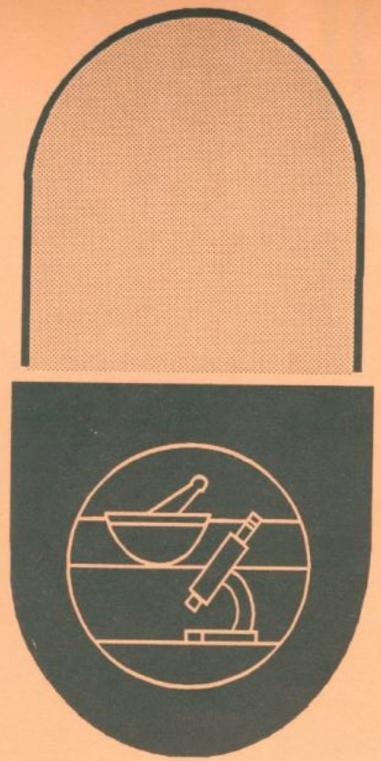
CUMULATIVE SUPPLEMENT 8

JAN'91-AUG'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

LOUIS COLLEGE OF PHARMACY LIBRARY

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

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11TH EDITION

Cumulative Supplement

August 1991

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AUGUST 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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
GIST BROCADES	BROCADES PHARMA bv	BROCADES PHARMA
ICI PHARMACEUTICALS PR INC	IPR PHARMACEUTICALS INC	IPR
PHARMACIA LABORATORIES DIV PHARMACIA INC	KABI PHARMACIA	KABI
REID ROWELL INC	SOLVAY PHARMACEUTICALS	SOLVAY

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	9900	
SINGLE SOURCE	2030 (20.1%)	2090 (21.0%)	2110 (21.3%)	
MULTISOURCE	8093 (79.9%)	7863 (79.0%)	7790 (78.7%)	
THERAPEUTICALLY EQUIVALENT	7222 (71.3%)	7061 (71.0%)	6937 (70.1%)	
NOT THERAPEUTICALLY EQUIVALENT	752 (7.4%)	660 (6.6%)	702 (7.1%)	
EXCEPTIONS[1]	119 (1.2%)	142 (1.4%)	151 (1.5%)	
NEW MOLECULAR ENTITIES APPROVED	--	5	4	
NUMBER OF APPLICANTS	400	408	417	

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

ACETAMINOPHEN; CODEINE PHOSPHATE

CAPSULE; ORAL

	PROVAL #4			
AA	SOLVAY	325MG;30MG		N85685 001
	TYLENOL W/ CODEINE NO. 3			
AA	JOHNSON RW	300MG;30MG		N87422 001
	TYLENOL W/ CODEINE NO. 4			
	JOHNSON RW	300MG;60MG		N87421 001
	∂ JOHNSON RW	300MG;60MG		N87421 001

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
	TYLENOL W/ CODEINE			
AA	JOHNSON RW	325MG;15MG		N85056 002
AA		325MG;30MG		N85056 003
		325MG;7.5MG		N85056 001
		325MG;60MG		N85056 004
	∂ JOHNSON RW	325MG;7.5MG		N85056 001
	∂	325MG;15MG		N85056 002
	∂	325MG;30MG		N85056 003
	∂	325MG;60MG		N85056 004

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

	HYDROCODONE BITARTRATE AND ACETAMINOPHEN			
AA	PHARM BASICS	500MG;5MG		N89291 001 MAY 29, 1987
B*	PHARM BASICS	500MG;5MG		N89291 001 MAY 29, 1987
>ADD > AA	WATSON	500MG;2.5MG¤		N81079 001 AUG 30, 1991
>ADD > AA		500MG;7.5MG¤		N81080 001 AUG 30, 1991
>ADD > AA		750MG;7.5MG¤		N81083 001 AUG 30, 1991

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL

	TYLOX-325			
	JOHNSON RW	325MG;5MG		N88246 001 NOV 08, 1984
	∂ JOHNSON RW	325MG;5MG		N88246 001 NOV 08, 1984

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

	PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN			
AA	CHELSEA	325MG;50MG		N71336 001 DEC 11, 1986
AA		650MG;100MG		N71337 001 DEC 11, 1986
B*	CHELSEA	325MG;50MG		N71336 001 DEC 11, 1986
B*		650MG;100MG		N71337 001 DEC 11, 1986

ACETAZOLAMIDE

TABLET; ORAL

	ACETAZOLAMIDE			
>ADD >	∂ ALRA	250MG		N83320 001
>DLT >	∂ DANMAX	250MG		N83320 001

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC

	DELEX			
AT	NORWICH EATON	2%		N86845 001
	∂ NORWICH EATON	2%		N86845 001

ACETIC ACID, GLACIAL; HYDROCORTISONE

SOLUTION/DROPS; OTIC

	DELEX HC			
AT	NORWICH EATON	2%;1%		N86844 001
	∂ NORWICH EATON	2%;1%		N86844 001

ACETOHEXAMIDE

TABLET; ORAL

ACETOHEXAMIDE

B*	PHARM BASICS	250MG	N70753 001	NOV 03, 1986
B*		500MG	N70754 001	NOV 03, 1986

ACETOPHENAZINE MALEATE

TABLET; ORAL

TINDAL

BP	SCHERING	20MG	N12254 002	
	∂ SCHERING	20MG		

ACYCLOVIR

TABLET; ORAL

ZOVIRAX

	BURROUGHS WELLCOME	400MG¤	N20089 001	APR 30, 1991
		800MG¤	N20089 002	APR 30, 1991

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 > AB	WATSON	EQ 2MG BASE¤	N72764 001	AUG 28, 1991
> ADD > AB		EQ 4MG BASE¤	N72765 001	AUG 28, 1991

ALCOHOL

INJECTABLE; INJECTION

ALCOHOL 5% IN DEXTROSE 5%

AP	CUTTER	5ML/100ML	N83483 001	
	∂ CUTTER	5ML/100ML		

ALGLUCERASE

INJECTABLE; INJECTION

CEREDASE

	GENZYME	80 UNITS/ML¤	N20057 003	APR 05, 1991

ALLOPURINOL

TABLET; ORAL

ALLOPURINOL

AB	BOLAR	300MG	N18241 002	NOV 16, 1984
AB	PUREPAC	100MG	N70579 001	APR 14, 1986
AB		300MG	N70580 001	APR 14, 1986
	∂ PUREPAC	100MG		
	∂	300MG		

ALPRAZOLAM

TABLET; ORAL

XANAX

	UPJOHN	2MG	N18276 004	NOV 27, 1985

AMANTADINE HYDROCHLORIDE

SYRUP; ORAL

AMANTADINE HCL

> ADD > AA	COPLEY	50MG/5ML¤	N73115 001	AUG 23, 1991

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

AMILORIDE HCL AND HYDROCHLOROTHIAZIDE

AB	ROYCE	5MG;50MG¤	N73334 001 JUL 19, 1991

AMINOPHYLLINE

INJECTABLE; INJECTION

AMINOPHYLLINE

/AP/	/INTL/MEDICATION/	/25MG/ML/	/N87867/001/ /NOV/10,/1983/
/AP/		/25MG/ML/	/N87868/001/ /NOV/10,/1983/
∂	INTL MEDICATION	25MG/ML	N87867 001 NOV 10, 1983
∂		25MG/ML	N87868 001 NOV 10, 1983
/AP/	/SOLOPAK/	/25MG/ML/	/N88429/001/ /MAY/30,/1985/
∂	SOLOPAK	25MG/ML	N88429 001 MAY 30, 1985

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITID

/AB/	/SQUIBB/	/10MG/	/N86454/001/
/AB/		/25MG/	/N86454/002/
/AB/		/50MG/	/N86454/003/
/AB/		/75MG/	/N86454/004/
/AB/		/100MG/	/N86454/005/
∂	SQUIBB	10MG	N86454 001
∂		25MG	N86454 002
∂		50MG	N86454 003
∂		75MG	N86454 004
∂		100MG	N86454 005

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL

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

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL

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

AMOXAPINE

TABLET; ORAL

AMOXAPINE

AB	GENEVA	25MG¤	N72943 001 JUN 28, 1991
AB		50MG¤	N72944 001 JUN 28, 1991
AB		100MG¤	N72878 001 JUN 28, 1991
AB		150MG¤	N72879 001 JUN 28, 1991

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

/AP/ /INTL/MEDICATION/ /EQ 1GM BASE/VIAL/ /N62634/002/

/AP/ /EQ 2GM BASE/VIAL/ /N62634/003/

	∂ INTL MEDICATION	EQ 1GM BASE/VIAL	N62634 002 JAN 09, 1987
	∂	EQ 2GM BASE/VIAL	N62634 003 JAN 09, 1987

POLYCILLIN-N

> ADD > AP BRISTOL EQ 10GM BASE/VIAL N61395 006

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

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

INJECTABLE; INJECTION

MVC PLUS

> DLT >/AP/ /ASCOT/ /10MG/ML;0.006MG/ML;0.5UGM/ML;/ /1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML;/ /0.4MG/ML;0.36MG/ML;0.3MG/ML;/ /330 UNITS /ML;1 IU/ML/ /N18439/002/ /AUG/08,/1985/

> DLT >
> DLT >
> DLT >
> DLT >
> ADD > AP STERIS 10MG/ML;0.006MG/ML;0.5UGM/ML; 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML; 0.4MG/ML;0.36MG/ML;0.3MG/ML; 330 UNITS /ML;1 IU/ML N18439 002 AUG 08, 1985
> ADD >
> ADD >
> ADD >
> ADD >

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

/BUTALBITAL W/ ASPIRIN AND CAFFEINE/

/AB/ /CHELSEA/ /325MG;50MG;40MG/ /N86231/00 /FEB/12,/198

BUTALBITAL, ASPIRIN AND CAFFEINE

AB CHELSEA 325MG;50MG;40MG N86231 00 FEB 12, 198

TABLET; ORAL

/BUTALBITAL W/ ASPIRIN AND CAFFEINE/

/AB/ /CHELSEA/ /325MG;50MG;40MG/ /N86237/00 /MAR/23,/198

BUTALBITAL, ASPIRIN AND CAFFEINE

AB CHELSEA 325MG;50MG;40MG N86237 00 MAR 23, 198

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

ORPHENGESIC

B* PAR 385MG;30MG;25MG N71642 001 JUN 23, 1987

/BX/ /385MG;30MG;25MG/ /N71642/001 /JUN/23,/1987

ORPHENGESIC FORTE

B* PAR 770MG;60MG;50MG N71643 001 JUN 23, 1987

/BX/ /770MG;60MG;50MG/ /N71643/001 /JUN/23,/1987

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

COMPOUND 65

> ADD > ∂ ALRA 389MG;32.4MG;65MG N84553 002 AUG 17, 1983

> ADD >
> DLT >
> DLT >

/∂/BANMAX/ /389MG;32.4MG;65MG/ /N84553/002/ /AUG/17,/1983/

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

/LOMOTIL/

/AA/ /CORD/ /0.025MG;2.5MG/ /N85311/002/

LONOX

AA CORD 0.025MG;2.5MG N85311 002

BACLOFEN

TABLET; ORAL

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

BENAZEPRIL HYDROCHLORIDE

TABLET; ORAL

LOTENSIN			
CIBA			
	EQ 5MG BASE/M	N19851 001	
	EQ 10MG BASE/M	JUN 25, 1991	
	EQ 20MG BASE/M	N19851 002	
	EQ 40MG BASE/M	JUN 25, 1991	
		N19851 003	
		JUN 25, 1991	
		N19851 004	
		JUN 25, 1991	

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE				
/AA/	/PHARM/BASICS/	/0.5MG/	/N89211/001/	
/AA/		/1MG/	/JUN/14,/1988/	
/AA/		/2MG/	/N89212/001/	
B*	PHARM BASICS	0.5MG	/JUN/14,/1988/	
B*		1MG	/N89213/001/	
B*		2MG	/JUN/14,/1988/	
			N89211 001	
			JUN 14, 1988	
			N89212 001	
			JUN 14, 1988	
			N89213 001	
			JUN 14, 1988	

BERACTANT

SUSPENSION; INTRATRACHEAL

SURVANTA				
ROSS				
	25MG/ML/M		N20032 001	
			JUL 01, 1991	

>DLT<
>ADD<

BETHANECHOL CHLORIDE

TABLET; ORAL

DUVOID				
/AA/	/NORWICH/EATON/	/10MG/	/N86262/001/	
/AA/		/25MG/	/N85882/002/	
/AA/		/25MG/	/N86263/001/	
/AA/		/50MG/	/N85882/003/	
AA	ROBERTS	10MG	N86262 001	
AA		25MG	N86263 001	
AA		50MG	N85882 003	

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER			
/ABBOTT/	/800MG/100ML/	/N19008/001/	
@ ABBOTT	800MG/100ML	/APR/16,/1986/	
		N19008 001	
		APR 16, 1986	

BROMPHENIRAMINE MALEATE

TABLET; ORAL

BROMPHENIRAMINE MALEATE				
/AA/	/PAR/	/4MG/	/N87009/001/	
	@ PAR	4MG	N87009 001	
/AA/	/VITARINE/	/4MG/	/N85850/001/	
	@ VITARINE	4MG	N85850 001	

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

/ELIXIR;ORAL/				
/BIPHETAP/				
/PHARM/BASICS/		/4MG/5ML;25MG/5ML/	/N88687/001/	
@ PHARM BASICS		4MG/5ML;25MG/5ML	/SEP/26,/1984/	
			N88687 001	
			SEP 26, 1984	

