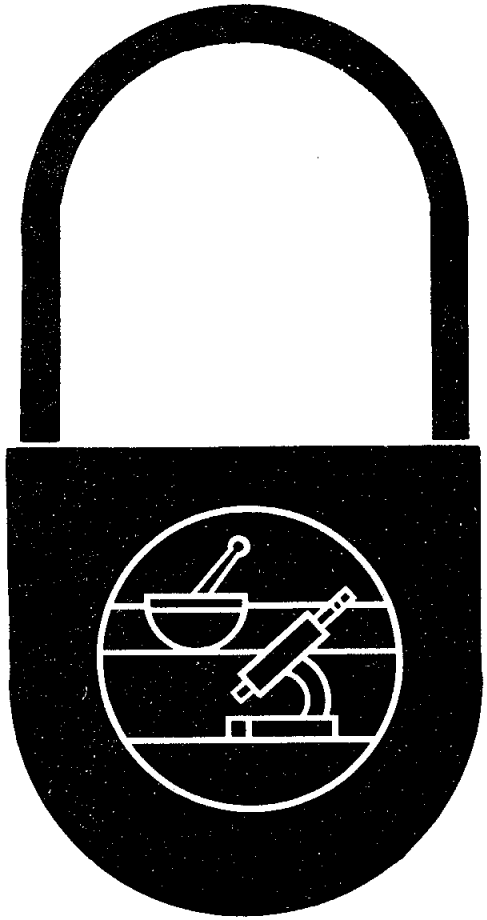
CUMULATIVE SUPPLEMENT 1
JAN '89



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

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with

THERAPEUTIC EQUIVALENCE EVALUATIONS

9TH EDITION

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JANUARY 1989

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9th EDITION

CUMULATIVE SUPPLEMENT 1

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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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

1.4 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1987) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

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

New Molecular Entity

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

COUNTS CUMULATIVE BY QUARTER[1]

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[2]	118 (1.1%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	374			

*This number is inclusive of products discontinued since December 1987, and any products approved or discontinued through December 1988.

[1]Cumulative counts are calculated from January 1, 1988 to, and including, the month indicated.
[2]Amino acid-containing products of varying composition (see Introduction, page 1-7 of the List).

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

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

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

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

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL

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

ALBUTEROL SULFATE

TABLET; ORAL

>ADD>		**ALBUTEROL SULFATE**		
>ADD>	AB	SIDMAK LABS	EQ 2MG BASE¤	N72316 001
>ADD>			DEC 05, 1989 : JAN 30, 1989	
>ADD>	AB		EQ 4MG BASE¤	N72317 001
>ADD>			DEC 05, 1989 : JAN 30, 1989	

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

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

AMINOPHYLLINE

TABLET; ORAL

		AMINOPHYLLINE		
>DLT>	/BB/	/CORD LABS/	/100MG/	/N85261/003/
>ADD>		∂ CORD LABS	100MG	N85261 003

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

		AMITRIPTYLINE HCL		
>DLT>	/AB/	/PBI/	/25MG/	/N87775/001/
>DLT>				/FEB/10,/1982/
>ADD>		∂ PBI	25MG	N87775 001
>ADD>				FEB 10, 1982

AMMONIUM LACTATE

LOTION; TOPICAL
LAC-HYDRIN

>DLT>		/BRISTOL/MYERS/	/EQ/12%/ACID/	/N19155/001/
>DLT>				/APR/24,/1985/
>ADD>		WESTWOOD PHARMS	EQ 12% ACID	N19155 001
>ADD>				APR 24, 1985

AMOXICILLIN

PDWDER FOR RECONSTITUTION; ORAL
AMOXICILLIN

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

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL AHD ATROPINE SULFATE

>DLT>/AA/		/LEDERLE/LABS/	/0.025MG;2.5MG/	/N86950/001/
>ADD>		ə LEDERLE LABS	0.025MG;2.5MG	N86950 001

DIPHENOXYLATE HCL W/ ATROPINE SULFATE

>DLT>/AA/		/PBI/	/0.025MG;2.5MG/	/N87842/001/
>DLT>				/MAR/29,/1982/
>ADD>		ə PBI	0.025MG;2.5MG	N87842 001
>ADD>				MAR 29, 1982

