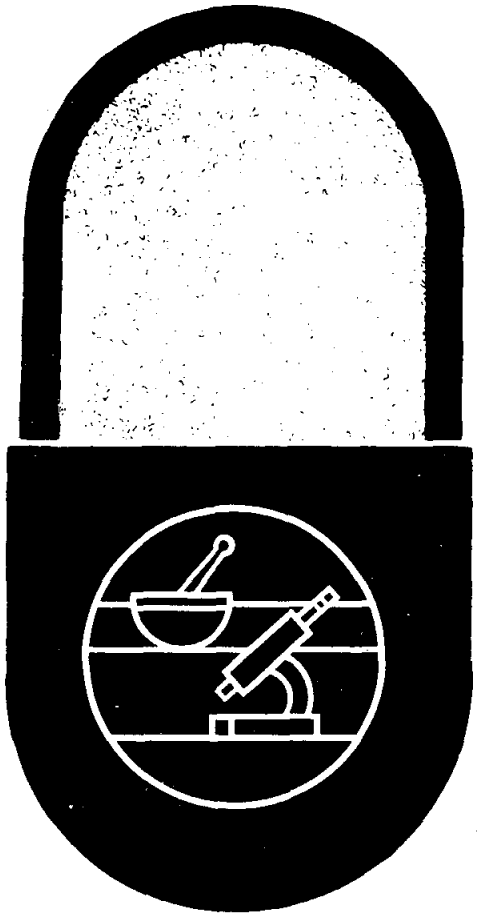
CUMULATIVE SUPPLEMENT 2
JAN'88-FEB'88



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

APPROVED DRUG PRODUCTS

with

THERAPEUTIC EQUIVALENCE EVALUATIONS

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FEBRUARY 1988

CONTENTS

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CUMULATIVE SUPPLEMENT 2

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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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

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			
SINGLE SOURCE	2096 (21.6%)			
MULTISOURCE	7613 (78.4%)			
THERAPEUTICALLY EQUIVALENT	6691 (68.9%)			
NOT THERAPEUTICALLY EQUIVALENT	848 (8.7%)			
EXCEPTIONS[2]	74 (0.8%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	349			

(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

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

ACETAMINOPHEN; CODEINE PHOSPHATE

ELIXIR; ORAL

TYLENOL W/ CODEINE

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

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

>ADD >	AA	MUTUAL PHARM	300MG;15MG¤	N89671 001	
>ADD >				FEB 10, 1988	
>ADD >	AA		300MG;30MG¤	N89672 001	
>ADD >				FEB 10, 1988	
>ADD >	AA		300MG;60MG¤	N89673 001	
>ADD >				FEB 10, 1988	

TYLENOL W/ CODEINE

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

TYLENOL W/ CODEINE NO. 1

>DLT >	AA	MCNEIL LABS	300MG;7.5MG	N85055 001	
>ADD >	AA	MCNEIL PHARM	300MG;7.5MG	N85055 001	

TYLENOL W/ CODEINE NO. 2

>DLT >	AA	MCNEIL LABS	300MG;15MG	N85055 002	
>ADD >	AA	MCNEIL PHARM	300MG;15MG	N85055 002	

TYLENOL W/ CODEINE NO. 3

>DLT >	AA	MCNEIL LABS	300MG;30MG	N85055 003	
>ADD >	AA	MCNEIL PHARM	300MG;30MG	N85055 003	

TYLENOL W/ CODEINE NO. 4

>DLT >	AA	MCNEIL LABS	300MG;60MG	N85055 004	
>ADD >	AA	MCNEIL PHARM	300MG;60MG	N85055 004	

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

>ADD >	AB	MYLAN PHARMS	650MG;100MG¤	N72195 001	
>ADD >				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	

AMINOPHYLLINE

TABLET; ORAL

AMINOPHYLLINE

>DLT >	BD	BARR LABS	100MG	N88297 001	
>DLT >				AUG 19, 1983	
>ADD >	BD	∂ BARR LABS	100MG	N88297 001	
>ADD >				AUG 19, 1983	
>DLT >	BD		200MG	N88298 001	
>DLT >				AUG 19, 1983	
>ADD >	BD	∂	200MG	N88298 001	
>ADD >				AUG 19, 1983	

