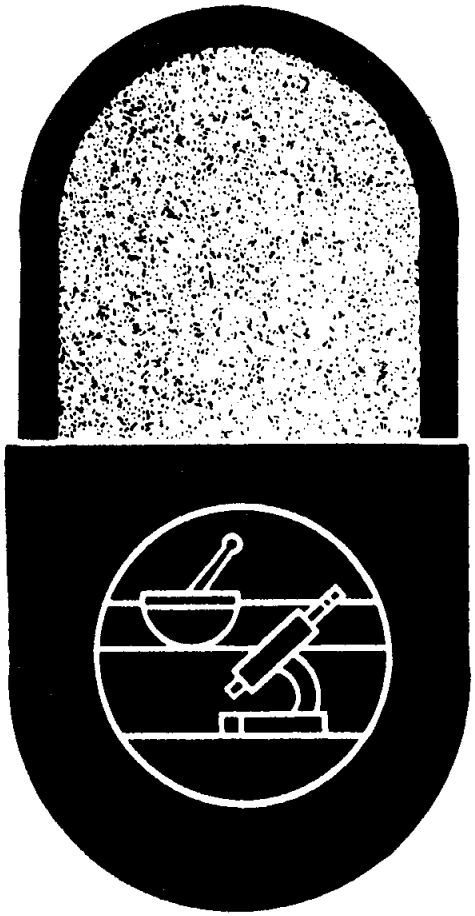
CUMULATIVE SUPPLEMENT 4
JAN'89-APR'89



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 DF MANAGEMENT

APPROVED DRUG PRODUCTS

with

THERAPEUTIC EQUIVALENCE EVALUATIONS

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CUMULATIVE SUPPLEMENT 4

APRIL 1989

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.

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

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

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

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

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

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

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

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

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

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

1.3 APPLICANT (NAME) CHANGES

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

APPLICANT (NAME) CHANGES

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

1.4 CORRECTIONS TO THE 9TH EDITION

a. The locator tabs for the "OTC Drug Product List" and the "Product Name Index Listed by Applicant" were not printed within the List.

b. The locator tab for the "Drug Products Which Must Demonstrate *in vivo* Bioavailability Only If Product Fails to Achieve Adequate Dissolution" is placed incorrectly within the List.

c. On page 3-374, "ANDA Suitability Petitions," the heading "Petitions Approved" should read "Petitions Denied."

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

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

DEFINITIONS

Drug Product

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

New Molecular Entity

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

COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 1988	MAR 1989	JUN 1989	SEP 1989
DRUG PRODUCTS LISTED	10091	10157		
SINGLE SOURCE	1983 (19.7%)	1993 (19.6%)		
MULTISOURCE	8108 (80.3%)	8164 (80.4%)		
THERAPEUTICALLY EQUIVALENT	7242 (71.8%)	7321 (72.1%)		
NOT THERAPEUTICALLY EQUIVALENT	748 (7.4%)	726 (7.1%)		
EXCEPTIONS[1]	118 (1.1%)	117 (1.2%)		
NEW MOLECULAR ENTITIES APPROVED	--	3		
NUMBER OF APPLICANTS	374	393		

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

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

>ADD>		ROXANE LABS	500MG;15MG℠	N89511 001 APR 25, 1989
>ADD>			500MG;30MG℠	N89512 001 APR 25, 1989
>ADD>			500MG;60MG℠	N89513 001 APR 25, 1989

ACETAMINOPHEN W/ CODEINE PHOSPHATE

/AA/	/PBI/		/300MG;30MG/	/N87919/001/ /JUN/22,/1982/
/AA/			/300MG;60MG/	/N87920/001/ /JUN/22,/1982/
	a PBI		300MG;30MG	N87919 001 JUN 22, 1982
	a		300MG;60MG	N87920 001 JUN 22, 1982
>DLT>/AA/	/WHITE/TN/PAULSN/		/300MG;30MG/	/N84360/001/
/AA/			/300MG;60MG/	/N85607/001/
>AOD>	a WHITE TN PAULSN		300MG;30MG	N84360 001
	a		300MG;60MG	N85607 001
	/PAPA-DEINE #3/			
/AA/	/VANGARD/LABS/		/300MG;30MG/	/N88037/001/ /MAR/20,/1984/
	a VANGARD LABS		300MG;30MG	N88037 001 MAR 20, 1984
	/PAPA-DEINE #4/			
/AA/	/VANGARD/LABS/		/300MG;60MG/	/N88715/001/ /MAR/20,/1984/
	a VANGARD LABS		300MG;60MG	N88715 001 MAR 20, 1984

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

ALLAY

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

ACETAMINOPHEN; OXYCDDONE HYDROCHLORIDE

TABLET; ORAL

OXYCODONE 5/APAP 500

AA	DUPONT PHARMS	500MG;5MG	N85911 001

ROXICET 5/500

AA	ROXANE LABS	500MG;5MG℠	N89775 001 JAN 12, 1989

ACETAZOLAMIOE

TABLET; ORAL

ACETAZOLAMIDE

/AA/	/VANGARD/LABS/		/250MG/	/N87654/001/ /FEB/05,/1982/
	a VANGARO LABS		250MG	N87654 001 FEB 05, 1982

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

AB	AM THERPTCS	EQ 2MG BASE℠	N72449 001 DEC 05, 1989 : FEB 01, 1989
AB		EQ 4MG BASE℠	N72450 001 DEC 05, 1989 : FEB 01, 1989
>AOD> AB	BIOCRAFT LABS	EQ 2MG BASE℠	N72619 001 OEC 05, 1989 : APR 07, 1989
>ADD>			
>ADO> AB		EQ 4MG BASE℠	N72620 001 DEC 05, 1989 : APR 07, 1989
>ADD>			
AB	CORD LABS	EQ 2MG BASE℠	N72151 001 DEC 05, 1989 : MAR 23, 1989
AB		EQ 4MG BASE℠	N72152 001 DEC 05, 1989 : MAR 23, 1989
AB	MUTUAL PHARM	EQ 2MG BASE℠	N72636 001 DEC 05, 1989 : FEB 01, 1989
AB		EQ 4MG BASE℠	N72637 001 DEC 05, 1989 : FEB 01, 1989
AB	SIOMAK LABS	EQ 2MG BASE℠	N72316 001 DEC 05, 1989 : JAN 30, 1989
AB		EQ 4MG BASE℠	N72317 001 DEC 05, 1989 : JAN 30, 1989

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

TRAVASOL 2.75% IN DEXTROSE 10% IN PLASTIC CONTAINER		
BAXTER	2.75%;10GM/100ML	N19520 002 SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 15% IN PLASTIC CONTAINER		
BAXTER	2.75%;15GM/100ML	N19520 003 SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 20% IN PLASTIC CONTAINER		
BAXTER	2.75%;20GM/100ML	N19520 004 SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 25% IN PLASTIC CONTAINER		
BAXTER	2.75%;25GM/100ML	N19520 005 SEP 23, 1988

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

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

AMINOPHYLLINE

TABLET; ORAL

	AMINOPHYLLINE			
BO	CORD LABS	100MG	N85261 003	
a	CORD LABS	100MG	N85261 003	

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

	AMITRIPTYLINE HCL			
AB	PBI	25MG	N87775 001	FEB 10, 1982
AB	ROXANE LABS	10MG	N86144 001	
AB		25MG	N86145 001	
AB		50MG	N86143 001	
AB		75MG	N86147 001	
AB		100MG	N86146 001	
AB		150MG	N86148 001	
a	ROXANE LABS	10MG	N86144 001	
a		25MG	N86145 001	
a		50MG	N86143 001	
a		75MG	N86147 001	
a		100MG	N86146 001	
a		150MG	N86148 001	

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

	AMITRIPTYLINE HCL			
AB	VANGARD LABS	10MG	N87632 001	FEB 01, 1982
AB		25MG	N87570 001	FEB 08, 1982
AB		50MG	N87616 001	FEB 08, 1982
AB		75MG	N87617 001	FEB 05, 1982
AB		100MG	N87639 001	FEB 08, 1982
a	VANGARD LABS	10MG	N87632 001	FEB 01, 1982
a		25MG	N87570 001	FEB 08, 1982
a		50MG	N87616 001	FEB 08, 1982
a		75MG	N87617 001	FEB 05, 1982
a		100MG	N87639 001	FEB 08, 1982

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

	PERPHENAZINE AND AMITRIPTYLINE HCL			
AB	DANBURY PHARMA	10MG;2MG	N72539 001	FEB 15, 1989
AB		10MG;4MG	N72540 001	FEB 15, 1989
AB		25MG;2MG	N72541 001	FEB 15, 1989
AB		25MG;4MG	N72134 001	FEB 15, 1989
AB		50MG;4MG	N72135 001	FEB 15, 1989

AMMONIUM LACTATE

LOTION; TOPICAL

	LAC-HYDRIN			
	BRISTOL/MYERS	EQ 12% ACID	N19155 001	APR 24, 1985
	WESTWOOD PHARMS	EQ 12% ACID	N19155 001	APR 24, 1985

AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

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

POWDER FOR RECONSTITUTION; ORAL
AMOXICILLIN

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

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL
AMPICILLIN

AB	CLONMEL CHEMS	EQ 125MG BASE/5ML*	N62982 001 FEB 10, 1989
AB		EQ 250MG BASE/5ML*	N62982 002 FEB 10, 1989

/TABLET;CHEWABLE;ORAL/
/POLYCILLIN/

	/BRISTOL LABS/	/EQ 125MG BASE/	/N50093 001/
	a BRISTOL LABS	EQ 125MG BASE	N50093 001

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL
BUTALBITAL W/ ASPIRIN & CAFFEINE

