CUMULATIVE SUPPLEMENT 6

JAN'92-JUN'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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June 1992

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CUMULATIVE SUPPLEMENT 6

JUNE 1992

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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 ABBREIVATED 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 ABBREIVATED NAME)
NORWICH EATON PHARMS INC SUB PROCTOR & GAMBLE CO (NORWICH EATON)	PROCTER & GAMBLE PHARMACEUTICALS INC (P&G)
RECKITT AND COLMAN PHARMACEUTICALS INC (R & C)	RECKITT AND COLMAN PHARMACEUTICALS INC (RECKITT AND COLMAN)
VITARINE PHARMACEUTICALS INC (VITARINE)	EON LABS MANUFACTURING INC (EON LABS)

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).

PRESCRIPTION DRUG PRODUCT LIST
12TH EDITION
CUMULATIVE SUPPLEMENT NUMBER 6 / JAN'92 - JUN'92

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL
/ACETAMINOPHEN AND CODEINE/
/AA/ /VITARINE/ /300MG;15MG/ /N87433/001/
/AA/ /300MG;30MG/ /N85917/001/
/AA/ /300MG;60MG/ /N87423/001/

ACETAMINOPHEN AND CODEINE PHOSPHATE
∂ 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

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

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/
/AB/	∂ 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
	∂	25MG	N88698 001 SEP 25, 1984
	∂	50MG	N88699 001 SEP 25, 1984
	∂	75MG	N88700 001 SEP 25, 1984
	∂	100MG	N88701 001 SEP 25, 1984
	∂	150MG	N88702 001 SEP 25, 1984

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/

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

UTIMOX

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 500MG BASE	N50310 002
∂	BRISTOL	EQ 250MG BASE	N50310 001
∂		EQ 500MG BASE	N50310 002

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

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

ORPHENADRINE COMPOUND DOUBLE STRENGTH

> ADD >	∂ EON LABS	770MG;60MG;50MG	N71565 001
> ADD >			JUN 23, 1988
> DLT >	/∂/VITARINE/	/770MG;60MG;50MG/	/N71565/001/
> DLT >			/JUN/23,/1988/

ASPIRIN; MEPROBAMATE

TABLET; ORAL

MEPRO-ASPIRIN

> ADD >	∂ EON LABS	325MG;200MG	N89127 001
> ADD >			MAR 02, 1987
> DLT >	/∂/VITARINE/	/325MG;200MG/	/N89127/001/
> DLT >			/MAR/02,/1987/

ATENOLOL

TABLET; ORAL

ATENOLOL

AB	APOTHECON	50MG¤	N73317 001
			MAR 20, 1992
AB		100MG¤	N73318 001
			MAR 20, 1992
AB	GENEVA	25MG¤	N74052 001
			MAY 01, 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

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

/AA/	/VITARINE/	/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

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

TABLET; ORAL

BACLOFEN

AB	BIOCRAFT	10MG¤	N73043 001
			FEB 27, 1992
AB		20MG¤	N73044 001
			FEB 27, 1992
/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

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	TARO	EQ 0.05% BASE¤	N73552 001 APR 30, 1992

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

BITOLTEROL MESYLATE

SOLUTION; INHALATION

TORNALATE

/STERLING/WINTHROP/	/0.2%¤/		/N19548/001/ /FEB/19,/1992/
STERLING	0.2%¤		N19548 001 FEB 19, 1992

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

/AP/	/LYPHOMED/	/50MG/ML/		/N70134/001/ /FEB/12,/1986/
	∂ LYPHOMED	50MG/ML		N70134 001 FEB 12, 1986

BROMPHENIRAMINE MALEATE

TABLET; ORAL

BROMPHENIRAMINE MALEATE

>DLT >/AA/	/PIONEER/PHARMS/	/4MG/		/N88604/001/ /JUL/13,/1984/
>DLT >				
>ADD >	∂ PIONEER PHARMS	4MG		N88604 001 JUL 13, 1984
>ADD >				

BUTABARBITAL SODIUM

TABLET; ORAL

BUTABARBITAL SODIUM

>ADD >	∂ EON LABS	15MG	N85938 001
>ADD >	∂	30MG	N85934 001

BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM

>DLT>		/3/VITARINE/	/15MG/	/N85938/001/	
>DLT>		/3/	/30MG/	/N85934/001/	
		SODIUM BUTABARBITAL			
	/AA/	/WEST/WARD/	/15MG/	/N85418/001/	
	/AA/		/30MG/	/N85432/001/	
		@ WEST WARD	15MG	N85418 001	
		@	30MG	N85432 001	

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

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL

>ADD>	B*	EON LABS	350MG	N89566 001	AUG 30, 1988

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL

>DLT>	/B*/	/VITARINE/	/350MG/	/N89566/001/	/AUG/30,/1988/

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL
CEFADROXIL

AB	ZENITH	EQ 500MG BASE	N62766 001	MAR 03, 1987
	/3/	/EQ/500MG/BASE/	/N62766/001/	/MAR/03,/1987/

TABLET; ORAL
CEFADROXIL

AB	ZENITH	EQ 1GM BASE	N62774 001	APR 08, 1987
	/3/	/EQ/1GM/BASE/	/N62774/001/	/APR/08,/1987/

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

CEFTAZIDIME (ARGININE FORMULATION)

