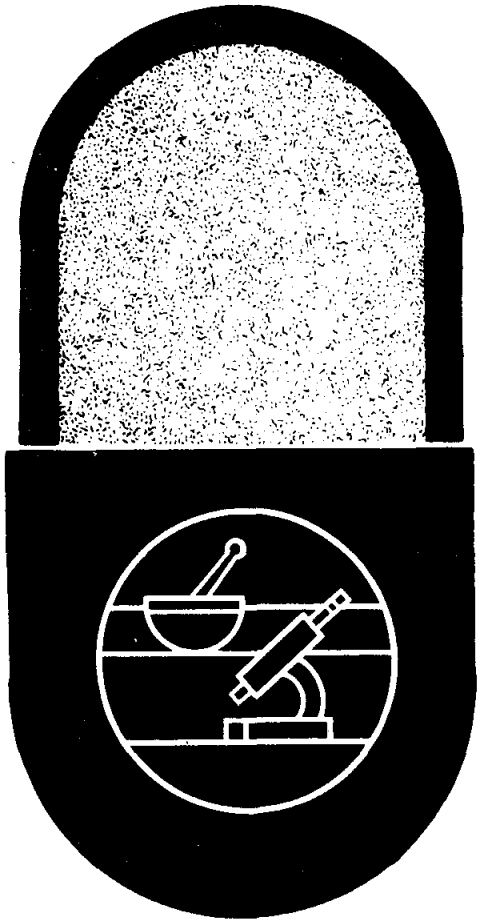
CUMULATIVE SUPPLEMENT 2

JAN'89-FEB'89



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

9TH EDITION

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

APPROVED DRUG PRODUCTS

with

THERAPEUTIC EQUIVALENCE EVALUATIONS

9TH EDITION

CUMULATIVE SUPPLEMENT 2

FEBRUARY 1989

CONTENTS

APPROVED DRUG PRODUCTS

with

THERAPEUTIC EQUIVALENCE EVALUATIONS

9th EDITION

CUMULATIVE SUPPLEMENT 2

FEBRUARY 1989

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 9th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products in the Division of Blood and Blood Products approved under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.

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

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

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

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the List will not be repeated for context.] The effective date for the approved drug product (the earliest date a product may be marketed) appears, when appropriate, to the left of the approval date.

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

Additions new to the Prescription Drug Product List, OTC Drug Product List, Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act List and the Patent and Exclusivity Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item. A newly approved product is also identified by a lozenge (◆) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

Deletions new to the Prescription Drug Product List, OTC Drug Product List, Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act List and the Patent and Exclusivity Data are indicated by the symbol >DLT> (DELETE) to the left of the line containing overstruck print. The >DLT> symbol is dropped in subsequent Cumulative Supplements for that item. The overstruck print will remain in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act List and the Patent and Exclusivity Data will be dropped in subsequent Cumulative Supplements.

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

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

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

1.3 APPLICANT (NAME) CHANGES

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

APPLICANT (NAME) CHANGES

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

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 1988) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product, provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 1988	MAR 1989	JUN 1989	SEP 1989
DRUG PRODUCTS LISTED	10091			
SINGLE SOURCE	1983 (19.7%)			
MULTISOURCE	8108 (80.3%)			
THERAPEUTICALLY EQUIVALENT	7242 (71.8%)			
NOT THERAPEUTICALLY EQUIVALENT	748 (7.4%)			
EXCEPTIONS[1]	118 (1.1%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	374			

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

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

	ACETAMINOPHEN W/ CODEINE PHOSPHATE			
AA	PBI	300MG;30MG	N87919 001	JUN 22, 1982
AA	∂ PBI	300MG;60MG	N87920 001	JUN 22, 1982
	PAPA-DEINE #3			
AA	VANGARD LABS	300MG;30MG	N88037 001	MAR 20, 1984
	PAPA-DEINE #4			
AA	VANGARD LABS	300MG;60MG	N88715 001	MAR 20, 1984

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

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

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL

	OXYCODONE 5/APAP 500			
AA	DUPONT PHARMS	500MG;5MG	N85911 001	
	ROXICET 5/500			
AA	ROXANE LABS	500MG;5MG¤	N89775 001	JAN 12, 1989

