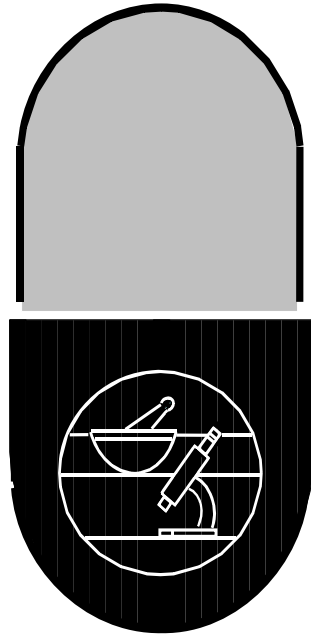


**CUMULATIVE  
SUPPLEMENT 04  
April 2006**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**26<sup>th</sup> EDITION**

**Department of Health and Human Services**

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

2006

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

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**26<sup>th</sup> EDITION**

**Cumulative Supplement 04**

**April 2006**

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Note:

Historically, the Electronic Orange Book (EOB) and Cumulative Supplement (CS) have been updated monthly, each month updated by the end of the second full working week of the following month.

As of February 2005, we are also providing daily EOB product information for new generic drug approvals. Daily generic updates will provide the consumer with the most current listing of approved generic products. Previously, a first-time-generic approved early in the month would not be published in the CS for several weeks. Daily generic updates are especially important since the Orange Book listing may be relevant for substitution.

As a result, the monthly CS will include generic approvals and related product changes current to the day of publication (e.g., the June CS will include generic approvals up to the second week of July). Patent information is also current to the day of publication.

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**26<sup>th</sup> EDITION**

**CUMULATIVE SUPPLEMENT 04**

**April 2006**

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

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

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

## 1.2 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>
AVENTIS PHARMACEUTICALS INC (AVENTIS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
AVENTIS PHARMACEUTICAL PRODUCTS INC (AVENTIS PHARMS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)

DERMIK LABORATORIES DIV AVENTIS PHARMACEUTICALS INC (DERMIK LABS)	SANOFI AVENTIS US LLC  (SANOFI AVENTIS US)
DERMIK LABORATORIES INC (DERMIK LABS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
DERMIK LABORATORIES INC SUB RORER (DERMIK LABS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
CLAY PARK LABORATORIES INC (CLAY PARK)	PERRIGO NEW YORK INC (PERRIGO NEW YORK)
CLAY PARK LABS INC (CLAY PARK)	PERRIGO NEW YORK INC (PERRIGO NEW YORK)
LOREX PHARMACEUTICALS (LOREX)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
MARTEC PHARMACEUTICALS (MARTEC)	MARTEC USA LLC (MARTEC USA LLC)
MARTEC SCIENTIFIC INC (MARTEC)	MARTEC USA LLC (MARTEC USA LLC)
PRIVATE FORMULATIONS INC (PRIVATE FMLTNS)	LEINER HEALTH PRODUCTS INC (LEINER HLTH PRODS)
PHARMACEUTICAL FORMULATIONS INC (PHARM FORM)	LEINER HEALTH PRODUCTS INC (LEINER HLTH PRODS)
SANOFI AVENTIS US INC (SANOFI AVENTIS US)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
SANOFI-AVENTIS US INC (SANOFI AVENTIS)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
SANOFI INC (SANOFI)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
SANOFI SYNTHELABO INC (SANOFI SYNTHELABO)	SANOFI AVENTIS US LLC (SANOFI AVENTIS US)
SANOFI SYNTHELABO RESEARCH DIV SANOFI SYNTHELABO INC (SANOFI SYN RES)	SANOFI AVENTIS US LLC  (SANOFI AVENTIS US)
STERIS LABORATORIES INC (STERIS)	WATSON LABORATORIES INC (WATSON)
UCB PHARMA INC (UCB PHARMA)	UCB INC (UCB INC)

### 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.

The 25th edition and current monthly supplement are available in an electronic downloadable Portable Document Format (PDF) at the EOB home page by clicking on the Annual Edition. 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 2005</u>	<u>MAR 2006</u>	<u>SEP 2006</u>	<u>DEC 2006</u>
DRUG PRODUCTS LISTED	11368	11487		
SINGLE SOURCE	2428	2461		
	(21.4%)	(21.4%)		
MULTISOURCE	8851	8937		
	(77.9%)	(77.8%)		
THERAPEUTICALLY	8642	8730		
EQUIVALENT	(76.04%)	(76.0%)		
NOT THERAPEUTICALLY	209	207		
EQUIVALENT	(1.8%)	(1.8%)		
EXCEPTIONS <sup>1</sup>	89	89		
	(0.8%)	(0.8%)		
NEW MOLECULAR ENTITIES				
APPROVED	11	6		
NUMBER OF APPLICANTS	628	629		

<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 - 26TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2006

1-1

ACETAMINOPHEN; BUTALBITAL

TABLET; ORAL

BUTAPAP

AB	+	MIKART	650MG;50MG	N89988	001	Oct 26, 1992	Jan	CRLD
		SEDAPAP						
		@ MAYRAND	650MG;50MG	N88944	001	Oct 17, 1985	Jan	DISC

ACETAMINOPHEN; CODEINE PHOSPHATE

SOLUTION; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

		@ CLONMEL	120MG/5ML;12MG/5ML	N40098	001	Sep 20, 1996	Jan	DISC
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TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

>D>	AA	TEVA	300MG;60MG	N88629	001	Mar 06, 1985	Apr	CRLD
>A>	AA	+	300MG;60MG	N88629	001	Mar 06, 1985	Apr	CRLD

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

		@ ENDO PHARMS	500MG;7.5MG	N40280	001	Sep 30, 1998	Feb	DISC
		@	650MG;7.5MG	N40280	002	Sep 30, 1998	Feb	DISC
		@	650MG;10MG	N40280	003	Sep 30, 1998	Feb	DISC
		@	750MG;7.5MG	N40281	002	Sep 30, 1998	Feb	DISC
		MIKART	300MG;5MG	N40658	001	Jan 19, 2006	Jan	NEWA
		+	300MG;7.5MG	N40556	002	Mar 24, 2006	Mar	NEWA
AA		VINTAGE PHARMS	325MG;5MG	N40655	001	Jan 19, 2006	Jan	NEWA
AA			325MG;7.5MG	N40656	001	Jan 19, 2006	Jan	NEWA
		HY-PHEN						
		@ ASCHER	500MG;5MG	N87677	001	May 03, 1982	Mar	DISC

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL

OXYCODONE AND ACETAMINOPHEN

>A>	+	MIKART	400MG;5MG	N40687	001	Apr 27, 2006	Apr	NEWA
>A>	+		400MG;7.5MG	N40698	001	Apr 27, 2006	Apr	NEWA
>A>	+		400MG;10MG	N40692	001	Apr 27, 2006	Apr	NEWA
>A>			500MG;10MG	N40676	001	Apr 19, 2006	Apr	NEWA

ACETAZOLAMIDE

TABLET; ORAL

ACETAZOLAMIDE

AB	+	TARO	250MG	N40195	002	May 28, 1997	Mar	CRLD
		DIAMOX						
		@ DURAMED PHARMS BARR	125MG	N08943	001		Mar	DISC
		@	250MG	N08943	002		Mar	DISC

ACETIC ACID, GLACIAL; HYDROCORTISONE

SOLUTION/DROPS; OTIC

HYDROCORTISONE AND ACETIC ACID

AT		VINTAGE	2%;1%	N40609	001	Feb 06, 2006	Jan	NEWA
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ALBUTEROL

AEROSOL, METERED; INHALATION

ALBUTEROL

@ GENPHARM	0.09MG/INH	N73045 001	Aug 19, 1997	Feb	DISC
@ PLIVA	0.09MG/INH	N74072 001	Aug 01, 1996	Feb	DISC

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

AN	RXELITE	EQ 0.083% BASE	N77569 001	Apr 04, 2006	Mar	NEWA
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ALPHA-TOCOPHEROL ACETATE; ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A PALMITATE; VITAMIN K

INJECTABLE; INJECTION

INFUVITE ADULT

+	SANDOZ	2 IU/ML;40MG/ML;12UGM/ML;40 IU/ML;1UGM/ML;3MG/ML;120UGM/ML;8M G/ML;1.2MG/ML;0.72MG/ML;1.2MG/ML; 660 IU/ML;0.03MG/ML	N21163 001	May 18, 2000	Jan	CAHN
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INJECTABLE; IV (INFUSION)

INFUVITE ADULT

+	SANDOZ	2 IU/ML;40MG/ML;12UGM/ML;40 IU/ML;1UGM/ML;3MG/ML;120UGM/ML;8M G/ML;1.2MG/ML;0.72MG/ML;1.2MG/ML; 660 IU/ML;30UGM/ML	N21559 001	Jun 16, 2003	Jan	CAHN
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ALPRAZOLAM

TABLET, EXTENDED RELEASE; ORAL

ALPRAZOLAM

AB	MYLAN	0.5MG	N77391 002	Jan 26, 2006	Jan	NEWA
AB		1MG	N77391 003	Jan 26, 2006	Jan	NEWA
AB		2MG	N77391 004	Jan 26, 2006	Jan	NEWA
AB		3MG	N77391 001	Jan 26, 2006	Jan	NEWA

XANAX XR

AB	PHARMACIA AND UPJOHN	0.5MG	N21434 001	Jan 17, 2003	Jan	CFTG
AB		1MG	N21434 002	Jan 17, 2003	Jan	CFTG
AB		2MG	N21434 003	Jan 17, 2003	Jan	CFTG
AB	+	3MG	N21434 004	Jan 17, 2003	Jan	CFTG

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL

AMANTADINE HYDROCHLORIDE

AB	AMIDE PHARM	100MG	N77659 001	Feb 23, 2006	Feb	NEWA
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AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

CAPSULE; ORAL

LOTREL

>A>	NOVARTIS	EQ 5MG BASE;40MG	N20364 007	Apr 11, 2006	Apr	NEWA
>D>	+	EQ 10MG BASE;20MG	N20364 005	Jun 20, 2002	Apr	CRLD
>A>		EQ 10MG BASE;20MG	N20364 005	Jun 20, 2002	Apr	CRLD
>A>	+	EQ 10MG BASE;40MG	N20364 006	Apr 11, 2006	Apr	NEWA

AMMONIUM LACTATE

CREAM; TOPICAL

AMMONIUM LACTATE

AB	PADDOCK	EQ 12% BASE	N76829 001	Feb 07, 2006	Jan	NEWA
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AMOXICILLIN

CAPSULE; ORAL					
AMOXICILLIN					
AB	AM ANTIBIOTICS	250MG	N62058 001	Jan	CAHN
AB		500MG	N62058 002	Jan	CAHN
FOR SUSPENSION; ORAL					
AMOXICILLIN					
AB	AM ANTIBIOTICS	125MG/5ML	N62059 001	Jan	CAHN
AB		250MG/5ML	N62059 002	Jan	CAHN
TABLET; ORAL					
AMOXICILLIN					
AB	HIKMA	875MG	N65255 001	Mar 29, 2006	Mar NEWA

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL					
AMPICILLIN TRIHYDRATE					
	@ AM ANTIBIOTICS	EQ 250MG BASE	N61602 001	Jan	CAHN
	@	EQ 500MG BASE	N61602 002	Jan	CAHN
FOR SUSPENSION; ORAL					
AMPICILLIN TRIHYDRATE					
	@ AM ANTIBIOTICS	EQ 125MG BASE/5ML	N61601 001	Jan	CAHN
	@	EQ 250MG BASE/5ML	N61601 002	Jan	CAHN

ANIDULAFUNGIN

INJECTABLE; IV (INFUSION)					
ERAXIS					
+	VICURON	50MG/VIAL	N21632 001	Feb 17, 2006	Feb NEWA

ANISINDIONE

TABLET; ORAL					
MIRADON					
	@ SCHERING	50MG	N10909 003	Jan	DISC

>D> ARTICAINE HYDROCHLORIDE; EPINEPHRINE

>D>	INJECTABLE; INJECTION				
>D>	SEPTOCAINE				
>D>	DEPROCO	4%;EQ 0.005MG BASE/ML	N22010 001	Mar 30, 2006	Apr CAIN
		4%;EQ 0.005MG BASE/ML	N22010 001	Mar 30, 2006	Mar NEWA
>D>	+	4%; EQ 0.017MG BASE/1.7ML (4%; EQ 0.01MG BASE/ML)	N20971 001	Apr 03, 2000	Apr CAIN
	+	4%; EQ 0.017MG BASE/1.7ML (4%; EQ 0.01MG BASE/ML)	N20971 001	Apr 03, 2000	Mar CPOT

>A> ARTICAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE

>A>	INJECTABLE; INJECTION					
>A>	SEPTOCAINE					
>A>	+	DEPROCO	4%;EQ 0.0085MG BASE/1.7ML(4%; EQ 0.005MG BASE/ML)	N22010 001	Mar 30, 2006	Apr CAIN
>A>	+		4%; EQ 0.017MG BASE/1.7ML (4%; EQ 0.01MG BASE/ML)	N20971 001	Apr 03, 2000	Apr CAIN

ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID;  
NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K

INJECTABLE; IV (INFUSION)

INFUVITE PEDIATRIC

+	SANDOZ	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.1 4MG/VIAL;17MG/VIAL;1MG/VIAL;1.4MG /VIAL;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL	N21265 001	Feb 21, 2001	Jan	CAHN
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INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE)

+	SANDOZ	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.1 4MG/VIAL;17MG/VIAL;1MG/VIAL;1.4MG /VIAL;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL	N21646 001	Jan 29, 2004	Jan	CAHN
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ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL

BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE

@ ENDO PHARMS 325MG;50MG;40MG;30MG

N75351 001 Mar 05, 1999 Feb DISC

&gt;A&gt; FIORINAL W/CODEINE

&gt;A&gt; AB + WATSON PHARMS 325MG;50MG;40MG;30MG

N19429 003 Oct 26, 1990 Apr CTNA

&gt;D&gt; FIORINAL W/CODEINE NO 3

&gt;D&gt; AB + WATSON PHARMS 325MG;50MG;40MG;30MG

N19429 003 Oct 26, 1990 Apr CTNA

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

TABLET; ORAL

PERCODAN-DEMI

@ ENDO PHARMS 325MG;2.25MG;0.19MG

N07337 005 Feb DISC

BACAMPICILLIN HYDROCHLORIDE

FOR SUSPENSION; ORAL

SPECTROBID

@ PFIZER 125MG/5ML

N50556 001 Mar 23, 1982 Feb DISC

TABLET; ORAL

SPECTROBID

@ PFIZER 400MG

N50520 001 Feb DISC

BENAZEPRIL HYDROCHLORIDE

TABLET; ORAL

BENAZEPRIL HYDROCHLORIDE

AB APOTEX INC 5MG N77128 001 Mar 08, 2006 Feb NEWA

AB 10MG N77128 002 Mar 08, 2006 Feb NEWA

AB 20MG N77128 003 Mar 08, 2006 Feb NEWA

AB 40MG N77128 004 Mar 08, 2006 Feb NEWA

AB BIOKEY 5MG N76820 001 Feb 03, 2006 Jan NEWA

AB 10MG N76820 002 Feb 03, 2006 Jan NEWA

AB 20MG N76820 003 Feb 03, 2006 Jan NEWA

AB 40MG N76820 004 Feb 03, 2006 Jan NEWA

BENZPHETAMINE HYDROCHLORIDE

TABLET; ORAL

BENZPHETAMINE HYDROCHLORIDE

&gt;A&gt; AA PADDOCK 50MG N40578 001 Apr 17, 2006 Apr NEWA

DIDREX

&gt;D&gt; + PHARMACIA AND UPJOHN 50MG N12427 002 Apr CFTG

&gt;A&gt; AA + 50MG N12427 002 Apr CFTG

BENZQUINAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

EMETE-CON

@ PFIZER

EQ 50MG BASE/VIAL

N16820 001

Mar DISC

BETAINE, ANHYDROUS

FOR SOLUTION; ORAL

CYSTADANE

+ JAZZ

1GM/SCOOPFUL

N20576 001 Oct 25, 1996 Feb CAHN

BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE

OINTMENT; TOPICAL

TACLONEX

+ LEO PHARM PRODS

0.064%;0.005%

N21852 001 Jan 09, 2006 Jan NEWA

BRIMONIDINE TARTRATE

SOLUTION/DROPS; OPHTHALMIC

BRIMONIDINE TARTRATE

AT AKORN

0.2%

N76439 001 Mar 14, 2006 Feb NEWA

BRINZOLAMIDE

SUSPENSION/DROPS; OPHTHALMIC

AZOPT

+ ALCON

1%

N20816 001 Apr 01, 1998 Feb CAHN

BUDESONIDE

SPRAY, METERED; NASAL

RHINOCORT

+ ASTRAZENECA

0.032MG/INH

N20746 001 Oct 01, 1999 Mar CRLD

@

0.064MG/INH

N20746 002 Oct 01, 1999 Mar DISC

BUMETANIDE

INJECTABLE; INJECTION

BUMETANIDE

AP + BEDFORD

0.25MG/ML

N74441 001 Jan 27, 1995 Feb CRLD

BUMEX

@ ROCHE

0.25MG/ML

N18226 001 Feb 28, 1983 Feb DISC

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

BUPIVACAINE HYDROCHLORIDE

&gt;A&gt; + HOSPIRA

0.5%

N22046 002 Jul 13, 1983 Apr NEWA

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE

INJECTABLE; INJECTION

BUPIVACAINE HYDROCHLORIDE W/EPINEPHRINE

&gt;A&gt; + HOSPIRA

0.5%;EQ 0.009MG BASE/ML

N22046 001 Jul 13, 1983 Apr NEWA

BUPROPION HYDROCHLORIDE

TABLET; ORAL

BUPROPION HYDROCHLORIDE

AB APOTEX INC

75MG

N76143 001 Jan 17, 2006 Jan NEWA

AB

100MG

N76143 002 Jan 17, 2006 Jan NEWA

BUSULFAN

INJECTABLE; INJECTION  
BUSULFEX

+ PDL BIOPHARMA INC 6MG/ML N20954 001 Feb 04, 1999 Jan CAHN

CAFFEINE; ERGOTAMINE TARTRATE

SUPPOSITORY; RECTAL

CAFERGOT

@ NOVARTIS 100MG;2MG N09000 002 Feb DISC

MIGERGOT

+ G AND W LABS 100MG;2MG N86557 001 Oct 04, 1983 Feb CRLD

CALCIPOTRIENE

CREAM; TOPICAL

DOVONEX

+ LEO PHARM 0.005% N20554 001 Jul 22, 1996 Feb CAHN

OINTMENT; TOPICAL

DOVONEX

+ LEO PHARM 0.005% N20273 001 Dec 29, 1993 Feb CAHN

SOLUTION; TOPICAL

DOVONEX

+ LEO PHARM 0.005% N20611 001 Mar 03, 1997 Feb CAHN

CALCITONIN, SALMON

INJECTABLE; INJECTION

MIACALCIN

+ NOVARTIS 200 IU/ML N17808 002 Mar 29, 1991 Jan CTEC

CALCITRIOL

CAPSULE; ORAL

CALCITRIOL

AB ROXANE 0.25UGM N76917 001 Mar 27, 2006 Mar NEWA

INJECTABLE; INJECTION

CALCITRIOL

AP GENIX THERAP 0.001MG/ML N77102 001 Feb 08, 2006 Jan NEWA

CAPTAPRIL

TABLET; ORAL

CAPTAPRIL

@ CLONMEL HLTHCARE 12.5MG

N74423 001 Feb 13, 1996 Jan DISC

@ 25MG

N74423 002 Feb 13, 1996 Jan DISC

@ 50MG

N74423 003 Feb 13, 1996 Jan DISC

@ 100MG

N74423 004 Feb 13, 1996 Jan DISC

@ ENDO LABS 12.5MG

N74418 001 Feb 13, 1996 Feb DISC

@ 25MG

N74418 002 Feb 13, 1996 Feb DISC

@ 50MG

N74418 003 Feb 13, 1996 Feb DISC

@ 100MG

N74418 004 Feb 13, 1996 Feb DISC

CAPTAPRIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL

CAPTAPRIL AND HYDROCHLOROTHIAZIDE

@ ENDO LABS 25MG;15MG

N74788 001 Dec 29, 1997 Feb DISC

@ 25MG;25MG

N74788 002 Dec 29, 1997 Feb DISC

@ 50MG;15MG

N74788 004 Dec 29, 1997 Feb DISC

## TABLET; ORAL

CAPTOPRIL AND HYDROCHLOROTHIAZIDE

@ ENDO LABS	50MG;25MG	N74788 003	Dec 29, 1997	Feb	DISC
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CARBOPLATIN

## INJECTABLE; INJECTION

CARBOPLATIN

AP	WATSON LABS	50MG/VIAL	N77383 001	Jan 27, 2006	Jan	NEWA
AP		150MG/VIAL	N77383 002	Jan 27, 2006	Jan	NEWA
AP		450MG/VIAL	N77383 003	Jan 27, 2006	Jan	NEWA

## INJECTABLE; IV (INFUSION)

CARBOPLATIN

	@ AM PHARM	EQ 50MG/5ML (10MG/ML)	N77247 001	Oct 21, 2004	Feb	DISC
AP		EQ 50MG/5ML (10MG/ML)	N77266 001	Feb 15, 2006	Jan	NEWA
	@	EQ 150MG/15ML (10MG/ML)	N77247 002	Oct 21, 2004	Feb	DISC
AP		EQ 150MG/15ML (10MG/ML)	N77266 002	Feb 15, 2006	Jan	NEWA
AP		EQ 450MG/45ML (10MG/ML)	N77266 003	Feb 15, 2006	Jan	NEWA
AP		EQ 600MG/60ML (10MG/ML)	N77266 004	Feb 15, 2006	Jan	NEWA
AP	BEDFORD LABS	EQ 600MG/60ML (10MG/ML)	N77244 004	Jan 20, 2006	Jan	NEWA

CEFADROXIL/CEFADROXIL HEMIHYDRATE

## CAPSULE; ORAL

CEFADROXIL

AB	+	IVAX PHARMS	EQ 500MG BASE	N62766 001	Mar 03, 1987	Mar	CRLD
AB		TEVA PHARMS	EQ 500MG BASE	N65282 001	Jan 20, 2006	Jan	NEWA
AB		WESTWARD	EQ 500MG BASE	N65311 001	Feb 07, 2006	Jan	NEWA

DURICEF

@ WARNER CHILCOTT	EQ 500MG BASE	N50512 001		Jan	DISC
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## FOR SUSPENSION; ORAL

CEFADROXIL

	RANBAXY	EQ 125MG BASE/5ML	N65115 001	Mar 26, 2003	Feb	CTEC
AB	TEVA PHARMS	EQ 250MG BASE/5ML	N65278 001	Jan 20, 2006	Jan	NEWA
AB		EQ 500MG BASE/5ML	N65278 002	Jan 20, 2006	Jan	NEWA

DURICEF

@ WARNER CHILCOTT	EQ 125MG BASE/5ML	N50527 002		Feb	DISC
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## TABLET; ORAL

CEFADROXIL

AB		HIKMA	EQ 1GM BASE	N65260 001	Mar 30, 2006	Mar	NEWA
AB	+	IVAX PHARMS	EQ 1GM BASE	N62774 001	Apr 08, 1987	Feb	CRLD

DURICEF

@ WARNER CHILCOTT	EQ 1GM BASE	N50528 001		Jan	DISC
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CEFOXITIN SODIUM

## INJECTABLE; INJECTION

CEFOXITIN

AP		ORCHID HLTHCARE	EQ 1GM BASE/VIAL	N65313 001	Jan 23, 2006	Jan	NEWA
AP			EQ 2GM BASE/VIAL	N65313 002	Jan 23, 2006	Jan	NEWA
AP			EQ 10GM BASE/VIAL	N65312 001	Feb 13, 2006	Jan	NEWA

CEFOXITIN AND DEXTROSE IN DUPLEX CONTAINER

AP		B BRAUN	EQ 1GM BASE/VIAL	N65214 001	Mar 10, 2006	Feb	NEWA
AP			EQ 2GM BASE/VIAL	N65214 002	Mar 10, 2006	Feb	NEWA



CEFTRIAZONE

INJECTABLE; INJECTION

CEFTRIAZONE

>A>	AP	TEVA	EQ 10GM BASE/VIAL	N65274 001	May 01, 2006	Apr	NEWA
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CEFTRIAZONE SODIUM

INJECTABLE; IM-IV

CEFTRIAZONE

AP	AM PHARM PARTNERS	EQ 250MG BASE/VIAL	N65245 001	Feb 15, 2006	Jan	NEWA
AP		EQ 500MG BASE/VIAL	N65245 002	Feb 15, 2006	Jan	NEWA
AP		EQ 1GM BASE/VIAL	N65245 003	Feb 15, 2006	Jan	NEWA
AP		EQ 2GM BASE/VIAL	N65245 004	Feb 15, 2006	Jan	NEWA

INJECTABLE; INJECTION

CEFTRIAZONE

AP	AM PHARM	EQ 10GM BASE/VIAL	N65252 001	Feb 15, 2006	Jan	NEWA
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CEFUROXIME AXETIL

TABLET; ORAL

CEFUROXIME AXETIL

AB	AUROBINDO PHARMA LTD	EQ 125MG BASE	N65308 001	Mar 29, 2006	Mar	NEWA
AB		EQ 250MG BASE	N65308 002	Mar 29, 2006	Mar	NEWA
AB		EQ 500MG BASE	N65308 003	Mar 29, 2006	Mar	NEWA

CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN

AB	HIKMA	EQ 250MG BASE	N65215 001	Jan 24, 2006	Jan	NEWA
AB		EQ 500MG BASE	N65215 002	Jan 24, 2006	Jan	NEWA

CEPHRADINE

CAPSULE; ORAL

ANSPOR

@ GLAXOSMITHKLINE

@

		250MG	N61859 001		Mar	DISC
		500MG	N61859 002		Mar	DISC

CICLOPIROX

CREAM; TOPICAL

CICLOPIROX

AB	PERRIGO	0.77%	N77364 001	Mar 03, 2006	Mar	CAHN
AB	PERRIGO NEW YORK	0.77%	N77364 001	Mar 03, 2006	Feb	NEWA

CILOSTAZOL

TABLET; ORAL

CILOSTAZOL

AB	MUTUAL PHARM	50MG	N77208 002	Mar 29, 2006	Mar	NEWA	
AB		100MG	N77208 001	Mar 29, 2006	Mar	NEWA	
>A>	AB	MYLAN	50MG	N77323 002	Apr 20, 2006	Apr	NEWA
>A>	AB		100MG	N77323 001	Apr 20, 2006	Apr	NEWA

CIMETIDINE

TABLET; ORAL

CIMETIDINE

@ ENDO PHARMS

@

		200MG	N74281 001	May 17, 1994	Feb	DISC
		300MG	N74281 002	May 17, 1994	Feb	DISC

## TABLET; ORAL

## CIMETIDINE

@ ENDO PHARMS	400MG	N74281 003	May 17, 1994	Feb	DISC
@	800MG	N74329 001	May 17, 1994	Feb	DISC

CIMETIDINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## CIMETIDINE HYDROCHLORIDE

@ ENDO PHARMS	EQ 300MG BASE/2ML	N74005 001	Aug 31, 1994	Feb	DISC
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## SOLUTION; ORAL

## CIMETIDINE HYDROCHLORIDE

@ ENDO PHARMS	EQ 300MG BASE/5ML	N74251 001	Dec 22, 1994	Feb	DISC
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CITALOPRAM HYDROBROMIDE

## TABLET; ORAL

## CITALOPRAM HYDROBROMIDE

AB	TARO	EQ 10MG BASE	N77278 001	Mar 22, 2006	Mar	NEWA
AB		EQ 20MG BASE	N77278 002	Mar 22, 2006	Mar	NEWA
AB		EQ 40MG BASE	N77278 003	Mar 22, 2006	Mar	NEWA
AB	TEVA PHARMS	EQ 10MG BASE	N77213 001	Mar 31, 2006	Mar	NEWA
AB		EQ 20MG BASE	N77213 002	Mar 31, 2006	Mar	NEWA
AB		EQ 40MG BASE	N77213 003	Mar 31, 2006	Mar	NEWA

CLARITHROMYCIN

## TABLET, EXTENDED RELEASE; ORAL

## CLARITHROMYCIN

>D>	RANBAXY	1GM	N65210 001	Jan 26, 2005	Apr	CRLD
>A>	+	1GM	N65210 001	Jan 26, 2005	Apr	CRLD

CLINDAMYCIN PHOSPHATE

## SOLUTION; TOPICAL

## CLINDAMYCIN PHOSPHATE

AT	ALTANA	EQ 1% BASE	N65254 001	Feb 14, 2006	Jan	NEWA
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CLOBETASOL PROPIONATE

## SPRAY; TOPICAL

## CLOBEX

+	GALDERMA LABS LP	0.05%	N21835 001	Oct 27, 2005	Feb	CAHN
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CLOPIDOGREL BISULFATE

## TABLET; ORAL

## CLOPIDOGREL BISULFATE

AB	APOTEX	EQ 75MG BASE	N76274 001	Jan 20, 2006	Jan	NEWA	
AB	PLAVIX						
AB	+	SANOFI SYNTHELABO	EQ 75MG BASE	N20839 001	Nov 17, 1997	Jan	CFTG

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

## SYRUP; ORAL

## PROMETH VC W/ CODEINE

+	ALPHARMA US PHARMS	10MG/5ML;5MG/5ML;6.25MG/5ML	N88764 001	Oct 31, 1984	Jan	CTEC
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## PROMETHAZINE VC W/ CODEINE

@	MORTON GROVE	10MG/5ML;5MG/5ML;6.25MG/5ML	N88896 001	Jan 04, 1985	Jan	DISC
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CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE WITH CODEINE SYRUP

AA	VINTAGE	10MG/5ML;6.25MG/5ML	N40650 001	Jan 31, 2006	Jan	NEWA
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COLESTIPOL HYDROCHLORIDE

GRANULE; ORAL

COLESTID

>D>	+	PHARMACIA AND UPJOHN	5GM/PACKET	N17563 004	Sep 22, 1995	Apr	CFTG
>D>			5GM/SCOOPFUL	N17563 003	Sep 22, 1995	Apr	CFTG
>A>	AB		5GM/SCOOPFUL	N17563 003	Sep 22, 1995	Apr	CFTG
>A>	AB	+	5GM/PACKET	N17563 004	Sep 22, 1995	Apr	CFTG
>A>		COLESTIPOL HYDROCHLORIDE					
>A>	AB	IMPAX LABS	5GM/SCOOPFUL	N77277 001	May 02, 2006	Apr	NEWA
>A>	AB		5GM/PACKET	N77277 002	May 02, 2006	Apr	NEWA
>A>		FLAVORED COLESTID					
>D>	+	PHARMACIA AND UPJOHN	5GM/PACKET	N17563 001		Apr	CRLD
>A>			5GM/PACKET	N17563 001		Apr	CRLD

CROMOLYN SODIUM

SOLUTION, CONCENTRATE; ORAL

GASTROCROM

	+	AZUR PHARMA	100MG/5ML	N20479 001	Feb 29, 1996	Feb	CAHN
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CYANOCOBALAMIN

GEL, METERED; NASAL

NASCOBAL

	@	QOL MEDCL	0.5MG/INH	N19722 001	Nov 05, 1996	Mar	DISC
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CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL

CYCLOBENZAPRINE HYDROCHLORIDE

>A>	AB	JUBILANT PHARMS	5MG	N77563 001	Apr 19, 2006	Apr	NEWA
>A>	AB		10MG	N77563 002	Apr 19, 2006	Apr	NEWA
		CYCLOBENZAPRINE HYDROCHLORIDE					
	AB	AMIDE PHARM	5MG	N77291 001	Feb 03, 2006	Jan	NEWA
	AB	MUTUAL PHARM	5MG	N73541 002	Apr 06, 2006	Mar	NEWA
	AB	MYLAN	5MG	N73144 002	Feb 03, 2006	Jan	NEWA
	AB	SANDOZ	5MG	N72854 002	Feb 03, 2006	Jan	NEWA
	AB	WATSON LABS	5MG	N71611 002	Feb 03, 2006	Jan	NEWA
			7.5MG	N71611 003	Feb 03, 2006	Jan	NEWA
		FLEXERIL					
	AB	MCNEIL CONS SPECLT	5MG	N17821 001		Jan	CFTG

DEFEROXAMINE MESYLATE

INJECTABLE; INJECTION

DEFEROXAMINE MESYLATE

AP	SICOR PHARMS	500MG/VIAL	N76806 001	Mar 31, 2006	Mar	NEWA
AP		2GM/VIAL	N76806 002	Mar 31, 2006	Mar	NEWA

DEMECLOCYCLINE HYDROCHLORIDE

TABLET; ORAL

DECLOMYCIN

	@	GLADES PHARMS LLC	75MG	N50261 001		Mar	CAHN
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<u>TABLET; ORAL</u>							
DECLOMYCIN							
AB	GLADES PHARMS LLC	150MG	N50261	002	Mar	CAHN	
AB	+	300MG	N50261	003	Mar	CAHN	
	@ PROTEIN DESIGN LABS	75MG	N50261	001	Feb	CAHN	
AB		150MG	N50261	002	Feb	CAHN	
AB	+	300MG	N50261	003	Feb	CAHN	
<u>DESLORATADINE; PSEUDOEPHEDRINE SULFATE</u>							
TABLET, EXTENDED RELEASE; ORAL							
CLARINEX-D 12 HOUR							
+	SCHERING	2.5MG;120MG	N21313	001	Feb 01, 2006	Feb NEWA	
<u>DESMOPRESSIN ACETATE</u>							
INJECTABLE; INJECTION							
DESMOPRESSIN ACETATE							
	@ BEDFORD	0.004MG/ML	N74575	001	Feb 18, 2000	Jan DISC	
DESMOPRESSIN ACETATE PRESERVATIVE FREE							
	@ BEDFORD	0.004MG/ML	N74574	001	Feb 18, 2000	Jan DISC	
TABLET; ORAL							
DESMOPRESSIN ACETATE							
AB	APOTEX	0.1MG	N77414	001	Mar 07, 2006	Feb NEWA	
AB		0.2MG	N77414	002	Mar 07, 2006	Feb NEWA	
AB	TEVA PHARMS	0.1MG	N77122	001	Jan 25, 2006	Jan NEWA	
AB		0.2MG	N77122	002	Jan 25, 2006	Jan NEWA	
<u>DESOGESTREL; ETHINYL ESTRADIOL</u>							
TABLET; ORAL-28							
MIRCETTE							
AB	+	DURAMED	0.15MG,N/A;0.02MG,0.01MG	N20713	001	Apr 22, 1998	Feb CAHN
AB	+		0.15MG,N/A;0.02MG,0.01MG	N20713	001	Apr 22, 1998	Feb CAHN
<u>DEXAMETHASONE SODIUM PHOSPHATE</u>							
INJECTABLE; INJECTION							
DEXAMETHASONE							
AP	BAXTER HLTHCARE	EQ 10MG PHOSPHATE/ML	N87702	001	Sep 07, 1982	Mar CAHN	
<u>DEXTROAMPHETAMINE SULFATE</u>							
TABLET; ORAL							
DEXTROAMPHETAMINE SULFATE							
	@ ENDO PHARMS	5MG	N40299	001	May 13, 1999	Feb DISC	
<u>DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE</u>							
SYRUP; ORAL							
PROMETHAZINE DM							
AA	VINTAGE	15MG/5ML;6.25MG/5ML	N40649	001	Feb 14, 2006	Jan NEWA	
<u>DIAZEPAM</u>							
TABLET; ORAL							
DIAZEPAM							
AB	VINTAGE PHARMS	2MG	N77749	001	Mar 31, 2006	Mar NEWA	
AB		5MG	N77749	002	Mar 31, 2006	Mar NEWA	
AB		10MG	N77749	003	Mar 31, 2006	Mar NEWA	

