

CUMULATIVE
SUPPLEMENT 8
AUG'99

APPROVED DRUG PRODUCTS

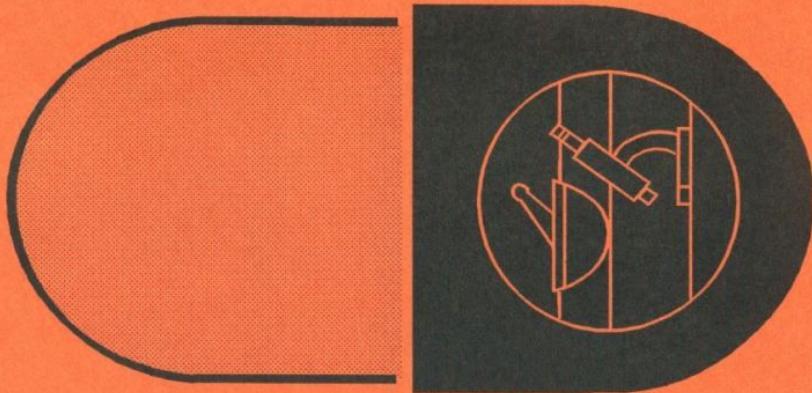
WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

19TH EDITION

U.S. 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

1999

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Aug
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S.O.
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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

19TH EDITION

Cumulative Supplement 8

AUGUST 1999

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Library Use Only

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

19TH EDITION

**CUMULATIVE SUPPLEMENT 8
AUGUST 1999**

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, 19th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.

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. Patent and Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the patent and/or exclusivity expires. Refer to the Patent and Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Information regarding drug patents and exclusivity for an approved product will appear in this addendum as it is received and may not correspond with the month the drug product is approved and published in the Rx/OTC sections of the Cumulative Supplement.

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.)

New additions to the Prescription Drug Product List, OTC Drug Product List, and 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 >**DLT**> (DELETE) to the left of the line. The >**DLT**> symbol is dropped in subsequent Cumulative Supplements for that item. The shaded print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements (hard copy only) for this edition.

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 19th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 20th Edition.

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)

PENEDERM INC
(PENEDERM)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

BERTEK PHARMACEUTICALS
(BERTEK PHARMS)

1.3 DICLOFENAC SODIUM OPHTHALMIC SOLUTION 0.1%

Two NDAs have been approved for diclofenac sodium ophthalmic solution 0.1% (DSOS), (1) Ciba's NDA 20-037 for Voltaren and (2) Falcon Pharms' (Alcon) NDA 20-809 for DSOS. Alcon was required to do a study comparing their DSOS to Voltaren and to a placebo control in post cataract surgical inflammation. This study was necessary to demonstrate that the different formulation of the Alcon drug product did not affect the safety and/or effectiveness of the proposed drug product for this indication. Prior to the approval of Alcon's DSOS Ciba did clinical studies and was approved for two additional indications for the temporary relief of pain and photophobia in patients undergoing corneal refractive surgery. Three years of Waxman-Hatch marketing exclusivity was granted to Ciba for these two new uses.

Since the treatment of pain has a different site of action than the anti-inflammatory or photophobia indications the Agency did not have information to support a recommendation that the Alcon and Ciba DSOS are therapeutically equivalent for the treatment of pain. The designation of therapeutic equivalence at this time applies only to the anti-inflammatory indication. The therapeutic equivalence designation will apply to the photophobia indication upon expiration of Ciba's marketing exclusivity.

1.4 AVAILABILITY OF THE EDITION

The 19th 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 \$78.00 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 19th annual edition of the 1998 Orange Book Patent and Exclusivity List is at
<http://www.fda.gov/cder/orange/19bookpub.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 current listing of the Orphan Product Designations and Approvals is available at
<http://www.fda.gov/orphan/designat/list.htm>.

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 1998) 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 1998</u>	<u>MAR 1999</u>	<u>JUN 1999</u>	<u>SEP 1999</u>
DRUG PRODUCTS LISTED	9923	9975	10009	10009
SINGLE SOURCE	2504 (25.2%)	2520 (25.3%)	2523 (25.2%)	2523 (25.2%)
MULTI-SOURCE	7308 (73.6%)	7344 (73.6%)	7375 (73.7%)	7375 (73.7%)
THERAPEUTICALLY EQUIVALENT	6934 (69.9%)	6969 (69.9%)	7012 (70.1%)	7012 (70.1%)
NOT THERAPEUTICALLY EQUIVALENT	374 (3.8%)	375 (3.8%)	363 (3.6%)	363 (3.6%)
EXCEPTIONS ¹	111 (1.1%)	111 (1.1%)	111 (1.1%)	111 (1.1%)
NEW MOLECULAR ENTITIES APPROVED	10	3	5	5
NUMBER OF APPLICANTS	563	570	568	568

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

PREScription DRUG PRODUCT LIST

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER
19TH EDITION

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL		TABLET; ORAL	
<u>FEMCET</u>		<u>OXYCODONE AND ACETAMINOPHEN</u>	
> DLT >	<u>AB</u>	N89102 001 JUN 19, 1985	<u>AA</u> AMIDE PHARM <u>PERCOCEIT</u> ENDO PHARMS
> DLT >	MALLINCKRODT	325MG; 50MG; 40MG 325MG; 50MG; 40MG	325MG; 2.5MG 325MG; 2.5MG
> ADD >	@	N89102 001 JUN 19, 1985	N89023 001 JUN 19, 1985
> ADD >	TRIAD	325MG; 50MG; 40MG 325MG; 50MG; 40MG	ENDO PHARMS 325MG; 5MG 325MG; 5MG
> DLT >	MALLINCKRODT	325MG; 50MG; 40MG 325MG; 50MG; 40MG	325MG; 2.5MG 325MG; 2.5MG
> DLT >	@	N89023 001 JUN 19, 1985	+ +
> ADD >		N89023 001 JUN 19, 1985	500MG; 7.5MG 500MG; 7.5MG
> ADD >			JUL 26, 1999 N40341 001 650MG; 10MG N40341 002 650MG; 10MG
> ADD >		TABLET; ORAL <u>BUTALBITAL, ACETAMINOPHEN, AND CAFFEINE</u>	
> ADD >		<u>WEST WARD</u> 500MG; 50MG; 40MG	
> ADD >		N40336 001 AUG 18, 1999	
> ADD >		N40330 001 JUN 25, 1999	
> ADD >		N40330 002 JUN 25, 1999	
> ADD >		N40330 001 JUN 25, 1999	
> ADD >		N40330 001 JUN 25, 1999	
> ADD >		N40330 001 JUN 25, 1999	

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

ACETAMINOPHEN; HYDROCODONE BITARTRATE

ACLTRETIN	
CAPSULE; ORAL ALLAY NORTON HN	N89907 001 JAN 13, 1989 500MG; 5MG
A ZENITH GOLDLINE	N89907 001 JAN 13, 1989 500MG; 5MG
A HYDROCODONE BITARTRATE AND ACETAMINOPHEN MALLINCKRODT	N88956 001 JUL 19, 1985 500MG; 5MG
A ZYDONE MALLINCKRODT	N88956 001 JUL 19, 1985 500MG; 5MG
CAPSULE; ORAL SORIATANE HLR	N19821 001 OCT 28, 1996 10MG
A	N19821 002 OCT 28, 1996
A	N19821 003 OCT 28, 1996
A	N19821 004 OCT 28, 1996
A	N19821 005 OCT 28, 1996

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL
OXYCODONE AND ACETAMINOPHEN
DURAMED 500MG; 5MG

CAPSULE; ORAL
ACYCLOVIR
STASON

AB

N40289 001
MAR 16, 1999

200MG

N75090 001
JAN 26, 1999

N75090 001
JAN 26, 1999
200MG
AB
STASSON
ACYCLOVIR
CAPSULE; ORAL

ALPRAZOLAM

TABLET; ORAL
ALPRAZOLAM
ALPHAPHARM

2MG

> ADD >
 > ADD

N74046 004
 MAY 07, 1997

AMINO ACIDSAMINO ACIDS

TABLET; INJECTION <u>NEOPHAM</u> 6.4% <u>PHARMACIA AND UPJOHN</u> 6.4%	INJECTABLE; INJECTION NOVAMINE 11.4% <u>FRESENIUS KABI</u> 11.4% <u>PHARMACIA AND UPJOHN</u> 11.4%
	NOVAMINE 15% <u>FRESENIUS KABI</u> 15% <u>PHARMACIA AND UPJOHN</u> 15%
	NOVAMINE 8.5% <u>FRESENIUS KABI</u> 8.5% <u>PHARMACIA AND UPJOHN</u> 8.5%
	AMINO ACIDS: MAGNESIUM CHLORIDE; POTASSIUM ACETATE; POTASSIUM CHLORIDE; SODIUM ACETATE
	INJECTABLE; INJECTION VEINAMINE 8% <u>FRESENIUS KABI</u> 8%; 61MG/100ML; 211MG/100ML; <u>PHARMACIA AND UPJOHN</u> 56MG/100ML; 388MG/100ML; N17957 001 <u>PHARMACIA AND UPJOHN</u> 8%; 61MG/100ML; 211MG/100ML; <u>PHARMACIA AND UPJOHN</u> 56MG/100ML; 388MG/100ML; N17957 003

AMINO ACIDS: MAGNESIUM CHLORIDE; POTASSIUM ACETATE; POTASSIUM CHLORIDE; SODIUM ACETATEAMINO ACIDS

TABLET; TOPICAL <u>CYCLOCORT</u> @ FUJISAWA HLTHCARE	0.025% 0.1% 0.025% 0.1%
Lotion; TOPICAL <u>CYCLOCORT</u> + FUJISAWA HLTHCARE	0.1% 0.1% 0.1% 0.1%
OINTMENT; TOPICAL <u>CYCLOCORT</u> + FUJISAWA HLTHCARE	0.1% 0.1% 0.1% 0.1%
AMINO ACIDS	AMINOPHYLLINE
	INJECTABLE; INJECTION <u>AMINOPHYLLINE</u> <u>SMITH AND NEPHEW</u>

AMINOPHYLLINE

TABLET; INJECTION <u>AMINOPHYLLINE</u> <u>SMITH AND NEPHEW</u>	25MG/ML

TABLET; INJECTION <u>AMINOPHYLLINE</u> <u>SMITH AND NEPHEW</u>	25MG/ML

TABLET; INJECTION <u>AMINOPHYLLINE</u> <u>SMITH AND NEPHEW</u>	25MG/ML

AMIODARONE HYDROCHLORIDEAMIODARONE HCLALPHAPHARMAMIODARONE HCLALPHAPHARMAMIODARONE HCLALPHAPHARMAMIODARONE HCLALPHAPHARMAMIODARONE HCLALPHAPHARMAMIODARONE HCLALPHAPHARMAMIODARONE HCLALPHAPHARMAMIODARONE HCLALPHAPHARMAMIODARONE HCLALPHAPHARMAMIODARONE HCLALPHAPHARM

AMIODARONE HYDROCHLORIDE

TABLET; ORAL
AMIODARONE HCL

AB NOVOPHARM 200MG

AMITRIPTYLINE HYDROCHLORIDE
INJECTABLE; INJECTION
AMITRIPTYLINE HCL

AP STERIS 10MG/ML

AP * ELAVIL 10MG/ML

AP * ZENECA + 10MG/ML

TABLET; ORAL
AMITRIPTYLINE HCL

AB ENDER ROCHE

100MG
10MG

25MG
50MG

75MG
100MG

100MG
10MG

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

AB ENDER ROCHE

100MG
10MG

25MG
50MG

75MG
100MG

100MG
10MG

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

AB ENDER ROCHE

100MG
10MG

25MG
50MG

75MG
100MG

100MG
10MG

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

250MG
500MG

AB AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

AB RANBAXY

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

IMURAN

• ADD > AP + FARO PHARMS
 AP * GLAXO WELLCOME

• DLT > AP

EQ 100MG BASE/VIAL
EQ 100MG BASE/VIAL

OINTMENT, AUGMENTED; TOPICAL
BETAMETHASONE DIPROPIONATE
ALTANA
EQ 0.05% BASE

AB

N17391 001
 N17391 001

N75373 001

BETAMETHASONE DIPROPIONATE

OINTMENT, AUGMENTED; TOPICAL
BETAMETHASONE DIPROPIONATE
ALTANA EQ 0.05% BASE

BACITRACIN; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC BACITRACIN-NEOMYCIN-POLYMYXIN W/ HYDROCORTISONE ACETATE	AEROSOL; TOPICAL LUXIQ + CONNECTICS	EQ 0.12% BASE	N20934 001 FEB 28, 1999
* ALTANA	400 UNITS/GM; EQ 3.5MG BASE/GM; 10,000 UNITS/GM	N60731 002	
@ PHARMADERM	400 UNITS/GM; EQ 3 .5MG BASE/GM; 10,000 UNITS/GM	N60731 002	
+ +	400 UNITS/GM; EQ 3 .5MG BASE/GM; 10,000 UNITS/GM	N62166 002	
	400 UNITS/GM; EQ 3 .5MG BASE/GM; 10,000 UNITS/GM	N62166 002	

BENDROFLUMETHIAZIDE: NADOLOL

EENZET PENTECOSTEELYSSTEEN

INJECTABLE; INJECTION
PRE-PEN
BAYER
+ HOLLISTER STIER LABS 60 UMOLAR
N50114 001
N50114 001
6MG/ML
+ ORPHAN MEDCL
BUSULFEX
INJECTABLE; INJECTION
N20954 001
FEB 04, 1999

卷之三

N11215 001
NOV 25 1996
CREAM; VAGINAL
EBMSTAT
* SYNTEX 2%

MON 25 JUN 1992
N9215 001

BUTOCONAZOLE NITRATE

CREAM; VAGINAL
FEMSTAT®
@ SYNTEX

FEMSTAT ONE
+ KV PHARM
※ SYNTEX

AT AKORN
ENDOSOL EXTRA
N20079 001
NOV 27, 1991

AT ALLERGAN
N20079 001
NOV 27, 1991

CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE

SOLUTION; IRRIGATION
ENDOSOL EXTRA
AT AKORN
N20079 001
NOV 27, 1991

AT ALLERGAN
N20079 001
NOV 27, 1991

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

INJECTABLE; INJECTION
ISOCOLYTE R/W DEXTROSE 5% IN PLASTIC CONTAINER
B. BRAUN
N18271 001
JAN 17, 1993

② 3.7MG/100ML; 5GM/100ML; 3.1MG/100ML;
1.20MG/100ML; 3.30MG/100ML;
8.8MG/100ML
3.7MG/100ML; 5GM/100ML; 3.1MG/100ML;
1.20MG/100ML; 3.30MG/100ML;
8.8MG/100ML