>DLT >	/AB/	/BOOTS LABS/	/325MG;50MG;40MG/	/N87048 002/ /DEC 09, 1983/
>DLT >				
>ADD >	AB	PHARMAFAIR	325MG;50MG;40MG	N87048 002 DEC 09, 1983
>ADD >				

ASPIRIN; CARISOPRODOL

TABLET; ORAL
CARISOPRODOL AND ASPIRIN

AB	PAR PHARM	325MG;200MG*	N89594 001 MAR 31, 1989

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE

/AA/	/LEDERLE LABS/	/0.025MG;2.5MG/	/N86950 001/
	a LEDERLE LABS	0.025MG;2.5MG	N86950 001

DIPHENOXYLATE HCL W/ ATROPINE SULFATE

/AA/	/PBI/	/0.025MG;2.5MG/	/N87842 001/ /MAR 29, 1982/
	a PBI	0.025MG;2.5MG	N87842 001 MAR 29, 1982

/LO-TROL/

/AA/	/VANGARD LABS/	/0.025MG;2.5MG/	/N88009 001/ /MAR 25, 1983/
	a VANGARD LABS	0.025MG;2.5MG	N88009 001 MAR 25, 1983

BENZONATATE

CAPSULE; ORAL
TESSALON

/DUPONT PHARMS/	/100MG/	/N11210 001/
FOREST LABS	100MG	N11210 001

BENZTROPINE MESYLATE

TABLET; ORAL
BENZTROPINE MESYLATE

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

BETHANECHOL CHLORIDE

TABLET; ORAL
BETHANECHOL CHLORIDE

>OLT >	/AA/	/CHELSEA LABS/	/5MG/	/N85841 001/
>AOD >		a CHELSEA LABS	5MG	N85841 001

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER

> ADD >	AP	BAXTER	200MG/100ML	N19837 002
> ADD >				APR 12, 1989
> ADD >	AP		400MG/100ML	N19837 001
> ADD >				APR 12, 1989

BROMPHENIRAMINE MALEATE

ELIXIR; ORAL

BROMPHENIRAMINE MALEATE

> DLT >	/AA/	/PBI/	/2MG/5ML/	/N87964/001/
> DLT >				/JAN/25/1983/
> ADD >		∂ PBI	2MG/5ML	N87964 001
> ADD >				JAN 25, 1983

TABLET; ORAL

BROMPHENIRAMINE MALEATE

> DLT >	/AA/	/CHELSEA LABS/	/4MG/	/N85769/001/
> ADD >		∂ CHELSEA LABS	4MG	N85769 001

BUTABARBITAL SODIUM

TABLET; ORAL

BUTABARBITAL SODIUM

/AA/		/WHITE TN PAULSN/	/30MG/	/N83337/001/
		∂ WHITE TN PAULSN	30MG	N83337 001

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

AT		BAXTER	18.3MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML	N17512 004
/AT/			/25.7MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML/	/N17512/004/

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION

LACTATED RINGER'S IN PLASTIC CONTAINER

/AP/		/CUTTER BIOL/	/20MG/100ML;30MG/100ML;600MG/100ML; 310MG/100ML/	/N18417/001/
		∂ CUTTER BIOL	20MG/100ML;30MG/100ML;600MG/100ML; 310MG/100ML	N18417 001

CARBOPLATIN

INJECTABLE; INJECTION

PARAPLATIN

	BRISTOL MYERS	50MG/VIAL	N19880 001
			MAR 03, 1989
		150MG/VIAL	N19880 002
			MAR 03, 1989
		450MG/VIAL	N19880 003
			MAR 03, 1989

/CARBOPROST/

/INJECTABLE;INJECTION/

/PROSTIN/15M/

	/UPJOHN/	/EQ 0.25MG BASE/ML/	/N17989/001/

CARBOPROST TROMETHAMINE

INJECTABLE; INJECTION

HEBAMATE

	UPJOHN	EQ 0.25MG BASE/ML	N17989 001

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

> ADD >	AA	CORD LABS	350MG	N81025 001
> ADD >				APR 13, 1989

CEFADROXIL

CAPSULE; ORAL

CEFADROXIL

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

CEFADROXIL

POWDER FOR RECONSTITUTION; ORAL

CEFADROXIL

AB	BIOCRAFT LABS	EQ 125MG BASE/5ML*	N62698 001	MAR 01, 1989
AB		EQ 250MG BASE/5ML*	N62698 002	MAR 01, 1989
AB		EQ 500MG BASE/5ML*	N62698 003	MAR 01, 1989

ULTRACEF

AB	BRISTOL LABS	EQ 125MG BASE/5ML	N62334 001	
AB		EQ 125MG BASE/5ML	N62376 001	MAR 16, 1982
AB		EQ 250MG BASE/5ML	N62334 002	
AB		EQ 250MG BASE/5ML	N62376 002	MAR 16, 1982

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

AP	TAG PHARMS	EQ 250MG BASE/VIAL*	N63016 001	MAR 14, 1989
AP		EQ 500MG BASE/VIAL*	N63016 002	MAR 14, 1989
AP		EQ 1GM BASE/VIAL*	N63016 003	MAR 14, 1989

>ADD> CEFIXIME

>ADD> POWDER FOR RECONSTITUTION; ORAL

>ADD> SUPRAX

>ADD>	LEDERLE LABS	100MG/5ML*	N50622 001 APR 28, 1989

>ADD> TABLET; ORAL

>ADD> SUPRAX

>ADD>	LEDERLE LABS	200MG*	N50621 001 APR 28, 1989
>ADD>		400MG*	N50621 002 APR 28, 1989

CEFPIRAMIDE SODIUM

INJECTABLE; INJECTION

CEFPIRAMIDE SODIUM

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

>ADD> CEFTAZIDIME SODIUM

>ADD> INJECTABLE; INJECTION

>ADD> FORTAZ IN PLASTIC CONTAINER

>ADD>	GLAXO	EQ 1OMG BASE/ML*	N50634 001 APR 28, 1989
>ADD>		EQ 2OMG BASE/ML*	N50634 002 APR 28, 1989
>ADD>		EQ 4OMG BASE/ML*	N50634 003 APR 28, 1989

CEFUROXIME SODIUM

INJECTABLE; INJECTION

>ADD> ZINACEF IN PLASTIC CONTAINER

>ADD>	GLAXO	EQ 15MG BASE/ML*	N50643 001 APR 28, 1989
>ADD>		EQ 30MG BASE/ML*	N50643 002 APR 28, 1989

CEPHALEXIN

TABLET; ORAL

CEPHALEXIN

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

CERULETIDE DIETHYLAMINE

/INJECTABLE;/INJECTION/

/TYMTRAN/

/ADRIA/LABS/	/0.02MG/ML/	/N18296/001/
@ ADRIA LABS	0.02MG/ML	N18296 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

/AB/	/VANGARD/LABS/	/5MG/	/N88129/001/ /MAR/28,/1983/
/AB/		/10MG/	/N88010/001/ /MAR/28,/1983/
/AB/		/25MG/	/N88130/001/ /MAR/28,/1983/
	a VANGARD LABS	5MG	N88129 001 MAR 28, 1983
	a	10MG	N88010 001 MAR 28, 1983
	a	25MG	N88130 001 MAR 28, 1983

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

>DLT >/AA/	/CHELSEA/LABS/	/4MG/	/N85139/001/
>ADD >	a CHELSEA LABS	4MG	N85139 001
/AA/	/LEDERLE/LABS/	/4MG/	/N86941/001/
	a LEDERLE LABS	4MG	N86941 001

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CHLORPHENIRAMINE MALEATE AND PHENYLPROPANOLAMINE HCL

AB	CORD LABS	12MG;75MG[CR]	N88940 001 JAN 26, 1989

ORNADE

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

CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL

TUSSIONEX

	FISONS	EQ 8MG MALEATE/5ML; EQ 10MG BITARTRATE/5ML	N19111 001 DEC 31, 1987
	/PENNWALT/	/EQ/8MG/MALEATE/5ML;/ /EQ/10MG/BITARTRATE/5ML/	/N19111/001/ /DEC/31,/1987/

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL

CHLORPROMAZINE HCL

/BP/	/VANGARD/LABS/	/10MG/	/N88038/001/ /AUG/16,/1982/
/BP/		/25MG/	/N87645/001/
/BP/		/50MG/	/N87646/001/
	a VANGARD LABS	10MG	N88038 001 AUG 16, 1982
	a	25MG	N87645 001
	a	50MG	N87646 001

CHLORTHALIDONE

TABLET; ORAL

CHLORTHALIDONE

/AB/	/VANGARD/LABS/	/25MG/	/N88012/001/ /JUL/14,/1982/
/AB/		/50MG/	/N88073/001/ /MAR/25,/1983/
	a VANGARD LABS	25MG	N88012 001 JUL 14, 1982
	a	50MG	N88073 001 MAR 25, 1983

CHLORZOXAZONE

TABLET; ORAL

CHLORZOXAZONE

/AA/	/CHELSEA/LABS/	/250MG/	/N86948/001/ /AUG/09,/1982/
	a CHELSEA LABS	250MG	N86948 001 AUG 09, 1982
AA	PIONEER PHARMS	250MG[CR]	N89592 001 JAN 06, 1989
AA		500MG[CR]	N89948 001 JAN 06, 1989