AMINOSALICYLATE SODIUM

TABLET; ORAL

TEEBACIN

>DLT >	BP	CNSOL MIDLAND	500MG	N07320 002	
>ADD >	BP	∂ CNSOL MIDLAND	500MG	N07320 002	

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

>ADD >	AB	CLONMEL CHEMS	250MG¤	N62884 001	
>ADD >				FEB 25, 1988	
>AOD >	AB		500MG¤	N62881 001	
>ADD >				FEB 25, 1988	

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL
AMPICILLIN

>ADD >	AB	CLONMEL CHEMS	EQ 250MG BASE¤	N62883 001	
>ADO >				FEB 25, 1988	
>ADD >	AB		EQ 500MG BASE¤	N62882 001	
>ADD >				FEB 25, 1988	

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
COMPOUND 65

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

>DLT >	/BP/	/PRIVATE/FMLTNS/	/50MG/	/N83206/001/	
>AOD >	BP	@ 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

>AOD >	AP	QUAO PHARMS	50MG/ML¤	N71181 001	
>AOD >				FEB 16, 1988	

BROMPHENIRAMINE MALEATE

TABLET; ORAL
BROMPHENIRAMINE MALEATE

>DLT >/AA/	/BARR/LABS/	/4MG/	/N84468/001/		
>ADD >	AA	@ BARR LABS	4MG	N84468 001	

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

INJECTABLE; INJECTION

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

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION
LACTATED RINGER'S IN PLASTIC CONTAINER

>ADD >	AP	KENDALL MCGAW	20MG/100ML;30MG/100ML;600MG/100ML;		
>ADD >			310MG/100ML¤	N19632 001	
>ADD >				FEB 29, 1988	

CARBAMAZEPINE

TABLET, CHEWABLE; ORAL
CARBAMAZEPINE

>ADD >					
>ADD >	AB	WARNER CHILCOTT	100MG¤	N71940 001	
>ADO >				FEB 01, 1988	
		TEGRETOL			
>ADO >	AB	GEIGY PHARMS	100MG	N18281 001	

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

AHCEF

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

CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN

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

CEPHRADINE

CAPSULE; ORAL

CEPHRADINE

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

CHLORDIAZEPOXIDE HYOROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

> DLT >	/AB/	/PUREPAC/PHARM/	/5MG/		/N85155/001/
> ADD >	AB	∂ PUREPAC PHARM	5MG		N85155 001
> DLT >	/AB/		/10MG/		/N84939/002/
> AOD >	AB	∂	10MG		N84939 002
> DLT >	/AB/		/25MG/		/N85144/001/
> AOO >	AB	∂	25MG		N85144 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

LYGEN

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

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

> DLT >	/AA/	/BARR/LABS/	/4MG/		/N80700/001/
> ADD >	AA	∂ BARR LABS	4MG		N80700 001

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

> ADD >	AB	WATSON LABS	3.75MG¤	N71852 001	FEB 09, 1988
> ADD >					
> ADD >	AB		7.5MG¤	N71853 001	FEB 09, 1988
> ADD >					
> ADD >	AB		15MG¤	N71854 001	FEB 09, 1988
> ADD >					

