

APPROVED DRUG PRODUCTS

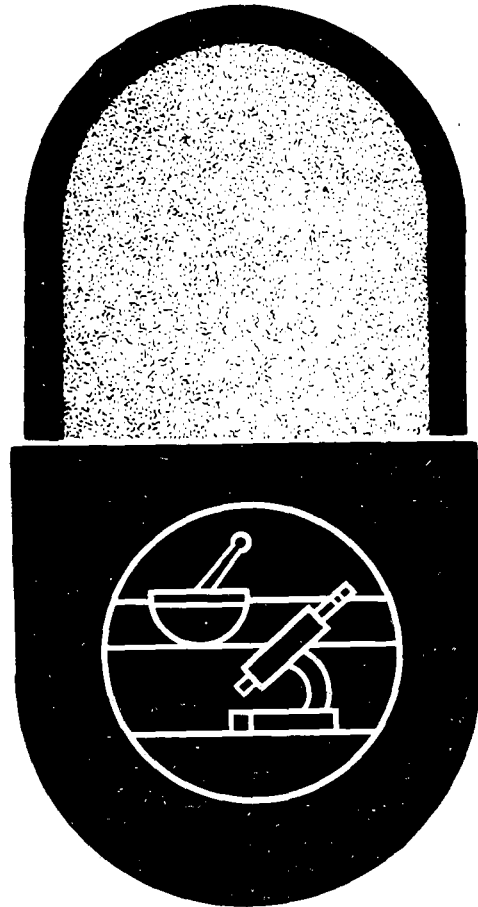
With Therapeutic Equivalence Evaluations



The "Orange Book"

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**CUMULATIVE
SUPPLEMENT 12
JAN'90-DEC'90**



APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

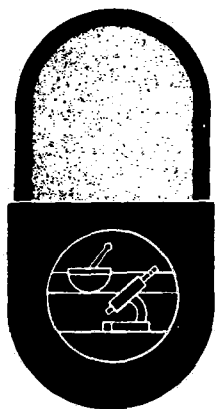
10TH EDITION

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION**

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APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**11th EDITION
1991**

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AMPHETAMINE RESIN COMPLEX; DEXTROAMPHETAMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

BIPHETAMINE 12.5

/PENWALT/

/EQ/6.25MG/BASE/

/EQ/6.25MG/BASE/

/N10093/001/

BIPHETAMINE 20

FISONS

EQ 10MG BASE;

EQ 10MG BASE

N10093 003

/PENWALT/

/EQ/10MG/BASE/

/EQ/10MG/BASE/

/N10093/003/

BIPHETAMINE 7.5

FISONS

EQ 3.75MG BASE;

EQ 3.75MG BASE

N10093 009

/PENWALT/

/EQ/3.75MG/BASE/

/EQ/3.75MG/BASE/

/N10093/009/

ANTAZOLINE PHOSPHATE; NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

VASOCON-A

IOLAB PHARMS

0.5%;0.05%

N18746 001

APR 30, 1990

ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL

FIORINAL M/CODEINE NO 3

SANDOZ

325MG;50MG;40MG;30MG

N19429 003

OCT 26, 1990

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

/ORPHENADRINE/COMPOUND/

/BX/ /VITARINE/

/305MG;30MG;25MG/

/N71564/001/

/JUN/23,/1988/

Q VITARINE

385MG;30MG;25MG

N71564 001

JUN 23, 1988

/ORPHENADRINE/COMPOUND/DOUBLE/STRENGTH/

/BX/ /VITARINE/

/770MG;60MG;50MG/

/N71565/001/

/JUN/23,/1988/

Q VITARINE

770MG;60MG;50MG

N71565 001

JUN 23, 1988

ASPIRIN; MEPROBAMATE

TABLET; ORAL

/MEPRO-ASPIRIN/

/AB/ /VITARINE/

/325MG;200MG/

/N89127/001/

/MAR/02,/1987/

Q VITARINE

325MG;200MG

N89127 001

MAR 02, 1987

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

TABLET; ORAL

OXYCODONE AND ASPIRIN

AA BARR LABS

325MG;4.5MG;0.38MG

N87794 001

MAY 26, 1982

/OXYCODONE W/ ASPIRIN/

/AA/ /BARR/LABS/

/325MG;4.5MG;0.38MG/

/N87794/001/

/MAY/26,/1982/

ATENOLOL

TABLET; ORAL

TENORMIN

ICI PHARM

25MG

N18240 004

APR 09, 1990

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL

ATENOLOL AND CHLORTHALIDONE

AB ICI PHARMS

50MG;25MG

N72301 001

MAY 31, 1990

AB

100MG;25MG

N72302 001

MAY 31, 1990

TENORETIC 100

AB STUART PHARMS

100MG;25MG

N18760 001

JUN 08, 1984

TENORETIC 50

AB STUART PHARMS

50MG;25MG

N18760 002

JUN 08, 1984

ATROPINE SULFATE

AEROSOL, METERED; INHALATION

ATROPINE SULFATE

DEPT ARMY

EQ 0.36MG BASE/INH

N20056 001

SEP 19, 1990

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

AA	MYLAN PHARMS	0.025MG;2.5MG	N85762 001
/AA/	/PARKE/DAVIS/	/0.025MG;2.5MG/	/N87131/001/
	3 PARKE DAVIS	0.025MG;2.5MG	N87131 001
/AA/	/DIPHENOXYLATE HCL W/ ATROPINE SULFATE/		
/AA/	/MYLAN/PHARMS/	/0.025MG;2.5MG/	/N85762/001/

ATROPINE SULFATE; MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

ATROPINE AND DEMEROL

/AP/	/STERLING/DRUG/	/0.4MG/ML;50MG/ML/	/N87853/001/
/AP/		/0.4MG/ML;75MG/ML/	/NOV/26,/1982/
/AP/		/0.4MG/ML;100MG/ML/	/N87847/001/
			/NOV/26,/1982/
	STERLING DRUG	0.4MG/ML;50MG/ML	N87853 001
		0.4MG/ML;75MG/ML	NOV 26, 1982
		0.4MG/ML;100MG/ML	N87847 001
			NOV 26, 1982
			N87848 001
			NOV 26, 1982

MEPERIDINE AND ATROPINE SULFATE

/AP/	/WYETH/AYERST/LABS/	/0.4MG/ML;50MG/ML/	/N85121/001/
/AP/		/0.4MG/ML;75MG/ML/	/N85121/002/
/AP/		/0.4MG/ML;100MG/ML/	/N85121/003/
	3 WYETH AYERST LABS	0.4MG/ML;50MG/ML	N85121 001
	3	0.4MG/ML;75MG/ML	N85121 002
	3	0.4MG/ML;100MG/ML	N85121 003

BACLOFEN

TABLET; ORAL

BACLOFEN

/BX/	/VITARINE/	/10MG/	/N71901/001/
/BX/		/20MG/	/APR/13,/1988/
	3 VITARINE	10MG	N71901 001
			APR 13, 1988
	3	20MG	N71902 001
			APR 13, 1988

> ADD > LTORRESAL
 > ADD > AB GEIGY PHARMS 20MG
 > ADD >

BACLOFEN

TABLET; ORAL

> DLT >	/LTORRESAL DS/		/N17851/003/
> DLT >	/AB/ /GEIGY/PHARMS/	/20MG/	/JAN/20,/1982/
> DLT >			

> ADD > BEPRIDIL HYDROCHLORIDE

> ADD > TABLET; ORAL

> ADD >	<u>BEPADIN</u>		
> ADD >	AB WALLACE	200MG	N19001 001
> ADD >			DEC 28, 1990
> ADD >	AB	300MG	N19001 002
> ADD >			DEC 28, 1990
> ADD >	AB	400MG	N19001 003
> ADD >			DEC 28, 1990
> ADD >	<u>VASCOR</u>		
> ADD >	AB RW JOHNSON	200MG	N19002 001
> ADD >			DEC 28, 1990
> ADD >	AB	300MG	N19002 002
> ADD >			DEC 28, 1990
> ADD >	AB	400MG	N19002 003
> ADD >			DEC 28, 1990

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

BETAMETHASONE DIPROPIONATE

AB	CLAY PARK LABS	EQ 0.05% BASE	N72536 001
			JAN 31, 1990

LOTION; TOPICAL

BETAMETHASONE DIPROPIONATE

AB	CLAY PARK LABS	EQ 0.05% BASE	N72538 001
			JAN 31, 1990

OINTMENT; TOPICAL

BETAMETHASONE DIPROPIONATE

AB	CLAY PARK LABS	EQ 0.05% BASE	N72526 001
			JAN 31, 1990

BROMPHENIRAMINE MALEATE

INJECTABLE; INJECTION

BROMPHENIRAMINE MALEATE

	/STERIS/LABS/	/100MG/ML/	/N83820/001/
	3 STERIS LABS	100MG/ML	N83820 001

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

AB	CORD LABS	3.75MG	N72512 001
			MAY 11, 1990
AB		7.5MG	N72513 001
			MAY 11, 1990
AB		15MG	N72514 001
			MAY 11, 1990

CLOTTRIMAZOLE

CREAM; VAGINAL

/AT/	/GYNÉ-LOTRIMIN/	/12/	/N18852/001/
	/SCHERING/		
/AT/	MYCELEX-G	/12/	/N18230/001/
	/MILES/PHARM/		
	MILES PHARM	1%	N18230 001

TABLET; VAGINAL

/AT/	/GYNÉ-LOTRIMIN/	/100MG/	/N17717/001/
	/SCHERING/		
/AT/	MYCELEX-G	/100MG/	/N18182/001/
	/MILES/PHARM/		
	MILES PHARM	100MG	N18182 001

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE;
TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

/AA/	/PSEUDOEPHEDRINE 'C/	/10MG/5ML; 30MG/5ML/	/N88833/001/
	/PBI/	/1.25MG/5ML/	/NOV 16, 1984/

TRIPROLIDINE HCL, PSEUDOEPHEDRINE HCL AND CODEINE
PHOSPHATE

AA	PBI	10MG/5ML; 30MG/5ML;	N88833 001
		1.25MG/5ML	NOV 16, 1984

CYANOCOBALAMIN; TANNIC ACID; ZINC ACETATE

/INJECTABLE;/INJECTION/

/DEPINAR/

/ARMOUR/PHARM/

a ARMOUR PHARM

/0.5MG/ML; 2.5MG/ML;/

/1MG/ML/

0.5MG/ML; 2.3MG/ML;

1MG/ML

/N11208/001/

N11208 001

CYCLOSPORINE

CAPSULE; ORAL

SANDIMMUNE

SANDOZ PHARMS

25MG

N50625 001

MAR 02, 1990

N50625 002

MAR 02, 1990

100MG

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL

CYPROHEPTADINE HCL

/AA/

/KV/PHARM/

a KV PHARM

/4MG/

4MG

/N86737/001/

N86737 001

> DLT >

/AA/

/SUPERPHARM/

/4MG/

4MG

/N87405/001/

N87405 001

> ADD >

a SUPERPHARM

CYTARABINE

INJECTABLE; INJECTION

CYTARABINE

BULL LABS

20MG/ML

N71868 001

JUN 04, 1990

N72168 001

AUG 31, 1990

20MG/ML

> ADD >

DAPIPAZOLE HYDROCHLORIDE

> ADD >

SOLUTION/DROPS; OPHTHALMIC

> ADD >

REV-EYES

> ADD >

ANGELINI PHARMS

0.5%

N19849 001

DEC 31, 1990

> ADD >

> DLT > /COLFOSCERIL/PALMITATE/

> DLT > /POWDER/FOR/RECONSTITUTION;/INTRATRACHEAL/

> DLT > /EXOSURF/NEONATAL/

> DLT > /BURROUGHS/HELLC/ /100MG/VIAL/

> DLT > /N28844/001/

/AUG 02, 1990/

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL		
DESIPRAMINE HCL		
/BX/	/VITARINE/	/10MG/
		/N72167/001/
		/FEB/03/1988/
/BX/		/25MG/
		/N71601/001/
		/JUN/05/1987/
/BX/		/50MG/
		/N71588/001/
		/JUN/05/1987/
/BX/		/75MG/
		/N71602/001/
		/OCT/05/1987/
/BX/		/100MG/
		/N71766/001/
		/OCT/05/1987/
/BX/		/150MG/
		/N72254/001/
		/FEB/03/1988/
Q	VITARINE	10MG
		N72167 001
Q		FEB 03, 1988
Q		N71601 001
		JUN 05, 1987
Q		N71588 001
		JUN 05, 1987
Q		N71602 001
		OCT 05, 1987
Q		N71766 001
		OCT 05, 1987
Q		N72254 001
		FEB 03, 1988

DESMOPRESSIN ACETATE

SOLUTION; NASAL		
CONCENTRAID		
> ADD >	FERRING LABS	0.01% N19776 001 DEC 26, 1990
> ADD >		
> ADD >		

DESOXIMETASONE

CREAM; TOPICAL		
<u>DESOXIMETASONE</u>		
AB	TARO PHARMS	0.05% N73210 001 NOV 30, 1990
AB		0.25% N73193 001 NOV 30, 1990
<u>TOPICORT</u>		
AB	HOECHST	0.25% N17856 001
<u>TOPICORT LP</u>		
AB	HOECHST	0.05% N18309 001

DEXAMETHASONE

TABLET; ORAL		
DEXAMETHASONE		
Q	BARR LABS	0.5MG N84766 001

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION		
<u>DEXAMETHASONE SODIUM PHOSPHATE</u>		
/AP/	/INTL/MEDTN/SYS/	/EQ 20MG PHOSPHATE/ML/
		/N88522/001/
		/FEB/17/1984/
Q	INTL MEDTN SYS	EQ 20MG PHOSPHATE/ML N88522 001 FEB 17, 1984
AP	KENDALL MCGAW	EQ 4MG PHOSPHATE/ML N81125 001 AUG 31, 1990
AP		EQ 10MG PHOSPHATE/ML N81126 001 AUG 31, 1990

OPHTHALMIC

MAXIDEX		
AT	ALCON LABS	EQ 0.05% PHOSPHATE N83342 001
/OINTMENT;/OPHTHALMIC;/OTIC/		
/MAXIDEX/		
/At/	/ALCON/LABS/	/EQ 0.05% PHOSPHATE/
		/N83342/001/
/SOLUTION/DROPS;/OPHTHALMIC/		
/DEXAMETHASONE SODIUM PHOSPHATE/		
/At/	/STERIS/LABS/	/EQ 0.1% PHOSPHATE/
		/N88771/001/
		/JAN/16/1985/

SOLUTION/DROPS; OPHTHALMIC, OTIC

<u>DEXAMETHASONE SODIUM PHOSPHATE</u>		
AT	STERIS LABS	EQ 0.1% PHOSPHATE N88771 001 JAN 16, 1985

DEXTROAMPHETAMINE SULFATE

> DLT >	/CAPSULE;/ORAL/	
> DLT >	/DEXAMPEX/	
> DLT >	/LEMMON/	/15MG/
> ADD >	Q LEMMON	15MG N85355 001

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC

CONTAINER

KENDALL MCGAW

3.3GM/100ML;
300MG/100MLMN19631 016
JAN 19, 1990DEZOCINE

INJECTABLE; INJECTION

DALGAN

ASTRA PHARM

5MG/ML

N19082 001
DEC 29, 1989

10MG/ML

N19082 002

DEC 29, 1989

15MG/ML

N19082 003

DEC 29, 1989

/WETH/ATERST/LABS/

/5MG/ML/

/N19082/001/

/DEC/29/1989/

/10MG/ML/

/N19082/002/

/DEC/29/1989/

/15MG/ML/

/N19082/003/

/DEC/29/1989/

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

/HYPAQUE-M/

/STERLING/DRUG/

/2/

/50%;25%/

/60%;30%/

/N10220/001/

/N10220/002/

HYPAQUE-M, 75%

STERLING DRUG

50%;25%

N10220 003

HYPAQUE-M, 90%

STERLING DRUG

60%;30%

N10220 002

DIAZEPAM

INJECTABLE; INJECTION

DIAZEPAM

a DEPT ARMY

5MG/MLM

N20124 001
DEC 05, 1990

> ADD >

> ADD >

TABLET; ORAL

DIAZEPAM

/BX/ /SUPERPHARM/

/10MG/

/N70644/001/

/DEC/11/1985/

a SUPERPHARM

10MG

N70644 001

DEC 11, 1985

DICLOXACILLIN SODIUM

POWDER FOR RECONSTITUTION; ORAL

DYNAPEN

/AA/ /BRISTOL/LABS/

/EQ 62.5MG BASE/5ML/

/N50337/002/

a BRISTOL LABS

EQ 62.5MG BASE/5ML

N50337 002

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

> DLT >/AA/

/LEMMON/

/25MG/

/N88642/001/

> DLT >

/SEP/20/1984/

> ADD >

a LEMMON

25MG

N88642 001

> ADD >

SEP 20, 1984

TENUATE

/AA/

/MERRELL/DOW/PHARMS/

/25MG/

/N17668/001/

a MERRELL DOW PHARMS

25MG

N17668 001

TABLET, EXTENDED RELEASE; ORAL

TENUATE

/BC/

/MERRELL/DOW/PHARMS/

/75MG/

/N17669/001/

a MERRELL DOW PHARMS

75MG

N17669 001

DIGOXIN

INJECTABLE; INJECTION

DIGOXIN

/AP/

/LYPHOMED/

/0.25MG/ML/

/N83217/001/

a LYPHOMED

0.25MG/ML

N83217 001

DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE

/INJECTABLE; INJECTION/

/EMBOLEX/

/SANDOZ/PHARMS/

/0.5MG/0.7ML; 5,000 UNITS/0.7ML/

/7.46MG/0.7ML/

/N18885/002/

/NOV/30/1984/

a SANDOZ PHARMS

0.5MG/0.7ML; 5,000 UNITS/0.7ML;

