CUMULATIVE SUPPLEMENT 5

JAN'93-MAY'93

APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

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

Prepared By
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Office of Management
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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, 13th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

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

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

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

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

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the " ə " symbol to designate their non-marketed status. All products having a " ə " symbol in the 12th Cumulative Supplement of the 13th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 14th 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 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 5, 1985 (50 FR 27688)
Tranylcypromine Sulfate	MAR 22, 1984 (49 FR 10708)

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)
ASTRA PHARMACEUTICAL PRODUCTS INC (ASTRA)	ASTRA USA INC (ASTRA)
BAKER CUMMINS PHARMACEUTICALS INC (BAKER CUMMINS)	BAKER NORTON PHARMACEUTICALS INC (BAKER NORTON)
BOLAR PHARMACEUTICALS CO INC (BOLAR)	CIRCA PHARMACEUTICALS INC (CIRCA)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
HERBERT LABORATORIES DIV SMITH KLINE AND FRENCH CO (HERBERT)	ALLERGAN HERBERT DIV ALLERGAN INC (ALLERGAN HERBERT)
RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIV MCNEILAB (JOHNSON RW)	RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIV ORTHO PHARMACEUTICAL CORP (JOHNSON RW)

1.4 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 1993.

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1992) 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 1992	MAR 1993	JUN 1993	SEP 1993
DRUG PRODUCTS LISTED	9488	9392		
SINGLE SOURCE	2245 (23.7%)	2243 (23.9%)		
MULTISOURCE	7243 (76.3%)	7149 (76.1%)		
THERAPEUTICALLY EQUIVALENT	6516 (68.6%)	6432 (68.5%)		
NOT THERAPEUTICALLY EQUIVALENT	577 (6.1%)	562 (5.9%)		
EXCEPTIONS[1]	150 (1.6%)	155 (1.7%)		
NEW MOLECULAR ENTITIES APPROVED	--	3		
NUMBER OF APPLICANTS	477	484		

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

ANOQUAN

/AB/	/MALLARD/	/325MG;50MG;40MG/	/N87628/001/ /OCT/01,/1986/	
AB	ROBERTS HAUCK	325MG;50MG;40MG	N87628 001 OCT 01, 1986	

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

COMPAL

AA	PURDUE FREDERICK	356.4MG;30MG;16MG	N88584 001 MAR 04, 1986	
/AA/	/SOLVAY/	/356.4MG;30MG;16MG/	/N88584/001/ /MAR/04,/1986/	

ACETAMINOPHEN; CODEINE PHOSPHATE

CAPSULE; ORAL

>ADD>	ACETAMINOPHEN AND CODEINE PHOSPHATE			
>ADD>	∂ LEMMON	300MG;30MG	N88324 001 DEC 29, 1983	
>ADD>				
>DLT>	/ACETAMINOPHEN/W//CODEINE/#3/			
>DLT>	/LEMMON/	/300MG;30MG/	/N88324/001/ /DEC/29,/1983/	
>DLT>				

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

ALLAY

/AA/	/LUCHEM/	/500MG;5MG/	/N89907/001/ /JAN/13,/1989/	
AA	NORTON HN	500MG;5MG	N89907 001 JAN 13, 1989	

TABLET; ORAL

ANEXSIA

AA	BOEHRINGER MANNHEIM	500MG;5MG	N89160 001 APR 23, 1987	
/AA/	/SKCP/	/500MG;5MG/	/N89160/001/ /APR/23,/1987/	

ANEXSIA 7.5/650

AA	BOEHRINGER MANNHEIM	650MG;7.5MG	N89725 001 SEP 30, 1987	
/AA/	/SKCP/	/650MG;7.5MG/	/N89725/001/ /SEP/30,/1987/	

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

>DLT>	/DURADYNE DHC/			
>DLT> /AA/	/FOREST PHARMS/	/500MG;5MG/	/N87809/001/ /MAR/17,/1983/	
>DLT>				
>ADD>	∂ FOREST PHARMS	500MG;5MG	N87809 001 MAR 17, 1983	
>ADD>				

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

/AA/	/LUCHEM/	/500MG;5MG/	/N89696/001/ /APR/21,/1988/	
AA	NORTON HN	500MG;5MG	N89696 001 APR 21, 1988	
>DLT>	/NORCET/			
>DLT> /AA/	/ABANA/	/500MG;5MG/	/N88871/001/ /MAY/15,/1986/	
>DLT>				
>ADD>	∂ ABANA	500MG;5MG	N88871 001 MAY 15, 1986	
>ADD>				
	/TYCOLET/			
/AA/	/JOHNSON/RW/	/500MG;5MG/	/N89385/001/ /AUG/27,/1986/	
	∂ JOHNSON RW	500MG;5MG	N89385 001 AUG 27, 1986	

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

/ACETAZOLAMIDE SODIUM/

/AP/	/QUAD/	/EQ 500MG/VIAL/	/N89619/001/ /JAN/13,/1988/	
	∂ QUAD	EQ 500MG/VIAL	N89619 001 JAN 13, 1988	

DIAMOX

/AP/	/LEDERLE/	/EQ 500MG/VIAL/	/N09388/001/ /DEC/05,/1990/	
	LEDERLE	EQ 500MG/VIAL	N09388 001 DEC 05, 1990	

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ZOVIRAX

>ADD>	+ BURROUGHS WELLCOME	EQ 1GM BASE/VIAL	N18603 002 JUN 29, 1989	
>ADD>				
>ADD>	∂	EQ 250MG BASE/VIAL	N18603 003 AUG 30, 1983	
>ADD>				

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE

>ADD > AN	COPLEY	EQ 0.083% BASE	N73495 001	
>ADD >			MAY 28, 1993	

SYRUP; ORAL
ALBUTEROL SULFATE

AA	WATSON LABS	EQ 2MG BASE/5ML	N73165 001	
			APR 29, 1993	

TABLET, EXTENDED RELEASE; ORAL
PROVENTIL

/AB/	/#//SCHERING/	/EQ 4MG BASE/	/N19383/001/	
			/JUL/13,/1987/	
BC +	SCHERING	EQ 4MG BASE	N19383 001	
			JUL 13, 1987	

VOLMAX

/AB/	/GLAXO/	/EQ 4MG BASE/	/N19604/002/	
			/DEC/23,/1992/	
BC	GLAXO	EQ 4MG BASE	N19604 002	
			DEC 23, 1992	

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL
AMANTADINE HCL

/AB/	/BOLAR/	/100MG/	/N71382/001/	
			/JAN/21,/1987/	
	∂ BOLAR	100MG	N71382 001	
			JAN 21, 1987	

>DLT >	/TABLET;/ORAL/			
>DLT >	/SYMMETREL/			
>DLT >	/#//DUPONT/	/100MG/	/N18101/001/	
>ADD >	∂ DUPONT	100MG	N18101 001	

AMDINOCILLIN

>DLT >	/INJECTABLE;/INJECTION/			
>DLT >	/COACTIN/			
>DLT >	/ROCHE/	/250MG/VIAL/	/N50565/001/	
>DLT >			/DEC/21,/1984/	
>DLT >		/500MG/VIAL/	/N50565/002/	
>DLT >			/DEC/21,/1984/	
>DLT >		/1GM/VIAL/	/N50565/003/	
>DLT >			/DEC/21,/1984/	

AMDINOCILLIN

>DLT >	/INJECTABLE;/INJECTION/			
>DLT >	/COACTIN/			
>DLT >	∂ ROCHE	250MG/VIAL	N50565 001	
>ADD >			DEC 21, 1984	
>ADD >	∂	500MG/VIAL	N50565 002	
>ADD >			DEC 21, 1984	
>ADD >	∂	1GM/VIAL	N50565 003	
>ADD >			DEC 21, 1984	

AMINO ACIDS

INJECTABLE; INJECTION
NOVAMINE 15% SULFITE FREE IN PLASTIC CONTAINER

BAXTER	15%	N20107 001	
		FEB 05, 1993	
/NOVAMINE/8.5%/			
/KABIVITRUM/	/8.5%/	/N17957/002/	
		/AUG/09,/1982/	
∂ KABIVITRUM	8.5%	N17957 002	
		AUG 09, 1982	

TRAVASOL 10% IN PLASTIC CONTAINER

BAXTER	10%	N18931 003	
		AUG 23, 1984	
	/10%/	/N18931/004/	
		/APR/21,/1988/	

/TRAVASOL/10%/W/O/ELECTROLYTES/IN/PLASTIC/CONTAINER/

/BAXTER/	/10%/	/N18931/003/	
		/AUG/23,/1984/	

TRAVASOL 5.5% IN PLASTIC CONTAINER

BAXTER	5.5%	N18931 001	
		AUG 23, 1984	

/TRAVASOL/5.5%/W/O/ELECTROLYTES/IN/PLASTIC/CONTAINER/

/BAXTER/	/5.5%/	/N18931/001/	
		/AUG/23,/1984/	

TRAVASOL 8.5% IN PLASTIC CONTAINER

BAXTER	8.5%	N18931 002	
		AUG 23, 1984	

/TRAVASOL/8.5%/W/O/ELECTROLYTES/IN/PLASTIC/CONTAINER/

/BAXTER/	/8.5%/	/N18931/002/	
		/AUG/23,/1984/	

AMINOCAPROIC ACID

INJECTABLE; INJECTION
AMINOCAPROIC ACID

/AP/	/LYPHOMED/	/250MG/ML/	/N70522/001/	
			/JUN/17,/1986/	
	∂ LYPHOMED	250MG/ML	N70522 001	
			JUN 17, 1986	

AMINOPHYLLINE

INJECTABLE; INJECTION

AMINOPHYLLINE

> ADD >	AP	FUJISAWA	25MG/ML	N88407 001
> ADD >				JAN 25, 1984
> DLT >	/AP/	/LYPHOMED/	/25MG/ML/	/N88407/001/
> DLT >				/JAN/25,/1984/

AMITRIPTYLINE HYDROCHLORIDE

INJECTABLE; INJECTION

ELAVIL

/AP/	/MSD/	/10MG/ML/	/N12704/001/
AP	ZENECA	10MG/ML	N12704 001

TABLET; ORAL

ELAVIL

/AB/	/MSD/	/10MG/	/N12703/001/
/AB/		/25MG/	/N12703/003/
/AB/		/50MG/	/N12703/004/
/AB/		/75MG/	/N12703/005/
/AB/		/100MG/	/N12703/006/
/AB/		/150MG/	/N12703/007/
AB	ZENECA	10MG	N12703 001
AB	+	25MG	N12703 003
AB		50MG	N12703 004
AB		75MG	N12703 005
AB		100MG	N12703 006
AB		150MG	N12703 007

AMOXICILLIN

CAPSULE; ORAL

TRIMOX

/AB/	/SQUIBB/	/250MG/	/N62098/001/
/AB/		/250MG/	/N62152/001/
/AB/		/500MG/	/N62098/002/
/AB/		/500MG/	/N62152/002/
	∂ APOTHECON	250MG	N62098 001
	∂	250MG	N62152 001
	∂	500MG	N62098 002
	∂	500MG	N62152 002

AMOXICILLIN

POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN

> ADD >	AB	CLONMEL	125MG/5ML	N62927 001
> ADD >				NOV 25, 1988
> ADD >	AB		250MG/5ML	N62927 002
> ADD >				NOV 25, 1988
> DLT >	/BX/		/125MG/5ML/	/N62927/001/
> DLT >				/NOV/25,/1988/
> DLT >	/BX/		/250MG/5ML/	/N62927/002/
> DLT >				/NOV/25,/1988/

TRIMOX

/AB/	/SQUIBB/	/125MG/5ML/	/N62099/001/
/AB/		/125MG/5ML/	/N62154/001/
/AB/		/250MG/5ML/	/N62099/002/
/AB/		/250MG/5ML/	/N62154/002/
	∂ APOTHECON	125MG/5ML	N62099 001
	∂	125MG/5ML	N62154 001
	∂	250MG/5ML	N62099 002
	∂	250MG/5ML	N62154 002

AMPHETAMINE ADIPATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE ADIPATE; DEXTROAMPHETAMINE SULFATE

/CAPSULE;/ORAL/

DELCOBESE

LEMMON

/1.25MG;1.25MG;1.25MG;/		
/1.25MG/	/N83564/001/	
/2.5MG;2.5MG;2.5MG;2.5MG/	/N83564/002/	
/3.75MG;3.75MG;3.75MG;/		
/3.75MG/	/N83564/003/	
/5MG;5MG;5MG;5MG/	/N83564/004/	
∂ LEMMON	1.25MG;1.25MG;1.25MG; 1.25MG	N83564 001
∂	2.5MG;2.5MG;2.5MG;2.5MG	N83564 002
∂	3.75MG;3.75MG;3.75MG; 3.75MG	N83564 003
∂	5MG;5MG;5MG;5MG	N83564 004

/TABLET;/ORAL/

DELCOBESE

LEMMON

/1.25MG;1.25MG;1.25MG;/	
/1.25MG/	/N83563/004/
/2.5MG;2.5MG;2.5MG;2.5MG/	/N83563/003/
/3.75MG;3.75MG;3.75MG;/	
/3.75MG/	/N83563/002/
/5MG;5MG;5MG;5MG/	/N83563/001/

AMPHETAMINE ADIPATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE ADIPATE; DEXTROAMPHETAMINE SULFATE

/TABLET;/ORAL/
/DELCOBESE/

∂	LEMMON	1.25MG;1.25MG;1.25MG; 1.25MG	N83563 004
∂		2.5MG;2.5MG;2.5MG;2.5MG	N83563 003
∂		3.75MG;3.75MG;3.75MG; 3.75MG	N83563 002
∂		5MG;5MG;5MG;5MG	N83563 001

AMPICILLIN SODIUM

INJECTABLE; INJECTION
AMPICILLIN SODIUM

AP	HANFORD	EQ 125MG BASE/VIAL	N63143 001 APR 15, 1993
AP		EQ 250MG BASE/VIAL	N63145 001 APR 15, 1993
AP		EQ 500MG BASE/VIAL	N63146 001 APR 15, 1993
AP		EQ 500MG BASE/VIAL	N63147 001 APR 15, 1993
AP		EQ 1GM BASE/VIAL	N62772 001 APR 15, 1993
AP		EQ 1GM BASE/VIAL	N63139 001 APR 15, 1993
AP		EQ 2GM BASE/VIAL	N63140 001 APR 15, 1993
AP		EQ 2GM BASE/VIAL	N63141 001 APR 15, 1993
AP		EQ 10GM BASE/VIAL	N63142 001 APR 15, 1993
/AP/	/LILLY/	/EQ 500MG BASE/VIAL/	/N62565/001/ /APR 04, 1985/
/AP/		/EQ 1GM BASE/VIAL/	/N62565/002/ /APR 04, 1985/
/AP/		/EQ 2GM BASE/VIAL/	/N62565/003/ /JUN 24, 1986/
	∂ LILLY	EQ 500MG BASE/VIAL	N62565 001 APR 04, 1985
	∂	EQ 1GM BASE/VIAL	N62565 002 APR 04, 1985
	∂	EQ 2GM BASE/VIAL	N62565 003 JUN 24, 1986
	PENBRITIN-S /WYETH/AYERST/	/EQ 4GM BASE/VIAL/	/N50072/006/
	∂ WYETH AYERST	EQ 4GM BASE/VIAL	N50072 006

AMPICILLIN SODIUM; SULBACTAM SODIUM

INJECTABLE; INJECTION
UNASYN

	/PFIZER/	/EQ 500MG BASE/VIAL;/ /EQ 250MG BASE/VIAL/	/N50608/003/ /DEC 31, 1986/
	∂ PFIZER	EQ 500MG BASE/VIAL; EQ 250MG BASE/VIAL	N50608 003 DEC 31, 1986

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL
/PRINCIPEN '250'/

/AB/	/SQUIBB/	/EQ 250MG BASE/	/N50056/001/
/AB/		/EQ 250MG BASE/	/N62157/002/
	∂ APOTHECON	EQ 250MG BASE	N50056 001
	∂	EQ 250MG BASE	N62157 002

/PRINCIPEN '500'/

/AB/	/SQUIBB/	/EQ 500MG BASE/	/N50056/002/
/AB/		/EQ 500MG BASE/	/N62157/001/
	∂ APOTHECON	EQ 500MG BASE	N50056 002
	∂	EQ 500MG BASE	N62157 001

POWDER FOR RECONSTITUTION; ORAL
/PRINCIPEN '125'/

/AB/	/SQUIBB/	/EQ 125MG BASE/5ML/	/N60127/002/
/AB/		/EQ 125MG BASE/5ML/	/N62151/001/
	∂ APOTHECON	EQ 125MG BASE/5ML	N60127 002
	∂	EQ 125MG BASE/5ML	N62151 001

/PRINCIPEN '250'/

/AB/	/SQUIBB/	/EQ 250MG BASE/5ML/	/N60127/001/
/AB/		/EQ 250MG BASE/5ML/	/N62151/002/
	∂ APOTHECON	EQ 250MG BASE/5ML	N60127 001
	∂	EQ 250MG BASE/5ML	N62151 002

AMPICILLIN/AMPICILLIN TRIHYDRATE; PROBENECID

/CAPSULE;/ORAL/
/PRINCIPEN/W/PROBENECID/

/+//SQUIBB/		/EQ 389MG BASE;111MG/	/N50488/001/
		/EQ 389MG BASE;111MG/	/N62150/001/
	∂ APOTHECON	EQ 389MG BASE;111MG	N50488 001
	∂	EQ 389MG BASE;111MG	N62150 001

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
/AP/	/LYPHOMED/	/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/

