CUMULATIVE SUPPLEMENT 4

JAN'93-APR'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

Approved drug products with therapeutic equivalence

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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

Cumulative Supplement 4

APRIL 1993

CONTENTS

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

CUMULATIVE SUPPLEMENT 4

APRIL 1993

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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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

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

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

COMPAL

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

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

/AA/	/LUCHEM/	/500MG;5MG/	/N89696/001/ /APR/21,/1988/
AA	NORTON HN	500MG;5MG	N89696 001 APR 21, 1988

> DLT >		/TYCOLET/		
> DLT >	/AA/	/JOHNSON/RW/	/500MG;5MG/	/N89385/001/ /AUG/27,/1986/
> DLT >				
> ADD >		@ JOHNSON RW	500MG;5MG	N89385 001 AUG 27, 1986
> ADD >				

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

> DLT >		/ACETAZOLAMIDE SODIUM/		
> DLT >	/AP/	/QUAD/	/EQ 500MG/VIAL/	/N89619/001/ /JAN/13,/1988/
> DLT >				
> ADD >		@ QUAD	EQ 500MG/VIAL	N89619 001 JAN 13, 1988
> ADD >				

DIAMOX

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

ALBUTEROL SULFATE

SYRUP; ORAL

ALBUTEROL SULFATE

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

TABLET, EXTENDED RELEASE; ORAL

PROVENTIL

> DLT >	/AB/	/+//SCHERING/	/EQ 4MG BASE/	/N19383/001/ /JUL/13,/1987/
> DLT >				
> ADD >	BC	+ SCHERING	EQ 4MG BASE	N19383 001 JUL 13, 1987
> ADD >				

VOLMAX

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

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL

AMANTADINE HCL

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

AMINO ACIDS

INJECTABLE; INJECTION

NOVAMINE 15% SULFITE FREE IN PLASTIC CONTAINER

BAXTER	15%	N20107 001 FEB 05, 1993

AMINO ACIDS

INJECTABLE; INJECTION

/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/27,/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

AMITRIPTYLINE HYDROCHLORIDE

INJECTABLE; INJECTION

ELAVIL

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

AMITRIPTYLINE HYDROCHLORIDE

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

POWDER FOR RECONSTITUTION; ORAL

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

/TABLET;/ORAL/
/DELCOBESE/
/LEMMON/

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

AMPICILLIN SODIUM

INJECTABLE; INJECTION
AMPICILLIN SODIUM

> ADD >	AP	HANFORD	EQ 125MG BASE/VIAL	N63143 001 APR 15, 1993
> ADD >	AP		EQ 250MG BASE/VIAL	N63145 001 APR 15, 1993
> ADD >	AP		EQ 500MG BASE/VIAL	N63146 001 APR 15, 1993
> ADD >	AP		EQ 500MG BASE/VIAL	N63147 001 APR 15, 1993
> ADD >	AP		EQ 1GM BASE/VIAL	N62772 001 APR 15, 1993
> ADD >	AP		EQ 1GM BASE/VIAL	N63139 001 APR 15, 1993
> ADD >	AP		EQ 2GM BASE/VIAL	N63140 001 APR 15, 1993
> ADD >	AP		EQ 2GM BASE/VIAL	N63141 001 APR 15, 1993
> ADD >	AP		EQ 10GM BASE/VIAL	N63142 001 APR 15, 1993
/ADD/	/AP/	/LILLY/	/EQ 500MG BASE/VIAL/	/N62565/001/ /APR/04,/1985/
/ADD/	/AP/		/EQ 1GM BASE/VIAL/	/N62565/002/ /APR/04,/1985/
/ADD/	/AP/		/EQ 2GM BASE/VIAL/	/N62565/003/ /JUN/24,/1986/
		ə LILLY	EQ 500MG BASE/VIAL	N62565 001 APR 04, 1985
		ə	EQ 1GM BASE/VIAL	N62565 002 APR 04, 1985
		ə	EQ 2GM BASE/VIAL	N62565 003 JUN 24, 1986

PENBRITIN-S

> DLT >	/WYETH/AYERST/	/EQ/4GM/BASE/VIAL/	/N50072/006/
> ADD >	ə WYETH AYERST	EQ 4GM BASE/VIAL	N50072 006

AMPICILLIN SODIUM; SULBACTAM SODIUM

INJECTABLE; INJECTION
UNASYN

> DLT >	/PFIZER/	/EQ/500MG/BASE/VIAL;/	
> DLT >		/EQ/250MG/BASE/VIAL/	/N50608/003/ /DEC/31,/1986/
> DLT >			
> ADD >	ə PFIZER	EQ 500MG BASE/VIAL; EQ 250MG BASE/VIAL	N50608 003 DEC 31, 1986
> ADD >			
> ADD >			

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

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		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

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL

ATENOLOL AND CHLORTHALIDONE

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

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

AZATHIOPRINE

>DLT>	AP	QUAD	EQ 100MG BASE/VIAL	N71056 001 JUN 08, 1988
>ADD>	@	QUAD	EQ 100MG BASE/VIAL	N71056 001 JUN 08, 1988

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION
IMURAN
>DLT >/AP/ /BURROUGHS/WELLCOME/ /EQ 100MG BASE/VIAL/ /N17391/001/
>ADD > BURROUGHS WELLCOME EQ 100MG BASE/VIAL N17391 001

AZLOCILLIN SODIUM

INJECTABLE; INJECTION
AZLIN
/MILES/ /EQ/2GM/BASE/VIAL/ /N62388/001/ /SEP/08,/1982/
∂ MILES EQ 2GM BASE/VIAL N62388 001 SEP 08, 1982
/EQ/2GM/BASE/VIAL/ /N62417/001/ /OCT/12,/1982/
∂ EQ 2GM BASE/VIAL N62417 001 OCT 12, 1982
/EQ/4GM/BASE/VIAL/ /N62388/003/ /SEP/08,/1982/
∂ EQ 4GM BASE/VIAL N62388 003 SEP 08, 1982
/EQ/4GM/BASE/VIAL/ /N62417/003/ /OCT/12,/1982/
∂ EQ 4GM BASE/VIAL N62417 003 OCT 12, 1982

BENTIROMIDE

SOLUTION; ORAL
CHYMEX
/ADRIA/ /500MG/7.5ML/ /N18366/001/ /DEC/29,/1983/
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
>DLT > /AQUATAG/
>DLT > /BP/ /SOLVAY/ /50MG/ /N16001/002/
>ADD > ∂ SOLVAY 50MG N16001 002

EXNA
>DLT > /BP/+//ROBINS/ /50MG/ /N12489/001/
>ADD > + ROBINS 50MG N12489 001

BEPRIDIL HYDROCHLORIDE

TABLET; ORAL
/BEPADIN/
>DLT >/AB/ /WALLACE/ /200MG/ /N19001/001/ /DEC/28,/1990/
>DLT >/AB/ /300MG/ /N19001/002/ /DEC/28,/1990/
>DLT >/AB/ /400MG/ /N19001/003/ /DEC/28,/1990/
>ADD > ∂ WALLACE 200MG N19001 001 DEC 28, 1990
>ADD > ∂ 300MG N19001 002 DEC 28, 1990
>ADD > ∂ 400MG N19001 003 DEC 28, 1990

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

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL
BETAMETHASONE DIPROPIONATE
/AB/ /PHARMADERM/ /EQ 0.05% BASE/ /N19136/001/ /JUN/26,/1984/
∂ PHARMADERM EQ 0.05% BASE N19136 001 JUN 26, 1984

