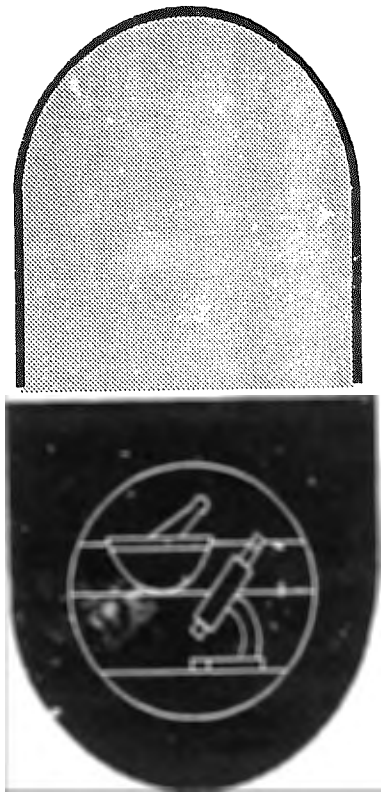
CUMULATIVE
SUPPLEMENT 2

JAN'92-FEB'92



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION

Cumulative Supplement 2

February 1992

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CUMULATIVE SUPPLEMENT 2

FEBRUARY 1992

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, 12th 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 with approval under Section 505 of the Act administered by the Division of Blood and Blood Products and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products 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. Also shown is the application number and product number (FDA's internal file number) for reference purposes. 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 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, 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, 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 remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements.

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy 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 12th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 13th 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

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; or when an applicant name is changed to meet internal publication standards. Therefore, 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 (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREIVATED NAME)
RECKITT AND COLMAN PHARMACEUTICALS INC (R & C)	RECKITT AND COLMAN PHARMACEUTICALS INC (RECKITT AND COLMAN)
BARNES HIND PHARMACEUTICALS INC (BARNES HIND)	SOLA BARNES HIND (SOLA BARNES HIND)

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 1991) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

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

New Molecular Entity

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

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 1991	MAR 1992	JUN 1992	SEP 1992
DRUG PRODUCTS LISTED	9258			
SINGLE SOURCE	2187 (22.8%)			
MULTISOURCE	7397 (77.2%)			
THERAPEUTICALLY EQUIVALENT	6580 (68.7%)			
NOT THERAPEUTICALLY EQUIVALENT	664 (6.9%)			
EXCEPTIONS[1]	153 (1.6%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	430			

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

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

	ACETAMINOPHEN W/ CODEINE PHOSPHATE			
/AA/	/CHELSEA/	/300MG;15MG/		/N87277/001/
			> DLT >	/MAY/26,/1982/
/AA/		/300MG;30MG/	> DLT >	/N87276/001/
			> ADD >	/MAY/26,/1982/
/AA/		/300MG;60MG/	> ADD >	/N87275/001/
				/MAY/26,/1982/
	@ CHELSEA	300MG;15MG		N87277 001
				MAY 26, 1982
	@	300MG;30MG		N87276 001
				MAY 26, 1982
	@	300MG;60MG		N87275 001
				MAY 26, 1982

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

	HYDROCODONE BITARTRATE AND ACETAMINOPHEN		
AA	MIKART	500MG;5MG*	N89697 001
			JAN 28, 1992
/B*/	/PHARM/BASICS/	/500MG;5MG/	/N89291/001/
			/MAY/29,/1987/
	@ PHARM BASICS	500MG;5MG	N89291 001
			MAY 29, 1987

ACETOHEXAMIDE

TABLET; ORAL

	ACETOHEXAMIDE		
/B*/	/PHARM/BASICS/	/250MG/	/N70753/001/
			/NOV/03,/1986/
/B*/		/500MG/	/N70754/001/
			/NOV/03,/1986/
	@ PHARM BASICS	250MG	N70753 001
			NOV 03, 1986
	@	500MG	N70754 001
			NOV 03, 1986

ALBUTEROL SULFATE

SOLUTION; INHALATION

		ALBUTEROL SULFATE		
> ADD >	AN	DEY	EQ 0.083% BASE*	N72652 001
> ADD >				FEB 21, 1992
		PROVENTIL		
> ADD >	AN	SCHERING	EQ 0.083% BASE	N19243 002
> ADD >				JAN 14, 1987

ALLOPURINOL

TABLET; ORAL

	ALLOPURINOL			
/AA/	/BOLAR/	/100MG/		/N18241/001/
			> DLT >	/NOV/16,/1984/
	@ BOLAR	100MG	> ADD >	N18241 001
			> ADD >	NOV 16, 1984

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

	CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL		
/B*/	/PHARM/BASICS/	/EQ/12.5MG/BASE;5MG/	/N70477/001/
			/JAN/12,/1988/
/B*/		/EQ/25MG/BASE;10MG/	/N70478/001/
			/JAN/12,/1988/
	@ PHARM BASICS	EQ 12.5MG BASE;5MG	N70477 001
			JAN 12, 1988
	@	EQ 25MG BASE;10MG	N70478 001
			JAN 12, 1988

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

	PERPHENAZINE AND AMITRIPTYLINE HCL		
/2/	/CHELSEA/	/50MG;4MG/	/N71558/001/
			/MAR/02,/1987/

AMOXICILLIN

CAPSULE; ORAL

	/UTIMOX/		
/AB/	/PARKE/DAVIS/	/250MG/	/N62107/001/
/AB/		/500MG/	/N62107/002/
	@ PARKE DAVIS	250MG	N62107 001
	@	500MG	N62107 002

POWDER FOR RECONSTITUTION; ORAL

	/UTIMOX/		
/AB/	/PARKE/DAVIS/	/125MG/5ML/	/N62107/003/
/AB/		/250MG/5ML/	/N62107/004/
	@ PARKE DAVIS	125MG/5ML	N62107 003
	@	250MG/5ML	N62107 004

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN W/ CODEINE PHOSPHATE

/AA/	/CHELSEA/	/300MG;15MG/	/N87277/001/ /MAY/26/1982/	
/AA/		/300MG;30MG/	/N87276/001/ /MAY/26/1982/	
/AA/		/300MG;60MG/	/N87275/001/ /MAY/26/1982/	
	ə CHELSEA	300MG;15MG	N87277 001 MAY 26, 1982	
	ə	300MG;30MG	N87276 001 MAY 26, 1982	
	ə	300MG;60MG	N87275 001 MAY 26, 1982	

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA	MIKART	500MG;5MG*	N89697 001 JAN 28, 1992	
/B*/	/PHARM/BASICS/	/500MG;5MG/	/N89291/001/ /MAY/29/1987/	
	ə PHARM BASICS	500MG;5MG	N89291 001 MAY 29, 1987	

ACETOHEXAMIDE

TABLET; ORAL

ACETOHEXAMIDE

/B*/	/PHARM/BASICS/	/250MG/	/N70753/001/ /NOV/03/1986/	
/B*/		/500MG/	/N70754/001/ /NOV/03/1986/	
	ə PHARM BASICS	250MG	N70753 001 NOV 03, 1986	
	ə	500MG	N70754 001 NOV 03, 1986	

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

> ADD > AN	DEY	EQ 0.083% BASE*	N72652 001 FEB 21, 1992	

PROVENTIL

> ADD > AN	SCHERING	EQ 0.083% BASE	N19243 002 JAN 14, 1987	

ALLOPURINOL

TABLET; ORAL

ALLOPURINOL

> DLT > /AA/	/BOLAR/	/100MG/	/N18241/001/ /NOV/16/1984/	
	ə BOLAR	100MG	N18241 001 NOV 16, 1984	

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL

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

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL

/3/	/CHELSEA/	/50MG;4MG/	/N71558/001/ /MAR/02/1987/	

AMOXICILLIN

CAPSULE; ORAL

/UTIMOX/

/AA/	/PARKE/DAVIS/	/250MG/	/N62107/001/	
/AA/		/500MG/	/N62107/002/	
	ə PARKE DAVIS	250MG	N62107 001	
	ə	500MG	N62107 002	

POWDER FOR RECONSTITUTION; ORAL

/UTIMOX/

/AA/	/PARKE/DAVIS/	/125MG/5ML/	/N62107/001/	
/AA/		/250MG/5ML/	/N62107/002/	
	ə PARKE DAVIS	125MG/5ML	N62107 001	
	ə	250MG/5ML	N62107 002	

