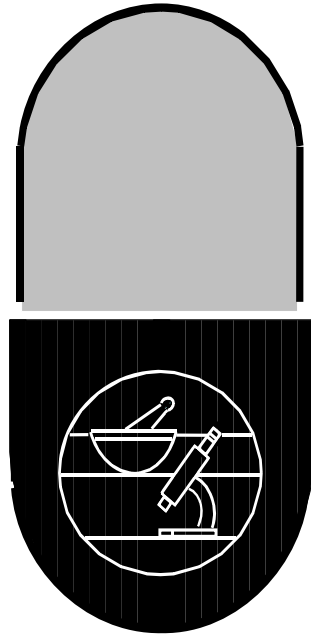


**CUMULATIVE
SUPPLEMENT 03
March 2007**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

27th EDITION

Department of Health and Human Services

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

2007

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

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

27th EDITION

Cumulative Supplement 03

March 2007

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

27th EDITION

**CUMULATIVE SUPPLEMENT 03
March 2007**

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, 27th 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 26th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 27th Edition. The current edition

Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

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

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

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

1.2 CUMULATIVE SUPPLEMENT CONTENT

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

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

Currently, the monthly PDF CS includes:

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

- New Drug Application (NDA) approvals (20,000 and 50,000 series) appear in the CS month they were approved.
- Patent information, also updated daily in the EOB, is current to the date of publication.
- Exclusivity information is updated monthly and current to the date of publication.

Every effort is made to ensure the Cumulative Supplement is current and accurate. Applicant holders are requested to inform the FDA Orange Book Staff (OBS) of any changes or corrections. The OBS can be contacted by email at drugproducts@cderr.fda.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>
BIONICHE PHARMA (BIONICHE PHARMA)	BIONICHE PHARMA USA LLC (BIONICHE PHARMA)
BIONICHE PHARMA (CANADA) LTD (BIONICHE (CANADA))	BIONICHE PHARMA USA LLC (BIONICHE PHARMA)
BIONICHE PHARMA USA INC (BIONICHE PHARMA USA)	BIONICHE PHARMA USA LLC (BIONICHE PHARMA)

1.4 AVAILABILITY OF THE EDITION

Since 1997, the Electronic Orange Book Query (EOBQ) <http://www.fda.gov/cder/ob/default.htm>, 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 Annual Edition. 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://www.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/cder/rxotcdpl/pdplarchive.htm>

There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at <http://www.fda.gov/cder/orange/obreadme.htm>. The drug product text files are provided in eobzip.exe and 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 2004) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

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

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt,

ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

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

<u>CATEGORIES COUNTED</u>	<u>DEC 2006</u>	<u>MAR 2007</u>	<u>JUN 2007</u>	<u>SEPT 2007</u>
DRUG PRODUCTS LISTED	11896	12063		
SINGLE SOURCE	2471	2471		
	(20.8%)	(20.5%)		
MULTISOURCE	9336	9503		
	(78.5%)	(78.8%)		
THERAPEUTICALLY EQUIVALENT	9139	9320		
	(76.8%)	(77.3%)		
NOT THERAPEUTICALLY EQUIVALENT	197	183		
	(1.7%)	(1.5%)		
EXCEPTIONS ¹	89	89		
	(0.7%)	(0.7%)		
NEW MOLECULAR ENTITIES APPROVED	10	4		
NUMBER OF APPLICANTS	666	675		

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 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 - 27TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2007

1-1

ABARELIX

INJECTABLE; INTRAMUSCULAR

PLENAXIS

@ SPECIALITY EUROPEAN 100MG/VIAL

N21320 001 Nov 25, 2003 Feb CAHN

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

>A> AA BOCA PHARMA 356.4MG;30MG;16MG N40688 001 Apr 03, 2007 Mar NEWA

>D> + MIKART 356.4MG;30MG;16MG N40109 001 Aug 26, 1997 Mar CTEC

>A> AA + 356.4MG;30MG;16MG N40109 001 Aug 26, 1997 Mar CTEC

TABLET; ORAL

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

>A> AA BOCA PHARMA 712.8MG;60MG;32MG N40701 001 Apr 03, 2007 Mar NEWA

AA + MIKART 712.8MG;60MG;32MG N40316 001 Apr 28, 1999 Feb CTEC

AA WEST WARD 712.8MG;60MG;32MG N40637 001 Sep 22, 2006 Feb CTEC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA INTERPHARM 500MG;10MG

N40813 001 Feb 23, 2007 Feb NEWA

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

>A> AB WOCKHARDT 325MG;50MG

N77677 001 Mar 16, 2007 Mar NEWA

>A> AB 650MG;100MG

N77677 002 Mar 16, 2007 Mar NEWA

ALBUTEROL

AEROSOL, METERED; INHALATION

ALBUTEROL

>D> AB ARMSTRONG PHARMS 0.09MG/INH

N72273 001 Aug 14, 1996 Mar CRLD

>A> + 0.09MG/INH

N72273 001 Aug 14, 1996 Mar CRLD

>D> AB IVAX PHARMS 0.09MG/INH

N73272 001 Dec 28, 1995 Mar DISC

>A> @ 0.09MG/INH

N73272 001 Dec 28, 1995 Mar DISC

>D> VENTOLIN

>D> AB + GLAXOSMITHKLINE 0.09MG/INH

N18473 001 Mar DISC

>A> @ 0.09MG/INH

N18473 001 Mar DISC

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

AN APOTEX INC EQ 0.083% BASE

N75717 001 Feb 02, 2007 Jan NEWA

TABLET, EXTENDED RELEASE; ORAL

ALBUTEROL SULFATE

AB MYLAN EQ 4MG BASE

N78092 002 Jan 29, 2007 Jan NEWA

AB EQ 8MG BASE

N78092 001 Jan 29, 2007 Jan NEWA

VOSPIRE ER

AB DAVA PHARMS INC EQ 4MG BASE

N76130 002 Sep 26, 2002 Jan CTEC

AB + EQ 8MG BASE

N76130 003 Sep 26, 2002 Jan CTEC

>A> ALISKIREN HEMIFUMARATE

>A> TABLET; ORAL

>A> TEKTURNA

>A> NOVARTIS EQ 150MG BASE N21985 001 Mar 05, 2007 Mar NEWA

>A> + EQ 300MG BASE N21985 002 Mar 05, 2007 Mar NEWA

ALPRAZOLAM

TABLET; ORAL

ALPRAZOLAM

AB APOTEX INC 0.25MG N77741 001 Jan 19, 2007 Jan NEWA

AB 0.5MG N77741 002 Jan 19, 2007 Jan NEWA

AB 1MG N77741 003 Jan 19, 2007 Jan NEWA

AB 2MG N77741 004 Jan 19, 2007 Jan NEWA

>D> @ DAVA INTL INC 0.25MG N74174 001 Oct 19, 1993 Mar CMFD

>A> AB 0.25MG N74174 001 Oct 19, 1993 Mar CMFD

@ 0.25MG N74174 001 Oct 19, 1993 Feb CAHN

>D> @ 0.5MG N74174 002 Oct 19, 1993 Mar CMFD

>A> AB 0.5MG N74174 002 Oct 19, 1993 Mar CMFD

@ 0.5MG N74174 002 Oct 19, 1993 Feb CAHN

>D> @ 1MG N74174 003 Oct 19, 1993 Mar CMFD

>A> AB 1MG N74174 003 Oct 19, 1993 Mar CMFD

@ 1MG N74174 003 Oct 19, 1993 Feb CAHN

>D> @ 2MG N74174 004 Oct 19, 1993 Mar CMFD

>A> AB 2MG N74174 004 Oct 19, 1993 Mar CMFD

@ 2MG N74174 004 Oct 19, 1993 Feb CAHN

TABLET, EXTENDED RELEASE; ORAL

ALPRAZOLAM

AB ACTAVIS ELIZABETH 0.5MG N78056 001 Feb 13, 2007 Jan NEWA

AB 1MG N78056 002 Feb 13, 2007 Jan NEWA

AB 2MG N78056 003 Feb 13, 2007 Jan NEWA

AB 3MG N78056 004 Feb 13, 2007 Jan NEWA

AB COREPHARMA 0.5MG N77996 001 Jan 31, 2007 Jan NEWA

AB 1MG N77996 002 Jan 31, 2007 Jan NEWA

AB 2MG N77996 003 Jan 31, 2007 Jan NEWA

AB 3MG N77996 004 Jan 31, 2007 Jan NEWA

AB TEVA PHARMS 0.5MG N77979 001 Feb 28, 2007 Feb NEWA

AB 1MG N77979 002 Feb 28, 2007 Feb NEWA

AB 2MG N77979 003 Feb 28, 2007 Feb NEWA

AB 3MG N77979 004 Feb 28, 2007 Feb NEWA

TABLET, ORALLY DISINTEGRATING; ORAL

NIRAVAM

+ SCHWARZ PHARMA 1MG N21726 003 Jan 19, 2005 Jan CRLD

2MG N21726 004 Jan 19, 2005 Jan CRLD

AMINO ACIDS

INJECTABLE; INJECTION

NOVAMINE 11.4%

+ HOSPIRA 11.4% (11.4GM/100ML) N17957 003 Aug 09, 1982 Jan CRLD

NOVAMINE 15%

+ HOSPIRA 15% (15GM/100ML) N17957 004 Nov 28, 1986 Jan CRLD

AMOXICILLIN

CAPSULE; ORAL

AMOXICILLIN

AB HIKMA PHARMS 250MG N65291 001 Feb 05, 2007 Jan NEWA

CAPSULE; ORAL

AMOXICILLIN

AB	HIKMA PHARMS	500MG	N65291 002	Feb 05, 2007	Jan	NEWA
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FOR SUSPENSION; ORAL

AMOXICILLIN

>A>	AB	SANDOZ	125MG/5ML	N65387 001	Mar 26, 2007	Mar	NEWA
>A>	AB		200MG/5ML	N65378 001	Mar 26, 2007	Mar	NEWA
>A>	AB		250MG/5ML	N65387 002	Mar 26, 2007	Mar	NEWA
>A>	AB		400MG/5ML	N65378 002	Mar 26, 2007	Mar	NEWA

TABLET, FOR SUSPENSION; ORAL

AMOXICILLIN

AB	AUROBINDO PHARMA	200MG	N65324 001	Jan 17, 2007	Jan	NEWA
AB		400MG	N65324 002	Jan 17, 2007	Jan	NEWA

DISPERMOX

AB	RANBAXY	200MG	N65080 002	Aug 11, 2003	Jan	CTEC
AB	+	400MG	N65080 001	Aug 11, 2003	Jan	CTEC

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

AB	RANBAXY	600MG/5ML;EQ 42.9MG BASE/5ML	N65207 002	Jan 30, 2007	Jan	NEWA		
>D>	AB	+	AUGMENTIN ES-600					
		GLAXOSMITHKLINE	600MG/5ML;EQ 42.9MG BASE/5ML	N50755 001	Jun 22, 2001	Mar	CAHN	
>A>	AB	+	SMITHKLINE BEECHAM	600MG/5ML;EQ 42.9MG BASE/5ML	N50755 001	Jun 22, 2001	Mar	CAHN

ARIPIPIRAZOLE

TABLET; ORAL

ABILIFY

	OTSUKA	15MG	N21436 002	Nov 15, 2002	Feb	CRLD
		30MG	N21436 004	Nov 15, 2002	Feb	CRLD

TABLET, ORALLY DISINTEGRATING; ORAL

ABILIFY

+	OTSUKA	10MG	N21729 002	Jun 07, 2006	Feb	CRLD
		30MG	N21729 005	Jun 07, 2006	Feb	CRLD

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

NORGESIC

AB	GRACEWAY	385MG;30MG;25MG	N13416 003	Oct 27, 1982	Jan	CAHN
AB	+	NORGESIC FORTE				
	GRACEWAY	770MG;60MG;50MG	N13416 004	Oct 27, 1982	Jan	CAHN

AZATHIOPRINE

TABLET; ORAL

AZATHIOPRINE

>A>	AB	ZYDUS PHARMS USA	50MG	N77621 001	Mar 15, 2007	Mar	NEWA
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AZITHROMYCIN

INJECTABLE; INJECTION

AZITHROMYCIN

AP	PLIVA HRVATSKA DOO	EQ 500MG BASE/VIAL	N65265 001	Jan 18, 2007	Jan	NEWA
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BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

CORTISPORIN

@	MONARCH PHARMS	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N50416 002		Feb	DISC
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NEOMYCIN AND POLYMYXIN B SULFATES, BACITRACIN ZINC AND HYDROCORTISONE

+	BAUSCH AND LOMB	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N64068 001	Oct 30, 1995	Feb	CTEC
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BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

NEOSPORIN

@	MONARCH PHARMS	400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N50417 001		Feb	DISC
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BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

POLYSPORIN

@	MONARCH PHARMS	500 UNITS/GM;10,000 UNITS/GM	N61229 001		Feb	DISC
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BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION

QVAR 40

>D>	+	3M	0.04MG/INH	N20911 002	Sep 15, 2000	Mar	CAHN
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>A>	+	IVAX RES	0.04MG/INH	N20911 002	Sep 15, 2000	Mar	CAHN
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QVAR 80

>D>	+	3M	0.08MG/INH	N20911 001	Sep 15, 2000	Mar	CAHN
-----	---	----	------------	------------	--------------	-----	------

>A>	+	IVAX RES	0.08MG/INH	N20911 001	Sep 15, 2000	Mar	CAHN
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BENDROFLUMETHIAZIDE; NADOLOL

TABLET; ORAL

CORZIDE

>D>		KING PHARMS	5MG;40MG	N18647 001	May 25, 1983	Mar	CFTG
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>A>	AB		5MG;40MG	N18647 001	May 25, 1983	Mar	CFTG
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>D>	+		5MG;80MG	N18647 002	May 25, 1983	Mar	CFTG
-----	---	--	----------	------------	--------------	-----	------

>A>	AB	+	5MG;80MG	N18647 002	May 25, 1983	Mar	CFTG
-----	----	---	----------	------------	--------------	-----	------

>A>		NADOLOL AND BENDROFLUMETHIAZIDE					
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>A>	AB	IMPAX LABS	5MG;40MG	N77833 001	Mar 30, 2007	Mar	NEWA
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>A>	AB		5MG;80MG	N77833 002	Mar 30, 2007	Mar	NEWA
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BENZONATATE

CAPSULE; ORAL

BENZONATATE

>A>	AA	THE PHARMA NETWORK	100MG	N40627 001	Mar 30, 2007	Mar	NEWA
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BENZPHETAMINE HYDROCHLORIDE

TABLET; ORAL

BENZPHETAMINE HYDROCHLORIDE

>A>	AA	TEDOR PHARM	50MG	N40747 001	Mar 30, 2007	Mar	NEWA
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BUDESONIDE

POWDER, METERED; INHALATION

PULMICORT FLEXHALER

		ASTRAZENECA	0.08MG/INH	N21949 001	Jul 12, 2006	Feb	CTNA
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+			0.16MG/INH	N21949 002	Jul 12, 2006	Feb	CTNA
---	--	--	------------	------------	--------------	-----	------

BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE

SPRAY, METERED; INHALATION

SYMBICORT

+	ASTRAZENECA	0.08MG/INH;0.045MG/INH	N21929 001	Jul 21, 2006	Jan	CAIN
+		0.16MG/INH;0.045MG/INH	N21929 002	Jul 21, 2006	Jan	CAIN

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

BUPRENORPHINE HYDROCHLORIDE

>A>	AP	PHARMAFORCE	EQ 0.3MG BASE/ML	N78331 001	Mar 27, 2007	Mar	NEWA
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CABERGOLINE

TABLET; ORAL

CABERGOLINE

AB		IVAX PHARMS INC	0.5MG	N77750 001	Mar 07, 2007	Feb	NEWA
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CARBOPLATIN

INJECTABLE; IV (INFUSION)

CARBOPLATIN

>A>	AP	SICOR PHARMS	EQ 50MG/5ML (10MG/ML)	N77389 001	Mar 30, 2007	Mar	NEWA
>A>	AP		EQ 150MG/15ML (10MG/ML)	N77389 002	Mar 30, 2007	Mar	NEWA
>A>	AP		EQ 450MG/45ML (10MG/ML)	N77389 003	Mar 30, 2007	Mar	NEWA
	AP	WATSON LABS	EQ 50MG/5ML (10MG/ML)	N77861 001	Jan 18, 2007	Jan	NEWA
	AP		EQ 150MG/15ML (10MG/ML)	N77861 002	Jan 18, 2007	Jan	NEWA
	AP		EQ 450MG/45ML (10MG/ML)	N77861 003	Jan 18, 2007	Jan	NEWA
	AP		EQ 600MG/60ML (10MG/ML)	N77861 004	Jan 18, 2007	Jan	NEWA

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

AA		SUN PHARM INDS LTD	350MG	N40755 001	Feb 27, 2007	Feb	NEWA
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CEFACLOR

CAPSULE; ORAL

CEFACLOR

>A>	AB	HIKMA	EQ 250MG BASE	N65350 001	Apr 03, 2007	Mar	NEWA
>A>	AB		EQ 500MG BASE	N65350 002	Apr 03, 2007	Mar	NEWA

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

CEFADROXIL

AB		AUROBINDO PHARMA	500MG	N65352 001	Jan 25, 2007	Jan	NEWA
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CEFDINIR

