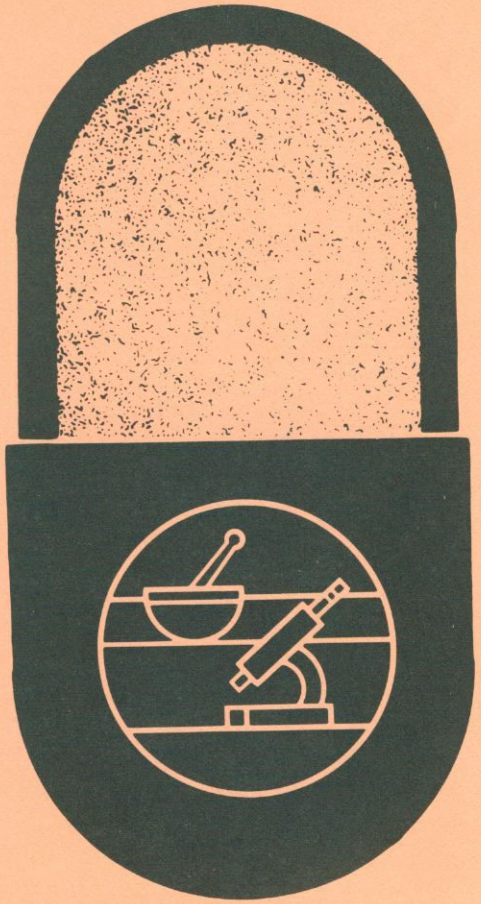
CUMULATIVE SUPPLEMENT 3

JAN'91-MAR'91



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

11TH EDITION

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

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

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New 11th Edition

APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

11th EDITION
1991

CONTENTS

- Prescription Drug Product List
- OTC Drug Product List
- Drug Products with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products List
- Discontinued Drug Product List
- Orphan Drug Product Designations
- Drug Products Which Must Demonstrate in vivo Bioavailability Only if Product Fails to Achieve Adequate Dissolution
- Biopharmaceutic Guidance Availability
- ANDA Suitability Petitions
- Patent and Exclusivity Information

See Subscription Form Inside Back Cover

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MARCH 1991

CONTENTS

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11TH EDITION

CUMULATIVE SUPPLEMENT 3

MARCH 1991

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, 11th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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, along with the application number and product number (FDA's internal file number). 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 " ə " symbol to designate their non-marketed status. All products having a " ə" symbol in the 12th Cumulative Supplement of the 11th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 12th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the appropriate Drug Product List.

Products	Federal Register Reference
Nitroglycerin (capsule, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 5, 1985 (50 FR 27688)
Tranylcypromine Sulfate	MAR 22, 1984 (49 FR 10708)

1.3 APPLICANT (NAME) CHANGES

Because 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, 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)	NEW APPLICANT (NAME)	ABBREVIATED NAME
CORD LABORATORIES INC	GENEVA PHARMACEUTICALS INC	GENEVA
PHARMACIA LABORATORIES DIV PHARMACIA INC	KABI PHARMACIA	KABI

1.4 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 1990) 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 1990	MAR 1991	JUN 1991	SEP 1991
DRUG PRODUCTS LISTED	10003	9953		
SINGLE SOURCE	2090 (20.9%)	2090 (21.0%)		
MULTISOURCE	7913 (79.1%)	7863 (79.0%)		
THERAPEUTICALLY EQUIVALENT	7093 (70.9%)	7061 (71.0%)		
NOT THERAPEUTICALLY EQUIVALENT	685 (6.9%)	660 (6.6%)		
EXCEPTIONS[1]	135 (1.3%)	142 (1.4%)		
NEW MOLECULAR ENTITIES APPROVED	—	5		
NUMBER OF APPLICANTS	424	408		

[1]Amino acid-containing products of varying composition (see Introduction, page 1-8 of the List).

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE NO. 2

>DLT>	/AA/	/AM THERAP/	/300MG;15MG/	/N89481/001/	/MAR/03,/1987/
>DLT>					
>ADD>		@ AM THERAP	300MG;15MG	N89481 001	MAR 03, 1987
>ADD>					

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

AB	DANBURY	EQ 2MG BASE¤	N72629 001	JAN 31, 1991
AB		EQ 4MG BASE¤	N72630 001	JAN 31, 1991
AB	MYLAN	EQ 2MG BASE¤	N72893 001	JAN 17, 1991
AB		EQ 4MG BASE¤	N72894 001	JAN 17, 1991

ALLOPURINOL

TABLET; ORAL

ALLOPURINOL

/AB/	/PUREPAC/	/100MG/	/N70579/001/	/APR/14,/1986/
/AB/		/300MG/	/N70580/001/	/APR/14,/1986/
	@ PUREPAC	100MG	N70579 001	APR 14, 1986
	@	300MG	N70580 001	APR 14, 1986

ALPRAZOLAM

TABLET; ORAL

XANAX

/S/	/UPJOHN/	/2MG/	/N18276/004/	/NOV/27,/1985/
	UPJOHN	2MG	N18276 004	NOV 27, 1985

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE; VITAMIN A; VITAMIN E

INJECTABLE; INJECTION

M,V,I,-12 LYOPHILIZED

/AP/	/ARMOUR/	/100MG/VIAL;0.06MG/VIAL;/ /0.005MG/VIAL;15MG/VIAL;5UGM/VIAL;/ /0.4MG/VIAL;40MG/VIAL;4MG/VIAL;/ /3.6MG/VIAL;3MG/VIAL;1MG/VIAL;/ /10MG/VIAL/	/N18933/002/	/AUG/08,/1985/
AP	ASTRA	100MG/VIAL;0.06MG/VIAL; 0.005MG/VIAL;15MG/VIAL;5UGM/VIAL; 0.4MG/VIAL;40MG/VIAL;4MG/VIAL; 3.6MG/VIAL;3MG/VIAL;1MG/VIAL; 10MG/VIAL	N18933 002	AUG 08, 1985

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

>DLT>		/BUTALBITAL W/ ASPIRIN AND CAFFEINE/			
>DLT>	/AB/	/CHELSEA/	/325MG;50MG;40MG/	/N86231/002/	/FEB/12,/1985/
>DLT>					
>ADD>		**BUTALBITAL, ASPIRIN AND CAFFEINE**			
>ADD>	AB	CHELSEA	325MG;50MG;40MG	N86231 002	FEB 12, 1985
>ADD>					

TABLET; ORAL

>DLT>		/BUTALBITAL W/ ASPIRIN AND CAFFEINE/			
>DLT>	/AB/	/CHELSEA/	/325MG;50MG;40MG/	/N86237/002/	/MAR/23,/1984/
>DLT>					
>ADD>		**BUTALBITAL, ASPIRIN AND CAFFEINE**			
>ADD>	AB	CHELSEA	325MG;50MG;40MG	N86237 002	MAR 23, 1984
>ADD>					

BUTABARBITAL SODIUM

TABLET; ORAL

BUTABARBITAL SODIUM

/AA/	/CORD/	/15MG/		/N84292/003/	/FEB/09,/1982/
/AA/		/30MG/		/N84272/002/	
	@ CORD	15MG		N84292 003	FEB 09, 1982
	@	30MG		N84272 002	
/AA/	/WHITE/TOWNE/PAULSEN/	/15MG/		/N83325/002/	
	@ WHITE TOWNE PAULSEN	15MG		N83325 002	