N18269 002
JAN 17, 1993

N18269 001
JAN 17, 1993

N18269 002
JAN 17, 1993

N18269 001
AUG 30, 1996

N18269 003
AUG 30, 1996

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CITRATE

INJECTABLE; INJECTION
ISOCOLYTE E/W DEXTROSE 5% IN PLASTIC CONTAINER
B. BRAUN
N19215 001
NOV 25, 1985

N19881 001
FEB 07, 1997
N19881 001
FEB 07, 1997

② 3.5MG/100ML; 5GM/100ML; 3.0MG/100ML;
7.4MG/100ML; 6.40MG/100ML; 5.00MG/100ML;
7.4MG/100ML

3.5MG/100ML; 5GM/100ML; 3.0MG/100ML;
7.4MG/100ML; 6.40MG/100ML; 5.00MG/100ML;
7.4MG/100ML

CAPECITABINE

TABLET; ORAL
XELODA
HLR
ROCHE
150MG

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL
BAKER NORTON
12.5MG

N74590 004
AUG 30, 1996

N74590 002
AUG 30, 1996

N74590 001
AUG 30, 1996

N74590 003
AUG 30, 1996

N74590 004
AUG 30, 1996

N74590 002
AUG 30, 1996

N74590 001
AUG 30, 1996

N74590 003
AUG 30, 1996

N74590 004
AUG 30, 1996

N74590 002
AUG 30, 1996

N74590 003
AUG 30, 1996

CHOLESTYRAMINE

CHITOSAN HYDROGEL OVIDE

POWDER; ORAL
CHOLESTYRAMINE LIGHT
COPLEY PHARM
EQ 4GM RESIN/SCOOPFUL

CHYMOPIGMENT

DOWNED LOG

FOR RECONSOLIDATION; OPHTHALMIC
DATABASE * CIBA 300 UNITS/VIAL
@ ZOLYSE 300 UNITS/VIAL
ALKON 750 UNITS/VIAL
+

TABLET; ORAL
PILETAL
OTSUKA

CISPLATIN INJECTABLE; INJECTION CISPLATIN

PLATINOL-AQ + BRISTOL M

CLARITHROMYCIN

GRANULE, FOR RECONSTITUTION; ORAL
BIAXIN
ABBOTT
187MG/5ML

			N 4139 001
> ADD ^	AFFILIATION US	FILMCO	AUG 03, 1994
> DLT ^	NBC		N 74139 001
> DLT ^			AUG 03, 1994
> DLT ^			

CLOBETASOL PROPIONATE

CREAM; TOPICAL <u>CLOBETASOL PROPIONATE (EQUOLINATE)</u> ALTANA	AB @	0 . 0 5 %	MAY 26, 1999 N75430 001	MAY 26, 1999 N75430 001
GEL; TOPICAL <u>CLOBETASOL PROPIONATE</u> TARO	AB	0 . 0 5 %	N75279 001 MAY 28, 1999	AB MYLAN
SOLUTION; TOPICAL <u>CLOBETASOL PROPIONATE</u> ALTANA	AT	0 . 0 5 %	N75391 001 FEB 08, 1999	COLISTIMETHATE SODIUM
				COLISTIMETHATE INJECTION

CLOZAPINE

TABLET; ORAL <u>CLOZAPINE</u> GENEVIA	AB AB	25MG 100MG	N74546 001 AUG 30, 1996 N74546 002 AUG 30, 1996	AUG 30, 1996 N74546 001 AUG 30, 1996 N75417 001 MAY 27, 1999
AB TARO	AB	25MG	N75279 001 MAY 28, 1999	AB MYLAN
AT ALTANA	AB	100MG	N75391 001 FEB 08, 1999	COLISTIMETHATE SODIUM

CLOMIPHENE CITRATE

TABLET; ORAL <u>CLOMIPHENE CITRATE</u> PAR PHARM	AB AB > ADD > ADD	50MG	N75528 001 AUG 30, 1999	EQ 150MG BASE/VIAL EQ 150MG BASE/VIAL EQ 150MG BASE/VIAL
				INJECTABLE; INJECTION

CLOMIPHENE CITRATE

TABLET; ORAL <u>CLOMIPHENE CITRATE</u> PAR PHARM	AB	EQ 150MG BASE/VIAL EQ 150MG BASE/VIAL EQ 150MG BASE/VIAL	N64216 001 FEB 26, 1999
			INJECTABLE; INJECTION

CLOXA CILLIN SODIUM

CAPSULE; ORAL <u>CLOXA PEN</u> SMITHKLINE BECHAM	AB AB AB AB > ADD > ADD	EQ 250MG BASE EQ 500MG BASE EQ 250MG BASE EQ 500MG BASE EQ 250MG BASE EQ 500MG BASE	N62233 001 N62233 002 N62233 001 N62233 002 N62233 001 N62233 002	AP + STERIS 40 UNITS/VIAL 40 UNITS/VIAL 40 UNITS/VIAL 40 UNITS/VIAL 40 UNITS/VIAL 40 UNITS/VIAL
POWDER FOR RECONSTITUTION; ORAL <u>CLOXA CILLIN SODIUM</u> TEVA	AB AB AB AB AB AB	EQ 125MG BASE/5ML EQ 125MG BASE/5ML EQ 125MG BASE/5ML EQ 125MG BASE/5ML EQ 125MG BASE/5ML EQ 125MG BASE/5ML	N62268 001 N62268 001 N61453 001 N61453 001	CROMOLYN SODIUM CAPSULE; ORAL GASTROCRON * MEDeva 100MG 100MG
				INJECTABLE; INJECTION
				EQ 125MG BASE/5ML EQ 125MG BASE/5ML EQ 125MG BASE/5ML EQ 125MG BASE/5ML EQ 125MG BASE/5ML EQ 125MG BASE/5ML
				N88772 001 NOV 21, 1994 N88772 001 NOV 21, 1994
				N19188 001 DEC 22, 1989 N19188 001 DEC 22, 1989

<u>CROMOLYN SODIUM</u>		<u>DACARBAZINE</u>	
SOLUTION; INHALATION <u>CROMOLYN SODIUM</u>	<u>1.0MG/ML</u>	INJECTABLE; INJECTION <u>DACARBAZINE</u>	
<u>AN</u> ALPHARMA		<u>AP</u> AM PHARM PARTNERS	100MG/VIAL N75371 001
SOLUTION/DROPS; OPHTHALMIC <u>CROMOLYN SODIUM</u>	<u>4%</u>	<u>> ADD ></u> <u>> ADD ></u> <u>> ADD ></u>	AUG 27, 1999 N75371 002
<u>AT</u> ALCON		<u>DTIC-DOME</u>	AUG 27, 1999
<u>CROMOPTIC</u>	<u>4%</u>	<u>AP</u> + BAYER	N17575 001
<u>AT</u> KING PHARMS		<u>* *</u>	N17575 001
		<u>DAUNORUBICIN HYDROCHLORIDE</u>	
		INJECTABLE; INJECTION <u>CEREBRIDINE</u>	
		<u>AP</u> + BEDFORD	EQ 20MG BASE/VIAL N64103 001
		<u>*</u>	FEB 03, 1995 N64103 001
		<u>DAUNORUBICIN HCL</u>	FEB 03, 1995 N64103 001
		<u>BIGMAR</u>	
		<u>EQ 20MG BASE/VIAL</u>	
		<u>DESMOPRESSIN ACETATE</u>	
		<u>AB</u> DDAVP	SPRAY, METERED; NASAL N17922 003
		<u>*</u>	AUG 07, 1996 N17922 003
		<u>DESMOPRESSIN ACETATE</u>	AUG 07, 1996 N17922 003
		<u>BAUSCH AND LOMB</u>	
		<u>0.01MG/SPRAY</u>	
		<u>DESOGESTREL; ETHINYL ESTRADIOL</u>	
		TABLET; OPAL-21 <u>DESOGESTREL AND ETHINYL ESTRADIOL</u>	
		<u>DURAMED</u>	0.15MG; 0.03MG N75256 001
		<u>*</u>	AUG 12, 1999
		<u>ORTHO-CEPT</u>	
		<u>AB</u> + JOHNSON RW	N20301 001
		<u>> ADD ></u>	DEC 14, 1992
		<u>AB</u> + SKYEPHARMA	
		<u>1.0MG/ML</u>	
		<u>1.0MG/ML</u>	
		<u>10MG/ML</u>	
		<u>CYTARABINE</u>	
		INJECTABLE, LIPOSOMAL; INJECTION <u>DEPOCYT</u>	
		<u>*</u> DEPOCETH	
		<u>AB</u> + ADD	
		<u>> DLT ></u>	
		<u>> ADD ></u>	
		<u>> ADD ></u>	
		<u>> ADD ></u>	

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-21
ORTHO-CERPT
* JOHNSON RW
0.15MG; 0.03MG
N20301 001
DEC 14 1992

TABLET; ORAL-28
DESOGESTREL AND ETHINYL ESTRADIOL
DURAMED

DEXAMETHASONE

SUSPENSION/D

<u>DECONTAMINATION</u>	<u>STERILIS.</u>	<u>MAXIDEX</u>	<u>ALCON</u>
<u>AT</u>	<u>@</u>	<u>*</u>	<u>+</u>
<u>AT</u>	<u>0.1%</u>	<u>0.1%</u>	<u>0.1%</u>

TABLET; ORAL

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DEXAMETHASONE;

OINTMENT; OP.

MAIL ROOM

FALCON D.

SUSPENSION/D

MALIKUL ALICON

N50023 002

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFAIE

SUSPENSION/DROPS; OPHTHALMIC

AT + FALCON PHARMS 0.1% EQ 3.5MG BASE/ML
10,000 UNITS/ML N50023 002

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE: INJECTION

<u>DECADRON</u>	<u>EQ 24MG PHOSPHATE /ML</u>	N12071 00
<u> + MERCK</u>	<u>EQ 24MG PHOSPHATE /ML</u>	N12071 00
<u>DEXAMETHASONE SODIUM PHOSPHATE</u>	<u>EQ 4MG PHOSPHATE /ML</u>	N83702 00
<u>STERIS</u>	<u>EQ 24MG PHOSPHATE /ML</u>	N85606 00
<u> ①</u>	<u>EQ 4MG PHOSPHATE /ML</u>	N83702 00
<u> ②</u>	<u>EQ 24MG PHOSPHATE /ML</u>	N85606 00

DEXTROAMPHETAMINE SULFATE
TABLET; ORAL
DEXTROAMPHETAMINE SULFATE
ENDO PHARMS **5MG**

DEXTROSE; SODIUM CHLORIDE
INJECTABLE, INJECTION
DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC
CONTAINER

<u>AP</u>	<u>DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER B BRAUN</u>	2.5GM/100ML; 450MG/100ML 5GM/100ML; 110MG/100ML	N18030 00 N18030 00
<u>AP</u>	<u>DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER B BRAUN</u>	5GM/100ML; 200MG/100ML 5GM/100ML; 200MG/100ML	N18030 00 N18030 00
<u>AP</u>	<u>DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER B BRAUN</u>	5GM/100ML; 330MG/100ML 5GM/100ML; 330MG/100ML	N18030 00 N18030 00
<u>AP</u>	<u>DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER B BRAUN</u>	5GM/100ML; 450MG/100ML 5GM/100ML; 450MG/100ML	N18030 00 N18030 00

DIFLORASONE DIACETATE

OINTMENT; TOPICAL
DIFLORASONE DIACETATE 0.05%
AB TARO

AB + PSORCON PHARMACIA AND UPJOHN 0.05%
 * 0.05%

TABLET; ORAL
DIFLUNISAL
AB PUREPAC PHARM 250MG
AB 500MG
AB 250MG
AB 500MG

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CARDIZEM CD 120MG
AB3 + CARDERM

AB3 + 180MG
AB3 + 240MG
AB3 + 300MG
BC * 120MG
BC * 180MG
BC * 240MG
BC * 300MG

CARTIA XT
ANDRX PHARMS

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CARTIA XT
ANDRX PHARMS 1.80MG
AB3 240MG
N19260 001
AUG 28, 1985
N19260 001
AUG 28, 1985

AB3 300MG
AB3 420MG

AB3 180MG
AB3 240MG
AB3 300MG

AB3 180MG
AB3 240MG
AB3 300MG

N75331 001
MAY 14, 1999

N74752 001
JUL 09, 1998

N74752 003
JUL 09, 1998

N74752 004
JUL 09, 1998

N74752 002
JUL 09, 1998

N74752 001
JUL 09, 1998

N74752 003
JUL 09, 1998

N74752 004
JUL 09, 1998

N75106 001
APR 29, 1999

DIPHENHYDRAMINE HYDROCHLORIDE

ELIXIR; ORAL
DIPHENHYDRAMINE HYDROCHLORIDE
AB3 12.5MG/5ML
AB3 12.5MG/5ML
AB 5ML

AB 12.5MG/5ML
AB 12.5MG/5ML

NB0763 002
NB0763 002

N20062 001
AUG 10, 1992

N20062 002
DEC 27, 1991

N20062 003
DEC 27, 1991

N20062 004
DEC 27, 1991

N20062 001
AUG 10, 1992

N20062 002
DEC 27, 1991

N20062 003
DEC 27, 1991

N20062 004
DEC 27, 1991

N20062 001
AUG 10, 1992

N20062 002
DEC 27, 1991

N20062 003
DEC 27, 1991

N20062 004
DEC 27, 1991

N73636 001
JUN 30, 1994

N73636 001
JUN 30, 1994

N89425 001
JUL 12, 1990

<u>DIPYRIDAMOLE</u>	TABLET; ORAL <u>DIPYRIDAMOLE</u> * BUREFAC PHARM	25MG	> ADD > N89425 001 JUL 12, 1990	> ADD > N10598 002 @ HOECHST MARION RSSL 10MG; 10MG > ADD >
<u>DOXYLAMINE SUCCINATE; PYRIDOXINE HYDROCHLORIDE</u>				
				TABLET, EXTENDED RELEASE; ORAL BENDECTIN @ HOECHST MARION RSSL 10MG; 10MG
				N10598 002
<u>DIRITHROMYCIN</u>				
	TABLET, DELAYED RELEASE; ORAL DYNABAC * LILLY	250MG	N50678 001 JUN 19, 1995	INJECTABLE; INJECTION DROPERIDOL SOLOPAK AP AP
	+ LILLY RES LABS	250MG	N50678 001 JUN 19, 1995	2 . 5MG /ML AP AP
			JUN 19, 1995	2 . 5MG /ML AP AP
<u>DOPAMINE HYDROCHLORIDE</u>				
	INJECTABLE; INJECTION DOPAMINE HCL SMITH AND NEPHEW	40MG/ML	N70046 001 AUG 29, 1985	2 . 5MG /ML AP AP
		80MG/ML	N70047 001 AUG 29, 1985	2 . 5MG /ML AP AP
	@	40MG/ML	N70046 001 AUG 29, 1985	2 . 5MG /ML AP AP
	@	80MG/ML	N70047 001 AUG 29, 1985	2 . 5MG /ML AP AP
<u>DOXERCALCIFEROL</u>				
	CAPSULE; ORAL HECTOROL + BONE CARE	2 . 5 UGM	N20862 001 JUN 09, 1999	> ADD > > ADD >
<u>DOXORUBICIN HYDROCHLORIDE</u>				
	INJECTABLE, LIPOSOMAL; INJECTION DOXIL + ALZA	2MG/ML	N50718 001 NOV 17, 1995	INJECTABLE; INJECTION SUS-PHRINE + FOREST LABS SUS-PHRINE SULFITE-FREE FOREST LABS
	* SEQUUS	2MG/ML	N50718 001 NOV 17, 1995	5MG/ML 1 . 5MG/AMP
<u>ENALAPRIL MALEATE; FELODIPINE</u>				
				TABLET, EXTENDED RELEASE; ORAL LEXXEL + ASTRA PHARMS
				N20668 002 OCT 28, 1998
<u>EPINEPHRINE</u>				
				INJECTABLE; INJECTION SUS-PHRINE + FOREST LABS SUS-PHRINE SULFITE-FREE FOREST LABS
				N07942 001 NOV 05, 1999

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN' 99 - AUG' 99

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<u>EPINEPHRINE</u>		<u>ESTRADIOL</u>	
INJECTABLE; INJECTION SUS-PHRINE SULFITE-FREE + FOREST LABS	5MG/ML	N07942 001 <u>AB</u> <u>ESTRADIOL</u> MYLAN	<u>0.5MG</u>
ERGOTAMINE TARTRATE		<u>AB</u>	<u>1MG</u>
AEROSOL, Metered, Inhalation Medihaler Ergotamine * 3mg @ 0.36MG/INH	0.36MG/INH	<u>AB</u> INHALATION	<u>2MG</u>
ERYTHROMYCIN			
SOLUTION; TOPICAL C-SOLVE-2 BIOGLAN PHAR	2%	N62468 001 JUL 03, 1985 N62468 001 JUL 03, 1985	<u>0.9MG</u>
			<u>0.625MG</u>
		+ ESTRADIOL	<u>0.9MG</u>
FILM, EXTENDED RELEASE; TRANSDERMAL CLIMARA	0.025MG/24HR	N20375 004 MAR 05, 1999	<u>ESTRONE</u>
BX + BERLEX LABS			
<u>ESTRADIOL</u>		<u>INJECTABLE; INJECTION</u>	
ESTRADOL MENOREST	0.0375MG/24HR	N20538 001 JUL 31, 1996 N20538 003 JUL 31, 1996 N20538 002 JUL 31, 1996 N20538 004 JUL 31, 1996	NATURAL ESTROGENIC SUBSTANCE-ESTRONE 2MG/ML * STERIS @ ESTROPIRATE
AB	<u>0.0375MG/24HR</u>		<u>N85237 001</u>
AB	<u>0.05MG/24HR</u>		<u>NOV 23, 1982</u>
AB	<u>0.075MG/24HR</u>		<u>N85237 002</u>
AB	<u>0.1MG/24HR</u>		<u>NOV 23, 1982</u>
AB			<u>MAR 24, 1999</u>
<u>VIVELLE-DOT</u>		<u>CREAM; VAGINAL</u>	
NOVARTIS	0.0375MG/24HR	N20538 001 JUL 31, 1996 N20538 003 JUL 31, 1996 N20538 002 JUL 31, 1996 N20538 004 JUL 31, 1996	OPEN * ABBOTT + PHARMACIA AND UPJOHN 1.5MG/GM
AB	<u>0.05MG/24HR</u>		<u>N84710 001</u>
AB	<u>0.075MG/24HR</u>		<u>N84710 001</u>
AB	<u>0.1MG/24HR</u>		
AB		<u>AB</u> ESTROPIRATE	<u>N40359 001</u>
		<u>> ADD ></u> <u>> ADD ></u>	<u>AUG 26, 1999</u>

