

CUMULATIVE
SUPPLEMENT 5

JAN'95-MAY'95

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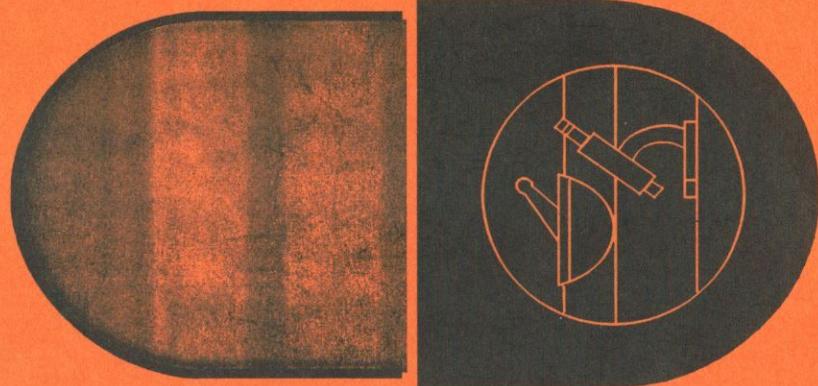
APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

15TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT
DIVISION OF DRUG INFORMATION RESOURCES



RM
301.45
.A66
1995
May 15
Suppl

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Prepared By
Division of Drug Information Resources
Office of Management
Center for Drug Evaluation and Research, FDA

1.0
1.1
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2.0
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PATE

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APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS

15TH EDITION

Cumulative Supplement 5

MAY 1995

RM301.45 .A66 1995 May Suppl

Approved drug products with
therapeutic equivalence

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

15TH EDITION

CUMULATIVE SUPPLEMENT 5
MAY 1995

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, 15th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

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.)

Additions new 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.

Deletions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >**DLT**> (DELETE) to the left of the line containing shaded print. 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 for this edition. However, the shaded print in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements.

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 15th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 16th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required

to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the appropriate Drug Product List.

<u>Products</u>	<u>Federal Register Reference</u>
Nitroglycerin (capsule, controlled release;oral)	SEP 07, 1984 (49 FR 35428)
Nitroglycerin (film, extended release; transdermal*)	JUL 15, 1993 (58 FR 38129)
Nitroglycerin (tablet, controlled release;oral)	SEP 07, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 05, 1985 (50 FR 27688)

*The Federal Register of July 15, 1993 (58 FR 38129) announced that the FDA was revoking the temporary exemption for nitroglycerin in a transdermal delivery system. Marketing of a drug product that is the subject of a conditionally approved ANDA may continue by meeting the requirements listed in the Federal Register. Firms wishing to submit a new ANDA before a drug product is approved (NDA or ANDA) and appears in the List should submit a 505(b)(2) application following the directions contained in the Federal Register. Nitro-Dur has been selected as the reference listed drug. The preamble to the final rule (57 FR 17958) states if there are multiple NDA's, the reference listed drug generally will be the market leader. This is the basis upon which Nitro-Dur was selected. In addition, the preamble states that, in multiple NDA situations, a product not designated as the reference listed drug and not shown to be bioequivalent to the reference listed drug may be shielded from generic competition. This is the case with Summit's Transderm-Nitro. The Office of Generic Drugs (OGD) has been requested to have a second listed drug as provided for in the Final Rule. OGD has granted this request. Therefore, at the time that Schering's and Summit's supplements are fully approved and their products are entered into the List, we will have two reference listed drugs for the nitroglycerin transdermal systems. Firms may, therefore, elect to conduct bioequivalence studies against either of these products. It is conceivable that a non-referenced listed drug may be fully approved and appear in the List; in this case, the Agency's referenced listed drug will not change and a 505(b)(2) application will be appropriate until the reference listed drugs are fully approved. Once they are fully approved, a 505(j) application will be the appropriate mechanism for an ANDA submission.

1.3 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation

of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will automatically 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. However, when the applicant name change is one which may not be easily recognized or located in the listing (e.g., White Towne Paulsen [Former Abbreviated Name] is changed to Whiteworth Towne [New Abbreviated Name], the name change will appear in this section and will be identified with an asterisk.

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)

BOOTS PHARMACEUTICALS INC
(BOOTS)

BRIAN PHARMACEUTICALS INC
(BRIAN)

DORSEY LABORATORIES DIV
SANDOZ WANDER INC
(DORSEY)

MILES PHARMACEUTICAL DIV
MILES INC
(MILES)

PENNEX PHARMACEUTICALS INC
(PENNEX)

TAP PHARMACEUTICALS INC
(TAP PHARMS)

NEW APPLICANT NAME (NEW ABBREVIATED NAME)

KNOLL PHARMACEUTICAL COMPANY
SUB BASF CORPORATION
(KNOLL PHARM)

HYGENICS PHARMACEUTICALS INC
(HYGENICS)

SANDOZ CONSUMER HEALTH CARE
GROUP DIV SANDOZ
PHARMACEUTICALS CORP
(SANDOZ)

BAYER CORPORATION
(BAYER)

MORTON GROVE PHARMACEUTICALS INC
(MORTON GROVE)

TAP HOLDINGS INC
(TAP HOLDINGS)

1.4 AVAILABILITY OF THE PUBLICATION AND UPDATING PROCEDURES

The *Approved Drug Products with Therapeutic Equivalence Evaluations* (Prescription Drug Products, OTC Drug Products and the Discontinued Drug Product Lists) is now available on diskette, on a quarterly basis, from the National Technical Information Service. The telephone number for the Subscription Department is (703) 487-6430. Written inquiries regarding this subscription may be forwarded to 5285 Port Royal Road Springfield, VA 22161.

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 sections 505 and 507 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 1994) 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 1994</u>	<u>MAR 1995</u>	<u>JUN 1995</u>	<u>SEP 1995</u>
DRUG PRODUCTS LISTED	9141	9195		
SINGLE SOURCE	2178 (23.8%)	2186 (23.8%)		
MULTI-SOURCE	6963 (76.2%)	7009 (76.2%)		
THERAPEUTICALLY EQUIVALENT	6330 (69.2%)	6380 (69.4%)		
NOT THERAPEUTICALLY EQUIVALENT	453 (5.0%)	453 (4.9%)		
EXCEPTIONS ¹	180 (2.0%)	176 (1.9%)		
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	534	541		

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

AMPICILLIN SODIUMINJECTABLE; INJECTION

AMPICILLIN SODIUM
@ CONSOLIDATED PHARM EQ 125MG BASE/VIAL
@ EQ 250MG BASE/VIAL
@ EQ 500MG BASE/VIAL
@ EQ 1GM BASE/VIAL
@ EQ 2GM BASE/VIAL
@ EQ 125MG BASE/VIAL
@ EQ 250MG BASE/VIAL
@ EQ 500MG BASE/VIAL
@ EQ 1GM BASE/VIAL
@ EQ 2GM BASE/VIAL

N61936 005
N61936 001
N61936 002
N61936 003
N61936 004
N61936 005
N61936 001
N61936 002
N61936 003
N61936 004

AMPICILLIN/AMPICILLIN TRIHYDRATECAPSULE; ORALAMPICILLIN TRIHYDRATE

CONSOLIDATED PHARM EQ 250MG BASE
EQ 500MG BASE
EQ 250MG BASE
EQ 500MG BASE

N61602 001
N61602 002
N61602 001
N61602 002

POWDER FOR RECONSTITUTION; ORALAMPICILLIN TRIHYDRATE

CONSOLIDATED PHARM EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
COPANOS EQ 500MG BASE/5ML
POLYCILLIN EQ 500MG BASE/5ML
BRISTOL EQ 500MG BASE/5ML
+ EQ 500MG BASE/5ML

N61601 001
N61601 002
N61601 001
N61601 002
N50308 003
N50308 003

ANTAZOLINE PHOSPHATE; NAPHAZOLINE HYDROCHLORIDE

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

SOLUTION/DROPS; OPHTHALMIC
VISOCON-A
+ CIBA VISION 0.5% 0.05%

N18746 001
APR 30, 1990

ASPIRIN; METHOCARBAMOL
TABLET; ORAL
METHOCARBAMOL AND ASPIRIN
325MG; 400MG

N81145 001
JAN 31, 1995

ATENOLOLTABLET; ORALATENOLOLCOPLEY PHARM

5.0MG
100MG
5.0MG
100MG
5.0MG
100MG
5.0MG
100MG

ATOVAQUONE

SUSPENSION; ORAL
MEPRON
+ BURROUGHS WELLCOME

750MG/5ML

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION
AZATHIOPRINE SODIUM
BEDFORD
AP
IMURAN
AP + BURROUGHS WELLCOME

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
BACITRACIN ZINC AND POLYMYXIN B SULFATE
ADV REMEDIES
AT
BAUSCH AND LOMB
AT + POLYSPORIN
500 UNITS/GM;
10,000 UNITS/GM
500 UNITS/GM;
10,000 UNITS/GM

N64028 001
JAN 30, 1995
N64046 001
JAN 26, 1995
N61229 001
JAN 31, 1995

BENDROFLUMETHIAZIDE

TABLET; ORAL

NATURETIN-1.0	1.0MG	N12164 003	> ADD >	AP	+	MARCAINE HCL	0.25%
+ APOTHECON	1.0MG	N12164 003	> ADD >	AP	+	SANOFI WINTHROP	0.5%
* SQUIBB			> ADD >	AP	+		
NATURETIN-2.5	2.5MG	N12164 001	> ADD >	AP	+		0.75%
@ APOTHECON	2.5MG	N12164 001	> DLT >	AP	*	STERLING WINTHROP	0.25%
* SQUIBB			> DLT >	AP	*		
NATURETIN-5	5MG	N12164 002	> DLT >	AP	*		0.5%
APOTHECON	5MG	N12164 002	> DLT >	AP	*		0.75%
SQUIBB							

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

MARCAINE HCL	0.25%; 0.0091MG/ML	N16964 004
+ SANOFI WINTHROP	0.5%; 0.0091MG/ML	N16964 008
AP	+ SANOFI WINTHROP	N16964 009
AP	+ SANOFI WINTHROP	N16964 009
AP	+ SANOFI WINTHROP	N16964 009
AP	+ SANOFI WINTHROP	N16964 009
AP	+ SANOFI WINTHROP	N16964 009
AP	+ SANOFI WINTHROP	N16964 009
AP	+ SANOFI WINTHROP	N16964 009
AP	+ SANOFI WINTHROP	N16964 009

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLLOL	50MG/ML	N17954 001	> ADD >	AP	+	MARCAINE HCL W/ EPINEPHRINE	0.25%; 0.0091MG/ML
DUPONT MERCK	50MG/ML	N17954 001	> ADD >	AP	+		0.5%; 0.0091MG/ML
FAULDING			> DLT >	AP	*		0.75%; 0.0091MG/ML
			> DLT >	AP	*		0.25%; 0.0091MG/ML
			> DLT >	AP	*		0.5%; 0.0091MG/ML
			> DLT >	AP	*		0.75%; 0.0091MG/ML

BUMETANIDE

INJECTABLE; INJECTION

BUMETANIDE	0.25MG/ML	N74441 001	JAN 27, 1995	AP	+	CALCITONIN, SALMON	200 IU/ML
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TABLET; ORAL

BUMETANIDE	0.5MG	N74225 001	APR 24, 1995	AB	+	CAPTOPRIL	N73690 001
ZENITH LABS	1MG	N74225 002	APR 24, 1995	AB	+		APR 14, 1995
	2MG	N74225 003	APR 24, 1995	AB	+		

BUMETANIDE

AB	0.5MG	N18225 002	FEB 28, 1983	AB	+ CAPTOPRIL	N18343 005
AB	1MG	N18225 001	FEB 28, 1983	AB	+ CAPTOPRIL	N18343 002
AB	2MG	N18225 003	JUN 14, 1985	AB	+ CAPTOPRIL	N18343 001
AB	2MG			AB	+ CAPTOPRIL	N18343 003
AB	2MG			AB	+ CAPTOPRIL	N74472 001
AB	2.5MG			AB	+ CAPTOPRIL	N74472 002
AB	5.0MG			AB	+ CAPTOPRIL	MAR 31, 1995
				AB	+ CAPTOPRIL	N74472 003
				AB	+ CAPTOPRIL	MAR 31, 1995

