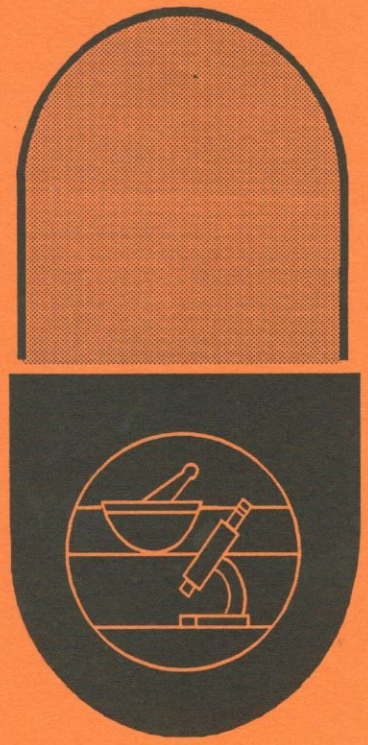
CUMULATIVE SUPPLEMENT 3

JAN'94-MAR'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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

14TH EDITION

Cumulative Supplement 3

MARCH 1994

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14TH EDITION

CUMULATIVE SUPPLEMENT 3

MARCH 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)
BANNER GELATIN PRODUCTS CORP (BANNER GELATIN)	BANNER PHARMACAPS INC (BANNER PHARMACAPS)
DUPONT PHARMACEUTICALS (DUPONT)	DUPONT MERCK PHARMACEUTICALS CO (DUPONT MERCK)
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 MARCH 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			
SINGLE SOURCE	2144 (23.5%)			
MULTISOURCE	6996 (76.5%)			
THERAPEUTICALLY EQUIVALENT	6292 (68.8%)			
NOT THERAPEUTICALLY EQUIVALENT	527 (5.8%)			
EXCEPTIONS[1]	177 (1.9%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	526			

[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

>ADD> ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE

>ADD> CAPSULE; ORAL
>ADD> SEMPREX-D
>ADD> + BURROUGHS WELLCOME 8MG;60MG N19806 001 MAR 25, 1994
>ADD>

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/	/ELKINS/SINN/	/EQ 50MG BASE/ML/	/N63274/001/	/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

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

TABLET; ORAL

AMINOPHYLLINE

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

AMOXICILLIN

CAPSULE; ORAL

POLYMOX

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

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

INJECTABLE; INJECTION

> DLT >		/M.V.C. 966/		
> DLT >	/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/
> ADD >		∂ 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

> ADD >	AB	GENPHARM	50MG	N74126 001 MAR 23, 1994
> ADD >	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

/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

BETAMETHASONE DIPROPIONATE

CREAM, AUGMENTED; TOPICAL

> DLT >		/DIPROLENE/		
> DLT >		/+//SCHERING/	/EQ/0.05%/BASE/	/N19408/001/ /JAN/31,/1986/
> ADD >		∂ SCHERING	EQ 0.05% BASE	N19408 001 JAN 31, 1986

GEL; TOPICAL

DIPROLENE

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

BUDESONIDE

AEROSOL, METERED; NASAL

RHINOCORT

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

BUTABARBITAL SODIUM

TABLET; ORAL

SODIUM BUTABARBITAL

> DLT >	/AA/	/ZENITH/	/30MG/	/N84040/001/
> ADD >		∂ ZENITH	30MG	N84040 001

CARBAMAZEPINE

SUSPENSION; ORAL

TEGRETOL

> ADD >		+ BASEL PHARMS	100MG/5ML	N18927 001 DEC 18, 1987
> DLT >		/+//GEIGY/	/100MG/5ML/	/N18927/001/ /DEC/18,/1987/

TABLET; ORAL

TEGRETOL

> ADD >	AB	+ BASEL PHARMS	200MG	N16608 001
> DLT >	/AB/	/+//GEIGY/	/200MG/	/N16608/001/

TABLET, CHEWABLE; ORAL

TEGRETOL

> ADD >	AB	+ BASEL PHARMS	100MG	N18281 001
> DLT >	/AB/	/+//GEIGY/	/100MG/	/N18281/001/

CARBIDOPA; LEVODOPA

TABLET; ORAL
CARBIDOPA AND LEVODOPA

> ADD >	AB	SCS PHARMS	10MG;100MG	N74080 001 MAR 25, 1994
> ADD >	AB		25MG;100MG	N74080 002 MAR 25, 1994
> ADD >	AB		25MG;250MG	N74080 003 MAR 25, 1994