CHYMOPAPAIN

INJECTABLE; INJECTION

CHYMODIACTIN

	/BAXTER/	/4,000/UNITS/VIAL/	/N18663/002/ /AUG/21,/1984/
		/10,000/UNITS/VIAL/	/N18663/001/ /NOV/10,/1982/

CHYMOPAPAIN

INJECTABLE; INJECTION
CHYMODIACTIN

BOOTS (USA)	4,000 UNITS/VIAL	N18663 002 AUG 21, 1984	> ADD >	
	10,000 UNITS/VIAL	N18663 001 NOV 10, 1982		
/DISEASE/ /BOOTS/PHARMS/	/12,500/UNITS/VIAL/	/N18625/001/ /JAN/18,/1984/		
ə BOOTS PHARMS	12,500 UNITS/VIAL	N18625 001 JAN 18, 1984	> OLT >	

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

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

SOLUTION; TOPICAL
CLINDAMYCIN PHOSPHATE

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

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM

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

CLOXACILLIN SODIUM

POWDER FOR RECONSTITUTION; ORAL
CLOXACILLIN SODIUM

AA	NOVOPHARM	EQ 125MG BASE/5ML	N62978 001 APR 06, 1989	> ADD >

COBALT CHLORIDE, CO-60; CYANOCOBALAMIN; CYANOCOBALAMIN, CO-60; INTRINSIC FACTOR

/N/A;/N/A/ /RUBRATOPE-60/KIT/ /SQUIBB/		/N/A;N/A;N/A;N/A/	/N16090/001/	> OLT > > DLT > > DLT >
ə SQUIBB		N/A;N/A;N/A;N/A	N16090 001	> ADD >

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE

/BP/	/WHITE/TN/PAULSN/	/25MG/	/N80341/001/	> DLT >
ə WHITE TN PAULSN		25MG	N80341 001	> ADD >

CYANOCOBALAMIN

INJECTABLE; INJECTION
/REDACTED/

/AP/	/MS&D/	/1MG/ML/	/N06668/010/	
ə MS&D		1MG/ML	N06668 010	
/VI-TWEL/				
/AP/	/BERLEX/LABS/	/1MG/ML/	/N07012/002/	
ə BERLEX LABS		1MG/ML	N07012 002	

DEMECLOCYCLINE HYDROCHLORIDE

/SYRUP;/ORAL/ /DECLOMYCIN/ /LEDERLE/LABS/		/75MG/5ML/	/N50257/001/	
ə LEDERLE LABS		75MG/5ML	N50257 001	

DEXAMETHASONE

TABLET; ORAL
DEXAMETHASONE

/BP/	/CHELSEA/LABS/	/1.5MG/	/N85840/001/	> DLT >
ə CHELSEA LABS		1.5MG	N85840 001	> ADD >

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION

>DLT>		CARDIOGRAFIN			
>DLT>		SQUIBB	85%		N11620 002
>ADD>		SQUIBB	85%		N11620 002

DIAZEPAM

TABLET; ORAL

DIAZEPAM

>ADD>	AB	MARTEC PHARM	10MG	N72402 001
>ADD>				APR 25, 1989

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL

DICYCLOMINE HCL

	AB	PIONEER PHARMS	10MG	N89361 001
				JAN 10, 1989

DIETHYLCARBAMAZINE CITRATE

TABLET; ORAL

HETRAZAN

	LEDERLE LABS	50MG	N06459 001

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM SR

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

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

	AA	VANGARD LABS	25MG	N88034 001
				OCT 27, 1982
	AA		50MG	N87630 001
	AA	WHITE TN PAULSN	50MG	N88080 001
		∂ WHITE TN PAULSN	50MG	N88080 001

ELIXIR; ORAL

>DLT>		DIPHEN		
>DLT>	AA	PBI	12.5MG/5ML	N84640 001
>ADD>		∂ PBI	12.5MG/5ML	N84640 001

DIPHENHYDRAMINE HCL

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

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOPAMINE HCL

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

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

DOXEPIN HCL

	AB	QUANTUM PHARMCS	EQ 100MG BASE	N72375 001
				MAR 15, 1989
	AB		EQ 150MG BASE	N72376 001
				MAR 15, 1989

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ADRIAMYCIN PFS

	AP	ADRIA LABS	2MG/ML	N50629 001
				DEC 23, 1987
	AP		2MG/ML	N50629 002
				MAY 03, 1988

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ADRIAMYCIN RDF

AP	ADRIA LABS	10MG/VIAL	N50467 001	
AP		20MG/VIAL	N50467 003	
			MAY 20, 1985	
AP		50MG/VIAL	N50467 002	

DOXORUBICIN HCL

AP	CETUS BEN VENUE	2MG/ML*	N62975 001	
			MAR 17, 1989	
AP		10MG/VIAL*	N62921 001	
			MAR 17, 1989	
AP		20MG/VIAL*	N62921 002	
			MAR 17, 1989	
AP		50MG/VIAL*	N62921 003	
			MAR 17, 1989	

RUBEX

>ADD > AP	BRISTOL MYERS USP&NG	10MG/VIAL*	N62926 001	
>ADD >			APR 13, 1989	
>ADD > AP		50MG/VIAL*	N62926 002	
>ADD >			APR 13, 1989	
>ADD >		100MG/VIAL*	N62926 003	
>ADD >			APR 13, 1989	

DOXYCYCLINE HYCLATE

INJECTABLE; INJECTION

DOXYCYCLINE HYCLATE

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

DROPERIDOL; FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE AND DROPERIDOL

>ADD > AP	ASTRA PHARM PRDDS	2.5MG/ML;		
>ADD >		EQ 0.05MG BASE/ML*	N72026 001	
>ADD >			APR 13, 1989	
>ADD > AP		2.5MG/ML;		
>ADD >		EQ 0.05MG BASE/ML*	N72027 001	
>ADD >			APR 13, 1989	
>ADD > AP		2.5MG/ML;		
>ADD >		EQ 0.05MG BASE/ML*	N72028 001	
>ADD >			APR 13, 1989	

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

ERGOLOID MESYLATES

/AA/	/LEDERLE/LABS/	/0.5MG/	/N86984/001/	
/AA/		/1MG/	/N86985/001/	
	a LEDERLE LABS	0.5MG	N86984 001	
	a	1MG	N86985 001	
/AA/	/VANGARD/LABS/	/0.5MG/	/N88013/001/	
			/SEP/20,/1982/	
/AA/		/1MG/	/N88014/001/	
			/SEP/20,/1982/	
	a VANGARD LABS	0.5MG	N88013 001	
			SEP 20, 1982	
	a	1MG	N88014 001	
			SEP 20, 1982	

ESTROGENS, CONJUGATED

TABLET; ORAL

CONJUGATED ESTROGENS

>ADD > BP	CHELSEA LABS	0.625MG	N85800 001	
>ADD > BP		1.25MG	N85801 001	
>ADD > BP		2.5MG	N85826 001	
>DLT > /B$/		/0.625MG/	/N85800/001/	
>DLT > /B$/		/1.25MG/	/N85801/001/	
>DLT > /B$/		/2.5MG/	/N85826/001/	
>ADD > BP	DURAMED PHARMS	0.3MG	N86492 001	
>ADD > BP		0.625MG	N83272 001	
>ADD > BP		1.25MG	N83294 001	
>ADD > BP		2.5MG	N83295 001	
>DLT > /B$/		/0.3MG/	/N86492/001/	
>DLT > /B$/		/0.625MG/	/N83272/001/	
>DLT > /B$/		/1.25MG/	/N83294/001/	
>DLT > /B$/		/2.5MG/	/N83295/001/	
>ADD > BP	ZENITH LABS	0.3MG	N88569 001	
>ADD >			NOV 29, 1984	
>ADD > BP		0.625MG	N83373 001	
>ADD > BP		1.25MG	N83601 001	
>ADD > BP		2.5MG	N83602 001	
>DLT > /B$/		/0.3MG/	/N88569/001/	
>DLT >			/NOV/29,/1984/	
>DLT > /B$/		/0.625MG/	/N83373/001/	
>DLT > /B$/		/1.25MG/	/N83601/001/	
>DLT > /B$/		/2.5MG/	/N83602/001/	

ESTROGENS, CONJUGATED

TABLET; ORAL
PREMARIN

> ADD >	BP	WYETH AYERST LABS	0.3MG	N04782 003	
> ADD >	BP		0.625MG	N04782 004	
> ADD >	BP		1.25MG	N04782 001	
> ADD >	BP		2.5MG	N04782 002	
> DLT >	/BP/		/0.3MG/	/N04782/003/	
> DLT >	/BP/		/0.625MG/	/N04782/004/	
> DLT >	/BP/		/0.9MG/	/N04782/005/	
> DLT >				/JAN/26/1984/	
> DLT >	/BP/		/1.25MG/	/N04782/001/	
> DLT >	/BP/		/2.5MG/	/N04782/002/	
> ADD >			0.9MG	N04782 005	
> ADD >				JAN 26, 1984	