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

	AMCILL			
/AB/	/PARKE/DAVIS/	/EQ 250MG BASE/	/N62041/001/	
/AB/		/EQ 500MG BASE/	/N62041/002/	
	∂ PARKE DAVIS	EQ 250MG BASE	N62041 001	
	∂	EQ 500MG BASE	N62041 002	

POWDER FOR RECONSTITUTION; ORAL

	AMCILL			
/AB/	/PARKE/DAVIS/	/EQ 125MG BASE/5ML/	/N62030/001/	
/AB/		/EQ 250MG BASE/5ML/	/N62030/002/	
	∂ PARKE DAVIS	EQ 125MG BASE/5ML	N62030 001	
	∂	EQ 250MG BASE/5ML	N62030 002	

ATENOLOL

TABLET; ORAL

ATENOLOL

AB	MYLAN	50MG*	N73456 001	JAN 24, 1992
AB		100MG*	N73457 001	JAN 24, 1992

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

/AA/	/CHELSEA/	/0.025MG;2.5MG/	/N85876/001/	
	∂ CHELSEA	0.025MG;2.5MG	N85876 001	

DIPHENOXYLATE HCL W/ ATROPINE SULFATE

>DLT >/AA/	/VITARINE/	/0.025MG;2.5MG/	/N86173/001/	
>ADD >	∂ VITARINE	0.025MG;2.5MG	N86173 001	

BACLOFEN

TABLET; ORAL

BACLOFEN

>ADD > AB	BIOCRAFT	10MG*	N73043 001	FEB 27, 1992
>ADD >				
>ADD > AB		20MG*	N73044 001	FEB 27, 1992
>ADD >				

BACLOFEN

TABLET; ORAL

BACLOFEN

/B*/	/PHARM/BASICS/	/10MG/	/N71260/001/	/MAY/06,/1988/
/B*/		/20MG/	/N71261/001/	/MAY/06,/1988/
	∂ PHARM BASICS	10MG	N71260 001	MAY 06, 1988
	∂	20MG	N71261 001	MAY 06, 1988

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

AA	MUTUAL PHARM	1MG*	N81264 001	JAN 23, 1992
AA		2MG*	N81265 001	JAN 23, 1992
/B*/	/PHARM/BASICS/	/0.5MG/	/N89211/001/	/JUN/14,/1988/
/B*/		/1MG/	/N89212/001/	/JUN/14,/1988/
/B*/		/2MG/	/N89213/001/	/JUN/14,/1988/
	∂ PHARM BASICS	0.5MG	N89211 001	JUN 14, 1988
	∂	1MG	N89212 001	JUN 14, 1988
	∂	2MG	N89213 001	JUN 14, 1988

BETHANECHOL CHLORIDE

TABLET; ORAL

BETHANECHOL CHLORIDE

>DLT >/AA/	/VITARINE/	/5MG/	/N84353/001/	
>DLT >/AA/		/10MG/	/N84378/001/	
>DLT >/AA/		/10MG/	/N84379/001/	
>DLT >/AA/		/25MG/	/N84383/001/	
>DLT >/AA/		/25MG/	/N84384/001/	
>ADD >	∂ VITARINE	5MG	N84353 001	
>ADD >	∂	10MG	N84378 001	
>ADD >	∂	10MG	N84379 001	
>ADD >	∂	25MG	N84383 001	
>ADD >	∂	25MG	N84384 001	

BITOLTEROL MESYLATE

>ADD>	SOLUTION; INHALATION			
>ADD>	TORNALATE			
>ADD>	STERLING WINTHROP	0.2%	N19548 001 FEB 19, 1992	
>ADD>				

BUTABARBITAL SODIUM

TABLET; ORAL

	SODIUM BUTABARBITAL			
>DLT>/AA/	/WEST/WARD/	/15MG/	/N85418/001/	
>DLT>/AA/		/30MG/	/N85432/001/	
>ADD>	ə WEST WARD	15MG	N85418 001	
>ADD>	ə	30MG	N85432 001	

CARBAMAZEPINE

TABLET; ORAL

	CARBAMAZEPINE			
/B*/	/PHARM/BASICS/	/200MG/	/N70300/001/ MAY/15/1986/	
	ə PHARM BASICS	200MG	N70300 001 MAY 15, 1986	

CARISOPRODOL

TABLET; ORAL

	CARISOPRODOL			
/AA/	/VITARINE/	/350MG/	/N89566/001/ AUG/30/1988/	
B*	VITARINE	350MG	N89566 001 AUG 30, 1988	

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

	ROCEPHIN			
>DLT>	/ROCHE/	/EQ/250MG/BASE/VIAL/	/N62510/001/ MAR/12/1985/	
>DLT>				
>ADD>	ə ROCHE	EQ 250MG BASE/VIAL	N62510 001 MAR 12, 1985	
>ADD>				
>DLT>		/EQ/500MG/BASE/VIAL/	/N62510/002/ MAR/12/1985/	
>DLT>				
>ADD>	ə	EQ 500MG BASE/VIAL	N62510 002 MAR 12, 1985	
>ADD>				
>DLT>		/EQ/1GM/BASE/VIAL/	/N62510/003/ MAR/12/1985/	
>DLT>				
>ADD>	ə	EQ 1GM BASE/VIAL	N62510 003 MAR 12, 1985	
>ADD>				

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

	CHLORDIAZEPOXIDE HCL			
/AB/	/PARKE/DAVIS/	/5MG/		/N85163/001/
/AB/		/10MG/		/N84598/001/
/AB/		/25MG/		/N85164/001/
	ə PARKE DAVIS	5MG		N85163 001
	ə	10MG		N84598 001
	ə	25MG		N85164 001
>DLT>/AA/	/WEST/WARD/	/5MG/		/N85014/001/
>DLT>/AA/		/10MG/		/N85000/001/
>DLT>/AA/		/25MG/		/N85294/001/
>ADD>	ə WEST WARD	5MG		N85014 001
>ADD>	ə	10MG		N85000 001
>ADD>	ə	25MG		N85294 001

CHLOROQUINE PHOSPHATE

TABLET; ORAL

	CHLOROQUINE PHOSPHATE			
>DLT>/AA/	/WEST/WARD/	/EQ 150MG BASE/		/N85[illegible]/001/
>ADD>	ə WEST WARD	EQ 150MG BASE		N85[illegible] 001

CHLORPROPAMIDE

TABLET; ORAL

	CHLORPROPAMIDE			
/B*/	/PHARM/BASICS/	/100MG/	/N88708/001/	
/B*/		/250MG/	/AUG/30,/1984/ /N88709/001/	
	∂ PHARM BASICS	100MG	/AUG/30,/1984/ N88708 001	
	∂	250MG	AUG 30, 1984 N88709 001	
>DLT >/AB/	/VITARINE/	/250MG/	AUG 30, 1984 /N84669/001/	
>ADD >	∂ VITARINE	250MG	N84669 001	

CINOXACIN

CAPSULE; ORAL

	CINOXACIN			
>ADD > AB	LILLY	250MG	N18067 001	
>ADD > AB	+	500MG	N18067 002	
>ADD >	CINOXACIN			
>ADD > AB	BIOCRAFT	250MG*	N73005 001	
>ADD >			FEB 28, 1992	
>ADD > AB		500MG*	N73006 001	
>ADD >			FEB 28, 1992	

CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATE

SOLUTION; IRRIGATION

	RENACIDIN			
>DLT >	/GUARDIAN/LABS/	/6.602GM/100ML;6.198GM/100ML;/ /3.177GM/100ML/	/N19481/001/	
>DLT >			/OCT/02,/1990/	
>DLT >				
>ADD >	GUARDIAN LABS	6.602GM/100ML;198MG/100ML; 3.177GM/100ML	N19481 001 OCT 02, 1990	
>ADD >				
>ADD >				

CLEMASTINE FUMARATE

TABLET; ORAL

	CLEMASTINE FUMARATE			
AB	LEMMON	1.34MG*	N73282 001	
AB		2.68MG*	JAN 31, 1992 N73283 001	
	TAVIST		JAN 31, 1992	
AB	+ DORSEY	2.68MG	N17661 001	
	TAVIST-1			
AB	DORSEY	1.34MG	N17661 002	

