CUMULATIVE SUPPLEMENT 8

JAN'92-AUG'92

APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH 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
Center for Drug Evaluation and Research, FDA

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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, 12th 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 Division of Blood and Blood Products and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 Division of Blood and Blood Products 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. A newly approved product is also identified by a lozenge (⧫) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

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 12th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 13th Edition.

1.2 CEFADROXIL/CEFADROXIL HEMIHYDRATE ACTIVE INGREDIENT HEADING

The active ingredient heading Cefadroxil/Cefadroxil Hemihydrate replaces the active ingredient heading Cefadroxil which is currently listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, 12th Edition. All products which are listed under Cefadroxil (which is understood to be the monohydrate form) in the 12th Edition will now be listed along with the newly approved duplicate drug products under the new active ingredient, Cefadroxil/Cefadroxil Hemihydrate.

1.3 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)

1.4 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)
BARNES HIND PHARMACEUTICALS INC (BARNES HIND)	SOLA BARNES HIND (SOLA BARNES HIND)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
MERCK SHARP AND DOHME RESEARCH LABS DIV MERCK AND CO INC (MSD)	MERCK RESEARCH LABORATORIES DIV MERCK AND CO INC (MERCK)
NORWICH EATON PHARMS INC SUB PROCTOR & GAMBLE CO (NORWICH EATON)	PROCTER & GAMBLE PHARMACEUTICALS INC (P&G)
OFFICE SURGEON GENERAL DEPT ARMY (DEPT ARMY)	OFFICE SURGEON GENERAL DEPT ARMY (US ARMY)
RECKITT AND COLMAN PHARMACEUTICALS INC (R & C)	RECKITT AND COLMAN PHARMACEUTICALS INC (RECKITT AND COLMAN)
SOLOPAK LABORATORIES (SOLOPAK)	SMITH AND NEPHEW SOLOPAK DIVISION OF SMITH AND NEPHEW (SMITH NEPHEW SOLOPAK)
VICKS HEALTH CARE DIV RICHARDSON VICKS INC (VICKS HLTH CARE)	VICKS HEALTH CARE DIV RICHARDSON VICKS INC (VICKS HEALTH CARE)
WHITBY PHARMACEUTICALS INC (WHITBY PHARMS)	WHITBY PHARMACEUTICALS INC (WHITBY)
US CHEMICAL MARKETING GROUP INC (US CHEM MKTG)	US CHEMICAL MARKETING GROUP INC (US CHEM)

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 1991) 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 1991	MAR 1992	JUN 1992	SEP 1992
DRUG PRODUCTS LISTED	9584	9473	9476	
SINGLE SOURCE	2187 (22.8%)	2222 (23.4%)	2227 (23.5%)	
MULTISOURCE	7397 (77.2%)	7251 (76.6%)	7249 (76.5%)	
THERAPEUTICALLY EQUIVALENT	6580 (68.7%)	6510 (68.7%)	6494 (68.5%)	
NOT THERAPEUTICALLY EQUIVALENT	664 (6.9%)	592 (6.3%)	595 (6.3%)	
EXCEPTIONS[1]	153 (1.6%)	149 (1.6%)	160 (1.7%)	
NEW MOLECULAR ENTITIES APPROVED	--	4	2	
NUMBER OF APPLICANTS	430	437	455	

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL
FIORICET W/ CODEINE
+ SANDOZ 325MG;50MG;40MG;30MG¤ N20232 001
JUL 30, 1992

ACETAMINOPHEN; CODEINE PHOSPHATE

ELIXIR; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE
AA PHARM BASICS 120MG/5ML;12MG/5ML N87006 001
/TYLENOL W/ CODEINE/
/AA/ /PHARM BASICS/ /120MG/5ML;12MG/5ML/ /N87006/001/

TABLET; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE
∂ EON LABS 300MG;15MG N87433 001
∂ 300MG;30MG N85917 001
∂ 300MG;60MG N87423 001
AA GENEVA 300MG;30MG¤ N81250 001
JUL 16, 1992
AA 300MG;60MG¤ N81249 001
JUL 16, 1992
∂ PARKE DAVIS 300MG;15MG N85992 001
∂ 300MG;30MG N85218 002
/∂/VITARINE/ /300MG;15MG¤/ /N87433/001/
/∂/ /300MG;30MG¤/ /N85917/001/
/∂/ /300MG;60MG¤/ /N87423/001/
ACETAMINOPHEN W/ CODEINE PHOSPHATE
/AA/ /CHELSEA/ /300MG;15MG/ /N87277/001/
/MAY 26, 1982/
/AA/ /300MG;30MG/ /N87276/001/
/MAY 26, 1982/
/AA/ /300MG;60MG/ /N87275/001/
/MAY 26, 1982/
∂ CHELSEA 300MG;15MG N87277 001
MAY 26, 1982
∂ 300MG;30MG N87276 001
MAY 26, 1982
∂ 300MG;60MG N87275 001
MAY 26, 1982
/AA/ /PARKE/DAVIS/ /300MG;15MG/ /N85992/001/
/AA/ /300MG;30MG/ /N85218/002/

ACETAMINOPHEN; HYDROCODONE BITARTRATE

ELIXIR; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN
MIKART 500MG/15ML;5MG/15ML¤ N89557 001
APR 29, 1992
> ADD > 500MG/15ML;7.5MG/15ML¤ N81051 001
> ADD > AUG 28, 1992

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN
AA MIKART 500MG;5MG¤ N89697 001
JAN 28, 1992
650MG;10MG¤ N81223 001
MAY 29, 1992
/B*/ /PHARM/BASICS/ /500MG;5MG/ /N89291/001/
/MAY 29, 1987/
∂ PHARM BASICS 500MG;5MG N89291 001
MAY 29, 1987

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

TABLET; ORAL
PROPOXYPHENE HCL AND ACETAMINOPHEN
AA MYLAN 650MG;65MG N83978 001
∂ 325MG;32MG N83689 001
/PROPOXYPHENE HCL W/ APAP/
/AA/ /MYLAN/ /650MG;65MG/ /N83978/001/
/325MG;32MG/ /N83689/001/

ACETOHEXAMIDE

TABLET; ORAL
ACETOHEXAMIDE
/B*/ /PHARM/BASICS/ /250MG/ /N70753/001/
/NOV 03, 1986/
/B*/ /500MG/ /N70754/001/
/NOV 03, 1986/
∂ PHARM BASICS 250MG N70753 001
NOV 03, 1986
∂ 500MG N70754 001
NOV 03, 1986

ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL
ACETYLCYSTEINE

AN	CETUS BEN VENUE	10%¤	N72323 001 APR 30, 1992
AN		20%¤	N72324 001 APR 30, 1992

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE

AN	DEY	EQ 0.083% BASE¤	N72652 001 FEB 21, 1992

PROVENTIL

AN	SCHERING	EQ 0.083% BASE	N19243 002 JAN 14, 1987

VENTOLIN

AN	GLAXO	EQ 0.083% BASE¤	N19773 001 APR 23, 1992

SYRUP; ORAL
ALBUTEROL SULFATE

AA	LEMMON	EQ 2MG BASE/5ML¤	N73419 001 MAR 30, 1992

ALGLUCERASE

INJECTABLE; INJECTION
CEREDASE

	GENZYME	10 UNITS/ML¤	N20057 004 MAY 08, 1992

ALLOPURINOL

TABLET; ORAL
ALLOPURINOL

/AB/	/BOLAR/	/100MG/	/N18241/001/ /NOV 16, 1984/
	∂ BOLAR	100MG	N18241 001 NOV 16, 1984

AMIKACIN SULFATE

INJECTABLE; INJECTION
AMIKACIN

AP	ELKINS SINN	EQ 50MG BASE/ML¤	N63274 001 MAY 18, 1992
AP		EQ 250MG BASE/ML¤	N63275 001 MAY 18, 1992

AMIKIN

AP	BRISTOL	EQ 50MG BASE/ML	N50495 001
AP		EQ 50MG BASE/ML	N62562 001 SEP 20, 1984
AP		EQ 250MG BASE/ML	N50495 002
AP		EQ 250MG BASE/ML	N62562 002 SEP 20, 1984

AMINO ACIDS; MAGNESIUM ACETATE; POTASSIUM ACETATE; SODIUM CHLORIDE

	> DLT >	/INJECTABLE;/INJECTION/		
	> DLT >	/AMINOSYN/3.5%/M/		
	> DLT >	/ABBOTT/	/3.5%;21MG/100ML;128MG/100ML;/	
	> DLT >		/234MG/100ML/	/N17789/001/
	> ADD >	∂ ABBOTT	3.5%;21MG/100ML;128MG/100ML;	
	> ADD >		234MG/100ML	N17789 001

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
/AMITRIL/

/AB/	/WARNER/CHILCOTT/	/10MG/	/N83939/001/
/AB/		/25MG/	/N83937/001/
/AB/		/50MG/	/N83938/002/
/AB/		/75MG/	/N84957/001/
/AB/		/100MG/	/N85093/001/
/AB/		/150MG/	/N86295/001/
	∂ WARNER CHILCOTT	10MG	N83939 001
	∂	25MG	N83937 001
	∂	50MG	N83938 002
	∂	75MG	N84957 001
	∂	100MG	N85093 001
	∂	150MG	N86295 001

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

/BP/	/PAR/	/10MG/	/N88697/001/ /SEP/25,/1984/				
/BP/		/25MG/	/N88698/001/ /SEP/25,/1984/				
/BP/		/50MG/	/N88699/001/ /SEP/25,/1984/				
/BP/		/75MG/	/N88700/001/ /SEP/25,/1984/				
/BP/		/100MG/	/N88701/001/ /SEP/25,/1984/				
/BP/		/150MG/	/N88702/001/ /SEP/25,/1984/				
	∂ PAR	10MG	N88697 001 SEP 25, 1984	> ADD >	AB		
	∂	25MG	N88698 001 SEP 25, 1984	> ADD >	AB		
	∂	50MG	N88699 001 SEP 25, 1984	> ADD >	AB		
	∂	75MG	N88700 001 SEP 25, 1984	> ADD >	AB		
	∂	100MG	N88701 001 SEP 25, 1984	> ADD >			
	∂	150MG	N88702 001 SEP 25, 1984	> ADD >			

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL
CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL

/B*/	/PHARM/BASICS/	/EQ/12.5MG/BASE;5MG/	/N70477/001/ /JAN/12,/1988/				
/B*/		/EQ/25MG/BASE;10MG/	/N70478/001/ /JAN/12,/1988/				
	∂ PHARM BASICS	EQ 12.5MG BASE;5MG	N70477 001 JAN 12, 1988				
	∂	EQ 25MG BASE;10MG	N70478 001 JAN 12, 1988				

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL
PERPHENAZINE AND AMITRIPTYLINE HCL

/3/CHELSEA/		/50MG;4MG/	/N71558/001/ /MAR/02,/1987/				

AMLODIPINE BESYLATE

TABLET; ORAL
NORVASC

+	PFIZER	EQ 10MG BASE¤	N19787 003 JUL 31, 1992				
		EQ 2.5MG BASE¤	N19787 001 JUL 31, 1992				
		EQ 5MG BASE¤	N19787 002 JUL 31, 1992				

AMOXAPINE

TABLET; ORAL
AMOXAPINE

	DANBURY	25MG¤	N72688 001 AUG 28, 1992				
		50MG¤	N72689 001 AUG 28, 1992				
		100MG¤	N72690 001 AUG 28, 1992				
		150MG¤	N72691 001 AUG 28, 1992				

AMOXICILLIN

CAPSULE; ORAL
POLYMOX

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

		/UTIMOX/					
/AB/	/PARKE/DAVIS/	/250MG/	/N62107/001/				
/AB/		/500MG/	/N62107/002/				
	∂ PARKE DAVIS	250MG	N62107 001				
	∂	500MG	N62107 002				

POWDER FOR RECONSTITUTION; ORAL
AMOXICILLIN

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

AMOXICILLIN

POWDER FOR RECONSTITUTION; ORAL

	/AMOXIL/			
/AB/	/PARKE/DAVIS/	/125MG/5ML/	/N62127/001/	
/AB/		/250MG/5ML/	/N62127/002/	
	∂ PARKE DAVIS	125MG/5ML	N62127 001	
	∂	250MG/5ML	N62127 002	

AMPHOTERICIN B

INJECTABLE; INJECTION

AMPHOTERICIN B

AP	PHARMA TEK	50MG/VIAL*	N63206 001	APR 29, 1992

AMPICILLIN SODIUM

INJECTABLE; INJECTION

POLYCILLIN-N

/AP/	/BRISTOL/	/EQ 125MG BASE/VIAL/	/N50309/001/	
/AP/		/EQ 250MG BASE/VIAL/	/N50309/002/	
/AP/		/EQ 500MG BASE/VIAL/	/N50309/003/	
/AP/		/EQ 1GM BASE/VIAL/	/N50309/004/	
/AP/		/EQ 2GM BASE/VIAL/	/N50309/005/	
	∂ BRISTOL	EQ 125MG BASE/VIAL	N50309 001	
	∂	EQ 250MG BASE/VIAL	N50309 002	
	∂	EQ 500MG BASE/VIAL	N50309 003	
	∂	EQ 1GM BASE/VIAL	N50309 004	
	∂	EQ 2GM BASE/VIAL	N50309 005	

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

	/AMCILL/			
/AB/	/PARKE/DAVIS/	/EQ 250MG BASE/	/N62041/001/	
/AB/		/EQ 500MG BASE/	/N62041/002/	
	∂ PARKE DAVIS	EQ 250MG BASE	N62041 001	
	∂	EQ 500MG BASE	N62041 002	

POLYCILLIN

/AB/	/BRISTOL/	/EQ 250MG BASE/	/N50310/001/	
/AB/		/EQ 250MG BASE/	/N61392/001/	
AB	+ BRISTOL	EQ 250MG BASE	N61392 001	
/AB/		/EQ 500MG BASE/	/N50310/002/	
	∂	EQ 250MG BASE	N50310 001	
	∂	EQ 500MG BASE	N50310 002	

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

	/AMCILL/			
/AB/	/PARKE/DAVIS/	/EQ 125MG BASE/5ML/	/N62030/001/	
/AB/		/EQ 250MG BASE/5ML/	/N62030/002/	
	∂ PARKE DAVIS	EQ 125MG BASE/5ML	N62030 001	
	∂	EQ 250MG BASE/5ML	N62030 002	

POLYCILLIN

/AB/	/BRISTOL/	/EQ 100MG BASE/ML/	/N50308/004/	
/AB/		/EQ 100MG BASE/ML/	/N61394/001/	
	∂ BRISTOL	EQ 100MG BASE/ML	N50308 004	
		EQ 100MG BASE/ML	N61394 001	

AMPICILLIN/AMPICILLIN TRIHYDRATE; PROBENECID

POWDER FOR RECONSTITUTION; ORAL

POLYCILLIN-PRB

/AB/	/BRISTOL/	/EQ 3.5GM BASE/BOT; 1GM/BOT/	/N50457/001/	
/AB/		/EQ 3.5GM BASE/BOT; 1GM/BOT/	/N61898/001/	
AB	+ BRISTOL	EQ 3.5GM BASE/BOT; 1GM/BOT	N61898 001	
	∂	EQ 3.5GM BASE/BOT; 1GM/BOT	N50457 001	

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

	ORPHENADRINE COMPOUND			
	∂ EON LABS	385MG;30MG;25MG	N71564 001	JUN 23, 1988
	/∂/VITARINE/	/385MG;30MG;25MG/	/N71564/001/ /JUN/23,/1988/	
	ORPHENADRINE COMPOUND DOUBLE STRENGTH			
	∂ EON LABS	770MG;60MG;50MG	N71565 001	JUN 23, 1988
	/∂/VITARINE/	/770MG;60MG;50MG/	/N71565/001/ /JUN/23,/1988/	

ASPIRIN; MEPROBAMATE

TABLET; ORAL

	MEPRO-ASPIRIN			
	∂ EON LABS	325MG;200MG	N89127 001	MAR 02, 1987
	/∂/VITARINE/	/325MG;200MG/	/N89127/001/ /MAR/02,/1987/	

ATENOLOL

TABLET; ORAL

ATENOLOL

AB	APOTHECON	50MG¤	N73317 C01	MAR 20, 1992
AB		100MG¤	N73318 001	MAR 20, 1992
AB	GENEVA	25MG¤	N74052 001	MAY 01, 1992
AB	IPR	25MG¤	N73646 001	JUL 31, 1992
AB	LEDERLE	25MG¤	N74099 001	APR 28, 1992
AB	MYLAN	50MG¤	N73456 001	JAN 24, 1992
AB		100MG¤	N73457 001	JAN 24, 1992

TENORMIN

AB	ICI	25MG	N18240 004	APR 09, 1990

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL

ATENOLOL AND CHLORTHALIDONE

AB	DANBURY	50MG;25MG¤	N73665 001	JUL 02, 1992
AB		100MG;25MG¤	N73665 002	JUL 02, 1992

TENORETIC 100

AB	+ ICI	100MG;25MG	N18760 001	JUN 08, 1984
/AB/	/+//STUART/	/100MG;25MG/	/N18760/001/	/JUN/08,/1984/

TENORETIC 50

AB	ICI	50MG;25MG	N18760 002	JUN 08, 1984
/AB/	/STUART/	/50MG;25MG/	/N18760/002/	/JUN/08,/1984/

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

/AA/	/CHELSEA/	/0.025MG;2.5MG/	/N85876/001/
	∂ CHELSEA	0.025MG;2.5MG	N85876 001

DIPHENOXYLATE HCL W/ ATROPINE SULFATE

	∂ EON LABS	0.025MG;2.5MG	N86173 001
	/∂/VITARINE/	/0.025MG;2.5MG¤/	/N86173/001/

/AZITHROMYCIN/

/CAPSULE;/ORAL/

/ZITHROMAX/

	/+//PFIZER/	/250MG/	/N50670/001/ /NOV/01,/1991/

AZITHROMYCIN DIHYDRATE

CAPSULE; ORAL

ZITHROMAX

	+ PFIZER	EQ 250MG BASE	N50670 001 NOV 01, 1991

BACLOFEN

INJECTABLE; INJECTION

LIORESAL

	MEDTRONIC	0.5MG/ML¤	N20075 001 JUN 17, 1992
		2MG/ML¤	N20075 002 JUN 17, 1992

TABLET; ORAL

BACLOFEN

AB	BIOCRAFT	10MG¤	N73043 001	FEB 27, 1992
AB		20MG¤	N73044 001	FEB 27, 1992
	∂ EON LABS	10MG	N71901 001	APR 13, 1988
	∂	20MG	N71902 001	APR 13, 1988
/B*/	/PHARM/BASICS/	/10MG/	/N71260/001/	/MAY/06,/1988/
/B*/		/20MG/	/N71261/001/	/MAY/06,/1988/
	∂ PHARM BASICS	10MG	N71260 001	MAY 06, 1988
	∂	20MG	N71261 001	MAY 06, 1988
	/∂/VITARINE/	/10MG/	/N71901/001/	/APR/13,/1988/
	/∂/	/20MG/	/N71902/001/	/APR/13,/1988/

BENAZEPRIL HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

	LOTENSIN HCT + CIBA	20MG;25MG¤	N20033 003 MAY 19, 1992
		5MG;6.25MG¤	N20033 001 MAY 19, 1992
		10MG;12.5MG¤	N20033 002 MAY 19, 1992
		20MG;12.5MG¤	N20033 004 MAY 19, 1992

BENZTROPINE MESYLATE

TABLET; ORAL

	BENZTROPINE MESYLATE		
AA	MUTUAL PHARM	1MG¤	N81264 001 JAN 23, 1992
AA		2MG¤	N81265 001 JAN 23, 1992
/B*/	/PHARM/BASICS/	/0.5MG/	/N89211/001/ /JUN/14,/1988/
/B*/		/1MG/	/N89212/001/ /JUN/14,/1988/
/B*/		/2MG/	/N89213/001/ /JUN/14,/1988/
	∂ PHARM BASICS	0.5MG	N89211 001 JUN 14, 1988
	∂	1MG	N89212 001 JUN 14, 1988
	∂	2MG	N89213 001 JUN 14, 1988

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

	BETAMETHASONE DIPROPIONATE		
/AB/	/CLAY/PARK/	/EQ 0.05% BASE/	/N72536/001/ /JAN/31,/1990/
B*	CLAY PARK	EQ 0.05% BASE	N72536 001 JAN 31, 1990
AB	TARO	EQ 0.05% BASE¤	N73552 001 APR 30, 1992

BETAMETHASONE DIPROPIONATE

OINTMENT; TOPICAL

	BETAMETHASONE DIPROPIONATE		
/AB/	/CLAY/PARK/	/EQ 0.05% BASE/	/N72526/001/ /JAN/31,/1990/
B*	CLAY PARK	EQ 0.05% BASE	N72526 001 JAN 31, 1990

BETAMETHASONE VALERATE

CREAM; TOPICAL

	BETAMETHASONE VALERATE		
/AB/	/PHARMAFAIR/	/EQ 0.1% BASE/	/N70485/001/ /MAY/29,/1987/
	∂ PHARMAFAIR	EQ 0.1% BASE	N70485 001 MAY 29, 1987

OINTMENT; TOPICAL

	BETAMETHASONE VALERATE		
/AB/	/CLAY/PARK/	/EQ 0.1% BASE/	/N71478/001/ /DEC/23,/1987/
B*	CLAY PARK	EQ 0.1% BASE	N71478 001 DEC 23, 1987
/AB/	/PHARMAFAIR/	/EQ 0.1% BASE/	/N70486/001/ /MAY/29,/1987/
	∂ PHARMAFAIR	EQ 0.1% BASE	N70486 001 MAY 29, 1987

