

# **APPROVED DRUG PRODUCTS**

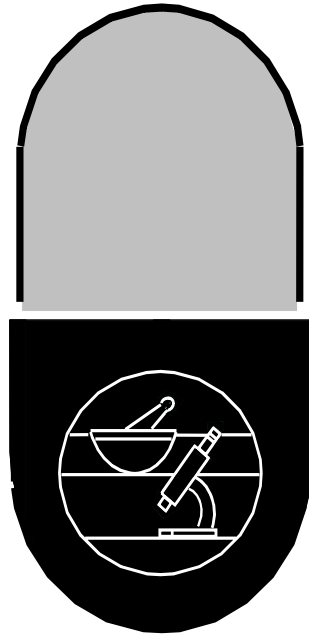
## **With Therapeutic Equivalence Evaluations**



**The "Orange Book"**

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**CUMULATIVE  
SUPPLEMENT 3  
MARCH 2005**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**25<sup>th</sup> EDITION**

**Department of Health and Human Services**

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

2005

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

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**25<sup>th</sup> EDITION**

**Cumulative Supplement 3**

**March 2005**

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**CUMULATIVE SUPPLEMENT 3  
March 2005**

**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, 25th 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 25th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 26th 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 Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> 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 Lists are arranged in alphabetical order by active ingredient name. In addition, the trade name will be displayed to the right of the active ingredient name for each product. 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 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>
FUJISAWA HEALTHCARE (FUJISAWA HLTHCARE)	ASTELLAS PHARMA US INC (ASTELLAS)
SHIRE LABORATORIES INC (SHIRE LABS)	SHIRE DEVELOPMENT INC (SHIRE)
SHIRE PHARMACEUTICAL DEVELOPMENT INC (SHIRE PHARM)	SHIRE DEVELOPMENT INC (SHIRE)
YAMANOUCHI PHARMA AMERICA INC (YAMANOUCHI)	ASTELLAS PHARMA US INC (ASTELLAS)

### 1.3 AVAILABILITY OF THE EDITION

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements will not be available in a published paper version. Since 1997, the Electronic Orange Book (EOB) <http://www.fda.gov/cder/ob/default.htm>, has been available on the internet and has become the updated-every-month Orange Book.

By April, the 25th edition and current monthly supplement will be available in an electronic downloadable Portable Document Format (PDF) at the EOB home page by clicking on the EOB Preface. The PDF annual and cumulative supplements will duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

The Electronic Orange Book Query (EOB) is at <http://www.fda.gov/cder/ob/default.htm>. 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. Currently, In addition to monthly updates, in the public interest, the EOB is updated on a daily basis with new generic product approval information and new patent information. Current month updates are accomplished by the third week of the following month.

There are historical lists of Orange Book cumulative supplement product monthly changes at <http://www.fda.gov/cder/rxotcdpl/pdplarchive.htm>

There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at <http://www.fda.gov/cder/orange/obreadme.htm>. The drug product text files are zipped into eobzip.exe. The files are updated concurrently with the monthly cumulative supplements. Appendix A and Appendix B text files of the annual Orange Book Edition 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>.

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

## DESCRIPTION OF REPORT

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

The baseline column (Dec 2004) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

## DEFINITIONS

### Drug Product

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

### New Molecular Entity

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

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

<u>CATEGORIES COUNTED</u>	<u>DEC 2004</u>	<u>MAR 2005</u>	<u>JUN 2005</u>	<u>SEP 2005</u>
DRUG PRODUCTS LISTED	11082	11184		
SINGLE SOURCE	2427 (21.9%)	2437 (21.8%)		
MULTISOURCE	8547 (77.1%)	8637 (77.2%)		
THERAPEUTICALLY EQUIVALENT	8327 (75.1%)	8428 (75.4%)		
NOT THERAPEUTICALLY EQUIVALENT	220 (2.0%)	209 (1.9%)		
EXCEPTIONS <sup>1</sup>	108 (1.0%)	110 (1.0%)		
NEW MOLECULAR ENTITIES				
APPROVED	9	2		
NUMBER OF APPLICANTS	625	631		

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

## 1.5 CUMULATIVE SUPPLEMENT LEGEND

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



The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

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

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

The change code and description:

NEWA	New drug product approval usually in the supplement month.
CAHN	Applicant holder firm name has changed.
CAIN	Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name and all products will be added under the changed ingredient(s) name.
CDFR	Change. Dosage Form; Route of Administration.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status.
CMS1	Change. Miscellaneous addition to list.
CMS2	Change. Miscellaneous deletion from list.
CPOT	Change. Potency amount/unit.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
CTNA	Change. Trade Name.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.
WDAG	Withdrawn. The applicant holder has notified the FDA in writing that the product is no longer being marketed resulting in the product approval being withdrawn by mutual agreement. The product will be listed in the Discontinued Section.
WDRP	Withdrawn. The application approval has been withdrawn for failure to provide Annual Reports. The product will be moved to the Discontinued Section in the next edition.

PRESCRIPTION DRUG PRODUCT LIST - 25TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2005

1-1

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, APAP, AND CAFFEINE

AB WATSON LABS 325MG;50MG;40MG N89536 001 Feb 16, 1988 Feb CAHN

ACETAMINOPHEN; TRAMADOL HYDROCHLORIDE

TABLET; ORAL

ACETAMINOPHEN AND TRAMADOL HCL

>A> AB KALI LABS 325MG;37.5MG N76475 001 Apr 21, 2005 Mar NEWA

ULTRACET

>D> + ORTHO MCNEIL PHARM 325MG;37.5MG N21123 001 Aug 15, 2001 Mar CFTG

>A> AB + 325MG;37.5MG N21123 001 Aug 15, 2001 Mar CFTG

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC

ACETIC ACID

AT + MORTON GROVE 2% N40166 001 Jul 26, 1996 Jan CRLD

AT VINTAGE 2% N40607 001 Feb 24, 2005 Feb NEWA

VOSOL

@ MEDPOINTE PHARM HLC 2% N12179 001 Jan DISC

ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE; ORAL

SEMPREX-D

>D> + CELLTECH PHARMS 8MG;60MG N19806 001 Mar 25, 1994 Mar CAHN

>A> + UCB 8MG;60MG N19806 001 Mar 25, 1994 Mar CAHN

ACYCLOVIR

CAPSULE; ORAL

ACYCLOVIR

>D> AB COPLEY PHARM 200MG N74914 001 Nov 26, 1997 Mar CAHN

>A> AB TEVA PHARMS 200MG N74914 001 Nov 26, 1997 Mar CAHN

TABLET; ORAL

ACYCLOVIR

>D> AB COPLEY PHARM 400MG N75021 001 Mar 18, 1998 Mar CAHN

>D> AB 800MG N75021 002 Mar 18, 1998 Mar CAHN

>A> AB TEVA PHARMS 400MG N75021 001 Mar 18, 1998 Mar CAHN

>A> AB 800MG N75021 002 Mar 18, 1998 Mar CAHN

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ACYCLOVIR

@ ABBOTT EQ 50MG BASE/ML N75114 001 Jul 26, 1999 Feb DISC

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

AN + DEY EQ 0.083% BASE N72652 001 Feb 21, 1992 Jan CRLD

ALPRAZOLAM

TABLET, ORALLY DISINTEGRATING; ORAL

NIRAVAM

SCHWARZ PHARMA 0.25MG N21726 001 Jan 19, 2005 Jan NEWA

## TABLET, ORALLY DISINTEGRATING; ORAL

## NIRAVAM

		SCHWARZ PHARMA	0.5MG	N21726 002	Jan 19, 2005	Jan	NEWA
			1MG	N21726 003	Jan 19, 2005	Jan	NEWA
		+	2MG	N21726 004	Jan 19, 2005	Jan	NEWA

AMANTADINE HYDROCHLORIDE

## SYRUP; ORAL

## AMANTADINE HCL

>D>	AA	COPLEY PHARM	50MG/5ML	N73115 001	Aug 23, 1991	Mar	CAHN
>A>	AA	TEVA PHARMS	50MG/5ML	N73115 001	Aug 23, 1991	Mar	CAHN

AMINO ACIDS

## INJECTABLE; INJECTION

## AMINOSYN 7%

>D>		@ HOSPIRA	7% (7GM/100ML)	N17673 002		Mar	CMFD
>A>			7% (7GM/100ML)	N17673 002		Mar	CMFD

## AMINOSYN 8.5%

>D>		@ HOSPIRA	8.5% (8.5GM/100ML)	N17673 004		Mar	CMFD
>A>			8.5% (8.5GM/100ML)	N17673 004		Mar	CMFD

AMIODARONE

## INJECTABLE; INTRAVENOUS

## AMIODARONE HCL

>A>	AP	APOTEX	50MG/ML	N77161 001	Apr 20, 2005	Mar	NEWA
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AMIODARONE HYDROCHLORIDE

## INJECTABLE; INJECTION

## AMIODARONE HCL

>D>	AP	AM PHARM PARTNERS	50MG/ML	N75761 001	Oct 15, 2002	Mar	CRLD
>A>	AP	+	50MG/ML	N75761 001	Oct 15, 2002	Mar	CRLD
>D>	AP	APOTEX	50MG/ML	N76394 001	Apr 25, 2003	Mar	CRLD
>A>	AP	+	50MG/ML	N76394 001	Apr 25, 2003	Mar	CRLD
>D>	AP	BEDFORD	50MG/ML	N76018 001	Oct 15, 2002	Mar	CRLD
>A>	AP	+	50MG/ML	N76018 001	Oct 15, 2002	Mar	CRLD
>D>	AP	BEDFORD LABS	50MG/ML	N76299 001	Oct 24, 2002	Mar	CRLD
>A>	AP	+	50MG/ML	N76299 001	Oct 24, 2002	Mar	CRLD
>D>	AP	BEN VENUE	50MG/ML	N76088 001	Oct 15, 2002	Mar	CRLD
>A>	AP	+	50MG/ML	N76088 001	Oct 15, 2002	Mar	CRLD
>D>	AP	BIONICHE (CANADA)	50MG/ML	N76217 001	Oct 15, 2002	Mar	CRLD
>A>	AP	+	50MG/ML	N76217 001	Oct 15, 2002	Mar	CRLD
>D>	AP	MAYNE PHARMA USA	50MG/ML	N76108 001	Oct 15, 2002	Mar	CRLD
>A>	AP	+	50MG/ML	N76108 001	Oct 15, 2002	Mar	CRLD
>D>	AP	SICOR PHARMS	50MG/ML	N76163 001	Sep 05, 2003	Mar	CRLD
>A>	AP	+	50MG/ML	N76163 001	Sep 05, 2003	Mar	CRLD

## TABLET; ORAL

## AMIODARONE HCL

>A>	AB	AUROSAL PHARMS	200MG	N77069 001	Apr 08, 2005	Mar	NEWA
>A>	AB		400MG	N77069 002	Apr 08, 2005	Mar	NEWA
>D>	AB	COPLEY PHARM	200MG	N74739 001	Nov 30, 1998	Mar	CAHN
>D>		TARO	100MG	N75424 002	Dec 18, 2002	Mar	CTEC
>A>	AB		100MG	N75424 002	Dec 18, 2002	Mar	CTEC
>A>	AB	TEVA PHARMS	200MG	N74739 001	Nov 30, 1998	Mar	CAHN
		PACERONE					
>A>	AB	UPSHER SMITH	100MG	N75135 002	Apr 12, 2005	Mar	NEWA

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

AB	HIKMA PHARMS	200MG/5ML;EQ 28.5MG BASE/5ML	N65191 002	Jan 25, 2005	Jan	NEWA
AB		400MG/5ML;EQ 57MG BASE/5ML	N65191 001	Jan 25, 2005	Jan	NEWA

TABLET, CHEWABLE; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

AB	TEVA	200MG;EQ 28.5MG BASE	N65205 001	Feb 09, 2005	Jan	NEWA
AB		400MG;EQ 57MG BASE	N65205 002	Feb 09, 2005	Jan	NEWA

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

AP	INSTITUTO BIOCHEMICO	EQ 125MG BASE/VIAL	N62797 001	Jul 12, 1993	Jan	CMFD
AP		EQ 2GM BASE/VIAL	N62797 002	Jul 12, 1993	Jan	CAHN

ANAGRELIDE HYDROCHLORIDE

CAPSULE; ORAL

AGRYLIN

>D>	SHIRE	EQ 0.5MG BASE	N20333 001	Mar 14, 1997	Mar	CFTG	
>A>	AB	EQ 0.5MG BASE	N20333 001	Mar 14, 1997	Mar	CFTG	
>D>	+	EQ 1MG BASE	N20333 002	Mar 14, 1997	Mar	CFTG	
>A>	AB	EQ 1MG BASE	N20333 002	Mar 14, 1997	Mar	CFTG	
>A>	ANAGRELIDE HCL						
>A>	AB	BARR	EQ 0.5MG BASE	N76530 001	Apr 18, 2005	Mar	NEWA
>A>	AB		EQ 1MG BASE	N76530 002	Apr 18, 2005	Mar	NEWA
>A>	AB	EON	EQ 0.5MG BASE	N76683 001	Apr 18, 2005	Mar	NEWA
>A>	AB		EQ 1MG BASE	N76683 002	Apr 18, 2005	Mar	NEWA
>A>	AB	IMPAX LABS	EQ 0.5MG BASE	N76910 001	Apr 18, 2005	Mar	NEWA
>A>	AB		EQ 1MG BASE	N76910 002	Apr 18, 2005	Mar	NEWA
>A>	AB	IVAX PHARMS	EQ 0.5MG BASE	N76468 001	Apr 18, 2005	Mar	NEWA
>A>	AB		EQ 1MG BASE	N76468 002	Apr 18, 2005	Mar	NEWA
>A>	AB	MYLAN	EQ 0.5MG BASE	N76811 001	Apr 18, 2005	Mar	NEWA
>A>	AB		EQ 1MG BASE	N76811 002	Apr 18, 2005	Mar	NEWA
>A>	AB	ROXANE	EQ 0.5MG BASE	N76489 001	Apr 18, 2005	Mar	NEWA
>A>	AB		EQ 1MG BASE	N76489 002	Apr 18, 2005	Mar	NEWA
>A>	AB	WATSON LABS	EQ 0.5MG BASE	N76417 001	Apr 18, 2005	Mar	NEWA
>A>	AB		EQ 1MG BASE	N76417 002	Apr 18, 2005	Mar	NEWA

ATENOLOL

TABLET; ORAL

ATENOLOL

>D>	AB	COPLEY PHARM	50MG	N74120 001	Feb 24, 1995	Mar	CAHN
>D>	AB		100MG	N74120 002	Feb 24, 1995	Mar	CAHN
>D>		MYLAN	25MG	N73457 002	Apr 26, 1999	Mar	CTEC
>A>	AB		25MG	N73457 002	Apr 26, 1999	Mar	CTEC
>A>	AB	TEVA PHARMS	50MG	N74120 001	Feb 24, 1995	Mar	CAHN
>A>	AB		100MG	N74120 002	Feb 24, 1995	Mar	CAHN
	AB	ZYDUS PHARMS USA	25MG	N76900 001	Jan 28, 2005	Jan	NEWA
	AB		50MG	N76900 002	Jan 28, 2005	Jan	NEWA
	AB		100MG	N76900 003	Jan 28, 2005	Jan	NEWA

