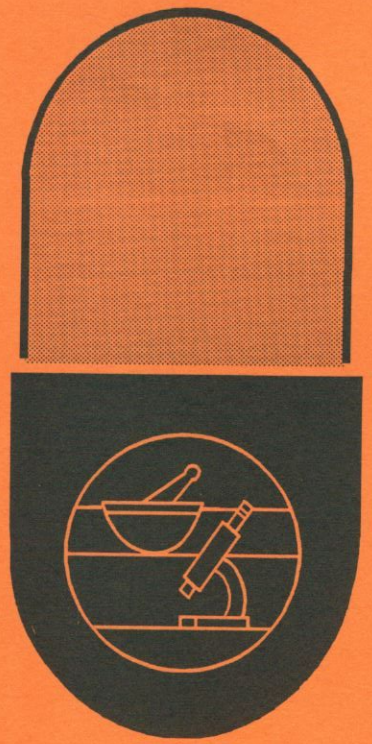
CUMULATIVE
SUPPLEMENT 5

JAN'94-MAY'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 5

MAY 1994

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CUMULATIVE SUPPLEMENT 5

MAY 1994

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 14th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to place an asterisk (*) to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement.

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the List will not be repeated for context.]

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Additions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >**ADD**> to the left of the line on which new information exists. The >**ADD**> symbol is then dropped in subsequent Cumulative Supplements for that item.

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

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the " ∂ " symbol to designate their non-marketed status. All products having a " ∂ " symbol in the 12th Cumulative Supplement of the 14th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 15th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the appropriate Drug Product List.

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)
DUPONT PHARMACEUTICALS (DUPONT)	DUPONT MERCK PHARMACEUTICALS CO (DUPONT MERCK)
GYNEX INC (GYNEX)	BTG PHARMACEUTICALS CORP SUB BIOTECHNOLOGY GENERAL CORP (BTG PHARMS)
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 MAY 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		
SINGLE SOURCE	2144 (23.5%)	2151 (23.5%)		
MULTISOURCE	6996 (76.5%)	7002 (76.5%)		
THERAPEUTICALLY EQUIVALENT	6292 (68.8%)	6306 (68.9%)		
NOT THERAPEUTICALLY EQUIVALENT	527 (5.8%)	513 (5.6%)		
EXCEPTIONS[1]	177 (1.9%)	183 (2.0%)		
NEW MOLECULAR ENTITIES APPROVED	--	6		
NUMBER OF APPLICANTS	526	528		

[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

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
/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

AMIKACIN SULFATE

INJECTABLE; INJECTION
/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

AMINOPHYLLINE

INJECTABLE; INJECTION
AMINOPHYLLINE

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

TABLET; ORAL
AMINOPHYLLINE

>DLT> /BD/	/LANNETT/	/100MG/	/N84588/001/	
>DLT> /BD/		/200MG/	/N84588/002/	
>ADD>	@ LANNETT	100MG	N84588 001	
>ADD>	@	200MG	N84588 002	
AB	RICHLYN	**100MG**	**N84574 001**	
AB		**200MG**	**N84576 001**	
/BD/		/100MG/	/N84574/001/	
/BD/		/200MG/	/N84576/001/	

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/

[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.

AMPHETAMINE SULFATE

>DLT>	/TABLET;/ORAL/			
>DLT>	/AMPHETAMINE/SULFATE/			
>DLT>	/LANNETT/	/5MG/	/N83901/001/ /AUG/31,/1984/	
>DLT>		/10MG/	/N83901/002/ /AUG/31,/1984/	
>ADD>	@ LANNETT	5MG	N83901 001 AUG 31, 1984	
>ADD>	@	10MG	N83901 002 AUG 31, 1984	

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

BACITRACIN

OINTMENT; OPHTHALMIC
BACITRACIN

/**AI**/	/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

>DLT>	/EMULSION;/TOPICAL/		
>DLT>	/BENZYL/BENZOATE/		
>DLT>	/+//LANNETT/	/50%/	/N84535/001/
>ADD>	@ 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