DIFLORASONE DIACETATE

CREAM; TOPICAL		DIFLORASONE DIACETATE							
BX	+	ALTANA	0.05%	N76263	001	Dec 20, 2002	Jan	CRLD	
		FLORONE							
		@ PHARMACIA AND UPJOHN	0.05%	N17741	001		Jan	DISC	
		FLORONE E							
		@ PHARMACIA AND UPJOHN	0.05%	N19259	001	Aug 28, 1985	Jan	DISC	
OINTMENT; TOPICAL		DIFLORASONE DIACETATE							
AB	+	TARO	0.05%	N75331	001	May 14, 1999	Jan	CRLD	
		FLORONE							
		@ PHARMACIA AND UPJOHN	0.05%	N17994	001		Jan	DISC	
		PSORCON							
		@ PHARMACIA AND UPJOHN	0.05%	N19260	001	Aug 28, 1985	Jan	DISC	

DIGOXIN

INJECTABLE; INJECTION		DIGOXIN							
AP		SANDOZ	0.25MG/ML	N40481	001	Aug 21, 2003	Jan	CAHN	

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL		DILTZAC							
AB4		APOTEX INC	120MG	N76395	001	Feb 01, 2006	Jan	NEWA	
AB4			180MG	N76395	002	Feb 01, 2006	Jan	NEWA	
AB4			240MG	N76395	003	Feb 01, 2006	Jan	NEWA	
AB4			300MG	N76395	004	Feb 01, 2006	Jan	NEWA	
AB4			360MG	N76395	005	Feb 01, 2006	Jan	NEWA	

DIPYRIDAMOLE

TABLET; ORAL		DIPYRIDAMOLE							
>A>	AB	AMIDE PHARM	25MG	N40542	001	Apr 21, 2006	Apr	NEWA	
>A>	AB		50MG	N40542	002	Apr 21, 2006	Apr	NEWA	
>A>	AB		75MG	N40542	003	Apr 21, 2006	Apr	NEWA	

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL		DISOPYRAMIDE PHOSPHATE							
		@ IVAX PHARMS	EQ 100MG BASE	N70186	001	Nov 18, 1985	Jan	DISC	
		@	EQ 150MG BASE	N70187	001	Nov 18, 1985	Jan	DISC	
		@ SANDOZ	EQ 100MG BASE	N70470	001	Dec 10, 1985	Jan	DISC	
		@	EQ 150MG BASE	N70471	001	Dec 10, 1985	Jan	DISC	

DOLASETRON MESYLATE

INJECTABLE; INJECTION		ANZEMET							
+		SANOFI AVENTIS US	EQ 12.5MG BASE/0.625ML (EQ 20MG BASE/ML)	N20624	002	Sep 11, 1997	Mar	CAIN	
+			EQ 100MG BASE/5ML (EQ 20MG BASE/ML)	N20624	001	Sep 11, 1997	Mar	CAIN	
+			EQ 500MG BASE/25ML (EQ 20MG BASE/ML)	N20624	003	Dec 11, 2001	Mar	CAIN	

## TABLET; ORAL

## ANZEMET

	SANOFI AVENTIS US	EQ 50MG BASE	N20623 001	Sep 11, 1997	Mar	CAIN
+		EQ 100MG BASE	N20623 002	Sep 11, 1997	Mar	CAIN

DOPAMINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## DOPAMINE HYDROCHLORIDE

>D>	AP	+	HOSPIRA	40MG/ML	N74403 001	May 23, 1996	Apr	DISC
>A>			@	40MG/ML	N74403 001	May 23, 1996	Apr	DISC
>D>	AP	+	INTL MEDICATION	40MG/ML	N18014 001		Apr	DISC
>A>			@	40MG/ML	N18014 001		Apr	DISC
>D>	AP	+	SICOR PHARMS	40MG/ML	N72999 001	Oct 23, 1991	Apr	DISC
>A>			@	40MG/ML	N72999 001	Oct 23, 1991	Apr	DISC
>D>	AP	+		80MG/ML	N73000 001	Oct 23, 1991	Apr	DISC
>A>			@	80MG/ML	N73000 001	Oct 23, 1991	Apr	DISC

DOXYCYCLINE

## CAPSULE; ORAL

## DOXYCYCLINE

## @ PAR PHARM

EQ 75MG BASE

N65055 004 Apr 18, 2005 Mar DISC

## @

EQ 150MG BASE

N65055 003 Jul 15, 2005 Mar DISC

## RANBAXY

EQ 75MG BASE

N65053 003 Sep 10, 2003 Mar CTEC

## TABLET; ORAL

## DOXYCYCLINE

## PAR PHARM

EQ 75MG BASE

N65070 003 Dec 30, 2002 Mar CMFD

DOXYCYCLINE HYCLATE

## CAPSULE, DELAYED RELEASE; ORAL

## DORYX

>D>	AB		FH FAULDING CO LTD	EQ 75MG BASE	N50582 002	Aug 13, 2001	Apr	DISC
>A>			@	EQ 75MG BASE	N50582 002	Aug 13, 2001	Apr	DISC
>D>	AB	+		EQ 100MG BASE	N50582 001	Jul 22, 1985	Apr	DISC
>A>			@	EQ 100MG BASE	N50582 001	Jul 22, 1985	Apr	DISC
>D>	AB		WARNER CHILCOTT	EQ 100MG BASE	N62653 001	Oct 30, 1985	Apr	DISC
>A>			@	EQ 100MG BASE	N62653 001	Oct 30, 1985	Apr	DISC

## DOXYCYCLINE HYCLATE

>D>	AB		SANDOZ	EQ 75MG BASE	N65281 001	Dec 21, 2005	Apr	CTEC
>A>				EQ 75MG BASE	N65281 001	Dec 21, 2005	Apr	CTEC
>D>	AB			EQ 100MG BASE	N65281 002	Dec 21, 2005	Apr	CRLD
>A>		+		EQ 100MG BASE	N65281 002	Dec 21, 2005	Apr	CRLD

## TABLET; ORAL

## DOXYCYCLINE HYCLATE

## AB PAR PHARM

EQ 20MG BASE

N65287 001 Feb 28, 2006 Feb NEWA

DROSPIRENONE; ETHINYL ESTRADIOL

## TABLET; ORAL

## YAZ

## + BERLEX LABS

3MG;0.02MG

N21676 001 Mar 16, 2006 Mar NEWA

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## XYLOCAINE W/ EPINEPHRINE

## + DENTSPLY PHARM

0.02MG/ML;2%

N21381 002

Mar CRLD

ERYTHROMYCINSOLUTION; TOPICAL  
A/T/S

AT		TARO PHARMS NORTH	2%		N62405 001	Nov 18, 1982	Feb	CAHN
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ESTAZOLAMTABLET; ORAL  
ESTAZOLAM

>D>	AB	IVAX PHARMS	1MG		N74826 001	Jul 03, 1997	Apr	CAHN
>D>	AB		2MG		N74826 002	Jul 03, 1997	Apr	CAHN
>A>	AB	PAR PHARM	1MG		N74826 001	Jul 03, 1997	Apr	CAHN
>A>	AB		2MG		N74826 002	Jul 03, 1997	Apr	CAHN

ESTRADIOLGEL; TOPICAL  
ESTROGEL

@ ASCEND 0.06%

N21166 001 Feb 09, 2004 Jan CAHN

GEL, METERED; TOPICAL

ESTROGEL  
+ ASCEND 0.06%

N21166 002 Feb 09, 2004 Jan CAHN

ESTRADIOL HEMIHYDRATEEMULSION; TOPICAL  
ESTRASORB

+ ESPRIT PHARMA 0.25%

N21371 001 Oct 09, 2003 Feb CAHN

ESTROGENS, CONJUGATED SYNTHETIC BTABLET; ORAL  
ENJUVIA

		DURAMED	0.3MG		N21443 001	Dec 20, 2004	Mar	CMFD
			0.45MG		N21443 002	Dec 20, 2004	Mar	CMFD
			0.625MG		N21443 003	May 10, 2004	Mar	CMFD
			1.25MG		N21443 004	May 10, 2004	Mar	CMFD

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

BALZIVA-21

BARR 0.035MG;0.4MG

N76198 001 Apr 22, 2004 Mar CRLD

TABLET; ORAL-28

OVCON-35

AB + WARNER CHILCOTT 0.035MG;0.4MG

N17716 001 Mar CRLD

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL

LOESTRIN 24 FE

+ WARNER CHILCOTT 0.02MG;1MG

N21871 001 Feb 17, 2006 Feb NEWA

ETODOLAC

CAPSULE; ORAL

ETODOLAC

@ ENDO PHARMS 200MG

N74842 001 Jul 17, 1997 Feb DISC

@ 300MG

N74842 002 Jul 17, 1997 Feb DISC

AB + TARO 300MG

N75078 002 Apr 30, 1998 Mar CRLD

## CAPSULE; ORAL

LODINE

@ WYETH PHARMS INC	300MG	N18922 003	Jan 31, 1991	Mar	DISC
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## TABLET; ORAL

ETODOLAC

@ ENDO PHARMS	400MG	N74841 001	Jun 27, 1997	Feb	DISC
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FENOFIBRATE

## CAPSULE; ORAL

LIPOFEN

CIPHER	50MG	N21612 001	Jan 11, 2006	Jan	NEWA
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	100MG	N21612 002	Jan 11, 2006	Jan	NEWA
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+	150MG	N21612 003	Jan 11, 2006	Jan	NEWA
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## TABLET; ORAL

FENOFIBRATE

AB	+	TEVA	160MG	N76433 002	May 13, 2005	Jan	CRLD
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TRICOR

@ ABBOTT	54MG	N21203 001	Sep 04, 2001	Jan	DISC
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@	160MG	N21203 003	Sep 04, 2001	Jan	DISC
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FENOLDOPAM MESYLATE

## INJECTABLE; INJECTION

FENOLDOPAM MESYLATE

AP		SANDOZ	EQ 10MG BASE/ML	N77155 001	Feb 15, 2005	Jan	CAHN
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FENOPROFEN CALCIUM

## TABLET; ORAL

FENOPROFEN CALCIUM

@ CLONMEL HLTHCARE	EQ 600MG BASE	N72326 001	Aug 17, 1988	Jan	DISC
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FENTANYL CITRATE

## TROCHE/LOZENGE; TRANSMUCOSAL

ACTIQ (SUGAR-FREE)

CEPHALON	EQ 0.2MG BASE	N20747 001	Nov 04, 1998	Mar	CTNA
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+	EQ 0.4MG BASE	N20747 002	Nov 04, 1998	Mar	CTNA
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	EQ 0.6MG BASE	N20747 003	Nov 04, 1998	Mar	CTNA
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	EQ 0.8MG BASE	N20747 004	Nov 04, 1998	Mar	CTNA
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	EQ 1.2MG BASE	N20747 005	Nov 04, 1998	Mar	CTNA
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	EQ 1.6MG BASE	N20747 006	Nov 04, 1998	Mar	CTNA
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FEXOFENADINE HYDROCHLORIDE

## TABLET; ORAL

FEXOFENADINE HYDROCHLORIDE

AB		DR REDDYS LABS LTD	30MG	N76502 001	Apr 11, 2006	Mar	NEWA
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AB			60MG	N76502 002	Apr 11, 2006	Mar	NEWA
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AB			180MG	N76502 003	Apr 11, 2006	Mar	NEWA
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FLUCONAZOLE

## TABLET; ORAL

FLUCONAZOLE

AB		GLENMARK PHARMA	50MG	N77253 001	Jan 25, 2006	Jan	NEWA
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AB			100MG	N77253 002	Jan 25, 2006	Jan	NEWA
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AB			150MG	N77253 003	Jan 25, 2006	Jan	NEWA
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AB			200MG	N77253 004	Jan 25, 2006	Jan	NEWA
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FLUMAZENIL

INJECTABLE; INJECTION

FLUMAZENIL

AP	SANDOZ	0.5MG/5ML (0.1MG/ML)	N77071 001	May 03, 2005	Jan	CAHN
AP		1MG/10ML (0.1MG/ML)	N77071 002	May 03, 2005	Jan	CAHN

FLUNISOLIDE

AEROSOL, METERED; INHALATION

AEROSPAN HFA

+	FOREST LABS	EQ 78UGM BASE/INH	N21247 001	Jan 27, 2006	Jan	NEWA
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FLUORESCEIN SODIUM

INJECTABLE; INTRAVENOUS

FLUORESCITE

+	ALCON RES	EQ 500MG BASE/5ML (EQ 100MG BASE/ML)	N21980 001	Mar 28, 2006	Mar	NEWA
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FLUOROURACIL

INJECTABLE; INJECTION

ADRUCIL

AP	+	SICOR PHARMS	50MG/ML	N40023 001	Oct 18, 1991	Mar	CRLD
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FLUOROURACIL

AP	+	AM PHARM PARTNERS	50MG/ML	N40278 001	Sep 30, 1998	Mar	CRLD
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AP	+		50MG/ML	N40279 001	Sep 30, 1998	Mar	CRLD
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AP	+		50MG/ML	N40291 001	Mar 24, 1999	Mar	CRLD
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AP	+		50MG/ML	N40379 001	Nov 15, 2000	Mar	CRLD
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>D>	AP	+	BEDFORD	50MG/ML	N89508 001	Jan 26, 1988	Apr	DISC
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>A>			@	50MG/ML	N89508 001	Jan 26, 1988	Apr	DISC
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AP	+		50MG/ML	N89508 001	Jan 26, 1988	Mar	CRLD
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AP	+	SICOR PHARMS	50MG/ML	N40333 001	Jan 27, 2000	Mar	CRLD
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AP	+		50MG/ML	N40334 001	Feb 25, 2000	Mar	CRLD
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>D>	AP	+	STERIS	50MG/ML	N87792 001	Oct 13, 1982	Apr	DISC
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AP	+		50MG/ML	N87792 001	Oct 13, 1982	Mar	CRLD
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>A>			@ WATSON LABS	50MG/ML	N87792 001	Oct 13, 1982	Apr	DISC
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FLUPHENAZINE HYDROCHLORIDE

ELIXIR; ORAL

FLUPHENAZINE HYDROCHLORIDE

>D>	AA		PHARM ASSOC	2.5MG/5ML	N40146 001	Aug 21, 1996	Apr	CRLD
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>A>		+		2.5MG/5ML	N40146 001	Aug 21, 1996	Apr	CRLD
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>D>	AA		TEVA PHARMS	2.5MG/5ML	N81310 001	Apr 29, 1993	Apr	DISC
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>A>			@	2.5MG/5ML	N81310 001	Apr 29, 1993	Apr	DISC
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>D>			PROLIXIN					
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>D>	AA	+	APOTHECON	2.5MG/5ML	N12145 003		Apr	DISC
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>A>			@	2.5MG/5ML	N12145 003		Apr	DISC
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FLUTAMIDE

CAPSULE; ORAL

FLUTAMIDE

>A>	AB		PAR PHARM	125MG	N75298 001	Sep 18, 2001	Apr	CAHN
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>D>	AB		TEVA	125MG	N75298 001	Sep 18, 2001	Apr	CAHN
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FLUTICASONE PROPIONATE

OINTMENT; TOPICAL

FLUTICASONE PROPIONATE

AB	G AND W LABS	0.005%	N77168 001	Mar 03, 2006	Feb	NEWA
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SPRAY, METERED; NASAL

FLONASE

AB	+ GLAXOSMITHKLINE	0.05MG/SPRAY	N20121 001	Oct 19, 1994	Feb	CFTG
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FLUTICASONE PROPIONATE

AB	ROXANE	0.05MG/SPRAY	N76504 001	Feb 22, 2006	Feb	NEWA
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FLUVOXAMINE MALEATE

TABLET; ORAL

FLUVOXAMINE MALEATE

AB	CARACO	25MG	N75900 001	Feb 23, 2006	Feb	NEWA
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AB		50MG	N75900 002	Feb 23, 2006	Feb	NEWA
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AB		100MG	N75900 003	Feb 23, 2006	Feb	NEWA
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FOSCARNET SODIUM

INJECTABLE; INJECTION

FOSCARNET SODIUM

AP	HOSPIRA	2.4GM/100ML	N77174 001	May 31, 2005	Feb	CAHN
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GABAPENTIN

CAPSULE; ORAL

GABAPENTIN

AB	SANDOZ	100MG	N75428 001	Jan 24, 2006	Jan	NEWA
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AB		300MG	N75428 002	Jan 24, 2006	Jan	NEWA
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AB		400MG	N75428 003	Jan 24, 2006	Jan	NEWA
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TABLET; ORAL

GABAPENTIN

AB	SANDOZ	600MG	N76120 001	Jan 27, 2006	Jan	NEWA
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AB		800MG	N76120 002	Jan 27, 2006	Jan	NEWA
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GADOVERSETAMIDE

INJECTABLE; INJECTION

OPTIMARK

+	MALLINCKRODT	1654.5MG/5ML (330.9MG/ML)	N20937 001	Dec 08, 1999	Jan	CPOT
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+		3309MG/10ML (330.9MG/ML)	N20937 002	Dec 08, 1999	Jan	NEWA
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+		4963.5MG/15ML (330.9MG/ML)	N20937 003	Dec 08, 1999	Jan	NEWA
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+		6618MG/20ML (330.9MG/ML)	N20937 004	Dec 08, 1999	Jan	NEWA
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+		16.545GM/50ML (330.9MG/ML)	N20975 001	Dec 08, 1999	Jan	CPOT
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OPTIMARK IN PLASTIC CONTAINER