CALCITONIN, SALMON

INJECTABLE; INJECTION

		CALCIMAR			
> ADD >	AP	RHONE POULENC RORER	200 IU/ML	N17769 001	
		MIACALCIN			
> ADD >	AP	SANDOZ	200 IU/ML¤	N17808 002	
> ADD >				MAR 29, 1991	

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

/INJECTABLE;/INJECTION/
/ACETATED/RINGER'S/IN/PLASTIC/CONTAINER/

/MCGAW/		20MG/100ML;30MG/100ML;380MG/100ML; 600MG/100ML/	/N18725/001/ /NOV/29,/1982/	
ə MCGAW		20MG/100ML;30MG/100ML;380MG/100ML; 600MG/100ML	N18725 001 NOV 29, 1982	

CALCIUM GLUCEPTATE

INJECTABLE; INJECTION

		CALCIUM GLUCEPTATE		
/AP/	/ABBOTT/	/EQ 90MG CALCIUM/5ML/	/N83159/001/	
	ə ABBOTT	EQ 90MG CALCIUM/5ML	N83159 001	

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

> ADD >		ANCEF IN PLASTIC CONTAINER		
> ADD >		BAXTER	EQ 10MG BASE/ML¤	N63002 001
> ADD >				MAR 28, 1991
> ADD >			EQ 20MG BASE/ML¤	N63002 002
> ADD >				MAR 28, 1991

CEPHRADINE

CAPSULE; ORAL

		/VELOSEF'250/		
/AB/	/ERSANA/	/250MG/	/N50548/001/	
	ə ERSANA	250MG	N50548 001	
		/VELOSEF'500/		
/AB/	/ERSANA/	/500MG/	/N50548/002/	
	ə ERSANA	500MG	N50548 002	

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION

		CHLORPHENIRAMINE MALEATE		
/AP/	/LEMMON/	/10MG/ML/	/N83593/001/	
AP	STERIS	10MG/ML	N83593 001	

TABLET; ORAL

		CHLORPHENIRAMINE MALEATE		
> DLT >/AA/	/VITARINE/	/4MG/	/N85837/001/	
> ADD >	ə VITARINE	4MG	N85837 001	
> DLT >	/PHENETRON/			
> DLT >/AA/	/LANNETT/	/4MG/	/N80846/001/	
> ADD >	ə LANNETT	4MG	N80846 001	

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

		CHLORPROMAZINE HCL		
/AP/	/LEMMON/	/25MG/ML/	/N85591/001/	
AP	STERIS	25MG/ML	N85591 001	

CHLORTHALIDONE

TABLET; ORAL

		CHLORTHALIDONE		
/AB/	/SUPERPHARM/	/25MG/	/N87473/001/ /FEB/09,/1983/	
	ə SUPERPHARM	25MG	N87473 001 FEB 09, 1983	

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

		CLINDAMYCIN PHOSPHATE		
/AP/	/LEMMON/	/EQ 150MG BASE/ML/	/N62900/001/ /JUN/08,/1988/	
/AP/		/EQ 150MG BASE/ML/	/N63079/001/ /MAR/05,/1990/	
AP	STERIS	EQ 150MG BASE/ML	N62900 001 JUN 08, 1988	
AP		EQ 150MG BASE/ML	N63079 001 MAR 05, 1990	

CORTISONE ACETATE

INJECTABLE; INJECTION
CORTISONE ACETATE

/BP/	/LEMMON/	/25MG/ML/	/N85677/001/	
/BP/		/50MG/ML/	/N85677/002/	
BP	STERIS	25MG/ML	N85677 001	
BP		50MG/ML	N85677 002	

CYANOCOBALAMIN

INJECTABLE; INJECTION
COBAVITE

/AP/	/LEMMON/	/0.1MG/ML/	/N83013/001/	
/AP/		/1MG/ML/	/N83064/001/	
AP	STERIS	0.1MG/ML	N83013 001	
AP		1MG/ML	N83064 001	

CYANOCOBALAMIN

/AP/	/LEMMON/	/0.1MG/ML/	/N83120/001/	
/AP/		/1MG/ML/	/N83120/002/	
>_DLT_>/AP/	/LYPHOMED/	/0.03MG/ML/	/N80510/003/	
>_DLT_>/AP/		/0.1MG/ML/	/N80510/001/	
>_DLT_>/AP/		/1MG/ML/	/N80510/002/	
>_ADD_>	@ LYPHOMED	0.03MG/ML	N80510 003	
>_ADD_>	@	0.1MG/ML	N80510 001	
>_ADD_>	@	1MG/ML	N80510 002	
AP	STERIS	0.1MG/ML	N83120 001	
AP		1MG/ML	N83120 002	

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
CYCLOPENTOLATE HCL

AT	STERIS	1%	N89162 001	
			JAN 24, 1991	

DESMOPRESSIN ACETATE

SOLUTION; NASAL
CONCENTRAID

BX	FERRING	0.01%	N19776 001	
			DEC 26, 1990	
		/0.01%/	/N19776/001/	
			/DEC/26/1990/	

DDAVP

BX	RHONE POULENC RORER	0.01%	N17922 001	
		/0.01%/	/N17922/001/	

DEXAMETHASONE

TABLET; ORAL
DEXAMETHASONE

>_DLT_> /BP/	/CORD/	/0.75MG/	/N80399/001/	
>_ADD_>	@ CORD	0.75MG	N80399 001	

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION
/DEXACEN-4/

/AP/	/CENTRAL/PHARMS/	/EQ 4MG PHOSPHATE/ML/	/N84342/001/	
	@ CENTRAL PHARMS	EQ 4MG PHOSPHATE/ML	N84342 001	

DEXAMETHASONE SODIUM PHOSPHATE

/AP/	/LEMMON/	/EQ 4MG PHOSPHATE/ML/	/N84355/001/	
AP	STERIS	EQ 4MG PHOSPHATE/ML	N84355 001	

DEXTROSE

INJECTABLE; INJECTION
DEXTROSE 10% IN PLASTIC CONTAINER

/AP/	/CUTTER/	/10GM/100ML/	/N18504/001/	
	@ CUTTER	10GM/100ML	N18504 001	

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER

/AP/	/MCGAW/	/5GM/100ML;220MG/100ML;/		
		/450MG/100ML/	/N18268/002/	
	MCGAW	5GM/100ML;220MG/100ML; 450MG/100ML	N18268 002	

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION
DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

/AP/	/CUTTER/	/5GM/100ML;200MG/100ML/	/N18399/001/	
	@ CUTTER	5GM/100ML;200MG/100ML	N18399 001	

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

/AP/	/ABBOTT/	/5GM/100ML;300MG/100ML/	/N17799/001/	
	ABBOTT	5GM/100ML;300MG/100ML	N17799 001	
/AP/	/CUTTER/	/5GM/100ML;300MG/100ML/	/N18501/001/	
	@ CUTTER	5GM/100ML;300MG/100ML	N18501 001	

