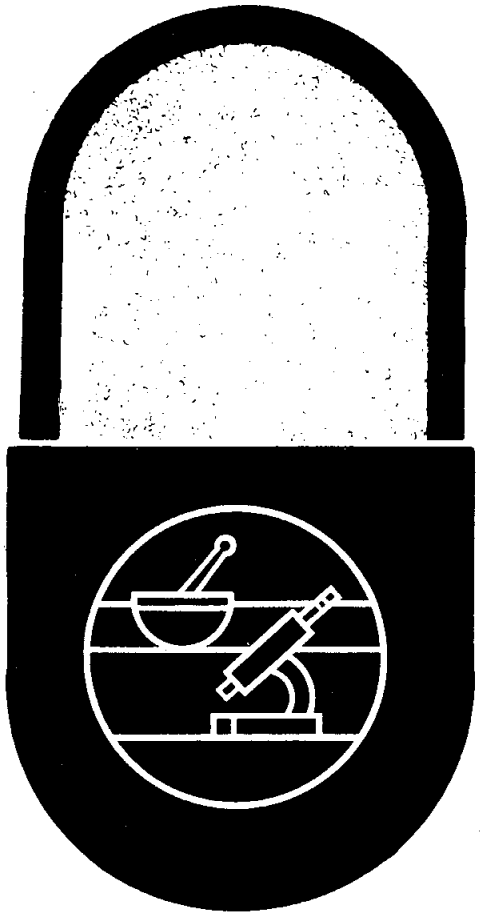
CUMULATIVE SUPPLEMENT 3
JAN'88-MAR'88



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

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CUMULATIVE SUPPLEMENT 3

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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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER[1]

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

*This number is inclusive of products discontinued since December 1987, and any products approved or discontinued through March 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, APAP, AND CAFFEINE

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

ACETAMINOPHEN; CODEINE PHOSPHATE

ELIXIR; ORAL

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	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

TYLENOL W/ CODEINE

/AA/	/MCNEIL/LABS/	/325MG;7.5MG/	/N85056/001/
/AA/		/325MG;15MG/	/N85056/002/
/AA/		/325MG;30MG/	/N85056/003/
/AA/		/325MG;60MG/	/N85056/004/
AA	MCNEIL PHARM	325MG;7.5MG	N85056 001
AA		325MG;15MG	N85056 002
AA		325MG;30MG	N85056 003
AA		325MG;60MG	N85056 004

TYLENOL W/ CODEINE NO. 1

/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

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

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

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

AB	MYLAN PHARMS	650MG;100MG	N72195 001 FEB 16, 1988

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

ACETAZOLAMIDE SODIUM

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

DIAMOX

AP	LEDERLE LABS	500MG/VIAL	N09388 001

ALSEROXYLON

TABLET; ORAL

RAUTENSIN

>DLT>	/BP/	/DORSEY/LABS/	/2MG/	/N09215/001/
>ADD>		@ DORSEY LABS	2MG	N09215 001

AMINOPHYLLINE

TABLET; ORAL

AMINOPHYLLINE

/BP/	/BARR/LABS/	/100MG/	/N88297/001/ /AUG 19, 1983/
	@ BARR LABS	100MG	N88297 001 AUG 19, 1983
/BP/		/200MG/	/N88298/001/ /AUG 19, 1983/
	@	200MG	N88298 001 AUG 19, 1983
>DLT>	/2/VALE/CHEM/	/100MG/	/N84533/001/
>ADD>	BD VALE CHEM	100MG	N84533 001

AMINOSALICYLATE SODIUM

TABLET; ORAL

TEEBACIN

/BP/	/CNSOL/MIDLAND/	/500MG/	/N07320/002/
	@ CNSOL MIDLAND	500MG	N07320 002

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIL

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

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL

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

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

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

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

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

COMPOUND 65

/AB/	/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	

BENZTHIAZIDE

TABLET; ORAL

BENZTHIAZIDE

/DP/	/PRIVATE/FMLTNS/	/50MG/	/N83206/001/	
	@ PRIVATE FMLTNS	50MG	N83206 001	

BETAMETHASONE VALERATE

CREAM; TOPICAL

DERMABET

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

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	N8446B 001	

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	

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
ANCEF

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¤	N628D7 005	JAN 12, 1988
AP		EQ 20GM BASE/VIAL¤	N62807 006	JAN 12, 1988

CEPHALEXIN

CAPSULE; ORAL
CEPHALEXIN

>ADD> AB	JEROME STEVENS	EQ 250MG BASE¤	N62870 001	MAR 17, 1988
>ADD> 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

CEPHRADINE

CAPSULE; ORAL
CEPHRADINE

AB	VITARINE	250MG¤	N62813 001	FEB 25, 1988
AB		500MG¤	N62813 002	FEB 25, 1988

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

/AB/	/PUREPAC/PHARM/	/5MG/	/N85155/001/	
	a PUREPAC PHARM	5MG	N85155 001	
/AB/		/10MG/	/N84939/002/	
	a	10MG	N84939 002	
/AB/		/25MG/	/N85144/001/	
	a	25MG	N85144 001	

LYGEN

/AB/	/BANMAX/PHARMS/	/5MG/	/N85107/002/	
	a BANMAX PHARMS	5MG	N85107 002	
/AB/		/10MG/	/N85009/001/	
	a	10MG	N85009 001	
/AB/		/25MG/	/N85108/001/	
	a	25MG	N85108 001	

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

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

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

>ADD >	AP	QUAD PHARMS	EQ 150MG BASE/ML¤	N62877 001
>ADD >				MAR 15, 1988
>ADD >	AP	SOLOPAK LABS	EQ 150MG BASE/ML¤	N62819 001
>ADD >				MAR 15, 1988
>ADD >	AP		EQ 150MG BASE/ML¤	N62852 001
>ADD >				MAR 17, 1988