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

BUDESONIDE

AEROSOL, METERED; NASAL
RHINOCORT

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

BUTABARBITAL SODIUM

ELIXIR; ORAL

>DLT >	/BUTALAN/		
>DLT >	/LANNETT/	/33.3MG/5ML/	/N85880/001/
>ADD >	@ LANNETT	33.3MG/5ML	N85880 001

TABLET; ORAL
BUTISOL SODIUM

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

CARBAMAZEPINE

TABLET, CHEWABLE; ORAL
TEGRETOL

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

TABLET; ORAL
/CEFADROXIL/

/@/ZENITH/	/EQ/1GM/BASE/	/N62774/001/ /APR/08,/1987/

CEFADROXIL

AB	ZENITH	**EQ 1GM BASE**	**N62774 001** APR 08, 1987

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

CHLORAMPHENICOL

OINTMENT; OPHTHALMIC
/CHLOROFAIR/

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

SOLUTION/DROPS; OPHTHALMIC
/CHLOROFAIR/

/AI/	/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

>ADD>				
>ADD> AB	ENDO LABS	200MG		**N74281 001** MAY 17, 1994
>ADD>				
>ADD> AB		300MG		**N74281 002** MAY 17, 1994
>ADD>				
>ADD> AB		400MG		**N74281 003** MAY 17, 1994
>ADD>				
>ADD> AB		800MG		**N74329 001** MAY 17, 1994
>ADD>				

CIMETIDINE

TABLET; ORAL

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

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

		CLINDAMYCIN PHOSPHATE		
/**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

CLOBETASOL PROPIONATE

GEL; TOPICAL

		TEMOVATE		
	+	GLAXO	0.05%	N20337 001
				APR 29, 1994

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

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

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

>DLT>	/**ESTRAGUARD**/		
>DLT>/**AT**/	/SOLVAY/	/**0.01%**/	/N84436/001/
>ADD>	@ 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
	/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	

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

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

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	

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	

ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
/DELADUMONE/

/AO//+//SQUIBB/	/4MG/ML;90MG/ML/	/N09545/001/	>ADD>
@ SQUIBB	4MG/ML;90MG/ML	N09545 001	>ADD>
			>ADD>
			>ADD>
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

ESTROGENS, ESTERIFIED

TABLET; ORAL
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

>DLT> /BP/ /STERIS/	/2MG/ML/	/N83397/001/	
>ADD> @ 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

ETODOLAC

TABLET; ORAL
LODINE

>ADD>		
>ADD>		
>ADD> + WYETH AYERST	400MG	N18922 004
>ADD>		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

FAMOTIDINE

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

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
/AT/ /PHARMAFAIR/ /0.01%/ /N88449/001/ /FEB/08,/1984/

@ PHARMAFAIR 0.01% N88449 001 FEB 08, 1984

FOLIC ACID

TABLET; ORAL
FOLIC ACID
/AA/ /PUREPAC/ /1MG/ /N80784/001/
@ PUREPAC 1MG N80784 001

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**

GENTAMICIN SULFATE

CREAM; TOPICAL
GENTAFAIR
/AT/ /PHARMAFAIR/ /EQ 1MG BASE/GM/ /N62458/001/ /SEP/01,/1983/
AT PHARMAFAIR **EQ 0.1% BASE** **N62458 001** 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
AP + SCHERING **EQ 2MG BASE/ML** **N50505 001**
/+/ /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**

GENTAMICIN SULFATE

OINTMENT; TOPICAL

GENTAFAIR

/AT/	/PHARMAFAIR/	/EQ 1MG BASE/GM/	/N62444/001/ /MAY/26,/1983/
AT	PHARMAFAIR	EQ 0.1% BASE	N62444 001 MAY 26, 1983

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

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

SOLUTION/DROPS; OPHTHALMIC

GENTAMICIN SULFATE

/AT/	/AKORN/	/EQ 3MG BASE/ML/	/N62635/001/ /JAN/08,/1987/
AT	AKORN	EQ 0.3% BASE	N62635 001 JAN 08, 1987
> ADD > 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

