

APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations

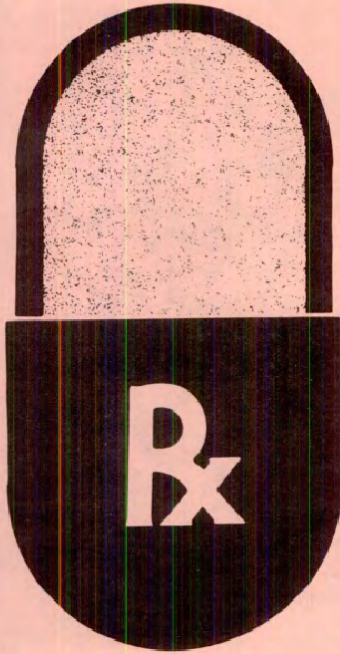


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**CUMULATIVE
SUPPLEMENT 8**
AUG '84 - APR '85



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.

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 >DEL> (DELETE) to the left of the line containing the overstruck print. The >DEL> symbol is dropped in subsequent cumulative supplements for that item.

A newly approved product is identified by the lozenge (x) 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.

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

(continued)

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

<u>Former Applicant (Name)</u>	<u>New Applicant (Name)</u>	<u>New Abbreviated Name</u>
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."

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.

Drug Product Count

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.

New Molecular Entity

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.

Drug Product Definition

From the data presented under Section B, users should be able to observe such things as (1) newly approved, DESI effective and marketed drug products which are added to the list; (2) products that are being removed, 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 in that results from all additions, deletions and category changes is reflected in the quarterly counts for multisource and single source products.

USE 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.

DESCRIPTION OF REPORT

III. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

A. COUNTS CUMULATIVE BY QUARTERS

<u>CATEGORIES COUNTED</u>	<u>JULY '84 (BASELINE)</u>	<u>OCT '84</u>	<u>JAN '85</u>
DRUG PRODUCTS LISTED	7415	7609	7746
SINGLE SOURCE	2005 (27.0%)	2045 (26.9%)	2077 (26.8%)
MULTISOURCE (1)	5410 (72.9%)	5564 (73.1%)	5669 (73.2%)
THERAPEUTICALLY EQUIVALENT	4393 (59.2%)	4497 (59.1%)	4598 (59.4%)
NOT THERAPEUTICALLY EQUIVALENT	999 (13.4%)	1032 (13.5%)	1038 (13.4%)
EXCEPTIONS (2)	18 (0.3%)	26 (0.3%)	23 (0.3%)
NEW MOLECULAR ENTITIES APPROVED	-	4	9
NUMBER OF APPLICANTS	295	300	304

B. ACTIVITY FOR SUPPLEMENT NUMBER 8

	<u>FEB '85</u>	<u>MAR '85</u>	<u>APR '85</u>	<u>CUMULATIVE</u>
DRUG PRODUCTS ADDED:	44	53	63	160
NEWLY APPROVED	43	53	63	159
DESI EFFECTIVE	1	0	0	1
REMARKETED	0	0	0	0
DRUG PRODUCTS REMOVED:	1	1	3	5
WITHDRAWN APPROVAL	0	0	0	0
RX TO OTC SWITCH	1	0	0	1
DISCONTINUED MARKETING	0	1	3	4
NET GAIN IN DRUG PRODUCTS	43	52	60	155
SINGLE SOURCE PRODUCTS APPROVED	6	9	13	28
MULTISOURCE DRUG PRODUCTS APPROVED	38	44	50	132
NEW MOLECULAR ENTITIES APPROVED:	0	0	2	2
AS THE ENTITY	0	0	0	0
AS A SALT, ESTER OR DERIVATIVE				
OF THE ENTITY	0	0	2	2

(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 1-5 OF THE LIST)

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APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE SUPPLEMENT NUMBER 8 / AUGUST '84 - APRIL '85

1

ACEBUTOLOL HYDROCHLORIDE (PAGE 3-1)

CAPSULE; ORAL
 SETRAL
 IVES LABS/AMMO EQ 200MG BASEM N 18917
 EQ 400MG BASEM N 18917

ACETAMINOPHEN; BUTALBITAL (PAGE 3-1)

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE (PAGE 3-1)

CAPSULE; ORAL
 BUTALBITAL, ACETAMINOPHEN, CAFFEINE
 AB DH GRAHAM LABS 325MG;50MG;40MG N 88758
 AB 325MG;50MG;40MG N 88765
 > ADD > AB 325MG;50MG;40MG N 89067
 AB ESGIC
 GILBERT LABORATORIES 325MG;50MG;40MG N 88825
 TABLET; ORAL
 AB ESGIC
 GILBERT LABORATORIES 325MG;50MG;40MG N 87629
 AB EXTRICET
 SANDOZ PHARMS/SANDOZ 325MG;50MG;40MG N 88616
 AB REPAN
 DH GRAHAM LABS 325MG;50MG;40MG N 87804