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

>ADD >	AB	CHELSEA LABS	3.75MG¤	N71878 001
>ADD >				MAR 15, 1988
>ADD >	AB		7.5MG¤	N71879 001
>ADD >				MAR 15, 1988
>ADD >	AB		15MG¤	N71860 001
>ADD >				MAR 15, 1988

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

>ADD >	AB	WARNER CHILCOTT	3.75MG¤	N71774 001
>ADD >				MAR 01, 1988
>ADD >	AB		7.5MG¤	N71775 001
>ADD >				MAR 01, 1988
>ADD >	AB		15MG¤	N71776 001
>ADD >				MAR 01, 1988

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

>ADD >	AB	WARNER CHILCOTT	3.75MG¤	N71828 001
>ADD >				MAR 03, 1988
>ADD >	AB		7.5MG¤	N71829 001
>ADD >				MAR 03, 1988
>ADD >	AB		15MG¤	N71830 001
>ADD >				MAR 03, 1988
	AB	WATSON LABS	3.75MG¤	N71852 001
				FEB 09, 1988
	AB		7.5MG¤	N71853 001
				FEB 09, 1988
	AB		15MG¤	N71854 001
				FEB 09, 1988

COLCHICINE; PROBENECID

TABLET; ORAL

PROBENECID AND COLCHICINE

/BP/	/BEECHAM/LABS/	/0.5MG;500MG/	/N84321/001/
	a BEECHAM LABS	0.5MG;500MG	N84321 001

PROBENECID W/ COLCHICINE

/BP/	/LEDERLE/LABS/	/0.5MG;500MG/	/N86954/001/
	a 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

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

	DESIPRAMINE HCL			
AB	VITARINE	10MG¤	N72167 001	
			FEB 03, 1988	
AB		150MG¤	N72254 001	
			FEB 03, 1988	
	NORPRAMIN			
AB	MERRELL DOW	10MG	N14399 007	
			FEB 11, 1982	
AB		150MG	N14399 006	

DEXAMETHASONE

TABLET; ORAL

	DEXAMETHASONE			
/BP/	/BARR/LABS/	/0.25MG/	/N84013/001/	
	ə BARR LABS	0.25MG	N84013 001	
/BP/		/0.25MG/	/N84764/001/	
	ə	0.25MG	N84764 001	
/BP/		/0.5MG/	/N84084/001/	
	ə	0.5MG	N84084 001	
/BP/		/0.75MG/	/N84081/001/	
	ə	0.75MG	N84081 001	
/BP/		/0.75MG/	/N84765/001/	
	ə	0.75MG	N84765 001	
/BP/		/1.5MG/	/N84086/001/	
	ə	1.5MG	N84086 001	
/BP/		/1.5MG/	/N84763/001/	
	ə	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	
	DEXTRDSE 7.7% IN PLASTIC CONTAINER			
	KENDALL MCGAW	7.7GM/100ML¤	N19626 003	
			FEB 02, 1988	

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

>DLT>	/DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/W//POTASSIUM/CHLORIDE/			
>DLT>	/0.075%/IN/PLASTIC/CONTAINER/			
>DLT>	/ABBOTT/LABS/	/5GM/100ML;74.5MG/100ML;/		
>DLT>		/300MG/100ML/		/N18876/001/
>DLT>				/JAN 17,/1986/
>DLT>	/DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/W//POTASSIUM/CHLORIDE/			
>DLT>	/0.15%/IN/PLASTIC/CONTAINER/			
>DLT>	//ABBOTT/LABS/	/5GM/100ML;149MG/100ML;/		
>DLT>		/300MG/100ML/		/N18876/002/
>DLT>				/JAN 17,/1986/
>DLT>	/DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/W//POTASSIUM/CHLORIDE/			
>DLT>	/0.22%/IN/PLASTIC/CONTAINER/			
>DLT>	//ABBOTT/LABS/	/5GM/100ML;224MG/100ML;/		
>DLT>		/300MG/100ML/		/N18876/003/
>DLT>				/JAN 17,/1986/
>DLT>	/DEXTROSE/5%;/SODIUM/CHLORIDE/0.225%;/POTASSIUM/CHLORIDE/			
>DLT>	/0.15%/IN/PLASTIC/CONTAINER/			
>DLT>	//ABBOTT/LABS/	/5GM/100ML;150MG/100ML;/		
>DLT>		/225MG/100ML/		/N18365/001/
>DLT>	**/DEXTROSE 5%; SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/**			
>DLT>	**/0.22% IN PLASTIC CONTAINER/**			
>DLT>/AP/	//ABBOTT/LABS/	/5GM/100ML;224MG/100ML;/		
>DLT>		/450MG/100ML/		/N18362/002/
>DLT>	**/DEXTROSE 5%; SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/**			
>DLT>	**/0.3% IN PLASTIC CONTAINER/**			
>DLT>/AP/	//ABBOTT/LABS/	/5GM/100ML;225MG/100ML;/		
>DLT>		/450MG/100ML/		/N18362/003/

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER			
	KENDALL MCGAW	10GM/100ML;37MG/100ML; 200MG/100ML¤	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/100ML¤	N19630 037 FEB 17, 1988
POTASSIUM CHLDRIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER			
	KENDALL MCGAW	10GM/100ML;37MG/100ML; 900MG/100ML¤	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/100ML¤	N19630 001 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

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

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;37MG/100ML; 330MG/100ML‡ 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/100ML‡ 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/100ML‡ 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/100ML‡ N19630 032 FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENOALL MCGAW 10GM/100ML;75MG/100ML; 450MG/100ML‡ 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/100ML‡ N19630 044 FEB 17, 1988