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

BUPRENEX				
/NORWICH/EATON/		/EQ/0.3MG/BASE/ML/	/N18401/001/	
R AND C		EQ 0.3MG BASE/ML	N18401 001	

BUPROPION HYDROCHLORIDE

TABLET; ORAL
WELLBUTRIN
/BURROUGHS/WELLCOME/ /50MG/ /N18644/001/
/DEC/30,/1985/
@ BURROUGHS WELLCOME 50MG N18644 001
DEC 30, 1985

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
/AB/ /PHARM/BASICS/ /200MG/ /N70300/
/MAY/15,/1
B* PHARM BASICS 200MG N70300
MAY 15, 1

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL
SINEMET CR
MSD 50MG;200MG* N19856
MAY 30, 1

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL
/AA/ /BOLAR/ /350MG/ /N85433/0
@ BOLAR 350MG N85433 0

CEFADROXIL

CAPSULE; ORAL
ULTRACEF
/AB/ /BRISTOL/ /EQ 500MG BASE/ /N62378/0
/MAR/16,/198
@ BRISTOL EQ 500MG BASE N62378 00
MAR 16, 198

POWDER FOR RECONSTITUTION; ORAL
ULTRACEF
/AB/ /BRISTOL/ /EQ 125MG BASE/5ML/ /N62376/00
/AB/ /EQ 250MG BASE/5ML/ /MAR/16,/198
/N62376/00
/AB/ /EQ 500MG BASE/5ML/ /MAR/16,/198
/N62376/00
@ BRISTOL EQ 125MG BASE/5ML /MAR/16,/198
N62376 00
@ EQ 250MG BASE/5ML MAR 16, 198
N62376 002
@ EQ 500MG BASE/5ML MAR 16, 1982
N62376 003
MAR 16, 1982

CEFADROXIL

TABLET; ORAL

	ULTRACEF			
/AB/	/BRISTOL/	/EQ 1GM BASE/	/N62408/001/	
	@ BRISTOL	EQ 1GM BASE	/AUG/31,/1982/	
			N62408 001	
			AUG 31, 1982	

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

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

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL

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

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION

	/CEPHALOTHIN/			
/AP/	/INTL/MEDICATION/	/EQ 1GM BASE/VIAL/	/N62426/002/	
/AP/		/EQ 2GM BASE/VIAL/	/MAY/03,/1985/	
/AP/		/EQ 4GM BASE/VIAL/	/N62426/003/	
		/EQ/500MG/BASE/VIAL/	/MAY/03,/1985/	
	@ INTL MEDICATION	EQ 500MG BASE/VIAL	/N62426/004/	
	@	EQ 1GM BASE/VIAL	/MAY/03,/1985/	
	@	EQ 2GM BASE/VIAL	/N62426/001/	
	@	EQ 4GM BASE/VIAL	/MAY/03,/1985/	
			N62426 001	
			MAY 03, 1985	
			N62426 002	
			MAY 03, 1985	
			N62426 003	
			MAY 03, 1985	
			N62426 004	
			MAY 03, 1985	

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	

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

	CHLORDIAZEPOXIDE HCL			
/AB/	/SUPERPHARM/	/5MG/	/N88987/001/	
/AB/		/10MG/	/APR/25,/1985/	
/AB/		/25MG/	/N88986/001/	
	@ SUPERPHARM	5MG	/APR/25,/1985/	
	@	10MG	/N88988/001/	
	@	25MG	/APR/25,/1985/	
			N88987 001	
			APR 25, 1985	
			N88986 001	
			APR 25, 1985	
			N88988 001	
			APR 25, 1985	
	LYGEN			
> ADD >	@ ALRA	5MG	N85107 001	
> ADD >	@	10MG	N85009 001	
> ADD >	@	25MG	N85108 001	
> DLT >	/@/BANMAX/	/5MG/	/N85107/001/	
> DLT >	/@/	/10MG/	/N85009/001/	
> DLT >	/@/	/25MG/	/N85108/001/	

CHLOROTHIAZIDE

TABLET; ORAL

		CHLOROTHIAZIDE			
> DLT >	/AB/	/CHELSEA/	/500MG/	/N86796/001/	
> DLT >				/AUG/15,/1983/	
> ADD >	B*	CHELSEA	500MG	N86796 001	
> ADD >				AUG 15, 1983	

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION

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

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

AA	MILES	4MG	N83381 001
∂	MILES	4MG	

CHLORPHENIRAMINE MALEATE

AA	VITARINE	4MG	N85837 001
∂	VITARINE	4MG	

CHLORPHENIRAMINE MALEATE

AA	LANNETT	4MG	N80846 001
∂	LANNETT	4MG	

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

CHLORPROMAZINE HCL

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

CHLORPROPAMIDE

TABLET; ORAL

CHLORPROPAMIDE

B*	PHARM BASICS	100MG	N88708 001 AUG 30, 1984
B*		250MG	N88709 001 AUG 30, 1984

CHLORTHALIDONE

TABLET; ORAL

CHLORTHALIDONE

AA	SUPERPHARM	25MG	N87473 001 FEB 09, 1983
∂	SUPERPHARM	25MG	

CHLORZOXAZONE

TABLET; ORAL

CHLORZOXAZONE

AA	DANBURY	500MG*	N81019 001 JUL 29, 1991

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HCL

AB	DANBURY	EQ 75MG BASE*	N63082 001 JUL 31, 1991
AB		EQ 150MG BASE*	N63083 001 JUL 31, 1991

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

CLIOQUINOL; HYDROCORTISONE

CREAM; TOPICAL

VIOFORM-HYDROCORTISONE

CIBA	3%;0.5%	N10412 002
	3%;1%	N10412 001

OINTMENT; TOPICAL

VIOFORM-HYDROCORTISONE

∂ CIBA	3%;0.5%	N10412 004
	3%;1%	N10412 003

CLOFIBRATE

CAPSULE; ORAL

CLOFIBRATE

AB	NOVOPHARM	500MG*	N72600 001 JUL 25, 1991

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HCL

AB	DURAMED	0.2MG	N71102 001 AUG 14, 1986
∂	DURAMED	0.2MG	

CHLORZOXAZONE

TABLET; ORAL

CHLORZOXAZONE

AA	DANBURY	500MG*	N81019 001 JUL 29, 1991

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HCL

/AB/	/DURAMED/	/0.2MG/	/N71102/001/ /AUG/14,/1986/
∂	DURAMED	0.2MG	N71102 001 AUG 14, 1986

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

/AB/	/PHARM BASICS/	/3.75MG/	/N71242/001/ /MAY/20,/1987/
/AB/		/7.5MG/	/N71243/001/ /MAY/20,/1987/
/AB/		/15MG/	/N71244/001/ /MAY/20,/1987/
B*	PHARM BASICS	3.75MG	N71242 001 MAY 20, 1987
B*		7.5MG	N71243 001 MAY 20, 1987
B*		15MG	N71244 001 MAY 20, 1987
/AB/	/PUREPAC/	/3.75MG/	/N71924/001/ /APR/25,/1988/
∂	PUREPAC	3.75MG	N71924 001 APR 25, 1988
/AB/	/SEARLE/	/3.75MG/	/N71727/001/ /DEC/18,/1987/
/AB/		/7.5MG/	/N71728/001/ /DEC/18,/1987/
/AB/		/15MG/	/N71729/001/ /DEC/18,/1987/
∂	SEARLE	3.75MG	N71727 001 DEC 18, 1987
∂		7.5MG	N71728 001 DEC 18, 1987
∂		15MG	N71729 001 DEC 18, 1987

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

/AB/	/AM THERAP/	/3.75MG/	/N71747/001/ /JUN/09,/1987/
/AB/		/7.5MG/	/N71748/001/ /JUN/09,/1987/
/AB/		/15MG/	/N71749/001/ /JUN/09,/1987/
∂	AM THERAP	3.75MG	N71747 001 JUN 09, 1987
∂		7.5MG	N71748 001 JUN 09, 1987
∂		15MG	N71749 001 JUN 09, 1987

CLOTRIMAZOLE

CREAM; VAGINAL

> DLT >	/GYNE-LOTRIMIN/		
> DLT >/AT/	/SCHERING/	/1%/	/N18052/001/

TABLET; VAGINAL

> DLT >	/GYNE-LOTRIMIN/		
> DLT >/AT/	/SCHERING/	/100MG/	/N17717/001/

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

	AKORN	1MG/ML	N87969 001 NOV 10, 1983
/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/
∂	LYPHOMED	0.03MG/ML	N80510 003
∂		0.1MG/ML	N80510 001
∂		1MG/ML	N80510 002
AP	STERIS	0.1MG/ML	N83120 001
AP		1MG/ML	N83120 002

DODECAMIN

/AP/	/AKORN/	/1MG/ML/	/N87969/001/ /NOV/10,/1983/

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL

CYCLOBENZAPRINE HCL

AB	MYLAN	10MG*	N73144 001 MAY 31, 1991

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

AK-PENTOLATE			
AT AKORN	1%		N85555 001
/CYCLOPENTOLATE HCL/			
/AT/ /AKORN/	/1%/		/N85555/001/
CYCLOPENTOLATE HCL			
AT STERIS	1%¤		N89162 001 JAN 24, 1991

CYPROHEPTADINE HYDROCHLORIDE

SYRUP; ORAL

CYPROHEPTADINE HCL			
>DLT >/AA/ /NASKA/	/2MG/5ML/		/N89021/001/ /DEC/21,/1987/
>DLT >			
>ADD > @ NASKA	2MG/5ML		N89021 001 DEC 21, 1987
>ADD >			

DANAZOL

CAPSULE; ORAL

DANAZOL			
/AA/ /AM THERAP/	/200MG/		/N71569/001/ /DEC/30,/1987/
B* AM THERAP	200MG		N71569 001 DEC 30, 1987

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

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

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% /0.01%/		N17922 001 /N17922/001/

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE			
/BP/ /CORD/	/0.75MG/		/N80399/001/ N80399 001
@ CORD	0.75MG		

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

SOLUTION/DROPS; OPHTHALMIC

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

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 10% IN PLASTIC CONTAINER			
/AP/ /CUTTER/	/10GM/100ML/		/N18564/001/
@ CUTTER	10GM/100ML		N18504 001
DEXTROSE 50% IN PLASTIC CONTAINER			
AP BAXTER	50GM/100ML¤		N20047 001 JUL 02, 1991
DEXTROSE 60% IN PLASTIC CONTAINER			
AP BAXTER	60GM/100ML¤		N20047 002 JUL 02, 1991

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 70% IN PLASTIC CONTAINER

AP	BAXTER	70GM/100ML¤	N20047 003	JUL 02, 1991

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/	
	ə 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/	
	ə 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/	
	ə CUTTER	5GM/100ML;450MG/100ML	N18400 001	

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

/DIATRIZOATE-60/

/AP/	/INTL MEDICATION/	/52%;8%/	/N88166/001/	/JUN/17,/1983/
	ə INTL MEDICATION	52%;8%	N88166 001	JUN 17, 1983

DIATRIZOATE SODIUM

INJECTABLE; INJECTION

/MD-60/

/AP/	/MALLINCKRODT/	/50%/	/N87075/001/	
	ə 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

/a/	/SUPERPHARM/	/2MG/	/N70642/001/	/DEC/11,/1985/
/a/		/5MG/	/N70643/001/	/DEC/11,/1985/
/a/		/10MG/	/N70644/001/	/DEC/11,/1985/

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC

VOLTAREN

	CIBA	0.1%¤	N20037 001	MAR 28, 1991

DIETHYLSTILBESTROL

TABLET; ORAL

STILBESTROL

>DLT>	/BP/	/TABLICAPS/	/0.5MG/	/N83004/001/	
>ADD>		ə TABLICAPS	0.5MG	N83004 001	
>DLT>		/STILBETIN/			
>DLT>	/BP/	/SQUIBB/	/0.5MG/	/N04056/008/	
>DLT>	/BP/		/1MG/	/N04056/009/	
>DLT>	/BP/		/5MG/	/N04056/010/	
>DLT>			/0.1MG/	/N04056/007/	
>DLT>			/0.25MG/	/N04056/017/	
>ADD>		ə SQUIBB	0.1MG	N04056 007	
>ADD>		ə	0.25MG	N04056 017	
>ADD>		ə	0.5MG	N04056 008	
>ADD>		ə	1MG	N04056 009	
>ADD>		ə	5MG	N04056 010	

DIMENHYDRINATE

INJECTABLE; INJECTION
DIMENHYDRINATE
/AP/ /LEMMON/ /50MG/ML/ /N83531/001/
AP STERIS 50MG/ML N83531 001

LIQUID; ORAL
DIMENHYDRINATE
> ADD > ∂ ALRA 12.5MG/4ML N80715 001
> DLT > /∂/BANMAX/ /12.5MG/4ML/ /N80715/001/

/TABLET;ORAL/
/DIMENHYDRINATE/
/AA/ /CHELSEA/ /50MG/ /N85166/001/
∂ CHELSEA 50MG N85166 001

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL
> ADD > ∂ ALRA 25MG N80519 004
> ADD > ∂ ALRA 50MG N80519 003
> DLT > /∂/BANMAX/ /50MG/ /N80519/003/