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

/AP/	/CUTTER/	/5GM/100ML;450MG/100ML/	/N18400/001/	
	@ CUTTER	5GM/100ML;450MG/100ML	N18400 001	

DIAZEPAM

INJECTABLE; INJECTION

	DIAZEPAM				
/AP/	/LEMMON/	/5MG/ML/	/N70911/001/ /AUG/28,/1986/		
/AP/		/5MG/ML/	/N70912/001/ /AUG/28,/1986/		
/AP/		/5MG/ML/	/N70930/001/ /DEC/01,/1986/		
AP	STERIS	5MG/ML	N70911 001 AUG 28, 1986		
AP		5MG/ML	N70912 001 AUG 28, 1986		
AP		5MG/ML	N70930 001 DEC 01, 1986		

TABLET; ORAL

	DIAZEPAM				
>DLT> /BX/	/SUPERPHARM/	/2MG/	/N70642/001/ /DEC/11,/1985/		
>DLT> /BX/		/5MG/	/N70643/001/ /DEC/11,/1985/		
>ADD>	ə SUPERPHARM	2MG	N70642 001 DEC 11, 1985		
>ADD>	ə	5MG	N70643 001 DEC 11, 1985		

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC

>ADD>	VOLTAREN				
>ADD>	CIBA	0.1%¤	N20037 001 MAR 28, 1991		

DIMENHYDRINATE

INJECTABLE; INJECTION

	DIMENHYDRINATE				
/AP/	/LEMMON/	/50MG/ML/	/N83531/001/		
AP	STERIS	50MG/ML	N83531 001		

DIPHENHYDRAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

	DIPHENHYDRAMINE HCL				
>DLT> /AP/	/ELKINS/SINN/	/50MG/ML/	/N83183/001/		
>ADD>	ə ELKINS SINN	50MG/ML	N83183 001		
/AP/	/LEMMON/	/10MG/ML/	/N83533/001/		
AP	STERIS	10MG/ML	N83533 001		

DIPYRIDAMOLE

TABLET; ORAL

	DIPYRIDAMOLE				
AB	LEDERLE	25MG¤			N88999 001 FEB 05, 1991
AB		50MG¤			N89000 001 FEB 05, 1991
AB		75MG¤			N89001 001 FEB 05, 1991

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

	DOBUTREX				
	LILLY	EQ 12.5MG BASE/ML	/EQ/250MG/BASE/VIAL/		N17820 002 /N17820/002/

DOXACURIUM CHLORIDE

>ADD> INJECTABLE; INJECTION

	NUROMAX				
	BURROUGHS WELLCOME	EQ 1MG BASE/ML¤			N19946 001 MAR 07, 1991

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

	DOXEPIN HCL				
>ADD> AB	ROYCE	EQ 10MG BASE¤			N72985 001 MAR 29, 1991
>ADD> AB		EQ 25MG BASE¤			N72986 001 MAR 29, 1991
>ADD> AB		EQ 50MG BASE¤			N72987 001 MAR 29, 1991

INJECTABLE; INJECTION

DIPHENHYDRAMINE HCL

> DLT >	/AP/	/ELKINS/SINN/	/50MG/ML/	/N83183/001/
> ADD >		@ ELKINS SINN	50MG/ML	N83183 001
	/AP/	/LEMMON/	/10MG/ML/	/N83533/001/
	AP	STERIS	10MG/ML	N83533 001

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ADRIAMYCIN PFS

AP	ADRIA	2MG/ML	N50629 001 DEC 23, 1987
AP		200MG/100ML	N50629 002 MAY 03, 1988
AP		2MG/ML¤	N63165 001 JAN 30, 1991
AP		200MG/100ML¤	N63165 002 JAN 30, 1991
		/2MG/ML/	/N50629/002/ /MAY/03,/1988/

DOXORUBICIN HCL

AP	CETUS BEN VENUE	2MG/ML	N62975 001 MAR 17, 1989

DROPERIDOL

INJECTABLE; INJECTION

DROPERIDOL

/AP/	/ASTRA/	/2.5MG/ML/	/N72020/001/ /OCT/19,/1988/
	@ ASTRA	2.5MG/ML	N72020 001 OCT 19, 1988

EDETATE DISODIUM

INJECTABLE; INJECTION

DISODIUM EDETATE

/AP/	/LEMMON/	/150MG/ML/	/N84356/001/
AP	STERIS	150MG/ML	N84356 001

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL W/ EPINEPHRINE

/S/LEMMON/	/0.01MG/ML;1%/	/N85463/001/
@ STERIS	0.01MG/ML;1%	N85463 001

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

/DEAPRIL-ST/

/AA/	/BRISTOL/MYERS/SQUIBB/1MG/		/N85020/002/
	@ BRISTOL MYERS SQUIBB 1MG		N85020 002

ERYTHROMYCIN

SOLUTION; TOPICAL

ERYTHROMYCIN

AT	CLAY PARK	2%¤	N63038 001 JAN 11, 1991

ESTROGENS, CONJUGATED

TABLET; ORAL

CONJUGATED ESTROGENS

	/BP/	/DURAMED/	/0.3MG/	/N86492/001/
	BP	@ DURAMED	0.3MG	N86492 001
	/BP/		/0.625MG/	/N83272/001/
	BP	@	0.625MG	N83272 001
	/BP/		/1.25MG/	/N83294/001/
	BP	@	1.25MG	N83294 001
	/BP/		/2.5MG/	/N83295/001/
	BP	@	2.5MG	N83295 001
> DLT >	/BP/	/ZENITH/	/0.3MG/	/N88569/001/ /NOV/29,/1984/
> DLT >	/BP/		/0.625MG/	/N83373/001/
> DLT >	/BP/		/1.25MG/	/N83601/001/
> DLT >	/BP/		/2.5MG/	/N83602/001/
> ADD >		@ ZENITH	0.3MG	N88569 001 NOV 29, 1984
> ADD >		@	0.625MG	N83373 001
> ADD >		@	1.25MG	N83601 001
> ADD >		@	2.5MG	N83602 001

ESTROPIPATE

TABLET; ORAL

OGEN

AB	ABBOTT	0.75MG	N83220 001

ORTHO-EST

AB	JOHNSON RW	0.75MG¤	N89567 001 FEB 27, 1991

ETODOLAC

CAPSULE; ORAL

LODINE

WYETH AYERST	200MG¤	N18922 002 JAN 31, 1991
	300MG¤	N18922 003 JAN 31, 1991

GALLIUM NITRATE

INJECTABLE; INJECTION
GANITE
FUJISAWA PHARM 25MG/ML N19961 002 JAN 17, 1991

HALOBETASOL PROPIONATE

CREAM; TOPICAL
ULTRAVATE
/BRISTOL/MYERS/SQUIBB/0.05%/ /N19967/001/ /DEC/27,/1990/
WESTWOOD SQUIBB 0.05% N19967 001 DEC 27, 1990

OINTMENT; TOPICAL
ULTRAVATE
/BRISTOL/MYERS/SQUIBB/0.05%/ /N19968/001/ /DEC/17,/1990/
WESTWOOD SQUIBB 0.05% N19968 001 DEC 17, 1990

