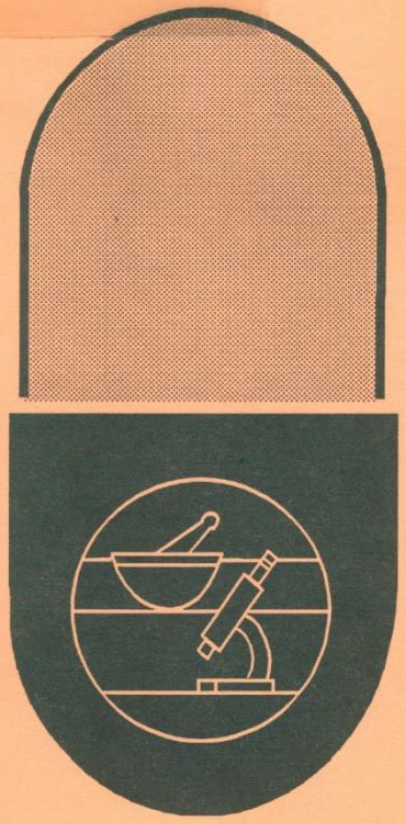
CUMULATIVE SUPPLEMENT 4

JAN'92-APR'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

APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION

Cumulative Supplement 4

April 1992

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION

CUMULATIVE SUPPLEMENT 4

APRIL 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 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)

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	9258	9473		
SINGLE SOURCE	2187 (22.8%)	2222 (23.4%)		
MULTISOURCE	7397 (77.2%)	7251 (76.6%)		
THERAPEUTICALLY EQUIVALENT	6580 (68.7%)	6510 (68.7%)		
NOT THERAPEUTICALLY EQUIVALENT	664 (6.9%)	592 (6.3%)		
EXCEPTIONS[1]	153 (1.6%)	149 (1.6%)		
NEW MOLECULAR ENTITIES APPROVED	--	4		
NUMBER OF APPLICANTS	430	437		

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

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

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

> ADD > 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
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

> ADD > AA	MYLAN	650MG;65MG	N83978 001	
> ADD >	∂	325MG;32MG	N83689 001	
> DLT >	PROPOXYPHENE HCL W/ APAP			
> DLT > AA	MYLAN	650MG;65MG	N83978 001	
> DLT >		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

> ADD > AN	CETUS BEN VENUE	10%¤	N72323 001	APR 30, 1992
> ADD > 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

> ADD > VENTOLIN

> ADD > 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

ALLOPURINOL

TABLET; ORAL
ALLOPURINOL

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

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	>DLT>	
@		25MG	N88698 001 SEP 25, 1984	>DLT>	
@		50MG	N88699 001 SEP 25, 1984	>ADD>	
@		75MG	N88700 001 SEP 25, 1984	>ADD>	
@		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/	>ADD>	
@ 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

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

	PHARMA TEK	50MG/VIAL¤	AP	>ADD>	N63206 001 APR 29, 1992

AMPICILLIN SODIUM

INJECTABLE; INJECTION

POLYCILLIN-N

>DLT>	/AP/	/BRISTOL/	/EQ 125MG BASE/VIAL/	/N50309/001/
>DLT>	/AP/		/EQ 250MG BASE/VIAL/	/N50309/002/
>DLT>	/AP/		/EQ 500MG BASE/VIAL/	/N50309/003/
>DLT>	/AP/		/EQ 1GM BASE/VIAL/	/N50309/004/
>DLT>	/AP/		/EQ 2GM BASE/VIAL/	/N50309/005/
>ADD>		ə BRISTOL	EQ 125MG BASE/VIAL	N50309 001
>ADD>		ə	EQ 250MG BASE/VIAL	N50309 002
>ADD>		ə	EQ 500MG BASE/VIAL	N50309 003
>ADD>		ə	EQ 1GM BASE/VIAL	N50309 004
>ADD>		ə	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/	
	ə PARKE DAVIS	EQ 250MG BASE	N62041 001	
	ə	EQ 500MG BASE	N62041 002	

POLYCILLIN

>DLT>	/AB/	/BRISTOL/	/EQ 250MG BASE/	/N50310/001/
>DLT>	/AB/		/EQ 500MG BASE/	/N50310/002/
>ADD>		ə BRISTOL	EQ 250MG BASE	N50310 001
>ADD>		ə	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/	
	ə PARKE DAVIS	EQ 125MG BASE/5ML	N62030 001	
	ə	EQ 250MG BASE/5ML	N62030 002	

POLYCILLIN

>DLT>	/AB/	/BRISTOL/	/EQ 100MG BASE/ML/	/N50308/004/
>DLT>	/AB/		/EQ 100MG BASE/ML/	/N61394/001/
>ADD>		ə BRISTOL	EQ 100MG BASE/ML	N50308 004
>ADD>			EQ 100MG BASE/ML	N61394 001

AMPICILLIN/AMPICILLIN TRIHYDRATE; PROBENECID

POWDER FOR RECONSTITUTION; ORAL

POLYCILLIN-PRB

>DLT>	/AB/	/BRISTOL/	/EQ 3.5GM BASE/BOT/	
>DLT>			/1GM/BOT/	/N50457/001/
>ADD>		ə BRISTOL	EQ 3.5GM BASE/BOT;	
>ADD>			1GM/BOT	N50457 001