BETAMETHASONE DIPROPIONATE

LOTION; TOPICAL

BETAMETHASONE DIPROPIONATE

/AB/	/PHARMADERM/	/EQ 0.05% BASE/	/N70274/001/ /AUG/12,/1985/	
	∂ PHARMADERM	EQ 0.05% BASE	N70274 001 AUG 12, 1985	

OINTMENT; TOPICAL

BETAMETHASONE DIPROPIONATE

>DLT >/AB/	/PHARMADERM/	/EQ 0.05% BASE/	/N19140/001/ /SEP/04,/1984/	
>DLT > >ADD > >ADD >	∂ 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/	
	∂ PHARMADERM	EQ 0.1% BASE	N18860 002 AUG 31, 1983	

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

/AB/	/PHARMADERM/	/EQ 0.1% BASE/	/N18864/001/ /AUG/31,/1983/	
	∂ PHARMADERM	EQ 0.1% BASE	N18864 001 AUG 31, 1983	

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

/AA/	/ZENITH/	/4MG/		/N84351/001/
	∂ ZENITH	4MG		N84351 001

CALCITONIN, SALMON

INJECTABLE; INJECTION

CALCIMAR

>DLT >/AP/	/RHONE/POULENC/RORER/	/200 IU/ML/		/N17769/001/
>ADD > AP	+ RHONE POULENC RORER	200 IU/ML		N17769 001

MIACALCIN

>DLT > >DLT > >ADD > >ADD >	/SANDOZ/	/100 IU/ML/		/N17808/001/ /JUL/03,/1986/
	∂ SANDOZ	100 IU/ML		N17808 001 JUL 03, 1986

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

CARISOPRODOL

>DLT >	/CAPSULE;ORAL/			
>DLT >	/SOMA/			
>DLT >	/WALLACE/	/250MG/		/N11792/003/
>ADD >	∂ WALLACE	250MG		N11792 003

CARISOPRODOL

TABLET; ORAL

	CARISOPRODOL			
>DLT> /AA/	/PIONEER/PHARMS/	/350MG/	/N89390/001/	
>DLT>			/OCT/13,/1988/	
>ADD>	@ PIONEER PHARMS	350MG	N89390 001	
>ADD>			OCT 13, 1988	
	/RELA/			
/AA/	/SCHERING/	/350MG/	/N12155/001/	
	@ 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

>DLT>	/INJECTABLE;/INJECTION/			
>DLT>	/CEFMAX/			
>DLT>	/TAP/	/EQ/500MG/BASE/VIAL/	/N50571/001/	
>DLT>			/DEC/30,/1987/	
>DLT>		/EQ/1GM/BASE/VIAL/	/N50571/002/	
>DLT>			/DEC/30,/1987/	
>DLT>		/EQ/2GM/BASE/VIAL/	/N50571/003/	
>DLT>			/DEC/30,/1987/	
>ADD>	@ TAP	EQ 500MG BASE/VIAL	N50571 001	
>ADD>			DEC 30, 1987	
>ADD>	@	EQ 1GM BASE/VIAL	N50571 002	
>ADD>			DEC 30, 1987	
>ADD>	@	EQ 2GM BASE/VIAL	N50571 003	
>ADD>			DEC 30, 1987	

CEFOTETAN DISODIUM

INJECTABLE; INJECTION

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

CEFOTIAM HYDROCHLORIDE

>DLT>	/INJECTABLE;/INJECTION/			
>DLT>	/CERADON/			
>DLT>	/TAKEDA/	/EQ/1GM/BASE/VIAL/	/N50601/001/	
>DLT>			/DEC/30,/1988/	
>ADD>	@ TAKEDA	EQ 1GM BASE/VIAL	N50601 001	
>ADD>			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

>DLT>	/INJECTABLE;/INJECTION/			
>DLT>	/CEFPIRAMIDE/SODIUM/			
>DLT>	/WYETH/AYERST/	/EQ/1GM/BASE/VIAL/	/N50633/002/	
>DLT>			/JAN/31,/1989/	
>DLT>		/EQ/2GM/BASE/VIAL/	/N50633/003/	
>DLT>			/JAN/31,/1989/	
>DLT>		/EQ/10GM/BASE/VIAL/	/N50633/005/	
>DLT>			/JAN/31,/1989/	
>ADD>	@ WYETH AYERST	EQ 1GM BASE/VIAL	N50633 002	
>ADD>			JAN 31, 1989	
>ADD>	@	EQ 2GM BASE/VIAL	N50633 003	
>ADD>			JAN 31, 1989	
>ADD>	@	EQ 10GM BASE/VIAL	N50633 005	
>ADD>			JAN 31, 1989	

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION

>ADD>	CEFTAZIDIME SODIUM IN PLASTIC CONTAINER			
>ADD> AP	BAXTER	EQ 10MG BASE/ML	N63221 001	
>ADD>			APR 29, 1993	
>ADD> AP		EQ 20MG BASE/ML	N63221 002	
>ADD>			APR 29, 1993	
>ADD> AP		EQ 40MG BASE/ML	N63221 003	
>ADD>			APR 29, 1993	

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION
FORTAZ IN PLASTIC CONTAINER

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

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION
CEFIZOX

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

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

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

CELLULOSE SODIUM PHOSPHATE

POWDER; ORAL
CALCIBIND

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

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
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

>DLT >/AB/	/MSD/	/150MG;250MG/	/N16016/001/
>ADD >	MSD	150MG;250MG	N16016 001

ALDOCLOR-250

>DLT >/AB//+//MSD/		/250MG;250MG/	/N16016/002/
>ADD >	+ MSD	250MG;250MG	N16016 002

>DLT > /METHYLDOPA AND CHLOROTHIAZIDE/

>DLT >/AB/	/PAR/	/150MG;250MG/	/N70783/001/ /NOV/06,/1987/
>DLT >			
>DLT >/AB/		/250MG;250MG/	/N70654/001/ /NOV/06,/1987/
>DLT >			
>ADD >	@ PAR	150MG;250MG	N70783 001 NOV 06, 1987
>ADD >			
>ADD >	@	250MG;250MG	N70654 001 NOV 06, 1987
>ADD >			

CHLOROTRIANISENE

CAPSULE; ORAL
TACE

>DLT >	/MERRELL/DOW/	/72MG/	/N16235/001/
>ADD >	@ 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

> DLT >	/AB/	/PHARM/BASICS/	/50MG/	/N89052/001/ /JUN/01,/1987/
> DLT >				
> ADD >		@ PHARM BASICS	50MG	N89052 001 JUN 01, 1987
> ADD >				

CHLORTHALIDONE; METOPROLOL TARTRATE

/CAPSULE;/ORAL/
/LOPRESSIDONE/

/+/	/CIBA/	/25MG;200MG/	/N19451/002/ /DEC/31,/1987/
		/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

> DLT >	/AA/	/PIONEER/PHARMS/	/250MG/	/N89592/001/ /JAN/06,/1989/
> DLT >				
> DLT >	/AA/		/500MG/	/N89948/001/ /JAN/06,/1989/
> DLT >				
> ADD >		@ PIONEER PHARMS	250MG	N89592 001 JAN 06, 1989
> ADD >				
> ADD >		@	500MG	N89948 001 JAN 06, 1989
> ADD >				