ATOMOXETINE HYDROCHLORIDE

CAPSULE; ORAL

STRATTERA

LILLY

80MG

N21411 007 Feb 14, 2005 Feb NEWA

100MG

N21411 008 Feb 14, 2005 Feb NEWA

>D> BENZYL PENICILLOYL-POLYLYSINE

&gt;D&gt; INJECTABLE; INJECTION

&gt;D&gt; PRE-PEN

&gt;D&gt; + HOLLISTER STIER LABS 60UMOLAR

N50114 001 Mar DISC

&gt;A&gt; @ 60UMOLAR

N50114 001 Mar DISC

BETAMETHASONE DIPROPIONATE

LOTION; TOPICAL

BETAMETHASONE DIPROPIONATE

&gt;D&gt; AB COPLEY PHARM EQ 0.05% BASE

N71882 001 Jun 06, 1988 Mar CAHN

&gt;A&gt; AB TEVA PHARMS EQ 0.05% BASE

N71882 001 Jun 06, 1988 Mar CAHN

OINTMENT; TOPICAL

ALPHATREX

@ SAVAGE LABS

EQ 0.05% BASE

N19143 001 Sep 04, 1984 Jan DISC

BETAMETHASONE VALERATE

LOTION; TOPICAL

BETAMETHASONE VALERATE

&gt;D&gt; AB COPLEY PHARM EQ 0.1% BASE

N71883 001 Apr 22, 1988 Mar CAHN

&gt;A&gt; AB TEVA PHARMS EQ 0.1% BASE

N71883 001 Apr 22, 1988 Mar CAHN

BISOPROLOL FUMARATE

TABLET; ORAL

BISOPROLOL FUMARATE

&gt;D&gt; AB COPLEY PHARM 5MG

N75644 001 Jun 26, 2001 Mar CAHN

&gt;D&gt; AB 10MG

N75644 002 Jun 26, 2001 Mar CAHN

&gt;A&gt; AB TEVA PHARMS 5MG

N75644 001 Jun 26, 2001 Mar CAHN

&gt;A&gt; AB 10MG

N75644 002 Jun 26, 2001 Mar CAHN

>A> BROMFENAC SODIUM

&gt;A&gt; SOLUTION/DROPS; OPHTHALMIC

&gt;A&gt; XIBROM

&gt;A&gt; + ISTA PHARMS 0.09%

N21664 001 Mar 24, 2005 Mar NEWA

BROMOCRIPTINE MESYLATE

CAPSULE; ORAL

BROMOCRIPTINE MESYLATE

&gt;A&gt; AB MYLAN EQ 5MG BASE

N77226 001 Apr 04, 2005 Mar NEWA

PARLODEL

&gt;D&gt; + NOVARTIS EQ 5MG BASE

N17962 002 Mar 01, 1982 Mar CTEC

&gt;A&gt; AB + EQ 5MG BASE

N17962 002 Mar 01, 1982 Mar CTEC

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

BUPRENORPHINE HCL

AP BEDFORD

EQ 0.3MG BASE/ML

N76931 001 Mar 02, 2005 Feb NEWA

CAFFEINE; ERGOTAMINE TARTRATE

SUPPOSITORY; RECTAL  
MIGERGOT

BR G AND W LABS 100MG;2MG N86557 001 Oct 04, 1983 Feb CMFD

CAPTOPRIL

TABLET; ORAL  
CAPTOPRIL

>D> AB COPLEY PHARM 12.5MG N74462 001 Feb 13, 1996 Mar CAHN  
>D> AB 25MG N74462 002 Feb 13, 1996 Mar CAHN  
>D> AB 50MG N74462 003 Feb 13, 1996 Mar CAHN  
>D> AB 100MG N74462 004 Feb 13, 1996 Mar CAHN  
>A> AB TEVA PHARMS 12.5MG N74462 001 Feb 13, 1996 Mar CAHN  
>A> AB 25MG N74462 002 Feb 13, 1996 Mar CAHN  
>A> AB 50MG N74462 003 Feb 13, 1996 Mar CAHN  
>A> AB 100MG N74462 004 Feb 13, 1996 Mar CAHN

CARBAMAZEPINE

SUSPENSION; ORAL  
CARBAMAZEPINE

>D> AB TARO 100MG/5ML N75875 001 Dec 21, 2000 Mar DISC  
>A> @ 100MG/5ML N75875 001 Dec 21, 2000 Mar DISC

CARBOPLATIN

INJECTABLE; INJECTION  
CARBOPLATIN

>A> AP EON 50MG/VIAL N76959 001 Mar 18, 2005 Mar NEWA  
>A> AP 150MG/VIAL N76959 002 Mar 18, 2005 Mar NEWA  
>A> AP 450MG/VIAL N76959 003 Mar 18, 2005 Mar NEWA

CEFACLOR

CAPSULE; ORAL

>D> CECLOR  
>D> AB LILLY EQ 250MG BASE N50521 001 Mar DISC  
>A> @ EQ 250MG BASE N50521 001 Mar DISC  
>D> AB + EQ 500MG BASE N50521 002 Mar DISC  
>A> @ EQ 500MG BASE N50521 002 Mar DISC  
CEFACLOR  
>D> AB RANBAXY EQ 500MG BASE N64156 002 Aug 28, 1997 Mar CRLD  
>A> AB + EQ 500MG BASE N64156 002 Aug 28, 1997 Mar CRLD  
FOR SUSPENSION; ORAL  
CECLOR  
>D> AB + CEPH INTL EQ 375MG BASE/5ML N62206 004 Apr 20, 1988 Mar CRLD  
>A> AB EQ 375MG BASE/5ML N62206 004 Apr 20, 1988 Mar CRLD  
>D> AB LILLY EQ 125MG BASE/5ML N50522 001 Mar DISC  
>A> @ EQ 125MG BASE/5ML N50522 001 Mar DISC  
>D> AB + EQ 250MG BASE/5ML N50522 002 Mar DISC  
>A> @ EQ 250MG BASE/5ML N50522 002 Mar DISC  
CEFACLOR  
>D> AB RANBAXY EQ 375MG BASE/5ML N64155 001 Oct 02, 1997 Mar CRLD  
>A> AB + EQ 375MG BASE/5ML N64155 001 Oct 02, 1997 Mar CRLD

CEFAZOLIN SODIUM

INJECTABLE; INJECTION  
CEFAZOLIN SODIUM

>D>	AP	AM PHARM PARTNERS	EQ 500MG BASE/VIAL	N64169 001	Aug 14, 1998	Mar	CRLD
>A>	AP	+	EQ 500MG BASE/VIAL	N64169 001	Aug 14, 1998	Mar	CRLD
>D>	AP		EQ 1GM BASE/VIAL	N64169 002	Aug 14, 1998	Mar	CRLD
>A>	AP	+	EQ 1GM BASE/VIAL	N64169 002	Aug 14, 1998	Mar	CRLD
>D>	AP		EQ 10GM BASE/VIAL	N64170 001	Mar 18, 1998	Mar	CRLD
>A>	AP	+	EQ 10GM BASE/VIAL	N64170 001	Mar 18, 1998	Mar	CRLD

CEPHALEXIN

CAPSULE; ORAL  
CEPHALEXIN

>D>	AB	APOTHECON	EQ 250MG BASE	N63186 001	Dec 30, 1994	Mar	DISC
>A>		@	EQ 250MG BASE	N63186 001	Dec 30, 1994	Mar	DISC
>D>	AB		EQ 500MG BASE	N63186 002	Dec 30, 1994	Mar	DISC
>A>		@	EQ 500MG BASE	N63186 002	Dec 30, 1994	Mar	DISC
	AB	BELCHER	EQ 250MG BASE	N62713 001	Jul 15, 1988	Jan	CAHN
	AB		EQ 500MG BASE	N62713 002	Jul 15, 1988	Jan	CAHN
	AB	SUN PHARM INDS (IN)	EQ 250MG BASE	N62791 001	Jun 11, 1987	Jan	CAHN
	AB		EQ 500MG BASE	N62791 002	Jun 11, 1987	Jan	CAHN
	AB	YUNG SHIN PHARM	EQ 250MG BASE	N65152 001	Feb 24, 2005	Feb	NEWA
	AB		EQ 500MG BASE	N65152 002	Feb 24, 2005	Feb	NEWA

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL  
CODEPREX

>D>	+	CELLTECH PHARMS	EQ 4MG MALEATE/5ML;EQ 20MG BASE/5ML	N21369 001	Jun 21, 2004	Mar	CAHN
>A>	+	UCB	EQ 4MG MALEATE/5ML;EQ 20MG BASE/5ML	N21369 001	Jun 21, 2004	Mar	CAHN

CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL  
TUSSIONEX

>D>	+	CELLTECH PHARMS	EQ 8MG MALEATE/5ML;EQ 10MG BITARTRATE/5ML	N19111 001	Dec 31, 1987	Mar	CAHN
>A>	+	UCB	EQ 8MG MALEATE/5ML;EQ 10MG BITARTRATE/5ML	N19111 001	Dec 31, 1987	Mar	CAHN

CHOLESTYRAMINE

POWDER; ORAL  
CHOLESTYRAMINE

>D>	AB	COPLEY PHARM	EQ 4GM RESIN/PACKET	N74554 001	Oct 02, 1996	Mar	CAHN
>D>	AB		EQ 4GM RESIN/SCOOPFUL	N74554 002	Oct 02, 1996	Mar	CAHN
>A>	AB	TEVA PHARMS	EQ 4GM RESIN/PACKET	N74554 001	Oct 02, 1996	Mar	CAHN
>A>	AB		EQ 4GM RESIN/SCOOPFUL	N74554 002	Oct 02, 1996	Mar	CAHN
>D>	AB	COPLEY PHARM	EQ 4GM RESIN/PACKET	N74555 001	Sep 30, 1998	Mar	CAHN
>D>	AB		EQ 4GM RESIN/SCOOPFUL	N74555 002	Sep 30, 1998	Mar	CAHN
>A>	AB	TEVA PHARMS	EQ 4GM RESIN/PACKET	N74555 001	Sep 30, 1998	Mar	CAHN
>A>	AB		EQ 4GM RESIN/SCOOPFUL	N74555 002	Sep 30, 1998	Mar	CAHN

CICLOPIROX

CREAM; TOPICAL  
CICLOPIROX

>A>	AB	TARO	0.77%	N76790 001	Apr 12, 2005	Mar	NEWA
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CILOSTAZOL

TABLET; ORAL

CILOSTAZOL

AB	COREPHARMA	50MG	N77150 001	Mar 11, 2005	Feb	NEWA
AB	IVAX PHARMS	100MG	N77020 002	Mar 01, 2005	Feb	NEWA

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL

CIMETIDINE HCL

>D>	AA	COPLEY PHARM	EQ 300MG BASE/5ML	N74859 001	Jul 09, 1998	Mar	CAHN
>A>	AA	TEVA PHARMS	EQ 300MG BASE/5ML	N74859 001	Jul 09, 1998	Mar	CAHN

CIPROFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CIPROFLOXACIN

AT	HITECH PHARMA	EQ 0.3% BASE	N76673 001	Jan 21, 2005	Jan	NEWA
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TABLET; ORAL

CIPROFLOXACIN

AB	COBALT	EQ 100MG BASE	N76794 001	Feb 10, 2005	Jan	NEWA
AB	SANDOZ	EQ 100MG BASE	N75939 001	Mar 03, 2005	Feb	NEWA
AB	TARO	EQ 100MG BASE	N76912 001	Feb 18, 2005	Jan	NEWA

CITALOPRAM HYDROBROMIDE

TABLET; ORAL

CITALOPRAM HYDROBROMIDE

AB	MYLAN	EQ 10MG BASE	N77039 001	Feb 03, 2005	Jan	NEWA
AB		EQ 20MG BASE	N77039 002	Feb 03, 2005	Jan	NEWA
AB		EQ 40MG BASE	N77039 003	Feb 03, 2005	Jan	NEWA

CLARITHROMYCIN

TABLET, EXTENDED RELEASE; ORAL

CLARITHROMYCIN

RANBAXY

1GM

N65210 001	Jan 26, 2005	Jan	NEWA
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TABLET; ORAL

CLARITHROMYCIN

AB	GENPHARM	250MG	N65195 001	Mar 11, 2005	Feb	NEWA
AB		500MG	N65195 002	Mar 11, 2005	Feb	NEWA

CLEMASTINE FUMARATE

SYRUP; ORAL

CLEMASTINE FUMARATE

>D>	AA	COPLEY PHARM	EQ 0.5MG BASE/5ML	N73095 001	Apr 21, 1992	Mar	CAHN
>A>	AA	TEVA PHARMS	EQ 0.5MG BASE/5ML	N73095 001	Apr 21, 1992	Mar	CAHN

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HYDROCHLORIDE

AB	ZYDUS PHARMS USA	EQ 75MG BASE	N65217 001	Jan 31, 2005	Jan	NEWA
AB		EQ 150MG BASE	N65217 002	Jan 31, 2005	Jan	NEWA
AB		EQ 300MG BASE	N65217 003	Jan 31, 2005	Jan	NEWA

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

>D>		@ HOSPIRA	EQ 150MG BASE/ML	N62943 001	Sep 29, 1988	Mar	CMFD
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## INJECTABLE; INJECTION

## CLINDAMYCIN PHOSPHATE

>A>	AP	HOSPIRA	EQ 150MG BASE/ML	N62943 001	Sep 29, 1988	Mar	CMFD
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CLOBETASOL PROPIONATE

## CREAM; TOPICAL

## CLOBETASOL PROPIONATE

>D>	AB1	COPLEY PHARM	0.05%	N74087 001	Feb 16, 1994	Mar	CAHN
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>A>	AB1	TEVA PHARMS	0.05%	N74087 001	Feb 16, 1994	Mar	CAHN
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## OINTMENT; TOPICAL

## CLOBETASOL PROPIONATE

>D>	AB	COPLEY PHARM	0.05%	N74089 001	Feb 16, 1994	Mar	CAHN
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>A>	AB	TEVA PHARMS	0.05%	N74089 001	Feb 16, 1994	Mar	CAHN
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CLOTRIMAZOLE

## CREAM; TOPICAL

## CLOTRIMAZOLE

+	TARO	1%	N72640 001	Aug 31, 1993	Feb	CRLD
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## LOTTRIMIN

@	SCHERING PLOUGH	1%	N17619 001		Feb	DISC
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## MYCELEX

@	BAYER PHARMS	1%	N18183 001		Feb	DISC
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CROMOLYN SODIUM

## SOLUTION, CONCENTRATE; ORAL

## GASTROCROM

>D>	+	CELLTECH PHARMS	100MG/5ML	N20479 001	Feb 29, 1996	Mar	CAHN
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>A>	+	UCB	100MG/5ML	N20479 001	Feb 29, 1996	Mar	CAHN
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CYANOCOBALAMIN

## SPRAY, METERED; NASAL

## NASCOBAL

+	NASTECH PHARM	0.5MG/SPRAY	N21642 001	Jan 31, 2005	Jan	NEWA
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+	QUESTCOR PHARMS	0.5MG/SPRAY	N21642 001	Jan 31, 2005	Feb	CAHN
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CYCLOSPORINE

## CAPSULE; ORAL

## CYCLOSPORINE

>A>	AB1	IVAX PHARMS	25MG	N65110 003	Mar 29, 2005	Mar	NEWA
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>A>	AB1		50MG	N65110 001	Mar 29, 2005	Mar	NEWA
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>A>	AB1		100MG	N65110 002	Mar 29, 2005	Mar	NEWA
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## GENGRAF

>D>	BX	ABBOTT	50MG	N65003 002	May 12, 2000	Mar	CTEC
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>A>	AB1		50MG	N65003 002	May 12, 2000	Mar	CTEC
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## SOLUTION; ORAL

## CYCLOSPORINE

>A>	AB1	IVAX PHARMS	100MG/ML	N65078 001	Mar 25, 2005	Mar	NEWA
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CYPROHEPTADINE HYDROCHLORIDE

## TABLET; ORAL

## CYPROHEPTADINE HCL

@	ABC HOLDING	4MG	N88212 001	May 26, 1983	Feb	DISC
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DALTEPARIN SODIUM

INJECTABLE; INJECTION  
FRAGMIN

+ PHARMACIA AND UPJOHN 7,500 IU/0.3ML N20287 005 Apr 04, 2002 Jan NEWA

DANTROLENE SODIUM

CAPSULE; ORAL  
DANTRIUM

AB PROCTER AND GAMBLE 25MG N17443 001 Feb CFTG  
AB 50MG N17443 003 Feb CFTG  
AB + 100MG N17443 002 Feb CFTG

DANTROLENE SODIUM

AB IMPAX LABS 25MG N76856 001 Mar 01, 2005 Feb NEWA  
AB 50MG N76856 002 Mar 01, 2005 Feb NEWA  
AB 100MG N76856 003 Mar 01, 2005 Feb NEWA

