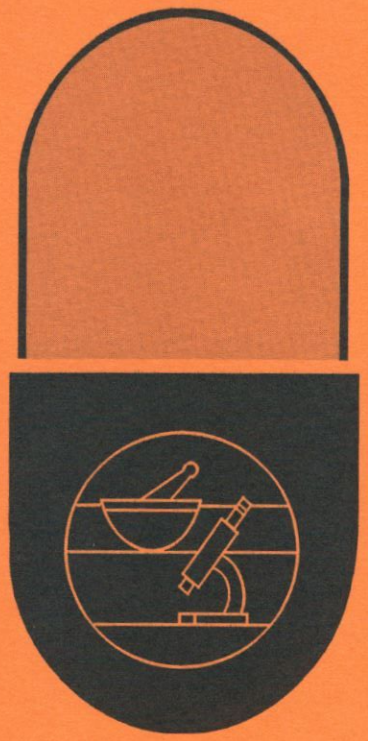
CUMULATIVE SUPPLEMENT 6

JAN'94-JUN'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

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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

14TH EDITION

Cumulative Supplement 6

JUNE 1994

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CUMULATIVE SUPPLEMENT 6

JUNE 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 " ə " symbol to designate their non-marketed status. All products having a " ə " 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.

Products	Federal Register Reference
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

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
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 sumitted 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.

TYPE 6 NDA NUMBER	ORIGINAL NDA NUMBER	ACTIVE INGREDIENT (TRADE NAME)	DOSAGE FORM (ROUTE)
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

CATEGORIES COUNTED	DEC 1993	MAR 1994	JUN 1994	SEP 1994
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	

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

ACETIC ACID, GLACIAL; ALUMINUM ACETATE

SOLUTION/DROPS; OTIC
ACETIC ACID 2% IN AQUEOUS ALUMINUM ACETATE

AT	BAUSCH AND LOMB	2%;0.79%	N40063 001	
			FEB 25, 1994	
> DLT >	/BOROFAIR/			
> DLT >/AT/	/PHARMAFAIR/	/2%;0.79%/	/N88606/001/	
> DLT >			/AUG/21,/1985/	
> ADD >	@ PHARMAFAIR	2%;0.79%	N88606 001	
> ADD >			AUG 21, 1985	

ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE; ORAL
SEMPREX-D

+	BURROUGHS WELLCOME	8MG;60MG	N19806 001	
			MAR 25, 1994	

ALPRAZOLAM

TABLET; ORAL
ALPRAZOLAM

AB	MYLAN	0.25MG	N74215 001	
			JAN 27, 1994	
AB		0.5MG	N74215 002	
			JAN 27, 1994	
AB		1MG	N74215 003	
			JAN 27, 1994	
AB		2MG	N74215 004	
			JAN 27, 1994	
AB	NOVOPHARM	0.25MG	N74085 001	
			FEB 16, 1994	
AB		0.5MG	N74085 002	
			FEB 16, 1994	
AB		1MG	N74085 003	
			FEB 16, 1994	

AMIKACIN SULFATE

INJECTABLE; INJECTION
AMIKACIN

AP	BEDFORD	EQ 50MG BASE/ML	N63313 001	
			APR 11, 1994	
AP		EQ 250MG BASE/ML	N63315 001	
			APR 11, 1994	

AMIKACIN SULFATE

INJECTABLE; INJECTION
AMIKACIN

/AP/	/ELKINS/SINN/	/EQ 50MG BASE/ML/	/N63274/001/	1
			/MAY/18,/1992/	
AP +	ELKINS SINN	EQ 50MG BASE/ML	N63274 001	
			MAY 18, 1992	
/AP/		/EQ 250MG BASE/ML/	/N63275/001/	
			/MAY/18,/1992/	
AP +		EQ 250MG BASE/ML	N63275 001	
			MAY 18, 1992	
	/AMIKIN/			
/AP//+/	/BRISTOL/	/EQ 50MG BASE/ML/	/N50495/001/	
/AP/		/EQ 50MG BASE/ML/	/N62562/001/	
			/SEP/20,/1984/	
/AP//+/		/EQ 250MG BASE/ML/	/N50495/002/	
/AP/		/EQ 250MG BASE/ML/	/N62562/002/	
			/SEP/20,/1984/	
	@ APOTHECON	EQ 50MG BASE/ML	N50495 001	
	@	EQ 250MG BASE/ML	N50495 002	
	@ BRISTOL	EQ 50MG BASE/ML	N62562 001	
			SEP 20, 1984	
	@	EQ 250MG BASE/ML	N62562 002	
			SEP 20, 1984	

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION
AMINOSYN II 5% IN DEXTROSE 25% IN PLASTIC CONTAINER

> DLT >	/ABBOTT/	/5%;25GM/100ML/	/N19565/001/	
> DLT >			/DEC/17,/1986/	
> ADD >	@ ABBOTT	5%;25GM/100ML	N19565 001	
> ADD >			DEC 17, 1986	

AMINOPHYLLINE

INJECTABLE; INJECTION
AMINOPHYLLINE

/AP/	/FUJISAWA/	/25MG/ML/	/N87886/001/	
			/AUG/30,/1983/	
	@ FUJISAWA	25MG/ML	N87886 001	
			AUG 30, 1983	

TABLET; ORAL
AMINOPHYLLINE

/BD/	/LANNETT/	/100MG/	/N84588/001/	
/BD/		/200MG/	/N84588/002/	
	@ LANNETT	100MG	N84588 001	
	@	200MG	N84588 002	

[1]DUE TO PROGRAMMING CHANGES, EACH FIELD ON A PREVIOUSLY DELETED OR CURRENTLY DELETED DRUG PRODUCT LINE HAS BEEN CHANGED TO ONLY SHOW THE OVERSTRUCK SYMBOL BEFORE AND AFTER EACH FIELD RATHER THAN OVER EACH CHARACTER OF THE ENTIRE ENTRY.

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE

AB	RICHLYN	100MG	N84574 001
AB		200MG	N84576 001
/BD/		/100MG/	/N84574/001/
/BD/		/200MG/	/N84576/001/

AMINOSALICYLIC ACID

>ADD>	GRANULE, DELAYED RELEASE; ORAL			
>ADD>	PASER			
>ADD>	+ JACOBUS	4GM/PACKET	N74346 001	
>ADD>			JUN 30, 1994	

AMOXICILLIN

CAPSULE; ORAL
POLYMOX

AB	APOTHECON	250MG	N63099 001
			MAR 20, 1992
AB		500MG	N63099 002
			MAR 20, 1992
/AB/	/BRISTOL/MYERS/	/250MG/	/N63099/001/
			/MAR/20,/1992/
/AB/		/500MG/	/N63099/002/
			/MAR/20,/1992/

POWDER FOR RECONSTITUTION; ORAL

>DLT>	/POLYMOX/			
>DLT>/AB/	/BRISTOL/	/125MG/5ML/	/N61851/001/	
>DLT>/AB/		/125MG/5ML/	/N62323/001/	
>DLT>/AB/		/250MG/5ML/	/N61851/002/	
>DLT>/AB/		/250MG/5ML/	/N62323/002/	
>ADD>	@ APOTHECON	125MG/5ML	N61851 001	
>ADD>	@	125MG/5ML	N62323 001	
>ADD>	@	250MG/5ML	N61851 002	
>ADD>	@	250MG/5ML	N62323 002	

AMPHETAMINE SULFATE

/TABLET;/ORAL/
/AMPHETAMINE/SULFATE/

/LANNETT/	/5MG/	/N83901/001/	
		/AUG/31,/1984/	
	/10MG/	/N83901/002/	
		/AUG/31,/1984/	

AMPHETAMINE SULFATE

/TABLET;/ORAL/
/AMPHETAMINE/SULFATE/

@ LANNETT	5MG	N83901 001	
		AUG 31, 1984	
@	10MG	N83901 002	
		AUG 31, 1984	

AMPHOTERICIN B

INJECTABLE; INJECTION
AMPHOTERICIN B

>DLT>/AP/	/FUJISAWA/	/50MG/VIAL/	/N62728/001/	
>DLT>			/APR/13,/1987/	
>ADD>	@ FUJISAWA	50MG/VIAL	N62728 001	
>ADD>			APR 13, 1987	

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL
POLYCILLIN

>ADD>	@ APOTHECON	EQ 125MG BASE/5ML	N62297 001
>ADD>	@	EQ 250MG BASE/5ML	N62297 002
>DLT>/AB/	/BRISTOL/	/EQ 125MG BASE/5ML/	/N62297/001/
>DLT>/AB/		/EQ 250MG BASE/5ML/	/N62297/002/

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

INJECTABLE; INJECTION
/M.V.C. 9+3/

/AP/	/FUJISAWA/	/10MG/ML;0.006MG/ML;0.5UGM/ML;/	
		/1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML;/	
		/0.4MG/ML;0.36MG/ML;0.3MG/ML;/	
		/330 UNITS/ML;1 IU/ML/	/N18440/002/
			/AUG/08,/1985/
	@ FUJISAWA	10MG/ML;0.006MG/ML;0.5UGM/ML;	
		1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML;	
		0.4MG/ML;0.36MG/ML;0.3MG/ML;	
		330 UNITS/ML;1 IU/ML	N18440 002
			AUG 08, 1985

ATENOLOL

TABLET; ORAL
ATENOLOL

AB	GENPHARM	50MG	N74126 001	
			MAR 23, 1994	
AB		100MG	N74126 002	
			MAR 23, 1994	
AB	INVAMED	25MG	N74265 001	
			FEB 28, 1994	
AB		50MG	N74265 002	
			FEB 28, 1994	
AB		100MG	N74265 003	
			FEB 28, 1994	

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

>_DLT_>	/LOFENE/			
>_DLT_>/AA/	/LANNETT/	/0.025MG;2.5MG/	/N85372/001/	
>_ADD_>	@ LANNETT	0.025MG;2.5MG	N85372 001	

BACITRACIN

OINTMENT; OPHTHALMIC
BACITRACIN

/AT/	/PHARMAFAIR/	/500 UNITS/GM/	/N62453/001/	
			/MAR/28,/1984/	
	@ PHARMAFAIR	500 UNITS/GM	N62453 001	
			MAR 28, 1984	

BACLOFEN

TABLET; ORAL
BACLOFEN

AB	ROYCE	10MG	N73092 001	
			JAN 28, 1994	
AB		20MG	N73093 001	
			JAN 28, 1994	

BENZYL BENZOATE

EMULSION;/TOPICAL/
/BENZYL/BENZOATE/

/+//LANNETT/	/50%/	/N84535/001/	
@ LANNETT	50%	N84535 001	

BETAMETHASONE DIPROPIONATE

CREAM, AUGMENTED; TOPICAL
/DIPROLENE/

/+//SCHERING/	/EQ/0.05%/BASE/	/N19408/001/	
		/JAN/31,/1986/	
@ SCHERING	EQ 0.05% BASE	N19408 001	
		JAN 31, 1986	

GEL; TOPICAL
DIPROLENE

+ SCHERING	EQ 0.05% BASE	N19408 002	
		NOV 22, 1991	

BETAMETHASONE VALERATE

OINTMENT; TOPICAL
BETAMETHASONE VALERATE

/B*/	/CLAY/PARK/	/EQ/0.1%/BASE/	/N71478/001/	
			/DEC/23,/1987/	
	@ CLAY PARK	EQ 0.1% BASE	N71478 001	
			DEC 23, 1987	

BETHANECHOL CHLORIDE

TABLET; ORAL
BETHANECHOL CHLORIDE

/AA/	/LANNETT/	/5MG/	/N84702/001/
/AA/		/10MG/	/N84712/001/
/AA/		/25MG/	/N84074/001/
	@ LANNETT	5MG	N84702 001
	@	10MG	N84712 001
	@	25MG	N84074 001

BUDESONIDE

AEROSOL, METERED; NASAL
RHINOCORT

+ ASTRA	0.05MG/INH	N20233 001
		FEB 14, 1994

BUTABARBITAL SODIUM

ELIXIR; ORAL
/BUTALAN/

/LANNETT/	/33.3MG/5ML/	/N85880/001/
@ LANNETT	33.3MG/5ML	N85880 001

BUTABARBITAL SODIUM

TABLET; ORAL

		BUTISOL SODIUM		
/AA/	/WALLACE/	/100MG/	/N00793/005/	
	WALLACE	100MG	N00793 005	
		SODIUM BUTABARBITAL		
/AA/	/LANNETT/	/100MG/	/N85881/001/	
	@ LANNETT	100MG	N85881 001	
/AA/	/ZENITH/	/30MG/	/N84040/001/	
	@ ZENITH	30MG	N84040 001	

CAFFEINE; ERGOTAMINE TARTRATE

SUPPOSITORY; RECTAL

>_ADD_>		MIGERGOT		
>_ADD_>	BR	G AND W LABS	100MG;2MG	N86557 001
>_ADD_>				OCT 04, 1983
>_DLT_>		/WIGRAINE/		
>_DLT_>	/BR/	/ORGANON/	/100MG;2MG/	/N86557/001/
>_DLT_>				/OCT/04,/1983/

>_ADD_> CALCIFEDIOL

CAPSULE; ORAL

>_ADD_>	CALDEROL		
>_ADD_>	+ ORGANON	0.05MG	N18312 002
>_ADD_>		0.02MG	N18312 001

>_DLT_> CALCIFEDIOL, ANHYDROUS

>_DLT_>	/CAPSULE;/ORAL/		
>_DLT_>	/CALDEROL/		
>_DLT_>	/+//ORGANON/	/0.05MG/	/N18312/002/
>_DLT_>		/0.02MG/	/N18312/001/

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

DELFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER

>_ADD_> AT	FRESENIUS	18.4MG/100ML;1.5GM/100ML;	
>_ADD_>		5.08MG/100ML;538MG/100ML;	
>_ADD_>		448MG/100ML	N20171 001
>_ADD_>			AUG 19, 1992

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

DELFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER

>_ADD_> AT	FRESENIUS	18.4MG/100ML;2.5GM/100ML;	
>_ADD_>		5.08MG/100ML;538MG/100ML;	
>_ADD_>		448MG/100ML	N20171 002
>_ADD_>			AUG 19, 1992

DELFLEX W/ DEXTROSE 4.25% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER

>_ADD_> AT	FRESENIUS	18.4MG/100ML;4.25GM/100ML;	
>_ADD_>		5.08MG/100ML;538MG/100ML;	
>_ADD_>		448MG/100ML	N20171 003
>_ADD_>			AUG 19, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

>_ADD_> AT	BAXTER	18.3MG/100ML;1.5GM/100ML;	
>_ADD_>		5.08MG/100ML;538MG/100ML;	
>_ADD_>		448MG/100ML	N20183 001
>_ADD_>			DEC 04, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

>_ADD_> AT	BAXTER	18.3MG/100ML;2.5GM/100ML;	
>_ADD_>		5.08MG/100ML;538MG/100ML;	
>_ADD_>		448MG/100ML	N20183 002
>_ADD_>			DEC 04, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

>_ADD_> AT	BAXTER	18.3MG/100ML;3.5GM/100ML;	
>_ADD_>		5.08MG/100ML;538MG/100ML;	
>_ADD_>		448MG/100ML	N20183 003
>_ADD_>			DEC 04, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