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL
CEFADROXIL

> ADD >	AB	ZENITH	EQ 500MG BASE	N62766 001 MAR 03, 1987
> DLT >		/CEFADROXIL/		
> DLT >		/3/ZENITH/	/EQ/500MG/BASE/	/N62766/001/ /MAR/03,/1987/

TABLET; ORAL
CEFADROXIL

> ADD >	AB	ZENITH	EQ 1GM BASE	N62774 001 APR 08, 1987
> DLT >		/CEFADROXIL/		
> DLT >		/3/ZENITH/	/EQ/1GM/BASE/	/N62774/001/ /APR/08,/1987/

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION
CEFIZOX

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

CHLORAMPHENICOL

OINTMENT; OPHTHALMIC
/CHLOROFAIR/

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

CHLORAMPHENICOL

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

> DLT >	/AA/	/ZENITH/	/4MG/	/N80779/001/
> ADD >		@ ZENITH	4MG	N80779 001

CHLORTHALIDONE

TABLET; ORAL
THALITONE

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

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

> DLT >	/AP/	/DUPONT/	/EQ 150MG BASE/ML/	/N62908/001/ /FEB/01,/1989/
> ADD >		@ DUPONT MERCK	EQ 150MG BASE/ML	N62908 001 FEB 01, 1989
> DLT >	/AP/	/FUJISAWA/	/EQ 150MG BASE/ML/	/N62747/001/ /JUN/03,/1988/
> ADD >		@ 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	

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

CORTISONE ACETATE

INJECTABLE; INJECTION

>DLT>	/CORTISONE/ACETATE/			
>DLT>	/BP/ /STERIS/	/25MG/ML/	/N85677/001/	
>DLT>	/BP/	/50MG/ML/	/N85677/002/	
	/BP/ /STERIS/	/25MG/ML/	/N83147/003/	
	/BP/	/50MG/ML/	/N83147/004/	
	@ STERIS	25MG/ML	N83147 003	
>ADD>	@	25MG/ML	N85677 001	
	@	50MG/ML	N83147 004	
>ADD>	@	50MG/ML	N85677 002	

CORTISONE ACETATE

INJECTABLE; INJECTION

	/CORTISONE/ACETATE/			
	/BP/ /UPJOHN/	/25MG/ML/	/N08126/002/	
	@ UPJOHN	25MG/ML	N08126 002	
	CORTONE			
>DLT>	/BP/ /MSD/	/25MG/ML/	/N07110/002/	
>DLT>	/BP/+/	/50MG/ML/	/N07110/003/	
>ADD>	+ MSD	50MG/ML	N07110 003	
>ADD>		25MG/ML	N07110 002	

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL

	CYPROHEPTADINE HCL			
>DLT>/AA/	/CHELSEA/	/4MG/	/N86165/001/	
>ADD>	@ CHELSEA	4MG	N86165 001	

CYTARABINE

INJECTABLE; INJECTION

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

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

>ADD>	DESMOPRESSIN ACETATE			
>ADD>	+ RHONE POULENC RORER	0.15MG/INH	N20355 001	
>ADD>			MAR 07, 1994	

DEXTROAMPHETAMINE SULFATE

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

DEXTROTHYROXINE SODIUM

TABLET; ORAL

	CHOLOXIN			
	+ BOOTS	4MG	N12302 004	
	/+/	/6MG/	/N12302/006/	
		/4MG/	/N12302/004/	
	@	6MG	N12302 006	

DILTIAZEM HYDROCHLORIDE

TABLET; ORAL
DILTIAZEM HCL

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

ERYTHROMYCIN

SOLUTION; TOPICAL
ERYTHROMYCIN

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/	
	ə DISTA	EQ 200MG BASE/5ML	N62177 001	
	ə	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	
	ə	EQ 400MG BASE	N61905 001	

ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
/DELANUMONE/

/AO//+//SQUIBB/	/4MG/ML;90MG/ML/	/N09545/001/	
ə 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

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

ETHAMBUTOL HYDROCHLORIDE

TABLET; ORAL
MYAMBUTOL

>ADD>	+ LEDERLE	400MG	N16320 003	
>DLT>	/+/	/500MG/	/N16320/004/	
>DLT>		/200MG/	/N16320/002/	
>ADD>	ə	200MG	N16320 002	
>DLT>		/400MG/	/N16320/003/	
>ADD>	ə	500MG	N16320 004	

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/	

FLUMAZENIL

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

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

INJECTABLE; INJECTION
GARAMYCIN
>ADD > AP + SCHERING — EQ 2MG BASE/ML — N50505 001
>DLT > /+/ /EQ/2MG/BASE/ML/ /N50505/001/

GLYCOPYRROLATE

INJECTABLE; INJECTION
GLYCOPYRROLATE
>DLT >/AP/ /FUJISAWA/ /0.2MG/ML/ /N88475/001/
>DLT > /JUN/12,/1984/
>ADD > @ FUJISAWA — 0.2MG/ML — N88475 001 JUN 12, 1984
>ADD >

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

GUANABENZ ACETATE

TABLET; ORAL
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
>DLT >/AB/ /ZENITH/ /50MG/ /N84658/001/
>ADD > @ ZENITH — 50MG — N84658 001

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL
DYAZIDE
>DLT >/AB//+//SMITHKLINE/BEECHAM/ /25MG;50MG/ /N16042/002/
>ADD > SMITHKLINE BEECHAM — 25MG;37.5MG — N16042 003 MAR 03, 1994
>ADD >
>ADD > @ — 25MG;50MG — N16042 002
TRIAMTERENE AND HYDROCHLOROTHIAZIDE
>DLT >/AB/ /GENEVA/PHARMS/ /25MG;50MG/ /N73191/001/
>DLT > /JUL/31,/1991/
>ADD > + GENEVA PHARMS — 25MG;50MG — N73191 001 JUL 31, 1991
>ADD >

HYDROCORTISONE

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

> DLT >	/AT/	/PARKE/DAVIS/	/1%/		/N89914/001/
> DLT >					/JAN/03,/1989/
> ADD >		@ PARKE DAVIS	1%		N89914 001
> ADD >					JAN 03, 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

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

> ADD > INSULIN BIOSYNTHETIC HUMAN

> ADD > INJECTABLE; INJECTION
> ADD > HUMULIN R

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

> ADD > IOBENGUANE SULFATE I 131

> ADD > INJECTABLE; INJECTION
> ADD > IOBENGUANE SULFATE I 131

> ADD >		CIS	2.3 MCI/ML	N20084 001
> ADD >				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

KANAMYCIN SULFATE

CAPSULE; ORAL
KANTREX

> DLT >	/+//APOTHECON/	/EQ/500MG/BASE/		/N61911/001/
> ADD >	+ APOTHECON	EQ 500MG BASE		N62726 001
> ADD >				MAR 06, 1987
	@	EQ 500MG BASE		N60516 001
> ADD >	@	EQ 500MG BASE		N61911 001
> DLT >		/EQ/500MG/BASE/		/N62726/001/
> DLT >				/MAR/06,/1987/
	/AB//+//BRISTOL/	/EQ 500MG BASE/		/N60516/001/