ACETAZOLAMIDE

TABLET; ORAL

		ACETAZOLAMIDE			
>DLT >DLT >ADD >ADD >	AA	VANGARD LABS	250MG	N87654 001	FEB 05, 1982

ALBUTEROL SULFATE

TABLET; ORAL

		ALBUTEROL SULFATE			
>ADD >	AB	AM THERPTCS	EQ 2MG BASE¤	N72449 001	DEC 05, 1989 : FEB 01, 1989
>ADD >	AB		EQ 4MG BASE¤	N72450 001	DEC 05, 1989 : FEB 01, 1989
>ADD >	AB	MUTUAL PHARM	EQ 2MG BASE¤	N72636 001	DEC 05, 1989 : FEB 01, 1989
>ADD >	AB		EQ 4MG BASE¤	N72637 001	DEC 05, 1989 : FEB 01, 1989
	AB	SIDMAK LABS	EQ 2MG BASE¤	N72316 001	DEC 05, 1989 : JAN 30, 1989
	AB		EQ 4MG BASE¤	N72317 001	DEC 05, 1989 : JAN 30, 1989

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

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

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE

/BD/	/CORD/LABS/	/100MG/	/N85261/003/	
	ə CORD LABS	100MG	N85261 003	

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

/AB/	/PBI/	/25MG/	/N87775/001/		
			/FEB/10,/1982/		
	ə PBI	25MG	N87775 001		
			FEB 10, 1982		
> DLT > /AB/	/ROXANE/LABS/	/10MG/	/N86144/001/		
> DLT > /AB/		/25MG/	/N86145/001/		
> DLT > /AB/		/50MG/	/N86143/001/		
> DLT > /AB/		/75MG/	/N86147/001/		
> DLT > /AB/		/100MG/	/N86146/001/		
> DLT > /AB/		/150MG/	/N86148/001/		
> ADD >	ə ROXANE LABS	10MG	N86144 001		
> ADD >	ə	25MG	N86145 001		
> ADD >	ə	50MG	N86143 001		
> ADD >	ə	75MG	N86147 001		
> ADD >	ə	100MG	N86146 001		
> ADD >	ə	150MG	N86148 001		

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL
PERPHENAZINE AND AMITRIPTYLINE HCL

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

AMMONIUM LACTATE

LOTION; TOPICAL
LAC-HYDRIN

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

AMMONIUM LACTATE

LOTION; TOPICAL
LAC-HYDRIN

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

AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

> ADD >	AB	TAG PHARMS	250MG	N63030 001
> ADD >				FEB 28, 1989
> ADD >	AB		500MG	N63031 001
> ADD >				FEB 28, 1989

POWDER FOR RECONSTITUTION; ORAL
AMOXICILLIN

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

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL
AMPICILLIN

> ADD >	AB	CLONMEL CHEMS	EQ 125MG BASE/5ML		N62982 001
> ADD >					FEB 10, 1989
> ADD >	AB		EQ 250MG BASE/5ML		N62982 002
> ADD >					FEB 10, 1989
> DLT >	/TABLET;/CHEWABLE;/ORAL/				
> DLT >	/POLYCILLIN;/				
> DLT >	/BRISTOL/LABS/	/EQ/125MG/BASE/			/N50093/001/
> ADD >	ə BRISTOL LABS	EQ 125MG BASE			N50093 001

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE

/AA/	/LEDERLE/LABS/	/0.025MG;2.5MG/		/N86950/001/
	ə LEDERLE LABS	0.025MG;2.5MG		N86950 001
	DIPHENOXYLATE HCL W/ ATROPINE SULFATE			
/AA/	/PBI/	/0.025MG;2.5MG/		/N87842/001/
				/MAR/29,/1982/
	ə PBI	0.025MG;2.5MG		N87842 001
				MAR 29, 1982

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

> DLT >		/LO-TROL/		
> DLT >	/AA/	/VANGARD LABS/	/0.025MG;2.5MG/	/N88009/001/ /MAR 25, 1983/
> DLT >				
> ADD >		ə VANGARD LABS	0.025MG;2.5MG	N88009 001 MAR 25, 1983
> ADD >				