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL
AB APOTHECON 100MG

N74472 004
MAR 31, 1995

CARBACHOL

SOLUTION; INTRAOCULAR
CARBASTAT

AT CIBA 0.01%

N73677 001
APR 28, 1995

AT + MIOSTAT 0.01%

N16968 001
APR 28, 1995

CEFACLOR

CAPSULE; ORAL
CECLOR
AB + LILLY

AB AB + AB CEFACLOR
AB LEDERLE

EQ 250MG BASE
EQ 250MG BASE
EQ 500MG BASE
EQ 500MG BASE
EQ 250MG BASE

EQ 500MG BASE
EQ 250MG BASE
EQ 500MG BASE
EQ 500MG BASE
EQ 125MG BASE/5ML

N50521 001
N62205 001
N50521 002
N62205 002

N64107 001
APR 27, 1995

> DLT >

> ADD >

AP
APR 27, 1995

ZENITH LABS
CEFAZOLIN SODIUM
EPIKINS SINK

EQ 250MG BASE/VIAL
EQ 500MG BASE/VIAL

N50504 001
N50504 001

N50504 001
N50504 001

POWDER FOR RECONSTITUTION; ORAL

CECLOR
AB + LILLY

AB AB + AB CEFACLOR
AB LEDERLE

EQ 125MG BASE/5ML
EQ 125MG BASE/5ML
EQ 187MG BASE/5ML
EQ 250MG BASE/5ML
EQ 250MG BASE/5ML

EQ 250MG BASE/5ML
EQ 375MG BASE/5ML
EQ 375MG BASE/5ML

N62206 001
N62206 003
APR 20, 1988

N62206 002
N62206 002
N62206 002
N62206 002

N62206 004
APR 20, 1988

N64114 001
APR 28, 1995

N64115 001
APR 28, 1995

N64116 001
APR 28, 1995

N64110 001
APR 28, 1995

N64087 001
APR 28, 1995

N64086 001
APR 28, 1995

N64070 001
APR 28, 1995

CEFAZOLE NAFAZECEFAZOLE NAFAZEINJECTTABLE; INJECTION

MANDOL
+ LILLY

@

EQ 500MG BASE/VIAL
EQ 500MG BASE/VIAL
EQ 500MG BASE/VIAL
EQ 500MG BASE/VIAL

EQ 250MG BASE/VIAL
EQ 250MG BASE/VIAL
EQ 250MG BASE/VIAL

EQ 1GM BASE/VIAL
EQ 1GM BASE/VIAL
EQ 1GM BASE/VIAL

EQ 5GM BASE/VIAL
EQ 10GM BASE/VIAL
EQ 20GM BASE/VIAL

N62807 001
JAN 12, 1988

N62807 002
JAN 12, 1988

N62807 003
JAN 12, 1988

N62807 004
JAN 12, 1988

N62807 005
JAN 12, 1988

N62807 006
JAN 12, 1988

N62807 007
JAN 12, 1988

N62807 008
JAN 12, 1988

CEFAZOLE NAFAZEPOWDER FOR RECONSTITUTION; ORAL

CECLOR
AB + LILLY

AB + CEFACLOR
AB LEDERLE

EQ 125MG BASE/5ML
EQ 187MG BASE/5ML
EQ 375MG BASE/5ML

EQ 250MG BASE/5ML
EQ 250MG BASE/5ML
EQ 375MG BASE/5ML

N60522 001
N62206 001
N62206 003
APR 20, 1988

N60522 002
N62206 002
N62206 002

N62206 004
APR 20, 1988

N64114 001
APR 28, 1995

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

@ ELKINS SINN

EQ 1GM BASE/VIAL

N62807 003

JAN 12, 1988

@

EQ 5GM BASE/VIAL

N62807 004

JAN 12, 1988

@

EQ 10GM BASE/VIAL

N62807 005

JAN 12, 1988

@

EQ 20GM BASE/VIAL

N62807 006

JAN 12, 1988

@

EQ 40GM BASE/VIAL

N62807 007

JAN 12, 1988

> ADD >

> DLT >

> ADD >

> DLT >

> ADD >

> ADD >

> DLT >

> ADD >

CEFOXITIN SODIUM

INJECTABLE; INJECTION

MEPOXIN

+ MERCK SHARP DOHME

EQ 20MG BASE/ML

SEP 20, 1984

EQ 40MG BASE/ML

SEP 20, 1984

EQ 20MG BASE/ML

SEP 20, 1984

EQ 40MG BASE/ML

SEP 20, 1984

CEFOPERAZONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN

+ ROCHE

AP *

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

CEFRON

+ ROCHES

EQ 250MG BASE/VIAL

MAR 31, 1984

EQ 500MG BASE/VIAL

MAR 31, 1984

EQ 1GM BASE/VIAL

MAR 31, 1985

CEFUROXIME SODIUM

INJECTABLE; INJECTION

KEFROX

+ LILLY

AP *

<u>CEPHALEXIN</u>		<u>CHLORAMPHENICOL</u>	
> ADD >	<u>AB</u>	<u>POWDER FOR RECONSTITUTION; ORAL CEPHALEXIN APOTHECON</u>	<u>EQ 125MG BASE/5ML</u>
> ADD >	<u>AB</u>		<u>N62986 001 APR 18, 1991</u>
> ADD >	<u>AB</u>		<u>N62987 001 JUL 25, 1989</u>
> ADD >	<u>AB</u>		<u>N62986 001 APR 18, 1991</u>
> DLT >	<u>AB</u>	<u>SQUIBB MARK</u>	<u>EQ 125MG BASE/5ML</u>
> DLT >	<u>AB</u>		<u>N62987 001 APR 18, 1991</u>
> DLT >	<u>AB</u>		<u>N62987 001 JUL 25, 1989</u>
> DLT >	<u>AB</u>		<u>N63593 001 N86095 001 N86095 001</u>
		<u>CEPHRADINE</u>	
		<u>CAPSULE; ORAL VELOSEF</u>	<u>CHLORPROMAZINE HYDROCHLORIDE</u>
> ADD >	<u>AB</u>	<u>+ APOTHECON</u>	<u>250MG</u>
> ADD >	<u>AB</u>	<u>+ ERSANA</u>	<u>N61764 001 N61764 002 N61764 002</u>
> DLT >	<u>AB</u>	<u>* ERSANA</u>	<u>N85591 001 N85591 001</u>
> DLT >	<u>AB</u>		
		<u>INJECTABLE; INJECTION VELOSEF</u>	<u>CHLORPROMAZINE HYDROCHLORIDE</u>
> ADD >	<u>AB</u>	<u>+ APOTHECON</u>	<u>250MG/VIAL</u>
> ADD >	<u>AB</u>	<u>+ ERSANA</u>	<u>500MG 250MG 500MG</u>
> DLT >	<u>AB</u>	<u>* ERSANA</u>	<u>N61976 001 N61976 002 N61976 004</u>
> DLT >	<u>AB</u>		<u>N61976 003 N61976 005</u>
		<u>INJECTABLE; INJECTION VELOSEF</u>	<u>CHLORPROPAMIDE</u>
> ADD >	<u>AB</u>	<u>+ APOTHECON</u>	<u>250MG/VIAL</u>
> ADD >	<u>AB</u>	<u>+ ERSANA</u>	<u>500MG/VIAL 1GM/VIAL</u>
> ADD >	<u>AB</u>	<u>+ SQUIBB</u>	<u>2GM/VIAL</u>
> ADD >	<u>AB</u>		<u>4GM/VIAL</u>
> DLT >	<u>AB</u>		<u>250MG/VIAL</u>
> DLT >	<u>AB</u>		<u>500MG/VIAL</u>
> DLT >	<u>AB</u>		<u>1GM/VIAL</u>
> DLT >	<u>AB</u>		<u>2GM/VIAL</u>
> DLT >	<u>AB</u>		<u>4GM/VIAL</u>
> DLT >	<u>AB</u>		<u>N61976 004 N61976 003 N61976 005</u>
		<u>POWDER FOR RECONSTITUTION; ORAL VELOSEF '125, APOTHECON</u>	<u>CHLORPROPAamide</u>
> ADD >	<u>AB</u>	<u>+ ERSANA</u>	<u>125MG/5ML 125MG/5ML</u>
> DLT >	<u>AB</u>	<u>* ERSANA</u>	<u>N61763 001</u>
> ADD >	<u>AB</u>	<u>VELOSEF '250, APOTHECON</u>	<u>N61763 002 N61763 002</u>
> DLT >	<u>AB</u>	<u>* ERSANA</u>	<u>N71621 001 N71621 001 N71621 001</u>
		<u>CHLORAMPHENICOL</u>	
		<u>CAPSULE; ORAL MYCHEL</u>	<u>EQ 4GM RESIN/BAR</u>
			<u>EQ 4GM RESIN/BAR</u>
			<u>* PARKE DAVIS</u>
			<u>MAY 26, 1988 N71739 001 MAY 26, 1988</u>
		<u>ARMENPHARM</u>	<u>N60851 001</u>
			<u>250MG</u>

CHOLESTYRAMINE

BAR, CHEWABLE; ORAL
CHOLYBAR
 @ PARKE DAVIS

EQ 4 GM RESIN/BAR
 EQ 4 GM RESIN/BAR

TABLET; ORAL
 QUESTRAN
 * BRISTOL MYERS SQUIBB

EQ 1GM RESIN
 @
 EQ 1GM RESIN

CIMETIDINE

<u>TABLET; ORAL</u>	<u>CIMETIDINE</u>	<u>200MG</u>	N74100 001 JAN 31, 1995
		<u>300MG</u>	N74100 002 JAN 31, 1995
		<u>400MG</u>	N74100 003 JAN 31, 1995
		<u>800MG</u>	N74100 004 JAN 31, 1995
		<u>200MG</u>	N74365 001 FEB 28, 1995
		<u>300MG</u>	N74365 002 FEB 28, 1995
		<u>400MG</u>	N74365 003 FEB 28, 1995
		<u>800MG</u>	N74365 004 FEB 28, 1995
		<u>200MG</u>	N74401 001 MAY 30, 1995
		<u>300MG</u>	N74401 002 MAY 30, 1995
		<u>400MG</u>	N74401 003 MAY 30, 1995
		<u>800MG</u>	N74402 001 MAY 30, 1995

TABLET; ORAL
CIMETIDINE

GENEVA PHARMS

@
 EQ 1GM RESIN

N50537 002
FEB 22, 1994

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
CIMETIDINE HCL

<u>AT</u>	<u>AP</u>	<u>EQ 300MG BASE/2ML</u>	N74344 001 JAN 31, 1995
	<u>AP</u>	<u>EQ 300MG BASE/2ML</u>	N74345 001 JAN 31, 1995
	<u>AP</u>	<u>EQ 300MG BASE/2ML</u>	N74422 001 JAN 31, 1995

N50537 002
FEB 22, 1994

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL
CLINDAMYCIN

<u>UPJOHN</u>	<u>UPJOHN</u>	<u>EQ 1% BASE</u>	N50537 002 FEB 22, 1994
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N50537 002
FEB 22, 1994

CLOTECIN

SWAB; TOPICAL
CLOTECIN

<u>UPJOHN</u>	<u>UPJOHN</u>	<u>EQ 1% BASE</u>	N50537 002 FEB 22, 1994
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N50537 002
FEB 22, 1994

CLOBETASOL PROPIONATE

OINTMENT; TOPICAL
CLOBETASOL

<u>EMBELLINE</u>	<u>EMBELLINE</u>	<u>0 .05%</u>	N74221 001 MAR 31, 1995
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N74221 001
MAR 31, 1995

CLOTRIMAZOLE

SOLUTION; TOPICAL
CLOTRIMAZOLE

<u>AT</u>	<u>AT</u>	<u>1%</u>	N73306 001 FEB 28, 1995
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N73306 001
FEB 28, 1995

CORTICOTROPIN

INJECTABLE; INJECTION
CORTICOTROPIN

<u>ACTH</u>	<u>ACTH</u>	<u>40 UNITS/VIAL</u>	N08317 004 NO8317 004
<u>AP</u>	<u>AP</u>	<u>40 UNITS/VIAL</u>	(@)

N08317 004
NO8317 004

CROMOLYN SODIUM

SOLUTION/DROPS; OPHTHALMIC
CROLOM
AT BAUSCH AND LOMB 4%

AT + OPTICROM 4%

AT + FISONS 4%

CYANOCOBALAMIN

INJECTABLE; INJECTION
 CYANOCOBALAMIN
 @ WARNER CHILCOTT

RUBRAMIN PC
AP * SQUIBB 0.1MG/ML
SYTOBEX
AP PARKER DAVIS 1MG/ML

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
CYCLOBENZAPRINE HCL
AB BARR 10MG

>
ADD >
ADD >

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL
CYPROHEPTADINE HCL
AB ASCOT 4MG

>
DLT >
DLT >
ADD >
ADD >

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
DAUNORUBICIN HCL
AP CETUS BEN VENUE EQ 20MG BASE/VIAL

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION
 DDAVP
 + RHONE POULENC RORER 0.015MG/ML

N74443 001
 JAN 30, 1995

N18155 001
 OCT 03, 1984

SPRAY, METERED, NASAL
 DESMOPRESSIN ACETATE
 + RHONE POULENC RORER 0.15MG/INH

N20355 001
 MAR 07, 1994

STIMATE
 + RHONE POULENC RORER 0.15MG/INH

N20355 001
 MAR 07, 1994

N07085 002
 NOV 02, 1994

N06799 002
 NOV 02, 1994

N07085 002
 NOV 02, 1994

DEXAMETHASONE

AEROSOL; TOPICAL
 DECASPRAY
 * MERCK SHARP DOHME
 +
N20071 001
 DEC 10, 1992

N20071 001
 DEC 10, 1992

N20071 001
 DEC 10, 1992

N20301 001
 DEC 14, 1992

N73541 001
 MAY 23, 1995

TABLET; ORAL
 HEXADROL
 ORGANON
 BP
 BP
 BP

N12675 001
 N12675 007

N12675 002
 N12675 009

N12675 004
 N12675 007

N12675 005
 N12675 009

N12675 006
 N12675 007

N12675 007
 N12675 009

N64103 001
 FEB 03, 1995

> ADD >	<u>DEXRAZOXANE HYDROCHLORIDE</u>		
> ADD >	INJECTABLE; INJECTION		
> ADD >	ZINECARD	EQ 250MG BASE/VIAL	N20212 001
> ADD >	+ PHARMACIA		MAY 26, 1995
> ADD >			> ADD >
> ADD >			AB
> ADD >			> ADD >
> ADD >			AB
> ADD >			> ADD >
	DEXTROSE		AB
	INJECTABLE; INJECTION		> ADD >
	DEXTROSE 2.5% IN PLASTIC CONTAINER		AB
	MCGAN	2.5GM/100ML	N19626 001
@			FEB 02, 1988
			N19626 001
			FEB 02, 1988
	DEXTROSE 7.7% IN PLASTIC CONTAINER		N19626 003
	MCGAN	7.7GM/100ML	FEB 02, 1988
@			N19626 003
			FEB 02, 1988
	DIAZEPAM		DIMENHYDRINATE
	INJECTABLE; INJECTION		INJECTABLE; INJECTION
	<u>DIAZEPAM</u>	<u>5MG/ML</u>	<u>DIMENHYDRINATE</u>
	FUJISAWA		<u>50MG/ML</u>
@			
			AP
			STERIS
			(@)
	DINOPROSTONE		
			INSERT, EXTENDED RELEASE; VAGINAL
			CERVIDIL
			+ CONTROLLED THERAP
			10MG
	DICLOFENAC POTASSIUM		
	TABLET; ORAL		
	CATAFLAM	25MG	N20142 001
	GEIGY		NOV 24, 1993
@			N20142 001
			NOV 24, 1993
			> DLT >
			AB
			> ADD >
	DIPHENHYDRAMINE HYDROCHLORIDE		
	CAPSULE; ORAL		
	<u>DIPHENHYDRAMINE HCL</u>	<u>50MG</u>	<u>50MG</u>
	WESTWARD PHARM		
			(@)
			N83567 001
			N83567 001

DIPIVEFRIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
DIPIVEFRIN HCL
BAUSCH AND LOMB 0.1%