COLCHICINE; PROBENECID

TABLET; ORAL

PROBENECID AND COLCHICINE

> OLT >	/BP/	/BEECHAM/LABS/	/0.5MG;500MG/		/N84321/001/
> ADD >	BP	∂ BEECHAM LABS	0.5MG;500MG		N84321 001

PROBENECID W/ COLCHICINE

> DLT >	/BP/	/LEDERLE/LABS/	/0.5MG;500MG/		/N86954/001/
> ADD >	BP	∂ LEDERLE LABS	0.5MG;500MG		N86954 001

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL

CYCLOBENZAPRINE HCL

> AOD >					
> ADO >	AB	DANBURY PHARMA	10MG¤		N71611 001
> AOD >				MAY 03, 1989 :	FEB 29, 1988

FLEXERIL

> ADD >	AB	MS&D	10MG		N17821 002

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

DESIPRAMINE HCL

> ADD >	AB	VITARINE	10MG¤	N72167 001	
> ADD >				FEB 03, 1988	
> ADD >	AB		150MG¤	N72254 001	
> ADD >				FEB 03, 1988	

NORPRAMIN

> ADD >	AB	MERRELL DOW	10MG	N14399 007	
> ADD >				FEB 11, 1982	
> ADD >	AB		150MG	N14399 006	

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE

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

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 10% IN PLASTIC CONTAINER

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

DEXTROSE 2.5% IN PLASTIC CONTAINER

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

DEXTROSE 5% IN PLASTIC CONTAINER

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

DEXTROSE 7.7% IN PLASTIC CONTAINER

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

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

> ADD >	POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER		
> ADD >	KENDALL MCGAW	10GM/100ML;37MG/100ML; 200MG/100ML¤	N19630 031
> ADD >			FEB 17, 1988
> ADD >	POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER		
> ADD >	KENDALL MCGAW	10GM/100ML;37MG/100ML; 450MG/100ML¤	N19630 037
> ADD >			FEB 17, 1988
> ADD >	POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER		
> ADD >	KENDALL MCGAW	10GM/100ML;37MG/100ML; 900MG/100ML¤	N19630 043
> ADD >			FEB 17, 1988
> ADD >	POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER		
> ADD >	KENDALL MCGAW	5GM/100ML;37MG/100ML; 110MG/100ML¤	N19630 001
> ADD >			FEB 17, 1988
> ADD >	POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER		
> ADD >	KENDALL MCGAW	5GM/100ML;37MG/100ML; 200MG/100ML¤	N19630 007
> ADD >			FEB 17, 1988
> ADD >	POTASSIUM CHLORIOE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER		
> ADD >	KENDALL MCGAW	5GM/100ML;37MG/100ML; 330MG/100ML¤	N19630 013
> ADD >			FEB 17, 1988
> ADD >	POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER		
> ADD >	KENDALL MCGAW	5GM/100ML;37MG/100ML; 450MG/100ML¤	N19630 019
> ADD >			FEB 17, 1988
> ADD >	POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER		
> ADD >	KENDALL MCGAW	5GM/100ML;37MG/100ML; 900MG/100ML¤	N19630 025
> ADD >			FEB 17, 1988
> ADD >	POTASSIUM CHLORIDE 0.075% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER		
> ADD >	KENDALL MCGAW	10GM/100ML;75MG/100ML; 200MG/100ML¤	N19630 032
> ADD >			FEB 17, 1988
> ADD >	PDTASSIUM CHLORIDE 0.075% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER		
> ADD >	KENDALL MCGAW	10GM/100ML;75MG/100ML; 450MG/100ML¤	N19630 038
> ADD >			FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

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

> ADD > **POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM**
> ADD > **CHLORIDE 0.2% IN PLASTIC CONTAINER**
> ADD > AP KENDALL MCGAW 5GM/100ML;75MG/100ML;
> ADD > 200MG/10DML¤ N19630 008
> ADD > FEB 17, 1988

> ADD > **POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM**
> ADD > **CHLORIDE 0.33% IN PLASTIC CONTAINER**
> ADD > AP KENDALL MCGAW 5GM/100ML;75MG/10DML;
> ADD > 330MG/100ML¤ N1963D D14
> ADD > FEB 17, 1988

> ADD > **POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM**
> ADD > **CHLORIDE 0.45% IN PLASTIC CONTAINER**
> ADD > AP KENDALL MCGAW 5GM/100ML;75MG/100ML;
> ADD > 450MG/100ML¤ N19630 02D
> ADD > FEB 17, 1988

> ADD > **POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM**
> ADD > **CHLORIDE 0.9% IN PLASTIC CONTAINER**
> ADD > AP KENDALL MCGAW 5GM/100ML;75MG/10DML;
> ADD > 900MG/100ML¤ N1963D D26
> ADD > FEB 17, 1988

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

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

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

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

> ADD > POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM
> ADD > CHLORIDE 0.11% IN PLASTIC CONTAINER
> ADD > KENDALL MCGAW 5GM/10DML;110MG/100ML;
> ADD > 110MG/100ML¤ N19630 003
> ADD > FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

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

> ADD > POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM
> ADD > CHLORIDE 0.33% IN PLASTIC CONTAINER
> ADD > KENDALL MCGAW 5GM/100ML;110MG/10DML;
> ADD > 330MG/100ML¤ N1963D 015
> ADD > FEB 17, 1988

> ADD > POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM
> ADD > CHLORIDE 0.45% IN PLASTIC CONTAINER
> ADD > KENDALL MCGAW 5GM/100ML;110MG/100ML;
> ADD > 450MG/100ML¤ N19630 D21
> ADD > FEB 17, 1988

> ADD > POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM
> ADD > CHLORIDE 0.9% IN PLASTIC CONTAINER
> ADD > KENDALL MCGAW 5GM/100ML;110MG/100ML;
> ADD > 900MG/10DML¤ N19630 D27
> ADD > FEB 17, 1988

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

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

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

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

> ADD > **CHLORIDE 0.33% IN PLASTIC CONTAINER**
> ADD > AP KENDALL MCGAW 5GM/100ML;150MG/100ML;
> ADD > 330MG/100ML¤ N1963D 016
> ADD > FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

