APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

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CUMULATIVE SUPPLEMENT 4

AUG'84 - DEC'84

5th ed.
Suppl. 4

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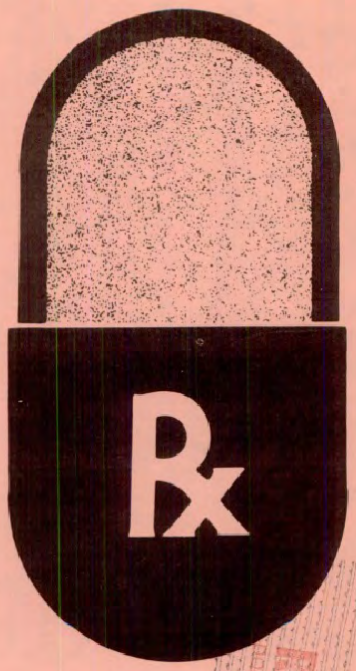

APPROVED PRESCRIPTION DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

5TH EDITION

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FOOD AND DRUG ADMINISTRATION
APPROVED PRESCRIPTION DRUG PRODUCTS
WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS
CUMULATIVE SUPPLEMENT

I. PREFACE

This cumulative supplement is one of a series of monthly updates to the Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 5th Edition (the List), to cover interim revisions to the annual publication of the List in its entirety. The List is comprised of several parts and some by their nature, are identified by the term "list." The cumulative supplements routinely provide updates to two of these lists: The Drug Product List and the DESI Addendum.

The List cannot be used effectively without the current cumulative supplement. Users may wish to place an asterisk (*) in the List to the left of the ingredient(s) in the Drug Product List and the product name in the Addendum to indicate that changes to that entry appear in the cumulative supplement. It is also suggested that earlier cumulative supplements be discarded to avoid possible confusion. In this way, only the List and current cumulative supplement need be referenced.

A. DRUG PRODUCT LIST

The Drug Product List cumulative supplements include the changes made since August 1, 1984. Each subsequent cumulative supplement replaces the previous month's cumulative supplement.

Information in this cumulative supplement follows the format of the Drug Product List. 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.)

Context information on drug products is provided in each cumulative supplement for completeness to assist in locating the proper place in the Drug Product List for the revision. (Strength(s) which already exist in the publication will not be repeated for context.) A page number in parentheses referring to the Drug Product List is located to the right of the ingredient(s).

Additions to the Drug Product List are indicated by new information in the cumulative supplement. Additions new to the current cumulative supplement are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is dropped in subsequent cumulative supplements for that item.

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Deletions from the Drug Product List are indicated by overstruck print in the cumulative supplement. Deletions new to the current cumulative supplement are indicated by the symbol >DLT> (DELETE) to the left of the line containing the overstruck print. The >DLT> symbol is dropped in subsequent cumulative supplements for that item.

A newly approved product is identified by the lozenge (◆) to the right of its strength. This identifier remains throughout all cumulative supplements for this edition.

B. ADDENDUM: DESI Pending List

Information in this cumulative supplement follows the format of the Addendum. Additions and deletions are indicated in the same manner as in the cumulative supplement to the Drug Product List. A change in Current Status of a DESI product is also indicated by an addition and a deletion.

II. SPECIAL NOTES

A. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

Categories of counts derived from product information in the Drug Product List and from this cumulative supplement are presented. The report includes counts of new molecular entities approved by the agency during the current month.

B. 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 Drug Product List.

Products	Federal Register Reference
dicyclomine hydrochloride	JUN 22, 1984 (49 FR 25681)
isosorbide dinitrate	AUG 3, 1984 (49 FR 31151)
nandrolone decanoate	JUL 15, 1983 (48 FR 32395)

(continued)

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Products	Federal Register Reference
(continued)	
neomycin sulfate with either: dexamethasone sodium phosphate, fluocinolone acetonide, flurandrenolide, hydrocortisone, or methylprednisolone acetate. [topical anti-infectives for dermatologic use]	MAR 26, 1984 (49 FR 11888)
neomycin sulfate, polymyxin B sulfate, bacitracin zinc, and hydrocortisone [topical ointment]	MAY 4, 1984 (49 FR 19147)
nitroglycerin (capsule,controlled release;oral)	SEP 7, 1984 (49 FR 35428)
nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
parenteral multivitamin products	SEP 17, 1984 (49 FR 36446)
phenazopyridine hydrochloride and sulfamethoxazole	JUL 29, 1983 (48 FR 34516)
sulfanilamide and aminacrine	AUG 22, 1983 (48 FR 38097)
tranylcypromine sulfate	MAR 22, 1984 (49 FR 10708)

C. 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 Special Notes 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. The current list of applicant holder changes follows.

APPLICANT (NAME) CHANGES

Former Applicant (Name)	New Applicant (Name)	New Abbreviated Name
OHIO MEDICAL ANESTHETICS	ANAQUEST	ANAQUEST

D. ADDENDUM: DRUG PRICE COMPETITION AND PATENT TERM RESTORATION

The addendum of this supplement provides information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984."

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III. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

DESCRIPTION OF REPORT

The following report provides summary counts derived from product information in the Drug Product List and the current cumulative supplement. The counts appear in two sections. Section A. refers to the products in the List and Section B. to products in the current cumulative supplement. A new column of data will appear in Section A. each three-month period following July '84. Section A. therefore will provide baseline and quarterly data while Section B. provides monthly activity.

USE OF REPORT

From the data presented under Section B., users should be able to observe such things as (1) newly approved, DESI effective and remarketed drug products which are added to the List; (2) products that are being removed from the List as the result of withdrawal of approval, changes from prescription to over-the-counter status and discontinued marketing of products; and, (3) trends in approval of products as either multisource or single source during each month within the quarter. The report does not reflect category changes from multisource to single source and vice versa. However, the net gain that results from all additions, deletions and category changes is reflected in the quarterly counts for multisource and single source products.

Drug Product Definition

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

New Molecular Entity

The active moiety 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 part of a combination.

Drug Product Count

This report provides counts in several categories from the list composed of domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Counts of products still pending in the DESI review are not provided. Excluded also are those approved drug products marketed by distributors; those marketed solely abroad; and products now regarded as medical devices, biologics or foods.

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

A. COUNTS CUMULATIVE BY QUARTERS

CATEGORIES COUNTED	JULY '84 (BASELINE)	OCT '84
DRUG PRODUCTS LISTED	7415	7609
SINGLE SOURCE	2005 (27.0%)	2045 (26.9%)
MULTISOURCE(1)	5410 (72.9%)	5564 (73.1%)
THERAPEUTICALLY EQUIVALENT	4393 (59.2%)	4497 (59.1%)
NOT THERAPEUTICALLY EQUIVALENT	999 (13.4%)	1032 (13.5%)
EXCEPTIONS(2)	18 (0.3%)	26 (0.3%)
NEW MOLECULAR ENTITIES APPROVED	-	4
NUMBER OF APPLICANTS	295	300

B. ACTIVITY FOR SUPPLEMENT NUMBER 4

	NOV '84		DEC '84		CUMULATIVE	
DRUG PRODUCTS ADDED:	65		68		133	
NEWLY APPROVED		65		68		133
DESI EFFECTIVE		0		0		0
REMARKETED		0		0		0
DRUG PRODUCTS REMOVED:	1		0		1	
WITHDRAWN APPROVAL		0		0		0
RX TO OTC SWITCH		0		0		0
DISCONTINUED MARKETING		1		0		1
NET GAIN IN DRUG PRODUCTS	64		68		132	
SINGLE SOURCE PRODUCTS APPROVED	16		26		42	
MULTISOURCE DRUG PRODUCTS APPROVED	49		42		91	
NEW MOLECULAR ENTITIES APPROVED:	2		7		9	
AS THE ENTITY		0		2		2
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY		2		5		7

(1) THERAPEUTIC EQUIVALENCE EVALUATIONS PROVIDED ONLY FOR MULTISOURCE PRODUCTS (i.e., AVAILABLE FROM MORE THAN ONE APPLICANT)
(2) AMINO ACID-CONTAINING PRODUCTS OF VARYING COMPOSITION (SEE PAGE I-5 OF THE LIST)

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> ADD > ACEBUTOLOL HYDROCHLORIDE (PAGE 3-1)

> ADD > CAPSULE; ORAL
> ADD > SECTRAL
> ADD > IVES LABS/AMHO EQ 200MG BASE* N 18917
> ADD > EQ 400MG BASE* N 18917

ACETAMINOPHEN; BUTALBITAL (PAGE 3-1)

TABLET; ORAL
BUTALBITAL AND ACETAMINOPHEN
DANBURY PHARMACAL 325MG;50MG* N 87550

ACETAMINOPHEN; BUTALBITAL; CAFFEINE (PAGE 3-1)

> ADD > CAPSULE; ORAL
> ADD > ESGIC
> ADD > GILBERT LABORATORIES 325MG;50MG;40MG* N 88825

TABLET; ORAL
ESGIC
AB GILBERT LABORATORIES 325MG;50MG;40MG* N 87629
FIORICET
AB SANDOZ PHARMS/SANDOZ 325MG;50MG;40MG* N 88616

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-2)

TABLET; ORAL
> ADD > HYDROCODONE BITARTRATE W/ ACETAMINOPHEN
> ADD > AA BARR LABORATORIES 500MG;5MG* N 88577

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 3-2)

CAPSULE; ORAL
> ADD > TYLOX
> ADD > MCNEIL PHARM 500MG;5MG* N 88790
TYLOX-325
MCNEIL PHARM 325MG;5MG* N 88246

TABLET; ORAL
/CONTACT/
OXYCET
AA HALSEY DRUG 325MG;5MG* N 87463

ACETIC ACID, GLACIAL (PAGE 3-3)

SOLUTION/DROPS; OTIC
ACETIC ACID
AT THAMES PHARMACAL 2%* N 88638

ALLOPURINOL (PAGE 3-5)

TABLET; ORAL
ALLOPURINOL
AB BOLAR PHARMACEUTICAL 100MG* N 18241
AB 300MG* N 18241
AB CHELSEA LABORATORIES 100MG* N 18785
AB 300MG* N 18785
AB DANBURY PHARMACAL 100MG* N 18832
AB 300MG* N 18877

> ADD > AMDINOCILLIN (PAGE 3-6)

> ADD > INJECTABLE; INJECTION
> ADD > COACTIN
> ADD > HOFFMANN-LA ROCHE 250MG/VIAL* N 50565
> ADD > 500MG/VIAL* N 50565
> ADD > 1GM/VIAL* N 50565

AMIKACIN SULFATE (PAGE 3-6)

INJECTABLE; INJECTION
AMIKIN
BRISTOL LABS/B-M EQ 50MG BASE/ML* N 62562
EQ 250MG BASE/ML* N 62562

AMINO ACIDS (PAGE 3-6)

INJECTABLE; INJECTION
BRANCHAMIN 4%
TRAVENOL LABS 4%* N 18678
BRANCHAMIN 4% IN PLASTIC CONTAINER
TRAVENOL LABS 4%* N 18684
TRAVASOL 10% W/O ELECTROLYTES IN PLASTIC CONTAINER
TRAVENOL LABS 10%* N 18931
TRAVASOL 5.5% W/O ELECTROLYTES IN PLASTIC CONTAINER
TRAVENOL LABS 5.5%* N 18931
TRAVASOL 8.5% W/O ELECTROLYTES IN PLASTIC CONTAINER
TRAVENOL LABS 8.5%* N 18931

AMINO ACIDS; DEXTROSE (PAGE 3-7)

INJECTABLE; INJECTION
AMINOSYN 3.5% W/ DEXTROSE 5% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 3.5GM/100ML N 19120

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AMINO ACIDS; DEXTROSE (PAGE 3-7)

INJECTABLE; INJECTION
AMINOSYN 3.5% W/ DEXTROSE 25% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 3.5%;25GM/100ML N 19118
AMINOSYN 4.25% W/ DEXTROSE 25% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 4.25%;25GM/100ML N 19119

AMINOPHYLLINE; SODIUM CHLORIDE (PAGE 3-9)

INJECTABLE; INJECTION
> ADD > AMINOPHYLLINE IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
> ADD > AP ABBOTT LABORATORIES 100MG/100ML;450MG/100ML* N 18924
> ADD > AP 200MG/100ML;450MG/100ML* N 18924
> ADD > 400MG/100ML;450MG/100ML* N 18924
> ADD > 500MG/100ML;450MG/100ML* N 18924
AMINOPHYLLINE 0.1% IN SODIUM CHLORIDE 0.45%
> ADD > AP ABBOTT LABORATORIES 100MG/100ML;450MG/100ML* N 88147
AMINOPHYLLINE 0.2% IN SODIUM CHLORIDE 0.45%
> ADD > AP ABBOTT LABORATORIES 200MG/100ML;450MG/100ML* N 88147

AMITRIPTYLINE HYDROCHLORIDE (PAGE 3-10)

TABLET; ORAL
AMITRIPTYLINE HCL
BP AMERICAN THERAPEUTIC 25MG* N 88672
BP 50MG* N 88673
BP 75MG* N 88674
BP 100MG* N 88675
BP PAR PHARMACEUTICAL 10MG* N 88697
BP 25MG* N 88698
BP 50MG* N 88699
BP 75MG* N 88700
BP 100MG* N 88701
BP 150MG* N 88702
BP SIDMAK LABORATORIES 10MG* N 88883
BP 25MG* N 88884
BP 50MG* N 88885
BP 75MG* N 88886
BP 100MG* N 88887
BP 150MG* N 88888
BP SUPERPHARM 10MG* N 88853
BP 25MG* N 88854
BP 50MG* N 88855
BP 75MG* N 88856
BP 100MG* N 88857

AMOXICILLIN; POTASSIUM CLAVULANATE (PAGE 3-13)

POWDER FOR RECONSTITUTION; ORAL
AUGMENTIN '125'
BEECHAM LABS/BEECHAM 125MG/5ML;
EQ 31.25MG ACID/5ML* N 50575

AMOXICILLIN; POTASSIUM CLAVULANATE (PAGE 3-13)

POWDER FOR RECONSTITUTION; ORAL
AUGMENTIN '250'
BEECHAM LABS/BEECHAM 250MG/5ML;EQ 62.5MG ACID/5ML* N 50575

TABLET; ORAL
AUGMENTIN '250'
BEECHAM LABS/BEECHAM 250MG;EQ 125MG ACID* N 50564
AUGMENTIN '500'
BEECHAM LABS/BEECHAM 500MG;EQ 125MG ACID* N 50564

AMPHETAMINE SULFATE (PAGE 3-13)

TABLET; ORAL
AMPHETAMINE SULFATE
LANNETT 5MG* N 83901
10MG* N 83901

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-16)

TABLET; ORAL
BUTALBITAL COMPOUND
AB ZENITH LABORATORIES 325MG;50MG;40MG* N 85441

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE (PAGE 3-16)

CAPSULE; ORAL
PROPOXYPHENE COMPOUND 65
> ADD > AA ZENITH LABORATORIES 389MG;32.4MG;65MG* N 83077
PROPOXYPHENE HCL W/ ASPIRIN AND CAFFEINE
AA CHELSEA LABORATORIES 389MG;32.4MG;65MG* N 85732

BENZOYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

GEL; TOPICAL
BENZAMYCIN
DERMIK/RORER-AMCHEM 5%;3%* N 50557

~~BENZTHIAZIDE; RESERPINE~~ (PAGE 3-21)

~~TABLET; ORAL~~
~~EXNA-R~~
~~AH ROBINS~~ ~~50MG;0.125MG~~ ~~N 14861~~

BETAMETHASONE DIPROPIONATE (PAGE 3-22)

OINTMENT; TOPICAL
ALPHATREX
AB SAVAGE LABS/BYK-GLDN EQ 0.05% BASE* N 19143

BETAMETHASONE DIPROPIONATE (PAGE 3-22)

OINTMENT; TOPICAL
BETAMETHASONE DIPROPIONATE
AB E FOUGERA/BYK-GLDN EQ 0.05% BASE* N 19141
AB PHARMADERM/BYK-GLDN EQ 0.05% BASE* N 19140
DIPROLENE
BX SCHERING EQ 0.05% N 18741
DIPROSONE
AB SCHERING EQ 0.05% N 17691

BETAMETHASONE VALERATE (PAGE 3-22)

CREAM; TOPICAL
BETATREX
/AP/ /SAVAGE LABS/BYK-GLDN/EQ 0.1% BASE/ /N 18862/
AB SAVAGE LABS/BYK-GLDN EQ 0.1% BASE N 18862
VALNAC
AB NMC LABORATORIES EQ 0.1% BASE* N 70050

OINTMENT; TOPICAL
VALNAC
AB NMC LABORATORIES EQ 0.1% BASE* N 70051

> ADD > BITOLTEROL MESYLATE (PAGE 3-24)

> ADD > AEROSOL; INHALATION
> ADD > TORNALATE
> ADD > WINTHROP-BREON/STERL 0.37MG/INH* N 18770

BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE (PAGE 3-24)

SYRUP; ORAL
AMBAY
AA BAY LABORATORIES 12.5MG/5ML;10MG/5ML* N 88626
AMBENYL
AA MARION LABORATORIES 12.5MG/5ML;10MG/5ML N 09319
BROMANYL
AA NATL PHARM MFG/BARRE 12.5MG/5ML;10MG/5ML* N 88343

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-25)

ELIXIR; ORAL
BIPHETAP
BAY LABORATORIES 4MG/5ML;25MG/5ML* N 88687
/ELIXIR DIHETAPP/
/AH ROBINS/ /4MG/5ML;25MG/5ML/ /N 13687/

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-25)

/TABLET, CONTROLLED RELEASE; ORAL/
/DIHETAPP/
/AH ROBINS/ /12MG;75MG/ /N 12436/

/BUPRENORPHINE HYDROCHLORIDE/(PAGE 3-26)

/INJECTABLE; INJECTION/
/BUPRENEX/
/NORWICH EATON/PAG/ /EQ 0.3MG BASE/ML/ /N 18401/

BUTABARBITAL SODIUM (PAGE 3-26)

ELIXIR; ORAL
/SODIUM BUTABARBITAL/
BUTABARBITAL SODIUM

CALCITONIN (PAGE 3-27)

INJECTABLE; INJECTION
CALCIMAR
> DLT > /ARMOUR PHARM/ /200 MRC UNITS/ML/ /N 17769/
> DLT > /ARMOUR PHARM/ /400 MRC UNITS/VIAL/ /N 17497/
> ADD > ARMOUR PHARM 200 IU/ML N 17769
> ADD > 400 IU/VIAL N 17497

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-28)

SOLUTION; INTRAPERITONEAL
DELFLEX W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
AT DELMED 25.7MG/100ML;1.5GM/100ML;
15.2MG/100ML;567MG/100ML;
392MG/100ML* N 18883
DELFLEX W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
AT DELMED 25.7MG/100ML;2.5GM/100ML;
15.2MG/100ML;567MG/100ML;
392MG/100ML* N 18883
DELFLEX W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
AT DELMED 25.7MG/100ML;4.25GM/100ML;
15.2MG/100ML;567MG/100ML;
392MG/100ML* N 18883
DELFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM IN PLASTIC CONTAINER
AT DELMED 25.7MG/100ML;1.5GM/100ML;
5.08MG/100ML;538MG/100ML;
448MG/100ML* N 18883
DELFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM IN PLASTIC CONTAINER
AT DELMED 25.7MG/100ML;2.5GM/100ML;
5.08MG/100ML;538MG/100ML;
448MG/100ML* N 18883

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CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-28)

SOLUTION; INTRAPERITONEAL
DELFLEX W/ DEXTROSE 4.25% LOW MAGNESIUM IN PLASTIC CONTAINER

AT	DELMED	25.7MG/100ML;4.25GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML*	N 18883

CALCIUM GLUCEPTATE (PAGE 3-30)

INJECTABLE; INJECTION
CALCIUM GLUCEPTATE

/AB/	/INTL MEDICATION SYS//	EQ 50MG CALCIUM/ML/	/N 67455/

CAPTOPRIL; HYDROCHLOROTHIAZIDE (PAGE 3-31)

TABLET; ORAL

	CAPOZIDE 25/15		
	ER SQUIBB AND SONS	25MG;15MG*	N 18709
	CAPOZIDE 25/25		
	ER SQUIBB AND SONS	25MG;25MG*	N 18709
	CAPOZIDE 50/15		
	ER SQUIBB AND SONS	50MG;15MG*	N 18709
	CAPOZIDE 50/25		
	ER SQUIBB AND SONS	50MG;25MG*	N 18709

CARBACHOL (PAGE 3-31)

/SOLUTION/DROPS; OPHTHALMIC/
INJECTABLE; INJECTION

CEFORANIDE (PAGE 3-33)

INJECTABLE; INJECTION
PRECEF

BRISTOL LABS/B-M	500MG/VIAL*	N 62579
	1GM/VIAL*	N 62579
	2GM/VIAL*	N 62579
	10GM/VIAL*	N 62579
	20GM/VIAL*	N 62579

CEFOXITIN SODIUM; DEXTROSE (PAGE 3-33)

INJECTABLE; INJECTION
MEFOXIN IN DEXTROSE 5% IN PLASTIC CONTAINER

MS&D/MERCK	EQ 20MG BASE/ML;50MG/ML*	N 50581
	EQ 40MG BASE/ML;50MG/ML*	N 50581

CEFOXITIN SODIUM; SODIUM CHLORIDE (PAGE 3-33)

INJECTABLE; INJECTION
MEFOXIN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

MS&D/MERCK	EQ 20MG BASE/ML;9MG/ML*	N 50581
	EQ 40MG BASE/ML;9MG/ML*	N 50581

CEFTIZOXIME SODIUM; DEXTROSE (PAGE 3-33)

INJECTABLE; INJECTION
CEFIZOX IN DEXTROSE 5% IN PLASTIC CONTAINER

SK&F LABORATORIES	EQ 20MG BASE/ML;50MG/ML*	N 50589
	EQ 40MG BASE/ML;50MG/ML*	N 50589

>_ADD_> CEFTRIAXONE SODIUM (PAGE 3-33)

>_ADD_> INJECTABLE; INJECTION
>_ADD_> ROCEPHIN

>_ADD_> HOFFMANN-LA ROCHE	EQ 250MG BASE/VIAL*	N 50585
>_ADD_>	EQ 500MG BASE/VIAL*	N 50585
>_ADD_>	EQ 10GM BASE/VIAL*	N 50585
>_ADD_>	EQ 2GM BASE/VIAL*	N 50585
>_ADD_>	EQ 10GM BASE/VIAL*	N 50585

CELLULOSE SODIUM PHOSPHATE (PAGE 3-34)

POWDER; ORAL
CALCIBIND

MISSION PHARMACAL	300GM/BOT*	N 18757

CHLORPROPAMIDE (PAGE 3-42)

TABLET; ORAL
CHLORPROPAMIDE

AB	BARR LABORATORIES	100MG*		N 88812
AB		250MG*		N 88813
AB	CHELSEA LABORATORIES	100MG*		N 86865
AB	COLMED LABORATORIES	100MG*		N 88708
AB		250MG*		N 88709
AB	CORD LABORATORIES	100MG*		N 88725
AB		250MG*		N 88726
AB	DANBURY PHARMACAL	100MG*		N 88852
AB		250MG*		N 88826
AB	DURAMED PHARMS	100MG*		N 88918
AB		250MG*		N 88919
AB	LEMMON	100MG*		N 88768
AB	SUPERPHARM	100MG*		N 88694
AB		250MG*		N 88695
AB	ZENITH LABORATORIES	100MG*		N 88940
>_ADD_>	GLUCAMIDE			
>_ADD_> AB	LEMMON	250MG*		N 88641

CHYMOPAPAIN (PAGE 3-43)

INJECTABLE; INJECTION
CHYMODIACTIN
SMITH LABORATORIES 4,000 UNITS/VIAL* N 18663

CISPLATIN (PAGE 3-44)

INJECTABLE; INJECTION
~~/PLATINOL/~~
~~/BRISTOL LABS/B-M/ /1MG/ML/ /50MG/VIAL/ /N 18057/ /N 18057/~~
PLATINOL-AQ
BRISTOL LABS/B-M 0.5MG/ML N 18057

CLONIDINE (PAGE 3-45)

FILM, CONTROLLED RELEASE; PERCUTANEOUS
CATAPRES-TTS-1
BOEHRINGER INGELHEIM 2.5MG* N 18891
CATAPRES-TTS-2
BOEHRINGER INGELHEIM 5MG* N 18891
CATAPRES-TTS-3
BOEHRINGER INGELHEIM 7.5MG* N 18891

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-46)

SYRUP; ORAL
PHENERGAN VC W/ CODEINE
AA WYETH LABS/AMRO 10MG/5ML;5MG/5ML;6.25MG/5ML N 08306
PROMETH VC W/ CODEINE
AA NATL PHARM MFG/BARRE 10MG/5ML;5MG/5ML;6.25MG/5ML* N 88764

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-46)

SYRUP; ORAL
PHENERGAN W/ CODEINE
AA WYETH LABS/AMRO 10MG/5ML;6.25MG/5ML N 08306
PROMETH W/ CODEINE
AA NATL PHARM MFG/BARRE 10MG/5ML;6.25MG/5ML* N 88763
> ADD > PROMETHAZINE W/ CODEINE
> ADD > AA BAY LABORATORIES 10MG/5ML;6.25MG/5ML* N 88875

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE (PAGE 3-46)

SYRUP; ORAL
ACTIFED W/ CODEINE
AA BURROUGHS WELLCOME 10MG/5ML;30MG/5ML;1.25MG/5ML N 12575
PSEUDODINE C
AA BAY LABORATORIES 10MG/5ML;30MG/5ML;1.25MG/5ML* N 88833

CORTICOTROPIN (PAGE 3-47)

INJECTABLE; INJECTION
CORTICOTROPIN
AP CARTER-GLOGAU LABS 40 UNITS/VIAL* N 88772

CROMOLYN SODIUM (PAGE 3-48)

SOLUTION/DROPS; OPHTHALMIC
OPTICROM
FISONS 4%* N 18155

DESERPIDINE; METHYCLOTHIAZIDE (PAGE 3-52)

TABLET; ORAL
ENDURONYL
BP ABBOTT LABORATORIES 0.25MG;5MG N 12775
ENDURONYL FORTE
BP ABBOTT LABORATORIES 0.5MG;5MG N 12775
METHYCLOTHIAZIDE AND DESERPIDINE
BP BOLAR PHARMACEUTICAL 0.25MG;5MG* N 88486
BP 0.5MG;5MG* N 88452

DESONIDE (PAGE 3-53)

CREAM; TOPICAL
> ADD > DESOWEN
> ADD > AB OWEN LABS/DERM PRODS 0.05%* N 19048
TRIDESILON
> ADD > AB MILES PHARMS/MILES 0.05% N 17010

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMIXIN B SULFATE (PAGE 3-55)

SUSPENSION/DROPS; OPHTHALMIC
DEXACIDIN
AT COOPERVISION PHARMS 0.1%;EQ 3.5MG BASE/ML;
AT 10,000 UNITS/ML* N 62544

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-57)

SYRUP; ORAL
PHENERGAN W/ DEXTROMETHORPHAN
AA WYETH LABS/AMRO 15MG/5ML;6.25MG/5ML N 11265
PROMETH W/ DEXTROMETHORPHAN
AA NATL PHARM MFG/BARRE 15MG/5ML;6.25MG/5ML* N 88762

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DEXTROSE (PAGE 3-57)

INJECTABLE; INJECTION
DEXTROSE 38.5% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 38.5GM/100ML* N 18923

DEXTROSE; HEPARIN SODIUM (PAGE 3-58)

INJECTABLE; INJECTION
> ADD > HEPARIN SODIUM 1000 UNITS AND DEXTROSE 5% IN PLASTIC
> ADD > CONTAINER
> ADD > AP AM MCGAW/AM HOSP 5GM/100ML;200 UNITS/100ML* N 19130
> ADD > HEPARIN SODIUM 2000 UNITS AND DEXTROSE 5% IN PLASTIC
> ADD > CONTAINER
> ADD > AP AM MCGAW/AM HOSP 5GM/100ML;200 UNITS/100ML* N 19130
> ADD > HEPARIN SODIUM 5000 UNITS AND DEXTROSE 5% IN PLASTIC
> ADD > CONTAINER
> ADD > AM MCGAW/AM HOSP 5GM/100ML;1,000 UNITS/100ML* N 19130