ESTROPIPAPE

TABLET; ORAL <u>ESTROPIPAPE</u>			
<u>AB</u>	<u>MYLAN</u>	<u>1.5MG</u>	
<u>> ADD ></u>		<u>3MG</u>	
<u>> ADD ></u>			
<u>> ADD ></u>			
<u>AB</u>	<u>OGEN .625</u>	<u>0.75MG</u>	
<u>AB</u>	<u>ABBOTT</u>	<u>PHARMACIA AND UPJOHN</u>	<u>0.75MG</u>
<u>AB</u>	<u>OGEN 1.25</u>	<u>1.5MG</u>	
<u>AB</u>	<u>ABBOTT</u>	<u>PHARMACIA AND UPJOHN</u>	<u>1.5MG</u>
<u>AB</u>	<u>OGEN 2.5</u>	<u>3MG</u>	
<u>AB</u>	<u>* ABBOTT</u>	<u>PHARMACIA AND UPJOHN</u>	<u>3MG</u>
<u>AB</u>	<u>OGEN 5</u>	<u>6MG</u>	
<u>AB</u>	<u>ABBOTT</u>	<u>PHARMACIA AND UPJOHN</u>	<u>6MG</u>

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21 LEVILITE			
		<u>0 .02MG; 0 .1MG</u>	
		<u>0 .02MG; 0 .1MG</u>	

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21 BREVICON 21-DAY			
<u>AB</u>	<u>SEARLE</u>	<u>0.025MG; 0.5MG</u>	
<u>AB</u>	<u>WATSON LABS</u>	<u>0.035MG; 0.5MG</u>	
<u>AB</u>	<u>NORINYL 1+35 21-DAY</u>	<u>0.035MG; 1MG</u>	
<u>AB</u>	<u>SEARLE</u>	<u>0.035MG; 1MG</u>	
<u>AB</u>	<u>WATSON LABS</u>	<u>0.035MG; 1MG</u>	
<u>* SEARLE</u>	<u>TRI-NORINYL 21-DAY</u>	<u>0 .025MG; 0 .035MG; 0 .5MG; 1MG</u>	<u>N18977 001</u>
<u>+ WATSON LABS</u>			<u>APR 13, 1984</u>
<u>+ WATSON LABS</u>		<u>0 .035MG, 0 .035MG; 0 .5MG, 1MG</u>	<u>N18977 001</u>
			<u>APR 13, 1984</u>

TABLET; ORAL-28 BREVICON 28-DAY			
<u>AB</u>	<u>SEARLE</u>	<u>0.035MG; 0.5MG</u>	

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28 BREVICON 28-DAY			
<u>AB</u>	<u>WATSON LABS</u>	<u>0 .035MG; 0 .5MG</u>	
<u>NORINYL 1+35 28-DAY</u>	<u>SEARLE</u>	<u>0 .035MG; 1MG</u>	<u>N17565 002</u>
<u>AB</u>	<u>WATSON LABS</u>	<u>0 .035MG; 1MG</u>	<u>N17565 002</u>
<u>TRI-NORINYL 28-DAY</u>	<u>SEARLE</u>	<u>0 .035MG; 0 .035MG; 0 .5MG; 1MG</u>	<u>N18977 002</u>
<u>WATSON LABS</u>		<u>0 .035MG, 0 .035MG; 0 .5MG, 1MG</u>	<u>APR 13, 1984</u>
<u>WATSON LABS</u>		<u>0 .035MG; 0 .035MG; 0 .5MG; 1MG</u>	<u>APR 13, 1984</u>

TABLET; ORAL-28 BREVICON 28-DAY			
<u>AB</u>	<u>NORINYL 1+35 28-DAY</u>	<u>0 .035MG; 1MG</u>	<u>N17565 002</u>
<u>AB</u>	<u>SEARLE</u>	<u>0 .035MG; 1MG</u>	<u>N17565 002</u>
<u>TRI-NORINYL 28-DAY</u>	<u>SEARLE</u>	<u>0 .035MG; 0 .035MG; 0 .5MG; 1MG</u>	<u>N18977 002</u>

TABLET; ORAL-21 LO/OVRAL			
<u>AB</u>	<u>+ WYETH AYERST</u>	<u>0 .03MG; 0 .3MG</u>	<u>N17612 001</u>
	<u>*</u>	<u>0 .03MG; 0 .3MG</u>	<u>N17612 001</u>

TABLET; ORAL-21 LO/OVRAL			
<u>AB</u>	<u>* WYETH AYERST</u>	<u>0 .03MG; 0 .3MG</u>	<u>N17612 001</u>
	<u>SCS</u>	<u>0 .03MG; 0 .3MG</u>	<u>N17612 001</u>

TABLET; ORAL-28 LO/OVRAL-28			
<u>AB</u>	<u>WYETH AYERST</u>	<u>0 .03MG; 0 .3MG</u>	<u>N175288 001</u>
	<u>SCS</u>	<u>0 .03MG; 0 .3MG</u>	<u>JUL 28, 1999</u>

TABLET; ORAL-28 LOW-OGESTREL-21			
<u>AB</u>	<u>WYETH AYERST</u>	<u>0 .03MG; 0 .3MG</u>	<u>N175288 001</u>
	<u>SCS</u>	<u>0 .03MG; 0 .3MG</u>	<u>JUL 28, 1999</u>

TABLET; ORAL-28 LOW-OGESTREL-28			
<u>AB</u>	<u>WYETH AYERST</u>	<u>0 .03MG; 0 .3MG</u>	<u>N175288 002</u>
	<u>SCS</u>	<u>0 .03MG; 0 .3MG</u>	<u>JUL 28, 1999</u>

TABLET; ORAL-28 ETODOLAC			
<u>AB</u>	<u>ETODOLAC</u>	<u>500MG</u>	<u>N74903 002</u>
	<u>EON</u>	<u>400MG</u>	<u>N74847 001</u>

TABLET; ORAL-28 NOVOPHARM			
	<u>NOVOPHARM</u>	<u>500MG</u>	<u>N74847 002</u>
			<u>APR 23, 1999</u>

GALLAMINE TRIETHIODIDE

INJECTABLE; INJECTION
PLAXEDIL
* DAVIS AND GIBCK
©

GALLIUM NITRATE

INJECTABLE; INJECTION
GANITE
* SOLOPAK

GANIRELIX ACETATE
INJECTABLE; INJE
ANTAGON

GENTAMICIN SULFATE

GLPIZIE

TABLET; ORAL
GLUCOTROL
EFIZER
®

GLYBURIDE

TABLET; ORAL <u>GLYBURIDE (MICRON)</u>	
25MGS/M1	N19961 002 JAN 17, 1991
25MG/ML	N19961 002 JAN 17, 1991
	> <u>ADD</u> > > <u>ADD</u> >
EQ 250 UGM BASE/0 .5ML	MYLAN NOVOPHARM
	AB AB
	AB AB
	AB

<u>GENTAMICIN SULFATE</u>	<u>SCOIOPAK</u>	AP	AP	②	EQ 10MG BASE/ML	EQ 40MG BASE/ML	EQ 10MG BASE/ML	EQ 40MG BASE/ML	SOLUTION/DROPS; OPHTHALMIC	<u>GENTAMICIN SULFATE</u>	AT	AT
										<u>FALCON PHARMS</u>	<u>FALCON</u>	

N17783 003
MAY 11, 1993
N17783 003
MAY 11, 1993

N74591	003
DEC 22,	1997
N74591	003
DEC 22,	1997
N74792	003
AUG 17,	1999
N74686	001
APR 20,	1999
N74686	002
APR 20,	1999
N74686	003
APR 20,	1999
N74686	004
APR 20,	1999

N86947 001	N12827 001
JUN 24, 1983	N12827 002
N86947 001	N12827 002
JUN 24, 1983	

0.2MG/ML
0 . 2MG /ML

GLYCOPYRROLATE

**INJECTABLE; INJECTION
GLYCOPYRROLATE**

SERUMS

(®)

TABLET; ORAL

ROBINUL

+ HORIZON PHARM

* ROBINS AH

ROBINUL FORTE

+ HORIZON PHARM

* ROBINS AH

<u>HEPARIN SODIUM</u>									
SOLUTION/DROPS; OPHTHALMIC <u>NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN</u>									
<u>STERIS</u> <u>EQ 0.025MG/ML; EQ 1.75MG BASE/ML;</u> <u>10,000 UNITS/ML</u>									
@ <u>N62788 001</u> <u>JUN 11, 1987</u>									
<u>0.025MG/ML; EQ 1.75MG BASE/ML;</u> <u>10,000 UNITS/ML</u>									
@ <u>N62788 001</u> <u>JUN 11, 1987</u>									
<u>HALOPERIDOL DECANOATE</u>									
INJECTABLE; INJECTION <u>HALOPERIDOL DECANOATE</u>									
<u>AO GENSTA SICOR PHARMS</u> <u>EQ 50MG BASE/ML</u>									
@ <u>N75393 001</u> <u>MAY 11, 1999</u>									
<u>AO</u> <u>EQ 100MG BASE/ML</u>									
@ <u>N75393 002</u> <u>MAY 11, 1999</u>									
<u>AO</u> <u>EQ 100MG BASE/ML</u>									
@ <u>MAY 11, 1999</u>									
<u>HALOPERIDOL LACTATE</u>									
INJECTABLE; INJECTION <u>HALOPERIDOL</u>									
<u>AP</u> <u>SOLOPAK</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70801 001</u> <u>DEC 14, 1987</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70864 001</u> <u>DEC 14, 1987</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70864 001</u> <u>DEC 14, 1987</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70864 001</u> <u>DEC 14, 1987</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70744 001</u> <u>MAY 17, 1988</u>									
<u>AP</u> <u>EQ 5MG BASE/ML</u>									
@ <u>N70713 001</u> <									

<u>HYDRALAZINE HYDROCHLORIDE; HYDROCHLORTIAZIDE</u>	
CAPSULE; ORAL HYDRALAZINE HCL AND HYDROCHLORTIAZIDE 25MG; 25MG	N87608 001 FEB 08, 1982 N87213 001 FEB 08, 1982 N87608 001 FEB 08, 1982 N87213 001 FEB 08, 1982
AB SOLVAY	AB + SOLVAY AB * CORTENEMA
> DLT > > DLT > > DLT > > ADD > > ADD > > ADD > > ADD >	AB BR AB COPLEY PHARM
50MG; 50MG 25MG; 25MG 50MG; 50MG 50MG; 50MG 50MG; 50MG 50MG; 50MG 50MG; 50MG	100MG/6 OML 100MG/6 OML 100MG/6 OML 100MG/6 OML 100MG/6 OML 100MG/6 OML 100MG/6 OML
<u>HYDRALAZINE HYDROCHLORIDE; HYDROCHLORTIAZIDE; RESERPINE</u>	
TABLET; ORAL RESERPINE, HYDRALAZINE HCL AND HYDROCHLORTIAZIDE 25MG; 15MG; 0.1MG	N88376 001 OCT 28, 1983 N88376 001 OCT 28, 1983
BP SOLVAY	BP ADD @ ADD ADD ADD ADD
25MG; 15MG; 0.1MG 25MG; 15MG; 0.1MG 25MG; 15MG; 0.1MG 25MG; 15MG; 0.1MG 25MG; 15MG; 0.1MG 25MG; 15MG; 0.1MG 25MG; 15MG; 0.1MG	> DLT > > DLT > > DLT > > ADD > > ADD > > ADD > > ADD >
<u>HYDROCHLORTIAZIDE; IRBESARTAN</u>	
TABLET; ORAL AVALIDE ④ SANOFI SYNTHELABO	N20758 001 SEP 30, 1997 N20758 002 SEP 30, 1997 N20758 003 AUG 31, 1998
+ AVAPRO HCT ④ SANOFI	N20758 001 SEP 30, 1997 N20758 002 SEP 30, 1997
12.5MG; 7.5MG 12.5MG; 15.0MG 12.5MG; 30.0MG	EQ 100MG BASE/VIAL EQ 250MG BASE/VIAL EQ 500MG BASE/VIAL EQ 100MG BASE/VIAL EQ 100MG BASE/VIAL EQ 250MG BASE/VIAL EQ 500MG BASE/VIAL EQ 100MG BASE/VIAL
<u>HYDROCHLORTIAZIDE; TRIAMTERENE</u>	
CAPSULE; ORAL TRIAMTERENE AND HYDROCHLORTIAZIDE 25MG; 37.5MG	N84737 002 N84738 001 N84737 001 N84737 001 N84747 001 N84748 001 N84737 002 N84738 001 N84737 001 N84747 001 N84748 001
AB DURAMED	N75052 001 JUN 18, 1999

HYDROXYAMPHETAMINE HYDROBROMIDE

SOLUTION/DROPS; OPHTHALMIC
PAREDRINE
+ AKORN
* PHARMICS

1%

1%

1%

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IBUPROFEN

TABLET; ORAL

IBUPROFEN

AB ZENITH GOLDLINE

800MG

N71769 001

MAY 08, 1987

AB MOTRIN

MCNEIL

300MG

N17463 003

400MG

N17463 002

600MG

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 003

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

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MAY 22, 1985

N20418 001

NOV 16, 1994

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MAY 22, 1985

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MAY 22, 1985

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NOV 16, 1994

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MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

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N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

MAY 22, 1985

N20418 001

NOV 16, 1994

N17463 002

N17463 004

N17463 005

INSULIN HUMAN

INJECTABLE; INJECTION
VELOSULIN BR
+ NOVO NORDISK
100 UNITS/ML

INJECTABLE; INJECTION
VELOSULIN BR
+ NOVO NORDISK

LIQUID; INHALATION
FORANE AN + BAXTER PHARM PROD 99.9%
FORANE AN + OMECOPA 99.9%
FORANE N17624 001
FORANE N17624 001

IPRATROPIUM BROMIDE

**SOLUTION; INHALATION
IPRATROPIUM BROMIDE
ALPHARMA**

ISOETHARINE HYDROCHLORIDE

卷之三

AB	ZENECA	<u>3000G</u>	30MG	N88124 001 AUG 21, 1990
				N88124 001 AUG 21, 1990

ISOTRETINOIN
CAPSULE; ORAL
ACUTANE

20MG	N18662 004 MAR 28, 1983
40MG	N18662 003 MAY 07, 1982
10MG	N18662 002 MAY 07, 1982
	N18662 004 MAR 28, 1983
20MG	N18662 003 MAY 07, 1982
40MG	N18662 003 MAY 07, 1982