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

CLONIDINE HYDROCHLORIDE

TABLET; ORAL
CLONIDINE HCL

> DLT >	/AB/	/BIOCRAFT/	/0.1MG/	/N70747/001/ /MAR/20,/1986/
> DLT >				
> DLT >	/AB/		/0.2MG/	/N70702/001/ /MAR/20,/1986/
> DLT >				
> DLT >	/AB/		/0.3MG/	/N70659/001/ /MAR/20,/1986/
> DLT >				
> ADD >		@ BIOCRAFT	0.1MG	N70747 001 JUL 08, 1986
> ADD >				
> ADD >		@	0.2MG	N70702 001 JUL 08, 1986
> ADD >				
> ADD >		@	0.3MG	N70659 001 JUL 08, 1986
> ADD >				

CLOTRIMAZOLE

/CREAM;/VAGINAL/
/GYNE-LOTRIMIN/

/BT/	/SCHERING/	/1%/	/N18052/001/
/MYCELEX-G/			
/BT/	/MILES/	/1%/	/N18230/001/

/TABLET;/VAGINAL/
/GYNE-LOTRIMIN/

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

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE

/BP/	/HEATHER/	/25MG/	/N85736/001/
	@ HEATHER	25MG	N85736 001

CYANOCOBALAMIN

INJECTABLE; INJECTION
CYANOCOBALAMIN

/AP/	/FUJISAWA/	/1MG/ML/	/N83075/001/		
	@ FUJISAWA	1MG/ML	N83075 001		

CYCLACILLIN

>DLT>	/POWDER/FOR/RECONSTITUTION;/ORAL/				
>DLT>	/CYCLAPEN-W/				
>DLT>	/+//WYETH/AYERST/	/500MG/5ML/	/N50508/003/		
>DLT>		/125MG/5ML/	/N50508/001/		
>DLT>		/250MG/5ML/	/N50508/002/		
>ADD>	@ WYETH AYERST	125MG/5ML	N50508 001		
>ADD>	@	250MG/5ML	N50508 002		
>ADD>	@	500MG/5ML	N50508 003		

CYCLIZINE LACTATE

>DLT>	/INJECTABLE;/INJECTION/				
>DLT>	/MAREZINE/				
>DLT>	/BURROUGHS/WELLCOME/	/50MG/ML/	/N09495/001/		
>ADD>	@ BURROUGHS WELLCOME	50MG/ML	N09495 001		

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
CYCLOBENZAPRINE HCL

>ADD>	AB	INVAMED	10MG	N73683 001	
>ADD>				FEB 26, 1993	

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION
NEOSAR

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

DESIPRAMINE HYDROCHLORIDE

/CAPSULE;/ORAL/
/PERTOFRANE/

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

DESLANOSIDE

>DLT>	/INJECTABLE;/INJECTION/				
>DLT>	/CEDILANID-D/				
>DLT>	/SANDOZ/	/0.2MG/ML/	/N09282/002/		
>ADD>	@ 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/	
@ CIBA	25MG/ML	N08822 001	

DEXAMETHASONE

ELIXIR; ORAL
DEXAMETHASONE

>ADD>	AA	BARRE	0.5MG/5ML	N88997 001	
>ADD>				OCT 10, 1986	
>DLT>	/AA/	/NASKA/	/0.5MG/5ML/	/N88997/001/	
>DLT>				/OCT/10;/1986/	

SOLUTION; ORAL
/DEXAMETHASONE/

/ROXANE/	/0.5MG/5ML/		/N88248/001/	
@ ROXANE	0.5MG/5ML		N88248 001	
			/SEP/01;/1983/	
			SEP 01, 1983	

DEXAMETHASONE

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

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

DIAZEPAM

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
/+/	/MEDCL/MKTG/	/50MG/	/N17425/001/

INJECTABLE; INJECTION

/DIAZOXIDE/

>DLT>				
>DLT>/AP/	/QUAD/	/15MG/ML/	/N71908/001/	/JAN/26,/1988/
>DLT>				
>ADD>	ə QUAD	15MG/ML	N71908 001	JAN 26, 1988
>ADD>				

HYPERSTAT

>DLT>/AP/	/SCHERING/	/15MG/ML/	/N16996/001/
>ADD>	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

>DLT>/AB/	/PIONEER/PHARMS/	/10MG/	/N89361/001/	/JAN/10,/1989/
>DLT>				
>ADD>	ə PIONEER PHARMS	10MG	N89361 001	JAN 10, 1989
>ADD>				

DICYCLOMINE HYDROCHLORIDE

TABLET; ORAL
DICYCLOMINE HCL

>DLT >/AB/	/PIONEER/PHARMS/	/20MG/	/N88585/001/	
>DLT >			/AUG/20,/1986/	
>ADD >	ə PIONEER PHARMS	20MG	N88585 001	
>ADD >			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

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOPAMINE HCL

/AP/	/LYPHOMED/	/40MG/ML/	/N70012/001/
			/JUN/12,/1985/
	ə LYPHOMED	40MG/ML	N70012 001
			JUN 12, 1985

DOXYCYCLINE HYCLATE

CAPSULE; ORAL
DOXYCYCLINE HYCLATE

>DLT >/AB/	/PAR/	/EQ 50MG BASE/	/N62434/001/
>DLT >			/OCT/19,/1984/
>DLT >/AB/		/EQ 100MG BASE/	/N62442/001/
>DLT >			/DEC/22,/1983/
>ADD >	ə PAR	EQ 50MG BASE	N62434 001
>ADD >			OCT 19, 1984
>ADD >	ə	EQ 100MG BASE	N62442 001
>ADD >			DEC 22, 1983

DROPERIDOL

INJECTABLE; INJECTION
DROPERIDOL

>DLT >/AP/	/QUAD/	/2.5MG/ML/	/N71941/001/
>DLT >			/AUG/17,/1988/
>ADD >	ə QUAD	2.5MG/ML	N71941 001
>ADD >			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

>DLT >	/INJECTABLE;/INJECTION/		
>DLT >	/ORNIDYL/		
>DLT >	/MERRELL/DOW/	/200MG/ML/	/N19879/002/
>DLT >			/NOV/28,/1990/
>ADD >	ə MERRELL DOW	200MG/ML	N19879 002
>ADD >			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

ERYTHROMYCIN

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

>DLT>	/SANDOZ/	/0.5MG/	/N17993/003/
>ADD>	@ 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

AA	FISONS	2MG	N87693 001 FEB 24, 1983
/@/		/2MG/	/N87693/001/ /FEB/24,/1983/

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

>DLT>	/POWDER;/FOR/RX/COMPOUNDING/		
>DLT>	/ERYTHROMYCIN/		
>DLT>	/PADDOCK/	/100%/	/N50610/001/ /NOV/07,/1986/
>DLT>			
>ADD>	@ PADDOCK	100%	N50610 001 NOV 07, 1986
>ADD>			

ERYTHROMYCIN

SOLUTION; TOPICAL
ERYTHROMYCIN

>ADD>	AT	BARRE	2%	N62957 001 JUL 21, 1988
>DLT>	/AT/	/NASKA/	/2%/	/N62957/001/ /JUL/21,/1988/

ESTROGENS, CONJUGATED

CREAM; TOPICAL, VAGINAL
PREMARIN

>ADD>	+ AYERST	0.625MG/GM	N20216 001
>DLT>	/+//WYETH/AYERST/	/0.625MG/GM/	/N83273/001/

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORETHIN 1/35E-21

>ADD>	AB	ROBERTS	0.035MG;1MG	N71480 001 APR 12, 1988
>DLT>	/AB/	/SCHIAPPARELLI/SEARLE/	0.035MG;1MG/	/N71480/001/ /APR/12,/1988/