> ADD > DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM
> ADD > PHOSPHATE, DIBASIC; SODIUM ACETATE (PAGE 3-58)

> ADD > INJECTABLE; INJECTION
> ADD > ISOLYTE P W/ DEXTROSE 5% IN PLASTIC CONTAINER
> ADD > AM MCGAW/AM HOSP 5GM/100ML;31MG/100ML;130MG/100ML;
> ADD > 26MG/100ML;320MG/100ML* N 19025

DEXTROSE; THEOPHYLLINE (PAGE 3-62)

INJECTABLE; INJECTION
THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER
AP TRAVENOL LABS 5GM/100ML;40MG/100ML N 18649
AP 5GM/100ML;80MG/100ML N 18649
AP 5GM/100ML;160MG/100ML N 18649
AP 5GM/100ML;200MG/100ML N 18649
AP 5GM/100ML;400MG/100ML N 18649
THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER
AP AM MCGAW/AM HOSP 5GM/100ML;40MG/100ML* N 19083
THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER
AP AM MCGAW/AM HOSP 5GM/100ML;80MG/100ML* N 19083
THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER
AP AM MCGAW/AM HOSP 5GM/100ML;160MG/100ML* N 19083
THEOPHYLLINE 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER
AP AM MCGAW/AM HOSP 5GM/100ML;200MG/100ML* N 19212
THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER
AP AM MCGAW/AM HOSP 5GM/100ML;400MG/100ML* N 19212
> ADD > THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER
> ADD > AP ABBOTT LABORATORIES 5GM/100ML;40MG/100ML* N 19211
> ADD > AP 5GM/100ML;80MG/100ML* N 19211
> ADD > AP 5GM/100ML;160MG/100ML* N 19211
> ADD > AP 5GM/100ML;200MG/100ML* N 19211
> ADD > AP 5GM/100ML;400MG/100ML* N 19211

DICYCLOMINE HYDROCHLORIDE (PAGE 3-64)

CAPSULE; ORAL
BENTYL
MERRELL DOW/DOW CHEM 10MG* N 07409

INJECTABLE; INJECTION
BENTYL
MERRELL DOW/DOW CHEM 10MG/ML* N 08370

SYRUP; ORAL
BENTYL
MERRELL DOW/DOW CHEM 10MG/5ML* N 07961

TABLET; ORAL
BENTYL
MERRELL DOW/DOW CHEM 20MG* N 07409

DIETHYLPROPION HYDROCHLORIDE (PAGE 3-65)

TABLET; ORAL
DIETHYLPROPION HCL
AA LEMMON 25MG* N 88642

DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE (PAGE 3-66)

INJECTABLE; INJECTION
EMBOLEX
SANDOZ PHARMS/SANDOZ 0.5MG/0.5ML;2,500 UNITS/0.5ML;
5.33MG/0.5ML* N 18885
0.5MG/0.7ML;5,000 UNITS/0.7ML;
7.46MG/0.7ML* N 18885

DISULFIRAM (PAGE 3-68)

TABLET; ORAL
DISULFIRAM
BX PAR PHARMACEUTICAL 250MG* N 88792
BX 500MG* N 88793

DIVALPROEX SODIUM (PAGE 3-69)

TABLET, ENTERIC COATED; ORAL
DEPAKOTE
ABBOTT LABORATORIES EQ 125MG BASE* N 18723

DOXYCYCLINE HYCLATE (PAGE 3-70)

CAPSULE; ORAL
DOXY-LEMMON
AB LEMMON EQ 50MG BASE* N 62497
DOXYCYCLINE HYCLATE
AB PAR PHARMACEUTICAL EQ 50MG BASE* N 62434
AB SUPERPHARM EQ 50MG BASE* N 62469
AB EQ 100MG BASE* N 62469
AB WEST-WARD EQ 50MG BASE* N 62396
AB ZENITH LABORATORIES EQ 50MG BASE* N 62500
AB EQ 100MG BASE* N 62500

TABLET; ORAL
DOXYCYCLINE HYCLATE
AB ZENITH LABORATORIES EQ 100MG BASE* N 62505

DOXYLAMINE SUCCINATE (PAGE 3-70)

TABLET; ORAL
DECAPRYN
AA MERRELL DOW/DOW CHEM 25MG N 06412
DOXYLAMINE SUCCINATE
AA QUANTUM PHARMICS 25MG* N 88603

ESTROGENS, CONJUGATED (PAGE 3-76)

TABLET; ORAL
CONJUGATED ESTROGENS
BS ZENITH LABORATORIES 0.3MG* N 88569

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE (PAGE 3-78)

TABLET; ORAL-21
/DEMULEN/
DEMULEN 1/50-21

TABLET; ORAL-28
/DEMULEN-28/
DEMULEN 1/50-28

ETHINYL ESTRADIOL; LEVONORGESTREL (PAGE 3-78)

TABLET; ORAL-21
TRIPHASIL-21
WYETH LABS/AMHO 0.03MG,0.04MG,0.03MG; 0.05MG,0.075MG,0.125MG* N 19192

TABLET; ORAL-28
TRIPHASIL-28
WYETH LABS/AMHO 0.03MG,0.04MG,0.03MG; 0.05MG,0.075MG,0.125MG* N 19190

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE (PAGE 3-79)

TABLET; ORAL-21
/LOESTRIN 1.5/30/
LOESTRIN 21 1.5/30

FLUNISOLIDE (PAGE 3-82)

AEROSOL; INHALATION
BRONALIDE
SYNTEX LABS/SYNTEX 0.025MG/INH* N 18340

FLUOCINOLONE ACETONIDE (PAGE 3-82)

CREAM; TOPICAL
FLUOCINOLONE ACETONIDE
AT PHARMAFAIR 0.01%* N 88499
AT 0.025%* N 88506
FLUONID
AT HERBERT LABS/ALLERGN 0.025%* N 87156
/AT/ /MARION LABORATORIES/ /0.01%/ /N 80434/
/AT/ /0.025%/ /N 80434/

OINTMENT; TOPICAL
FLUONID
AT HERBERT LABS/ALLERGN 0.025%* N 87157
/AT/ /MARION LABORATORIES/ /0.025%/ /N 80433/

SOLUTION; TOPICAL
FLUONID
/AT/ /MARION LABORATORIES/ /0.01%/ /N 80432/

/FOLLICLE STIMULATING HORMONE; LUTEINIZING HORMONE/ (PAGE 3-85)
LUTEINIZING HORMONE; MENOTROPINS (PAGE 3-118)

FLUOROURACIL (PAGE 3-83)

INJECTABLE; INJECTION
FLUOROURACIL
> ADD > AP SOLOPAK LABORATORIES 50MG/100ML* N 88766
> ADD > AP 50MG/100ML* N 88767

FUROSEMIDE (PAGE 3-86)

TABLET; ORAL
FUROSEMIDE
AB CORD LABORATORIES 80MG* N 18569
AB LEDERLE LABS/AM CYAN 80MG* N 18415
AB PARKE-DAVIS/W-L 80MG* N 18419
LASIX
AB HOECHST-ROUSSEL 80MG N 16273

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GENTAMICIN SULFATE (PAGE 3-86)

OINTMENT; TOPICAL
GENTAMICIN SULFATE

AT	E FOUGERA/BYK-GLDN	EQ 1MG BASE/GM*	N 62533
AT	PHARMADERM/BYK-GLDN	EQ 1MG BASE/GM*	N 62534

SOLUTION/DROPS; OPHTHALMIC
GENOPTIC

AT	ALLERGAN PHARMS	EQ 3MG BASE/ML*	N 62452

GLUTETHIMIDE (PAGE 3-88)

TABLET; ORAL
GLUTETHIMIDE

/AA/	/ZENITH LABORATORIES/	/50MG/	/N 83683/

HALCINONIDE (PAGE 3-90)

CREAM; TOPICAL
/HALCINERM/
HALCG-E

HEPARIN SODIUM (PAGE 3-91)

INJECTABLE; INJECTABLE
HEP-FLUSH 10

AP	LYPHOMED	10 UNITS/ML*	N 17651

HEPARIN LOCK FLUSH

AP	LYPHOMED	100 UNITS/ML*	N 17651
AP	SOLOPAK LABORATORIES	10 UNITS/ML*	N 88457
AP		10 UNITS/ML*	N 80530
AP		100 UNITS/ML*	N 88581

HEPARIN SODIUM

/AP/	ELKINS-SINN/AHROBINS	/20,000 UNITS/ML/	/N 17037/
/AP/		/40,000 UNITS/ML/	/N 17037/
		/250 UNITS/ML/	/N 17037/

HEXACHLOROPHENE (PAGE 3-94)

EMULSION; TOPICAL
TURGEX

	XTTRIUM LABS	3%*	N 19055

HYDRALAZINE HYDROCHLORIDE (PAGE 3-95)

TABLET; ORAL
HYDRALAZINE HCL

	AA	ANIDE PHARMACEUTICAL	25MG*	N 88560
	AA		50MG*	N 88549
> ADD >	AA	ASCOT HOSP PHARMS	25MG*	N 88310
> ADD >	AA		50MG*	N 88311
	AA	SUPERPHARM	10MG*	N 88787
	AA		25MG*	N 88788
	AA		50MG*	N 88789

HYDROCHLOROTHIAZIDE ((PAGE 3-96)

TABLET; ORAL
HYDROCHLOROTHIAZIDE

> ADD >	AB	SUPERPHARM	25MG*	N 88827
> ADD >	AB		50MG*	N 88828
> ADD >	AB		100MG*	N 88829

> ADD > HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE (PAGE 3-98)

> ADD > TABLET; ORAL
> ADD > LOPRESSOR HCT 50/25
> ADD > GEIGY/CIBA-GEIGY 25MG;50MG* N 18303
> ADD > LOPRESSOR HCT 100/25
> ADD > GEIGY/CIBA-GEIGY 25MG;100MG* N 18303
> ADD > LOPRESSOR HCT 100/50
> ADD > GEIGY/CIBA-GEIGY 50MG;100MG* N 18303

HYDROCHLOROTHIZIDE; SPIRONOLACTONE (PAGE 3-98)

TABLET; ORAL
SPIRONOLACTONE + HYDROCHLOROTHIAZIDE

AB	ASCOT HOSP PHARMS	25MG;25MG*	N 88025

HYDROCHLOROTHIAZIDE; TIMOLOL MALEATE (PAGE 3-98)

TABLET; ORAL
/TIMOLIDE/
TIMOLIDE 10-25

HYDROCHLOROTHIAZIDE; TRIAMTERENE (PAGE 3-98)

TABLET; ORAL
MAXZIDE

MYLAN PHARMS	50MG;75MG*	N 19129

HYDROCORTISONE (PAGE 3-99)

CREAM; TOPICAL
HYDROCORTISONE
AT THAMES PHARMACAL 2.5%* N 88799

POWDER; FOR RX COMPOUNDING
H-CORT
/AA/ /PARANEX LABORATORIES/ 100%/ /N 87834/
AA TORCH LABORATORIES 100% N 87834

HYDROCORTISONE ACETATE (PAGE 3-102)

/AEROSOL; TOPICAL/
/EPIFOAM/
/REED&CARNRICK PHARMS/1%/ /N 86457/

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE (PAGE 3-103)

AEROSOL; TOPICAL
EPIFOAM
REED&CARNRICK PHARMS 1%;1% N 86457

HYDROFLUMETHIAZIDE (PAGE 3-104)

TABLET; ORAL
HYDROFLUMETHIAZIDE
AB CHELSEA LABORATORIES 50MG* N 88528

HYDROXYZINE HYDROCHLORIDE (PAGE 3-105)

TABLET; ORAL
HYDROXYZINE HCL
AB PUREPAC/KALIPHARMA 10MG* N 88120
AB 25MG* N 88121
AB 50MG* N 88122
>ADD> AB SUPERPHARM 10MG* N 88794
>ADD> AB 25MG* N 88795
>ADD> AB 50MG* N 88796

IMIPRAMINE HYDROCHLORIDE (PAGE 3-107)

TABLET; ORAL
SK-PRAMINE
>DLT>/AB/ /SK&F LABORATORIES/ /10MG/ /N 16683/
>DLT>/AB/ /25MG/ /N 16683/
>DLT> /BP/ /50MG/ /N 16683/
>ADD> AB SK&F LABORATORIES 10MG N 83827
>ADD> AB 25MG N 83827
>ADD> BP 50MG N 83827

INDOMETHACIN (PAGE 3-108)

CAPSULE; ORAL
INDOMETHACIN
AB PAR PHARMACEUTICAL 25MG* N 18829
AB 50MG* N 18829
AB PARKE-DAVIS/W-L 25MG* N 18806
AB 50MG* N 18806

SUPPOSITORY; RECTAL
INDOCIN
MS&D RES LABS/MERCK 50MG* N 17814

>ADD> IODOHIPPURATE SODIUM, I-123 (PAGE 3-109)

>ADD> INJECTABLE; INJECTION
>ADD> NEPHROFLOW
>ADD> MEDI-PHYSICS 1MCI/ML* N 18289

ISOETHARINE MESYLATE (PAGE 3-110)

AEROSOL; INHALATION
BRONKOMETER
/BREON LABS/STERLING/ 0.61%/ /N 12339/
BN BREON LABS/STERLING 0.34MG/INH N 12339
ISOETHARINE MESYLATE
BN NATL PHARM MFG/BARRE 0.34MG/INH* N 87858

KANAMYCIN SULFATE (PAGE 3-112)

INJECTABLE; INJECTION
KANTREX
AP BRISTOL LABS/B-M EQ 75MG BASE/2ML* N 62564
AP EQ 500MG BASE/2ML* N 62564
AP EQ 1GM BASE/3ML* N 62564

LABETALOL HYDROCHLORIDE (PAGE 3-113)

INJECTABLE; INJECTION
NORMODYNE
SCHERING 5MG/ML* N 18687

TABLET; ORAL
NORMODYNE
AB SCHERING 200MG* N 18686
AB 300MG* N 18686
AB 400MG* N 18686
TRANDATE
AB GLAXO 200MG* N 18716
AB 300MG* N 18716
AB 400MG* N 18716

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LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE (PAGE 3-114)

INJECTABLE; INJECTION
SCANDONEST L
AP DEPROCO 0.05MG/ML;2%* N 88388

LINDANE (PAGE 3-116)

LOTION; TOPICAL
LINDANE
AT BAY LABORATORIES 1%* N 88190

SHAMPOO; TOPICAL
LINDANE
AT BAY LABORATORIES 1%* N 88191

MEPERIDINE HYDROCHLORIDE (PAGE 3-122)

INJECTABLE; INJECTION
MEPERIDINE HCL
AP ABBOTT LABORATORIES 10MG/ML* N 88432
AP INTL MEDICATION SYS 10MG/ML N 86332

TABLET; ORAL
MEPERIDINE HCL
AA BARR LABORATORIES 100MG* N 88640

MEPHENTERMINE SULFATE (PAGE 3-123)

INJECTABLE; INJECTION
WYAMINE SULFATE
>DLT> /WYETH LABS/AMHO/ /15MG/ML/ /N 08248/
>DLT> /30MG/ML/ /N 08248/
>ADD> WYETH LABS/AMHO EQ 15MG BASE/ML N 08248
>ADD> EQ 30MG BASE/ML N 08248

MEPIVACAINE HYDROCHLORIDE (PAGE 3-123)

INJECTABLE; INJECTION
CARBOCAINE
AP BREON LABS/STERLING 2% N 12250
MEPIVACAINE HCL
AP CARTER-GLOSAU LABS 1%* N 83769
AP 2%* N 83770
POLOCAINE
AP ASTRA PHARM PRODS 3%* N 83653
SCANDONEST PLAIN
AP DEPROCO 3%* N 83337

MEPROBAMATE (PAGE 3-123)

TABLET; ORAL
MEPROBAMATE
/AA/ /MEDICAST/ /200MG/ /N 86229/
/AA/ /400MG/ /N 86229/

METHOTREXATE SODIUM (PAGE 3-128)

INJECTABLE; INJECTION
MEXATE
BRISTOL LABS/B-M EQ 250MG BASE/VIAL* N 86358

METHYCLOTHIAZIDE (PAGE 3-129)

TABLET; ORAL
METHYCLOTHIAZIDE
AB CHELSEA LABORATORIES 2.5MG* N 88750
AB 5MG* N 88724

METRONIDAZOLE (PAGE 3-133)

INJECTABLE; INJECTION
METRONIDAZOLE
>ADD> AP LYPHOMED 500MG/100ML* N 70071
>ADD>
METRYL IV
>ADD> AP LEMMON 500MG/100ML* N 70042

TABLET; ORAL
METRONIDAZOLE
>ADD> AB SIDMAK LABORATORIES 250MG* N 70027
>ADD> AB 500MG* N 70033
>ADD> AB SUPERPHARM 250MG* N 70008
>ADD> AB 500MG* N 70009
METRYL
>ADD> AB LEMMON 250MG* N 70035

MICONAZOLE NITRATE (PAGE 3-134)

SUPPOSITORY; VAGINAL
MONISTAT 3
ORTHO PHARMACEUTICAL 200MG* N 18888

MORPHINE SULFATE (PAGE 3-135)

INJECTABLE; INJECTION
DURAMORPH PF
ELKINS-SINN/AHROBINS 0.5MG/ML* N 18565
1MG/ML* N 18565

NAFCILLIN SODIUM (PAGE 3-135)

INJECTABLE; INJECTION
NAFCIL
AP BRISTOL LABS/B-M EQ 10GM BASE/VIAL* N 62527
NALLFEN
AP BEECHAM LABS/BEECHAM EQ 10GM BASE/VIAL N 61999

NALTREXONE HYDROCHLORIDE (PAGE 3-136)

TABLET; ORAL
TREXAN
DUPONT PHARMS/DUPONT 50MG* N 18932

NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-137)

SOLUTION/DROPS; OPHTHALMIC
STATROL
ALCON LABORATORIES EQ 3.5MG BASE/ML; 16,250 UNITS/ML* N 62339

> ADD > NOMIFENSINE MALEATE (PAGE 3-140)

> ADD > CAPSULE; ORAL
> ADD > MERITAL
> ADD > HOECHST-ROUSSEL 25MG* N 18224
> ADD > 50MG* N 18224

NYSTATIN (PAGE 3-141)

SUSPENSION; ORAL
NYSTATIN
AA BAY LABORATORIES 100,000 UNITS/ML* N 62512

TABLET; ORAL
NYSTATIN
AA QUANTUM PHARMICS 500,000 UNITS* N 62525

OXTRIPHYLLINE (PAGE 3-143)

ELIXIR; ORAL
CHOLEDYL
AA PARKE-DAVIS/W-L 100MG/5ML* N 09268
OXTRIPHYLLINE
AA BAY LABORATORIES 100MG/5ML N 88243

OXYPHENBUTAZONE (PAGE 3-143)

TABLET; ORAL
OXYPHENBUTAZONE
AB BOLAR PHARMACEUTICAL 100MG* N 83399
TANDEARIL
AB GEIGY/CIBA-GEIGY 100MG N 12542

PENTAMIDINE ISETHIONATE (PAGE 3-148)

INJECTABLE; INJECTION
PENTAM 300
LYPHOMED 300MG/VIAL* N 19264

PHENTERMINE HYDROCHLORIDE (PAGE 3-151)

CAPSULE; ORAL
PHENTERMINE HCL
> ADD > AA PHARM BASICS 30MG* N 88797

PENTOXIFYLLINE (PAGE 3-149)

TABLET, CONTROLLED RELEASE; ORAL
TRENTAL
HOECHST-ROUSSEL 400MG* N 18631

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-153)

SYRUP; ORAL
PHENERGAN VC
AA WYETH LABS/AMHO 5MG/5ML;6.25MG/5ML N 08604
PROMETH VC PLAIN
AA NATL PHARM MFG/BARRE 5MG/5ML;6.25MG/5ML* N 88761

PHENYTOIN SODIUM (PAGE 3-153)

INJECTABLE; INJECTION
PHENYTOIN SODIUM
> ADD > AP SOLOPAK LABORATORIES 50MG/ML* N 88519
> ADD > AP 50MG/ML* N 88520
> ADD > AP 50MG/ML* N 88521

PHENYTOIN SODIUM, EXTENDED (PAGE 3-153)

CAPSULE; ORAL
DILANTIN
> ADD > AB PARKE-DAVIS/W-L 100MG N 84369
> ADD > EXTENDED PHENYTOIN SODIUM
> ADD > AB BOLAR PHARMACEUTICAL 100MG* N 83711

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PILOCARPINE HYDROCHLORIDE (PAGE 3-154)

GEL; OPHTHALMIC
PILOPINE HS
ALCON LABORATORIES 4% N 18796

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE (PAGE 3-155)

POWDER FOR RECONSTITUTION; ORAL
COLYTE
EDLAW PREPARATIONS 120GM/PACKET;1.49GM/PACKET; 3.36GM/PACKET;2.92GM/PACKET; 11.36GM/PACKET* N 18983
227.1GM/PACKET;2.82GM/PACKET 6.36GM/PACKET;5.53GM/PACKET; 21.5GM/PACKET;* N 18983
360GM/PACKET;4.476M/PACKET; 10.08GM/PACKET;8.76GM/PACKET; 34.08GM/PACKET* N 18983

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM (PAGE 3-160)

OINTMENT; OPHTHALMIC
PREDSULFAIR
AT PHARMAFAIR 0.5%;10% N 88032
VASOCIDIN
AT COOPERVISION PHARMS 0.5%;10%* N 88791

PREDNISONE (PAGE 3-161)

SOLUTION; ORAL
PREDNISONE
ROXANE LABORATORIES 5MG/5ML* N 88703

TABLET; ORAL
PREDNISONE
BX SUPERPHARM 5MG* N 88865
BX 10MG* N 88866
BX 20MG* N 88867

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-163)

TABLET, CONTROLLED RELEASE; ORAL
> ADD > PROCAINAMIDE HCL
> ADD > AB BOLAR PHARMACEUTICAL 250MG* N 88533
> ADD > AB 500MG* N 83534
> ADD > AB 750MG* N 88535
PROCAN SR
> DLT > /BC/ PARKE-DAVIS/W-L /500MG/ N 86468
> ADD > AB 500MG N 86468
> ADD > AB 250MG N 86065
> ADD > AB 750MG N 87510

PROCHLORPERAZINE EDISYLATE (PAGE 3-164)

CONCENTRATE; ORAL
PROCHLORPERAZINE EDISYLATE
AA BAY LABORATORIES EQ 10MG BASE/ML* N 88598

SYRUP; ORAL
PROCHLORPERAZINE EDISYLATE
AA BAY LABORATORIES EQ 5MG BASE/5ML* N 88597

PROPOXYPHENE HYDROCHLORIDE (PAGE 3-167)

CAPSULE; ORAL
PROPOXYPHENE HCL
AA LEMMON 65MG* N 88615

PROTAMINE SULFATE (PAGE 3-168)

INJECTABLE; INJECTION
PROTAMINE SULFATE
UPJOHN 250MG/VIAL* N 07413

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE (PAGE 3-169)

SYRUP; ORAL
TRIPROLIDINE HCL AND PSEUDOEPHEDRINE HCL
AA PHARMAFAIR 30MG/5ML;1.25MG/5ML* N 88541

TABLET; ORAL
TRIPROLIDINE HCL AND PSEUDOEPHEDRINE HCL
> ADD > AA ZENITH LABORATORIES 60MG;2.5MG* N 85273

QUINIDINE SULFATE (PAGE 3-170)

TABLET; ORAL
CIN-QUIN
/AB/ ROXELL LABORATORIES /200MG/ /N 87255/

RANITIDINE HYDROCHLORIDE (PAGE 3-171)

INJECTABLE; INJECTION
ZANTAC
GLAXO EQ 25MG BASE/ML* N 19090

RITODRINE HYDROCHLORIDE (PAGE 3-173)

INJECTABLE; INJECTION
~~/RITODRINE HCL/~~
~~/AP/ /DUPHAR LABS/ /10MG/ML/ /N 18580/~~
YUTOPAR
/AP/ ASTRA PHARM PRODS 10MG/ML N 18580
15MG/ML* N 18580

TABLET; ORAL
~~/RITODRINE HCL/~~
~~/AB/ /DUPHAR LABS/ /10MG/ /N 18580/~~
YUTOPAR
/AB/ ASTRA PHARM PRODUCTS 10MG N 18555

SAFFLOWER OIL; SOYBEAN OIL (PAGE 3-174)

INJECTABLE; INJECTION
LIPOSYN II 10%
ABBOTT LABORATORIES 5%;5%* N 18997
LIPOSYN II 20%
ABBOTT LABORATORIES 10%;10%* N 18991

SCOPOLAMINE (PAGE 3-174)

FILM, CONTROLLED RELEASE; PERCUTANEOUS
~~/TRANSDERM-V/~~
~~/ALZA/ /1.5MG/ /N 17874/~~
TRANSDERM-SCOP
CIBA/CIBA-GEIGY 1.5MG N 17874

SODIUM CHLORIDE (PAGE 3-176)

INJECTABLE; INJECTION
SODIUM CHLORIDE IN PLASTIC CONTAINER
~~/AP/ /AM MCGAW/AM HOSP/ /900MG/100ML/ /N 17464/~~
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP AM MCGAW/AM HOSP 900MG/100ML N 17464

SODIUM LACTATE (PAGE 3-178)

INJECTABLE; INJECTION
SODIUM LACTATE IN PLASTIC CONTAINER
ABBOTT LABORATORIES 5MEQ/ML* N 18947

SODIUM POLYSTYRENE SULFONATE (PAGE 3-179)

POWDER; ORAL, RECTAL
KAYEXALATE
AA BREON LABS/STERLING 453.6GM/BOT N 11287

SODIUM POLYSTYRENE SULFONATE (PAGE 3-179)

POWDER; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
AA BAY LABORATORIES 453.6GM/BOT* N 88786

SUSPENSION; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
AA BAY LABORATORIES 15GM/60ML* N 88717

SOYBEAN OIL (PAGE 3-180)

INJECTABLE; INJECTION
LIPOSYN III 10%
AP ABBOTT LABORATORIES 10%* N 18969
LIPOSYN III 20%
AP ABBOTT LABORATORIES 20%* N 18970

SUCCINYLCHOLINE CHLORIDE (PAGE 3-181)

INJECTABLE; INJECTION
SUCCINYLCHOLINE CHLORIDE
~~/AP/ /TRAVENOL LABS/ /500MG/VIAL/ /N 80263/~~
~~/AP/ /1GM/VIAL/ /N 80263/~~

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-183)

TABLET; ORAL
SULFAMETHOXAZOLE & TRIMETHOPRIM
AB HEATHER DRUG 400MG;80MG* N 18946
AB 800MG;160MG* N 18946
SULFAMETHOXAZOLE AND TRIMETHOPRIM
AB BARR LABORATORIES 400MG;80MG* N 70006
SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH
AB BARR LABORATORIES 800MG;160MG* N 70007
TRIMETH/SULFA D/S
AB CHELSEA LABORATORIES 800MG;160MG* N 70000
TRIMETH/SULFA S/S
AB CHELSEA LABORATORIES 400MG;80MG* N 70002

TERBUTALINE SULFATE (PAGE 3-187)

AEROSOL; INHALATION
BRETHAIRE
GEIGY/CIBA-GEIGY 0.2MG/INH* N 18762

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THIORIDAZINE HYDROCHLORIDE (PAGE 3-192)

TABLET; ORAL
THIORIDAZINE HCL

AB	BARR LABORATORIES	150MG*	N 88737
AB		200MG*	N 88738
AB	CORD LABORATORIES	100MG*	N 88135

TOBRAMYCIN (PAGE 3-194)

SOLUTION/DROPS; OPHTHALMIC
TOBREX

>ADD>	ALCON LABORATORIES	0.3%*	N 62535

TOCAINIDE HYDROCHLORIDE (PAGE 3-194)

TABLET; ORAL
TONOCARD

	MS&D/MERCK	400MG*	N 18257
		600MG*	N 18257

TOLAZAMIDE (PAGE 3-194)

TABLET; ORAL
TOLAZAMIDE

AB	ZENITH LABORATORIES	100MG*	N 18894
AB		250MG*	N 18894
AB		500MG*	N 18894

TOLINASE

AB	UPJOHN	100MG	N 15500
AB		250MG	N 15500
AB		500MG	N 15500

TOLBUTAMIDE (PAGE 3-194)

TABLET; ORAL
TOLBUTAMIDE

AB	SUPERPHARM	500MG*	N 88893

TRIAMCINOLONE ACETONIDE (PAGE 3-195)

CREAM; TOPICAL
ARISTOCORT A

AT	LEDERLE LABS/AM CYAN	0.025%*	N 88818
AT		0.1%*	N 88819
AT		0.5%*	N 88820

OINTMENT; TOPICAL
ARISTOCORT A

AT	LEDERLE LABS/AM CYAN	0.1%*	N 88780
AT		0.5%*	N 88781

TRIAMCINOLONE ACETONIDE (PAGE 3-195)

OINTMENT; TOPICAL
TRIAMCINOLONE ACETONIDE

AT	PHARMADERM/BYK-GLDN	0.025%*	N 88692
AT		0.1%*	N 88690

TRYMEX

AT	SAVAGE LABS/BYK-GLDN	0.025%*	N 88693
AT		0.1%*	N 88691

>ADD> TRILOSTANE (PAGE 3-199)

>ADD> CAPSULE; ORAL
>ADD> MODRASTANE

>ADD>	WINTHROP LABS/STERL	30MG*	N 18719
>ADD>		60MG*	N 18719

TRISULFAPYRIMIDINES (PAGE 3-200)

SUSPENSION; ORAL
/TRIPLE SULFONA/

/AB/	/VALE CHEMICAL/	/500MG/5ML/	/N 60167/

VERAPAMIL HYDROCHLORIDE (PAGE 3-202)

TABLET; ORAL
CALAN

AB	SEARLE/SEARLE PHARMS	80MG*	N 18817
AB		120MG*	N 18817

ISOPTIN

AB	KNOLL PHARMACEUTICAL	80MG	N 18593
AB		120MG	N 18593

/ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;
/ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE;
/PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM;
/THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E/(PAGE AD2)

/INJECTABLE; INJECTION/
/N.V.I. PEDIATRIC/
/USV PHARMACEUTICAL/ /80MG/VIAL;0.02MG/VIAL;0.001MG/VIAL;/
/5MG/VIAL;0.01MG/VIAL;0.14MG/VIAL;/
/17MG/VIAL;0.2MG/VIAL;/
/EQ 1.1MG BASE/VIAL;1.4MG/VIAL;/
/EQ 1.2MG BASE/VIAL;0.7MG/VIAL;/
/7MG/VIAL/ /N 18920/

/ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;
/ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE;
/HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE;
/HYDROCHLORIDE; VITAMIN A; VITAMIN E/(PAGE AD2)
(SEE SPECIAL NOTE B.)