> ADD > AT >
> ADD >

N74188 001	MAY 19, 1995
EQ 125MG BASE	
<u>DEPAKOTE ABBOTT</u>	
> DLT >	
> DLT >	
> ADD >	
> ADD >	

DIVALPROEX SODIUM

CAPSULE, DELAYED REL PELLETS; ORAL
DEPAKOTE
ABBOTT

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

N19680 001	SEP 12, 1989
EQ 125MG VALPROIC ACID	N19680 001
<u>DEPAKOTE ABBOTT</u>	
> DLT >	
> DLT >	
> ADD >	
> ADD >	

TABLET, DELAYED RELEASE; ORAL

DEPAKOTE
ABBOTT

> DLT >
> ADD >

EQ 125MG BASE	N18723 003
EQ 250MG BASE	OCT 26, 1984
EQ 500MG BASE	N18723 001
EQ 500MG BASE	MAR 10, 1983
EQ 125MG VALPROIC ACID	N18723 002
EQ 250MG VALPROIC ACID	MAR 10, 1983
EQ 500MG VALPROIC ACID	MAR 10, 1983
<u>DEPAKOTE ABBOTT</u>	
> DLT >	> DLT >
> DLT >	> DLT >
> ADD >	> ADD >
> ADD >	+ OCLASSEN
> ADD >	> ADD >
> ADD >	> ADD >
> ADD >	> ADD >
> ADD >	> ADD >
> ADD >	> ADD >

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOBUTAMINE HCL
ASTRA

> ADD >
> ADD >

N74098 001	FEB 21, 1995
EQ 12.5MG BASE/ML	N74292 001
<u>ASTRA</u>	
EQ 12.5MG BASE/ML	FEB 16, 1995
<u>SANOFI WINTHROP</u>	
EQ 12.5MG BASE/ML	

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
INTROPIN
DUPOINT MERCK

> ADD >
> ADD >

N17395 003	N17395 001
EQ 40MG/ML	N17395 002
80MG/ML	
160MG/ML	

<u>DROPERIDOL</u>			
INJECTABLE; INJECTION		> DLT >	DROPS; ORAL
<u>DP</u> DUPONT MERCK	<u>2.5MG/ML</u>	> DLT >	PEDIAMYCIN
<u>AP</u> FAULDING	<u>2.5MG/ML</u>	> DLT >	+ ROSS LABS
<u>EDETA TE DISODIUM</u>			
INJECTABLE; INJECTION			SUSPENSION; ORAL
* 3M	200MG/ML		<u>WYAMYCIN E</u>
@	200MG/ML		WYETH AYERST
<u>ERYTHROMYCIN</u>			
TABLET, DELAYED RELEASE; ORAL		> ADD >	EQ 200MG BASE/5ML
<u>ERIC</u>	<u>250MG</u>	> ADD >	EQ 400MG BASE/5ML
<u>AB</u> * PARKE DAVIS	<u>250MG</u>	> ADD >	EQ 200MG BASE/5ML
<u>AB</u>	<u>250MG</u>		EQ 400MG BASE/5ML
<u>AB</u> +	<u>250MG</u>		EQ 200MG BASE/5ML
@	250MG		EQ 400MG BASE/5ML
<u>ERYTHROMYCIN ESTOLATE</u>			
DROPS; ORAL		> DLT >	SUSPENSION/DROPS; ORAL
ILLOSONE		> DLT >	PEDIAMYCIN
+ DISTA		> DLT >	+ ROSS LABS
			@
			@
<u>ERYTHROMYCIN STEARATE</u>			
CAPSULE, DELAYED RELEASE; ORAL			TABLET; ORAL
<u>ERIC</u>	<u>250MG</u>		<u>ETHRIL 250</u>
<u>AB</u> * PARKE DAVIS	<u>250MG</u>		SQUIBB
<u>AB</u>	<u>250MG</u>		(@) SQUIBB
<u>AB</u> +	<u>250MG</u>		<u>ETHRIL 500</u>
@	250MG		SQUIBB
			(@) SQUIBB
<u>ESTRADIOL</u>			
TABLET, DELAYED RELEASE; ORAL			FILM, EXTENDED RELEASE; TRANSDERMAL
<u>ERBIMYCIN</u>	<u>250MG</u>		VIVELLE
<u>AB</u> ROBINS AB	<u>250MG</u>		CIBA GEIGY
@	250MG		
<u>ERYTHROMYCIN</u>			
DROPS; ORAL		> DLT >	OCT 28, 1994
ILLOSONE		> DLT >	N20323 002
+ DISTA		> DLT >	OCT 28, 1994
			N20323 004
			OCT 28, 1994
			N20323 001
			OCT 28, 1994
			N20323 003
			OCT 28, 1994
			N20323 002
			OCT 28, 1994
			N20323 004
			OCT 28, 1994
			N20323 003
			OCT 28, 1994
			N20323 002
			OCT 28, 1994
			N20323 003
			OCT 28, 1994

ETHINYL ESTRADIOL; NORETHINDRONEFLUNISOLIDE

TABLET; ORAL-21

OVCON-35
+ BRISTOL MYERS SQUIBB 0.035MG; 0.4MG
* MEAD JOHNSON 0.035MG; 0.4MGN18127 001
N18127 001TABLET; ORAL-28
OVCON-35
BRISTOL MYERS SQUIBB 0.035MG; 0.4MG
MEAD JOHNSON 0.035MG; 0.4MGOVCON-50
@ BRISTOL MYERS SQUIBB 0.05MG; 1MG
MEAD JOHNSON 0.05MG; 1MGN18128 001
N18128 001TABLET; ORAL-50
OVCON-35
BRISTOL MYERS SQUIBB 0.035MG; 0.4MG
MEAD JOHNSON 0.035MG; 0.4MGOVCON-50
@ BRISTOL MYERS SQUIBB 0.05MG; 1MG
MEAD JOHNSON 0.05MG; 1MGN17716 001
N17716 001TABLET; ORAL-50
OVCON-50
BRISTOL MYERS SQUIBB 0.05MG; 1MG
MEAD JOHNSON 0.05MG; 1MGN17576 001
N17576 001N17716 001
N17716 001ETOPOSIDE

INJECTABLE; INJECTION

TOPOSAR

AP PHARMACIA 20MG/ML

N74166 001
FEB 27, 1995TABLET; ORAL
LIPIDIL
+ LABS FOURNIER 100MG
@ 100MGN19304 001
DEC 31, 1993
N19304 001
DEC 31, 1993CAPSULE; ORAL
LIPIDIL
+ LABS FOURNIER 100MG
@ 100MGN19304 001
DEC 31, 1993
N19304 001
DEC 31, 1993FLUDROCORTISONE ACETATE

TABLET; ORAL

FLORINEF

> ADD >
> DLT >
+ APOTHECON SQUIBB 0.1MG
0.1MGN10060 001
N10060 001
AB + FLUOCINONIDE
AB FLUOCINONIDE EMOLLIENT BASE
AB LIDEX
AB + SYNTEX
AB LIDEX-E
SYNTEXTABLET; ORAL
FLORINEF
+ APOTHECON SQUIBB 0.1MG
0.1MGN16908 002
N16908 003
N16908 002
N16908 003TABLET; ORAL
FLORINEF
+ APOTHECON SQUIBB 0.1MG
0.1MGN16908 002
N16908 003
N16908 002
N16908 003FLUNISOLIDE

SPRAY, METERED; NASAL

NASALIDE

BX + SYNTEX 0.025MG/INH

N18148 001

FLUOCINONIDE

GEL; TOPICAL
FLUOCINONIDE
AB + HAMILTON PHARMA CA 0.05%
AB * LIDEX 0.05%

OINTMENT; TOPICAL

FLUOCINONIDE
AB + HAMILTON PHARMA CA 0.05%
AB * LIDEX 0.05%

SOLUTION; TOPICAL

FLUOCINONIDE
AT FOUGERA 0.05%
AT + HAMILTON PHARMA CA 0.05%
AT * LIDEX 0.05%

FLURBIPROFEN

TABLET; ORAL
FLURBIPROFEN
AB LEMMON 100MG
AB NOVOPHARM 50MG
AB ZENITH LABS 100MG
AB 50MG
AB 100MG
AB > ADD >
AB > ADD >

FLURBIPROFEN SODIUM

SOLUTION/DROPS; OPHTHALMIC
FLURBIPROFEN SODIUM
AT BAUSCH AND LOMB 0.03%
AT + ALLERGAN 0.03%

FOSINOPRIL SODIUM

TABLET; ORAL
FOSINOPRIL
AB BRISTOL MYERS SQUIBB 20MG
N17373 001
N17373 001
AB +
AB 40MG
N16909 002
N16909 002
AB GEMFIBROZIL

CAPSULE; ORAL
GEMFIBROZIL
AB * MYLAN 300MG
AB @
AB PURÉPAC PHARM 300MG
AB @
AB LOPID 300MG
AB * PARKE DAVIS 300MG
AB @
AB CHELSEA LABS 600MG
AB MYLAN 600MG
AB GENTAMICIN SULFATE
AT ALCON SOLUTION/DROPS; OPHTHALMIC
GENTAMICIN SULFATE
AT ALCON EQ 0.3% BASE

N19915 003
MAY 16, 1991
N19915 003
MAY 16, 1991
N19915 004
MAR 28, 1995
N73466 001
JAN 25, 1993
N73466 001
JAN 25, 1993
N72929 001
JAN 29, 1993
N72929 001
JAN 29, 1993
N18422 002
N18422 002
N72934 001
FEB 27, 1995
N18849 001
APR 06, 1984
N18849 001
APR 06, 1984
N74431 001
MAY 31, 1995
N74405 002
MAY 24, 1995
N74405 001
MAY 24, 1995
N74411 001
MAY 31, 1995
N74411 002
MAY 31, 1995
N74442 001
APR 28, 1995
N74452 001
FEB 16, 1995
N62196 001
DEC 31, 1986

GLIPIZIDE

TABLET; ORAL
GLIPIZIDE
AB GENEVA PHARMS 5MG
N74305 001
APR 07, 1995

GLIPIZIDE

TABLET; ORAL
GLIPIZIDE
 GENEVA PHARMS

AB WATSON LABS
AB

10MG
5MG
10MG

TABLET; ORAL		TABLET; ORAL	
		<u>GUANABENZ ACETATE</u>	<u>EQ 4MG BASE</u>
<u>AB</u>	ZENITH LABS	EQ 8MG BASE	
N74305 002 APR 07, 1995			
N74223 001 FEB 27, 1995			
N74223 002 FEB 27, 1995			

GUANFACINE HYDROCHLORIDE

TABLET; ORAL,

TENEX
 ROBBINS AH

1MG
 *
 2MG
 3MG

N20055 001
 APR 17, 1992
 N20055 002
 APR 17, 1992

N20055 001
 APR 17, 1992
 N20055 002
 APR 17, 1992

N20051 001
 MAR 04, 1992
 N20051 002
 MAR 04, 1992

CREAM; TOPICAL
HALOG

* WESTWOOD SQUIBB

0.1%
 + HALOG-E

0.1%
 WESTWOOD SQUIBB

0.1%
 WESTWOOD SQUIBB

0.1%
 HEPARIN CALCIUM

INJECTABLE; INJECTION

CALCIPARINE

* CHOAY

@ SANOFI WINTHROP

N20305 001
 MAR 16, 1995

GRANISETRON HYDROCHLORIDE

TABLET; ORAL
 KYTRIL
 + SMITHKLINE BEECHAM

N17556 001
 N17556 001
 N18234 001
 N18234 001

25,000 UNITS/ML

25,000 UNITS/ML

N18237 001
 N18237 001

HEPARIN SODIUMINJECTABLE; INJECTION
HEPARIN LOCK FLUSH

AP SANOFI WINTHROP 10 UNITS/ML

AP 100 UNITS/ML

HEPARIN SODIUM

AP * ABBOTT 2,500 UNITS/ML

AP 2,000 UNITS/ML

AP 10,000 UNITS/ML

AP 5,000 UNITS/0.5ML

AP PHARMA SERVE NY 1,000 UNITS/ML

AP NYETH AYERST 2,500 UNITS/ML

AP + HEPARIN SODIUM 1000 UNITS AND DEXTROSE 5% IN PLASTIC

AP > DLT > CONTAINER 200 UNITS/100ML

AP > DLT > MCCAW 200 UNITS/100ML

AP @ ADD > HEPARIN SODIUM 2000 UNITS IN DEXTROSE 5% IN PLASTIC

AP > DLT > CONTAINER 200 UNITS/100ML

AP > DLT > MCCAW 200 UNITS/100ML

AP @ ADD > HEPARIN SODIUM 5000 UNITS IN DEXTROSE 5% IN PLASTIC

AP > DLT > CONTAINER 1,000 UNITS/100ML

AP @ ADD > HEPARIN SODIUM PRESERVATIVE FREE

AP + ABBOTT 2,500 UNITS/ML

AP + FUJISAWA 1,000 UNITS/ML

AP + PHARMA SERVE NY 1,000 UNITS/ML

AP N86129 001

HEPARIN SODIUMINJECTABLE; INJECTION
HEPARIN SODIUM PRESERVATIVE FREE

AP N40082 001 FEB 28, 1995

AP N40082 002 FEB 28, 1995

AP + > DLT > AP LIQUAMIN LOCK FLUSH

AP APR 07, 1986 > DLT > AP ORGANON

AP NO5264 013 > DLT > AP LIQUAMIN SODIUM

AP APR 07, 1986 > DLT > AP ORGANON

AP N17017 013 > DLT > AP LIQUAMIN SODIUM

AP APR 07, 1986 > DLT > AP ORGANON

AP N17037 013 > DLT > AP LIQUAMIN SODIUM

AP APR 07, 1986 > DLT > AP LIQUAMIN SODIUM

AP N86129 001 > DLT > AP LIQUAMIN SODIUM

AP N17007 007 > DLT > AP LIQUAMIN SODIUM

AP APR 07, 1986 > DLT > AP LIQUAMIN SODIUM

AP N19130 001 > DLT > AP LIQUAMIN SODIUM

AP DEC 31, 1984 > DLT > AP LIQUAMIN SODIUM

AP N19130 001 > DLT > AP LIQUAMIN SODIUM

AP DEC 31, 1984 > DLT > AP LIQUAMIN SODIUM

AP N19130 002 > DLT > AP LIQUAMIN SODIUM

AP DEC 31, 1984 > DLT > AP LIQUAMIN SODIUM

AP N19130 003 > DLT > AP LIQUAMIN SODIUM

AP DEC 31, 1984 > DLT > AP LIQUAMIN SODIUM

AP N19130 004 > DLT > AP LIQUAMIN SODIUM

AP APR 07, 1986 > DLT > AP LIQUAMIN SODIUM

AP N19130 005 > DLT > AP LIQUAMIN SODIUM

AP APR 28, 1986 > DLT > AP LIQUAMIN SODIUM

AP APR 28, 1986 > DLT > AP LIQUAMIN SODIUM

AP APR 28, 1986 > DLT > AP LIQUAMIN SODIUM

AP APR 28, 1986 > DLT > AP LIQUAMIN SODIUM

AP APR 28, 1986 > DLT > AP LIQUAMIN SODIUM

AP APR 28, 1986 > DLT > AP LIQUAMIN SODIUM

N89522 001 MAY 04, 1987

N89522 001 MAY 04, 1987

N00552 007 NO0552 007

N00552 007 NO0552 007

N00552 004 NO0552 004

N00552 003 NO0552 003

N00552 005 NO0552 004

N00552 003 NO0552 003

N00552 005 NO0552 005

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

TABLET; ORAL
HYZAAR
+ MERCK
12.5MG; 50MG

N20387 001
APR 28, 1995

>
ADD
>

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE

TABLET; ORAL
LOPRESSOR HCT
CIBA
25MG; 50MG
25MG; 100MG
50MG; 100MG
+
LOPRESSOR HCT 100/25
CIBA
25MG; 100MG
*
LOPRESSOR HCT 100/50
CIBA
50MG; 100MG
LOPRESSOR HCT 50/25
CIBA
25MG; 50MG