TABLET; ORAL-28
NORETHIN 1/35E-28

>ADD>	AB	ROBERTS	0.035MG;1MG	N71481 001 APR 12, 1988
>DLT>	/AB/	/SCHIAPPARELLI/SEARLE/	0.035MG;1MG/	/N71481/001/ /APR/12,/1988/

ETHYNODIOL DIACETATE; MESTRANOL

>DLT>	/TABLET;/ORAL-21/		
>DLT>	/OVULEN-21/		
>DLT>	/+//SEARLE/	/1MG;0.1MG/	/N16029/003/
>ADD>	@ SEARLE	1MG;0.1MG	N16029 003
>DLT>	/TABLET;/ORAL-28/		
>DLT>	/OVULEN-28/		
>DLT>	/SEARLE/	/1MG;0.1MG/	/N16705/001/
>ADD>	@ SEARLE	1MG;0.1MG	N16705 001

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL
FLUOCINOLONE ACETONIDE

>DLT>	/AT/	/PHARMADERM/	/0.025%/		/N88045/001/ /DEC/16,/1982/
>DLT>					
>ADD>		∂ PHARMADERM	0.025%		N88045 001
>ADD>					DEC 16, 1982

OINTMENT; TOPICAL
FLUOCINOLONE ACETONIDE

>DLT>	/AT/	/PHARMADERM/	/0.025%/		/N88046/001/ /DEC/16,/1982/
>DLT>					
>ADD>		∂ PHARMADERM	0.025%		N88046 001
>ADD>					DEC 16, 1982

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL

>DLT>	/AP/	/MARCHAR/	/50MG/ML/		/N87791/001/ /JAN/18,/1983/
>DLT>					
>ADD>		∂ MARCHAR	50MG/ML		N87791 001
>ADD>					JAN 18, 1983

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL
PROZAC

		LILLY	EQ 10MG BASE		N18936 006
					DEC 23, 1992

FLUPHENAZINE HYDROCHLORIDE

ELIXIR; ORAL
FLUPHENAZINE HCL

>ADD>					
>ADD>	AA	COPLEY	2.5MG/5ML		N81310 001
>ADD>					APR 29, 1993
		PROLIXIN			
>ADD>	AA	SQUIBB	2.5MG/5ML		N12145 003

FOLIC ACID

TABLET; ORAL
FOLIC ACID

>DLT>	/AA/	/PIONEER/PHARMS/	/1MG/		/N88949/001/ /SEP/13,/1985/
>DLT>					
>ADD>		∂ PIONEER PHARMS	1MG		N88949 001
>ADD>					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

>ADD>		+ PFIZER	10MG		N17783 002
>ADD>					MAY 08, 1984
>ADD>			5MG		N17783 001
>ADD>					MAY 08, 1984
>DLT>		/+//ROERIG/	/10MG/		/N17783/002/ /MAY/08,/1984/
>DLT>					
>DLT>			/5MG/		/N17783/001/ /MAY/08,/1984/
>DLT>					

GLUCAGON HYDROCHLORIDE

INJECTABLE; INJECTION

GLUCAGON

>DLT >/AP/	/LILLY/	/EQ 1MG BASE/VIAL/	/N12122/001/	
>ADD >	LILLY	EQ 1MG BASE/VIAL	N12122 001	
>DLT >/AP/	/QUAD/	/EQ 1MG BASE/VIAL/	/N71022/001/ /MAR/04,/1987/	
>DLT >				
>ADD >	∂ QUAD	EQ 1MG BASE/VIAL	N71022 001 MAR 04, 1987	
>ADD >				

GLUTETHIMIDE

>DLT >	/CAPSULE;/ORAL/		
>DLT >	/DORIDEN/		
>DLT >	/S/RHONE/POULENC/RORER//500MG/	/N09519/008/	

GRISEOFULVIN, MICROCRYSTALLINE

CAPSULE; ORAL

GRISACTIN

>DLT >	/WYETH/AYERST/	/125MG/	/N50051/002/
>ADD >	∂ WYETH AYERST	125MG	N50051 002

HALOPERIDOL LACTATE

CONCENTRATE; ORAL

HALOPERIDOL

AA	PHARM ASSOC	EQ 2MG BASE/ML	N73037 001 FEB 26, 1993

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

>DLT >	/TURGEX/		
>DLT >	/XTTRIUM/	/3%/	/N18375/001/
>ADD >	∂ XTTRIUM	3%	N18375 001

EMULSION; TOPICAL

>DLT >	/TURGEX/		
>DLT >/AT/	/XTTRIUM/	/3%/	/N19055/001/ /NOV/30,/1984/
>DLT >			
>ADD >	∂ XTTRIUM	3%	N19055 001 NOV 30, 1984
>ADD >			

SOLUTION; TOPICAL

/DIAL/

/AT/	/ARMOUR/DIAL/	/0.25%/	/N17421/002/
	∂ DIAL	0.25%	N17421 002

GERMA-MEDICA "MG"

/AT/	/HUNTINGTON/	/0.25%/	/N17412/002/
	HUNTINGTON	0.25%	N17412 002

SPONGE; TOPICAL

/HEXASCRUB/

>DLT >	/PROF/DSPLS/		
>DLT >/AT/	/PROF/DSPLS/	/3%/	/N18363/001/
>ADD >	∂ PROF DSPLS	3%	N18363 001

HEXAFLUORENIUM BROMIDE

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

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL

ZESTORETIC 20/12.5

>DLT >/AB/	/IMPERIAL/CHEM/	/12.5MG;20MG/	/N19888/001/ /SEP/20,/1990/
>DLT >			
>ADD > AB	ZENECA	12.5MG;20MG	N19888 001 SEP 20, 1990
>ADD >			

ZESTORETIC 20/25

>DLT >/AB/	/IMPERIAL/CHEM/	/25MG;20MG/	/N19888/002/ /JUL/20,/1989/
>DLT >			
>ADD > AB	ZENECA	25MG;20MG	N19888 002 JUL 20, 1989
>ADD >			

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

>ADD >	AT	BARRE	2.5%	N89682 001 MAR 10, 1988	
>ADD >					
/AT/	/BIOCRAFT/	/0.5%/	/N80400/002/		
/AT/		/1%/	/N80400/003/		
/AT/		/2.5%/	/N80400/004/		
	ə BIOCRAFT	0.5%	N80400 002		
	ə	1%	N80400 003		
	ə	2.5%	N80400 004		
>DLT >/AT/	/NASKA/	/2.5%/	/N89682/001/ /MAR/10,/1988/		
>DLT >					
/AT/	/PHARMADERM/	/1%/	/N88845/001/ /FEB/27,/1986/		
	ə PHARMADERM	1%	N88845 001 FEB 27, 1986		

LOTION; TOPICAL

ACTICORT

AT	BAKER NORTON	1%	N86535 001
/AT/	/KEY/PHARMS/	/1%/	/N86535/001/

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION; OTIC

>DLT >	/NEOMYCIN SULFATE; POLYMYXIN B SULFATE; HYDROCORTISONE/		
>DLT >/AT/	/PHARMAFAIR/	/12;EQ 3.5MG BASE/ML;/ /10,000 UNITS/ML/	/N62617/001/ /SEP/18,/1985/
>DLT >			
>DLT >			
>ADD >	ə PHARMAFAIR	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62617 001 SEP 18, 1985
>ADD >			
>ADD >			