ASPIRIN; BUTALBITAL

TABLET; ORAL
AXOTAL

/+//ADRIA/		/650MG;50MG/	/N88305/001/ /OCT/13,/1983/
+	SAVAGE	650MG;50MG	N88305 001 OCT 13, 1983

ATENOLOL

TABLET; ORAL
ATENOLOL

AB		MUTUAL PHARM	50MG	N73475 001 MAR 30, 1993
AB			100MG	N73476 001 MAR 30, 1993
>ADD>	AB	NOVOPHARM	50MG	N73315 001 MAY 28, 1993
>ADD>	AB		100MG	N73316 001 MAY 28, 1993

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL
ATENOLOL AND CHLORTHALIDONE

AB	MUTUAL PHARM	50MG;25MG	N73581 001 APR 29, 1993
AB		100MG;25MG	N73582 001 APR 29, 1993

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION
/AZATHIOPRINE/

/AP/	/QUAD/	/EQ 100MG BASE/VIAL/	/N71056/001/ /JUN/08,/1988/
	ə QUAD	EQ 100MG BASE/VIAL	N71056 001 JUN 08, 1988

IMURAN

/AP/	/BURROUGHS/WELLCOME/	/EQ 100MG BASE/VIAL/	/N17391/001/
	BURROUGHS WELLCOME	EQ 100MG BASE/VIAL	N17391 001

AZLOCILLIN SODIUM

INJECTABLE; INJECTION
AZLIN

	/MILES/	/EQ/2GM/BASE/VIAL/	/N62388/001/ /SEP/08,/1982/
	ə MILES	EQ 2GM BASE/VIAL	N62388 001 SEP 08, 1982
		/EQ/2GM/BASE/VIAL/	/N62417/001/ /OCT/12,/1982/
	ə	EQ 2GM BASE/VIAL	N62417 001 OCT 12, 1982
		/EQ/4GM/BASE/VIAL/	/N62388/003/ /SEP/08,/1982/
	ə	EQ 4GM BASE/VIAL	N62388 003 SEP 08, 1982
		/EQ/4GM/BASE/VIAL/	/N62417/003/ /OCT/12,/1982/
	ə	EQ 4GM BASE/VIAL	N62417 003 OCT 12, 1982

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
BACITRACIN-NEOMYCIN-POLYMYXIN

>DLT>	/PHARMADERM/	/400/UNITS/GM;EQ/3.5MG/BASE/GM;/ /5,000/UNITS/GM/	/N62167/001/
>ADD>	ə PHARMADERM	400 UNITS/GM;EQ 3.5MG BASE/GM; 5,000 UNITS/GM	N62167 001

BENTIROMIDE

SOLUTION; ORAL
CHYMEX

	/ADRIA/	/500MG/7.5ML/	/N18366/001/ /DEC/29,/1983/

BENTIROMIDE

SOLUTION; ORAL

CHYMEX SAVAGE	500MG/7.5ML	N18366 001 DEC 29, 1983	

BENZONATATE

CAPSULE; ORAL

BENZONATATE			
AA PHARMACAPS	100MG	N81297 001 JAN 29, 1993	
TESSALON			
AA FOREST LABS	100MG	N11210 001	

BENZTHIAZIDE

TABLET; ORAL

/AQUATAG/			
/BP/ /SOLVAY/	/50MG/	/N16001/002/	
ə SOLVAY	50MG	N16001 002	
EXNA			
/BP/+//ROBINS/	/50MG/	/N12489/001/	
+ ROBINS	50MG	N12489 001	

BEPRIDIL HYDROCHLORIDE

TABLET; ORAL

/BEPADIN/			
/AB/ /WALLACE/	/200MG/	/N19001/001/	/DEC/28,/1990/
/AB/	/300MG/	/N19001/002/	/DEC/28,/1990/
/AB/	/400MG/	/N19001/003/	/DEC/28,/1990/
ə WALLACE	200MG	N19001 001	DEC 28, 1990
ə	300MG	N19001 002	DEC 28, 1990
ə	400MG	N19001 003	DEC 28, 1990

BEPRIDIL HYDROCHLORIDE

TABLET; ORAL

VASCOR			
/AB/ /JOHNSON/RW/	/200MG/	/N19002/001/	/DEC/28,/1990/
/AB/	/300MG/	/N19002/002/	/DEC/28,/1990/
/AB//+/	/400MG/	/N19002/003/	/DEC/28,/1990/
+ JOHNSON RW	400MG	N19002 003	DEC 28, 1990
	200MG	N19002 001	DEC 28, 1990
	300MG	N19002 002	DEC 28, 1990

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

BETAMETHASONE DIPROPIONATE			
/AB/ /PHARMADERM/	/EQ 0.05% BASE/	/N19136/001/	/JUN/26,/1984/
ə PHARMADERM	EQ 0.05% BASE	N19136 001	JUN 26, 1984

LOTION; TOPICAL

BETAMETHASONE DIPROPIONATE			
/AB/ /PHARMADERM/	/EQ 0.05% BASE/	/N70274/001/	/AUG/12,/1985/
ə PHARMADERM	EQ 0.05% BASE	N70274 001	AUG 12, 1985

OINTMENT; TOPICAL

BETAMETHASONE DIPROPIONATE			
/AB/ /PHARMADERM/	/EQ 0.05% BASE/	/N19140/001/	/SEP/04,/1984/
ə PHARMADERM	EQ 0.05% BASE	N19140 001	SEP 04, 1984

BETAMETHASONE VALERATE

CREAM; TOPICAL

BETAMETHASONE VALERATE			
/AB/ /PHARMADERM/	/EQ 0.1% BASE/	/N18860/002/	/AUG/31,/1983/
ə PHARMADERM	EQ 0.1% BASE	N18860 002	AUG 31, 1983

BETAMETHASONE VALERATE

LOTION; TOPICAL

	BETAMETHASONE VALERATE			
/AB/	/PHARMADERM/	/EQ 0.1% BASE/	/N18870/001/	
			/AUG/31,/1983/	
	∂ PHARMADERM	EQ 0.1% BASE	N18870 001	
			AUG 31, 1983	

OINTMENT; TOPICAL

	BETAMETHASONE VALERATE			
>ADD > AB	NMC	EQ 0.1% BASE	N70051 001	
>ADD >			OCT 10, 1984	
	BETAMETHASONE VALERATE			
/AB/	/PHARMADERM/	/EQ 0.1% BASE/	/N18864/001/	
			/AUG/31,/1983/	
	∂ PHARMADERM	EQ 0.1% BASE	N18864 001	
			AUG 31, 1983	
>DLT >	/VALHAC/			
>DLT >/AB/	/NMC/	/EQ 0.1% BASE/	/N70051/001/	
>DLT >			/OCT/10,/1984/	

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

ZIAC			
+ LEDERLE	10MG;6.25MG	N20186 002	
		MAR 26, 1993	
	2.5MG;6.25MG	N20186 003	
		MAR 26, 1993	
	5MG;6.25MG	N20186 001	
		MAR 26, 1993	

BROMPHENIRAMINE MALEATE

TABLET; ORAL

	BROMPHENIRAMINE MALEATE			
>DLT >/AA/	/ANABOLICS/	/4MG/	/N86187/001/	
>ADD >	∂ ANABOLICS	4MG	N86187 001	
>ADD > AA	NYLOS TRADING	4MG	N85592 001	
>DLT >/AA/	/TABLICAPS/	/4MG/	/N85592/001/	
/AA/	/ZENITH/	/4MG/	/N84351/001/	
	∂ ZENITH	4MG	N84351 001	

CALCITONIN, SALMON

INJECTABLE; INJECTION

	CALCIMAR			
/AP/	/RHONE/POULENC/RORER//200 IU/ML/		/N17769/001/	
AP +	RHONE POULENC RORER	200 IU/ML	N17769 001	
	MIACALCIN			
	/SANDOZ/	/100/IU/ML/	/N17808/001/	
			/JUL/03,/1986/	
	∂ SANDOZ	100 IU/ML	N17808 001	
			JUL 03, 1986	

CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE

SOLUTION; IRRIGATION

	ENDOSOL PLUS			
>ADD > AT	ALLERGAN	0.154MG/ML;0.92MG/ML;0.184MG/ML;		
>ADD >		0.2MG/ML;0.38MG/ML;2.1MG/ML;		
>ADD >		7.14MG/ML;0.42MG/ML	N20079 001	
>ADD >			NOV 27, 1991	
>DLT >/AT/	/ENTRAVISION/	/0.154MG/ML;0.92MG/ML;0.184MG/ML;/		
>DLT >		/0.2MG/ML;0.38MG/ML;2.1MG/ML;/		
>DLT >		/7.14MG/ML;0.42MG/ML/	/N20079/001/	
>DLT >			/NOV/27,/1991/	

CALCIUM GLUCEPTATE

INJECTABLE; INJECTION

	CALCIUM GLUCEPTATE			
/AP/	/LYPHOMED/	/EQ 90MG CALCIUM/5ML/	/N89373/001/	
			/APR/30,/1987/	
	∂ LYPHOMED	EQ 90MG CALCIUM/5ML	N89373 001	
			APR 30, 1987	

CARBINOXAMINE MALEATE

>DLT >	/TABLET;ORAL/			
>DLT >	/CLISTIN/			
>DLT >	/JOHNSON/RW/	/4MG/	/N08915/001/	
>ADD >	∂ JOHNSON RW	4MG	N08915 001	

CARISOPRODOL

/CAPSULE;ORAL/			
/SOMA/			
/WALLACE/	/250MG/	/N11792/003/	
∂ WALLACE	250MG	N11792 003	

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

/AA/	/PIONEER/PHARMS/	/350MG/	/N89390/001/ /OCT/13,/1988/
	ə PIONEER PHARMS	350MG	N89390 001 OCT 13, 1988
	/RELA/		
/AA/	/SCHERING/	/350MG/	/N12155/001/
	ə SCHERING	350MG	N12155 001

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

OPTIPRESS

	/BURROUGHS/WELLCOME/	/1%/	/N19972/001/ /MAY/23,/1990/
	OTSUKA	1%	N19972 001 MAY 23, 1990

CEFMENOXIME HYDROCHLORIDE

/INJECTABLE;/INJECTION/

/CEFMAX/

	/TAP/	/EQ/500MG/BASE/VIAL/	/N50571/001/ /DEC/30,/1987/
		/EQ/1GM/BASE/VIAL/	/N50571/002/ /DEC/30,/1987/
		/EQ/2GM/BASE/VIAL/	/N50571/003/ /DEC/30,/1987/
	ə TAP	EQ 500MG BASE/VIAL	N50571 001 DEC 30, 1987
	ə	EQ 1GM BASE/VIAL	N50571 002 DEC 30, 1987
	ə	EQ 2GM BASE/VIAL	N50571 003 DEC 30, 1987

CEFOTETAN DISODIUM

INJECTABLE; INJECTION

CEFOTAN

AP	STUART	EQ 1GM BASE/VIAL	N50588 001 DEC 27, 1985
AP		EQ 2GM BASE/VIAL	N50588 002 DEC 27, 1985
AP	ZENECA	EQ 1GM BASE/VIAL	N63293 001 APR 29, 1993
AP		EQ 2GM BASE/VIAL	N63293 002 APR 29, 1993

CEFOTIAM HYDROCHLORIDE

/INJECTABLE;/INJECTION/

/CERADON/

	/TAKEDA/	/EQ/1GM/BASE/VIAL/	/N50601/001/ /DEC/30,/1988/
	ə TAKEDA	EQ 1GM BASE/VIAL	N50601 001 DEC 30, 1988

CEFOXITIN SODIUM

INJECTABLE; INJECTION

MEFOXIN IN PLASTIC CONTAINER

	MERCK	EQ 20MG BASE/ML	N63182 001 JAN 25, 1993
		EQ 40MG BASE/ML	N63182 002 JAN 25, 1993

CEFPIRAMIDE SODIUM

/INJECTABLE;/INJECTION/

/CEFPIRAMIDE/SODIUM/

	/WYETH/AYERST/	/EQ/1GM/BASE/VIAL/	/N50633/002/ /JAN/31,/1989/
		/EQ/2GM/BASE/VIAL/	/N50633/003/ /JAN/31,/1989/
		/EQ/10GM/BASE/VIAL/	/N50633/005/ /JAN/31,/1989/
	ə WYETH AYERST	EQ 1GM BASE/VIAL	N50633 002 JAN 31, 1989
	ə	EQ 2GM BASE/VIAL	N50633 003 JAN 31, 1989
	ə	EQ 10GM BASE/VIAL	N50633 005 JAN 31, 1989

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION

CEFTAZIDIME SODIUM IN PLASTIC CONTAINER

AP	BAXTER	EQ 10MG BASE/ML	N63221 001 APR 29, 1993
AP		EQ 20MG BASE/ML	N63221 002 APR 29, 1993
AP		EQ 40MG BASE/ML	N63221 003 APR 29, 1993

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION
FORTAZ IN PLASTIC CONTAINER

AP	GLAXO	EQ 10MG BASE/ML	N50634 001 APR 28, 1989
AP		EQ 20MG BASE/ML	N50634 002 APR 28, 1989
AP		EQ 40MG BASE/ML	N50634 003 APR 28, 1989

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION
CEFIZOX

	FUJISAWA	EQ 10GM BASE/VIAL	N50560 005 MAR 19, 1993

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER

>DLT>	/ROCHE/	/EQ/10MG/BASE/ML/	/N50624/001/ /FEB/11,/1987/
>DLT>			
>ADD>	@ ROCHE	EQ 10MG BASE/ML	N50624 001 FEB 11, 1987
>ADD>			

CEFUROXIME SODIUM

INJECTABLE; INJECTION
CEFUROXIME

AP	MARSAM	EQ 750MG BASE/VIAL	N64035 001 FEB 26, 1993
AP		EQ 1.5GM BASE/VIAL	N64035 002 FEB 26, 1993
AP		EQ 7.5GM BASE/VIAL	N64036 001 FEB 26, 1993

KEFUROX

AP	LILLY	EQ 7.5GM BASE/VIAL	N62591 003 DEC 17, 1987

ZINACEF

AP	GLAXO	EQ 7.5GM BASE/VIAL	N50558 004 OCT 23, 1986

CELLULOSE SODIUM PHOSPHATE

POWDER; ORAL
CALCIBIND

/+/	/MISSION/PHARMA/	/2.5GM/PACKET/	/N18757/002/ /DEC/28,/1982/
	@ MISSION PHARMA	2.5GM/PACKET	N18757 002 DEC 28, 1982

CHLORDIAZEPOXIDE

>DLT>	/CAPSULE;/EXTENDED/RELEASE;/ORAL/		
>DLT>	/LIBRELEASE/		
>DLT>	/+/ROCHE/	/30MG/	/N17813/001/ /SEP/12,/1983/
>DLT>			
>ADD>	@ ROCHE	30MG	N17813 001 SEP 12, 1983
>ADD>			

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
CHLORDIAZEPOXIDE HCL

>DLT>	/AB/	/PIONEER/PHARMS/	/25MG/	/N89558/001/ /JUL/15,/1988/
>DLT>				
>ADD>		@ PIONEER PHARMS	25MG	N89558 001 JUL 15, 1988
>ADD>				

LIBRIUM

/AB/	/ROCHE/	/5MG/	/N12249/002/
/AB/		/10MG/	/N12249/001/
/AB/	/+/	/25MG/	/N12249/003/
/AB/		/25MG/	/N85475/001/
AB	+ ROCHE	25MG	N85475 001
	@	5MG	N12249 002
	@	10MG	N12249 001
	@	25MG	N12249 003

CHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
ALDOCLOR-150

/AB/	/MSD/	/150MG;250MG/	/N16016/001/
	MSD	150MG;250MG	N16016 001

ALDOCLOR-250

/AB/	/+/MSD/	/250MG;250MG/	/N16016/002/
	+ MSD	250MG;250MG	N16016 002

CHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
METHYLDOPA AND CHLOROTHIAZIDE

AB	PAR	150MG;250MG	N70783 001	NOV 06, 1987
AB		250MG;250MG	N70654 001	NOV 06, 1987
	∂ PAR	150MG;250MG	N70783 001	NOV 06, 1987
	∂	250MG;250MG	N70654 001	NOV 06, 1987

CHLOROTRIANISENE

CAPSULE; ORAL
TACE

MERRELL DOW	72MG	N16235 001	
∂ MERRELL DOW	72MG	N16235 001	

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHLORPROMAZINE HCL

AP	LYPHOMED	25MG/ML	N84911 001
	∂ LYPHOMED	25MG/ML	N84911 001

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

AB	PHARM BASICS	50MG	N89052 001 JUN 01, 1987
	∂ PHARM BASICS	50MG	N89052 001 JUN 01, 1987

CHLORTHALIDONE; METOPROLOL TARTRATE

CAPSULE; ORAL
LOPRESSIDONE

*	CIBA	25MG;200MG	N19451 002 DEC 31, 1987
*	CIBA	25MG;100MG	N19451 001 DEC 31, 1987
	∂ CIBA	25MG;100MG	N19451 001 DEC 31, 1987
	∂	25MG;200MG	N19451 002 DEC 31, 1987

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

AA	PIONEER PHARMS	250MG	N89592 001	JAN 06, 1989
AA		500MG	N89948 001	JAN 06, 1989
	∂ PIONEER PHARMS	250MG	N89592 001	JAN 06, 1989
	∂	500MG	N89948 001	JAN 06, 1989

CHYMOTRYPSIN

POWDER FOR RECONSTITUTION; OPHTHALMIC
CATARASE

>ADD>	+ IOLAB	300 UNITS/VIAL	N16938 001	
>DLT>		150 UNITS/VIAL	N18121 001	
>ADD>	∂	150 UNITS/VIAL	N18121 001	
>DLT>		300 UNITS/VIAL	N16938 001	

