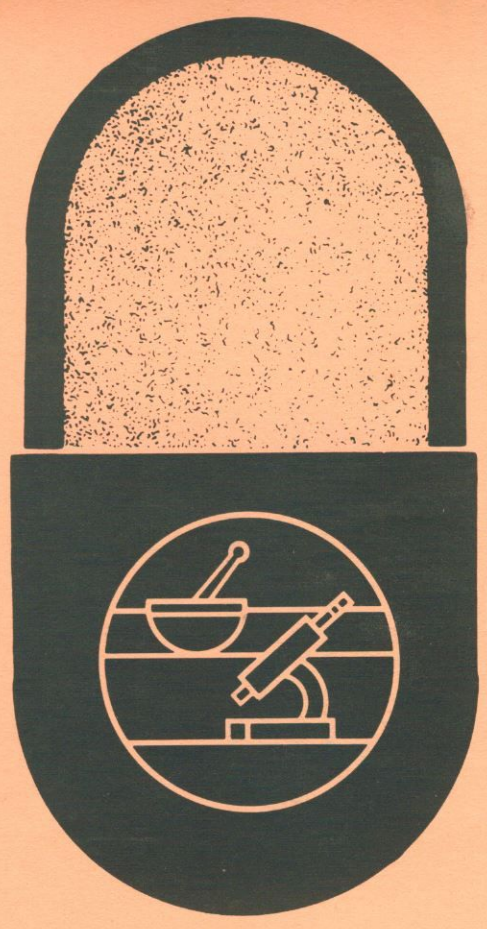
CUMULATIVE
SUPPLEMENT 2
JAN'90-FEB'90



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

10TH EDITION

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

1.0
1.1
1.2
1.3
1.4

2.0
2.1
2.2
2.3

2.4
2.5

2.6
2.7

PATE

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with

THERAPEUTIC EQUIVALENCE EVALUATIONS

10TH EDITION

CUMULATIVE SUPPLEMENT 2

FEBRUARY 1990

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with

THERAPEUTIC EQUIVALENCE EVALUATIONS

10th EDITION

CUMULATIVE SUPPLEMENT 2

FEBRUARY 1990

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, 10th 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Division of Blood and Blood Products and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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 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, 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 with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products 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 with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products 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 with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products 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 "ə" symbol to designate their non-marketed status. All products having a "ə" symbol in the 12th Cumulative Supplement of the 10th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 11th 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
MARION LABORATORIES	MARION MERRELL DOW INC	MARION MERRELL DOW

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 1989) 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 1989	MAR 1990	JUN 1990	SEP 1990
DRUG PRODUCTS LISTED	10123			
SINGLE SOURCE	2030 (20.1%)			
MULTISOURCE	8093 (79.9%)			
THERAPEUTICALLY EQUIVALENT	7222 (71.3%)			
NOT THERAPEUTICALLY EQUIVALENT	752 (7.4%)			
EXCEPTIONS[1]	119 (1.2%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	400			

[1]Amino acid-containing products of varying composition (see Introduction, page 1-8 of the List).

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>DLT >	/AA/	/PBI/	/500MG;5MG/	/N89290/001/ /MAY/29,/1987/
>DLT >				
>ADD >		ə PBI	500MG;5MG	N89290 001 MAY 29, 1987
>ADD >				

ALBUTEROL SULFATE

TABLET; ORAL
ALBUTEROL SULFATE

AB	WARNER CHILCOTT	EQ 2MG BASE¤	N72817 001 JAN 09, 1990
AB		EQ 4MG BASE¤	N72818 001 JAN 09, 1990

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL
PERPHENAZINE AND AMITRIPTYLINE HCL

/AB/	/CHELSEA/LABS/	/50MG;4MG/	/N71558/001/ /MAR/02,/1987/
BX	CHELSEA LABS	50MG;4MG	N71558 001 MAR 02, 1987

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL
/ORPHENADRINE/COMPOUND/

/BX/	/VITARINE/	/385MG;30MG;25MG/	/N71564/001/ /JUN/23,/1988/
	ə VITARINE	385MG;30MG;25MG	N71564 001 JUN 23, 1988

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL
/ORPHENADRINE/COMPOUND/DOUBLE/STRENGTH/