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

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

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

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

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

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;75MG/100ML; 110MG/100ML‡ 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/100ML‡ 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/100ML‡ 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/100ML‡ 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/100ML‡ 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/100ML‡ 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/100ML‡ 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/100ML‡ N19630 021 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;110MG/100ML; 900MG/100ML¤ N19630 D27 FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;150MG/100ML; 200MG/100ML¤ N19630 D34 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/100ML¤ 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/10DML; 900MG/10DML¤ N19630 D46 FEB 17, 1988

AP POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENOALL MCGAW 5GM/100ML;150MG/100ML; 200MG/100ML¤ N19630 D10 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/100ML¤ N19630 016 FEB 17, 1988

AP POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENOALL MCGAW 5GM/100ML;150MG/100ML; 450MG/100ML¤ 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/100ML¤ 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/100ML¤ 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/100ML¤ N19630 035 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

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

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;220MG/100ML; 900MG/100ML¤ N19630 D47 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/100ML¤ N19630 005 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/10DML;220MG/1DDML; 200MG/100ML¤ N19630 011 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
KENOALL MCGAW 5GM/1DOML;220MG/100ML; 330MG/100ML¤ N19630 D17 FEB 17, 1988

POTASSIUM CHLORIDE D.22% IN DEXTROSE 5% ANO SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;220MG/100ML; 450MG/100ML¤ N19630 023 FEB 17, 1988

POTASSIUM CHLORIDE D.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;220MG/100ML; 900MG/100ML¤ 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/100ML¤ N19630 036 FEB 17, 1988

POTASSIUM CHLORIDE D.3% IN OEXTROSE 10% AND SOOIUM CHLORIDE D.45% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;300MG/100ML; 450MG/100ML¤ N19630 042 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 10% AND SODIUM CHLORIDE D.9% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/10DML;300MG/100ML; 900MG/100ML¤ N19630 048 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTIDN

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML;300MG/100ML; 200MG/100ML¤ N19630 012 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML;300MG/100ML; 330MG/100ML¤ 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/100ML¤ 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/100ML¤ 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/100ML¤ N19630 006 FEB 17, 1988

> ADD > POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

> ADD > AP ABBOTT LABS 5GM/100ML;74.5MG/100ML; 450MG/100ML¤ N18362 009 JUL 05, 1983

> ADD > AP 5GM/100ML;149MG/100ML; 450MG/100ML¤ N18362 005 MAR 28, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

> ADD > AP ABBOTT LABS 5GM/100ML;74.5MG/100ML; 900MG/100ML¤ N19691 002 MAR 24, 1988

> ADD > AP 5GM/100ML;149MG/100ML; 900MG/100ML¤ N19691 004 MAR 24, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

> ADD > POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

> ADD > ABBOTT LABS 5GM/100ML;74.5MG/100ML; 225MG/100ML¤ N18365 002 JUL 05, 1983

> ADD > 5GM/100ML;149MG/100ML; 225MG/100ML¤ N18365 006 MAR 28, 1988

> ADD > POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

> ADD > ABBOTT LABS 5GM/100ML;74.5MG/100ML; 300MG/100ML N18876 001 JAN 17, 1986

> ADD > 5GM/100ML;149MG/100ML; 300MG/100ML¤ N18876 006 MAR 28, 1988

> ADD > POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

> ADD > AP TRAVENOL LABS 5GM/100ML;75MG/100ML; 900MG/100ML¤ N19308 004 APR 05, 1985

> ADD > POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

> ADD > AP ABBOTT LABS 5GM/100ML;224MG/100ML; 450MG/100ML¤ N18362 006 MAR 28, 1988

> ADD > POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

> ADD > AP ABBOTT LABS 5GM/100ML;224MG/100ML; 900MG/100ML¤ N19691 006 MAR 24, 1988

> ADD > POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

> ADD > ABBOTT LABS 5GM/100ML;224MG/100ML; 225MG/100ML¤ N18365 008 MAR 28, 1988

> ADD > POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

> ADD > ABBOTT LABS 5GM/100ML;224MG/100ML; 300MG/100ML¤ N18876 007 MAR 28, 1988

> ADD > POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

> ADD > AP ABBOTT LABS 5GM/100ML;149MG/100ML; 450MG/100ML¤ N18362 010 JUL 05, 1983

> ADD > AP 5GM/100ML;298MG/100ML; 450MG/100ML¤ N18362 007 MAR 28, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

> ADD > AP ABBOTT LABS 5GM/100ML;149MG/100ML; 900MG/100ML¤ N19691 005 MAR 24, 1988

> ADD > AP 5GM/100ML;298MG/100ML; 900MG/100ML¤ N19691 008 MAR 24, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