/INJECTABLE; INJECTION/
/N.V.I.-12/
/USV PHARMACEUTICAL/ /100MG/VIAL;0.06MG/VIAL;0.005MG/VIAL;/
/15MG/VIAL;0.005MG/VIAL;0.4MG/VIAL;/
/40MG/VIAL;4MG/VIAL;3.6MG/VIAL;/
/3MG/VIAL;1MG/VIAL;/
/10 IU/VIAL/ /N 18933/

/ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;
/ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE;
/HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE; VITAMIN
/A/(PAGE AD2)
(SEE SPECIAL NOTE B.)

/INJECTABLE; INJECTION/
/MVC PLUS/
/ASCOT HOSP PHARMS/ /10MG/ML;0.006MG/ML;0.5 USP/ML;/
/1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML;/
/0.4MG/ML;0.36MG/ML;0.3MG/ML;/
/330 IU/ML/ /N 18439/

/ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC
/ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN;
/THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN D; VITAMIN E/
(PAGE AD2)
(SEE SPECIAL NOTE B.)

/INJECTABLE; INJECTION/
/N.V.C. 343/
/LYPHONED/ /20MG/ML;0.012MG/ML;0.001MG/ML;
/3MG/ML;0.09MG/ML;8MG/ML;0.8MG/ML;/
/0.72MG/ML;0.6MG/ML;660 IU/ML;/
/[illegible]/ /N 18444/

/ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; FOLIC ACID;
/NIACINAMIDE; PANTHENOL; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN;
/THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN D; VITAMIN E/
(PAGE AD2)
(SEE SPECIAL NOTE B.)

/INJECTABLE; INJECTION/
/MULTIVITAMIN ADDITIVE/
/ABBOTT LABORATORIES/ /100MG/5ML;0.06MG/5ML;0.005MG/5ML;
/0.4MG/5ML;80MG/5ML;15MG/5ML;/
/5.8MG/5ML;4.4MG/5ML;3.3MG/5ML;/
/3300 IU/5ML;200 IU/5ML;/
/10 IU/5ML/ /N 18423/

/ASCORBIC ACID; BIOTIN; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE/
/HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE/(PAGE AD2)
(SEE SPECIAL NOTE B.)

/INJECTABLE; INJECTION/
/BEROCCA C/
/HOFFMAN-LA ROCHE/ /50MG/ML;0.1MG/ML;10MG/ML;40MG/ML;/
/10MG/ML;5MG/ML;5MG/ML/ /N 06071/

/BEROCCA C 500/
/HOFFMAN-LA ROCHE/ /125MG/ML;10MG/ML;10MG/ML;40MG/ML/
/10MG/ML;5MG/ML;5MG/ML/ /N 06071/

/ASCORBIC ACID; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE/
/HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE; VITAMIN A;/
/VITAMIN D; VITAMIN E/(PAGE AD3)
(SEE SPECIAL NOTE B.)

/INJECTABLE; INJECTION/
/N.V.I./
/USV PHARMACEUTICAL/ /50MG/ML;0.5MG/ML;10MG/ML;1.5MG/ML;
/1MG/ML;5MG/ML;1,000 IU/ML;100 IU/ML;/
/0.5MG/ML/ /N 06809/
/100MG/ML;5MG/ML;20MG/ML;3MG/ML;/
/5MG/ML;10MG/ML;2,000 IU/ML;/
/200 IU/ML;1MG/ML/ /N 06809/

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/ISOSORBIDE DINITRATE/(PAGE AD5)
(ALL PRODUCTS - SEE SPECIAL NOTE B.)

/TABLET;ORAL/
/ISOSORBIDE DINITRATE/
/BARR LABORATORIES/ /30MG/ /N.87564/

/TABLET;SUBLINGUAL/
/ISOSORBIDE DINITRATE/
/BARR LABORATORIES/ /10MG/ /N.87545/

/TABLET;CONTROLLED RELEASE;ORAL/
/ISOCHRON/
/FOREST LABORATORIES//20MG/ /N.88428/

NITROGLYCERIN (PAGE AD7)

/CAPSULE;CONTROLLED RELEASE;ORAL/
(ALL PRODUCTS - SEE SPECIAL NOTE B.)

/TABLET;CONTROLLED RELEASE;ORAL/
(ALL PRODUCTS - SEE SPECIAL NOTE B.)

CURRENT STATUS - INEFFECTIVE

/BENTYL W/ PHENOBARBITAL/ /MERRELL DOW/DOW CHEM/
/DICYCLOMINE HYDROCHLORIDE; PHENOBARBITAL/

BEROCCA C HOFFMANN-LA ROCHE
ASCORBIC ACID; BIOTIN; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE

BEROCCA C 500 HOFFMANN-LA ROCHE
ASCORBIC ACID; BIOTIN; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE

DIMETAPP AH ROBINS
BROMPHENIRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE; PHENYLPROPANOLAMINE HYDROCHLORIDE

ELIXIR DIMETAPP AH ROBINS
BROMPHENIRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE; PHENYLPROPANOLAMINE HYDROCHLORIDE

/TERRA-CORTRIL/ /PFIZER LABS/PFIZER/
/HYDROCORTISONE; OXYTETRACYCLINE HCL/

TUSS-ORNADE SK&F LABORATORIES
CARAMIPHEN EDISYLATE; CHLORPHENIRAMINE MALEATE; ISOPROPAMIDE IODIDE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CURRENT STATUS - EFFECTIVENESS TO BE DETERMINED

M.V.I. PEDIATRIC USV PHARMACEUTICAL
ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E

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ADDENDUM D: DRUG PRICE COMPETITION AND PATENT TERM RESTORATION

On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984. The Act amends section 505 of the Federal Food, Drug and Cosmetic Act, authorizing the Agency to accept abbreviated new drug applications for most previously approved drug products. This new legislation also provides for extending the term of a patent which claims a product, use, or method of manufacture that was subject to a regulatory review period in accordance with the Act.

The statute requires that FDA make publicly available a list of approved drug products containing the following information:

1) an alphabetical list of all drugs by official and proprietary name approved for safety and effectiveness, with monthly updates;

2) the application number and approval date for each drug product approved after 1981; and

3) whether *in vitro* and/or *in vivo* bioequivalence studies are required for ANDA approval.

The *Approved Prescription Drug Products with Therapeutic Equivalence Evaluations*, 5th Edition, (APDP) and its monthly supplements will be used to satisfy this new requirement.

In addition, the APDP will identify drugs which qualify under the new statute for periods of exclusivity (during which ANDAs and paper NDAs for those drugs may not be submitted or made effective as identified below) and will provide information on the current patent status of the listed drugs. Exclusivity prevents the filing and/or approval of ANDAs or paper NDAs. It does not prevent the filing or approval of a second NDA. Applications qualifying for periods of exclusivity are:

(1) A new drug application approved between January 1, 1982, and September 24, 1984, for a drug product involving an active ingredient (including any ester or salt of the active ingredient) which had never been approved in any other application. Approval of an ANDA or paper NDA for the same drug may not be *made effective* for a period of *ten years* from the date of the approval of the original application.

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(2) A new drug application approved after September 24, 1984, for a drug product involving an active ingredient (including any ester or salt of the active ingredient) which has never been approved in any other new drug application. Generally, no subsequent ANDA or paper NDA for the same drug may be submitted for a period of five years from the date of approval of the original application, except that such an application may be submitted after four years if it contains a certification that a patent claiming the drug is invalid or will not be infringed by the product for which approval is sought.

(3) A new drug application approved after September 24, 1984, for a drug product involving an active ingredient (or any ester or salt of that active ingredient) that has been approved in an earlier new drug application and which includes reports of new clinical investigations (other than bioavailability studies). Such investigations must have been sponsored by the applicant and must have been essential to approval of the application. If these requirements are met, the approval of a subsequent ANDA or NDA may not be made effective for the same drug before the expiration of three years from the date of approval of the original application.

(4) A supplement to a new drug application approved after September 24, 1984, which contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the firm submitting the supplement. The approval of a subsequent application for a change approved in the supplement may not be made effective for three years from the date of approval of the original supplement.

(5) A new drug application (or supplement to a new drug application) approved during the period from January 1, 1982, to September 24, 1984, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application. The approval of a subsequent application for the drug or the change made in a supplement may not be made effective for two years from September 24, 1984.

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The Act requires approved new drug applications to be supplemented with the required patent information by October 24, 1984. Patent information must now be filed with all newly submitted drug applications, and no NDA may be approved after September 24, 1984, without the pertinent patent information. The patent numbers and the expiration dates of any appropriate product or use patent on a marketed drug that is the subject of an approved NDA will be published in the APDP. Patent information on unapproved applications or on patents beyond the scope of the Act will not be published.

The following explains how the APDP implements this.

Antibiotics, Insulin and Biologicals

Title I of the Act has been interpreted by the Agency not to include antibiotic and insulin products. Because of this, (1) antibiotic and insulin products are not considered eligible for exclusivity protection, (2) holders of approved applications for insulin and antibiotic products need not submit the patent information as required of NDA application holders, and (3) Antibiotic Form 6 sponsors are not required to provide the patent certification statement which must be included in ANDAs.

However, Title II, the patent term restoration portion of the Act, specifically addresses antibiotic, non-antibiotic, and human biological products (as those terms are used in the Federal Food, Drug and Cosmetic and Public Health Service Acts) in its provisions.

Bioavailability/Bioequivalence Requirements

The therapeutic equivalence evaluation codes in Appendix D of the APDP will enable firms to determine whether *in vitro* and/or *in vivo* bioavailability/bioequivalence study data must be included with their ANDA submissions.

Currently, drugs approved prior to 1962 fall into three major biopharmaceutic classes: (1) those which pose an actual or potential bioequivalence problem, and for which demonstration of bioequivalence through *in vivo* testing and acceptable dissolution performance is necessary; (2) those which pose an actual or potential bioequivalence problem but for which an *in vivo* study may be waived if acceptable dissolution performance is demonstrated (the list of such drugs is provided under TABLE I); and (3) those which pose no actual or potential bioequivalence problem and for which the only biopharmaceutic requirement is demonstration of acceptable dissolution for solid oral dosage forms.

All firms submitting an abbreviated new drug application for a single source drug product or a drug product which was first approved after 1962 will be required to demonstrate *in vivo* bioequivalence or else submit information sufficient to permit the Agency to waive demonstration of *in vivo* bioequivalence. Manufacturers of drug products formulated in dosage forms which do not present bioequivalence problems, such as an intravenous solution, may request that the *in vivo* bioequivalence requirement be waived.

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Before the passage of the Drug Price Competition and Patent Term Restoration Act, the Agency approved various drugs with bioavailability/bioequivalence problems and deferred the in vivo testing requirement for a number of reasons. The new law requires information to show that the proposed ANDA drug product is bioequivalent to the listed drug. Therefore, new applications for drugs such as amitriptyline hydrochloride which formerly may have been approved without an in vivo study now require an in vivo study as a condition for approval under the new Act.

Topicals

In the absence of contrary data, FDA regarded all pharmaceutically equivalent topical products of pre-1962 (DESI) drugs to be therapeutically equivalent. However, the Agency required that applicants for topical drug products initially approved after 1962, including "paper NDAs," either demonstrate the safety and efficacy of their products through clinical trials or through a bioequivalence study in order to be evaluated as therapeutically equivalent.

The new Act requires applicants to demonstrate the bioequivalence of their topical drug product to the listed drug as one of the requirements for ANDA approval. This is the same policy that is presently being used in the "paper NDA" approval process. The Agency is now reviewing the therapeutic equivalence evaluation policy that has been made on the pre-1962 topical products to determine whether a change in this policy is warranted. In the meantime, an in vivo demonstration of bioequivalence will be required for approval of all topical products unless a waiver or in vitro alternatives can be justified by the applicant.

OTC Drug Products Eligible for Abbreviated New Drug Applications

Previous editions of the APDP excluded OTC drug products because the main purpose of that publication was to provide information to states regarding FDAs recommendation as to which generic prescription drug products were acceptable candidates for drug product selection. With the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, the Agency now has the responsibility to publish an up-to-date list of all marketed drug products, OTC as well as prescription, that have been approved for safety and efficacy and for which new drug applications are required. There are some drugs for which there are both approved and unapproved OTC drug products in the market place. This situation occurs as a result of the Agency's current OTC compliance policy which allows the marketing of various unapproved OTC drug products pending the effective date of the applicable final OTC monograph. The OTC products included in APDP cumulative supplement TABLE II are limited to those for which approved applications are currently required as a condition of marketing. Appropriate patent numbers and expiration dates are also included.

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NDA's Approved by the Office of Biological Research and Review Not Previously Published in the APDP

All products accepted and approved under Section 505 of the Act as NDAs by the Office of Biological Research and Review (OBRR) will now be published in the APDP (see TABLE III). The application holder should have submitted relevant patent and exclusivity information as for other NDA drug products. These products will be listed drugs and ANDA applications may be submitted for marketing of drugs from this group. Appropriate patent numbers and expiration dates are also included.

Patent and Exclusivity Information

It was originally planned that Table IV of Cumulative Supplement 2 to the APDP would contain patent and exclusivity information. Because some firms submitted patent information in excess of that covered by the statute, FDA has reviewed all of the patent information to assure that only appropriate patents are listed. The patents that FDA regards as covered by the statutory provisions for submission of patent information are those on the active ingredient or ingredients, or use patents for a particular indication or method of using the product. The agency will not publish patents relating to chemical intermediates, methods of manufacturing, excipients or formulations. Table IV contains patent numbers and expiration dates and, for drug products approved after 1982, the date of approval and application number as required by the Act.

Firms submitting ANDAs after September 24, 1984, that certified that no patent information had been filed should now amend their applications with the appropriate patent certification statement.

Table IV now also identifies drugs which qualify under the new statute for periods of 5 or 10 years exclusivity. To qualify for 10 years exclusivity, a new drug application must have been approved between January 1, 1982, and September 24, 1984, for a drug product involving a new chemical entity (NCE), including any ester or salt of the chemical entity, which had never been approved in any other application. To qualify for 5 years exclusivity, the NCE must have been approved after September 24, 1984.

FDA invites comments from all interested parties on whether it has excluded any patent or exclusivity information that should have been included or included patent or exclusivity information that should have been excluded. Any revisions to the list will be published in subsequent supplements.

FDA plans to publish the remaining exclusivity information, drugs which qualify for 2 or 3 years exlusivity, in the 5th supplement to the the APDP.

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TABLE I. LIST OF DRUG PRODUCTS WHICH MUST DEMONSTRATE IN VIVO BIOAVAILABILITY ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION

ACETAMINOPHEN; ASPIRIN; BUTALBITAL;
CAPSULE OR TABLET; ORAL
160-165MG; 160-165MG; 50MG

ACETAMINOPHEN; ASPIRIN; BUTALBITAL
CAPSULE OR TABLET; ORAL
325MG; 325MG; 50MG

ACETAMINOPHEN; ASPIRIN; BUTALBITAL; CAFFEINE
CAPSULE OR TABLET; ORAL
160-165MG; 160-165MG; 50MG; 40MG

ACETAMINOPHEN; ASPIRIN; BUTALBITAL; CAFFEINE
CAPSULE OR TABLET; ORAL
325MG; 325MG; 50MG; 40MG

ACETAMINOPHEN; BUTALBITAL
CAPSULE OR TABLET; ORAL
325; 50MG
650; 50MG

ACETAMINOPHEN; BUTALBITAL; CAFFEINE
CAPSULE OR TABLET; ORAL
325MG; 50MG; 40MG
650MG; 50MG; 40MG

AMINOPHYLLINE
TABLET; ORAL
100MG
200MG

ASPIRIN; BUTALBITAL;
CAPSULE OR TABLET; ORAL
325; 50MG
650; 50MG

ASPIRIN; BUTALBITAL, CAFFEINE
CAPSULE OR TABLET; ORAL
325MG; 50MG; 40MG;
650MG; 50MG; 40MG;

ASPIRIN; CAFFEINE; CARISOPRODOL
TABLET; ORAL
160MG; 32MG; 200MG

ASPIRIN; CAFFEINE; CARISOPRODOL; CODEINE PHOSPHATE
TABLET; ORAL
160MG; 32MG; 200MG; 16MG

ASPIRIN; CARISOPRODOL
TABLET; ORAL
325MG; 200MG

ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE
325MG; 200MG; 10MG

ASPIRIN; MEPROBAMATE
TABLET; ORAL
325MG; 200MG

ASPIRIN; METHOCARBAMOL
TABLET; ORAL
325MG; 200MG

CHLOROTHIAZIDE
TABLET; ORAL
250MG

ESTROGENS, CONJUGATED; MEPROBAMATE
TABLET; ORAL
0.4MG; 200MG
0.4MG; 400MG

HYDROXYZINE HYDROCHLORIDE
TABLET; ORAL
10MG
25MG
50MG
100MG

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TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ACETAMINOPHEN 120MG	NEOPAP (SUPPOSITORY; RECTAL)	WEBCON PHARMS/ALCON	16-401 11-07-68		
ACETAMINOPHEN 650MG	TYLENOL (SUPPOSITORY; RECTAL)	MCNEIL LABORATORIES	17-756 05-26-76		
ACETAMINOPHEN 120MG	TYLENOL (SUPPOSITORY; RECTAL)	MCNEIL LABORATORIES	17-756 05-26-76		
ACETAMINOPHEN 120MG	ACEPHEN (SUPPOSITORY; RECTAL)	G AND W LABORATORIES	18-060 02-09-78		
ACETAMINOPHEN 650MG	ACEPHEN (SUPPOSITORY; RECTAL)	G AND W LABORATORIES	18-060 02-09-78		
ACETAMINOPHEN 650MG	ACETAMINOPHEN (SUPPOSITORY; RECTAL)	UPSHER-SMITH LABS	18-337 04-22-80		
ACETAMINOPHEN 120MG	ACETAMINOPHEN (SUPPOSITORY; RECTAL)	UPSHER-SMITH LABS	18-337 09-12-83		
ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE 80MG; 20MG	GAVISCON (TABLET, CHEWABLE; ORAL)	MARION LABORATORIES	18-685 12-09-83		
ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE 160MG; 40MG	GAVISCON-2 (TABLET, CHEWABLE; ORAL)	MARION LABORATORIES	18-685 12-09-83		
BROMPHENIRAMINE MALEATE 8MG	DIMETANE (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	10-799 06-10-83		

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TABLE II.1 OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
BROMPHENIRAMINE MALEATE 12MG	DIMETANE (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	10-799 06-10-83		
CHLORHEXIDINE GLUCONATE 0.5%	HIBITANE (TINCTURE; TOPICAL)	ICI AMERICAS	18-049 12-18-78		
CHLORHEXIDINE GLUCONATE 0.5%	HIBISTAT (SOLUTION; TOPICAL)	ICI AMERICAS	18-300 05-23-80		
CHLORHEXIDINE GLUCONATE 4%	EXIDINE (SOLUTION; TOPICAL)	XTTRIUM LABS	19-125 12-24-84		
CHLORHEXIDINE GLUCONATE 4%	EXIDINE (AEROSOL; TOPICAL)	XTTRIUM LABS	19-127 12-24-84		
CHLORHEXIDINE GLUCONATE 4%	HIBICLENS (SOLUTION; TOPICAL)	ICI AMERICAS	17-768 09-17-76		
CHLORHEXIDINE GLUCONATE 4%	HIBICLENS (SPONGE; TOPICAL)	ICI AMERICAS	18-423 08-27-81		
CHLORPHENIRAMINE MALEATE 8MG	TELDRIN (CAPSULE, CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	17-369 05-11-78		
CHLORPHENIRAMINE MALEATE 12MG	TELDRIN (CAPSULE, CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	17-369 05-11-78		
CHLORPHENIRAMINE MALEATE 8MG	CHLOR-TRIMETON (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	07-638 10-18-78		
CHLORPHENIRAMINE MALEATE 12MG	CHLOR-TRIMETON (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	07-638 10-18-78		

TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 8MG; 75MG	CONTAC (CAPSULE, CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	18-099 02-04-80		
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 12MG; 75MG	TRIAMINIC-12 (TABLET, CONTROLLED RELEASE; ORAL)	DORSEY LABS/SANDOZ	18-115 07-23-81		
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 4MG; 25MG	DEMAZIN (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-556 05-14-84		
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 8MG; 75MG	PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE (CAPSULE, CONTROLLED RELEASE; ORAL)	CENTRAL PHARMS	18-809 05-07-84		
CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE 8MG; 120MG	CHLOR-TRIMETON (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-397 03-31-81		
CHLORPHENIRAMINE POLISTIREX; PHENYLPROPANOLAMINE POLISTIREX EQ 4MG MALEATE/5ML; EQ 37.5MG HCL/5ML	CORSYM (SYRUP; ORAL)	PENNWALT PHARM	18-050 01-04-84		
DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE 6MG; 120MG	DRIXORAL (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	13-483 09-13-82		

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TABLE II.1. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE 6MG; 120MG	DISOPHROL (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	13-483 09-13-82		
DEXTROMETHORPHAN RESIN COMPLEX EQ 30MG HBR/5ML	DELSYM (SUSPENSION, CONTROLLED RELEASE; ORAL)	PENNWALT PHARM	18-658 10-08-82		
DIPHENHYDRAMINE HYDROCHLORIDE 12.5MG/5ML	BENYLIN (SYRUP; ORAL)	PARKE-DAVIS/W-L	06-514 08-07-81		
DOXYLAMINE SUCCINATE 25MG	UNISOM (TABLET; ORAL)	PFIZER	18-066 10-06-78		
IBUPROFEN 200MG	ADVIL (TABLET; ORAL)	WHITEHALL LABS/AMHO	18-989 05-18-84	3385886 05-28-85	
IBUPROFEN 200MG	NUPRIN (TABLET; ORAL)	UPJOHN MANUFACTURING	19-012 05-18-84	3385886 05-28-85	
INSULIN SUSPENSION, ISOPHANE, BEEF 40 UNITS/ML	SEMILENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-929 02-08-77		
INSULIN SUSPENSION, ISOPHANE, BEEF 100 UNITS/ML	SEMILENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-929 02-08-77		
INSULIN SUSPENSION, ISOPHANE, BIOSYNTHETIC HUMAN 100 UNITS/ML	HUMULIN N (INJECTABLE; INJECTION)	ELI LILLY	18-781 10-28-82		
INSULIN SUSPENSION, ISOPHANE, MIXED BEEF AND PORK 40 UNITS/ML	NPH ILETIN (BEEF-PORK) (INJECTABLE; INJECTION)	LILLY RES LABS DIV	17-936 02-08-77		

TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
INSULIN SUSPENSION, ISOPHANE, MIXED BEEF AND PORK 100 UNITS/ML	NPH ILETIN (BEEF-PORK) (INJECTABLE; INJECTION)	LILLY RES LABS DIV	17-936 02-08-77		
INSULIN SUSPENSION, ISOPHANE, PURIFIED BEEF 100 UNITS/ML	NPH ILETIN II (INJECTABLE; INJECTION)	ELI LILLY	18-479 06-12-80		
INSULIN SUSPENSION, ISOPHANE, PURIFIED PORK 100 UNITS/ML	INSULIN INSULATARD NPH NORDISK (INJECTABLE; INJECTION)	NORDISK	18-194 01-16-80		
INSULIN SUSPENSION, ISOPHANE, PURIFIED PORK 100 UNITS/ML	NPH ILETIN II (PORK) (INJECTABLE; INJECTION)	ELI LILLY	18-345 12-05-79		
INSULIN SUSPENSION, ISOPHANE, PURIFIED PORK 100 UNITS/ML	PROTAPHANE (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-623 07-30-81		
INSULIN SUSPENSION, ISOPHANE, PURIFIED PORK; INSULIN, PURIFIED PORK 100 UNITS/ML	INSULIN NORDISK MIXTARD (PORK) (INJECTABLE; INJECTION)	NORDISK	18-195 01-16-80		
INSULIN SUSPENSION, PROTAMINE ZINC, MIXED BEEF AND PORK 100 UNITS/ML	PROTAMINE, ZINC & ILETIN (BEEF-PORK) (INJECTABLE; INJECTION)	ELI LILLY	17-932 02-08-77		
INSULIN SUSPENSION, PROTAMINE ZINC, MIXED BEEF AND PORK; INSULIN, MIXED BEEF AND PORK 100 UNITS/ML	PROTAMINE, ZINC & ILETIN (BEEF-PORK) (INJECTABLE; INJECTION)	ELI LILLY	17-932 02-08-77		