HALOPERIDOL LACTATE

INJECTABLE; INJECTION
HALOPERIDOL

/AP/ /LEMMON/	/EQ 5MG BASE/ML/	/N70713/001/ /MAY/17,/1988/
/AP/	/EQ 5MG BASE/ML/	/N70714/001/ /MAY/17,/1988/
/AP/	/EQ 5MG BASE/ML/	/N70744/001/ /MAY/17,/1988/
AP STERIS	EQ 5MG BASE/ML	N70713 001 MAY 17, 1988
AP	EQ 5MG BASE/ML	N70714 001 MAY 17, 1988
AP	EQ 5MG BASE/ML	N70744 001 MAY 17, 1988

HEPARIN SODIUM

INJECTABLE; INJECTION
/HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5%/
/AP/ /ABBOTT/ /10,000 UNITS/100ML/ /N18911/006/ /JAN/30,/1985/
ə ABBOTT 10,000 UNITS/100ML N18911 006 JAN 30, 1985

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDRALAZINE HCL
/AP/ /SOLOPAK/ /20MG/ML/ /N88517/001/ /AUG/22,/1985/
ə SOLOPAK 20MG/ML N88517 001 AUG 22, 1985

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
RESERPINE AND HYDROCHLOROTHIAZIDE
/BP/ /CORD/ /50MG;0.125MG/ /N88200/001/ /JAN/31,/1984/
ə CORD 50MG;0.125MG N88200 001 JAN 31, 1984

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE
/AT/ /WHITE/TOWNE/PAULSEN//1%/ /N80496/002/
ə WHITE TOWNE PAULSEN 1% N80496 002

> DLT > /LOTION;/TOPICAL/
> DLT > /TEXACORT/
> DLT >/AT/ /COOPERCARE/ /1%/ /N80425/001/

SOLUTION; TOPICAL
PENECORT
> ADD > AT HERBERT 1% N88214 001 JUN 06, 1984
> ADD >
> ADD > TEXACORT
> ADD > AT GENDERM 1% N80425 001

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC
OTOCORT
/AT/ /LEMMON/ /1%;EQ 3.5MG BASE/ML;/ /10,000 UNITS/ML/ /N60730/002/
AT STERIS 1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML N60730 002

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION; OTIC

OTOCORT

/AT/	/LEMMON/	/1%;EQ 3.5MG BASE/ML;/ /10,000 UNITS/ML/	/N62521/001/ /JUL/11,/1985/
AT	STERIS	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62521 001 JUL 11, 1985

HYDROCORTISONE ACETATE

INJECTABLE; INJECTION

HYDROCORTISONE ACETATE

/BP/	/LEMMON/	/25MG/ML/	/N83759/001/
/BP/		/50MG/ML/	/N83759/002/
BP	STERIS	25MG/ML	N83759 001
BP		50MG/ML	N83759 002

HYDROCORTISONE BUTYRATE

/CREAM;/TOPICAL/

/LOCOID/

	/OWEN/GALDERMA/	/0.1%/	/N18795/001/ /JAN/07,/1983/
	@ OWEN GALDERMA	0.1%	N18795 001 JAN 07, 1983

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION

HYDROCORTISONE SODIUM SUCCINATE

	/AP/	/LYPHOMED/	/EQ 100MG BASE/VIAL/	/N88712/001/ /JUN/08,/1984/
>DLT>	/AP/		/EQ 250MG BASE/VIAL/	/N88668/001/ /JUN/08,/1984/
>DLT>	/AP/		/EQ 500MG BASE/VIAL/	/N88669/001/ /JUN/08,/1984/
>DLT>	/AP/		/EQ 1GM BASE/VIAL/	/N88670/001/ /JUN/08,/1984/
>DLT>		@ LYPHOMED	EQ 100MG BASE/VIAL	N88712 001 JUN 08, 1984
>ADD>		@	EQ 250MG BASE/VIAL	N88668 001 JUN 08, 1984
>ADD>		@	EQ 500MG BASE/VIAL	N88669 001 JUN 08, 1984
>ADD>		@	EQ 1GM BASE/VIAL	N88670 001 JUN 08, 1984

HYDROXOCOBALAMIN

INJECTABLE; INJECTION

HYDROCOBALAMIN

/AP/	/LEMMON/	/1MG/ML/	/N85528/001/
AP	STERIS	1MG/ML	N85528 001

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HCL

/AP/	/LEMMON/	/25MG/ML/	/N87274/001/
/AP/		/50MG/ML/	/N87274/002/
AP	STERIS	25MG/ML	N87274 001
AP		50MG/ML	N87274 002

TABLET; ORAL

HYDROXYZINE HCL

/AB/	/BARR/	/10MG/	/N88409/001/ /NOV/15,/1983/
	@ BARR	10MG	N88409 001 NOV 15, 1983

HYDROXYZINE PAMOATE

CAPSULE; ORAL

HYDROXYZINE PAMOATE

>DLT>	/AB/	/VANGARD/	/EQ 25MG HCL/	/N88392/001/ /SEP/19,/1983/
>DLT>				
>ADD>		@ VANGARD	EQ 25MG HCL	N88392 001 SEP 19, 1983
>ADD>				

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

	/AB/	/ROXANE/	/25MG/	/N70353/001/ /JUN/18,/1985/
>DLT>	/AB/		/50MG/	/N70354/001/ /JUN/18,/1985/
>DLT>				
		@ ROXANE	25MG	N70353 001 JUN 18, 1985
>ADD>		@	50MG	N70354 001 JUN 18, 1985
>ADD>				

IOPAMIDOL

INJECTABLE; INJECTION

ISOVUE-M 200 SQUIBB	41%	N18735 001 DEC 31, 1985
/ISOVUE-200/ /SQUIBB/	/41%/	/N18735/001/ /DEC/31,/1985/
ISOVUE-200 SQUIBB	41%¤	N18735 006 JUL 07, 1987

KETOCONAZOLE

> DLT >	/SUSPENSION;/ORAL/		> ADD >		
> DLT >	/NIZORAL/		> ADD >		
> DLT >	/JANSSEN/	/100MG/5ML/	> ADD >	AB	/N70767/001/ /NOV/07,/1986/
> DLT >			> ADD >		
> ADD >	∂ JANSSEN	100MG/5ML	> ADD >	AB	N70767 001 NOV 07, 1986
> ADD >			> ADD >		

LEVONORGESTREL

IMPLANT; IMPLANTATION

/LEVONORGESTREL/SYSTEM/ /WYETH/AYERST/	/36MG/IMPLANT/	/N20088/001/ /DEC/10,/1990/	> ADD >		
			> ADD >		
NORPLANT SYSTEM WYETH AYERST	36MG/IMPLANT	N20088 001 DEC 10, 1990			

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL					
/∂/LEMMON/	/1%/	/N83627/001/	/AP/	/CUTTER/	/10GM/100ML/
/∂/	/2%/	/N83627/002/			
∂ STERIS	1%	N83627 001		∂ CUTTER	10GM/100ML
∂	2%	N83627 002			