BETHANECHOL CHLORIDE

TABLET; ORAL

	BETHANECHOL CHLORIDE		
/AA/	/VITARINE/	/5MG/	/N84353/001/
/AA/		/10MG/	/N84378/001/
/AA/		/10MG/	/N84379/001/
/AA/		/25MG/	/N84383/001/
/AA/		/25MG/	/N84384/001/
	∂ VITARINE	5MG	N84353 001
	∂	10MG	N84378 001
	∂	10MG	N84379 001
	∂	25MG	N84383 001
	∂	25MG	N84384 001

BISOPROLOL FUMARATE

TABLET; ORAL
ZEBETA
+ LEDERLE 10MG¤ N19982 001
JUL 31, 1992
5MG¤ N19982 002
JUL 31, 1992

BITOLTEROL MESYLATE

SOLUTION; INHALATION
TORNALATE
/STERLING/WINTHROP/ /0.2%/ /N19548/001/ > ADD >
/FEB/19,/1992/ > ADD >
STERLING 0.2%¤ N19548 001 > ADD >
FEB 19, 1992 > ADD >
> ADD >
> ADD >
> ADD >

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE
/AP/ /LYPHOMED/ /50MG/ML/ /N70134/001/ > ADD >
/FEB/12,/1986/ > ADD >
@ LYPHOMED 50MG/ML N70134 001 > ADD >
FEB 12, 1986 > ADD >
> ADD >
> ADD >
> ADD >

BROMPHENIRAMINE MALEATE

TABLET; ORAL
BROMPHENIRAMINE MALEATE
/AA/ /PIONEER/PHARMS/ /4MG/ /N88604/001/
/JUL/13,/1984/
@ PIONEER PHARMS 4MG N88604 001
JUL 13, 1984

BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM
@ EON LABS 15MG N85938 001
@ 30MG N85934 001
/@/VITARINE/ /15MG/ /N85938/001/
/@/ /30MG/ /N85934/001/
SODIUM BUTABARBITAL
/AA/ /WEST/WARD/ /15MG/ /N85418/001/
/AA/ /30MG/ /N85432/001/
@ WEST WARD 15MG N85418 001
@ 30MG N85432 001

BUTORPHANOL TARTRATE

SPRAY, METERED; NASAL
STADOL
+ BRISTOL MYERS SQUIBB 1MG/INH N19890 001
DEC 12, 1991
/1MG/INH/ /N19890/001/
/DEC/12,/1991/

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

SOLUTION; INTRAPERITONEAL
DELFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER
FRESENIUS 18.4MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML¤ N20171 001
AUG 19, 1992
DELFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER
FRESENIUS 18.4MG/100ML;2.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML¤ N20171 002
AUG 19, 1992
DELFLEX W/ DEXTROSE 4.25% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER
FRESENIUS 18.4MG/100ML;4.25GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML¤ N20171 003
AUG 19, 1992

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
DEXTROSE 5% IN RINGER'S IN PLASTIC CONTAINER
AP MCGAW 33MG/100ML;5GM/100ML;30MG/100ML; 860MG/100ML¤ N20000 001
APR 17, 1992

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
RINGER'S IN PLASTIC CONTAINER
AP MCGAW 33MG/100ML;30MG/100ML; 860MG/100ML¤ N20002 001
APR 17, 1992

CARBAMAZEPINE

TABLET; ORAL
CARBAMAZEPINE

/AB/	/PARKE/DAVIS/	/200MG/	/N70429/001/ /JAN/02,/1987/	
/B*/	/PHARM/BASICS/	/200MG/	/N70300/001/ /MAY/15,/1986/	
	∂ PHARM BASICS	200MG	N70300 001 MAY 15, 1986	
	∂ WARNER CHILCOTT	200MG	N70429 001 JAN 02, 1987	

TABLET, CHEWABLE; ORAL
EPITOL

AB	LEMMON	100MG¤	N73524 001 JUL 29, 1992

CARBIDOPA; LEVODOPA

TABLET; ORAL
CARBIDOPA AND LEVODOPA

> ADD >				
> ADD >	AB	LEMMON	10MG;100MG¤	N73618 001 AUG 28, 1992
> ADD >				
> ADD >	AB		25MG;100MG¤	N73589 001 AUG 28, 1992
> ADD >				
> ADD >	AB		25MG;250MG¤	N73607 001 AUG 28, 1992
> ADD >				

SINEMET

> ADD >	AB	MSD	10MG;100MG	N17555 001
> ADD >	AB		25MG;100MG	N17555 003
> ADD >	AB	+	25MG;250MG	N17555 002

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL

B*	EON LABS	350MG	N89566 001 AUG 30, 1988	
/B*/	/VITARINE/	/350MG/	/N89566/001/ /AUG/30,/1988/	

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL
CEFADROXIL

AB	ZENITH	EQ 500MG BASE	N62766 001 MAR 03, 1987	
/∂/		/EQ/500MG/BASE/	/N62766/001/ /MAR/03,/1987/	

TABLET; ORAL
CEFADROXIL

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

> ADD > CEFPODOXIME PROXETIL

> ADD > GRANULE, FOR RECONSTITUTION; ORAL
> ADD > BAHAN

> ADD >	AB	SANKYO	EQ 50MG BASE/5ML¤	N50688 002 AUG 07, 1992
> ADD >	AB		EQ 100MG BASE/5ML¤	N50688 001 AUG 07, 1992

> ADD > VANTIN

> ADD >	AB	UPJOHN	EQ 50MG BASE/5ML¤	N50675 001 AUG 07, 1992
> ADD >	AB	+	EQ 100MG BASE/5ML¤	N50675 002 AUG 07, 1992

> ADD > TABLET; ORAL
> ADD > BAHAN

> ADD >	AB	SANKYO	EQ 100MG BASE¤	N50687 001 AUG 07, 1992
> ADD >	AB		EQ 200MG BASE¤	N50687 002 AUG 07, 1992

> ADD > VANTIN

> ADD >	AB	UPJOHN	EQ 100MG BASE¤	N50674 001 AUG 07, 1992
> ADD >	AB	+	EQ 200MG BASE¤	N50674 002 AUG 07, 1992

CEFPROZIL

POWDER FOR RECONSTITUTION; ORAL
CEFZIL
+ BRISTOL MYERS SQUIBB 250MG/5ML — N50665 002 — DEC 23, 1991
/250MG/5ML/ — /N50665/002/ — /DEC/23,/1991/

TABLET; ORAL
CEFZIL
+ BRISTOL MYERS SQUIBB 500MG — N50664 002 — DEC 23, 1991
/500MG/ — /N50664/002/ — /DEC/23,/1991/

CEFTAZIDIME

INJECTABLE; INJECTION
/CEPTAZ/
/GLAXO/

/500MG/VIAL/	/N50646/001/	/SEP/27,/1990/
/1GM/VIAL/	/N50646/002/	/SEP/27,/1990/
/2GM/VIAL/	/N50646/003/	/SEP/27,/1990/
/10GM/VIAL/	/N50646/004/	/SEP/27,/1990/

CEFTAZIDIME (ARGININE FORMULATION)

INJECTABLE; INJECTION

	CEPTAZ		
AP	GLAXO	1GM/VIAL	N50646 002 SEP 27, 1990
AP		2GM/VIAL	N50646 003 SEP 27, 1990
AP		10GM/VIAL	N50646 004 SEP 27, 1990
		500MG/VIAL	N50646 001 SEP 27, 1990
	PENTACEF		
AP	SMITHKLINE BEECHAM	1GM/VIAL¤	N64006 001 MAR 31, 1992
AP		2GM/VIAL¤	N64006 002 MAR 31, 1992
AP		10GM/VIAL¤	N64008 002 MAR 31, 1992
		6GM/VIAL¤	N64008 001 MAR 31, 1992

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN
/ROCHE/ — /EQ/250MG/BASE/VIAL/ — /N62510/001/ /MAR/12,/1985/

∂ ROCHE	EQ 250MG BASE/VIAL	N62510 001 MAR 12, 1985
	/EQ/500MG/BASE/VIAL/	/N62510/002/ /MAR/12,/1985/
∂	EQ 500MG BASE/VIAL	N62510 002 MAR 12, 1985
	/EQ/1GM/BASE/VIAL/	/N62510/003/ /MAR/12,/1985/
∂	EQ 1GM BASE/VIAL	N62510 003 MAR 12, 1985

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
CHLORDIAZEPOXIDE HCL

	∂ EON LABS	5MG	N84919 001
	∂	10MG	N84920 001
	∂	25MG	N84823 001
/AB/	/PARKE/DAVIS/	/5MG/	/N85163/001/
/AB/		/10MG/	/N84598/001/
/AB/		/25MG/	/N85164/001/
	∂ PARKE DAVIS	5MG	N85163 001
	∂	10MG	N84598 001
	∂	25MG	N85164 001
/AB/	/VITARINE/	/5MG/	/N84919/001/
/AB/		/10MG/	/N84920/001/
/AB/		/25MG/	/N84823/001/
/AB/	/WEST/WARD/	/5MG/	/N85014/001/
/AB/		/10MG/	/N85000/001/
/AB/		/25MG/	/N85294/001/
	∂ WEST WARD	5MG	N85014 001
	∂	10MG	N85000 001
	∂	25MG	N85294 001

CHLOROQUINE PHOSPHATE

TABLET; ORAL
CHLOROQUINE PHOSPHATE

/AA/	/WEST/WARD/	/EQ 150MG BASE/	/N83082/001/
	∂ WEST WARD	EQ 150MG BASE	N83082 001

CHLOROTHIAZIDE

TABLET; ORAL
CHLOROTHIAZIDE

	@ EON LABS	250MG	N85485 001	
/@/	/VITARINE/	/250MG/	/N85485/001/	

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

/AA/	/PIONEER/PHARMS/	/4MG/	/N88556/001/ /JUL/13,/1984/	
	@ PIONEER PHARMS	4MG	N88556 001 JUL 13, 1984	

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

	@ EON LABS	250MG	N84669 001	
/B*/	/PHARM/BASICS/	/100MG/	/N88708/001/ /AUG/30,/1984/	
/B*/		/250MG/	/N88709/001/ /AUG/30,/1984/	
	@ PHARM BASICS	100MG	N88708 001 AUG 30, 1984	
	@	250MG	N88709 001 AUG 30, 1984	
	/@/VITARINE/	/250MG/	/N84669/001/	

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

AB	EON LABS	50MG	N87118 001	
/AB/	/VITARINE/	/50MG/	/N87118/001/	
/AB/	/WARNER/CHILCOTT/	/25MG/	/N87515/001/ /JAN/24,/1983/	
/AB/		/50MG/	/N87516/001/ /FEB/09,/1983/	
	@ WARNER CHILCOTT	25MG	N87515 001 JAN 24, 1983	
	@	50MG	N87516 001 FEB 09, 1983	

THALITONE

/AB/	/BOEHRINGER/INGELHEIM/	/25MG/	/N88051/001/ /NOV/12,/1982/	
		/15MG/	/N19574/001/ /DEC/20,/1988/	

CHLORTHALIDONE

TABLET; ORAL
THALITONE

BX	HORUS	25MG	N88051 001 NOV 12, 1982	
		15MG	N19574 001 DEC 20, 1988	

CHYMOTRYPSIN

POWDER FOR RECONSTITUTION; OPHTHALMIC
/ALPHA CHYMAR/

/AT/	/BARNES/HIND/	/750 UNITS/VIAL/	/N11837/001/	
	@ SOLA BARNES HIND	750 UNITS/VIAL	N11837 001	

ZOLYSE

/AT/	/ALCON/	/750 UNITS/VIAL/	/N11903/001/	
	ALCON	750 UNITS/VIAL	N11903 001	

CINOXACIN

CAPSULE; ORAL
CINOBAC

AB	LILLY	250MG	N18067 001
AB	+	500MG	N18067 002

CINOXACIN

AB	BIOCRAFT	250MG¤	N73005 001 FEB 28, 1992
AB		500MG¤	N73006 001 FEB 28, 1992

CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATE

SOLUTION; IRRIGATION
RENACIDIN

	/GUARDIAN/LABS/	/6.602GM/100ML;0.198GM/100ML; 3.177GM/100ML/	/N19481/001/ /OCT/02,/1990/
	GUARDIAN LABS	6.602GM/100ML;198MG/100ML; 3.177GM/100ML	N19481 001 OCT 02, 1990

CLEMASTINE FUMARATE

SYRUP; ORAL
CLEMASTINE FUMARATE

AA	COPLEY	EQ 0.5MG BASE/5ML¤	N73095 001 APR 21, 1992

CLEMASTINE FUMARATE

SYRUP; ORAL
TAVIST

AA	DORSEY	EQ 0.5MG BASE/5ML	N18675 001	JUN 28, 1985

TABLET; ORAL
CLEMASTINE FUMARATE

>DLT>	/AB/	/LEMMON/	/1.34MG¤/	/N73282/001/ /JAN/31,/1992/
>DLT>	AB	LEMMON	2.68MG¤	N73283 001 JAN 31, 1992
>ADD>			1.34MG¤	N73282 001 JAN 31, 1992
>ADD>				
>DLT>		/TAVIST-1/		
>DLT>	/AB/	/DORSEY/	/1.34MG/	/N17661/002/
>ADD>		∂ SANDOZ	1.34MG	N17661 002

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

>DLT>		/TABLET;/EXTENDED/RELEASE;/ORAL/		
>DLT>		/TAVIST/D/		
>DLT>		/+//SANDOZ/	/EQ/1MG/BASE;75MG/	/N18298/001/ /DEC/15,/1982/
>ADD>		∂ SANDOZ	EQ 1MG BASE;75MG	N18298 001 DEC 15, 1982
>ADD>				

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL
CLINDAMYCIN HCL

∂ EON LABS	EQ 75MG BASE	N62910 001	JUL 05, 1988
∂	EQ 150MG BASE	N62910 002	JUL 05, 1988
/∂/VITARINE/	/EQ/75MG/BASE/	/N62910/001/ /JUL/05,/1988/	
/∂/	/EQ/150MG/BASE/	/N62910/002/ /JUL/05,/1988/	

CLINDAMYCIN PHOSPHATE

>ADD>		CREAM; VAGINAL		
>ADD>		CLEOCIN		
>ADD>	+	UPJOHN	EQ 2% BASE¤	N50680 001 AUG 11, 1992
>ADD>				

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

AP		GENSIA	EQ 150MG BASE/ML¤	N63282 001 MAY 29, 1992

CLIOQUINOL; NYSTATIN

/OINTMENT;/TOPICAL/
/NYSTAFORM/

	/MILES/	/10MG/GM;/ /100,000/UNITS/GM/	/N50235/001/
	∂ MILES	10MG/GM; 100,000 UNITS/GM	N50235 001

CLOFIBRATE

CAPSULE; ORAL
CLOFIBRATE

AB		PHARMACAPS	500MG¤	N73396 001 MAR 20, 1992

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL
CLORAZEPATE DIPOTASSIUM

/B*/	/PHARM/BASICS/	/3.75MG/	/N71242/001/ /MAY/20,/1987/	
/B*/		/7.5MG/	/N71243/001/ /MAY/20,/1987/	
/B*/		/15MG/	/N71244/001/ /MAY/20,/1987/	
	∂ PHARM BASICS	3.75MG	N71242 001 MAY 20, 1987	
	∂	7.5MG	N71243 001 MAY 20, 1987	
	∂	15MG	N71244 001 MAY 20, 1987	

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

/AB/	/WARNER/CHILCOTT/	/3.75MG/	/N71828/001/	/MAR/03,/1988/
/AB/		/7.5MG/	/N71829/001/	/MAR/03,/1988/
/AB/		/15MG/	/N71830/001/	/MAR/03,/1988/
	ə WARNER CHILCOTT	3.75MG	N71828 001	MAR 03, 1988
	ə	7.5MG	N71829 001	MAR 03, 1988
	ə	15MG	N71830 001	MAR 03, 1988

CLOTRIMAZOLE

CREAM; TOPICAL

LOTRIMIN

/AT//+//SCHERING/		/1%/	/N17619/001/	
BX +	SCHERING	1%	N17619 001	

MYCELEX

/AT/	/MILES/	/1%/	/N18183/001/	
BX	MILES	1%	N18183 001	

COLCHICINE; PROBENECID

TABLET; ORAL

/PROBEN-C/

/BP/	/CHELSEA/	/0.5MG;500MG/	/N85552/001/	
	ə CHELSEA	0.5MG;500MG	N85552 001	

PROBENECID AND COLCHICINE

BP	EON LABS	0.5MG;500MG	N86130 001	
/BP/	/VITARINE/	/0.5MG;500MG/	/N86130/001/	

CYANOCOBALAMIN

INJECTABLE; INJECTION

CYANOCOBALAMIN

/AP/	/LUITPOLD/	/0.03MG/ML/	/N80668/001/	
	ə LUITPOLD	0.03MG/ML	N80668 001	

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CYCLOPENTOLATE HCL

/AT/	/BARNES/HIND/	/1%/	/N84863/001/	
	ə SOLA BARNES HIND	1%	N84863 001	

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

DESIPRAMINE HCL

AB	EON LABS	25MG	N71601 001	JUN 05, 1987
AB		50MG	N71588 001	JUN 05, 1987
AB		75MG	N71602 001	OCT 05, 1987
AB		100MG	N71766 001	OCT 05, 1987
	ə	10MG	N72167 001	FEB 03, 1988
	ə	150MG	N72254 001	FEB 03, 1988
/B*/	/PHARM/BASICS/	/25MG/	/N71864/001/	/SEP/09,/1987/
/B*/		/50MG/	/N71865/001/	/SEP/09,/1987/
/B*/		/75MG/	/N71866/001/	/SEP/09,/1987/
/B*/		/100MG/	/N71867/001/	/SEP/09,/1987/
	ə PHARM BASICS	25MG	N71864 001	SEP 09, 1987
	ə	50MG	N71865 001	SEP 09, 1987
	ə	75MG	N71866 001	SEP 09, 1987
	ə	100MG	N71867 001	SEP 09, 1987
/AB/	/VITARINE/	/25MG/	/N71601/001/	/JUN/05,/1987/
/AB/		/50MG/	/N71588/001/	/JUN/05,/1987/
/AB/		/75MG/	/N71602/001/	/OCT/05,/1987/
/AB/		/100MG/	/N71766/001/	/OCT/05,/1987/
	/ə/	/10MG/	/N72167/001/	/FEB/03,/1988/
	/ə/	/150MG/	/N72254/001/	/FEB/03,/1988/

DESONIDE

CREAM; TOPICAL
DESONIDE

AB	TARO	0.05%¤	N73548 001 JUN 30, 1992

LOTION; TOPICAL
DESOWEN

OWEN GALDERMA	0.05%¤	N72354 001 JAN 24, 1992

DEXAMETHASONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
DEXAIR

/BAUSCH/AND/LOMB/	/EQ/0.1%/PHOSPHATE/	/N88433/001/ /DEC/15,/1983/
PHARMAFAIR	EQ 0.1% PHOSPHATE	N88433 001 DEC 15, 1983

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE 0.075% IN DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

MCGAW	3.3GM/100ML;75MG/100ML; 300MG/100ML¤	N19630 049 MAY 07, 1992

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

MCGAW	3.3GM/100ML;110MG/100ML; 300MG/100ML¤	N19630 050 MAY 07, 1992

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

MCGAW	3.3GM/100ML;150MG/100ML; 300MG/100ML¤	N19630 051 MAY 07, 1992

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

MCGAW	3.3GM/100ML;220MG/100ML; 300MG/100ML¤	N19630 052 MAY 07, 1992

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

MCGAW	3.3GM/100ML;300MG/100ML; 300MG/100ML¤	N19630 053 MAY 07, 1992

DIAZEPAM

INJECTABLE; INJECTION
DIAZEPAM

/AB/	/PARKE/DAVIS/	/5MG/ML/	/N71614/001/ /OCT/22,/1987/
/AP/		/5MG/ML/	/N71613/001/ /OCT/22,/1987/
	ə PARKE DAVIS	5MG/ML	N71613 001 OCT 22, 1987
	ə	5MG/ML	N71614 001 OCT 22, 1987

TABLET; ORAL
DIAZEPAM

/AB/	/PARKE/DAVIS/	/2MG/	/N70209/001/ /SEP/04,/1985/
/AB/		/5MG/	/N70210/001/ /SEP/04,/1985/
/AB/		/10MG/	/N70222/001/ /SEP/04,/1985/
/AB/	/PIONEER/PHARMS/	/2MG/	/N70787/001/ /AUG/02,/1988/
/AB/		/5MG/	/N70788/001/ /AUG/02,/1988/
/AB/		/10MG/	/N70776/001/ /AUG/02,/1988/
	ə PIONEER PHARMS	2MG	N70787 001 AUG 02, 1988
	ə	5MG	N70788 001 AUG 02, 1988
	ə	10MG	N70776 001 AUG 02, 1988
	ə WARNER CHILCOTT	2MG	N70209 001 SEP 04, 1985
	ə	5MG	N70210 001 SEP 04, 1985
	ə	10MG	N70222 001 SEP 04, 1985

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL
DIETHYLPROPION HCL

ə EON LABS	25MG	N85916 001
/S/VITARINE/	/25MG¤/	/N85916/001/

DIFLUNISAL

TABLET; ORAL

DIFLUNISAL

AB		LEMMON	250MG¤	N73679 001 JUL 31, 1992
AB			500MG¤	N73673 001 JUL 31, 1992

DOLOBID

AB		MSD	250MG	N18445 001 APR 19, 1982
AB	+		500MG	N18445 002 APR 19, 1982

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM CD

BC	+	MARION MERRELL DOW	180MG	N20062 002 DEC 27, 1991
BC	+		240MG	N20062 003 DEC 27, 1991
>ADD>	+		120MG¤	N20062 001 AUG 10, 1992
>ADD>	+		300MG	N20062 004 DEC 27, 1991
			/300MG/	/N20062/004/ /DEC/27,/1991/