ATENOLOL

TABLET; ORAL

ATENOLOL

	AB	APOTHECON	50MG	N73317 001 MAR 20, 1992
	AB		100MG	N73318 001 MAR 20, 1992
>ADD>	AB	LEDERLE	25MG	N74099 001 APR 28, 1992
>ADD>	AB	MYLAN	50MG	N73456 001 JAN 24, 1992
	AB		100MG	N73457 001 JAN 24, 1992

TENORMIN

>ADD>	AB	ICI	25MG	N18240 004 APR 09, 1990
>ADD>				

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

/AB/	/CHELSEA/	/0.025MG;2.5MG/	/N85876/001/	
	ə CHELSEA	0.025MG;2.5MG	N85876 001	

DIPHENOXYLATE HCL W/ ATROPINE SULFATE

/AB/	/VITARINE/	/0.025MG;2.5MG/	/N86173/001/	
	ə VITARINE	0.025MG;2.5MG	N86173 001	

>DLT> /AZITHROMYCIN/

>DLT>	/CAPSULE;ORAL/		
>DLT>	/ZITHROMAX/		
>DLT>	/+//PFIZER/	/250MG/	/N50676/001/
>DLT>			/N50676/002/ 01;/1991/

>ADD> **AZITHROMYCIN DIHYDRATE**

>ADD> CAPSULE; ORAL
>ADD> ZITHROMAX
>ADD> + PFIZER — EQ 250MG BASE — N50670 001 — NOV 01, 1991
>ADD>

BACLOFEN

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

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

>ADD> 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

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

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE

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

BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM

/AA/	/VITARINE/	/30MG/	/N85934/001/	
∂	VITARINE	30MG	N85934 001	

BUTABARBITAL SODIUM

TABLET; ORAL

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

> ADD >	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

> ADD >	AP	MCGAW	33MG/100ML;30MG/100ML; 860MG/100ML¤	N20002 001 APR 17, 1992

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

/B*/	/PHARM/BASICS/	/200MG/	/N70300/001/ /MAY/15,/1986/	
∂	PHARM BASICS	200MG	N70300 001 MAY 15, 1986	

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

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

> ADD > **CEFADROXIL/CEFADROXIL HEMIHYDRATE**

CAPSULE; ORAL

> ADD > **CEFADROXIL**

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

TABLET; ORAL

> ADD > **CEFADROXIL**

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

CEFTAZIDIME

INJECTABLE; INJECTION

/CEPTAZ/

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

CEFTAZIDIME (ARGININE FORMULATION)

INJECTABLE; INJECTION

CEPTAZ

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

PENTACEF

AP	SMITHKLINE BEECHAM	1GM/VIAL¤	N64006 001 MAR 31, 1992
AP		2GM/VIAL¤	N64006 002 MAR 31, 1992
AP		10GM/VIAL¤	N64008 002 MAR 31, 1992
		6GM/VIAL¤	N64008 001 MAR 31, 1992

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN

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

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

/AA/	/PARKE/DAVIS/	/5MG/	/N85163/001/	>DLT>	
/AB/		/10MG/	/N84598/001/	>DLT>	
/AB/		/25MG/	/N85164/001/	>DLT>	
∂ PARKE DAVIS		5MG	N85163 001	>ADD>	
∂		10MG	N84598 001	>ADD>	
∂		25MG	N85164 001	>ADD>	
/AA/	/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

/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
/AB/	/VITARINE/	/250MG/	/N84669/001/	
∂ VITARINE		250MG	N84669 001	

CHLORTHALIDONE

TABLET; ORAL

THALITONE

>DLT>/AB/	/BOEHRINGER/INGELHEIM/	/25MG/	/N88051/001/	/NOV/12,/1982/	
>DLT>		/15MG/	/N19574/001/	/DEC/20,/1988/	
>ADD>	BX HORUS	25MG	N88051 001	NOV 12, 1982	
>ADD>		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

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

>ADD > AA COPLEY EQ 0.5MG BASE/5ML* N73095 001 APR 21, 1992

>ADD >

TAVIST

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

>ADD >

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

CLIOQUINOL; NYSTATIN

>DLT > /OINTMENT;/TOPICAL/

>DLT > /NYSTAFORM/

>DLT > /MILES/ /10MG/GM;/

>DLT > /100,000/UNITS/GM/ /N50235/001/

>ADD > ə MILES 10MG/GM; 100,000 UNITS/GM N50235 001

>ADD >

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/

ə PHARM BASICS 3.75MG N71242 001 MAY 20, 1987

ə 7.5MG N71243 001 MAY 20, 1987

ə 15MG N71244 001 MAY 20, 1987

CLOTRIMAZOLE

CREAM; TOPICAL

LOTRIMIN

>DLT >/AT//+//SCHERING/ /1%/ /N17619/001/

>ADD > BX + SCHERING 1% N17619 001

MYCELEX

>DLT >/AT/ /MILES/ /1%/ /N18183/001/

>ADD > BX MILES 1% N18183 001

COLCHICINE; PROBENECID

TABLET; ORAL

/PROBEN-C/

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

ə CHELSEA 0.5MG;500MG N85552 001

CYANOCOBALAMIN

INJECTABLE; INJECTION

CYANOCOBALAMIN

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

ə LUITPOLD 0.03MG/ML N80668 001

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CYCLOPENTOLATE HCL

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

ə SOLA BARNES HIND 1% N84863 001

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

	DESIPRAMINE HCL			
/B*/	/PHARM/BASICS/	/25MG/	/N71864/001/	/SEP/09,/1987/
/B*/		/50MG/	/N71865/001/	/SEP/09,/1987/
/B*/		/75MG/	/N71866/001/	/SEP/09,/1987/
/B*/		/100MG/	/N71867/001/	/SEP/09,/1987/
	∂ 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

