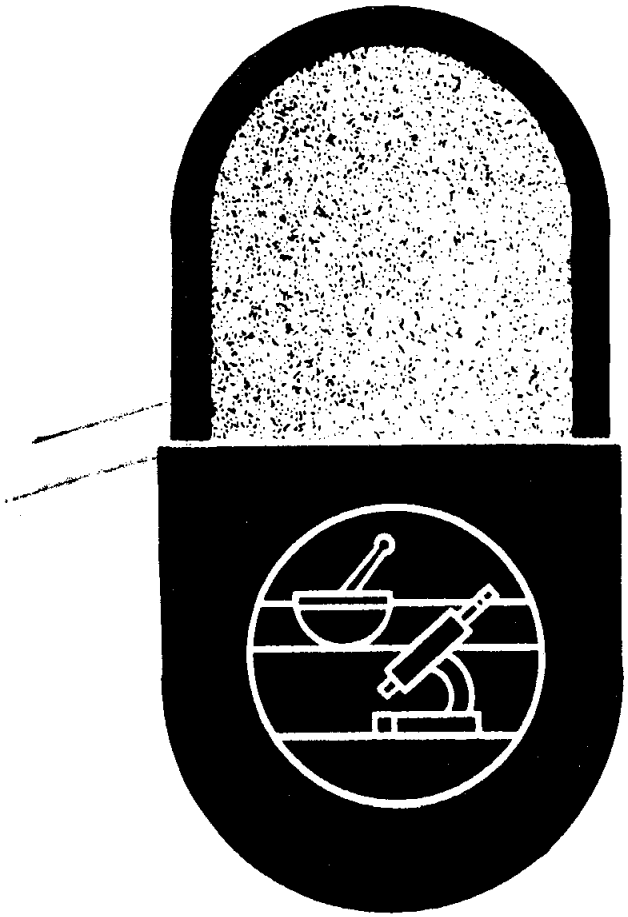
CUMULATIVE SUPPLEMENT 5
JAN'89-MAY'89



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

9TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR ORUG EVALUATION ANO RESEARCH
OFFICE OF MANAGEMENT

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

APPROVED DRUG PRODUCTS

with

THERAPEUTIC EQUIVALENCE EVALUATIONS

9TH EDITION

CUMULATIVE SUPPLEMENT 5

MAY 1989

CONTENTS

APPROVED DRUG PRODUCTS

with

THERAPEUTIC EQUIVALENCE EVALUATIONS

9th EDITION

CUMULATIVE SUPPLEMENT 5

MAY 1989

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, 9th 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 in the Division of Blood and Blood Products approved under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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 in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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 effective date for the approved drug product (the earliest date a product may be marketed) appears, when appropriate, to the left of the approval date.

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, Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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, Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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 will remain in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act List and the Patent and Exclusivity Data will be dropped in subsequent Cumulative Supplements.

Products discontinued from marketing or products which have had their approval withdrawn for other than safety or effectiveness reasons, will be flagged in this Cumulative Supplement with the " ə " symbol to designate their non-marketed status. All products having a " ə " symbol in the 12th Cumulative Supplement of the 9th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 9th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

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

1.3 APPLICANT (NAME) CHANGES

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

APPLICANT (NAME) CHANGES

FORMER APPLICANT (NAME)	NEW APPLICANT (NAME)	NEW ABBREVIATED NAME
SCHERING CORP	SCHERING CORP SUB SCHERING PLOUGH CORP	SCHERING

1.4 CORRECTIONS TO THE 9TH EDITION

a. The locator tabs for the "OTC Drug Product List" and the "Product Name Index Listed by Applicant" were not printed within the List.

b. The locator tabs for the "Drug Products Which Must Demonstrate in vivo Bioavailability Only If Product Fails to Achieve Adequate Dissolution," "ANDA Suitability Petitions," "Product Name Index," and "Product Name Index Listed by Applicant" were placed incorrectly within the List.

c. On page 3-374, "ANDA Suitability Petitions," the heading "Petitions Approved" should read "Petitions Denied."

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1988) 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 1988	MAR 1989	JUN 1989	SEP 1989
DRUG PRODUCTS LISTED	10091	10157		
SINGLE SOURCE	1983 (19.7%)	1993 (19.6%)		
MULTISOURCE	8108 (80.3%)	8164 (80.4%)		
THERAPEUTICALLY EQUIVALENT	7242 (71.8%)	7321 (72.1%)		
NOT THERAPEUTICALLY EQUIVALENT	748 (7.4%)	726 (7.1%)		
EXCEPTIONS[1]	118 (1.1%)	117 (1.2%)		
NEW MOLECULAR ENTITIES APPROVED	--	3		
NUMBER OF APPLICANTS	374	393		

[1] Amino acid-containing products of varying composition (see Introduction, page 1-7 of the List).

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

	RDXANE LABS	500MG;15MG¤		N89511 001 APR 25, 1989
		500MG;30MG¤		N89512 001 APR 25, 1989
		500MG;60MG¤		N89513 001 APR 25, 1989

ACETAMINOPHEN W/ CODEINE PHOSPHATE

AA	PBI	300MG;30MG		N87919 001 JUN 22, 1982
AA		300MG;60MG		N87920 001 JUN 22, 1982
	∂ PBI	300MG;30MG		N87919 001 JUN 22, 1982
	∂	300MG;60MG		N87920 001 JUN 22, 1982
AA	WHITE TN PAULSN	300MG;30MG		N84360 001
AA		300MG;60MG		N85607 001
	∂ WHITE TN PAULSN	300MG;30MG		N84360 001
	∂	300MG;60MG		N85607 001

PAPA-DEINE #3

AA	VANGARD LABS	300MG;30MG		N88037 001 MAR 20, 1984
	∂ VANGARD LABS	300MG;30MG		N88037 001 MAR 20, 1984

PAPA-DEINE #4

AA	VANGARD LABS	300MG;60MG		N88715 001 MAR 20, 1984
	∂ VANGARD LABS	300MG;60MG		N88715 001 MAR 20, 1984

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

ALLAY

AA	LUCHEM PHARMS	500MG;5MG¤		N89907 001 JAN 13, 1989

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL

OXYCODONE AND ACETAMINOPHEN

> ADD >				
> ADD >	AA	HALSEY DRUG	500MG;5MG¤	N89994 001 MAY 04, 1989
> ADD >				

TYLOX

> ADD >	AA	MCNEIL PHARM	500MG;5MG	N88790 001 DEC 12, 1984
> ADD >				

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL

OXYCODONE 5/APAP 500

AA	DUPONT PHARMS	5DOMG;5MG		N85911 001

ROXICET 5/500

AA	ROXANE LABS	500MG;5MG¤		N89775 001 JAN 12, 1989

ACETAZOLAMIDE

TABLET; ORAL

ACETAZOLAMIDE

AA	VANGARD LABS	250MG		N87654 001 FEB 05, 1982
	∂ VANGARD LABS	250MG		N87654 001 FEB 05, 1982

ACETRIZOATE SODIUM

> DLT >		SOLUTION; INTRAUTERINE			
> DLT >		SALPIX			
> DLT >		ORTHO PHARM	53%		N09008 001
> ADD >		∂ ORTHO PHARM	53%		N09008 001

ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL

ACETYLCYSTEINE

> ADD >	AN	DUPONT CRI CARE	10%¤		N71364 001 MAY 01, 1989
> ADD >	AN		20%¤		N71365 001 MAY 01, 1989

MUCOMYST

> ADD >	AN	MEAD JOHNSON	10%		N13601 002
> ADD >	AN		20%		N13601 001

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

AB	AM THERPTCS	EQ 2MG BASE¤		N72449 001 DEC 05, 1989 : FEB 01, 1989
AB		EQ 4MG BASE¤		N72450 001 DEC 05, 1989 : FEB 01, 1989
AB	BIOCRAFT LABS	EQ 2MG BASE¤		N72619 001 DEC 05, 1989 : APR 07, 1989
AB		EQ 4MG BASE¤		N72620 001 DEC 05, 1989 : APR 07, 1989

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

AB	CORD LABS	EQ 2MG BASE¤	N72151 001
		DEC 05, 1989 : MAR 23, 1989	
AB		EQ 4MG BASE¤	N72152 001
		DEC 05, 1989 : MAR 23, 1989	
AB	MUTUAL PHARM	EQ 2MG BASE¤	N72636 001
		DEC 05, 1989 : FEB 01, 1989	
AB		EQ 4MG BASE¤	N72637 001
		DEC 05, 1989 : FEB 01, 1989	
AB	SIDMAK LABS	EQ 2MG BASE¤	N72316 001
		DEC 05, 1989 : JAN 30, 1989	
AB		EQ 4MG BASE¤	N72317 001
		DEC 05, 1989 : JAN 30, 1989	

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

TRAVASOL 2.75% IN DEXTROSE 10% IN PLASTIC CONTAINER		
BAXTER	2.75%;10GM/100ML	N19520 002
		SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 15% IN PLASTIC CONTAINER		
BAXTER	2.75%;15GM/100ML	N19520 003
		SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 20% IN PLASTIC CONTAINER		
BAXTER	2.75%;20GM/100ML	N19520 004
		SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 25% IN PLASTIC CONTAINER		
BAXTER	2.75%;25GM/100ML	N19520 005
		SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 5% IN PLASTIC CONTAINER		
BAXTER	2.75%;5GM/100ML	N19520 001
		SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 10% IN PLASTIC CONTAINER		
BAXTER	4.25%;10GM/100ML	N19520 007
		SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 15% IN PLASTIC CONTAINER		
BAXTER	4.25%;15GM/100ML	N19520 008
		SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 20% IN PLASTIC CONTAINER		
BAXTER	4.25%;20GM/100ML	N19520 009
		SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 25% IN PLASTIC CONTAINER		
BAXTER	4.25%;25GM/100ML	N19520 010
		SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 5% IN PLASTIC CONTAINER		
BAXTER	4.25%;5GM/100ML	N19520 006
		SEP 23, 1988

AMINOPHYLLINE

TABLET; ORAL

AMINOPHYLLINE

/BD/	/CORD LABS/	/100MG/	/N85261/001/
	ə CORD LABS	100MG	N85261 001

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE HCL

>DLT>	/AB/	/LEDERLE LABS/	/10MG/	/N87366/001/
>DLT>				/JAN/04,/1982/
>DLT>	/AB/		/25MG/	/N87367/001/
>DLT>				/MAY/03,/1982/
>DLT>	/AB/		/50MG/	/N87181/001/
>DLT>				/JAN/04,/1982/
>DLT>	/AB/		/75MG/	/N87369/001/
>DLT>				/JAN/04,/1982/
>DLT>	/AB/		/100MG/	/N87368/001/
>DLT>				/MAY/03,/1982/
>DLT>	/AB/		/150MG/	/N87370/001/
>DLT>				/JAN/04,/1982/
>ADD>		ə LEDERLE LABS	10MG	N87366 001
>ADD>				JAN 04, 1982
>ADD>		ə	25MG	N87367 001
>ADD>				MAY 03, 1982
>ADD>		ə	50MG	N87181 001
>ADD>				JAN 04, 1982
>ADD>		ə	75MG	N87369 001
>ADD>				JAN 04, 1982
>ADD>		ə	100MG	N87368 001
>ADD>				MAY 03, 1982
>ADD>		ə	150MG	N87370 001
>ADD>				JAN 04, 1982
	/AB/	/PBI/	/25MG/	/N87775/001/
				/FEB/10,/1982/
		ə PBI	25MG	N87775 001
				FEB 10, 1982
	/AB/	/ROXANE LABS/	/10MG/	/N86144/001/
	/AB/		/25MG/	/N86145/001/
	/AB/		/50MG/	/N86143/001/
	/AB/		/75MG/	/N86147/001/
	/AB/		/100MG/	/N86146/001/
	/AB/		/150MG/	/N86148/001/
		ə ROXANE LABS	10MG	N86144 001
		ə	25MG	N86145 001
		ə	50MG	N86143 001
		ə	75MG	N86147 001
		ə	100MG	N86146 001
		ə	150MG	N86148 001