> ADD > ABBOTT LABS 5GM/100ML;149MG/100ML; 225MG/100ML N18365 001

> ADD > 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

> ADD > ABBOTT LABS 5GM/100ML;149MG/100ML; 300MG/100ML N18876 002 JAN 17, 1986

> ADD > 5GM/100ML;298MG/100ML; 300MG/100ML¤ N18876 008 MAR 28, 1988

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

> ADD > 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

> ADD > AP ABBOTT LABS 5GM/100ML;224MG/100ML; 900MG/100ML¤ N19691 007 MAR 24, 1988

POTASSIUM CHLDRIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

> ADD > 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

> ADD > 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

> ADD > AP TRAVENOL LABS 5GM/100ML;224MG/100ML; 900MG/100ML¤ N19308 006 APR 05, 1985

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

> ADD > 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

> ADD > AP ABBOTT LABS 5GM/100ML;298MG/100ML; 900MG/100ML¤ N19691 009 MAR 24, 1988

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

> ADD > ABBOTT LABS 5GM/100ML;298MG/100ML; 225MG/100ML¤ N18365 004 JUL 05, 1983

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

> ADD > ABBOTT LABS 5GM/100ML;298MG/100ML; 300MG/100ML¤ N18876 004 MAR 28, 1988

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

> ADD > AP ABBOTT LABS 5GM/100ML;74.5MG/100ML; 450MG/100ML¤ N18362 008 MAR 28, 1988

> ADD > AP 5GM/100ML;149MG/100ML; 450MG/100ML¤ N18362 004 MAR 28, 1988

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

> ADD > AP ABBOTT LABS 5GM/100ML;74.5MG/100ML; 900MG/100ML¤ N19691 001 MAR 24, 1988

> ADD > AP 5GM/100ML;149MG/100ML; 900MG/100ML¤ N19691 003 MAR 24, 1988

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

> ADD > ABBOTT LABS 5GM/100ML;74.5MG/100ML; 225MG/100ML¤ N18365 005 MAR 28, 1988

> ADD > 5GM/100ML;149MG/100ML; 225MG/100ML¤ N18365 007 MAR 28, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

> ADD > POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

> ADD >	ABBOTT LABS	5GM/100ML;74.5MG/100ML; 300MG/100ML¤	N18876 005 MAR 28, 1988
> ADD >		5GM/100ML;149MG/100ML; 300MG/100ML¤	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/100ML¤	N19631 011 FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

	KENDALL MCGAW	10GM/100ML;200MG/100ML¤	N19631 012 FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER

	KENDALL MCGAW	10GM/100ML;330MG/100ML#	N19631 013 FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

	KENDALL MCGAW	10GM/100ML;450MG/100ML#	N19631 014 FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	10GM/100ML;900MG/100ML¤	N19631 015 FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER

	KENDALL MCGAW	2.5GM/100ML; 110MG/100ML¤	N19631 001 FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

	KENDALL MCGAW	2.5GM/100ML; 200MG/100ML¤	N19631 002 FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLDRIDE 0.33% IN PLASTIC CONTAINER

	KENDALL MCGAW	2.5GM/100ML; 330MG/100ML¤	N19631 003 FEB 24, 1988

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	2.5GM/100ML; 450MG/100ML¤	N19631 004 FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE D.9% IN PLASTIC CONTAINER

	KENDALL MCGAW	2.5GM/100ML; 900MG/100ML¤	N19631 005 FEB 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER

	KENDALL MCGAW	5GM/100ML;110MG/100ML¤	N19631 006 FEB 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	5GM/100ML;200MG/100ML¤	N19631 007 FEB 24, 1988

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

DIAZOXIDE

INJECTABLE; INJECTION

DIAZOXIDE

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

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

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

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

	DOXEPIN HCL			
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

INJECTABLE; INJECTION

		DOXYCYCLINE			
> ADD >	AP	BEN VENUE LABS	EQ 100MG BASE/VIAL¤	N62569 001	MAR 09, 1988
> ADD >	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

ENALAPRILAT

INJECTABLE; INJECTION

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

ERYTHROMYCIN

SOLUTION; TOPICAL

	ETS-2%			
AT	PADDOCK LABS	2%¤	N62687 001	FEB 05, 1988

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/	
	ə BRISTOL LABS	EQ 250MG BASE	N61304 001	
/AB/		/EQ 250MG BASE/	/N61887 001/	
	ə	EQ 250MG BASE	N61887 001	
	ERYPAR			
/AB/	/PARKE DAVIS/	/EQ 250MG BASE/	/N62032 001/	
	ə PARKE DAVIS	EQ 250MG BASE	N62032 001	
/AB/		/EQ 500MG BASE/	/N62032 002/	
	ə	EQ 500MG BASE	N62032 002	
	ERYTHROCIN STEARATE			
/AB/	/ABBOTT LABS/	/EQ 125MG BASE/	/N60359 002/	
	ə ABBOTT LABS	EQ 125MG BASE	N60359 002	
	ERYTHROMYCIN STEARATE			
/AB/	/LEDERLE LABS/	/EQ 250MG BASE/	/N62089 001/	
	ə LEDERLE LABS	EQ 250MG BASE	N62089 001	
/AB/		/EQ 500MG BASE/	/N62089 002/	
	ə	EQ 500MG BASE	N62089 002	
	PFIZER-E			
/AB/	/PFIZER LABS/	/EQ 500MG BASE/	/N61791 002/	
	ə PFIZER LABS	EQ 500MG BASE	N61791 002	

FLUOCINOLONE ACETONIDE

OIL; TOPICAL

DERMA-SMOOTHE/FS			
	HILL DERM	0.01%¤	N19452 001 FEB 03, 1988

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL

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

FLUPHENAZINE HYDROCHLORIDE

TABLET; ORAL
PERMITIL

> ADD >	BP	SCHERING	2.5MG	N12034 004
> ADD >	BP		5MG	N12034 005
> ADD >	BP		10MG	N12034 006
> DLT >				
> DLT >				
> DLT >				

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

	@ BARR LABS	1MG	N89177 001 JAN 08, 1986

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE

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

TABLET; ORAL
FUROSEMIDE

AB	BARR LABS	80MG	N70100 001 JAN 26, 1988

FUROSEMIDE

TABLET; ORAL
FUROSEMIDE

AB	DANBURY PHARMA	80MG	N71594 001 FEB 09, 1988

HALOPERIDOL

TABLET; ORAL
HALDOL SOLUTAB

	@ 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
> ADD > AB	CORD LABS	10MG	N71210 001 MAR 11, 1988
> ADD > AB		20MG	N71211 001 MAR 11, 1988

HALOPERIDOL LACTATE

CONCENTRATE; ORAL
HALDOL

AA	MCNEIL PHARM	EQ 2MG BASE/ML	N15922 001

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HCL

	@ PUREPAC PHARM	50MG	N88178 001 AUG 15, 1983

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

/AB/	/BANMAX/PHARMS/	/25MG/	/N86369/001/	
	ə BANMAX PHARMS	25MG	N86369 001	
/AB/		/50MG/	/N83554/001/	
	ə	50MG	N83554 001	