CLADRIBINE

INJECTABLE; INJECTION
LEUSTATIN

+	JOHNSON RW	1MG/ML	N20229 001 FEB 26, 1993

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL
CLEOCIN

AB	+ UPJOHN	EQ 75MG BASE	N50162 001
AB	+	EQ 75MG BASE	N61809 001
AB	+	EQ 150MG BASE	N50162 002
AB	+	EQ 150MG BASE	N61809 002
	∂	EQ 75MG BASE	N61809 001
	∂	EQ 150MG BASE	N61809 002

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLEOCIN PHOSPHATE

>ADD>	AP + UPJOHN	EQ 150MG BASE/ML	N50441 001	

CLONIDINE HYDROCHLORIDE

TABLET; ORAL
CLONIDINE HCL

/AB/	/BIOCRAFT/	/0.1MG/	/N70747/001/ /MAR/20/1986/
/AB/		/0.2MG/	/N70702/001/ /MAR/20/1986/
/AB/		/0.3MG/	/N70659/001/ /MAR/20/1986/
	ə BIOCRAFT	0.1MG	N70747 001 JUL 08, 1986
	ə	0.2MG	N70702 001 JUL 08, 1986
	ə	0.3MG	N70659 001 JUL 08, 1986

CLOTRIMAZOLE

/CREAM;/VAGINAL/
/GYNE-LOTRIMIN/

/BT/	/SCHERING/	/1%/	/N18052/001/
/BT/	/MYCELEX-G/ /MILES/	/1%/	/N18236/001/

/TABLET;/VAGINAL/
/GYNE-LOTRIMIN/

/BT/	/SCHERING/	/100MG/	/N17717/001/
/BT/	/MYCELEX-G/ /MILES/	/100MG/	/N18182/001/

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE

/BP/	/HEATHER/	/25MG/	/N85736/001/
	ə HEATHER	25MG	N85736 001

CYANOCOBALAMIN

INJECTABLE; INJECTION
CYANOCOBALAMIN

>ADD>	AP	FUJISAWA	0.1MG/ML	N80557 002
>ADD>	AP		1MG/ML	N80557 003
	/AP/		/1MG/ML/	/N83075/001/
		ə	1MG/ML	N83075 001
>DLT>	/AP/	/LYPHOMED/	/0.1MG/ML/	/N80557/002/
>DLT>	/AP/		/1MG/ML/	/N80557/003/

CYCLACILLIN

/POWDER/FOR/RECONSTITUTION;/ORAL/
/CYCLAPEN-W/

/+//WYETH/AYERST/		/500MG/5ML/	/N50508/003/
		/125MG/5ML/	/N50508/001/
		/250MG/5ML/	/N50508/002/
	ə WYETH AYERST	125MG/5ML	N50508 001
	ə	250MG/5ML	N50508 002
	ə	500MG/5ML	N50508 003

CYCLIZINE LACTATE

/INJECTABLE;/INJECTION/
/MAREZINE/

/BURROUGHS/WELLCOME/		/50MG/ML/	/N09495/001/
ə BURROUGHS WELLCOME		50MG/ML	N09495 001

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
CYCLOBENZAPRINE HCL

AB	INVAMED	10MG	N73683 001 FEB 26, 1993

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION
NEOSAR

AP	ADRIA	100MG/VIAL	N40015 001 APR 29, 1993
AP		200MG/VIAL	N40015 002 APR 29, 1993
AP		500MG/VIAL	N40015 003 APR 29, 1993
AP		1GM/VIAL	N40015 004 APR 29, 1993
AP		2GM/VIAL	N40015 005 APR 29, 1993

DESIPRAMINE HYDROCHLORIDE

/CAPSULE;/ORAL/
/PERTOFRANE/

/+//RHONE/POULENC/RORER/		/50MG/	/N13621/002/
		/25MG/	/N13621/001/
	ə RHONE POULENC RORER	25MG	N13621 001
	ə	50MG	N13621 002

DESLANOSIDE

/INJECTABLE;/INJECTION/
/CEDILANID-D/
/SANDOZ/ /0.2MG/ML/ /N09282/002/
ə SANDOZ 0.2MG/ML N09282 002

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL
DDAVP
RHONE POULENC RORER 0.01MG/INH N17922 002
FEB 06, 1989

DESOXYCORTICOSTERONE PIVALATE

/INJECTABLE;/INJECTION/
/PERCORTEN/
/CIBA/ /25MG/ML/ /N08822/001/
ə CIBA 25MG/ML N08822 001

DEXAMETHASONE

ELIXIR; ORAL
DEXAMETHASONE
AA BARRE 0.5MG/5ML N88997 001
OCT 10, 1986
/AA/ /NASKA/ /0.5MG/5ML/ /N88997/001/
/OCT/10/1986/

SOLUTION; ORAL
/DEXAMETHASONE/
/ROXANE/ /0.5MG/5ML/ /N88248/001/
/SEP/01/1983/
ə ROXANE 0.5MG/5ML N88248 001
SEP 01, 1983

TABLET; ORAL
DECADRON
AB MSD 0.5MG N11664 001
AB + 0.75MG N11664 002
AB 1.5MG N11664 003
AB 4MG N11664 005
/BP/ /0.5MG/ /N11664/001/
/BP/+/ /0.75MG/ /N11664/002/
/BP/ /1.5MG/ /N11664/003/
/BP/ /4MG/ /N11664/005/

DEXAMETHASONE

TABLET; ORAL
DEXAMETHASONE
AB ROXANE 0.5MG N84611 001
AB 0.75MG N84613 001
AB 1.5MG N84610 001
AB 4MG N84612 001
/BP/ /0.5MG/ /N84611/001/
/BP/ /0.75MG/ /N84613/001/
/BP/ /1.5MG/ /N84610/001/
/BP/ /4MG/ /N84612/001/

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL
/DEXAMPEX/
/AA/ /LEMMON/ /5MG/ /N83735/001/
/AA/ /10MG/ /N83735/002/
ə LEMMON 5MG N83735 001
ə 10MG N83735 002

DIAZEPAM

INJECTABLE; INJECTION
DIAZEPAM
AP MARSAM 5MG/ML N72370 001
JAN 29, 1993
AP 5MG/ML N72371 001
JAN 29, 1993
AP 5MG/ML N72397 001
JAN 29, 1993

TABLET; ORAL
DIAZEPAM
/AB/ /ZENITH/ /2MG/ /N70360/001/
/SEP/04/1985/
/AB/ /5MG/ /N70361/001/
/SEP/04/1985/
ə ZENITH 2MG N70360 001
SEP 04, 1985
ə 5MG N70361 001
SEP 04, 1985

DIAZOXIDE

CAPSULE; ORAL
PROGLYCEM
+ BAKER NORTON 50MG N17425 001

DIAZOXIDE

CAPSULE; ORAL
PROGLYCEM
/*//MEDCL/MKTG/ /50MG/ /N17425/001/

INJECTABLE; INJECTION
/DIAZOXIDE/
/AP/ /QUAD/ /15MG/ML/ /N71908/001/
/JAN/26,/1988/

- ∂ QUAD — 15MG/ML — N71908 001 JAN 26, 1988

HYPERSTAT
/AP/ /SCHERING/ /15MG/ML/ /N16996/001/
SCHERING — 15MG/ML — N16996 001

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
VOLTAREN
/CIBA/ /0.1%/ /N20037/001/
/MAR/28,/1991/

CIBA VISION — 0.1% — N20037 001 MAR 28, 1991

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL
DICYCLOMINE HCL
/AB/ /PIONEER/PHARMS/ /10MG/ /N89361/001/
/JAN/10,/1989/

- ∂ PIONEER PHARMS — 10MG — N89361 001 JAN 10, 1989

TABLET; ORAL
DICYCLOMINE HCL
/AB/ /PIONEER/PHARMS/ /20MG/ /N88585/001/
/AUG/20,/1986/

- ∂ PIONEER PHARMS — 20MG — N88585 001 AUG 20, 1986

DILTIAZEM HYDROCHLORIDE

TABLET; ORAL
DILTIAZEM HCL

AB	APOTHECON	30MG	N74051 001	MAR 31, 1993
AB		60MG	N74051 002	MAR 31, 1993
AB		90MG	N74051 003	MAR 31, 1993
AB		120MG	N74051 004	MAR 31, 1993

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL

>DLT> /AA/	/LEMMON/	/25MG/	/N85874/001/	
>DLT> /AA/		/50MG/	/N85874/002/	
>ADD>	∂ LEMMON	25MG	N85874 001	
>ADD>	∂	50MG	N85874 002	

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOPAMINE HCL
/AP/ /LYPHOMED/ /40MG/ML/ /N70012/001/
/JUN/12,/1985/

- ∂ LYPHOMED — 40MG/ML — N70012 001 JUN 12, 1985

DOXYCYCLINE HYCLATE

CAPSULE; ORAL
DOXYCYCLINE HYCLATE

/AB/	/PAR/	/EQ 50MG BASE/	/N62434/001/	/OCT/19,/1984/
/AB/		/EQ 100MG BASE/	/N62442/001/	/DEC/22,/1983/
	∂ PAR	EQ 50MG BASE	N62434 001	OCT 19, 1984
	∂	EQ 100MG BASE	N62442 001	DEC 22, 1983

DOXYCYCLINE HYCLATE

TABLET; ORAL
DOXYCYCLINE HYCLATE

>DLT >/AB/	/HEATHER/	/EQ 100MG BASE/	/N62462/001/		
>DLT >			/MAY/11,/1983/		
>ADD >	∂ HEATHER	EQ 100MG BASE	N62462 001		
>ADD >			MAY 11, 1983		

DROPERIDOL

INJECTABLE; INJECTION
DROPERIDOL

/AP/	/QUAD/	/2.5MG/ML/	/N71941/001/		
			/AUG/17,/1988/		
	∂ QUAD	2.5MG/ML	N71941 001		
			AUG 17, 1988		
/AP/	/SMITH/NEPHEW/SOLOPAK/	2.5MG/ML/	/N71754/001/		
			/SEP/06,/1988/		
/AP/		/2.5MG/ML/	/N71755/001/		
			/SEP/06,/1988/		
AP	SOLOPAK	2.5MG/ML	N71754 001		
			SEP 06, 1988		
AP		2.5MG/ML	N71755 001		
			SEP 06, 1988		

EFLORNITHINE HYDROCHLORIDE

/INJECTABLE;/INJECTION/					
/ORNIDYL/					
	/MERRELL/DOW/	/200MG/ML/	/N19879/002/		
			/NOV/28,/1990/		
	∂ MERRELL DOW	200MG/ML	N19879 002		
			NOV 28, 1990		

ENOXACIN

TABLET; ORAL
PENETREX

/+//PARKE/DAVIS/		/400MG/	/N19616/005/		
			/DEC/31,/1991/		
		/200MG/	/N19616/004/		
			/DEC/31,/1991/		
+	RHONE POULENC RORER	400MG	N19616 005		
			DEC 31, 1991		
		200MG	N19616 004		
			DEC 31, 1991		

ENOXAPARIN SODIUM

INJECTABLE; INJECTION
LOVENOX

RHONE POULENC RORER	30MG/0.3ML	N20164 001	
		MAR 29, 1993	

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL AND EPINEPHRINE

AP	STERLING WINTHROP	0.01MG/ML;2%	N40057 002
			FEB 26, 1993
AP		0.02MG/ML;2%	N40057 001
			FEB 26, 1993

ERGOLOID MESYLATES

TABLET; ORAL
HYDERGINE

/SANDOZ/	/0.5MG/	/N17993/003/	
∂ SANDOZ	0.5MG	N17993 003	

TABLET; SUBLINGUAL
HYDROGENATED ERGOT ALKALOIDS

/AA/	/ZENITH/	/0.5MG/	/N87186/001/
	∂ ZENITH	0.5MG	N87186 001

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL
ERGOMAR

>DLT >/AA/	/FISONS/	/2MG/	/N87693/001/		
>DLT >			/FEB/24,/1983/		
>ADD > AA	LOTUS	2MG	N87693 001		
>ADD >			FEB 24, 1983		

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL

>DLT >	/ERYC/SPRINKLES/				
>DLT >	/+//FAULDING/	/125MG/	/N50593/001/		
>DLT >			/JUL/22,/1985/		
>ADD >	∂ FAULDING	125MG	N50593 001		
>ADD >			JUL 22, 1985		

ERYTHROMYCIN

GEL; TOPICAL
ERYGEL
/AT/ /HERBERT/ /2%/ /N50617/001/ /OCT/21,/1987/
AT + HERBERT 2% N50617 001 OCT 21, 1987

ERYTHROMYCIN
AT STIEFEL 2% N63211 001 JAN 29, 1993

OINTMENT; OPHTHALMIC
ERYTHROMYCIN
>DLT >/AT/ /PHARMADERM/ /5MG/GM/ /N62446/001/ /SEP/26,/1983/
>DLT >
>ADD > ∂ PHARMADERM 5MG/GM N62446 001 SEP 26, 1983
>ADD >

/POWDER;/FOR/RX/COMPOUNDING/
/ERYTHROMYCIN/
/PADDOCK/ /100%/ /N50610/001/ /NOV/07,/1986/
∂ PADDOCK 100% N50610 001 NOV 07, 1986

SOLUTION; TOPICAL
>ADD > ERYTHRA-DERM
>ADD > AT PADDOCK 2% N62687 001 FEB 05, 1988
>ADD >

ERYTHROMYCIN
AT BARRE 2% N62957 001 JUL 21, 1988
/AT/ /NASKA/ /2%/ /N62957/001/ /JUL/21,/1988/
>DLT > /ETS-2%/
>DLT >/AT/ /PADDOCK/ /2%/ /N62687/001/ /FEB/05,/1988/
>DLT >

ERYTHROMYCIN ESTOLATE

SUSPENSION; ORAL
ERYTHROMYCIN ESTOLATE
>ADD > ∂ LIFE LABORATORIES EQ 250MG BASE/5ML N62362 001 DEC 17, 1982
>ADD >

ESMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION
BREVIBLOC
>ADD > + ANAQUEST 10MG/ML N19386 001 AUG 15, 1988
>ADD >
>ADD > + 250MG/ML N19386 002 DEC 31, 1986
>ADD >
>DLT > /DUPONT/ /10MG/ML/ /N19386/001/ /AUG/15,/1988/
>DLT >
>DLT > /250MG/ML/ /N19386/002/ /DEC/31,/1986/
>DLT >

ESTROGENS, CONJUGATED

CREAM; TOPICAL, VAGINAL
PREMARIN
+ AYERST 0.625MG/GM N20216 001
/+//WYETH/AYERST/ /0.625MG/GM/ /N83273/001/

TABLET; ORAL
PREMARIN
>ADD > + WYETH AYERST 1.25MG N04782 001
/+/ /2.5MG/ /N04782/002/
>DLT > /1.25MG/ /N04782/001/
>DLT >
>ADD > 2.5MG N04782 002

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORETHIN 1/35E-21
AB ROBERTS 0.035MG;1MG N71480 001 APR 12, 1988
/AB/ /SCHIAPPARELLI/SEARLE/0.035MG;1MG/ /N71480/001/ /APR/12,/1988/

TABLET; ORAL-28
NORETHIN 1/35E-28
AB ROBERTS 0.035MG;1MG N71481 001 APR 12, 1988
/AB/ /SCHIAPPARELLI/SEARLE/0.035MG;1MG/ /N71481/001/ /APR/12,/1988/

ETHYNODIOL DIACETATE; MESTRANOL

/TABLET;/ORAL-21/
/OVULEN-21/
/+//SEARLE/ /1MG;0.1MG/ /N16029/003/

ETHYNODIOL DIACETATE; MESTRANOL

/TABLET;/ORAL-21/
/OVULEN-21/
@ SEARLE — 1MG;0.1MG — N16029 003

/TABLET;/ORAL-28/
/OVULEN-28/
/SEARLE/ — /1MG;0.1MG/ — /N16705/001/
@ SEARLE — 1MG;0.1MG — N16705 001

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL
FLUOCINOLONE ACETONIDE

> DLT >/AT/ /PHARMADERM/ /0.01%/ — /N88047/001/ /DEC/16,/1982/
> DLT >
/AT/ /0.025%/ — /N88045/001/ /DEC/16,/1982/

> ADD > @ PHARMADERM — 0.01% — N88047 001 DEC 16, 1982
> ADD >
@ — 0.025% — N88045 001 DEC 16, 1982

OINTMENT; TOPICAL
FLUOCINOLONE ACETONIDE

/AT/ /PHARMADERM/ /0.025%/ — /N88046/001/ /DEC/16,/1982/

@ PHARMADERM — 0.025% — N88046 001 DEC 16, 1982

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL

/AP/ /MARCHAR/ /50MG/ML/ — /N87791/001/ /JAN/18,/1983/

@ MARCHAR — 50MG/ML — N87791 001 JAN 18, 1983

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL
PROZAC
LILLY — EQ 10MG BASE — N18936 006 DEC 23, 1992