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANTREX

>DLT >/AP//+//APOTHECON/	/EQ 75MG BASE/2ML/	/N61655/003/				
>DLT >/AP/	/EQ 75MG BASE/2ML/	/N61901/003/				
>ADD > AP + APOTHECON	EQ 75MG BASE/2ML	N61901 003	>ADD >	AT	0.5%	N74326 001
>DLT >/AP//+/	/EQ 500MG BASE/2ML/	/N61655/001/	>ADD >			MAR 04, 1994
>DLT >/AP/	/EQ 500MG BASE/2ML/	/N61901/001/				
>ADD > AP +	EQ 500MG BASE/2ML	N61901 001				
>DLT >/AP//+/	/EQ 1GM BASE/3ML/	/N61655/002/				
>DLT >/AP/	/EQ 1GM BASE/3ML/	/N61901/002/				
>ADD > AP +	EQ 1GM BASE/3ML	N61901 002				
>ADD > @	EQ 75MG BASE/2ML	N61655 003				
@	EQ 75MG BASE/2ML	N62564 001 SEP 21, 1984				
>ADD > @	EQ 500MG BASE/2ML	N61655 001				
@	EQ 500MG BASE/2ML	N62564 002 SEP 21, 1984				
>ADD > @	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

>ADD > AT + ALLERGAN	0.25%	N19814 001 JUN 28, 1989	>ADD >	AB	GENEVA PHARMS	50MG	N73288 001 MAR 25, 1994
>ADD >			>ADD >			
>ADD > AT +	0.5%	N19219 002 DEC 19, 1985	>ADD >	AB		100MG	N73289 001 MAR 25, 1994
>ADD >			>ADD >			

LEVOBUNOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

LEVOBUNOLOL HCL

>ADD >					
>ADD > AT	BAUSCH AND LOMB	0.25%	N74307 001 MAR 04, 1994		
>ADD >					
>ADD > AT		0.5%	N74326 001 MAR 04, 1994		
>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

>DLT >/AP/ /ADRIA/	/EQ 25MG BASE/ML/	/N89180/001/ /JAN/03,/1986/				
>DLT >						
>ADD > @ ADRIA	EQ 25MG BASE/ML	N89180 001 JAN 03, 1986				
>ADD >						

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

MINOCYCLINE HYDROCHLORIDE

TABLET; ORAL
/MINOCIN/
/ə/LEDERLE/ /EQ/50MG/BASE/ /N50451/003/ /AUG/10,/1982/
/ə/ /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
ə EQ 20GM BASE/VIAL N50320 006

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
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 14MG/24HR N20076 002 NOV 27, 1991
BC 21MG/24HR N20076 003 NOV 27, 1991
/BC/ /CIBA/GEIGY/ /7MG/24HR/ /N20076/001/ /NOV/27,/1991/
/BC/ /14MG/24HR/ /N20076/002/ /NOV/27,/1991/
/BC/ /21MG/24HR/ /N20076/003/ /NOV/27,/1991/

NITROGLYCERIN

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

NORETHINDRONE

TABLET; ORAL
/NORLUTIN/
/+//PARKE/DAVIS/ /5MG/ /N10895/002/
ə 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/ /JUL/30,/1986/	
	∂ PHARMAFAIR	100,000 UNITS/GM;0.1%	N62657 001 JUL 30, 1986	

ORPHENADRINE HYDROCHLORIDE

/TABLET;/ORAL/
/DISIPAL/

/3M/	/50MG/	/N10653/001/	
∂ 3M	50MG	N10653 001	

PAROXETINE HYDROCHLORIDE

TABLET; ORAL
PAXIL

>ADD>	+ SMITHKLINE BEECHAM	EQ 30MG BASE	N20031 003 DEC 29, 1992	
>ADD>				
>DLT>		/EQ/30MG/BASE/	/N20031/003/ /DEC/29,/1992/	
>DLT>				

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/

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
PHENDIMETRAZINE TARTRATE

>DLT>/AA/	/ZENITH/	/35MG/	/N85611/001/	
>ADD>	∂ ZENITH	35MG	N85611 001	

PILOCARPINE HYDROCHLORIDE

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

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

>DLT>/AP/	/FUJISAWA/	/2MEQ/ML/	/N87885/001/ /FEB/03,/1983/	
>DLT>				
>ADD>	∂ FUJISAWA	2MEQ/ML	N87885 001 FEB 03, 1983	
>ADD>				

