

APPROVED DRUG PRODUCTS

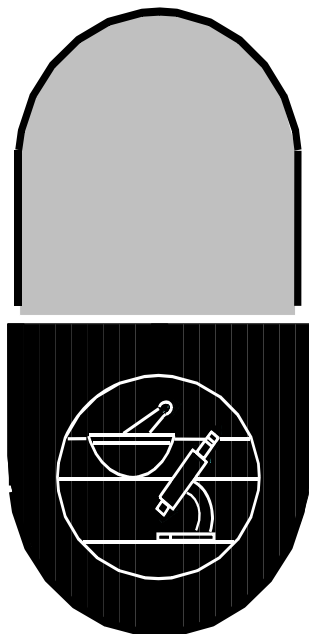
With Therapeutic Equivalence Evaluations



The "Orange Book"

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**CUMULATIVE
SUPPLEMENT 03
March 2010**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

30th EDITION

Department of Health and Human Services

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

2010

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

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

30th EDITION

Cumulative Supplement 03

March 2010

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30th EDITION

**CUMULATIVE SUPPLEMENT 03
March 2010**

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

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

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

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

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

1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

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

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

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

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

1.3 APPLICANT NAME CHANGES

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

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

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

PROCTER AND GAMBLE CO PHARMACEUTICALS
INC SUB PROCTER AND GAMBLE CO
(PROCTER AND GAMBLE)

WARNER CHILCOTT CO LLC
(WARNER CHILCOTT)

SCIELE PHARMA INC
(SCIELE PHARMA INC)

SHIONOGI PHARMA INC
(SHIONOGI PHARMA)

TEVA PHARMACEUTICALS USA
(TEVA PHARMS)

IVAX PHARMACEUTICALS INC SUB
TEVA PHARMACEUTICALS USA
(IVAX SUB TEVA PHARMS)

ZENITH GOLDLINE LABORATORIES INC
(ZENITH GOLDLINE)
ZENITH GOLDLINE PHARMACEUTICALS
(ZENITH GOLDLINE)

IVAX PHARMACEUTICALS INC SUB
TEVA PHARMACEUTICALS USA
(IVAX SUB TEVA PHARMS)
IVAX PHARMACEUTICALS INC SUB
TEVA PHARMACEUTICALS USA
(IVAX SUB TEVA PHARMS)

ZENITH GOLDLINE PHARMACEUTICALS INC
(ZENITH GOLDLINE)

IVAX PHARMACEUTICALS INC SUB
TEVA PHARMACEUTICALS USA
(IVAX SUB TEVA PHARMS)

1.4 AVAILABILITY OF THE EDITION

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

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

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

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

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

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

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

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

DEFINITIONS

Drug Product

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

New Molecular Entity

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

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

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

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

1.6 CUMULATIVE SUPPLEMENT LEGEND

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

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

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

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

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

The change code and description:

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

PRESCRIPTION DRUG PRODUCT LIST - 30TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

1-1

ACETAMINOPHEN; BUTALBITAL

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

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

ACETAMINOPHEN; HYDROCODONE BITARTRATE

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

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE

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

ACITRETIN

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

ACYCLOVIR

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

TABLET; ORALACYCLOVIR

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

ADAPALENE

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

ALBUTEROL SULFATESOLUTION; INHALATIONALBUTEROL SULFATE

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

ALENDRONATE SODIUMTABLET; ORALALENDRONATE SODIUM

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

ALPRAZOLAMTABLET, ORALLY DISINTEGRATING; ORALALPRAZOLAM

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

AMLODIPINE BESYLATETABLET; ORALAMLODIPINE BESYLATE

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

AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDECAPSULE; ORALAMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE

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

CAPSULE; ORAL

AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE

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

AMOXICILLIN

FOR SUSPENSION; ORAL

TRIMOX

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

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AUGMENTIN '125'

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

TABLET; ORAL

AUGMENTIN '250'

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

TABLET, EXTENDED RELEASE; ORAL

AUGMENTIN XR

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

INJECTABLE, LIPID COMPLEX; INJECTION

ABELCET

+	SIGMA TAU	5MG/ML	N050724 001	Nov 20, 1995	Feb	CAHN
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AMPICILLIN SODIUM; SULBACTAM SODIUM

INJECTABLE; INJECTION

AMPICILLIN AND SULBACTAM

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

ARMODAFINIL

TABLET; ORAL

NUVIGIL

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

ARTEMETHER; LUMEFANTRINE

TABLET; ORAL

COARTEM

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

ARTICAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE

INJECTABLE; INJECTION

ARTICAINE HYDROCHLORIDE WITH EPINEPHRINE

PIERREL

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

+		4%;EQ 0.018MG BASE/1.8ML (EQ 0.01MG BASE/ML)	N022466 002	Feb 26, 2010	Feb	NEWA
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ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

FIORINAL

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

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

BUTALBITAL, ASPIRIN AND CAFFEINE

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

SPRAY, METERED; NASAL

ASTELIN

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

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

INJECTABLE; INJECTION

AZITHROMYCIN

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

FOR SOLUTION; INHALATION

CAYSTON

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

TABLET; ORAL

BACLOFEN

AB		MATRIX LABS LTD	10MG	A090334 001	Feb 18, 2010	Jan	NEWA
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AB			20MG	A090334 002	Feb 18, 2010	Jan	NEWA
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TABLET, ORALLY DISINTEGRATING; ORAL

KEMSTRO

@ SCHWARZ PHARMA

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N021589 001	Oct 30, 2003	Jan	DISC
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N021589 002	Oct 30, 2003	Jan	DISC
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BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION

QVAR 40

+ TEVA BRANDED PHARM	0.04MG/INH	N020911 002	Sep 15, 2000	Feb	CAHN
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QVAR 80

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

TABLET; ORAL

BENAZEPRIL HYDROCHLORIDE

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

BENZTROPINE MESYLATE

INJECTABLE; INJECTION

BENZTROPINE MESYLATE

>A>	AP	PHARMAFORCE	1MG/ML	A091152 001	Mar 29, 2010	Mar	NEWA
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TABLET; ORAL

BENZTROPINE MESYLATE

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

BETAMETHASONE ACETATE; BETAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

BETAMETHASONE ACETATE AND BETAMETHASONE SODIUM PHOSPHATE

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

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

BETAXOLOL HYDROCHLORIDE

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

TABLET; ORAL

BETAXOLOL HYDROCHLORIDE

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

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE

INJECTABLE; INJECTION

BUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE

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

INJECTABLE; INJECTIONBUPIVACAINE HYDROCHLORIDE AND EPINEPHRINE

>A>	AP	HOSPIRA	0.5%;0.005MG/ML	A071170 001	Jun 16, 1988	Mar	CMFD
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BUPROPION HYDROCHLORIDETABLET, EXTENDED RELEASE; ORALBUPROPION HYDROCHLORIDE

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

BUSPIRONE HYDROCHLORIDETABLET; ORALBUSPAR

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

BUSPIRONE HYDROCHLORIDE

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

CABERGOLINETABLET; ORALCABERGOLINE

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

CALCIPOTRIENE

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

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATESOLUTION; IRRIGATIONBALANCED SALT

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

>A>	AA	INVAGEN PHARMS	4MG	A090435 001	Apr 15, 2010	Mar	NEWA
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CARBOPLATININJECTABLE; IV (INFUSION)CARBOPLATIN

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

INJECTABLE; IV (INFUSION)CARBOPLATIN

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

>A> CARGLUMIC ACID>A> TABLET; ORAL>A> CARBAGLU

>A>	+	ORPHAN EUROPE	200MG	N022562 001	Mar 18, 2010	Mar	NEWA
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CARVEDILOL PHOSPHATECAPSULE, EXTENDED RELEASE; ORALCOREG CR

+	SB PHARMC0	40MG	N022012 003	Oct 20, 2006	Feb	CRLD
		80MG	N022012 004	Oct 20, 2006	Feb	CRLD

CEFACLORTABLET, EXTENDED RELEASE; ORALCEFACLOR

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

CEFADROXIL/CEFADROXIL HEMIHYDRATECAPSULE; ORALCEFADROXIL

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

FOR SUSPENSION; ORALCEFADROXIL

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

CEFOTAXIME SODIUMINJECTABLE; INJECTIONCEFOTAXIME SODIUM

AP		CEPHAZONE PHARMA	EQ 10GM BASE/VIAL	A065348 001	Jan 25, 2010	Jan	NEWA
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CEFOXITIN SODIUMINJECTABLE; INJECTIONCEFOXITIN

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

CEFPROZILFOR SUSPENSION; ORALCEFPROZIL

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

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

SYRUP; ORAL

CETIRIZINE HYDROCHLORIDE

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

SHAMPOO; TOPICAL

CICLOPIROX

AT	PERRIGO	1%	A078594 001	Feb 16, 2010	Jan	NEWA
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SOLUTION; TOPICAL

CICLOPIROX

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

TABLET; ORAL

CIPRO

AB	+	BAYER HLTHCARE	EQ 500MG BASE	N019537 003	Oct 22, 1987	Feb	CRLD
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AB			EQ 750MG BASE	N019537 004	Oct 22, 1987	Feb	CRLD
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CLINDAMYCIN PHOSPHATE

AEROSOL, FOAM; TOPICAL

CLINDAMYCIN PHOSPHATE

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

>D>	+	STIEFEL LABS INC	1%	N050801 001	Oct 22, 2004	Mar	CFTG
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>A>	AT	+	1%	N050801 001	Oct 22, 2004	Mar	CFTG
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CREAM; VAGINAL

CLINDAMYCIN PHOSPHATE

>D>	AB	ALTANA PHARMA	EQ 2% BASE	A065139 001	Dec 27, 2004	Mar	CAHN
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>A>	AB	NYCOMED US	EQ 2% BASE	A065139 001	Dec 27, 2004	Mar	CAHN
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CLOBETASOL PROPIONATE

OINTMENT; TOPICAL

CLOBETASOL PROPIONATE

>D>	AB	FOUGERA	0.05%	A074407 001	Feb 23, 1996	Mar	CAHN
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>A>	AB	NYCOMED US	0.05%	A074407 001	Feb 23, 1996	Mar	CAHN
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CLONIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

DURACLON

>A>	AP	BIONICHE PHARMA USA	1 MG/10 ML (0.1 MG/ML)	N020615 001	Oct 02, 1996	Mar	CAHN
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>A>	AP	+	5 MG/10 ML (0.5 MG/ML)	N020615 002	Apr 27, 1999	Mar	CAHN
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>D>	AP	XANODYNE PHARM	1 MG/10 ML (0.1 MG/ML)	N020615 001	Oct 02, 1996	Mar	CAHN
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>D>	AP	+	5 MG/10 ML (0.5 MG/ML)	N020615 002	Apr 27, 1999	Mar	CAHN
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CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE HYDROCHLORIDE AND CODEINE PHOSPHATE