>D> DESIRUDIN

>D> INJECTABLE; SUBCUTANEOUS

>D> IPRIVASK

>D> + CANYON 15MG/VIAL N21271 001 Apr 04, 2003 Mar CAIN

>A> DESIRUDIN RECOMBINANT

>A> INJECTABLE; SUBCUTANEOUS

>A> IPRIVASK

>A> + CANYON 15MG/VIAL N21271 001 Apr 04, 2003 Mar CAIN

DESLORATADINE; PSEUDOEPHEDRINE SULFATE

>A> TABLET, EXTENDED RELEASE; ORAL

>A> CLARINEX D 24 HOUR

>A> + SCHERING 5MG;240MG N21605 001 Mar 03, 2005 Mar NEWA

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

DESMOPRESSIN ACETATE (NEEDS NO REFRIGERATION)

AB APOTEX 0.01MG/SPRAY N76703 001 Jan 27, 2005 Jan NEWA

DESONIDE

CREAM; TOPICAL

DESONIDE

>D> AB COPLEY PHARM 0.05% N74027 001 Sep 28, 1992 Mar CAHN

>A> AB TEVA PHARMS 0.05% N74027 001 Sep 28, 1992 Mar CAHN

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE

>D> + PAR PHARM 0.25MG N88149 001 Apr 28, 1983 Mar CRLD

>A> 0.25MG N88149 001 Apr 28, 1983 Mar CRLD

>D> BP + ROXANE 1.5MG N84610 001 Mar CRLD

>A> BP 1.5MG N84610 001 Mar CRLD

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 50% IN PLASTIC CONTAINER

>D> @ HOSPIRA 500MG/ML N19445 001 Jun 03, 1986 Mar CMFD

>A> AP 500MG/ML N19445 001 Jun 03, 1986 Mar CMFD

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL  
DICLOFENAC SODIUM

>D>	AB	COPLEY PHARM	25MG	N74459 001	Jun 25, 1997	Mar	CAHN
>D>	AB		50MG	N74459 002	Jun 25, 1997	Mar	CAHN
>D>	AB		75MG	N74459 003	Jun 25, 1997	Mar	CAHN
>A>	AB	TEVA PHARMS	25MG	N74459 001	Jun 25, 1997	Mar	CAHN
>A>	AB		50MG	N74459 002	Jun 25, 1997	Mar	CAHN
>A>	AB		75MG	N74459 003	Jun 25, 1997	Mar	CAHN

DICYCLOMINE HYDROCHLORIDE

SYRUP; ORAL  
BENTYL

>D>	+	AXCAN SCANDIPHARM	10MG/5ML	N07961 002	Oct 15, 1984	Mar	CTEC
>A>	AA	+	10MG/5ML	N07961 002	Oct 15, 1984	Mar	CTEC
>A>		DICYCLOMINE HCL					
>A>	AA	MIKART	10MG/5ML	N40169 001	Mar 24, 2005	Mar	NEWA

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

@ ABC HOLDING

25MG

N88267 001 Aug 25, 1983 Feb DISC

@

25MG

N88268 001 Aug 25, 1983 Feb DISC

TENUATE

+ AVENTIS PHARMS

25MG

N11722 002 Feb CTEC

DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION

CARDIZEM

>D>	AP	+	BIOVAIL	5MG/ML	N20027 001	Oct 24, 1991	Mar	CAHN
>D>		+		25MG/VIAL	N20027 003	Aug 18, 1995	Mar	CAHN
>A>	AP	+	BIOVAIL LABS INTL	5MG/ML	N20027 001	Oct 24, 1991	Mar	CAHN
>A>		+		25MG/VIAL	N20027 003	Aug 18, 1995	Mar	CAHN

TABLET, EXTENDED RELEASE; ORAL

CARDIZEM LA

>D>			BIOVAIL	120MG	N21392 001	Feb 06, 2003	Mar	CAHN
>D>				180MG	N21392 002	Feb 06, 2003	Mar	CAHN
>D>				240MG	N21392 003	Feb 06, 2003	Mar	CAHN
>D>				300MG	N21392 004	Feb 06, 2003	Mar	CAHN
>D>				360MG	N21392 005	Feb 06, 2003	Mar	CAHN
>D>		+		420MG	N21392 006	Feb 06, 2003	Mar	CAHN
>A>			BIOVAIL LABS INTL	120MG	N21392 001	Feb 06, 2003	Mar	CAHN
>A>				180MG	N21392 002	Feb 06, 2003	Mar	CAHN
>A>				240MG	N21392 003	Feb 06, 2003	Mar	CAHN
>A>				300MG	N21392 004	Feb 06, 2003	Mar	CAHN
>A>				360MG	N21392 005	Feb 06, 2003	Mar	CAHN
>A>		+		420MG	N21392 006	Feb 06, 2003	Mar	CAHN

TABLET; ORAL

CARDIZEM

>D>	AB		BIOVAIL	30MG	N18602 001	Nov 05, 1982	Mar	CAHN
>D>	AB			60MG	N18602 002	Nov 05, 1982	Mar	CAHN
>D>	AB			90MG	N18602 003	Dec 08, 1986	Mar	CAHN
>D>	AB	+		120MG	N18602 004	Dec 08, 1986	Mar	CAHN
>A>	AB		BIOVAIL LABS INTL	30MG	N18602 001	Nov 05, 1982	Mar	CAHN
>A>	AB			60MG	N18602 002	Nov 05, 1982	Mar	CAHN

## TABLET; ORAL

## CARDIZEM

>A>	AB	BIOVAIL LABS INTL	90MG	N18602 003	Dec 08, 1986	Mar	CAHN
>A>	AB	+	120MG	N18602 004	Dec 08, 1986	Mar	CAHN
DILTIAZEM HCL							
>D>	AB	COPLEY PHARM	30MG	N74067 001	Nov 05, 1992	Mar	CAHN
>D>	AB		60MG	N74067 002	Nov 05, 1992	Mar	CAHN
>D>	AB		90MG	N74067 003	Nov 05, 1992	Mar	CAHN
>D>	AB		120MG	N74067 004	Nov 05, 1992	Mar	CAHN
>A>	AB	TEVA PHARMS	30MG	N74067 001	Nov 05, 1992	Mar	CAHN
>A>	AB		60MG	N74067 002	Nov 05, 1992	Mar	CAHN
>A>	AB		90MG	N74067 003	Nov 05, 1992	Mar	CAHN
>A>	AB		120MG	N74067 004	Nov 05, 1992	Mar	CAHN

DOXAZOSIN MESYLATE

## TABLET, EXTENDED RELEASE; ORAL

## CARDURA XL

		PFIZER	EQ 4MG BASE	N21269 001	Feb 22, 2005	Feb	NEWA
		+	EQ 8MG BASE	N21269 002	Feb 22, 2005	Feb	NEWA

DOXEPIN HYDROCHLORIDE

## CONCENTRATE; ORAL

## DOXEPIN HCL

>D>	AA	COPLEY PHARM	EQ 10MG BASE/ML	N71609 001	Nov 09, 1987	Mar	CAHN
>A>	AA	TEVA PHARMS	EQ 10MG BASE/ML	N71609 001	Nov 09, 1987	Mar	CAHN

DOXYCYCLINE

## CAPSULE; ORAL

## DOXYCYCLINE

>A>	AB	PAR PHARM	EQ 75MG BASE	N65055 004	Apr 18, 2005	Mar	NEWA	
>D>		+	RANBAXY	EQ 75MG BASE	N65053 003	Sep 10, 2003	Mar	CTEC
>A>	AB		EQ 75MG BASE	N65053 003	Sep 10, 2003	Mar	CTEC	

ENALAPRIL MALEATE

## TABLET; ORAL

## ENALAPRIL MALEATE

## @ APOTHECON

## @

## @

## @

## VASOTEC

			2.5MG	N75583 001	Aug 22, 2000	Feb	DISC
			5MG	N75583 002	Aug 22, 2000	Feb	DISC
			10MG	N75583 003	Aug 22, 2000	Feb	DISC
			20MG	N75583 004	Aug 22, 2000	Feb	DISC
>D>	AB	BIOVAIL	2.5MG	N18998 005	Jul 26, 1988	Mar	CAHN
>D>	AB		5MG	N18998 001	Dec 24, 1985	Mar	CAHN
>D>	AB		10MG	N18998 002	Dec 24, 1985	Mar	CAHN
>D>	AB	+	20MG	N18998 003	Dec 24, 1985	Mar	CAHN
>A>	AB	BIOVAIL LABS INTL	2.5MG	N18998 005	Jul 26, 1988	Mar	CAHN
>A>	AB		5MG	N18998 001	Dec 24, 1985	Mar	CAHN
>A>	AB		10MG	N18998 002	Dec 24, 1985	Mar	CAHN
>A>	AB	+	20MG	N18998 003	Dec 24, 1985	Mar	CAHN

ENALAPRIL MALEATE; HYDROCHLOROTHIAZIDE

## TABLET; ORAL

## VASERETIC

>D>	AB	BIOVAIL	5MG;12.5MG	N19221 003	Jul 12, 1995	Mar	CAHN
>D>	AB	+	10MG;25MG	N19221 001	Oct 31, 1986	Mar	CAHN
>A>	AB	BIOVAIL LABS INTL	5MG;12.5MG	N19221 003	Jul 12, 1995	Mar	CAHN

## TABLET; ORAL

## VASERETIC

>A>	AB	+	BIOVAIL LABS INTL	10MG;25MG	N19221	001	Oct 31, 1986	Mar	CAHN
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ENALAPRILAT

## INJECTABLE; INJECTION

## VASOTEC

>D>	AP	+	BIOVAIL	1.25MG/ML	N19309	001	Feb 09, 1988	Mar	CAHN
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>A>	AP	+	BIOVAIL LABS INTL	1.25MG/ML	N19309	001	Feb 09, 1988	Mar	CAHN
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>A> ENTECAVIR

## SOLUTION; ORAL

## BARACLUDE

>A>		+	BRISTOL MYERS SQUIBB	0.05MG/ML	N21798	001	Mar 29, 2005	Mar	NEWA
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## TABLET; ORAL

## BARACLUDE

>A>			BRISTOL MYERS SQUIBB	0.5MG	N21797	001	Mar 29, 2005	Mar	NEWA
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>A>		+		1MG	N21797	002	Mar 29, 2005	Mar	NEWA
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EPINEPHRINE

## INJECTABLE; IM-SC

## TWINJECT 0.30

		+	HOLLISTER STIER LABS	EQ 0.3MG /DELIVERY	N20800	001	May 30, 2003	Feb	CTNA
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ERYTHROMYCIN

## SOLUTION; TOPICAL

## ERYMAX

AT			MERZ PHARMS	2%	N62508	002	Jul 11, 1985	Jan	CAHN
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ERYTHROMYCIN ESTOLATE

## CAPSULE; ORAL

## ERYTHROMYCIN ESTOLATE

		@	BARR	EQ 250MG BASE	N62162	002		Feb	DISC
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ESOMEPRAZOLE MAGNESIUM

## CAPSULE, DELAYED REL PELLETS; ORAL

## NEXIUM

			ASTRAZENECA	EQ 20MG BASE	N21153	001	Feb 20, 2001	Jan	CRLD
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>A> ESOMEPRAZOLE SODIUM

## INJECTABLE; INTRAVENOUS

## NEXIUM IV

>A>		+	ASTRAZENECA	20MG/VIAL	N21689	001	Mar 31, 2005	Mar	NEWA
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>A>		+		40MG/VIAL	N21689	002	Mar 31, 2005	Mar	NEWA
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ESTRADIOL

## FILM, EXTENDED RELEASE; TRANSDERMAL

## CLIMARA

AB2	+		BERLEX	0.025MG/24HR	N20375	004	Mar 05, 1999	Jan	CFTG
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AB2	+			0.075MG/24HR	N20375	003	Mar 23, 1998	Jan	CFTG
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## ESCLIM

		@	WOMEN FIRST HLTHCARE	0.025MG/24HR	N20847	001	Aug 04, 1998	Jan	DISC
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		@		0.0375MG/24HR	N20847	002	Aug 04, 1998	Jan	DISC
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		@		0.05MG/24HR	N20847	003	Aug 04, 1998	Jan	DISC
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		@		0.075MG/24HR	N20847	004	Aug 04, 1998	Jan	DISC
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		@		0.1MG/24HR	N20847	005	Aug 04, 1998	Jan	DISC
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## FILM, EXTENDED RELEASE; TRANSDERMAL

ESTRADIOL								
AB2	MYLAN TECHNOLOGIES	0.025MG/24HR	N75182 003	Jan 26, 2005	Jan	NEWA		
AB2		0.075MG/24HR	N75182 002	Jan 26, 2005	Jan	NEWA		
VIVELLE								
	@ NOVARTIS	0.025MG/24HR	N20323 005	Aug 16, 2000	Jan	DISC		
AB1		0.05MG/24HR	N20323 002	Oct 28, 1994	Jan	CRLD		
AB1		0.1MG/24HR	N20323 004	Oct 28, 1994	Jan	CRLD		
VIVELLE-DOT								
BX	+ NOVARTIS	0.025MG/24HR	N20538 009	May 03, 2002	Jan	CRLD		
BX	+	0.0375MG/24HR	N20538 005	Jan 08, 1999	Jan	CRLD		
AB1	+	0.05MG/24HR	N20538 006	Jan 08, 1999	Jan	CRLD		
BX	+	0.075MG/24HR	N20538 007	Jan 08, 1999	Jan	CRLD		
AB1	+	0.1MG/24HR	N20538 008	Jan 08, 1999	Jan	CRLD		

ESTROGENS, CONJUGATED SYNTHETIC B

>D>	TABLET; ORAL							
>D>	ENJUVIA							
>A>	@ DURAMED	0.3MG	N21443 001	Dec 20, 2004	Mar	DISC		
>A>	@	0.45MG	N21443 002	Dec 20, 2004	Mar	DISC		

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21								
NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)								
>D>	AB	+ WATSON LABS	0.035MG,0.035MG;0.5MG,1MG	N71041 001	Sep 24, 1991	Mar	CTEC	
>A>		+	0.035MG,0.035MG;0.5MG,1MG	N71041 001	Sep 24, 1991	Mar	CTEC	
NORTREL 7/7/7								
>D>	AB	BARR	0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG	N75478 001	Aug 30, 2002	Mar	CTEC	
>A>			0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG	N75478 001	Aug 30, 2002	Mar	CTEC	
TABLET; ORAL-28								
NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)								
>D>	AB	WATSON LABS	0.035MG,0.035MG;0.5MG,1MG	N71042 001	Sep 24, 1991	Mar	CTEC	
>A>			0.035MG,0.035MG;0.5MG,1MG	N71042 001	Sep 24, 1991	Mar	CTEC	
ORTHO-NOVUM 10/11-28								
>D>	AB	ORTHO MCNEIL PHARM	0.035MG,0.035MG;0.5MG,1MG	N18354 002	Jan 11, 1982	Mar	CRLD	
>A>	AB	+	0.035MG,0.035MG;0.5MG,1MG	N18354 002	Jan 11, 1982	Mar	CRLD	
ORTHO-NOVUM 7/14-28								
		@ ORTHO MCNEIL PHARM	0.035MG,0.035MG;0.5MG,1MG	N19004 002	Apr 04, 1984	Feb	DISC	
OVCON-35								
>D>	AB	+ WARNER CHILCOTT	0.035MG;0.4MG	N17716 001		Mar	CRLD	
>A>	AB		0.035MG;0.4MG	N17716 001		Mar	CRLD	

ETHOSUXIMIDE

SYRUP; ORAL								
ETHOSUXIMIDE								
>D>	AA	COPLEY PHARM	250MG/5ML	N81306 001	Jul 30, 1993	Mar	CAHN	
>A>	AA	TEVA PHARMS	250MG/5ML	N81306 001	Jul 30, 1993	Mar	CAHN	

