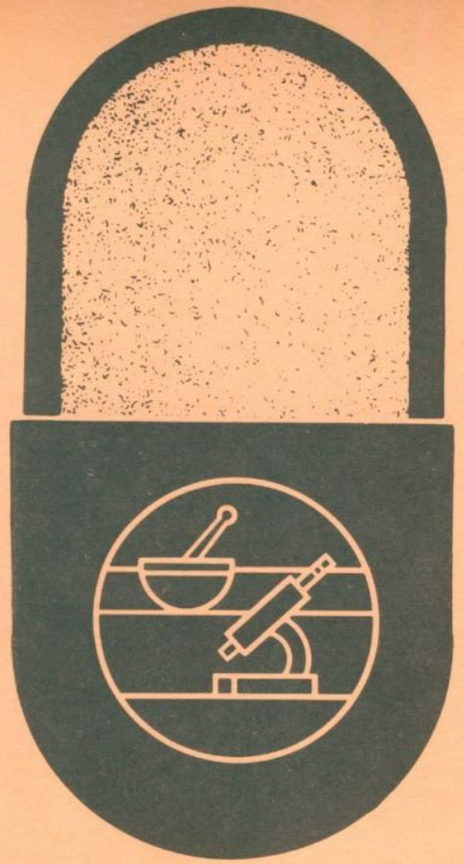
CUMULATIVE SUPPLEMENT 7

JAN'91-JUL'91



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

11TH EDITION

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

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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

11TH EDITION

Cumulative Supplement

July 1991

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CUMULATIVE SUPPLEMENT 7

JULY 1991

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 11th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Division of Blood and Blood Products and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product, along with the application number and product number (FDA's internal file number). All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to place an asterisk (*) to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement.

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the List will not be repeated for context.]

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Additions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item. A newly approved product is also identified by a lozenge (⌑) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

Deletions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >DLT> (DELETE) to the left of the line containing overstruck print. The >DLT> symbol is dropped in subsequent Cumulative Supplements for that item. The overstruck print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements.

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the " ∋ " symbol to designate their non-marketed status. All products having a " ∋ " symbol in the 12th Cumulative Supplement of the 11th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 12th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

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

1.3 CHANGE OF A THERAPEUTIC EQUIVALENCY CODE FOR A DRUG ENTITY

Methylphenidate Hydrochloride:

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

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

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

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

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

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

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

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

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

1.4 THE B* THERAPEUTIC EQUIVALENCE CODE

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

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

1.5 APPLICANT (NAME) CHANGES

Because it is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name, the cumulation of these transfers and name changes will be identified in this section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the Cumulative Supplement.

APPLICANT (NAME) CHANGES

FORMER APPLICANT (NAME)	NEW APPLICANT (NAME)	ABBREVIATED NAME
CORD LABORATORIES INC	GENEVA PHARMACEUTICALS INC	GENEVA
PHARMACIA LABORATORIES DIV PHARMACIA INC	KABI PHARMACIA	KABI
REID ROWELL INC	SOLVAY PHARMACEUTICALS	SOLVAY
ICI PHARMACEUTICALS PR INC	IPR PHARMACEUTICALS INC	IPR

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

/TYLENOL W/ CODEINE #4/

/AA/	/SOLVAY/	/325MG;30MG/	/N085685/001/	
	@ SOLVAY	325MG;30MG	N85685 001	
>_DLT_>	/TYLENOL W/ CODEINE NO. 3/			
>_DLT_>/AA/	/JOHNSON/RW/	/300MG;30MG/	/N087422/001/	
>_ADD_>	@ JOHNSON RW	300MG;30MG	N87422 001	
>_DLT_>	/TYLENOL W/ CODEINE NO. 4/			
>_DLT_>	/JOHNSON/RW/	/300MG;60MG/	/N087421/001/	
>_ADD_>	@ JOHNSON RW	300MG;60MG	N87421 001	

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE NO. 2

/AA/	/AM THERAP/	/300MG;15MG/	/N089481/001/	
	@ AM THERAP	300MG;15MG	/MAR/03,/1987/	
			N89481 001	
			MAR 03, 1987	
>_DLT_>	/TYLENOL W/ CODEINE/			
>_DLT_>/AA/	/JOHNSON/RW/	/325MG;15MG/	/N085056/002/	
>_DLT_>/AA/		/325MG;30MG/	/N085056/003/	
>_DLT_>		/325MG;7.5MG/	/N085056/001/	
>_DLT_>		/325MG;60MG/	/N085056/004/	
>_ADD_>	@ JOHNSON RW	325MG;7.5MG	N85056 001	
>_ADD_>	@	325MG;15MG	N85056 002	
>_ADD_>	@	325MG;30MG	N85056 003	
>_ADD_>	@	325MG;60MG	N85056 004	

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

/AA/	/PHARM/BASICS/	/500MG;5MG/	/N089291/001/	
B*	PHARM BASICS	500MG;5MG	/MAY/29,/1987/	
			N89291 001	
			MAY 29, 1987	

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL

>_DLT_>	/TYLOX-325/			
>_DLT_>	/JOHNSON/RW/	/325MG;5MG/	/N088246/001/	
>_DLT_>			/NOV/08,/1984/	
>_ADD_>	@ JOHNSON RW	325MG;5MG	N38246 001	
>_ADD_>			NOV 08, 1984	

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

/AB/	/CHELSEA/	/325MG;50MG/	/N071336/001/	
			/DEC/11,/1986/	
/AB/		/650MG;100MG/	/N071337/001/	
			/DEC/11,/1986/	
B*	CHELSEA	325MG;50MG	N71336 001	
			DEC 11, 1986	
B*		650MG;100MG	N71337 001	
			DEC 11, 1986	

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC

/DROLEX/

/AT/	/NORWICH/EATON/	/2%/	/N086845/001/	
	@ NORWICH EATON	2%	N86845 001	

ACETIC ACID, GLACIAL; HYDROCORTISONE

SOLUTION/DROPS; OTIC

/DROLEX HC/

/AT/	/NORWICH/EATON/	/2%;1%/	/N086844/001/	
	@ NORWICH EATON	2%;1%	N86844 001	

ACETOHEXAMIDE

TABLET; ORAL

ACETOHEXAMIDE

>_DLT_>/AB/	/PHARM/BASICS/	/250MG/	/N070753/001/	
>_DLT_>			/NOV/03,/1986/	
>_DLT_>/AB/		/500MG/	/N070754/001/	
>_DLT_>			/NOV/03,/1986/	
>_ADD_> B*	PHARM BASICS	250MG	N70753 001	
>_ADD_>			NOV 03, 1986	
>_ADD_> B*		500MG	N70754 001	
>_ADD_>			NOV 03, 1986	

ACETOPHENAZINE MALEATE

>_DLT_>	/TABLET;ORAL/			
>_DLT_>	/TINDAL/			
>_DLT_> /BP/	/SCHERING/	/20MG/	/N012254/002/	
>_ADD_>	@ SCHERING	20MG	N12254 002	