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

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

CARBOPROST

INJECTABLE; INJECTION

HEBAMATE

> ADD >		UPJOHN	EQ 0.25MG BASE/ML	N17989 001
> DLT >		/PROSTIN/15M/		
> DLT >		/UPJOHN/	/EQ/0.25MG/BASE/ML/	/N17989/001/

CEFADROXIL

CAPSULE; ORAL

CEFADROXIL

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

CEFPIRAMIDE SODIUM

INJECTABLE; INJECTION

CEFPIRAMIDE SODIUM

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

CEPHALEXIN

TABLET; ORAL

CEPHALEXIN

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

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

> DLT >	/AA/	/VANGARD LABS/	/5MG/	/N88129/001/ /MAR 28, 1983/
> DLT >				
> DLT >	/AA/		/10MG/	/N88010/001/ /MAR 28, 1983/
> DLT >				
> DLT >	/AA/		/25MG/	/N88130/001/ /MAR 28, 1983/
> DLT >				
> ADD >		ə VANGARD LABS	5MG	N88129 001 MAR 28, 1983
> ADD >				
> ADD >		ə	10MG	N88010 001 MAR 28, 1983
> ADD >				
> ADD >		ə	25MG	N88130 001 MAR 28, 1983
> ADD >				

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

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

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CHLORPHENIRAMINE MALEATE AND PHENYLPROPANOLAMINE HCL

AB	CORD LABS	12MG;75MG*	N88940 001 JAN 26, 1989

ORNADE

AB	SK&F LABS	12MG;75MG	N12152 004
/BC/		/12MG;75MG/	/N12152/004/

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL
CHLORPROMAZINE HCL

> DLT >	/BP/	/VANGARD LABS/	/10MG/	/N88038/001/	
> DLT >				/AUG 16, 1982/	
> DLT >	/BP/		/25MG/	/N87645/001/	
> DLT >	/BP/		/50MG/	/N87646/001/	
> ADD >		∂ VANGARD LABS	10MG	N88038 001	
> ADD >				AUG 16, 1982	
> ADD >		∂	25MG	N87645 001	
> ADD >		∂	50MG	N87646 001	

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

> DLT >	/AB/	/VANGARD LABS/	/25MG/	/N88012/001/	
> DLT >				/JUL 14, 1982/	
> DLT >	/AB/		/50MG/	/N88073/001/	
> DLT >				/MAR 25, 1983/	
> ADD >		∂ VANGARD LABS	25MG	N88012 001	
> ADD >				JUL 14, 1982	
> ADD >		∂	50MG	N88073 001	
> ADD >				MAR 25, 1983	

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

AA		PIONEER PHARMS	250MG*	N89592 001
				JAN 06, 1989
AA			500MG*	N89948 001
				JAN 06, 1989

CHYMOPAPAIN

INJECTABLE; INJECTION
/DISCASE/

> DLT >		/BOOTS PHARMS/	/12,500 UNITS/VIAL/	/N18625/001/
> DLT >				/JAN 18, 1984/
> ADD >		∂ BOOTS PHARMS	12,500 UNITS/VIAL	N18625 001
> ADD >				JAN 18, 1984

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

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

SOLUTION; TOPICAL
CLINDAMYCIN PHOSPHATE

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

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM

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

DEMECLOCYCLINE HYDROCHLORIDE

> DLT >	/SYRUP; ORAL/		
> DLT >	/DECLOMYCIN; /		
> DLT >	/LEDERLE LABS/	/75MG/5ML/	/N50257/001/
> ADD >	∂ LEDERLE LABS	75MG/5ML	N50257 001

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL
DICYCLOMINE HCL

AB	PIONEER PHARMS	10MG*	N89361 001
			JAN 10, 1989

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

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

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

	DIPHENHYDRAMINE HCL			
>DLT >/AA/	/VANGARD/LABS/	/25MG/	/N88034/001/	
>DLT >			/OCT 27, 1982/	
>DLT >/AA/		/50MG/	/N87630/001/	
>ADD >	∂ VANGARD LABS	25MG	N88034 001	
>ADD >			OCT 27, 1982	
>ADD >	∂	50MG	N87630 001	

