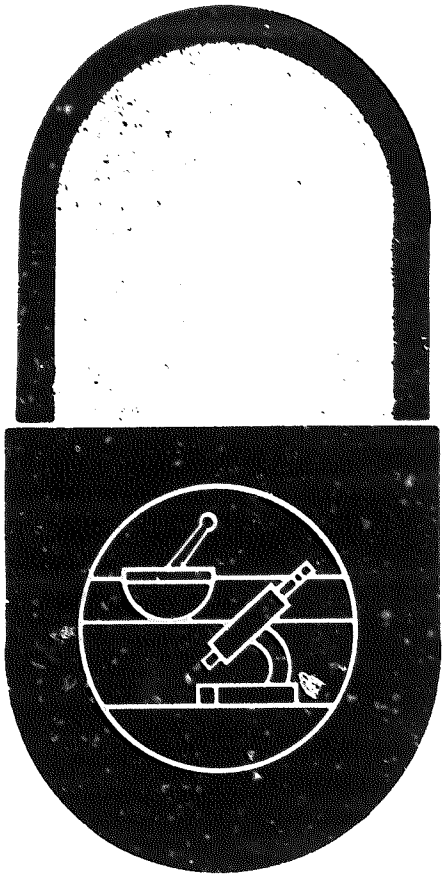
AUG 24 1988 HE20.4215/2nd/Supp.6

CUMULATIVE SUPPLEMENT 6
JAN'88-JUN'88



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

8TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT

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CUMULATIVE SUPPLEMENT 6

JUNE 1988

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, 8th 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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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, List of Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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, List of Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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 List of Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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 8th 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 (ointment;topical)	SEP 3, 1986 (51 FR 31371)
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.

1.4 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 1987) 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.

COUNTS CUMULATIVE BY QUARTER[1]

CATEGORIES COUNTED	DEC 1987	MAR 1988	JUN 1988
DRUG PRODUCTS LISTED	9709	9528	9769*
SINGLE SOURCE	2096 (21.6%)	1997 (21.0%)	1975 (20.2%)
MULTISOURCE	7613 (78.4%)	7531 (79.0%)	7794 (79.8%)
THERAPEUTICALLY EQUIVALENT	6691 (68.9%)	6660 (69.9%)	6937 (71.0%)
NOT THERAPEUTICALLY EQUIVALENT	848 (8.7%)	770 (8.1%)	757 (7.8%)
EXCEPTIONS[2]	74 (0.8%)	101 (1.0)	100 (1.0%)
NEW MOLECULAR ENTITIES APPROVED	--	1	2
NUMBER OF APPLICANTS	349	361	378

*This number is inclusive of products discontinued since December 1987, and any products approved or discontinued through June 1988.

(1) Cumulative counts are calculated from January 1, 1988 to, and including, the month indicated.

(2) Amino acid-containing products of varying composition (see Introduction, page I-8 of the List).

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

	MIKART	500MG;50MG;40MG	N89451 001
			MAY 23, 1988

BUTALBITAL, APAP, AND CAFFEINE

AB	HALSEY DRUG	325MG;50MG;40MG	N89536 001
			FEB 16, 1988

ACETAMINOPHEN; CODEINE PHOSPHATE

ELIXIR; ORAL

MYAPAP AND CODEINE

AA	MY K LABS	120MG/5ML;12MG/5ML	N87006 001

MYAPAP W/ CODEINE

/AA/	/MYK/LABS/	/120MG/5ML;12MG/5ML/	/N87006/001/

TYLENOL W/ CODEINE

/AA/	/MCNEIL/LABS/	/120MG/5ML;12MG/5ML/	/N85057/001/
AA	MCNEIL PHARM	120MG/5ML;12MG/5ML	N85057 001

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

/AA/	/BOOTS/LABS/	/300MG;30MG/	/N87762/001/
			/DEC 10, 1982/
AA	MUTUAL PHARM	300MG;15MG	N89671 001
			FEB 10, 1988
AA		300MG;30MG	N89672 001
			FEB 10, 1988
AA		300MG;60MG	N89673 001
			FEB 10, 1988
AA	PHARMAFAIR	300MG;30MG	N87762 001
			DEC 10, 1982

TYLENOL W/ CODEINE

/AA/	/MCNEIL/LABS/	[illegible]	/N85056/001/
/AA/		[illegible]	/N85056/002/
/AA/		[illegible]	/N85056/003/
/AA/		[illegible]	/N85056/004/
AA	MCNEIL PHARM	[illegible]	N85056 001
AA		[illegible]	N85056 002
AA		325MG;30MG	N85056 003
AA		325MG;60MG	N85056 004

TYLENOL W/ CODEINE NO. 3

/AA/	/MCNEIL/LABS/	/300MG;7.5MG/	/N85055/001/
AA	MCNEIL PHARM	300MG;7.5MG	N85055 001

TYLENOL W/ CODEINE NO. 2

/AA/	/MCNEIL/LABS/	/300MG;15MG/	/N85055/002/
AA	MCNEIL PHARM	300MG;15MG	N85055 002

TYLENOL W/ CODEINE NO. 3

/AA/	/MCNEIL/LABS/	/300MG;30MG/	/N85055/003/
AA	MCNEIL PHARM	300MG;30MG	N85055 003

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

TYLENOL W/ CODEINE NO. 4

/AA/	/MCNEIL/LABS/	/300MG;60MG/	/N85055/004/
AA	MCNEIL PHARM	300MG;60MG	N85055 004

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

CO-GESIC

	AA	CENTRAL PHARMS	500MG;5MG	N89360 001
				MAR 02, 1988

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>ADD>	AA	BEECHAM LABS	650MG;7.5MG	N89725 001
>ADD>				SEP 30, 1987
	AA	LUCHEM PHARMS	500MG;5MG	N89696 001
				APR 21, 1988
>ADD>	AA	MIKART	650MG;7.5MG	N89689 001
>ADD>				JUN 29, 1988

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

	AB	HALSEY DRUG	325MG;50MG	N72105 001
				MAY 13, 1988
	AB		650MG;100MG	N72106 001
				MAY 13, 1988
	AB	MYLAN PHARMS	650MG;100MG	N72195 001
				FEB 16, 1988

ACETAZOLAMIDE

TABLET; ORAL

ACETAZOLAMIDE

>ADD>	AB	MUTUAL PHARM	125MG	N89752 001
>ADD>				JUN 22, 1988
>ADD>	AB		250MG	N89753 001
>ADD>				JUN 22, 1988

DIAMOX

>ADD>	AB	LEDERLE LABS	125MG	N08943 001

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

ACETAZOLAMIDE SODIUM

AP	QUAD PHARMS	500MG/VIAL*	N89619 001 JAN 13, 1988

DIAMOX

AP	LEDERLE LABS	500MG/VIAL	N09388 001

ALBUTEROL SULFATE

CAPSULE; INHALATION

VENTOLIN ROTACAPS

GLAXO	EQ 0.2MG BASE*	N19489 001 MAY 04, 1988

ALSEROXYLON

TABLET; ORAL

RAUTENSIN

/BP/	/DORSEY/LABS/	/2MG/	/N09215/001/
	∂ DORSEY LABS	2MG	N09215 001

AMCINONIDE

> ADD > LOTION; TOPICAL

> ADD > CYCLOCORT

> ADD > LEDERLE LABS 0.1%* N19729 001
> ADD > JUN 13, 1988

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

AMILORIDE HCL AND HYDROCHLOROTHIAZIDE

AB	BARR LABS	5MG;50MG*	N71111 001 MAY 10, 1988

AMINO ACIDS

INJECTABLE; INJECTION

NEOPHAN 6.4%

/KABIVITRUM/	/6.4%/	/N18792/001/ /JAN 17, 1984/
∂ KABIVITRUM	6.4%	N18792 001 JAN 17, 1984

TRAVASOL 10% IN PLASTIC CONTAINER

BAXTER	10%*	N18931 004 APR 27, 1988

AMINOCAPROIC ACID

INJECTABLE; INJECTION

AMINOCAPROIC ACID

> ADD > AP	ABBOTT LABS	250MG/ML*	N70888 001 JUN 16, 1988
> ADD >			

AMINOPHYLLINE

TABLET; ORAL

AMINOPHYLLINE

/RX/	/BARR LABS/	/100MG/	/N88297/001/ /AUG 19, 1983/
/RX/		/200MG/	/N88298/001/ /AUG 19, 1983/
	∂ BARR LABS	100MG	N88297 001 AUG 19, 1983
	∂	200MG	N88298 001 AUG 19, 1983
/RX//∂/VALE CHEM/		/100MG/	/N84533/001/
	VALE CHEM	100MG	N84533 001

AMINOSALICYLATE SODIUM

TABLET; ORAL

TEEBACIN

/RX/	/CNSOL MIDLAND/	/500MG/	/N07320/002/
	∂ CNSOL MIDLAND	500MG	N07320 002

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIL

/RX/	/PARKE/DAVIS/	/10MG/	/N83936/001/
/RX/		/25MG/	/N83937/001/
/RX/		/50MG/	/N83938/002/
/RX/		/75MG/	/N84957/001/
/RX/		/100MG/	/N85093/001/
/RX/		/150MG/	/N86295/001/
AB	WARNER CHILCOTT	10MG	N83939 001
AB		25MG	N83937 001
AB		50MG	N83938 002
AB		75MG	N84957 001
AB		100MG	N85093 001
AB		150MG	N86295 001

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL

AB	PAR PHARM	EQ 12.5MG BASE;5MG*	N72277 001	MAY 09, 1988
AB		25MG;10MG*	N72278 001	MAY 09, 1988
AB	PHARM BASICS	EQ 12.5MG BASE;5MG*	N70477 001	JAN 12, 1988
AB		EQ 25MG BASE;10MG*	N70478 001	JAN 12, 1988

AMOXICILLIN

CAPSULE; ORAL

AMOXICILLIN

AB	CLONMEL CHEMS	250MG*	N62884 001	FEB 25, 1988
AB		500MG*	N62881 001	FEB 25, 1988

POWDER FOR RECONSTITUTION; ORAL

POLYMOX

AB	BRSTL MYRS IND	125MG/5ML*	N62885 001	MAR 08, 1988
AB		250MG/5ML*	N62885 002	MAR 08, 1988

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

AMPICILLIN

AB	CLONMEL CHEMS	EQ 250MG BASE*	N62883 001	FEB 25, 1988
AB		EQ 500MG BASE*	N62882 001	FEB 25, 1988

POLYCILLIN

AB	BRSTL MYRS IND	EQ 250MG BASE*	N62888 001	MAR 04, 1988
AB		EQ 500MG BASE*	N62888 002	MAR 04, 1988

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

ORPHENADRINE COMPOUND

> ADD >				
> ADD > AB	VITARINE	385MG;30MG;25MG*	N71564 001	JUN 23, 1988
> ADD >				

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

ORPHENADRINE COMPOUND DOUBLE STRENGTH

> ADD >				
> ADD > AB	VITARINE	770MG;60MG;50MG*	N71565 001	JUN 23, 1988
> ADD >				

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

COMPOUND 65

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

ASPIRIN; HYDROCODONE BITARTRATE

TABLET; ORAL

AZDONE

	CENTRAL PHARMS	500MG;5MG*	N89420 001	JAN 25, 1988

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

> ADD >		AZATHIOPRINE		
> ADD > AP		QUAD PHARMS	EQ 100MG BASE/VIAL*	N71056 001 JUN 08, 1988
> ADD >				
		IMURAN		
> ADD > AP		BURROUGHS WELLC	EQ 100MG BASE/VIAL	N17391 001

BACLOFEN

TABLET; ORAL

BACLOFEN

AB	PHARM BASICS	10MG*	N71260 001	MAY 06, 1988
AB		20MG*	N71261 001	MAY 06, 1988
AB	VITARINE	10MG*	N71901 001	APR 13, 1988
AB		20MG*	N71902 001	APR 13, 1988
		LIORESAL		
AB	GEIGY PHARMS	10MG	N17851 001	
		LIORESAL DS		
AB	GEIGY PHARMS	20MG	N17851 003	JAN 20, 1982

BENZTHIAZIDE

TABLET; ORAL

BENZTHIAZIDE

/BP/	/PRIVATE FHLTNS/	/50MG/	/N83206/001/	> ADD >	
	∂ PRIVATE FHLTNS	50MG	N83206 001	> ADD >	

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

AA	PAR PHARM	0.5MG	N88877 001 APR 11, 1985		
AA		1MG	N88894 001 APR 11, 1985		
AA		2MG	N88895 001 APR 11, 1985		
/BP/		/0.5MG/	/N88877/001/ /APR/11,/1985/		
/BP/		/1MG/	/N88894/001/ /APR/11,/1985/		
/BP/		/2MG/	/N88895/001/ /APR/11,/1985/		
> ADD > AA	PHARM BASICS	0.5MG∗	N89211 001 JUN 14, 1988		
> ADD > AA		1MG∗	N89212 001 JUN 14, 1988		
> ADD > AA		2MG∗	N89213 001 JUN 14, 1988		
AA	QUANTUM PHARMCS	0.5MG	N88514 001 JAN 31, 1984		
AA		1MG	N88510 001 JAN 31, 1984		
AA		2MG	N88511 001 JAN 31, 1984		
/BP/		/0.5MG/	/N88514/001/ /JAN/31,/1984/		
/BP/		/1MG/	/N88510/001/ /JAN/31,/1984/		
/BP/		/2MG/	/N88511/001/ /JAN/31,/1984/		

ROBENTIN

AA	MS&D	0.5MG	N09193 004
AA		1MG	N09193 003
AA		2MG	N09193 002
/BP/		/0.5MG/	/N09193/004/
/BP/		/1MG/	/N09193/003/
/BP/		/2MG/	/N09193/002/

BETAMETHASONE DIPROPIONATE

LOTION; TOPICAL

BETAMETHASONE DIPROPIONATE

AB	COPLEY PHARM	EQ 0.05% BASE∗	N71882 001 JUN 06, 1988		

BETAMETHASONE VALERATE

CREAM; TOPICAL

BETAMETHASONE VALERATE

AB	TARO PHARMS	EQ 0.1% BASE∗	N72041 001 JAN 06, 1988		

LOTION; TOPICAL

BETAMETHASONE VALERATE

AB	COPLEY PHARM	EQ 0.1% BASE∗	N71883 001 APR 22, 1988		

BETHANECHOL CHLORIDE

INJECTABLE; INJECTION

BETHANECHOL CHLORIDE

AP	QUAD PHARMS	5MG/ML∗	N89815 001 APR 12, 1988		

URECHOLINE

AP	MS&D	5MG/ML	N06536 001		

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

AP	QUAD PHARMS	50MG/ML∗	N71181 001 FEB 16, 1988		

BROMPHENIRAMINE MALEATE

TABLET; ORAL

BROMPHENIRAMINE MALEATE

/AA/	/BARR LABS/	/4MG/	/N84468/001/		
	∂ BARR LABS	4MG	N84468 001		

> ADD > BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE

> ADD > INJECTABLE; INJECTION
> ADD > BUPIVACAINE HCL AND EPINEPHRINE
> ADD > ABBOTT LABS 0.25%;0.005MG/ML* N71166 001
> ADD > JUN 16, 1988
> ADD > 0.25%;0.005MG/ML* N71165 001
> ADD > JUN 16, 1988
> ADD > 0.25%;0.005MG/ML* N71167 001
> ADD > JUN 16, 1988
> ADD > 0.5%;0.005MG/ML* N71168 001
> ADD > JUN 16, 1988
> ADD > 0.5%;0.005MG/ML* N71169 001
> ADD > JUN 16, 1988
> ADD > 0.5%;0.005MG/ML* N71170 001
> ADD > JUN 16, 1988
> ADD > 0.75%;0.005MG/ML* N71171 001
> ADD > JUN 16, 1988