CAPSULE; ORAL

CEFDINIR

>A>	AB	SANDOZ	300MG	N65330 001	Apr 06, 2007	Mar	NEWA
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FOR SUSPENSION; ORAL

CEFDINIR

>A>	AB	SANDOZ	125MG/5ML	N65337 001	Apr 06, 2007	Mar	NEWA
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>A>	AB		250MG/5ML	N65337 002	Apr 06, 2007	Mar	NEWA
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OMNICEF

>D>		+	ABBOTT	250MG/5ML	N50749 002	Jul 29, 2004	Mar	CFTG
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>A>	AB	+		250MG/5ML	N50749 002	Jul 29, 2004	Mar	CFTG
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CEFIXIME

SUSPENSION; ORAL

>A>		CEFIXIME							
>A>		LUPIN PHARMS	200MG/5ML	N65355	001	Apr 10, 2007	Mar	NEWA	

CEFPROZIL

FOR SUSPENSION; ORAL

CEFPROZIL

AB		AUROBINDO PHARMA	125MG/5ML	N65381	001	Jan 30, 2007	Jan	NEWA	
AB			250MG/5ML	N65381	002	Jan 30, 2007	Jan	NEWA	

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION

CEFIZOX

		@ ASTELLAS	EQ 1GM BASE/VIAL	N50560	002	Sep 15, 1983	Feb	DISC	
		+	EQ 1GM BASE/VIAL	N63294	002	Mar 31, 1994	Feb	CRLD	

CEFTRIAZONE SODIUM

INJECTABLE; IM-IV

CEFTRIAZONE

>A>	AP	CEPHAZONE PHARMA	EQ 250MG BASE/VIAL	N65294	001	Mar 26, 2007	Mar	NEWA	
>A>	AP		EQ 500MG BASE/VIAL	N65294	002	Mar 26, 2007	Mar	NEWA	
>A>	AP		EQ 1GM BASE/VIAL	N65294	003	Mar 26, 2007	Mar	NEWA	
>A>	AP		EQ 2GM BASE/VIAL	N65294	004	Mar 26, 2007	Mar	NEWA	
	AP	HANFORD GC	EQ 1GM BASE/VIAL	N65268	001	Feb 28, 2007	Feb	NEWA	
	AP		EQ 2GM BASE/VIAL	N65268	002	Feb 28, 2007	Feb	NEWA	
>A>	AP	SICOR PHARMS	EQ 250MG BASE/VIAL	N65227	001	Mar 15, 2007	Mar	NEWA	
>A>	AP		EQ 500MG BASE/VIAL	N65227	002	Mar 15, 2007	Mar	NEWA	
>A>	AP		EQ 1GM BASE/VIAL	N65227	003	Mar 15, 2007	Mar	NEWA	
>A>	AP		EQ 2GM BASE/VIAL	N65227	004	Mar 15, 2007	Mar	NEWA	

INJECTABLE; INJECTION

CEFTRIAZONE

AP		HANFORD GC	EQ 10GM BASE/VIAL	N65269	001	Feb 28, 2007	Feb	NEWA	
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CELECOXIB

CAPSULE; ORAL

CELEBREX

		GD SEARLE	50MG	N20998	004	Dec 15, 2006	Jan	NEWA	
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CHLORAMPHENICOL SODIUM SUCCINATE

INJECTABLE; INJECTION

CHLORAMPHENICOL SODIUM SUCCINATE

		+ ABRAXIS PHARM	EQ 1GM BASE/VIAL	N62365	001	Aug 25, 1982	Feb	CRLD	
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CHLOROMYCETIN

		@ PARKEDALE	EQ 1GM BASE/VIAL	N50155	001		Feb	DISC	
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CHLOROTHIAZIDE

SUSPENSION; ORAL

DIURIL

		+ SALIX PHARMS	250MG/5ML	N11870	001		Feb	CAHN	
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CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

>D> SUSPENSION, EXTENDED RELEASE; ORAL

>D> CODEPREX

>D> + UCB INC EQ 4MG MALEATE/5ML;EQ 20MG N21369 001 Jun 21, 2004 Mar DISC
BASE/5ML>A> @ EQ 4MG MALEATE/5ML;EQ 20MG N21369 001 Jun 21, 2004 Mar DISC
BASE/5MLCIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

CIPRO XR

>D> + BAYER PHARMS 212.6MG;EQ 287.5MG BASE N21473 001 Dec 13, 2002 Mar CFTG

>A> AB + 212.6MG;EQ 287.5MG BASE N21473 001 Dec 13, 2002 Mar CFTG

>D> + 425.2MG;EQ 574.9MG BASE N21473 002 Aug 28, 2003 Mar CFTG

>A> AB + 425.2MG;EQ 574.9MG BASE N21473 002 Aug 28, 2003 Mar CFTG

CIPROFLOXACIN EXTENDED RELEASE

>A> AB DR REDDYS LABS LTD 425.2MG;EQ 574.9MG BASE N77701 001 Mar 26, 2007 Mar NEWA

>A> AB MYLAN 212.6MG;EQ 287.5MG BASE N78183 001 Mar 22, 2007 Mar NEWA

>A> AB 425.2MG;EQ 574.9MG BASE N78183 002 Mar 22, 2007 Mar NEWA

CISPLATIN

INJECTABLE; INJECTION

CISPLATIN

>D> AP BEDFORD 10MG/VIAL N74713 001 Nov 14, 2000 Mar DISC

>A> @ 10MG/VIAL N74713 001 Nov 14, 2000 Mar DISC

>D> AP 50MG/VIAL N74713 002 Nov 14, 2000 Mar DISC

>A> @ 50MG/VIAL N74713 002 Nov 14, 2000 Mar DISC

PLATINOL

>D> AP + BRISTOL MYERS 10MG/VIAL N18057 001 Mar CTEC

>A> + 10MG/VIAL N18057 001 Mar CTEC

>D> AP + 50MG/VIAL N18057 002 Mar CTEC

>A> + 50MG/VIAL N18057 002 Mar CTEC

CITALOPRAM HYDROBROMIDE

CAPSULE; ORAL

CITALOPRAM HYDROBROMIDE

ALPHAPHARM

EQ 10MG BASE

N77668 001 Feb 28, 2007 Feb NEWA

EQ 20MG BASE

N77668 002 Feb 28, 2007 Feb NEWA

+

EQ 40MG BASE

N77668 003 Feb 28, 2007 Feb NEWA

TABLET; ORAL

CITALOPRAM HYDROBROMIDE

>A> AB TORRENT PHARMS EQ 10MG BASE N78216 001 Mar 27, 2007 Mar NEWA

>A> AB EQ 20MG BASE N78216 002 Mar 27, 2007 Mar NEWA

>A> AB EQ 40MG BASE N78216 003 Mar 27, 2007 Mar NEWA

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

>A> AP ABRAXIS PHARM EQ 150MG BASE/ML N65346 001 Mar 29, 2007 Mar NEWA

CLOBETASOL PROPIONATE

AEROSOL, FOAM; TOPICAL

OLUX E

+ CONNETICS

0.05%

N22013 001 Jan 12, 2007 Jan NEWA

SOLUTION; TOPICAL

CLOBETASOL PROPIONATE

AT	ALTANA	0.05%	N75391 001	Feb 08, 1999	Feb	CMFD
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CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HYDROCHLORIDE

AB	VINTAGE	0.1MG	N77901 001	Mar 09, 2007	Feb	NEWA
AB		0.2MG	N77901 002	Mar 09, 2007	Feb	NEWA
AB		0.3MG	N77901 003	Mar 09, 2007	Feb	NEWA

CYCLOBENZAPRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

AMRIX

	ECR	15MG	N21777 001	Feb 01, 2007	Feb	NEWA
+		30MG	N21777 002	Feb 01, 2007	Feb	NEWA

TABLET; ORAL

CYCLOBENZAPRINE HYDROCHLORIDE

AB	VINTAGE PHARMS	5MG	N77797 001	Feb 28, 2007	Feb	NEWA
AB		10MG	N77797 002	Feb 28, 2007	Feb	NEWA

DEMECLOCYCLINE HYDROCHLORIDE

TABLET; ORAL

DECLOMYCIN

>D>	@ GLADES PHARMS LLC	75MG	N50261 001		Mar	CAHN
>D>	AB	150MG	N50261 002		Mar	CAHN
>D>	AB +	300MG	N50261 003		Mar	CAHN
>A>	@ STIEFEL	75MG	N50261 001		Mar	CAHN
>A>	AB	150MG	N50261 002		Mar	CAHN
>A>	AB +	300MG	N50261 003		Mar	CAHN

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

DESIPRAMINE HYDROCHLORIDE

>A>	AB	ACTAVIS TOTOWA	10MG	N74430 001	Feb 09, 1996	Mar	CAHN
>A>	AB		25MG	N71601 001	Jun 05, 1987	Mar	CAHN
>A>	AB		75MG	N71602 001	Oct 05, 1987	Mar	CAHN
>A>	AB		100MG	N71766 001	Oct 05, 1987	Mar	CAHN
>A>	AB		150MG	N74430 002	Feb 09, 1996	Mar	CAHN
>A>	AB	AMIDE PHARM	50MG	N71588 001	Jun 05, 1987	Mar	CAHN
>D>	AB	SANDOZ	10MG	N74430 001	Feb 09, 1996	Mar	CAHN
>D>	AB		25MG	N71601 001	Jun 05, 1987	Mar	CAHN
>D>	AB		50MG	N71588 001	Jun 05, 1987	Mar	CAHN
>D>	AB		75MG	N71602 001	Oct 05, 1987	Mar	CAHN
>D>	AB		100MG	N71766 001	Oct 05, 1987	Mar	CAHN
>D>	AB		150MG	N74430 002	Feb 09, 1996	Mar	CAHN

DEXMETHYLPHENIDATE HYDROCHLORIDE

TABLET; ORAL

DEXMETHYLPHENIDATE HYDROCHLORIDE

AB	TEVA PHARMS	2.5MG	N77107 003	Jan 29, 2007	Jan	NEWA
AB		5MG	N77107 001	Jan 29, 2007	Jan	NEWA
AB		10MG	N77107 002	Jan 29, 2007	Jan	NEWA
AB	FOCALIN					
AB	NOVARTIS	2.5MG	N21278 001	Nov 13, 2001	Jan	CFTG

TABLET; ORAL

FOCALIN

AB		NOVARTIS	5MG	N21278 002	Nov 13, 2001	Jan	CFTG
AB	+		10MG	N21278 003	Nov 13, 2001	Jan	CFTG

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

DEXEDRINE

@ GLAXOSMITHKLINE

5MG

N84935 001

Feb DISC

DEXTROSTAT

>A>	AA	+	SHIRE	5MG	N84051 001		Mar	CAHN
>A>	AA	+		10MG	N84051 002		Mar	CAHN
>D>	AA	+	SHIRE RICHWOOD	5MG	N84051 001		Mar	CAHN
>D>	AA	+		10MG	N84051 002		Mar	CAHN

DICLOFENAC EPOLAMINE

PATCH; TOPICAL

FLECTOR

+ INST BIOCHEM

1.3%

N21234 001 Jan 31, 2007 Jan NEWA

DIDANOSINE

FOR SOLUTION; ORAL

DIDANOSINE

AA		AUROBINDO PHARMA	10MG/ML	N78112 001	Mar 08, 2007	Feb	NEWA
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VIDEX

AA	+	BRISTOL MYERS SQUIBB	10MG/ML	N20156 001	Oct 09, 1991	Feb	CFTG
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DIMYRISTOYL LECITHIN; PERFLEXANE

INJECTABLE; INTRAVENOUS

IMAGENT

@ IMCOR PHARMS CO

0.92MG/VIAL;0.092MG/VIAL

N21191 001 May 31, 2002 Feb CAHN

DIPHENHYDRAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

BENADRYL

>A>		@ MCNEIL CONS	10MG/ML	N06146 001			Mar	CAHN
>A>	AP	+		50MG/ML	N06146 002		Mar	CAHN
>D>		@ PARKE DAVIS	10MG/ML	N06146 001			Mar	CAHN
>D>	AP	+		50MG/ML	N06146 002		Mar	CAHN
			BENADRYL PRESERVATIVE FREE					
>A>	AP	+	MCNEIL CONS	50MG/ML	N09486 001		Mar	CAHN
>D>	AP	+	PARKE DAVIS	50MG/ML	N09486 001		Mar	CAHN

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

AB		MURTY PHARMS	25MG	N40733 001	Feb 13, 2007	Jan	NEWA
AB			50MG	N40733 002	Feb 13, 2007	Jan	NEWA
AB			75MG	N40733 003	Feb 13, 2007	Jan	NEWA

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

RUBEX

>D>								
>D>	AP		BRISTOL MYERS SQUIBB	10MG/VIAL	N62926 001	Apr 13, 1989	Mar	DISC
>A>			@	10MG/VIAL	N62926 001	Apr 13, 1989	Mar	DISC

INJECTABLE; INJECTION

>D>		RUBEX							
>D>	AP	BRISTOL MYERS SQUIBB	50MG/VIAL	N62926	002	Apr 13, 1989	Mar	DISC	
>A>		@	50MG/VIAL	N62926	002	Apr 13, 1989	Mar	DISC	
>D>			100MG/VIAL	N62926	003	Apr 13, 1989	Mar	DISC	
>A>		@	100MG/VIAL	N62926	003	Apr 13, 1989	Mar	DISC	

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE

AB		RANBAXY	EQ 75MG BASE	N65053	003	Sep 10, 2003	Jan	CTEC	
		MONODOX							
AB		OCLASSEN	EQ 75MG BASE	N50641	003	Oct 18, 2006	Jan	NEWA	

EDETATE CALCIUM DISODIUM

INJECTABLE; INJECTION

CALCIUM DISODIUM VERSENATE

		+ GRACEWAY	200MG/ML	N08922	001		Jan	CAHN	
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TABLET; ORAL

CALCIUM DISODIUM VERSENATE

		@ GRACEWAY	500MG	N08922	002		Jan	CAHN	
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ENALAPRILAT

INJECTABLE; INJECTION

ENALAPRILAT

>D>	AP	BEDFORD	1.25MG/ML	N75634	001	Aug 22, 2000	Mar	CRLD	
>A>	AP	+	1.25MG/ML	N75634	001	Aug 22, 2000	Mar	CRLD	
>D>		VASOTEC							
>D>	AP	+ BIOVAIL LABS INTL	1.25MG/ML	N19309	001	Feb 09, 1988	Mar	DISC	
>A>		@	1.25MG/ML	N19309	001	Feb 09, 1988	Mar	DISC	

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL

ERGOMAR

		+ ROSEDALE THERAPEUTIC	2MG	N87693	001	Feb 24, 1983	Jan	CAHN	
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ESTRADIOL

GEL, METERED; TRANSDERMAL

ELESTRIN

BX	+	BRADLEY PHARMS	0.06%	N21813	001	Dec 15, 2006	Jan	CAHN	
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TABLET; ORAL

ESTRADIOL

		@ HERITAGE PHARMS INC	0.5MG	N40275	001	Dec 29, 1998	Feb	CAHN	
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		@	1MG	N40275	002	Dec 29, 1998	Feb	CAHN	
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		@	2MG	N40275	003	Dec 29, 1998	Feb	CAHN	
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ETHINYL ESTRADIOL; NORETHINDRONE

TABLET, CHEWABLE; ORAL-28

OVCON-35 FE

		+ WARNER CHILCOTT	0.035MG;0.4MG	N21490	001	Nov 14, 2003	Jan	CTNA	
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ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL-21

MICROGESTIN 1.5/30

AB		WATSON LABS	0.03MG;1.5MG	N75548	002	Jul 30, 2003	Jan	NEWA	
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TABLET; ORAL-21
MICROGESTIN 1/20

AB WATSON LABS 0.02MG;1MG N75647 002 Jul 30, 2003 Jan NEWA

FAMOTIDINE

FOR SUSPENSION; ORAL
PEPCID

+ SALIX PHARMS 40MG/5ML N19527 001 Feb 02, 1987 Feb CAHN

FENOFIBRATE

TABLET; ORAL
TRIGLIDE

SKYEPHARMA AG 50MG N21350 001 May 07, 2005 Jan CAHN
BX 160MG N21350 002 May 07, 2005 Jan CAHN