HYDROXYZINE HYDROCHLORIDE

SYRUP; ORAL

HYDROXYZINE HCL

>ADD >	AA	BARRE	10MG/5ML	N88785 001 FEB 03, 1988
>ADD >				
>DLT >/AA/	/NASKA/	/10MG/5ML/	/N88785/001/ /FEB/03,/1988/	
>DLT >				

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

>DLT >/AB/	/PAR/	/300MG/	/N70328/001/ /AUG/06,/1985/	
>DLT >				
>ADD >	ə PAR	300MG	N70328 001 AUG 06, 1985	
>ADD >				
	/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

>ADD >	RHONE POULENC RORER	1.25MG	N18538 002 APR 29, 1993
>ADD >			

IOTROLAN

>DLT >	/INJECTABLE;/INTRATHECAL/			
>DLT >	/OSMOVIST/			
>DLT >	/BERLEX/	/EQ/190MG/IODINE/ML/	/N19580/001/ /DEC/07,/1989/	
>DLT >		/EQ/240MG/IODINE/ML/	/N19580/002/ /DEC/07,/1989/	
>DLT >				
>ADD >	ə BERLEX	EQ 190MG IODINE/ML	N19580 001 DEC 07, 1989	
>ADD >				
>ADD >	ə	EQ 240MG IODINE/ML	N19580 002 DEC 07, 1989	
>ADD >				

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	

ISOFLURANE

LIQUID; INHALATION
FORANE

AN	+ ANAQUEST	99.9%	N17624 001	

ISOFLURANE

AN	ABBOTT	99.9%	N74097 001	
			JAN 25, 1993	

ISONIAZID

TABLET; ORAL
/STANOZIDE/

>DLT>				
>DLT>/AA/	/EVERYLIFE/	/300MG/	/N80126/002/	
>ADD>	∂ 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
/KLEBCIL/

/AP/	/SMITHKLINE/BEECHAM/	/EQ 75MG BASE/2ML/	/N62170/001/	
/AP/		/EQ 500MG BASE/2ML/	/N62170/002/	
/AP/		/EQ 1GM BASE/3ML/	/N62170/003/	
	∂ SMITHKLINE BEECHAM	EQ 75MG BASE/2ML	N62170 001	
	∂	EQ 500MG BASE/2ML	N62170 002	
	∂	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/	
	/GENERLAC/			
/AA/	/PHARM/BASICS/	/10GM/15ML/	/N71842/001/	
			/SEP/27,/1988/	
	/LACTULOSE/			
	/SOLVAY/	/10GM/15ML/	/N17906/001/	
	/PORTALAC/			
/AA/	/SOLVAY/	/10GM/15ML/	/N72374/001/	
			/MAR/22,/1989/	

SOLUTION; ORAL, RECTAL
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

LACTULOSE

	∂ SOLVAY	10GM/15ML	N17906 001

LACTULOSE

SOLUTION; ORAL, RECTAL
PORTALAC

AA	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	
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

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

LUPRON DEPOT

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

LUPRON DEPOT-PED

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

LIDOCAINE

/SUPPOSITORY;/RECTAL/
/XYLOCAINE/

/ASTRA/	/100MG/	/N13077/001/	
ə ASTRA	100MG	N13077 001	

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL

/AP/	/LYPHOMED/	/1%/	/N86761/001/	
/AP/		/2%/	/N86761/002/	
ə LYPHOMED		1%	N86761 001	
ə		2%	N86761 002	

JELLY; TOPICAL
LIDOCAINE HCL

>ADD> AT	COPLEY	2%	N81318 001	
>ADD>			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

ə FOREST LABS	0.25MG;0.0625MG	N16807 006	
/ə/RHONE/POULENC/RORER//0.25MG;0.0625MG/		/N16807/006/	

LISINOPRIL

TABLET; ORAL
ZESTRIL

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

>ADD > LORATADINE

>ADD > TABLET; ORAL
>ADD > CLARITIN

>ADD >	+ SCHERING	10MG	N19658 001
>ADD >			APR 12, 1993

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/

MESTRANOL; NORETHINDRONE

>DLT >	/TABLET;/ORAL-20/		
>DLT >	/NORINYL/		
>DLT >	/SYNTEX/	/0.1MG;2MG/	/N13625/004/
>ADD >	@ SYNTEX	0.1MG;2MG	N13625 004

MESTRANOL; NORETHINDRONE

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

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

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

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

MESTRANOL; NORETHYNODREL

>DLT >	/TABLET;/ORAL/		
>DLT >	/ENOVID/		
>DLT >	/+//SEARLE/	/0.15MG;9.85MG/	/N10976/005/
>DLT >		/0.075MG;5MG/	/N10976/008/
>ADD >	@ SEARLE	0.075MG;5MG	N10976 008
>ADD >	@	0.15MG;9.85MG	N10976 005

METHADONE HYDROCHLORIDE

TABLET; ORAL
METHADOSE

>ADD > AA	MALLINCKRODT	5MG	N40050 001
>ADD >			APR 15, 1993
>ADD > AA		10MG	N40050 002
>ADD >			APR 15, 1993

TABLET, DISPERSIBLE; ORAL
METHADONE HCL

>ADD > AA	LILLY	40MG	N17058 001
>ADD >	METHADOSE		
>ADD > AA	MALLINCKRODT	40MG	N74184 001
>ADD >			APR 29, 1993

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL
/METHAMPEX/

/AA/	/LEMMON/	/10MG/	/N83889/001/
	@ LEMMON	10MG	N83889 001

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL
METHAMPHETAMINE HCL

/AA/	/REXAR/	/10MG/	/N84931/002/	
	REXAR	10MG	N84931 002	

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL

>DLT >/AA/	/PIONEER/PHARMS/	/500MG/	/N88731/001/	
>DLT >			/DEC/13,/1985/	
>DLT >/AA/		/750MG/	/N89082/001/	
>DLT >			/DEC/13,/1985/	
>ADD >	ə PIONEER PHARMS	500MG	N88731 001	
>ADD >			DEC 13, 1985	
>ADD >	ə	750MG	N89082 001	
>ADD >			DEC 13, 1985	

METHOTREXATE SODIUM

INJECTABLE; INJECTION
METHOTREXATE SODIUM

/AP/	/LYPHOMED/	/EQ 25MG BASE/ML/	/N89263/001/	
			/JUN/13,/1986/	
	ə 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/	
	ə 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/	
	ə LYPHOMED	EQ 40MG BASE/VIAL	N89143 001	
			MAR 28, 1986	
	ə	EQ 125MG BASE/VIAL	N89144 001	
			MAR 28, 1986	
	ə	EQ 500MG BASE/VIAL	N89187 001	
			MAR 28, 1986	
	ə	EQ 1GM BASE/VIAL	N89189 001	
			MAR 28, 1986	

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
METOCLOPRAMIDE HCL

>ADD > AB	MUTUAL PHARM	EQ 10MG BASE	N71536 001	
			APR 28, 1993	
>ADD >				
>DLT >/AB/	/PAR/	/EQ 10MG BASE/	/N70342/001/	
>DLT >			/MAR/25,/1986/	
>ADD >	ə PAR	EQ 10MG BASE	N70342 001	
>ADD >			MAR 25, 1986	

