

**CUMULATIVE
SUPPLEMENT 4
APRIL 2001**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

21ST EDITION

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Information Technology
Division of Data Management and Services

2001

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Prepared By
Division of Data Management and Services
Office of Information Technology
Center for Drug Evaluation and Research
Food and Drug Administration

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21ST EDITION

CUMULATIVE SUPPLEMENT 4
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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, 21st 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 place an asterisk (*) 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. [Strength(s) which already exist in the List will not be repeated for context.]

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, 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 21st Edition List will then be added to the "Discontinued Drug Product List" appearing in the 22nd Edition. The current edition Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. 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 in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >A>. The Patent and Exclusivity Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item.

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

1.2 APPLICANT NAME CHANGES

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

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated

Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

CAMALL CO INC
(CAMALL)

ABC HOLDING CORPORATION
(ABC HOLDING)

KNOLL PHARMACEUTICAL COMPANY
(KNOLL PHARM)

ABBOTT LABORATORIES PHARMACEUTICAL PRODUCTS
(ABBOTT)

MEDEVA AMERICAS INC
(MEDEVA)

CELLTECH PHARMACEUTICALS INC
(CELLTECH PHARMS)

MEDEVA PHARMACEUTICALS INC
(MEDEVA)

CELLTECH PHARMACEUTICALS INC
(CELLTECH PHARMS)

MEDEVA INC
(MEDEVA)

CELLTECH PHARMACEUTICALS INC
(CELLTECH PHARMS)

MEDEVA PHARMACEUTICALS CA INC
(MEDEVA PHARMS CA)

CELLTECH MANUFACTURING CA INC
(CELLTECH MFG CA INC)

MEDEVA PHARMACEUTICALS MA INC
(MEDEVA PHARMS MA)

CELLTECH MANUFACTURING INC
(CELLTECH MFG)

NOVOPHARM LTD
(NOVOPHARM)

TEVA PHARMACEUTICALS USA
(TEVA)

NOVOPHARM PHARMACEUTICAL CO
(NOVOPHARM PHARM)

TEVA PHARMACEUTICALS USA
(TEVA)

NOVOPHARM NC INC
(NOVOPHARM NC)

TEVA PHARMACEUTICALS USA
(TEVA)

1.3 AVAILABILITY OF THE EDITION

The 21st Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

Superintendent of Documents
Government Printing Office
P.O. Box 371954
Pittsburgh, PA 15250-7954

The telephone number to charge your subscription is 202-512-1800. The cost is \$101.00 annually.

The Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book) and related drug information is also available on the Internet at the Food and Drug Administration, Center for Drug Evaluation and Research, Drug Info page.

There is an Electronic Orange Book Query (EOB) at <http://www.fda.gov/cder/ob>. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder or applicant 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. The data is updated concurrently with the publication of the annual edition or monthly cumulative supplements.

The Internet version of the hard copy Orange Book annual edition is at <http://www.fda.gov/cder/orange/adp.htm>.

The Internet version of the hard copy monthly supplement is at <http://www.fda.gov/cder/orange/supplement/cspreface.htm>. Changes to the annual edition are listed separately by month.

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

The 21st annual edition of the 2000 Orange Book Patent and Exclusivity List is at <http://www.fda.gov/cder/orange/21bookpub.pdf>.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at <http://www.fda.gov/cder/orange/supplement/patents.pdf>.

The Patent Term Extension and new Patents, Docket Number *95S-0117, is at <http://www.fda.gov/cder/orange/docket.pdf>. It is updated monthly as soon as available and as otherwise needed.

The Drug Price Competition and Patent Term Restoration Act requires that patent information be filed with all newly submitted Section 505 drug applications. To facilitate industry submission of the information, a patent submission sample format is available in HTML and PDF format at:

<http://www.fda.gov/cder/orange/patdecl.pdf>

<http://www.fda.gov/cder/orange/patdecl.html>

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

1.4 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 2000) 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 2000</u>	<u>MAR 2001</u>	<u>JUN 2001</u>	<u>SEP 2001</u>
DRUG PRODUCTS LISTED	10360	10372		
SINGLE SOURCE	2682 (25.9%)	2696 (26.0%)		
MULTISOURCE	7568 (73.1%)	7566 (72.9%)		
THERAPEUTICALLY EQUIVALENT	7257 (70.0%)	7263 (70.0%)		
NOT THERAPEUTICALLY EQUIVALENT	311 (3.0%)	303 (2.9%)		
EXCEPTIONS ¹	110 (1.1%)	110 (1.1%)		
NEW MOLECULAR ENTITIES APPROVED	2	6		
NUMBER OF APPLICANTS	594	582		

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

Please Note

1.5 CUMULATIVE SUPPLEMENT LEGEND

The 21st Edition Orange book (OB) Cumulative Supplement (CS) layout has changed. The new format follows the Annual Edition and previous CS format. The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form;Route and then by trade name. The manner of displaying the individual product information has changed.

The individual product record follows the previous format layout for Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Approval number, product number, and approval date. Two new columns have been added to provide more information. 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.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.
CTNA	Change. Trade Name.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
WDRP	Withdrawn. The application approval has been withdrawn for failure to provide Annual Reports. The product will be moved to the Discontinued Section in the next edition.

ACETAMINOPHEN; BUTALBITAL

CAPSULE; ORAL

TRIAPRIN

@ DUNHALL

325MG;50MG

N89268 001 JUL 02, 1987 FEB WDRP

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

ANOQUAN

@ ROBERTS AND HAUCK

325MG;50MG;40MG

N87628 001 OCT 01, 1986 FEB WDRP

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL

BUTALBITAL; ACETAMINOPHEN; AND CAFFEINE WITH CODEINE PHOSPHATE

325MG;50MG;40MG;30MG

N75618 001 MAR 23, 2001 MAR NEWA

AB WEST WARD

FIORICET W/ CODEINE

325MG;50MG;40MG;30MG

N20232 001 JUL 30, 1992 MAR CFTG

AB + NOVARTIS

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

TABLET; ORAL

ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE

712.8MG;60MG;32MG

N40316 001 APR 28, 1999 JAN CTNA

+ MIKART

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

CAPITAL WITH CODEINE

@ CARNRICK

325MG;30MG

N83643 001 MAY 31, 1974 FEB WDRP

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

750MG;10MG

N40094 004 MAR 22, 1999 APR NEWA

>A>

+ WATSON LABS

LORTAB

325MG;5MG

N40099.001 JUN 25, 1997 JAN CAHN

AA + WATSON LABS

NORCO

325MG;7.5MG

N40148 003 SEP 12, 2000 APR NEWA

>A>

AA WATSON LABS

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

650MG;100MG

N75738 001 FEB 02, 2001 FEB NEWA

AB MALLINCKRODT

325MG;50MG

N74843 002 FEB 15, 2001 FEB NEWA

AB VINTAGE PHARMS

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ACYCLOVIR

AP GENZIA SICOR PHARMS

EQ 50MG BASE/ML

N75627 001 MAR 28, 2001 MAR NEWA

ALBUTEROL SULFATE

AEROSOL, METERED; INHALATION

VENTOLIN HFA

>A>

+ GLAXO

EQ 0.09MG BASE/INH

N20983 001 APR 19, 2001 APR NEWA

>A>

ALBUTEROL SULFATE

SOLUTION; INHALATION

>A> ACCUNEB

>A> + DEY EQ 0.021% BASE N20949 002 APR 30, 2001 APR NEWA

>A> + EQ 0.042% BASE N20949 001 APR 30, 2001 APR NEWA

ALBUTEROL SULFATE

AN ROXANE EQ 0.083% BASE N75129 001 FEB 13, 2001 FEB NEWA

ALBUTEROL SULFATE; IPRATROPIUM BROMIDE

SOLUTION; INHALATION

DUONEB

+ DEY EQ 0.083% BASE;0.017% BASE N20950 001 MAR 21, 2001 MAR NEWA

AMIKACIN SULFATE

INJECTABLE; INJECTION

AMIKACIN SULFATE

>D> AP ABBOTT EQ 250MG BASE/ML N63265 001 NOV 30, 1994 APR DISC

>D> AP EQ 250MG BASE/ML N63266 001 OCT 31, 1994 APR DISC

>A> @ EQ 250MG BASE/ML N63265 001 NOV 30, 1994 APR DISC

>A> @ EQ 250MG BASE/ML N63266 001 OCT 31, 1994 APR DISC

>D> AP ELKINS SINN EQ 250MG BASE/ML N63275 001 MAY 18, 1992 APR DISC

>A> @ EQ 250MG BASE/ML N63275 001 MAY 18, 1992 APR DISC

AMIODARONE HYDROCHLORIDE

TABLET; ORAL

AMIODARONE HCL

AB BARR 200MG N75389 001 JAN 25, 2001 JAN NEWA

AB TARO 200MG N75424 001 MAR 30, 2001 MAR NEWA

AMOXICILLIN

CAPSULE; ORAL

AMOXICILLIN

@ LABS ATRAL 250MG N62528 001 AUG 07, 1985 FEB WDRP

@ 500MG N62528 002 AUG 07, 1985 FEB WDRP

>D> AB MYLAN 250MG N62067 001 AUG 14, 1980 APR DISC

>D> AB 500MG N62067 002 AUG 14, 1980 APR DISC

>A> @ 250MG N62067 001 AUG 14, 1980 APR DISC

>A> @ 500MG N62067 002 AUG 14, 1980 APR DISC

>D> AB TEVA 250MG N63030 001 FEB 28, 1989 APR DISC

>D> AB 500MG N63031 001 FEB 28, 1989 APR DISC

>A> @ 250MG N63030 001 FEB 28, 1989 APR DISC

>A> @ 500MG N63031 001 FEB 28, 1989 APR DISC

TRIMOX

>D> AB APOTHECON 250MG N63099 001 MAR 20, 1992 APR DISC

>D> AB 500MG N63099 002 MAR 20, 1992 APR DISC

>A> @ 250MG N63099 001 MAR 20, 1992 APR DISC

>A> @ 500MG N63099 002 MAR 20, 1992 APR DISC

>D> WYMOX

>D> AB WYETH AYERST 250MG N62120 001 APR 28, 1978 APR DISC

>D> AB 500MG N62120 002 APR 28, 1978 APR DISC

>A> @ 250MG N62120 001 APR 28, 1978 APR DISC

>A> @ 500MG N62120 002 APR 28, 1978 APR DISC

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE;
DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

ADDERALL 7.5

>D>	+	SHIRE	1.875MG;1.875MG;1.875MG;1.875MG	N11522 011	AUG 31, 2000	APR	CTEC
>A>			875MG				
			1.875MG;1.875MG;1.875MG;1.875MG	N11522 011	AUG 31, 2000	APR	CTEC
			875MG				

AMPHOTERICIN B

INJECTABLE, LIPID COMPLEX; INJECTION

AMPHOTEC

+	INTERMUNE PHARMS	50MG/VIAL	N50729 001	NOV 22, 1996	FEB	CAHN
+		100MG/VIAL	N50729 002	NOV 22, 1996	FEB	CAHN

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

>D>	AP	HANFORD GC	EQ 125MG BASE/VIAL	N63143 001	APR 15, 1993	APR	DISC
>D>	AP		EQ 250MG BASE/VIAL	N63145 001	APR 15, 1993	APR	DISC
>D>	AP		EQ 500MG BASE/VIAL	N63146 001	APR 15, 1993	APR	DISC
>D>	AP		EQ 500MG BASE/VIAL	N63147 001	APR 15, 1993	APR	DISC
>D>	AP		EQ 1GM BASE/VIAL	N63139 001	APR 15, 1993	APR	DISC
>D>	AP		EQ 2GM BASE/VIAL	N63140 001	APR 15, 1993	APR	DISC
>D>	AP		EQ 2GM BASE/VIAL	N63141 001	APR 15, 1993	APR	DISC
>D>	AP		EQ 10GM BASE/VIAL	N63142 001	APR 15, 1993	APR	DISC
>A>	@		EQ 125MG BASE/VIAL	N63143 001	APR 15, 1993	APR	DISC
>A>	@		EQ 250MG BASE/VIAL	N63145 001	APR 15, 1993	APR	DISC
>A>	@		EQ 500MG BASE/VIAL	N63146 001	APR 15, 1993	APR	DISC
>A>	@		EQ 500MG BASE/VIAL	N63147 001	APR 15, 1993	APR	DISC
>A>	@		EQ 1GM BASE/VIAL	N63139 001	APR 15, 1993	APR	DISC
>A>	@		EQ 2GM BASE/VIAL	N63140 001	APR 15, 1993	APR	DISC
>A>	@		EQ 2GM BASE/VIAL	N63141 001	APR 15, 1993	APR	DISC
>A>	@		EQ 10GM BASE/VIAL	N63142 001	APR 15, 1993	APR	DISC

AMPICILLIN/AMPICILLIN TRIHYDRATE

FOR SUSPENSION; ORAL

TOTACILLIN

@	SMITHKLINE BEECHAM	EQ 125MG BASE/5ML	N60666 001	MAY 07, 1970	FEB	WDRP
@		EQ 250MG BASE/5ML	N60666 002	MAY 07, 1970	FEB	WDRP

ARBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

GENESA

@	GENSIA AUTOMEDICS	0.05MG/ML	N20420 001	SEP 12, 1997	MAR	DISC
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ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID;
NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K

INJECTABLE; IV (INFUSION)

INFUVITE PEDIATRIC

+	SABEX	80MG/VIAL;0.02MG/VIAL;400IU/VIAL;0.001MG/VIAL;5MG/V
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IAL;0.14MG/VIAL;17MG/VIAL;
1MG/VIAL;1.4MG/VIAL;1.2MG/
VIAL;7 IU/VIAL;2,300
IU/VIAL;0.2MG/VIAL

N21265 001 FEB 21, 2001 FEB NEWA

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID;
NIACINAMIDE; PHYTONADIONE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE
HYDROCHLORIDE; VITAMIN A; VITAMIN E

FOR SOLUTION; IV (INFUSION)

M.V.I. PEDIATRIC

+ ASTRAZENECA

80MG/VIAL;0.02MG/VIAL;0.00
1MG/VIAL;5MG/VIAL;0.01MG/
VIAL;0.14MG/VIAL;17MG/VIAL;
0.2MG/VIAL;1MG/VIAL;1.4MG/
VIAL;EQ 1.2MG
BASE/VIAL;0.7MG/VIAL;7MG/
VIAL

N18920 001 SEP 21, 2000 FEB NEWA

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

INVAGESIC

AB GENEVA PHARMS TECH

385MG;30MG;25MG

N74817 001 NOV 27, 1996 JAN CAHN

INVAGESIC FORTE

AB GENEVA PHARMS TECH

770MG;60MG;50MG

N74817 002 NOV 27, 1996 JAN CAHN

ATORVASTATIN CALCIUM

TABLET; ORAL

LIPITOR

PFIZER

EQ 10MG BASE
EQ 20MG BASE
EQ 40MG BASE
EQ 80MG BASE

N20702 001 DEC 17, 1996 MAR CAHN
N20702 002 DEC 17, 1996 MAR CAHN
N20702 003 DEC 17, 1996 MAR CAHN
N20702 004 APR 07, 2000 MAR CAHN

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

@ INWOOD LABS

0.025MG;2.5MG

N85509 001 MAR 09, 1978 FEB WDRP

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

NEO-POLYCIN

@ DOW PHARM

500 UNITS/GM;EQ 3.5MG
BASE/GM;10,000 UNITS/GM

N60647 001 APR 19, 1954 FEB WDRP

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

BETAMETHASONE DIPROPIONATE

>D> AB CLAY PARK

EQ 0.05% BASE

N74579 001 NOV 26, 1997 APR DISC

>A> @

EQ 0.05% BASE

N74579 001 NOV 26, 1997 APR DISC

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

BETAXOLOL HCL

>A> AT BAUSCH AND LOMB

EQ 0.5% BASE

N75630 001 APR 12, 2001 APR NEWA

BIMATOPROST

SOLUTION/DROPS; OPHTHALMIC

LUMIGAN

+ ALLERGAN	0.03%	N21275 001	MAR 16, 2001	MAR NEWA
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BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE

AB TEVA	2.5MG;6.25MG	N75686 001	JAN 19, 2001	JAN NEWA
AB	5MG;6.25MG	N75686 002	JAN 19, 2001	JAN NEWA
AB	10MG;6.25MG	N75686 003	JAN 19, 2001	JAN NEWA

BRIMONIDINE TARTRATE

SOLUTION/DROPS; OPHTHALMIC

ALPHAGAN

>D> + ALLERGAN	0.5%	N20490 001	MAR 13, 1997	APR DISC
>A> @	0.5%	N20490 001	MAR 13, 1997	APR DISC
ALPHAGAN P				
+ ALLERGAN	0.15%	N21262 001	MAR 16, 2001	MAR NEWA

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

WELLBUTRIN SR

>D> + GLAXO WELLCOME	50MG	N20358 001	OCT 04, 1996	APR CTEC
>A>	50MG	N20358 001	OCT 04, 1996	APR CTEC
>D> +	100MG	N20358 002	OCT 04, 1996	APR CTEC
>A>	100MG	N20358 002	OCT 04, 1996	APR CTEC

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

BUSPAR

AB BRISTOL MYERS SQUIBB	5MG	N18731 001	SEP 29, 1986	MAR CFTG
AB	10MG	N18731 002	SEP 29, 1986	MAR CFTG
AB	15MG	N18731 003	APR 22, 1996	MAR NEWA
BUSPIRONE HCL				
AB DANBURY PHARMA	5MG	N74253 001	MAR 28, 2001	MAR NEWA
AB	10MG	N74253 002	MAR 28, 2001	MAR NEWA
AB MYLAN	15MG	N75272 003	MAR 28, 2001	MAR NEWA
AB PAR PHARM	7.5MG	N75467 002	MAR 28, 2001	MAR NEWA

CALCIUM ACETATE

CAPSULE; ORAL

PHOSLO

>A> BRAINTREE	EQ 84.5MG CALCIUM	N21160 001	APR 02, 2001	APR NEWA
>A> +	EQ 169MG CALCIUM	N21160 002	APR 02, 2001	APR NEWA

CAPTOPRIL

TABLET; ORAL

CAPTOPRIL

AB GENEVA PHARMS TECH	12.5MG	N74481 001	FEB 13, 1996	JAN CAHN
AB	25MG	N74481 002	FEB 13, 1996	JAN CAHN
AB	50MG	N74481 003	FEB 13, 1996	JAN CAHN

AB		100MG	N74481 004	FEB 13, 1996	JAN CAHN
<u>CARBACHOL</u>					
	SOLUTION; INTRAOCULAR				
	CARBASTAT				
AT	NOVARTIS	0.01%	N73677 001	APR 28, 1995	FEB CAHN
<u>CARBIDOPA; LEVODOPA</u>					
	TABLET; ORAL				
	CARBIDOPA AND LEVODOPA				
	@ SCS	10MG;100MG	N74080 001	MAR 25, 1994	FEB WDRP
	@	25MG;100MG	N74080 002	MAR 25, 1994	FEB WDRP
	@	25MG;250MG	N74080 003	MAR 25, 1994	FEB WDRP
	@				
<u>CASPOFUNGIN ACETATE</u>					
	INJECTABLE; IV (INFUSION)				
	CANCIDAS				
	+ MERCK RES	50MG/VIAL	N21227 001	JAN 26, 2001	JAN NEWA
	+	70MG/VIAL	N21227 002	JAN 26, 2001	JAN NEWA
<u>CEFACTOR</u>					
	TABLET, EXTENDED RELEASE; ORAL				
	CECLOR CD				
AB	+ LILLY	EQ 500MG BASE	N50673 002	JUN 28, 1996	JAN CFTG
>D>	+	EQ 375MG BASE	N50673 001	JUN 28, 1996	APR CTEC
>A>		EQ 375MG BASE	N50673 001	JUN 28, 1996	APR CTEC
	CEFACTOR				
AB	ZENITH GOLDLINE	EQ 500MG BASE	N65057 001	JAN 05, 2001	JAN NEWA
<u>CEFAZOLIN SODIUM</u>					
	INJECTABLE; INJECTION				
	CEFAZOLIN SODIUM				
>D>	AP	EQ 250MG BASE/VIAL	N63016 001	MAR 14, 1989	APR DISC
>D>	AP	EQ 500MG BASE/VIAL	N63016 002	MAR 14, 1989	APR DISC
>D>	AP	EQ 1GM BASE/VIAL	N63016 003	MAR 14, 1989	APR DISC
>A>	@	EQ 250MG BASE/VIAL	N63016 001	MAR 14, 1989	APR DISC
>A>	@	EQ 500MG BASE/VIAL	N63016 002	MAR 14, 1989	APR DISC
>A>	@	EQ 1GM BASE/VIAL	N63016 003	MAR 14, 1989	APR DISC
<u>CEFONICID SODIUM</u>					
	INJECTABLE; INJECTION				
	MONOCID				
>D>	SMITHKLINE BEECHAM	EQ 1GM BASE/VIAL	N63295 001	JUL 26, 1993	APR DISC
>A>	@	EQ 1GM BASE/VIAL	N63295 001	JUL 26, 1993	APR DISC
<u>CEFTAZIDIME</u>					
	INJECTABLE; INJECTION				
	TAZICEF				
AP	ABBOTT	500MG/VIAL	N62662 001	MAR 06, 1986	JAN CAHN
AP		1GM/VIAL	N62662 002	MAR 06, 1986	JAN CAHN
AP		1GM/VIAL	N64032 001	OCT 31, 1993	JAN CAHN
AP		2GM/VIAL	N62662 003	MAR 06, 1986	JAN CAHN
AP		2GM/VIAL	N64032 002	OCT 31, 1993	JAN CAHN
AP					

>D>
>D>
>D>
>A>
>A>

AP		6GM/VIAL	N62662 004	MAR 06, 1986	JAN CAHN
<u>CEFUROXIME SODIUM</u>					
INJECTABLE; INJECTION					
CEFUROXIME AND DEXTROSE IN DUPLEX CONTAINER					
+ B BRAUN		EQ 15MG BASE/ML	N50780 001	FEB 21, 2001	FEB NEWA
+		EQ 30MG BASE/ML	N50780 002	FEB 21, 2001	FEB NEWA
<u>CEPHALOTHIN SODIUM</u>					
INJECTABLE; INJECTION					
>D>		KEFLIN IN PLASTIC CONTAINER	N62549 001	SEP 10, 1985	APR DISC
>D>	AP +	LILLY	N62549 002	SEP 10, 1985	APR DISC
>D>	AP +		N62549 001	SEP 10, 1985	APR DISC
>A>	@		N62549 002	SEP 10, 1985	APR DISC
>A>	@				
<u>CHLORAMPHENICOL</u>					
SOLUTION/DROPS; OPHTHALMIC					
CHLORAMPHENICOL					
@ AKORN		0.5%	N62042 001	AUG 31, 1981	FEB WDRP
<u>CHLORDIAZEPOXIDE HYDROCHLORIDE</u>					
CAPSULE; ORAL					
CHLORDIAZACHEL					
@ RACHELLE		5MG	N85086 001	MAY 11, 1976	FEB WDRP
@		10MG	N84639 001	MAY 11, 1976	FEB WDRP
@		25MG	N85087 001	MAY 11, 1976	FEB WDRP
CHLORDIAZEPOXIDE HCL					
@ FERRANTE		5MG	N85118 001	SEP 02, 1981	FEB WDRP
@		10MG	N85119 001	SEP 02, 1976	FEB WDRP
@		25MG	N85120 001	SEP 02, 1976	FEB WDRP
<u>CHLORPHENIRAMINE MALEATE</u>					
TABLET; ORAL					
CHLORPHENIRAMINE MALEATE					
@ PHARMAVITE		4MG	N85104 001	FEB 11, 1977	FEB WDRP
@ WEST WARD		4MG	N83787 001	OCT 18, 1973	FEB WDRP
<u>CIMETIDINE</u>					
TABLET; ORAL					
CIMETIDINE					
AB	GENEVA PHARMS TECH	200MG	N74506 001	JAN 24, 1996	JAN CAHN
AB		300MG	N74506 002	JAN 24, 1996	JAN CAHN
AB		400MG	N74506 003	JAN 24, 1996	JAN CAHN
AB		800MG	N74506 004	JAN 24, 1996	JAN CAHN
<u>CLINDAMYCIN HYDROCHLORIDE</u>					
CAPSULE; ORAL					
CLEOCIN HCL					
AB +	PHARMACIA AND UPJOHN	EQ 300MG BASE	N50162 003	APR 14, 1988	FEB CFTG
AB	RANBAXY	EQ 150MG BASE	N65061 001	FEB 02, 2001	FEB NEWA
AB		EQ 300MG BASE	N65061 002	FEB 02, 2001	FEB NEWA

CLINDAMYCIN PHOSPHATE
 INJECTABLE; INJECTION
 CLINDAMYCIN PHOSPHATE
 >D> AP GENSIA SICOR PHARMS EQ 150MG BASE/ML N63041 001 DEC 29, 1989 APR DISC
 >D> AP EQ 150MG BASE/ML N63282 001 MAY 29, 1992 APR DISC
 >A> @ EQ 150MG BASE/ML N63041 001 DEC 29, 1989 APR DISC
 >A> @ EQ 150MG BASE/ML N63282 001 MAY 29, 1992 APR DISC

CLOBETASOL PROPIONATE
 CREAM; TOPICAL
 CLOBETASOL PROPIONATE
 AB1 STIEFEL 0.05% N75338 001 FEB 09, 2001 FEB NEWA

CLONAZEPAM
 TABLET; ORAL
 CLONAZEPAM
 >A> AB CARACO 0.5MG N75423 001 APR 27, 2001 APR NEWA
 >A> AB 1MG N75423 002 APR 27, 2001 APR NEWA
 >A> AB 2MG N75423 003 APR 27, 2001 APR NEWA

CLORAZEPATE DIPOTASSIUM
 CAPSULE; ORAL
 CLORAZEPATE DIPOTASSIUM
 @ ABLE 3.75MG N71777 001 JUL 14, 1987 JAN DISC
 @ 7.5MG N71778 001 JUL 14, 1987 JAN DISC
 @ 15MG N71779 001 JUL 14, 1987 JAN DISC

CROMOLYN SODIUM
 SOLUTION/DROPS; OPHTHALMIC
 CROMOLYN SODIUM
 AT NOVEX 4% N75615 001 JAN 26, 2001 JAN NEWA

DESERPIDINE; HYDROCHLOROTHIAZIDE
 TABLET; ORAL
 ORETICYL 25
 @ ABBOTT 0.125MG;25MG N12148 001 DEC 14, 1959 MAR DISC
 ORETICYL 50
 @ ABBOTT 0.125MG;50MG N12148 003 DEC 14, 1959 MAR DISC
 ORETICYL FORTE
 @ ABBOTT 0.25MG;25MG N12148 002 DEC 14, 1959 MAR DISC

DESONIDE
 OINTMENT; TOPICAL
 DESONIDE
 AB ALTANA 0.05% N75751 001 MAR 12, 2001 MAR NEWA

DEXAMETHASONE SODIUM PHOSPHATE
 INJECTABLE; INJECTION
 DEXAMETHASONE SODIUM PHOSPHATE
 @ DELL LABS EQ 4MG PHOSPHATE/ML N83161 001 JUN 06, 1978 FEB WDRP
 SOLUTION/DROPS; OTIC
 @ AKORN EQ 0.1% PHOSPHATE N84855 001 JUN 29, 1976 FEB WDRP

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

	OINTMENT; OPHTHALMIC				
	DEXACIDIN				
AT	NOVARTIS	0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N62566 001	FEB 22, 1985	FEB CAHN
	SUSPENSION/DROPS; OPHTHALMIC				
AT	NOVARTIS	0.1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N62544 001	OCT 29, 1984	FEB CAHN

DEXTROAMPHETAMINE SULFATE

	TABLET; ORAL				
	DEXTROAMPHETAMINE SULFATE				
AA	BARR	5MG	N40361 001	JAN 31, 2001	JAN NEWA
AA		10MG	N40361 002	JAN 31, 2001	JAN NEWA
	DEXTROSTAT				
AA +	SHIRE RICHWOOD	10MG	N84051 002	MAY 29, 1975	JAN CFTG

DICLOFENAC POTASSIUM

	TABLET; ORAL				
	DICLOFENAC POTASSIUM				
AB	EON	50MG	N75582 001	FEB 23, 2001	FEB NEWA

DICLOFENAC SODIUM

	GEL; TOPICAL				
	SOLARAZE				
+	BIOGLAN PHARMA PLC	3%	N21005 001	OCT 16, 2000	MAR CAHN

DICLOXACILLIN SODIUM

	CAPSULE; ORAL				
>D>	DYCILL				
>D>	AB	SMITHKLINE BEECHAM	EQ 250MG BASE	N62238 001	DEC 31, 1979 APR DISC
>D>	AB		EQ 500MG BASE	N62238 002	DEC 31, 1979 APR DISC
>A>	@		EQ 250MG BASE	N62238 001	DEC 31, 1979 APR DISC
>A>	@		EQ 500MG BASE	N62238 002	DEC 31, 1979 APR DISC

DILTIAZEM HYDROCHLORIDE

	CAPSULE, EXTENDED RELEASE; ORAL				
	DILTIAZEM HCL				
AB2	MYLAN	120MG	N75124 002	MAR 18, 2098	MAR CTEC

DIPHENHYDRAMINE HYDROCHLORIDE

	CAPSULE; ORAL				
	DIPHENHYDRAMINE HCL				
	@	NEWTRON PHARMS	25MG	N86543 001	FEB 08, 1979 FEB WDRP
	@		50MG	N86544 001	FEB 08, 1979 FEB WDRP

DISULFIRAM

	TABLET; ORAL				
	ANTABUSE				
		ODYSSEY PHARMS	250MG	N88482 001	DEC 08, 1983 JAN CAHN
			500MG	N88483 001	DEC 08, 1983 JAN CAHN
+			250MG	N07883 003	NOV 03, 1970 MAR CAHN
	@	SIDMAK LABS			