INJECTABLE; INJECTION
SPORANOX
+ JANSSEN
10MG/ML
N20966 001
MAR 30, 1999

LABETALOL HYDROCHLORIDE

<u>LEUCOVORIN CALCIUM</u>				
TABLET; ORAL TELLCOPORIN AB * GLAXO WELLCOME	EQ 25MG BASE @	> DLT > N18342 002 JUL 08, 1993	FILM EXTENDED RELEASE; TRANSDERMAL LIDODERM * HIND HEALTHCARE	N20612 001 MAR 19, 1999
	EQ 5MG BASE @	> DLT > N18342 001 JUL 08, 1993		
	EQ 25MG BASE @	> DLT > N18342 002 JUL 08, 1993	LIDOCAINE; PRLOCAINE AEROSOL; TOPICAL EMLA * ASTRA PHARMS	N20612 001 FEB 04, 1998
<u>LEVALBUTEROL HYDROCHLORIDE</u>				
SOLUTION; INHALATION XOPENEX + SEPRACOR +	EQ 0 .021% BASE EQ 0 .042% BASE +	N20837 001 MAR 25, 1999 N20837 002 MAR 25, 1999	DISC; TOPICAL EMLA + ASTRA PHARMS	N20962 001 FEB 04, 1998
<u>LEVONORGESTREL</u>				
> ADD >	<u>LEVOBUPIVACAINE HYDROCHLORIDE</u>			
> ADD >	INJECTABLE; INJECTION CHIROCAINE DARWIN DISCOVERY	EQ 2 .5MG BASE/ML EQ 5MG BASE/ML EQ 7 .5MG BASE/ML	TABLET; ORAL ZESTRIL ZENECA	N19777 006 JAN 20, 1999
> ADD >	> ADD >	N20997 001 AUG 05, 1999		
> ADD >	> ADD >	N20997 002 AUG 05, 1999	LITHIUM CARBONATE	
> ADD >	> ADD >	N20997 003 AUG 05, 1999	CAPSULE; ORAL LITHONATE SOLVAX	
> ADD >	> ADD >	N20997 004 AUG 05, 1999		
> ADD >		N16782 001 N16782 001		
<u>LIDOCAINE</u>				
> ADD >	FILM, EXTENDED RELEASE; TOPICAL LIDODERM + TEIKOKU PHARMA USA	0 .75MG 700MG/12HR	CAPSULE; ORAL IMODIUM * JANSSEN	N16834 001 N16834 001 N16980 001 N17694 001
> ADD >	> ADD >			
> ADD >	> ADD >			
> ADD >				

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL
IMODIUM

AB + JANSSEN
④ MCNEIL CONS

2MG
2MG
2MG

200MG

N17690 001
N17694 001
N17690 001

> ADD
> ADD

> ADD
> ADD

> ADD
> ADD

> ADD
> DLT

> DLT
> DLT

LOPACARBEF

INJECTABLE; INJECTION

LUTEINIZING HORMONE; MENOTROPINS (FSH,LH)

REPRONEX

FERRING

150 IU/VIAL; 150 IU/VIAL

N21047 001

AUG 27, 1999

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL
IMODIUM

AB + JANSSEN
④ MCNEIL CONS

2MG
2MG
2MG

200MG

N17690 001
N17694 001
N17690 001

> ADD
> ADD

> ADD
> ADD

> ADD
> ADD

> ADD
> DLT

> DLT
> DLT

LOTEPREDNOL ETABONATE

SUSPENSION/DROPS; OPHTHALMIC

LOTEMAX
* PHARMOS

0 . 5 %

N20841 001

MAR 09, 1998

> ADD
> ADD

LOTEPREDNOL ETABONATE

TABLET, CHEWABLE; ORAL

VERMOX
* JANSSEN

100MG

N17481 001

AUG 02, 1983

JUN 27, 1983

N87460 001

JUN 27, 1983

MEBENDAZOLE

TABLET, CHEWABLE; ORAL
VERMOX
AB + MCNEIL CONS 100MG

> DLT >
> DLT >
> DLT >
> ADD >

MECLOCYCLINE SULFOSALICYLATE

CREAM, TOPICAL
MECTAN
* JOHNSON AND JOHNSON 1%
@

MEDROXYPROGESTERONE ACETATE

TABLET, ORAL
CYCRIN
BSI

2.5MG
5MG
10MG
2.5MG
5MG
10MG
@

DEMEROL

INJECTABLE; INJECTION
DEMEROL
AP + ABBOTT 2.5MG/ML
AP + ABBOTT 5.0MG/ML
AP + ABBOTT 7.5MG/ML
AP + SANOFI 10.0MG/ML
AP + SANOFI 2.5MG/ML
AP + SANOFI 5.0MG/ML
AP + SANOFI 7.5MG/ML
AP + ABBOTT 10.0MG/ML

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
MEPERIDINE HCL
AP ASTRA PHARMS 1.0MG/ML
AP INT'L MEDICATION 1.0MG/ML
AP MALLINCKRODT 1.0MG/ML
AP STERIS 1.0MG/ML
AP + ABOTT 1.0MG/ML
AP ASTRA PHARMS 1.0MG/ML
AP FAULDING 1.0MG/ML
AP INT'L MEDICATION 1.0MG/ML
AP MALLINCKRODT 1.0MG/ML
AP STERIS 1.0MG/ML
SYRUP; ORAL
DEMEROL
AA + ABBOTT 5.0MG/5ML
AA + SANOFI 5.0MG/5ML

TABLET; ORAL
DEMEROL
AA + ABBOTT 5.0MG
AA + SANOFI 10.0MG

INJECTABLE; INJECTION
MERSALYL-THEOPHYLLINE
+ STERIS
100MG/ML; 50MG/ML
N84875 001

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
MEPERIDINE HCL
NB1002 001 JUL 30, 1993
NB1309 001 AUG 30, 1993
N40163 001 MAY 12, 1997
N73443 001 MAR 17, 1992
N88432 001 AUG 16, 1984
N81002 001 JUL 30, 1993
N40305 001 MAR 10, 1999
N81309 001 AUG 30, 1993
N40163 001 MAY 12, 1997
N73443 001 MAR 17, 1992

<u>MERSALYL SODIUM; THEOPHYLLINE</u>		
INJECTABLE; INJECTION MERSALYL THEOPHYLLINE ® STERIS	100MG/ML; 50MG/ML	N84875 001
<u>METHFORMIN HYDROCHLORIDE</u>		
TABLET; ORAL GLUCOPHAGE * BRISTOL MYERS SQUIBB	500MG 625MG 750MG	N20357 001 MAR 03, 1995 N20357 003 NOV 05, 1998 N20357 004 NOV 05, 1998 N20357 001 MAR 03, 1995 N20357 003 NOV 05, 1998 N20357 004 NOV 05, 1998
<u>METHOTREXATE SODIUM</u>		
INJECTABLE; INJECTION <u>METHOTREXATE</u> BIGMAR	<u>EQ 25MG BASE/ML</u>	N40263 001 FEB 26, 1999
<u>METHOTREXATE PRESERVATIVE FREE</u>	<u>EQ 25MG BASE/ML</u>	N40265 001 FEB 26, 1999
<u>METHOTREXATE SODIUM</u> * LEDERLE	<u>EQ 1GM BASE/VIAL</u>	N40266 001 FEB 26, 1999
<u>METHOTREXATE SODIUM PRESERVATIVE FREE</u>	<u>EQ 1GM BASE/VIAL</u>	N11719 009 APR 07, 1988
<u>TABLET; ORAL</u> <u>METHOTREXATE SODIUM</u> DURAMED	<u>EQ 2.5MG BASE</u>	N40233 001 JUN 17, 1999
<u>METHOTRIMEPRAZINE</u>		
INJECTABLE; INJECTION LEVOPRONE * IMMUNEX ®	20MG/ML 20MG/ML	N15865 001 N15865 001
<u>METHOKSALEN</u>		
INJECTABLE; INJECTION UVADEX + THERAKOS	0.02MG/ML	N20969 001 FEB 25, 1999
<u>METHYLDOPATE HYDROCHLORIDE</u>		
INJECTABLE; INJECTION <u>METHYLDOPATE HCL</u> SMITH AND NEPHEW	<u>50MG/ML</u>	N70841 001 JAN 02, 1987 N70841 001 JAN 02, 1987
<u>METHYLPREDNISOLONE SODIUM SUCCINATE</u>		
INJECTABLE; INJECTION <u>METHYLPREDNISOLONE</u> STERIS	<u>EQ 40MG BASE/VIAL</u>	NB6953 001 JUL 22, 1982 N87030 001
<u>EQ 125MG BASE/VIAL</u>		JUL 22, 1982
<u>EQ 500MG BASE/VIAL</u>		N88523 001
		JUL 24, 1984
<u>EQ 1GM BASE/VIAL</u>		N88524 001
		JUL 24, 1984
<u>EQ 40MG BASE/VIAL</u>		N86953 001
		JUL 22, 1982
		N87030 001
<u>EQ 125MG BASE/VIAL</u>		JUL 22, 1982
<u>EQ 500MG BASE/VIAL</u>		N88523 001
		JUL 24, 1984
<u>EQ 1GM BASE/VIAL</u>		N88524 001
		JUL 24, 1984
<u>EQ 40MG BASE/VIAL</u>		
<u>EQ 125MG BASE/VIAL</u>		
<u>EQ 500MG BASE/VIAL</u>		
<u>EQ 1GM BASE/VIAL</u>		

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL
SMITH AND NEPHEW

AB AP * +

SCS

METRONIDAZOLE

STERIS

AP

AP *

AP

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

MINOCYCLINE HCL
+ DANBURY PHARMA

EQ 5MG BASE/ML

EQ 5MG BASE/ML

EQ 100MG BASE

METOLAZONE

TABLET; ORAL

ZAROXYLON

MEDERYA

+

METRONIDAZOLE

INJECTABLE; INJECTION

NADOLOL

TABLET; ORAL

CORGARD

APOTHECON

20MG

VECTRIN

WARNER CHILCOTT

EQ 50MG BASE

EQ 100MG BASE

N63066 001

AUG 14, 1990

N63067 001

JUL 31, 1990

N63066 001

AUG 14, 1990

N63067 001

JUL 31, 1990

N18063 005

OCT 28, 1986

N18063 001

N18063 002

N18063 003

N18063 004

N18063 005

OCT 28, 1986

N18063 001

N18063 002

N18063 003

N18063 004

N18063 005

N18063 006

N18063 007

N18063 008

N18063 009

N18063 010

N18063 011

N18063 012

N18063 013

N18063 014

N18063 015

N18063 016

N18063 017

N18063 018

N18063 019

N18063 020

N18063 021

N18063 022

N18063 023

N18063 024

N18063 025

N18063 026

N18063 027

N18063 028

N18063 029

N18063 030

N18063 031

N18063 032

N18063 033

N18063 034

N18063 035

N18063 036

N18063 037

N18063 038

N18063 039

N18063 040

N18063 041

N18063 042

N18063 043

N18063 044

N18063 045

N18063 046

N18063 047

N18063 048

N18063 049

N18063 050

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N18063 154

N18063 155

N18063 156

N18063 157

N18063 158

N18063 159

N18063 160

N18063 161

N18063 162

N18063 163

N18063 164

N18063 165

N18063 166

N18063 167

N18063 168

NITROGLYCERININJECTABLE; INJECTION
NITROGLYCERIN
④ SMITH AND NEPHEW

5MG/ML

N70633 001
JUN 19, 1986
>ADD>
>ADD>OINTMENT; TRANSDERMAL
NITROGLYCERIN
ALTANA

2%

N8735 001
JUL 08, 1988
N8735 001
JUL 08, 1988
>ADD>
>ADD>
>ADD>
>ADD>SPRAY, METERED; SUBLINGUAL
NITROLINGUAL PUMPSPRAY
+ POHL BOSKAMP 0.4MG/SPRAYN18705 002
JAN 10, 1997OMEPRAZOLECAPSULE, DELAYED REL PELLETS; ORAL
PRILOSEC
④ ASTRA PHARMS

10MG

N19810 003
OCT 05, 1995
N19810 003
OCT 05, 1995
>ADD>
>ADD>
>ADD>

10MG

N19810 003
OCT 05, 1995
N19810 003
OCT 05, 1995
>ADD>
>ADD>
>ADD>ONDANSETRONTABLET, ORALLY DISINTEGRATING; ORAL
ZOFTRAN ODT
GLAXO WELLCOME

EQ 4MG BASE

EQ 8MG BASE

EQ 8MG BASE

N20781 001
JAN 27, 1999
N20781 002
JAN 27, 1999
N20781 001
JAN 27, 1999
N20781 002
JAN 27, 1999
>DLT>
>DLT>
>ADD>
>ADD>ONDANSETRON HYDROCHLORIDETABLET; ORAL
ZOFTRAN
④ GLAXO WELLCOME

EQ 8MG BASE

EQ 8MG BASE

EQ 8MG BASE

N20103 002
DEC 31, 1992
>DLT>
>DLT>
>ADD>
>ADD>ONDANSETRON HYDROCHLORIDE

TABLET; ORAL

ZOFTRAN
+ GLAXO WELLCOME

EQ 24MG BASE

N20103 003
AUG 27, 1999ORLISTATCAPSULE; ORAL
XENICAL
+ ROCHE

120MG

N20766 001
APR 23, 1999TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE
AB KIEL

100MG

N40249 001
JAN 29, 1999OXYBUTYNIN CHLORIDESYRUP; ORAL
OXYBUTYNIN CHLORIDE
AA MIKART

5MG/5ML

N75039 001
JAN 29, 1999TABLET, EXTENDED RELEASE; ORAL
DITROPAN XL
+ ALZA

15MG

N20897 003
JUN 22, 1999OXYTETRACYCLINE CALCIUMSYRUP; ORAL
TETRAMYCIN
* PFIZER
@EQ 125MG BASE/5ML
EQ 125MG BASE/5MLN60595 001
N60595 001OXYTETRACYCLINE HYDROCHLORIDETABLET; ORAL
TETRAMYCIN
* PFIZER

EQ 125MG BASE/5ML

N60595 001
N60595 001

EQ 250MG BASE/VIAL

OXYTETRACYCLINE HYDROCHLORIDE

INJECTABLE; INJECTION
TERRAMYCIN
+ PFIZER

OXYTETRACYCLINE HYDROCHLORIDE; POLYMYXIN B SULFATE
EQ 500MG BASE/VIAL

OINTMENT; OTIC TERAMYCIN W/ POLYMYXIN * PFIZER	EQ 5MG BASE/GM 10,000 UNITS/GM	EQ 5MG BASE/GM 10,000 UNITS/GM
TABLET; VAGINAL TERAMYCIN-POLYMYXIN * PFIZER	EQ 100MG BASE; 100,000 UNITS	EQ 100MG BASE; 100,000 UNITS
	②	②

הנִזְמָנָן בְּרַאשׁ

PAROXETINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PAXIL CR
+ SMITHKLINE BEECHAM EQ 250

PAXIL
SMITHLINE BECHTEL

AROXETINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PAXIL CR
+ SMITHKLINE BEECHAM EQ 25MG BASE

<u>PEMOLINE</u>			
TABLET; ORAL			
<u>CLEERT</u>			
ABOTT			
+			
	*		
	+		
<u>PEMOLINE</u>			
COPLEY PHARM			
INVAMED			
<u>3.7 .5MG</u>			
<u>75MG</u>			
1.8 .75MG			
3.7 .5MG			
7.5MG			
18 .75MG			
<u>3.7 .5MG</u>			
<u>75MG</u>			
3.7 .5MG			
75MG			

EENTOXIFYLINE

N20936 002
FEB 16, 1999

N16832	002
NJ6832	003
N16832	001
N16832	002
N16832	003
N16832	001
N75030	001
JAN 29,	1999
N75030	002
JAN 29,	1999
N75286	002
JUN 30,	1999
N75286	003