METRONIDAZOLE

TABLET; ORAL
/SAFETC/

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

MICONAZOLE NITRATE

/CREAM;/VAGINAL/
/MONISTAT/1/

/JOHNSON/RW/	/2%/	/N17450/001/	

MICONAZOLE NITRATE

/SUPPOSITORY;/VAGINAL/
/MONISTAT/7/
/JOHNSON/RW/ /100MG/ /N18520/001/ /MAR/15,/1982/

MORICIZINE HYDROCHLORIDE

TABLET; ORAL
ETHMOZINE

/DUPONT/	/200MG/	/N19753/001/ /JUN/19,/1990/	
	/250MG/	/N19753/002/ /JUN/19,/1990/	
	/300MG/	/N19753/003/ /JUN/19,/1990/	
ROBERTS	200MG	N19753 001 JUN 19, 1990	
	250MG	N19753 002 JUN 19, 1990	
	300MG	N19753 003 JUN 19, 1990	

NABILONE

/CAPSULE;/ORAL/
/CESAMET/
/+//LILLY/ /1MG/ /N18677/001/ /DEC/26,/1985/
@ LILLY 1MG N18677 001 DEC 26, 1985

NAFCILLIN SODIUM

>DLT> /POWDER/FOR/RECONSTITUTION;/ORAL/
>DLT> /UNIPEN/
>DLT> /+//WYETH/AYERST/ /EQ/250MG/BASE/5ML/ /N50199/001/
>ADD> @ 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

NANDROLONE DECANOATE

INJECTABLE; INJECTION
NANDROLONE DECANOATE

/AQ/	/LYPHOMED/	/100MG/ML/	/N88290/001/ /OCT/03,/1983/	
/AQ/		/200MG/ML/	/N88317/001/ /OCT/14,/1983/	
	@ LYPHOMED	100MG/ML	N88290 001 OCT 03, 1983	
	@	200MG/ML	N88317 001 OCT 14, 1983	

NIACIN

>DLT> /CAPSULE;/ORAL/
>DLT> /WAMPOCAP/
>DLT> /WALLACE/ /500MG/ /N11073/003/
>ADD> @ WALLACE 500MG N11073 003

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

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL
>ADD> ADALAT CC
>ADD> BC MILES 30MG N20198 001 APR 21, 1993
>ADD> BC 60MG N20198 002 APR 21, 1993
>ADD> BC 90MG N20198 003 APR 21, 1993

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL
PROCARDIA XL

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

NITROFURANTOIN

TABLET; ORAL
NITROFURANTOIN

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

>ADD>	AT	BARRE	100,000 UNITS/GM	N62949 001 JUN 13, 1988
>ADD>				
>DLT>	/AT/	/NASKA/	/100,000 UNITS/GM/	/N62949/001/ /JUN/13,/1988/
>DLT>				
	AT	TARO	100,000 UNITS/GM	N64022 001 JAN 29, 1993

NYSTATIN

OINTMENT; TOPICAL
NYSTATIN

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

SUSPENSION; ORAL
NYSTATIN

>ADD>	AA	BARRE	100,000 UNITS/ML	N62571 001 OCT 29, 1985
>ADD>				
>DLT>	/AA/	/NASKA/	/100,000 UNITS/ML/	/N62571/001/ /OCT/29,/1985/
>DLT>				
	/AA/	/PHARMADERM/	/100,000 UNITS/ML/	/N62518/001/ /JUL/06,/1984/
		@ PHARMADERM	100,000 UNITS/ML	N62518 001 JUL 06, 1984

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
NYSTATIN AND TRIAMCINOLONE ACETONIDE

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

NYSTATIN-TRIAMCINOLONE ACETONIDE

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

OINTMENT; TOPICAL
NYSTATIN AND TRIAMCINOLONE ACETONIDE

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

OCTREOTIDE ACETATE

INJECTABLE; INJECTION
SANDOSTATIN

>DLT>	/SANDOZ/	/EQ/50UGM/BASE/ML/	/N19667/001/	
>DLT>			/OCT/21,/1988/	
>ADD>	SANDOZ	EQ 0.05MG BASE/ML	N19667 001	
>ADD>			OCT 21, 1988	
>DLT>		/EQ/100UGM/BASE/ML/	/N19667/002/	
>DLT>			/OCT/21,/1988/	
>ADD>		EQ 0.1MG BASE/ML	N19667 002	
>ADD>			OCT 21, 1988	
>ADD>		EQ 0.2MG BASE/ML	N19667 004	
>ADD>			JUN 12, 1991	
>DLT>		/EQ/500UGM/BASE/ML/	/N19667/003/	
>DLT>			/OCT/21,/1988/	
>ADD>		EQ 0.5MG BASE/ML	N19667 003	
>ADD>			OCT 21, 1988	
>ADD>		EQ 1MG BASE/ML	N19667 005	
>ADD>			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	

PENICILLIN G BENZATHINE

INJECTABLE; INJECTION
BICILLIN L-A

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

PENICILLIN G BENZATHINE

>DLT>	/TABLET;/ORAL/			
>DLT>	/BICILLIN/			
>DLT>	/+//WYETH/AYERST/	/200,000/UNITS/	/N50128/001/	
>ADD>	@ 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	
	/PENTIDS '400'/			
/AB/	/SQUIBB/	/400,000 UNITS/	/N60392/004/	
/AB/		/400,000 UNITS/	/N62155/003/	
	@ APOTHECON	400,000 UNITS	N60392 004	
	@	400,000 UNITS	N62155 003	
	/PENTIDS '800'/			
/AB/	/SQUIBB/	/800,000 UNITS/	/N60392/005/	
/AB/		/800,000 UNITS/	/N62155/004/	
	@ APOTHECON	800,000 UNITS	N60392 005	
	@	800,000 UNITS	N62155 004	

PENICILLIN G PROCAINE

INJECTABLE; INJECTION
/DURACILLIN A.S./

/AP/	/LILLY/	/300,000 UNITS/ML/	/N60093/001/	
	@ LILLY	300,000 UNITS/ML	N60093 001	

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

/AA/	/SQUIBB/	/EQ 125MG BASE/5ML/	/N61206/001/				
/AA/		/EQ 125MG BASE/5ML/	/N62153/001/				
@ APOTHECON		EQ 125MG BASE/5ML	N61206 001				
@		EQ 125MG BASE/5ML	N62153 001				
/AA/	/SQUIBB/	/EQ 250MG BASE/5ML/	/N61206/002/				
/AA/		/EQ 250MG BASE/5ML/	/N62153/002/				
@ APOTHECON		EQ 250MG BASE/5ML	N61206 002				
@		EQ 250MG BASE/5ML	N62153 002				

TABLET; ORAL

/AB/	/SQUIBB/	/EQ 250MG BASE/	/N61164/001/	> ADD >			
/AB/		/EQ 250MG BASE/	/N62156/002/	> ADD >			
@ APOTHECON		EQ 250MG BASE	N61164 001	> ADD >			
@		EQ 250MG BASE	N62156 002	> ADD >			
/AB/	/SQUIBB/	/EQ 500MG BASE/	/N61164/002/				
/AB/		/EQ 500MG BASE/	/N62156/001/				
@ APOTHECON		EQ 500MG BASE	N61164 002				
@		EQ 500MG BASE	N62156 001				

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL

/AA/	/ZENITH/	/30MG/	/N86329/001/				
@ 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

> DLT > /BP/	/MSD/	/10MG/ML/	/N12223/001/				
> ADD > BP +	MSD	10MG/ML	N12223 001				

PHYTONADIONE

INJECTABLE; INJECTION

KONAKION

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

PINDOLOL

TABLET; ORAL

PINDOLOL

AB	GENEVA	5MG	N73608 001 MAR 29, 1993
AB		10MG	N73609 001 MAR 29, 1993
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