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

INJECTABLE; INJECTION

COSYNTROPIN

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

SPRAY, METERED; NASAL

CALOMIST

@ FLEMING

25MCG/SPRAY

N022102 001 Jul 27, 2007 Jan DISC

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION

CYTOXAN

AP + BAXTER HLTHCARE 500MG/VIAL

N012142 003 Feb CMFD

AP + 1GM/VIAL

N012142 004 Aug 30, 1982 Feb CMFD

AP + 2GM/VIAL

N012142 005 Aug 30, 1982 Feb CMFD

LYOPHILIZED CYTOXAN

@ BAXTER HLTHCARE 100MG/VIAL

N012142 006 Dec 05, 1985 Feb DISC

@ 200MG/VIAL

N012142 007 Dec 10, 1985 Feb DISC

@ 500MG/VIAL

N012142 008 Jan 04, 1984 Feb DISC

@ 1GM/VIAL

N012142 010 Sep 24, 1985 Feb DISC

@ 2GM/VIAL

N012142 009 Dec 10, 1984 Feb DISC

CYTARABINE

INJECTABLE; INJECTION

CYTARABINE

>D> HOSPIRA 20MG/ML

A072168 001 Aug 31, 1990 Mar CRLD

>A> AP + 20MG/ML

A072168 001 Aug 31, 1990 Mar CRLD

DACTINOMYCIN

INJECTABLE; INJECTION

COSMEGEN

>D> + LUNDBECK INC 0.5MG/VIAL

N050682 001 Mar CFTG

>A> AP + 0.5MG/VIAL

N050682 001 Mar CFTG

>A> DACTINOMYCIN

>A> AP BEDFORD 0.5MG/VIAL

A090304 001 Mar 16, 2010 Mar NEWA

DALFAMPRIDINE

TABLET, EXTENDED RELEASE; ORAL

AMPYRA

+ ACORDA 10MG

N022250 001 Jan 22, 2010 Jan NEWA

DESLOTRADINE

TABLET; ORAL

CLARINEX

AB + SCHERING PLOUGH 5MG

N021165 001 Dec 21, 2001 Jan CFTG

DESLOTRADINE

AB ORCHID HLTHCARE 5MG

A078357 001 Feb 19, 2010 Jan NEWA

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

STIMATE (NEEDS NO REFRIGERATION)

@ CSL BEHRING 1.5MG/SPRAY

N020355 002 Oct 24, 2007 Jan DISC

DEXLANSOPRAZOLE

CAPSULE, DELAYED RELEASE; ORAL

DEXILANT

>A> TAKEDA PHARMS 30MG

N022287 001 Jan 30, 2009 Mar CTNA

>A> + 60MG

N022287 002 Jan 30, 2009 Mar CTNA

CAPSULE, DELAYED RELEASE; ORAL									
>D>	KAPIDEX								
>D>	TAKEDA PHARMS	30MG	N022287	001	Jan 30,	2009	Mar	CTNA	
>D>	+	60MG	N022287	002	Jan 30,	2009	Mar	CTNA	
<u>DEXMEDETOMIDINE HYDROCHLORIDE</u>									
INJECTABLE; INJECTION									
PRECEDEX									
	+	HOSPIRA	EQ 100MCG BASE/ML (EQ100MCG BASE/ML)	N021038	001	Dec 17,	1999	Jan	CAIN
<u>DIAZOXIDE</u>									
CAPSULE; ORAL									
PROGLYCEM									
	@	TEVA BRANDED PHARM	50MG	N017425	001		Feb	CAHN	
	@		100MG	N017425	002		Feb	CAHN	
<u>DICLOFENAC POTASSIUM</u>									
FOR SOLUTION; ORAL									
CAMBIA									
>D>	+	KOWA PHARMS	50MG	N022165	001	Jun 17,	2009	Mar	CAHN
>A>	+	NAUTILUS NEUROSCIENC	50MG	N022165	001	Jun 17,	2009	Mar	CAHN
TABLET; ORAL									
DICLOFENAC POTASSIUM									
	@	SANDOZ	50MG	A075582	001	Feb 23,	2001	Jan	DISC
<u>DIDANOSINE</u>									
CAPSULE, DELAYED REL PELLETS; ORAL									
DIDANOSINE									
>A>	AB	MATRIX LABS LTD	125MG	A090788	001	Apr 08,	2010	Mar	NEWA
>A>	AB		200MG	A090788	002	Apr 08,	2010	Mar	NEWA
>A>	AB		250MG	A090788	003	Apr 08,	2010	Mar	NEWA
>A>	AB		400MG	A090788	004	Apr 08,	2010	Mar	NEWA
<u>DIFLORASONE DIACETATE</u>									
CREAM; TOPICAL									
DIFLORASONE DIACETATE									
>D>	AB1	ALTANA	0.05%	A075187	001	Mar 30,	1998	Mar	CRLD
>A>	AB1	+	0.05%	A075187	001	Mar 30,	1998	Mar	CRLD
PSORCON									
	@	SANOFI AVENTIS US	0.05%	N020205	001	Nov 20,	1992	Feb	DISC
<u>DILTIAZEM HYDROCHLORIDE</u>									
TABLET, EXTENDED RELEASE; ORAL									
CARDIZEM LA									
AB		BIOVAIL LABS INTL	120MG	N021392	001	Feb 06,	2003	Feb	CFTG
AB			180MG	N021392	002	Feb 06,	2003	Feb	CFTG
AB			240MG	N021392	003	Feb 06,	2003	Feb	CFTG
AB			300MG	N021392	004	Feb 06,	2003	Feb	CFTG
AB			360MG	N021392	005	Feb 06,	2003	Feb	CFTG
AB	+		420MG	N021392	006	Feb 06,	2003	Feb	CFTG
DILTIAZEM HYDROCHLORIDE									
AB		WATSON LABS FLORIDA	120MG	A077686	006	Mar 15,	2010	Feb	NEWA
AB			180MG	A077686	005	Mar 15,	2010	Feb	NEWA
AB			240MG	A077686	004	Mar 15,	2010	Feb	NEWA
AB			300MG	A077686	003	Mar 15,	2010	Feb	NEWA

TABLET, EXTENDED RELEASE; ORAL
DILTIAZEM HYDROCHLORIDE

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

DOXEPIN HYDROCHLORIDE

>A> TABLET; ORAL

>A> SILENOR

>A>	SOMAXON	EQ 3MG BASE	N022036 001	Mar 17, 2010	Mar	NEWA
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>A>	+	EQ 6MG BASE	N022036 002	Mar 17, 2010	Mar	NEWA
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ELTROMBOPAG OLAMINE

TABLET; ORAL

PROMACTA

>A>	GLAXOSMITHKLINE	EQ 75MG ACID	N022291 003	Sep 08, 2009	Mar	NEWA
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>D> ENALAPRIL MALEATE; FELODIPINE

>D> TABLET, EXTENDED RELEASE; ORAL

>D> LEXXEL

>D>	+	ASTRAZENECA	5MG;5MG	N020668 001	Dec 27, 1996	Mar	DISC
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>A>	@	5MG;5MG	N020668 001	Dec 27, 1996	Mar	DISC
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EPINEPHRINE

INJECTABLE; IM-SC

>A> ADRENAClick

>A>	+	SHIONOGI PHARMA	EQ 0.15MG /DELIVERY	N020800 003	Nov 25, 2009	Mar	NEWA
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>A>	+		EQ 0.3MG /DELIVERY	N020800 004	Nov 25, 2009	Mar	NEWA
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TWINJECT 0.15

+	SHIONOGI PHARMA	EQ 0.15MG /DELIVERY	N020800 002	May 28, 2004	Jan	CAHN
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TWINJECT 0.3

+	SHIONOGI PHARMA	EQ 0.3MG /DELIVERY	N020800 001	May 30, 2003	Jan	CAHN
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EPIRUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

EPIRUBICIN HYDROCHLORIDE

>A>	AP	BIONICHE PHARMA USA	50MG/25ML (2MG/ML)	A065371 001	Nov 28, 2007	Mar	CAHN
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>A>	AP		200MG/100ML (2MG/ML)	A065371 002	Nov 28, 2007	Mar	CAHN
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>D>	AP	GENERAMEDIX	50MG/25ML (2MG/ML)	A065371 001	Nov 28, 2007	Mar	CAHN
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>D>	AP		200MG/100ML (2MG/ML)	A065371 002	Nov 28, 2007	Mar	CAHN
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>A>	AP	X GEN PHARMS	50MG/25ML (2MG/ML)	A090075 001	Mar 25, 2010	Mar	NEWA
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>A>	AP		200MG/100ML (2MG/ML)	A090075 002	Mar 25, 2010	Mar	NEWA
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ESTRADIOL VALERATE

INJECTABLE; INJECTION

ESTRADIOL VALERATE

AO	PHARMAFORCE	20MG/ML	A090920 001	Jan 19, 2010	Jan	NEWA
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AO		40MG/ML	A090920 002	Jan 19, 2010	Jan	NEWA
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ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

NORETHINDRONE AND ETHINYL ESTRADIOL

WATSON LABS 0.035MG;0.4MG

A078379 001	Feb 23, 2010	Feb	NEWA
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TABLET; ORAL-28

NORETHINDRONE AND ETHINYL ESTRADIOL

AB	WATSON LABS	0.035MG,0.035MG,0.035MG;0.5MG,0.7 5MG,1MG	A076393 001	Feb 04, 2010	Jan	NEWA
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TABLET; ORAL-28

NORETHINDRONE AND ETHINYL ESTRADIOL

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

TABLET; ORAL

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

AB	WATSON LABS	0.02MG;1MG	A078267 001	Sep 01, 2009	Jan	CDFR
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TABLET; ORAL-28

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL

>A>	AB	WATSON LABS	0.02MG,0.03MG,0.035MG;1MG,1MG,1MG	A076629 001	Mar 18, 2010	Mar	NEWA
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NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

AB	VINTAGE	0.02MG;1MG	A077077 001	May 20, 2005	Feb	CAHN
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AB		0.03MG;1.5MG	A077075 001	Apr 28, 2005	Feb	CAHN
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ETHINYL ESTRADIOL; NORGESTIMATE

TABLET; ORAL-28

PREVIFEM

AB	VINTAGE	0.035MG;0.25MG	A076334 001	Jan 09, 2004	Feb	CAHN
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TRI-PREVIFEM

AB	VINTAGE	0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.25MG	A076335 001	Mar 26, 2004	Feb	CAHN
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FAMOTIDINE

INJECTABLE; INJECTION

FAMOTIDINE

AP	+	BAXTER HLTHCARE	10MG/ML	A075488 001	Apr 16, 2001	Feb	CRLD
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AP	+		10MG/ML	A075799 001	Apr 30, 2002	Feb	CRLD
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FAMOTIDINE PRESERVATIVE FREE

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

AP	+	BAXTER HLTHCARE	0.4MG/ML	A075591 001	May 10, 2001	Feb	CRLD
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TABLET, ORALLY DISINTEGRATING; ORAL

FLUXID

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

CAPSULE; ORAL

ANTARA (MICRONIZED)

	LUPIN ATLANTIS	43MG	N021695 001	Nov 30, 2004	Jan	CAHN
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	@	87MG	N021695 002	Nov 30, 2004	Jan	CAHN
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+		130MG	N021695 003	Nov 30, 2004	Jan	CAHN
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TABLET; ORAL