N75093	001
AUG 10,	1999
N74874	001
MAY 25,	1999
N75191	001
JUN 09,	1999
N74962	001
MAR 31,	1999

MEC 30-1991
M20184 001

卷八

ACEDON THEOREM

PERINDOPRIL ERBUMINE

TABLET; ORAL ACTOS TAKEDA		EQ 15MG BASE TAKEDA	N21073 001 JUL 15, 1999
N20184 001 DEC 30, 1993 N20184 001 DEC 30, 1993 N20184 001 DEC 30, 1993 N20184 002 DEC 30, 1993 N20184 003 DEC 30, 1993		EQ 30MG BASE EQ 45MG BASE	N21073 002 JUL 15, 1999 N21073 003 JUL 15, 1999
@ SOLVAY		+ + + + + + + + +	
DEC 30, 1993 DEC 30, 1993			
<u>POLYETHYLENE GLYCOL 3350</u>			
POWDER FOR RECONSTITUTION; ORAL MIRALAX + BRAINTREE		1.7GM/SCOOPFUL 1.7GM/SCOOPFUL	N20698 001 FEB 18, 1999
<u>PHENDIMETRAZINE TARTRATE</u>			
TABLET; ORAL MEG CHEMISTS PCT FORM ②			
AA N85914 001 N85914 001 N85697 001 N85697 001		<u>POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE</u> <u>SOLUTION/DROPS; OPHTHALMIC</u> <u>TRIMETHOPRIM SULFATE AND POLYMYXIN B SULFATE</u> <u>AT RECON</u>	
AA N17352 001 N17352 001		<u>POTASSIUM CHLORIDE</u>	N64211 001 APR 13, 1998
<u>PHENTERMINE HYDROCHLORIDE</u>			
CAPSULE; ORAL FASTIN SMITHKLINE BEECHAM ②			
AA N86945 001 N86945 001 JUL 20, 1983		<u>CAPSULE, EXTENDED RELEASE; ORAL</u> <u>MICRO-K</u> <u>KV PHARM</u> <u>ROBINS AH</u>	N18238 001 N18238 001
AA PENTERMINE HCL EON ②		<u>AB</u> <u>AB</u> <u>MICRO-K 1.0</u> <u>AB</u> <u>AB</u> <u>AB</u>	
AA PHENYTOIN SODIUM SPERDIS ②		<u>8MEQ</u> <u>8MEQ</u> <u>1.0MEQ</u> <u>1.0MEQ</u> <u>1.0MEQ</u>	MAY 14, 1984 N18238 002 N18238 002 MAY 14, 1984 N18238 002 MAY 14, 1984
<u>INJECTABLE: INJECTION PHENYTOIN SODIUM</u>			
AA N85434 001 N85434 001		<u>50MG/ML</u> <u>50MG/ML</u>	N19561 003 N19561 003
GRANULE, FOR RECONSTITUTION ER; ORAL MICRO-K LS ② KV PHARM			N19561 003 N19561 003
2 OMEQ/PACKET			

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN' 99 - AUG' 99

ROFECOXIB

TABLET; ORAL
VIOTXX
+ MERCK

25MG

CREAM; TOPICAL
THERMAZENE
KENDALL LP

1%ABABSHERWOOD MERCK1%ROSIGLITTAZONE MALEATE

TABLET; ORAL
AVANDIA
SMITHKLINE BEECHAM

EQ 2MG BASE
EQ 4MG BASE
EQ 8MG BASE

N21071 002
MAY 25, 1999
N21071 003
MAY 25, 1999
N21071 004
MAY 25, 1999

POWDER; ORAL
BUPHENYL
+ MEDICIS

> ADD >> ADD >> DLT >> DLT >* UCYCLID* UCYCLID* UCYCLID* UCYCLIDSODIUM PHENYLBUTYRATE

TABLET; ORAL
BUPHENYL
+ MEDICIS

3GM/TEASPOONFUL3GM/TEASPOONFUL* UCYCLID* UCYCLID

TABLET; ORAL
SHERWOOD MERCK

1%ABABSHERWOOD MERCK1%ABABSHERWOOD MERCK1%ABAB</

SOYBEAN OIL

SULFACETAMIDE SODIUM

INJECTABLE; INJECTION
INTRALIPID 30%
AP + FRESENIUS KABI 30%
AP + PHARMACIA AND UPJOHN 30%
SOLUTION/DROPS; OPHTHALMIC
SULFACECTAMIDE SODIUM 3.0%
AKORN
AT
 N19942 001 DEC 30, 1993
 N19942 001 DEC 30, 1993
 N40216 001 MAY 25, 1999

SPIRONOLACTONE

INJECTABLE; INJECTION

50
MUTUAL PHARM

> <u>ADD</u> >	<u>AB</u>	<u>100MG</u>	N89424 003	AUG 24, 1998
> <u>ADD</u> >	<u>AB</u>	<u>25MG</u>	N87998 001	N50708 001
FOREPAC PHARM				
EQ 1IMG BASE				
APR 08, 1994				

SULFACETAMIDE SODIUM

35 CIS N/A N/A

SOLUTION/DROPS; OPHTHALMIC		TECHNETIUM TC-99M ALBUMIN COLLOID KIT	
SODIUM SULFACETAMIDE		INJECTABLE; INJECTION	
AKORN	10%	N83021 001 N83021 002 N83021 003	MICROLITE CIS
AKORN	15%	N83021 001 N83021 002	N/A
AKORN	30%	N83021 001 N83021 002 N83021 003	N/A
AKORN	10%	N83021 001 N83021 002 N83021 003	DUPONT PHARMS
AKORN	15%	N83021 001 N83021 002 N83021 003	N/A
AKORN	30%	N83021 001 N83021 002 N83021 003	N/A
AKORN	10%	N40215 001	MAY 25, 1999

> ADD > TECHNETIUM TC-99M DEPREOTIDE > ADD > TEMOZOLOMIDE

> ADD > INJECTABLE; INJECTION
NEO TECT KIT
+ DIATIDE N/A > ADD > CAPSULE; ORAL
TEMODAR
SCHERING 20MG
N21012 001
AUG 03, 1999 > ADD > 100MG
N21029 003
AUG 11, 1999 > ADD > 250MG
N21029 004
AUG 11, 1999 > ADD >

> ADD > TECHNETIUM TC-99M DISOFENIN KIT

INJECTABLE; INJECTION
HEPATOLITE CIS N/A N18467 001
MAR 16, 1982
N18467 001
MAR 16, 1982 > ADD > INJECTABLE; INJECTION
BRETHINE * NOVARTIS 1MG/ML
+ NOVARTIS 1MG/ML

> DLT > TECHNETIUM TC-99M LIDOFENIN KIT

INJECTABLE; INJECTION
TECHNESCAN HIDA
DRAXIMAGE N/A > DLT > TABLET; ORAL
BRETHINE * NOVARTIS 2.5MG
N18489 001
OCT 31, 1986 N18489 001
OCT 31, 1986 > DLT > + BRICASYL
HOECHST MARION RSSL 2.5MG
N17849 001
N17849 002
N17849 001
N17849 002 > ADD > TABLET; ORAL
BRETHINE * NOVARTIS 2.5MG
N17849 001
N17849 002 > ADD > + BRICASYL
HOECHST MARION RSSL 2.5MG
N17618 001
N17618 002
N17618 001
N17618 002 > ADD >

> DLT > TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION
OSTEOLITE AP
CIS DUPONT PHARMS N/A N17972 001
N17972 001 > DLT > TERIPARATIDE ACETATE

> DLT > TECHNETIUM TC-99M PYRO/TRIMETA PHOSPHATES KIT

INJECTABLE; INJECTION
PYROLITE AP
CIS DUPONT PHARMS N/A N17684 001
N17684 001 > ADD > INJECTABLE; INJECTION
PARATHYR * RHONE POULENC RORER 200 UNITS/VIAL
N19498 001
DEC 23, 1987 > ADD > TESTOSTERONE ENANTHATE

> ADD > CAPSULE; ORAL
TEMODAR
SCHERING 5MG
N21029 001
AUG 11, 1999 > ADD > INJECTABLE; INJECTION
TESTOSTERONE ENANTHATE
SPLATICS 1000MG/ML
N055599 001

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
TESTOSTERONE ENANTHATE
④ STERIS
100MG/ML

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL
EUROPA PHARM

**TETRACYCIN
RETIPHARMICS**

6

THEORY AND PRACTICE IN THE FIELD OF CULTURAL HERITAGE

CAPSULES, EXTENDED RELEASE; ORAL
THEOCLEAR L.A. - 130
CENT PHARMS 13.0MG
@ SCHWARZ PHARMA 1.30MG
THEOCLEAR L.A. - 260
centr. ointm. 260
@ SCHWARZ PHARMA 2.60MG

INJECTABLE: INFECTION

DEXTROSE 5% IN PLASTIC CONTAINER 4.0MG/100ML	N19083 NOV 07, 1 N19083 NOV 07, 1
DEXTROSE 5% IN PLASTIC CONTAINER 8.0MG/100ML	N19083 NOV 07, 1 N19083 NOV 07, 1
DEXTROSE 5% IN PLASTIC CONTAINER 8.0MG/100ML	N19083 NOV 07, 1 N19083 NOV 07, 1
DEXTROSE 5% IN PLASTIC CONTAINER 16.0MG/100ML	N19083 NOV 07, 1 N19083 NOV 07, 1

<u>AB</u>	<u>+</u>	SYNTEX	<u>25.0MG</u>		
				@	
				*	
				<u>SYNTEX USA</u>	<u>TICLOPIDINE HCL</u>
				<u>EON</u>	<u>25.0MG</u>
<u>ADD</u>	<u>></u>	<u>AB</u>			
<u>ADD</u>	<u>></u>				

THEOPHYLLINE

INJECTABLE; INJECTION
THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER
160MG/10ML
© MCCANN
N19083 01
NOV 07 19

TABLET EXTENDED RELEASE: QD81

N85665 001
N85665 002
N85665 003
N85665 004

N70969 001

OCT 16, 1987
N70969 001

N20646 005
15 1200

N19979	081
MAR 24,	1993
N19979	002
OCT 31,	1991
N19979	001
MAR 24,	1993
N19979	002
OCT 31,	1991

TRIAMCINOLONE ACETONIDE

GEL; TOPICAL ARISTOCORT @ LEDERLE	0.1%	NB33300 001	TABLET; ORAL <u>TRIFLE SULFOID</u> + PAL PAK	167MG; 167MG; 167MG	N80094 001
<u>OINTMENT; TOPICAL</u>					
AT ARISTOCORT AT FUJISAWA HLTHCARE	0.1% 0.5% 0.1% 0.5%	N80750 004 N80745 002 N80750 004 N80745 002	SOLUTION/DROPS; OPHTHALMIC <u>TROPICAMIDE</u> AT STERIS	0.5%	N89171 001 DEC 28, 1990
AT LEDERLE		N80750 003 N80745 003 N88781 001	@	0.5%	N89171 001 DEC 28, 1990
AT ARISTOCORT A AT FUJISAWA HLTHCARE	0.1% 0.5% 0.1% 0.5%	N80750 004 N80745 003 N88781 001	OCT 05, 1984 NB0750 003 NB0745 003 N88781 001	UREA, C-13	OCT 05, 1984
AT + @ LEDERLE	0.1% 0.5% 0.1% 0.5%	N80750 003 N80745 003 N88781 001	POWDER FOR RECONSTITUTION; ORAL PYLORI-CHEK BREATH TEST + ALIMENTERICS	100MG/VIAL	FEB 04, 1999
<u>TRIAMCINOLONE DIACETATE</u>					
SYRUP; OPAL ARISTOCORT FUJISAWA HLTHCARE	2MG/5ML 2MG/5ML	N11960 004 N11960 004	SOLUTION; VALSTAR PRESERVATIVE FREE * ANTHRA		N20892 001 SEP 25, 1998
LEDERLE					
<u>TRIMETHOBENZAMIDE HYDROCHLORIDE</u>					
INJECTABLE; INJECTION TRIMETHOBENZAMIDE HCL AP SMITH AND NEPHEW	100MG/ML	NB8960 001 APR 04, 1986	SOLUTION; INTRAVESICAL VALSTAR PRESERVATIVE FREE + ANTHRA	40MG/ML	N20892 001 SEP 25, 1998
④	100MG/ML	N88960 001 APR 04, 1986			
<u>TRISULFAPYRIMIDINES (SULFADIAZINE; SULFAMERAZINE; SULFAMETHAZINE)</u>					
TABLET; ORAL SULFA-TRIFLE #2 AB * GLOBAL PHARM	167MG; 167MG; 167MG 167MG; 167MG; 167MG	N88979 001 N80079 001	> ADD > AP > ADD > AP > ADD > AP	10MG/VIAL 20MG/VIAL 10MG/VIAL	N75218 001 AUG 23, 1999
④ TRIPLE SULFOID	167MG; 167MG; 167MG	N80094 001	> ADD > AP	GENSIA	N75218 002 AUG 23, 1999
AB PAL PAK					N74688 001 AUG 25, 1999

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN' 99 - AUG' 99

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> ADD >
ZALEPLON

> ADD >
> ADD >
> ADD >
> ADD >
CAPSULE; ORAL
SONATA
+ WYETH AYERST
10MG
N20859 002
AUG 13, 1999

ZANAMIVIR

CAPSULE; INHALATION
RELENZA
+ GLAXO WELLCOME
5MG
N21036 001
JUL 26, 1999

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OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN' 99 - AUG' 99

<u>ACETAMINOPHEN</u>		<u>CITMETIDINE</u>	<u>N20951 001</u>
SUPPOSITORY; RECTAL	ACEPHEN	SUSPENSION; ORAL	JUL 09, 1999
* G AND W LABS	12.0MG 32.5MG	TAGAMET HB 200 + SMITHKLINE BEECHAM	200MG/20ML
	65.0MG 12.0MG	TABLET; ORAL	N75425 001
	32.5MG	CIMETIDINE DANBURY PHARMA	JUL 29, 1999
	65.0MG	ZENITH GOLDLINE	N75345 001
ACETAMINOPHEN			JUN 16, 1999
ASCENT PEDS	12.0MG		
+ UPSSHER SMITH	3.25MG 6.50MG 12.0MG	SEP 12, 1983 N18337 003 N18337 002	CLOTRIMAZOLE N18337 002
	3.25MG 6.50MG 12.0MG	SEP 12, 1983 N18337 003 N18337 002	CREAM; TOPICAL LOTRIMIN AF SCHERING PLUGH
INFANTS' FEVERALL	8.0MG	SEP 12, 1983 N18337 003 N18337 002	Lotion; TOPICAL LOTRIMIN AF SCHERING
ASCENT PEDS	8.0MG	AUG 26, 1992 N18337 004 N18337 004	Lotion; TOPICAL LOTRIMIN AF SCHERING PLUGH
UPSSHER SMITH	8.0MG	AUG 26, 1992 N18337 004	
<u>CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE</u>			N17613 002
CAPSULE, EXTENDED RELEASE; ORAL			OCT 27, 1989
CONTACT	8MG; 75MG	N18099 001	
* SMITHKLINE	8MG; 75MG	N18099 001	
@ PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE	8MG; 75MG	N18809 001	EPINEPHRINE BITARTRATE
PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE	8MG; 75MG	MAY 07, 1984	AEROSOL, METERED, INHALATION
CENT PHARMS	8MG; 75MG	N18809 001	NEBUHALER-EPI
	8MG; 75MG	MAY 07, 1984	* 3M 0.3MG/INH
			④
TABLET, EXTENDED RELEASE; ORAL			
CONTACT	12MG; 75MG	N19613 001	FAMOTIDINE
NOVARTIS	12MG; 75MG	JUN 13, 1986	TABLET; ORAL
	12MG; 75MG	N19613 001	PEPCID AC
		JUN 13, 1986	MERCK
		> ADD > ADD	
TRIMINIC-12	12MG; 75MG	N18115 001	
* NOVARTIS	12MG; 75MG	N18115 001	

IBUPROFEN

SUSPENSION; ORAL
IBUPROFEN
ALPHARMA

**TABLET; ORAL
IBUPROFEN
LINK**

NORTON HN
ZENITH GOLDLINE
JUNIOR STRENGTH
PERRIGO

CAPSULE; ORAL
 PROVEL
 * NOVARTIS
 + WHITEHALL ROB
 INSULIN ZINC SUSP PU
 INJECTABLE; INJECT
 LENTE LIATIN II
 * LILLY

MITSUBISHI ELECTRIC

N75010 001 MAR 01, 1999 N75139 001 MAR 01, 1999
SUPPOSITORY: VAGINAL
MICONAZOLE NITRATE
ALPHAMETHINE DURADM
2%, 200MG

N71144	001	ALPHATOCOL US	PHTHALO	100MG
ISBN 20,	1987	MMC		100MG
N72901	001			
DEC 19,	1991			
N72903	001			
DEC 19,	1991			
		<u>MINOXIDIL</u>		
N71144	001	SOLUTION; TOPICAL		
JAN 20,	1987	MINOXIDIL (FOR MEN)		
N72901	001	PERRIGO		
DEC 19,	1991			
N72903	001			
DEC 19,	1991			
		<u>MINOXIDIL (FOR WOMEN)</u>		
N75367	001	PERRIGO		
APR 22,	1991			