ESTROGENS, ESTERIFIED

TABLET; ORAL
FEMOGEN

/BP/	/PRIVATE/FMLTNS/	/2.5MG/	/N85007/001/	
	@ PRIVATE FMLTNS	2.5MG	N85007 001	

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORCEPT-E 1/35 21

AB	GYNOPHARMA	0.035MG;1MG	N71545 001	
			FEB 09, 1989	

TABLET; ORAL-28
NORCEPT-E 1/35 28

AB	GYNOPHARMA	0.035MG;1MG	N71546 001	
			FEB 09, 1989	

FERROUS CITRATE, FE-59

> DLT >	/INJECTABLE;/INJECTION/			
> DLT >	/FERROUS/CITRATE/FE/59/			
> DLT >	/MALLINCKRODT/	/25/UCI/ML/	/N16729/001/	
> ADD >	@ MALLINCKRODT	25 UCI/ML	N16729 001	

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE

AB	LEMMON	0.05%	N72488 001	
			FEB 06, 1989	
AB		0.05%	N72490 001	
			FEB 07, 1989	

VASODERM E

AB	TJ ROACO	0.05%	N72494 001	
			JAN 19, 1989	

GEL; TOPICAL
FLUOCINONIDE

AB	LEMMON	0.05%	N72537 001	
			FEB 07, 1989	

LIDEX

AB	SYNTEX LABS	0.05%	N17373 001	

SOLUTION; TOPICAL
FLUOCINONIDE

AT	LEMMON	0.05%	N72511 001	
			FEB 07, 1989	

FLUOXYMESTERONE

TABLET; ORAL
ANDROID-F

> DLT >	/BP/	/BROWN/PHARM/	/10MG/	/N87196/001/
> ADD >	BP	ICN PHARMS	10MG	N87196 001
		FLUOXYMESTERONE		
> DLT >	/BP/	/BROWN/PHARM/	/10MG/	/N88221/001/
> DLT >				/MAY/05/1983/
> ADD >	BP	ICN PHARMS	10MG	N88221 001
> ADD >				MAY 05, 1983

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL

AB	CHELSEA LABS	15MG	N72368 001	
			MAR 30, 1989	
AB		30MG	N72369 001	
			MAR 30, 1989	

FLUTAMIDE

CAPSULE; ORAL
EULEXIN
SCHERING 125MG¤ N18554 001
JAN 27, 1989

FOLIC ACID

TABLET; ORAL
FOLIC ACID
/AA/ /PBI/ /1MG/ /N87828/001/
/MAY/13,/1982/
ə PBI 1MG N87828 001
MAY 13, 1982
>DLT >/AA/ /VANGARD/LABS/ /1MG/ /N88730/001/
>DLT > /MAR/23,/1984/
>ADD > ə VANGARD LABS 1MG N88730 001
>ADD > MAR 23, 1984
/AA/ /WHITE/TN/PAULSN/ /1MG/ /N80691/002/
ə WHITE TN PAULSN 1MG N80691 002

GEMFIBROZIL

CAPSULE; ORAL
LOPID
/PARKE/DAVIS/ /200MG/ /N18422/001/
ə PARKE DAVIS 200MG N18422 001

TABLET; ORAL
LOPID
PARKE DAVIS 600MG N18422 003
NOV 20, 1986

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM
>ADD > AP STERIS LABS 40,000 UNITS/ML N17064 006
>DLT > /ə/ /40,000/UNITS/ML/ /N17064/006/
HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER
AP BAXTER 4,000 UNITS/100ML N18814 001
OCT 31, 1983
HEPARIN SODIUM 20,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER
AP ABBOTT LABS 4,000 UNITS/100ML¤ N19805 001
JAN 25, 1989

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER
AP ABBOTT LABS 5,000 UNITS/100ML¤ N19805 002
JAN 25, 1989

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HCL
/AA/ /PBI/ /25MG/ /N87780/001/
/MAR/29,/1982/
/AA/ /50MG/ /N87751/001/
/MAR/29,/1982/
ə PBI 25MG N87780 001
MAR 29, 1982
ə 50MG N87751 001
MAR 29, 1982

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE
/AA/ /PBI/ /25MG/ /N87827/001/
/APR/19,/1982/
/AA/ /50MG/ /N87752/001/
/APR/19,/1982/
ə PBI 25MG N87827 001
APR 19, 1982
ə 50MG N87752 001
APR 19, 1982
/AA/ /VANGARD/LABS/ /25MG/ /N87638/001/
/AA/ /50MG/ /N87610/001/
ə VANGARD LABS 25MG N87638 001
ə 50MG N87610 001
/AA/ /WHITE/TN/PAULSN/ /25MG/ /N83809/002/
/AA/ /50MG/ /N83809/001/
>DLT >/AA/ /100MG/ /N85347/001/
ə WHITE TN PAULSN 25MG N83809 002
ə 50MG N83809 001
>ADD > ə 100MG N85347 001

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL
PRINZIDE 12.5
MS&D RES LABS 12.5MG;20MG¤ N19778 001
FEB 16, 1989

HYDROCHLOROTHIAZIOE; LISINOPRIL

TABLET; ORAL
PRINZIDE 25

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

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
METHYLDOPA AND HYDROCHLOROTHIAZIDE

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

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
H.R. 50

BP	WHITE TN PAULSN	50MG;0.125MG	N85338 001		

HYOROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE

AB	PBI	25MG;25MG	N87651 001		
AB	VANGARD LABS	25MG;25MG	N87655 001		

HYOROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

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

HYOROCORTISONE ACETATE

CREAM; TOPICAL
HYDROCORTISONE ACETATE

AT	PARKE DAVIS	1%	N89914 001		JAN 03, 1989

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-HYDROCORT

AP	ABBOTT LABS	EQ 100MG BASE/VIAL	N89577 001	ADD	APR 11, 1989
AP		EQ 250MG BASE/VIAL	N89578 001	ADD	APR 11, 1989
AP		EQ 500MG BASE/VIAL	N89579 001	ADD	APR 11, 1989
AP		EQ 1GM BASE/VIAL	N89580 001	AOD	APR 11, 1989

HYDROFLUMETHIAZIDE

TABLET; ORAL
HYDROFLUMETHIAZIDE

AB	CHELSEA LABS	50MG	N88528 001	DLT	AUG 15, 1984

HYOROXOCOBALAMIN

INJECTABLE; INJECTION
HYDROXOCOBALAMIN

AP	LYPHOMED	1MG/ML	N84921 001	DLT	

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL
IMIPRAMINE HCL

AB	PBI	25MG	N87776 001		FEB 10, 1982

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL
IMIPRAMINE HCL

/AB/	/VANGARD LABS/	/10MG/	/N88036/001/	/NOV 03, 1982/
/AB/		/25MG/	/N87619/001/	/FEB 09, 1982/
/AB/		/50MG/	/N87631/001/	/JAN 04, 1982/
	a VANGARD LABS	10MG	N88036 001	NOV 03, 1982
	a	25MG	N87619 001	FEB 09, 1982
	a	50MG	N87631 001	JAN 04, 1982