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
/PREDAIR FORTE/

/AT/	/PHARMAFAIR/	/EQ 0.5% PHOSPHATE/	/N88165/001/ /MAR/28,/1983/	
	∂ PHARMAFAIR	EQ 0.9% PHOSPHATE	N88165 001 MAR 28, 1983	

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL
/REMSED/

>DLT>			
>DLT> /BP/	/DUPONT/	/25MG/	/N83176/002/

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

> DLT > /REMSED/
> ADD > @ DUPONT 25MG N83176 002

PROPANTHELINE BROMIDE

TABLET; ORAL
PRO-BANTHINE
AA ROBERTS LABS 7.5MG N08732 003
AA 15MG N08732 002
/AA/ /SCS/PHARMS/ /7.5MG/ /N08732/003/
/AA/ /15MG/ /N08732/002/

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

> ADD > CAPSULE; ORAL
> ADD > ZANTAC 150
> ADD > GLAXO EQ 150MG BASE N20095 001
> ADD > MAR 08, 1994
> ADD > ZANTAC 300
> ADD > + GLAXO EQ 300MG BASE N20095 002
> ADD > MAR 08, 1994

> ADD > GRANULE, EFFERVESCENT; ORAL
> ADD > ZANTAC 150
> ADD > + GLAXO EQ 150MG BASE/PACKET N20251 002
> ADD > MAR 31, 1994

> ADD > TABLET, EFFERVESCENT; ORAL
> ADD > ZANTAC 150
> ADD > + GLAXO EQ 150MG BASE N20251 001
> ADD > MAR 31, 1994

> ADD > ROCURONIUM BROMIDE

> ADD > INJECTABLE; INJECTION
> ADD > ZEMURON
> ADD > + ORGANON 10MG/ML N20214 002
> ADD > MAR 17, 1994
> ADD > ZEMURON (P/F)
> ADD > + ORGANON 10MG/ML N20214 001
> ADD > 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
> DLT > /S/BIOPLASTY/ /1%/ /N19608/001/
> DLT > /NOV/30,/1989/
> ADD > @ ENQUAY 1% N19608 001
> ADD > NOV 30, 1989

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

TABLET; ORAL
> DLT > /UROPLUS DS/
> DLT > /AB/ /SHIONOGI/ /800MG;160MG/ /N71816/001/
> DLT > /SEP/28,/1987/

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

>DLT>		/UROPLUS DS/			
>ADD>		ə SHIONOGI	800MG;160MG	N71816 001	
>ADD>				SEP 28, 1987	
>DLT>		/UROPLUS SS/			
>DLT>	/AB/	/SHIONOGI/	/400MG;80MG/	/N71815/001/	
>DLT>				/SEP/28,/1987/	
>ADD>		ə SHIONOGI	400MG;80MG	N71815 001	
>ADD>				SEP 28, 1987	

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

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

TETRACYCLINE HYDROCHLORIDE

SYRUP; ORAL

>ADD>		ACHROMYCIN V			
>ADD>	AB	+ LEDERLE	125MG/5ML	N50263 002	
>ADD>		SUMYCIN			
>ADD>	AB	SQUIBB	125MG/5ML	N60400 001	
>ADD>		TETRACYCLINE HCL			
>ADD>	AB	BARRE	125MG/5ML	N60633 001	
>ADD>	AB	MK	125MG/5ML	N60174 001	
>ADD>	AB	PUREPAC	125MG/5ML	N60291 001	