	@	500MG		N07883 002	JUN 01, 1953	MAR	CAHN
<u>DOXAZOSIN MESYLATE</u>							
TABLET; ORAL							
DOXAZOSIN MESYLATE							
AB	TEVA	EQ 1MG BASE		N75353 001	JAN 12, 2001	JAN	NEWA
AB		EQ 2MG BASE		N75353 002	JAN 12, 2001	JAN	NEWA
AB		EQ 4MG BASE		N75353 003	JAN 12, 2001	JAN	NEWA
AB		EQ 8MG BASE		N75353 004	JAN 12, 2001	JAN	NEWA
<u>DOXYCYCLINE</u>							
FOR SUSPENSION; ORAL							
DOXYCHEL							
	@ RACHELLE	EQ 25MG BASE/5ML		N61720 001	JUN 18, 1973	FEB	WDRP
VIBRAMYCIN							
	+ PFIZER	EQ 25MG BASE/5ML		N50006 001	DEC 06, 1967	FEB	CTEC
<u>DOXYCYCLINE HYCLATE</u>							
CAPSULE; ORAL							
>D>	DOXY-LEMMON						
>D>	AB TEVA	EQ 50MG BASE		N62497 001	AUG 23, 1984	APR	DISC
>D>	AB	EQ 100MG BASE		N62497 002	JUN 15, 1984	APR	DISC
>A>	@	EQ 50MG BASE		N62497 001	AUG 23, 1984	APR	DISC
>A>	@	EQ 100MG BASE		N62497 002	JUN 15, 1984	APR	DISC
DOXYCYCLINE HYCLATE							
>D>	AB CHELSEA LABS	EQ 50MG BASE		N62142 001	AUG 12, 1981	APR	DISC
>D>	AB	EQ 100MG BASE		N62142 002	AUG 12, 1981	APR	DISC
>A>	@	EQ 50MG BASE		N62142 001	AUG 12, 1981	APR	DISC
>A>	@	EQ 100MG BASE		N62142 002	AUG 12, 1981	APR	DISC
>D>	AB HALSEY	EQ 50MG BASE		N62418 001	JAN 28, 1983	APR	DISC
>D>	AB	EQ 100MG BASE		N62418 002	JAN 28, 1983	APR	DISC
>A>	@	EQ 50MG BASE		N62418 001	JAN 28, 1983	APR	DISC
>A>	@	EQ 100MG BASE		N62418 002	JAN 28, 1983	APR	DISC
INJECTABLE; INJECTION							
DOXYCHEL HYCLATE							
	@ RACHELLE	EQ 100MG BASE/VIAL		N61953 001	SEP 10, 1980	FEB	WDRP
DOXYCYCLINE							
>D>	AP ELKINS SINN	EQ 100MG BASE/VIAL		N62450 001	OCT 27, 1983	APR	DISC
>D>	AP	EQ 200MG BASE/VIAL		N62450 002	OCT 27, 1983	APR	DISC
>A>	@	EQ 100MG BASE/VIAL		N62450 001	OCT 27, 1983	APR	DISC
>A>	@	EQ 200MG BASE/VIAL		N62450 002	OCT 27, 1983	APR	DISC
TABLET; ORAL							
DOXYCYCLINE HYCLATE							
>D>	AB HALSEY	EQ 100MG BASE		N62391 001	SEP 30, 1982	APR	DISC
>A>	@	EQ 100MG BASE		N62391 001	SEP 30, 1982	APR	DISC
PERIOSTAT							
	+ COLLAGENEX PHARMS	20MG		N50783 001	FEB 02, 2001	FEB	NEWA
<u>ENALAPRIL MALEATE</u>							
TABLET; ORAL							
ENALAPRIL MALEATE							
AB	TARO	2.5MG		N75657 001	JAN 23, 2001	JAN	NEWA
AB		5MG		N75657 002	JAN 23, 2001	JAN	NEWA

AB		10MG	N75657 003	JAN 23, 2001	JAN	NEWA
AB		20MG	N75657 004	JAN 23, 2001	JAN	NEWA
AB	TORPHARM	2.5MG	N75178 002	MAR 23, 2001	MAR	NEWA
AB		5MG	N75178 001	MAR 23, 2001	MAR	NEWA
AB		10MG	N75178 003	MAR 23, 2001	MAR	NEWA
AB		20MG	N75178 004	MAR 23, 2001	MAR	NEWA
<u>ENFLURANE</u>						
LIQUID; INHALATION						
ENFLURANE						
AN	MINRAD	99.9%	N74396 001	JUL 29, 1994	FEB	CAHN
<u>ENOXAPARIN SODIUM</u>						
INJECTABLE; SUBCUTANEOUS						
LOVENOX						
>A>	+	AVENTIS	30MG/0.3ML	N20164 001	MAR 29, 1993	APR CAHN
>A>	+		40MG/0.4ML	N20164 002	JAN 30, 1998	APR CAHN
>A>	+		60MG/0.6ML	N20164 003	MAR 27, 1998	APR CAHN
>A>	+		80MG/0.8ML	N20164 004	MAR 27, 1998	APR CAHN
>A>	+		90MG/0.6ML	N20164 006	JUN 02, 2000	APR CAHN
>A>	+		100MG/ML	N20164 005	MAR 27, 1998	APR CAHN
>A>	+		120MG/0.8ML	N20164 007	JUN 02, 2000	APR CAHN
>A>	+		150MG/ML	N20164 008	JUN 02, 2000	APR CAHN
>D>	+	AVENTIS PHARMS	30MG/0.3ML	N20164 001	MAR 29, 1993	APR CAHN
>D>	+		40MG/0.4ML	N20164 002	JAN 30, 1998	APR CAHN
>D>	+		60MG/0.6ML	N20164 003	MAR 27, 1998	APR CAHN
>D>	+		80MG/0.8ML	N20164 004	MAR 27, 1998	APR CAHN
>D>	+		100MG/ML	N20164 005	MAR 27, 1998	APR CAHN
>D>	+		90MG/0.6ML	N20164 006	JUN 02, 2000	APR CAHN
>D>	+		120MG/0.8ML	N20164 007	JUN 02, 2000	APR CAHN
>D>	+		150MG/ML	N20164 008	JUN 02, 2000	APR CAHN
<u>EPINEPHRINE BITARTRATE; ETIDOCAINE HYDROCHLORIDE</u>						
INJECTABLE; INJECTION						
DURANEST						
>D>	+	ASTRAZENECA	0.005MG/ML;1%	N17751 006	AUG 30, 1976	APR CAHN
>D>	+		0.005MG/ML;1.5%	N17751 007	AUG 30, 1976	APR CAHN
>A>	+	DENTSPLY PHARM	0.005MG/ML;1%	N17751 006	AUG 30, 1976	APR CAHN
>A>	+		0.005MG/ML;1.5%	N17751 007	AUG 30, 1976	APR CAHN
<u>EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE</u>						
INJECTABLE; INJECTION						
>D>	@	ASTRAZENECA	0.005MG/ML;0.5%	N17751 004	AUG 30, 1976	APR CAHN
>A>	@	DENTSPLY PHARM	0.005MG/ML;0.5%	N17751 004	AUG 30, 1976	APR CAHN
<u>EPINEPHRINE; LIDOCAINE HYDROCHLORIDE</u>						
INJECTABLE; INJECTION						
LIDOCATON						
	@	PHARMATON	0.02MG/ML;2%	N84728 001	AUG 17, 1983	FEB WDRP

ERGOCALCIFEROL

CAPSULE; ORAL

VITAMIN D

@ IMPAX LABS

50,000 IU

N80951 001 JUL 13, 1973 FEB DISC

ERYTHROMYCIN

SOLUTION; TOPICAL

ERYTHROMYCIN

>D> AT CLAY PARK

2%

N63038 001 JAN 11, 1991 APR DISC

>A> @

2%

N63038 001 JAN 11, 1991 APR DISC

TABLET, DELAYED RELEASE; ORAL

E-BASE

>D> AB BARR

333MG

N63028 001 MAY 15, 1990 APR DISC

>A> @

333MG

N63028 001 MAY 15, 1990 APR DISC

ERYTHROMYCIN ESTOLATE

CAPSULE; ORAL

ERYTHROMYCIN ESTOLATE

>D> AB DANBURY PHARMA

EQ 250MG BASE

N62087 001 JUN 14, 1979 APR DISC

>A> @

EQ 250MG BASE

N62087 001 JUN 14, 1979 APR DISC

>D> SUSPENSION/DROPS; ORAL

>D> ILOSONE

>D> + LILLY

EQ 100MG BASE/ML

N61894 003 JAN 07, 1975 APR DISC

>A> @

EQ 100MG BASE/ML

N61894 003 JAN 07, 1975 APR DISC

>D> TABLET; ORAL

>D> ILOSONE

>D> + LILLY

EQ 500MG BASE

N61896 001 JAN 03, 1975 APR DISC

>A> @

EQ 500MG BASE

N61896 001 JAN 03, 1975 APR DISC

ERYTHROMYCIN STEARATE

TABLET; ORAL

WYAMYCIN S

>D> AB WYETH AYERST

EQ 250MG BASE

N61675 001 OCT 06, 1972 APR DISC

>D> AB

EQ 500MG BASE

N61675 002 JUL 13, 1973 APR DISC

>A> @

EQ 250MG BASE

N61675 001 OCT 06, 1972 APR DISC

>A> @

EQ 500MG BASE

N61675 002 JUL 13, 1973 APR DISC

ESOMEPRAZOLE MAGNESIUM

CAPSULE, DELAYED REL PELLETS; ORAL

NEXIUM

+ ASTRAZENECA

EQ 20MG BASE

N21153 001 FEB 20, 2001 FEB NEWA

+

EQ 40MG BASE

N21153 002 FEB 20, 2001 FEB NEWA

ESTRADIOL; NORETHINDRONE ACETATE

FILM, EXTENDED RELEASE; TRANSDERMAL

COMBIPATCH

NOVARTIS

0.05MG/24HR;0.14MG/24HR

N20870 001 AUG 07, 1998 MAR CAHN

+

0.05MG/24HR;0.25MG/24HR

N20870 002 AUG 07, 1998 MAR CAHN

ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE

TABLET; ORAL-28

PREMPRO

+ WYETH AYERST

0.625MG;0.625MG;2.5MG;2.5M

		G	N20527 001	NOV 17, 1995	JAN	CTNA
+		0.625MG;0.625MG;5MG;5MG	N20527 003	JAN 09, 1998	JAN	CTNA
	PREMPRO (PREMARIN;CYCRIN)					
+	WYETH AYERST	0.625MG;0.625MG;2.5MG;2.5M				
		G	N20303 001	DEC 30, 1994	JAN	CTNA
<u>ESTROPIPATE</u>						
TABLET; ORAL						
ORTHO-EST						
AB	WOMEN FIRST HLTHCARE	0.75MG	N89567 001	FEB 27, 1991	JAN	CAHN
AB		1.5MG	N89582 001	JUL 17, 1991	JAN	CAHN
<u>ETHINYL ESTRADIOL; LEVONORGESTREL</u>						
TABLET; ORAL-21						
>A>	ALESSE					
>A>	AB + WYETH AYERST	0.02MG;0.1MG	N20683 001	MAR 27, 1997	APR	CTEC
>D>	BX +	0.02MG;0.1MG	N20683 001	MAR 27, 1997	APR	CTEC
>A>	AVIANE-21					
>A>	AB DURAMED	0.02MG;0.1MG	N75796 002	APR 30, 2001	APR	NEWA
TABLET; ORAL-28						
>A>	ALESSE					
>A>	AB WYETH AYERST	0.02MG;0.1MG	N20683 002	MAR 27, 1997	APR	CTEC
>D>	BX	0.02MG;0.1MG	N20683 002	MAR 27, 1997	APR	CTEC
>A>	AVIANE-28					
>A>	AB DURAMED	0.02MG;0.1MG	N75796 001	APR 30, 2001	APR	NEWA
<u>ETHINYL ESTRADIOL; NORETHINDRONE ACETATE</u>						
TABLET; ORAL-28						
LOESTRIN FE 1.5/30						
AB	+ PARKE DAVIS	0.03MG;1.5MG	N17355 001	APR 30, 1973	FEB	CFTG
LOESTRIN FE 1/20						
AB	+ PARKE DAVIS	0.02MG;1MG	N17354 001	APR 30, 1973	FEB	CFTG
MICROGESTIN FE 1.5/30						
AB	WATSON LABS	0.03MG;1.5MG	N75548 001	FEB 05, 2001	FEB	NEWA
MICROGESTIN FE 1/20						
AB	WATSON LABS	0.02MG;1MG	N75647 001	FEB 05, 2001	FEB	NEWA
<u>ETHOSUXIMIDE</u>						
SYRUP; ORAL						
ZARONTIN						
AA	+ PARKE DAVIS	250MG/5ML	N80258 001	FEB 13, 1974	JAN	CRLD
<u>ETIDOCAINE HYDROCHLORIDE</u>						
INJECTABLE; INJECTION						
DURANEST						
>D>	@ ASTRAZENECA	0.5%	N17751 003	AUG 30, 1976	APR	CAHN
>D>	+	1%	N17751 005	AUG 30, 1976	APR	CAHN
>A>	@ DENTSPLY PHARM	0.5%	N17751 003	AUG 30, 1976	APR	CAHN
>A>	+	1%	N17751 005	AUG 30, 1976	APR	CAHN
<u>ETODOLAC</u>						
TABLET, EXTENDED RELEASE; ORAL						
ETODOLAC						
AB	TEVA	400MG	N75665 003	FEB 05, 2001	FEB	NEWA

FAMCICLOVIR

TABLET; ORAL

FAMVIR

NOVARTIS	125MG	N20363 003	DEC 11, 1995	JAN	CAHN
	250MG	N20363 001	APR 26, 1996	JAN	CAHN
+	500MG	N20363 002	JUN 29, 1994	JAN	CAHN

FAMOTIDINE

INJECTABLE; INJECTION

>A>	FAMOTIDINE				
>A>	AP	AM PHARM PARTNERS	10MG/ML	N75709 001	APR 16, 2001 APR NEWA
>A>	AP	APOTHECON	10MG/ML	N75707 001	APR 16, 2001 APR NEWA
>A>	AP	BEDFORD	10MG/ML	N75651 001	APR 16, 2001 APR NEWA
>A>	AP		10MG/ML	N75684 001	APR 16, 2001 APR NEWA
>A>	AP	ESI LEDERLE	10MG/ML	N75488 001	APR 16, 2001 APR NEWA
>A>	AP	FAULDING	10MG/ML	N75705 001	APR 16, 2001 APR NEWA
>A>	FAMOTIDINE PRESERVATIVE FREE				
>A>	AP	AM PHARM PARTNERS	10MG/ML	N75813 001	APR 16, 2001 APR NEWA
>A>	AP	APOTHECON	10MG/ML	N75708 001	APR 16, 2001 APR NEWA
>A>	AP	BEDFORD	10MG/ML	N75622 001	APR 16, 2001 APR NEWA
>A>	AP	BEN VENUE	10MG/ML	N75825 001	APR 17, 2001 APR NEWA
>A>	AP	ESI LEDERLE	10MG/ML	N75486 001	APR 16, 2001 APR NEWA
>A>	AP	FAULDING	10MG/ML	N75669 001	APR 16, 2001 APR NEWA
>A>	PEPCID				
>A>	AP +	MERCK	10MG/ML	N19510 001	NOV 04, 1986 APR CFTG
>D>	+		10MG/ML	N19510 001	NOV 04, 1986 APR CFTG
>A>	PEPCID PRESERVATIVE FREE				
>A>	AP +	MERCK	10MG/ML	N19510 004	NOV 04, 1986 APR CFTG
>D>	+		10MG/ML	N19510 004	NOV 04, 1986 APR CFTG
>A>	TABLET; ORAL				
>A>	FAMOTIDINE				
>A>	AB	CARLSBAD	20MG	N75805 001	APR 16, 2001 APR NEWA
>A>	AB		40MG	N75805 002	APR 16, 2001 APR NEWA
>A>	AB	DANBURY PHARMA	20MG	N75062 002	APR 16, 2001 APR NEWA
>A>	AB		40MG	N75062 001	APR 16, 2001 APR NEWA
>A>	AB	DR REDDYS LABS LTD	20MG	N75718 001	APR 16, 2001 APR NEWA
>A>	AB		40MG	N75718 002	APR 16, 2001 APR NEWA
>A>	AB	EON	20MG	N75793 001	APR 16, 2001 APR NEWA
>A>	AB		40MG	N75793 002	APR 16, 2001 APR NEWA
>A>	AB	GENEVA PHARMS	20MG	N75302 001	APR 16, 2001 APR NEWA
>A>	AB		40MG	N75302 002	APR 16, 2001 APR NEWA
>A>	AB	GENPHARM	20MG	N75457 001	APR 18, 2001 APR NEWA
>A>	AB		40MG	N75457 002	APR 18, 2001 APR NEWA
>A>	AB	MYLAN	20MG	N75704 001	APR 16, 2001 APR NEWA
>A>	AB		40MG	N75704 002	APR 16, 2001 APR NEWA
>A>	AB	TEVA	20MG	N75311 001	APR 16, 2001 APR NEWA
>A>	AB		40MG	N75311 002	APR 16, 2001 APR NEWA
>A>	AB	WOCKHARDT	20MG	N75786 001	APR 16, 2001 APR NEWA
>A>	AB		40MG	N75786 002	APR 16, 2001 APR NEWA
>A>	AB	ZENITH GOLDLINE	20MG	N75511 001	APR 16, 2001 APR NEWA
>A>	AB		40MG	N75511 002	APR 16, 2001 APR NEWA
>A>	PEPCID				