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
METHYLDOPA AND HYDROCHLOROTHIAZIDE

/AB/	/PUREPAC/PHARM/	/50MG;500MG/	/N70689/001/ /APR/24,/1986/		
	ə PUREPAC PHARM	50MG;500MG	N70689 001 APR 24, 1986		
>ADD >	AB	ZENITH LABS	15MG;250MG¤	N71458 001 MAR 08, 1988	
>ADD >					
>ADD >	AB		25MG;250MG¤	N71459 001 MAR 08, 1988	
>ADD >					
>ADD >	AB		30MG;500MG¤	N71460 001 MAR 08, 1988	
>ADD >					
>ADD >	AB		50MG;500MG¤	N71461 001 MAR 08, 1988	
>ADD >					

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE

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

HYDROCHLORDTHIAZIDE; RESERPINE

TABLET; ORAL
RESERPINE AND HYDROCHLOROTHIAZIDE

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

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

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

TABLET; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

AB	DANBURY PHARMA	50MG;75MG¤	N71969 001 APR 17, 1988 : JAN 15, 1988	
AB	QUANTUM PHARMCS	50MG;75MG¤	N71980 001 APR 17, 1988 : FEB 01, 1988	

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

>ADD >	AT	NASKA PHARMA	1%¤	N89706 001 MAR 10, 1988
>ADD >				
>ADD >	AT		2.5%¤	N89682 001 MAR 10, 1988
>ADD >				

LOTION; TOPICAL
BETA-HC

AT	BETA DERM	1%¤	N89495 001 JAN 25, 1988	

OINTMENT; TOPICAL
HYDROCORTISONE

>ADD >	AT	NASKA PHARMA	1%¤	N89704 001 MAR 10, 1988
>ADD >				

TABLET; ORAL
HYDROCORTISONE

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

HYDROXYZINE HYDROCHLORIDE

SYRUP; ORAL
HYDROXYZINE HCL

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

IBUPROFEN

TABLET; ORAL
IBUPROFEN

AB	HALSEY DRUG	800MG*	N72137 001	FEB 05, 1988
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
PRAMINE

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

IOHEXOL

INJECTABLE; INJECTION
OMNIPAQUE 180

ə	STERLING DRUG	38.8%	N18956 001 DEC 26, 1985

ISOSORBIDE DINITRATE

TABLET; ORAL
ISOSORBIDE DINITRATE

AB	BARR LABS	30MG*	N87564 001	SEP 18, 1986
> ADD > AB	CORD LABS	5MG*	N86221 001	JAN 07, 1988
> ADD > AB		10MG*	N86223 001	JAN 07, 1988

ISOSORBIDE DINITRATE

TABLET; ORAL
ISOSORBIDE DINITRATE

> ADD > AB	DANBURY PHARMA	5MG*	N86034 001	JAN 06, 1988
> ADD > AB		10MG*	N86032 001	JAN 07, 1988
AB	PAR PHARM	30MG*	N87946 001	JAN 12, 1988

TABLET; SUBLINGUAL
ISOSORBIDE DINITRATE

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

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM

> ADD > AP	BEN VENUE LABS	EQ 100MG BASE/VIAL*	N89717 001	MAR 28, 1988
> ADD > AP	QUAD PHARMS	EQ 100MG BASE/VIAL	N89636 001	DEC 24, 1987

LINCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION
LINCOCIN

> ADD > AP	UPJOHN	EQ 300MG BASE/ML	N50317 001	

LINCOMYCIN HCL

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

LORAZEPAM

TABLET; ORAL
LORAZEPAM

AB	WARNER CHILCOTT	1MG*	N71038 001	JAN 12, 1988
AB		2MG*	N71039 001	JAN 12, 1988

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

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

ANTIVERT

> ADD >	AA	ROERIG	50MG	N10721 001 JAN 20, 1982

MECLIZINE HCL

> AOD >	AA	PAR PHARM	50MG¤	N89674 001 MAR 31, 1988

MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

> AOD >	AB	PAR PHARM	EQ 50MG BASE¤	N72077 001 MAR 10, 1988
> ADD >	AB		EQ 100MG BASE¤	N72078 001 MAR 10, 1988
> ADD >	AB	PHARM BASICS	EQ 50MG BASE¤	N71007 001 MAR 25, 1988
> ADD >	AB		EQ 100MG BASE¤	N71008 001 MAR 25, 1988

METAPROTERENOL SULFATE

TABLET; ORAL

ALUPENT

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

METAPROTERENOL SULFATE

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/	
	a BARR LABS	500MG	N84488 001	

METHOXSALEN

CAPSULE; ORAL

> DLT >	/OXSORALEN/			
> DLT >	/ELDER PHARMS/	/10MG/	/N09048/001/	
> ADD >	8-MOP			
> ADD >	ELDER PHARMS	10MG	N09048 001	

METHYLDOPA

TABLET; ORAL

METHYLDOPA

> ADD >	AB	CORD LABS	125MG¤	N71700 001 MAR 02, 1988
> ADD >	AB	HALSEY DRUG	125MG¤	N71751 001 MAR 28, 1988
> ADD >	AB		250MG¤	N71752 001 MAR 28, 1988
> ADD >	AB		500MG¤	N71753 001 MAR 28, 1988