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		

ALCOHOL

INJECTABLE; INJECTION

/ALCOHOL 5% IN DEXTROSE 5%/			/5ML/100ML/	/N83483/001/
>DLT> >DLT> /AP/	/CUTTER/		5ML/100ML	N83483 001
>ADD>	ə CUTTER			

ALGLUCERASE

INJECTABLE; INJECTION

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

ALLOPURINOL

TABLET; ORAL

ALLOPURINOL				
/AB/	/BOLAR/	/300MG/		/N18241/002/
	ə BOLAR	300MG		/NOV/16,/1984/
				N18241 002
				NOV 16, 1984

ALLOPURINOL

TABLET; ORAL

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

ALPRAZOLAM

TABLET; ORAL

XANAX /PHARMACIA & UPJOHN/	/2MG/		/N18276/004/ /NOV/27,/1985/
UPJOHN	2MG		N18276 004 NOV 27, 1985

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

AMILORIDE HCL AND HYDROCHLOROTHIAZIDE				
>ADD> AB ROYCE	5MG;50MG¤			N73334 001 JUL 19, 1991
>ADD>				

AMINOPHYLLINE

INJECTABLE; INJECTION

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

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

>DLT>	/ANTIID/			
>DLT>/AB/	/SQUIBB/	/10MG/	/N86454/001/	
>DLT>/AB/		/25MG/	/N86454/002/	
>DLT>/AB/		/50MG/	/N86454/003/	
>DLT>/AB/		/75MG/	/N86454/004/	
>DLT>/AB/		/100MG/	/N86454/005/	
>ADD>	@ SQUIBB	10MG	N86454 001	
>ADD>	@	25MG	N86454 002	
>ADD>	@	50MG	N86454 003	
>ADD>	@	75MG	N86454 004	
>ADD>	@	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/	
3*	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/	
			/JAN/09;/1987/	
/AP/		/EQ 2GM BASE/VIAL/	/N62634/003/	
			/JAN/09;/1987/	
@	INTL MEDICATION	EQ 1GM BASE/VIAL	N62634 002	
			JAN 09, 1987	
@		EQ 2GM BASE/VIAL	N62634 003	
			JAN 09, 1987	

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

INJECTABLE; INJECTION
M.V.I.-12 LYOPHILIZED

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

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

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL
/BUTALBITAL W/ ASPIRIN AND CAFFEINE/
/AB/ /CHELSEA/ /325MG;50MG;40MG/ /N86231/002/ /FEB/12,/1985/

	BUTALBITAL, ASPIRIN AND CAFFEINE		
AB	CHELSEA	325MG;50MG;40MG	N86231 002 FEB 12, 1985

TABLET; ORAL
/BUTALBITAL W/ ASPIRIN AND CAFFEINE/
/AB/ /CHELSEA/ /325MG;50MG;40MG/ /N86237/002/ /MAR/23,/1984/

	BUTALBITAL, ASPIRIN AND CAFFEINE		
AB	CHELSEA	325MG;50MG;40MG	N86237 002 MAR 23, 1984

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL
ORPHENGESIC
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/

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
/LOMOXATE/
/AA/ /CORD/ /0.025MG;2.5MG/ /N85311/002/
LOMOX
AA CORD 0.025MG;2.5MG N85311 002

BACLOFEN

TABLET; ORAL
BACLOFEN
/AB/ /PHARM/BASICS/ /10MG/ /N71260/001/ /MAY/06,/1988/
/AB/ /20MG/ /N71261/001/ /MAY/06,/1988/

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

BENAZEPRIL HYDROCHLORIDE

TABLET; ORAL
LOTENSIN
CIBA

EQ 5MG BASE¤	N19851 001	JUN 25, 1991
EQ 10MG BASE¤	N19851 002	JUN 25, 1991
EQ 20MG BASE¤	N19851 003	JUN 25, 1991
EQ 40MG BASE¤	N19851 004	JUN 25, 1991

BENZTROPINE MESYLATE

TABLET; ORAL
BENZTROPINE MESYLATE
>DLT>/AA/ /PHARM/BASICS/ /0.5MG/ /N89211/001/ /JUN/14,/1988/
>DLT> /1MG/ /N89212/001/ /JUN/14,/1988/
>DLT>/AA/ /2MG/ /N89213/001/ /JUN/14,/1988/
>DLT>
>DLT>/AA/
>DLT>
>ADD> B* PHARM BASICS 0.5MG N89211 001 JUN 14, 1988
>ADD>
>ADD> B* 1MG N89212 001 JUN 14, 1988
>ADD>
>ADD> B* 2MG N89213 001 JUN 14, 1988
>ADD>

>ADD> BERACTANT

>ADD> SUSPENSION; INTRATRACHEAL
>ADD> SURVANTA
>ADD> ROSS 25MG/ML* N20032 001
>ADD> JUL 01, 1991

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/
		/APR/16;/1986/
@ ABBOTT	800MG/100ML	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/
		/SEP/26;/1984/
@ PHARM BASICS	4MG/5ML;25MG/5ML	N88687 001
		SEP 26, 1984

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;/	/N18725/001/
	/600MG/100ML/	/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

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

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL

	SINEMET CR			
	MSD	50MG;200MG¤	N19856 001 MAY 30, 1991	

CARISOPRODOL

TABLET; ORAL

/AA/	CARISOPRODOL /BOLAR/	/350MG/	/N85433/001/	
	∂ BOLAR	350MG	N85433 001	

CEFADROXIL

CAPSULE; ORAL

/AB/	ULTRACEF /BRISTOL/	/EQ 500MG BASE/	/N62378/001/ /MAR/16,/1982/	
	∂ BRISTOL	EQ 500MG BASE	N62378 001 MAR 16, 1982	

POWDER FOR RECONSTITUTION; ORAL

/AB/	ULTRACEF /BRISTOL/	/EQ 125MG BASE/5ML/	/N62376/001/ /MAR/16,/1982/	
/AB/		/EQ 250MG BASE/5ML/	/N62376/002/ /MAR/16,/1982/	
/AB/		/EQ 500MG BASE/5ML/	/N62376/003/ /MAR/16,/1982/	
	∂ BRISTOL	EQ 125MG BASE/5ML	N62376 001 MAR 16, 1982	
	∂	EQ 250MG BASE/5ML	N62376 002 MAR 16, 1982	
	∂	EQ 500MG BASE/5ML	N62376 003 MAR 16, 1982	

CEFADROXIL

TABLET; ORAL

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

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

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

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL

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

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION

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

CEPHRADINE

CAPSULE; ORAL

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

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

/AB/	/SUPERPHARM/	/5MG/	/N88987/001/ /APR 25, 1985/	
/AB/		/10MG/	/N88986/001/ /APR 25, 1985/	
/AB/		/25MG/	/N88988/001/ /APR 25, 1985/	
	∂ SUPERPHARM	5MG	N88987 001 APR 25, 1985	
	∂	10MG	N88986 001 APR 25, 1985	
	∂	25MG	N88988 001 APR 25, 1985	

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION

CHLORPHENIRAMINE MALEATE

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

TABLET; ORAL

> DLT >	/ANTAGONATE/			
> DLT >	/AA/ /MILES/	/4MG/	/N83381/001/	
> ADD >	∂ MILES	4MG	N83381 001	
	CHLORPHENIRAMINE MALEATE			
	/AA/ /VITARINE/	/4MG/	/N85837/001/	
	∂ VITARINE	4MG	N85837 001	
	/PHENETRON/			
	/AA/ /LANNETT/	/4MG/	/N80846/001/	
	∂ LANNETT	4MG	N80846 001	