/BX/	/VITARINE/	/770MG;60MG;50MG/	/N71565/001/ /JUN/23,/1988/
	ə VITARINE	770MG;60MG;50MG	N71565 001 JUN 23, 1988

BACLOFEN

TABLET; ORAL
BACLOFEN

/BX/	/VITARINE/	/10MG/	/N71901/001/ /APR/13,/1988/
/BX/		/20MG/	/N71902/001/ /APR/13,/1988/
	ə VITARINE	10MG	N71901 001 APR 13, 1988
	ə	20MG	N71902 001 APR 13, 1988

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL
BETAMETHASONE DIPROPIONATE

AB	CLAY PARK LABS	EQ 0.05% BASE¤	N72536 001 JAN 31, 1990

LOTION; TOPICAL
BETAMETHASONE DIPROPIONATE

AB	CLAY PARK LABS	EQ 0.05% BASE¤	N72538 001 JAN 31, 1990

OINTMENT; TOPICAL
BETAMETHASONE DIPROPIONATE

AB	CLAY PARK LABS	EQ 0.05% BASE¤	N72526 001 JAN 31, 1990

CEPHALEXIN

CAPSULE; ORAL
CEPHALEXIN MONOHYDRATE

/BX/	/VITARINE/	/EQ/250MG/BASE/	/N62159/001/
/BX/		/EQ/500MG/BASE/	/N62159/002/
	ə VITARINE	EQ 250MG BASE	N62159 001
	ə	EQ 500MG BASE	N62159 002

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL
CEPHALEXIN

/BX/	/VITARINE/	/EQ/125MG/BASE/5ML/	/N62779/001/	
			/DEC/22,/1987/	
/BX/		/EQ/250MG/BASE/5ML/	/N62781/001/	
			/DEC/22,/1987/	
	ə VITARINE	EQ 125MG BASE/5ML	N62779 001	
			DEC 22, 1987	
	ə	EQ 250MG BASE/5ML	N62781 001	
			DEC 22, 1987	

TABLET; ORAL
CEPHALEXIN

/BX/	/VITARINE/	/EQ/250MG/BASE/	/N62863/001/	
			/AUG/11,/1988/	> ADD >
/BX/		/EQ/500MG/BASE/	/N62863/002/	> ADD >
			/AUG/11,/1988/	> ADD >
/BX/		/EQ/1GM/BASE/	/N62863/003/	> ADD >
			/AUG/11,/1988/	
	ə VITARINE	EQ 250MG BASE	N62863 001	
			AUG 11, 1988	
	ə	EQ 500MG BASE	N62863 002	
			AUG 11, 1988	
	ə	EQ 1GM BASE	N62863 003	
			AUG 11, 1988	

CEPHAPIRIN SODIUM

INJECTABLE; INJECTION
CEPHAPIRIN SODIUM

> DLT >/AP/	/LYPHOMED/	/EQ 20GM BASE/VIAL/	/N62723/005/		
			/NOV/17,/1986/		
> DLT >					
> ADD >	ə LYPHOMED	EQ 20GM BASE/VIAL	N62723 005		
> ADD >			NOV 17, 1986		

CEPHRADINE

CAPSULE; ORAL
CEPHRADINE

/BX/	/VITARINE/	/250MG/	/N62813/001/	
			/FEB/25,/1988/	
/BX/		/500MG/	/N62813/002/	
			/FEB/25,/1988/	
	ə VITARINE	250MG	N62813 001	
			FEB 25, 1988	
	ə	500MG	N62813 002	
			FEB 25, 1988	

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL
CLINDAMYCIN HCL

/BX/	/VITARINE/	/EQ/75MG/BASE/	/N62910/001/	
			/JUL/05,/1988/	
/BX/		/EQ/150MG/BASE/	/N62910/002/	
			/JUL/05,/1988/	
	ə VITARINE	EQ 75MG BASE	N62910 001	
			JUL 05, 1988	
	ə	EQ 150MG BASE	N62910 002	
			JUL 05, 1988	