INJECTABLE; INJECTION
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

>ADD>	∂ EON LABS	5MG	N84919 001	
>ADD>	∂	10MG	N84920 001	
>ADD>	∂	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	
>DLT>/AB/	/VITARINE/	/5MG/	/N84919/001/	
>DLT>/AB/		/10MG/	/N84920/001/	
>DLT>/AB/		/25MG/	/N84823/001/	

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
CHLORDIAZEPOXIDE HCL

/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

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

>ADD>	∂ 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
>DLT>	/S/VITARINE/	/250MG/		/N84669/001/

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

>ADD> AB	EON LABS	50MG		N87118 001
>DLT>/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

CHLORTHALIDONE

TABLET; ORAL

THALITONE

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

TAVIST

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

TABLET; ORAL

CLEMASTINE FUMARATE

AB	LEMMON	1.34MG¤	N73282 001 JAN 31, 1992	
AB		2.68MG¤	N73283 001 JAN 31, 1992	

TAVIST

AB	+ DORSEY	2.68MG	N17661 001	

TAVIST-1

AB	DORSEY	1.34MG	N17661 002	

CLINDAMYCIN PHOSPHATE

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	

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/	
∂ CHELSEA	0.5MG;500MG	N85552 001	

PROBENECID AND COLCHICINE

>ADD>	BP	EON LABS	0.5MG;500MG	N86130 001	
>DLT>	/BP/	/VITARINE/	/0.5MG;500MG/	/N86130/001/	

CYANOCOBALAMIN

INJECTABLE; INJECTION
CYANOCOBALAMIN

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

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
CYCLOPENTOLATE HCL

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

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPRAMINE HCL

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

DESONIDE

CREAM; TOPICAL
DESONIDE

>ADD>	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

>DLT>	/BAUSCH/AND/LOMB/	/EQ/0.1%/PHOSPHATE/	/N86433/001/	/DEC/15,/1983/
>ADD>	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

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/
>DLT>/AB/		/PIONEER/PHARMS/	/2MG/	/N70787/001/	/AUG/02,/1988/
>DLT>/AB/			/5MG/	/N70788/001/	/AUG/02,/1988/
>DLT>/AB/			/10MG/	/N70776/001/	/AUG/02,/1988/
>ADD>	@ PIONEER PHARMS		2MG	N70787 001	AUG 02, 1988
>ADD>	@		5MG	N70788 001	AUG 02, 1988
>ADD>	@		10MG	N70776 001	AUG 02, 1988
	@ WARNER CHILCOTT		2MG	N70209 001	SEP 04, 1985
	@		5MG	N70210 001	SEP 04, 1985
	@		10MG	N70222 001	SEP 04, 1985

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL
DIETHYLPROPION HCL

/AA/	/VITARINE/	/25MG/	/N85916/001/	
@ VITARINE		25MG	N85916 001	

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
+		300MG	N20062 004	DEC 27, 1991
		/300MG/	/N20062/004/	/DEC/27,/1991/

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
DILACOR XR

BC	RHONE POULENC RORER	180MG¤	N20092 002 MAY 29, 1992
BC		240MG¤	N20092 003 MAY 29, 1992
	ə	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

>ADD > AA	EON LABS	25MG	N80845 002
>ADD > AA		50MG	N80845 001
>DLT >/AA/	/PIONEER/PHARMS/	/25MG/	/N89101/001/ /DEC/20,/1985/
>DLT >			
>DLT >/AA/		/50MG/	/N88880/001/ /DEC/20,/1985/
>DLT >			
>ADD >	ə PIONEER PHARMS	25MG	N89101 001 DEC 20, 1985
>ADD >			
>ADD >	ə	50MG	N88880 001 DEC 20, 1985
>ADD >			
>DLT >/AA/	/VITARINE/	/25MG/	/N80845/002/
>DLT >/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/
	ə INTERPHARM	EQ 100MG BASE	N71190 001 JAN 15, 1987
	ə	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

/B*/	/INTERPHARM/	/EQ/50MG/BASE/	/N62763/001/ /SEP/02,/1988/	
/B*/		/EQ/100MG/BASE/	/N62763/002/ /SEP/02,/1988/	
	∂ INTERPHARM	EQ 50MG BASE	N62763 001 SEP 02, 1988	
	∂	EQ 100MG BASE	N62763 002 SEP 02, 1988	

CAPSULE, COATED PELLETS; ORAL
DOXYCYCLINE HYCLATE

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

TABLET; ORAL
DOXYCYCLINE HYCLATE

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

DROPERIDOL

INJECTABLE; INJECTION
DROPERIDOL

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

ERGOLOID MESYLATES

TABLET; SUBLINGUAL
ALKERGOT

>ADD<		∂ EON LABS	0.5MG	N85153 001
>ADD<		∂	1MG	N87417 001
>DLT<		/∂/VITARINE/	/0.5MG/	/N85153/001/
>DLT<		/∂/	/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
SANSAC

AT	OWEN GALDERMA	2%	N62522 001 JAN 24, 1985	

/SANSACNE/

/AT/	/OWEN/GALDERMA/	/2%/	/N62522/001/ /JAN/24,/1985/	

TABLET, COATED PARTICLES; ORAL
PCE

	ABBOTT	500MG	N50611 002 AUG 22, 1990

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

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

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
>ADD> AP STERIS EQ 0.05MG BASE/ML* N73488 001 JUN 30, 1992
>ADD>