ELIXIR; ORAL

	DIPHENHYDRAMINE HCL			
/AA/	/PRIVATE/FMLTNS/	/12.5MG/5ML/	/N85287/001/	
	∂ PRIVATE FMLTNS	12.5MG/5ML	N85287 001	

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

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

DOXYCYCLINE HYCLATE

INJECTABLE; INJECTION

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

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

	ERGOLOID MESYLATES			
/AA/	/LEDERLE/LABS/	/0.5MG/	/N86984/001/	
/AA/		/1MG/	/N86985/001/	
	∂ LEDERLE LABS	0.5MG	N86984 001	
	∂	1MG	N86985 001	
>DLT >/AA/	/VANGARD/LABS/	/0.5MG/	/N88013/001/	
>DLT >			/SEP 20, 1982/	
>DLT >/AA/		/1MG/	/N88014/001/	
>DLT >			/SEP 20, 1982/	
>ADD >	∂ VANGARD LABS	0.5MG	N88013 001	
>ADD >			SEP 20, 1982	
>ADD >	∂	1MG	N88014 001	
>ADD >			SEP 20, 1982	

ESTROGENS, ESTERIFIED

TABLET; ORAL

	FEMOGEN			
>DLT > /BS/	/PRIVATE/FMLTNS/	/2.5MG/	/N85007/001/	
>ADD >	∂ PRIVATE FMLTNS	2.5MG	N85007 001	

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

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

TABLET; ORAL-28

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

FLUOCINONIDE

CREAM; TOPICAL

	FLUOCINONIDE			
>ADD > AB	LEMMON	0.05%*	N72488 001	
>ADD >			FEB 06, 1989	
>ADD > AB		0.05%*	N72490 001	
>ADD >			FEB 07, 1989	
	VASODERM E			
AB	TJ ROACO	0.05%*	N72494 001	
			JAN 19, 1989	

FLUOCINONIDE

GEL; TOPICAL
FLUOCINONIDE

> ADD >				
> ADD >	AB	LEMMON	0.05%N	N72537 001 FEB 07, 1989
> ADD >				
		LIDEX		
> ADD >	AB	SYNTEX LABS	0.05%	N17373 001

SOLUTION; TOPICAL
FLUOCINONIDE

> ADD >	AT	LEMMON	0.05%N	N72511 001 FEB 07, 1989
> ADD >				

FLUTAMIDE

CAPSULE; ORAL
EULEXIN

SCHERING	125MGN	N18554 001 JAN 27, 1989

FOLIC ACID

TABLET; ORAL
FOLIC ACID

/AA/	/PBI/	/1MG/	/N87828/001/ /MAY/13,/1982/
	ə PBI	1MG	N87828 001 MAY 13, 1982

GEMFIBROZIL

CAPSULE; ORAL
LOPID

/PARKE/DAVIS/	/200MG/	/N18422/001/
ə PARKE DAVIS	200MG	N18422 001

TABLET; ORAL
LOPID

PARKE DAVIS	600MG	N18422 003 NOV 20, 1986

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER

AP	BAXTER	4,000 UNITS/100ML	N18814 001 OCT 31, 1983

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM 20,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	ABBOTT LABS	4,000 UNITS/100MLN	N19805 001 JAN 25, 1989

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

AP	ABBOTT LABS	5,000 UNITS/100MLN	N19805 002 JAN 25, 1989

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HCL

/AA/	/PBI/	/10MG/	/N87780/001/ /MAR/29,/1982/
/AA/		/50MG/	/N87751/001/ /MAR/29,/1982/
	ə PBI	25MG	N87780 001 MAR 29, 1982
	ə	50MG	N87751 001 MAR 29, 1982

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

/AA/	/PBI/	/25MG/	/N87827/001/ /APR/19,/1982/
/AA/		/50MG/	/N87752/001/ /APR/19,/1982/
	ə PBI	25MG	N87827 001 APR 19, 1982
	ə	50MG	N87752 001 APR 19, 1982
> DLT >/AA/	/VANGARD/LABS/	/25MG/	/N87638/001/
> DLT >/AA/		/50MG/	/N87610/001/
> ADD >	ə VANGARD LABS	25MG	N87638 001
> ADD >	ə	50MG	N87610 001

> ADD > HYDROCHLOROTHIAZIDE; LISINOPRIL

> ADD > TABLET; ORAL
> ADD > PRINZIDE 12.5

> ADD >	MS&D RES LABS	12.5MG;20MGN	N19778 001 FEB 16, 1989
> ADD >			

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL
PRINZIDE 25

>ADD >		MS&D RES LABS	25MG;20MG	N19778 002	
>ADD >				FEB 16, 1989	

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
METHYLDOPA AND HYDROCHLOROTHIAZIDE