CEFADROXIL

CAPSULE; ORAL
CEFADROXIL

>ADD>	AB	PUREPAC PHARM	EQ 500MG BASE¤	N63017 001
>ADD>				JAN 05, 1989

>ADD> CEFPIRAMIDE SODIUM

INJECTABLE; INJECTION
CEFPIRAMIDE SODIUM

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

CEPHALEXIN

TABLET; ORAL
CEPHALEXIN

>ADD>	AB	BIOCRAFT LABS	EQ 250MG BASE¤	N63023 001
>ADD>				JAN 12, 1989
>ADD>	AB		EQ 500MG BASE¤	N63024 001
>ADD>				JAN 12, 1989

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

>DLT>/AA/		/LEDERLE/LABS/	/4MG/	/N86941/001/
>ADD>		ə LEDERLE LABS	4MG	N86941 001

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CHLORPHENIRAMINE MALEATE AHD PHENYLPROPANOLAMINE HCL

>ADD>	AB	CORD LABS	12MG;75MG¤	N88940 001
>ADD>				JAN 26, 1989

ORNADE

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

CHLORZOXAZONE

TABLET; DRAL
CHLORZOXAZOHE

>ADD>	AA	PIONEER PHARMS	250MG¤	N89592 001
>ADD>				JAN 06, 1989
>ADD>	AA		500MG¤	N89948 001
>ADD>				JAN 06, 1989

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL
CLINDAMYCIN PHOSPHATE

>ADD>	AT	COPLEY PHARM	EQ 1% BASE¤	N62944 001
>ADD>				JAN 11, 1989

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

> DLT >	/AB/	/LEDERLE/LABS/	/3.75MG/	/N72013/001/ /DEC/15,/1987/
> DLT >			/7.5MG/	/N72014/001/ /DEC/15,/1987/
> DLT >	/AB/		/15MG/	/N72015/001/ /DEC/15,/1987/
> ADD >		ə LEDERLE LABS	3.75MG	N72013 001 DEC 15, 1987
> ADD >		ə	7.5MG	N72014 001 DEC 15, 1987
> ADD >		ə	15MG	N72015 001 DEC 15, 1987

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL

DICYCLOMIHE HCL

> ADD >	AB	PIONEER PHARMS	10MG¤	N89361 001 JAN 10, 1989

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM SR

> ADD >		MARION LABS	60MG¤	N19471 001 JAN 23, 1989
> ADD >			90MG¤	N19471 002 JAN 23, 1989
> ADD >			120MG¤	N19471 003 JAN 23, 1989
> ADD >		ə	180MG¤	N19471 004 JAN 23, 1989

DIPHENHYDRAMINE HYDROCHLORIDE

ELIXIR; ORAL

DIPHENHYDRAMINE HCL

> DLT >	/AA/	/PRIVATE/FMLTNS/	/12.5MG/5ML/	/N85287/001/
> ADD >		ə PRIVATE FMLTNS	12.5MG/5ML	N85287 001

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOPAMINE HCL

> ADD >	AP	ABBOTT LABS	40MG/ML¤	N70656 001 JAN 24, 1989
> ADD >	AP		80MG/ML¤	N70657 001 JAN 24, 1989

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

ERGOLOID MESYLATES

> DLT >	/AA/	/LEDERLE/LABS/	/0.5MG/	/N86984/001/
> DLT >	/AA/		/1MG/	/N86985/001/
> ADD >		ə LEDERLE LABS	0.5MG	N86984 001
> ADD >		ə	1MG	N86985 001

FLUOCINONIDE

CREAM; TOPICAL

VASODERM E

> ADD >	AB	TJ ROACO	0.05%¤	N72494 001 JAN 19, 1989

FLUTAMIDE

CAPSULE; ORAL

EULEXIN

> ADD >		SCHERING	125MG¤	N18554 001 JAN 27, 1989

FOLIC ACID

TABLET; ORAL

FOLIC ACID

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

GEMFIBROZIL

CAPSULE; ORAL

LOPID

> DLT >		/PARKE/DAVIS/	/200MG/	/N18422/001/
> ADD >		ə PARKE DAVIS	200MG	N18422 001

GEMFIBROZIL

TABLET; ORAL
LOPID

> ADD >		PARKE DAVIS	600MG	N18422 003
> ADD >				NOV 20, 1986

HEPARIN SODIUM

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

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

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

> ADD >	AP	ABBOTT LABS	4,000 UNITS/100ML¤	N19805 001
> ADD >				JAN 25, 1989

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

> ADD >	AP	ABBOTT LABS	5,000 UNITS/100ML¤	N19805 002
> ADD >				JAN 25, 1989

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HCL

> DLT >	/AA/	/PBI/	/25MG/	/N87780/001/
> DLT >				/MAR/29,/1982/
> DLT >	/AA/		/50MG/	/N87751/001/
> DLT >				/MAR/29,/1982/
> ADD >		∂ PBI	25MG	N87780 001
> ADD >				MAR 29, 1982
> ADD >		∂	50MG	N87751 001
> ADD >				MAR 29, 1982

