

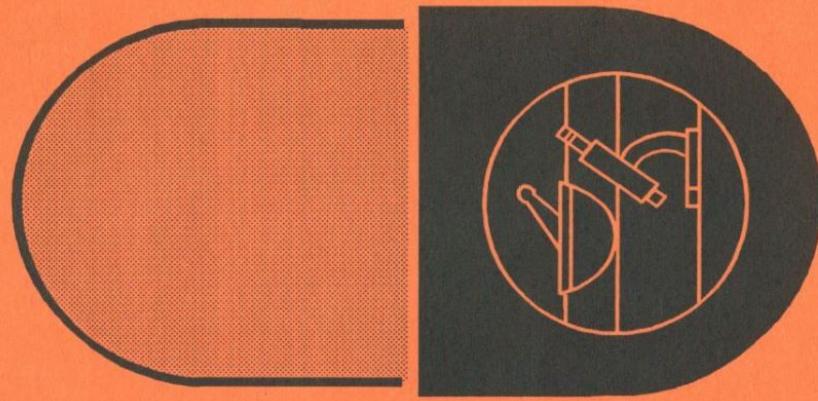
CUMULATIVE
SUPPLEMENT 7
JAN'94-JUL'94

APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

14TH EDITION

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



RM
301.45
.A66
1994
Jul
Suppl

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

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

14TH EDITION

Cumulative Supplement 7

JULY 1994

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Approved drug products with
therapeutic equivalence
C:355661 M:174736 O:12937927
APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

14TH EDITION

CUMULATIVE SUPPLEMENT 7

JULY 1994

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, 14th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 overstruck print. The >**DLT**> symbol is dropped in subsequent Cumulative Supplements for that item. The overstruck print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck 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 14th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 15th 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; or when an applicant name is changed to meet internal publication standards. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the Cumulative Supplement.

APPLICANT NAME CHANGES

<u>FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)</u>	<u>NEW APPLICANT NAME (NEW ABBREVIATED NAME)</u>
ADRIA LABORATORIES DIV ERBAMONT INC (ADRIA)	PHARMACIA INC (PHARMACIA)
BANNER GELATIN PRODUCTS CORP (BANNER GELATIN)	BANNER PHARMACAPS INC (BANNER PHARMACAPS)
CLONMEL CHEMICALS CO LTD (CLONMEL)	CLONMEL HEALTHCARE LIMITED (CLONMEL)
DUPONT PHARMACEUTICALS (DUPONT)	DUPONT MERCK PHARMACEUTICALS CO (DUPONT MERCK)
GYNEX INC (GYNEX)	BTG PHARMACEUTICALS CORP SUB BIOTECHNOLOGY GENERAL CORP (BTG PHARMS)
MALLINCKRODT SPECIALTY CHEMICALS CO (MALLINCKRODT)	MALLINCKRODT CHEMICAL INC (MALLINCKRODT)
NORTH AMERICAN CHEMICAL CORP (NORTH AM CHEM)	GOLDEN PHARMACEUTICALS (GOLDEN PHARM)
PHARMACAPS INC (PHARMACAPS)	BANNER PHARMACAPS INC (BANNER PHARMACAPS)
RICHLYN LABORATORIES INC (RICHLYN)	GLOBAL PHARMACEUTICAL CORPORATION (GLOBAL PHARM)

1.4 NEW INDICATIONS FOR PREVIOUSLY APPROVED DRUG PRODUCTS

When an application is submitted to FDA for a new indication for a drug product that duplicates a drug product (same active moiety, same salt, same formulation, or same combination) already approved or marketed in the United States by the same firm, the application is either submitted as a supplement to the original NDA (if the clinical expertise for the review of the new indication resides in the same division that reviewed the original NDA), or as a "Type 6 NDA" and assigned a new NDA number (if the clinical expertise for the review of the new indication resides in another review division). When an application is submitted to FDA for a new indication for a drug product that duplicates a drug product (same active moiety, same salt, same formulation, or same combination) already approved or marketed in the United States by a different firm, the application is classified as "Type 6" and assigned a new NDA number. For administrative purposes, FDA has been listing all "Type 6 NDA's" in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, (ADP), even when the application was submitted by the original NDA holder. However, FDA has determined that the practice of listing a separate "Type 6 NDA" number in the ADP when the applicant is the original NDA holder may cause confusion to the ADP reader.

Accordingly, to prevent confusion and to eliminate duplicity of data, the approval of an application for a new indication for a previously approved drug product submitted by the original NDA holder will no longer be listed in the ADP. Any exclusivity awarded for that approval will be shown in the Patent and Exclusivity Information Addendum under the original NDA number. However, approval of an application for a new indication submitted by an applicant other than the original NDA holder will be shown in the appropriate drug product list of the ADP. Any exclusivity awarded will be shown under the NDA number of the new applicant.

All approvals of "Type 6" applications submitted by the original NDA holder currently in the ADP are listed in the table below. For reference purposes, the original NDA number is listed next to the corresponding "Type 6 NDA Number". This data ("Type

6 NDA Number") will continue to be listed in the remaining Cumulative Supplements to the 14th Edition of the ADP; but it will not appear in the 15th Edition of the ADP.

<u>TYPE 6 NDA NUMBER</u>	<u>ORIGINAL NDA NUMBER</u>	<u>ACTIVE INGREDIENT (TRADE NAME)</u>	<u>DOSAGE FORM (ROUTE)</u>
17-117	16-020	AMANTADINE HCL (SYMMETREL)	CAPSULE (ORAL)
17-118	16-023	AMANTADINE HCL (SYMMETREL)	SYRUP (ORAL)
50-697	50-662	CLARITHROMYCIN (BIAXIN)	TABLET (ORAL)
19-576	19-084	KETOCONAZOLE (NIZORAL)	CREAM (TOPICAL)
19-648	19-084	KETOCONAZOLE (NIZORAL)	CREAM (TOPICAL)
18-064	18-063	NADOLOL (CORGARD)	TABLET (ORAL)
20-109	19-886	NAFARELIN ACETATE (SYNAREL)	SPRAY, METERED (NASAL)
20-223	19-057	TERAZOSIN HCL (HYTRIN)	TABLET (ORAL)

1.5 USP MONOGRAPH TITLE ADDITIONS OR CHANGES

The U.S. Pharmacopeia (USP) periodically makes additions to or changes in monograph titles. Some of these additions or changes may affect dosage form terms listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (ADP). Instead of making the change in each affected product, the Cumulative Supplement (CS) will list applicable monograph title and dosage form additions or changes in this section. These will appear as soon as the modified USP monograph title is official. It is possible for these additions or changes to be listed in this section before all applicant holders have made labeling modifications.

The monograph title additions or changes shown below will remain in this section in each succeeding supplement of this edition. Once the next edition of the ADP is published, the products affected by the title additions or changes will be displayed with the new dosage form in the appropriate drug list. As notification to the reader, these monograph title additions or changes will also be listed in a special section of the ADP.

USP MONOGRAPH TITLE ADDITIONS OR CHANGES

FORMER USP MONOGRAPH TITLE
(FORMER ADP DOSAGE FORM; ROUTE)

NEW USP MONOGRAPH TITLE
(NEW ADP DOSAGE FORM; ROUTE)

THERE WERE NO USP MONOGRAPH TITLE ADDITIONS OR CHANGES DURING THE MONTH OF JUNE 1994.

1.6 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 1993) 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 1993</u>	<u>MAR 1994</u>	<u>JUN 1994</u>	<u>SEP 1994</u>
DRUG PRODUCTS LISTED	9140	9153	9079	
SINGLE SOURCE	2144 (23.5%)	2151 (23.5%)	2150 (23.7%)	
MULTISOURCE	6996 (76.5%)	7002 (76.5%)	6929 (76.3%)	
THERAPEUTICALLY EQUIVALENT	6292 (68.8%)	6306 (68.9%)	6290 (69.3%)	
NOT THERAPEUTICALLY EQUIVALENT	527 (5.8%)	513 (5.6%)	458 (5.0%)	
EXCEPTIONS ¹	177 (1.9%)	183 (2.0%)	181 (2.0%)	
NEW MOLECULAR ENTITIES APPROVED	--	6	5	
NUMBER OF APPLICANTS	526	528	490	

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

ACETAMINOPHEN; BUTALBITAL; CAFFEEINE

> DLT >	CAPSULE; ORAL /MEDIGESIC PLUS/	/N89115/001 /JAN/14, 1986/	AB	TABLET; ORAL ALPRAZOLAM MYLAN	0.25MG
> DLT > /AB/	/US/CHEM/		AB		0.5MG
> DLT >	MEDIGESIC PLUS	N89115 001 JAN 14, 1986	AB		1MG
> ADD >	@ US CHEM	325MG; 50MG; 40MG	AB		2MG
> ADD >			AB		0.25MG
	ACETIC ACID, GLACIAL; ALUMINUM ACETATE		AB	NOVOPHARM	0.25MG
	SOLUTION/DROPS; OTIC ACETIC ACID 2% IN AQUEOUS ALUMINUM ACETATE		AB		0.5MG
AT	BAUSCH AND LOMB 2%; 0.79%	N40063 001 FEB 25, 1994	AB		1MG
/AI/	/BOROFAIR/ /PHARMAFAIR/	/N88606/001/1 /AUG/21, 1985/ N88606 001 AUG 21, 1985	> ADD > AB > ADD > AB	ZENITH LABS	0.25MG
@	PHARMAFAIR	2%; 0.79%			0.5MG
	ACRIVASTINE; PSEUDOEPHENDRINE HYDROCHLORIDE				1MG
	CAPSULE; ORAL SEMPREX-D + BURROUGHS WELLCOME	8MG; 60MG	N19806 001 MAR 25, 1994	AMIKACIN SULFATE INJECTABLE; INJECTION AMIKACIN BEDFORD	2MG
	ALBUTEROL SULFATE		AP	EQ 50MG BASE/ML	0.5MG
	ALBUTEROL SULFATE /WARNER/CHILCOTT/		AP	EQ 50MG BASE/ML	0.5MG
> DLT > /AB/	/EQ 2MG BASE/	/N72817/001 /JAN/09, 1990/	/AP/	/EQ 50MG BASE/ML	0.5MG
> DLT >	/EQ 4MG BASE/	/N72818/001 /JAN/09, 1990/	AP +	EQ 50MG BASE/ML	0.5MG
> DLT > /AB/		/JAN/09, 1990/	/AP/	/EQ 250MG BASE/ML	0.5MG
> ADD >	@ WARNER CHILCOTT	N72817 001 JAN 09, 1990	AP +	EQ 250MG BASE/ML	0.5MG
> ADD >	@	N72818 001 JAN 09, 1990			
> ADD > /ADD/					

AMIKACIN SULFATE

INJECTABLE; INJECTION

/AMIKIN/
/AP//+//BRISTOL/
/AP//EQ 50MG BASE/ML/
/EQ 50MG BASE/ML//N50495/001/
/N62562/001//SEP/20, 1984/
/N50495/002//N62562/002/
/SEP/20, 1984/@ APOTHECON
@ BRISTOL@ FUJISAWA@ KING PHARMS@ RICHLYN@ SMITHKLINE/BEECHAMAMINO ACIDS, DEXTROSE

INJECTABLE; INJECTION

AMINOSYN II 5% IN DEXTROSE 25% IN PLASTIC CONTAINER
/ABBOTT//5%; 25GM/100ML/
/N19565/001//DEC/17, 1986/
/N19565/001/@ ABBOTT5%; 25GM/100MLDEC 17, 1986AMINOSALICYLIC ACID

GRANULE, DELAYED RELEASE; ORAL

PASER
+ JACOBUS4GM/PACKETN74346 001
JUN 30, 1994AMINOPHYLLINE

INJECTABLE; INJECTION

AMINOPHYLLINE/FUJISAWA/> ADD > AP> DLT > AP//EQ 50MG BASE/ML/
/EQ 50MG BASE/ML//N50495/001/
/N62562/001//SEP/20, 1984/
/N50495/002//N62562/002/
/SEP/20, 1984/@ APOTHECON@ RICHLYN@ SMITHKLINE/BEECHAM/25MG/ML/
/25MG/ML//100MG/
/200MG/100MG
200MG100MG
200MG/100MG/
/200MG//N84588/001/
/N84588/002/N84588 001
N84588 002N84574 001
N84576 001/N84574/001/
/N84576/001/

GRANULE, DELAYED RELEASE; ORAL

PASER
+ JACOBUS4GM/PACKETN74346 001
JUN 30, 1994AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE HCL/LEMMON/> DLT > AB/
> DLT > AB/> DLT > AB/
&

AMPHETAMINE SULFATE

<u>/TABLET; ORAL/ /AMPHETAMINE/SULFATE/ /LANNETT/</u>	<u>/5MG/ /10MG/</u>	<u>/N83901/001/ /AUG/31,/1984/ /N83901/002/ /AUG/31,/1984/ N83901 001 AUG 31, 1984 N83901 002 AUG 31, 1984</u>	<u>AB AB AB AB AB</u>	<u>50MG 100MG 25MG 50MG 100MG</u>	<u>N74126 001 MAR 23, 1994 N74126 002 MAR 23, 1994 N74265 001 FEB 28, 1994 N74265 002 FEB 28, 1994 N74265 003 FEB 28, 1994</u>
<u>@ LANNETT</u>	<u>5MG</u>				
<u>@</u>	<u>10MG</u>				

AMPHOTERICIN B

<u>INJECTABLE; INJECTION AMPHOTERICIN B /FUJISAWA/</u>	<u>/50MG/VIAL/ 50MG/VIAL</u>	<u>/N62728/001/ /APR/13,/1987/ N62728 001 APR 13, 1987</u>	<u>AB/</u>	<u>/LOFENE/ /AA/</u>	<u>/0.025MG; 2.5MG/ 0.025MG; 2.5MG</u>

AMPICILLIN/AMPICILLIN TRIHYDRATE

<u>POWDER FOR RECONSTITUTION; ORAL POLYCILLIN @ APOTHECON</u>	<u>EQ 1.25MG BASE/5ML EQ 2.50MG BASE/5ML EQ 1.25MG BASE/5ML/ EQ 2.50MG BASE/5ML/</u>	<u>N62297 001 N62297 002 N62297/001/ N62297/002/</u>	<u>>_DLT_>/AI/ >_ADD_>/AI/</u>	<u>BACITRACIN /PHARMADERM/ @ PHARMADERM /PHARMAFAIR/</u>	<u>/500 UNITS/GM/ 500 UNITS/GM/ /500 UNITS/GM/ 500 UNITS/GM</u>
<u>/AB/ /AB/</u>					

