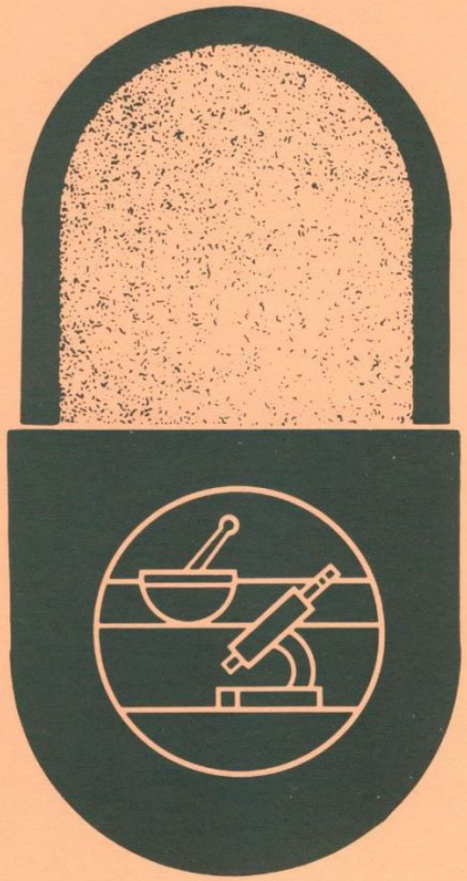
CUMULATIVE SUPPLEMENT 4

JAN'91-APR'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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

11TH EDITION

Cumulative Supplement

April 1991

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CUMULATIVE SUPPLEMENT 4

APRIL 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 " ∋ " symbol to designate their non-marketed status. All products having a " ∋ " 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 CHANGE OF A THERAPEUTIC EQUIVALENCY CODE FOR A DRUG ENTITY

Methylphenidate Hydrochloride:

In its initial considerations, the Agency did not classify methylphenidate hydrochloride (MPD) as having an actual or potential bioequivalence problem (42 FR 1624, January 7, 1977). MPD in oral tablet form (Ritalin™, manufactured by Ciba Pharmaceuticals) is a DESI drug product that was raised to the effective status on October 7, 1970 (35 FR 15771). MPD in tablet form remained single source until December 23, 1977 when it became available from MD Pharmaceutical. In the first and subsequent editions of the "Orange Book" this drug product has been coded **AA**.

Recently, FDA's Therapeutic Inequivalence Action Coordination Committee (TIACC) investigated a report from the Kaiser Permanente Medical Care Program in Oakland, California, suggesting therapeutic inequivalence regarding duration of action in a marketed lot of MD Pharmaceutical MPD tablets. Samples from MD Pharmaceutical and Ciba were tested in accordance with USP dissolution test procedures by an FDA field laboratory. Although both products met the single point USP criteria of not less than 75% of the labeled amount of MPD dissolved within 45 minutes, the dissolution profile of the MD Pharmaceutical product was much faster than that of the Ciba product.

Based on these in vitro dissolution data, FDA commissioned an in vivo bioequivalence study under its extramural contract research program. The bioequivalence study indicated that at one-half and three-fourths hours after administration of a single 20 mg dose, somewhat more of MD Pharmaceutical's product had been absorbed compared to Ciba's Ritalin. However, the MD Pharmaceutical MPD 20 mg tablets met FDA's criteria for rate and extent of absorbtion, and were considered to be bioequivalent to Ciba's Ritalin 20 mg tablets.

Because of the in vitro dissolution data coupled with new information discovered during the course of this evaluation, the FDA has proposed a change in the therapeutic equivalence code from **AA** to **BP** for listed MPD tablets. This change requires that firms submitting an ANDA for MPD tablets submit an acceptable in vivo bioequivalence study to gain approval in addition to submission of all previously required information.

Agency reasons for considering this change in the equivalence code is as follows:

1) Although early work suggested that MPD tablets are completely absorbed, recent studies utilizing more specific techniques calculated the relative bioavailability to be 11 to 53%. (Chan et al: Pediatrics, **72**, 56-59, 1983). This raised concerns regarding possible approval of a superbioavailable drug product.

2) The current dl-MPD pharmacological activity derives primarily from the d isomer which may exhibit non-linear kinetics. (Srinivas et al: Journal of Pharmacology and Experimental Therapeutics, **241**, 300-306, 1987).

3) The previously cited in vitro dissolution data suggesting that substantial differences in in vitro dissolution may exist between different formulations of MPD.

The Agency invites written comments and scientific data regarding the Agency's proposal to change the therapeutic equivalence code for listed MPD oral tablets from **AA** to **BP**. The comment period will be 60 days from the first day in the monthly Supplement.

1.4 THE B* THERAPEUTIC EQUIVALENCE CODE

Drug products requiring further FDA investigation and review to determine therapeutic equivalence.

The code **B*** is assigned to products that were previously assigned an **A** code if FDA receives new information that raises a significant question regarding therapeutic equivalence that can be resolved only through further Agency investigation and/or review of data and information submitted by the applicant. The **B*** code signifies that the Agency will take no position regarding the therapeutic equivalence of the product until the Agency completes its investigation and review.

1.5 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

1.6 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	10123	9953		
SINGLE SOURCE	2030 (20.1%)	2090 (21.0%)		
MULTISOURCE	8093 (79.9%)	7863 (79.0%)		
THERAPEUTICALLY EQUIVALENT	7222 (71.3%)	7061 (71.0%)		
NOT THERAPEUTICALLY EQUIVALENT	752 (7.4%)	660 (6.6%)		
EXCEPTIONS[1]	119 (1.2%)	142 (1.4%)		
NEW MOLECULAR ENTITIES APPROVED	--	5		
NUMBER OF APPLICANTS	400	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

/AA/	/AM THERAP/	/300MG;15MG/	/N89481/001/ /MAR/03,/1987/	
	∂ AM THERAP	300MG;15MG	N89481 001 MAR 03, 1987	

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

>DLT >/AA/	/CHELSEA/	/325MG;50MG/	/N71336/001/ /DEC/11,/1986/		
>DLT >					
>DLT >/AA/		/650MG;100MG/	/N71337/001/ /DEC/11,/1986/		
>DLT >					
>ADD > B*	CHELSEA	325MG;50MG	N71336 001 DEC 11, 1986		
>ADD >					
>ADD > B*		650MG;100MG	N71337 001 DEC 11, 1986		
>ADD >					