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL
INDOMETHACIN

AB	INWOOD LABS	75MG	N72410 001	MAR 15, 1989

LACTULOSE

SYRUP; ORAL
DUPHALAC

AA	REID ROWELL	10GM/15ML	N72372 001	MAR 22, 1989

SYRUP; ORAL, RECTAL
LACTULOSE

>DLT>	/AA/	/KALI/DUPHAR/	/10GM/15ML/	/N17906/001/	
>ADD>	AA	REID ROWELL	10GM/15ML	N17906 001	

PORTALAC

AA	REID ROWELL	10GM/15ML	N72374 001	MAR 22, 1989

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM

>ADD>	LEDERLE LABS	EQ 350MG BASE/VIAL	N08107 005	APR 05, 1989
>ADD>				

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
WELLCOVORIN

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

LEUPROLIDE ACETATE

INJECTABLE; INJECTION
LUPRON DEPOT

>DLT>		/TAP/PHARMS/	/7.5MG/VIAL/	/N19732/001/	
>ADD>		TAKEDA ABBOTT R&D	7.5MG/VIAL	N19732 001	JAN 26, 1989
>ADD>					

LEVOTHYROXINE SODIUM; LIOTHYRONINE SODIUM

TABLET; ORAL
THYROLAR-0.25

>DLT>		/ARMOUR/PHARM/	/0.0125MG;0.0031MG/	/N16807/001/	
>ADD>		RORER PHARM	0.0125MG;D.0031MG	N16807 001	

THYROLAR-0.5

>DLT>		/ARMOUR/PHARM/	/0.025MG;0.00625MG/	/N16807/005/	
>ADD>		RORER PHARM	0.025MG;0.00625MG	N16807 005	

THYROLAR-1

>DLT>		/ARMOUR/PHARM/	/0.05MG;0.0125MG/	/N16807/004/	
>ADD>		RORER PHARM	0.05MG;0.0125MG	N16807 004	

THYROLAR-2

>DLT>		/ARMOUR/PHARM/	/0.1MG;0.025MG/	/N16807/002/	
>ADD>		RORER PHARM	0.1MG;0.025MG	N16807 002	

THYROLAR-3

>DLT>		/ARMOUR/PHARM/	/0.15MG;0.0375MG/	/N16807/003/	
>ADD>		RORER PHARM	0.15MG;D.0375MG	N16807 003	

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
XYLOCAINE

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

INJECTABLE; SPINAL
LIDOCAINE HCL AND DEXTROSE 7.5%

>ADD>	AP	ABBOTT LABS	5%	N83914 001	
>DLT>		/LIDOCAINE HCL W/ DEXTROSE/			
>DLT>	/AP/	/ABBOTT/LABS/	/5%/	/N83914/001/	

LISINOPRIL

TABLET; ORAL

PRINIVIL

> ADD > AB MS&D RES LABS 40MG N19558 004 DEC 29, 1987

ZESTRIL

> ADD > AB IMPERIAL CHEM 40MG N19777 D04 MAY 19, 1988

> ADD >

LITHIUM CARBONATE

CAPSULE; DRAL

LITHIUM CARBONATE

AB PBI 300MG¤ N72542 001 FEB 01, 1989

MANNITOL

SOLUTION; IRRIGATION

/RESECTISOL/ /KENDALL/MCGAW/ /5GM/100ML/ /N16704/002/

a KENDALL MCGAW 5GM/100ML N16704 002

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

MECLIZINE HCL

/AA/ /VANGARD/LABS/ /12.5MG/ /N87877/001/ /APR/20,/1982/

/AA/ /25MG/ /N87620/001/ /JAN/04,/1982/

a VANGARD LABS 12.5MG N87877 001 APR 20, 1982

a 25MG N87620 001 JAN 04, 1982

MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

AB BARR LABS EQ 50MG BASE¤ N72848 001 MAR 20, 1989

AB EQ 100MG BASE¤ N72809 001 MAR 20, 1989

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERIDINE HCL

AP ASTRA PHARM PRODS 25MG/ML¤ N89781 001 MAR 31, 1989

AP 50MG/ML¤ N89782 001 MAR 31, 1989

AP 50MG/ML¤ N89783 001 MAR 31, 1989

AP 50MG/ML¤ N89784 001 MAR 31, 1989

AP 75MG/ML¤ N89785 001 MAR 31, 1989

AP 100MG/ML¤ N89786 001 MAR 31, 1989

AP 100MG/ML¤ N89787 001 MAR 31, 1989

AP 100MG/ML¤ N89788 001 MAR 31, 1989

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

/AA/ /LEDERLE/LABS/ /400MG/ /N86299/001/

a LEDERLE LABS 400MG N86299 001

/AA/ /VANGARD/LABS/ /400MG/ /N88011/001/ /JUL/14,/1982/

a VANGARD LABS 400MG N88011 001 JUL 14, 1982

/AA/ /WHITE/TN/PAULSN/ /200MG/ /N83830/001/

/AA/ /400MG/ /N83442/001/

a WHITE TN PAULSN 200MG N83830 001

a 400MG N83442 001

MESNA

INJECTABLE; INJECTION

MESNEX

ASTA PHARMA 100MG/ML N19884 001 DEC 30, 1988

/BRISTOL/MYERS/ /100MG/ML/ /N19864/001/ /DEC/30,/1988/

METHOTREXATE SODIUM

INJECTABLE; INJECTION
MEXATE-AQ PRESERVED

>ADD >					
>ADD >	AP	BRISTOL MYERS	EQ 25MG BASE/ML	N89887 001	
>ADD >				APR 14, 1989	

METHYLPREDNISOLONE ACETATE

/ENEMA;/RECTAL/
/MEDROL/

		/UPJOHN/	/40MG/BOT/	/N18102/001/	
		@ UPJOHN	40MG/BOT	N18102 001	

METHYLTESTOSTERONE

TABLET; BUCCAL
ANDROID 5

>DLT >		/BROWN/PHARM/	/5MG/	/N87222/001/	
>ADD >		ICN PHARMS	5MG	N87222 001	

TABLET; ORAL
ANDROID 10

>DLT >/AB/		/BROWN/PHARM/	/10MG/	/N86450/001/	
>ADD >	AB	ICN PHARMS	10MG	N86450 001	

ANDROID 25

>DLT >/AB/		/BROWN/PHARM/	/25MG/	/N87147/001/	
>ADD >	AB	ICN PHARMS	25MG	N87147 001	

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL

AP	BULL LABS	EQ 10MG BASE/2ML	N71990 001	
			JAN 18, 1989	
AP	DUPONT CRI CARE	EQ 10MG BASE/2ML	N71291 001	
			MAR 03, 1989	

METOPROLOL TARTRATE

TABLET; ORAL
LOPRESSOR

AB	GEIGY PHARMS	50MG	N17963 001
AB		100MG	N17963 002

METOPROLOL TARTRATE

AB	HENRY SCHEIN	50MG	N71690 001 †
			FEB 08, 1989
AB		100MG	N71691 001 †
			FEB 08, 1989

MOMETASONE FUROATE

LOTION; TOPICAL
ELOCON

SCHERING	0.1%	N19796 001	
		MAR 30, 1989	

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
NALBUPHINE HCL

AP	ABBOTT LABS	10MG/ML	N70914 001	
			FEB 03, 1989	
AP		10MG/ML	N70915 001	
			FEB 03, 1989	
AP		20MG/ML	N70916 001	
			FEB 03, 1989	
AP		20MG/ML	N70917 001	
			FEB 03, 1989	
AP		20MG/ML	N70918 001	
			FEB 03, 1989	
>ADD > AP	ASTRA PHARM PRODS	10MG/ML	N72070 001	
>ADD >			APR 10, 1989	
>ADD > AP		10MG/ML	N72071 001	
>ADD >			APR 10, 1989	
>ADD > AP		10MG/ML	N72072 001	
>ADD >			APR 10, 1989	
>ADD > AP		20MG/ML	N72073 001	
>ADD >			APR 10, 1989	
>ADD > AP		20MG/ML	N72074 001	
>ADD >			APR 10, 1989	
>ADD > AP		20MG/ML	N72075 001	
>ADD >			APR 10, 1989	

† DELAYED EFFECTIVE DATE PENDING COURT DECISION

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE HCL

> ADD >	AP	ASTRA PHARM PRODS	0.02MG/ML¤	N72081 001	APR 11, 1989
> ADD >	AP		0.02MG/ML¤	N72082 001	APR 11, 1989
> ADD >	AP		0.02MG/ML¤	N72083 001	APR 11, 1989
> ADD >	AP		0.02MG/ML¤	N72084 001	APR 11, 1989
> ADD >	AP		0.02MG/ML¤	N72085 001	APR 11, 1989
> ADD >	AP		0.4MG/ML¤	N72086 001	APR 11, 1989
> ADD >	AP		0.4MG/ML¤	N72087 001	APR 11, 1989
> ADD >	AP		0.4MG/ML¤	N72088 001	APR 11, 1989
> ADD >	AP		0.4MG/ML¤	N72089 001	APR 11, 1989
> ADD >	AP		0.4MG/ML¤	N72090 001	APR 11, 1989
> ADD >	AP		1MG/ML¤	N72091 001	APR 11, 1989
> ADD >	AP		1MG/ML¤	N72092 001	APR 11, 1989
> ADD >	AP		1MG/ML¤	N72093 001	APR 11, 1989

NIACIN

TABLET; ORAL
NIACIN

> DLT >	/AA/	/CHELSEA/LABS/	/500MG/	/N85172/001/	
> ADD >		ə CHELSEA LABS	500MG	N85172 001	

NIFEDIPINE

CAPSULE; ORAL
NIFEDIPINE

> ADD >	AB	PUREPAC PHARM	10MG¤	N72579 001 †	APR 28, 1989
> ADD >	AB		20MG¤	N72556 001 †	APR 28, 1989

OXACILLIN SODIUM

INJECTABLE; INJECTION
OXACILLIN SODIUM

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

OXYBUTYNIN CHLORIDE

TABLET; ORAL
OXYBUTYNIN CHLORIDE

> ADD >	AB	BOLAR PHARM	5MG¤	N72485 001	APR 19, 1989

PANCURONIUM BROMIDE

INJECTABLE; INJECTION
PANCURONIUM BROMIDE

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

PENBUTOLOL SULFATE

TABLET; ORAL
LEVATOL

		/LILLY/	/10MG/	/N18976/001/	/DEC/30,/1987/
		REED & CARNRICK	10MG	N18976 001	DEC 30, 1987

PENICILLIN G BENZATHINE

/SUSPENSION;/ORAL/
/BICILLIN/

		/WYETH/AYERST/LABS/	/300,000/UNITS/5ML/	/N50126/002/	
		ə WYETH AYERST LABS	300,000 UNITS/5ML	N50126 002	

† DELAYED EFFECTIVE DATE PENDING COURT DECISION

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN V POTASSIUM

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

PENTOBARBITAL SODIUM

CAPSULE; ORAL
PENTOBARBITAL SODIUM

AA	WHITE TN PAULSN	100MG	N83338 001

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
DI-METREX

AA	PRIVATE FMLTNS	35MG	N85698 001

PHENDIMETRAZINE TARTRATE

AA	PRIVATE FMLTNS	35MG	N85199 001

PHENYL AMINOSALICYLATE

POWDER; ORAL
PHENY-PAS-TEBAMIN

	PURDUE FRDRK	50%	N11695 002

TABLET; ORAL
PHENY-PAS-TEBAMIN

	PURDUE FRDRK	500MG	N11695 003

PHENYLEPHRINE HYDROCHLORIDE; PYRILAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC
PREFRIN-A

	ALLERGAN PHARMS	0.12%;0.1%	N07953 001

POTASSIUM CHLORIDE; SODIUM CHLORIDE

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

AP	BAXTER	75MG/100ML;900MG/100ML	N17648 004

AP	KENDALL MCGAW	75MG/100ML;900MG/100ML	N18722 001 NOV 09, 1982

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER

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

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

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

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

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

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
PRAZOSIN HCL

>ADD>	AB	AM THERPTCS	EQ 1MG BASE*	N72782 001 MAY 16, 1989 : APR 11, 1989
>ADD>	AB		EQ 2MG BASE*	N72783 001 MAY 16, 1989 : APR 11, 1989
>ADD>	AB		EQ 5MG BASE*	N72784 001 MAY 16, 1989 : APR 11, 1989
>ADD>	AB	CORD LABS	EQ 1MG BASE*	N72576 001 MAY 16, 1989 : APR 10, 1989
>ADD>	AB		EQ 2MG BASE*	N72577 001 MAY 16, 1989 : APR 10, 1989
>ADD>	AB		EQ 5MG BASE*	N72578 001 MAY 16, 1989 : APR 10, 1989