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

METOCLOPRAMIDE HCL

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

MEZLOCILLIN SODIUM MONOHYDRATE

INJECTABLE; INJECTION

MEZLIN

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

MITOMYCIN

INJECTABLE; INJECTION
MUTAMYCIN

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

NAFTIFINE HYDROCHLORIDE

CREAM; TOPICAL
NAFTIN

	HERBERT LABS	1%	N19599 001		
			FEB 29, 1988		

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE HCL

>ADD> AP	INTL MEDTN SYS	1MG/ML*	N72076 001		
>ADD>			MAR 24, 1988		

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
AVENTYL HCL

BD	LILLY	EQ 10MG BASE	N14684 001		
BD		EQ 25MG BASE	N14684 002		
/BP/		/EQ 10MG BASE/	/N14684/001/		
/BP/		/EQ 25MG BASE/	/N14684/002/		

PAMELOR

BD	SANDOZ PHARMS	EQ 10MG BASE	N18013 001		
BD		EQ 25MG BASE	N18013 002		
/BP/		/EQ 10MG BASE/	/N18013/001/		
/BP/		/EQ 25MG BASE/	/N18013/002/		

NYSTATIN

SUSPENSION; ORAL
NYSTATIN

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

OXAZEPAM

CAPSULE; ORAL
OXAZEPAM

>ADD> AB	AM THERPTCS	10MG*	N71955 001		
>ADD>			MAR 03, 1988		
>ADD> AB		15MG*	N71956 001		
>ADD>			MAR 03, 1988		
>ADD> AB		30MG*	N71957 001		
>ADD>			MAR 03, 1988		
>ADD> AB	CHELSEA LABS	10MG*	N71661 001		
>ADD>			MAR 02, 1988		
>ADD> AB		15MG*	N71662 001		
>ADD>			MAR 02, 1988		
>ADD> AB		30MG*	N71663 001		
>ADD>			MAR 02, 1988		

SERAX

>ADD> AB	WYETH	10MG	N15539 002		
>ADD> AB		15MG	N15539 004		
>ADD> AB		30MG	N15539 006		
>DLT> /BP/		/10MG/	/N15539/002/		
>DLT> /BP/		/15MG/	/N15539/004/		
>DLT> /BP/		/30MG/	/N15539/006/		

ZAXOPAM

>ADD> AB	QUANTUM PHARMCS	10MG*	N70650 001		
>ADD>			MAR 01, 1988		
>ADD> AB		15MG*	N70640 001		
>ADD>			MAR 01, 1988		
>ADD> AB		30MG*	N70641 001		
>ADD>			MAR 01, 1988		

OXYBUTYNIN CHLORIDE

TABLET; ORAL
DITROPAN

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

OXYTETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
OXYTETRACYCLINE HCL

/AB/	/PUREPAC PHARM/	/EQ 250MG BASE/	/N60634/001/		
	∂ PUREPAC PHARM	EQ 250MG BASE	N60634 001		

PANCURONIUM BROMIDE

INJECTABLE; INJECTION

> ADD >		PANCURONIUM			
> ADD >	AP	ELKINS SINN	1MG/ML*	N72058 001	
> ADD >				MAR 23, 1988	
> ADD >	AP		2MG/ML*	N72059 001	
> ADD >				MAR 23, 1988	
> ADD >	AP		2MG/ML*	N72060 001	
> ADD >				MAR 23, 1988	
> ADD >		PANCURONIUM BROMIDE			
> ADD >	AP	ASTRA PHARM PRODS	1MG/ML*	N72210 001	
> ADD >				MAR 31, 1988	
> ADD >	AP		2MG/ML*	N72211 001	
> ADD >				MAR 31, 1988	
> ADD >	AP		2MG/ML*	N72212 001	
> ADD >				MAR 31, 1988	
> ADD >	AP		2MG/ML*	N72213 001	
> ADD >				MAR 31, 1988	
		PAVULON			
> ADD >	AP	ORGANON	1MG/ML	N17015 002	
> ADD >	AP		2MG/ML	N17015 001	

PENICILLIN G POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

		PENICILLIN G POTASSIUM		
/AA/		/PUREPAC/PHARM/	/400,000 UNITS/5ML/	/N61740/002/
	ə	PUREPAC PHARM	400,000 UNITS/5ML	N61740 002

TABLET; ORAL

		PENICILLIN G POTASSIUM		
/AA/		/PUREPAC/PHARM/	/250,000 UNITS/	/N61588/002/
	ə	PUREPAC PHARM	250,000 UNITS	N61588 002
/AB/			/400,000 UNITS/	/N61588/003/
	ə		400,000 UNITS	N61588 003

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

		PENICILLIN V POTASSIUM		
/AA/		/PUREPAC/PHARM/	/EQ 250MG BASE/5ML/	/N61758/002/
	ə	PUREPAC PHARM	EQ 250MG BASE/5ML	N61758 002

TABLET; ORAL

		PENICILLIN V POTASSIUM		
/AA/		/PUREPAC/PHARM/	/EQ 250MG BASE/	/N61571/002/
	ə	PUREPAC PHARM	EQ 250MG BASE	N61571 002
/AB/			/EQ 500MG BASE/	/N61571/003/
	ə		EQ 500MG BASE	N61571 003

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

		PHENDIMETRAZINE TARTRATE		
/AA/		/BARR/LABS/	/35MG/	/N83644/001/
	ə	BARR LABS	35MG	N83644 001
/AA/			/35MG/	/N83684/001/
	ə		35MG	N83684 001
/AA/			/35MG/	/N83686/001/
	ə		35MG	N83686 001
/AA/			/35MG/	/N83687/001/
	ə		35MG	N83687 001
/AA/			/35MG/	/N84831/001/
	ə		35MG	N84831 001
/AA/			/35MG/	/N84834/001/
	ə		35MG	N84834 001
/AA/			/35MG/	/N84835/001/
	ə		35MG	N84835 001