ACYCLOVIR

>ADD >	TABLET; ORAL			
>ADD >	ZOVIRAX			
>ADD >	BURROUGHS WELLCOME	400MG*	N20089 001 APR 30, 1991	
>ADD >				
>ADD >		800MG*	N20089 002 APR 30, 1991	
>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

>ADD >	**ALGLUCERASE**			
>ADD >	INJECTABLE; INJECTION			
>ADD >	CEREDASE			
>ADD >	GENZYME	80 UNITS/ML*		N20057 003 APR 05, 1991
>ADD >				

ALLOPURINOL

TABLET; ORAL
ALLOPURINOL

/AA/	/PUREPAC/	/100MG/	/N70579/001/ /APR/14,/1986/	
/AA/		/300MG/	/N70580/001/ /APR/14,/1986/	
	∂ PUREPAC	100MG	N70579 001 APR 14, 1986	
	∂	300MG	N70580 001 APR 14, 1986	

ALPRAZOLAM

TABLET; ORAL
XANAX

/3/UPJOHN/		/2MG/	/N18276/004/ /NOV/27,/1985/	
	UPJOHN	2MG	N18276 004 NOV 27, 1985	

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL
PERPHENAZINE AND AMITRIPTYLINE HCL

> DLT >	/AA/	/CHELSEA/	/10MG;2MG/	/N71384/001/	
> DLT >				/NOV/03,/1986/	
> DLT >	/AA/		/10MG;4MG/	/N71386/001/	
> DLT >				/NOV/03,/1986/	
> DLT >	/AA/		/25MG;2MG/	/N71385/001/	
> DLT >				/NOV/03,/1986/	
> DLT >	/AA/		/25MG;4MG/	/N71387/001/	
> DLT >				/NOV/03,/1986/	
> ADD >	B*	CHELSEA	10MG;2MG	N71384 001	
> ADD >				NOV 03, 1986	
> ADD >	B*		10MG;4MG	N71386 001	
> ADD >				NOV 03, 1986	
> ADD >	B*		25MG;2MG	N71385 001	
> ADD >				NOV 03, 1986	
> ADD >	B*		25MG;4MG	N71387 001	
> ADD >				NOV 03, 1986	
> ADD >	B*		50MG;4MG	N71558 001	
> ADD >				MAR 02, 1987	
> DLT >	/BX/		/50MG;4MG/	/N71558/001/	
> DLT >				/MAR/02,/1987/	

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
BUTALBITAL W/ ASPIRIN AND CAFFEINE

/AA/	/CHELSEA/	/325MG;50MG;40MG/	/N86231/002/	
			/FEB/12,/1985/	

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL
BUTALBITAL, ASPIRIN AND CAFFEINE

AB	CHELSEA	325MG;50MG;40MG	N86231 002	
			FEB 12, 1985	

TABLET; ORAL
BUTALBITAL W/ ASPIRIN AND CAFFEINE

/AA/	/CHELSEA/	/325MG;50MG;40MG/	/N86231/002/	
			/MAR/23,/1984/	

BUTALBITAL, ASPIRIN AND CAFFEINE

AB	CHELSEA	325MG;50MG;40MG	N86237 002	
			MAR 23, 1984	

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL
ORPHENGESIC

> ADD >	B*	PAR	385MG;30MG;25MG	N71642 001
> ADD >				JUN 23, 1987
> DLT >	/BX/		/385MG;30MG;25MG/	/N71642/001/
> DLT >				/JUN/23,/1987/

ORPHENGESIC FORTE

> ADD >	B*	PAR	770MG;60MG;50MG	N71643 001
> ADD >				JUN 23, 1987
> DLT >	/BX/		/770MG;60MG;50MG/	/N71643/001/
> DLT >				/JUN/23,/1987/

BACLOFEN

TABLET; ORAL
BACLOFEN

> DLT >	/AA/	/PHARM/BASICS/	/10MG/	/N71260/001/
> DLT >				/MAY/06,/1988/
> DLT >	/AA/		/20MG/	/N71261/001/
> DLT >				/MAY/06,/1988/
> ADD >	B*	PHARM BASICS	10MG	N71260 001
> ADD >				MAY 06, 1988
> ADD >	B*		20MG	N71261 001
> ADD >				MAY 06, 1988

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		
AP	RHONE POULENC RORER	200 IU/ML	N17769 001
	MIACALCIN		
AP	SANDOZ	200 IU/ML*	N17808 002
			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/	
∂ 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/
	∂ ABBOTT	EQ 90MG CALCIUM/5ML	N83159 001

CARBAMAZEPINE

TABLET; ORAL

	CARBAMAZEPINE			
>DLT >/AA/	/PHARM/BASICS/	/200MG/	/N70300/001/	
>DLT >			/MAY/15,/1986/	
>ADD > B*	PHARM BASICS	200MG	N70300 001	
>ADD >			MAY 15, 1986	

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

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

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL

		CEPHALEXIN		
>ADD >	AB	SQUIBB MARK	EQ 125MG BASE/5ML*	N62986 001
>ADD >				APR 18, 1991

CEPHRADINE

CAPSULE; ORAL

		/VELOSEF '250'/		
/AB/	/ERSANA/	/250MG/		/N50548/001/
	∂ ERSANA	250MG		N50548 001
		/VELOSEF '500'/		
/AB/	/ERSANA/	/500MG/		/N50548/002/
	∂ 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		
/AA/	/VITARINE/	/4MG/		/N85837/001/
	∂ VITARINE	4MG		N85837 001
		/PHENETRON/		
/AA/	/LANNETT/	/4MG/		/N80846/001/
	∂ 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

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HCL

>DLT >/AB/	/DURAMED/	/0.2MG/	/N71102/001/	/AUG/14,/1986/
>ADD > ə DURAMED		0.2MG	N71102 001	AUG 14, 1986

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

>DLT >/AB/	/PUREPAC/	/3.75MG/	/N71924/001/	/APR/25,/1988/
>ADD > ə PUREPAC		3.75MG	N71924 001	APR 25, 1988

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

>DLT >/AB/	/SEARLE/	/3.75MG/	/N71727/001/	/DEC/18,/1987/
>DLT >/AB/		/7.5MG/	/N71728/001/	/DEC/18,/1987/
>DLT >/AB/		/15MG/	/N71729/001/	/DEC/18,/1987/
>ADD > ə SEARLE		3.75MG	N71727 001	DEC 18, 1987
>ADD > ə		7.5MG	N71728 001	DEC 18, 1987
>ADD > ə		15MG	N71729 001	DEC 18, 1987