FENOGLIDE

	SHIONOGI PHARMA	40MG	N022118 001	Aug 10, 2007	Jan	CAHN
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+		120MG	N022118 002	Aug 10, 2007	Jan	CAHN
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FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

ALLEGRA D 24 HOUR

>D>	+	SANOFI AVENTIS US	180MG;240MG	N021704 001	Oct 19, 2004	Mar	CFTG
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>A>	AB	+	180MG;240MG	N021704 001	Oct 19, 2004	Mar	CFTG
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FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

>A>	AB	DR REDDYS LABS LTD	180MG;240MG	A079043 001	Mar 17, 2010	Mar	NEWA
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FINASTERIDE

TABLET; ORAL

FINASTERIDE

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

INJECTABLE; INJECTION

FLUCONAZOLE IN SODIUM CHLORIDE 0.9%

BEDFORD

100MG/50ML (2MG/ML)

A076087	002	Sep 26, 2008	Jan	CTNA
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FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

@ HOSPIRA

200MG/100ML (2MG/ML)

A076617	001	Jul 29, 2004	Feb	DISC
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@

400MG/200ML (2MG/ML)

A076617	002	Jul 29, 2004	Feb	DISC
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FLUNISOLIDE

AEROSOL, METERED; INHALATION

AEROSPAN HFA

+ ACTON PHARMS

EQ 78MCG BASE/INH

N021247	001	Jan 27, 2006	Feb	CAHN
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SPRAY, METERED; NASAL

NASAREL

AB +

TEVA BRANDED PHARM

0.029MG/SPRAY

N020409	001	Mar 08, 1995	Feb	CAHN
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FLUOROURACIL

CREAM; TOPICAL

FLUOROURACIL

AB

TARO

5%

A090368	001	Mar 05, 2010	Feb	NEWA
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INJECTABLE; INJECTION

FLUOROURACIL

>A>

AP

+

BIONICHE PHARMA

500MG/10ML (50MG/ML)

A040743	002	Apr 26, 2007	Mar	CAHN
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>A>

AP

+

1GM/20ML (50MG/ML)

A040743	001	Apr 26, 2007	Mar	CAHN
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>A>

AP

+

2.5GM/50ML (50MG/ML)

A040798	002	Apr 26, 2007	Mar	CAHN
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>A>

AP

+

5GM/100ML (50MG/ML)

A040798	001	Apr 26, 2007	Mar	CAHN
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>D>

AP

+

GENERAMEDIX

500MG/10ML (50MG/ML)

A040743	002	Apr 26, 2007	Mar	CAHN
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>D>

AP

+

1GM/20ML (50MG/ML)

A040743	001	Apr 26, 2007	Mar	CAHN
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>D>

AP

+

2.5GM/50ML (50MG/ML)

A040798	002	Apr 26, 2007	Mar	CAHN
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>D>

AP

+

5GM/100ML (50MG/ML)

A040798	001	Apr 26, 2007	Mar	CAHN
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FLUOXETINE HYDROCHLORIDE

CAPSULE, DELAYED REL PELLETS; ORAL

>A>

FLUOXETINE HYDROCHLORIDE

>A>

AB

BARR

EQ 90MG BASE

A076237	001	Mar 24, 2010	Mar	NEWA
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>A>

AB

DR REDDYS LABS LTD

EQ 90MG BASE

A078572	001	Mar 22, 2010	Mar	NEWA
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PROZAC WEEKLY

>D>

+

LILLY

EQ 90MG BASE

N021235	001	Feb 26, 2001	Mar	CFTG
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>A>

AB

+

EQ 90MG BASE

N021235	001	Feb 26, 2001	Mar	CFTG
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SOLUTION; ORAL

FLUOXETINE HYDROCHLORIDE

AA

LANNETT

EQ 20MG BASE/5ML

A076458	001	May 14, 2004	Feb	CAHN
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FOLIC ACID

TABLET; ORAL

FOLIC ACID

AA

+

PHARMAX

1MG

A040625	001	Jul 21, 2005	Jan	CRLD
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AA

+

WATSON LABS

1MG

A080680	001		Jan	CMFD
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FOMEPIZOLE

INJECTABLE; INJECTION

FOMEPIZOLE

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

FOSPHENYTOIN SODIUM

INJECTABLE; INJECTION

FOSPHENYTOIN SODIUM

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

INJECTABLE; INJECTION

OPTIMARK IN PLASTIC CONTAINER

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

GANCICLOVIR SODIUM

INJECTABLE; INJECTION

CYTOVENE

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

GEMFIBROZIL

TABLET; ORAL

GEMFIBROZIL

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

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLYBURIDE AND METFORMIN HYDROCHLORIDE

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

GLYCOPYRROLATE

TABLET; ORAL

ROBINUL

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

GRANISETRON HYDROCHLORIDE

INJECTABLE; INJECTION

GRANISETRON HYDROCHLORIDE

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

GRISEOFULVIN, MICROCRYSTALLINE

TABLET; ORAL

FULVICIN-U/F

@ ELORAC

250MG

A060569 002

Feb CAHN

@

500MG

A060569 001

Feb CAHN

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

GUANFACINE HYDROCHLORIDE

AB MIKAH PHARMA EQ 1MG BASE

A074673 001 Feb 28, 1997 Feb CAHN

AB EQ 2MG BASE

A074673 002 Feb 28, 1997 Feb CAHN

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALDOL

@ ORTHO MCNEIL JANSSEN EQ 5MG BASE/ML

N015923 001

Feb DISC

HALOPERIDOL

AP + TEVA PARENTERAL EQ 5MG BASE/ML

A076035 001 Aug 29, 2001 Feb CRLD

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HYDROCHLORIDE

AA HERITAGE PHARMS INC 10MG

A086242 001 Feb 04, 2010 Jan NEWA

AA 100MG

A086242 004 Feb 04, 2010 Jan NEWA

AA ZYDUS PHARMS USA 10MG

A040858 001 Feb 26, 2010 Feb NEWA

AA 25MG

A040858 002 Feb 26, 2010 Feb NEWA

AA 50MG

A040858 003 Feb 26, 2010 Feb NEWA

AA 100MG

A040858 004 Feb 26, 2010 Feb NEWA

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDROCHLOROTHIAZIDE

AB UNICHEM 12.5MG

A090510 001 Jan 19, 2010 Jan NEWA

HYDROCHLOROTHIAZIDE; LISINAPRIL

TABLET; ORAL

LISINAPRIL AND HYDROCHLOROTHIAZIDE

@ TEVA 12.5MG;10MG

A075869 001 Jul 01, 2002 Jan DISC

@ 12.5MG;20MG

A075869 002 Jul 01, 2002 Jan DISC

@ 25MG;20MG

A075869 003 Jul 01, 2002 Jan DISC

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

TABLET; ORAL

HYZAAR

>D> MERCK 12.5MG;50MG

N020387 001 Apr 28, 1995 Mar CFTG

>A> AB 12.5MG;50MG

N020387 001 Apr 28, 1995 Mar CFTG

>D> 12.5MG;100MG

N020387 003 Oct 20, 2005 Mar CFTG

>A> AB 12.5MG;100MG

N020387 003 Oct 20, 2005 Mar CFTG

>D> + 25MG;100MG

N020387 002 Nov 10, 1998 Mar CFTG

>A> AB + 25MG;100MG

N020387 002 Nov 10, 1998 Mar CFTG

>A> LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

>A> AB MYLAN 12.5MG;100MG

A091652 002 Apr 06, 2010 Mar NEWA

>A> AB ROXANE 12.5MG;100MG

A077732 001 Apr 06, 2010 Mar NEWA

>A> AB TEVA PHARMS 12.5MG;50MG

A077157 001 Apr 06, 2010 Mar NEWA

>A> AB 12.5MG;100MG

A077157 002 Apr 06, 2010 Mar NEWA

TABLET; ORAL

>A> LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE

>A> AB TEVA PHARMS 25MG;100MG A077157 003 Apr 06, 2010 Mar NEWA

>A> AB TORRENT PHARMS 12.5MG;100MG A090528 003 Apr 06, 2010 Mar NEWA

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATETABLET; ORAL

METOPROLOL TARTRATE AND HYDROCHLOROTHIAZIDE

AB + MYLAN 25MG;100MG A076792 002 Aug 20, 2004 Jan CRLD

50MG;100MG A076792 003 Aug 20, 2004 Jan CTEC

HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDETABLET; ORAL

MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

>A> AB GLENMARK PHARMS 12.5MG;7.5MG A090718 001 Mar 17, 2010 Mar NEWA

>A> AB 12.5MG;15MG A090718 002 Mar 17, 2010 Mar NEWA

>A> AB 25MG;15MG A090718 003 Mar 17, 2010 Mar NEWA

HYDROCORTISONECREAM; TOPICAL

HYDROCORTISONE

AT + FOUGERA 1% A080693 003 Feb CRLD

AT + 2.5% A089414 001 Dec 16, 1986 Feb CRLD

HYTONE

@ SANOFI AVENTIS US 1% A080472 003 Feb DISC

@ 2.5% A080472 004 Feb DISC

LOTION; TOPICAL

HYTONE

@ SANOFI AVENTIS US 1% A080473 003 Feb DISC

@ 2.5% A080473 004 Nov 30, 1982 Feb DISC

HYDROMORPHONE HYDROCHLORIDEINJECTABLE; INJECTION

HYDROMORPHONE HYDROCHLORIDE

>A> AP AKORN 10MG/ML A078228 001 Apr 14, 2010 Mar NEWA

>A> AP 10MG/ML A078261 001 Apr 14, 2010 Mar NEWA

>A> TABLET, EXTENDED RELEASE; ORAL

>A> EXALGO

>A> MALLINCKRODT INC 8MG N021217 001 Mar 01, 2010 Mar NEWA

>A> 12MG N021217 002 Mar 01, 2010 Mar NEWA

>A> + 16MG N021217 003 Mar 01, 2010 Mar NEWA

IBUPROFENTABLET; ORAL

IBUPROFEN

AB CONTRACT PHARMACAL 400MG A071267 001 Oct 15, 1986 Jan CAHN

AB 600MG A071268 001 Oct 15, 1986 Jan CAHN

AB 800MG A072300 001 Jul 01, 1988 Jan CAHN

IBUTILIDE FUMARATEINJECTABLE; INJECTION

IBUTILIDE FUMARATE

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

>D> AP GENERAMEDIX 0.1MG/ML A090924 001 Jan 11, 2010 Mar CAHN

IFOSFAMIDE

INJECTABLE; INJECTION

IFEX

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

IFOSFAMIDE

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

IFOSFAMIDE; MESNA

INJECTABLE; INJECTION

IFEX/MESNEX KIT

@ BAXTER HLTHCARE

@

1GM/VIAL;100MG/ML	N019763 003	Oct 10, 1992	Feb	DISC
3GM/VIAL;100MG/ML	N019763 004	Oct 10, 1992	Feb	DISC

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HYDROCHLORIDE

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

IMIQUIMOD

CREAM; TOPICAL

ALDARA

AB	+	GRACEWAY	5%	N020723 001	Feb 27, 1997	Feb	CFTG
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IMIQUIMOD