PHENTERMINE RESIN COMPLEX

CAPSULE, CONTROLLED RELEASE; ORAL

		IONAMIN-30		
AB		PENNWALT	EQ 30MG BASE	N11613 002
		PHENTERMINE RESIN 30		
AB		QUANTUM PHARMCS	EQ 30MG BASE*	N89120 001
				FEB 04, 1988

POTASSIUM CHLORIDE

INJECTABLE; INJECTION

			POTASSIUM CHLORIDE		
> ADD >	AP	STERIS LABS	2MEQ/ML*	N89163 001	
> ADD >				MAR 10, 1988	

PREDNISOLONE

TABLET; ORAL

		PREDNISOLONE		
/BX/		/BARR/LABS/	/5MG/	/N84426/002/
	ə	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	

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION

PROCHLORPERAZINE EDISYLATE

AP	QUAD PHARMS	EQ 5MG BASE/ML	N89637 001 FEB 01, 1988
AP		EQ 5MG BASE/ML	N89638 001 FEB 01, 1988

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

PROMETHAZINE HCL

BP	a BARR LABS	12.5MG	N84555 001
BP	a	25MG	N84554 001
BP	a	50MG	N84557 001

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL

AA	a BANMAX PHARMS	65MG	N83184 001
AA	a BARR LABS	65MG	N83186 001

PROTAMINE SULFATE

INJECTABLE; INJECTION

PROTAMINE SULFATE

> DLT >	AP	a UPJOHN	50MG/VIAL	N07413 001
> ADD >				
> DLT >			250MG/VIAL	N07413 002
> DLT >				AUG 02, 1984
> ADD >		a	250MG/VIAL	
> ADD >				

RAUWOLFIA SERPENTINA

TABLET; ORAL

RAUVAL

> DLT >				
> ADD >	BP	VALE CHEM	50MG	N09108 002
> DLT >			100MG	
> ADD >	BP		100MG	N09108 004

RESERPINE

TABLET; ORAL

RESERPINE

BP	a BARR LABS	0.25MG	N80721 002

SECOBARBITAL SODIUM

CAPSULE; ORAL

SODIUM SECOBARBITAL

AA	a BARR LABS	100MG	N84225 001

SODIUM CHLORIDE

INJECTABLE; INJECTION

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

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

SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

> ADD >	AP	KENDALL MCGAW	450MG/100ML	N19635 001
> ADD >				MAR 09, 1988

SODIUM CHLORIDE 5% IN PLASTIC CONTAINER

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

SODIUM CHLORIDE

INJECTABLE; INJECTION

SODIUM CHLORIDE 5% IN PLASTIC CONTAINER

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

SULFAMETHOXAZOLE

TABLET; ORAL

SULFAMETHOXAZOLE

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

SULFISOXAZOLE

TABLET; ORAL

SULFISOXAZOLE

/AB/	/BARR LABS/	/500MG/		/N84031 001/
	∂ BARR LABS	500MG		N84031 001

SULINDAC

TABLET; ORAL

CLINORIL

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

SULINDAC

> ADD >	AB	DANBURY PHARMA	150MG¤	N71891 001 APR 03, 1990 : MAR 03, 1988
> ADD >	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

THEOPHYLLINE

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

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

AB		PAR PHARM	150MG¤	N89764 001 FEB 09, 1988
AB			200MG¤	N89765 001 FEB 09, 1988

TOLAZAMIDE

TABLET; ORAL

TOLAZAMIDE

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

TOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE

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

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

DESYREL

> ADD >	AB	MEAD JOHNSON	150MG	N18207 003 MAR 25, 1985

TRAZON-150

> ADD >	AB	SIDMAK LABS	150MG¤	N71525 001 MAR 09, 1988

TRIAMCINOLONE

TABLET; ORAL
TRIAMCINOLONE

/BP/	/BARR/LABS/	/2MG/	/N84286/001/	>ADD>	AP		N84286 002
	a BARR LABS	2MG	N84286 001	>ADD>			MAR 21, 1986
/BP/		/2MG/	/N84318/001/	>ADD>	AP		N84318 002
	a	2MG	N84318 001	>ADD>			MAR 21, 1986
/BP/		/4MG/	/N84267/001/	>ADD>	AP		N84267 002
	a	4MG	N84267 001	>ADD>			MAR 13, 1987
/BP/		/4MG/	/N84319/001/	>ADD>	AP		N84319 002
	a	4MG	N84319 001	>ADD>			NOV 17, 1987
/BP/		/8MG/	/N84268/001/				
	a	8MG	N84268 001	>ADD>	AP		N84268 002
/BP/		/8MG/	/N84320/001/	>ADD>			MAR 30, 1988
	a	8MG	N84320 001				

TRIMETHOPRIM

TABLET; ORAL
TRIMETHOPRIM

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

	CIBA PHARM	150MG	N19594 001 DEC 31, 1987	>ADD>			
		300MG	N19594 002 DEC 31, 1987	>ADD>			
	/SIPHARMEX/	/150MG/	/N19594/001/ /DEC/31/1987/	>ADD>			
		/300MG/	/N19594/002/ /DEC/31/1987/	>ADD>			

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION
VANCOCIN HCL

	LILLY	EQ 1GM BASE/VIAL	N60180 002 MAR 21, 1986	>ADD>	AP		
		EQ 1GM BASE/VIAL	N62476 002 MAR 21, 1986	>ADD>	AP		
		EQ 1GM BASE/VIAL	N62716 002 MAR 13, 1987	>ADD>	AP		
		EQ 1GM BASE/VIAL	N62812 002 NOV 17, 1987	>ADD>	AP		

