, 2014	DP U-3			
	>A> 7157584	May 22, 2025	DS			
	>A> 7572920	Jan 07, 2025	DP U-3			
<u>AZITHROMYCIN - ZMAX</u>						
N050797 001	>A> 7887844	Feb 14, 2024	DP			
<u>CELECOXIB - CELEBREX</u>						
N020998 001	>A> 5760068	Jun 02, 2015	U-672			
<u>CELECOXIB - CELEBREX</u>						
N020998 002	>A> 5760068	Jun 02, 2015	U-672			
<u>CELECOXIB - CELEBREX</u>						
N020998 003	>A> 5760068	Jun 02, 2015	U-672			
<u>CINACALCET HYDROCHLORIDE - SENSIPAR</u>						
N021688 001					>A> I-634 >A> M-101	Feb 25, 2014 Feb 25, 2014
<u>CINACALCET HYDROCHLORIDE - SENSIPAR</u>						
N021688 002					>A> I-634 >A> M-101	Feb 25, 2014 Feb 25, 2014
<u>CINACALCET HYDROCHLORIDE - SENSIPAR</u>						
N021688 003					>A> I-634 >A> M-101	Feb 25, 2014 Feb 25, 2014
<u>CLOPIDOGREL BISULFATE - PLAVIX</u>						
N020839 001	4847265	Nov 17, 2011	DS DP			
	4847265*PED	May 17, 2012				
	5576328	Jan 31, 2014	U-432	Y		
	5576328*PED	Jul 31, 2014				
	6429210	Jun 10, 2019	DS DP			
	6429210*PED	Dec 10, 2019				
	6504030	Jun 10, 2019	DS			
	6504030*PED	Dec 10, 2019				
<u>CLOPIDOGREL BISULFATE - PLAVIX</u>						
N020839 002	4847265	Nov 17, 2011	DS DP			
	4847265*PED	May 17, 2012				
	6429210	Jun 10, 2019	DS DP			
	6429210*PED	Dec 10, 2019				
	6504030	Jun 10, 2019	DS			
	6504030*PED	Dec 10, 2019				
<u>DESIRUDIN RECOMBINANT - IPRIVASK</u>						
N021271 001	6103515	Aug 15, 2017	DS			
<u>DICLOFENAC POTASSIUM - ZIPSOR</u>						
N022202 001	>A> 7884095	Feb 24, 2029	U-1111			
	>A> 7884095*PED	Aug 24, 2029				
<u>DORIPENEM - DORIBAX</u>						
N022106 001	>A> 5317016	Jun 05, 2015	DS DP U-282			