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL
 ACETAMINOPHEN AND CODEINE PHOSPHATE
 AA ZENITH LABORATORIES 300MG;60MG N 87083
 ACETAMINOPHEN W/ CODEINE #2 N 88627
 AA LEMMON 300MG;15MG N 88628
 ACETAMINOPHEN W/ CODEINE #3 N 88629
 AA LEMMON 300MG;30MG
 ACETAMINOPHEN W/ CODEINE #4 N 87883
 AA LEMMON 300MG;60MG
 /ACETAMINOPHEN W/ CODEINE PHOSPHATE #4/
 /AA/ ZENITH LABORATORIES/300MG;60MG/

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-2)

CAPSULE; ORAL
 ACETAMINOPHEN AND HYDROCODONE BITARTRATE
 AA CENTRAL PHARMS 500MG;5MG N 88898
 TABLET; ORAL
 HYDROCODONE BITARTRATE W/ ACETAMINOPHEN
 AA BARR LABORATORIES 500MG;5MG N 88577

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 3-2)

CAPSULE; ORAL
 TYLOX
 MCNEIL PHARM 500MG;5MG N 88790
 TYLOX-325
 MCNEIL PHARM 325MG;5MG N 88246
 TABLET; ORAL
 /OXYCODONE/
 /OXYCODONE/
 AA HALSEY DRUG 325MG;5MG N 87463

ACETIC ACID, GLACIAL (PAGE 3-3)

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

ACETIC ACID, GLACIAL; HYDROCORTISONE (PAGE 3-3)

SOLUTION/DROPS; OTIC
 HYDROCORTISONE AND ACETIC ACID
 AT THAMES PHARMACAL 2%;1% N 88759

ACYCLOVIR (PAGE 3-4)

CAPSULE; ORAL
 ZOVRAX
 BURROUGHS WELLCOME 200MG N 18828

ALBUTEROL SULFATE (PAGE 3-5)

> ADD > SYRUP; ORAL
 > ADD > PROVENTIL
 > ADD > SCHERING EQ 2MG BASE/5ML N 18062

> ADD > AMMONIUM LACTATE (PAGE 3-12)

> ADD > LOTION; TOPICAL
 > ADD > AMMONIUM LACTATE
 > ADD > BRISTOL-MEYERS EQ 12% ACID N 19155

AMOXICILLIN; POTASSIUM CLAVULANATE (PAGE 3-13)

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

AMPICILLIN SODIUM (PAGE 3-14)

INJECTABLE; INJECTION
 AMPICILLIN SODIUM
 ELI LILLY EQ 500MG BASE/VIAL N 62565
 EQ 1GM BASE/VIAL N 62565

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-16)

CAPSULE; ORAL
 BUTALBITAL W/ ASPIRIN AND CAFFEINE
 CHELSEA LABORATORIES 325MG; 50MG; 40MG N 86231

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

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

CAPSULE; ORAL
 PROPOXYPHENE COMPOUND 65
 AA LEMMON 389MG; 32.4MG; 65MG N 89025
 AA ZENITH LABORATORIES 389MG; 32.4MG; 65MG N 83077
 PROPOXYPHENE HCL W/ ASPIRIN AND CAFFEINE
 AA CHELSEA LABORATORIES 389MG; 32.4MG; 65MG N 85732

ASPIRIN; METHOCARBAMOL (PAGE 3-17)

TABLET; ORAL
 /METHOCARBAMOL W/ ASPIRIN/
 METHOCARBAMOL AND ASPIRIN

BENZOYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

GEL; TOPICAL
 BENZAMYCIN
 DERMIX/RORER 5%; 32M N 50557

/BENZTHIAZIDE; RESERPINE/ (PAGE 3-21)

/TABLET; ORAL/
 /EXNA-B/
 /AM ROBINS/ /50MG; 0.125MG/ /N 14461/

BENZTROPINE MESYLATE (PAGE 3-21)

TABLET; ORAL
 BENZTROPINE MESYLATE
 > ADD > BP PAR PHARMACEUTICAL 0.5MG N 88877
 > ADD > BP 1MG N 88894
 > ADD > BP 2MG N 88895

BETAMETHASONE DIPROPIONATE (PAGE 3-22)

ointment; TOPICAL
 ALPHATREX
 AB SAVAGE LABS/BYK-GLDN EQ 0.05% BASE N 19143
 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% BASE N 18741
 AB DIPROSONE
 AB SCHERING EQ 0.05% BASE N 17691

BETAMETHASONE VALERATE (PAGE 3-22)

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

ointment; TOPICAL
 VALNAG
 AB NMC LABORATORIES EQ 0.1% BASE N 70051

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

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-29)