FLUPHENAZINE HYDROCHLORIDE

ELIXIR; ORAL
FLUPHENAZINE HCL

AA COPLEY — 2.5MG/5ML — N81310 001 APR 29, 1993

PROLIXIN
AA SQUIBB — 2.5MG/5ML — N12145 003

FOLIC ACID

TABLET; ORAL
FOLIC ACID

/AA/ /PIONEER/PHARMS/ /1MG/ — /N88049/001/ /SEP/13,/1985/

@ PIONEER PHARMS — 1MG — N88949 001 SEP 13, 1985

GADODIAMIDE

INJECTABLE; INJECTION
OMNISCAN
STERLING WINTHROP — 287MG/ML — N20123 001 JAN 08, 1993

GEMFIBROZIL

CAPSULE; ORAL
GEMFIBROZIL

AB MYLAN — 300MG — N73466 001 JAN 25, 1993

AB PUREPAC — 300MG — N72929 001 JAN 29, 1993

LOPID
AB + PARKE DAVIS — 300MG — N18422 002

GENTAMICIN SULFATE

CREAM; TOPICAL
GENTAMICIN SULFATE

/AT/ /PHARMADERM/ /EQ 1MG BASE/GM/ — /N62530/001/ /JUL/05,/1984/

@ PHARMADERM — EQ 1MG BASE/GM — N62530 001 JUL 05, 1984

GLIPIZIDE

TABLET; ORAL
GLUCOTROL
+ PFIZER — 10MG — N17783 002 MAY 08, 1984
>ADD< — 2.5MG — N17783 003 MAY 11, 1993
>ADD< — 5MG — N17783 001 MAY 08, 1984
/+//ROERIG/ — /10MG/ — /N17783/002/ /MAY/08,/1984/
/5MG/ — /N17783/001/ /MAY/08,/1984/

GLUCAGON HYDROCHLORIDE

INJECTABLE; INJECTION
GLUCAGON
/AP/ /LILLY/ — /EQ 1MG BASE/VIAL/ — /N12122/001/
LILLY — EQ 1MG BASE/VIAL — N12122 001
/AP/ /QUAD/ — /EQ 1MG BASE/VIAL/ — /N71022/001/ /MAR/04,/1987/
∂ QUAD — EQ 1MG BASE/VIAL — N71022 001 MAR 04, 1987

GLUTETHIMIDE

CAPSULE; ORAL
DORIDEN
/∂/RHONE/POULENC/RORER//500MG/ — /N09519/008/

GRISEOFULVIN, MICROCRYSTALLINE

CAPSULE; ORAL
GRISACTIN
/WYETH/AYERST/ — /125MG/ — /N50051/002/
∂ WYETH AYERST — 125MG — N50051 002

HALOPERIDOL LACTATE

CONCENTRATE; ORAL
HALOPERIDOL
AA PHARM ASSOC — EQ 2MG BASE/ML — N73037 001 FEB 26, 1993

HALOPERIDOL LACTATE

INJECTABLE; INJECTION
HALOPERIDOL
AP MARSAM — EQ 5MG BASE/ML — N72516 001 FEB 25, 1993
AP — EQ 5MG BASE/ML — N72517 001 FEB 25, 1993
/AP/ /SMITH/NEPHEW/SOLOPAK/ — /EQ 5MG BASE/ML/ — /N70801/001/ /DEC/14,/1987/
/AP/ — /EQ 5MG BASE/ML/ — /N70864/001/ /DEC/14,/1987/
AP SOLOPAK — EQ 5MG BASE/ML — N70801 001 DEC 14, 1987
AP — EQ 5MG BASE/ML — N70864 001 DEC 14, 1987

HEXACHLOROPHENE

AEROSOL; TOPICAL
/TURGEX/
/XTTRIUM/ — /3%/ — /N18375/001/
∂ XTTRIUM — 3% — N18375 001

EMULSION; TOPICAL
>DLT< /HEXA-GERM/
>DLT</AT/ /HUNTINGTON/ — /3%/ — /N17411/001/
>ADD< ∂ HUNTINGTON — 3% — N17411 001
/TURGEX/
/AT/ /XTTRIUM/ — /3%/ — /N19055/001/ /NOV/30,/1984/
∂ XTTRIUM — 3% — N19055 001 NOV 30, 1984

/SOLUTION;/TOPICAL/
/DIAL/
/AT/ /ARMOUR/DIAL/ — /0.25%/ — /N17421/002/
∂ DIAL — 0.25% — N17421 002

>DLT< /GERMA-MEDICA/
>DLT< /HUNTINGTON/ — /1%/ — /N17412/001/
>ADD< ∂ HUNTINGTON — 1% — N17412 001
>DLT< /GERMA-MEDICA/'MG'/
>DLT< /HUNTINGTON/ — /0.25%/ — /N17412/002/
>ADD< ∂ HUNTINGTON — 0.25% — N17412 002

SPONGE; TOPICAL
/HEXASCRUB/
/AT/ /PROF/DSPLS/ — /3%/ — /N18363/001/
∂ PROF DSPLS — 3% — N18363 001

HEXAFLUORENIUM BROMIDE

/INJECTABLE;/INJECTION/
/MYLAXEN/
/WALLACE/ /20MG/ML/ /N09789/003/
∂ WALLACE 20MG/ML N09789 003

HYDRALAZINE HYDROCHLORIDE; RESERPINE

> DLT > /TABLET;/ORAL/
> DLT > /SERPASIL-APRESOLINE/
> DLT > /+//CIBA/ /50MG;0.2MG/ /N09296/002/
> DLT > /25MG;0.1MG/ /N09296/004/
> ADD > ∂ CIBA 25MG;0.1MG N09296 004
> ADD > ∂ 50MG;0.2MG N09296 002

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL
ZESTORETIC 20/12.5
/AB/ /IMPERIAL/CHEM/ /12.5MG;20MG/ /N19888/001/
/SEP/20,/1990/
AB ZENECA 12.5MG;20MG N19888 001
SEP 20, 1990

ZESTORETIC 20/25
/AB/ /IMPERIAL/CHEM/ /25MG;20MG/ /N19888/002/
/JUL/20,/1989/
AB ZENECA 25MG;20MG N19888 002
JUL 20, 1989

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE
AT BARRE 2.5% N89682 001
MAR 10, 1988
/AT/ /BIOCRAFT/ /0.5%/ /N80400/002/
/AT/ /1%/ /N80400/003/
/AT/ /2.5%/ /N80400/004/
∂ BIOCRAFT 0.5% N80400 002
∂ 1% N80400 003
∂ 2.5% N80400 004
/AT/ /NASKA/ /2.5%/ /N89682/001/
/MAR/10,/1988/
/AT/ /PHARMADERM/ /1%/ /N88845/001/
/FEB/27,/1986/
∂ PHARMADERM 1% N88845 001
FEB 27, 1986

HYDROCORTISONE

LOTION; TOPICAL
ACTICORT
AT BAKER NORTON 1% N86535 001
/AT/ /KEY/PHARMS/ /1%/ /N86535/001/

OINTMENT; TOPICAL
HYDROCORTISONE
> ADD > AT FOUGERA 2.5% N81203 001
> ADD > MAY 28, 1993

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION; OTIC
/NEOMYCIN SULFATE; POLYMYXIN B SULFATE & HYDROCORTISONE/
/AT/ /PHARMAFAIR/ /1%;EQ 3.5MG BASE/ML;/
/10,000 UNITS/ML/ /N62617/001/
/SEP/18,/1985/
∂ PHARMAFAIR 1%;EQ 3.5MG BASE/ML;
10,000 UNITS/ML N62617 001
SEP 18, 1985

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL
> ADD > AP FUJISAWA 25MG/ML N88184 001
> ADD > MAR 31, 1983
> ADD > AP 50MG/ML N88185 001
> ADD > MAR 31, 1983
> DLT > /AP/ /LYPHOMED/ /25MG/ML/ /N88184/001/
> DLT > /MAR/31,/1983/
> DLT > /AP/ /50MG/ML/ /N88185/001/
> DLT > /MAR/31,/1983/

SYRUP; ORAL
HYDROXYZINE HCL
AA BARRE 10MG/5ML N88785 001
FEB 03, 1988
/AA/ /NASKA/ /10MG/5ML/ /N88785/001/
/FEB/03,/1988/

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL
HYDROXYZINE HCL

>DLT >/AB/	/CHELSEA/	/10MG/	/N86827/001/	
>DLT >/AB/		/25MG/	/N86829/001/	
>DLT >/AB/		/50MG/	/N86836/001/	
>ADD >	∂ CHELSEA	10MG	N86827 001	
>ADD >	∂	25MG	N86829 001	
>ADD >	∂	50MG	N86836 001	

IBUPROFEN

TABLET; ORAL
IBUPROFEN

AB	NORTON HN	400MG	N71145 001	SEP 23, 1986
AB		600MG	N71146 001	SEP 23, 1986
AB		800MG	N71769 001	MAY 08, 1987

IBUPROFEN

/AB/	/PAR/	/300MG/	/N70328/001/	/AUG/06/1985/
	∂ PAR	300MG	N70328 001	AUG 06, 1985

/IFEN/

/AB/	/LUCHEM/	/400MG/	/N71145/001/	/SEP/23/1986/
/AB/		/600MG/	/N71146/001/	/SEP/23/1986/
/AB/		/800MG/	/N71769/001/	/MAY/08/1987/

INDAPAMIDE

TABLET; ORAL
LOZOL

RHONE POULENC RORER	1.25MG	N18538 002	APR 29, 1993

IOTROLAN

/INJECTABLE;/INTRATHECAL/
/OSMOVIST/
/BERLEX/ /EQ/180MG/IODINE/ML/ /N19580/001/ /DEC/07/1989/
/EQ/240MG/IODINE/ML/ /N19580/002/ /DEC/07/1989/

IOTROLAN

/INJECTABLE;/INTRATHECAL/
/OSMOVIST/

∂ BERLEX	EQ 180MG IODINE/ML	N19580 001	DEC 07, 1989
∂	EQ 240MG IODINE/ML	N19580 002	DEC 07, 1989

IRON DEXTRAN

INJECTABLE; INJECTION
>ADD > INFED
>ADD > BP + Schein Pharm EQ 50MG IRON/ML N17441 001
>DLT > /IRON/DEXTRAN/
>DLT > /BP/ /STERIS/ /EQ/50MG/IRON/ML/ /N17441/001/

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
ISOETHARINE HCL

/AN/	/ASTRA/	/0.125%/	/N87938/001/	/NOV/15/1982/
		/0.062%/	/N87937/001/	/NOV/15/1982/
	∂ ASTRA	0.062%	N87937 001	NOV 15, 1982
	∂	0.125%	N87938 001	NOV 15, 1982
>DLT >/AN/	/PARKE/DAVIS/	/1%/	/N85889/001/	
>DLT >		/0.5%/	/N85997/001/	
>ADD >	∂ PARKE DAVIS	0.5%	N85997 001	
>ADD >	∂	1%	N85889 001	

ISOFLURANE

LIQUID; INHALATION
FORANE

AN +	ANAQUEST	99.9%	N17624 001

ISOFLURANE

AN	ABBOTT	99.9%	N74097 001 JAN 25, 1993

ISONIAZID

TABLET; ORAL
/STANOZIDE/

/AA/	/EVERYLIFE/	/300MG/	/N80126/002/	
	∂ EVERYLIFE	300MG	N80126 002	

ISOSORBIDE DINITRATE

TABLET; ORAL

SORBITRATE

/AB/	/ICI/	/20MG/	/N86405/002/ /AUG/21,/1990/	
/AB/		/30MG/	/N88124/001/ /AUG/21,/1990/	
/AB/		/40MG/	/N88125/001/ /AUG/21,/1990/	
AB	ZENECA	20MG	N86405 002 AUG 21, 1990	
AB		30MG	N88124 001 AUG 21, 1990	
AB		40MG	N88125 001 AUG 21, 1990	

KANAMYCIN SULFATE

INJECTABLE; INJECTION

/KLEOCIN/

/AP/	/SMITHKLINE/BEECHAM/	/EQ 75MG BASE/2ML/	/N62170/001/
/AP/		/EQ 500MG BASE/2ML/	/N62170/002/
/AP/		/EQ 1GM BASE/3ML/	/N62170/003/
	ə SMITHKLINE BEECHAM	EQ 75MG BASE/2ML	N62170 001
	ə	EQ 500MG BASE/2ML	N62170 002
	ə	EQ 1GM BASE/3ML	N62170 003

KETOPROFEN

CAPSULE; ORAL

KETOPROFEN

AB	LEDERLE	25MG	N74014 001 JAN 29, 1993	
AB		50MG	N74014 002 JAN 29, 1993	
AB		75MG	N74014 003 JAN 29, 1993	

LACTULOSE

SOLUTION; ORAL

/CEPHULAC/

/AA/	/MERRELL/DOW/	/10GM/15ML/	/N17657/001/	

/ENULOSE/

/AA/	/BARRE/	/10GM/15ML/	/N71548/001/ /AUG/15,/1988/	

LACTULOSE

SOLUTION; ORAL

>ADD>		EVALOSE		
>ADD>	AA	COPLEY	10GM/15ML	N73497 001 MAY 28, 1993
>ADD>				

/GENERLAC/

/AA/	/PHARM/BASICS/	/10GM/15ML/	/N71842/001/ /SEP/27,/1988/	

/LACTULOSE/

	/SOLVAY/	/10GM/15ML/	/N17906/001/	

>ADD>		LAXILOSE		
>ADD>	AA	TECHNILAB	10GM/15ML	N73686 001 MAY 28, 1993
>ADD>				

SOLUTION; ORAL, RECTAL

>ADD>		ACILAC		
>ADD>	AA	TECHNILAB	10GM/15ML	N73685 001 MAY 28, 1993
>ADD>				
		CEPHULAC		
	AA	MERRELL DOW	10GM/15ML	N17657 001
		ENULOSE		
	AA	BARRE	10GM/15ML	N71548 001 AUG 15, 1988
		GENERLAC		
	AA	PHARM BASICS	10GM/15ML	N71842 001 SEP 27, 1988
>ADD>		HEPTALAC		
>ADD>	AA	COPLEY	10GM/15ML	N73504 001 MAY 28, 1993
>ADD>				
		LACTULOSE		
	ə	SOLVAY	10GM/15ML	N17906 001
>DLT>		/PORTALAC/		
>DLT>	/AA/	/SOLVAY/	/10GM/15ML/	/N72374/001/ /MAR/22,/1989/
>DLT>				
>ADD>				
>ADD>	ə	SOLVAY	10GM/15ML	N72374 001 MAR 22, 1989

LEUCOVORIN CALCIUM

TABLET; ORAL

LEUCOVORIN CALCIUM

AB	LEDERLE	EQ 10MG BASE	N71962 001 NOV 19, 1987
AB	+	EQ 15MG BASE	N71104 001 MAR 04, 1987

LEUCOVORIN CALCIUM

TABLET; ORAL
LEUCOVORIN CALCIUM

AB	ROXANE	EQ 5MG BASE	N72733 001 FEB 22, 1993	
AB		EQ 10MG BASE	N72734 001 FEB 22, 1993	
AB		EQ 15MG BASE	N72735 001 FEB 22, 1993	
AB		EQ 25MG BASE	N72736 001 FEB 22, 1993	

LEUPROLIDE ACETATE

INJECTABLE; INJECTION
LUPRON

+	TAP	1MG/0.2ML	N19010 001 APR 09, 1985
		/1MG/0.2ML/	/N19010/001/ /APR/09,/1985/
		5MG/ML	N20263 001 APR 16, 1993

LUPRON DEPOT

+	TAP	3.75MG/VIAL	N20011 001 OCT 22, 1990
+		7.5MG/VIAL	N19732 001 JAN 26, 1989
		/3.75MG/VIAL/	/N20011/001/ /OCT/22,/1990/
		/7.5MG/VIAL/	/N19732/001/ /JAN/26,/1989/

LUPRON DEPOT-PED

+	TAP	3.75MG/VIAL&7.5MG/VIAL	N20263 003 APR 16, 1993
+		7.5MG/VIAL&7.5MG/VIAL	N20263 004 APR 16, 1993
+		7.5MG/VIAL	N20263 002 APR 16, 1993

LIDOCAINE

/SUPPOSITORY;/RECTAL/
/XYLOCAINE/

	/ASTRA/	/100MG/	/N13077/001/
∂	ASTRA	100MG	N13077 001

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL

> ADD >	AP	FUJISAWA	1%	N80404 002
> ADD >	AP		2%	N80404 003
> DLT >	/AP/	/LYPHOMED/	/1%/	/N80404/002/
	/AP/		/1%/	/N86761/001/
> DLT >	/AP/		/2%/	/N80404/003/
	/AP/		/2%/	/N86761/002/
	∂	LYPHOMED	1%	N86761 001
	∂		2%	N86761 002

JELLY; TOPICAL
LIDOCAINE HCL

AT		COPLEY	2%	N81318 001 APR 29, 1993

LIOTRIX (T4;T3)

TABLET; ORAL

	THYROLAR-0.25			
		FOREST LABS	0.0125MG;0.0031MG	N16807 001
		/RHONE/POULENC/RORER//0.0125MG;0.0031MG/		/N16807/001/
	THYROLAR-0.5			
		FOREST LABS	0.025MG;0.00625MG	N16807 005
		/RHONE/POULENC/RORER//0.025MG;0.00625MG/		/N16807/005/
	THYROLAR-1			
		FOREST LABS	0.05MG;0.0125MG	N16807 004
		/RHONE/POULENC/RORER//0.05MG;0.0125MG/		/N16807/004/
	THYROLAR-2			
		FOREST LABS	0.1MG;0.025MG	N16807 002
		/RHONE/POULENC/RORER//0.1MG;0.025MG/		/N16807/002/
	THYROLAR-3			
+		FOREST LABS	0.15MG;0.0375MG	N16807 003
/+/		/RHONE/POULENC/RORER//0.15MG;0.0375MG/		/N16807/003/
	THYROLAR-5			
∂		FOREST LABS	0.25MG;0.0625MG	N16807 006
/∂/		/RHONE/POULENC/RORER//0.25MG;0.0625MG/		/N16807/006/