NAPROXEN SODIUM

TABLET, ORAL
NAPROXEN SODIUM
GRANULES
NOVOPHARM NC
EQ 200MG BAS
N20402 001
APR 20, 1995
N20402 001

WTCOTTON

N19983 003
DEC 23, 1998
N19983 004
DEC 23, 1998

NICOTINE FILM EXTENDED DELAYED TRANSDERMAL

N18477 001

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL NICOTINE POLACRILEX CIRCA	EQ 2MG BASE EQ 4MG BASE	N74507 001 MAR 15, 1999 N74707 001 MAR 19, 1999
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NONOXYNOL-9

SPONGE; VAGINAL TODAY @ ALLENDALE PHARMS	1GM	N18683 001 APR 01, 1983 N18683 001 APR 01, 1983
© KRITTERKILL ROBBINS	1GM	

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL PSEUDOEPHEDRINE HCL PERRIGO	120MG	N75153 001 FEB 26, 1999
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RANITIDINE HYDROCHLORIDE

TABLET, ORAL RANITIDINE HCl NOVOPHARM	EQ 75MG BASE	N75094 001 JUN 21, 1999 N75132 001
RANBAXY	EQ 75MG BASE	
ZANTAC 75 * GLAXO WELLCO	EQ 75MG BASE	N20520 001 DEC 19, 1995
+ WARNER LAMBERT	EQ 75MG BASE	N20520 001 DEC 19, 1995

TERBINAFINE HYDROCHLORIDE

CREAM; TOPICAL LAMISIL + NOVARTIS	1%	N20980 001 MAR 09, 1999
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DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST

CUMULATIVE SUPPLEMENT NUMBER 8 AUG '99

NO AUGUST 1999 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 Product Designations and Approvals List
August 1999

Name Generic Name <u>TN=Trade Name</u>	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
111Indium pentetreotide TN= SomatoTher	Treatment of somatostatin receptor positive neuroendocrine tumors.	Louisiana State University Medical Center Foundation 1600 Canal St. 10th Floor New Orleans, LA 70112 DD=06/10/1999
166Ho-DOTMP TN=	Treatment of multiple myeloma.	NeoRx Corporation 410 W. Harrison Seattle, WA 98119 DD=02/10/1999
6-hydroxymethylalicycylfulvene TN=	Treatment of histologically confirmed advanced or metastatic pancreatic cancer.	MGI Pharma, Inc. Suite 300E, Opus Center 9900 Bren Road East Minnetonka, MN 55343 DD=04/06/1999
6-hydroxymethylalicycylfulvene TN=	Treatment of ovarian cancer.	MGI Pharma, Inc. 9900 Bren Road East Suite 300E, Opus Center Minnetonka, MN 55343 DD=07/06/1999
6-hydroxymethylalicycylfulvene TN=	Treatment of renal cell carcinoma.	MGI Pharma, Inc. 9900 Bren Road East Suite 300 E, Opus Center Minnetonka, MN 55343 DD=07/27/1999

Orphan Product Designations and Approvals List
August 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Alitretinoin TN= Panretin	Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.	Ligand Pharmaceuticals Inc. 10275 Science Center Drive San Diego, CA 92121 DD=03/24/1998 MA=02/02/1999
Amifostine TN= Ethyol	Reduction of the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer.	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street, Suite 400 Conshohocken, PA 19428 DD=05/12/1998 MA=06/24/1999
Antihemophilic factor/von Willebrand factor complex (human), dried, pasteurized TN= Humate-P	Treatment and prevention of bleeding in hemophilia A (classical hemophilia) in adult patients; and treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand disease, and in mild and moderate von Willebrand disease where use of desmopressin is known or suspected to be inadequate in adult and pediatric patients.	Centeon Pharma GmbH Emil-von-Behring-Strasse 76 35041 Marburg Germany, DD=10/16/1992 MA=04/01/1999
Artesunate TN=	Treatment of malaria.	World Health Organisation Special Programme for Research and Training in Tropical Diseases Via Appia Geneva 27, Switzerland, DD=07/19/1999

Orphan Product Designations and Approvals List
August 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Atovaquone TN= Mepron	Prevention of Pneumocystis carinii pneumonia (PCP) in high-risk, HIV-infected patients defined by a history of one or more episodes of PCP and/or a peripheral CD4+ (T4 helper/inducer) lymphocyte count less than or equal to 200/mm ³ .	Glaxo Wellcome Research and Development 5 Moore Drive PO Box 13398 Research Triangle Park, NC 27709 DD=08/14/1991 MA=01/05/1999
Autologous DNP-conjugated tumor vaccine TN= M-Vax	For adjuvant therapy in melanoma patients with surgically resectable lymph node metastasis (Stage III and limited Stage IV disease).	Avax Technologies, Inc. 4520 Main St. Suite 930 Kansas City, MO 64111 DD=02/23/1999
Beraprost TN=	Treatment of pulmonary arterial hypertension associated with any New York Heart Association classification (Class I, II, III, or IV).	United Therapeutics Corporation 68 T.W. Alexander Drive, PO Box 14186 Research Triangle Park, NC 27709 DD=04/29/1999
Bexarotene TN= Targretin	Treatment of cutaneous T-cell lymphoma.	Ligand Pharmaceuticals, Inc. 10275 Science Center Dr. San Diego, CA 92121 DD=06/18/1999
Bleomycin TN= Blenoxane	Treatment of pancreatic cancer.	Genetronics, Inc. 11199 Sorrento Valley Rd. San Diego, CA 92121 DD=02/09/1999

Orphan Product Designations and Approvals List
August 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Busulfan TN= Busulfex	As preparative therapy in the treatment of malignancies with bone marrow transplantation.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=07/28/1994 MA=02/04/1999
CT-2584 mesylate TN=	Treatment of adult soft tissue sarcoma.	Cell Therapeutics, Inc. 201 Elliott Ave. West Suite 400 Seattle, WA 98119 DD=04/16/1999
CT-2584 mesylate TN=	Treatment of malignant mesothelioma.	Cell Therapeutics, Inc. 201 Elliott Ave. West Seattle, WA 98119 DD=04/16/1999
Coagulation factor VIIa (recombinant) TN= NovoSeven	Treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX.	Novo Nordisk Pharmaceuticals, Inc. 100 Overlook Center Suite 200 Princeton, NJ 08540 DD=06/06/1988 MA=03/25/1999
Cytarabine liposomal TN= DepoCyt	Treatment of neoplastic meningitis.	DepoTech Corporation 10450 Science Center Drive San Diego, CA 92121 DD=06/02/1993 MA=04/01/1999
Decitabine TN=	Treatment of myelodysplastic syndromes.	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem, The Netherlands DD=03/08/1999

Orphan Product Designations and Approvals List
August 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Decitabine TN=	Treatment of chronic myelogenous leukemia.	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem, The Netherlands DD=03/08/1999
Denileukin diftitox TN= Ontak	Treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor.	Seragen, Inc. 97 South Street Hopkinton, MA 01748 DD=08/21/1996 MA=02/05/1999
Doxorubicin liposome TN= Doxil	Treatment of ovarian cancer.	Alza Corporation 1550 Plymouth St. PO Box 7210 Mountain View, CA 94039 DD=11/04/1998 MA=06/28/1999
Epoprostenol TN= Flolan	Treatment of secondary pulmonary hypertension due to intrinsic precapillary pulmonary vascular disease.	Glaxo Wellcome Inc. Five Moore Dr. PO Box 13398 Research Triangle Park, NC 27709 DD=03/22/1999
Etanercept TN= Enbrel	Reduction in signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.	Immunex Corporation 51 University St. Seattle, WA 98101 DD=10/27/1998 MA=05/27/1999

Orphan Product Designations and Approvals List
August 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Etanercept TN= Enbrel	Treatment of Wegener's granulomatosis.	Stone, MD, MPH, John H. Johns Hopkins Vasculitis Center, Division of Rheumatology 1830 East Monument St., Suite 7500 Baltimore, MD 21205 DD=04/06/1999
Fluoxetine TN= Prozac	Treatment of autism.	Hollander, MD, Eric Mt. Sinai School of Medicine, Dept. of Psychiatry Box 1230, One Gustave L. Levy Place New York, NY 10029 DD=04/30/1999
Guanfacine TN= Tenex	Treatment of fragile X syndrome.	Watson Laboratories, Inc. 311 Bonnie Circle PO Box 1900 Corona, CA 91718 DD=08/05/1999
Humanized MAb (IDE-C-131) to CD40L TN=	Treatment of systemic lupus erythematosus.	Idec Pharmaceuticals Corporation 3030 Callan Rd. San Diego, CA 92121 DD=02/09/1999
Interferon beta-1a (recombinant human) TN= Avonex	Treatment of pulmonary fibrosis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=01/07/1999

Orphan Product Designations and Approvals List
August 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Iodine I-131 radiolabeled chimeric MAb tumor necrosis treatment (TNT-1B) TN= 131I-chTNT-1	Treatment of glioblastoma multiforme and anaplastic astrocytoma.	Technicclone Corporation 14282 Franklin Ave. Tustin, CA 92780 DD=02/12/1999
Japanese encephalitis vaccine (live, attenuated) TN=	Prevention of Japanese encephalitis.	Boran Pharmaceuticals 3F, Koryo Academytel, 437-3 Ahyun-Dong, Mapo-Gu, Seoul 121-010 South Korea, DD=05/19/1999
L-5-hydroxytryptophan TN=	Treatment of tetrahydrobiopterin deficiency.	Watson Laboratories, Inc. 311 Bonnie Circle P.O. Box 1900 Corona, CA 91718 DD=01/20/1999
Lactic acid TN= Aphthaid	Treatment of severe aphthous stomatitis in severely, terminally immunocompromised patients.	Frontier Pharmaceutical, Inc. SUNY Farmingdale Conklin Hall Farmingdale, NY 11735 DD=06/29/1999
Lidocaine patch 5% TN= Lidoderm Patch	For relief of allodynia (painful hypersensitivity), and chronic pain in post-herpetic neuralgia.	Hind Health Care, Inc. 3707 Williams Rd., Suite 101 San Jose, CA 95117 DD=10/24/1995 MA=03/19/1999

Orphan Product Designations and Approvals List
August 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Liposomal-cis-bi s-neodecanoato-t mesothelioma. rans-R,R-1,2-dia minocyclohexane- Pt (II) TN=	Treatment of malignant s-neodecanoato-t mesothelioma.	Aronex Pharmaceuticals, Inc. 8707 Technolgy Forest Place The Woodlands, TX 77381 DD=09/01/1999
Lisofylline TN=	Treatment of patients undergoing induction therapy for acute myeloid leukemia.	Cell Therapeutics, Inc. 201 Elliot Ave. W., Suite 400 Seattle, WA 98119 DD=06/10/1999
Marijuana TN=	Treatment of HIV-associated wasting syndrome.	Multidisciplinary Association for Psychedelic Studies, Inc. 3 Francis St. Belmont, MA 02478 DD=05/25/1999
Mitoxantrone TN= Novantrone	Treatment of secondary-progressive multiple sclerosis.	Immunex Corporation 51 University St. Seattle, WA 98101 DD=08/13/1999
Mitoxantrone TN= Novantrone	Treatment of progressive-relapsing multiple sclerosis.	Immunex Corporation 51 University St. Seattle, WA 98101 DD=08/13/1999
Murine MAb to polymorphic epithelial mucin, human milk fat globule 1 TN= Theragyn	Adjuvant treatment of ovarian cancer.	Antisoma West Africa House Hanger Lane London W5 3QR, UK DD=03/22/1999

Orphan Product Designations and Approvals List
August 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
N-acetylgalactosamine-4-sulfatas e, recombinant human TN=	Treatment of mucopolysaccharidosis Type VI (Maroteaux-Lamy syndrome).	BioMarin Pharmaceutical, Inc. 11 Pimental Court Novato, CA 94949 DD=02/17/1999
Parovirus B19 (recombinant VP1 and VP2; S.frugiperda cells) vaccine TN= MEDI-491	Prevention of transient aplastic crisis in patients with sickle cell anemia.	MedImmune, Inc. 35 West Watkins Mill Rd. Gaithersburg, MD 20878 DD=05/07/1999
Pegylated arginine deiminase TN= Hepacid	Treatment of hepatocellular carcinoma.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=03/26/1999
Pegylated arginine deiminase TN= Melanocid	Treatment of invasive malignant melanoma.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=04/12/1999
Recombinant human C1-esterase inhibitor TN=	Prophylactic treatment of angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.	Pharming N.V. Cipalstreet 3 B-2440 Geel, Belgium DD=02/23/1999
Recombinant human C1-esterase inhibitor TN=	Treatment of (acute attacks of) angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.	Pharming N.V. Cipalstreet 3 B-2440 Geel, Belgium DD=02/23/1999

Orphan Product Designations and Approvals List
August 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Recombinant human insulin-like growth factor-I/insulin -like growth factor binding protein-3 TN=	Treatment of major burns that require hospitalization.	Celtrix Pharmaceuticals, Inc. 3055 Patrick Henry Dr. Santa Clara, CA 95054 DD=06/15/1999
Recombinant human nerve growth factor TN=	Treatment of HIV-associated sensory neuropathy.	Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 DD=04/16/1999
Recombinant humanized MAb 5c8 TN=	Prevention of rejection of solid organ transplants.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=03/22/1999
Recombinant humanized MAb 5c8 TN=	Prevention of rejection of pancreatic islet cell transplants.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=03/22/1999
Rifalazil TN=	Treatment of pulmonary tuberculosis.	PathoGenesis Corporation 201 Elliott Avenue West Suite 150 Seattle, WA 98119 DD=04/13/1999
SCH 58500 TN=	Treatment of primary ovarian cancer.	Schering Corporation 2000 Galloping Hill Rd. Kenilworth, NJ 07033 DD=04/12/1999

Orphan Product Designations and Approvals List
August 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Sodium 1,3-propanedisulfonate TN=	Treatment of secondary amyloidosis.	Neurochem, Inc. 7220 Frederick Banting, Suite 100 Saint-Laurent, Quebec Canada H4S 2A1, DD=04/06/1999
Sodium dichloroacetate TN= Ceresine	Treatment of severe head injury.	Cypros Pharmaceutical Corporation 2714 Loker Avenue West Carlsbad, CA 92008 DD=06/14/1999
Somatropin [rDNA] TN= Genotropin	Treatment of short stature in patients with Prader-Willi syndrome.	Pharmacia & Upjohn 7000 Portage Rd. 0633-298-113 Kalamazoo, MI 49001 DD=07/06/1999
Synthetic human secretin TN=	For use in the evaluation of exocrine pancreas function.	ChiRhoClin, Inc. 1550 Gallaudet Ave. Silver Spring, MD 20905 DD=06/16/1999
Synthetic human secretin TN=	For use in obtaining desquamated pancreatic cells for cytopathologic examination in pancreatic carcinoma.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/16/1999
Synthetic human secretin TN=	For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/16/1999
Synthetic porcine secretin TN=	For use in the evaluation of exocrine pancreas function.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/18/1999

Orphan Product Designations and Approvals List
August 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Synthetic porcine secretin TN=	For use in obtaining desquamated pancreatic cells for cytopathologic examination in pancreatic carcinoma.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/18/1999
Synthetic porcine secretin TN=	For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/18/1999
Temozolomide TN= Temodar	Treatment of recurrent malignant glioma.	Schering-Plough Research Institute 2000 Galloping Hill Rd. Kenilworth, NJ 07033 DD=10/05/1998 MA=08/11/1999
Thalidomide TN= Thalomid	Treatment of Crohn's disease.	Celgene Corporation 7 Powder Horn Dr. Warren, NJ 07059 DD=04/06/1999
Tobramycin TN= Tobi	Treatment of bronchiectasis patients infected with Pseudomonas aeruginosa.	PathoGenesis Corporation 201 Elliott Avenue West Suite 150 Seattle, WA 98119 DD=06/18/1999
Transgenic human alpha 1 antitrypsin TN=	Treatment of emphysema secondary to alpha 1 antitrypsin deficiency.	PPL Therapeutics (Scotland) Limited Roslin, Edinburgh EH25 9PP Scotland U.K. DD=05/19/1999