FAMOTIDINE

TABLET; ORAL

>A> PEPCID

>A>	AB	MERCK	20MG	N19462 001	OCT 15, 1986	APR	CFTG
>A>	AB	+	40MG	N19462 002	OCT 15, 1986	APR	CFTG
>D>			20MG	N19462 001	OCT 15, 1986	APR	CFTG
>D>		+	40MG	N19462 002	OCT 15, 1986	APR	CFTG

FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE PRESERVATIVE FREE

	@	MARSAM	EQ 0.05MG BASE/ML	N74917 001	FEB 03, 1998	JAN	DISC
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FLOXURIDINE

INJECTABLE; INJECTION

FLOXURIDINE

AP		AM PHARM PARTNERS	500MG/VIAL	N75837 001	FEB 22, 2001	FEB	NEWA
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FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

FLUOCINOLONE ACETONIDE

>D>	AT	CLAY PARK	0.01%	N86810 001	MAR 04, 1982	APR	DISC
>D>	AT		0.025%	N86811 001	MAR 04, 1982	APR	DISC
>A>		@	0.01%	N86810 001	MAR 04, 1982	APR	DISC
>A>		@	0.025%	N86811 001	MAR 04, 1982	APR	DISC

FLUOROMETHOLONE

SUSPENSION; OPHTHALMIC

FLUOR-OP

AB		NOVARTIS	0.1%	N70185 001	FEB 27, 1986	FEB	CAHN
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FLUOXETINE HYDROCHLORIDE

CAPSULE, DELAYED REL PELLETS; ORAL

PROZAC WEEKLY

	+	LILLY	EQ 90MG BASE	N21235 001	FEB 26, 2001	FEB	NEWA
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FLURBIPROFEN

TABLET; ORAL

FLURBIPROFEN

>A>	AB	CARACO	50MG	N75058 001	APR 27, 2001	APR	NEWA
>A>	AB		100MG	N75058 002	APR 27, 2001	APR	NEWA

FLUVOXAMINE MALEATE

TABLET; ORAL

FLUVOXAMINE MALEATE

AB		BARR	25MG	N75897 001	JAN 25, 2001	JAN	NEWA
AB			50MG	N75897 002	JAN 25, 2001	JAN	NEWA
AB			100MG	N75897 003	JAN 25, 2001	JAN	NEWA
AB		INVAMED	25MG	N75887 001	JAN 05, 2001	JAN	NEWA
AB			50MG	N75887 002	JAN 05, 2001	JAN	NEWA
AB			100MG	N75887 003	JAN 05, 2001	JAN	NEWA
AB		SYNTHON PHARMS	25MG	N75899 001	JAN 17, 2001	JAN	NEWA
AB			50MG	N75899 002	JAN 17, 2001	JAN	NEWA

	AB		100MG	N75899 003	JAN 17, 2001	JAN	NEWA
>A>	AB	WATSON LABS	25MG	N75894 001	APR 18, 2001	APR	NEWA
>A>	AB		50MG	N75894 002	APR 18, 2001	APR	NEWA
>A>	AB		100MG	N75894 003	APR 18, 2001	APR	NEWA
	AB	ZENITH GOLDLINE	25MG	N75898 001	MAR 12, 2001	MAR	NEWA
	AB		50MG	N75898 002	MAR 12, 2001	MAR	NEWA
	AB		100MG	N75898 003	MAR 12, 2001	MAR	NEWA
<u>FORMOTEROL FUMARATE</u>							
CAPSULE; INHALATION							
FORADIL							
	+	NOVARTIS	0.012MG/INH	N20831 001	FEB 16, 2001	FEB	NEWA
<u>GABAPENTIN</u>							
CAPSULE; ORAL							
NEURONTIN							
		PFIZER	100MG	N20235 001	DEC 30, 1993	MAR	CAHN
			300MG	N20235 002	DEC 30, 1993	MAR	CAHN
	+		400MG	N20235 003	DEC 30, 1993	MAR	CAHN
<u>GALANTAMINE HYDROBROMIDE</u>							
TABLET; ORAL							
REMINYL							
		JANSSEN RES FDN	EQ 4MG BASE	N21169 001	FEB 28, 2001	FEB	NEWA
			EQ 8MG BASE	N21169 002	FEB 28, 2001	FEB	NEWA
	+		EQ 12MG BASE	N21169 003	FEB 28, 2001	FEB	NEWA
<u>GEMFIBROZIL</u>							
TABLET; ORAL							
GEMFIBROZIL							
	AB	GENEVA PHARMS TECH	600MG	N74615 001	SEP 29, 1995	JAN	CAHN
<u>GENTAMICIN SULFATE</u>							
INJECTABLE; INJECTION							
GENTAMICIN SULFATE							
>D>	AP	GENSIA SICOR PHARMS	EQ 40MG BASE/ML	N63106 002	NOV 21, 1991	APR	DISC
>A>		@	EQ 40MG BASE/ML	N63106 002	NOV 21, 1991	APR	DISC
>D>	AP	STERIS	EQ 10MG BASE/ML	N62318 002	AUG 20, 1981	APR	DISC
>D>	AP		EQ 40MG BASE/ML	N62318 001	JUN 02, 1981	APR	DISC
>A>		@	EQ 10MG BASE/ML	N62318 002	AUG 20, 1981	APR	DISC
>A>		@	EQ 40MG BASE/ML	N62318 001	JUN 02, 1981	APR	DISC
		U-GENCIN					
		@ PHARMACIA AND UPJOHN	EQ 10MG BASE/ML	N62248 001	MAY 02, 1980	FEB	WDRP
		@	EQ 40MG BASE/ML	N62248 002	MAY 02, 1980	FEB	WDRP
>D>		INJECTABLE; INTRATHECAL					
>D>		GARAMYCIN					
>D>	+	SCHERING	EQ 2MG BASE/ML	N50505 001	OCT 01, 1979	APR	DISC
>A>		@	EQ 2MG BASE/ML	N50505 001	OCT 01, 1979	APR	DISC
OINTMENT; OPHTHALMIC							
GENTACIDIN							
	AT	NOVARTIS	EQ 0.3% BASE	N62501 001	JUL 26, 1984	FEB	CAHN
SOLUTION/DROPS; OPHTHALMIC							
	AT	NOVARTIS	EQ 0.3% BASE	N62480 001	MAR 30, 1984	FEB	CAHN

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

GENTAMICIN SULFATE

>D>	AT	ALCON UNIVERSAL	EQ 0.3% BASE	N62523 001	NOV 25, 1985	APR	DISC
>A>		@	EQ 0.3% BASE	N62523 001	NOV 25, 1985	APR	DISC

GLIPIZIDE

TABLET; ORAL

GLIPIZIDE

AB		GENEVA PHARMS TECH	5MG	N74542 001	JUN 20, 1995	JAN	CAHN
AB			10MG	N74542 002	JUN 20, 1995	JAN	CAHN

GRISEOFULVIN, MICROCRYSTALLINE

SUSPENSION; ORAL

GRIFULVIN V

+	J AND J		125MG/5ML	N62483 001	JAN 26, 1984	MAR	CRLD
	@	JOHNSON AND JOHNSON	125MG/5ML	N50448 001	MAY 19, 1972	MAR	DISC

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL

GRISACTIN ULTRA

>D>	AB	WYETH AYERST	125MG	N62178 001	MAR 13, 1980	APR	DISC
>D>	AB		250MG	N62178 002	MAR 13, 1980	APR	DISC
>A>		@	125MG	N62178 001	MAR 13, 1980	APR	DISC
>A>		@	250MG	N62178 002	MAR 13, 1980	APR	DISC

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALOPERIDOL LACTATE

AP		AM PHARM PARTNERS	EQ 5MG BASE/ML	N75689 001	MAR 09, 2001	MAR	NEWA
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HALOTHANE

LIQUID; INHALATION

HALOTHANE

		@	BH	99.99%	N84977 001	JUL 14, 1976	JAN	DISC
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HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM PRESERVATIVE FREE

		@	PHARMA SERVE NY	1,000 UNITS/ML	N86129 001	FEB 22, 1980	FEB	WDRP
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HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDRALAZINE HCL

AP		AM PHARM PARTNERS	20MG/ML	N40388 001	MAR 13, 2001	MAR	NEWA
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HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

RESERPINE AND HYDROCHLOROTHIAZIDE-50

		@	WEST WARD	50MG;0.125MG	N88189 001	MAY 10, 1984	FEB	WDRP
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HYDROCORTISONE

CREAM; TOPICAL

HC (HYDROCORTISONE)

@ C AND M PHARMA 0.5%
 @ 1%

N80482 003 MAR 20, 1973 FEB WDRP
 N80482 004 MAR 20, 1973 FEB WDRP

HYDROCORTISONE

@ TOPIDERM 1%
 PROTOCORT

N89273 001 FEB 17, 1989 FEB WDRP

@ MONARCH PHARMS 1%

N83011 001 APR 26, 1973 FEB DISC

LOTION; TOPICAL

BETA-HC

@ BETA DERMAC 1%

N89495 001 JAN 25, 1988 FEB WDRP

GLYCORT

@ HERAN 1%

N87489 001 OCT 03, 1983 FEB WDRP

OINTMENT; TOPICAL

HC (HYDROCORTISONE)

@ C AND M PHARMA 1%

N80481 002 MAR 20, 1973 FEB WDRP

POWDER; FOR RX COMPOUNDING

H-CORT

@ TORCH 100%

N87834 001 MAR 29, 1982 FEB WDRP

HYDROCORTISONE ACETATE

CREAM; TOPICAL

MICORT-HC

FERNDAL LABS 2.5%

N40396 001 FEB 27, 2001 FEB NEWA

HYDROCORTISONE ACETATE; NEOMYCIN SULFATE

OINTMENT; TOPICAL

NEO-CORTEF

>D> + PHARMACIA AND UPJOHN 1%;EQ 3.5MG BASE/GM
 >A> @ 1%;EQ 3.5MG BASE/GM

N60751 002 MAY 18, 1965 APR DISC
 N60751 002 MAY 18, 1965 APR DISC

SUSPENSION/DROPS; OPHTHALMIC

COR-OTICIN

@ AKORN 1.5%;EQ 3.5MG BASE/ML

N60188 001 OCT 26, 1968 FEB WDRP

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC

NEO-OTOSOL-HC

>D> AT ALCON 1%;EQ 3.5MG BASE/ML;10,000
 UNITS/ML

N62423 001 AUG 25, 1983 APR DISC

>A> @ 1%;EQ 3.5MG BASE/ML;10,000
 UNITS/ML

N62423 001 AUG 25, 1983 APR DISC

SUSPENSION/DROPS; OTIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

>D> AT ALCON UNIVERSAL 1%;EQ 3.5MG BASE/ML;10,000
 UNITS/ML

N62488 001 NOV 06, 1985 APR DISC

>A> @ 1%;EQ 3.5MG BASE/ML;10,000
 UNITS/ML

N62488 001 NOV 06, 1985 APR DISC

HYDROXYZINE PAMOATE

CAPSULE; ORAL

HYDROXYZINE PAMOATE

@ VANGARD

EQ 50MG HCL

N88393 001 SEP 19, 1983 FEB WDRP

INDAPAMIDE

TABLET; ORAL

INDAPAMIDE

AB GENEVA PHARMS TECH

1.25MG

N74594 001 MAY 23, 1996 JAN CAHN

AB

2.5MG

N74594 002 MAY 23, 1996 JAN CAHN

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

IPRATROPIUM BROMIDE

AN ASLUNG PHARM

0.02%

N75693 001 JAN 26, 2001 JAN NEWA

AN NOVEX

0.02%

N75441 001 MAR 28, 2001 MAR NEWA

AN WARRICK PHARMS

0.02%

N75507 001 JAN 19, 2001 JAN NEWA

ISOFLURANE

LIQUID; INHALATION

ISOFLURANE

AN MINRAD

99.9%

N74416 001 SEP 30, 1994 FEB CAHN

ISOTRETINOIN

CAPSULE; ORAL

ACCUTANE

>D> HLR

20MG

N18662 004 MAR 28, 1983 APR CTEC

>A> +

20MG

N18662 004 MAR 28, 1983 APR CTEC

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANAMYCIN SULFATE

>D> AP LOCH

EQ 1GM BASE/3ML

N63025 001 JUL 31, 1992 APR DISC

>A> @

EQ 1GM BASE/3ML

N63025 001 JUL 31, 1992 APR DISC

LAMOTRIGINE

TABLET, CHEWABLE; ORAL

LAMICTAL CD

GLAXO WELLCOME

2MG

N20764 004 SEP 08, 2000 MAR NEWA

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUM PRESERVATIVE FREE

AP LUITPOLD

EQ 50MG BASE/VIAL

N40338 001 JAN 31, 2001 JAN NEWA

LEVOCARNITINE

INJECTABLE; INJECTION

CARNITOR

AP + SIGMA TAU

200MG/ML

N20182 001 DEC 16, 1992 MAR CFTG

LEVOCARNITINE

AP BEDFORD

200MG/ML

N75567 001 MAR 29, 2001 MAR NEWA

AP GENZIA SICOR PHARMS

200MG/ML

N75881 001 MAR 29, 2001 MAR NEWA

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCATON

@ PHARMATON

2%

N84727 001 AUG 17, 1983 FEB WDRP

LISINAPRIL

TABLET; ORAL

ZESTRIL

>D> AB + ASTRAZENECA

10MG

N19777 002 MAY 19, 1988 APR CTEC

>A> AB

10MG

N19777 002 MAY 19, 1988 APR CTEC

MEPROBAMATE

TABLET; ORAL

AMOSENE

@ FERNDAL LABS

400MG

N84030 001 MAY 10, 1974 FEB WDRP

MESALAMINE

SUPPOSITORY; RECTAL

CANASA

+ AXCAN SCANDIPHARM

500MG

N21252 001 JAN 05, 2001 JAN NEWA

MESNA

INJECTABLE; INTRAVENOUS

MESNA

>A>

>A> AP AM PHARM PARTNERS

100MG/ML

N75811 001 APR 26, 2001 APR NEWA

>A>

AP GENZIA SICOR PHARMS

100MG/ML

N75764 001 APR 27, 2001 APR NEWA

>A>

MESNEX

>A>

AP + ASTA

100MG/ML

N19884 001 DEC 30, 1988 APR CFTG

>D>

+

100MG/ML

N19884 001 DEC 30, 1988 APR CFTG

METAPROTERENOL SULFATE

SOLUTION; INHALATION

METAPROTERENOL SULFATE

AN NOVEX

0.4%

N75402 001 FEB 28, 2001 FEB NEWA

AN

0.6%

N75403 001 FEB 28, 2001 FEB NEWA

METHIMAZOLE

TABLET; ORAL

METHIMAZOLE

AB EON

5MG

N40411 001 MAR 27, 2001 MAR NEWA

AB

10MG

N40411 002 MAR 27, 2001 MAR NEWA

METHOTREXATE SODIUM

TABLET; ORAL

Trexall

BARR

EQ 5MG BASE

N40385 001 MAR 21, 2001 MAR NEWA

EQ 7.5MG BASE

N40385 002 MAR 21, 2001 MAR NEWA

EQ 10MG BASE

N40385 003 MAR 21, 2001 MAR NEWA

+

EQ 15MG BASE

N40385 004 MAR 21, 2001 MAR NEWA

METHYLPHENIDATE HYDROCHLORIDE

>A>	CAPSULE, EXTENDED RELEASE; ORAL				
>A>	METADATE CD				
>A>	+	CELLTECH PHARMS	20MG	N21259 001	APR 03, 2001 APR NEWA
	TABLET; ORAL				
>A>	METHYLPHENIDATE HCL				
AB	ABLE		5MG	N40404 001	MAR 29, 2001 MAR NEWA
AB			10MG	N40404 002	MAR 29, 2001 MAR NEWA
AB			20MG	N40404 003	MAR 29, 2001 MAR NEWA
	TABLET, EXTENDED RELEASE; ORAL				
>A>	METADATE ER				
>A>	AB	CELLTECH PHARMS	10MG	N40306 001	OCT 20, 1999 APR CTEC
>D>	AB	+ MEDEVA	10MG	N40306 001	OCT 20, 1999 APR CTEC
>A>	METHYLPHENIDATE HCL				
AB	DANBURY PHARMA		20MG	N40410 001	FEB 09, 2001 FEB NEWA