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

CHLORPROMAZINE HCL

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

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

CHLORPROMAZINE HCL

AP	STERIS	25MG/ML	N85591 001	

CHLORPROPAMIDE

TABLET; ORAL

CHLORPROPAMIDE

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

CHLORTHALIDONE

TABLET; ORAL

CHLORTHALIDONE

/AB/	/SUPERPHARM/	/25MG/	/N87473/001/ /FEB 09, 1983/	
	∂ SUPERPHARM	25MG	N87473 001 FEB 09, 1983	

CHLORZOXAZONE

TABLET; ORAL

CHLORZOXAZONE

> ADD >	AA	DANBURY	500MG‡	N81019 001 JUL 29, 1991
> ADD >				

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HCL

> ADD >	AB	DANBURY	EQ 75MG BASE‡	N63082 001 JUL 31, 1991
> ADD >				
> ADD >	AB		EQ 150MG BASE‡	N63083 001 JUL 31, 1991
> ADD >				

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

>ADD >	AB	NOVOPHARM	500MG	N72600 001
				JUL 25, 1991
>ADD >				

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	

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
CODAVITE

/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/
/AB/	/LYPHOMED/	/0.03MG/ML/	/N80510/003/
/AB/		/0.1MG/ML/	/N80510/001/
/AB/		/1MG/ML/	/N80510/002/
a	LYPHONED	0.03MG/ML	N80510 003
a		0.1MG/ML	N80510 001
a		1MG/ML	N80510 002
AP	STERIS	0.1MG/ML	N83120 001
AP		1MG/ML	N83120 002

/DODECAHIN/

/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 HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
CYCLOPENTOLATE HCL

AT	STERIS	1%*	N89162 001 JAN 24, 1991

DANAZOL

CAPSULE; ORAL
DANAZOL

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

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPRAMINE HCL

/AB/	/PHARM/BASICS/	/25MG/	/N71864/001/ /SEP/09/1987/
/AB/		/50MG/	/N71865/001/ /SEP/09/1987/
/AB/		/75MG/	/N71866/001/ /SEP/09/1987/
/AB/		/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%	N17922 001
		/0.01%/	/N17922/001/

DEXAMETHASONE

TABLET; ORAL
DEXAMETHASONE

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

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION
/DEXACEN-4/

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

DEXAMETHASONE SODIUM PHOSPHATE

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

SOLUTION/DROPS; OPHTHALMIC
DEXAIR

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

DEXTROSE

INJECTABLE; INJECTION
DEXTROSE 10% IN PLASTIC CONTAINER

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

DEXTROSE 50% IN PLASTIC CONTAINER

> ADD >	AP	BAXTER	50GM/100ML*	N20047 001
> ADD >				JUL 02, 1991

DEXTROSE 60% IN PLASTIC CONTAINER

> ADD >	AP	BAXTER	60GM/100ML*	N20047 002
> ADD >				JUL 02, 1991

DEXTROSE 70% IN PLASTIC CONTAINER

> ADD >	AP	BAXTER	70GM/100ML*	N20047 003
> ADD >				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/
	@ CUTTER	5GM/100ML;200MG/100ML	N18399 001

DEXTROSE 5% AND SODIUM CHLORIDE 0,3% IN PLASTIC CONTAINER

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

DEXTROSE 5% AND SODIUM CHLORIDE 0,45% IN PLASTIC CONTAINER

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

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION
/DIATRIZOATE-60/

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

DIATRIZOATE SODIUM

INJECTABLE; INJECTION
/MD-50/

/AP/	/MALLINCKRODT/	/50%/	/N87075/001/
	@ 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

DIAZEPAM

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

DIMENHYDRINATE

INJECTABLE; INJECTION
DIMENHYDRINATE

AP	STERIS	50MG/ML	N83531 001

TABLET; ORAL
DIMENHYDRINATE

AA	CHELSEA	50MG	N85166 001
	@ CHELSEA	50MG	

DIPHENHYDRAMINE HYDROCHLORIDE

ELIXIR; ORAL
DIPHENHYDRAMINE HCL

AA	KV	12.5MG/5ML	N85621 001
	@ KV	12.5MG/5ML	

INJECTABLE; INJECTION
DIPHENHYDRAMINE HCL

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

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOPAMINE HCL

AP	SOLOPAK	40MG/ML	N70011 001 AUG 29, 1985
	@ SOLOPAK	40MG/ML	

DOXACURIUM CHLORIDE

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

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
DOXEPIN HCL

/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/	/N88966/001/ OCT/06,/1985/

DROPERIDOL

INJECTABLE; INJECTION
DROPERIDOL

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

EDETATE DISODIUM

INJECTABLE; INJECTION
DISODIUM EDETATE

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

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL W/ EPINEPHRINE

/3/LEMMON/	/0.01MG/ML;1%/	/N85463/001/
∂ STERIS	0.01MG/ML;1%	N85463 001

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL W/ EPINEPHRINE
/ə/ /LEMMON/ /0.01MG/ML;1%/ /N85463/001/
ə STERIS 0.01MG/ML;1% N85463 001

ERGOLOID MESYLATES

TABLET; SUBLINGUAL
/BRISTOL-ST/
/AA/ /BRISTOL/MYERS/SQUIBB/1MG/ /N85020/002/
ə BRISTOL MYERS SQUIBB 1MG N85020 002
ERGOLOID MESYLATES
/AA/ /KV/ /0.5MG/ /N86265/001/
/AA/ /1MG/ /N86264/001/
ə KV 0.5MG N86265 001
ə 1MG N86264 001

ERYTHROMYCIN

SOLUTION; TOPICAL
ERYTHROMYCIN
AT CLAY PARK 2% N63038 001
JAN 11, 1991
/AT/ /LILLY/ /2%/ /N50532/001/
ə LILLY 2% N50532 001

ESTROGENS, CONJUGATED

TABLET; ORAL
CONJUGATED ESTROGENS
/BP/ /CHELSEA/ /1.25MG/ /N85801/001/
/BP/ /2.5MG/ /N85826/001/
/ə/ /0.625MG/ /N85800/001/
/ə/COPD/ /0.3MG/ /N86078/001/
/ə/ /0.625MG/ /N83761/001/
/ə/ /1.25MG/ /N83763/001/
/ə/ /2.5MG/ /N83762/001/
/ə/DUPAMED/ /0.3MG/ /N86432/001/
/ə/ /0.625MG/ /N83272/001/
/ə/ /1.25MG/ /N83294/001/
/ə/ /2.5MG/ /N83295/001/
/ə/HEATHER/ /0.625MG/ /N83356/001/
/ə/ /1.25MG/ /N83360/001/
/ə/ /2.5MG/ /N84650/001/
/ə/PRIVATE/FORM/ /0.625MG/ /N83354/003/
/ə/ /1.25MG/ /N83592/001/
/ə/ /2.5MG/ /N85908/001/