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

	CLORAZEPATE DIPOTASSIUM			
/B*/	/PHARM/BASICS/	/3.75MG/	/N71242/001/	
/B*/		/7.5MG/	/MAY/20,/1987/ /N71243/001/	
/B*/		/15MG/	/MAY/20,/1987/ /N71244/001/	
	∂ PHARM BASICS	3.75MG	/MAY/20,/1987/ N71242 001	
	∂	7.5MG	MAY 20, 1987 N71243 001	
	∂	15MG	MAY 20, 1987 N71244 001	
			MAY 20, 1987	

COLCHICINE; PROBENECID

TABLET; ORAL

	PROBEN-C			
/BP/	/CHELSEA/	/0.5MG;500MG/	/N85552/001/	
	∂ CHELSEA	0.5MG;500MG	N85552 001	

CYANOCOBALAMIN

INJECTABLE; INJECTION

	CYANOCOBALAMIN			
>DLT >/AP/	/LUITPOLD/	/0.03MG/ML/	/N80668/001/	
>ADD >	∂ LUITPOLD	0.03MG/ML	N80668 001	

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

	CYCLOPENTOLATE HCL			
>DLT >/AT/	/BARNES/HIND/	/1%/	/N84863/001/	
>ADD >	∂ SOLA BARNES HIND	1%	N84863 001	

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPRAMINE HCL

/B*/	/PHARM/BASICS/	/25MG/	/N71863/001/ /SEP/09,/1987/	> DLT >/AB/	/INTERPHARM/	/EQ 100MG BASE/	/N71190/001/ /JAN/15,/1987/
				> DLT >			
/B*/		/50MG/	/N71865/001/ /SEP/09,/1987/	> DLT >/AB/		/EQ 150MG BASE/	/N71191/001/ /JAN/15,/1987/
				> DLT >			
/B*/		/75MG/	/N71866/001/ /SEP/09,/1987/	> ADD >	B* INTERPHARM	EQ 100MG BASE	N71190 001 JAN 15, 1987
				> ADD >			
/B*/		/100MG/	/N71867/001/ /SEP/09,/1987/	> ADD >	B*	EQ 150MG BASE	N71191 001 JAN 15, 1987
				> ADD >			
	∂ PHARM BASICS	25MG	N71864 001 SEP 09, 1987				
	∂	50MG	N71865 001 SEP 09, 1987				
	∂	75MG	N71866 001 SEP 09, 1987				
	∂	100MG	N71867 001 SEP 09, 1987				

DESONIDE

LOTION; TOPICAL
DESOWEN

OWEN GALDERMA	0.05%*	N72354 001 JAN 24, 1992

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL
DIETHYLPROPION HCL

> DLT >/AA/	/VITARINE/	/25MG/	/N85916/001/	> ADD >	B* INTERPHARM	EQ 50MG BASE	N62763 001 SEP 02, 1988
> ADD >	∂ VITARINE	25MG	N85916 001	> ADD >	B*	EQ 100MG BASE	N62763 002 SEP 02, 1988

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL
DISOPYRAMIDE PHOSPHATE

/B*/	/CHELSEA/	/EQ/100MG/BASE/	/N71020/001/ /DEC/01,/1986/	> DLT >/AB/	/INTERPHARM/	/EQ 100MG BASE/	/N62764/001/ /SEP/02,/1988/
				> DLT >			
/B*/		/EQ/150MG/BASE/	/N71021/001/ /DEC/01,/1986/	> ADD >	B* INTERPHARM	EQ 100MG BASE	N62764 001 SEP 02, 1988
				> ADD >			

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL
DISOPYRAMIDE PHOSPHATE

> DLT >/AB/	/INTERPHARM/	/EQ 100MG BASE/	/N71190/001/ /JAN/15,/1987/				
> DLT >							
> DLT >/AB/		/EQ 150MG BASE/	/N71191/001/ /JAN/15,/1987/				
> DLT >							
> ADD >	B* INTERPHARM	EQ 100MG BASE	N71190 001 JAN 15, 1987				
> ADD >							
> ADD >	B*	EQ 150MG BASE	N71191 001 JAN 15, 1987				
> ADD >							

DOXAPRAM HYDROCHLORIDE

INJECTABLE; INJECTION
DOPRAM

AP	ROBINS	20MG/ML	N14879 001

DOXAPRAM HCL

AP	STERIS	20MG/ML*	N73529 001 JAN 30, 1992

DOXYCYCLINE HYCLATE

CAPSULE; ORAL
DOXYCYCLINE HYCLATE

> DLT >/AB/	/INTERPHARM/	/EQ 50MG BASE/	/N62763/001/ /SEP/02,/1988/				
> DLT >							
> DLT >/AB/		/EQ 100MG BASE/	/N62763/002/ /SEP/02,/1988/				
> DLT >							
> ADD >	B* INTERPHARM	EQ 50MG BASE	N62763 001 SEP 02, 1988				
> ADD >							
> ADD >	B*	EQ 100MG BASE	N62763 002 SEP 02, 1988				
> ADD >							

TABLET; ORAL
DOXYCYCLINE HYCLATE

> DLT >/AB/	/INTERPHARM/	/EQ 100MG BASE/	/N62764/001/ /SEP/02,/1988/				
> DLT >							
> ADD >	B* INTERPHARM	EQ 100MG BASE	N62764 001 SEP 02, 1988				
> ADD >							

DROPERIDOL

INJECTABLE; INJECTION

		DROPERIDOL			
/AP/	/SOLOPAK/	/2.5MG/ML/		/N71750/001/ /SEP/06,/1988/	
	@ SOLOPAK	2.5MG/ML		N71750 001 SEP 06, 1988	

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

> DLT >		/ERGOLOID/			
> DLT >	/AA/	/VITARINE/	/0.5MG/ /1MG/	/N85153/001/ /N87417/001/	
> ADD >		@ VITARINE	0.5MG	N85153 001	
> ADD >		@	1MG	N87417 001	

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL

> DLT >		/ERGOMAR/			
> DLT >	/AA/	/FISONS/	/2MG/	/N87693/001/ /FEB/24,/1983/	
> ADD >		@ FISONS	2MG	N87693 001 FEB 24, 1983	

ERYTHROMYCIN

TABLET, COATED PARTICLES; ORAL

		PCE			
> ADD >		ABBOTT	500MG	N50611 002 AUG 22, 1990	

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

> ADD >		GENCEPT 0.5/35-21			
> ADD >	AB	GENCON	0.035MG;0.5MG	N72692 001 FEB 28, 1992	
> ADD >		GENCEPT 1/35-21			
> ADD >	AB	GENCON	0.035MG;1MG	N72693 001 FEB 28, 1992	
> ADD >		GENCEPT 10/11-21			
> ADD >	AB	GENCON	0.035MG;0.5MG AND 1MG	N72694 001 FEB 28, 1992	

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28

> ADD >		GENCEPT 0.5/35-28			
> ADD >	AB	GENCON	0.035MG;0.5MG	N72695 001 FEB 28, 1992	
> ADD >		GENCEPT 1/35-28			
> ADD >	AB	GENCON	0.035MG;1MG	N72696 001 FEB 28, 1992	
> ADD >		GENCEPT 10/11-28			
> ADD >	AB	GENCON	0.035MG;0.5MG AND 1MG	N72697 001 FEB 28, 1992	

FELODIPINE

TABLET, EXTENDED RELEASE; ORAL

		PLENDIL			
> DLT >		/MSD/	/5MG/	/N19834/001/ /JUL/26,/1991/	
> ADD >		MSD	5MG	N19834 001 JUL 25, 1991	
> DLT >			/10MG/	/N19834/002/ /JUL/26,/1991/	
> ADD >			10MG	N19834 002 JUL 25, 1991	

FLUOCINONIDE

CREAM; TOPICAL

		FLUOCINONIDE			
> ADD >	AB	NMC	0.05%	N73085 001 FEB 14, 1992	

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

		FLURAZEPAM HCL			
/B*/	/PHARM/BASICS/		/15MG/	/N70562/001/ /JUL/09,/1987/	
/B*/			/30MG/	/N70563/001/ /JUL/09,/1987/	
	@ PHARM BASICS		15MG	N70562 001 JUL 09, 1987	
	@		30MG	N70563 001 JUL 09, 1987	