METHYLTESTOSTERONE

	TABLET; BUCCAL				
	ORETON				
	@	SCHERING	10MG	N80281 001	AUG 03, 1979 FEB DISC

METOCLOPRAMIDE HYDROCHLORIDE

	SOLUTION; INJECTION				
	METOCLOPRAMIDE				
AA	UDL		EQ 5MG BASE/5ML	N75051 001	JAN 26, 2001 JAN NEWA
	TABLET; ORAL				
	METOCLOPRAMIDE HCL				
AB	GENEVA PHARMS TECH		EQ 5MG BASE	N74478 001	OCT 05, 1995 JAN CAHN
AB			EQ 10MG BASE	N74478 002	OCT 05, 1995 JAN CAHN

METOPROLOL SUCCINATE

	TABLET, EXTENDED RELEASE; ORAL				
	TOPROL-XL				
	+	ASTRAZENECA	EQ 25MG TARTRATE	N19962 004	FEB 05, 2001 FEB NEWA

METRONIDAZOLE

	TABLET; ORAL				
	PROTOSTAT				
	@	JOHNSON RW	250MG	N18871 001	MAR 02, 1983 MAR DISC
	@		500MG	N18871 002	MAR 02, 1983 MAR DISC

MINOCYCLINE HYDROCHLORIDE

	CAPSULE; ORAL				
	MINOCIN				
AB	LEDERLE		EQ 75MG BASE	N50649 003	FEB 12, 2001 MAR NEWA
AB	+		EQ 100MG BASE	N50649 002	MAY 31, 1990 MAR CRLD
	MINOCYCLINE HCL				
AB	DANBURY PHARMA		EQ 100MG BASE	N63065 001	DEC 30, 1991 MAR CRLD
>A>	AB	IMPAX LABS	EQ 75MG BASE	N65005 003	APR 18, 2001 APR NEWA
	POWDER, EXTENDED RELEASE; DENTAL				
	ARESTIN				
	+	ORAPHARMA	EQ 1MG BASE	N50781 001	FEB 16, 2001 FEB NEWA

MIRTAZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL
REMERON SOLTAB

+ ORGANON INC

15MG
30MG
45MG

N21208 001 JAN 12, 2001 JAN NEWA
N21208 002 JAN 12, 2001 JAN NEWA
N21208 003 JAN 12, 2001 JAN NEWA

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
MORPHINE SULFATE

AB WATSON LABS

100MG

N75656 001 JAN 30, 2001 JAN NEWA

NADOLOL

TABLET; ORAL
NADOLOL

AB GENEVA PHARMS TECH

20MG

AB

40MG

AB

80MG

N74501 001 NOV 09, 1995 JAN CAHN
N74501 002 NOV 09, 1995 JAN CAHN
N74501 003 NOV 09, 1995 JAN CAHN

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE

@ WYETH AYERST
@
@
@

0.02MG/ML

0.02MG/ML

0.4MG/ML

0.4MG/ML

N70188 001 SEP 24, 1986 JAN DISC
N70189 001 SEP 24, 1986 JAN DISC
N70190 001 SEP 24, 1986 JAN DISC
N70191 001 SEP 24, 1986 JAN DISC

NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
VASOCON

AT NOVARTIS

0.1%

N80235 002 MAR 24, 1983 FEB CAHN

NAPROXEN

TABLET, EXTENDED RELEASE; ORAL
NAPROXEN

>A> AB + ALPHAPHARM

375MG

>A> AB +

500MG

N75390 001 APR 19, 2001 APR NEWA
N75390 002 APR 19, 2001 APR NEWA

NAPROXEN SODIUM

TABLET; ORAL
NAPROXEN SODIUM

AB GENEVA PHARMS TECH

EQ 250MG BASE

AB

EQ 500MG BASE

N74495 001 DEC 05, 1994 JAN CAHN
N74495 002 DEC 05, 1994 JAN CAHN

NEFAZODONE HYDROCHLORIDE

TABLET; ORAL
SERZONE

+ BRISTOL MYERS SQUIBB

50MG

>D>

>A>

50MG

N20152 001 DEC 22, 1994 APR CTEC
N20152 001 DEC 22, 1994 APR CTEC

<u>NIFEDIPINE</u>							
CAPSULE; ORAL							
NIFEDIPINE							
	@ CHASE LABS NJ	10MG		N72409 001	JUL 04, 1990	FEB	WDRP
	@	20MG		N73421 001	JUN 19, 1991	FEB	WDRP
TABLET, EXTENDED RELEASE; ORAL							
ADALAT CC							
>D>	AB + BAYER	30MG		N20198 001	APR 21, 1993	APR	CTEC
>A>	AB	30MG		N20198 001	APR 21, 1993	APR	CTEC
NIFEDIPINE							
AB2	BIOVAIL	30MG		N75289 002	FEB 06, 2001	FEB	NEWA
PROCARDIA XL							
AB2 +	PFIZER	30MG		N19684 001	SEP 06, 1989	FEB	CTEC
<u>NITROFURAZONE</u>							
POWDER; TOPICAL							
FURACIN							
	@ ROBERTS LABS	0.2%		N83791 001	OCT 17, 1975	FEB	WDRP
<u>NITROGLYCERIN</u>							
AEROSOL; SUBLINGUAL							
NITROLINGUAL							
>D>	+ POHL BOSKAMP	0.4MG/SPRAY		N18705 001	OCT 31, 1985	APR	DISC
>A>	@	0.4MG/SPRAY		N18705 001	OCT 31, 1985	APR	DISC
<u>NYSTATIN</u>							
TABLET; VAGINAL							
KOROSTATIN							
	@ HOLLAND RANTOS	100,000 UNITS		N61718 001	SEP 30, 1974	FEB	WDRP
<u>OXACILLIN SODIUM</u>							
INJECTABLE; INJECTION							
BACTOCILL							
	@ SMITHKLINE BEECHAM	EQ 1GM BASE/VIAL		N62736 001	DEC 19, 1986	FEB	DISC
	@	EQ 2GM BASE/VIAL		N62736 002	DEC 19, 1986	FEB	DISC
OXACILLIN SODIUM							
AP +	APOTHECON	EQ 1GM BASE/VIAL		N61490 003	APR 08, 1971	FEB	CRLD
AP +		EQ 2GM BASE/VIAL		N62737 002	DEC 23, 1986	FEB	CRLD
<u>OXAPROZIN</u>							
TABLET; ORAL							
DAYPRO							
AB +	SEARLE	600MG		N18841 004	OCT 29, 1992	JAN	CFTG
OXAPROZIN							
AB	DR REDDYS LABS LTD	600MG		N75855 001	JAN 31, 2001	JAN	NEWA
AB	EON	600MG		N75845 001	JAN 31, 2001	JAN	NEWA
>A>	AB	GENEVA PHARMS	600MG	N75850 001	APR 27, 2001	APR	NEWA
AB	GENPHARM	600MG		N75847 001	FEB 28, 2001	FEB	NEWA
>A>	AB	INVAMED	600MG	N75842 001	APR 12, 2001	APR	NEWA
AB	WATSON LABS	600MG		N75848 001	FEB 09, 2001	FEB	NEWA

OXYTETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

OXYTETRACYCLINE HCL

@ IMPAX LABS

EQ 250MG BASE

N60760 001 AUG 09, 1967 FEB DISC

@ PROTER

EQ 250MG BASE

N60869 001 JAN 29, 1964 FEB WDRP

PACLITAXEL

INJECTABLE; INJECTION

PACLITAXEL

AP ZENITH GOLDLINE

6MG/ML

N75297 001 MAR 27, 2001 MAR NEWA

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION

AREDIA

>A> AP + NOVARTIS

30MG/VIAL

N20036 001 OCT 31, 1991 APR CFTG

>A> AP +

90MG/VIAL

N20036 004 MAY 06, 1993 APR CFTG

>D> +

30MG/VIAL

N20036 001 OCT 31, 1991 APR CFTG

>D> +

90MG/VIAL

N20036 004 MAY 06, 1993 APR CFTG

>A> PAMIDRONATE DISODIUM

>A> AP BEDFORD

30MG/VIAL

N75290 001 APR 30, 2001 APR NEWA

>A> AP

90MG/VIAL

N75290 003 APR 30, 2001 APR NEWA

PANTOPRAZOLE SODIUM

INJECTABLE; IV (INFUSION)

PROTONIX IV

+ WYETH AYERST

EQ 40MG BASE/VIAL

N20988 001 MAR 22, 2001 MAR NEWA

PEMOLINE

TABLET; ORAL

PEMOLINE

AB MALLINCKRODT

18.75MG

N75726 003 MAR 30, 2001 MAR NEWA

AB

37.5MG

N75726 002 MAR 30, 2001 MAR NEWA

AB

75MG

N75726 001 MAR 30, 2001 MAR NEWA

PENICILLIN G SODIUM

INJECTABLE; IM-IV

PENICILLIN G SODIUM

+ BIOCHEMIE

5,000,000 UNITS/VIAL

N65068 001 FEB 26, 2001 FEB NEWA

@ MARSAM

5,000,000 UNITS/VIAL

N63014 001 SEP 13, 1988 FEB DISC

PERPHENAZINE

CONCENTRATE; ORAL

TRILAFON

@ SCHERING

16MG/5ML

N11557 001 DEC 12, 1958 MAR DISC

PHENYTOIN

SUSPENSION; ORAL

PHENYTOIN

AB UDL

125MG/5ML

N40342 001 JAN 31, 2001 JAN NEWA

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL
K-DUR 10

>D>	AB +	KEY PHARMS	10MEQ	N19439 002	JUN 13, 1986	APR	CTEC
>A>	AB		10MEQ	N19439 002	JUN 13, 1986	APR	CTEC

PREDNICARBATE

OINTMENT; TOPICAL
DERMATOP

	+	AVENTIS PHARMS	0.1%	N19568 001	SEP 23, 1991	MAR	CMFD
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PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

OINTMENT; OPHTHALMIC
VASOCIDIN

AT		NOVARTIS	0.5%;10%	N88791 001	OCT 05, 1984	FEB	CAHN
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SUSPENSION/DROPS; OPHTHALMIC
METIMYD

	+	SCHERING	0.5%;10%	N10210 001	FEB 24, 1956	FEB	CTEC
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PREDAMIDE

	@	AKORN	0.5%;10%	N88059 001	JUL 29, 1983	FEB	WDRP
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SULPHRIN

	@	BAUSCH AND LOMB	0.5%;10%	N88089 001	DEC 28, 1982	FEB	WDRP
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PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
INFLAMASE FORTE

AT +		NOVARTIS	EQ 0.9% PHOSPHATE	N80751 002	DEC 19, 1973	FEB	CAHN
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INFLAMASE MILD

AT +		NOVARTIS	EQ 0.11% PHOSPHATE	N80751 001	DEC 19, 1973	FEB	CAHN
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PREDNISOLONE SODIUM PHOSPHATE

	@	AKORN	EQ 0.11% PHOSPHATE	N83358 001	AUG 21, 1974	FEB	WDRP
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	@		EQ 0.9% PHOSPHATE	N83358 002	AUG 21, 1974	FEB	WDRP
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PROCHLORPERAZINE MALEATE

TABLET; ORAL

PROCHLORPERAZINE MALEATE

AB		GENEVA PHARMS TECH	EQ 5MG BASE	N40101 001	JUL 19, 1996	JAN	CAHN
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AB			EQ 10MG BASE	N40101 002	JUL 19, 1996	JAN	CAHN
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AB			EQ 25MG BASE	N40101 003	JUL 19, 1996	JAN	CAHN
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PROGESTERONE

INJECTABLE; INJECTION

>A>		PROGESTERONE					
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>A>	AO	AM PHARM PARTNERS	50MG/ML	N75906 001	APR 25, 2001	APR	NEWA
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>D>	AO +	STERIS	50MG/ML	N17362 002	MAY 08, 1978	APR	CFTG
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>A>	AO +		50MG/ML	N17362 002	MAY 08, 1978	APR	CFTG
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PROTRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

PROTRIPTYLINE HCL

AB		ODYSSEY PHARMS	5MG	N73644 001	AUG 24, 1995	JAN	CAHN
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AB			10MG	N73645 001	AUG 24, 1995	JAN	CAHN
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PROTRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

VIVACTIL

AB	ODYSSEY PHARMS	5MG	N73644 001	AUG 24, 1995	MAR	CTNA
AB +		10MG	N73645 001	AUG 24, 1995	MAR	CTNA
	@ SIDMAK LABS	5MG	N16012 001	SEP 27, 1967	MAR	DISC
	@	10MG	N16012 002	SEP 27, 1967	MAR	DISC

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

TRILITRON

@ NEWTRON PHARMS	30MG/5ML;1.25MG/5ML	N88474 001	FEB 12, 1985	FEB	WDRP
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QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL

QUINAGLUTE

BX +	BERLEX LABS	324MG	N16647 001	DEC 08, 1969	MAR	CTEC
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QUINIDINE GLUCONATE

BX	DANBURY PHARMA	324MG	N87810 001	SEP 29, 1982	MAR	CTEC
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@ GENEVA PHARMS	324MG	N89894 001	DEC 15, 1988	MAR	DISC
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BX	MUTUAL PHARM	324MG	N89338 001	FEB 11, 1987	MAR	CTEC
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QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

@ IMPAX LABS	200MG	N83347 001	DEC 08, 1976	FEB	DISC
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RIFAMPIN

CAPSULE; ORAL

RIFAMPIN

AB	VERSAPHARM	150MG	N65028 001	MAR 14, 2001	MAR	NEWA
AB		300MG	N65028 002	MAR 14, 2001	MAR	NEWA

RISPERIDONE

TABLET; ORAL

RISPERDAL

>A>	JANSSEN	0.5MG	N20272 007	JAN 27, 1999	APR	CRLD
>A>	+	1MG	N20272 001	DEC 29, 1993	APR	CRLD
>A>		4MG	N20272 004	DEC 29, 1993	APR	CRLD
>D>	+ JANSSEN RES FDN	0.5MG	N20272 007	JAN 27, 1999	APR	CRLD
>D>		1MG	N20272 001	DEC 29, 1993	APR	CRLD
>D>	+	4MG	N20272 004	DEC 29, 1993	APR	CRLD

SECOBARBITAL SODIUM

CAPSULE; ORAL

SECOBARBITAL SODIUM

@ ICN	100MG	N85477 001	DEC 10, 1981	FEB	WDRP
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SIMVASTATIN