CARDIZEM SR

	+	MARION MERRELL DOW	60MG	N19471 001 JAN 23, 1989
	+		90MG	N19471 002 JAN 23, 1989
			/60MG/	/N19471/001/ /JAN/23,/1989/
			/90MG/	/N19471/002/ /JAN/23,/1989/

DILACOR XR

BC		RHONE POULENC RORER	180MG¤	N20092 002 MAY 29, 1992
BC			240MG¤	N20092 003 MAY 29, 1992
	∂		120MG¤	N20092 001 MAY 29, 1992

INJECTABLE; INJECTION

CARDIZEM

		MARION MERRELL DOW	5MG/ML	N20027 001 OCT 24, 1991
			/25MG/VIAL/	/N20027/001/ /OCT/24,/1991/
			/50MG/VIAL/	/N20027/002/ /OCT/24,/1991/

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

AA		EON LABS	25MG	N80845 002
AA			50MG	N80845 001
/AA/		/PIONEER/PHARMS/	/25MG/	/N89101/001/ /DEC/20,/1985/
/AA/			/50MG/	/N88880/001/ /DEC/20,/1985/
	∂	PIONEER PHARMS	25MG	N89101 001 DEC 20, 1985
	∂		50MG	N88880 001 DEC 20, 1985
/AA/		/VITARINE/	/25MG/	/N80845/002/
/AA/			/50MG/	/N80845/001/

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

AB		GENEVA	50MG¤	N87562 001 FEB 25, 1992
AB			75MG¤	N87561 001 FEB 25, 1992

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL

DISOPYRAMIDE PHOSPHATE

/B*/		/CHELSEA/	/EQ/100MG/BASE/	/N71020/001/ /DEC/01,/1986/
/B*/			/EQ/150MG/BASE/	/N71021/001/ /DEC/01,/1986/
/B*/		/INTERPHARM/	/EQ/100MG/BASE/	/N71190/001/ /JAN/15,/1987/
/B*/			/EQ/150MG/BASE/	/N71191/001/ /JAN/15,/1987/
	∂	INTERPHARM	EQ 100MG BASE	N71190 001 JAN 15, 1987
	∂		EQ 150MG BASE	N71191 001 JAN 15, 1987

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOPAMINE HCL

/AP/	/LYPHOMED/	/40MG/ML/	/N70058/001/ /MAR/20,/1985/
/AP/		/80MG/ML/	/N70059/001/ /MAR/20,/1985/
/AP/		/160MG/ML/	/N70364/001/ /DEC/04,/1985/
	ə LYPHOMED	40MG/ML	N70058 001 MAR 20, 1985
	ə	80MG/ML	N70059 001 MAR 20, 1985
	ə	160MG/ML	N70364 001 DEC 04, 1985

DOXAPRAM HYDROCHLORIDE

INJECTABLE; INJECTION

DOPRAM

AP	ROBINS	20MG/ML	N14879 001

DOXAPRAM HCL

AP	STERIS	20MG/ML¤	N73529 001 JAN 30, 1992

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

	ə EON LABS	EQ 50MG BASE	N62780 001 APR 12, 1988
	ə	EQ 100MG BASE	N62227 001
/B*/	/INTERPHARM/	/EQ/50MG/BASE/	/N62763/001/ /SEP/02,/1988/
/B*/		/EQ/100MG/BASE/	/N62763/002/ /SEP/02,/1988/
	ə INTERPHARM	EQ 50MG BASE	N62763 001 SEP 02, 1988
	ə	EQ 100MG BASE	N62763 002 SEP 02, 1988
/AB/	/PARKE/DAVIS/	/EQ 50MG BASE/	/N62594/001/ /DEC/05,/1985/
/AB/		/EQ 100MG BASE/	/N62594/002/ /DEC/05,/1985/
	/ə/VITARINE/	/EQ/50MG/BASE/	/N62780/001/ /APR/12,/1988/
	/ə/	/EQ/100MG/BASE/	/N62227/001/

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

ə WARNER CHILCOTT	EQ 50MG BASE	N62594 001 DEC 05, 1985
ə	EQ 100MG BASE	N62594 002 DEC 05, 1985

CAPSULE, COATED PELLETS; ORAL

DOXYCYCLINE HYCLATE

AB	SIDMAK	EQ 100MG BASE¤	N63187 001 JUN 30, 1992

TABLET; ORAL

DOXYCYCLINE HYCLATE

/B*/	/INTERPHARM/	/EQ/100MG/BASE/	/N62764/001/ /SEP/02,/1988/
	ə INTERPHARM	EQ 100MG BASE	N62764 001 SEP 02, 1988
/AB/	/PARKE/DAVIS/	/EQ 100MG BASE/	/N62593/001/ /AUG/28,/1985/
	ə WARNER CHILCOTT	EQ 100MG BASE	N62593 001 AUG 28, 1985

DROPERIDOL

INJECTABLE; INJECTION

DROPERIDOL

/AP/	/SOLOPAK/	/2.5MG/ML/	/N71750/001/ /SEP/06,/1988/
	ə SOLOPAK	2.5MG/ML	N71750 001 SEP 06, 1988

ENOXACIN

TABLET; ORAL

PENETREX

+	PARKE DAVIS	400MG	N19616 005 DEC 31, 1991
		/400MG/	/N19616/005/ /DEC/31,/1991/

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

	ALKERGOT		
	∂ EON LABS	0.5MG	N85153 001
	∂	1MG	N87417 001
/∂/	/VITARINE/	/0.5MG/	/N85153/001/
/∂/		/1MG/	/N87417/001/

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL

	ERGOMAR		
AA	FISONS	2MG	N87693 001 FEB 24, 1983
	∂ FISONS	2MG	N87693 001 FEB 24, 1983

ERYTHROMYCIN

SOLUTION; TOPICAL

	C-SOLVE-2		
AT	SYOSSET	2%	N62468 001 JUL 03, 1985
	ERYTHROMYCIN		
AT	PHARM BASICS	2%	N62825 001 OCT 23, 1987
/AT/	/PHARM BASICS/	/2%/	/N62825/001/ /OCT 23, 1987/
	SANSAC		
AT	OWEN GALDERMA	2%	N62522 001 JAN 24, 1985
/AT/	/OWEN GALDERMA/	/2%/	/N62522/001/ /JAN 24, 1985/

TABLET, COATED PARTICLES; ORAL

	PCE		
	ABBOTT	500MG	N50611 002 AUG 22, 1990

ESTROPIPATE

TABLET; ORAL

	OGEN		
AB	ABBOTT	0.75MG	N83220 001
AB	ABBOTT	1.5MG	N83220 002
	OGEN 2.5		
	ABBOTT	3MG	N83220 003
	OGEN 5		
	ABBOTT	6MG	N83220 004

ETHINYL ESTRADIOL

TABLET; ORAL

	ESTINYL		
BP	SCHERING	0.05MG	N05292 002
	FEMINONE		
BP	UPJOHN	0.05MG	N16649 001

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

	GENCEPT 0.5/35-21		
AB	GENCON	0.035MG;0.5MG¤	N72692 001 FEB 28, 1992
	GENCEPT 1/35-21		
AB	GENCON	0.035MG;1MG¤	N72693 001 FEB 28, 1992
	GENCEPT 10/11-21		
AB	GENCON	0.035MG;0.5MG AND 1MG¤	N72694 001 FEB 28, 1992
	N.E.E. 1/35 21		
AB	METROMED	0.035MG;1MG	N71541 001 DEC 14, 1987
	∂ LPI	0.035MG;1MG	N71541 001 DEC 14, 1987

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28

GENCEPT 0.5/35-28

AB	GENCON	0.035MG;0.5MG¤	N72695 001 FEB 28, 1992

GENCEPT 1/35-28

AB	GENCON	0.035MG;1MG¤	N72696 001 FEB 28, 1992

GENCEPT 10/11-28

AB	GENCON	0.035MG;0.5MG AND 1MG¤	N72697 001 FEB 28, 1992

/N.E.E. 1/35 28;/

/AB/	/METROMED/	/0.035MG;1MG/	/N71542/001/ /DEC/14,/1987/
	∂ LPI	0.035MG;1MG	N71542 001 DEC 14, 1987

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET; ORAL-21

ORTHO TRI-CYCLEN

+	JOHNSON RW	0.035MG; 0.18MG,0.215MG,0.25MG¤	N19697 002 JUL 03, 1992

TABLET; ORAL-28

ORTHO TRI-CYCLEN

	JOHNSON RW	0.035MG; 0.18MG,0.215MG,0.25MG¤	N19697 001 JUL 03, 1992

FELODIPINE

TABLET, EXTENDED RELEASE; ORAL

PLENDIL

/MERCK/	/5MG/		/N19834/001/ /JUL/26,/1991/
MERCK	5MG		N19834 001 JUL 25, 1991
	/10MG/		/N19834/002/ /JUL/26,/1991/
	10MG		N19834 002 JUL 25, 1991

FENOPROFEN CALCIUM

CAPSULE; ORAL

FENOPROFEN CALCIUM

/AB/	/HALSEY/	/EQ 200MG BASE/	/N72355/001/ /JUL/05,/1988/
/AB/		/EQ 300MG BASE/	/N72356/001/ /JUL/05,/1988/
	∂ HALSEY	EQ 200MG BASE	N72355 001 JUL 05, 1988
	∂	EQ 300MG BASE	N72356 001 JUL 05, 1988

TABLET; ORAL

FENOPROFEN CALCIUM

/AB/	/HALSEY/	/EQ 600MG BASE/	/N72357/001/ /JUL/05,/1988/
	∂ HALSEY	EQ 600MG BASE	N72357 001 JUL 05, 1988

FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE

AP	STERIS	EQ 0.05MG BASE/ML¤	N73488 001 JUN 30, 1992

FINASTERIDE

TABLET; ORAL

PROSCAR

+	MSD	5MG¤	N20180 001 JUN 19, 1992

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

FLUONID

>ADD>	AT	ALLERGAN HERBERT	0.025%	N87156 002 SEP 06, 1984
>ADD> >DLT>/	AT/	/HERBERT/	/0.025%/	/N87156/002/ /SEP/06,/1984/
>DLT>				

FLUOCINONIDE

CREAM; TOPICAL

	FLUOCINONIDE		
/AB/	/CLAY/PARK/	/0.05%/	/N71790/001/ /APR/25,/1988/
B*	CLAY PARK	0.05%	N71790 001 APR 25, 1988
AB	NMC	0.05%¤	N73085 001 FEB 14, 1992

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

	FLURAZEPAM HCL		
/B*/	/PHARM/BASICS/	/15MG/	/N70562/001/ /JUL/09,/1987/
/B*/		/30MG/	/N70563/001/ /JUL/09,/1987/
	∂ PHARM BASICS	15MG	N70562 001 JUL 09, 1987
	∂	30MG	N70563 001 JUL 09, 1987

FOLIC ACID

TABLET; ORAL

	FOLIC ACID		
	∂ EON LABS	1MG	N84472 001
/AA/	/LILLY/	/1MG/	/N06135/003/
	∂ LILLY	1MG	N06135 003
	/∂/VITARINE/	/1MG¤/	/N84472/001/

FURAZOLIDONE

SUSPENSION; ORAL

	FUROXONE		
+	ROBERTS	50MG/15ML /50MG/15ML/	N11323 002 /N11323/002/

TABLET; ORAL

	FUROXONE		
+	ROBERTS	100MG /100MG/	N11270 002 /N11270/002/

FUROSEMIDE

INJECTABLE; INJECTION

	FUROSEMIDE		
/AP/	/LYPHOMED/	/10MG/ML/	/N18507/001/ /JUL/30,/1982/
	∂ LYPHOMED	10MG/ML	N18507 001 JUL 30, 1982

TABLET; ORAL

	FUROSEMIDE		
/AB/	/CHELSEA/	/20MG/	/N18369/001/ /MAY/14,/1982/
/AB/		/40MG/	/N18369/002/ /MAY/14,/1982/
	∂ CHELSEA	20MG	N18369 001 MAY 14, 1982
	∂	40MG	N18369 002 MAY 14, 1982
	∂ EON LABS	40MG	N18750 002 JUL 30, 1984
	/∂/VITARINE/	/40MG¤/	/N18750/002/ /JUL/30,/1984/

GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION

	GALLIUM CITRATE GA 67		
/BS/	/DUPONT/	/2MCI/ML/	/N17478/001/
BS	DUPONT MERCK	2MCI/ML	N17478 001

GLYBURIDE

TABLET; ORAL

	GLUBATE		
BX	HOECHST ROUSSEL	1.5MG¤	N20055 001 APR 17, 1992
BX		3MG¤	N20055 002 APR 17, 1992

	GLYNASE		
BX	UPJOHN	1.5MG	N20051 001 MAR 04, 1992
BX +		3MG	N20051 002 MAR 04, 1992

GONADORELIN ACETATE

INJECTABLE; INJECTION
LUTREPULSE PUMP KIT

> ADD >	FERRING	0.8MG/VIAL	N19687 001 OCT 10, 1989	
> ADD >				
> ADD >		3.2MG/VIAL	N19687 002 OCT 10, 1989	
> ADD >				
> DLT >	/JOHNSON/RW/	/0.8MG/VIAL/	/N19687/001/ /OCT/10,/1989/	
> DLT >				
> DLT >		/3.2MG/VIAL/	/N19687/002/ /OCT/10,/1989/	
> DLT >				

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL
ULTRAGRIS-165

AB	SIDMAK	165MG¤	N62645 001 JUN 30, 1992

ULTRAGRIS-330

AB	SIDMAK	330MG¤	N62646 001 JUN 30, 1992

HALOFANTRINE HYDROCHLORIDE

TABLET; ORAL
HALFAN

+	SMITHKLINE BEECHAM	250MG¤	N20250 001 JUL 24, 1992

HALOPERIDOL

TABLET; ORAL
HALOPERIDOL

/AB/	/ROYCE/	/0.5MG/		/N71722/001/ /DEC/24,/1987/
/AB/		/1MG/		/N71723/001/ /DEC/24,/1987/
/AB/		/2MG/		/N71724/001/ /DEC/24,/1987/
/AB/		/5MG/		/N71725/001/ /DEC/24,/1987/
/AB/		/10MG/		/N72121/001/ /DEC/24,/1987/
/AB/		/20MG/		/N72122/001/ /DEC/24,/1987/
	ə ROYCE	0.5MG	N71722 001 DEC 24, 1987	
	ə	1MG	N71723 001 DEC 24, 1987	
	ə	2MG	N71724 001 DEC 24, 1987	
	ə	5MG	N71725 001 DEC 24, 1987	
	ə	10MG	N72121 001 DEC 24, 1987	
	ə	20MG	N72122 001 DEC 24, 1987	

HALOPERIDOL LACTATE

INJECTABLE; INJECTION
HALOPERIDOL

/AP/	/LYPHOMED/	/EQ 5MG BASE/ML/		/N71187/001/ /JAN/20,/1987/
	ə LYPHOMED	EQ 5MG BASE/ML	N71187 001 JAN 20, 1987	

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH

/AP/	/LUITPOLD/	/10 UNITS/ML/		/N89063/001/ /OCT/09,/1985/
/AP/		/100 UNITS/ML/		/N89064/001/ /OCT/09,/1985/
	ə LUITPOLD	10 UNITS/ML	N89063 001 OCT 09, 1985	
	ə	100 UNITS/ML	N89064 001 OCT 09, 1985	

HEPARIN SODIUM

INJECTABLE; INJECTION

/HEPARIN LOCK FLUSH PRESERVATIVE FREE/

/AP/	/LYPHOMED/	/10 UNITS/ML/	/N17029/011/ /SEP/22,/1987/
/AP/		/100 UNITS/ML/	/N17029/012/ /SEP/22,/1987/
	ə LYPHOMED	10 UNITS/ML	N17029 011 SEP 22, 1987
	ə	100 UNITS/ML	N17029 012 SEP 22, 1987

/HEPARIN LOCK FLUSH PRESERVATIVE FREE IN PLASTIC CONTAINER;/

/AP/	/LYPHOMED/	/10 UNITS/ML/	/N17029/008/ /SEP/22,/1987/
/AP/		/100 UNITS/ML/	/N17029/009/ /SEP/22,/1987/
	ə LYPHOMED	10 UNITS/ML	N17029 008 SEP 22, 1987
	ə	100 UNITS/ML	N17029 009 SEP 22, 1987

HEPARIN SODIUM

/AP/	/LUITPOLD/	/1,000 UNITS/ML/	/N87452/001/ /OCT/31,/1983/
	ə LUITPOLD	1,000 UNITS/ML	N87452 001 OCT 31, 1983

HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5%

/3/	/ABBOTT/	/10,000/UNITS/100ML/	/N18911/006/ /JAN/30,/1985/
AP	ABBOTT	10,000 UNITS/100ML	N18911 006 JAN 30, 1985

HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	MCGAW	200 UNITS/100ML¤	N19953 001 JUL 20, 1992

HEPARIN SODIUM 12500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	MCGAW	5,000 UNITS/100ML¤	N19802 001 JUL 20, 1992

HEPARIN SODIUM 20000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	MCGAW	4,000 UNITS/100ML¤	N19952 001 JUL 20, 1992

HEPARIN SODIUM 25000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	MCGAW	5,000 UNITS/100ML¤	N19952 004 JUL 20, 1992
AP		10,000 UNITS/100ML¤	N19952 005 JUL 20, 1992

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	MCGAW	5,000 UNITS/100ML¤	N19802 005 JUL 20, 1992
AP		10,000 UNITS/100ML¤	N19802 002 JUL 20, 1992

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

	MCGAW	5,000 UNITS/100ML¤	N19802 003 JUL 20, 1992

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

APRESOLINE

/AP/	/CIBA/	/20MG/ML/	/N083303/003/
	CIBA	20MG/ML	N08303 003

/HYDRALAZINE HCL/

/AP/	/LYPHOMED/	/20MG/ML/	/N089532/001/ /AUG/11,/1987/
	ə LYPHOMED	20MG/ML	N89532 001 AUG 11, 1987

TABLET; ORAL

HYDRALAZINE HCL

	ə EON LABS	50MG	N85088 001
/AA/	/VANGARD/	/25MG/	/N87712/001/
	ə VANGARD	25MG	N87712 001
/3/	/VITARINE/	/50MG/	/N85088/001/

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

/HYDRAL/

/AB/	/SOLVAY/	/25MG;25MG/	/N87608/001/ /FEB/08,/1982/
/AB/		/50MG;50MG/	/N87213/001/ /FEB/08,/1982/
/AB/		/100MG;50MG/	/N87609/001/ /FEB/08,/1982/

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL
HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

AB	SOLVAY	25MG;25MG	N87608 001 FEB 08, 1982
AB		50MG;50MG	N87213 001 FEB 08, 1982
	∂	100MG;50MG	N87609 001 FEB 08, 1982

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
HYDRAP-ES

	∂ EON LABS	25MG;15MG;0.1MG	N84876 001
	/∂/VITARINE/	/25MG;15MG;0.1MG/	/N84876/001/

HYDRALAZINE HYDROCHLORIDE; RESERPINE

TABLET; ORAL
DRALSERP

	∂ EON LABS	25MG;0.1MG	N84617 001
	/∂/VITARINE/	/25MG;0.1MG#/	/N84617/001/

SERPASIL-APRESOLINE

/BP/	/CIBA/	/25MG;0.1MG/	/N09296/004/
	CIBA	25MG;0.1MG	N09296 004

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

AB	DANBURY	25MG¤	N81189 001 JAN 24, 1992
AB		100MG¤	N81190 001 JAN 24, 1992
AB	EON LABS	25MG	N83899 001
AB		50MG	N85219 001
>_DLT_>/AB/	/HEATHER/	/50MG/	/N84135/001/
>_ADD_>	∂ HEATHER	50MG	N84135 001
/AB/	/VITARINE/	/25MG/	/N83899/001/
/AB/		/50MG/	/N85219/001/

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

>_DLT_>/AB/	/WARNER/CHILCOTT/	/25MG/	/N87586/001/ /MAY/03,/1982/
>_DLT_>			
>_DLT_>/AB/		/50MG/	/N87587/001/ /MAY/03,/1982/
>_DLT_>			
>_ADD_>	∂ WARNER CHILCOTT	25MG	N87586 001 MAY 03, 1982
>_ADD_>			
>_ADD_>	∂	50MG	N87587 001 MAY 03, 1982
>_ADD_>			

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
HYDRO-SERP 25

>_ADD_>	∂ EON LABS	25MG;0.125MG	N84827 001
>_DLT_>	/∂/VITARINE/	/25MG;0.125MG/	/N84827/001/

HYDRO-SERP 50

	∂ EON LABS	50MG;0.125MG	N85213 001
	/∂/VITARINE/	/50MG;0.125MG/	/N85213/001/

/SERPASIL-ESIDRIX/#1/

/BP/	/CIBA/	/25MG;0.1MG/	/N11878/003/
	∂ CIBA	25MG;0.1MG	N11878 003

/SERPASIL-ESIDRIX/#2/

/BP/	/CIBA/	/50MG;0.1MG/	/N11878/005/
	∂ CIBA	50MG;0.1MG	N11878 005

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL
MAXZIDE-25

AB	MYLAN	25MG;37.5MG	N19129 003 MAY 13, 1988

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

B*	EON LABS	50MG;75MG	N71360 001 DEC 08, 1987
AB	GENEVA	25MG;37.5MG¤	N73281 001 APR 30, 1992
/B*/	/VITARINE/	/50MG;75MG/	/N71360/001/ /DEC/08,/1987/