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TABLE II.1 OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED BEEF 40 UNITS/ML	PROTAMINE ZINC INSULIN (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-928 02-08-77		
INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED BEEF 100 UNITS/ML	PROTAMINE ZINC INSULIN (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-928 02-08-77		
INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED BEEF; INSULIN, PURIFIED BEEF 100 UNITS/ML	PROTAMINE ZINC AND ILETIN II (INJECTABLE; INJECTION)	ELI LILLY	18-476 06-12-80		
INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED PORK; INSULIN, PURIFIED PORK 100 UNITS/ML	PROTAMINE ZINC AND ILETIN II(PORK) (INJECTABLE; INJECTION)	ELI LILLY	18-346 12-05-79		
INSULIN ZINC SUSPENSION, BEEF 40 UNITS/ML	LENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-998 02-08-77		
INSULIN ZINC SUSPENSION, BEEF 100 UNITS/ML	LENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-998 02-08-77		
INSULIN ZINC SUSPENSION, BIOSYNTHETIC HUMAN 100 UNITS/ML	MONOTARD HUMAN (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-777 08-30-83		
INSULIN ZINC SUSPENSION, EXTENDED, PURIFIED BEEF 100 UNITS/ML	ULTRATARD (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-385 03-17-80		

TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
INSULIN ZINC SUSPENSION, EXTENDED, PURIFIED BEEF 100 UNITS/ML	ULTRALENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-997 02-08-77		
INSULIN ZINC SUSPENSION, PROMPT, BEEF 100 UNITS/ML	SEMILENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-996 02-08-77		
INSULIN ZINC SUSPENSION, PROMPT, PURIFIED PORK 100 UNITS/ML	SEMITARD (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-382 03-17-80		
INSULIN ZINC SUSPENSION, PURIFIED BEEF 100 UNITS/ML	LENTE ILETIN II (INJECTABLE; INJECTION)	ELI LILLY	18-477 06-12-80		
INSULIN ZINC SUSPENSION, PURIFIED BEEF AND PORK 100 UNITS/ML	LENTARD (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-384 03-17-80		
INSULIN ZINC SUSPENSION, PURIFIED PORK 100 UNITS/ML	LENTE ILETIN II (PORK) (INJECTABLE; INJECTION)	ELI LILLY	18-347 12-05-79		
INSULIN ZINC SUSPENSION, PURIFIED PORK 100 UNITS/ML	MONOTARD (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-383 03-17-80		
INSULIN, BIOSYNTHETIC HUMAN 100 UNITS/ML	ACTRAPID HUMAN (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-778 08-30-83		

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TABLE III: OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
INSULIN, BIOSYNTHETIC HUMAN 100 UNITS/ML	HUMULIN R (INJECTABLE; INJECTION)	ELI LILLY	18-780 10-28-82		
INSULIN, PORK 40 UNITS/ML	INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-926 02-08-77		
INSULIN, PORK 100 UNITS/ML	INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-926 02-08-77		
INSULIN, PURIFIED BEEF 100 UNITS/ML	REGULAR ILETIN II (INJECTABLE; INJECTION)	ELI LILLY	18-478 06-12-80		
INSULIN, PURIFIED PORK 100 UNITS/ML	INSULIN NORDISK QUICK (PORK) (INJECTABLE; INJECTION)	NORDISK INSULIN LABS	18-193 01-16-80		
INSULIN, PURIFIED PORK 100 UNITS/ML	REGULAR ILETIN II (PORK) (INJECTABLE; INJECTION)	ELI LILLY	18-344 12-05-79		
INSULIN, PURIFIED PORK 100 UNITS/ML	ACTRAPID (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-381 03-17-80		
NONOXYNOL-9 1GM	TODAY (SPONGE; VAGINAL)	VLI CORPORATION	18-683 04-01-83		
POTASSIUM IODIDE 130MG	THYRO-BLOCK (TABLET; ORAL)	WALLACE LABS/C-W	18-307 11-09-79		
POTASSIUM IODIDE 1GM/ML	POTASSIUM IODIDE (SOLUTION; ORAL)	ROXANE LABORATORIES	18-551 02-19-82		
POTASSIUM IODIDE 130MG	IOSAT (TABLET; ORAL)	ANBEX	18-664 10-14-82		

TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
PSEUDOEPHEDRINE HYDROCHLORIDE 120MG	SUDAFED S.A. (CAPSULE, CONTROLLED RELEASE; ORAL)	BURROUGHS WELLCOME	17-941 01-15-79		
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	ACTIFED (SYRUP; ORAL)	BURROUGHS WELLCOME	11-935 11-26-82		
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	ACTIFED (TABLET; ORAL)	BURROUGHS WELLCOME	11-936 11-26-82		
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	ALLERBAN PLUS (SYRUP; ORAL)	BAY LABORATORIES	88-116 03-04-83		
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRI-SUDO (TABLET; ORAL)	MD PHARMACEUTICAL	85-024 01-10-84		
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPODRINE (TABLET; ORAL)	DANBURY PHARMACAL	88-112 01-20-83		
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	TRIOFED (SYRUP; ORAL)	NATL PHARM MFG/BARRE	88-115 03-04-83		
PSEUDOEPHEDRINE SULFATE 120MG	AFRINOL (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-191 10-30-80		
TIOCONAZOLE 1%	TROSYD (CREAM; TOPICAL)	PFIZER CEN RES/PFIZR	18-682 02-18-83	4062966 12-13-94	NCE 02-18-93

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	10-102 12-14-61		
ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	11-912 9-2-59		
ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	10-855 06-11-59		
ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	16-918 3-17-78		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE-1 SOLUTION	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	80-77 11-6-80		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION	NONE (INJECTABLE; INJECTION)	DELMED	78-519 4-23-80		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION	NONE (INJECTABLE; INJECTION)	TERUMO AMERICA	82-528 11-3-82		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	77-420 5-12-78		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	16-527 6-22-70		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	80-222 8-23-82		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	16-907 5-15-73		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TERUMO AMERICA	78-1211 6-10-81		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	17-401 12-6-77		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	81-1012 6-28-83		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP WITH: AS-1: DEXTROSE USP 2.2GM/100ML, SODIUM CHLORIDE USP 0.9GM/100ML, MANNITOL USP 0.75GM/100ML, ADENINE 0.27GM/100ML	ADSOL[R] RED CELL PRESERVATION SOLUTION (INJECTABLE; INJECTION)	TRAVENOL LABS	81-1104 5-16-83		
ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION WITH: AS-2: CITRIC ACID USP 0.42GM/100ML, DIBASIC SODIUM PHOSPHATE USP 0.285GM/100ML, SODIUM CHLORIDE USP 0.718 GM/100ML, ADENINE 0.017GM/100ML, DEXTROSE USP 0.396GM/100ML, SODIUM CITRATE USP 0.588GM/100ML	AS-2 NUTRICEL ADITIVE SYSTEM (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	82-915 9-22-83		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION WITH: AS-3: CITRIC ACID USP 0.042 GM/100ML, MONOBASIC SODIUM PHOSPHATE USP 0.276GM/100ML, SODIUM CHLORIDE USP 0.410 GM/100ML, ADENINE 0.30 GM/100ML, DEXTROSE USP 1.10 GM/100ML, SODIUM CITRATE USP 0.588GM/100ML	AS-3 NUTRICEL ADDITIVE SYSTEM (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	82-915 10-19-84		
ANTICOAGULANT HEPARIN SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	77-822 5-17-78		
ANTICOAGULANT HEPARIN SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	81-1217 5-16-83		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	81-416 10-12-83		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	76-305 6-30-78		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	16-702 12-28-70		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TERUMO AMERICA	78-1214 2-8-80		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	77-923 1-20-78		

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TABLE III. NDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	16-375 7-25-67		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	16-375 7-25-67		
DEXTRAN 75, 6% 6GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	8-819 3-31-53		
DEXTRAN 75, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	8-819 3-31-53		
DEXTRAN 75, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-253 2-4-83		
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	AMERICAN MCGAW	16-767 4-6-70		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	AMERICAN MCGAW	16-767 4-6-70		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTRAN 70, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	AMERICAN MCGAW	9-024 8-18-69		
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	16-653 9-23-69		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	16-653 9-23-69		
DEXTRAN 70, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	8-716 8-11-69		
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	PHARMACHEM	16-836 11-14-70		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	PHARMACHEM	16-836 11-14-70		
DEXTRAN 75, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	PHARMACHEM	8-564 9-19-52		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTRAN 75, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	PHARMACHEM	16-759 8-19-70		
DEXTRAN 1 150MG/ML IN SODIUM CHLORIDE 0.6% 6MG/ML	FROMIT (INJECTABLE;INJECTION)	PHARMACIA LABS	83-715 10-30-84		
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	RHEOMACRODEX[R] (INJECTABLE; INJECTION)	PHARMACIA LABS	14-716 1-18-67		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	RHEOMACRODEX[R] (INJECTABLE; INJECTION)	PHARMACIA LABS	14-716 1-18-67		
DEXTRAN 70, 6% 6GM/100ML IN DEXTROSE 5% 5GM/100ML	MACRODEX[R] (INJECTABLE; INJECTION)	PHARMACIA LABS	6-826 6-8-54		
DEXTRAN 70, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	MACRODEX[R] (INJECTABLE; INJECTION)	PHARMACIA LABS	6-826 6-8-54		
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	GENTRAN[R] 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	16-628 11-4-68		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	GENTRAN[R] 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	16-628 11-4-68		
DEXTRAN 75, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	GENTRAN[R] 75 (INJECTABLE; INJECTION)	TRAVENOL LABS	16-607 1-26-70		
DEXTRAN 75, 6% INVERTED SUGAR 10% 6GM/100ML;10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	6% GENTRAN[R] 75 AND 10% TRAVERT[R] (INJECTABLE; INJECTION)	TRAVENOL LABS	8-788 2-9-53		
HETASTARCH, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	HESPAN[R] (INJECTABLE; INJECTION)	AM CRITICAL CARE	16-889 7-17-72	3523938 8-11-87	
PROPIOLACTONE 99% 99GM/100ML	BETAPRONE (SOLUTION; CHEMICAL STERILIZING AGENT)	ONEAL JONES&FELDMAN	11-657 9-11-59		
UROKINASE 5000 IU/VIAL	ABBOKINASE OPEN-CATHETER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	76-1021 12-15-83		
UROKINASE 250,000 IU/VIAL	ABBOKINASE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	76-1021 7-31-78		
UROKINASE 250,000 IU/VIAL	BREOKINASE (INJECTABLE; INJECTION)	STERLING DRUG	17-873 8-28-79		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ACEBUTOLOL HYDROCHLORIDE EQ 200MG BASE	SECTRAL (CAPSULE; ORAL)	IVES LABS/AMHO	18-917 12-28-84	3726919 04-10-90 3857952 12-31-91	NCE 12-28-89
ACEBUTOLOL HYDROCHLORIDE EQ 300MG BASE	SECTRAL (CAPSULE; ORAL)	IVES LABS/AMHO	18-917 12-28-84	3726919 04-10-90 3857952 12-31-91	NCE 12-28-89
ACEBUTOLOL HYDROCHLORIDE EQ 400MG BASE	SECTRAL (CAPSULE; ORAL)	IVES LABS/AMHO	18-917 12-28-84	3726919 04-10-90 3857952 12-31-91	NCE 12-28-89
ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE 625MG; EQ 25MG BASE	TALACEN (TABLET; ORAL)	STERLING DRUG	18-458 09-23-82	4105659 08-08-95	
ACETAZOLAMIDE 500MG	DIAMOX (CAPSULE, CONTROLLED RELEASE; ORAL)	LEDERLE LABS/AM CYAN	12-945 01-25-62	3544005 06-08-88	
ACETIC ACID, GLACIAL 250MG/100ML	ACETIC ACID 0.25% IN PLASTIC CONTAINER (SOLUTION; URETHRAL)	TRAVENOL LABS	18-523 02-19-82		
ACETOHYDROXAMIC ACID 250MG	LITHOSTAT (TABLET; ORAL)	URO-RESEARCH	18-749 05-31-83		NCE 05-31-93
ACYCLOVIR 5%	ZOVIRAX (OINTMENT; TOPICAL)	BURROUGHS WELLCOME	18-604 03-29-82	4199574 04-22-97	NCE 03-29-92

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ACYCLOVIR SODIUM EQ 500MG BASE/VIAL	ZOVIRAX (INJECTABLE; INJECTION)	BURROUGHS WELLCOME	18-603 10-22-82	4199574 04-22-97	NCE 03-29-92
ALBUTEROL 0.09MG/INH	PROVENTIL (AEROSOL; INHALATION)	SCHERING	17-559 05-01-81	3644353 02-22-89 3705233 12-05-89	
ALBUTEROL 0.09MG/INH	VENTOLIN (AEROSOL; INHALATION)	GLAXO	18-473 05-01-81	3644353 02-22-89 3705233 12-05-89	
ALBUTEROL SULFATE EQ 2MG BASE	PROVENTIL (TABLET; ORAL)	SCHERING	17-853 05-07-82	3644353 02-22-89 3705233 12-05-89	
ALBUTEROL SULFATE EQ 4MG BASE	PROVENTIL (TABLET; ORAL)	SCHERING	17-853 05-07-82	3644353 02-22-89 3705233 12-05-89	
ALCLOMETASONE DIPROPIONATE 0.05%	VADERM (OINTMENT; TOPICAL)	SCHERING	18-702 12-14-82	4124707 11-07-95	NCE 12-14-92
ALCLOMETASONE DIPROPIONATE 0.05%	VADERM (CREAM; TOPICAL)	SCHERING	18-707 12-14-82	4124707 11-07-95	NCE 12-14-92
ALLOPURINOL 100MG	ALLOPURINOL (TABLET; ORAL)	BOLAR PHARMACEUTICAL	18-241 11-16-84		
ALLOPURINOL 300MG	ALLOPURINOL (TABLET; ORAL)	BOLAR PHARMACEUTICAL	18-241 11-16-84		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ALLOPURINOL 100MG	ALLOPURINOL (TABLET; ORAL)	CHELSEA LABORATORIES	18-785 09-28-84		
ALLOPURINOL 300MG	ALLOPURINOL (TABLET; ORAL)	CHELSEA LABORATORIES	18-785 09-28-84		
ALLOPURINOL 100MG	ALLOPURINOL (TABLET; ORAL)	DANBURY PHARMACAL	18-832 09-28-84		
ALLOPURINOL 300MG	ALLOPURINOL (TABLET; ORAL)	DANBURY PHARMACAL	18-877 09-28-84		
ALLOPURINOL 100MG	ZYLOPRIM (TABLET; ORAL)	BURROUGHS WELLCOME	16-084 08-19-66	3624205 11-30-88	
ALLOPURINOL 300MG	ZYLOPRIM (TABLET; ORAL)	BURROUGHS WELLCOME	16-084 01-14-74	3624205 11-30-88	
ALLOPURINOL 100MG	LOPURIN (TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-297 06-10-80	3624205 11-30-88	
ALLOPURINOL 300MG	LOPURIN (TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-297 06-10-80	3624205 11-30-88	
ALPRAZOLAM 0.25MG	XANAX (TABLET; ORAL)	UPJOHN	18-276 10-16-81	3987052 10-19-93 3980789 09-14-93	
ALPRAZOLAM 0.5MG	XANAX (TABLET; ORAL)	UPJOHN	18-276 10-16-81	3987052 10-19-93 3980789 09-14-93	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ALPRAZOLAM 1MG	XANAX (TABLET; ORAL)	UP JOHN	18-276 10-16-81	3987052 10-19-93 3980789 09-14-93	
AMCINONIDE 0.1%	CYCLOCORT (CREAM; TOPICAL)	LEDERLE LABS/AM CYAN	18-116 10-18-71	4158055 06-12-96	
AMCINONIDE 0.1%	CYCLOCORT (OINTMENT; TOPICAL)	LEDERLE LABS/AM CYAN	18-498 11-13-81	4158055 06-12-96	
AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE 5MG; 50MG	MODURETIC 5/50 (TABLET; ORAL)	MS&D/MERCK	18-201 10-05-81	3781430 12-25-90	
AMINO ACIDS 6.9%	FREAMINE HBC 6.9% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	16-822 05-17-83		
AMINO ACIDS 6.5%	RENAMIN W/O ELECTROLYTES (INJECTABLE; INJECTION)	TRAVENOL LABS	17-493 10-15-82		
AMINO ACIDS 8.5%	NOVAMINE 8.5% (INJECTABLE; INJECTION)	CUTTER LABS/MILES	17-957 08-09-82		
AMINO ACIDS 11.4%	NOVAMINE 11.4% (INJECTABLE; INJECTION)	CUTTER LABS/MILES	17-957 08-09-82		
AMINO ACIDS 8%	HEPATAMINE 8% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-676 08-03-82	3950529 04-13-93	
AMINO ACIDS 4%	BRANCHAMIN 4% (INJECTABLE; INJECTION)	TRAVENOL LABS	18-678 09-28-84	4438144 03-20-01	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
AMINO ACIDS 4%	BRANCHAMIN 4% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-684 09-28-84	4438144 03-20-01	
AMINO ACIDS 6.5%	NEOPHAM 6.5% (INJECTABLE; INJECTION)	CUTTER-VITRUM	18-792 01-17-84		
AMINO ACIDS 3.5%	AMINOSYN 3.5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-804 05-15-84		
AMINO ACIDS 3.5%	AMINOSYN 3.5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-875 08-08-84		
AMINO ACIDS 5.2%	AMINESS 5.2% ESSENTIAL AMINO ACIDS W/ HISTADINE (INJECTABLE; INJECTION)	CUTTER-VITRUM	18-901 04-06-84		
AMINO ACIDS 5.5%	TRAVASOL 5.5% W/O ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-931 08-23-84		
AMINO ACIDS 8.5%	TRAVASOL 8.5% W/O ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-931 08-23-84		
AMINO ACIDS 10%	TRAVASOL 10% W/O ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-931 08-23-84		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
AMINO ACIDS 6%	TROPHAMINE 6% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-018 07-20-84		
AMINO ACIDS; CALCIUM ACETATE; GLYCERIN; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 3%; 26MG/100ML; 3GM/100ML; 54MG/100ML; 41MG/100ML; 149MG/100ML; 204MG/100ML; 117MG/100ML	PERIPHRAMINE (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-582 05-08-82		
AMINO ACIDS; DEXTROSE 3.5%; 5%	AMINOSYN 3.5% W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-120 10-11-84		
AMINO ACIDS; DEXTROSE 3.5%; 25%	AMINOSYN 3.5% W/ DEXTROSE 25% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-118 10-11-84		
AMINO ACIDS; DEXTROSE 4.25%; 25%	AMINOSYN 4.25% W/ DEXTROSE 25% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-119 10-11-84		
AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; SODIUM CHLORIDE 3.5%; 21MG/100ML; 40MG/100ML; 128MG/100ML; 234MG/100ML	AMINOSYN 3.5% M IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-804 05-15-84		

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AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; SODIUM CHLORIDE 3.5%; 21MG/100ML; 40MG/100ML; 128MG/100ML; 234MG/100ML	AMINOSYN 3.5% M IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-875 08-08-84		
AMINOACETIC ACID 1.5GM/100ML	AMINOACETIC ACID 1.5% IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-522 02-19-82		
AMINOCAPROIC ACID 250MG/ML	AMINOCAPROIC ACID (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-590 10-29-82		
AMINOGLUTETHIMIDE 250MG	CYTADREN (TABLET; ORAL)	CIBA/CIBA-GEIGY	18-202 10-29-80	3595960 07-27-88 3944671 03-16-93	
AMINOPHYLLINE 300MG/5ML	SOMOPHYLLIN (ENEMA; RECTAL)	FISONS	18-232 04-02-82		
AMINOPHYLLINE; SODIUM CHLORIDE 100MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-924 12-12-84		
AMINOPHYLLINE; SODIUM CHLORIDE 200MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-924 12-12-84		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
AMINOPHYLLINE; SODIUM CHLORIDE 400MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-924 12-12-84		
AMINOPHYLLINE; SODIUM CHLORIDE 500MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-924 12-12-84		
AMITRIPTYLINE HYDROCHLORIDE 10MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 04-07-61	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE 25MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 07-05-74	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE 50MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 04-07-61	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE 75MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 10-28-76	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE 100MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 10-28-76	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE 150MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 09-17-76	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE 10MG/ML	ELAVIL (INJECTABLE; INJECTION)	MS&D/MERCK	12-704 04-11-61	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE 12.5MG; 5MG	LIMBITROL (TABLET; ORAL)	HOFFMANN-LA ROCHE	16-949 12-23-77	3384663 05-21-85 4316897 02-23-99	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE 25MG; 10MG	LIMBITROL (TABLET; ORAL)	HOFFMANN-LA ROCHE	16-949 12-23-77	3384663 05-21-85 4316897 02-23-99	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 4MG	ETRAFON A (TABLET; ORAL)	SCHERING	14-713 12-30-65	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 2MG	ETRAFON 2-25 (TABLET; ORAL)	SCHERING	14-713 12-30-65	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 4MG	ETRAFON-FORTE (TABLET; ORAL)	SCHERING	14-713 12-30-65	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 2MG	ETRAFON 2-10 (TABLET; ORAL)	SCHERING	14-713 12-30-65	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 4MG	TRIAVIL 4-10 (TABLET; ORAL)	MS&D/MERCK	14-715 12-30-65	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 2MG	TRIAVIL 2-25 (TABLET; ORAL)	MS&D/MERCK	14-715 08-23-65	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 2MG	TRIAVIL 2-10 (TABLET; ORAL)	MS&D/MERCK	14-715 04-04-67	3384663 05-21-85	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 4MG	TRIAVIL 4-25 (TABLET; ORAL)	MS&D/MERCK	14-715 08-25-65	3384663 05-21-85	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 50MG; 4MG	TRIAVIL 4-50 (TABLET; ORAL)	MS&D/MERCK	14-715 03-15-78	3384663 05-21-85	
AMOXAPINE 25MG	ASENDIN (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-021 09-22-80	3546226 12-08-87 3663696 05-16-89 3681357 08-01-89	
AMOXAPINE 50MG	ASENDIN (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-021 09-22-80	3546226 12-08-87 3663696 05-16-89 3681357 08-01-89	
AMOXAPINE 100MG	ASENDIN (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-021 09-22-80	3546226 12-08-87 3663696 05-16-89 3681357 08-01-89	
AMOXAPINE 150MG	ASENDIN (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-021 09-22-80	3546226 12-08-87 3663696 05-16-89 3681357 08-01-89	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
AMRINONE LACTATE EQ 5MG BASE/ML	INOCOR (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	18-700 07-31-84	4072746 02-07-95	NCE 07-31-94
ASPIRIN; CAFFEINE; DIHYDROCODEINE BITARTRATE 356.4MG; 30MG; 16MG	SYNALGOS-DC (CAPSULE; ORAL)	IVES LABS/AMHO	11-483 09-06-83		
ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE 385MG; 30MG; 25MG	NORGESIC (TABLET; ORAL)	RIKER LABS/3M	13-416 10-27-82		
ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE 770MG; 60MG; 50MG	NORGESIC FORTE (TABLET; ORAL)	RIKER LABS/3M	13-416 10-27-82		
ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE 389MG; 32.4MG; 32MG	DARVON COMPOUND (CAPSULE; ORAL)	ELI LILLY INDSTRS/PR	10-996 03-08-83		
ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE 389MG; 32.4MG; 65MG	DARVON COMPOUND-65 (CAPSULE; ORAL)	ELI LILLY INDSTRS/PR	10-996 03-08-83		
ASPIRIN; CARISOPRODOL 325MG; 200MG	SOMA COMPOUND (TABLET; ORAL)	WALLACE PHARMS/C-W	12-365 07-11-83		
ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE 325MG; 200MG; 16MG	SOMA COMPOUND W/ CODEINE (TABLET; ORAL)	WALLACE PHARMS/C-W	12-366 07-11-83		
ASPIRIN; MEPROBAMATE 325MG; 200MG	EQUAGESIC (TABLET; ORAL)	WYETH LABS/AMHO	11-702 12-29-83		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ASPIRIN; PENTAZOCINE HYDROCHLORIDE 325MG; EQ 12.5MG BASE	TALWIN COMPOUND (TABLET; ORAL)	WINTHROP LABS/STERL	16-891 11-12-75	4105659 08-08-95	
ATENOLOL 50MG	TENORMIN (TABLET; ORAL)	STUART PHARMS/ICI AM	18-240 08-19-81	3663607 05-16-89 3934032 01-20-93 3836671 09-17-91	
ATENOLOL 100MG	TENORMIN (TABLET; ORAL)	STUART PHARMS/ICI AM	18-240 08-19-81	3663607 05-16-89 3934032 01-20-93 3836671 09-17-91	
ATENOLOL; CHLORTHALIDONE 100MG; 25MG	TENORETIC 100 (TABLET; ORAL)	STUART PHARMS/ICI AM	18-760 06-08-84	3663607 05-16-89 3934032 01-20-93 3836671 09-17-91	
ATENOLOL; CHLORTHALIDONE 50MG; 25MG	TENORETIC 50 (TABLET; ORAL)	STUART PHARMS/ICI AM	18-760 06-08-84	3663607 05-16-89 3934032 01-20-93 3836671 09-17-91	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ATRACURIUM BESYLATE 10MG/ML	TRACRIUM (INJECTABLE; INJECTION)	BURROUGHS WELLCOME	18-831 11-23-83	4179507 12-18-96	NCE 11-23-93
ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE 0.025MG; 0.5MG	MOTOFEN HALF-STRENGTH (TABLET; ORAL)	MCNEIL LABORATORIES	17-744 07-14-78	3646207 02-28-89	
ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE 0.025MG; 1MG	MOTOFEN (TABLET; ORAL)	MCNEIL LABORATORIES	17-744 07-14-78	3646207 02-28-89	
AZATADINE MALEATE 1MG	OPTIMINE (TABLET; ORAL)	SCHERING	17-601 03-29-77	3366635 01-30-85 3419565 12-31-85 3717647 02-20-90	
AZATADINE MALEATE; PSEUDOEPHEDRINE SULFATE 1MG; 120MG	TRINALIN (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-506 03-23-82	3366635 01-30-85 3419565 12-31-85 3717647 02-20-90	
BACLOFEN 10MG	LIORESAL (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-851 11-22-77	3471548 10-07-86	
BACLOFEN 20MG	LIORESAL DS (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-851 01-20-82	3471548 10-07-86	
BENDROFLUMETHIAZIDE 2.5MG	NATURETIN-2.5 (TABLET; ORAL)	ER SQUIBB AND SONS	12-164 12-07-59	3392168 07-09-85	
BENDROFLUMETHIAZIDE 5MG	NATURETIN-5 (TABLET; ORAL)	ER SQUIBB AND SONS	12-164 12-07-59	3392168 07-09-85	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
BENDROFLUMETHIAZIDE 10MG	NATURETIN-10 (TABLET; ORAL)	ER SQUIBB AND SONS	12-164 03-29-77	3392168 07-09-85	
BENDROFLUMETHIAZIDE; NADOLOL 5MG; 40MG	CORZIDE (TABLET; ORAL)	ER SQUIBB AND SONS	18-647 05-25-83	3982021 09-21-93 3935267 01-27-93	
BENDROFLUMETHIAZIDE; NADOLOL 5MG; 80MG	CORZIDE (TABLET; ORAL)	ER SQUIBB AND SONS	18-647 05-25-83	3982021 09-21-93 3935267 01-27-93	
BENTIROMIDE 500MG/7.5ML	CHYMEX (SOLUTION; ORAL)	ADRIA LABORATORIES	18-366 12-29-83	3801562 04-02-91 3745212 07-10-90	NCE 12-29-93
BETAMETHASONE 0.6MG	CELESTONE (TABLET; ORAL)	SCHERING	12-657 04-17-61	3485854 12-23-86	
BETAMETHASONE 0.6MG/5ML	CELESTONE (SYRUP; ORAL)	SCHERING	14-215 04-18-64	3485854 12-23-86	
BETAMETHASONE 0.2%	CELESTONE (CREAM; TOPICAL)	SCHERING	14-762 04-10-64	3485854 12-23-86	
BETAMETHASONE ACETATE; BETAMETHASONE SODIUM PHOSPHATE 3MG/ML; EQ 3MG BASE/ML	CELESTONE SOLUSPAN (INJECTABLE; INJECTION)	SCHERING	14-602 03-03-65	3485854 12-23-86	
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	DIPROLENE (OINTMENT; TOPICAL)	SCHERING	18-741 07-27-83		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (CREAM; TOPICAL)	PHARMADERM/BYK-GLDN	19-136 06-26-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (CREAM; TOPICAL)	E FOUGERA/BYK-GLDN	19-137 06-26-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	ALPHATREX (CREAM; TOPICAL)	SAVAGE LABS/BYK-GLDN	19-138 06-26-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (OINTMENT; TOPICAL)	PHARMADERM/BYK-GLDN	19-140 09-04-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (OINTMENT; TOPICAL)	E FOUGERA/BYK-GLDN	19-141 09-04-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	ALPHATREX (OINTMENT; TOPICAL)	SAVAGE LABS/BYK-GLDN	19-143 09-04-84		
BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE EQ 0.05% BASE; 1%	LOTRISONE (CREAM; TOPICAL)	SCHERING	18-827 07-10-84	3660577 05-02-89 3705172 12-05-89 4298604 11-03-98 3839573 10-01-91	
BETAMETHASONE VALERATE EQ 0.1% BASE	BETA-VAL (CREAM; TOPICAL)	LEMMON	18-642 03-24-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETADERM (CREAM; TOPICAL)	TJ ROACO	18-839 06-30-83		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (CREAM; TOPICAL)	PHARMADERM/BYK-GLDN	18-860 08-31-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (CREAM; TOPICAL)	E FOUGERA/BYK-GLDN	18-861 08-31-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETATREX (CREAM; TOPICAL)	SAVAGE LABS/BYK-GLDN	18-862 08-31-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETATREX (OINTMENT; TOPICAL)	SAVAGE LABS/BYK-GLDN	18-863 08-31-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (OINTMENT; TOPICAL)	PHARMADERM/BYK-GLDN	18-864 08-31-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (OINTMENT; TOPICAL)	E FOUGERA/BYK-GLDN	18-865 08-31-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (LOTION; TOPICAL)	E FOUGERA/BYK-GLDN	18-866 08-31-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETATREX (LOTION; TOPICAL)	SAVAGE LABS/BYK-GLDN	18-867 08-31-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (LOTION; TOPICAL)	PHARMADERM/BYK-GLDN	18-870 08-31-83		
BETHANIDINE SULFATE 10MG	TENATHAN (TABLET; ORAL)	AH ROBINS	17-675 05-29-81	3495013 02-10-87	
BETHANIDINE SULFATE 25MG	TENATHAN (TABLET; ORAL)	AH ROBINS	17-675 05-29-81	3495013 02-10-87	
BITOLTEROL MESYLATE 0.8%	TORNALATE (AEROSOL; INHALATION)	WINTHROP-BREON/STERL	18-770 12-28-84	4138581 02-06-96	NCE 12-28-89