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

<u>INJECTABLE; INJECTION /M.V.C. 9+3/ /FUJISAWA/</u>	<u>/1.0MG/ML; 0.006MG/ML; 0.5UGH/ML; /1.5MG/ML; 20 IU/ML; 0.04MG/ML; 4MC/ML; /0.4MG/ML; 0.36MG/ML; 0.3MG/ML/ /330 UNITS/ML; 1 IU/ML/</u>	<u>/N18440/002/ /AUG/08,/1985/ BACLOFEN ROYCE</u>	<u>AB</u>	<u>1.0MG 20MG</u>	<u>N73092 001 JAN 28, 1994 N73093 001 JAN 28, 1994 N84535 001 /50%/ @ LANNETT</u>
<u>@ FUJISAWA</u>					

BETAMETHASONE DIPROPIONATE

CREAM, AUGMENTED; TOPICAL
/DIPROLENE/
/+//SCHERRING/
@ SCHERRING

/EQ/0 .05% /BASE/
EQ 0 .05% BASE

/N19408/001/
/JAN/31/1986/
N19408 001
JAN 31, 1986

N20233 001
FEB 14, 1994

BUDESONIDE

AEROSOL, METERED; NASAL
RHINOCORT
+ ASTRA

0 .05MG/INH

GEL; TOPICAL
DIPROLENE
+ SCHERRING

EQ 0 .05% BASE

N19408 002
NOV 22, 1991

/N85880/001/
N85880 001

BETAMETHASONE VALERATE

OINTMENT; TOPICAL
BETAMETHASONE VALERATE
/B* / CLAY/PARK/
@ CLAY PARK

/EQ/0 .1% /BASE/
EQ 0 .1% BASE

/N71478/001/
/DEC/23,/1987/
N71478 001
DEC 23, 1987

/N19408/001/
/JAN/31/1986/
N19408 001
JAN 31, 1986

BUTABARBITAL SODIUM

ELIXIR; ORAL
/BUTALAN/
@ LANNETT

/33 .3MG/5ML/
33 .3MG/5ML

BUTAISON SODIUM

/100MG/
100MG

/N00793/005/
N00793 005

SODIUM BUTABARBITAL

/N85881/001/
N85881 001

/NB4040/001/
NB4040 001

/N85880/001/
N85880 001

CALCIFFEDIOL

/100MG/2MG
100MG/2MG

/N00793/005/
N00793 005

BETHANECHOL CHLORIDE

TABLET; ORAL
BETHANECHOL CHLORIDE
/AA/ /LANNETT/
/AA/ @ LANNETT
/AA/ @

/5MG/
/10MG/
/25MG/
5MG
10MG
25MG

/N84702/001/
/N84712/001/
/N84074/001/
N84702 001
N84712 001
N84074 001

MIGERGOT
BR G AND W LABS

100MG/2MG

/N86557/001/
N86557 001

OCT 04, 1983

/BR/ /WIGRAINE/
/ORGANON/

/100MG/2MG/
/100MG/2MG

/OCT/04,/1983/

CAFFEINE; ERGOTAMINE TARTRATE

/100MG/
100MG

/N00793/005/
N00793 005

/N85881/001/
N85881 001

/NB4040/001/
NB4040 001

/N86557/001/
N86557 001

/OCT/04,/1983/

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL
DIMETANE-DX
> DLT > AA/ /ROBINS/AH/
> DLT >
> DLT >

/2MG/5ML; 10MG/5ML; /
/30MG/5ML/

/N11694/007/
/MAR/29,/1984/

N18312 002
N18312 001

CALCIFFEDIOL, ANHYDROUS

/CAPSULE ;/ORAL/
/CALDEROL/
/+ //ORGANON/

/0 .05MG/
/0 .02MG/

/N18312/002/
/N18312/001/

	CALCIUM CHLORIDE, DEXTROSE, MAGNESIUM CHLORIDE, SODIUM CHLORIDE; SODIUM LACTATE	SOLUTION; INTRAPERITONEAL DEFLEX W/ DEXTROSE 1.5% LOW CALCIUM IN PLASTIC CONTAINER	AT FRESENIUS	18.4MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N20171 001	AUG 19, 1992	AT ABBOTT	SOLUTION; INTRAPERITONEAL INPERSOL-LC/LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER	18.4MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N20374 002	JUN 13, 1994
		DEFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER	AT FRESENIUS	18.4MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N20171 002	AUG 19, 1992	AT ABBOTT	SOLUTION; INTRAPERITONEAL INPERSOL-LC/LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER	18.4MG/100ML; 3.5GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N20374 003	JUN 13, 1994
		DEFLEX W/ DEXTROSE 4.25% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER	AT FRESENIUS	18.4MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N20171 003	AUG 19, 1992	AT ABBOTT	SOLUTION; INTRAPERITONEAL INPERSOL-LC/LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER	18.4MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N20374 004	JUN 13, 1994
		DIAEAL LOW CALCIUM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER	AT BAXTER	18.3MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N20183 001	DEC 04, 1992		/INJECTABLE; /INJECTION /CARBACHOL /@/PHARMAFAIR /	/0.01%/ /N70292/001/ /MAY/21./1986/		
		DIAEAL LOW CALCIUM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER	AT BAXTER	18.3MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N20183 002	DEC 04, 1992		/MIOSTAT /+//ALCON /	/0.01%/ /N16968/001/		
		DIAEAL LOW CALCIUM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER	AT BAXTER	18.3MG/100ML; 3.5GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N20183 003	DEC 04, 1992		SOLUTION; INTRAOCULAR CARBACHOL @ PHARMAFAIR	0.01%	N70292 001	MAY 21, 1986
		DIAEAL LOW CALCIUM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER	AT BAXTER	18.3MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N20183 004	DEC 04, 1992		MIOSTAT + ALCON	0.01%	N16968 001	
		DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER	AT BAXTER	18.3MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N20183 005	DEC 04, 1992		CARBAMAZEPINE			
		DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER	AT BAXTER	18.3MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N20183 006	DEC 04, 1992		SUSPENSION; ORAL TEGRETOL + BASEL PHARMS	100MG/5ML	N18927 001	DEC 18, 1987
		INPERSOL-LC/LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER	AT ABBOTT	18.4MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N17512 004			/+//GEIGY /	/100MG/5ML /	/N18927/001/ /DEC/18./1987/	
		INPERSOL-LC/LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER	AT ABBOTT	18.4MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 53.8MG/100ML; 44.8MG/100ML	N20374 001	JUN 13, 1994		TABLET; ORAL TEGRETOL AB + BASEL PHARMS /AB//+//GEIGY /	200MG /200MG /	N16608 001	/N16608/001/

CARBAMAZEPINE

TABLET, CHEWABLE; ORAL

TEGRETOL**AB + BASEL PHARMS
/AB//+//GEICY/****N18281 001
/N18281/001/**TABLET, ORAL
ULTRACEF**AB APOTHECON
/AB/ /BRISTOL/****N100MG
/100MG/**

CARBIDOPA; LEVODOPA

TABLET; ORAL
CARBIDOPA AND LEVODOPA**AB SCS****10MG;100MG****N74080 001
MAR 25, 1994****25MG;100MG****N74080 002
MAR 25, 1994****25MG;250MG****N74080 003
MAR 25, 1994****25MG;250MG****N74080 004
MAR 25, 1994****25MG;250MG****N74080 005
MAR 25, 1994****25MG;250MG****N74080 006
MAR 25, 1994****25MG;250MG****N74080 007
MAR 25, 1994****25MG;250MG****N74080 008
MAR 25, 1994****25MG;250MG****N74080 009
MAR 25, 1994****25MG;250MG****N74080 010
MAR 25, 1994****25MG;250MG****N74080 011
MAR 25, 1994****25MG;250MG****N74080 012
MAR 25, 1994****25MG;250MG****N74080 013
MAR 25, 1994****25MG;250MG****N74080 014
MAR 25, 1994****25MG;250MG****N74080 015
MAR 25, 1994****25MG;250MG****N74080 016
MAR 25, 1994****25MG;250MG****N74080 017
MAR 25, 1994****25MG;250MG****N74080 018
MAR 25, 1994****25MG;250MG****N74080 019
MAR 25, 1994****25MG;250MG****N74080 020
MAR 25, 1994****25MG;250MG****N74080 021
MAR 25, 1994****25MG;250MG****N74080 022
MAR 25, 1994****25MG;250MG****N74080 023
MAR 25, 1994****25MG;250MG****N74080 024
MAR 25, 1994****25MG;250MG****N74080 025
MAR 25, 1994****25MG;250MG****N74080 026
MAR 25, 1994****25MG;250MG****N74080 027
MAR 25, 1994****25MG;250MG****N74080 028
MAR 25, 1994****25MG;250MG****N74080 029
MAR 25, 1994****25MG;250MG****N74080 030
MAR 25, 1994****25MG;250MG****N74080 031
MAR 25, 1994****25MG;250MG****N74080 032
MAR 25, 1994****25MG;250MG****N74080 033
MAR 25, 1994****25MG;250MG****N74080 034
MAR 25, 1994****25MG;250MG****N74080 035
MAR 25, 1994****25MG;250MG****N74080 036
MAR 25, 1994****25MG;250MG****N74080 037
MAR 25, 1994****25MG;250MG****N74080 038
MAR 25, 1994****25MG;250MG****N74080 039
MAR 25, 1994****25MG;250MG****N74080 040
MAR 25, 1994****25MG;250MG****N74080 041
MAR 25, 1994****25MG;250MG****N74080 042
MAR 25, 1994****25MG;250MG****N74080 043
MAR 25, 1994****25MG;250MG****N74080 044
MAR 25, 1994****25MG;250MG****N74080 045
MAR 25, 1994****25MG;250MG****N74080 046
MAR 25, 1994****25MG;250MG****N74080 047
MAR 25, 1994****25MG;250MG****N74080 048
MAR 25, 1994****25MG;250MG****N74080 049
MAR 25, 1994****25MG;250MG****N74080 050
MAR 25, 1994****25MG;250MG****N74080 051
MAR 25, 1994****25MG;250MG****N74080 052
MAR 25, 1994****25MG;250MG****N74080 053
MAR 25, 1994****25MG;250MG****N74080 054
MAR 25, 1994****25MG;250MG****N74080 055
MAR 25, 1994****25MG;250MG****N74080 056
MAR 25, 1994****25MG;250MG****N74080 057
MAR 25, 1994****25MG;250MG****N74080 058
MAR 25, 1994****25MG;250MG****N74080 059
MAR 25, 1994****25MG;250MG****N74080 060
MAR 25, 1994****25MG;250MG****N74080 061
MAR 25, 1994****25MG;250MG****N74080 062
MAR 25, 1994****25MG;250MG****N74080 063
MAR 25, 1994****25MG;250MG****N74080 064
MAR 25, 1994****25MG;250MG****N74080 065
MAR 25, 1994****25MG;250MG****N74080 066
MAR 25, 1994****25MG;250MG****N74080 067
MAR 25, 1994****25MG;250MG****N74080 068
MAR 25, 1994****25MG;250MG****N74080 069
MAR 25, 1994****25MG;250MG****N74080 070
MAR 25, 1994****25MG;250MG****N74080 071
MAR 25, 1994****25MG;250MG****N74080 072
MAR 25, 1994****25MG;250MG****N74080 073
MAR 25, 1994****25MG;250MG****N74080 074
MAR 25, 1994****25MG;250MG****N74080 075
MAR 25, 1994****25MG;250MG****N74080 076
MAR 25, 1994****25MG;250MG****N74080 077
MAR 25, 1994****25MG;250MG****N74080 078
MAR 25, 1994****25MG;250MG****N74080 079
MAR 25, 1994****25MG;250MG****N74080 080
MAR 25, 1994****25MG;250MG****N74080 081
MAR 25, 1994****25MG;250MG****N74080 082
MAR 25, 1994****25MG;250MG****N74080 083
MAR 25, 1994****25MG;250MG****N74080 084
MAR 25, 1994****25MG;250MG****N74080 085
MAR 25, 1994****25MG;250MG****N74080 086
MAR 25, 1994****25MG;250MG****N74080 087
MAR 25, 1994****25MG;250MG****N74080 088
MAR 25, 1994****25MG;250MG****N74080 089
MAR 25, 1994****25MG;250MG****N74080 090
MAR 25, 1994****25MG;250MG****N74080 091
MAR 25, 1994****25MG;250MG****N74080 092
MAR 25, 1994****25MG;250MG****N74080 093
MAR 25, 1994****25MG;250MG****N74080 094
MAR 25, 1994****25MG;250MG****N74080 095
MAR 25, 1994****25MG;250MG****N74080 096
MAR 25, 1994****25MG;250MG****N74080 097
MAR 25, 1994****25MG;250MG****N74080 098
MAR 25, 1994****25MG;250MG****N74080 099
MAR 25, 1994****25MG;250MG****N74080 100
MAR 25, 1994****25MG;250MG****N74080 101
MAR 25, 1994****25MG;250MG****N74080 102
MAR 25, 1994****25MG;250MG****N74080 103
MAR 25, 1994****25MG;250MG****N74080 104
MAR 25, 1994****25MG;250MG****N74080 105
MAR 25, 1994****25MG;250MG****N74080 106
MAR 25, 1994**

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION /AP/ <u>SEFFIN</u> / /GLAXO/	/EQ 1GM BASE/VIAL/ /EQ 2GM BASE/VIAL/ /+ /	/N62435/001/ /N62435/002/ /N62435/003/ /N62435/004/ @ GLAXO @ @	TABLET; ORAL THALITONE + HORUS THERAP 15MG /15MG/	N19574 001 DEC 20, 1988 /N19574/001/ /DEC/20,/1988/
CHLORTHALIDONE				

CHLORTHYRAMINE

EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL	NOV 15, 1983 NOV 15, 1983 NOV 15, 1983	TABLET; ORAL QUESTRAN + BRISTOL MYERS SQUIBB EQ 1GM RESIN	N73403 001 APR 28, 1994