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION								
FENOLDOPAM MESYLATE								
AP	SABEX 2002	EQ 10MG BASE/ML	N77155 001	Feb 15, 2005	Jan	NEWA		

FENTANYL

	FILM, EXTENDED RELEASE; TRANSDERMAL						
	DURAGESIC-100						
AB	ALZA	100UGM/HR	N19813	001	Aug 07, 1990	Jan	CFTG
	DURAGESIC-12						
	ALZA	12.5UGM/HR	N19813	005	Feb 04, 2005	Feb	NEWA
	DURAGESIC-25						
AB	+ ALZA	25UGM/HR	N19813	004	Aug 07, 1990	Jan	CFTG
	DURAGESIC-50						
AB	ALZA	50UGM/HR	N19813	003	Aug 07, 1990	Jan	CFTG
	DURAGESIC-75						
AB	ALZA	75UGM/HR	N19813	002	Aug 07, 1990	Jan	CFTG
	FENTANYL						
AB	MYLAN TECHNOLOGIES	25UGM/HR	N76258	001	Jan 28, 2005	Jan	NEWA
AB		50UGM/HR	N76258	002	Jan 28, 2005	Jan	NEWA
AB		75UGM/HR	N76258	003	Jan 28, 2005	Jan	NEWA
AB		100UGM/HR	N76258	004	Jan 28, 2005	Jan	NEWA

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

	TABLET, EXTENDED RELEASE; ORAL						
	ALLEGRA-D 12 HOUR						
>D>	+ AVENTIS PHARMS	60MG;120MG	N20786	001	Dec 24, 1997	Mar	CFTG
>A>	AB +	60MG;120MG	N20786	001	Dec 24, 1997	Mar	CFTG
>A>	FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCL						
>A>	AB BARR	60MG;120MG	N76236	001	Apr 14, 2005	Mar	NEWA

FLUCONAZOLE

	INJECTABLE; INJECTION						
	FLUCONAZOLE IN DEXTROSE 5% IN PLASTIC CONTAINER						
>A>	AP APOTEX	200MG/100ML	N76888	001	Mar 25, 2005	Mar	NEWA
	FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER						
>A>	AP APOTEX	200MG/100ML	N76889	001	Mar 25, 2005	Mar	NEWA

FLUOCINONIDE

	CREAM; TOPICAL						
	VANOS						
	+ MEDICIS	0.1%	N21758	001	Feb 11, 2005	Feb	NEWA
	SOLUTION; TOPICAL						
	FLUOCINONIDE						
>D>	AT COPLEY PHARM	0.05%	N72522	001	Sep 28, 1990	Mar	CAHN
>A>	AT TEVA PHARMS	0.05%	N72522	001	Sep 28, 1990	Mar	CAHN

FLUPHENAZINE HYDROCHLORIDE

	CONCENTRATE; ORAL						
	FLUPHENAZINE HCL						
>D>	AA COPLEY PHARM	5MG/ML	N73058	001	Aug 30, 1991	Mar	CAHN
>A>	AA TEVA PHARMS	5MG/ML	N73058	001	Aug 30, 1991	Mar	CAHN
	ELIXIR; ORAL						
	FLUPHENAZINE HCL						
>D>	AA COPLEY PHARM	2.5MG/5ML	N81310	001	Apr 29, 1993	Mar	CAHN
>A>	AA TEVA PHARMS	2.5MG/5ML	N81310	001	Apr 29, 1993	Mar	CAHN

FLUTICASONE PROPIONATE

AEROSOL, METERED; INHALATION

FLOVENT

+	GLAXOSMITHKLINE	0.044MG/INH	N20548 001	Mar 27, 1996	Jan	CRLD
+		0.11MG/INH	N20548 002	Mar 27, 1996	Jan	CRLD

FLOVENT HFA

+	GLAXOSMITHKLINE	0.044MG/INH	N21433 003	May 14, 2004	Jan	CRLD
+		0.11MG/INH	N21433 002	May 14, 2004	Jan	CRLD

&gt;A&gt; LOTION; TOPICAL

&gt;A&gt; CUTIVATE

>A>	+	GLAXOSMITHKLINE	0.05%	N21152 001	Mar 31, 2005	Mar	NEWA
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FOLLITROPIN ALFA/BETA

INJECTABLE; SUBCUTANEOUS

FOLLISTIM AQ

+	ORGANON USA INC	150 IU/0.18ML	N21211 003	Feb 11, 2004	Feb	NEWA
+		300 IU/0.36ML	N21211 001	Mar 23, 2004	Jan	CPOT
+		600 IU/0.72ML	N21211 002	Mar 23, 2004	Jan	CPOT
+		900 IU/1.08ML	N21211 004	Feb 11, 2005	Feb	NEWA

FOMIVIRSEN SODIUM

INJECTABLE; INJECTION

VITRAVENE PRESERVATIVE FREE

@	NOVARTIS	6.6MG/ML	N20961 001	Aug 26, 1998	Feb	DISC
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FOSINOPRIL SODIUM

TABLET; ORAL

FOSINOPRIL SODIUM

>A>	AB	INVAGEN PHARMS	10MG	N77222 001	Apr 20, 2005	Mar	NEWA
>A>	AB		20MG	N77222 002	Apr 20, 2005	Mar	NEWA
>A>	AB		40MG	N77222 003	Apr 20, 2005	Mar	NEWA

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

AP	+	LUITPOLD	10MG/ML	N18579 001	Nov 30, 1983	Feb	CRLD
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LASIX

@	AVENTIS PHARMS	10MG/ML	N16363 001		Feb	DISC
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GABAPENTIN

CAPSULE; ORAL

GABAPENTIN

>A>	AB	APOTEX	100MG	N75360 001	Apr 06, 2005	Mar	NEWA
>A>	AB		300MG	N75360 002	Apr 06, 2005	Mar	NEWA
>A>	AB		400MG	N75360 003	Apr 06, 2005	Mar	NEWA
>A>	AB	EON	100MG	N75539 001	Apr 06, 2005	Mar	NEWA
>A>	AB		300MG	N75539 002	Apr 06, 2005	Mar	NEWA
>A>	AB		400MG	N75539 003	Apr 06, 2005	Mar	NEWA
>A>	AB	IVAX PHARMS	100MG	N75477 001	Mar 23, 2005	Mar	NEWA
>A>	AB		300MG	N75477 002	Mar 23, 2005	Mar	NEWA
>A>	AB		400MG	N75477 003	Mar 23, 2005	Mar	NEWA



GALANTAMINE HYDROBROMIDE

CAPSULE, EXTENDED RELEASE; ORAL

REMINYL

+	JOHNSON AND JOHNSON	EQ 8MG BASE	N21615 001	Dec 22, 2004	Jan	CRLD
		EQ 24MG BASE	N21615 003	Dec 22, 2004	Jan	CRLD

GATIFLOXACIN

INJECTABLE; INJECTION

TEQUIN

>D>	+	BRISTOL MYERS SQUIBB	EQ 2MG /ML(200MG/100ML)	N21062 001	Dec 17, 1999	Mar	CPOT
>D>	+		EQ 2MG /ML(400MG/200ML)	N21062 002	Dec 17, 1999	Mar	CPOT
>D>	+		EQ 10MG /ML(400MG)	N21062 004	Dec 17, 1999	Mar	CPOT
>A>	+		400MG/40ML(10MG/ML)	N21062 004	Dec 17, 1999	Mar	CPOT
		TEQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER					
>A>	+	BRISTOL MYERS SQUIBB	200MG/100ML(2MG/ML)	N21062 001	Dec 17, 1999	Mar	CPOT
>A>	+		400MG/200ML(2MG/ML)	N21062 002	Dec 17, 1999	Mar	CPOT

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLYBURIDE AND METFORMIN HCL

AB		TEVA	1.25MG;250MG	N76821 001	Jan 27, 2005	Jan	NEWA
AB			2.5MG;500MG	N76821 002	Jan 27, 2005	Jan	NEWA
AB			5MG;500MG	N76821 003	Jan 27, 2005	Jan	NEWA

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION

CHORIONIC GONADOTROPIN

		@ WATSON LABS (UTAH)	2,000 UNITS/VIAL	N17016 009	Dec 27, 1984	Feb	CAHN
		@	2,000 UNITS/VIAL	N17016 011	Feb 16, 1990	Feb	CAHN
		@	5,000 UNITS/VIAL	N17016 006		Feb	CAHN
AP	+		10,000 UNITS/VIAL	N17016 007		Feb	CAHN
		@	15,000 UNITS/VIAL	N17016 010	Feb 15, 1985	Feb	CAHN
		@	20,000 UNITS/VIAL	N17016 004		Feb	CAHN

GRISEOFULVIN, MICROCRYSTALLINE

SUSPENSION; ORAL

GRIFULVIN V

AB	+	J AND J	125MG/5ML	N62483 001	Jan 26, 1984	Feb	CFTG
AB		STIEFEL	125MG/5ML	N65200 001	Mar 02, 2005	Feb	NEWA

GUANABENZ ACETATE

TABLET; ORAL

GUANABENZ ACETATE

>D>	AB	COPLEY PHARM	EQ 4MG BASE	N74267 001	Jun 01, 1994	Mar	CAHN
>D>	AB		EQ 8MG BASE	N74267 002	Jun 01, 1994	Mar	CAHN
>A>	AB	TEVA PHARMS	EQ 4MG BASE	N74267 001	Jun 01, 1994	Mar	CAHN
>A>	AB		EQ 8MG BASE	N74267 002	Jun 01, 1994	Mar	CAHN

HALOPERIDOL LACTATE

CONCENTRATE; ORAL

HALOPERIDOL

>D>	AA	+	COPLEY PHARM	EQ 2MG BASE/ML	N71617 001	Dec 01, 1988	Mar	CAHN
>A>	AA	+	TEVA PHARMS	EQ 2MG BASE/ML	N71617 001	Dec 01, 1988	Mar	CAHN

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL

HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

AA	IVAX PHARMS	1.5MG/5ML;5MG/5ML	N40285 001	Jul 19, 1999	Jan	CAHN
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HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

@ ABC HOLDING

10MG

N88846 001 Feb 26, 1985 Feb DISC

@

25MG

N88847 001 Feb 26, 1985 Feb DISC

@

50MG

N88848 001 Feb 26, 1985 Feb DISC

@

100MG

N88849 001 Feb 26, 1985 Feb DISC

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

@ ABC HOLDING

25MG

N85683 001 Feb DISC

@

50MG

N83965 001 Feb DISC

@

50MG

N85672 001 Feb DISC

HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET; ORAL

AVALIDE

>D>	+	SANOFI SYNTHELABO	12.5MG;300MG	N20758 003	Aug 31, 1998	Mar	CRLD
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>A>			12.5MG;300MG	N20758 003	Aug 31, 1998	Mar	CRLD
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>A>	+		25MG;300MG	N20758 004	Mar 15, 2005	Mar	NEWA
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HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

QUINAPRIL HCL AND HYDROCHLOROTHIAZIDE

>A>	AB	MYLAN	12.5MG;EQ 10MG BASE	N77093 001	Mar 28, 2005	Mar	NEWA
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>A>	AB		12.5MG;EQ 20MG BASE	N77093 002	Mar 28, 2005	Mar	NEWA
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>A>	AB		25MG;EQ 20MG BASE	N77093 003	Mar 28, 2005	Mar	NEWA
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HYDROCHLOROTHIAZIDE; VALSARTAN

TABLET; ORAL

DIOVAN HCT

>D>	+	NOVARTIS	12.5MG;160MG	N20818 002	Mar 06, 1998	Mar	CRLD
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>A>			12.5MG;160MG	N20818 002	Mar 06, 1998	Mar	CRLD
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>D>			25MG;160MG	N20818 003	Jan 17, 2002	Mar	CRLD
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>A>	+		25MG;160MG	N20818 003	Jan 17, 2002	Mar	CRLD
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HYDROCORTISONE

ENEMA; RECTAL

HYDROCORTISONE

>D>	AB	COPLEY PHARM	100MG/60ML	N74171 001	May 27, 1994	Mar	CAHN
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>A>	AB	TEVA PHARMS	100MG/60ML	N74171 001	May 27, 1994	Mar	CAHN
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HYDROCORTISONE VALERATE

CREAM; TOPICAL

HYDROCORTISONE VALERATE

>D>	AB	COPLEY PHARM	0.2%	N74489 001	Aug 12, 1998	Mar	CAHN
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>A>	AB	TEVA PHARMS	0.2%	N74489 001	Aug 12, 1998	Mar	CAHN
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HYDROMORPHONE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL  
PALLADONE

	PURDUE PHARMA LP	16MG	N21044 002	Sep 24, 2004	Feb	CRLD
+		32MG	N21044 004	Sep 24, 2004	Feb	CRLD

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL  
HYDROXYCHLOROQUINE SULFATE

>D>	AB	COPLEY PHARM	200MG	N40081 001	Sep 30, 1994	Mar	CAHN
>A>	AB	TEVA PHARMS	200MG	N40081 001	Sep 30, 1994	Mar	CAHN

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION  
HYDROXYPROGESTERONE CAPROATE

>D>	@	STERIS	125MG/ML	N17439 001		Mar	CAHN
>D>	@		250MG/ML	N17439 002		Mar	CAHN
>A>	@	WATSON LABS	125MG/ML	N17439 001		Mar	CAHN
>A>	@		250MG/ML	N17439 002		Mar	CAHN

IBANDRONATE SODIUM

TABLET; ORAL  
BONIVA

	+	ROCHE	EQ 2.5MG BASE	N21455 001	May 16, 2003	Feb	CMFD
>A>			EQ 150MG BASE	N21455 002	Mar 24, 2005	Mar	NEWA

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL  
IMIPRAMINE HCL

	@	TEVA	10MG	N83729 001		Feb	DISC
	@		25MG	N83729 004		Feb	DISC
	@		50MG	N83729 003		Feb	DISC

IRON DEXTRAN

INJECTABLE; INJECTION  
INFED

BP	+	WATSON LABS (UTAH)	EQ 50MG IRON/ML	N17441 001		Feb	CAHN
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IRON SUCROSE

INJECTABLE; INTRAVENOUS  
VENOFER

>D>	+	LUITPOLD	EQ 20MG BASE/ML	N21135 001	Nov 06, 2000	Mar	CPOT
>A>	+		EQ 100MG BASE/5ML(EQ 20MG BASE/ML)	N21135 001	Nov 06, 2000	Mar	CPOT
>A>			EQ 50MG BASE/2.5ML(EQ 20MG BASE/ML)	N21135 002	Mar 20, 2005	Mar	NEWA
>A>			EQ 75MG BASE/3.75ML(EQ 20MG BASE/ML)	N21135 003	Mar 29, 2005	Mar	NEWA

ISRADIPINE

TABLET, EXTENDED RELEASE; ORAL  
DYNACIRC CR

>D>	+	RELIANT PHARMS	5MG	N20336 001	Jun 01, 1994	Mar	CRLD
>A>			5MG	N20336 001	Jun 01, 1994	Mar	CRLD

KANAMYCIN SULFATE

CAPSULE; ORAL

KANTREX

@ APOTHECON

EQ 500MG BASE

N62726 001 Mar 06, 1987 Feb DISC

KETOCONAZOLE

SHAMPOO; TOPICAL

KETOCONAZOLE

&gt;A&gt; AB

QLT USA

2%

N76942 001 Apr 11, 2005 Mar NEWA

LACTULOSE

SOLUTION; ORAL

EVALOSE

&gt;D&gt; AA

COPLEY PHARM

10GM/15ML

N73497 001 May 28, 1993 Mar CAHN

&gt;A&gt; AA

TEVA PHARMS

10GM/15ML

N73497 001 May 28, 1993 Mar CAHN

SOLUTION; ORAL, RECTAL

HEPTALAC

&gt;D&gt; AA

COPLEY PHARM

10GM/15ML

N73504 001 May 28, 1993 Mar CAHN

&gt;A&gt; AA

TEVA PHARMS

10GM/15ML

N73504 001 May 28, 1993 Mar CAHN

&gt;D&gt;