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

/AB/	/VANGARD LABS/	/10MG/	/N87632 001/	/FEB 01, 1982/
/AB/		/25MG/	/N87570 001/	/FEB 08, 1982/
/AB/		/50MG/	/N87616 001/	/FEB 08, 1982/
/AB/		/75MG/	/N87617 001/	/FEB 05, 1982/
/AB/		/100MG/	/N87639 001/	/FEB 08, 1982/
	∂ VANGARD LABS	10MG	N87632 001	FEB 01, 1982
	∂	25MG	N87570 001	FEB 08, 1982
	∂	50MG	N87616 001	FEB 08, 1982
	∂	75MG	N87617 001	FEB 05, 1982
	∂	100MG	N87639 001	FEB 08, 1982

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL
PERPHENAZINE AND AMITRIPTYLINE HCL

AB	DANBURY PHARMA	10MG;2MG¤	N72539 001 FEB 15, 1989
AB		10MG;4MG¤	N72540 001 FEB 15, 1989
AB		25MG;2MG¤	N72541 001 FEB 15, 1989
AB		25MG;4MG¤	N72134 001 FEB 15, 1989
AB		50MG;4MG¤	N72135 001 FEB 15, 1989

AMMONIUM LACTATE

LOTION; TOPICAL
LAC-HYDRIN

/BRISTOL/MYERS/	/EQ/12%/ACID/	/N19155/001/	/APR/24,/1985/
WESTWOOD PHARMS	EQ 12% ACID	N19155 001	APR 24, 1985

AMOXAPINE

TABLET; ORAL
AMOXAPINE

>ADD>	AB	WATSON LABS	25MG¤	N72418 001 MAY 11, 1989
>ADD>	AB		50MG¤	N72419 001 MAY 11, 1989
>ADD>	AB		100MG¤	N72420 001 MAY 11, 1989
>ADD>	AB		150MG¤	N72421 001 MAY 11, 1989

ASENDIN

>ADD>	AB	LEDERLE LABS	25MG	N18021 001
>ADD>	AB		50MG	N18021 002
>ADD>	AB		100MG	N18021 003
>ADD>	AB		150MG	N18021 004

AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

>ADD>	AB	LEMMON	250MG¤	N63030 001 FEB 28, 1989
>AOD>				
>ADD>	AB		500MG¤	N63031 001 FEB 28, 1989
>ADD>				
>DLT>		/TAG/PHARMS/	/250MG/	/N63030/001/ /FEB/28,/1989/
>DLT>				
>DLT>			/500MG/	/N63031/001/ /FEB/28,/1989/
>OLT>				

POWDER FOR RECONSTITUTION; ORAL
AMOXICILLIN

AB	NOVOPHARM	250MG/5ML¤	N63001 001 JAN 06, 1989

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL
AMPICILLIN

AB	CLONMEL CHEMS	EQ 125MG BASE/5ML¤	N62982 001 FEB 10, 1989
AB		EQ 250MG BASE/5ML¤	N62982 002 FEB 10, 1989

/TABLET;CHEWABLE;ORAL/			
/POLYCILLIN/			
/BRISTOL LABS/	/EQ/125MG/BASE/	/N50093/001/	
∂ BRISTOL LABS	EQ 125MG BASE	N50093 001	

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL
BUTALBITAL W/ ASPIRIN & CAFFEINE

AB	PHARMAFAIR	325MG;50MG;40MG	N87048 002 DEC 09, 1983

ASPIRIN; CARISOPRODOL

TABLET; ORAL
CARISOPRODOL AND ASPIRIN

AB	PAR PHARM	325MG;200MG	N89594 001 MAR 31, 1989

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE

AA	∂ LEDERLE LABS	D.025MG;2.5MG	N86950 001

DIPHENOXYLATE HCL W/ ATROPINE SULFATE

AA	∂ PBI	0.025MG;2.5MG	N87842 001 MAR 29, 1982
AA	∂ VANGARD LABS	0.025MG;2.5MG	N88009 001 MAR 25, 1983

AZTREONAM

INJECTABLE; INJECTION
AZACTAM IN PLASTIC CONTAINER

> ADD >	SQUIBB	10MG/ML	N50632 003 MAY 24, 1989
> ADD >		20MG/ML	N50632 002 MAY 24, 1989
> ADD >		40MG/ML	N50632 001 MAY 24, 1989

BENDROFLUMETHIAZIDE

TABLET; ORAL

> DLT >	NATURETIN-2.5		
> DLT >	SQUIBB	2.5MG	N12164 001

BENDROFLUMETHIAZIDE

TABLET; ORAL

> DLT >	NATURETIN-2.5		
> ADD >	∂ SQUIBB	2.5MG	N12164 001

BENZONATATE

CAPSULE; ORAL
TESSALON

	DUPONT PHARMS	100MG	N11210 001
	FOREST LABS	100MG	N11210 001

BENZTROPINE MESYLATE

TABLET; ORAL
BENZTROPINE MESYLATE

AA	INVAMED	0.5MG	N72264 001 FEB 27, 1989
AA		1MG	N72265 001 FEB 27, 1989
AA		2MG	N72266 001 FEB 27, 1989

BETHANECHOL CHLORIDE

TABLET; ORAL
BETHANECHOL CHLORIDE

AA	CHELSEA LABS	5MG	N85841 001
	∂ CHELSEA LABS	5MG	N85841 001

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	BAXTER	200MG/100ML	N19837 002 APR 12, 1989
AP		400MG/100ML	N19837 001 APR 12, 1989

BROMPHENIRAMINE MALEATE

ELIXIR; ORAL
BROMPHENIRAMINE MALEATE

AA	PBI	2MG/5ML	N87964 001 JAN 25, 1983
	∂ PBI	2MG/5ML	N87964 001 JAN 25, 1983

BROMPHENIRAMINE MALEATE

TABLET; ORAL
BROMPHENIRAMINE MALEATE

AA	CHELSEA LABS	4MG		N85769 001

BUPROPION HYDROCHLORIDE

TABLET; ORAL
WELLBUTRIN

> DLT >	BURROUGHS WELLC	50MG	N18644 001 DEC 30, 1985
> DLT >		75MG	N18644 002 DEC 30, 1985
> DLT >		100MG	N18644 003 DEC 30, 1985
> ADD >	BURROUGHS WELLC	50MG	N18644 001 DEC 30, 1985
> ADD >		75MG	N18644 002 DEC 30, 1985
> ADD >		100MG	N18644 003 DEC 30, 1985

BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM

AA	WHITE TN PAULSN	30MG	N83337 001

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL
DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

AT	BAXTER	18.3MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML	N17512 004
AT		25.7MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML	N17512 004

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; IRRIGATION
RINGER'S IN PLASTIC CONTAINER

> DLT > AT	ABBOTT LABS	33MG/100ML;30MG/100ML; 860MG/100ML	N18462 001
> ADD >	ABBOTT LABS	33MG/100ML;30MG/100ML; 860MG/100ML	N18462 001

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION
LACTATED RINGER'S IN PLASTIC CONTAINER

AP	CUTTER BIOL	20MG/100ML;30MG/100ML;600MG/100ML; 310MG/100ML	N18417 001

CARBOPLATIN

INJECTABLE; INJECTION
PARAPLATIN

	BRISTOL MYERS	50MG/VIAL*	N19880 001 MAR 03, 1989
		150MG/VIAL*	N19880 002 MAR 03, 1989
		450MG/VIAL*	N19880 003 MAR 03, 1989

CARBOPROST

INJECTABLE; INJECTION
PROSTIN/15M

	UPJOHN	EQ 0.25MG BASE/ML	N17989 001

CARBOPROST TROMETHAMINE

INJECTABLE; INJECTION
HEBAMATE

	UPJOHN	EQ 0.25MG BASE/ML	N17989 001

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL

AA	CORD LABS	350MG*	N81025 001 APR 13, 1989

CARTEOLOL HYDROCHLORIDE

TABLET; ORAL
CARTRDL

>DLT>		/ABBOTT/LABS/	/10MG/	/N19204/003/
>DLT>				/DEC/28,/1988/
>ADD>		∂ ABBOTT LABS	10MG	N19204 003
>ADD>				DEC 28, 1988

CEFADROXIL

CAPSULE; ORAL
CEFADROXIL

AB	BIOCRAFT LABS	EQ 500MG BASE¤	N62695 001
			FEB 10, 1989
AB	PUREPAC PHARM	EQ 500MG BASE¤	N63017 001
			JAN 05, 1989

POWDER FOR RECONSTITUTION; ORAL
CEFADROXIL

AB	BIDCRAFT LABS	EQ 125MG BASE/5ML¤	N62698 001
			MAR 01, 1989
AB		EQ 250MG BASE/5ML¤	N62698 002
			MAR 01, 1989
AB		EQ 500MG BASE/5ML¤	N62698 003
			MAR 01, 1989

ULTRACEF

AB	BRISTOL LABS	EQ 125MG BASE/5ML	N62334 001
AB		EQ 125MG BASE/5ML	N62376 001
			MAR 16, 1982
AB		EQ 250MG BASE/5ML	N62334 002
AB		EQ 250MG BASE/5ML	N62376 002
			MAR 16, 1982

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM

>ADD>	AP	LEMMON	EQ 250MG BASE/VIAL¤	N63016 001
>ADD>				MAR 14, 1989
>ADD>	AP		EQ 500MG BASE/VIAL¤	N63016 002
>ADD>				MAR 14, 1989
>ADD>	AP		EQ 1GM BASE/VIAL¤	N63016 003
>ADD>				MAR 14, 1989
>DLT>		/TAG/PHARMS/	/EQ/1MG/BASE/VIAL/	/N63016/003/
>DLT>				/MAR/14,/1989/
>DLT>			/EQ/250MG/BASE/VIAL/	/N63016/001/
>DLT>				/MAR/14,/1989/
>DLT>			/EQ/500/BASE/VIAL/	/N63016/002/
>DLT>				/MAR/14,/1989/