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

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

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

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

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

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

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

> AOD > POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
> ADD > KENDALL MCGAW 5GM/100ML;220MG/100ML; 20DMG/100ML¤ N1963D 011 FEB 17, 1988

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

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

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

> ADD > POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE D.9% IN PLASTIC CONTAINER
> ADD > KENDALL MCGAW 5GM/100ML;220MG/100ML; 900MG/100ML¤ N19630 029 FEB 17, 1988

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

> ADD > POTASSIUM CHLORIDE D.3% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
> ADD > KENDALL MCGAW 10GM/10DML;300MG/100ML; 450MG/100ML¤ N19630 042 FEB 17, 1988

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

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

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

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

> ADD > **POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER**
> ADD > AP KENDALL MCGAW 5GM/100ML;3D0MG/100ML; 900MG/100ML¤ N19630 030 FEB 17, 1988

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

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

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

>ADD >		DEXTROSE 10% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER		
>ADD >		KENDALL MCGAW	10GM/100ML;110MG/100ML¤	N19631 011 FEB 24, 1988
		DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER		
>ADD >		KENDALL MCGAW	10GM/100ML;200MG/100ML¤	N19631 012 FEB 24, 1988
		DEXTROSE 10% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER		
>ADD >		KENDALL MCGAW	10GM/100ML;330MG/100ML#	N19631 013 FEB 24, 1988
		DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER		
>ADD >		KENDALL MCGAW	10GM/100ML;450MG/100ML#	N19631 014 FEB 24, 1988
		DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER		
>ADD >	AP	KENDALL MCGAW	10GM/100ML;900MG/100ML¤	N19631 015 FEB 24, 1988
		DEXTROSE 2.5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER		
>ADD >		KENDALL MCGAW	2.5GM/100ML; 110MG/100ML¤	N19631 001 FEB 24, 1988
		DEXTROSE 2.5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER		
>ADD >		KENDALL MCGAW	2.5GM/100ML; 200MG/100ML¤	N19631 002 FEB 24, 1988
		DEXTROSE 2.5% AND SODIUM CHLDRIDE 0.33% IN PLASTIC CONTAINER		
>ADD >		KENDALL MCGAW	2.5GM/100ML; 330MG/100ML¤	N19631 003 FEB 24, 1988
		DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER		
>ADD >	AP	KENDALL MCGAW	2.5GM/100ML; 450MG/100ML¤	N19631 004 FEB 24, 1988
		DEXTROSE 2.5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER		
>ADD >		KENDALL MCGAW	2.5GM/100ML; 900MG/100ML¤	N19631 005 FEB 24, 1988
		DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER		
>ADD >		KENDALL MCGAW	5GM/100ML;110MG/100ML¤	N19631 006 FEB 24, 1988
		DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER		
>ADD >	AP	KENDALL MCGAW	5GM/100ML;200MG/100ML¤	N19631 007 FEB 24, 1988

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

		DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER		
>ADD >	AP	KENDALL MCGAW	5GM/100ML;330MG/100ML¤	N19631 008 FEB 24, 1988
		DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER		
>ADD >	AP	KENDALL MCGAW	5GM/100ML;450MG/100ML¤	N19631 009 FEB 24, 1988
		DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER		
>ADD >	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		
>ADD >	AB	BARR LABS	EQ 25MG BASE¤	N71502 001 FEB 18, 1988
>ADD >	AB		EQ 50MG BASE¤	N71653 001 FEB 18, 1988
>ADD >	AB		EQ 75MG BASE¤	N71654 001 FEB 18, 1988
>ADD >	AB		EQ 100MG BASE¤	N71521 001 FEB 18, 1988
>ADD >	AB	CHELSEA LABS	EQ 75MG BASE¤	N71763 001 FEB 09, 1988
>ADD >	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

DROPERIOOL

INJECTABLE; INJECTION
DROPERIDOL

> ADO >	AP	ABBOTT LABS	2.5MG/ML	N71981 001
> ADD >				FEB 29, 198B

> ADD > **ENALAPRILAT**

> ADD > INJECTABLE; INJECTION
> AOO > VASOTEC

> ADD >		MS&O RES LABS	1.25MG/ML	N19309 001
> ADD >				FEB 09, 1988

ERYTHROMYCIN

SOLUTION; TOPICAL
> AOO > **ETS-2%**

> ADD >	AT	PADDOCK LABS	2%	N62687 001
> ADD >				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