7.46MG/0.7ML

N18885 002

NOV 30, 1984

DIMENHYDRINATE

TABLET; ORAL

DIMENHYDRINATE

/AA/

/ANABOLIC/

/50MG/

/N85985/001/

a ANABOLIC

50MG

N85985 001

DIMENHYDRINATE

TABLET; ORAL

> DLT > /AA/ /CHELSEA LABS/ /50MG/ /N85166/002/
 > ADD > CHELSEA LABS 50MG N85166 002

DINOPROST TROMETHAMINE

/INJECTABLE; INJECTION/
 /PROSTIN/F2/ALPHA/
 @ UPJOHN

/EQ 5MG BASE/ML/ /N17434/001/
 EQ 5MG BASE/ML N17434 001

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

/AA/ /ANABOLIC/ /25MG/ /N83634/001/
 @ ANABOLIC 25MG N83634 001
 /AA/ /HEATHER DRUG/ /25MG/ /N84524/001/
 /AA/ 25MG N84524 001
 @ HEATHER DRUG 50MG N83953 001
 @ 50MG N83953 001
 > DLT > /AA/ /SUPERPHARM/ /50MG/ /N89041/001/
 > DLT > MAY 15, 1985
 > ADD > @ SUPERPHARM 50MG N89041 001
 > ADD > MAY 15, 1985

DIPYRIDAMOLE

> ADD > INJECTABLE; INJECTION
 > ADD > IV PERSANTINE
 > ADD > BOEHR INGEL 5MG/ML
 > ADD > N19817 001
 DEC 13, 1990

TABLET; ORAL

DIPYRIDAMOLE

AB BARR LABS 25MG N87184 001
 OCT 03, 1990
 AB 50MG N87716 001
 OCT 03, 1990
 AB 75MG N87717 001
 OCT 03, 1990
 AB PUREPAC PHARM 25MG N89425 001
 JUL 12, 1990
 AB 50MG N89426 001
 JUL 12, 1990
 AB 75MG N89427 001
 JUL 12, 1990

DIPYRIDAMOLE

TABLET; ORAL

PERSANTINE

AB BOEHR INGEL 25MG N12836 003
 DEC 22, 1986
 AB 50MG N12836 004
 FEB 06, 1987
 AB 75MG N12836 005
 FEB 06, 1987

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL

DISOPYRAMIDE PHOSPHATE

/AB/ /CHELSEA LABS/ /EQ 100MG BASE/ /N71020/001/
 /AB/ /EQ 150MG BASE/ /N71021/001/
 BX CHELSEA LABS EQ 100MG BASE N71020 001
 BX EQ 150MG BASE N71021 001
 /AB/ /SUPERPHARM/ /EQ 150MG BASE/ /N70941/001/
 @ SUPERPHARM EQ 150MG BASE N70941 001
 FEB 09, 1987

DIVALPROEX SODIUM

TABLET, DELAYED RELEASE; ORAL

DEPAKOTE CP

ABBOTT LABS

EQ 250MG BASEM N19794 001
 JUL 11, 1990
 EQ 500MG BASEM N19794 002
 JUL 11, 1990

DOXAZOSIN MESYLATE

TABLET; ORAL

CARDURA

PFIZER

EQ 1MG BASEM N19668 001
 NOV 02, 1990
 EQ 2MG BASEM N19668 002
 NOV 02, 1990
 EQ 4MG BASEM N19668 003
 NOV 02, 1990
 EQ 8MG BASEM N19668 004
 NOV 02, 1990

DOXEPIH HYDROCHLORIDE

CAPSULE; ORAL

ADAPIN

AB FISONS

AB

AB

AB

AB

AB

EQ 10MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 75MG BASE

EQ 100MG BASE

EQ 150MG BASE

N16987 001

N16987 002

N16987 003

N16987 006

N16987 004

N16987 007

APR 13, 1987

/AB/

/PENWALT/

/EQ 10MG BASE/

/EQ 25MG BASE/

/EQ 50MG BASE/

/EQ 75MG BASE/

/EQ 100MG BASE/

/EQ 150MG BASE/

/N16987/001/

/N16987/002/

/N16987/003/

/N16987/006/

/N16987/004/

/N16987/007/

/APR 13, 1987/

DOXEPIH HCL

PUREPAC PHARM

> ADD > AB

EQ 10MG BASEM

N73054 001

> ADD > AB

EQ 25MG BASEM

DEC 28, 1990

> ADD > AB

EQ 50MG BASEM

N72109 001

> ADD > AB

EQ 100MG BASEM

DEC 28, 1990

> ADD > AB

EQ 150MG BASEM

N73055 001

> ADD > AB

EQ 200MG BASEM

DEC 28, 1990

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

DOXORUBICIN HCL

AP PHARMACHEMIE BV

AP

10MG/VIALM

N63097 001

AP

20MG/VIALM

MAY 21, 1990

AP

50MG/VIALM

N63097 002

AP

EQ 100MG BASEM

MAY 21, 1990

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

/BX/ /VITARINE/

/BX/

/EQ 50MG BASE/

/EQ 100MG BASE/

a VITARINE

EQ 50MG BASE

a

EQ 100MG BASE

/N62227/001/

/APR 12, 1988/

/N62227/001/

N62780 001

APR 12, 1988

N62227 001

DOXYCYCLINE HYCLATE

INJECTABLE; INJECTION

VIBRAMYCIN

AP PFIZER LABS

AP

EQ 100MG BASE/VIAL

EQ 200MG BASE/VIAL

/EQ 100MG BASE/VIAL/

/EQ 200MG BASE/VIAL/

N50442 002

N50442 001

/N50442/002/

/N50442/001/

DYDROGESTERONE

TABLET; ORAL

GYNOREST

/a/ KALI/DUPHAR/

/a/

a REID ROWELL

a

/5MG/

/10MG/

5MG

10MG

/N17388/001/

/N17388/002/

N17388 001

N17388 002

EFLORNITHINE HYDROCHLORIDE

INJECTABLE; INJECTION

ORNIDYL

MERRELL DOW PHARMS

200MG/MLM

N19879 002

NOV 28, 1990

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL AND EPINEPHRINE

AP ELKINS SINN

AP

0.01MG/ML;1%

0.01MG/ML;2%

N80406 001

N80406 002

/LIDOCAINE HCL W/ EPINEPHRINE/

/AP/ /ELKINS/SINN/

/AP/

/0.01MG/ML;12/

/0.01MG/ML;22/

/N88486/001/

/N88486/002/

ERGOLOID MESYLATES

TABLET; ORAL

GERIMAL

/AB/ /CHELSEA/LABS/

/AB/

/1MG/

a CHELSEA LABS

1MG

/N88287/001/

/MAR 22, 1984/

N88207 001

MAR 22, 1984

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

ERGOLOID MESYLATES

/AA/ /SUPERPHARM/ /0.5MG/

/AA/ /1MG/

a SUPERPHARM 0.5MG

a 1MG

/N6233/001/

/SEP/23/1986/

/N6234/001/

/SEP/23/1986/

N89233 001

SEP 23, 1986

N89234 001

SEP 23, 1986

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL

ERYC

AB FAULding 250MG

N50536 001

SOLUTION; TOPICAL

ERYTHROMYCIN

/At/ /BARRE/NATL/ /22/

/At/ /22/

a BARRE NATL 2%

a 2%

/N6237/001/

/APR/19/1982/

/N6234/001/

/FEB/25/1982/

N62327 001

APR 19, 1982

N62342 001

FEB 25, 1982

/N6252/001/

/JAN/24/1985/

N62522 001

JAN 24, 1985

> DLT > /SANSAC/

> DLT > /At/ /OWEN/LABS/ /22/

> DLT > /22/

> ADD > SANSACHE

> ADD > AT OWEN GALDERMA 2%

> ADD > /22/

TABLET, DELAYED RELEASE; ORAL

E-BASE

AB BARR LABS 333MG

N63028 001

MAY 15, 1990

AB 333MG

N63086 001

MAY 15, 1990

E-MYCIN

AB BOOTS USA 250MG

N60272 001

AB 333MG

N60272 002

/AB/ /UPJOHN/ /250MG/

/N60272/001/

/AB/ /333MG/

/N60272/002/

ERYTHROMYCIN ESTOLATE

SUSPENSION; ORAL

ERYTHROMYCIN ESTOLATE

AB BARR LABS EQ 125MG BASE/5ML

N62169 001

OCT 17, 1990

AB EQ 250MG BASE/5ML

N62169 002

OCT 17, 1990

ERYTHROMYCIN ETHYLSUCCINATE; SULFISOXAZOLE ACETYL

GRANULE; ORAL

ERYTHROMYCIN ETHYLSUCCINATE AND SULFISOXAZOLE ACETYL

AB BARR LABS EQ 200MG BASE/5ML;

N62759 001

EQ 600MG BASE/5ML

MAY 20, 1988

ERYTHROMYCIN STEARATE

TABLET; ORAL

ERYTHROMYCIN STEARATE

AB BARR LABS EQ 500MG BASE

N63179 001

MAY 15, 1990

> ADD > ESTAZOLAM

> ADD > TABLET; ORAL

> ADD > PROSOM

> ADD > ABBOTT LABS 1MG

N19080 001

> ADD > 2MG

DEC 26, 1990

> ADD > 2MG

N19080 002

> ADD > 2MG

DEC 26, 1990

ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION

DITATE-DS

/Ad/ /SAVAGE/LABS/ /8MG/ML;180MG/ML/ /N66423/001/

SAVAGE LABS 8MG/ML;180MG/ML

N86423 001

TESTOSTERONE ENANTHATE AND ESTRADIOL VALERATE

AO STERIS LABS 4MG/ML;90MG/ML

N85865 001

a 8MG/ML;180MG/ML

N85860 001

/Ad/ /TESTOSTERONE ENANTHATE-ESTRADIOL VALERATE/ /N65865/001/

/Ad/ /STERIS/LABS/ /4MG/ML;90MG/ML/ /N65860/001/

/Ad/ /8MG/ML;180MG/ML/ /N65860/001/

GUANFACINE HYDROCHLORIDETABLET; ORAL
TENEX

> DLT > /AH/ROBINS/ /3MG/ /N19032/003/
 > DLT > /NOV/07/1988/
 > ADD > @ AH ROBINS 3MG N19032 003
 > ADD > NOV 07, 1988

HALCINONIDE

CREAM; TOPICAL

HALOG

/AT/ /SQUIBB/ /0.1%/ /N17556/001/
 /0.025%/ /N17818/001/
 WESTWOOD PHARMS 0.025% N17818 001
 0.1% N17556 001

HALOG-E

/AT/ /SQUIBB/ /0.1%/ /N18234/001/
 WESTWOOD PHARMS 0.1% N18234 001

OINTMENT; TOPICAL

HALOG

/SQUIBB/ /0.1%/ /N17824/001/
 WESTWOOD PHARMS 0.1% N17824 001

SOLUTION; TOPICAL

HALOG

/SQUIBB/ /0.1%/ /N17823/001/
 WESTWOOD PHARMS 0.1% N17823 001

> ADD > HALOBETASOL PROPIONATE

> ADD > CREAM; TOPICAL

> ADD > ULTRAVATE

> ADD > BRISTOL MEYERS 0.05% N19967 001
 > ADD > DEC 27, 1990

> ADD > OINTMENT; TOPICAL

> ADD > ULTRAVATE

> ADD > BRISTOL MEYERS 0.05% N19968 001
 > ADD > DEC 17, 1990

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH

/AP/ /LYPHOMED/ /100 UNITS/ML/ /N17651/010/
 @ LYPHOMED 100 UNITS/ML N17651 010

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH

/AP/ /SOLOPAK/LABS/ /10 UNITS/ML/ /N87958/001/
 @ SOLOPAK LABS 10 UNITS/ML N87958 001
 APR 20, 1983

HEPARIN SODIUM

/AP/ /CHAMBERLIN/ /1,000 UNITS/ML/ /N17130/001/
 /5,000 UNITS/ML/ /N17130/002/
 /10,000 UNITS/ML/ /N17130/003/
 /20,000 UNITS/ML/ /N17130/004/

@ CHAMBERLIN

@ 1,000 UNITS/ML N17130 001
 @ 5,000 UNITS/ML N17130 002
 @ 10,000 UNITS/ML N17130 003
 @ 20,000 UNITS/ML N17130 004

/AP/ /LYPHOMED/ /1,000 UNITS/ML/ /N17033/001/
 /5,000 UNITS/ML/ /N17651/005/
 /10,000 UNITS/ML/ /N17651/003/
 /20,000 UNITS/ML/ /N17651/008/

@ LYPHOMED

@ 1,000 UNITS/ML N17033 001
 @ 5,000 UNITS/ML N17651 005
 @ 10,000 UNITS/ML N17651 003
 @ 20,000 UNITS/ML N17651 008

/MYETH/AYERST/LABS/ /15,000 UNITS/ML/ /N17007/005/
 @ MYETH AYERST LABS 15,000 UNITS/ML N17007 005

> DLT > /HEPARIN/SODIUM/10,000 UNITS/IN/DEXTROSE/5% IN/PLASTIC/
 > DLT > /CONTAINER/
 > DLT > /BAXTER/ /2,000 UNITS/100ML/ /N18814/002/
 > DLT > JUL 09, 1985

> ADD > @ BAXTER 2,000 UNITS/100ML N18814 002
 > ADD > JUL 09, 1985

HOMATROPINE METHYLBROMIDE

/TABLET;/CHEWABLE;/ORAL/

/EQUIPIN/

/MISSION/PHARMA/ /3MG/ /N86310/001/
 @ MISSION PHARMA 3MG N86310 001

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

/AA/	/SUPERPHARM/	/10MG/	/N88787/001/
			/AUG/28./1984/
/AA/		/25MG/	/N88788/001/
			/AUG/28./1984/
/AA/		/50MG/	/N88789/001/
			/AUG/28./1984/
	Q SUPERPHARM	10MG	N88787 001
			AUG 28, 1984
	Q	25MG	N88788 001
			AUG 28, 1984
	Q	50MG	N88789 001
			AUG 28, 1984

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

/AB/	/SUPERPHARM/	/25MG;25MG/	/N89200/001/
			/FEB/09./1987/
	Q SUPERPHARM	25MG;25MG	N89200 001
			FEB 09, 1987
> DLT >	/HYDRALAZINE HCL W/ HYDROCHLOROTHIAZIDE 100/50/		
> DLT >/AB/	/ZENITH/LABS/	/100MG;50MG/	/N88358/001/
> DLT >			/APR/10./1984/
> ADD >	Q ZENITH LABS	100MG;50MG	N88358 001
> ADD >			APR 10, 1984

TABLET; ORAL

HYDRALAZINE AND HYDROCHLOROTHIAZIDE

/BP/	/CHELSEA/LABS/	/25MG;15MG/	/N85827/001/
	Q CHELSEA LABS	25MG;15MG	N85827 001

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

UNIPRES

/BP/	/REID/ROWELL/	/25MG;15MG;0.1MG/	/N85893/001/
	Q REID ROWELL	25MG;15MG;0.1MG	N85893 001

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

/AB/	/REID/ROWELL/	/25MG/	/N85323/001/
	Q REID ROWELL	25MG	N85323 001

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

> DLT >/AB/	/ROXANE/LABS/	/25MG/	/N85004/001/
> DLT >/AB/		/50MG/	/N85005/001/
> ADD >	Q ROXANE LABS	25MG	N85004 001
> ADD >	Q	50MG	N85005 001

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL

PRINZIDE 12.5

AB	MS&D RES LABS	12.5MG;20MG	N19778 001
			FEB 16, 1989

ZESTORETIC 20/12.5

AB	IMPERIAL CHEM	12.5MG;20MG	N19888 001
			SEP 20, 1990

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

DYAZIDE

/AB/	/SK&F/LABS/	/25MG;50MG/	/N16042/002/
	SK&F LABS	25MG;50MG	N16042 002
/BX/	/TRIAMTERENE/AND/HYDROCHLOROTHIAZIDE/		
	/BOLAR/PHARM/	/25MG;50MG/	/N71845/001/
			/AUG/21./1987/

TABLET; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

/BX/	/VITARINE/	/50MG;75MG/	/N71360/001/
	Q VITARINE	50MG;75MG	/DEC/08./1987/
			N71360 001
			DEC 08, 1987

HYDROCODONE BITARTRATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

HYCOMINE

DUPONT

5MG/5ML;25MG/5ML	N19410 001
	AUG 17, 1990

HYCOMINE PEDIATRIC

DUPONT

2.5MG/5ML;12.5MG/5ML	N19411 001
	AUG 17, 1990

HYDROCORTISONECREAM; TOPICAL
HYDROCORTISONE

/At/	/PBI/	/1%/ /SEP/27/1983/	/N88027/001/ /SEP/27/1983/
/At/		/2.5%/ /SEP/27/1983/	/N88029/001/ /SEP/27/1983/
	a PBI	1%	N88027 001
	a	2.5%	SEP 27, 1983
			N88029 001
			SEP 27, 1983
/At/	/HYDROTEX/ /SYOSSET/LABS/	/1%/ /APR/04/1988/	/N87427/001/ /APR/04/1988/
At	<u>NOGENIC HC</u> SYOSSET LABS	1%	N87427 001
			APR 04, 1988