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

GLUCOTROL

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

TABLET, EXTENDED RELEASE; ORAL

GLUCOTROL XL

+	PFIZER	5MG	NZ0329 001 APR 26, 1994
+		10MG	NZ0329 002 APR 26, 1994

GLYCOPYRROLATE

INJECTABLE; INJECTION

GLYCOPYRROLATE

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

GUANABENZ ACETATE

TABLET; ORAL
GUANABENZ ACETATE

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/

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

ENEMA; RECTAL
CORTENEMA

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

HYDROCORTISONE

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

GEL; TOPICAL
/NUTRACORT/

>DLT>				
>DLT>	/**AT**//+//GALDERMA/		/**1%**/	/N84698/001/
>ADD>	@ GALDERMA		1%	N84698 001

PENECORT

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

LOTION; TOPICAL
HYDROCORTISONE

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

OINTMENT; TOPICAL
HYDROCORTISONE

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

HYDROCORTISONE ACETATE

CREAM; TOPICAL
HYDROCORTISONE ACETATE

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

INJECTABLE; INJECTION
HYDROCORTISONE ACETATE

>DLT>	/BP/	/STERIS/	/50MG/ML/	/N85214/001/
>ADD>		@ STERIS	50MG/ML	N85214 001

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

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

> ADD > IMIGLUCERASE

> ADD > INJECTABLE; INJECTION
> ADD > CEREZYME

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

INSULIN BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
HUMULIN R

	+ LILLY	500 UNITS/ML	N18780 004 MAR 31, 1994

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/
	@ MEDI PHYSICS	1MCI/ML	N18289 001 DEC 28, 1984

> ADD > ISONIAZID; PYRAZINAMIDE; RIFAMPIN

> ADD > TABLET; ORAL
> ADD > RIFATER

> ADD >	+ MARION MERRELL DOW	50MG;300MG;120MG	N50705 001 MAY 31, 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
/+//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 HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
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
> DLT > /ARESTOCAINE HCL W/ LEVONORDEFRIN/
> DLT >/AP/ /CARLISLE/ /0.05MG/ML;2%/ /N85010/001/
> ADD > @ 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

LITHIUM CARBONATE

TABLET, EXTENDED RELEASE; ORAL
/LITHOBID/
/+//CIBA/ /300MG/ /N18027/001/
@ CIBA 300MG N18027 001

LORAZEPAM

INJECTABLE; INJECTION
ATIVAN
AP + WYETH AYERST 2MG/ML N18140 001
AP + 4MG/ML N18140 002

LORAZEPAM

INJECTABLE; INJECTION
LORAZEPAM

>ADD >	**AP**	ABBOTT	**2MG/ML**	**N74280 001** MAY 27, 1994
>ADD >				
>ADD >	**AP**		**2MG/ML**	**N74282 001** MAY 27, 1994
>ADD >				
>ADD >	**AP**		**4MG/ML**	**N74280 002** MAY 27, 1994
>ADD >				
>ADD >	**AP**		**4MG/ML**	**N74282 002** MAY 27, 1994
>ADD >				
	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

MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
>DLT > **/ARESTOCAINE HCL/**

>DLT >/**AP**/	/CARLISLE/	**/3%/**	/N84777/002/ /APR/18,/1982/
>DLT >			
>ADD >	@ SOLVAY	3%	N84777 002 APR 18, 1982
>ADD >			

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

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
/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
>ADD > **AB**	WATSON LABS	**50MG**	**N74217 001** MAY 27, 1994
>ADD >			
>ADD > **AB**		**100MG**	**N74217 002** MAY 27, 1994
>ADD >			

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
NAFAZAIR

>ADD>	**AT**	BAUSCH AND LOMB	**0.1%**	**N40073 001**
>ADD>				MAY 25, 1994

NAPROXEN

SUSPENSION; ORAL
NAPROSYN

AB	+	SYNTEX	**25MG/ML**	**N18965 001**
				MAR 23, 1987

NAPROXEN

AB	ROXANE	**25MG/ML**	**N74190 001**
			MAR 30, 1994

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

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL
HABITROL

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

NITROGLYCERIN

INJECTABLE; INJECTION
/NITRONAL/
/+//BOSKAMP/ /1MG/ML/ /N18672/001/
/AUG/30,/1983/
@ G POHL BOSKAMP 1MG/ML N18672 001
AUG 30, 1983

NITROGLYCERIN

INJECTABLE; INJECTION
NITROSTAT

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

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

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
NYSTATIN AND TRIAMCINOLONE ACETONIDE

/AT/	/PHARMAFAIR/	/**100,000 UNITS/GM**;**0.1%**/		/N62657/001/
	@ PHARMAFAIR	100,000 UNITS/GM;0.1%		/JUL/30,/1986/ N62657 001 JUL 30, 1986