>ADD> FINASTERIDE

>ADD> TABLET; ORAL
>ADD> PROSCAR
>ADD> + MSD 5MG* N20180 001 JUN 19, 1992
>ADD>

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE
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
/AA/ /LILLY/ /1MG/ /N06135/003/
∂ LILLY 1MG N06135 003
/AA/ /VITARINE/ /1MG/ /N84472/001/
∂ VITARINE 1MG N84472 001

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

FUROSEMIDE

TABLET; ORAL

FUROSEMIDE

/AB/	/VITARINE/	/40MG/	/N18750/002/ /JUL/30/1984/
	∂ VITARINE	40MG	N18750 002 JUL 30, 1984

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

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL

ULTRAGRIS-165

>ADD<	AB	SIDMAK	165MG¤	N62645 001 JUN 30, 1992

ULTRAGRIS-330

>ADD<	AB	SIDMAK	330MG¤	N62646 001 JUN 30, 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/
	∂ ROYCE	0.5MG	N71722 001 DEC 24, 1987
	∂	1MG	N71723 001 DEC 24, 1987
	∂	2MG	N71724 001 DEC 24, 1987
	∂	5MG	N71725 001 DEC 24, 1987
	∂	10MG	N72121 001 DEC 24, 1987
	∂	20MG	N72122 001 DEC 24, 1987

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALOPERIDOL

>DLT<	/AP/	/LYPHOMED/	/EQ 5MG BASE/ML/	/N71187/001/ /JAN/20/1987/
>ADD<		∂ 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/
	∂ LUITPOLD	10 UNITS/ML	N89063 001 OCT 09, 1985
	∂	100 UNITS/ML	N89064 001 OCT 09, 1985

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM

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

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

APRESOLINE

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

/HYDRALAZINE HCL/

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

TABLET; ORAL

HYDRALAZINE HCL

>ADD>	@ EON LABS	50MG	N85088 001	
>DLT>	/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 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

>ADD>	@ EON LABS	25MG;15MG;0.1MG	N84876 001	
>DLT>	/3/VITARINE/	/25MG;15MG;0.1MG/	/N84876/001/	

HYDRALAZINE HYDROCHLORIDE; RESERPINE

TABLET; ORAL

/DRALSERP/

/BP/	/VITARINE/	/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	
>ADD> AB	EON LABS	25MG	N83899 001	
>ADD> AB		50MG	N85219 001	
>DLT>/AB/	/VITARINE/	/25MG/	/N83899/001/	
>DLT>/AB/		/50MG/	/N85219/001/	

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

/HYDRO-SERP/'25'/

/BP/	/VITARINE/	/25MG;0.125MG/	/N84827/001/	
	@ VITARINE	25MG;0.125MG	N84827 001	

HYDRO-SERP 50

>ADD>	@ EON LABS	50MG;0.125MG	N85213 001	
>DLT>	/3/VITARINE/	/50MG;0.125MG/	/N85213/001/	
>DLT>	/SERPASIL-ESIDRIX/#1/			
>DLT> /BP/	/CIBA/	/25MG;0.1MG/	/N11878/003/	
>ADD>	@ CIBA	25MG;0.1MG	N11878 003	
>DLT>	/SERPASIL-ESIDRIX/#2/			
>DLT> /BP/	/CIBA/	/50MG;0.1MG/	/N11878/005/	
>ADD>	@ 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

AB	GENEVA	25MG;37.5MG¤	N73281 001	APR 30, 1992

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

> DLT >	/AT/	/BAUSCH/AND/LOMB/	/1%/	/N87838/001/	/JUL/28,/1982/
> DLT >					
> ADD >	AT	PHARMAFAIR	1%	N87838 001	JUL 28, 1982
> ADD >					

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

> ADD >				
> ADD >	AT	ABLE	1%¤	N81274 001	JUN 19, 1992
> ADD >					

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

> ADD >	AB	EON LABS	10MG	N87246 002	
> ADD >	AB		25MG	N85247 001	
> ADD >	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
> DLT >/AB/	/VITARINE/		/10MG/	/N87246/002/	
> DLT >/AB/			/25MG/	/N85247/001/	
> DLT >/AB/			/50MG/	/N87245/001/	

HYDROXYZINE PAMOATE

CAPSULE; ORAL

HY-PAM

> ADD >	AB	EON LABS	EQ 25MG HCL	N87479 001
> DLT >/AB/		/VITARINE/	/EQ 25MG HCL/	/N87479/001/

HYDROXYZINE PAMOATE

> ADD >	AB	EON LABS	EQ 50MG HCL	N86183 001
> DLT >/AB/		/VITARINE/	/EQ 50MG HCL/	/N86183/001/

IBUPROFEN

TABLET; ORAL
IBUPROFEN

>ADD >	AB	LEMMON	400MG¤	N73343 001 JUN 30, 1992
>ADD >	AB		600MG¤	N73344 001 JUN 30, 1992
>ADD >	AB		800MG¤	N73345 001 JUN 30, 1992
>DLT >	/AB/	/SUPERPHARM/	/600MG/	/N70709/001/ /APR/25,/1986/
		∂ SUPERPHARM	600MG	N70709 001 APR 25, 1986

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL
IMIPRAMINE HCL

>ADD >	AB	EON LABS	10MG	N85200 001
>ADD >	AB		50MG	N85133 001
>DLT >	/AB/	/VITARINE/	/50MG/	/N85133/001/
>DLT >		/∂/	/10MG/	/N85200/001/