TETRACYCLINE HYDROCHLORIDE

SYRUP; ORAL

>ADD>		TETRACYN			
>ADD>	AB	PFIPHARMECS	125MG/5ML	N60095 001	
>ADD>		TETRAMED			
>ADD>	AB	ZENITH	125MG/5ML	N61468 001	

FIBER, EXTENDED RELEASE; PERIODONTAL

ACTISITE

>ADD>	+	ON SITE	12.7MG/FIBER	N50653 001
>ADD>				MAR 25, 1994

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

THEOPHYLLINE

		ə CENCI	80MG/15ML	N87679 001
				APR 15, 1982
/AB/		/LIFE/LABS/	/80MG/15ML/	/N87679/001/
				/APR/15,/1982/

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

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

TRIAZOLAM

TABLET; ORAL

		HALCION		
> ADD >	AB	UPJOHN	0.125MG	N17892 003
> ADD >				APR 26, 1985
> ADD >	AB		0.25MG	N17892 001
> ADD >				NOV 15, 1982
> ADD >		**TRIAZOLAM**		
> ADD >	AB	ALPHAPHARM	0.125MG	N74031 001
> ADD >				MAR 25, 1994
> ADD >	AB		0.25MG	N74031 002
> ADD >				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		
> DLT >/AP/		/FUJISAWA/	/1MG/ML/	/N70411/001/
> DLT >				/SEP/10,/1986/
> ADD >		⊖ FUJISAWA	1MG/ML	N70411 001
> ADD >				SEP 10, 1986
		VINCRISTINE SULFATE PFS		
/AP/		/BULL/	/1MG/ML/	/N71484/001/
				/APR/19,/1988/
AP		FAULDING	1MG/ML	N71484 001
				APR 19, 1988

IBUPROFEN

TABLET; ORAL
IBUPROFEN

>ADD<	MCNEIL	200MG	N73019 001 MAR 30, 1994
>ADD<	PRIVATE FORM	200MG	N73691 001 FEB 25, 1994

INSULIN SUSP ISOPHANE BEEF

INJECTABLE; INJECTION
NPH INSULIN

>DLT<	/#//NOVO/NORDISK/	/40/UNITS/ML/	/N17929/001/
>ADD<	@ 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

>DLT<	/#//BURROUGHS/WELLCOME/	/1%/	/N19918/001/
>DLT<			/MAY/02,/1990/
>ADD<	+ WARNER WELLCOME	1%	N19918 001
>ADD<			MAY 02, 1990

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
SUDAFED 12 HOUR

>DLT<	/#//BURROUGHS/WELLCOME/	/120MG/	/N73585/001/
>DLT<			/OCT/31,/1991/
>ADD<	+ WARNER WELLCOME	120MG	N73585 001
>ADD<			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 3 / MAR '94

NO MARCH 1994 APPROVALS

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

NAME *Generic/Chemical* *TN=Trade Name*	***INDICATION DESIGNATED***	***SPONSOR & ADDRESS*** *DD=Date Designated* *MA=Marketing Approval*
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 / /
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 / /
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 / /
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 / /
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 SYNDROME.	LEIRAS, INCORPORATED 1850 CENTENNIAL PARK DRIVE, SUITE 450 RESTON VA 22091 DD 03/01/94 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 / /
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 / /
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 / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

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

ORPHAN DRUG APPROVALS

DESMOPRESSIN ACETATE TN= DDAVP HIGH CONCENTRATION (1.5 MG/ML) NASAL SPRAY	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
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

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

NO MARCH 1994 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE

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.

ALBUTEROL (METERED DOSE INHALER - *IN VIVO*)	JAN 27, 1994
PHENYTOIN (SUSPENSION AND CHEWABLE TABLET)	MAR 04, 1994
PHENYTOIN SODIUM (CAPSULE, EXTENDED AND PROMPT)	MAR 04, 1994