TABLET; ORAL

ZOCOR

>D>	+ MERCK	5MG	N19766 001	DEC 23, 1991	APR	CTEC
>A>		5MG	N19766 001	DEC 23, 1991	APR	CTEC

>A>
>A>
>A>
>A>

>D>
>A>
>A>
>A>
>A>
>A>
>A>

>A>
>A>
>D>

SOTALOL HYDROCHLORIDE

TABLET; ORAL

SORINE

>A>	AB	UPSHER SMITH	80MG	N75500 001	APR 27, 2001	APR	NEWA
>A>	AB		120MG	N75500 004	APR 27, 2001	APR	NEWA
>A>	AB		160MG	N75500 002	APR 27, 2001	APR	NEWA
>A>	AB		240MG	N75500 003	APR 27, 2001	APR	NEWA

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

SULF-10

@ NOVARTIS

10%

N80025 001 JUN 03, 1971 FEB CAHN

SULF-15

AT NOVARTIS

15%

N89047 001 OCT 31, 1995 FEB CAHN

SULTEN-10

@ BAUSCH AND LOMB

10%

N87818 001 FEB 03, 1983 FEB WDRP

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL

TRIMETH/SULFA

@ NASKA

200MG/5ML;40MG/5ML

N72399 001 MAY 23, 1988 FEB WDRP

SULFANILAMIDE

CREAM; VAGINAL

AVC

AT + NOVAVAX

15%

N06530 003 JAN 27, 1987 JAN CAHN

SUPPOSITORY; VAGINAL

+ NOVAVAX

1.05GM

N06530 004 JAN 27, 1987 JAN CAHN

TECHNETIUM TC-99M APCITIDE

INJECTABLE; INJECTION

ACUTECT

>D> DIATIDE

N/A

N20887 001 SEP 14, 1998 APR CAHN

>A> DIATIDE RES LABS

N/A

N20887 001 SEP 14, 1998 APR CAHN

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

TERAZOSIN HCL

>A> AB TORPHARM

EQ 1MG BASE

N75498 001 APR 12, 2001 APR NEWA

>A> AB

EQ 2MG BASE

N75498 002 APR 12, 2001 APR NEWA

>A> AB

EQ 5MG BASE

N75498 003 APR 12, 2001 APR NEWA

>A> AB

EQ 10MG BASE

N75498 004 APR 12, 2001 APR NEWA

AB ZENITH GOLDLINE

EQ 1MG BASE

N75614 002 JAN 30, 2001 JAN NEWA

AB

EQ 2MG BASE

N75614 001 JAN 30, 2001 JAN NEWA

AB

EQ 5MG BASE

N75614 003 JAN 30, 2001 JAN NEWA

AB

EQ 10MG BASE

N75614 004 JAN 30, 2001 JAN NEWA

THIOTEPA

INJECTABLE; INJECTION

THIOPLEX

>A> AP + IMMUNEX

15MG/VIAL

N20058 001 DEC 22, 1994 APR CFTG

>D> +

15MG/VIAL

N20058 001 DEC 22, 1994 APR CFTG

THIOTEPA

INJECTABLE; INJECTION

>A>		THIOTEPA				
>A>	AP	BEDFORD	15MG/VIAL	N75547 001	APR 02, 2001	APR NEWA
>A>	AP	GENSIA SICOR PHARMS	15MG/VIAL	N75730 001	APR 20, 2001	APR NEWA
>A>	+		30MG/VIAL	N75730 002	APR 20, 2001	APR NEWA
>D>	+	IMMUNEX	15MG/VIAL	N11683 001	FEB 19, 1959	APR DISC
>A>	@		15MG/VIAL	N11683 001	FEB 19, 1959	APR DISC

THYROGLOBULIN

TABLET; ORAL

THYROGLOBULIN

@ IMPAX LABS

64.8MG

N80151 001 AUG 07, 1973 FEB DISC

TOPIRAMATE

TABLET; ORAL

TOPAMAX

+ JOHNSON RW

25MG

N20505 004 DEC 24, 1996 MAR CRLD

200MG

N20505 002 DEC 24, 1996 MAR CRLD

TRAVOPROST

SOLUTION/DROPS; OPHTHALMIC

TRAVATAN

+ ALCON UNIVERSAL

0.004%

N21257 001 MAR 16, 2001 MAR NEWA

TRIAMCINOLONE

TABLET; ORAL

TRIAMCINOLONE

@ IMPAX LABS

4MG

N84340 001 APR 22, 1975 FEB DISC

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

TRIAMCINOLONE ACETONIDE

@ TOPIDERM

0.025%

N89274 001 FEB 21, 1989 FEB WDRP

@

0.1%

N89275 001 FEB 21, 1989 FEB WDRP

@

0.5%

N89276 001 FEB 21, 1989 FEB WDRP

TRICHLORMETHIAZIDE

TABLET; ORAL

TRICHLOREX

@ LANNETT

4MG

N85630 001 MAY 16, 1977 FEB WDRP

TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL

TRIFLUOPERAZINE HCL

AB GENEVA PHARMS TECH

EQ 1MG BASE

N40153 001 OCT 25, 1996 JAN CAHN

AB

EQ 2MG BASE

N40153 002 OCT 25, 1996 JAN CAHN

AB

EQ 5MG BASE

N40153 003 OCT 25, 1996 JAN CAHN

AB

EQ 10MG BASE

N40153 004 OCT 25, 1996 JAN CAHN

VALGANCICLOVIR HYDROCHLORIDE

TABLET; ORAL

VALCYTE

+	SYNTEX (USA) INC LLC	EQ 450MG BASE	N21304 001	MAR 29, 2001	MAR NEWA
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VITAMIN A PALMITATE

CAPSULE; ORAL

VITAMIN A

@	WEST WARD	EQ 50,000 UNITS BASE	N80967 001	MAY 04, 1973	FEB WDRP
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ZIPRASIDONE HYDROCHLORIDE

CAPSULE; ORAL

GEODON

PFIZER

		20MG	N20825 001	FEB 05, 2001	FEB NEWA
		40MG	N20825 002	FEB 05, 2001	FEB NEWA
		60MG	N20825 003	FEB 05, 2001	FEB NEWA
+		80MG	N20825 004	FEB 05, 2001	FEB NEWA

ZOLMITRIPTAN

TABLET, ORALLY DISINTEGRATING; ORAL

ZOMIG-ZMT

ASTRAZENECA

2.5MG

			N21231 001	FEB 13, 2001	FEB NEWA
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ACETAMINOPHEN

SUPPOSITORY; RECTAL

ACETAMINOPHEN

ALPHARMA US PHARM	120MG	N18337 003	SEP 12, 1983	MAR	CAHN
	325MG	N18337 002	AUG 21, 1981	MAR	CAHN
+	650MG	N18337 001	APR 22, 1980	MAR	CAHN
INFANTS' FEVERALL					
ALPHARMA US PHARM	80MG	N18337 004	AUG 26, 1992	MAR	CAHN

ACETAMINOPHEN; CLEMASTINE FUMARATE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL

TAVIST ALLERGY/SINUS/HEADACHE

+	NOVARTIS	500MG;EQ 0.25MG BASE;30MG	N21082 001	MAR 01, 2001	MAR	NEWA
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CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

TAVIST-D

@	NOVARTIS	1.34MG;75MG	N18298 002	AUG 21, 1992	JAN	DISC
@		1.34MG;75MG	N20640 001	AUG 09, 1996	JAN	DISC

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL

>A>	IBUPROHM COLD AND SINUS					
>A>	OHM LABS	200MG;30MG	N74567 001	APR 17, 2001	APR	NEWA

MICONAZOLE NITRATE

CREAM; TOPICAL

MONISTAT 3 COMBINATION PACK

+	PERSONAL PRODS	2%;4%	N21261 001	FEB 02, 2001	FEB	NEWA
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CREAM; VAGINAL

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

CUMULATIVE SUPPLEMENT NUMBER 4 APRIL '01

NO APRIL 2001 APPROVALS

This data is provided to the Division of Data Management and Services from the Office of Orphan Products Development and it is not edited prior to publication.

Orphan Products Designations and Approvals List
April 2001

Name:		Sponsor & Address
Generic Name	Indication Designated:	DD=Date Designated
TN=Trade Name		MA=Marketing Approval
Alendronate disodium TN=Fosamax	Treatment of the bone manifestations of Gaucher disease	Richard J. Wenstrup, M.D. Division of Human Genetics Children's Hospital Research Cincinnati OH 45229-3039 DD= 2/13/01 MA=
B Lymphocyte Stimulator TN=BLyS	Treatment of common variable immunodeficiency (CVID)	Human Genome Sciences, Inc. 9410 Key West Avenue Rockville MD 20850 DD= 2/21/01 MA=
Busulfan TN=Spartajet-Busulfan	Intrathecal therapy for neoplastic meningitis	The Brain Tumor Center at Duke Duke University Medical Center Room 047, Baker House, South Durham NC 27710 DD= 3/5/01 MA=
Coenzyme Q10 TN=	For the treatment of Huntington's disease	Vitaline Corporation 385 Williamson Way Ashland OR 97520 DD= 3/5/01 MA=
docosahexanoic acid-paclitaxel TN=Taxoprexin	Treatment of hormone-refractory prostate cancer.	Protarga, Inc. 1100 East Hector Street Suite 450 Conshohocken PA 19428-2377 DD= 3/5/01 MA=
h5G1.1mAb TN=	Idiopathic membranous glomerular nephropathy	Alexion Pharmaceuticals, Inc. 352 Knotter Drive Cheshire CT 06410 DD= 3/5/01 MA=

Orphan Products Designations and Approvals List
April 2001

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Hsp E7 TN=	Treatment of recurrent respiratory papillomatosis (RRP)	StressGen Biotechnologies, Inc. 409 2nd Avenue Suite 201 Collegeville PA 19426-2655 DD= 3/19/01 MA=
Imatinib TN=Glivec	Treatment of chronic myelogenous leukemia	Novartis Pharmaceuticals 59 Route 10 East Hanover NJ 07936-1080 DD= 1/31/01 MA=
Interferon-alfa-1b TN=	Treatment of multiple myeloma	Ernest C. Borden Center for Cancer Drug Discovery 9500 Euclid Avenue Cleveland OH 44195 DD= 4/17/01 MA=
Medroxyprogesterone acetate TN=Hematrol	Treatment of immune thrombocytopenic purpura.	InKine Pharmaceutical Company, 1787 Sentry Parkway West Building 18, Suite 440 Blue Bell PA 19422 DD= 2/22/01 MA=
MTC-DOX for Injection TN=	Treatment of hepatocellular carcinoma	FeRx Incorporated 4330 La Jolla Village Drive Suite #250 San Diego CA 92122 DD= 1/3/01 MA=
Nitroprusside TN=	Treatment and prevention of cerebral vasospasm following subarachnoid hemorrhage.	Thomas, MD, Jeffrey Evan Thomas Jefferson University and 834 Walnut Street, Suite 650 Philadelphia PA 19107-5102 DD= 2/21/01 MA=

Orphan Products Designations and Approvals List
April 2001

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Novel Acting Thrombolytic (NAT) TN=	Treatment of peripheral arterial occlusion (PAO)	Amgen, Inc. One Amgen Center Drive Thousand Oaks CA 91320-1799 DD= 1/26/01 MA=
NZ-1002 TN=	Enzyme replacement therapy in patients with all subtypes of Mucopolysaccharidosis I.	Novazyme Pharmaceuticals, Inc. 800 Research Parkway Suite 200 Oklahoma City OK 73104 DD= 4/11/01 MA=
p1-(uridine 5'-)-p4-(2'-deoxycytidin e 5'-) tetraphosphate, tetrasodium salt TN=	For the treatment of cystic fibrosis	Inspire Pharmaceuticals, Inc. 4222 Emperor Blvd. Suite 470 Durham NC 27703 DD= 3/7/01 MA=
Perflubron TN=LiquiVent	Treatment of acute respiratory distress disease (ARDS) in adults	Alliance Pharmaceutical Corp. 3040 Science Park Road San Diego CA 92191 DD= 4/26/01 MA=
Polyethylene glycol (PEG)-uricase TN=	To control the clinical consequences of hyperuricemia in patients with severe gout in whom conventional therapy is contraindicated or has been ineffective.	Bio-Technology General Corporation 70 Wood Avenue South Iselin NJ 08830 DD= 2/21/01 MA=
Pyruvate TN=	Treatment of interstitial lung disease.	Cellular Sciences, Inc 84 park Avenue P.O. Box 968 Flemington NJ 08822 DD= 2/21/01 MA=

Orphan Products Designations and Approvals List
April 2001

Name: Generic Name <u>TN=Trade Name</u>	<u>Indication Designated:</u>	Sponsor & Address DD=Date Designated MA=Marketing Approval
Recombinant Human Alpha-Fetoprotein TN=	Treatment of myasthenia gravis	Atlantic Biopharmaceuticals, Inc. 50 Church Street 5th floor Cambridge MA 02138 DD= 2/22/01 MA=
Synthetic Human Parathyroid Hormone 1-34 TN=	Treatment of hypoparathyroidism	Orphan Pharmaceuticals, U.S., Inc. 1101 Kermit Drive, Suite 608 Nashville TN 37217 DD= 1/26/01 MA=
Unconjugated Chimeric (human-murine) G250 IgG monoclonal antibody TN=	Treatment of renal cell carcinoma.	Wilex Biotechnology GmbH Grillparzerstrasse 10B 81675 Munich Germany DE DD= 3/22/01 MA=
Vasoactive intestinal peptide TN=	Treatment of Acute Respiratory Distress Syndrome.	Sami I. Said, M.D. State University of New York at Health Sciences Center T17, 040 Stony Brook NY 11794-8172 DD= 3/9/01 MA=
Virulizin TN= Virulizin	Treatment of pancreatic cancer.	Lorus Therapeutics Inc. 7100 Woodbine Avenue, Suite 215 Markham, ON L3R 5J2 Canada DD= 2/1/01 MA=

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

NO APRIL 2001 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
021227 002	CASPOFUNGIN ACETATE;CANCIDAS	5952300	MAR 28, 2017		NCE	JAN 26, 2006
		5378804	MAR 16, 2013			
		5514650	MAR 16, 2013			
		5792746	MAR 16, 2013			
		6136783	MAR 28, 2017			
019111 001	CHLORPHENIRAMINE POLYSTIREX;TUSSIONEX	4762709	AUG 09, 2005			
021022 001	CYCLOPIROX;PENLAC	4957730	SEP 18, 2007	U-379		
020705 001	DELAVIRDINE MESYLATE;RESCRIPTOR	6177101	JUN 11, 2018			
021005 001	DICLOFENAC SODIUM;SOLARAZE					
020154 002	DIDANOSINE;VIDEX	4861759	AUG 29, 2006		NP	OCT 16, 2003
		5254539	AUG 29, 2006	U-248		
020154 003	DIDANOSINE;VIDEX	5880106	JUL 22, 2011	U-248		
		4861759	AUG 29, 2006	U-248		
020154 004	DIDANOSINE;VIDEX	5254539	AUG 29, 2006	U-248		
		5880106	JUL 22, 2011	U-248		
020154 005	DIDANOSINE;VIDEX	4861759	AUG 29, 2006	U-248		
		5254539	AUG 29, 2006	U-248		
020154 006	DIDANOSINE;VIDEX	5880106	JUL 22, 2011	U-248		
		4861759	AUG 29, 2006	U-248		
020155 003	DIDANOSINE;VIDEX	5254539	AUG 29, 2006	U-248		
		4861759	AUG 29, 2006	U-248		
020155 004	DIDANOSINE;VIDEX	5254539	AUG 29, 2006	U-248		
		4861759	AUG 29, 2006	U-248		
020155 005	DIDANOSINE;VIDEX	5254539	AUG 29, 2006	U-248		
		4861759	AUG 29, 2006	U-248		
020156 001	DIDANOSINE;VIDEX	5254539	AUG 29, 2006	U-248		
		4861759	AUG 29, 2006	U-248		
021183 001	DIDANOSINE;VIDEX EC	5254539	AUG 29, 2006	U-248		
		4861759	AUG 29, 2006	U-248		
021183 002	DIDANOSINE;VIDEX EC	5254539	AUG 29, 2006	U-248		
		4861759	AUG 29, 2006	U-248		
021183 003	DIDANOSINE;VIDEX EC	5254539	AUG 29, 2006	U-248		
		4861759	AUG 29, 2006	U-248		
021183 004	DIDANOSINE;VIDEX EC	5254539	AUG 29, 2006	U-248		
		4861759	AUG 29, 2006	U-248		
020623 001	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	5254539	AUG 29, 2006	U-248		
020623 002	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906755	JUL 02, 2011	U-248		
020624 001	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906755	JUL 02, 2011	U-248		
021098 001	DROSPIRENONE;YASMIN	4906755	JUL 02, 2011	U-248		