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION
FENOLDOPAM MESYLATE

AP SICOR PHARMS EQ 10MG BASE/ML N77826 001 Mar 07, 2007 Feb NEWA

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL
DURAGESIC-12

AB ALZA 12.5UGM/HR N19813 005 Feb 04, 2005 Jan CFTG

FENTANYL-100

AB LAVIPHARM LABS 100UGM/HR N77051 004 Aug 04, 2006 Jan CTNA

AB MYLAN TECHNOLOGIES 100UGM/HR N76258 004 Jan 28, 2005 Jan CTNA

FENTANYL-12

AB MYLAN TECHNOLOGIES 12.5UGM/HR N76258 005 Jan 23, 2007 Jan NEWA

FENTANYL-25

AB LAVIPHARM LABS 25UGM/HR N77051 001 Aug 04, 2006 Jan CTNA

AB MYLAN TECHNOLOGIES 25UGM/HR N76258 001 Jan 28, 2005 Jan CTNA

FENTANYL-50

AB LAVIPHARM LABS 50UGM/HR N77051 002 Aug 04, 2006 Jan CTNA

AB MYLAN TECHNOLOGIES 50UGM/HR N76258 002 Jan 28, 2005 Jan CTNA

FENTANYL-75

AB LAVIPHARM LABS 75UGM/HR N77051 003 Aug 04, 2006 Jan CTNA

AB MYLAN TECHNOLOGIES 75UGM/HR N76258 003 Jan 28, 2005 Jan CTNA

FENTANYL CITRATE

TABLET; BUCCAL
FENTORA

>A> CEPHALON EQ 0.3MG BASE N21947 006 Mar 02, 2007 Mar NEWA

FINASTERIDE

TABLET; ORAL
FINASTERIDE

>A> AB ACTAVIS TOTOWA 5MG N77914 001 Mar 28, 2007 Mar NEWA

AB DR REDDYS LABS LTD 5MG N76437 001 Feb 28, 2007 Feb NEWA

FLECAINIDE ACETATE

TABLET; ORAL
TAMBOCOR

AB GRACEWAY 50MG N18830 004 Aug 23, 1988 Jan CAHN

AB 100MG N18830 001 Oct 31, 1985 Jan CAHN

TABLET; ORAL

TAMBOCOR

AB	+	GRACEWAY	150MG	N18830 003	Jun 03, 1988	Jan	CAHN
		@	200MG	N18830 002	Oct 31, 1985	Jan	CAHN

FLUDARABINE PHOSPHATE

INJECTABLE; INJECTION

FLUDARABINE PHOSPHATE

>A>	AP	MAYNE PHARMA USA	50MG/VIAL	N77790 001	Apr 06, 2007	Mar	NEWA
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FLUOXETINE HYDROCHLORIDE

SOLUTION; ORAL

FLUOXETINE HYDROCHLORIDE

AA		SILARX	EQ 20MG BASE/5ML	N77849 001	Feb 09, 2007	Jan	NEWA
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FLUPHENAZINE DECANOATE

INJECTABLE; INJECTION

FLUPHENAZINE DECANOATE

AO	+	BEDFORD	25MG/ML	N74531 001	Aug 30, 1996	Jan	CRLD
		PROLIXIN DECANOATE					
		@ BRISTOL MYERS SQUIBB	25MG/ML	N16727 001		Jan	DISC

FLUPHENAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

FLUPHENAZINE HYDROCHLORIDE

	+	ABRAXIS PHARM	2.5MG/ML	N89556 001	Apr 16, 1987	Jan	CRLD
		PROLIXIN					
		@ APOTHECON	2.5MG/ML	N11751 005		Jan	DISC

TABLET; ORAL

FLUPHENAZINE HYDROCHLORIDE

AB	+	MYLAN	10MG	N89804 001	Aug 12, 1988	Feb	CRLD
		PROLIXIN					
		@ APOTHECON	1MG	N11751 004		Jan	DISC
		@	2.5MG	N11751 001		Jan	DISC
		@	5MG	N11751 003		Jan	DISC
		@	10MG	N11751 002		Jan	DISC

FOLIC ACID

INJECTABLE; INJECTION

FOLIC ACID

	+	ABRAXIS PHARM	5MG/ML	N89202 001	Feb 18, 1986	Jan	CTEC
		@ BEN VENUE	5MG/ML	N81066 001	Dec 29, 1993	Jan	DISC

FOLLITROPIN ALFA/BETA

INJECTABLE; SUBCUTANEOUS

GONAL-F

>A>		@ EMD SERONO	37.5 IU/VIAL	N20378 003	May 25, 2000	Mar	CAHN
>A>		@	37.5 IU/VIAL	N21765 001	Mar 25, 2004	Mar	CAHN
>A>		@	75 IU/VIAL	N20378 001	Sep 29, 1997	Mar	CAHN
>A>		@	150 IU/VIAL	N20378 002	Sep 29, 1997	Mar	CAHN
>A>		@	150 IU/VIAL	N21765 003	Mar 25, 2004	Mar	CAHN
>A>	+		450 IU/VIAL	N20378 005	Mar 26, 2004	Mar	CAHN
>D>		@ SERONO INC	37.5 IU/VIAL	N20378 003	May 25, 2000	Mar	CAHN
>D>		@	37.5 IU/VIAL	N21765 001	Mar 25, 2004	Mar	CAHN
>D>		@	75 IU/VIAL	N20378 001	Sep 29, 1997	Mar	CAHN

INJECTABLE; SUBCUTANEOUS

GONAL-F

>D>	@	SERONO INC	150 IU/VIAL	N20378 002	Sep 29, 1997	Mar	CAHN
>D>	@		150 IU/VIAL	N21765 003	Mar 25, 2004	Mar	CAHN
>D>	+		450 IU/VIAL	N20378 005	Mar 26, 2004	Mar	CAHN
<u>GONAL-F RFF</u>							
>A>	+	EMD SERONO	75 IU/VIAL	N21765 002	Mar 25, 2004	Mar	CAHN
>D>	+	SERONO INC	75 IU/VIAL	N21765 002	Mar 25, 2004	Mar	CAHN

FORMOTEROL FUMARATE

POWDER; INHALATION

FORADIL CERTIHALER

	+	NOVARTIS	0.0085MG/INH	N21592 001	Dec 15, 2006	Jan	CRLD
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FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

>A>	AP	WOCKHARDT	10MG/ML	N77941 001	Mar 22, 2007	Mar	NEWA
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GABAPENTIN

TABLET; ORAL

GABAPENTIN

AB	+	IVAX PHARMS	800MG	N76017 005	Apr 29, 2005	Feb	CRLD
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NEURONTIN

AB		PFIZER PHARMS	800MG	N20882 002	Oct 09, 1998	Feb	CRLD
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GEMFIBROZIL

TABLET; ORAL

GEMFIBROZIL

>A>	AB	PERRIGO R AND D	600MG	N78012 001	Mar 26, 2007	Mar	NEWA
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HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM

>D>	AP	ABRAXIS PHARM	1,000 UNITS/ML	N17979 001		Mar	DISC
>A>		@	1,000 UNITS/ML	N17979 001		Mar	DISC
>D>	AP		10,000 UNITS/ML	N17979 002		Mar	DISC
>A>		@	10,000 UNITS/ML	N17979 002		Mar	DISC
		@ WATSON LABS	1,000 UNITS/ML	N17064 002		Feb	CAHN
		@	2,500 UNITS/ML	N17064 015		Feb	CAHN
		@	3,000 UNITS/ML	N17064 016		Feb	CAHN
		@	4,000 UNITS/ML	N17064 017		Feb	CAHN
		@	5,000 UNITS/ML	N17064 003		Feb	CAHN
		@	6,000 UNITS/ML	N17064 018		Feb	CAHN
		@	7,500 UNITS/ML	N17064 019		Feb	CAHN
		@	10,000 UNITS/ML	N17064 004		Feb	CAHN
		@	20,000 UNITS/ML	N17064 005		Feb	CAHN
		@	40,000 UNITS/ML	N17064 006		Feb	CAHN

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HYDROCHLORIDE

	@	HERITAGE PHARMS INC	25MG	N86243 001		Feb	CAHN
	@		50MG	N86242 002		Feb	CAHN

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

AB	ACTAVIS ELIZABETH	12.5MG	N40707 001	Feb 27, 2007	Feb	NEWA
>A>	AB	CARACO	25MG	N40810 001	Mar 27, 2007	Mar
>A>	AB		50MG	N40810 002	Mar 27, 2007	Mar
>A>	AB	EXCELLIUM	25MG	N40702 001	Mar 16, 2007	Mar
>A>	AB		50MG	N40702 002	Mar 16, 2007	Mar
AB	HERITAGE PHARMS INC	25MG	N85181 001		Feb	CAHN
AB		50MG	N85182 001		Feb	CAHN
AB	MYLAN	12.5MG	N40770 001	Jan 23, 2007	Feb	CTEC
		12.5MG	N40770 001	Jan 23, 2007	Jan	NEWA
AB		25MG	N40735 002	Jan 23, 2007	Jan	NEWA
AB		50MG	N40735 003	Jan 23, 2007	Jan	NEWA

HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDE

TABLET; ORAL

MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

AB	TEVA	12.5MG; 7.5MG	N76980 001	Mar 07, 2007	Feb	NEWA
AB		12.5MG; 15MG	N76980 003	Mar 07, 2007	Feb	NEWA
AB		25MG; 15MG	N76980 002	Mar 07, 2007	Feb	NEWA
	UNIRETIC					
AB	SCHWARZ PHARMA	12.5MG; 7.5MG	N20729 001	Jun 27, 1997	Feb	CFTG
AB		12.5MG; 15MG	N20729 003	Feb 14, 2002	Feb	CFTG
AB	+	25MG; 15MG	N20729 002	Jun 27, 1997	Feb	CFTG

HYDROCORTISONE

TABLET; ORAL

CORTEF

>D>		PHARMACIA AND UPJOHN	5MG	N08697 003		Mar	CFTG
>A>	AB		5MG	N08697 003		Mar	CFTG
>D>			10MG	N08697 001		Mar	CFTG
>A>	AB		10MG	N08697 001		Mar	CFTG
			10MG	N08697 001		Feb	CMFD
>D>	BP	+	20MG	N08697 002		Mar	CTEC
>A>	AB	+	20MG	N08697 002		Mar	CTEC
>A>		HYDROCORTISONE					
>A>	AB	STIEFEL	5MG	N40646 001	Mar 30, 2007	Mar	NEWA
>A>	AB		10MG	N40646 002	Mar 30, 2007	Mar	NEWA
>A>	AB		20MG	N40646 003	Mar 30, 2007	Mar	NEWA

HYDROMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROMORPHONE HYDROCHLORIDE

@	WATSON LABS	10MG/ML	N74317 001	Aug 23, 1995	Feb	DISC
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HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HYDROCHLORIDE

@	HOSPIRA	25MG/ML	N87416 001		Feb	DISC
@		50MG/ML	N87546 001		Feb	DISC
@	WATSON LABS	50MG/ML	N85779 001		Feb	DISC

TABLET; ORAL

HYDROXYZINE HYDROCHLORIDE

>A>	AB	KVK-TECH INC	10MG	N40786 001	Mar 20, 2007	Mar	NEWA
>A>	AB		25MG	N40787 001	Mar 20, 2007	Mar	NEWA
>A>	AB		50MG	N40788 001	Mar 20, 2007	Mar	NEWA

IFOSFAMIDE

INJECTABLE; INJECTION

IFSOFAMIDE

>A>	+	SICOR PHARMS	1GM/20ML (50MG/ML)	N76657 001	Apr 04, 2007	Mar	NEWA
>A>	+		3GM/60ML (50MG/ML)	N76657 002	Apr 04, 2007	Mar	NEWA

ILOPROST

SOLUTION; INHALATION

VENTAVIS

+	ACTELION		10UGM/ML (10UGM/ML)	N21779 002	Dec 08, 2005	Jan	CAHN
+			20UGM/2ML (10UGM/ML)	N21779 001	Dec 29, 2004	Jan	CAHN
+	ACTELION PHARM		10UGM/ML (10UGM/ML)	N21779 002	Dec 08, 2005	Feb	CAHN
+			20UGM/2ML (10UGM/ML)	N21779 001	Dec 29, 2004	Feb	CAHN

IMIQUIMOD

CREAM; TOPICAL

ALDARA

+	GRACEWAY		5%	N20723 001	Feb 27, 1997	Jan	CAHN
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INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

	@	HERITAGE PHARMS INC	25MG	N18851 001	May 18, 1984	Feb	CAHN
	@		50MG	N18851 002	May 18, 1984	Feb	CAHN
AB		MYLAN	25MG	N18858 001	Apr 20, 1984	Feb	CTEC
>D>	AB	+	50MG	N18858 002	Apr 20, 1984	Mar	DISC
>A>		@	50MG	N18858 002	Apr 20, 1984	Mar	DISC
>D>	AB		50MG	N70624 001	Sep 04, 1985	Mar	CRLD
>A>	AB	+	50MG	N70624 001	Sep 04, 1985	Mar	CRLD
	AB	SANDOZ	25MG	N70673 001	Apr 29, 1987	Feb	CMFD
	AB		50MG	N70674 001	Apr 29, 1987	Feb	CMFD

IRON SUCROSE

INJECTABLE; INTRAVENOUS

VENOFER

@	LUITPOLD		EQ 50MG BASE/2.5ML(EQ 20MG BASE/ML)	N21135 002	Mar 20, 2005	Feb	DISC
@			EQ 75MG BASE/3.75ML(EQ 20MG BASE/ML)	N21135 003	Mar 29, 2005	Feb	DISC
			EQ 200MG BASE/10ML(EQ 20MG BASE/ML)	N21135 004	Feb 09, 2007	Feb	NEWA

ISOSORBIDE DINITRATE

TABLET; ORAL

ISOSORBIDE DINITRATE

AB		WEST WARD	30MG	N40591 001	Jan 10, 2007	Jan	NEWA
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KETOPROFEN

CAPSULE; ORAL

KETOPROFEN

AB		HERITAGE PHARMS INC	25MG	N74014 001	Jan 29, 1993	Feb	CAHN
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CAPSULE; ORALKETOPROFEN

AB	HERITAGE PHARMS INC	50MG	N74014 002	Jan 29, 1993	Feb	CAHN
AB		75MG	N74014 003	Jan 29, 1993	Feb	CAHN

KETOROLAC TROMETHAMINEINJECTABLE; INJECTIONKETOROLAC TROMETHAMINE

>D>	AP	AMPHASTAR PHARM	15MG/ML	N76209 001	Jul 21, 2004	Mar	DISC
>A>		@	15MG/ML	N76209 001	Jul 21, 2004	Mar	DISC
>D>	AP		30MG/ML	N76209 002	Jul 21, 2004	Mar	DISC
>A>		@	30MG/ML	N76209 002	Jul 21, 2004	Mar	DISC
>D>	AP	APOTEX INC	30MG/ML	N75626 001	Jul 24, 2001	Mar	DISC
>A>		@	30MG/ML	N75626 001	Jul 24, 2001	Mar	DISC
>D>	AP		30MG/ML	N77201 001	Oct 14, 2005	Mar	DISC
>A>		@	30MG/ML	N77201 001	Oct 14, 2005	Mar	DISC
>D>	AP	GLAND PHARMA LTD	15MG/ML	N76722 001	Jul 27, 2004	Mar	DISC
>A>		@	15MG/ML	N76722 001	Jul 27, 2004	Mar	DISC
>D>	AP		30MG/ML	N76722 002	Jul 27, 2004	Mar	DISC
>A>		@	30MG/ML	N76722 002	Jul 27, 2004	Mar	DISC
>A>	AP	WOCKHARDT	15MG/ML	N77942 001	Mar 27, 2007	Mar	NEWA
>A>	AP		30MG/ML	N77942 002	Mar 27, 2007	Mar	NEWA
>A>	AP		30MG/ML	N77943 001	Mar 27, 2007	Mar	NEWA

>A> LAPATINIB DITOSYLATE>A> TABLET; ORAL>A> TYKERB

>A>	+	GLAXOSMITHKLINE	EQ 250MG BASE	N22059 001	Mar 13, 2007	Mar	NEWA
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LEUCOVORIN CALCIUMTABLET; ORALLEUCOVORIN CALCIUM@ PHARMACHEMIE@

EQ 5MG BASE

N73099 001 Mar 28, 1997 Jan DISC

EQ 25MG BASE

N73101 001 Mar 28, 1997 Jan DISC

LEUPROLIDE ACETATEINJECTABLE; SUBCUTANEOUSELIGARD+ SANOFI AVENTIS US++++

7.5MG/VIAL

N21343 001 Jan 23, 2002 Jan CAHN

22.5MG/VIAL

N21379 001 Jul 24, 2002 Jan CAHN

30MG/VIAL

N21488 001 Feb 13, 2003 Jan CAHN

45MG/VIAL

N21731 001 Dec 14, 2004 Jan CAHN

LEVOCARNITINESOLUTION; ORALCARNITOR SF

>A>	AA	SIGMA TAU	1GM/10ML	N19257 002	Mar 28, 2007	Mar	NEWA
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LIDOCAINEPATCH; TOPICALLIDOCAINE+ NOVEN

46.1MG/PATCH

N20575 002 May 21, 1996 Jan CDJR

LIDOCAINE HYDROCHLORIDE

SOLUTION; ORAL						
LIDOCAINE HYDROCHLORIDE VISCOUS						
AT	VINTAGE	2%	N40708 001	Feb 27, 2007	Feb	NEWA
SOLUTION; TOPICAL						
LIDOCAINE HYDROCHLORIDE						
AT	VINTAGE	4%	N40710 001	Feb 27, 2007	Feb	NEWA