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/
/AP/	/LYPHOMED/	/0.03MG/ML/	/N80510/003/
/AP/		/0.1MG/ML/	/N80510/001/
/AP/		/1MG/ML/	/N80510/002/
ə LYPHOMED		0.03MG/ML	N80510 003
ə		0.1MG/ML	N80510 001
ə		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

DANAZOL

CAPSULE; ORAL
DANAZOL

> DLT >	/AA/	/AM THERAP/	/200MG/	/N71569/001/ /DEC/30,/1987/
> DLT >				
> ADD >	B*	AM THERAP	200MG	N71569 001 DEC 30, 1987
> ADD >				

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPRAMINE HCL

> DLT >	/AA/	/PHARM BASICS/	/25MG/	/N71864/001/ /SEP/09,/1987/
> DLT >				
> DLT >	/AA/		/50MG/	/N71865/001/ /SEP/09,/1987/
> DLT >				
> DLT >	/AA/		/75MG/	/N71866/001/ /SEP/09,/1987/
> DLT >				
> DLT >	/AA/		/100MG/	/N71867/001/ /SEP/09,/1987/
> DLT >				
> ADD >	B*	PHARM BASICS	25MG	N71864 001 SEP 09, 1987
> ADD >				
> ADD >	B*		50MG	N71865 001 SEP 09, 1987
> ADD >				
> ADD >	B*		75MG	N71866 001 SEP 09, 1987
> ADD >				
> ADD >	B*		100MG	N71867 001 SEP 09, 1987
> ADD >				

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

/BP/	/CORD/	/0.75MG/		/N80399/001/
	∂ 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

DIATRIZOATE SODIUM

INJECTABLE; INJECTION

>DLT >	/MD-56/			
>DLT >/AP/	/MALLINCKRODT/	/50%/	/N87075/001/	
>ADD >	@ MALLINCKRODT	50%	N87075 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 >	/2/SUPERPHARM/	/2MG/	/N70642/001/	
>DLT >			/DEC/11,/1985/	
>DLT >	/2/	/5MG/	/N70643/001/	
>DLT >			/DEC/11,/1985/	
>DLT >	/2/	/10MG/	/N70644/001/	
>DLT >			/DEC/11,/1985/	

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC

VOLTAREN

CIBA	0.1%*	N20037 001	
		MAR 28, 1991	

DIMENHYDRINATE

INJECTABLE; INJECTION

DIMENHYDRINATE

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

>DLT >	/TABLET;/ORAL/			
>DLT >	/DIMENHYDRINATE/			
>DLT >/AA/	/CHELSEA/	/50MG/	/N85166/001/	

DIMENHYDRINATE

>DLT >	/TABLET;/ORAL/			
>DLT >	/DIMENHYDRINATE/			
>ADD >	@ CHELSEA	50MG	N85166 001	

DIPHENHYDRAMINE HYDROCHLORIDE

ELIXIR; ORAL

DIPHENHYDRAMINE HCL

>DLT >/AA/	/KV/	/12.5MG/5ML/	/N85621/001/	
>ADD >	@ KV	12.5MG/5ML	N85621 001	

INJECTABLE; INJECTION

DIPHENHYDRAMINE HCL

/AP/	/ELKINS/SINN/	/50MG/ML/	/N83183/001/	
	@ 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

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL

DISOPYRAMIDE PHOSPHATE

>ADD >	B*	CHELSEA	EQ 100MG BASE	N71020 001
>ADD >				DEC 01, 1986
>ADD >	B*		EQ 150MG BASE	N71021 001
>ADD >				DEC 01, 1986
>DLT >	/BX/		/EQ/100MG/BASE/	/N71020/001/
>DLT >				/DEC/01,/1986/
>DLT >	/BX/		/EQ/150MG/BASE/	/N71021/001/
>DLT >				/DEC/01,/1986/

DISOPYRAMIDE PHOSPHATE

DOXORUBICIN HYDROCHLORIDE

>_DLT_> /TABLET;ORAL/
>_DLT_> /DIMENHYDRINATE/
>_DLT_>/AA/ /CHELSEA/ /50MG/ /N85166/001/

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL
DISOPYRAMIDE PHOSPHATE

>_DLT_>/AB/	/MYLAN/	/EQ 100MG BASE/	/N70138/001/ /JUN/14,/1985/	
>_DLT_>				
>_DLT_>/AB/		/EQ 150MG BASE/	/N70139/001/ /JUN/14,/1985/	
>_DLT_>				
>_ADD_>	∂ MYLAN	EQ 100MG BASE	N70138 001 JUN 14, 1985	
>_ADD_>				
>_ADD_>	∂	EQ 150MG BASE	N70139 001 JUN 14, 1985	
>_ADD_>				

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOBUTREX

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

DOXACURIUM CHLORIDE

INJECTABLE; INJECTION
NUROMAX

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

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
DOXEPIN HCL

>_DLT_>/AB/	/PUREPAC/	/EQ 75MG BASE/	/N72386/001/ /SEP/08,/1988/	
>_DLT_>				
>_DLT_>/AB/		/EQ 150MG BASE/	/N72387/001/ /SEP/08,/1988/	
>_DLT_>				
>_ADD_>	∂ PUREPAC	EQ 75MG BASE	N72386 001 SEP 08, 1988	
>_ADD_>				
>_ADD_>	∂	EQ 150MG BASE	N72387 001 SEP 08, 1988	
>_ADD_>				
AB	ROYCE	EQ 10MG BASE¤	N72985 001 MAR 29, 1991	
AB		EQ 25MG BASE¤	N72986 001 MAR 29, 1991	
AB		EQ 50MG BASE¤	N72987 001 MAR 29, 1991	

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

DOXYCYCLINE HYCLATE

TABLET; ORAL
DOXYCYCLINE HYCLATE

>_DLT_>/AB/	/CHELSEA/	/EQ 100MG BASE/	/N62392/002/ /MAR/31,/1983/
>_DLT_>			
>_ADD_>	∂ CHELSEA	EQ 100MG BASE	N62392 002 MAR 31, 1983
>_ADD_>			