LISINOPRIL

TABLET; ORAL
ZESTRIL

/AB/	/IMPERIAL/CHEM/	/5MG/	/N19777/001/ /MAY/19,/1988/	
/AB/		/10MG/	/N19777/002/ /MAY/19,/1988/	
/AB/		/20MG/	/N19777/003/ /MAY/19,/1988/	
/AB//+/		/40MG/	/N19777/004/ /MAY/19,/1988/	
AB	ZENECA	5MG	N19777 001 MAY 19, 1988	
AB		10MG	N19777 002 MAY 19, 1988	
AB		20MG	N19777 003 MAY 19, 1988	
AB	+	40MG	N19777 004 MAY 19, 1988	
		2.5MG	N19777 005 APR 29, 1993	

LORATADINE

TABLET; ORAL
CLARITIN

+	SCHERING	10MG	N19658 001 APR 12, 1993

MAFENIDE ACETATE

CREAM; TOPICAL
SULFAMYLON

>ADD< >DLT<	+ DOW B HICKAM /STERLING/	EQ 85MG BASE/GM /EQ/85MG/BASE/GM/	N16763 001 /N16763/001/

MANGANESE SULFATE

INJECTABLE; INJECTION
MANGANESE SULFATE

FUJISAWA		EQ 0.1MG MANGANESE/ML	N19228 001 MAY 05, 1987
/LYPHOMED/		/EQ/0.1MG/MANGANESE/ML/	/N19228/001/ /MAY/05,/1987/

MENADIOL SODIUM DIPHOSPHATE

>DLT<	/INJECTABLE;/INJECTION/			
>DLT<	/SYNKAYVITE/			
>DLT<	/ROCHE/	/5MG/ML/		/N03718/004/
>DLT<		/10MG/ML/		/N03718/006/
>DLT<		/37.5MG/ML/		/N03718/008/
>ADD<	∂ ROCHE	5MG/ML		N03718 004
>ADD<	∂	10MG/ML		N03718 006
>ADD<	∂	37.5MG/ML		N03718 008

>DLT<	/TABLET;/ORAL/		
>DLT<	/SYNKAYVITE/		
>DLT<	/ROCHE/	/5MG/	/N03718/010/
>ADD<	∂ ROCHE	5MG	N03718 010

MESALAMINE

CAPSULE, EXTENDED RELEASE; ORAL
PENTASA

+	MARION MERRELL DOW	250MG	N20049 001 MAY 10, 1993

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21
NORETHIN 1/50M-21

AB	ROBERTS	0.05MG;1MG	N71539 001 APR 12, 1988
/AB/	/SCHIAPPARELLI/SEARLE/	0.05MG;1MG/	/N71539/001/ /APR/12,/1988/

TABLET; ORAL-28
NORETHIN 1/50M-28

AB	ROBERTS	0.05MG;1MG	N71540 001 APR 12, 1988
/AB/	/SCHIAPPARELLI/SEARLE/	0.05MG;1MG/	/N71540/001/ /APR/12,/1988/

MESTRANOL; NORETHYNODREL

/TABLET;/ORAL/
/ENOVID/
/+//SEARLE/ /0.15MG;9.85MG/ /N10976/005/
/0.075MG;5MG/ /N10976/008/
∂ SEARLE 0.075MG;5MG N10976 008
∂ 0.15MG;9.85MG N10976 005

METARAMINOL BITARTRATE

INJECTABLE; INJECTION
METARAMINOL BITARTRATE
> ADD > AP FUJISAWA EQ 10MG BASE/ML N80431 001
> ADD > AP EQ 10MG BASE/ML N80722 001
> DLT >/AP/ /LYPHOMED/ /EQ 10MG BASE/ML/ /N80431/001/
> DLT >/AP/ /EQ 10MG BASE/ML/ /N80722/001/

METHADONE HYDROCHLORIDE

TABLET; ORAL
METHADOSE
AA MALLINCKRODT 5MG N40050 001
APR 15, 1993
AA 10MG N40050 002
APR 15, 1993

TABLET, DISPERSIBLE; ORAL
METHADOHE HCL
AA LILLY 40MG N17058 001
METHADOSE
AA MALLINCKRODT 40MG N74184 001
APR 29, 1993

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL
/METHAMPEX/
/AA/ /LEMMON/ /10MG/ /N83889/001/
∂ LEMMON 10MG N83889 001

METHAMPHETAMINE HCL
> DLT >/AA/ /LEMMON/ /5MG/ /N86359/001/
> ADD > ∂ LEMMON 5MG N86359 001
/AA/ /REXAR/ /10MG/ /N84931/002/
REXAR 10MG N84931 002

METHOCARBAMOL

TABLET; ORAL
> DLT > /DELAXIN/
> DLT >/AA/ /FERNDALE/ /500MG/ /N85454/001/
> ADD > ∂ FERNDALE 500MG N85454 001

METHOCARBAMOL
> ADD > AA NYLOS TRADING 750MG N85033 001
/AA/ /PIONEER/PHARMS/ /500MG/ /N88731/001/
/DEC/13,/1985/
/AA/ /750MG/ /N89082/001/
/DEC/13,/1985/
∂ PIONEER PHARMS 500MG N88731 001
DEC 13, 1985
∂ 750MG N89082 001
DEC 13, 1985
> DLT >/AA/ /TABLICAPS/ /750MG/ /N85033/001/

METHOTREXATE SODIUM

INJECTABLE; INJECTION
METHOTREXATE SODIUM
/AP/ /LYPHOMED/ /EQ 25MG BASE/ML/ /N89263/001/
/JUN/13,/1986/
∂ LYPHOMED EQ 25MG BASE/ML N89263 001
JUN 13, 1986

METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION
METHYLDOPATE HCL
/AP/ /LYPHOMED/ /50MG/ML/ /N70652/001/
/JUN/03,/1986/
∂ LYPHOMED 50MG/ML N70652 001
JUN 03, 1986

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

METHYLPREDNISOLONE SODIUM SUCCINATE

/AP/	/LYPHOMED/	/EQ 40MG BASE/VIAL/	/N89143/001/ /MAR/28,/1986/
/AP/		/EQ 125MG BASE/VIAL/	/N89144/001/ /MAR/28,/1986/
/AP/		/EQ 500MG BASE/VIAL/	/N89187/001/ /MAR/28,/1986/
/AP/		/EQ 1GM BASE/VIAL/	/N89189/001/ /MAR/28,/1986/
	∂ LYPHOMED	EQ 40MG BASE/VIAL	N89143 001 MAR 28, 1986
	∂	EQ 125MG BASE/VIAL	N89144 001 MAR 28, 1986
	∂	EQ 500MG BASE/VIAL	N89187 001 MAR 28, 1986
	∂	EQ 1GM BASE/VIAL	N89189 001 MAR 28, 1986

METHYLTESTOSTERONE

CAPSULE; ORAL

>DLT>	/METHYLTESTOSTERONE/		
>DLT>	/BP/+//HEATHER/	/10MG/	/N84967/001/
>ADD>	∂ HEATHER	10MG	N84967 001

METHYPRYLON

>DLT>	/CAPSULE;/ORAL/		
>DLT>	/NOLUDAR/		
>DLT>	/ROCHE/	/300MG/	/N09660/008/
>ADD>	∂ ROCHE	300MG	N09660 008
>DLT>	/TABLET;/ORAL/		
>DLT>	/NOLUDAR/		
>DLT>	/ROCHE/	/200MG/	/N09660/004/
>ADD>	∂ ROCHE	200MG	N09660 004

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

METOCLOPRAMIDE HCL

AB	MUTUAL PHARM	EQ 10MG BASE	N71536 001 APR 28, 1993

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

METOCLOPRAMIDE HCL

/AB/	/PAR/	/EQ 10MG BASE/	/N70342/001/ /MAR/25,/1986/
	∂ PAR	EQ 10MG BASE	N70342 001 MAR 25, 1986

METRONIDAZOLE

TABLET; ORAL

/GASTRIC/

/AB/	/SAVAGE/	/250MG/	/N70029/001/ /MAR/19,/1985/
/AB/		/500MG/	/N70731/001/ /JUN/08,/1987/
	∂ SAVAGE	250MG	N70029 001 MAR 19, 1985
	∂	500MG	N70731 001 JUN 08, 1987

MICONAZOLE NITRATE

	/CREAM;/VAGINAL/ /MONISTAT/1/ /JOHNSON/RW/	/2%/	/N17456/001/
>ADD>	CREAM, SUPPOSITORY; TOPICAL, VAGINAL		
>ADD>	MONISTAT DUAL-PAK		
>ADD>	+ JOHNSON RW	2%;200MG	N18888 002 OCT 17, 1988
>ADD>			
>DLT>	/LOTION;/TOPICAL/		
>DLT>	/MONISTAT-DERM/		
>DLT>	/+//JOHNSON/RW/	/2%/	/N17739/001/
>ADD>	∂ JOHNSON RW	2%	N17739 001
	/SUPPOSITORY;/VAGINAL/ /MONISTAT/1/ /JOHNSON/RW/	/100MG/	/N16526/001/ /MAR/15,/1982/

MORICIZINE HYDROCHLORIDE

TABLET; ORAL
ETHMOZINE
/DUPONT/

	/200MG/	/N19753/001/ /JUN/19,/1990/	>DLT >/AP/ >DLT >	
	/250MG/	/N19753/002/ /JUN/19,/1990/	>DLT >/AP/ >DLT >	
	/300MG/	/N19753/003/ /JUN/19,/1990/	>DLT >/AP/ >DLT >	
ROBERTS	200MG	N19753 001 JUN 19, 1990	>ADD > >ADD >	∂ DUPONT 0.4MG/ML
	250MG	N19753 002 JUN 19, 1990	>ADD > >ADD >	∂ 1MG/ML
	300MG	N19753 003 JUN 19, 1990	>ADD > >ADD >	∂ 1MG/ML

NABILONE

/CAPSULE;/ORAL/
/CESAMET/
/+//LILLY/

	/1MG/	/N18677/001/ /DEC/26,/1985/	/AG/	/LYPHOMED/ /100MG/ML/
∂ LILLY	1MG	N18677 001 DEC 26, 1985	/AG/	/200MG/ML/
			∂ LYPHOMED	100MG/ML
			∂	200MG/ML

NAFCILLIN SODIUM

/POWDER/FOR/RECONSTITUTION;/ORAL/
/UNIPEN/
/+//WYETH/AYERST/ /EQ/250MG/BASE/5ML/ /N50199/001/
∂ WYETH AYERST EQ 250MG BASE/5ML N50199 001

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
NALBUPHINE HYDROCHLORIDE
ABBOTT 1.5MG/ML N20200 001 MAR 12, 1993

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE HCL
/AP/ /LYPHOMED/ /0.02MG/ML/ /N70661/001/ /NOV/17,/1986/
∂ LYPHOMED 0.02MG/ML N70661 001 NOV 17, 1986

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NARCAN

/DUPONT/	/0.4MG/ML/	/N71083/001/ /JUL/28,/1988/		
	/1MG/ML/	/N71084/001/ /JUL/28,/1988/		
	/1MG/ML/	/N71311/001/ /JUL/28,/1988/		
∂ DUPONT	0.4MG/ML	N71083 001 JUL 28, 1988		
∂	1MG/ML	N71084 001 JUL 28, 1988		
∂	1MG/ML	N71311 001 JUL 28, 1988		

NANDROLONE DECANOATE

INJECTABLE; INJECTION
NANDROLONE DECANOATE

/AG/ /LYPHOMED/	/100MG/ML/	/N88290/001/ /OCT/03,/1983/		
/AG/	/200MG/ML/	/N88317/001/ /OCT/14,/1983/		
∂ LYPHOMED	100MG/ML	N88290 001 OCT 03, 1983		
∂	200MG/ML	N88317 001 OCT 14, 1983		

NIACIN

/CAPSULE;/ORAL/
/WAMPOCAP/
/WALLACE/ /500MG/ /N11073/003/
∂ WALLACE 500MG N11073 003

TABLET; ORAL
NIACIN
/AA/ /ZENITH/ /500MG/ /N83180/001/
∂ ZENITH 500MG N83180 001

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

ADALAT CC

BC	MILES	30MG	N20198 001 APR 21, 1993
BC		60MG	N20198 002 APR 21, 1993
BC		90MG	N20198 003 APR 21, 1993

PROCARDIA XL

BC +	PFIZER	30MG	N19684 001 SEP 06, 1989
BC +		60MG	N19684 002 SEP 06, 1989
BC +		90MG	N19684 003 SEP 06, 1989
/+/		/30MG/	/N19684/001/ /SEP/06,/1989/
/+/		/60MG/	/N19684/002/ /SEP/06,/1989/
/+/		/90MG/	/N19684/003/ /SEP/06,/1989/

NITROFURANTOIN

TABLET; ORAL

NITROFURANTOIN

/AB/	/ZENITH/	/50MG/	/N80078/002/
/AB/		/100MG/	/N80078/001/
	ə ZENITH	50MG	N80078 002
	ə	100MG	N80078 001

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

NITROFURANTOIN

AB	ZENITH	50MG	N73671 001 JAN 28, 1993
AB		100MG	N73652 001 JAN 28, 1993

NYSTATIN

CREAM; TOPICAL

NYSTATIN

AT	BARRE	100,000 UNITS/GM	N62949 001 JUN 13, 1988
/AT/	/NASKA/	/100,000 UNITS/GM/	/N62949/001/ /JUN/13,/1988/

NYSTATIN

CREAM; TOPICAL

NYSTATIN

AT	TARO	100,000 UNITS/GM	N64022 001 JAN 29, 1993

OINTMENT; TOPICAL

NYSTATIN

AT	BARRE	100,000 UNITS/GM	N62840 001 NOV 13, 1987
/AT/	/NASKA/	/100,000 UNITS/GM/	/N62840/001/ /NOV/13,/1987/

POWDER; ORAL

/BACITRACIN 100/

>DLT>				
>DLT>/AA/	/BARLAN/		/100%/	/N62489/001/ /APR/27,/1988/
>DLT>				
>ADD>				
>ADD>	ə BARLAN		100%	N62489 001 APR 27, 1988

SUSPENSION; ORAL

MYCOSTATIN

>ADD> AA	BRISTOL MYERS SQUIBB		100,000 UNITS/ML	N61533 001
>DLT>/AA/	/SQUIBB/		/100,000 UNITS/ML/	/N61533/001/

NYSTATIN

AA	BARRE	100,000 UNITS/ML	N62571 001 OCT 29, 1985
/AA/	/NASKA/	/100,000 UNITS/ML/	/N62571/001/ /OCT/29,/1985/
/AA/	/PHARMADERM/	/100,000 UNITS/ML/	/N62518/001/ /JUL/06,/1984/
	ə PHARMADERM	100,000 UNITS/ML	N62518 001 JUL 06, 1984

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

NYSTATIN AND TRIAMCINOLONE ACETONIDE

AT	BARRE	100,000 UNITS/GM;0.1%	N63010 001 DEC 20, 1988
/AT/	/NASKA/	/100,000 UNITS/GM;0.1%/	/N63010/001/ /DEC/20,/1988/

NYSTATIN-TRIAMCINOLONE ACETONIDE

/AT/	/PHARMADERM/	/100,000 UNITS/GM;0.1%/	/N62596/001/ /OCT/08,/1985/
	ə PHARMADERM	100,000 UNITS/GM;0.1%	N62596 001 OCT 08, 1985

NYSTATIN; TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL
NYSTATIN AND TRIAMCINOLONE ACETONIDE

AT	TARO	100,000 UNITS/GM;0.1%	N63305 001 MAR 29, 1993	> ADD >	

OCTREOTIDE ACETATE

INJECTABLE; INJECTION
SANDOSTATIN

/SANDOZ/	/EQ/500UGM/BASE/ML/	/N19667/001/ /OCT/21,/1988/	
SANDOZ	EQ 0.05MG BASE/ML	N19667 001 OCT 21, 1988	
	/EQ/100UGM/BASE/ML/	/N19667/002/ /OCT/21,/1988/	
	EQ 0.1MG BASE/ML	N19667 002 OCT 21, 1988	
	EQ 0.2MG BASE/ML	N19667 004 JUN 12, 1991	
	/EQ/500UGM/BASE/ML/	/N19667/003/ /OCT/21,/1988/	
	EQ 0.5MG BASE/ML	N19667 003 OCT 21, 1988	
	EQ 1MG BASE/ML	N19667 005 JUN 12, 1991	

OXPRENOLOL HYDROCHLORIDE

CAPSULE;ORAL
TRASICOR

/+//CIBA/	/160MG/	/N18166/004/ /DEC/28,/1983/	
	/20MG/	/N18166/001/ /DEC/28,/1983/	
	/40MG/	/N18166/002/ /DEC/28,/1983/	
	/80MG/	/N18166/003/ /DEC/28,/1983/	
@ CIBA	20MG	N18166 001 DEC 28, 1983	
@	40MG	N18166 002 DEC 28, 1983	
@	80MG	N18166 003 DEC 28, 1983	
@	160MG	N18166 004 DEC 28, 1983	

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION
AREDIA

+ CIBA GEIGY	60MG/VIAL	N20036 003 MAY 06, 1993	> ADD >
+	90MG/VIAL	N20036 004 MAY 06, 1993	> ADD >

PENICILLIN G BENZATHINE

INJECTABLE; INJECTION
BICILLIN L-A

/+//WYETH/AYERST/	/300,000/UNITS/ML/	/N50131/001/
+ WYETH AYERST	300,000 UNITS/ML	N50141 003
@	300,000 UNITS/ML	N50131 001
	/300,000/UNITS/ML/	/N50141/003/