DESONIDE

LOTION; TOPICAL

	DESOWEN		
	OWEN GALDERMA	0.05%¤	N72354 001 JAN 24, 1992

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

	DIETHYLPROPION HCL			
/AA/	/VITARINE/	/25MG/	/N85916/001/	
	∂ VITARINE	25MG	N85916 001	

DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION

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

DIPYRIDAMOLE

TABLET; ORAL

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

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL

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

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

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

DOXAPRAM HYDROCHLORIDE

INJECTABLE; INJECTION

	DOPRAM		
AP	ROBINS	20MG/ML	N14879 001

DOXAPRAM HYDROCHLORIDE

INJECTABLE; INJECTION
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/
	ə INTERPHARM	EQ 50MG BASE¤	N62763 001	SEP 02, 1988
	ə	EQ 100MG BASE¤	N62763 002	SEP 02, 1988

TABLET; ORAL
DOXYCYCLINE HYCLATE

/B*/	/INTERPHARM/	/EQ/100MG/BASE¤/	/N62764/001/	/SEP/02,/1988/
	ə INTERPHARM	EQ 100MG BASE¤	N62764 001	SEP 02, 1988

DROPERIDOL

INJECTABLE; INJECTION
DROPERIDOL

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

ERGOLOID MESYLATES

TABLET; SUBLINGUAL
/ALKERGOT/

/AA/	/VITARINE/	/0.5MG/	/N85153/001/	
/AA/		/1MG/	/N87417/001/	
	ə VITARINE	0.5MG	N85153 001	
	ə	1MG	N87417 001	

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL
/ERGOMAR/

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

ERYTHROMYCIN

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

FENOPROFEN CALCIUM

CAPSULE; ORAL
FENOPROFEN CALCIUM

>DLT >/AB/	/HALSEY/	/EQ 200MG BASE/	/N72355/001/ /JUL/05,/1988/
>DLT >			
>DLT >/AB/		/EQ 300MG BASE/	/N72356/001/ /JUL/05,/1988/
>DLT >			
>ADD >	a HALSEY	EQ 200MG BASE	N72355 001 JUL 05, 1988
>ADD >			
>ADD >	a	EQ 300MG BASE	N72356 001 JUL 05, 1988
>ADD >			

TABLET; ORAL
FENOPROFEN CALCIUM

>DLT >/AB/	/HALSEY/	/EQ 600MG BASE/	/N72357/001/ /JUL/05,/1988/
>DLT >			
>ADD >	a HALSEY	EQ 600MG BASE	N72357 001 JUL 05, 1988
>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/
	a PHARM BASICS	15MG	N70562 001 JUL 09, 1987
	a	30MG	N70563 001 JUL 09, 1987

FOLIC ACID

TABLET; ORAL
FOLIC ACID

>DLT >/AA/	/LILLY/	/1MG/	/N06135/003/
>ADD >	a LILLY	1MG	N06135 003
/AA/	/VITARINE/	/1MG/	/N84472/001/
	a VITARINE	1MG	N84472 001

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE

/AP/	/LYPHOMED/	/10MG/ML/	/N18507/001/ /JUL/30,/1982/
	a 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/
	a CHELSEA	20MG	N18369 001 MAY 14, 1982
	a	40MG	N18369 002 MAY 14, 1982
/AB/	/VITARINE/	/40MG/	/N18750/002/ /JUL/30,/1984/
	a VITARINE	40MG	N18750 002 JUL 30, 1984

GLYBURIDE

TABLET; ORAL

		GLUBATE		
>ADD>	BX	HOECHST ROUSSEL	1.5MG¤	N20055 001 APR 17, 1992
>ADD>	BX		3MG¤	N20055 002 APR 17, 1992
		GLYNASE		
>ADD>	BX	UPJOHN	1.5MG	N20051 001 MAR 04, 1992
>ADD>	BX +		3MG	N20051 002 MAR 04, 1992

HEPARIN SODIUM

INJECTABLE; INJECTION

		HEPARIN LOCK FLUSH		
/AP/	/LUITPOLD/	/10 UNITS/ML/	/N89063/001/ /OCT/09,/1985/	
/AP/		/100 UNITS/ML/	/N89064/001/ /OCT/09,/1985/	
	ə LUITPOLD	10 UNITS/ML	N89063 001 OCT 09, 1985	
	ə	100 UNITS/ML	N89064 001 OCT 09, 1985	
		HEPARIN SODIUM		
/AP/	/LUITPOLD/	/1,000 UNITS/ML/	/N87452/001/ /OCT/31,/1983/	
	ə LUITPOLD	1,000 UNITS/ML	N87452 001 OCT 31, 1983	
		HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5%		
/3/	/ABBOTT/	/10,000/UNITS/100ML/	/N18911/006/ /JAN/30,/1985/	
AP	ABBOTT	10,000 UNITS/100ML	N18911 006 JAN 30, 1985	