FOLIC ACID

TABLET; ORAL
FOLIC ACID

>_DLT_>/	AA/	/VITARINE/	/1MG/	/N84472/001/	
>_ADD_>		ə VITARINE	1MG	N84472 001	

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH

>_DLT_>/	AP/	/LUITPOLD/	/10 UNITS/ML/	/N89063/001/	/OCT/09,/1985/
>_DLT_>					
>_DLT_>/	AP/		/100 UNITS/ML/	/N89064/001/	/OCT/09,/1985/
>_DLT_>					
>_ADD_>		ə LUITPOLD	10 UNITS/ML	N89063 001	OCT 09, 1985
>_ADD_>					
>_ADD_>		ə	100 UNITS/ML	N89064 001	OCT 09, 1985
>_ADD_>					

HEPARIN SODIUM

>_DLT_>/	AP/	/LUITPOLD/	/1,000 UNITS/ML/	/N87452/001/	/OCT/31,/1983/
>_DLT_>					
>_ADD_>		ə LUITPOLD	1,000 UNITS/ML	N87452 001	OCT 31, 1983
>_ADD_>					

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HCL

>_DLT_>/	AA/	/VITARINE/	/50MG/	/N85088/001/	
>_ADD_>		ə VITARINE	50MG	N85088 001	

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
HYDRAP-ES

>_DLT_>					
>_DLT_> /B*/		/VITARINE/	/25MG;15MG;0.1MG/	/N84876/001/	
>_ADD_>		ə VITARINE	25MG;15MG;0.1MG	N84876 001	

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

AB	DANBURY	25MG		N81189 001 JAN 24, 1992
AB		100MG		N81190 001 JAN 24, 1992

HYDROFLUMETHIAZIDE; RESERPINE

TABLET; ORAL
/HYDROFLUMETHIAZIDE/AND/RESERPINE/

/B*/		/PHARM/BASICS/	/50MG;0.125MG/	/N88195/001/	/OCT/26,/1983/
		ə PHARM BASICS	50MG;0.125MG	N88195 001	OCT 26, 1983

HYDROXYAMPHETAMINE HYDROBROMIDE; TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC
PAREMYD

ALLERGAN	1%;0.25%		N19261 001 JAN 30, 1992

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL
HYDROXYZINE HCL

/B*/		/PHARM/BASICS/	/10MG/	/N89121/001/	/MAR/20,/1986/
/B*/			/25MG/	/N89122/001/	/MAR/20,/1986/
/B*/			/50MG/	/N89123/001/	/MAR/20,/1986/
		ə PHARM BASICS	10MG	N89121 001	MAR 20, 1986
		ə	25MG	N89122 001	MAR 20, 1986
		ə	50MG	N89123 001	MAR 20, 1986

IOVERSOL

INJECTABLE; INJECTION
OPTIRAY 300

MALLINCKRODT	64%		N19710 004 JAN 22, 1992

OPTIRAY 350

MALLINCKRODT	74%		N19710 005 JAN 22, 1992

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM

> DLT >	/AP/	/LYPHOMED/	/EQ 50MG BASE/VIAL/	/N88939/001/
> DLT >				/DEC/01/1986/
> ADD >		∂ LYPHOMED	EQ 50MG BASE/VIAL	N88939 001
> ADD >				DEC 01, 1986

LEVODOPA

CAPSULE; ORAL
DOPAR

> DLT >	/*/	/NORWICH/EATON/	/500MG/	/N16913/002/
> DLT >			/100MG/	/N16913/003/
> DLT >			/250MG/	/N16913/001/
> ADD >		+ ROBERTS	500MG	N16913 002
> ADD >			100MG	N16913 003
> ADD >			250MG	N16913 001

LITHIUM CARBONATE

CAPSULE; ORAL
LITHIUM CARBONATE

/B*/	/PHARM/BASICS/	/300MG/	/N72542/001/	
			/FEB/01/1989/	
	∂ PHARM BASICS	300MG	N72542 001	
			FEB 01, 1989	

> ADD > LOMEFLOXACIN HYDROCHLORIDE

> ADD > TABLET; ORAL
> ADD > MAXAQUIN
> ADD > + SEARLE EQ 400MG BASE N20013 001
> ADD > FEB 21, 1992

LORAZEPAM

TABLET; ORAL
LORAZEPAM

/B*/	/PHARM/BASICS/	/1MG/	/N70539/001/	
			/DEC/22/1986/	
/B*/		/2MG/	/N70540/001/	
			/DEC/22/1986/	
	∂ PHARM BASICS	1MG	N70539 001	
			DEC 22, 1986	
	∂	2MG	N70540 001	
			DEC 22, 1986	

MECLOFENAMATE SODIUM

CAPSULE; ORAL
MECLOFENAMATE SODIUM

/B*/	/PHARM/BASICS/	/EQ/50MG/BASE/	/N71007/001/
			/MAR/25/1988/
/B*/		/EQ/100MG/BASE/	/N71008/001/
			/MAR/25/1988/
	∂ PHARM BASICS	EQ 50MG BASE	N71007 001
			MAR 25, 1988
	∂	EQ 100MG BASE	N71008 001
			MAR 25, 1988

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE

/B*/	/PHARM/BASICS/	/20MG/	/N70646/001/
			/OCT/02/1987/
/B*/		/40MG/	/N70647/001/
			/OCT/02/1987/
	∂ PHARM BASICS	20MG	N70646 001
			OCT 02, 1987
	∂	40MG	N70647 001
			OCT 02, 1987

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
MEPERIDINE HCL

/AP/	/PARKE/DAVIS/	/50MG/ML/	/N80364/002/
/AP/		/100MG/ML/	/N80364/001/
	∂ PARKE DAVIS	50MG/ML	N80364 002
	∂	100MG/ML	N80364 001

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE

/AA/	/PARKE/DAVIS/	/200MG/	/N84744/001/
/AA/		/400MG/	/N84744/002/
	∂ PARKE DAVIS	200MG	N84744 001
	∂	400MG	N84744 002

MESALAMINE

TABLET, DELAYED RELEASE; ORAL
ASACOL
+ NORWICH EATON 400MG㊎ N19651 001 JAN 31, 1992

METAPROTERENOL SULFATE

SYRUP; ORAL
METAPROTERENOL SULFATE
>ADD > AA BIOCRAFT 10MG/5ML㊎ N72761 001 FEB 27, 1992
>ADD >

TABLET; ORAL
METAPROTERENOL SULFATE

/B*/	/PHARM/BASICS/	/10MG/	/N71013/001/JAN/25,/1988/
/B*/		/20MG/	/N71014/001/JAN/25,/1988/
	∂ PHARM BASICS	10MG	N71013 001 JAN 25, 1988
	∂	20MG	N71014 001 JAN 25, 1988

METHYCLOTHIAZIDE

TABLET; ORAL
METHYCLOTHIAZIDE

/B*/	/PHARM/BASICS/	/5MG/	/N88745/001/MAR/21,/1985/
	∂ PHARM BASICS	5MG	N88745 001 MAR 21, 1985

METHYLDOPA

TABLET; ORAL
METHYLDOPA

>DLT >/AB/	/PARKE/DAVIS/	/125MG/	/N70331/001/APR/15,/1986/
>DLT >			
>DLT >/AB/		/250MG/	/N70332/001/APR/15,/1986/
>DLT >			
>DLT >/AB/		/500MG/	/N70333/001/APR/15,/1986/
>DLT >			
>ADD >	∂ PARKE DAVIS	125MG	N70331 001 APR 15, 1986
>ADD >			
>ADD >	∂	250MG	N70332 001 APR 15, 1986
>ADD >			
>ADD >	∂	500MG	N70333 001 APR 15, 1986
>ADD >			

METOCLOPRAMIDE HYDROCHLORIDE

CONCENTRATE; ORAL
METOCLOPRAMIDE INTENSOL
ROXANE EQ 10MG BASE/ML㊎ N72995 001 JAN 30, 1992

TABLET; ORAL
METOCLOPRAMIDE HCL

>DLT >/AB/	/INTERPHARM/	/EQ 10MG BASE/	/N71213/001/SEP/24,/1986/
>DLT >			
>ADD > B*	INTERPHARM	EQ 10MG BASE	N71213 001 SEP 24, 1986
>ADD >			
/B*/	/PHARM/BASICS/	/EQ/10MG/BASE/	/N70339/001/JUL/29,/1985/
	∂ PHARM BASICS	EQ 10MG BASE	N70339 001 JUL 29, 1985

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL
TOPROL XL
+ HASSLE EQ 50MG TARTRATE㊎ N19962 001 JAN 10, 1992
+ EQ 100MG TARTRATE㊎ N19962 002 JAN 10, 1992
+ EQ 200MG TARTRATE㊎ N19962 003 JAN 10, 1992