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

SOLUTION; INTRAPERITONEAL
DIANEAL PD-1 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
> ADD > AT BAXTER 25.7MG/100ML;3.5GM/100ML;
> ADD > 15.2MG/100ML;567MG/100ML;
> ADD > 392MG/100ML* N17512 010
> ADD > NOV 18, 1985
DIANEAL PD-2 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
> ADD > AT BAXTER 25.7MG/100ML;3.5GM/100ML;
> ADD > 5.08MG/100ML;538MG/100ML;
> ADD > 448MG/100ML* N17512 011
> ADD > NOV 18, 1985
> ADD > INPERSOL W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
> ADD > AT ABBOTT LABS 25.7MG/100ML;3.5GM/100ML;
> ADD > 15.2MG/100ML;567MG/100ML;
> ADD > 392MG/100ML* N18379 007
> ADD > JUN 24, 1988
> ADD > INPERSOL-LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
> ADD > AT ABBOTT LABS 25.7MG/100ML;3.5GM/100ML;
> ADD > 5.08MG/100ML;538MG/100ML;
> ADD > 448MG/100ML* N18379 008
> ADD > JUN 24, 1988

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION
DEXTROSE 2.5% IN HALF-STRENGTH LACTATED RINGER'S IN PLASTIC CONTAINER
KENDALL MCGAW 10MG/100ML;2.5GM/100ML;15MG/100ML; 300MG/100ML; 160MG/100ML* N19634 001
FEB 24, 1988
DEXTROSE 4% IN MODIFIED LACTATED RINGER'S IN PLASTIC CONTAINER
KENDALL MCGAW 4MG/100ML;4GM/100ML;6MG/100ML; 120MG/100ML;62MG/100ML* N19634 002
FEB 24, 1988
DEXTROSE 5% IN LACTATED RINGER'S IN PLASTIC CONTAINER
AP KENDALL MCGAW 20MG/100ML;5GM/100ML;30MG/100ML; 600MG/100ML; 310MG/100ML* N19634 003
FEB 24, 1988

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION
LACTATED RINGER'S IN PLASTIC CONTAINER
AP KENDALL MCGAW 20MG/100ML;30MG/100ML;600MG/100ML; 310MG/100ML* N19632 001
FEB 29, 1988

CARBAMAZEPINE

TABLET, CHEWABLE; ORAL
CARBAMAZEPINE
AB WARNER CHILCOTT 100MG* N71940 001
FEB 01, 1988
TEGRETOL
AB GEIGY PHARMS 100MG N18281 001

CEFACLOR

POWDER FOR RECONSTITUTION; ORAL
CECLOR
LILLY EQ 187MG BASE/5ML* N62206 003
APR 20, 1988
EQ 375MG BASE/5ML* N62206 004
APR 20, 1988

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

	ANGEF			
AP	SK&F LABS	EQ 5GM BASE/VIAL	N50461 004	
	CEFAZOLIN SODIUM			
AP	ELKINS SINN	EQ 250MG BASE/VIAL*	N62807 001	JAN 12, 1988
AP		EQ 500MG BASE/VIAL*	N62807 002	JAN 12, 1988
AP		EQ 1GM BASE/VIAL*	N62807 003	JAN 12, 1988
AP		EQ 5GM BASE/VIAL*	N62807 004	JAN 12, 1988
AP		EQ 10GM BASE/VIAL*	N62807 005	JAN 12, 1988
AP		EQ 20GM BASE/VIAL*	N62807 006	JAN 12, 1988

CEFOTETAN DISODIUM

INJECTABLE; INJECTION

	CEFOTAN			
	STUART PHARMS	EQ 10GM BASE/VIAL*	N50588 003	APR 25, 1988

CEPHALEXIN

CAPSULE; ORAL

	CEPHALEXIN			
AB	JEROME STEVENS	EQ 250MG BASE*	N62870 001	MAR 17, 1988
AB		EQ 500MG BASE*	N62869 001	MAR 17, 1988
AB	TAG PHARMS	EQ 250MG BASE*	N62821 001	FEB 05, 1988
AB		EQ 500MG BASE*	N62823 001	FEB 05, 1988
>ADD> AB	YOSHITOMI PHARM	EQ 250MG BASE*	N62872 001	JUN 20, 1988

PONDER FOR RECONSTITUTION; ORAL

	CEPHALEXIN			
AB	TAG PHARMS	EQ 125MG BASE/5ML*	N62873 001	MAY 23, 1988
AB		EQ 250MG BASE/5ML*	N62867 001	APR 15, 1988

CEPHALEXIN HYDROCHLORIDE

TABLET; ORAL

	KEFTAB			
	LILLY	EQ 333MG BASE*	N50614 003	MAY 16, 1988

CEPHRADINE

CAPSULE; ORAL

	CEPHRADINE			
AB	BARR LABS	250MG*	N62850 001	APR 22, 1988
AB		500MG*	N62851 001	APR 22, 1988
AB	VITARINE	250MG*	N62813 001	FEB 25, 1988
AB		500MG*	N62813 002	FEB 25, 1988

PONDER FOR RECONSTITUTION; ORAL

	CEPHRADINE			
AB	BARR LABS	125MG/5ML*	N62858 001	MAY 19, 1988
AB		250MG/5ML*	N62859 001	MAY 19, 1988

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

	CHLORDIAZEPOXIDE HCL		
/AB/	/PUREPAC/PHARM/	/5MG/	/N85155/001/
/AB/		/10MG/	/N84939/002/
/AB/		/25MG/	/N85144/001/
	∂ PUREPAC PHARM	5MG	N85155 001
	∂	10MG	N84939 002
	∂	25MG	N85144 001
	LYGEN		
/AB/	/BANMAX/PHARMS/	/5MG/	/N85107/002/
/AB/		/10MG/	/N85009/001/
/AB/		/25MG/	/N85108/001/
	∂ BANMAX PHARMS	5MG	N85107 002
	∂	10MG	N85009 001
	∂	25MG	N85108 001

CHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
CHLOROTHIAZIDE W/ RESERPINE

/BP/	/BOLAR/PHARM/	/250MG;0.125MG/		/N04853/001/
	@ BOLAR PHARM	250MG;0.125MG		N04853 001

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

/AA/	/BARR/LABS/	/4MG/		/N80700/001/
	@ BARR LABS	4MG		N80700 001

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHLORPROMAZINE HCL

AP	MARSAM PHARMS	25MG/ML		N89563 001 APR 15, 1988

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

AA	BARR LABS	500MG		N89895 001 MAY 04, 1988
AA	CORD LABS	250MG		N89852 001 MAY 04, 1988
AA		500MG		N89853 001 MAY 04, 1988
AA	LEMMON	500MG		N89859 001 MAY 04, 1988

PARAFON FORTE DSC

AA	MCNEIL PHARM	500MG		N11529 002 JUN 15, 1987

CHOLESTYRAMINE

BAR, CHEWABLE; ORAL
CHOLYBAR

	PARKE DAVIS	EQ 4GM RESIN/BAR		N71621 001 MAY 26, 1988
		EQ 4GM RESIN/BAR		N71739 001 MAY 26, 1988

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL
CLEOCIN HCL

	UPJOHN	EQ 300MG BASE		N50162 003 APR 14, 1988

CLINDAMYCIN PHOSPHATE

INJECTABLE; IM-IV
CLINDAMYCIN PHOSPHATE

AP	LOCH PHARMS	EQ 150MG BASE/ML		N62905 001 MAY 09, 1988

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

AP	ELKINS SINN	EQ 150MG BASE/ML		N62953 001 APR 21, 1988
AP	LEDERLE PARNTLS	EQ 150MG BASE/ML		N62889 001 APR 25, 1988
AP	LEMMON	EQ 150MG BASE/ML	> ADD >	N62900 001 JUN 08, 1988
AP	LYPHOMED	EQ 150MG BASE/ML	> ADD >	N62747 001 JUN 03, 1988
AP	QUAD PHARMS	EQ 150MG BASE/ML	> ADD >	N62877 001 MAR 15, 1988
AP	SOLOPAK LABS	EQ 150MG BASE/ML	> ADD >	N62819 001 MAR 15, 1988
AP		EQ 150MG BASE/ML	> ADD >	N62852 001 MAR 17, 1988

CLOFIBRATE

CAPSULE; ORAL
CLOFIBRATE

AB	CORD LABS	500MG		N72191 001 MAY 02, 1988

CLONIDINE HYDROCHLORIDE

TABLET; ORAL
CLONIDINE HCL

AB	LEDERLE LABS	0.1MG		N71783 001 APR 05, 1988
AB		0.2MG		N71784 001 APR 05, 1988
AB		0.3MG		N71785 001 APR 05, 1988

CLONIDINE HYDROCHLORIDE

TABLET; ORAL
CLONIDINE HCL

>ADD>	AB	NARNER CHILCOTT	0.1MG	N72138 001 JUN 13, 1988
>ADD>				
>ADD>	AB		0.2MG	N72139 001 JUN 13, 1988
>ADD>				
>ADD>	AB		0.3MG	N72140 001 JUN 13, 1988
>ADD>				

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL
CLORAZEPATE DIPOTASSIUM

AB		CHELSEA LABS	3.75MG	N71878 001 MAR 15, 1988
AB			7.5MG	N71879 001 MAR 15, 1988
AB			15MG	N71860 001 MAR 15, 1988
AB		PUREPAC PHARM	3.75MG	N71924 001 APR 25, 1988
AB			7.5MG	N71925 001 APR 25, 1988
AB			15MG	N71926 001 APR 25, 1988
AB		NARNER CHILCOTT	3.75MG	N71774 001 MAR 01, 1988
AB			7.5MG	N71775 001 MAR 01, 1988
AB			15MG	N71776 001 MAR 01, 1988

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM

AB		NARNER CHILCOTT	3.75MG	N71828 001 MAR 03, 1988
AB			7.5MG	N71829 001 MAR 03, 1988
AB			15MG	N71830 001 MAR 03, 1988
AB		NATSON LABS	3.75MG	N71852 001 FEB 09, 1988
AB			7.5MG	N71853 001 FEB 09, 1988
AB			15MG	N71854 001 FEB 09, 1988

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL
GEN-XENE

AB		ALRA LABS	3.75MG	N71787 001 APR 26, 1988
AB			7.5MG	N71788 001 APR 26, 1988
AB			15MG	N71789 001 APR 26, 1988

CLOXACILLIN SODIUM

POWDER FOR RECONSTITUTION; ORAL
CLOXACILLIN SODIUM

AA		BIOCRAFT LABS	EQ 125MG BASE/5ML	N62268 001
/AA/			/EQ 125MG BASE/5ML/	/N62268/001/
TEGOPEN				
AA		BRISTOL LABS	EQ 125MG BASE/5ML	N50192 001
AA			EQ 125MG BASE/5ML	N61453 001
/AA/			/EQ 125MG BASE/5ML/	/N50192/001/
/AA/			/EQ 125MG BASE/5ML/	/N61453/001/

COLCHICINE; PROBENECID

TABLET; ORAL
PROBENECID AND COLCHICINE

/BP/		/BEECHAM LABS/	/0.5MG;500MG/	/N84321/001/
		∂ BEECHAM LABS	0.5MG;500MG	N84321 001
PROBENECID W/ COLCHICINE				
/BP/		/LEDERLE LABS/	/0.5MG;500MG/	/N86954/001/
		∂ LEDERLE LABS	0.5MG;500MG	N86954 001

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
CYCLOBENZAPRINE HCL

AB		DANBURY PHARMA	10MG	N71611 001 MAY 03, 1989 : FEB 29, 1988
FLEXERIL				
AB		MS&D	10MG	N17821 002

DACARBAZINE

INJECTABLE; INJECTION
DACARBAZINE

		QUAD PHARMS	500MG/VIAL	N71563 001 MAY 06, 1988

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

DESIPRAMINE HCL

	AB	CORD LABS	10MG	N72099 001 MAY 24, 1988
	AB		25MG	N72100 001 MAY 24, 1988
	AB		50MG	N72101 001 MAY 24, 1988
> ADD >	AB		75MG	N72102 001 JUN 20, 1988
> ADD >	AB		100MG	N72103 001 JUN 20, 1988
> ADD >	AB		150MG	N72104 001 JUN 20, 1988
	AB	VITARINE	10MG	N72167 001 FEB 03, 1988
	AB		150MG	N72254 001 FEB 03, 1988

NORPRAMIN

	AB	MERRELL DON	10MG	N14399 007 FEB 11, 1982
	AB		150MG	N14399 006

DESONIDE

OINTMENT; TOPICAL

DESOWEN

> ADD >	AB	OWEN LABS	0.05%	N71425 001 JUN 15, 1988

TRIDESILON

> ADD >	AB	MILES PHARM	0.05%	N17426 001

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE

/BP/	/BARR LABS/	/0.25MG/	/N84013/001/	
/BP/		/0.25MG/	/N84764/001/	
/BP/		/0.5MG/	/N84084/001/	
/BP/		/0.75MG/	/N84081/001/	
/BP/		/0.75MG/	/N84765/001/	
/BP/		/1.5MG/	/N84086/001/	
/BP/		/1.5MG/	/N84763/001/	
	a BARR LABS	0.25MG	N84013 001	
	a	0.25MG	N84764 001	
	a	0.5MG	N84084 001	
	a	0.75MG	N84081 001	
	a	0.75MG	N84765 001	
	a	1.5MG	N84086 001	
	a	1.5MG	N84763 001	

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 10% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	10GM/100ML	N19626 004 FEB 02, 1988

DEXTROSE 2.5% IN PLASTIC CONTAINER

KENDALL MCGAW	2.5GM/100ML	N19626 001 FEB 02, 1988

DEXTROSE 5% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	5GM/100ML	N19626 002 FEB 02, 1988

DEXTROSE 7.7% IN PLASTIC CONTAINER

KENDALL MCGAW	7.7GM/100ML	N19626 003 FEB 02, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

/DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/W/POTASSIUM/CHLORIDE/0.075%/IN/PLASTIC/CONTAINER/

/ABBOTT/LABS/ /5GM/100ML;74.5MG/100ML;/ /300MG/100ML/ /N18816/001/ /JAN/17,/1986/

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

/DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/N//POTASSIUM/CHLORIDE/
/0.15%/IN/PLASTIC/CONTAINER/
/ABBOTT/LABS/ /5GM/100ML;149MG/100ML;/
/300MG/100ML/ /N16876/ddz/
/JAN/17,/1986/

/DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/N//POTASSIUM/CHLORIDE/
/0.224%/IN/PLASTIC/CONTAINER/
/ABBOTT/LABS/ /5GM/100ML;224MG/100ML;/
/300MG/100ML/ /N16876/ddz/
/JAN/17,/1986/

/DEXTROSE/5%/SODIUM/CHLORIDE/0.225%/POTASSIUM/CHLORIDE/
/0.15%/IN/PLASTIC/CONTAINER/
/ABBOTT/LABS/ /5GM/100ML;150MG/100ML;/
/225MG/100ML/ /N16365/ddi/

/DEXTROSE 5%; SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/
/0.224% IN PLASTIC CONTAINER/
/AP/ /ABBOTT/LABS/ /5GM/100ML;224MG/100ML;/
/450MG/100ML/ /N16362/ddz/

/DEXTROSE 5%; SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/
/0.3% IN PLASTIC CONTAINER/
/AP/ /ABBOTT/LABS/ /5GM/100ML;300MG/100ML;/
/450MG/100ML/ /N16362/ddz/