CEFIXIME

POWDER FOR RECONSTITUTION; ORAL
SUPRAX

	LEDERLE LABS	100MG/5ML¤	N50622 001
			APR 28, 1989

TABLET; ORAL
SUPRAX

	LEDERLE LABS	200MG¤	N50621 001
			APR 28, 1989
		400MG¤	N50621 002
			APR 28, 1989

CEFPIRAMIDE SODIUM

INJECTABLE; INJECTION
CEFPIRAMIDE SODIUM

	WYETH AYERST LABS	EQ 1GM BASE/VIAL¤	N50633 002
			JAN 31, 1989
		EQ 2GM BASE/VIAL¤	N50633 003
			JAN 31, 1989
		EQ 10GM BASE/VIAL¤	N50633 005
			JAN 31, 1989

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION
FORTAZ IN PLASTIC CONTAINER

	GLAXO	EQ 10MG BASE/ML¤	N50634 001
			APR 28, 1989
		EQ 20MG BASE/ML¤	N50634 002
			APR 28, 1989
		EQ 40MG BASE/ML¤	N50634 003
			APR 28, 1989

CEFUROXIME SODIUM

INJECTABLE; INJECTION
ZINACEF IN PLASTIC CONTAINER

	GLAXO	EQ 15MG BASE/ML¤	N50643 001
			APR 28, 1989
		EQ 30MG BASE/ML¤	N50643 002
			APR 28, 1989

CEPHALEXIN

CAPSULE; ORAL
CEPHALEXIN

> ADD >	AB	LEMMON	EQ 250MG BASE	N62821 001
> ADD >				FEB 05, 1988
> ADD >	AB		EQ 500MG BASE	N62823 001
> ADD >				FEB 05, 1988
> DLT >	/AB/	/TAG/PHARMS/	/EQ 250MG BASE/	/N62821/001/
> DLT >				/FEB/05,/1988/
> DLT >	/AB/		/EQ 500MG BASE/	/N62823/001/
> DLT >				/FEB/05,/1988/

POWDER FOR RECONSTITUTION; ORAL
CEPHALEXIN

> ADD >	AB	LEMMON	EQ 125MG BASE/5ML	N62873 001
> ADD >				MAY 23, 1988
> ADD >	AB		EQ 250MG BASE/5ML	N62867 001
> ADD >				APR 15, 1988
> DLT >	/AB/	/TAG/PHARMS/	/EQ 125MG BASE/5ML/	/N62873/001/
> DLT >				/MAY/23,/1988/
> DLT >	/AB/		/EQ 250MG BASE/5ML/	/N62867/001/
> DLT >				/APR/15,/1988/

TABLET; ORAL
CEPHALEXIN

AB	BIOCRAFT LABS	EQ 250MG BASE¤	N63023 001
			JAN 12, 1989
AB		EQ 500MG BASE¤	N63024 001
			JAN 12, 1989

CERULETIDE DIETHYLAMINE

/INJECTABLE;/INJECTION/
/TYMTRAN/

/ADRIA/LABS/	/0.02MG/ML/	/N18296/001/
ə ADRIA LABS	0.02MG/ML	N18296 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
CHLORDIAZEPOXIDE HCL

/AB/	/VANGARD/LABS/	/5MG/	/N88129/001/
			/MAR/28,/1983/
/AB/		/10MG/	/N88010/001/
			/MAR/28,/1983/
/AB/		/25MG/	/N88130/001/
			/MAR/28,/1983/
ə VANGARD LABS	5MG		N88129 001
			MAR 28, 1983
ə	10MG		N88010 001
			MAR 28, 1983
ə	25MG		N88130 001
			MAR 28, 1983

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

/AA/	/CHELSEA/LABS/	/4MG/	/N85139/001/
ə CHELSEA LABS		4MG	N85139 001
/AA/	/LEDERLE/LABS/	/4MG/	/N86941/001/
ə LEDERLE LABS		4MG	N86941 001

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CHLORPHENIRAMINE MALEATE AND PHENYLPROPANOLAMINE HCL

AB	CORD LABS	12MG;75MG¤	N88940 001
			JAN 26, 1989
	ORNADE		
AB	SK&F LABS	12MG;75MG	N12152 004
/BC/		/12MG;75MG/	/N12152/004/

CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL
TUSSIONEX
FISONS — EQ 8MG MALEATE/5ML; EQ 10MG BITARTRATE/5ML — N19111 001 — DEC 31, 1987

/PENNWALT/ — /EQ/8MG/MALEATE/5ML;/ /EQ/10MG/BITARTRATE/5ML/ — /N19111/001/ /DEC/31,/1987/

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL
CHLORPROMAZINE HCL

/BP/	/VANGARD/LABS/	/10MG/	/N88038/001/ /AUG/16,/1982/
/BP/		/25MG/	/N87645/001/
/BP/		/50MG/	/N87646/001/
	ə VANGARD LABS	10MG	N88038 001 AUG 16, 1982
	ə	25MG	N87645 001
	ə	50MG	N87646 001

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

/AB/	/VANGARD/LABS/	/25MG/	/N88012/001/ /JUL/14,/1982/
/AB/		/50MG/	/N88073/001/ /MAR/25,/1983/
	ə VANGARD LABS	25MG	N88012 001 JUL 14, 1982
	ə	50MG	N88073 001 MAR 25, 1983

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

/AA/	/CHELSEA/LABS/	/250MG/	/N86948/001/ /AUG/09,/1982/
	ə CHELSEA LABS	250MG	N86948 001 AUG 09, 1982
AA	PIONEER PHARMS	250MG¤	N89592 001 JAN 06, 1989
AA		500MG¤	N89948 001 JAN 06, 1989

CHYMOPAPAIN

INJECTABLE; INJECTION
CHYMODIACTIN

/BAXTER/		/4,000/UNITS/VIAL/	/N18663/002/ /AUG/21,/1984/
		/10,000/UNITS/VIAL/	/N18663/001/ /NOV/10,/1982/

CHYMOPAPAIN

INJECTABLE; INJECTION
CHYMODIACTIN

	BOOTS (USA)	4,000 UNITS/VIAL	N18663 002 AUG 21, 1984
		10,000 UNITS/VIAL	N18663 001 NOV 10, 1982
/DISCASE/	/BOOTS/PHARMS/	/12,500/UNITS/VIAL/	/N18625/001/ /JAN/18,/1984/
	ə BOOTS PHARMS	12,500 UNITS/VIAL	N18625 001 JAN 18, 1984

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

AP	ASTRA PHARM PRODS	EQ 150MG BASE/ML¤	N62928 001 FEB 13, 1989
AP	DUPONT CRI CARE	EQ 150MG BASE/ML¤	N62908 001 FEB 01, 1989

>ADD> >ADD> >AOD> >ADO>

LOTION; TOPICAL
CLEOCIN T

	UPJOHN	EQ 1% BASE¤	N50600 001 MAY 31, 1989

SOLUTION; TOPICAL
CLINDAMYCIN PHOSPHATE

AT	COPLEY PHARM	EQ 1% BASE¤	N62944 001 JAN 11, 1989

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM

/AB/	/LEDERLE/LABS/	/3.75MG/	/N72013/001/ /DEC/15,/1987/
/AB/		/7.5MG/	/N72014/001/ /DEC/15,/1987/
/AB/		/15MG/	/N72015/001/ /DEC/15,/1987/
	ə LEDERLE LABS	3.75MG	N72013 001 DEC 15, 1987
	ə	7.5MG	N72014 001 DEC 15, 1987
	ə	15MG	N72015 001 DEC 15, 1987

CLOXACILLIN SODIUM

POWDER FOR RECONSTITUTION; ORAL
CLOXACILLIN SODIUM
AA NOVOPHARM EQ 125MG BASE/5ML N62978 001 APR 06, 1989

COBALT CHLORIDE, CO-60; CYANOCOBALAMIN; CYANOCOBALAMIN, CO-60; INTRINSIC FACTOR

/N/A;/N/A/
/RUBRATOPE-60/KIT/
/SQUIBB/ /N/A;N/A;N/A;N/A/ /N16090/001/
ə SQUIBB N/A;N/A;N/A;N/A N16090 001

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE
/BP/ /WHITE/TN/PAULSN/ /25MG/ /N80341/001/
ə WHITE TN PAULSN 25MG N80341 001

CYANOCOBALAMIN

INJECTABLE; INJECTION
/REDISOL/
/BP/ /MSD/ /1MG/ML/ /N06668/010/
ə MS&D 1MG/ML N06668 010
/VI-TWEL/
/BP/ /BERLEX/LABS/ /1MG/ML/ /N07012/002/
ə BERLEX LABS 1MG/ML N07012 002

DEMECLOCYCLINE HYDROCHLORIDE

/SYRUP;/ORAL/
/DECLOMYCIN/
/LEDERLE/LABS/ /75MG/5ML/ /N50257/001/
ə LEDERLE LABS 75MG/5ML N50257 001

DEXAMETHASONE

SUSPENSION/DROPS; OPHTHALMIC
>ADD> DEXAMETHASONE
>ADD> AT STERIS LABS 0.1% N89170 001 MAY 09, 1989
>ADD>
MAXIDEX
>ADD> AT ALCON LABS 0.1% N13422 001

DEXAMETHASONE

TABLET; ORAL
DEXAMETHASONE
/BP/ /CHELSEA/LABS/ /1.5MG/ /N85840/001/
ə CHELSEA LABS 1.5MG N85840 001

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION
/CARDIOGRAFIN/
/SQUIBB/ /85%/ /N11620/002/
SQUIBB 85% N11620 002

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION
HYPAQUE-M
>DLT> /STERLING/DRUG/ /60%;30%/ /N10220/002/
>ADD> ə STERLING DRUG 60%;30% N10220 002

DIAZEPAM

TABLET; ORAL
DIAZEPAM
AB MARTEC PHARM 10MG N72402 001 APR 25, 1989

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL
DICYCLOMINE HCL
AB PIONEER PHARMS 10MG N89361 001 JAN 10, 1989

DIETHYLCARBAMAZINE CITRATE

TABLET; ORAL
HETRAZAN
/Ə/LEDERLE/LABS/ /50MG/ /N06459/001/
LEDERLE LABS 50MG N06459 001

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

	CARDIZEM SR			
	MARION LABS	60MG¤		N19471 001 JAN 23, 1989
		90MG¤		N19471 002 JAN 23, 1989
		120MG¤		N19471 003 JAN 23, 1989
	ə	180MG¤		N19471 004 JAN 23, 1989

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

	DIPHENHYDRAMINE HCL			
/AA/	/VANGARD LABS/	/25MG/	/N88034/001/	/OCT 27, 1982/
/AA/		/50MG/	/N87630/001/	
	ə VANGARD LABS	25MG	N88034 001	OCT 27, 1982
	ə	50MG	N87630 001	
/AA/	/WHITE TN PAULSN/	/50MG/	/N80800/001/	
	ə WHITE TN PAULSN	50MG	N80800 001	