>ADD >	AB	DANBURY PHARMA	15MG;250MG	N70958 001	
>ADD >				FEB 06, 1989	
	AB		25MG;250MG	N70959 001	
				JAN 19, 1989	
	AB		30MG;500MG	N71069 001	
				JAN 19, 1989	
>ADD >	AB		50MG;500MG	N70960 001	
>ADD >				FEB 06, 1989	

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE

/AB/		/PBI/	/25MG;25MG/	/N87651/001/	
		∂ PBI	25MG;25MG	N87651 001	
>DLT >/AB/		/VANGARD LABS/	/25MG;25MG/	/N87655/001/	
>ADD >		∂ VANGARD LABS	25MG;25MG	N87655 001	

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

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

HYDROCORTISONE ACETATE

CREAM; TOPICAL
HYDROCORTISONE ACETATE

	AT	PARKE DAVIS	1%	N89914 001	
				JAN 03, 1989	

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL
IMIPRAMINE HCL

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

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
WELLCOVORIN

	AP	BURROUGHS WELLC	EQ 50MG BASE/VIAL	N89465 001	
				JAN 23, 1989	
	AP		EQ 100MG BASE/VIAL	N89834 001	
				JAN 23, 1989	
			EQ 25MG BASE/VIAL	N89833 001	
				JAN 23, 1989	

LEUPROLIDE ACETATE

INJECTABLE; INJECTION
LUPRON DEPOT

		TAP PHARMS	7.5MG/VIAL	N19732 001	
				JAN 26, 1989	

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
XYLOCAINE

>ADD >	AP	ASTRA PHARM PRODS	1%	N16801 005	
>ADD >				JAN 19, 1988	

LITHIUM CARBONATE

CAPSULE; ORAL

LITHIUM CARBONATE

> ADD >	AB	PBI	300MG*	N72542 001	
> ADD >				FEB 01, 1989	

MANNITOL

SOLUTION; IRRIGATION

> DLT >		/RESECTISOL;/		
> DLT >		/KENDALL/MCGAW/	/5GM/100ML/	/N16704/002/
> ADD >		ə KENDALL MCGAW	5GM/100ML	N16704 002

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

MECLIZINE HCL

> DLT >	/AA/	/VANGARD/LABS/	/12.5MG/	/N87877/001/
> DLT >				/APR/20,/1982/
> DLT >	/AA/		/25MG/	/N87620/001/
> DLT >				/JAN/04,/1982/
> ADD >		ə VANGARD LABS	12.5MG	N87877 001
> ADD >				APR 20, 1982
> ADD >		ə	25MG	N87620 001
> ADD >				JAN 04, 1982

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

> DLT >	/AA/	/VANGARD/LABS/	/400MG/	/N88011/001/
> DLT >				/JUL/14,/1982/
> ADD >		ə VANGARD LABS	400MG	N88011 001
> ADD >				JUL 14, 1982

METHYLPREDNISOLONE ACETATE

> DLT >		/ENEMA;/RECTAL/		
> DLT >		/MEDROL;/		
> DLT >		/UPJOHN/	/40MG/BOT/	/N18102/001/
> ADD >		ə UPJOHN	40MG/BOT	N18102 001

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL

> ADD >	AP	BULL LABS	EQ 10MG BASE/2ML*	N71990 001	
> ADD >				JAN 18, 1989	

METOPROLOL TARTRATE

TABLET; ORAL

LOPRESSOR

> ADD >	AB	GEIGY PHARMS	50MG	N17963 001	
> ADD >	AB		100MG	N17963 002	
> ADD >		METOPROLOL TARTRATE			
> ADD >	AB	HENRY SCHEIN	50MG*	N71690 001	†
> ADD >				FEB 08, 1989	
> ADD >	AB		100MG*	N71691 001	†
> ADD >				FEB 08, 1989	