>_ADD_> AT	BAXTER	18.3MG/100ML;4.25GM/100ML;	
>_ADD_>		5.08MG/100ML;538MG/100ML;	
>_ADD_>		448MG/100ML	N20183 004
>_ADD_>			DEC 04, 1992

DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

>_ADD_> AT	BAXTER	18.3MG/100ML;1.5GM/100ML;	
>_ADD_>		5.08MG/100ML;538MG/100ML;	
>_ADD_>		448MG/100ML	N17512 004

INPERSOL-LC/LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

>_ADD_> AT	ABBOTT	18.4MG/100ML;1.5GM/100ML;	
>_ADD_>		5.08MG/100ML;538MG/100ML;	
>_ADD_>		448MG/100ML	N20374 001
>_ADD_>			JUN 13, 1994

INPERSOL-LC/LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

>_ADD_> AT	ABBOTT	18.4MG/100ML;2.5GM/100ML;	
>_ADD_>		5.08MG/100ML;538MG/100ML;	
>_ADD_>		448MG/100ML	N20374 002
>_ADD_>			JUN 13, 1994

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

>_ADD_>		**INPERSOL-LC/LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER**		
>_ADD_>	**AT**	ABBOTT	**18.4MG/100ML;3.5GM/100ML;**	
>_ADD_>			**5.08MG/100ML;538MG/100ML;**	
>_ADD_>			**448MG/100ML**	**N20374 003**
>_ADD_>				JUN 13, 1994
>_ADD_>		**INPERSOL-LC/LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER**		
>_ADD_>	**AT**	ABBOTT	**18.4MG/100ML;4.25GM/100ML;**	
>_ADD_>			**5.08MG/100ML;538MG/100ML;**	
>_ADD_>			**448MG/100ML**	**N20374 004**
>_ADD_>				JUN 13, 1994

CARBACHOL

>_DLT_>	/INJECTABLE;/INJECTION/			
>_DLT_>	/CARBACHOL/			
>_DLT_>	/@/PHARMAFAIR/	/0.01%/	/N70292/001/	
>_DLT_>			/MAY/21,/1986/	
>_DLT_>	/MIOSTAT/			
>_DLT_>	/+//ALCON/	/0.01%/	/N16968/001/	

>_ADD_>	SOLUTION; INTRAOCULAR			
>_ADD_>	CARBACHOL			
>_ADD_>	@ PHARMAFAIR	0.01%	N70292 001	
>_ADD_>			MAY 21, 1986	
>_ADD_>	MIOSTAT			
>_ADD_>	+ ALCON	0.01%	N16968 001	

CARBAMAZEPINE

SUSPENSION; ORAL

	TEGRETOL			
	+ BASEL PHARMS	100MG/5ML	N18927 001	
			DEC 18, 1987	
	/+//GEIGY/	/100MG/5ML/	/N18927/001/	
			/DEC/18,/1987/	

TABLET; ORAL

	TEGRETOL			
AB	+ BASEL PHARMS	**200MG**	**N16608 001**	
/AB/	/+//GEIGY/	**/200MG/**	/N16608/001/	

TABLET, CHEWABLE; ORAL

TEGRETOL			
AB	+ BASEL PHARMS	**100MG**	**N18281 001**

CARBAMAZEPINE

TABLET, CHEWABLE; ORAL

TEGRETOL			
/AB/	/+//GEIGY/	**/100MG/**	/N18281/001/

CARBIDOPA; LEVODOPA

TABLET; ORAL

	CARBIDOPA AND LEVODOPA			
AB	SCS	**10MG;100MG**	**N74080 001**	
			MAR 25, 1994	
AB		**25MG;100MG**	**N74080 002**	
			MAR 25, 1994	
AB		**25MG;250MG**	**N74080 003**	
			MAR 25, 1994	

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

	/CEFADROXIL/			
	/@/ZENITH/	/EQ/500MG/BASE/	/N62766/001/	
			/MAR/03,/1987/	
	CEFADROXIL			
AB	ZENITH	**EQ 500MG BASE**	**N62766 001**	
			MAR 03, 1987	

POWDER FOR RECONSTITUTION; ORAL

>_ADD_>	**CEFADROXIL**			
>_ADD_> **AB**	APOTHECON	**EQ 125MG BASE/5ML**	**N62334 001**	
>_ADD_> **AB**		**EQ 250MG BASE/5ML**	**N62334 002**	
>_ADD_> **AB**		**EQ 500MG BASE/5ML**	**N62334 003**	
>_DLT_>	**/ULTRACEF/**			
>_DLT_>**/AB/**	/BRISTOL/	**/EQ 125MG BASE/5ML/**	/N62334/001/	
>_DLT_>**/AB/**		**/EQ 250MG BASE/5ML/**	/N62334/002/	
>_DLT_>**/AB/**		**/EQ 500MG BASE/5ML/**	/N62334/003/	

TABLET; ORAL

	/CEFADROXIL/			
	/@/ZENITH/	/EQ/1GM/BASE/	/N62774/001/	
			/APR/08,/1987/	
	CEFADROXIL			
AB	ZENITH	**EQ 1GM BASE**	**N62774 001**	
			APR 08, 1987	
	ULTRACEF			
>_ADD_> **AB**	APOTHECON	**EQ 1GM BASE**	**N62390 001**	
>_ADD_>			JUN 10, 1982	
>_DLT_>**/AB/**	/BRISTOL/	**/EQ 1GM BASE/**	/N62390/001/	
>_DLT_>			/JUN/10,/1982/	

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM

/AP/	/FUJISAWA/	/EQ 500MG BASE/VIAL/	/N62688/002/ /NOV/17,/1986/	
/AP/		/EQ 1GM BASE/VIAL/	/N62688/003/ /NOV/17,/1986/	
/AP/		/EQ 10GM BASE/VIAL/	/N62688/004/ /NOV/17,/1986/	
/AP/		/EQ 20GM BASE/VIAL/	/N62688/005/ /AUG/03,/1987/	
	@ FUJISAWA	EQ 500MG BASE/VIAL	N62688 002 NOV 17, 1986	
	@	EQ 1GM BASE/VIAL	N62688 003 NOV 17, 1986	
	@	EQ 10GM BASE/VIAL	N62688 004 NOV 17, 1986	
	@	EQ 20GM BASE/VIAL	N62688 005 AUG 03, 1987	

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION
CEFIZOX

	FUJISAWA	EQ 1GM BASE/VIAL	N63294 002 MAR 31, 1994
		EQ 2GM BASE/VIAL	N63294 003 MAR 31, 1994

CEFUROXIME AXETIL

>_ADD_> POWDER FOR RECONSTITUTION; ORAL
>_ADD_> CEFTIN

>_ADD_>	+ GLAXO	EQ 125MG BASE/5ML	N50672 001 JUN 30, 1994

>_ADD_>

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION
>_DLT_> /SEFFIN/

>_DLT_>/AP/	/GLAXO/	/EQ 1GM BASE/VIAL/	/N62435/001/ /NOV/15,/1983/	
>_DLT_>/AP/		/EQ 2GM BASE/VIAL/	/N62435/002/ /NOV/15,/1983/	
>_DLT_>	/+/	/EQ/10GM/BASE/VIAL/	/N62435/003/ /NOV/15,/1983/	

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION

>_DLT_>	/SEFFIN/			
>_ADD_>	@ GLAXO	EQ 1GM BASE/VIAL	N62435 001 NOV 15, 1983	
>_ADD_>	@	EQ 2GM BASE/VIAL	N62435 002 NOV 15, 1983	
>_ADD_>	@	EQ 10GM BASE/VIAL	N62435 003 NOV 15, 1983	

CHLORAMPHENICOL

OINTMENT; OPHTHALMIC
/CHLOROFAIR/

/AT/	/PHARMAFAIR/	/1%/	/N62439/001/ /APR/21,/1983/	
	@ PHARMAFAIR	1%	N62439 001 APR 21, 1983	

SOLUTION/DROPS; OPHTHALMIC
/CHLOROFAIR/

/AT/	/PHARMAFAIR/	/0.5%/	/N62437/001/ /APR/14,/1983/	
	@ PHARMAFAIR	0.5%	N62437 001 APR 14, 1983	

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL
PERIDEX

AT	+ PROCTER AND GAMBLE	0.12%	**N19028 001** AUG 13, 1986	

PERIOGARD

AT	COLGATE PALMOLIVE	0.12%	**N73695 001** JAN 14, 1994	

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

/AA/	/ZENITH/	/4MG/	/N80779/001/	
	@ ZENITH	4MG	N80779 001	

CHLORTHALIDONE

TABLET; ORAL

	THALITONE			
+	HORUS THERAP	15MG	N19574 001	DEC 20, 1988
		/15MG/	/N19574/001/	/DEC/20,/1988/

CHOLESTYRAMINE

TABLET; ORAL

	QUESTRAN			
+	BRISTOL MYERS SQUIBB	EQ 1GM RESIN	N73403 001	APR 28, 1994

CIMETIDINE

TABLET; ORAL

	CIMETIDINE			
AB	ENDO LABS	200MG	N74281 001	MAY 17, 1994
AB		300MG	N74281 002	MAY 17, 1994
AB		400MG	N74281 003	MAY 17, 1994
AB		800MG	N74329 001	MAY 17, 1994
AB	MYLAN	200MG	N74246 001	MAY 17, 1994
AB		300MG	N74246 002	MAY 17, 1994
AB		400MG	N74246 003	MAY 17, 1994
AB		800MG	N74246 004	MAY 17, 1994
AB	NOVOPHARM	200MG	N74151 001	MAY 17, 1994
AB		300MG	N74151 002	MAY 17, 1994
AB		400MG	N74151 003	MAY 17, 1994
AB		800MG	N74463 001	MAY 17, 1994
	TAGAMET			
AB	SMITHKLINE BEECHAM	200MG	N17920 002	
AB		300MG	N17920 003	
AB		400MG	N17920 004	DEC 14, 1983
AB	+	800MG	N17920 005	APR 30, 1986

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL

			CIMETIDINE HCL			
> ADD >	> ADD >	AA	BARRE	EQ 300MG BASE/5ML	N74176 001	JUN 01, 1994
> ADD >	> ADD >					
			TAGAMET			
> ADD >	> ADD >	AA	SMITHKLINE BEECHAM	EQ 300MG BASE/5ML	N17924 001	

CLEMASTINE FUMARATE

SYRUP; ORAL

			CLEMASTINE FUMARATE			
> ADD >	> ADD >	AA	LEMMON	EQ 0.5MG BASE/5ML	N73399 001	JUN 30, 1994

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

			CLINDAMYCIN PHOSPHATE			
> ADD >	> ADD >	AP	BEDFORD	EQ 150MG BASE/ML	N63163 001	JUN 30, 1994
	/AP/		/DUPONT/	/EQ 150MG BASE/ML/	/N62908/001/	/FEB/01,/1989/
			@ DUPONT MERCK	EQ 150MG BASE/ML	N62908 001	FEB 01, 1989
	/AP/		/FUJISAWA/	/EQ 150MG BASE/ML/	/N62747/001/	/JUN/03,/1988/
			@ FUJISAWA	EQ 150MG BASE/ML	N62747 001	JUN 03, 1988

CLOBETASOL PROPIONATE

CREAM; TOPICAL

		CLOBETASOL PROPIONATE			
AB	COPLEY		0.05%	N74087 001	FEB 16, 1994
		TEMOVATE			
AB	+ GLAXO		0.05%	N19322 001	DEC 27, 1985
> ADD >	AB +		0.05%	N20340 001	JUN 17, 1994

GEL; TOPICAL

	TEMOVATE		
+	GLAXO	0.05%	N20337 001 APR 29, 1994

CLOBETASOL PROPIONATE

OINTMENT; TOPICAL

	CLOBETASOL PROPIONATE		
AB	COPLEY	**0.05%**	**N74089 001** FEB 16, 1994
	TEMOVATE		
AB	+ GLAXO	**0.05%**	**N19323 001** DEC 27, 1985

CLOMIPRAMINE HYDROCHLORIDE

CAPSULE; ORAL

	ANAFRANIL		
	+ BASEL PHARMS	75MG	N19906 003 DEC 29, 1989
		25MG	N19906 001 DEC 29, 1989
		50MG	N19906 002 DEC 29, 1989
	/+//CIBA/	/75MG/	/N19906/003/ /DEC/29,/1989/
		/25MG/	/N19906/001/ /DEC/29,/1989/
		/50MG/	/N19906/002/ /DEC/29,/1989/

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

	PROMETHAZINE VC W/ CODEINE		
AA	PENNEX PHARMS	**10MG/5ML;5MG/5ML; 6.25MG/5ML**	**N88896 001** JAN 04, 1985
	/@/	/10MG/5ML;5MG/5ML;/ /6.25MG/5ML/	/N88896/001/ /JAN/04,/1985/

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

	PROMETHAZINE W/ CODEINE		
AA	PENNEX PHARMS	**10MG/5ML;6.25MG/5ML**	**N88875 001** DEC 17, 1984
	/@/	/10MG/5ML;6.25MG/5ML/	/N88875/001/ /DEC/17,/1984/

CORTISONE ACETATE

INJECTABLE; INJECTION

	/CORTISONE/ACETATE/		
	/BP/ /STERIS/	/25MG/ML/	/N85677/001/
	/BP/	/50MG/ML/	/N85677/002/
	/BP/	/25MG/ML/	/N83147/003/
	/BP/	/50MG/ML/	/N83147/004/
	/BP/ /UPJOHN/	/25MG/ML/	/N08126/002/
	@ STERIS	25MG/ML	N83147 003
	@	25MG/ML	N85677 001
	@	50MG/ML	N83147 004
	@	50MG/ML	N85677 002
	@ UPJOHN	25MG/ML	N08126 002
	CORTONE		
	/BP/ /MSD/	/25MG/ML/	/N07110/002/
	/BP/+/	/50MG/ML/	/N07110/003/
	+ MSD	50MG/ML	N07110 003
		25MG/ML	N07110 002

CROMOLYN SODIUM

SOLUTION; INHALATION

	CROMOLYN SODIUM		
AN	DEY	**10MG/ML**	**N74209 001** APR 26, 1994
	INTAL		
AN	+ FISONS	**10MG/ML**	**N18596 001** MAY 28, 1982

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

	PENTOLAIR		
AT	BAUSCH AND LOMB	**1%**	**N40075 001** APR 29, 1994

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL

	CYPROHEPTADINE HCL		
/AA/	/CHELSEA/LABS/	**/4MG/**	/N86165/001/
	@ CHELSEA LABS	4MG	N86165 001

CYTARABINE

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

DACTINOMYCIN

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

DESMOPRESSIN ACETATE

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

DEXTROAMPHETAMINE SULFATE

/ELIXIR;/ORAL/
/DEXEDRINE/
/SMITHKLINE/BEECHAM/ /5MG/5ML/ /N83902/001/
@ SMITHKLINE BEECHAM 5MG/5ML N83902 001

TABLET; ORAL
DEXTROAMPHETAMINE SULFATE
>DLT>/AA/ /LANNETT/ /5MG/ /N83903/001/
>DLT>/AA/ /10MG/ /N83903/003/
>ADD> @ LANNETT 5MG N83903 001
>ADD> @ 10MG N83903 003
>DLT> /15MG/ /N85652/001/
>ADD> @ 15MG N85652 001