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

/AT/	/BAUSCH/AND/LOMB/	/1%/	/N87838/001/ /JUL/28,/1982/

HYDROCORTISONE

CREAM; TOPICAL

	HYDROCORTISONE		
AT	PHARMAFAIR	1%	N87838 001 JUL 28, 1982

LOTION; TOPICAL

	/CORT-DOME/		
/AT/	/MILES/	/0.5%/	/N09895/003/
/AT/		/1%/	/N09895/001/
	ə MILES	0.5%	N09895 003
	ə	1%	N09895 001

SOLUTION; TOPICAL

	TEXACORT		
	GENDERM	2.5%¤	N81271 001 APR 17, 1992

TABLET; ORAL

	/HYCORTOLE/		
	/ə/VITARINE/	/20MG/	/N80642/002/
	HYDROCORTISONE		
	ə EON LABS	20MG	N80642 002

HYDROCORTISONE ACETATE

CREAM; TOPICAL

	HEMSOL-HC		
AT	ABLE	1%¤	N81274 001 JUN 19, 1992

HYDROFLUMETHIAZIDE; RESERPINE

TABLET; ORAL

	/HYDROFLUMETHIAZIDE/AND/RESERPINE/		
/B*/	/PHARM/BASICS/	/50MG;0.125MG/	/N88195/001/ /OCT/26,/1983/
	ə PHARM BASICS	50MG;0.125MG	N88195 001 OCT 26, 1983

HYDROXYAMPHETAMINE HYDROBROMIDE; TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC

	PAREMYD		
	ALLERGAN	1%;0.25%¤	N19261 001 JAN 30, 1992

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

	HYDROXYZINE HCL		
AB	EON LABS	10MG	N87246 002
AB		25MG	N85247 001
AB		50MG	N87245 001
/B*/	/PHARM/BASICS/	/10MG/	/N89121/001/ /MAR/20,/1986/
/B*/		/25MG/	/N89122/001/ /MAR/20,/1986/
/B*/		/50MG/	/N89123/001/ /MAR/20,/1986/
	ə PHARM BASICS	10MG	N89121 001 MAR 20, 1986
	ə	25MG	N89122 001 MAR 20, 1986
	ə	50MG	N89123 001 MAR 20, 1986
/AB/	/VITARINE/	/10MG/	/N87246/002/
/AB/		/25MG/	/N85247/001/
/AB/		/50MG/	/N87245/001/

HYDROXYZINE PAMOATE

CAPSULE; ORAL

	HY-PAM		
AB	EON LABS	EQ 25MG HCL	N87479 001
/AB/	/VITARINE/	/EQ 25MG HCL/	/N87479/001/
	HYDROXYZINE PAMOATE		
AB	EON LABS	EQ 50MG HCL	N86183 001
/AB/	/VITARINE/	/EQ 50MG HCL/	/N86183/001/

IBUPROFEN

TABLET; ORAL

	IBUPROFEN		
AB	LEMMON	400MG¤	N73343 001 JUN 30, 1992
AB		600MG¤	N73344 001 JUN 30, 1992
AB		800MG¤	N73345 001 JUN 30, 1992
/AB/	/SUPERPHARM/	/600MG/	/N70709/001/ /APR/25,/1986/
	ə SUPERPHARM	600MG	N70709 001 APR 25, 1986

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL
IMIPRAMINE HCL

AB	EON LABS	10MG	N85200 001	
AB		25MG	N84869 002	
AB		50MG	N85133 001	
/AB/	/VITARINE/	/25MG/	/N84869/002/	
/AB/		/50MG/	/N85133/001/	
	/ə/	/10MG/	/N85200/001/	

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

	ə EON LABS	25MG	N71711 001 JUL 05, 1988	
	ə	50MG	N71712 001 JUL 05, 1988	
	/ə/VITARINE/	/25MG/	/N71711/001/ /JUL/05,/1988/	
	/ə/	/50MG/	/N71712/001/ /JUL/05,/1988/	

CAPSULE, EXTENDED RELEASE; ORAL
INDOMETHACIN

B*	EON LABS	75MG	N71531 001 JUL 21, 1987
/B*/	/VITARINE/	/75MG/	/N71531/001/ /JUL/21,/1987/

SUPPOSITORY; RECTAL
INDOCIN

>ADD> AB	+ MERCK	50MG	N17814 001 AUG 13, 1984	
>ADD>				
>ADD>	INDOMETHEGAN			
>ADD> AB	G AND W	50MG¤	N73314 001 AUG 31, 1992	
>ADD>				

IOFETAMINE HYDROCHLORIDE I-123

INJECTABLE; INJECTION
SPECTAMINE IMP

/MEDI/PHYSICS/	/1/MCI/ML/	/N19432/001/ /DEC/24,/1987/
	1 MCI/ML	N19432 001 DEC 24, 1987

IOPAMIDOL

INJECTABLE; INJECTION
ISOVUE-250

	SQUIBB	51%¤	N18735 007 JUL 06, 1992

IOPHENDYLATE

>DLT>	/INJECTABLE;/INJECTION/		
>DLT>	/PANTOPAQUE/		
>DLT>	/LAFAYETTE/	/100%/	/N05319/001/
>ADD>	ə ALCON	100%	N05319 001

IOVERSOL

INJECTABLE; INJECTION
OPTIRAY 300

	MALLINCKRODT	64%¤	N19710 004 JAN 22, 1992
	OPTIRAY 350		
	MALLINCKRODT	74%¤	N19710 005 JAN 22, 1992

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
ISOETHARINE HCL

/AN/	/ARMOUR/	/0.125%/	/N87936/001/ /NOV/15,/1982/	
/AN/		/0.167%/	/N88470/001/ /MAR/14,/1984/	
/AN/		/0.2%/	/N88471/001/ /MAR/14,/1984/	
/AN/		/0.25%/	/N88472/001/ /MAR/14,/1984/	
		/0.062%/	/N87937/001/ /NOV/15,/1982/	
AN	ASTRA	0.125%	N87938 001 NOV 15, 1982	
		0.062%	N87937 001 NOV 15, 1982	
	ə	0.167%	N88470 001 MAR 14, 1984	
	ə	0.2%	N88471 001 MAR 14, 1984	
	ə	0.25%	N88472 001 MAR 14, 1984	

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
ISOETHARINE HCL

/AN/	/DEY/	/0.08%/	/N88187/001/ /DEC/03,/1982/	
/AN/		/0.1%/	/N87389/001/	
/AN/		/0.17%/	/N87390/001/	
/AN/		/0.25%/	/N88188/001/ /DEC/03,/1982/	
/AN/		/1%/	/N86763/001/	
	ə DEY	0.08%	N88187 001 DEC 03, 1982	
	ə	0.1%	N87389 001	
	ə	0.17%	N87390 001	
	ə	0.25%	N88188 001 DEC 03, 1982	
	ə	1%	N86763 001	
	ISOETHARINE HCL S/F			
AN	DEY	0.17%	N89819 001 NOV 22, 1988	
		/0.17%/	/N89819/001/ /NOV/22,/1988/	

ISONIAZID

TABLET; ORAL
ISONIAZID

AA	EON LABS	100MG	N08678 002
AA		300MG	N08678 003
/AA/	/LILLY/	/100MG/	/N08499/002/
/AA/		/300MG/	/N08499/003/
	ə LILLY	100MG	N08499 002
	ə	300MG	N08499 003
/AA/	/VITARINE/	/100MG/	/N08678/002/
/AA/		/300MG/	/N08678/003/

ISOPROTERENOL HYDROCHLORIDE

SOLUTION; INHALATION
ISOPROTERENOL HCL

/AN/	/DEY/	/0.5%/	/N86764/001/ /JAN/04,/1982/	
	ə DEY	0.5%	N86764 001 JAN 04, 1982	

ISOSORBIDE MONONITRATE

TABLET; ORAL
ISMO

+	WYETH	20MG		N19091 001 DEC 30, 1991
		/20MG/		/N19091/001/ /DEC/30,/1991/

KANAMYCIN SULFATE

INJECTABLE; INJECTION
KANAMYCIN SULFATE

AP	LOCH	EQ 75MG BASE/2ML¤		N63021 001 JUL 31, 1992
AP		EQ 500MG BASE/2ML¤		N63022 001 JUL 31, 1992
AP		EQ 1GM BASE/3ML¤		N63025 001 JUL 31, 1992

KETOROLAC TROMETHAMINE

TABLET; ORAL
TORADOL

+	SYNTEX	10MG		N19645 001 DEC 20, 1991
		/10MG/		/N19645/001/ /DEC/20,/1991/

LACTULOSE

SYRUP; ORAL
LACTULOSE

> ADD >	AA	PACO	10GM/15ML¤	N73160 001 AUG 25, 1992
> ADD >	AA	ROXANE LABS	10GM/15ML¤	N73591 001 MAY 29, 1992

SYRUP; ORAL, RECTAL
LACTULOSE

> ADD >	AA	PACO	10GM/15ML¤	N72029 001 AUG 25, 1992
> ADD >	AA	ROXANE LABS	10GM/15ML¤	N73590 001 MAY 29, 1992

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM
/AP/ /LYPHOMED/ /EQ 50MG BASE/VIAL/ /N88939/001/ /DEC/01,/1986/
∂ LYPHOMED EQ 50MG BASE/VIAL N88939 001 DEC 01, 1986

LEVOCARNITINE

SOLUTION; ORAL
CARNITOR
AA SIGMA TAU 1GM/10ML N19257 001 APR 10, 1986
/VITACARN/
/AA/ /MCGAW/ /1GM/10ML/ /N19257/001/ /APR/10,/1986/

LEVODOPA

CAPSULE; ORAL
DOPAR
/+///P/AND/S/ /500MG/ /N16913/002/
/100MG/ /N16913/003/
/250MG/ /N16913/001/
+ ROBERTS 500MG N16913 002
100MG N16913 003
250MG N16913 001

LEVORPHANOL TARTRATE

TABLET; ORAL
LEVO-DROMORAN
+ ROCHE 2MG N08720 001 DEC 19, 1991
/2MG/ /N08720/001/ /DEC/19,/1991/

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL
/INTL/MEDICATION/ /1GM/VIAL/ /N18543/001/
∂ INTL MEDICATION 1GM/VIAL N18543 001
/2GM/VIAL/ /N18543/002/
∂ 2GM/VIAL N18543 002

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER
AP MCGAW 200MG/100ML¤ N19830 002 APR 08, 1992
LIDOCAINE HCL 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER
AP MCGAW 400MG/100ML¤ N19830 003 APR 08, 1992
LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER
AP MCGAW 800MG/100ML¤ N19830 004 APR 08, 1992

LITHIUM CARBONATE

CAPSULE; ORAL
LITHIUM CARBONATE
/B*/ /PHARM/BASICS/ /300MG/ /N72542/001/ /FEB/01,/1989/
∂ PHARM BASICS 300MG N72542 001 FEB 01, 1989

LOMEFLOXACIN HYDROCHLORIDE

TABLET; ORAL
MAXAQUIN
+ SEARLE EQ 400MG BASE¤ N20013 001 FEB 21, 1992

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL
LOPERAMIDE HCL
>ADD> AB GENEVA 2MG¤ N72993 001 AUG 28, 1992
>ADD> AB LEMMON 2MG¤ N73192 001 APR 30, 1992

LORACARBEF

CAPSULE; ORAL
LORABID
+ LILLY 200MG N50668 001 DEC 31, 1991
/200MG/ /N50668/001/ /DEC/31,/1991/

LORACARBEF

POWDER FOR RECONSTITUTION; ORAL
LORABID
+ LILLY — 200MG/5ML — N50667 002 DEC 31, 1991
/200MG/5ML/ — /N50667/002/ /DEC/31,/1991/

LORAZEPAM

TABLET; ORAL
LORAZEPAM
/B*/ /PHARM/BASICS/ — /1MG/ — /N70539/001/ /DEC/22,/1986/
/B*/ — /2MG/ — /N70540/001/ /DEC/22,/1986/
∂ PHARM BASICS — 1MG — N70539 001 DEC 22, 1986
∂ — 2MG — N70540 001 DEC 22, 1986

MECLOFENAMATE SODIUM

CAPSULE; ORAL
MECLOFENAMATE SODIUM
/B*/ /PHARM/BASICS/ — /EQ/50MG/BASE/ — /N71007/001/ /MAR/25,/1988/
/B*/ — /EQ/100MG/BASE/ — /N71008/001/ /MAR/25,/1988/
∂ PHARM BASICS — EQ 50MG BASE — N71007 001 MAR 25, 1988
∂ — EQ 100MG BASE — N71008 001 MAR 25, 1988

MEFENAMIC ACID

CAPSULE; ORAL
MEFENAMIC ACID
∂ EON LABS — 250MG — N72179 001 APR 21, 1988 — >DLT >
/∂/VITARINE/ — /250MG/ — /N72179/001/ /APR/21,/1988/ — >ADD >

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE
/B*/ /PHARM/BASICS/ — /20MG/ — /N70646/001/ /OCT/02,/1987/
/B*/ — /40MG/ — /N70647/001/ /OCT/02,/1987/
∂ PHARM BASICS — 20MG — N70646 001 OCT 02, 1987
∂ — 40MG — N70647 001 OCT 02, 1987

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
MEPERIDINE HCL
AP ABBOTT — 10MG/ML — N88432 001 AUG 16, 1984
/AP/ /PARKE/DAVIS/ — /50MG/ML/ — /N80364/002/
/AP/ — /75MG/ML/ — /N80364/003/
/AP/ — /100MG/ML/ — /N80364/001/
∂ PARKE DAVIS — 50MG/ML — N80364 002
∂ — 75MG/ML — N80364 003
∂ — 100MG/ML — N80364 001
AP STERIS — 10MG/ML* — N73443 001 MAR 17, 1992
AP — 50MG/ML* — N73444 001 MAR 17, 1992
AP — 100MG/ML* — N73445 001 MAR 17, 1992

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE
∂ ELKINS SINN — 200MG — N15426 002
∂ — 400MG — N15426 001
AA EON LABS — 200MG — N14547 002
AA — 400MG — N14547 001
/AA/ /HEATHER/ — /600MG/ — /N84329/001/
∂ HEATHER — 600MG — N84329 001
/AA/ /ICN/ — /200MG/ — /N15139/006/
/AA/ — /400MG/ — /N15139/005/
∂ ICN — 200MG — N15139 006
∂ — 400MG — N15139 005
/AA/ /PARKE/DAVIS/ — /200MG/ — /N84744/001/
/AA/ — /400MG/ — /N84744/002/
∂ PARKE DAVIS — 200MG — N84744 001
∂ — 400MG — N84744 002

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE

/ə/	/QUANTUM/PHARMICS/	/200MG/	/N15426/002/	
/ə/		/400MG/	/N15426/001/	
/AA/	/VITARINE/	/200MG/	/N14547/002/	
/AA/		/400MG/	/N14547/001/	

MESALAMINE

TABLET, DELAYED RELEASE; ORAL
ASACOL

+	P AND G	400MG¤	N19651 001 JAN 31, 1992

METAPROTERENOL SULFATE

SOLUTION; INHALATION
METAPROTERENOL SULFATE

/AN/	/ARMOUR/	/0.4%/	/N71275/001/ /JUL/27,/1988/
/AN/		/0.6%/	/N71018/001/ /JUL/27,/1988/
AN	ASTRA	0.4%	N71275 001 JUL 27, 1988
AN		0.6%	N71018 001 JUL 27, 1988
	/DEY/	/0.33%/	/N71806/001/ /AUG/05,/1988/
	ə DEY	0.33%	N71806 001 AUG 05, 1988
	PROMETA		
AN	MURO	5%¤	N73340 001 MAR 30, 1992

SYRUP; ORAL
METAPROTERENOL SULFATE

AA	BIOCRAFT	10MG/5ML¤	N72761 001 FEB 27, 1992
AA	SILARX	10MG/5ML¤	N73632 001 JUL 22, 1992

METAPROTERENOL SULFATE

TABLET; ORAL
METAPROTERENOL SULFATE

/B*/	/PHARM/BASICS/	/10MG/	/N71013/001/ /JAN/25,/1988/
/B*/		/20MG/	/N71014/001/ /JAN/25,/1988/
	ə PHARM BASICS	10MG	N71013 001 JAN 25, 1988
	ə	20MG	N71014 001 JAN 25, 1988

METHADONE HYDROCHLORIDE

TABLET, DISPERSIBLE; ORAL
WESTADONE

	ə EON LABS	2.5MG	N17108 001
	ə	5MG	N17108 002
	ə	10MG	N17108 003
	ə	40MG	N17108 004
/ə/	/VITARINE/	/2.5MG/	/N17108/001/
/ə/		/5MG/	/N17108/002/
/ə/		/10MG/	/N17108/003/
/ə/		/40MG/	/N17108/004/

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL

AA	EON LABS	500MG	N87283 001	
AA		750MG	N87282 001	
>DLT> /AA/	/HEATHER/	/500MG/	/N84675/001/	
>DLT> /AA/		/750MG/	/N84924/001/	
>ADD>	ə HEATHER	500MG	N84675 001	
>ADD>	ə	750MG	N84924 001	
/AA/	/VITARINE/	/500MG/	/N87283/001/	
/AA/		/750MG/	/N87282/001/	

METHOTREXATE SODIUM

TABLET; ORAL
METHOTREXATE

AB	MYLAN	EQ 2.5MG BASE¤	N81235 001 MAY 15, 1992

METHYCLOTHIAZIDE

TABLET; ORAL
METHYCLOTHIAZIDE

/B*/	/PHARM/BASICS/	/5MG/	/N88745/001/ /MAR/21,/1985/	
	ə PHARM BASICS	5MG	N88745 001 MAR 21, 1985	

METHYLDOPA

TABLET; ORAL
METHYLDOPA

/AB/	/PARKE/DAVIS/	/125MG/	/N70331/001/ /APR/15,/1986/	
/AB/		/250MG/	/N70332/001/ /APR/15,/1986/	
/AB/		/500MG/	/N70333/001/ /APR/15,/1986/	
	ə PARKE DAVIS	125MG	N70331 001 APR 15, 1986	
	ə	250MG	N70332 001 APR 15, 1986	
	ə	500MG	N70333 001 APR 15, 1986	

METHYLPREDNISOLONE

TABLET; ORAL
METHYLPREDNISOLONE

	ə EON LABS	4MG	N87341 001
/ə/	/VITARINE/	/4MG/	/N87341/001/

METOCLOPRAMIDE HYDROCHLORIDE

CONCENTRATE; ORAL
METOCLOPRAMIDE INTENSOL

	ROXANE	EQ 10MG BASE/ML¤	N72995 001 JAN 30, 1992

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL

AP	CETUS BEN VENUE	EQ 10MG BASE/2ML¤	N72155 001 MAR 30, 1992	
AP		EQ 10MG BASE/2ML¤	N72244 001 MAR 30, 1992	>ADD>
AP		EQ 10MG BASE/2ML¤	N72247 001 MAY 18, 1992	>ADD>

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
METOCLOPRAMIDE HCL

/B*/	/INTERPHARM/	/EQ/10MG/BASE/	/N71213/001/ /SEP/24,/1986/
	ə INTERPHARM	EQ 10MG BASE	N71213 001 SEP 24, 1986
/B*/	/PHARM/BASICS/	/EQ/10MG/BASE/	/N70339/001/ /JUL/29,/1985/
	ə PHARM BASICS	EQ 10MG BASE	N70339 001 JUL 29, 1985

METOLAZONE

TABLET; ORAL
/DIURIL/

/AB/	/SCHIAPPARELLI/SEARLE/	2.5MG/	/N18535/001/	
/AB/		5MG/	/N18535/002/	
/AB/		10MG/	/N18535/003/	
	ə SCHIAPPARELLI SEARLE	2.5MG	N18535 001	
	ə	5MG	N18535 002	
	ə	10MG	N18535 003	

ZAROXOLYN

/AB/	/FISONS/	/2.5MG/	/N17386/001/	
/AB/		/5MG/	/N17386/002/	
/AB/		/10MG/	/N17386/003/	
	+ FISONS	10MG	N17386 003	
		2.5MG	N17386 001	
		5MG	N17386 002	

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL
TOPROL XL

+	HASSLE	EQ 50MG TARTRATE¤	N19962 001 JAN 10, 1992
+		EQ 100MG TARTRATE¤	N19962 002 JAN 10, 1992
+		EQ 200MG TARTRATE¤	N19962 003 JAN 10, 1992

METRONIDAZOLE

GEL; VAGINAL
METROGEL

+	CURATEK	0.75%¤	N20208 001 AUG 17, 1992

METRONIDAZOLE

INJECTABLE; INJECTION
METRONIDAZOLE

/AP/	/LYPHOMED/	/500MG/100ML/	/N70071/001/ /DEC/03,/1984/	
	∂ LYPHOMED	500MG/100ML	N70071 001 DEC 03, 1984	

TABLET; ORAL
METRONIDAZOLE

AB	EON LABS	250MG	N18620 001 MAR 04, 1982	
AB		500MG	N18620 002 JUN 02, 1983	
/AB/	/VITARINE/	/250MG/	/N18620/001/ /MAR/04,/1982/	
/AB/		/500MG/	/N18620/002/ /JUN/02,/1983/	

METRONIDAZOLE HYDROCHLORIDE

INJECTABLE; INJECTION
FLAGYL I.V.