Orphan Product Designations and Approvals List
August 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Yttrium-90 radiolabeled humanized monoclonal anti-carcinoembr cyonic antigen IgG antibody TN= Cea-Cide	Treatment of ovarian carcinoma.	Immunomedics, Inc. 300 American Rd. Morris Plains, NJ 07950 DD=08/03/1999

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

NO AUGUST 1999 ADDITIONS

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, 19TH 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

NP* NEW PRODUCT (MINT FLAVORED)

REFERENCES NEW DOSING SCHEDULE

D-50 INFORMATION FOR USE OF CONVERT IN POST-CARDIAC SURGERY PATIENTS

NEW INDICATION

- I-250 PRIMARY PREVENTION OF CORONARY HEART DISEASE IN PATIENTS WITHOUT SYMPTOMATIC CARDIOVASCULAR DISEASE WHO HAVE AVERAGE TO MODERATELY ELEVATED TOTAL-C AND LDL-C AND BELOW AVERAGE HDL-C
- I-251 TREATMENT OF GENERALIZED ANXIETY DISORDER
- I-252 NEW COMBINATION USE OF PRECOSE FOR PATIENTS WITH TYPE 2 DIABETES TREATED WITH DIET PLUS METFORMIN
- I-253 COMBINATION USE OF PRECOSE FOR PATIENTS WITH TYPE 2 DIABETES TREATED WITH DIET PLUS INSULIN
- I-254 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS (LOSS OF BONE MASS)
- I-255 PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA (PCP)
- I-256 USE IN TREATMENT OF SMALL CELL LUNG CANCER SENSITIVE DISEASE AFTER FAILURE OF FIRST-LINE CHEMOTHERAPY
- I-257 TREATMENT OF CHRONIC HEPATITIS B ASSOCIATED WITH EVIDENCE OF HEPATITIS B VIRAL REPLICATION AND ACTIVE LIVER INFLAMMATION
- I-258 FOR PERENNIAL NONALLERGIC RHINITIS FOR AGES FOUR AND ABOVE
- I-259 PROPHYLAXIS OF DEEP VEIN THROMBOSIS (DVT), WHICH MAY LEAD TO PULMONARY EMBOLISM, IN PATIENTS UNDERGOING HIP REPLACEMENT SURGERY
- I-260 EXPANDED PEDIATRIC USE IN CHILDREN YOUNGER THAN ONE MONTH OF AGE TO BIRTH (WITH A GESTATIONAL AGE OF 37 WEEKS OR GREATER)
- I-261 TREATMENT OF SOCIAL ANXIETY DISORDER
- I-262 TREATMENT OR PREVENTION OF BRONCHOSPASM WITH REVERSIBLE OBSTRUCTIVE AIRWAY DISEASE AND FOR THE PREVENTION OF EXERCISE INDUCED BRONCHOSPASM IN CHILDREN AGES 4-12
- I-263 TREATMENT OF UNSTABLE ANGINA AND NON-Q-WAVE MYOCARDIAL INFARCTION FOR THE PREVENTION OF ISCHEMIC COMPLICATIONS IN PATIENTS ON CONCURRENT ASPIRIN THERAPY
- I-264 PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH RADIATION, INCLUDING TOTAL BODY IRRADIATION (TBI) AND FRACTIONATED ABDOMINAL RADIATION
- I-265 TREATMENT OF ATOPIC DERMATITIS IN PEDIATRIC PATIENTS 6 YEARS AND OLDER
- I-266 USE OF TOPAMAX AS ADJUNCTIVE THERAPY IN PEDIATRIC PATIENTS AGES 2-16 YEARS WITH PARTIAL ONSET SEIZURES
- I-267 USE IN PEDIATRIC PATIENTS 3 MONTHS OLD AND OLDER-FOR CORTICOSTEROID-RESPONSIVE DERMATOSES
- I-268 PROPHYLAXIS AND CHRONIC TREATMENT OF ASTHMA IN PATIENTS 7-11 YEARS OF AGE

PATENT AND EXCLUSIVITY TERMS

NEW INDICATION

I-269 PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH HIGHLY EMETOGENIC CANCER CHEMOTHERAPY, INCLUDING CISPLATIN

REFERENCES MISCELLANEOUS EXCLUSIVITY CODES

M-1 INFORMATION REGARDING SUPERIORITY CLAIM OVER RANITIDINE FOR DAY AND NIGHT HEARTBURN ADDED TO CLINICAL STUDIES SECTION

PATENT USE CODE

- U-254 USE OF AGGRASTAT IN COMBINATION WITH HEPARIN
- U-255 IMPROVED WAKEFULNESS IN PATIENTS WITH EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY
- U-256 TREATMENT OF HIV INFECITION IN COMBINATION WITH ONE OR MORE ADDITIONAL HIV ANTIVIRAL AGENTS
- U-257 TREATMENT OF HIV INFECTION
- U-258 TREATMENT OF NEURODEGENERATIVE DISEASES
- U-259 TREATMENT OF ANDROGENIC ALOPECIA BY ORAL ADMINISTRATION OF DRUG SUBSTANCE
- U-260 REDUCTION OF INTRAOCCULAR PRESSURE IN PATIENTS WITH OPEN ANGLE GLAUCOMA AND OCULAR HYPERTENSION WHO ARE INTOLERANT OF OTHER IOP LOWERING MEDICATIONS OR INSUFFICIENTLY RESPONSIVE TO ANOTHER IOP LOWERING MEDICATION
- U-261 TREATING BENIGN PROSTATIC HYPERPLASIA WITH A GENUS OF COMPOUNDS, INCLUDING FINASTERIDE
- U-262 TREATING BENIGN PROSTATIC HYPERTROPHY WITH FINASTERIDE
- U-263 METHOD OF TREATING A MALIGNANT CONDITION THROUGH INTRAVASCULAR ADMINISTRATION OF BUSULFAN. METHOD FOR TREATING LEUKEMIA OR LYMPHOMA IN A PATIENT UNDERGOING A BONE MARROW TRANSPLANT THROUGH INTRAVENOUS ADMINISTRATION OF BUSULFAN.
- U-264 METHOD OF TREATING A MALIGNANT DISEASE THROUGH PARENTERAL ADMINISTRATION OF BUSULFAN. METHOD FOR TREATING A PATIENT UNDERGOING A BONE MARROW TRANSPLANT THROUGH INTRAVASCULAR ADMINISTRATION OF BUSULFAN.
- U-265 USE AS A LAXATIVE
- U-266 OSTEOARTHRITIS
- U-267 METHOD FOR PREVENTING HEARTBURN
- U-268 ACROMEGALY
- U-269 EXCESS GH-SECRETION OR GASTRO-INTESTINAL DISORDERS
- U-270 METHOD FOR IMPROVING THE TIME FOR ADMINISTRATION OR THE TIME BETWEEN CHANGES OF GIVING SETS FOR THE DRUG PRODUCT
- U-271 METHOD OF TREATING TUMORS
- U-272 METHOD OF TREATING CARCINOMA
- U-273 CUTANEOUS T-CELL LYMPHOMA
- U-274 ZANAMIVIR FOR INHALATION
- U-275 METHOD OF USE OF THE DRUG SUBSTANCE
- U-276 METHOD OF USE OF LEVOBUPIVACAINE
- U-277 NEUROLOGICAL AND OTHER DISORDERS (TREATMENT OF EPILEPSY, BID ORAL DOSING)
- U-278 METHOD OF USE OF THE INDICATION OF THE DRUG PRODUCT
- U-279 METHOD OF USE OF THE APPROVED PRODUCT
- U-280 TREATING PRECIPITATED ACUTE URINARY RETENTION WITH FINASTERIDE
- U-281 ANTIMYCOTIC USES, SPECIFICALLY, TREATMENT OF ONYCHOMYCOSIS
- U-282 METHOD OF TREATING BACTERIAL INFECTIONS

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 EXPIRES	EXCL CODE	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020482 004	ACARBOSE; PRECOSE					I-252	SEP 29, 2001
020338 001	ADAPALENE; DIFFERIN	4717720	MAY 31, 2010	U-134		I-253	SEP 29, 2001
020380 001	ADAPALENE; DIFFERIN	RE34440	MAR 31, 2010	U-275			
>ADD>		4717720	MAY 31, 2010	U-134			
>ADD>		RE34440	MAY 31, 2010	U-275			
>ADD>		5164402	NOV 17, 2009	U-282			
020760 001	ALATROFLOXACIN MESYLATE; TROVAN PRESERVATIVE FREE	5763154	JUN 15, 2015	U-282			
020760 002	ALATROFLOXACIN MESYLATE; TROVAN PRESERVATIVE FREE	5164402	NOV 17, 2009	U-282			
>ADD>		5763154	JUN 15, 2015	U-282			
020503 001	ALBUTEROL SULFATE; PROVENTIL-HFA	4594359	JUN 10, 2003			I-262	JUN 02, 2002
019621 001	ALBUTEROL SULFATE; VENTOLIN					ODE	FEB 02, 2006
020886 001	ALITRETINOIN; PANRETIN					NCE	FEB 02, 2004
020221 001	AMIFOSTINE; ETHYOL					ODE	JUN 24, 2006
020508 001	AMMONIUM LACTATE; LAC-HYDRIN					PED	FEB 29, 2000
021007 001	AMPRENAVIR; AGENERASE					NCE	APR 15, 2004
021007 002	AMPRENAVIR; AGENERASE					NCE	APR 15, 2004
021039 001	AMPRENAVIR; AGENERASE					ODE	JAN 05, 2006
020500 001	ATOVAQUONE; MEPRON					I-255	JAN 05, 2002
020711 002	BUPROPION HYDROCHLORIDE; ZYBAN	5763493	AUG 12, 2013				
020711 003	BUPROPION HYDROCHLORIDE; ZYBAN	5763493	AUG 12, 2013				
020954 001	BUSULFAN; BUSULFEX	5430057	SEP 30, 2013	U-263	ODE		
>ADD>		5559148	MAY 24, 2015	U-264	NDF		
020793 001	CAFFCIT					NE	SEP 21, 2002
020313 002	CALCITONIN, SALMON; MIACALCIN	575565	JUN 02, 2015				
020896 001	CAPECITABINE; XELODA	5472949	DEC 14, 2013	U-271			
020896 002	CAPECITABINE; XELODA	4966691	NOV 08, 2008	U-272			
>ADD>		5472949	DEC 14, 2013	U-271			
020712 001	CARBAMAZEPINE; CARBATROL	4966691	NOV 08, 2008	U-272			
020712 002	CARBAMAZEPINE; CARBATROL	5912013	JUN 15, 2016	U-277			
020998 001	CELECOXIB; CELEBREX	5912013	JUN 15, 2016	U-277			
020998 002	CELECOXIB; CELEBREX	5760068	JUN 02, 2015	U-19			
020740 005	CERIVASTATIN SODIUM; BAYCOL	5466823	NOV 30, 2013				
>ADD>		5466823	NOV 30, 2013				
020638 001	CIDOFUVIR; VISTIDE	5563165	JAN 17, 2009			NS	MAY 24, 2002
020863 001	CILOSTAZOL; PLETAL	5006530	NOV 26, 2011				
020863 002	CILOSTAZOL; PLETAL	5117080	JUN 26, 2010				
>ADD>		5142051					
019537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4277479	AUG 29, 2000				
020767 001	CISAPRIDE MONOHYDRATE; PROPULSID QUICKSOLV	4670444	AUG 29, 2000				
021041 001	CYTARABINE; DEPOCYT	5246754	DEC 09, 2003	U-36			
		5648093	FEB 15, 2011				
			JUL 15, 2014				
				ODE	APR 01, 2006		
				NP	APR 01, 2002		

PRESCRIPTION AND OTC DRUG PRODUCT

PATENT AND EXCLUSIVITY DATA

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/ PED EXPIRES	EXCL CODE	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020287 001	DALTEPARIN SODIUM; FRAGMIN			I-263	MAY 25,	2002	
020287 003	DALTEPARIN SODIUM; FRAGMIN			I-259	MAR 30,	2002	
020287 004	DALTEPARIN SODIUM; FRAGMIN			I-263	MAY 25,	2002	
017922 001	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	JUN 29,	2013	
017922 002	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	JUN 29,	2013	
017922 003	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	JUN 29,	2013	
018938 001	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	JUN 29,	2013	
018938 002	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	JUN 29,	2013	
019955 001	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	JUN 29,	2013	
019955 002	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	JUN 29,	2013	
074752 001	DILTIAZEM HYDROCHLORIDE; CARTIA XT			PC	DEC 19,	1999	
074752 003	DILTIAZEM HYDROCHLORIDE; CARTIA XT			PC	DEC 19,	1999	
074752 004	DILTIAZEM HYDROCHLORIDE; CARTIA XT			PC	DEC 19,	1999	
020449 001	DOCETAXEL; TAXOTERE	4814470	MAY 14,	2010			
050718 001	DOXORUBICIN HYDROCHLORIDE; DOXIL	5438072	NOV 22,	2013			
020972 001	EFAVIRENZ; SUSTIVA	5698582	JUL 03,	2012			
020972 002	EFAVIRENZ; SUSTIVA	5714512	JUL 03,	2012			
020972 003	EFAVIRENZ; SUSTIVA	5602116	APR 03,	2015	U-278 NCE	JUN 09,	2004
020375 001	ESTRADIOL; CLIMARA	5811423	AUG 07,	2012	U-256	JUN 28,	2006
020375 002	ESTRADIOL; CLIMARA	5519021	MAY 21,	2013			
020375 003	ESTRADIOL; CLIMARA	5663169	SEP 02,	2014	U-257		
020375 004	ESTRADIOL; CLIMARA	5811423	AUG 07,	2012	U-256		
020908 001	ESTRADIOL; VAGIFEM	5519021	MAY 21,	2013			
020992 002	ESTROGENS, CONJUGATED SYNTHETIC A; CENESTIN	5663169	SEP 02,	2014	U-257		
020992 003	ESTROGENS, CONJUGATED; PREMPRO 14/14	5519021	MAY 21,	2013			
020527 001	ESTROGENS, CONJUGATED; PREMPRO 14/14	5663169	SEP 02,	2014	U-257		
>ADD>		5811423	AUG 07,	2012	U-256		
>ADD>					I-254	MAR 05,	2002
020363 001	FAMCICLOVIR; FAMVIR	5223261	JUN 29,	2010	I-254	MAR 05,	2002
020363 003	FAMCICLOVIR; FAMVIR				I-254	MAR 05,	2002
020325 001	FAMOTIDINE; PEPCID AC				I-254	MAR 05,	2002
020801 001	FAMOTIDINE; PEPCID AC				NP	MAR 26,	2002
>ADD>					NP	MAR 24,	2002
						MAR 24,	2002