AB		NYCOMED US	5%	A078548 001	Feb 25, 2010	Feb	NEWA
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>A> ZYCLARA

>A>	+	GRACEWAY	3.75%	N022483 001	Mar 25, 2010	Mar	NEWA
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INAMRINONE LACTATE

INJECTABLE; INJECTION

AMRINONE LACTATE

@ BAXTER HLTHCARE CORP

EQ 5MG BASE/ML

A075542 001	May 10, 2000	Feb	DISC
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+ BEDFORD

A075513 001	May 09, 2000	Feb	CTEC
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INDOMETHACIN

INJECTABLE; INJECTION

INDOMETHACIN

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

INJECTABLE; INJECTION

IRINOTECAN HYDROCHLORIDE

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

TABLET, EXTENDED RELEASE; ORAL

ISOSORBIDE DINITRATE

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

LABETALOL HYDROCHLORIDE

INJECTABLE; INJECTION

LABETALOL HYDROCHLORIDE

AP			SAGENT STRIDES	5MG/ML	A079134	001	Feb 03,	2010	Jan	NEWA
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TABLET; ORAL

TRANDATE

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

CAPSULE; ORAL

REVLIMID

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

SOLUTION; ORAL

LEVETIRACETAM

AA			WOCKHARDT	100MG/ML	A090028	001	Mar 03,	2010	Feb	NEWA
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TABLET; ORAL

LEVETIRACETAM

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

CAPSULE; ORAL

TIROSINT

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

CREAM; TOPICAL

LIDOCAINE AND PRILOCAINE

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

SOLUTION; SUBCUTANEOUS

VICTOZA

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

TABLET; ORAL

LISINOPRIL

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

LITHIUM CARBONATE

CAPSULE; ORAL

ESKALITH

@ NOVEN THERAP	300MG	N016860 001		Jan	DISC
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LOSARTAN POTASSIUM

TABLET; ORAL

COZAAR

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

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

ANTIVERT

AA +	PFIZER	50MG	N010721 001	Jan 20, 1982	Jan	CMFD
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TABLET, CHEWABLE; ORAL

ANTIVERT

@ PFIZER	25MG	N010721 005		Jan	DISC
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MELPHALAN HYDROCHLORIDE

INJECTABLE; INJECTION

MELPHALAN HYDROCHLORIDE

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

MEMANTINE HYDROCHLORIDE

TABLET; ORAL

MEMANTINE HYDROCHLORIDE

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

MEPERIDINE HYDROCHLORIDE

SYRUP; ORAL

MEPERIDINE HYDROCHLORIDE

+ ROXANE 50MG/5ML

A088744 001 Jan 30, 1985 Feb CRLD

TABLET; ORAL

DEMEROL

@ SANOFI AVENTIS US 50MG

N005010 001 Feb DISC

MEPERIDINE HYDROCHLORIDE

AA MIKAH PHARMA 50MG

A040331 001 May 28, 1999 Feb CAHN

AA 100MG

A040331 002 May 28, 1999 Feb CAHN

MESALAMINE

TABLET, DELAYED RELEASE; ORAL

ASACOL

+ WARNER CHILCOTT INC 400MG

N019651 001 Jan 31, 1992 Feb CAHN

ASACOL HD

+ WARNER CHILCOTT INC 800MG

N021830 001 May 29, 2008 Feb CAHN

MESNA

INJECTABLE; INTRAVENOUS

MESNA

>A> AP SAGENT STRIDES 100MG/ML

A090913 001 Apr 13, 2010 Mar NEWA

METAXALONE

TABLET; ORAL

>A> METAXALONE

>A> AB SANDOZ 800MG

A040445 001 Mar 31, 2010 Mar NEWA

SKELAXIN

>D> + KING PHARMS 800MG

N013217 003 Aug 30, 2002 Mar CFTG

>A> AB + 800MG

N013217 003 Aug 30, 2002 Mar CFTG

METFORMIN HYDROCHLORIDE

TABLET; ORAL

>D> METFORMIN HYDROCHLORIDE

>D> AB IPCA LABS LTD 500MG

A078422 001 Aug 06, 2007 Mar DISC

>A> @ 500MG

A078422 001 Aug 06, 2007 Mar DISC

>D> AB 850MG

A078422 002 Aug 06, 2007 Mar DISC

>A> @ 850MG

A078422 002 Aug 06, 2007 Mar DISC

>D> AB 1GM

A078422 003 Aug 06, 2007 Mar DISC

>A> @ 1GM

A078422 003 Aug 06, 2007 Mar DISC

TABLET, EXTENDED RELEASE; ORAL

METFORMIN HYDROCHLORIDE

AB TORRENT PHARMS 750MG

A079226 001 Feb 18, 2010 Jan NEWA

METHADONE HYDROCHLORIDE

INJECTABLE; INJECTION

DOLOPHINE HYDROCHLORIDE

>A> + BIONICHE PHARMA 10MG/ML

N021624 001 Mar CAHN

>D> + XANODYNE PHARM 10MG/ML

N021624 001 Mar CAHN

METHENAMINE HIPPURATE

TABLET; ORAL

UREX

AB CNTY LINE PHARMS 1GM

N016151 001 Feb CAHN

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE SODIUM PRESERVATIVE FREE

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

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HYDROCHLORIDE

@ HOSPIRA EQ 5MG BASE/ML

A074147 001 Aug 02, 1996 Feb DISC

TABLET; ORAL

METOCLOPRAMIDE HYDROCHLORIDE

@ SANDOZ EQ 10MG BASE

A074478 002 Oct 05, 1995 Jan DISC

@ WATSON LABS EQ 10MG BASE

A070511 001 Jan 22, 1986 Jan DISC

METRONIDAZOLE

TABLET; ORAL

METRONIDAZOLE

>D> @ PAR PHARM 250MG

A070040 001 Jan 29, 1985 Mar CAHN

>A> @ WORLD GEN 250MG

A070040 001 Jan 29, 1985 Mar CAHN

MILRINONE LACTATE

INJECTABLE; INJECTION

MILRINONE LACTATE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP + BAXTER HLTHCARE EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)

A075834 001 May 28, 2002 Feb CTEC

AP + EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)

A075834 002 May 28, 2002 Feb CRLD

MILRINONE LACTATE IN PLASTIC CONTAINER

AP HIKMA FARMACEUTICA EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)

A090038 001 Jan 21, 2010 Jan NEWA

AP EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)

A090038 002 Jan 21, 2010 Jan NEWA

PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER

@ SANOFI AVENTIS US EQ 20MG BASE/100ML (EQ 0.2MG BASE/ML)

N020343 003 Aug 09, 1994 Feb DISC

@ EQ 40MG BASE/200ML (EQ 0.2MG BASE/ML)

N020343 004 Aug 09, 1994 Feb DISC

MITOXANTRONE HYDROCHLORIDE

INJECTABLE; INJECTION

MITOXANTRONE HYDROCHLORIDE

>A> AP BIONICHE PHARMA USA EQ 20MG BASE/10ML (EQ 2MG BASE/ML)

A078980 001 Apr 13, 2009 Mar CAHN

>A> AP EQ 30MG BASE/15ML (EQ 2MG BASE/ML)

A078980 002 Apr 13, 2009 Mar CAHN

>D> AP GENERAMEDIX EQ 20MG BASE/10ML (EQ 2MG BASE/ML)

A078980 001 Apr 13, 2009 Mar CAHN

>D> AP EQ 30MG BASE/15ML (EQ 2MG BASE/ML)

A078980 002 Apr 13, 2009 Mar CAHN

MOEXIPRIL HYDROCHLORIDE

TABLET; ORAL

MOEXIPRIL HYDROCHLORIDE

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

MORPHINE SULFATE

SOLUTION; ORAL

MORPHINE SULFATE

ROXANE

20MG/5ML

N022195 002 Mar 17, 2008 Jan CRLD

+ 100MG/5ML

N022195 003 Jan 25, 2010 Jan NEWA

TABLET, EXTENDED RELEASE; ORAL

MORPHINE SULFATE

@ PURDUE PHARMA LP

15MG

A074862 001 Jul 07, 1998 Feb CAHN

@

30MG

A074862 002 Jul 07, 1998 Feb CAHN

@

60MG

A074862 003 Jul 07, 1998 Feb CAHN

@

100MG

A074769 001 Jul 02, 1998 Feb CAHN

@

200MG

A074769 002 Jul 02, 1998 Feb CAHN

NALIDIXIC ACID

TABLET; ORAL

NEGGRAM

@ SANOFI AVENTIS US

250MG

N014214 002

Feb DISC

@

500MG

N014214 004

Feb DISC

@

1GM

N014214 005

Feb DISC

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

PENTAZOCINE AND NALOXONE HYDROCHLORIDES

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

A074736 001 Jan 21, 1997 Feb CRLD

TALWIN NX

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

N018733 001 Dec 16, 1982 Feb DISC

NEOMYCIN SULFATE

TABLET; ORAL

NEOMYCIN SULFATE

>A> AA OMAN PHARM PRODUCTS 500MG

A065468 001 Mar 29, 2010 Mar NEWA

NICARDIPINE HYDROCHLORIDE

INJECTABLE; INJECTION

NICARDIPINE HYDROCHLORIDE

>A> AP BIONICHE PHARMA USA 25MG/10ML (2.5MG/ML)

A090664 001 Nov 17, 2009 Mar CAHN

>D> AP GENERAMEDIX 25MG/10ML (2.5MG/ML)