>DLT >/AP/	/LUITPOLD/	/2MEQ/ML/	/N80221/001/	
>DLT >/AP/		/2MEQ/ML/	/N80736/001/	
>ADD >	∂ LUITPOLD	2MEQ/ML	N80221 001	
>ADD >	∂	2MEQ/ML	N80736 001	

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

>DLT >	/POWDER/FOR/RECONSTITUTION;/ORAL/			
>DLT >	/POTASSIUM/CITRATE/			
>DLT >	/+//UNIV/TX/	/20MEQ/PACKET/	/N19647/001/	
>DLT >			/OCT/13,/1988/	
>DLT >		/10MEQ/PACKET/	/N19647/002/	
>DLT >			/OCT/13,/1988/	
>ADD >	∂ UNIV TX	10MEQ/PACKET	N19647 002	
>ADD >			OCT 13, 1988	
>ADD >	∂	20MEQ/PACKET	N19647 001	
>ADD >			OCT 13, 1988	

TABLET, EXTENDED RELEASE; ORAL

POTASSIUM CITRATE

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

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	
>DLT > /BX/	/KV/	/5MG/	/N84236/001/	
>ADD >	∂ KV	5MG	N84236 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

/BR/	/ALCON/	/25MG/	/N084901/001/
/BR/		/50MG/	/N084902/001/
BR	POLYMEDICA	25MG	N84901 001
BR		50MG	N84902 001

TABLET; ORAL
PROMETHAZINE HCL

/BP/	/BOLAR/	/25MG/	/N083204/001/
	@ BOLAR	25MG	N83204 001
/BP/	/ZENITH/	/50MG/	/N083613/001/
	@ ZENITH	50MG	N83613 001

PROPRANOLOL HYDROCHLORIDE

>_DLT_>	/SUSPENSION;/ORAL/			
>_DLT_>	/INDERAL/			
>_DLT_>	/WYETH/AYERST/	/10MG/ML/	/N019536/001/	
>_DLT_>			/DEC/12,/1986/	
>_ADD_>	@ WYETH AYERST	10MG/ML	N19536 001	
>_ADD_>			DEC 12, 1986	

PROTAMINE SULFATE

INJECTABLE; INJECTION
PROTAMINE SULFATE

>_DLT_>	/AP/ /QUAD/	/10MG/ML/	/N089306/001/	
>_DLT_>			/MAY/30,/1986/	
>_ADD_>	@ QUAD	10MG/ML	N89306 001	
>_ADD_>			MAY 30, 1986	

PYRANTEL PAMOATE

>_DLT_>	/SUSPENSION;/ORAL/		
>_DLT_>	/ANTIMINTH/		
>_DLT_>	/*//ROERIG/	/EQ/250MG/BASE/5ML/	/N016883/001/

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION
MESTINON

/AP/	/ICN/	/5MG/ML/	/N009830/001/
AP	ROCHE	5MG/ML	N09830 001

PYRIDOSTIGMINE BROMIDE

SYRUP; ORAL
MESTINON

	/ICN/	/60MG/5ML/	/N015193/001/
	ROCHE	60MG/5ML	N15193 001

TABLET; ORAL
MESTINON

/*//ICN/		/60MG/	/N009829/002/
+	ROCHE	60MG	N09829 002

TABLET, EXTENDED RELEASE; ORAL
MESTINON

/*//ICN/		/180MG/	/N011665/001/
+	ROCHE	180MG	N11665 001

QUAZEPAM

TABLET; ORAL
DORAL

/*//BAKER/NORTON/		/15MG/	/N018708/001/
			/DEC/27,/1985/
		/7.5MG/	/N018708/003/
			/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/	/N017917/001/
@ WARNER CHILCOTT		330MG	N17917 001

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION
RITODRINE HCL

>_DLT_>	/AP/ /QUAD/	/10MG/ML/	/N070700/001/	
>_DLT_>			/OCT/06,/1986/	
>_ADD_>	@ QUAD	10MG/ML	N70700 001	
>_ADD_>			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

>ADD>	ENQUAY	1%	N19608 001
>ADD>			NOV 30, 1989
>DLT>	/MARION/MERRELL/DOW/	/1%/	/N19608/001/
>DLT>			/NOV/30,/1989/

SODIUM CHLORIDE

INJECTABLE; INJECTION
BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	FUJISAWA	9MG/ML	N88911 001	
			FEB 07, 1985	
/AP/	/LYPHOMED/	/9MG/ML/	/N88911/001/	
			/FEB/07,/1985/	

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE

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

SULFAMETHIZOLE

TABLET; ORAL
THIOSULFIL

>DLT>	/WYETH/AYERST/	/250MG/	/N08565/001/
>ADD>	@ WYETH AYERST	250MG	N08565 001

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL
TRIMETH/SULFA

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

SULFISOXAZOLE

TABLET; ORAL
SULFISOXAZOLE

/AB/	/HEATHER/	/500MG/	/N80189/001/
	@ HEATHER	500MG	N80189 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

THEOPHYLLINE

ELIXIR; ORAL

>DLT>	/THEOPHYL-225/		
>DLT>	/JOHNSON/RW/	/112.5MG/15ML/	/N86485/001/
>ADD>	@ JOHNSON RW	112.5MG/15ML	N86485 001

THEOPHYLLINE

>ADD>	AA	BARRE	80MG/15ML	N89223 001
>ADD>				MAY 27, 1988
>DLT>	/AA/	/NASKA/	/80MG/15ML/	/N89223/001/
>DLT>				/MAY/27,/1988/

TABLET; ORAL
QUIBRON-T

>DLT>	/*//BRISTOL/MYERS/	/300MG/	/N88656/001/
>DLT>			/AUG/22,/1985/
>ADD>	+ ROBERTS	300MG	N88656 001
>ADD>			AUG 22, 1985
>DLT>	/THEOPHYL-225/		
>DLT>	/JOHNSON/RW/	/225MG/	/N84726/001/
>ADD>	@ JOHNSON RW	225MG	N84726 001

THEOPHYLLINE

/TABLET;/CHEWABLE;/ORAL/
/THEOPHYL/

DLT	/JOHNSON/RW/	/100MG/	/N86506/001/	
			/SEP/12,/1985/	
ADD	∂ JOHNSON RW	100MG	N86506 001	
ADD			SEP 12, 1985	

TABLET, EXTENDED RELEASE; ORAL
QUIBRON-T/SR

DLT	/BC/	/BRISTOL/MYERS/	/300MG/	/N87563/001/	
				/JUN/21,/1983/	
ADD	BC	ROBERTS	300MG	N87563 001	
ADD				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	

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL
THIORIDAZINE HCL

DLT	/AB/	/PAR/	/10MG/	/N88351/001/	
				/DEC/05,/1983/	
DLT	/AB/		/15MG/	/N88352/001/	
				/DEC/05,/1983/	
DLT	/AB/		/25MG/	/N88336/001/	
				/DEC/05,/1983/	
DLT	/AB/		/50MG/	/N88322/001/	
				/DEC/05,/1983/	
DLT	/AB/		/100MG/	/N88480/001/	
				/DEC/29,/1983/	
ADD	∂ PAR		10MG	N88351 001	
				DEC 05, 1983	
ADD	∂		15MG	N88352 001	
				DEC 05, 1983	
ADD	∂		25MG	N88336 001	
				DEC 05, 1983	
ADD	∂		50MG	N88322 001	
				DEC 05, 1983	
ADD	∂		100MG	N88480 001	
				DEC 29, 1983	