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
BRETYLIUM TOSYLATE 50MG/ML	BRETYLOL (INJECTABLE; INJECTION)	AM CRITICAL CARE/AHS	17-954 07-18-78	RE29618 04-29-86	
BROMOCRIPTINE MESYLATE EQ 2.5MG BASE	PARLODEL (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	17-962 06-28-78	3752888 08-14-90 3752814 08-14-90	
BROMOCRIPTINE MESYLATE EQ 5MG BASE	PARLODEL (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	17-962 03-01-82	3752888 08-14-90 3752814 08-14-90	
BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE 12.5MG/5ML; 10MG/5ML	AMBENYL (SYRUP; ORAL)	MARION LABORATORIES	09-319 01-10-84		
BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 12.5MG/5ML	DIMETANE-DC (SYRUP; ORAL)	AH ROBINS	11-694 03-29-84		
BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 30MG/5ML	DIMETANE-DX (SYRUP; ORAL)	AH ROBINS	11-694 03-29-84		
BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 30MG/5ML	DIMETANE-DX (SYRUP; ORAL)	AH ROBINS	19-279 08-24-84		

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TABLE IV. 9 NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 12MG; 75MG	DIMETAPP (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	12-436 04-02-84		
BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 4MG/5ML; 25MG/5ML	ELIXIR DIMETAPP (ELIXIR; ORAL)	AH ROBINS	13-087 03-29-84		
BUMETANIDE 1MG	BUMEX (TABLET; ORAL)	HOFFMANN-LA ROCHE	18-225 02-28-83	3634583 01-11-89 3806534 04-23-91	NCE 02-28-93
BUMETANIDE 0.5MG	BUMEX (TABLET; ORAL)	HOFFMANN-LA ROCHE	18-225 02-28-83	3634583 01-11-89 3806534 04-23-91	NCE 02-28-93
BUMETANIDE 0.25MG/ML	BUMEX (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	18-226 02-28-83	3634583 01-11-89 3806534 04-23-91	NCE 02-28-93
BUPIVACAINE HYDROCHLORIDE; DEXTROSE 0.75%; 8.25%	MARCAINE SPINAL (INJECTABLE; INJECTION)	BREON LABS/STERLING	18-692 05-04-84		
BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE 0.5%; 0.0091MG/ML	SENSORCAINE (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-304 09-02-83		
BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE 0.75%; 0.0091MG/ML	SENSORCAINE (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-304 09-02-83		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
BUTORPHANOL TARTRATE 1MG/ML	STADOL (INJECTABLE; INJECTION)	BRISTOL LABS/B-M	17-857 08-22-78	3819635 06-25-91	
BUTORPHANOL TARTRATE 2MG/ML	STADOL (INJECTABLE; INJECTION)	BRISTOL LABS/B-M	17-857 08-22-78	3819635 06-25-91	
CALCEFEDIOL, ANHYDROUS 0.02MG	CALDEROL (CAPSULE; ORAL)	UPJOHN	18-312 08-05-80	3833622 09-03-91 3565924 03-23-86	
CALCEFEDIOL, ANHYDROUS 0.05MG	CALDEROL (CAPSULE; ORAL)	UPJOHN	18-312 08-05-80	3833622 09-03-91 3565924 03-23-86	
CALCITRIOL 0.25 UGM	ROCALTROL (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-044 08-17-78	3697559 10-10-89 4391802 07-05-00 4341774 07-27-99 4225596 09-30-97	
CALCITRIOL 0.5 UGM	ROCALTROL (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-044 08-17-78	3697559 10-10-89 4391802 07-05-00 4341774 07-27-99 4225596 09-30-97	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE 34MG/100ML; 5GM/100ML; 30MG/100ML; 74MG/100ML; 640MG/100ML; 500MG/100ML; 74MG/100ML	ISOLYTE E W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-269 01-17-83		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 510MG/100ML; 30GM/100ML; 200MG/100ML; 9.2GM/100ML; 9.6GM/100ML	DIALYTE CONCENTRATE W/ DEXTROSE 30% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807 08-26-83		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 510MG/100ML; 50GM/100ML; 200MG/100ML; 9.2GM/100ML; 9.6GM/100ML	DIALYTE CONCENTRATE W/ DEXTROSE 50% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807 08-26-83		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 510MG/100ML; 30GM/100ML; 200MG/100ML; 9.4GM/100ML; 11GM/100ML	DIALYTE CONCENTRATE W/ DEXTROSE 30% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807 08-26-83		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 510MG/100ML; 50GM/100ML; 200MG/100ML; 9.4GM/100ML; 11GM/100ML	DIALYTE CONCENTRATE W/ DEXTROSE 50% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807 08-26-83		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 1.5GM/100ML; 15.2MG/100ML; 567MG/100ML; 392MG/100ML	DELFLEX W/ DEXTROSE 1.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 2.5GM/100ML; 15.2MG/100ML; 567MG/100ML; 392MG/100ML	DELFLEX W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 4.25GM/100ML; 15.2MG/100ML; 567MG/100ML; 392MG/100ML	DELFLEX W/ DEXTROSE 4.25% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	DELFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	DELFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML 15.2MG/100ML; 567MG/100ML; 392MG/100ML	DELFLEX W/ DEXTROSE 4.25% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	INPERSOL-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	INPERSOL-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	INPERSOL-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 26MG/100ML; 2.5GM/100ML; 15MG/100ML; 560MG/100ML; 390MG/100ML	DIALYTE W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-460 11-02-83		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 33MG/100ML; 5GM/100ML; 30MG/100ML; 860MG/100ML	DEXTROSE 5% AND RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-635 02-07-83		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 16.5MG/ML; 25.4MG/ML; 74.6MG/ML; 121MG/ML; 16.1MG/ML	TPN ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-895 07-20-84		
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE 35MG/100ML; 30MG/100ML; 74MG/100ML; 640MG/100ML; 500MG/100ML; 74MG/100ML	ISOLYTE E IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-899 10-31-83		
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 17.6MG/100ML; 325.3MG/100ML; 119.3MG/100ML; 643MG/100ML	PLEGISOL IN PLASTIC CONTAINER (SOLUTION; PERFUSION, CARDIAC)	ABBOTT LABORATORIES	18-608 02-26-82		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 20MG/100ML; 30MG/100ML; 380MG/100ML; 600MG/100ML	ACETATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-725 11-29-82		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 33MG/100ML; 30MG/100ML; 860MG/100ML	RINGER'S IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-495 02-19-82		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 33MG/100ML; 30MG/100ML; 860MG/100ML	RINGERS INJECTION IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-648 02-07-83		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 33MG/100ML; 30MG/100ML; 860MG/100ML	RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-721 11-09-82		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 20MG/100ML; 30MG/100ML; 600MG/100ML; 310MG/100ML	LACTATED RINGER'S IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-494 02-19-82		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 20MG/100ML; 30MG/100ML; 600MG/100ML; 310MG/100ML	LACTATED RINGER'S IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	AM MCGAW/AM HOSP	18-681 12-27-82		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 20MG/100ML; 30MG/100ML; 600MG/100ML; 310MG/100ML	LACTATED RINGER'S IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-921 04-03-84		
CALCIUM METRIZOATE; MAGNESIUM METRIZOATE; MEGLUMINE METRIZOATE; METRIZOATE SODIUM 0.78MG/ML; 0.15MG/ML; 75.9MG/ML; 16.6MG/ML	ISOPAQUE 440 (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	16-847 11-17-73	3476802 11-04-86	
CALCIUM; MEGLUMINE; METRIZOIC ACID 0.35MG/ML; 140.1MG/ML; 461.8MG/ML	ISOPAQUE 280 (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-506 04-30-74	3476802 11-04-86	
CAPTOPRIL 50MG	CAPOTEN (TABLET; ORAL)	ER SQUIBB AND SONS	18-343 04-06-81	4105776 08-08-95	
CAPTOPRIL 25MG	CAPOTEN (TABLET; ORAL)	ER SQUIBB AND SONS	18-343 04-06-81	4105776 08-08-95	
CAPTOPRIL 100MG	CAPOTEN (TABLET; ORAL)	ER SQUIBB AND SONS	18-343 04-06-81	4105776 08-08-95	
CAPTOPRIL; HYDROCHLOROTHIAZIDE 25MG; 15MG	CAPOZIDE 25/15 (TABLET; ORAL)	ER SQUIBB AND SONS	18-709 10-12-84	4105776 08-08-95 4217347 08-12-97	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CAPTOPRIL; HYDROCHLOROTHIAZIDE 50MG; 15MG	CAPOZIDE 50/15 (TABLET; ORAL)	ER SQUIBB AND SONS	18-709 10-12-84	4105776 08-08-95 4217347 08-12-97	
CAPTOPRIL; HYDROCHLOROTHIAZIDE 50MG; 25MG	CAPOZIDE 50/25 (TABLET; ORAL)	ER SQUIBB AND SONS	18-709 10-12-84	4105776 08-08-95 4217347 08-12-97	
CARBAMAZEPINE 200MG	TEGRETOL (TABLET; ORAL)	GEIGY/CIBA-GEIGY	16-608 03-11-68	4409212 10-11-00	
CARBAMAZEPINE 100MG	TEGRETOL (TABLET, CHEWABLE; ORAL)	GEIGY/CIBA-GEIGY	18-281 12-14-81	4409212 10-11-00	
CARBIDOPA 25MG	LODOSYN (TABLET; ORAL)	MS&D/MERCK	17-830 04-25-77	3830827 08-20-91 3781415 12-25-90	
CARBIDOPA; LEVODOPA 10MG; 100MG	SINEMET (TABLET; ORAL)	MS&D/MERCK	17-555 05-02-75	3769424 10-30-90 3781415 12-25-90 3830827 08-20-91 RE29892 10-30-90	
CARBIDOPA; LEVODOPA 25MG; 250MG	SINEMET (TABLET; ORAL)	MS&D/MERCK	17-555 05-02-75	3769424 10-30-90 3781415 12-25-90 3830827 08-20-91 RE29892 10-30-90	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CARBIDOPA, LEVODOPA 25MG; 100MG	SINEMET (TABLET; ORAL)	MS&D/MERCK	17-555 03-13-80	3769424 10-30-90 3781415 12-25-90 3830827 08-20-91 RE29892 10-30-90	
CARBOPROST TROMETHAMINE EQ 0.25MG BASE/ML	PROSTIN/15M (INJECTABLE; INJECTION)	UPJOHN	17-989 01-09-79	3728382 04-17-90	
CELLULOSE SODIUM PHOSPHATE 2.5GM/PACKET	CALCIBIND (POWDER; ORAL)	MISSION PHARMACAL	18-757 12-28-82		NCE 12-28-92
CERULETIDE DIETHYLAMINE 0.02MG/ML	TYMTRAN (INJECTABLE; INJECTION)	ADRIA LABORATORIES	18-296 12-24-81	3472832 10-14-86	
CHENODIOL 250MG	CHENIX (TABLET; ORAL)	ROWELL LABORATORIES	18-513 07-28-83		NCE 07-28-93
CHLORDIAZEPOXIDE 25MG	LIBRITABS (TABLET; ORAL)	ROCHE PRODUCTS	13-071 10-31-66	4316897 02-23-99	
CHLORDIAZEPOXIDE 5MG	LIBRITABS (TABLET; ORAL)	ROCHE PRODUCTS	13-071 10-31-66	4316897 02-23-99	
CHLORDIAZEPOXIDE 10MG	LIBRITABS (TABLET; ORAL)	ROCHE PRODUCTS	13-071 10-31-66	4316897 02-23-99	
CHLORDIAZEPOXIDE 30MG	LIBRELEASE (CAPSULE, CONTROLLED RELEASE; ORAL)	HOFFMANN-LA ROCHE	17-813 09-12-83	4316897 02-23-99	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CHLORDIAZEPOXIDE HYDROCHLORIDE 5MG	LIBRIUM (CAPSULE; ORAL)	ROCHE PRODUCTS	12-249 02-24-60	4316897 02-23-99	
CHLORDIAZEPOXIDE HYDROCHLORIDE 10MG	LIBRIUM (CAPSULE; ORAL)	ROCHE PRODUCTS	12-249 02-24-60	4316897 02-23-99	
CHLORDIAZEPOXIDE HYDROCHLORIDE 25MG	LIBRIUM (CAPSULE; ORAL)	ROCHE PRODUCTS	12-249 02-24-60	4316897 02-23-99	
CHLORDIAZEPOXIDE HYDROCHLORIDE 100MG/AMP	LIBRIUM (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	12-301 07-21-61	4316897 02-23-99	
CHLORDIAZEPOXIDE HYDROCHLORIDE; CLIDINIUM BROMIDE 5MG; 2.5MG	LIBRAX (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	12-750 05-02-61	4316897 02-23-99	
CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED 5MG; 0.2MG	MENRIUM 5-2 (TABLET; ORAL)	HOFFMANN-LA ROCHE	14-740 10-27-69	4316897 02-23-99	
CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED 5MG; 0.4MG	MENRIUM 5-4 (TABLET; ORAL)	HOFFMANN-LA ROCHE	14-740 10-27-69	4316897 02-23-99	
CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED 10MG; 0.4MG	MENRIUM 10-4 (TABLET; ORAL)	HOFFMANN-LA ROCHE	14-740 10-27-69	4316897 02-23-99	
CHLOROXINE 2%	CAPITROL (SHAMPOO; TOPICAL)	WESTWOOD PHARMS	17-594 10-19-76	3886277 05-27-92	
CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE 15MG; 0.1MG	COMBIPRES (TABLET; ORAL)	BOEHRINGER INGELHEIM	17-503 08-22-74	3454701 07-08-86	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE 15MG; 0.2MG	COMBIPRES (TABLET; ORAL)	BOEHRINGER INGELHEIM	17-503 08-22-74	3454701 07-08-86	
CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE 15MG; 0.3MG	COMBIPRES (TABLET; ORAL)	BOEHRINGER INGELHEIM	17-503 04-10-84	3454701 07-08-86	
CHOLESTYRAMINE EQ 4GM RESIN/PACKET	QUESTRAN (POWDER; ORAL)	MEAD JOHNSON/B-M	16-019 12-06-66	3383281 05-18-85	
CHOLESTYRAMINE EQ 4GM RESIN/PACKET	QUESTRAN (POWDER; ORAL)	MEAD JOHNSON/B-M	16-640 08-03-73	3383281 05-18-85	
CHYMOPAPAIN 12,500 UNITS/VIAL	DISCASE (INJECTABLE; INJECTION)	TRAVENOL LABS	18-625 01-18-84		
CHYMOPAPAIN 10,000 UNITS/VIAL	CHYMODIACTIN (INJECTABLE; INJECTION)	SMITH LABORATORIES	18-663 11-10-82	4439423 03-26-01	NCE 11-10-92
CHYMOPAPAIN 4,000 UNITS/VIAL	CHYMODIACTIN (INJECTABLE; INJECTION)	SMITH LABORATORIES	18-663 08-21-84	4439423 03-26-01	
CICLOPIROX OLAMINE 1%	LOPROX (CREAM; TOPICAL)	HOECHST-ROUSSEL	18-748 12-30-82	3883545 05-13-92	NCE 12-30-92
CIMETIDINE 200MG	TAGAMET (TABLET; ORAL)	SK&F LAB	17-920 08-16-77	3950333 04-13-93 4024271 05-17-94	
CIMETIDINE 300MG	TAGAMET (TABLET; ORAL)	SK&F LAB	17-920 08-16-77	3950333 04-13-93 4024271 05-17-94	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CIMETIDINE 400MG	TAGAMET (TABLET; ORAL)	SK&F LAB	17-920 12-14-83	3950333 04-13-93 4024271 05-17-94	
CIMETIDINE HYDROCHLORIDE EQ 300MG BASE/5ML	TAGAMET (SOLUTION; ORAL)	SK&F LAB	17-924 08-16-77	3950333 04-13-93 4024271 05-17-94	
CIMETIDINE HYDROCHLORIDE EQ 150MG BASE/ML	TAGAMET (INJECTABLE; INJECTION)	SK&F LAB	17-939 08-16-77	3950333 04-13-93 4024271 05-17-94	
CINOXACIN 250MG	CINOBAC (CAPSULE; ORAL)	ELI LILLY	18-067 06-13-80	3669965 06-13-89	
CINOXACIN 500MG	CINOBAC (CAPSULE; ORAL)	ELI LILLY	18-067 06-13-80	3669965 06-13-89	
CISPLATIN 0.5MG/ML	PLATINOL-AQ	BRISTOL LABS/B-M	18-507 07-18-84	4177263 12-04-96	
CITRIC ACID; MAGNESIUM OXIDE; SODIUM CARBONATE 3.24GM/100ML; 380MG/100ML; 430MG/100ML	IRRIGATING SOLUTION G IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-519 06-22-82		
CITRIC ACID; MAGNESIUM OXIDE; SODIUM CARBONATE 3.24GM/100ML; 380MG/100ML; 430MG/100ML	UROLOGIC G IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	ABBOTT LABORATORIES	18-904 05-27-83		
CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE EQ 1MG BASE; 75MG	TAVIST D (TABLET, CONTROLLED RELEASE; ORAL)	DORSEY LABS/SANDOZ	18-298 12-15-82	3933999 01-20-93	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CLOMIPHENE CITRATE 50MG	CLOMIPHENE CITRATE (TABLET; ORAL)	PLANTEX/IKAPHARM	18-361 03-22-82		
CLONAZEPAM 0.5MG	CLONOPIN (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-533 06-04-75	4316897 02-23-99	
CLONAZEPAM 1MG	CLONOPIN (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-533 06-04-75	4316897 02-23-99	
CLONAZEPAM 2MG	CLONOPIN (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-533 06-04-75	4316897 02-23-99	
CLONIDINE 2.5MG	CATAPRES-TTS-1 (FILM, CONTROLLED RELEASE; PERCUTANEOUS)	BOEHRINGER INGELHEIM	18-891 10-10-84	3454701 07-08-86	
CLONIDINE 5MG	CATAPRES-TTS-2 (FILM, CONTROLLED RELEASE; PERCUTANEOUS)	BOEHRINGER INGELHEIM	18-891 10-10-84	3454701 07-08-86	
CLONIDINE 7.5MG	CATAPRES-TTS-3 (FILM, CONTROLLED RELEASE; PERCUTANEOUS)	BOEHRINGER INGELHEIM	18-891 10-10-84	3454701 07-08-86	
CLONIDINE HYDROCHLORIDE 0.1MG	CATAPRES (TABLET; ORAL)	BOEHRINGER INGELHEIM	17-407 09-03-74	3454701 07-08-86	
CLONIDINE HYDROCHLORIDE 0.2MG	CATAPRES (TABLET; ORAL)	BOEHRINGER INGELHEIM	17-407 09-03-74	3454701 07-08-86	
CLONIDINE HYDROCHLORIDE 0.3MG	CATAPRES (TABLET; ORAL)	BOEHRINGER INGELHEIM	17-407 09-20-79	3454701 07-08-86	
CLORAZEPATE DIPOTASSIUM 3.75MG	TRANXENE (CAPSULE; ORAL)	ABBOTT LABORATORIES	17-105 06-23-72	RE28315 06-23-87	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CLORAZEPATE DIPOTASSIUM 7.5MG	TRANXENE (CAPSULE; ORAL)	ABBOTT LABORATORIES	17-105 06-23-72	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 15MG	TRANXENE (CAPSULE; ORAL)	ABBOTT LABORATORIES	17-105 06-23-72	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 22.5MG	TRANXENE SD (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-31-75	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 11.25MG	TRANXENE SD (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 08-04-76	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 3.75MG	TRANXENE (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-10-80	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 7.5MG	TRANXENE (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-10-80	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 15MG	TRANXENE (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-10-80	RE28315 06-23-87	
CLOTRIMAZOLE 1%	LOTRIMIN (SOLUTION; TOPICAL)	SCHERING	17-613 02-03-75	3660577 05-02-89 3705172 12-05-89 3839573 10-01-91	
CLOTRIMAZOLE 1%	LOTRIMIN (CREAM; TOPICAL)	SCHERING	17-619 03-18-75	3660577 05-02-89 3705172 12-05-89 3839573 10-01-91	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CLOTRIMAZOLE 1%	GYNE-LOTRIMIN (CREAM; VAGINAL)	SCHERING	18-052 11-08-78	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 100MG	GYNE-LOTRIMIN (TABLET; VAGINAL)	SCHERING	17-717 03-24-76	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 1%	MYCELEX (SOLUTION; TOPICAL)	MILES PHARMS/MILES	18-181 01-15-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 100MG	MYCELEX-G (TABLET; VAGINAL)	MILES PHARMS/MILES	18-182 02-27-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CLOTRIMAZOLE 1%	MYCELEX (CREAM; TOPICAL)	MILES PHARMS/MILES	18-183 01-15-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 1%	MYCELEX-G (CREAM; VAGINAL)	MILES PHARMS/MILES	18-230 02-16-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 10MG	MYCELEX (TROCHE/LOZENGE; ORAL)	MILES PHARMS/MILES	18-713 06-17-83	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 1%	LOTRIMIN (LOTION; TOPICAL)	SCHERING	18-813 02-17-84	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE 10MG/5ML; 5MG/5ML; 6.25MG/5ML	PHENERGAN VC W/ CODEINE (SYRUP; ORAL)	WYETH LABS/AMHO	08-306 04-02-84		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE 10MG/5ML; 6.25MG/5ML	PHENERGAN W/ CODEINE (SYRUP; ORAL)	WYETH LABS/AMHO	08-306 04-02-84		
CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 10MG/5ML; 30MG/5ML; 1.25MG/5ML	ACTIFED W/ CODEINE (SYRUP; ORAL)	BURROUGHS WELLCOME	12-575 04-04-84		
COLESTIPOL HYDROCHLORIDE 5GM/PACKET	COLESTID (GRANULE; ORAL)	UPJOHN	17-563 04-04-77	3692895 09-19-89	
COLESTIPOL HYDROCHLORIDE 500GM/BOT	COLESTID (GRANULE; ORAL)	UPJOHN	17-563 04-04-77	3692895 09-19-89	
COPPER 89MG	CU-7 (INTRAUTERINE DEVICE; INTRAUTERINE)	SEARLE PHARMS	17-408 02-25-74	3563235 02-16-88 4040417 08-09-94 3783861 01-08-91 3803308 12-01-87 RE28399 04-29-92	
COPPER 120MG	TATUM-T (INTRAUTERINE DEVICE; INTRAUTERINE)	SEARLE PHARMS	18-205 08-16-79	3563235 02-16-88 4040417 08-09-94 3783861 01-08-91 3803308 12-01-87 RE28399 04-29-92	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CROMOLYN SODIUM 20MG	INTAL (CAPSULE; INHALATION)	FISONS	16-990 06-20-73	3686412 08-22-89 3777033 08-22-89 3419578 12-31-85	
CROMOLYN SODIUM 4%	NASALCROM (SOLUTION; NASAL)	FISONS	18-306 03-18-83	3686412 08-22-89 3777033 08-22-89 3419578 12-31-85 3975536 08-17-93 4053628 10-11-94	
CROMOLYN SODIUM 4%	OPTICROM (SOLUTION; OPHTHALMIC)	FISONS	18-155 10-03-84	3686412 08-22-89 3777033 08-22-89 3419578 12-31-85 3975536 08-17-93 4053628 10-11-94	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CROMOLYN SODIUM 10MG/ML	INTAL (SOLUTION; INHALATION)	FISONS	18-596 05-28-82	3686412 08-22-89 3777033 08-22-89 3419578 12-31-85 3975536 08-17-93	
CYCLOBENZAPRINE HYDROCHLORIDE 5MG	FLEXERIL (TABLET; ORAL)	MS&D/MERCK	17-821 08-26-77	3454643 07-08-86 3882246 05-06-92	
CYCLOBENZAPRINE HYDROCHLORIDE 10MG	FLEXERIL (TABLET; ORAL)	MS&D/MERCK	17-821 08-26-77	3454643 07-08-86 3882246 05-06-92	
CYCLOPHOSPHAMIDE 1GM/VIAL	CYTOXAN (INJECTABLE; INJECTION)	MEAD JOHNSON/B-M	12-142 08-30-82		
CYCLOPHOSPHAMIDE 2GM/VIAL	CYTOXAN (INJECTABLE; INJECTION)	MEAD JOHNSON/B-M	12-142 08-30-82		
DANTROLENE SODIUM 25MG	DANTRIUM (CAPSULE; ORAL)	NORWICH EATON/P&G	17-443 01-15-74	3415821 12-10-85	
DANTROLENE SODIUM 100MG	DANTRIUM (CAPSULE; ORAL)	NORWICH EATON/P&G	17-443 01-15-74	3415821 12-10-85	
DANTROLENE SODIUM 50MG	DANTRIUM (CAPSULE; ORAL)	NORWICH EATON/P&G	17-443 10-10-75	3415821 12-10-85	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DANTROLENE SODIUM 20MG/VIAL	DANTRIUM (INJECTABLE; INJECTION)	NORWICH EATON/P&G	18-264 09-18-79	3415821 12-10-85	
DEFEROXAMINE MESYLATE 500MG/VIAL	DESFERAL MESYLATE (INJECTABLE; INJECTION)	CIBA/CIBA-GEIGY	16-267 04-01-68	3471476 10-07-86	
DESIPRAMINE HYDROCHLORIDE 25MG	PERTOFRANE (CAPSULE; ORAL)	USV LABORATORIES	13-621 12-18-64	3454698 07-08-86 3454554 07-08-86	
DESIPRAMINE HYDROCHLORIDE 50MG	PERTOFRANE (CAPSULE; ORAL)	USV LABORATORIES	13-621 04-10-68	3454698 07-08-86 3454554 07-08-86	
DESIPRAMINE HYDROCHLORIDE 25MG	NORPRAMIN (TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399 11-20-64	3454698 07-08-86 3454554 07-08-86	
DESIPRAMINE HYDROCHLORIDE 50MG	NORPRAMIN (TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399 01-09-67	3454698 07-08-86 3454554 07-08-86	
DESIPRAMINE HYDROCHLORIDE 75MG	NORPRAMIN (TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399 03-01-77	3454698 07-08-86 3454554 07-08-86	
DESIPRAMINE HYDROCHLORIDE 100MG	NORPRAMIN (TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399 03-01-77	3454698 07-08-86 3454554 07-08-86	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DESIPRAMINE HYDROCHLORIDE 150MG	NORPRAMIN (TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399 03-01-77	3454698 07-08-86 3454554 07-08-86	
DESIPRAMINE HYDROCHLORIDE 10MG	NORPRAMIN (TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399 02-11-82	3454698 07-08-86 3454554 07-08-86	
DESMOPRESSIN ACETATE 0.01%	DDAVP (SOLUTION; NASAL)	ARMOUR PHARM	17-922 02-21-78	3497491 02-24-87	
DESMOPRESSIN ACETATE 0.004MG/ML	DDAVP (INJECTABLE; INJECTION)	ARMOUR PHARM	18-938 03-30-84	3497491 02-24-87	
DESONIDE 0.05%	DESOWEN (CREAM; TOPICAL)	OWEN LABS/DERM PRODS	19-048 12-14-84		
DESOXIMETASONE 0.05%	TOPICORT (GEL; TOPICAL)	HOECHST-ROUSSEL	18-586 03-29-82		
DESOXIMETASONE 0.25%	TOPICORT (OINTMENT; TOPICAL)	HOECHST-ROUSSEL	18-763 09-30-83		
DEXAMETHASONE 0.5MG	DECADRON (TABLET; ORAL)	MS&D/MERCK	11-664 10-30-58	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE 0.75MG	DECADRON (TABLET; ORAL)	MS&D/MERCK	11-664 10-30-58	3375261 03-26-85 RE28369 03-26-85	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXAMETHASONE 1.5MG	DECADRON (TABLET; ORAL)	MS&D/MERCK	11-664 10-30-58	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE 0.25MG	DECADRON (TABLET; ORAL)	MS&D/MERCK	11-664 07-26-79	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE 4MG	DECADRON (TABLET; ORAL)	MS&D/MERCK	11-664 07-26-79	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE 6MG	DECADRON (TABLET; ORAL)	MS&D/MERCK	11-664 07-30-82	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE 0.5MG/5ML	DECADRON (ELIXIR; ORAL)	MS&D/MERCK	12-376 09-02-60	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE 0.5MG/5ML	HEXADROL (ELIXIR; ORAL)	ORGANON/AKZONA	12-674 04-23-64	RE28369 03-26-85	
DEXAMETHASONE 0.5MG	HEXADROL (TABLET; ORAL)	ORGANON/AKZONA	12-675 07-01-78	RE28369 03-26-85	
DEXAMETHASONE 0.75MG	HEXADROL (TABLET; ORAL)	ORGANON/AKZONA	12-675 07-01-78	RE28369 03-26-85	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXAMETHASONE 1.5MG	HEXADROL (TABLET; ORAL)	ORGANON/AKZONA	12-675 09-24-65	RE28369 03-26-85	
DEXAMETHASONE 4MG	HEXADROL (TABLET; ORAL)	ORGANON/AKZONA	12-675 07-01-74	RE28369 03-26-85	
DEXAMETHASONE 10MG/25GM	DECASPRAY (AEROSOL; TOPICAL)	MS&D/MERCK	12-731 03-29-61	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE 0.04%	HEXADROL (CREAM; TOPICAL)	ORGANON/AKZONA	13-304 01-09-67	RE28369 03-26-85	
DEXAMETHASONE 0.1%	DECADERM (GEL; TOPICAL)	MS&D/MERCK	13-538 05-03-65	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE ACETATE EQ 8MG BASE/ML	DECADRON-LA (INJECTABLE; INJECTION)	MS&D/MERCK	16-675 09-06-73	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 0.05% PHOSPHATE	DECADRON (OINTMENT; OPHTHALMIC)	MS&D/MERCK	11-977 09-02-59	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 0.1% PHOSPHATE	DECADRON (CREAM; TOPICAL)	MS&D/MERCK	11-983 08-26-59	3375261 03-26-85 RE28369 03-26-85	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXAMETHASONE SODIUM PHOSPHATE EQ 0.1% PHOSPHATE	DECADRON (SOLUTION; OPHTHALMIC, OTIC)	MS&D/MERCK	11-984 09-23-59	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 4MG PHOSPHATE/ML	DECADRON (INJECTABLE; INJECTION)	MS&D/MERCK	12-071 05-12-61	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 24MG PHOSPHATE/ML	DECADRON (INJECTABLE; INJECTION)	MS&D/MERCK	12-071 03-01-77	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 0.1MG PHOSPHATE/INH	DECADRON (AEROSOL; INHALATION)	MS&D/MERCK	13-413 09-17-62	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 0.1MG PHOSPHATE/INH	DECADRON (AEROSOL; NASAL)	MS&D/MERCK	14-242 12-17-65	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 4MG PHOSPHATE/ML	HEXADROL (INJECTABLE; INJECTION)	ORGANON/AKZONA	14-694 03-14-75	RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 10MG PHOSPHATE/ML	HEXADROL (INJECTABLE; INJECTION)	ORGANON/AKZONA	14-694 03-14-75	RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 20MG PHOSPHATE/ML	HEXADROL (INJECTABLE; INJECTION)	ORGANON/AKZONA	14-694 04-27-81	RE28369 03-26-85	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXAMETHASONE SODIUM PHOSPHATE; LIDOCAINE HYDROCHLORIDE EQ 4MG PHOSPHATE/ML; 10MG/ML	DECADRON W/ XYLOCAINE (INJECTABLE; INJECTION)	MS&D/MERCK	13-334 07-11-62	3375261 03-26-85 RE28369 03-26-85	
DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE 15MG/5ML; 6.25MG/5ML	PHENERGAN W/ DEXTROMETHORPHAN (SYRUP; ORAL)	WYETH LABS/AMHO	11-265 04-02-84		
DEXTROSE 60GM/100ML	DEXTROSE 60% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	17-521 03-26-82		
DEXTROSE 70GM/100ML	DEXTROSE 70% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	17-521 03-26-82		
DEXTROSE 60GM/100ML	DEXTROSE 60% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	17-995 04-27-78	3729568 04-24-90	
DEXTROSE 60GM/100ML	DEXTROSE 60% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	17-995 09-22-82	3729568 04-24-90	
DEXTROSE 70GM/100ML	DEXTROSE 70% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-561 03-23-82		
DEXTROSE 40GM/100ML	DEXTROSE 40% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-562 03-23-82		
DEXTROSE 50GM/100ML	DEXTROSE 50% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-563 03-23-82		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTROSE 20GM/100ML	DEXTROSE 20% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-564 03-23-82		
DEXTROSE 38.5GM/100ML	DEXTROSE 38.5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-923 09-19-84		
DEXTROSE 50MG/ML	DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-222 07-13-84		
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 80MG/100ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 02-04-82		
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 160MG/100ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 02-04-82		
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 80MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83		
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 160MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83		
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 320MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83		
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 200 UNITS/100ML	HEPARIN SODIUM 1,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-130 12-31-83		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 200 UNITS/100ML	HEPARIN SODIUM 2,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-130 12-31-83		
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 1,000 UNITS/100ML	HEPARIN SODIUM 5,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-130 12-31-83		
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 4,000 UNITS/100ML	HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-814 10-31-83		
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 800MG/100ML	LIDOCAINE HCL 0.8% IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-388 11-05-82		
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 800MG/100ML	LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-461 02-22-82		
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 200MG/100ML	LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-967 03-30-84		
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 400MG/100ML	LIDOCAINE HCL 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-967 03-30-84		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 800MG/100ML	LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-967 03-30-84		
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE DIBASIC; SODIUM ACETATE 5GM/100ML; 31MG/100ML; 130MG/100ML; 26MG/100ML; 320MG/100ML	ISOLYTE P W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-025 12-27-84		
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 75MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82		
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 150MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82		
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 220MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82		
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 300MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTROSE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM LACTATE 5GM/100ML; 205MG/100ML; 100MG/100ML; 120MG/100ML; 220MG/100ML	DEXTROSE 5% AND ELECTROLYTE NO 75 IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-840 06-29-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 75MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 5MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 75MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 40MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTROSE; THEOPHYLLINE 5GM/100ML; 40MG/100ML	THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-083 11-07-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 80MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 80MG/100ML	THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-083 11-07-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 160MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 160MG/100ML	THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-083 11-07-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 200MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTROSE; THEOPHYLLINE 5GM/100ML; 200MG/100ML	THEOPHYLLINE 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-212 11-07-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 400MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 400MG/100ML	THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-212 11-07-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 400MG/100ML	THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-649 07-26-82		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 80MG/100ML	THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-649 07-26-82		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 160MG/100ML	THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-649 07-26-82		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTROSE; THEOPHYLLINE 5GM/100ML; 200MG/100ML	THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-649 07-26-82		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 400MG/100ML	THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-649 07-26-82		
DIAZEPAM 2MG	VALIUM (TABLET; ORAL)	HOFFMANN-LA ROCHE	13-263 11-15-63	4316897 02-23-99 3371085 02-27-85	
DIAZEPAM 5MG	VALIUM (TABLET; ORAL)	HOFFMANN-LA ROCHE	13-263 11-15-63	4316897 02-23-99 3371085 02-27-85	
DIAZEPAM 10MG	VALIUM (TABLET; ORAL)	HOFFMANN-LA ROCHE	13-263 11-15-63	4316897 02-23-99 3371085 02-27-85	
DIAZEPAM 5MG/ML	VALIUM (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	16-087 08-24-66	4316897 02-23-99 3371085 02-27-85	
DIAZEPAM 15MG	VALRELEASE (CAPSULE, CONTROLLED RELEASE; ORAL)	HOFFMANN-LA ROCHE	18-179 03-12-81	4316897 02-23-99 3371085 02-27-85	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DICYCLOMINE HYDROCHLORIDE 10MG	BENTYL (CAPSULE; ORAL)	MERRELL DOW/DOW CHEM	07-409 10-15-84		
DICYCLOMINE HYDROCHLORIDE 20MG	BENTYL (CAPSULE; ORAL)	MERRELL DOW/DOW CHEM	07-409 10-15-84		
DICYCLOMINE HYDROCHLORIDE 10MG/ML	BENTYL (INJECTABLE; INJECTION)	MERRELL DOW/DOW CHEM	08-370 10-15-84		
DICYCLOMINE HYDROCHLORIDE 10MG/5ML	BENTYL (SYRUP; ORAL)	MERRELL DOW/DOW CHEM	07-961 10-15-84		
DIFLORASONE DIACETATE 0.05%	FLORONE (CREAM; TOPICAL)	UPJOHN	17-741 09-14-77	3980778 09-14-93	
DIFLORASONE DIACETATE 0.05%	FLORONE (OINTMENT; TOPICAL)	UPJOHN	17-994 03-01-78	3980778 09-14-93	
DIFLUNISAL 250MG	DOLOBID (TABLET; ORAL)	MS&D/MERCK	18-445 04-19-82	3714226 08-01-89 3674870 07-04-89	NCE 04-19-92
DIFLUNISAL 500MG	DOLOBID (TABLET; ORAL)	MS&D/MERCK	18-445 04-19-82	3714226 08-01-89 3674870 07-04-89	NCE 04-19-92
DIGOXIN 0.2MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82		
DIGOXIN 0.05MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DIGOXIN 0.1MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82		
DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE 0.5MG/0.5ML; 2500 UNITS/0.5ML; 5.33MG/0.5ML	EMBOLEX (INJECTABLE; INJECTION)	SANDOZ PHARMS/SANDOZ	18-885 11-30-84		
DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE 0.5MG/0.7ML; 5000 UNITS/0.7ML; 7.46MG/0.7ML	EMBOLEX (INJECTABLE; INJECTION)	SANDOZ PHARMS/SANDOZ	18-885 11-30-84		
DILTIAZEM HYDROCHLORIDE 30MG	CARDIZEM (TABLET; ORAL)	MARION LABORATORIES	18-602 11-05-82	3562257 02-09-88	NCE 11-05-92
DILTIAZEM HYDROCHLORIDE 60MG	CARDIZEM (TABLET; ORAL)	MARION LABORATORIES	18-602 11-05-82	3562257 02-09-88	NCE 11-05-92
DINOPROST TROMETHAMINE EQ 5MG BASE/ML	PROSTIN F2 ALPHA (INJECTABLE; INJECTION)	UPJOHN	17-434 11-26-73	3706789 12-19-89 3778506 12-11-90	
DINOPROSTONE 20MG	PROSTIN E2 (SUPPOSITORY; VAGINAL)	UPJOHN	17-810 08-23-77	3899587 08-12-92 3598858 08-10-88	
DIPIVEFRIN HYDROCHLORIDE 0.1%	PROPINE (SOLUTION; OPHTHALMIC)	ALLERGAN PHARMS	18-239 05-02-80	3839584 10-01-91 3809714 05-07-91	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DISOPYRAMIDE PHOSPHATE EQ 100MG BASE	NORPACE CR (CAPSULE, CONTROLLED RELEASE; ORAL)	SEARLE/SEARLE PHARMS	18-655 07-20-82		
DISOPYRAMIDE PHOSPHATE EQ 150MG BASE	NORPACE CR (CAPSULE, CONTROLLED RELEASE; ORAL)	SEARLE/SEARLE PHARMS	18-655 07-20-82		
DIVALPROEX SODIUM EQ 250MG BASE	DEPAKOTE (TABLET, ENTERIC COATED; ORAL)	ABBOTT LABORATORIES	18-723 03-10-83		
DIVALPROEX SODIUM EQ 500MG BASE	DEPAKOTE (TABLET, ENTERIC COATED; ORAL)	ABBOTT LABORATORIES	18-723 03-10-83		
DOBUTAMINE HYDROCHLORIDE EQ 250MG BASE/VIAL	DOBUTREX (INJECTABLE; INJECTION)	ELI LILLY	17-820 07-18-78	3987200 10-19-93	
DOPAMINE HYDROCHLORIDE 80MG/ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 07-09-82		
DOPAMINE HYDROCHLORIDE 80MG/ML	DOPAMINE (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-398 03-22-82		
DOPAMINE HYDROCHLORIDE 40MG/ML	DOPAMINE HCL (INJECTABLE; INJECTION)	BRISTOL LABS/B-M	18-549 03-11-83		
DOPAMINE HYDROCHLORIDE 40MG/ML	DOPAMINE (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-656 06-28-83		
DOXEPIN HYDROCHLORIDE EQ 25MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 09-23-69	3420851 01-07-86	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DOXEPIN HYDROCHLORIDE EQ 50MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 09-23-69	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 10MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 03-31-75	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 100MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 03-31-75	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 75MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 06-04-76	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 150MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 03-15-78	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 10MG BASE	ADAPIN (CAPSULE; ORAL)	PENNWALT PHARM	16-987 01-31-72	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 25MG BASE	ADAPIN (CAPSULE; ORAL)	PENNWALT PHARM	16-987 01-31-72	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 50MG BASE	ADAPIN (CAPSULE; ORAL)	PENNWALT PHARM	16-987 01-31-72	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 100MG BASE	ADAPIN (CAPSULE; ORAL)	PENNWALT PHARM	16-987 12-12-77	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 75MG BASE	ADAPIN (CAPSULE; ORAL)	PENNWALT PHARM	16-987 04-15-80	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 10MG BASE/ML	SINEQUAN (CONCENTRATE; ORAL)	PFIZER LABS/PFIZER	17-516 03-11-74	3420851 01-07-86	
ECONAZOLE NITRATE 1%	SPECTAZOLE (CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	18-751 12-23-82	3717655 02-20-90 3839574 10-01-91	NCE 12-23-92