LOTION; TOPICAL
HYDROCORTISONE

> DLT >	/At/	/BARRE/NATL/	/0.5%/ /JUN/07/1982/	/N87317/001/ /JUN/07/1982/
> DLT >			/1%/ /JUN/07/1982/	/N87315/001/ /JUN/07/1982/
> DLT >	/At/			
> DLT >				
> ADD >	a	BARRE NATL	0.5%	N87317 001
> ADD >				JUN 07, 1982
> ADD >	a		1%	N87315 001
> ADD >				JUN 07, 1982

OINTMENT; TOPICAL
HYDROCORTISONE

/At/	/PBI/	/1%/ /SEP/27/1983/	/N88061/001/ /SEP/27/1983/
/At/		/2.5%/ /SEP/27/1983/	/N88039/001/ /SEP/27/1983/
	a PBI	1%	N88061 001
	a	2.5%	SEP 27, 1983
			N88039 001
			SEP 27, 1983

TABLET; ORAL

/BP/	/HYCORTOLE/ /VITARINE/	/20MG/ 20MG	/N80642/002/ N80642 002
/BP/	/ANABOLIC/ a ANABOLIC	/20MG/ 20MG	/N83140/001/ N83140 001

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION; OTIC

PEDIOTIC

At	BURROUGHS WELLC	1% EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62822 001 SEP 29, 1987
/At/	/PEDIOTIC CORTISPORIN/ /BURROUGHS WELLC/	/1% EQ 3.5MG BASE/ML/ /10,000 UNITS/ML/	/N62822/001/ /SEP/29/1987/

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HCL

/AP/	/SOLOPAK/LABS/	/25MG/ML/ 25MG/ML	/N87592/001/ N87592 001
	a SOLOPAK LABS		

IBUPROFEN

TABLET; ORAL

IBUPROFEN

/AB/	/MCNEIL/CONSUMER/	/400MG/ 400MG	/N70081/001/ JUN 16, 1986
/AB/		/600MG/ 600MG	/N70476/001/ JUN 16, 1986
	a MCNEIL CONSUMER		N70081 001
	a		N70476 001
			JUN 16, 1986
/AB/	/SUPERPHARM/	/400MG/ 400MG	/N70708/001/ APR 25, 1986
BX	SUPERPHARM		N70708 001
			APR 25, 1986

IDARUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

IDAMYCIN

	ADRIA LABS	5MG/VIALM	N50661 002 SEP 27, 1990
		10MG/VIALM	N50661 001 SEP 27, 1990

IFOSFAMIDE

INJECTABLE; INJECTION

IFEX

> ADD >	BRISTOL SQUIBB	3GM/VIAL	N19763 002
> ADD >			DEC 30, 1988
> DLT >	/2/BRISTOL/SQUIBB/	/3GM/VIAL/	/N19763/002/
> DLT >			/DEC/30,1988/

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HCL

AB	MUTUAL PHARM	10MG	N81048 001
			JUN 05, 1990
AB		25MG	N81049 001
			JUN 05, 1990
AB		50MG	N81050 001
			JUN 05, 1990

> DLT >	/PRESAMINE/		
> DLT >	/AB/	/10MG/	/N11836/006/
> DLT >	/RORER/PHARM/	/25MG/	/N11836/003/
> DLT >	/AB/	/50MG/	/N11836/007/
> ADD >	3 RHONE POULENC RORER	10MG	N11836 006
> ADD >	3	25MG	N11836 003
> ADD >	3	50MG	N11836 007

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

/BX/	/VITARINE/	/25MG/	/N71711/001/
			/JUL/05,1988/
/BX/		/50MG/	/N71712/001/
			/JUL/05,1988/
3	VITARINE	25MG	N71711 001
			JUL 05, 1988
3		50MG	N71712 001
			JUL 05, 1988
/AB/	/ZENITH/LABS/	/25MG/	/N18730/001/
			/MAY/04,1984/
/AB/		/50MG/	/N18730/002/
			/MAY/04,1984/
3	ZENITH LABS	25MG	N18730 001
			MAY 04, 1984
3		50MG	N18730 002
			MAY 04, 1984

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL

INDOMETHACIN

/BX/	/VITARINE/	/75MG/	/N71531/001/
			/JUL/21,1987/
3	VITARINE	75MG	N71531 001
			JUL 21, 1987

IODOHIPPURATE SODIUM, I-131

INJECTABLE; INJECTION

IODOHIPPURATE SODIUM I 131

CIS US	0.2MCI/ML	N17313 001
/SORIN/	/0.2MCI/ML/	/N17313/001/

IOTHALAMATE SODIUM

INJECTABLE; INJECTION

CONRAY 325

MALLINCKRODT	54.3%	N17685 001
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CONRAY 400

MALLINCKRODT	66.8%	N14295 001
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/CONRAY-325/

/MALLINCKRODT/	/54.3%/	/N17685/001/
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/CONRAY-400/

/MALLINCKRODT/	/66.8%/	/N14295/001/
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ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

ISOETHARINE HCL

AN	DEY LABS	0.08%	N88187 001
			DEC 03, 1982
		/0.08%/	/N88187/001/
			/DEC/03,1982/

AN INTL MEDTN SYS

	0.08%	N86651 002
	/0.0833%/	/N86651/002/

AN ISOETHARINE HCL S/F

DEY LABS	0.08%	N89817 001
		NOV 22, 1988
	/0.08%/	/N89817/001/
		/NOV/22,1988/

ISONIAZID

TABLET; ORAL

ISONIAZID

/AA/ /ANABOLIC/ /100MG/
 @ ANABOLIC 100MG
 /AA/ /PUREPAC/PHARM/ /50MG/
 /AA/ /100MG/
 @ PUREPAC PHARM 50MG
 @ 100MG

/N84050/001/
 N84050 001
 /N80132/003/
 /JUL/14,/1982/
 /N80132/004/
 /JUL/14,/1982/
 N80132 003
 JUL 14, 1982
 N80132 004
 JUL 14, 1982

ISOPROTERENOL HYDROCHLORIDE

INJECTABLE; INJECTION

ISOPROTERENOL HCL

/AP/ /LYPHOMED/ /0.2MG/ML/
 @ LYPHOMED 0.2MG/ML

/N83431/001/
 N83431 001

ISOSORBIDE DINITRATE

TABLET; ORAL

ISOSORBIDE DINITRATE

/AA/ /SUPERPHARM/ /5MG/
 /AA/ /10MG/
 /AA/ /20MG/
 @ SUPERPHARM 5MG
 @ 10MG
 @ 20MG

/N89190/001/
 /FEB/17,/1987/
 /N89191/001/
 /FEB/17,/1987/
 /N89192/001/
 /FEB/17,/1987/
 N89190 001
 FEB 17, 1987
 N89191 001
 FEB 17, 1987
 N89192 001
 FEB 17, 1987

> ADD > ISRADIPINE

> ADD > CAPSULE; ORAL
 > ADD > DYNACIRC
 > ADD > SANDOZ PHARMS 2.5MG
 > ADD > 5MG
 > ADD >

N19546 001
 DEC 20, 1990
 N19546 002
 DEC 20, 1990

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANAMYCIN SULFATE

/AP/ /WARNER/CHILCOTT/ /EQ 1GM BASE/3ML/
 @ WARNER CHILCOTT EQ 1GM BASE/3ML

/N63092/001/
 /OCT/11,/1989/
 N63092 001
 OCT 11, 1989

KETOCONAZOLE

SHAMPOO; TOPICAL

NIZORAL

JANSSEN RES

2/M

N19927 001
 AUG 31, 1990

LEUPROLIDE ACETATE

INJECTABLE; INJECTION

LUPRON/DEPOT/

/TAKEDA/ABBOTT/

/7.5MG/VIAL/

/N19732/001/
 /JAN/26,/1989/

LUPRON DEPOT

TAP PHARMS

3.75MG/VIALM

7.5MG/VIAL

N20011 001
 OCT 22, 1990
 N19732 001
 JAN 26, 1989

LEVAMISOLE HYDROCHLORIDE

TABLET; ORAL

ERGAMISOL

JANSSEN RES

EQ 50MG BASEM

N20035 001
 JUN 18, 1990

> ADD > LEVONORGESTREL

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

IMPLANT; IMPLANTATION

LEVONORGESTREL SYSTEM

WYETH AYERST LABS

36MG/IMPLANTM

N20088 001
 DEC 10, 1990

NORPLANT

@ POPULATION COUNCIL

36MG/IMPLANTM

N19897 001
 DEC 10, 1990

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

/AA/ /LIDOCAINE HCL/ /1.5%/

/AP/ /ABBOTT/LABS/ /1.5%/

ABBOTT LABS 1.5%

/AA/ /LYPHOMED/ /1.5%/

/AP/ /1.5%/

/AP/ /2.5%/

LYPHOMED 1%

1.5%

2%

/N88330/001/

/MAY/17/1984/

N88330 001

MAY 17, 1984

/N88420/003/

/N88420/005/

/N88420/002/

N80420 003

N80420 005

N80420 002

LINDANE

LOTION; TOPICAL

/AA/ /GAMENE/

/AT/ /BARNES/HIND/ /1%/

BARNES HIND 1%

/N84989/001/

N84989 001

SHAMPOO; TOPICAL

/AA/ /GAMENE/

/AT/ /BARNES/HIND/ /1%/

BARNES HIND 1%

/N84988/001/

N84988 001

MANNITOL

INJECTABLE; INJECTION

> ADD > MANNITOL 15% IN PLASTIC CONTAINER

> ADD > AP ABBOTT LABS 15GM/100ML

> ADD >

> ADD > MANNITOL 20% IN PLASTIC CONTAINER

> ADD > AP ABBOTT LABS 20GM/100ML

> ADD >

N19603 003

JAN 08, 1990

N19603 004

JAN 08, 1990

MANNITOL; SORBITOL

SOLUTION; IRRIGATION

/AA/ /SORBITOL-MANNITOL/

/AT/ /ABBOTT/LABS/ /540MG/100ML/

ABBOTT LABS 540MG/100ML;

2.7GM/100ML

/N80224/001/

N80224 001

MANNITOL; SORBITOL

SOLUTION; IRRIGATION

SORBITOL-MANNITOL IN PLASTIC CONTAINER

/AT/ /ABBOTT/LABS/ /540MG/100ML/

/AT/ /2.7GM/100ML/

/540MG/100ML/

/2.7GM/100ML/

ABBOTT LABS 540MG/100ML;

2.7GM/100ML

540MG/100ML;

2.7GM/100ML

/N17636/001/

/N18316/001/

N17636 001

N18316 001

MEBUTAMATE

/TABLETS; ORAL/

/DORMATE/

/WALLACE/PHARMS/ /600MG/

B WALLACE PHARMS 600MG

/N17374/001/

N17374 001

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

MECLIZINE HCL

/AA/ /ANABOLIC/ /25MG/

B ANABOLIC 25MG

/AA/ /CANALL/ /12.5MG/

/AA/ /25MG/

/AA/ /SUPERPHARM/ /12.5MG/

/AA/ /25MG/

B SUPERPHARM 12.5MG

B 25MG

/N85891/001/

N85891 001

/N84464/001/

/N84713/001/

/N89113/001/

/AUG/20/1985/

/N89114/001/

/AUG/20/1985/

N89113 001

AUG 20, 1985

N89114 001

AUG 20, 1985

TABLET, CHEWABLE; ORAL

MECLIZINE HCL

/AA/ /ANABOLIC/ /25MG/

B ANABOLIC 25MG

/N86392/001/

N86392 001

MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

/BX/	/BOLAR/PHARM/	/EQ/50MG/BASE/	/N70400/001/
			/NOV/25./1986/
/BX/		/EQ/100MG/BASE/	/N70401/001/
			/NOV/25./1986/
	Q BOLAR PHARM	EQ 50MG BASE	N70400 001
	Q	EQ 100MG BASE	NOV 25, 1986
			N70401 001
			NOV 25, 1986
/BX/	/VITARINE/	/EQ/50MG/BASE/	/N71710/001/
			/JUN/15./1988/
/BX/		/EQ/100MG/BASE/	/N71684/001/
			/JUN/15./1988/
	Q VITARINE	EQ 50MG BASE	N71710 001
	Q	EQ 100MG BASE	JUN 15, 1988
			N71684 001
			JUN 15, 1988

MEFENAMIC ACID

CAPSULE; ORAL

MEFENAMIC ACID

/BX/	/VITARINE/	/250MG/	/N72179/001/
			/APR/21./1988/
	Q VITARINE	250MG	N72179 001
			APR 21, 1988

PONSTEL

/AB/	/PARKE/DAVIS/	/250MG/	/N15034/003/
AB	PARKE DAVIS	250MG	N15034 003

MEGESTROL ACETATE

TABLET; ORAL

MEGESTROL ACETATE

/AB/	/PBI/	/20MG/	/N70646/001/
			/OCT/02./1987/
/AB/		/40MG/	/N70647/001/
			/OCT/02./1987/
BX	PBI	20MG	N70646 001
			OCT 02, 1987
BX		40MG	N70647 001
			OCT 02, 1987

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERIDINE HCL

/AB/	/INTL/MEDTN/SYS/	/10MG/ML/	/N86332/001/
	Q INTL MEDTN SYS	10MG/ML	N86332 001

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

/AA/	/ANABOLIC/	/200MG/	/N84420/001/
/AA/		/400MG/	/N84589/002/
	Q ANABOLIC	200MG	N84220 001
	Q	400MG	N84589 002
/AA/	/PRIVATE/FMLTNS/	/400MG/	/N14601/001/
	Q PRIVATE FMLTNS	400MG	N14601 001
/AA/	/REID/ROWELL/	/200MG/	/N84435/001/
	Q REID ROWELL	200MG	N84435 001

MESALAMINE

> ADD >

SUPPOSITORY; RECTAL

> ADD >

ROWASA

> ADD >

REID ROWELL

> ADD >

500MG

N19919 001
DEC 18, 1990

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21

NORETHIN 1/50M-21

AB	SCHIAPPARELLI SEARLE	0.05MG;1MG	N71539 001
			APR 12, 1988
/AB/	/SEARLE/	/0.05MG;1MG/	/N71539/001/
			/APR/12./1988/
	/NORINYL/1+00/21-DAY/		
	/SYNTEX/(FP)/	/0.08MG;1MG/	/N16724/001/
	Q SYNTEX (FP)	0.08MG;1MG	N16724 001

TABLET; ORAL-28

NORETHIN 1/50M-28

AB	SCHIAPPARELLI SEARLE	0.05MG;1MG	N71540 001
			APR 12, 1988
/AB/	/SEARLE/	/0.05MG;1MG/	/N71540/001/
			/APR/12./1988/
	/NORINYL/1+00/28-DAY/		
	/SYNTEX/(FP)/	/0.08MG;1MG/	/N16725/001/
	Q SYNTEX (FP)	0.08MG;1MG	N16725 001