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;37MG/100ML; 200MG/100MLM N19630 031 FEB 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;37MG/100ML; 450MG/100MLM N19630 037 FEB 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;37MG/100ML; 900MG/100MLM N19630 043 FEB 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;37MG/100ML; 110MG/100MLM N19630 001 FEB 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;37MG/100ML; 200MG/100MLM N19630 007 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;37MG/100ML; 330MG/100MLM N19630 013 FEB 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;37MG/100ML; 450MG/100MLM N19630 019 FEB 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;37MG/100ML; 900MG/100MLM N19630 025 FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;75MG/100ML; 200MG/100MLM N19630 032 FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;75MG/100ML; 450MG/100MLM N19630 038 FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;75MG/100ML; 900MG/100MLM N19630 044 FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;75MG/100ML; 200MG/100MLM N19630 008 FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;75MG/100ML; 330MG/100MLM N19630 014 FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;75MG/100ML; 450MG/100MLM N19630 020 FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;75MG/100ML; 900MG/100MLM N19630 026 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;75MG/100ML; 110MG/100MLM N19630 002 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;110MG/100ML; 200MG/100MLM N19630 033 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;110MG/100ML; 450MG/100MLM N19630 039 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;110MG/100ML; 900MG/100MLM N19630 045 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;110MG/100ML; 110MG/100MLM N19630 003 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;110MG/100ML; 200MG/100MLM N19630 009 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;110MG/100ML; 330MG/100MLM N19630 015 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;110MG/100ML; 450MG/100MLM N19630 021 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;110MG/100ML; 900MG/100MLM N19630 027 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;150MG/100ML; 200MG/100MLM N19630 034 FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;150MG/100ML; 450MG/100MLM N19630 040 FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;150MG/100ML; 900MG/100MLM N19630 046 FEB 17, 1988

AP POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;150MG/100ML; 200MG/100MLM N19630 010 FEB 17, 1988

AP POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;150MG/100ML; 330MG/100MLM N19630 016 FEB 17, 1988

AP POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;150MG/100ML; 450MG/100MLM N19630 022 FEB 17, 1988

AP POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;150MG/100ML; 900MG/100MLM N19630 028 FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;150MG/100ML; 110MG/100MLM N19630 004 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;220MG/100ML; 200MG/100MLM N19630 035 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;220MG/100ML; 450MG/100MLM N19630 041 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;220MG/100ML; 900MG/100MLM N19630 047 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;220MG/100ML; 110MG/100MLM N19630 005 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;220MG/100ML; 200MG/100MLM N19630 011 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;220MG/100ML; 330MG/100MLM N19630 017 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;220MG/100ML; 450MG/100MLM N19630 023 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;220MG/100ML; 900MG/100MLM N19630 029 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;300MG/100ML; 200MG/100MLM N19630 036 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;300MG/100ML; 450MG/100MLM N19630 042 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;300MG/100ML; 900MG/100MLM N19630 048 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;300MG/100ML; 200MG/100MLM N19630 012 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;300MG/100ML; 330MG/100MLM N19630 018 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;300MG/100ML; 450MG/100MLM N19630 024 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;300MG/100ML; 900MG/100MLM N19630 030 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;300MG/100ML; 110MG/100MLM N19630 006 FEB 17, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP ABBOTT LABS 5GM/100ML;74.5MG/100ML; 450MG/100MLM N18362 009 JUL 05, 1983
AP 5GM/100ML;149MG/100ML; 450MG/100MLM N18362 005 MAR 28, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP ABBOTT LABS 5GM/100ML;74.5MG/100ML; 900MG/100MLM N19691 002 MAR 24, 1988
AP 5GM/100ML;149MG/100ML; 900MG/100MLM N19691 004 MAR 24, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER
ABBOTT LABS 5GM/100ML;74.5MG/100ML; 225MG/100MLM N18365 002 JUL 05, 1983
5GM/100ML;149MG/100ML; 225MG/100MLM N18365 006 MAR 28, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
ABBOTT LABS — 5GM/100ML;74.5MG/100ML; 300MG/100ML — N18876 001 — JAN 17, 1986
5GM/100ML;149MG/100ML; 300MG/100ML‡ — N18876 006 — MAR 28, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP TRAVENOL LABS — 5GM/100ML;75MG/100ML; 900MG/100ML‡ — N19308 004 — APR 05, 1985

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP ABBOTT LABS — 5GM/100ML;224MG/100ML; 450MG/100ML‡ — N18362 006 — MAR 28, 1988

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP ABBOTT LABS — 5GM/100ML;224MG/100ML; 900MG/100ML‡ — N19691 006 — MAR 24, 1988

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER
ABBOTT LABS — 5GM/100ML;224MG/100ML; 225MG/100ML‡ — N18365 008 — MAR 28, 1988

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
ABBOTT LABS — 5GM/100ML;224MG/100ML; 300MG/100ML‡ — N18876 007 — MAR 28, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP ABBOTT LABS — 5GM/100ML;149MG/100ML; 450MG/100ML‡ — N18362 010 — JUL 05, 1983
AP — 5GM/100ML;298MG/100ML; 450MG/100ML‡ — N18362 007 — MAR 28, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP ABBOTT LABS — 5GM/100ML;149MG/100ML; 900MG/100ML‡ — N19691 005 — MAR 24, 1988
AP — 5GM/100ML;298MG/100ML; 900MG/100ML‡ — N19691 008 — MAR 24, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER
ABBOTT LABS — 5GM/100ML;149MG/100ML; 225MG/100ML — N18365 001
5GM/100ML;298MG/100ML; 225MG/100ML‡ — N18365 009 — MAR 28, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
ABBOTT LABS — 5GM/100ML;298MG/100ML; 300MG/100ML‡ — N18876 008 — MAR 28, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% IN SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
ABBOTT LABS — 5GM/100ML;149MG/100ML; 300MG/100ML — N18876 002 — JAN 17, 1986

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP ABBOTT LABS — 5GM/100ML;224MG/100ML; 450MG/100ML — N18362 002

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP ABBOTT LABS — 5GM/100ML;224MG/100ML; 900MG/100ML‡ — N19691 007 — MAR 24, 1988

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER
ABBOTT LABS — 5GM/100ML;224MG/100ML; 225MG/100ML‡ — N18365 003 — JUL 05, 1983

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
ABBOTT LABS — 5GM/100ML;224MG/100ML; 300MG/100ML — N18876 003 — JAN 17, 1986

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP TRAVENOL LABS — 5GM/100ML;224MG/100ML; 900MG/100ML‡ — N19308 006 — APR 05, 1985

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP ABBOTT LABS — 5GM/100ML;298MG/100ML; 450MG/100ML — N18362 003

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP ABBOTT LABS — 5GM/100ML;298MG/100ML; 900MG/100ML‡ — N19691 009 — MAR 24, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER
ABBOTT LABS 5GM/100ML;298MG/100ML; 225MG/100MLM N18365 004 JUL 05, 1983

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
ABBOTT LABS 5GM/100ML;298MG/100ML; 300MG/100MLM N18876 004 MAR 28, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP ABBOTT LABS 5GM/100ML;74.5MG/100ML; 450MG/100MLM N18362 008 MAR 28, 1988
AP 5GM/100ML;149MG/100ML; 450MG/100MLM N18362 004 MAR 28, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP ABBOTT LABS 5GM/100ML;74.5MG/100ML; 900MG/100MLM N19691 001 MAR 24, 1988
AP 5GM/100ML;149MG/100ML; 900MG/100MLM N19691 003 MAR 24, 1988

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER
ABBOTT LABS 5GM/100ML;74.5MG/100ML; 225MG/100MLM N18365 005 MAR 28, 1988
5GM/100ML;149MG/100ML; 225MG/100MLM N18365 007 MAR 28, 1988

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
ABBOTT LABS 5GM/100ML;74.5MG/100ML; 300MG/100MLM N18876 005 MAR 28, 1988
5GM/100ML;149MG/100ML; 300MG/100MLM N18876 009 MAR 28, 1988

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 10% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;110MG/100MLM N19631 011 FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;200MG/100MLM N19631 012 FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;330MG/100MLM N19631 013 FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;450MG/100MLM N19631 014 FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP KENDALL MCGAW 10GM/100ML;900MG/100MLM N19631 015 FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 2.5GM/100ML; 110MG/100MLM N19631 001 FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 2.5GM/100ML; 200MG/100MLM N19631 002 FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
KENDALL MCGAW 2.5GM/100ML; 330MG/100MLM N19631 003 FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP KENDALL MCGAW 2.5GM/100ML; 450MG/100MLM N19631 004 FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 2.5GM/100ML; 900MG/100MLM N19631 005 FEB 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;110MG/100MLM N19631 006 FEB 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;200MG/100MLM N19631 007 FEB 24, 1988

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	5GM/100ML;330MG/100ML‡	N19631 008	FEB 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	5GM/100ML;450MG/100ML‡	N19631 009	FEB 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	5GM/100ML;900MG/100ML‡	N19631 010	FEB 24, 1988

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

RENOCAL-76

>ADD>				
>ADD> AP	SQUIBB DIAGS	66%;10%‡	N89347 001	JUN 01, 1988
>ADD>				

DIAZEPAM

TABLET; ORAL

G-PAM

AB	QUANTUM PHARMCS	2MG‡	N72431 001	APR 29, 1988
AB		5MG‡	N72432 001	APR 29, 1988
AB		10MG‡	N72433 001	APR 29, 1988

DIAZOXIDE

INJECTABLE; INJECTION

DIAZOXIDE

AP	QUAD PHARMS	15MG/ML‡	N71908 001	JAN 26, 1988

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOPAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	BAXTER	80MG/100ML	N19615 001	MAR 27, 1987
AP		160MG/100ML	N19615 002	MAR 27, 1987
AP		320MG/100ML	N19615 003	MAR 27, 1987
		640MG/100ML	N19615 004	MAR 27, 1987
/AP/	/TRAVENOL LABS/	/80MG/100ML/	/N19615/001/	/MAR 27, 1987/
/AP/		/160MG/100ML/	/N19615/002/	/MAR 27, 1987/
/AP/		/320MG/100ML/	/N19615/003/	/MAR 27, 1987/
		/640MG/100ML/	/N19615/004/	/MAR 27, 1987/

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

ADAPIN

AB	PENNWALT	EQ 150MG BASE	N16987 007	APR 13, 1987

DOXEPIN HCL

AB	BARR LABS	EQ 25MG BASE‡	N71502 001	FEB 18, 1988
AB		EQ 50MG BASE‡	N71653 001	FEB 18, 1988
AB		EQ 75MG BASE‡	N71654 001	FEB 18, 1988
AB		EQ 100MG BASE‡	N71521 001	FEB 18, 1988
AB	CHELSEA LABS	EQ 75MG BASE‡	N71763 001	FEB 09, 1988
AB		EQ 150MG BASE‡	N71764 001	FEB 09, 1988
AB	LEDERLE LABS	EQ 10MG BASE‡	N71685 001	JAN 05, 1988
AB		EQ 25MG BASE‡	N71686 001	JAN 05, 1988
AB		EQ 50MG BASE‡	N71673 001	JAN 05, 1988
AB		EQ 75MG BASE‡	N71674 001	JAN 05, 1988
AB		EQ 100MG BASE‡	N71675 001	JAN 05, 1988
AB		EQ 150MG BASE‡	N71676 001	JAN 05, 1988

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

AB	VITARINE	EQ 50MG BASE*	N62780 001 APR 12, 1988

INJECTABLE; INJECTION

DOXYCYCLINE

AP	BEN VENUE LABS	EQ 100MG BASE/VIAL*	N62569 001 MAR 09, 1988
AP		EQ 200MG BASE/VIAL*	N62569 002 MAR 09, 1988

DROPERIDOL

INJECTABLE; INJECTION

DROPERIDOL

AP	ABBOTT LABS	2.5MG/ML*	N71981 001 FEB 29, 1988
AP	DUPONT CRI CARE	2.5MG/ML*	N71645 001 APR 07, 1988

DROPERIDOL; FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE AND DROPERIDOL

AP	ABBOTT LABS	2.5MG/ML; EQ 0.05MG BASE/ML*	N71982 001 MAY 04, 1988

INNOVAR

AP	JANSSEN PHARMA	2.5MG/ML; EQ 0.05MG BASE/ML*	N16049 001

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

REVERSOL

AP	ORGANON	10MG/ML*	N89624 001 MAY 13, 1988

ENALAPRILAT

INJECTABLE; INJECTION

VASOTEC

	MS&D RES LABS	1.25MG/ML*	N19309 001 FEB 09, 1988

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL AND EPINEPHRINE

>ADD> AP >ADD>	ABBOTT LABS	0.005MG/ML;0.5%*	N89635 001 JUN 21, 1988
>ADD> AP >ADD>		0.005MG/ML;1%*	N89649 001 JUN 21, 1988
>ADD> AP >ADD>		0.005MG/ML;1.5%*	N89645 001 JUN 21, 1988
>ADD> AP >ADD>		0.005MG/ML;1.5%*	N89650 001 JUN 21, 1988
>ADD> AP >ADD>		0.005MG/ML;2%*	N89651 001 JUN 21, 1988
>ADD> AP >ADD>		0.01MG/ML;1%*	N89644 001 JUN 21, 1988
>ADD> AP >ADD>		0.01MG/ML;2%*	N89646 001 JUN 21, 1988

OCTOCAINE

/AP/	/NOVOCOL CHEM/	/0.01MG/ML;2%/	/N84046/001/
AP	NOVOCOL PHARM	0.01MG/ML;2%	N84048 001
/AP/		/0.02MG/ML;2%/	/N84048/002/
AP		0.02MG/ML;2%	N84048 002

XYLOCAINE W/ EPINEPHRINE

>ADD> AP >ADD>	ASTRA PHARM PRODS	0.005MG/ML;0.5%*	N06488 013
>ADD> AP >ADD>		0.005MG/ML;1%	N06488 018 NOV 13, 1986
>ADD> AP >ADD>		0.005MG/ML;2%	N06488 019 NOV 13, 1986

ERGOLOID MESYLATES

TABLET; ORAL

ERGOLOID MESYLATES

/AA/	/CHELSEA LABS/	/1MG/	/N88207/001/ /MAR 22, 1984/

GERIMAL

AB	CHELSEA LABS	1MG	N88207 001 MAR 22, 1984

TABLET; SUBLINGUAL

CIRCANOL

/AA/	/RIKER LABS/	/0.5MG/	/N84868/001/
/AA/		/1MG/	/N85809/001/
a	RIKER LABS	0.5MG	N84868 001
a		1MG	N85809 001

ERGOLOID MESYLATES

/AA/	/CHELSEA LABS/	/0.5MG/	/N86189/001/
/AA/		/1MG/	/N86188/001/

GERIMAL

AA	CHELSEA LABS	0.5MG	N86189 001
AA		1MG	N86188 001

ERYTHROMYCIN

SOLUTION; TOPICAL
ETS-2%
AT PADDOCK LABS 2%* N62687 001
FEB 05, 1988

ERYTHROMYCIN ETHYLSUCCINATE; SULFISOXAZOLE ACETYL

GRANULE; ORAL
ERYTHROMYCIN ETHYLSUCCINATE AND SULFISOXAZOLE ACETYL
AR BARR LABS EQ 200MG BASE/5 ML; EQ 600MG BASE/5ML* N62759 001
MAY 20, 1988
> ADD > ERYZOLE
> ADD > AR ALRA LABS EQ 200MG BASE/5ML; EQ 600MG BASE/5ML* N62758 001
> ADD > JUN 15, 1988
> ADD >
PEDIAZOLE
AR ROSS LABS EQ 200MG BASE/5ML; EQ 600MG BASE/5ML* N50529 001