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

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

		HYDRALAZINE HCL		
/AA/	/VITARINE/	/50MG/	/N85088/001/	
	ə VITARINE	50MG	N85088 001	

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

		/HYDRAP-ES/		
/BP/	/VITARINE/	/25MG;15MG;0.1MG/	/N84876/001/	
	ə VITARINE	25MG;15MG;0.1MG	N84876 001	

HYDRALAZINE HYDROCHLORIDE; RESERPINE

TABLET; ORAL

		/DRALSERP/		
/BP/	/VITARINE/	/25MG;0.1MG/	/N84617/001/	
	ə 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

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

		/HYDRO-SERP/'25'/		
/BP/	/VITARINE/	/25MG;0.125MG/	/N84827/001/	
	ə VITARINE	25MG;0.125MG	N84827 001	
		/HYDRO-SERP/'50'/		
/BP/	/VITARINE/	/50MG;0.125MG/	/N85213/001/	
	ə VITARINE	50MG;0.125MG	N85213 001	

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL

MAXZIDE-25

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

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

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

HYDROCORTISONE

LOTION; TOPICAL

/CORT-DOME/

>DLT >				/N089895/003/
>DLT >	/AT/	/MILES/	/0.5%/	/N089895/003/
>DLT >	/AT/		/1%/	/N089895/001/
>ADD >		∂ MILES	0.5%	N09895 003
>ADD >		∂	1%	N09895 001

SOLUTION; TOPICAL

TEXACORT

>ADD >		GENDERM	2.5%¤	N81271 001
>ADD >				APR 17, 1992

HYDROFLUMETHIAZIDE; RESERPINE

TABLET; ORAL

/HYDROFLUMETHIAZIDE AND RESERPINE/

/B*/	/PHARM BASICS/	/50MG;0.125MG/	/N088195/001/	
			/OCT 26, 1983/	
	∂ 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

/B*/	/PHARM BASICS/	/10MG/	/N089121/001/	
			/MAR 20, 1986/	
/B*/		/25MG/	/N089122/001/	
			/MAR 20, 1986/	
/B*/		/50MG/	/N089123/001/	
			/MAR 20, 1986/	
	∂ PHARM BASICS	10MG	N89121 001	
			MAR 20, 1986	
	∂	25MG	N89122 001	
			MAR 20, 1986	
	∂	50MG	N89123 001	
			MAR 20, 1986	

IBUPROFEN

TABLET; ORAL

IBUPROFEN

/AB/	/SUPERPHARM/	/600MG/	/N070709/001/	
			/APR 25, 1986/	
	∂ SUPERPHARM	600MG	N70709 001	
			APR 25, 1986	

IOFETAMINE HYDROCHLORIDE I-123

INJECTABLE; INJECTION

SPECTAMINE

>ADD >		IMP	1 MCI/ML	N19432 001
>ADD >				DEC 24, 1987
>DLT >		/MEDI PHYSICS/	/1 MCI/ML/	/N019432/001/
>DLT >				/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/	/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	> DLT >		
	ə	0.17%	N87390 001	> ADD >		
	ə	0.25%	N88188 001	> DLT >		
			DEC 03, 1982	> ADD >		
	ə	1%	N06763 001			

ISOETHARINE HCL S/F

/AN/	/DEY/	/0.17%/	/N89819/001/ /NOV/22,/1988/	> ADD >		
	DEY	0.17%	N89819 001 NOV 22, 1988	> ADD >		

ISOPROTERENOL HYDROCHLORIDE

SOLUTION; INHALATION
ISOPROTERENOL HCL

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

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/G/		/500MG/	/N16913/002/			
		/100MG/	/N16913/003/	> ADD >	AB	LEMMON 2MG¤ N73192 001 APR 30, 1992
		/250MG/	/N16913/001/	> ADD >		

LEVODOPA

CAPSULE; ORAL
DOPAR

+	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			
		/2GM/VIAL/	/N18543/002/			
	ə	2GM/VIAL	N18543 002			

LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER

> ADD >	AP	MCGAW	200MG/100ML¤	N19830 002 APR 08, 1992		
> ADD >						

LIDOCAINE HCL 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER

> ADD >	AP	MCGAW	400MG/100ML¤	N19830 003 APR 08, 1992		
> ADD >						

LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER

> ADD >	AP	MCGAW	800MG/100ML¤	N19830 004 APR 08, 1992		
> ADD >						

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

> ADD >	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	

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/ /AP/	/PARKE/DAVIS/	/50MG/ML/ /100MG/ML/	/N80364/002/ /N80364/001/
∂ PARKE DAVIS		50MG/ML	N80364 002
∂		100MG/ML	N80364 001

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
MEPERIDINE HCL

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/ /AA/	/PARKE/DAVIS/	/200MG/ /400MG/	/N84744/001/ /N84744/002/
	∂ PARKE DAVIS	200MG	N84744 001
	∂	400MG	N84744 002
	/3/QUANTUM/PHARMICS/	/200MG/	/N15426/002/
	/3/	/400MG/	/N15426/001/