METAPROTERENOL SULFATE

TABLET; ORAL

METAPROTERENOL SULFATE

AB BIOCRAFT LABS 10MG

N72519 001 > DLT >

MAR 30, 1990 > ADD >

AB 20MG

N72520 001

MAR 30, 1990

METHARBITAL

/TABLET;/ORAL/

/SEMORIL/

/ABBOTT/LABS/

3 ABBOTT LABS

/100MG/

100MG

/N08322/001/

N08322 001

METHDILAZINE HYDROCHLORIDE

SYRUP; ORAL

/METHDILAZINE HCL/

/BARRE/NATL/

3 BARRE NATL

/4MG/5ML/

4MG/5ML

/N87122/001/

N87122 001

TACARYL

/WESTWOOD/PHARMS/

WESTWOOD SQUIBB

/4MG/5ML/

4MG/5ML

/N11950/001/

N11950 007

METHICILLIN SODIUM

INJECTABLE; INJECTION

STAPHICILLIN

/BRISTOL/LABS/

3 BRISTOL LABS

/EQ/900MG/BASE/VIAL/

EQ 900MG BASE/VIAL

/N50117/001/

N50117 001

/EQ/3.6GM/BASE/VIAL/

EQ 3.6GM BASE/VIAL

/N50117/002/

N50117 002

/EQ/5.4GM/BASE/VIAL/

EQ 5.4GM BASE/VIAL

/N50117/003/

N50117 003

METHOTREXATE SODIUM

TABLET; ORAL

METHOTREXATE

AB BARR LABS EQ 2.5MG BASE

N81099 001

OCT 15, 1990

AB LEDERLE LABS EQ 2.5MG BASE

N08085 002

METHOXSALEN

CAPSULE; ORAL

8-MOP

/ELDER/PHARMS/

ICN PHARMS

/10MG/

10MG

/N09048/001/

N09048 001

CAPSULE, LIQUID FILLED; ORAL

OXSORALEN-ULTRA

/ELDER/PHARMS/

/10MG/

ICN PHARMS

10MG

/N19600/001/

/OCT/30./1986/

N19600 001

OCT 30, 1986

LOTION; TOPICAL

OXSORALEN

/ELDER/PHARMS/

ICN PHARMS

/1%/

1%

/N09048/002/

N09048 002

METHYCLOTHIAZIDE; PARGYLINE HYDROCHLORIDE

/TABLET;/ORAL/

/EUTRON/

/ABBOTT/LABS/

3 ABBOTT LABS

/5MG;25MG/

5MG;25MG

/N16047/001/

N16047 001

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

METHYLPREDNISOLONE SODIUM SUCCINATE

/AB/ /INTL/MEDTN/SYS/ /EQ 40MG BASE/VIAL/

/N87812/001/

/FEB/09./1983/

/AB/ /EQ 125MG BASE/VIAL/

/N87813/001/

/FEB/09./1983/

/AB/ /EQ 500MG BASE/VIAL/

/N87851/001/

/FEB/09./1983/

/AB/ /EQ 1GM BASE/VIAL/

/N87852/001/

/FEB/09./1983/

3 INTL MEDTN SYS EQ 40MG BASE/VIAL

N87812 001

3 EQ 125MG BASE/VIAL

FEB 09, 1983

3 EQ 500MG BASE/VIAL

N87851 001

3 EQ 1GM BASE/VIAL

FEB 09, 1983

N87852 001

FEB 09, 1983

OCTREOTIDE ACETATEINJECTABLE; INJECTION
SANDOSTATIN

/SANDOZ/PHARMS/

/EQ/0.55MG/BASE/ML/

/N19667/001/

SANDOZ PHARMS

EQ 50UGM BASE/ML

/OCT/21./1988/

N19667 001

OCT 21, 1988

/EQ/0.1MG/BASE/ML/

/N19667/002/

/OCT/21./1988/

EQ 100UGM BASE/ML

N19667 002

OCT 21, 1988

/EQ/0.5MG/BASE/ML/

/N19667/003/

/OCT/21./1988/

EQ 500UGM BASE/ML

N19667 003

OCT 21, 1988

> ADD > OFLOXACIN> ADD > TABLET; ORAL> ADD > FLOXIN> ADD > RW JOHNSON

200MGX

N19735 001

DEC 28, 1990

> ADD > 300MGX

N19735 002

DEC 28, 1990

> ADD > 400MGX

N19735 003

DEC 28, 1990

OLSALAZINE SODIUM

CAPSULE; ORAL

DIPENTUM

PHARMACIA

250MGX

N19715 001

JUL 31, 1990

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

/LOSEC/

/MS&D/RES/LABS/

/20MG/

/N19810/001/

/SEP/14./1989/

PRILOSEC

MS&D RES LABS

20MG

N19810 001

SEP 14, 1989

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

/AB/ /CHELSEA/LABS/

/10MG/

/N71661/001/

/MAR/02./1988/

/AB/

/15MG/

/N71662/001/

/MAR/02./1988/

/AB/

/30MG/

/N71663/001/

/MAR/02./1988/

BX CHELSEA LABS

10MG

N71661 001

MAR 02, 1988

BX

15MG

N71662 001

MAR 02, 1988

BX

30MG

N71663 001

MAR 02, 1988

AB DANBURY PHARMA

10MGX

N72952 001

SEP 28, 1990

AB

15MGX

N72953 001

SEP 28, 1990

AB

30MGX

N72954 001

SEP 28, 1990

PANCURONIUM BROMIDE

INJECTABLE; INJECTION

PANCURONIUM BROMIDE

AP KENDALL MCGAW

1MG/MLX

N72759 001

JUL 31, 1990

AP

2MG/MLX

N72760 001

JUL 31, 1990

PEGADEMASE BOVINE

INJECTABLE; INJECTION

ADAGEN

ENZON

250 UNITS/MLX

N19818 001

MAR 21, 1990

PENBUTOLOL SULFATE

TABLET; ORAL

LEVATOL

/REED/A/CARNRICK/

/10MG/

/N18976/001/

/DEC/30./1987/

a REED & CARNRICK

10MG

N18976 001

DEC 30, 1987

20MG

N18976 004

JAN 05, 1989

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION
PENICILLIN G POTASSIUM IN PLASTIC CONTAINER
BAXTER 20,000 UNITS/MLM
40,000 UNITS/MLM
60,000 UNITS/MLM

N50638 001
JUN 25, 1990
N50638 002
JUN 25, 1990
N50638 003
JUN 25, 1990

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION
PENTAM 300

> ADD >
> ADD >
> DLT >
> DLT >
FUJISAWA PHARM 300MG/VIAL
/LYPHOMED/ /300MG/VIAL/

N19264 001
OCT 16, 1984
/N19264/001/
/OCT 16, 1984/

POWDER FOR RECONSTITUTION; INHALATION
NEBUPENT

> ADD >
> ADD >
> DLT >
> DLT >
FUJISAWA PHARM 300MG/VIAL
/LYPHOMED/ /300MG/VIAL/

N19887 001
JUN 15, 1989
/N19887/001/
/JUN 15, 1989/

PENTOBARBITAL SODIUM

CAPSULE; ORAL
SODIUM PENTOBARBITAL

/AA/ /ANABOLIC/ /100MG/
a ANABOLIC 100MG

/N84590/001/
N84590 001

/TABLET; ORAL/
/SODIUM PENTOBARBITAL/
/ANABOLIC/
a ANABOLIC /100MG/
100MG

/N84238/001/
N84238 001

PERPHENAZINE

TABLET; ORAL
PERPHENAZINE

/AA/ /CHELSEA LABS/ /8MG/
BX CHELSEA LABS 8MG

/N89700/001/
/DEC 23, 1987/
N89700 001
DEC 23, 1987

PHENAZOPYRIDINE HYDROCHLORIDE; SULFISOXAZOLE

TABLET; ORAL
AZO GANTRISIN
ROCHE

50MG;500MG

N19358 001
AUG 31, 1990

PHENDIMETRAZINE TARTRATE

CAPSULE; ORAL

> DLT > /SPRIN-3/
> DLT > /AA/ /REID ROWELL/ /35MG/
> ADD > a REID ROWELL 35MG

/N85897/001/
N85897 001

CAPSULE, EXTENDED RELEASE; ORAL

> DLT > /HELFIAT-105/
> DLT > /BC/ /REID ROWELL/ /105MG/
> DLT >
> ADD > a REID ROWELL 105MG
> ADD >

/N87487/001/
/OCT 13, 1982/
N87487 001
OCT 13, 1982

TABLET; ORAL

/AA/ /ALPHAZINE/
/VITARINE/ /35MG/
a VITARINE 35MG

/N85034/001/
N85034 001

PHENDIMETRAZINE TARTRATE

/AA/ /VITARINE/ /35MG/
a VITARINE 35MG
> DLT > /AA/ /ZENITH LABS/ /35MG/
> DLT > /AA/ /35MG/
> ADD > a ZENITH LABS 35MG
> ADD > a 35MG
> DLT > /STATOBEX-G/
> DLT > /AA/ /LEMMON/ /35MG/
> ADD > a LEMMON 35MG

/N85830/001/
N85830 001
/N83682/001/
/N85612/001/
N83682 001
N85612 001
/N85095/001/
N85095 001

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL
> DLT > /AA/ /LEMMON/ /30MG/
> ADD > a LEMMON 30MG

/N87126/001/
N87126 001

TABLET; ORAL

PHENTERMINE HCL
/AA/ /VITARINE/ /8MG/
/AA/ /8MG/
a VITARINE 8MG
a 8MG
> DLT > /AA/ /ZENITH LABS/ /8MG/
> ADD > a ZENITH LABS 8MG

/N85671/001/
/N85689/001/
N85671 001
N85689 001
/N85553/001/
N85553 001

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

IONAMIN-15

FISONS

/PENNYALT/

EQ 15MG BASE

/EQ/15MG/BASE/

N11613 004

/N11613/004/

IONAMIN-30

FISONS

/PENNYALT/

EQ 30MG BASE

/EQ/30MG/BASE/

N11613 002

/N11613/002/

PHENYLBUTAZONE

CAPSULE; ORAL

PHENYLBUTAZONE

> DLT > /AB/

/ZENITH/LABS/

/100MG/

> DLT >

> ADD >

a ZENITH LABS

100MG

/N88218/001/

/JUN/24/1983/

N88218 001

JUN 24, 1983

PHENYTOIN SODIUM

INJECTABLE; INJECTION

PHENYTOIN SODIUM

/AB/

/WARNER/CHILCOTT/

/50MG/ML/

a WARNER CHILCOTT

50MG/MLM

/N89900/001/

/MAR/30/1990/

N89900 001

MAR 30, 1990

PHENYTOIN SODIUM, EXTENDED

CAPSULE; ORAL

DILANTIN

> DLT > /AB/

/PARKE/DAVIS/

/100MG/

> ADD >

PARKE DAVIS

100MG

/N84349/002/

N84349 002

EXTENDED PHENYTOIN SODIUM

/AB/

/SIDMAK/LABS/

/100MG/

a SIDMAK LABS

100MG

/N89441/001/

/DEC/18/1986/

N89441 001

DEC 18, 1986

PHENYTEX

/BX/

/BOLAR/PHARM/

/100MG/

a BOLAR PHARM

100MG

/N88711/001/

/DEC/21/1984/

N88711 001

DEC 21, 1984

PHYTONADIONE

INJECTABLE; INJECTION

VITAMIN K1

/BP/ /ABBOTT/LABS/

/10MG/ML/

a ABBOTT LABS

10MG/ML

/N87956/001/

/JUL/25/1983/

N87956 001

JUL 25, 1983

PIPECURONIUM BROMIDE

INJECTABLE; INJECTION

ARDUAN

ORGANON

1MG/MLM

N19638 001

JUN 26, 1990

PIPERAZINE CITRATE

SYRUP; ORAL

/BRYREL/

/AA/ /STERLING/DRUG/

/EQ 500MG BASE/5ML/

a STERLING DRUG

EQ 500MG BASE/5ML

/N17796/001/

N17796 001

> ADD > PODOFILOX

> ADD >

SOLUTION; TOPICAL

> ADD >

CONDYLOX

> ADD >

OCLASSEN PHARMS

0.5%M

N19795 001

> ADD >

DEC 13, 1990

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

POWDER FOR RECONSTITUTION; ORAL

GLYCOPREP

AA

SUPERPHARM

236GM/BOT;2.97GM/BOT;6.74GM/BOT;

5.86GM/BOT;22.74GM/BOT

N72319 001

DEC 23, 1988

/AA/

/TOSK/MED/PRODS/

/236GM/BOT;2.97GM/BOT;6.74GM/BOT/

/5.86GM/BOT;22.74GM/BOT/

/N72319/001/

/DEC/23/1988/

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

K-LEASE

AB

ADRIA LABS

10 MEGM

N72427 001

MAR 28, 1990

POTASSIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

/AA/	/LYPHOMED/	/2MEQ/ML/	/N80204/001/
	Q LYPHOMED	2MEQ/ML	N80204 001
> ADD >	POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER		
> ADD >	BAXTER	746MG/100MLM	N19904 005
			DEC 17, 1990
> ADD >	POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER		
> ADD >	BAXTER	1.49GM/100MLM	N19904 006
			DEC 17, 1990

PREDNISOLONETABLET; ORAL
PREDNISOLONE

> DLT >	/BX/	/LEMMON/	/5MG/	/N80398/001/
> ADD >		Q LEMMON	5MG	N80398 001
	/BX/	/SUPERPHARM/	/5MG/	/N88892/001/
		Q SUPERPHARM	5MG	N88892 001
				FEB 26, 1985
	/BX/	/UDL LABS/	/5MG/	/N87987/001/
		Q UDL LABS	5MG	N87987 001
				JAN 18, 1983

PREDNISOLONE ACETATEINJECTABLE; INJECTION
PREDNISOLONE ACETATE

/BP/	/AKORN/	/25MG/ML/	/N83032/001/
	Q AKORN	25MG/ML	N83032 001

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC

/METRETON/			
/SCHERING/	/EQ 0.5% PHOSPHATE/	/N83834/001/	
Q SCHERING	EQ 0.5% PHOSPHATE	N83834 001	

PREDNISONETABLET; ORAL
PREDNISONE

> DLT >	/BX/	/LEDERLE LABS/	/5MG/	/N86968/001/
> ADD >		Q LEDERLE LABS	5MG	N86968 001

PREDNISONE

TABLET; ORAL

PREDNISONE

> DLT >	/BX/	/LEMMON/	/5MG/	/N80397/001/
> ADD >		Q LEMMON	5MG	N80397 001
	/AA/	/PRIVATE/FMLTNS/	/20MG/	/N85151/001/
		Q PRIVATE FMLTNS	20MG	N85151 001
	/BX/	/UDL LABS/	/5MG/	/N87984/001/
				JAN 18, 1983
	/BX/		/10MG/	/N87985/001/
				JAN 18, 1983
	/BX/		/20MG/	/N87986/001/
				JAN 18, 1983
		Q UDL LABS	5MG	N87984 001
			10MG	N87985 001
			20MG	N87986 001
> DLT >	/BX/	/ZENITH LABS/	/20MG/	/N84134/001/
> ADD >		Q ZENITH LABS	20MG	N84134 001

PROBENECID

TABLET; ORAL

PROBENECID

> DLT >	/AA/	/LEDERLE LABS/	/500MG/	/N86917/001/
> ADD >		Q LEDERLE LABS	500MG	N86917 001

PROCHLORPERAZINE EDISYLATE

CONCENTRATE; ORAL

PROCHLORPERAZINE

> DLT >	/AA/	/BARRE NATL/	/EQ 10MG BASE/ML/	/N87153/001/
> DLT >				JUN 08, 1982
> ADD >		Q BARRE NATL	EQ 10MG BASE/ML	N87153 001
> ADD >				JUN 08, 1982

PROCHLORPERAZINE EDISYLATE

> DLT >	/AA/	/PBI/	/EQ 10MG BASE/ML/	/N88598/001/
> DLT >				OCT 25, 1984
> ADD >		PBI	EQ 10MG BASE/ML	N88598 001
> ADD >				OCT 25, 1984

SYRUP; ORAL

PROCHLORPERAZINE EDISYLATE

> DLT >	/AA/	/BARRE NATL/	/EQ 5MG BASE/5ML/	/N87154/001/
> DLT >				SEP 01, 1982
> ADD >		Q BARRE NATL	EQ 5MG BASE/5ML	N87154 001
> ADD >				SEP 01, 1982

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

<u>INDERAL</u>		
/AB/	/WYETH/AYERST/LABS/	/90MG/
	a WYETH AYERST LABS	90MG
		N16418/010/ OCT/18./1982/ N16418 010 OCT 18, 1982
<u>PROPRANOLOL</u>		
/AB/	/MYLAN/PHARMS/	/10MG/
/AB/		/20MG/
/AB/		/40MG/
/AB/		/80MG/
		N70211/001/ NOV/19./1985/ N70212/001/ NOV/19./1985/ N70213/001/ NOV/19./1985/ N70214/001/ NOV/19./1985/

PROPRANOLOL HCL

<u>AB</u>	<u>DANBURY/PHARMA/</u>	<u>20MG</u>	<u>/N71183/001/</u>
	2 DANBURY PHARMA	90MG	<u>/OCT/06./1986/</u>
			N71183 001
> <u>AB</u>	<u>/LEMMON/</u>	<u>20MG</u>	OCT 06, 1986
>			<u>/N70233/001/</u>
>	2 LEMMON	20MG	<u>/JUN/23./1986/</u>
>			N70233 001
<u>AB</u>	MARTEC PHARM	<u>10MG</u>	JUN 23, 1986
			N70120 001
<u>AB</u>		<u>20MG</u>	AUG 06, 1985
			N70121 001
<u>AB</u>		<u>40MG</u>	AUG 06, 1985
			N70122 001
<u>AB</u>		<u>60MG</u>	AUG 06, 1985
			N70123 001
AB		80MG	OCT 29, 1986
			N70124 001

<u>AB</u>	<u>BOMG</u>	<u>DATE</u>
		N70124 001
		AUG 06, 1985
/2/	/10MG/	/N70120/001/
		/AUG/06./1985/
/2/	/20MG/	/N70121/001/
		/AUG/06./1985/
/2/	/40MG/	/N70122/001/
		/AUG/06./1985/
/2/	/60MG/	/N70123/001/
		/OCT/29./1986/
/2/	/80MG/	/N70124/001/
		/AUG/06./1985/

PROPANTHLINE BROMIDE

AA/ /PRIVATE/FMLTNS/ /15MG/ /N80977/001/
2 PRIVATE FMLTNS 15MG N80977 001

CAPSULE; ORAL

<u>PROPOXYPHENE HCL</u>			
/AA/	/ANABOLIC/	/65MG/	/N83185/001/
	Q ANABOLIC	65MG	N83185 001
/AA/	/PRIVATE/FMLTNS/	/32MG/	/N83464/001/
/AA/		/65MG/	/N83113/001/
	Q PRIVATE FMLTNS	32MG	N83464 001
	Q	65MG	N83113 001