/AP/	/SCHIAPPARELLI/SEARLE/	/EQ 500MG BASE/VIAL/	/N18353/001/	
	SCHIAPPARELLI SEARLE	EQ 500MG BASE/VIAL	N18353 001	

/METRONIDAZOLE HCL/

/AP/	/LYPHOMED/	/EQ 500MG BASE/VIAL/	/N70295/001/ /OCT/15,/1985/	
	∂ LYPHOMED	EQ 500MG BASE/VIAL	N70295 001 OCT 15, 1985	

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL
MINOCYCLINE HCL

AB	BIOCRAFT	EQ 50MG BASE¤	N63011 001 MAR 02, 1992		
AB		EQ 100MG BASE¤	N63009 001 MAR 02, 1992	> DLT > > ADD >	

SUSPENSION; ORAL
MINOCIN

+	LEDERLE	EQ 50MG BASE/5ML	N50445 001	

MINOCYCLINE HYDROCHLORIDE

/SYRUP;/ORAL/
/MINOCIN/

/+//LEDERLE/	/EQ/50MG/BASE/5ML/	/N50445/001/	

MINOXIDIL

TABLET; ORAL
MINOXIDIL

/B*/	/PHARM/BASICS/	/2.5MG/	/N71537/001/ /DEC/16,/1988/	
	∂ PHARM BASICS	2.5MG	N71537 001 DEC 16, 1988	
/AB/	/ROYCE/	/2.5MG/	/N71799/001/ /NOV/10,/1987/	
/AB/		/10MG/	/N71796/001/ /NOV/10,/1987/	
	∂ ROYCE	2.5MG	N71799 001 NOV 10, 1987	
	∂	10MG	N71796 001 NOV 10, 1987	

MIVACURIUM CHLORIDE

INJECTABLE; INJECTION
MIVACRON

BURROUGHS WELLCOME	EQ 2MG BASE/ML¤	N20098 001 JAN 22, 1992	

MIVACRON IN DEXTROSE 5% IN PLASTIC CONTAINER

BURROUGHS WELLCOME	EQ 0.5MG BASE/ML¤	N20098 002 JAN 22, 1992	
	EQ 50MG BASE/100ML¤	N20098 003 JAN 22, 1992	

MONOBENZONE

CREAM; TOPICAL
BENOQUIN

/ELDER/	/20%/	/N08173/003/	> DLT > > ADD >	
ICN	20%	N08173 003		

NABUMETONE

TABLET; ORAL
RELAFEN
+ SMITHKLINE BEECHAM 750MG N19583 002
DEC 24, 1991
/750MG/ /N19583/002/
/DEC/24,/1991/

NAFARELIN ACETATE

SPRAY, METERED; NASAL
SYNAREL
SYNTEX EQ 0.2MG BASE/INH¤ N20109 001
FEB 26, 1992

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
/NALBUPHINE/
/AP/ /LYPHOMED/ /10MG/ML/ /N70751/001/
/JUL/02,/1986/
/AP/ /20MG/ML/ /N70752/001/
/JUL/02,/1986/
a LYPHOMED 10MG/ML N70751 001
JUL 02, 1986
a 20MG/ML N70752 001
JUL 02, 1986

NEOMYCIN SULFATE

TABLET; ORAL
NEOMYCIN SULFATE
AA EON LABS EQ 350MG BASE N61586 001
/AA/ /VITARINE/ /EQ 350MG BASE/ /N61586/001/

NIACIN

TABLET; ORAL
NIACIN
AA WOCKHARDT LTD 500MG¤ N81134 001
APR 28, 1992

NICARDIPINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CARDENE SR
+ SYNTEX 30MG¤ N20005 001
FEB 21, 1992
+ 45MG¤ N20005 002
FEB 21, 1992
+ 60MG¤ N20005 003
FEB 21, 1992

INJECTABLE; INJECTION
CARDENE
DUPONT MERCK 2.5MG/ML¤ N19734 001
JAN 30, 1992

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL
NICODERM
/BC/ /MARION/MERRELL/DOW/ /7MG/24HR/ /N20165/001/
/NOV/07,/1991/
BC + MARION MERRELL DOW 7MG/24HR N20165 001
NOV 07, 1991
/BC/ /14MG/24HR/ /N20165/002/
/NOV/07,/1991/
BC + 14MG/24HR N20165 002
NOV 07, 1991
/BC/ /21MG/24HR/ /N20165/003/
/NOV/07,/1991/
BC + 21MG/24HR N20165 003
NOV 07, 1991

NICOTROL
+ KABI 5MG/16HR¤ N20150 001
APR 22, 1992
+ 10MG/16HR¤ N20150 002
APR 22, 1992
+ 15MG/16HR¤ N20150 003
APR 22, 1992

PROSTEP
+ ELAN 11MG/24HR¤ N19983 001
JAN 28, 1992
+ 22MG/24HR¤ N19983 002
JAN 28, 1992

NICOTINE POLACRILEX

>ADD>	GUM, CHEWING; BUCCAL			
>ADD>	NICORETTE			
>ADD>	MERRELL DOW	EQ 2MG BASE	N18612 001	
>ADD>			JAN 13, 1984	
>ADD>	NICORETTE DS			
>ADD>	+ MERRELL DOW	EQ 4MG BASE¤	N20066 001	
>ADD>			JUN 08, 1992	
>DLT>	/GUM;/CHEWING;/ORAL/			
>DLT>	/NICORETTE/			
>DLT>	/+//MERRELL/DOW/	/EQ/2MG/BASE/	/N18612/001/	
>DLT>			/JAN/13,/1984/	
>DLT>	/NICORETTE/DS/			
>DLT>	/+//MERRELL/DOW/	/4MG¤/	/N20066/001/	
>DLT>			/JUN/08,/1992/	

NIFEDIPINE

CAPSULE; ORAL

NIFEDIPINE

AB	NOVOPHARM	10MG¤	N72651 001	
			FEB 19, 1992	
AB	SCHERER	20MG¤	N74045 001	
			APR 30, 1992	

NITROFURANTOIN

TABLET; ORAL

NITROFURANTOIN

	@ EON LABS	50MG	N80043 001
	@	100MG	N80043 002
/@/	/VITARINE/	/50MG/	/N80043/001/
/@/		/100MG/	/N80043/002/

NITROFURANTOIN; NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE, EXTENDED RELEASE; ORAL

MACROBID

+	P AND G	75MG;25MG	N20064 001
			DEC 24, 1991
		/75MG;25MG/	/N20064/001/
			/DEC/24,/1991/

NITROFURAZONE

DRESSING; TOPICAL

FURACIN

>DLT>/AT/	/P/AND/G/	/0.2%/	/N05795/001/	
>ADD> AT	ROBERTS	0.2%	N05795 001	

NITROGLYCERIN

INJECTABLE; INJECTION

NITROGLYCERIN

/AP/	/LUITPOLD/	/5MG/ML/	/N71492/001/	
			/MAY/24,/1988/	
	@ LUITPOLD	5MG/ML	N71492 001	
			MAY 24, 1988	

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL

NORTRIPTYLINE HCL

AB	DANBURY	EQ 10MG BASE¤	N73553 001	
			MAR 30, 1992	
AB		EQ 25MG BASE¤	N73554 001	
			MAR 30, 1992	
AB		EQ 50MG BASE¤	N73555 001	
			MAR 30, 1992	
AB		EQ 75MG BASE¤	N73556 001	
			MAR 30, 1992	

PAMELOR

AB	SANDOZ	EQ 10MG BASE	N18013 001
AB		EQ 25MG BASE	N18013 002
AB		EQ 50MG BASE	N18013 004
AB +		EQ 75MG BASE	N18013 003
/BD/		/EQ/10MG/BASE/	/N18013/001/
/BD/		/EQ/25MG/BASE/	/N18013/002/

NYSTATIN

/SUPPOSITORY;/VAGINAL/

/NYSERT/

	/P/AND/G/	/100,000/UNITS/	/N50478/001/
	@ P AND G	100,000 UNITS	N50478 001

NYSTATIN

TABLET; ORAL
NYSTATIN

/AA/	/CHELSEA/	/500,000 UNITS/	/N62402/001/ /DEC/16,/1982/
@	CHELSEA	500,000 UNITS	N62402 001 DEC 16, 1982
AA	EON LABS	500,000 UNITS	N62065 001
/AA/	/VITARINE/	/500,000 UNITS/	/N62065/001/

TABLET; VAGINAL
NYSTATIN

@	EON LABS	100,000 UNITS	N61965 001
/@/	/VITARINE/	/100,000/UNITS@/	/N61965/001/

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
NYSTATIN AND TRIAMCINOLONE ACETONIDE

/AT/	/CLAY/PARK/	/100,000 UNITS/GM;0.1%/	/N62186/002/ /JUN/06,/1985/
B*	CLAY PARK	100,000 UNITS/GM;0.1%	N62186 002 JUN 06, 1985

OFLOXACIN

INJECTABLE; INJECTION
FLOXIN

	JOHNSON RW	20MG/ML¤	N20087 002 MAR 31, 1992
		40MG/ML¤	N20087 003 MAR 31, 1992

FLOXIN IN DEXTROSE 5%

	JOHNSON RW	400MG/100ML¤	N20087 001 MAR 31, 1992

FLOXIN IN DEXTROSE 5% IN PLASTIC CONTAINER

	JOHNSON RW	4MG/ML¤	N20087 004 MAR 31, 1992
		400MG/100ML¤	N20087 005 MAR 31, 1992

OXAZEPAM

CAPSULE; ORAL
OXAZEPAM

/B*/	/CHELSEA/	/10MG/	/N71661/001/ /MAR/02,/1988/
/B*/		/15MG/	/N71662/001/ /MAR/02,/1988/
/B*/		/30MG/	/N71663/001/ /MAR/02,/1988/

OXYBUTYNIN CHLORIDE

TABLET; ORAL
OXYBUTYNIN CHLORIDE

/B*/	/PHARM/BASICS/	/5MG/	/N70746/001/ /MAR/10,/1988/
@	PHARM BASICS	5MG	N70746 001 MAR 10, 1988

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION
PENICILLIN G POTASSIUM

/AP/	/PARKE/DAVIS/	/1,000,000 UNITS/VIAL/	/N62003/001/
/AP/		/5,000,000 UNITS/VIAL/	/N62003/002/
@	PARKE DAVIS	1,000,000 UNITS/VIAL	N62003 001
@		5,000,000 UNITS/VIAL	N62003 002

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
/PENAPAR-VK/

/AA/	/PARKE/DAVIS/	/EQ 125MG BASE/5ML/	/N62002/001/
/AA/		/EQ 250MG BASE/5ML/	/N62002/002/
@	PARKE DAVIS	EQ 125MG BASE/5ML	N62002 001
@		EQ 250MG BASE/5ML	N62002 002

TABLET; ORAL
/PENAPAR-VK/

/AB/	/PARKE/DAVIS/	/EQ 250MG BASE/	/N62001/001/
/AB/		/EQ 500MG BASE/	/N62001/002/
@	PARKE DAVIS	EQ 250MG BASE	N62001 001
@		EQ 500MG BASE	N62001 002

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION

PENTAM 300

AP	FUJISAWA	300MG/VIAL	N19264 001 OCT 16, 1984

PENTAMIDINE ISETHIONATE

AP	ABBOTT	300MG/VIAL*	N73479 001 JUN 30, 1992

PERPHENAZINE

TABLET; ORAL

PERPHENAZINE

/B*/	/CHELSEA/	/8MG/	/N89700/001/ /DEC/23,/1987/

PHENDIMETRAZINE TARTRATE

CAPSULE; ORAL

PHENDIMETRAZINE TARTRATE

AA	EON LABS	35MG	N85633 001
AA		35MG	N85694 001
AA		35MG	N85695 001
AA		35MG	N85702 001
/AA/	/VITARINE/	/35MG/	/N85633/001/
/AA/		/35MG/	/N85694/001/
/AA/		/35MG/	/N85695/001/
/AA/		/35MG/	/N85702/001/

CAPSULE, EXTENDED RELEASE; ORAL

PHENDIMETRAZINE TARTRATE

BC	EON LABS	105MG	N18074 001
/BC/	/VITARINE/	/105MG/	/N18074/001/

TABLET; ORAL

ALPHAZINE

	∂ EON LABS	35MG	N85034 001
	/∂/VITARINE/	/35MG/	/N85034/001/

/DIETINE/

/AA/	/PHARM/BASICS/	/35MG/	/N83805/001/
/AA/		/35MG/	/N84398/001/
/AA/		/35MG/	/N84399/001/

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

PHENDIMETRAZINE TARTRATE

AA	EON LABS	35MG	N85402 001
> ADD > AA		35MG	N85830 001
> DLT >	/∂/	/35MG/	/N85830/001/

PHENDIMETRAZINE TARTRATE

AA	PHARM BASICS	35MG	N84399 001
	∂	35MG	N83805 001
	∂	35MG	N84398 001

PHENDIMETRAZINE TARTRATE

/AA/	/VITARINE/	/35MG/	/N85402/001/

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL

AA	EON LABS	15MG	N87301 001
AA		30MG	N87190 001
AA		30MG	N87208 001
AA		30MG	N87223 001
/AA/	/VITARINE/	/15MG/	/N87301/001/
/AA/		/30MG/	/N87190/001/
/AA/		/30MG/	/N87208/001/
/AA/		/30MG/	/N87223/001/

TABLET; ORAL

PHENTERMINE HCL

	∂ EON LABS	8MG	N85671 001
	∂	8MG	N85689 001
	/∂/VITARINE/	/8MG/	/N85671/001/
	/∂/	/8MG/	/N85689/001/

PHENYLBUTAZONE

CAPSULE; ORAL

/AZOLID/

/AB/	/RHONE/POULENC/RORER//100MG/		/N87260/001/
	∂ RHONE POULENC RORER	100MG	N87260 001

TABLET; ORAL

/AZOLID/

/AB/	/RHONE/POULENC/RORER//100MG/		/N87091/001/
	∂ RHONE POULENC RORER	100MG	N87091 001

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL

		PHENYTOIN SODIUM		
AB		CHELSEA	100MG	N85894 001
	∂	CHELSEA	100MG	N85894 001

PIROXICAM

CAPSULE; ORAL

		FELDENE		
AB		PFIZER	10MG	N18147 002 APR 06, 1982
AB	+		20MG	N18147 003 APR 06, 1982
		PIROXICAM		
> ADD > AB		COPLEY	10MG¤	N74103 001 AUG 28, 1992
> ADD > AB			20MG¤	N74103 002 AUG 28, 1992
> ADD > AB		MYLAN	10MG¤	N74102 001 JUL 31, 1992
AB			20MG¤	N74102 002 JUL 31, 1992
AB		SCHIAPPARELLI SEARLE	10MG¤	N74036 001 MAY 29, 1992
AB			20MG¤	N74036 002 MAY 29, 1992

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS

POWDER FOR RECONSTITUTION; ORAL

		CO-LAV		
AA		COPLEY	240GM/BOT;2.98GM/BOT;6.72GM/BOT; 5.84GM/BOT;22.72GM/BOT¤	N73428 001 JAN 28, 1992
		GO-EVAC		
AA		COPLEY	236GM/BOT;2.97GM/BOT;6.74GM/BOT; 5.86GM/BOT;22.74GM/BOT¤	N73433 001 APR 28, 1992

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

		K-LEASE		
AB		ADRIA	8MEQ¤	N73398 001 JAN 28, 1992
		MICRO-K		
AB		ROBINS	8MEQ	N18238 001

TABLET, EXTENDED RELEASE; ORAL

		KLOR-CON		
AB		UPSHER SMITH	8MEQ	N19123 001 APR 17, 1986
BC		KLOTRIX	10MEQ	N17850 001
BC		MEAD JOHNSON	10MEQ	N17850 001

PRAZEPAM

CAPSULE; ORAL

		CENTRAX		
AB		PARKE DAVIS	5MG	N18144 001
AB	+		10MG	N18144 002
		PRAZEPAM		
B*		PHARM BASICS	5MG	N70427 001 NOV 06, 1987
B*			10MG	N70428 001 NOV 06, 1987
	∂	PHARM BASICS	5MG	N70427 001 NOV 06, 1987
	∂		10MG	N70428 001 NOV 06, 1987

PRAZOSIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

		MINIPRESS XL		
	+	PFIZER	2.5MG¤	N19775 001 JAN 29, 1992
	+		5MG¤	N19775 002 JAN 29, 1992

PREDNISOLONE

TABLET; ORAL
PREDNISOLONE

	∂ EON LABS	5MG	N84773 001
/BX/	/HEATHER/	/5MG/	/N80326/001/
	∂ HEATHER	5MG	N80326 001
	/∂/VITARINE/	/5MG∂/	/N84773/001/

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

SUSPENSION/DROPS; OPHTHALMIC
BLEPHAMIDE

/AT/	/ALLERGAN/	/0.22;10%/	/N12813/002/
	ALLERGAN	0.2%;10%	N12813 002
	/PREDSULFATR II/		
/AT/	/PHARMAFAIR/	/0.22;10%/	/N88837/001/ /DEC/24,/1985/
	∂ PHARMAFAIR	0.2%;10%	N88837 001 DEC 24, 1985

PREDNISONE

TABLET; ORAL
/FERNISONE/

/BX/	/FERNDALE/	/5MG/	/N83364/001/
	∂ FERNDALE	5MG	N83364 001
	PREDNISONE		
	∂ EON LABS	5MG	N84774 001
AB	RICHLYN	5MG	N80782 001
/BX/		/5MG/	/N80782/001/
	/∂/VITARINE/	/5MG∂/	/N84774/001/

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PROCAINAMIDE HCL

/AB/	/BOLAR/	/250MG/	/N88533/001/ /DEC/03,/1984/
/AB/		/500MG/	/N88534/001/ /DEC/03,/1984/
/AB/		/750MG/	/N88535/001/ /NOV/03,/1984/
	∂ BOLAR	250MG	N88533 001 DEC 03, 1984
	∂	500MG	N88534 001 DEC 03, 1984
	∂	750MG	N88535 001 NOV 03, 1984

PROCAINE HYDROCHLORIDE; TETRACYCLINE HYDROCHLORIDE

INJECTABLE; INJECTION
ACHROMYCIN

AP	LEDERLE	40MG/VIAL;100MG/VIAL	N50267 002
AP		40MG/VIAL;100MG/VIAL	N50276 001
AP		40MG/VIAL;250MG/VIAL	N50267 003
	TETRACYN		
AP	PFIZER	40MG/VIAL;250MG/VIAL	N60285 003
	∂	40MG/VIAL;100MG/VIAL	N60285 002

PROCHLORPERAZINE MALEATE

TABLET; ORAL
COMPAZINE

/AB/	/SKF/	/EQ 5MG BASE/	/N10571/001/
/AB/		/EQ 10MG BASE/	/N10571/002/
/AB//+/		/EQ 25MG BASE/	/N10571/003/
	+ SKF	EQ 25MG BASE	N10571 003
		EQ 5MG BASE	N10571 001
		EQ 10MG BASE	N10571 002

PROCHLORPERAZINE MALEATE

TABLET; ORAL
/PROCHLORPERAZINE/MALEATE/

/B*/	/DURAMED/	/EQ/5MG/BASE/	/N89484/001/ /JAN/20,/1987/
/B*/		/EQ/10MG/BASE/	/N89485/001/ /JAN/20,/1987/
/B*/		/EQ/25MG/BASE/	/N89486/001/ /JAN/20,/1987/
	ə DURAMED	EQ 5MG BASE	N89484 001 JAN 20, 1987
	ə	EQ 10MG BASE	N89485 001 JAN 20, 1987
	ə	EQ 25MG BASE	N89486 001 JAN 20, 1987

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL
PROMETHAZINE HCL

	ə EON LABS	25MG	N85146 001
	ə	50MG	N85146 002
/ə/	/VITARINE/	/25MG/	/N85146/001/
/ə/		/50MG/	/N85146/002/

PROPANTHELINE BROMIDE

TABLET; ORAL
PROPANTHELINE BROMIDE

> DLT >/AA/	/HEATHER/	/15MG/	/N85780/001/
> ADD >	ə HEATHER	15MG	N85780 001

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPOXYPHENE HCL

	ə EON LABS	65MG	N83870 002
	ə	65MG	N86495 001
> ADD > /AA/	/VITARINE/	/32MG/	/N84014/001/
/AB/		/65MG/	/N83688/001/
	ə VITARINE	32MG	N84014 001
	ə	65MG	N83688 001
/ə/		/65MG/	/N83870/002/
> DLT > /ə/		/65MG/	/N86495/001/
	/PROPOXYPHENE HCL 65/		
/AA/	/PARKE/DAVIS/	/65MG/	/N83786/001/
	ə WARNER CHILCOTT	65MG	N83786 001

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

/AB/	/SUPERPHARM/	/10MG/	/N71515/001/ /JUN/08,/1988/
/AB/		/20MG/	/N71516/001/ /JUN/08,/1988/
	ə SUPERPHARM	10MG	N71515 001 JUN 08, 1988
	ə	20MG	N71516 001 JUN 08, 1988

PROTIRELIN

INJECTABLE; INJECTION
RELEFACT TRH

AP	FERRING	0.5MG/ML	N18087 001
/AP/	/HOECHST/ROUSSEL/	/0.5MG/ML/	/N18087/001/

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL
PSEUDOEPHEDRINE HCL AND TRIPROLIDINE HCL

AA	EON LABS	60MG;2.5MG	N88193 001 MAY 17, 1983
/AA/	/VITARINE/	/60MG;2.5MG/	/N88193/001/ /MAY/17,/1983/

PYRAZINAMIDE

TABLET; ORAL
PYRAZINAMIDE

AB	+ LEDERLE	500MG	N80157 001
AB	MIKART	500MG*	N81319 001 JUN 30, 1992

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION
PYRIDOXINE HCL

/AP/	/LUITPOLD/	/100MG/ML/	/N80669/001/
	ə LUITPOLD	100MG/ML	N80669 001

QUINETHAZONE; RESERPINE

/TABLET;/ORAL/
/HYDROMOX/R/
/LEDERLE/ /50MG;0.125MG/ /N13927/001/

∂ LEDERLE 50MG;0.125MG N13927 001

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE
∂ ELKINS SINN 200MG N83622 001
AB EON LABS 200MG N84631 001
AB 300MG N88072 001
SEP 26, 1983