+	MALLINCKRODT	1654.5MG/5ML (330.9MG/ML)	N20976 001	Dec 08, 1999	Jan	CPOT
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+		3309MG/10ML (330.9MG/ML)	N20976 002	Dec 08, 1999	Jan	NEWA
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+		4963.5MG/15ML (330.9MG/ML)	N20976 003	Dec 08, 1999	Jan	NEWA
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+		6618MG/20ML (330.9MG/ML)	N20976 004	Dec 08, 1999	Jan	NEWA
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GLIMEPIRIDE

TABLET; ORAL

GLIMEPIRIDE

AB	COBALT	1MG	N77280 001	Feb 03, 2006	Jan	NEWA
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AB		2MG	N77280 002	Feb 03, 2006	Jan	NEWA
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AB		4MG	N77280 003	Feb 03, 2006	Jan	NEWA
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AB	GENPHARM	1MG	N77486 001	Feb 10, 2006	Jan	NEWA
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## TABLET; ORAL

## GLIMEPIRIDE

AB	GENPHARM	2MG	N77486 002	Feb 10, 2006	Jan	NEWA
AB		4MG	N77486 003	Feb 10, 2006	Jan	NEWA

GLIPIZIDE

## TABLET; ORAL

## GLIPIZIDE

@ ENDO PHARMS

5MG

N74378 001 Nov 28, 1994 Feb DISC

@

10MG

N74378 002 Nov 28, 1994 Feb DISC

## TABLET, EXTENDED RELEASE; ORAL

## GLIPIZIDE

AB	WATSON LABS	2.5MG	N76467 003	Mar 27, 2006	Mar	NEWA
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## GLUCOTROL XL

AB	PFIZER	2.5MG	N20329 003	Aug 10, 1999	Mar	CFTG
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GLYBURIDE

## TABLET; ORAL

## DIABETA

BX	+ SANOFI AVENTIS US	5MG	N17532 003	May 01, 1984	Feb	CRLD
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HALOBETASOL PROPIONATE

## CREAM; TOPICAL

## HALOBETASOL PROPIONATE

>D>	AB	AGIS INDS	0.05%	N77123 001	Dec 16, 2004	Apr	CAHN
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>A>	AB	PERRIGO ISRAEL	0.05%	N77123 001	Dec 16, 2004	Apr	CAHN
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## OINTMENT; TOPICAL

## HALOBETASOL PROPIONATE

AB	PERRIGO	0.05%	N76872 001	Dec 16, 2004	Mar	CAHN
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HALOPERIDOL DECANOATE

## INJECTABLE; INJECTION

## HALOPERIDOL DECANOATE

AO	SANDOZ	EQ 50MG BASE/ML	N76463 001	Jun 24, 2005	Jan	CAHN
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AO		EQ 100MG BASE/ML	N76463 002	Jun 24, 2005	Jan	CAHN
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HALOPERIDOL LACTATE

## INJECTABLE; INJECTION

## HALOPERIDOL

AP	SANDOZ	EQ 5MG BASE/ML	N76464 001	Sep 29, 2004	Jan	CAHN
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HYDRALAZINE HYDROCHLORIDE

## TABLET; ORAL

## APRESOLINE

@ NOVARTIS

10MG

N08303 004 Feb DISC

@

25MG

N08303 001 Feb DISC

@

50MG

N08303 002 Feb DISC

@

100MG

N08303 005 Feb DISC

## HYDRALAZINE HYDROCHLORIDE

AA	+ PLIVA	10MG	N89097 001	Dec 18, 1985	Feb	CRLD
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AA		25MG	N88467 001	May 01, 1984	Feb	CRLD
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AA		50MG	N88468 001	May 01, 1984	Feb	CRLD
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AA		100MG	N89098 001	Dec 18, 1985	Feb	CRLD
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HYDROCHLOROTHIAZIDE; LISINAPRIL

TABLET; ORAL

LISINAPRIL AND HYDROCHLOROTHIAZIDE

AB	AUROBINDO	12.5MG;10MG	N77606 001	Mar 14, 2006	Feb	NEWA
AB		12.5MG;20MG	N77606 002	Mar 14, 2006	Feb	NEWA
AB		25MG;20MG	N77606 003	Mar 14, 2006	Feb	NEWA

HYDROCHLOROTHIAZIDE; VALSARTAN

TABLET; ORAL

DIOVAN HCT

>A>	NOVARTIS	12.5MG;320MG	N20818 004	Apr 28, 2006	Apr	NEWA
>D>	+	25MG;160MG	N20818 003	Jan 17, 2002	Apr	CRLD
>A>		25MG;160MG	N20818 003	Jan 17, 2002	Apr	CRLD
>A>	+	25MG;320MG	N20818 005	Apr 28, 2006	Apr	NEWA

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION

A-HYDROCORT

AP	HOSPIRA	EQ 100MG BASE/VIAL	N40666 001	Apr 06, 2006	Mar	NEWA
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HYDROCORTISONE; NEOMYCIN; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OTIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

>A>	AT	PHARMAFORCE	1%;EQ 3.5MG BASE;10,000 UNITS	N65219 001	May 01, 2006	Apr	NEWA
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HYDROXYZINE PAMOATE

CAPSULE; ORAL

HYDROXYZINE PAMOATE

BARR

EQ 100MG HCL

N88488 001 Jun 15, 1984 Mar CTEC

VISTARIL

@ PFIZER

EQ 100MG HCL

N11459 006 Mar DISC

IBANDRONATE SODIUM

INJECTABLE; INTRAVENOUS

BONIVA

+ ROCHE

EQ 3MG BASE/3ML

N21858 001 Jan 06, 2006 Jan NEWA

IBUPROFEN LYSINE

>A>							
>A>							
>A>	+	FARMACON IL	EQ 20MG BASE/2ML (EQ 10MG BASE/ML)	N21903 001	Apr 13, 2006	Apr	NEWA

INDOMETHACIN

SUPPOSITORY; RECTAL

INDOMETHACIN

>A>							
>A>	+	G AND W LABS	50MG	N73314 001	Aug 31, 1992	Apr	CTNA
>D>		INDOMETHEGAN					
>D>	+	G AND W LABS	50MG	N73314 001	Aug 31, 1992	Apr	CTNA

INSULIN GLULISINE RECOMBINANT

INJECTABLE; SUBCUTANEOUS

APIDRA

+ SANOFI AVENTIS US

1000 UNITS/10ML (100 UNITS/ML)

N21629 001 Apr 16, 2004 Mar CMFD

+

300 UNITS/3ML (100 UNITS/ML)

N21629 002 Dec 20, 2005 Mar CMFD

INSULIN RECOMBINANT HUMAN

POWDER; INHALATION

EXUBERA

	PFIZER	1MG/INH	N21868	001	Jan 27, 2006	Jan	NEWA
+		3MG/INH	N21868	002	Jan 27, 2006	Jan	NEWA

ISONIAZID

INJECTABLE; INJECTION

ISONIAZID

AP	SANDOZ	100MG/ML	N40648	001	Jul 05, 2005	Jan	CAHN
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ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL

ISOSORBIDE MONONITRATE

AB	WEST WARD	30MG	N76813	002	Mar 30, 2006	Mar	NEWA
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ISRADIPINE

CAPSULE; ORAL

ISRADIPINE

>D>	ABRIKA PHARMS	5MG	N77317	002	Jan 05, 2006	Apr	CTEC	
>A>	AB	5MG	N77317	002	Jan 05, 2006	Apr	CTEC	
>A>	AB	AMIDE PHARM	2.5MG	N77169	001	Apr 24, 2006	Apr	NEWA
>A>	AB	5MG	N77169	002	Apr 24, 2006	Apr	NEWA	

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION

KETOROLAC TROMETHAMINE

AP	SANDOZ	15MG/ML	N76271	001	Oct 06, 2004	Jan	CAHN
AP		30MG/ML	N76271	002	Oct 06, 2004	Jan	CAHN

KETOTIFEN FUMARATE

SOLUTION/DROPS; OPHTHALMIC

KETOTIFEN FUMARATE

>A>	AT	APOTEX	EQ 0.025% BASE	N77354	001	May 09, 2006	Apr	NEWA
>D>	+	NOVARTIS	EQ 0.025% BASE	N21066	001	Jul 02, 1999	Apr	CFTG
>A>	AT	+	EQ 0.025% BASE	N21066	001	Jul 02, 1999	Apr	CFTG

LANSOPRAZOLE; NAPROXEN

CAPSULE, DELAYED REL PELLETS, TABLET; ORAL

PREVACID NAPRAPAC 250 (COPACKAGED)

	TAP PHARM	15MG,N/A;N/A,250MG	N21507	002	Nov 14, 2003	Feb	CTNA
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PREVACID NAPRAPAC 375 (COPACKAGED)

	TAP PHARM	15MG,N/A;N/A,375MG	N21507	003	Nov 14, 2003	Feb	CTNA
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PREVACID NAPRAPAC 500 (COPACKAGED)

+	TAP PHARM	15MG,N/A;N/A,500MG	N21507	004	Nov 14, 2003	Feb	CTNA
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LEVETIRACETAM

TABLET; ORAL

KEPPRA

	UCB INC	750MG	N21035	003	Nov 30, 1999	Mar	CRLD
+		1GM	N21035	004	Jan 06, 2006	Mar	NEWA

LEVOBETAXOLOL HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC

BETAXON

@ ALCON

EQ 0.5% BASE

N21114 001 Feb 23, 2000 Feb CAHN

LIDOCAINE HYDROCHLORIDE

JELLY; TOPICAL

ANESTACON

AT + POLYMEDICA

2%

N80429 001

Jan CDFR

LIDOCAINE; TETRACAINE

PATCH; TOPICAL

SYNERA

+ ENDO PHARMS

70MG;70MG

N21623 001 Jun 23, 2005 Feb CAHN

LISINOPRIL

TABLET; ORAL

LISINOPRIL

AB AUROBINDO

2.5MG

N77622 001 Feb 22, 2006 Feb NEWA

AB

5MG

N77622 002 Feb 22, 2006 Feb NEWA

AB

10MG

N77622 003 Feb 22, 2006 Feb NEWA

AB

20MG

N77622 004 Feb 22, 2006 Feb NEWA

AB

30MG

N77622 005 Feb 22, 2006 Feb NEWA

AB

40MG

N77622 006 Feb 22, 2006 Feb NEWA

LORAZEPAM

TABLET; ORAL

LORAZEPAM

AB MYLAN

0.5MG

N77657 001 Mar 16, 2006 Mar NEWA

AB

1MG

N77657 002 Mar 16, 2006 Mar NEWA

AB

2MG

N77657 003 Mar 16, 2006 Mar NEWA

&gt;A&gt; AB

VINTAGE PHARMS

0.5MG

N77754 001 May 10, 2006 Apr NEWA

&gt;A&gt; AB

1MG

N77754 002 May 10, 2006 Apr NEWA

&gt;A&gt; AB

2MG

N77754 003 May 10, 2006 Apr NEWA

LOVASTATIN

TABLET; ORAL

LOVASTATIN

&gt;A&gt; AB MUTUAL PHARM

10MG

N77520 001 Apr 14, 2006 Apr NEWA

&gt;A&gt; AB

20MG

N77520 002 Apr 14, 2006 Apr NEWA

&gt;A&gt; AB

40MG

N77520 003 Apr 14, 2006 Apr NEWA

LOVASTATIN; NIACIN

TABLET, EXTENDED RELEASE; ORAL

ADVICOR

+ KOS LIFE

20MG;750MG

N21249 002 Dec 17, 2001 Feb CMFD

LUBIPROSTONE

CAPSULE; ORAL

AMITIZA

+ SUCAMPO PHARMS

24UGM

N21908 001 Jan 31, 2006 Jan NEWA

MAGNESIUM HYDROXIDE; OMEPRAZOLE; SODIUM BICARBONATE

TABLET, CHEWABLE; ORAL

ZEGERID

	SANTARUS	700MG;20MG;600MG	N21850 001	Mar 24, 2006	Mar	NEWA
+		700MG;40MG;600MG	N21850 002	Mar 24, 2006	Mar	NEWA

MEDROXYPROGESTERONE ACETATE

INJECTABLE; SUBCUTANEOUS

DEPO-SUBQ PROVERA 104

+	PHARMACIA AND UPJOHN	104MG/0.65ML	N21583 001	Dec 17, 2004	Jan	CAHN
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MEGESTROL ACETATE

SUSPENSION; ORAL

MEGESTROL ACETATE

AB	APOTEX	40MG/ML	N77404 001	Feb 16, 2006	Jan	NEWA
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MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

	@ ROXANE	600MG	N84332 001		Jan	DISC
	@ SANDOZ	200MG	N14547 002		Jan	DISC
	@	400MG	N14547 001		Jan	DISC
	@	400MG	N80655 001		Jan	DISC
	@ SCHERER LABS	400MG	N83343 001		Jan	DISC
	@ TABLICAPS	400MG	N83494 001		Jan	DISC
AA	+ WATSON LABS	200MG	N83304 001		Jan	CRLD
	@	200MG	N85720 001		Jan	DISC
	+	400MG	N83308 001		Jan	CRLD
	@	400MG	N85721 001		Jan	DISC
	MILTOWN					
	@ MEDPOINTE PHARM HLC	200MG	N09698 004		Jan	DISC
	@	400MG	N09698 002		Jan	DISC
	TRANMEP					
	@ SOLVAY	400MG	N16249 001		Jan	DISC

MESALAMINE

ENEMA; RECTAL

ROWASA

>A>	AB	+ ALAVEN PHARM	4GM/60ML	N19618 001	Dec 24, 1987	Apr	CAHN
>D>	AB	+ SOLVAY	4GM/60ML	N19618 001	Dec 24, 1987	Apr	CAHN

METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

GLUMETZA

BX	DEPOMED INC	500MG	N21748 001	Jun 03, 2005	Jan	CAHN
BX		1GM	N21748 002	Jun 03, 2005	Jan	CAHN
	METFORMIN HYDROCHLORIDE					
AB	SUN PHARM INDS (IN)	500MG	N77336 001	Feb 09, 2006	Jan	NEWA
AB		750MG	N77336 002	Feb 09, 2006	Jan	NEWA

>D> METHOTREXATE

&gt;D&gt; INJECTABLE; INJECTION

&gt;D&gt; METHOTREXATE PRESERVATIVE FREE

>D>	+	BEDFORD	EQ 1GM BASE/VIAL	N40632 001	Aug 12, 2005	Apr	CAHN
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METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE PRESERVATIVE FREE

>A>	+	BEDFORD	EQ 1GM BASE/VIAL	N40632 001	Aug 12, 2005	Apr	CAIN
>D>	AP	+	MAYNE PHARMA USA	ED 1GM BASE/40ML (25 MG/ML)	N11719 012	Apr 13, 2005	Apr CPOT
>A>	+		EQ 1GM BASE/40ML (25 MG/ML)	N11719 012	Apr 13, 2005	Apr	CPOT

METHOTREXATE SODIUM

>D>	AP		BEDFORD	EQ 50 MG BASE/2ML (25 ML/ML)	N89340 001	Sep 16, 1986	Apr CPOT
>A>	AP	+		EQ 50MG BASE/2ML (25MG/ML)	N89340 001	Sep 16, 1986	Apr CPOT
>D>	AP			EQ 100MG BASE/4ML (25 MG/ML)	N89341 001	Sep 16, 1986	Apr CTEC
>A>	+			EQ 100MG BASE/4ML (25 MG/ML)	N89341 001	Sep 16, 1986	Apr CTEC
>D>	AP			EQ 200MG BASE/8ML (25 MG/ML)	N89342 001	Sep 16, 1986	Apr CTEC
>A>	+			EQ 200MG BASE/8ML (25 MG/ML)	N89342 001	Sep 16, 1986	Apr CTEC
>D>	AP			EQ 250MG BASE/10ML (25 MG/ML)	N89343 001	Sep 16, 1986	Apr CTEC
>A>	+			EQ 250MG BASE/10ML (25 MG/ML)	N89343 001	Sep 16, 1986	Apr CTEC

METHYLPHENIDATE

FILM, EXTENDED RELEASE; TRANSDERMAL

DAYTRANA

>A>	+	SHIRE	10MG/9HR (1.1MG/HR)	N21514 001	Apr 06, 2006	Apr	NEWA
>A>	+		15MG/9HR (1.6MG/HR)	N21514 002	Apr 06, 2006	Apr	NEWA
>A>	+		20MG/9HR (2.2MG/HR)	N21514 003	Apr 06, 2006	Apr	NEWA
>A>	+		30MG/9HR (3.3MG/HR)	N21514 004	Apr 06, 2006	Apr	NEWA

METHYLPHENIDATE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

METADATE CD

BX		UCB INC	40MG	N21259 004	Feb 19, 2006	Feb	NEWA
			50MG	N21259 005	Feb 19, 2006	Feb	NEWA
	+		60MG	N21259 006	Feb 19, 2006	Feb	NEWA
BX	+	NOVARTIS	40MG	N21284 003	Jun 05, 2002	Feb	CTEC

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

METOCLOPRAMIDE HYDROCHLORIDE

>D>		@	MUTUAL PHARM	EQ 5MG BASE	N71536 002	Jan 16, 1997	Apr CMFD
>A>	AB			EQ 5MG BASE	N71536 002	Jan 16, 1997	Apr CMFD
>D>		@		EQ 10MG BASE	N71536 001	Apr 28, 1993	Apr CMFD
>A>	AB			EQ 10MG BASE	N71536 001	Apr 28, 1993	Apr CMFD

MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE

OINTMENT; TOPICAL

VUSION

+	BARRIER	0.25%;81.35%;15%	N21026 001	Feb 16, 2006	Feb	NEWA
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MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

MIDAZOLAM HYDROCHLORIDE

AP	+	HOSPIRA	EQ 5MG BASE/ML	N75293 002	Jun 20, 2000	Mar	CRLD
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MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

MINOCIN

AB	TRIAx PHARMS	EQ 50MG BASE	N50649 001	May 31, 1990	Feb	CAHN
	@	EQ 75MG BASE	N50649 003	Feb 12, 2001	Feb	CAHN
AB	+	EQ 100MG BASE	N50649 002	May 31, 1990	Feb	CAHN

MIRTAZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL

MIRTAZAPINE

AB	AUROBINDO PHARMA LTD	45MG	N77376 004	Feb 28, 2006	Feb	NEWA
AB	BARR	45MG	N76307 003	Feb 28, 2006	Feb	NEWA

MITOXANTRONE HYDROCHLORIDE

INJECTABLE; INJECTION

MITOXANTRONE

AP	AM PHARM	EQ 20MG BASE/10ML (2MG/ML)	N77496 001	Apr 11, 2006	Mar	NEWA
AP		EQ 25MG BASE/12.5ML (2MG/ML)	N77496 002	Apr 11, 2006	Mar	NEWA
AP		EQ 30MG BASE/15ML (2MG/ML)	N77496 003	Apr 11, 2006	Mar	NEWA
AP	BEDFORD	EQ 20MG BASE/10ML (2MG/ML)	N76611 001	Apr 11, 2006	Mar	NEWA
AP		EQ 25MG BASE/12.5ML (2MG/ML)	N76611 002	Apr 11, 2006	Mar	NEWA
AP		EQ 30MG BASE/15ML (2MG/ML)	N76611 003	Apr 11, 2006	Mar	NEWA
AP	MAYNE PHARMA USA	EQ 20MG BASE/10ML (2MG/ML)	N76871 001	Apr 11, 2006	Mar	NEWA
AP		EQ 25MG BASE/12.5ML (2MG/ML)	N76871 002	Apr 11, 2006	Mar	NEWA
AP		EQ 30MG BASE/15ML (2MG/ML)	N76871 003	Apr 11, 2006	Mar	NEWA
AP	SICOR PHARMS	EQ 20MG BASE/10ML (2MG/ML)	N77356 001	Apr 11, 2006	Mar	NEWA
AP		EQ 25MG BASE/12.5ML (2MG/ML)	N77356 002	Apr 11, 2006	Mar	NEWA
AP		EQ 30MG BASE/15ML (2MG/ML)	N77356 003	Apr 11, 2006	Mar	NEWA
	NOVANTRONE					
AP	+ SERONO INC	EQ 20MG BASE/10ML(2MG/ML)	N19297 001	Dec 23, 1987	Mar	CFTG
AP	+	EQ 25MG BASE/12.5ML (2MG/ML)	N19297 002	Dec 23, 1987	Mar	CFTG
AP	+	EQ 30MG BASE/15ML (2MG/ML)	N19297 003	Dec 23, 1987	Mar	CFTG

MOMETASONE FUROATE

LOTION; TOPICAL

MOMETASONE FUROATE

AB	PERRIGO	0.1%	N77180 001	Apr 06, 2005	Mar	CAHN
AB	TARO	0.1%	N76788 001	Mar 15, 2006	Feb	NEWA

MORPHINE SULFATE

INJECTABLE; INJECTION

MORPHINE SULFATE

HOSPIRA

5MG/ML

N19916 002 Mar 30, 2006 Mar NEWA

NABUMETONE

TABLET; ORAL

NABUMETONE

>D>	AB	IVAX PHARMS	500MG	N76009 001	Jan 24, 2003	Apr	CAHN
>D>	AB		750MG	N76009 002	Jan 24, 2003	Apr	CAHN
>A>	AB	PAR PHARM	500MG	N76009 001	Jan 24, 2003	Apr	CAHN
>A>	AB		750MG	N76009 002	Jan 24, 2003	Apr	CAHN

NAFCILLIN SODIUM

INJECTABLE; INJECTION

NAFCILLIN SODIUM

>D>	AP	SANDOZ	EQ 1GM BASE/VIAL	N62527 002	Aug 02, 1984	Apr	CRLD
>A>	AP	+	EQ 1GM BASE/VIAL	N62527 002	Aug 02, 1984	Apr	CRLD
>D>	AP		EQ 1GM BASE/VIAL	N62732 001	Dec 23, 1986	Apr	CRLD
>A>	AP	+	EQ 1GM BASE/VIAL	N62732 001	Dec 23, 1986	Apr	CRLD
>D>	AP		EQ 2GM BASE/VIAL	N62527 003	Aug 02, 1984	Apr	CRLD
>A>	AP	+	EQ 2GM BASE/VIAL	N62527 003	Aug 02, 1984	Apr	CRLD
>D>	AP		EQ 2GM BASE/VIAL	N62732 002	Dec 23, 1986	Apr	CRLD
>A>	AP	+	EQ 2GM BASE/VIAL	N62732 002	Dec 23, 1986	Apr	CRLD
>D>	AP		EQ 10GM BASE/VIAL	N62527 004	Aug 02, 1984	Apr	CRLD
>A>	AP	+	EQ 10GM BASE/VIAL	N62527 004	Aug 02, 1984	Apr	CRLD

NALTREXONE

>A>		FOR SUSPENSION, EXTENDED RELEASE; INTRAMUSCULAR					
>A>		VIVITROL					
>A>	+	ALKERMES	380MG/VIAL	N21897 001	Apr 13, 2006	Apr	NEWA

NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION; IRRIGATION

NEOSPORIN AND POLYMYXIN B SULFATE

AT		X GEN PHARMS	EQ 40MG BASE/ML;200,000 UNITS/ML	N65106 001	Jan 31, 2006	Jan	NEWA
AT			EQ 800MG BASE/20ML;4,000,000 UNITS/20ML (EQ 40MG BASE/ML;200,000 UNITS/ML)	N65108 001	Jan 31, 2006	Jan	NEWA
		NEOSPORIN G.U. IRRIGANT					
AT	+	MONARCH PHARMS	EQ 40MG BASE/ML;200,000 UNITS/ML	N60707 001		Jan	CTEC
AT	+		EQ 800MG BASE/20ML;4,000,000 UNITS/20ML (EQ 40MG BASE/ML;200,000 UNITS/ML)	N60707 002		Jan	NEWA

NICARDIPINE HYDROCHLORIDE

CAPSULE; ORAL

NICARDIPINE HYDROCHLORIDE

>A>	AB	BARR	20MG	N74439 001	Dec 10, 1996	Apr	CAHN
>A>	AB		30MG	N74439 002	Dec 10, 1996	Apr	CAHN
>D>	AB	IVAX PHARMS	20MG	N74439 001	Dec 10, 1996	Apr	CAHN
>D>	AB		30MG	N74439 002	Dec 10, 1996	Apr	CAHN

INJECTABLE; INJECTION

CARDENE

	+	PDL BIOPHARMA INC	2.5MG/ML	N19734 001	Jan 30, 1992	Jan	CAHN
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NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

AFEDITAB CR

AB1		WATSON LABS	30MG	N75128 001	Mar 10, 2000	Jan	CAHN
AB1			60MG	N75659 001	Oct 26, 2001	Jan	CAHN

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

OCTREOTIDE ACETATE

AP		AM PHARM	EQ 0.2MG BASE/ML	N77450 001	Feb 10, 2006	Jan	NEWA
AP			EQ 1MG BASE/ML	N77450 002	Feb 10, 2006	Jan	NEWA
		OCTREOTIDE ACETATE (PRESERVATIVE FREE)					
AP		AM PHARM	EQ 0.05MG BASE/ML	N77457 001	Feb 10, 2006	Jan	NEWA

INJECTABLE; INJECTIONOCTREOTIDE ACETATE (PRESERVATIVE FREE)

AP	AM PHARM	EQ 0.1MG BASE/ML	N77457 002	Feb 10, 2006	Jan	NEWA
AP		EQ 0.5MG BASE/ML	N77457 003	Feb 10, 2006	Jan	NEWA

OFLOXACIN

## TABLET; ORAL

## OFLOXACIN

AB	DR REDDYS LABS LTD	200MG	N77098 001	Feb 10, 2006	Jan	NEWA
AB		300MG	N77098 002	Feb 10, 2006	Jan	NEWA
AB		400MG	N77098 003	Feb 10, 2006	Jan	NEWA

OMEPRAZOLE; SODIUM BICARBONATE

## CAPSULE; ORAL

## ZEGERID

## SANTARUS

		20MG;1.1GM	N21849 001	Feb 27, 2006	Feb	NEWA
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+		40MG;1.1GM	N21849 002	Feb 27, 2006	Feb	NEWA
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## FOR SUSPENSION; ORAL

## ZEGERID

## SANTARUS

		20MG/PACKET;1.68GM/PACKET	N21636 001	Jun 15, 2004	Feb	CAIN
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+		40MG/PACKET;1.68GM/PACKET	N21706 001	Dec 21, 2004	Feb	CAIN
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OXYMETHOLONE

## TABLET; ORAL

## ANADROL-50

>A>	+	ALAVEN PHARM	50MG	N16848 001		Apr	CAHN
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>D>	+	UNIMED PHARMS	50MG	N16848 001		Apr	CAHN
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PACLITAXEL

## FOR SUSPENSION; IV (INFUSION)

## ABRAXANE

>A>	+	ABRAXIS BIOSCIENCE	100MG/VIAL	N21660 001	Jan 07, 2005	Apr	CAHN
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>D>	+	AM BIOSCIENCE	100MG/VIAL	N21660 001	Jan 07, 2005	Apr	CAHN
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PAROXETINE MESYLATE

## TABLET; ORAL

## PEXEVA

>A>		JDS PHARMS	EQ 10MG BASE	N21299 001	Jul 03, 2003	Apr	CAHN
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>A>			EQ 20MG BASE	N21299 002	Jul 03, 2003	Apr	CAHN
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>A>			EQ 30MG BASE	N21299 003	Jul 03, 2003	Apr	CAHN
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>A>	+		EQ 40MG BASE	N21299 004	Jul 03, 2003	Apr	CAHN
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>D>		SYNTHON PHARMS	EQ 10MG BASE	N21299 001	Jul 03, 2003	Apr	CAHN
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>D>			EQ 20MG BASE	N21299 002	Jul 03, 2003	Apr	CAHN
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>D>			EQ 30MG BASE	N21299 003	Jul 03, 2003	Apr	CAHN
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>D>	+		EQ 40MG BASE	N21299 004	Jul 03, 2003	Apr	CAHN
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PENICILLIN V POTASSIUM

## FOR SOLUTION; ORAL

## PENICILLIN V POTASSIUM

AA	AM ANTIBIOTICS	EQ 125MG BASE/5ML	N61529 001		Jan	CAHN
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AA		EQ 250MG BASE/5ML	N61529 002		Jan	CAHN
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## TABLET; ORAL

## PENICILLIN V POTASSIUM

## @ AM ANTIBIOTICS

## @

		EQ 250MG BASE	N61528 001		Jan	CAHN
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		EQ 500MG BASE	N61528 002		Jan	CAHN
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PERGOLIDE MESYLATE

TABLET; ORAL

PERGOLIDE MESYLATE

>A>	AB	PAR PHARM	EQ 0.05MG BASE	N76061 001	Nov 27, 2002	Apr	CAHN
>A>	AB		EQ 0.25MG BASE	N76061 002	Nov 27, 2002	Apr	CAHN
>A>	AB		EQ 1MG BASE	N76061 003	Nov 27, 2002	Apr	CAHN
>D>	AB	TEVA	EQ 0.05MG BASE	N76061 001	Nov 27, 2002	Apr	CAHN
>D>	AB		EQ 0.25MG BASE	N76061 002	Nov 27, 2002	Apr	CAHN
>D>	AB		EQ 1MG BASE	N76061 003	Nov 27, 2002	Apr	CAHN
		PERMAX					
	AB	VALEANT	EQ 0.05MG BASE	N19385 001	Dec 30, 1988	Jan	CRLD
	AB	+	EQ 0.25MG BASE	N19385 002	Dec 30, 1988	Jan	CRLD

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETH VC PLAIN

	+	ALPHARMA US PHARMS	5MG/5ML; 6.25MG/5ML	N88761 001	Nov 08, 1984	Jan	CTEC
		PROMETHAZINE VC PLAIN					
		@ MORTON GROVE	5MG/5ML; 6.25MG/5ML	N88897 001	Jan 04, 1985	Jan	DISC

PHYTONADIONE

INJECTABLE; INJECTION

AQUAMEPHYTON

		@ MERCK	1MG/0.5ML	N12223 002		Feb	DISC
		@	10MG/ML	N12223 001		Feb	DISC
		VITAMIN K1					
BP	+	HOSPIRA	1MG/0.5ML	N87954 001	Jul 25, 1983	Feb	CRLD
	+		10MG/ML	N87955 001	Jul 25, 1983	Feb	CRLD

PILOCARPINE HYDROCHLORIDE

TABLET; ORAL

PILOCARPINE HYDROCHLORIDE

	AB	IMPAX LABS	5MG	N77248 001	Mar 31, 2006	Mar	NEWA	
	AB		7.5MG	N77248 002	Mar 31, 2006	Mar	NEWA	
		SALAGEN						
	AB	+	MGI PHARMA INC	7.5MG	N20237 002	Apr 18, 2003	Mar	CFTG

POLYETHYLENE GLYCOL 3350

FOR SOLUTION; ORAL

POLYETHYLENE GLYCOL 3350

>A>	AA	TEVA PHARMS	17GM/SCOOPFUL	N77445 001	May 04, 2006	Apr	NEWA
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POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

KLOR-CON

	AB	UPSHER SMITH	8MEQ	N19123 001	Apr 17, 1986	Jan	CRLD	
		POTASSIUM CHLORIDE						
	AB	+	COPLLEY PHARM	8MEQ	N70618 001	Sep 09, 1987	Jan	CRLD

PRAVASTATIN SODIUM

TABLET; ORAL

PRAVACHOL

>D>		BRISTOL MYERS SQUIBB	10MG	N19898 002	Oct 31, 1991	Apr	CFTG
>A>	AB		10MG	N19898 002	Oct 31, 1991	Apr	CFTG

## TABLET; ORAL

## PRAVACHOL

>D>		BRISTOL MYERS SQUIBB	20MG	N19898 003	Oct 31, 1991	Apr	CFTG
>A>	AB		20MG	N19898 003	Oct 31, 1991	Apr	CFTG
>D>			40MG	N19898 004	Mar 22, 1993	Apr	CFTG
>A>	AB		40MG	N19898 004	Mar 22, 1993	Apr	CFTG
>A>		PRAVASTATIN SODIUM					
>A>	AB	TEVA	10MG	N76056 001	Apr 24, 2006	Apr	NEWA
>A>	AB		20MG	N76056 002	Apr 24, 2006	Apr	NEWA
>A>	AB		40MG	N76056 003	Apr 24, 2006	Apr	NEWA

PRAZOSIN HYDROCHLORIDE

## CAPSULE; ORAL

## PRAZOSIN HYDROCHLORIDE

		@ CLONMEL HLTHCARE	EQ 1MG BASE	N72705 001	May 16, 1989	Jan	DISC
		@	EQ 5MG BASE	N72707 001	May 16, 1989	Jan	DISC

PREDNISOLONE ACETATE

## INJECTABLE; INJECTION

## PREDNISOLONE ACETATE

		@ STERIS	25MG/ML	N83398 001		Mar	DISC
		@	50MG/ML	N83764 001		Mar	DISC

PROMETHAZINE HYDROCHLORIDE

## SUPPOSITORY; RECTAL

## PHENERGAN

		@ WYETH PHARMS INC	12.5MG	N10926 002		Mar	DISC
		@	25MG	N10926 001		Mar	DISC

## PROMETHAZINE HYDROCHLORIDE

AB	+	G AND W LABS	25MG	N40428 001	Feb 05, 2002	Mar	CRLD
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## PROMETHEGAN

	+	G AND W LABS	50MG	N87165 001	Aug 14, 1987	Jan	CRLD
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## SYRUP; ORAL

## PROMETHAZINE HYDROCHLORIDE

>A>	AA	VINTAGE	6.25MG/5ML	N40643 001	Apr 26, 2006	Apr	NEWA
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PROPOFOL

## INJECTABLE; INJECTION

## PROPOFOL

AB		HOSPIRA	10MG/ML	N77908 001	Mar 17, 2006	Mar	NEWA
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PROPOXYPHENE HYDROCHLORIDE

## CAPSULE; ORAL

## PROPOXYPHENE HYDROCHLORIDE

AA		PAR PHARM	65MG	N80269 001		Mar	CAHN
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PROPRANOLOL HYDROCHLORIDE

## INJECTABLE; INJECTION

## PROPRANOLOL HYDROCHLORIDE

AP		SANDOZ	1MG/ML	N76400 001	Feb 26, 2003	Jan	CAHN
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PYRIDOSTIGMINE BROMIDE

## INJECTABLE; INJECTION

## REGONOL

AP		SANDOZ	5MG/ML	N17398 001		Jan	CAHN
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QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

QUINAPRIL HYDROCHLORIDE

AB	TORPHARM	EQ 5MG BASE	N76240 001	Jan 26, 2006	Jan	NEWA
AB		EQ 10MG BASE	N76240 002	Jan 26, 2006	Jan	NEWA
AB		EQ 20MG BASE	N76240 003	Jan 26, 2006	Jan	NEWA
AB		EQ 40MG BASE	N76240 004	Jan 26, 2006	Jan	NEWA

QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL

QUINIDINE GLUCONATE

BX	+	MUTUAL PHARM	324MG	N89338 001	Feb 11, 1987	Jan	CTEC
BX		WATSON LABS	324MG	N87810 001	Sep 29, 1982	Jan	CMFD

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

	@	CLOMEL HLTHCARE	200MG	N87011 001		Jan	DISC
	@	LANNETT	200MG	N83743 001		Jan	DISC
	@	MUTUAL PHARM	100MG	N81029 001	Apr 14, 1989	Jan	DISC
	@	PHARM FORM	200MG	N83808 001		Jan	DISC
	@	SANDOZ	200MG	N84631 001		Jan	DISC
	@		200MG	N84914 001		Jan	DISC
AB			200MG	N88072 002		Jan	NEWA
	@		300MG	N89839 001	Sep 29, 1988	Jan	DISC
	@	WATSON LABS	200MG	N83288 001		Jan	DISC
	@		200MG	N85140 002		Jan	DISC