LISDEXAMFETAMINE DIMESYLATE

CAPSULE; ORAL						
VYVANSE						
	NEW RIVER	30MG	N21977 001	Feb 23, 2007	Feb	NEWA
		50MG	N21977 002	Feb 23, 2007	Feb	NEWA
+		70MG	N21977 003	Feb 23, 2007	Feb	NEWA

LOVASTATIN

TABLET; ORAL						
LOVASTATIN						
AB	APOTEX INC	10MG	N77748 001	Feb 28, 2007	Feb	NEWA
AB		20MG	N77748 002	Feb 28, 2007	Feb	NEWA
AB		40MG	N77748 003	Feb 28, 2007	Feb	NEWA
TABLET, EXTENDED RELEASE; ORAL						
ALTOPREV						
	@ ANDRX LABS LLC	10MG	N21316 001	Jun 26, 2002	Feb	DISC

LOVASTATIN; NIACIN

TABLET, EXTENDED RELEASE; ORAL						
ADVICOR						
>A>	+	ABBOTT	20MG;500MG	N21249 001	Dec 17, 2001	Mar CAHN
>A>	+		20MG;750MG	N21249 002	Dec 17, 2001	Mar CAHN
>A>	+		20MG;1GM	N21249 003	Dec 17, 2001	Mar CAHN
>A>	+		40MG;1GM	N21249 004	Apr 27, 2006	Mar CAHN
>D>	+	KOS LIFE	20MG;500MG	N21249 001	Dec 17, 2001	Mar CAHN
>D>	+		20MG;750MG	N21249 002	Dec 17, 2001	Mar CAHN
>D>	+		20MG;1GM	N21249 003	Dec 17, 2001	Mar CAHN
>D>	+		40MG;1GM	N21249 004	Apr 27, 2006	Mar CAHN

MAGNESIUM SULFATE

INJECTABLE; INJECTION						
MAGNESIUM SULFATE IN PLASTIC CONTAINER						
	HOSPIRA	2GM/50ML (40MG/ML)	N20309 003	Jan 26, 2007	Jan	NEWA
+		4GM/100ML (40MG/ML)	N20309 001	Jun 24, 1994	Jan	CPOT
+		4GM/50ML (80MG/ML)	N20309 002	Jun 24, 1994	Jan	CPOT

MESALAMINE

TABLET, DELAYED RELEASE; ORAL						
LIALDA						
+	SHIRE	1.2GM	N22000 001	Jan 16, 2007	Jan	NEWA

METFORMIN HYDROCHLORIDE

TABLET; ORAL						
METFORMIN HYDROCHLORIDE						
AB	TORRENT PHARMS	500MG	N77711 001	Jan 24, 2007	Jan	NEWA
AB		850MG	N77711 002	Jan 24, 2007	Jan	NEWA

TABLET; ORAL

METFORMIN HYDROCHLORIDE

AB	TORRENT PHARMS	1GM	N77711 003	Jan 24, 2007	Jan	NEWA
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>A> METFORMIN HYDROCHLORIDE; SITAGLIPTIN PHOSPHATE

>A> TABLET; ORAL

>A> JANUMET

>A>	MERCK	500MG;EQ 50MG BASE	N22044 001	Mar 30, 2007	Mar	NEWA
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>A>	+	1GM;EQ 50MG BASE	N22044 002	Mar 30, 2007	Mar	NEWA
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METHYLPHENIDATE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

CONCERTA

	JOHNSON AND JOHNSON	18MG	N21121 001	Aug 01, 2000	Feb	CAHN
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		27MG	N21121 004	Apr 01, 2002	Feb	CAHN
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		36MG	N21121 002	Aug 01, 2000	Feb	CAHN
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+		54MG	N21121 003	Dec 08, 2000	Feb	CAHN
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METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

METHYLPREDNISOLONE SODIUM SUCCINATE

AP	BEDFORD LABS	EQ 40MG BASE/VIAL	N40662 001	Feb 21, 2007	Feb	NEWA
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AP		EQ 125MG BASE/VIAL	N40641 002	Feb 21, 2007	Feb	NEWA
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AP		EQ 500MG BASE/VIAL	N40641 003	Feb 21, 2007	Feb	NEWA
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AP		EQ 500MG BASE/VIAL	N40709 001	Feb 21, 2007	Feb	NEWA
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AP		EQ 1GM BASE/VIAL	N40641 004	Feb 21, 2007	Feb	NEWA
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AP		EQ 1GM BASE/VIAL	N40709 002	Feb 21, 2007	Feb	NEWA
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METRONIDAZOLE

GEL; VAGINAL

METROGEL-VAGINAL

AB	+	GRACEWAY	0.75%	N20208 001	Aug 17, 1992	Jan	CAHN
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MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

MIDAZOLAM HYDROCHLORIDE

AP	TAYLOR	EQ 1MG BASE/ML	N75494 001	Jun 30, 2000	Feb	CAHN
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AP		EQ 5MG BASE/ML	N75494 002	Jun 30, 2000	Feb	CAHN
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MIDAZOLAM HYDROCHLORIDE PRESERVATIVE FREE

AP	+	HOSPIRA	EQ 1MG BASE/ML	N75857 001	Jul 22, 2002	Feb	CTNA
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AP	+		EQ 5MG BASE/ML	N75857 002	Jul 22, 2002	Feb	CTNA
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MITOMYCIN

INJECTABLE; INJECTION

MITOZYTREX

+	SUPERGEN	5MG/VIAL	N50763 001	Nov 14, 2002	Jan	CTNA
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MITOXANTRONE HYDROCHLORIDE

INJECTABLE; INJECTION

NOVANTRONE

>A>	AP	+	EMD SERONO	EQ 20MG BASE/10ML (2MG/ML)	N19297 001	Dec 23, 1987	Mar	CAHN
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>A>	AP	+		EQ 25MG BASE/12.5ML (2MG/ML)	N19297 002	Dec 23, 1987	Mar	CAHN
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>A>	AP	+		EQ 30MG BASE/15ML (2MG/ML)	N19297 003	Dec 23, 1987	Mar	CAHN
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>D>	AP	+	SERONO INC	EQ 20MG BASE/10ML (2MG/ML)	N19297 001	Dec 23, 1987	Mar	CAHN
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>D>	AP	+		EQ 25MG BASE/12.5ML (2MG/ML)	N19297 002	Dec 23, 1987	Mar	CAHN
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INJECTABLE; INJECTION

NOVANTRONE

>D>	AP	+	SERONO INC	EQ 30MG BASE/15ML (2MG/ML)	N19297 003	Dec 23, 1987	Mar	CAHN
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MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

AVINZA

>A>	BX		KING PHARMS	30MG	N21260 001	Mar 20, 2002	Mar	CAHN
>A>	BX			60MG	N21260 002	Mar 20, 2002	Mar	CAHN
>A>				90MG	N21260 003	Mar 20, 2002	Mar	CAHN
>A>		+		120MG	N21260 004	Mar 20, 2002	Mar	CAHN
>D>	BX		LIGAND	30MG	N21260 001	Mar 20, 2002	Mar	CAHN
>D>	BX			60MG	N21260 002	Mar 20, 2002	Mar	CAHN
>D>				90MG	N21260 003	Mar 20, 2002	Mar	CAHN
>D>		+		120MG	N21260 004	Mar 20, 2002	Mar	CAHN

KADIAN

ALPHARMA US PHARMS 200MG

N20616 007 Feb 27, 2007 Feb NEWA

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

NALBUPHINE HYDROCHLORIDE

AP	+		HOSPIRA	10MG/ML	N70914 001	Feb 03, 1989	Feb	CRLD
AP	+			10MG/ML	N70915 001	Feb 03, 1989	Feb	CRLD
AP	+			20MG/ML	N70916 001	Feb 03, 1989	Feb	CRLD
AP	+			20MG/ML	N70918 001	Feb 03, 1989	Feb	CRLD
			NUBAIN					
		@	ENDO PHARMS	10MG/ML	N18024 001		Feb	DISC
		@		20MG/ML	N18024 002	May 27, 1982	Feb	DISC

NAPROXEN

TABLET; ORAL

NAPROXEN

>A>	AB		GLENMARK PHARMS INC	250MG	N78250 001	Mar 28, 2007	Mar	NEWA
>A>	AB			375MG	N78250 002	Mar 28, 2007	Mar	NEWA
>A>	AB			500MG	N78250 003	Mar 28, 2007	Mar	NEWA

NELFINAVIR MESYLATE

>D>			FOR SUSPENSION; ORAL					
>D>			VIRACEPT					
>D>		+	AGOURON	EQ 50MG BASE/SCOOPFUL	N20778 001	Mar 14, 1997	Mar	CDFR
>A>			POWDER; ORAL					
>A>			VIRACEPT					
>A>		+	AGOURON	EQ 50MG BASE/SCOOPFUL	N20778 001	Mar 14, 1997	Mar	CDFR

NESIRITIDE RECOMBINANT

FOR SOLUTION; INTRAVENOUS

NATRECOR

+			ALZA CORP	1.5MG/VIAL	N20920 001	Aug 10, 2001	Jan	CAHN
+			SCIOS	1.5MG/VIAL	N20920 001	Aug 10, 2001	Feb	CAHN

NIACIN

TABLET, EXTENDED RELEASE; ORAL

NIASPAN

>A>		@	ABBOTT	375MG	N20381 001	Jul 28, 1997	Mar	CAHN
>A>		+		500MG	N20381 002	Jul 28, 1997	Mar	CAHN

TABLET, EXTENDED RELEASE; ORAL

NIASPAN

>A>	+	ABBOTT	750MG	N20381 003	Jul 28, 1997	Mar	CAHN
>A>	+		1GM	N20381 004	Jul 28, 1997	Mar	CAHN
>D>		@ KOS LIFE	375MG	N20381 001	Jul 28, 1997	Mar	CAHN
>D>	+		500MG	N20381 002	Jul 28, 1997	Mar	CAHN
>D>	+		750MG	N20381 003	Jul 28, 1997	Mar	CAHN
>D>	+		1GM	N20381 004	Jul 28, 1997	Mar	CAHN
NIASPAN TITRATION STARTER PACK							
>A>		@ ABBOTT	375MG;500MG;750MG	N20381 005	Jul 28, 1997	Mar	CAHN
>D>		@ KOS LIFE	375MG;500MG;750MG	N20381 005	Jul 28, 1997	Mar	CAHN

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL

MINITRAN

AB1		GRACEWAY	0.1MG/HR	N89771 001	Aug 30, 1996	Jan	CAHN
AB1			0.2MG/HR	N89772 001	Aug 30, 1996	Jan	CAHN
AB1			0.4MG/HR	N89773 001	Aug 30, 1996	Jan	CAHN
AB1			0.6MG/HR	N89774 001	Aug 30, 1996	Jan	CAHN

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ONDANSETRON HYDROCHLORIDE

AP		HOSPIRA	EQ 2MG BASE/ML	N77840 001	Jan 19, 2007	Jan	NEWA
>D>	AP	PHARMAFORCE	EQ 2MG BASE/ML	N77582 001	Dec 26, 2006	Mar	CAHN
>A>	AP	PLIVA	EQ 2MG BASE/ML	N77582 001	Dec 26, 2006	Mar	CAHN
>A>	AP	SPECTRUM PHARMS	EQ 2MG BASE/ML	N78180 001	Mar 26, 2007	Mar	NEWA

ONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER

AP		HOSPIRA	EQ 0.64MG BASE/ML	N77348 001	Feb 01, 2007	Jan	NEWA
AP		MAYNE PHARMA USA	EQ 0.64MG BASE/ML	N76978 001	Feb 26, 2007	Feb	NEWA

ONDANSETRON HYDROCHLORIDE PRESERVATIVE FREE

>D>	AP	PHARMAFORCE	EQ 2MG BASE/ML	N77387 001	Dec 26, 2006	Mar	CAHN
>A>	AP	PLIVA	EQ 2MG BASE/ML	N77387 001	Dec 26, 2006	Mar	CAHN

ZOFRAN AND DEXTROSE IN PLASTIC CONTAINER

AP	+	GLAXOSMITHKLINE	EQ 0.64MG BASE/ML	N20403 001	Jan 31, 1995	Jan	CTNA
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ORPHENADRINE CITRATE

INJECTABLE; INJECTION

NORFLEX

AP	+	GRACEWAY	30MG/ML	N13055 001		Jan	CAHN
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TABLET, EXTENDED RELEASE; ORAL

NORFLEX

@ GRACEWAY

			100MG	N12157 001		Jan	CAHN
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ORPHENADRINE CITRATE

>A>	AB	ACTAVIS TOTOWA	100MG	N40284 001	Jun 19, 1998	Mar	CAHN
>D>	AB	SANDOZ	100MG	N40284 001	Jun 19, 1998	Mar	CAHN

OXANDROLONE

TABLET; ORAL

OXANDROLONE

>A>	AB	UPSHER SMITH	10MG	N78033 001	Mar 22, 2007	Mar	NEWA
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OXYCODONE HYDROCHLORIDE

TABLET; ORAL

OXYCODONE HYDROCHLORIDE

>D>		KV PHARM	5MG	N77290 001	Dec 08, 2005	Mar	CTEC
>A>	AB		5MG	N77290 001	Dec 08, 2005	Mar	CTEC
>A>	AB	TYCO HLTHCARE	5MG	N78206 001	Mar 19, 2007	Mar	NEWA
	AB	VINTAGE PHARMS	15MG	N77712 001	Jan 31, 2007	Jan	NEWA
	AB		30MG	N77712 002	Jan 31, 2007	Jan	NEWA
		ROXICODONE					
	AB	+ XANODYNE PHARMS INC	15MG	N21011 001	Aug 31, 2000	Feb	CAHN
	AB		30MG	N21011 002	Aug 31, 2000	Feb	CAHN

PAROXETINE HYDROCHLORIDE

TABLET; ORAL

PAROXETINE HYDROCHLORIDE

	AB	ZYDUS PHARMS USA	EQ 10MG BASE	N77584 001	Mar 07, 2007	Feb	NEWA
	AB		EQ 20MG BASE	N77584 002	Mar 07, 2007	Feb	NEWA
	AB		EQ 30MG BASE	N77584 003	Mar 07, 2007	Feb	NEWA
	AB		EQ 40MG BASE	N77584 004	Mar 07, 2007	Feb	NEWA

PENTOSTATIN

INJECTABLE; INJECTION

NIPENT

>A>		+ HOSPIRA INC	10MG/VIAL	N20122 001	Oct 11, 1991	Mar	CAHN
>D>		+ MAYNE PHARMA USA	10MG/VIAL	N20122 001	Oct 11, 1991	Mar	CAHN

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE; ORAL

PENTOXIFYLLINE

	AB	HERITAGE PHARMS INC	400MG	N74877 001	Jul 08, 1997	Feb	CAHN
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>D> PERGOLIDE MESYLATE

TABLET; ORAL

PERGOLIDE MESYLATE

>D>	AB	IVAX PHARMS	EQ 0.05MG BASE	N76094 001	Sep 04, 2003	Mar	DISC
>A>		@	EQ 0.05MG BASE	N76094 001	Sep 04, 2003	Mar	DISC
>D>	AB		EQ 0.25MG BASE	N76094 002	Sep 04, 2003	Mar	DISC
>A>		@	EQ 0.25MG BASE	N76094 002	Sep 04, 2003	Mar	DISC
>D>	AB		EQ 1MG BASE	N76094 003	Sep 04, 2003	Mar	DISC
>A>		@	EQ 1MG BASE	N76094 003	Sep 04, 2003	Mar	DISC
>D>	AB	PAR PHARM	EQ 0.05MG BASE	N76061 001	Nov 27, 2002	Mar	DISC
>A>		@	EQ 0.05MG BASE	N76061 001	Nov 27, 2002	Mar	DISC
>D>	AB		EQ 0.25MG BASE	N76061 002	Nov 27, 2002	Mar	DISC
>A>		@	EQ 0.25MG BASE	N76061 002	Nov 27, 2002	Mar	DISC
>D>	AB		EQ 1MG BASE	N76061 003	Nov 27, 2002	Mar	DISC
>A>		@	EQ 1MG BASE	N76061 003	Nov 27, 2002	Mar	DISC
>D>		PERMAX					
>D>	AB	VALEANT PHARM INTL	EQ 0.05MG BASE	N19385 001	Dec 30, 1988	Mar	DISC
>A>		@	EQ 0.05MG BASE	N19385 001	Dec 30, 1988	Mar	DISC
	AB		EQ 0.05MG BASE	N19385 001	Dec 30, 1988	Jan	CAHN
>D>	AB	+	EQ 0.25MG BASE	N19385 002	Dec 30, 1988	Mar	DISC
>A>		@	EQ 0.25MG BASE	N19385 002	Dec 30, 1988	Mar	DISC
	AB	+	EQ 0.25MG BASE	N19385 002	Dec 30, 1988	Jan	CAHN
>D>	AB		EQ 1MG BASE	N19385 003	Dec 30, 1988	Mar	DISC

>D> TABLET; ORAL
 >D> PERMAX
 >A> @ VALEANT PHARM INTL EQ 1MG BASE N19385 003 Dec 30, 1988 Mar DISC
 AB EQ 1MG BASE N19385 003 Dec 30, 1988 Jan CAHN