N18303 001
DEC 31, 1984
N18303 002
DEC 31, 1984
N18303 003
DEC 31, 1984
N18303 002
DEC 31, 1984
N18303 003
DEC 31, 1984
N18303 001
DEC 31, 1984
N18303 003
DEC 31, 1984

>
DLT
>
DLT
>
ADD
>
ADD
>

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

N18303 001
DEC 31, 1984

>
DLT
>
DLT
>
ADD
>
ADD
>

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

N183026 001
N85026 001

>
ADD
>
ADD
>
ADD
>
ADD
>

HYDROCORTISONE

ENEMA; RECTAL
CORTENEMA

N16199 001
N16199 001

>
ADD
>

HYDROCORTISONE

ENEMA; RECTAL
HYDROCORTISONE

N20387 001
APR 28, 1995

>
DLT
>
DLT
>
ADD
>
ADD
>

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL

N18303 001
DEC 31, 1984

>
AP
>

IBUPROFEN

SUSPENSION; ORAL

N183026 001
MAR 30, 1995

BX +

IBUPROFEN

SUSPENSION; ORAL

N183026 001
SEP 19, 1989

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
SEP 19, 1989

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

IBUPROFEN

SUSPENSION/DROPS; ORAL

N183026 001
MAY 25, 1995

BX +

> ADD > IOPROMIDE
 > ADD > INJECTABLE; INJECTION
 > ADD > ULTRAVIST
 > ADD > + BERLEX
 > ADD > EQ 150MG IODINE/ML
 > ADD > MAY 10, 1995 N20220 004
 > ADD > EQ 240MG IODINE/ML N20220 003
 > ADD > MAY 10, 1995 N20220 002
 > ADD > EQ 300MG IODINE/ML N20220 001
 > ADD > MAY 10, 1995 N20220 000
 > ADD > EQ 370MG IODINE/ML N20220 001
 > ADD > MAY 10, 1995 N20220 003

ISOFLURANE

SOLUTION; INHALATION
I-SOETHARINE HCL S/F
 * DEX 1%
 AN @ 1%
 > DLT >
 > DLT >
 > ADD >
 > ADD >

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL
 IMDUR
 @ SCHERING
 +
 +

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
 LEUCOVORIN CALCIUM
 + CETUS BEN VENUE
 EQ 200MG BASE/VIAL
 MAR 30, 1995 N20225 001
 AUG 12, 1993 > ADD >
 N20225 002 > ADD >
 AUG 12, 1993 120MG
 N20225 003
 N20225 001
 AUG 12, 1993 30MG
 N20225 002
 AUG 12, 1993 60MG
 @ SCHERRING PLough
 * Scherring Plough
 LEUPROLIDE ACETATE

INJECTABLE; INJECTION
 LUPRON
 + TAP HOLDINGS
 * TAP PHARMS

KANAMYCIN SULFATE

INJECTABLE; INJECTION
KANAMYCIN
 ELKINS SINN
 AF AP AP
 MAY 10, 1995 N62324 001
 EQ 75MG BASE/2ML
 EQ 500MG BASE/2ML
 EQ 1GM BASE/3ML
 MAY 10, 1995 N62324 002
 EQ 75MG BASE/2ML
 EQ 500MG BASE/2ML
 EQ 1GM BASE/3ML
 MAY 10, 1995 N62324 003
 EQ 75MG BASE/2ML
 EQ 500MG BASE/2ML
 EQ 1GM BASE/3ML
 MAY 10, 1995 N62324 004
 EQ 75MG BASE/2ML
 EQ 500MG BASE/2ML
 EQ 1GM BASE/3ML
 MAY 10, 1995 N62324 005

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL
 ORUVAIL
 + WYETH AYERST
 100MG
 150MG
 +
 +
 SEP 15, 1986 N89252 001
 SEP 15, 1986 N89252 002
 SEP 15, 1986 N89252 003
 > ADD >
LANSOPRAZOLE
 CAPSULE, DELAYED REL GRANULES; ORAL
 PREVACID
 TAP HOLDINGS
 15MG
 30MG
 +
 +
 > ADD >
 > ADD >
 > ADD >
 > ADD >
 > ADD >

LEUPROLIDE ACETATE

N19816 003
 FEB 08, 1995 N20406 001
 N19816 002
 FEB 08, 1995 N20406 002
 MAY 10, 1995 N20406 003
 MAY 10, 1995 N20406 004

N19810 001
 APR 09, 1985 N19810 001
 MAY 10, 1985 N19810 001

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE									
<u>LINDANE</u>	LOTION; TOPICAL <u>SCABENE</u> STIEFEL	1% 1%	<u>N86769</u> 001 N86769 001	> DLT > > AT > > ADD >	> DLT > > AT > > ADD >	SOLUTION; IRRIGATION <u>PHYSIOLYTIC IN PLASTIC CONTAINER</u> MC GRAW	30MG/100ML; 3.7MG/100ML; 3.7MG/100ML; 530MG/100ML; 500MG/100ML	N13024 001 JUN 08, 1984	
	SHAMPOO; TOPICAL <u>SCABENE</u> STIEFEL	1% 1% @	<u>N87940</u> 001 APR 08, 1983 N87940 001 APR 08, 1983	> DLT > > AT > > ADD > > ADD >	> DLT > > AT > > ADD > > ADD >	<u>PHYSIOSOL IN PLASTIC CONTAINER</u> ABBOTT	30MG/100ML; 37MG/100ML; 370MG/100ML; 521MG/100ML; 500MG/100ML	JUL 08 1982 N17637 002	
	LISINOPRIL				> DLT > > AT > > ADD > > ADD >		30MG/100ML; 37MG/100ML; 222MG/100ML; 526MG/100ML; 502MG/100ML	JUL 08 1982 N17637 002	
	TABLET; ORAL <u>PRINIVIL</u> MERCK	2.5MG	<u>N19558</u> 006 JAN 28, 1994 N19558 006	> DLT > > AT > > ADD > > ADD >	> DLT > > AT > > ADD > > ADD >	<u>SYNOVALYTE IN PLASTIC CONTAINER</u> HAXTER	30MG/100ML; 37MG/100ML; 36.8MG/100ML; 520MG/100ML; 502MG/100ML	N19226 001 JAN 25, 1985	
	ZESTRIL	2.5MG	<u>N19777</u> 005 APR 29, 1993 N19777 005	@ APR 29, 1993 APR 29, 1993	@ APR 29, 1993 APR 29, 1993	MANNITOL			
						INJECTABLE; INJECTION <u>MANNITOL 10%</u> ABBOTT	10GM/100ML 10GM/100ML	N16269 002 N16269 002	
	LITHIUM CARBONATE								
	TABLET; ORAL <u>LITHOTABS</u> SOLVAY + MERCK	300MG 300MG	<u>N16980</u> 001 N16980 001	> DLT > > ADD >	> DLT > > ADD >	<u>MANNITOL 15%</u> ABBOTT	15GM/100ML 15GM/100ML	N16269 003 N16269 003	
	LOSARTAN POTASSIUM								
	TABLET; ORAL COZAAR MERCK	25MG	N20386 001 APR 14, 1995 N20386 002	> DLT > > ADD >	> DLT > > ADD >	<u>MANNITOL 20%</u> ABBOTT	20GM/100ML 20GM/100ML	N16269 004 N16269 004	
		50MG	APR 14, 1995	@ APR 14, 1995	@ APR 14, 1995	<u>MANNITOL 25%</u> ABBOTT	12.5GM/50ML 12.5GM/50ML	N16269 005 N16269 006	
		+ +					12.5GM/50ML 5GM/100ML	AUG 25, 1994 N16269 005 N16269 001 N16269 001	

<u>MEBENDAZOLE</u>	
TABLET, CHEWABLE; ORAL <u>MEBENDAZOLE</u>	
<u>AB</u> COPLEY PHARM	<u>100MG</u>
<u>AB</u> + <u>VERMOX</u>	
<u>AB</u> + <u>JANSSEN</u>	<u>100MG</u>

METHOTRIMEPRAZINE

INJECTABLE; INJECTION LEVOPROME + IMMUNEX LEDERLE	20MG/ML 20MG/ML
<u>N15865 001</u>	
<u>N15865 001</u>	

<u>N73580 001</u>	
JAN 04, 1995	

<u>N17481 001</u>	
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MEGESTROL ACETATE

TABLET; ORAL <u>MEGACE</u>	
BRISTOL MYERS SQUIBB	20MG
<u>AB</u> + <u>MEAD JOHNSON</u>	<u>40MG</u>
<u>AB</u> + <u>*</u>	<u>20MG</u>
<u>AB</u> + <u>*</u>	<u>40MG</u>

<u>N16979 001</u>	
N16979 002	
<u>N16979 001</u>	
N16979 002	

<u>N16979 001</u>	
N16979 002	

METFORMIN HYDROCHLORIDE

TABLET; ORAL GLUCOPHAGE	
BRISTOL MYERS SQUIBB	500MG
<u>+</u>	
	850MG
	500MG
	850MG
	850MG

<u>N20357 001</u>	
DEC 29, 1994	
<u>N20357 002</u>	
DEC 29, 1994	
<u>N20357 001</u>	
DEC 29, 1994	
<u>N20357 002</u>	
DEC 29, 1994	

METHADONE HYDROCHLORIDE

POWDER; FOR RX COMPOUNDING METHADONE HCL	
MALLINCKRODT	50GM/BOT 100GM/BOT 500GM/BOT
<u>AB</u>	
TABLET, DISPERSIBLE; ORAL <u>METHADONE HCL</u>	
ROXANE	<u>40MG</u>
<u>AB</u>	

<u>N06383 002</u>	
N06383 003	
<u>N06383 004</u>	

<u>N74081 001</u>	
APR 28, 1995	

<u>N70847 001</u>	
NOV 07, 1988	
<u>N71291 001</u>	
MAR 03, 1989	
<u>N70847 001</u>	
NOV 07, 1988	
<u>N71291 001</u>	
MAR 03, 1989	

<u>N70847 001</u>	
NOV 07, 1988	
<u>N71291 001</u>	
MAR 03, 1989	

<u>N74453 001</u>	
APR 27, 1995	
<u>N74453 002</u>	
APR 27, 1995	

METHOLOL TARTRATE

TABLET; ORAL <u>METOPROLOL TARTRATE</u>	
LEMMON	50MG
<u>AB</u>	
<u>AB</u>	
<u>AB</u>	

<u>N74141 001</u>	
JAN 31, 1995	
<u>N74141 002</u>	
JAN 31, 1995	
<u>N74453 001</u>	
APR 27, 1995	
<u>N74453 002</u>	
APR 27, 1995	

<u>METRONIDAZOLE</u>	<u>CAPSULE; ORAL</u> FLAGYL + SEARLE	375MG	N20334 001 MAY 03, 1995	INJECTABLE; INJECTION <u>MITOMYCIN</u> <u>AP</u> CETUS BEN VENUE	5MG/VIAL	N64117 001 APR 19, 1995
					20MG/VIAL	N64117 002 APR 19, 1995
<u>METYRAPONE</u>	<u>TABLET; ORAL</u> METOPIRONE * CIBA ®	250MG 250MG	N12911 001 N12911 001	TABLET; ORAL UNIVASC SPKU	7.5MG	N20312 001 APR 19, 1995
				+ +	15MG	N20312 002 APR 19, 1995
<u>MEXILETINE HYDROCHLORIDE</u>	<u>CAPSULE; ORAL</u> <u>MEXILETINE HCL</u> NOVOPHARM	<u>150MG</u> <u>200MG</u> <u>250MG</u>	N74377 001 MAY 16, 1995 N74377 002 MAY 16, 1995 N74377 003 MAY 16, 1995	> ADD > > ADD > > ADD > > ADD > > ADD > > ADD >	<u>MYCOPHENOLATE MOFETIL</u> CAPSULE; ORAL CELLCEPT + SYNTAX	N50722 001 MAY 03, 1995
<u>MEXITIL</u>	<u>BOEHRINGER INGELHEIM</u>	<u>150MG</u> <u>200MG</u> <u>250MG</u>	N18873 002 DEC 30, 1985 N18873 003 DEC 30, 1985 N18873 004 DEC 30, 1985	> ADD > > ADD > > ADD > > ADD > > ADD >	<u>NALMEFENE HYDROCHLORIDE</u> INJECTABLE; INJECTION REVEX ORMEDA	N20459 001 APR 17, 1995
					+	N20459 002 APR 17, 1995
<u>MICONAZOLE NITRATE</u>	SUPPOSITORY; VAGINAL					
		<u>MICONAZOLE NITRATE</u>	<u>200MG</u> <u>ABBE</u> <u>NMC</u>		<u>NAPROXEN</u>	
	> DLT > AB	N73508 001 NOV 19, 1993	> ADD >	TABLET; ORAL <u>NAPROXEN</u>	250MG	N74457 001 MAY 31, 1995
	> DLT > AB	N73508 001 NOV 19, 1993	> ADD >	AB CHELSEA LABS		N74457 002 MAY 31, 1995
	> ADD > AB		> ADD >		375MG	
	> ADD > AB		> ADD >		500MG	
	> ADD > AB		> ADD >			