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ENFLURANE 99.9%	ETHRANE (LIQUID; INHALATION)	ANAQUEST/BOC	17-087 08-28-72	3469011 09-23-86 3527813 09-08-87	
EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE 0.005MG/ML; 0.5%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE 0.005MG/ML; 1%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE 0.005MG/ML; 1.5%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
ERGOLOID MESYLATES 1MG	HYDERGINE LC (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-706 01-18-83		
ESTROGENS, CONJUGATED 0.9MG	PREMARIN (TABLET; ORAL)	AYERST LABS/AMHO	04-782 01-26-84		
ETHINYL ESTRADIOL; LEVONORGESTREL 0.03MG; 0.15MG	NORDETTE-21 (TABLET; ORAL-21)	WYETH LABS/AMHO	18-668 05-10-82	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ETHINYL ESTRADIOL; LEVONORGESTREL 0.03MG; 0.15MG	NORDETTE-28 (TABLET; ORAL-28)	WYETH LABS/AMHO	18-782 07-21-82	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	
ETHINYL ESTRADIOL; LEVONORGESTREL 0.03MG; 0.05MG 0.04MG; 0.075MG 0.03MG; 0.125MG	TRIPHASIL-28 (TABLET; ORAL-28)	WYETH LABS/AMHO	19-190 11-01-84	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91 3957982 05-18-93	
ETHINYL ESTRADIOL; LEVONORGESTREL 0.03MG; 0.05MG 0.04MG; 0.075MG 0.03MG; 0.125MG	TRIPHASIL-21 (TABLET; ORAL-21)	WYETH LABS/AMHO	19-192 11-01-84	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91 3957982 05-18-93	
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 10/11-21 (TABLET; ORAL-21)	ORTHO PHARMACEUTICAL	18-354 01-11-82		
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 10/11-28 (TABLET; ORAL-28)	ORTHO PHARMACEUTICAL	18-354 01-11-82		
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	TRI-NORINYL 21-DAY (TABLET; ORAL-21)	SYNTEX (FP)	18-977 04-13-84	4390531 06-28-00	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	TRI-NORINYL 28-DAY (TABLET; ORAL-28)	SYNTEX (FP)	18-977 04-13-84	4390531 06-28-00	
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG, 0.75MG AND 1MG	ORTHO-NOVUM 7/7/7-21 (TABLET; ORAL-21)	ORTHO PHARMACEUTICAL	18-985 04-04-84		
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG, 0.75MG AND 1MG	ORTHO-NOVUM 7/7/7-28 (TABLET; ORAL-28)	ORTHO PHARMACEUTICAL	18-985 04-04-84		
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 7/14-21 (TABLET; ORAL-21)	ORTHO PHARMACEUTICAL	19-004 04-04-84		
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 7/14-28 (TABLET; ORAL-28)	ORTHO PHARMACEUTICAL	19-004 04-04-84		
ETHINYL ESTRADIOL; NORGESTREL 0.05MG; 0.5MG	OVRAL (TABLET; ORAL-21)	WYETH LABS/AMHO	16-672 04-16-68	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	
ETHINYL ESTRADIOL; NORGESTREL 0.05MG; 0.5MG	OVRAL-28 (TABLET; ORAL-28)	WYETH LABS/AMHO	16-806 11-26-68	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ETHINYL ESTRADIOL; NORGESTREL 0.03MG; 0.3MG	LO/OVRAL (TABLET; ORAL-21)	WYETH LABS/AMHO	17-612 03-17-75	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	
ETHINYL ESTRADIOL; NORGESTREL 0.03MG; 0.3MG	LO/OVRAL-28 (TABLET; ORAL-28)	WYETH LABS/AMHO	17-802 03-16-76	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	
ETIDOCAINE HYDROCHLORIDE 0.5%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
ETIDOCAINE HYDROCHLORIDE 1%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
ETIDRONATE DISODIUM 200MG	DIDRONEL (TABLET; ORAL)	NORWICH EATON/P&G	17-831 09-01-77	4254114 03-03-98 4216211 09-05-97 4137309 01-30-96 3683080 08-08-89	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ETIDRONATE DISODIUM 400MG	DIDRONEL (TABLET; ORAL)	NORWICH EATON/P&G	17-831 07-06-84	4254114 03-03-98 4216211 09-05-97 4137309 01-30-96 3683080 08-08-89	
ETOMIDATE 2MG/ML	AMIDATE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-227 09-07-82		NCE 09-07-92
ETOPOSIDE 20MG/ML	VEPESID (INJECTABLE; INJECTION)	BRISTOL LABS/B-M	18-768 11-10-83	3524844 08-18-87	NCE 11-10-93
FENFLURAMINE HYDROCHLORIDE 60MG	PONDIMIN (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	16-618 07-27-82		
FENOPROFEN CALCIUM EQ 300MG BASE	NALFON (CAPSULE; ORAL)	DISTA PRODS/LILLY	17-604 03-16-76	3600437 08-17-88	
FENOPROFEN CALCIUM EQ 200MG BASE	NALFON 200 (CAPSULE; ORAL)	DISTA PRODS/LILLY	17-604 10-15-80	3600437 08-17-88	
FENOPROFEN CALCIUM EQ 600MG BASE	NALFON (TABLET; ORAL)	DISTA PRODS/LILLY	17-710 03-16-76	3600437 08-17-88	
FENTANYL CITRATE EQ 0.05MG BASE/ML	FENTANYL (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	19-101 07-11-84		
FLUCYTOSINE 250MG	ANCOBON (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	17-001 11-26-71	3368938 02-13-85	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
FLUCYTOSINE 500MG	ANCOBON (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	17-001 11-26-71	3368938 02-13-85	
FLUNISOLIDE 0.025MG/INH	BRONALIDE (AEROSOL; INHALATION)	SYNTEX LABS/SYNTEX	18-340 08-17-84		
FLUOCINONIDE 0.05%	LIDEX (SOLUTION; TOPICAL)	SYNTEX LABS/SYNTEX	18-849 04-06-84		
FLUOCINONIDE 0.05%	VASODERM (CREAM; TOPICAL)	K-LINE PHARMS	19-117 06-26-84		
FLUPHENAZINE DECANOATE 25MG/ML	PROLIXIN DECANOATE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	16-727 06-20-72	3394131 07-23-85	
FLUPHENAZINE ENANTHATE 25MG/ML	PROLIXIN ENANTHATE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	16-110 03-15-67	3394131 07-23-85	
FLURANDRENOLIDE 0.004MG/SQ CM	CORDRAN (TAPE; TOPICAL)	DISTA PRODS/LILLY	16-455 07-29-69	3632740 01-04-89	
FLURAZEPAM HYDROCHLORIDE 15MG	DALMANE (CAPSULE; ORAL)	ROCHE PRODUCTS	16-721 04-07-70	4316897 02-23-99	
FLURAZEPAM HYDROCHLORIDE 30MG	DALMANE (CAPSULE; ORAL)	ROCHE PRODUCTS	16-721 04-07-70	4316897 02-23-99	
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	CHELSEA LABORATORIES	18-369 05-14-82		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	CHELSEA LABORATORIES	18-369 05-14-82		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	SUPERPHARM	18-370 02-10-83		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	SUPERPHARM	18-370 06-26-84		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	ZENITH LABORATORIES	18-413 11-30-83		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	ZENITH LABORATORIES	18-413 11-30-83		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-415 07-27-82		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-415 07-27-82		
FUROSEMIDE 80MG	FUROSEMIDE (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-415 11-26-84		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	PARKE-DAVIS/W-L	18-419 01-31-83		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	PARKE-DAVIS/W-L	18-419 01-31-83		
FUROSEMIDE 80MG	FUROSEMIDE (TABLET; ORAL)	PARKE-DAVIS/W-L	18-419 11-13-84		
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	PARKE-DAVIS/W-L	18-420 02-26-82		
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	LYPHOMED	18-507 07-30-82		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
FUROSEMIDE 80MG	FUROSEMIDE (TABLET; ORAL)	CORD LABORATORIES	18-569 08-14-84		
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	NATCON	18-579 11-30-83		
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-667 05-28-82		
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	WYETH LABS/AMHO	18-670 07-20-82		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	DRUMMER/PHOENIX	18-750 07-30-84		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	INTL MEDICATION SYS	18-753 02-28-84		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	INTL MEDICATION SYS	18-753 02-28-84		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	BARR LABORATORIES	18-790 11-29-83		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	ROXANE LABORATORIES	18-823 11-10-83		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	ROXANE LABORATORIES	18-823 11-10-83		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	KALAPHARM	18-868 06-28-83		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	KALAPHARM	18-868 06-28-83		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	INVENEX LABS/LIFE	18-902 05-22-84		
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	INVENEX LABS/LIFE	19-036 08-13-84		
GEMFIBROZIL 200MG	LOPID (CAPSULE; ORAL)	PARKE-DAVIS/W-L	18-422 12-21-81	3674836 07-04-89	
GEMFIBROZIL 300MG	LOPID (CAPSULE; ORAL)	PARKE-DAVIS/W-L	18-422 12-21-81	3674836 07-04-89	
GLIPIZIDE 5MG	GLUCOTROL (TABLET; ORAL)	ROERIG/PFIZER	17-783 05-08-84	3669966 04-21-92	NCE 05-08-94
GLIPIZIDE 10MG	GLUCOTROL (TABLET; ORAL)	ROERIG/PFIZER	17-783 05-08-84	3669966 04-21-92	NCE 05-08-94
GLYBURIDE 1.25MG	MICRONASE (TABLET; ORAL)	UPJOHN	17-498 05-01-84	3426067 04-21-92 3454635 04-21-92 3507954 04-21-92 3507961 04-21-92	NCE 05-01-94
GLYBURIDE 2.5MG	MICRONASE (TABLET; ORAL)	UPJOHN	17-498 05-01-84	3426067 04-21-92 3454635 04-21-92 3507954 04-21-92 3507961 04-21-92	NCE 05-01-94

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
GLYBURIDE 5MG	MICRONASE (TABLET; ORAL)	UPJOHN	17-498 05-01-84	3426067 04-21-92 3454635 04-21-92 3507954 04-21-92 3507961 04-21-92	NCE 05-01-94
GLYBURIDE 1.25MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532 05-01-84	3426067 04-21-92 3454635 04-21-92 3507961 04-21-92 3507954 04-21-92 4060634 09-07-93	NCE 05-01-94
GLYBURIDE 2.5MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532 05-01-84	3426067 04-21-92 3454635 04-21-92 3507961 04-21-92 3507954 04-21-92 4060634 09-07-93	NCE 05-01-94

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
GLYBURIDE 5MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532 05-01-84	3426067 04-21-92 3454635 04-21-92 3507961 04-21-92 3507954 04-21-92 4060634 09-07-93	NCE 05-01-94
GONADORELIN HYDROCHLORIDE EQ 0.1MG BASE/VIAL	FACTREL (INJECTABLE; INJECTION)	AYERST LABS/AMHO	18-123 09-30-82	3947569 03-30-93 4110438 08-29-95	NCE 09-30-92
GONADORELIN HYDROCHLORIDE EQ 0.5MG BASE/VIAL	FACTREL (INJECTABLE; INJECTION)	AYERST LABS/AMHO	18-123 09-30-82	3947569 03-30-93 4110438 08-29-95	NCE 09-30-92
GUANABENZ ACETATE EQ 4MG BASE	WYTENSIN (TABLET; ORAL)	WYETH LABS/AMHO	18-587 09-07-82	3658993 04-25-89	NCE 09-07-92
GUANABENZ ACETATE EQ 8MG BASE	WYTENSIN (TABLET; ORAL)	WYETH LABS/AMHO	18-587 09-07-82	3658993 04-25-89	NCE 09-07-92
GUANADREL SULFATE 10MG	HYLOREL (TABLET; ORAL)	UPJOHN	18-104 12-29-82	3547951 12-15-87	NCE 12-29-92
GUANADREL SULFATE 25MG	HYLOREL (TABLET; ORAL)	UPJOHN	18-104 12-29-82	3547951 12-15-87	NCE 12-29-92