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

NALBUPHINE HCL

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

OXACILLIN SODIUM

INJECTABLE; INJECTION

OXACILLIN SODIUM

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

† DELAYED EFFECTIVE DATE PENDING COURT DECISION

PANCURONIUM BROMIDE

INJECTABLE; INJECTION
PANCURONIUM BROMIDE

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

PENICILLIN G BENZATHINE

> DLT >	/SUSPENSION;ORAL/			
> DLT >	/BICILLIN/			
> DLT >	/WYETH/AYERST/LABS/	/300,000/UNITS/5ML/	/N50126/002/	
> ADD >	@ WYETH AYERST LABS	300,000 UNITS/5ML	N50126 002	

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN V POTASSIUM

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

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

> DLT >	/DI-METHEX/			
> DLT >/AA/	/PRIVATE/FMLTNS/	/35MG/	/N85698/001/	
> ADD >	@ PRIVATE FMLTNS	35MG	N85698 001	
PHENDIMETRAZINE TARTRATE				
> DLT >/AA/	/PRIVATE/FMLTNS/	/35MG/	/N85199/001/	
> ADD >	@ PRIVATE FMLTNS	35MG	N85199 001	

POTASSIUM CHLORIDE; SODIUM CHLORIDE

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

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

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.15% IN
PLASTIC CONTAINER

> DLT >/AP/	/KENDALL/MCGAW/	/150MG/100ML;/		
> DLT >		/900MG/100ML/	/N18722/002/	
> DLT >			/NOV/09,/1982/	
> ADD >	@ KENDALL MCGAW	150MG/100ML;		
> ADD >		900MG/100ML	N18722 002	
> ADD >			NOV 09, 1982	

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

> DLT >/AP/	/KENDALL/MCGAW/	/220MG/100ML;/		
> DLT >		/900MG/100ML/	/N18722/003/	
> DLT >			/NOV/09,/1982/	
> ADD >	@ KENDALL MCGAW	220MG/100ML;		
> ADD >		900MG/100ML	N18722 003	
> ADD >			NOV 09, 1982	

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

> DLT >/AP/	/KENDALL/MCGAW/	/300MG/100ML;/		
> DLT >		/900MG/100ML/	/N18722/004/	
> DLT >			/NOV/09,/1982/	
> ADD >	@ KENDALL MCGAW	300MG/100ML;		
> ADD >		900MG/100ML	N18722 004	
> ADD >			NOV 09, 1982	

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
PRAZOSIN HCL

> ADD >	AB DANBURY PHARMA	EQ 1MG BASE*	N72352 001	MAY 16, 1989 : JAN 11, 1989
> ADD >	AB	EQ 2MG BASE*	N72333 001	MAY 16, 1989 : JAN 11, 1989
> ADD >	AB	EQ 5MG BASE*	N72609 001	MAY 16, 1989 : JAN 11, 1989
> ADD >	AB MYLAN PHARMS	EQ 1MG BASE*	N72573 001	MAY 16, 1989 : FEB 28, 1989
> ADD >	AB	EQ 2MG BASE*	N72574 001	MAY 16, 1989 : FEB 28, 1989
> ADD >	AB	EQ 5MG BASE*	N72575 001	MAY 16, 1989 : FEB 28, 1989

PREDNISOLONE

SYRUP; ORAL
PRELONE

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

PREDNISONE

SOLUTION; ORAL

PREDNISONE INTENSOL

	ROXANE LABS	5MG/ML	N88810 001 FEB 20, 1985

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

TABLET; ORAL

DELTASONE

AB	UPJOHN	50MG	N09986 008
/BX/		/50MG/	/N09986/008/

PREDNISONE

AB	CORD LABS	10MG*	N89983 001 JAN 12, 1989
AB		50MG*	N89984 001 JAN 12, 1989
> DLT > /BX/	/VANGARD/LABS/	/5MG/	/N87682/001/ /JAN/15,/1982/
> DLT >			
> DLT > /BX/		/20MG/	/N87701/001/ /JAN/15,/1982/
> DLT >			
> ADD >	a VANGARD LABS	5MG	N87682 001 JAN 15, 1982
> ADD >			
> ADD >	a	20MG	N87701 001 JAN 15, 1982
> ADD >			

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL

PROCAINAMIDE HCL

> DLT > /AB/	/VANGARD/LABS/	/250MG/	/N87643/001/ /JUN/01,/1982/
> DLT >			
> DLT > /AB/		/500MG/	/N87875/001/ /JUN/01,/1982/
> DLT >			
> ADD >	a VANGARD LABS	250MG	N87643 001 JUN 01, 1982
> ADD >			
> ADD >	a	500MG	N87875 001 JUN 01, 1982
> ADD >			