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

>ADD >		∂ EON LABS	25MG	N71711 001 JUL 05, 1988
>ADD >		∂	50MG	N71712 001 JUL 05, 1988
>DLT >		/∂/VITARINE/	/25MG/	/N71711/001/ /JUL/05,/1988/
>DLT >		/∂/	/50MG/	/N71712/001/ /JUL/05,/1988/

CAPSULE, EXTENDED RELEASE; ORAL
INDOMETHACIN

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

IOFETAMINE HYDROCHLORIDE I-123

INJECTABLE; INJECTION
SPECTAMINE

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

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%/	/N87938/001/ /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
	∂	0.167%	N88470 001 MAR 14, 1984
	∂	0.2%	N88471 001 MAR 14, 1984
	∂	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/

ISOPROTERENOL HYDROCHLORIDE

SOLUTION; INHALATION
ISOPROTERENOL HCL

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

LACTULOSE

SYRUP; ORAL
LACTULOSE

AA	ROXANE LABS	10GM/15ML¤	N73591 001 MAY 29, 1992

SYRUP; ORAL, RECTAL
LACTULOSE

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/
	ə LYPHOMED	EQ 50MG BASE/VIAL	N88939 001 DEC 01, 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

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL

/INTL/MEDICATION/		/1GM/VIAL/	/N18543/001/
	ə INTL MEDICATION	1GM/VIAL	N18543 001
	ə	/2GM/VIAL/	/N18543/002/
		2GM/VIAL	N18543 002
	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/
	ə 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
AB LEMMON — 2MG¤ — N73192 001 APR 30, 1992

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
>ADD> ∂ EON LABS — 250MG — N72179 001 APR 21, 1988
>ADD>
>DLT> /∂/VITARINE/ — /250MG/ — /N72179/001/APR/21,/1988/
>DLT>

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/ — /100MG/ML/ — /N80364/001/
∂ PARKE DAVIS — 50MG/ML — N80364 002
∂ — 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/ /PARKE/DAVIS/ — /200MG/ — /N84744/001/
/AA/ — /400MG/ — /N84744/002/
∂ PARKE DAVIS — 200MG — N84744 001
∂ — 400MG — N84744 002
/∂/QUANTUM/PHARMICS/ — /200MG/ — /N15426/002/
/∂/ — /400MG/ — /N15426/001/

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	
>_DLT_>	/DEY/	/0.33%/	/N71806/001/ /AUG/05,/1988/	
>_DLT_>				
>_ADD_>	∂ DEY	0.33%	N71806 001 AUG 05, 1988	
>_ADD_>				
	PROMETA			
AN	MURO	5%¤	N73340 001 MAR 30, 1992	

SYRUP; ORAL
METAPROTERENOL SULFATE

AA	BIOCRAFT	10MG/5ML¤	N72761 001 FEB 27, 1992

TABLET; ORAL
METAPROTERENOL SULFATE

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

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL

>_ADD_>	AA	EON LABS	500MG	N87283 001
>_ADD_>	AA		750MG	N87282 001
>_DLT_>	/AA/	/VITARINE/	/500MG/	/N87283/001/
>_DLT_>	/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/
	∂ 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/
	∂ PARKE DAVIS	125MG	N70331 001 APR 15, 1986
	∂	250MG	N70332 001 APR 15, 1986
	∂	500MG	N70333 001 APR 15, 1986

METHYLPREDNISOLONE

TABLET; ORAL
METHYLPREDNISOLONE

>_ADD_>	∂ EON LABS	4MG	N87341 001
>_DLT_>	/∂/VITARINE/	/4MG/	/N87341/001/

METOCLOPRAMIDE HYDROCHLORIDE

CONCENTRATE; ORAL
METOCLOPRAMIDE INTENSOL

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

METOCLOPRAMIDE HYDROCHLORIDE

METOPROLOL SUCCINATE

METOCLOPRAMIDE HYDROCHLORIDE

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
AP		EQ 10MG BASE/2ML¤	N72247 001 MAY 18, 1992

TABLET; ORAL
METOCLOPRAMIDE HCL

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

METOLAZONE

TABLET; ORAL
/DIULO/

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

INJECTABLE; INJECTION
METRONIDAZOLE

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

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

>ADD> SUSPENSION; ORAL
>ADD> MINOCIN
>ADD> + LEDERLE EQ 50MG BASE/5ML N50445 001

MINOCYCLINE HYDROCHLORIDE

>DLT>	/SYRUP;ORAL/			
>DLT>	/MINOCIN/			
>DLT>	/+//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	
/AD/	/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

NAFARELIN ACETATE

SPRAY, METERED; NASAL

SYNAREL

SYNTEX	EQ 0.2MG BASE/INH¤	N20109 001 FEB 26, 1992

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

>DLT>		/NALBUPHINE/		
>DLT>	/AP/	/LYPHOMED/	/10MG/ML/	/N70751/001/ /JUL/02,/1986/
>DLT>	/AP/		/20MG/ML/	/N70752/001/ /JUL/02,/1986/
>ADD>		∂ LYPHOMED	10MG/ML	N70751 001 JUL 02, 1986
>ADD>		∂	20MG/ML	N70752 001 JUL 02, 1986