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

> DLT >	/AB/	/PBI/	/25MG/	/N87827/001/
> DLT >				/APR/19,/1982/
> DLT >	/AB/		/50MG/	/N87752/001/
> DLT >				/APR/19,/1982/
> ADD >		∂ PBI	25MG	N87827 001
> ADD >				APR 19, 1982
> ADD >		∂	50MG	N87752 001
> ADD >				APR 19, 1982

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
METHYLDOPA AND HYDROCHLOROTHIAZIDE

> ADD >	AB	DANBURY PHARMA	25MG;250MG¤	N70959 001
> ADD >				JAN 19, 1989
> ADD >	AB		30MG;500MG¤	N71069 001
> ADD >				JAN 19, 1989

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE

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

HYDROCORTISONE ACETATE

CREAM; TOPICAL
HYDROCORTISONE ACETATE

> ADD >	AT	PARKE DAVIS	1%¤	N89914 001
> ADD >				JAN 03, 1989

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL
IMIPRAMINE HCL

> DLT >	/AB/	/PBI/	/25MG/	/N87776/001/
> DLT >				/FEB/10,/1982/
> ADD >		∂ PBI	25MG	N87776 001
> ADD >				FEB 10, 1982

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
WELLCOVORIN

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

LEUPROLIDE ACETATE

INJECTABLE; INJECTION
LUPRON DEPOT

> ADD >		TAP PHARMS	7.5MG/VIAL¤	N19732 001	
> ADD >				JAN 26, 19B9	

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL

> ADD >	AP	BULL LABS	EQ 10MG BASE/2ML¤	N71990 001	
> ADD >				JAN 18, 19B9	

PANCURONIUM BROMIDE

INJECTABLE; INJECTION
PANCURONIUM BROMIDE

> ADD >	AP	ABBOTT LABS	1MG/ML¤	N72320 DD1	
> ADD >				JAN 19, 1989	
> ADD >	AP		2MG/ML¤	N72321 001	
> ADD >				JAN 19, 1989	

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
PRAZOSIN HCL

> ADD >	AB	DANBURY PHARMA	EQ 1MG BASE¤	N72352 001	
> ADD >			MAY 16, 1989 :	JAN 11, 1989	
> ADD >	AB		EQ 2MG BASE¤	N72333 001	
> ADD >			MAY 16, 1989 :	JAN 11, 1989	
> ADD >	AB		EQ 5MG BASE¤	N72609 001	
> ADD >			MAY 16, 1989 :	JAN 11, 1989	

PREDNISOLONE

SYRUP; ORAL
PRELONE

> ADD >		MURO PHARM	5MG/5ML¤	N89654 001	
> ADD >				JAN 17, 1989	

PREDNISONE

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

PREDNISONE

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

TABLET; ORAL
DELTASONE

> ADD >	AB	UPJOHN	50MG	N09986 008	
> DLT >	/BX/		/50MG/	/N09986 008/	

PREDNISONE

> ADD >	AB	CORD LABS	10MG¤	N89983 001	
> ADD >				JAN 12, 1989	
> ADD >	AB		50MG¤	N89984 001	
> ADD >				JAN 12, 1989	

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

> DLT >	/AB/	/LEDERLE LABS/	/10MG/	/N72117 001/	
> DLT >				/JUN 23, 1988/	
> DLT >	/AB/		/20MG/	/N72118 001/	
> DLT >				/JUN 23, 1988/	
> DLT >	/AB/		/40MG/	/N72119 001/	
> DLT >				/JUN 23, 1988/	
> DLT >	/AB/		/80MG/	/N72120 001/	
> DLT >				/JUN 23, 1988/	
> ADD >		∂ LEDERLE LABS	10MG	N72117 001	
> ADD >				JUN 23, 1988	
> ADD >		∂	20MG	N72118 001	
> ADD >				JUN 23, 1988	
> ADD >		∂	40MG	N72119 001	
> ADD >				JUN 23, 1988	
> ADD >		∂	80MG	N72120 001	
> ADD >				JUN 23, 1988	