ESTROGENS, CONJUGATED

TABLET; ORAL
CONJUGATED ESTROGENS
/BP/ /ZENITH/ /0.3MG/ /N88569/001/
/NOV/29/1984/
/BP/ /0.625MG/ /N83373/001/
/BP/ /1.25MG/ /N83601/001/
/BP/ /2.5MG/ /N83602/001/
ə ZENITH 0.3MG N88569 001
NOV 29, 1984
ə 0.625MG N83373 001
ə 1.25MG N83601 001
ə 2.5MG N83602 001

ESTROPIPATE

TABLET; ORAL
OGEN
AB ABBOTT 0.75MG N83220 001
> ADD > AB 1.5MG N83220 002
ORTHO-EST
AB JOHNSON RW 0.75MG‡ N89567 001
FEB 27, 1991
> ADD > AB 1.5MG‡ N89582 001
> ADD > JUL 17, 1991

ETODOLAC

CAPSULE; ORAL
LODINE
WYETH AYERST 200MG‡ N18922 002
JAN 31, 1991
300MG‡ N18922 003
JAN 31, 1991

> ADD > FELODIPINE

> ADD > TABLET, EXTENDED RELEASE; ORAL
> ADD > PLENDIL
> ADD > MSD 5MG‡ N19834 001
> ADD > JUL 26, 1991
> ADD > 10MG‡ N19834 002
> ADD > JUL 26, 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/	/VASCODERM/ /TARO/	/0.05%/	/N19117/001/ /JUN/26,/1984/
/AB/	/VASCODERM E/ /TICAN/	/0.05%/	/N72494/001/ /JAN/19,/1989/

FLUOROURACIL

INJECTABLE; INJECTION
ADRUCIL

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

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL

>ADD> AB	GENEVA	15MG¤	N71716 001 JUL 31, 1991
>ADD> AB		30MG¤	N71717 001 JUL 31, 1991
>ADD> /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

FUROSEMIDE

/AP/	/SOLOPAK/	/10MG/ML/	/N70023/001/ /FEB/05,/1986/
	@ SOLOPAK	10MG/ML	N70023 001 FEB 05, 1986

GALLIUM NITRATE

INJECTABLE; INJECTION

GANITE

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

GLUTETHIMIDE

TABLET; ORAL

/DORIDEN/

/AA/	/RHONE/POULENC/RORER/	/250MG/	/N09519/002/
/AA/		/500MG/	/N09519/005/
	@ RHONE POULENC RORER	250MG	N09519 002
	@	500MG	N09519 005

GLUTETHIMIDE

/AA/	/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 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/
	@ 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

/AP/	/SOLOPAK/	/100 UNITS/ML/	/N87959/001/ /APR/20,/1983/
	@ SOLOPAK	100 UNITS/ML	N87959 001 APR 20, 1983
	/HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5%/		
/AP/	/ABBOTT/	/10,000 UNITS/100ML/	/N18911/006/ /JAN/30,/1985/
	@ ABBOTT	10,000 UNITS/100ML	N18911 006 JAN 30, 1985

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDRALAZINE HCL

/AP/	/SOLOPAK/	/20MG/ML/	/N88517/001/ /AUG/22,/1985/
/AP/		/20MG/ML/	/N88518/001/ /APR/20,/1984/
	@ SOLOPAK	20MG/ML	N88517 001 AUG 22, 1985
	@	20MG/ML	N88518 001 APR 20, 1984

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

	HYDRALAZINE HCL			
/AA/	/CHELSEA/	/25MG/	/N085532/002/ /MAY/24,/1982/	
/AA/		/50MG/	/N085533/002/ /MAY/25,/1982/	
	@ CHELSEA	25MG	N85532 002 MAY 24, 1982	
	@	50MG	N85533 002 MAY 25, 1982	

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

	HYDROCHLOROTHIAZIDE W/ RESERPINE			
/BP/	/BOLAR/	/50MG;0.125MG/	/N083666/001/	
	@ BOLAR	50MG;0.125MG	N83666 001	
	RESERPINE AND HYDROCHLOROTHIAZIDE			
/BP/	/CORD/	/50MG;0.125MG/	/N088200/001/ /JAN/31,/1984/	
	@ CORD	50MG;0.125MG	N88200 001 JAN 31, 1984	

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL

	SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE			
/AB/	/SUPERPHARM/	/25MG;25MG/	/N089137/001/ /AUG/26,/1985/	
	@ SUPERPHARM	25MG;25MG	N89137 001 AUG 26, 1985	

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

	DYAZIDE			
>ADD> AB	SKF	25MG;50MG	N16042 002	
>ADD>	TRIAMTERENE AND HYDROCHLOROTHIAZIDE			
>ADD> AB	GENEVA	25MG;50MG*	N73191 001 JUL 31, 1991	
>ADD>				

TABLET; ORAL

	TRIAMTERENE AND HYDROCHLOROTHIAZIDE			
B*	PAR	50MG;75MG	N72337 001 MAY 11, 1988	
/BX/		/50MG;75MG/	/N072337/001/ /MAY/11,/1988/	

HYDROCORTISONE

CREAM; TOPICAL

	/H-CORT/			
/AT/	/PHARMS/ASSOC/	/0.5%/	/N086823/001/	
	@ PHARMS ASSOC	0.5%	N86823 001	
	HYDROCORTISONE			
/AT/	/WHITE/TOWNE/PAULSEN/	/1%/	/N080496/002/	
	@ WHITE TOWNE PAULSEN	1%	N80496 002	

LOTION;TOPICAL

	/TEXACORT/		
/AT/	/COOPERCARE/	/1%/	/N080425/001/

SOLUTION; TOPICAL

	PENECORT		
AT	HERBERT	1%	N88214 001 JUN 06, 1984
	TEXACORT		
AT	GENDERM	1%	N80425 001

TABLET; ORAL

	HYDROCORTISONE			
/BP/	/PUREPAC/	/20MG/	/N080395/001/	
	@ PUREPAC	20MG	N80395 001	

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC

	OTOCORT			
/AT/	/LEMMON/	/1%;EQ 3.5MG BASE/ML;/ /10,000 UNITS/ML/	/N060730/002/	
AT	STERIS	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N60730 002	

SUSPENSION; OTIC

	OTOCORT			
/AT/	/LEMMON/	/1%;EQ 3.5MG BASE/ML;/ /10,000 UNITS/ML/	/N062521/001/ /JUL/11,/1985/	
AT	STERIS	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62521 001 JUL 11, 1985	

HYDROCORTISONE ACETATE

INJECTABLE; INJECTION

	HYDROCORTISONE ACETATE			
/BP/ /BP/	/LEMMON/	/25MG/ML/ /50MG/ML/	/N083759/001/ /N083759/002/	

HYDROCORTISONE ACETATE

HYDROXOCOBALAMIN

TABLET; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

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

HYDROCORTISONE ACETATE

INJECTABLE; INJECTION
HYDROCORTISONE ACETATE

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

HYDROCORTISONE ACETATE

INJECTABLE; INJECTION
HYDROCORTISONE ACETATE

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

HYDROCORTISONE BUTYRATE

/CREAM;/TOPICAL/
/LOCOID/
/OWEN/GALDERMA/ /0.1%/ /N18795/001/
/JAN/07,/1983/

@ OWEN GALDERMA	0.1%	N18795 001 JAN 07, 1983

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION
HYDROCORTISONE SODIUM SUCCINATE