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

/A/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/
ə BRISTOL MYERS SQUIBB 1MG N85020 002

ERGOLOID MESYLATES

>DLT> /AA/ /KV/ /0.5MG/ /N86265/001/
>DLT> /AA/ /1MG/ /N86264/001/
>ADD> ə KV 0.5MG N86265 001
>ADD> ə 1MG N86264 001

ERYTHROMYCIN

SOLUTION; TOPICAL

ERYTHROMYCIN

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

ESTROGENS, CONJUGATED

TABLET; ORAL

CONJUGATED ESTROGENS

>DLT> /BP/ /CHELSEA/ /1.25MG/ /N85801/001/
>DLT> /BP/ /2.5MG/ /N85826/001/
>DLT> /ə/ /0.625MG/ /N85600/001/
>DLT> /ə/CORD/ /0.3MG/ /N86070/001/
>DLT> /ə/ /0.625MG/ /N83761/001/
>DLT> /ə/ /1.25MG/ /N83763/001/
>DLT> /ə/ /2.5MG/ /N83762/001/
>DLT> /ə/DURAMED/ /0.3MG/ /N86492/001/
>DLT> /ə/ /0.625MG/ /N83272/001/
>DLT> /ə/ /1.25MG/ /N83294/001/
>DLT> /ə/ /2.5MG/ /N83295/001/
>DLT> /ə/HEATHER/ /0.625MG/ /N83356/001/
>DLT> /ə/ /1.25MG/ /N83360/001/
>DLT> /ə/ /2.5MG/ /N84650/001/
>DLT> /ə/PRIVATE/FORM/ /0.625MG/ /N83354/003/
>DLT> /ə/ /1.25MG/ /N83592/001/
>DLT> /ə/ /2.5MG/ /N85908/001/
/BP/ /ZENITH/ /0.3MG/ /N88569/001/
/NOV/29/1984/

/BP/ /0.625MG/ /N83373/001/
/BP/ /1.25MG/ /N83601/001/
/BP/ /2.5MG/ /N83602/001/
ə ZENITH 0.3MG N88569 001
NOV 29, 1984

ə 0.625MG N83373 001
ə 1.25MG N83601 001
ə 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

FENOPROFEN CALCIUM

CAPSULE; ORAL

FENOPROFEN CALCIUM

>ADD> AB WARNER CHILCOTT EQ 200MG BASE¤ N72946 001 APR 30, 1991
>ADD>
>ADD> AB EQ 300MG BASE¤ N72472 001 APR 30, 1991
>ADD>

FLUDARABINE PHOSPHATE

>ADD>

>ADD> INJECTABLE; INJECTION
>ADD> FLUDARA
>ADD> BERLEX 50MG/VIAL¤ N20038 001 APR 18, 1991
>ADD>

FLUOXETINE HYDROCHLORIDE

>ADD> SOLUTION; ORAL
>ADD> PROZAC
>ADD> LILLY EQ 20MG BASE/5ML¤ N20101 001 APR 24, 1991
>ADD>

GALLIUM NITRATE

INJECTABLE; INJECTION

GANITE

FUJISAWA PHARM 25MG/ML¤ N19961 002 JAN 17, 1991

GLUTETHIMIDE

TABLET; ORAL

>DLT>	/DORIDEN/				
>DLT>/AA/	/RHONE/POULENC/RORER/	/250MG/	/N09519/002/		
>DLT>/AA/		/500MG/	/N09519/005/		
>ADD>	@ RHONE POULENC RORER	250MG	N09519 002		
>ADD>	@	500MG	N09519 005		

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 LOCK FLUSH

>DLT>/AP/	/SOLOPAK/	/100 UNITS/ML/	/N87959/001/	
>DLT>			/APR/20,/1983/	
>ADD>	@ SOLOPAK	100 UNITS/ML	N87959 001	
>ADD>			APR 20, 1983	

HEPARIN SODIUM

INJECTABLE; INJECTION

/HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5%/

/AP/	/ABBOTT/	/10,000 UNITS/100ML/	/N18911/006/	
			/JAN/30,/1985/	
@ 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/	
@ SOLOPAK		20MG/ML	N88517 001	
			AUG 22, 1985	

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

HYDROCHLOROTHIAZIDE W/ RESERPINE

>DLT> /BP/	/BOLAR/	/50MG;0.125MG/	/N83666/001/	
>ADD>	@ BOLAR	50MG;0.125MG	N83666 001	

RESERPINE AND HYDROCHLOROTHIAZIDE

/BP/	/CORD/	/50MG;0.125MG/	/N88200/001/	
			/JAN/31,/1984/	
@ CORD		50MG;0.125MG	N88200 001	
			JAN 31, 1984	

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

>ADD> B*	PAR	50MG;75MG	N72337 001	
>ADD>			MAY 11, 1988	
>DLT> /BX/		/50MG;75MG/	/N72337/001/	
>DLT>			/MAY/11,/1988/	

HYDROCORTISONE

CREAM; TOPICAL

>DLT>	/H-CORT/			
>DLT>/AT/	/PHARMS ASSOC/	/0.5%/	/N86823/001/	
>ADD>	@ PHARMS ASSOC	0.5%	N86823 001	

HYDROCORTISONE

/AT/	/WHITE/TOWNE/PAULSEN/	/1%/	/N80496/002/	
@ WHITE TOWNE PAULSEN		1%	N80496 002	

HYDROCORTISONE

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

SOLUTION; TOPICAL
PENECORT
AT HERBERT 1% N88214 001 JUN 06, 1984

TEXACORT
AT GENDERM 1% N80425 001

TABLET; ORAL
HYDROCORTISONE
> DLT > /BP/ /PUREPAC/ /20MG/ /N80395/001/
> ADD > ∂ PUREPAC 20MG N80395 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

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

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL
HYDROXYZINE HCL

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

HYDROXYZINE PAMOATE

CAPSULE; ORAL
HYDROXYZINE PAMOATE

/AB/	/VANGARD/	/EQ 25MG HCL/	/N88392/001/ /SEP/19,/1983/	
ə VANGARD		EQ 25MG HCL	N88392 001 SEP 19, 1983	

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

/AB/	/ROXANE/	/25MG/	/N70353/001/ /JUN/18,/1985/	
/AB/		/50MG/	/N70354/001/ /JUN/18,/1985/	
ə ROXANE		25MG	N70353 001 JUN 18, 1985	
ə		50MG	N70354 001 JUN 18, 1985	