ELIXIR; ORAL
DIPHENHYDRAMINE HCL
/AA/ /KV/ /12.5MG/5ML/ /N85621/001/
∂ 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
B* CHELSEA EQ 100MG BASE N71020 001
DEC 01, 1986
B* EQ 150MG BASE N71021 001
DEC 01, 1986
/BX/ /EQ/100MG/BASE/ /N71020/001/
/DEC/01,/1986/
/BX/ /EQ/150MG/BASE/ /N71021/001/
/DEC/01,/1986/
/AB/ /MYLAN/ /EQ 100MG BASE/ /N70138/001/
/JUN/14,/1985/
/AB/ /EQ 150MG BASE/ /N70139/001/
/JUN/14,/1985/
∂ MYLAN EQ 100MG BASE N70138 001
JUN 14, 1985
∂ EQ 150MG BASE N70139 001
JUN 14, 1985

DOBUTAMINE HYDROCHLORIDE

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

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOPAMINE HCL
/AP/ /SOLOPAK/ /40MG/ML/ /N70011/001/
/AUG/29,/1985/
∂ SOLOPAK 40MG/ML N70011 001
AUG 29, 1985

DOXACURIUM CHLORIDE

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

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

DOXEPIN HCL

>DLT >	/AB/	/CHELSEA/	/EQ 10MG BASE/	/N70952/001/	/MAR/04,/1987/
>DLT >					
>DLT >	/AB/		/EQ 25MG BASE/	/N70953/001/	/MAY/15,/1986/
>DLT >					
>DLT >	/AB/		/EQ 50MG BASE/	/N70954/001/	/MAY/15,/1986/
>DLT >					
>DLT >	/AB/		/EQ 75MG BASE/	/N71763/001/	/FEB/09,/1988/
>DLT >					
>DLT >	/AB/		/EQ 100MG BASE/	/N70955/001/	/MAY/15,/1986/
>DLT >					
>DLT >	/AB/		/EQ 150MG BASE/	/N71764/001/	/FEB/09,/1988/
>DLT >					
>ADD >	B*	CHELSEA	EQ 10MG BASE	N70952 001	MAR 04, 1987
>ADD >					
>ADD >	B*		EQ 25MG BASE	N70953 001	MAY 15, 1986
>ADD >					
>ADD >	B*		EQ 50MG BASE	N70954 001	MAY 15, 1986
>ADD >					
>ADD >	B*		EQ 75MG BASE	N71763 001	FEB 09, 1988
>ADD >					
>ADD >	B*		EQ 100MG BASE	N70955 001	MAY 15, 1986
>ADD >					
>ADD >	B*		EQ 150MG BASE	N71764 001	FEB 09, 1988
>ADD >					
	/AB/	/PUREPAC/	/EQ 75MG BASE/	/N72386/001/	/SEP/08,/1988/
	/AB/		/EQ 150MG BASE/	/N72387/001/	/SEP/08,/1988/
		∂ PUREPAC	EQ 75MG BASE	N72386 001	SEP 08, 1988
		∂	EQ 150MG BASE	N72387 001	SEP 08, 1988
	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

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

/AB/	/SUPERPHARM/	/EQ 50MG BASE/	/N62469/001/	/OCT/31,/1984/
/AB/		/EQ 100MG BASE/	/N62469/002/	/OCT/31,/1984/
	∂ SUPERPHARM	EQ 50MG BASE	N62469 001	OCT 31, 1984
	∂	EQ 100MG BASE	N62469 002	OCT 31, 1984

TABLET; ORAL

DOXYCYCLINE HYCLATE

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

DOXYLAMINE SUCCINATE

/TABLET;/ORAL/

/DOXYLAMINE SUCCINATE/

/AA/	/COPLEY/	/25MG/	/N88900/001/	/OCT/08,/1985/

DROPERIDOL

INJECTABLE; INJECTION

	DROPERIDOL		
AP	ASTRA	2.5MG/ML	N72020 001 OCT 19, 1988
	∂ ASTRA	2.5MG/ML	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		
	LEMMON	0.01MG/ML;1%	N85463 001
	∂ STERIS	0.01MG/ML;1%	N85463 001

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

	DEARIL-SI		
AA	BRISTOL MYERS SQUIBB	1MG	N85020 002
	∂ BRISTOL MYERS SQUIBB	1MG	N85020 002
	ERGOLOID MESYLATES		
AA	KV	0.5MG	N86265 001
AA		1MG	N86264 001
	∂ KV	0.5MG	N86265 001
	∂	1MG	N86264 001

ERYTHROMYCIN

GEL; TOPICAL

> ADD >	E/GEL		
> ADD >	FULTON	2%	N63107 001 AUG 23, 1991
> ADD >			

SOLUTION; TOPICAL

	ERYTHROMYCIN		
AT	CLAY PARK	2%	N63038 001 JAN 11, 1991
AT	LILLY	2%	N50532 001
	∂ LILLY	2%	N50532 001

ESTROGENS, CONJUGATED

TABLET; ORAL

	CONJUGATED ESTROGENS		
BP	CHELSEA	1.25MG	N85001 001
BP		2.5MG	N85826 001
AA		0.625MG	N85000 001
AA	CORD	0.3MG	N86070 001
AA		0.625MG	N83761 001
AA		1.25MG	N83763 001
AA		2.5MG	N83762 001
AA	DURAMED	0.3MG	N86492 001
AA		0.625MG	N83272 001
AA		1.25MG	N83294 001
AA		2.5MG	N83295 001
AA	HEATHER	0.625MG	N83356 001
AA		1.25MG	N83360 001
AA		2.5MG	N84650 001
AA	PRIVATE FORM	0.625MG	N83354 003
AA		1.25MG	N83592 001
AA		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
	∂ ZENITH	0.3MG	N88569 001 NOV 29, 1984
	∂	0.625MG	N83373 001
	∂	1.25MG	N83601 001
	∂	2.5MG	N83602 001

ESTROGENS, CONJUGATED; MEPROBAMATE

TABLET; ORAL

> DLT >	MILPREM-200			
> DLT >	BS	WALLACE	0.45MG;200MG	N11045 002
> ADD >	∂ WALLACE		0.45MG;200MG	N11045 002
> DLT >	MILPREM-400			
> DLT >	BS	WALLACE	0.45MG;400MG	N11045 001
> ADD >	∂ WALLACE		0.45MG;400MG	N11045 001
	PMB 200			
> DLT >	BS	WYETH AYERST	0.45MG;200MG	N10971 005
> ADD >	WYETH AYERST		0.45MG;200MG	N10971 005
	PMB 400			
> DLT >	BS	WYETH AYERST	0.45MG;400MG	N10971 003
> ADD >	WYETH AYERST		0.45MG;400MG	N10971 003

ESTROGENS, ESTERIFIED

TABLET; ORAL

>DLT>		/EVEX/		
>DLT>	/BS/	/SYNTEX/	/0.625MG/	/N84215/001/
>DLT>	/BS/		/1.25MG/	/N83376/002/
>ADD>		∂ SYNTEX	0.625MG	N84215 001
>ADD>		∂	1.25MG	N83376 002

ESTROPIPATE

TABLET; ORAL

OGEN

AB	ABBOTT	0.75MG	N83220 001
AB		1.5MG	N83220 002

ORTHO-EST

AB	JOHNSON RW	0.75MG*	N89567 001 FEB 27, 1991
AB		1.5MG*	N89582 001 JUL 17, 1991

ETODOLAC

CAPSULE; ORAL

LODINE

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

FELODIPINE

TABLET, EXTENDED RELEASE; ORAL

PLENDIL

	MSD	5MG*	N19834 001 JUL 26, 1991
		10MG*	N19834 002 JUL 26, 1991

FENOPROFEN CALCIUM

CAPSULE; ORAL

FENOPROFEN CALCIUM

>ADD> AB	DANBURY	EQ 200MG BASE*	N72981 001 AUG 19, 1991
>ADD> AB		EQ 300MG BASE*	N72982 001 AUG 19, 1991

FENOPROFEN CALCIUM

CAPSULE; ORAL

FENOPROFEN CALCIUM

AB	WARNER CHILCOTT	EQ 200MG BASE*	N72946 001 APR 30, 1991
AB		EQ 300MG BASE*	N72472 001 APR 30, 1991

TABLET; ORAL

FENOPROFEN CALCIUM

/AB/	/PHARM BASICS/	/EQ 600MG BASE/	/N72362/001/ /JUN/16,/1988/
	∂ PHARM BASICS	EQ 600MG BASE	N72362 001 JUN 16, 1988

FLUDARABINE PHOSPHATE

INJECTABLE; INJECTION

FLUDARA

	BERLEX	50MG/VIAL*	N20038 001 APR 18, 1991

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

/FLUOCET/

/AT/	/NMC/	/0.01%/	/N88361/001/ /JAN/16,/1984/

FLUOCINOLONE ACETONIDE

AT	NMC	0.01%	N88361 001 JAN 16, 1984

FLUOCINONIDE

CREAM; TOPICAL

FLUOCINONIDE

AB	TARO	0.05%	N19117 001 JUN 26, 1984
AB	TICAN	0.05%	N72494 001 JAN 19, 1989
/AB/	/VASODERM/ /TARO/	/0.05%/	/N19117/001/ /JUN/26,/1984/
/AB/	/VASODERM-E/ /TICAN/	/0.05%/	/N72494/001/ /JAN/19,/1989/

FLUOROURACIL

INJECTABLE; INJECTION

ADRUCIL

AP ADRIA 50MG/ML* N81222 001 JUN 28, 1991

>ADD > AP 50MG/ML* N81225 001 AUG 28, 1991

>ADD >

/AP/ /FLUOROURACIL/ /SOLOPAK/ /50MG/ML/ /N88766/001/ /DEC/28/1984/

∂ SOLOPAK 50MG/ML N88766 001 DEC 28, 1984

FLUOXETINE HYDROCHLORIDE

SOLUTION; ORAL

PROZAC

LILLY EQ 20MG BASE/5ML* N20101 001 APR 24, 1991

FLUPHENAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

>ADD >

>ADD > AA FLUPHENAZINE HCL COPLEY 5MG/ML* N73058 001 AUG 30, 1991

>ADD >

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

FLURAZEPAM HCL

AB GENEVA 15MG* N71716 001 JUL 31, 1991

AB 30MG* N71717 001 JUL 31, 1991

/AB/ /PHARM/BASICS/ /15MG/ /N70562/001/ /JUL/09/1987/

/AB/ /30MG/ /N70563/001/ /JUL/09/1987/

B* PHARM BASICS 15MG N70562 001 JUL 09, 1987

B* 30MG N70563 001 JUL 09, 1987

FOSINOPRIL SODIUM

TABLET; ORAL

MONOPRIL

BRISTOL MYERS SQUIBB 10MG* N19915 002 MAY 16, 1991

20MG* N19915 003 MAY 16, 1991

FUROSEMIDE

INJECTABLE; INJECTION

/AP/ /FUROSEMIDE/ /SOLOPAK/ /10MG/ML/ /N70023/001/ /FEB/05/1986/

∂ SOLOPAK 10MG/ML N70023 001 FEB 05, 1986

>ADD > AP STERLING 10MG/ML* N72080 001 AUG 13, 1991

>ADD >

GALLIUM NITRATE

INJECTABLE; INJECTION

GANITE

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

GENTIAN VIOLET

>DLT > /TAMPON;/VAGINAL/

>DLT > /GENAPAX/

>DLT > /KEY/PHARMS/ /5MG/ /N85017/001/

>ADD > ∂ KEY PHARMS 5MG N85017 001

GLUTETHIMIDE

TABLET; ORAL

/DORIDEN/

/AA/ /RHONE/POULENC/RORER/ /250MG/ /N09519/002/

/AA/ /500MG/ /N09519/005/

∂ RHONE POULENC RORER 250MG N09519 002

∂ 500MG N09519 005

/AA/ /GLUTETHIMIDE/ /CHELSEA/ /500MG/ /N85763/001/

∂ CHELSEA 500MG N85763 001

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

TABLET; ORAL
HALOPERIDOL

>ADD >	AB	DANBURY	10MG*	N72113 001 AUG 27, 1991
>ADD >				
>ADD >	AB		20MG*	N72353 001 AUG 27, 1991
>ADD >				

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/	/SOLOPAK/	/EQ 5MG BASE/ML/	/N70802/001/ /DEC/14,/1987/	
	ə SOLOPAK	EQ 5MG BASE/ML	N70802 001 DEC 14, 1987	
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/		/INTL/MEDICATION/	/10 UNITS/ML/	/N86351/001/
>ADD >		ə INTL MEDICATION	10 UNITS/ML	N86351 001
>DLT >			/500/UNITS/ML/	/N86351/002/
>ADD >		ə	500 UNITS/ML	N86351 002
/AP/	/SOLOPAK/		/100 UNITS/ML/	/N87959/001/ /APR/20,/1983/
	ə SOLOPAK		100 UNITS/ML	N87959 001 APR 20, 1983

HEPARIN SODIUM

>DLT >/AP/		/LYPHOMED/	/5,000 UNITS/ML/	/N17029/002/
>ADD >		ə LYPHOMED	5,000 UNITS/ML	N17029 002
		/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/
/AP/			/20MG/ML/	/N88518/001/ /APR/20,/1984/
	ə SOLOPAK		20MG/ML	N88517 001 AUG 22, 1985
	ə		20MG/ML	N88518 001 APR 20, 1984

TABLET; ORAL
HYDRALAZINE HCL

/AA/	/CHELSEA/		/25MG/	/N85532/002/ /MAY/24,/1982/
/AA/			/50MG/	/N85533/002/ /MAY/25,/1982/
	ə CHELSEA		25MG	N85532 002 MAY 24, 1982
	ə		50MG	N85533 002 MAY 25, 1982