/AP/	/LYPHOMED/	/EQ 100MG BASE/VIAL/	/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

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

HYDROXOCOBALAMIN

INJECTABLE; INJECTION
HYDROCOBALAMIN

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

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION
/DURA-LUTIN/

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

HYDROXYZINE PAMOATE

CAPSULE; ORAL

		HYDROXYZINE PAMOATE			
> ADD >	AB	DANBURY	EQ 25MG HCL¤	N81165 001	
				JUL 31, 1991	
> ADD >					
	AB	GENEVA	EQ 25MG HCL¤	N81127 001	
				JUN 28, 1991	
	AB		EQ 50MG HCL¤	N81128 001	
				JUN 28, 1991	
	AB		EQ 100MG HCL¤	N81129 001	
				JUN 28, 1991	
	/AB/	/SUPERPHARM/	/EQ 25MG HCL/	/N89031/001/	
				/JAN/02,/1987/	
	/AB/		/EQ 50MG HCL/	/N89032/001/	
				/JAN/02,/1987/	
	/AB/		/EQ 100MG HCL/	/N89033/001/	
				/JAN/02,/1987/	
		ə SUPERPHARM	EQ 25MG HCL	N89031 001	
				JAN 02, 1987	
		ə	EQ 50MG HCL	N89032 001	
				JAN 02, 1987	
		ə	EQ 100MG HCL	N89033 001	
				JAN 02, 1987	
	/AB/	/VANGARD/	/EQ 25MG HCL/	/N88392/001/	
				/SEP/19,/1983/	
		ə VANGARD	EQ 25MG HCL	N88392 001	
				SEP 19, 1983	

IBUPROFEN

TABLET; ORAL

		IBUPROFEN			
	/RX/	/SUPERPHARM/	/400MG/	/N70708/001/	
				/APR/25,/1986/	

INDOMETHACIN

CAPSULE; ORAL

		INDOMETHACIN			
> ADD >	AB	DANBURY	25MG¤	N72996 001	
				JUL 31, 1991	
> ADD >					
> ADD >	AB		50MG¤	N72997 001	
				JUL 31, 1991	
> ADD >					

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	

AEROSOL, METERED; INHALATION

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

ISONIAZID

SYRUP; ORAL

>DLT>	/RIMIFON/		
>DLT>/AA/	/ROCHE/	/50MG/5ML/	/N08420/001/
>ADD>	@ ROCHE	50MG/5ML	N08420 001

TABLET; ORAL

ISONIAZID

AA	ZENITH	300MG	N83610 001

KETOCONAZOLE

/SUSPENSION;ORAL/

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

LEVONORGESTREL

IMPLANT; IMPLANTATION

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

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL

>DLT>/AP/	/CUTTER/	/1%/	/N80414/001/
>DLT>/AP/		/2%/	/N80414/002/
>ADD>	@ CUTTER	1%	N80414 001
>ADD>	@	2%	N80414 002
	/S/LEMMON/	/1%/	/N83627/001/
	/S/	/2%/	/N83627/002/
	@ STERIS	1%	N83627 001
	@	2%	N83627 002

SOLUTION; TOPICAL

LIDOCAINE HCL

/AT/	/PACO/	/4%/	/N89688/001/
	@ PACO	4%	/JUN/30,/1989/ 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/
B*	PHARM BASICS	300MG	/FEB/01,/1989/ N72542 001 FEB 01, 1989

LORAZEPAM

CONCENTRATE; ORAL

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

TABLET; ORAL

LORAZEPAM

/BX/	/AM/THERAP/	/0.5MG/	/N70727/001/
/BX/		/1MG/	/MAR/07,/1986/
/BX/		/2MG/	/N70728/001/
	@ AM THERAP	0.5MG	/MAR/07,/1986/
	@	1MG	/N70729/001/
	@	2MG	/MAR/07,/1986/
AB	MUTUAL PHARM	0.5MG*	N70727 001 MAR 07, 1986
AB		1MG*	N70728 001 MAR 07, 1986
AB		2MG*	N70729 001 MAR 07, 1986
/AB/	/PHARM/BASICS/	/1MG/	N72553 001 MAR 29, 1991
/AB/		/2MG/	N72554 001 MAR 29, 1991
B*	PHARM BASICS	1MG	N72555 001 MAR 29, 1991
B*		2MG	/N70539/001/
			/DEC/22,/1986/
			/N70540/001/
			/DEC/22,/1986/
			N70539 001 DEC 22, 1986
			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/	
	ə CUTTER	10GM/100ML	N16472 002	
	MANNITOL 15%			
/AP/	/CUTTER/	/15GM/100ML/	/N16472/005/	
	ə CUTTER	15GM/100ML	N16472 005	
	MANNITOL 20%			
/AP/	/CUTTER/	/20GM/100ML/	/N16472/004/	
	ə CUTTER	20GM/100ML	N16472 004	

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

METAPROTERENOL SULFATE

TABLET; ORAL

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

METHADONE HYDROCHLORIDE

/TABLET;/EFFERVESCENT;/ORAL/
/WESTWOOD/
/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

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

>DLT>/AB/	/ROXANE/	/125MG/	/N70192/001/
>DLT>			/APR/25,/1986/
>DLT>/AB/		/250MG/	/N70193/001/
>DLT>			/APR/25,/1986/
>DLT>/AB/		/500MG/	/N70194/001/
>DLT>			/APR/25,/1986/
>ADD>	@ ROXANE	125MG	N70192 001
>ADD>			APR 25, 1986
>ADD>	@	250MG	N70193 001
>ADD>			APR 25, 1986
>ADD>	@	500MG	N70194 001
>ADD>			APR 25, 1986

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION
METHYLPREDNISOLONE ACETATE

/@/LEMMON/		/20MG/ML/	/N87248/001/
/@/		/40MG/ML/	/N85374/001/
/@/		/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/
>DLT >/AB/	/PHARM/BASICS/	/EQ 10MG BASE/	/N70339/001/ /JUL/29,/1985/
>DLT >			N70339 001 JUL 29, 1985
>ADD > B*	PHARM BASICS	EQ 10MG BASE	N70598 001 FEB 02, 1987
>ADD > AB	SCHERING	EQ 10MG BASE	

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

METRONIDAZOLE

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

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

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

MORPHINE SULFATE

INJECTABLE; INJECTION
INFUMORPH
>_ADD_> ELKINS SINN 10MG/ML* N18565 003 JUL 19, 1991
>_ADD_> 25MG/ML* N18565 004 JUL 19, 1991
>_ADD_>
>_ADD_>

NALOXONE HYDROCHLORIDE

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

NANDROLONE DECANOATE

INJECTABLE; INJECTION
NANDROLONE DECANOATE
/AO/ /LEMMON/ /50MG/ML/ /N87538/001/ /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/ /MAY/08/1987/
@ LYPHOMED 5MG/ML N71203 001 MAY 08, 1987
/AP/ /SOLOPAK/ /5MG/ML/ /N70634/001/ /JUN/19/1986/
@ SOLOPAK 5MG/ML N70634 001 JUN 19, 1986