IOPAMIDOL

INJECTABLE; INJECTION
ISOVUE-M 200

SQUIBB	41%	N18735 001 DEC 31, 1985	

ISOVUE-200

/SQUIBB/	/41%/	/N18735/001/ /DEC/31,/1985/		
SQUIBB	41%	N18735 006 JUL 07, 1987	> ADD > B*	PHARM BASICS 300MG

KETOCONAZOLE

/SUSPENSION;/ORAL/
/NIZORAL/

/JANSSEN/	/100MG/5ML/	/N70767/001/ /NOV/07,/1986/	
ə JANSSEN	100MG/5ML	N70767 001 NOV 07, 1986	

LEVONORGESTREL

IMPLANT; IMPLANTATION
/LEVONORGESTREL/SYSTEM/

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

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL

/STERIS/	/1%/	/N83627/001/	
/ə/	/2%/	/N83627/002/	
ə STERIS	1%	N83627 001	
ə	2%	N83627 002	

LINCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION
LINCOMYCIN HCL

> ADD > AP		STERIS	EQ 300MG BASE/ML¤	N63180 001 APR 16, 1991
> ADD >				

LITHIUM CARBONATE

CAPSULE; ORAL
LITHIUM CARBONATE

> DLT >/AB/		/PHARM/BASICS/	/300MG/	/N72542/001/ /FEB/01,/1989/	
> DLT > > ADD >	B*	PHARM BASICS	300MG	N72542 001 FEB 01, 1989	
> ADD >					

LORAZEPAM

TABLET; ORAL

LORAZEPAM

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

LOVASTATIN

TABLET; ORAL

MEVACOR

MSD	10MG‡	N19643 002
		MAR 28, 1991

MANNITOL

INJECTABLE; INJECTION

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

MEGESTROL ACETATE

TABLET; ORAL

MEGESTROL ACETATE

B*	PHARM BASICS	20MG	N70646 001
			OCT 02, 1987
B*		40MG	N70647 001
			OCT 02, 1987
/BX/		/20MG/	/N70646/001/
			/OCT/02,/1987/
/BX/		/40MG/	/N70647/001/
			/OCT/02,/1987/

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERIDINE HCL

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

METAPROTERENOL SULFATE

TABLET; ORAL

METAPROTERENOL SULFATE

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

METAPROTERENOL SULFATE

TABLET; ORAL
METAPROTERENOL SULFATE

> DLT >	/AB/	/PHARM BASICS/	/10MG/	/N71013/001/ /JAN/25,/1988/
> DLT >				
> DLT >	/AB/		/20MG/	/N71014/001/ /JAN/25,/1988/
> DLT >				
> ADD >	B*	PHARM BASICS	10MG	N71013 001 JAN 25, 1988
> ADD >				
> ADD >	B*		20MG	N71014 001 JAN 25, 1988
> ADD >				

METHADONE HYDROCHLORIDE

/TABLET;/EFFERVESCENT;/ORAL/
/METADONE/
/VITARINE/

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

INJECTABLE; INJECTION
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/
/AP/		/EQ 1GM BASE/VIAL/	/N89188/001/ /MAR/28,/1986/
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
ə		EQ 1GM BASE/VIAL	N89188 001 MAR 28, 1986

METHYPRYLON

TABLET; ORAL
NOLUDAR

	/ROCHE/	/50MG/	/N09660/002/
ə 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

		METRONIDAZOLE			
> ADD >	AP	STERIS	500MG/100ML	N70042 001 DEC 20, 1984	
> ADD >					
> DLT >		METRIC IV			
> DLT >	AP	STERIS	500MG/100ML	N70042 001 DEC 20, 1984	
> DLT >					

MICONAZOLE NITRATE

CREAM; VAGINAL

	MONISTAT 7			
AT	JOHNSON RW	2%	N17456 001	

SUPPOSITORY; VAGINAL

	MONISTAT 7			
AT	JOHNSON RW	100MG	N18526 001 MAR 15, 1982	

MINOXIDIL

TABLET; ORAL

		MINOXIDIL			
> DLT >	AB	PHARM BASICS	2.5MG	N71537 001 DEC 16, 1988	
> DLT >					
> ADD >	B*	PHARM BASICS	2.5MG	N71537 001 DEC 16, 1988	
> ADD >					

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

		NALOXONE			
AP	ELKINS SINN	0.4MG/ML	N70496 001 OCT 22, 1985		
	∂ ELKINS SINN	0.4MG/ML	N70496 001 OCT 22, 1985		

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		

NANDROLONE DECANOATE

INJECTABLE; INJECTION

		NANDROLONE DECANOATE			
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			
AB	WEST WARD	500MG	N83718 001		
	∂ WEST WARD	500MG	N83718 001		

NITROGLYCERIN

INJECTABLE; INJECTION

		NITROL			
> DLT >	AP	KREMERS URBAN	0.8MG/ML	N18774 001 JAN 19, 1983	
> DLT >					
> ADD >		∂ RORER	0.8MG/ML	N18774 001 JAN 19, 1983	
> ADD >					
		NITROSTAT			
> DLT >	AP	PARKE DAVIS	0.8MG/ML	N18588 001	
> ADD >		PARKE DAVIS	0.8MG/ML	N18588 001	

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

	ZOFRAN				
	GLAXO	EQ 2MG BASE/ML*	N20007 001 JAN 04, 1991		

OXAZEPAM

CAPSULE; ORAL
OXAZEPAM

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

PERPHENAZINE

TABLET; ORAL
PERPHENAZINE

>ADD>	B*	CHELSEA	8MG	N89700 001	
>ADD>				DEC 23, 1987	
>DLT>	/BX/		/8MG/	/N89700/001/	
>DLT>				/DEC/23,/1987/	

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE; ORAL
PHENDIMETRAZINE TARTRATE

/BC/	/VITARINE/	/105MG/	/N18074/001/	
	@ VITARINE	105MG	N18074 001	

TABLET; ORAL
PHENDIMETRAZINE TARTRATE

/AA/	/CORD/	/35MG/	/N86365/001/	
	@ 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	

>ADD> POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM
>ADD> BICARBONATE; SODIUM CHLORIDE