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

>ADD >	ə ALRA	25MG	N86369 001
>ADD >	ə	50MG	N83554 001

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

> DLT > /3/BANMAX/ /25MG/ /N86369/001/
> DLT > /3/ /50MG/ /N83554/001/

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
HYDROCHLOROTHIAZIDE W/ RESERPINE

/BP/ /BOLAR/ /50MG;0.125MG/ /N83666/001/
@ 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; SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE

/AB/ /SUPERPHARM/ /25MG;25MG/ /N89137/001/
/AUG/26,/1985/
@ SUPERPHARM 25MG;25MG N89137 001
AUG 26, 1985

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL
DYAZIDE

AB SKF 25MG;50MG N16042 002

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

AB GENEVA 25MG;50MG N73191 001
JUL 31, 1991

TABLET; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

B* PAR 50MG;75MG N72337 001
MAY 11, 1988

/BX/ /50MG;75MG/ /N72337/001/
/MAY/11,/1988/

HYDROCORTISONE

CREAM; TOPICAL
/H-CORT/

/AT/ /PHARMS ASSOC/ /0.5%/ /N86823/001/

HYDROCORTISONE

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

PENECORT

> DLT >/AT/ /HERBERT/ /2.5%/ /N88250/001/
> DLT > /JUN/06,/1984/
> ADD > AT PARKE DAVIS 2.5% N88250 001
> ADD > JUN 06, 1984

SYNACORT

> DLT >/AT/ /SYNTEX/ /0.5%/ /N87459/001/
> ADD > @ SYNTEX 0.5% N87459 001

/LOTION;TOPICAL/
/TEXACORT/

/AT/ /COOPERCARE/ /1%/ /N86425/001/

SOLUTION; TOPICAL
PENECORT

AT HERBERT 1% N88214 001
JUN 06, 1984

TEXACORT

AT GENDERM 1% N80425 001

TABLET; ORAL
HYDROCORTISONE

/BP/ /PUREPAC/ /20MG/ /N80395/001/
@ PUREPAC 20MG N80395 001

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC
OTOCORT

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

SUSPENSION; OTIC
OTOCORT

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

>DLT<	/HYDROCORTISONE/BUTYRATE/		
>DLT<	/∂/GIST/	/0.1%/	/N18514/001/
>DLT<			/MAR/31,/1982/
	/LOCOID/		
	/OWEN/GALDERMA/	/0.1%/	/N18795/001/
			/JAN/07,/1983/
>ADD<	LOCOID		
>ADD<	GIST	0.1%	N18514 001
>ADD<			MAR 31, 1982
	∂ OWEN GALDERMA	0.1%	N18795 001
			JAN 07, 1983

SOLUTION; TOPICAL

>DLT<	/HYDROCORTISONE BUTYRATE/		
>DLT< /AT/	/GIST/	/0.1%/	/N19116/001/
>DLT<			/FEB/25,/1987/
>DLT<	/LOCOID/		
>DLT< /AT/	/OWEN/GALDERMA/	/0.1%/	/N19819/001/
>DLT<			/SEP/15,/1988/
>ADD<	LOCOID		
>ADD<	GIST	0.1%	N19116 001
>ADD<			FEB 25, 1987
>ADD<	∂ OWEN GALDERMA	0.1%	N19819 001
>ADD<			SEP 15, 1988

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION
HYDROCORTISONE SODIUM SUCCINATE

/AP/	/LYPHOMED/	/EQ 100MG BASE/VIAL/	/N88667/001/
			/JUN/08,/1984/
/AP/		/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	N88667 001
			JUN 08, 1984
∂		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

HYDROFLUMETHIAZIDE; RESERPINE

TABLET; ORAL
HYDROFLUMETHIAZIDE AND RESERPINE

B*	PHARM BASICS	50MG;0.125MG	N88195 001
			OCT 26, 1983
/BP/		/50MG;0.125MG/	/N88195/001/
			/OCT/26,/1983/

HYDROXOCOBALAMIN

INJECTABLE; INJECTION
HYDROCOBALAMIN

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

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION
/DURA-CUTIN/

/AO/	/STERIS/	/125MG/ML/	/N17439/001/
/AO/		/250MG/ML/	/N17439/002/
	HYDROXYPROGESTERONE CAPROATE		
AO	STERIS	125MG/ML	N17439 001
AO		250MG/ML	N17439 002

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	>DLT>	
/AB/	/PHARM/BASICS/	/10MG/	/N89121/001/ MAR/20,/1986/	>DLT>	
/AB/		/25MG/	/N89122/001/ MAR/20,/1986/	>DLT>	
/AB/		/50MG/	/N89123/001/ MAR/20,/1986/	>DLT>	
B*	PHARM BASICS	10MG	N89121 001 MAR 20, 1986	>ADD>	
B*		25MG	N89122 001 MAR 20, 1986	>ADD>	
B*		50MG	N89123 001 MAR 20, 1986	>ADD>	

HYDROXYZINE PAMOATE

CAPSULE; ORAL

HYDROXYZINE PAMOATE

AB	DANBURY	EQ 25MG HCL*	N81165 001 JUL 31, 1991	>ADD>	
AB	GENEVA	EQ 25MG HCL*	N81127 001 JUN 28, 1991	>ADD>	
AB		EQ 50MG HCL*	N81128 001 JUN 28, 1991	>DLT>	
AB		EQ 100MG HCL*	N81129 001 JUN 28, 1991	>DLT>	
/AB/	/SUPERPHARM/	/EQ 25MG HCL/	/N89031/001/ /JAN/02,/1987/	>DLT>	
/AB/		/EQ 50MG HCL/	/N89032/001/ /JAN/02,/1987/	>DLT>	
/AB/		/EQ 100MG HCL/	/N89033/001/ /JAN/02,/1987/	>DLT>	
	∂ SUPERPHARM	EQ 25MG HCL	N89031 001 JAN 02, 1987	>ADD>	
	∂	EQ 50MG HCL	N89032 001 JAN 02, 1987	>ADD>	
	∂	EQ 100MG HCL	N89033 001 JAN 02, 1987	>ADD>	

HYDROXYZINE PAMOATE

CAPSULE; ORAL

HYDROXYZINE PAMOATE

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

IBUPROFEN

TABLET; ORAL

IBUPROFEN

/AB/	/CHELSEA/	/400MG/	/N70038/001/ /SEP/06,/1985/		
/AB/		/600MG/	/N70041/001/ /SEP/06,/1985/		
/AB/		/800MG/	/N71911/001/ /OCT/13,/1987/		
B*	CHELSEA	400MG	N70038 001 SEP 06, 1985		
B*		600MG	N70041 001 SEP 06, 1985		
B*		800MG	N71911 001 OCT 13, 1987		
/BX/	/SUPERPHARM/	/400MG/	/N70708/001/ /APR/25,/1986/		

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

PRAMINE

∂ ALRA	10MG	N83827 001		
∂	25MG	N83827 002		
∂	50MG	N83827 003		
/∂/BANMAX/	/10MG/	/N83827/001/		
/∂/	/25MG/	/N83827/002/		
/∂/	/50MG/	/N83827/003/		

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

AB	DANBURY	25MG*	N72996 001 JUL 31, 1991
AB		50MG*	N72997 001 JUL 31, 1991

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
/AB/	/SUPERPHARM/	/50MG/	/N70488/001/ /OCT/10,/1986/
	ə SUPERPHARM	50MG	N70488 001 OCT 10, 1986

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

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
ISOETHARINE HCL

AN	ARMOUR	0.125%*	N89615 001 JUN 13, 1991
AN		0.167%*	N89616 001 JUN 13, 1991
AN		0.2%*	N89617 001 JUN 13, 1991
AN		0.25%*	N89618 001 JUN 13, 1991
		0.062%*	N89614 001 JUN 13, 1991

ISOETHARINE MESYLATE

AEROSOL, METERED; INHALATION
BRONKOMETER

/BN/	/STERLING/	/0.34MG/BASE/INH/	/N12339/001/
BN	STERLING	0.34MG/INH	N12339 007

ISONIAZID

SYRUP; ORAL
/ENIDEN/

/AA/	/ROCHE/	/50MG/5ML/	/N08420/001/
	ə ROCHE	50MG/5ML	N08420 001

TABLET; ORAL
ISONIAZID

AA	ZENITH	300MG	N83610 001

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

	/AP/	/CUTTER/	/1%/	/N80414/001/
	/AP/		/2%/	/N80414/002/
		ə CUTTER	1%	N80414 001
		ə	2%	N80414 002
> DLT >	/AP/	/ELKINS/SINN/	/0.5%/	/N85131/001/
> DLT >	/AP/		/4%/	/N84626/001/
> ADD >		ə ELKINS SINN	0.5%	N85131 001
> ADD >		ə	4%	N84626 001
	/3/	/LEMMON/	/1%/	/N83627/001/
	/3/		/2%/	/N83627/002/
		ə STERIS	1%	N83627 001
		ə	2%	N83627 002

LIDOCAINE HYDROCHLORIDE

SOLUTION; TOPICAL
LIDOCAINE HCL
/AI/ /PACO/ /4%/ /N89688/001/ /JUN/30,/1989/
∂ PACO 4% N89688 001 JUN 30, 1989

LINCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION
LINCOMYCIN HCL
AP STERIS EQ 300MG BASE/ML* N63180 001 APR 16, 1991

LITHIUM CARBONATE

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

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL
IMODIUM
> ADD > AB JANSSEN 2MG N17690 001
> ADD > AB 2MG N17694 001
> ADD >
LOPERAMIDE HCL
> ADD > AB NOVOPHARM 2MG* N73122 001 AUG 30, 1991
> ADD >

LORAZEPAM

CONCENTRATE; ORAL
LORAZEPAM INTENSOL
ROXANE 2MG/ML* N72755 001 JUN 28, 1991

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
AB MUTUAL PHARM 0.5MG* N72553 001 MAR 29, 1991
AB 1MG* N72554 001 MAR 29, 1991
AB 2MG* N72555 001 MAR 29, 1991
/AB/ /PHARM/BASICS/ /1MG/ /N70539/001/ /DEC/22,/1986/
/AB/ /2MG/ /N70540/001/ /DEC/22,/1986/
B* PHARM BASICS 1MG N70539 001 DEC 22, 1986
B* 2MG N70540 001 DEC 22, 1986

LOVASTATIN

TABLET; ORAL
MEVACOR
MSD 10MG* N19643 002 MAR 28, 1991

MANNITOL

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

MECLOFENAMATE SODIUM

MEPROBAMATE

MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

/AB/	/PHARM/BASICS/	/EQ 50MG BASE/	/N71007/001/ /MAR/25;/1988/	
/AB/		/EQ 100MG BASE/	/N71008/001/ /MAR/25;/1988/	
B*	PHARM BASICS	EQ 50MG BASE	N71007 001 MAR 25, 1988	
B*		EQ 100MG BASE	N71008 001 MAR 25, 1988	

MEGESTROL ACETATE

TABLET; ORAL

MEGESTROL ACETATE

B*	PHARM BASICS	20MG	N70646 001 OCT 02, 1987	
B*		40MG	N70647 001 OCT 02, 1987	
/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/	
	∂ ELKINS SINN	25MG/ML	N88279 001 JUN 15, 1984	
	∂	50MG/ML	N88280 001 JUN 15, 1984	
	∂	75MG/ML	N88281 001 JUN 15, 1984	
	∂	100MG/ML	N88282 001 JUN 15, 1984	

MEPROBAMATE

TABLET; ORAL

BAMATE

		∂ ALRA	200MG		N80380 001
		∂	400MG		N80380 002
>DLT>	/∂/BANNAX/		/200MG/		/N80380/001/
>DLT>	/∂/		/400MG/		/N80380/002/

METAPROTERENOL SULFATE

SYRUP; ORAL

METAPROTERENOL SULFATE

>ADD> AA	COPLEY	10MG/5ML*		N73034 001 AUG 30, 1991

TABLET; ORAL

METAPROTERENOL SULFATE

/AB/	/AM/THERAP/	/10MG/		/N72054/001/ /JUN/23;/1988/
/AB/		/20MG/		/N72055/001/ /JUN/23;/1988/
	∂ AM THERAP	10MG		N72054 001 JUN 23, 1988
	∂	20MG		N72055 001 JUN 23, 1988
AB	DANBURY	10MG*		N73013 001 JAN 31, 1991
AB		20MG*		N72795 001 JAN 31, 1991
/AB/	/PHARM/BASICS/	/10MG/		/N71013/001/ /JAN/25;/1988/
/AB/		/20MG/		/N71014/001/ /JAN/25;/1988/
B*	PHARM BASICS	10MG		N71013 001 JAN 25, 1988
B*		20MG		N71014 001 JAN 25, 1988

METARAMINOL BITARTRATE

INJECTABLE; INJECTION

METARAMINOL BITARTRATE

>DLT>/AP/	/ERISTOL/	/EQ 10MG BASE/ML/		/N80431/001/
>ADD> AP	LYPHOMED	EQ 10MG BASE/ML		N80431 001

METHADONE HYDROCHLORIDE

/TABLET;/EFFERVESCENT;/ORAL/

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

METHOTREXATE SODIUM

INJECTABLE; INJECTION

FOLEX PFS

> ADD > AP	ADRIA	EQ 25MG BASE/ML*	N81242 001 AUG 23, 1991

> ADD >

METHYCLOTHIAZIDE

TABLET; ORAL

METHYCLOTHIAZIDE

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

METHYLDOPA

TABLET; ORAL

METHYLDOPA

/AA/	/ROXANE/	/125MG/	/N70192/001/ /APR/25,/1986/
/AA/		/250MG/	/N70193/001/ /APR/25,/1986/
/AA/		/500MG/	/N70194/001/ /APR/25,/1986/
	∂ ROXANE	125MG	N70192 001 APR 25, 1986
	∂	250MG	N70193 001 APR 25, 1986
	∂	500MG	N70194 001 APR 25, 1986