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
 PHENTERMINE HYDROCHLORIDE
 AA + SANDOZ 30MG N87190 001 Feb CRLD
 AA TG UNITED INC 30MG N40083 001 Mar 07, 1997 Feb CAHN

PILOCARPINE HYDROCHLORIDE

TABLET; ORAL
 PILOCARPINE HYDROCHLORIDE
 AB ROXANE 7.5MG N76963 002 Feb 27, 2007 Feb NEWA

PIPERACILLIN SODIUM

INJECTABLE; INJECTION
 PIPERACILLIN
 + ISTITUTO BIOCHIMICO EQ 2GM BASE/VIAL N65114 001 Nov 14, 2003 Feb CAHN
 + EQ 3GM BASE/VIAL N65114 002 Nov 14, 2003 Feb CAHN
 + EQ 4GM BASE/VIAL N65114 003 Nov 14, 2003 Feb CAHN
 + EQ 40GM BASE/VIAL N65157 001 Jul 12, 2004 Feb CAHN

PIRBUTEROL ACETATE

AEROSOL, METERED; INHALATION
 MAXAIR
 @ GRACEWAY EQ 0.2MG BASE/INH N19009 001 Dec 30, 1986 Jan CAHN
 + EQ 0.2MG BASE/INH N20014 001 Nov 30, 1992 Jan CAHN

POLYETHYLENE GLYCOL 3350

FOR SOLUTION; ORAL
 POLYETHYLENE GLYCOL 3350
 AA ANABOLIC LABS 17GM/SCOOPFUL N77706 001 Sep 27, 2006 Jan CAHN

PREDNICARBATE

OINTMENT; TOPICAL
 DERMATOP
 AB + SANOFI AVENTIS US 0.1% N19568 001 Sep 23, 1991 Feb CFTG
 PREDNICARBATE
 AB ALTANA 0.1% N77236 001 Mar 09, 2007 Feb NEWA

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL
 PROCAINAMIDE HYDROCHLORIDE
 @ IVAX PHARMS 250MG N84604 001 Jan DISC
 @ 375MG N84595 001 Jan DISC
 @ 500MG N84606 001 Jan DISC
 @ WATSON LABS 250MG N83287 001 Jan DISC
 @ 375MG N84403 001 Jan DISC
 @ 500MG N84280 001 Jan DISC
 PRONESTYL
 @ APOTHECON 250MG N07335 001 Jan DISC
 @ 375MG N07335 004 Jan DISC
 @ 500MG N07335 003 Jan DISC

TABLET, EXTENDED RELEASE; ORAL

PRONESTYL-SR

@ APOTHECON	500MG	N87361 001	Jan	DISC
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PROCHLORPERAZINE

SUPPOSITORY; RECTAL

COMPAZINE

@ GLAXOSMITHKLINE	25MG	N11127 002	Feb	DISC
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PROCHLORPERAZINE

AB + G AND W LABS	25MG	N40058 001	Nov 24, 1993	Feb	CRLD
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PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION

COMPAZINE

@ GLAXOSMITHKLINE	EQ 5MG BASE/ML	N10742 002	Feb	DISC
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PROCHLORPERAZINE

@ BAXTER HLTHCARE	EQ 5MG BASE/ML	N87759 001	Oct 01, 1982	Feb	DISC
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PROCHLORPERAZINE EDISYLATE

AP + BAXTER HLTHCARE	EQ 5MG BASE/ML	N89903 001	Aug 29, 1989	Feb	CRLD
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@ HOSPIRA	EQ 5MG BASE/ML	N89703 001	Apr 07, 1988	Feb	DISC
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@ WATSON LABS	EQ 5MG BASE/ML	N89530 001	Jul 08, 1987	Feb	DISC
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PROCHLORPERAZINE MALEATE

CAPSULE, EXTENDED RELEASE; ORAL

COMPAZINE

@ GLAXOSMITHKLINE	EQ 15MG BASE	N21019 002	Oct 06, 1999	Jan	DISC
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TABLET; ORAL

COMPAZINE

@ GLAXOSMITHKLINE	EQ 5MG BASE	N10571 001	Feb	DISC
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@	EQ 10MG BASE	N10571 002	Feb	DISC
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@	EQ 25MG BASE	N10571 003	Feb	DISC
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PROCHLORPERAZINE MALEATE

AB + SANDOZ	EQ 10MG BASE	N40101 002	Jul 19, 1996	Feb	CRLD
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@	EQ 25MG BASE	N40101 003	Jul 19, 1996	Feb	DISC
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PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE HYDROCHLORIDE

>A> AA TARO	6.25MG/5ML	N40718 001	Apr 04, 2007	Mar	NEWA
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PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

DOLENE

@ HERITAGE PHARMS INC	65MG	N80530 001	Feb	CAHN
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PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

INDERAL LA

AB WYETH PHARMS INC	60MG	N18553 004	Mar 18, 1987	Jan	CTEC
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AB	80MG	N18553 002	Apr 19, 1983	Jan	CTEC
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AB	120MG	N18553 003	Apr 19, 1983	Jan	CTEC
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AB +	160MG	N18553 001	Apr 19, 1983	Jan	CTEC
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PROPRANOLOL HYDROCHLORIDE

AB MYLAN	60MG	N78022 001	Feb 15, 2007	Feb	NEWA
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AB	80MG	N78022 002	Feb 15, 2007	Feb	NEWA
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CAPSULE, EXTENDED RELEASE; ORALPROPRANOLOL HYDROCHLORIDE

AB	MYLAN	120MG	N78022 003	Feb 15, 2007	Feb	NEWA
AB		160MG	N78022 004	Feb 15, 2007	Feb	NEWA
AB	PAR PHARM	60MG	N78065 001	Jan 26, 2007	Jan	NEWA
AB		80MG	N78065 002	Jan 26, 2007	Jan	NEWA
AB		120MG	N78065 003	Jan 26, 2007	Jan	NEWA
AB		160MG	N78065 004	Jan 26, 2007	Jan	NEWA

TABLET; ORALINDERAL

	@ WYETH PHARMS INC	10MG	N16418 001		Jan	DISC
	@	20MG	N16418 003		Jan	DISC

PYRIDOXINE HYDROCHLORIDEINJECTABLE; INJECTIONPYRIDOXINE HYDROCHLORIDE

+	ABRAXIS PHARM	100MG/ML	N80618 001		Jan	CRLD
	@ WATSON LABS	100MG/ML	N80572 001		Jan	DISC

QUINIDINE SULFATETABLET; ORALQUINIDINE SULFATE

>D>	AB	WATSON LABS	200MG	N83288 001		Mar	DISC
>A>		@	200MG	N83288 001		Mar	DISC

RABEPRAZOLE SODIUMTABLET, DELAYED RELEASE; ORALACIPHEX

AB	+	EISAI MEDCL RES	20MG	N20973 002	Aug 19, 1999	Feb	CFTG
AB		RABEPRAZOLE SODIUM					
AB		TEVA	20MG	N76822 001	Feb 21, 2007	Feb	NEWA

RAMIPRILCAPSULE; ORALALTACE

		KING PHARMS	1.25MG	N19901 001	Jan 28, 1991	Jan	CTEC
			2.5MG	N19901 002	Jan 28, 1991	Jan	CTEC
			5MG	N19901 003	Jan 28, 1991	Jan	CTEC
	+		10MG	N19901 004	Jan 28, 1991	Jan	CTEC
		RAMIPRIL					
		@ COBALT	1.25MG	N76549 001	Oct 24, 2005	Jan	DISC
		@	2.5MG	N76549 002	Oct 24, 2005	Jan	DISC
		@	5MG	N76549 003	Oct 24, 2005	Jan	DISC
		@	10MG	N76549 004	Oct 24, 2005	Jan	DISC

TABLET; ORALALTACE

		COBALT	1.25MG	N22021 001	Feb 27, 2007	Feb	NEWA
			2.5MG	N22021 002	Feb 27, 2007	Feb	NEWA
			5MG	N22021 003	Feb 27, 2007	Feb	NEWA
	+		10MG	N22021 004	Feb 27, 2007	Feb	NEWA

RANITIDINE HYDROCHLORIDESYRUP; ORALRANITIDINE HYDROCHLORIDE

AA		ALPHARMA US PHARMS	EQ 15MG BASE/ML	N76124 001	Feb 21, 2007	Feb	NEWA
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SYRUP; ORAL

ZANTAC

AA	+	GLAXOSMITHKLINE	EQ 15MG BASE/ML	N19675	001	Dec 30, 1988	Feb	CFTG
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RIBAVIRIN

TABLET; ORAL

RIBAVIRIN

>D>		THREE RIVERS PHARMS	400MG	N77456	002	Dec 05, 2005	Mar	CTEC
>A>	AB		400MG	N77456	002	Dec 05, 2005	Mar	CTEC
>D>		+	600MG	N77456	003	Dec 05, 2005	Mar	CTEC
>A>	AB	+	600MG	N77456	003	Dec 05, 2005	Mar	CTEC
>A>	AB	ZYDUS PHARMS USA	400MG	N77094	002	Mar 16, 2007	Mar	NEWA
>A>	AB		600MG	N77094	003	Mar 16, 2007	Mar	NEWA

SERMORELIN ACETATE

INJECTABLE; INJECTION

GEREF

+	EMD SERONO	EQ 0.05MG BASE/AMP	N19863	001	Dec 28, 1990	Feb	CAHN
	@	EQ 0.5MG BASE/VIAL	N20443	001	Sep 26, 1997	Feb	CAHN
	@	EQ 1MG BASE/VIAL	N20443	002	Sep 26, 1997	Feb	CAHN

SERTRALINE HYDROCHLORIDE

CONCENTRATE; ORAL

SERTRALINE HYDROCHLORIDE

AA		RANBAXY	EQ 20MG BASE/ML	N78053	001	Feb 05, 2007	Feb	CTEC
AB			EQ 20MG BASE/ML	N78053	001	Feb 05, 2007	Jan	NEWA
AA		ROXANE	EQ 20MG BASE/ML	N76934	001	Jun 30, 2006	Feb	CTEC
		ZOLOFT						
AA	+	PFIZER	EQ 20MG BASE/ML	N20990	001	Dec 07, 1999	Feb	CTEC

TABLET; ORAL

SERTRALINE HYDROCHLORIDE

AB		ACTAVIS ELIZABETH	EQ 25MG BASE	N77345	001	Feb 06, 2007	Jan	NEWA
AB			EQ 50MG BASE	N77345	002	Feb 06, 2007	Jan	NEWA
AB			EQ 100MG BASE	N77345	003	Feb 06, 2007	Jan	NEWA
AB		APOTEX INC	EQ 25MG BASE	N76882	001	Feb 06, 2007	Jan	NEWA
AB			EQ 50MG BASE	N76882	002	Feb 06, 2007	Jan	NEWA
AB			EQ 100MG BASE	N76882	003	Feb 06, 2007	Jan	NEWA
AB		AUROBINDO PHARMA	EQ 25MG BASE	N77206	001	Feb 06, 2007	Jan	NEWA
AB			EQ 50MG BASE	N77206	002	Feb 06, 2007	Jan	NEWA
AB			EQ 100MG BASE	N77206	003	Feb 06, 2007	Jan	NEWA
AB		COBALT	EQ 25MG BASE	N77663	001	Feb 06, 2007	Jan	NEWA
AB			EQ 50MG BASE	N77663	002	Feb 06, 2007	Jan	NEWA
AB			EQ 100MG BASE	N77663	003	Feb 06, 2007	Jan	NEWA
>A>	AB	GENPHARM	EQ 25MG BASE	N76540	001	Mar 20, 2007	Mar	NEWA
>A>	AB		EQ 50MG BASE	N76540	002	Mar 20, 2007	Mar	NEWA
>A>	AB		EQ 100MG BASE	N76540	003	Mar 20, 2007	Mar	NEWA
AB		INVAGEN PHARMS	EQ 25MG BASE	N77397	001	Feb 06, 2007	Jan	NEWA
AB			EQ 50MG BASE	N77397	002	Feb 06, 2007	Jan	NEWA
AB			EQ 100MG BASE	N77397	003	Feb 06, 2007	Jan	NEWA
AB		LUPIN	EQ 25MG BASE	N77670	001	Feb 06, 2007	Jan	NEWA
AB			EQ 50MG BASE	N77670	002	Feb 06, 2007	Jan	NEWA
AB			EQ 100MG BASE	N77670	003	Feb 06, 2007	Jan	NEWA
AB		MUTUAL PHARM	EQ 25MG BASE	N77818	001	Feb 06, 2007	Jan	NEWA
AB			EQ 50MG BASE	N77818	002	Feb 06, 2007	Jan	NEWA
AB			EQ 100MG BASE	N77818	003	Feb 06, 2007	Jan	NEWA
AB		MYLAN	EQ 25MG BASE	N76671	001	Feb 06, 2007	Jan	NEWA

TABLET; ORAL

SERTRALINE HYDROCHLORIDE

AB	MYLAN	EQ 50MG BASE	N76671 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N76671 003	Feb 06, 2007	Jan	NEWA
AB	PLIVA HRVATSKA DOO	EQ 25MG BASE	N77299 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77299 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77299 003	Feb 06, 2007	Jan	NEWA
AB	RANBAXY	EQ 25MG BASE	N77977 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77977 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77977 003	Feb 06, 2007	Jan	NEWA
		EQ 150MG BASE	N77977 004	Feb 06, 2007	Jan	NEWA
		EQ 200MG BASE	N77977 005	Feb 06, 2007	Jan	NEWA
AB	ROXANE	EQ 25MG BASE	N76881 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N76881 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N76881 003	Feb 06, 2007	Jan	NEWA
AB	SANDOZ	EQ 25MG BASE	N77713 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77713 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77713 003	Feb 06, 2007	Jan	NEWA
AB	SUN PHARM INDS (IN)	EQ 25MG BASE	N78108 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N78108 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N78108 003	Feb 06, 2007	Jan	NEWA
AB	TORRENT PHARMS	EQ 25MG BASE	N77765 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77765 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77765 003	Feb 06, 2007	Jan	NEWA
AB	WATSON LABS	EQ 25MG BASE	N77162 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77162 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77162 003	Feb 06, 2007	Jan	NEWA
AB	ZYDUS PHARMS USA	EQ 25MG BASE	N77106 001	Feb 06, 2007	Jan	NEWA
AB		EQ 50MG BASE	N77106 002	Feb 06, 2007	Jan	NEWA
AB		EQ 100MG BASE	N77106 003	Feb 06, 2007	Jan	NEWA

SODIUM LACTATE

INJECTABLE; INJECTION

SODIUM LACTATE IN PLASTIC CONTAINER

+	HOSPIRA	5MEQ/ML	N18947 001	Sep 05, 1984	Feb	CRLD
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SOMATROPIN RECOMBINANT

INJECTABLE; INJECTION

SAIZEN

BX	EMD SERONO	4MG/VIAL	N19764 005	Jan 16, 2007	Feb	CAHN
BX		5MG/VIAL	N19764 002	Oct 08, 1996	Feb	CAHN
	@	6MG/VIAL	N19764 001	Oct 08, 1996	Feb	CAHN
+		8.8MG/VIAL	N19764 003	Aug 29, 2000	Feb	CAHN
BX	SERONO	4MG/VIAL	N19764 005	Jan 16, 2007	Jan	NEWA
	SEROSTIM					
BX	EMD SERONO	4MG/VIAL	N20604 003	Jul 25, 1997	Feb	CAHN
BX		5MG/VIAL	N20604 002	Aug 23, 1996	Feb	CAHN
BX		6MG/VIAL	N20604 001	Aug 23, 1996	Feb	CAHN
	@	8.8MG/VIAL	N20604 004	Sep 06, 2001	Feb	CAHN
	INJECTABLE; SUBCUTANEOUS					
	SEROSTIM LQ					
	@ EMD SERONO	6MG/0.5ML	N20604 005	Feb 11, 2005	Feb	CAHN

SOTALOL HYDROCHLORIDE

TABLET; ORAL

SOTALOL HYDROCHLORIDE

AB2	MYLAN	80MG	N77616 001	Feb 07, 2007	Jan	NEWA
AB2		120MG	N77616 002	Feb 07, 2007	Jan	NEWA
AB2		160MG	N77616 003	Feb 07, 2007	Jan	NEWA

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

BACTRIM

@	MUTUAL PHARM	80MG/ML;16MG/ML	N18374 001		Feb	DISC
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SUSPENSION; ORAL

BACTRIM PEDIATRIC

@	MUTUAL PHARM	200MG/5ML;40MG/5ML	N17560 002		Feb	DISC
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SEPTRA

@	MONARCH PHARMS	200MG/5ML;40MG/5ML	N17598 001		Feb	DISC
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SEPTRA GRAPE

@	MONARCH PHARMS	200MG/5ML;40MG/5ML	N17598 002	Feb 12, 1986	Feb	DISC
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SULFAMETHOXAZOLE AND TRIMETHOPRIM