A090664 001 Nov 17, 2009 Mar CAHN

NIFEDIPINE

CAPSULE; ORAL

NIFEDIPINE

>A> AB INTERGEL PHARM 10MG

A072781 001 Jul 30, 1993 Mar CAHN

>D> AB INVERNESS MEDCL 10MG

A072781 001 Jul 30, 1993 Mar CAHN

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL

SULAR

+ SHIONOGI PHARMA 8.5MG

N020356 008 Jan 02, 2008 Jan CAHN

@

10MG

N020356 001 Feb 02, 1995 Jan CAHN

TABLET, EXTENDED RELEASE; ORAL

SULAR

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

NITROFURANTOIN

SUSPENSION; ORAL

FURADANTIN

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

AEROSOL; SUBLINGUAL

NITROLINGUAL

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

SPRAY, METERED; SUBLINGUAL

NITROLINGUAL PUMPSPRAY

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

OFLOXACIN

TABLET; ORAL

OFLOXACIN

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

ONDANSETRON

TABLET, ORALLY DISINTEGRATING; ORAL

ONDANSETRON

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

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ONDANSETRON HYDROCHLORIDE

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

TABLET, EXTENDED RELEASE; ORAL

ORPHENADRINE CITRATE

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

INJECTABLE; INJECTION

OXALIPLATIN

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

OXCARBAZEPINE

TABLET; ORAL

OXCARBAZEPINE

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

PALIPERIDONE PALMITATE

SUSPENSION, EXTENDED RELEASE; INTRAMUSCULAR

INVEGA SUSTENNA

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

INJECTABLE; INJECTION

PAMIDRONATE DISODIUM

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

PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

CAPSULE, DELAYED RELEASE; ORAL

CREON

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

PEGADEMASE BOVINE

INJECTABLE; INJECTION

ADAGEN

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

TABLET; ORAL

PERINDOPRIL ERBUMINE

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

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE; ORAL

BONTRIL

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

CAPSULE; ORAL

PHENTERMINE HYDROCHLORIDE

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

>A> POLIDOCANOL

>A> SOLUTION; INTRAVENOUS

>A> ASCLERA

>A> CHEMISCH FBRK KRSSLR 10MG/2ML (5MG/ML) N021201 001 Mar 30, 2010 Mar NEWA

>A> + 20MG/2ML (10MG/ML) N021201 002 Mar 30, 2010 Mar NEWA

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

FOR SOLUTION; ORAL

LAX-LYTE WITH FLAVOR PACKS

AA PADDOCK 420GM/BOT;1.48GM/BOT;5.72GM/BOT;1 1.2GM/BOT A079232 001 Feb 25, 2010 Feb NEWA

>A> PEG-3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE

>A> AA MYLAN 420GM/BOT;1.48GM/BOT;5.72GM/BOT;1 1.2GM/BOT A090409 001 Apr 02, 2010 Mar NEWA

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

FOR SOLUTION; ORAL

PEG 3350 AND ELECTROLYTES

AA MYLAN 236GM;2.97GM;6.74GM;5.86GM;22.74GM A090928 001 Jan 28, 2010 Jan NEWA

POLYETHYLENE GLYCOL 3350 AND ELECTROLYTES

AA PADDOCK LABS 240GM/BOT;2.98GM/BOT;6.72GM/BOT;5 .84GM/BOT;22.72GM/BOT A090712 001 Feb 25, 2010 Feb NEWA

POTASSIUM CITRATE

TABLET, EXTENDED RELEASE; ORAL

UROCIT-K

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

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET; ORAL

MIRAPEX

>D> BOEHRINGER INGELHEIM 0.75MG N020667 007 Jul 30, 2007 Mar CFTG

>A> AB 0.75MG N020667 007 Jul 30, 2007 Mar CFTG

>A> PRAMIPEXOLE DIHYDROCHLORIDE

>A> AB MYLAN 0.75MG A090764 001 Apr 09, 2010 Mar NEWA

TABLET, EXTENDED RELEASE; ORAL

MIRAPEX ER

BOEHRINGER INGELHEIM 0.375MG N022421 001 Feb 19, 2010 Feb NEWA

0.75MG N022421 002 Feb 19, 2010 Feb NEWA

1.5MG N022421 003 Feb 19, 2010 Feb NEWA

3MG N022421 004 Feb 19, 2010 Feb NEWA

+ 4.5MG N022421 005 Feb 19, 2010 Feb NEWA

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HYDROCHLORIDE

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

@ EQ 2MG BASE A072333 001 May 16, 1989 Jan DISC

PREDNISONE

TABLET; ORAL

PREDNISONE

AB CONTRACT PHARMACAL 5MG A080209 001 Jan CAHN

PREGABALIN

SOLUTION; ORAL

LYRICA

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

INJECTABLE; INJECTION

PROCAINE HYDROCHLORIDE

	@ WATSON LABS	1%	A080658 001		Jan	DISC
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PROCHLORPERAZINE MALEATE

TABLET; ORAL

PROCHLORPERAZINE MALEATE

	@ DURAMED PHARMS BARR	EQ 5MG BASE	A040207 001	May 01, 1997	Jan	DISC
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	@	EQ 10MG BASE	A040207 002	May 01, 1997	Jan	DISC
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PROCOMP

AB	CADISTA PHARMS	EQ 5MG BASE	A040268 001	Feb 27, 1998	Jan	CTNA
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AB		EQ 10MG BASE	A040268 002	Feb 27, 1998	Jan	CTNA
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PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HYDROCHLORIDE

	@ PAR PHARM	65MG	A080269 001		Jan	DISC
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QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

	@ CONTRACT PHARMACAL	200MG	A083808 001		Jan	CAHN
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RIFAXIMIN

TABLET; ORAL

XIFAXAN

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

INJECTABLE; INTRAMUSCULAR

RISPERDAL CONSTA

+	ORTHO MCNEIL JANSSEN	25MG/VIAL	N021346 001	Oct 29, 2003	Jan	CRLD
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		50MG/VIAL	N021346 003	Oct 29, 2003	Jan	CRLD
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TABLET; ORAL

RISPERIDONE

	@ SYNTHON PHARMS	0.25MG	A078187 001	Oct 22, 2009	Feb	DISC
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	@	0.5MG	A078187 002	Oct 22, 2009	Feb	DISC
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	@	1MG	A078187 003	Oct 22, 2009	Feb	DISC
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	@	2MG	A078187 004	Oct 22, 2009	Feb	DISC
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	@	3MG	A078187 005	Oct 22, 2009	Feb	DISC
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	@	4MG	A078187 006	Oct 22, 2009	Feb	DISC
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RITONAVIR

TABLET; ORAL

RITONAVIR

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

CAPSULE; ORAL

EXELON

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

INJECTABLE; INJECTION

ROCURONIUM BROMIDE

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

ROPINIROLE HYDROCHLORIDE

TABLET; ORAL

ROPINIROLE HYDROCHLORIDE

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

SELEGILINE HYDROCHLORIDE

TABLET; ORAL

SELEGILINE HYDROCHLORIDE

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

SODIUM BICARBONATE

INJECTABLE; INJECTION

SODIUM BICARBONATE

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

INJECTABLE; INJECTION

NORDITROPIN FLEXPRO

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

STAVUDINE

CAPSULE; ORAL

STAVUDINE

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

CAPSULE; ORAL

STAVUDINE

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

TABLET; ORAL

SUCRALFATE

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

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

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

CAPSULE; ORAL

FLOMAX

AB	+	BOEHRINGER INGELHEIM	0.4MG	N020579 001	Apr 15, 1997	Feb	CFTG
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TAMSULOSIN HYDROCHLORIDE

AB		IMPAX LABS	0.4MG	A090377 001	Mar 02, 2010	Feb	NEWA
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TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR

SOLUTION; INJECTION, ORAL

TECHNELITE

+	LANTHEUS MEDCL	0.0083-2.7 CI/GENERATOR	N017771 001		Feb	CRLD
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ULTRA-TECHNEKOW FM

+	MALLINCKRODT	0.25-3 CI/GENERATOR	N017243 002		Feb	CRLD
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TEMOZOLOMIDE

CAPSULE; ORAL

TEMODAR

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

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

CREAM; VAGINAL

TERCONAZOLE

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

ELIXIR; ORAL

ELIXOPHYLLIN

>A>	+	CARACO	80MG/15ML	A085186 001		Mar	CAHN
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ELIXIR; ORAL
 ELIXOPHYLLIN
 >D> + FOREST LABS 80MG/15ML A085186 001 Mar CAHN
 TABLET, EXTENDED RELEASE; ORAL
 THEOCHRON
 >A> AB CARACO 100MG A088320 001 Feb 21, 1985 Mar CAHN
 >A> AB 200MG A088321 001 Feb 21, 1985 Mar CAHN
 >A> AB 300MG A087400 002 Jan 11, 1983 Mar CAHN
 >D> AB INWOOD LABS 100MG A088320 001 Feb 21, 1985 Mar CAHN
 >D> AB 200MG A088321 001 Feb 21, 1985 Mar CAHN
 >D> AB 300MG A087400 002 Jan 11, 1983 Mar CAHN

TINZAPARIN SODIUM

INJECTABLE; INJECTION
 INNOHEP

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

TOPIRAMATE

TABLET; ORAL

TOPIRAMATE

@ PLIVA HRVATSKA D00 25MG A077905 001 Mar 30, 2009 Jan DISC

@ 50MG A077905 002 Mar 30, 2009 Jan DISC

@ 100MG A077905 003 Mar 30, 2009 Jan DISC

@ 200MG A077905 004 Mar 30, 2009 Jan DISC

TRAMADOL HYDROCHLORIDE

TABLET, ORALLY DISINTEGRATING; ORAL

TRAMADOL HYDROCHLORIDE

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

>A> + 50MG N021693 001 May 05, 2005 Mar CMFD

TRANOLAPRIL

TABLET; ORAL

TRANOLAPRIL

AB EPIC PHARMA 1MG A078508 003 Jun 18, 2008 Feb CAHN

AB 2MG A078508 001 Jun 18, 2008 Feb CAHN

AB 4MG A078508 002 Jun 18, 2008 Feb CAHN

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HYDROCHLORIDE

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

AB 100MG A072193 001 Feb 02, 1989 Feb CAHN

TABLET, EXTENDED RELEASE; ORAL

OLEPTRO

LABOPHARM 150MG N022411 001 Feb 02, 2010 Feb NEWA

+ 300MG N022411 002 Feb 02, 2010 Feb NEWA

TRETINOIN

CAPSULE; ORAL

TRETINOIN

+ BARR 10MG A077684 001 Jun 22, 2007 Feb CRLD

VESANOID

@ ROCHE 10MG N020438 001 Nov 22, 1995 Feb DISC

TRETINOIN

TRIPTORELIN PAMOATE

INJECTABLE; INTRAMUSCULAR

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

UNOPROSTONE ISOPROPYL

SOLUTION/DROPS; OPHTHALMIC

RESCULA

@ SUCAMPO PHARMS 0.15% N021214 001 Aug 03, 2000 Jan DISC

UREA, C-14

CAPSULE; ORAL

PYTEST

+ AVENT 1uCi N020617 001 May 09, 1997 Feb CAHN

PYTEST KIT

+ AVENT 1uCi N020617 002 May 09, 1997 Feb CAHN

URSODIOL

CAPSULE; ORAL

URSODIOL

AB	MIKAH PHARMA	300MG	A075517 001	Mar 14, 2000	Feb	CAHN
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AB	MYLAN	300MG	A090530 001 Feb 17, 2010 Jan NEWA
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VALPROATE SODIUM

INJECTABLE; INJECTION

VALPROATE SODIUM

AP	HIKMA FARMACEUTICA	EQ 100MG BASE/ML	A078523 001	Feb 17, 2010	Jan	NEWA
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VANCOMYCIN HYDROCHLORIDE

INJECTABLE: INJECTION

VANCOMYCIN HYDROCHLORIDE

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

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

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

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

VECURONIUM BROMIDE

INJECTABLE; INJECTION

VECURONIUM BROMIDE

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>D>  AP          GENERAMEDIX          10MG/VIAL          A078274 001  Dec 29, 2008 Mar  CAHN
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>D> AP 20MG/VIAL A078274 002 Dec 29, 2008 Mar CAHN

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

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

VELAGLUCERASE ALFA

INJECTABLE; IV (INFUSION)