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

METHYLPREDNISOLONE ACETATE

	/3/LEMMON/	/20MG/ML/	/N87248/001/
	/3/	/40MG/ML/	/N85374/001/
	/3/	/80MG/ML/	/N86507/001/
	∂ STERIS	20MG/ML	N87248 001
	∂	40MG/ML	N85374 001
	∂	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/
/AP/		/EQ 1GM BASE/VIAL/	/N89188/001/ /MAR/28,/1986/
	∂ LYPHOMED	EQ 40MG BASE/VIAL	N88676 001 JUN 08, 1984
	∂	EQ 125MG BASE/VIAL	N88677 001 JUN 08, 1984
	∂	EQ 500MG BASE/VIAL	N88678 001 JUN 08, 1984
	∂	EQ 500MG BASE/VIAL	N89186 001 MAR 28, 1986
	∂	EQ 1GM BASE/VIAL	N88679 001 JUN 08, 1984
	∂	EQ 1GM BASE/VIAL	N89188 001 MAR 28, 1986

METHYLTESTOSTERONE

TABLET; BUCCAL/SUBLINGUAL
METHYLTESTOSTERONE

/BP/	/PHARM/BASICS/	/10MG/	/N80271/001/
	∂ PHARM BASICS	10MG	N80271 001

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
/AP/	/SOLOPAK/	/EQ 10MG BASE/2ML/	/N70622/001/ /MAR/02,/1987/
	∂ SOLOPAK	EQ 10MG BASE/2ML	N70622 001 MAR 02, 1987

SYRUP; ORAL
METOCLOPRAMIDE HCL

AA	PHARMS ASSOC	EQ 5MG BASE/5ML*	N72744 001 MAY 28, 1991

TABLET; ORAL
METOCLOPRAMIDE HCL

AB	LEDERLE	EQ 10MG BASE*	N72639 001 MAY 09, 1991
/AB/	/MARTEC/	/EQ 10MG BASE/	/N70598/001/ /FEB/02,/1987/
/AB/	/PHARM/BASICS/	/EQ 10MG BASE/	/N70339/001/ /JUL/29,/1985/
B*	PHARM BASICS	EQ 10MG BASE	N70339 001 JUL 29, 1985
AB	SCHERING	EQ 10MG BASE	N70598 001 FEB 02, 1987

METRONIDAZOLE

INJECTABLE; INJECTION
METRONIDAZOLE

/AP/	/INTL/MEDICATION/	/500MG/100ML/	/N70004/001/ /MAY/08,/1985/
	∂ INTL MEDICATION	500MG/100ML	N70004 001 MAY 08, 1985
AP	STERIS	500MG/100ML	N70042 001 DEC 20, 1984

METRYL IV

/AP/	/STERIS/	/500MG/100ML/	/N70042/001/ /DEC/20,/1984/

TABLET; ORAL
METRONIDAZOLE

/AB/	/SUPERPHARM/	/250MG/	/N70008/001/ /DEC/11,/1984/
/AB/		/500MG/	/N70009/001/ /DEC/11,/1984/
	∂ SUPERPHARM	250MG	N70008 001 DEC 11, 1984
	∂	500MG	N70009 001 DEC 11, 1984

MICONAZOLE NITRATE

/CREAM;/VAGINAL/
/MONISTAT 1/

/AT/	/JOHNSON/RW/	/2%/	/N17450/001/

/SUPPOSITORY;/VAGINAL/
/MONISTAT 1/

/AT/	/JOHNSON/RW/	/100MG/	/N18520/001/ /MAR/15,/1982/

MILRINONE LACTATE

/INJECTABLE;/INJECTION/
/MILRINONE/LACTATE/

	/STERLING/	/EQ/1MG/BASE/ML/	/N19436/001/ /DEC/31,/1987/
	∂ STERLING	EQ 1MG BASE/ML	N19436 001 DEC 31, 1987

MINOXIDIL

TABLET; ORAL

	MINOXIDIL			
/AA/	/PHARM BASICS/	/2.5MG/	/N71537/001/	/DEC/16,/1988/
B*	PHARM BASICS	2.5MG	N71537 001	DEC 16, 1988

MORPHINE SULFATE

INJECTABLE; INJECTION

	INFUMORPH			
	ELKINS SINN	10MG/ML¤	N18565 003	JUL 19, 1991
		25MG/ML¤	N18565 004	JUL 19, 1991

TABLET, EXTENDED RELEASE; ORAL

	MS CONTIN			
>ADD>	BC PURDUE FREDERICK	30MG	N19516 001	MAY 29, 1987
>ADD>	BC	60MG	N19516 002	APR 08, 1988
>ADD>	BC	100MG	N19516 004	JAN 16, 1990
	ORAMORPH SR			
>ADD>	BC ROXANE LABS	30MG¤	N19977 001	AUG 15, 1991
>ADD>	BC	60MG¤	N19977 002	AUG 15, 1991
>ADD>	BC	100MG¤	N19977 003	AUG 15, 1991

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/
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			
/AA/	/WEST/WARD/	/500MG/	/N83718/001/	
	@ WEST WARD	500MG	N83718 001	

NIFEDIPINE

CAPSULE; ORAL

	NIFEDIPINE			
AB	CHASE	20MG¤	N73421 001	JUN 19, 1991

NITROFURAZONE

CREAM; TOPICAL

	FURACIN			
	/NORWICH/EATON/	/0.2%/	/N83789/001/	
	ROBERTS	0.2%	N83789 001	

POWDER; TOPICAL

	FURACIN			
	/NORWICH/EATON/	/0.2%/	/N83791/001/	
	ROBERTS	0.2%	N83791 001	

NITROGLYCERIN

INJECTABLE; INJECTION

NITROGLYCERIN

/AP/	/LYPHOMED/	/5MG/ML/	/N71203/001/	> DLT >	/AP/	/ELKINS/SINN/	/EQ 250MG BASE/VIAL/
			/MAY/08,/1987/	> DLT >			/N62711/001/
	∂ LYPHOMED	5MG/ML	N71203 001	> DLT >	/AP/		/FEB/03,/1989/
			MAY 08, 1987	> DLT >			/EQ 500MG BASE/VIAL/
/AP/	/SOLOPAK/	/5MG/ML/	/N70634/001/	> DLT >	/AP/		/N62711/002/
			/JUN/19,/1986/	> DLT >			/FEB/03,/1989/
	∂ SOLOPAK	5MG/ML	N70634 001	> DLT >	/AP/		/EQ 1GM BASE/VIAL/
			JUN 19, 1986	> DLT >			/N62711/003/
	NITROL			> DLT >	/AP/		/FEB/03,/1989/
/AP/	/KREMERS/URBAN/	/0.8MG/ML/	/N18774/001/	> DLT >			/EQ 2GM BASE/VIAL/
			/JAN/19,/1983/	> DLT >	/AP/		/N62711/004/
	∂ RORER	0.8MG/ML	N18774 001	> DLT >			/FEB/03,/1989/
			JAN 19, 1983	> ADD >		∂ ELKINS SINN	EQ 250MG BASE/VIAL
	NITROSTAT			> ADD >			N62711 001
/AP/	/PARKE/DAVIS/	/0.8MG/ML/	/N18588/001/	> ADD >		∂	EQ 500MG BASE/VIAL
	PARKE DAVIS	0.8MG/ML	N18588 001	> ADD >			N62711 002
				> ADD >		∂	EQ 1GM BASE/VIAL
				> ADD >			N62711 003
				> ADD >		∂	EQ 2GM BASE/VIAL
				> ADD >			N62711 004
				> ADD >		∂	EQ 4GM BASE/VIAL
				> ADD >			N62711 005
				> ADD >		∂	EQ 10GM BASE/VIAL
				> ADD >			N62711 006

FEB 03, 1989

NORFLOXACIN

SOLUTION/DROPS; OPHTHALMIC

	CHIBROXIN			
	MSD	0.3%	N19757 001	JUN 17, 1991

NYSTATIN

CREAM; TOPICAL

/AT/	/CANDEX/ /MILES/	/100,000 UNITS/GM/	/N61810/001/
	∂ MILES	100,000 UNITS/GM	N61810 001

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

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

OXACILLIN SODIUM

INJECTABLE; INJECTION

OXACILLIN SODIUM

	∂ ELKINS SINN	EQ 250MG BASE/VIAL	N62711 001
			FEB 03, 1989
	∂	EQ 500MG BASE/VIAL	N62711 002
			FEB 03, 1989
	∂	EQ 1GM BASE/VIAL	N62711 003
			FEB 03, 1989
	∂	EQ 2GM BASE/VIAL	N62711 004
			FEB 03, 1989
	∂	EQ 4GM BASE/VIAL	N62711 005
			FEB 03, 1989
	∂	EQ 10GM BASE/VIAL	N62711 006
			FEB 03, 1989

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

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

PENTOBARBITAL SODIUM

CAPSULE; ORAL
SODIUM PENTOBARBITAL
/AA/ /CHELSEA/ /100MG/ /N85791/001/
@ CHELSEA 100MG N85791 001

PERPHENAZINE

TABLET; ORAL
PERPHENAZINE
B* CHELSEA 8MG N89700 001
DEC 23, 1987
/BX/ /8MG/ /N89700/001/
/DEC/23,/1987/

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE; ORAL
PHENDIMETRAZINE TARTRATE
BC VITARINE 105MG N18074 001
/3/ /105MG /N18074/001/
/SPRX-105/
/BC/ /SOLVAY/ /105MG/ /N88024/001/
/DEC/22,/1982/
@ SOLVAY 105MG N88024 001
DEC 22, 1982

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

PHENYTOIN SODIUM

INJECTABLE; INJECTION
PHENYTOIN SODIUM
/AP/ /SOLOPAK/ /50MG/ML/ /N88521/001/
/DEC/18,/1984/
@ SOLOPAK 50MG/ML N88521 001
DEC 18, 1984

PINACIDIL

CAPSULE, EXTENDED RELEASE; ORAL
PINDAC
LEO 12.5MG N19456 001
DEC 28, 1989
25MG N19456 002
DEC 28, 1989
/LILLY/ /12.5MG/ /N19456/001/
/DEC/28,/1989/
/25MG/ /N19456/002/
/DEC/28,/1989/

PIPERAZINE CITRATE

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

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

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

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

POWDER FOR RECONSTITUTION; ORAL
GLYCOPREP
AA GOLDLINE 236GM/BOT;2.97GM/BOT;6.74GM/BOT; 5.86GM/BOT;22.74GM/BOT N72319 001
DEC 23, 1988
/AA/ /SUPERPHARM/ /236GM/BOT;2.97GM/BOT;6.74GM/BOT; 5.86GM/BOT;22.74GM/BOT/ /N72319/001/
/DEC/23,/1988/

POTASSIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

/AP/	/CUTTER/	/1MEQ/ML/	/N80195/002/
/AP/		/2MEQ/ML/	/N80195/001/
/AP/		/3MEQ/ML/	/N80195/003/
	∂ CUTTER	1MEQ/ML	N80195 002
	∂	2MEQ/ML	N80195 001
	∂	3MEQ/ML	N80195 003
/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

/AB/	/PHARM/BASICS/	/5MG/	/N70427/001/
			/NOV/06,/1987/
/AB/		/10MG/	/N70428/001/
			/NOV/06,/1987/
B*	PHARM BASICS	5MG	N70427 001 NOV 06, 1987
B*		10MG	N70428 001 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

/DELTA-DOME/

/BX/	/MILES/	/5MG/	/N80293/001/
	∂ MILES	5MG	N80293 001

PREDNISONE

TABLET; ORAL

PREDNICEN-M

AB	CENTRAL PHARMS	5MG	N84655 001
/BX/		/5MG/	/N84655/001/

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
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
	/∂/	/1MG/	/N87800/001/ /APR/22,/1982/
	/∂/	/2.5MG/	/N87801/001/ /APR/22,/1982/
	/∂/	/10MG/	/N84122/001/
	/∂/	/20MG/	/N87342/001/
	/∂/	/50MG/	/N84283/001/

PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

PROCAINE HCL

/AP/	/CUTTER/	/1%/	/N80415/001/
/AP/		/2%/	/N80415/002/
	∂ CUTTER	1%	N80415 001
	∂	2%	N80415 002
/AP/	/LEMMON/	/1%/	/N83535/001/
/AP/		/2%/	/N83535/002/
AP	STERIS	1%	N83535 001
AP		2%	N83535 002