CHLORAMPHENICOL

OINTMENT; OPHTHALMIC /AT/ <u>CHLOROFAIR</u> / @ PHARMAFAIR	/1%/ 1% @ PHARMAFAIR	/N62439/001/ /APR/21,/1983/ N62439 001 APR 21, 1983	TABLET; ORAL CIMETIDINE ENDO LABS 200MG	N74281 001 MAY 17, 1994 N74281 002 MAY 17, 1994 N74281 003 MAY 17, 1994 N74329 001 MAY 17, 1994 N74246 001 MAY 17, 1994 N74246 002 MAY 17, 1994 N74246 003 MAY 17, 1994 N74246 004 MAY 17, 1994 N74151 001 MAY 17, 1994 N74151 002 MAY 17, 1994 N74151 003 MAY 17, 1994 N74463 001 MAY 17, 1994
SOLUTION/DROPS; OPHTHALMIC /AT/ <u>CHLOROFAIR</u> / @ PHARMAFAIR	/0.5%/ 0.5% @ PHARMAFAIR	/N62437/001/ /APR/14,/1983/ N62437 001 APR 14, 1983	AB	
CHLORHEXIDINE GLUCONATE				
SOLUTION; DENTAL PERIDEX				
AT + PROCTER AND GAMBLE	0.12%	N19028 001 AUG 13, 1986	AB	
PERIOGARD				
AT COLGATE PALMOLIVE	0.12%	N73695 001 JAN 14, 1994	AB	
TAGAMENT				
CHLORPHENIRAMINE MALEATE				
TABLET; ORAL CHLORPHENIRAMINE MALEATE /AA/ <u>ZENITH</u> / @ ZENITH	/4MG/ 4MG/ N80779 001	AB +	AB	N17920 002 N17920 003 N17920 004 DEC 14, 1983 N17920 005 APR 30, 1986

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL CIMETIDINE HCL	A BARRE	EQ_300MG BASE/5ML	N74176 001 JUN 01, 1994	AB COPLLEY	OINTMENT; TOPICAL CLORETISOL PROPIONATE 0.05%	N74089 001 FEB 16, 1994
TAGAMET	A SMITHKLINE BEECHAM	EQ_300MG BASE/5ML	N17924 001	AB + GLAXO	TEMOVATE 0.05%	N19323 001 DEC 27 1985

CLOSET ASOL PROPIONATE

OINTMENT; TOPICAL CLORETASOL PROPIONATE COBLEY	0.05%	N74089 001 FEB 16, 1994
AB TEMOVATE AB + GLAXO	0.05%	N19323 001 DEC 27 1985

CINEMASTINE FILMARATE

A	<u>SYRUP; ORAL CLEMMISTINE FUMARATE LEMON</u>	EQ .5MG BASE/5ML	N73399 001 JUN 30, 1994	CAPSULE; ORAL ANAFRANIL + BASEL PHARMS	75MG 25MG 50MG	N119906 003 DEC 29, 1989 N119906 001 DEC 29, 1989 N119906 002 DEC 29, 1989 /N119906/003 /DEC/29,/1989 /N119906/001, /DEC/29,/1989 /N119906/002/ /DEC/29,/1989
P	<u>INJECTABLE; INJECTION CLINDAMYCIN PHOSPHATE BEDFORD</u>	EQ 150MG BASE/ML	N63163 001 JUN 30, 1994 /N62908/001/ /FEB/01,/1989/ N62908 001 FEB 01, 1989 /N62747/001/ /JUN/03,/1988/ N62747 001 JUN 03, 1988	/+//CIBA/ /+/CIBA/ /25MG/ /50MG/	/+//CIBA/ /25MG/ /50MG/	/+//CIBA/ /25MG/ /50MG/
P/	<u>@ DUPONT MERCK</u>	EQ 150MG BASE/ML				
P/	<u>@ FUJISAWA</u>	EQ 150MG BASE/ML				
P/	<u>@ FUJISAWA</u>	EQ 150MG BASE/ML				

CLOBETASOL PROPIONATE

PENNEX
10MG/5ML; 6.25MG/5ML
/10MG/5ML; 6.25MG/5ML/
/@/ N88875 001
DEC 17 / 1984
/N88875/001
/DEC/17/1984

N20337 001
APR 29, 1994

COLESTIPOL HYDROCHLORIDE

> ADD > TABLET; ORAL
 > ADD > COLESTID
 > ADD > UPJOHN
 > ADD >

1GM
 N20222 001
 JUL 19, 1994

TABLET; ORAL
CYPROHEPTADINE HCL
 /AA/
 @ CHELSEA LABS /
 /4MG/
 /4MG

/N86165/001/
 N86165 001

CORTISONE ACETATE

INJECTABLE; INJECTION
/CORTISONE/ACETATE/
 /BP/ /STERIS/
 /BP/
 /BP/
 /BP/
 /BP/
 /BP/
 @ STERIS
 @
 @
 @
 @
 @ UPJOHN
 CORTONE
 /BP/ /MSD/
 /BP/+ / MSD
 + MSD
 25MG/ML
 50MG/ML
 50MG/ML
 25MG/ML
 25MG/ML
 25MG/ML
 50MG/ML
 50MG/ML
 25MG/ML
 /25MG/ML/
 /50MG/ML/
 50MG/ML
 50MG/ML
 25MG/ML
 /NO7110/002/
 /NO7110/003/
 NO7110 003
 NO7110 002
 25MG/ML
 50MG/ML
 25MG/ML

SOLUTION; INHALATION
CROMOLYN SODIUM
 AN DEV
 INTAL
 AN + FISONS
 10MG/ML
 10MG/ML

N74209 001
 APR 26, 1994

N18596 001
 MAY 28, 1982

> ADD >
 > ADD >
 > ADD >
 > ADD >

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

DESMOPRESSIN ACETATE
 SPRAY, METERED; NASAL
 DESMOPRESSIN ACETATE
 + RHONE POULENC RORER 0.15MG/INH
 N20355 001
 MAR 07, 1994

DEXAMETHASONE, NEOMYCIN SULFATE, POLYMYXIN B SULFATE
 OINTMENT; OPHTHALMIC
DEXASPORIN
 BAUSCH AND LOMB
 0.1% EQ 3.5MG BASE;
 10,000 UNITS
 N64063 001
 JUL 25, 1994

> DLT >
 > DLT >

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
PENTOLAIR
 BAUSCH AND LOMB 1Z

N40075 001
 APR 29, 1994

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

AEROSOL, METERED; INHALATION
/DECADRON/
 /+//MSD/
 DEXACORT
 + MEDEVA
 EQ 0.1MG PHOSPHATE/INH N14242 001
 /EQ/0.1MG PHOSPHATE/INH/ /N14242/001/
 AEROSOL, METERED; INHALATION
/DECADRON/
 /+//MSD/

CYTARABINE

INJECTABLE; INJECTION
CYTARABINE
 + BULL
 20MG/ML
 N72945 001
 FEB 28, 1994

INJECTABLE; INJECTION
COSMEGEN
 + MERCK SHARP DOHME
 0.5MG/VIAL
 /+//MSD/
 N50682 001
 /N60467/001/

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL
CYPROHEPTADINE HCL
 /AA/
 @ CHELSEA LABS /
 /4MG/
 /4MG

DEXAMETHASONE_SODIUM PHOSPHATE

> ADD > AEROSOL, METERED; INHALATION
 DEXACORT
 + MEDEVA EQ 0.1MG PHOSPHATE/INH N13413 001

> ADD > /N844-36/001/
 DIENESTROL
 /ESTRAGUARD/
 @ SOLVAY
 0.01%

/ELIXIR ; ORAL/
 /DEXEDRINE/
 /SMITHKLINE/BEECHAM / 5MG/5ML /
 @ SMITHKLINE BEECHAM 5MG/5ML

DEXTRAMPHETAMINE SULFATE

/AA/ /LANNETT/
 /AA/ @ LANNETT
 @ @
 TABLET; ORAL
DEXTRAMPHETAMINE SULFATE
 /5MG/
 /10MG/
 5MG
 10MG
 /15MG/
 15MG

/BP/ /SMITHKLINE/BEECHAM / 5MG/5ML /
 @ SMITHKLINE BEECHAM 5MG/5ML

/BP/ /SOLVAY/
 @ SOLVAY
 0.01%

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PROMETHAZINE W/ DEXTROMETHORPHAN
AA PENNEX
 /@/ /15MG/5ML; 6.25MG/5ML
 JAN 04, 1985 N88864 001
 /N88864/001/
 /JAN/04./1985/

DEXTROSE

INJECTABLE; INJECTION
DEXTROSE 5% IN PLASTIC CONTAINER
AP MCCAW 50MG/ML N16730 002

DILTAZEM HYDROCHLORIDE
 N16730 002

DEXTROTHYROXINE_SODIUM

TABLET; ORAL
CHOLOXIN
 + BOOTS
 /+/
 4MG
 /6MG/
 /4MG/
 6MG
 @ N12302 004
 /N12302/006/
 /N12302/004/
 N12302 006

DILTAZEM HYDROCHLORIDE
 N16730 002

TABLET; ORAL
DILTAZEM HCL
MB NOVOPHARM

N74084 001
 FEB 25, 1994
N74084 002
 FEB 25, 1994

30MG
MB
 60MG
 @

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE, ORAL
DIPHENHYDRAMINE HCL
/LANNETT/
A/A/
@ LANNETT
©
/N80868/001/
/N80868/002/
N80868 001
N80868 002
25MG/
50MG/
25MG
50MG
LIQUID, INHALATION
ENFLURANE
INHALON
>_ADD_> AN
>_ADD_>
99.9%
N74396 001
JUL 29, 1994

DIPIVEFRIN HYDROCHLORIDE

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION		DOBUTAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER	
> ADD >	AP	ABBOTT	EQ 400MG BASE/100ML N20
> ADD >			JUL 0
> ADD >	AP	BAXTER	N20
> ADD >			OCT 1

DOXEPIN HYDROCHLORIDE

SCREAM; TOPICAL
ZONALON + GENDER

DOXORUBICIN HYDROCHLORIDE

**INJECTABLE; INJECTION
ADRIAMYCIN PFS
/AP//+//ADRIA/**

/AP/

200MG/100ML

200MG/100ML

/AI/ /BARRE/ ERYTHROMYCIN /26/

/N62957/001/
JUL/21/1988/
N62957 001
JUL 21, 1988
N64039 001
JUN 27 1984

ENELURANE

N74396 001
JUL 29, 1994
LIQUID; INHALATION
ENFLURANE
INHALON
29.92
> ADD > AN
> ADD >

CAPSULE: ORAL

/AA/	<u>/LILLY/</u>	/50,000 IU/ 50,000 IU	/N80884/001/ N80884 001
VITAMIN D			
/AA/	<u>/LANNETT/</u>	/50,000 IU/ 50,000 IU	/N80825/001/ N80825 001
/AA/	<u>/WEST/WARD/</u>	/50,000 IU/ 50,000 IU	/N83102/001/ N83102 001
	@ WEST WARD PHARM		

ERYTHROMYCIN

CAPSULES, DELAYED REL PELLETS; ORAL
ERIC /PARKE/DAVIS/ /**250MG**/
/AB/ @ PARKE DAVIS 250MG
/N62546/001 /JUL/25,/1985
N62546 001 JUL 25 , 1985

OINTMENT; OPHTHALMIC
ERYTHROMYCIN
BAUSCH AND LOMB

SOLUTION: TOPICAL
ERYTHROMYCIN
/ΔΙ/ /BARRE/
/2g/
/N62957/001
/JUL/21,/1988

ETHINYL ESTRADIOL; FERROUS FUMARATE, NORETHINDRONE

ETOPOSIDE

/TABLET; ORAL-28/
 /NORQUEST/FE/
 /+//SYNTEX/
 @ SYNTEX
 /0.035MG ; 75MG, 1MG /
 0.035MG ; 75MG, 1MG
 JUL 18, 1986

FAMCICLOVIR

/TABLET; ORAL-21
 NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)
 /WATSON /
 /0.035MG ; 0.5MG/AND/1IMG /
 SEP/24,/1991/
 AB WATSON LABS
 0.035MG ; 0.5MG AND 1MG
 N71041 001
 SEP 24 , 1991

FAMOTIDINE

/TABLET; ORAL-21
 NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)
 /WATSON /
 /0.035MG ; 0.5MG /
 SEP/24,/1991/
 AB WATSON LABS
 0.035MG ; 0.5MG AND 1MG
 N71041 001
 SEP 24 , 1991

FAMOTIDINE

/TABLET; ORAL-21
 NORTHO-NOVUM 7/14-21
 AB + JOHNSON RW
 0.035MG ; 0.5MG AND 1MG
 APR 04 , 1984
 /@/
 DLT /
 /0.035MG ; 0.5MG/AND/1IMG /
 /N19004/001/
 /APR/04/1984/
 /APR/04/1984/
 /APR/04/1984/

N18926/001/
 N18926 001
 JUL 18 , 1986

FLUCONAZOLE

/TABLET; ORAL-28
 NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)
 /WATSON /
 /0.035MG ; 0.5MG/AND/1IMG /
 /N71042/001/
 /SEP/24,/1991/
 AB WATSON LABS
 0.035MG ; 0.5MG AND 1MG
 N71042 001
 SEP 24 , 1991

FLUCONAZOLE

/TABLET; ORAL-28
 NORTHO-NOVUM 7/14-28
 AB + JOHNSON RW
 0.035MG ; 0.5MG AND 1MG
 N19004 002
 APR 04 , 1984
 /@/
 DLT /
 /0.035MG ; 0.5MG/AND/1IMG /
 /N19004/002/
 /APR/04/1984/
 /APR/04/1984/