SOLUTION; INTRAPERITONEAL

DELFLX 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
DIANEAL PD-1 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
 AT TRAVENOL LABS 25.7MG/100ML; 1.5GM/100ML;
 15.2MG/100ML; 567MG/100ML;
 392MG/100ML N 17512
DIANEAL PD-1 W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
 AT TRAVENOL LABS 25.7MG/100ML; 2.5GM/100ML;
 15.2MG/100ML; 567MG/100ML;
 392MG/100ML N 17512
DIANEAL PD-1 W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
 AT TRAVENOL LABS 25.7MG/100ML; 4.25GM/100ML;
 15.2MG/100ML; 567MG/100ML;
 392MG/100ML N 17512

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-29)

INJECTABLE; INJECTION

> ADD > POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND
 > ADD > LACTATED RINGER'S IN PLASTIC CONTAINER
 > ADD > AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
 105MG/100ML; 600MG/100ML;
 310MG/100ML N 19367
 > ADD > AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
 179MG/100ML; 600MG/100ML;
 310MG/100ML N 19367
 > ADD > POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND
 > ADD > LACTATED RINGER'S IN PLASTIC CONTAINER
 > ADD > AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
 254MG/100ML; 600MG/100ML;
 310MG/100ML N 19367
 > ADD > POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND
 > ADD > LACTATED RINGER'S IN PLASTIC CONTAINER
 > ADD > AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
 179MG/100ML; 600MG/100ML;
 310MG/100ML N 19367
 > ADD > AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
 328MG/100ML; 600MG/100ML;
 310MG/100ML N 19367
 > ADD > POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND
 > ADD > LACTATED RINGER'S IN PLASTIC CONTAINER
 > ADD > AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
 254MG/100ML; 600MG/100ML;
 310MG/100ML N 19367
 > ADD > POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND
 > ADD > LACTATED RINGER'S IN PLASTIC CONTAINER
 > ADD > AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
 328MG/100ML; 600MG/100ML;
 310MG/100ML N 19367

INJECTABLE; INJECTION

> ADD > POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND
 > ADD > LACTATED RINGER'S IN PLASTIC CONTAINER
 > ADD > AP TRAVENOL LABS 20MG/100ML; 5GM/100ML;
 105MG/100ML; 600MG/100ML;
 310MG/100ML N 19367

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-29)

INJECTABLE; INJECTION

> DLT > /PLASMA-LYTE IN PLASTIC CONTAINER/
 > ADD > PLASMA-LYTE R IN PLASTIC CONTAINER

CALCIUM GLUCEPATE (PAGE 3-30)

INJECTABLE; INJECTION

/AP/ CALCIUM GLUCEPATE
 /INTL MEDICATION SYS//Eq 90MG CALCIUM/ML/ /N 87455/

CAPTOPRIL (PAGE 3-31)

TABLET; ORAL

CAPOTEN
 ER SQUIBB AND SONS 12.5MGW N18343

CAPTOPRIL; HYDROCHLOROTHIAZIDE (PAGE 3-31)

TABLET; ORAL

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

CARBACHOL (PAGE 3-31)

/SOLUTION/DROPS; OPHTHALMIC/
 INJECTABLE; INJECTION

9

CHLORPROPAMIDE (PAGE 3-42)

TABLET; ORAL

CHLORPROPAMIDE

AB	BARR LABORATORIES	100MG	N 88812
AB		250MG	N 88813
AB	CHELSEA LABORATORIES	100MG	N 88865
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
> ADD >	SIDMAK LABORATORIES	100MG	N 88921
> ADD >		250MG	N 88922
AB	SUPERPHARM	100MG	N 88694
AB		250MG	N 88695
AB	ZENITH LABORATORIES	100MG	N 88840
AB	<u>GLUCANTIDE</u>		
AB	LEMMON	250MG	N 88641

CHYMOPAPAIN (PAGE 3-43)

INJECTABLE; INJECTION

CHYMOTACTIN

SMITH LABORATORIES	4,000 UNITS/VIAL	N 18663
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CISPLATIN (PAGE 3-44)

INJECTABLE; INJECTION

PLATINOL

BRISTOL LABS/B-N	10MG/ML	N 18857
	50MG/VIAL	N 18857

PLATINOL-AQ		
BRISTOL LABS/B-N	0.5MG/ML	N 18057

CLONIPHENE CITRATE (PAGE 3-45)

TABLET; ORAL

CLONID

BP/	MERRELL DOW/DOW CHEM	50MG	N 16131
AB			N 16131
BP/	<u>CLONIPHENE CITRATE</u>		
AB	PLANTEX/IKAPHARM	50MG	N 18361

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

CLOTIMAZOLE (PAGE 3-45)