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

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

DEXTROSE

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

DEXTROTHYROXINE SODIUM

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

DIENESTROL

CREAM; VAGINAL
/ESTRAGUARD/
/AI/ /SOLVAY/ **/0.01%/** /N84436/001/
@ SOLVAY 0.01% N84436 001

DIETHYLSTILBESTROL

TABLET; ORAL
DIETHYLSTILBESTROL
/BP/ /LILLY/ /1MG/ /N04041/004/
/BP/+/ /5MG/ /N04041/005/
+ LILLY 5MG N04041 005
1MG N04041 004

STILBESTROL
/BP/ /TABLICAPS/ /1MG/ /N83002/001/
/BP/ /5MG/ /N83006/001/
@ TABLICAPS 1MG N83002 001
@ 5MG N83006 001

TABLET, DELAYED RELEASE; ORAL
/STILBESTROL/
/BE/ /TABLICAPS/ /0.5MG/ /N83003/001/
/BE/ /1MG/ /N83005/001/
/BE/ /5MG/ /N83007/001/
@ TABLICAPS 0.5MG N83003 001
@ 1MG N83005 001
@ 5MG N83007 001

DIETHYLSTILBESTROL

TABLET, DELAYED RELEASE; ORAL
/STILBETIN/

/BE/	/SQUIBB/	/0.5MG/	/N04056/012/	
/BE/		/1MG/	/N04056/013/	
/BE/		/5MG/	/N04056/014/	
	@ SQUIBB	0.5MG	N04056 012	
	@	1MG	N04056 013	
	@	5MG	N04056 014	

DILTIAZEM HYDROCHLORIDE

TABLET; ORAL
DILTIAZEM HCL

AB	NOVOPHARM	**30MG**	**N74084 001**	
			FEB 25, 1994	
AB		**60MG**	**N74084 002**	
			FEB 25, 1994	

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL

>_DLT_>/**AA**/	/LANNETT/	/**25MG**/	/N80868/001/	
>_DLT_>/**AA**/		/**50MG**/	/N80868/002/	
>_ADD_>	@ LANNETT	25MG	N80868 001	
>_ADD_>	@	50MG	N80868 002	

DIPIVEFRIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
DIPIVEFRIN HCL

>_ADD_>				
>_ADD_> **AT**	ALCON	**0.1%**	**N73636 001**	
>_ADD_>			JUN 30, 1994	
	PROPINE			
>_ADD_> **AT**	+ ALLERGAN	**0.1%**	**N18239 001**	

DOXEPIN HYDROCHLORIDE

CREAM; TOPICAL
ZONALON

	+ GENDERM	5%	N20126 001	
			APR 01, 1994	

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
ADRIAMYCIN PFS

/**AP**//+//ADRIA/		/**200MG/100ML**/	/N50629/002/	
			/MAY/03,/1988/	
/**AP**/		/**200MG/100ML**/	/N63165/002/	
			/JAN/30,/1991/	
	+ ADRIA	200MG/100ML	N50629 002	
			MAY 03, 1988	
		200MG/100ML	N63165 002	
			JAN 30, 1991	

ERGOCALCIFEROL

CAPSULE; ORAL
/DELTALIN/

>_DLT_>				
>_DLT_>/**AA**/	/LILLY/	/**50,000 IU**/	/N80884/001/	
>_ADD_>	@ LILLY	50,000 IU	N80884 001	
	VITAMIN D			
>_DLT_>/**AA**/	/LANNETT/	/**50,000 IU**/	/N80825/001/	
>_ADD_>	@ LANNETT	50,000 IU	N80825 001	
>_DLT_>/**AA**/	/WEST/WARD/	/**50,000 IU**/	/N83102/001/	
>_ADD_>	@ WEST WARD PHARM	50,000 IU	N83102 001	

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL
ERYC

/**AB**/	/PARKE/DAVIS/	/**250MG**/	/N62546/001/	
			/JUL/25,/1985/	
	@ PARKE DAVIS	250MG	N62546 001	
			JUL 25, 1985	

SOLUTION; TOPICAL
ERYTHROMYCIN

/**AT**/	/BARRE/	/**2%**/	/N62957/001/	
			/JUL/21,/1988/	
	@ BARRE	2%	N62957 001	
			JUL 21, 1988	
AT	BAUSCH AND LOMB	**2%**	**N64039 001**	
			JAN 27, 1994	
>_DLT_>/**AT**/	/PHARMAFAIR/	/**2%**/	/N62616/001/	
>_DLT_>			/JUL/25,/1985/	
>_ADD_>	@ PHARMAFAIR	2%	N62616 001	
>_ADD_>			JUL 25, 1985	

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL
ERYTHROMYCIN ETHYLSUCCINATE

/AB/	/DISTA/	/EQ 200MG BASE/5ML/	/N62177/001/	
/AB/		/EQ 400MG BASE/5ML/	/N62177/002/	
	@ DISTA	EQ 200MG BASE/5ML	N62177 001	
	@	EQ 400MG BASE/5ML	N62177 002	
>_DLT_>/AB/	/PHARMAFAIR/	/EQ 200MG BASE/5ML/	/N62559/001/	
>_DLT_>			/MAR/15,/1985/	
>_ADD_>	@ PHARMAFAIR	EQ 200MG BASE/5ML	N62559 001	
>_ADD_>			MAR 15, 1985	

TABLET; ORAL
E.E.S. 400

/AB//+/	/ABBOTT/	/EQ 400MG BASE/	/N61905/001/	
/AB/		/EQ 400MG BASE/	/N61905/002/	
			/AUG/12,/1982/	
AB +	ABBOTT	EQ 400MG BASE	N61905 002	
			AUG 12, 1982	
	@	EQ 400MG BASE	N61905 001	

ERYTHROMYCIN STEARATE

TABLET; ORAL
/ERYPAR/

/AB/	/PARKE/DAVIS/	/EQ 250MG BASE/	/N62322/001/	
	ERYPAR			
	@ WARNER CHILCOTT	EQ 250MG BASE	N62322 001	
	ERYTHROMYCIN STEARATE			
>_DLT_>/AB/	/PUREPAC/	/EQ 250MG BASE/	/N61743/001/	
>_ADD_>	@ PUREPAC PHARM	EQ 250MG BASE	N61743 001	

ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
/DELADUMONE/

/AO//+/	/SQUIBB/	/4MG/ML;90MG/ML/	/N09545/001/	
	@ SQUIBB	4MG/ML;90MG/ML	N09545 001	
	TESTOSTERONE ENANTHATE AND ESTRADIOL VALERATE			
/AO/	/STERIS/	/4MG/ML;90MG/ML/	/N85865/001/	
	+ STERIS	4MG/ML;90MG/ML	N85865 001	

ESTROGENS, ESTERIFIED

TABLET; ORAL
ESTRATAB

/BS/	/SOLVAY/	/0.625MG/	/N83209/001/
BS +	SOLVAY	0.625MG	N83209 001
/BS/		/2.5MG/	/N83857/001/
BS +		2.5MG	N83857 001
	MENEST		
/BS/+/	/SMITHKLINE/BEECHAM/	/0.625MG/	/N84948/001/
BS	SMITHKLINE BEECHAM	0.625MG	N84948 001
/BS/+/		/2.5MG/	/N84949/001/
BS		2.5MG	N84949 001

ESTRONE

INJECTABLE; INJECTION
ESTRONE

/BP/	/STERIS/	/2MG/ML/	/N83397/001/
	@ STERIS	2MG/ML	N83397 001

ETHAMBUTOL HYDROCHLORIDE

TABLET; ORAL
MYAMBUTOL

+	LEDERLE	400MG	N16320 003
/+/		/500MG/	/N16320/004/
		/200MG/	/N16320/002/
	@	200MG	N16320 002
		/400MG/	/N16320/003/
	@	500MG	N16320 004

ETHINAMATE

>_DLT_>	/CAPSULE;/ORAL/			
>_DLT_>	/VALMID/			
>_DLT_>	/DISTA/	/500MG/	/N09750/001/	
>_ADD_>	@ DISTA	500MG	N09750 001	

ETHINYL ESTRADIOL; FERROUS FUMARATE; NORETHINDRONE

>_DLT_>	/TABLET;/ORAL-28/			
>_DLT_>	/NORQUEST/FE/			
>_DLT_>	/+//SYNTEX/	/0.035MG;75MG;1MG/	/N18926/001/	
>_DLT_>			/JUL/18,/1986/	
>_ADD_>	@ SYNTEX	0.035MG;75MG;1MG	N18926 001	
>_ADD_>			JUL 18, 1986	

ETODOLAC

TABLET; ORAL
LODINE
+ WYETH AYERST 400MG N18922 004 JUL 29, 1993

ETOPOSIDE

INJECTABLE; INJECTION
ETOPOSIDE
AP GENSIA **20MG/ML** **N74284 001** FEB 10, 1994

VEPESID
AP + BRISTOL **20MG/ML** **N18768 001** NOV 10, 1983

>ADD> FAMCICLOVIR

>ADD> TABLET; ORAL
>ADD> FAMVIR
>ADD> + SMITHKLINE BEECHAM 500MG N20363 002 JUN 29, 1994
>ADD>

FAMOTIDINE

INJECTABLE; INJECTION
PEPCID IN PLASTIC CONTAINER
+ MERCK 0.4MG/ML N20249 001 FEB 18, 1994

FLUCONAZOLE

TABLET; ORAL
DIFLUCAN
>DLT> /+//PFIZER/ /50MG/ /N19949/001/ /JAN/29,/1990/
>DLT>
>DLT> /+/ /100MG/ /N19949/002/ /JAN/29,/1990/
>DLT>
>ADD> PFIZER 50MG N19949 001 JAN 29, 1990
>ADD>
>ADD> 100MG N19949 002 JAN 29, 1990
>ADD>
>ADD> 150MG N20322 001 JUN 30, 1994
>ADD>

FLUMAZENIL

INJECTABLE; INJECTION
/MAZICON/
/+//ROCHE/ /0.1MG/ML/ /N20073/001/ /DEC/20,/1991/

ROMAZICON
+ ROCHE 0.1MG/ML N20073 001 DEC 20, 1991

FLUOCINOLONE ACETONIDE

SOLUTION; TOPICAL
FLUOCINOLONE ACETONIDE
/**AI**/ /PHARMAFAIR/ /**0.01%**/ /N88449/001/ /FEB/08,/1984/

@ PHARMAFAIR 0.01% N88449 001 FEB 08, 1984

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE
>DLT> /B*/ /CLAY/PARK/ /0.05%/ /N71790/001/ /JUL/13,/1988/
>DLT>
>ADD> @ CLAY PARK 0.05% N71790 001 JUL 13, 1988
>ADD>

FLUOROURACIL

INJECTABLE; INJECTION
ADRUCIL
>DLT> /**AP**//+//ADRIA/ /**50MG/ML**/ /N17959/001/ /OCT/18,/1991/
>DLT> /**AP**/ /**50MG/ML**/ /N40023/001/
>DLT>
>ADD> **AP** + PHARMACIA **50MG/ML** **N40023 001** OCT 18, 1991
>ADD>
>ADD> @ 50MG/ML N17959 001

FLURANDRENOLIDE

CREAM; TOPICAL
CORDRAN SP
>DLT> /+//DISTA/ /0.025%/ /N12806/003/
>DLT> /+/ /0.05%/ /N12806/002/
>ADD> + LILLY 0.025% N12806 003
>ADD> + 0.05% N12806 002

FLURANDRENOLIDE

LOTION; TOPICAL
CORDRAN

>_DLT_>/AT//+//DISTA/	/0.05%/	/N13790/001/
>_ADD_> AT + LILLY	0.05%	N13790 001

OINTMENT; TOPICAL
CORDRAN

>_DLT_>	/+//DISTA/	/0.025%/	/N12806/004/
>_DLT_>	/+/	/0.05%/	/N12806/001/
>_ADD_>	+ LILLY	0.025%	N12806 004
>_ADD_>	+	0.05%	N12806 001

TAPE; TOPICAL
CORDRAN

>_DLT_>	/+//DISTA/	/0.004MG/SQ/CM/	/N16455/001/
>_ADD_>	+ LILLY	0.004MG/SQ CM	N16455 001

FLURBIPROFEN

TABLET; ORAL
ANSAID

>_ADD_> AB	UPJOHN	50MG	N18766 002
>_ADD_>			OCT 31, 1988
>_ADD_> AB +		100MG	N18766 003
>_ADD_>			OCT 31, 1988
>_ADD_>	FLURBIPROFEN		
>_ADD_> AB	MYLAN	50MG	N74358 001
>_ADD_>			JUN 20, 1994
>_ADD_> AB		100MG	N74358 002
>_ADD_>			JUN 20, 1994

FOLIC ACID

TABLET; ORAL
FOLIC ACID

>_DLT_>/AA/	/LANNETT/	/1MG/	/N80816/001/
>_ADD_>	@ LANNETT	1MG	N80816 001
/AA/	/PUREPAC/	/1MG/	/N80784/001/
	@ PUREPAC	1MG	N80784 001

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE

>_ADD_> AP	MARSAM	10MG/ML	N74017 001
>_ADD_>			JUN 30, 1994

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE

>_DLT_>/AP/	/ORGANON/	/10MG/ML/	/N70017/001/
>_DLT_>			/DEC/15,/1986/
>_ADD_>	@ ORGANON	10MG/ML	N70017 001
>_ADD_>			DEC 15, 1986

GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION
GALLIUM CITRATE GA 67

BS	DUPONT	2MCI/ML	N17478 001
/BS/	/DUPONT/MERCK/	/2MCI/ML/	/N17478/001/

GENTAMICIN SULFATE

CREAM; TOPICAL
GARAMYCIN

/AT//+//SCHERING/		/EQ 1MG BASE/GM/	/N60462/001/
AT + SCHERING		EQ 0.1% BASE	N60462 001
>_DLT_>	/GENTAFAIR/		
>_DLT_>/AT/	/PHARMAFAIR/	/EQ 0.1% BASE/	/N62458/001/
>_DLT_>			/SEP/01,/1983/
>_ADD_>	@ PHARMAFAIR	EQ 0.1% BASE	N62458 001
>_ADD_>			SEP 01, 1983
	GENTAMICIN		
/AT/	/CLAY/PARK/	/EQ 1MG BASE/GM/	/N62307/001/
AT	CLAY PARK	EQ 0.1% BASE	N62307 001
	GENTAMICIN SULFATE		
AT	BAUSCH AND LOMB	EQ 0.1% BASE	N64056 001
			APR 29, 1994
/AT/	/FOUGERA/	/EQ 1MG BASE/GM/	/N62531/001/
			/JUL/05,/1984/
AT	FOUGERA	EQ 0.1% BASE	N62531 001
			JUL 05, 1984
/AT/	/NMC/	/EQ 1MG BASE/GM/	/N62471/001/
			/SEP/27,/1983/
AT	NMC	EQ 0.1% BASE	N62471 001
			SEP 27, 1983
/AT/	/THAMES/	/EQ 1MG BASE/GM/	/N62427/001/
			/MAY/26,/1983/
AT	THAMES	EQ 0.1% BASE	N62427 001
			MAY 26, 1983