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL
THIORIDAZINE HCL

/AB/	/ZENITH/	/100MG/	/N88273/001/	
			/OCT/03,/1983/	
∂ ZENITH		100MG	N88273 001	
			OCT 03, 1983	

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL
TICLID

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

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

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

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	

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL
TRIAMCINOLONE ACETONIDE

> ADD > AT	BARRE	0.5%	N89913 001	
> ADD >			DEC 23, 1988	
> DLT >/AT/	/NASKA/	/0.5%/	/N89913/001/	
> DLT >			/DEC/23,/1988/	
/AT/	/PHARMADERM/	/0.025%/	/N88692/001/	
			/AUG/02,/1984/	
/AT/		/0.1%/	/N88690/001/	
			/AUG/02,/1984/	
	@ PHARMADERM	0.025%	N88692 001	
			AUG 02, 1984	
	@	0.1%	N88690 001	
			AUG 02, 1984	

TRIFLUPROMAZINE

/SUSPENSION;/ORAL/

/VESPRIN/			
/SQUIBB/	/EQ/50MG/HCL/5ML/	/N11491/004/	
@ APOTHECON	EQ 50MG HCL/5ML	N11491 004	

TUBOCURARINE CHLORIDE

INJECTABLE; INJECTION
TUBOCURARINE CHLORIDE

> DLT >/AP/	/QUAD/	/3MG/ML/	/N89442/001/	
> DLT >			/AUG/12,/1988/	
> ADD >	@ QUAD	3MG/ML	N89442 001	
> ADD >			AUG 12, 1988	

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

> ADD >	VANCOCIN HCL IN PLASTIC CONTAINER			
> ADD >	+ LILLY	EQ 500MG BASE/100ML	N50671 001	
> ADD >			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

@ STERLING	EQ 50,000 UNITS BASE	N83187 001	
VITAMIN A			
/AA/ /ZENITH/	/EQ 50,000 UNITS BASE/	/N83035/001/	
/AA/	/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-PFAN

/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

>ADD> CREAM, SUPPOSITORY; TOPICAL, VAGINAL
>ADD> GYNE-LOTRIMIN COMBINATION PACK
>ADD> + SCHERING PLOUGH 1%;100MG N20289 002
>ADD> APR 26, 1993

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
DIPHENHYDRAMINE HCL
>ADD> BARRE 12.5MG/5ML N70497 001
>ADD> APR 25, 1989
>DLT> /NASKA/ /12.5MG/5ML/ /N70497/001/
>DLT> /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/

MICONAZOLE NITRATE

>ADD> CREAM, SUPPOSITORY; TOPICAL, VAGINAL
>ADD> MONISTAT 7 COMBINATION PACK
>ADD> + ADVANCED CARE 2%;100MG N20288 002
>ADD> APR 26, 1993

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

/CAPSULE;/ORAL/
/ACTIFED/
/BURROUGHS/WELLCOME/ /60MG;2.5MG/ /N19208/001/
/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/
/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/

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

/TABLET;/ORAL/
/TRIPROLIDINE/HCL/AND/PSEUDOEPHEDRINE/HCL/
/CHELSEA/ /60MG;2.5MG/ /N88118/002/
/JAN/26,/1984/

INDIUM^{111} CHLORIDE

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

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January thru April 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 / /
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 / /
C[illegible]SCERIL 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 / /
[illegible]INIL	TREATMENT OF EXCESSIVE DAYTIME SLEEPINESS IN NARCOLEPSY.	CEPHALON, INC. 145 BRANDYWINE PARKWAY

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

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

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 APRIL 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

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.

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

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

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

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
	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
	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
>ADD>	18936 006	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001			
>ADD>			4194009	APR 19, 1994			
>ADD>			4018895	APR 19, 1994	U-12		
	20068 001	FOSCARNET SODIUM; FOSCAVIR	4215113	JUN 06, 2000	U-64	NCE	SEP 27, 1996
	20123 001	GADODIAMIDE; OMNISCAN	4687659	AUG 18, 2004	U-76	NCE	JAN 08, 1998
	19726 001	GOSERELIN ACETATE; ZOLADEX				I-88	FEB 02, 1996
	19891 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID				NCE	JAN 11, 1994
>ADD>						NDF	DEC 07, 1995
	19892 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID				NCE	JAN 11, 1994
>ADD>						NDF	DEC 07, 1995
>ADD>	18538 002	INDAPAMIDE; LOZOL				NS	APR 29, 1996
>ADD>						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

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
			4454151	JUN 12, 2001	U-75	NDF	NOV 09, 1995
			4089969	MAY 16, 1997	U-75		
>ADD>	20263 001	LEUPROLIDE ACETATE; LUPRON	4005063	JAN 25, 1996		ODE	APR 16, 2000
>ADD>						NP	APR 16, 1996
>ADD>	20263 002	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4005063	JAN 25, 1996		ODE	APR 16, 2000
>ADD>						NP	APR 16, 1996
>ADD>	20263 003	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4005063	JAN 25, 1996		ODE	APR 16, 2000
>ADD>						NP	APR 16, 1996
>ADD>	20263 004	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4005063	JAN 25, 1996		ODE	APR 16, 2000
>ADD>						NP	APR 16, 1996
	18948 001	LEVOCARNITINE; CARNITOR				I-86	DEC 16, 1995
	18948 002	LEVOCARNITINE; CARNITOR				I-86	DEC 16, 1995
>ADD>	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	SEP 04, 1998		NCE	APR 12, 1998
	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
>ADD>	20198 001	NIFEDIPINE; ADALAT CC	4892741	JAN 09, 2007			
>ADD>	20198 002	NIFEDIPINE; ADALAT CC	4892741	JAN 09, 2007			
>ADD>	20198 003	NIFEDIPINE; ADALAT CC	4892741	JAN 09, 2007			
>ADD>	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>	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
>ADD>	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
	19839 004	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
	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
>ADD>	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

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19862 001	INDIUM 111 CHLORIDE; INDICLOR				NCE	DEC 29, 1997

*U.S. Government Printing Office: 1993 — 342-345/60011

New 13th Edition

APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

Superintendent of Documents Subscription Order Form

Order Processing Code
* 7023

Charge your order. It's easy! MasterCard VISA

☐ **Yes,** please send me the following indicated subscriptions:

__ subscriptions of **APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS**, ADP, and the monthly Cumulative Supplements, for $55.00 per year.

The total cost of my order is $_____. Prices include regular domestic postage and handling and are subject to change. International customers please add 25%.

For privacy protection, check the box below:

☐ Do not make my name available to other mailers.

Please choose method of payment:

☐ Check payable to Superintendent of Documents
☐ GPO Deposit Account ☐☐☐☐☐☐☐☐ – ☐☐
☐ VISA or MasterCard
☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

_____
(Company or personal name)

_____
(Additional address/attention line)

_____
(Street address)

_____
(City, State, ZIP Code)

(_____) _____
(Daytime phone including area code)

_____
(Purchase Order No.)

_____
(Credit card expiration date)

Thank you for your order!

_____
(Authorizing Signature) (04/93)

Mail To: Superintendent of Documents, Government Printing Office, P.O. Box 371954 Pittsburgh, PA 15250-7954
To **FAX** your charge order, call (202) 512-2233.
To charge your subscription call (202) 783-3238.