CLOBETASOL PROPIONATE

SOLUTION; TOPICAL
TEMOVATE

GLAXO	0.05%		N19966 001
			FEB 22, 1990

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPRAMINE HCL

/BX/	/VITARINE/	/10MG/	/N72167/001/	
			/FEB/03,/1988/	
/BX/		/25MG/	/N71601/001/	
			/JUN/05,/1987/	
/BX/		/50MG/	/N71588/001/	
			/JUN/05,/1987/	
/BX/		/75MG/	/N71602/001/	
			/OCT/05,/1987/	
/BX/		/100MG/	/N71766/001/	
			/OCT/05,/1987/	
/BX/		/150MG/	/N72254/001/	
			/FEB/03,/1988/	
	ə VITARINE	10MG	N72167 001	
			FEB 03, 1988	
	ə	25MG	N71601 001	
			JUN 05, 1987	
	ə	50MG	N71588 001	
			JUN 05, 1987	
	ə	75MG	N71602 001	
			OCT 05, 1987	
	ə	100MG	N71766 001	
			OCT 05, 1987	
	ə	150MG	N72254 001	
			FEB 03, 1988	

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION
DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

KENDALL MCGAW	3.3GM/100ML; 300MG/100ML		N19631 016
			JAN 19, 1990

DICLOXACILLIN SODIUM

POWDER FOR RECONSTITUTION; ORAL
DYNAPEN

> DLT >/AB/	/BRISTOL/LABS/	/EQ 62.5MG BASE/5ML/	/N50337/002/	
> ADD >	ə BRISTOL LABS	EQ 62.5MG BASE/5ML	N50337 002	

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL
DISOPYRAMIDE PHOSPHATE

/AB/	/CHELSEA/LABS/	/EQ 100MG BASE/	/N71020/001/	
			/DEC/01,/1986/	
/AB/		/EQ 150MG BASE/	/N71021/001/	
			/DEC/01,/1986/	
BX	CHELSEA LABS	EQ 100MG BASE	N71020 001	
			DEC 01, 1986	
BX		EQ 150MG BASE	N71021 001	
			DEC 01, 1986	

DOXYCYCLINE HYCLATE

CAPSULE; ORAL
DOXYCYCLINE HYCLATE

/BX/	/VITARINE/	/EQ/50MG/BASE/	/N62780/001/	
			/APR/12,/1988/	
/BX/		/EQ/100MG/BASE/	/N62227/001/	
	ə VITARINE	EQ 50MG BASE	N62780 001	
			APR 12, 1988	
	ə	EQ 100MG BASE	N62227 001	

INJECTABLE; INJECTION
> ADD > VIBRAMYCIN

> ADD > AP	PFIZER LABS	EQ 100MG BASE/VIAL	N50442 002	
> ADD > AP		EQ 200MG BASE/VIAL	N50442 001	
> DLT >	/ə/	/EQ/100MG/BASE/VIAL/	/N50442/002/	
> DLT >	/ə/	/EQ/200MG/BASE/VIAL/	/N50442/001/	

DYDROGESTERONE

TABLET; ORAL
GYNOREST

/ə/KALI/DUPHAR/	/5MG/		/N17388/001/
/ə/	/10MG/		/N17388/002/
ə REID ROWELL	5MG		N17388 001
ə	10MG		N17388 002

ERYTHROMYCIN

SOLUTION; TOPICAL
ERYTHROMYCIN

> DLT >/AT/	/BARRE/NATL/	/2%/	/N62327/001/	
> DLT >			/APR/19,/1982/	
> DLT >/AT/		/2%/	/N62342/001/	
> DLT >			/FEB/25,/1982/	
> ADD >	ə BARRE NATL	2%	N62327 001	
> ADD >			APR 19, 1982	
> ADD >	ə	2%	N62342 001	
> ADD >			FEB 25, 1982	