LORAZEPAM

TABLET; ORAL

LORAZEPAM					
/BX/	/AM/THERAP/	/0.5MG/	/N70727/001/ /MAR/07,/1986/		
/BX/		/1MG/	/N70728/001/ /MAR/07,/1986/		
/BX/		/2MG/	/N70729/001/ /MAR/07,/1986/		
	∂ AM THERAP	0.5MG	N70727 001 MAR 07, 1986		
	∂	1MG	N70728 001 MAR 07, 1986		
	∂	2MG	N70729 001 MAR 07, 1986		
> ADD >	AB	MUTUAL PHARM	0.5MG¤	N72553 001 MAR 29, 1991	
> ADD >	AB		1MG¤	N72554 001 MAR 29, 1991	
> ADD >	AB		2MG¤	N72555 001 MAR 29, 1991	

LOVASTATIN

TABLET; ORAL

MEVACOR MSD	10MG¤	N19643 002 MAR 28, 1991	> ADD > > ADD >	

MANNITOL

INJECTABLE; INJECTION

MANNITOL 10% /CUTTER/ ∂ CUTTER	/10GM/100ML/ 10GM/100ML	/N16472/002/ N16472 002	/AP/	
MANNITOL 15% /CUTTER/ ∂ CUTTER	/15GM/100ML/ 15GM/100ML	/N16472/005/ N16472 005	/AP/	
MANNITOL 20% /CUTTER/ ∂ CUTTER	/20GM/100ML/ 20GM/100ML	/N16472/004/ N16472 004	/AP/	

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERIDINE HCL

> DLT >	/AP/	/ELKINS/SINN/	/25MG/ML/	/N88279/001/ /JUN/15,/1984/
> DLT >				
> DLT >	/AP/		/50MG/ML/	/N88280/001/ /JUN/15,/1984/
> DLT >				
> DLT >	/AP/		/75MG/ML/	/N88281/001/ /JUN/15,/1984/
> DLT >				
> DLT >	/AP/		/100MG/ML/	/N88282/001/ /JUN/15,/1984/
> DLT >				
> ADD >		ə ELKINS SINN	25MG/ML	N88279 001 JUN 15, 1984
> ADD >				
> ADD >		ə	50MG/ML	N88280 001 JUN 15, 1984
> ADD >				
> ADD >		ə	75MG/ML	N88281 001 JUN 15, 1984
> ADD >				
> ADD >		ə	100MG/ML	N88282 001 JUN 15, 1984
> ADD >				

METAPROTERENOL SULFATE

TABLET; ORAL

METAPROTERENOL SULFATE

> DLT >	/AB/	/AM/THERAP/	/10MG/	/N72054/001/ /JUN/23,/1988/
> DLT >				
	/AB/		/20MG/	/N72055/001/ /JUN/23,/1988/
> ADD >		ə AM THERAP	10MG	N72054 001 JUN 23, 1988
> ADD >				
		ə	20MG	N72055 001 JUN 23, 1988
	AB	DANBURY	10MG¤	N73013 001 JAN 31, 1991
	AB		20MG¤	N72795 001 JAN 31, 1991

METHADONE HYDROCHLORIDE

> DLT >	/TABLET;/EFFERVESCENT;/ORAL/			
> DLT >	/WESTADONE/			
> DLT >	/VITARINE/		/2.5MG/	/N17108/001/
> DLT >			/5MG/	/N17108/002/
> DLT >			/10MG/	/N17108/003/
> DLT >			/40MG/	/N17108/004/
> ADD >		ə VITARINE	2.5MG	N17108 001
> ADD >		ə	5MG	N17108 002
> ADD >		ə	10MG	N17108 003
> ADD >		ə	40MG	N17108 004

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

METHYLPREDNISOLONE ACETATE

/ə/	/LEMMON/	/20MG/ML/	/N87248/001/
/ə/		/40MG/ML/	/N85374/001/
/ə/		/80MG/ML/	/N86507/001/
ə	STERIS	20MG/ML	N87248 001
ə		40MG/ML	N85374 001
ə		80MG/ML	N86507 001

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

A-METHAPRED

AP	ABBOTT	EQ 40MG BASE/VIAL¤	N89573 001 FEB 22, 1991
AP		EQ 125MG BASE/VIAL¤	N89574 001 FEB 22, 1991
AP		EQ 500MG BASE/VIAL¤	N89575 001 FEB 22, 1991
AP		EQ 1GM BASE/VIAL¤	N89576 001 FEB 22, 1991

METHYLPREDNISOLONE SODIUM SUCCINATE

	/AP/	/LYPHOMED/	/EQ 40MG BASE/VIAL/	/N88676/001/ /JUN/08,/1984/
	/AP/		/EQ 125MG BASE/VIAL/	/N88677/001/ /JUN/08,/1984/
	/AP/		/EQ 500MG BASE/VIAL/	/N88678/001/ /JUN/08,/1984/
	/AP/		/EQ 500MG BASE/VIAL/	/N89186/001/ /MAR/28,/1986/
	/AP/		/EQ 1GM BASE/VIAL/	/N88679/001/ /JUN/08,/1984/
> DLT >	/AP/		/EQ 1GM BASE/VIAL/	/N89188/001/ /MAR/28,/1986/
> DLT >				
		ə LYPHOMED	EQ 40MG BASE/VIAL	N88676 001 JUN 08, 1984
		ə	EQ 125MG BASE/VIAL	N88677 001 JUN 08, 1984
		ə	EQ 500MG BASE/VIAL	N88678 001 JUN 08, 1984
		ə	EQ 500MG BASE/VIAL	N89186 001 MAR 28, 1986
		ə	EQ 1GM BASE/VIAL	N88679 001 JUN 08, 1984
> ADD >		ə	EQ 1GM BASE/VIAL	N89188 001 MAR 28, 1986
> ADD >				

METHYPRYLON

TABLET; ORAL
NOLUDAR
/ROCHE/ /50MG/ /N09660/002/
@ ROCHE 50MG N09660 002

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL
AP ABBOTT EQ 10MG BASE/2ML¤ N73117 001 JAN 17, 1991
AP EQ 10MG BASE/2ML¤ N73118 001 JAN 17, 1991

METRONIDAZOLE

INJECTABLE; INJECTION
METRYL IV
/AP/ /LEMMON/ /500MG/100ML/ /N70042/001/ /DEC/20,/1984/
AP STERIS 500MG/100ML N70042 001 DEC 20, 1984

MICONAZOLE NITRATE

/CREAM;/VAGINAL/
/MONISTAT 7/
/AT/ /JOHNSON/RW/ /2%/ /N17456/001/

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

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE
>_DLT_>/AP/ /ELKINS/SINN/ /0.4MG/ML/ /N70496/001/ /OCT/22,/1985/
>_DLT_>
>_ADD_> @ ELKINS SINN 0.4MG/ML N70496 001 OCT 22, 1985
>_ADD_>

NANDROLONE DECANOATE

INJECTABLE; INJECTION
NANDROLONE DECANOATE
/AO/ /LEMMON/ /50MG/ML/ /N87598/001/ /OCT/06,/1983/
/AO/ /50MG/ML/ /N88554/001/ /FEB/10,/1986/
/AO/ /100MG/ML/ /N87599/001/ /OCT/06,/1983/
AO STERIS 50MG/ML N87598 001 OCT 06, 1983
AO 50MG/ML N88554 001 FEB 10, 1986
AO 100MG/ML N87599 001 OCT 06, 1983