ELIXIR; ORAL

	/DIPHEN/			
/AA/	/PBI/	/12.5MG/5ML/	/N84640/001/	
	ə PBI	12.5MG/5ML	N84640 001	
	DIPHENHYDRAMINE HCL			
>ADD> AA	CENCI LABS	12.5MG/5ML	N87941 001	DEC 17, 1982
>ADD>				
>DLT>/AA/	/LIFE LABS/	/12.5MG/5ML/	/N87941/001/	/DEC 17, 1982/
>DLT>				
/AA/	/PRIVATE FMLTNS/	/12.5MG/5ML/	/N85287/001/	
	ə PRIVATE FMLTNS	12.5MG/5ML	N85287 001	

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

	DOPAMINE HCL			
AP	ABBOTT LABS	40MG/ML¤	N70656 001	JAN 24, 1989
AP		80MG/ML¤	N70657 001	JAN 24, 1989

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

	DOXEPIN HCL			
AB	QUANTUM PHARMCS	EQ 100MG BASE¤	N72375 001	MAR 15, 1989
AB		EQ 150MG BASE¤	N72376 001	MAR 15, 1989

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

	ADRIAMYCIN PFS			
AP	ADRIA LABS	2MG/ML	N50629 002	MAY 03, 1988
AP		2MG/ML	N50629 001	DEC 23, 1987
	ADRIAMYCIN RDF			
AP	ADRIA LABS	10MG/VIAL	N50467 001	
AP		20MG/VIAL	N50467 003	MAY 20, 1985
AP		50MG/VIAL	N50467 002	
	DOXORUBICIN HCL			
AP	CETUS BEN VENUE	2MG/ML¤	N62975 001	MAR 17, 1989
AP		10MG/VIAL¤	N62921 001	MAR 17, 1989
AP		20MG/VIAL¤	N62921 002	MAR 17, 1989
AP		50MG/VIAL¤	N62921 003	MAR 17, 1989
	RUBEX			
AP	BRISTOL MYERS	10MG/VIAL¤	N62926 001	APR 13, 1989
AP		50MG/VIAL¤	N62926 002	APR 13, 1989
		100MG/VIAL¤	N62926 003	APR 13, 1989

DOXYCYCLINE HYCLATE

INJECTABLE; INJECTION

	DOXYCYCLINE HYCLATE			
AP	LEDERLE PARNTLS	EQ 100MG BASE/VIAL¤	N62992 001	FEB 16, 1989
AP		EQ 200MG BASE/VIAL¤	N62992 002	FEB 16, 1989

DROPERIDOL; FENTANYL CITRATE

INJECTABLE; INJECTION
FENTANYL CITRATE AND DROPERIDOL

AP	ASTRA PHARM PRODS	2.5MG/ML; EQ 0.05MG BASE/ML	N72026 001	APR 13, 1989
AP		2.5MG/ML; EQ 0.05MG BASE/ML	N72027 001	APR 13, 1989
AP		2.5MG/ML; EQ 0.05MG BASE/ML	N72028 001	APR 13, 1989

ERGOLOID MESYLATES

TABLET; SUBLINGUAL
ERGOLOID MESYLATES

AA	LEDERLE LABS	0.5MG	N86984 001	
AA		1MG	N86985 001	
AA	VANGARD LABS	0.5MG	N88013 001	SEP 20, 1982
AA		1MG	N88014 001	SEP 20, 1982

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL
ERYTHROMYCIN

> ADD >	AB	BARR LABS	250MG	N63098 001	MAY 04, 1989

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION
ERYTHROMYCIN LACTOBIONATE

> ADD >	AP	LEDERLE PARNTLS	EQ 500MG BASE/VIAL	N62993 001	MAY 09, 1989
> ADD >	AP		EQ 1GM BASE/VIAL	N62993 002	MAY 09, 1989

ESMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION
BREVIBLOC

> ADD >	DUPONT PHARMS	100MG/ML	N19386 003	
> ADD >				DEC 31, 1986

ESTROGENS, CONJUGATED

TABLET; ORAL
CONJUGATED ESTROGENS

BP	CHELSEA LABS	0.625MG	N85800 001	
BP		1.25MG	N85801 001	
BP		2.5MG	N85826 001	
BP	DURAMED PHARMS	0.3MG	N86492 001	
BP		0.625MG	N83272 001	
BP		1.25MG	N83294 001	
BP		2.5MG	N83295 001	
BP	ZENITH LABS	0.3MG	N88569 001	NOV 29, 1984
BP		0.625MG	N83373 001	
BP		1.25MG	N83601 001	
BP		2.5MG	N83602 001	

PREMARIN

BP	WYETH AYERST LABS	0.3MG	N04782 003	
BP		0.625MG	N04782 004	
BP		1.25MG	N04782 001	
BP		2.5MG	N04782 002	
BP		0.9MG	N04782 005	JAN 26, 1984

ESTROGENS, ESTERIFIED

TABLET; ORAL
FEMOGEN
/BS/ /PRIVATE/FMLTNS/ /2.5MG/ /N85007/001/
∂ PRIVATE FMLTNS 2.5MG N85007 001

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORCEPT-E 1/35 21
AB GYNOPHARMA 0.035MG;1MG* N71545 001
FEB 09, 1989

TABLET; ORAL-28
NORCEPT-E 1/35 28
AB GYNOPHARMA 0.035MG;1MG* N71546 001
FEB 09, 1989

FERROUS CITRATE, FE-59

/INJECTABLE;/INJECTION/
/FERROUS/CITRATE/FE/59/
/MALLINCKRODT/ /25/UCI/ML/ /N16729/001/
∂ MALLINCKRODT 25 UCI/ML N16729 001

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE
AB LEMMON 0.05%* N72488 001
FEB 06, 1989
AB 0.05%* N72490 001
FEB 07, 1989

VASODERM E
AB TJ ROACO 0.05%* N72494 001
JAN 19, 1989

GEL; TOPICAL
FLUOCINONIDE
AB LEMMON 0.05%* N72537 001
FEB 07, 1989

LIDEX
AB SYNTEX LABS 0.05% N17373 001

SOLUTION; TOPICAL
FLUOCINONIDE
AT LEMMON 0.05%* N72511 001
FEB 07, 1989

FLUOXYMESTERONE

TABLET; ORAL
ANDROID-F
/BP/ /BROWN/PHARM/ /10MG/ /N87196/001/
BP ICN PHARMS 10MG N87196 001
FLUOXYMESTERONE
/BP/ /BROWN/PHARM/ /10MG/ /N88221/001/
/MAY/05,/1983/
BP ICN PHARMS 10MG N88221 001
MAY 05, 1983

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL
AB CHELSEA LABS 15MG* N72368 001
MAR 30, 1989
AB 30MG* N72369 001
MAR 30, 1989

FLUTAMIDE

CAPSULE; ORAL
EULEXIN
SCHERING 125MG* N18554 001
JAN 27, 1989

FOLIC ACID

TABLET; ORAL
FOLIC ACID
/AA/ /PBI/ /1MG/ /N87828/001/
/MAY/13,/1982/
∂ PBI 1MG N87828 001
MAY 13, 1982
/AA/ /VANGARD/LABS/ /1MG/ /N86736/001/
/MAR/23,/1984/
∂ VANGARD LABS 1MG N88730 001
MAR 23, 1984
/AA/ /WHITE/TN/PAULSN/ /1MG/ /N80691/002/
∂ WHITE TN PAULSN 1MG N80691 002

GEMFIBROZIL

CAPSULE; ORAL
LOPID
/PARKE/DAVIS/ /200MG/ /N18422/001/
∂ PARKE DAVIS 200MG N18422 001

GEMFIBROZIL

TABLET; ORAL
LOPID
PARKE DAVIS 600MG N18422 003
NOV 20, 1986

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM
AP STERIS LABS 40,000 UNITS/ML N17D64 DD6
/S/ /40,000/UNITS/ML/ /N17064/006/
HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER
AP BAXTER 4,000 UNITS/100ML N18814 001
OCT 31, 1983
HEPARIN SODIUM 20,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER
AP ABBOTT LABS 4,000 UNITS/100ML N19805 001
JAN 25, 1989
HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER
AP ABBOTT LABS 5,000 UNITS/100ML N19805 002
JAN 25, 1989

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HCL
/AA/ /PBI/ /25MG/ /N87780/001/
/MAR/29,/1982/
/AA/ /50MG/ /N87751/001/
/MAR/29,/1982/
a PBI 25MG N87780 001
MAR 29, 1982
a 50MG N87751 001
MAR 29, 1982
>DLT >/AA/ /VANGARD/LABS/ /50MG/ /N87908/001/
>DLT > /MAY/07,/1982/
>ADD > a VANGARD LABS 50MG N87908 001
>ADD > MAY 07, 1982

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE
/AB/ /PBI/ /25MG/ /N87827/001/
/APR/19,/1982/
/AB/ /50MG/ /N87752/001/
/APR/19,/1982/
a PBI 25MG N87827 001
APR 19, 1982
a 5DMG N87752 001
APR 19, 1982
/AB/ /VANGARD/LABS/ /25MG/ /N87638/001/
/AB/ /50MG/ /N87610/001/
a VANGARD LABS 25MG N87638 001
a 50MG N87610 001
/AB/ /WHITE/TN/PAULSN/ /25MG/ /N83809/002/
/AB/ /50MG/ /N83809/001/
/AB/ /100MG/ /N85347/001/
a WHITE TN PAULSN 25MG N83809 D02
a 50MG N83809 001
a 100MG N85347 001

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL
PRINZIDE 12.5
MS&D RES LABS 12.5MG;20MG N19778 001
FEB 16, 1989
PRINZIDE 25
MS&D RES LABS 25MG;20MG N19778 002
FEB 16, 1989

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
METHYLDOPA AND HYDROCHLOROTHIAZIDE
AB DANBURY PHARMA 15MG;250MG N70958 001
FEB 06, 1989
AB 25MG;250MG N70959 001
JAN 19, 1989
AB 30MG;500MG N71069 001
JAN 19, 1989
AB 50MG;500MG N70960 001
FEB 06, 1989

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

/BP/	/H.R.-50/ /WHITE/TN/PAULSN/	/50MG;0.125MG/	/N85338/001/
	ə WHITE TN PAULSN	50MG;0.125MG	N85338 001

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE

/AB/	/PBI/	/25MG;25MG/	/N87651/001/
	ə PBI	25MG;25MG	N87651 001
/AB/	/VANGARD/LABS/	/25MG;25MG/	/N87655/001/
	ə VANGARD LABS	25MG;25MG	N87655 001

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

AT	NMC LABS	2.5%¤	N89754 001 FEB 01, 1989
AT	TOPIDERM	1%¤	N89273 001 FEB 17, 1989

HYDROCORTISONE ACETATE

CREAM; TOPICAL

HYDROCORTISONE ACETATE

AT	PARKE DAVIS	1%¤	N89914 001 JAN 03, 1989

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION

A-HYDROCORT

AP	ABBOTT LABS	EQ 100MG BASE/VIAL¤	N89577 001 APR 11, 1989
AP		EQ 250MG BASE/VIAL¤	N89578 001 APR 11, 1989
AP		EQ 500MG BASE/VIAL¤	N89579 001 APR 11, 1989
AP		EQ 1GM BASE/VIAL¤	N89580 001 APR 11, 1989