INJECTABLE; INJECTION
GARAMYCIN

>_DLT_>	/GARAMYCIN/		
>_DLT_>/AP//+//SCHERING/		/EQ 2MG BASE/ML/	/N50505/001/

GENTAMICIN SULFATE

>_ADD_> INJECTABLE; INTRATHECAL
>_ADD_> GARAMYCIN
>_ADD_> + SCHERING — EQ 2MG BASE/ML — N50505 001

OINTMENT; OPHTHALMIC

GARAMYCIN

/AT//+//SCHERING/	/EQ 3MG BASE/GM/	/N50425/001/
AT + SCHERING	EQ 0.3% BASE	N50425 001

GENTACIDIN

/AT/	/IOLAB/	/EQ 3MG BASE/GM/	/N62501/001/ /JUL/26,/1984/
AT	IOLAB	EQ 0.3% BASE	N62501 001 JUL 26, 1984

OINTMENT; TOPICAL

GARAMYCIN

/AT//+//SCHERING/	/EQ 1MG BASE/GM/	/N60463/001/
AT + SCHERING	EQ 0.1% BASE	N60463 001

>_DLT_> /GENTAFAIR/
>_DLT_>/AT/ /PHARMAFAIR/ — /EQ 0.1% BASE/ — /N62444/001/ /MAY/26,/1983/
>_DLT_>

>_ADD_> @ PHARMAFAIR — EQ 0.1% BASE — N62444 001 MAY 26, 1983
>_ADD_>

GENTAMICIN

/AT/	/CLAY/PARK/	/EQ 1MG BASE/GM/	/N62351/001/ /FEB/18,/1982/
AT	CLAY PARK	EQ 0.1% BASE	N62351 001 FEB 18, 1982

GENTAMICIN SULFATE

AT	BAUSCH AND LOMB	EQ 0.1% BASE	N64054 001 APR 29, 1994
/AT/	/FOUGERA/	/EQ 1MG BASE/GM/	/N62533/001/ /OCT/05,/1984/
AT	FOUGERA	EQ 0.1% BASE	N62533 001 OCT 05, 1984
/AT/	/NMC/	/EQ 1MG BASE/GM/	/N62496/001/ /MAR/14,/1984/
AT	NMC	EQ 0.1% BASE	N62496 001 MAR 14, 1984
/AT/	/PHARMADERM/	/EQ 1MG BASE/GM/	/N62534/001/ /OCT/10,/1984/
AT	PHARMADERM	EQ 0.1% BASE	N62534 001 OCT 10, 1984
/AT/	/THAMES/	/EQ 1MG BASE/GM/	/N62477/001/ /DEC/23,/1983/
AT	THAMES	EQ 0.1% BASE	N62477 001 DEC 23, 1983

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

GARAMYCIN

/AT//+//SCHERING/	/EQ 3MG BASE/ML/	/N50039/002/
AT + SCHERING	EQ 0.3% BASE	N50039 002

GENOPTIC

/AT/	/ALLERGAN/	/EQ 3MG BASE/ML/	/N62452/001/ /OCT/10,/1984/
AT	ALLERGAN	EQ 0.3% BASE	N62452 001 OCT 10, 1984

GENTACIDIN

/AT/	/IOLAB/	/EQ 3MG BASE/ML/	/N62480/001/ /MAR/30,/1984/
AT	IOLAB	EQ 0.3% BASE	N62480 001 MAR 30, 1984

GENTAFAIR

/AT/	/PHARMAFAIR/	/EQ 3MG BASE/ML/	/N62440/001/ /MAY/03,/1983/
AT	PHARMAFAIR	EQ 0.3% BASE	N62440 001 MAY 03, 1983

GENTAMICIN SULFATE

/AT/	/AKORN/	/EQ 3MG BASE/ML/	/N62635/001/ /JAN/08,/1987/
AT	AKORN	EQ 0.3% BASE	N62635 001 JAN 08, 1987
AT	BAUSCH AND LOMB	EQ 0.3% BASE	N64048 001 MAY 11, 1994
/AT/	/STERIS/	/EQ 3MG BASE/ML/	/N62523/001/ /NOV/25,/1985/
AT	STERIS	EQ 0.3% BASE	N62523 001 NOV 25, 1985

GLIPIZIDE

TABLET; ORAL

GLIPIZIDE

AB	MYLAN	5MG	N74226 001 MAY 10, 1994
AB		10MG	N74226 002 MAY 10, 1994

GLUCOTROL

AB	PFIZER	5MG	N17783 001 MAY 08, 1984
AB +		10MG	N17783 002 MAY 08, 1984

GLIPIZIDE

TABLET, EXTENDED RELEASE; ORAL
GLUCOTROL XL

	+ PFIZER	5MG	N20329 001	
			APR 26, 1994	
	+	10MG	N20329 002	
			APR 26, 1994	

GLUTETHIMIDE

TABLET; ORAL
GLUTETHIMIDE

>DLT >	/AA/	/HALSEY/	/250MG/	/N89458/001/	
>DLT >				/OCT/10,/1986/	
>ADD >		HALSEY	250MG	N89458 001	
>ADD >				OCT 10, 1986	
>DLT >	/AA/	/LANNETT/	/250MG/	/N83475/001/	
>DLT >	/AA/		/500MG/	/N85571/001/	
>ADD >		@ LANNETT	250MG	N83475 001	
>ADD >		@	500MG	N85571 001	

GLYCOPYRROLATE

INJECTABLE; INJECTION
GLYCOPYRROLATE

/AP/	/FUJISAWA/	/0.2MG/ML/	/N88475/001/	
			/JUN/12,/1984/	
	@ FUJISAWA	0.2MG/ML	N88475 001	
			JUN 12, 1984	

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION
CHORIONIC GONADOTROPIN

>DLT >	/AP/	/FUJISAWA/	/5,000 UNITS/VIAL/	/N17067/001/
>DLT >	/AP/		/20,000 UNITS/VIAL/	/N17067/003/
>ADD >		@ FUJISAWA	5,000 UNITS/VIAL	N17067 001
>ADD >		@	20,000 UNITS/VIAL	N17067 003

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC
>DLT > **/NEOMYCIN SULFATE AND POLYMYXIN B SULFATE GRAMICIDIN/**

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

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC
>DLT > **/NEOMYCIN SULFATE AND POLYMYXIN B SULFATE GRAMICIDIN/**

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

GUANABENZ ACETATE

TABLET; ORAL
GUANABENZ ACETATE

>ADD >	AB	COPLEY PHARM	EQ 4MG BASE	N74267 001
>ADD >				JUN 01, 1994
>ADD >	AB		EQ 8MG BASE	N74267 002
>ADD >				JUN 01, 1994
	AB	WATSON LABS	EQ 4MG BASE	N74025 001
				FEB 28, 1994
	AB		EQ 8MG BASE	N74025 002
				FEB 28, 1994
		WYTENSIN		
	AB	WYETH AYERST	EQ 4MG BASE	N18587 001
				SEP 07, 1982
	AB +		EQ 8MG BASE	N18587 002
				SEP 07, 1982

HEPARIN CALCIUM

INJECTABLE; INJECTION
CALCIPARINE

	+ CHOAY	25,000 UNITS/ML	N18237 001
	/+//DUPONT/	/25,000/UNITS/ML/	/N18237/001/

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

>DLT >	/BP/	/DANBURY/PHARMA/	/25MG;15MG;0.1MG/	/N87556/001/
>ADD >		@ DANBURY PHARMA	25MG;15MG;0.1MG	N87556 001

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

	/AB/	/ZENITH/	/50MG/	/N84658/001/
		@ ZENITH	50MG	N84658 001

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
HYDROCHLOROTHIAZIDE W/ RESERPINE

/BP/	/ROXANE/	/50MG;0.125MG/	/N84603/001/
	@ ROXANE	50MG;0.125MG	N84603 001

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL
DYAZIDE

/**AB**/	/+/SMITHKLINE/BEECHAM/	/**25MG**;**50MG**/	/N16042/002/
	SMITHKLINE BEECHAM	25MG;37.5MG	N16042 003 MAR 03, 1994
	@	25MG;50MG	N16042 002

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

/**AB**/	/GENEVA/PHARMS/	/**25MG**;**50MG**/	/N73191/001/ /JUL/31,/1991/
	+ GENEVA PHARMS	25MG;50MG	N73191 001 JUL 31, 1991

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

>_DLT_>/**AT**/	/LEMMON/	/**1%**/		/N85191/001/
>_ADD_>	@ LEMMON	1%		N85191 001

ENEMA; RECTAL
CORTENEMA

AT	+ SOLVAY	**100MG/60ML**	**N16199 001**

HYDROCORTISONE

AT	COPLEY	**100MG/60ML**	**N74171 001** MAY 27, 1994

GEL; TOPICAL
/NUTRACORT/

/**AT**/	/+/GALDERMA/	/**1%**/	/N84698/001/
	@ GALDERMA	1%	N84698 001

PENECORT

/**AT**/	/ALLERGAN/HERBERT/	/**1%**/	/N88215/001/ /JUN/06,/1984/
	+ ALLERGAN HERBERT	1%	N88215 001 JUN 06, 1984

HYDROCORTISONE

LOTION; TOPICAL
HYDROCORTISONE

/**AI**/	/CLAY/PARK/	/**1%**/	/N85663/001/
	@ CLAY PARK	1%	N85663 001

OINTMENT; TOPICAL
HYDROCORTISONE

/**AI**/	/CLAY/PARK/	/**1%**/	/N85028/001/
	@ CLAY PARK	1%	N85028 001

TABLET; ORAL
HYDROCORTISONE

>_DLT_> /BP/	/DANBURY/PHARMA/	/20MG/		/N80355/001/
>_ADD_>	@ DANBURY PHARMA	20MG		N80355 001

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC
>_DLT_> **/NEOMYCIN SULFATE-POLYMYXIN B SULFATE-HYDROCORTISONE/**

>_DLT_>/**AI**/	/PHARMAFAIR/	/**1%**;**EQ 3.5MG BASE/ML**;/		
>_DLT_>		/**10,000 UNITS/ML**/		/N62394/001/
>_DLT_>				/SEP/29,/1982/
>_ADD_>	@ PHARMAFAIR	1%;EQ 3.5MG BASE/ML;		
>_ADD_>		10,000 UNITS/ML		N62394 001
>_ADD_>				SEP 29, 1982

SUSPENSION; OTIC
>_DLT_> **/OTICAIR/**

>_DLT_>/**AI**/	/PHARMAFAIR/	/**1%**;**EQ 3.5MG BASE/ML**;/		
>_DLT_>		/**10,000 UNITS/ML**/		/N62399/001/
>_DLT_>				/NOV/18,/1982/
>_ADD_>	@ PHARMAFAIR	1%;EQ 3.5MG BASE/ML;		
>_ADD_>		10,000 UNITS/ML		N62399 001
>_ADD_>				NOV 18, 1982

HYDROCORTISONE ACETATE

CREAM; TOPICAL
HYDROCORTISONE ACETATE

/**AI**/	/PARKE/DAVIS/	/**1%**/	/N89914/001/ /JAN/03,/1989/
	@ PARKE DAVIS	1%	N89914 001 JAN 03, 1989

HYDROCORTISONE ACETATE

INJECTABLE; INJECTION
HYDROCORTISONE ACETATE

/BP/	/STERIS/	/50MG/ML/	/N85214/001/
	@ STERIS	50MG/ML	N85214 001

HYDROCORTISONE BUTYRATE

CREAM; TOPICAL
LOCOID

>_DLT_>	/+//BROCADES/PHARMA/	/0.1%/	/N18514/001/
>_DLT_>			/MAR/31,/1982/
>_ADD_>	+ YAMANOUCHI	0.1%	N18514 001
>_ADD_>			MAR 31, 1982

OINTMENT; TOPICAL
LOCOID

>_DLT_>	/@/BROCADES/PHARMA/	/0.1%/	/N18652/001/
>_DLT_>			/OCT/29,/1982/
>_ADD_>	@ YAMANOUCHI	0.1%	N18652 001
>_ADD_>			OCT 29, 1982

SOLUTION; TOPICAL
LOCOID

>_DLT_>	/+//BROCADES/PHARMA/	/0.1%/	/N19116/001/
>_DLT_>			/FEB/25,/1987/
>_ADD_>	+ YAMANOUCHI	0.1%	N19116 001
>_ADD_>			FEB 25, 1987

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-HYDROCORT

/AP/	/ABBOTT/	/EQ 250MG BASE/VIAL/	/N89578/001/
			/APR/11,/1989/
/AP/		/EQ 500MG BASE/VIAL/	/N89579/001/
			/APR/11,/1989/
/AP/		/EQ 1GM BASE/VIAL/	/N89580/001/
			/APR/11,/1989/
	@ ABBOTT	EQ 250MG BASE/VIAL	N89578 001
			APR 11, 1989
	@	EQ 500MG BASE/VIAL	N89579 001
			APR 11, 1989
	@	EQ 1GM BASE/VIAL	N89580 001
			APR 11, 1989

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION
/**DELALUTIN**/

/AO/	/+//SQUIBB/	/125MG/ML/	/N10347/004/
/AO/		/125MG/ML/	/N16911/001/
/AO/	/+/	/250MG/ML/	/N10347/002/
/AO/		/250MG/ML/	/N16911/002/
	@ SQUIBB	125MG/ML	N10347 004
	@	125MG/ML	N16911 001
	@	250MG/ML	N10347 002
	@	250MG/ML	N16911 002

HYDROXYPROGESTERONE CAPROATE

/AO/	/STERIS/	/125MG/ML/	/N17439/001/
AO	+ STERIS	125MG/ML	**N17439 001**
/AO/		/250MG/ML/	/N17439/002/
	+	250MG/ML	N17439 002

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL

>_DLT_>/AP/	/SMITH/NEPHEW/SOLOPAK/	/25MG/ML/	/N87591/001/
>_DLT_>/AP/		/50MG/ML/	/N87593/001/
>_DLT_>/AP/		/50MG/ML/	/N87595/001/
>_ADD_> AP	SOLOPAK	25MG/ML	**N87591 001**
>_ADD_> AP		50MG/ML	**N87593 001**
>_ADD_> AP		50MG/ML	**N87595 001**
>_DLT_>	/ORGATRAX/		
>_DLT_>/AP/	/ORGANON/	/25MG/ML/	/N87014/001/
>_DLT_>/AP/		/50MG/ML/	/N87014/002/
>_ADD_>	@ ORGANON	25MG/ML	N87014 001
>_ADD_>	@	50MG/ML	N87014 002

TABLET; ORAL
HYDROXYZINE HCL

AB	ROYCE	10MG	**N81149 001**
			MAR 18, 1994
AB		25MG	**N81150 001**
			MAR 18, 1994
AB		50MG	**N81151 001**
			MAR 18, 1994