PROCHLORPERAZINE EDISYLATE

CONCENTRATE; ORAL
PROCHLORPERAZINE EDISYLATE

PHARM BASICS	EQ 10MG BASE/ML	N88598 001		
∂ PHARM BASICS	EQ 10MG BASE/ML	N88598 001	OCT 25, 1984	

SYRUP; ORAL
COMPAZINE

SKF	EQ 5MG BASE/5ML	N11188 001		

PROCHLORPERAZINE EDISYLATE

PHARM BASICS	EQ 5MG BASE/5ML	N88597 001		
∂ PHARM BASICS	EQ 5MG BASE/5ML	N88597 001	OCT 25, 1984	

PROCHLORPERAZINE MALEATE

TABLET; ORAL
PROCHLORPERAZINE MALEATE

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

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROMETHAZINE HCL

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

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPOXYPHENE HCL

> ADD > ∂ ALRA	65MG	N83184 001		
> DLT > ∂ DANMAX	65MG	N83184 001		

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPOXYPHENE HCL

> DLT > ∂ DANMAX	65MG	N83184 001		

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION
PROPRANOLOL HCL

AP SOLOPAK	1MG/ML	N70135 001	APR 15, 1986	
∂ SOLOPAK	1MG/ML	N70135 001	APR 15, 1986	

SOLUTION; ORAL
PROPRANOLOL HCL

PHARM BASICS	20MG/5ML	N71984 001	MAR 03, 1989	
	40MG/5ML	N71985 001	MAR 03, 1989	
∂	20MG/5ML	N71984 001	MAR 03, 1989	
	40MG/5ML	N71985 001	MAR 03, 1989	
ROXANE	20MG/5ML	N70979 001	MAY 15, 1987	
	40MG/5ML	N70690 001	MAY 15, 1987	

TABLET; ORAL
PROPRANOLOL HCL

DURAMED	40MG	N70308 001	SEP 09, 1985	
	60MG	N70309 001	OCT 01, 1986	
	80MG	N70310 001	SEP 09, 1985	
B* DURAMED	40MG	N70308 001	SEP 09, 1985	
B*	60MG	N70309 001	OCT 01, 1986	
B*	80MG	N70310 001	SEP 09, 1985	

CAPSULE; ORAL
PROPOXYPHENE HCL
> ADD > @ ALRA 65MG N83184 001

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

/AB/	/MARTEC/	/10MG/	/N70120/001/	
/AB/		/20MG/	/AUG/06,/1985/ /N70121/001/	
/AB/		/40MG/	/AUG/06,/1985/ /N70122/001/	
/AB/		/60MG/	/AUG/06,/1985/ /N70123/001/	
/AB/		/80MG/	/OCT/29,/1986/ /N70124/001/	
AB	SCHERING	10MG	/AUG/06,/1985/ N70120 001	
AB		20MG	AUG 06, 1985 N70121 001	
AB		40MG	AUG 06, 1985 N70122 001	
AB		60MG	AUG 06, 1985 N70123 001	
AB		80MG	OCT 29, 1986 N70124 001	
/AB/	/SUPERPHARM/	/40MG/	AUG 06, 1985 /N71517/001/	
/AB/		/80MG/	/JUN/08,/1988/ /N71518/001/	
	@ SUPERPHARM	40MG	/JUN/08,/1988/ N71517 001	
	@	80MG	JUN 08, 1988 N71518 001 JUN 08, 1988	

> ADD > PSEUDOEPHEDRINE HYDROCHLORIDE; TERFENADINE

> ADD > TABLET, EXTENDED RELEASE; ORAL
> ADD > SELDANE-D
> ADD > MERRELL DOW 120MG;60MG@ N19664 001
> ADD > AUG 19, 1991

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
/AA/	/RICHLYN/	/25MG/	/N80808/001/
	RICHLYN	25MG	N80808 001

QUAZEPAM

TABLET; ORAL
DORAL

> ADD >	BAKER CUMMINS	7.5MG	N18708 003 FEB 26, 1987
> ADD >		15MG	N18708 001 DEC 27, 1985
> ADD >			
> ADD >			
> ADD >			
> DLT >	/DORMALIN/		
> DLT >	/BAKER/CUMMINS/	/7.5MG/	/N18708/003/ /FEB/26,/1987/
> DLT >			
> DLT >		/15MG/	/N18708/001/ /DEC/27,/1985/
> DLT >			

QUINESTROL

TABLET; ORAL
ESTROVIS

	PARKE DAVIS	0.1MG	N16768 002

QUINIDINE GLUCONATE

/TABLET;/ORAL/
/QUINACT/
/BERLEX/

	/266MG/	/N85978/001/
	/400MG/	/N86099/001/
@ BERLEX	266MG	N85978 001
@	400MG	N86099 001

TABLET, EXTENDED RELEASE; ORAL
/QUINAITINE/

> DLT >			
> DLT > /AB/	/BOLAR/	/324MG/	/N87448/001/
> ADD >	@ BOLAR	324MG	N87448 001

QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL

	QUINIDINE GLUCONATE			
AB	ROXANE	324MG	N88431 001	JAN 06, 1984
∂ ROXANE		324MG	N88431 001	JAN 06, 1984

QUINIDINE SULFATE

TABLET; ORAL

	QUINIDINE SULFATE			
AB	VANGARD	200MG	N87909 001	JUL 13, 1982
∂ VANGARD		200MG	N87909 001	JUL 13, 1982
	QUINORA			
AB	KEY PHARMS	200MG	N83576 001	
∂ 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	
BP		0.25MG	N80723 002	
∂ WHITE TOWNE PAULSEN		0.1MG	N80723 001	
∂		0.25MG	N80723 002	
		1MG	N80723 003	
∂		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

SECOBARBITAL SODIUM

CAPSULE; ORAL

	SECOBARBITAL SODIUM			
AA	WYETH AYERST	100MG	N86390 001	
∂ WYETH AYERST		100MG	N86390 001	

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
∂ 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	ATLANTIS	80MG/ML;16MG/ML	N71556 001	

SULFAMETHOXAZOLE; TRIMETHOPRIM

SULINDAC

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

SULFAMETHOXAZOLE AND TRIMETHOPRIM

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

SUSPENSION; ORAL

COTRIM PEDIATRIC

AB	LEMMON	200MG/5ML;40MG/5ML		N70028 001 OCT 29, 1985
/AB/	/PLANTEX/	/200MG/5ML;40MG/5ML/		/N70028/001/ /OCT/29,/1985/

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

/AB/	/PHARM/BASICS/	/400MG;80MG/		/N70203/001/ /NOV/08,/1985/
/AB/		/800MG;160MG/		/N70204/001/ /NOV/08,/1985/
B*	PHARM BASICS	400MG;80MG		N70203 001 NOV 08, 1985
B*		800MG;160MG		N70204 001 NOV 08, 1985
> ADD > AB	ROXANE	400MG;80MG	¤	N72768 001 AUG 30, 1991

SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH

> ADD > AB	ROXANE LABS	800MG;160MG	¤	N72769 001 AUG 30, 1991

SULFISOXAZOLE

TABLET; ORAL

SOXAZOLE

> ADD >	∂ ALRA	500MG		N80366 001
> DLT >	/∂/BANMAX/	/500MG/		/N80366/001/

SULINDAC

TABLET; ORAL

SULINDAC

> ADD > AB	GENEVA	150MG	¤	N72712 001 AUG 30, 1991
> ADD > AB		200MG	¤	N72713 001 AUG 30, 1991
AB	MUTUAL PHARM	150MG	¤	N72050 001 APR 17, 1991
AB		200MG	¤	N72051 001 APR 17, 1991

SULINDAC

TABLET; ORAL

SULINDAC

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

TECHNETIUM TC-99M RED BLOOD CELL KIT

INJECTABLE; INJECTION

ULTRATAG

MALLINCKRODT	N/A	¤	N19981 001 JUN 10, 1991

TEMAZEPAM

CAPSULE; ORAL

TEMAZEPAM

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

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

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

TESTOSTERONE PROPIONATE

INJECTABLE; INJECTION
TESTOSTERONE PROPIONATE

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

THEOPHYLLINE

CAPSULE; ORAL
/SOMOPHYLLIN-T/

/BX/	/FISONS/	/100MG/	/N87155/001/ /FEB/25,/1985/
/BX/		/200MG/	/N87155/002/ /FEB/25,/1985/
/BX/		/250MG/	/N87155/003/ /FEB/25,/1985/
	∂ FISONS	100MG	N87155 001 FEB 25, 1985
	∂	200MG	N87155 002 FEB 25, 1985
	∂	250MG	N87155 003 FEB 25, 1985

THEOPHYLLINE

/BX/	/SCHERER/	/100MG/	/N84731/002/ /NOV/07,/1986/
/BX/		/200MG/	/N84731/001/ /NOV/07,/1986/
/BX/		/250MG/	/N84731/003/ /NOV/07,/1986/
	∂ SCHERER	100MG	N84731 002 NOV 07, 1986
	∂	200MG	N84731 001 NOV 07, 1986
	∂	250MG	N84731 003 NOV 07, 1986

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
/THEOPHYL-SR/

/BC/	/JOHNSON/RW/	/125MG/	/N86480/001/ /FEB/08,/1985/
	∂ JOHNSON RW	125MG	N86480 001 FEB 08, 1985

/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

THEOPHYLLINE-SR

/BC/	/SCHERER/	/300MG/	/N88255/001/ /JUN/12,/1986/
	∂ SCHERER	300MG	N88255 001 JUN 12, 1986

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/	/1MG/	/N71884/001/	/AUG/12,/1987/
/AB/		/2MG/	/N71885/001/	/AUG/12,/1987/
/AB/		/10MG/	/N71887/001/	/AUG/12,/1987/
	∂ AM THERAP	1MG	N71884 001	AUG 12, 1987
	∂	2MG	N71885 001	AUG 12, 1987
	∂	10MG	N71887 001	AUG 12, 1987

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

	THIOTHIXENE HCL			
/AA/	/PACO/	/EQ 5MG BASE/ML/	/N71939/001/	/DEC/16,/1988/
		/EQ/1MG/BASE/ML/	/N71917/001/	/SEP/20,/1989/
	∂ PACO	EQ 5MG BASE/ML	N71939 001	DEC 16, 1988
		EQ 1MG BASE/ML	N71917 001	SEP 20, 1989

TIMOLOL MALEATE

TABLET; ORAL

	TIMOLOL MALEATE			
AB	DANBURY	5MG¤	N72917 001	JUL 31, 1991
AB		10MG¤	N72918 001	JUL 31, 1991
AB		20MG¤	N72919 001	JUL 31, 1991
/AB/	/PHARM/BASICS/	/5MG/	/N72001/001/	/JAN/10,/1989/
/AB/		/10MG/	/N72002/001/	/JAN/10,/1989/
/AB/		/20MG/	/N72003/001/	/JAN/10,/1989/
B*	PHARM BASICS	5MG	N72001 001	JAN 10, 1989
B*		10MG	N72002 001	JAN 10, 1989
B*		20MG	N72003 001	JAN 10, 1989

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

	TOBRAMYCIN SULFATE			
AP	ABBOTT	EQ 10MG BASE/ML¤	N63080 001	APR 30, 1991
AP		EQ 10MG BASE/ML¤	N63112 001	APR 30, 1991
AP		EQ 40MG BASE/ML¤	N63111 001	APR 30, 1991
AP		EQ 40MG BASE/ML¤	N63161 001	MAY 29, 1991
AP	LEDERLE	EQ 10MG BASE/ML¤	N63113 001	APR 26, 1991
AP		EQ 40MG BASE/ML¤	N63117 001	APR 26, 1991
AP		EQ 40MG BASE/ML¤	N63118 001	JUL 29, 1991

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

/AB/	/CHELSEA/	/100MG/	/N70285/001/ /JAN/09,/1986/	
/AB/		/250MG/	/N70286/001/ /JAN/09,/1986/	
/AB/		/500MG/	/N70287/001/ /JAN/09,/1986/	
B*	CHELSEA	100MG	N70285 001 JAN 09, 1986	
B*		250MG	N70286 001 JAN 09, 1986	
B*		500MG	N70287 001 JAN 09, 1986	
/AB/	/PHARM/BASICS/	/100MG/	/N71355/001/ /JAN/11,/1988/	
/AB/		/250MG/	/N70168/001/ /APR/02,/1986/	
/AB/		/500MG/	/N70169/001/ /APR/02,/1986/	
B*	PHARM BASICS	100MG	N71355 001 JAN 11, 1988	
B*		250MG	N70168 001 APR 02, 1986	
B*		500MG	N70169 001 APR 02, 1986	

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

> ADD >	∂ ALRA	500MG	N86141 001	
> DLT >	/∂/BANMAX/	/500MG/	/N86141/001/	

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

/AB/	/CHELSEA/	/50MG/	/N70568/001/ /OCT/10,/1986/	
/AB/		/100MG/	/N70569/001/ /OCT/10,/1986/	
B*	CHELSEA	50MG	N70568 001 OCT 10, 1986	
B*		100MG	N70569 001 OCT 10, 1986	

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

AB	MYLAN	50MG*		N71405 001 FEB 27, 1991
AB		100MG*		N71406 001 FEB 27, 1991
/AB/	/PHARM/BASICS/	/50MG/		/N70491/001/ /APR/29,/1987/
/AB/		/100MG/		/N70492/001/ /APR/29,/1987/
B*	PHARM BASICS	50MG		N70491 001 APR 29, 1987
B*		100MG		N70492 001 APR 29, 1987

TRETINOIN

GEL; TOPICAL
RETIN-A

/AT/	/JOHNSON/RW/	/0.01%/	/N17519/003/

TRIAMCINOLONE ACETONIDE

AEROSOL, METERED; NASAL
NASACORT

RHONE POULENC RORER	55UGM/INH*	N19798 001 JUL 11, 1991

CREAM; TOPICAL
TRIAMCINOLONE ACETONIDE

AT	G AND W	0.025%*	N89797 001 MAY 31, 1991
AT		0.1%*	N89798 001 MAY 31, 1991
/AT/	/PHARM/BASICS/	/0.025%/	/N88094/001/ /SEP/01,/1983/
/AT/		/0.1%/	/N88095/001/ /SEP/01,/1983/
/AT/		/0.5%/	/N88096/001/ /SEP/01,/1983/
∂	PHARM BASICS	0.025%	N88094 001 SEP 01, 1983
∂		0.1%	N88095 001 SEP 01, 1983
∂		0.5%	N88096 001 SEP 01, 1983