> DLT >	/AB/	/BRISTOL/LABS/	/EQ 250MG BASE/	/N61304/001/
> ADD >	AB	@ BRISTOL LABS	EQ 250MG BASE	N61304 001
> DLT >	/AB/		/EQ 250MG BASE/	/N61887/001/
> ADD >	AB	@	EQ 250MG BASE	N61887 001

ERYPAR

> OLT >	/AB/	/PARKE/DAVIS/	/EQ 250MG BASE/	/N62032/001/
> ADO >	AB	@ PARKE DAVIS	EQ 250MG BASE	N62032 001
> OLT >	/AB/		/EQ 500MG BASE/	/N62032/002/
> ADO >	AB	@	EQ 500MG BASE	N62032 002

ERYTHROCIN STEARATE

> OLT >	/AB/	/ABBOTT/LABS/	/EQ 125MG BASE/	/N60359/002/
> ADO >	AB	@ ABBOTT LABS	EQ 125MG BASE	N60359 002

ERYTHROMYCIN STEARATE

TABLET; ORAL
ERYTHROMYCIN STEARATE

> DLT >	/AB/	/LEDERLE/LABS/	/EQ 250MG BASE/	/N62089/001/
> ADD >	AB	@ LEDERLE LABS	EQ 250MG BASE	N62089 001
> DLT >	/AB/		/EQ 500MG BASE/	/N62089/002/
> ADD >	AB	@	EQ 500MG BASE	N62089 002

PFIZER-E

> DLT >	/AB/	/PFIZER/LABS/	/EQ 500MG BASE/	/N61791/002/
> ADO >	AB	@ PFIZER LABS	EQ 500MG BASE	N61791 002

FLUOCINOLONE ACETONIDE

> ADD > OIL; TOPICAL
> ADD > DERMA-SMOOTHE/FS

> ADD >	HILL DERMS	0.01%	N19452 001
> ADD >			FEB 03, 1988

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL

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

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

> DLT >	/AA/	/BARR/LABS/	/1MG/	/N89177/001/
> OLT >				/JAN 08, 1986/
> ADO >	AA	@ BARR LABS	1MG	N89177 001
> ADD >				JAN 08, 1986

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

AP	PARKE/DAVIS	10MG/ML	N18426 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
> ADD > AB	DANBURY PHARMA	80MG	N71594 001	FEB 09, 1988

HALOPERIDOL

TABLET; ORAL

HALDOL SOLUTAB

> DLT >	MCNEIL LABS	1MG	N17079 001	
> ADD >	∂ 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

HALOPERIOOL LACTATE

CONCENTRATE; ORAL

HALDOL

> DLT > AA	MCNEIL LABS	EQ 2MG BASE/ML	N15922 001	
> ADD > AA	MCNEIL PHARM	EQ 2MG BASE/ML	N15922 001	

HYDRALAZINE HYDROCHLORIOE

TABLET; ORAL

HYDRALAZINE HCL

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

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

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

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

> DLT > AB	PUREPAC/PHARM	50MG;500MG	N70689 001	APR 24, 1986
> ADD > AB	∂ PUREPAC PHARM	50MG;500MG	N70689 001	APR 24, 1986

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE

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

> DLT > BP	BARR LABS	25MG;0.125MG	N84580 001	
> ADD > BP	∂ BARR LABS	25MG;0.125MG	N84580 001	
> DLT > BP		50MG;0.125MG	N84579 001	
> ADD > BP	∂	50MG;0.125MG	N84579 001	

HYDROCHLOROTHIAZIOE; TRIAMTERENE

CAPSULE; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

> ADD > 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
> ADD > AB	QUANTUM PHARMCS	50MG;75MG	N71980 001	APR 17, 1988 : FEB 01, 1988

HYDROCORTISONE

LOTION; TOPICAL
BETA-HC

AT	BETA DERM	1%	N89495 OD1 JAN 25, 1988	

TABLET; ORAL
HYDROCORTISONE

> DLT >	/BP/	/BARR/LABS/	/20MG/	/N83999/001/
> ADD >	BP	ə BARR LABS	20MG	N83999 001

HYDROXYZINE HYDROCHLORIDE

SYRUP; ORAL
HYDROXYZINE HCL

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

IBUPROFEN

TABLET; ORAL
IBUPROFEN

> ADD >	AB	HALSEY DRUG	800MG	N72137 001 FEB 05, 1988
	AB	INVAMED	400MG	N72064 001 JAN 14, 1988
	AB		600MG	N72065 OD1 JAN 14, 1988
	AB		800MG	N71938 001 JAN 14, 1988
> ADD >	AB	MEDICOPHARMA	400MG	N71644 001 FEB 01, 1988
> ADD >	AB	PUREPAC PHARM	800MG	N71964 001 FEB 01, 1988