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
HALAZEPAM 20MG	PAXIPAM (TABLET; ORAL)	SCHERING	17-736 09-24-81	3429874 02-25-86	
HALAZEPAM 40MG	PAXIPAM (TABLET; ORAL)	SCHERING	17-736 09-24-81	3429874 02-25-86	
HALOPERIDOL 0.5MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 04-12-67	3438991 04-15-86	
HALOPERIDOL 1MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 04-12-67	3438991 04-15-86	
HALOPERIDOL 2MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 04-12-67	3438991 04-15-86	
HALOPERIDOL 5MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 04-16-74	3438991 04-15-86	
HALOPERIDOL 10MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 04-16-74	3438991 04-15-86	
HALOPERIDOL 20MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 02-02-82	3438991 04-15-86	
HALOPERIDOL LACTATE EQ 2MG BASE/ML	HALDOL (CONCENTRATE; ORAL)	MCNEIL LABORATORIES	15-922 04-12-67	3438991 04-15-86	
HALOPERIDOL LACTATE EQ 5MG BASE/ML	HALDOL (INJECTABLE; INJECTION)	MCNEIL LABORATORIES	15-923 05-18-71	3438991 04-15-86	
HEPARIN SODIUM 10 UNITS/ML	HEPARIN LOCK FLUSH (INJECTABLE; INJECTION)	INVENEX LABS/LIFE	17-029 05-06-82		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
HEPARIN SODIUM; SODIUM CHLORIDE 200 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 1000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-609 04-28-82		
HEPARIN SODIUM; SODIUM CHLORIDE 200 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 2000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-609 04-28-82		
HEPARIN SODIUM; SODIUM CHLORIDE 500 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 5000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-609 04-28-82		
HEPARIN SODIUM; SODIUM CHLORIDE 1,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 100 UNITS/ML; 4.5MG/ML	HEPARIN SODIUM 5,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEXACHLOROPHENE 3%	TURGEX (SOLUTION; TOPICAL)	XTTRIUM LABS	19-055 11-30-84		
HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE 25MG; 50MG	LOPRESSOR HCT 50/25 (TABLET; ORAL)	GEIGY/CIBA-GEIGY	18-303 12-31-84	3876802 04-08-92 3998790 12-21-93	
HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE 25MG; 100MG	LOPRESSOR HCT 100/25 (TABLET; ORAL)	GEIGY/CIBA-GEIGY	18-303 12-31-84	3876802 04-08-92 3998790 12-21-93	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE 50MG; 100MG	LOPRESSOR HCT 100/50 (TABLET; ORAL)	GEIGY/CIBA-GEIGY	18-303 12-31-84	3876802 04-08-92 3998790 12-21-93	
HYDROCHLOROTHIAZIDE; TIMOLOL MALEATE 25MG; 10MG	TIMOLIDE (TABLET; ORAL)	MS&D/MERCK	18-061 12-11-81	3655663 04-11-89 4238485 12-09-97	
HYDROCHLOROTHIAZIDE; TRIAMTERENE 50MG; 75MG	MAXZIDE (TABLET; ORAL)	MYLAN PHARMS	19-129 10-22-84	4444769 04-24-01	
HYDROCORTISONE ACETATE 10%	CORTIFOAM (AEROSOL; RECTAL)	REED&CARNRICK PHARMS	17-351 02-10-82		
HYDROCORTISONE BUTYRATE 0.1%	LOCOID (CREAM; TOPICAL)	OWEN LABS/DERM PRODS	18-795 01-07-83		
HYDROCORTISONE BUTYRATE 0.1%	LOCOID (OINTMENT; TOPICAL)	OWEN LABS/DERM PRODS	19-106 07-03-84		
HYDROCORTISONE VALERATE 0.2%	WESTCORT (OINTMENT; TOPICAL)	WESTWOOD PHARMS	18-726 08-08-83		
HYDROMORPHONE HYDROCHLORIDE 10MG/ML	DILAUDID-HP (INJECTABLE; INJECTION)	KNOLL PHARMACEUTICAL	19-034 01-11-84		NCE 01-11-94
HYDROXYUREA 500MG	HYDREA (CAPSULE; ORAL)	ER SQUIBB AND SONS	16-295 12-07-67	3968249 07-06-93	
IBUPROFEN 400MG	MOTRIN (TABLET; ORAL)	UPJOHN MANUFACTURING	17-463 09-19-74	3385886 05-28-85	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
IBUPROFEN 300MG	MOTRIN (TABLET; ORAL)	UPJOHN MANUFACTURING	17-463 09-19-74	3385886 05-28-85	
IBUPROFEN 600MG	MOTRIN (TABLET; ORAL)	UPJOHN MANUFACTURING	17-463 03-09-79	3385886 05-28-85	
IBUPROFEN 400MG	RUFEN (TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-197 05-19-81	3385886 05-28-85	
IBUPROFEN 600MG	RUFEN (TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-197 03-05-84	3385886 05-28-85	
INDAPAMIDE 2.5MG	LOZOL (TABLET; ORAL)	USV PHARMACEUTICAL	18-538 07-06-83	3565911 02-23-88	NCE 07-06-93
INDOMETHACIN 50MG	INDOCIN (SUPPOSITORY; RECTAL)	MS&D RES LABS/MERCK	17-814 08-13-84		
INDOMETHACIN 75MG	INDOCIN SR (CAPSULE, CONTROLLED RELEASE; ORAL)	MS&D/MERCK	18-185 02-23-82		
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	CHELSEA LABORATORIES	18-690 07-31-84		
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	CHELSEA LABORATORIES	18-690 07-31-84		
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	ZENITH LABORATORIES	18-730 05-04-84		
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	ZENITH LABORATORIES	18-730 05-04-84		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	PAR PHARMACEUTICAL	18-829 08-06-84		
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	PAR PHARMACEUTICAL	18-829 08-06-84		
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	18-851 05-18-84		
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	18-851 05-18-84		
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	MYLAN PHARMS	18-858 04-20-84		
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	MYLAN PHARMS	18-858 04-20-84		
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	PARKE-DAVIS/W-L	18-806 11-23-84		
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	PARKE-DAVIS/W-L	18-806 11-23-84		
IODOHIPPURATE SODIUM, I-123 1MCI/ML	NEPHROFLOW (INJECTABLE; INJECTION)	MEDI-PHYSICS	18-289 12-28-84		NCE 12-28-89
IODOXAMATE MEGLUMINE 40.3%	CHOLOVUE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	18-076 08-14-81	3654272 04-04-89	
IODOXAMATE MEGLUMINE 9.9%	CHOLOVUE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	18-077 08-14-81	3654272 04-04-89	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ISOFLURANE 99.9%	FORANE (GAS; INHALATION)	ANAQUEST/BOC	17-624 12-18-79	3535425 01-24-93 3535388 01-24-93	
ISOTRETINOIN 10MG	ACCUTANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662 05-07-82	4200647 04-29-97 4322438 03-30-99 4464394 08-07-01	NCE 05-07-92
ISOTRETINOIN 20MG	ACCUTANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662 03-28-83	4200647 04-29-97 4322438 03-30-99 4464394 08-07-01	NCE 05-07-92
ISOTRETINOIN 40MG	ACCUTANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662 05-07-82	4200647 04-29-97 4322438 03-30-99 4464394 08-07-01	NCE 05-07-92
KETOCONAZOLE 200MG	NIZORAL (TABLET; ORAL)	JANSSEN PHARMA	18-533 06-12-81	4335125 06-15-99	
LABETALOL HYDROCHLORIDE 200MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-686 08-01-84	4012444 03-15-94 4006755 01-03-95	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
LABETALOL HYDROCHLORIDE 300MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-686 08-01-84	4012444 03-15-94 4006755 01-03-95	NCE 08-01-94
LABETALOL HYDROCHLORIDE 400MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-686 08-01-84	4012444 03-15-94 4006755 01-03-95	NCE 08-01-94
LABETALOL HYDROCHLORIDE 5MG/ML	NORMODYNE (INJECTABLE; INJECTION)	SCHERING	18-687 08-01-84	4012444 03-15-94 4006755 01-03-95 4328213 05-04-99	NCE 08-01-94
LABETALOL HYDROCHLORIDE 200MG	TRANDATE (TABLET; ORAL)	GLAXO	18-716 08-01-84	4012444 03-15-94 4006755 01-03-95	NCE 08-01-94
LABETALOL HYDROCHLORIDE 300MG	TRANDATE (TABLET; ORAL)	GLAXO	18-716 08-01-84	4012444 03-15-94 4006755 01-03-95	NCE 08-01-94
LABETALOL HYDROCHLORIDE 400MG	TRANDATE (TABLET; ORAL)	GLAXO	18-716 08-01-84	4012444 03-15-94 4006755 01-03-95	NCE 08-01-94

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
LACTULOSE 10GM/15ML	CEPHULAC (SYRUP; ORAL)	MERRELL DOW/DOW CHEM	17-657 03-25-76	3461204 08-12-86 3867524 02-18-92 3860708 01-14-92 3860707 01-14-92 3562388 02-09-88 3558774 01-26-88	
LEUCOVORIN CALCIUM EQ 5MG BASE	WELLCOVORIN (TABLET; ORAL)	BURROUGHS WELLCOME	18-342 07-08-83		
LEUCOVORIN CALCIUM EQ 25MG BASE	WELLCOVORIN (TABLET; ORAL)	BURROUGHS WELLCOME	18-342 07-08-83		
LITHIUM CARBONATE 450MG	ESKALITH CR (TABLET, CONTROLLED RELEASE; ORAL)	SK&F LABORATORIES	18-152 03-29-82		
LITHIUM CARBONATE 300MG	LITHIUM CARBONATE (TABLET; ORAL)	ROXANE LABORATORIES	18-558 01-29-82		
LOPERAMIDE HYDROCHLORIDE 2MG	IMODIUM (CAPSULE; ORAL)	JANSSEN PHARMA	17-694 12-28-76	3714159 01-30-90	
LOPERAMIDE HYDROCHLORIDE 1MG/5ML	IMODIUM (SOLUTION; ORAL)	JANSSEN PHARMA	19-037 07-31-84	3714159 01-30-90	
LOXAPINE HYDROCHLORIDE EQ 50MG BASE/ML	LOXITANE (INJECTABLE; INJECTION)	LEDERLE LABS/AM CYAN	18-039 10-26-79	3546226 12-08-87	

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TABLE LVO.1 NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
LOXAPINE HYDROCHLORIDE EQ 25MG BASE/ML	LOXITANE (CONCENTRATE; ORAL)	LEDERLE LABS/AM CYAN	17-658 05-04-76	3546226 12-08-87 4049809 09-20-94	
LOXAPINE SUCCINATE EQ 5MG BASE	LOXITANE (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	17-525 10-25-77	3546226 12-08-87	
LOXAPINE SUCCINATE EQ 10MG BASE	LOXITANE (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	17-525 02-25-75	3546226 12-08-87	
LOXAPINE SUCCINATE EQ 25MG BASE	LOXITANE (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	17-525 02-25-75	3546226 12-08-87	
LOXAPINE SUCCINATE EQ 50MG BASE	LOXITANE (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	17-525 02-25-75	3546226 12-08-87	
MAFENIDE ACETATE EQ 85MG BASE/GM	SULFAMYLON (CREAM; TOPICAL)	WINTHROP LABS/STERL	16-763 01-24-69	3497599 01-26-88	
MAGNESIUM ACETATE TETRAHYDRATE; POTASSIUM ACETATE; SODIUM CHLORIDE 32MG/100ML; 128MG/100ML; 234MG/100ML	PLASMA-LYTE 56 IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-047 06-15-84		
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE; SODIUM PHOSPHATE 30MG/100ML; 37MG/100ML; 0.82MG/100ML; 370MG/100ML; 530MG/100ML; 500MG/100ML; 12MG/100ML	ISOLYTES PH 7.4 IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-006 04-04-84		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE 30MG/100ML; 37MG/100ML; 222MG/100ML; 526MG/100ML; 502MG/100ML	PHYSIOSOL IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	ABBOTT LABORATORIES	17-637 07-08-82		
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE 30MG/100ML; 37MG/100ML; 222MG/100ML; 526MG/100ML; 502MG/100ML	PHYSIOSOL IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	ABBOTT LABORATORIES	18-406 07-08-82		
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE 30MG/100ML; 37MG/100ML; 370MG/100ML; 530MG/100ML; 500MG/100ML	PHYSIOLYTE IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	AM MCGAW/AM HOSP	19-024 06-08-84		
MAGNESIUM SULFATE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE 20MG/100ML; 40MG/100ML; 6.25MG/100ML; 800MG/100ML; 8.75MG/100ML	TIS-U-SOL (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-508 02-19-82		
MALATHION 0.5%	PRIODERM (LOTION; TOPICAL)	PURDUE FREDERICK	18-613 08-02-82		NCE 08-02-92
MAPROTILINE HYDROCHLORIDE 25MG	LUDIOMIL (TABLET; ORAL)	CIBA/CIBA-GEIGY	17-543 12-01-80	3399201 08-27-85	
MAPROTILINE HYDROCHLORIDE 50MG	LUDIOMIL (TABLET; ORAL)	CIBA/CIBA-GEIGY	17-543 12-01-80	3399201 08-27-85	
MAPROTILINE HYDROCHLORIDE 75MG	LUDIOMIL (TABLET; ORAL)	CIBA/CIBA-GEIGY	17-543 09-30-82	3399201 08-27-85	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
MAZINDOL 1MG	SANOREX (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	17-247 06-14-73	3763178 10-02-90	
MAZINDOL 2MG	SANOREX (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	17-247 06-14-73	3763178 10-02-90	
MAZINDOL 2MG	MAZANOR (TABLET; ORAL)	WYETH LABS/AMHO	17-980 08-28-80	3763178 10-02-90	
MAZINDOL 1MG	MAZANOR (TABLET; ORAL)	WYETH LABS/AMHO	17-980 02-02-82	3763178 10-02-90	
MEBENDAZOLE 100MG	VERMOX (TABLET, CHEWABLE; ORAL)	JANSSEN PHARMA	17-481 06-28-74	3657267 04-18-89	
MEDROXYPROGESTERONE ACETATE 100MG/ML	DEPO-PROVERA (INJECTABLE; INJECTION)	UPJOHN	12-541 01-16-76	3377364 04-09-85	
MEDROXYPROGESTERONE ACETATE 400MG/ML	DEPO-PROVERA (INJECTABLE; INJECTION)	UPJOHN	12-541 01-16-76	3377364 04-09-85	
MEGLUMINE; METRIZOIC ACID 140.1MG/ML; 461.8MG/ML	ISOPAQUE-280 (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-506 04-30-74	3476802 11-04-86	
METAPROTERENOL SULFATE 20MG	ALUPENT (TABLET; ORAL)	BOEHRINGER INGELHEIM	15-874 05-13-74	3422196 01-14-86	
METAPROTERENOL SULFATE 10MG	ALUPENT (TABLET; ORAL)	BOEHRINGER INGELHEIM	15-874 08-08-77	3422196 01-14-86	
METAPROTERENOL SULFATE 0.65MG/INH	ALUPENT (AEROSOL; INHALATION)	BOEHRINGER INGELHEIM	16-402 07-31-73	3422196 01-14-86	
METAPROTERENOL SULFATE 10MG/5ML	ALUPENT (SYRUP; ORAL)	BOEHRINGER INGELHEIM	17-571 05-23-75	3422196 01-14-86	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
METAPROTERENOL SULFATE 5%	ALUPENT (SOLUTION; INHALATION)	BOEHRINGER INGELHEIM	17-659 09-18-80	3422196 01-14-86	
METAPROTERENOL SULFATE 0.6%	ALUPENT (SOLUTION; INHALATION)	BOEHRINGER INGELHEIM	18-761 06-30-83	3422196 01-14-86	
METHYLDOPA 250MG	METHYLDOPA (TABLET; ORAL)	CORD LABORATORIES	18-934 06-29-84		
METHYLDOPA 500MG	METHYLDOPA (TABLET; ORAL)	CORD LABORATORIES	18-934 06-29-84		
METHYLPHENIDATE HYDROCHLORIDE 20MG	RITALIN-SR (TABLET, CONTROLLED RELEASE; ORAL)	CIBA/CIBA-GEIGY	18-029 03-30-82		
METOCLOPRAMIDE EQ 5MG BASE/5ML	REGLAN (SYRUP; ORAL)	AH ROBINS	18-821 3-25-83		
METOPROLOL TARTRATE 50MG	LOPRESSOR (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-963 08-07-78	3998790 12-21-93	
METOPROLOL TARTRATE 100MG	LOPRESSOR (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-963 08-07-78	3998790 12-21-93	
METOPROLOL TARTRATE 1MG/ML	LOPRESSOR (INJECTABLE; INJECTION)	GEIGY/CIBA-GEIGY	18-704 03-30-84	3998790 12-21-93	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
METRIZAMIDE 3.75GM/VIAL	AMIPAQUE (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-982 08-23-78	3701771 10-31-89	
METRIZAMIDE 6.75GM/VIAL	AMIPAQUE (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-982 08-23-78	3701771 10-31-89	
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	ZENITH LABORATORIES	18-517 05-05-82		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	CHELSEA LABORATORIES	18-599 09-17-82		
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	CHELSEA LABORATORIES	18-599 02-13-84		
METRONIDAZOLE 250MG	METRYL (TABLET; ORAL)	DRUMMER/PHOENIX	18-620 03-04-82		
METRONIDAZOLE 500MG	METRYL 500 (TABLET; ORAL)	DRUMMER/PHOENIX	18-620 06-02-83		
METRONIDAZOLE 500MG/100ML	METRO I.V. (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-674 08-31-82		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	CORD LABORATORIES	18-740 10-22-82		
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	CORD LABORATORIES	18-740 10-22-82		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	DANBURY PHARMACAL	18-764 09-17-82		
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	DANBURY PHARMACAL	18-764 12-20-82		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	BARR LABORATORIES	18-818 02-16-83		
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	BARR LABORATORIES	18-818 02-16-83		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	PAR PHARMACEUTICAL	18-845 08-18-83		
METRONIDAZOLE 250MG	PROTOSTAT (TABLET; ORAL)	ORTHO PHARMACEUTICAL	18-871 03-02-83		
METRONIDAZOLE 500MG	PROTOSTAT (TABLET; ORAL)	ORTHO PHARMACEUTICAL	18-871 03-02-83		
METRONIDAZOLE 500MG/100ML	METRONIDAZOLE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-889 11-18-83		
METRONIDAZOLE 500MG/100ML	METRONIDAZOLE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-890 11-18-83		
METRONIDAZOLE 500MG/100ML	METRO I.V. IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-900 09-29-83		
METRONIDAZOLE 500MG/100ML	METRONIDAZOLE (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-907 03-30-84		
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	PAR PHARMACEUTICAL	18-930 08-18-83		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	LNK INTERNATIONAL	19-029 04-10-84		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
METYROSINE 250MG	DEMSER (CAPSULE; ORAL)	MS&D/MERCK	17-871 10-03-79	3362879 01-09-85	
MICONAZOLE 10MG/ML	MONISTAT (INJECTABLE; INJECTION)	JANSSEN PHARMA	18-040 10-04-78	3717655 02-20-90 3839574 10-01-91	
MICONAZOLE NITRATE 2%	MONISTAT 7 (CREAM; VAGINAL)	ORTHO PHARMACEUTICAL	17-450 01-30-74	3717655 02-20-90 3839574 10-01-91	
MICONAZOLE NITRATE 2%	MONISTAT-DERM (CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-494 01-30-74	3717655 02-20-90 3839574 10-01-91	
MICONAZOLE NITRATE 2%	MONISTAT-DERM (LOTION; TOPICAL)	ORTHO PHARMACEUTICAL	17-739 12-16-75	3717655 02-20-90 3839574 10-01-91	
MICONAZOLE NITRATE 100MG	MONISTAT 7 (SUPPOSITORY; VAGINAL)	ORTHO PHARMACEUTICAL	18-520 03-15-82	3717655 02-20-90 3839574 10-01-91	
MICONAZOLE NITRATE 200MG	MONISTAT 3 (SUPPOSITORY; VAGINAL)	ORTHO PHARMACEUTICAL	18-888 08-15-84	3717655 02-20-90 3839574 10-01-91	
MINOXIDIL 2.5MG	LONITEN (TABLET; ORAL)	UPJOHN	18-154 10-18-79	3461461 08-12-86	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
MINOXIDIL 10MG	LONITEN (TABLET; ORAL)	UPJOHN	18-154 10-18-79	3461461 08-12-86	
MOLINDONE HYDROCHLORIDE 5MG	MOBAN (TABLET; ORAL)	DUPONT PHARMS/DUPONT	17-111 07-03-74	3491093 01-20-87	
MOLINDONE HYDROCHLORIDE 10MG	MOBAN (TABLET; ORAL)	DUPONT PHARMS/DUPONT	17-111 07-03-74	3491093 01-20-87	
MOLINDONE HYDROCHLORIDE 25MG	MOBAN (TABLET; ORAL)	DUPONT PHARMS/DUPONT	17-111 07-03-74	3491093 01-20-87	
MOLINDONE HYDROCHLORIDE 50MG	MOBAN (TABLET; ORAL)	DUPONT PHARMS/DUPONT	17-111 01-05-81	3491093 01-20-87	
MOLINDONE HYDROCHLORIDE 100MG	MOBAN (TABLET; ORAL)	DUPONT PHARMS/DUPONT	17-111 01-05-81	3491093 01-20-87	
MOLINDONE HYDROCHLORIDE 20MG/ML	MOBAN (CONCENTRATE; ORAL)	DUPONT PHARMS/DUPONT	17-938 12-28-79	3491093 01-20-87	
MORPHINE SULFATE 0.5MG/ML	DURAMORPH PF (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-565 09-18-84		
MORPHINE SULFATE 1MG/ML	DURAMORPH PF (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-565 09-18-84		
NADOLOL 40MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-063 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 80MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-063 12-10-79	3982021 09-21-93 3935267 01-27-93	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
NADOLOL 120MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-063 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 160MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-063 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 40MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-064 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 80MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-064 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 120MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-064 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 160MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-064 12-10-79	3982021 09-21-93 3935267 01-27-93	
NALBUPHINE HYDROCHLORIDE 10MG/ML	NUBAIN (INJECTABLE; INJECTION)	DUPONT PHARMS/DUPONT	18-024 05-15-79	3393197 07-16-85	
NALIDIXIC ACID 250MG	NEGGRAM (TABLET; ORAL)	WINTHROP LABS/STERL	14-214 12-27-67	3590036 06-29-88	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
NALIDIXIC ACID 500MG	NEGGRAM (TABLET; ORAL)	WINTHROP LABS/STERL	14-214 03-06-64	3590036 06-29-88	
NALIDIXIC ACID 1GM	NEGGRAM (TABLET; ORAL)	WINTHROP LABS/STERL	14-214 03-06-64	3590036 06-29-88	
NALIDIXIC ACID 250MG/5ML	NEGGRAM (SUSPENSION; ORAL)	WINTHROP LABS/STERL	17-430 04-17-73	3590036 06-29-88	
NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE 0.5MG; EQ 50MG BASE	TALWIN NX (TABLET; ORAL)	WINTHROP LABS/STERL	18-733 12-16-82	4105659 08-08-95	
NALTREXONE HYDROCHLORIDE 50MG	TREXAN (TABLET; ORAL)	DUPONT PHARMS/DUPONT	18-932 11-20-84		NCE 11-20-89
NAPROXEN 125MG	NAPROSYN (TABLET; ORAL)	SYNTEX PR	17-581 03-11-76	3998966 12-21-93 4009197 09-09-92 4001301 09-09-92 3904682 09-09-92	
NAPROXEN 250MG	NAPROSYN (TABLET; ORAL)	SYNTEX PR	17-581 03-11-76	3998966 12-21-93 4009197 09-09-92 4001301 09-09-92 3904682 09-09-92	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
NAPROXEN 375MG	NAPROSYN (TABLET; ORAL)	SYNTEX PR	17-581 07-18-80	3998966 12-21-93 4009197 09-09-92 4001301 09-09-92 3904682 09-09-92	
NAPROXEN 500MG	NAPROSYN (TABLET; ORAL)	SYNTEX PR	17-581 04-15-82	3998966 12-21-93 4009197 09-09-92 4001301 09-09-92 3904682 09-09-92	
NAPROXEN SODIUM 275MG	ANAPROX (TABLET; ORAL)	SYNTEX PR	18-164 09-04-80	3998966 12-21-93 4001301 09-09-92 4009197 09-09-92	
NICLOSAMIDE 500MG	NICLOCIDE (TABLET, CHEWABLE; ORAL)	MILES PHARMS/MILES	18-669 05-14-82		NCE 05-14-92
NICOTINE RESIN COMPLEX EQ 2MG BASE	NICORETTE (GUM, CHEWING; ORAL)	MERRELL DOW/DOW CHEM	18-612 01-13-84		NCE 01-13-94
NIFEDIPINE 10MG	PROCARDIA (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-482 12-31-81	3644627 02-22-89	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
NITROGLYCERIN 0.5MG/ML	TRIDIL (INJECTABLE; INJECTION)	AM CRITICAL CARE/AHS	18-537 06-16-83		
NITROGLYCERIN 5MG/ML	NITROSTAT (INJECTABLE; INJECTION)	PARKE-DAVIS/W-L	18-588 12-23-83		
NITROGLYCERIN 5MG/ML	NITRO-BID (INJECTABLE; INJECTION)	MARION LABORATORIES	18-621 01-05-82		
NITROGLYCERIN 1MG/ML	NITRONAL (INJECTABLE; INJECTION)	G POHL-BOSKAMP	18-672 08-30-83		
NITROGLYCERIN 5MG/ML	NITRONAL (INJECTABLE; INJECTION)	G POHL-BOSKAMP	18-672 08-30-83		
NITROGLYCERIN 0.8MG/ML	NITROL (INJECTABLE; INJECTION)	KREMERS-URBAN	18-774 01-19-83		
NOMIFENSINE MALEATE 25MG	MERITAL (CAPSULE; ORAL)	HOECHST-ROUSSEL	18-224 12-31-84		NCE 12-31-89
NOMIFENSINE MALEATE 50MG	MERITAL (CAPSULE; ORAL)	HOECHST-ROUSSEL	18-224 12-31-84		NCE 12-31-89
NORETHINDRONE ACETATE 5MG	AYGESTIN (TABLET; ORAL)	AYERST LABS/AMHO	18-405 04-21-82		
NORGESTREL 0.075MG	OVRETTE (TABLET; ORAL)	WYETH LABS/AMHO	17-031 10-23-73	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	
NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE	AVENTYL HCL (CAPSULE; ORAL)	ELI LILLY	14-684 11-06-64	3922305 11-25-92	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
NORTRIPTYLINE HYDROCHLORIDE EQ 25MG BASE	AVENTYL HCL (CAPSULE; ORAL)	ELI LILLY	14-684 11-06-64	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE/5ML	AVENTYL HCL (SOLUTION; ORAL)	ELI LILLY	14-685 11-06-64	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE/5ML	PAMELOR (SOLUTION; ORAL)	SANDOZ PHARMS/SANDOZ	18-012 08-01-77	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE	PAMELOR (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-013 08-01-77	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 25MG BASE	PAMELOR (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-013 08-01-77	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 75MG BASE	PAMELOR (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-013 06-14-79	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 50MG BASE	PAMELOR (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-013 06-14-79	3922305 11-25-92	
OXAMNIQUINE 250MG	VANSIL (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-069 07-23-80	3903283 09-02-92 3821228 06-28-91 3925391 12-09-92	
OXPRENOLOL HYDROCHLORIDE 20MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83	3483221 12-09-86	NCE 12-28-93
OXPRENOLOL HYDROCHLORIDE 40MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83	3483221 12-09-86	NCE 12-28-93
OXPRENOLOL HYDROCHLORIDE 80MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83	3483221 12-09-86	NCE 12-28-93