MINOXIDIL

TABLET; ORAL
MINOXIDIL
/B*/ /PHARM/BASICS/ /2.5MG/ /N71537/001/ /DEC/16,/1988/
@ PHARM BASICS 2.5MG N71537 001 DEC 16, 1988

MIVACURIUM CHLORIDE

INJECTABLE; INJECTION
MIVACRON
BURROUGHS WELLCOME EQ 2MG BASE/ML N20098 001 JAN 22, 1992

MIVACRON IN DEXTROSE 5% IN PLASTIC CONTAINER
BURROUGHS WELLCOME EQ 0.5MG BASE/ML N20098 002 JAN 22, 1992
EQ 50MG BASE/100ML N20098 003 JAN 22, 1992

NAFARELIN ACETATE

SPRAY, METERED; NASAL
SYNAREL
>ADD > SYNTEX EQ 0.2MG BASE/INH N20109 001 FEB 26, 1992
>ADD >

NICARDIPINE HYDROCHLORIDE

>ADD > CAPSULE, EXTENDED RELEASE; ORAL
>ADD > CARDENE SR
>ADD > + SYNTEX 30MG N20005 001 FEB 21, 1992
>ADD >
>ADD > + 45MG N20005 002 FEB 21, 1992
>ADD >
>ADD > + 60MG N20005 003 FEB 21, 1992
>ADD >

INJECTABLE; INJECTION
CARDENE
DUPONT MERCK 2.5MG/ML N19734 001 JAN 30, 1992

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL
PROSTEP
+ ELAN 11MG/24HR N19983 001 JAN 28, 1992
+ 22MG/24HR N19983 002 JAN 28, 1992

NIFEDIPINE

CAPSULE; ORAL
NIFEDIPINE
>ADD > AB NOVOPHARM 10MG N72651 001 FEB 19, 1992
>ADD >

NITROFURANTOIN

TABLET; ORAL
NITROFURANTOIN
>DLT >/AB/ /VITARINE/ /50MG/ /N80043/001/
>DLT >/AB/ /100MG/ /N80043/002/
>ADD > @ VITARINE 50MG N80043 001
>ADD > @ 100MG N80043 002

NITROGLYCERIN

INJECTABLE; INJECTION
NITROGLYCERIN
>DLT >/AP/ /LUITPOLD/ /5MG/ML/ /N71492/001/ /MAY/24,/1988/
>DLT >
>ADD > @ LUITPOLD 5MG/ML N71492 001 MAY 24, 1988
>ADD >

NYSTATIN

TABLET; ORAL
NYSTATIN
/AA/ /CHELSEA/ /500,000 UNITS/ /DEC/18,/1991/
@ CHELSEA 500,000 UNITS N71440 DEC 18

OXAZEPAM

CAPSULE; ORAL
OXAZEPAM

/B*/	/CHELSEA/	/10MG/	/N71661/001/ /MAR/02,/1988/
/B*/		/15MG/	/N71662/001/ /MAR/02,/1988/
/B*/		/30MG/	/N71663/001/ /MAR/02,/1988/

OXYBUTYNIN CHLORIDE

TABLET; ORAL
OXYBUTYNIN CHLORIDE

/B*/	/PHARM/BASICS/	/5MG/	/N70746/001/ /MAR/10,/1988/
	∂ PHARM BASICS	5MG	N70746 001 MAR 10, 1988

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION
PENICILLIN G POTASSIUM

/AP/	/PARKE/DAVIS/	/1,000,000 UNITS/VIAL/	/N62003/001/
/AP/		/5,000,000 UNITS/VIAL/	/N62003/002/
	∂ PARKE DAVIS	1,000,000 UNITS/VIAL	N62003 001
	∂	5,000,000 UNITS/VIAL	N62003 002

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
/PENAPAR-VK/

/AA/	/PARKE/DAVIS/	/EQ 125MG BASE/5ML/	/N62002/001/
/AA/		/EQ 250MG BASE/5ML/	/N62002/002/
	∂ PARKE DAVIS	EQ 125MG BASE/5ML	N62002 001
	∂	EQ 250MG BASE/5ML	N62002 002

TABLET; ORAL
/PENAPAR-VK/

/AB/	/PARKE/DAVIS/	/EQ 250MG BASE/	/N62001/001/
/AB/		/EQ 500MG BASE/	/N62001/002/
	∂ PARKE DAVIS	EQ 250MG BASE	N62001 001
	∂	EQ 500MG BASE	N62001 002

PERPHENAZINE

TABLET; ORAL
PERPHENAZINE

/B*/	/CHELSEA/	/8MG/	/N89700/001/ /DEC/23,/1987/

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL
/PHENYTOIN/SODIUM/

/B*/	/CHELSEA/	/100MG/	/N85694/001/
	∂ CHELSEA	100MG	N85094 001

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

POWDER FOR RECONSTITUTION; ORAL
CO-LAV

AA	COPLEY	240GM/BOT;2.98GM/BOT;6.72GM/BOT; 5.84GM/BOT;22.72GM/BOT¤	N73428 001 JAN 28, 1992

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
K-LEASE

AB	ADRIA	8MEQ¤	N73398 001 JAN 28, 1992

MICRO-K

AB	ROBINS	8MEQ	N18238 001

PRAZEPAM

CAPSULE; ORAL
CENTRAX

/AB/	/PARKE/DAVIS/	/5MG/	/N18144/001/
/AB/		/10MG/	/N18144/002/
/*/	+ PARKE DAVIS	10MG	N18144 002
		5MG	N18144 001

PRAZEPAM

CAPSULE; ORAL
/PRAZEPAM/

/B*/ /PHARM/BASICS/	/5MG/	/N70427/001/	/NOV/06,/1987/
/B*/	/10MG/	/N70428/001/	/NOV/06,/1987/
ə PHARM BASICS	5MG	N70427 001	NOV 06, 1987
ə	10MG	N70428 001	NOV 06, 1987

PRAZOSIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
MINIPRESS XL

+ PFIZER	2.5MG	N19775 001 JAN 29, 1992
+	5MG	N19775 002 JAN 29, 1992

PREDNISONE

TABLET; ORAL
PREDNISONE

>ADD > AB	RICHLYN	5MG	N80782 001
>DLT > /B*/		/5MG/	/N80782/001/

PROCHLORPERAZINE MALEATE

TABLET; ORAL
COMPAZINE

>DLT >/AB/	/SKF/	/EQ 5MG BASE/	/N10571/001/
>DLT >/AB/		/EQ 10MG BASE/	/N10571/002/
>DLT >/AB/		/EQ 25MG BASE/	/N10571/003/
>ADD >	+ SKF	EQ 25MG BASE	N10571 003
>ADD >		EQ 5MG BASE	N10571 001
>ADD >		EQ 10MG BASE	N10571 002

PROCHLORPERAZINE MALEATE

TABLET; ORAL
/PROCHLORPERAZINE/MALEATE/

>DLT >			
>DLT > /B*/	/DURAMED/	/EQ/5MG/BASE/	/N89484/001/ /JAN/20,/1987/
>DLT >			
>DLT > /B*/		/EQ/10MG/BASE/	/N89485/001/ /JAN/20,/1987/
>DLT >			
>DLT > /B*/		/EQ/25MG/BASE/	/N89486/001/ /JAN/20,/1987/
>DLT >			
>ADD >	ə DURAMED	EQ 5MG BASE	N89484 001 JAN 20, 1987
>ADD >			
>ADD >	ə	EQ 10MG BASE	N89485 001 JAN 20, 1987
>ADD >			
>ADD >	ə	EQ 25MG BASE	N89486 001 JAN 20, 1987
>ADD >			

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPOXYPHENE HCL

>DLT >/AA/	/VITARINE/	/32MG/	/N84014/001/
>DLT >/AA/		/65MG/	/N83688/001/
>DLT >/AA/		/65MG/	/N83870/002/
>DLT >/AA/		/65MG/	/N86495/001/
>ADD >	ə VITARINE	32MG	N84014 001
>ADD >	ə	65MG	N83688 001
>ADD >	ə	65MG	N83870 002
>ADD >	ə	65MG	N86495 001