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

> DLT >	/AB/	/PBI/	/200MG/	/N87837 001/	
> DLT >				/APR 14, 1982/	
> ADD >		∂ PBI	200MG	N87837 001	
> ADD >				APR 14, 1982	

SINCALIDE

INJECTABLE; INJECTION
KINEVAC

>DLT >		/SQUIBB/	/0.005MG/VIAL/		/N17697/001/
>ADD >		SQUIBB DIAGS	0.005MG/VIAL		N17697 001

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE

>ADD >	AA	CAROLINA MED	454GM/BOT¤		N89910 001
>ADD >					JAN 19, 1989

TIMOLOL MALEATE

TABLET; ORAL
BLOCADREN

>ADD >	AB	MS&D	5MG		N18017 001
>ADD >	AB		10MG		N18017 002
>ADD >	AB		20MG		N18017 004
>ADD >		**TIMOLOL MALEATE**			
>ADD >	AB	PBI	5MG¤		N72001 001
>ADD >				APR 11, 1989 :	JAN 10, 1989
>ADD >	AB		10MG¤		N72002 001
>ADD >				APR 11, 1989 :	JAN 10, 1989
>ADD >	AB		20MG¤		N72003 001
>ADD >				APR 11, 1989 :	JAN 10, 1989

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL

>ADD >	AB	SIDMAK LABS	80MG¤		N72124 001
>ADD >					JAN 26, 1989
>ADD >	AB		120MG¤		N72125 001
>ADD >					JAN 26, 1989

ACETAMINOPHEN

SUPPOSITORY; RECTAL

ACEPHEN

>_ADD_>	@ G&W LABS	325MG	N18060 003
>_ADD_>			DEC 18, 1986

IBUPROFEN

TABLET; ORAL

IBUPROFEN

>_ADD_>	MUTUAL PHARM	200MG	N72249 001
>_ADD_>			JAN 10, 1989

DRUG PRODUCTS IN THE DIVISION OF BLOOD AND BLOOD PRODUCTS / CUMULATIVE SUPPLEMENT NUMBER 1 / JAN'89 - JAN'89
APPROVED UNDER SECTION 505 OF THE ACT LIST

NO JANUARY 1989 APPROVALS

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

SECTION 526 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT CONTAINS PROVISIONS WHEREBY FDA MAY DESIGNATE A SPONSOR'S DRUG, ANTIBIOTIC, OR BIDLOGICAL 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 JANUARY 1989 APPROVALS

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.

NO JANUARY 1989 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, 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

NO JANUARY 1989 APPROVALS NOR DENIALS

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

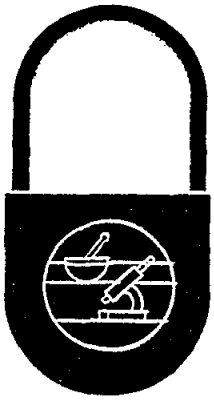
U-42 METHOD FOR TREATING PROSTATE ADENOCARCINOMA COMPRISING ADMINISTERING AN ANTIANDROGEN INCLUDING FLUTAMIDE AND AN LHRH AGONIST

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>	19471 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
>ADD>						NP	JAN 23, 1992
>ADD>	19471 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
>ADD>						NP	JAN 23, 1992
>ADD>	19471 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
>ADD>						NP	JAN 23, 1992
>ADD>	19471 004	DILTIAZEM HYDRDCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
>ADD>						NP	JAN 23, 1992
>ADD>	18554 001	FLUTAMIDE; EULEXIN	4474813	NOV 30, 1993		NCE	JAN 27, 1994
>ADD>			4472382	SEP 18, 2001	U-42		
>ADD>			4329364	MAY 11, 1999	U-41		
>ADD>	18422 001	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
>ADD>	18422 002	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
>ADD>	18422 003	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
>ADD>	19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4005063	JAN 25, 1996		NCE	APR 09, 1990
>ADD>						NP	JAN 26, 1992
>DLT>	19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 1989		NCE	MAR 01, 1993
>ADD>	19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 2000		NCE	MAR 01, 1993
>DLT>	18963 001	TECHNETIUM TC-99M MEBROFENIN KIT; CHOLETEC	4418208	JAN 21, 2001		NCE	JAN 21, 1992
>ADD>	18963 001	TECHNETIUM TC-99M MEBROFENIN KIT; CHOLETEC	4418208	JAN 21, 2001		NCE	JAN 21, 1992

Available in March 1989

New 9th Edition



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WITH
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