TABLET;ORAL
BICILLIN

/+//WYETH/AYERST/	/200,000/UNITS/	/N50128/001/
@ WYETH AYERST	200,000 UNITS	N50128 001

PENICILLIN G POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN

/AA/	/BIOCRAFT/	/200,000 UNITS/5ML/	/N60307/002/
	BIOCRAFT	200,000 UNITS/5ML	N60307 002
	/PENTIDS '200'/		
/AA/	/SQUIBB/	/200,000 UNITS/5ML/	/N62149/001/
@ APOTHECON		200,000 UNITS/5ML	N62149 001
	/PENTIDS '400'/		
/AA/	/SQUIBB/	/400,000 UNITS/5ML/	/N62149/002/
@ APOTHECON		400,000 UNITS/5ML	N62149 002

TABLET; ORAL
PENICILLIN G POTASSIUM

@ APOTHECON		250,000 UNITS	N60392 003
/AB/	/SQUIBB/	/250,000 UNITS/	/N60392/003/
	/PENTIDS '200'/		
/AB/	/SQUIBB/	/200,000 UNITS/	/N62155/001/
@ APOTHECON		200,000 UNITS	N62155 001
	/PENTIDS '250'/		
/AB/	/SQUIBB/	/250,000 UNITS/	/N62155/002/
@ APOTHECON		250,000 UNITS	N62155 002

PENICILLIN G POTASSIUM

TABLET; ORAL

	/PENTIDS,400/			
/AB/	/SQUIBB/	/400,000 UNITS/	/N60392/004/	
/AB/		/400,000 UNITS/	/N62155/003/	
	ə APOTHECON	400,000 UNITS	N60392 004	
	ə	400,000 UNITS	N62155 003	
	/PENTIDS,800/			
/AB/	/SQUIBB/	/800,000 UNITS/	/N60392/005/	
/AB/		/800,000 UNITS/	/N62155/004/	
	ə APOTHECON	800,000 UNITS	N60392 005	
	ə	800,000 UNITS	N62155 004	

PENICILLIN G PROCAINE

INJECTABLE; INJECTION

	/DURACILLIN A.S./			
/AP/	/LILLY/	/300,000 UNITS/ML/	/N60093/001/	
	ə LILLY	300,000 UNITS/ML	N60093 001	

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

	/VEETIDS,125/			
/AA/	/SQUIBB/	/EQ 125MG BASE/5ML/	/N61206/001/	
/AA/		/EQ 125MG BASE/5ML/	/N62153/001/	
	ə APOTHECON	EQ 125MG BASE/5ML	N61206 001	
	ə	EQ 125MG BASE/5ML	N62153 001	
	/VEETIDS,250/			
/AA/	/SQUIBB/	/EQ 250MG BASE/5ML/	/N61206/002/	
/AA/		/EQ 250MG BASE/5ML/	/N62153/002/	
	ə APOTHECON	EQ 250MG BASE/5ML	N61206 002	
	ə	EQ 250MG BASE/5ML	N62153 002	

TABLET; ORAL

	/VEETIDS,250/			
/AB/	/SQUIBB/	/EQ 250MG BASE/	/N61164/001/	
/AB/		/EQ 250MG BASE/	/N62156/002/	
	ə APOTHECON	EQ 250MG BASE	N61164 001	
	ə	EQ 250MG BASE	N62156 002	
	/VEETIDS,500/			
/AB/	/SQUIBB/	/EQ 500MG BASE/	/N61164/002/	
/AB/		/EQ 500MG BASE/	/N62156/001/	
	ə APOTHECON	EQ 500MG BASE	N61164 002	
	ə	EQ 500MG BASE	N62156 001	

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

		/ADIPHEN/		
>_DLT_>				
>_DLT_>/AA/		/FERNDALE/	/35MG/	/N83655/001/
>_ADD_>	ə FERNDALE		35MG	N83655 001
>_DLT_>		/METRA/		
>_DLT_>/AA/		/FOREST/PHARMS/	/35MG/	/N83754/001/
>_ADD_>	ə FOREST PHARMS		35MG	N83754 001

PHENDIMETRAZINE TARTRATE

>_DLT_>/AA/		/ANABOLICS/	/35MG/	/N86020/001/
>_ADD_>	ə ANABOLICS		35MG	N86020 001
>_DLT_>/AA/		/FERNDALE/	/35MG/	/N86834/001/
>_DLT_>				/SEP/15,/1983/
>_ADD_>	ə FERNDALE		35MG	N86834 001
>_ADD_>				SEP 15, 1983

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

		ADIPEX-P		
>_DLT_>/AA/		/LEMMON/	/30MG/	/N86911/001/
		PHENTERMINE HCL		
>_ADD_>	ə LEMMON		30MG	N86911 001
/AA/		/ZENITH/	/30MG/	/N86329/001/
	ə ZENITH		30MG	N86329 001

PHENYLBUTAZONE

CAPSULE; ORAL

		PHENYLBUTAZONE		
/AB/		/CHELSEA/	/100MG/	/N87756/001/
				/DEC/17,/1982/
B*	CHELSEA		100MG	N87756 001
				DEC 17, 1982

PHYTONADIONE

INJECTABLE; INJECTION

		AQUAMEPHYTON		
/BP/	/MSD/		/10MG/ML/	/N12223/001/
BP +	MSD		10MG/ML	N12223 001

PHYTONADIONE

INJECTABLE; INJECTION

KONAKION

/BP/	/+//ROCHE/	/10MG/ML/	/N11745/003/	> ADD > AP
BP	ROCHE	10MG/ML	N11745 003	> ADD > AP
				> ADD >

PINDOLOL

TABLET; ORAL

PINDOLOL

AB	GENEVA	5MG	N73608 001 MAR 29, 1993	> DLT >
AB		10MG	N73609 001 MAR 29, 1993	> DLT >
AB	PUREPAC	5MG	N74125 001 APR 28, 1993	
AB		10MG	N74125 002 APR 28, 1993	
AB	ZENITH	5MG	N73687 001 FEB 26, 1993	
AB		10MG	N73687 002 FEB 26, 1993	

PIROXICAM

CAPSULE; ORAL

PIROXICAM

AB	MUTUAL PHARM	10MG	N73535 001 MAR 12, 1993
AB		20MG	N73536 001 MAR 12, 1993
AB	ROXANE	10MG	N73651 001 FEB 26, 1993
AB		20MG	N73651 002 FEB 26, 1993

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

K-LEASE

/AB/	/ADRIA/	/8MEQ/	/N73398/001/ /JAN/28,/1992/
/AB/		/10 MEQ/	/N72427/001/ /MAR/28,/1990/
AB	SAVAGE	8MEQ	N73398 001 JAN 28, 1992
AB		10 MEQ	N72427 001 MAR 28, 1990

POTASSIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

	FUJISAWA	2MEQ/ML	N84290 001
		2MEQ/ML	N87787 001 APR 20, 1982
/AP/	/LUITPOLD/	/2MEQ/ML/	/N80221/001/
/AP/		/2MEQ/ML/	/N80736/001/
	LUITPOLD	2MEQ/ML	N80221 001
		2MEQ/ML	N80736 001
	/LYPHOMED/	/2MEQ/ML/	/N84290/001/
		/2MEQ/ML/	/N87787/001/ /APR/20,/1982/

TABLET, EXTENDED RELEASE; ORAL

K+8

AB	ALRA	8MEQ	N70998 001 JAN 25, 1993

KAON CL

	/ADRIA/	/6.7MEQ/	/N17046/001/
	SAVAGE	6.7MEQ	N17046 001

KAON CL-10

/BC/	/ADRIA/	/10MEQ/	/N17046/002/
BC	SAVAGE	10MEQ	N17046 002

POTASSIUM CITRATE

/POWDER/FOR/RECONSTITUTION;/ORAL/
/POTASSIUM/CITRATE/

/+//UNIV/TX/	/20MEQ/PACKET/	/N19647/001/ /OCT/13,/1988/
	/10MEQ/PACKET/	/N19647/002/ /OCT/13,/1988/
UNIV TX	10MEQ/PACKET	N19647 002 OCT 13, 1988
	20MEQ/PACKET	N19647 001 OCT 13, 1988

TABLET, EXTENDED RELEASE; ORAL

POTASSIUM CITRATE

/+//UNIV/TX/	/5MEQ/	/N19071/001/ /AUG/30,/1985/
+ UNIV TX	10MEQ	N19071 002 AUG 31, 1992
	5MEQ	N19071 001 AUG 30, 1985

PRAVASTATIN SODIUM

TABLET; ORAL
PRAVACHOL
/+//BRISTOL/MYERS/SQUIBB/20MG/ /N19898/003/ /OCT/31,/1991/
+ BRISTOL MYERS SQUIBB 40MG N19898 004 MAR 22, 1993
20MG N19898 003 OCT 31, 1991

PRAZEPAM

/TABLET;/ORAL/
/CENTRAX/
/+//PARKE/DAVIS/ /10MG/ /N17415/001/
@ PARKE DAVIS 10MG N17415 001

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
>ADD> SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE
>ADD> AT STERIS EQ 0.23% PHOSPHATE;10% N73630 001 MAY 27, 1993
>ADD>
VASOCIDIN
>ADD> AT IOLAB EQ 0.23% PHOSPHATE;10% N18988 001 AUG 26, 1988
>ADD>

PREDNISONE

TABLET; ORAL
DELTASONE
AB UPJOHN 2.5MG N09986 005
/BX/ /2.5MG/ /N09986/005/
PREDNISONE
/AB/ /HEATHER/ /10MG/ /N84341/001/
/AB/ /20MG/ /N85543/001/
/AB/ /50MG/ /N86946/001/
@ HEATHER 10MG N84341 001
@ 20MG N85543 001
@ 50MG N86946 001
/BX/ /KV/ /5MG/ /N84236/001/
@ KV 5MG N84236 001
>ADD> BX NYLOS TRADING 5MG N85115 001
>DLT> /BX/ /TABLICAPS/ /5MG/ /N85115/001/

PROCAINAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
PROCAINAMIDE HCL
/AP/ /LYPHOMED/ /100MG/ML/ /N89415/001/ /NOV/17,/1986/
/AP/ /500MG/ML/ /N89416/001/ /NOV/17,/1986/
@ LYPHOMED 100MG/ML N89415 001 NOV 17, 1986
@ 500MG/ML N89416 001 NOV 17, 1986

PROMETHAZINE HYDROCHLORIDE

SUPPOSITORY; RECTAL
PROMETHACON
/BP/ /ALCON/ /25MG/ /N84901/001/
/BP/ /50MG/ /N84902/001/
BR POLYMEDICA 25MG N84901 001
BR 50MG N84902 001

TABLET; ORAL
PROMETHAZINE HCL
/BP/ /BOLAR/ /25MG/ /N83204/001/
@ BOLAR 25MG N83204 001
/BP/ /ZENITH/ /50MG/ /N83613/001/
@ ZENITH 50MG N83613 001

PROPRANOLOL HYDROCHLORIDE

/SUSPENSION;/ORAL/
/INDERAL/
/WYETH/AYERST/ /10MG/ML/ /N19536/001/ /DEC/12,/1986/
@ WYETH AYERST 10MG/ML N19536 001 DEC 12, 1986

PROTAMINE SULFATE

INJECTABLE; INJECTION
PROTAMINE SULFATE
/AP/ /QUAD/ /10MG/ML/ /N89306/001/ /MAY/30,/1986/
@ QUAD 10MG/ML N89306 001 MAY 30, 1986

PYRANTEL PAMOATE

	/SUSPENSION;/ORAL/		
	/ANTIMINTH/		
/+//ROERIG/	/EQ/250MG/BASE/5ML/	/N16883/001/	

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

	MESTINON		
/AP/	/ICN/	/5MG/ML/	/N09830/001/
AP	ROCHE	5MG/ML	N09830 001

SYRUP; ORAL

	MESTINON		
	/ICN/	/60MG/5ML/	/N15193/001/
	ROCHE	60MG/5ML	N15193 001

TABLET; ORAL

	MESTINON		
/+//ICN/		/60MG/	/N09829/002/
+	ROCHE	60MG	N09829 002

TABLET, EXTENDED RELEASE; ORAL

	MESTINON		
/+//ICN/		/180MG/	/N11665/001/
+	ROCHE	180MG	N11665 001

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION

	PYRIDOXINE HCL		
>ADD > AP	FUJISAWA	100MG/ML	N80618 001
>DLT >/AP/	/LYPHOMED/	/100MG/ML/	/N80618/001/

QUAZEPAM

TABLET; ORAL

	DORAL		
/+//BAKER/NORTON/		/15MG/	/N18708/001/
			/DEC/27,/1985/
		/7.5MG/	/N18708/003/
			/FEB/26,/1987/
+	WALLACE	15MG	N18708 001
			DEC 27, 1985
		7.5MG	N18708 003
			FEB 26, 1987

QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL

	/DURAQUIN/		
	/PARKE/DAVIS/	/330MG/	/N17917/001/
∂	WARNER CHILCOTT	330MG	N17917 001

QUINIDINE SULFATE

TABLET; ORAL

		QUINIDINE SULFATE		
>DLT >/AB/		/PARKE/DAVIS/	/200MG/	/N83879/001/
>ADD >	∂	WARNER CHILCOTT	200MG	N83879 001

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION

		RITODRINE HCL		
/AP/		/QUAD/	/10MG/ML/	/N70700/001/
				/OCT/06,/1986/
	∂	QUAD	10MG/ML	N70700 001
				OCT 06, 1986

SERACTIDE ACETATE

/INJECTABLE;/INJECTION/			
/ACTHAR/GEL-SYNTHETIC/			
	/ARMOUR/	/40/UNITS/ML/	/N17861/001/
		/80/UNITS/ML/	/N17861/002/
	∂ ARMOUR	40 UNITS/ML	N17861 001
	∂	80 UNITS/ML	N17861 002

SILVER SULFADIAZINE

DRESSING; TOPICAL

	SILDIMAC		
	ENQUAY	1%	N19608 001
			NOV 30, 1989
/MARION/MERRELL/DOW/		/1%/	/N19608/001/
			/NOV/30,/1989/

SODIUM CHLORIDE

INJECTABLE; INJECTION

	BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER		
AP	FUJISAWA	9MG/ML	N88911 001
			FEB 07, 1985

SODIUM CHLORIDE

INJECTABLE; INJECTION
BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/	/LYPHOMED/	/2MG/ML/		/N88011/001/	
				/FEB/07,/1985/	
	SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER				
>_DLT_>	/J/LYPHOMED/	/234MG/ML/		/N19329/001/	
>_DLT_>				/APR/22,/1987/	
>_ADD_>	J FUJISAWA	234MG/ML	N19329 001		
>_ADD_>			APR 22, 1987		

SOYBEAN OIL

INJECTABLE; INJECTION
NUTRILIPID 10%

>_ADD_>	AP	MCGAW	10%	N19531 001	
>_ADD_>				MAY 28, 1993	
	NUTRILIPID 20%				
>_ADD_>	AP	MCGAW	20%	N19531 002	
>_ADD_>				MAY 28, 1993	

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE

/AB/	/CHELSEA/	/25MG/		/N87078/001/	
B*	CHELSEA	25MG		N87078 001	

SULFAMETHIZOLE

TABLET; ORAL
THIOSULFIL

	/WYETH/AYERST/	/250MG/		/N08565/001/	
	J WYETH AYERST	250MG		N08565 001	

SULFAMETHOXAZOLE

TABLET; ORAL

>_DLT_>	/GANTANOL-DS/				
>_DLT_>	/ROCHE/	/1GM/		/N12715/003/	
>_ADD_>	J ROCHE	1GM		N12715 003	

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL
TRIMETH/SULFA

AB	BARRE	200MG/5ML;40MG/5ML		N72289 001	
				MAY 23, 1988	
AB		200MG/5ML;40MG/5ML		N72398 001	
				MAY 23, 1988	
/AB/	/NASKA/	/200MG/5ML;40MG/5ML/		/N72289/001/	
				/MAY/23,/1988/	
/AB/		/200MG/5ML;40MG/5ML/		/N72398/001/	
				/MAY/23,/1988/	

SULFISOXAZOLE

TABLET; ORAL
SULFISOXAZOLE

/AB/	/HEATHER/	/500MG/		/N80189/001/	
	J HEATHER	500MG		N80189 001	

SULFISOXAZOLE ACETYL

>_DLT_>	/EMULSION;/ORAL/				
>_DLT_>	/LIPO/GANTRISIN/				
>_DLT_>	/ROCHE/	/EQ/1GM/BASE/5ML/		/N09182/009/	
>_ADD_>	J ROCHE	EQ 1GM BASE/5ML		N09182 009	

SULFISOXAZOLE DIOLAMINE

>_DLT_>	/OINTMENT;/OPHTHALMIC/				
>_DLT_>	/GANTRISIN/				
>_DLT_>	/ROCHE/	/EQ/4%/BASE/		/N08414/002/	
>_ADD_>	J ROCHE	EQ 4% BASE		N08414 002	

TAMOXIFEN CITRATE

TABLET; ORAL
NOLVADEX

>_DLT_>	/+//STUART/	/EQ/10MG/BASE/		/N17970/001/	
>_ADD_>	+ ZENECA	EQ 10MG BASE		N17970 001	

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

>_DLT_>	/A-N/STANNOUS/AGGREGATED/ALBUMIN/				
>_DLT_> /BS/	/BENEDICT/	/N/A/		/N17916/001/	
>_ADD_>	J BENEDICT	N/A		N17916 001	