ETODOLAC

/TABLET; ORAL
 LODINE
 + WYETH AYERST
 400MG
 JUL 29 , 1993

N18922 004
 JUL 29 , 1993

N18768 001
 NOV 10 , 1983

N20363 002
 JUN 29 , 1994

N20249 001
 FEB 18 , 1994

N20073 001
 DEC 20 , 1991

N20073 001
 DEC 20 , 1991

N74284 001
 FEB 10 , 1994

0.1MG/ML

0.1MG/ML

0.1MG/ML

FLUOCINOLONE ACETONIDE

SOLUTION; TOPICAL
FLUOCINOLONE ACETONIDE **0.01%**/
/AI/ /PHARMAFAIR/
@ PHARMAFAIR 0.01%

FLURANDRENOLIDE

OINTMENT; TOPICAL
FLURANDRENOLIDE
/N88449/001/
/FEB/08/1984/
N88449 001
FEB 08 , 1984

OINTMENT; TOPICAL
FLURANDRENOLIDE
CORDRAN
+ LILLY
+

TAPE; TOPICAL
FLURANDRENOLIDE
/+//DISTA/
+ LILLY

TABLET; ORAL
FLURBIPROFEN
/N71790/001/
/JUL/13/1988/
N71790 001
JUL 13 , 1988

OINTMENT; TOPICAL
FLURBIPROFEN
CORDRAN
+ LILLY
+

TAPE; TOPICAL
FLURBIPROFEN
/+//DISTA/
+ LILLY

OINTMENT; TOPICAL
FLURBIPROFEN
CORDRAN
+ LILLY
+

TAPE; TOPICAL
FLURBIPROFEN
/0 . 004MG/SQ/CM/
0 . 004MG/SQ CM

OINTMENT; TOPICAL
FLURBIPROFEN
CORDRAN
+ LILLY
+

TAPE; TOPICAL
FLURBIPROFEN
/0 . 004MG/SQ/CM/
0 . 004MG/SQ CM

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE
/B* / /CLAY/PARK/
@ CLAY PARK 0.05%/

OINTMENT; TOPICAL
FLUOCINONIDE
/N88449/001/
/FEB/08/1984/
N88449 001
FEB 08 , 1984

TAPE; TOPICAL
FLUOCINONIDE
/+//DISTA/
+ LILLY

OINTMENT; TOPICAL
FLURBIPROFEN
CORDRAN
+ LILLY
+

TAPE; TOPICAL
FLURBIPROFEN
/+//DISTA/
+ LILLY

OINTMENT; TOPICAL
FLURBIPROFEN
CORDRAN
+ LILLY
+

TAPE; TOPICAL
FLURBIPROFEN
/+//DISTA/
+ LILLY

OINTMENT; TOPICAL
FLURBIPROFEN
CORDRAN
+ LILLY
+

TAPE; TOPICAL
FLURBIPROFEN
/+//DISTA/
+ LILLY

FLUOROURACIL

INJECTABLE; INJECTION
ADRUCIL
/AP//+//ADRIA/
/AP/

INJECTABLE; INJECTION
ADRUCIL
/50MG/ML/
/50MG/ML/

FLUOROURACIL

INJECTABLE; INJECTION
ADRUCIL
/50MG/ML/
/50MG/ML/

FLUOREMIDE

CREAM; TOPICAL
FLUOREMIDE
/+//DISTA/
/+//DISTA/
+ LILLY
+

CREAM; TOPICAL
FLUOREMIDE
CORDRAN SF
/+//DISTA/
/+//DISTA/
+ LILLY
+

CREAM; TOPICAL
FLUOREMIDE
CORDRAN SF
/+//DISTA/
/+//DISTA/
+ LILLY
+

CREAM; TOPICAL
FLUOREMIDE
CORDRAN SF
/+//DISTA/
/+//DISTA/
+ LILLY
+

CREAM; TOPICAL
FLUOREMIDE
CORDRAN SF
/+//DISTA/
/+//DISTA/
+ LILLY
+

CREAM; TOPICAL
FLUOREMIDE
CORDRAN SF
/+//DISTA/
/+//DISTA/
+ LILLY
+

CREAM; TOPICAL
FLUOREMIDE
CORDRAN SF
/+//DISTA/
/+//DISTA/
+ LILLY
+

CREAM; TOPICAL
FLUOREMIDE
CORDRAN SF
/+//DISTA/
/+//DISTA/
+ LILLY
+

CREAM; TOPICAL
FLUOREMIDE
CORDRAN SF
/+//DISTA/
/+//DISTA/
+ LILLY
+

FLURANDRENOLIDE

OINTMENT; TOPICAL
FLURANDRENOLIDE
/AI//+//DISTA/
/AI/ + LILLY

OINTMENT; TOPICAL
FLURANDRENOLIDE
CORDRAN
 $\frac{0.025\%}{0.05\%}$

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

GARANICIN

/AI//+//SCHERRING/
AT + SCHERRING/
GENOPTIC
/AI/ /ALLERGAN/

/EQ 3MG BASE/ML/
EQ 0.3% BASE
/EQ 3MG BASE/ML/

AT ALLERGAN
EQ 0.3% BASE

GENTACIDIN

/IOLAB/
AT IOLAB
EQ 0.3% BASE

/EQ 3MG BASE/ML/
EQ 0.3% BASE
/EQ 3MG BASE/ML/

AT PHARMAFAIR/
AT PHARMAFAIR
EQ 0.3% BASE

GENTAMICIN SULFATE

/AI/ /AKORN/
AT AKORN
EQ 0.3% BASE

/EQ 3MG BASE/ML/
EQ 0.3% BASE
/EQ 3MG BASE/ML/

AT BAUSCH AND LOMB
EQ 0.3% BASE
/AI/ /STERIS/

AT STERIS
EQ 0.3% BASE

GLIPIZIDE

TABLET; ORAL
GLIPIZIDE
AB MYLAN

5MG
10MG

GLUCOTROL
AB PFIZER

5MG
10MG

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

/NEOMYCIN SULFATE AND POLYMYXIN B SULFATE GRAMICIDIN
/AI/ /PHARMAFAIR/ /0.025MG/ML; EQ. 1.75MG BASE/ML;/
/10,000 UNITS/ML/ /N62383/001/ /AUG/31./1982/

GLIPIZIDE

TABLET, EXTENDED RELEASE; ORAL
GLUCOTROL XL
+ PFIZER

N50039 002/
N50039 002
+
5MG

N62452/001/
OCT/10/1984/
N62452 001
OCT 10, 1984

N62480/001/
MAR/30/1984/
N62480 001
MAR 30, 1984

N62440/001/
MAY/03/1983/
N62440 001
MAY 03, 1983

N62635/001/
JAN/08/1987/
N62635 001
JAN 08, 1987

N64048 001
MAY 11, 1994

N62523/001/
NOV/25/1985/
N62523 001
NOV 25, 1985

N62635/001/
JAN/08/1987/
N62635 001
JAN 08, 1987

N64048 001
MAY 11, 1994

N62523/001/
NOV/25/1985/
N62523 001
NOV 25, 1985

INJECTABLE; INJECTION
GLYCOPYRROLATE
/AP/ /FUJISAWA/

N62635/001/
JAN/08/1987/
N62635 001
JAN 08, 1987

N64048 001
MAY 11, 1994

N62523/001/
NOV/25/1985/
N62523 001
NOV 25, 1985

INJECTABLE; INJECTION
GLYCOPYRROLATE
/AP/ /FUJISAWA/

N62635/001/
JAN/08/1987/
N62635 001
JAN 08, 1987

N64048 001
MAY 11, 1994

N62523/001/
NOV/25/1985/
N62523 001
NOV 25, 1985

INJECTABLE; INJECTION
CHORIONIC GONADOTROPIN
/AP/ /FUJISAWA/

N17783 001
MAY 08, 1984
N17783 002
MAY 08, 1984

N17783 001
MAY 08, 1984
N17783 002
MAY 08, 1984

N17067/001/
N17067/003/
N17067 001
N17067 003

CONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION
CHORIONIC GONADOTROPIN
/AP/ /FUJISAWA/

N17783 001
MAY 10, 1994
N17783 002
MAY 10, 1994

N17783 001
MAY 08, 1984
N17783 002
MAY 08, 1984

N17783 001
MAY 08, 1984
N17783 002
MAY 08, 1984

N17783 001
MAY 08, 1984
N17783 002
MAY 08, 1984

N17783 001
MAY 08, 1984
N17783 002
MAY 08, 1984

N17783 001
MAY 08, 1984
N17783 002
MAY 08, 1984

N17783 001
MAY 08, 1984
N17783 002
MAY 08, 1984

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'94 - JUL '94

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GRAMICIDIN, NEOMYCIN SULFATE, POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC
/NEOMYCIN SULFATE AND POLYMYXIN B SULFATE GRAMICIDIN/

@ PHARMAFAIR 0.025MG/ML;EQ 1.75MG BASE/ML;
10,000 UNITS/ML N62383 001
AUG 31, 1982

GUANABENZ ACETATE

TABLET; ORAL

GUANABENZ ACETATE

AB COPLEY PHARM

EO 4MG BASE

EO 8MG BASE

HYDROCHLOROTHIAZIDE, RESERPINE

TABLET; ORAL
HYDROCHLOROTHIAZIDE W/ RESERPINE
/BP/ @ ROXANE/
50MG ; 0.125MG/
50MG ; 0.125MG/
/N84603/001/
N84603 001

HYDROCHLOROTHIAZIDE, TRIAMTERENE

CAPSULE; ORAL
DYAZIDE
/AB//+//SMITHKLINE/BEECHAM / 25MG; 50MG/
SMITHKLINE BEECHAM 25MG ; 37.5MG
@ TRIAMTERENE AND HYDROCHLOROTHIAZIDE
/AB/ /GENEVA/PHARMS/ 25MG; 50MG/
+ GENEVA PHARMS 25MG ; 50MG
HYDROCORTISONE
CREAM, TOPICAL
HYDROCORTISONE
/AI/ /LEMMON/ 1/2/
> DLT >/AI/ @ LEMMON 1/2/
> DLT > /PHARMAFAIR/ 1/2/
> ADD > @ PHARMAFAIR 1%
> ADD >
/N73191/001/
N73191 001
JUL 31, 1991

HYDRAZINE HYDROCHLORIDE, HYDROCHLOROTHIAZIDE, RESERPINE
TABLET; ORAL
RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE
/BP/ @ DANBURY PHARMA/ 25MG ; 15MG ; 0.1MG /
@ DANBURY PHARMA 25MG ; 15MG ; 0.1MG /
/N87556/001/
N87556 001
/N85191/001/
N85191 001
JUL 28, 1982

HYDRAZINE HYDROCHLORIDE
TABLET; ORAL
HYDROCHLOROTHIAZIDE
/AB/ /ZENITH/ 50MG/
@ ZENITH
/N84658/001/
N84658 001
/AI/ /ALLERGAN/HERBERT/ 1/2/
+ ALLERGAN HERBERT 1%
/N88215/001/
N88215 001
/JUN/06/1984/
N88215 001
JUN 06 , 1984

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION

/DELLALUTIN/
 /AO//+//SQUIBB/
 /AO/
 /AO//+/
 /AO/
 @ SQUIBB
 @
 @
 @
 @
 /AO/
 AO + STERIS
 /AO/
 +

/125MG/ML/
 /125MG/ML/
 /250MG/ML/
 /250MG/ML/
 125MG/ML
 125MG/ML
 250MG/ML
 250MG/ML

/125MG/ML/
 /250MG/ML/
 125MG/ML
 125MG/ML
 250MG/ML
 250MG/ML

/125MG/ML/
 125MG/ML
 /250MG/ML/
 /250MG/ML/
 250MG/ML

INJECTABLE; INJECTION

OCTREOSCAN
 MALLINCKRODT
 3MCU/ML

N10347/004/
 /N16911/001/
 /N10347/002/
 /N16911/002/
 N10347 004
 N16911 001
 N10347 002
 N16911 002
 N10347 002
 N16911 002

INDOMETHACIN
 INDOMETHACIN
 CAPSULE; ORAL
 INDOMETHACIN
 /AB/
 /CHELSEA/LABS/
 /25MG/
 /AB/
 /50MG/
 @ CHELSEA LABS
 25MG
 @
 50MG

INDIUM IN-111 PENTETREOTIDE KIT

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HCL
 /SMITH/NEPHEW/SOLOPAK/25MG/ML/
 /50MG/ML/
 /50MG/ML/
 SOLOPAK
 AP
 AP
 AP
 AP
 /ORGATRAX/
 /ORGANON/
 @ ORGANON
 @
 /25MG/ML/
 /50MG/ML/
 25MG/ML
 50MG/ML

INSULIN BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
 HUMULIN R
 + LILLY
 500 UNITS/ML

N87591/001/
 /N87593/001/
 /N87595/001/
 N87591 001
 N87593 001
 N87595 001
 N87014/001/
 /N87014/002/
 N87014 001
 N87014 002
 INVERT SUGAR
 /INJECTABLE;/INJECTION/
 /TRAVERT/10%IN/PLASTIC/CONTAINER/
 /BAXTER/
 @ BAXTER
 /N16717/001/
 N16717 001

TABLET; ORAL
 HYDROXYZINE HCL

AB ROYCE 10MG
 AB 25MG
 AB 50MG
 N81149 001
 MAR 18, 1994
 N81150 001
 MAR 18, 1994
 N81151 001
 MAR 18, 1994
 LOBENGUANE SULFATE I 131
 INJECTABLE; INJECTION
 LOBENGUANE SULFATE I 131
 CIS
 2.3MCU/ML
 N20084 001
 MAR 25, 1994
 IODOHIPPURATE SODIUM, I-123
 /INJECTABLE;/INJECTION/
 /NEPHROFLOW/
 /MEDI/PHYSICS/ /1MCU/ML/
 /N18289/001/
 /DEC/28,/1984/

IMIGLUERASE

INJECTABLE; INJECTION
 CEREZYME
 + GENZYME
 200 UNITS/VIAL
 N20367 001
 MAY 23, 1994

LEVOBUNOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

BETAGAN

AT + ALLERGAN 0.25%

AT + 0.5%

LEVOBUNOLOL HCL

AT BAUSCH AND LOMB 0.25%

AT 0.5%

LEVONORDEFERIN; MEPIVACAINE HYDROCHLORIDE
INJECTABLE; INJECTION
/AP/ /ARESTOCAINE HCL W/ LEVONORDEFERIN/
@ SOLVAY /0.05MG/ML; 2%/
0.05MG/ML; 2%LIDOCAINA HYDROCHLORIDE
SOLUTION; TOPICALMYLOCaine

AT PENNEX 4%

/ @ /

PEDIATRIC LTA KIT

/AI/ /ABBOTT/ 2%

@ ABBOTT 2%

LIOTRIX (T4;T3)