NITROL
/AP/ /KREMERS/URBAN/ /0.8MG/ML/ /N18774/001/ /JAN/19/1983/
@ RORER 0.8MG/ML N18774 001 JAN 19, 1983

NITROSTAT
/AP/ /PARKE/DAVIS/ /0.8MG/ML/ /N18588/001/
PARKE DAVIS 0.8MG/ML N18588 001

NORFLOXACIN

SOLUTION/DROPS; OPHTHALMIC
CHIBROXIN
MSD 0.3%* N19757 001 JUN 17, 1991

NYSTATIN

CREAM; TOPICAL
>_DLT_> /CANNEX/
>_DLT_>/AT/ /MILES/ /100,000 UNITS/GM/ /N61810/001/
>_ADD_> @ MILES 100,000 UNITS/GM N61810 001

ONDANSETRON HYDROCHLORIDE

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

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/
ə 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/

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE; ORAL
/SPRX-105/
/BC/ /SOLVAY/ — /105MG/ — /N88024/001/ /DEC/22,/1982/
ə SOLVAY — 105MG — N88024 001 DEC 22, 1982

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

PHENYTOIN SODIUM

INJECTABLE; INJECTION
PHENYTOIN SODIUM
/SOLOPAK/ — /50MG/ML/ — /N88521/001/ /DEC/18,/1984/
ə 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/
ə BARRE — EQ 500MG BASE/5ML — N80774 001

> DLT > /AP/
> DLT >
> ADD >
> ADD >

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

>ADD > AA	GOLDLINE LABORATORIE	236GM/BOT;2.97GM/BOT;6.74GM/BOT; 5.86GM/BOT;22.74GM/BOT	N72319 001 DEC 23, 1988	
>DLT >/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

>DLT >/AP/	/CUTTER/	/1MEQ/ML/	/N80195/002/	
>DLT >/AP/		/2MEQ/ML/	/N80195/001/	
>DLT >/AP/		/3MEQ/ML/	/N80195/003/	
>ADD >	@ CUTTER	1MEQ/ML	N80195 002	
>ADD >	@	2MEQ/ML	N80195 001	
>ADD >	@	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-DONE/

>DLT >	/MILES/	/5MG/	/N80293/001/
>DLT > /BX/		/5MG/	/N80293/001/
>ADD >	@ MILES	5MG	N80293 001
	PREDNICEN-M		
>ADD > AB	CENTRAL PHARMS	5MG	N84655 001
>DLT > /BX/		/5MG/	/N84655/001/
	PREDNISONE		
/BX/	/AM/THERAP/	/5MG/	/N89381/001/ /NOV/06,/1986/
/BX/		/10MG/	/N89388/001/ /NOV/06,/1986/
/BX/		/20MG/	/N89389/001/ /NOV/06,/1986/
	@ AM THERAP	5MG	N89387 001 NOV 06, 1986
	@	10MG	N89388 001 NOV 06, 1986
	@	20MG	N89389 001 NOV 06, 1986

PREDNISONE

TABLET; ORAL

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

PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

	PROCAINE HCL		
>_DLT_>/AP/	/CUTTER/	/1%/	/N80415/001/
>_DLT_>/AP/		/2%/	/N80415/002/
>_ADD_>	∂ CUTTER	1%	N80415 001
>_ADD_>	∂	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/	/A65548/001/	
∂ PHARM BASICS	EQ 10MG BASE/ML	N88598 001 OCT 25, 1984	

SYRUP; ORAL

	COMPAZINE		
/AA/	/SKF/	/EQ 5MG BASE/5ML/	/N11188/001/
	SKF	EQ 5MG BASE/5ML	N11188 001
	PROCHLORPERAZINE EDISYLATE		
/AA/ /PHARM BASICS/		/EQ 5MG BASE/5ML/	/A65547/001/
∂ PHARM BASICS		EQ 5MG BASE/5ML	N88597 001 OCT 25, 1984

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

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

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

TABLET; ORAL

	PROPRANOLOL HCL		
>_DLT_>/AB/	/DURAMED/	/40MG/	/N70308/001/ /SEP/09;/1985/
>_DLT_>		/60MG/	/N70309/001/ /OCT/01;/1986/
>_DLT_>/AB/		/80MG/	/N70310/001/ /SEP/09;/1985/
>_DLT_>		40MG	N70308 001 SEP 09, 1985
>_DLT_>/AB/		60MG	N70309 001 OCT 01, 1986
>_DLT_>		80MG	N70310 001 SEP 09, 1985
>_ADD_> B*	DURAMED		
>_ADD_>			
>_ADD_> B*			
>_ADD_>			
>_ADD_> B*			
>_ADD_>			

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

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

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/
	ə CHELSEA	25MG	N85231 001
/AA/	/RICHLYN/	/25MG/	/N80808/001/
	RICHLYN	25MG	N80808 001

QUINESTROL

TABLET; ORAL

ESTROVIS

PARKE DAVIS	0.1MG	N16768 002

QUINIDINE GLUCONATE

/TABLET;/ORAL/

/QUINACT/

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

TABLET, EXTENDED RELEASE; ORAL

QUINIDINE GLUCONATE

/AB/	/ROXANE/	/324MG/	/N88431/001/ /JAN/06,/1984/
	ə ROXANE	324MG	N88431 001 JAN 06, 1984

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

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

QUINORA

/AB/	/KEY/PHARMS/	/200MG/	/N83576/001/
	ə 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/
ə	WHITE TOWNE PAULSEN	0.1MG	N80723 001
ə		0.25MG	N80723 002
		/1MG/	/N80723/003/
ə		1MG	N80723 003

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION
RITODRINE HCL

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

RITODRINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

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

SECOBARBITAL SODIUM

CAPSULE; ORAL
SECOBARBITAL SODIUM

/AA/	/WYETH/AYERST/	/100MG/	/N86390/001/
ə	WYETH AYERST	100MG	N86390 001

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL
SELENIUM SULFIDE

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

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
SODIUM NITROPRUSSIDE

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

SUCCIMER

CAPSULE; ORAL
CHEMET
MCNEIL

100MG¤	N19998 002	JAN 30, 1991

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION
COTRIM
STERIS

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

SUSPENSION; ORAL
COTRIM PEDIATRIC

>ADD> >ADD> AB	LEMMON	200MG/5ML;40MG/5ML	N70028 001 OCT 29, 1985
>ADD> >DLT> >DLT> /AB/ >DLT>	/SULFAMETHOXAZOLE AND TRIMETHOPRIM/ /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

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL
SELENIUM SULFIDE

AT	CLAY PARK	2.5%	N89996 001 JAN 10, 1991

SULINDAC

TABLET; ORAL
SULINDAC

AB	MUTUAL PHARM	150MG	N72050 001 APR 17, 1991
AB		200MG	N72051 001 APR 17, 1991
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 RN	0.8%	N19964 001 FEB 21, 1991