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION
PYRIDOXINE HCL

>DLT >/AA/	/LUITPOLD/	/100MG/ML/	/N80669/001/
>ADD >	ə LUITPOLD	100MG/ML	N80669 001

SODIUM POLYSTYRENE SULFONATE

SUSPENSION; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE

>DLT >/AA/	/ROXANE/	/15GM/60ML/	/N88453/001/ /NOV/17,/1993/
>DLT >			
>ADD >	ə ROXANE	15GM/60ML	N88453 001 NOV 17, 1993
>ADD >			

> ADD > **SODIUM THIOSULFATE**

> ADD > INJECTABLE; INJECTION
> ADD > SODIUM THIOSULFATE

> ADD >	DEPT ARMY	250MG/ML	N20166 001 FEB 14, 1992	

> ADD >

SULFAMETHIZOLE

TABLET; ORAL

> DLT >	~~PROKLAR~~			
> DLT > /AB/	~~FOREST PHARMS~~	~~500MG~~	~~N80273 001~~	
> ADD >	∂ FOREST PHARMS	500MG	N80273 001	

THIOSULFIL

> DLT > /AB/	~~WYETH AYERST~~	~~500MG~~	~~N08565 004~~	
> ADD >	+ WYETH AYERST	500MG	N08565 004	

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

> DLT > /AB/	~~INTERPHARM~~	~~400MG;80MG~~	~~N71299 001 OCT 27, 1987~~	
> DLT >				
> DLT > /AB/		~~800MG;160MG~~	~~N71300 001 OCT 27, 1987~~	
> DLT >				
> ADD > B*	INTERPHARM	400MG;80MG	N71299 001 OCT 27, 1987	
> ADD >				
> ADD > B*		800MG;160MG	N71300 001 OCT 27, 1987	
> ADD >				
/B*/	~~PHARM BASICS~~	~~400MG;80MG~~	~~N70203 001 NOV 08, 1985~~	
/B*/		~~800MG;160MG~~	~~N70204 001 NOV 08, 1985~~	
	∂ PHARM BASICS	400MG;80MG	N70203 001 NOV 08, 1985	
	∂	800MG;160MG	N70204 001 NOV 08, 1985	

SULFISOXAZOLE

TABLET; ORAL

	~~SULFALAB~~			
/AB/	~~PARKE DAVIS~~	~~500MG~~	~~N84955 001~~	
	∂ PARKE DAVIS	500MG	N84955 001	

SULFISOXAZOLE

> DLT > /AB/	~~WEST WARD~~	~~500MG~~	~~N80379 001~~	
> ADD >	∂ WEST WARD	500MG	N80379 001	

SULINDAC

TABLET; ORAL

SULINDAC

> ADD > AB	LEMMON	150MG	N72972 001 FEB 28, 1992	
> ADD >				
> ADD > AB		200MG	N72973 001 FEB 28, 1992	
> ADD >				

TEMAFLOXACIN HYDROCHLORIDE

TABLET; ORAL

OMNIFLOX

+ ABBOTT	EQ 600MG BASE	N20043 004 JAN 30, 1992	
	EQ 400MG BASE	N20043 003 JAN 30, 1992	

TEMAZEPAM

CAPSULE; ORAL

TEMAZEPAM

/B*/	~~PHARM BASICS~~	~~15MG~~	~~N70489 001 JUL 07, 1986~~	
/B*/		~~30MG~~	~~N70490 001 JUL 07, 1986~~	
	∂ PHARM BASICS	15MG	N70489 001 JUL 07, 1986	
	∂	30MG	N70490 001 JUL 07, 1986	

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

THEO-24

> ADD >	SEARLE	400MG	N81034 001 FEB 28, 1992	
> ADD >				

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

THIAMINE HCL

> DLT > /AP/	~~LUITPOLD~~	~~100MG/ML~~	~~N80667 001~~	
> ADD >	∂ LUITPOLD	100MG/ML	N80667 001	
/AP/	~~PARKE DAVIS~~	~~100MG/ML~~	~~N80770 001~~	
	∂ PARKE DAVIS	100MG/ML	N80770 001	

TIMOLOL MALEATE

TABLET; ORAL
TIMOLOL MALEATE

/B*/ /PHARM/BASICS/	/5MG/	/N72001/001/ /JAN/10,/1989/
/B*/	/10MG/	/N72002/001/ /JAN/10,/1989/
/B*/	/20MG/	/N72003/001/ /JAN/10,/1989/
∂ PHARM BASICS	5MG	N72001 001 JAN 10, 1989
∂	10MG	N72002 001 JAN 10, 1989
∂	20MG	N72003 001 JAN 10, 1989

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION
TOBRAMYCIN SULFATE

AP	GENSIA	EQ 40MG BASE/ML*	N63100 001 JAN 30, 1992

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

>DLT>	/AB/ /INTERPHARM/	/250MG/	/N71270/001/ /SEP/23,/1986/
>DLT>	/AB/	/500MG/	/N71271/001/ /SEP/23,/1986/
>ADD>	B* INTERPHARM	250MG	N71270 001 SEP 23, 1986
>ADD>	B*	500MG	N71271 001 SEP 23, 1986
	/B*/ /PHARM/BASICS/	/100MG/	/N71355/001/ /JAN/11,/1988/
	/B*/	/250MG/	/N70168/001/ /APR/02,/1986/
	/B*/	/500MG/	/N70169/001/ /APR/02,/1986/
	∂ PHARM BASICS	100MG	N71355 001 JAN 11, 1988
	∂	250MG	N70168 001 APR 02, 1986
	∂	500MG	N70169 001 APR 02, 1986

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

/AB/	/PARKE/DAVIS/	/500MG/	/N86047/001/
∂ PARKE DAVIS		500MG	N86047 001

TOLMETIN SODIUM

CAPSULE; ORAL
TOLMETIN SODIUM

AB	BAKER CUMMINS	EQ 400MG BASE*	N73392 001 JAN 24, 1992
AB	PUREPAC	EQ 400MG BASE*	N73308 001 JAN 24, 1992

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

/B*/ /PHARM/BASICS/	/50MG/	/N70491/001/ /APR/29,/1987/
/B*/	/100MG/	/N70492/001/ /APR/29,/1987/
∂ PHARM BASICS	50MG	N70491 001 APR 29, 1987
∂	100MG	N70492 001 APR 29, 1987

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
SURMONTIL

/AB/	/WYETH/AYERST/	/EQ 25MG BASE/	/N16792/001/
/AB/		/EQ 50MG BASE/	/N16792/002/
/AB//+/		/EQ 100MG BASE/	/N16792/003/ /SEP/15,/1982/
+ WYETH AYERST		EQ 100MG BASE	N16792 003 SEP 15, 1982
		EQ 25MG BASE	N16792 001
		EQ 50MG BASE	N16792 002

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
/TRIMIPRAMINE/MALEATE/

/B*/	/PHARM/BASICS/	/EQ/25MG/BASE/	/N71283/001/ /DEC/08,/1987/	
/B*/		/EQ/50MG/BASE/	/N71284/001/ /DEC/08,/1987/	
/B*/		/EQ/100MG/BASE/	/N71285/001/ /DEC/08,/1987/	
	∂ PHARM BASICS	EQ 25MG BASE	N71283 001 DEC 08, 1987	
	∂	EQ 50MG BASE	N71284 001 DEC 08, 1987	
	∂	EQ 100MG BASE	N71285 001 DEC 08, 1987	

TRISULFAPYRIMIDINES

SUSPENSION; ORAL
/SULFALOID/

DLT >				
DLT >/AB/	/FOREST/PHARMS/	/500MG/5ML/	/N80100/001/	
ADD >	∂ FOREST PHARMS	500MG/5ML	N80100 001	

VECURONIUM BROMIDE

INJECTABLE; INJECTION
NORCURON
ORGANON 20MG/VIAL‡ N18776 003 JAN 03, 1992

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
VERELAN
◆ ELAN 180MG‡ N19614 003 JAN 09, 1992

TABLET; ORAL
VERAPAMIL HCL

/B*/	/CHELSEA/	/80MG/	/N70421/001/ /SEP/17,/1986/	
/B*/		/120MG/	/N70422/001/ /SEP/17,/1986/	

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL

> DLT >/AB/	/PARKE/DAVIS/	/80MG/	/N70340/001/ /AUG/20,/1986/	
> DLT >				
> DLT >/AB/		/120MG/	/N70341/001/ /AUG/20,/1986/	
> DLT >				
> ADD >	∂ PARKE DAVIS	80MG	N70340 001 AUG 20, 1986	
> ADD >				
> ADD >	∂	120MG	N70341 001 AUG 20, 1986	
> ADD >				