HYDROFLUMETHIAZIDE

TABLET; ORAL

HYDROFLUMETHIAZIDE

/AB/	/CHELSEA/LABS/	/50MG/	/N88528/001/ /AUG/15,/1984/
	ə CHELSEA LABS	50MG	N88528 001 AUG 15, 1984

HYDROXOCOBALAMIN

INJECTABLE; INJECTION

HYDROXOCOBALAMIN

/AP/	/LYPHOMED/	/1MG/ML/	/N84921/001/
	ə LYPHOMED	1MG/ML	N84921 001

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HCL

/AB/	/PBI/	/25MG/	/N87776/001/ /FEB/10,/1982/
	ə PBI	25MG	N87776 001 FEB 10, 1982
/AB/	/VANGARD/LABS/	/10MG/	/N88036/001/ /NOV/03,/1982/
/AB/		/25MG/	/N87619/001/ /FEB/09,/1982/
/AB/		/50MG/	/N87631/001/ /JAN/04,/1982/
	ə VANGARD LABS	10MG	N88036 001 NOV 03, 1982
	ə	25MG	N87619 001 FEB 09, 1982
	ə	50MG	N87631 001 JAN 04, 1982

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL

INDOMETHACIN

AB	INWOOD LABS	75MG¤	N72410 001 MAR 15, 1989

LACTULOSE

SYRUP; ORAL
DUPHALAC
AA REID ROWELL 10GM/15ML N72372 001 MAR 22, 1989

SYRUP; ORAL, RECTAL
LACTULOSE
/AA/ /KALI/DUPHAR/ /10GM/15ML/ /N17906/001/
AA REID ROWELL 10GM/15ML N17906 001
PORTALAC
AA REID ROWELL 10GM/15ML N72374 001 MAR 22, 1989

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM
LEDERLE LABS EQ 350MG BASE/VIAL N08107 005 APR 05, 1989
WELLCOVORIN
AP BURROUGHS WELLC EQ 50MG BASE/VIAL N89465 001 JAN 23, 1989
AP EQ 100MG BASE/VIAL N89834 001 JAN 23, 1989
EQ 25MG BASE/VIAL N89833 001 JAN 23, 1989

LEUPROLIDE ACETATE

INJECTABLE; INJECTION
LUPRON DEPOT
/TAP/PHARMS/ /7.5MG/VIAL/ /N19732/001/
TAKEDA ABBOTT R&D 7.5MG/VIAL N19732 001 JAN 26, 1989

LEVOTHYROXINE SODIUM; LIOTHYRONINE SODIUM

TABLET; ORAL
THYROLAR-0.25
/ARMOUR/PHARM/ /0.0125MG;0.0031MG/ /N16807/001/
RORER PHARM 0.0125MG;0.0031MG N16807 001
THYROLAR-0.5
/ARMOUR/PHARM/ /0.025MG;0.00625MG/ /N16807/005/
RORER PHARM 0.025MG;0.00625MG N16807 005
THYROLAR-1
/ARMOUR/PHARM/ /0.05MG;0.0125MG/ /N16807/004/
RORER PHARM 0.05MG;0.0125MG N16807 004

LEVOTHYROXINE SODIUM; LIOTHYRONINE SODIUM

TABLET; ORAL
THYROLAR-2
/ARMOUR/PHARM/ /0.1MG;0.025MG/ /N16807/002/
RORER PHARM 0.1MG;0.025MG N16807 002
THYROLAR-3
/ARMOUR/PHARM/ /0.15MG;0.0375MG/ /N16807/003/
RORER PHARM 0.15MG;0.0375MG N16807 003

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
XYLOCAINE
AP ASTRA PHARM PRODS 1% N16801 005 JAN 19, 1988

INJECTABLE; SPINAL
LIDOCAINE HCL AND DEXTROSE 7.5%
AP ABBOTT LABS 5% N83914 001
/LIDOCAINE HCL W/ DEXTROSE/
/AP/ /ABBOTT LABS/ /5%/ /N83914/001/

LISINOPRIL

TABLET; ORAL
PRINIVIL
AB MS&D RES LABS 40MG N19558 004 OCT 25, 1988
ZESTRIL
AB IMPERIAL CHEM 40MG N19777 004 MAY 19, 1988

LITHIUM CARBONATE

CAPSULE; ORAL
LITHIUM CARBONATE
AB PBI 300MG N72542 001 FEB 01, 1989

MANNITOL

SOLUTION; IRRIGATION
/RESECTISOL/
/KENDALL/MCGAW/ /5GM/100ML/ /N16704/002/
KENDALL MCGAW 5GM/100ML N16704 002

MECLIZINE HYDROCHLORIDE

TABLET; DRAL

	MECLIZINE HCL			
/AA/	/VANGARD LABS/	/12.5MG/	/N87877 001/	/APR 20, 1982/
/AA/		/25MG/	/N87620 001/	/JAN 04, 1982/
	ə VANGARD LABS	12.5MG	N87877 001	APR 20, 1982
	ə	25MG	N87620 001	JAN 04, 1982

MECLOFENAMATE SODIUM

CAPSULE; ORAL

	MECLOFENAMATE SODIUM			
AB	BARR LABS	EQ 50MG BASE*	N72848 001	MAR 20, 1989
AB		EQ 100MG BASE*	N72809 001	MAR 20, 1989

> ADD > MEFLOQUINE HYDROCHLORIDE

> ADD > TABLET; ORAL

> ADD >	LARIAM			
> ADD >	ROCHE	250MG*	N19591 001	MAY 02, 1989
> ADD >	MEFLOQUINE HCL			
> ADD >	ə WALTER REED	250MG*	N19578 001	MAY 02, 1989

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

	MEPERIDINE HCL			
AP	ASTRA PHARM PRODS	25MG/ML*	N89781 001	MAR 31, 1989
AP		50MG/ML*	N89782 001	MAR 31, 1989
AP		50MG/ML*	N89783 001	MAR 31, 1989
AP		50MG/ML*	N89784 001	MAR 31, 1989
AP		75MG/ML*	N89785 001	MAR 31, 1989
AP		100MG/ML*	N89786 001	MAR 31, 1989
AP		100MG/ML*	N89787 001	MAR 31, 1989
AP		100MG/ML*	N89788 001	MAR 31, 1989

MEPROBAMATE

TABLET; ORAL

	MEPROBAMATE			
/AA/	/LEDERLE LABS/	/400MG/	/N86299 001/	
	ə LEDERLE LABS	400MG	N86299 001	
/AA/	/VANGARD LABS/	/400MG/	/N88011 001/	/JUL 14, 1982/
	ə VANGARD LABS	400MG	N88011 001	JUL 14, 1982
/AA/	/WHITE TN PAULSN/	/200MG/	/N83830 001/	
/AA/		/400MG/	/N83442 001/	
	ə WHITE TN PAULSN	200MG	N83830 001	
	ə	400MG	N83442 001	

MESNA

INJECTABLE; INJECTION

MESNEX			
ASTA PHARMA	100MG/ML	N19884 001	DEC 30, 1988
/BRISTOL MYERS/	/100MG/ML/	/N19884 001/	/DEC 30, 1988/

METHOTREXATE SODIUM

INJECTABLE; INJECTION
MEXATE-AQ PRESERVED

AP	BRISTOL MYERS	EQ 25MG BASE/ML	N89887 001 APR 14, 1989

METHYLPREDNISOLONE

TABLET; ORAL
METHYLPREDNISOLONE

> ADD >	AB	CHELSEA LABS	4MG	N86161 001 FEB 09, 1982
> ADD >				
> OLT >	/BP/		/4MG/	/N86161/001/ /FEB/09,/1982/
> DLT >				

METHYLPREONISOLONE ACETATE

/ENEMA;/RECTAL/
/MEDROL/

	/UPJOHN/	/40MG/BOT/	/N18102/001/
	ə UPJOHN	40MG/BOT	N18102 001

METHYLTESTOSTERONE

TABLET; BUCCAL
ANDROID 5

	/BROWN/PHARM/	/5MG/	/N87222/001/
	ICN PHARMS	5MG	N87222 001

TABLET; ORAL
ANDROID 10

/AB/	/BROWN/PHARM/	/10MG/	/N86450/001/
AB	ICN PHARMS	10MG	N86450 001

ANDROID 25

/AB/	/BROWN/PHARM/	/25MG/	/N87147/001/
AB	ICN PHARMS	25MG	N87147 001

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL

AP	BULL LABS	EQ 10MG BASE/2ML	N71990 001 JAN 18, 1989
AP	OUPONT CRI CARE	EQ 10MG BASE/2ML	N71291 001 MAR 03, 1989

METOPROLOL TARTRATE

TABLET; ORAL
LOPRESSOR

AB	GEIGY PHARMS	50MG	N17963 001
AB		100MG	N17963 002

METOPROLOL TARTRATE

AB	HENRY SCHEIN	50MG	N71690 001 DEC 21, 1993 : FEB 08, 1989
AB		100MG	N71691 001 DEC 21, 1993 : FEB 08, 1989

METRIZAMIDE

INJECTABLE; INJECTION
AMIPAQUE

> DLT >	/STERLING/DRUG/	/2.5GM/VIAL/	/N17982/003/ /SEP/12,/1983/
> DLT >			
> ADD >	ə STERLING DRUG	2.5GM/VIAL	N17982 003 SEP 12, 1983
> ADD >			

MOMETASONE FUROATE

LOTION; TOPICAL
ELOCON

	SCHERING	0.1%	N19796 001 MAR 30, 1989

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
NALBUPHINE HCL

AP	ABBOTT LABS	10MG/ML	N70914 001 FEB 03, 1989
AP		10MG/ML	N70915 001 FEB 03, 1989
AP		20MG/ML	N70916 001 FEB 03, 1989
AP		20MG/ML	N70917 001 FEB 03, 1989
AP		20MG/ML	N70918 001 FEB 03, 1989

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

NALBUPHINE HCL

AP	ASTRA PHARM PRODS	10MG/ML¤	N72070 001 APR 10, 1989	
AP		10MG/ML¤	N72071 001 APR 10, 1989	
AP		10MG/ML¤	N72072 001 APR 10, 1989	
AP		20MG/ML¤	N72073 001 APR 10, 1989	
AP		20MG/ML¤	N72074 001 APR 10, 1989	
AP		20MG/ML¤	N72075 001 APR 10, 1989	

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE HCL

AP	ASTRA PHARM PRODS	0.02MG/ML¤	N72081 001 APR 11, 1989	
AP		0.02MG/ML¤	N72082 001 APR 11, 1989	
AP		0.02MG/ML¤	N72083 001 APR 11, 1989	
AP		0.02MG/ML¤	N72084 001 APR 11, 1989	
AP		0.02MG/ML¤	N72085 001 APR 11, 1989	
AP		0.4MG/ML¤	N72086 001 APR 11, 1989	
AP		0.4MG/ML¤	N72087 001 APR 11, 1989	
AP		0.4MG/ML¤	N72088 001 APR 11, 1989	
AP		0.4MG/ML¤	N72089 001 APR 11, 1989	
AP		0.4MG/ML¤	N72090 001 APR 11, 1989	
AP		1MG/ML¤	N72091 001 APR 11, 1989	
AP		1MG/ML¤	N72092 001 APR 11, 1989	
AP		1MG/ML¤	N72093 001 APR 11, 1989	

NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

MURO'S OPCON

> DLT >	AT	MURO PHARM	0.1%	N87506 001

OPCON

> ADD >	AT	BAUSCH & LOMB	0.1%	N87506 001

NIACIN

TABLET; ORAL

NIACIN

	a	CHELSEA LABS	500MG	N85172 001

NIFEDIPINE

CAPSULE; ORAL

NIFEDIPINE

	AB	PUREPAC PHARM	10MG¤	N72579 001 † APR 28, 1989
	AB		20MG¤	N72556 001 † APR 28, 1989

OXACILLIN SODIUM

INJECTABLE; INJECTION

OXACILLIN SODIUM

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

OXYBUTYNIN CHLORIDE

TABLET; ORAL

OXYBUTYNIN CHLORIDE

	AB	BOLAR PHARM	5MG¤	N72485 001 APR 19, 1989

† DELAYED EFFECTIVE DATE PENDING COURT DECISION

PANCURONIUM BROMIDE

INJECTABLE; INJECTION
PANCURONIUM BROMIDE

AP	ABBOTT LABS	1MG/ML	N72320 001	
			JAN 19, 1989	
AP		2MG/ML	N72321 001	
			JAN 19, 1989	

PENBUTOLOL SULFATE

TABLET; ORAL
LEVATOL

/LILLY/	/10MG/	/N18976/001/		
		/DEC/30,/1987/		
REED & CARNRICK	10MG	N18976 001		
		DEC 30, 1987		

PENICILLIN G BENZATHINE

/SUSPENSION;/ORAL/
/BICILLIN/

/WYETH/AYERST/LABS/	/300,000/UNITS/5ML/	/N50126/002/	>ADD>	
@ WYETH AYERST LABS	300,000 UNITS/5ML	N50126 002	>ADD>	
			>ADD>	

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN V POTASSIUM

AA	CLONMEL CHEMS	EQ 125MG BASE/5ML	N62981 001
			FEB 10, 1989
AA		EQ 250MG BASE/5ML	N62981 002
			FEB 10, 1989

PENTOBARBITAL SODIUM

CAPSULE; ORAL
PENTOBARBITAL SODIUM

/AA/	/WHITE/TN/PAULSN/	/100MG/	/N83338/001/
	@ WHITE TN PAULSN	100MG	N83338 001

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
/DI-METREX/

/AA/	/PRIVATE/FMLTNS/	/35MG/	/N85698/001/
	@ PRIVATE FMLTNS	35MG	N85698 001

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
PHENDIMETRAZINE TARTRATE

/AA/	/PRIVATE/FMLTNS/	/35MG/	/N85199/001/	
	@ PRIVATE FMLTNS	35MG	N85199 001	

PHENYL AMINOSALICYLATE

/POWDER;/ORAL/
/PHENY-PAS-TEBAMIN/

/PURDUE/FRDRK/	/50%/	/N11695/002/	
@ PURDUE FRDRK	50%	N11695 002	

/TABLET;/ORAL/
/PHENY-PAS-TEBAMIN/

/PURDUE/FRDRK/	/500MG/	/N11695/003/	
@ PURDUE FRDRK	500MG	N11695 003	

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PHENERGAN VC

AA	WYETH AYERST LABS	5MG/5ML;6.25MG/5ML	N08604 003	
			APR 02, 1984	

PHENYLEPHRINE HYDROCHLORIDE; PYRILAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC
PREFRIN-A

ALLERGAN PHARMS	0.12%;0.1%	N07953 001	

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER

/AP/	/BAXTER/	/75MG/100ML;900MG/100ML/	/N17648/004/
	@ BAXTER	75MG/100ML;900MG/100ML	N17648 004
/AP/	/KENDALL/MCGAW/	/75MG/100ML;900MG/100ML/	/N18722/001/
			/NOV/09,/1982/
	@ KENDALL MCGAW	75MG/100ML;900MG/100ML	N18722 001
			NOV 09, 1982

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER

/AP/ /KENDALL/MCGAW/ /150MG/100ML;/ /900MG/100ML/ /N16722/002/ /NOV/09,/1982/

a KENDALL MCGAW 150MG/100ML; 900MG/100ML N18722 002 NOV 09, 1982

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER

/AP/ /KENDALL/MCGAW/ /220MG/100ML;/ /900MG/100ML/ /N16722/003/ /NOV/09,/1982/

a KENDALL MCGAW 220MG/100ML; 900MG/100ML N18722 003 NOV 09, 1982

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

/AP/ /KENDALL/MCGAW/ /300MG/100ML;/ /900MG/100ML/ /N16722/004/ /NOV/09,/1982/

a KENDALL MCGAW 300MG/100ML; 900MG/100ML N18722 004 NOV 09, 1982

PRALIDOXIME CHLORIDE

>DLT> /TABLET;ORAL/

>DLT> /PROTOPAM/CHLORIDE/

>DLT> /WYETH/AYERST/LABS/ /500MG/ /N14122/002/

>ADD> a WYETH AYERST LABS 500MG N14122 002

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HCL

AB	AM THERPTCS	EQ 1MG BASE¤	N72782 001
		MAY 16, 1989 : APR 11, 1989	
AB		EQ 2MG BASE¤	N72783 001
		MAY 16, 1989 : APR 11, 1989	
AB		EQ 5MG BASE¤	N72784 001
		MAY 16, 1989 : APR 11, 1989	
AB	CORD LABS	EQ 1MG BASE¤	N72576 001
		MAY 16, 1989 : APR 10, 1989	
AB		EQ 2MG BASE¤	N72577 001
		MAY 16, 1989 : APR 10, 1989	
AB		EQ 5MG BASE¤	N72578 001
		MAY 16, 1989 : APR 10, 1989	

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HCL

AB	DANBURY PHARMA	EQ 1MG BASE¤	N72352 001
		MAY 16, 1989 : JAN 11, 1989	
AB		EQ 2MG BASE¤	N72333 001
		MAY 16, 1989 : JAN 11, 1989	
AB		EQ 5MG BASE¤	N72609 001
		MAY 16, 1989 : JAN 11, 1989	
AB	LEDERLE LABS	EQ 1MG BASE¤	N72705 001
		MAY 16, 1989 : MAR 15, 1989	
AB		EQ 2MG BASE¤	N72706 001
		MAY 16, 1989 : MAR 15, 1989	
AB		EQ 5MG BASE¤	N72707 001
		MAY 16, 1989 : MAR 15, 1989	
AB	MYLAN PHARMS	EQ 1MG BASE¤	N72573 001
		MAY 16, 1989 : FEB 28, 1989	
AB		EQ 2MG BASE¤	N72574 001
		MAY 16, 1989 : FEB 28, 1989	
AB		EQ 5MG BASE¤	N72575 001
		MAY 16, 1989 : FEB 28, 1989	
AB	PUREPAC PHARM	EQ 1MG BASE¤	N72991 001
		MAY 16, 1989 : APR 26, 1989	
AB		EQ 2MG BASE¤	N72921 001
		MAY 16, 1989 : APR 26, 1989	
AB		EQ 5MG BASE¤	N72992 001
		MAY 16, 1989 : APR 26, 1989	
/AB/	/ZENITH/LABS/	/EQ 1MG BASE/	/N71994/001/
			/SEP/12,/1988/
AB	ZENITH LABS	EQ 1MG BASE	N71994 001
		MAY 16, 1989 : SEP 12, 1988	
/AB/		/EQ 2MG BASE/	/N71995/001/
			/SEP/12,/1988/
AB		EQ 2MG BASE	N71995 001
		MAY 16, 1989 : SEP 12, 1988	
/AB/		/EQ 5MG BASE/	/N71745/001/
			/SEP/12,/1988/
AB		EQ 5MG BASE	N71745 001
		MAY 16, 1989 : SEP 12, 1988	

PREDNISOLONE

SYRUP; ORAL

PRELONE

MURO PHARM 5MG/5ML¤ N89654 001 JAN 17, 1989

TABLET; ORAL

PREONISDLONE

/BX/ /WHITE/TN/PAULSN/ /5MG/ /N80342/001/

a WHITE TN PAULSN 5MG N80342 001

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

SUSPENSION/DROPS; OPHTHALMIC

	SULPHRIN			
> ADD > AT	BAUSCH & LOMB	0.5%;10%	N88089 001	
> ADD >			DEC 28, 1982	
> DLT >/AT/	/MURO/PHARM/	/0.5%;10%/	/N88089/001/	
> DLT >			/DEC/28,/1982/	

PREDNISONE

SOLUTION; ORAL

	PREDNISONE INTENSOL			
	ROXANE LABS	5MG/ML	N88810 001	
			FEB 20, 1985	
	/SYRUP;ORAL/			
	/PREDNISONE INTENSOL/			
	/ROXANE LABS/	/5MG/ML/	/N88810/001/	
			/FEB/20,/1985/	

TABLET; ORAL

	DELTASONE			
AB	UPJOHN	50MG	N09986 008	
/BX/		/50MG/	/N09986/008/	
	PREDNISONE			
AB	CORD LABS	10MG◈	N89983 001	
			JAN 12, 1989	
AB		50MG◈	N89984 001	
			JAN 12, 1989	
/BX/	/VANGARD LABS/	/5MG/	/N87682/001/	
			/JAN/15,/1982/	
/BX/		/20MG/	/N87701/001/	
			/JAN/15,/1982/	
	ə VANGARD LABS	5MG	N87682 001	
			JAN 15, 1982	
	ə	20MG	N87701 001	
			JAN 15, 1982	
/AB/	/WHITE TN PAULSN/	/10MG/	/N89028/001/	
			/JUL/24,/1986/	
/BX/		/2.5MG/	/N84913/001/	
/BX/		/5MG/	/N80343/001/	
/BX/		/20MG/	/N84913/002/	
	ə WHITE TN PAULSN	2.5MG	N84913 001	
	ə	5MG	N80343 001	
	ə	10MG	N89028 001	
			JUL 24, 1986	
		20MG	N84913 002	
	/SERVISONE/			
/BX/	/LEDERLE LABS/	/5MG/	/N80223/001/	
	ə LEDERLE LABS	5MG	N80223 001	

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL

	PROCAINAMIDE HCL			
/AB/	/VANGARD LABS/	/250MG/	/N87643/001/	
			/JUN/01,/1982/	
/AB/		/500MG/	/N87875/001/	
			/JUN/01,/1982/	
	ə VANGARD LABS	250MG	N87643 001	
			JUN 01, 1982	
	ə	500MG	N87875 001	
			JUN 01, 1982	