IMIGLUCERASE

INJECTABLE; INJECTION
CEREZYME

	+ GENZYME	200 UNITS/VIAL	N20367 001
			MAY 23, 1994

>ADD> INDIUM IN-111 PENTETREOTIDE KIT

>ADD> INJECTABLE; INJECTION
>ADD> OCTREOSCAN
>ADD> MALLINCKRODT 3MCI/ML/ N20314 001
>ADD> JUN 02, 1994

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN
>DLT>/AB/ /CHELSEA/LABS/ /25MG/ /N18690/001/
>DLT> /JUL/31,/1984/
>DLT>/AB/ /50MG/ /N18690/002/
>DLT> /JUL/31,/1984/
>ADD> @ CHELSEA LABS 25MG N18690 001
>ADD> JUL 31, 1984
>ADD> @ 50MG N18690 002
>ADD> JUL 31, 1984

INSULIN BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
HUMULIN R
+ LILLY 500 UNITS/ML N18780 004
MAR 31, 1994

INVERT SUGAR

>DLT> /INJECTABLE;/INJECTION/
>DLT> /TRAVERT/10%/IN/PLASTIC/CONTAINER/
>DLT> /BAXTER/ /10GM/100ML/ /N16717/001/
>ADD> @ BAXTER 10GM/100ML N16717 001

IOBENGUANE SULFATE I 131

INJECTABLE; INJECTION
IOBENGUANE SULFATE I 131
CIS 2.3MCI/ML N20084 001
MAR 25, 1994

IODOHIPPURATE SODIUM, I-123

/INJECTABLE;/INJECTION/
/NEPHROFLOW/
/MEDI/PHYSICS/ /1MCI/ML/ /N18289/001/
/DEC/28,/1984/

IODOHIPPURATE SODIUM, I-123

/INJECTABLE;/INJECTION/
/NEPHROFLOW/
@ MEDI PHYSICS 1MCI/ML N18289 001
DEC 28, 1984

ISONIAZID; PYRAZINAMIDE; RIFAMPIN

TABLET; ORAL
RIFATER
+ MARION MERRELL DOW 50MG;300MG;120MG N50705 001
MAY 31, 1994

ISOPROTERENOL HYDROCHLORIDE

AEROSOL, METERED; INHALATION
ISUPREL
>DLT> /+//STERLING/WINTHROP/ /0.113MG/INH/ /N11178/001/
>ADD> + STERLING WINTHROP 0.131MG/INH N11178 001

ISRADIPINE

CAPSULE; ORAL
DYNACIRC
>ADD> + SANDOZ 5MG N19546 002
>ADD> DEC 20, 1990
>DLT> /5MG/ /N19546/002/
>DLT> /DEC/20,/1990/

>ADD> TABLET, EXTENDED RELEASE; ORAL
>ADD> DYNACIRC CR
>ADD> + SANDOZ 5MG N20336 001
>ADD> JUN 01, 1994
>ADD> + 10MG N20336 002
>ADD> JUN 01, 1994

KANAMYCIN SULFATE

CAPSULE; ORAL
KANTREX
/+//APOTHECON/ /EQ/500MG/BASE/ /N61911/001/
+ APOTHECON EQ 500MG BASE N62726 001
MAR 06, 1987
@ EQ 500MG BASE N60516 001
@ EQ 500MG BASE N61911 001
/EQ/500MG/BASE/ /N62726/001/
/MAR/06,/1987/

KANAMYCIN SULFATE

CAPSULE; ORAL
KANTREX
/AB//+//BRISTOL/ /EQ 500MG BASE/ /N60516/001/

INJECTABLE; INJECTION
KANTREX
/AP//+//APOTHECON/ /EQ 75MG BASE/2ML/ /N61655/003/
/AP/ /EQ 75MG BASE/2ML/ /N61901/003/
AP + APOTHECON EQ 75MG BASE/2ML N61901 003
/AP//+/ /EQ 500MG BASE/2ML/ /N61655/001/
/AP/ /EQ 500MG BASE/2ML/ /N61901/001/
AP + EQ 500MG BASE/2ML N61901 001
/AP//+/ /EQ 1GM BASE/3ML/ /N61655/002/
/AP/ /EQ 1GM BASE/3ML/ /N61901/002/
AP + EQ 1GM BASE/3ML N61901 002
@ EQ 75MG BASE/2ML N61655 003
@ EQ 75MG BASE/2ML N62564 001
SEP 21, 1984
@ EQ 500MG BASE/2ML N61655 001
@ EQ 500MG BASE/2ML N62564 002
SEP 21, 1984
@ EQ 1GM BASE/3ML N61655 002
@ EQ 1GM BASE/3ML N62564 003
SEP 21, 1984
/AP/ /BRISTOL/ /EQ 75MG BASE/2ML/ /N62564/001/
/SEP/21,/1984/
/AP/ /EQ 500MG BASE/2ML/ /N62564/002/
/SEP/21,/1984/
/AP/ /EQ 1GM BASE/3ML/ /N62564/003/
/SEP/21,/1984/

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM
>ADD> AP ELKINS SINN EQ 100MG BASE/VIAL N81224 001
>ADD> JUN 03, 1994
/+//IMMUNEX/ /EQ/3MG/BASE/ML/ /N08107/001/
@ IMMUNEX EQ 3MG BASE/ML N08107 001

LEVOBUNOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
BETAGAN
AT + ALLERGAN 0.25% N19814 001
JUN 28, 1989
AT + 0.5% N19219 002
DEC 19, 1985
LEVOBUNOLOL HCL
AT BAUSCH AND LOMB 0.25% N74307 001
MAR 04, 1994
AT 0.5% N74326 001
MAR 04, 1994

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
/ARESTOCAINE HCL W/ LEVONORDEFRIN/
/AP/ /CARLISLE/ /0.05MG/ML;2%/ /N85010/001/
@ SOLVAY 0.05MG/ML;2% N85010 001

LIDOCAINE HYDROCHLORIDE

SOLUTION; TOPICAL
MYLOCAINE
AT PENNEX PHARMS 4% N87881 001
NOV 18, 1982
/@/ /4%/ /N87881/001/
/NOV/18,/1982/
PEDIATRIC LTA KIT
/AT/ /ABBOTT/ /2%/ /N88572/001/
/JUL/31,/1984/
@ ABBOTT 2% N88572 001
JUL 31, 1984

LISINOPRIL

TABLET; ORAL
PRINIVIL
>ADD> AB MERCK 2.5MG N19558 006
>ADD> JAN 28, 1994
ZESTRIL
>ADD> AB ZENECA 2.5MG N19777 005
>ADD> APR 29, 1993

LITHIUM CARBONATE

TABLET, EXTENDED RELEASE; ORAL

	/LITHOBID/			
/+//CIBA/		/300MG/	/N18027/001/	N20309 001
@ CIBA		300MG	N18027 001	JUN 24, 1994

LORAZEPAM

INJECTABLE; INJECTION

	ATIVAN			
AP +	WYETH AYERST	**2MG/ML**	**N18140 001**	
AP +		**4MG/ML**	**N18140 002**	
	LORAZEPAM			
AP	ABBOTT	**2MG/ML**	**N74280 001**	
			MAY 27, 1994	
AP		**2MG/ML**	**N74282 001**	
			MAY 27, 1994	
AP		**4MG/ML**	**N74280 002**	
			MAY 27, 1994	
AP		**4MG/ML**	**N74282 002**	
			MAY 27, 1994	
AP	STERIS	**2MG/ML**	**N74276 001**	
			APR 15, 1994	
AP		**4MG/ML**	**N74276 002**	
			APR 15, 1994	
AP	STERLING WINTHROP	**2MG/ML**	**N74243 001**	
			APR 12, 1994	
AP		**2MG/ML**	**N74300 001**	
			APR 12, 1994	
AP		**4MG/ML**	**N74243 002**	
			APR 12, 1994	

TABLET; ORAL

	LORAZEPAM			
>_DLT_>/**AB**/	/WARNER/CHILCOTT/	**/1MG/**		
>_DLT_>			/N71038/001/	
>_DLT_>/**AB**/		**/2MG/**	/JAN/12,/1988/	
>_DLT_>			/N71039/001/	
>_ADD_>	@ WARNER CHILCOTT	1MG	/JAN/12,/1988/	
>_ADD_>			N71038 001	
>_ADD_>	@	2MG	JAN 12, 1988	
>_ADD_>			N71039 001	
			JAN 12, 1988	

MAGNESIUM SULFATE

INJECTABLE; INJECTION

>_ADD_>	MAGNESIUM SULFATE IN PLASTIC CONTAINER			
>_ADD_>	ABBOTT	4GM/100ML		N20309 001
>_ADD_>				JUN 24, 1994
>_ADD_>		80MG/ML		N20309 002
>_ADD_>				JUN 24, 1994

MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

	/ARESTOCAINE HCL/			
/AP/	/CARLISLE/	**/3%/**		/N84777/002/
				/APR/18,/1982/
	@ SOLVAY	3%		N84777 002
				APR 18, 1982

MEPROBAMATE

TABLET; ORAL

>_DLT_>	**/MEPRIAM/**			
>_DLT_>/**AA**/	/LEMMON/	**/400MG/**		/N16069/001/
>_ADD_>	@ LEMMON	400MG		N16069 001

METARAMINOL BITARTRATE

INJECTABLE; INJECTION

	METARAMINOL BITARTRATE			
>_DLT_>/**AP**/	/FUJISAWA/	**/EQ 10MG BASE/ML/**		/N80431/001/
>_ADD_>	@ FUJISAWA	EQ 10MG BASE/ML		N80431 001

METHAZOLAMIDE

TABLET; ORAL

	METHAZOLAMIDE			
AB	MIKART	**25MG**		**N40062 001**
				JAN 27, 1994
AB		**50MG**		**N40062 002**
				JAN 27, 1994

METHOTREXATE SODIUM

INJECTABLE; INJECTION
FOLEX PFS

/**AP**/	/ADRIA/	/**EQ 25MG BASE/ML**/	/N89180/001/ /JAN/03,/1986/
	@ ADRIA	EQ 25MG BASE/ML	N89180 001 JAN 03, 1986

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-METHAPRED

>DLT >/**AP**/	/ABBOTT/	/**EQ 40MG BASE/VIAL**/	/N89573/001/ /FEB/22,/1991/
>DLT >/**AP**/		/**EQ 125MG BASE/VIAL**/	/N89574/001/ /FEB/22,/1991/
>DLT >/**AP**/		/**EQ 500MG BASE/VIAL**/	/N89575/001/ /FEB/22,/1991/
>ADD >	@ ABBOTT	EQ 40MG BASE/VIAL	N89573 001 FEB 22, 1991
>ADD >	@	EQ 125MG BASE/VIAL	N89574 001 FEB 22, 1991
>ADD >	@	EQ 500MG BASE/VIAL	N89575 001 FEB 22, 1991
>DLT >	/**METHYLPREDNISOLONE**/		
>DLT >/**AP**/	/ORGANON/	/**EQ 500MG BASE/VIAL**/	/N87535/001/ /JUN/25,/1982/
>DLT >/**AP**/		/**EQ 1GM BASE/VIAL**/	/N87535/002/ /JUN/25,/1982/
>ADD >	@ ORGANON	EQ 500MG BASE/VIAL	N87535 001 JUN 25, 1982
>ADD >	@	EQ 1GM BASE/VIAL	N87535 002 JUN 25, 1982

METHYLTESTOSTERONE

TABLET; BUCCAL/SUBLINGUAL
METHYLTESTOSTERONE

	/PRIVATE/FORM/	/5MG/	/N83836/001/
	@ PRIVATE FORM	5MG	N83836 001
/BP/	/TABLICAPS/	/10MG/	/N85125/001/
	@ TABLICAPS	10MG	N85125 001

TABLET; ORAL
METHYLTESTOSTERONE

/BP/	/PUREPAC/	/10MG/	/N80475/002/
/BP/		/25MG/	/N80475/003/
	@ PUREPAC	10MG	N80475 002
	@	25MG	N80475 003

METHYLTESTOSTERONE

TABLET; ORAL
METHYLTESTOSTERONE

/BP/	/TABLICAPS/	/10MG/	/N80313/001/
/BP/		/25MG/	/N85270/001/
	@ TABLICAPS	10MG	N80313 001
	@	25MG	N85270 001
/BP/	/WEST/WARD/	/10MG/	/N84331/001/
/BP/		/25MG/	/N84331/002/
	@ WEST WARD	10MG	N84331 001
	@	25MG	N84331 002

METOPROLOL TARTRATE

TABLET; ORAL
METOPROLOL TARTRATE

AB	APOTHECON	50MG	N74258 001 JAN 27, 1994
AB		100MG	N74258 002 JAN 27, 1994
AB	COPLEY	50MG	N74333 001 JAN 27, 1994
AB		100MG	N74333 002 JAN 27, 1994
AB	GENEVA PHARMS	50MG	N73288 001 MAR 25, 1994
AB		100MG	N73289 001 MAR 25, 1994
AB	WATSON LABS	50MG	N74217 001 MAY 27, 1994
AB		100MG	N74217 002 MAY 27, 1994

MINOCYCLINE HYDROCHLORIDE

TABLET; ORAL
/MINOCIN/

	/@/LEDERLE/	/EQ/50MG/BASE/	/N50451/003/ /AUG/10,/1982/
	/@/	/EQ/100MG/BASE/	/N50451/002/ /AUG/10,/1982/
	MINOCYCLINE HCL LEDERLE	EQ 50MG BASE	N50451 003 AUG 10, 1982
		EQ 100MG BASE	N50451 002 AUG 10, 1982

NAFCILLIN SODIUM

INJECTABLE; INJECTION

	NAFCIL			
AP	APOTHECON	**EQ 500MG BASE/VIAL**	**N61984 001**	
AP		**EQ 1GM BASE/VIAL**	**N61984 002**	
AP		**EQ 2GM BASE/VIAL**	**N61984 003**	
AP		**EQ 4GM BASE/VIAL**	**N61984 005**	
/AP/	/BRISTOL/	**/EQ 500MG BASE/VIAL/**	/N61984/001/	
/AP/		**/EQ 1GM BASE/VIAL/**	/N61984/002/	
/AP/		**/EQ 2GM BASE/VIAL/**	/N61984/003/	
/AP/		**/EQ 4GM BASE/VIAL/**	/N61984/005/	
	UNIPEN			
AP	WYETH AYERST	**EQ 10GM BASE/VIAL**	**N50320 005**	
	@	EQ 20GM BASE/VIAL	N50320 006	

NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

>_DLT_>	**/NAFAZAIR/**			
>_DLT_>**/AT/**	/PHARMAFAIR/	**/0.1%/**	/N88101/001/	
>_DLT_>			/APR/15,/1983/	
	NAFAZAIR			
AT	BAUSCH AND LOMB	**0.1%**	**N40073 001**	
>_ADD_>	@ PHARMAFAIR	0.1%	MAY 25, 1994	
>_ADD_>			N88101 001	
			APR 15, 1983	

NAPROXEN

SUSPENSION; ORAL

	NAPROSYN			
AB +	SYNTEX	**25MG/ML**	**N18965 001**	
			MAR 23, 1987	
	NAPROXEN			
AB	ROXANE	**25MG/ML**	**N74190 001**	
			MAR 30, 1994	

TABLET; ORAL

	NAPROSYN			
>_DLT_>**/AB/**	/SYNTEX/	**/500MG/**	/N17581/004/	
>_DLT_>			/APR/15,/1982/	
>_ADD_> **AB** +	SYNTEX	**500MG**	**N17581 004**	
>_ADD_>			APR 15, 1982	