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HCL

AB	DANBURY PHARMA	EQ 1MG BASE¤	N72352 001	MAY 16, 1989 : JAN 11, 1989
AB		EQ 2MG BASE¤	N72333 001	MAY 16, 1989 : JAN 11, 1989
AB		EQ 5MG BASE¤	N72609 001	MAY 16, 1989 : JAN 11, 1989
AB	LEDERLE LABS	EQ 1MG BASE¤	N72705 001	MAY 16, 1989 : MAR 15, 1989
AB		EQ 2MG BASE¤	N72706 001	MAY 16, 1989 : MAR 15, 1989
AB		EQ 5MG BASE¤	N72707 001	MAY 16, 1989 : MAR 15, 1989
AB	MYLAN PHARMS	EQ 1MG BASE¤	N72573 001	MAY 16, 1989 : FEB 28, 1989
AB		EQ 2MG BASE¤	N72574 001	MAY 16, 1989 : FEB 28, 1989
AB		EQ 5MG BASE¤	N72575 001	MAY 16, 1989 : FEB 28, 1989
> ADD > AB	PUREPAC PHARM	EQ 1MG BASE¤	N72991 001	MAY 16, 1989 : APR 26, 1989
> ADD > AB		EQ 2MG BASE¤	N72921 001	MAY 16, 1989 : APR 26, 1989
> ADD > AB		EQ 5MG BASE¤	N72992 001	MAY 16, 1989 : APR 26, 1989
/AB/	/ZENITH/LABS/	/EQ 1MG BASE/	/N71994/001/	/SEP/12,/1988/
AB	ZENITH LABS	EQ 1MG BASE	N71994 001	MAY 16, 1989 : SEP 12, 1988
/AB/		/EQ 2MG BASE/	/N71995/001/	/SEP/12,/1988/
AB		EQ 2MG BASE	N71995 001	MAY 16, 1989 : SEP 12, 1988
/AB/		/EQ 5MG BASE/	/N71745/001/	/SEP/12,/1988/
AB		EQ 5MG BASE	N71745 001	MAY 16, 1989 : SEP 12, 1988

PREDNISOLONE

SYRUP; ORAL

PRELONE

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

TABLET; ORAL

PREDNISOLONE

/BX/	/WHITE/TN/PAULSN/	/5MG/	/N80342/001/
	a WHITE TN PAULSN	5MG	N80342 001

PREDNISONE

SOLUTION; ORAL

PREDNISONE INTENSOL

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

TABLET; ORAL

DELTASONE

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

PREDNISONE

AB	CORD LABS	10MG¤	N89983 001 JAN 12, 1989
AB		50MG¤	N89984 001 JAN 12, 1989
/BX/	/VANGARD/LABS/	/5MG/	/N87682/001/ /JAN/15,/1982/
/BX/		/20MG/	/N87701/001/ /JAN/15,/1982/
	a VANGARD LABS	5MG	N87682 001 JAN 15, 1982
	a	20MG	N87701 001 JAN 15, 1982
> DLT >/AB/	/WHITE/TN/PAULSN/	/10MG/	/N89028/001/ /JUL/24,/1986/
> DLT > /BX/		/2.5MG/	/N84913/001/
> DLT > /BX/		/5MG/	/N80343/001/
> DLT > /BX/		/20MG/	/N84913/002/
> ADD >	a WHITE TN PAULSN	2.5MG	N84913 001
	a	5MG	N80343 001
> ADD >	a	10MG	N89028 001 JUL 24, 1986
> ADD >		20MG	N84913 002
/BX/	/SERVISONE/ /LEDERLE/LABS/	/5MG/	/N80223/001/
	a LEDERLE LABS	5MG	N80223 001

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL

PROCAINAMIDE HCL

/AB/	/VANGARD LABS/	/250MG/	/N87643 001/	/JUN 01, 1982/
/AB/		/500MG/	/N87875 001/	/JUN 01, 1982/
	ə VANGARD LABS	250MG	N87643 001	JUN 01, 1982
	ə	500MG	N87875 001	JUN 01, 1982

TABLET, EXTENDED RELEASE; ORAL

PROCAINAMIDE HCL

AB	INWOOD LABS	500MG‡	N89840 001 MAR 06, 1989

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

PROMETHAZINE HCL

> DLT >	/BP/ /CHELSEA LABS/	/12.5MG/	/N85986 001/	
> DLT >	/BP/	/50MG/	/N85664 001/	
> ADD >	ə CHELSEA LABS	12.5MG	N85986 001	
> ADD >	ə	50MG	N85664 001	

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

INDERAL LA

> ADD >	AB	WYETH AYERST LABS	60MG	N18553 004 MAR 18, 1987
> ADD >	AB		80MG	N18553 002 APR 19, 1983
> ADD >	AB		120MG	N18553 003 APR 19, 1983
> ADD >	AB		160MG	N18553 001 APR 19, 1983

PROPRANOLOL HCL

> ADD >	AB	INWOOD LABS	60MG‡	N72499 001 APR 11, 1989
> ADD >	AB		80MG‡	N72500 001 APR 11, 1989
> ADD >	AB		120MG‡	N72501 001 APR 11, 1989
> ADD >	AB		160MG‡	N72502 001 APR 11, 1989

PROPRANOLOL HYDROCHLORIDE

SOLUTION; ORAL

PROPRANOLOL HCL

AA	PBI	20MG/5ML‡	N71984 001 MAR 03, 1989
AA		40MG/5ML‡	N71985 001 MAR 03, 1989
AA	ROXANE LABS	20MG/5ML	N70979 001 MAY 15, 1987
AA		40MG/5ML	N70690 001 MAY 15, 1987

TABLET; ORAL

PROPRANOLOL HCL

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

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

MESTINON

AP	ICN PHARMS	5MG/ML	N09830 001	
/AP/	/ROCHE/	/5MG/ML/	/N09830 001/	

SYRUP; ORAL

MESTINON

	ICN PHARMS	60MG/5ML	N15193 001
	/ROCHE/	/60MG/5ML/	/N15193 001/

TABLET; ORAL

MESTINON

	ICN PHARMS	60MG	N09829 002
	/ROCHE/	/60MG/	/N09829 002/

TABLET, EXTENDED RELEASE; ORAL

MESTINON

	ICN PHARMS	180MG	N11665 001

PYRIDOSTIGMINE BROMIDE

TABLET, EXTENDED RELEASE; DRAL
MESTINON
/ROCHE/ /180MG/ /N11665/001/

QUINIDINE GLUCONATE

INJECTABLE; INJECTION
QUINIDINE GLUCONATE
/LILLY/ /80MG/ML/ /N07529/001/
LILLY 80MG/ML N07529 002
FEB 10, 1989

QUINIDINE SULFATE

TABLET; DRAL
QUINIDINE SULFATE
> ADD > AB MUTUAL PHARM 100MG N81029 001
> ADD > APR 14, 1989
> ADD > AB 200MG N81030 001
> ADD > APR 14, 1989
> ADD > AB 300MG N81031 001
> ADD > APR 14, 1989
/AB/ /PBI/ /200MG/ /N87837/001/
/APR/14/1982/
a PBI 200MG N87837 001
APR 14, 1982
/AB/ /WHITE/TN/PAULSN/ /200MG/ /N85444/001/
a WHITE TN PAULSN 200MG N85444 001

SECOBARBITAL SODIUM

CAPSULE; DRAL
SECOBARBITAL SODIUM
/AB/ /WHITE/TN/PAULSN/ /100MG/ /N85798/001/
a WHITE TN PAULSN 100MG N85798 001
SODIUM SECOBARBITAL
> DLT >/AB/ /CHELSEA/LABS/ /100MG/ /N85792/001/
> ADD > a CHELSEA LABS 100MG N85792 001

SECRETIN

INJECTABLE; INJECTION
SECRETIN-FERRING
FERRING LABS 75CU/VIAL N18290 001
/SECRETIN-KABI/
/PHARMACIA/LABS/ /75CU/VIAL/ /N18290/001/

SINCALIDE

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

SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
/AP/ /CUTTER/BIOL/ /450MG/100ML/ /N18503/001/
a CUTTER BIOL 450MG/100ML N18503 001
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
/AP/ /CUTTER/BIOL/ /900MG/100ML/ /N18502/001/
a CUTTER BIDL 900MG/100ML N18502 D01

SOLUTION; IRRIGATION
/SODIUM CHLORIDE IN PLASTIC CONTAINER/
/AI/ /CUTTER/BIOL/ /900MG/100ML/ /N18247/001/
a CUTTER BIDL 900MG/100ML N18247 001