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION
ERYTHROCIN
AP ABBOTT LABS EQ 500MG BASE/VIAL* N62586 001
JAN 04, 1988
AP EQ 1GM BASE/VIAL* N62586 002
JAN 04, 1988

ERYTHROMYCIN STEARATE

TABLET; ORAL
BRISTAMYCIN
/AB/ /BRISTOL LABS/ /EQ 250MG BASE/ /N61304/001/
/AB/ /EQ 250MG BASE/ /N61887/001/
∂ BRISTOL LABS EQ 250MG BASE N61304 001
∂ EQ 250MG BASE N61887 001
ERYPAR
/AB/ /PARKE/DAVIS/ /EQ 250MG BASE/ /N62032/001/
/AB/ /EQ 500MG BASE/ /N62032/002/
∂ PARKE DAVIS EQ 250MG BASE N62032 001
∂ EQ 500MG BASE N62032 002
ERYTHROCIN STEARATE
/AB/ /ABBOTT LABS/ /EQ 125MG BASE/ /N60359/002/
∂ ABBOTT LABS EQ 125MG BASE N60359 002

ERYTHROMYCIN STEARATE

TABLET; ORAL
ERYTHROMYCIN STEARATE
/AB/ /LEDERLE LABS/ /EQ 250MG BASE/ /N62089/001/
/AB/ /EQ 500MG BASE/ /N62089/002/
∂ LEDERLE LABS EQ 250MG BASE N62089 001
∂ EQ 500MG BASE N62089 002
PFIZER-E
/AB/ /PFIZER LABS/ /EQ 500MG BASE/ /N61791/002/
∂ PFIZER LABS EQ 500MG BASE N61791 002

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORETHIN 1/35E-21
AB SEARLE PHARMS 0.035MG;1MG* N71480 001
APR 12, 1988
NORETHINDRONE AND ETHINYL ESTRADIOL
AB NATSON LABS 0.035MG;0.5MG AND 1MG* N71043 001
APR 01, 1988
ORTHO-NOVUM 10/11-21
AB ORTHO PHARM 0.035MG;0.5MG AND 1MG N18354 001
JAN 11, 1982

TABLET; ORAL-28
NORETHIN 1/35E-28
AB SEARLE PHARMS 0.035MG;1MG* N71481 001
APR 12, 1988
NORETHINDRONE AND ETHINYL ESTRADIOL
AB NATSON LABS 0.035MG;0.5MG AND 1MG* N71044 001
APR 01, 1988
ORTHO-NOVUM 10/11-28
AB ORTHO PHARM 0.035MG;0.5MG AND 1MG N18354 002
JAN 11, 1982

FENOPROFEN CALCIUM

CAPSULE; ORAL
FENOPROFEN CALCIUM
AB QUANTUM PHARMCS EQ 200MG BASE* N72214 001
AUG 17, 1988 : APR 14, 1988
AB EQ 300MG BASE* N71738 001
AUG 17, 1988 : APR 14, 1988
NALFON
AB DISTA PRODS EQ 300MG BASE N17604 002
NALFON 200
AB DISTA PRODS EQ 200MG BASE N17604 003

FENOPROFEN CALCIUM

TABLET; ORAL
FENOPROFEN CALCIUM

> ADD >	AB	AM THERPTCS	EQ 600MG BASE‡		N72309 001
> ADD >				AUG 17, 1988 :	JUN 16, 1988
> ADD >	AB	CHELSEA LABS	EQ 600MG BASE‡		N72407 001
> ADD >				AUG 17, 1988 :	JUN 13, 1988
	AB	LEDERLE LABS	EQ 600MG BASE‡		N72326 001
				AUG 17, 1988 :	APR 20, 1988
> ADD >	AB	MYLAN PHARMS	EQ 600MG BASE‡		N72267 001
> ADD >				AUG 17, 1988 :	JUN 08, 1988
> ADD >	AB	PHARM BASICS	EQ 600MG BASE‡		N72362 001
> ADD >				AUG 17, 1988 :	JUN 16, 1988
	AB	PUREPAC PHARM	EQ 600MG BASE‡		N72274 001
					MAY 02, 1988
	AB	QUANTUM PHARMCS	EQ 600MG BASE‡		N72194 001
				AUG 17, 1988 :	APR 14, 1988

NALFON

AB	DISTA PRODS	EQ 600MG BASE		N17710 001

FLECAINIDE ACETATE

TABLET; ORAL
TAMBOCOR

> ADD >	RIKER LABS	150MG‡		N18830 003
> ADD >				JUN 03, 1988

FLUOCINOLONE ACETONIDE

OIL; TOPICAL
DERMA-SMOOTHE/FS

	HILL DERM	0.01%‡		N19452 001
				FEB 03, 1988

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE

AB	CLAY PARK LABS	0.05%‡		N71790 001
			JUL 13, 1988 :	APR 25, 1988

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL

AP	BEN VENUE LABS	50MG/ML‡		N89508 001
				JAN 26, 1988

FLUPHENAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
FLUPHENAZINE HCL

> ADD >	AP	QUAD PHARMS	2.5MG/ML‡	N89800 001
> ADD >				JUN 08, 1988

TABLET; ORAL
PERMITIL

/B/	/SCHERING/	/2.5MG/	/N12034/004/
/B/		/5MG/	/N12034/005/
/B/		/10MG/	/N12034/006/
BP	SCHERING	2.5MG	N12034 004
BP		5MG	N12034 005
BP		10MG	N12034 006

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL

AB	HALSEY DRUG	15MG‡	N71808 001
			JAN 07, 1988
AB		30MG‡	N71809 001
			JAN 07, 1988

FOLIC ACID

TABLET; ORAL
FOLIC ACID

/AA/	/BARR LABS/	/1MG/	/N89177/001/
			/JAN 08, 1986/
	∂ BARR LABS	1MG	N89177 001
			JAN 08, 1986

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE

/AP/	/PARKE,DAVIS/	/10MG/ML/	/N18420/001/
			/FEB 26, 1982/
AP	WARNER CHILCOTT	10MG/ML	N18420 001
			FEB 26, 1982

TABLET; ORAL
FUROSEMIDE

AB	BARR LABS	80MG‡	N70100 001
			JAN 26, 1988
AB	DANBURY PHARMA	80MG‡	N71594 001
			FEB 09, 1988

> ADD > GADOPENTETATE DIMEGLUMINE

> ADD > INJECTABLE; INJECTION
> ADD > MAGNEVIST
> ADD > BERLEX LABS 469.01MG/ML* N19596 001 JUN 02, 1988
> ADD >

GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION
GALLIUM CITRATE GA 67
> DLT > /MEDI PHYSICS/ /1MCI/ML/ /N17700/001/
> ADD > @ MEDI PHYSICS 1MCI/ML N17700 001

> ADD > GENTAMICIN SULFATE; PREDNISOLONE ACETATE

> ADD > SUSPENSION/DROPS; OPHTHALMIC
> ADD > PRED-G
> ADD > ALLERGAN PHARMS EQ 0.3% BASE;1%* N50586 001 JUN 10, 1988
> ADD >

GLYCOPYRROLATE

INJECTABLE; INJECTION
GLYCOPYRROLATE
> ADD > AP ABBOTT LABS 0.2MG/ML* N89393 001 JUN 15, 1988
> ADD >

HALOPERIDOL

TABLET; ORAL
HALDOL SOLUTAB
/A/ /MCNEIL/LABS/ /1MG/ /N17079/001/
@ MCNEIL PHARM 1MG N17079 001
HALOPERIDOL
AB BARR LABS 5MG* N71212 001 JAN 07, 1988
AB 10MG* N71173 001 JAN 07, 1988
AB 20MG* N71177 001 JAN 07, 1988

HALOPERIDOL

TABLET; ORAL
HALOPERIDOL
> ADD > AB BOLAR PHARM 0.5MG* N71571 001 JUN 03, 1988
> ADD >
> ADD > AB 1MG* N71572 001 JUN 03, 1988
> ADD >
> ADD > AB 2MG* N71573 001 JUN 03, 1988
> ADD >
> ADD > AB 5MG* N71374 001 JUN 03, 1988
> ADD >
> ADD > AB 10MG* N71375 001 JUN 03, 1988
> ADD >
> ADD > AB 20MG* N71376 001 JUN 03, 1988
> ADD >
AB CORD LABS 10MG* N71210 001 MAR 11, 1988
AB 20MG* N71211 001 MAR 11, 1988

HALOPERIDOL LACTATE

CONCENTRATE; ORAL
HALDOL
/AA/ /MCNEIL/LABS/ /EQ 2MG BASE/ML/ /N15922/001/
AA MCNEIL PHARM EQ 2MG BASE/ML N15922 001
HALOPERIDOL INTENSOL
AA ROXANE LABS EQ 2MG BASE/ML* N72045 001 APR 12, 1988

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

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER
/AP/ /ABBOTT/LABS/ /10,000 UNITS/100ML/ /N19339/003/ /MAR 27, 1985/
@ ABBOTT LABS 10,000 UNITS/100ML N19339 003 MAR 27, 1985

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM 1000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	BAXTER	200 UNITS/100ML	N18609 001 APR 28, 1982
/AP/	/TRAVENOL/LABS/	/200 UNITS/100ML/	/N18609/001/ /APR/28,/1982/

HEPARIN SODIUM 12,500 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

/AP/	/ABBOTT/LABS/	/5,000 UNITS/100ML/	/N19339/001/ /MAR/27,/1985/
∂	ABBOTT LABS	5,000 UNITS/100ML	N19339 001 MAR 27, 1985

HEPARIN SODIUM 2000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	BAXTER	200 UNITS/100ML	N18609 002 APR 28, 1982
/AP/	/TRAVENOL/LABS/	/200 UNITS/100ML/	/N18609/002/ /APR/28,/1982/

HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

/AP/	/ABBOTT/LABS/	/5,000 UNITS/100ML/	/N19339/004/ /MAR/27,/1985/
/AP/		/10,000 UNITS/100ML/	/N19339/002/ /MAR/27,/1985/
∂	ABBOTT LABS	5,000 UNITS/100ML	N19339 004 MAR 27, 1985
∂		10,000 UNITS/100ML	N19339 002 MAR 27, 1985

HEPARIN SODIUM 5000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	BAXTER	500 UNITS/100ML	N18609 003 APR 28, 1982
/AP/	/TRAVENOL/LABS/	/500 UNITS/100ML/	/N18609/003/ /APR/28,/1982/

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

/AA/	/PUREPAC/PHARM/	/50MG/	/N88178/001/ /AUG/15,/1983/
∂	PUREPAC PHARM	50MG	N88178 001 AUG 15, 1983

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDRAL

AB	REID RONELL	25MG;25MG	N87608 001 FEB 08, 1982
AB		50MG;50MG	N87213 001 FEB 08, 1982
/∂/		/25MG;25MG/	/N87608/001/ /FEB/08,/1982/
/∂/		/50MG;50MG/	/N87213/001/ /FEB/08,/1982/

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

/BP/	/REID/RONELL/	/25MG;15MG;0.1MG/	/N87210/001/
BP	REID RONELL	25MG;15MG;0.1MG	N88376 001 OCT 28, 1983
∂		25MG;15MG;0.1MG	N87210 001
/∂/		/25MG;15MG;0.1MG/	/N88376/001/ /OCT/28,/1983/

HYDROCHLOROTHIAZIDE

SOLUTION; ORAL

HYDROCHLOROTHIAZIDE

>ADD>	AA	MY K LABS	50MG/5ML[M]	N89661 001 JUN 20, 1988
>ADD>	AA	ROXANE LABS	50MG/5ML	N88587 001 JUL 02, 1984

TABLET; ORAL

HYDROCHLOROTHIAZIDE

/AA/	/BANMAX/PHARMS/	/25MG/	/N86369/001/
/AA/		/50MG/	/N83554/001/
∂	BANMAX PHARMS	25MG	N86369 001
∂		50MG	N83554 001

HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDE

TABLET; ORAL

NORMOZIDE

/SCHERING/		/25MG;400MG/	/N19046/004/ /APR/06,/1987/
∂	SCHERING	25MG;400MG	N19046 004 APR 06, 1987

HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDE

TABLET; ORAL

TRANDATE HCT

AB	GLAXO	25MG;100MG	N19174 001	APR 10, 1987
AB		25MG;200MG	N19174 002	APR 10, 1987
AB		25MG;300MG	N19174 003	APR 10, 1987
	∂	25MG;400MG	N19174 004	APR 10, 1987

~~TRANDATE-HCT~~

~~AB GLAXO 25MG;100MG N19174/001 APR 10, 1987~~

~~AB 25MG;200MG N19174/002 APR 10, 1987~~

~~AB 25MG;300MG N19174/003 APR 10, 1987~~

~~AB 25MG;400MG N19174/004 APR 10, 1987~~

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

AB	NOVOPHARM	15MG;250MG	N71819 001	APR 08, 1988
AB		25MG;250MG	N71820 001	APR 08, 1988
AB		30MG;500MG	N71821 001	APR 08, 1988
AB		50MG;500MG	N71822 001	APR 08, 1988
~~AB~~	~~PUREPAC PHARM~~	~~50MG;500MG~~	~~N70689 001~~	~~APR 24, 1986~~
	∂ PUREPAC PHARM	50MG;500MG	N70689 001	APR 24, 1986
AB	ZENITH LABS	15MG;250MG	N71458 001	MAR 08, 1988
AB		25MG;250MG	N71459 001	MAR 08, 1988
AB		30MG;500MG	N71460 001	MAR 08, 1988
AB		50MG;500MG	N71461 001	MAR 08, 1988

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE

AB	SIDMAK LABS	25MG;40MG	N72042 001	MAR 14, 1988
AB		25MG;80MG	N72043 001	MAR 14, 1988
AB	WARNER CHILCOTT	25MG;40MG	N71771 001	JAN 26, 1988
AB		25MG;80MG	N71772 001	JAN 26, 1988

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

RESERPINE AND HYDROCHLOROTHIAZIDE

~~BP~~	~~BARR LABS~~	~~25MG;0.125MG~~	~~N84580/001~~
~~BP~~		~~50MG;0.125MG~~	~~N84579/001~~
	∂ BARR LABS	25MG;0.125MG	N84580 001
	∂	50MG;0.125MG	N84579 001

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

AB	VITARINE	25MG;50MG	N71737 001	FEB 12, 1988

TABLET; ORAL

MAXZIDE-25MG

	MYLAN PHARMS	25MG;37.5MG	N19129 003	MAY 13, 1988

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

AB	CORD LABS	50MG;75MG	N72011 001	JUN 17, 1988
AB	DANBURY PHARMA	50MG;75MG	N71969 001	APR 17, 1988 : JAN 15, 1988
AB	PAR PHARM	50MG;75MG	N72337 001	MAY 11, 1988
AB	QUANTUM PHARMCS	50MG;75MG	N71980 001	APR 17, 1988 : FEB 01, 1988

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

AI	NASKA PHARMA	1%	N89706 001	MAR 10, 1988
AI		2.5%	N89682 001	MAR 10, 1988
AI	NMC LABS	1%	N87795 001	MAY 03, 1983

HYDROTEX

AI	SYOSSET LABS	1%	N87427 001	APR 04, 1988

/HYDRO/

/AI/	/NMC LABS/	/1%/	/N87795/001/	/MAY 03, 1983/

LOTION; TOPICAL

BETA-HC

AI	BETA DERM	1%	N89495 001	JAN 25, 1988

HYDROCORTISONE

AI	NASKA PHARMA	1%	N89705 001	APR 25, 1988

OINTMENT; TOPICAL

HC (HYDROCORTISONE)