<u>NAPROXEN</u>		
TABLET; ORAL		
<u>NAPROXEN</u>		
<u>AB</u>	<u>DANBURY PHARMA</u>	<u>250MG</u>
<u>AB</u>		<u>375MG</u>
<u>AB</u>		<u>500MG</u>
<u>AB</u>	<u>MOVA</u>	<u>250MG</u>
<u>AB</u>		<u>375MG</u>
		<u>500MG</u>
<u>AB</u>	<u>ZENITH LABS</u>	<u>250MG</u>
<u>AB</u>		<u>375MG</u>
<u>AB</u>		<u>500MG</u>

<u>NAPROXEN SODIUM</u>		
TABLET; ORAL		
<u>NAPROXEN SODIUM</u>		
<u>AB</u>	<u>CHELSEA LABS</u>	<u>EQ 250MG BASE</u>
<u>AB</u>		<u>EQ 500MG BASE</u>
<u>AB</u>	<u>PUREPAC PHARM</u>	<u>EQ 250MG BASE</u>
<u>AB</u>		<u>EQ 500MG BASE</u>
<u>AB</u>	<u>ZENITH LABS</u>	<u>EQ 250MG BASE</u>
<u>AB</u>		<u>EQ 500MG BASE</u>

<u>NEOMYCIN SULFATE</u>		
TABLET; ORAL		
<u>NEOMYCIN SULFATE</u>		
<u>AB</u>	<u>BIOCRAFT</u>	<u>EQ 350MG BASE</u>
<u>AB</u>		<u>EQ 350MG BASE</u>
<u>AB</u>	<u>LILLY</u>	<u>EQ 350MG BASE</u>

<u>NICOTINE</u>		
FILM, EXTENDED RELEASE; TRANSDERMAL		
<u>NICOTINE</u>		
<u>BC</u>	<u>HABITROL</u>	<u>7MG/24HR</u>
<u>BC</u>	<u>* BASEL PHARMS</u>	<u>14MG/24HR</u>
<u>BC</u>	<u>*</u>	<u>21MG/24HR</u>
<u>BC</u>	<u>CIBA</u>	<u>7MG/24HR</u>
<u>BC</u>	<u>+</u>	<u>14MG/24HR</u>
<u>BC</u>	<u>+</u>	<u>21MG/24HR</u>

<u>NICOTINE POLACRILEX</u>		
GUM, CHEWING; BUCCAL		
<u>NICOTINE</u>		
<u>BC</u>	<u>MERRILL DOW</u>	<u>EQ 2MG BASE</u>
<u>BC</u>	<u>*</u>	<u>SMITHKLINE BEECHAM H</u>
<u>BC</u>	<u>+</u>	<u>2MG BASE</u>
<u>BC</u>	<u>MERRILL DOW</u>	<u>EQ 4MG BASE</u>
<u>BC</u>	<u>*</u>	<u>SMITHKLINE BEECHAM H</u>
<u>BC</u>	<u>+</u>	<u>4MG BASE</u>

<u>NISOLDIPINE</u>		
TABLET, EXTENDED RELEASE; ORAL		
<u>NISOLDIPINE</u>		
<u>AB</u>	<u>NISOCOR</u>	<u>10MG</u>
<u>AB</u>	<u>+ MILES</u>	<u>20MG</u>

<u>N20076</u>	<u>001</u>
<u>NOV 27, 1991</u>	
<u>N20076</u>	<u>002</u>
<u>NOV 27, 1991</u>	
<u>N20076</u>	<u>003</u>
<u>NOV 27, 1991</u>	
<u>N20076</u>	<u>001</u>
<u>NOV 27, 1991</u>	
<u>N20076</u>	<u>001</u>
<u>NOV 27, 1991</u>	
<u>N20076</u>	<u>002</u>
<u>NOV 27, 1991</u>	

<u>N60104</u>	<u>001</u>
<u>N60104</u>	<u>001</u>
<u>N60385</u>	<u>001</u>

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL
NISOCOR
+ MILES 3.0MG
+ 4.0MG

N20356 003
FEB 02, 1995
N20356 004
FEB 02, 1995

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL
NITROFURANTOIN
AB GENEVA PHARMS 2.5MG
AB 5.0MG
AB 10.0MG

N74336 001
JAN 25, 1995
N74336 002
JAN 25, 1995
N74336 003
JAN 25, 1995

FILM, EXTENDED RELEASE; TRANSDERMAL
NITRO-DUR
+ KEY PHARMS 0.1MG/HR
+ 0.2MG/HR
+ 0.3MG/HR
+ 0.4MG/HR
+ 0.6MG/HR
+ 0.8MG/HR

N20145 001
APR 04, 1995
N20145 002
APR 04, 1995
N20145 003
APR 04, 1995
N20145 004
APR 04, 1995
N20145 005
APR 04, 1995
N20145 006
APR 04, 1995

NYROSTAT
AP PARKE DAVIS 5MG/ML
* @
AP TRIDIL DUPONT MERCK 5MG/ML

N18588 002
DEC 23, 1983
N18588 003
N18588 001
N18588 002
DEC 23, 1983
N18537 001

NITROGLYCERIN

TABLET, INJECTION
TRIDIL
* DUPONT MERCK 0.5MG/ML
AP + FAULDING 5MG/ML
0.5MG/ML

N18537 002
JUN 16, 1993
N18537 001
N18537 002
JUN 16, 1983

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
NORTRIPTYLINE HCL
AB LEMMON EQ 10MG BASE
AB EQ 25MG BASE
AB EQ 50MG BASE
AB EQ 75MG BASE

NYSTATIN
TABLET; ORAL
MYCOSTATIN
AA + APOTHECON 500,000 UNITS
AA * SQUIERS 500,000 UNITS
TABLET; VAGINAL
NYSTATIN
AA LEMMON 100,000 UNITS
@ 100,000 UNITS
@ 100,000 UNITS
@ DEC 23, 1983
N62502 001
N60574 001
N60574 001
N62502 001
N62502 001
N62502 001
DEC 23, 1983
N62502 001
DEC 23, 1983
N62502 001
DEC 23, 1983

NYSTATIN; TRIAMCINOLONE ACETONIDE
OINTMENT; TOPICAL
NYSTATIN AND TRIAMCINOLONE ACETONIDE
AA PHARMAPAIR 100,000 UNITS/GM, 0.1%
@ 100,000 UNITS/GM, 0.1%
@ 100,000 UNITS/GM, 0.1%
N62656 001
JUL 30, 1986
N62656 001
JUL 30, 1986

N18537 001

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION
ZOFTRAN IN PLASTIC CONTAINER
+ GLAXO EQ 0.64MG BASE/ML

N20403 001

JAN 31, 1995

OXPHENCYCLIMINE HYDROCHLORIDE

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

TABLET; ORAL
DARICON
* PFIZER
@

10MG
10MGPENICILLAMINE

TABLET; ORAL
DEEPEN
+ WALLACE
DEEPEN 250
* WALLACE

250MG
250MGPENICILLIN G POTASSIUM

INJECTABLE; INJECTION
PFIZERPEN
PFIZER
AP +
AP +
AP +
AP +
AP +

N60657 001
N60657 001
N60657 002
N60657 002
N60657 002
N60657 003
N60657 003

1,000,000 UNITS/VIAL
1,000,000 UNITS/VIAL
5,000,000 UNITS/VIAL
5,000,000 UNITS/VIAL
20,000,000 UNITS/VIAL
20,000,000 UNITS/VIAL

20,000,000 UNITS/VIAL

TABLET; ORAL
PENICILLIN G POTASSIUM
DISTA
AP
@ LILLY

N11612 001
N11612 001

INJECTABLE; INJECTION
PENICILLIN G PROCAINE
@ CONSOLIDATED PHARM
@ COPANOS
@ COPANOS

N60403 001
N60403 001

1,000,000 UNITS/VIAL
1,000,000 UNITS/VIAL
5,000,000 UNITS/VIAL
5,000,000 UNITS/VIAL
20,000,000 UNITS/VIAL

N73447 001
AP APR 28, 1994

PENICILLIN G PROCAINE

INJECTABLE; INJECTION
PENICILLIN G PROCAINE
@ CONSOLIDATED PHARM
@ COPANOS
@ COPANOS

N60800 001
N60800 002
N60800 003
N60800 004
N60800 001
N60800 002
N60800 003
N60806 004
N60806 002
N60806 003
N60806 004
N60384 001
N60384 005
N60384 005
N60601 001
N60384 004
N60384 003
N60384 004
N60384 003
N60384 002
N60384 001
N60384 005
N60601 001

300,000 UNITS/ML
600,000 UNITS/1.2ML
300,000 UNITS/ML
600,000 UNITS/1.2ML

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN V POTASSIUM
CONSOLIDATED PHARM
@ COPANOS
@ COPANOS

N61529 001
N61529 002
N61529 001
N61529 002

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 125MG BASE/5ML
EQ 250MG BASE/5ML

PENICILLIN V POTASSIUM

TABLET; ORAL
PENICILLIN V POTASSIUM
CONSOLIDATED PHARM
@ COPANOS
@ COPANOS

N61528 001
N61528 002
N61528 001
N61528 002

EQ 250MG BASE
EQ 500MG BASE
EQ 250MG BASE
EQ 500MG BASE

INJECTABLE; INJECTION
PENTAMIDINE ISETHIONATE
INJECTABLE; INJECTION
PENTACARENAT
ARMOUR

N73447 001
AP APR 28, 1994

<u>PENTAMIDINE ISETHIONATE</u>		<u>PHENTERMINE HYDROCHLORIDE</u>	
INJECTABLE; INJECTION		CAPSULE; ORAL	
PENTACARINAT RHONE POULENC Rorer	300MG/VIAL	PHENTERMINE HCL	30MG
> DLT >	N73447 001 APR 26, 1994	N87777 001 NOV 01, 1985	
> DLT >	> DLT >	N87777 001 NOV 01, 1985	
	> ADD >		
	> ADD >		
<u>PERINDOPRIL ERBUMINE</u>		<u>PHENTERMINE RESIN COMPLEX</u>	
TABLET; ORAL		CAPSULE, EXTENDED RELEASE; ORAL	
ACEON AMARIC	2MG	TOMAMIN FISONS	EQ 15MG BASE
	4MG	+ TOMAMIN-15 FISONS	EQ 30MG BASE
+	8MG	TOMAMIN-30 FISONS	EQ 15MG BASE
JOHNSON & W	2MG	* FISONS	EQ 30MG BASE
	4MG		
*	8MG		
		PINDOLOL	
		TABLET; ORAL	
		PINDOLOL	5MG
		AB ROYCE LABS	
		10MG	
<u>PHENDIMETRAZINE TARTRATE</u>		<u>N74437 001</u>	
CAPSULE, EXTENDED RELEASE; ORAL		FEB 27, 1995	
MELFIAT-105	105MG	N74437 002	
@ NUMARK	105MG	FEB 27, 1995	
	105MG		
<u>POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE</u>		<u>N87487 001</u>	
CAPSULE, EXTENDED RELEASE; ORAL		OCT 13, 1982	
MELFIAT-105	105MG	N87487 001	
@ SOLVAY	105MG	OCT 13, 1982	
<u>POWDER FOR RECONSTITUTION; ORAL</u>		<u>N88024 001</u>	
		DEC 22, 1982	
SPRX-105	105MG	N88024 001	
@ NUMARK	105MG	DEC 22, 1982	
	105MG	N88024 001	
		DEC 22, 1982	
<u>TABLET; ORAL</u>		<u>N8790 002</u>	
MELFIAT	3.5MG	N8790 002	
@ NUMARK	3.5MG	N8790 002	
	3.5MG		
<u>PHENDIMETRAZINE TARTRATE</u>		<u>N83790 001</u>	
<u>> ADD ></u>		<u>N83790 001</u>	
<u>> DLT ></u>		<u>N83790 001</u>	
<u>> ADD ></u>		<u>N83790 001</u>	
<u>> DLT ></u>		<u>N83790 001</u>	

<u>POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS POWDER FOR RECONSTITUTION; ORAL</u>	<u>PROCAINAMIDE HYDROCHLORIDE</u>
<u><u>GOLLYTELY</u> <u>BRAINTREE</u></u>	N17371 002 N17371 003 N17371 001 N17371 002 N17371 003
<u><u>AA</u></u>	<u>227.1GM/PACKET; 2.82GM/PACKET;</u> <u>6.36GM/PACKET; 5.33GM/PACKET;</u> <u>21.5GM/PACKET</u>
	N19011 002 JUN 02, 1992
	> <u>ADD</u> > > <u>ADD</u> > > <u>DLT</u> > > <u>DLT</u> > > <u>DLT</u> >
<u>POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE</u>	<u>TABLET, EXTENDED RELEASE; ORAL</u>
<u>CAPSULE; ORAL</u>	
<u>MINIZIDE</u>	
<u>FEI</u>	
*	
	0 .5MG 1MG 0 .5MG 2MG 0 .5MG 5MG
	0 .5MG; EQ 1MG BASE 0 .5MG; EQ 2MG BASE 0 .5MG; EQ 5MG BASE
+	
<u>POTASSIUM CHLORIDE</u>	
<u>TABLET, EXTENDED RELEASE; ORAL</u>	
<u>KION CL</u>	
<u>SAVAGE LABS</u>	
@	
<u>KION CL 10</u>	
<u>SAVAGE LABS</u>	
@	
	6 .7MEQ 6 .7MEQ 1.0MEQ 1.0MEQ
	N17046 001 N17046 001 N17046 002 N17046 002
	> <u>ADD</u> > > <u>DLT</u> >
<u>PREDNISOLONE SODIUM PHOSPHATE</u>	
<u>INJECTABLE; INJECTION</u>	
<u>HYDELTRASOL</u>	
* <u>MERCK SHARP DOHME</u>	<u>EQ 20MG PHOSPHATE/ML</u>
+ <u>PREDNISOLONE SODIUM PHOSPHATE</u>	<u>EQ 20MG PHOSPHATE/ML</u>
<u>STERIS</u>	<u>EQ 20MG PHOSPHATE/ML</u>
@	<u>EQ 20MG PHOSPHATE/ML</u>
	N11583 002 N11583 002
	> <u>ADD</u> > > <u>DLT</u> >
<u>PROCAINAMIDE HYDROCHLORIDE</u>	<u>TABLET, HYDROCHLORIDE</u>
<u>TABLET; ORAL</u>	
<u>PRONESTYL</u>	
<u>APOTHECON</u>	
> <u>ADD</u> >	