@	TEVA	200MG/5ML;40MG/5ML	N18812 002	Jun 10, 1983	Feb	DISC
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@		200MG/5ML;40MG/5ML	N18812 001	Jan 28, 1983	Feb	DISC
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AB	+	TEVA PHARMS	200MG/5ML;40MG/5ML	N77612 001	Nov 13, 2006	Feb	CRLD
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AB		VINTAGE	200MG/5ML;40MG/5ML	N77785 001	Jan 24, 2007	Jan	NEWA
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>D> SULFATRIM

>D>	AB		ACTAVIS MID ATLANTIC	200MG/5ML;40MG/5ML	N18615 002	Jan 07, 1983	Mar	DISC
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>A>		@		200MG/5ML;40MG/5ML	N18615 002	Jan 07, 1983	Mar	DISC
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TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB		VINTAGE	400MG;80MG	N78060 002	Jan 25, 2007	Jan	NEWA
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AB			800MG;160MG	N78060 001	Jan 25, 2007	Jan	NEWA
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SULFASALAZINE

TABLET; ORAL

SULFASALAZINE

@	HERITAGE PHARMS INC	500MG	N80197 001		Feb	CAHN
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SULINDAC

TABLET; ORAL

SULINDAC

@	HERITAGE PHARMS INC	150MG	N73262 002	Sep 06, 1991	Feb	CAHN
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@		200MG	N73262 001	Sep 06, 1991	Feb	CAHN
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TAMOXIFEN CITRATE

TABLET; ORAL

NOLVADEX

>D>	AB		ASTRAZENECA	EQ 10MG BASE	N17970 001		Mar	DISC
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>A>		@		EQ 10MG BASE	N17970 001		Mar	DISC
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>D>	AB	+		EQ 20MG BASE	N17970 002	Mar 21, 1994	Mar	DISC
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>A>		@		EQ 20MG BASE	N17970 002	Mar 21, 1994	Mar	DISC
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TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION

DRAXIMAGE MDP-10

AP	+	DRAXIMAGE	N/A	N18035 001		Jan	CTNA
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INJECTABLE; INJECTION

DRAXIMAGE MDP-25

+	DRAXIMAGE	N/A	N18035	002	Feb 27, 2004	Jan	NEWA
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>D> TEGASEROD MALEATE

>D> TABLET; ORAL

>D> ZELNORM

>D>	NOVARTIS	EQ 2MG BASE	N21200	001	Jul 24, 2002	Mar	DISC
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>A>	@	EQ 2MG BASE	N21200	001	Jul 24, 2002	Mar	DISC
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>D>	+	EQ 6MG BASE	N21200	002	Jul 24, 2002	Mar	DISC
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>A>	@	EQ 6MG BASE	N21200	002	Jul 24, 2002	Mar	DISC
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TERCONAZOLE

SUPPOSITORY; VAGINAL

TERCONAZOLE

AB	TARO	80MG	N77553	001	Mar 09, 2007	Feb	NEWA
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THALIDOMIDE

CAPSULE; ORAL

THALOMID

CELGENE

150MG

N20785	004	Jan 10, 2007	Jan	NEWA
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THEOPHYLLINE

TABLET; ORAL

QUIBRON-T

@ MONARCH PHARMS

300MG

N88656	001	Aug 22, 1985	Feb	DISC
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THEOLAIR

>D>	+	3M	125MG	N86399	001	Mar	CAHN
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>D>	+		250MG	N86399	002	Mar	CAHN
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>A>	+	GRACEWAY	125MG	N86399	001	Mar	CAHN
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>A>	+		250MG	N86399	002	Mar	CAHN
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TABLET, EXTENDED RELEASE; ORAL

QUIBRON-T/SR

@ MONARCH PHARMS

300MG

N87563	001	Jun 21, 1983	Feb	DISC
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TOLCAPONE

TABLET; ORAL

TASMAR

VALEANT PHARM INTL

100MG

N20697	001	Jan 29, 1998	Jan	CAHN
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+		200MG	N20697	002	Jan 29, 1998	Jan	CAHN
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TRAMADOL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

ULTRAM ER

BIOVAIL LABS INTL

100MG

N21692	001	Sep 08, 2005	Feb	CTNA
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200MG

N21692	002	Sep 08, 2005	Feb	CTNA
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+		300MG	N21692	003	Sep 08, 2005	Feb	CTNA
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TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HYDROCHLORIDE

>A>	AB	APOTEX	50MG	N71258	001	Mar 25, 1987	Mar	CAHN
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>D>	AB	BARR	50MG	N71258	001	Mar 25, 1987	Mar	CAHN
-----	----	------	------	--------	-----	--------------	-----	------

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

KENALOG

>D>	AT	+	APOTHECON	0.5%	N83943 001			Mar	DISC
>A>			@	0.5%	N83943 001			Mar	DISC

VALACYCLOVIR HYDROCHLORIDE

TABLET; ORAL

VALACYCLOVIR HYDROCHLORIDE

AB			RANBAXY	EQ 500MG BASE	N76588 001	Jan 31, 2007	Jan	NEWA
AB				EQ 1GM BASE	N76588 002	Jan 31, 2007	Jan	NEWA
			VALTREX					
AB			GLAXOSMITHKLINE	EQ 500MG BASE	N20487 001	Jun 23, 1995	Jan	CFTG
AB		+		EQ 1GM BASE	N20487 002	Jun 23, 1995	Jan	CFTG

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION

ISOPTIN

@ FSC

2.5MG/ML

N18485 001

Feb DISC

VERAPAMIL HYDROCHLORIDE

@ LUITPOLD

2.5MG/ML

N70225 001

Nov 12, 1985

Feb DISC

AP		+		2.5MG/ML	N70617 001	Nov 12, 1985	Feb	CRLD
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TABLET; ORAL

CALAN

AB		+	GD SEARLE LLC	120MG	N18817 002	Sep 10, 1984	Feb	CRLD
----	--	---	---------------	-------	------------	--------------	-----	------

ISOPTIN

@ FSC

40MG

N18593 003

Nov 23, 1987

Feb DISC

@

80MG

N18593 001

Mar 08, 1982

Feb DISC

@

120MG

N18593 002

Mar 08, 1982

Feb DISC

VERAPAMIL HYDROCHLORIDE

@ HERITAGE PHARMS INC

80MG

N71880 001

Apr 05, 1988

Feb CAHN

@

120MG

N71881 001

Apr 05, 1988

Feb CAHN

ZONISAMIDE

CAPSULE; ORAL

ZONISAMIDE

AB			COREPHARMA	25MG	N77876 001	Feb 21, 2007	Feb	NEWA
AB				50MG	N77876 002	Feb 21, 2007	Feb	NEWA
AB				100MG	N77876 003	Feb 21, 2007	Feb	NEWA

OTC DRUG PRODUCT LIST - 27TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 3 - March 2007

2-1

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SPONGE; TOPICAL

CHLORAPREP ONE-STEP

+	ENTURIA INC	2%;70% (10.5ML)	N20832 004	Aug 20, 2003	Jan	CAHN
+		2%;70% (3ML)	N20832 001	Jul 14, 2000	Jan	CAHN
+		2%;70% (26ML)	N20832 006	Nov 21, 2006	Jan	CAHN

CHLORAPREP ONE-STEP FREPP

+	ENTURIA INC	2%;70% (1.5ML)	N20832 003	Apr 26, 2002	Jan	CAHN
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CHLORAPREP WITH TINT

+	ENTURIA INC	2%;70% (3ML)	N20832 007	Oct 10, 2006	Feb	NEWA
+		2%;70% (26ML)	N20832 002	May 03, 2005	Jan	CAHN
+		2%;70% (10.5ML)	N20832 005	Apr 03, 2006	Jan	CAHN

SWAB; TOPICAL

CHLORAPREP ONE-STEP SEPP

+	ENTURIA INC	2%;70% (0.67ML)	N21555 001	Oct 07, 2002	Jan	CAHN
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CHLORAPREP SINGLE SWABSTICK

+	ENTURIA INC	2%;70% (1.75ML)	N21555 002	May 10, 2005	Jan	CAHN
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DOXYLAMINE SUCCINATE

TABLET; ORAL

UNISOM

+	CHATTEM	25MG	N18066 001		Feb	CAHN
+	MCNEIL CONS	25MG	N18066 001		Jan	CAHN

FAMOTIDINE

TABLET, CHEWABLE; ORAL

FAMOTIDINE

>D>	PERRIGO	10MG	N75715 001	Aug 22, 2003	Mar	CRLD
>A>	+	10MG	N75715 001	Aug 22, 2003	Mar	CRLD
>D>	PEPCID AC					
>D>	+	MERCK	N20801 001	Sep 24, 1998	Mar	DISC
>A>	@	10MG	N20801 001	Sep 24, 1998	Mar	DISC

IBUPROFEN

CAPSULE; ORAL

ADVIL LIQUI-GELS

+	WYETH CONS	EQ 200MG FREE ACID AND POTASSIUM SALT	N20402 001	Apr 20, 1995	Jan	CAIN
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ADVIL MIGRAINE LIQUI-GELS

+	WYETH CONS	EQ 200MG FREE ACID AND POTASSIUM SALT	N20402 002	Mar 16, 2000	Jan	CAIN
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KETOTIFEN FUMARATE

SOLUTION/DROPS; OPHTHALMIC

ALAWAY

+	BAUSCH AND LOMB	EQ 0.025% BASE	N21996 001	Dec 01, 2006	Jan	CAHN
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LOPERAMIDE HYDROCHLORIDE

TABLET, CHEWABLE; ORAL

IMODIUM A-D EZ CHEWS

+	MCNEIL	2MG	N20448 001	Jul 24, 1997	Jan	CTNA
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NONOXYNOL-9

SPONGE; VAGINAL
TODAY

+ ALLENDALE PHARMS 1GM N18683 001 Apr 01, 1983 Feb CMFD

ORLISTAT

CAPSULE; ORAL
ALLI

+ GLAXOSMITHKLINE CONS 60MG N21887 001 Feb 07, 2007 Feb NEWA

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
SUDAFED 12 HOUR

>A> + MCNEIL CONS 120MG N73585 001 Oct 31, 1991 Mar CAHN
>D> + WARNER LAMBERT 120MG N73585 001 Oct 31, 1991 Mar CAHN

RANITIDINE HYDROCHLORIDE

TABLET, EFFERVESCENT; ORAL
ZANTAC 75

@ BOEHRINGER INGELHEIM EQ 75MG BASE N20745 001 Feb 26, 1998 Feb CAHN

TABLET; ORAL
ZANTAC 150

+ BOEHRINGER INGELHEIM EQ 150MG BASE N21698 001 Aug 31, 2004 Jan CAHN

ZANTAC 75
BOEHRINGER INGELHEIM EQ 75MG BASE N20520 001 Dec 19, 1995 Jan CAHN

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

CUMULATIVE SUPPLEMENT NUMBER 03 MARCH 2007

NO MARCH 2007 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 2007 ADDITIONS

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

See report footnotes for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>ALBUTEROL SULFATE - VENTOLIN HFA</u>					
020983 001	6558651	Dec 19, 2016	DP		
	6743413	Jun 01, 2021	DP	U-716	
<u>ALISKIREN HEMIFUMARATE - TEKTURNA</u>					
021985 001				>A> NCE	Mar 05, 2012
<u>ALISKIREN HEMIFUMARATE - TEKTURNA</u>					
021985 002				>A> NCE	Mar 05, 2012
<u>ANIDULAFUNGIN - ERAXIS</u>					
021632 002	5965525	Oct 12, 2016	DS DP	U-540	
	6384013	Mar 19, 2012	DS		
	6743777	Mar 19, 2012		DP U-540	
	6960564	Apr 12, 2021		DP U-540	
<u>ARFORMOTEROL TARTRATE - BROVANA</u>					
021912 001	5795564	Apr 03, 2012		U-793	
	6068833	Apr 03, 2012		U-793	
	6589508	Apr 03, 2012		U-793	
	6866839	Apr 03, 2012		U-793	
<u>ASCORBIC ACID; POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM ASCORBATE; SODIUM CHLORIDE; SODIUM SULFATE - MOVIPREP</u>					
021881 001	7169381	Sep 01, 2024	DS DP		
<u>ATORVASTATIN CALCIUM - LIPITOR</u>					
020702 001				I-523	Mar 02, 2010
<u>ATORVASTATIN CALCIUM - LIPITOR</u>					
020702 002				I-523	Mar 02, 2010
<u>ATORVASTATIN CALCIUM - LIPITOR</u>					
020702 003				I-523	Mar 02, 2010
<u>ATORVASTATIN CALCIUM - LIPITOR</u>					
020702 004				I-523	Mar 02, 2010
<u>AVOBENZONE; ECAMSULE; OCTOCRYLENE - CAPITAL SOLEIL 15</u>					
021501 001				NC NP	Jul 21, 2009 Oct 02, 2009
<u>AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE - ANTHELIOS 20</u>					
021471 001				NC	Oct 05, 2009
<u>BALSALAZIDE DISODIUM - COLAZAL</u>					
020610 001				ODE >A> PED	Dec 20, 2013 Jun 20, 2014
<u>BORTEZOMIB - VELCADE</u>					
021602 001	>A> 5780454	May 03, 2017	DP		
<u>BOSENTAN - TRACLEER</u>					
021290 001				M-64	Feb 15, 2010
<u>BOSENTAN - TRACLEER</u>					
021290 002				M-64	Feb 15, 2010
<u>BUDESONIDE - PULMICORT RESPULES</u>					
020929 001	6899099	Dec 23, 2018		U-645	
<u>BUDESONIDE - PULMICORT RESPULES</u>					
020929 002	6899099	Dec 23, 2018		U-645	
<u>BUPROPION HYDROCHLORIDE - BUPROPION HYDROCHLORIDE</u>					
077284 002				PC	Jun 12, 2007
<u>BUPROPION HYDROCHLORIDE - BUPROPION HYDROCHLORIDE</u>					
077415 002				PC	Jun 12, 2007
<u>CARVEDILOL - COREG</u>					
020297 001				>A> M-61 >A> PED	Feb 23, 2010 Aug 23, 2010
<u>CARVEDILOL - COREG</u>					
020297 002				>A> M-61 >A> PED	Feb 23, 2010 Aug 23, 2010

**PRESCRIPTION AND OTC DRUG PRODUCT
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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>CARVEDILOL - COREG</u>					
020297 003				>A> M-61 >A> PED	Feb 23, 2010 Aug 23, 2010
<u>CARVEDILOL - COREG</u>					
020297 004				>A> M-61 >A> PED	Feb 23, 2010 Aug 23, 2010
<u>CELECOXIB - CELEBREX</u>					
020998 004	5466823	Nov 30, 2013	DS	I-466	Jul 29, 2008
	5466823*PED	May 30, 2014		NPP	Dec 15, 2009
	5563165	Nov 30, 2013	DP	PED	Jun 15, 2010
	5563165*PED	May 30, 2014		PED	Jan 29, 2009
	5760068	Jun 02, 2015		U-672	
	5760068*PED	Dec 02, 2015			
<u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - CHLORAPREP ONE-STEP</u>					
020832 006	6991394	Jan 31, 2024	DP		
<u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - CHLORAPREP WITH TINT</u>					
020832 002	6991394	Jan 31, 2024	DP		
<u>CICLESONIDE - OMNARIS</u>					
022004 001	5482934	Jan 09, 2013	DS DP	U-557	
	6767901	Oct 21, 2020	DP		
	6939559	Apr 21, 2019	DP		
<u>CLOBETASOL PROPIONATE - OLUX E</u>					
022013 001	6730288	Sep 08, 2019	DP	NP	Jan 12, 2010
	7029659	Sep 08, 2019	DP		
<u>CLOZAPINE - FAZACLO ODT</u>					
021590 001	>A> 5178878	Jan 12, 2010	DP		
<u>CLOZAPINE - FAZACLO ODT</u>					
021590 002	>A> 5178878	Jan 12, 2010	DP		
<u>CLOZAPINE - FAZACLO ODT</u>					
021590 003	>A> 5178878	Jan 12, 2010	DP		
<u>COLESTIPOL HYDROCHLORIDE - COLESTIPOL HYDROCHLORIDE</u>					
077510 001				PC	Jun 12, 2007
<u>CONIVAPTAN HYDROCHLORIDE - VAPRISOL</u>					
021697 001				>A> I-526	Feb 28, 2010
<u>CYCLOBENZAPRINE HYDROCHLORIDE - AMRIX</u>					
021777 001				NDF	Feb 01, 2010
<u>CYCLOBENZAPRINE HYDROCHLORIDE - AMRIX</u>					
021777 002				NDF	Feb 01, 2010
<u>DASATINIB - SPRYCEL</u>					
021986 001	7153856	Apr 28, 2020		U-780	
<u>DASATINIB - SPRYCEL</u>					
021986 002	7153856	Apr 28, 2020		U-780	
<u>DASATINIB - SPRYCEL</u>					
021986 003	7153856	Apr 28, 2020		U-780	
<u>DECITABINE - DACOGEN</u>					
021790 001				ODE	May 02, 2013
<u>DEXMETHYLPHENIDATE HYDROCHLORIDE - FOCALIN XR</u>					
021802 004	5837284	Dec 04, 2015	DP		
	5908850	Dec 04, 2015		U-678	
	6228398	Nov 01, 2019	DP	U-676	
	6528530	Dec 04, 2015	DP		
	6635284	Dec 04, 2015	DP	U-677	
	6730325	Nov 01, 2019	DP	U-676	
<u>DICLOFENAC EPOLAMINE - FLECTOR</u>					
021234 001	4948805	Nov 09, 2007	DS	NE	Jan 31, 2010
	5607690	Apr 13, 2014	DP	NDF	Jan 31, 2010