/∂/QUANTUM/PHARMICS/ /200MG/ /N83622/001/
/AB/ /VITARINE/ /200MG/ /N84631/001/
/AB/ /300MG/ /N88072/001/
/SEP/26,/1983/

RAUWOLFIA SERPENTINA

TABLET; ORAL
/RAUVERID/
/BP/ /FOREST/PHARMS/ /50MG/ /N09255/008/
WOLFINA
∂ FOREST PHARMS 50MG N09255 008

RESERPINE

TABLET; ORAL
RESERPINE
BP EON LABS 0.1MG N09838 001
BP 0.25MG N09838 002
/BP/ /VITARINE/ /0.1MG/ /N09838/001/
/BP/ /0.25MG/ /N09838/002/

> DLT > /SERPATE/
> DLT > /BP/ /VALE/ /0.1MG/ /N09453/001/
> DLT > /BP/ /0.25MG/ /N09453/002/
> ADD > ∂ VALE 0.1MG N09453 001
> ADD > ∂ 0.25MG N09453 002

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION
RITODRINE HCL
/AP/ /LYPHOMED/ /10MG/ML/ /N71188/001/
/JUL/23,/1987/
/AP/ /15MG/ML/ /N71189/001/
/JUL/23,/1987/

∂ LYPHOMED 10MG/ML N71188 001
JUL 23, 1987

∂ 15MG/ML N71189 001
JUL 23, 1987

SODIUM CHLORIDE

INJECTABLE; INJECTION
/SODIUM/CHLORIDE/23.4%/IN/PLASTIC/CONTAINER/
/LYPHOMED/ /234MG/ML/ /N19329/001/
/APR/22,/1987/

∂ LYPHOMED 234MG/ML N19329 001
APR 22, 1987

SODIUM LACTATE

INJECTABLE; INJECTION
SODIUM LACTATE 1/6 MOLAR IN PLASTIC CONTAINER
AP MCGAW 1.87GM/100ML¤ N20004 001
APR 21, 1992

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
NITROPRESS
AP ABBOTT 25MG/ML N71961 001
AUG 01, 1988

SODIUM NITROPRUSSIDE
AP GENSIA 25MG/ML¤ N73465 001
MAR 30, 1992

SODIUM POLYSTYRENE SULFONATE

SUSPENSION; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
/AA/ /ROXANE/ /15GM/60ML/ /N88453/001/
/NOV/17,/1983/

∂ ROXANE 15GM/60ML N88453 001
NOV 17, 1983

SODIUM THIOSULFATE

INJECTABLE; INJECTION
SODIUM THIOSULFATE
DEPT ARMY 250MG/ML¤ N20166 001 FEB 14, 1992

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE
>DLT >/AB/ /PARKE/DAVIS/ /25MG/ /N87952/001/ /NOV/18,/1982/
>DLT >
>ADD > ə WARNER CHILCOTT 25MG N87952 001 NOV 18, 1982
>ADD >

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION
SUCCINYLCHOLINE CHLORIDE
/INTL/MEDICATION/ /100MG/VIAL/ /N85400/001/ /FEB/04,/1982/
ə INTL MEDICATION 100MG/VIAL N85400 001 FEB 04, 1982

/SULFABENZAMIDE;/SULFACETAMIDE;/SULFATHIAZOLE/

/CREAM;/VAGINAL/
/SULTRIN/
/JOHNSON/RW/ /3.72;2.862;3.422/ /N85794/001/

/TABLET;/VAGINAL/
/SULTRIN/
/JOHNSON/RW/ /184MG;143.75MG;172.5MG/ /N85794/002/
/TRIPLE/SULFA/
/ə/FOUGERA/ /184MG;143.75MG;172.5MG/ /N88463/001/ /JAN/03,/1985/
/ə/PHARMADERM/ /184MG;143.75MG;172.5MG/ /N88462/001/ /JAN/03,/1985/

/SULFABENZAMIDE;/SULFACETAMIDE;/SULFATHIAZOLE;/UREA/

/CREAM;/VAGINAL/
/GYNE-SULF/
/AT/ /G/AND/W/ /3.72;2.862;3.422;0.642/ /N88607/001/ /JUN/09,/1986/

/SULFABENZAMIDE;/SULFACETAMIDE;/SULFATHIAZOLE;/UREA/

/CREAM;/VAGINAL/
/TRIPLE SULFA/
/AT/ /CLAY/PARK/ /3.72;2.862;3.422;0.642/ /N87285/001/ /NOV/15,/1982/
/AT/ /FOUGERA/ /3.72;2.862;3.422;0.642/ /N86424/001/
/AT/ /NMC/ /3.72;2.862;3.422;0.642/ /N87864/001/ /SEP/01,/1982/
/AT/ /PHARMADERM/ /3.72;2.862;3.422;0.642/ /N87887/001/ /JUL/23,/1982/

/VAGILIA/
/AT/ /LEMMON/ /3.72;2.862;3.422;0.642/ /N88821/001/ /NOV/09,/1987/

SULFAMETHIZOLE

TABLET; ORAL
/PROKLAR/
/AB/ /FOREST/PHARMS/ /500MG/ /N80273/001/
ə FOREST PHARMS 500MG N80273 001

THIOSULFIL
/AB/ +//WYETH/AYERST/ /500MG/ /N08565/004/
+ WYETH AYERST 500MG N08565 004

SULFAMETHOXAZOLE

TABLET; ORAL
/UROBAK/
/AB/ /SHIONOGI/ /500MG/ /N87307/001/
ə SHIONOGI 500MG N87307 001

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION
SULFAMETHOXAZOLE AND TRIMETHOPRIM
AP CETUS BEN VENUE 80MG/ML;16MG/ML¤ N72383 001 APR 29, 1992

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM
AB EON LABS 400MG;80MG N18598 001 MAY 19, 1982

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

/AB/	/INTERPHARM/	/400MG;80MG/	/N71299/001/ /OCT/27,/1987/	
/AB/		/800MG;160MG/	/N71300/001/ /OCT/27,/1987/	
B*	INTERPHARM	400MG;80MG	N71299 001 OCT 27, 1987	
B*		800MG;160MG	N71300 001 OCT 27, 1987	
/AB/	/MARTEC/	/400MG;80MG/	/N72408/001/ /DEC/07,/1988/	
	∂ MARTEC	400MG;80MG	N72408 001 DEC 07, 1988	
/B*/	/PHARM/BASICS/	/400MG;80MG/	/N70203/001/ /NOV/08,/1985/	
/B*/		/800MG;160MG/	/N70204/001/ /NOV/08,/1985/	
	∂ PHARM BASICS	400MG;80MG	N70203 001 NOV 08, 1985	
	∂	800MG;160MG	N70204 001 NOV 08, 1985	
/AB/	/VITARINE/	/400MG;80MG/	/N18598/001/ /MAY/19,/1982/	

SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH

AB	EON LABS	800MG;160MG	N18598 004 MAY 19, 1982
/AB/	/MARTEC/	/800MG;160MG/	/N72417/001/ /DEC/07,/1988/
	∂ MARTEC	800MG;160MG	N72417 001 DEC 07, 1988
/AB/	/VITARINE/	/800MG;160MG/	/N18598/004/ /MAY/19,/1982/

SULFASALAZINE

TABLET; ORAL

SULFASALAZINE

	∂ EON LABS	500MG	N86184 001
	/∂/VITARINE/	/500MG/	/N86184/001/

SULFISOXAZOLE

TABLET; ORAL

/SULFALAX/

/AB/	/PARKE/DAVIS/	/500MG/	/N84955/001/	
	∂ PARKE DAVIS	500MG	N84955 001	

SULFISOXAZOLE

TABLET; ORAL

SULFISOXAZOLE

/AB/	/WEST/WARD/	/500MG/	/N80379/001/	
	∂ WEST WARD	500MG	N80379 001	

SULINDAC

TABLET; ORAL

SULINDAC

AB	LEMMON	150MG¤	N72972 001 FEB 28, 1992
AB		200MG¤	N72973 001 FEB 28, 1992

TALBUTAL

/TABLET;/ORAL/

/LOTUSATE/

	/STERLING/	/120MG/	/N09410/005/
	∂ STERLING	120MG	N09410 005

TECHNETIUM TC-99M RED BLOOD CELL KIT

INJECTABLE; INJECTION

RBC-SCAN

	CADEMA	N/A¤	N20063 001 JUN 11, 1992

TEMAFLOXACIN HYDROCHLORIDE

>DLT>	/TABLET;/ORAL/			
>DLT>	/OMNIFLOX/			
>DLT>	/+//ABBOTT/	/EQ/600MG/BASE¤/	/N20043/004/ /JAN/30,/1992/	
>DLT>				
>DLT>	/OMNIFLOX/			
>DLT>	/ABBOTT/	/EQ/400MG/BASE¤/	/N20043/003/ /JAN/30,/1992/	
>DLT>				
>ADD>	∂ ABBOTT	EQ 400MG BASE¤	N20043 003 JAN 30, 1992	
>ADD>				
>ADD>	∂	EQ 600MG BASE¤	N20043 004 JAN 30, 1992	
>ADD>				

TEMAZEPAM

CAPSULE; ORAL
TEMAZEPAM

/B*/	/PHARM/BASICS/	/15MG/	/N70489/001/ /JUL/07,/1986/
/B*/		/30MG/	/N70490/001/ /JUL/07,/1986/
	∂ PHARM BASICS	15MG	N70489 001 JUL 07, 1986
	∂	30MG	N70490 001 JUL 07, 1986

TENIPOSIDE

INJECTABLE; INJECTION
VUMON

	BRISTOL MYERS SQUIBB	10MG/ML*	N20119 001 JUL 14, 1992

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
DELATESTRYL

AO	GYNEX	200MG/ML	N09165 003
	∂	200MG/ML	N09165 001
/AO/	/SQUIBB/	/200MG/ML/	/N09165/003/
/∂/		/200MG/ML/	/N09165/001/

TETRACYCLINE

SYRUP; ORAL
/BIOCYCLINE/

/AB/	/BARRE/	/EQ 125MG HCL/5ML/	/N60633/001/
	TETRACYCLINE		
AB	BARRE	EQ 125MG HCL/5ML	N60633 001

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
/CYCLOPAR/

/AB/	/PARKE/DAVIS/	/250MG/	/N61725/001/
/AB/		/250MG/	/N62175/001/
/AB/		/250MG/	/N62332/001/
/AB/		/500MG/	/N61725/002/
/AB/		/500MG/	/N62332/002/

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
/CYCLOPAR/

∂	WARNER CHILCOTT	250MG	N61725 001
∂		250MG	N62175 001
∂		250MG	N62332 001
∂		500MG	N61725 002
∂		500MG	N62332 002

TETRACYCLINE HCL

AB	EON LABS	250MG	N61471 001
∂		500MG	N61471 002 SEP 06, 1988
/AB/	/PARKE/DAVIS/	/250MG/	/N62300/001/
/AB/		/500MG/	/N62300/002/
/AB/	/VITARINE/	/250MG/	/N61471/001/
/∂/		/500MG/	/N61471/002/ /SEP/06,/1988/
AB	WARNER CHILCOTT	250MG	N62300 001
AB		500MG	N62300 002

/INJECTABLE;/INJECTION/
/ACHROMYCIN/

/AP/	/LEDERLE/	/100MG/VIAL/	/N50267/002/
/AP/		/100MG/VIAL/	/N50276/001/
/AP/		/250MG/VIAL/	/N50267/003/
	/TETRACYN/		
/AP/	/PFIZER/	/250MG/VIAL/	/N60285/003/
/∂/		/100MG/VIAL/	/N60285/002/

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
SOMOPHYLLIN-CRT

/BC/	/FISONS/	/50MG/	/N87763/001/ /FEB/27,/1985/
/BC/		/100MG/	/N87194/001/
/BC/		/200MG/	/N88382/001/ /FEB/27,/1985/
/BC/		/250MG/	/N87193/001/
/BC/		/300MG/	/N88383/001/ /FEB/27,/1985/
BC	GRAHAM LABS	50MG	N87763 001 FEB 27, 1985
BC		100MG	N87194 001
BC		200MG	N88382 001 FEB 27, 1985
BC		250MG	N87193 001
BC		300MG	N88383 001 FEB 27, 1985

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
THEO-24

/BC/	/SEARLE/	/100MG/	/N87942/001/ /AUG/22,/1983/
/BC/		/200MG/	/N87943/001/ /AUG/22,/1983/
/BC/		/300MG/	/N87944/001/ /AUG/22,/1983/
		/400MG¤/	/N81034/001/ /FEB/28,/1992/
BC	WHITBY PHARMS	100MG	N87942 001 AUG 22, 1983
BC		200MG	N87943 001 AUG 22, 1983
BC		300MG	N87944 001 AUG 22, 1983
		400MG¤	N81034 001 FEB 28, 1992

THEOPHYLLINE

∂ EON LABS	260MG	N87462 001 MAY 11, 1982
/∂/VITARINE/	/260MG/	/N87462/001/ /MAY/11,/1982/

INJECTABLE; INJECTION
THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER

>ADD>	AP	MCGAW	40MG/100ML¤	N19826 001 AUG 14, 1992
>ADD>				

THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER

>ADD>	AP	MCGAW	80MG/100ML¤	N19826 002 AUG 14, 1992
>ADD>				

THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER

>ADD>	AP	MCGAW	160MG/100ML¤	N19826 003 AUG 14, 1992
>ADD>				

THEOPHYLLINE 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER

>ADD>	AP	MCGAW	200MG/100ML¤	N19826 004 AUG 14, 1992
>ADD>				

THEOPHYLLINE 0.32% AND DEXTROSE 5% IN PLASTIC CONTAINER

>ADD>	AP	MCGAW	320MG/100ML¤	N19826 006 AUG 14, 1992
>ADD>				

THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER

>ADD>	AP	MCGAW	400MG/100ML¤	N19826 005 AUG 14, 1992
>ADD>				

TABLET, EXTENDED RELEASE; ORAL
T-PHYL

BC	PURDUE FREDERICK	200MG	N88253 001 AUG 17, 1983

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL
/THEOCONTIN/

/BC/	/PURDUE/FREDERICK/	/200MG/	/N88253/001/ /AUG/17,/1983/

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
THIAMINE HCL

/AP/	/LUITPOLD/	/100MG/ML/	/N80667/001/
	∂ LUITPOLD	100MG/ML	N80667 001
/AP/	/PARKE/DAVIS/	/100MG/ML/	/N80770/001/
	∂ PARKE DAVIS	100MG/ML	N80770 001

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL
THIORIDAZINE HCL

/AB/	/PAR/	/150MG/	/N89764/001/ /FEB/09,/1988/
/AB/		/200MG/	/N89765/001/ /FEB/09,/1988/
	∂ PAR	150MG	N89764 001 FEB 09, 1988
	∂	200MG	N89765 001 FEB 09, 1988

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL
THIOTHIXENE HCL INTENSOL

AA	ROXANE	EQ 5MG BASE/ML¤	N73494 001 JUN 30, 1992

TIMOLOL MALEATE

TABLET; ORAL
TIMOLOL MALEATE

/B*/	/PHARM/BASICS/	/5MG/	/N72001/001/ /JAN/10,/1989/
/B*/		/10MG/	/N72002/001/ /JAN/10,/1989/
/B*/		/20MG/	/N72003/001/ /JAN/10,/1989/
	ə PHARM BASICS	5MG	N72001 001 JAN 10, 1989
	ə	10MG	N72002 001 JAN 10, 1989
	ə	20MG	N72003 001 JAN 10, 1989

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION
TOBRAMYCIN SULFATE

AP	ABBOTT	EQ 40MG BASE/ML¤	N63116 001 MAY 18, 1992
AP	GENSIA	EQ 40MG BASE/ML¤	N63100 001 JAN 30, 1992

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

/AB/	/INTERPHARM/	/250MG/	/N71270/001/ /SEP/23,/1986/
/AB/		/500MG/	/N71271/001/ /SEP/23,/1986/
B*	INTERPHARM	250MG	N71270 001 SEP 23, 1986
B*		500MG	N71271 001 SEP 23, 1986
/B*/	/PHARM/BASICS/	/100MG/	/N71355/001/ /JAN/11,/1988/
/B*/		/250MG/	/N70168/001/ /APR/02,/1986/
/B*/		/500MG/	/N70169/001/ /APR/02,/1986/
	ə PHARM BASICS	100MG	N71355 001 JAN 11, 1988
	ə	250MG	N70168 001 APR 02, 1986
	ə	500MG	N70169 001 APR 02, 1986

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

AB	EON LABS	500MG	N12678 001
/AB/	/PARKE/DAVIS/	/500MG/	/N86047/001/
	ə PARKE DISCS	500MG	N86047 001
/AB/	/VITARINE/	/500MG/	/N12678/001/

TOLMETIN SODIUM

CAPSULE; ORAL
TOLMETIN SODIUM

AB	BAKER CUMMINS	EQ 400MG BASE¤	N73392 001 JAN 24, 1992
AB	GENEVA	EQ 400MG BASE¤	N73462 001 APR 30, 1992
AB	LEMMON	EQ 400MG BASE¤	N73519 001 MAY 29, 1992
AB	PUREPAC	EQ 400MG BASE¤	N73308 001 JAN 24, 1992

TABLET; ORAL
TOLECTIN 600

AB	+ JOHNSON RW	EQ 600MG BASE	N17628 002 MAR 08, 1989

TOLMETIN SODIUM

AB	GENEVA	EQ 200MG BASE¤	N73588 001 JUL 31, 1992
AB	PUREPAC	EQ 600MG BASE¤	N73527 001 JUN 30, 1992

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

/B*/	/PHARM/BASICS/	/50MG/	/N70491/001/ /APR/29,/1987/
/B*/		/100MG/	/N70492/001/ /APR/29,/1987/
	ə PHARM BASICS	50MG	N70491 001 APR 29, 1987
	ə	100MG	N70492 001 APR 29, 1987

TRICHLORMETHIAZIDE

TABLET; ORAL
TRICHLORMETHIAZIDE

>ADD>	ə	EON LABS	4MG	N86171 001
>DLT>	/ə/	/VITARINE/	/4MG/	/N86171/001/

TRIDIHEXETHYL CHLORIDE

>DLT>	/TABLET;ORAL/			
>DLT>	/PATHILON/			
>DLT>		/LEDERLE/	/25MG/	/N09489/005/
>ADD>	ə	LEDERLE	25MG	N09489 005

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
SURMONTIL

/AB/		/WYETH/AYERST/	/EQ 25MG BASE/	/N16792/001/
/AB/			/EQ 50MG BASE/	/N16792/002/
/AB/	/+/		/EQ 100MG BASE/	/N16792/003/
				/SEP/15,/1982/
	+	WYETH AYERST	EQ 100MG BASE	N16792 003
				SEP 15, 1982
			EQ 25MG BASE	N16792 001
			EQ 50MG BASE	N16792 002

/TRIMIPRAMINE/MALEATE/

/B*/		/PHARM/BASICS/	/EQ/25MG/BASE/	/N71283/001/
				/DEC/08,/1987/
/B*/			/EQ/50MG/BASE/	/N71284/001/
				/DEC/08,/1987/
/B*/			/EQ/100MG/BASE/	/N71285/001/
				/DEC/08,/1987/

TRIMIPRAMINE MALEATE

ə	EON LABS	EQ 25MG BASE	N71832 001
			SEP 10, 1987
ə		EQ 50MG BASE	N71833 001
			SEP 10, 1987
ə		EQ 100MG BASE	N71834 001
			SEP 10, 1987
ə	PHARM BASICS	EQ 25MG BASE	N71283 001
			DEC 08, 1987
ə		EQ 50MG BASE	N71284 001
			DEC 08, 1987
ə		EQ 100MG BASE	N71285 001
			DEC 08, 1987

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
TRIMIPRAMINE MALEATE

/ə/	/VITARINE/	/EQ/25MG/BASE/	/N71832/001/
			/SEP/10,/1987/
/ə/		/EQ/50MG/BASE/	/N71833/001/
			/SEP/10,/1987/
/ə/		/EQ/100MG/BASE/	/N71834/001/
			/SEP/10,/1987/

TRIPLE SULFA (SULFABENZAMIDE;SULFACETAMIDE;SULFATHIAZOLE)

CREAM; VAGINAL
GYNE-SULF

AT	G AND W	3.7%;2.86%;3.42%	N88607 001
			JUN 09, 1986

SULTRIN

AT	JOHNSON RW	3.7%;2.86%;3.42%	N05794 001

TRIPLE SULFA

AT	CLAY PARK	3.7%;2.86%;3.42%	N87285 001
			NOV 15, 1982
AT	FOUGERA	3.7%;2.86%;3.42%	N86424 001
AT	NMC	3.7%;2.86%;3.42%	N87864 001
			SEP 01, 1982