<u>SUCCINYLCHOLINE CHLORIDE</u>		<u>TETRACYCLINE HYDROCHLORIDE</u>	
INJECTABLE; INJECTION <u>SUCOSTRIN</u> @ APOTHECON AP SQUIBB	100MG/ML 2.0MG/ML 1.00MG/ML	> DLT > > DLT > > DLT > > ADD >	OINTMENT: OPHTHALMIC, OTIC ACROMYCIN * LEDERLE 1.0MG/GM
	N08847 003 N08847 001 N08847 003	> DLT > > DLT > > ADD >	SUSPENSION: ORAL <u>ACROMYCIN V</u> SUMYCIN APOTHECON
		> ADD > > ADD >	125MG/5ML 125MG/5ML 125MG/5ML 125MG/5ML 125MG/5ML 125MG/5ML 125MG/5ML 125MG/5ML
<u>SULFAMETHOXAZOLE; TRIMETHOPRIM SUSPENSION; ORAL TRIMETH/SULFA</u>	<u>2000MG/5ML; 40MG/5ML</u>	N72289 001 MAX 23, 1988 N72289 001 MAY 23, 1988	BARRE MK LABS PUREPAC PHARM TETRACYCIN PF PHARMECS TETRAMED ZENITH LABS
AB	AB	> DLT > > DLT > > ADD > > ADD >	SYRUP; ORAL <u>ACROMYCIN V</u> * LEDERLE SUMYCIN SOUTIBB TETRACYCLINE HCL BARRE MK LABS PUREPAC PHARM TETRACYCIN PF PHARMECS TETRAMED ZENITH LABS
		> DLT > > DLT > > ADD > > ADD >	125MG/5ML 125MG/5ML 125MG/5ML 125MG/5ML 125MG/5ML 125MG/5ML 125MG/5ML 125MG/5ML
<u>TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR</u>		N17771 001 N17771 001	
SOLUTION; INJECTION, ORAL TECHNELITE DUPONT	0.0083 - 2.7 CI/GENERATOR	> DLT > > DLT > > DLT > > DLT >	
<u>TECHNETIUM TC 99M GENERATOR</u>		> DLT > > DLT > > DLT >	
DUPONT	0.0063 - 2.7 CI/GENERATOR	> DLT > > DLT > > DLT >	
		> DLT > > DLT >	
<u>TETRACYCLINE HYDROCHLORIDE</u>			
CAPSULE; ORAL <u>TETRACYCLINE HCL</u>	25.00MG 50.00MG	N62686 001 JUL 24, 1986 N62686 002 JUL 24, 1986	CAPSULE, EXTENDED RELEASE; ORAL THEOPHYLLINE THEOPHYLLINE FAULDING 100MG
AB	AB	> DLT > > DLT >	200MG 300MG
		> DLT >	250MG 500MG
FIBER, EXTENDED RELEASE; PERIODONTAL ACTISITE * ON SITE	12.7MG/FIBER	N50653 001 MAR 25, 1994 N50653 002 JUL 24, 1986	BC BC BC BC
@	25.00MG	N50653 001 MAR 25, 1994	200MG
@	50.00MG	N50653 001 MAR 25, 1994	300MG
+ ON SITE ALZA	12.7MG/FIBER	MAR 25, 1994	TABLET, EXTENDED RELEASE; ORAL LABID + PROCTER AND GAMBLE 250MG
		N50266 001	N89976 001 JAN 04, 1995 N89977 001 JAN 04, 1995 N89932 001 JAN 04, 1995
> ADD > > ADD > > ADD >	OINTMENT; OPHTHALMIC ACROMYCIN + LEDERLE	1.0MG/GM	N87225 001

THEOPHYLLINE

TABLET, TABID @ PROCTER AND GAMBLE	EXTENDED RELEASE; ORAL 250MG	N87225 001	<u>AT</u>	<u>TIMOLOL MALEATE</u>
BC 3M	250MG	N86363 002 JUL 16, 1987	<u>AT</u>	<u>EQ 0 .25% BASE</u>
	250MG	N86363 002 JUL 16, 1987	<u>AT</u>	<u>EQ 0 .5% BASE</u>
<u>AB</u>	<u>THEOPHYLLINE</u> INWOOD LABS	<u>450MG</u>	<u>AT</u> + MERCK <u>AT</u> +	<u>TILOCNAZOLE</u>
BC	UNI-DUR + KEY PHARMS	400MG 600MG	JAN 04, 1995 JAN 04, 1995	OINTMENT; VAGINAL VAGISTAT-1 + BRISTOL MYERS
	+			6 .5%
BC	UNIPHYL PURDUE FREDERICK	400MG	SEP 01, 1982	* BRISTOL MYERS SQUIBB 6 .5%

THIOTEPA

INJECTABLE; INJECTION <u>THIOPLEX</u> IMMUNEX	15MG/VIAL	N20058 001 DEC 22, 1994	TONOCARD	TABLET; ORAL
AP	LEDERLE	N20058 001 DEC 22, 1994	+	ASTRA MERCK
AP	<u>THIOTEPA</u> * IMMUNEX	15MG/VIAL 15MG/VIAL	MERCK SHARP DOWNS	400MG
	+		*	600MG
				111683 001 N11683 001 NOV 09, 1984

TIMOLOL

SOLUTION/DROPS; OPHTHALMIC BETIMOL + LEIRAS	EQ 0 .25% BASE	N20439 001 MAR 31, 1995	TABLET; ORAL ULTRAM	TABLET; ORAL
	EQ 0 .5% BASE	N20439 002 MAR 31, 1995	+ JOHNSON RW	50MG
			@	100MG

TOCAINIDE HYDROCHLORIDE

		N18257 001 NOV 09, 1984	
		N18257 002 NOV 09, 1984	
		N18257 001 NOV 09, 1984	
		N18257 001 NOV 09, 1984	
		N18257 002 NOV 09, 1984	

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL KENALOG-H WESTWOOD SQUIBB	<u>AT</u> <u>AT</u> <u>DLT</u>	<u>></u> <u>></u> <u>></u>	0.1% <u>0.1%</u>	N86240 001 N86240 001	CAPSULE; ORAL MODRASTANE SANOFI WINTHROP	3.0MG 6.0MG	N18719 002 DEC 31, 1984 N18719 001 DEC 31, 1984
INJECTABLE; INJECTION KENALOG-10 + APOTHECON * WESTWOOD SQUIBB	<u>ADD</u> <u>DLT</u>	<u>></u> <u>></u>	1.0MG/ML 1.0MG/ML	N12041 001 N12041 001	3.0MG 6.0MG	@ @	N18719 002 DEC 1, 1984 N18719 001 DEC 31, 1984
KENALOG-40 APOTHECON WESTWOOD SQUIBB	<u>ADD</u> <u>DLT</u>	<u>></u> <u>></u>	4.0MG/ML 4.0MG/ML	N14901 001 N14901 001			
Lotion; Topical KENALOG APOTHECON	<u>ADD</u> <u>ADD</u> <u>ADD</u> <u>ADD</u> <u>DLT</u> <u>DLT</u> <u>DLT</u> <u>DLT</u>	<u>></u> <u>></u> <u>></u> <u>></u> <u>></u> <u>></u> <u>></u> <u>></u>	0.025% 0.1% 0.025% 0.1% 0.025% 0.1% 0.025% 0.1%	N84343 001 N84343 002 N11602 003 N11602 001 N84343 001 N84343 002 N11602 003 N11602 001	INJECTABLE; INJECTION TUBOCURARINE CHLORIDE	<u>AP</u> <u>AP</u> <u>AP</u> <u>AP</u> <u>VALPROIC ACID</u> <u>SYRUP; ORAL</u> <u>VALPROIC ACID</u>	<u>3MG/ML</u> <u>3MG/ML</u> <u>3MG/ML</u> <u>3MG/ML</u> <u>VALPROIC ACID</u> <u>SYRUP; ORAL</u> <u>VALPROIC ACID</u>
Ointment; Topical TRIAMCINOLONE ACETONIDE IN ABSORBASE + CAROLINA MEDCL	<u>ADD</u> <u>DLT</u>	<u>></u> <u>></u>	0.05% 0.05%	N89595 001 MAR 23, 1995	VANCOMYCIN HYDROCHLORIDE	<u>HIA</u> <u>HIA</u>	25.0MG/5ML HIGH TECH PHARMA
Paste; Dental KENALOG IN ORABASE	<u>ADD</u> <u>DLT</u>	<u>></u> <u>></u>	0.1% 0.1%	N12097 001 N12097 001	POWDER FOR RECONSTITUTION; ORAL VANCOCIN HCL	<u>AB</u> <u>AB</u>	<u>EQ 500MG BASE/6ML</u> <u>EQ 500MG BASE/6ML</u>
TRICHLORMETHIAZIDE					+ + + + VALCOLED LEDERLE	<u>AB</u> <u>AB</u> <u>AB</u> <u>AB</u>	<u>EQ 500MG BASE/6ML</u> <u>EQ 500MG BASE/6ML</u> <u>EQ 500MG BASE/6ML</u> <u>EQ 500MG BASE/6ML</u>
TABLET; ORAL NAQUA SCHEERING	<u>DLT</u> <u>ADD</u>	<u>></u> <u>></u>	2MG 2MG	N12265 001 N12265 001	VITAMIN A	<u>AA</u> <u>AA</u>	50,000 USP UNITS 50,000 USP UNITS
VITAMIN A					CAPSULE; ORAL VITAMIN A BANNER PHARMACAPS		NR3973 001 N83973 001

VITAMIN A PALMITATE

CAPSULE; ORAL		
<u>VITAMIN A</u>		
@ BANNER PHARMACAPS	EQ 50,000 UNITS BASE	N80702 .001
	EQ 50,000 UNITS BASE	N80702 .001

<u>VITAMIN A PALMITATE</u>		
@ BANNER PHARMACAPS	EQ 50,000 UNITS BASE	N83948 .001
	EQ 50,000 UNITS BASE	N83948 .001

WARFARIN SODIUM

INJECTABLE; INJECTION		
COUmadin		
+ DUPONT MERCK	5MG/VIAL	N09218 024

FEB 07, 1995

<u>ACETAMINOPHEN</u>	<u>IBUPROFEN</u>	
SUPPOSITORY; RECTAL ACETAMINOPHEN ABLE	TABLET; ORAL MIDOL WINTHROP	200MG N71001 001 SEP 02, 1987
120MG FEB 27, 1995		N70591 001 SEP 02, 1987
325MG N73107 001 FEB 27, 1995	@	N71001 001 SEP 02, 1987
650MG N73108 001 FEB 27, 1995	@	SEP 02, 1987
<u>ANTAZOLINE PHOSPHATE; NAPHAZOLINE HYDROCHLORIDE</u>	<u>INSULIN PORK</u>	
> ADD > > ADD > > ADD > > ADD >	INJECTABLE; INJECTION INSULIN + NOVO NORDISK REGULAR INSULIN + NOVO NORDISK	100 UNITS/ML N17926 003 N17926 003
SOLUTION/DROPS; OPHTHALMIC VASOCON-A + CIBA	N18746 002 JUL 11, 1994	100 UNITS/ML 100 UNITS/ML
0.5% .0.05%		
<u>FAMOTIDINE</u>	<u>INSULIN PURIFIED PORK</u>	
TABLET; ORAL PEPCID AC + MERCK	N20325 001 APR 28, 1995	100 UNITS/ML N18193 001 N18193 001
10MG	@	
<u>IBUPROFEN</u>	<u>INSULIN PURIFIED PORK; INSULIN SUSP ISOPHANE PURIFIED PORK</u>	
CAPSULE; ORAL MIDOL + WINTHROP	INJECTABLE; INJECTION INSULIN NORDISK MIXTARD (PORK) + NOVO NORISK @	30 UNITS/ML; 70 UNITS/ML N18195 001 30 UNITS/ML; 70 UNITS/ML N18195 001
200MG N70626 001 SEP 02, 1987		
200MG N1002 001 SEP 02, 1987		
200MG N70626 001 SEP 02, 1987		
200MG N71002 001 SEP 02, 1987		
@		
200MG N70626 001 SEP 02, 1987		
200MG N71002 001 SEP 02, 1987		
<u>PROVEL</u>	<u>INSULIN SEMISYNTHETIC PURIFIED HUMAN; INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN</u>	
+ SANDOZ	INJECTABLE; INJECTION MIXTARD HUMAN 70/30 + NOVO NORISK @	30 UNITS/ML; 70 UNITS/ML N19585 001 30 UNITS/ML; 70 UNITS/ML N19585 001 30 UNITS/ML; 70 UNITS/ML N19585 001 MAR 11, 1988
200MG N20402 001 APR 20, 1995	> DLT > > DLT > > DLT > @	
	> ADD > > ADD > > ADD >	
<u>TABLET; ORAL</u>		
MIDOL WINTHROP	N70591 001 SEP 02, 1987	30 UNITS/ML; 70 UNITS/ML N19441 001 JUL 11, 1986
200MG		

INSULIN SEMISYNTHETIC PURIFIED HUMAN; INSULIN SUSP ISOPHANE
SEMISYNTHETIC PURIFIED HUMANINJECTABLE; INJECTION

NOVOLIN 70/30

@ NOVO NORDISK

30 UNITS/ML; 70 UNITS/ML
N19441 001
JUL 11, 1986INSULIN SUSP ISOPHANE PURIFIED PORKINJECTABLE; INJECTION

INSULIN INSULATARD NPH NORDISK

@ NOVO NORDISK

100 UNITS/ML
100 UNITS/ML
100 UNITS/MLINSULIN SUSP PROTAMINE ZINC PURIFIED BEEFINJECTABLE; INJECTION

PROTAMINE ZINC AND ILETIN II

+ LILLY

100 UNITS/ML
100 UNITS/ML
100 UNITS/ML
100 UNITS/ML
100 UNITS/ML

+ SQUIBB

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NONOXYNOL-9AEROSOL; VAGINAL

DELFEN

@ ORTHO

12 . 5%

N14349 002

SOLUTION; ORAL
POTASSIUM IODIDE

+ ROXANE

@

1GM/ML

N18551 001

FEB 19, 1982

N18551 001

FEB 19, 1982

PYRITHIONE ZINCLOTION; TOPICAL

+ HEAD & SHOULDERS CONDITIONER

+ PROCTER AND GAMBLE

0 . 3 %

N19412 002

MAR 10, 1986

N19412 002

MAR 10, 1986

FEB 19, 1982

N18551 001

FEB 19, 1982

MICONAZOLE NITRATECREAM; VAGINAL

MICONAZOLE NITRATE

LEMMON

2%

N74136 001

JAN 04, 1995

NAPROXEN SODIUMTABLET; ORAL

ALEVE

HAMILTON PHARMS

EQ 200MG BASE

N20204 002

JAN 11, 1994

N20204 002

JAN 11, 1994

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 5 / MAY '95

HETASTARCH 6% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION
6% HETASTARCH IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
6GM/100ML; 0.9GM/100ML N74193
ABBOTT JAN 30, 1995