VPRIV

SHIRE HUMAN GENETIC 400 UNITS/VIAL N022575 001 Feb 26, 2010 Feb NEWA

POWDER; IV (INFUSION)

VPRIV

+	SHIRE HUMAN GENETIC	200 UNITS/VIAL	N022575 002	Feb 26, 2010	Feb	NEWA
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VENLAFAXINE HYDROCHLORIDE

TABLET; ORAL

VENLAFAXINE HYDROCHLORIDE

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

ZOLPIDEM TARTRATE

TABLET; ORAL

ZOLPIDEM TARTRATE

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

OTC DRUG PRODUCT LIST - 30TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2010

2-1

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

AUROBINDO PHARMA 5MG/5ML

A090750 002 Feb 02, 2010 Jan NEWA

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

AUROBINDO PHARMA 5MG/5ML

A090750 001 Feb 02, 2010 Jan NEWA

TABLET; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

AMNEAL PHARMS NY 5MG

A078780 001 Jan 21, 2010 Jan NEWA

10MG

A078780 004 Jan 21, 2010 Jan NEWA

>A> TORRENT PHARMS LLC 5MG

A079191 001 Apr 15, 2010 Mar NEWA

>A> 10MG

A079191 004 Apr 15, 2010 Mar NEWA

CETIRIZINE HYDROCHLORIDE HIVES RELIEF

AMNEAL PHARMS NY 5MG

A078780 003 Jan 21, 2010 Jan NEWA

10MG

A078780 002 Jan 21, 2010 Jan NEWA

>A> TORRENT PHARMS LLC 5MG

A079191 003 Apr 15, 2010 Mar NEWA

>A> 10MG

A079191 002 Apr 15, 2010 Mar NEWA

CIMETIDINE

TABLET; ORAL

CIMETIDINE

CONTRACT PHARMACAL 200MG

A074961 001 Jun 19, 1998 Jan CAHN

200MG

A074963 001 Jun 19, 1998 Jan CAHN

IBUPROFEN

CAPSULE; ORAL

IBUPROFEN

+ CONTRACT PHARMACAL 200MG

A074782 001 Jul 06, 1998 Jan CAHN

TABLET; ORAL

IBUPROFEN

CONTRACT PHARMACAL 200MG

A071732 001 Sep 10, 1987 Jan CAHN

200MG

A071735 001 Sep 10, 1987 Jan CAHN

200MG

A072299 001 Jul 01, 1988 Jan CAHN

200MG

A073691 001 Feb 25, 1994 Jan CAHN

PROFEN

CONTRACT PHARMACAL 200MG

A071265 001 Oct 15, 1986 Jan CAHN

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL

IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE

CONTRACT PHARMACAL 200MG;30MG

A075588 001 Apr 08, 2002 Jan CAHN

LOPERAMIDE HYDROCHLORIDE

TABLET; ORAL

LOPERAMIDE HYDROCHLORIDE

CONTRACT PHARMACAL 2MG

A073254 001 Jul 30, 1993 Jan CAHN

LORATADINE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

CLARITIN-D

>D> @ SCHERING PLOUGH 5MG;120MG

N019670 002 Nov 27, 2002 Mar CMFD

>A> + 5MG;120MG

N019670 002 Nov 27, 2002 Mar CMFD

TABLET, EXTENDED RELEASE; ORAL

LORATADINE AND PSEUDOEPHEDRINE SULFATE

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

MICONAZOLE NITRATE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL

MONISTAT 1 COMBINATION PACK

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

CREAM; VAGINAL

MICONAZOLE NITRATE

		PERRIGO R AND D	4%	A091366 001	Jan 15, 2010	Jan	NEWA
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NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC

VISINE-A

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

TABLET, EXTENDED RELEASE; ORAL

SUDAFED 24 HOUR

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

TABLET; ORAL

RANITIDINE HYDROCHLORIDE

		CONTRACT PHARMACAL	EQ 75MG BASE	A075094 001	Jun 21, 1999	Jan	CAHN
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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 03 MARCH 2010

NO MARCH 2010 APPROVALS

ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

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

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

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

NO MARCH 2010 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST - 30TH EDITION

A - 1

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

See List footnote for information regarding List content

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

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

See List footnote for information regarding List content

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

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

See List footnote for information regarding List content

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

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<u>COLESEVELAM HYDROCHLORIDE - WELCHOL</u>						
N022362 002	5607669	Jun 10, 2014	U-757			
	5607669*PED	Dec 10, 2014				
	5679717	Apr 29, 2014	U-757			
	5679717*PED	Oct 29, 2014				
	5693675	Dec 02, 2014	DS			
	5693675*PED	Jun 02, 2015				
	5917007	Apr 29, 2014	DS U-757			
	5917007*PED	Oct 29, 2014				
	5919832	Apr 29, 2014	DS			
	5919832*PED	Oct 29, 2014				
	6066678	Apr 29, 2014	DS U-757			
	6066678*PED	Oct 29, 2014				
	6433026	Apr 29, 2014	DS			
	6433026*PED	Oct 29, 2014				
	6784254	Apr 29, 2014	DS DP			
	6784254*PED	Oct 29, 2014				
	7101960	Apr 29, 2014	DS DP U-757			
	7101960*PED	Oct 29, 2014				
	7229613	Apr 17, 2022	U-493			
	7229613*PED	Oct 17, 2022				
<u>DALFAMPRIDINE - AMPYRA</u>						
N022250 001	5370879	Dec 06, 2011	DP		NCE	Jan 22, 2015
	5540938	Jul 30, 2013	U-1030		ODE	Jan 22, 2017
<u>DECITABINE - DACOGEN</u>						
N021790 001					>A> D-123	Mar 11, 2013
<u>DICLOFENAC POTASSIUM - CAMBIA</u>						
N022165 001	>A> 7482377	May 15, 2017	DS DP U-436		NDF	Jun 17, 2012
<u>DICLOFENAC POTASSIUM - ZIPSOR</u>						
N022202 001	6365180	Jul 15, 2019	DP U-980			
	7662858	Feb 24, 2029	U-1035			
<u>DOCETAXEL - TAXOTERE</u>						
N020449 001	>A> 4814470	May 14, 2010	DS DP		>A> I-543	Sep 28, 2010
	>A> 4814470*PED	Nov 14, 2010			>A> I-542	Sep 28, 2010
	>A> 5438072	Nov 22, 2013	DP		>A> PED	Mar 28, 2011
	>A> 5438072*PED	May 22, 2014				
	>A> 5698582	Jul 03, 2012	DP			
	>A> 5698582*PED	Jan 03, 2013				
	>A> 5714512	Jul 03, 2012	DP			
	>A> 5714512*PED	Jan 03, 2013				
	>A> 5750561	Jul 03, 2012	DP			
	>A> 5750561*PED	Jan 03, 2013				

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<u>DOXEPIN HYDROCHLORIDE - SILENOR</u>						
N022036 001	>A> 5502047	Mar 22, 2013	U-620			
	>A> 5585115	Jan 09, 2015	DP			
	>A> 5725884	Sep 30, 2016	DP			
	>A> 5866166	Jun 10, 2016	DP			
	>A> 5948438	Jun 04, 2017	DP			
	>A> 6103219	Dec 17, 2017	DP			
	>A> 6106865	Nov 12, 2019	DP			
	>A> 6211229	Feb 17, 2020	U-620			
<u>DOXEPIN HYDROCHLORIDE - SILENOR</u>						
N022036 002	>A> 5502047	Mar 22, 2013	U-620			
	>A> 5585115	Jan 09, 2015	DP			
	>A> 5725884	Sep 30, 2016	DP			
	>A> 5866166	Jun 10, 2016	DP			
	>A> 5948438	Jun 04, 2017	DP			
	>A> 6103219	Dec 17, 2017	DP			
	>A> 6106865	Nov 12, 2019	DP			
	>A> 6211229	Feb 17, 2020	U-620			
<u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>						
N021427 003	5023269	Jun 11, 2013	DS DP U-799			
	5023269	Jun 11, 2013	DS DP U-797			
	5023269	Jun 11, 2013	DS DP U-795			
	5508276	Jul 18, 2014	DP			
<u>ELTROMBOPAG OLAMINE - PROMACTA</u>						
N022291 003	>A> 6280959	Oct 30, 2018	DS DP U-930		>A> NCE	Nov 20, 2013
	>A> 7160870	Dec 08, 2021	DS DP U-930		>A> ODE	Nov 20, 2015
	>A> 7332481	May 24, 2021	U-930			
	>A> 7452874	May 24, 2021	DS DP			
	>A> 7473686	May 24, 2021	DS DP U-930			
	>A> 7547719	Mar 04, 2024	DS DP U-930			
<u>EPINEPHRINE - ADRENALINE</u>						
N020800 003	>A> 5665071	May 27, 2013	DP			
<u>EPINEPHRINE - ADRENALINE</u>						
N020800 004	>A> 5665071	May 27, 2013	DP			
<u>ESTRADIOL ACETATE - FEMTRACE</u>						
N021633 001	>A> 7572779	Mar 02, 2024	U-904			
<u>ESTRADIOL ACETATE - FEMTRACE</u>						
N021633 002	>A> 7572779	Mar 02, 2024	U-904			
<u>ESTRADIOL ACETATE - FEMTRACE</u>						
N021633 003	>A> 7572779	Mar 02, 2024	U-904			
<u>ETHINYL ESTRADIOL; LEVONORGESTREL - SEASONIQUE</u>						
N021840 001	7615545	Jun 15, 2023	U-1			
<u>EZETIMIBE - ZETIA</u>						
N021445 001	7612058	Jan 25, 2022	U-1027			
	7612058*PED	Jul 25, 2022				

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<u>FENOFIBRATE - FENOGLIDE</u>						
N022118 001	7658944	Dec 09, 2024	DP			
<u>FENOFIBRATE - FENOGLIDE</u>						
N022118 002	7658944	Dec 09, 2024	DP			
<u>FEXOFENADINE HYDROCHLORIDE - ALLEGRA</u>						
N020872 001	>A> 7662835	May 18, 2014	U-139			
	>A> 7662835*PED	Nov 18, 2014				
	>A> 7666881	May 18, 2014	U-139			
	>A> 7666881*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE - ALLEGRA</u>						
N020872 002	>A> 7662835	May 18, 2014	U-139			
	>A> 7662835*PED	Nov 18, 2014				
	>A> 7666881	May 18, 2014	U-139			
	>A> 7666881*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE - ALLEGRA</u>						
N020872 004	>A> 7662835	May 18, 2014	U-139			
	>A> 7662835*PED	Nov 18, 2014				
	>A> 7666881	May 18, 2014	U-139			
	>A> 7666881*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE - ALLEGRA</u>						
N021909 001	>A> 7662835	May 18, 2014	U-139			
	>A> 7662835*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - ALLEGRA D 24 HOUR</u>						
N021704 001	>A> 7662835	May 18, 2014	U-139			
	>A> 7662835*PED	Nov 18, 2014				
<u>FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE - ALLEGRA-D 12 HOUR</u>						
N020786 001	>A> 7662835	May 18, 2014	U-139			
	>A> 7662835*PED	Nov 18, 2014				
	>A> 7666881	May 18, 2014	U-139			
	>A> 7666881*PED	Nov 18, 2014				
<u>GADOBENATE DIMEGLUMINE - MULTIANCE</u>						
N021357 001					>A> NPP	Mar 17, 2013
<u>GADOBENATE DIMEGLUMINE - MULTIANCE</u>						
N021357 002					>A> NPP	Mar 17, 2013
<u>GADOBENATE DIMEGLUMINE - MULTIANCE</u>						
N021357 003					>A> NPP	Mar 17, 2013
<u>GADOBENATE DIMEGLUMINE - MULTIANCE</u>						
N021357 004					>A> NPP	Mar 17, 2013
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u>						
N020387 001	5608075****	Mar 04, 2014		Y		
	5608075*PED	Sep 04, 2014				
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u>						
N020387 002	5608075****	Mar 04, 2014		Y		
	5608075*PED	Sep 04, 2014				