>DLT>	/3/	/C&M PHARMA/	/0.5%/	/N86481/001/	
>DLT>	/3/		/1%/	/N86481/002/	
>ADD>	AI	C&M PHARMA	1%	N80481 002	

HYDROCORTISONE

	NASKA PHARMA	1%	N89704 001	MAR 10, 1988

TABLET; ORAL

HYDROCORTISONE

/BP/	/BARR LABS/	/20MG/	/N83999/001/	
	∂ BARR LABS	20MG	N83999 001	

HYDROCORTISONE ACETATE

CREAM; TOPICAL

HYDROCORTISONE ACETATE

>ADD>	AI	THAMES PHARMA	1%	N89472 001	JUN 13, 1988
>ADD>					

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL; TOPICAL

EPIFOAM

AI	REED & CARNRICK	1%;1%	N86457 001	

HYDROCORTISONE ACETATE 1% AND PRAMOXINE HCL 1%

AI	COPLEY PHARM	1%;1%	N89440 001	MAY 17, 1988

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

AI	STERIS LABS	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62874 001	MAY 11, 1988

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HCL

/AP/	/ALTANA/	/25MG/ML/	/N87273/001/	/APR 20, 1982/
/AP/		/50MG/ML/	/N87273/002/	/APR 20, 1982/
	∂ ALTANA	25MG/ML	N87273 001	APR 20, 1982
	∂	50MG/ML	N87273 002	APR 20, 1982

SYRUP; ORAL

HYDROXYZINE HCL

AA	NASKA PHARMA	10MG/5ML	N88785 001	FEB 03, 1988

TABLET; ORAL

HYDROXYZINE HCL

AB	HALSEY DRUG	10MG	N89366 001	MAY 02, 1988
AB		25MG	N89117 001	MAY 02, 1988
AB		50MG	N89396 001	MAY 02, 1988

IBUPROFEN

TABLET; ORAL

IBUPROFEN

AB	HALSEY DRUG	800MG	N72137 001	FEB 05, 1988

IBUPROFEN

TABLET; ORAL
IBUPROFEN

AB	INVAMED	400MG	N72064 001 JAN 14, 1988
AB		600MG	N72065 001 JAN 14, 1988
AB		800MG	N71938 001 JAN 14, 1988
AB	MEDICOPHARMA	400MG	N71644 001 FEB 01, 1988
AB	PUREPAC PHARM	800MG	N71964 001 FEB 01, 1988

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL
IMIPRAMINE

/AA/	/BANMAX/PHARMS/	/10MG/	/N83827/001/
/AA/		/25MG/	/N83827/002/
/BP/		/50MG/	/N83827/003/
	ə BANMAX PHARMS	50MG	N83827 003
	ə	10MG	N83827 001
	ə	25MG	N83827 002

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

AB	NOVOPHARM	25MG	N71342 001 APR 18, 1988
AB		50MG	N71343 001 APR 18, 1988

IOHEXOL

INJECTABLE; INJECTION
OMNIPAQUE 180

/A/	/STERLING/DRUG/	/38.6Z/	/N18956/001/ /DEC/26,/1985/
AP	STERLING DRUG	38.8%	N18956 001 DEC 26, 1985

ISONIAZID

TABLET; ORAL
LANIAZID

> ADD > AA	LANNETT	300MG	N89776 001 JUN 13, 1988

ISOSORBIDE DINITRATE

TABLET; ORAL
ISOSORBIDE DINITRATE

AB	BARR LABS	30MG	N87564 001 SEP 18, 1986
AB	CORD LABS	5MG	N86221 001 JAN 07, 1988
AB		10MG	N86223 001 JAN 07, 1988
AB		20MG	N89367 001 APR 07, 1988
AB	DANBURY PHARMA	5MG	N86034 001 JAN 06, 1988
AB		10MG	N86032 001 JAN 07, 1988
AB	PAR PHARM	30MG	N87946 001 JAN 12, 1988

TABLET; SUBLINGUAL
ISOSORBIDE DINITRATE

AB	CORD LABS	2.5MG	N86225 001 FEB 19, 1988
AB		5MG	N86222 001 FEB 19, 1988
AB	DANBURY PHARMA	2.5MG	N86033 001 FEB 26, 1988
AB		5MG	N86031 001 SEP 29, 1987

KETAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
KETALAR

AP	PARKE DAVIS	EQ 10MG BASE/ML	N16812 001
AP		EQ 50MG BASE/ML	N16812 002
AP		EQ 100MG BASE/ML	N16812 003
	KETAMINE HCL		
AP	QUAD PHARMS	EQ 10MG BASE/ML	N71949 001 APR 11, 1988
AP		EQ 50MG BASE/ML	N71950 001 APR 11, 1988
AP		EQ 100MG BASE/ML	N71951 001 APR 11, 1988

LACTULOSE

SYRUP; ORAL
LACTULOSE
∂ KALI DUPHAR — 10GM/15ML — N17906 001

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM

AP	BEN VENUE LABS	EQ 100MG BASE/VIAL*	N89717 001	MAR 28, 1988
> ADD > AP	INTL PHARM	EQ 3MG BASE/ML*	N89[illegible] 001	JUN 01, 1988
> ADD > AP		EQ 50MG BASE/VIAL*	N89353 001	JUN 01, 1988
> ADD > AP	LEDERLE LABS	EQ 3MG BASE/ML	N08107 001	
AP		EQ 100MG BASE/VIAL*	N08107 004	MAY 23, 1988
AP	QUAD PHARMS	EQ 100MG BASE/VIAL	N89636 001	DEC 24, 1987

LEVODOPA

CAPSULE; ORAL
BENDOPA

[illegible]	[illegible]	[illegible]	[illegible]
∂ ICN PHARMS	100MG	N16948 003	
∂	250MG	N16948 001	
∂	500MG	N16948 002	

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
XYLOCAINE MCL W/ LEVONORDEFRIN

[illegible]	[illegible]	[illegible]	[illegible]
AP	NOVOCOL PHARM	0.05MG/ML;2%	N84697 001

POLOCAINE W/ LEVONORDEFRIN

AP	ASTRA PHARM PRODS	0.05MG/ML;2%*	N89517 001 APR 14, 1988

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE MCL

AP	ABBOTT LABS	20%*	N89362 001	MAY 25, 1988
> DLT > [illegible]	[illegible]	[illegible]	[illegible]	[illegible]
> DLT > AP		[illegible]	[illegible]	[illegible]
> ADD >	∂ LEMMON	1%	N83627 001	
> ADD >	∂	2%	N83627 002	

LINCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION
LINCOCIN

AP	UPJOHN	EQ 300MG BASE/ML	N50317 001	

LINCOMYCIN MCL

AP	QUAD PHARMS	EQ 300MG BASE/ML*	N62784 001	MAR 14, 1988

LISINOPRIL

TABLET; ORAL
PRINIVIL

AB	MSD RES LABS	5MG	N19558 001	DEC 29, 1987
AB		10MG	N19558 002	DEC 29, 1987
AB		20MG	N19558 003	DEC 29, 1987

ZESTRIL

AB	IMPERIAL CHEM	5MG*	N19777 001	MAY 19, 1988
AB		10MG*	N19777 002	MAY 19, 1988
AB		20MG*	N19777 003	MAY 19, 1988

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL
IMODIUM

[illegible]	[illegible]	[illegible]	[illegible]
∂ JANSSEN PHARMA	1MG/5ML	N19037 001	JUL 31, 1984

LORAZEPAM

TABLET; ORAL

LORAZEPAM

AB	CORD LABS	0.5MG*	N71193 001	APR 15, 1988
AB		1MG*	N71194 001	APR 15, 1988
AB		2MG*	N71195 001	APR 15, 1988
AB	MARNER CHILCOTT	1MG*	N71038 001	JAN 12, 1988
AB		2MG*	N71039 001	JAN 12, 1988

LOXAPINE SUCCINATE

CAPSULE; ORAL

LOXAPINE SUCCINATE

>ADD > AB	MATSON LABS	EQ 5MG BASE*	N72204 001	JUN 15, 1988
>ADD > AB		EQ 10MG BASE*	N72205 001	JUN 15, 1988
>ADD > AB		EQ 25MG BASE*	N72206 001	JUN 15, 1988
>ADD > AB		EQ 50MG BASE*	N72062 001	JUN 15, 1988

LOXITANE

>ADD > AB	LEDERLE LABS	EQ 5MG BASE	N17525 001
>ADD > AB		EQ 10MG BASE	N17525 002
>ADD > AB		EQ 25MG BASE	N17525 003
>ADD > AB		EQ 50MG BASE	N17525 004

MAPROTILINE HYDROCHLORIDE

TABLET; ORAL

MAPROTILINE HCL

AB	AM THERPTCS	25MG*	N72129 001	JAN 14, 1988
AB		50MG*	N72130 001	JAN 14, 1988
AB		75MG*	N72131 001	JAN 14, 1988
>ADD > AB	MATSON LABS	25MG*	N72162 001	JUN 01, 1988
>ADD > AB		50MG*	N72163 001	JUN 01, 1988
>ADD > AB		75MG*	N72164 001	JUN 01, 1988

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

ANTIVERT

AA	ROERIG	50MG	N10721 001	JAN 20, 1982

MECLIZINE HCL

AA	PAR PHARM	50MG*	N89674 001	MAR 31, 1988

MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

AB	PAR PHARM	EQ 50MG BASE*	N72077 001	MAR 10, 1988
AB		EQ 100MG BASE*	N72078 001	MAR 10, 1988
AB	PHARM BASICS	EQ 50MG BASE*	N71007 001	MAR 25, 1988
AB		EQ 100MG BASE*	N71008 001	MAR 25, 1988
>ADD > AB	VITARINE	EQ 50MG BASE*	N71710 001	JUN 15, 1988
>ADD > AB		EQ 100MG BASE*	N71684 001	JUN 15, 1988

MEFENAMIC ACID

CAPSULE; ORAL

MEFENAMIC ACID

AB	VITARINE	250MG*	N72179 001	APR 21, 1988

PONSTEL

AB	PARKE DAVIS PR	250MG	N15034 003

MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

ISOCAINE HCL

/AA/	/NOVOCOL PHARM/	/1%/	/N80925/001/	
AP	NOVOCOL PHARM	3%	N80925 001	

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

/AA/	/MALLARD/	/400MG/	/N15072/002/	
a	MALLARD	400MG	N15072 002	

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE

/AA/	/PHARM BASICS/	/400MG/	/N87845/001/ MAR 18, 1982/	> ADD > > ADD >	
/AA/		/400MG/	/N87826/001/ MAR 18, 1982/	> ADD > > ADD >	
	∂ PHARM BASICS	200MG	N87825 001 MAR 18, 1982	> ADD > > ADD >	AB
	∂	400MG	N87826 001 MAR 18, 1982	> ADD > > ADD >	AB

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21
NORETHIN 1/50M-21

AB	SEARLE PHARMS	0.05MG;1MG	N71539 001 APR 12, 1988

TABLET; ORAL-28
NORETHIN 1/50M-28

AB	SEARLE PHARMS	0.05MG;1MG	N71540 001 APR 12, 1988

MESTRANOL; NORETHYNODREL

TABLET; ORAL-20
ENOVID

/AA/	/SEARLE/	/0.075MG;5MG/	/N10976/004/
	∂ SEARLE	0.075MG;5MG	N10976 004

ENOVID-E

/AA/	/SEARLE/	/0.1MG;2.5MG/	/N10976/006/
	∂ SEARLE	0.1MG;2.5MG	N10976 006

METAPROTERENOL SULFATE

SOLUTION; INHALATION
METAPROTERENOL SULFATE

> ADD > > ADD >	AN	MY K LABS	5%	N72190 001 JUN 07, 1988

TABLET; ORAL
ALUPENT

AB	BOEHR INGEL	10MG	N15874 002
AB		20MG	N15874 001

METAPROTERENOL SULFATE

TABLET; ORAL
METAPROTERENOL SULFATE

AB	AM THERPTCS	10MG	N72054 001 JUN 23, 1988	
AB		20MG	N72055 001 JUN 23, 1988	
AB	PAR PHARM	10MG	N72024 001 JUN 28, 1988	
AB		20MG	N72025 001 JUN 28, 1988	
AB	PHARM BASICS	10MG	N71013 001 JAN 25, 1988	
AB		20MG	N71014 001 JAN 25, 1988	

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL

/AA/	/BARR LABS/	/500MG/	/N84488/001/
	∂ BARR LABS	500MG	N84488 001

METHOTREXATE SODIUM

INJECTABLE; INJECTION
METHOTREXATE

LEDERLE LABS	EQ 1GM BASE/VIAL	N11719 009 APR 07, 1988

METHOXSALEN

CAPSULE; ORAL
/OXSORALEN/

/BP/	/ELDER PHARMS/	/10MG/	/N09048/001/
	8-MOP		
	ELDER PHARMS	10MG	N09048 001

METHYLDOPA

TABLET; ORAL
METHYLDOPA

AB	CORD LABS	125MG	N71700 001 MAR 02, 1988

METHYLDOPA

TABLET; ORAL
METHYLDOPA

AB	HALSEY DRUG	125MG*	N71751 001	MAR 28, 1988
AB		250MG*	N71752 001	MAR 28, 1988
AB		500MG*	N71753 001	MAR 28, 1988

METHYLPHENIDATE HYDROCHLORIDE

TABLET, CONTROLLED RELEASE; ORAL
METHYLPHENIDATE HCL

>ADD > AB	MD PHARM	20MG*	N89601 001	JUN 01, 1988

RITALIN-SR

>ADD > AB	CIBA PHARM	20MG	N18029 001	MAR 30, 1982

METHYLPREDNISOLONE

TABLET; ORAL
MEDROL

AB	UPJOHN	2MG	N11153 005	
AB		32MG	N11153 006	

METHYLPREDNISOLONE

AB	PAR PHARM	16MG*	N89207 001	APR 25, 1988
AB		24MG*	N89208 001	APR 25, 1988
AB		32MG*	N89209 001	APR 25, 1988

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
CLOPRA

>ADD > AB	QUANTUM PHARMCS	EQ 5MG BASE*	N72384 001	JUN 02, 1988

METOCLOPRAMIDE HCL

AB	SIDMAK LABS	EQ 10MG BASE*	N71250 001	FEB 03, 1988

REGLAN

>ADD > AB	ROBINS	EQ 5MG BASE	N17854 002	MAY 05, 1987

METOCURINE IODIDE

INJECTABLE; INJECTION
>ADD > METOCURINE IODIDE

>ADD > AP	QUAD PHARMS	2MG/ML*	N89443 001	JUN 01, 1988

>ADD >

METUBINE IODIDE

>ADD > AP	LILLY	2MG/ML	N06632 003	

MEZLOCILLIN SODIUM MONOHYDRATE

INJECTABLE; INJECTION
MEZLIN

	MILES PHARM	EQ 20GM BASE/VIAL*	N50549 005	MAR 02, 1988
		EQ 20GM BASE/VIAL*	N62372 004	MAR 02, 1988

MITOMYCIN

INJECTABLE; INJECTION
MUTAMYCIN

	BRISTOL MYERS	40MG/VIAL*	N62336 003	MAR 10, 1988

MORPHINE SULFATE

INJECTABLE; INJECTION
MORPHINE SULFATE

AP	ABBOTT LABS	0.5MG/ML*	N71849 001	MAY 11, 1988
AP		1MG/ML*	N71850 001	MAY 11, 1988

TABLET, CONTROLLED RELEASE; ORAL
MS CONTIN

	PURDUE FRDRK	60MG*	N19516 002	APR 08, 1988

NAFTIFINE HYDROCHLORIDE

CREAM; TOPICAL
NAFTIN

	HERBERT LABS	1%	N19599 001	FEB 29, 1988

NALIDIXIC ACID

TABLET; ORAL
NALIDIXIC ACID

>ADD >	AB	DANBURY PHARMA	250MG*		N71936 001
>ADD >				JUN 29, 1988 : JUN 28, 1988	
>ADD >	AB		500MG*		N72061 001
>ADD >				JUN 29, 1988 : JUN 28, 1988	
>ADD >	AB		1GM*		N71919 001
>ADD >				JUN 29, 1988 : JUN 28, 1988	