LEPIRUDIN

&gt;D&gt;

INJECTABLE; INJECTION

&gt;D&gt;

REFLUDAN

&gt;D&gt;

+ BERLEX

50MG/VIAL

N20807 001 Mar 06, 1998 Mar CAIN

&gt;A&gt;

LEPIRUDIN RECOMBINANT

&gt;A&gt;

INJECTABLE; INJECTION

&gt;A&gt;

REFLUDAN

&gt;A&gt;

+ BERLEX

50MG/VIAL

N20807 001 Mar 06, 1998 Mar CAIN

LEUPROLIDE ACETATE

INJECTABLE; SUBCUTANEOUS

ELIGARD

+ QLT USA

22.5MG/VIAL

N21379 001 Jul 24, 2002 Jan CAHN

LEVALBUTEROL TARTRATE

&gt;A&gt;

AEROSOL, METERED; INHALATION

&gt;A&gt;

XOPENEX HFA

&gt;A&gt;

+ SEPRACOR

EQ 0.045MG BASE/INH

N21730 001 Mar 11, 2005 Mar NEWA

LEVOFLOXACIN

TABLET; ORAL

LEVAQUIN

&gt;D&gt; AB

ORTHO MCNEIL PHARM

250MG

N20634 001 Dec 20, 1996 Mar CTEC

&gt;A&gt;

250MG

N20634 001 Dec 20, 1996 Mar CTEC

&gt;D&gt; AB

500MG

N20634 002 Dec 20, 1996 Mar CTEC

&gt;A&gt;

500MG

N20634 002 Dec 20, 1996 Mar CTEC

AB

+

750MG

N20634 003 Sep 08, 2000 Jan CFTG

LEVOFLOXACIN

AB

TEVA

750MG

N76361 003 Jan 26, 2005 Jan NEWA

LIDOCAINE HYDROCHLORIDE

JELLY; TOPICAL

LIDOCAINE HCL

&gt;D&gt; AT

COPLEY PHARM

2%

N81318 001 Apr 29, 1993 Mar CAHN

		JELLY; TOPICAL							
		LIDOCAINE HCL							
>A>	AT	TEVA PHARMS	2%	N81318	001	Apr 29, 1993	Mar	CAHN	
		<u>LORAZEPAM</u>							
		SOLUTION; ORAL							
		LORAZEPAM							
		ROXANE	0.5MG/5ML	N74648	001	Mar 18, 1997	Jan	CMFD	
		<u>MANGAFODIPIR TRISODIUM</u>							
		INJECTABLE; INJECTION							
		TESLASCAN							
		@ GE HEALTHCARE	37.9MG/ML	N20652	001	Nov 26, 1997	Jan	DISC	
		<u>MEBENDAZOLE</u>							
		TABLET, CHEWABLE; ORAL							
		MEBENDAZOLE							
>D>	AB	COPLBY PHARM	100MG	N73580	001	Jan 04, 1995	Mar	CAHN	
>A>	AB	TEVA PHARMS	100MG	N73580	001	Jan 04, 1995	Mar	CAHN	
		<u>MECLIZINE HYDROCHLORIDE</u>							
		TABLET; ORAL							
		MECLIZINE HCL							
		@ ABC HOLDING	12.5MG	N85253	001		Feb	DISC	
		@	25MG	N85252	001		Feb	DISC	
		<u>MEGESTROL ACETATE</u>							
		SUSPENSION; ORAL							
		MEGESTROL ACETATE							
>D>	AB	COPLBY PHARM	40MG/ML	N75681	001	May 05, 2003	Mar	CAHN	
>A>	AB	TEVA PHARMS	40MG/ML	N75681	001	May 05, 2003	Mar	CAHN	
		<u>MEQUINOL; TRETINOIN</u>							
		SOLUTION; TOPICAL							
		SOLAGE							
		+ BARRIER	2%;0.01%	N20922	001	Dec 10, 1999	Feb	CAHN	
		<u>METAPROTERENOL SULFATE</u>							
		SYRUP; ORAL							
		METAPROTERENOL SULFATE							
>D>		@ COPLBY PHARM	10MG/5ML	N73034	001	Aug 30, 1991	Mar	CAHN	
>A>		@ TEVA PHARMS	10MG/5ML	N73034	001	Aug 30, 1991	Mar	CAHN	
		<u>METFORMIN HYDROCHLORIDE</u>							
		TABLET, EXTENDED RELEASE; ORAL							
		METFORMIN HCL							
>A>	AB	ANDRX PHARMS	750MG	N76869	001	Apr 12, 2005	Mar	NEWA	
>A>	AB	PUREPAC PHARM	750MG	N76878	001	Apr 13, 2005	Mar	NEWA	
>A>	AB	TEVA	750MG	N76864	001	Apr 12, 2005	Mar	NEWA	
>A>	AB	ZYDUS PHARMS USA	500MG	N77060	001	Apr 20, 2005	Mar	NEWA	
		TABLET; ORAL							
		METFORMIN HCL							
>A>	AB	ZYDUS PHARMS USA	500MG	N77064	001	Apr 18, 2005	Mar	NEWA	
>A>	AB		850MG	N77064	002	Apr 18, 2005	Mar	NEWA	
>A>	AB		1GM	N77064	003	Apr 18, 2005	Mar	NEWA	

METHAZOLAMIDE

TABLET; ORAL

METHAZOLAMIDE

>D>	AB	COPLEY PHARM	25MG	N40001 001	Jun 30, 1993	Mar	CAHN
>D>	AB		50MG	N40001 002	Jun 30, 1993	Mar	CAHN
>A>	AB	TEVA PHARMS	25MG	N40001 001	Jun 30, 1993	Mar	CAHN
>A>	AB		50MG	N40001 002	Jun 30, 1993	Mar	CAHN

METHIMAZOLE

TABLET; ORAL

METHIMAZOLE

AB		CEDAR PHARMS	5MG	N40547 001	Feb 18, 2005	Jan	NEWA
AB			10MG	N40547 002	Feb 18, 2005	Jan	NEWA
AB			20MG	N40547 004	Feb 18, 2005	Jan	NEWA
AB	+	GENPHARM	20MG	N40350 003	Jun 07, 2001	Jan	CFTG

METHYLDOPA

TABLET; ORAL

ALDOMET

@ MERCK

500MG

N13400 002

Jan DISC

METHYLDOPA

AB	+	MYLAN	500MG	N70076 001	Apr 18, 1985	Jan	CRLD
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METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION

ALDOMET

@ MERCK

50MG/ML

N13401 001

Jan DISC

METHYLDOPATE HCL

AP	+	LUITPOLD	50MG/ML	N71279 001	Oct 02, 1987	Jan	CRLD
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METHYLERGONOVINE MALEATE

TABLET; ORAL

METHERGINE

+ NOVARTIS

0.2MG

N06035 003

Jan CRLD

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

DEPO-MEDROL

AB	+	PHARMACIA AND UPJOHN	40MG/ML	N11757 001		Feb	CFTG
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AB	+		80MG/ML	N11757 004		Feb	CFTG
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METHYLPREDNISOLONE ACETATE

AB		SICOR PHARMS	40MG/ML	N40557 001	Feb 23, 2005	Feb	NEWA
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AB			80MG/ML	N40557 002	Feb 23, 2005	Feb	NEWA
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METOLAZONE

TABLET; ORAL

ZAROXOLYN

>D>	AB	CELLTECH PHARMS	2.5MG	N17386 001		Mar	CAHN
>D>	AB	+	5MG	N17386 002		Mar	CAHN
>D>	AB	+	10MG	N17386 003		Mar	CAHN
>A>	AB	UCB	2.5MG	N17386 001		Mar	CAHN
>A>	AB	+	5MG	N17386 002		Mar	CAHN
>A>	AB	+	10MG	N17386 003		Mar	CAHN

METOPROLOL TARTRATE

TABLET; ORAL

METOPROLOL TARTRATE

>D>	AB	COPLEY PHARM	50MG	N74333 001	Jan 27, 1994	Mar	CAHN
>D>	AB		100MG	N74333 002	Jan 27, 1994	Mar	CAHN
>A>	AB	TEVA PHARMS	50MG	N74333 001	Jan 27, 1994	Mar	CAHN
>A>	AB		100MG	N74333 002	Jan 27, 1994	Mar	CAHN

>A> MICAFUNGIN SODIUM

&gt;A&gt; INJECTABLE; IV (INFUSION)

&gt;A&gt; MYCAMINE

>A>	+	ASTELLAS	50MG/VIAL	N21506 002	Mar 16, 2005	Mar	NEWA
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MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

MIDAZOLAM HCL

>D>		@ HOSPIRA	EQ 1MG BASE/ML	N75293 001	Jun 20, 2000	Mar	CMFD
>A>	AP		EQ 1MG BASE/ML	N75293 001	Jun 20, 2000	Mar	CMFD
>D>		@	EQ 5MG BASE/ML	N75293 002	Jun 20, 2000	Mar	CMFD
>A>	AP		EQ 5MG BASE/ML	N75293 002	Jun 20, 2000	Mar	CMFD
	AP	INTL MEDICATED	EQ 1MG BASE/ML	N76144 001	Jan 26, 2005	Jan	NEWA
	AP		EQ 5MG BASE/ML	N76144 002	Jan 26, 2005	Jan	NEWA

MOMETASONE FUROATE

CREAM; TOPICAL

ELOCON

	AB	+	SCHERING	0.1%	N19625 001	May 06, 1987	Jan	CFTG
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MOMETASONE FUROATE

>A>	AB	ALTANA	0.1%	N76171 001	Apr 08, 2005	Mar	NEWA
	AB	TARO	0.1%	N76679 001	Dec 21, 2004	Jan	NEWA

LOTION; TOPICAL

ELOCON

>D>		+	SCHERING	0.1%	N19796 001	Mar 30, 1989	Mar	CFTG
>A>	AB	+		0.1%	N19796 001	Mar 30, 1989	Mar	CFTG
>A>			MOMETASONE FUROATE					
>A>	AB	AGIS INDS	0.1%	N77180 001	Apr 06, 2005	Mar	NEWA	

OINTMENT; TOPICAL

MOMETASONE FUROATE

>A>	AB	ALTANA	0.1%	N77061 001	Mar 28, 2005	Mar	NEWA
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&gt;A&gt; POWDER; INHALATION

&gt;A&gt; ASMANEX TWISTHALER

>A>	+	SCHERING	0.22MG/INH	N21067 001	Mar 30, 2005	Mar	NEWA
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MOMETASONE FUROATE MONOHYDRATE

SPRAY, METERED; NASAL

NASONEX

>D>	+	SCHERING PLOUGH	EQ 0.05MG BASE/SPRAY	N20762 001	Oct 01, 1997	Mar	CAHN
>A>	+	SHIRE	EQ 0.05MG BASE/SPRAY	N20762 001	Oct 01, 1997	Mar	CAHN

MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

AVINZA

>D>	BX	+	LIGAND	30MG	N21260 001	Mar 20, 2002	Mar	CRLD
>A>	BX			30MG	N21260 001	Mar 20, 2002	Mar	CRLD
>D>	BX	+		60MG	N21260 002	Mar 20, 2002	Mar	CRLD

## CAPSULE, EXTENDED RELEASE; ORAL

## AVINZA

>A>	BX	LIGAND	60MG	N21260 002	Mar 20, 2002	Mar	CRLD
>D>		+	90MG	N21260 003	Mar 20, 2002	Mar	CRLD
>A>			90MG	N21260 003	Mar 20, 2002	Mar	CRLD

## KADIAN

>D>		+	ALPHARMA US PHARMS	20MG	N20616 001	Jul 03, 1996	Mar	CRLD
>A>				20MG	N20616 001	Jul 03, 1996	Mar	CRLD
>D>	BX	+		30MG	N20616 004	Mar 09, 2001	Mar	CRLD
>A>	BX			30MG	N20616 004	Mar 09, 2001	Mar	CRLD
>D>		+		50MG	N20616 002	Jul 03, 1996	Mar	CRLD
>A>				50MG	N20616 002	Jul 03, 1996	Mar	CRLD
>D>	BX	+		60MG	N20616 005	Mar 09, 2001	Mar	CRLD
>A>	BX			60MG	N20616 005	Mar 09, 2001	Mar	CRLD

NADOLOL

## TABLET; ORAL

## NADOLOL

>D>	AB	COPLEY PHARM	80MG	N74368 001	Aug 31, 1994	Mar	CAHN
>D>	AB		120MG	N74368 002	Aug 31, 1994	Mar	CAHN
>D>	AB		160MG	N74368 003	Aug 31, 1994	Mar	CAHN
>A>	AB	TEVA PHARMS	80MG	N74368 001	Aug 31, 1994	Mar	CAHN
>A>	AB		120MG	N74368 002	Aug 31, 1994	Mar	CAHN
>A>	AB		160MG	N74368 003	Aug 31, 1994	Mar	CAHN

NALOXONE HYDROCHLORIDE

## INJECTABLE; INJECTION

## NALOXONE HCL

>D>		@ HOSPIRA	0.4MG/ML	N70172 001	Sep 24, 1986	Mar	CMFD
>A>	AP		0.4MG/ML	N70172 001	Sep 24, 1986	Mar	CMFD

NAPROXEN

## TABLET; ORAL

## NAPROXEN

>D>	AB	COPLEY PHARM	250MG	N74207 001	Dec 21, 1993	Mar	CAHN
>D>	AB		375MG	N74207 002	Dec 21, 1993	Mar	CAHN
>D>	AB		500MG	N74207 003	Dec 21, 1993	Mar	CAHN
>A>	AB	TEVA PHARMS	250MG	N74207 001	Dec 21, 1993	Mar	CAHN
>A>	AB		375MG	N74207 002	Dec 21, 1993	Mar	CAHN
>A>	AB		500MG	N74207 003	Dec 21, 1993	Mar	CAHN

NAPROXEN SODIUM

## TABLET; ORAL

## NAPROXEN SODIUM

>D>	AB	COPLEY PHARM	EQ 250MG BASE	N74289 001	Jan 27, 1994	Mar	CAHN
>D>	AB		EQ 500MG BASE	N74289 002	Jan 27, 1994	Mar	CAHN
>A>	AB	TEVA PHARMS	EQ 250MG BASE	N74289 001	Jan 27, 1994	Mar	CAHN
>A>	AB		EQ 500MG BASE	N74289 002	Jan 27, 1994	Mar	CAHN

NIACIN

## TABLET, EXTENDED RELEASE; ORAL

## NIACIN

>A>	AB	BARR	1GM	N76250 001	Apr 14, 2005	Mar	NEWA	
>D>		+	KOS	1GM	N20381 004	Jul 28, 1997	Mar	CFTG
>A>	AB	+		1GM	N20381 004	Jul 28, 1997	Mar	CFTG



NICARDIPINE HYDROCHLORIDE

INJECTABLE; INJECTION  
CARDENE

>A>	+	ESP PHARMA	2.5MG/ML	N19734 001	Jan 30, 1992	Mar	CAHN
>D>	+	ROCHE PALO	2.5MG/ML	N19734 001	Jan 30, 1992	Mar	CAHN

NITROFURANTOIN; NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL  
NITROFURANTOIN (MONOHYDRATE/MACROCRYSTALS)

>A>	AB	EON	75MG;25MG	N77066 001	Apr 05, 2005	Mar	NEWA
>A>	AB	RANBAXY	75MG;25MG	N76951 001	Mar 30, 2005	Mar	NEWA

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

OCTREOTIDE ACETATE

>A>							
>A>	AP	BEDFORD	EQ 0.2MG BASE/ML	N76330 001	Apr 08, 2005	Mar	NEWA
>A>	AP		EQ 1MG BASE/ML	N76330 002	Apr 08, 2005	Mar	NEWA
>A>			OCTREOTIDE ACETATE (PRESERVATIVE FREE)				
>A>	AP	BEDFORD	EQ 0.05MG BASE/ML	N76313 001	Mar 28, 2005	Mar	NEWA
>A>	AP		EQ 0.1MG BASE/ML	N76313 003	Mar 28, 2005	Mar	NEWA
>A>	AP		EQ 0.5MG BASE/ML	N76313 002	Mar 28, 2005	Mar	NEWA