OINTMENT; TOPICAL
NYSTATIN-TRIAMCINOLONE ACETONIDE

/AT/	/PHARMADERM/	/**100,000 UNITS/GM**;**0.1%**/		/N62603/001/
	@ PHARMADERM	100,000 UNITS/GM;0.1%		/OCT/09,/1985/ 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		N20031 003 DEC 29, 1992
		/EQ/30MG/BASE/		/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

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
PHENDIMETRAZINE TARTRATE

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

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PROMETHAZINE VC PLAIN

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

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

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
/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
/BX/	/NYLOS/	/5MG/	/N85115/001/
	@ NYLOS	5MG	N85115 001
/BX/	/REXALL/	/5MG/	/N80232/001/
	@ REXALL	5MG	N80232 001

PREDNISONE

TABLET; ORAL
PREDNISONE

/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/

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/

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL

/BD/	/TABLICAPS/	/50MG/	/N80840/001/
	@ TABLICAPS	50MG	N80840 001

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL
/ALLERFED/

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

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

SILVER SULFADIAZINE

DRESSING; TOPICAL

SILDIMAC			
/@/BIOPLASTY/	/1%/	/N19608/001/	>DLT>
		/NOV/30,/1989/	>ADD>
@ ENQUAY	1%	N19608 001	>ADD>
		NOV 30, 1989	>DLT>

SOTALOL HYDROCHLORIDE

TABLET; ORAL

BETAPACE		
BERLEX	120MG	N19865 005
		APR 20, 1994

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

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

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

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

TABLET; ORAL

/UROPLUS DS/			
/AB/ /SHIONOGI/	/800MG;160MG/	/N71816/001/	
		/SEP/28,/1987/	
@ SHIONOGI	800MG;160MG	N71816 001	
		SEP 28, 1987	
/UROPLUS SS/			
/AB/ /SHIONOGI/	/400MG;80MG/	/N71815/001/	
		/SEP/28,/1987/	
@ SHIONOGI	400MG;80MG	N71815 001	
		SEP 28, 1987	

SULFASALAZINE

SUSPENSION; ORAL

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

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 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/

TETRACYCLINE

/SYRUP;/ORAL/

	/TETRACYCLINE/		
/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

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

CAPSULE, EXTENDED RELEASE; ORAL

	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

	THEOPHYLLINE		
	@ CENCI	80MG/15ML	N87679 001 APR 15, 1982
/AA/	/LIFE/LABS/	/80MG/15ML/	/N87679/001/ /APR/15,/1982/

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC

		TOBRAMYCIN		
>ADD>	AT	STERIS	0.3%	N63176 001 MAY 25, 1994
>ADD>				

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

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

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/

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

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

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 SUSP ISOPHANE BEEF

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

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

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
SUDAFED 12 HOUR
+ WARNER WELLCOME 120MG N73585 001
OCT 31, 1991

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 5 / MAY '94

NO MAY 1994 APPROVALS

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January-May, 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 / /
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 / /
CHOLINE CHLORIDE TN=	TREATMENT OF CHOLINE DEFICIENCY,SPECIFICALLY THE CHOLINE DEFICIENCY, HEPATIC STEATOSIS, AND CHOLESTASIS, ASSOCIATED WITH LONG-TERM PARENTERAL NUTRITION.	BUCHMAN, ALAN M.D. 6550 FANNIN, SUITE 1122 HOUSTON TX 77030 DD 02/10/94 MA / /
CLADRIBINE TN= LEUSTATIN	TREATMENT OF THE CHRONIC PROGRESSIVE FORM OF MULTIPLE SCLEROSIS.	BEUTLER, ERNEST M.D. 10666 NORTH TORREY PINES ROAD LA JOLLA CA 92037 DD 04/19/94 MA / /
CY-1899 TN=	TREATMENT OF CHRONIC ACTIVE HEPATITIS B INFECTION IN HLA-A2 POSITIVE PATIENTS.	CYTEL CORPORATION 3525 JOHN HOPKINS COURT SAN DIEGO CA 92121 DD 03/16/94 MA / /
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

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
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 / /
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-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 / /
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 / /
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 / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD= Date Designated MA= Marketing Approval
SOMATROPIN TN= PROTROPIN II	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 MAY 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, 13TH 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
LOPERAMIDE HYDROCHLORIDE TABLET, EFFERVESCENT; ORAL	1MG	93 P-0332/ CP1	ELLIS PHARM CONSULTING	NEW DOSAGE FORM	APPROVED FEB 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