VANCOLED

	LEDERLE LABS	EQ 1GM BASE/VIAL*	N62682 002 MAR 30, 1988	>ADD>	AP		

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
CALAN

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

ISOPTIN

	KNOLL PHARM	40MG	N18593 003 NOV 23, 1987		AB		

VERAPAMIL HCL

	MUTUAL PHARM	80MG*	N71488 001 JAN 13, 1988		AB		
		120MG*	N71489 001 JAN 13, 1988		AB		

VINCRISTINE SULFATE

INJECTABLE; INJECTION
VINCRISTINE SULFATE

	QUAD PHARMS	1MG/VIAL*	N71222 001 MAR 07, 1988	>ADD>			
		2MG/VIAL*	N71223 001 MAR 07, 1988	>ADD>			
		5MG/VIAL*	N71937 001 MAR 07, 1988	>ADD>			

WATER FOR INJECTION, STERILE

LIQUID; N/A
STERILE WATER FOR INJECTION IN PLASTIC CONTAINER

	KENDALL MCGAW	100%*	N19633 001 FEB 29, 1988		AP		

ACETAMINOPHEN

SUPPOSITORY; RECTAL

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

IBUPROFEN

TABLET; ORAL

IBUPROFEN		
> ADD > DANBURY PHARMA	200MG¤	N71905 001
> AOD >		MAR 08, 1988
INVAMED	200MG¤	N71807 001
		FEB 25, 1988
MEDICOPHARMA	200MG¤	N71639 001
		FEB 02, 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/
∂	200MG	N19012 001
		MAY 18, 1984
∂	200MG	N19012 003
		JUL 29, 1987

INSULIN SEMISYNTHETIC PURIFIED HUMAN; INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN

INJECTABLE; INJECTION

> ADD > MIXTARD HUMAN 70/30		
> ADD > NORDISK USA	30 UNITS/ML;	
> ADD >	70 UNITS/ML¤	N19585 001
> ADD >		MAR 11, 1988

> ADD > LOPERAMIDE HYDROCHLORIDE

> ADD > SOLUTION; ORAL

> ADD > IMODIUM A-D

> AOD > MCNEIL CONSUMER 1MG/5ML¤ N19487 001

NONOXYNOL-9

SPONGE; VAGINAL

TODAY		
/VLI/	/1GM/	/N18683/001/
		/APR/01,/1983/
WHITEHALL LABS	1GM	N18683 001
		APR 01, 1983

NO MARCH 1988 APPROVALS

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.

NO MARCH 1988 APPROVALS

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

NO MARCH 1988 ACTIONS

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	
CYCLOBENZAPRINE HYDROCHLORIDE (TABLET)	JAN 25, 1988	
FENOPROFEN (CAPSULE AND TABLET)	AUG 27, 1987	FEB 03, 1988
INDOMETHACIN (CAPSULE)	JAN 27, 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	87 N-0032/ CP0006	MIKART	NEW DOSAGE FORM	APPROVED JAN 13, 1988
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

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
FLUOROURACIL INJECTABLE; INJECTION	50MG/ML (5ML/VIAL)	88 P-0052/CP	BEN VENUE LABS	NEW STRENGTH	APPROVED MAR 21, 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
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
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
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
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	100MG/ML (1ML/VIAL) (2ML/VIAL)	87 P-0283/CP	LYPHOMED	NEW DOSAGE FORM NEW STRENGTH	DENIED JAN 21, 1988
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	500MG/ML (1ML/VIAL) (2ML/VIAL)	87 P-0283/CP	LYPHOMED	NEW DOSAGE FORM NEW STRENGTH	DENIED JAN 21, 1988
METOCLOPRAMIDE HYDROCHLORIDE INJECTABLE; INJECTION	1MG/ML (50ML/VIAL)	87 P-0090/CP	INTL MEDTN SYS	NEW STRENGTH	DENIED FEB 08, 1988
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 PROOUCTS 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	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

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

	APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	17920 002	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994		D-13	MAR 31, 1991
>ADD>			3950333	APR 13, 1993		D-12	APR 30, 1989
>ADD>	17920 003	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994		D-13	MAR 31, 1991
>ADD>			3950333	APR 13, 1993		D-12	APR 30, 1989
>ADD>	17920 004	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994		D-13	MAR 31, 1991
>ADD>			3950333	APR 13, 1993		D-12	APR 30, 1989
>ADD>	17920 005	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994		D-13	MAR 31, 1991
			3950333	APR 13, 1993		D-12	APR 30, 1989
>ADD>	17924 001	CIMETIDINE HYDROCHLORIDE; TAGAMET	4024271	MAY 17, 1994		D-13	MAR 31, 1991
>ADD>			3950333	APR 13, 1993		D-12	APR 30, 1989
	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		
	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		
>ADD>	19404 001	FLURBIPROFEN SODIUM; OCUFEN	3793457	FEB 19, 1993			
>DLT>	19404 001	FLURBIPROFEN SODIUM; OCUFEN	3793457	FEB 19, 1993			
	18061 001	HYDROCHLOROTHIAZIDE; TIMOLIDE 10-25	3655663	APR 11, 1989		D-2	FEB 03, 1991
	18956 003	IOHEXOL; OMNIPAQUE 300	4021481	MAY 03, 1994		I-55	FEB 01, 1988
						I-58	FEB 01, 1988
>ADD>	19085 001	IPRATROPIUM BROMIDE; ATROVENT	3681500	AUG 01, 1991		NCE	DEC 29, 1991
>DLT>	19085 001	IPRATROPIUM BROMIDE; ATROVENT	3681500	AUG 01, 1989		NCE	DEC 29, 1991
>ADD>	09048 001	METHOXSALEN; 8-MOP				I-72	MAR 23, 1991
	18677 001	NABILONE; CESAMET	4087545	MAY 02, 1997	U-7		
	19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 1998		NCE	FEB 29, 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 A	3872226	MAR 18, 1992			
			3863004	JAN 28, 1992	U-31		

	APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	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			
>ADD>	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

SUBSCRIPTION FORM

APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS 8TH EDITION (1988)

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