TABLET; ORAL

/EUTHROID-0.5/

/PARKE/DAVIS/

@ PARKE DAVIS

/EUTHROID-1/

/PARKE/DAVIS/

@ PARKE DAVIS

/EUTHROID-2/

/PARKE/DAVIS/

@ PARKE DAVIS

/EUTHROID-3/

/+ /PARKE/DAVIS/

@ PARKE DAVIS

LEISINOPRIL

TABLET; ORAL

PRINIVIL

AB MERCK

ZESTRILL

AB ZENECA

LITHIUM CARBONATE
TABLET, EXTENDED RELEASE; ORAL
/LITHOBID/
/+ //CIBA/
@ CIBA

LORAZEPAM

INJECTABLE; INJECTION

ATIVAN

AP + WYETH AYERST

AP + LORAZEPAM

ABBOTT

2MG/ML

2MG/ML

4MG/ML

N19558 006
JAN 28, 1994N19219 002
DEC 19, 1985N74307 001
MAR 04, 1994N74326 001
MAR 04, 1994N85010 001/
N85010 001N87881 001
NOV 18, 1982/N87881/001/
/NOV/18,/1982/N88572 001/
/JUL/31,/1984/
N88572 001
JUL 31, 1984

AP STERIS

AP

LORAZEPAM

TABLET; ORAL
LORAZEPAM
 /AB/ /WARNER/CHILCOTT/ /1MG/
 /AB/ /2MG/
 @ WARNER CHILCOTT 1MG
 @ 2MG

METHAZOLAMIDE

TABLET; ORAL
METHAZOLAMIDE
 AB MIKART 2.5MG
 /N71038/001/
 /JAN/12/1988/
 /N71039/001/
 /JAN/12/1988/
 N71038 001
 JAN 12, 1988
 N71039 001
 JAN 12, 1988
 > DLT > /TABLET; CHEWABLE; ORAL/
 > DLT > /TACARYL/
 > DLT > /WESTWOOD/SQUIBB/
 > ADD > @ WESTWOOD SQUIBB /
 /N11950/009/
 N11950 009

INJECTABLE; INJECTION
MAGNESIUM SULFATE IN PLASTIC CONTAINER
 ABBOTT 4GM/100ML
 80MG/ML

N20309 001
 JUN 24, 1994
 N20309 002
 JUN 24, 1994
 > DLT > /SYRUP; ORAL/
 > DLT > /TACARYL/
 > DLT > /WESTWOOD/SQUIBB/
 > ADD > @ WESTWOOD SQUIBB /
 /N11950/007/
 N11950 007

MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
ARRESTOCAINE HCL/
 /AP/ /CARLISLE/ /3%/
 @ SOLVAY 3%
 APR 18, 1982
 > DLT > /TABLET; ORAL/
 > DLT > /TACARYL/
 > ADD > /WESTWOOD/SQUIBB/
 @ WESTWOOD SQUIBB /
 /N84777/002/
 /APR/18./1982/
 N84777 002
 APR 18, 1982
 /N11950/006/
 N11950 006

METHOTREXATE SODIUM

INJECTABLE; INJECTION
FOLEX PFS
 /AP/ /ADRIA/
 /AA/ /LEMON/ /400MG/
 @ LEMON 400MG
 /N16069/001/
 N16069 001
 > ADD > /EQ 25MG BASE/ML/
 > DLT > /EQ 25MG BASE/ML/
 /N11950/001/
 N11950 001

METARAMINOL BITARTRATE

INJECTABLE; INJECTION
METARAMINOL BITARTRATE
 /AP/ /FUJISAWA/ /EQ 10MG BASE/ML/
 @ FUJISAWA / EQ 10MG BASE/ML/
 /N80431/001/
 N80431 001
 > ADD > AA
 > DLT > AA /
 /NO8848 001/
 /NO8848/001/

METHSCOPOLAMINE BROMIDE

TABLET; ORAL
PAMINE
 BRADLEY
 @ UPJOHN /
 2.5MG
 /2.5MG/

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '94 - JUL '94

METHYLPEREDISILOXANE SODIUM SUCINATE

INJECTABLE INFECTION

ABBR/ITEM	ITEM	INN	MANUFACTURER	STRENGTH		
/AP/	/ABBOTT/	/EQ 40MG BASE/VIAL/	/N89573/001/ /FEB/22./1991/	>ADD_> AB	KING PHARMS	EQ 10MG BASE
/AP/	/	/EQ 125MG BASE/VIAL/	/N89574/001/ /FEB/22./1991/	>ADD_> >DLT_>/AB/ >DLT_>	/SMITHKLINE/BEECHAM/	/EQ 10MG BASE/

METOCLOPRAMIDE HYDROCHLORIDE

INFECTABLE: INFECTION

A. INDIVIDUALS	B. INDIVIDUALS	C. INDIVIDUALS
/AP/ /ABBOTT/	/EQ 40MG BASE/VIAL/ /FEB/22./1991/ /N89573/001/	MAZOLIN KING PHARMS /SMITHKLINE/BEECHAM/ /EQ 10MG BASE/
/AP/	/EQ 125MG BASE/VIAL/ /FEB/22./1991/ /N89574/001/	>ADD_> AB >ADD_> >DLT_>/AB/ >DLT_>
		N70106 001 MAR 04, 1986 /N70106/001/ /MAR/04,/1986/

MINOCYCLINE HYDROCHLORIDE

METHYLTESTOSTERONE

/BP/	/25MG/	/NB0475/003/	@ LEDERLE/	/EQ/50MG/BASE/	/N50451/003/
	@ PUREPAC	N80475 002			/AUG/10,/1982/
	@	N80475 003			/N50451/002/
/BP/	/TABLICAPS/	/NB0313/001/	/@/	/EQ/100MG/BASE/	/AUG/10,/1982/
/BP/	/TABLICAPS/	/NB85270/001/			
	@ TABLICAPS	N80313 001			
	@	N85270 001			
/BP/	/WEST/WARD/	/NB84331/001/			
/BP/	@ WEST WARD	/NB84331/002/			
	@	N84331 001			
		N84331 002			
		25MG			

TABLET; ORAL

/BP/	/25MG/	/NB0475/003/	@ LEDERLE/	/EQ/50MG/BASE/	/N50451/003/
	@ PUREPAC	N80475 002			/AUG/10,/1982/
	@	N80475 003			/N50451/002/
/BP/	/TABLICAPS/	/NB0313/001/	/@/	/EQ/100MG/BASE/	/AUG/10,/1982/
/BP/	/TABLICAPS/	/NB85270/001/			
	@ TABLICAPS	N80313 001			
	@	N85270 001			
/BP/	/WEST/WARD/	/NB84331/001/			
/BP/	@ WEST WARD	/NB84331/002/			
	@	N84331 001			
		N84331 002			
		25MG			

/BP/	/25MG/	/NB0475/003/	@ LEDERLE/	/EQ/50MG/BASE/	/N50451/003/
	@ PUREPAC	N80475 002			/AUG/10,/1982/
	@	N80475 003			/N50451/002/
/BP/	/TABLICAPS/	/NB0313/001/	/@/	/EQ/100MG/BASE/	/AUG/10,/1982/
/BP/	/TABLICAPS/	/NB85270/001/			
	@ TABLICAPS	N80313 001			
	@	N85270 001			
/BP/	/WEST/WARD/	/NB84331/001/			
/BP/	@ WEST WARD	/NB84331/002/			
	@	N84331 001			
		N84331 002			
		25MG			

NITROFURANTOIN

TABLET; ORAL
 /**FURALAN**/
 /LANNETT/
/AB/
/AB/ @ LANNETT
 @

/50MG/
 /100MG/
 50MG
 100MG

NITROFURAZONE

OINTMENT; TOPICAL
 NITROFURAZONE
/AI/ /LANNETT/
 @ LANNETT

/0.2%/
 0.2%

NITROGLYCERIN

INJECTABLE; INJECTION
 NITROGLYCERIN
/AP/ /INTL/MEDICATION/

/5MG/ML/
 /SEP/10/,1985/
 N70026 001

5MG/ML
 /1MG/ML/
 @ INTL MEDICATION

/NITRONAL/
 /+//BOSKAMP/
 @ G FOHL BOSKAMP

1MG/ML

NITROSTAT
/AP/ /PARKE/DAVIS/

/5MG/ML/
 5MG/ML

10MG/ML
 /10MG/ML/
 @ PARKE DAVIS

10MG/ML

10MG/ML
 /10MG/ML/
 @

NORETHINDRONE

TABLET; ORAL
 /NORIUTIN/
 /+//PARKE/DAVIS/
 @ PARKE DAVIS

/5MG/
 5MG

NYSTATIN

SUSPENSION; ORAL
 NYSTATIN
 BAUSH AND LOMB
/AA/ /PHARMAFAIR/
 @ PHARMAFAIR

100,000 UNITS/ML

100,000 UNITS/ML
/AA/ /PHARMAFAIR/
 @ PHARMAFAIR

100,000 UNITS/ML

NYSTATIN

SUSPENSION; ORAL
 NYSTATIN
 BAUSH AND LOMB
/AA/ /PHARMAFAIR/
 @ PHARMAFAIR

100,000 UNITS/ML

100,000 UNITS/ML
/AA/ /PHARMAFAIR/
 @ PHARMAFAIR

100,000 UNITS/ML

OMEPAZOLE

CAPSULE, DELAYED REL PELETS, ORAL
PRILOSEC/+/MERCK/
>_DLT_>

/20MG/

ORPHENADRINE HYDROCHLORIDE

/TABLET; ORAL/
DISIPAL/
/3M/
@ 3M/50MG/
50MG

PENICILLIN G POTASSIUM

TABLET; ORAL
PAXIL
+ SMITHKLINE BEECHAM

EQ 30MG BASE

/EQ/30MG/BASE/

PENICILLIN G POTASSIUM

N20031 003

DEC 29, 1992

/N20031/003/

/DEC/29/1992/

1,000,000 UNITS/VIAL
5,000,000 UNITS/VIAL
10,000,000 UNITS/VIAL
20,000,000 UNITS/VIAL
/1,000,000 UNITS/VIAL/
/5,000,000 UNITS/VIAL/
/10,000,000 UNITS/VIAL/
/20,000,000 UNITS/VIAL/

N60362 001

N60362 003

N60362 004

N60362 002

N60362/001/

N60362/003/

N60362/004/

N60362/002/

/N60362/002/

/N60362/001/

/N60362/003/

/N60362/004/

/N60362/002/

/N60362/001/

PENTOBARBITAL SODIUM

CAPSULE, ORAL
/PENTOBARBITAL SODIUM/
/AA/ /LANNETT/
/AA/ @ LANNETT
@ 50MG/
100MG
N85937 001
N85937 001
N85937 001

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
PHENDIMETRAZINE TARTRATE
/AA/ /ZENTH/
@ ZENTH
/35MG/
35MG
N85611 001
N85611 001

PHENTERMINE HYDROCHLORIDE

CAPSULE, ORAL
PHENTERMINE HCL
/AA/ /LANNETT/
@ LANNETT
30MG
N87022/001/
/FEB/03/1983/
N87022 001
FEB 03, 1983

PHENYLEPHRINE HYDROCHLORIDE, PROMETHAZINE HYDROCHLORIDE

SYRUP, ORAL
PROMETHAZINE VC PLAIN
AA PENNEX
/AA/
/ /
5MG/5ML, 6.25MG/5ML
/5MG/5ML, 6 .25MG/5ML /
N88897 001
JAN 04, 1985
/N88897/001/
/JAN/04//1985/
N80857 001
N80857 002

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL
/DIPHENYLAMIN/SODIUM/
/BX/ /LANNETT/
@ LANNETT
30MG/
100MG
N80857/002/
/N80857/001/
N80857 001
N80857 002

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION
PENTACARINAT
AP RHONE POULENC RORER
300MG/VIAL
AP 73447 001
APR 28, 1994

PREDNISONE

BBOBAN THE INE DOMIDE

TABLET; ORAL PREDNISONE /BX/ /BX/ @ INWOOD	/1MG/ /INWOOD/ 1MG/ 1MG	/N80328/001/ /N80306/001/ N80328 001 N80306 001	AA AA	ROBERTS LABS /SCS/ /AA/ /AA/	7.5MG 15MG /7.5MG/ 15MG/
/BX/ /BX/ /MK/LABS/ /BX/ /NYLOS/ /BX/ @ NYLOS	/2.5MG/ 2.5MG/ /2.5MG/ /2.5MG/ /2.5MG/ /REXALL/ @ REXALL	/N80563/001/ /N80563/002/ /N80563/001/ /N805115/001/ /N805115 001 /N80232/001/ N80232 001		SOLUTION/DROPS ; OPHTHALMIC /KAINAIR/	
/BX/ /SPERTI/ /BX/ @ SPERTI	/1MG/ /1MG/ /2.5MG/ /2.5MG/ 1MG 2.5MG	/N80359/001/ /N80359/002/ /N80359/003/ N80359 001 N80359 002 N80359 003	AI AI	/PHARMAFAIR / @ PHARMAFAIR	/0.5%/ 0.5%
/BX/ @ SPERTI	5MG 5MG	N80359 003		PROPYLTIOURACIL	
/BX/ @ WHITE/TOWNE/PAULSEN//20MG/ /BX/ @ WHITE TOWNE PAULSEN	/N84913/002/ /N84913 002 /N80371/001/ /N80371 001	/N84913/002/ /N84913 002 /N80371/001/ /N80371 001		TABLET; ORAL PROPYLTIOURACIL	
/BX/ /1ST/TX/ @ 1ST TX	20MG /5MG/ 5MG			/BD/ @ LANNETT/ /BD/ @ TABLICAPS/ /BD/ @ TABLICAPS	/50MG/ 50MG/ 50MG/ 50MG
PROMETHAZINE HYDROCHLORIDE					
SYRUP; ORAL PROMETHAZINE PLAIN AA	6.25MG/5ML /@/	N87953 001 NOV 15, 1982 /N87953/001/ /NOV/15,/1982/		PROTIRELIN INJECTABLE; INJECTION /RELEFACT TRH/	
PENNEX	6.25MG/5ML			/AP/ /FERRING/LABS/ AP	
				THYREL TRH FERRING LABS	/0.5MG/ML/ 0.5MG/ML
PROMETHAZINE HYDROCHLORIDE					
TABLET; ORAL PROMETHAZINE HCL /BP/ /BP/	PROMETHAZINE HCL /TABLICAPS/ @ TABLICAPS @ /RENSED/	/N84080/001/ /N84027/001/ N84080 001 N84027 001		PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE TABLET; ORAL /ALLERFED/	
/BP/ /BP/	/25MG/ 1.2.5MG 25MG	/12.5MG/ /25MG/ 1.2.5MG 25MG		/60MG/2.5MG/ 60MG ; 2.5MG	
/DUPLICON/				@ PRIVATE FORM	
@ DUPONT/					