WARFARIN SODIUM

TABLET; ORAL
/WARFARIN/SODIUM/

/B*/	/PHARM/BASICS/	/2MG/	/N88719/001/ /JUN/27,/1985/	
/B*/		/2.5MG/	/N88720/001/ /AUG/06,/1985/	
/B*/		/5MG/	/N88721/001/ /JUL/02,/1985/	
	∂ PHARM BASICS	2MG	N88719 001 JUN 27, 1985	
	∂	2.5MG	N88720 001 AUG 06, 1985	
	∂	5MG	N88721 001 JUL 02, 1985	

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
MICROCOL
JOHNSON AND JOHNSON 0.5% N72292 001
JAN 28, 1992

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
ADD > SILPHEN
ADD > SILARX 12.5MG/5ML N72646 001
ADD > FEB 27, 1992

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL
LOPERAMIDE HCL
PERRIGO 1MG/5ML N73243 001
JAN 21, 1992

SODIUM MONOFLUOROPHOSPHATE

ADD > PASTE; DENTAL
ADD > EXTRA-STRENGTH AIM
DLT > /3/CHESEBROUGH/PONDS/ /1.2%/ /N19518/001/
DLT > /JUN/03,/1987/
ADD > CHESEBROUGH PONDS 1.2% N19518 001
ADD > JUN 03, 1987

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 2 / JAN '92 - FEB '92

DEXTRAN, 75, 6% INVERTED SUGAR 10% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION

6% GENTRAN 75 AND 10% TRAVERT

TRAVENOL LABS	6GM/100ML;0.9GM/100ML 0.9GM/100ML	N08788

UROKINASE

INJECTABLE; INJECTION

BREOKINASE

STERLING DRUG	250,000 IU/VIAL	N17873

ORPHAN DRUG PRODUCT DESIGNATIONS

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

WHEN A PRODUCT IS GRANTED ORPHAN DRUG DESIGNATION, IT WILL APPEAR IN THIS SECTION. ONCE A BIOLOGICAL OR DRUG PRODUCT IS LICENSED/APPROVED FOR MARKETING, IT WILL BE LISTED IN THIS SECTION AND ASTERISKED, AS APPROPRIATE, TO DENOTE MARKETING/EXCLUSIVE APPROVAL STATUS. IN ADDITION, THE EXCLUSIVITY EXPIRATION DATE WILL BE DISPLAYED FOLLOWING THE APPROVED DESIGNATED INDICATION(S).

THE FOLLOWING DRUGS AND BIOLOGICALS HAVE BEEN GRANTED ORPHAN ORUG DESIGNATION PURSUANT TO SECTION 526 OF THE FOOD, DRUG, AND COSMETIC ACT AS AMENDEO BY THE ORPHAN DRUG ACT [PUBLIC LAW 97-414].

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ANANAIN, COMOSAIN TRADE: VIANAIN	FOR THE ENZYMATIC DEBRIDEMENT OF SEVERE BURNS.	GENZYME CORPORATION
GENERIC: ANTITHROMBIN III TRADE: THROMBATE III*/**	USE AS REPLACEMENT THERAPY IN CONGENITAL DEFICIENCY OF ANTITHROMBIN-III FOR PREVENTION AND TREATMENT OF OF THROMBOSIS AND PULMONARY EMBOLI. [DEC 13, 1996]	CUTTER BIOLOGICAL
GENERIC: BOTULINUM TOXIN TYPE B TRADE: NOT ESTABLISHED	TREATMENT OF CERVICAL DYSTONIA.	ATHENA NEUROSCIENCES, INC
GENERIC: CILIARY NEUROTROPHIC FACTOR TRADE: NOT ESTABLISHED	TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.	ROGENERON PHARMACEUTICALS, INC
GENERIC: CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR TRADE: NOT ESTABLISHED	FOR CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR PROTEIN REPLACEMENT THERAPY IN CYSTIC FIBROSIS PATIENTS.	GENZYME CORPORATION

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: SARGRAMOSTIM TRADE: LEUKINE*/**	TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANT, FOR THE PROMOTION OF EARLY ENGRAFTMENT, AND FOR THE TREATMENT OF GRAFT FAILURE AND DELAY OF ENGRAFTMENT.*/** [DEC 31, 1998] TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANTS IN PATIENTS WITH NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE AND ACUTE LYMPHOBLASTIC LEUKEMIA.*/** [MAR 05, 1998]	IMMUNEX

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: DAPSONE TRADE: DAPSONE	FOR THE COMBINATION TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA IN CONJUNCTION WITH TRIMETHOPRIM.	JACOBUS PHARMACEUTICAL COMPANY
GENERIC: DIAZEPAM VISCOUS SOLUTION FOR RECTAL ADMINISTRATION TRADE: DIASTAT	TREATMENT OF ACUTE REPETITIVE SEIZURES.	UPSHER SMITH LABORATORIES, INC
GENERIC: HUMAN THYROID STIMULATING HORMONE (TSH) TRADE: THYROGEN	AS AN ADJUNCT IN THE DIAGNOSIS OF THYROID CANCER.	GENZYME CORPORATION
GENERIC: L-BACLOFEN TRADE: NEURALGON	TREATMENT OF INTRACTABLE SPASTICITY IN CHILDREN WITH CEREBRAL PALSY.	MERICON INDUSTRIES, INC
GENERIC: LIOTHYRONINE SODIUM TRADE: TRIOSTAT*/**	TREATMENT OF MYXEDEMA COMA/PRE-COMA. [DEC 31, 1998]	SMITHKLINE BEECHAM
GENERIC: LOXORIBINE TRADE: NOT ESTABLISHED	TREATMENT OF COMMON VARIABLE IMMUNODEFICIENCY.	R.W. JOHNSON RESEARCH INSTITUTE
GENERIC; MELPHALAN TRADE: ALKERAN FOR INJECTION	TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA FOR WHOM ORAL THERAPY IS INAPPROPRIATE.	BURROUGHS WELLCOME COMPANY
GENERIC: PAPAVERINE (TOPICAL GEL) TRADE: NOT ESTABLISHED	TREATMENT OF SEXUAL DYSFUNCTION IN SPINAL CORD INJURY PATIENTS.	PHARMEDIC COMPANY
GENERIC: PARA-AMINDSALICYLIC ACID TRADE: NOT ESTABLISHED	TREATMENT OF TUBERCULOSIS INFECTIONS.	JACOBUS PHARMACEUTICAL COMPANY
GENERIC: PILOCARPINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF XEROSTOMIA AND KERATOCONJUNCTIVITIS SICCA IN SJOGREN'S SYNDROME PATIENTS.	MGI PHARMA, INC

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

NO FEBRUARY 1992 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, HFD-650, MPN-2 ROOM 278, 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, 12TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO FEBRUARY 1992 ADDITIONS

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, 12TH 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	PETITION	REASON FOR STATUS
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	5MG/ML (50ML/CONTAINER)	91 P-0387/ CP1	ABBOTT	NEW STRENGTH	APPROVED FEB 18, 1992
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	10MG/ML (100ML/CONTAINER)	91 P-0387/ CP1	ABBOTT	NEW STRENGTH	APPROVED FEB 18, 1992

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	PETITION	REASON FOR STATUS
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (50ML/VIAL)	91 P-0076/ CP1	ADRIA	NEW STRENGTH	DENIED FEB 19, 1992

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, 12TH 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-67	TREATMENT OF ACUTE ASTHMATIC ATTACKS IN CHILDREN SIX YEARS OF AGE AND OLDER
I-68	CENTRAL PRECOCIOUS PUBERTY
I-69	SHORT TERM TREATMENT OF PATIENTS WITH SYMPTOMS OF GASTROESOPHAGEAL REFLUX DISEASE (GERD), AND FOR THE SHORT TERM TREATMENT OF ESOPHAGITIS DUE TO GERD INCLUDING ULCERATIVE DISEASE DIAGNOSED BY ENDOSCOPY
I-70	USE IN COMBINATION WITH 5-FLUOROURACIL TO PROLONG SURVIVAL IN THE PALLIATIVE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER

REFERENCES
PATENT USE CODE

U-57	OPHTHALMIC USE OF NORFLOXACIN
U-58	METHOD OF TREATING INFLAMMATORY INTESTINAL DISEASES
U-59	METHOD OF TREATING HYPERCHOLESTEROLEMIA