TRIAMCINOLONE ACETONIDE

TRIMETHOBENZAMIDE HYDROCHLORIDE

TRIAMCINOLONE ACETONIDE

/GEL;/TOPICAL/
/ARISTOGEL/
/LEDERLE/ /0.1%/ /N83380/001/
∂ LEDERLE 0.1% N83380 001

OINTMENT; TOPICAL
ARISTOCORT A
/AT/ /LEDERLE/ /0.5%/ /N88781/001/
/OCT/05,/1984/
∂ LEDERLE 0.5% N88781 001
OCT 05, 1984

/KENAC/
/AT/ /NMC/ /0.1%/ /N87799/001/
/JUN/07,/1982/

TRIAMCINOLONE ACETONIDE
AT NMC 0.1% N87799 001
JUN 07, 1982

/AT/ /PHARM/BASICS/ /0.025%/ /N88090/001/
/SEP/01,/1983/
/AT/ /0.1%/ /N88091/001/
/SEP/01,/1983/
/AT/ /0.5%/ /N88092/001/
/SEP/01,/1983/
∂ PHARM BASICS 0.025% N88090 001
SEP 01, 1983
∂ 0.1% N88091 001
SEP 01, 1983
∂ 0.5% N88092 001
SEP 01, 1983

TRIAMCINOLONE DIACETATE

INJECTABLE; INJECTION
TRIAMCINOLONE DIACETATE
/BP/ /LEMMON/ /40MG/ML/ /N85529/001/
BP STERIS 40MG/ML N85529 001

TRIMEPRAZINE TARTRATE

SYRUP; ORAL
TEMARIL
/AA/ /HERBERT/ /EQ 2.5MG BASE/5ML/ /N11316/003/
HERBERT EQ 2.5MG BASE/5ML N11316 003

/TRIMEPRAZINE TARTRATE/
/AA/ /PHARM/BASICS/ /EQ 2.5MG BASE/5ML/ /N88285/001/
/APR/11,/1985/
∂ PHARM BASICS EQ 2.5MG BASE/5ML N88285 001
APR 11, 1985

TRIMETHOBENZAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
TRIMETHOBENZAMIDE HCL
/AP/ /SOLOPAK/ /100MG/ML/ /N89043/001/
/APR/04,/1986/
∂ SOLOPAK 100MG/ML N89043 001
APR 04, 1986

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
TRIMIPRAMINE MALEATE
/AA/ /PHARM/BASICS/ /EQ 25MG BASE/ /N71283/001/
/DEC/08,/1987/
/AA/ /EQ 50MG BASE/ /N71284/001/
/DEC/08,/1987/
/AA/ /EQ 100MG BASE/ /N71285/001/
/DEC/08,/1987/
B* PHARM BASICS EQ 25MG BASE N71283 001
DEC 08, 1987
B* EQ 50MG BASE N71284 001
DEC 08, 1987
B* EQ 100MG BASE N71285 001
DEC 08, 1987

TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL
TRIPROLIDINE HCL
/AA/ /DANBURY/ /2.5MG/ /N85094/001/
DANBURY 2.5MG N85094 001
/AA/ /VITARINE/ /2.5MG/ /N85610/001/
∂ VITARINE 2.5MG N85610 001

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 HCL
/AP/ /SOLOPAK/ /2.5MG/ML/ /N70697/001/
/JUL/31,/1987/
∂ SOLOPAK 2.5MG/ML N70697 001
JUL 31, 1987

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL

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

TABLET, EXTENDED RELEASE; ORAL
ISOPTIN SR

	KNOLL	120MG*	N19152 003 MAR 06, 1991

VITAMIN A PALMITATE

CAPSULE; ORAL

/AA/	/VI-DOM-A/ /MILES/	/EQ 50,000 UNITS BASE/	/N80972/001/
	@ MILES	EQ 50,000 UNITS BASE	N80972 001

XYLOSE

POWDER; ORAL

	XYLO-PFAN		
AA	ADRIA	25GM/BOT /25GM/BOT/	N17605 001 /N17605/001/
	XYLOSE		
AA	LYNE	25GM/BOT	N18856 001 MAR 26, 1987
/A/		/25GM/BOT/	/N18856/001/ /MAR/26,/1987/

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
EXIDINE
/S/XTTRIUM/ /2%/ /N19422/001/ /DEC/17,/1985/
XTTRIUM 2% N19422 001 DEC 17, 1985
MICRODERM
JOHNSON AND JOHNSON 4%# N72255 001 APR 15, 1991

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

CLOTRIMAZOLE

CREAM; TOPICAL
>ADD< MYCELEX
>ADD< MILES 1%# N18183 002 APR 01, 1991

SOLUTION; TOPICAL
>ADD< MYCELEX
>ADD< MILES 1%# N18181 002 APR 01, 1991

DOXYLAMINE SUCCINATE

TABLET; ORAL
DOXYLAMINE SUCCINATE
COPLEY 25MG N88900 002 FEB 12, 1988

HYDROCORTISONE

/OINTMENT;TOPICAL/
/HC/(HYDROCORTISONE)/
/C/AND/M/
@ C AND M /0.5%/ 0.5% /N80481/001/ N80481 001

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL
>ADD< ADVIL COLD AND SINUS
>ADD< WHITEHALL 200MG;30MG N19771 001 SEP 19, 1989

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

>DLT< TABLET; ORAL
>DLT< /CHADVIL/
>DLT< /WHITEHALL/ /200MG;30MG/ /N19771/001/ /SEP/19,/1989/

INSULIN BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
NOVOLIN R
NOVO NORDISK 100UNITS/ML# N19938 001 JUN 25, 1991

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
NOVOLIN 70/30
NOVO NORDISK 30UNITS/ML;70UNITS/ML# N19991 001 JUN 25, 1991

INSULIN PORK

>DLT< INJECTABLE; INJECTION
>ADD< INSULIN
/NOVO/NORDISK/
@ NOVO NORDISK /40/UNITS/ML/ 40 UNITS/ML /N17926/001/ N17926 001

INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
NOVOLIN N
NOVO NORDISK 100UNITS/ML# N19959 001 JUL 01, 1991

INSULIN ZINC SUSP BEEF

>DLT< INJECTABLE; INJECTION
>ADD< LENTE INSULIN
/NOVO/NORDISK/
@ NOVO NORDISK /40/UNITS/ML/ 40 UNITS/ML /N17998/001/ N17998 001

INSULIN ZINC SUSP BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
NOVOLIN L
NOVO NORDISK — 100UNITS/ML¤ — N19965 001 JUN 25, 1991

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

HETASTARCH 6% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

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

PENTASTARCH 10% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

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: ALPHA-GALACTOSIDASE A TRADE: CC-GALACTOSIDASE	TREATMENT OF ALPHA-GALACTOSIDASE A DEFICIENCY. (FABRY'S DISEASE).	DAVID H. CALHOUN, PH.D. CITY COLLEGE OF NEW YORK
GENERIC: ANTIVENOM (CROTALIDAE) PURIFIED (AVIAN) TRADE: NOT ESTABLISHED	TREATMENT OF ENVENOMATION BY POISONOUS SNAKES BELONGING TO THE CROTALIDAE FAMILY.	OPHIDIAN PHARMA
GENERIC: BOTULINUM TOXIN TYPE A TRADE: OCULINUM*/**	TREATMENT OF STRABISMUS ASSOCIATED WITH DYSTONIA IN ADULTS (PATIENTS 12 YEARS OF AGE AND ABOVE).*/** [DEC 29, 1996] TREATMENT OF BLEPHAROSPASM ASSOCIATED WITH DYSTONIA IN ADULTS (PATIENTS 12 YEARS OF AGE AND ABOVE).*/** [DEC 29, 1996] TREATMENT OF CERVICAL DYSTONIA.	ALLERGAN

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: CHIMERIC M-T412 (HUMAN-MURINE) IGG MONOCLONAL ANTI-CD4 ANTIBODY TRADE: NOT ESTABLISHED	TREATMENT OF MULTIPLE SCLEROSIS.	CENTOCOR, INC
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: EPOETIN ALPHA (RECOMBINANT-HUMAN) TRADE: EPOGEN*/**	TREATMENT OF ANEMIA ASSOCIATED WITH HIV INFECTION OR HIV TREATMENT. [TREATMENT OF AZT-INDUCED ANEMIA IN HIV INFECTED PATIENTS.*/**] [DEC 31, 1997]	AMGEN
GENERIC: HUMAN MONOCLONAL ANTIBODY AGAINST HEPATITIS B VIRUS TRADE: NOT ESTABLISHED	PROPHYLAXIS OF HEPATITIS B REINFECTION IN PATIENTS UNDERGOING LIVER TRANSPLANTATION SECONDARY TO END-STAGE CHRONIC HEPATITIS B INFECTION.	SANDOZ PHARMACEUTICALS CORPORATION
GENERIC: INSULIN-LIKE GROWTH FACTOR-1 TRADE: MYOTROPHIN	TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.	CEPHALON, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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. INTRALESIONAL AND/OR SYSTEMIC TREATMENT OF AIDS-RELATED KAPOSI'S SARCOMA.	BIOGEN
GENERIC: INTERLEUKIN-1 ALPHA, HUMAN RECOMBINANT TRADE: NOT ESTABLISHED	FOR THE PROMOTION OF EARLY ENGRAFTMENT IN BONE MARROW TRANSPLANTATION. FOR HEMATOPOIETIC POTENTIATION IN APLASTIC ANEMIA.	IMMUNEX CORPORATION
GENERIC: INTERLEUKIN-3, RECOMBINANT HUMAN TRADE: NOT ESTABLISHED	PROMOTION OF ERYTHROPOIESIS IN DIAMOND-BLACKFAN ANEMIA (CONGENITAL PURE CELL RED APLASIA).	IMMUNEX CORPORATION
GENERIC: MONOCLONAL ANTIBODY PM-81 TRADE: NOT ESTABLISHED	ADJUNCTIVE TREATMENT OF ACUTE MYELOGENOUS LEUKEMIA.	MEDAREX, INC
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: MYELIN TRADE: NOT ESTABLISHED	TREATMENT OF MULTIPLE SCLEROSIS.	AUTOIMMUNE, INC
GENERIC: POLY I: POLY $C_{12}U$ TRADE: AMPLIGEN	TREATMENT OF RENAL CELL CARCINOMA.	HEM RESEARCH, 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:	RECOMBINANT SECRETORY LEUCOCYTE PROTEASE INHIBITOR	TREATMENT OF CONGENITAL ALPHA-1 ANTITRYPSIN DEFICIENCY. TREATMENT OF CYSTIC FIBROSIS.	SYNERGEN, INC
TRADE:	NOT ESTABLISHED		

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL		DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC:	RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-B4) TO B CELL (CD 19)	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
TRADE:	NOT ESTABLISHED		
GENERIC:	RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (N901) TO CD56 POSITIVE CELLS	TREATMENT OF SMALL CELL LUNG CANCER.	IMMUNOGEN, INC
TRADE:	NOT ESTABLISHED		
GENERIC:	SARGRAMOSTIM	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
TRADE:	LEUKINE*/**		
GENERIC:	THYMOSIN ALPHA-1	ADJUNCTIVE TREATMENT OF CHRONIC ACTIVE HEPATITIS B.	ALPHA 1 BIOMEDICALS, INC
TRADE:	NOT ESTABLISHED		

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: BERACTANT TRADE: SURVANTA*/**	PREVENTION OF NEONATAL RESPIRATORY DISTRESS SYNDROME (RDS).*/** [JUL 1, 1998] TREATMENT OF NEONATAL RESPIRATORY DISTRESS SYNDROME (RDS).*/** [JUL 1, 1998]	ROSS
GENERIC: CALCIUM GLUCONATE GEL TRADE: H-F GEL	EMERGENCY TOPICAL TREATMENT OF HYDROGEN FLUORIDE (HYDROFLUORIC ACID) BURNS.	LTR PHARMACEUTICALS, INC
GENERIC: CYCLOSPORINE 2% OPHTHALMIC OINTMENT TRADE: SANDIMMUNE	TREATMENT OF PATIENTS AT HIGH RISK OF GRAFT REJECTION FOLLOWING PENETRATING KERATOPLASTY. USE IN CORNEAL MELTING SYNDROMES OF KNOWN OR PRESUMED IMMUNOLOGIC ETIOPATHOGENESIS INCLUDING MOOREN'S ULCER.	SANDOZ PHARMACEUTICALS CORP
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: ETIDRONATE DISODIUM TRADE: DIDRONEL	PREVENTION OF DEGENERATIVE METABOLIC BONE DISEASE OCCURRING IN PATIENTS WHO REQUIRE LONG TERM (6 MONTHS OR GREATER) TOTAL PARENTERAL NUTRITION. TREATMENT OF DEGENERATIVE METABOLIC BONE DISEASE OCCURRING IN PATIENTS WHO REQUIRE LONG TERM (6 MONTHS OR GREATER) TOTAL PARENTERAL NUTRITION.	MGI PHARMA, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: FLUDARABINE PHOSPHATE TRADE: FLUDARA*/**	TREATMENT OF REFRACTORY B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA. [APR 18, 1998]	BERLEX
GENERIC: FOSPHENYTOIN TRADE: NOT ESTABLISHED	ACUTE TREATMENT OF PATIENTS WITH STATUS EPILEPTICUS OF THE GRAND MAL TYPE.	WARNER-LAMBERT COMPANY
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: HISTRELIN TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE INTERMITTENT PORPHYRIA, HEREDITARY COPROPORPHYRIA, AND VARIEGATE PORPHYRIA.	KARL E. ANDERSON, M.D. UNIVERSITY OF TEXAS
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: L-LEUCOVORIN CALCIUM TRADE: ISOVORIN	USE IN CONJUNCTION WITH HIGH-DOSE METHOTREXATE IN THE TREATMENT OF OSTEOSARCOMA.	LEDERLE LABORATORIES
GENERIC: NIFEDIPINE TRADE: NOT ESTABLISHED	TREATMENT OF INTERSTITIAL CYSTITIS.	JONATHAN FLEISCHMANN, M.D. CLEVELAND METROHEALTH MEDICAL CENTER
GENERIC: OFLOXACIN TRADE: NOT ESTABLISHED	TREATMENT OF BACTERIAL CORNEAL ULCERS.	ALLERGAN, INC
GENERIC: PENTOSTATIN TRADE: NOT ESTABLISHED	TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA.	WARNER LAMBERT COMPANY