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

NICOTROL

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

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL

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

NICOTINE POLACRILEX

GUM, CHEWING; ORAL

> ADD >	NICORETTE DS			
> ADD >	+ MERRELL DOW	4MG¤		N20066 001
> ADD >				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			
> ADD >	∂ EON LABS	50MG		N80043 001
> ADD >	∂	100MG		N80043 002
> DLT >	/∂/VITARINE/	/50MG/		/N80043/001/
> DLT >	/∂/	/100MG/		/N80043/002/

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

TABLET; ORAL

	NYSTATIN			
/AA/	/CHELSEA/	/500,000 UNITS/		/N62402/001/
				/DEC/16,/1982/
	∂ CHELSEA	500,000 UNITS		N62402 001
				DEC 16, 1982

TABLET; VAGINAL

	NYSTATIN			
/AT/	/VITARINE/	/100,000 UNITS/		/N61965/001/
	∂ VITARINE	100,000 UNITS		N61965 001

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/	> ADD >	AP	FUJISAWA	300MG/VIAL
/B*/		/15MG/	/N71662/001/ MAR/02,/1988/	> ADD >			
/B*/		/30MG/	/N71663/001/ MAR/02,/1988/	> ADD >			

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/	> ADD >			
/AA/		/EQ 250MG BASE/5ML/	/N62002/002/	> ADD >			
	∂ PARKE DAVIS	EQ 125MG BASE/5ML	N62002 001	> DLT >			
	∂	EQ 250MG BASE/5ML	N62002 002	> DLT >			

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

						FUJISAWA	300MG/VIAL

PENTAMIDINE ISETHIONATE

						ABBOTT	300MG/VIAL*

	N19264 001 OCT 16, 1984
	N73479 001 JUN 30, 1992

PERPHENAZINE

TABLET; ORAL
PERPHENAZINE

/B*/	/CHELSEA/	/8MG/	/N86766/001/ DEC/23,/1987/

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
/PHENTINE/

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

PHENDIMETRAZINE TARTRATE

					AA	PHARM BASICS	35MG
						∂	35MG
						∂	35MG

N84399 001
N83805 001
N84398 001

PHENTERMINE HYDROCHLORIDE

TABLET; ORAL
PHENTERMINE HCL

						∂ EON LABS	8MG
						∂	8MG
						/$/VITARINE/	/8MG/
						/$/	/8MG/

N85671 001
N85689 001
/N85671/001/
/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/

TABLET; ORAL
/AZOLID/
/AB/ /RHONE/POULENC/RORER//100MG/ /N87091/001/

PHENYLBUTAZONE

TABLET; ORAL
/AZOLID/
@ RHONE POULENC RORER 100MG N87091 001

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL
/PHENYTOIN/SODIUM/
/BX/ /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
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
>DLT >/AA/ /COPLEY/ /236MG/BOT;2.97GM/BOT;6.74GM/BOT;/
>DLT > /5.86GM/BOT;22.74GM/BOT¤ /N73433/001/
>DLT > /APR/28,/1992/
>ADD > AA COPLEY 236GM/BOT;2.97GM/BOT;6.74GM/BOT;
>ADD > 5.86GM/BOT;22.74GM/BOT¤ N73433 001
>ADD > APR 28, 1992

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
K-LEASE
AB ADRIA 8MEQ¤ N73398 001
JAN 28, 1992

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
MICRO-K
AB ROBINS 8MEQ N18238 001

TABLET, EXTENDED RELEASE; ORAL
KLOR-CON
>ADD > AB UPSHER SMITH 8MEQ N19123 001
>ADD > APR 17, 1986
>DLT > /BC/ /8MEQ/ /N19123/001/
>DLT > /APR/17,/1986/

KLOTRIX
BC APOTHECON 10MEQ N17850 001
/BC/ /MEAD/JOHNSON/ /10MEQ/ /N17850/001/

PRAZEPAM

CAPSULE; ORAL
CENTRAX
/AB/ /PARKE/DAVIS/ /5MG/ /N18144/001/
/AB//+/ /10MG/ /N18144/002/
+ PARKE DAVIS 10MG N18144 002
5MG N18144 001

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

PREDNISONE

TABLET; ORAL

> DLT >	/FERNISONE/			
> DLT >	/BX/ /FERNDALE/	/5MG/	/N83364/001/	
> ADD >	∂ FERNDALE	5MG	N83364 001	
	PREDNISONE			
AB	RICHLYN	5MG		
/BX/		/5MG/	N80782 001	
/BX/	/VITARINE/	/5MG/	/N80782/001/	
	∂ VITARINE	5MG	/N84774/001/	
			N84774 001	

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

	PROCAINAMIDE HCL			
/AB/	/BOLAR/	/250MG/	/N88533/001/	
/AB/		/500MG/	/DEC 03, 1984/	
/AB/		/750MG/	/N88534/001/	
	∂ BOLAR	250MG	/DEC 03, 1984/	
	∂	500MG	/N88535/001/	
	∂	750MG	/NOV 03, 1984/	
			N88533 001	
			DEC 03, 1984	
			N88534 001	
			DEC 03, 1984	
			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;/			
/B*/	/DURAMED/	/EQ/5MG/BASE/	/N89484/001/	
/B*/		/EQ/10MG/BASE/	/JAN/20,/1987/	
/B*/		/EQ/25MG/BASE/	/N89485/001/	
	∂ DURAMED	EQ 5MG BASE	/JAN/20,/1987/	
	∂	EQ 10MG BASE	/N89486/001/	
	∂	EQ 25MG BASE	/JAN/20,/1987/	
			N89484 001	
			JAN 20, 1987	
			N89485 001	
			JAN 20, 1987	
			N89486 001	
			JAN 20, 1987	