PYRIDOSTIGMINE BROMIDE

TABLET; ORAL
/PYRIDOSTIGMINE/BROMIDE/
/KALI/DUPHAR/ /30MG/
@ SOLVAY

30MG
/NOV/27/1990/
N89572 001
Nov 27, 1990

QUINIDINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
QUININDEX
AB + ROBINS AH 300MG
QUINIDINE SULFATE
AB COPLEY PHARM 300MG

EQ 150MG BASE
+ GLAXO

RANITIDINE HYDROCHLORIDE

CAPSULE; ORAL
ZANTAC 150
GLAXO

EQ 150MG BASE
+ GLAXO

N20095 001
MAR 08, 1994

N20095 002
MAR 08, 1994

GRANULE, EFFERVESCENT; ORAL

ZANTAC 150
+ GLAXO

EQ 150MG BASE/PACKET
EQ 150MG BASE

N20251 002
MAR 31, 1994

TABLET, EFFERVESCENT; ORAL
ZANTAC 150
+ GLAXO

EQ 150MG BASE
EQ 150MG BASE

N20251 001
MAR 31, 1994

ROCURONIUM BROMIDE

INJECTABLE; INJECTION
ZEMURON
+ ORGANON
ZEMURON (P/F)
+ ORGANON

10MG/ML
10MG/ML

SOTALOL HYDROCHLORIDE

N20214 002
MAR 17, 1994

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
NITROPRESS
/AP/ /ABBOTT/
@ ABBOTT

N18450 001
MAR 30, 1989

CAPSULE; ORAL
SECOBARBITAL SODIUM
/AA/ /LANNETT/
/AA/ @ LANNETT
50MG
100MG

N20236 001
FEB 04, 1994

SILVER SULFADIAZINE

DRESSING; TOPICAL
SILDIMAC
/BIOPLASTY/
@ ENQUAY
1%

/NOV/30/1989/
N19608 001
NOV 30, 1989

TABLET; ORAL

BETAPACE
BERLEX
120MG

N19865 005
APR 20, 1994

/50MG/VIAL/
50MG/VIAL

N18450 001
MAR 30, 1989

STAVUDINE

CAPSULE; ORAL
ZERIT + BRISTOL MYERS SQUIBB 40MG

N20412 005	JUN 24, 1994
N20412 001	JUN 24, 1994
N20412 002	JUN 24, 1994
N20412 003	JUN 24, 1994
N20412 004	JUN 24, 1994
N20412 006	JUN 24, 1994

STREPTOMYCIN SULFATE

SULFACETAMIDE SODIUM

**/AT/ /PHARMAFAIR/
/SULFAIR FORTE/
SOLUTION/DROPS; OPHTHALMIC
/30%**

@ PHARMAFAIR	30%
<u>/AI/</u>	<u>/SULFAIR-15/</u>
@ PHARMAFAIR	15%

SULFADIAZINE

SULFADIAZINE
EON LABS

五百三

SUN FAMELY OWN ZONE • TIME HOBBIEST

**INJECTABLE; INJECTION
SULFAMETHOXAZOLE AND
/FUJISAWA/**

N70223/00
DEC/29./198
N70223 00
DEC 29 . 198

/N117560/001
N117560 001

/N117560/002/
N117560 002

/N772398/001/
/MAY/23/1988

N772398 001

MAY 23 1988

/N18598/003/
/MAY/19,/1982/
N18598 003
MAY 19, 1982

/N71816/001/
/SEP/28,/1987/
N71816 001
SEP 28, 1987

/N71815/001/
/SEP/28,/1987/
N71815 001
SEP 28, 1987

/N18605/001/
N86983 001
N18605 001
/N86983/001/

/250MC/5ML

SUSPENSION; ORAL
AZULFIDINE
/+ //PHARMACIA/
+ PHARMACIA
@

SULEASALAZINE

SULFISOXAZOLE

TABLET; ORAL
SULFISOXAZOLE
/AB/ /LANNETT/

TABLET; ORAL
SULFISOXAZOLE
/AB/
/LANNETT/
@ LANNETT
/500MG/
500MG

N80085 001 /
N80085 001 /

/SYRUP ; ORAL /
/ACHROMYCIN V /
/AB / + //LEDERLE /
/SUMYCIN /

TESTAMENT

/SYRUP; /ORAL/	
/ACHROMYCIN V/	
/AB/ /+//LEDERLE/	/N50263/002/
/SUNYCIN/	/N60400/001/
/AB/ /SQUIBB/	/N60633/001/
/TETRACYCLINE/	/N60174/001/
/AB/ /BARRE/	/N60291/001/
/AB/ /MK/LABS/	/N60095/001/
/TETRACYCLINE HCL/	/N61468/001/
/AB/ /PUREAC/	
/TETRACYN/	
/AB/ /PFPIPHARMECS/	
/TETRAMED/	
/AB/ /ZENITH/	
35/001/ 35 001	
08 001 1994	
08 002 1994	

INJECTABLE; INJECTION PROGRAF

N50709 001
APP 08 1994

TETRACYCLINE HYDROCHLORIDE

CAPSULE: ORAL

WEIGHT & CUTTING UNIT

TABLET; ORAL
NOLVADEX
+ ZENECA
EQ 20MG BASE

N17970 002
MAR 21 1994

FIBER, EXTENDED RELEASE; PERIODONTAL
ACTISITE
+ ON SITE 12.7MG/FIBER
N50653 001
MAR 25, 1994

TECHNETIUM TC-99M OXIDRONATE KIT

INJECTABLE; INJECTION
/OSTEOSCAN-HDP/
/MALLINCKRODT/
TECHNESCAN HDP

/N18321/001/

SYRUP; ORAL

AB	+ LEDERLE	<u>125MG/5ML</u>	N50263 002
AB	SUMYCIN	<u>125MG/5ML</u>	N60400 001
	SQUIBB		

/DUPONT/MERCK /

TABLET; ORAL
 > DLT > /PANMYCIN/
 > DLT > /AB/ /UP JOHN/
 > ADD > /ADD/ @ UP JOHN
 > ADD > /ADD/ @ UP JOHN

TABLET; ORAL
AB/ /PANMYCIN/
 /UP-JOHN/
 @ UP-JOHN
/500MG/
 250MG
 500MG
 1000MG
 2000MG
 4000MG
 8000MG
 16000MG
 32000MG
 64000MG
 128000MG
 256000MG
 512000MG
 1024000MG
 2048000MG
 4096000MG
 8192000MG
 16384000MG
 32768000MG
 65536000MG
 131072000MG
 262144000MG
 524288000MG
 1048576000MG
 2097152000MG
 4194304000MG
 8388608000MG
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 33554432000MG
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 4294967296000MG
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 68719476736000MG
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 274877906944000MG
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 17592186044416000MG
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 31025044461485092030667044204676533332665641025600000MG
 620500889229701840613330884093533332665641025600000MG
 12410017744584036812266717681870666665641025600000MG
 2482003548916807362453333534174133332665641025600000MG
 49640070978336147249066734823482666665641025600000MG
 9928014195667229449813333584696133332665641025600000MG
 19856028391334458896266769693382666665641025600000MG
 3971205678266891779253333778676133332665641025600000MG
 7942411356533783558513333557352666665641025600000MG
 1588482273306756711706673115470533332665641025600000MG
 317696454661351342341333351044133332665641025600000MG
 6353929093227026846826672808882666665641025600000MG
 1270785818645405369653333501776133332665641025600000MG
 2541571637290810739306672503552666665641025600000MG
 508314327458162147861333350710533332665641025600000MG
 1016628654916324297226672254210666665641025600000MG
 203325730983264859445333350842133332665641025600000MG
 4066514619665297188906672108842666665641025600000MG
 8133029239330594377813333516884133332665641025600000MG
 16266058478661188755626671017768133332665641025600000MG
 32532116957322377511253333533568133332665641025600000MG
 6506423391464475502250667052734133332665641025600000MG
 130128467829289510050133335670826666656410

TOBROAMYCIN SUFLATE

INJECTABLE; INJECTION
 TOBRAMYCIN SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC
 CONTAINER
 + ABBOTT EQ 1.6MG BASE/ML N6308 JUN 02

TRIAZOLAM

INJECTABLE; INJECTION TOBRAMYCIN SULFATE IN CONTAINER	SODIUM CHLORIDE 0.9% IN PLASTIC	TABLET; ORAL TRILOZOLAM	<u>AB</u>	<u>0.125MG</u>	N74031 001 MAR 25, 1994
+ ABBOTT	EQ 1.6MG BASE/ML	N63081 006 JUN 02, 1993	<u>AB</u>	<u>0.25MG</u>	N74031 002 MAR 25, 1994
TRIAMCINOLONE		AB ROXANE	<u>AB</u>	<u>0.125MG</u>	N74224 001 JUN 01, 1994
			<u>AB</u>	<u>0.25MG</u>	N74224 002 JUN 01, 1994
TABLET; ORAL TRIAMCINOLONE					TRISULFAPYRIMIDINES (SULFADIAZINE; SULFAMERAZINE; SULFAMETHAZINE)
BP /	/MYLAN /				/N84406 /001 /
	@ MYLAN				N84406 001
					/2MG /
					2MG

VINBLASTINE SULFATE

INJECTABLE; INJECTION
VINBLASTINE SULFATE

/AP/ /BULL/

AP FAULDING

10MG/VIAL

VINCRISTINE SULFATE

INJECTABLE; INJECTION
VINCRISTINE SULFATE

/AP/ /FUJISAWA/

@ FUJISAWA

1MG/ML

/N70411/001/
/SEP/10,/1986/

N70411 001

SEP 10, 1986

/N71484/001/
/APR/19,/1988/

N71484 001

APR 19, 1988

VINCRISTINE SULFATE PFS
/AP/ /BULL/

FAULDING

1MG/ML

/N70411/001/
/SEP/10,/1986/

N70411 001

SEP 10, 1986

/N71484/001/
/APR/19,/1988/

N71484 001

APR 19, 1988

ACETAMINOPHEN

SUPPOSITORY; RECTAL
INFANTS' FEVERALL
UPSHER SMITH
80MG
AUG 26, 1992

TABLET, EXTENDED RELEASE; ORAL
TYLENOl
+ MCNEIL
650MG

CLOTRIMAZOLE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
MYCELEX-7 COMBINATION PACK
MILES
1% ; 100MG

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
DIPHENHYDRAMINE HCL
/BARRE/
@ BARRE
/12.5MG/5ML/
12.5MG/5ML

IBUPROFEN

TABLET; ORAL
IBUPROFEN
MCNEIL
200MG
PRIVATE FORM

INSULIN BIOSYNTHETIC HUMAN

INJECTABLE, INJECTION
/HUMULIN/BR/
/+//LILLY/
100 UNITS/ML

INSULIN SUSP ISOPHANE BEEF

INJECTABLE; INJECTION
NPH INSULIN
/+//NOVO/NORDISK/
@ NOVO NORDISK
/40 UNITS/ML/
40 UNITS/ML

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC
NAPHCON-A
+ ALCON
OPCON-A
+ BAUSCH AND LOMB
0.025%; 0.3%
0.027%; 0.315%

NAPROXEN SODIUM

TABLET; ORAL
ALEVE
HAMILTON PHARMS
EQ 200MG BASE
/N70497/001/
/APR/25,/1989/
N70497 001
APR 25, 1989
PERMETHRIN
LOTION; TOPICAL
NIX
/+//BURROUGHS/WELLCOME/
1%/
+ WARNER WELLCOME

/N19529/001/
/APR/28,/1986/
N19529 001
APR 28, 1986
/N19918/001/
/MAY/02,/1990/
N19918 001
MAY 02, 1990

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
EFIDAC/24
+ CIBA
240MG

/N20021/002/
/ALZA/
/240MG/
SUDAFED 12 HOUR
/+//BURROUGHS/WELLCOME/
120MG/
@ LILLY
100 UNITS/ML
+ WARNER WELLCOME
120MG

/N73585/001/
/OCT/31,/1991/
N73585 001
OCT 31, 1991

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 7 / JULY '94

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP

INJECTABLE; INJECTION
BLOOD PACK UNIT CPDA-1 IN PLASTIC CONTAINER
BAXTER HLTCHCARE N94004
JUL 28, 1994

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS**[January-July, 1994]****NAME**

Generic/Chemical
TN= Trade Name

INDICATION DESIGNATED**SPONSOR & ADDRESS**

DD= Date Designated
MA= Marketing Approval

8-METHOXALEN
TN= UVADEX

FOR THE PREVENTION OF ACUTE REJECTION OF CARDIAC ALLOGRAFTS.

THERAKOS, INCORPORATED
201 BRANDYWINE PARKWAY
WEST CHESTER PA 19380
DD 05/12/94 MA / /

AMINOSALICYLIC ACID
TN= PASER GRANULES

TREATMENT OF TUBERCULOSIS INFECTIONS.

JACOBUS PHARMACEUTICAL COMPANY
37 CLEVELAND LANE
PRINCETON NJ 08540
DD 02/19/92 MA 06/30/94

AMIODARONE HCL
TN= CORDARONE

FOR THE ACUTE TREATMENT AND PROPHYLAXIS OF LIFE-THREATENING VENTRICULAR TACHYCARDIA OR VENTRICULAR FIBRILLATION.

WYETH-AYERST LABORATORIES
P.O. BOX 8299
PHILADELPHIA PA 19101-1245
DD 03/16/94 MA / /

AMMONIUM TETRATHIOMOLYBDATE
TN=

TREATMENT OF WILSON'S DISEASE.

BREWER, GEORGE J. M.D.
UNIVERSITY OF MICHIGAN MEDICAL SCHOOL
ANN ARBOR MI 48109-0618
DD 01/31/94 MA / /

ANTIVENIN, POLYVALENT CROTALID (OVINE) FAB
TN= CROTAB

TREATMENT OF ENVENOMATIONS INFlicted BY NORTH AMERICAN CROTALID SNAKES.