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL
PRAMINE

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

IOHEXOL

INJECTABLE; INJECTION
OMNIPAQUE 180

> DLT >	/AP/	/WINTHROP/PHARM/	/38.8%/	/N18956/001/ /DEC/26,/1985/
> DLT >				
> ADD >	AP	WINTHROP PHARM	38.8%	N18956 001 DEC 26, 1985
> ADD >				

ISOSORBIDE DINITRATE

TABLET; ORAL
ISOSORBIDE DINITRATE

	AB	BARR LABS	30MG	N87564 001 SEP 18, 1986
> ADD >	AB	DANBURY PHARMA	5MG	N86034 001 JAN 06, 1988
> ADD >				
> ADD >	AB		10MG	N86032 001 JAN 07, 1988
> ADD >				
	AB	PAR PHARM	30MG	N87946 001 JAN 12, 1988

TABLET; SUBLINGUAL
ISOSORBIDE DINITRATE

> ADD >	AB	DANBURY PHARMA	2.5MG	N86033 001 FEB 26, 1988
> ADD >				
> ADD >	AB		5MG	N86031 001 SEP 29, 1987
> ADD >				

LORAZEPAM

TABLET; ORAL
LORAZEPAM

	AB	WARNER CHILCOTT	1MG	N71038 OD1 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 OD1 JAN 14, 1988
	AB		75MG	N72131 OD1 JAN 14, 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

> DLT >	AA	BARR LABS	500MG	N64488 001
> ADD >	AA	∂ BARR LABS	500MG	N84488 001

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

METOCLOPRAMIDE HCL

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

> ADD > NAFTIFINE HYDROCHLORIDE

> ADD > CREAM; TOPICAL

> ADD > NAFTIN

> ADD >		HERBERT LABS	1%	N19599 001
> ADD >				FEB 29, 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

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

OXYTETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

OXYTETRACYCLINE HCL

> DLT >	AB	PUREPAC PHARM	EQ 250MG BASE	N60634 001
> ADD >	AB	∂ PUREPAC PHARM	EQ 250MG BASE	N60634 001

PENICILLIN G POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN G POTASSIUM

> DLT >	AB	PUREPAC PHARM	400,000 UNITS/5ML	N61740 002
> ADD >	AA	∂ PUREPAC PHARM	400,000 UNITS/5ML	N61740 002

TABLET; ORAL

PENICILLIN G POTASSIUM

> DLT >	AB	PUREPAC PHARM	250,000 UNITS	N61588 002
> ADD >	AB	∂ PUREPAC PHARM	250,000 UNITS	N61588 002
> DLT >	AB		400,000 UNITS	N61588 003
> ADD >	AB	∂	400,000 UNITS	N61588 003

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN V POTASSIUM

> DLT >	AB	PUREPAC PHARM	EQ 250MG BASE/5ML	N61758 002
> ADD >	AA	∂ PUREPAC PHARM	EQ 250MG BASE/5ML	N61758 002

TABLET; ORAL

PENICILLIN V POTASSIUM

> DLT >	AB	PUREPAC PHARM	EQ 250MG BASE	N61571 002
> ADD >	AB	∂ PUREPAC PHARM	EQ 250MG BASE	N61571 002
> OLT >	AB		EQ 500MG BASE	N61571 003
> ADD >	AB	∂	EQ 500MG BASE	N61571 003

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

		PHENDIMETRAZINE TARTRATE			
> DLT >	/AA/	/BARR/LABS/	/35MG/	/N83644/001/	
> ADD >	AA	@ BARR LABS	35MG	N83644 001	
> DLT >	/AA/		/35MG/	/N83684/001/	
> ADD >	AA	@	35MG	N83684 001	
> DLT >	/AA/		/35MG/	/N83686/001/	
> ADD >	AA	@	35MG	N83686 001	
> DLT >	/AA/		/35MG/	/N83687/001/	
> ADD >	AA	@	35MG	N83687 001	
> DLT >	/AA/		/35MG/	/N84831/001/	
> ADD >	AA	@	35MG	N84831 001	
> DLT >	/AA/		/35MG/	/N84834/001/	
> ADD >	AA	@	35MG	N84834 001	
> DLT >	/AA/		/35MG/	/N84835/001/	
> ADD >	AA	@	35MG	N84835 001	