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

AB MYLAN PHARMS 10MG

N70211 001

AB 20MG

NOV 19, 1985

AB 40MG

N70212 001

NOV 19, 1985

AB 80MG

N70213 001

NOV 19, 1985

N70214 001

NOV 19, 1985

/N72068/001/

/JUL/29/1988/

N72068 001

JUL 29, 1988

> DLT > /AB/ /ZENITH/LABS/ /60MG/

> DLT >

> ADD > @ ZENITH LABS 60MG

> ADD >

PROPYLTHIOURACIL

TABLET; ORAL

PROPYLTHIOURACIL

/BP/ /ANABOLIC/ /50MG/

/N80285/001/

@ ANABOLIC 50MG

N80285 001

> DLT > /BP/ /ZENITH/LABS/ /50MG/

/N80215/001/

> ADD > @ ZENITH LABS 50MG

N80215 001

PROTEIN HYDROLYSATE

INJECTABLE; INJECTION

AMINOSOL 5%

/ABBOTT/LABS/ /5%Z/

/N05932/012/

@ ABBOTT LABS 5%

/JAN/31/1985/

N05932 012

JAN 31, 1985

/INJECTABLE; INJECTION/

/HYPROTIGEN 5Z/

/BP/ /KENDALL MCGAW/ /5Z/

/N06170/003/

/JAN/10/1984/

@ KENDALL MCGAW 5%

N06170 003

JAN 10, 1984

PYRIDOSTIGMINE BROMIDE

TABLET; ORAL

PYRIDOSTIGMINE BROMIDE

PUREPAC PHARM 30MG

N89572 001

NOV 27, 1990

QUAZEPAM

TABLET; ORAL

DORMALIN

BAKER CUMMINS

7.5MG

N18708 003

FEB 26, 1987

N18708 001

DEC 27, 1985

/N18708/003/

/FEB/26/1987/

/N18708/001/

/DEC/27/1985/

/SCHERING/ /7.5MG/

/15MG/

QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL

QUINIDINE GLUCONATE

/AB/ /SUPERPHARM/ /324MG/

/N89164/001/

/NOV/21/1985/

@ SUPERPHARM 324MG

N89164 001

NOV 21, 1985

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

/AB/ /LEDERLE/LABS/ /200MG/

/N86176/001/

@ LEDERLE LABS 200MG

N86176 001

RAUWOLFIA SERPENTINA

TABLET; ORAL

/WOLFINA/

/BP/ /FOREST/PHARMS/ /100MG/

/N09255/006/

@ FOREST PHARMS 100MG

N09255 006

SARALASIN ACETATE

/INJECTABLE; INJECTION/

/SARENIN/

/NORWICH/EATON/

@ NORWICH EATON

/EQ 0.6MG BASE/ML/

EQ 0.6MG BASE/ML

/N18009/001/

N18009 001

SECobarbital Sodium

CAPSULE; ORAL

SODIUM SECobarbital

/AP/	/KV/PHARM/	/100MG/	/N85285/001/
	Q KV PHARM	100MG	N85285 001

INJECTABLE; INJECTION

SODIUM SECobarbital

/AP/	/LILLY/	/50MG/ML/	/N07392/002/
	Q LILLY	50MG/ML	N07392 002

SODIUM CHLORIDE

INJECTABLE; INJECTION

SODIUM CHLORIDE 5% IN PLASTIC CONTAINER

/AP/	/BAXTER/	/5GM/100ML/	/N19022/002/
	BAXTER	5GM/100ML	N19022 002
			NOV 01, 1983
/AP/	/KENDALL/MCGAW/	/5GM/100ML/	/N19635/004/
	Q KENDALL MCGAW	5GM/100ML	N19635 004
			MAR 09, 1988

> ADD > SERMORELIN ACETATE

> ADD > INJECTABLE; INJECTION

> ADD > Geref

> ADD >	SERONO LABS	EQ 0.05MG BASE/AMPM	N19863 001
> ADD >			DEC 28, 1990

SODIUM BICARBONATE; TARTARIC ACID

GRANULE, EFFERVESCENT; ORAL

BAROS

> ADD >	E Z EM	460MG/GM;420MG/GM	N18509 001
> ADD >			AUG 07, 1985
> DLT >	/LAFAYETTE/	/460MG/GM;420MG/GM/	/N18509/001/
> DLT >			/AUG/07/1985/

SODIUM CHLORIDE

INJECTABLE; INJECTION

SODIUM CHLORIDE

/AP/	/ABBOTT/LABS/	/20GM/100ML/	/N17013/001/
	Q ABBOTT LABS	20GM/100ML	N17013 001

SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	BAXTER	450MG/100ML	N18016 001
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SODIUM CHLORIDE 0.45% IN WATER IN PLASTIC CONTAINER

/AP/	/BAXTER/	/450MG/100ML/	/N18016/001/
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SODIUM CHLORIDE 3% IN PLASTIC CONTAINER

/AP/	/BAXTER/	/3GM/100ML/	/N19022/001/
			/NOV/01/1983/

BAXTER

N19022 001

NOV 01, 1983

/AP/	/KENDALL/MCGAW/	/3GM/100ML/	/N19635/003/
------	-----------------	-------------	--------------

N19635 003

MAR 09, 1988

Q KENDALL MCGAW

SOYBEAN OIL

INJECTABLE; INJECTION

LIPOSYN III 10%

AP	ABBOTT LABS	10%	N18969 001
			SEP 24, 1984
/3/		/10%/	/N18969/001/
			/SEP/24/1984/

LIPOSYN III 20%

AP	ABBOTT LABS	20%	N18970 001
			SEP 25, 1984
/3/		/20%/	/N18970/001/
			/SEP/25/1984/

TRAVAMULSION 20%

/AP/	/BAXTER/	/20%/	/N18758/001/
			/FEB/15/1983/
	Q BAXTER	20%	N18758 001
			FEB 15, 1983

SULCONAZOLE NITRATE

CREAM; TOPICAL

EXELDERM

> ADD >	WESTWOOD SQUIBB	1%	N18737 001
> ADD >			FEB 28, 1989
> DLT >	/SULCOSYN/		/N18737/001/
> DLT >	/WESTWOOD/PHARMS/	/1%/	/FEB/28/1989/
> DLT >			

SOLUTION; TOPICAL

EXELDERM

> ADD >	Q WESTWOOD SQUIBB	1%	N18738 001
> ADD >			AUG 30, 1985
> DLT >	/SULCOSYN/		/N18738/001/
> DLT >	/3/SYNTEX/LABS/	/1%/	/AUG/30/1985/
> DLT >			

SULFAMETHIZOLE

TABLET; ORAL

/MICROSUL/
FOREST PHARMS/
a FOREST PHARMS/1GM/
1GM/N86012/001/
N86012 001SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL

> DLT > /SULMEPRIM/
> DLT > /AB/ /PBI/
> DLT >
> ADD > a PBI
> ADD >/200MG/5ML;40MG/5ML/
200MG/5ML;40MG/5ML/N70063/001/
/AUG/01./1986/
N70063 001
AUG 01, 1986/AB/ /SULMEPRIM PEDIATRIC/
/PBI/
a PBI/200MG/5ML;40MG/5ML/
200MG/5ML;40MG/5ML/N70064/001/
/AUG/01./1986/
N70064 001
AUG 01, 1986SULFASALAZINE

TABLET; ORAL

/S.A.S.-500/
/AB/ /REID/ROWELL/
a REID ROWELL
SULFASALAZINE
/BP/ /VITARINE/
a VITARINE/500MG/
500MG
/500MG/
500MG/N83450/001/
N83450 001
/N86184/001/
N86184 001SULFISOXAZOLE

TABLET; ORAL

/SULSOXIN/
/AB/ /REID/ROWELL/
a REID ROWELL/500MG/
500MG/N80040/001/
N80040 001SULINDAC

TABLET; ORAL

/SULINDAC/
/AB/ /AM/THERPICS/
/AB//150MG/
/200MG//N72171/001/
/APR/03./1990/;/MAY/23./1988/
/N72172/001/
/APR/03./1990/;/MAY/23./1988/TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

AN-MAA
BS CIS US N/A
/BS/ /SORIN/ /N/A/N17792 001
/N17792/001/TECHNETIUM TC-99M MERTIATIDE KIT

INJECTABLE; INJECTION

TECHNISCAN MAG3
MALLINCKRODT N/AN19882 001
JUN 15, 1990TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION

AN-DTPA
AP CIS US N/A
/AP/ /SYNCOR/INTL/ /N/A/N17714 001
/N17714/001/> ADD > TECHNETIUM TC-99M SESTAMIBI KIT

> ADD > INJECTABLE; INJECTION

> ADD > CARDIOLITE
> ADD > DUPONT DIAG N/A
> ADD >N19785 001
DEC 21, 1990TECHNETIUM TC-99M SODIUM PERTECHNETATE

SOLUTION; INJECTION, ORAL

SODIUM PERTECHNETATE TC 99M
/MEDI/PHYSICS/ /2-100MCI/ML/
a MEDI PHYSICS 2-100MCI/ML/N17471/001/
N17471 001> ADD > TECHNETIUM TC-99M TEBOROXIME KIT

> ADD > INJECTABLE; INJECTION

> ADD > CARDIOTEC
> ADD > SQUIBB DIAGS N/A
> ADD >N19928 001
DEC 19, 1990

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

TETRACYCLINE HCL

/BX/ /VITARINE/ /250MG/
/BX/ /500MG/
a VITARINE 250MG
a 500MG

/N61471/001/
/N61471/002/
/SEP/06/1983/
N61471 001
N61471 002
SEP 06, 1983

TETRACYCLINE PHOSPHATE COMPLEX

CAPSULE; ORAL

TETREX

/BRISTOL LABS/

a BRISTOL LABS

a

/EQ/250MG/HCL/
EQ 250MG HCL
/EQ/500MG/HCL/
EQ 500MG HCL

/N50212/002/
N50212 002
/N50212/003/
N50212 003

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

THEOPHYL-SR

/BC/ /RW/JOHNSON/

a RW JOHNSON

250MG

/N86471/001/
/FEB/08/1985/
N86471 001
FEB 08, 1985

THEOPHYLLINE

/BC/ /VITARINE/

a VITARINE

260MG

/N87462/001/
/MAY/11/1982/
N87462 001
MAY 11, 1982

ELIXIR; ORAL

THEOPHYLLINE

> DLT > /AA/ /BELL/PHARMA/
> ADD > a PERRIGO

/80MG/15ML/
80MG/15ML

/N85952/001/
N85952 001

SYRUP; ORAL

THEOPHYLLINE

> DLT > /AA/ /BARRE/NATL/
> ADD > a BARRE NATL

/150MG/15ML/
150MG/15ML

/N86545/001/
N86545 001

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL

THEOCHRON

AB INWOOD LABS

100MG

N88320 001
FEB 21, 1985
N88321 001
FEB 21, 1985
N87400 002
JAN 11, 1983

AB

200MG

AB

300MG

/AB/ /THEOPHYLLINE/
/INWOOD LABS/

/100MG/

/N88320/001/
/FEB/21/1985/
/N88321/001/
/FEB/21/1985/
/N87400/002/
/JAN/11/1983/

/AB/

/200MG/

/AB/

/300MG/

THEOPHYLLINE

AB SIDMAK LABS

100MG

N89807 001
APR 30, 1990
N89808 001
APR 30, 1990
N89763 001
APR 30, 1990

AB

200MG

AB

300MG

TIMOLOL MALEATE

TABLET; ORAL

TIMOLOL MALEATE

AB MYLAN PHARMS

5MG

N72666 001
JUN 08, 1990
N72667 001
JUN 08, 1990
N72668 001
JUN 08, 1990

AB

10MG

AB

20MG

/BX/ /QUANTUM/PHARMS/

/10MG/

/BX/

/20MG/

a QUANTUM PHARMS

10MG

a

20MG

/N72467/001/
/MAY/19/1989/
/N72468/001/
/MAY/19/1989/
N72467 001
MAY 19, 1989
N72468 001
MAY 19, 1989

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

ABBOTT LABS

EQ 80MG BASE/100MLM N63081 001
JUL 31, 1990
EQ 1.2MG BASE/MLM N63081 003
JUL 31, 1990

TOLAZAMIDE

TABLET; ORAL

TOLAZAMIDE

/AB/ /SUPERPHARM/ /250MG/ /N70763/001/
/JUN/16,/1986/
/AB/ /500MG/ /N70764/001/
/JUN/16,/1986/
3 SUPERPHARM 250MG N70763 001
JUN 16, 1986
3 500MG N70764 001
JUN 16, 1986

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

DESYREL

AB BRISTOL MYERS 50MG N18207 001
AB 100MG N18207 002
AB 150MG N18207 003
MAR 25, 1985
300MG N18207 004
NOV 07, 1988
/AB/ /HEAD/JOHNSON/ /50MG/ /N18207/001/
/AB/ /100MG/ /N18207/002/
/AB/ /150MG/ /N18207/003/
/MAR/25,/1985/

TRAZODONE HCL

AB CORD LABS 50MG N72484 001
APR 30, 1990
AB 100MG N72483 001
APR 30, 1990

TRIAMCINOLONE ACETONIDE

AEROSOL; TOPICAL

KENALOG

> DLT > /SQUIBB/ /0.147MG/GM/ /N12104/001/
> ADD > WESTWOOD SQUIBB 0.147MG/GM N12104 001

TRIAMCINOLONE ACETONIDE

AEROSOL, METERED; INHALATION

AZMACORT

RHONE POULENC RORER 0.25MG/INH

/RORER/PHARM/ /0.25MG/INH/

N18117 001
APR 23, 1983
/N18117/001/
/APR/23,/1983/

CREAM; TOPICAL

ELUTEN

/AT/ /SYOSSET/LABS/ /0.025%/

/AT/ /0.1%/

/AT/ /0.5%/

KENALOG

/AT/ /SQUIBB/ /0.025%/

> DLT > /AT/ /0.1%/

> ADD > /AT/ /0.5%/

AT WESTWOOD PHARMS 0.025%

AT 0.1%

> ADD > AT WESTWOOD SQUIBB 0.5%

KENALOG-H

> DLT > /AT/ /SQUIBB/ /0.1%/

> ADD > AT WESTWOOD SQUIBB 0.1%

> DLT > /AT/ /TRIACORT/ /0.1%/

> ADD > /AT/ /REID/ROWELL/ 0.1%

TRITATEX

AT SYOSSET LABS 0.025%

AT 0.1%

AT 0.5%

INJECTABLE; INJECTION

KENALOG-10

> DLT > /SQUIBB/ /10MG/ML/

> ADD > WESTWOOD SQUIBB 10MG/ML

KENALOG-40

> DLT > /BP/ /SQUIBB/ /40MG/ML/

> ADD > BP WESTWOOD SQUIBB 40MG/ML

LOTION; TOPICAL

KENALOG

> DLT > /AT/ /SQUIBB/ /0.025%/

> DLT > /AT/ /0.1%/

> ADD > AT WESTWOOD SQUIBB 0.025%

> ADD > AT 0.1%

/N87430/001/
/NOV/01,/1988/
/N87429/001/
/NOV/01,/1988/
/N87428/001/
/NOV/01,/1988/

/N11601/003/
/N11601/006/
/N83943/001/
N11601 003
N11601 006
N83943 001

/N86240/001/
N86240 001

/N87113/001/
N87113 001

N87430 001
NOV 01, 1988
N87429 001
NOV 01, 1988
N87428 001
NOV 01, 1988

/N12041/001/
N12041 001

/N14901/001/
N14901 001

/N84343/001/
/N84343/002/
N84343 001
N84343 002

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

KENALOG

/AT/ /SQUIBB/ /0.025%/ /N11600/001/
 /AT/ /0.12/ /N11600/001/
 > DLT > /AT/ /0.5%/ /N83944/001/
 AT WESTWOOD PHARMS /0.025/ N11600 003
 AT /0.1/ N11600 001
 > ADD > AT WESTWOOD SQUIBB /0.5/ N83944 001

TRIAMTERENE

CAPSULE; ORAL

DYRENIUM

/SK&F/

SK&F LABS

/50MG/ /N13174/001/
 /100MG/ /N13174/002/
 50MG N13174 001
 100MG N13174 002

TRICHLORMETHIAZIDE

TABLET; ORAL

TRICHLORMETHIAZIDE

/BP/ /CHELSEA/LABS/ /4MG/ /N85962/001/
 @ CHELSEA LABS 4MG N85962 001

TRIENTINE HYDROCHLORIDE

CAPSULE; ORAL

/CUPRID/

/MS&D/

SYPRINE

MS&D

/250MG/

250MG

/N19194/001/
 /NOV 08, 1985/

N19194 001
 NOV 08, 1985

TRIMEPAZINE TARTRATE

SYRUP; ORAL

TRIMEPAZINE TARTRATE

/AA/ /BARRE/NATL/ /EQ 2.5MG BASE/5ML/

@ BARRE NATL

EQ 2.5MG BASE/5ML

/N85015/001/
 /FEB 18, 1982/
 N85015 001
 FEB 18, 1982

TRIMIPRAMINE MALEATE

CAPSULE; ORAL

TRIMIPRAMINE MALEATE

/BX/ /VITARINE/ /EQ/25MG/BASE/ /N71832/001/
 /BX/ /EQ/50MG/BASE/ /SEP 10, 1987/
 /BX/ /EQ/100MG/BASE/ /N71833/001/
 /N71834/001/
 /SEP 10, 1987/