ESTROGENS, CONJUGATED

TABLET; ORAL
CONJUGATED ESTROGENS

/BP/	/CHELSEA/LABS/	/0.625MG/	/N85800/001/	
	ə CHELSEA LABS	0.625MG	N85800 001	

FLUCONAZOLE

INJECTABLE; INJECTION
DIFLUCAN

PFIZER CTL RES	2MG/ML		N19950 001
			JAN 29, 1990

TABLET; ORAL
DIFLUCAN

PFIZER CTL RES	50MG		N19949 001
			JAN 29, 1990
	100MG		N19949 002
			JAN 29, 1990
	200MG		N19949 003
			JAN 29, 1990

FLUNISOLIDE

>DLT>	/SPRAY;/INHALATION/NASAL/			
>DLT>	/NASALIDE/			
>DLT>	/SYNTEX/LABS/	/0.025MG/INH/	/N18148/001/	
>ADD>	SPRAY, METERED; NASAL			
>ADD>	NASALIDE			
>ADD>	SYNTEX LABS	0.025MG/INH	N18148 001	

GONADOTROPIN, CHORIONIC

	INJECTABLE; INJECTION			
	CHORIONIC GONADOTROPIN			
>ADD>	STERIS LABS	2,000 UNITS/VIAL¤	N17016 011	
>ADD>			FEB 16, 1990	

HYDROCHLOROTHIAZIDE; TRIAMTERENE

	TABLET; ORAL			
	TRIAMTERENE AND HYDROCHLOROTHIAZIDE			
/BX/	/VITARINE/	/50MG;75MG/	/N71360/001/	
			/DEC/08,/1987/	
	ə VITARINE	50MG;75MG	N71360 001	
			DEC 08, 1987	

IBUPROFEN

	TABLET; ORAL			
	IBUPROFEN			
/AB/	/MCNEIL/CONSUMER/	/600MG/	/N70476/001/	
			/JUN/16,/1986/	
	ə MCNEIL CONSUMER	600MG	N70476 001	
			JUN 16, 1986	

INDOMETHACIN

	CAPSULE; ORAL			
	INDOMETHACIN			
/BX/	/VITARINE/	/25MG/	/N71711/001/	
			/JUL/05,/1988/	
/BX/		/50MG/	/N71712/001/	
			/JUL/05,/1988/	
	ə VITARINE	25MG	N71711 001	
			JUL 05, 1988	
	ə	50MG	N71712 001	
			JUL 05, 1988	

INDOMETHACIN

	CAPSULE; ORAL			
	INDOMETHACIN			
/AB/	/ZENITH/LABS/	/25MG/	/N18730/001/	
			/MAY/04,/1984/	
/AB/		/50MG/	/N18730/002/	
			/MAY/04,/1984/	
	ə ZENITH LABS	25MG	N18730 001	
			MAY 04, 1984	
	ə	50MG	N18730 002	
			MAY 04, 1984	

	CAPSULE, EXTENDED RELEASE; ORAL			
	INDOMETHACIN			
/BX/	/VITARINE/	/75MG/	/N71531/001/	
			/JUL/21,/1987/	
	ə VITARINE	75MG	N71531 001	
			JUL 21, 1987	

IODOHIPPURATE SODIUM, I-131

	INJECTABLE; INJECTION			
	IODOHIPPURATE SODIUM I 131			
>ADD>	CIS US	0.2MCI/ML	N17313 001	
>DLT>	/SORIN/	/0.2MCI/ML/	/N17313/001/	

MECLOFENAMATE SODIUM

	CAPSULE; ORAL			
	MECLOFENAMATE SODIUM			
/BX/	/VITARINE/	/EQ/50MG/BASE/	/N71710/001/	
			/JUN/15,/1988/	
/BX/		/EQ/100MG/BASE/	/N71684/001/	
			/JUN/15,/1988/	
	ə VITARINE	EQ 50MG BASE	N71710 001	
			JUN 15, 1988	
	ə	EQ 100MG BASE	N71684 001	
			JUN 15, 1988	