TABLET, EXTENDED RELEASE; ORAL

	PROCAINAMIDE HCL			
AB	INWOOD LABS	500MG◈	N89840 001	
			MAR 06, 1989	

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

	PROMETHAZINE HCL			
/BP/	/CHELSEA LABS/	/12.5MG/	/N85986/001/	
/BP/		/50MG/	/N85664/001/	
	ə CHELSEA LABS	12.5MG	N85986 001	
	ə	50MG	N85664 001	

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

	INDERAL LA			
AB	WYETH AYERST LABS	60MG	N18553 004	
			MAR 18, 1987	
AB		80MG	N18553 002	
			APR 19, 1983	
AB		120MG	N18553 003	
			APR 19, 1983	
AB		160MG	N18553 001	
			APR 19, 1983	
	PROPRANOLOL HCL			
AB	INWOOD LABS	60MG◈	N72499 001	
			APR 11, 1989	
AB		80MG◈	N72500 001	
			APR 11, 1989	
AB		120MG◈	N72501 001	
			APR 11, 1989	
AB		160MG◈	N72502 001	
			APR 11, 1989	

PROPRANOLOL HYDROCHLORIDE

SOLUTION; ORAL
PROPRANOLOL HCL

AA	PBI	20MG/5ML¤	N71984 001 MAR 03, 1989
AA		40MG/5ML¤	N71985 001 MAR 03, 1989
AA	ROXANE LABS	20MG/5ML	N70979 001 MAY 15, 1987
AA		40MG/5ML	N70690 001 MAY 15, 1987

TABLET; ORAL
PROPRANOLOL HCL

/AB/	/LEDERLE LABS/	/10MG/	/N72117/001/ /JUN 23, 1988/
/AB/		/20MG/	/N72118/001/ /JUN 23, 1988/
/AB/		/40MG/	/N72119/001/ /JUN 23, 1988/
/AB/		/80MG/	/N72120/001/ /JUN 23, 1988/
	a LEDERLE LABS	10MG	N72117 001 JUN 23, 1988
	a	20MG	N72118 001 JUN 23, 1988
	a	40MG	N72119 001 JUN 23, 1988
	a	80MG	N72120 001 JUN 23, 1988

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION
MESTINON

AP	ICN PHARMS	5MG/ML	N09830 001
/AP/	/ROCHE/	/5MG/ML/	/N09830/001/

SYRUP; ORAL
MESTINON

ICN PHARMS	60MG/5ML	N15193 001
/ROCHE/	/60MG/5ML/	/N15193/001/

TABLET; ORAL
MESTINON

ICN PHARMS	60MG	N09829 002
/ROCHE/	/60MG/	/N09829/002/

TABLET, EXTENDED RELEASE; ORAL
MESTINON

ICN PHARMS	180MG	N11665 001

PYRIDOSTIGMINE BROMIDE

TABLET, EXTENDED RELEASE; ORAL
MESTINON

/ROCHE/	/180MG/	/N11665/001/

QUINIDINE GLUCONATE

INJECTABLE; INJECTION
QUINIDINE GLUCONATE

/LILLY/	/80MG/ML/	/N07529/001/
LILLY	80MG/ML¤	N07529 002 FEB 10, 1989

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

AB	MUTUAL PHARM	100MG¤	N81029 001 APR 14, 1989
AB		200MG¤	N81030 001 APR 14, 1989
AB		300MG¤	N81031 001 APR 14, 1989
/AB/	/PBI/	/200MG/	/N87837/001/ /APR 14, 1982/
	a PBI	200MG	N87837 001 APR 14, 1982
/AB/	/WHITE TN PAULSN/	/200MG/	/N85444/001/
	a WHITE TN PAULSN	200MG	N85444 001

RESERPINE

TABLET; ORAL
RESERPINE

>DLT>	/BP/	/ZENITH LABS/	/0.1MG/	/N11185/001/
>DLT>	/BP/		/0.25MG/	/N11185/002/
>ADD>		a ZENITH LABS	0.1MG	N11185 001
>ADO>		a	0.25MG	N11185 002

RIFAMPIN

>AOO> INJECTABLE; INJECTION
>ADD> RIFADIN
>ADD> MERRELL DOW 600MG/VIAL¤ N50627 001
>AOO> MAY 25, 1989

SECOBARBITAL SODIUM

CAPSULE; ORAL

	SECOBARBITAL SODIUM				
/AA/	/WHITE/TN/PAULSN/	/100MG/	/N85798/001/		
	ə WHITE TN PAULSN	100MG	N85798 001		
	SODIUM SECOBARBITAL				
/AA/	/CHELSEA/LABS/	/100MG/	/N85792/001/		
	ə CHELSEA LABS	100MG	N85792 001		

SECRETIN

INJECTABLE; INJECTION

	SECRETIN-FERRING				
	FERRING LABS	75CU/VIAL	N18290 001		
	/SECRETIN-KABI/				
	/PHARMACIA/LABS/	/75CU/VIAL/	/N18290/001/		

SINCALIDE

INJECTABLE; INJECTION

	KINEVAC				
	/SQUIBB/	/0.005MG/VIAL/	/N17697/001/		
	SQUIBB DIAGS	0.005MG/VIAL	N17697 001		

SODIUM CHLORIDE

INJECTABLE; INJECTION

	SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER			>DLT>	
/AP/	/CUTTER/BIOL/	/450MG/100ML/	/N18503/001/	>DLT>	
	ə CUTTER BIOL	450MG/100ML	N18503 001	>ADD>	
	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER			>ADD>	
/AP/	/CUTTER/BIOL/	/900MG/100ML/	/N18502/001/		
	ə CUTTER BIOL	900MG/100ML	N18502 001		

SOLUTION; IRRIGATION

	/SODIUM CHLORIDE IN PLASTIC CONTAINER/				
/AI/	/CUTTER/BIOL/	/900MG/100ML/	/N18247/001/		
	ə CUTTER BIOL	900MG/100ML	N18247 001		

SODIUM IODIDE, I-123

CAPSULE; ORAL

	SODIUM IODIDE I 123				
AA	BENEDICT NUCLR	200 UCI	N18671 002 MAY 27, 1982		

SODIUM IODIDE, I-123

CAPSULE; ORAL

	SODIUM IODIDE I 123				
AA	MALLINCKRODT	100 UCI			N71909 001 FEB 28, 1989
AA		200 UCI			N71910 001 FEB 28, 1989

SODIUM PHOSPHATE, P-32

SOLUTION; INJECTION, ORAL

	/PHOSPHOTOPE/				
	/SQUIBB/	/1-8MCI/VIAL/	/N10927/001/		
	ə SQUIBB	1-8MCI/VIAL	N10927 001		

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL

	SODIUM POLYSTYRENE SULFONATE				
AA	CAROLINA MED	454GM/BOT			N89910 001 JAN 19, 1989

SOMATROPIN, BIOSYNTHETIC

INJECTABLE; INJECTION

	HUMATROPE				
	/LILLY/	/2MG/VIAL/	/N19640/001/		/JUN/23,/1987/
	ə LILLY	2MG/VIAL	N19640 001		JUN 23, 1987

SPIRONOLACTONE

TABLET; ORAL

	SPIRONOLACTONE				
/AB/	/VANGARD/LABS/	/25MG/	/N87648/001/		/FEB/01,/1982/
	ə VANGARD LABS	25MG	N87648 001 FEB 01, 1982		

SULCONAZOLE NITRATE

CREAM; TOPICAL

	SULCOSYN				
	SYNTEX LABS	1%			N18737 001 FEB 28, 1989

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULTEN-10

> ADD >	AT	BAUSCH & LOMB	10%	N87818 001
> ADD >				FEB 03, 1983
> DLT >	/AT/	/MURO/PHARM/	/10%/	/N87818/001/
> DLT >				/FEB/03,/1983/

SULFINPYRAZONE

CAPSULE; ORAL
SULFINPYRAZONE

/AA/	/VANGARD/LABS/	/200MG/	/N88666/001/
			/FEB/17,/1984/
	ə VANGARD LABS	200MG	N88666 001
			FEB 17, 1984

TECHNETIUM TC-99M FERPENTETATE KIT

/INJECTABLE;/INJECTION/
/RENOTEC/

/SQUIBB/	/N/A/	/N17045/001/
ə SQUIBB	N/A	N17045 001

TECHNETIUM TC-99M SODIUM PERTECHNETATE

SOLUTION; INJECTION, ORAL
SODIUM PERTECHNETATE TC 99M

AP	CIS US	12MCI/ML	N17321 001
AP		24MCI/ML	N17321 002
AP		48MCI/ML	N17321 003
	/GAMMA/DIAG/LABS/	/10-60MCI/ML/	/N17725/001/
	MALLINCKRODT	10-60MCI/ML	N17725 001
/AP/	/SYNCOR/INTL/	/12MCI/ML/	/N17321/001/
/AP/		/24MCI/ML/	/N17321/002/
/AP/		/48MCI/ML/	/N17321/003/

TECHNETIUM TC-99M SULFUR COLLOID

SOLUTION; INJECTION, ORAL
TECHNETIUM TC 99M SULFUR COLLOID

/GAMMA/DIAG/LABS/	/3MCI/ML/	/N17724/001/
MALLINCKRODT	3MCI/ML	N17724 001

THALLOUS CHLORIDE, TL-201

INJECTABLE; INJECTION
THALLOUS CHLORIDE TL 201

AP	SQUIBB DIAGS	1MCI/ML	N18548 001
			DEC 30, 1982

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
SLO-BID

> ADD >	BC	RORER PHARM	75MG	N89539 001
> ADD >				MAY 10, 1989
> ADD >	BC		125MG	N89540 001
> ADD >				MAY 10, 1989

THEO-DUR SPRINKLE

> ADD >	BC	KEY PHARMS	75MG	N88015 001
> ADD >				SEP 10, 1985

TABLET, EXTENDED RELEASE; ORAL
THEO-DUR

AB	KEY PHARMS	100MG	N85328 001
AB		200MG	N86998 001
/BC/		/100MG/	/N85328/001/
/BC/		/200MG/	/N86998/001/

THEOPHYLLINE

AB	INWOOD LABS	100MG	N88320 001
			FEB 21, 1985
AB		200MG	N88321 001
			FEB 21, 1985
/BC/		/100MG/	/N88320/001/
			/FEB/21,/1985/
/BC/		/200MG/	/N88321/001/
			/FEB/21,/1985/