@ VITARINE

EQ 25MG BASE

N71832 001

@

EQ 50MG BASE

SEP 10, 1987

@

EQ 100MG BASE

N71833 001

SEP 10, 1987

N71834 001

SEP 10, 1987

TRISULFAPYRIMIDINES

SUSPENSION; ORAL

TRIPLE SULFA

/AB/ /BARRE/NATL/ /500MG/5ML/ /N80280/001/
 @ BARRE NATL 500MG/5ML N80280 001

TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC

TROPICAMIDE

> ADD > AT STERIS LABS /0.5/M
 > ADD > /1/M
 > ADD > AT
 > ADD >

N89171 001

DEC 28, 1990

N89172 001

DEC 28, 1990

UREA

INJECTABLE; INJECTION

STERILE UREA

/AP/ /ABBOTT/LABS/ /40GM/VIAL/ /N17698/001/
 @ ABBOTT LABS 40GM/VIAL N17698 001

UREAPHIL

/AP/ /ABBOTT/LABS/ /40GM/VIAL/ /N12154/001/
 ABBOTT LABS 40GM/VIAL N12154 001

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

VANCOMYCIN HCL

> ADD > AP ABBOTT LABS /EQ 5GM BASE/VIAL/
 > ADD >

N63076 001

DEC 21, 1990

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

VERELAN

ELAN PHARM

120MG

N19614 001

MAY 29, 1990

240MG

N19614 002

MAY 29, 1990

INJECTABLE; INJECTION

CALAN

/AP/ /SEARLE/

/2.5MG/ML/

/N19038/001/

/MAR/30./1984/

a SEARLE

2.5MG/ML

N19038 001

MAR 30, 1984

VERAPAMIL HCL

/AP/ /LYPHOMED/

/2.5MG/ML/

/N70348/001/

/MAY/01./1986/

a LYPHOMED

2.5MG/ML

N70348 001

MAY 01, 1986

TABLET; ORAL

VERAPAMIL HCL

/AP/ /CHELSEA/LABS/

/80MG/

/N70421/001/

/SEP/17./1986/

/AP/

/120MG/

/N70422/001/

/SEP/17./1986/

BX CHELSEA LABS

80MG

N70421 001

SEP 17, 1986

BX

120MG

N70422 001

SEP 17, 1986

VINBLASTINE SULFATE

INJECTABLE; INJECTION

VELSAR

/AP/ /ADRIA/LABS/

/10MG/VIAL/

/N89565/001/

/AUG/18./1987/

AP BULL LABS

10MG/VIAL

N89565 001

AUG 18, 1987

VITAMIN A PALMITATE

CAPSULE; ORAL

ALPHALIN

/AA/ /LILLY/

/EQ 50,000 UNITS BASE/

/N80883/001/

a LILLY

EQ 50,000 UNITS BASE

N80883 001

VITAMIN A

/AA/ /SQUIBB/

/EQ 50,000 UNITS BASE/

/N80860/001/

a SQUIBB

EQ 50,000 UNITS BASE

N80860 001

VITAMIN A PALMITATE

CAPSULE; ORAL

> DLT >

/VITAMIN A SOLUBILIZED/

> DLT > /AA/

/LEMON/

> ADD >

a LEMON

/EQ 50,000 UNITS BASE/

EQ 50,000 UNITS BASE

/N80921/001/

N80921 001

WARFARIN SODIUM

/INJECTABLE; INJECTION/

/COUMADIN/

/DUPONT PHARMS/

/50MG/VIAL/

/N09218/020/

a DUPONT PHARMS

/75MG/VIAL/

/N09218/012/

a

50MG/VIAL

N09218 020

75MG/VIAL

N09218 012

TABLET; ORAL

COUMADIN

DUPONT PHARMS

1MG

N09218 022

MAR 01, 1990

ZIDOVUDINE

INJECTABLE; INJECTION

RETROVIR

BURROUGHS WELLC

10MG/ML

N19951 001

FEB 02, 1990

CLOTRIMAZOLE

CREAM; VAGINAL
GYNE-LOTTRIMIN
SCHERING

1/4

N18052 002
NOV 30, 1990

TABLET; VAGINAL
GYNE-LOTTRIMIN
SCHERING

100MG

N17717 002
NOV 30, 1990

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL

DIPHENHYDRAMINE HCL

AA HI TECH PHARMA

12.5MG/5ML

N72416 001
SEP 28, 1990

IBUPROFEN

TABLET; ORAL
IBUPROFEN

/ZENITH/LABS/

/200MG/

N72040 001/
APR/29/1988/
N72040 001
APR 29, 1988

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

3 ZENITH LABS

200MG

PERMETHRIN

LOTION; TOPICAL
NIX

BURROUGHS WELLC

1/4

N19918 001
MAY 02, 1990

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '90 - DEC '90

NO DECEMBER 1990 APPROVALS

ORPHAN DRUG PRODUCT DESIGNATIONS

SECTION 526 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT CONTAINS PROVISIONS WHEREBY FDA MAY DESIGNATE A SPONSOR'S DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT AS A "DESIGNATED ORPHAN DRUG." SECTION 527 OF THE ACT ESTABLISHES A PROCESS WHEREBY A SPONSOR MAY RECEIVE SEVEN YEARS OF EXCLUSIVE APPROVAL STATUS IF THAT SPONSOR IS THE FIRST TO ACHIEVE NEW DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT APPROVAL FOR A DESIGNATED ORPHAN DRUG FOR THE DESIGNATED INDICATION(S). THE EXCLUSIVE APPROVAL MAY BE REVOKED BY WRITTEN CONSENT OF THE SPONSOR OR BY FDA ACTION AFTER FINDING THAT THE SPONSOR HOLDING EXCLUSIVE APPROVAL CANNOT ASSURE THE AVAILABILITY OF SUFFICIENT QUANTITIES OF THE DRUG TO MEET THE NEEDS OF PATIENTS WITH THE DESIGNATED ORPHAN INDICATION(S).

WHEN A PRODUCT IS GRANTED ORPHAN DRUG DESIGNATION, IT WILL APPEAR IN THIS SECTION. ONCE A BIOLOGICAL OR DRUG PRODUCT IS LICENSED/APPROVED FOR MARKETING, IT WILL BE LISTED IN THIS SECTION AND ASTERISKED, AS APPROPRIATE, TO DENOTE MARKETING/EXCLUSIVE APPROVAL STATUS. IN ADDITION, THE EXCLUSIVITY EXPIRATION DATE WILL BE DISPLAYED FOLLOWING THE APPROVED DESIGNATED INDICATION(S).

THE FOLLOWING DRUGS AND BIOLOGICALS HAVE BEEN GRANTED ORPHAN DRUG DESIGNATION PURSUANT TO SECTION 526 OF THE FOOD, DRUG, AND COSMETIC ACT AS AMENDED BY THE ORPHAN DRUG ACT [PUBLIC LAW 97-414].

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL

DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]

SPONSOR NAME

GENERIC: ANTI-CYTOMEGALOVIRUS MONOCLONAL
ANTIBODIES

TRADE: NOT ESTABLISHED

PREVENTION OF HUMAN CYTOMEGALOVIRUS INFECTION IN
BONE MARROW AND ORGAN TRANSPLANT PATIENTS.
TREATMENT OF HUMAN CYTOMEGALOVIRUS INFECTION IN
BONE MARROW AND ORGAN TRANSPLANT PATIENTS.
PREVENTION OF HUMAN CYTOMEGALOVIRUS INFECTION IN
PATIENTS DIAGNOSED WITH AIDS.
TREATMENT OF HUMAN CYTOMEGALOVIRUS INFECTION IN
PATIENTS DIAGNOSED WITH AIDS.

MEDIMORPHICS

GENERIC: BOTULINUM TOXIN TYPE A

TRADE: OCULINUM*/**

TREATMENT OF STRABISMUS ASSOCIATED WITH DYSTONIA IN
ADULTS (PATIENTS 12 YEARS OF AGE AND ABOVE).
TREATMENT OF BLEPHAROSPASM ASSOCIATED WITH
DYSTONIA IN ADULTS (PATIENTS 12 YEARS OF AGE
AND ABOVE).*/** [DEC 29, 1996]

ALAN B. SCOTT, M.D.

GENERIC: BOVINE COLOSTRUM

TRADE: NOT ESTABLISHED

TREATMENT OF AIDS-RELATED DIARRHEA.

DONALD H. HASTINGS, D.V.M.

GENERIC: COAGULATION FACTOR IX (HUMAN)

TRADE: ALPHANINE

FOR USE AS REPLACEMENT THERAPY IN PATIENTS WITH
HEMOPHILIA B FOR THE PREVENTION AND CONTROL OF
BLEEDING EPISODES, AND DURING SURGERY TO CORRECT
DEFECTIVE HEMOSTASIS.

ALPHA THERPTCS

GENERIC: CYTOMEGALOVIRUS IMMUNE GLOBULIN (HUMAN)

TRADE: NOT ESTABLISHED*/**

PREVENTION OR ATTENUATION OF PRIMARY CYTOMEGALO-
VIRUS DISEASE IN IMMUNOSUPPRESSED RECIPIENTS OF
ORGAN TRANSPLANTS. [APR 17, 1997]

MASSACHUSETTS PUBLIC HEALTH
BIOLOGIC LABS

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: C1-INHIBITOR TRADE: C1-INHIBITOR (HUMAN) VAPOR HEATED, IMMUNO	PREVENTION OF ACUTE ATTACKS OF ANGIOEDEMA, INCLUDING SHORT-TERM PROPHYLAXIS FOR PATIENTS REQUIRING DENTAL OR OTHER SURGICAL PROCEDURES. TREATMENT OF ACUTE ATTACKS OF ANGIOEDEMA.	IMMUNO CLIN RES
GENERIC: CD4 IMMUNOGLOBULIN G (RECOMBINANT HUMAN) TRADE: NOT ESTABLISHED	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) RESULTING FROM INFECTION WITH THE HUMAN IMMUNODEFICIENCY VIRUS (HIV-1).	GENETECH
GENERIC: CD-45 MONOCLONAL ANTIBODIES TRADE: NOT ESTABLISHED	PREVENTION OF ACUTE GRAFT REJECTION OF HUMAN ORGAN TRANSPLANTS.	NJC ENTERPRISES
GENERIC: DISACCHARIDE TRIPEPTIDE GLYCEROL DIPALMITOYL (DTP-GDP) TRADE: IMMOTHER	TREATMENT OF PULMONARY AND HEPATIC METASTASES IN COLORECTAL ADENOCARCINOMA PATIENTS.	IMMUNOTHERAPEUTICS
GENERIC: GRANULOCYTE-COLONY STIMULATING FACTOR (RECOMBINANT-METHIONYL HUMAN) TRADE: NEUPOGEN	TREATMENT OF MYELODYSPLASTIC SYNDROME. TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANTS. TREATMENT OF PATIENTS WITH SEVERE CHRONIC NEUTROPENIA (ABSOLUTE NEUTROPHIL COUNT LESS THAN 500 PER CUBIC MILLIMETER).	AMGEN
GENERIC: GRANULOCYTE MACROPHAGE-COLONY STIMULATING FACTOR TRADE: NOT ESTABLISHED	TREATMENT OF NEUTROPENIA DUE TO HAIRY CELL LEUKEMIA. TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA TO INCREASE GRANULOCYTE COUNTS.	SCHERING PLOUGH

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: GROUP B STREPTOCOCCUS IMMUNE GLOBULIN TRADE: NOT ESTABLISHED	TREATMENT OF NEONATES WITH DISSEMINATED GROUP B STREPTOCOCCAL INFECTION.	UNIVAX
GENERIC: [INDIUM 111 MURINE ANTI-CEA MONOCLONAL ANTIBODY TYPE ZCE 025] TRADE: CEAKER	FOR THE DETECTION OF SUSPECTED AND PREVIOUSLY UNIDENTIFIED TUMOR FOCI OF RECURRENT COLORECTAL CARCINOMA.	HYBRITECH
GENERIC: INTERFERON ALPHA-2A (RECOMBINANT) TRADE: ROFERON-A	TREATMENT OF METASTATIC RENAL CELL CARCINOMA IN COMBINATION WITH TECELEUKIN. TREATMENT OF METASTATIC MALIGNANT MELANOMA IN COMBINATION WITH TECELEUKIN. CONCOMITANT ADMINISTRATION WITH FLUOROURACIL FOR THE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER.	ROCHE
GENERIC: INTERFERON ALPHA-2B (RECOMBINANT) TRADE: INTRON A	TREATMENT OF PATIENTS WITH CHRONIC DELTA HEPATITIS.	SCHERING PLOUGH
GENERIC: INTERLEUKIN-2 POLYETHYLENE CONJUGATE; RECOMBINANT E. COLI TRADE: NOT ESTABLISHED	TREATMENT OF PRIMARY IMMUNODEFICIENCY DISEASE ASSOCIATED WITH T-CELL DEFECTS.	CETUS
GENERIC: LACTOBIN TRADE: LACTOBIN	TREATMENT OF AIDS ASSOCIATED DIARRHEA UNRESPONSIVE TO INITIAL ANTIDIARRHEAL THERAPY.	ROXANE LABS

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: LEUKOPOIETIN TRADE: LEUKINE	TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANT, FOR THE PROMOTION OF EARLY ENGRAFTMENT, AND FOR THE TREATMENT OF GRAFT FAILURE AND DELAY OF ENGRAFTMENT.	IMMUNEX
GENERIC: MONOCLONAL ANTIBODIES PM-81 AND AML 2-23 TRADE: NOT ESTABLISHED	FOR EXOGENOUS DEPLETION OF CD14 AND CD15 POSITIVE ACUTE MYELOID LEUKEMIC BONE MARROW CELLS FROM PATIENTS UNDERGOING BONE MARROW TRANSPLANTATION.	MEDAREX
GENERIC: MUCOID EXOPOLYSACCHARIDE PSEUDOMONAS HYPERIMMUNE GLOBULIN TRADE: MEPIG	PREVENTION OF PULMONARY INFECTIONS DUE TO PSEUDOMONAS AERUGINOSA IN PATIENTS WITH CYSTIC FIBROSIS.	UNIVAX BIOLOGICS
GENERIC: ONCORAD OV103 TRADE: NOT ESTABLISHED	TREATMENT OF OVARIAN CARCINOMA.	CYTOGEN
GENERIC: RESPIRATORY SYNCYTIAL VIRUS IMMUNE GLOBULIN (HUMAN) TRADE: HYPERMUNE RSV	PROPHYLAXIS OF RESPIRATORY SYNCYTIAL VIRUS LOWER RESPIRATORY INFECTIONS IN INFANTS AND YOUNG CHILDREN AT HIGH RISK OF SERIOUS DISEASE. TREATMENT OF RESPIRATORY SYNCYTIAL VIRUS LOWER RESPIRATORY INFECTIONS IN HOSPITALIZED INFANTS AND YOUNG CHILDREN.	MOLECULAR VACCINES
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-MY ⁹) TO MYELOID CELLS (CD-33) TRADE: NOT ESTABLISHED	FOR USE IN THE EX VIVO TREATMENT OF AUTOLOGOUS BONE MARROW AND SUBSEQUENT REINFUSION IN PATIENTS WITH ACUTE MYELOGENOUS LEUKEMIA.	IMMUNOGEN

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL

GENERIC: TECELEUKIN

TRADE: NOT ESTABLISHED

DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]

TREATMENT OF METASTATIC MALIGNANT MELANOMA.
 TREATMENT OF METASTATIC RENAL CELL CARCINOMA.
 TREATMENT OF METASTATIC MALIGNANT MELANOMA IN
 COMBINATION WITH ROFERON-A.
 TREATMENT OF METASTATIC RENAL CELL CARCINOMA IN
 COMBINATION WITH ROFERON-A (INTERFERON ALPHA-2A,
 RECOMBINANT/ROCHE).