NIACIN

TABLET; ORAL
NIACIN
>_DLT_>/AA/ /WEST/WARD/ /500MG/ /N83718/001/
>_ADD_> @ WEST WARD 500MG N83718 001

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION
ZOFRAN
GLAXO EQ 2MG BASE/ML¤ N20007 001 JAN 04, 1991

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE; ORAL
PHENDIMETRAZINE TARTRATE
/BC/ /VITARINE/ /105MG/ /N18074/001/
@ VITARINE 105MG N18074 001

TABLET; ORAL
PHENDIMETRAZINE TARTRATE
>_DLT_>/AA/ /CORD/ /35MG/ /N86365/001/
>_ADD_> @ CORD 35MG N86365 001

PIPERAZINE CITRATE

SYRUP; ORAL
PIPERAZINE CITRATE
/AA/ /BARRE/ /EQ 500MG BASE/5ML/ /N80774/001/
@ BARRE EQ 500MG BASE/5ML N80774 001

POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

> DLT >/AP/	/ELKINS/SINN/	/2MEQ/ML/	/N80203/001/	
> ADD >	@ ELKINS SINN	2MEQ/ML	N80203 001	
/AP/	/LEMMON/	/2MEQ/ML/	/N86208/001/	
/AP/		/3MEQ/ML/	/N86210/001/	
> DLT >/AP/	/LILLY/	/2MEQ/ML/	/N07865/002/	
> ADD >	@ LILLY	2MEQ/ML	N07865 002	
AP	STERIS	2MEQ/ML	N86208 001	
AP		3MEQ/ML	N86210 001	

PREDNISOLONE ACETATE

INJECTABLE; INJECTION
PREDNISOLONE ACETATE

/BP/	/CENTRAL/PHARMS/	/25MG/ML/	/N84717/001/
	@ CENTRAL PHARMS	25MG/ML	N84717 001
/BP/	/LEMMON/	/25MG/ML/	/N83654/001/
/BP/		/50MG/ML/	/N85781/001/
BP	STERIS	25MG/ML	N83654 001
BP		50MG/ML	N85781 001

PREDNISONE

TABLET; ORAL
PREDNISONE

/BX/	/AM/THERAP/	/5MG/	/N89387/001/	/NOV/06,/1986/
/BX/		/10MG/	/N89388/001/	/NOV/06,/1986/
/BX/		/20MG/	/N89389/001/	/NOV/06,/1986/
	@ AM THERAP	5MG	N89387 001	NOV 06, 1986
	@	10MG	N89388 001	NOV 06, 1986
	@	20MG	N89389 001	NOV 06, 1986

PREDNISONE

TABLET; ORAL
PREDNISONE

/AB/	/ROXANE/	/1MG/	/N87800/001/	/APR/22,/1982/
> DLT >/AB/		/2.5MG/	/N87801/001/	/APR/22,/1982/
> DLT >				
> DLT >/AB/		/10MG/	/N84122/001/	
> DLT >/AB/		/20MG/	/N87342/001/	
> DLT >/AB/		/50MG/	/N84283/001/	
	@ ROXANE	1MG	N87800 001	APR 22, 1982
> ADD >	@	2.5MG	N87801 001	APR 22, 1982
> ADD >				
> ADD >	@	10MG	N84122 001	
> ADD >	@	20MG	N87342 001	
> ADD >	@	50MG	N84283 001	

PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROCAINE HCL

/AP/	/LEMMON/	/1%/	/N83535/001/
/AP/		/2%/	/N83535/002/
AP	STERIS	1%	N83535 001
AP		2%	N83535 002

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROMETHAZINE HCL

/AP/	/LEMMON/	/25MG/ML/	/N83532/001/
/AP/		/50MG/ML/	/N83532/002/
AP	STERIS	25MG/ML	N83532 001
AP		50MG/ML	N83532 002

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION
PYRIDOXINE HCL

/AP/	/LEMMON/	/100MG/ML/	/N83760/001/
AP	STERIS	100MG/ML	N83760 001

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

> DLT > / AB /	/VANGARD/	/200MG/	/N87909/001/	
> DLT >			/JUL/13,/1982/	
> ADD >	ə VANGARD	200MG	N87909 001	
> ADD >			JUL 13, 1982	

RAMIPRIL

CAPSULE; ORAL

ALTACE

HOECHST ROUSSEL	1.25MG¤	N19901 001	
		JAN 28, 1991	
	2.5MG¤	N19901 002	
		JAN 28, 1991	
	5MG¤	N19901 003	
		JAN 28, 1991	
	10MG¤	N19901 004	
		JAN 28, 1991	

RESERPINE

TABLET; ORAL

RESERPINE

/BP/	/WHITE/TOWNE/PAULSEN/	/0.1MG/	/N80723/001/	
/BP/		/0.25MG/	/N80723/002/	
	ə WHITE TOWNE PAULSEN	0.1MG	N80723 001	
	ə	0.25MG	N80723 002	
		/1MG/	/N80723/003/	
	ə	1MG	N80723 003	

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION

RITODRINE HCL

AP	ABBOTT	10MG/ML¤	N71618 001	
			FEB 28, 1991	
AP		15MG/ML¤	N71619 001	
			FEB 28, 1991	

RITODRINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT	30MG/100ML¤	N71438 001	
		JAN 22, 1991	

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL

SELENIUM SULFIDE

AT	CLAY PARK	2.5%¤	N89996 001	
			JAN 10, 1991	

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION

SODIUM NITROPRUSSIDE

/AP/	/LYPHOMED/	/50MG/VIAL/	/N70031/001/	
			/JAN/17,/1985/	
	ə LYPHOMED	50MG/VIAL	N70031 001	
			JAN 17, 1985	

SUCCIMER

CAPSULE; ORAL

CHEMET

MCNEIL	100MG¤	N19998 002	
		JAN 30, 1991	

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

COTRIM

/AP/	/LEMMON/	/80MG/ML;16MG/ML/	/N71556/001/	
			/DEC/17,/1987/	
AP	STERIS	80MG/ML;16MG/ML	N71556 001	
			DEC 17, 1987	

SULINDAC

TABLET; ORAL

SULINDAC

> ADD > AB	WARNER CHILCOTT	150MG¤	N72710 001	
			MAR 25, 1991	
> ADD >				
> ADD > AB		200MG¤	N72711 001	
			MAR 25, 1991	
> ADD >				

TERCONAZOLE

CREAM; VAGINAL

TERAZOL 3

JOHNSON RW	0.8%¤	N19964 001	
		FEB 21, 1991	

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION
TESTOSTERONE CYPIONATE

/AO/	/LEMMON/	/100MG/ML/	/N84401/001/
/AO/		/200MG/ML/	/N84401/002/
AO	STERIS	100MG/ML	N84401 001
AO		200MG/ML	N84401 002

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
TESTOSTERONE ENANTHATE

/AO/	/LEMMON/	/100MG/ML/	/N83667/001/
/AO/		/200MG/ML/	/N83667/002/
AO	STERIS	100MG/ML	N83667 001
AO		200MG/ML	N83667 002