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

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

QUINIDINE GLUCONATE

INJECTABLE; INJECTION

QUINIDINE GLUCONATE

> DLT >	/LILLY/	/80MG/ML/	/N07529/001/
> ADD >	LILLY	80MG/ML*	N07529 002 FEB 10, 1989
> ADD >			

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

/AB/	/PBI/	/200MG/	/N87837/001/ /APR/14,/1982/
	a PBI	200MG	N87837 001 APR 14, 1982

SECRETIN

INJECTABLE; INJECTION

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

SINCALIDE

INJECTABLE; INJECTION
KINEVAC
/SQUIBB/ /0.005MG/VIAL/ /N17697/001/
SQUIBB DIAGS 0.005MG/VIAL N17697 001

SODIUM IODIDE, I-123

CAPSULE; ORAL
SODIUM IODIDE I 123
> ADD > AA BENEDICT NUCLR 200 UCI N18671 002
> ADD > MAY 27, 1982
> ADD > AA MALLINCKRODT 100 UCI* N71909 001
> ADD > FEB 28, 1989
> ADD > AA 200 UCI* N71910 001
> ADD > FEB 28, 1989

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
AA CAROLINA MED 454GM/BOT* N89910 001
JAN 19, 1989

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE
> DLT >/AB/ /VANGARD/LABS/ /25MG/ /N87648/001/
> DLT > /FEB/01,/1982/
> ADD > a VANGARD LABS 25MG N87648 001
> ADD > FEB 01, 1982

SULCONAZOLE NITRATE

> ADD > CREAM; TOPICAL
> ADD > SULCOSYN
> ADD > SYNTEX LABS 1%* N18737 001
> ADD > FEB 28, 1989

TIMOLOL MALEATE

TABLET; ORAL
BLOCADREN
AB MS&D 5MG N18017 001
AB 10MG N18017 002
AB 20MG N18017 004

TIMOLOL MALEATE

TABLET; ORAL
TIMOLOL MALEATE
AB PBI 5MG* N72001 001
APR 11, 1989 : JAN 10, 1989
AB 10MG* N72002 001
APR 11, 1989 : JAN 10, 1989
AB 20MG* N72003 001
APR 11, 1989 : JAN 10, 1989

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE
> DLT >/AB/ /VANGARD/LABS/ /500MG/ /N87876/001/
> DLT > /APR/20,/1982/
> ADD > a VANGARD LABS 500MG N87876 001
> ADD > APR 20, 1982

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL
> ADD > AB LEMMON 50MG* N72192 001
> ADD > FEB 02, 1989
> ADD > AB 100MG* N72193 001
> ADD > FEB 02, 1989

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
TRIAMCINOLONE ACETONIDE
> ADD > AT TOPIDERM 0.025%* N89274 001
> ADD > FEB 21, 1989
> ADD > AT 0.1%* N89275 001
> ADD > FEB 21, 1989
> ADD > AT 0.5%* N89276 001
> ADD > FEB 21, 1989

TRIHEXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL
TRIHEXYPHENIDYL HCL
> DLT >/AB/ /VANGARD/LABS/ /2MG/ /N88035/001/
> DLT > /JUL/30,/1982/
> ADD > a VANGARD LABS 2MG N88035 001
> ADD > JUL 30, 1982

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL

		VERAPAMIL HCL		
> ADD >	AB	MYLAN PHARMS	80MG*	N71482 001
> ADD >				FEB 15, 1989
> ADD >	AB		120MG*	N71483 001
> ADD >				FEB 15, 1989
	AB	SIDMAK LABS	80MG*	N72124 D01
				JAN 26, 1989
	AB		120MG*	N72125 001
				JAN 26, 1989

ACETAMINOPHEN

SUPPOSITORY; RECTAL

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

IBUPROFEN

TABLET; ORAL

IBUPROFEN		
MUTUAL PHARM	200MG	N72249 001 JAN 10, 1989

NO FEBRUARY 1989 ADDITIONS

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, 9TH 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 1989 APPROVALS