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

	PROMETHAZINE HCL			
> ADD >	∂ EON LABS	25MG	N85146 001	
> ADD >	∂	50MG	N85146 002	
> DLT >	/∂/VITARINE/	/25MG/	/N85146/001/	
> DLT >	/∂/	/50MG/	/N85146/002/	

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

	PROPOXYPHENE HCL			
/AA/	/VITARINE/	/32MG/	/N84014/001/	
/AA/		/65MG/	/N83688/001/	
/AA/		/65MG/	/N83870/002/	
/AA/		/65MG/	/N86495/001/	
	∂ VITARINE	32MG	N84014 001	
	∂	65MG	N83688 001	
	∂	65MG	N83870 002	
	∂	65MG	N86495 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

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

PYRAZINAMIDE

TABLET; ORAL
PYRAZINAMIDE

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

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/
ə LEDERLE	50MG;0.125MG	N13927 001

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

ə ELKINS SINN	200MG	N83622 001
/ə/QUANTUM/PHARMICS/	/200MG/	/N83622/001/

RAUWOLFIA SERPENTINA

TABLET; ORAL
/RAUVERID/

/BP/	/FOREST/PHARMS/	/50MG/	/N09255/008/
	WOLFINA		
	ə 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/

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION
RITODRINE HCL

>DLT>/AB/	/LYPHOMED/	/10MG/ML/	/N71188/001/ /JUL/23,/1987/
>DLT>			
>DLT>/AB/		/15MG/ML/	/N71189/001/ /JUL/23,/1987/
>DLT>			
>ADD>	ə LYPHOMED	10MG/ML	N71188 001 JUL 23, 1987
>ADD>			
>ADD>	ə	15MG/ML	N71189 001 JUL 23, 1987
>ADD>			

SODIUM CHLORIDE

INJECTABLE; INJECTION

> DLT > /SODIUM/CHLORIDE/23.4%/IN/PLASTIC/CONTAINER/ /N19329/001/
> DLT > /LYPHOMED/ /234MG/ML/ /APR/22,/1987/
> DLT >
> ADD > @ LYPHOMED 234MG/ML N19329 001
> ADD > 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

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION

SUCCINYLCHOLINE CHLORIDE

/INTL/MEDICATION/ /100MG/VIAL/ /N85400/001/
/FEB/04,/1982/

@ INTL MEDICATION 100MG/VIAL N85400 001
FEB 04, 1982

/SULFABENZAMIDE;/SULFACETAMIDE;/SULFATHIAZOLE/

/CREAM;/VAGINAL/

/SULTRIN/

/JOHNSON/RW/ /3.72;2.86;3.42%/ /N85794/001/

/TABLET;/VAGINAL/

/SULTRIN/

/JOHNSON/RW/ /184MG;143.75MG;172.5MG/ /N85794/002/

/TRIPLE/SULFA/

/3/FOUGERA/ /184MG;143.75MG;172.5MG/ /N88463/001/
/JAN/03,/1985/

/3/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/ /N86607/001/
/JUN/09,/1986/

/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/

@ FOREST PHARMS 500MG N80273 001

SULFAMETHIZOLE

TABLET; ORAL
THIOSULFIL
/AB//+//WYETH/AYERST/ /500MG/ /N08565/004/
+ WYETH AYERST 500MG N08565 004

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/ /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
SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH
/AB/ /MARTEC/ /800MG;160MG/ /N72417/001/
/DEC/07/1988/
∂ MARTEC 800MG;160MG N72417 001
DEC 07, 1988

SULFASALAZINE

TABLET; ORAL
SULFASALAZINE
>ADD> ∂ EON LABS 500MG N86184 001
>DLT> /∂/VITARINE/ /500MG/ /N86184/001/

SULFISOXAZOLE

TABLET; ORAL
/SULFALAR/
/AB/ /PARKE/DAVIS/ /500MG/ /N84955/001/
∂ PARKE DAVIS 500MG N84955 001

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

>ADD> INJECTABLE; INJECTION
>ADD> RBC-SCAN
>ADD> CADEMA N/A¤ N20063 001
>ADD> JUN 11, 1992

TEMAFLOXACIN HYDROCHLORIDE

TABLET; ORAL
OMNIFLOX
+ ABBOTT EQ 600MG BASE¤ N20043 004
JAN 30, 1992
EQ 400MG BASE¤ N20043 003
JAN 30, 1992

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	

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
/DOXYCYCLINE/

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

TETRACYCLINE HYDROCHLORIDE

/INJECTABLE;/INJECTION/
/ACHROMYCIN/

/AP/	/LEDERLE/	/100MG/VIAL/	/N50267/002/		
/AP/		/100MG/VIAL/	/N50276/001/	>ADD>	
/AP/		/250MG/VIAL/	/N50267/003/	>ADD>	
				>DLT>	
	/TETRACYN/			>DLT>	
/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	
	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/	