SODIUM IODIDE, I-123

CAPSULE; DRAL
SODIUM IODIDE I 123
AA BENEDICT NUCLR 200 UCI N18671 002
MAY 27, 1982
AA MALLINCKRDDT 100 UCI N71909 001
FEB 28, 1989
AA 200 UCI N71910 001
FEB 28, 1989

SODIUM PHOSPHATE, P-32

SOLUTION; INJECTION, DRAL
> DLT > /PHOSPHOTOPE/
> DLT > /SQUIBB/ /1-8MCI/VIAL/ /N10927/001/
> ADD > a SQUIBB 1-8MCI/VIAL N10927 001

SODIUM POLYSTYRENE SULFONATE

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

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE

/AB/	/VANGARD LABS/	/25MG/	/N87648/001/	
			/FEB 01, 1982/	
	a VANGARD LABS	25MG	N87648 001	
			FEB 01, 1982	

SULCONAZOLE NITRATE

CREAM; TOPICAL
SULCOSYN

	SYNTEX LABS	1%	N18737 001
			FEB 28, 1989

SULFINPYRAZONE

CAPSULE; ORAL
SULFINPYRAZONE

> DLT > /AB/	/VANGARD LABS/	/200MG/	/N88666/001/	
> DLT >			/FEB 17, 1984/	
> ADD >	a VANGARD LABS	200MG	N88666 001	
> ADD >			FEB 17, 1984	

TECHNETIUM TC-99M FERPENTETATE KIT

> DLT >	/INJECTABLE;INJECTION/			
> DLT >	/RENOTEC/			
> DLT >	/SQUIBB/	/N/A/	/N17045/001/	
> ADD >	a SQUIBB	N/A	N17045 001	

TECHNETIUM TC-99M SODIUM PERTECHNETATE

SOLUTION; INJECTION, ORAL
SODIUM PERTECHNETATE TC 99M

AP	CIS US	12MCI/ML	N17321 001	
AP		24MCI/ML	N17321 002	
AP		48MCI/ML	N17321 003	
> DLT >	/SANTA/DIAG/LABS/	/10-60MCI/ML/	/N17725/001/	
> ADD >	MALLINCKRODT	10-60MCI/ML	N17725 001	
/AP/	/SYNCOR/INTL/	/12MCI/ML/	/N17321/001/	
/AP/		/24MCI/ML/	/N17321/002/	
/AP/		/48MCI/ML/	/N17321/003/	

TECHNETIUM TC-99M SULFUR COLLOID

SOLUTION; INJECTION, ORAL
TECHNETIUM TC 99M SULFUR COLLOID

> DLT >	/SANTA/DIAG/LABS/	/3MCI/ML/	/N17724/001/	
> ADD >	MALLINCKRODT	3MCI/ML	N17724 001	

THALLOUS CHLORIDE, TL-201

INJECTABLE; INJECTION
THALLOUS CHLORIDE TL 201

AP	SQUIBB DIAGS	1MCI/ML	N18548 001
			DEC 30, 1982

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL
THEO-DUR

AB	KEY PHARMS	100MG	N85328 001	
AB		200MG	N86998 001	
/BC/		/100MG/	/N85328/001/	
/BC/		/200MG/	/N86998/001/	
	THEOPHYLLINE			
AB	INWOOD LABS	100MG	N88320 001	
			FEB 21, 1985	
AB		200MG	N88321 001	
			FEB 21, 1985	
/BC/		/100MG/	/N88320/001/	
			/FEB 21, 1985/	
/BC/		/200MG/	/N88321/001/	
			/FEB 21, 1985/	

THIOTHIXENE HYDROCHLORIDE

INJECTABLE; INJECTION
NAVANE

> DLT >	/ROERIG/	/EQ 5MG BASE/ML/	/N16904/002/	
> ADD >	ROERIG	EQ 10MG BASE/VIAL	N16904 002	

TIMOLOL MALEATE

TABLET; ORAL
BLOCADREN

AB	MS&D	5MG	N18017 001
AB		10MG	N18017 002
AB		20MG	N18017 004

TIMOLOL MALEATE

TABLET; ORAL
TIMOLOL MALEATE

AB	BOLAR PHARM	5MG¤		N72269 001	
			APR 11, 1989 :	MAR 14, 1989	
AB		10MG¤		N72270 001	
			APR 11, 1989 :	MAR 14, 1989	
AB		20MG¤		N72271 001	
			APR 11, 1989 :	MAR 14, 1989	
> ADD > AB	CORD LABS	5MG¤		N72550 001	
> ADD >				APR 13, 1989	
> ADD > AB		10MG¤		N72551 001	
> ADD >				APR 13, 1989	
> ADD > AB		20MG¤		N72552 001	
> ADD >				APR 13, 1989	
AB	PBI	5MG¤		N72001 001	
			APR 11, 1989 :	JAN 10, 1989	
AB		10MG¤		N72002 001	
			APR 11, 1989 :	JAN 10, 1989	
AB		20MG¤		N72003 001	
			APR 11, 1989 :	JAN 10, 1989	

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

/AA/	/VANGARD LABS/	/500MG/	/N87876/001/ /APR 20, 1982/
∂ VANGARD LABS		500MG	N87876 001 APR 20, 1982

TOLMETIN SODIUM

TABLET; ORAL
TOLECTIN 600

MCNEIL PHARM	EQ 600MG BASE¤		N17628 002 MAR 08, 1989

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

AB	LEMMON	50MG¤	N72192 001 FEB 02, 1989
AB		100MG¤	N72193 001 FEB 02, 1989

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
TRIAMCINOLONE ACETONIDE

AT	TOPIDERM	0.025%¤	N89274 001 FEB 21, 1989
AT		0.1%¤	N89275 001 FEB 21, 1989
AT		0.5%¤	N89276 001 FEB 21, 1989

TRIHEXYPHENIDYL HYDROCHLORIDE

ELIXIR; ORAL
ARTANE

> ADD > AA	LEDERLE LABS	2MG/5ML	N06773 009
> ADD >	TRIHEXYPHENIDYL HCL		
> ADD > AA	LIQUIPHARM	2MG/5ML¤	N89514 001 APR 07, 1989
> ADD >			

TABLET; ORAL
TRIHEXYPHENIDYL HCL

/AA/	/VANGARD LABS/	/2MG/	/N88035/001/ /JUL 30, 1982/
∂ VANGARD LABS		2MG	N88035 001 JUL 30, 1982

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL

> ADD > AB	CHELSEA LABS	40MG¤	N72799 001 APR 28, 1989
> ADD >			
AB	MYLAN PHARMS	80MG¤	N71482 001 FEB 15, 1989
AB		120MG¤	N71483 001 FEB 15, 1989
AB	SIDMAK LABS	80MG¤	N72124 001 JAN 26, 1989
AB		120MG¤	N72125 001 JAN 26, 1989

WATER FOR IRRIGATION, STERILE

LIQUID; IRRIGATION
STERILE WATER IN PLASTIC CONTAINER

/AI/	/CUTTER BIOL/	/100%/	/N18246/001/
∂ CUTTER BIOL		100%	N18246 001

ACETAMINOPHEN

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

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL
BIOSCRUB
KW GRIFFEN 4%¤ N19822 001 MAR 31, 1989

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
PSEUDO-CHLOR
KV PHARM 12MG;120MG¤ N71455 001 MAR 01, 1989

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL
PENNTUSS
FISONS EQ 4MG MALEATE/5ML; EQ 10MG BASE/5ML N18928 001 AUG 14, 1985
/PENNTUSS/ /EQ/4MG/MALEATE/5ML;/ /EQ/10MG/BASE/5ML/ /N18928/001/ /AUG/14,/1985/

CHLORPHENIRAMINE POLISTIREX; PHENYLPROPANOLAMINE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL
CORSYM
FISONS EQ 4MG MALEATE/5ML; EQ 37.5MG HCL/5ML N18050 001 JAN 04, 1984
/PENNTUSS/ /EQ/4MG/MALEATE/5ML;/ /EQ/37.5MG/HCL/5ML/ /N18050/001/ /JAN/04,/1984/

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
DIPHENHYDRAMINE HCL
NASKA PHARMA 12.5MG/5ML¤ N7D497 001 APR 25, 1989

IBUPROFEN

TABLET; ORAL
IBUPROFEN
MUTUAL PHARM 200MG¤ N72249 001 JAN 10, 1989

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
HUMULIN 70/30
LILLY 30 UNITS/ML; 70 UNITS/ML¤ N19717 001 APR 25, 1989

OXYMETAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
VISINE II
PFIZER 0.025%¤ N19407 001 MAR 31, 1989

POVIDONE-IODINE

SOLUTION; TOPICAL
POVIDONE IODINE
BAXTER 1%¤ N19522 001 MAR 31, 1989

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
TRIPROLIDINE AND PSEUDOEPHRINE HCL
KV PHARM 120MG;5MG¤ N71798 001 MAR 16, 1989

SYRUP; ORAL
/MYFED/
/PBI/ /30MG/5ML;1.25MG/5ML/ /N88116/001/ /MAR/04,/1983/

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

>_DLT_>	/MYFED/		
>_ADD_>	ə PBI	30MG/5ML;1.25MG/5ML	N88116 001
>_ADD_>			MAR 04, 1983

PSEUDOEPHEDRINE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL

PSEUDO-12		
FISONS	EQ 60MG HCL/5ML	N19401 001
		JUN 19, 1987
/PENNWALT/	/EQ/60MG/HCL/5ML/	/N19401/001/
		/JUN/19,/1987/

DRUG PRODUCTS IN THE DIVISION OF BLOOD AND BLOOD PRODUCTS / CUMULATIVE SUPPLEMENT NUMBER 4 / JAN'89- APR'89
APPROVED UNDER SECTION 505 OF THE ACT LIST

NO APRIL 1989 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).