MEFENAMIC ACID

	CAPSULE; ORAL			
	/MEFENAMIC/ACID/			
/BX/	/VITARINE/	/250MG/	/N72179/001/	
			/APR/21,/1988/	
	ə VITARINE	250MG	N72179 001	
			APR 21, 1988	

MEFENAMIC ACID

	CAPSULE; ORAL			
	PONSTEL			
/AB/	/PARKE/DAVIS/PR/	/250MG/	/N15034/003/	
AB	PARKE DAVIS PR	250MG	N15034 003	

METHICILLIN SODIUM

	INJECTABLE; INJECTION			
	STAPHCILLIN			
>DLT>	/BRISTOL/LABS/	/EQ/900MG/BASE/VIAL/	/N50117/001/	
>ADD>	ə BRISTOL LABS	EQ 900MG BASE/VIAL	N50117 001	
>DLT>		/EQ/3.6GM/BASE/VIAL/	/N50117/002/	
>ADD>	ə	EQ 3.6GM BASE/VIAL	N50117 002	
>DLT>		/EQ/5.4GM/BASE/VIAL/	/N50117/003/	
>ADD>	ə	EQ 5.4GM BASE/VIAL	N50117 003	

METOCLOPRAMIDE HYDROCHLORIDE

	TABLET; ORAL			
	METOCLOPRAMIDE HCL			
AB	CORD LABS	EQ 10MG BASE¤	N72215 001	
			JAN 30, 1990	
AB	MARTEC PHARM	EQ 10MG BASE	N70598 001	
			FEB 02, 1987	
/ə/		/EQ/10MG/BASE/	/N70598/001/	
			/FEB/02,/1987/	

MORPHINE SULFATE

	TABLET, EXTENDED RELEASE; ORAL			
	MS CONTIN			
	PURDUE FRDRK	100MG¤	N19516 004	
			JAN 16, 1990	

NAFARELIN ACETATE

>ADD>	SPRAY, METERED; NASAL			
>ADD>	SYNAREL			
>ADD>	SYNTEX LABS	EQ 2MG BASE/ML¤	N19886 001	
>ADD>			FEB 13, 1990	

NIFEDIPINE

	CAPSULE; ORAL			
	NIFEDIPINE			
/AB/	/PUREPAC/PHARM/	/20MG/	/N72556/001/	
			/APR/28,/1989/	
AB	PUREPAC PHARM	20MG	N72556 001	
			SEP 20, 1990 : APR 28, 1989	

NITROGLYCERIN

	INJECTABLE; INJECTION			
	NITRO-BID			
>ADD> AP	MARION LABS	10MG/ML¤	N71159 001	
>ADD>			FEB 28, 1990	

OXAZEPAM

	CAPSULE; ORAL			
	OXAZEPAM			
/AB/	/CHELSEA/LABS/	/30MG/	/N71663/001/	
			/MAR/02,/1988/	
BX	CHELSEA LABS	30MG	N71663 001	
			MAR 02, 1988	

PERPHENAZINE

	TABLET; ORAL			
	PERPHENAZINE			
/AB/	/CHELSEA/LABS/	/8MG/	/N89700/001/	
			/DEC/23,/1987/	
BX	CHELSEA LABS	8MG	N89700 001	
			DEC 23, 1987	

PHENYTOIN SODIUM, EXTENDED

	CAPSULE; ORAL			
	PHENYTEX			
/AB/	/BOLAR/PHARM/	/100MG/	/N88711/001/	
			/DEC/21,/1984/	
BX	BOLAR PHARM	100MG	N88711 001	
			DEC 21, 1984	