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<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE</u>						
A077157 001					>A> PC	Oct 03, 2010
<u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - LOSARTAN POTASSIUM AND HYDROCHLOROTHIAZIDE</u>						
A077157 003					>A> PC	Oct 03, 2010
<u>HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL - BENICAR HCT</u>						
N021532 002	6878703	Nov 19, 2021	U-3	Y		
<u>HYDROMORPHONE HYDROCHLORIDE - EXALGO</u>						
N021217 001					>A> NDF	Mar 01, 2013
<u>HYDROMORPHONE HYDROCHLORIDE - EXALGO</u>						
N021217 002					>A> NDF	Mar 01, 2013
<u>HYDROMORPHONE HYDROCHLORIDE - EXALGO</u>						
N021217 003					>A> NDF	Mar 01, 2013
<u>IMIQUIMOD - IMIQUIMOD</u>						
A078548 001					PC	Aug 24, 2010
<u>IMIQUIMOD - ZYCLARA</u>						
N022483 001					>A> NP	Mar 25, 2013
<u>INSULIN GLULISINE RECOMBINANT - APIDRA SOLOSTAR</u>						
N021629 003	6221633	Jun 18, 2018	DS DP U-471			
	6960561	Jan 25, 2023	DP U-471			
	7452860	Mar 22, 2022	DP			
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N022115 001					I-622 NDF PED	Jan 29, 2013 May 29, 2012 Nov 29, 2012
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N022115 002					I-622 NDF PED	Jan 29, 2013 May 29, 2012 Nov 29, 2012
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N022115 003					I-622 NDF PED	Jan 29, 2013 May 29, 2012 Nov 29, 2012
<u>LAMOTRIGINE - LAMICTAL XR</u>						
N022115 004					I-622 NDF PED	Jan 29, 2013 May 29, 2012 Nov 29, 2012
<u>LAPATINIB DITOSYLATE - TYKERB</u>						
N022059 001	>A> 6713485	Sep 29, 2020	DS DP U-800		I-620	Jan 29, 2013
<u>LEVETIRACETAM - KEPPRA</u>						
N021872 001					I-563 PED	Mar 19, 2010 Sep 19, 2010
<u>LIRAGLUTIDE RECOMBINANT - VICTOZA</u>						
N022341 001	6268343	Aug 22, 2017	DS DP U-968		NCE	Jan 25, 2015
	6458924	Aug 22, 2017	DS DP U-968			
	7235627	Aug 22, 2017	DS DP			

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LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 001	7655630	Feb 24, 2023	DS		>A> M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP U-727			
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	>A> 7674774	Mar 18, 2023	DP U-842			
	>A> 7678770	Mar 25, 2023	U-842			
	>A> 7678771	Mar 25, 2023	DP U-842			
	>A> 7687466	Feb 24, 2023	DP			
	>A> 7687467	Apr 08, 2023	DP U-842			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 002	7655630	Feb 24, 2023	DS		>A> M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP U-727			
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	>A> 7674774	Mar 18, 2023	DP U-842			
	>A> 7678770	Mar 25, 2023	U-842			
	>A> 7678771	Mar 25, 2023	DP U-842			
	>A> 7687466	Feb 24, 2023	DP			
	>A> 7687467	Apr 08, 2023	DP U-842			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 003	7655630	Feb 24, 2023	DS		>A> M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP U-727			
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	>A> 7674774	Mar 18, 2023	DP U-842			
	>A> 7678770	Mar 25, 2023	U-842			
	>A> 7678771	Mar 25, 2023	DP U-842			
	>A> 7687466	Feb 24, 2023	DP			
	>A> 7687467	Apr 08, 2023	DP U-842			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 004	7655630	Feb 24, 2023	DS		>A> M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP U-727			
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	>A> 7678770	Mar 25, 2023	U-842			
	>A> 7687466	Feb 24, 2023	DP			
LISDEXAMFETAMINE DIMESYLATE - VYVANSE						
N021977 005	7655630	Feb 24, 2023	DS		>A> M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP U-727			
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	>A> 7674774	Mar 18, 2023	DP U-842			
	>A> 7678770	Mar 25, 2023	U-842			
	>A> 7678771	Mar 25, 2023	DP U-842			
	>A> 7687466	Feb 24, 2023	DP			
	>A> 7687467	Apr 08, 2023	DP U-842			

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<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 006	7655630	Feb 24, 2023	DS		>A> M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP U-727			
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	>A> 7674774	Mar 18, 2023	DP U-842			
	>A> 7678770	Mar 25, 2023	U-842			
	>A> 7678771	Mar 25, 2023	DP U-842			
	>A> 7687466	Feb 24, 2023	DP			
	>A> 7687467	Apr 08, 2023	DP U-842			
<u>LOSARTAN POTASSIUM - COZAAR</u>						
N020386 001	5608075****	Mar 04, 2014		Y		
	5608075*PED	Sep 04, 2014				
<u>LOSARTAN POTASSIUM - COZAAR</u>						
N020386 002	5608075****	Mar 04, 2014		Y		
	5608075*PED	Sep 04, 2014				
<u>LOSARTAN POTASSIUM - COZAAR</u>						
N020386 003	5608075****	Mar 04, 2014		Y		
	5608075*PED	Sep 04, 2014				
<u>LOSARTAN POTASSIUM - LOSARTAN POTASSIUM</u>						
A076958 001					>A> PC	Oct 03, 2010
<u>LOSARTAN POTASSIUM - LOSARTAN POTASSIUM</u>						
A076958 002					>A> PC	Oct 06, 2010
<u>LOSARTAN POTASSIUM - LOSARTAN POTASSIUM</u>						
A076958 003					>A> PC	Oct 03, 2010
<u>MESALAMINE - SFROWASA</u>						
N019618 002	7645801	Jul 24, 2027	DS DP			
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>						
N022044 001	>A> 6890898	Feb 02, 2019	U-803			
	>A> 6890898	Feb 02, 2019	U-1038			
	>A> 6890898	Feb 02, 2019	U-1036			
	>A> 7078381	Feb 02, 2019	U-803			
	>A> 7078381	Feb 02, 2019	U-1038			
	>A> 7078381	Feb 02, 2019	U-1036			
	>A> 7125873	Jul 26, 2022	DP U-803			
	>A> 7125873	Jul 26, 2022	DP U-1038			
	>A> 7125873	Jul 26, 2022	DP U-1036			
<u>METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE - JANUMET</u>						
N022044 002	>A> 6890898	Feb 02, 2019	U-803			
	>A> 6890898	Feb 02, 2019	U-1038			
	>A> 6890898	Feb 02, 2019	U-1036			
	>A> 7078381	Feb 02, 2019	U-803			
	>A> 7078381	Feb 02, 2019	U-1038			
	>A> 7078381	Feb 02, 2019	U-1036			
	>A> 7125873	Jul 26, 2022	DP U-803			
	>A> 7125873	Jul 26, 2022	DP U-1038			
	>A> 7125873	Jul 26, 2022	DP U-1036			

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<u>METHYLPHENIDATE HYDROCHLORIDE - METHYLIN</u>						
N021419 001	>A> 7691880	Oct 07, 2024	DP			
<u>METHYLPHENIDATE HYDROCHLORIDE - METHYLIN</u>						
N021419 002	>A> 7691880	Oct 07, 2024	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 001	>A> 7682633	Jun 19, 2027	U-443			
	>A> 7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 002	>A> 7682633	Jun 19, 2027	U-443			
	>A> 7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 003	>A> 7682633	Jun 19, 2027	U-443			
	>A> 7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 004	>A> 7682633	Jun 19, 2027	U-443			
	>A> 7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 005	>A> 7682633	Jun 19, 2027	U-443			
	>A> 7682634	Jun 19, 2027	DP			
<u>MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE - EMBEDA</u>						
N022321 006	>A> 7682633	Jun 19, 2027	U-443			
	>A> 7682634	Jun 19, 2027	DP			
<u>MOXIFLOXACIN HYDROCHLORIDE - VIGAMOX</u>						
N021598 001	>A> 7671070	Sep 29, 2019	U-709			
	>A> 7671070*PED	Mar 29, 2020				
<u>NICARDIPINE HYDROCHLORIDE - CARDENE IN 0.83% SODIUM CHLORIDE IN PLASTIC CONTAINER</u>						
N019734 004	7659291	Apr 18, 2027	U-1029			
<u>NICARDIPINE HYDROCHLORIDE - CARDENE IN 0.86% SODIUM CHLORIDE IN PLASTIC CONTAINER</u>						
N019734 003	7659291	Apr 18, 2027	U-1029			
<u>NICARDIPINE HYDROCHLORIDE - CARDENE IN 4.8% DEXTROSE IN PLASTIC CONTAINER</u>						
N019734 002	7659291	Apr 18, 2027	U-1029			
<u>NICARDIPINE HYDROCHLORIDE - CARDENE IN 5.0% DEXTROSE IN PLASTIC CONTAINER</u>						
N019734 005	7659291	Apr 18, 2027	U-1029			
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
N021286 001					NPP PED	Feb 04, 2013 Aug 04, 2010
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
N021286 003					NPP PED	Feb 04, 2013 Aug 04, 2010
<u>OLMESARTAN MEDOXOMIL - BENICAR</u>						
N021286 004					NPP PED	Feb 04, 2013 Aug 04, 2010
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021087 001					M-90	Feb 22, 2013

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<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021087	002				M-90	Feb 22, 2013
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021087	003				M-90	Feb 22, 2010
<u>OSELTAMIVIR PHOSPHATE - TAMIFLU</u>						
N021246	001				M-90	Feb 22, 2013
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	001	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	002	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	003	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	004	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	005	>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	006	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	007	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYCODONE HYDROCHLORIDE - OXYCONTIN</u>						
N020553	008	>A> 7674799	Mar 30, 2025	DS		
		>A> 7674800	Mar 30, 2025	DS		
		>A> 7683072	Mar 30, 2025	DS		
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610	001	>A> 7276250	Feb 04, 2023	DP U-826		
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610	002	>A> 7276250	Feb 04, 2023	DP U-826		
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610	003	>A> 7276250	Feb 04, 2023	DP U-826		
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610	004	>A> 7276250	Feb 04, 2023	DP U-826		