>ADD> POWDER FOR RECONSTITUTION; ORAL
>ADD> NULYTELY
>ADD> BRAINTREE 420GM/BOT;1.48GM/BOT;5.72GM/BOT;
>ADD> 11.2GM/BOT N19797 001
>ADD> APR 22, 1991

POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

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

PRAZEPAM

CAPSULE; ORAL
PRAZEPAM

>DLT>	/AA/	/PHARM/BASICS/	/5MG/	/N70427/001/	
>DLT>				/NOV/06,/1987/	
>DLT>	/AA/		/10MG/	/N70428/001/	
>DLT>				/NOV/06,/1987/	
>ADD>	B*	PHARM BASICS	5MG	N70427 001	
>ADD>				NOV 06, 1987	
>ADD>	B*		10MG	N70428 001	
>ADD>				NOV 06, 1987	

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/	> ADD >	
			/NOV/06,/1986/	> ADD >	
/BX/		/10MG/	/N89388/001/	> DLT >	
			/NOV/06,/1986/	> DLT >	
/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		
/AB/	/ROXANE/	/1MG/	/N87800/001/		
			/APR/22,/1982/		
/AB/		/2.5MG/	/N87801/001/		
			/APR/22,/1982/		
/AB/		/10MG/	/N84122/001/		
/AB/		/20MG/	/N87342/001/		
/AB/		/50MG/	/N84283/001/	> DLT >/AA/	/CHELSEA/
	∂ ROXANE	1MG	N87800 001	> ADD >	∂ CHELSEA
			APR 22, 1982	> DLT >/AB/	/RICHLYN/
	∂	2.5MG	N87801 001	> ADD >	RICHLYN
			APR 22, 1982		
	∂	10MG	N84122 001		
	∂	20MG	N87342 001		
	∂	50MG	N84283 001		

/25MG/	/N85231/001/	
25MG	N85231 001	
/25MG/	/N80808/001/	
25MG	N80808 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

PYRIDOSTIGMINE BROMIDE

TABLET; ORAL
PYRIDOSTIGMINE BROMIDE

KALI DUPHAR	30MG	N89572 001	
		NOV 27, 1990	
/PUREPAC/	/30MG/	/N89572/001/	
		/NOV/27,/1990/	

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION
PYRIDOXINE HCL

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

PYRILAMINE MALEATE

TABLET; ORAL
PYRILAMINE MALEATE

/AA/	/CHELSEA/	/25MG/	/N85231/001/
∂ CHELSEA	25MG	N85231 001	
/AB/	/RICHLYN/	/25MG/	/N80808/001/
RICHLYN	25MG	N80808 001	

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

/AB/	/VANGARD/	/200MG/	/N87909/001/
			/JUL/13,/1982/
∂ VANGARD	200MG	N87909 001	
		JUL 13, 1982	
QUINORA			
> DLT >/AB/	/KEY PHARMS/	/200MG/	/N83576/001/
> ADD >	∂ KEY PHARMS	200MG	N83576 001

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/	>DLT>	
/BP/		/0.25MG/	/N80723/002/	>DLT>	
	@ WHITE TOWNE PAULSEN	0.1MG	N80723 001	>DLT>	
	@	0.25MG	N80723 002	>ADD >	AP
		/1MG/	/N80723/003/	>ADD >	
	@	1MG	N80723 003		

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION
RITODRINE HCL

AP	ABBOTT	10MG/ML¤	N71618 001	>ADD >	AB	MUTUAL PHARM 150MG¤ N72050 001 APR 17, 1991
			FEB 28, 1991	>ADD >		
AP		15MG/ML¤	N71619 001	>ADD >	AB	200MG¤ N72051 001 APR 17, 1991
			FEB 28, 1991	>ADD >		
	RITODRINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER				AB	WARNER CHILCOTT 150MG¤ N72710 001 MAR 25, 1991
	ABBOTT	30MG/100ML¤	N71438 001		AB	200MG¤ N72711 001 MAR 25, 1991
			JAN 22, 1991			

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL
SELENIUM SULFIDE

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

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
SODIUM NITROPRUSSIDE

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

SUCCIMER

CAPSULE; ORAL
CHEMET
MCNEIL 100MG¤ N19998 002 JAN 30, 1991

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION
/GENERIC/

/AP/	/STERIS/	/80MG/ML;16MG/ML/	/N71556/001/	/DEC/17,/1987/	
	SULFAMETHOXAZOLE AND TRIMETHOPRIM				
>ADD >	AP	STERIS	80MG/ML;16MG/ML	N71556 001 DEC 17, 1987	

SULINDAC

TABLET; ORAL
SULINDAC

>ADD >	AB	MUTUAL PHARM	150MG¤	N72050 001 APR 17, 1991	
>ADD >	AB		200MG¤	N72051 001 APR 17, 1991	
	AB	WARNER CHILCOTT	150MG¤	N72710 001 MAR 25, 1991	
	AB		200MG¤	N72711 001 MAR 25, 1991	

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

TABLET; ORAL

	/THEOCLEAR-100/		
/BD/	/CENTRAL/PHARMS/	/100MG/	/N85353/002/
	a CENTRAL PHARMS	100MG	N85353 002
	/THEOCLEAR-200/		
/BD/	/CENTRAL/PHARMS/	/200MG/	/N85353/001/
	a 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/
	a LYPHOMED	100MG/ML	N80509 001
AP	STERIS	100MG/ML	N83534 001
AP		200MG/ML	N83534 002

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

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

THIOTHIXENE

CAPSULE; ORAL

THIOTHIXENE

/AA/	/AM/THERAP/	/2MG/	/N71885/001/ /AUG/12,/1987/
	a AM THERAP	2MG	N71885 001 AUG 12, 1987

TIMOLOL MALEATE

TABLET; ORAL

TIMOLOL MALEATE

>DLT>/AA/	/PHARM/BASICS/	/5MG/	>ADD>	B*	/N72001/001/ /JAN/10,/1989/
>DLT>					
>DLT>/AA/		/10MG/	>ADD>	B*	/N72002/001/ /JAN/10,/1989/
>DLT>					
>DLT>/AA/		/20MG/	>ADD>	B*	/N72003/001/ /JAN/10,/1989/
>DLT>					
>ADD> B*	PHARM BASICS	5MG			N72001 001 JAN 10, 1989
>ADD>					
>ADD> B*		10MG			N72002 001 JAN 10, 1989
>ADD>					
>ADD> B*		20MG			N72003 001 JAN 10, 1989
>ADD>					