RANITIDINE

INJECTABLE; INJECTION

RANITIDINE

AP		BEDFORD	EQ 25MG BASE/ML	N77458 001	Feb 16, 2006	Feb	NEWA
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RANOLAZINE

TABLET, EXTENDED RELEASE; ORAL

RANEXA

	+	CV THERAP	500MG	N21526 002	Jan 27, 2006	Jan	NEWA
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RISPERIDONE

TABLET, ORALLY DISINTEGRATING; ORAL

RISPERDAL

		JANSSEN PHARMA	3MG	N21444 004	Dec 23, 2004	Mar	CMFD
			4MG	N21444 005	Dec 23, 2004	Mar	CMFD

SELEGILINE

FILM, EXTENDED RELEASE; TRANSDERMAL

EMSAM

		SOMERSET	6MG/24HR	N21336 001	Feb 27, 2006	Mar	CAIN
			9MG/24HR	N21336 002	Feb 27, 2006	Mar	CAIN
	+		12MG/24HR	N21336 003	Feb 27, 2006	Mar	CAIN

SELEGILINE HYDROCHLORIDE

FILM, EXTENDED RELEASE; TRANSDERMAL

EMSAM

	SOMERSET	6MG/24HR	N21336 001	Feb 27, 2006	Feb	NEWA
		9MG/24HR	N21336 002	Feb 27, 2006	Feb	NEWA
+		12MG/24HR	N21336 003	Feb 27, 2006	Feb	NEWA

SODIUM PHOSPHATE, DIBASIC, ANHYDROUS; SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE

TABLET; ORAL

OSMOPREP

+	SALIX PHARMS	0.398GM;1.102GM	N21892 001	Mar 16, 2006	Mar	NEWA
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SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE

AB	PUREPAC PHARM	25MG	N40353 003	Mar 15, 2006	Feb	NEWA
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SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION

ANECTINE

AP	+	SANDOZ	20MG/ML	N08453 002		Jan	CAHN
		@	50MG/ML	N08453 003		Jan	CAHN
		@	500MG/VIAL	N08453 001		Jan	CAHN
		@	1GM/VIAL	N08453 004		Jan	CAHN

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

SULFACETAMIDE SODIUM

>A>	AT	ALCON	30%	N89068 001	May 05, 1987	Apr	CAHN
>D>	AT	STERIS	30%	N89068 001	May 05, 1987	Apr	CAHN

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL

BACTRIM PEDIATRIC

>D>		@ MUTUAL PHARM	200MG/5ML; 40MG/5ML	N17560 002		Apr	CMFD
>A>	AB		200MG/5ML; 40MG/5ML	N17560 002		Apr	CMFD

SUMATRIPTAN SUCCINATE

INJECTABLE; SUBCUTANEOUS

IMITREX

+	GLAXOSMITHKLINE	EQ 6MG BASE/0.5ML (12MG/ML)	N20080 001	Dec 28, 1992	Feb	CDFR
+	GLAXOSMITHKLINE	EQ 4MG BASE/0.5ML (8MG/ML)	N20080 002	Feb 01, 2006	Feb	NEWA
+		EQ 6MG BASE/0.5ML (12MG/ML)	N20080 003	Dec 23, 1996	Feb	NEWA

SUNITINIB MALATE

CAPSULE; ORAL

SUTENT

	PFIZER	12.5MG	N21938 001	Jan 26, 2006	Jan	NEWA
		25MG	N21938 002	Jan 26, 2006	Jan	NEWA
+		50MG	N21938 003	Jan 26, 2006	Jan	NEWA

TECHNETIUM TC-99M APCITIDEINJECTABLE; INJECTION  
ACUTECT

>D>		BERLEX LABS	N/A	N20887	001	Sep 14, 1998	Apr	CAHN
>A>		CIS BIO INTL SA	N/A	N20887	001	Sep 14, 1998	Apr	CAHN

TECHNETIUM TC-99M DEPREOTIDEINJECTABLE; INJECTION  
NEO TECT KIT

>D>	+	BERLEX LABS	N/A	N21012	001	Aug 03, 1999	Apr	CAHN
>A>	+	CIS BIO INTL SA	N/A	N21012	001	Aug 03, 1999	Apr	CAHN

TERCONAZOLESUPPOSITORY; VAGINAL  
TERAZOL 3

AB	+	ORTHO MCNEIL PHARM	80MG	N19641	001	May 24, 1988	Mar	CFTG
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TERCONAZOLE

AB		PERRIGO NEW YORK	80MG	N77149	001	Mar 17, 2006	Mar	NEWA
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TESTOSTERONEGEL; TRANSDERMAL  
ANDROGEL

AB	+	UNIMED PHARMS	1%	N21015	001	Feb 28, 2000	Jan	CTEC
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TESTOSTERONE

AB		WATSON LABS	1%	N76737	001	Jan 27, 2006	Jan	NEWA
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TESTOSTERONE ENANTHATEINJECTABLE; INJECTION  
DELATESTRYL

AO	+	INDEVUS PHARMS	200MG/ML	N09165	003		Jan	CAHN
		@	200MG/ML	N09165	001		Jan	CAHN

TETRACYCLINE HYDROCHLORIDECAPSULE; ORAL  
ACHROMYCIN V

>D>		@ CLONMEL HLTHCARE	250MG	N50278	003		Apr	CAHN
>D>		@	500MG	N50278	001		Apr	CAHN
>A>		@ SCIREG INTL INC	250MG	N50278	003		Apr	CAHN
>A>		@	500MG	N50278	001		Apr	CAHN

THALLOUS CHLORIDE, TL-201INJECTABLE; INJECTION  
THALLOUS CHLORIDE TL 201

AP		TRACE RADIOCHEMICALS	1mCi/ML	N75569	001	Nov 21, 2001	Feb	CAHN
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THEOPHYLLINETABLET, EXTENDED RELEASE; ORAL  
THEOPHYLLINE

>A>	AB	NOSTRUM	400MG	N40595	001	Apr 21, 2006	Apr	NEWA
>A>	AB		600MG	N40560	002	Apr 21, 2006	Apr	NEWA
		UNIPHYL						
>D>	+	PURDUE FREDERICK	400MG	N87571	001	Sep 01, 1982	Apr	CTEC
>A>	AB	+	400MG	N87571	001	Sep 01, 1982	Apr	CTEC
>D>	+		600MG	N40086	001	Apr 15, 1996	Apr	CTEC



	TABLET, EXTENDED RELEASE; ORAL					
	UNIPHYL					
>A>	AB	+ PURDUE FREDERICK	600MG	N40086 001	Apr 15, 1996	Apr CTEC
	<u>TINIDAZOLE</u>					
	TABLET; ORAL					
	TINDAMAX					
		MISSION PHARMA	250MG	N21618 001	May 17, 2004	Jan CAHN
		+	500MG	N21618 002	May 17, 2004	Jan CAHN
	<u>TRAMADOL HYDROCHLORIDE</u>					
	TABLET; ORAL					
	TRAMADOL HYDROCHLORIDE					
		@ IVAX PHARMS	50MG	N75963 001	Jul 03, 2002	Jan DISC
	<u>TRIAMCINOLONE DIACETATE</u>					
	INJECTABLE; INJECTION					
	ARISTOCORT					
		@ SANDOZ	25MG/ML	N11685 003		Jan CAHN
		@	40MG/ML	N12802 001		Jan CAHN
	<u>TRIAMCINOLONE HEXACETONIDE</u>					
	INJECTABLE; INJECTION					
	ARISTOSPAN					
		+ SANDOZ	5MG/ML	N16466 001		Jan CAHN
		+	20MG/ML	N16466 002		Jan CAHN
	<u>TRIPLENNAMINE HYDROCHLORIDE</u>					
	TABLET; ORAL					
	PBZ					
		@ NOVARTIS	50MG	N05914 002		Jan DISC
	<u>TROLEANDOMYCIN</u>					
	CAPSULE; ORAL					
	TAO					
		@ PFIZER	EQ 250MG BASE	N50336 002		Mar DISC
	<u>UNOPROSTONE ISOPROPYL</u>					
	SOLUTION/DROPS; OPHTHALMIC					
	RESCULA					
		+ R TECH UENO LTD	0.15%	N21214 001	Aug 03, 2000	Feb CAHN
	<u>UROKINASE</u>					
	INJECTABLE; INJECTION					
	ABBOKINASE					
>D>		@ ABBOTT	5,000 IU/VIAL	N21846 003		Apr CAHN
>D>		@	9,000 IU/VIAL	N21846 002		Apr CAHN
>D>		+	250,000 IU/VIAL	N21846 001		Apr CAHN
>A>		@ IMARX THERAP	5,000 IU/VIAL	N21846 003		Apr CAHN
>A>		@	9,000 IU/VIAL	N21846 002		Apr CAHN
>A>		+	250,000 IU/VIAL	N21846 001		Apr CAHN

VECURONIUM BROMIDE

INJECTABLE; INJECTION  
VECURONIUM BROMIDE

AP	+	BEDFORD	20MG/VIAL	N75549 002	Jun 13, 2000	Jan	CRLD
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ZIDOVUDINE

CAPSULE; ORAL  
RETROVIR

AB	+	GLAXOSMITHKLINE	100MG	N19655 001	Mar 19, 1987	Mar	CFTG
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ZIDOVUDINE

AB		AUROBINDO PHARMA LTD	100MG	N78128 001	Mar 27, 2006	Mar	NEWA
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ZIPRASIDONE HYDROCHLORIDE

SUSPENSION; ORAL  
GEODON

	+	PFIZER INC	EQ 10MG BASE/ML	N21483 001	Mar 29, 2006	Mar	NEWA
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ZONISAMIDE

CAPSULE; ORAL  
ZONISAMIDE

AB		GLENMARK PHARMS	25MG	N77651 001	Jan 30, 2006	Jan	NEWA
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AB			50MG	N77651 002	Jan 30, 2006	Jan	NEWA
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AB			100MG	N77651 003	Jan 30, 2006	Jan	NEWA
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AB		SUN PHARM INDS (IN)	25MG	N77634 001	Mar 17, 2006	Mar	NEWA
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AB			50MG	N77634 002	Mar 17, 2006	Mar	NEWA
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AB			100MG	N77634 003	Mar 17, 2006	Mar	NEWA
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>A>	AB	WATSON LABS	25MG	N77650 001	Apr 20, 2006	Apr	NEWA
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>A>	AB		50MG	N77650 002	Apr 20, 2006	Apr	NEWA
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>A>	AB		100MG	N77650 003	Apr 20, 2006	Apr	NEWA
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OTC DRUG PRODUCT LIST - 26TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 4 - April 2006

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CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SPONGE; TOPICAL

CHLORAPREP WITH TINT

>A> + MEDI FLEX INC 2%;70% (10.5ML) N20832 005 Apr 03, 2006 Apr NEWA

CROMOLYN SODIUM

SPRAY, METERED; NASAL

CROMOLYN SODIUM

ALPHARMA US PHARMS 5.2MG/SPRAY

N74800 001 Jul 26, 2001 Jan CPOT

+ BAUSCH AND LOMB 5.2MG/SPRAY

N75702 001 Jul 03, 2001 Jan CRLD

NASALCROM

@ PHARMACIA UPJOHN 5.2MG/SPRAY

N20463 001 Jan 03, 1997 Jan DISC

KETOPROFEN

TABLET; ORAL

ACTRON

@ BAYER 12.5MG

N20499 001 Oct 06, 1995 Feb DISC

ORUDIS KT

@ WYETH CONS 12.5MG

N20429 001 Oct 06, 1995 Feb DISC

LOPERAMIDE HYDROCHLORIDE

SUSPENSION; ORAL

IMODIUM A-D

+ MCNEIL 1MG/7.5ML

N19487 002 Jul 08, 2004 Mar CDFR

LORATADINE

TABLET; ORAL

LORATADINE

APOTEX 10MG

N76471 001 Feb 14, 2006 Jan NEWA

MINOXIDIL

AEROSOL, FOAM; TOPICAL

MEN'S ROGAINE

+ PHARMACIA AND UPJOHN 5%

N21812 001 Jan 20, 2006 Jan NEWA

NAPROXEN SODIUM

CAPSULE; ORAL

NAPROXEN SODIUM

+ BANNER PHARMACAPS EQ 200MG BASE

N21920 001 Feb 17, 2006 Feb NEWA

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL

NICORETTE

>D> GLAXOSMITHKLINE EQ 2MG BASE N18612 003 Dec 23, 1998 Apr CTNA

>D> EQ 2MG BASE N18612 004 Sep 25, 2000 Mar CRLD

EQ 2MG BASE N18612 003 Dec 23, 1998 Mar CRLD

>D> EQ 4MG BASE N20066 003 Dec 23, 1998 Apr CTNA

EQ 4MG BASE N20066 003 Dec 23, 1998 Mar CRLD

EQ 4MG BASE N20066 004 Sep 25, 2000 Mar CRLD

>A> NICORETTE (MINT)

>A> GLAXOSMITHKLINE EQ 2MG BASE N18612 003 Dec 23, 1998 Apr CTNA

>A> EQ 4MG BASE N20066 003 Dec 23, 1998 Apr CTNA

## GUM, CHEWING; BUCCAL

>A>	NICOTINE POLACRILEX								
>A>	PERRIGO	EQ 2MG BASE	N76776	001	Sep 16, 2004	Apr	CTNA		
>A>		EQ 2MG BASE	N76777	001	Sep 16, 2004	Apr	CTNA		
>A>		EQ 4MG BASE	N76778	001	Sep 16, 2004	Apr	CTNA		
>A>		EQ 4MG BASE	N76779	001	Sep 16, 2004	Apr	CTNA		
>A>	WATSON LABS	EQ 2MG BASE	N76569	001	Jul 29, 2004	Apr	CTNA		
>A>		EQ 4MG BASE	N76568	002	Jul 29, 2004	Apr	CTNA		
>D>	NICOTINE POLACRILEX (MINT)								
>D>	PERRIGO	EQ 2MG BASE	N76777	001	Sep 16, 2004	Apr	CTNA		
>D>		EQ 4MG BASE	N76779	001	Sep 16, 2004	Apr	CTNA		
>D>	WATSON LABS	EQ 2MG BASE	N76569	001	Jul 29, 2004	Apr	CTNA		
>D>		EQ 4MG BASE	N76568	002	Jul 29, 2004	Apr	CTNA		
>D>	NICOTINE POLACRILEX (ORANGE)								
>D>	PERRIGO	EQ 2MG BASE	N76776	001	Sep 16, 2004	Apr	CTNA		
>D>		EQ 4MG BASE	N76778	001	Sep 16, 2004	Apr	CTNA		

## TROCHE/LOZENGE; ORAL

## NICOTINE POLACRILEX

	PERRIGO R AND D	EQ 2MG BASE	N77007	001	Jan 31, 2006	Jan	NEWA		
		EQ 4MG BASE	N77007	002	Jan 31, 2006	Jan	NEWA		

RANITIDINE HYDROCHLORIDE

## TABLET; ORAL

## RANITIDINE

	WOCKHARDT	EQ 75MG BASE	N76760	001	Feb 24, 2006	Feb	NEWA		
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**DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT  
ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST**

**CUMULATIVE SUPPLEMENT NUMBER 04 APRIL 2006**

NO APRIL 2006 APPROVALS

## ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

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

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

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

NO APRIL 2006 ADDITIONS

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

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ABACAVIR SULFATE; LAMIVUDINE - EPZICOM</u>					
021652 001	5034394	Dec 18, 2011	DS DP	D-40	Aug 02, 2007
	5034394*PED	Jun 18, 2012			
	5047407	Nov 17, 2009	DS DP	U-257	
	5047407*PED	May 17, 2010			
	5089500	Jun 26, 2009		U-257	
	5089500*PED	Dec 26, 2009			
	5905082	May 18, 2016	DS DP		
	5905082*PED	Nov 18, 2016			
	6294540	May 14, 2018	DS DP	U-257	
	6294540*PED	Nov 14, 2018			
<u>ALBUTEROL SULFATE - PROAIR HFA</u>					
021457 001				I-235	Feb 03, 2009
<u>ALBUTEROL SULFATE - VENTOLIN HFA</u>					
020983 001	>A> 6131566	Apr 14, 2015	DP	U-716	
	>A> 6131566	Apr 14, 2015	DP	U-589	
	>A> 6532955	Apr 14, 2015	DP	U-716	
	>A> 6532955	Apr 14, 2015	DP	U-590	
<u>ALENDRONATE SODIUM; CHOLECALCIFEROL - FOSAMAX PLUS D</u>					
021762 001				NC	Apr 07, 2008
<u>ALFUZOSIN HYDROCHLORIDE - UROXATRAL</u>					
021287 001	4661491	May 27, 2007		U-706	
<u>AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE - LOTREL</u>					
020364 006				>A> NS	Apr 11, 2009
<u>AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE - LOTREL</u>					
020364 007				>A> NS	Apr 11, 2009
<u>ANIDULAFUNGIN - ERAXIS</u>					
021632 001	5965525	Oct 12, 2016	DS DP	U-540	Feb 17, 2011
	6384013	Mar 19, 2012	DS		
	6743777	Mar 19, 2012	DP	U-540	
	6960564	Apr 12, 2021	DP	U-540	
<u>APREPITANT - EMEND</u>					
021549 001	5145684	Jan 25, 2011	DP		
<u>APREPITANT - EMEND</u>					
021549 002	5145684	Jan 25, 2011	DP		
<u>ARIPIPRAZOLE - ABILIFY</u>					
021436 001				I-488	Mar 01, 2008
<u>ARIPIPRAZOLE - ABILIFY</u>					
021436 002				I-488	Mar 01, 2008
<u>ARIPIPRAZOLE - ABILIFY</u>					
021436 003				I-488	Mar 01, 2008
<u>ARIPIPRAZOLE - ABILIFY</u>					
021436 004				I-488	Mar 01, 2008
<u>ARIPIPRAZOLE - ABILIFY</u>					
021436 005				I-488	Mar 01, 2008
<u>ARIPIPRAZOLE - ABILIFY</u>					
021436 006				I-488	Mar 01, 2008
<u>ARIPIPRAZOLE - ABILIFY</u>					
021713 001	6977257	Apr 24, 2022	DS DP	I-488	Mar 01, 2008
<u>ARTICAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE - SEPTOCAINE</u>					
022010 001				>A> NP	Mar 30, 2009
<u>AZELASTINE HYDROCHLORIDE - ASTELIN</u>					
020114 001				D-102	Feb 17, 2009
<u>BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATE - TACLONEX</u>					
021852 001	4866048	Dec 29, 2007	DS DP	U-88	Jan 09, 2009
	4866048	Dec 29, 2007	DS DP	U-193	
	5763426	Jun 09, 2015	DS DP		
	6753013	Jan 27, 2020	DP	U-88	
	6753013	Jan 27, 2020	DP	U-193	