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

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

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
>ADD>	19806 001	ACRIVASTINE; SEMPREX-D	4650807	MAR 17, 2004	U-93		
>ADD>			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
>ADD>	18731 001	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646	MAR 14, 2008	U-13		
>ADD>	18731 002	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646	MAR 14, 2008	U-13		
>ADD>	18343 001	CAPTOPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-10	JAN 28, 1997
>ADD>	18343 002	CAPTOPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-10	JAN 28, 1997
>ADD>	18343 003	CAPTOPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-10	JAN 28, 1997
>ADD>	18343 005	CAPTOPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-10	JAN 28, 1997
>ADD>	20062 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011			
>ADD>	20062 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011			
>ADD>	20062 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011			
>ADD>	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-10	DEC 30, 1996
	19949 002	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-10	DEC 30, 1996
	19949 003	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-10	DEC 30, 1996
	19950 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-10	DEC 30, 1996
	18936 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4018895	APR 19, 1994	U-12	I-10	FEB 28, 1997
	18936 006	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001		I-10	FEB 28, 1997
	20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001		I-10	FEB 28, 1997
>ADD>	20235 001	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
>ADD>	20235 002	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
>ADD>	20235 003	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
	19778 003	HYDROCHLOROTHIAZIDE; PRINZIDE 10-12.5	4472380	SEP 18, 2001			
			4374829	DEC 30, 2001	U-3	NS	NOV 18, 1996
	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>	20084 001	IOBENGUANE SULFATE I 131; IOBENGUANE SULFATE I 131				NCE	MAR 25, 1999
>ADD>	20083 001	ITRACONAZOLE; SPORANOX				I-104	MAR 29, 1997
	20219 001	LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN	4369184	JAN 18, 2000		NCE	NOV 10, 1998

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	20264 001	MEGESTROL ACETATE; MEGACE				NDF	SEP 10, 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
>ADD>	20237 001	PILOCARPINE HYDROCHLORIDE; SALAGEN				ODE	MAR 22, 2001
>ADD>						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
>ADD>	20095 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4521431	JUN 04, 2002		I-75	MAY 19, 1995
>ADD>			4128658	DEC 05, 1995		D-21	FEB 28, 1997
>ADD>	20095 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	4521431	JUN 04, 2002		I-75	MAY 19, 1995
>ADD>			4128658	DEC 05, 1995		D-21	FEB 28, 1997
>ADD>	20251 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4521431	JUN 04, 2002		I-75	MAY 19, 1995
>ADD>			4128658	DEC 05, 1995		D-21	FEB 28, 1997
>ADD>	20251 002	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4521431	JUN 04, 2002		I-75	MAY 19, 1995
>ADD>			4128658	DEC 05, 1995		D-21	FEB 28, 1997
>ADD>	20214 001	ROCURONIUM BROMIDE; ZEMURON (P/F)	4894369	JAN 16, 2007		NCE	MAR 17, 1999
>ADD>	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
	17376 001	SULFAMETHOXAZOLE; SEPTRA	4209513	JUN 24, 1997		I-10	JAN 07, 1997
	17376 002	SULFAMETHOXAZOLE; SEPTRA DS	4209513	JUN 24, 1997		I-10	JAN 07, 1997
	17377 001	SULFAMETHOXAZOLE; BACTRIM				I-10	JAN 07, 1997
	17377 002	SULFAMETHOXAZOLE; BACTRIM DS				I-10	JAN 07, 1997
	17560 002	SULFAMETHOXAZOLE; BACTRIM PEDIATRIC				I-10	JAN 07, 1997
	17598 001	SULFAMETHOXAZOLE; SEPTRA				I-10	JAN 07, 1997
	17598 002	SULFAMETHOXAZOLE; SEPTRA GRAPE				I-10	JAN 07, 1997
>DLT>	~~20284 001~~	~~SULFAMETHOXAZOLE; SEPTRA~~	~~4209513~~	~~JUN 24, 1997~~			
>DLT>	~~20284 002~~	~~SULFAMETHOXAZOLE; SEPTRA~~	~~4209513~~	~~JUN 24, 1997~~			
>ADD>	19762 001	TESTOSTERONE; TESTODERM	4867982	FEB 16, 2005			
>ADD>			4725439	FEB 16, 2005			
>ADD>			4704282	NOV 03, 2004		NDF	OCT 12, 1996
>ADD>	19762 002	TESTOSTERONE; TESTODERM	4867982	FEB 16, 2005			
>ADD>			4725439	FEB 16, 2005			
>ADD>			4704282	NOV 03, 2004		NDF	OCT 12, 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
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 — 301-037/80010