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

NO FEBRUARY 1989 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR IN VIVO BIOEQUIVALENCE STUDIES AND IN VITRO DISSOLUTION TESTING AVAILABLE FROM THE DIVISION OF BIOEQUIVALENCE, HFN-250, ROOM 17B-06, 5600 FISHERS LANE, ROCKVILLE, MD 20857. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 9TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
ALBULTEROL; METAPROTERENOL SULFATE (METERED DOSE INHALER)	AUG 25, 1988	FEB 09, 1989

ANDA SUITABILITY PETITIONS

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

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 9TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CARMUSTINE, STERILE INJECTABLE; INJECTION	200MG/VIAL	88 P-0410/CP	QUAD PHARMS	NEW STRENGTH	APPROVED FEB 13, 1989
HALOPERIDOL DECANOATE INJECTABLE; INJECTION	EQ 50MG BASE/ML (2ML/CONTAINER)	88 P-0411/CP	QUAD PHARMS	NEW STRENGTH	APPROVED FEB 13, 1989

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, 9TH 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 INDICATION

I-84	ADJUNCTIVE THERAPY TO DIET TO REDUCE THE RISK OF CORONARY ARTERY DISEASE

PATENT USE CODE

U-41	METHOD FOR TREATING PROSTATIC CARCINOMA COMPRISING ADMINISTERING FLUTAMIDE
U-42	METHOD FOR TREATING PROSTATE ADENOCARCINOMA COMPRISING ADMINISTERING AN ANTIANDROGEN INCLUDING FLUTAMIDE AND AN LHRH AGONIST
U-43	REDUCING CHOLESTEROL IN CHOLELITHIASIS PATIENTS
U-44	REDUCING CHOLESTEROL GALLSTONES AND/OR FRAGMENTS THEREOF
U-45	DISSOLVING CHOLESTEROL GALLSTONES AND/OR FRAGMENTS THEREOF

PRESCRIPTIDN AND DTC DRUG PRDDUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19471 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	19471 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	19471 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	19471 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	18554 001	FLUTAMIDE; EULEXIN	4474813	NOV 30, 1993		NCE	JAN 27, 1994
			4472382	SEP 18, 2001	U-42		
			4329364	MAY 11, 1999	U-41		
	18422 001	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
	18422 002	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
	18422 003	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
>ADD>	19778 001	HYDRDCHLOROTHIAZIDE; PRINZIDE 12.5	4472380	SEP 18, 2001		NC	FEB 16, 1992
>ADD>			4374829	DEC 30, 2001		NCE	DEC 29, 1992
>ADD>	19778 0D2	HYDROCHLOROTHIAZIDE; PRINZIDE 25	4472380	SEP 18, 2001		NC	FEB 16, 1992
>ADD>			4374829	DEC 30, 2001		NCE	DEC 29, 1992
	19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4005063	JAN 25, 1996		NCE	APR 09, 1990
						NP	JAN 26, 1992
>ADD>	19625 001	MOMETASONE FUROATE; ELDCON	4808610	FEB 28, 2006			
	19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 2000		NCE	MAR 01, 1993
>DLT>	19508 001	NIZATIDINE; AXID	4375547	MAR 01, 2000		NCE	APR 12, 1993
>ADD>	19508 001	NIZATIDINE; AXID	4375547	MAR D1, 2002		NCE	APR 12, 1993
>DLT>	19508 002	NIZATIDINE; AXID	4375547	MAR 01, 2000		NCE	APR 12, 1993
>ADD>	19508 D02	NIZATIDINE; AXID	4375547	MAR 01, 2002		NCE	APR 12, 1993
>ADD>	18737 D01	SULCONAZOLE NITRATE; SULCOSYN	4055652	OCT 25, 1996		NCE	AUG 30, 1990
>ADD>						NDF	FEB 28, 1992
>ADD>	19594 001	URSODIOL; ACTIGALL	RE30910	JAN 07, 1994	U-43		
>ADD>			RE30910	JAN 07, 1994	U-44		
>ADD>			RE30910	JAN 07, 1994	U-45		
>ADD>	19594 0D2	URSODIOL; ACTIGALL	RE30910	JAN D7, 1994	U-43		
>ADD>			RE30910	JAN 07, 1994	U-44		
>ADD>			RE30910	JAN 07, 1994	U-45		