PHENTERMINE RESIN COMPLEX

CAPSULE, CONTROLLED RELEASE; ORAL

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

PREDNISOLONE

TABLET; ORAL

		PREDNISOLONE			
> DLT >	/BX/	/BARR/LABS/	/5MG/	/N84426/002/	
> ADD >	BX	@ BARR LABS	5MG	N84426 002	

PREDNISONE

TABLET; ORAL

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

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION

		PROCHLORPERAZINE EDISYLATE			
> ADD >	AP	QUAD PHARMS	EQ 5MG BASE/ML*	N89637 001	
> ADD >				FEB 01, 1988	
> ADD >	AP		EQ 5MG BASE/ML*	N89638 001	
> ADD >				FEB 01, 1988	

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

		PROMETHAZINE HCL			
> DLT >	/BP/	/BARR/LABS/	/12.5MG/	/N84555/001/	
> ADD >	BP	@ BARR LABS	12.5MG	N84555 001	
> DLT >	/BP/		/25MG/	/N84554/001/	
> ADD >	BP	@	25MG	N84554 001	
> DLT >	/BP/		/50MG/	/N84557/001/	
> ADD >	BP	@	50MG	N84557 001	

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

		PROPOXYPHENE HCL			
	/AA/	/BANMAX/PHARMS/	/65MG/	/N83184/001/	
	AA	@ BANMAX PHARMS	65MG	N83184 001	
> DLT >	/AA/	/BARR/LABS/	/65MG/	/N83186/001/	
> ADD >	AA	@ BARR LABS	65MG	N83186 001	

RESERPINE

TABLET; ORAL
RESERPINE

> DLT >	/BP/	/BARR/LABS/	/0.25MG/	/N80721/002/	
> ADD >	BP	ə BARR LABS	0.25MG	N80721 002	

SECOBARBITAL SODIUM

CAPSULE; ORAL
SODIUM SECOBARBITAL

> DLT >	/AA/	/BARR/LABS/	/100MG/	/N84225/001/	
> ADD >	AA	ə BARR LABS	100MG	N84225 001	

SULFAMETHOXAZOLE

TABLET; ORAL
SULFAMETHOXAZOLE

> DLT >	/AB/	/BARR/LABS/	/500MG/	/N87189/001/	
> DLT >				/JUL/25/1983/	
> ADD >	AB	ə BARR LABS	500MG	N87189 001	
> ADD >				JUL 25, 1983	

SULFISOXAZOLE

TABLET; ORAL
SULFISOXAZOLE

> DLT >	/AB/	/BARR/LABS/	/500MG/	/N84031/001/	
> ADD >	AB	ə BARR LABS	500MG	N84031 001	

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

> ADD >	AB	PAR PHARM	150MG	N89764 001
> ADD >				FEB 09, 1988
> ADD >	AB		200MG	N89765 001
> ADD >				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/	
AB	ə BANMAX PHARMS	500MG	N86141 001	

TRIAMCINOLONE

TABLET; ORAL
TRIAMCINOLONE

> DLT >	/BP/	/BARR/LABS/	/2MG/	/N84286/001/	
> ADD >	BP	ə BARR LABS	2MG	N84286 001	
> DLT >	/BP/		/2MG/	/N84318/001/	
> ADD >	BP	ə	2MG	N84318 001	
> DLT >	/BP/		/4MG/	/N84267/001/	
> ADD >	BP	ə	4MG	N84267 001	
> DLT >	/BP/		/4MG/	/N84319/001/	
> ADD >	BP	ə	4MG	N84319 001	
> DLT >	/BP/		/8MG/	/N84268/001/	
> ADD >	BP	ə	8MG	N84268 001	
> DLT >	/BP/		/8MG/	/N84320/001/	
> ADD >	BP	ə	8MG	N84320 001	

TRIMETHOPRIM

TABLET; ORAL
TRIMETHOPRIM

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

TRIPELENNAMINE HYDROCHLORIDE

TABLET; ORAL
TRIPELENNAMINE HCL

>DLT >/AA/	/BARR/LABS/	/50MG/	/N80744/001/
>ADD > AA	ə BARR LABS	50MG	N80744 001

URSODIOL

CAPSULE; ORAL
OEURSIL

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

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
CALAN

>ADD > AB	SEARLE	40MG*	N18817 003
>ADD >			FEB 23, 1988
>ADD >		160MG*	N18817 004
>ADD >			FEB 23, 1988
ISOPTIN			
>ADD > AB	KNOLL PHARM	40MG	N18593 003
>ADD >			NOV 23, 1987
VERAPAMIL HCL			
AB	MUTUAL PHARM	80MG*	N71488 001
			JAN 13, 1988
AB		120MG*	N71489 001
			JAN 13, 1988