MESALAMINE

TABLET, DELAYED RELEASE; ORAL
ASACOL

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

METAPROTERENOL SULFATE

SOLUTION; INHALATION
PROMETA

AN	MURO	5%¤	N73340 001 MAR 30, 1992

SYRUP; ORAL
METAPROTERENOL SULFATE

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

METAPROTERENOL SULFATE

SYRUP; ORAL
METAPROTERENOL SULFATE

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

METOCLOPRAMIDE HYDROCHLORIDE

METAPROTERENOL SULFATE

TABLET; ORAL
METAPROTERENOL SULFATE

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

METHYCLOTHIAZIDE

TABLET; ORAL
METHYCLOTHIAZIDE

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

METHYLDOPA

TABLET; ORAL
METHYLDOPA

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

METHYLPREDNISOLONE

TABLET; ORAL
METHYLPREDNISOLONE

/BP/	/VITARINE/	/4MG/	/N87341/001/
	ə VITARINE	4MG	N87341 001

METOCLOPRAMIDE HYDROCHLORIDE

CONCENTRATE; ORAL
METOCLOPRAMIDE INTENSOL

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

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL

AP	CETUS BEN VENUE	EQ 10MG BASE/2ML¤	N72155 001 MAR 30, 1992
AP		EQ 10MG BASE/2ML¤	N72244 001 MAR 30, 1992

TABLET; ORAL
METOCLOPRAMIDE HCL

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

METOLAZONE

TABLET; ORAL
/DIULO/

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

ZAROXOLYN

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

MINOXIDIL

TABLET; ORAL

	MINOXIDIL			
/B‡/	/PHARM/BASICS/	/2.5MG/	/N71537/001/ /DEC/16,/1988/	
	∂ PHARM BASICS	2.5MG	N71537 001 DEC 16, 1988	
> DLT >	/AB/ /ROYCE/	/2.5MG/	/N71799/001/ /NOV/10,/1987/	
> DLT >		/10MG/	/N71796/001/ /NOV/10,/1987/	
> DLT >	∂ ROYCE	2.5MG	N71799 001 NOV 10, 1987	
> ADD >	∂	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

NIACIN

TABLET; ORAL

	NIACIN			
> ADD > 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

> ADD >	NICOTROL			
> ADD >	+ KABI	5MG/16HR¤		N20150 001 APR 22, 1992
> ADD >	+	10MG/16HR¤		N20150 002 APR 22, 1992
> ADD >	+	15MG/16HR¤		N20150 003 APR 22, 1992
> ADD >	PROSTEP			
> ADD >	+ ELAN	11MG/24HR¤		N19983 001 JAN 28, 1992
> ADD >	+	22MG/24HR¤		N19983 002 JAN 28, 1992

NIFEDIPINE

CAPSULE; ORAL

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

NITROFURANTOIN

TABLET; ORAL

	NITROFURANTOIN			
/AB/ /AB/	/VITARINE/	/50MG/ /100MG/		/N80043/001/ /N80043/002/
	∂ VITARINE	50MG		N80043 001
	∂	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
AB + /BP/ /BP/		/EQ 10MG BASE/ /EQ 25MG BASE/		/N18013/001/ /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/
/B*/		/15MG/	/N71662/001/	/MAR/02,/1988/
/B*/		/30MG/	/N71663/001/	/MAR/02,/1988/

OXYBUTYNIN CHLORIDE

TABLET; ORAL

OXYBUTYNIN CHLORIDE				
/B*/	/PHARM/BASICS/	/5MG/	/N70746/001/	/MAR/10,/1988/
∂ PHARM BASICS		5MG	N70746 001	MAR 10, 1988

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION

PENICILLIN G POTASSIUM				
/AP/	/PARKE/DAVIS/	/1,000,000 UNITS/VIAL/	/N62003/001/	
/AP/		/5,000,000 UNITS/VIAL/	/N62003/002/	
∂ PARKE DAVIS		1,000,000 UNITS/VIAL	N62003 001	
∂		5,000,000 UNITS/VIAL	N62003 002	

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENAPAR-VK				
/AA/	/PARKE/DAVIS/	/EQ 125MG BASE/5ML/	/N62002/001/	
/AA/		/EQ 250MG BASE/5ML/	/N62002/002/	
∂ PARKE DAVIS		EQ 125MG BASE/5ML	N62002 001	
∂		EQ 250MG BASE/5ML	N62002 002	

TABLET; ORAL

PENAPAR-VK				
/AB/	/PARKE/DAVIS/	/EQ 250MG BASE/	/N62001/001/	
/AB/		/EQ 500MG BASE/	/N62001/002/	
∂ PARKE DAVIS		EQ 250MG BASE	N62001 001	
∂		EQ 500MG BASE	N62001 002	

PERPHENAZINE

TABLET; ORAL

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

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

>DLT>	/OBEZINE/			
>DLT>/AA/	/PHARM/BASICS/	/35MG/	/N83805/001/	
>DLT>/AA/		/35MG/	/N84398/001/	
>DLT>/AA/		/35MG/	/N84399/001/	

PHENDIMETRAZINE TARTRATE

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

PHENYLBUTAZONE

CAPSULE; ORAL

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

TABLET; ORAL

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

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL
/PHENYTOIN/SODIUM/
/BX/ /CHELSEA/ /100MG/ /N85894/001/
∂ CHELSEA 100MG N85894 001