THE "CUMULATIVE LIST OF ORPHAN DRUG PRODUCT DESIGNATIONS," ISSUED AS AN ADDENDUM TO THE 9TH EDITION OF APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, IS CURRENT THROUGH MARCH 31, 1989. THIS SECTION OF THE CUMULATIVE SUPPLEMENT WILL SERVE AS AN UPDATE TO THAT ADDENDUM AND WILL REPLACE THE FORMER SECTION ENTITLED "ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL." THE NDA NUMBER/LICENSE NUMBER, APPROVAL DATE, DOSAGE FORM, ROUTE OF ADMINISTRATION, AND STRENGTH THAT APPEARED IN THE FORMER SECTION MAY BE FOUND ELSEWHERE IN THIS PUBLICATION FOR APPRDVED DRUGS; FOR LICENSED BIOLOGICALS, THIS INFORMATION WILL NO LONGER BE DISPLAYED.

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).

REFER BACK TO THE ADDENDUM TO APPROVED DRUG PRODUCTS, 9TH EDITION FOR A FULL LISTING OF ORPHAN DRUG PRODUCTS DESIGNATIONS. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

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].

DRUG DESIGNATIONS
[Approved for Marketing*]
[Exclusive Approval**]

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: FLUDARABINE PHOSPHATE TRADE: NOT ESTABLISHED	TREATMENT OF NON-HODGKIN'S LYMPHOMA (NHL).	TRITON BIOSCIENCES 1501 HARBOR BAY PARKWAY ALAMEDA, CA 94501

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

NO APRIL 1989 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

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

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

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
ALBULTEROL; METAPROTERENOL SULFATE (METERED DOSE INHALER)	AUG 25, 1988	FEB 09, 1989
TOLMETIN SODIUM (CAPSULE AND TABLET)	APR 20, 1989	

ANDA SUITABILITY PETITIONS

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

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

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	650MG 10MG	88 P-0416/CP	MORAVEC	NEW STRENGTH	APPROVED MAR 01, 1989
CARMUSTINE, STERILE INJECTABLE; INJECTION	200MG/VIAL	88 P-0410/CP	QUAD PHARMS	NEW STRENGTH	APPROVED FEB 13, 1989
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	20MG/ML (250ML/CONTAINER)	88 P-0379/CP	BAXTER	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 01, 1989

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
HALOPERIDOL DECANOATE INJECTABLE; INJECTION	EQ 50MG BASE/ML (2ML/CONTAINER)	88 P-0411/CP	QUAD PHARMS	NEW STRENGTH	APPROVED FEB 13, 1989
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE IN PLASTIC CONTAINER POWDER FOR RECONSTITUTION; ORAL	59GM/PACKET 0.7425GM/PACKET 1.685GM/PACKET 1.465M/PACKET 5.685GM/PACKET	88P-0419/CP	GUIDELINES	NEW STRENGTH	APPROVED MAR 01, 1989
PREDNISONE CAPSULE; ORAL	1MG 2.5MG 5MG 10MG 20MG 25MG 50MG	88 P-0391/CP	ASCHER	NEW DOSAGE FORM	APPROVED MAR 01, 1989
THIOTEPA, STERILE INJECTABLE; INJECTION	30MG/VIAL 60MG/VIAL	88 P-0412/CP	QUAD PHARMS	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 01, 1989

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 9TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES

NEW INDICATION

I-84	ADJUNCTIVE THERAPY TO DIET TO REDUCE THE RISK OF CORONARY ARTERY DISEASE
I-85	SELECTIVE ADULT VISCERAL ARTERIOGRAPHY
I-86	METASTATIC BREAST CANCER IN PREMENOPAUSAL WOMEN AS AN ALTERNATIVE TO OOPHORECTOMY OR OVARIAN IRRADIATION
I-87	TREATMENT OF TINEA PEDIS
I-88	CONTRAST ENHANCEMENT AGENT TO FACILITATE VISUALIZATION OF LESIONS IN THE SPINE AND ASSOCIATED TISSUES

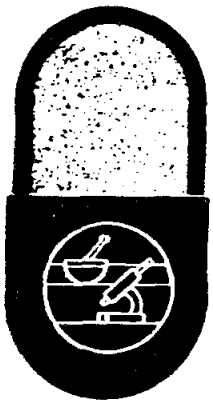
PATENT USE CODE

U-41	METHOD FOR TREATING PROSTATIC CARCINOMA COMPRISING ADMINISTERING FLUTAMIDE
U-42	METHOD FOR TREATING PROSTATE ADENOCARCINOMA COMPRISING ADMINISTERING AN ANTIANDROGEN INCLUDING FLUTAMIDE AND AN LHRH AGONIST
U-43	REDUCING CHOLESTEROL IN CHOLELITHIASIS PATIENTS
U-44	REDUCING CHOLESTEROL GALLSTONES AND/OR FRAGMENTS THEREOF
U-45	DISSOLVING CHOLESTEROL GALLSTONES AND/OR FRAGMENTS THEREOF
U-46	CEREBRAL, CORONARY, PERIPHERAL, VISCERAL AND RENAL ARTERIOGRAPHY, AORTOGRAPHY AND LEFT VENTRICULOGRAPHY
U-47	CT IMAGING OF THE HEAD AND BODY, AND INTRAVENOUS EXCRETORY UROGRAPHY
U-48	CEREBRAL ANGIOGRAPHY, AND VENOGRAPHY
U-49	INTRA-ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY
U-50	PALLIATIVE TREATMENT OF PATIENTS WITH OVARIAN CARCINOMA RECURRENT AFTER PRIOR CHEMOTHERAPY, INCLUDING PATIENTS WHO HAVE BEEN PREVIOUSLY TREATED WITH CISPLATIN

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19880 001	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19880 002	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19880 003	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19471 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	19471 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	19471 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	19471 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	18554 001	FLUTAMIDE; EULEXIN	4474813	NOV 30, 1993		NCE	JAN 27, 1994
			4472382	SEP 18, 2001	U-42		
			4329364	MAY 11, 1999	U-41		
>ADD>	19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST				I-88	APR 28, 1992
	18422 001	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
	18422 002	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
	18422 003	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
	19778 001	HYDROCHLOROTHIAZIDE; PRINZIDE 12.5	4472380	SEP 18, 2001		NCE	DEC 29, 1992
			4374829	DEC 30, 2001		NC	FEB 16, 1992
	19778 002	HYDROCHLOROTHIAZIDE; PRINZIOE 25	4472380	SEP 18, 2001		NCE	DEC 29, 1992
			4374829	DEC 30, 2001		NC	FEB 16, 1992
	18956 003	IOHEXOL; OMNIPAQUE 300	4021481	MAY 03, 1994		I-85	MAR 31, 1992
	18956 004	IOHEXOL; OMNIPAQUE 350	4021481	MAY 03, 1994		I-85	MAR 31, 1992
	19710 001	IOVERSOL; OPTIRAY-320	4396598	AUG 02, 2000	U-46	NCE	DEC 30, 1993
			4396598	AUG 02, 2000	U-47		
	19710 002	IOVERSOL; OPTIRAY-240	4396598	AUG 02, 2000	U-48	NCE	DEC 30, 1993
	19710 003	IOVERSOL; OPTIRAY-160	4396598	AUG 02, 2000	U-49	NCE	DEC 30, 1993
>ADD>	08107 005	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				ODE	AUG 31, 1995
>ADD>						I-79	AUG 31, 1995
	19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4005063	JAN 25, 1996		NCE	APR 09, 1990
						NP	JAN 26, 1992
>ADD>	19777 004	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
	19625 001	MOMETASONE FUROATE; ELOCON	4808610	FEB 28, 2006			
	19796 001	MOMETASONE FUROATE; ELOCON	4775529	OCT 04, 2005		NCE	APR 30, 1992
			4472393	SEP 18, 2001		NDF	MAR 30, 1992
	19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 2000		NCE	MAR 01, 1993
>ADD>						I-87	APR 05, 1992

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19508 001	NIZATIDINE; AXID	4375547	MAR 01, 2002		NCE	APR 12, 1993
19508 002	NIZATIDINE; AXID	4375547	MAR 01, 2002		NCE	APR 12, 1993
19407 001	OXYMETAZOLINE HYDRDCHLORIDE; VISINE II				NDF	MAY 30, 1989
18737 001	SULCONAZOLE NITRATE; SULCOSYN	4055652	OCT 25, 1996		NCE	AUG 30, 1990
					NDF	FEB 28, 1992
17970 001	TAMOXIFEN CITRATE; NOLVADEX				I-86	MAR 16, 1992
19829 001	TECHNETIUM TC-99M EXAMETAZIME KIT; CERETEC	4789736	DEC 06, 2005			
19594 001	URSODIOL; ACTIGALL	RE30910	JAN 07, 1994	U-43		
		RE30910	JAN 07, 1994	U-44		
		RE30910	JAN 07, 1994	U-45		
19594 002	URSODIOL; ACTIGALL	RE30910	JAN 07, 1994	U-43		
		RE30910	JAN 07, 1994	U-44		
		RE30910	JAN 07, 1994	U-45		

New 9th Edition



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