PIPERAZINE CITRATE

	SYRUP; ORAL			
	/BRYREL/			
/AA/	/STERLING/DRUG/	/EQ 500MG BASE/5ML/	/N17796/001/	

PIPERAZINE CITRATE

SYRUP; ORAL
/BRYREL/
ə STERLING DRUG — EQ 500MG BASE/5ML — N17796 001

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

AB	MARTEC PHARM	10MG	N70120 001 AUG 06, 1985
AB		20MG	N70121 001 AUG 06, 1985
AB		40MG	N70122 001 AUG 06, 1985
AB		60MG	N70123 001 OCT 29, 1986
AB		80MG	N70124 001 AUG 06, 1985
/ə/		/10MG/	/N70120/001/ /AUG/06,/1985/
/ə/		/20MG/	/N70121/001/ /AUG/06,/1985/
/ə/		/40MG/	/N70122/001/ /AUG/06,/1985/
/ə/		/60MG/	/N70123/001/ /OCT/29,/1986/
/ə/		/80MG/	/N70124/001/ /AUG/06,/1985/

PROTEIN HYDROLYSATE

INJECTABLE; INJECTION
AMINOSOL 5%

/AP/	/ABBOTT/LABS/	/5%/	/N05932/012/ /JAN/31,/1985/
	ABBOTT LABS	5%	N05932 012 JAN 31, 1985
/AP/	/HYPROTIGEN 5%/ /KENDALL/MCGAW/	/5%/	/N06170/003/ /JAN/10,/1984/
	ə KENDALL MCGAW	5%	N06170 003 JAN 10, 1984

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION
AN-DTPA

>ADD> AP	CIS US	N/A	N17714 001

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION
AN-DTPA

>DLT>/AP/	/SYNCOR/INTL/	/N/A/	/N17714/001/

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL

/BX/	/VITARINE/	/250MG/	/N61471/001/
/BX/		/500MG/	/N61471/002/ /SEP/06,/1988/
ə VITARINE		250MG	N61471 001
ə		500MG	N61471 002 SEP 06, 1988

TETRACYCLINE PHOSPHATE COMPLEX

CAPSULE; ORAL
TETREX

>DLT>	/BRISTOL/LABS/	/EQ/250MG/HCL/	/N50212/002/
>ADD>	ə BRISTOL LABS	EQ 250MG HCL	N50212 002
>DLT>		/EQ/500MG/HCL/	/N50212/003/
>ADD>	ə	EQ 500MG HCL	N50212 003

TRIENTINE HYDROCHLORIDE

CAPSULE; ORAL

>DLT>	/CUPRID/		
>DLT>	/MS&D/	/250MG/	/N19194/001/ /NOV/08,/1985/
>DLT>			
>ADD>	SYPRINE		
>ADD>	MS&D	250MG	N19194 001 NOV 08, 1985
>ADD>			

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
TRIMIPRAMINE MALEATE

/BX/	/VITARINE/	/EQ/25MG/BASE/	/N71832/001/ /SEP/10,/1987/
/BX/		/EQ/50MG/BASE/	/N71833/001/ /SEP/10,/1987/
/BX/		/EQ/100MG/BASE/	/N71834/001/ /SEP/10,/1987/
ə VITARINE		EQ 25MG BASE	N71832 001 SEP 10, 1987
ə		EQ 50MG BASE	N71833 001 SEP 10, 1987
ə		EQ 100MG BASE	N71834 001 SEP 10, 1987

UREA

INJECTABLE; INJECTION
/STERILE UREA/

/AP/	/ABBOTT/LABS/	/40GM/VIAL/	/N17698/001/
	ə ABBOTT LABS	40GM/VIAL	N17698 001
UREAPHIL			
/AP/	/ABBOTT/LABS/	/40GM/VIAL/	/N12154/001/
	ABBOTT LABS	40GM/VIAL	N12154 001