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
> ADD > AA COPLEY 236MG/BOT;2.97GM/BOT;6.74GM/BOT; 5.86GM/BOT;22.74GM/BOT¤ N73433 001 APR 28, 1992

POTASSIUM CHLORIDE

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

MICRO-K
AB ROBINS 8MEQ N18238 001

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/ /VITARINE/ /5MG/ /N84773/001/
∂ VITARINE 5MG N84773 001

PREDNISONE

TABLET; ORAL
PREDNISONE
AB RICHLYN 5MG N80782 001
/BX/ /5MG/ /N80782/001/
/BX/ /VITARINE/ /5MG/ /N84774/001/
∂ VITARINE 5MG N84774 001

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PROCAINAMIDE HCL
/AB/ /BOLAR/ /250MG/ /N88533/001/ /DEC/03,/1984/
/AB/ /500MG/ /N88534/001/ /DEC/03,/1984/
/AB/ /750MG/ /N88535/001/ /NOV/03,/1984/
∂ BOLAR 250MG N88533 001 DEC 03, 1984
∂ 500MG N88534 001 DEC 03, 1984
∂ 750MG N88535 001 NOV 03, 1984

PROCAINE HYDROCHLORIDE; TETRACYCLINE HYDROCHLORIDE

INJECTABLE; INJECTION
ACHROMYCIN
AP LEDERLE 40MG/VIAL;100MG/VIAL N50267 002
AP 40MG/VIAL;100MG/VIAL N50276 001
AP 40MG/VIAL;250MG/VIAL N50267 003

PROCAINE HYDROCHLORIDE; TETRACYCLINE HYDROCHLORIDE

INJECTABLE; INJECTION

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

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

PROMETHAZINE HCL

/BP/	/VITARINE/	/25MG/	/N85146/001/	
/BP/		/50MG/	/N85146/002/	
	∂ VITARINE	25MG	N85146 001	
	∂	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/	
	∂ SUPERPHARM	10MG	N71515 001 JUN 08, 1988	
	∂	20MG	N71516 001 JUN 08, 1988	

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION

PYRIDOXINE HCL

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

QUINETHAZONE; RESERPINE

>DLT>	/TABLET;ORAL/			
>DLT>	/HYDROMOX/R/			
>DLT>	/LEDERLE/	/50MG;0.125MG/	/N13927/001/	
>ADD>	∂ LEDERLE	50MG;0.125MG	N13927 001	

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

>ADD>	∂ ELKINS SINN	200MG	N83622 001	
>DLT>	/∂/QUANTUM PHARMICS/	/200MG/	/N83622/001/	

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE
>ADD > ∂ ELKINS SINN 200MG N83622 001
>DLT > /∂/QUANTUM/PHARMICS/ /200MG/ /N83622/001/

RAUWOLFIA SERPENTINA

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

SODIUM LACTATE

INJECTABLE; INJECTION
>ADD > SODIUM LACTATE 1/6 MOLAR IN PLASTIC CONTAINER
>ADD > AP MCGAW 1.87GM/100ML¤ N20004 001
>ADD > 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

>DLT > /SULFABENZAMIDE;/SULFACETAMIDE;/SULFATHIAZOLE/

>DLT > /CREAM;/VAGINAL/
>DLT > /SULTRIN/
>DLT > /JOHNSON/RW/ /3.72;2.86%;3.42%/ /N05794/001/

>DLT > /SULFABENZAMIDE;/SULFACETAMIDE;/SULFATHIAZOLE/

>DLT > /TABLET;/VAGINAL/
>DLT > /SULTRIN/
>DLT > /JOHNSON/RW/ /186MG;143.75MG;172.5MG/ /N05794/002/

>DLT > /SULFABENZAMIDE;/SULFACETAMIDE;/SULFATHIAZOLE;/UREA/

>DLT > /CREAM;/VAGINAL/
>DLT > /GYNE-SULF/
>DLT >/AT/ /G/AND/W/ /3.72;2.862;3.422;0.642/ /N88607/001/
>DLT > /JUN/09,/1986/
>DLT > /TRIPLE SULFA/
>DLT >/AT/ /CLAY/PARK/ /3.72;2.862;3.422;0.642/ /N87285/001/
>DLT > /NOV/15,/1982/
>DLT >/AT/ /FOUGERA/ /3.72;2.862;3.422;0.642/ /N86424/001/
>DLT >/AT/ /NMC/ /3.72;2.862;3.422;0.642/ /N87864/001/
>DLT > /SEP/01,/1982/
>DLT >/AT/ /PHARMADERM/ /3.72;2.862;3.422;0.642/ /N87887/001/
>DLT > /JUL/23,/1982/
>DLT > /VAGILIA/
>DLT >/AT/ /LEMMON/ /3.72;2.862;3.422;0.642/ /N88821/001/
>DLT > /NOV/09,/1987/

SULFAMETHIZOLE

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

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

SULFAMETHOXAZOLE; TRIMETHOPRIM

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

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB	INTERPHARM	400MG;80MG	N71299 001	OCT 27, 1987
AB		800MG;160MG	N71300 001	OCT 27, 1987
AB	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

SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH

AB	MARTEC	800MG;160MG	N72417 001	DEC 07, 1988

SULFISOXAZOLE

TABLET; ORAL

SULFALAR

AB	PARKE DAVIS	500MG	N84955 001	

SULFISOXAZOLE

AB	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

> DLT >		TABLET; ORAL			
> DLT >		LOTUSATE			
> DLT >		STERLING	120MG		N09410 005
> ADD >		STERLING	120MG		N09410 005

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

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION

DELATESTRYL

> ADD >	AQ	GYNEX	200MG/ML		N09165 003
> ADD >			200MG/ML		N09165 001
> DLT >	AQ		200MG/ML		N09165 003
> DLT >			200MG/ML		N09165 001

TETRACYCLINE

SYRUP; ORAL

TETRACYCLINE

> DLT >	AB	BARRE	EQ 125MG HCL/5ML	N60633 001
> ADD >	AB	BARRE	EQ 125MG HCL/5ML	N60633 001

SULINDAC

TABLET; ORAL

SULINDAC

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

TETRACYCLINE

SYRUP; ORAL

>DLT>		/BIOCYCLINE/			
>DLT>/AB/		/BARRE/	/EQ 125MG HCL/5ML/	/N60633/001/	
>ADD>		TETRACYCLINE			
>ADD> AB		BARRE	EQ 125MG HCL/5ML	N60633 001	

TETRACYCLINE HYDROCHLORIDE

/INJECTABLE;/INJECTION/

/ACHROMYCIN/

/AP/	/LEDERLE/	/100MG/VIAL/	/N50267/002/
/AP/		/100MG/VIAL/	/N50276/001/
/AP/		/250MG/VIAL/	/N50267/003/

/TETRACYN/

/AP/	/PFIZER/	/250MG/VIAL/	/N60285/003/
/S/		/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

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

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

>DLT>/AB/	/PAR/	/150MG/	/N89764/001/	/FEB/09,/1988/
>DLT>				
>DLT>/AB/		/200MG/	/N89765/001/	/FEB/09,/1988/
>DLT>				
>ADD>	@ PAR	150MG	N89764 001	FEB 09, 1988
>ADD>				
>ADD>	@	200MG	N89765 001	FEB 09, 1988
>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	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
> ADD >	AB	GENEVA	EQ 400MG BASE*	N73462 001 APR 30, 1992
> ADD >	AB	PUREPAC	EQ 400MG BASE*	N73308 001 JAN 24, 1992

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

> ADD > TRIPLE SULFA (SULFABENZAMIDE;SULFACETAMIDE;SULFATHIAZOLE)

> ADD > CREAM; VAGINAL
> ADD > GYNE-SULF
> ADD > AT G AND W 3.7%;2.86%;3.42% N88607 001 JUN 09, 1986
> ADD >
> ADD > SULTRIN
> ADD > AT JOHNSON RW 3.7%;2.86%;3.42% N05794 001
> ADD > TRIPLE SULFA
> ADD > AT CLAY PARK 3.7%;2.86%;3.42% N87285 001 NOV 15, 1982
> ADD >
> ADD > AT FOUGERA 3.7%;2.86%;3.42% N86424 001
> ADD > AT NMC 3.7%;2.86%;3.42% N87864 001 SEP 01, 1982
> ADD >
> ADD > TRYSUL
> ADD > AT SAVAGE 3.7%;2.86%;3.42% N87887 001 JUL 23, 1982
> ADD >
> ADD > VAGILIA
> ADD > ∂ LEMMON 3.7%;2.86%;3.42% N88821 001 NOV 09, 1987
> ADD >

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

TRISULFAPYRIMIDINES

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

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL
/B*/ /CHELSEA/ /80MG/ /N70421/001/ /SEP/17,/1986/
/B*/ /120MG/ /N70422/001/ /SEP/17,/1986/
/AB/ /PARKE/DAVIS/ /80MG/ /N70340/001/ /AUG/20,/1986/
/AB/ /120MG/ /N70341/001/ /AUG/20,/1986/
∂ PARKE DAVIS 80MG N70340 001 AUG 20, 1986
∂ 120MG N70341 001 AUG 20, 1986

VITAMIN A PALMITATE

CAPSULE; ORAL
VITAMIN A
> ADD > ∂ ELKINS SINN EQ 50,000 UNITS BASE N85479 001
> DLT > /∂/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

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

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
>ADD<
>ADD<
>ADD<
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
>ADD<
>ADD<
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

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: 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.	SYNTEX-SYNERGEN NEUROSCIENCE
GENERIC: CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR TRADE: NOT ESTABLISHED	FOR CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR PROTEIN REPLACEMENT THERAPY IN CYSTIC FIBROSIS PATIENTS.	GENZYME CORPORATION