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION
TOBRAMYCIN SULFATE

>ADD >	AP	ABBOTT	EQ 10MG BASE/ML*	N63080 001 APR 30, 1991	
>ADD >	AP		EQ 10MG BASE/ML*	N63112 001 APR 30, 1991	
>ADD >	AP		EQ 40MG BASE/ML*	N63111 001 APR 30, 1991	
>ADD >	AP	LEDERLE	EQ 10MG BASE/ML*	N63113 001 APR 26, 1991	
>ADD >	AP		EQ 40MG BASE/ML*	N63117 001 APR 26, 1991	

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

>DLT >/AB/		/CHELSEA/	/100MG/	/N70285/001/ /JAN/09,/1986/	
>DLT >/AB/			/250MG/	/N70286/001/ /JAN/09,/1986/	
>DLT >/AB/			/500MG/	/N70287/001/ /JAN/09,/1986/	
>ADD >	B*	CHELSEA	100MG	N70285 001 JAN 09, 1986	
>ADD >	B*		250MG	N70286 001 JAN 09, 1986	
>ADD >	B*		500MG	N70287 001 JAN 09, 1986	

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

>DLT >/AB/		/CHELSEA/	/50MG/	/N70568/001/ /OCT/10,/1986/	
>DLT >/AB/			/100MG/	/N70569/001/ /OCT/10,/1986/	
>ADD >	B*	CHELSEA	50MG	N70568 001 OCT 10, 1986	
>ADD >	B*		100MG	N70569 001 OCT 10, 1986	
	AB	MYLAN	50MG*	N71405 001 FEB 27, 1991	
	AB		100MG*	N71406 001 FEB 27, 1991	

TRIAMCINOLONE ACETONIDE

>DLT >		/GEL;/TOPICAL/		
>DLT >		/ARISTOGEL/		
>DLT >		/LEDERLE/	/0.1%/	/N83380/001/
>ADD >		∂ LEDERLE	0.1%	N83380 001

OINTMENT; TOPICAL
ARISTOCORT A

>DLT >/AT/		/LEDERLE/	/0.5%/	/N88781/001/ /OCT/05,/1984/
>ADD >		∂ LEDERLE	0.5%	N88781 001 OCT 05, 1984

TRIAMCINOLONE DIACETATE

INJECTABLE; INJECTION
TRIAMCINOLONE DIACETATE

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

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
TRIMIPRAMINE MALEATE

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

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION
/CALAN/

/AP/		/SEARLE/	/2.5MG/ML/	/N18925/001/ /MAR/30,/1984/
		∂ SEARLE	2.5MG/ML	N18925 001 MAR 30, 1984

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL

>ADD >	B*	CHELSEA	80MG	N70421 001
>ADD >				SEP 17, 1986
>ADD >	B*		120MG	N70422 001
>ADD >				SEP 17, 1986
>DLT >	/BX/		/80MG/	/N70421/001/
>DLT >				/SEP/17,/1986/
>DLT >	/BX/		/120MG/	/N70422/001/
>DLT >				/SEP/17,/1986/

TABLET, EXTENDED RELEASE; ORAL
ISOPTIN SR

		KNOLL	120MG@	N19152 003
				MAR 06, 1991

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL

> ADD > MICRODERM

> ADD > JOHNSON AND JOHNSON 4%Ⓡ N72255 001

> ADD > APR 15, 1991

SPONGE; TOPICAL

MICRODERM

JOHNSON AND JOHNSON 4%Ⓡ N72295 001

FEB 28, 1991

HYDROCORTISONE

/OINTMENT;TOPICAL/

/HC/(HYDROCORTISONE)/

/C/AND/M/ /0.5%/ /N80481 001/

Ⓐ 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 4 / JAN '91 - APR '91

HETASTARCH 6% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION			
HESPAN			
DUPONT MERCK PHARM		6GM/100ML;0.9GM/100ML	N890105 APR 04, 1991

PENTASTARCH 10% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION			
PENTASPAN			
DUPONT MERCK PHARM		10GM/100ML;0.9GM/100ML	N890104 APR 04, 1991

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. SYSTEMIC TREATMENT OF CUTANEOUS T-CELL LYMPHOMA. SYSTEMIC TREATMENT OF CUTANEOUS MALIGNANT MELANOMA.	BIOGEN
GENERIC: MUCOID EXOPOLYSACCHARIDE PSEUDOMONAS HYPERIMMUNE GLOBULIN TRADE: MEPIG	TREATMENT OF PULMONARY INFECTIONS DUE TO PSEUDOMONAS AERUGINOSA IN PATIENTS WITH CYSTIC FIBROSIS.	UNIVAX BIOLOGICS, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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 ASSOICATED 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: ALGLUCERASE TRADE: CEREDASE*/**	REPLACEMENT THERAPY IN PATIENTS WITH GAUCHER'S DISEASE TYPE I. [APR 5, 1998]	GENZYME
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	UNIMED, INC
GENERIC: FLUDARABINE PHOSPHATE TRADE: FLUDARA*/**	TREATMENT OF REFRACTORY B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA. [APR 18, 1998]	BERLEX
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 CYCLOPORIN A TO DIMINISH THE NEPHROTOXICITY INDUCED BY CYCLOSPORIN IN ORGAN TRANSPLANTATION.	PHARMEDIC COMPANY
GENERIC: OFLOXACIN TRADE: NOT ESTABLISHED	TREATMENT OF BACTERIAL CORNEAL ULCERS.	ALLERGAN, INC