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

/TECHNETIUM/TC/99M/MAA/				
/BS/	/MEDI/PHYSICS/	/N/A/	/N17773/001/	
	@ MEDI PHYSICS	N/A	N17773 001	

TEMAZEPAM

CAPSULE; ORAL

TEMAZEPAM

> ADD >	AB	DANBURY	15MG	N71446 001	
> ADD >				MAY 21, 1993	
> ADD >	AB		30MG	N71447 001	
> ADD >				MAY 21, 1993	

TETRACYCLINE HYDROCHLORIDE

TABLET; ORAL

SUMYCIN

> ADD >	AB	APOTHECON	50MG	N61147 003	
> ADD >	AB		100MG	N61147 002	
> ADD >	AB		250MG	N61147 001	
> ADD >	AB	+	500MG	N61147 004	
> DLT >/	AB/	/SQUIBB/	/50MG/	/N61147/003/	
> DLT >/	AB/		/100MG/	/N61147/002/	
> DLT >/	AB/		/250MG/	/N61147/001/	
> DLT >/	AB//+/		/500MG/	/N61147/004/	

THEOPHYLLINE

ELIXIR; ORAL

/THEOPHYL-225/				
/JOHNSON/RW/		/112.5MG/15ML/	/N86485/001/	
@ JOHNSON RW		112.5MG/15ML	N86485 001	
THEOPHYLLINE				
AA	BARRE	80MG/15ML	N89223 001	
			MAY 27, 1988	
/AA/	/NASKA/	/80MG/15ML/	/N89223/001/	
			/MAY/27,/1988/	

TABLET; ORAL

QUIBRON-T			
/+//BRISTOL/MYERS/	/300MG/	/N88656/001/	
		/AUG/22,/1985/	
+ ROBERTS	300MG	N88656 001	
		AUG 22, 1985	

THEOPHYLLINE

TABLET; ORAL

/THEOPHYL-225/				
/JOHNSON/RW/		/225MG/	/N84726/001/	
@ JOHNSON RW		225MG	N84726 001	

/TABLET,/CHEWABLE;/ORAL/

/THEOPHYL/			
/JOHNSON/RW/	/100MG/	/N86506/001/	
		/SEP/12,/1985/	
@ JOHNSON RW	100MG	N86506 001	
		SEP 12, 1985	

TABLET, EXTENDED RELEASE; ORAL

QUIBRON-T/SR				
/BC/	/BRISTOL/MYERS/	/300MG/	/N87563/001/	
			/JUN/21,/1983/	
BC	ROBERTS	300MG	N87563 001	
			JUN 21, 1983	

THEOPHYLLINE SODIUM GLYCINATE

ELIXIR;/ORAL/

/SYNOPHYLATE/			
/CENTRAL/PHARMS/	/EQ/165MG/BASE/15ML/	/N06333/008/	
@ CENTRAL PHARMS	EQ 165MG BASE/15ML	N06333 008	

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

THIAMINE HCL

> ADD >	AP	FUJISAWA	100MG/ML	N80556 001
> DLT >/	AP/	/LYPHOMED/	/100MG/ML/	/N80556/001/

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL
THIORIDAZINE HCL

/AB/	/PAR/	/10MG/	/N88351/001/ /DEC/05,/1983/	
/AB/		/15MG/	/N88352/001/ /DEC/05,/1983/	
/AB/		/25MG/	/N88336/001/ /DEC/05,/1983/	
/AB/		/50MG/	/N88322/001/ /DEC/05,/1983/	
/AB/		/100MG/	/N88480/001/ /DEC/29,/1983/	
	∂ PAR	10MG	N88351 001 DEC 05, 1983	
	∂	15MG	N88352 001 DEC 05, 1983	
	∂	25MG	N88336 001 DEC 05, 1983	
	∂	50MG	N88322 001 DEC 05, 1983	
	∂	100MG	N88480 001 DEC 29, 1983	
/AB/	/ZENITH/	/100MG/	/N88273/001/ /OCT/03,/1983/	
	∂ ZENITH	100MG	N88273 001 OCT 03, 1983	

TICARCILLIN DISODIUM

INJECTABLE; INJECTION
TICAR

>ADD>	+ SMITHKLINE BEECHAM	EQ 20GM BASE/VIAL	N50497 004	
>ADD>	+	EQ 30GM BASE/VIAL	N50497 005	
>ADD>			APR 04, 1984	

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL
TICLID

+ SYNTEX	250MG	N19979 002 OCT 31, 1991	
∂	125MG	N19979 001 MAR 24, 1993	
	/250MG/	/N19979/002/ /OCT/31,/1991/	

TOLMETIN SODIUM

CAPSULE; ORAL
TOLMETIN SODIUM

>ADD> AB	MYLAN	EQ 400MG BASE	N73393 001 MAY 27, 1993	
>ADD>				

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

AB	MUTUAL PHARM	50MG	N73136 001 MAR 24, 1993
AB		100MG	N73137 001 MAR 24, 1993

TRETINOIN

>DLT>	/SWAB;/TOPICAL/		
>DLT>	/RETIN-A/		
>DLT>	/+//JOHNSON/RW/	/0.05%/	/N16921/002/
>ADD>	∂ JOHNSON RW	0.05%	N16921 002

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
TRIAMCINOLONE ACETONIDE

/AT/	/PHARMADERM/	/0.025%/	/N87990/001/ /JUL/07,/1983/
/AT/		/0.1%/	/N87991/001/ /JUL/07,/1983/
/AT/		/0.5%/	/N87992/001/ /JUL/07,/1983/
	∂ PHARMADERM	0.025%	N87990 001 JUL 07, 1983
	∂	0.1%	N87991 001 JUL 07, 1983
	∂	0.5%	N87992 001 JUL 07, 1983

OINTMENT; TOPICAL
TRIAMCINOLONE ACETONIDE

AT	BARRE	0.5%	N89913 001 DEC 23, 1988
/AT/	/NASKA/	/0.5%/	/N89913/001/ /DEC/23,/1988/

TRIAMCINOLONE ACETONIDE

TRIPELENNAMINE HYDROCHLORIDE

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

	TRIAMCINOLONE ACETONIDE			
/AT/	/PHARMADERM/	/0.025%/	/N88692/001/	
			/AUG/02,/1984/	
/AT/		/0.1%/	/N88690/001/	
			/AUG/02,/1984/	
	ə PHARMADERM	0.025%	N88692 001	
			AUG 02, 1984	
	ə	0.1%	N88690 001	
			AUG 02, 1984	

TRIFLUOPERAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

>DLT>	/TEE/			
>DLT>/AA/	/GENEVA/	/EQ 10MG BASE/ML/	/N85787/001/	
>DLT>			/APR/15,/1982/	
	TRIFLUOPERAZINE HCL			
>ADD> AA	GENEVA	EQ 10MG BASE/ML	N85787 001	
>ADD>			APR 15, 1982	

TABLET; ORAL

>DLT>	/TEE/			
>DLT>/AB/	/GENEVA/	/EQ 1MG BASE/	/N85785/001/	
>DLT>/AB/		/EQ 2MG BASE/	/N85786/001/	
>DLT>/AB/		/EQ 5MG BASE/	/N85789/001/	
>DLT>/AB/		/EQ 10MG BASE/	/N85788/001/	
	TRIFLUOPERAZINE HCL			
>ADD> AB	GENEVA	EQ 1MG BASE	N85785 001	
>ADD> AB		EQ 2MG BASE	N85786 001	
>ADD> AB		EQ 5MG BASE	N85789 001	
>ADD> AB		EQ 10MG BASE	N85788 001	

TRIFLUPROMAZINE

/SUSPENSION;/ORAL/			
/VESPRIN/			
/SQUIBB/	/EQ/50MG/HCL/5ML/	/N11491/004/	
ə APOTHECON	EQ 50MG HCL/5ML	N11491 004	

TRIHEXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL

	TRIHEXYPHENIDYL HCL			
>ADD> AA	NYLOS TRADING	5MG	N85622 001	
>DLT>/AA/	/TABLICAPS/	/5MG/	/N85622/001/	

TRIPELENNAMINE HYDROCHLORIDE

TABLET; ORAL

	TRIPELENNAMINE HCL			
>DLT>/AA/	/HEATHER/	/50MG/	/N83989/001/	
>ADD>	ə HEATHER	50MG	N83989 001	
>ADD> AA	NYLOS TRADING	50MG	N85412 001	
>DLT>/AA/	/TABLICAPS/	/50MG/	/N85412/001/	

TUBOCURARINE CHLORIDE

INJECTABLE; INJECTION

	TUBOCURARINE CHLORIDE			
/AP/	/QUAD/	/5MG/ML/	/N89442/001/	
			/AUG/12,/1988/	
	ə QUAD	3MG/ML	N89442 001	
			AUG 12, 1988	

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

	VANCOCIN HCL IN PLASTIC CONTAINER		
	+ LILLY	EQ 500MG BASE/100ML	N50671 001
			APR 29, 1993

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION

	VERAPAMIL HCL		
AP	MARSAM	2.5MG/ML	N72233 001
			FEB 26, 1993

VINBLASTINE SULFATE

INJECTABLE; INJECTION

	VINBLASTINE SULFATE		
	FUJISAWA	1MG/ML	N89515 001
			APR 29, 1987
	/LYPHOMED/	/1MG/ML/	/N89515/001/
			/APR/29,/1987/

VITAMIN A PALMITATE

CAPSULE; ORAL

	AFAXIN		
	ə STERLING	EQ 50,000 UNITS BASE	N83187 001

VITAMIN A PALMITATE

CAPSULE; ORAL

		VITAMIN A		
> DLT >	AA	WHARTON	EQ 50,000 UNITS BASE	N83665 001
> ADD >		@ WHARTON	EQ 50,000 UNITS BASE	N83665 001
	AA	ZENITH	EQ 50,000 UNITS BASE	N83035 001
	AA	ZENITH	EQ 50,000 UNITS BASE	N83190 001
		@ ZENITH	EQ 50,000 UNITS BASE	N83035 001
		@	EQ 50,000 UNITS BASE	N83190 001

XENON, XE-133

GAS; INHALATION

	XENON XE 133		
AA	MEDI PHYSICS	10MCI/VIAL	N17687 002
AA		20MCI/VIAL	N17687 003

XYLOSE

POWDER; ORAL

	XYLO-PFAH		
AA	ADRIA	25GM/BOT	N17605 001
AA	SAVAGE	25GM/BOT	N17605 001

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

ISOCLOR		
CIBA	8MG;120MG	N18747 001 MAR 06, 1986
/FISONS/	/8MG;120MG/	/N18747/001/ /MAR/06/1986/

CLOTRIMAZOLE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL

GYNE-LOTRIMIN COMBINATION PACK		
+ SCHERING PLOUGH	1%;100MG	N20289 002 APR 26, 1993

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL

DIPHENHYDRAMINE HCL		
BARRE	12.5MG/5ML	N70497 001 APR 25, 1989
/NASKA/	/12.5MG/5ML/	/N70497/001/ /APR/25/1989/

IBUPROFEN

TABLET; ORAL

IBUPROFEN		
/LUCHEM/	/200MG/	/N72901/001/ /DEC/19/1991/
	/200MG/	/N72903/001/ /DEC/19/1991/
IBUPROFEN		
NORTON HN	200MG	N71144 001 JAN 20, 1987
	200MG	N72901 001 DEC 19, 1991
	200MG	N72903 001 DEC 19, 1991
/IBUPROFEN/		
/OHM/	/200MG/	/N71214/001/ /DEC/01/1986/
IBUPROFEN		
/ZENITH/	/200MG/	/N71154/001/ /OCT/27/1987/
∂ ZENITH	200MG	N71154 001 OCT 27, 1987

IBUPROFEN

TABLET; ORAL

IBUPROHM		
OHM	200MG	N71214 001 DEC 01, 1986
/NEUVIL/		
/LUCHEM/	/200MG/	/N71144/001/ /JAN/20/1987/

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL

LOPERAMIDE HCL		
WATSON LABS	1MG/5ML	N73062 001 MAY 28, 1993

MICONAZOLE NITRATE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL

MONISTAT 7 COMBINATION PACK		
+ ADVANCED CARE	2%;100MG	N20288 002 APR 26, 1993

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

/CAPSULE;ORAL/

/ACTIFED/		
/BURROUGHS/WELLCOME/	/60MG;2.5MG/	/N19268/001/ /JAN/15/1985/

/SYRUP;ORAL/

/ACTIFED/		
/BURROUGHS/WELLCOME/	/30MG/5ML;1.25MG/5ML/	/N11935/003/ /NOV/26/1982/
/TRIOFED/		
/BARRE/	/30MG/5ML;1.25MG/5ML/	/N88115/001/ /MAR/04/1983/
/TRIPOSED/		
/HALSEY/	/30MG/5ML;1.25MG/5ML/	/N88213/002/ /MAR/30/1984/

/TABLET;ORAL/

/ACTIFED/		
/BURROUGHS/WELLCOME/	/60MG;2.5MG/	/N11936/002/ /NOV/26/1982/

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

/TABLET;/ORAL/

/TRI-SUDO/		
/MD/PHARM/	/60MG;2.5MG/	/N85024/002/ /JAN/10,/1984/
/TRIPODRINE/		
/DANBURY/	/60MG;2.5MG/	/N88112/001/ /JAN/20,/1983/
/TRIPOSED/		
/HALSEY/	/60MG;2.5MG/	/N88192/002/ /MAY/01,/1984/
/TRIPROLIDINE/HCL/AND/PSEUDOEPHEDRINE/HCL/		
/CHELSEA/	/60MG;2.5MG/	/N88118/002/ /JAN/26,/1984/

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 '93

INDIUM^{111} CHLORIDE

SOLUTION; INJECTION
INDICLOR
AMERSHAM N/A N19862
DEC 29, 1992

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January thru May 1993]

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
AMINOSALICYLATE SODIUM TN=	TREATMENT OF CROHN'S DISEASE.	SYNCOM PHARMACEUTICALS, INC. 155 PASSAIC AVENUE FAIRFIELD NJ 07004 DD 04/06/93 MA / /
AMINOSIDINE TN= GABBROMICINA	TREATMENT OF TUBERCULOSIS.	UNIVERSITY OF ILLINOIS AT CHICAGO 833 SOUTH WOOD STREET M/C 886 ROOM 176 CHICAGO IL 60612 DD 05/14/93 MA / /
APOMORPHINE HCL INJECTION TN=	TREATMENT OF THE ON-OFF FLUCTUATIONS ASSOCIATED WITH LATE-STAGE PARKINSON'S DISEASE.	BRITANNIA PHARMACEUTICALS LTD FORUM HOUSE, BRIGHTON ROAD REDHILL, SURREY UK DD 04/22/93 MA / /
ATOVAQUONE TN= MEPRON	TREATMENT AND SUPPRESSION OF TOXOPLASMA GONDII ENCEPHALITIS.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 03/16/93 MA / /
ATOVAQUONE TN= MEPRON	PRIMARY PROPHYLAXIS OF HIV-INFECTED PERSONS AT HIGH RISK FOR DEVELOPING TOXOPLASMA GONDII ENCEPHALITIS.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 03/16/93 MA / /
CLADRIBINE TN= LEUSTATIN INJECTION	TREATMENT OF NON-HODGKIN'S LYMPHOMA.	R.W.JOHNSON RESEARCH INSTITUTE ROUTE 202 SOUTH, P.O. BOX 300 RARITAN NJ 08869-0602 DD 04/19/93 MA / /
COLFOSCERIL PALMITATE, CETYL ALCOHOL, TYLOXAPOL TN= EXOSURF	TREATMENT OF ADULT RESPIRATORY DISTRESS SYNDROME.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 01/11/93 MA / /
CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR GENE TN=	TREATMENT OF CYSTIC FIBROSIS.	GENETIC THERAPY, INC. 19 FIRSTFIELD ROAD GAITHERSBURG MD 20878 DD 01/08/93 MA / /
FACTOR XIII, RECOMBINANT TN=	TREATMENT OF CONGENITAL FACTOR XIII DEFICIENCY.	ZYMOGENETICS, INC. 4225 ROOSEVELT WAY SEATTLE WA 98105 DD 04/22/93 MA / /
HUMANIZED ANTI-TAC TN=	PREVENTION OF ACUTE RENAL ALLOGRAFT REJECTION.	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND STREET NUTLEY NJ 07110 DD 03/05/93 MA / /
HUMANIZED ANTI-TAC TN=	PREVENTION OF ACUTE GRAFT-VS-HOST DISEASE FOLLOWING BONE MARROW TRANSPLANTATION.	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND STREET NUTLEY NJ 07110 DD 03/05/93 MA / /
IMMUNE GLOBULIN INTRAVENOUS (HUMAN) TN= GAMIMUNE N	INFECTION PROPHYLAXIS IN PEDIATRIC PATIENTS AFFECTED WITH THE HUMAN IMMUNODEFICIENCY VIRUS.	MILES, INC. 4TH & PARKER STREETS BERKELEY CA 94710 DD 02/18/93 MA / /
INTERFERON BETA (RECOMBINANT HUMAN) TN=	TREATMENT OF PRIMARY BRAIN TUMORS.	BIOGEN, INC. 14 CAMBRIDGE CENTER CAMBRIDGE MA 02142 DD 01/13/93 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD= Date Designated MA= Marketing Approval
LIPOSOMAL DAUNORUBICIN TN= DAUNOXOME	TREATMENT OF PATIENTS WITH ADVANCED HIV-ASSOCIATED KAPOSI'S SARCOMA.	VESTAR, INC. 650 CLIFFSIDE DRIVE SAN DIMAS CA 91773 DD 05/14/93 MA / /
MODAFINIL TN=	TREATMENT OF EXCESSIVE DAYTIME SLEEPINESS IN NARCOLEPSY.	CEPHALON, INC. 145 BRANDYWINE PARKWAY WEST CHESTER PA 19380-4245 DD 03/15/93 MA / /
MONOCLONAL ANTIBODY FOR IMMUNIZATION AGAINST LUPUS NEPHRITIS TN=	TREATMENT OF LUPUS NEPHRITIS.	MEDCLONE, INC. 2435 MILITARY AVENUE LOS ANGELES CA 90064 DD 01/07/93 MA / /
MONOLAURIN TN= GLYLORIN	TREATMENT OF CONGENITAL PRIMARY ICHTHYOSIS.	CELLEGY PHARMACEUTICALS, INC. 371 BEL MARIN KEYS, SUITE 210 NOVATO CA 94949 DD 04/29/93 MA / /
PROTEIN C CONCENTRATE TN= PROTEIN C CONCENTRATE (HUMAN) VAPOR HEATED, IMMUNO	FOR USE IN THE PREVENTION AND TREATMENT OF PURPURA FULMINANS IN MENINGOCOCCEMIA.	IMMUNO CLINICAL RESEARCH CORP. 750 LEXINGTON AVENUE, 19TH FLOOR NEW YORK NY 10022 DD 04/22/93 MA / /
RETINAMIDE TN=	TREATMENT OF MYELODYSPLASTIC SYNDROMES.	SPARTA PHARMACEUTICALS, INCORPORATED PO BOX 13288 RESEARCH TRIANGLE PK NC 27709 DD 05/06/93 MA / /
RILUZOLE TN=	TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.	RHONE-POULENC RORER PHARM. 500 ARCOLA ROAD, PO BOX 1200 COLLEGEVILLE PA 19426-0107 DD 03/16/93 MA / /
SOMATROPIN TN= BIOTROPIN	TREATMENT OF CACHEXIA ASSOCIATED WITH AIDS.	BIO-TECHNOLOGY GENERAL CORPORATION 1250 BROADWAY, 20th FLOOR NEW YORK NY 10001 DD 02/12/93 MA / /
THALIDOMIDE TN=	TREATMENT OF THE CLINICAL MANIFESTATIONS OF MYCOBACTERIAL INFECTION CAUSED BY MYCOBACTERIUM TUBERCULOSIS AND NON-TUBERCULOUS MYCOBACTERIA.	CELGENE CORPORATION 7 POWDER HORN DRIVE WARREN NJ 07059 DD 01/12/93 MA / /
TRETINOIN TN= TRETINOIN LF, IV	TREATMENT OF ACUTE AND CHRONIC LEUKEMIA.	ARGUS PHARMACEUTICALS, INC. 3400 RESEARCH FOREST DRIVE THE WOODLANDS TX 77381 DD 01/14/93 MA / /
TUMOR NECROSIS FACTOR-BINDING PROTEIN 1 TN=	TREATMENT OF SYMPTOMATIC PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH CD4 COUNTS LESS THAN 200 CELLS PER MM3.	SERONO LABORATORIES, INC. 100 LONGWATER CIRCLE NORWELL MA 02061 DD 01/06/93 MA / /
TUMOR NECROSIS FACTOR-BINDING PROTEIN II TN=	TREATMENT OF SYMPTOMATIC PATIENTS WITH THE ACQUIRED IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH CD4 T-CELL COUNTS LESS THAN 200 CELLS PER MM3.	SERONO LABORATORIES, INC. 100 LONGWATER CIRCLE NORWELL MA 02061 DD 01/06/93 MA / /