TESTOSTERONE PROPIONATE

INJECTABLE; INJECTION
TESTOSTERONE PROPIONATE

/AO/	/LEMMON/	/25MG/ML/	/N85490/001/
/AO/		/50MG/ML/	/N85490/002/
/AO/		/100MG/ML/	/N83595/003/
AO	STERIS	25MG/ML	N85490 001
AO		50MG/ML	N85490 002
AO		100MG/ML	N83595 003

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
/THEOPHYLLINE/

/BC/	/CENTRAL/PHARMS/	/125MG/	/N88654/001/ FEB/12,/1985/
/BC/		/250MG/	/N88689/001/ FEB/12,/1985/
	@ CENTRAL PHARMS	125MG	N88654 001 FEB 12, 1985
	@	250MG	N88689 001 FEB 12, 1985

TABLET; ORAL
/THEOCLEAR-100/

/BD/	/CENTRAL/PHARMS/	/100MG/	/N85353/002/
	@ CENTRAL PHARMS	100MG	N85353 002

/THEOCLEAR-200/

/BD/	/CENTRAL/PHARMS/	/200MG/	/N85353/001/
	@ CENTRAL PHARMS	200MG	N85353 001

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
THIAMINE HCL

/AP/	/LEMMON/	/100MG/ML/	/N83534/001/
/AP/		/200MG/ML/	/N83534/002/
/AP/	/LYPHOMED/	/100MG/ML/	/N80509/001/
	@ LYPHOMED	100MG/ML	N80509 001
AP	STERIS	100MG/ML	N83534 001
AP		200MG/ML	N83534 002

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL
THIORIDAZINE HCL

/AB/	/ROXANE/	/10MG/	/N88663/001/ MAR/15,/1984/
/AB/		/25MG/	/N88664/001/ MAR/15,/1984/
/AB/		/50MG/	/N88665/001/ MAR/15,/1984/
/AB/		/100MG/	/N89048/001/ FEB/26,/1985/
	@ ROXANE	10MG	N88663 001 MAR 15, 1984
	@	25MG	N88664 001 MAR 15, 1984
	@	50MG	N88665 001 MAR 15, 1984
	@	100MG	N89048 001 FEB 26, 1985

THIOTHIXENE

CAPSULE; ORAL
THIOTHIXENE

/AB/	/AM/THERAP/	/2MG/	/N71885/001/ AUG/12,/1987/
	@ AM THERAP	2MG	N71885 001 AUG 12, 1987

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

AB	MYLAN	50MG*	N71405 001 FEB 27, 1991
AB		100MG*	N71406 001 FEB 27, 1991

TRIAMCINOLONE DIACETATE

INJECTABLE; INJECTION
TRIAMCINOLONE DIACETATE

/BP/	/LEMMON/	/40MG/ML/	/N85529/001/
BP	STERIS	40MG/ML	N85529 001

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION

> DLT >		/CALAN/		
> DLT >	/AP/	/SEARLE/	/2.5MG/ML/	/N18925/001/ /MAR/30/1984/
> DLT >				
> ADD >		@ SEARLE	2.5MG/ML	N18925 001 MAR 30, 1984
> ADD >				

TABLET, EXTENDED RELEASE; ORAL
ISOPTIN SR

> ADD >	KNOLL	120MG¤	N19152 003 MAR 06, 1991
> ADD >			

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL
MICRODERM
JOHNSON AND JOHNSON 4%¤ N72295 001
FEB 28, 1991

HYDROCORTISONE

>_DLT_> /OINTMENT;TOPICAL/
>_DLT_> /HC/(HYDROCORTISONE)/
>_DLT_> /C/AND/M/ /0.5%/ /N80481/001/
>_ADD_> ∂ C AND M 0.5% N80481 001

MICONAZOLE NITRATE

CREAM; VAGINAL
MONISTAT 7
JOHNSON RW 2%¤ N17450 002
FEB 15, 1991

SUPPOSITORY; VAGINAL
MONISTAT 7
JOHNSON RW 100MG¤ N18520 002
FEB 15, 1991

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 3 / JAN '91 - MAR '91

NO MARCH 1991 APPROVALS

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: ANTIVENOM (CROTALIDAE) PURIFIED (AVIAN) TRADE: NOT ESTABLISHED	TREATMENT OF ENVENOMATION BY POISONOUS SNAKES BELONGING TO THE CROTALIDAE FAMILY.	OPHIDIAN PHARMA
GENERIC: CYTOMEGALOVIRUS IMMUNE GLOBULIN INTRAVENOUS (HUMAN) TRADE: NOT ESTABLISHED	USE IN CONJUNCTION WITH GANCICLOVIR SODIUM FOR THE TREATMENT OF CYTOMEGALOVIRUS PNEUMONIA IN BONE MARROW TRANSPLANT PATIENTS.	MILES, INC
GENERIC: INTERFERON (RECOMBINANT, BETA) TRADE: R-IFN-BETA	SYSTEMIC TREATMENT OF METASTATIC RENAL CELL CARCINOMA.	BIOGEN

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: MUCOID EXOPOLYSACCHARIDE PSEUDOMONAS HYPERIMMUNE GLOBULIN TRADE: MEPIG	TREATMENT OF PULMONARY INFECTIONS DUE TO PSEUDOMONAS AERUGINOSA IN PATIENTS WITH CYSTIC FIBROSIS.	UNIVAX BIOLOGICS, INC
GENERIC: RECOMBINANT HUMAN DEOXYRIBONUCLEASE (RHDNASE) TRADE: NOT ESTABLISHED	TO REDUCE MUCOUS VISCOSITY AND ENABLE CLEARANCE OF AIRWAY SECRETIONS IN PATIENTS WITH CYSTIC FIBROSIS.	GENENTECH, INC
GENERIC: RECOMBINANT SECRETORY LEUCOCYTE PROTEASE INHIBITOR TRADE: NOT ESTABLISHED	TREATMENT OF CONGENITAL ALPHA-1 ANTITRYPSIN DEFICIENCY. TREATMENT OF CYSTIC FIBROSIS.	SYNERGEN, INC
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-B4) TO B CELL (CD 19) TRADE: NOT ESTABLISHED	FOR THE EX-VIVO PURGING OF LEUKEMIC CELLS FROM THE BONE MARROW OF NON-T CELL ACUTE LYMPHOCYTIC LEUKEMIA PATIENTS WHO ARE IN COMPLETE REMISSION.	IMMUNOGEN, INC
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (N901) TO CD56 POSITIVE CELLS TRADE: NOT ESTABLISHED	TREATMENT OF SMALL CELL LUNG CANCER.	IMMUNOGEN, INC
GENERIC: SARGRAMOSTIM TRADE: LEUKINE*/**	TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANTS IN PATIENTS WITH NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE AND ACUTE LYMPHOBLASTIC LEUKEMIA. [MAR 5, 1998]	IMMUNEX