THIOTHIXENE HYDROCHLORIDE

INJECTABLE; INJECTION
NAVANE

/ROERIG/	/EQ/5MG/BASE/ML/	/N16904/002/
ROERIG	EQ 10MG BASE/VIAL	N16904 002

TIMOLOL MALEATE

TABLET; ORAL
BLOCADREN

AB	MS&D	5MG	N18017 001
AB		10MG	N18017 002
AB		20MG	N18017 004

TIMOLOL MALEATE

TABLET; ORAL
TIMOLOL MALEATE

AB	BOLAR PHARM	5MG¤		N72269 001 APR 11, 1989 : MAR 14, 1989
AB		10MG¤		N72270 001 APR 11, 1989 : MAR 14, 1989
AB		20MG¤		N72271 001 APR 11, 1989 : MAR 14, 1989
AB	CORD LABS	5MG¤		N72550 001 APR 13, 1989
AB		10MG¤		N72551 001 APR 13, 1989
AB		20MG¤		N72552 001 APR 13, 1989
AB	PBI	5MG¤		N72001 001 APR 11, 1989 : JAN 10, 1989
AB		10MG¤		N72002 001 APR 11, 1989 : JAN 10, 1989
AB		20MG¤		N72003 001 APR 11, 1989 : JAN 10, 1989
>ADD> AB	QUANTUM PHARMCS	5MG¤		N72466 001 MAY 19, 1989
>ADD> AB		10MG¤		N72467 001 MAY 19, 1989
>ADD> AB		20MG¤		N72468 001 MAY 19, 1989

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

/AB/	/VANGARD LABS/	/500MG/		/N87876 001/ /APR 20, 1982/
	ə VANGARD LABS	500MG		N87876 001 APR 20, 1982

TOLMETIN SODIUM

TABLET; ORAL
TOLECTIN 600

	MCNEIL PHARM	EQ 600MG BASE¤		N17628 002 MAR 08, 1989

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

AB	LEMMON	50MG¤		N72192 001 FEB 02, 1989
AB		100MG¤		N72193 001 FEB 02, 1989

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
TRIAMCINOLONE ACETONIDE

AT	TOPIDERM	0.025%¤		N89274 001 FEB 21, 1989
AT		0.1%¤		N89275 001 FEB 21, 1989
AT		0.5%¤		N89276 001 FEB 21, 1989

TRIHEXYPHENIDYL HYDROCHLORIDE

ELIXIR; ORAL
ARTANE

AA	LEDERLE LABS	2MG/5ML		N06773 009

TRIHEXYPHENIDYL HCL

AA	LIQUIPHARM	2MG/5ML¤		N89514 001 APR 07, 1989

TABLET; ORAL
TRIHEXYPHENIDYL HCL

/AA/	/VANGARD LABS/	/2MG/		/N88035 001/ /JUL 30, 1982/
	ə VANGARD LABS	2MG		N88035 001 JUL 30, 1982

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL

AB	CHELSEA LABS	40MG¤		N72799 001 APR 28, 1989
AB	MYLAN PHARMS	80MG¤		N71482 001 FEB 15, 1989
AB		120MG¤		N71483 001 FEB 15, 1989
AB	SIDMAK LABS	80MG¤		N72124 001 JAN 26, 1989
AB		120MG¤		N72125 001 JAN 26, 1989

WATER FOR IRRIGATION, STERILE

LIQUID; IRRIGATION

STERILE WATER IN PLASTIC CONTAINER			
/BI/	/CUTTER/BIOL/	/100/	/N18246/001/
	∂ CUTTER BIOL	100%	N18246 001

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACEPHEN
G&W LABS 325MG N18060 003
DEC 18, 1986

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL
BIOSCRUB
KW GRIFFEN 4% N19822 001
MAR 31, 1989

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
PSEUDO-CHLOR
KV PHARM 12MG;120MG N71455 001
MAR 01, 1989

PSEUDOEPHEDRINE HCL/CHLORPHENIRAMINE MALEATE
>DLT< /GRAHAM/LABS/ /8MG;120MG/ /N18844/001/
>DLT< /MAR/20,/1985/
>ADD< ə GRAHAM LABS 8MG;120MG N18844 001
>ADD< MAR 20, 1985

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL
PENNTUSS
FISONS EQ 4MG MALEATE/5ML;
EQ 10MG BASE/5ML N18928 001
AUG 14, 1985

/PENNWALT/ /EQ/4MG/MALEATE/5ML;/ /N18928/001/
/EQ/10MG/BASE/5ML/ /AUG/14,/1985/

CHLORPHENIRAMINE POLISTIREX; PHENYLPROPANOLAMINE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL
CORSYM
FISONS EQ 4MG MALEATE/5ML;
EQ 37.5MG HCL/5ML N18050 001
JAN 04, 1984

/PENNWALT/ /EQ/4MG/MALEATE/5ML;/ /N18050/001/
/EQ/37.5MG/HCL/5ML/ /JAN/04,/1984/

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
DIPHENHYDRAMINE HCL
NASKA PHARMA 12.5MG/5ML N70497 001
APR 25, 1989

IBUPROFEN

TABLET; ORAL
IBUPROFEN
MUTUAL PHARM 200MG N72249 001
JAN 10, 1989

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
HUMULIN 70/30
LILLY 30 UNITS/ML;
70 UNITS/ML N19717 001
APR 25, 1989

OXYMETAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
VISINE II
PFIZER 0.025% N19407 001
MAR 31, 1989

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

>DLT< /SYRUP;/ORAL/
>DLT< /PHENERGAN/VC/
>DLT< /WYETH/AYERST/LABS/ /10MG/5ML;6.25MG/5ML/ /N08604/004/
>DLT< /AUG/11,/1988/
>ADD< ə WYETH AYERST LABS 10MG/5ML;6.25MG/5ML N08604 004
>ADD< AUG 11, 1988

POVIDONE-IODINE

SOLUTION; TOPICAL
POVIDONE IODINE
BAXTER 1% N19522 001
MAR 31, 1989

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
TRIPROLIDINE AND PSEUDOEPHRINE HCL

KV PHARM	120MG;5MG	N71798 001 MAR 16, 1989

SYRUP; ORAL

/MYFED/ /PBI/	/30MG/5ML;1.25MG/5ML/	/N88116/001/ /MAR/04,/1983/
@ PBI	30MG/5ML;1.25MG/5ML	N88116 001 MAR 04, 1983

PSEUDOEPHEDRINE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL
PSEUDO-12

FISONS	EQ 60MG HCL/5ML	N19401 001 JUN 19, 1987
/PENNWALT/	/EQ/60MG/HCL/5ML/	/N19401/001/ /JUN/19,/1987/

DRUG PRODUCTS IN THE DIVISION OF BLOOD AND BLOOD PRODUCTS / CUMULATIVE SUPPLEMENT NUMBER 5 / JAN'89- MAY'89
APPROVED UNDER SECTION 505 OF THE ACT LIST

NO MAY 1989 APPROVALS

ORPHAN DRUG PRODUCT DESIGNATIONS

SECTION 526 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT CONTAINS PROVISIONS WHEREBY FDA MAY DESIGNATE A SPONSOR'S DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT AS A "DESIGNATED ORPHAN DRUG." SECTION 527 OF THE ACT ESTABLISHES A PROCESS WHEREBY A SPONSOR MAY RECEIVE SEVEN YEARS OF EXCLUSIVE APPROVAL STATUS IF THAT SPONSOR IS THE FIRST TO ACHIEVE NEW DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT APPROVAL FOR A DESIGNATED ORPHAN DRUG FOR THE DESIGNATED INDICATION(S). THE EXCLUSIVE APPROVAL MAY BE REVOKED BY WRITTEN CONSENT OF THE SPONSOR OR BY FDA ACTION AFTER FINDING THAT THE SPONSDR 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).

THE "CUMULATIVE LIST OF ORPHAN DRUG PRODUCT DESIGNATIONS," ISSUED AS AN ADDENDUM TO THE 9TH EDITION OF APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, IS CURRENT THROUGH MARCH 31, 1989. THIS SECTION OF THE CUMULATIVE SUPPLEMENT WILL SERVE AS AN UPDATE TO THAT ADDENDUM AND WILL REPLACE THE FORMER SECTION ENTITLED "ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL." THE NDA NUMBER/LICENSE NUMBER, APPROVAL DATE, DOSAGE FORM, ROUTE OF ADMINISTRATION, AND STRENGTH THAT APPEARED IN THE FORMER SECTION MAY BE FOUND ELSEWHERE IN THIS PUBLICATION FOR APPROVED DRUGS; FOR LICENSED BIOLOGICALS, THIS INFORMATION WILL NO LONGER BE DISPLAYED.

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).

REFER BACK TO THE ADDENDUM TO APPROVED DRUG PRODUCTS, 9TH EDITION FOR A FULL LISTING OF ORPHAN DRUG PRODUCTS DESIGNATIONS. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

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].

DRUG DESIGNATIONS
[Approved for Marketing*]
[Exclusive Approval**]

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: BROMHEXINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF MILD TO MODERATE KERATOCONJUNCTIVITIS SICCA IN PATIENTS WITH SJOGREN'S SYNDROME.	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. 90 EAST RIDGE P.O. BOX 368 RIDGEFIELD, CT 06877
GENERIC: FLUDARABINE PHOSPHATE TRADE: NOT ESTABLISHED	TREATMENT OF NON-HODGKIN'S LYMPHOMA (NHL).	TRITON BIOSCIENCES 1501 HARBOR BAY PARKWAY ALAMEDA, CA 94501
GENERIC: SOMATROPIN TRADE: SAIZEN	ENHANCEMENT OF NITROGEN RETENTION IN HOSPITALIZED PATIENTS SUFFERING FROM SEVERE BURNS.	SERONO LABORATORIES 100 LONGWATER CIRCLE NORWELL, MA 02061

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

NO MAY 1989 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, HFN-250, ROOM 17B-06, 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, 9TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
ALBULTEROL; METAPROTERENOL SULFATE (METERED DOSE INHALER)	AUG 25, 19B8	FEB 09, 1989
TOLMETIN SODIUM (CAPSULE AND TABLET)	APR 20, 1989	

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, 9TH 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
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	650MG 10MG	88 P-0416/CP	MORAVEC	NEW STRENGTH	APPROVED MAR 01, 1989
CARMUSTINE, STERILE INJECTABLE; INJECTION	200MG/VIAL	88 P-0410/CP	QUAD PHARMS	NEW STRENGTH	APPROVED FEB 13, 1989
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	20MG/ML (250ML/CONTAINER)	88 P-0379/CP	BAXTER	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 01, 1989

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
HALOPERIDOL CONCENTRATE; ORAL	EQ 0.5MG/5ML	89P-0088/CP	UDL LABS	NEW STRENGTH	APPROVED MAY 11, 1989
HALOPERIDOL DECANOATE INJECTABLE; INJECTION	EQ 50MG BASE/ML (2ML/CONTAINER)	88 P-0411/CP	QUAD PHARMS	NEW STRENGTH	APPROVED FEB 13, 1989
HYDROCORTISONE VALERATE LOTION; TOPICAL	0.2%	89P-0028/CP	MCKENNA, CONNER & CUNEO	NEW DOSAGE FORM	APPROVED MAY 10, 1989
HYDROCORTISONE VALERATE SOLUTION; TOPICAL	0.2%	89P-0029/CP	MCKENNA, CONNER & CUNEO	NEW DOSAGE FORM	APPROVED MAY 10, 1989
MORPHINE SULFATE CAPSULE, EXTENDED RELEASE; ORAL	30MG	89P-0071/CP	OXFORD RES INTL	NEW DOSAGE FORM	APPROVED MAY 10, 1989