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

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>BIVALIRUDIN - ANGIOMAX</u>					
020873 001				I-486	Nov 30, 2008
<u>BORTEZOMIB - VELCADE</u>					
021602 001				ODE	Mar 25, 2012
<u>BRIMONIDINE TARTRATE - ALPHAGAN P</u>					
021770 001	5424078	Jun 13, 2012	DP		
	5424078*PED	Dec 13, 2012			
	6562873	Jul 10, 2021	DP		
	6562873*PED	Jan 10, 2022			
	6627210	Jul 18, 2021	DP		
	6627210*PED	Jan 18, 2022			
	6641834	Jul 28, 2021	DP		
	6641834*PED	Jan 28, 2022			
	6673337	Jul 26, 2021	DP		
	6673337*PED	Jan 26, 2022			
<u>BROMFENAC SODIUM - XIBROM</u>					
021664 001				I-485	Jan 27, 2009
<u>BUDESONIDE - PULMICORT RESPULES</u>					
020929 001	6899099	Dec 23, 2018	U-645		
	6899099*PED	Jun 23, 2019			
<u>BUDESONIDE - PULMICORT RESPULES</u>					
020929 002	6899099	Dec 23, 2018	U-645		
	6899099*PED	Jun 23, 2019			
<u>BUDESONIDE - RHINOCORT</u>					
020746 001	6986904	Apr 29, 2017	DP	U-699	
<u>BUDESONIDE - RHINOCORT</u>					
020746 002	6986904	Apr 29, 2017	DP	U-699	
<u>CALCIUM CARBONATE; RISEDRONATE SODIUM - ACTONEL WITH CALCIUM (COPACKAGED)</u>					
021823 001				M-52	Jan 24, 2009
<u>CEFDITOREN PIVOXIL - SPECTRACEF</u>					
021222 001	>A> 4839350	Apr 14, 2009	DS DP		
<u>CETIRIZINE HYDROCHLORIDE - ZYRTEC</u>					
019835 001	>A> 4525358	Jun 25, 2007	DS DP	U-565	
	>A> 4525358*PED	Dec 25, 2007			
<u>CETIRIZINE HYDROCHLORIDE - ZYRTEC</u>					
019835 002	>A> 4525358	Jun 25, 2007	DS DP	U-565	
	>A> 4525358*PED	Dec 25, 2007			
<u>CETIRIZINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - ZYRTEC-D 12 HOUR</u>					
021150 001	>A> 7014867	Jun 10, 2022	DP		
<u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - CHLORAPREP SINGLE SWABSTICK</u>					
021555 002	5690958	Sep 30, 2016	DP		
<u>CICLOPIROX - LOPROX</u>					
020519 001	7018656	Sep 05, 2018	DP		
	7026337	Apr 02, 2018		U-714	
<u>CONIVAPTAN HYDROCHLORIDE - VAPRISOL</u>					
021697 001	5723606	Mar 03, 2015	DS DP	U-698	
<u>DESFLURANE - SUPRANE</u>					
020118 001	5617906	Apr 08, 2014	DP		
<u>DESLORATADINE - CLARINEX</u>					
021165 001	>A> 4659716	Mar 31, 2007	DP	U-725	
	>A> 4659716	Mar 31, 2007	DP	U-427	
	>A> 4659716*PED	Oct 01, 2007		U-427	
<u>DESLORATADINE - CLARINEX</u>					
021300 001	>A> 4659716	Mar 31, 2007	DP	U-725	
	>A> 4659716	Mar 31, 2007	DP	U-611	
	>A> 4659716*PED	Oct 01, 2007			
<u>DESLORATADINE - CLARINEX</u>					
021312 001	>A> 4659716	Mar 31, 2007	DP	U-725	
	>A> 4659716	Mar 31, 2007	DP	U-427	
	>A> 4659716*PED	Oct 01, 2007		U-427	

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<u>DESLOMATADINE - CLARINEX</u>					
021312 002	>A> 4659716	Mar 31, 2007	DP U-725		
	>A> 4659716	Mar 31, 2007	DP U-427		
	>A> 4659716*PED	Oct 01, 2007	DP		
<u>DESLOMATADINE; PSEUDOEPHEDRINE SULFATE - CLARINEX D 24 HOUR</u>					
021605 001	>A> 4659716	Mar 31, 2007	DP U-726		
	>A> 4659716	Mar 31, 2007	DP U-644		
	>A> 4659716*PED 6979463	Oct 01, 2007 Mar 28, 2022	DP		
<u>DESLOMATADINE; PSEUDOEPHEDRINE SULFATE - CLARINEX-D 12 HOUR</u>					
021313 001	>A> 4659716	Mar 31, 2007	DP U-707	NCE	Dec 21, 2006
	>A> 4659716*PED	Oct 01, 2007		NC	Mar 03, 2008
	6100274	Jul 07, 2019	DP	PED	Jun 21, 2007
	6100274*PED	Jan 07, 2010			
	6709676	Feb 18, 2021	DP U-707		
<u>DOCETAXEL - TAXOTERE</u>					
020449 001	5750561	Jul 03, 2012	DP	I-490	Mar 22, 2009
<u>DONEPEZIL HYDROCHLORIDE - ARICEPT ODT</u>					
021720 001	4895841	Nov 25, 2010	DS DP U-713		
<u>DONEPEZIL HYDROCHLORIDE - ARICEPT ODT</u>					
021720 002	4895841	Nov 25, 2010	DS DP U-713		
<u>DROSPIRENONE; ETHINYL ESTRADIOL - YAZ</u>					
021676 001	>A> 5569652	Oct 29, 2013		U-1 NP	Mar 16, 2009
	>A> 5798338	Jul 10, 2015	DP		
	>A> 6787531	Aug 31, 2020	DP		
	>A> 6933395	Aug 11, 2017	DP		
	>A> RE37564	Jun 30, 2014	DP		
	>A> RE37838	Jun 30, 2014	DP		
	>A> RE38253	Jun 30, 2014	DP		
<u>EPLERENONE - INSPRA</u>					
021437 001	>A> 4559332	Apr 09, 2007	DS DP U-537		
<u>EPLERENONE - INSPRA</u>					
021437 002	>A> 4559332	Apr 09, 2007	DS DP U-537		
<u>EPLERENONE - INSPRA</u>					
021437 003	>A> 4559332	Apr 09, 2007	DS DP U-537		
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>					
021153 001	>A> 4738974	Apr 19, 2007	DS DP U-635	I-484	Nov 24, 2007
	>A> 4738974	Apr 19, 2007	DS DP U-373	>A> NPP	Apr 28, 2009
	>A> 4738974*PED	Oct 19, 2007	U-373		
<u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u>					
021153 002	>A> 4738974	Apr 19, 2007	DS DP U-635	I-484	Nov 24, 2007
	>A> 4738974	Apr 19, 2007	DS DP U-373	>A> NPP	Apr 28, 2009
	>A> 4738974*PED	Oct 19, 2007	U-373		
<u>ETHINYL ESTRADIOL; NORELGESTROMIN - ORTHO EVRA</u>					
021180 001	5876746	Nov 20, 2015	DP U-514		
<u>ETHINYL ESTRADIOL; NORETHINDRONE - OVCON-35</u>					
021490 001	>A> 6667050	Apr 06, 2019	DP U-1		
<u>ETHINYL ESTRADIOL; NORETHINDRONE ACETATE - LOESTRIN 24 FE</u>					
021871 001	5552394	Jul 22, 2014	U-1	NP	Feb 17, 2009
<u>FENOFIBRATE - FENOFIBRATE</u>					
076433 001				PC	May 22, 2006
<u>FENOFIBRATE - FENOFIBRATE</u>					
076433 002				PC	May 22, 2006
<u>FENOFIBRATE - LIPOFEN</u>					
021612 001	5545628	Jan 10, 2015	U-701		
<u>FENOFIBRATE - LIPOFEN</u>					
021612 002	5545628	Jan 10, 2015	U-701		
<u>FENOFIBRATE - LIPOFEN</u>					
021612 003	5545628	Jan 10, 2015	U-701		

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<u>FENOFIBRATE - TRICOR</u>					
021656 001	>A> 7037529	Jan 09, 2018	DP		
	>A> 7041319	Jan 09, 2018	DP		
<u>FENOFIBRATE - TRICOR</u>					
021656 002	>A> 7037529	Jan 09, 2018	DP		
	>A> 7041319	Jan 09, 2018	DP		
<u>FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - ALLEGRA D 24 HOUR</u>					
021704 001	>A> RE39069	May 29, 2018	DP		
<u>FLUNISOLIDE - AEROSPAN HFA</u>					
021247 001				NP	Jan 27, 2009
<u>FLUOCINOLONE ACETONIDE - RETISERT</u>					
021737 001	6217895	Mar 22, 2019	DP	U-708	
	6548078	Mar 22, 2019	DP	U-708	
<u>FLUOCINONIDE - VANOS</u>					
021758 001				I-487	Mar 02, 2009
<u>FLUOXETINE HYDROCHLORIDE - PROZAC WEEKLY</u>					
021235 001	RE39030	May 29, 2017	DP	U-397	
	RE39030	May 29, 2017	DP	U-396	
<u>FLUTICASONE PROPIONATE - FLOVENT HFA</u>					
021433 001	5658549	Sep 19, 2014	DP	U-710	NPP Feb 28, 2009
	5674472	Oct 07, 2014	DP		
	6251368	Dec 04, 2012	DP		
<u>FLUTICASONE PROPIONATE - FLOVENT HFA</u>					
021433 002	5658549	Sep 19, 2014	DP	U-710	NPP Feb 28, 2009
	5674472	Oct 07, 2014	DP		
	6251368	Dec 04, 2012	DP		
<u>FLUTICASONE PROPIONATE - FLOVENT HFA</u>					
021433 003	5658549	Sep 19, 2014	DP	U-710	NPP Feb 28, 2009
	5674472	Oct 07, 2014	DP		
	6251368	Dec 04, 2012	DP		
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50</u>					
021077 001	4992474	Feb 12, 2008		U-211	
	4992474*PED	Aug 12, 2008		U-211	
	5126375	Feb 12, 2008			
	5126375*PED	Aug 12, 2008			
	5225445	Feb 12, 2008		U-211	
	5225445*PED	Aug 12, 2008		U-211	
	6536427	Mar 01, 2011	DP		
	6536427*PED	Sep 01, 2011			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50</u>					
021077 002	4992474	Feb 12, 2008		U-211	
	4992474*PED	Aug 12, 2008		U-211	
	5126375	Feb 12, 2008			
	5126375*PED	Aug 12, 2008			
	5225445	Feb 12, 2008		U-211	
	5225445*PED	Aug 12, 2008		U-211	
	6536427	Mar 01, 2011	DP		
	6536427*PED	Sep 01, 2011			
<u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50</u>					
021077 003	4992474	Feb 12, 2008		U-211	
	4992474*PED	Aug 12, 2008		U-211	
	5126375	Feb 12, 2008			
	5126375*PED	Aug 12, 2008			
	5225445	Feb 12, 2008		U-211	
	5225445*PED	Aug 12, 2008		U-211	
	6536427	Mar 01, 2011	DP		
	6536427*PED	Sep 01, 2011			
<u>FROVATRIPTAN SUCCINATE - FROVA</u>					
021006 001	5464864	Nov 07, 2015		U-436	
<u>FULVESTRANT - FASLODEX</u>					
021344 001	4659516	Oct 01, 2006			

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<u>GLIMEPIRIDE - AMARYL</u>					
020496 001				M-54 PED	Nov 28, 2008 May 28, 2009
<u>GLIMEPIRIDE - AMARYL</u>					
020496 002				M-54 PED	Nov 28, 2008 May 28, 2009
<u>GLIMEPIRIDE - AMARYL</u>					
020496 003				M-54 PED	Nov 28, 2008 May 28, 2009
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>					
021700 001	5002953	Sep 17, 2011	DS DP	U-690	
	5002953*PED	Mar 17, 2012			
	5741803	Apr 21, 2015	DS DP	U-690	
	5741803*PED	Oct 21, 2015			
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>					
021700 002	5002953	Sep 17, 2011	DS DP	U-690	
	5002953*PED	Mar 17, 2012			
	5741803	Apr 21, 2015	DS DP	U-690	
	5741803*PED	Oct 21, 2015			
<u>GLIMEPIRIDE; ROSIGLITAZONE MALEATE - AVANDARYL</u>					
021700 003	5002953	Sep 17, 2011	DS DP	U-690	
	5002953*PED	Mar 17, 2012			
	5741803	Apr 21, 2015	DS DP	U-690	
	5741803*PED	Oct 21, 2015			
<u>HYALURONIDASE RECOMBINANT HUMAN - HYLENEX RECOMBINANT</u>					
021859 001				NCE	Dec 02, 2010
<u>HYDROCHLOROTHIAZIDE; VALSARTAN - DIOVAN HCT</u>					
020818 004				>A> NS	Apr 28, 2009
<u>HYDROCHLOROTHIAZIDE; VALSARTAN - DIOVAN HCT</u>					
020818 005				>A> NS	Apr 28, 2009
<u>IBANDRONATE SODIUM - BONIVA</u>					
021455 001	4927814	Jul 09, 2007	DS DP	U-642	
	6143326	Apr 21, 2017		U-642	
<u>IBANDRONATE SODIUM - BONIVA</u>					
021858 001	4927814	Jul 09, 2007	DS DP	U-700	NDF NCE Jan 06, 2009 May 16, 2008
<u>IBUPROFEN LYSINE - NEOPROFEN</u>					
021903 001				>A> NE >A> ODE	Apr 13, 2009 Apr 13, 2013
<u>INSULIN DETEMIR RECOMBINANT - LEVEMIR</u>					
021536 001				I-489	Oct 19, 2008
<u>INSULIN RECOMBINANT HUMAN - EXUBERA</u>					
021868 001	5740794	Apr 21, 2015	DP	NP	Jan 27, 2009
	5997848	Mar 07, 2014		U-704	
	6051256	Mar 07, 2014	DP		
	6257233	May 14, 2019		U-704	
	6423344	Mar 07, 2014	DP		
	6543448	Sep 21, 2014	DP		
	6546929	May 14, 2019		U-704	
	6582728	Jun 24, 2020	DP		
	6592904	Mar 07, 2014	DP		
	6685967	Sep 11, 2018	DP		
	6737045	Mar 07, 2014		U-704	
	RE37872	Feb 12, 2010	DP		
	RE38385	Feb 12, 2010	DP		

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<u>INSULIN RECOMBINANT HUMAN - EXUBERA</u>					
021868 002	5740794	Apr 21, 2015	DP	NP	Jan 27, 2009
	5997848	Mar 07, 2014		U-704	
	6051256	Mar 07, 2014	DP		
	6257233	May 14, 2019		U-704	
	6423344	Mar 07, 2014	DP		
	6543448	Sep 21, 2014	DP		
	6546929	May 14, 2019		U-704	
	6582728	Jun 24, 2020	DP		
	6592904	Mar 07, 2014	DP		
	6685967	Sep 11, 2018	DP		
	6737045	Mar 07, 2014		U-704	
	RE37872	Feb 12, 2010	DP		
	RE38385	Feb 12, 2010	DP		
<u>IPRATROPIUM BROMIDE - ATROVENT HFA</u>					
021527 001	6983743	May 26, 2020	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
020406 001	6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
020406 002	6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
021281 001	6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
021281 002	6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
021428 001	6749864	Feb 13, 2007	DP		
<u>LANSOPRAZOLE - PREVACID</u>					
021428 002	6749864	Feb 13, 2007	DP		
<u>LANTHANUM CARBONATE - FOSRENOL</u>					
021468 003	5968976	Mar 19, 2016	DP	U-613	
<u>LANTHANUM CARBONATE - FOSRENOL</u>					
021468 004	5968976	Mar 19, 2016	DP	U-613	
<u>LENALIDOMIDE - REVLIMID</u>					
021880 001	5635517	Jul 24, 2016	DS		Dec 27, 2012
	6045501	Aug 28, 2018		U-694	
	6315720	Oct 23, 2020		U-694	
	6555554	Jul 24, 2016	DP		
	6561976	Aug 28, 2018		U-694	
	6561977	Oct 23, 2020		U-694	
	6755784	Oct 23, 2020		U-694	
	6908432	Aug 28, 2018		U-694	
<u>LENALIDOMIDE - REVLIMID</u>					
021880 002	5635517	Jul 24, 2016	DS		Dec 27, 2012
	6045501	Aug 28, 2018		U-694	
	6315720	Oct 23, 2020		U-694	
	6555554	Jul 24, 2016	DP		
	6561976	Aug 28, 2018		U-694	
	6561977	Oct 23, 2020		U-694	
	6755784	Oct 23, 2020		U-694	
	6908432	Aug 28, 2018		U-694	
<u>LEVETIRACETAM - KEPPRA</u>					
021035 004				>A> NPP	Jun 21, 2008
<u>LIDOCAINE; TETRACAINE - SYNERA</u>					
021623 001				NC	Jun 23, 2009