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL

/AB/	/CHELSEA/LABS/	/80MG/	/N70421/001/ /SEP/17,/1986/
BX	CHELSEA LABS	80MG	N70421 001 SEP 17, 1986

ZIDOVUDINE

>ADD> INJECTABLE; INJECTION
>ADD> RETROVIR
>ADD> BURROUGHS WELLC — 10MG/ML — N19951 001
>ADD> FEB 02, 1990

NO FEBRUARY 1990 APPROVALS

NO FEBRUARY 1990 APPROVALS

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 DRUG DESIGNATION PURSUANT TO SECTION 526 OF THE FOOD, DRUG, AND COSMETIC ACT AS AMENDED 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 AND ADDRESS
GENERIC: BOTULINUM A TOXIN TRADE: OCULINUM*/**	TREATMENT OF STRABISMUS ASSOCIATED WITH DYSTONIA IN ADULTS (PATIENTS 12 YEARS OF AGE AND ABOVE). TREATMENT OF BLEPHAROSPASM ASSOCIATED WITH DYSTONIA IN ADULTS (PATIENTS 12 YEARS OF AGE AND ABOVE)*/**. [DEC 29, 1996]	ALAN B. SCOTT, M.D. 2232 WEBSTER ST. SAN FRANCISCO, CA 94115
GENERIC: [INDIUM 111 MURINE ANTI-CEA MONOCLONAL ANTIBODY TYPE ZCE 025 (IN 111 MUROMONAB-CEA)] TRADE: CEAKER	FOR THE DETECTION OF SUSPECTED AND PREVIOUSLY UNIDENTIFIED TUMOR FOCI OF RECURRENT COLORECTAL CARCINOMA.	HYBRITECH, INC. 11095 TORREYANNA RD. SAN DIEGO, CA 92121
GENERIC: INTERLEUKIN-2 POLYETHYLENE CONJUGATE; RECOMBINANT E. COLI TRADE: PEG-IL2	TREATMENT OF PRIMARY IMMUNODEFICIENCY DISEASE ASSOCIATED WITH T-CELL DEFECTS.	CETUS CORP. 1400 FIFTY-THIRD ST. EMERYVILLE, CA 94608
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-MY^9) TO MYELOID CELLS (CD-33) TRADE: ANTI-MY^9-BR	FOR USE IN THE EX VIVO TREATMENT OF AUTOLOGOUS BONE MARROW AND SUBSEQUENT REINFUSION IN PATIENTS WITH ACUTE MYELOGENOUS LEUKEMIA.	IMMUNOGEN, INC. 148 SIDNEY ST. CAMBRIDGE, MA 02139
GENERIC: TECELEUKIN TRADE: NOT ESTABLISHED	TREATMENT OF METASTATIC MALIGNANT MELANOMA.	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND ST. NUTLEY, NJ 07110
GENERIC: TECELEUKIN TRADE: NOT ESTABLISHED	TREATMENT OF METASTATIC RENAL CELL CARCINOMA.	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND ST. NUTLEY, NJ 07110

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: CROMOLYN SODIUM TRADE: GASTROCROM*/**	MASTOCYTOSIS. [DECEMBER 22, 1996]	FISONS CORP. 2 PRESTON CT. BEDFORD, MA 01730
GENERIC: DYNAMINE TRADE: NOT ESTABLISHED	TREATMENT OF LAMBERT-EATON MYASTHENIC SYNDROME.	MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH MAYO CLINIC AND FOUNDATION 200 S.W. 1ST AVE. ROCHESTER, MN 55905
GENERIC: GLYCEROL, 10% TRADE: NOT ESTABLISHED	TO DECREASE INTRACRANIAL HYPERTENSION AND/OR ALLEVIATE CEREBRAL EDEMA IN PATIENTS WHO MAY BENEFIT FROM OSMOTHERAPY.	CHUGAI PHARMACEUTICAL CO., LTD. 1-9, KYOBASHI 2-CHOME CHUO-KU, TOKYO 104, JAPAN
GENERIC: GONADORELIN ACETATE TRADE: LUTREPULSE*/**	TREATMENT OF PRIMARY HYPOTHALAMIC AMENORRHEA. [OCT 10, 1996]	R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE ROUTE 202, P.O. BOX 300 RARITAN, NJ 08869
GENERIC: RHEOTHRX TRADE: NOT ESTABLISHED	TREATMENT OF SEVERE BURNS IN HOSPITALIZED PATIENTS.	CYTRX CORP. 150 TECHNOLOGY PKWY. TECHNOLOGY PARK/ ATLANTA NORCROSS, GA 30092
GENERIC: SERMORELIN ACETATE [GRF(1-29)NH2] TRADE: GEREF	AS AN ADJUNT TO GONADOTROPIN THERAPY IN THE INDUCTION OF OVULATION IN WOMEN WITH ANOVULATORY OR OLIGO-OVULATORY INFERTILITY WHO FAIL TO OVULATE IN RESPONSE TO ADEQUATE TREATMENT WITH CLOMIPHENE CITRATE ALONE AND GONADOTROPIN THERAPY ALONE.	SERONO LABS. 100 LONGWATER CIRCLE NORWELL, MA 02061