THERAPEUTIC ANTIBODIES INC.
1500 21ST AVENUE SOUTH, SUITE 310
NASHVILLE TN 37212
DD 01/12/94 MA / /

ARGININE BUTYRATE
TN=

TREATMENT OF SICKLE CELL DISEASE AND BETA THALASSEMIA.

VERTEX PHARMACEUTICALS, INC.
40 ALLSTON STREET
CAMBRIDGE MA 02139-4211
DD 05/25/94 MA / /

AUTOLYMPHOCYTE THERAPY
TN=

TREATMENT OF RENAL CELL CARCINOMA.

CELLCOR INCORPORATED
200 WELLS AVENUE
NEWTON MA 02159
DD 07/12/94 MA / /

BETAINe
TN=

TREATMENT OF HOMOCYSTINURIA.

ORPHAN MEDICAL
13911 RIDGEDALE DRIVE
MINNETONKA MN 55305
DD 05/16/94 MA / /

BOVINE IMMUNOGLOBULIN CONCENTRATE, CRYPTOSPORIDIUM PARVUM
TN= SPORIDIN-G

TREATMENT AND SYMPTOMATIC RELIEF OF CRYPTOSPORIDIUM PARVUM INFECTION OF THE GASTROINTESTINAL TRACT IN IMMUNOCOMPROMISED PATIENTS.

GALAGEN, INCORPORATED
4001 LEXINGTON AVENUE NORTH
ARDEN HILLS MN 55126-2998
DD 03/01/94 MA / /

BUPRENORPHINE HYDROCHLORIDE
TN=

TREATMENT OF OPIATE ADDICTION IN OPIATE USERS.

RECKITT & COLMAN
PHARMACEUTICALS, INC.
1901 HUGUENOT ROAD
RICHMOND VA 23235
DD 06/15/94 MA / /

BUSULFAN
TN=

FOR USE AS PREPARATIVE THERAPY FOR MALIGNANCIES TREATED WITH BONE MARROW TRANSPLANTATION.

SPARTA PHARMACEUTICALS
P.O. BOX 13288
RESEARCH TRIANGLE PK NC 27709
DD 04/21/94 MA / /

BUSULFAN
TN=

AS PREPARATIVE THERAPY IN THE TREATMENT OF MALIGNANCIES WITH BONE MARROW TRANSPLANTATION.

ORPHAN MEDICAL
13911 RIDGEDALE DRIVE
MINNETONKA MN 55305
DD 07/28/94 MA / /

CCD 1042
TN=

TREATMENT OF INFANTILE SPASMS.

COSENSYS, INC.
213 TECHNOLOGY DRIVE
IRVINE CA 92718
DD 05/25/94 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD= Date Designated MA= Marketing Approval
CHIMERIC (MURINE VARIABLE, HUMAN CONSTANT) MAB TO CD20 TN=	TREATMENT OF NON-HODGKIN'S B-CELL LYMPHOMA.	IDECK PHARMACEUTICALS CORPORATION 11011 TORREYANA ROAD SAN DIEGO CA 92121 DD 06/13/94 MA / /
CHOLINE CHLORIDE TN=	TREATMENT OF CHOLINE DEFICIENCY, SPECIFICALLY THE CHOLINE DEFICIENCY, HEPATIC STEATOSIS, AND CHOLESTASIS, ASSOCIATED WITH LONG-TERM PARENTERAL NUTRITION.	BUCHMAN, ALAN M.D. 6550 FANNIN, SUITE 1122 HOUSTON TX 77030 DD 02/10/94 MA / /
CLADRIBINE TN= LEUSTATIN	TREATMENT OF THE CHRONIC PROGRESSIVE FORM OF MULTIPLE SCLEROSIS.	BEUTLER, ERNEST M.D. 10666 NORTH TORREY PINES ROAD LA JOLLA CA 92037 DD 04/19/94 MA / /
CY-1899 TN=	TREATMENT OF CHRONIC ACTIVE HEPATITIS B INFECTION IN HLA-A2 POSITIVE PATIENTS.	CYTEL CORPORATION 3525 JOHN HOPKINS COURT SAN DIEGO CA 92121 DD 03/16/94 MA / /
DEHYDROEPIANDROSTERONE TN=	TREATMENT OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AND THE REDUCTION IN THE USE OF STEROIDS IN STEROID-DEPENDENT SLE PATIENTS.	GENELABS TECHNOLOGIES, INC. 505 PENOBSCOT DRIVE REDWOOD CITY CA 94063 DD 07/13/94 MA / /
DESMOPRESSIN ACETATE TN=	TREATMENT OF MILD HEMOPHILIA A AND VON WILLEBRAND'S DISEASE.	RHONE-POULENC RORER PHARM. 500 ARCOLA ROAD COLLEGEVILLE PA 19426 DD 01/22/91 MA 03/07/94
FGN-1 TN=	FOR THE SUPPRESSION AND CONTROL OF COLONIC ADENOMATOUS POLYPSES IN THE INHERITED DISEASE ADENOMATOUS POLYPOSIS COLI.	CELL PATHWAYS, INC. 1700 BROADWAY, SUITE 2000 DENVER CO 80290 DD 02/14/94 MA / /
GAMMALINOLENIC ACID TN=	TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.	ZURIER, ROBERT B. M.D. 55 LAKE AVE. UNIV. OF MASS. MED. CTR. WORCESTER MA 01655 DD 07/27/94 MA / /
HEME ARGINATE TN= NORMOSANG	TREATMENT OF MYELODYSPLASTIC SYNDROMES.	LEIRAS, INCORPORATED 1850 CENTENNIAL PARK DRIVE, SUITE 450 RESTON VA 22091 DD 03/01/94 MA / /
I-131 RADIOLABELED B1 MONOCLONAL ANTIBODY TN=	TREATMENT OF NON-HODGKIN'S B-CELL LYMPHOMA.	COULTER CORPORATION 11800 S.W. 147 AVENUE, P.O. BOX 169015 MIAMI FL 33116-9015 DD 05/16/94 MA / /
IMIGLUCERASE TN= CEREZYME	FOR REPLACEMENT THERAPY IN PATIENTS WITH TYPES I, II, AND III GAUCHER'S DISEASE.	GENZYME CORPORATION ONE KENDALL SQUARE CAMBRIDGE MA 02139 DD 11/05/91 MA 05/23/94
ISOBUTYRAMIDE TN=	TREATMENT OF SICKLE CELL DISEASE AND BETA THALASSEMIA.	VERTEX PHARMACEUTICALS INCORPORATED 40 ALLSTON STREET CAMBRIDGE MA 02139-4211 DD 05/25/94 MA / /
L-2-OXOTHIAZOLIDINE-4-CARBOXYLIC ACID TN= PROCYSTEINE	TREATMENT OF ADULT RESPIRATORY DISTRESS SYNDROME.	FREE RADICAL SCIENCES, INC. 245 FIRST STREET CAMBRIDGE MA 02142 DD 06/14/94 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME
Generic/Chemical
TN= Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD=Date Designated
MA=Marketing Approval

L-CYSTEINE
TN=

FOR THE PREVENTION AND LESSENING OF PHOTOSENSITIVITY IN ERYTHROPOIETIC PROTOPORPHYRIA.

TYSON AND ASSOCIATES
12832 SOUTH CHADRON AVENUE
HAWTHORNE CA 90250
DD 05/16/94 MA / /

LIPOSOME ENCAPSULATED RECOMBINANT INTERLEUKIN-2
TN=

TREATMENT OF CANCERS OF THE KIDNEY AND RENAL PELVIS.

ONCOTHERAPEUTICS, INC.
1002 EASTPARK BOULEVARD
CRANBURY NJ 08512
DD 06/20/94 MA / /

MITOGUZONE
TN=

TREATMENT OF DIFFUSE NON-HODGKIN'S LYMPHOMA, INCLUDING AIDS-RELATED DIFFUSE NON-HODGKIN'S LYMPHOMA.

CTRC RESEARCH FOUNDATION
11812 BECKET STREET
POTOMAC MD 20854
DD 03/18/94 MA / /

N-TRIFLUOROACETYLADRIAMYCIN-14-V
ALERATE
TN=

TREATMENT OF CARCINOMA IN SITU OF THE URINARY BLADDER.

ANTHRA PHARMACEUTICALS, INC.
19 CARSON ROAD
PRINCETON NJ 08540
DD 05/23/94 MA / /

OXANDROLONE
TN= HEPANDRIN

TREATMENT OF MODERATE/SEVERE ACUTE ALCOHOLIC HEPATITIS IN THE PRESENCE OF MODERATE PROTEIN CALORIE MALNUTRITION.

BIO-TECHNOLOGY GENERAL CORPORATION
70 WOOD AVENUE SOUTH
ISELIN NJ 08830
DD 03/18/94 MA / /

PEGASPARGASE
TN= ONCASPAR

TREATMENT OF ACUTE LYMPHOCYTIC LEUKEMIA (ALL).

ENZON, INC.
40 KINGSBRIDGE ROAD
PISCATAWAY NJ 08854-3998
DD 10/20/89 MA 02/01/94

PILOCARPINE
TN= SALAGEN

TREATMENT OF XEROSTOMIA INDUCED BY RADIATION THERAPY FOR HEAD AND NECK CANCER.

MGI PHARMA, INC.
SUITE 300 E, 9900 BRENT ROAD EAST
MINNEAPOLIS MN 55343-9667
DD 09/24/90 MA 03/22/94

RECOMBINANT HUMAN GELSOLIN
TN=

TREATMENT OF THE RESPIRATORY SYMPTOMS OF CYSTIC FIBROSIS.

BIOGEN, INC.
14 CAMBRIDGE CENTER
CAMBRIDGE MA 02124
DD 01/12/94 MA / /

REDUCED L-GLUTATHIONE
TN= CACHEXON

TREATMENT OF AIDS-ASSOCIATED CACHEXIA.

TELLURIDE PHARMACEUTICAL CORPORATION
146 FLANDERS DRIVE
HILLSBOROUGH NJ 08876-4656
DD 02/14/94 MA / /

RIFAMPIN, ISONIAZID,
PYRAZINAMIDE
TN= RIFATER

SHORT-COURSE TREATMENT OF TUBERCULOSIS.

MARION MERRELL DOW, INC.
P.O. BOX 9627
KANSAS CITY MO 64134-0627
DD 09/12/85 MA 05/31/94

SULFADIAZINE
TN=

FOR USE IN COMBINATION WITH PYRIMETHAMINE FOR THE TREATMENT OF TOXOPLASMA GONDII ENCEPHALITIS IN PATIENTS WITH AND WITHOUT ACQUIRED IMMUNODEFICIENCY SYNDROME.

EON LABS MANUFACTURING, INC.
227-15 NORTH CONDUIT AVENUE
LAURELTON NY 11413
DD 03/14/94 MA / /

TIZANIDINE HCL
TN= ZANAFLEX

TREATMENT OF SPASTICITY ASSOCIATED WITH MULTIPLE SCLEROSIS AND SPINAL CORD INJURY.

ATHENA NEUROSCIENCES, INC.
800F GATEWAY BOULEVARD
SOUTH SAN FRANCISCO CA 94080
DD 01/31/94 MA / /

TREOSULFAN
TN= OVASTAT

TREATMENT OF OVARIAN CANCER.

MEDAC GmbH c/o PRINCETON REG.
ASSOC.
65 SOUTH MAIN STREET
PENNINGTON NJ 08534
DD 05/16/94 MA / /

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

NO JULY 1994 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, 14TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

ALBUTEROL (METERED DOSE INHALER - *IN VIVO*)
FLURBIPROFEN (TABLET)
PHENYTOIN (SUSPENSION AND CHEWABLE TABLET)
PHENYTOIN SODIUM (CAPSULE, EXTENDED AND PROMPT)

JAN 27, 1994
DEC 24, 1992 FEB 04, 1994
MAR 04, 1994
MAR 04, 1994

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 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

ACYCLOVIR TABLET; ORAL	200MG	93 P-0339/ CP1	NOVOPHARM	NEW DOSAGE FORM	APPROVED FEB 08, 1994
ACYCLOVIR SODIUM INJECTABLE; INJECTION	25MG/ML (20ML/VIAL) (40ML/VIAL)	93 P-0469/ CP1	FAULDING	NEW DOSAGE FORM	APPROVED JUN 09, 1994
ESTRADIOL TABLET; ORAL	1.5MG	93 P-0344/ CP1	BRISTOL MYERS SQIBB	NEW STRENGTH	APPROVED JUN 08, 1994
LOPERAMIDE HYDROCHLORIDE TABLET, EFFERVESCENT; ORAL	1MG	93 P-0332/ CP1	ELLIS PHARM CONSULTING	NEW DOSAGE FORM	APPROVED FEB 08, 1994
METHYLTESTOSTERONE CAPSULE; ORAL	25MG	93 P-0459/ CP1	ICN	NEW DOSAGE FORM	APPROVED JUN 08, 1994
MORPHINE SULFATE CAPSULE, EXTENDED RELEASE; ORAL	15MG 60MG 100MG	93 P-0446/ CP1	PHARMA CONSULT	NEW DOSAGE FORM	APPROVED JUN 08, 1994
MORPHINE SULFATE CAPSULE, EXTENDED RELEASE; ORAL	90MG	93 P-0446/ CP1	PHARMA CONSULT	NEW DOSAGE FORM NEW STRENGTH	APPROVED JUN 08, 1994
PREDNISONE TABLET, CHEWABLE; ORAL	1MG 2.5MG 20MG 50MG	93 P-0333/ CP1	DURA	NEW DOSAGE FORM	APPROVED JUN 08, 1994
PSEUDOEPHENDRINE HYDROCHLORIDE; TERFENADINE CAPSULE, EXTENDED RELEASE; ORAL	120MG 60MG	93 P-0367/ CP1	EURAND AMERICA	NEW DOSAGE FORM	APPROVED FEB 08, 1994

ERRATA

CIMETIDINE TABLET, EFFERVESCENT; ORAL	200MG 300MG 400MG 800MG	93 P-0048/ CP1*	FLEMINGTON PHARM	NEW DOSAGE FORM	APPROVED SEP 18, 1993
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*Not previously published