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2011

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<u>DORIPENEM - DORIBAX</u>						
N022106 002	>A> 5317016	Jun 05, 2015	DS DP U-282			
<u>DROSPIRENONE; ETHINYL ESTRADIOL; LEVOMEFOLATE CALCIUM - SAFYRAL</u>						
N022574 001	5798338	Jul 10, 2015	DP			
	6441168	Apr 17, 2020	DS			
	6958326	Dec 20, 2021	DP			
	7163931	Mar 03, 2022	U-1			
<u>ESOMEPRAZOLE MAGNESIUM; NAPROXEN - VIMOVO</u>						
N022511 001	>A> 5714504	Feb 03, 2015	DP U-1053			
	>A> 5714504*PED	Aug 03, 2015				
	>A> 5900424	May 04, 2016	DS U-1053			
	>A> 5900424*PED	Nov 04, 2016				
	>A> 6369085	May 25, 2018	DS DP U-1053			
	>A> 6369085*PED	Nov 25, 2018				
	>A> 6875872	May 27, 2014	DS			
	>A> 6875872*PED	Nov 27, 2014				
	>A> 7411070	May 25, 2018	DS U-1053			
	>A> 7411070*PED	Nov 25, 2018				
<u>ESOMEPRAZOLE MAGNESIUM; NAPROXEN - VIMOVO</u>						
N022511 002	>A> 5714504	Feb 03, 2015	DP U-1053			
	>A> 5714504*PED	Aug 03, 2015				
	>A> 5900424	May 04, 2016	DS U-1053			
	>A> 5900424*PED	Nov 04, 2016				
	>A> 6369085	May 25, 2018	DS DP U-1053			
	>A> 6369085*PED	Nov 25, 2018				
	>A> 6875872	May 27, 2014	DS			
	>A> 6875872*PED	Nov 27, 2014				
	>A> 7411070	May 25, 2018	DS U-1053			
	>A> 7411070*PED	Nov 25, 2018				
<u>ETHINYL ESTRADIOL; LEVONORGESTREL - LOSEASONIQUE</u>						
N022262 001	7858605	Jun 23, 2023	DP			
<u>ETHINYL ESTRADIOL; LEVONORGESTREL - SEASONIQUE</u>						
N021840 001	7858605	Jun 23, 2023	DP			
<u>ETHINYL ESTRADIOL; NORETHINDRONE - NORETHINDRONE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE</u>						
N022573 001	5552394	Jul 22, 2014	U-828			
	6667050	Apr 06, 2019	DP U-828			
<u>ETRAVIRINE - INTELENCE</u>						
N022187 001	>A> 7887845	Mar 25, 2019	DP			
<u>ETRAVIRINE - INTELENCE</u>						
N022187 002	6878717	Nov 05, 2019	U-1016		NCE	Jan 18, 2013
	7037917	Nov 05, 2019	DS DP U-1016			
	>A> 7887845	Mar 25, 2019	DP			
<u>EXENATIDE SYNTHETIC - BYETTA</u>						
N021773 001	5424286	Dec 01, 2016	U-653			
	5424286	Dec 01, 2016	U-1108			

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>EXENATIDE SYNTHETIC - BYETTA</u>						
N021773 002	5424286	Dec 01, 2016	U-653			
	5424286	Dec 01, 2016	U-1108			
<u>FAMCICLOVIR - FAMVIR</u>						
N020363 001					M-98	Jan 31, 2014
<u>FAMCICLOVIR - FAMVIR</u>						
N020363 002					M-98	Jan 31, 2014
<u>FAMCICLOVIR - FAMVIR</u>						
N020363 003					M-98	Jan 31, 2014
<u>FENOFIBRATE - ANTARA (MICRONIZED)</u>						
N021695 001	7863331	Aug 08, 2020	U-1107			
	7863331	Aug 08, 2020	U-1106			
<u>FENOFIBRATE - ANTARA (MICRONIZED)</u>						
N021695 003	>A> 7863331	Aug 08, 2020	U-1107			
	>A> 7863331	Aug 08, 2020	U-1106			
<u>FENTANYL CITRATE - ABSTRAL</u>						
N022510 001	>A> 6759059	Sep 24, 2019	DP U-767			
	>A> 6761910	Sep 24, 2019	DP U-767			
<u>FENTANYL CITRATE - ABSTRAL</u>						
N022510 002	>A> 6759059	Sep 24, 2019	DP U-767			
	>A> 6761910	Sep 24, 2019	DP U-767			
<u>FENTANYL CITRATE - ABSTRAL</u>						
N022510 003	>A> 6759059	Sep 24, 2019	DP U-767			
	>A> 6761910	Sep 24, 2019	DP U-767			
<u>FENTANYL CITRATE - ABSTRAL</u>						
N022510 004	>A> 6759059	Sep 24, 2019	DP U-767			
	>A> 6761910	Sep 24, 2019	DP U-767			
<u>FENTANYL CITRATE - ABSTRAL</u>						
N022510 005	>A> 6759059	Sep 24, 2019	DP U-767			
	>A> 6761910	Sep 24, 2019	DP U-767			
<u>FENTANYL CITRATE - ABSTRAL</u>						
N022510 006	>A> 6759059	Sep 24, 2019	DP U-767			
	>A> 6761910	Sep 24, 2019	DP U-767			
<u>FERUMOXYTOL - FERAHEME</u>						
N022180 001	7871597	Mar 08, 2020	DS DP			
<u>FESOTERODINE FUMARATE - TOVIAZ</u>						
N022030 001	7855230	May 11, 2019	U-913			
<u>FESOTERODINE FUMARATE - TOVIAZ</u>						
N022030 002	7855230	May 11, 2019	U-913			
<u>FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE</u>						
A079043 001					PC	Jul 27, 2011