SPONSOR NAME

ROCHE

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ALL-TRANS RETINOIC ACID TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE PROMYELOCYTIC LEUKEMIA.	ROCHE
GENERIC: ALPHA-GALACTOSIDASE A TRADE: FABRASE	TREATMENT OF FABRY'S DISEASE.	ROBERT J. DESNICK, M.D., PH.D. MOUNT SINAI SCHOOL OF MEDICINE
GENERIC: AMILORIDE HCL SOLUTION FOR INHALATION TRADE: NOT ESTABLISHED	TREATMENT OF CYSTIC FIBROSIS.	GLAXO
GENERIC: BMY-45622 TRADE: NOT ESTABLISHED	TREATMENT OF OVARIAN CANCER.	BRISTOL SQUIBB
GENERIC: CALCITONIN SALMON NASAL SPRAY TRADE: MIACALCIN	TREATMENT OF SYMPTOMATIC PAGET'S DISEASE OF BONE (OSTEITIS DEFORMANS).	SANDOZ
GENERIC: CALCIUM ACETATE TRADE: PHOSLO*/**	TREATMENT OF HYPERPHOSPHATEMIA IN END STAGE RENAL DISEASE (ESRD). [DEC 10, 1997]	BRAINTREE LABS
GENERIC: CALCIUM CARBONATE TRADE: R & D CALCIUM CARBONATE/600	TREATMENT OF HYPERPHOSPHATEMIA IN PATIENTS WITH END STAGE RENAL DISEASE (ESRD).	R AND D LABS
GENERIC: CALCIUM GLUCONATE GEL 2.5% TRADE: NOT ESTABLISHED	EMERGENCY TOPICAL TREATMENT OF HYDROGEN FLUORIDE (HYDROFLUORIC ACID) BURNS.	PADDOCK LABS

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: CETYL ALCOHOL; COLFOSCERIL PALMITATE; TYLOXAPOL TRADE: EXOSURF NEONATAL*/**	PREVENTION OF HYALINE MEMBRANE DISEASE (HMD), ALSO KNOWN AS RESPIRATORY DISTRESS SYNDROME (RDS), IN INFANTS BORN AT 32 WEEKS GESTATION OR LESS.*/** [AUG 02, 1997] TREATMENT OF ESTABLISHED HMD AT ALL GESTATIONAL AGES.*/** [AUG 02, 1997]	BURROUGHS WELLC
GENERIC: CROMOLYN SODIUM TRADE: GASTROCROM*/**	MASTOCYTOSIS. [DEC 22, 1996]	FISONS
GENERIC: DEHYDREX TRADE: NOT ESTABLISHED	TREATMENT OF RECURRENT CORNEAL EROSION UNRESPONSIVE TO CONVENTIONAL THERAPY.	HOLLES LABS
GENERIC: DEXTRAN SULFATE (INHALED, AEROSOLIZED) TRADE: UENDEX	ADJUNCT TO THE TREATMENT OF CYSTIC FIBROSIS.	THOMAS P. KENNEDY, M.D. J. HOIDAL, M.D. DUKE UNIVERSITY MEDICAL CENTER
GENERIC: DISODIUM CLODRONATE TETRAHYDRATE TRADE: BONEFOS	TREATMENT OF INCREASED BONE RESORPTION DUE TO MALIGNANCY.	LEIRAS PHARMS
GENERIC: DYNAMINE TRADE: NOT ESTABLISHED	TREATMENT OF LAMBERT-EATON MYASTHENIC SYNDROME.	MAYO CLINIC AND FOUNDATION
GENERIC: EFLORNITHINE HCL (DFMO) TRADE: ORNIDYL*/**	TREATMENT OF TRYPAOSOMA BRUCEI GAMBIENSE SLEEPING SICKNESS.*/** [NOV 28, 1997]	MERRELL DOW

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: FLUOROURACIL	CONCOMITANT ADMINISTRATION WITH ROFERON-A FOR THE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER.	ROCHE
GENERIC: GENTAMICIN LIPOSOME INJECTION TRADE: NOT ESTABLISHED	TREATMENT OF DISSEMINATED MYCOBACTERIUM AVIUM-INTRACELLULARE INFECTION.	LIPOSOME
GENERIC: GONADORELIN ACETATE TRADE: LUTREPULSE*/**	TREATMENT OF PRIMARY HYPOTHALAMIC AMENORRHEA. [OCT 10, 1996]	RW JOHNSON
GENERIC: GOSSYPOL TRADE: NOT ESTABLISHED	TREATMENT OF CANCER OF THE ADRENAL CORTEX.	MARCUS M. REIDENBERG, M.D. CORNELL UNIVERSITY MEDICAL COLLEGE
GENERIC: HYDROXYUREA TRADE: HYDREA	TREATMENT OF SICKLE CELL ANEMIA AS SHOWN BY THE PRESENCE OF HEMOGLOBIN S.	BRISTOL SQUIBB
GENERIC: IDARUBICIN HYDROCHLORIDE TRADE: IDAMYCIN*/**	TREATMENT OF ACUTE MYELOGENOUS LEUKEMIA (AML), ALSO REFERRED TO AS ACUTE NONLYMPHOCYTIC LEUKEMIA (ANLL). [SEP 27, 1990]	ADRIA LABS
GENERIC: ILOPROST TRADE: NOT ESTABLISHED	TREATMENT OF HEPARIN-ASSOCIATED THROMBOCYTOPENIA.	BERLEX LABS
GENERIC: L-BACLOFEN TRADE: NOT ESTABLISHED	TREATMENT OF TRIGEMINAL NEURALGIA.	GERHARD H. FROMM, M.D. UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG

DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]

SPONSOR NAME

GENERIC: L-LEUCOVORIN CALCIUM
TRADE: ISOVORIN

USE IN COMBINATION CHEMOTHERAPY WITH THE APPROVED AGENT 5-FLUOROURACIL IN THE PALLIATIVE TREATMENT OF ADVANCED METASTATIC ADENOCARCINOMA OF THE COLON AND RECTUM.

LEDERLE LABS

GENERIC: LEUPEPTIN
TRADE: NOT ESTABLISHED

ADJUNCT TO MICROSURGICAL PERIPHERAL NERVE REPAIR.

LAWRENCE C. HURST, M.D.
STATE UNIVERSITY OF NEW YORK

GENERIC: LIOTHYRONINE INJECTION
TRADE: NOT ESTABLISHED

TREATMENT OF MYXEDEMA COMA/PRE-COMA.

SMITHKLINE BEECHAM

GENERIC: MAFENIDE ACETATE SOLUTION
TRADE: SULFAMYLOX

FOR USE IN THE PREVENTION OF GRAFT LOSS OF MESHD AUTOGRAFTS ON EXCISED BURN WOUNDS.

STERLING DRUG

GENERIC: MEFLOQUINE HCL
TRADE: LARIAM*/**

TREATMENT OF ACUTE MALARIA DUE TO PLASMODIUM FALCIPARUM AND PLASMODIUM VIVAX.*/** [MAY 02, 1996]
PROPHYLAXIS OF PLASMODIUM FALCIPARUM MALARIA WHICH IS RESISTANT TO OTHER AVAILABLE DRUGS.*/** [MAY 02, 1996]

ROCHE

GENERIC: METHOTREXATE USP WITH LAUROCAPRAM
TRADE: NOT ESTABLISHED

TOPICAL TREATMENT OF MYCOSIS FUNGOIDES.

WHITBY RES

GENERIC: MICROBUBBLE CONTRAST AGENT
TRADE: FILMIX (NEUROSONOGRAPHIC CONTRAST AGENT)

INTRAOPERATIVE AID IN THE IDENTIFICATION AND LOCALIZATION OF INTRACRANIAL TUMORS.

CAV-CON

GENERIC: MORPHINE SULFATE CONCENTRATE
TRADE: INFUMORPH

FOR USE IN MICROINFUSION DEVICES FOR INTRASPINAL ADMINISTRATION IN THE TREATMENT OF INTRACTABLE CHRONIC PAIN.

ELKINS SINN

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: N-ACETYL PROCAINAMIDE TRADE: NAPA	TO LOWER THE DEFIBRILLATION ENERGY REQUIREMENT SUFFICIENTLY TO ALLOW AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (AICD) THERAPY IN THOSE PATIENTS WHO COULD OTHERWISE NOT USE THE DEVICE.	MEDCO RES
GENERIC: OXANDROLONE TRADE: NOT ESTABLISHED	TREATMENT OF CONSTITUTIONAL DELAY OF GROWTH AND PUBERTY. TREATMENT OF SHORT STATURE ASSOCIATED WITH TURNER'S SYNDROME.	GYNEX
GENERIC: PEGADEMASE BOVINE TRADE: ADAGEN*/**	USE AS ENZYME REPLACEMENT THERAPY FOR ADENOSINE DEAMINASE (ADA) DEFICIENCY IN PATIENTS WITH SEVERE COMBINED IMMUNODEFICIENCY (SCID) WHO ARE NOT SUITABLE CANDIDATES FOR (OR WHO HAVE FAILED) BONE MARROW TRANSPLANTATION. [MAR 21, 1997]	ENZON
GENERIC: PILOCARPINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF XEROSTOMIA INDUCED BY RADIATION THERAPY FOR HEAD AND NECK CANCER.	MGI PHARMA
GENERIC: POLOXAMER 188 TRADE: RHEOTHRX COPOLYMER	TREATMENT OF SEVERE BURNS REQUIRING HOSPITALIZATION.	CYTRX
GENERIC: PR-122 (REDOX-PHENYTOIN) TRADE: NOT ESTABLISHED	FOR THE EMERGENCY RESCUE TREATMENT OF STATUS EPILEPTICUS, GRAND MAL TYPE.	PHARMATEC
GENERIC: PR-225 (REDOX ACYCLOVIR) TRADE: NOT ESTABLISHED	TREATMENT OF HERPES SIMPLEX ENCEPHALITIS IN INDIVIDUALS AFFLICTED WITH AIDS.	PHARMATEC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: PR-239 (REDOX-PENICILLIN G) TRADE: NOT ESTABLISHED	TREATMENT OF AIDS ASSOCIATED NEUROSYPHILIS.	PHARMATEC
GENERIC: PR-320 (MOLECUSOL-CARBAMAZEPINE) TRADE: NOT ESTABLISHED	FOR THE EMERGENCY RESCUE TREATMENT OF STATUS EPILEPTICUS, GRAND MAL TYPE.	PHARMATEC
GENERIC: RHEOTHRX TRADE: NOT ESTABLISHED	TREATMENT OF SEVERE BURNS IN HOSPITALIZED PATIENTS.	CYTRX
GENERIC: SERMORELIN ACETATE TRADE: GERE	AS AN ADJUNCT TO GONADOTROPIN THERAPY IN THE INDUCTION OF OVULATION IN WOMEN WITH ANOVULATORY OR OLIGO-OVULATORY INFERTILITY WHO FAIL TO OVULATE IN RESPONSE TO ADEQUATE TREATMENT WITH CLOMIPHENE CITRATE ALONE AND GONADOTROPIN THERAPY ALONE.	SERONO LABS
GENERIC: SHORT CHAIN FATTY ACID SOLUTION TRADE: NOT ESTABLISHED	TREATMENT OF THE ACTIVE PHASE OF ULCERATIVE COLITIS WITH INVOLVEMENT RESTRICTED TO THE LEFT SIDE OF THE COLON.	RICHARD I. BREUER EVANSTON HOSP
GENERIC: SK&F 110679 TRADE: NOT ESTABLISHED	LONG TERM TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE DUE TO A LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION.	SK&F LABS
GENERIC: SODIUM DICHLOROACETATE TRADE: NOT ESTABLISHED	TREATMENT OF CONGENITAL LACTIC ACIDOSIS. TREATMENT OF HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA.	PETER STACPOOLE, M.D., PH.D. UNIVERSITY OF FLORIDA

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: SOMATROPIN TRADE: HUMATROPE	TREATMENT OF SHORT STATURE ASSOCIATED WITH TURNER'S SYNDROME.	LILLY
GENERIC: SUCRALFATE TRADE: NOT ESTABLISHED	TREATMENT OF ORAL COMPLICATIONS OF CHEMOTHERAPY IN BONE MARROW TRANSPLANT RECIPIENTS.	NASKA PHARMA
GENERIC: SULFAPYRIDINE TRADE: NOT ESTABLISHED	TREATMENT OF DERMATITIS HERPETIFORMIS.	JACOBUS PHARM
GENERIC: THALIDOMIDE TRADE: NOT ESTABLISHED	TREATMENT OF GRAFT VERSUS HOST DISEASE (GVHD) IN PATIENTS RECEIVING BONE MARROW TRANSPLANTATION (BMT). PREVENTION OF GVHD IN PATIENTS RECEIVING BMT.	ANDRULIS RES
GENERIC: TRIPTORELIN PAMOATE TRADE: DECAPEPTYL INJECTION	FOR USE IN THE PALLIATIVE TREATMENT OF ADVANCED OVARIAN CARCINOMA OF EPITHELIAL ORIGIN.	ORGANON
GENERIC: 2-CHLORODEOXYADENOSINE TRADE: NOT ESTABLISHED	TREATMENT OF HAIRY CELL LEUKEMIA. TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA.	RW JOHNSON
GENERIC: 2-CHLORO-2'-DEOXYADENOSINE TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE MYELOID LEUKEMIA.	ST JUDE CHILDRENS
GENERIC: 2,3-DIMERCAPTOSUCCINIC ACID TRADE: CHEMET	PREVENTION OF CYSTINE KIDNEY STONE FORMATION IN PATIENTS WITH HOMOZYGOUS CYSTINURIA WHO ARE PRONE TO STONE DEVELOPMENT.	MCNEIL CONSUMER

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG

DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]

SPONSOR NAME

GENERIC: 3,4-DIAMINOPYRIDINE
TRADE: NOT ESTABLISHED

TREATMENT OF LAMBERT-EATON MYASTHENIC SYNDROME.

JACOBUS PHARM

GENERIC: 566C80
TRADE: NOT ESTABLISHED

TREATMENT OF AIDS ASSOCIATED PNEUMOCYSTIS CARINII
PNEUMONIA (PCP).

BURROUGHS WELLC

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
TOLMETIN SODIUM TABLET; ORAL	EQ 400MG BASE	90 P-0011/CP	QUANTUM PHARMCS	NEW STRENGTH	APPROVED MAY 03, 1990
VERAPAMIL HYDROCHLORIDE TABLET, EXTENDED RELEASE; ORAL	120MG	89 P-0220/CP	LEDERLE LABS	NEW STRENGTH	APPROVED JAN 11, 1990

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CLONIDINE HYDROCHLORIDE CAPSULE, EXTENDED RELEASE; ORAL	0.2MG	88 P-0365/CP	BOEHR INGEL	NEW DOSAGE FORM	DENIED JAN 11, 1990

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 10TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEUDLE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES NEW INDICATION

- I-41 MIGRAINE HEADACHE PROPHYLAXIS
- I-42 HERPES ZOSTER
- I-43 HERPES SIMPLEX ENCEPHALITIS
- I-44 MAINTENANCE THERAPY IN HEALED DUODENAL ULCER PATIENTS AT DOSE OF 1 GRAM TWICE DAILY
- I-45 ACUTE TREATMENT OF VARICELLA ZOSTER VIRUS
- I-46 USE IN PEDIATRIC COMPUTED TOMOGRAPHIC HEAD AND BODY IMAGING
- I-47 TREATMENT OF PEDIATRIC PATIENTS WITH SYMPTOMATIC HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
- I-48 PEDIATRIC ANGIOCARDIOGRAPHY
- I-49 TREATMENT OF TRAVELERS' DIARRHEA DUE TO SUSCEPTIBLE STRAINS OF ENTEROTOXIGENIC
ESCHERICHIA COLI
- I-50 FOR USE IN WOMEN WITH AXILLARY NODE-NEGATIVE BREAST CANCER
- I-51 TREATMENT OF PRIMARY DYSMENORRHEA AND FOR THE TREATMENT OF IDIOPATHIC HEAVY MENSTRUAL BLOOD
LOSS
- I-52 PEDIATRIC EXCRETORY UROGRAPHY
- I-53 TREATMENT OF PANIC DISORDER, WITH OR WITHOUT AGORAPHOBIA
- I-54 RENAL CONCENTRATION CAPACITY TEST

REFERENCES PATENT USE CODE

- U-42 ADJUVANT TREATMENT IN COMBINATION WITH FLUOROURACIL AFTER SURGICAL RESECTION IN PATIENTS WITH
DUKES' STAGE C COLON CANCER
- U-43 MANAGEMENT OF CHRONIC PAIN IN PATIENTS REQUIRING OPIOID ANALGESIA

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
18828 001	ACYCLOVIR; ZOVIRAX				I-45	APR 20, 1993
19909 001	ACYCLOVIR; ZOVIRAX				I-45	APR 26, 1993
18603 001	ACYCLOVIR SODIUM; ZOVIRAX				I-43	FEB 09, 1993
18276 001	ALPRAZOLAM; XANAX	3980789	SEP 14, 1993		I-42	FEB 09, 1993
18276 002	ALPRAZOLAM; XANAX	3980789	SEP 14, 1993		I-53	NOV 06, 1993
18276 003	ALPRAZOLAM; XANAX	3980789	SEP 14, 1993		I-53	NOV 06, 1993
18276 004	ALPRAZOLAM; XANAX	3987052	OCT 19, 1993		I-53	NOV 06, 1993
>ADD>	19926 001				NCE	DEC 26, 1995
>ADD>	19155 001					
>DLT>	19188 001	4105783	APR 20, 1997			
>ADD>	18746 001				NC	APR 30, 1993
	19429 003				NC	OCT 26, 1993
	18240 004					
		3934032	JAN 20, 1993	U-3		
		3836671	SEP 17, 1991	U-39	I-39	SEP 13, 1992
		3836671	SEP 17, 1991	U-8		
72303 001	ATENOLOL; ATENOLOL	3934032	JAN 20, 1993	U-3	I-39	SEP 13, 1992
		3836671	SEP 17, 1991	U-39		
		3836671	SEP 17, 1991	U-8		
72304 001	ATENOLOL; ATENOLOL	3934032	JAN 20, 1993	U-3	I-39	SEP 13, 1992
		3836671	SEP 17, 1991	U-39		
		3836671	SEP 17, 1991	U-8		
>ADD>	20056 001				NDF	SEP 19, 1993
>ADD>	19001 001				NCE	DEC 28, 1995
>ADD>	19001 002				NCE	DEC 28, 1995
>ADD>	19001 003				NCE	DEC 28, 1995
>ADD>	19002 001				NCE	DEC 28, 1995
>ADD>	19002 002				NCE	DEC 28, 1995
>ADD>	19002 003				NCE	DEC 28, 1995
>ADD>	19845 001				NDF	DEC 29, 1992
>ADD>	19976 001				NDF	DEC 10, 1993
>ADD>					ODE	DEC 10, 1997
19880 001	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998			
19880 002	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998			
19880 003	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998			
19972 001	CARTEOLOL HYDROCHLORIDE; OPTIPRESS	4309432	JAN 05, 1999		NDF	MAY 23, 1993
		3910924	OCT 07, 1994		NCE	DEC 28, 1993