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION
TESTOSTERONE CYPIONATE

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

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
TESTOSTERONE ENANTHATE

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

TESTOSTERONE PROPIONATE

INJECTABLE; INJECTION
TESTOSTERONE PROPIONATE

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

THEOPHYLLINE

CAPSULE; ORAL
/SCHERER/

/BX/	/FISONS/	/100MG/	/N87155/001/ /FEB 25, 1985/
/BX/		/200MG/	/N87155/002/ /FEB 25, 1985/
/BX/		/250MG/	/N87155/003/ /FEB 25, 1985/
	a FISONS	100MG	N87155 001 FEB 25, 1985
	a	200MG	N87155 002 FEB 25, 1985
	a	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/
	a SCHERER	100MG	N84731 002 NOV 07, 1986
	a	200MG	N84731 001 NOV 07, 1986
	a	250MG	N84731 003 NOV 07, 1986

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

> DLT >	/BC/	/THEOPHYL-SR/ JOHNSON RW	/125MG/	/N86480/001/ /FEB/08,/1985/	
		@ JOHNSON RW	125MG	N86480 001 FEB 08, 1985	
> DLT >	/BC/	/THEOPHYLLINE/ 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	
> DLT >	/BC/	THEOPHYLLINE-SR SCHERER	/300MG/	/N88255/001/ /JUN/12,/1986/	
		@ SCHERER	300MG	N88255 001 JUN 12, 1986	

TABLET; ORAL

/BD/	/THEOCLEAR-100/ CENTRAL PHARMS	/100MG/	/N85353/002/	
	@ CENTRAL PHARMS	100MG	N85353 002	
/BD/	/THEOCLEAR-200/ 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

> ADD >	AB	DANBURY	5MG¤	N72917 001 JUL 31, 1991
> ADD >				
> ADD >	AB		10MG¤	N72918 001 JUL 31, 1991
> ADD >				
> ADD >	AB		20MG¤	N72919 001 JUL 31, 1991
> ADD >				
	/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
> ADD >	AP		EQ 40MG BASE/ML¤	N63118 001 JUL 29, 1991
> ADD >				

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

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

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

	TRAZODONE HCL			
/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%/	/N17579/003/

TRIAMCINOLONE ACETONIDE

AEROSOL, METERED; NASAL

>ADD>	NASACORT			
>ADD>	RHONE POULENC RORER	55UGM/INH¤	N19798 001	
>ADD>			JUL 11, 1991	
>ADD>				

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/	
	ə PHARM BASICS	0.025%	N88094 001	
			SEP 01, 1983	
	ə	0.1%	N88095 001	
			SEP 01, 1983	
	ə	0.5%	N88096 001	
			SEP 01, 1983	

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

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

	ARISTOCORT A			
/AT/	/LEDERLE/	/0.5%/	/N88781/001/	
			/OCT/05,/1984/	
	ə LEDERLE	0.5%	N88781 001	
			OCT 05, 1984	
	/KENAG/			
/AT/	/NMC/	/0.1%/	/N87799/001/	
			/JUN/07,/1982/	
	TRIAMCINOLONE ACETONIDE		N87799 001	
AT	NMC	0.1%	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/	
	ə PHARM BASICS	0.025%	N88090 001	
			SEP 01, 1983	
	ə	0.1%	N88091 001	
			SEP 01, 1983	
	ə	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/	
	ə PHARM BASICS	EQ 2.5MG BASE/5ML	N88285 001	
			APR 11, 1985	

/GEL;/TOPICAL/
/ARISTOGEL/
/LEDERLE/
@ LEDERLE

/0.1%/
0.1%

/N83380/001/
N83380 001

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/
/AB/		/EQ 50MG BASE/	/N71284/001/ /DEC/08,/1987/
/AB/		/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

/VIT-DOM-A/

> DLT >				
> DLT >/AA/	/MILES/	/EQ 50,000 UNITS BASE/	/N80972/001/
> ADD >	@ MILES	EQ 50,000 UNITS BASE	N80972 001

XYLOSE

POWDER; ORAL

XYLO-PFAN

AA	ADRIA	25GM/BOT	N17605 001
		/25GM/BOT/	/N17605/001/

XYLOSE

AA	LYNE	25GM/BOT	N18856 001 MAR 26, 1987
		/25GM/BOT/	/N18856/001/ /MAR/26,/1987/

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
EXIDINE
/S/XTTRIUM/ /2%/ /N19422/001/ > ADD >
/DEC/17,/1985/ > ADD >
XTTRIUM 2% N19422 001 > ADD >
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

DOXYLAMINE SUCCINATE

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

HYDROCORTISONE

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

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 SUSP ISOPHANE BIOSYNTHETIC HUMAN

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

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

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

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

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

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) TRADE: NOT ESTABLISHED	FOR THE EX-VIVO PURGING OF LEUKEMIC CELLS FROM THE BONE MARROW OF NON-T CELL ACUTE LYMPHOCYTIC LEUKEMIA PATIENTS WHO ARE IN COMPLETE REMISSION.	IMMUNOGEN, INC
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (N901) TO CD56 POSITIVE CELLS TRADE: NOT ESTABLISHED	TREATMENT OF SMALL CELL LUNG CANCER.	IMMUNOGEN, INC
GENERIC: SARGRAMOSTIM TRADE: LEUKINE*/**	TREATMENT OF NEUTROPENIA ASSOICATED WITH BONE MARROW TRANSPLANTS IN PATIENTS WITH NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE AND ACUTE LYMPHOBLASTIC LEUKEMIA. [MAR 5, 1998]	IMMUNEX
GENERIC: THYMOSIN ALPHA-1 TRADE: NOT ESTABLISHED	ADJUNCTIVE TREATMENT OF CHRONIC ACTIVE HEPATITIS B.	ALPHA 1 BIOMEDICALS, INC

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: CALCIUM GLUCONATE GEL TRADE: H-F GEL	EMERGENCY TOPICAL TREATMENT OF HYDROGEN FLUORIDE (HYDROFLUORIC ACID) BURNS.	LTR PHARMACEUTICALS, INC
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
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

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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: 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
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

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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: 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

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

NO JULY 1991 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR IN VIVO BIOEQUIVALENCE STUDIES AND IN VITRO DISSOLUTION TESTING AVAILABLE FROM THE DIVISION OF BIOEQUIVALENCE, HFD-650, MPN-2 ROOM 278, 5600 FISHERS LANE, ROCKVILLE, MD 20857. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 11TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO JULY 1991 ADDITIONS

ANDA SUITABILITY PETITIONS

THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED AND REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANCH, HFA-305, ROOM 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 11TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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