WATER FOR INJECTION, STERILE

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

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

(ALL PRODUCTS - SEE INTRODUCTION)

ACETAMINOPHEN

SUPPOSITORY; RECTAL
TYLENOL

>_ADD_>	MCNEIL CONSUMER	120MG	N17756 DD2
>_ADD_>		650MG	N17756 001
>_DLT_>	/MCNEIL/LABS/	/120MG/	/N17756/002/
>_DLT_>		/650MG/	/N17756/001/

IBUPROFEN

TABLET; ORAL
IBUPROFEN

>_ADD_>	INVAMED	200MG∝	N71807 001
>_ADD_>			FEB 25, 1988
>_ADD_>	MEDICOPHARMA	200MG∝	N71639 001
>_ADD_>			FEB 02, 1988

NUPRIN

>_ADD_>	BRISTOL MYERS	200MG∝	N72035 001
>_ADD_>			FEB 16, 1988
>_ADD_>		200MG∝	N72036 001
>_ADD_>			FEB 16, 1988
>_DLT_>	/UPJOHN/	/200MG/	/N19012/001/
>_DLT_>			/MAY/18,/1984/
>_DLT_>		/200MG/	/N19012/003/
>_DLT_>			/JUL/29,/1987/
>_ADD_>	ə	200MG	N19012 001
>_ADD_>			MAY 18, 1984
>_ADD_>	ə	200MG	N19012 003
>_ADD_>			JUL 29, 1987

NONOXYNOL-9

SPONGE; VAGINAL
TODAY

>_DLT_>	/VLI/	/1GM/	/N18683/001/
>_DLT_>			/APR/01,/1983/
>_ADD_>	WHITEHALL LABS	1GM	N18683 001
>_ADD_>			APR 01, 1983

NO FEBRUARY 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 FEBRUARY 1988 APPROVALS

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

NO FEBRUARY 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	

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
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
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 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

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>	19309 001	ENALAPRILAT; VASOTEC	4374829	FEB 22, 2000		NDF	FEB 09, 1991
>ADD>	18981 002	ENCAINIDE HYDROCHLORIDE; ENKAID	RE30811	DEC 20, 1996	U-32		
>ADD>	18981 003	ENCAINIDE HYDROCHLORIDE; ENKAID	RE30811	DEC 20, 1996	U-32		
>ADD>	18981 004	ENCAINIDE HYDROCHLORIDE; ENKAID	RE30811	DEC 20, 1996	U-32		
>ADD>	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>	18061 001	HYDROCHLOROTHIAZIDE; TIMOLIDE 10-25	3655663	APR 11, 1989		D-2	FEB 03, 1991
>ADD>	18956 003	IOHEXOL; OMNIPAQUE 300	4021481	MAY 03, 1994		I-55	FEB 01, 1988
>ADD>						I-58	FEB 01, 1988
>ADD>	18956 004	IOHEXOL; OMNIPAQUE 350	4021481	MAY 03, 1994		I-55	FEB 01, 1988
	18677 001	NABILONE; CESAMET	4087545	MAY 02, 1997	U-7		
>ADD>	19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 1998		NCE	FEB 29, 1993
>ADD>	19009 001	PIRBUTEROL ACETATE; EXIREL	4175128	NOV 20, 1996			
>ADD>			3786160	JAN 15, 1993			
>ADD>			3700681	OCT 24, 1989		NCE	DEC 30, 1991
>ADD>	17881 001	TECHNETIUM TC 99M ALBUMIN AGGREGATED KIT; TECHNETIUM TC 99M	3872226	MAR 18, 1992			
>ADD>			3B63004	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
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			4026894	MAY 31, 1994			
	19057 003	TERAZDSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 1998	U-5	NCE	AUG 07, 1992
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			4026894	MAY 31, 1994			
	19057 004	TERAZOSIN HYDRDCHLORIDE; HYTRIN	4251532	FEB 17, 1998	U-5	NCE	AUG 07, 1992
			4112097	SEP 05, 1995	U-5		
			4026894	MAY 31, 1994			
>ADD>	18817 003	VERAPAMIL HYDROCHLORIDE; CALAN				I-50	DEC 16, 1989
>ADD>						I-51	DEC 16, 1989
>ADD>	18817 004	VERAPAMIL HYDROCHLORIDE; CALAN				I-50	DEC 16, 1989
>ADD>						I-51	DEC 16, 1989

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