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2011

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>FULVESTRANT - FASLODEX</u>						
N021344 001	6774122	Jan 09, 2021	U-596		D-126	Sep 09, 2013
	6774122*PED	Jul 09, 2021			PED	Mar 09, 2014
	7456160	Jan 09, 2021	U-596			
	7456160*PED	Jul 09, 2021				
<u>GABAPENTIN - GABAPENTIN</u>						
A078974 001					>A> PC	Aug 22, 2011
<u>GABAPENTIN - GRALISE</u>						
N022544 001					NP	Jan 28, 2014
<u>GABAPENTIN - GRALISE</u>						
N022544 002					NP	Jan 28, 2014
<u>GEMCITABINE HYDROCHLORIDE - GEMCITABINE</u>						
A079183 001					PC	May 14, 2011
<u>GEMCITABINE HYDROCHLORIDE - GEMCITABINE HYDROCHLORIDE</u>						
A077983 001					PC	Jul 24, 2011
<u>GEMCITABINE HYDROCHLORIDE - GEMCITABINE HYDROCHLORIDE</u>						
A077983 002					PC	Jul 24, 2011
<u>GUANFACINE HYDROCHLORIDE - INTUNIV</u>						
N022037 001					>A> I-635	Feb 25, 2014
<u>GUANFACINE HYDROCHLORIDE - INTUNIV</u>						
N022037 002					>A> I-635	Feb 25, 2014
<u>GUANFACINE HYDROCHLORIDE - INTUNIV</u>						
N022037 003					>A> I-635	Feb 25, 2014
<u>GUANFACINE HYDROCHLORIDE - INTUNIV</u>						
N022037 004					>A> I-635	Feb 25, 2014
<u>HYDROXYPROGESTERONE CAPROATE - MAKENA</u>						
N021945 001					>A> ODE	Feb 03, 2018
<u>IOFLUPANE I-123 - DATSCAN</u>						
N022454 001					NCE	Jan 14, 2016
<u>LANREOTIDE ACETATE - SOMATULINE DEPOT</u>						
N022074 001	5595760	Mar 08, 2020	DP U-831		>A> D-131	Mar 04, 2014
<u>LANREOTIDE ACETATE - SOMATULINE DEPOT</u>						
N022074 002	5595760	Mar 08, 2020	DP U-831		>A> D-131	Mar 04, 2014
<u>LANREOTIDE ACETATE - SOMATULINE DEPOT</u>						
N022074 003	5595760	Mar 08, 2020	DP U-831		>A> D-131	Mar 04, 2014
<u>LANSOPRAZOLE - PREVACID</u>						
N021428 001	>A> 7875292	May 17, 2019	DP			
	>A> 7875292*PED	Nov 17, 2019				
<u>LANSOPRAZOLE - PREVACID</u>						
N021428 002	>A> 7875292	May 17, 2019	DP			
	>A> 7875292*PED	Nov 17, 2019				
<u>LENALIDOMIDE - REVLIMID</u>						
N021880 001	7855217	Nov 24, 2024	DS DP			

## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2011

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>LENALIDOMIDE - REVLIMID</u>						
N021880 002	7855217	Nov 24, 2024	DS DP			
<u>LENALIDOMIDE - REVLIMID</u>						
N021880 004	7855217	Nov 24, 2024	DS DP			
<u>METRONIDAZOLE - VANDAZOLE</u>						
N021806 001	7456207	Sep 22, 2024	DP			
<u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>						
N022256 001	>A> 7888342	Nov 05, 2021		U-882		
<u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>						
N022256 002	>A> 7888342	Nov 05, 2021		U-882		
<u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>						
N022256 003	>A> 7888342	Nov 05, 2021		U-882		
<u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u>						
N022256 004	>A> 7888342	Nov 05, 2021		U-882		
<u>MOMETASONE FUROATE MONOHYDRATE - NASONEX</u>						
N020762 001					M-99	Jan 19, 2014
<u>PERFLUTREN - DEFINITY</u>						
N021064 001	5585112	Dec 17, 2013	DP			
<u>PLERIXAFOR - MOZOBIL</u>						
N022311 001	>A> RE42152	Dec 10, 2013	DP			
<u>RALTEGRAVIR POTASSIUM - ISENTRESS</u>						
N022145 001	>A> 7169780	Oct 03, 2023	DS DP			
<u>RETAPAMULIN - ALTABAX</u>						
N022055 001	7875630	Feb 14, 2027	DS			
	>A> RE39128	Apr 12, 2021	DS DP U-805			
<u>ROFLUMILAST - DALIRESP</u>						
N022522 001					>A> NCE	Feb 28, 2016
<u>SODIUM NITRITE; SODIUM THIOSULFATE - NITHIODOTE</u>						
N201444 001					>A> ODE	Jan 14, 2018
<u>SODIUM OXYBATE - XYREM</u>						
N021196 001	>A> 7668730	Jun 16, 2024		U-1110		
	>A> 7895059	Dec 17, 2022		U-1110		
<u>SPINOSAD - NATROBA</u>						
N022408 001	5496931	Mar 05, 2013	DS	U-1105	NCE	Jan 18, 2016
	6063771	Jun 22, 2019		DP U-1105		
	6342482	Jun 22, 2019		DP U-1105		
	7030095	Jul 02, 2021		DP U-1105		
<u>SUMATRIPTAN SUCCINATE - SUMAVEL DOSEPRO</u>						
N022239 001	>A> 7776007	Apr 09, 2025	DP			
<u>TELBIVUDINE - TYZEKA</u>						
N022011 001	>A> 7858594	Sep 11, 2023	DS DP U-999			



## PATENT &amp; EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 2 - February 2011

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>THALIDOMIDE - THALOMID</u>						
N020785 001	7874984	Aug 28, 2018	U-733			
	7874984	Aug 28, 2018	U-732			
	7874984	Aug 28, 2018	U-442			
	7874984	Aug 28, 2018	U-371			
	7874984	Aug 28, 2018	U-1109			
<u>THALIDOMIDE - THALOMID</u>						
N020785 002	7874984	Aug 28, 2018	U-733			
	7874984	Aug 28, 2018	U-732			
	7874984	Aug 28, 2018	U-442			
	7874984	Aug 28, 2018	U-371			
	7874984	Aug 28, 2018	U-1109			
<u>THALIDOMIDE - THALOMID</u>						
N020785 003	7874984	Aug 28, 2018	U-733			
	7874984	Aug 28, 2018	U-732			
	7874984	Aug 28, 2018	U-442			
	7874984	Aug 28, 2018	U-371			
	7874984	Aug 28, 2018	U-1109			
<u>THALIDOMIDE - THALOMID</u>						
N020785 004	7874984	Aug 28, 2018	U-733			
	7874984	Aug 28, 2018	U-732			
	7874984	Aug 28, 2018	U-442			
	7874984	Aug 28, 2018	U-371			
	7874984	Aug 28, 2018	U-1109			
<u>TIGECYCLINE - TYGACIL</u>						
N021821 001	7879828	Feb 05, 2029	DP			
<u>VILAZODONE HYDROCHLORIDE - VIIBRYD</u>						
N022567 001	5532241	Sep 29, 2014	DS DP		NCE	Jan 21, 2016
	7834020	Jun 05, 2022	DS DP U-839			
<u>VILAZODONE HYDROCHLORIDE - VIIBRYD</u>						
N022567 002	5532241	Sep 29, 2014	DS DP		NCE	Jan 21, 2016
	7834020	Jun 05, 2022	DS DP U-839			
<u>VILAZODONE HYDROCHLORIDE - VIIBRYD</u>						
N022567 003	5532241	Sep 29, 2014	DS DP		NCE	Jan 21, 2016
	7834020	Jun 05, 2022	DS DP U-839			
<u>ZOLPIDEM TARTRATE - ZOLPIDEM TARTRATE</u>						
A078148 001					PC	Jun 04, 2011

## 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, 31<sup>st</sup> Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

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