**PREScription AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA**
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	USE CODE	EXCLUS EXPIRES
019304 002	FENOFIBRATE; TRICOR (MICRONIZED)	4895726	JAN 19, 2009	NP	NOV 04,	2001
020747 001	FENTANYL CITRATE; ACTIQ			NP	NOV 04,	2001
020747 002	FENTANYL CITRATE; ACTIQ			NP	NOV 04,	2001
020747 003	FENTANYL CITRATE; ACTIQ			NP	NOV 04,	2001
020747 004	FENTANYL CITRATE; ACTIQ			NP	NOV 04,	2001
020747 005	FENTANYL CITRATE; ACTIQ			NP	NOV 04,	2001
020747 006	FENTANYL CITRATE; ACTIQ			NCE	FEB 18,	2004
020955 001	FERRIC SODIUM GLUCONATE; FERRELCT					
020625 001	FEKOGENADINE HYDROCHLORIDE; ALLEGRA	5855912	FEB 28, 2015			
020788 001	FINASTERIDE; PROPECIA	5738872	FEB 28, 2015			
020180 001	FINASTERIDE; PROSCAR	5571817	NOV 05, 2013			
>ADD>		5886184	NOV 19, 2012			
>ADD>		5942519	OCT 23, 2018			
>ADD>		4760071	JUN 19, 2006			
>ADD>		586184	JUN 19, 2012			
>ADD>		4377584	MAR 22, 2000			
019452 001	FLUOCINOLONE ACETONIDE; DERMA-SMOOTH/F/S	4626549	DEC 02, 2003			
020101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4626549	DEC 02, 2003			
020974 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4626549	DEC 02, 2003			
020974 002	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001			
019958 001	FLUTICASONE PROPIONATE; CUTIVATE	4626549	DEC 02, 2003			
020121 001	FLUTICASONE PROPIONATE; FLONASE	4626549	DEC 02, 2003			
020882 001	GABAPENTIN; NEURONTIN	4087544	JAN 16, 2000			
020882 002	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010			
021057 001	GANTIRELIX ACETATE; ANTAGON	4087544	JAN 16, 2000			
>ADD>		4087544	JAN 16, 2000			
>ADD>		4087544	JAN 16, 2000			
>ADD>		5084479	JAN 02, 2010			
>ADD>		4801577	FEB 05, 2007			
020509 001	GEMCITABINE HYDROCHLORIDE; GEMZAR	5767082	JUN 16, 2015			
020509 002	GEMCITABINE HYDROCHLORIDE; GEMZAR	5084479	JAN 02, 2010			
020496 001	GLIMEPIRIDE; AMARYL	4808614	MAY 15, 2010			
020496 002	GLIMEPIRIDE; AMARYL	4807544	MAY 15, 2010			
>ADD>		4379785	APR 06, 2005			
020496 003	GLIMEPIRIDE; AMARYL	4379785	APR 06, 2005			
020305 001	GRANISETRON HYDROCHLORIDE; KYTRIL	4379785	APR 06, 2005			
020305 002	HYDROCHLOROTHIAZIDE; AVALIDE	5270317	MAR 20, 2011			
020758 003	INSULIN HUMAN; VELOSULIN BR					
020491 001	I BUTILIDE FUMARATE; CORVERT					
021028 001	ITRACONAZOLE; SPORANOX	4791111	DEC 23, 2005			
020083 001	ITRACONAZOLE; SPORANOX	4791111	DEC 23, 2005			
020657 001	ITRACONAZOLE; SPORANOX	4791111	DEC 23, 2005			
020966 001	ITRACONAZOLE; SPORANOX	4267179	JUN 23, 2000			
021066 001	KETOTIFEN FUMARATE; ZADITOR	5905082	MAY 18, 2016			
020564 001	LAMIVUDINE; EPIVIR					

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	USE CODE	EXCLUSIVITY CODE	EXPIRES
>ADD> 021003 001	LAMIVUDINE; EPIVIR-HBV	5047407	FEB 08, 2009 JUL 02, 2013	U-250	I-257	DEC 08,	2001
>ADD>		5532246	MAY 18, 2016				
>ADD>		5905082	FEB 08, 2009				
>ADD>		5047407	JUL 02, 2013				
>ADD>		5532246					
>ADD> 021004 001	LAMIVUDINE; EPIVIR-HBV						
>ADD> 020764 001	LAMOTRIGINE; LAMICTAL CD						
>ADD>	020764 002	LAMOTRIGINE; LAMICTAL CD					
>ADD>	020764 003	LAMOTRIGINE; LAMICTAL CD					
>ADD> 020406 001	LANSOPRAZOLE; PREVACID						
>ADD>	020406 002	LANSOPRAZOLE; PREVACID					
>ADD> 020597 001	LATANOPROST; XALATAN						
020517 002	LEUPROLIDE ACETATE; LUPRON DEPOT-4	5296504	MAR 22, 2011				
020837 001	LEVALBUTEROL HYDROCHLORIDE; XOPENEX	5422368	MAR 22, 2011				
020837 002	LEVALBUTEROL HYDROCHLORIDE; XOPENEX	4599353	JUL 28, 2006				
020997 001	LEVOBUPIVACAINE HYDROCHLORIDE; CHIROCAINE	5708011	OCT 13, 2014				
020997 002	LEVOBUPIVACAINE HYDROCHLORIDE; CHIROCAINE	5708011	OCT 13, 2014				
020997 003	LEVOBUPIVACAINE HYDROCHLORIDE; CHIROCAINE	5708011	OCT 13, 2014				
021045 001	LEVONORGESTREL; PLAN B						
019941 001	LIDOCAINE; EMLA						
020612 001	LIDOCAINE; LIODERM	4374829	DEC 30, 2001				
019777 006	LISINOPRIL; ZESTRIL	4231938	JUN 15, 2001				
019643 002	LOVASTATIN; MEVACOR	4231938	JUN 15, 2001				
019643 003	LOVASTATIN; MEVACOR	4231938	JUN 15, 2001				
019643 004	LOVASTATIN; MEVACOR	4845075	APR 11, 2009				
020969 001	METHOXSALEN; UVADERX	5036102	JUL 30, 2008				
020968 001	MICONAZOLE NITRATE; MONISTAT DUAL- PAK	499375	MAR 12, 2008				
020682 001	MIGLITOL; GLYSET	5514698	MAR 21, 2014				
020682 002	MIGLITOL; GLYSET	4639436	JAN 27, 2009				
020682 003	MIGLITOL; GLYSET	4639436	JAN 27, 2009				
020717 001	MODAFINIL; PROVIGIL	4177290	MAR 09, 1999				
020717 002	MODAFINIL; PROVIGIL	5618845	OCT 06, 2014				
018612 003	NICOTINE POLACRILEX; NICORETTE (MINT)	4927855	MAY 22, 2007				
020066 003	NICOTINE POLACRILEX; NICORETTE (MINT)						
020385 001	NICOTINE; NICOTROL	5656255	AUG 12, 2014				
021008 001	OCTREOTIDE ACETATE; SANDOSTATIN LAR	5688530	NOV 18, 2014				
021008 002	OCTREOTIDE ACETATE; SANDOSTATIN LAR	4395403	NOV 21, 2002				
		5538739	JUL 23, 2013				
		5639480	JUN 17, 2014				
		5922338	JUL 13, 2016				
		5688530	NOV 18, 2014				
		4395403	NOV 21, 2002				
		5538739	JUL 23, 2013				
		5639480	JUN 17, 2014				
		5922338	JUL 13, 2016				
		NP*	DEC 23,	2001			
		NP*	DEC 23,	2001			
		U-268	ODE	NOV 25,	2005		
		U-269					
		U-269					
		U-269					
		U-269					

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

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PATENT AND EXCISE TAXABILITY DATA

*BED and BED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	EXCLUS CODE	EXCLUS CODE	EXCLUS CODE
020710 001	PAROXETINE HYDROCHLORIDE; PAXIL	5872132	MAY 19, 2015				
020885 001	PAROXETINE HYDROCHLORIDE; PAXIL	5900423	MAY 19, 2015				
020885 002	PAROXETINE HYDROCHLORIDE; PAXIL	5872132	MAY 19, 2015				
020885 003	PAROXETINE HYDROCHLORIDE; PAXIL	5900423	MAY 19, 2015				
020885 004	PAROXETINE HYDROCHLORIDE; PAXIL	5872132	MAY 19, 2015				
020936 001	PAROXETINE HYDROCHLORIDE; PAXIL CR	5900423	MAY 19, 2015				
020936 002	PAROXETINE HYDROCHLORIDE; PAXIL CR	5872132	MAY 19, 2015				
>ADD>	PEMIROLAST POTASSIUM; ALAMAST	5034230	DEC 23, 2008	U-184	PED	MAR 24,	
>ADD>	PIOGLITAZONE HYDROCHLORIDE; ACTOS	5034230*PED	JUN 23, 2009	U-184	NCE	SEP 24,	
021073 001	PIOGLITAZONE HYDROCHLORIDE; ACTOS	4444779	JUL 27, 1999	NCE	JUL 15,		
021073 002	PIOGLITAZONE HYDROCHLORIDE; ACTOS	4687777	JAN 17, 2006				
021073 003	PIOGLITAZONE HYDROCHLORIDE; ACTOS	4444779	JUL 27, 1999	NCE	JUL 15,		
020698 001	POLYETHYLENE GLYCOL 3350; MIRALAX	5710183	JUL 14, 2015	U-265	NP	FEB 18,	
019627 002	PROPOFOL; DIPRIVAN	5714520	MAR 22, 2015				
		5714520*PED	SEP 22, 2015				
		5731355	MAR 22, 2015				
		5731355*PED	SEP 22, 2015				
		5731356	MAR 22, 2015				
		5731356*PED	SEP 22, 2015				
		5908869	MAR 22, 2015				
		5908869*PED	SEP 22, 2015				
075102 001	PROPOFOL; PROPOFOL	4879288	MAR 20, 2007			OCT 16,	
020639 004	QUETiapine FUMARATE; SEROQUEL					SEP 26,	
020973 002	RABEPRAZOLE SODIUM ACIPIHEX					AUG 19,	
075094 001	RANITIDINE HYDROCHLORIDE; RANITIDINE HCL					JAN 13,	
>ADD>	RAPACURONIUM BROMIDE; RAPLON	5418226	APR 14, 2013			AUG 18,	
>ADD>	RAPACURONIUM BROMIDE; RAPLON	5418226	APR 14, 2013			AUG 18,	
020984 002	RIBAVIRIN; REBTOL	5914128	DBC 22, 2017				
020903 001	RISPERIDONE; RISPERDAL	5158952	OCT 27, 2009	U-90	D-37	OCT 17,	
020272 007	RISPERIDONE; RISPERDAL	4804663	DBC 29, 2007	U-90	D-37	OCT 17,	
020272 008	RITONAVIR; NORVIR	4804663	DBC 29, 2007	U-90	D-37	OCT 17,	
		5158952	OCT 27, 2009	U-90			
		5948436	SEP 13, 2013				

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PATENT AND EXCLUSIVITY DATA

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APPL/PROD NUMBER	INGREDIENT NAME ; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020865 001	RIZATRIPTAN BENZOATE; MAXALT-MLT	5457895	OCT 01, 2013			
020865 002	RIZATRIPTAN BENZOATE; MAXALT-MLT ROFECOXIB; VIOXX	5457895	OCT 01, 2013	U-266	NCE	MAY 20, 2004
021042 001	ROFECOXIB; VIOXX	5474995	JUN 24, 2013	U-266	NCE	MAY 20, 2004
021042 002	ROFECOXIB; VIOXX	5691374	NOV 25, 2013	U-266	NCE	MAY 20, 2004
021052 001	ROFECOXIB; VIOXX	5474995	JUN 24, 2013	U-266	NCE	MAY 20, 2004
021052 002	ROFECOXIB; VIOXX	5691374	NOV 25, 2013	U-266	NCE	MAY 20, 2004
021071 002	ROSIGLITAZONE MALEATE; AVANDIA	5474995	JUN 24, 2013	U-266	NCE	MAY 20, 2004
021071 003	ROSIGLITAZONE MALEATE; AVANDIA	5691374	NOV 25, 2013	U-266	NCE	MAY 20, 2004
021071 004	ROSIGLITAZONE MALEATE; AVANDIA SOMATROPIN, BIOSYNTHETIC, HUMATROPE	5474995	JUN 24, 2013	U-266	NCE	MAY 20, 2004
019640 005	SOMATROPIN, BIOSYNTHETIC, HUMATROPE	5691374	NOV 25, 2013	U-266	NCE	MAY 20, 2004
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019640 006	SOMATROPIN, BIOSYNTHETIC, HUMATROPE	5474995	JUN 24, 2013	U-266	NCE	MAY 20, 2004
019640 007	SOMATROPIN, BIOSYNTHETIC, HUMATROPE	5691374	NOV 25, 2013	U-266	NCE	MAY 20, 2004
>ADD>						
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021012 001	TECHNETIUM TC-99M DEPREOTIDE; NEO TECT KIT TEMOZOLOMIDE; TEMODAR	5260291	NOV 09, 2010			
021029 001	TEMOZOLOMIDE; TEMODAR	5260291	NOV 09, 2010			
021029 002	TEMOZOLOMIDE; TEMODAR	5260291	NOV 09, 2010			
021029 003	TEMOZOLOMIDE; TEMODAR	5260291	NOV 09, 2010			
021029 004	TEMOZOLOMIDE; TEMODAR	5260291	NOV 09, 2010			
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074823 001	TERAZOSIN HYDROCHLORIDE; TERAZOSIN HCL	4680291	JUL 14, 2004	U-281		
074823 002	TERAZOSIN HYDROCHLORIDE; TERAZOSIN HCL	4680291	JUL 14, 2004	U-73	NCE	DEC 30, 1999
074823 003	TERAZOSIN HYDROCHLORIDE; TERAZOSIN HCL	4755534	DEC 30, 2006	U-73	NP	APR 29, 2001
074823 004	TERBINAFINE HYDROCHLORIDE; LAMISIL	4680291	JUL 14, 2004	U-281	NCE	DEC 30, 1999
>ADD>						
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020539 001	TERBINAFINE HYDROCHLORIDE; LAMISIL	5840327	AUG 15, 2016			
020749 001	TERBINAFINE HYDROCHLORIDE; LAMISIL	5840327	AUG 15, 2016			
020980 001	TERBINAFINE HYDROCHLORIDE; LAMISIL	5010090	OCT 07, 2008			
>ADD>						
020846 001	TERBINAFINE; LAMISIL	5354760	MAR 24, 2012			
>ADD>						
019762 001	TESTOSTERONE ; TESTODERM	5292756	MAY 14, 2012	U-230		
019762 002	TESTOSTERONE ; TESTODERM	5880136	SEP 27, 2010	U-254		
020646 005	TIAGABINE HYDROCHLORIDE; GABITRIL	5292756	MAY 14, 2012	U-230		
020912 001	TIROFIBAN HYDROCHLORIDE; AGGRASTAT	5880136	SEP 27, 2010	U-254	I-266	JUL 23, 2002
020913 001	TIROFIBAN HYDROCHLORIDE; AGGRASTAT	5880136	SEP 27, 2010	I-266	JUL 23, 2002	
020505 001	TOPIRAMATE; TOPAMAX	5880136	SEP 27, 2010	I-266	JUL 23, 2002	
020505 002	TOPIRAMATE; TOPAMAX	5880136	SEP 27, 2010	I-266	JUL 23, 2002	
020505 003	TOPIRAMATE; TOPAMAX	5880136	SEP 27, 2010	I-266	JUL 23, 2002	

PRESCRIPTION AND OTC DRUG PRODUCT

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PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020505 004	TOPIRAMATE ; TOPAMAX			I-266	JUL 23,	2002	
020505 005	TOPIRAMATE ; TOPAMAX			I-266	JUL 23,	2002	
020505 006	TOPIRAMATE ; TOPAMAX			I-266	JUL 23,	2002	
020844 001	TOPIRAMATE ; TOPAMAX SPRINKLE			I-266	JUL 23,	2002	
020844 002	TOPIRAMATE ; TOPAMAX SPRINKLE			I-266	JUL 23,	2002	
020844 003	TOPIRAMATE ; TOPAMAX SPRINKLE			I-266	JUL 23,	2002	
020671 001	TOPOTECAN HYDROCHLORIDE ; HYCAMTIN			I-256	NOV 30,	2001	
020759 001	TROVAFLOXACIN MESYLATE ; TROVAN						
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020759 002	TROVAFLOXACIN MESYLATE ; TROVAN						
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020900 001	UREA, C-13 ; PYLORI - CHEK BREATH TEST			NCE	SEP 17,	2001	
020699 001	VENLAFAXINE HYDROCHLORIDE ; EFFEXOR XR				I-251	MAR 11,	2002
020699 002	VENLAFAXINE HYDROCHLORIDE ; EFFEXOR XR				I-251	MAR 11,	2002
020699 003	VENLAFAXINE HYDROCHLORIDE ; EFFEXOR XR				I-251	MAR 11,	2002
020699 004	VENLAFAXINE HYDROCHLORIDE ; EFFEXOR XR				I-251	MAR 11,	2002
019614 004	VERAPAMIL HYDROCHLORIDE ; VERELAN PM						
020943 001	VERAPAMIL HYDROCHLORIDE ; VERELAN PM						
020943 002	VERAPAMIL HYDROCHLORIDE ; VERELAN PM						
020943 003	VERAPAMIL HYDROCHLORIDE ; VERELAN PM						
020547 001	ZAFIRLUKAST ; ACCOLATE						
020859 001	ZALEPLON ; SONATA						
020859 002	ZALEPLON ; SONATA						
021036 001	ZANAMIVIR ; RELENZA						
>ADD>							
020547 001	ZALEPLON ; SONATA						
020859 001	ZALEPLON ; SONATA						
020859 002	ZALEPLON ; SONATA						
021036 001	ZANAMIVIR ; RELENZA						