TRYSUL

AT	SAVAGE	3.7%;2.86%;3.42%	N87887 001
			JUL 23, 1982

VAGILIA

ə	LEMMON	3.7%;2.86%;3.42%	N88821 001
			NOV 09, 1987

TABLET; VAGINAL
SULTRIN

JOHNSON RW	184MG;143.75MG;172.5MG	N05794 002

TRIPLE SULFA

ə FOUGERA	184MG;143.75MG;172.5MG	N88463 001
		JAN 03, 1985
ə PHARMADERM	184MG;143.75MG;172.5MG	N88462 001
		JAN 03, 1985

TRISULFAPYRIMIDINES

SUSPENSION; ORAL
/SULFAMETO/

/AB/		/FOREST/PHARMS/	/500MG/5ML/	/N80100/001/
	ə	FOREST PHARMS	500MG/5ML	N80100 001

VALPROIC ACID

SYRUP; ORAL

> ADD >		VALPROIC ACID		
> ADD >	AA	COPLEY	250MG/5ML¤	N73178 001 AUG 25, 1992
> ADD >				

VECURONIUM BROMIDE

INJECTABLE; INJECTION

	NORCURON		
	ORGANON	20MG/VIAL¤	N18776 003 JAN 03, 1992

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

	VERELAN		
+	ELAN	180MG¤	N19614 003 JAN 09, 1992

TABLET; ORAL

	VERAPAMIL HCL		
/B*/	/CHELSEA/	/80MG/	/N70421/001/ /SEP/17,/1986/
/B*/		/120MG/	/N70422/001/ /SEP/17,/1986/
AB	GENEVA	40MG¤	N73168 001 JUL 31, 1992
/AB/	/PARKE/DAVIS/	/80MG/	/N70340/001/ /AUG/20,/1986/
/AB/		/120MG/	/N70341/001/ /AUG/20,/1986/
	∂ PARKE DAVIS	80MG	N70340 001 AUG 20, 1986
	∂	120MG	N70341 001 AUG 20, 1986

TABLET, EXTENDED RELEASE; ORAL

	ISOPTIN SR		
AB	+ KNOLL	240MG	N19152 001 DEC 16, 1986
	VERAPAMIL HCL		
AB	BAKER CUMMINS	240MG¤	N73568 001 JUL 31, 1992

VITAMIN A

CAPSULE; ORAL

	AQUASOL A		
AA	ASTRA	50,000 USP UNITS	N83080 001
		25,000 USP UNITS	N83080 002
/AA/	/USV/	/50,000 USP UNITS/	/N83080/001/
		/25,000/USP/UNITS/	/N83080/002/

VITAMIN A PALMITATE

CAPSULE; ORAL

	VITAMIN A		
	∂ ELKINS SINN	EQ 50,000 UNITS BASE	N85479 001
	/∂/QUANTUM/PHARMICS/	/EQ/50,000/UNITS/BASE/	/N85479/001/

WARFARIN SODIUM

TABLET; ORAL

	/WARFARIN/SODIUM/		
/B*/	/PHARM/BASICS/	/2MG/	/N86719/001/ /JUN/27,/1985/
/B*/		/2.5MG/	/N86720/001/ /AUG/06,/1985/
/B*/		/5MG/	/N86721/001/ /JUL/02,/1985/
	∂ PHARM BASICS	2MG	N86719 001 JUN 27, 1985
	∂	2.5MG	N86720 001 AUG 06, 1985
	∂	5MG	N86721 001 JUL 02, 1985

ZALCITABINE

TABLET; ORAL

	HIVID		
+	ROCHE	0.75MG¤	N20199 002 JUN 19, 1992
		0.375MG¤	N20199 001 JUN 19, 1992

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACEPHEN
G AND W 120MG¤ N72218 001
MAR 27, 1992
325MG¤ N72344 001
MAR 27, 1992
650MG¤ N72237 001
MAR 27, 1992

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
MICROCOL
JOHNSON AND JOHNSON 0.5%¤ N72292 001
JAN 28, 1992

STERI-STAT
>ADD< MATRIX MED 4% N70104 001
>ADD< JUL 24, 1986
>DLT< /MEDCL/SYSTEMS/ /4%/ /N70104/001/
>DLT< /JUL/24,/1986/

CLEMASTINE FUMARATE

>ADD< TABLET; ORAL
>ADD< TAVIST-1
>ADD< SANDOZ 1.34MG¤ N17661 003
>ADD< AUG 21, 1992

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

>ADD< TABLET, EXTENDED RELEASE; ORAL
>ADD< TAVIST-D
>ADD< SANDOZ 1.34MG;75MG¤ N18298 002
>ADD< AUG 21, 1992

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
>DLT< /RESPORAL/
>DLT< /PIONEER/PHARMS/ /6MG;120MG/ /N89139/001/
>DLT< /JUN/16,/1988/
>ADD< @ PIONEER PHARMS 6MG;120MG N89139 001
>ADD< JUN 16, 1988

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
DIPHENHYDRAMINE HCL
>ADD< CUMBERLAND SWAN 12.5MG/5ML¤ N73611 001
>ADD< AUG 20, 1992
SILPHEN
SILARX 12.5MG/5ML¤ N72646 001
FEB 27, 1992

IBUPROFEN

TABLET; ORAL
IBUPROFEN
TAG 200MG¤ N73141 001
MAY 29, 1992

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
HUMULIN 50/50
LILLY 50 UNITS/ML;50 UNITS/ML¤ N20100 001
APR 29, 1992

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL
LOPERAMIDE HCL
PERRIGO 1MG/5ML¤ N73243 001
JAN 21, 1992
ROXANE 1MG/5ML¤ N73079 001
APR 30, 1992

SODIUM MONOFLUOROPHOSPHATE

PASTE; DENTAL
EXTRA-STRENGTH AIM
/3/CHESEBROUGH/PONDS/ /1.2%/ /N19518/001/
/JUN/03,/1987/
CHESEBROUGH PONDS 1.2% N19518 001
JUN 03, 1987

DEXTRAN, 75, 6% INVERTED SUGAR 10% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION

6% GENTRAN 75 AND 10% TRAVERT

TRAVENOL LABS	6GM/100ML;0.9GM/100ML 0.9GM/100ML	N08788

UROKINASE

INJECTABLE; INJECTION

BREOKINASE

STERLING DRUG	250,000 IU/VIAL	N17873

ORPHAN DRUG PRODUCT DESIGNATIONS

SECTION 526 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT CONTAINS PROVISIONS WHEREBY FDA MAY DESIGNATE A SPONSOR'S DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT AS A "DESIGNATED ORPHAN DRUG." SECTION 527 OF THE ACT ESTABLISHES A PROCESS WHEREBY A SPONSOR MAY RECEIVE SEVEN YEARS OF EXCLUSIVE APPROVAL STATUS IF THAT SPONSOR IS THE FIRST TO ACHIEVE NEW DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT APPROVAL FOR A DESIGNATED ORPHAN DRUG FOR THE DESIGNATED INDICATION(S). THE EXCLUSIVE APPROVAL MAY BE REVOKED BY WRITTEN CONSENT OF THE SPONSOR OR BY FDA ACTION AFTER FINDING THAT THE SPONSOR HOLDING EXCLUSIVE APPROVAL CANNOT ASSURE THE AVAILABILITY OF SUFFICIENT QUANTITIES OF THE DRUG TO MEET THE NEEDS OF PATIENTS WITH THE DESIGNATED ORPHAN INDICATION(S).

WHEN A PRODUCT IS GRANTED ORPHAN DRUG DESIGNATION, IT WILL APPEAR IN THIS SECTION. ONCE A BIOLOGICAL OR DRUG PRODUCT IS LICENSED/APPROVED FOR MARKETING, IT WILL BE LISTED IN THIS SECTION AND ASTERISKED, AS APPROPRIATE, TO DENOTE MARKETING/EXCLUSIVE APPROVAL STATUS. IN ADDITION, THE EXCLUSIVITY EXPIRATION DATE WILL BE DISPLAYED FOLLOWING THE APPROVED DESIGNATED INDICATION(S).

THE FOLLOWING DRUGS AND BIOLOGICALS HAVE BEEN GRANTED ORPHAN DRUG DESIGNATION PURSUANT TO SECTION 526 OF THE FOOD, DRUG, AND COSMETIC ACT AS AMENDED BY THE ORPHAN DRUG ACT [PUBLIC LAW 97-414].

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS
[Approved for Marketing*]
[Exclusive Approval**]

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ALDESLEUKIN TRADE: PROLEUKIN*/**	TREATMENT OF PRIMARY IMMUNODEFICIENCY DISEASE ASSOCIATED WITH T-CELL DEFECTS.*/** [MAY 05, 1999]	CETUS
GENERIC: ANANAIN, COMOSAIN TRADE: VIANAIN	FOR THE ENZYMATIC DEBRIDEMENT OF SEVERE BURNS.	GENZYME CORPORATION
GENERIC: ANTITHROMBIN III TRADE: THROMBATE III*/**	USE AS REPLACEMENT THERAPY IN CONGENITAL DEFICIENCY OF ANTITHROMBIN-III FOR PREVENTION AND TREATMENT OF OF THROMBOSIS AND PULMONARY EMBOLI. [DEC 13, 1996]	CUTTER BIOLOGICAL
GENERIC: BOTULINUM TOXIN TYPE B TRADE: NOT ESTABLISHED	TREATMENT OF CERVICAL DYSTONIA.	ATHENA NEUROSCIENCES, INC
GENERIC: CILIARY NEUROTROPHIC FACTOR TRADE: NOT ESTABLISHED	TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.	ROGENERON PHARMACEUTICALS, INC
GENERIC: CILIARY NEUROTROPHIC FACTOR, RECOMBINANT HUMAN TRADE: NOT ESTABLISHED	TREATMENT OF SPINAL MUSCULAR ATROPHIES. TREATMENT OF MOTOR NEURON DISEASE (INCLUDING AMYOTROPHIC LATERAL SCLEROSIS, PROGRESSIVE MUSCULAR ATROPHY, PROGRESSIVE BULBAR PALSY, AND PRIMARY LATERAL SCLEROSIS).	SYNTEX-SYNERGEN NEUROSCIENCE

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: COAGULATION FACTOR IX TRADE: MONONINE*/**	REPLACEMENT TREATMENT AND PROPHYLAXIS OF THE HEMORRHAGIC COMPLICATIONS OF HEMOPHILIA B. [AUG 20, 1999]	ARMOUR PHARMACEUTICAL
GENERIC: CYSTIC FIBROSIS GENE THERAPY TRADE: NOT ESTABLISHED	TREATMENT OF CYSTIC FIBROSIS.	GENZYME CORPORATION
GENERIC: CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR TRADE: NOT ESTABLISHED	FOR CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR PROTEIN REPLACEMENT THERAPY IN CYSTIC FIBROSIS PATIENTS.	GENZYME CORPORATION
GENERIC: HIV NEUTRALIZING ANTIBODIES TRADE: IMMUPATH	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	HEMACARE CORPORATION
GENERIC: HUMAN IMMUNODEFICIENCY VIRUS IMMUNE GLOBULIN TRADE: NOT ESTABLISHED	TREATMENT OF HIV-INFECTED PREGNANT WOMEN AND INFANTS OF HIV-INFECTED MOTHERS.	ABBOTT LABORATORIES
GENERIC: IMPORTED FIRE ANT VENOM, ALLERGENIC EXTRACT TRADE: NOT ESTABLISHED	FOR SKIN TESTING OF VICTIMS OF FIRE ANT STINGS TO CONFIRM FIRE ANT SENSITIVITY AND IF POSITIVE, FOR USE AS IMMUNOTHERAPY FOR THE PREVENTION OF IgE-MEDIATED ANAPHYLACTIC REACTIONS.	ALK LABORATORIES, INC
GENERIC: INTERFERON (RECOMBINANT HUMAN, BETA) TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE NON-A, NON-B HEPATITIS.	BIOGEN, INC
GENERIC: PROTEIN C CONCENTRATE TRADE: PROTEIN C CONCENTRATE (HUMAN) VAPOR HEATED, IMMUNO	FOR REPLACEMENT THERAPY IN PATIENTS WITH CONGENITAL OR ACQUIRED PROTEIN C DEFICIENCY FOR THE PREVENTION AND TREATMENT OF WARFARIN-INDUCED SKIN NECROSIS DURING ORAL ANTICOAGULATION. FOR REPLACEMENT THERAPY IN CONGENITAL PROTEIN C DEFICIENCY FOR THE PREVENTION AND TREATMENT OF THROMBOSIS, PULMONARY EMBOLI, AND PURPURA FULMINANS.	IMMUNO CLINICAL RESEARCH CORPORATION

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: SARGRAMOSTIM TRADE: LEUKINE*/**	TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANT, FOR THE PROMOTION OF EARLY ENGRAFTMENT, AND FOR THE TREATMENT OF GRAFT FAILURE AND DELAY OF ENGRAFTMENT.*/** [DEC 31, 1998] TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANTS IN PATIENTS WITH NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE AND ACUTE LYMPHOBLASTIC LEUKEMIA.*/** [MAR 05, 1998]	IMMUNEX
GENERIC: SECRETORY LEUKOCYTE PROTEASE INHIBITOR TRADE: NOT ESTABLISHED	TREATMENT OF BRONCHOPULMONARY DYSPLASIA.	SYNERGEN, INC
GENERIC: TECHNETIUM TC99M MURINE MONOCLONAL ANTIBODY (IGG2A) TO BCE TRADE: IMMURAID-LL-2[99mTc]	DIAGNOSTIC IMAGING IN THE EVALUATION OF THE EXTENT OF DISEASE IN PATIENTS WITH HISTOLOGICALLY CONFIRMED DIAGNOSIS OF NON-HODGKIN'S B-CELL LYMPHOMA, ACUTE B-CELL LYMPHOBLASTIC LEUKEMIA (IN CHILDREN AND ADULTS), AND CHRONIC B-CELL LYMPHOCYTIC LEUKEMIA.	IMMUNOMEDICS, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS
[Approved for Marketing*]
[Exclusive Approval**]

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ANARITIDE ACETATE TRADE: AURICULIN	IMPROVEMENT OF EARLY RENAL ALLOGRAFT FUNCTION FOLLOWING RENAL TRANSPLANTATION. TREATMENT OF PATIENTS WITH ACUTE RENAL FAILURE.	SCIOS, INC
GENERIC: ARGININE BUTYRATE TRADE: NOT ESTABLISHED	TREATMENT OF BETA-HEMOGLOBINOPATHIES AND BETA-THALASSEMIA.	SUSAN P. PERRINE, M.D.
GENERIC: BACLOFEN (INTRATHECAL) TRADE: LIORESAL	TREATMENT OF INTRACTABLE SPASTICITY CAUSED BY SPINAL CORD INJURY, MULTIPLE SCLEROSIS, AND OTHER SPINAL DISEASES (INCLUDING SPINAL ISCHEMIA, SPINAL TUMOR, TRANSVERSE MYELITIS, CERVICAL SPONDYLOSIS, AND DEGENERATIVE MYELOPATHY.	MEDTRONIC, INC
GENERIC: BUTYRYLCHOLINESTERASE TRADE: NOT ESTABLISHED	FOR THE REDUCTION AND CLEARANCE OF TOXIC BLOOD LEVELS OF COCAINE ENCOUNTERED DURING A DRUG OVERDOSE.	PHARMAVENE, INC
GENERIC: DAPSONE TRADE: DAPSONE	FOR THE COMBINATION TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA IN CONJUNCTION WITH TRIMETHOPRIM.	JACOBUS PHARMACEUTICAL COMPANY
GENERIC: DIANEAL PD-2 PERITONEAL DIALYSIS SOLN WITH 1.1% AMINO ACIDS TRADE: NUTRINEAL PD-2 PERITONEAL DIALYSIS SOLN WITH 1.1% AMINO ACIDS	FOR USE AS A NUTRITIONAL SUPPLEMENT FOR THE TREATMENT OF MALNOURISHMENT IN PATIENTS UNDERGOING CONTINUOUS AMBULATORY PERITONEAL DIALYSIS.	BAXTER HEALTHCARE CORPORATION
GENERIC: DIAZEPAM VISCOUS SOLUTION FOR RECTAL ADMINISTRATION TRADE: DIASTAT	TREATMENT OF ACUTE REPETITIVE SEIZURES.	UPSHER SMITH LABORATORIES, INC
GENERIC: FIAU TRADE: NOT ESTABLISHED	ADJUNCTIVE TREATMENT OF CHRONIC ACTIVE HEPATITIS B.	OCLASSEN PHARMACEUTICALS, INC
GENERIC: HALOFANTRINE HCL TRADE: HALFAN*/**	TREATMENT OF MILD TO MODERATE ACUTE MALARIA CAUSED BY SUSCEPTIBLE STRAINS OF P. FALCIPARUM AND P. VIVAX. [JUL 24, 1999]	SMITHKLINE BEECHAM
GENERIC: HUMAN THYROID STIMULATING HORMONE (TSH) TRADE: THYROGEN	AS AN ADJUNCT IN THE DIAGNOSIS OF THYROID CANCER.	GENZYME CORPORATION

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: L-BACLOFEN TRADE: NEURALGON	TREATMENT OF INTRACTABLE SPASTICITY IN CHILDREN WITH CEREBRAL PALSY.	WTD, INC
GENERIC: L-THREONINE TRADE: NOT ESTABLISHED	TREATMENT OF SPASTICITY ASSOCIATED WITH FAMILIAL SPASTIC PARAPARESIS.	INTERNEURON PHARMACEUTICALS, INC
GENERIC: LEVOCARNITINE TRADE: CARNITOR*/**	GENETIC CARNITINE DEFICIENCY.* TREATMENT OF MANIFESTATIONS OF CARNITINE DEFICIENCY IN PATIENTS WITH END STAGE RENAL DISEASE (ESRD) WHO REQUIRE DIALYSIS. PREVENTION OF SECONDARY CARNITINE DEFICIENCY IN VALPROIC ACID TOXICITY. TREATMENT OF SECONDARY CARNITINE DEFICIENCY IN VALPROIC ACID TOXICITY.	SIGMA TAU
GENERIC: LIOTHYRONINE SODIUM TRADE: TRIOSTAT*/**	TREATMENT OF MYXEDEMA COMA/PRE-COMA. [DEC 31, 1998]	SMITHKLINE BEECHAM
GENERIC: LOXORIBINE TRADE: NOT ESTABLISHED	TREATMENT OF COMMON VARIABLE IMMUNODEFICIENCY.	R.W. JOHNSON RESEARCH INSTITUTE
GENERIC: MELPHALAN TRADE: ALKERAN FOR INJECTION	TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA FOR WHOM ORAL THERAPY IS INAPPROPRIATE. FOR USE IN HYPERTHERMIC REGIONAL LIMB PERFUSION TO TREAT METASTATIC MELANOMA OF THE EXTREMITY.	BURROUGHS WELLCOME COMPANY
GENERIC: MINOCYCLINE HCL TRADE: MINOCIN	TREATMENT OF CHRONIC MALIGNANT PLEURAL EFFUSION.	LEDERLE LABORATORIES
GENERIC: PAPAVERINE (TOPICAL GEL) TRADE: NOT ESTABLISHED	TREATMENT OF SEXUAL DYSFUNCTION IN SPINAL CORD INJURY PATIENTS.	PHARMEDIC COMPANY
GENERIC: PARA-AMINOSALICYLIC ACID TRADE: NOT ESTABLISHED	TREATMENT OF TUBERCULOSIS INFECTIONS.	JACOBUS PHARMACEUTICAL COMPANY
GENERIC: PILOCARPINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF XEROSTOMIA AND KERATOCONJUNCTIVITIS SICCA IN SJOGREN'S SYNDROME PATIENTS.	MGI PHARMA, INC
GENERIC: POLYMERIC OXYGEN TRADE: NOT ESTABLISHED	TREATMENT OF SICKLE CELL ANEMIA.	CAPMED, USA

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: PPI-002 TRADE: NOT ESTABLISHED	TREATMENT OF MALIGNANT MESOTHELIOMA.	PLEXUS PHARMACEUTICALS, INC
GENERIC: SODIUM MONOMERCAPTOUNDECAHYDRO-CLOSODODECABORATE TRADE: BOROCELL	FOR USE IN BORON NEUTRON CAPTURE THERAPY IN THE TREATMENT OF GLIOBLASTOMA MULTIFORME.	NEUTRON TECHNOLOGY CORPORATION
GENERIC: SODIUM PHENYLBUTYRATE TRADE: NOT ESTABLISHED	TREATMENT OF SICKLING DISORDERS, WHICH INCLUDE S-S HEMOGLOBINOPATHY, S-C HEMOGLOBINOPATHY, AND S-THALASSEMIA HEMOGLOBINOPATHY.	JOHNS HOPKINS MEDICAL INSTITUTIONS
GENERIC: TENIPOSIDE TRADE: VUMON*/**	TREATMENT OF REFRACTORY CHILDHOOD ACUTE LYMPHOCYTIC LEUKEMIA (ALL). [JUL 14, 1999]	BRISTOL MYERS SQUIBB
GENERIC: ZALCITABINE TRADE: HIVID	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS). [JUN 19, 1999]	ROCHE
GENERIC: 9-CIS RETINOIC ACID TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE PROMYELOCYTIC LEUKEMIA.	LIGAND PHARMACUETICALS, INC

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

NO AUGUST 1992 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR IN VIVO BIOEQUIVALENCE STUDIES AND IN VITRO DISSOLUTION TESTING AVAILABLE FROM THE DIVISION OF BIOEQUIVALENCE, HFD-650, MPN-2 ROOM 279, 5600 FISHERS LANE, ROCKVILLE, MD 20857. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 12TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
CARBIDOPA AND LEVODOPA (TABLET)	JUN 19, 1992	
CIMETIDINE (TABLET)	JUN 12, 1992	
CORTICOSTEROID *IN VITRO* AND *IN VIVO* INTERIM (TOPICAL)	JUL 01, 1992	
DIFLUNISAL (TABLET)	MAY 16, 1992	
DILTIAZEM HYDROCHLORIDE (TABLET)	MAY 16, 1992	
GEMFIBROZIL (CAPSULE AND TABLET)	JUN 23, 1989	JUN 15, 1992
METOPROLOL TARTRATE (TABLET)	JUN 12, 1992	
NADOLOL (TABLET)	MAY 16, 1992	
NAPROXEN (TABLET)	JUN 12, 1992	
NORTRIPTYLINE HYDROCHLORIDE (CAPSULE)	JUN 15, 1992	
PIROXICAM (CAPSULE)	JUN 15, 1992	
STATISTICAL PROCEDURE FOR BIOEQUIVALENCE STUDIES USING A STANDARD TWO-TREATMENT CROSSOVER DESIGN	JUL 01, 1992	
TERFENADINE (TABLET)	JUN 12, 1992	