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January - May, 1995]

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
ADENO-AS'TED VIRAL-BASED VECTOR CYSTIC FIBROSIS GENE THERAPY TN=	TREATMENT OF CYSTIC FIBROSIS.	TARGETED GENETICS CORPORATION 1100 OLIVE WAY, SUITE 100 SEATTLE WA 98101 DD 02/15/95 MA / /
AMINOCAPROIC ACID TN=	FOR THE TOPICAL TREATMENT OF TRAUMATIC HYPHEMA OF THE EYE.	ORPHAN MEDICAL 13911 RIDGEDALE DRIVE MINNETONKA MN 55305 DD 01/06/95 MA / /
APL 400-020 TN=	TREATMENT OF CUTANEOUS T CELL LYMPHOMA.	APOLLON, INC. ONE GREAT VALLEY PARKWAY MALVERN PA 19355 DD 03/08/95 MA / /
CHONDROITINASE TN=	TREATMENT OF PATIENTS UNDERGOING VITRECTOMY.	STORZ OPHTHALMICS AMERICAN CYANAMID COMPANY PEARL RIVER NY 10965 DD 02/09/95 MA / /
CLOTRIMIDAZOLE TN=	TREATMENT OF SICKLE CELL DISEASE.	BRUGNARA, CARLO M.D. THE CHILDREN'S HOSPITAL BOSTON MA 02115 DD 04/24/95 MA / /
CYSTIC FIBROSIS TR GENE THERAPY (RECOMBINANT ADENOVIRUS) TN= ADgvCFTR.10	TREATMENT OF CYSTIC FIBROSIS.	GENVAC, INCORPORATED 12111 PARKLAWN DRIVE ROCKVILLE MD 20852 DD 03/09/95 MA / /
GLUTAMINE TN=	FOR USE WITH HUMAN GROWTH HORMONE IN THE TREATMENT OF SHORT BOWEL SYNDROME (NUTRIENT MALABSORPTION FROM THE GASTROINTESTINAL TRACT RESULTING FROM AN INADEQUATE ABSORPTIVE SURFACE).	RESEARCH TRIANGLE PHARMACEUTICALS 4364 SOUTH ALSTON AVENUE DURHAM NC 27713 DD 03/06/95 MA / /
GLYCERYL TRIOLEATE AND GLYCERYL TRIERUCATE TN=	TREATMENT OF ADRENOLEUKODYSTROPHY.	MOSER, HUGO W. M.D. JOHNS HOPKINS UNIVERSITY BALTIMORE MD 21205 DD 02/14/95 MA / /
HEPATITIS B IMMUNE GLOBULIN, INTRAVENOUS TN= H-BIGIV	PROPHYLAXIS AGAINST HEPATITIS B VIRUS REINFECTION IN LIVER TRANSPLANT PATIENTS.	NORTH AMERICAN BIOLOGICS, INC. 16500 N.W. 15th AVENUE MIAMI FL 33169 DD 03/08/95 MA / /
HUMAN GROWTH HORMONE TN=	FOR USE WITH GLUTAMINE IN THE TREATMENT OF SHORT BOWEL SYNDROME (NUTRIENT MALABSORPTION FROM THE GASTROINTESTINAL TRACT RESULTING FROM AN INADEQUATE ABSORPTIVE SURFACE).	RESEARCH TRIANGLE PHARMACEUTICALS 4364 SOUTH ALSTON AVENUE DURHAM NC 27713 DD 03/06/95 MA / /
HUMAN IMMUNODEFICIENCY VIRUS IMMUNE GLOBULIN TN= HIVIG	TREATMENT OF HIV-INFECTED PEDIATRIC PATIENTS.	NORTH AMERICAN BIOLOGICALS, INC. 16500 N.W. 15TH AVENUE MIAMI FL 33169 DD 01/04/95 MA / /
NTBC TN=	TREATMENT OF TYROSINEMIA TYPE 1.	SWEDISH ORPHAN AB ORPHAN PHARMACEUTICAL, USA, INC. NASHVILLE TN 37217 DD 05/16/95 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

36

NAME

Generic/Chemical
TN=Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD=Date Designated

MA=Marketing Approval

PHENYLALANINE AMMONIA-LYASE
TN= PHENYLASE

TREATMENT OF HYPERPHENYLALANINEMIA.

IBEX TECHNOLOGIES, INC.
5485 PARE
MONTREAL, QUEBEC
DD 03/08/95 MA / /

PURIFIED TYPE II COLLAGEN
TN= COLLORAL

TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.

AUTOIMMUNE, INCORPORATED
128 SPRING STREET
LEXINGTON MA 02173
DD 02/09/95 MA / /

RECOMBINANT HUMAN GELSOLIN
TN=

TREATMENT OF ACUTE AND CHRONIC RESPIRATORY SYMPTOMS OF BRONCHIECTASIS.

BIOGEN, INCORPORATED
14 CAMBRIDGE CENTER
CAMBRIDGE MA 02142
DD 03/06/95 MA / /

SARGRAMOSTIM
TN= LEUKINE

TO REDUCE NEUTROPENIA AND LEUKOPENIA AND DECREASE THE INCIDENCE OF DEATH DUE TO INFECTION IN PATIENTS WITH ACUTE MYELOGENOUS LEUKEMIA.

IMMUNEX CORPORATION
51 UNIVERSITY STREET
SEATTLE WA 98101
DD 03/06/95 MA / /

SU-101

TREATMENT OF MALIGNANT GLIOMA.

SUGEN, INC.
515 GALVESTON DRIVE
REDWOOD CITY CA 94063-4720
DD 05/25/95 MA / /

THALIDOMIDE
TN=

TREATMENT OF SEVERE RECURRENT APHTHOUS STOMATITIS IN SEVERELY, TERMINALLY IMMUNOCOMPROMISED PATIENTS.

CELGENE CORPORATION
P.O. BOX 4914
WARREN NJ 07059
DD 05/01/95 MA / /

THALIDOMIDE
TN=

TREATMENT AND PREVENTION OF RECURRENT APHTHOUS ULCERS IN SEVERELY, TERMINALLY IMMUNOCOMPROMISED PATIENTS.

ANDRULIS RESEARCH CORPORATION
11800 BALTIMORE AVENUE, SUITE 113
BELTSVILLE MD 20705
DD 05/15/95 MA / /

TYLOXAPOL
TN=

TREATMENT OF CYSTIC FIBROSIS.

KENNEDY & HOITAL, MDS
50 NORTH MEDICAL DRIVE, U OF UTAH
SALT LAKE CITY UT 84132
DD 03/08/95 MA / /

Rho (D) IMMUNE GLOBULIN
INTRAVENOUS (HUMAN)
TN= WinRho SD

TREATMENT OF IMMUNE THROMBOCYTOPENIC PURPURA.

RH PHARMACEUTICALS, INC.
104 CHANCELLOR MATHESON ROAD
WINNIPEG, MANITOBA
DD 11/09/93 MA 03/24/95

Approved Orphan Products

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

NO MAY 1995 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
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THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR *IN VIVO* BIOEQUIVALENCE STUDIES AND *IN VITRO* DISSOLUTION TESTING. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE (HFD-650, MPN-2 ROOM 279) 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 15TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO MAY 1995 GUIDANCES

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED AND REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANCH, HFA-305, ROOM 1-23, PARK BUILDING, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 15TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE TABLET; ORAL	150MG 180MG 15MG	94 P-0212/ CP1	MIKART	NEW DOSAGE FORM	APPROVED JAN 19, 1995
ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE TABLET; ORAL	150MG 180MG 30MG	94 P-0211/ CP1	MIKART	NEW DOSAGE FORM	APPROVED JAN 19, 1995
ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE TABLET; ORAL	150MG 180MG 60MG	94 P-0210/ CP1	MIKART	NEW DOSAGE FORM	APPROVED JAN 19, 1995
ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE TABLET; ORAL	712.8MG 60MG 32MG	93 P-0484/ CP1	MIKART	NEW DOSAGE FORM NEW STRENGTH	APPROVED JAN 19, 1995
ACETAMINOPHEN; CODEINE PHOSPHATE TABLET, CHEWABLE; ORAL	120MG 12MG	94 P-0182/ CP1	WE PHARMS	NEW DOSAGE FORM	APPROVED JAN 19, 1995
ALBUTEROL SULFATE TABLET, CHEWABLE; ORAL	EQ 2MG BASE EQ 4MG BASE	92 P-0335/ CP1	WE PHARMS	NEW DOSAGE FORM	APPROVED JAN 19, 1995
ATRACURIUM BESLYLATE INJECTABLE; INJECTION	25MG/ML	94 P-0314/ CP1	ABBOTT	NEW STRENGTH	APPROVED MAY 02, 1995
LEUCOVORIN CALCIUM INJECTABLE; INJECTION	EQ 10MG BASE/ML (100MG/VIAL)	93 P-0427/ CP3	ABBOTT	NEW DOSAGE FORM	APPROVED JAN 19, 1995
LEUCOVORIN CALCIUM INJECTABLE; INJECTION	EQ 10MG BASE/ML (250MG/VIAL)	93 P-0427/ CP2	ABBOTT	NEW DOSAGE FORM NEW STRENGTH	APPROVED JAN 19, 1995
SULFAMETHOXAZOLE; TRIMETHOPRIM TABLET, CHEWABLE; ORAL	200MG 40MG	94 P-0186/ CP1	DURA PHARMS	NEW DOSAGE FORM	APPROVED JAN 19, 1995
THIORIDAZINE HYDROCHLORIDE SOLUTION; ORAL	25MG/5ML	92 P-0283/ CP1	UDL LABS	NEW STRENGTH	APPROVED JAN 19, 1995

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
NICOTINE POLACRILEX LOLLIPOP; ORAL	2MG	93 P-0414/ CP1	SAVAGE	NEW DOSAGE FORM	DENIED MAY 02, 1995

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 15TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES NEW DOSING SCHEDULE

- D-26 ONCE WEEKLY APPLICATION
- D-27 BID DOSING IN PATIENTS 12 YEARS OF AGE AND OLDER FOR PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH MODERATELY EMETOGENIC CANCER CHEMOTHERAPY
- D-28 REVISED BASIS FOR CALCULATING THE RECOMMENDED STARTING DOSE IN ACCORDANCE WITH THE 1993 NATIONAL CHOLESTEROL EDUCATION PROGRAM GUIDELINES - DOSING RANGE EXPANDED TO 10-80MG/DAY

REFERENCES NEW INDICATION

- I-117 TO SLOW THE PROGRESSION OF CORONARY ATHEROSCLEROSIS IN PATIENTS WITH CORONARY HEART DISEASE
- I-118 PREVENTION OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLISM, FOLLOWING KNEE REPLACEMENT SURGERY
- I-119 TREATMENT OF ANEMIA CAUSED BY UTERINE LEIOMYOMATA IN WOMEN WHO FAIL IRON THERAPY
- I-120 MAINTENANCE THERAPY FOR GASTRIC ULCER PATIENTS AT REDUCED DOSAGE AFTER HEALING ACUTE ULCERS
- I-121 EXPANDED PATIENT POPULATION - USE IN ICU PATIENTS
- I-122 PSORIASIS OF THE SCALP
- I-123 RELIEF OF MILD TO MODERATE PAIN IN PATIENTS AGED 6 MONTHS AND OLDER
- I-124 LEUCOCYTE LABELED SCINTIGRAPHY AS AN ADJUNCT IN THE LOCALIZATION OF INTRA-ABDOMINAL INFECTION AND INFLAMMATORY BOWEL DISEASE
- I-125 EXPANSION OF CONSCIOUS SEDATION INDICATION TO INCLUDE SHORT THERAPEUTIC PROCEDURES
- I-126 ADJUNCT TO THALLIUM-201 MYOCARDIAL PERfusion IN PATIENTS UNABLE TO EXERCISE ADEQUATELY

REFERENCES PATENT USE CODE

- U-102 METHOD OF HORMONALLY TREATING MENOPAUSAL OR POST-MENOPAUSAL DISORDERS IN WOMEN
- U-103 TREATMENT OF OCULAR HYPERTENSION
- U-104 TREATMENT OF AQUEOUS HUMOR FORMATION AND INTRAOCCULAR PRESSURE
- U-105 EMESIS
- U-106 TREATMENT OF EPILEPSY
- U-107 TREATMENT OF HYPERTENSION AND ANGINA PECTORIS
- U-108 SHORT-TERM TREATMENT OF ACTIVE DUODENAL ULCER, GASTROESOPHAGEAL REFLUX DISEASE (GERD), SEVERE EROSIONAL ESOPHAGITIS, POORLY RESPONSIVE SYMPTOMATIC GERD AND PATHOLOGICAL HYPERSECRETORY CONDITIONS
- U-109 USE AS AN ADJUNCT TO DIET IN THE TREATMENT OF Elevated TOTAL CHOLESTEROL AND LDL-C LEVELS IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA WHOSE RESPONSE TO DIETARY RESTRICTION OF SATURATED FAT AND CHOLESTEROL AND OTHER NONPHARMACOLOGICAL MEASURES HAS NOT BEEN ADEQUATE