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
OXPRENOLOL HYDROCHLORIDE 160MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83	3483221 12-09-86	NCE 12-28-93
PANCURONIUM BROMIDE 2MG/ML	PAVULON (INJECTABLE; INJECTION)	ORGANON/AKZONA	17-015 10-24-72	3553212 01-05-88	
PANCURONIUM BROMIDE 1MG/ML	PAVULON (INJECTABLE; INJECTION)	ORGANON/AKZONA	17-015 09-14-73	3553212 01-05-88	
PARAMETHASONE ACETATE 1MG	HALDRONE (TABLET; ORAL)	ELI LILLY	12-772 04-17-61	3499016 03-03-87	
PARAMETHASONE ACETATE 2MG	HALDRONE (TABLET; ORAL)	ELI LILLY	12-772 04-17-61	3499016 03-03-87	
PENTAGASTRIN 0.25MG/ML	PEPTAVLON (INJECTABLE; INJECTION)	AYERST LABS/AMHO	17-048 07-26-74	3896103 07-22-92	
PENTAMIDINE ISETHIONATE 300MG/VIAL	PENTAM 300 (INJECTABLE; INJECTION)	LYPHOMED	19-129 10-16-84		
PENTAZOCINE LACTATE EQ 30MG BASE/ML	TALWIN (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	16-194 07-24-67	4105659 08-08-95	
PENTETATE INDIUM DISODIUM, IN-111 1MCI/ML	MPI INDIUM DTPA IN 111 (INJECTABLE; INJECTION)	MEDI-PHYSICS	17-707 02-18-82		NCE 02-18-92
PENTOXIFYLLINE 400MG	TRENTAL (TABLET, CONTROLLED RELEASE; ORAL)	HOECHST-ROUSSEL	18-631 08-30-84	3737433 06-05-90	NCE 08-30-94

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE 5MG/5ML; 6.25MG/5ML	PHENERGAN VC (SYRUP; ORAL)	WYETH LABS/AMHO	08-604 04-02-84		
PILOCARPINE 5MG	OCUSERT PILO-20 (INSERT, CONTROLLED RELEASE; OPHTHALMIC)	ALZA	17-431 07-29-74	391628 06-08-93	
PILOCARPINE 11MG	OCUSERT PILO-40 (INSERT, CONTROLLED RELEASE; OPHTHALMIC)	ALZA	17-548 07-29-72	391628 06-08-93	
PILOCARPINE HYDROCHLORIDE 4%	PILOPINE HS (GEL; OPHTHALMIC)	ALCON LABORATORIES	18-796 10-01-84		
PIMOZIDE 2MG	ORAP (TABLET; ORAL)	MCNEIL PHARM	17-473 07-31-84		NCE 07-31-94
PINDOLOL 5MG	VISKEN (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	18-285 09-03-82	3471515 10-07-86	NCE 09-03-92
PINDOLOL 10MG	VISKEN (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	18-285 09-03-82	3471515 10-07-86	NCE 09-03-92
PINDOLOL 15MG	VISKEN (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	18-285 09-03-82	3471515 10-07-86	NCE 09-03-92

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
PIROXICAM 10MG	FELDENE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-147 04-06-82	3591584 07-06-88 3674876 07-04-89 3862319 01-21-92 4100347 07-11-95 3927002 12-16-92 RE29668 12-10-91	NCE 04-06-92
PIROXICAM 20MG	FELDENE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-147 04-06-82	3591584 07-06-88 3674876 07-04-89 3862319 01-21-92 4100347 07-11-95 3927002 12-16-92 RE29668 12-10-91	NCE 04-06-92
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE 236GM/BOT; 2.97GM/BOT; 6.74GM/BOT; 5.86GM/BOT; 22.74GM/BOT	GOLYTELY (POWDER FOR RECONSTITUTION; ORAL)	BRAINTREE LABS	19-011 07-13-84		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE 120GM/PACKET; 1.49GM/PACKET; 3.36GM/PACKET; 2.92GM/PACKET; 11.36GM/PACKET	COLYTE (POWDER FOR RECONSTITUTION; ORAL)	EDLAW PREPARATIONS	18-983 10-26-84		
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE 227.1GM/PACKET; 2.82GM/PACKET; 6.36GM/PACKET; 5.53GM/PACKET; 21.5GM/PACKET	COLYTE (POWDER FOR RECONSTITUTION; ORAL)	EDLAW PREPARATIONS	18-983 10-26-84		
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE 360GM/PACKET; 4.47GM/PACKET; 10.08GM/PACKET; 8.76GM/PACKET; 34.08GM/PACKET	COLYTE (POWDER FOR RECONSTITUTION; ORAL)	EDLAW PREPARATIONS	18-983 10-26-84		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE 0.5MG; 1MG	MINIZIDE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-986 06-13-80	3511836 05-12-87 3663706 05-16-89 4130647 12-19-95	
POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE 0.5MG; 2MG	MINIZIDE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-986 06-13-80	3511836 05-12-87 3663706 05-16-89 4130647 12-19-95	
POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE 0.5MG; 5MG	MINIZIDE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-986 06-13-80	3511836 05-12-87 3663706 05-16-89 4130647 12-19-95	
POTASSIUM ACETATE 2MEQ/ML	POTASSIUM ACETATE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-896 07-20-84		
POTASSIUM CHLORIDE 10MEQ	KLOTRIX (TABLET, CONTROLLED RELEASE; ORAL)	MEAD JOHNSON/B-M	17-850 05-22-80	4140756 02-20-96	
POTASSIUM CHLORIDE; SODIUM CHLORIDE 150MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-630 02-17-83		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
POTASSIUM CHLORIDE; SODIUM CHLORIDE 300MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-630 02-17-83		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 150MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-630 02-17-83		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 300MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-630 02-17-83		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 75MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722 11-09-82		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 150MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722 11-09-82		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 220MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722 11-09-82		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 300MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722 11-09-82		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
PRALIDOXIME CHLORIDE 300MG/ML	PRALIDOXIME CHLORIDE (INJECTABLE; INJECTION)	AYERST LABS/AMHO	18-799 12-13-82		
PRALIDOXIME CHLORIDE 300MG/ML	PROTOPAM (INJECTABLE; INJECTION)	SURVIVAL TECHNOLOGY	18-986 04-26-83		
PRAZEPAM 20MG	CENTRAX (CAPSULE; ORAL)	PARKE-DAVIS/W-L	18-144 05-10-82		
PRAZIQUANTEL 600MG	BILTRICIDE (TABLET; ORAL)	MILES PHARMS/MILES	18-714 12-29-82	4001411 01-04-94	NCE 12-29-92
PRAZOSIN HYDROCHLORIDE 5MG	MINIPRESS (CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-442 06-23-76	3511836 05-12-87 3663706 05-16-89 4092315 05-30-95 4130647 12-19-95	
PRAZOSIN HYDROCHLORIDE 1MG	MINIPRESS (CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-442 06-23-76	3511836 05-12-87 3663706 05-16-89 4092315 05-30-95 4130647 12-19-95	

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
PRAZOSIN HYDROCHLORIDE 2MG	MINIPRESS (CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-442 06-23-76	3511836 05-12-87 3663706 05-16-89 4092315 05-30-95 4130647 12-19-95	
PROBUCOL 250MG	LORELCO (TABLET; ORAL)	MERRELL DOW/DOW CHEM	17-535 02-01-77	3576883 04-27-88 3862332 01-21-92	
PROCARBAZINE HYDROCHLORIDE EQ 50MG BASE	MATULANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	16-785 07-22-69	3520926 07-21-87	
PROPRANOLOL HYDROCHLORIDE 60MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 01-18-83		
PROPRANOLOL HYDROCHLORIDE 90MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 01-18-83		
PROPRANOLOL HYDROCHLORIDE 160MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	18-553 04-19-83		
PROPRANOLOL HYDROCHLORIDE 80MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	18-553 04-19-83		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
PROPRANOLOL HYDROCHLORIDE 120MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	18-553 04-19-83		
PROTAMINE SULFATE 250MG/VIAL	PROTAMINE SULFATE (INJECTABLE; INJECTION)	UPJOHN	07-413 08-02-84		
PROTIRELIN 0.5MG/ML	THYPINONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	17-638 11-05-76	3746697 07-17-90	
PROTIRELIN 0.5MG/ML	RELEFACT TRH (INJECTABLE; INJECTION)	HOECHST-ROUSSEL	18-087 07-18-78	3746697 07-17-90	
PROTRIPTYLINE HYDROCHLORIDE 5MG	VIVACTIL (TABLET; ORAL)	MS&D/MERCK	16-012 09-27-67	3372196 03-05-85	
PROTRIPTYLINE HYDROCHLORIDE 10MG	VIVACTIL (TABLET; ORAL)	MS&D/MERCK	16-012 09-27-67	3372196 03-05-85	
PYRANTEL PAMOATE EQ 250MG BASE/5ML	ANTIMINTH (SUSPENSION; ORAL)	ROERIG/PFIZER	16-883 12-30-71	3644624 02-22-89 3549624 12-22-87	
RANITIDINE HYDROCHLORIDE EQ 150MG BASE	ZANTAC (TABLET; ORAL)	GLAXO	18-703 06-09-83	4128658 12-05-95	NCE 06-09-93
RANITIDINE HYDROCHLORIDE EQ 25MG BASE/ML	ZANTAC (INJECTABLE; INJECTION)	GLAXO	19-090 10-19-84	4128658 12-05-95	NCE 06-09-93
RITODRINE HYDROCHLORIDE 10MG	YUTOPAR (TABLET; ORAL)	ASTRA PHARM PRODS	18-555 12-12-80	3410944 11-12-85	
RITODRINE HYDROCHLORIDE 10MG/ML	YUTOPAR (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-580 12-12-80	3410944 11-12-85	

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TABLE IV. 5 NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
RITODRINE HYDROCHLORIDE 15MG/ML	YUTOPAR (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-580 09-27-84	3410944 11-12-85	
SAFFLOWER OIL; SOYBEAN OIL 10%; 10%	LIPOSYN II 20% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-991 08-27-84		
SAFFLOWER OIL; SOYBEAN OIL 5%; 5%	LIPOSYN II 10% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-997 08-27-84		
SARALASIN ACETATE EQ 0.6MG BASE/ML	SARENIN (INJECTABLE; INJECTION)	NORWICH EATON/P&G	18-009 05-29-81	3932624 01-13-93 3886134 05-27-92	
SCOPOLAMINE 1.5MG	TRANSDERM-SCOP (FILM, CONTROLLED RELEASE; PERCUTANEOUS)	CIBA/CIBA-GEIGY	17-874 12-31-79	4031894 06-28-94 4262003 04-14-98	
SILVER SULFADIAZINE 1%	SILVADENE (CREAM; TOPICAL)	MARION LABORATORIES	17-381 11-26-73	3761590 09-24-90	
SILVER SULFADIAZINE 1%	SSD (CREAM; TOPICAL)	TRAVENOL LABS	18-578 02-25-82		
SINCALIDE 0.005MG/VIAL	KINEVAC (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-697 07-21-76	3839315 10-01-91	
SODIUM ACETATE, ANHYDROUS 2MEQ/ML	SODIUM ACETATE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-893 05-04-83		
SODIUM CHLORIDE 450MG/100ML	SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-497 02-19-82		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
SODIUM CHLORIDE 9MG/ML	BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-800 10-29-82		
HLORIDE	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-803 10-29-82		
SODIUM CHLORIDE 2.5MEQ/ML	SODIUM CHLORIDE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-897 07-20-84		
SODIUM CHLORIDE 3GM/100ML	SODIUM CHLORIDE 3% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-022 11-01-83		
SODIUM CHLORIDE 5GM/100ML	SODIUM CHLORIDE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-022 11-01-83		
SODIUM CHLORIDE 9MG/ML	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-217 07-13-84		
SODIUM CHLORIDE 9MG/ML	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-218 07-13-84		
SODIUM IODIDE, I-123 100 UCI	SODIUM IODIDE I 123 (CAPSULE; ORAL)	BENEDICT NUCLR PHARM	18-671 05-27-82		
SODIUM IODIDE, I-123 200 UCI	SODIUM IODIDE I 123 (CAPSULE; ORAL)	BENEDICT NUCLR PHARM	18-671 05-27-82		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
SODIUM IODIDE, I-123 400 UCI	SODIUM IODIDE I 123 (CAPSULE; ORAL)	BENEDICT NUCLR PHARM	18-671 05-27-82		
SODIUM LACTATE 5MEQ/ML	SODIUM LACTATE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-947 09-05-84		
SODIUM NITROPRUSSIDE 50MG/VIAL	SODIUM NITROPRUSSIDE (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-581 07-28-82		
SODIUM PHOSPHATE, DIBASIC; SODIUM PHOSPHATE, MONOBASIC 142MG/ML; 276MG/ML	SODIUM PHOSPHATES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-892 05-10-83		
SOMATROPIN 2 IU/VIAL	ASELLACRIN 2 (INJECTABLE; INJECTION)	SERONO LABS	17-726 07-21-83		
SORBITOL 3GM/100ML	SORBITOL 3% IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-512 05-27-82		
SOYBEAN OIL 10%	SOYACAL 10% (INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	18-465 06-29-83		
SOYBEAN OIL 10%	TRAVAMULSION 10% (INJECTABLE; INJECTION)	TRAVENOL LABS	18-660 02-26-82		
SOYBEAN OIL 20%	TRAVAMULSION 20% (INJECTABLE; INJECTION)	TRAVENOL LABS	18-758 02-15-83		
SOYBEAN OIL 20%	SOYACAL 20% (INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	18-786 06-29-83		
SOYBEAN OIL 10%	LIPOSYN III 10% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-969 09-24-84		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
SOYBEAN OIL 20%	LIPOSYN III 20% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-970 09-25-84		
STANOZOLOL 2MG	WINSTROL (TABLET; ORAL)	WINTHROP LABS/STERL	12-885 11-30-61	3704295 11-28-89	
STREPTOZOCIN 1GM/VIAL	ZANOSAR (INJECTABLE; INJECTION)	UPJOHN	17-961 05-07-82		NCE 05-07-92
SUCRALFATE 1GM	CARAFATE (TABLET; ORAL)	MARION LABORATORIES	18-333 10-30-81	3432489 03-11-86	
SUFENTANIL CITRATE EQ 0.05MG BASE/ML	SUFENTA (INJECTABLE; INJECTION)	JANSSEN PHARMA	19-050 05-04-84	3998834 12-21-93	NCE 05-04-94
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	BACTRIM (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-377 07-30-73	RE28636 06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	BACTRIM DS (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-377 03-01-78	RE28636 06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	BACTRIM (SUSPENSION; ORAL)	HOFFMANN-LA ROCHE	17-560 04-16-75	RE28636 06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	BACTRIM PEDIATRIC (SUSPENSION; ORAL)	HOFFMANN-LA ROCHE	17-560 12-10-79	RE28636 06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM 80MG/ML; 16MG/ML	BACTRIM (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	18-374 06-23-81	3551564 12-29-87 RE28636 06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	SULFAMETHOXAZOLE AND TRIMETHOPRIM (TABLET; ORAL)	DRUMMER/PHOENIX	18-598 05-19-82		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH (TABLET; ORAL)	DRUMMER/PHOENIX	18-598 05-19-82		
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	SULFATRIM PEDIATRIC (SUSPENSION; ORAL)	NATL PHARM MFG/BARRE	18-615 01-07-83		
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	SULFATRIM (SUSPENSION; ORAL)	NATL PHARM MFG/BARRE	18-615 01-07-83		
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	SMZ-TMP (SUSPENSION; ORAL)	BIOCRAFT LABS	18-812 01-28-83		
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	SMZ-TMP PEDIATRIC (SUSPENSION; ORAL)	BIOCRAFT LABS	18-812 06-10-83		
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	SULFAMETHOXAZOLE AND TRIMETHOPRIM (TABLET; ORAL)	DANBURY PHARMACAL	18-852 05-09-83		
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH (TABLET; ORAL)	DANBURY PHARMACAL	18-854 05-09-83		
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	SULFAMETHOXAZOLE & TRIMETHOPRIM (TABLET; ORAL)	HEATHER DRUG	18-946 08-10-84		
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	SULFAMETHOXAZOLE & TRIMETHOPRIM (TABLET; ORAL)	HEATHER DRUG	18-946 08-10-84		
SULFASALAZINE 500MG	AZULFIDINE (TABLET, ENTERIC COATED; ORAL)	PHARMACIA/PHARMACIA	07-073 04-06-83		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
SULINDAC 150MG	CLINORIL (TABLET; ORAL)	MS&D/MERCK	17-911 09-27-78	3654349 04-04-89 3725548 04-03-90	
SULINDAC 200MG	CLINORIL (TABLET; ORAL)	MS&D/MERCK	17-911 09-27-78	3725548 04-03-90 3654349 04-04-89	
SUTILAINS 82,000 UNITS/GM	TRAVASE (OINTMENT; TOPICAL)	TRAVENOL LABS	12-828 06-12-69	3409719 11-05-85	
TECHNETIUM, TC-99M SODIUM PERTECHNETATE GENERATOR 0.22-2.22CI/GENERATOR	MINITEC (SOLUTION; INTRAVENOUS, ORAL)	ER SQUIBB AND SONS	17-339 06-03-74	4041317 08-09-94	
TECHNETIUM, TC-99M, ALBUMIN AGGREGATED KIT N/A	CINTICHEM TECHNETIUM 99M MAA (INJECTABLE; INJECTION)	CINTICHEM	17-773 11-18-76	3987157 10-19-93	
TECHNETIUM, TC-99M, ALBUMIN COLLOID KIT N/A	MICROLITE (INJECTABLE; INJECTION)	MED DIAG/NE NUCLEAR	18-263 03-25-83	4226846 10-07-97	
TECHNETIUM, TC-99M, ALBUMIN KIT N/A	CINTICHEM TECHNETIUM 99M HSA (INJECTABLE; INJECTION)	CINTICHEM	17-775 04-01-77	3987157 10-19-93	
TECHNETIUM, TC-99M, DISOFENIN KIT N/A	HEPATOLITE (INJECTABLE; INJECTION)	MED DIAG/NE NUCLEAR	18-467 03-16-82		NCE 03-16-92
TECHNETIUM, TC-99M, GLUCEPTATE KIT N/A	TECHNESCAN GLUCEPTATE (INJECTABLE; INJECTION)	MS&D/MERCK	18-272 01-27-82	4027005 05-31-94	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
TECHNETIUM, TC-99M, MEDRONATE N/A	OSTEOLITE (INJECTABLE; INJECTION)	MED DIAG/NE NUCLEAR	17-972 12-16-77	4032625 06-26-94	
TECHNETIUM, TC-99M, MEDRONATE N/A	AMERSCAN (INJECTABLE; INJECTION)	AMERSHAM/RADIOCHEM	18-335 08-05-82		
TECHNETIUM, TC-99M, SUCCIMER KIT N/A	MPI DMSA KIDNEY REAGENT (INJECTABLE; INJECTION)	MEDI-PHYSICS	17-944 05-18-82	4208398 06-17-97 4233285 11-11-97	NCE 05-18-92
TERBUTALINE SULFATE 1MG/ML	BRICANYL (INJECTABLE; INJECTION)	MERRELL DOW/DOW CHEM	17-466 03-25-74	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 2.5MG	BRICANYL (TABLET; ORAL)	MERRELL DOW/DOW CHEM	17-618 04-22-75	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 5MG	BRICANYL (TABLET; ORAL)	MERRELL DOW/DOW CHEM	17-618 04-22-75	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 2.5MG	BRETHINE (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-849 05-17-76	3937838 02-10-93 4011258 03-08-94	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
TERBUTALINE SULFATE 5MG	BRETHINE (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-849 05-17-76	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 1MG/ML	BRETHINE (INJECTABLE; INJECTION)	GEIGY/CIBA-GEIGY	18-571 11-30-81	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 0.2MG/INH	BRETHAIRE (AEROSOL; INHALATION)	GEIGY/CIBA-GEIGY	18-762 08-17-84	3937838 02-10-93 4011258 03-08-94	
THALLOUS CHLORIDE, TL-201 2MCI/ML	THALLOUS CHLORIDE TL 201 (INJECTABLE; INJECTION)	MEDI-PHYSICS	18-110 02-01-82		
THALLOUS CHLORIDE, TL-201 1MCI/ML	THALLOUS CHLORIDE TL 201 (INJECTABLE; INJECTION)	AMERSHAM/RADIOCHEM	18-548 12-30-82		
TIMOLOL MALEATE 5MG	BLOCADREN (TABLET; ORAL)	MS&D/MERCK	18-017 11-25-81	3655663 04-11-89	
TIMOLOL MALEATE 10MG	BLOCADREN (TABLET; ORAL)	MS&D/MERCK	18-017 11-25-81	3655663 04-11-89	
TIMOLOL MALEATE 20MG	BLOCADREN (TABLET; ORAL)	MS&D/MERCK	18-017 11-25-81	3655663 04-11-89	
TIMOLOL MALEATE EQ 0.25% BASE	TIMOPTIC (SOLUTION; OPHTHALMIC)	MS&D/MERCK	18-086 08-17-78	4195085 03-25-97 3655663 04-11-89	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
TIMOLOL MALEATE EQ 0.5% BASE	TIMOPTIC (SOLUTION; OPHTHALMIC)	MS&D/MERCK	18-086 08-17-78	4195085 03-25-97 3655663 04-11-89	
TOCAINIDE HYDROCHLORIDE 400MG	TONOCARD (TABLET; ORAL)	MS&D/MERCK	18-257 11-09-84	4218477 08-19-97 4237068 12-02-97	NCE 11-09-94
TOCAINIDE HYDROCHLORIDE 600MG	TONOCARD (TABLET; ORAL)	MS&D/MERCK	18-257 11-09-84	4218477 08-19-97 4237068 12-02-97	NCE 11-09-94
TOLAZAMIDE 100MG	TOLAZAMIDE (TABLET; ORAL)	ZENITH LABORATORIES	18-894 11-02-84		
TOLAZAMIDE 250MG	TOLAZAMIDE (TABLET; ORAL)	ZENITH LABORATORIES	18-894 11-02-84		
TOLAZAMIDE 500MG	TOLAZAMIDE (TABLET; ORAL)	ZENITH LABORATORIES	18-894 11-02-84		
TOLMETIN SODIUM EQ 200MG BASE	TOLECTIN (TABLET; ORAL)	MCNEIL LABORATORIES	17-628 03-24-76	3752826 08-14-90	
TOLMETIN SODIUM EQ 400MG BASE	TOLECTIN DS (CAPSULE; ORAL)	MCNEIL LABORATORIES	18-084 10-30-79	3752826 08-14-90	
TRAZODONE HYDROCHLORIDE 50MG	DESYREL (TABLET; ORAL)	MEAD JOHNSON/B-M	18-207 12-24-81	3381009 04-30-85	
TRAZODONE HYDROCHLORIDE 100MG	DESYREL (TABLET; ORAL)	MEAD JOHNSON/B-M	18-207 12-24-81	3381009 04-30-85	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
TRETINOIN 0.05%	RETIN-A (SOLUTION; TOPICAL)	ORTHO PHARMACEUTICAL	16-921 10-20-71	3729568 04-24-90	
TRETINOIN 0.1%	RETIN-A (CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-340 01-26-73	3729568 04-24-90	
TRETINOIN 0.05%	RETIN-A (CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-522 07-19-74	3729568 04-24-90	
TRETINOIN 0.01%	RETIN-A (GEL; TOPICAL)	ORTHO PHARMACEUTICAL	17-955 10-05-78	3729568 04-24-90	
TRETINOIN 0.025%	RETIN-A (GEL; TOPICAL)	ORTHO PHARMACEUTICAL	17-579 04-18-75	3729568 04-24-90	
TRIAMCINOLONE ACETONIDE 0.25MG/INH	AZMACORT (AEROSOL; INHALATION)	WILLIAM H RORER	18-117 04-23-83	3897779 08-05-92 3927806 12-23-92	
TRIAZOLAM 0.25MG	HALCION (TABLET; ORAL)	UPJOHN	17-892 11-15-82	3980790 09-14-93 3987052 10-19-93	NCE 11-15-92
TRIAZOLAM 0.5MG	HALCION (TABLET; ORAL)	UPJOHN	17-892 11-15-82	3980790 09-14-93 3987052 10-19-93	NCE 11-15-92
TRILOSTANE 30MG	MODRASTANE (CAPSULE; ORAL)	WINTHROP LABS/STERL	18-719 12-21-84		NCE 12-21-89
TRILOSTANE 60MG	MODRASTANE (CAPSULE; ORAL)	WINTHROP LABS/STERL	18-719 12-21-84		NCE 12-21-89

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TABLE IV.- NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
TRIMETHOPRIM 200MG	PROLOPRIM (TABLET; ORAL)	BURROUGHS WELLCOME	17-943 07-14-82		
TRIMETHOPRIM 200MG	TRIMPEX 200 (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-952 11-09-82		
TRIMETHOPRIM 100MG	TRIMETHOPRIM (TABLET; ORAL)	BIOCRAFT LABS	18-679 07-30-82		
TRIMIPRAMINE MALEATE EQ 100MG BASE	SURMONTIL (CAPSULE; ORAL)	IVES LABS/AMHO	16-792 09-15-82		
VECURONIUM BROMIDE 10MG/VIAL	NORCURON (NC-45) (INJECTABLE; INJECTION)	ORGANON/AKZONA	18-776 04-30-84	3553212 01-05-88 4237126 12-02-97 4297351 10-27-98	NCE 04-30-94
VERAPAMIL HYDROCHLORIDE 80MG	ISOPTIN (TABLET; ORAL)	KNOLL PHARMACEUTICAL	18-593 03-08-82		
VERAPAMIL HYDROCHLORIDE 120MG	ISOPTIN (TABLET; ORAL)	KNOLL PHARMACEUTICAL	18-593 03-08-82		
VERAPAMIL HYDROCHLORIDE 80MG	CALAN (TABLET; ORAL)	SEARLE/SEARLE PHARMS	18-817 09-10-84		
VERAPAMIL HYDROCHLORIDE 120MG	CALAN (TABLET; ORAL)	SEARLE/SEARLE PHARMS	18-817 09-10-84		
VERAPAMIL HYDROCHLORIDE 2.5MG/ML	CALAN (INJECTABLE; INJECTION)	SEARLE PHARMS	18-925 03-30-84		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
VERAPAMIL HYDROCHLORIDE 2.5MG/ML	CALAN (INJECTABLE; INJECTION)	SEARLE PHARMS	19-038 03-30-84		
WATER FOR INJECTION, STERILE 100%	STERILE WATER FOR INJECTION IN PLASTIC CONTAINER (LIQUID; N/A)	TRAVENOL LABS	18-595 01-17-83		
WATER FOR INJECTION, STERILE 100%	STERILE WATER IN PLASTIC CONTAINER (LIQUID; N/A)	TRAVENOL LABS	18-632 06-30-82		
WATER FOR INJECTION, STERILE 100%	STERILE WATER IN PLASTIC CONTAINER (LIQUID; N/A)	ABBOTT LABORATORIES	18-801 10-27-82		
WATER FOR INJECTION, STERILE 100%	BACTERIOSTATIC WATER IN PLASTIC CONTAINER (LIQUID; N/A)	ABBOTT LABORATORIES	18-802 10-27-82		
WATER FOR INJECTION, STERILE 100%	STERILE WATER FOR INJECTION IN PLASTIC CONTAINER (LIQUID; N/A)	AM MCGAW/AM HOSP	19-077 03-02-84		
XENON, XE-127 5MCI/VIAL	XENON XE 127 (GAS; INHALATION)	MALLINCKRODT	18-536 10-01-82	NCE 10-01-92	
XENON, XE-127 10MCI/VIAL	XENON XE 127 (GAS; INHALATION)	MALLINCKRODT	18-536 10-01-82	NCE 10-01-92	
XENON, XE-133 10MCI/VIAL	XENON XE 133 (GAS; INHALATION)	MALLINCKRODT	18-327 03-09-82		
XENON, XE-133 20MCI/VIAL	XENON XE 133 (GAS; INHALATION)	MALLINCKRODT	18-327 03-09-82		

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