NAPROXEN

TABLET; ORAL

	NAPROXEN			
AB	ROXANE	**250MG**	**N74211 001**	
			FEB 28, 1994	
AB		**375MG**	**N74211 002**	
			FEB 28, 1994	
AB		**500MG**	**N74211 003**	
			FEB 28, 1994	

NAPROXEN SODIUM

TABLET; ORAL

	NAPROXEN SODIUM			
AB	COPLEY	**EQ 250MG BASE**	**N74289 001**	
			JAN 27, 1994	
AB		**EQ 500MG BASE**	**N74289 002**	
			JAN 27, 1994	

NEOMYCIN SULFATE

TABLET; ORAL

	NEOMYCIN SULFATE			
>_DLT_>**/AA/**	/LANNETT/	**/EQ 350MG BASE/**	/N60607/001/	
>_ADD_>	@ LANNETT	EQ 350MG BASE	N60607 001	

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL

	HABITROL			
/BC/	/BASEL/PHARMS/	/7MG/24HR/	/N20076/001/	
BC +	BASEL PHARMS	7MG/24HR	/NOV/27,/1991/	
			N20076 001	
/BC/		/14MG/24HR/	NOV 27, 1991	
			/N20076/002/	
BC +		14MG/24HR	/NOV/27,/1991/	
			N20076 002	
/BC/		/21MG/24HR/	NOV 27, 1991	
			/N20076/003/	
BC +		21MG/24HR	/NOV/27,/1991/	
			N20076 003	
			NOV 27, 1991	

NITROFURANTOIN

TABLET; ORAL

>_DLT_>	/FURALAN/			
>_DLT_>/AB/	/LANNETT/	/50MG/	/N80017/001/	
>_DLT_>/AB/		/100MG/	/N80017/002/	
>_ADD_>	@ LANNETT	50MG	N80017 001	
>_ADD_>	@	100MG	N80017 002	

NITROFURAZONE

OINTMENT; TOPICAL
NITROFURAZONE

>_DLT_>/AI/	/LANNETT/	/0.2%/	/N84393/001/	
>_ADD_>	@ LANNETT	0.2%	N84393 001	

NITROGLYCERIN

INJECTABLE; INJECTION
NITROGLYCERIN

>_DLT_>/AP/	/INTL/MEDICATION/	/5MG/ML/	/N70026/001/	
>_DLT_>			/SEP/10,/1985/	
>_ADD_>	@ INTL MEDICATION	5MG/ML	N70026 001	
>_ADD_>			SEP 10, 1985	
	/NITRONAL/			
	/+//BOSKAMP/	/1MG/ML/	/N18672/001/	
			/AUG/30,/1983/	
	@ G POHL BOSKAMP	1MG/ML	N18672 001	
			AUG 30, 1983	

NITROSTAT

/AP/	/PARKE/DAVIS/	/5MG/ML/	/N70863/001/	
			/JAN/08,/1987/	
	@ PARKE DAVIS	5MG/ML	N70863 001	
			JAN 08, 1987	
		/10MG/ML/	/N70871/001/	
			/JAN/08,/1987/	
	@	10MG/ML	N70871 001	
			JAN 08, 1987	
		/10MG/ML/	/N70872/001/	
			/JAN/08,/1987/	
	@	10MG/ML	N70872 001	
			JAN 08, 1987	

NORETHINDRONE

TABLET; ORAL
/NORLUTIN/

/+//PARKE/DAVIS/	/5MG/	/N10895/002/	
@ PARKE DAVIS	5MG	N10895 002	

NYSTATIN

SUSPENSION; ORAL
NYSTATIN

	AA	BAUSCH AND LOMB	100,000 UNITS/ML	N64042 001
				FEB 28, 1994
>_DLT_>/AA/	/PHARMAFAIR/	/100,000 UNITS/ML/		/N62541/001/
>_DLT_>				/JAN/16,/1985/
>_ADD_>	@ PHARMAFAIR	100,000 UNITS/ML		N62541 001
>_ADD_>				JAN 16, 1985

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
MYCOLOG-II

>_ADD_> AT	+ APOTHECON	100,000 UNITS/GM;0.1%		N60576 002
>_ADD_>				MAY 01, 1985
>_ADD_> AT		100,000 UNITS/GM;0.1%		N62606 001
>_ADD_>				MAY 15, 1985
>_DLT_>/AI//+//SQUIBB/		/100,000 UNITS/GM;0.1%/		/N60576/002/
>_DLT_>				/MAY/01,/1985/
>_DLT_>/AI/		/100,000 UNITS/GM;0.1%/		/N62606/001/
>_DLT_>				/MAY/15,/1985/

NYSTATIN AND TRIAMCINOLONE ACETONIDE

>_DLT_>/AI/	/BARRE/	/100,000 UNITS/GM;0.1%/		/N63010/001/
>_DLT_>				/DEC/20,/1988/
>_ADD_>	@ BARRE	100,000 UNITS/GM;0.1%		N63010 001
>_ADD_>				DEC 20, 1988
>_DLT_> /B*/	/CLAY/PARK/	/100,000/UNITS/GM;0.1%/		/N62186/002/
>_DLT_>				/JUN/06,/1985/
>_ADD_>	@ CLAY PARK	100,000 UNITS/GM;0.1%		N62186 002
>_ADD_>				JUN 06, 1985
/AI/	/PHARMAFAIR/	/100,000 UNITS/GM;0.1%/		/N62657/001/
				/JUL/30,/1986/
	@ PHARMAFAIR	100,000 UNITS/GM;0.1%		N62657 001
				JUL 30, 1986

OINTMENT; TOPICAL
NYSTATIN-TRIAMCINOLONE ACETONIDE

/AI/	/PHARMADERM/	/100,000 UNITS/GM;0.1%/		/N62603/001/
				/OCT/09,/1985/
	@ PHARMADERM	100,000 UNITS/GM;0.1%		N62603 001
				OCT 09, 1985

ORPHENADRINE HYDROCHLORIDE

/TABLET;/ORAL/
/DISIPAL/

/3M/	/50MG/	/N10653/001/	
@ 3M	50MG	N10653 001	

PAROXETINE HYDROCHLORIDE

TABLET; ORAL
PAXIL
+ SMITHKLINE BEECHAM — EQ 30MG BASE — /EQ/30MG/BASE/ — N20031 003 — DEC 29, 1992 — /N20031/003/ — /DEC/29,/1992/

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION
PENICILLIN G POTASSIUM

	@ APOTHECON	1,000,000 UNITS/VIAL	N60362 001	
	@	5,000,000 UNITS/VIAL	N60362 003	
	@	10,000,000 UNITS/VIAL	N60362 004	
	@	20,000,000 UNITS/VIAL	N60362 002	
/AP/	/SQUIBB/	/1,000,000 UNITS/VIAL/	/N60362/001/	
/AP/		/5,000,000 UNITS/VIAL/	/N60362/003/	
/AP/		/10,000,000 UNITS/VIAL/	/N60362/004/	
/AP/		/20,000,000 UNITS/VIAL/	/N60362/002/	

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION
PENTACARINAT
AP — RHONE POULENC RORER — 300MG/VIAL — N73447 001 — APR 28, 1994

PENTOBARBITAL SODIUM

CAPSULE; ORAL
>_DLT_> /**PENTOBARBITAL SODIUM**/

>_DLT_>/AA/	/LANNETT/	/50MG/	/N85937/001/	
>_DLT_>/AA/		/100MG/	/N85915/001/	
>_ADD_>	@ LANNETT	50MG	N85937 001	
>_ADD_>	@	100MG	N85915 001	

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
PHENDIMETRAZINE TARTRATE

/AA/	/ZENITH/	/35MG/	/N85611/001/	
	@ ZENITH	35MG	N85611 001	

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
PHENTERMINE HCL

>_DLT_>/AA/	/LANNETT/	/30MG/	/N87022/001/	
>_DLT_>			/FEB/03,/1983/	
>_ADD_>	@ LANNETT	30MG	N87022 001	
>_ADD_>			FEB 03, 1983	

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PROMETHAZINE VC PLAIN

AA	PENNEX PHARMS	5MG/5ML;6.25MG/5ML	N88897 001	
/@/		/5MG/5ML;6.25MG/5ML/	JAN 04, 1985	
			/N88897/001/	
			/JAN/04,/1985/	

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL
>_DLT_> /DIPHENYLAN/SODIUM/

>_DLT_>/BX/	/LANNETT/	/100MG/	/N80857/002/	
>_DLT_>		/30MG/	/N80857/001/	
>_ADD_>	@ LANNETT	30MG	N80857 001	
>_ADD_>	@	100MG	N80857 002	

PHYTONADIONE

INJECTABLE; INJECTION
PHYTONADIONE

/BP/	/SMITHKLINE/BEECHAM/	/1MG/0.5ML/	/N84060/001/	
/BP/		/10MG/ML/	/N84060/002/	
	@ SMITHKLINE BEECHAM	1MG/0.5ML	N84060 001	
	@	10MG/ML	N84060 002	

PILOCARPINE HYDROCHLORIDE

TABLET; ORAL
SALAGEN
+ MGI — 5MG — N20237 001 — MAR 22, 1994

PINDOLOL

TABLET; ORAL
PINDOLOL

AB	MUTUAL PHARM	5MG	N74063 001	JAN 27, 1994
AB		10MG	N74063 002	JAN 27, 1994

PIPERAZINE CITRATE

SYRUP; ORAL
>_DLT_> /VERMIDOL/

>_DLT_>/AA/	/SOLVAY/	/EQ 500MG BASE/5ML/	/N80992/001/	
>_ADD_>	@ SOLVAY	EQ 500MG BASE/5ML	N80992 001	

PIROXICAM

CAPSULE; ORAL
PIROXICAM

AB	NOVOPHARM	10MG	N73637 001	JAN 28, 1994
AB		20MG	N73638 001	JAN 28, 1994

POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

/AP/	/FUJISAWA/	/2MEQ/ML/	/N87885/001/	/FEB/03,/1983/
	@ FUJISAWA	2MEQ/ML	N87885 001	FEB 03, 1983

PREDNISOLONE

TABLET; ORAL
PREDNISOLONE

/BX/	/BUNDY/	/5MG/	/N83675/001/	
	@ BUNDY	5MG	N83675 001	
/BX/	/ICN/	/5MG/	/N80236/001/	
	@ ICN	5MG	N80236 001	
/BX/	/INWOOD/	/5MG/	/N80748/001/	
	@ INWOOD	5MG	N80748 001	
/BX/	/TABLICAPS/	/5MG/	/N85170/001/	
	@ TABLICAPS	5MG	N85170 001	

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
/PREDAIR FORTE/

/AT/	/PHARMAFAIR/	/EQ 0.9% PHOSPHATE/	/N88165/001/	/MAR/28,/1983/
	@ PHARMAFAIR	EQ 0.9% PHOSPHATE	N88165 001	MAR 28, 1983

PREDNISONE

TABLET; ORAL
PREDNISONE

/BX/	/BUNDY/	/5MG/	/N83676/001/	
	@ BUNDY	5MG	N83676 001	
>_DLT_> /BX/	/DANBURY/PHARMA/	/50MG/	/N86867/001/	
>_ADD_>	@ DANBURY PHARMA	50MG	N86867 001	
>_ADD_>	@ FERRANTE	2.5MG	N80563 001	
>_ADD_>	@ FERRANTE	5MG	N80563 002	
/BX/	/FIRST/TX/	/5MG/	/N80371/001/	
	@ FIRST TX	5MG	N80371 001	
/BX/	/ICN/	/5MG/	/N80237/001/	
	@ ICN	5MG	N80237 001	
/BX/	/INWOOD/	/1MG/	/N80328/001/	
/BX/		/2.5MG/	/N80306/001/	
	@ INWOOD	1MG	N80328 001	
	@	2.5MG	N80306 001	
>_DLT_> /BX/	/MK/	/2.5MG/	/N80563/001/	
>_DLT_> /BX/		/5MG/	/N80563/002/	
/BX/	/NYLOS/	/5MG/	/N85115/001/	
	@ NYLOS	5MG	N85115 001	
/BX/	/REXALL/	/5MG/	/N80232/001/	
	@ REXALL	5MG	N80232 001	
/BX/	/SPERTI/	/1MG/	/N80359/001/	
/BX/		/2.5MG/	/N80359/002/	
/BX/		/5MG/	/N80359/003/	
	@ SPERTI	1MG	N80359 001	
	@	2.5MG	N80359 002	
	@	5MG	N80359 003	
/BX/	/WHITE/TOWNE/PAULSEN/	/20MG/	/N84913/002/	
	@ WHITE TOWNE PAULSEN	20MG	N84913 002	

PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PROMETHAZINE PLAIN

AA	PENNEX PHARMS	6.25MG/5ML	N87953 001	NOV 15, 1982
	/@/	/6.25MG/5ML/	/N87953/001/	/NOV/15,/1982/

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL
PROMETHAZINE HCL

/BP/	/TABLICAPS/	/12.5MG/	/N84080/001/	
/BP/		/25MG/	/N84027/001/	
	@ TABLICAPS	12.5MG	N84080 001	
	@	25MG	N84027 001	
	/REMSED/			
/BP/	/DUPONT/	/25MG/	/N83176/002/	
	@ DUPONT	25MG	N83176 002	

PROPANTHELINE BROMIDE

TABLET; ORAL
PRO-BANTHINE

AA	ROBERTS LABS	**7.5MG**	**N08732 003**	
AA		**15MG**	**N08732 002**	
/**AA**/	/SCS/	/**7.5MG**/	/N08732/003/	
/**AA**/		/**15MG**/	/N08732/002/	

PROPARACAINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
/**KAINAIR**/

>_DLT_					
>_DLT_	/**AI**/	/PHARMAFAIR/	/**0.5%**/	/N88087/001/	
>_DLT_				/JUN/07,/1983/	
>_ADD_		@ PHARMAFAIR	0.5%	N88087 001	
>_ADD_				JUN 07, 1983	

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL

>_DLT_	/BD/	/LANNETT/	/50MG/	/N80016/001/	
>_ADD_		@ LANNETT	50MG	N80016 001	
	/BD/	/TABLICAPS/	/50MG/	/N80840/001/	
		@ TABLICAPS	50MG	N80840 001	

PROTIRELIN

INJECTABLE; INJECTION
/**RELEFACT TRH**/

>_DLT_					
>_DLT_	/**AP**/	/FERRING/LABS/	/**0.5MG/ML**/	/N18087/001/	
>_ADD_		**THYREL TRH**			
>_ADD_	**AP**	FERRING LABS	**0.5MG/ML**	**N18087 001**	

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL
/**ALLERFED**/

/**AA**/	/PRIVATE/FORM/	/**60MG;2.5MG**/	/N88860/001/	
	@ PRIVATE FORM	60MG;2.5MG	/JAN/31,/1985/	
			N88860 001	
			JAN 31, 1985	

PYRIDOSTIGMINE BROMIDE

TABLET; ORAL

>_DLT_	/PYRIDOSTIGMINE/BROMIDE/			
>_DLT_	/KALI/DUPHAR/	/30MG/	/N89572/001/	
>_DLT_			/NOV/27,/1990/	
>_ADD_	@ SOLVAY	30MG	N89572 001	
>_ADD_			NOV 27, 1990	

QUINIDINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
QUINIDEX

>_ADD_	**AB** + ROBINS AH	**300MG**	**N12796 002**	
>_ADD_	**QUINIDINE SULFATE**			
>_ADD_	**AB** COPLEY PHARM	**300MG**	**N40045 001**	
>_ADD_			JUN 30, 1994	

RANITIDINE HYDROCHLORIDE

CAPSULE; ORAL
ZANTAC 150

	GLAXO	EQ 150MG BASE	N20095 001
			MAR 08, 1994
	ZANTAC 300		
	+ GLAXO	EQ 300MG BASE	N20095 002
			MAR 08, 1994

GRANULE, EFFERVESCENT; ORAL
ZANTAC 150

	+ GLAXO	EQ 150MG BASE/PACKET	N20251 002
			MAR 31, 1994

TABLET, EFFERVESCENT; ORAL
ZANTAC 150

	+ GLAXO	EQ 150MG BASE	N20251 001
			MAR 31, 1994

ROCURONIUM BROMIDE

INJECTABLE; INJECTION
ZEMURON
+ ORGANON 10MG/ML N20214 002 MAR 17, 1994

ZEMURON (P/F)
+ ORGANON 10MG/ML N20214 001 MAR 17, 1994

SALMETEROL XINAFOATE

AEROSOL, METERED; INHALATION
SEREVENT
+ GLAXO EQ 0.021MG BASE/INH N20236 001 FEB 04, 1994

SECOBARBITAL SODIUM

CAPSULE; ORAL
SECOBARBITAL SODIUM

>_DLT_>/**AA**/	/LANNETT/	/**50MG**/	/N85909/001/
>_DLT_>/**AA**/		/**100MG**/	/N85903/001/
>_ADD_>	@ LANNETT	50MG	N85909 001
>_ADD_>	@	100MG	N85903 001

SECONAL SODIUM

>_DLT_>/**AA**/	/LILLY/	/**50MG**/	/N86101/001/
>_DLT_>			/OCT/03,/1983/
>_ADD_>	LILLY	50MG	N86101 001
>_ADD_>			OCT 03, 1983

SILVER SULFADIAZINE

DRESSING; TOPICAL
SILDIMAC
/@/BIOPLASTY/ /1%/ /N19608/001/ /NOV/30,/1989/
@ ENQUAY 1% N19608 001 NOV 30, 1989

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
NITROPRESS

>_DLT_>/**AP**/	/ABBOTT/	/**50MG/VIAL**/	/N18450/001/
>_ADD_>	@ ABBOTT	50MG/VIAL	N18450 001

SOTALOL HYDROCHLORIDE

TABLET; ORAL
BETAPACE
BERLEX 120MG N19865 005 APR 20, 1994

>_ADD_> STAVUDINE

>_ADD_> CAPSULE; ORAL
>_ADD_> ZERIT
>_ADD_> + BRISTOL MYERS SQUIBB 40MG N20412 005 JUN 24, 1994
>_ADD_>
>_ADD_> @ 5MG N20412 001 JUN 24, 1994
>_ADD_>
>_ADD_> 15MG N20412 002 JUN 24, 1994
>_ADD_>
>_ADD_> 20MG N20412 003 JUN 24, 1994
>_ADD_>
>_ADD_> 30MG N20412 004 JUN 24, 1994
>_ADD_>

STREPTOMYCIN SULFATE

INJECTABLE; INJECTION
STREPTOMYCIN SULFATE

>_DLT_>/**AP**/	/PFIZER/	/**EQ 1GM BASE/2ML**/	/N60111/001/
>_ADD_>	PFIZER	EQ 1GM BASE/2.5ML	N60111 001

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
/SULFAIR FORTE/

/**AT**/	/PHARMAFAIR/	/**30%**/	/N88385/001/ /OCT/13,/1983/
	@ PHARMAFAIR	30%	N88385 001 OCT 13, 1983

/SULFAIR-15/

>_DLT_>/**AT**/	/PHARMAFAIR/	/**15%**/	/N88186/001/ /MAY/25,/1983/
>_DLT_>			
>_ADD_>	@ PHARMAFAIR	15%	N88186 001 MAY 25, 1983
>_ADD_>			

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

SULFAMETHOXAZOLE AND TRIMETHOPRIM

/AP/	/FUJISAWA/	/80MG/ML;16MG/ML/	/N70223/001/ /DEC/29,/1987/ N70223 001 DEC 29, 1987	
	@ FUJISAWA	80MG/ML;16MG/ML		

SUSPENSION; ORAL

>_DLT_>	/BACTRIM/			
>_DLT_>/AB/	/+//ROCHE/	/200MG/5ML;40MG/5ML/	/N17560/001/ N17560 001	
>_ADD_>	@ ROCHE	200MG/5ML;40MG/5ML		

BACTRIM PEDIATRIC

>_DLT_>/AB/	/ROCHE/	/200MG/5ML;40MG/5ML/	/N17560/002/ N17560 002	
>_ADD_> AB	+ ROCHE	200MG/5ML;40MG/5ML		

TRIMETH/SULFA

>_DLT_>/AB/	/BARRE/	/200MG/5ML;40MG/5ML/	/N72398/001/ /MAY/23,/1988/ N72398 001 MAY 23, 1988	
>_DLT_>				
>_ADD_>	@ BARRE	200MG/5ML;40MG/5ML		
>_ADD_>				

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

>_DLT_>/AB/	/EON/LABS/	/400MG;80MG/	/N18598/003/ /MAY/19,/1982/ N18598 003 MAY 19, 1982	
>_DLT_>				
>_ADD_>	@ EON LABS	400MG;80MG		
>_ADD_>				

	/UROPLUS DS/			
/AB/	/SHIONOGI/	/800MG;160MG/	/N71816/001/ /SEP/28,/1987/ N71816 001 SEP 28, 1987	
	@ SHIONOGI	800MG;160MG		

	/UROPLUS SS/			
/AB/	/SHIONOGI/	/400MG;80MG/	/N71815/001/ /SEP/28,/1987/ N71815 001 SEP 28, 1987	
	@ SHIONOGI	400MG;80MG		

SULFASALAZINE

SUSPENSION; ORAL

AZULFIDINE			
/+//PHARMACIA/	/250MG/5ML/	/N18605/001/	
+ PHARMACIA	250MG/5ML	N86983 001	
@	250MG/5ML	N18605 001	
	/250MG/5ML/	/N86983/001/	

SULFISOXAZOLE

TABLET; ORAL

	SULFISOXAZOLE			
>_DLT_>/AB/	/LANNETT/	/500MG/	/N80085/001/ N80085 001	
>_ADD_>	@ LANNETT	500MG		

TACROLIMUS

CAPSULE; ORAL

PROGRAF			
+ FUJISAWA	EQ 1MG BASE	N50708 001 APR 08, 1994	
+	EQ 5MG BASE	N50708 002 APR 08, 1994	

INJECTABLE; INJECTION

PROGRAF			
+ FUJISAWA	EQ 5MG BASE/ML	N50709 001 APR 08, 1994	

TAMOXIFEN CITRATE

TABLET; ORAL

NOLVADEX			
+ ZENECA	EQ 20MG BASE	N17970 002 MAR 21, 1994	

TECHNETIUM TC-99M OXIDRONATE KIT

INJECTABLE; INJECTION

>_DLT_>	/OSTEOSCAN-HDP/			
>_DLT_>	/MALLINCKRODT/	/N/A/	/N18321/001/	
>_ADD_>	TECHNESCAN HDP			
>_ADD_>	MALLINGKRODT	N/A	N18321 001	

TECHNETIUM TC-99M SESTAMIBI KIT

INJECTABLE; INJECTION

CARDIOLITE			
DUPONT	N/A	N19785 001 DEC 21, 1990	
/DUPONT/MERCK/	/N/A/	/N19785/001/ /DEC/21,/1990/	

TETRACYCLINE

/SYRUP;/ORAL/
/ACHROMYCIN V/
/AB//+//LEDERLE/ /EQ 125MG HCL/5ML/ /N50263/002/
/SUMYCIN/
/AB/ /SQUIBB/ /EQ 125MG HCL/5ML/ /N60400/001/
/TETRACYCLINE/
/AB/ /BARRE/ /EQ 125MG HCL/5ML/ /N60633/001/
/AB/ /MK/ /EQ 125MG HCL/5ML/ /N60174/001/
/TETRACYCLINE HCL/
/AB/ /PUREPAC/ /EQ 125MG HCL/5ML/ /N60291/001/
/TETRACYN/
/AB/ /PFIPHARMECS/ /EQ 125MG HCL/5ML/ /N60095/001/
/TETRAMED/
/AB/ /ZENITH/ /EQ 125MG HCL/5ML/ /N61468/001/

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL
>_DLT_>/AB/ /ICN/ /500MG/ /N60471/002/
>_ADD_> @ ICN 500MG N60471 002

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

SYRUP; ORAL
ACHROMYCIN V
AB + LEDERLE 125MG/5ML N50263 002
SUMYCIN
AB SQUIBB 125MG/5ML N60400 001
TETRACYCLINE HCL
AB BARRE 125MG/5ML N60633 001
AB MK 125MG/5ML N60174 001
AB PUREPAC 125MG/5ML N60291 001
TETRACYN
AB PFIPHARMECS 125MG/5ML N60095 001
TETRAMED
AB ZENITH 125MG/5ML N61468 001

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
SLO-BID
AB RHONE POULENC RORER 100MG N87892 001
JAN 31, 1985
AB 125MG N89540 001
MAY 10, 1989
AB 200MG N87893 001
JAN 31, 1985
AB + 300MG N87894 001
JAN 31, 1985
THEOPHYLLINE
AB INWOOD LABS 100MG N40052 001
FEB 14, 1994
AB 125MG N40052 002
FEB 14, 1994
AB 200MG N40052 003
FEB 14, 1993
AB 300MG N40052 004
FEB 14, 1994

ELIXIR; ORAL
>_DLT_> /LANOPHYLLIN/
>_DLT_>/AA/ /LANNETT/ /80MG/15ML/ /N84578/001/
>_ADD_> @ LANNETT 80MG/15ML N84578 001

THEOPHYLLINE
>_DLT_>/AA/ /BARRE/ /80MG/15ML/ /N89223/001/
>_DLT_> /MAY/27,/1988/
>_ADD_> @ BARRE 80MG/15ML N89223 001
>_ADD_> MAY 27, 1988
@ CENCI 80MG/15ML N87679 001
APR 15, 1982
/AA/ /LIFE/LABS/ /80MG/15ML/ /N87679/001/
/APR/15,/1982/

INJECTABLE; INJECTION
THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER
>_ADD_> AP BAXTER 4MG/ML N18649 007
>_ADD_> JUL 26, 1982
THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER
>_ADD_> AP ABBOTT 4MG/ML N19211 007
>_ADD_> DEC 14, 1984
THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER
>_ADD_> AP MCGAW 4MG/ML N19212 003
>_ADD_> NOV 07, 1984

SYRUP; ORAL
>_DLT_> /THEOPHYLLINE/
>_DLT_>/AA/ /BARRE/ /80MG/15ML/ /N86001/001/
>_ADD_> @ BARRE 80MG/15ML N86001 001

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC
TOBRAMYCIN

AT	STERIS	0.3%	N63176 001 MAY 25, 1994

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION
TOBRAMYCIN SULFATE

AP	APOTHECON	EQ 10MG BASE/ML	N64021 001 MAY 31, 1994
AP		EQ 40MG BASE/ML	N64021 002 MAY 31, 1994
AP		EQ 40MG BASE/ML	N64026 001 MAY 31, 1994

TOBRAMYCIN SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

+	ABBOTT	EQ 1.6MG BASE/ML	N63081 006 JUN 02, 1993

TRIAMCINOLONE

TABLET; ORAL
TRIAMCINOLONE

/BP/	/MYLAN/	/2MG/	/N84406/001/
	@ MYLAN	2MG	N84406 001

TRIAMCINOLONE ACETONIDE

AEROSOL; TOPICAL
KENALOG

+	APOTHECON	0.147MG/GM	N12104 001
/+//WESTWOOD/SQUIBB/		/0.147MG/GM/	/N12104/001/

CREAM; TOPICAL
KENALOG

AT	+ APOTHECON	0.025%	N11601 003
AT	+	0.1%	N11601 006
AT	+	0.5%	N83943 001
/AT//+//WESTWOOD/SQUIBB/		/0.025%/	/N11601/003/
/AT//+/		/0.1%/	/N11601/006/
/AT//+/		/0.5%/	/N83943/001/

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL
KENALOG

AT	+ APOTHECON	0.025%	N11600 003
AT	+	0.1%	N11600 001
AT	+	0.5%	N83944 001
/AT//+//WESTWOOD/SQUIBB/		/0.025%/	/N11600/003/
/AT//+/		/0.1%/	/N11600/001/
/AT//+/		/0.5%/	/N83944/001/

TRIAZOLAM

TABLET; ORAL
HALCION

AB	UPJOHN	0.125MG	N17892 003 APR 26, 1985
AB		0.25MG	N17892 001 NOV 15, 1982

TRIAZOLAM

AB	ALPHAPHARM	0.125MG	N74031 001 MAR 25, 1994
AB		0.25MG	N74031 002 MAR 25, 1994
>ADD> AB	ROXANE	0.125MG	N74224 001 JUN 01, 1994
>ADD> AB		0.25MG	N74224 002 JUN 01, 1994

TRISULFAPYRIMIDINES (SULFADIAZINE;SULFAMERAZINE;SULFAMETHAZINE)

SUSPENSION; ORAL

>DLT>	/LANTRISUL/		
>DLT>/AB/	/LANNETT/	/500MG/5ML/	/N80123/002/
>ADD>	@ LANNETT	167MG/5ML;167MG/5ML;167	N80123 002

TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC
MYDRIAFAIR

>DLT>/AT/	/PHARMAFAIR/	/1%/	/N88230/001/
>DLT>			/SEP/16,/1983/
>ADD>	@ PHARMAFAIR	1%	N88230 001
>ADD>			SEP 16, 1983

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

	ISOPTIN SR			
AB	+ KNOLL	**180MG**		**N19152 002**
				DEC 15, 1989
	VERAPAMIL HCL			
AB	BAKER NORTON	**180MG**		**N74330 001**
				JAN 31, 1994

VINBLASTINE SULFATE

INJECTABLE; INJECTION

	VINBLASTINE SULFATE			
/**AP**/	/BULL/	/**10MG/VIAL**/		/N89565/001/
				/AUG/18,/1987/
AP	FAULDING	**10MG/VIAL**		**N89565 001**
				AUG 18, 1987

VINCRISTINE SULFATE

INJECTABLE; INJECTION

	VINCRISTINE SULFATE			
/**AP**/	/FUJISAWA/	/**1MG/ML**/		/N70411/001/
				/SEP/10,/1986/
	@ FUJISAWA	1MG/ML		N70411 001
				SEP 10, 1986
	VINCRISTINE SULFATE PFS			
/**AP**/	/BULL/	/**1MG/ML**/		/N71484/001/
				/APR/19,/1988/
AP	FAULDING	**1MG/ML**		**N71484 001**
				APR 19, 1988