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

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
	20089 001	ACYCLOVIR; ZOVIRAX	4199574	APR 22, 1997			
	20089 002	ACYCLOVIR; ZOVIRAX	4199574	APR 22, 1997			
						NCE	APR 05, 1996
						ODE	APR 05, 1998
	20057 003	ALGLUCERASE; CEREDASE	4508726	APR 02, 2002	U-46		
			4508726	APR 02, 2002	U-46		
	18276 001	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
	18276 002	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
	18276 003	ALPRAZOLAM; XANAX	3980789	SEP 14, 1993			
	18276 004	ALPRAZOLAM; XANAX				ODE	DEC 26, 1997
	19926 001	ALTRETAMINE; HEXALEN	4105783	OCT 26, 1995			
>ADD>	19155 001	AMMONIUM LACTATE; LAC-HYDRIN	[illegible]	[illegible]			
>DLT>	[illegible]	[illegible]	4072746	APR 23, 1998	U-7	NCE	JUL 31, 1994
	18700 001	AMRINONE LACTATE; INOCOR	4410520	OCT 18, 2000		NCE	JUN 25, 1996
	19851 001	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2000		NCE	JUN 25, 1996
	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	JUL 01, 1996
						NDF	MAY 30, 1994
>ADD>	20032 001	BERACTANT; SURVANTA	4900755	MAY 23, 2006			
>ADD>	19856 001	CARBIDOPA; SINEMET CR	4832957	MAY 23, 2006			
			3830827	AUG 20, 1991			
			4140707	AUG 25, 1998		I-58	JUL 05, 1994
>ADD>	19880 001	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998		I-58	JUL 05, 1994
>ADD>	19880 002	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998		I-58	JUL 05, 1994
>ADD>	19880 003	CARBOPLATIN; PARAPLATIN	3950333	APR 13, 1993		I-56	MAR 07, 1994
	17920 002	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
	17920 003	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
	17920 004	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
	17920 005	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
	17924 001	CIMETIDINE HYDROCHLORIDE; TAGAMET	4312860	NOV 23, 2001		NC	AUG 02, 1993
	20044 001	COLFOSCERIL PALMITATE; EXOSURF NEONATAL	[illegible]	[illegible]		NE	[illegible]
>ADD>	[illegible]	[illegible]	4252721	FEB 24, 1998		NCE	DEC 31, 1995
>DLT>	[illegible]	[illegible]	4605671	AUG 12, 2003			
	19849 001	DAPIPRAZOLE HYDROCHLORIDE; REV-EYES	4001331	JAN 04, 1996		NCE	DEC 29, 1994
	19082 001	DEZOCINE; DALGAN	3836670	SEP 09, 1991	U-48		
			4605671	AUG 12, 2003			
			4001331	JAN 04, 1996		NCE	DEC 29, 1994
	19082 002	DEZOCINE; DALGAN	3836670	SEP 09, 1991	U-48		
			4605671	AUG 12, 2003			
			4001331	JAN 04, 1996		NCE	DEC 29, 1994
	19082 003	DEZOCINE; DALGAN	3836670	SEP 09, 1991	U-48		

	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	4988731	JAN 29, 2008			
	19946 001	DOXACURIUM CHLORIDE; NUROMAX	4701460	OCT 20, 2004		NCE	MAR 07, 1996
	19668 001	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
	19668 002	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
	19668 003	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
	19668 004	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1997		NCE	NOV 02, 1995
>ADD>	19653 001	ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1996		NC	DEC 29, 1992
>DLT>	19653 001	ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1996		NC	DEC 29, 1992
>ADD>	19653 002	ETHINYL ESTRADIOL; ORTHO CYCLEN-28	4027019	MAY 31, 1996		NC	DEC 29, 1992
>DLT>	19653 002	ETHINYL ESTRADIOL; ORTHO CYCLEN-28	4027019	MAY 31, 1996		NC	DEC 29, 1992
	18922 002	ETODOLAC; LODINE	4076831	FEB 28, 1995	U-45		
	18922 003	ETODOLAC; LODINE	3939178	FEB 17, 1993		NCE	JAN 31, 1996
			4076831	FEB 28, 1995	U-45		
>ADD>	19834 001	FELODIPINE; PLENDIL	3939178	FEB 17, 1993		NCE	JAN 31, 1996
>ADD>	19834 002	FELODIPINE; PLENDIL	4264611	APR 28, 1998		NCE	JUL 26, 1996
	19949 001	FLUCONAZOLE; DIFLUCAN	4262611	APR 28, 1998		NCE	JUL 26, 1996
	19949 002	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		NCE	JAN 29, 1995
	19949 003	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		NCE	JAN 29, 1995
	19950 001	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		NCE	JAN 29, 1995
	20038 001	FLUDARABINE PHOSPHATE; FLUDARA	4404216	OCT 16, 2003		NCE	JAN 29, 1995
			4357324	NOV 02, 1999		NCE	APR 18, 1996
	20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC				ODE	APR 18, 1998
	19915 002	FOSINOPRIL SODIUM; MONOPRIL	4314081	FEB 02, 2001		NCE	DEC 29, 1992
			4384123	MAY 17, 2000			
	19915 003	FOSINOPRIL SODIUM; MONOPRIL	4337201	JUN 29, 1999		NCE	MAY 16, 1996
			4384123	MAY 17, 2000			
>ADD>	19961 002	GALLIUM NITRATE; GANITE	4337201	JUN 29, 1999		NCE	MAY 16, 1996
			4529593	JUL 16, 2002	U-49	NCE	JAN 17, 1996
	19967 001	HALOBETASOL PROPIONATE; ULTRAVATE				ODE	JAN 17, 1998
	19968 001	HALOBETASOL PROPIONATE; ULTRAVATE	4619921	OCT 28, 2003		NCE	DEC 17, 1995
>ADD>	19580 001	IOTROLAN; OSMOVIST	4619921	OCT 28, 2003		NCE	DEC 17, 1995
>DLT>	19580 001	IOTROLAN; OSMOVIST	4239747	DEC 16, 1999		NCE	DEC 07, 1994
>ADD>	19580 002	IOTROLAN; OSMOVIST	4239747	DEC 16, 2001		NCE	DEC 07, 1994
>DLT>	19580 002	IOTROLAN; OSMOVIST	4239747	DEC 16, 1999		NCE	DEC 07, 1994
			4239747	DEC 16, 2001		NCE	DEC 07, 1994

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19546 001	ISRADIPINE; DYNACIRC	4466972	AUG 21, 2001	U-3	NCE	DEC 20, 1995
	19546 002	ISRADIPINE; DYNACIRC	4466972	AUG 21, 2001	U-3	NCE	DEC 20, 1995
	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
	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>	19886 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1999		NCE	FEB 13, 1995
>DLT>	19886 001	NAFARELIN ACETATE; SYNAREL	A234871	NOV 18, 2001		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
>ADD>	19508 001	NIZATIDINE; AXID	4382090	MAY 03, 2000	U-18	I-59	JUL 26, 1994
>ADD>	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
>ADD>	19810 001	OMEPRAZOLE; PRILOSEC	4255431	MAR 10, 2000		I-57	JUN 12, 1994
>DLT>	19810 001	OMEPRAZOLE; PRILOSEC	A255431	MAR 10, 2002		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
	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
>ADD>	19627 001	PROPOFOL; DIPRIVAN	4056635	NOV 01, 1996		NCE	OCT 02, 1994
>DLT>	19627 001	PROPOFOL; DIPRIVAN	A056635	NOV 01, 1998		NCE	OCT 02, 1994

	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
	19998 002	SUCCIMER; CHEMET				NCE	JAN 30, 1996
						ODE	JAN 30, 1998
>ADD>	19981 001	TECHNETIUM TC-99M RED BLOOD CELL KIT; ULTRATAG				NP	JUN 10, 1994
	19785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4452774	JUN 05, 2001		NCE	DEC 21, 1995
	19785 002	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4452774	JUN 05, 2001		NCE	DEC 21, 1995
>ADD>	19614 002	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006		NDF	MAY 29, 1993
>DLT>	19614 002	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006		NDF	MAY 29, 1990

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