**PRESCRIPTION AND OTC DRUG PRODUCT
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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>DROSPIRENONE; ETHINYL ESTRADIOL - YAZ</u>					
021676 001	7163931	Dec 20, 2021	U-1	I-522	Jan 26, 2010
<u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>					
021427 001	>A> 5023269	Jun 11, 2008	DS DP U-795	I-524	Feb 23, 2010
	>A> 5023269	Jun 11, 2008	DS DP U-799		
	>A> 5023269	Jun 11, 2008	DS DP U-797		
	>A> 5023269	Jun 11, 2008	DS DP U-796		
	>A> 5023269	Jun 11, 2008	DS DP U-605		
<u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>					
021427 002	>A> 5023269	Jun 11, 2008	DS DP U-797	I-524	Feb 23, 2010
	>A> 5023269	Jun 11, 2008	DS DP U-799		
	>A> 5023269	Jun 11, 2008	DS DP U-796		
	>A> 5023269	Jun 11, 2008	DS DP U-795		
	>A> 5023269	Jun 11, 2008	DS DP U-605		
<u>DULOXETINE HYDROCHLORIDE - CYMBALTA</u>					
021427 004	>A> 5023269	Jun 11, 2008	DS DP U-795	I-524	Feb 23, 2010
	>A> 5023269	Jun 11, 2008	DS DP U-797		
	>A> 5023269	Jun 11, 2008	DS DP U-799		
	>A> 5023269	Jun 11, 2008	DS DP U-796		
	>A> 5023269	Jun 11, 2008	DS DP U-605		
<u>EMTRICITABINE - EMTRIVA</u>					
021500 001	5210085	May 11, 2010		U-257	
	5814639	Sep 29, 2015	DS DP		
	5914331	Sep 29, 2015	DS		
<u>ENTECAVIR - BARACLUDE</u>					
021798 001	>A> 5908638	Jul 26, 2015	DP		
<u>EPLERENONE - INSPRA</u>					
021437 001	>A> 4559332	Aug 11, 2007	DS DP U-537		
	7157101	Dec 08, 2019	DP U-664		
<u>EPLERENONE - INSPRA</u>					
021437 002	>A> 4559332	Aug 11, 2007	DS DP U-537		
	7157101	Dec 08, 2019	DP U-664		
<u>EPLERENONE - INSPRA</u>					
021437 003	>A> 4559332	Aug 11, 2007	DS DP U-537		
	7157101	Dec 08, 2019	DP U-664		
<u>ERTAPENEM SODIUM - INVANZ</u>					
021337 001	>A> 5478820	Nov 21, 2015	DS DP U-160		
	>A> 5478820*PED	May 21, 2016			
<u>ESTRADIOL; NORETHINDRONE ACETATE - ACTIVELLA</u>					
020907 002				D-104 I-525	Dec 28, 2009 Dec 29, 2009
<u>ESTROGENS, CONJUGATED SYNTHETIC A - CENESTIN</u>					
020992 001	>A> 5908638	Jul 26, 2015	DP		
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 001				M-63	Feb 06, 2010
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 002				M-63	Feb 06, 2010
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 003				M-63	Feb 06, 2010
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 004				M-63	Feb 06, 2010
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 005				M-63	Feb 06, 2010
<u>FENTANYL CITRATE - ACTIQ</u>					
020747 006				M-63	Feb 06, 2010

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

See report footnotes for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>FENTANYL CITRATE - FENTORA</u>					
021947 006				>A> NDF	Sep 25, 2009
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>					
021520 002	5229382	Apr 23, 2011	DS DP	NC	Dec 24, 2006
	5229382*PED	Oct 23, 2011		PED	Jun 24, 2007
	5945416	Mar 24, 2017	DS DP		
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>					
021520 003	5229382	Apr 23, 2011	DS DP	NC	Dec 24, 2006
	5229382*PED	Oct 23, 2011		PED	Jun 24, 2007
	5945416	Mar 24, 2017	DS DP		
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>					
021520 004	5229382	Apr 23, 2011	DS DP	NC	Dec 24, 2006
	5229382*PED	Oct 23, 2011		PED	Jun 24, 2007
	5945416	Mar 24, 2017	DS DP		
<u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u>					
021520 005	5229382	Apr 23, 2011	DS DP	NC	Dec 24, 2006
	5229382*PED	Oct 23, 2011		PED	Jun 24, 2007
	5945416	Mar 24, 2017	DS DP		
<u>FORMOTEROL FUMARATE - FORADIL CERTIHALER</u>					
021592 001	6182655	Dec 05, 2016	DP	NP	Dec 15, 2009
	6645466	Nov 10, 2019	DP		
<u>GALANTAMINE HYDROBROMIDE - RAZADYNE ER</u>					
021615 001	7160559	Dec 20, 2019	DP		
<u>GALANTAMINE HYDROBROMIDE - RAZADYNE ER</u>					
021615 002	7160559	Dec 20, 2019	DP		
<u>GALANTAMINE HYDROBROMIDE - RAZADYNE ER</u>					
021615 003	7160559	Dec 20, 2019	DP		
<u>HYDROCHLOROTHIAZIDE; VALSARTAN - DIOVAN HCT</u>					
020818 004	5399578	Mar 21, 2012	DS DP	U-3	
	6294197	Jun 18, 2017	DP	U-3	
<u>HYDROCHLOROTHIAZIDE; VALSARTAN - DIOVAN HCT</u>					
020818 005	5399578	Mar 21, 2012	DS DP	U-3	
	6294197	Jun 18, 2017	DP	U-3	
<u>HYDROXOCOBALAMIN - CYANOKIT</u>					
022041 002	5834448	Nov 14, 2016	DP	U-789	Dec 15, 2013
<u>IBANDRONATE SODIUM - BONIVA</u>					
021455 001	>A> 4927814	Jul 09, 2008	DS DP	U-700	
	>A> 4927814	Jul 09, 2008	DS DP	U-642	
<u>IBANDRONATE SODIUM - BONIVA</u>					
021455 002	>A> 4927814	Jul 09, 2008	DS DP	U-700	
	>A> 4927814	Jul 09, 2008	DS DP	U-642	
	>A> 7192938	May 06, 2023		U-798	
<u>IBUPROFEN LYSINE - NEOPROFEN</u>					
021903 001	6342530	Nov 14, 2020	DS DP	U-794	
	6344479	Mar 20, 2021	DS DP	U-794	
<u>IMATINIB MESYLATE - GLEEVEC</u>					
021335 001	6958335	Dec 19, 2021		U-791	
	6958335*PED	Jun 19, 2022			
<u>IMATINIB MESYLATE - GLEEVEC</u>					
021335 002	6958335	Dec 19, 2021		U-791	
	6958335*PED	Jun 19, 2022			
<u>IMATINIB MESYLATE - GLEEVEC</u>					
021588 001	6958335	Dec 19, 2021		U-791	
	6958335*PED	Jun 19, 2022			

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

See report footnotes for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>IMATINIB MESYLATE - GLEEVEC</u>					
021588 002	6958335	Dec 19, 2021	U-791		
	6958335*PED	Jun 19, 2022			
<u>IRON SUCROSE - VENOFER</u>					
021135 004				>A> I-474	Oct 17, 2008
				>A> I-459	Jun 17, 2008
<u>KETOCONAZOLE - XOLEGEL</u>					
021946 001	7179475	Dec 04, 2018	DP U-792		
<u>LAMOTRIGINE - LAMICTAL</u>					
020241 001	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
<u>LAMOTRIGINE - LAMICTAL</u>					
020241 002	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
<u>LAMOTRIGINE - LAMICTAL</u>					
020241 003	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
<u>LAMOTRIGINE - LAMICTAL</u>					
020241 004	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
<u>LAMOTRIGINE - LAMICTAL</u>					
020241 005	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
<u>LAMOTRIGINE - LAMICTAL</u>					
020241 006	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
<u>LAMOTRIGINE - LAMICTAL CD</u>					
020764 001	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
	5698226	Jan 29, 2012			
	5698226*PED	Jul 29, 2012			
<u>LAMOTRIGINE - LAMICTAL CD</u>					
020764 002	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
	5698226	Jan 29, 2012			
	5698226*PED	Jul 29, 2012			
<u>LAMOTRIGINE - LAMICTAL CD</u>					
020764 003	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
	5698226	Jan 29, 2012			
	5698226*PED	Jul 29, 2012			
<u>LAMOTRIGINE - LAMICTAL CD</u>					
020764 004	4602017	Jul 22, 2008	U-106	I-516	Sep 22, 2009
	4602017*PED	Jan 22, 2009		PED	Mar 22, 2010
	5698226	Jan 29, 2012			
	5698226*PED	Jul 29, 2012			
<u>LAPATINIB DITOSYLATE - TYKERB</u>					
022059 001				>A> NCE	Mar 13, 2012
<u>LATANOPROST - XALATAN</u>					
020597 001	7163959	Jun 19, 2010	DS		
<u>LENALIDOMIDE - REVLIMID</u>					
021880 001	>A> 7189740	Apr 11, 2023	U-769		
<u>LENALIDOMIDE - REVLIMID</u>					
021880 002	>A> 7189740	Apr 11, 2023	U-769		

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<u>LENALIDOMIDE - REVLIMID</u>					
021880 003	>A> 7189740	Apr 11, 2023	U-769		
<u>LENALIDOMIDE - REVLIMID</u>					
021880 004	>A> 7189740	Apr 11, 2023	U-769		
<u>LEVOFLOXACIN - LEVAQUIN</u>					
020634 001	>A> 5053407	Dec 20, 2010		>A> D-100	Aug 04, 2008
	>A> 5053407*PED	Jun 20, 2011		>A> D-83	Oct 23, 2006
				>A> PED	Feb 04, 2009
				>A> PED	Apr 23, 2007
<u>LEVOFLOXACIN - LEVAQUIN</u>					
020634 002	>A> 5053407	Dec 20, 2010		>A> D-100	Aug 04, 2008
	>A> 5053407*PED	Jun 20, 2011		>A> D-83	Oct 23, 2006
				>A> PED	Feb 04, 2009
				>A> PED	Apr 23, 2007
<u>LEVOFLOXACIN - LEVAQUIN</u>					
020634 003	>A> 5053407	Dec 20, 2010		>A> D-100	Aug 04, 2008
	>A> 5053407*PED	Jun 20, 2011		>A> D-83	Oct 23, 2006
				>A> PED	Apr 23, 2007
				>A> PED	Feb 04, 2009
<u>LEVOFLOXACIN - LEVAQUIN</u>					
020635 001	>A> 5043407*PED	Jun 20, 2011		>A> D-100	Aug 04, 2008
	>A> 5053407	Dec 20, 2010		>A> D-83	Oct 23, 2006
				>A> PED	Feb 04, 2009
				>A> PED	Apr 23, 2007
<u>LEVOFLOXACIN - LEVAQUIN</u>					
020635 004	>A> 5043407*PED	Jun 20, 2011		>A> D-100	Aug 04, 2008
	>A> 5053407	Dec 20, 2010		>A> D-83	Oct 23, 2006
				>A> PED	Apr 23, 2007
				>A> PED	Feb 04, 2009
<u>LEVOFLOXACIN - LEVAQUIN</u>					
021721 001	>A> 5053407	Dec 20, 2010	DS	U-36	>A> D-100
	>A> 5053407*PED	Jun 20, 2011			>A> PED
	>A> 6806256	Feb 26, 2022	DP		
	>A> 6806256*PED	Aug 26, 2022			
<u>LEVOFLOXACIN - LEVAQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER</u>					
020635 002	>A> 5043407*PED	Jun 20, 2011		>A> D-100	Aug 04, 2008
	>A> 5053407	Dec 20, 2010		>A> D-83	Oct 23, 2006
				>A> PED	Feb 04, 2009
				>A> PED	Apr 23, 2007
<u>LEVOFLOXACIN - LEVAQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER</u>					
020635 003	>A> 5043407*PED	Jun 20, 2011		>A> D-100	Aug 04, 2008
	>A> 5053407	Dec 20, 2010		>A> D-83	Oct 23, 2006
				>A> PED	Feb 04, 2009
				>A> PED	Apr 23, 2007
<u>LEVOFLOXACIN - LEVAQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER</u>					
020635 005	>A> 5043407*PED	Jun 20, 2011		>A> D-100	Aug 04, 2008
	>A> 5053407	Dec 20, 2010		>A> D-83	Oct 23, 2006
				>A> PED	Apr 23, 2007
				>A> PED	Feb 04, 2009
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>					
021977 001	>A> 7105486	Jun 29, 2023	U-727	NCE	Feb 23, 2012
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>					
021977 002	>A> 7105486	Jun 29, 2023	U-727	NCE	Feb 23, 2012
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>					
021977 003	>A> 7105486	Jun 29, 2023	U-727	NCE	Feb 23, 2012
<u>LOPERAMIDE HYDROCHLORIDE - IMODIUM A-D EZ CHEWS</u>					
020448 001	5489436	Feb 06, 2013		DP	
	6814978	Aug 26, 2021		DP	
<u>LOPINAVIR; RITONAVIR - KALETRA</u>					
021251 001	5914332	Dec 13, 2015	U-351		

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<u>LOPINAVIR; RITONAVIR - KALETRA</u>					
021906 001	7148359	Jul 19, 2019	DP		
<u>MESALAMINE - LIALDA</u>					
022000 001	6773720	Jun 08, 2020	DP	NP	Jan 16, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 001				M-62	Jan 31, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 002				M-62	Jan 31, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 003				M-62	Jan 31, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 004				M-62	Jan 31, 2010
<u>METFORMIN HYDROCHLORIDE; ROSIGLITAZONE MALEATE - AVANDAMET</u>					
021410 005				M-62	Jan 31, 2010
<u>MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE - VUSION</u>					
021026 001	>A> 4911932	Mar 27, 2008	DP	U-718	
<u>MOXIFLOXACIN HYDROCHLORIDE - VIGAMOX</u>					
021598 001	6716830	Sep 29, 2019	DP		
<u>OLANZAPINE - ZYPREXA</u>					
020592 001	5229382	Apr 23, 2011	DS DP	U-547	I-417
	5229382	Apr 23, 2011	DS DP	U-149	PED
	5229382*PED	Oct 23, 2011			
<u>OLANZAPINE - ZYPREXA</u>					
020592 002	5229382	Apr 23, 2011	DS DP	U-547	I-417
	5229382	Apr 23, 2011	DS DP	U-149	PED
	5229382*PED	Oct 23, 2011			
<u>OLANZAPINE - ZYPREXA</u>					
020592 003	5229382	Apr 23, 2011	DS DP	U-547	I-417
	5229382	Apr 23, 2011	DS DP	U-149	PED
	5229382*PED	Oct 23, 2011			
<u>OLANZAPINE - ZYPREXA</u>					
020592 004	5229382	Apr 23, 2011	DS DP	U-547	I-417
	5229382	Apr 23, 2011	DS DP	U-149	PED
	5229382*PED	Oct 23, 2011			
<u>OLANZAPINE - ZYPREXA</u>					
020592 005	5229382	Apr 23, 2011	DS DP	U-547	I-417
	5229382	Apr 23, 2011	DS DP	U-149	PED
	5229382*PED	Oct 23, 2011			
<u>OLANZAPINE - ZYPREXA</u>					
020592 006	5229382	Apr 23, 2011	DS DP	U-547	I-417
	5229382	Apr 23, 2011	DS DP	U-149	PED
	5229382*PED	Oct 23, 2011			
<u>OLANZAPINE - ZYPREXA</u>					
021253 001	5229382	Apr 23, 2011	DS DP	U-571	NP
	5229382*PED	Oct 23, 2011			NDF
					PED
					PED
<u>OLANZAPINE - ZYPREXA ZYDIS</u>					
021086 001	5229382	Apr 23, 2011		U-324	I-400
	5229382*PED	Oct 23, 2011			I-417
					PED
					PED
<u>OLANZAPINE - ZYPREXA ZYDIS</u>					
021086 002	5229382	Apr 23, 2011		U-324	I-400
	5229382*PED	Oct 23, 2011			I-417
					PED
					PED