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 SYDROME (AIDS).	CYTRX CORPORATION
GENERIC: RECOMBINANT HUMAN SUPEROXIDE DISMUTASE TRADE: NOT ESTABLISHED	PREVENTION OF BRONCHOPULMONARY DYSPLASIA IN PREMATURE NEONATES WEIGHING LESS THAN 1500 GMS.	BIO TECHNOLOGY GENERAL CORP
GENERIC: RIBAVIRIN TRADE: VIRAZOLE	TREATMENT OF HEMORRHAGIC FEVER WITH RENAL SYNDROME.	ICN PHARMACEUTICALS, INC
GENERIC: SUCCIMER TRADE: CHEMET*/**	TREATMENT OF LEAD POISONING IN CHILDREN.*/** [JAN 30, 1998] TREATMENT OF MERCURY INTOXICATION.	MCNEIL
GENERIC: 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 APRIL 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 APRIL 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
DOPAMINE HYDROCHLORIDE INJECTABLE; INJECTION	5MG/ML	90 P-0137/ CP1	ABBOTT	NEW STRENGTH	APPROVED APR 10, 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
U-47	STIMULATION OF THE RELEASE OF GROWTH HORMONE
U-48	ANALGESIA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	20057 003	ALGLUCERASE; CEREDASE				NCE	APR 05, 1996
>ADD>						ODE	APR 05, 1998
	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		
	19926 001	ALTRETAMINE; HEXALEN	3980789	SEP 14, 1993			
>ADD>	18700 001	AMRINONE LACTATE; INOCOR				ODE	DEC 26, 1997
>DLT>	18700 001	AMRINONE LACTATE; INOCOR	4072746	APR 23, 1998	U-7	NCE	JUL 31, 1994
	17920 002	CIMETIDINE; TAGAMET	4072746	FEB 07, 1995	U-7	NCE	JUL 31, 1994
	17920 003	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
	17920 004	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
	17920 005	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
>ADD>	17924 001	CIMETIDINE HYDROCHLORIDE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
>ADD>	19849 001	DAPIPRAZOLE HYDROCHLORIDE; REV-EYES	3950333	APR 13, 1993		I-56	MAR 07, 1994
>ADD>	19082 001	DEZOCINE; DALGAN	4252721	FEB 24, 1998		NCE	DEC 31, 1995
>ADD>			4001331	JAN 04, 1996		NCE	DEC 29, 1994
>ADD>	19082 002	DEZOCINE; DALGAN	3836670	SEP 09, 1991	U-48		
>ADD>			4001331	JAN 04, 1996		NCE	DEC 29, 1994
>ADD>	19082 003	DEZOCINE; DALGAN	3836670	SEP 09, 1991	U-48		
>ADD>			4001331	JAN 04, 1996		NCE	DEC 29, 1994
	20037 001	DICLOFENAC SODIUM; VOLTAREN	3836670	SEP 09, 1991	U-48		
	18723 001	DIVALPROEX SODIUM; DEPAKOTE	3652762	MAR 28, 1991		NDF	MAR 28, 1994
	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			
	19946 001	DOXACURIUM CHLORIDE; NUROMAX	4988731	JAN 29, 2008			
	19668 001	DOXAZOSIN MESYLATE; CARDURA	4701460	OCT 20, 2004		NCE	MAR 07, 1996
	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	4188390	FEB 12, 1997		NCE	NOV 02, 1995
	19653 002	ETHINYL ESTRADIOL; ORTHO CYCLEN-28	4027019	MAY 31, 1998		NC	DEC 29, 1992
	18922 002	ETODOLAC; LODINE	4027019	MAY 31, 1998		NC	DEC 29, 1992
	18922 003	ETODOLAC; LODINE	4076831	FEB 28, 1995	U-45		
			3939178	FEB 17, 1993		NCE	JAN 31, 1996
			4076831	FEB 28, 1995	U-45		
			3939178	FEB 17, 1993		NCE	JAN 31, 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
	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
>ADD>	20038 001	FLUDARABINE PHOSPHATE; FLUDARA	4357324	NOV 02, 1999		NCE	APR 18, 1996
						ODE	APR 18, 1998
>ADD>			4314081	FEB 02, 2001		NCE	DEC 29, 1992
>ADD>	20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC				ODE	JAN 17, 1998
>ADD>	19961 002	GALLIUM NITRATE; GANITE				NCE	JAN 17, 1996
			4619921	OCT 28, 2003		NCE	DEC 17, 1995
>ADD>	19967 001	HALOBETASOL PROPIONATE; ULTRAVATE	4619921	OCT 28, 2003		NCE	DEC 17, 1995
>ADD>	19968 001	HALOBETASOL PROPIONATE; ULTRAVATE	4466972	AUG 21, 2001	U-3	NCE	DEC 20, 1995
>ADD>	19546 001	ISRADIPINE; DYNACIRC	4466972	AUG 21, 2001	U-3	NCE	DEC 20, 1995
>ADD>	19546 002	ISRADIPINE; DYNACIRC	4012444	AUG 02, 1998		NCE	AUG 01, 1994
	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	3850911	NOV 26, 1991		NP	DEC 10, 1993
>ADD>	20088 001	LEVONORGESTREL; NORPLANT SYSTEM	3864487	FEB 04, 1994		NCE	JUN 19, 1995
>ADD>	19753 001	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1994		NCE	JUN 19, 1995
>DLT>	19753 001	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1994		NCE	JUN 19, 1995
>ADD>	19753 002	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1994		NCE	JUN 19, 1995
>DLT>	19753 002	MORICIZINE HYDROCHLORIDE; ETHMOZINE	4234571	NOV 18, 2001		NCE	FEB 13, 1995
>ADD>	19753 003	MORICIZINE HYDROCHLORIDE; ETHMOZINE	4783337	SEP 16, 2003		I-55	SEP 06, 1992
>DLT>	19753 003	MORICIZINE HYDROCHLORIDE; ETHMOZINE	4765989	SEP 16, 2003		D-2	SEP 06, 1992
	19886 001	NAFARELIN ACETATE; SYNAREL	4783337	SEP 16, 2003		I-55	SEP 06, 1992
	19684 001	NIFEDIPINE; PROCARDIA XL	4765989	SEP 16, 2003		D-2	SEP 06, 1992
	19684 002	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003		I-55	SEP 06, 1992
	19684 003	NIFEDIPINE; PROCARDIA XL	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			

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
	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
>ADD>	19797 001	POLYETHYLENE GLYCOL 3350; NULYTELY				NP	APR 22, 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
>ADD>	19863 001	SERMORELIN ACETATE; GEREF	4703035	MAY 14, 2002	U-47	NCE	DEC 28, 1995
>ADD>			4517181	MAY 14, 2002			
	19998 002	SUCCIMER; CHEMET				NCE	JAN 30, 1996
						ODE	JAN 30, 1998
>ADD>	19785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4452774	JUN 05, 2001		NCE	DEC 21, 1995
>ADD>	19785 002	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4452774	JUN 05, 2001		NCE	DEC 21, 1995