SANDOSTATIN

>D>	+	NOVARTIS	EQ 0.05MG BASE/ML	N19667 001	Oct 21, 1988	Mar	CFTG
>A>	AP	+	EQ 0.05MG BASE/ML	N19667 001	Oct 21, 1988	Mar	CFTG
>D>	+		EQ 0.1MG BASE/ML	N19667 002	Oct 21, 1988	Mar	CFTG
>A>	AP	+	EQ 0.1MG BASE/ML	N19667 002	Oct 21, 1988	Mar	CFTG
>D>	+		EQ 0.2MG BASE/ML	N19667 004	Jun 12, 1991	Mar	CFTG
>A>	AP	+	EQ 0.2MG BASE/ML	N19667 004	Jun 12, 1991	Mar	CFTG
>D>	+		EQ 0.5MG BASE/ML	N19667 003	Oct 21, 1988	Mar	CFTG
>A>	AP	+	EQ 0.5MG BASE/ML	N19667 003	Oct 21, 1988	Mar	CFTG
>D>	+		EQ 1MG BASE/ML	N19667 005	Jun 12, 1991	Mar	CFTG
>A>	AP	+	EQ 1MG BASE/ML	N19667 005	Jun 12, 1991	Mar	CFTG

OLSALAZINE SODIUM

CAPSULE; ORAL

DIPENTUM

>D>	+	CELLTECH PHARMS	250MG	N19715 001	Jul 31, 1990	Mar	CAHN
>A>	+	UCB	250MG	N19715 001	Jul 31, 1990	Mar	CAHN

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

PRILOSEC

>D>	AB	+	ASTRAZENECA	40MG	N19810 002	Jan 15, 1998	Mar	CTEC
>A>				40MG	N19810 002	Jan 15, 1998	Mar	CTEC

OXALIPLATIN

INJECTABLE; IV (INFUSION)

ELOXATIN

>D>		SANOFI	50MG/VIAL	N21492 001	Aug 09, 2002	Mar	CRLD
>A>	+		50MG/VIAL	N21492 001	Aug 09, 2002	Mar	CRLD
	+	SANOFI SYNTHELABO	50MG/10ML (5MG/ML)	N21759 001	Jan 31, 2005	Jan	NEWA
	+		100MG/20ML (5MG/ML)	N21759 002	Jan 31, 2005	Jan	NEWA

PACLITAXEL

FOR SUSPENSION; IV (INFUSION)

ABRAXANE

+ AM BIOSCIENCE 100MG/VIAL N21660 001 Jan 07, 2005 Jan NEWA

PEMOLINE

TABLET, CHEWABLE; ORAL

PEMOLINE

&gt;D&gt; AB COPLEY PHARM 37.5MG N75555 001 Feb 18, 2000 Mar CAHN

&gt;A&gt; AB TEVA PHARMS 37.5MG N75555 001 Feb 18, 2000 Mar CAHN

TABLET; ORAL

PEMOLINE

&gt;D&gt; AB COPLEY PHARM 18.75MG N75030 003 Feb 22, 2000 Mar CAHN

&gt;D&gt; AB 37.5MG N75030 001 Jan 29, 1999 Mar CAHN

&gt;D&gt; AB 75MG N75030 002 Jan 29, 1999 Mar CAHN

&gt;A&gt; AB TEVA PHARMS 18.75MG N75030 003 Feb 22, 2000 Mar CAHN

&gt;A&gt; AB 37.5MG N75030 001 Jan 29, 1999 Mar CAHN

&gt;A&gt; AB 75MG N75030 002 Jan 29, 1999 Mar CAHN

PENTOBARBITAL SODIUM

CAPSULE; ORAL

SODIUM PENTOBARBITAL

@ VALEANT PHARM INTL 100MG N83264 001 Jan DISC

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

BONTRIL PDM

AA + VALEANT 35MG N85272 001 Feb CRLD

CAM-METRAZINE

@ ABC HOLDING 35MG N83922 001 Feb DISC

@ 35MG N85318 001 Feb DISC

@ 35MG N85320 001 Feb DISC

@ 35MG N85321 001 Feb DISC

@ 35MG N85511 001 Feb DISC

@ CAMALL 35MG N85756 001 Feb DISC

PHENDIMETRAZINE TARTRATE

@ ABC HOLDING 35MG N85761 001 Feb DISC

@ 35MG N85941 001 Jun 27, 1983 Feb DISC

@ EON 35MG N85830 001 Feb DISC

X-TROZINE

@ SHIRE RICHWOOD 35MG N86553 001 Feb DISC

@ 35MG N86554 001 Feb DISC

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

ONA-MAST

@ MAST MM 30MG N86511 001 Feb DISC

@ 30MG N86516 001 Feb DISC

PHENTERMINE HCL

@ ABC HOLDING 18.75MG N88576 001 May 23, 1984 Feb DISC

@ 30MG N85417 001 Feb DISC

@ 30MG N86732 002 Feb DISC

@ 30MG N87215 001 Feb DISC

@ 37.5MG N87915 001 Dec 22, 1983 Feb DISC

@ 37.5MG N87918 001 Dec 22, 1983 Feb DISC

CAPSULE; ORAL

## PHENTERMINE HCL

@	ABC HOLDING	37.5MG	N87930 001	Oct 14, 1983	Feb	DISC
@		37.5MG	N88610 001	Jun 04, 1984	Feb	DISC
@		37.5MG	N88611 001	Jun 04, 1984	Feb	DISC
@		37.5MG	N88625 001	Aug 23, 1984	Feb	DISC
@	CAMALL	15MG	N86735 001		Feb	DISC
@		30MG	N87226 001		Feb	DISC

TABLET; ORAL

## ONA MAST

@	MAST MM	8MG	N86260 001		Feb	DISC
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## PHENTERMINE HCL

@	ABC HOLDING	8MG	N83923 001		Feb	DISC
@		8MG	N85319 001		Feb	DISC
@		37.5MG	N87805 001	Dec 06, 1982	Feb	DISC
@		37.5MG	N88596 001	Apr 04, 1984	Feb	DISC
>A>	AA LANNETT	37.5MG	N40555 001	Apr 15, 2005	Mar	NEWA

PHENTERMINE RESIN COMPLEXCAPSULE, EXTENDED RELEASE; ORAL

## IONAMIN

>D>	CELLTECH PHARMS	EQ 15MG BASE	N11613 004		Mar	CAHN
>D>	+	EQ 30MG BASE	N11613 002		Mar	CAHN
>A>	UCB	EQ 15MG BASE	N11613 004		Mar	CAHN
>A>	+	EQ 30MG BASE	N11613 002		Mar	CAHN

PHENYTOIN SODIUMINJECTABLE; INJECTION

## PHENYTOIN

>D>	+	ELKINS SINN	50MG/ML	N84307 001		Mar	CTEC
>A>	AP	+	50MG/ML	N84307 001		Mar	CTEC

## PHENYTOIN SODIUM

>D>	@	HOSPIRA	50MG/ML	N89521 001	Mar 17, 1987	Mar	CMFD
>A>	AP		50MG/ML	N89521 001	Mar 17, 1987	Mar	CMFD
>D>	@		50MG/ML	N89744 001	Dec 18, 1987	Mar	CMFD
>A>	AP		50MG/ML	N89744 001	Dec 18, 1987	Mar	CMFD

PIROXICAMCAPSULE; ORAL

## PIROXICAM

>D>	AB	COPLEY PHARM	10MG	N74103 001	Aug 28, 1992	Mar	CAHN
>D>	AB		20MG	N74103 002	Aug 28, 1992	Mar	CAHN
>A>	AB	TEVA PHARMS	10MG	N74103 001	Aug 28, 1992	Mar	CAHN
>A>	AB		20MG	N74103 002	Aug 28, 1992	Mar	CAHN

POTASSIUM CHLORIDEINJECTABLE; INJECTION

## POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER

>D>	@	HOSPIRA	14.9MG/ML	N20161 005	Nov 30, 1992	Mar	CMFD
>A>	AP		14.9MG/ML	N20161 005	Nov 30, 1992	Mar	CMFD
>D>	@		745MG/100ML	N20161 001	Nov 30, 1992	Mar	CMFD
>A>	AP		745MG/100ML	N20161 001	Nov 30, 1992	Mar	CMFD

## POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER

>D>	@	HOSPIRA	1.49GM/100ML	N20161 002	Nov 30, 1992	Mar	CMFD
>A>	AP		1.49GM/100ML	N20161 002	Nov 30, 1992	Mar	CMFD

POTASSIUM CITRATE

TABLET, EXTENDED RELEASE; ORAL

UROCIT-K

	MISSION PHARMA	5MEQ	N19071 001	Aug 30, 1985	Jan	CTNA
+		10MEQ	N19071 002	Aug 31, 1992	Jan	CTNA

>A> PRAMLINTIDE ACETATE

&gt;A&gt; INJECTABLE; SUBCUTANEOUS

&gt;A&gt; SYMLIN

>A>	+	AMYLIN	EQ 3MG BASE/5ML (EQ 0.6MG BASE/ML)	N21332 001	Mar 16, 2005	Mar	NEWA
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PREDNISOLONE

SYRUP; ORAL

PREDNISOLONE

>D>	AA	COPLEY PHARM	15MG/5ML	N40322 001	Jan 19, 2000	Mar	CAHN
	AA	IVAX PHARMS	15MG/5ML	N40287 001	May 28, 1999	Jan	CAHN
>A>	AA	TEVA PHARMS	15MG/5ML	N40322 001	Jan 19, 2000	Mar	CAHN

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION; ORAL

PEDIAPRED

>D>	AA	+	CELLTECH PHARMS	EQ 5MG BASE/5ML	N19157 001	May 28, 1986	Mar	CAHN
>A>	AA	+	UCB	EQ 5MG BASE/5ML	N19157 001	May 28, 1986	Mar	CAHN

PRIMIDONE

TABLET; ORAL

PRIMIDONE

	AB	VINTAGE PHARMS	50MG	N40586 001	Feb 24, 2005	Feb	NEWA
	AB		250MG	N40586 002	Feb 24, 2005	Feb	NEWA

PROCHLORPERAZINE MALEATE

TABLET; ORAL

PROCHLORPERAZINE MALEATE

>D>	AB	COPLEY PHARM	EQ 5MG BASE	N40120 001	Jul 11, 1996	Mar	CAHN
>D>	AB		EQ 10MG BASE	N40120 002	Jul 11, 1996	Mar	CAHN
>A>	AB	TEVA PHARMS	EQ 5MG BASE	N40120 001	Jul 11, 1996	Mar	CAHN
>A>	AB		EQ 10MG BASE	N40120 002	Jul 11, 1996	Mar	CAHN

PROGESTERONE

INJECTABLE; INJECTION

PROGESTERONE

AO	+	WATSON LABS (UTAH)	50MG/ML	N17362 002		Feb	CAHN
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PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

PROMETHAZINE HCL

	ABLE	12.5MG	N40558 001	Jul 01, 2004	Jan	CTEC
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PROPOFOL

INJECTABLE; INJECTION

PROPOFOL

>A>	AB	BEDFORD	10MG/ML	N74848 001	Apr 19, 2005	Mar	NEWA
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QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

QUINAPRIL HCL

AB	EON	EQ 5MG BASE	N76803 001	Mar 02, 2005	Feb	NEWA
AB		EQ 10MG BASE	N76803 002	Mar 02, 2005	Feb	NEWA
AB		EQ 20MG BASE	N76803 003	Mar 02, 2005	Feb	NEWA
AB		EQ 40MG BASE	N76803 004	Mar 02, 2005	Feb	NEWA
AB	PAR PHARM	EQ 5MG BASE	N76036 001	Jan 28, 2005	Jan	NEWA
AB		EQ 10MG BASE	N76036 002	Jan 28, 2005	Jan	NEWA
AB		EQ 20MG BASE	N76036 003	Jan 28, 2005	Jan	NEWA
AB		EQ 40MG BASE	N76036 004	Jan 28, 2005	Jan	NEWA

QUINIDINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

QUINIDINE SULFATE

>D>	+ COPLEY PHARM	300MG	N40045 001	Jun 30, 1994	Mar	CAHN
>A>	+ TEVA PHARMS	300MG	N40045 001	Jun 30, 1994	Mar	CAHN

RANITIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

RANITIDINE HCL

AP	BEN VENUE	EQ 25MG BASE/ML	N74777 001	Mar 02, 2005	Feb	NEWA
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SODIUM BENZOATE; SODIUM PHENYLACETATE

SOLUTION; IV (INFUSION)

AMMONUL

	+ UCYCLYD	10%;10% (5GM/50ML;5GM/50ML)	N20645 001	Feb 17, 2005	Feb	NEWA
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SODIUM CHLORIDE

SOLUTION; IRRIGATION

SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

>D>	@ HOSPIRA	450MG/100ML	N18380 001		Mar	CMFD
>A>	AT	450MG/100ML	N18380 001		Mar	CMFD

>D> SOMATREM

&gt;D&gt; INJECTABLE; INJECTION

&gt;D&gt; PROTROPIN

>D>	+ GENENTECH	5MG/VIAL	N19107 001	Oct 17, 1985	Mar	DISC
>A>	@	5MG/VIAL	N19107 001	Oct 17, 1985	Mar	DISC
>D>	+	10MG/VIAL	N19107 002	Oct 24, 1989	Mar	DISC
>A>	@	10MG/VIAL	N19107 002	Oct 24, 1989	Mar	DISC

SOMATROPIN RECOMBINANT

INJECTABLE; SUBCUTANEOUS

SEROSTIM LQ

SERONO

6MG/0.05VIAL

N20604 005	Feb 11, 2005	Feb	NEWA
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SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB	INTERPHARM	400MG;80MG	N76899 001	Jan 27, 2005	Jan	NEWA
AB		800MG;160MG	N76899 002	Jan 27, 2005	Jan	NEWA

TACROLIMUSCAPSULE; ORAL  
PROGRAF

+ FUJISAWA HLTHCARE EQ 1MG BASE N50708 001 Apr 08, 1994 Jan CRLD

TAMOXIFEN CITRATETABLET; ORAL  
TAMOXIFEN CITRATE  
@ PHARMACHEMIE

EQ 10MG BASE N74539 001 Mar 31, 2003 Feb DISC

TELITHROMYCINTABLET; ORAL  
KETEK

AVENTIS PHARMS 300MG N21144 002 Feb 09, 2005 Feb NEWA

TERBUTALINE SULFATETABLET; ORAL  
TERBUTALINE SULFATE

>A>	AB	LANNETT	2.5MG	N77152 001	Mar 25, 2005	Mar	NEWA
>A>	AB		5MG	N77152 002	Mar 25, 2005	Mar	NEWA

TERCONAZOLECREAM; VAGINAL  
TERCONAZOLE

AB ALTANA 0.4% N76712 001 Feb 18, 2005 Jan NEWA

TESTOSTERONE CYPIONATEINJECTABLE; INJECTION  
TESTOSTERONE CYPIONATE

AO PADDOCK 200MG/ML N40530 001 Jan 31, 2005 Jan NEWA

TETRACYCLINE HYDROCHLORIDECAPSULE; ORAL  
SUMYCIN

>D>	AB	APOTHECON	250MG	N60429 001		Mar	DISC
>A>		@	250MG	N60429 001		Mar	DISC
>D>	AB	+	500MG	N60429 003		Mar	DISC
>A>		@	500MG	N60429 003		Mar	DISC
>D>	AB	IVAX PHARMS	500MG	N60704 002		Mar	CRLD
>A>	AB	+	500MG	N60704 002		Mar	CRLD
		@ MAST MM	250MG	N62085 001		Feb	DISC