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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: SARGRAMOSTIM TRADE: LEUKINE*/**	TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANT, FOR THE PROMOTION OF EARLY ENGRAFTMENT, AND FOR THE TREATMENT OF GRAFT FAILURE AND DELAY OF ENGRAFTMENT.*/** [DEC 31, 1998] TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANTS IN PATIENTS WITH NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE AND ACUTE LYMPHOBLASTIC LEUKEMIA.*/** [MAR 05, 1998]	IMMUNEX
GENERIC: 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: DAPSONE TRADE: DAPSONE	FOR THE COMBINATION TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA IN CONJUNCTION WITH TRIMETHOPRIM.	JACOBUS PHARMACEUTICAL COMPANY
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.	MERICON INDUSTRIES, INC
GENERIC: LIOTHYRONINE SODIUM TRADE: TRIOSTAT*/**	TREATMENT OF MYXEDEMA COMA/PRE-COMA. [DEC 31, 1998]	SMITHKLINE BEECHAM
GENERIC: LOXORIBINE TRADE: NOT ESTABLISHED	TREATMENT OF COMMON VARIABLE IMMUNODEFICIENCY.	R.W. JOHNSON RESEARCH INSTITUTE
GENERIC: MELPHALAN TRADE: ALKERAN FOR INJECTION	TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA FOR WHOM ORAL THERAPY IS INAPPROPRIATE. FOR USE IN HYPERTHERMIC REGIONAL LIMB PERFUSION TO TREAT METASTATIC MELANOMA OF THE EXTREMITY.	BURROUGHS WELLCOME COMPANY

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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: SODIUM MONOMERCAPTOUNDECAHYDRO-CLOSODODECABORATE TRADE: BOROCELL	FOR USE IN BORON NEUTRON CAPTURE THERAPY IN THE TREATMENT OF GLIOBLASTOMA MULTIFORME.	NEUTRON TECHNOLOGY CORPORATION
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 APRIL 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.

NO APRIL 1992 ADDITIONS

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
ALBUTEROL SULFATE CAPSULE, EXTENDED RELEASE; ORAL	EQ 4MG BASE	91 P-0348/ CP1	HAMER	NEW DOSAGE FORM	APPROVED MAR 17, 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)

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

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
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
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			
19857 001	CIPROFLOXACIN; CIPRO IN DEXTROSE 5%	4957922	SEP 18, 2007			
		4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
19858 001	CIPROFLOXACIN; CIPRO IN SODIUM CHLORIDE 0.9%	4957922	SEP 18, 2007			
		4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
20037 001	DICLOFENAC SODIUM; VOLTAREN	4960799	OCT 02, 2007		NDF	MAR 28, 1994
20062 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008			
		4894240	JAN 16, 2007		NP	DEC 27, 1994
20062 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008			
		4894240	JAN 16, 2007		NP	DEC 27, 1994
20062 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008			
		4894240	JAN 16, 2007		NP	DEC 27, 1994
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
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
	20051 001	GLYBURIDE; GLYNASE PRESTAB	4916163	APR 10, 2007			
			4735805	APR 05, 2005			
			3507961	APR 21, 1992		NP	MAR 04, 1995
			3507954	APR 21, 1992			
			3454635	APR 21, 1992			
			3426067	APR 21, 1992			
	20051 002	GLYBURIDE; GLYNASE PRESTAB	4916163	APR 10, 2007			
			4735805	APR 05, 2005			
			3507961	APR 21, 1992		NP	MAR 04, 1995
			3507954	APR 21, 1992			
			3454635	APR 21, 1992			
			3426067	APR 21, 1992			
>ADD>	20055 001	GLYBURIDE; GLUBATE				NP	MAR 04, 1995
>ADD>	20055 002	GLYBURIDE; GLUBATE				NP	MAR 04, 1995
	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
>ADD>	20100 001	INSULIN BIOSYNTHETIC HUMAN; HUMULIN 50/50				NP	APR 29, 1995
	19645 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55	NDF	DEC 20, 1994
						NCE	NOV 30, 1994
	08107 001	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
	08107 002	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
	08107 004	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
	08107 005	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
	19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4917893	MAR 24, 2004			
			4849228	JUL 18, 2006			
			4728721	MAR 01, 2005			
			4677191	JUN 30, 2004			
			4652441	MAR 24, 2004			

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
	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
>ADD>			4061779	DEC 06, 1994	U-19		
	19583 002	NABUMETONE; RELAFEN	4420639	DEC 13, 2000		NCE	DEC 24, 1996
>ADD>			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
	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

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>	20150 001	NICOTINE; NICOTROL				NP	APR 22, 1995
>ADD>	20150 002	NICOTINE; NICOTROL				NP	APR 22, 1995
>ADD>	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
	19757 001	NORFLOXACIN; CHIBROXIN	4551456	NOV 05, 2002	U-57		
>ADD>	20087 001	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4382892	MAY 10, 2000		NCE	DEC 28, 1995
>ADD>	20087 002	OFLOXACIN; FLOXIN	4382892	MAY 10, 2000		NCE	DEC 28, 1995
>ADD>	20087 003	OFLOXACIN; FLOXIN	4382892	MAY 10, 2000		NCE	DEC 28, 1995
>ADD>	20087 004	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4382892	MAY 10, 2000		NCE	DEC 28, 1995
>ADD>	20087 005	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4382892	MAY 10, 2000		NCE	DEC 28, 1995
	19715 001	OLSALAZINE SODIUM; DIPENTUM	4559330	AUG 04, 2004	U-58	NCE	JUL 31, 1995
	19775 001	PRAZOSIN HYDROCHLORIDE; MINIPRESS XL				NDF	JAN 29, 1995
	19775 002	PRAZOSIN HYDROCHLORIDE; MINIPRESS XL				NDF	JAN 29, 1995
	19157 001	PREDNISOLONE SODIUM PHOSPHATE; PEDIAPRED	4448774	MAY 15, 2001			
	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
	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

*U.S. Government Printing Office: 1992 — 312-211/40011