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<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610 005	>A> 7276250	Feb 04, 2023	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610 006	>A> 7276250	Feb 04, 2023	DP U-826			
<u>OXYMORPHONE HYDROCHLORIDE - OPANA ER</u>						
N021610 007	>A> 7276250	Feb 04, 2023	DP U-826			
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP</u>						
N022210 001	7658918	Feb 20, 2028	DP			
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP</u>						
N022210 002	7658918	Feb 20, 2028	DP			
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP</u>						
N022210 003	7658918	Feb 20, 2028	DP			
<u>PANCRELIPASE (AMYLASE;LIPASE;PROTEASE) - ZENPEP</u>						
N022210 004	7658918	Feb 20, 2028	DP			
<u>PANTOPRAZOLE SODIUM - PROTONIX</u>						
N022020 001	7544370	Jun 07, 2026	DP			
	7544370*PED	Dec 07, 2026				
<u>PENCICLOVIR SODIUM - DENAVIR</u>						
N020629 001	>A> 5866581	Oct 04, 2014	U-501			
	>A> 6124304	Oct 04, 2014	U-501			
<u>POLIDOCANOL - ASCLERA</u>						
N021201 001					>A> NCE	Mar 30, 2015
<u>POLIDOCANOL - ASCLERA</u>						
N021201 002					>A> NCE	Mar 30, 2015
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 001	4886812	Oct 08, 2010	DS DP		>A> I-623	Mar 19, 2013
	>A> 7695734	Apr 26, 2028	DP		>A> NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 002	4886812	Oct 08, 2010	DS DP		>A> I-623	Mar 19, 2013
	>A> 7695734	Apr 26, 2028	DP		>A> NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 003	4886812	Oct 08, 2010	DS DP		>A> I-623	Mar 19, 2013
	>A> 7695734	Apr 26, 2028	DP		>A> NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 004	4886812	Oct 08, 2010	DS DP		>A> I-623	Mar 19, 2013
	>A> 7695734	Apr 26, 2028	DP		>A> NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - MIRAPEX ER</u>						
N022421 005	4886812	Oct 08, 2010	DS DP		>A> I-623	Mar 19, 2013
	>A> 7695734	Apr 26, 2028	DP		>A> NDF	Feb 19, 2013
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724 001					PC	Jul 03, 2010
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724 002					PC	Jul 03, 2010

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<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724 003					PC	Jul 03, 2010
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724 004					PC	Jul 03, 2010
<u>PRAMIPEXOLE DIHYDROCHLORIDE - PRAMIPEXOLE DIHYDROCHLORIDE</u>						
A077724 005					PC	Jul 03, 2010
<u>PREGABALIN - LYRICA</u>						
N022488 001	5563175	Oct 08, 2013	U-661		I-535	Jun 21, 2010
	6001876	Dec 30, 2018	U-819			
	6001876	Dec 30, 2018	U-55			
	6197819	Dec 30, 2018	DS DP			
<u>REGADENOSON - LEXISCAN</u>						
N022161 001	7655636	Jun 22, 2019	U-869			
	7655637	Jun 22, 2019	DS DP U-869			
<u>RIFAXIMIN - XIFAXAN</u>						
N021361 002	>A> 7045620	Jun 19, 2024	DS		>A> NP	Mar 24, 2013
<u>RITONAVIR - RITONAVIR</u>						
N022417 001	5541206	Jul 30, 2013	DS DP U-688			
	5541206*PED	Jan 30, 2014				
	5635523	Jun 03, 2014	U-688			
	5635523*PED	Dec 03, 2014				
	5648497	Jul 15, 2014	DS			
	5648497*PED	Jan 15, 2015				
	5674882	Oct 07, 2014	U-688			
	5674882*PED	Apr 07, 2015				
	6037157	Jun 26, 2016	U-688			
	6037157*PED	Dec 26, 2016				
	6703403	Jun 26, 2016	U-688			
	6703403*PED	Dec 26, 2016				
	7148359	Jul 19, 2019	DP			
	7148359*PED	Jan 19, 2020				
	7364752	Nov 10, 2020	DP U-688			
	7364752*PED	May 10, 2021				
<u>ROMIDEPSIN - ISTODAX</u>						
N022393 001					ODE	Nov 05, 2016
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>						
N021366 002	7030152	Apr 02, 2018	U-1032		I-621	Feb 08, 2013
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>						
N021366 003	7030152	Apr 02, 2018	U-1032		I-621	Feb 08, 2013
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>						
N021366 004	7030152	Apr 02, 2018	U-1032		I-621	Feb 08, 2013
<u>ROSUVASTATIN CALCIUM - CRESTOR</u>						
N021366 005	7030152	Apr 02, 2018	U-1032		I-621	Feb 08, 2013

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<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N021995 001	>A> 6890898	Feb 02, 2019	U-775			
	>A> 6890898	Feb 02, 2019	U-1039			
	>A> 6890898	Feb 02, 2019	U-1036			
	>A> 7078381	Feb 02, 2019	U-775			
	>A> 7078381	Feb 02, 2019	U-1038			
	>A> 7078381	Feb 02, 2019	U-1037			
	>A> 7078381	Feb 02, 2019	U-1036			
	>A> 7125873	Jul 26, 2022	U-775			
	>A> 7125873	Jul 26, 2022	U-1038			
	>A> 7125873	Jul 26, 2022	U-1037			
	>A> 7125873	Jul 26, 2022	U-1036			
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N021995 002	>A> 6890898	Feb 02, 2019	U-775			
	>A> 6890898	Feb 02, 2019	U-1039			
	>A> 6890898	Feb 02, 2019	U-1036			
	>A> 7078381	Feb 02, 2019	U-775			
	>A> 7078381	Feb 02, 2019	U-1038			
	>A> 7078381	Feb 02, 2019	U-1037			
	>A> 7078381	Feb 02, 2019	U-1036			
	>A> 7125873	Jul 26, 2022	U-775			
	>A> 7125873	Jul 26, 2022	U-1038			
	>A> 7125873	Jul 26, 2022	U-1037			
	>A> 7125873	Jul 26, 2022	U-1036			
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N021995 003	>A> 6890898	Feb 02, 2019	U-775			
	>A> 6890898	Feb 02, 2019	U-1039			
	>A> 6890898	Feb 02, 2019	U-1036			
	>A> 7078381	Feb 02, 2019	U-775			
	>A> 7078381	Feb 02, 2019	U-1038			
	>A> 7078381	Feb 02, 2019	U-1037			
	>A> 7078381	Feb 02, 2019	U-1036			
	>A> 7125873	Jul 26, 2022	U-775			
	>A> 7125873	Jul 26, 2022	U-1038			
	>A> 7125873	Jul 26, 2022	U-1037			
	>A> 7125873	Jul 26, 2022	U-1036			
<u>SODIUM OXYBATE - XYREM</u>						
N021196 001	7668730	Mar 07, 2024	U-1028			
<u>SODIUM PHOSPHATE, DIBASIC ANHYDROUS; SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE - OSMOPREP</u>						
N021892 001	>A> 7687075	Jun 22, 2028	DS DP			
<u>SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO</u>						
N021148 008	>A> 5849700	Dec 15, 2015	U-1041		>A> I-572	Oct 31, 2011
	>A> 5849704	Dec 15, 2015	DP U-1041		>A> I-551	Sep 20, 2010
					>A> I-536	May 31, 2010
					>A> ODE	May 31, 2014
<u>SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO</u>						
N021148 009	>A> 5849700	Dec 15, 2015	U-1041		>A> I-572	Oct 31, 2011
	>A> 5849704	Dec 15, 2015	DP U-1041		>A> I-551	Sep 20, 2010
					>A> I-536	May 31, 2010
					>A> ODE	May 31, 2010

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<u>SOMATROPIN RECOMBINANT - NORDITROPIN FLEXPRO</u>						
N021148 010	>A> 5849700	Dec 15, 2015	U-1041		>A> I-572	Oct 31, 2011
	>A> 5849704	Dec 15, 2015	DP U-1041		>A> I-551	Sep 20, 2010
					>A> I-536	May 31, 2010
					>A> ODE	May 31, 2014
<u>TENOFOVIR DISOPROXIL FUMARATE - VIREAD</u>						
N021356 001					>A> NPP	Mar 24, 2013
<u>TERBINAFINE - LAMISIL AT</u>						
N021958 001	>A> 5681849	Oct 28, 2014	DP			
	>A> 5681849*PED	Apr 28, 2015				
	>A> 5856355	May 18, 2012	DP U-540			
	>A> 5856355	May 18, 2012	DP U-504			
	>A> 5856355*PED	Nov 18, 2012				
<u>TIOTROPIUM BROMIDE MONOHYDRATE - SPIRIVA</u>						
N021395 001	7642268	Sep 24, 2021	DS DP			
<u>TOLTERODINE TARTRATE - DETROL</u>						
N020771 001	5559269	Nov 05, 2013	U-318	Y		
	5559269*PED	May 05, 2014				
<u>TOLTERODINE TARTRATE - DETROL</u>						
N020771 002	5559269	Nov 05, 2013	U-318	Y		
	5559269*PED	May 05, 2014				
<u>TRAZODONE HYDROCHLORIDE - OLEPTRO</u>						
N022411 001	6607748	Jun 29, 2020	DP		NDF	Feb 02, 2013
<u>TRAZODONE HYDROCHLORIDE - OLEPTRO</u>						
N022411 002	6607748	Jun 29, 2020	DP		NDF	Feb 02, 2013
<u>TRIPTORELIN PAMOATE - TRELSTAR</u>						
N022437 001	>A> 5776885	Jul 07, 2015	DP		>A> NP	Mar 10, 2013
<u>VARDENAFIL HYDROCHLORIDE - LEVITRA</u>						
N021400 001	>A> 7696206	Oct 31, 2018	DS DP U-533			
<u>VARDENAFIL HYDROCHLORIDE - LEVITRA</u>						
N021400 002	>A> 7696206	Oct 31, 2018	DS DP U-533			
<u>VARDENAFIL HYDROCHLORIDE - LEVITRA</u>						
N021400 003	>A> 7696206	Oct 31, 2018	DS DP U-533			
<u>VARDENAFIL HYDROCHLORIDE - LEVITRA</u>						
N021400 004	>A> 7696206	Oct 31, 2018	DS DP U-533			
<u>VARENICLINE TARTRATE - CHANTIX</u>						
N021928 001	>A> 7265119	Aug 03, 2022	DS DP U-56			
<u>VARENICLINE TARTRATE - CHANTIX</u>						
N021928 002	>A> 7265119	Aug 03, 2022	DS DP U-56			
<u>VELAGLUCERASE ALFA - VPRIV</u>						
N022575 001					NCE	Feb 26, 2015
<u>VELAGLUCERASE ALFA - VPRIV</u>						
N022575 002					NCE	Feb 26, 2015

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<u>VORINOSTAT - ZOLINZA</u>						
N021991 001	7652069	Mar 04, 2023	DS			

Footnote:

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

PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 29th 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>