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
>ADD>						
>ADD>						
>ADD>						
>ADD>						
19872 001	ACETAMINOPHEN; TYLENOL	5004613	APR 11, 2006	NDF	JUN 08, 1997	
		49668509	NOV 06, 2007	NC	MAR 03, 1998	
		48205322	APR 11, 2006	NCE	JUN 25, 1996	
20059 001	ADENOSINE; ADENOSCAN	4879303	NOV 07, 2006	NCE	JUL 31, 1997	
20364 002	AMLODIPINE BESYLATE; LOTREL	4572909	AUG 01, 2006	NC	MAR 03, 1998	
20364 003	AMLODIPINE BESYLATE; LOTREL	4410520	OCT 18, 2002	NCE	JUN 25, 1996	
20364 004	AMLODIPINE BESYLATE; LOTREL	4879303	NOV 07, 2006	NC	MAR 03, 1998	
		4572909	AUG 01, 2006	NCE	JUL 31, 1997	
		4410520	OCT 18, 2002	NC	MAR 03, 1998	
20500 001	ATOVAQUONE; MEPRON	4879303	NOV 07, 2006	NCE	JUN 25, 1996	
		4410520	OCT 18, 2002	NCE	JUL 31, 1997	
		5053432	OCT 01, 2008	NCE	NOV 25, 1997	
		4981874	AUG 15, 2009	U-69	FEB 08, 1998	
20222 001	COLESTIPOL HYDROCHLORIDE; COLESTID	4303651	JAN 04, 2000	NDF	JUL 19, 1997	
20287 001	DALTEPARIN SODIUM; FRAGMIN			NCE	DEC 22, 1999	
>ADD>	DEXAZOXANE; ZINECARO			NCE	MAY 26, 2000	
20212 001	DEXAZOXANE; ZINECARO			NCE	MAY 26, 2000	
20212 002	DEXAZOXANE; ZINECARO			I-120	OCT 15, 1995	
20092 001	DILTIAZEM HYDROCHLORIDE; DILACOR XR			I-120	OCT 15, 1995	
20092 002	DILTIAZEM HYDROCHLORIDE; DILACOR XR			I-120	OCT 15, 1995	
20092 003	DILTIAZEM HYDROCHLORIDE; DILACOR XR			I-120	OCT 15, 1995	
20411 001	DINOPROSTONE; CERVIDIL	4797413	JUN 30, 2004	NDF	MAR 30, 1998	
20408 001	DORZOLAMIDE HYDROCHLORIDE; TRUSOPT	4619939	OCT 28, 2003	U-103	DEC 09, 1999	
19946 001	DOXACURIUM CHLORIDE; NUROMAX			I-121	DEC 08, 1997	
19668 001	DOXAZOSEN MESYLATE; CARDURA			I-96	FEB 06, 1998	
19668 002	DOXAZOSEN MESYLATE; CARDURA			I-96	FEB 06, 1998	
19668 003	DOXAZOSEN MESYLATE; CARDURA			I-96	FEB 06, 1998	
19668 004	DOXAZOSEN MESYLATE; CARDURA			I-96	FEB 06, 1998	
20164 001	ENOXAPARIN SODIUM; LOVENOX			I-118	MAR 09, 1998	

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
20323 001	ESTRADIOL; VIVELLE	5300291	APR 05, 2011	NS	OCT 28, 1997	
		4994278	FEB 19, 2008			
		4994267	FEB 19, 2008			
20323 002	ESTRADIOL; VIVELLE	4814168	MAR 21, 2006			
		5300291	APR 05, 2011			
		4994278	FEB 19, 2008			
20323 003	ESTRADIOL; VIVELLE	4994267	FEB 19, 2008			
		4814168	MAR 21, 2006			
		5300291	APR 05, 2011			
		4994278	FEB 19, 2008			
20323 004	ESTRADIOL; VIVELLE	4994267	FEB 19, 2008			
		4814168	MAR 21, 2006			
		5300291	APR 05, 2011			
		4994278	FEB 19, 2008			
20375 001	ESTRADIOL; CLIMARA	5223261	JUN 29, 2010	D-26	DEC 22, 1997	
20375 002	ESTRADIOL; CLIMARA	5223261	JUN 29, 2010	D-26	DEC 22, 1997	
20303 001	ESTROGENS, CONJUGATED; PREMPRO (PREMARIN; CYCRIN 14/14)	4826831	MAY 02, 2006	U-102	NP DEC 30, 1997	
20325 001	FAMOTIDINE; PECID AC	4283408	AUG 11, 2000	NS	APR 28, 1998	
>ADD>		4803081	FEB 07, 2006			
>ADD>	19834 001 FELODIPINE; PLENIL	4264611	APR 28, 1998	U-3	NCE JUL 25, 1996	
>ADD>	19834 002 FELODIPINE; PLENIL	4803081	FEB 07, 2006			
>ADD>	19834 004 FELODIPINE; PLENIL	4264611	APR 28, 1998	U-3	NCE JUL 25, 1996	
>ADD>		4803081	FEB 07, 2006			
>ADD>		4264611	APR 28, 1998	U-3	NCE JUL 25, 1996	
19452 001	FLUOCINOLONE ACETONIDE; DERMA-SMOOTH/FS	4335121	MAR 15, 2002			
20121 001	FLUTICASONE PROPIONATE; FLONASE					
>ADD>		5354772	OCT 11, 2011	U-109	NCE T-122	FEB 16, 1998
>ADD>		5354772	OCT 11, 2011	U-109	NCE DEC 14, 1995	
>ADD>	20261 001 FLUVASTATIN SODIUM; LESCOL					OCT 19, 1997
>ADD>	20261 002 FLUVASTATIN SODIUM; LESCOL					
>ADD>	19915 002 FOSINOPRIL SODIUM; MONOPRIL	4384123	MAY 17, 2000	I-92	MAY 02, 1998	
>ADD>	19915 003 FOSINOPRIL SODIUM; MONOPRIL	4384123	MAY 17, 2000	I-92	MAY 02, 1998	
>ADD>	19915 004 FOSINOPRIL SODIUM; MONOPRIL	5006344	APR 09, 2008	I-92	MAY 02, 1998	
>ADD>		4384123	MAY 17, 2000	NCE	MAY 16, 1996	
		4337201	JUN 29, 2001			

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
20460 001	GANCICLOVIR; CYTOVENE	4507305	OCT 19, 1999	U-64	NDF	DEC 22, 1997
20305 001	GRANISETRON HYDROCHLORIDE; KYTRIL	435032	MAR 16, 2003	U-64	NCE	DEC 29, 1998
> <u>ADD</u> >		4888808	DEC 12, 2006	U-105	NDF	MAR 16, 1998
> <u>ADD</u> >	HYDROCHLORTIAZIDE; HYZAAR	5153197	OCT 06, 2009	U-3	NC	APR 28, 1998
> <u>ADD</u> >	IBUPROFEN; CHILDREN'S MOTRIN	5138069	AUG 11, 2009		NCE	APR 14, 2000
> <u>ADD</u> >	IBUPROFEN; MOTRIN	5374659	DEC 20, 2011		I-123	MAR 24, 1998
> <u>ADD</u> >	IBUPROFEN; MOTRIN	5320855	JUN 14, 2011		I-123	MAR 24, 1998
> <u>ADD</u> >	IBUPROFEN; MOTRIN	5215755	JUN 01, 2010		NDF	NOV 16, 1997
> <u>ADD</u> >	IBUPROFEN; MOTRIN	5320855	JUN 14, 2011		I-123	MAR 24, 1998
> <u>ADD</u> >	IBUPROFEN; MOTRIN	5215755	JUN 01, 2010		NDF	NOV 16, 1997
> <u>ADD</u> >	IBUPROFEN; OMNIPAUQUE 70	4396597	JUL 14, 1998		I-123	MAR 24, 1998
18956 007	IOHEXOL; OMNIPAUQUE 70	4250113	DEC 26, 1999			
> <u>ADD</u> >	IPRAMIDE; ULTRAVIST					
> <u>ADD</u> >	IPRAMIDE; ULTRAVIST					
> <u>ADD</u> >	IPRAMIDE; ULTRAVIST					
> <u>ADD</u> >	IPRAMIDE; ULTRAVIST					
20220 001	IPRAMIDE; ULTRAVIST					
20220 002	IPRAMIDE; ULTRAVIST					
20220 003	IPRAMIDE; ULTRAVIST					
20220 004	IPRAMIDE; ULTRAVIST					
20225 003	ISOSORBIDE MONONITRATE; IMDUR					
19816 002	KETOPROFEN; ORUVAIL					
19816 003	KETOPROFEN; ORUVAIL					
20241 001	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003		U-106	NCE
20241 002	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003		U-106	NCE
20241 003	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003		U-106	NCE
20241 004	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003		U-106	NCE
20241 005	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003		U-106	NCE
20241 006	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003		U-106	NCE
20406 001	LANSOPRAZOLE; PREVACID					
20406 002	LANSOPRAZOLE; PREVACID					
20011 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4005063	JAN 25, 1996			
19670 001	LORATADINE; CLARITIN-D	4282233	AUG 04, 2000			
> <u>ADD</u> >	LOSARTAN POTASSIUM; COZAAR	5153197	OCT 06, 2009	U-3	NCE	APR 14, 2000
> <u>ADD</u> >	LOSARTAN POTASSIUM; COZAAR	5138069	AUG 11, 2009		NCE	APR 14, 2000
> <u>ADD</u> >	LOSARTAN POTASSIUM; COZAAR	5153197	OCT 06, 2009	U-3		
> <u>ADD</u> >	LOSARTAN POTASSIUM; COZAAR	5138069	AUG 11, 2009		NCE	APR 14, 2000

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS EXPRES
19643 002	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999	I-117	FEB 08, 1998
19643 003	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999	I-117	FEB 08, 1998
19643 004	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999	I-117	FEB 08, 1998
> <u>ADD</u> >	19962 001 METOPROLOL SUCCINATE; TOPROL-XL	5081154	JAN 14, 2009		
> <u>ADD</u> >		5001161	MAR 19, 2008		
> <u>ADD</u> >	19962 002 METOPROLOL SUCCINATE; TOPROL-XL	4957745	SEP 18, 2007	U-107	NE JAN 10, 1995
> <u>ADD</u> >		5081154	JAN 14, 2009		
> <u>ADD</u> >	19962 003 METOPROLOL SUCCINATE; TOPROL-XL	5001161	MAR 19, 2008		
> <u>ADD</u> >		4957745	SEP 18, 2007	U-107	NE JAN 10, 1995
> <u>ADD</u> >	18654 001 MIDAZOLAM HYDROCHLORIDE; VERSED	4280957	DEC 20, 1999	I-125	APR 26, 1997
> <u>ADD</u> >	18654 002 MIDAZOLAM HYDROCHLORIDE; VERSED	4280957	DEC 20, 1999	I-125	APR 26, 1997
> <u>ADD</u> >	20312 001 MOEXIPRIL HYDROCHLORIDE; UNIVASC	4280957	DEC 20, 1999	NCE	APR 19, 2000
> <u>ADD</u> >	20312 002 MOEXIPRIL HYDROCHLORIDE; UNIVASC				
> <u>ADD</u> >	20459 001 NALMEFFENE HYDROCHLORIDE; REVEX				
> <u>ADD</u> >	20459 002 NALMEFFENE HYDROCHLORIDE; REVEX				
> <u>ADD</u> >	20198 001 NIIFEDIPINE; ADALAT CC	5264446	NOV 23, 2010	NCE	APR 19, 2000
> <u>ADD</u> >	20198 002 NIIFEDIPINE; ADALAT CC	5264446	NOV 23, 2010	NCE	APR 17, 2000
> <u>ADD</u> >	20356 001 NISOLDIPINE; NISOCOR	5264446	NOV 23, 2010	NCE	APR 17, 2000
> <u>ADD</u> >	20356 002 NISOLDIPINE; NISOCOR				
> <u>ADD</u> >	20356 003 NISOLDIPINE; NISOCOR				
> <u>ADD</u> >	20356 004 NISOLDIPINE; NISOCOR				
> <u>ADD</u> >	20145 001 NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010	NCE	FEB 02, 2000
> <u>ADD</u> >	20145 002 NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010	NCE	FEB 02, 2000
> <u>ADD</u> >	20145 003 NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010	NCE	FEB 02, 2000
> <u>ADD</u> >	20145 004 NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010	NCE	FEB 02, 2000
> <u>ADD</u> >	20145 005 NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010	NCE	FEB 02, 2000
> <u>ADD</u> >	20145 006 NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010	NCE	FEB 02, 2000
> <u>ADD</u> >	19810 001 OMEPRAZOLE; PRILOSEC	4853230	NOV 02, 2005	U-108	
> <u>ADD</u> >		4786505	NOV 22, 2005	U-108	
> <u>DLT</u> >		4286505	NOV 22, 2005	U-37	
> <u>ADD</u> >	20007 001 ONDANSETRON HYDROCHLORIDE; ZOFRAN	4255431	MAR 10, 2000	U-108	D-20 FEB 02, 1996
		4695578	JAN 04, 2005		

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
20103 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005	NCE	JAN 04, 1996	D-27 APR 10, 1998
20103 002	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005	NCE	JAN 04, 1996	I-9 APR 19, 1998
20403 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4753789	JUN 28, 2005	U-44	D-20 FEB 02, 1996	D-27 APR 10, 1998
		4695578	JAN 04, 2005	NCE	JAN 04, 1996	I-9 APR 19, 1998
		5061722	OCT 29, 2008	U-3		
19901 001	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
19901 002	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
19901 003	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
19901 004	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
18703 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4585790	APR 29, 2003			
18703 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	5028432	JUL 02, 2008			
19675 001	RANITIDINE HYDROCHLORIDE; ZANTAC	5028432	JUL 02, 2008			
20095 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5028432	JUL 02, 2008			
20095 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	5102665	APR 07, 2009			
20251 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5102665	APR 07, 2009			
20251 002	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5380972	JAN 10, 2012			
20236 001	SALMETEROL XINAFOATE; SEREVENT	4470972	SEP 11, 2001	U-3	NCE	DEC 29, 1999
20240 001	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2001	U-3	NCE	DEC 29, 1999
20240 002	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2001	U-3	NCE	DEC 29, 1999
20240 003	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2001	U-3	NCE	DEC 29, 1999
20240 004	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4789736	DEC 06, 2005			
19829 001	TECHNETIUM TC-99M EXAMETAZIME KIT; CERETEC				I-124 APR 07, 1998	

>ADD>

**PREScription AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA**

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS IVE	EXCLUS IVE EXPIRES
19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5412095	MAR 15, 2011			
19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	MAR 15, 2011			
19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5212176	MAY 18, 2010			
19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5412095	MAR 15, 2011			
20347 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	MAR 15, 2011			
20347 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5212176	MAY 18, 2010			
20347 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5412095	MAR 15, 2011			
20347 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5412095	MAR 15, 2011			
20439 001	TIMOLOL; BETIMOL	5231095	JUL 27, 2010			
20439 002	TIMOLOL; BETIMOL	5231095	JUL 27, 2010			
20281 001	TRAMADOL HYDROCHLORIDE; ULTRAM			NP	MAR 31, 1998	
20281 002	TRAMADOL HYDROCHLORIDE; ULTRAM			NP	MAR 31, 1998	
20388 001	VINORELBINE TARTRATE; NAVELBINE	4307100	DEC 22, 1998	NCE	MAR 03, 2000	

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