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

NO FEBRUARY 1990 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, 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, 10TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO FEBRUARY 1990 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, 10TH 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
HYDROCORTISONE SOLUTION; TOPICAL	2.5%	89 P-0175/CP	GENDERM	NEW STRENGTH	APPROVED JAN 11, 1990
PENTAMIDINE ISETHIONATE INJECTABLE; INJECTION	100MG/ML (3ML/VIAL)	89 P-0435/CP	ASTRA PHARM PRODS	NEW DOSAGE FORM	APPROVED JAN 18, 1990
VERAPAMIL HYDROCHLORIDE TABLET, EXTENDED-RELEASE; ORAL	120MG	89 P-0220/CP	LEDERLE LABS	NEW STRENGTH	APPROVED JAN 11, 1990

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CLONIDINE HYDROCHLORIDE CAPSULE, EXTENDED-RELEASE; ORAL	0.2MG	88 P-0365/CP	BOEHR INGEL	NEW DOSAGE FORM	DENIED JAN 11, 1990

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, 10TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEUDLE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO ADDITIONS FOR FEBRUARY 1990

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
	19845 001	BETAXOLOL HYDROCHLORIDE; BETOPTIC S	4311708	JAN 19, 1999		NDF	DEC 29, 1992
	19880 001	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998			
	19880 002	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998			
	19880 003	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998			
>ADD>	19966 001	CLOBETASOL PROPIONATE; TEMOVATE	3721687	MAR 20, 1992		NDF	FEB 22, 1993
>ADD>						NCE	DEC 27, 1990
	19949 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000			
			4404216	SEP 13, 2000		NCE	JAN 29, 1995
	19949 002	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000			
			4404216	SEP 13, 2000		NCE	JAN 29, 1995
	19949 003	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000			
			4404216	SEP 13, 2000		NCE	JAN 29, 1995
	19950 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000			
			4404216	SEP 13, 2000		NCE	JAN 29, 1995
	18554 001	FLUTAMIDE; EULEXIN	4329364	MAY 11, 2001	U-23		
	19693 001	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000			
	19693 002	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000			
	19693 003	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000			
	18956 002	IOHEXOL; OMNIPAQUE 240	4021481	MAY 03, 1994			
	19907 001	METIPRANOLOL HYDROCHLOIDE; METIPRANOLOL HCL				NCE	DEC 29, 1994
	19786 001	METOPROLOL FUMARATE; LOPRESSOR	3916899	NOV 04, 1992			
			3845770	NOV 05, 1991			
	19786 002	METOPROLOL FUMARATE; LOPRESSOR	3916899	NOV 04, 1992			
			3845770	NOV 05, 1991			
	19786 003	METOPROLOL FUMARATE; LOPRESSOR	4892739	JAN 09, 2007			
			3916899	NOV 04, 1992			
			3845770	NOV 05, 1991			
	19786 004	METOPROLOL FUMARATE; LOPRESSOR	4892739	JAN 09, 2007			
			3916899	NOV 04, 1992			
			3845770	NOV 05, 1991			
>ADD>	19886 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1997		NCE	FEB 13, 1995
>ADD>	19951 001	ZIDOVUDINE; RETROVIR				NCE	MAR 19, 1992
>ADD>						ODE	MAR 19, 1994

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