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, 14TH 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-21 ALTERNATIVE DOSAGE OF 300MG ONCE DAILY AFTER THE EVENING MEAL
- D-22 REDUCTION IN INFUSION TIME FROM 24 TO 4 HOURS FOR THE 60MG DOSE
- D-23 INCREASE MAXIMUM DOSE AND VARIATIONS IN THE DOSING REGIMEN
- D-24 FOR OVARIAN CANCER THE RECOMMENDED REGIMEN IS 135MG/M² OR 175MG/M² INTRAVENOUSLY OVER THREE HOURS EVERY THREE WEEKS

REFERENCES NEW INDICATION

- I-99 PEDIATRIC ANESTHESIA IN CHILDREN 3 YEARS AND OLDER
- I-100 TO DECREASE THE INCIDENCE OF CANDIDIASIS IN PATIENTS UNDERGOING BONE MARROW TRANSPLANTATION WHO RECEIVE CYTOTOXIC CHEMOTHERAPY AND/OR RADIATION THERAPY
- I-101 TREATMENT OF DIABETIC NEPHROPATHY IN PATIENTS WITH TYPE I INSULIN-DEPENDENT DIABETES MELLITUS AND RETINOPATHY
- I-102 TREATMENT OF OBSESSIVE-COMPULSIVE DISORDER
- I-103 PROPHYLAXIS AGAINST PNEUMOCYSTIS CARINII PNEUMONIA IN INDIVIDUALS WHO ARE IMMUNOCOMPROMISED AND CONSIDERED TO BE AT RISK OF DEVELOPING PNEUMOCYSTIS CARINII PNEUMONIA
- I-104 TREATMENT OF PULMONARY AND EXTRAPULMONARY ASPERGILLOSIS IN PATIENTS WHO ARE INTOLERANT OF OR WHO ARE REFRACTORY TO AMPHOTERICIN B THERAPY
- I-105 TREATMENT OF METASTATIC CARCINOMA OF THE BREAST AFTER FAILURE OF FIRST-LINE OR SUBSEQUENT CHEMOTHERAPY
- I-106 TREATMENT OF ACROMEGALY
- I-107 VAGINAL CANDIDIASIS
- I-108 EXPANDED USE-FOR ICU PATIENTS UNDERGOING LONG-TERM INFUSION DURING MECHANICAL VENTILATION

REFERENCES PATENT USE CODE

- U-91 ALTERNATIVE THERAPY TO TRIMETHOPRIM-SULFAMETHOXAZOLE FOR TREATMENT OF MODERATE-TO-SEVERE PNEUMOCYSTIS CARINII PNEUMONIA IN IMMUNOCOMPROMISED AND AIDS PATIENTS
- U-92 TREATMENT OF DIABETIC NEPHROPATHY IN PATIENTS WITH TYPE I INSULIN DEPENDENT DIABETES MELLITUS AND RETINOPATHY
- U-93 USE AS AN ANTIHISTAMINE/DECONGESTANT
- U-94 TREATMENT OF ADULTS WITH ADVANCED HIV INFECTION WHO ARE INTOLERANT OF APPROVED THERAPIES WITH PROVEN CLINICAL BENEFIT OR WHO HAVE EXPERIENCED SIGNIFICANT CLINICAL OR IMMUNOLOGIC DETERIORATION WHILE RECEIVING THESE THERAPIES OR FOR WHOM SUCH THERAPIES ARE CONTRAINDICATED
- U-95 SHORT TERM MANAGEMENT OF MODERATE PRURITIS IN ADULTS WITH ATOPIC DERMATITIS AND LICHEN SIMPLEX CHRONICUS

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
> <u>ADD</u> >	19872 001	ACETAMINOPHEN; TYLENOL	4650807	MAR 17, 2004	U-93	NDF	JUN 08, 1997
	19806 001	ACRIVASTINE; SEMPREX-D	4501893	FEB 26, 2002	NC	MAR 25, 1997	
> <u>ADD</u> >	74346 001	AMINOSALICYLIC ACID; PASER	4072746	JUL 31, 1998	U-7	ODE	JUN 30, 2001
	18700 001	AMINONE LACTATE; INOCOR				NCE	JUL 31, 1994
	20304 001	AFROTININ BOVINE; TRASYLOL				ODE	DEC 29, 2000
> <u>ADD</u> >	18831 001	ATRACURUM BESTYLATE; TRACRUM	4179507	DEC 18, 1996	I-108	JUN 06, 1997	
> <u>ADD</u> >	20233 001	BUDESONIDE; RHINOCORT				NCE	FEB 14, 1999
> <u>ADD</u> >	18731 001	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646	MAY 14, 2008	U-13		
> <u>ADD</u> >	18731 001	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646	MAR 14, 2008	U-13		
> <u>DLI</u> >	18731 002	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646	MAY 14, 2008	U-13		
> <u>DLI</u> >	18343 001	CAPTOPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-101	JAN 28, 1997
	18343 002	CAPTOPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-101	JAN 28, 1997
	18343 003	CAPTOPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-101	JAN 28, 1997
	18343 005	CAPTOPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-101	JAN 28, 1997
	18343 006	CAPTOPRIL; CAPOTEN	4105776	AUG 08, 1995	I-95	SEP 23, 1996	
	20355 001	DESMOPRESSIN ACETATE; DESMOPRESSIN ACETATE			NP	MAR 07, 1997	
					ODE	MAR 07, 2001	
	20062 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011			
	20062 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011			
	20062 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011			
	20062 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011			
> <u>ADD</u> >	20126 001	DOXEPTIN HYDROCHLORIDE; ZONALON	4395420	JUL 26, 2000	U-95	NDF	APR 01, 1997
> <u>ADD</u> >	18922 004	ETODOLAC; LODINE	4076831	FEB 28, 1997	U-45	NCE	JUN 29, 1999
	20363 002	FAMCICLOVIR; FAMVIR					
	20249 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000	I-69	DEC 10, 1994	
	19304 001	FENOFLIBRATE; LIPIDIL	4058552	NOV 15, 1994		NCE	DEC 31, 1998
	19949 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000	I-100	DEC 30, 1996	
	19949 002	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000	I-100	DEC 30, 1996	
	19949 003	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000	I-100	DEC 30, 1996	
	19950 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000	I-100	DEC 30, 1996	
	20322 001	FLUCONAZOLE; DIFLUCAN	4552884	NOV 12, 2002	I-100	DEC 30, 1996	
			4302460	NOV 24, 1998	NCE	JAN 29, 1995	
					NS	JUN 30, 1997	
					I-107	JUN 30, 1997	

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18936 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4018895	APR 19, 1994	U-12	I-102	FEB 28, 1997
18936 006	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001	I-102	FEB 28, 1997	I-102 FEB 28, 1997
20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001	I-102	FEB 28, 1997	I-102 FEB 28, 1997
20235 001	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
20235 002	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
20235 003	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
20329 001	GLIPIZIDE; GLUCOTROL XL	4472380	SEP 18, 2001		NDF	APR 26, 1997
20329 002	GLIPIZIDE; GLUCOTROL XL	4374829	DEC 30, 2001	U-3	NDF	APR 26, 1997
19778 003	HYDROCHLOROTHIAZIDE; PRINZIDE 10-12.5	4472380	SEP 18, 2001			
19888 001	HYDROCHLOROTHIAZIDE; ZESTORETIC 20-12.5	4374829	DEC 30, 2001	U-3		
19888 002	HYDROCHLOROTHIAZIDE; ZESTORETIC 20-25	4374829	DEC 30, 2001	U-3		
19888 003	HYDROCHLOROTHIAZIDE; ZESTORETIC 10-12.5	4472380	SEP 18, 2001			
20367 001	IMIGLUCERASE; CEREZYME	4374829	DEC 30, 2001	U-3		
20314 001	INDIUM IN-111 PENTETRETOIDE KIT; OCTREOSCAN				NCE	MAY 23, 1999
20084 001	10BENGUANE SULFATE I 131; 10BENGUANE SULFATE I 131				ODE	MAY 23, 2001
50705 001	ISONIAZID; RIFATER				NCE	JUN 02, 1999
20336 001	ISRADIPINE; DYNACIRC CR	5030456	JUL 09, 2008		NCE	MAR 25, 1999
>ADD>		4950486	AUG 21, 2007		NCE	MAY 31, 2001
>ADD>		4946687	AUG 07, 2007		NDF	JUN 01, 1997
>ADD>		4816263	MAR 28, 2006	U-3	NCE	DEC 20, 1995
>ADD>		4783337	SEP 16, 2003	U-3		
>ADD>		4466972	AUG 21, 2003	U-3		
>ADD>		5030456	JUL 09, 2008		NDF	JUN 01, 1997
>ADD>		4950486	AUG 21, 2007		NCE	DEC 20, 1995
>ADD>		4946687	AUG 07, 2007			
>ADD>		4816263	MAR 28, 2006	U-3		
>ADD>		4783337	SEP 16, 2003	U-3		
>ADD>		4466972	AUG 21, 2003	U-3		
20083 001	ITRACONAZOLE; SPORANOX	4369184	JAN 18, 2000			I-104 MAR 29, 1997
20219 001	LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN	4374829	DEC 30, 2001		NCE	NOV 10, 1998
19558 006	LISINOPRIL; PRINIVIL				I-92	JUN 09, 1996
20264 001	MEGESTROL ACETATE; MEGACE				NDF	SEP 10, 1997

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
> <u>ADD</u> >						
20065 001	NAPHAZOLINE HYDROCHLORIDE; OPCON-A					
20226 001	NAPHAZOLINE HYDROCHLORIDE; NAPHCON-A					
19667 001	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002	I-106	MAY 03,	1997
19667 002	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002	I-106	MAY 03,	1997
19667 003	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002	I-106	MAY 03,	1997
19667 004	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002	I-106	MAY 03,	1997
19667 005	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002	I-106	MAY 03,	1997
20262 001	PACLITAXEL; TAXOL					
> <u>ADD</u> >						
20036 001	PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004	D-22	APR 15,	1997
20036 003	PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004	D-22	APR 15,	1997
20036 004	PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004	D-22	APR 15,	1997
20184 001	PERINDOPRIL ERBITUME; ACEON	4508729	APR 02, 2002	NCE	DEC 30,	1998
20184 002	PERINDOPRIL ERBITUME; ACEON	4508729	APR 02, 2002	NCE	DEC 30,	1998
20184 003	PERINDOPRIL ERBITUME; ACEON	4508729	APR 02, 2002	NCE	DEC 30,	1998
20237 001	PILOCARPINE HYDROCHLORIDE; SALAGEN					
20279 001	PREDNICKARBATE; DERMATOP					
19627 001	PROPOFOL; DIPRIVAN					
20021 002	PSEUDOEPHEDRINE HYDROCHLORIDE; EFTIDAC/24					
18703 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4801461	MAY 05, 2004			
18703 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	4576604	MAR 18, 2003			
19675 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4128658	DEC 05, 1995	D-21	FEB 28,	1997
20095 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4128658	DEC 05, 1995	D-21	FEB 28,	1997
		4521431	JUN 04, 2002	D-21	FEB 28,	1997
		5028432	JUL 02, 2008			
		4521431	JUN 04, 2002	I-75	MAY 19,	1995
		4128658	DEC 05, 1995	D-21	FEB 28,	1997
		5028432	JUL 02, 2008			
		4521431	JUN 04, 2002	I-75	MAY 19,	1995
		4128658	DEC 05, 1995	D-21	FEB 28,	1997
		5102665	APR 07, 2009			
		4521431	JUN 04, 2002	I-75	MAY 19,	1995
		4128658	DEC 05, 1995	D-21	FEB 28,	1997
20251 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150					
20251 002	RANITIDINE HYDROCHLORIDE; ZANTAC 150					

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20214 001	ROCURONIUM BROMIDE; ZEMURON (P/F)	4894369	JAN 16, 2007	NCE	MAR 17, 1999	
20214 002	ROCURONIUM BROMIDE; ZEMURON	4894369	JAN 16, 2007	NCE	MAR 17, 1999	
20236 001	SALMETEROL XINAFOATE; SEREVENT	4992474	FEB 12, 2008	NCE	FEB 04, 1999	
19766 001	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	DEC 23, 1996	
19766 002	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	DEC 23, 1996	
19766 003	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	DEC 23, 1996	
19766 004	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	DEC 23, 1996	
19640 001	SOMATROPIN, BIOSYNTHETIC; HUMATROPE					
19640 004	SOMATROPIN, BIOSYNTHETIC; HUMATROPE					
19865 005	SOTALOL HYDROCHLORIDE; BETAPACE					
20412 001	STAUVIDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
20412 002	STAUVIDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
20412 003	STAUVIDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
20412 004	STAUVIDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
20412 005	STAUVIDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
17376 001	SULFAMETHOXAZOLE; SEPTRA	4209513	JUN 24, 1997	I-103	JAN 07, 1997	
17376 002	SULFAMETHOXAZOLE; SEPTRA DS	4209513	JUN 24, 1997	I-103	JAN 07, 1997	
17377 001	SULFAMETHOXAZOLE; BACTRIM DS					
17377 002	SULFAMETHOXAZOLE; BACTRIM DS					
17560 002	SULFAMETHOXAZOLE; BACTRIM PEDIATRIC					
17598 001	SULFAMETHOXAZOLE; SEPTRA					
17598 002	SULFAMETHOXAZOLE; SEPTRA GRAPE					
17970 002	TAMOXIFEN CITRATE; NOLVADEX	4536516	AUG 20, 2002			
19762 001	TESTOSTERONE; TESTODERM	4867982	FEB 16, 2005			
19762 002	TESTOSTERONE; TESTODERM	4725439	FEB 16, 2005			
20330 001	TIMOLOL MALEATE; TIMOPTIC-XE	4704282	NOV 03, 2004	NDF	OCT 12, 1996	
20330 002	TIMOLOL MALEATE; TIMOPTIC-XE	4861760	AUG 29, 2006			
20326 001	TRIMETREXATE GLUCURONATE; NEUTREXIN	4195085	MAR 25, 1997	NP	NOV 04, 1996	
		4861760	AUG 29, 2006			
		4195085	MAR 25, 1997	NP	NOV 04, 1996	
		4694007	SEP 15, 2004	U-91	ODE DEC 17, 2000	