ACETAMINOPHEN

SUPPOSITORY; RECTAL
>_ADD_> INFANTS' FEVERALL
>_ADD_> UPSHER SMITH 80MG N18337 004 AUG 26, 1992
>_ADD_>

>_ADD_> TABLET, EXTENDED RELEASE; ORAL
>_ADD_> TYLENOL
>_ADD_> + MCNEIL 650MG N19872 001 JUN 08, 1994
>_ADD_>

CLOTRIMAZOLE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
>_ADD_> MYCELEX-7 COMBINATION PACK
>_ADD_> MILES 1%;100MG N20389 002 JUN 23, 1994
>_ADD_>

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
DIPHENHYDRAMINE HCL
/BARRE/ /12.5MG/5ML/ /N70497/001/ /APR/25,/1989/
@ BARRE 12.5MG/5ML N70497 001 APR 25, 1989

IBUPROFEN

TABLET; ORAL
IBUPROFEN
MCNEIL 200MG N73019 001 MAR 30, 1994
PRIVATE FORM 200MG N73691 001 FEB 25, 1994

INSULIN BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
>_DLT_> /HUMULIN/BR/
>_DLT_> /+//LILLY/ /100/UNITS/ML/ /N19529/001/ /APR/28,/1986/
>_DLT_>
>_ADD_> @ LILLY 100 UNITS/ML N19529 001 APR 28, 1986
>_ADD_>

INSULIN SUSP ISOPHANE BEEF

INJECTABLE; INJECTION
NPH INSULIN
/+//NOVO/NORDISK/ /40/UNITS/ML/ /N17929/001/
@ NOVO NORDISK 40 UNITS/ML N17929 001

>_ADD_> NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

>_ADD_> SOLUTION/DROPS; OPHTHALMIC
>_ADD_> NAPHCON-A
>_ADD_> + ALCON 0.025%;0.3% N20226 001 JUN 08, 1994
>_ADD_>
>_ADD_> OPCON-A
>_ADD_> + BAUSCH AND LOMB 0.027%;0.315% N20065 001 JUN 08, 1994
>_ADD_>

NAPROXEN SODIUM

TABLET; ORAL
ALEVE
HAMILTON PHARMS EQ 200MG BASE N20204 002 JAN 11, 1994

PERMETHRIN

LOTION; TOPICAL
NIX
/+//BURROUGHS/WELLCOME/ /1%/ /N19918/001/ /MAY/02,/1990/
+ WARNER WELLCOME 1% N19918 001 MAY 02, 1990

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
>_ADD_> EFIDAC/24
>_ADD_> + CIBA 240MG N20021 002 DEC 15, 1992
>_ADD_>
>_DLT_> /PSEUDOEPHEDRINE/HCL/
>_DLT_> /ALZA/ /240MG/ /N20021/002/ /DEC/15,/1992/
>_DLT_>

SUDAFED 12 HOUR
/+//BURROUGHS/WELLCOME/ /120MG/ /N73585/001/ /OCT/31,/1991/
+ WARNER WELLCOME 120MG N73585 001 OCT 31, 1991

NO JUNE 1994 APPROVALS

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January-June, 1994]

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
8-METHOXSALEN 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 / /
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 / /
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 UNDER SECTION 526(A)(2)(B) OF THE FFDCA.	RECKITT & COLMAN PHARMACEUTICALS 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 / /
CCD 1042 TN=	TREATMENT OF INFANTILE SPASMS.	COCENSYS, INC. 213 TECHNOLOGY DRIVE IRVINE CA 92718 DD 05/25/94 MA / /
CHIMERIC (MURINE VARIABLE, HUMAN CONSTANT) MAB TO CD20 TN=	TREATMENT OF NON-HODGKIN'S B-CELL LYMPHOMA.	IDEC 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 / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
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 / /
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 POLYPS IN THE INHERITED DISEASE ADENOMATOUS POLYPOSIS COLI.	CELL PATHWAYS, INC. 1700 BROADWAY, SUITE 2000 DENVER CO 80290 DD 02/14/94 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. [APPROVAL INCLUDED TYPE I GAUCHER'S DISEASE ONLY]	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 / /
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 / /
MITOGUAZONE 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-VALERATE 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 / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD= Date Designated MA= Marketing Approval
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 BREN 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
SOMATROPIN TN= NUTROPIN	FOR USE IN THE LONG-TERM TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE DUE TO A LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION.	GENENTECH, INC. 460 POINT SAN BRUNO BOULEVARD SOUTH SAN FRANCISCO CA 94080 DD 03/06/87 MA 03/09/94
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 PENNINGTION NJ 08534 DD 05/16/94 MA / /

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

NO JUNE 1994 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
ALBUTEROL (METERED DOSE INHALER - *IN VIVO*)	JAN 27, 1994	
FLURBIPROFEN (TABLET)	DEC 24, 1992	FEB 04, 1994
PHENYTOIN (SUSPENSION AND CHEWABLE TABLET)	MAR 04, 1994	
PHENYTOIN SODIUM (CAPSULE, EXTENDED AND PROMPT)	MAR 04, 1994	

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.

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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
PSEUDOEPHEDRINE 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

*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

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

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

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
	19806 001	ACRIVASTINE; SEMPREX-D	4650807	MAR 17, 2004	U-93		
			4501893	FEB 26, 2002		NC	MAR 25, 1997
	18700 001	AMRINONE LACTATE; INOCOR	4072746	JUL 31, 1998	U-7	NCE	JUL 31, 1994
	20304 001	APROTININ BOVINE; TRASYLOL				ODE	DEC 29, 2000
	20233 001	BUDESONIDE; RHINOCORT				NCE	FEB 14, 1999
	18731 001	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646	MAR 14, 2008	U-13		
	18731 002	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646	MAR 14, 2008	U-13		
	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-101	JAN 28, 1997
						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			
>ADD>	20126 001	DOXEPIN HYDROCHLORIDE; ZONALON				NDF	APR 01, 1997
>ADD>	18922 004	ETODOLAC; LODINE				NCE	JAN 31, 1996
>ADD>	20363 002	FAMCICLOVIR; FAMVIR				NCE	JUN 29, 1999
	20249 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		I-69	DEC 10, 1994
	19304 001	FENOFIBRATE; 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
>ADD>	20322 001	FLUCONAZOLE; DIFLUCAN	4552884	NOV 12, 2002		I-100	DEC 30, 1996
>ADD>			4302460	NOV 24, 1998		NCE	JAN 29, 1995
>ADD>						NS	JUN 30, 1997
>ADD>						I-107	JUN 30, 1997
	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
	20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001		I-102	FEB 28, 1997

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
	20235 001	GABAPENTIN; NEURONTIN					
	20235 002	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
	20235 003	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
	20329 001	GLIPIZIDE; GLUCOTROL XL	4894476	JAN 16, 2007			
	20329 002	GLIPIZIDE; GLUCOTROL XL				NDF	APR 26, 1997
	19778 003	HYDROCHLOROTHIAZIDE; PRINZIDE 10-12.5				NDF	APR 26, 1997
			4472380	SEP 18, 2001			
	19888 001	HYDROCHLOROTHIAZIDE; ZESTORETIC 20-12.5	4374829	DEC 30, 2001	U-3	NS	NOV 18, 1996
			4472380	SEP 18, 2001			
	19888 002	HYDROCHLOROTHIAZIDE; ZESTORETIC 20-25	4374829	DEC 30, 2001	U-3		
	19888 003	HYDROCHLOROTHIAZIDE; ZESTORETIC 10-12.5	4374829	DEC 30, 2001	U-3		
			4472380	SEP 18, 2001			
	20367 001	IMIGLUCERASE; CEREZYME	4374829	DEC 30, 2001	U-3	NS	NOV 18, 1996
>ADD>							
>ADD>	20314 001	INDIUM IN-111 PENTETREOTIDE KIT; OCTREOSCAN				NCE	MAY 23, 1999
	20084 001	IOBENGUANE SULFATE I 131; IOBENGUANE SULFATE I 131				ODE	MAY 23, 2001
>ADD>	50705 001	ISONIAZID; RIFATER				NCE	JUN 02, 1999
>ADD>	20336 001	ISRADIPINE; DYNACIRC CR				NCE	MAR 25, 1999
>ADD>						ODE	MAY 31, 2001
>ADD>	20336 002	ISRADIPINE; DYNACIRC CR				NCE	DEC 20, 1995
>ADD>						NDF	JUN 01, 1997
	20083 001	ITRACONAZOLE; SPORANOX				NCE	DEC 20, 1995
	20219 001	LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN				NDF	JUN 01, 1997
	19558 006	LISINOPRIL; PRINIVIL	4369184	JAN 18, 2000		I-104	MAR 29, 1997
	20264 001	MEGESTROL ACETATE; MEGACE	4374829	DEC 30, 2001		NCE	NOV 10, 1998
	19667 001	OCTREOTIDE ACETATE; SANDOSTATIN				I-92	JUN 09, 1996
	19667 002	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		NDF	SEP 10, 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	4395403	JUL 26, 2002		I-106	MAY 03, 1997
	20036 001	PAMIDRONATE DISODIUM; AREDIA				I-106	MAY 03, 1997
	20036 003	PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004		I-105	APR 13, 1997
	20036 004	PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004		D-22	APR 15, 1997
	20184 001	PERINDOPRIL ERBUMINE; ACEON	4711880	DEC 08, 2004		D-22	APR 15, 1997
	20184 002	PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002		D-22	APR 15, 1997
	20184 003	PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002		NCE	DEC 30, 1998
	20237 001	PILOCARPINE HYDROCHLORIDE; SALAGEN	4508729	APR 02, 2002		NCE	DEC 30, 1998
						NCE	DEC 30, 1998
						ODE	MAR 22, 2001
						NDF	MAR 22, 1997

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
	20279 001	PREDNICARBATE; DERMATOP					
	19627 001	PROPOFOL; DIPRIVAN				NDF	OCT 29, 1996
>ADD>	20021 002	PSEUDOEPHEDRINE HYDROCHLORIDE; EFIDAC/24				I-99	OCT 26, 1996
>DLT>	~~20021 002~~	~~PSEUDOEPHEDRINE HYDROCHLORIDE; PSEUDOEPHEDRINE HCL~~	~~4801461~~	~~MAY 05, 2004~~			
>ADD>			4801461	MAY 05, 2004			
>DLT>			~~4576604~~	~~MAR 18, 2003~~			
			4576604	MAR 18, 2003			
	18703 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4128658	DEC 05, 1995		D-21	FEB 28, 1997
	18703 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	4128658	DEC 05, 1995		D-21	FEB 28, 1997
	19675 001	RANITIDINE HYDROCHLORIDE; ZANTAC	4521431	JUN 04, 2002		D-21	FEB 28, 1997
	20095 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5028432	JUL 02, 2008			
			4521431	JUN 04, 2002		I-75	MAY 19, 1995
	20095 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	4128658	DEC 05, 1995		D-21	FEB 28, 1997
			5028432	JUL 02, 2008			
			4521431	JUN 04, 2002		I-75	MAY 19, 1995
	20251 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4128658	DEC 05, 1995		D-21	FEB 28, 1997
			5102665	APR 07, 2009			
			4521431	JUN 04, 2002		I-75	MAY 19, 1995
	20251 002	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4128658	DEC 05, 1995		D-21	FEB 28, 1997
			5102665	APR 07, 2009			
			4521431	JUN 04, 2002		I-75	MAY 19, 1995
	20214 001	ROCURONIUM BROMIDE; ZEMURON (P/F)	4128658	DEC 05, 1995		D-21	FEB 28, 1997
	20214 002	ROCURONIUM BROMIDE; ZEMURON	4894369	JAN 16, 2007		NCE	MAR 17, 1999
	20236 001	SALMETEROL XINAFOATE; SEREVENT	4894369	JAN 16, 2007		NCE	MAR 17, 1999
>ADD>	19766 001	SIMVASTATIN; ZOCOR	4992474	FEB 12, 2008		NCE	FEB 04, 1999
>DLT>	~~19766 001~~	~~SIMVASTATIN; ZOCOR~~	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1996
>ADD>	19766 002	SIMVASTATIN; ZOCOR	~~4444784~~	~~DEC 24, 2005~~	~~U-59~~	~~NCE~~	~~DEC 23, 1997~~
>DLT>	~~19766 002~~	~~SIMVASTATIN; ZOCOR~~	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1996
>ADD>	19766 003	SIMVASTATIN; ZOCOR	~~4444784~~	~~DEC 24, 2005~~	~~U-59~~	~~NCE~~	~~DEC 23, 1997~~
>DLT>	~~19766 003~~	~~SIMVASTATIN; ZOCOR~~	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1996
>ADD>	19766 004	SIMVASTATIN; ZOCOR	~~4444784~~	~~DEC 24, 2005~~	~~U-59~~	~~NCE~~	~~DEC 23, 1997~~
>DLT>	~~19766 004~~	~~SIMVASTATIN; ZOCOR~~	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1996
	19640 001	SOMATROPIN, BIOSYNTHETIC; HUMATROPE	~~4444784~~	~~DEC 24, 2005~~	~~U-59~~	~~NCE~~	~~DEC 23, 1997~~
	19640 004	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				D-23	APR 15, 1997
						D-23	APR 15, 1997
	19865 005	SOTALOL HYDROCHLORIDE; BETAPACE					
						NCE	OCT 30, 1997
						ODE	OCT 30, 1999

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	20412 001	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
>ADD>	20412 002	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
>ADD>	20412 003	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
>ADD>	20412 004	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
>ADD>	20412 005	STAVUDINE; 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				I-103	JAN 07, 1997
	17377 002	SULFAMETHOXAZOLE; BACTRIM DS				I-103	JAN 07, 1997
	17560 002	SULFAMETHOXAZOLE; BACTRIM PEDIATRIC				I-103	JAN 07, 1997
	17598 001	SULFAMETHOXAZOLE; SEPTRA				I-103	JAN 07, 1997
	17598 002	SULFAMETHOXAZOLE; SEPTRA GRAPE				I-103	JAN 07, 1997
	17970 002	TAMOXIFEN CITRATE; NOLVADEX	4536516	AUG 20, 2002			
	19762 001	TESTOSTERONE; TESTODERM	4867982	FEB 16, 2005			
			4725439	FEB 16, 2005			
			4704282	NOV 03, 2004		NDF	OCT 12, 1996
	19762 002	TESTOSTERONE; TESTODERM	4867982	FEB 16, 2005			
			4725439	FEB 16, 2005			
			4704282	NOV 03, 2004		NDF	OCT 12, 1996
	20330 001	TIMOLOL MALEATE; TIMOPTIC-XE	4861760	AUG 29, 2006			
			4195085	MAR 25, 1997		NP	NOV 04, 1996
	20330 002	TIMOLOL MALEATE; TIMOPTIC-XE	4861760	AUG 29, 2006			
			4195085	MAR 25, 1997		NP	NOV 04, 1996
	20326 001	TRIMETREXATE GLUCURONATE; NEUTREXIN	4694007	SEP 15, 2004	U-91	ODE	DEC 17, 2000

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