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: CYSTEAMINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF NEPHROPATHIC CYSTINOSIS.	WARNER-LAMBERT COMPANY
GENERIC: DEFEROXAMINE AND DEXTRAN TRADE: BIO-RESCUE	TREATMENT OF ACUTE IRON POISONING.	BIOMEDICAL FRONTIERS, INC
GENERIC: DESMOPRESSIN ACETATE TRADE: DDAVP HIGH CONCENTRATION	TREATMENT OF MILD HEMOPHILIA A AND VON WILLEBRAND'S DISEASE.	RORER PHARMACEUTICAL CORP
GENERIC: DRONABINOL TRADE: MARINOL	STIMULATION OF APPETITE AND PREVENTION OF WEIGHT LOSS IN PATIENTS WITH A CONFIRMED DIAGNOSIS OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	UNIMED, INC
GENERIC: GALLIUM NITRATE TRADE: GANITE*/**	TREATMENT OF HYPERCALCEMIA OF MALIGNANCY. [JAN 17, 1998]	FUJISAWA PHARM
GENERIC: GENTAMICIN IMPREGNATED PMMA BEADS ON SURGICAL WIRE TRADE: SEPTOPAL	TREATMENT OF CHRONIC OSTEOMYELITIS OF POST-TRAUMATIC, POSTOPERATIVE OR HEMATOGENOUS ORIGIN.	E. MERCK, DARMSTADT
GENERIC: IDARUBICIN HCL TRADE: IDAMYCIN	TREATMENT OF ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN PEDIATRIC PATIENTS.	ADRIA
GENERIC: KETOCONAZOLE TRADE: NOT ESTABLISHED	FOR USE WITH CYCLOSPORIN A TO DIMINISH THE NEPHROTOXICITY INDUCED BY CYCLOSPORIN IN ORGAN TRANSPLANTATION.	PHARMEDIC COMPANY

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: PENTOSTATIN TRADE: NOT ESTABLISHED	TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA.	WARNER LAMBERT COMPANY
GENERIC: POLOXAMER 331 TRADE: PROTOX	INITIAL THERAPY OF TOXOPLASMOSIS IN PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	CYTRX CORPORATION
GENERIC: SUCCIMER TRADE: CHEMET*/**	TREATMENT OF LEAD POISONING IN CHILDREN.*/** [JAN 30, 1998] TREATMENT OF MERCURY INTOXICATION.	MCNEIL
ENERIC: SUCRALFATE TRADE: NOT ESTABLISHED	TREATMENT OF ORAL ULCERATIONS AND DYSPHAGIA IN PATIENTS WITH EPIDERMOLYSIS BULLOSA.	NASKA PHARMCAL CO
GENERIC: TESTOSTERONE SUBLINGUAL TRADE: NOT ESTABLISHED	TREATMENT OF CONSTITUTIONAL DELAY OF GROWTH AND PUBERTY IN BOYS.	GYNEX, INC
GENERIC: URSODEOXYCHOLIC ACID TRADE: ACTIGALL	MANAGEMENT OF THE CLINICAL SIGNS AND SYMPTOMS ASSOCIATED WITH PRIMARY BILIARY CIRRHOSIS.	CIBA GEIGY

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

NO MARCH 1991 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, 11TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO MARCH 1991 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, 11TH 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	REASON FOR PETITION	STATUS
CLOBETASOL PROPIONATE LOTION; TOPICAL	0.05%	90 P-0198/ CP1	KROSS	NEW DOSAGE FORM	APPROVED MAR 14, 1991
ESTRADIOL FILM, EXTENDED RELEASE; TRANSDERMAL	0.067MG/24HR	90 P-0125/ CP1	NOVEN PHARMS	NEW STRENGTH	APPROVED MAR 14, 1991
ESTRADIOL FILM, EXTENDED RELEASE; TRANSDERMAL	0.084MG/24HR	90 P-0125/ CP2	NOVEN PHARMS	NEW STRENGTH	APPROVED MAR 14, 1991

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, 11TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEUDLE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES
NEW INDICATION

I-55	HYPERTENSION
I-56	EROSIVE GASTROESOPHAGEAL REFLUX DISEASE

REFERENCES
PATENT USE CODE

U-44	RELIEF OF NAUSEA AND VOMITING
U-45	TREATMENT OF INFLAMMATION AND ANALGESIA
U-46	TREATMENT OF PANIC DISORDER

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
	18276 001	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
	18276 002	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
	18276 003	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
	18276 004	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
			3980789	SEP 14, 1993			
	19926 001	ALTRETAMINE; HEXALEN				ODE	DEC 26, 1997
>ADD>	17920 002	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
>ADD>	17920 003	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
>ADD>	17920 004	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
>ADD>	17920 005	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
>ADD>	20037 001	DICLOFENAC SODIUM; VOLTAREN	3652762	MAR 28, 1991		NDF	MAR 28, 1994
	18723 001	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
	18723 002	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
	18723 003	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
	19680 001	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
	19794 001	DIVALPROEX SODIUM; DEPAKOTE CP	4988731	JAN 29, 2008			
	19794 002	DIVALPROEX SODIUM; DEPAKOTE CP	4988731	JAN 29, 2008			
>ADD>	19946 001	DOXACURIUM CHLORIDE; NUROMAX	4701460	OCT 20, 2004		NCE	MAR 07, 1996
	19668 001	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
	19668 002	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
	19668 003	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
	19668 004	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
	19653 001	ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1998		NC	DEC 29, 1992
	19653 002	ETHINYL ESTRADIOL; ORTHO CYCLEN-28	4027019	MAY 31, 1998		NC	DEC 29, 1992
	18922 002	ETODOLAC; LODINE	4076831	FEB 28, 1995	U-45		
			3939178	FEB 17, 1993		NCE	JAN 31, 1996
	18922 003	ETODOLAC; LODINE	4076831	FEB 28, 1995	U-45		
			3939178	FEB 17, 1993		NCE	JAN 31, 1996
	19949 001	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		NCE	JAN 29, 1995
	19949 002	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		NCE	JAN 29, 1995
	19949 003	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		NCE	JAN 29, 1995
	19950 001	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		NCE	JAN 29, 1995
	19961 002	GALLIUM NITRATE; GANITE				NCE	JAN 17, 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
18686 001	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18687 001	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18687 002	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18687 003	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18687 004	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18716 001	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18716 002	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18716 003	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18716 004	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
19425 001	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
19886 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 2001		NCE	FEB 13, 1995
19684 001	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003		I-55	SEP 06, 1992
		4765989	SEP 16, 2003		D-2	SEP 06, 1992
19684 002	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003		I-55	SEP 06, 1992
19684 002	NIFEDIPINE; PROCARDIA XL	4765989	SEP 16, 2003		D-2	SEP 06, 1992
19684 003	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003		I-55	SEP 06, 1992
		4765989	SEP 16, 2003		D-2	SEP 06, 1992
20007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4753789	JUN 28, 2005	U-44	NCE	JAN 04, 1996
		4695578	SEP 22, 2004			
18631 001	PENTOXIFYLLINE; TRENTAL	3737433	APR 03, 1997		NCE	AUG 30, 1994
19456 001	PINACIDIL; PINDAC	RE31244	NOV 08, 1996	U-3	NCE	DEC 28, 1994
19456 002	PINACIDIL; PINDAC	RE31244	NOV 08, 1996	U-3	NCE	DEC 28, 1994
19901 001	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19901 002	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19901 003	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19901 004	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19998 002	SUCCIMER; CHEMET				NCE	JAN 30, 1996
					ODE	JAN 30, 1998