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	19548 001	BITOLTEROL MESYLATE; TORNALATE 0.2%	4336400	JUN 22, 1999	U-5		
>ADD>			4138581	FEB 06, 1998		NDF	FEB 19, 1995
>ADD>	19847 001	CIPROFLOXACIN; CIPRO	4808583	FEB 28, 2006			
>ADD>			4705789	NOV 10, 2004			
>ADD>	19857 001	CIPROFLOXACIN; CIPRD IN DEXTROSE 5%	4957922	SEP 18, 2007			
>ADD>			4808583	FEB 28, 2006			
>ADD>			4705789	NOV 10, 2004			
>ADD>	19858 001	CIPROFLOXACIN; CIPRO IN SODIUM CHLORIDE 0.9%	4957922	SEP 18, 2007			
>ADD>			4808583	FEB 28, 2006			
>ADD>			4705789	NOV 10, 2004			
	20062 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008			
			4894240	JAN 16, 2007		NP	DEC 27, 1994
	20062 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008			
			4894240	JAN 16, 2007		NP	DEC 27, 1994
	20062 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008			
			4894240	JAN 16, 2007		NP	DEC 27, 1994
>ADD>	19462 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		I-69	DEC 10, 1994
>ADD>	19462 002	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		I-69	DEC 10, 1994
>ADD>	19527 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		I-69	DEC 10, 1994
	20068 001	FOSCARNET SODIUM; FOSCAVIR	4771041	JUL 29, 1997			
			4665062	JUL 29, 1997			
			4339445	JUL 29, 1997			
			4215113	JUL 29, 1997		NCE	SEP 27, 1996
	19967 001	HALOBETASOL PROPIONATE; ULTRAVATE				D-1	DEC 31, 1994
	19968 001	HALOBETASOL PROPIONATE; ULTRAVATE				D-1	DEC 31, 1994
	19261 001	HYDROXYAMPHETAMINE HYDROBROMIDE; PAREMYD				NC	JAN 30, 1995
	19645 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55	NDF	DEC 20, 1994
						NCE	NOV 30, 1994
>ADD>	08107 001	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
>ADD>	08107 002	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
>ADD>	08107 004	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
>ADD>	08107 005	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4917893	MAR 24, 2004			
>ADD>			4849228	JUL 18, 2006			
>ADD>			4728721	MAR 01, 2005			
>ADD>			4677191	JUN 30, 2004			
>ADD>			4652441	MAR 24, 2004			
>ADD>	20011 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4917893	MAR 24, 2004			
>ADD>			4849228	JUL 18, 2006			
>ADD>			4728721	MAR 01, 2005			
>ADD>			4677191	JUN 30, 2004			
>ADD>			4652441	MAR 24, 2004			
	20105 001	LIOTHYRONINE SODIUM; TRIOSTAT				ODE	DEC 31, 1998
>ADD>	20013 001	LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN	4528287	JUL 09, 2002	U-36	NCE	FEB 21, 1997
	19651 001	MESALAMINE; ASACOL				NCE	DEC 24, 1992
						NDF	JAN 31, 1995
>ADD>	17659 001	METAPROTERENOL SULFATE; ALUPENT				I-67	NOV 14, 1994
>DLT>	~~17659 001~~	~~METAPROTERENOL SULFATE; ALUPENT~~				~~I-67~~	~~NOV 14, 1994~~
>ADD>	19962 001	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992		NE	JAN 10, 1995
			3876802	APR 08, 1992			
>ADD>	19962 002	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992		NE	JAN 10, 1995
>ADD>			3876802	APR 08, 1992			
>ADD>	19962 003	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992		NE	JAN 10, 1995
>ADD>			3876802	APR 08, 1992			
	20098 001	MIVACURIUM CHLORIDE; MIVACRON	4761418	AUG 02, 2005		NCE	JAN 22, 1997
	20098 002	MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5%	4761418	AUG 02, 2005		NCE	JAN 22, 1997
	19583 001	NABUMETONE; RELAFEN	4420639	DEC 13, 2000		NCE	DEC 24, 1996
	19583 002	NABUMETONE; RELAFEN	4420639	DEC 13, 2000		NCE	DEC 24, 1996
>ADD>	19886 001	NAFARELIN ACETATE; SYNAREL				I-68	FEB 26, 1995
>ADD>	20109 001	NAFARELIN ACETATE; NAFARELIN ACETATE	4234571	NOV 18, 1997		NCE	FEB 13, 1995
>ADD>						I-68	FEB 26, 1995
	19734 001	NICARDIPINE HYDROCHLORIDE; CARDENE				NDF	JAN 30, 1995
						NCE	DEC 21, 1993
>ADD>	20005 001	NICARDIPINE HYDROCHLORIDE; CARDENE SR				NDF	FEB 21, 1995
>ADD>	20005 002	NICARDIPINE HYDROCHLORIDE; CARDENE SR				NDF	FEB 21, 1995
>ADD>	20005 003	NICARDIPINE HYDROCHLORIDE; CARDENE SR				NDF	FEB 21, 1995
	19983 001	NICOTINE; PROSTEP	4946853	AUG 07, 2007	U-56	NS	JAN 28, 1995
	19983 002	NICOTINE; PROSTEP	4946853	AUG 07, 2007	U-56	NS	JAN 28, 1995

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	20076 001	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
>ADD>	20076 002	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
>ADD>	20076 003	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
	20165 001	NICOTINE; NICODERM	5004610	APR 02, 2008			
			4144317	SEP 09, 1992		NDF	NOV 07, 1994
	20165 002	NICOTINE; NICODERM	5004610	APR 02, 2008			
			4144317	SEP 09, 1992		NDF	NOV 07, 1994
	20165 003	NICOTINE; NICODERM	5004610	APR 02, 2008			
			4144317	SEP 09, 1992		NDF	NOV 07, 1994
>ADD>	19757 001	NORFLOXACIN; CHIBROXIN	4551456	NOV 05, 2002	U-57		
>ADD>	19715 001	OLSALAZINE SODIUM; DIPENTUM	4559330	AUG 04, 2004	U-58	NCE	JUL 31, 1995
	19775 001	PRAZOSIN HYDROCHLORIDE; MINIPRESS XL				NDF	JAN 29, 1995
	19775 002	PRAZOSIN HYDROCHLORIDE; MINIPRESS XL				NDF	JAN 29, 1995
>ADD>	19766 001	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
>ADD>	19766 002	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
>ADD>	19766 003	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
>ADD>	19766 004	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
>ADD>	20166 001	SODIUM THIOSULFATE; SODIUM THIOSULFATE				NCE	FEB 14, 1997
	20043 003	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	MAR 08, 2005	U-36	NCE	JAN 30, 1997
	20043 004	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	MAR 08, 2005	U-36	NCE	JAN 30, 1997
>DLT>	~~18163 001~~	~~TEMAZEPAM; RESTORIL~~				~~D-17~~	~~OCT 25, 1994~~
>DLT>	~~18163 001~~	~~TEMAZEPAM; RESTORIL~~				~~NS~~	~~OCT 25, 1994~~
>DLT>	~~18163 002~~	~~TEMAZEPAM; RESTORIL~~				~~D-17~~	~~OCT 25, 1994~~
>DLT>	~~18163 002~~	~~TEMAZEPAM; RESTORIL~~				~~NS~~	~~OCT 25, 1994~~
>DLT>	~~18163 003~~	~~TEMAZEPAM; RESTORIL~~				~~D-17~~	~~OCT 25, 1994~~
>ADD>	19614 003	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993
	19655 C01	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005			
			4833130	FEB 09, 2005		I-47	MAY 02, 1993
			4828838	FEB 09, 2005		ODE	MAR 19, 1994
			4724232	FEB 09, 2005		NCE	MAR 19, 1992
	19910 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005			
			4833130	FEB 09, 2005		ODE	MAR 19, 1994
			4818538	FEB 09, 2005		I-47	MAY 02, 1993
			4724232	FEB 09, 2005		NCE	MAR 19, 1992

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19951 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005			
		4833130	FEB 09, 2005		NCE	MAR 19, 1992
		4818538	FEB 09, 2005			
		4724232	FEB 09, 2005		ODE	MAR 19, 1994

*U.S. Government Printing Office: 1992 — 312-211/40009