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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 PROPIONATE TRADE: NOT ESTABLISHED	TREATMENT OF VULVAR DYSTROPHIES.	STAR PHARMACEUTICALS, INC
GENERIC: TESTOSTERONE SUBLINGUAL TRADE: NOT ESTABLISHED	TREATMENT OF CONSTITUTIONAL DELAY OF GROWTH AND PUBERTY IN BOYS.	GYNEX, INC
GENERIC: TIRATRICOL TRADE: TRIACANA	USE IN COMBINATION WITH LEVO-THYROXINE TO SUPPRESS THYROID STIMULATING HORMONE (TSH) IN PATIENTS WITH WELL-DIFFERENTIATED THYROID CANCER WHO ARE INTOLERANT TO ADEQUATE DOSES OF LEVO-THYROXINE ALONE.	MEDGENIX GROUP
GENERIC: URSODEOXYCHOLIC ACID TRADE: ACTIGALL	MANAGEMENT OF THE CLINICAL SIGNS AND SYMPTOMS ASSOCIATED WITH PRIMARY BILIARY CIRRHOSIS.	CIBA GEIGY
GENERIC: URSODEOXYCHOLIC ACID TRADE: URSOFALK	TREATMENT OF PATIENTS WITH PRIMARY BILIARY CIRRHOSIS.	INTERFALK U.S., INC

GENERIC: URSODEOXYCHOLIC ACID TRADE: ACTIGALL	MANAGEMENT OF THE CLINICAL SIGNS AND SYMPTOMS ASSOCIATED WITH PRIMARY BILIARY CIRRHOSIS.	CIBA GEIGY
GENERIC: URSODEOXYCHOLIC ACID TRADE: URSOFALK	TREATMENT OF PATIENTS WITH PRIMARY BILIARY CIRRHOSIS.	INTERFALK U.S., INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: 566C80 TRADE: NOT ESTABLISHED	PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA (PCP) IN HIGH-RISK, HIV-INFECTED PATIENTS DEFINED BY ONE OR BOTH OF THE FOLLOWING CRITERIA: (1) A HISTORY OF ONE OR MORE EPISODES OF PCP, (2) A PERIPHERAL CD4+ (T4 HELPER/INDUCER) LYMPHOCYTE COUNT LESS THAN OR EQUAL TO 200/MM^3.	BURROUGHS WELLCOME COMPANY

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

NO AUGUST 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.

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
ESTROGENS, CONJUGATED (TABLET)	AUG 21, 1991	

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
CARBAMAZEPINE SUSPENSION; ORAL	200MG/5ML	89 P-0399/CP	GUIDELINES	NEW DOSAGE FORM	APPROVED MAY 16, 1991
CLOBETASOL PROPIONATE LOTION; TOPICAL	0.05%	90 P-0198/ CP1	KROSS	NEW DOSAGE FORM	APPROVED MAR 14, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	100MG/VIAL	90 P-0250/ CP1	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	200MG/VIAL	90 P-0250/ CP2	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	500MG/VIAL	90 P-0250/ CP3	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	1GM/VIAL	90 P-0250/ CP4	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
DOPAMINE HYDROCHLORIDE INJECTABLE; INJECTION	5MG/ML	90 P-0137/ CP1	ABBOTT	NEW STRENGTH	APPROVED APR 10, 1991

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (25ML/VIAL)	91 P-0041/ CP1	ADRIA	NEW STRENGTH	APPROVED MAY 22, 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
I-57	SHORT-TERM TREATMENT OF ACTIVE DUODENAL ULCER
I-58	INITIAL TREATMENT OF ADVANCED OVARIAN CARCINOMA IN COMBINATION WITH OTHER APPROVED CHEMOTHERAPEUTIC AGENTS
I-59	ENDOSCOPICALLY DIAGNOSED ESOPHAGITIS, INCLUDING EROSIVE AND ULCERATIVE ESOPHAGITIS, AND ASSOCIATED HEARTBURN DUE TO GASTROESOPHAGEAL REFLUX DISEASE
I-60	SINGLE APPLICATION TREATMENT OF HEAD LICE IN CHILDREN TWO MONTHS TO TWO YEARS IN AGE
I-61	FEMALE ANDROGENETIC ALOPECIA

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
U-49	SYMPTOMATIC CANCER-RELATED HYPERCALCEMIA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	20089 001	ACYCLOVIR; ZOVIRAX	4199574	APR 22, 1997			
	20089 002	ACYCLOVIR; ZOVIRAX	4199574	APR 22, 1997			
	20057 003	ALGLUCERASE; CEREDASE				NCE	APR 05, 1996
						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			
	19155 001	AMMONIUM LACTATE; LAC-HYDRIN				ODE	DEC 26, 1997
	18700 001	AMRINONE LACTATE; INOCOR	4105783	OCT 26, 1995			
	19851 001	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4072746	APR 23, 1998	U-7	NCE	JUL 31, 1994
	19851 002	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2000		NCE	JUN 25, 1996
	19851 003	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2000		NCE	JUN 25, 1996
	19851 004	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2000		NCE	JUN 25, 1996
>ADD>	20032 001	BERACTANT; SURVANTA	4410520	OCT 18, 2000		NCE	JUN 25, 1996
						ODE	JUL 01, 1998
	19856 001	CARBIDOPA; SINEMET CR				NCE	JUL 01, 1996
			4900755	MAY 23, 2006			
			4832957	MAY 23, 2006			
	19880 001	CARBOPLATIN; PARAPLATIN	3830827	AUG 20, 1991		NDF	MAY 30, 1994
	19880 002	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998		I-58	JUL 05, 1994
	19880 003	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998		I-58	JUL 05, 1994
	20044 001	CETYL ALCOHOL; EXOSURF NEONATAL	4140707	AUG 25, 1998		I-58	JUL 05, 1994
	17920 002	CIMETIDINE; TAGAMET	4312860	NOV 23, 2001		NC	AUG 02, 1993
	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
	17924 001	CIMETIDINE HYDROCHLORIDE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
	19849 001	DAPIPRAZOLE HYDROCHLORIDE; REV-EYES	3950333	APR 13, 1993		I-56	MAR 07, 1994
	19082 001	DEZOCINE; DALGAN	4252721	FEB 24, 1998		NCE	DEC 31, 1995
			4605671	AUG 12, 2003			
	19082 002	DEZOCINE; DALGAN	4001331	JAN 04, 1996		NCE	DEC 29, 1994
			3836670	SEP 09, 1991	U-48		
			4605671	AUG 12, 2003			
	19082 003	DEZOCINE; DALGAN	4001331	JAN 04, 1996		NCE	DEC 29, 1994
			3836670	SEP 09, 1991	U-48		
			4605671	AUG 12, 2003			
			4001331	JAN 04, 1996		NCE	DEC 29, 1994
			3836670	SEP 09, 1991	U-48		

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
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	4701460	OCT 20, 2004		NCE	MAR 07, 1996
19946 001	DOXACURIUM CHLORIDE; NUROMAX	4188390	FEB 12, 1997		NCE	NOV 02, 1995
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	4027019	MAY 31, 1996		NC	DEC 29, 1992
19653 001	ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1996		NC	DEC 29, 1992
19653 002	ETHINYL ESTRADIOL; ORTHO CYCLEN-28	4076831	FEB 28, 1995	U-45		
18922 002	ETODOLAC; LODINE	3939178	FEB 17, 1993		NCE	JAN 31, 1996
		4076831	FEB 28, 1995	U-45		
18922 003	ETODOLAC; LODINE	3939178	FEB 17, 1993		NCE	JAN 31, 1996
		4264611	APR 28, 1998		NCE	JUL 26, 1996
19834 001	FELODIPINE; PLENDIL	4262611	APR 28, 1998		NCE	JUL 26, 1996
19834 002	FELODIPINE; PLENDIL	4404216	OCT 16, 2003		NCE	JAN 29, 1995
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	4357324	NOV 02, 1999		NCE	APR 18, 1996
20038 001	FLUDARABINE PHOSPHATE; FLUDARA				ODE	APR 18, 1998
		4314081	FEB 02, 2001		NCE	DEC 29, 1992
20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4384123	MAY 17, 2000			
19915 002	FOSINOPRIL SODIUM; MONOPRIL	4337201	JUN 29, 1999		NCE	MAY 16, 1996
		4384123	MAY 17, 2000			
19915 003	FOSINOPRIL SODIUM; MONOPRIL	4337201	JUN 29, 1999		NCE	MAY 16, 1996
		4529593	JUL 16, 2002	U-49	NCE	JAN 17, 1996
19961 002	GALLIUM NITRATE; GANITE				ODE	JAN 17, 1998
		4619921	OCT 28, 2003		NCE	DEC 17, 1995
19967 001	HALOBETASOL PROPIONATE; ULTRAVATE	4619921	OCT 28, 2003		NCE	DEC 17, 1995
19968 001	HALOBETASOL PROPIONATE; ULTRAVATE	4239747	DEC 16, 1999		NCE	DEC 07, 1994
19580 001	IOTROLAN; OSMOVIST	4239747	DEC 16, 1999		NCE	DEC 07, 1994
19580 002	IOTROLAN; OSMOVIST	4466972	AUG 21, 2001	U-3	NCE	DEC 20, 1995
19546 001	ISRADIPINE; DYNACIRC	4466972	AUG 21, 2001	U-3	NCE	DEC 20, 1995
19546 002	ISRADIPINE; DYNACIRC					

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
	20035 001	LEVAMISOLE HYDROCHLORIDE; ERGAMISOL	4584305	JUN 19, 2004	U-42	NCE	JUN 18, 1995
	20088 001	LEVONORGESTREL; NORPLANT SYSTEM	3850911	NOV 26, 1991		NP	DEC 10, 1993
>ADD>	19501 001	MINOXIDIL; ROGAINE				I-61	AUG 13, 1994
	19753 001	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1994		NCE	JUN 19, 1995
	19753 002	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1994		NCE	JUN 19, 1995
	19753 003	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1994		NCE	JUN 19, 1995
>ADD>	18565 003	MORPHINE SULFATE; INFUMORPH				ODE	JUL 19, 1998
>ADD>	18565 004	MORPHINE SULFATE; INFUMORPH				ODE	JUL 19, 1998
	19886 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1999		NCE	FEB 13, 1995
	18612 001	NICOTINE POLACRILEX; NICORETTE	3901248	AUG 26, 1992		NCE	JAN 13, 1994
	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
			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
	19508 001	NIZATIDINE; AXID	4382090	MAY 03, 2000	U-18	I-59	JUL 26, 1994
	19508 002	NIZATIDINE; AXID	4382090	MAY 03, 2000	U-18	I-59	JUL 26, 1994
	19757 001	NORFLOXACIN; CHIBROXIN	4551456	NOV 05, 2002			
			4146719	MAR 27, 1998		NDF	JUN 17, 1994
	19715 001	OLSALAZINE SODIUM; DIPENTUM	4559330	AUG 04, 2004		NCE	JUL 31, 1995
	19810 001	OMEPRAZOLE; PRILOSEC	4255431	MAR 10, 2000		I-57	JUN 12, 1994
	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
>ADD>	19918 001	PERMETHRIN; NIX				I-60	MAY 02, 1993
	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
	19797 001	POLYETHYLENE GLYCOL 3350; NULYTELY				NP	APR 22, 1994
	19627 001	PROPOFOL; DIPRIVAN	4056635	NOV 01, 1996		NCE	OCT 02, 1994

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
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
19863 001	SERMORELIN ACETATE; GEREF	4703035	MAY 14, 2002	U-47	NCE	DEC 28, 1995
		4517181	MAY 14, 2002		NCE	DEC 28, 1995
					NCE	JAN 30, 1996
19998 002	SUCCIMER; CHEMET				ODE	JAN 30, 1998
					NP	JUN 10, 1994
19981 001	TECHNETIUM TC-99M RED BLOOD CELL KIT; ULTRATAG	4452774	JUN 05, 2001		NCE	DEC 21, 1995
19785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4452774	JUN 05, 2001		NCE	DEC 21, 1995
19785 002	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993
19614 002	VERAPAMIL HYDROCHLORIDE; VERELAN					

New 11th Edition

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THERAPEUTIC EQUIVALENCE EVALUATIONS

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