ANDA SUITABILITY PETITIONS

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, 12TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	PETITION	REASON FOR STATUS
ACETAMINOPHEN; CODEINE PHOSPHATE TABLET; ORAL	500MG 7.5MG	91 P-0514/ CP1	SOFTAN	NEW STRENGTH	APPROVED JUN 03, 1992
ALBUTEROL SULFATE CAPSULE, EXTENDED RELEASE; ORAL	EQ 4MG BASE	91 P-0348/ CP1	HAMER	NEW DOSAGE FORM	APPROVED MAR 17, 1992
CHLORZOXAZONE TABLET; ORAL	750MG	91 P-0153/ CP1	MIKART	NEW STRENGTH	APPROVED JUN 03, 1992
HYDROCORTISONE ACETATE AEROSOL; TOPICAL	2.5%	92 P-0101/ CP1	HOGAN & HARTSON	NEW DOSAGE FORM	APPROVED JUL 08, 1992
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	5MG/ML (50ML/CONTAINER)	91 P-0387/ CP1	ABBOTT	NEW STRENGTH	APPROVED FEB 18, 1992
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	10MG/ML (100ML/CONTAINER)	91 P-0387/ CP1	ABBOTT	NEW STRENGTH	APPROVED FEB 18, 1992

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	PETITION	REASON FOR STATUS
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (50ML/VIAL)	91 P-0076/ CP1	ADRIA	NEW STRENGTH	DENIED FEB 19, 1992

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 12TH 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 INDICATION

I-67	TREATMENT OF ACUTE ASTHMATIC ATTACKS IN CHILDREN SIX YEARS OF AGE AND OLDER
I-68	CENTRAL PRECOCIOUS PUBERTY
I-69	SHORT TERM TREATMENT OF PATIENTS WITH SYMPTOMS OF GASTROESOPHAGEAL REFLUX DISEASE (GERD), AND FOR THE SHORT TERM TREATMENT OF ESOPHAGITIS DUE TO GERD INCLUDING ULCERATIVE DISEASE DIAGNOSED BY ENDOSCOPY
I-70	USE IN COMBINATION WITH 5-FLUOROURACIL TO PROLONG SURVIVAL IN THE PALLIATIVE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER
I-71	VARICELLA INFECTIONS (CHICKENPOX)
I-72	PREVENTION OF CMV DISEASE IN TRANSPLANT PATIENTS AT RISK FOR CMV DISEASE
I-73	INITIATE AND MAINTAIN MONITORED ANESTHESIA CARE (MAC) SEDATION DURING DIAGNOSTIC PROCEDURES
I-74	INTRAVENOUS DIGITAL SUBTRACTION ANGIOGRAPHY
I-75	TREATMENT OF ENDOSCOPICALLY DIAGNOSED EROSIVE ESOPHAGITIS

REFERENCES
PATENT USE CODE

U-57	OPHTHALMIC USE OF NORFLOXACIN
U-58	METHOD OF TREATING INFLAMMATORY INTESTINAL DISEASES
U-59	METHOD OF TREATING HYPERCHOLESTEROLEMIA
U-60	NASAL ADMINISTRATION OF BUTORPHANOL
U-61	CEREBRAL AND PERIPHERAL ARTERIOGRAPHY AND CT IMAGING OF THE HEAD
U-62	CORONARY ARTERIOGRAPHY, LEFT VENTRICULOGRAPHY, CT IMAGING OF THE BODY, INTRAVENOUS EXCRETORY UROGRAPHY, INTRAVENOUS DIGITAL SUBTRACTION ANGIOGRAPHY AND VENOGRAPHY
U-63	ISOPRENALINE ANTAGONISM ON THE HEART RATE OR BLOOD PRESSURE
U-64	TREATMENT OF VIRAL INFECTIONS

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
	20232 001	ACETAMINOPHEN; FIORICET W/ CODEINE				NC	OCT 26, 1993
	18828 001	ACYCLOVIR; ZOVIRAX				I-71	FEB 26, 1995
	19909 001	ACYCLOVIR; ZOVIRAX				I-71	FEB 26, 1995
	20089 001	ACYCLOVIR; ZOVIRAX				I-71	FEB 26, 1995
	20089 002	ACYCLOVIR; ZOVIRAX				I-71	FEB 26, 1995
	19787 001	AMLODIPINE BESYLATE; NORVASC	4572909	FEB 25, 2003		NCE	JUL 31, 1997
	19787 002	AMLODIPINE BESYLATE; NORVASC	4572909	FEB 25, 2003		NCE	JUL 31, 1997
	19787 003	AMLODIPINE BESYLATE; NORVASC	4572909	FEB 25, 2003		NCE	JUL 31, 1997
	20075 001	BACLOFEN; LIORESAL				ODE	JUN 17, 1999
						NDF	JUN 17, 1995
	20075 002	BACLOFEN; LIORESAL				ODE	JUN 17, 1999
						NDF	JUN 17, 1995
	19851 001	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2002		NCE	JUN 25, 1996
	19851 002	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2002		NCE	JUN 25, 1996
	19851 003	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2002		NCE	JUN 25, 1996
	19851 004	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2002		NCE	JUN 25, 1996
	20033 001	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NCE	JUN 25, 1996
						NC	MAY 19, 1995
	20033 002	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NCE	JUN 25, 1996
						NC	MAY 19, 1995
	20033 003	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NCE	JUN 25, 1996
						NC	MAY 19, 1995
	20033 004	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NCE	JUN 25, 1996
						NC	MAY 19, 1995
	19001 001	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
	19001 002	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
	19001 003	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
	19002 001	BEPRIDIL HYDROCHLORIDE; VASCOR	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
	19002 002	BEPRIDIL HYDROCHLORIDE; VASCOR	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
	19002 003	BEPRIDIL HYDROCHLORIDE; VASCOR	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
>ADD>	19982 001	BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
>DLT>	~~19982 001~~	~~BISOPROLOL FUMARATE; ZEBETA~~	~~4171370~~	~~OCT 16, 1996~~			
>ADD>	19982 002	BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
>DLT>	~~19982 002~~	~~BISOPROLOL FUMARATE; ZEBETA~~	~~4171370~~	~~OCT 16, 1996~~			
	19548 001	BITOLTEROL MESYLATE; TORNALATE	4336400	JUN 22, 1999	U-5		
			4138581	FEB 06, 1998		NDF	FEB 19, 1995
	19890 001	BUTORPHANOL TARTRATE; STADOL	4464378	AUG 07, 2001	U-60	NDF	DEC 12, 1994

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PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19847 001	CIPROFLOXACIN; CIPRO	4808583	FEB 28, 2006			
			4705789	NOV 10, 2004			
			4670444	OCT 01, 2002		NCE	OCT 22, 1992
	19857 001	CIPROFLOXACIN; CIPRO IN DEXTROSE 5%	4957922	SEP 18, 2007			
			4808583	FEB 28, 2006			
			4705789	NOV 10, 2004			
			4670444	OCT 01, 2002		NCE	OCT 22, 1992
	19858 001	CIPROFLOXACIN; CIPRO IN SODIUM CHLORIDE 0.9%	4957922	SEP 18, 2007			
			4808583	FEB 28, 2006			
			4705789	NOV 10, 2004			
			4670444	OCT 01, 2002		NCE	OCT 22, 1992
	19537 002	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	NCE	OCT 22, 1992
	19537 003	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	NCE	OCT 22, 1992
	19537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	NCE	OCT 22, 1992
	19992 001	CIPROFLOXACIN HYDROCHLORIDE; CILOXAN	4670444	OCT 01, 2002		NDF	DEC 31, 1993
	20037 001	DICLOFENAC SODIUM; VOLTAREN	4960799	OCT 02, 2007		NDF	MAR 28, 1994
	20027 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM				NCE	NOV 05, 1992
	20027 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM				NCE	NOV 05, 1992
>ADD>	20062 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008		NCE	NOV 05, 1992
>ADD>			4894240	JAN 16, 2007		NP	DEC 27, 1994
	20062 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008		NCE	NOV 05, 1992
			4894240	JAN 16, 2007		NP	DEC 27, 1994
	20062 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008		NCE	NOV 05, 1992
			4894240	JAN 16, 2007		NP	DEC 27, 1994
	20062 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008		NCE	NOV 05, 1992
			4894240	JAN 16, 2007		NP	DEC 27, 1994
	20092 001	DILTIAZEM HYDROCHLORIDE; DILACOR XR				NP	DEC 27, 1994
						NCE	NOV 05, 1992
	20092 002	DILTIAZEM HYDROCHLORIDE; DILACOR XR				NP	DEC 27, 1994
						NCE	NOV 05, 1992
	20092 003	DILTIAZEM HYDROCHLORIDE; DILACOR XR				NP	DEC 27, 1994
						NCE	NOV 05, 1992
	19946 001	DOXACURIUM CHLORIDE; NUROMAX	4701460	MAR 06, 2005		NCE	MAR 07, 1996
	19697 001	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN				NP	JUL 03, 1995
	19697 002	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN				NP	JUL 03, 1995

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19462 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		I-69	DEC 10, 1994
	19462 002	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		I-69	DEC 10, 1994
	19527 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		I-69	DEC 10, 1994
	19834 001	FELODIPINE; PLENDIL	4264611	APR 28, 1998		NCE	JUL 25, 1996
	19834 002	FELODIPINE; PLENDIL	4264611	APR 28, 1998		NCE	JUL 25, 1996
	20180 001	FINASTERIDE; PROSCAR	4760071	JUL 26, 2005			
			4377584	MAR 22, 2000		NCE	JUN 19, 1997
	20038 001	FLUDARABINE PHOSPHATE; FLUDARA	4357324	NOV 02, 2001		NCE	APR 18, 1996
>DLT>	~~18936 001~~	~~FLUOXETINE HYDROCHLORIDE; PROZAC~~	~~4590213~~	~~MAY 20, 2003~~			
>ADD>	20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4626549	DEC 02, 2003			
>ADD>			4194009	APR 19, 1994			
>ADD>			4018895	APR 19, 1994	U-12		
	20068 001	FOSCARNET SODIUM; FOSCAVIR	4771041	JUL 29, 1997			
			4665062	JUL 29, 1997			
			4339445	JUL 29, 1997			
			4339445	JUL 29, 1997	U-64		
			4215113	JUL 29, 1997		NCE	SEP 27, 1996
			4215113	JUL 29, 1997	U-64	NCE	SEP 27, 1996
	19915 002	FOSINOPRIL SODIUM; MONOPRIL	4337201	JUN 29, 2001		NCE	MAY 16, 1996
	19915 003	FOSINOPRIL SODIUM; MONOPRIL	4337201	JUN 29, 2001		NCE	MAY 16, 1996
	19661 001	GANCICLOVIR SODIUM; CYTOVENE	4507305	OCT 19, 1999	U-35	I-72	MAY 15, 1995
	20051 001	GLYBURIDE; GLYNASE	4916163	APR 10, 2007			
			4735805	APR 05, 2005		NCE	MAY 01, 1994
			3507961	APR 21, 1992		NP	MAR 04, 1995
			3507954	APR 21, 1992			
			3454635	APR 21, 1992			
			3426067	APR 21, 1992			
	20051 002	GLYBURIDE; GLYNASE	4916163	APR 10, 2007			
			4735805	APR 05, 2005		NCE	MAY 01, 1994
			3507961	APR 21, 1992		NP	MAR 04, 1995
			3507954	APR 21, 1992			
			3454635	APR 21, 1992			
			3426067	APR 21, 1992			
	20055 001	GLYBURIDE; GLUBATE				NP	MAR 04, 1995
						NCE	MAY 01, 1994
	20055 002	GLYBURIDE; GLUBATE				NP	MAR 04, 1995
						NCE	MAY 01, 1994

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19967 001	HALOBETASOL PROPIONATE; ULTRAVATE				D-1	DEC 31, 1994
	19968 001	HALOBETASOL PROPIONATE; ULTRAVATE				D-1	DEC 31, 1994
	20250 001	HALOFANTRINE HYDROCHLORIDE; HALFAN				NCE	JUL 24, 1997
>ADD>						ODE	JUL 24, 1999
	19046 001	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994		NCE	AUG 01, 1994
	19046 002	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994		NCE	AUG 01, 1994
	19046 003	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994		NCE	AUG 01, 1994
	19046 004	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994		NCE	AUG 01, 1994
	19174 001	HYDROCHLOROTHIAZIDE; TRANDATE HCT	4012444	MAR 15, 1994		NCE	AUG 01, 1994
	19174 002	HYDROCHLOROTHIAZIDE; TRANDATE HCT	4012444	MAR 15, 1994		NCE	AUG 01, 1994
	19174 003	HYDROCHLOROTHIAZIDE; TRANDATE HCT	4012444	MAR 15, 1994		NCE	AUG 01, 1994
	19174 004	HYDROCHLOROTHIAZIDE; TRANDATE HCT	4012444	MAR 15, 1994		NCE	AUG 01, 1994
	19261 001	HYDROXYAMPHETAMINE HYDROBROMIDE; PAREMYD				NC	JAN 30, 1995
	20100 001	INSULIN BIOSYNTHETIC HUMAN; HUMULIN 50/50				NP	APR 29, 1995
	19710 004	IOVERSOL; OPTIRAY 300	4396598	OCT 26, 2002	U-61	NS	JAN 22, 1995
	19710 005	IOVERSOL; OPTIRAY 350	4396598	OCT 26, 2002	U-62	NS	JAN 22, 1995
						I-74	JAN 22, 1995
	19645 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55	NDF	DEC 20, 1994
						NCE	NOV 30, 1994
	08107 001	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
	08107 002	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
	08107 004	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
	08107 005	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
	19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4917893	MAR 24, 2004			
			4849228	JUL 18, 2006			
			4728721	MAR 01, 2005			
			4677191	JUN 30, 2004			
			4652441	MAR 24, 2004			
	20011 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4917893	MAR 24, 2004			
			4849228	JUL 18, 2006			
			4728721	MAR 01, 2005			
			4677191	JUN 30, 2004			
			4652441	MAR 24, 2004			
	20105 001	LIOTHYRONINE SODIUM; TRIOSTAT				ODE	DEC 31, 1998
	20013 001	LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN	4528287	JUL 09, 2002	U-36	NCE	FEB 21, 1997

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19651 001	MESALAMINE; ASACOL				NCE	DEC 24, 1992
						NDF	JAN 31, 1995
	17659 001	METAPROTERENOL SULFATE; ALUPENT				I-67	NOV 14, 1994
	19962 001	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992		NE	JAN 10, 1995
			3876802	APR 08, 1992			
	19962 002	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992		NE	JAN 10, 1995
			3876802	APR 08, 1992			
	19962 003	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992		NE	JAN 10, 1995
			3876802	APR 08, 1992			
>ADD>	20208 001	METRONIDAZOLE; METROGEL				NDF	AUG 17, 1995
	20098 001	MIVACURIUM CHLORIDE; MIVACRON	4761418	AUG 02, 2005		NCE	JAN 22, 1997
	20098 002	MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5%	4761418	AUG 02, 2005		NCE	JAN 22, 1997
	19583 001	NABUMETONE; RELAFEN	4420639	DEC 13, 2000		NCE	DEC 24, 1996
			4061779	DEC 06, 1994	U-19		
	19583 002	NABUMETONE; RELAFEN	4420639	DEC 13, 2000		NCE	DEC 24, 1996
			4061779	DEC 06, 1994	U-19		
	19886 001	NAFARELIN ACETATE; SYNAREL				I-68	FEB 26, 1995
	20109 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1997		NCE	FEB 13, 1995
						I-68	FEB 26, 1995
	19734 001	NICARDIPINE HYDROCHLORIDE; CARDENE				NDF	JAN 30, 1995
						NCE	DEC 21, 1993
>ADD>	20005 001	NICARDIPINE HYDROCHLORIDE; CARDENE SR	3985758	OCT 12, 1995		NCE	DEC 21, 1993
						NDF	FEB 21, 1995
>ADD>	20005 002	NICARDIPINE HYDROCHLORIDE; CARDENE SR	3985758	OCT 12, 1995		NCE	DEC 21, 1993
						NDF	FEB 21, 1995
>ADD>	20005 003	NICARDIPINE HYDROCHLORIDE; CARDENE SR	3985758	OCT 12, 1995		NCE	DEC 21, 1993
						NDF	FEB 21, 1995
	19983 001	NICOTINE; PROSTEP	4946853	AUG 07, 2007	U-56	NS	JAN 28, 1995
	19983 002	NICOTINE; PROSTEP	4946853	AUG 07, 2007	U-56	NS	JAN 28, 1995
	20076 001	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
	20076 002	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
	20076 003	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
	20150 001	NICOTINE; NICOTROL				NP	APR 22, 1995
	20150 002	NICOTINE; NICOTROL				NP	APR 22, 1995
	20150 003	NICOTINE; NICOTROL				NP	APR 22, 1995

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PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20165 001	NICOTINE; NICODERM	5004610	APR 02, 2008			
		4144317	SEP 09, 1992		NDF	NOV 07, 1994
20165 002	NICOTINE; NICODERM	5004610	APR 02, 2008			
		4144317	SEP 09, 1992		NDF	NOV 07, 1994
20165 003	NICOTINE; NICODERM	5004610	APR 02, 2008			
		4144317	SEP 09, 1992		NDF	NOV 07, 1994
20064 001	NITROFURANTOIN; MACROBID	4798725	JAN 17, 2006			
		4772473	SEP 20, 2005		NDF	DEC 24, 1994
19757 001	NORFLOXACIN; CHIBROXIN	4551456	NOV 05, 2002	U-57		
20087 001	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4382892	MAY 10, 2000		NCE	DEC 28, 1995
20087 002	OFLOXACIN; FLOXIN	4382892	MAY 10, 2000		NCE	DEC 28, 1995
20087 003	OFLOXACIN; FLOXIN	4382892	MAY 10, 2000		NCE	DEC 28, 1995
20087 004	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4382892	MAY 10, 2000		NCE	DEC 28, 1995
20087 005	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4382892	MAY 10, 2000		NCE	DEC 28, 1995
19715 001	OLSALAZINE SODIUM; DIPENTUM	4559330	AUG 04, 2004	U-58	NCE	JUL 31, 1995
19775 001	PRAZOSIN HYDROCHLORIDE; MINIPRESS XL	5082668	SEP 16, 2003			
		4783337	SEP 16, 2003			
		4765989	SEP 16, 2003			
		4612008	SEP 16, 2003			
		4327725	MAY 04, 1999			
		4092315	MAY 30, 1995		NDF	JAN 29, 1995
19775 002	PRAZOSIN HYDROCHLORIDE; MINIPRESS XL	5082668	SEP 16, 2003			
		4783337	SEP 16, 2003			
		4765989	SEP 16, 2003			
		4612008	SEP 16, 2003			
		4327725	MAY 04, 1999			
		4092315	MAY 30, 1995		NDF	JAN 29, 1995
19157 001	PREDNISOLONE SODIUM PHOSPHATE; PEDIAPRED	4448774	MAY 15, 2001			
19627 001	PROPOFOL; DIPRIVAN	4798846	NOV 01, 1996		I-73	DEC 31, 1994
18703 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4521431	JUN 04, 2002		I-75	MAY 19, 1995
18703 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	4521431	JUN 04, 2002		I-75	MAY 19, 1995
19675 001	RANITIDINE HYDROCHLORIDE; ZANTAC	4128658	DEC 05, 1995		I-75	MAY 19, 1995
19766 001	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
19766 002	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
19766 003	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
19766 004	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
20166 001	SODIUM THIOSULFATE; SODIUM THIOSULFATE				NCE	FEB 14, 1997

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PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	20063 001	TECHNETIUM TC-99M RED BLOOD CELL KIT; RBC-SCAN				NP	JUN 11, 1995
	20043 003	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	MAR 08, 2005	U-36	NCE	JAN 30, 1997
	20043 004	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	MAR 08, 2005	U-36	NCE	JAN 30, 1997
	20119 001	TENIPOSIDE; VUMON				NCE	JUL 14, 1997
						ODE	JUL 14, 1999
>ADD>	19614 003	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993
	20199 001	ZALCITABINE; HIVID				NCE	JUN 19, 1997
						ODE	JUN 19, 1999
	20199 002	ZALCITABINE; HIVID				NCE	JUN 19, 1997
						ODE	JUN 19, 1999
	19655 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005			
			4833130	FEB 09, 2005		I-47	MAY 02, 1993
			4828838	FEB 09, 2005		ODE	MAR 19, 1994
			4724232	FEB 09, 2005		NCE	MAR 19, 1992
	19910 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005			
			4833130	FEB 09, 2005		ODE	MAR 19, 1994
			4818538	FEB 09, 2005		I-47	MAY 02, 1993
			4724232	FEB 09, 2005		NCE	MAR 19, 1992
	19951 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005			
			4833130	FEB 09, 2005		NCE	MAR 19, 1992
			4818538	FEB 09, 2005			
			4724232	FEB 09, 2005		ODE	MAR 19, 1994

*U.S. Government Printing Office: 1992 — 342-345/60002