NC MAY 11, 2004

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
018998 001	ENALAPRIL MALEATE; VASOTEC	4486420	DEC 04, 2001	U-122	M-7	DEC 13, 2004
018998 002	ENALAPRIL MALEATE; VASOTEC	4692435	DEC 24, 2004	U-123	M-7	DEC 13, 2004
018998 003	ENALAPRIL MALEATE; VASOTEC	5389618	FEB 14, 2012		M-7	DEC 13, 2004
018998 005	ENALAPRIL MALEATE; VASOTEC	4486420	DEC 04, 2001	U-122	M-7	DEC 13, 2004
020164 002	ENOXAPARIN SODIUM; LOVENOX	4692435	DEC 24, 2004	U-123		
020164 003	ENOXAPARIN SODIUM; LOVENOX	4486420	DEC 04, 2001	U-122		
020164 004	ENOXAPARIN SODIUM; LOVENOX	5389618	FEB 14, 2012			
020164 005	ENOXAPARIN SODIUM; LOVENOX	4486420	DEC 04, 2001	U-122		
020164 006	ENOXAPARIN SODIUM; LOVENOX	5389618	DEC 24, 2004	U-123		
020164 007	ENOXAPARIN SODIUM; LOVENOX	4486420	DEC 04, 2001	U-122		
020164 008	ENOXAPARIN SODIUM; LOVENOX	5389618	FEB 14, 2012			
>ADD>	EPTIFIBATIDE; INTEGRILIN	4508905	FEB 20, 2001	U-373	D-66	JUN 08, 2004
>ADD>	EPTIFIBATIDE; INTEGRILIN	4255431	APR 05, 2001	U-373	D-66	JUN 08, 2004
>ADD>	ESOMEPRAZOLE MAGNESIUM; NEXIUM	4738974	APR 19, 2005	U-373	NP	FEB 20, 2004
		4636499	MAY 30, 2005	U-373		
		5900424	MAY 04, 2016	U-373		
		4786505	APR 20, 2007	U-373		
		4853230	APR 20, 2007	U-373		
		5714504	FEB 03, 2015	U-373		
		5877192	MAY 27, 2014	U-373		
		5093342	FEB 02, 2010	U-373		
		5599794	FEB 04, 2014	U-373		
		5629305	FEB 04, 2014	U-373		
		5690960	NOV 25, 2014	U-373		
		6147103	OCT 09, 2018	U-373		
		6166213	OCT 09, 2018	U-373		
		6191148	OCT 09, 2018	U-373		
>ADD>	ESOMEPRAZOLE MAGNESIUM; NEXIUM	4508905	FEB 20, 2001	U-373	NP	FEB 20, 2004
		4255431	APR 05, 2001	U-373		
		4738974	APR 19, 2005	U-373		
		4636499	MAY 30, 2005	U-373		
		5900424	MAY 04, 2016	U-373		
		4786505	APR 20, 2007	U-373		
		4853230	APR 20, 2007	U-373		
		5714504	FEB 03, 2015	U-373		
		5877192	MAY 27, 2014	U-373		
		5093342	FEB 02, 2010	U-373		
		5599794	FEB 04, 2014	U-373		
		5629305	FEB 04, 2014	U-373		
		5690960	NOV 25, 2014	U-373		
		6147103	OCT 09, 2018	U-373		
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		6191148	OCT 09, 2018	U-373		
>ADD>	ESOMEPRAZOLE MAGNESIUM; NEXIUM	4508905	FEB 20, 2001	U-373	NP	FEB 20, 2004
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		4636499	MAY 30, 2005	U-373		
		5900424	MAY 04, 2016	U-373		
		4786505	APR 20, 2007	U-373		
		4853230	APR 20, 2007	U-373		
		5714504	FEB 03, 2015	U-373		
		5877192	MAY 27, 2014	U-373		
		5093342	FEB 02, 2010	U-373		
		5599794	FEB 04, 2014	U-373		
		5629305	FEB 04, 2014	U-373		
		5690960	NOV 25, 2014	U-373		
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		4636499	MAY 30, 2005	U-373		
		5900424	MAY 04, 2016	U-373		
		4786505	APR 20, 2007	U-373		
		4853230	APR 20, 2007	U-373		
		5714504	FEB 03, 2015	U-373		
		5877192	MAY 27, 2014	U-373		
		5093342	FEB 02, 2010	U-373		
		5599794	FEB 04, 2014	U-373		
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		4636499	MAY 30, 2005	U-373		
		5900424	MAY 04, 2016	U-373		
		4786505	APR 20, 2007	U-373		
		4853230	APR 20, 2007	U-373		
		5714504	FEB 03, 2015	U-373		
		5877192	MAY 27, 2014	U-373		
		5093342	FEB 02, 2010	U-373		
		5599794	FEB 04, 2014	U-373		
		5629305	FEB 04, 2014	U-373		
		5690960	NOV 25, 2014	U-373		
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		4636499	MAY 30, 2005	U-373		
		5900424	MAY 04, 2016	U-373		
		4786505	APR 20, 2007	U-373		
		4853230	APR 20, 2007	U-373		
		5714504	FEB 03, 2015	U-373		
		5877192	MAY 27, 2014	U-373		
		5093342	FEB 02, 2010	U-373		
		5599794	FEB 04, 2014	U-373		
		5629305	FEB 04, 2014	U-373		
		5690960	NOV 25, 2014	U-373		
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		6166213	OCT 09, 2018	U-373		
		6191148	OCT 09, 2018	U-373		
>ADD>	ESOMEPRAZOLE MAGNESIUM; NEXIUM	4508905	FEB 20, 2001	U-373	NP	FEB 20, 2004
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		4636499	MAY 30, 2005	U-373		
		5900424	MAY 04, 2016	U-373		
		4786505	APR 20, 2007	U-373		
		4853230	APR 20, 2007	U-373		
		5714504	FEB 03, 2015	U-373		
		5877192	MAY 27, 2014	U-373		
		5093342	FEB 02, 2010	U-373		
		5599794	FEB 04, 2014	U-373		
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>ADD>	ESOMEPRAZOLE MAGNESIUM; NEXIUM	4508905	FEB 20, 2001	U-373	NP	FEB 20, 2004
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		4636499	MAY 30, 2005	U-373		
		5900424	MAY 04, 2016	U-373		
		4786505	APR 20, 2007	U-373		
		4853230	APR 20, 2007	U-373		
		5714504	FEB 03, 2015	U-373		
		5877192	MAY 27, 2014	U-373		
		5093342	FEB 02, 2010	U-373		
		5599794	FEB 04, 2014	U-373		
		5629305	FEB 04, 2014	U-373		
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>ADD>	ESOMEPRAZOLE MAGNESIUM; NEXIUM	4508905	FEB 20, 2001	U-373	NP	FEB 20, 2004
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		4636499	MAY 30, 2005	U-373		
		5900424	MAY 04, 2016	U-373		
		4786505	APR 20, 2007	U-373		
		4853230	APR 20, 2007	U-373		
		5714504	FEB 03, 2015	U-373		
		5877192	MAY 27, 2014	U-373		
		5093342	FEB 02, 2010	U-373		
		5599794	FEB 04, 2014	U-373		
		5629305	FEB 04, 2014	U-373		
		5690960	NOV 25, 2014	U-373		
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		4636499	MAY 30, 2005	U-373		
		5900424	MAY 04, 2016	U-373		
		4786505	APR 20, 2007	U-373		
		4853230	APR 20, 2007	U-373		
		5714504	FEB 03, 2015	U-373		
		5877192	MAY 27, 2014	U-373		
		5093342	FEB 02, 2010	U-373		
		5599794	FEB 04, 2014	U-373		
		5629305	FEB 04, 2014	U-373		
		5690960	NOV 25, 2014	U-373		
		6147103	OCT 09, 2018	U-373		
		6166213	OCT 09, 2018	U-373		

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL USE EXPIRES	EXCLUS CODE	EXCLUS EXPIRES
020538 005	ESTRADIOL; VIVELLE-DOT	5599794 5629305 5690960 6147103 6166213 6191148 6024976 5474783 5656286 5958446 6024976 5474783 5656286 5958446 6024976	FEB 04, 2014 FEB 04, 2014 NOV 25, 2014 OCT 09, 2018 OCT 09, 2018 OCT 09, 2018 JAN 07, 2014 DEC 12, 2012 AUG 12, 2014 DEC 12, 2012 JAN 07, 2014 DEC 12, 2012 AUG 12, 2014 DEC 12, 2012 JAN 07, 2014	U-373 U-373 U-373	
020538 006	ESTRADIOL; VIVELLE-DOT	5474783 5656286 5958446 6024976 5474783 5656286 5958446 6024976	DEC 12, 2012 AUG 12, 2014 DEC 12, 2012 JAN 07, 2014 DEC 12, 2012 AUG 12, 2014 DEC 12, 2012 JAN 07, 2014		
020538 007	ESTRADIOL; VIVELLE-DOT	5958446 6024976 5474783 5656286 5958446 6024976	DEC 12, 2012 JAN 07, 2014 AUG 12, 2014 DEC 12, 2012 AUG 12, 2014 DEC 12, 2012		
020538 008	ESTRADIOL; VIVELLE-DOT	5474783 5656286 5958446 6024976	DEC 12, 2012 AUG 12, 2014 DEC 12, 2012 JAN 07, 2014		
020946 001	ETHINYL ESTRADIOL; PREVEN EMERGENCY CON			U-374	I-321 AUG 11, 2003 I-321 AUG 11, 2003 I-321 AUG 11, 2003 D-47 NOV 09, 2001 PED MAY 09, 2002
020584 001	ETODOLAC; LODINE XL				
020584 002	ETODOLAC; LODINE XL				
020584 003	ETODOLAC; LODINE XL				
020902 001	FAMOTIDINE; PEPCID AC				
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>ADD>					
020625 001	FEXOFENADINE HYDROCHLORIDE; ALLEGRA	6187791	MAY 11, 2012	U-138	
020872 001	FEXOFENADINE HYDROCHLORIDE; ALLEGRA	6187791	MAY 11, 2012	U-138	
020872 002	FEXOFENADINE HYDROCHLORIDE; ALLEGRA	6187791	MAY 11, 2012	U-138	
020872 004	FEXOFENADINE HYDROCHLORIDE; ALLEGRA	6187791	MAY 11, 2012	U-138	
020786 001	FEXOFENADINE HYDROCHLORIDE; ALLEGRA-D	6187791	MAY 11, 2012	U-138	
020985 001	FLUOROURACIL; FLUOROURACIL	4690825	OCT 04, 2005		
021235 001	FLUOXETINE HYDROCHLORIDE; PROZAC WEEKLY				
018936 007	FLUOXETINE HYDROCHLORIDE; SARAFEM				
021077 001	FLUTICASONE PROPIONATE; ADVAIR DISKUS 100/50				
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021077 002	FLUTICASONE PROPIONATE; ADVAIR DISKUS 250/50	5270305 5290815 5270305	SEP 07, 2010 MAR 01, 2011 SEP 07, 2010	U-387 U-386 U-387	FEB 26, 2004 JAN 06, 2004
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021077 003	FLUTICASONE PROPIONATE; ADVAIR DISKUS 500/50	5290815 5270305 5290815	MAR 01, 2011 SEP 07, 2010 MAR 01, 2011	U-386 U-387 U-386	
>ADD>					
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020831 001	FORMOTEROL FUMARATE; FORADIL				
021169 001	GALANTAMINE HYDROBROMIDE; REMINYL	4663318	JAN 15, 2006	NCE	FEB 16, 2006 FEB 28, 2006

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL USE EXPIRES	EXCLUS CODE	EXCLUS EXPIRES
021169 002	GALANTAMINE HYDROBROMIDE; REMINYL	4663318	JAN 15, 2006	NCE	FEB 28, 2006
021169 003	GALANTAMINE HYDROBROMIDE; REMINYL	4663318	JAN 15, 2006	NCE	FEB 28, 2006
021224 001	GALANTAMINE HYDROBROMIDE; REMINYL	4663318	JAN 15, 2006	NCE	FEB 28, 2006
020387 001	HYDROCHLOROTHIAZIDE; HYZAAR	5608075	MAR 04, 2014		
020387 002	HYDROCHLOROTHIAZIDE; HYZAAR	5608075	MAR 04, 2014		
020402 002	IBUPROFEN POTASSIUM; ADVIL MIGRAINE LIQUI			NP	MAR 16, 2003
021128 001	IBUPROFEN; CHILDREN'S MOTRIN CO	6211246	JUN 10, 2019	NCE	MAY 10, 2006
021335 002	IMATINIB MESYLATE; GLEEVEC			ODE	MAY 10, 2008
021081 001	INSULIN GLARGINE; LANTUS	5656722	SEP 12, 2014	I-327	OCT 27, 2003
020394 001	IPRATROPIUM BROMIDE; ATROVENT	4464394	AUG 07, 2001		
018662 002	ISOTRETINOIN; ACCUTANE	4464394*	PED FEB 07, 2002		
		4464394	AUG 07, 2001		
		4464394*	PED FEB 07, 2002		
018662 003	ISOTRETINOIN; ACCUTANE	4464394*	PED FEB 07, 2002		
		4464394	AUG 07, 2001		
018662 004	ISOTRETINOIN; ACCUTANE	4464394*	PED FEB 07, 2002		
		4464394	AUG 07, 2001		
020857 001	LAMIVUDINE; COMBIVIR	6180639	JAN 30, 2018	U-248	
020564 001	LAMIVUDINE; EPIVIR	6180639	JAN 30, 2018	U-248	
020596 001	LAMIVUDINE; EPIVIR	6180639	JAN 30, 2018	U-248	
021281 001	LANSOPRAZOLE; PREVACID			I-316	NOV 30, 2003
				M-1	JUL 06, 2002
				D-42	JUL 20, 2001
				I-316	NOV 30, 2003
				M-1	JUL 06, 2002
				D-42	JUL 20, 2001
021281 002	LANSOPRAZOLE; PREVACID				
020905 001	LEFLUNOMIDE; ARAVA	4284786	DEC 13, 2001		
020905 002	LEFLUNOMIDE; ARAVA	4284786	DEC 13, 2001		
020905 003	LEFLUNOMIDE; ARAVA	4284786	DEC 13, 2001		
021088 001	LEUPROLIDE ACETATE; VIADUR	6235712	JUN 13, 2017		
021226 001	LOPINAVIR; KALETRA	6232333	NOV 07, 2017		
020386 001	LOSARTAN POTASSIUM; COZAAR	5608075	MAR 04, 2014		
020386 002	LOSARTAN POTASSIUM; COZAAR	5608075	MAR 04, 2014		
020357 001	METFORMIN HYDROCHLORIDE; GLUCOPHAGE			M-6	APR 19, 2004
020357 002	METFORMIN HYDROCHLORIDE; GLUCOPHAGE			M-6	APR 19, 2004
020357 003	METFORMIN HYDROCHLORIDE; GLUCOPHAGE			M-6	APR 19, 2004
020357 004	METFORMIN HYDROCHLORIDE; GLUCOPHAGE			M-6	APR 19, 2004
020357 005	METFORMIN HYDROCHLORIDE; GLUCOPHAGE			M-6	APR 19, 2004
021121 001	METHYLPHENIDATE HYDROCHLORIDE; CONCERTA	4783337	SEP 16, 2003	U-372	
021121 002	METHYLPHENIDATE HYDROCHLORIDE; CONCERTA	4783337	SEP 16, 2003	U-372	
021121 003	METHYLPHENIDATE HYDROCHLORIDE; CONCERTA	4783337	SEP 16, 2003	U-372	
019962 001	METOPROLOL SUCCINATE; TOPROL-XL	4927640	MAY 22, 2007	I-194	FEB 05, 2004
		5246714	SEP 21, 2010		
019962 002	METOPROLOL SUCCINATE; TOPROL-XL	4927640	MAY 22, 2007	I-194	FEB 05, 2004
		5246714	SEP 21, 2010		