THIORIDAZINE HYDROCHLORIDECONCENTRATE; ORAL  
THIORIDAZINE HCL

>D>	AA	+	COPLBY PHARM	30MG/ML	N89602 001	Nov 09, 1987	Mar	CAHN
>D>	AA	+		100MG/ML	N89603 001	Nov 09, 1987	Mar	CAHN
>A>	AA	+	TEVA PHARMS	30MG/ML	N89602 001	Nov 09, 1987	Mar	CAHN
>A>	AA	+		100MG/ML	N89603 001	Nov 09, 1987	Mar	CAHN

THIOTHIXENE HYDROCHLORIDECONCENTRATE; ORAL  
THIOTHIXENE HCL

&gt;D&gt; AA COPLBY PHARM EQ 5MG BASE/ML N71554 001 Oct 16, 1987 Mar CAHN

		CONCENTRATE; ORAL							
		THIOTHIXENE HCL							
>A>	AA	TEVA PHARMS	EQ 5MG BASE/ML	N71554	001	Oct 16, 1987	Mar	CAHN	
		<u>TOREMIFENE CITRATE</u>							
		TABLET; ORAL							
		FARESTON							
	+	GTX INC	EQ 60MG BASE	N20497	001	May 29, 1997	Jan	CAHN	
		<u>TORSEMIDE</u>							
		TABLET; ORAL							
		TORSEMIDE							
	AB	ROXANE	5MG	N76943	001	Mar 01, 2005	Feb	NEWA	
	AB		10MG	N76943	002	Mar 01, 2005	Feb	NEWA	
	AB		20MG	N76943	003	Mar 01, 2005	Feb	NEWA	
		<u>TRETINOIN</u>							
		SOLUTION; TOPICAL							
		TRETINOIN							
>D>	AT	COPLEY PHARM	0.05%	N74873	001	Jun 19, 1998	Mar	CAHN	
>A>	AT	TEVA PHARMS	0.05%	N74873	001	Jun 19, 1998	Mar	CAHN	
		<u>TRICHLORMETHIAZIDE</u>							
		TABLET; ORAL							
		NAQUA							
	@	SCHERING	4MG	N12265	002		Feb	DISC	
		TRICHLORMETHIAZIDE							
	@	ABC HOLDING	4MG	N85568	001		Feb	DISC	
	@	PAR PHARM	2MG	N87007	001		Feb	DISC	
	@		4MG	N87005	001		Feb	DISC	
		<u>TRIMETHOPRIM HYDROCHLORIDE</u>							
		SOLUTION; ORAL							
		PRIMSOL							
	@	TARO PHARMS NORTH	EQ 25MG BASE/5ML	N74374	001	Jun 23, 1995	Jan	CAHN	
	+		EQ 50MG BASE/5ML	N74973	001	Jan 24, 2000	Jan	CAHN	
		<u>URSODIOL</u>							
		CAPSULE; ORAL							
		URSODIOL							
>D>	AB	COPLEY PHARM	300MG	N75592	001	May 25, 2000	Mar	CAHN	
>A>	AB	TEVA PHARMS	300MG	N75592	001	May 25, 2000	Mar	CAHN	
		<u>VALPROIC ACID</u>							
		SYRUP; ORAL							
		VALPROIC ACID							
>D>	AA	COPLEY PHARM	250MG/5ML	N73178	001	Aug 25, 1992	Mar	CAHN	
>A>	AA	TEVA PHARMS	250MG/5ML	N73178	001	Aug 25, 1992	Mar	CAHN	
		<u>VERAPAMIL HYDROCHLORIDE</u>							
		CAPSULE, EXTENDED RELEASE; ORAL							
		VERELAN PM							
>D>	+	ELAN PHARM	100MG	N20943	001	Nov 25, 1998	Mar	CRLD	
>A>			100MG	N20943	001	Nov 25, 1998	Mar	CRLD	
>D>	+		200MG	N20943	002	Nov 25, 1998	Mar	CRLD	
>A>			200MG	N20943	002	Nov 25, 1998	Mar	CRLD	

VINORELBINE TARTRATE

INJECTABLE; INJECTION

VINORELBINE TARTRATE

>A> AP AM PHARM EQ 10MG BASE/ML N76849 001 Apr 18, 2005 Mar NEWA



PRESCRIPTION DRUG PRODUCT LIST - 25TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2005

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ASPIRIN

TABLET; ORAL

BAYER EXTRA STRENGTH ASPIRIN FOR MIGRAINE PAIN

>D>	@ BAYER	500MG	N21317 001	Oct 18, 2001	Mar	CMFD
>A>		500MG	N21317 001	Oct 18, 2001	Mar	CMFD

CLOTRIMAZOLE

TABLET; VAGINAL

GYNIX

>D>	COPLBY PHARM	100MG	N73249 001	Feb 13, 1998	Mar	CAHN
>A>	TEVA PHARMS	100MG	N73249 001	Feb 13, 1998	Mar	CAHN

FAMOTIDINE

TABLET; ORAL

FAMOTIDINE

>A>	PERRIGO	10MG	N75400 001	Mar 18, 2005	Mar	NEWA
	WOCKHARDT	10MG	N77146 001	Mar 07, 2005	Feb	NEWA

LORATADINE

SYRUP; ORAL

CLARITIN HIVES RELIEF

@ SCHERING

1MG/ML

N20641 003 Nov 19, 2003 Jan DISC

MICONAZOLE NITRATE

CREAM; VAGINAL

MICONAZOLE 3

TARO

4%

N76773 001 Mar 02, 2005 Feb NEWA

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

**CUMULATIVE SUPPLEMENT NUMBER 03 MARCH 2005**

NO MARCH 2005 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 2005 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA  
See report footnote for information regarding report content

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
>ADD> >ADD>	021457 001 ALBUTEROL SULFATE;ALBUTEROL SULFATE HF	5695743	JUL 06, 2010	DP U491		
		5766573	NOV 29, 2009	U356		
		5605674	FEB 25, 2014	DP		
		6352684	NOV 28, 2009	DP		
	021726 001 ALPRAZOLAM;NIRAVAM	6221392	APR 09, 2018	DP		
		6024981	APR 09, 2018	DP		
	021726 002 ALPRAZOLAM;NIRAVAM	6221392	APR 09, 2018	DP		
		6024981	APR 09, 2018	DP		
	021726 003 ALPRAZOLAM;NIRAVAM	6221392	APR 09, 2018	DP		
		6024981	APR 09, 2018	DP		
	021726 004 ALPRAZOLAM;NIRAVAM	6221392	APR 09, 2018	DP		
		6024981	APR 09, 2018	DP		
	021713 001 ARIPIPIRAZOLE;ABILIFY				NCE	NOV 15, 2007
					I-437	SEP 29, 2007
					I-401	AUG 28, 2006
	021248 001 ARSENIC TRIOXIDE;TRISENOX	6855339	NOV 10, 2018	U617		
		6861076	NOV 10, 2018	U617		
>ADD>	021411 007 ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U494	NCE	NOV 26, 2007
>ADD>		5658590*PED	JAN 11, 2015		PED	MAY 26, 2008
>ADD>	021411 008 ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U494	NCE	NOV 26, 2007
>ADD>		5658590*PED	JAN 11, 2015		PED	MAY 26, 2008
>ADD>	021602 001 BORTEZOMIB;VELCADE				I-452	MAR 25, 2008
>ADD>	021664 001 BROMFENAC SODIUM;XIBROM				NP	MAR 24, 2008
	020838 001 CANDESARTAN CILEXETIL;ATACAND				I-448	FEB 22, 2008
	020838 002 CANDESARTAN CILEXETIL;ATACAND				I-448	FEB 22, 2008
	020838 003 CANDESARTAN CILEXETIL;ATACAND				I-448	FEB 22, 2008
	020838 004 CANDESARTAN CILEXETIL;ATACAND				I-448	FEB 22, 2008
	021710 001 CARBAMAZEPINE;EQUETRO	5326570	JUL 23, 2011	DP U627		
		5912013	JUN 15, 2016	DP		
	021710 002 CARBAMAZEPINE;EQUETRO	5326570	JUL 23, 2011	DP U627		
		5912013	JUN 15, 2016	DP		
	021710 003 CARBAMAZEPINE;EQUETRO	5326570	JUL 23, 2011	DP U627		
		5912013	JUN 15, 2016	DP		
>ADD>	021197 001 CETRORELIX;CETROTIDE	6863891	FEB 19, 2013	U426		
>ADD>	021197 002 CETRORELIX;CETROTIDE	6863891	FEB 19, 2013	U426		
	021673 001 CLOFARABINE;CLOLAR	5661136	AUG 26, 2014	U626		
		5384310	MAY 23, 2009	DS DP		
		4918179	JUN 14, 2005	DS		
>ADD>	020222 001 COLESTIPOL HYDROCHLORIDE;COLESTID	5490987	FEB 13, 2013	DP		
	021572 001 DAPTOMYCIN;CUBICIN	6852689	SEP 24, 2019	U282		
	021572 002 DAPTOMYCIN;CUBICIN	6852689	SEP 24, 2019	U282		
>ADD>	021513 001 DARIFENACIN HYDROBROMIDE;ENABLEX	6106864	AUG 21, 2016	DP U630		
>ADD>		5096890	MAR 13, 2010	DS DP U631		
>ADD>	021513 002 DARIFENACIN HYDROBROMIDE;ENABLEX	6106864	AUG 21, 2016	DP U630		
>ADD>		5096890	MAR 13, 2010	DS DP U631		
>ADD>	021271 001 DESIRUDIN RECOMBINANT;IPRIVASK				NCE	APR 04, 2008
	021605 001 DESLORATADINE;CLARINEX D 24 HOUR				NCE	DEC 21, 2006
					PED	JUN 21, 2007
					NC	MAR 03, 2008
>ADD>	076068 001 DEXRAZOXANE HYDROCHLORIDE;DEXRAZOXANE				PC	AUG 27, 2005
	021168 001 DIVALPROEX SODIUM;DEPAKOTE ER	6720004	DEC 18, 2018	DP		
	021168 002 DIVALPROEX SODIUM;DEPAKOTE ER	6720004	DEC 18, 2018	DP		

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
021269 001	DOXAZOSIN MESYLATE;CARDURA XL				NDF	FEB 22, 2008
>ADD> 021269 002	DOXAZOSIN MESYLATE;CARDURA XL	4837111	MAR 21, 2008	DP	NDF	FEB 22, 2008
>ADD> 021504 001	EPINEPHRINE;LIDOSITE TOPICAL SYS	6862473	SEP 30, 2013	DP		
021437 001	EPLERENONE; INSPRA	4559332	APR 09, 2005	DS DP U537		
021437 002	EPLERENONE; INSPRA	4559332	APR 09, 2005	DS DP U537		
021437 003	EPLERENONE; INSPRA	4559332	APR 09, 2005	DS DP U537		
021337 001	ERTAPENEM SODIUM;INVANZ	5478820	FEB 02, 2013		NCE	NOV 21, 2006
		5652233	FEB 02, 2013		PED	MAY 21, 2007
		5952323	MAY 15, 2017			
		5478820*PED	AUG 02, 2013			
		5652233*PED	AUG 02, 2013			
		5952323*PED	NOV 15, 2017			
076323 001	ESMOLOL HYDROCHLORIDE;ESMOLOL HCL				PC	MAY 01, 2005
>ADD> 021153 001	ESOMEPRAZOLE MAGNESIUM;NEXIUM	4738974	APR 19, 2006	DS DP U373		
>ADD>		4738974*PED	OCT 19, 2006	U635		
>ADD>		6875872	MAY 27, 2014	DS U373		
>ADD>		6875872*PED	NOV 27, 2014			
>ADD> 021153 002	ESOMEPRAZOLE MAGNESIUM;NEXIUM	4738974	APR 19, 2006	DS DP U373		
>ADD>		4738974*PED	OCT 19, 2006	U635		
>ADD>		6875872	MAY 27, 2014	DS U373		
>ADD>		6875872*PED	NOV 27, 2014			
>ADD> 021443 001	ESTROGENS, CONJUGATED SYNTHETIC B;ENJUVIA	6855703	FEB 12, 2021	DS DP U284	NP	DEC 20, 2007
>ADD>		6660726	MAR 08, 2021	DS DP U196		
				U284		
>ADD> 021443 002	ESTROGENS, CONJUGATED SYNTHETIC B;ENJUVIA	6855703	FEB 12, 2021	DS DP U284	NP	DEC 20, 2007
>ADD>		6660726	MAR 08, 2021	DS DP U196		
				U284		
>ADD> 021443 003	ESTROGENS, CONJUGATED SYNTHETIC B;ENJUVIA	6855703	FEB 12, 2021	DS DP U284		
>ADD>		6660726	MAR 08, 2021	DS DP U196		
				U284		
>ADD> 021443 004	ESTROGENS, CONJUGATED SYNTHETIC B;ENJUVIA	6855703	FEB 12, 2021	DS DP U284		
>ADD>		6660726	MAR 08, 2021	DS DP U196		
				U284		
>ADD> 021476 001	ESZOPICLONE;LUNESTA	6864257	AUG 30, 2012			
		6444673	JAN 16, 2012	DS DP		
		6319926	JAN 16, 2012		U620	
>ADD> 021476 002	ESZOPICLONE;LUNESTA	6864257	AUG 30, 2012		U629	
		6444673	JAN 16, 2012	DS DP		
		6319926	JAN 16, 2012		U620	
>ADD> 021476 003	ESZOPICLONE;LUNESTA	6864257	AUG 30, 2012		U629	
		6444673	JAN 16, 2012	DS DP		
		6319926	JAN 16, 2012		U620	
021712 001	FAMOTIDINE;FLUXID	6024981	APR 09, 2018	DP		
		6221392	APR 09, 2018	DP		
021712 002	FAMOTIDINE;FLUXID	6024981	APR 09, 2018	DP		
		6221392	APR 09, 2018	DP		
020747 001	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
020747 002	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
020747 003	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
020747 004	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
020747 005	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			
020747 006	FENTANYL CITRATE;ACTIQ	5785989	MAY 01, 2005			