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<u>LOPINAVIR; RITONAVIR - KALETRA</u>					
021906 001	5541206	Jul 30, 2013	DS DP	U-688	
	5541206*PED	Jan 30, 2014			
	5635523	Jun 03, 2014		U-688	
	5635523*PED	Dec 03, 2014			
	5648497	Jul 15, 2014	DS DP		
	5648497*PED	Jan 15, 2015			
	5674882	Oct 07, 2014		U-688	
	5674882*PED	Apr 07, 2015			
	5846987	Dec 29, 2012		U-688	
	5846987*PED	Jun 29, 2013			
	5886036	Dec 29, 2012	DP		
	5886036*PED	Jun 29, 2013			
	6037157	Jun 26, 2016		U-688	
	6037157*PED	Dec 26, 2016			
	6703403	Jun 26, 2016		U-688	
	6703403*PED	Dec 26, 2016			
<u>LOVASTATIN; NIACIN - ADVICOR</u>					
021249 001	7011848	Sep 20, 2013		U-712	
<u>LOVASTATIN; NIACIN - ADVICOR</u>					
021249 002	7011848	Sep 20, 2013		U-712	
<u>LOVASTATIN; NIACIN - ADVICOR</u>					
021249 003	7011848	Sep 20, 2013		U-712	
<u>LUBIPROSTONE - AMITIZA</u>					
021908 001	>A> 5284858	Feb 08, 2011	DS DP	NCE	Jan 31, 2011
	>A> 5317032	May 31, 2011	DS DP	U-717	
	>A> 6414016	Sep 05, 2020	DS DP	U-717	
	>A> 6583174	Oct 16, 2020	DS DP		
<u>MAGNESIUM HYDROXIDE; OMEPRAZOLE; SODIUM BICARBONATE - ZEGERID</u>					
021850 001	>A> 6645988	Jul 16, 2016	DS DP	U-623	
	>A> 6645988	Jul 16, 2016	DS DP	U-588	
<u>MAGNESIUM HYDROXIDE; OMEPRAZOLE; SODIUM BICARBONATE - ZEGERID</u>					
021850 002	>A> 6645988	Jul 16, 2016	DS DP	U-623	
	>A> 6645988	Jul 16, 2016	DS DP	U-588	
<u>MECASERMIN RINFABATE RECOMBINANT - IPLEX</u>					
021884 001	5200509	Apr 06, 2010	DS		
	5681818	Oct 28, 2014		U-697	
<u>MELOXICAM - MOBIC</u>					
020938 001				ODE PED	Aug 11, 2012 Feb 11, 2013
<u>MELOXICAM - MOBIC</u>					
020938 002				ODE PED	Aug 11, 2012 Feb 11, 2013
<u>MELOXICAM - MOBIC</u>					
021530 001				I-469 ODE PED PED	Aug 11, 2008 Aug 11, 2012 Feb 11, 2013 Feb 11, 2009
<u>MEQUINOL; TRETINOIN - SOLAGE</u>					
020922 001	>A> 5194247	Dec 10, 2013	DP	U-294	
<u>MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE - VUSION</u>					
021026 001	>A> 4911932	Mar 27, 2007	DP	U-718	NP Feb 16, 2009
<u>MINOXIDIL - MEN'S ROGAINE</u>					
021812 001	6946120	Apr 20, 2019	DP	U-702	NDF Jan 20, 2009
<u>MODAFINIL - PROVIGIL</u>					
020717 001	4927855	May 22, 2007		U-255	I-449 Jan 23, 2007
	4927855*PED	Nov 22, 2007			ODE Dec 24, 2005
	RE37516	Oct 06, 2014		U-255	PED Jul 23, 2007
	RE37516*PED	Apr 06, 2015			PED Jun 24, 2006

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<u>MODAFINIL - PROVIGIL</u>					
020717 002	4927855	May 22, 2007	U-255	I-449	Jan 23, 2007
	4927855*PED	Nov 22, 2007		ODE	Dec 24, 2005
	RE37516	Oct 06, 2014	U-255	PED	Jul 23, 2007
	RE37516*PED	Apr 06, 2015		PED	Jun 24, 2006
<u>MORPHINE SULFATE - KADIAN</u>					
020616 004	5378474	Mar 23, 2010			
<u>MORPHINE SULFATE - KADIAN</u>					
020616 005	5202128	Apr 13, 2010			
	5378474	Mar 23, 2010			
<u>MOXIFLOXACIN HYDROCHLORIDE - AVELOX</u>					
021085 001	4990517	Dec 08, 2011	DS DP	U-298	
	6610327	Oct 29, 2019		DP U-298	
<u>MOXIFLOXACIN HYDROCHLORIDE - AVELOX IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER</u>					
021277 001	4990517	Dec 08, 2011	DS DP	U-298	
	6548079	Jul 25, 2020		DP U-298	
<u>MOXIFLOXACIN HYDROCHLORIDE - VIGAMOX</u>					
021598 001	4990517	Dec 08, 2011	DS DP	U-709	
	4990517*PED	Jun 08, 2012			
<u>NALTREXONE - VIVITROL</u>					
021897 001				>A> NDF	Apr 13, 2009
<u>NELARABINE - ARRANON</u>					
021877 001	5747472	Feb 20, 2013		U-696	
	5747472	Feb 20, 2013		U-695	
	5747472	Feb 20, 2013		U-689	
	5821236	Feb 20, 2013		U-695	
<u>NIACIN - NIASPAN</u>					
020381 001	7011848	Sep 20, 2013		U-712	
<u>NIACIN - NIASPAN</u>					
020381 002	7011848	Sep 20, 2013		U-712	
<u>NIACIN - NIASPAN</u>					
020381 003	7011848	Sep 20, 2013		U-712	
<u>NIACIN - NIASPAN</u>					
020381 004	7011848	Sep 20, 2013		U-712	
<u>NIACIN - NIASPAN TITRATION STARTER PACK</u>					
020381 005	7011848	Sep 20, 2013		U-712	
<u>NICOTINE POLACRILEX - NICOTINE POLACRILEX</u>					
077007 001				PC	Aug 21, 2006
<u>NICOTINE POLACRILEX - NICOTINE POLACRILEX</u>					
077007 002				PC	Aug 21, 2006
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 001	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 002	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 003	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 004	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			
<u>OCTREOTIDE ACETATE - SANDOSTATIN</u>					
019667 005	5753618	May 19, 2015			
	5753618*PED	Nov 19, 2015			

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<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>					
021008 001	5538739	Jul 23, 2013		ODE	Nov 25, 2005
	5538739*PED	Jan 23, 2014		PED	May 25, 2006
	5639480	Jun 17, 2014			
	5639480*PED	Dec 17, 2014			
	5688530	Nov 18, 2014	U-268		
	5688530*PED	May 18, 2015			
	5922338	Jul 13, 2016			
	5922338*PED	Jan 13, 2017			
	5922682	Jul 13, 2016			
	5922682*PED	Jan 13, 2017			
<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>					
021008 002	5538739	Jul 23, 2013		ODE	Nov 25, 2005
	5538739*PED	Jan 23, 2014		PED	May 25, 2006
	5639480	Jun 17, 2014			
	5639480*PED	Dec 17, 2014			
	5688530	Nov 18, 2014	U-268		
	5688530*PED	May 18, 2015			
	5922338	Jul 13, 2016			
	5922338*PED	Jan 13, 2017			
	5922682	Jul 13, 2016			
	5922682*PED	Jan 13, 2017			
<u>OCTREOTIDE ACETATE - SANDOSTATIN LAR</u>					
021008 003	5538739	Jul 23, 2013		ODE	Nov 25, 2005
	5538739*PED	Jan 23, 2014		PED	May 25, 2006
	5639480	Jun 17, 2014			
	5639480*PED	Dec 17, 2014			
	5688530	Nov 18, 2014	U-268		
	5688530*PED	May 18, 2015			
	5922338	Jul 13, 2016			
	5922338*PED	Jan 13, 2017			
	5922682	Jul 13, 2016			
	5922682*PED	Jan 13, 2017			
<u>OMEPRAZOLE; SODIUM BICARBONATE - ZEGERID</u>					
021849 001	6489346	Jul 16, 2016	DS DP	U-588	
	6645988	Jul 16, 2016	DS DP		
	6699885	Jul 16, 2016		U-588	
<u>OMEPRAZOLE; SODIUM BICARBONATE - ZEGERID</u>					
021849 002	>A> 6489346	Jul 16, 2016	DS DP	U-623	
	>A> 6489346	Jul 16, 2016	DS DP	U-588	
	6645988	Jul 16, 2016	DS DP		
	>A> 6699885	Jul 16, 2016		U-623	
	>A> 6699885	Jul 16, 2016		U-588	
<u>OXALIPLATIN - ELOXATIN</u>					
021492 001	5420319	Aug 09, 2016	DS		
<u>OXALIPLATIN - ELOXATIN</u>					
021492 002	5420319	Aug 09, 2016	DS		
<u>OXALIPLATIN - ELOXATIN</u>					
021759 001	5420319	Aug 08, 2016	DS		
<u>OXALIPLATIN - ELOXATIN</u>					
021759 002	5420319	Aug 08, 2016	DS		
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021014 001	>A> 7037525	Feb 12, 2018		U-724	
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021014 002	>A> 7037525	Feb 12, 2018		U-724	
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021014 003	>A> 7037525	Feb 12, 2018		U-724	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 001	4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 002	4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 003	4843086	Jun 27, 2006		U-231	



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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 004	4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 005	4843086	Jun 27, 2006		U-231	
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX</u>					
020667 006	4843086	Jun 27, 2006		U-231	
<u>PRAVASTATIN SODIUM - PRAVASTATIN SODIUM</u>					
076056 001				>A> PC	Oct 21, 2006
<u>PRAVASTATIN SODIUM - PRAVASTATIN SODIUM</u>					
076056 002				>A> PC	Oct 21, 2006
<u>PRAVASTATIN SODIUM - PRAVASTATIN SODIUM</u>					
076056 003				>A> PC	Oct 21, 2006
<u>QUETIAPINE FUMARATE - SEROQUEL</u>					
020639 006	4879288	Sep 26, 2011	DS DP	U-550	
<u>QUETIAPINE FUMARATE - SEROQUEL</u>					
020639 007	4879288	Sep 26, 2011	DS DP	U-550	
<u>RALOXIFENE HYDROCHLORIDE - EVISTA</u>					
020815 001	RE38968	Jul 28, 2012		U-662	
	RE38968	Jul 28, 2012		U-657	
	RE39049	Jul 28, 2012		U-662	
	RE39049	Jul 28, 2012		U-657	
	RE39050	Mar 02, 2014		U-662	
	RE39050	Mar 02, 2014		U-657	
<u>RANOLAZINE - RANEXA</u>					
021526 002	4567264	May 18, 2006	DS		NCE Jan 27, 2011
	6303607	May 27, 2019		U-705	
	6369062	May 27, 2019		DP	
	6479496	May 27, 2019		U-705	
	6503911	May 27, 2019		DP	
	6525057	May 27, 2019		U-705	
	6562826	May 27, 2019		U-705	
	6617328	May 27, 2019		DP	
	6620814	May 27, 2019		U-705	
	6852724	May 27, 2019		U-705	
	6864258	May 27, 2019		U-705	
<u>RISEDRONATE SODIUM - ACTONEL</u>					
020835 001				M-52	Jan 24, 2009
<u>RISEDRONATE SODIUM - ACTONEL</u>					
020835 002				M-52	Jan 24, 2009
<u>RISEDRONATE SODIUM - ACTONEL</u>					
020835 003				M-52	Jan 24, 2009
<u>ROCURONIUM BROMIDE - ZEMURON (P/F)</u>					
020214 003	>A> 4894369	Apr 13, 2008			
<u>SALMETEROL XINAFOATE - SEREVENT</u>					
020236 001	4992474	Feb 12, 2008			
	4992474*PED	Aug 12, 2008			
	5126375	Feb 12, 2008			
	5126375*PED	Aug 12, 2008			
	5225445	Feb 12, 2008		U-182	
	5225445*PED	Aug 12, 2008			
<u>SALMETEROL XINAFOATE - SEREVENT</u>					
020692 001	4992474	Feb 12, 2008			
	4992474*PED	Aug 12, 2008			
	5126375	Feb 12, 2008			
	5126375*PED	Aug 12, 2008			
	5225445	Feb 12, 2008		U-211	
	5225445*PED	Aug 12, 2008			
<u>SELEGILINE - EMSAM</u>					
021336 001	RE34579	Aug 18, 2007	DS DP	U-711	NDF Feb 27, 2009
<u>SELEGILINE - EMSAM</u>					
021336 002	RE34579	Aug 18, 2007	DS DP	U-711	NDF Feb 27, 2009

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<u>SELEGILINE - EMSAM</u>					
021336 003	RE34579	Aug 18, 2007	DS DP U-711	NDF	Feb 27, 2009
<u>SEVELAMER HYDROCHLORIDE - RENAGEL</u>					
021179 001	7014846	Aug 11, 2013	DP U-246		
<u>SEVELAMER HYDROCHLORIDE - RENAGEL</u>					
021179 002	7014846	Aug 11, 2013	DP U-246		
<u>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS; SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE - OSMOPREP</u>					
021892 001	>A> 5616346	May 18, 2013	DP U-715	NP	Mar 16, 2009
<u>SORAFENIB TOSYLATE - NEXAVAR</u>					
021923 001				ODE	Dec 20, 2012
<u>SUNITINIB MALATE - SUTENT</u>					
021938 001	6573293	Feb 15, 2021	DS DP U-703	NCE	Jan 26, 2011
<u>SUNITINIB MALATE - SUTENT</u>					
021938 002	6573293	Feb 15, 2021	DS DP U-703	NCE	Jan 26, 2011
<u>SUNITINIB MALATE - SUTENT</u>					
021938 003	6573293	Feb 15, 2021	DS DP U-703	NCE	Jan 26, 2011
<u>TACROLIMUS - PROGRAF</u>					
050708 001				ODE	Mar 29, 2013
<u>TACROLIMUS - PROGRAF</u>					
050708 002				ODE	Mar 29, 2013
<u>TACROLIMUS - PROGRAF</u>					
050708 003				ODE	Mar 29, 2013
<u>TACROLIMUS - PROGRAF</u>					
050709 001				ODE	Mar 29, 2013
<u>TERIPARATIDE RECOMBINANT HUMAN - FORTEO</u>					
021318 001	6977077	Aug 19, 2019	U-597		
<u>THYROTROPIN ALFA - THYROGEN</u>					
020898 001				M-53	Jan 23, 2009
<u>TIOTROPIUM BROMIDE MONOHYDRATE - SPIRIVA</u>					
021395 001	>A> RE38912	Oct 11, 2021	DP		
<u>TOPIRAMATE - TOPAMAX</u>					
020505 001	>A> 7018983	Oct 13, 2015	U-723		
<u>TOPIRAMATE - TOPAMAX</u>					
020505 002	>A> 7018983	Oct 13, 2015	U-723		
<u>TOPIRAMATE - TOPAMAX</u>					
020505 003	>A> 7018983	Oct 13, 2015	U-723		
<u>TOPIRAMATE - TOPAMAX</u>					
020505 004	>A> 7018983	Oct 13, 2015	U-723		
<u>TOPIRAMATE - TOPAMAX</u>					
020505 005	>A> 7018983	Oct 13, 2015	U-723		
<u>TOPIRAMATE - TOPAMAX</u>					
020505 006	>A> 7018983	Oct 13, 2015	U-723		
<u>TOPIRAMATE - TOPAMAX SPRINKLE</u>					
020844 001	>A> 7018983	Oct 13, 2015	U-723		
<u>TOPIRAMATE - TOPAMAX SPRINKLE</u>					
020844 002	>A> 7018983	Oct 13, 2015	U-723		
<u>TOPIRAMATE - TOPAMAX SPRINKLE</u>					
020844 003	>A> 7018983	Oct 13, 2015	U-723		
<u>TREPROSTINIL SODIUM - REMODULIN</u>					
021272 001	5153222	Oct 06, 2014	U-455		
<u>TREPROSTINIL SODIUM - REMODULIN</u>					
021272 002	5153222	Oct 06, 2014	U-455		
<u>TREPROSTINIL SODIUM - REMODULIN</u>					
021272 003	5153222	Oct 06, 2014	U-455		
<u>TREPROSTINIL SODIUM - REMODULIN</u>					
021272 004	5153222	Oct 06, 2014	U-455		

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<u>ZANAMIVIR - RELENZA</u>					
021036 001	>A> 5648379	Jul 15, 2014	U-722	I-491	Mar 29, 2009
	>A> 5648379	Jul 15, 2014	U-721		
	>A> 5648379	Jul 15, 2014	U-274		
	>A> 6294572	Dec 15, 2014	DS DP		
<u>ZIPRASIDONE HYDROCHLORIDE - GEODON</u>					
021483 001	>A> 4831031	Mar 02, 2007	DS DP	U-720	
	>A> 5312925	Sep 01, 2012	DS DP	U-720	
	>A> 6150366	May 27, 2019	DP	U-719	
	>A> 6245766	Dec 18, 2018		U-601	
<u>ZOLEDRONIC ACID - ZOMETA</u>					
021223 001	4939130	Sep 02, 2012	DS DP	U-53	
<u>ZOLEDRONIC ACID - ZOMETA</u>					
021223 002	4939130	Sep 02, 2012	DS DP	U-53	

Footnote:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).

2. Patents submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor:

DS = Drug Substance claim

DP = Drug Product claim

U and number = Method of Use claim (may be multiple). Specific Method of use claims are listed at <http://www.fda.gov/cder/orange/patex.htm>

3. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. They may not be flagged with respect to other claims which may apply.

4. \*PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with \*PED as was done prior to August 18, 2003. Patents with \*PED added after August 18, 2003 will not contain any information relative to the patent itself other than the \*PED extension. Information related specifically to the patent will be conveyed on the original patent only.

## 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>

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