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE HCL

AP	ELKINS SINN	0.02MG/ML*		N71272 001
				MAY 24, 1988
AP		1MG/ML*		N71273 001
				MAY 24, 1988
AP		1MG/ML*		N71274 001
				MAY 24, 1988
AP		1MG/ML*		N71287 001
				MAY 24, 1988
AP	INTL MEDTN SYS	1MG/ML*		N72076 001
				MAR 24, 1988
AP		1MG/ML*		N72115 001
				APR 27, 1988

NITROFURANTOIN

TABLET; ORAL
NITROFURANTOIN

>DLT >/dd/		/BOLAR PHARM/	/100MG/	/N60447/002/
>ADD >		Ə BOLAR PHARM	100MG	N60447 002

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL
MACRODANTIN

>ADD >	AB	NORWICH EATON	50MG		N16620 001
>ADD >	AB		100MG		N16620 002
>ADD >		NITROFURANTOIN MACROCRYSTALLINE			
>ADD >	AB	BOLAR PHARM	50MG*		N70248 001
>ADD >					JUN 24, 1988
>ADD >	AB		100MG*		N70249 001
>ADD >					JUN 24, 1988

NITROGLYCERIN

INJECTABLE; INJECTION
NITROGLYCERIN

AP	LUITPOLD PHARMS	5MG/ML*		N71492 001
				MAY 24, 1988
AP		5MG/ML*		N72034 001
				MAY 24, 1988

NIZATIDINE

CAPSULE; ORAL
AXID
LILLY

	150MG*		N19508 001
			APR 12, 1988
	300MG*		N19508 002
			APR 12, 1988

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
AVENTYL HCL

BD	LILLY	EQ 10MG BASE		N14684 001
BD		EQ 25MG BASE		N14684 002
/BD/		/EQ 10MG BASE/		/N14684/001/
/BD/		/EQ 25MG BASE/		/N14684/002/
	PAMELOR			
BD	SANDOZ PHARMS	EQ 10MG BASE		N18013 001
BD		EQ 25MG BASE		N18013 002
/BD/		/EQ 10MG BASE/		/N18013/001/
/BD/		/EQ 25MG BASE/		/N18013/002/

NYSTATIN

CREAM; TOPICAL
NYSTATIN

>ADD >	AT	NASKA PHARMA	100,000 UNITS/GM*	N62949 001
>ADD >				JUN 13, 1988

SUSPENSION; ORAL
NYSTATIN

AA	THAMES PHARMA	100,000 UNITS/ML*		N62876 001
				FEB 29, 1988

OXAZEPAN

CAPSULE; ORAL

	OXAZEPAN			
AB	AN THERPTCS	10MG	N71955 001	MAR 03, 1988
AB		15MG	N71956 001	MAR 03, 1988
AB		30MG	N71957 001	MAR 03, 1988
AB	CHELSEA LABS	10MG	N71661 001	MAR 02, 1988
AB		15MG	N71662 001	MAR 02, 1988
AB		30MG	N71663 001	MAR 02, 1988
AB	CORD LABS	10MG	N71813 001	APR 19, 1988
AB		15MG	N71756 001	APR 19, 1988
AB		30MG	N71814 001	APR 19, 1988
/BP/	/MYLAN PHARMS/	/10MG/	/N71713/001/	/OCT 20, 1987/
/BP/		/15MG/	/N71714/001/	/OCT 20, 1987/
/BP/		/30MG/	/N71715/001/	/OCT 20, 1987/
	ə MYLAN PHARMS	10MG	N71713 001	OCT 20, 1987
	ə	15MG	N71714 001	OCT 20, 1987
	ə	30MG	N71715 001	OCT 20, 1987
AB	PUREPAC PHARM	10MG	N72251 001	APR 14, 1988
AB		15MG	N72252 001	APR 14, 1988
AB		30MG	N72253 001	APR 14, 1988
	SERAX			
AB	WYETH	10MG	N15539 002	
AB		15MG	N15539 004	
AB		30MG	N15539 006	
/BP/		/10MG/	/N15539/002/	
/BP/		/15MG/	/N15539/004/	
/BP/		/30MG/	/N15539/006/	

OXAZEPAN

CAPSULE; ORAL

	ZANOPAN			
AB	QUANTUM PHARMCS	10MG	N70650 001	MAR 01, 1988
AB		15MG	N70640 001	MAR 01, 1988
AB		30MG	N70641 001	MAR 01, 1988

OXYBUTYNIN CHLORIDE

TABLET; ORAL

	DITROPAN			
AB	MARION LABS	5MG	N17577 001	
	OXYBUTYNIN CHLORIDE			
AB	PHARM BASICS	5MG	N70746 001	MAR 10, 1988

OXYTETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

	OXYTETRACYCLINE HCL			
/AB/	/PUREPAC PHARM/	/EQ 250MG BASE/	/N60634/001/	
	ə PUREPAC PHARM	EQ 250MG BASE	N60634 001	

PANCURONIUM BROMIDE

INJECTABLE; INJECTION

	PANCURONIUM			
AP	ELKINS SINN	1MG/ML	N72058 001	MAR 23, 1988
AP		2MG/ML	N72059 001	MAR 23, 1988
AP		2MG/ML	N72060 001	MAR 23, 1988
	PANCURONIUM BROMIDE			
AP	ASTRA PHARM PRODS	1MG/ML	N72210 001	MAR 31, 1988
AP		2MG/ML	N72211 001	MAR 31, 1988
AP		2MG/ML	N72212 001	MAR 31, 1988
AP		2MG/ML	N72213 001	MAR 31, 1988
>ADD> AP	QUAD PHARMS	1MG/ML	N72209 001	JUN 03, 1988
>ADD> AP		2MG/ML	N72208 001	JUN 03, 1988

PANCURONIUM BROMIDE

INJECTABLE; INJECTION

PAVULON

AP	ORGANON	1MG/ML	N17015 002
AP		2MG/ML	N17015 001

PENICILLIN G POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN G POTASSIUM

[illegible]	[illegible]	[illegible]	[illegible]
∂	PUREPAC PHARM	400,000 UNITS/5ML	N61740 002

TABLET; ORAL

PENICILLIN G POTASSIUM

[illegible]	[illegible]	[illegible]	[illegible]
[illegible]		[illegible]	[illegible]
∂	PUREPAC PHARM	250,000 UNITS	N61588 002
∂		400,000 UNITS	N61588 003

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN V POTASSIUM

[illegible]	[illegible]	[illegible]	[illegible]
∂	PUREPAC PHARM	EQ 250MG BASE/5ML	N61758 002

TABLET; ORAL

PENICILLIN V POTASSIUM

[illegible]	[illegible]	[illegible]	[illegible]
[illegible]		[illegible]	[illegible]
∂	PUREPAC PHARM	EQ 250MG BASE	N61571 002
∂		EQ 500MG BASE	N61571 003

PERPHENAZINE

SYRUP; ORAL

TRILAFON

[illegible]	[illegible]	[illegible]	[illegible]
∂	SCHERING	2MG/5ML	N11294 002

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

PHENDIMETRAZINE TARTRATE

[illegible]	[illegible]	[illegible]	[illegible]
[illegible]		[illegible]	[illegible]
[illegible]		[illegible]	[illegible]
[illegible]		[illegible]	[illegible]
[illegible]		[illegible]	[illegible]
[illegible]		[illegible]	[illegible]
[illegible]		[illegible]	[illegible]
∂	BARR LABS	35MG	N83644 001
∂		35MG	N83684 001
∂		35MG	N83686 001
∂		35MG	N83687 001
∂		35MG	N84831 001
∂		35MG	N84834 001
∂		35MG	N84835 001

PHENTERMINE RESIN COMPLEX

CAPSULE, CONTROLLED RELEASE; ORAL

ZONAMIN-30

AB	PENNWALT	EQ 30MG BASE	N11613 002

PHENTERMINE RESIN 30

AB	QUANTUM PHARMCS	EQ 30MG BASE※	N89120 001 FEB 04, 1988

PIPERACETAZINE

TABLET; ORAL

QUIDE

[illegible]	[illegible]	[illegible]	[illegible]
	DON PHARMS	10MG	N13615 001
[illegible]		[illegible]	[illegible]
		25MG	N13615 002

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

POWDER FOR RECONSTITUTION; ORAL

COLONLYTE

AA	DYNAPHARM	227.1GM/PACKET;2.82GM/PACKET; 6.36GM/PACKET;5.53GM/PACKET; 21.5GM/PACKET※	N71320 001 APR 20, 1988

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

POWDER FOR RECONSTITUTION; ORAL
COLYTE

AB	REED & CARNRICK	227.1GM/PACKET;2.82GM/PACKET; 6.36GM/PACKET;5.53GM/PACKET; 21.5GM/PACKET	N18983 004 OCT 26, 1984

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

SOLUTION; ORAL
OCL

>DLT>	/3/ABBOTT/LABS/	/6GM/100ML;75MG/100ML;168MG/100ML;	
>DLT>		/146MG/100ML;	
>DLT>		/1.29GM/100ML/	/N19284/001/
>DLT>			/APR/30,/1986/
>ADD>	ABBOTT LABS	6GM/100ML;75MG/100ML;168MG/100ML;	
>ADD>		146MG/100ML;	
>ADD>		1.29GM/100ML	N19284 001
>ADD>			APR 30, 1986

POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

AP	STERIS LABS	2MEQ/ML	N89163 001 MAR 10, 1988

PREDNISOLONE

TABLET; ORAL
PREDNISOLONE

/BX/	/BARR/LABS/	/5MG/	/N84426/002/
	@ BARR LABS	5MG	N84426 002

PREDNISONE

TABLET; ORAL
PREDNISONE

AB	SUPERPHARM	5MG	N88865 001 OCT 25, 1984
AB		10MG	N88866 001 OCT 25, 1984
AB		20MG	N88867 001 OCT 25, 1984
/BX/		/5MG/	/N88865/001/ /OCT/25,/1984/
/BX/		/10MG/	/N88866/001/ /OCT/25,/1984/
/BX/		/20MG/	/N88867/001/ /OCT/25,/1984/

PROCAINAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
PROCAINAMIDE HCL

AP	WARNER CHILCOTT	100MG/ML	N89528 001 MAY 03, 1988
AP		500MG/ML	N89529 001 MAY 03, 1988

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION
PROCHLORPERAZINE EDISYLATE

AP	ELKINS SINN	EQ 5MG BASE/ML	N89523 001 MAY 03, 1988
AP	QUAD PHARMS	EQ 5MG BASE/ML	N89637 001 FEB 01, 1988
AP		EQ 5MG BASE/ML	N89638 001 FEB 01, 1988
AP	STERLING DRUG	EQ 5MG BASE/ML	N89703 001 APR 07, 1988

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROMETHAZINE HCL

AP	MARSAM PHARMS	25MG/ML	N89463 001 MAY 02, 1988
AP		50MG/ML	N89477 001 MAY 02, 1988

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL
PROMETHAZINE HCL

/BP/	/BARR/LABS/	/12.5MG/	/N84555/001/	
/BP/		/25MG/	/N84554/001/	
/BP/		/50MG/	/N84557/001/	
	∂ BARR LABS	12.5MG	N84555 001	
	∂	25MG	N84554 001	
	∂	50MG	N84557 001	

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPOXYPHENE HCL

/AA/	/BANMAX PHARMS/	/65MG/	/N83184/001/	
	∂ BANMAX PHARMS	65MG	N83184 001	
/AA/	/BARR/LABS/	/65MG/	/N83186/001/	
	∂ BARR LABS	65MG	N83186 001	

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

> ADD >	AB	LEDERLE LABS	10MG	N72117 001	JUN 23, 1988
> ADD >					
> ADD >	AB		20MG	N72118 001	JUN 23, 1988
> ADD >					
> ADD >	AB		40MG	N72119 001	JUN 23, 1988
> ADD >					
> ADD >	AB		80MG	N72120 001	JUN 23, 1988
> ADD >					
> DLT >/AA/		/PARKE/DAVIS/	/10MG/	/N70436/001/	/SEP/15./1986/
> DLT >					
	AB	SIDMAK LABS	10MG	N71972 001	APR 06, 1988
	AB		20MG	N71973 001	APR 06, 1988
	AB		40MG	N71974 001	APR 06, 1988
	AB		60MG	N71975 001	APR 06, 1988
	AB		80MG	N71976 001	APR 06, 1988
	AB		90MG	N71977 001	APR 06, 1988

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

> ADD >	AB	SUPERPHARM	10MG	N71515 001	JUN 08, 1988
> ADD >					
> ADD >	AB		20MG	N71516 001	JUN 08, 1988
> ADD >					
> ADD >	AB		40MG	N71517 001	JUN 08, 1988
> ADD >					
> ADD >	AB		80MG	N71518 001	JUN 08, 1988
> ADD >					
> ADD >	AB	WARNER CHILCOTT	10MG	N70438 001	SEP 15, 1986
> ADD >					

PROTAMINE SULFATE

INJECTABLE; INJECTION
PROTAMINE SULFATE

/AP/	/UPJOHN/	/50MG/VIAL/	/N07413/001/	
/AP/		/250MG/VIAL/	/N07413/002/	/AUG/02./1984/
	∂ UPJOHN	50MG/VIAL	N07413 001	
	∂	250MG/VIAL	N07413 002	AUG 02, 1984

QUINESTROL

TABLET; ORAL
ESTROVIS

/PARKE/DAVIS/	/0.1MG/	/N16768/002/	
∂ PARKE DAVIS	0.1MG	N16768 002	
	/0.2MG/	/N16768/003/	
∂	0.2MG	N16768 003	

RAUWOLFIA SERPENTINA

TABLET; ORAL
RAUVAL

/3/VALE/CHEM/	/50MG/	/N09108/002/	
/3/	/100MG/	/N09108/004/	
BP VALE CHEM	50MG	N09108 002	
BP	100MG	N09108 004	

RESERPINE

TABLET; ORAL
RESERPINE

/AB/	/BARR/LABS/	/0.25MG/	/N60721/002/	
	@ BARR LABS	0.25MG	N60721 002	

SECOBARBITAL SODIUM

CAPSULE; ORAL
SODIUM SECOBARBITAL

/AA/	/BARR/LABS/	/100MG/	/N84225/001/	
	@ BARR LABS	100MG	N84225 001	

SODIUM CHLORIDE

INJECTABLE; INJECTION

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	900MG/100ML	N19635 002	MAR 09, 1988

SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

>ADD> AP	ABBOTT LABS	450MG/100ML	N19759 001	JUN 08, 1988
>ADD> AP	KENDALL MCGAW	450MG/100ML	N19635 001	MAR 09, 1988

SODIUM CHLORIDE 3% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	3GM/100ML	N19635 003	MAR 09, 1988
AP	TRAVENOL LABS	3GM/100ML	N19022 001	NOV 01, 1983

SODIUM CHLORIDE 5% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	5GM/100ML	N19635 004	MAR 09, 1988
AP	TRAVENOL LABS	5GM/100ML	N19022 002	NOV 01, 1983