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

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

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			
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
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
20235 001	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
20235 002	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
20235 003	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
20329 001	GLIPIZIDE; GLUCOTROL XL				NDF	APR 26, 1997
20329 002	GLIPIZIDE; GLUCOTROL XL				NDF	APR 26, 1997
19778 003	HYDROCHLOROTHIAZIDE; PRINZIDE 10-12.5	4472380	SEP 18, 2001			
		4374829	DEC 30, 2001	U-3	NS	NOV 18, 1996

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
	19888 001	HYDROCHLOROTHIAZIDE; ZESTORETIC 20-12.5	4472380	SEP 18, 2001			
			4374829	DEC 30, 2001	U-3		
	19888 002	HYDROCHLOROTHIAZIDE; ZESTORETIC 20-25	4374829	DEC 30, 2001	U-3		
	19888 003	HYDROCHLOROTHIAZIDE; ZESTORETIC 10-12.5	4472380	SEP 18, 2001		NS	NOV 18, 1996
			4374829	DEC 30, 2001	U-3		
>ADD>	20367 001	IMIGLUCERASE; CEREZYME				NCE	MAY 23, 1999
	20084 001	IOBENGUANE SULFATE I 131; IOBENGUANE SULFATE I 131				NCE	MAR 25, 1999
	20083 001	ITRACONAZOLE; SPORANOX				I-104	MAR 29, 1997
	20219 001	LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN	4369184	JAN 18, 2000		NCE	NOV 10, 1998
>ADD>	19558 006	LISINOPRIL; PRINIVIL	4374829	DEC 30, 2001		I-92	JUN 09, 1996
	20264 001	MEGESTROL ACETATE; MEGACE				NDF	SEP 10, 1997
>ADD>	19667 001	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		I-106	MAY 03, 1997
>ADD>	19667 002	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		I-106	MAY 03, 1997
>ADD>	19667 003	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		I-106	MAY 03, 1997
>ADD>	19667 004	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		I-106	MAY 03, 1997
>ADD>	19667 005	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		I-106	MAY 03, 1997
	20262 001	PACLITAXEL; TAXOL				I-105	APR 13, 1997
>ADD>	20036 001	PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004		D-22	APR 15, 1997
>ADD>	20036 003	PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004		D-22	APR 15, 1997
>ADD>	20036 004	PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004		D-22	APR 15, 1997
	20184 001	PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002		NCE	DEC 30, 1998
	20184 002	PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002		NCE	DEC 30, 1998
	20184 003	PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002		NCE	DEC 30, 1998
	20237 001	PILOCARPINE HYDROCHLORIDE; SALAGEN				ODE	MAR 22, 2001
						NDF	MAR 22, 1997
	20279 001	PREDNICARBATE; DERMATOP				NDF	OCT 29, 1996
	19627 001	PROPOFOL; DIPRIVAN				I-99	OCT 26, 1996
	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
			4128658	DEC 05, 1995		D-21	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
	20251 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5102665	APR 07, 2009			
			4521431	JUN 04, 2002		I-75	MAY 19, 1995
			4128658	DEC 05, 1995		D-21	FEB 28, 1997
	20251 002	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5102665	APR 07, 2009			
			4521431	JUN 04, 2002		I-75	MAY 19, 1995
			4128658	DEC 05, 1995		D-21	FEB 28, 1997
	20214 001	ROCURONIUM BROMIDE; ZEMURON (P/F)	4894369	JAN 16, 2007		NCE	MAR 17, 1999
	20214 002	ROCURONIUM BROMIDE; ZEMURON	4894369	JAN 16, 2007		NCE	MAR 17, 1999
	20236 001	SALMETEROL XINAFOATE; SEREVENT	4992474	FEB 12, 2008		NCE	FEB 04, 1999
>ADD>	19640 001	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				D-23	APR 15, 1997
>ADD>	19640 004	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				D-23	APR 15, 1997
>ADD>	19865 005	SOTALOL HYDROCHLORIDE; BETAPACE				NCE	OCT 30, 1997
>ADD>						ODE	OCT 30, 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
>ADD>	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

*U.S. Government Printing Office: 1994 — 301-037/80012