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<u>OLANZAPINE - ZYPREXA ZYDIS</u>					
021086 003	5229382	Apr 23, 2011	U-324	I-400	Jul 10, 2006
	5229382*PED	Oct 23, 2011		I-417	Jan 14, 2007
				PED	Jan 10, 2007
				PED	Jul 14, 2007
<u>OLANZAPINE - ZYPREXA ZYDIS</u>					
021086 004	5229382	Apr 23, 2011	U-324	I-400	Jul 10, 2006
	5229382*PED	Oct 23, 2011		I-417	Jan 14, 2007
				PED	Jan 10, 2007
				PED	Jul 14, 2007
<u>ONDANSETRON - ONDANSETRON</u>					
076506 001				PC	Jun 24, 2007
<u>ONDANSETRON - ONDANSETRON</u>					
076506 002				PC	Jun 24, 2007
<u>ONDANSETRON HYDROCHLORIDE - ONDANSETRON HYDROCHLORIDE</u>					
076183 001				PC	Jun 24, 2007
<u>ONDANSETRON HYDROCHLORIDE - ONDANSETRON HYDROCHLORIDE</u>					
076183 002				PC	Jun 24, 2007
<u>ONDANSETRON HYDROCHLORIDE - ONDANSETRON HYDROCHLORIDE</u>					
076183 003				PC	Jun 24, 2007
<u>ORLISTAT - ALLI</u>					
021887 001	>A> 4598089	Jun 18, 2009	DS DP	>A> NP	Feb 07, 2010
	>A> 6004996	Jan 06, 2018	DP		
<u>OXALIPLATIN - ELOXATIN</u>					
021492 001				M-61	Jan 10, 2010
				PED	Jul 10, 2010
<u>OXALIPLATIN - ELOXATIN</u>					
021492 002				M-61	Jan 10, 2010
				PED	Jul 10, 2010
<u>OXALIPLATIN - ELOXATIN</u>					
021759 001	5420319	Aug 09, 2016	DS		
	5420319*PED	Feb 09, 2017			
<u>OXALIPLATIN - ELOXATIN</u>					
021759 002	5420319	Aug 09, 2016	DS		
	5420319*PED	Feb 09, 2017			
<u>OXALIPLATIN - ELOXATIN</u>					
021759 003	5290961	Jan 12, 2013	DS		
	5290961*PED	Jul 12, 2013			
	5338874	Apr 07, 2013	DS		
	5338874*PED	Oct 07, 2013			
	5420319	Aug 09, 2016	DS		
	5420319*PED	Feb 09, 2017			
	5716988	Aug 07, 2015		DP	
	5716988*PED	Feb 07, 2016			
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021014 001	7037525	Feb 12, 2018		U-724	
	7037525*PED	Aug 12, 2018			
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021014 002	7037525	Feb 12, 2018		U-724	
	7037525*PED	Aug 12, 2018			
<u>OXCARBAZEPINE - TRILEPTAL</u>					
021014 003	7037525	Feb 12, 2018		U-724	
	7037525*PED	Aug 12, 2018			
<u>OXYBUTYNIN - OXYTROL</u>					
021351 002	7179483	Apr 26, 2020	DS DP	U-318	
<u>PALIPERIDONE - INVEGA</u>					
021999 001	5158952	Oct 27, 2009	DP	U-90	

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<u>PALIPERIDONE - INVEGA</u>					
021999 002	5158952	Oct 27, 2009	DP U-90		
<u>PALIPERIDONE - INVEGA</u>					
021999 003	5158952	Oct 27, 2009	DP U-90		
<u>PALIPERIDONE - INVEGA</u>					
021999 004	5158952	Oct 27, 2009	DP U-90		
<u>PAROXETINE HYDROCHLORIDE - PAROXETINE HYDROCHLORIDE</u>					
077395 001				PC	Jun 10, 2007
<u>PAROXETINE HYDROCHLORIDE - PAXIL CR</u>					
020936 001	5789449	Jan 06, 2009	U-788		
	5789449*PED	Jul 06, 2009			
<u>PAROXETINE HYDROCHLORIDE - PAXIL CR</u>					
020936 002	5789449	Jan 06, 2009	U-788		
	5789449*PED	Jul 06, 2009			
<u>PAROXETINE HYDROCHLORIDE - PAXIL CR</u>					
020936 003	5789449	Jan 06, 2009	U-788		
	5789449*PED	Jul 06, 2009			
<u>RANITIDINE HYDROCHLORIDE - RANITIDINE HYDROCHLORIDE</u>					
076124 001				>A> PC	Sep 15, 2007
<u>RISPERIDONE - RISPERDAL</u>					
020272 001	4804663	Dec 29, 2007	U-90	I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008		I-413	Dec 04, 2006
				I-412	Dec 04, 2006
				PED	Jun 04, 2007
				PED	Jun 04, 2007
				PED	Apr 06, 2010
<u>RISPERIDONE - RISPERDAL</u>					
020272 002	4804663	Dec 29, 2007	U-90	I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008		I-413	Dec 04, 2006
				I-412	Dec 04, 2006
				PED	Jun 04, 2007
				PED	Jun 04, 2007
				PED	Apr 06, 2010
<u>RISPERIDONE - RISPERDAL</u>					
020272 003	4804663	Dec 29, 2007	U-90	I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008		I-413	Dec 04, 2006
				I-412	Dec 04, 2006
				PED	Jun 04, 2007
				PED	Jun 04, 2007
				PED	Apr 06, 2010
<u>RISPERIDONE - RISPERDAL</u>					
020272 004	4804663	Dec 29, 2007	U-90	I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008		I-413	Dec 04, 2006
				I-412	Dec 04, 2006
				PED	Jun 04, 2007
				PED	Jun 04, 2007
				PED	Apr 06, 2010
<u>RISPERIDONE - RISPERDAL</u>					
020272 005	4804663	Dec 29, 2007	U-90	I-413	Dec 04, 2006
	4804663*PED	Jun 29, 2008		I-412	Dec 04, 2006
				PED	Jun 04, 2007
				PED	Jun 04, 2007
<u>RISPERIDONE - RISPERDAL</u>					
020272 007	4804663	Dec 29, 2007	U-90	I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008		I-413	Dec 04, 2006
				I-412	Dec 04, 2006
				PED	Jun 04, 2007
				PED	Jun 04, 2007
				PED	Apr 06, 2010

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<u>RISPERIDONE - RISPERDAL</u>							
020272 008	4804663	Dec 29, 2007			U-90	I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008				I-413	Dec 04, 2006
						I-412	Dec 04, 2006
						PED	Jun 04, 2007
						PED	Jun 04, 2007
						PED	Apr 06, 2010
<u>RISPERIDONE - RISPERDAL</u>							
020588 001	4804663	Dec 29, 2007			U-90	I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008				I-413	Dec 04, 2006
	5453425	Jul 11, 2014				I-412	Dec 04, 2006
	5453425*PED	Jan 11, 2015				PED	Apr 06, 2010
	5616587	Jul 11, 2014				PED	Jun 04, 2007
	5616587*PED	Jan 11, 2015				PED	Jun 04, 2007
	RE39181	Jul 11, 2014		DP			
	RE39181*PED	Jan 11, 2015					
<u>RISPERIDONE - RISPERDAL</u>							
021444 001	4804663	Dec 29, 2007	DS	DP	U-516	I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008				I-413	Dec 04, 2006
	5648093	Jul 15, 2014		DP		I-412	Dec 04, 2006
	5648093*PED	Jan 15, 2015				PED	Jun 04, 2007
	6224905	Jun 10, 2017		DP		PED	Jun 04, 2007
	6244905*PED	Dec 10, 2017				PED	Apr 06, 2010
<u>RISPERIDONE - RISPERDAL</u>							
021444 002	4804663	Dec 29, 2007	DS	DP	U-516	I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008				I-413	Dec 04, 2006
	5648093	Jul 15, 2014		DP		I-412	Dec 04, 2006
	5648093*PED	Jan 15, 2015				PED	Jun 04, 2007
	6224905	Jun 10, 2017		DP		PED	Jun 04, 2007
	6244905*PED	Dec 10, 2017				PED	Apr 06, 2010
<u>RISPERIDONE - RISPERDAL</u>							
021444 003	4804663	Dec 29, 2007	DS	DP	U-516	I-509	Oct 06, 2009
	4804663*PED	Jun 29, 2008				I-413	Dec 04, 2006
	5648093	Jul 15, 2014		DP		I-412	Dec 04, 2006
	5648093*PED	Jan 15, 2015				PED	Apr 06, 2010
	6224905	Jun 10, 2017		DP		PED	Jun 04, 2007
	6244905*PED	Dec 10, 2017				PED	Jun 04, 2007
<u>RISPERIDONE - RISPERDAL</u>							
021444 004	4804663	Dec 29, 2007	DS	DP	U-516	I-509	Oct 06, 2009
	4804663	Dec 29, 2007	DS	DP	U-543	I-413	Dec 04, 2006
	4804663*PED	Jun 29, 2008				I-412	Dec 04, 2006
	5648093	Jul 15, 2014		DP		PED	Jun 04, 2007
	5648093*PED	Jan 15, 2015				PED	Jun 04, 2007
	6224905	Jun 10, 2017		DP		PED	Apr 06, 2010
	6244905*PED	Dec 10, 2017					
<u>RISPERIDONE - RISPERDAL</u>							
021444 005	4804663	Dec 29, 2007	DS	DP	U-516	I-509	Oct 06, 2009
	4804663	Dec 29, 2007	DS	DP	U-543	I-413	Dec 04, 2006
	4804663*PED	Jun 29, 2008				I-412	Dec 04, 2006
	5648093	Jul 15, 2014		DP		PED	Jun 04, 2007
	5648093*PED	Jan 15, 2015				PED	Jun 04, 2007
	6224905	Jun 10, 2017		DP		PED	Apr 06, 2010
	6244905*PED	Dec 10, 2017					

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<u>RISPERIDONE - RISPERDAL CONSTA</u>					
021346 001	4804663	Dec 29, 2007		NDF	Oct 29, 2006
	4804663*PED	Jun 29, 2008		PED	Apr 29, 2007
	5688801	Nov 18, 2014			
	5688801*PED	May 18, 2015			
	5770231	Nov 19, 2013			
	5770231*PED	May 19, 2014			
	5792477	May 02, 2017			
	5792477*PED	Nov 02, 2017			
	5916598	May 02, 2017			
	5916598*PED	Nov 02, 2017			
	5965168	Nov 19, 2013			
	5965168*PED	May 19, 2014			
	6110503	May 02, 2017			
	6110503*PED	Nov 02, 2017			
	6110921	Nov 19, 2013			
	6110921*PED	May 19, 2014			
	6194006	Dec 30, 2018			
	6194006*PED	Jun 30, 2019			
	6264987	May 19, 2020			
	6264987*PED	Nov 19, 2020			
	6368632	Nov 19, 2013		U-543	
	6368632*PED	May 19, 2014			
	6379703	Dec 30, 2018	DP		
	6379703*PED	Jun 30, 2019			
	6379704	May 19, 2020	DP		
	6379704*PED	Nov 19, 2020			
	6403114	May 02, 2017			
	6403114*PED	Nov 02, 2017			
	6534092	May 19, 2020	DP		
	6534092*PED	Nov 19, 2020			
	6596316	Dec 30, 2008	DP		
	6596316*PED	Jun 30, 2009			

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<u>RISPERIDONE - RISPERDAL CONSTA</u>					
021346 002	4804663	Dec 29, 2007		NDF	Oct 29, 2006
	4804663*PED	Jun 29, 2008		PED	Apr 29, 2007
	5688801	Nov 18, 2014			
	5688801*PED	May 18, 2015			
	5770231	Nov 19, 2013			
	5770231*PED	May 19, 2014			
	5792477	May 02, 2017			
	5792477*PED	Nov 02, 2017			
	5916598	May 02, 2017			
	5916598*PED	Nov 02, 2017			
	5965168	Nov 19, 2013			
	5965168*PED	May 19, 2014			
	6110503	May 02, 2017			
	6110503*PED	Nov 02, 2017			
	6110921	Nov 19, 2013			
	6110921*PED	May 19, 2014			
	6194006	Dec 30, 2018			
	6194006*PED	Jun 30, 2019			
	6264987	May 19, 2020			
	6264987*PED	Nov 19, 2020			
	6368632	Nov 19, 2013		U-543	
	6368632*PED	May 19, 2014			
	6379703	Dec 30, 2018	DP		
	6379703*PED	Jun 30, 2019			
	6379704	May 19, 2020	DP		
	6379704*PED	Nov 19, 2020			
	6403114	May 02, 2017			
	6403114*PED	Nov 02, 2017			
	6534092	May 19, 2020	DP		
	6534092*PED	Nov 19, 2020			
	6596316	Dec 30, 2008	DP		
	6596316*PED	Jun 30, 2009			

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

See report footnotes for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>RISPERIDONE - RISPERDAL CONSTA</u>					
021346 003	4804663	Dec 29, 2007		NDF	Oct 29, 2006
	4804663*PED	Jun 29, 2008		PED	Apr 29, 2007
	5688801	Nov 18, 2014			
	5688801*PED	May 18, 2015			
	5770231	Nov 19, 2013			
	5770231*PED	May 19, 2014			
	5792477	May 02, 2017			
	5792477*PED	Nov 02, 2017			
	5916598	May 02, 2017			
	5916598*PED	Nov 02, 2017			
	5965168	Nov 19, 2013			
	5965168*PED	May 19, 2014			
	6110503	May 02, 2017			
	6110503*PED	Nov 02, 2017			
	6110921	Nov 19, 2013			
	6110921*PED	May 19, 2014			
	6194006	Dec 30, 2018			
	6194006*PED	Jun 30, 2019			
	6264987	May 19, 2020			
	6264987*PED	Nov 19, 2020			
	6368632	Nov 19, 2013		U-543	
	6368632*PED	May 19, 2014			
	6379703	Dec 30, 2018	DP		
	6379703*PED	Jun 30, 2019			
	6379704	May 19, 2020	DP		
	6379704*PED	Nov 19, 2020			
	6403114	May 02, 2017			
	6403114*PED	Nov 02, 2017			
	6534092	May 19, 2020	DP		
	6534092*PED	Nov 19, 2020			
	6596316	Dec 30, 2008	DP		
	6596316*PED	Jun 30, 2009			
<u>SELEGILINE - EMSAM</u>					
021336 001	7150881	Jun 12, 2018	DS DP		
<u>SELEGILINE - EMSAM</u>					
021336 002	7150881	Jun 12, 2018	DS DP		
<u>SELEGILINE - EMSAM</u>					
021336 003	7150881	Jun 12, 2018	DS DP		
<u>SOMATROPIN RECOMBINANT - SAIZEN</u>					
019764 005				I-440	Aug 26, 2007
<u>TADALAFIL - CIALIS</u>					
021368 001	>A> 7182958	Apr 26, 2020	DP	U-155	
<u>TADALAFIL - CIALIS</u>					
021368 002	>A> 7182958	Apr 26, 2020	DP	U-155	
<u>TADALAFIL - CIALIS</u>					
021368 003	>A> 7182958	Apr 26, 2020	DP	U-155	
<u>TERIPARATIDE RECOMBINANT HUMAN - FORTEO</u>					
021318 001	7163684	Aug 19, 2019		U-790	

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See report footnotes for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>THALIDOMIDE - THALOMID</u>					
020785 004	5629327	May 13, 2014	U-731	ODE	May 23, 2013
	6045501	Aug 28, 2018	U-731		
	6235756	Mar 01, 2013	U-731		
	6315720	Oct 23, 2020	U-731		
	6561976	Aug 28, 2018	U-731		
	6561977	Oct 23, 2020	U-731		
	6755784	Oct 23, 2020	U-731		
	6869399	Oct 23, 2020	U-731		
	6908432	Aug 28, 2018	U-731		
	7141018	Oct 23, 2020	U-731		
<u>TIMOLOL MALEATE - TIMOLOL MALEATE</u>					
020963 001	6174524	Mar 26, 2019			
	6174524*PED	Sep 26, 2019			
<u>TIMOLOL MALEATE - TIMOLOL MALEATE</u>					
020963 002	6174524	Mar 26, 2019			
	6174524*PED	Sep 26, 2019			
<u>ZIPRASIDONE HYDROCHLORIDE - GEODON</u>					
021483 001	7175855	May 18, 2020	DP		
<u>ZOLPIDEM TARTRATE - AMBIEN</u>					
019908 001				>A> M-54	Mar 29, 2010
				>A> PED	Sep 29, 2010
<u>ZOLPIDEM TARTRATE - AMBIEN</u>					
019908 002				>A> M-54	Mar 29, 2010
				>A> PED	Sep 29, 2010

Footnotes:

- Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
- Patents submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor:
 DS = Drug Substance claim
 DP = Drug Product claim
 U and number = Method of Use claim (may be multiple). Specific Method of use claims are listed at <http://www.fda.gov/cder/orange/patex.htm>
- Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. They may not be flagged with respect to other claims which may apply.
- *PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with *PED as was done prior to August 18, 2003. Patents with *PED added after August 18, 2003 will not contain any information relative to the patent itself other than the *PED extension. Information related specifically to the patent will be conveyed on the original patent only.
- *** U.S. Patent Nos. RE 36481 and RE 36520 were relisted for Zocor (NDA 19-766) pursuant to the decision and related order in Ranbaxy Labs. v. Leavitt, No. 05-1838 (D.D.C. April 30, 2006). The '481 and '520 patents remained listed in Approved Drug Products with Therapeutic Equivalence Evaluations until any applicable periods of exclusivity pursuant to section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act were triggered and run. For additional information on this matter, please refer to Docket Nos. 2005P-0008 and 2005P-0046. Patents were subsequently delisted in the December 2006 Orange Book update as the exclusivity periods have triggered and run to expiration.

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, 27th Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

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

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