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL USE CODE	EXCLUS CODE	EXCLUS EXPIRES
019962 003	METOPROLOL SUCCINATE; TOPROL-XL	4927640		I-194	FEB 05, 2004
019962 004	METOPROLOL SUCCINATE; TOPROL-XL	5246714			
		4957745	U-107 NS		FEB 05, 2004
		5001161	U-107 I-194		FEB 05, 2004
		5081154	U-107		
		4927640			
		5246714			
021208 001	MIRTAZAPINE; REMERON SOLTAB	5178878		NCE	JUN 14, 2001
021208 002	MIRTAZAPINE; REMERON SOLTAB	5178878		NCE	JUN 14, 2001
021208 003	MIRTAZAPINE; REMERON SOLTAB	5178878		NCE	JUN 14, 2001
019297 001	MITOXANTHONE HYDROCHLORIDE; NOVANTHRONE	4617319		NCE	JUN 14, 2001
020829 002	MONTELUKAST SODIUM; SINGULAIR	5565473	U-390	I-324	OCT 13, 2003
020830 001	MONTELUKAST SODIUM; SINGULAIR	5565473	U-228		
020830 002	MONTELUKAST SODIUM; SINGULAIR	5565473	U-228		
021085 001	MOXIFLOXACIN HYDROCHLORIDE; AVELOX	5565473	U-228		
021204 001	NATEGLINIDE; STARLIX	RE34878		I-329	APR 27, 2004
		5463116			
021204 002	NATEGLINIDE; STARLIX	5463116			
		5488150			
		RE34878			
		5463116			
		5488150			
		6165497			
020165 004	NICOTINE; NICODERM CQ	5633008	U-388		
020165 005	NICOTINE; NICODERM CQ	5633008	U-389		
020165 006	NICOTINE; NICODERM CQ	6165497	U-388		
		5633008	U-389		
		6165497	U-388		
		5633008	U-389		
		6165497	U-388		
075269 001	NIFEDIPINE; NIFEDIPINE	5753618		PC	JUN 05, 2001
075269 002	NIFEDIPINE; NIFEDIPINE	5753618		PC	JUN 05, 2001
021008 001	OCTREOTIDE ACETATE; SANDOSTATIN LAR	5753618			
021008 002	OCTREOTIDE ACETATE; SANDOSTATIN LAR	5753618			
021008 003	OCTREOTIDE ACETATE; SANDOSTATIN LAR	5229382			
020592 005	OLANZAPINE; ZYPREXA	5605897			
		6020487			
		6020487			
		6020487			
		6020487			
		6150380			
021086 001	OLANZAPINE; ZYPREXA ZYDIS	6147103			
021086 002	OLANZAPINE; ZYPREXA ZYDIS	6166213			
021086 003	OLANZAPINE; ZYPREXA ZYDIS	6191148			
021086 004	OLANZAPINE; ZYPREXA ZYDIS	4255431*PED			
019810 001	OMEPRAZOLE; PRILLOSEC	4636499*PED			
		4786505*PED			
		4853230*PED			
		5093342*PED			
		5599794*PED			
		5629305*PED			
		6147103*PED			
		6150380*PED			
		6166213*PED			
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		4786505*PED			
		4853230*PED			
		5093342*PED			
		5599794*PED			
		5629305*PED			
		6147103*PED			
		6150380*PED			
		6166213*PED			
		6191148*PED			

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
019810 002	OMEPRAZOLE; PRILLOSEC	4508905	APR 02, 2002			
		6150380	NOV 10, 2018		PED	DEC 29, 2001
		6147103	OCT 09, 2018			
		6166213	OCT 09, 2018			
		6191148	OCT 09, 2018			
		4255431*PED	OCT 05, 2001		U-108	
		4636499*PED	JAN 30, 2006			
		4786505*PED	OCT 20, 2007		U-108	
		4853230*PED	OCT 20, 2007		U-108	
		5093342*PED	AUG 02, 2010		U-166	
		5599794*PED	AUG 04, 2014			
		5629305*PED	AUG 04, 2014		U-166	
		6147103*PED	APR 09, 2019		U-188	
		6150380*PED	MAY 10, 2019			
		6166213*PED	APR 09, 2019			
		6191148*PED	APR 09, 2019			
		4508905	APR 02, 2002			
019810 003	OMEPRAZOLE; PRILLOSEC	6150380	NOV 10, 2018		I-229	JUN 29, 2001
		6147103	OCT 09, 2018		PED	DEC 29, 2001
		6166213	NOV 10, 2018			
		6191148	OCT 09, 2018			
		4255431*PED	OCT 05, 2001		U-108	
		4636499*PED	JAN 30, 2006			
		4786505*PED	OCT 20, 2007		U-108	
		4853230*PED	OCT 20, 2007		U-108	
		5093342*PED	AUG 02, 2010		U-166	
		5599794*PED	AUG 04, 2014		U-166	
		5629305*PED	AUG 04, 2014		U-188	
		6147103*PED	APR 09, 2019			
		6150380*PED	MAY 10, 2019			
		6166213*PED	APR 09, 2019			
		6191148*PED	APR 09, 2019			
		4508905	APR 02, 2002			
021246 001	OSELTAMIVIR PHOSPHATE; TAMIFLU	5763483	DEC 27, 2016		U-376	NOV 17, 2003
		5866601	FEB 02, 2016		NDF	DEC 14, 2003
		5952375	FEB 02, 2016		NCE	OCT 27, 2004
020897 001	OXYBUTYRIN CHLORIDE; DITROPAN XL	6124355	MAY 22, 2015		U-378	
020897 002	OXYBUTYRIN CHLORIDE; DITROPAN XL	6124355	MAY 22, 2015		U-378	
020897 003	OXYBUTYRIN CHLORIDE; DITROPAN XL	6124355	MAY 22, 2015		U-378	
020262 001	PACLITAXEL; TAXOL	6124355	MAY 22, 2015		U-378	
020987 001	PANTOPRAZOLE SODIUM; PROTONIX	6150398	MAY 08, 2011		U-380	
020988 001	PANTOPRAZOLE SODIUM; PROTONIX IV					
020031 001	PAROXETINE HYDROCHLORIDE; PAXIL	4758579	JUL 19, 2005		I-330	JUN 12, 2004
					NDF	MAR 22, 2004
					NCE	FEB 02, 2005
					I-326	APR 13, 2004

>ADD>

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
 *PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020031 002	PAROXETINE HYDROCHLORIDE; PAXIL	4721723	DEC 29, 2006		I-326	APR 13, 2004
020031 003	PAROXETINE HYDROCHLORIDE; PAXIL	4839177	JUN 13, 2006		I-326	APR 13, 2004
020031 004	PAROXETINE HYDROCHLORIDE; PAXIL	5422123	JUN 06, 2012		I-326	APR 13, 2004
020031 005	PAROXETINE HYDROCHLORIDE; PAXIL	5789449	JAN 06, 2009		I-326	APR 13, 2004
020936 003	PAROXETINE HYDROCHLORIDE; PAXIL CR	5872132	MAY 19, 2015	U-286		
		5900423	MAY 19, 2015			
		6063927	APR 23, 2019			
		6080759	MAY 19, 2015			
		6121291	MAR 17, 2017		U-286	
		6133289	MAY 19, 2015		U-286	
		6172233	JAN 15, 2018			
		4886812	MAR 25, 2011			
					I-322	FEB 20, 2004
020667 005	PRAMIPEXOLE DIHYDROCHLORIDE; MIRAPEX	5045552	SEP 03, 2008	U-385		
019627 002	PROPOFOL; DIPRIVAN	5035899	APR 04, 2009	U-385		
020973 002	RABEPRAZOLE SODIUM; ACIPHEX	4418068	APR 03, 2002			
		6172046	SEP 21, 2017	U-377 PED		JUN 09, 2002
020815 001	RALOXIFENE HYDROCHLORIDE; EVISTA	5767097*PED	JUL 23, 2016	U-235 PED		DEC 03, 2001
020903 001	RIBAVIRIN; REBETOL	5914128*PED	JUN 22, 2018			
		6051252*PED	JUN 22, 2018			
		6063772*PED	JUL 23, 2017			
		6172046*PED	MAR 21, 2018			
		6232333	NOV 07, 2017		U-375	
		5474995	JUN 24, 2013		U-377	
020945 001	RITONAVIR; NORVIR	5691374	NOV 25, 2017			
021042 001	ROFECOXIB; VIOXX	6239173	JUN 24, 2013			
		5474995	JUN 24, 2013		U-266	
		5691374	NOV 25, 2017			
021042 002	ROFECOXIB; VIOXX	6239173	JUN 24, 2013			
		5691374	NOV 25, 2017			
021042 003	ROFECOXIB; VIOXX	6239173	JUN 24, 2013			
		5691374	NOV 25, 2017		U-266	
		6239173	JUN 24, 2013			
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		5691374	NOV 25, 2017			
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PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 21ST EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION.

ABBREVIATIONS

REFERENCES

NEW DOSING SCHEDULE

- D-65 CHANGE DOSING AND ADMINISTRATION TO INDICATE MAINTENANCE OF WEIGHT LOSS OVER AN 18 MONTH PERIOD THUS EXTENDING THE USE OF THIS DRUG FROM ONE TO TWO YEARS
 D-66 DOSING RECOMMENDATIONS FOR PATIENTS UNDERGOING PCI

NEW INDICATION

- I-321 JUVENILE RHEUMATOID ARTHRITIS
 I-322 USE OF DIPRIVAN IN PATIENTS 3 MONTHS TO 16 YEARS
 I-323 COLORECTAL CANCER
 I-324 REDUCING NEUROLOGIC DISABILITY AND/OR FREQUENCY OF CLINICAL RELAPSES IN PATIENTS WITH SECONDARY (CHRONIC) PROGRESSIVE, PROGRESSIVE RELAPSING, OR WORSENING RELAPSING-REMITTING MULTIPLE SCLEROSIS
 I-325 PREVENTION OF RELAPSE AND RECURRENCE OF DEPRESSION
 I-326 GENERALIZED ANXIETY DISORDER
 I-327 SYMPTOMATIC RELIEF OF RHINOORRHEA ASSOCIATED WITH SEASONAL ALLERGIC RHINITIS IN PATIENTS 5 YEARS AND OLDER
 I-328 PROPHYLAXIS AND CHRONIC TREATMENT OF ASTHMA IN PATIENTS 5-6 YEARS OF AGE
 I-329 UNCOMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS
 I-330 MAINTENANCE OF HEALING OF EROSIIVE ESOPHAGITIS AND CONTROL OF DAYTIME AND NIGHTTIME HEARTBURN SYSTEMS IN PATIENTS WITH GERD

MISCELLANEOUS EXCLUSIVITY CODES

- M-6 ADDITIONAL INFORMATION REGARDING CLINICAL STUDIES DONE WITH GLUOPHAGE/GLYBURIDE COMBINATION ADDED TO CLIN PHARM AND DOSING AND ADMIN
 M-7 CLINICAL PHARMACOLOGY IN PEDIATRIC PATIENTS; DOSAGE AND ADMINISTRATION INFORMATION
 M-8 ADDITIONAL INFORMATION FOR THE USE OF SONATA CAPSULES FOR UP TO 5 WEEKS (35 NIGHTS) OF TREATMENT IN A CONTROLLED TRIAL SETTING

PATENT AND EXCLUSIVITY TERMS

REFERENCES PATENT USE CODE

- U-372 METHOD FOR ADMINISTERING A BENEFICIAL DRUG TO THE GI TRACT OF AN ANIMAL, WHICH METHOD COMPRISES ADMITTING AN OSMOTIC DEVICE ORALLY INTO THE ANIMAL...
- U-373 GENERAL USE CLAIM SUBMITTED FOR 12 NEXIUM PATIENTS STATING "PERTINENT TO THE CAPSULE FORMULATION FOR NEXIUM AND ITS INDICATIONS FOR THE TREATMENT OF GERD AND ERADICATION OF H.PYLORI TO REDUCE THE RISK OF DUODENAL ULCER RECURRENCE
- U-374 KIT ADAPTED AND DESIGNED TO PROVIDE BOTH DATA ON THE CURRENT REPRODUCTIVE STATUS OF A PATIENT AND CONTRACEPTION FOR THOSE WHO ARE NOT PREGNANT, BUT RECENTLY ENGAGED IN UNPROTECTED SEX
- U-375 METHOD OF USING RIBAVIRIN FOR TREATING A DISEASE RESPONSIVE TO RIBAVIRIN, E.G. HEPATITIS C
- U-376 TREATMENT OF INFLUENZA
- U-377 METHOD OF TREATING PT WITH CHRONIC HEPATITIS C HAVING HCV GENOTYPE 1 AND VIRAL LOAD GREATER THAN 2 MILLION COPIES/ML TO ERADICATE DETECTABLE HCV-RNA BY ADMIN COMBINATION OF RIBAVIRIN AND INTERFERON ALFA-2B FOR A LEAST 24 WEEKS
- U-378 METHOD FOR TREATING INCONTINENCE
- U-379 METHOD OF TREATING ONYCHROMYCOSIS
- U-380 COMBINATIONS OF TAXOL (PACLITAXEL) AND CISPLATIN WHICH ARE SUITABLE FOR THE TREATMENT OF OVARIAN AND NON-SMALL CELL LUNG CARCINOMAS
- U-381 TREATMENT OF HYPERPHOSPHATEMIA
- U-382 METHOD OF STABILIZING PROSTAGLANDIN
- U-383 METHOD FOR TREATING GLAUCOMA AND OCULAR HYPERTENSION
- U-384 TREATMENT OF CMV RETINITIS
- U-385 TREATMENT OF PEPTIC ULCERS
- U-386 TREATMENT OF PATIENTS SUFFERING FROM A LATE ASTHMATIC REACTION OR LATE PHASE ASTHMA
- U-387 TREATMENT OF PATIENTS WITH RESPIRATORY DISORDERS
- U-388 SMOKING CESSATION AID APPLIED TO THE SKIN
- U-389 SMOKING CESSATION AID APPLIED TO THE SKIN ON WAKING AND REMOVED PRIOR TO SLEEP AFTER ABOUT 16 HOURS
- U-390 METHOD OF USING THE DRUG TO TREAT NEUROIMMUNOLOGIC DISEASES (INCLUDING MULTIPLE SCLEROSIS)