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20044 001	CETYL ALCOHOL; EXOSURF NEONATAL	4826821	MAY 02, 2006		ODE	AUG 02, 1997
>ADD>		4312860	JAN 26, 1999		NC	AUG 02, 1993
>DLT>		4312860	JAN 26, 1999		NCE	AUG 02, 1993
>ADD>	19847 001 CIPROFLOXACIN; CIPRO	4670444	JUN 02, 2004		NCE	OCT 22, 1992
>ADD>	19857 001 CIPROFLOXACIN; CIPRO IN DEXTROSE 5%	4670444	JUN 02, 2004		NCE	OCT 22, 1992
>ADD>	19857 002 CIPROFLOXACIN; CIPRO IN DEXTROSE 5%	4670444	JUN 02, 2004		NCE	OCT 22, 1992
>ADD>	19858 001 CIPROFLOXACIN; CIPRO IN SODIUM CHLORIDE 0.9%	4670444	JUN 02, 2004		NCE	OCT 22, 1992
>ADD>	19858 002 CIPROFLOXACIN; CIPRO IN SODIUM CHLORIDE 0.9%	4670444	JUN 02, 2004		NCE	OCT 22, 1992
>ADD>	19992 001 CIPROFLOXACIN HYDROCHLORIDE; CILOXAN	4670444	JUN 02, 2004		NDF	DEC 31, 1993
>ADD>					NCE	OCT 22, 1992
	19481 001 CITRIC ACID; RENACIDIN				ODE	OCT 02, 1997
	19966 001 CLOBETASOL PROPIONATE; TEMOVATE	3721687	MAR 20, 1992		NP	FEB 22, 1993
	19966 001 CLOBETASOL PROPIONATE; TEMOVATE				NCE	DEC 27, 1990
>ADD>	19849 001 DAPIPRAZOLE HYDROCHLORIDE; REV-EYES				NCE	DEC 31, 1995
>ADD>	19776 001 DESMOPRESSIN ACETATE; CONCENTRAID				I-54	DEC 26, 1993
>ADD>	19817 001 DIPYRIDAMOLE; IV PERSANTINE				NDF	DEC 13, 1993
	19668 001 DOXAZOSIN MESYLATE; CARDURA				NCE	NOV 02, 1995
	19668 002 DOXAZOSIN MESYLATE; CARDURA				NCE	NOV 02, 1995
	19668 003 DOXAZOSIN MESYLATE; CARDURA				NCE	NOV 02, 1995
	19668 004 DOXAZOSIN MESYLATE; CARDURA				NCE	NOV 02, 1995
	19879 002 EFLORNITHINE HYDROCHLORIDE; ORNIDYL	4413141	NOV 01, 2000		ODE	NOV 28, 1997
		4339151	AUG 16, 2000		NCE	NOV 28, 1995
>ADD>	19080 001 ESTAZOLAM; PROSOM	3987052	OCT 19, 1993		NCE	DEC 26, 1995
>ADD>	19080 002 ESTAZOLAM; PROSOM	3987052	OCT 19, 1993		NCE	DEC 26, 1995
	19653 001 ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1996		NC	DEC 29, 1992
	19653 002 ETHINYL ESTRADIOL; ORTHO CYCLEN-28	4027019	MAY 31, 1996		NC	DEC 29, 1992
	19813 001 FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43		
		4144317	SEP 09, 1992			
		4060084	JUN 28, 1994	U-43		
					NDF	AUG 07, 1993
19813 002	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43		
		4144317	SEP 09, 1992			
		4060084	JUN 28, 1994	U-43		
					NDF	AUG 07, 1993

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19813 003	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43		
		4144317	SEP 09, 1992			
		4060084	JUN 28, 1994	U-43		
19813 004	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43	NDF	AUG 07, 1993
		4144317	SEP 09, 1992			
		4060084	JUN 28, 1994	U-43		
19949 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		NDF	AUG 07, 1993
		4404216	SEP 13, 2000		NCE	JAN 29, 1995
19949 002	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		NCE	JAN 29, 1995
		4404216	SEP 13, 2000		NCE	JAN 29, 1995
19949 003	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		NCE	JAN 29, 1995
		4404216	SEP 13, 2000		NCE	JAN 29, 1995
19950 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		NCE	JAN 29, 1995
		4404216	SEP 13, 2000		NDF	AUG 27, 1993
20001 001	FLUOCINOLONE ACETONIDE; FS SHAMPOO					
18554 001	FLUTAMIDE; EULEXIN	4329364	MAY 11, 2001	U-23		
>ADD> 19957 001	FLUTICASONE PROPIONATE; CUTIVATE	4335121	JUN 15, 1999		NCE	DEC 14, 1995
>ADD> 19958 001	FLUTICASONE PROPIONATE; CUTIVATE	4335121	JUN 15, 1999		NCE	DEC 14, 1995
19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST	4963344	MAR 03, 2004		I-38	AUG 10, 1992
		4957939	MAR 03, 2004		I-31	APR 28, 1992
19661 001	GANCICLOVIR SODIUM; CYTOVENE	4355032	MAR 16, 2003	U-33	NCE	JUN 23, 1994
>ADD> 19726 001	GOSERELIN ACETATE; ZOLADEX	4100274	JUL 10, 1997		NCE	DEC 29, 1994
>DLT> 19726 001	GOSERELIN ACETATE; ZOLADEX	4100274	JUL 10, 1997		NCE	DEC 29, 1994
19032 001	GUANFACINE HYDROCHLORIDE; TENEX	3632645	OCT 26, 1990		NCE	OCT 27, 1991
19032 002	GUANFACINE HYDROCHLORIDE; TENEX	3632645	OCT 26, 1990		NCE	OCT 27, 1991
19032 003	GUANFACINE HYDROCHLORIDE; TENEX	3632645	OCT 26, 1990		NCE	OCT 27, 1991
17556 001	HALCINONIDE; HALOG	3892857	JUL 01, 1992			
17818 001	HALCINONIDE; HALOG	3892857	JUL 01, 1992			
17824 001	HALCINONIDE; HALOG	3892856	JUL 01, 1992			
18234 001	HALCINONIDE; HALOG-E	4048310	SEP 13, 1994			
>ADD> 19967 001	HALOBETASOL PROPIONATE; ULTRAVATE				NCE	DEC 17, 1995
>ADD> 19968 001	HALOBETASOL PROPIONATE; ULTRAVATE				NCE	DEC 17, 1995

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
50661 001	IDARUBICIN HYDROCHLORIDE; IDAMYCIN				ODE	SEP 27, 1997
50661 002	IDARUBICIN HYDROCHLORIDE; IDAMYCIN				ODE	SEP 27, 1997
>ADD> 19693 001	INDECAINIDE HYDROCHLORIDE; DECABID	4452745	JUN 05, 2003		NCE	DEC 29, 1994
>DLT> 19693 001	INDECAINIDE HYDROCHLORIDE; DECABID	4452745	JUN 05, 2003		NCE	DEC 29, 1994
>ADD> 19693 002	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000		NCE	DEC 29, 1994
>DLT> 19693 002	INDECAINIDE HYDROCHLORIDE; DECABID	4452745	JUN 05, 2003		NCE	DEC 29, 1994
>ADD> 19693 003	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000		NCE	DEC 29, 1994
>DLT> 19693 003	INDECAINIDE HYDROCHLORIDE; DECABID	4452745	JUN 05, 2003		NCE	DEC 29, 1994
18956 002	IOHEXOL; OMNIPAQUE 240	4382093	MAY 03, 2000			
18735 002	IOPAMIDOL; ISOVUE-300	4021481	MAY 03, 1994			
18735 003	IOPAMIDOL; ISOVUE-370				I-46	MAY 30, 1993
>ADD> 19580 001	IOTROLAN; OSMOVIST	4239747	DEC 16, 2001		I-52	SEP 21, 1993
>DLT> 19580 001	IOTROLAN; OSMOVIST	4239747	DEC 16, 2001		I-48	OCT 04, 1992
>ADD> 19580 002	IOTROLAN; OSMOVIST	4239747	DEC 16, 2001		NCE	DEC 07, 1994
>DLT> 19580 002	IOTROLAN; OSMOVIST	4239747	DEC 16, 2001		NCE	DEC 07, 1994
>ADD> 19546 001	ISRADIPINE; DYNACIRC	4239747	DEC 16, 2001		NCE	DEC 07, 1994
>ADD> 19546 002	ISRADIPINE; DYNACIRC				NCE	DEC 20, 1995
19927 001	KETOCONAZOLE; NIZORAL	4335125	JUN 15, 1999		NCE	DEC 20, 1995
>ADD> 19698 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997		NDF	AUG 31, 1993
>DLT> 19698 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997		NCE	NOV 30, 1994
>ADD> 19698 002	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997		NCE	NOV 30, 1994
>DLT> 19698 002	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997		NCE	NOV 30, 1994
>ADD> 19698 003	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997		NCE	NOV 30, 1994
>DLT> 19698 003	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997		NCE	NOV 30, 1994
20011 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4005063	JAN 25, 1996		NP	OCT 22, 1993
20035 001	LEVAMISOLE HYDROCHLORIDE; ERGAMISOL	4584305	APR 22, 2003		NP	OCT 22, 1993
>ADD> 19897 001	LEVONORGESTREL; NORPLANT	3959322	NOV 26, 1991	U-42	NCE	JUN 18, 1995
>ADD> 20088 001	LEVONORGESTREL; LEVONORGESTREL SYSTEM	3850911	NOV 26, 1991		NP	DEC 10, 1993
18006 001	MECLOFENAMATE SODIUM; MECLOMEN				NP	DEC 10, 1993
18006 002	MECLOFENAMATE SODIUM; MECLOMEN				I-51	JUL 23, 1993
19591 001	MEFLOQUINE HYDROCHLORIDE; LARIAM				I-51	JUL 23, 1993
>ADD> 19919 001	MESALAMINE; ROWASA				ODE	MAY 02, 1996
>ADD> 19907 001	METIPRANOLOL HYDROCHLORIDE; OPTIPRANOLOL				NCE	DEC 24, 1992
					NDF	DEC 18, 1993
					NCE	DEC 29, 1994

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PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19786 001	METOPROLOL FUMARATE; LOPRESSOR	3916899	NOV 04, 1992			
		3845770	NOV 05, 1991			
19786 002	METOPROLOL FUMARATE; LOPRESSOR	3916899	NOV 04, 1992			
		3845770	NOV 05, 1991			
19786 003	METOPROLOL FUMARATE; LOPRESSOR	4892739	JAN 09, 2007			
		3916899	NOV 04, 1992			
		3845770	NOV 05, 1991			
19786 004	METOPROLOL FUMARATE; LOPRESSOR	4892739	JAN 09, 2007			
19786 004	METOPROLOL FUMARATE; LOPRESSOR	3916899	NOV 04, 1992			
		3845770	NOV 05, 1991			
19753 001	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1992			
		3740395	JUN 19, 1990		NCE	JUN 19, 1995
19753 002	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1992			
		3740395	JUN 19, 1990		NCE	JUN 19, 1995
19753 003	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1992			
		3740395	JUN 19, 1990		NCE	JUN 19, 1995
>ADD>	19886 001 NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1999		NCE	FEB 13, 1995
>DLT>	19886 001 NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1999		NCE	FEB 13, 1995
	19356 001 NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 1998		NCE	MAR 01, 1993
					NDF	JUN 18, 1993
	19599 001 NAFTIFINE HYDROCHLORIDE; NAFTIN				D-1	JUL 05, 1993
	72409 001 NIFEDIPINE; NIFEDIPINE				PC	MAR 02, 1991
>ADD>	19735 001 OFLOXACIN; FLOXIN	4382892	MAY 10, 2000		NCE	DEC 28, 1995
>ADD>	19735 002 OFLOXACIN; FLOXIN	4382892	MAY 10, 2000		NCE	DEC 28, 1995
>ADD>	19735 003 OFLOXACIN; FLOXIN	4382892	MAY 10, 2000		NCE	DEC 28, 1995
	19715 001 OLSALAZINE SODIUM; DIPENTUM				NCE	JUL 31, 1995
	19810 001 OMEPRAZOLE; PRILOSEC	4255431	MAR 10, 2002			
	19818 001 PEGADEMASE BOVINE; ADAGEN	4179337	DEC 18, 1996		ODE	MAR 21, 1997
					NCE	MAR 21, 1995
	19918 001 PERMETHRIN; NIX	4024163	MAY 17, 1996		NCE	MAR 31, 1991
	19638 001 PIPECURONIUM BROMIDE; ARDUAN				NCE	JUN 26, 1995
	87361 001 PROCAINAMIDE HYDROCHLORIDE; PRONESTYL-SR	4252786	FEB 24, 1998			
	19627 001 PROPOFOL; DIPRIVAN	4056635	NOV 01, 1998		NCE	OCT 02, 1994
>ADD>	19414 001 RUBIDIUM CHLORIDE RB-82; CARDIOGEN-82	4400358	AUG 23, 2002		NCE	DEC 29, 1994
>DLT>	19414 001 RUBIDIUM CHLORIDE RB-82; CARDIOGEN-82	4400358	AUG 23, 2002		NCE	DEC 29, 1994
>ADD>	19863 001 SERMORELIN ACETATE; GEREF				NCE	DEC 28, 1995
	10929 001 SODIUM IODIDE, I-131; IODOTOPE	4349529	SEP 14, 1999			
	10929 002 SODIUM IODIDE, I-131; IODOTOPE	4349529	SEP 14, 1999			
	10929 003 SODIUM IODIDE, I-131; IODOTOPE	4349529	SEP 14, 1999			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
18333 001	SUCRALFATE; CARAFATE				I-44	MAY 11, 1993
17376 001	SULFAMETHOXAZOLE; SEPTRA	4209513	JUN 24, 1997		I-49	JUN 15, 1993
17376 002	SULFAMETHOXAZOLE; SEPTRA DS	4209513	JUN 24, 1997		I-49	JUN 15, 1993
17377 001	SULFAMETHOXAZOLE; BACTRIM				I-49	JUN 15, 1993
17377 002	SULFAMETHOXAZOLE; BACTRIM DS				I-49	JUN 15, 1993
17560 001	SULFAMETHOXAZOLE; BACTRIM				I-49	JUN 15, 1993
17560 002	SULFAMETHOXAZOLE; BACTRIM PEDIATRIC				I-49	JUN 15, 1993
17598 001	SULFAMETHOXAZOLE; SEPTRA				I-49	JUN 15, 1993
17598 002	SULFAMETHOXAZOLE; SEPTRA GRAPE				I-49	JUN 15, 1993
17970 001	TAMOXIFEN CITRATE; NOLVADEX	4536516	AUG 20, 2002		I-50	JUN 21, 1993
18107 001	TECHNETIUM TC-99M MEDRONATE KIT; MDP-SQUIBB	4115541	SEP 19, 1995			
19882 001	TECHNETIUM TC-99M MERTIATIDE KIT; TECHNISCAN MAG3				NCE	JUN 15, 1995
>ADD> 19785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE				NCE	DEC 21, 1995
>ADD> 19785 002	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE				NCE	DEC 21, 1995
17339 001	TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR; MINITEC	4041317	AUG 09, 1994			
		3920995	NOV 18, 1992			
		4705849	NOV 10, 2004			
>ADD> 19928 001	TECHNETIUM TC-99M TEBOROXIME KIT; CARDIOTEC				NCE	DEC 19, 1995
18017 001	TIMOLOL MALEATE; BLOCADREN				I-41	MAR 03, 1993
18017 002	TIMOLOL MALEATE; BLOCADREN				I-41	MAR 03, 1993
18017 004	TIMOLOL MALEATE; BLOCADREN				I-41	MAR 03, 1993
19614 001	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993
19614 002	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993
19655 001	ZIDOVUDINE; RETROVIR	4837208	FEB 02, 2005			
		4833130	FEB 02, 2005		I-47	MAY 02, 1993
		4828838	FEB 02, 2005		ODE	MAR 19, 1994
		4724232	FEB 02, 2005		NCE	MAR 19, 1992
19910 001	ZIDOVUDINE; RETROVIR	4837208	FEB 02, 2005			
		4833130	FEB 02, 2005		ODE	MAR 19, 1994
		4818538	FEB 02, 2005		I-47	MAY 02, 1993
		4724232	FEB 02, 2005		NCE	MAR 19, 1992
19951 001	ZIDOVUDINE; RETROVIR	4837208	FEB 02, 2005			
		4833130	FEB 02, 2005		NCE	MAR 19, 1992
		4818538	FEB 02, 2005			
		4724232	FEB 02, 2005		ODE	MAR 19, 1994

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