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
019813 005	FENTANYL;DURAGESIC-12				NPP	MAY 20, 2006
021758 001	FLUOCINONIDE;VANOS				PED	NOV 20, 2006
021077 001	FLUTICASON PROPIONATE;ADVAIR DISKUS 100/50	6536427	MAR 01, 2011	DP	NP	FEB 11, 2008
021077 002	FLUTICASON PROPIONATE;ADVAIR DISKUS 250/50	6536427	MAR 01, 2011	DP		
021077 003	FLUTICASON PROPIONATE;ADVAIR DISKUS 500/50	6536427	MAR 01, 2011	DP		
>ADD>	021152 001	FLUTICASON PROPIONATE;CUTIVATE			NDF	MAR 31, 2008
>ADD>	021169 001	GALANTAMINE HYDROBROMIDE;REMINYL	6358527	JUN 06, 2017	DP U322	
	021169 002	GALANTAMINE HYDROBROMIDE;REMINYL	6358527	JUN 06, 2017	DP U322	
	021169 003	GALANTAMINE HYDROBROMIDE;REMINYL	6358527	JUN 06, 2017	DP U322	
	020509 001	GEMCITABINE HYDROCHLORIDE;GEMZAR	4808614	MAY 15, 2010	DS	I-428 MAY 19, 2007
		5464826	NOV 07, 2012	U146	PED	NOV 19, 2007
		4808614*PED	NOV 15, 2010			
		5464826*PED	MAY 07, 2013			
	020509 002	GEMCITABINE HYDROCHLORIDE;GEMZAR	5464826	NOV 07, 2012	U146	I-428 MAY 19, 2007
		4808614	MAY 15, 2010	DS	PED	NOV 19, 2007
		4808614*PED	NOV 15, 2010			
		5464826*PED	MAY 07, 2013			
	020239 003	GRANISETRON HYDROCHLORIDE;KYTRIL	4886808	DEC 29, 2007	DS DP U89	I-369 AUG 16, 2005
	020239 004	GRANISETRON HYDROCHLORIDE;KYTRIL				I-369 AUG 16, 2005
>ADD>	021455 002	IBANDRONATE SODIUM;BONIVA			D-96	MAR 24, 2008
>ADD>					NS	MAR 24, 2008
>ADD>					NCE	MAY 16, 2008
	021335 001	IMATINIB MESYLATE;GLEEVEC	5521184	JAN 04, 2015		
	021335 002	IMATINIB MESYLATE;GLEEVEC	5521184	JAN 04, 2015		
	021588 001	IMATINIB MESYLATE;GLEEVEC	5521184	JAN 04, 2015		
	021588 002	IMATINIB MESYLATE;GLEEVEC	5521184	JAN 04, 2015		
>ADD>	076104 001	ITRACONAZOLE;ITRACONAZOLE				PC AUG 08, 2005
	020726 001	LETROZOLE;FEMARA				I-446 OCT 29, 2007
	021731 001	LEUPROLIDE ACETATE;ELIGARD	RE37950	OCT 03, 2008	DP U621	
		4938763	OCT 03, 2008	DP U621		
		5278201	JAN 11, 2011	DP		
		5324519	JUN 28, 2011	DP		
		5599552	FEB 04, 2014	DP U621		
		5739176	OCT 03, 2008	DP U621		
		6395293	SEP 28, 2013	DP		
		6565874	OCT 28, 2018	DP U621		
		6626870	MAR 27, 2020	DP		
		6773714	OCT 28, 2018	U621		
>ADD>	021730 001	LEVALBUTEROL TARTRATE;XOPENEX HFA				NP MAR 11, 2008
	021130 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	DS U319	NCE APR 18, 2005
		6559305	JAN 29, 2021	DS	NPP	DEC 19, 2005
		6514529	MAR 15, 2021	DP	I-402	JUL 22, 2006
		5688792*PED	MAY 18, 2015		I-431	JUN 23, 2007
		6514529*PED	SEP 15, 2021		PED	JAN 22, 2007
		6559305*PED	JUL 29, 2021		PED	OCT 18, 2005
					PED	DEC 23, 2007
					PED	JUN 19, 2006
	021130 002	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	DS U319	NCE APR 18, 2005
		6559305	JAN 29, 2021	DS	NPP	DEC 19, 2005
		6514529	MAR 15, 2021	DP	I-402	JUL 22, 2006
		5688792*PED	MAY 18, 2015		I-431	JUN 23, 2007
		6514529*PED	SEP 15, 2021		PED	JAN 22, 2007
		6559305*PED	JUL 29, 2021		PED	OCT 18, 2005
					PED	DEC 23, 2007

PRESCRIPTION AND OTC DRUG PRODUCT  
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
021131 001	LINEZOLID; ZYVOX	5688792 6559305 5688792*PED 6559305*PED	NOV 18, 2014 JAN 29, 2021 MAY 18, 2015 JUL 29, 2021	DS	U319	PED JUN 19, 2006 NCE APR 18, 2005 NPP DEC 19, 2005 I-402 JUL 22, 2006 I-431 JUN 23, 2007 PED JUN 19, 2006 PED JAN 22, 2007 PED OCT 18, 2005 PED DEC 23, 2007
021132 001	LINEZOLID; ZYVOX	5688792 6559305 5688792*PED 6559305*PED	NOV 18, 2014 JAN 29, 2021 MAY 18, 2015 JUL 29, 2021	DS DS	U319	NCE APR 18, 2005 NPP DEC 19, 2005 I-402 JUL 22, 2006 I-431 JUN 23, 2007 PED OCT 18, 2005 PED JAN 22, 2007 PED DEC 23, 2007 PED JUN 19, 2006
>ADD>	021316 001	LOVASTATIN; ALTOPREV	6485748	DEC 12, 2017	DP	
>ADD>	021316 002	LOVASTATIN; ALTOPREV	6485748	DEC 12, 2017	DP	
>ADD>	021316 003	LOVASTATIN; ALTOPREV	6485748	DEC 12, 2017	DP	
>ADD>	021316 004	LOVASTATIN; ALTOPREV	6485748	DEC 12, 2017	DP	
>ADD>	021583 001	MEDROXYPROGESTERONE ACETATE; DEPO-SUBQ PROVERA 10	6495534	MAY 15, 2020	DP	I-451 MAR 25, 2008
>ADD>	020938 001	MELOXICAM; MOBIC				NCE APR 13, 2005 I-430 JUL 16, 2007 PED OCT 13, 2005 PED JAN 16, 2008
>ADD>	021530 001	MELOXICAM; MOBIC	6184220 6184220*PED	MAR 25, 2019 SEP 25, 2019	DP	I-430 JUL 16, 2007 NCE APR 13, 2005 PED OCT 13, 2005 PED JAN 16, 2008
>ADD>	021574 001	METFORMIN HYDROCHLORIDE; FORTAMET	6866866	MAR 17, 2021	DP	
>ADD>	021574 002	METFORMIN HYDROCHLORIDE; FORTAMET	6866866	MAR 17, 2021	DP	
>ADD>	076863 001	METFORMIN HYDROCHLORIDE; METFORMIN HCL				PC APR 12, 2005
>ADD>	019962 001	METOPROLOL SUCCINATE; TOPROL-XL	5001161 4957745 5081154 4927640	SEP 18, 2007 SEP 18, 2007 SEP 18, 2007 MAY 22, 2007	DP DP DS DP	D-95 FEB 15, 2008
>ADD>	019962 002	METOPROLOL SUCCINATE; TOPROL-XL	5001161 4957745 5081154 4927640	SEP 18, 2007 SEP 18, 2007 SEP 18, 2007 MAY 22, 2007	DP DP DS DP	D-95 FEB 15, 2008
>ADD>	019962 003	METOPROLOL SUCCINATE; TOPROL-XL	4957745 5001161 5081154 4927640	SEP 18, 2007 SEP 18, 2007 SEP 18, 2007 MAY 22, 2007	DP DP DS DP	D-95 FEB 15, 2008
>ADD>	019962 004	METOPROLOL SUCCINATE; TOPROL-XL	4957745 5081154 4927640 5001161	SEP 18, 2007 SEP 18, 2007 MAY 22, 2007 SEP 18, 2007	DP DS DP DP	D-95 FEB 15, 2008
>ADD>	021506 002	MICAFUNGIN SODIUM; MYCAMINE				NCE MAR 16, 2010
>ADD>	020717 001	MODAFINIL; PROVIGIL				I-449 JAN 23, 2007
>ADD>	020717 002	MODAFINIL; PROVIGIL				I-449 JAN 23, 2007



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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
020762 001	MOMETASONE FUROATE MONOHYDRATE;NASONEX	5837699 6127353 6723713	JAN 27, 2014 OCT 03, 2017 JAN 27, 2014	DP U625 DS DP U625		
>ADD>	021067 001	MOMETASONE FUROATE;ASMANEX TWISTHALER			NP	MAR 30, 2008
	021204 001	NATEGLINIDE;STARLIX	RE34878 6844008	SEP 08, 2009 NOV 14, 2017		
	021204 002	NATEGLINIDE;STARLIX	RE34878 6844008	SEP 08, 2009 NOV 14, 2017	DP U214 DP U214	
>ADD>	019667 005	OCTREOTIDE ACETATE;SANDOSTATIN	5753618	JUL 08, 2008		
	021706 001	OMEPRAZOLE; ZEGERID	5840737 6489346 6645988 6780882 6699885	JUL 16, 2016 JUL 16, 2016 JUL 16, 2016 JUL 16, 2016 JUL 16, 2016	DS U623 DS DP U624 DS DP U623 DS DP U624	
					U623 U624	
>ADD>	020007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN			PED	SEP 25, 2008
>ADD>					D-97	MAR 25, 2008
>ADD>	020007 003	ONDANSETRON HYDROCHLORIDE; ZOFRAN PRESERVATIVE			PED	SEP 25, 2008
>ADD>					D-97	MAR 25, 2008
	021759 001	OXALIPLATIN; ELOXATIN			NCE	AUG 09, 2007
					I-441	NOV 04, 2007
	021759 002	OXALIPLATIN; ELOXATIN			NCE	AUG 09, 2007
					I-441	NOV 04, 2007
	021014 001	OXCARBAZEPINE; TRILEPTAL			NCE	JAN 14, 2005
					PED	JUL 14, 2005
	021014 002	OXCARBAZEPINE; TRILEPTAL			NCE	JAN 14, 2005
					PED	JUL 14, 2005
	021014 003	OXCARBAZEPINE; TRILEPTAL			NCE	JAN 14, 2005
					PED	JUL 14, 2005
	021285 001	OXCARBAZEPINE; TRILEPTAL			NCE	JAN 14, 2005
					PED	JUL 14, 2005
>ADD>	021660 001	PACLITAXEL; ABRAXANE	6749868	FEB 22, 2013	DP	
>ADD>			6537579	FEB 22, 2013	DP	U632
>ADD>			6753006	FEB 22, 2013	DP	
>ADD>			6506405	FEB 22, 2013	DP	U633
>ADD>			6096331	FEB 22, 2013	DP	U633
>ADD>			5498421	MAR 12, 2013	DP	U634
>ADD>			5439686	FEB 22, 2013	DP	
	021756 001	PEGAPTANIB SODIUM; MACUGEN	6051698	SEP 17, 2012	DS	
			5919455	OCT 27, 2013	DS	
			5932462	AUG 03, 2016	DS	
			6113906	OCT 27, 2013	DS	
			6011020	JAN 04, 2017	DS	
			6426335	JUN 11, 2010		U622
			6147204	JUN 11, 2010	DS	
>ADD>	021332 001	PRAMLINTIDE ACETATE; SYMLIN				NCE
	021446 001	PREGABALIN; LYRICA	6001876	JUL 16, 2017		U55
			6197819	MAR 06, 2018	DS DP	
	021446 002	PREGABALIN; LYRICA	6001876	JUL 16, 2017		U55
			6197819	MAR 06, 2018	DS DP	

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
021446 003	PREGABALIN; LYRICA	6001876	JUL 16, 2017	U55		
021446 004	PREGABALIN; LYRICA	6197819	MAR 06, 2018	DS DP U55		
021446 005	PREGABALIN; LYRICA	6001876	JUL 16, 2017	U55		
021446 006	PREGABALIN; LYRICA	6197819	MAR 06, 2018	DS DP U55		
021446 007	PREGABALIN; LYRICA	6001876	JUL 16, 2017	U55		
021446 008	PREGABALIN; LYRICA	6197819	MAR 06, 2018	DS DP U55		
021511 001	RIBAVIRIN; COPEGUS	6001876	JUL 16, 2017	U55		
>ADD> >ADD>	021071 002	ROSIGLITAZONE MALEATE; AVANDIA	5002953	AUG 30, 2008	DS DP U329	I-447 FEB 25, 2008
>ADD> >ADD>	021071 003	ROSIGLITAZONE MALEATE; AVANDIA	5741803	APR 21, 2015	DS DP U628 U329 U628	I-453 FEB 28, 2008
>ADD> >ADD>	021071 004	ROSIGLITAZONE MALEATE; AVANDIA	5002953	AUG 30, 2008	DS DP U329	I-453 FEB 28, 2008
>ADD> >ADD>	021366 002	ROSUVASTATIN CALCIUM; CRESTOR	6858618	DEC 17, 2021	U618	
>ADD> >ADD>	021366 003	ROSUVASTATIN CALCIUM; CRESTOR	6858618	DEC 17, 2021	U618	
>ADD> >ADD>	021366 004	ROSUVASTATIN CALCIUM; CRESTOR	6858618	DEC 17, 2021	U618	
>ADD> >ADD>	021366 005	ROSUVASTATIN CALCIUM; CRESTOR	6858618	DEC 17, 2021	U618	
>ADD> >ADD>	020645 001	SODIUM BENZOATE; AMMONUL				NDF ODE FEB 17, 2008 FEB 17, 2012
>ADD> >ADD>	020280 001	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	6152897	NOV 20, 2018	DP	
>ADD> >ADD>	020280 002	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	6152897	NOV 20, 2018	DP	
>ADD> >ADD>	020280 003	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	6152897	NOV 20, 2018	DP	
>ADD> >ADD>	020280 005	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	6152897	NOV 20, 2018	DP	
>ADD> >ADD>	020280 008	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	6152897	NOV 20, 2018	DP	
>ADD> >ADD>	020280 009	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	6152897	NOV 20, 2018	DP	
>ADD> >ADD>	021144 002	TELITHROMYCIN; KETEK				NCE APR 01, 2009
>ADD> >ADD>	021029 001	TEMOZOLOMIDE; TEMODAR	5260291	AUG 11, 2013	DS DP U619	ODE MAR 15, 2012
>ADD> >ADD>	021029 002	TEMOZOLOMIDE; TEMODAR	5260291*PED	FEB 11, 2014		I-450 MAR 15, 2008
>ADD> >ADD>	021029 003	TEMOZOLOMIDE; TEMODAR	5260291	AUG 11, 2013	DS DP U619	ODE MAR 15, 2012
>ADD> >ADD>	021029 004	TEMOZOLOMIDE; TEMODAR	5260291*PED	FEB 11, 2014		I-450 MAR 15, 2008
>ADD> >ADD>	020505 001	TOPIRAMATE; TOPAMAX	5260291	AUG 11, 2013	DS DP U619	ODE MAR 15, 2012
	020505 002	TOPIRAMATE; TOPAMAX	5260291*PED	FEB 11, 2014		I-450 MAR 15, 2008
	020505 003	TOPIRAMATE; TOPAMAX				I-41 AUG 11, 2007
	020505 004	TOPIRAMATE; TOPAMAX				I-41 AUG 11, 2007
	020505 005	TOPIRAMATE; TOPAMAX				I-41 AUG 11, 2007
	020505 006	TOPIRAMATE; TOPAMAX				I-41 AUG 11, 2007

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020844 001	TOPIRAMATE;TOPAMAX SPRINKLE				I-41	AUG 11, 2007
020844 002	TOPIRAMATE;TOPAMAX SPRINKLE				I-41	AUG 11, 2007
020844 003	TOPIRAMATE;TOPAMAX SPRINKLE				I-41	AUG 11, 2007
>ADD>	021266 001	VORICONAZOLE;VFEND	5567817	MAY 24, 2016	DS DP U540	
>ADD>	021266 002	VORICONAZOLE;VFEND	5567817	MAY 24, 2016	DS DP U540	
>ADD>	021267 001	VORICONAZOLE;VFEND	5567817	MAY 24, 2016	DS DP U540	
>ADD>	021630 001	VORICONAZOLE;VFEND	5567817	MAY 24, 2016	DS DP U540	
	021060 001	ZICONOTIDE;PRIALT	5795864	JUN 27, 2015	DP	
			5364842	DEC 30, 2011	U48	
			5859186	DEC 30, 2011	U55	
					U48	
					U55	
	021060 002	ZICONOTIDE;PRIALT	5795864	JUN 27, 2015	DP	
			5364842	DEC 30, 2011	U48	
			5859186	DEC 30, 2011	U55	
					U48	
					U55	
	021060 003	ZICONOTIDE;PRIALT	5795864	JUN 27, 2015	DP	
			5364842	DEC 30, 2011	U48	
			5859186	DEC 30, 2011	U55	
					U48	
					U55	
	021060 004	ZICONOTIDE;PRIALT	5795864	JUN 27, 2015	DP	
			5364842	DEC 30, 2011	U48	
			5859186	DEC 30, 2011	U55	
					U48	
					U55	

## Footnote:

- 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).
- Patents submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor:
  - DS = Drug Substance claim
  - DP = Drug Product claim
  - U and number = Method of Use claim (may be multiple). Specific Method of use claims are listed at <http://www.fda.gov/cder/orange/patex.htm>
- 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.
- \*PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with \*PED as was done prior to August 18, 2003. Patents with \*PED added after August 18, 2003 will not contain any information relative to the patent itself other than the \*PED extension. Information related specifically to the patent will be conveyed on the original patent only.

## 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, 25<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>