SODIUM SUCCINATE

INJECTABLE; INJECTION
SODIUM SUCCINATE

>DLT> >ADD>	/ELKINS/SINN/	/30%/	/N60516/001/	
	@ ELKINS SINN	30%	N60516 001	

SULFAMETHOXAZOLE

TABLET; ORAL
SULFAMETHOXAZOLE

/AB/	/BARR/LABS/	/500MG/	/N71169/001/	
	@ BARR LABS	500MG	/JUL 25, 1983/ N87189 001 JUL 25, 1983	

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL
TRIMETH/SULFA

AB	NASKA PHARMA	200MG/5ML;40MG/5ML	N72289 001	MAY 23, 1988
AB		200MG/5ML;40MG/5ML	N72398 001	MAY 23, 1988
AB		200MG/5ML;40MG/5ML	N72399 001	MAY 23, 1988

SULFISOXAZOLE

TABLET; ORAL
SULFISOXAZOLE

/AA/	/BARR/LABS/	/500MG/	/N84031/001/	
	@ BARR LABS	500MG	N84031 001	

SULINDAC

TABLET; ORAL
CLINORIL

AB	MS&D	150MG	N17911 001	
AB		200MG	N17911 002	

SULINDAC

AB	AM THERPTCS	150MG	N72171 001	MAY 23, 1988
AB		200MG	N72172 001	MAY 23, 1988
AB	DANBURY PHARMA	150MG	N71891 001	APR 03, 1990 : MAR 03, 1988
AB		200MG	N71795 001	APR 03, 1990 : MAR 03, 1988

TEMAZEPAM

CAPSULE; ORAL

TEMAZEPAM

AB	CORD LABS	15MG*	N71427 001	JAN 12, 1988
AB		30MG*	N71428 001	JAN 12, 1988

TERCONAZOLE

SUPPOSITORY; VAGINAL

TERAZOL 3

	ORTHO PHARM	80MG*	N19641 001 MAY 24, 1988

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

TETRACYCLINE HCL

>ADD>	AB	VITARINE	250MG	N61471 001

THEOPHYLLINE

ELIXIR; ORAL

THEOPHYLLINE

AA		NASKA PHARMA	80MG/15ML*	N89223 001 MAY 27, 1988

INJECTABLE; INJECTION

THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER

AP		TRAVENOL LABS	320MG/100ML	N18649 006 NOV 13, 1985

THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP		ABBOTT LABS	320MG/100ML*	N19211 006 JAN 20, 1988

TABLET, CONTROLLED RELEASE; ORAL

THEOLAIR-SR

BC		RIKER LABS	250MG	N86363 002 JUL 16, 1987
			/250MG/	/N86363/002/ /JUL/16/1987/

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

AB		PAR PHARM	150MG*	N89764 001 FEB 09, 1988
AB			200MG*	N89765 001 FEB 09, 1988
AB		ROXANE LABS	25MG	N88664 001 MAR 15, 1984

TIOCONAZOLE

OINTMENT; VAGINAL

VAGISTAT

>DLT>		/ROERIG/	/6.5%/	/N19355/001/ /DEC/30/1986/
>DLT>				
>ADD>		∂ ROERIG	6.5%	N19355 001 DEC 30, 1986
>ADD>				

TOLAZAMIDE

TABLET; ORAL

TOLAZAMIDE

AB		PHARM BASICS	100MG*	N71355 001 JAN 11, 1988

TOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE

/AA/		/BANMAX/PHARMS/	/500MG/	/N86141/001/
		∂ BANMAX PHARMS	500MG	N86141 001

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

DESYREL

AB		MEAD JOHNSON	150MG	N18207 003 MAR 25, 1985

TRAZODONE HCL

AB		PUREPAC PHARM	50MG*	N71636 001 APR 18, 1988
AB			100MG*	N71514 001 APR 18, 1988

TRAZON-150

AB		SIDMAK LABS	150MG*	N71525 001 MAR 09, 1988

TRIAMCINOLONE

TABLET; ORAL
TRIAMCINOLONE

/BP/	/BARR/LABS/	/2MG/	/N84286/001/	
/BP/		/2MG/	/N84318/001/	
/BP/		/4MG/	/N84267/001/	
/BP/		/4MG/	/N84319/001/	
/BP/		/8MG/	/N84268/001/	
/BP/		/8MG/	/N84320/001/	
	a BARR LABS	2MG	N84286 001	
	a	2MG	N84318 001	
	a	4MG	N84267 001	
	a	4MG	N84319 001	
	a	8MG	N84268 001	
	a	8MG	N84320 001	

TRIAZOLAM

TABLET; ORAL
HALCION

>DLT>	/UPJOHN/	/0.5MG/	/N17892/002/	
>DLT>			/NOV/15/1982/	
>ADD>	a UPJOHN	0.5MG	N17892 002	
>ADD>			NOV 15, 1982	

TRIDIHEXETHYL CHLORIDE

INJECTABLE; INJECTION
PATHILON

>DLT>	/LEDERLE/LABS/	/10MG/ML/	/N09729/001/	
>ADD>	a LEDERLE LABS	10MG/ML	N09729 001	

TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL
TRIFLUOPERAZINE HCL

>ADD>	AB	BOLAR PHARM	EQ 1MG BASE*	N85975 001	
>ADD>				JUN 23, 1988	
>ADD>	AB		EQ 2MG BASE*	N85976 001	
>ADD>				JUN 23, 1988	
>ADD>	AB		EQ 5MG BASE*	N85973 001	
>ADD>				JUN 23, 1988	
>ADD>	AB		EQ 10MG BASE*	N88710 001	
>ADD>				JUN 23, 1988	

TRIMETHOPRIM

TABLET; ORAL
TRIMETHOPRIM

>ADD>	AB	BARR LABS	100MG	N70494 001	
>ADD>				JAN 22, 1986	
	/AA/		/200MG/	/N70495/001/	
				/MAR/14/1986/	
>DLT>	/a/		/100MG/	/N70494/001/	
>DLT>				/JAN/22/1986/	
	a		200MG	N70495 001	
				MAR 14, 1986	

TRIPELENNAMINE HYDROCHLORIDE

TABLET; ORAL
TRIPELENNAMINE HCL

/AA/	/BARR/LABS/	/50MG/	/N80744/001/
	a BARR LABS	50MG	N80744 001

URSODIOL

CAPSULE; ORAL
DEURSIL

a CIBA PHARM	150MG	N19594 001
		DEC 31, 1987
a	300MG	N19594 002
		DEC 31, 1987
/CIBAPHARMEX/	/150MG/	/N19594/001/
		/DEC/31/1987/
	/300MG/	/N19594/002/
		/DEC/31/1987/

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION
LYPHOCIN

>ADD>	AP	LYPHOMED	EQ 1GM BASE/VIAL	N62663 002
>ADD>				JUL 31, 1987
>ADD>	AP		EQ 5GM BASE/VIAL*	N62663 003
>ADD>				JUN 03, 1988

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

VANCOCIN HCL

AP	LILLY	EQ 1GM BASE/VIAL	N60180 002	MAR 21, 1986
AP		EQ 1GM BASE/VIAL	N62476 002	MAR 21, 1986
AP		EQ 1GM BASE/VIAL	N62716 002	MAR 13, 1987
AP		EQ 1GM BASE/VIAL	N62812 002	NOV 17, 1987
AP		EQ 10GM BASE/VIAL	N62812 003	NOV 17, 1987
	VANCOLED			
AP	LEDERLE LABS	EQ 1GM BASE/VIAL*	N62682 002	MAR 30, 1988
> ADD > AP		EQ 5GM BASE/VIAL	N62682 004	MAY 11, 1988
> ADD > AP		EQ 10GM BASE/VIAL*	N62682 005	MAY 11, 1988
		EQ 2GM BASE/VIAL*	N62682 003	MAY 11, 1988

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL

CALAN

/AB/	/SEARLE/	/40MG/	/N18817/004/	/FEB/23,/1988/
AB	SEARLE PHARMS	40MG*	N18817 003	FEB 23, 1988
	∂	160MG	N18817 004	FEB 23, 1988

ISOPTIN

AB	KNOLL PHARM	40MG	N18593 003	NOV 23, 1987

VERAPAMIL HCL

AB	CORD LABS	80MG*	N71423 001	MAY 24, 1988
AB		120MG*	N71424 001	MAY 25, 1988
AB	LEDERLE LABS	80MG*	N71880 001	APR 05, 1988
AB		120MG*	N71881 001	APR 05, 1988
AB	MUTUAL PHARM	80MG*	N71488 001	JAN 13, 1988
AB		120MG*	N71489 001	JAN 13, 1988

VINCRISTINE SULFATE

INJECTABLE; INJECTION

VINCRISTINE SULFATE

AP	BULL LABS	1MG/VIAL*	N71559 001	APR 11, 1988
AP		2MG/VIAL*	N71560 001	APR 11, 1988
AP		5MG/VIAL*	N71561 001	APR 11, 1988
AP	QUAD PHARMS	1MG/VIAL	N71222 001	MAR 07, 1988
AP		2MG/VIAL	N71223 001	MAR 07, 1988
AP		5MG/VIAL	N71937 001	MAR 07, 1988

VINCRISTINE SULFATE PFS

AP	BULL LABS	1MG/ML*	N71484 001	APR 19, 1988

WATER FOR INJECTION, STERILE

LIQUID; N/A

STERILE WATER FOR INJECTION IN PLASTIC CONTAINER

AP	BAXTER	100%*	N18632 002	APR 19, 1988
AP	KENDALL MCGAW	100%*	N19633 001	FEB 29, 1988

XYLOSE

POWDER; ORAL

XYLOSE

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

ACETAMINOPHEN

SUPPOSITORY; RECTAL
TYLENOL

MCNEIL CONSUMER	120MG	N17756 002
	650MG	N17756 001
/MCNEIL/LABS/	/120MG/	/N17756/002/
	/650MG/	/N17756/001/

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, CONTROLLED RELEASE; ORAL
> ADD > RESPORAL

> ADD > PIONEER PHARMS	6MG;120MG	N89139 001
> ADD >		JUN 16, 1988

> ADD > HYDROCORTISONE

> ADD > OINTMENT; TOPICAL
> ADD > HC (HYDROCORTISONE)

> ADD > C&M PHARMA	0.5%	N80481 001

IBUPROFEN

TABLET; ORAL
IBUPROFEN

DANBURY PHARMA	200MG	N71905 001
		MAR 08, 1988
INTERPHARM	200MG	N72199 001
		MAY 23, 1988
INVAMED	200MG	N71807 001
		FEB 25, 1988
MEDICOPHARMA	200MG	N71639 001
		FEB 02, 1988
MYLAN PHARMS	200MG	N71870 001
		MAY 05, 1988
ZENITH LABS	200MG	N72040 001
		APR 29, 1988

NUPRIN

BRISTOL MYERS	200MG	N72035 001
		FEB 16, 1988
	200MG	N72036 001
		FEB 16, 1988
/UPJOHN/	/200MG/	/N19012/003/
		/JUL/29/1987/
	/200MG/	/N19012/001/
		/MAY/18/1984/
∂ UPJOHN	200MG	N19012 001
		MAY 18, 1984
∂	200MG	N19012 003
		JUL 29, 1987

INSULIN SEMISYNTHETIC PURIFIED HUMAN; INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN

INJECTABLE; INJECTION
MIXTARD HUMAN 70/30

NORDISK USA	30 UNITS/ML; 70 UNITS/ML	N19585 001
		MAR 11, 1988

INSULIN ZINC SUSP EXTENDED BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
HUMULIN U

/LILLY/	/40/UNITS/ML/	/N19571/001/
		/JUN/10/1987/
∂ LILLY	40 UNITS/ML	N19571 001
		JUN 10, 1987

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL
IMODIUM A-D

MCNEIL CONSUMER	1MG/5ML	N19487 001
		MAR 01, 1988

NONOXYNOL-9

SPONGE; VAGINAL
TODAY

/YLI/	/1GM/	/N18683/001/
		/APR/01/1983/
WHITEHALL LABS	1GM	N18683 001
		APR 01, 1983

DEXTRAN 70, 6% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION

MACRODEX(R)		
PHARMACIA INC	6GM/100ML;0.9GM/100ML	N 06826

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

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).

ORPHAN DRUG EXCLUSIVE APPROVAL STATUS (CODED ODE) APPLIES ONLY TO THE APPROVED OR LICENSED INDICATION(S) FOR WHICH ORPHAN DRUG DESIGNATION HAS BEEN GRANTED PURSUANT TO SECTION 526 OF THE ACT.

FOR THE FOLLOWING DRUG PRODUCTS WITH ORPHAN DRUG EXCLUSIVE APPROVAL STATUS, THE SPONSOR HAS SEVEN YEARS OF EXCLUSIVE APPROVAL FOR THE APPROVED INDICATION BEGINNING ON THE DATE OF NDA, ANTIBIOTIC APPLICATION, OR BIOLOGICAL LICENSE APPROVAL FOR THE DRUG. NO SUBSEQUENT SPONSOR MAY RECEIVE APPROVAL OF AN NDA, BIOLOGICAL LICENSE, PAPER NDA, ANTIBIOTIC APPLICATION, ANDA, OR ABBREVIATED ANTIBIOTIC APPLICATION DURING THE SEVEN YEAR PERIOD FOR THE DRUG AND INDICATION(S) FOR WHICH ODE STATUS IS MAINTAINED UNLESS THE EXCLUSIVE APPROVAL HAS BEEN REVOKED AS DESCRIBED ABOVE OR THE SUBSEQUENT SPONSOR HAS OBTAINED WRITTEN CONSENT FROM THE SPONSOR WHO HAS RECEIVED EXCLUSIVE APPROVAL.