TABLET, EXTENDED RELEASE; ORAL
T-PHYL

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

>ADD>				
>ADD>	AA	ROXANE	EQ 5MG BASE/ML*	N73494 001 JUN 30, 1992
>ADD>				

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/
	∂ PHARM BASICS	5MG	N72001 001 JAN 10, 1989
	∂	10MG	N72002 001 JAN 10, 1989
	∂	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/
	∂ PHARM BASICS	100MG	N71355 001 JAN 11, 1988
	∂	250MG	N70168 001 APR 02, 1986
	∂	500MG	N70169 001 APR 02, 1986

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

/AB/	/PARKE/DAVIS/	/500MG/	/N86047/001/
	∂ PARKE DAVIS	500MG	N86047 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

TOLMETIN SODIUM

CAPSULE; ORAL

	TOLMETIN SODIUM			
AB	LEMMON	EQ 400MG BASE*	N73519 001	MAY 29, 1992
AB	PUREPAC	EQ 400MG BASE*	N73308 001	JAN 24, 1992

TABLET; ORAL

		TOLECTIN 600			
> ADD >	AB	+ JOHNSON RW	EQ 600MG BASE	N17628 002	MAR 08, 1989
> ADD >					
		TOLMETIN SODIUM			
> ADD >	AB	PUREPAC	EQ 600MG BASE*	N73527 001	JUN 30, 1992
> ADD >					

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

	TRAZODONE HCL			
/B*/	/PHARM/BASICS/	/50MG/	/N70491/001/	/APR/29,/1987/
/B*/		/100MG/	/N70492/001/	/APR/29,/1987/
	∂ PHARM BASICS	50MG	N70491 001	APR 29, 1987
	∂	100MG	N70492 001	APR 29, 1987

TRICHLORMETHIAZIDE

TABLET; ORAL

	TRICHLORMETHIAZIDE			
/BP/	/VITARINE/	/4MG/	/N86171/001/	
	∂ VITARINE	4MG	N86171 001	

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/
	∂ PHARM BASICS	EQ 25MG BASE	N71283 001	DEC 08, 1987
	∂	EQ 50MG BASE	N71284 001	DEC 08, 1987
	∂	EQ 100MG BASE	N71285 001	DEC 08, 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			
	∂ LEMMON	3.7%;2.86%;3.42%	N88821 001	NOV 09, 1987

TABLET; VAGINAL

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

TABLET; VAGINAL
SULTRIN
JOHNSON RW 184MG;143.75MG;172.5MG N05794 002

TRIPLE SULFA (SULFABENZAMIDE;SULFACETAMIDE;SULFATHIAZOLE)

TABLET; VAGINAL
TRIPLE SULFA
∂ FOUGERA 184MG;143.75MG;172.5MG N88463 001 JAN 03, 1985
∂ PHARMADERM 184MG;143.75MG;172.5MG N88462 001 JAN 03, 1985

TRISULFAPYRIMIDINES

SUSPENSION; ORAL
/SULFALOID/
/AB/ /FOREST/PHARMS/ /500MG/5ML/ /N60100/001/
∂ FOREST PHARMS 500MG/5ML N80100 001

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/ >ADD>
/B*/ /120MG/ /N70422/001/ /SEP/17,/1986/ >ADD>
/AB/ /PARKE/DAVIS/ /80MG/ /N70340/001/ /AUG/20,/1986/ >ADD>
/AB/ /120MG/ /N70341/001/ /AUG/20,/1986/ >ADD>
∂ PARKE DAVIS 80MG N70340 001 AUG 20, 1986
∂ 120MG N70341 001 AUG 20, 1986

VITAMIN A

CAPSULE; ORAL
AQUASOL A
AA ASTRA 50,000 USP UNITS N83080 001
25,000 USP UNITS N83080 002
/AB/ /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
/S/QUANTUM/PHARMICS/ /EQ/50,000/UNITS/BASE/ /N85479/001/

WARFARIN SODIUM

TABLET; ORAL
/WARFARIN/SODIUM/
/B*/ /PHARM/BASICS/ /2MG/ /N88719/001/ /JUN/27,/1985/
/B*/ /2.5MG/ /N88720/001/ /AUG/06,/1985/
/B*/ /5MG/ /N88721/001/ /JUL/02,/1985/
∂ PHARM BASICS 2MG N88719 001 JUN 27, 1985
∂ 2.5MG N88720 001 AUG 06, 1985
∂ 5MG N88721 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

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
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
/S/CHESEBROUGH/PONDS/ /1.2%/ /N19518/001/
/JUN/03/1987/
CHESEBROUGH PONDS 1.2% N19518 001
JUN 03, 1987

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 6 / JAN '92 - JUN '92

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

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 CORPORATION
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: 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: 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
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

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ANARITIDE ACETATE TRADE: AURICULIN	IMPROVEMENT OF EARLY RENAL ALLOGRAFT FUNCTION FOLLOWING RENAL TRANSPLANTATION.	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: CYSTIC FIBROSIS GENE THERAPY TRADE: NOT ESTABLISHED	TREATMENT OF CYSTIC FIBROSIS.	GENZYME CORPORATION
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: HUMAN THYROID STIMULATING HORMONE (TSH) TRADE: THYROGEN	AS AN ADJUNCT IN THE DIAGNOSIS OF THYROID CANCER.	GENZYME CORPORATION
GENERIC: L-BACLOFEN TRADE: NEURALGON	TREATMENT OF INTRACTABLE SPASTICITY IN CHILDREN WITH CEREBRAL PALSY.	WTD, INC
GENERIC: LIOTHYRONINE SODIUM TRADE: TRIOSTAT*/**	TREATMENT OF MYXEDEMA COMA/PRE-COMA. [DEC 31, 1998]	SMITHKLINE BEECHAM