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

Orphan Drug Approvals

ANTIHEMOPHILIC FACTOR (RECOMBINANT) TN= KOGENATE	PROPHYLAXIS AND TREATMENT OF BLEEDING IN INDIVIDUALS WITH HEMOPHILIA A OR FOR PROPHYLAXIS WHEN SURGERY IS REQUIRED IN INDIVIDUALS WITH HEMOPHILIA A.	MILES, INC. 4TH & PARKER STREETS BERKELEY CA 94701 DD 09/25/89 MA 02/25/93
CLADRIBINE TN= LEUSTATIN INJECTION	TREATMENT OF HAIRY CELL LEUKEMIA.	R.W.JOHNSON RESEARCH INSTITUTE ROUTE 202, PO BOX 300 RARITAN NJ 08869-0602 DD 11/15/90 MA 02/26/93
LEUPROLIDE ACETATE TN= LUPRON INJECTION	TREATMENT OF CENTRAL PRECOCIOUS PUBERTY.	TAP PHARMACEUTICALS, INC. 2355 WAUKEGAN ROAD DEERFIELD IL 60015 DD 07/25/88 MA 04/16/93

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

NO MAY 1993 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.

BUMETANIDE (TABLET)	APR 23, 1993
CEFACLOR (CAPSULE AND SUSPENSION)	APR 23, 1993
GLIPIZIDE (TABLET)	APR 23, 1993
GLYBURIDE (TABLET)	APR 23, 1993
GUANABENZ ACETATE (TABLET)	APR 23, 1993
INDAPAMIDE (TABLET)	APR 23, 1993
KETOPROFEN (CAPSULE)	APR 23, 1993
PINDOLOL (TABLET)	APR 23, 1993
RANITIDINE HYDROCHLORIDE (TABLET)	APR 23, 1993
TRIAZOLAM (TABLET)	DEC 24, 1992

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
AMINOSALICYLIC ACID GRANULES, ENTERIC-COATED; ORAL	4GM/PACKET	92 P-0356/ CP1	JACOBUS	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 03, 1993
CHLORPROMAZINE HYDROCHLORIDE SOLUTION; ORAL	25MG/5ML	92 P-0284/ CP1	UDL	NEW STRENGTH	APPROVED JAN 07, 1993
DOBUTAMINE HYDROCHLORIDE INJECTABLE; INJECTION	EQ 12.5MG BASE/ML (40ML/VIAL)	92 P-0365/ CP1	LYPHOMED	NEW STRENGTH	APPROVED FEB 11, 1993
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (12.5MG/VIAL)	92 P-0355/ CP1	LEDERLE	NEW STRENGTH	APPROVED JAN 07, 1993
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (50ML/CONTAINER)	91 P-0460/ CP1	ABBOTT	NEW STRENGTH	APPROVED FEB 11, 1993
LACTULOSE CRYSTAL; ORAL	10GM/PACKET	92 P-0370/ CP1	BENNETT AND COMPANY	NEW DOSAGE FORM	APPROVED JAN 07, 1993
METHYLPHENIDATE HYDROCHLORIDE; TABLET, EXTENDED RELEASE; ORAL	10MG	92 P-0400/ CP1	MD PHARM	NEW STRENGTH	APPROVED MAR 22, 1993

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.

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, 13TH 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-20	SINGLE 32MG DOSE

REFERENCES
NEW INDICATION

I-87	RENAL IMAGING AGENT FOR USE IN CHILDREN
I-88	MANAGEMENT OF ENDOMETRIOSIS
I-89	EPIDURAL USE IN LABOR AND DELIVERY AS AN ANALGESIC ADJUNCT TO BUPIVACAINE
I-90	INTENSIVE CARE UNIT SEDATION
I-91	MONOTHERAPY USE FOR HYPERTENSION

REFERENCES
PATENT USE CODE

U-74	METHOD OF PROVIDING HYPNOTIC EFFECT
U-75	RELIEF OF OCULAR ITCHING DUE TO SEASONAL ALLERGIC CONJUNCTIVITIS
U-76	USE TO IMAGE A SUBJECT WITH A MAGNETIC RESONANCE IMAGING SYSTEM
U-77	TREATMENT OF SYMPTOMS OF SEASONAL ALLERGIC RHINITIS

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
	19604 001	ALBUTEROL SULFATE; VOLMAX	4851229	JUN 14, 2005			
			4777049	OCT 11, 2005			
			4751071	JUN 14, 2005			
	19604 002	ALBUTEROL SULFATE; VOLMAX	4851229	JUN 14, 2005			
			4777049	OCT 11, 2005			
			4751071	JUN 14, 2005		NS	DEC 23, 1995
>ADD>	19402 001	ASTEMIZOLE; HISMANAL	4219559	AUG 26, 1999		NCE	DEC 29, 1993
>DLT>	~~19402 001~~	~~ASTEMIZOLE; HISMANAL~~	~~4219559~~	~~AUG 26, 1997~~		~~NCE~~	~~DEC 29, 1993~~
	20045 001	AVOBENZONE; SHADE UVAGUARD	4522807	JUN 11, 2002		NC	DEC 07, 1995
			4387089	JUN 07, 2002			
	19807 001	BETAXOLOL HYDROCHLORIDE; KERLEDEX	4252984	AUG 30, 1999			
	19807 002	BETAXOLOL HYDROCHLORIDE; KERLEDEX	4252984	AUG 30, 1999			
	20186 001	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
						NC	FEB 26, 1996
	20186 002	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
						NC	FEB 26, 1996
	20186 003	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
						NC	FEB 26, 1996
	20229 001	CLADRIBINE; LEUSTATIN				NCE	FEB 26, 1998
						ODE	FEB 26, 2000
>ADD>	18723 001	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008			
>ADD>	18723 002	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008			
>ADD>	18723 003	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008			
>ADD>	19680 001	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008			
>ADD>	19794 001	DIVALPROEX SODIUM; DEPAKOTE CP	5212326	JAN 29, 2008			
>ADD>	19794 002	DIVALPROEX SODIUM; DEPAKOTE CP	5212326	JAN 29, 2008			
	18651 001	DRONABINOL; MARINOL				ODE	DEC 22, 1999
	18651 002	DRONABINOL; MARINOL				ODE	DEC 22, 1999
	18651 003	DRONABINOL; MARINOL				ODE	DEC 22, 1999
	19616 004	ENOXACIN; PENETREX	4359578	NOV 16, 2001		NCE	DEC 31, 1996
	19616 005	ENOXACIN; PENETREX	4359578	NOV 16, 2001		NCE	DEC 31, 1996
	20164 001	ENOXAPARIN SODIUM; LOVENOX				NCE	MAR 29, 1998
	20073 001	FLUMAZENIL; MAZICON	4316839	MAR 03, 2003		NCE	DEC 20, 1996
	18936 006	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001			
			4194009	APR 19, 1994			
			4018895	APR 19, 1994	U-12		
	20068 001	FOSCARNET SODIUM; FOSCAVIR	4215113	JUN 06, 2000	U-64	NCE	SEP 27, 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
	20123 001	GADODIAMIDE; OMNISCAN	4687659	AUG 18, 2004	U-76	NCE	JAN 08, 1998
>ADD>	17783 003	GLIPIZIDE; GLUCOTROL				NCE	MAY 08, 1994
	19726 001	GOSERELIN ACETATE; ZOLADEX				I-88	FEB 02, 1996
>ADD>	19032 001	GUANFACINE HYDROCHLORIDE; TENEX				I-91	MAY 11, 1996
>ADD>	19032 002	GUANFACINE HYDROCHLORIDE; TENEX				I-91	MAY 11, 1996
	19891 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID				NCE	JAN 11, 1994
						NDF	DEC 07, 1995
	19892 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID				NCE	JAN 11, 1994
						NDF	DEC 07, 1995
	18538 002	INDAPAMIDE; LOZOL				NS	APR 29, 1996
						NCE	JUL 06, 1993
	19084 001	KETOCONAZOLE; NIZORAL	4335125	JUN 15, 1999		I-30	JAN 27, 1996
	19700 001	KETOROLAC TROMETHAMINE; ACULAR	5110493	MAY 05, 2009	U-75	NCE	NOV 30, 1994
			4454151	JUN 12, 2001	U-75	NDF	NOV 09, 1995
			4089969	MAY 16, 1997	U-75		
>ADD>	20263 001	LEUPROLIDE ACETATE; LUPRON	4917893	MAR 24, 2004			
>ADD>			4849228	JUL 18, 2006		NP	APR 16, 1996
>ADD>			4728721	MAR 01, 2005			
>ADD>			4677191	JUN 30, 2004			
>ADD>			4652441	MAR 24, 2004			
			4005063	JAN 25, 1996		ODE	APR 16, 2000
>ADD>	20263 002	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4917893	MAR 24, 2004			
>ADD>			4849228	JUL 18, 2006		NP	APR 16, 1996
>ADD>			4728721	MAR 01, 2005			
>ADD>			4677191	JUN 30, 2004			
>ADD>			4652441	MAR 24, 2004			
			4005063	JAN 25, 1996		ODE	APR 16, 2000
>ADD>	20263 003	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4917893	MAR 24, 2004			
>ADD>			4849228	JUL 18, 2006		NP	APR 16, 1996
>ADD>			4728721	MAR 01, 2005			
>ADD>			4677191	JUN 30, 2004			
>ADD>			4652441	MAR 24, 2004			
			4005063	JAN 25, 1996		ODE	APR 16, 2000

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>	20263 004	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4917893	MAR 24, 2004			
>ADD>			4849228	JUL 18, 2006		NP	APR 16, 1996
>ADD>			4728721	MAR 01, 2005			
>ADD>			4677191	JUN 30, 2004			
>ADD>			4652441	MAR 24, 2004			
			4005063	JAN 25, 1996		ODE	APR 16, 2000
	18948 001	LEVOCARNITINE; CARNITOR				I-86	DEC 16, 1995
	18948 002	LEVOCARNITINE; CARNITOR				I-86	DEC 16, 1995
	19777 005	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001			
	20013 001	LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN	4528287	MAY 05, 2005	U-36	NCE	FEB 21, 1997
>ADD>	19658 001	LORATADINE; CLARITIN	4282233	AUG 04, 1998	U-77	NCE	APR 12, 1998
>DLT>	~~19658 001~~	~~LORATADINE; CLARITIN~~	~~4282233~~	~~SEP 04, 1998~~		~~NCE~~	~~APR 12, 1998~~
>ADD>	20049 001	MESALAMINE; PENTASA				NP	MAY 10, 1996
	20098 001	MIVACURIUM CHLORIDE; MIVACRON	4761418	JAN 22, 2006		NCE	JAN 22, 1997
	20098 002	MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5%	4761418	JAN 22, 2006		NCE	JAN 22, 1997
	19583 001	NABUMETONE; RELAFEN	4420639	DEC 13, 2002		NCE	DEC 24, 1996
	19583 002	NABUMETONE; RELAFEN	4420639	DEC 13, 2002		NCE	DEC 24, 1996
	20109 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1999		NCE	FEB 13, 1995
	20150 001	NICOTINE; NICOTROL	4915950	APR 10, 2007		NP	APR 22, 1995
	20150 002	NICOTINE; NICOTROL	4915950	APR 10, 2007		NP	APR 22, 1995
	20150 003	NICOTINE; NICOTROL	4915950	APR 10, 2007		NP	APR 22, 1995
	20066 001	NICOTINE POLACRILEX; NICORETTE DS				NCE	JAN 13, 1994
	20198 001	NIFEDIPINE; ADALAT CC	4892741	JAN 09, 2007			
	20198 002	NIFEDIPINE; ADALAT CC	4892741	JAN 09, 2007			
	20198 003	NIFEDIPINE; ADALAT CC	4892741	JAN 09, 2007			
	20007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 03, 2005		D-20	FEB 02, 1996
	20103 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	SEP 22, 2004		NCE	JAN 04, 1996
	20103 002	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	SEP 22, 2004		NCE	JAN 04, 1996
	20036 001	PAMIDRONATE DISODIUM; AREDIA	3962432	FEB 01, 1997	U-53		
>ADD>	20014 001	PIRBUTEROL ACETATE; MAXAIR	4664107	MAY 12, 2004			
	19898 004	PRAVASTATIN SODIUM; PRAVACHOL	4346227	AUG 24, 1999		NCE	OCT 31, 1996
	19568 001	PREDNICARBATE; DERMATOP	4242334	DEC 30, 1999	U-50	NE	SEP 23, 1994
	19627 001	PROPOFOL; DIPRIVAN				I-90	MAR 08, 1996
	50689 001	RIFABUTIN; MYCOBUTIN				ODE	DEC 23, 1999
	19839 001	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005		NCE	DEC 30, 1996
	19839 002	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005		NCE	DEC 30, 1996
	19839 003	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005		NCE	DEC 30, 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
19839 004	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005		NCE	DEC 30, 1996
19766 001	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
19766 002	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
19766 003	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
19766 004	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
19050 001	SUFENTANIL CITRATE; SUFENTA				NR	MAR 19, 1996
					I-89	MAR 19, 1996
20080 001	SUMATRIPTAN SUCCINATE; IMITREX	4816470	MAR 28, 2006	U-72		
19882 001	TECHNETIUM TC-99M MERTIATIDE KIT; TECHNESCAN MAG3				I-87	NOV 27, 1995
20043 003	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	JAN 30, 2006	U-36	NCE	JAN 30, 1997
20043 004	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	JAN 30, 2006	U-36	NCE	JAN 30, 1997
18163 003	TEMAZEPAM; RESTORIL	5030632	JUL 09, 2008	U-70	NS	OCT 25, 1994
19979 001	TICLOPIDINE HYDROCHLORIDE; TICLID	4051141	SEP 27, 1996		NCE	OCT 31, 1996
19979 002	TICLOPIDINE HYDROCHLORIDE; TICLID	4591592	NOV 01, 2005			
		4051141	SEP 27, 1996		NCE	OCT 31, 1996
18776 003	VECURONIUM BROMIDE; NORCURON	4297351	OCT 27, 1998			
		4237126	DEC 02, 1997		NCE	APR 30, 1994
19908 001	ZOLPIDEM TARTRATE; AMBIEN	4382938	MAY 10, 2000	U-74	NCE	DEC 16, 1997
19908 002	ZOLPIDEM TARTRATE; AMBIEN	4382938	MAY 10, 2000	U-74	NCE	DEC 16, 1997

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19862 001	INDIUM 111 CHLORIDE; INDICLOR				NCE	DEC 29, 1997

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