BIOLOGICAL PRODUCTS, ANTIBIOTICS, AND DRUGS THAT HAVE BEEN APPROVED UNDER SECTION 505 OR 507 OF THE ACT OR UNDER SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT FOR MARKETING AND HAVE BEEN GIVEN ORPHAN DRUG EXCLUSIVE APPROVAL WILL BE NOTED BY THE ABBREVIATION ODE IN THE PATENT AND EXCLUSIVITY INFORMATION ADDENDUM. DRUG PRODUCTS THAT HAVE RECEIVED THE WRITTEN PERMISSION OF THE SPONSOR THAT HAS ORPHAN DRUG EXCLUSIVE APPROVAL TO BE APPROVED UNDER SECTION 527(b)(2) OF THE ACT ARE ALSO NOTED BY THE ABBREVIATION ODE IN THE PATENT AND EXCLUSIVITY INFORMATION ADDENDUM. THESE DRUG PRODUCTS DO NOT HAVE ANY EXCLUSIVE APPROVAL RIGHTS OF THEIR OWN, BUT CAN BE MARKETED BECAUSE OF THE CONSENT GIVEN BY THE SPONSOR THAT HAS EXCLUSIVE APPROVAL. THESE PRODUCTS ARE MARKED BY AN (*) NEXT TO THE APPLICANT'S NAME.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 8TH EDITION FOR A FULL LISTING OF ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

DRUG PRODUCTS

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME DOSAGE FORM; ROUTE	APPLICANT	APPL. PROD. APPROVAL DATE	EXCLUSIVITY EXP. DATE
METHOTREXATE SODIUM EQ 1GM BASE/VIAL	METHOTREXATE SODIUM INJECTABLE; INJECTION	LEDERLE LABS	11719 009 APR 07, 1988	ODE APR 07, 1995

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

NO JUNE 1988 APPROVALS

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, 8TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NAME OF DRUG (DOSAGE FORM)	DATE	REVISED DATE
CARBAMAZEPINE (TABLET)	JAN 01, 1988	
CLINDAMYCIN (CAPSULE)	MAY 31, 1988	
CYCLOBENZAPRINE HYDROCHLORIDE (TABLET)	JAN 25, 1988	
DOXYCYCLINE HYCLATE (CAPSULE AND TABLET)	APR 11, 1988	
FENOPROFEN (CAPSULE AND TABLET)	AUG 27, 1987	FEB 03, 1988
INDOMETHACIN (CAPSULE)	JAN 27, 1988	
MESTRANOL; NORETHYNODREL (TABLET)	MAY 13, 1988	
METAPROTERENOL SULFATE (TABLET)	MAR 18, 1988	
NORETHINDRONE; ETHINYL ESTRADIOL (TABLET)	MAR 18, 1988	

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, 8TH 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
ASPIRIN; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 5MG	87 P-0376/CP	ANABOLIC	NEW STRENGTH	APPROVED FEB 12, 1988
ASPIRIN; HYDROCODONE BITARTRATE TABLET; ORAL	650MG 5MG	87 P-0376/ CP0002	ANABOLIC	NEW STRENGTH	APPROVED FEB 12, 1988
CHLORZOXAZONE CAPSULE; ORAL	500MG	82 N-0032/ CP0006	MIKART	NEW DOSAGE FORM	APPROVED JAN 13, 1988

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CISPLATIN INJECTABLE; INJECTION	1MG/ML (10ML/VIAL) (50ML/VIAL) (100ML/VIAL)	87 P-0421/CP	BULL LABS	NEW DOSAGE FORM NEW STRENGTH	APPROVED FEB 29, 1988
CISPLATIN INJECTABLE; INJECTION	1MG/ML (20ML/VIAL)	88 P-0010/CP	LYPHOMED	NEW DOSAGE FORM NEW STRENGTH	APPROVED APR 01, 1988
FLUOROURACIL INJECTABLE; INJECTION	50MG/ML (5ML/VIAL)	88 P-0052/CP	BEN VENUE LABS	NEW STRENGTH	APPROVED MAR 21, 1988
HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE SOFT GELATIN CAPSULE; ORAL	1.5MG 5MG	88 P-0061/CP	KLEINFELD, KAPLAN AND BECKER	NEW DOSAGE FORM	APPROVED MAY 12, 1988
HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE SOLUTION; ORAL	25MG/5ML 40MG/5ML	87 P-0399/CP	BURDITT, BOWLES, RADZIUS AND RUBERRY	NEW DOSAGE FORM	APPROVED FEB 16, 1988

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE SOLUTION; ORAL	25MG/5ML 80MG/5ML	87 P-0399/CP	BURDITT, BOWLES, RADZIUS AND RUBERRY	NEW DOSAGE FORM	APPROVED FEB 16, 1988
HYDROCHLOROTHIAZIDE; TRIAMTERENE TABLET; ORAL	25MG 50MG	87 P-0335/CP	PAR PHARM	NEW DOSAGE FORM	APPROVED FEB 26, 1988
MEPERIDINE HYDROCHLORIDE INJECTABLE; INJECTION	10MG/ML (50ML/CONTAINER)	88 P-0008/CP	LYPHOMED	NEW STRENGTH	APPROVED APR 01, 1988
METOCLOPRAMIDE HYDROCHLORIDE INTENSOL CONCENTRATE; ORAL	10MG/ML	88 P-0164/CP	ROXANE LABS	NEW STRENGTH	APPROVED JUN 28, 1988
NIFEDIPINE CAPSULE; ORAL	10MG	88 P-0072/CP	MARTEC PHARMS	NEW DOSAGE FORM	APPROVED MAY 11, 1988
NIFEDIPINE CAPSULE; ORAL	20MG	88 P-0072/ CP0002	MARTEC PHARMS	NEW DOSAGE FORM	APPROVED MAY 11, 1988

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
PHENYTOIN SODIUM INJECTABLE; INJECTION	100MG/VIAL	87 P-0367/CP	LYPHOMED	NEW DOSAGE FORM	APPROVED FEB 16, 1988
PHENYTOIN SODIUM INJECTABLE; INJECTION	250MG/VIAL	87 P-0367/CP	LYPHOMED	NEW DOSAGE FORM	APPROVED FEB 16, 1988
THEOPHYLLINE CAPSULE, CONTROLLED RELEASE; ORAL	450MG	88 P-0119/CP	RIKER LABS	NEW STRENGTH	APPROVED MAY 11, 1988
THIOTEPA (WITH DILUENT) INJECTABLE; INJECTION	15MG/VIAL	87 P-0382/CP	LYPHOMED	NEW DOSAGE FORM	APPROVED MAY 12, 1988
VERAPAMIL HYDROCHLORIDE CAPSULE, CONTROLLED RELEASE; ORAL	120MG 240MG	87 P-0233/CP	SEARLE	NEW DOSAGE FORM NEW STRENGTH	APPROVED FEB 26, 1988

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
BENZOYL METRONIDAZOLE SUSPENSION; ORAL	200MG/5ML	85 P-0258/CP	APKON LABS	NEW ESTER NEW INGREDIENT	DENIED MAR 19, 1986
BROMPHENIRAMINE MALEATE; HYDROCODONE BITARTRATE; PHENYLPROPANOLAMINE HYDROCHLORIDE SYRUP; ORAL	2MG/5ML 2.5MG/5ML 12.5MG/5ML	85 P-0237/CP	MIKART	NEW COMBINATION	DENIED MAY 11, 1988
BROMDIPHENHYDRAMINE HYDROCHLORIDE; HYDROCODONE BITARTRATE SOLUTION; ORAL	12.5MG/5ML 2.5MG/5ML	85 P-0255/CP	MIKART	NEW COMBINATION	DENIED MAY 11, 1988
BROMDIPHENHYDRAMINE HYDROCHLORIDE; HYDROCODONE BITARTRATE SYRUP; ORAL	12.5MG/5ML 2.5MG/5ML	85 P-0255/CP	MIKART	NEW COMBINATION	DENIED MAY 11, 1988
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	100MG/ML (1ML/VIAL) (2ML/VIAL)	87 P-0283/CP	LYPHOMED	NEW DOSAGE FORM NEW STRENGTH	DENIED JAN 21, 1988
CYCLOPHOSPHAMIDE	500MG/ML	87 P-0283/CP	LYPHOMED	NEW DOSAGE	DENIED

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE, SUSTAINED RELEASE; ORAL	75MG	87 P-0355/CP	PARKE DAVIS	NEW DOSAGE FORM NEW STRENGTH	DENIED MAY 11, 1988
HYDROCODONE BITARTRATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE SYRUP; ORAL	1.66MG/5ML 5MG/5ML 6.25MG/5ML	85 P-0389/CP	UAD LABS	NEW COMBINATION	DENIED MAY 11, 1988
HYDROCODONE BITARTRATE; PROMETHAZINE HYDROCHLORIDE SYRUP; ORAL	2.5MG/5ML 6.25MG/5ML	85 P-0256/CP	MIKART	NEW COMBINATION	DENIED MAY 11, 1988
METOCLOPRAMIDE HYDROCHLORIDE INJECTABLE; INJECTION	1MG/ML (50ML/VIAL)	87 P-0090/CP	INTL MEDTN SYS	NEW STRENGTH	DENIED FEB 08, 1988

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
METOCLOPRAMIDE HYDROCHLORIDE INJECTABLE; INJECTION	1MG/ML (75ML/VIAL)	87 P-0090/CP	INTL MEDTN SYS	NEW STRENGTH	DENIED FEB 08, 1988
METOCLOPRAMIDE HYDROCHLORIDE INJECTABLE; INJECTION	1MG/ML (100ML/VIAL)	87 P-0090/CP	INTL MEDTN SYS	NEW STRENGTH	DENIED FEB 08, 1988

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, 8TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES

NEW DOSING SCHEDULE

D-12	BEDTIME DOSING OF 800MG FOR TREATMENT OF ACTIVE DUODENAL ULCER
D-13	INCREASED MAXIMUM DAILY DOSAGE RECOMMENDATION
D-14	BEDTIME DOSING OF 800MG FOR TREATMENT OF ACTIVE BENIGN GASTRIC ULCER

NEW INDICATION

I-72	PHOTOPHERESIS IN THE PALLIATIVE TREATMENT OF SKIN MANIFESTATIONS OF CUTANEOUS T-CELL LYMPHOMA IN PERSONS NOT RESPONSIVE TO OTHER TREATMENT
I-73	FOLLICULAR STIMULATION IN VITRO FERTILIZATION
I-74	MANAGEMENT OF CONGESTIVE HEART FAILURE

EXCLUSIVITY TERMS

REFERENCES

PATENT USE CODE

U-26	METHOD OF TREATING ANIMALS SUFFERING FROM AN APPETITE DISORDER
U-27	METHOD OF BLOCKING THE UPTAKE OF MONOAMINES BY BRAIN NEURONS IN ANIMALS
U-28	METHOD FOR IMPROVING MEMORY IN MAMMALS
U-29	METHOD FOR TREATING AMNESIA
U-30	METHOD OF POTENTIATING CODEINE ANALGESIA IN MAMMALS
U-31	USE IN LUNG SCANNING PROCEDURES
U-32	TREATMENT OF VENTRICULAR AND SUPRAVENTRICULAR ARRHYTHMIAS
U-33	METHOD FOR INHIBITING GASTRIC SECRETION IN MAMMALS
U-34	TREATMENT OF INFLAMMATION

	APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19489 001	ALBUTEROL SULFATE; VENTOLIN ROTACAPS	3705233	DEC 05, 1989			
			3644353	FEB 22, 1989		NDF	MAY 04, 1991
>ADD>	18116 002	AMCINONIDE; CYCLOCORT	4158055	JUN 12, 1996	U-34		
>ADD>	18498 001	AMCINONIDE; CYCLOCORT	4158055	JUN 12, 1996	U-34		
>ADD>	18644 001	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002			
>DLT>	18644 001	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002			
>ADD>	18644 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002			
>DLT>	18644 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002			
>ADD>	18644 003	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002			
>DLT>	18644 003	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002			
	17920 002	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994		D-14	MAR 31, 1991
			3950333	APR 13, 1993		D-12	APR 30, 1989
	17920 003	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994		D-14	MAR 31, 1991
			3950333	APR 13, 1993		D-12	APR 30, 1989
	17920 004	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994		D-14	MAR 31, 1991
			3950333	APR 13, 1993		D-12	APR 30, 1989
	17920 005	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994		D-14	MAR 31, 1991
			3950333	APR 13, 1993		D-12	APR 30, 1989
	17924 001	CIMETIDINE HYDROCHLORIDE; TAGAMET	4024271	MAY 17, 1994		D-14	MAR 31, 1991
			3950333	APR 13, 1993		D-12	APR 30, 1989
>ADD>	18998 001	ENALAPRIL MALEATE; VASOTEC				I-74	JUN 24, 1991
>ADD>	18998 002	ENALAPRIL MALEATE; VASOTEC				I-74	JUN 24, 1991
>ADD>	18998 003	ENALAPRIL MALEATE; VASOTEC				I-74	JUN 24, 1991
	19309 001	ENALAPRILAT; VASOTEC	4374829	FEB 22, 2000		NDF	FEB 09, 1991
	18981 002	ENCAINIDE HYDROCHLORIDE; ENKAID	RE30811	DEC 20, 1996	U-32		
	18981 003	ENCAINIDE HYDROCHLORIDE; ENKAID	RE30811	DEC 20, 1996	U-32		
	18981 004	ENCAINIDE HYDROCHLORIDE; ENKAID	RE30811	DEC 20, 1996	U-32		
>ADD>	18830 003	FLECAINIDE ACETATE; TAMBOCOR	4005209	JAN 25, 1996		NS	JUN 03, 1991
>ADD>			3900481	AUG 19, 1992		NCE	OCT 31, 1990
	19452 001	FLUOCINOLONE ACETONIDE; DERMA-SMOOTHE/FS				NDF	FEB 03, 1991
	18936 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4683235	JUL 28, 2004	U-30		
			4647591	MAR 03, 2004	U-28		
			4647591	MAR 03, 2004	U-29		
			4626549	DEC 02, 2003	U-26		
			4626549	DEC 02, 2003	U-27		
			4194009	APR 19, 1994			
	19404 001	FLURBIPROFEN SODIUM; OCUFEN	3793457	FEB 19, 1993			
>ADD>	19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST	4647447	MAR 03, 2004		NCE	JUN 02, 1993
	18061 001	HYDROCHLOROTHIAZIDE; TIMOLIDE 10-25	3655663	APR 11, 1989		D-2	FEB 03, 1991
>ADD>	19129 003	HYDROCHLOROTHIAZIDE; MAXZIDE-25	4444769	APR 24, 2001		NS	MAY 13, 1991
	18956 003	IOHEXOL; OMNIPAQUE 300	4021481	MAY 03, 1994		I-55	FEB 01, 1988

	APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19085 001	IPRATROPIUM BROMIDE; ATROVENT	3681500	AUG 01, 1991		NCE	DEC 29, 1991
	19777 001	LISINOPRIL; ZESTRIL	4374829	FEB 22, 2000		NCE	DEC 29, 1992
	19777 002	LISINOPRIL; ZESTRIL	4374829	FEB 22, 2000		NCE	DEC 29, 1992
	19777 003	LISINOPRIL; ZESTRIL	4374829	FEB 22, 2000		NCE	DEC 29, 1992
	19487 001	LOPERAMIDE HYDROCHLORIDE; IMODIUM A-D	3714159	JAN 30, 1990			
>ADD>	11719 009	METHOTREXATE SODIUM; METHOTREXATE				ODE	APR 07, 1995
	09048 001	METHOXSALEN; 8-MOP				I-72	MAR 23, 1991
	19516 002	MORPHINE SULFATE; MS CONTIN				NDF	MAY 29, 1990
	18677 001	NABILONE; CESAMET	4087545	MAY 02, 1997	U-7		
	19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 1998		NCE	MAR 01, 1993
	19508 001	NIZATIDINE; AXID	4382090	MAY 03, 2000	U-33		
			4375547	MAR 01, 2000		NCE	APR 12, 1993
	19508 002	NIZATIDINE; AXID	4382090	MAY 03, 2000	U-33		
			4375547	MAR 01, 2000		NCE	APR 12, 1993
	19009 001	PIRBUTEROL ACETATE; EXIREL	4175128	NOV 20, 1996			
			3786160	JAN 15, 1993			
			3700681	OCT 24, 1989		NCE	DEC 30, 1991
	17881 001	TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT; TECHNETIUM TC 99M	A3872226	MAR 18, 1992			
			3863004	JAN 28, 1992	U-31		
	19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 1998	U-5	NCE	AUG 07, 1992
			4112097	SEP 05, 1995	U-5		
			4026894	MAY 31, 1994			
	19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 1998	U-5	NCE	AUG 07, 1992
			4112097	SEP 05, 1995	U-5		
			4026894	MAY 31, 1994			
	19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 1998	U-5	NCE	AUG 07, 1992
			4112097	SEP 05, 1995	U-5		
			4026894	MAY 31, 1994			
	19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 1998	U-5	NCE	AUG 07, 1992
			4112097	SEP 05, 1995	U-5		
			4026894	MAY 31, 1994			
	19641 001	TERCONAZOLE; TERAZOL 3	4358449	NOV 09, 1999		NCE	DEC 31, 1992
						NDF	MAY 24, 1991
	18207 003	TRAZODONE HYDROCHLORIDE; DESYREL	4258027	MAR 24, 1998			
			4215104	JUL 29, 1997			
	19415 002	UROFOLLITROPIN; METRODIN				I-73	MAR 01, 1991
	18817 003	VERAPAMIL HYDROCHLORIDE; CALAN				I-50	DEC 16, 1989
						I-51	DEC 16, 1989
	18817 004	VERAPAMIL HYDROCHLORIDE; CALAN				I-50	DEC 16, 1989
						I-51	DEC 16, 1989

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