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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
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: 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 JUNE 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 278, 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/LEVODOPA (TABLET)	JUN 19, 1992	
CIMETIDINE (TABLET)	JUN 12, 1992	
DIFLUNISAL (TABLET)	MAY 16, 1992	
DILTIAZEM HYDROCHLORIDE (TABLET)	MAY 16, 1992	
GEMFIBROZIL (CAPSULE AND TABLET)	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	
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 P0153/ CP1	MIKART	NEW STRENGTH	APPROVED JUN 03, 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

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
	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
>ADD>	20075 001	BACLOFEN; LIORESAL INTRATHECAL				ODE	JUN 17, 1999
>ADD>	20075 002	BACLOFEN; LIORESAL INTRATHECAL				ODE	JUN 17, 1999
	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
>ADD>	19002 001	BEPRIDIL HYDROCHLORIDE; VASCOR	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
>ADD>	19002 002	BEPRIDIL HYDROCHLORIDE; VASCOR	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
>ADD>	19002 003	BEPRIDIL HYDROCHLORIDE; VASCOR	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
	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
	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

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
	19858 001	CIPROFLOXACIN; CIPRO IN SODIUM CHLORIDE 0.9%	4957922	SEP 18, 2007			
			4808583	FEB 28, 2006			
			4705789	NOV 10, 2004			
	19537 002	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002		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	U-36	NCE	OCT 22, 1992
	20037 001	DICLOFENAC SODIUM; VOLTAREN	4670444	OCT 01, 2002		NDF	DEC 31, 1993
	20027 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM	4960799	OCT 02, 2007		NDF	MAR 28, 1994
						NCE	NOV 05, 1992
	20027 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM				NCE	NOV 05, 1992
	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
	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
>ADD>	20180 001	FINASTERIDE; PROSCAR	4760071	JUL 26, 2005			
>ADD>			4377584	MAR 22, 2000		NCE	JUN 19, 1997
	20038 001	FLUDARABINE PHOSPHATE; FLUDARA	4357324	NOV 02, 2001		NCE	APR 18, 1996
	20068 001	FOSCARNET SODIUM; FOSCAVIR	4771041	JUL 29, 1997			
			4665062	JUL 29, 1997			
			4339445	JUL 29, 1997			
			4215113	JUL 29, 1997		NCE	SEP 27, 1996

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	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
>DLT>	~~19661 001~~	~~GANCICLOVIR SODIUM; CYTOVENE~~				~~ODE~~	~~JUN 23, 1996~~
	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
	19967 001	HALOBETASOL PROPIONATE; ULTRAVATE				D-1	DEC 31, 1994
	19968 001	HALOBETASOL PROPIONATE; ULTRAVATE				D-1	DEC 31, 1994
	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
>ADD>	19710 004	IOVERSOL; OPTIRAY 300	4396598	OCT 26, 2002	U-61	NS	JAN 22, 1995
>ADD>	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

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

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
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
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			
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

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
	20005 001	NICARDIPINE HYDROCHLORIDE; CARDENE SR				NDF	FEB 21, 1995
	20005 002	NICARDIPINE HYDROCHLORIDE; CARDENE SR				NDF	FEB 21, 1995
	20005 003	NICARDIPINE HYDROCHLORIDE; CARDENE SR				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
	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
>ADD>	20064 001	NITROFURANTOIN; MACROBID	4798725	JAN 17, 2006			
>ADD>			4772473	SEP 20, 2005		NDF	DEC 24, 1994
			4551456	NOV 05, 2002	U-57		
	19757 001	NORFLOXACIN; CHIBROXIN	4382892	MAY 10, 2000		NCE	DEC 28, 1995
	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%	4559330	AUG 04, 2004	U-58	NCE	JUL 31, 1995
	19715 001	OLSALAZINE SODIUM; DIPENTUM					

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	19775 001	PRAZOSIN HYDROCHLORIDE; MINIPRESS XL	5082668	SEP 16, 2003			
>ADD>			4783337	SEP 16, 2003			
>ADD>			4765989	SEP 16, 2003			
>ADD>			4612008	SEP 16, 2003			
>ADD>			4327725	MAY 04, 1999			
>ADD>			4092315	MAY 30, 1995		NDF	JAN 29, 1995
>ADD>	19775 002	PRAZOSIN HYDROCHLORIDE; MINIPRESS XL	5082668	SEP 16, 2003			
>ADD>			4783337	SEP 16, 2003			
>ADD>			4765989	SEP 16, 2003			
>ADD>			4612008	SEP 16, 2003			
>ADD>			4327725	MAY 04, 1999			
>ADD>			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
>ADD>	18703 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4521431	JUN 04, 2002		I-75	MAY 19, 1995
>ADD>	18703 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	4521431	JUN 04, 2002		I-75	MAY 19, 1995
>ADD>	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
	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
	19614 003	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993
>ADD>	20199 001	ZALCITABINE; HIVID				NCE	JUN 19, 1997
>ADD>						ODE	JUN 19, 1999
>ADD>	20199 002	ZALCITABINE; HIVID				NCE	JUN 19, 1997
>ADD>						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

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
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

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