TABLET; VAGINAL

MYCELEX-G

HILES PHARMS/HILES	500MG	N 19069
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CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-46)

SYRUP; ORAL

PHENERGAN VO W/ CODEINE

AA	WYETH LABS/ANHO	10MG/5ML; 5MG/5ML; 6.25MG/5ML	N 88306
AA	PROMETH VO W/ CODEINE		
AA	NATL PHARM MFG/BARRE	10MG/5ML; 5MG/5ML; 6.25MG/5ML	N 88764
AA	PROMETHAZINE VO W/ CODEINE		
AA	BAY LABORATORIES	10MG/5ML; 5MG/5ML; 6.25MG/5ML	N 88896

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-46)

SYRUP; ORAL

PHENERGAN W/ CODEINE

AA	WYETH LABS/ANHO	10MG/5ML; 6.25MG/5ML	N 88306
AA	PROMETH W/ CODEINE		
AA	NATL PHARM MFG/BARRE	10MG/5ML; 6.25MG/5ML	N 88763
AA	PROMETHAZINE W/ CODEINE		
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
AA	<u>PSEUDODINE Q</u>		
AA	BAY LABORATORIES	10MG/5ML; 30MG/5ML; 1.25MG/5ML	N 88833
AA	<u>TRIACIN-Q</u>		
AA	NATL PHARM MFG/BARRE	10MG/5ML; 30MG/5ML; 1.25MG/5ML	N 88704

DESERPIDINE; METHYLCLOTHIAZIDE (PAGE 3-52)

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE (PAGE 3-56)

SOLUTION/DROPS; OPHTHALMIC			
AT	NEODECADRON MS&D/MERCK	EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML	N 50322
AT	NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE PHARMAFAIR	EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML	N 62539

/DEXBROPHENRANINE 'MALEATES' 'PSEUDOPHEDRINE' SULFATE/ (PAGE 3-56)

/TABLETS: ORAL/
/DISOPHROL/
/SCHERING/ /2MG;60MG/
/N 12334/

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-57)

SYRUP; ORAL			
AA	PHENERGAN W/ DEXTROMETHORPHAN MYETH LABS/AMHO	15MG/5ML; 6.25MG/5ML	N 11265
AA	PROMETH W/ DEXTROMETHORPHAN NATL PHARM MFG/BARRE	15MG/5ML; 6.25MG/5ML	N 88762
AA	PROMETHAZINE DM BAY LABORATORIES	15MG/5ML; 6.25MG/5ML	N 88864

DEXTROSE (PAGE 3-57)

INJECTABLE; INJECTION			
AP	DEXTROSE 30% IN PLASTIC CONTAINER ABBOTT LABORATORIES	30GM/100ML	N 19345
AP	TRAVENOL LABS	30GM/100ML	N 17521
	DEXTROSE 30.5% IN PLASTIC CONTAINER ABBOTT LABORATORIES	30.5GM/100ML	N 18923
AP	DEXTROSE 60% IN PLASTIC CONTAINER ABBOTT LABORATORIES	60GM/100ML	N 19346

DEXTROSE; HEPARIN SODIUM (PAGE 3-58)

INJECTABLE; INJECTION			
AP	HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% ABBOTT LABORATORIES	5GM/100ML; 10,000 UNITS/100ML	N 18911
AP	HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER ABBOTT LABORATORIES	5GM/100ML; 10,000 UNITS/100ML	N 19339
AP	HEPARIN SODIUM 1000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER AM MCGAW/AM HOSP	5GM/100ML; 200 UNITS/100ML	N 19130
	HEPARIN SODIUM 12,500 UNITS IN DEXTROSE 5% ABBOTT LABORATORIES	5GM/100ML; 5,000 UNITS/100ML	N 18911
AP	HEPARIN SODIUM 12,500 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER ABBOTT LABORATORIES	5GM/100ML; 5,000 UNITS/100ML	N 19339

DEXTROSE; HEPARIN SODIUM (PAGE 3-58)

INJECTABLE; INJECTION			
AP	HEPARIN SODIUM 2000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER AM MCGAW/AM HOSP	5GM/100ML; 200 UNITS/100ML	N 19130
AP	HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% ABBOTT LABORATORIES	5GM/100ML; 10,000 UNITS/100ML	N 18911
AP	HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER ABBOTT LABORATORIES	5GM/100ML; 5,000 UNITS/100ML	N 19339
AP	HEPARIN SODIUM 25000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER AM MCGAW/AM HOSP	5GM/100ML; 5,000 UNITS/100ML	N 19134
	HEPARIN SODIUM 5000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER AM MCGAW/AM HOSP	5GM/100ML; 1,000 UNITS/100ML	N 19130

DEXTROSE; LIDOCAINE HYDROCHLORIDE (PAGE 3-58)

INJECTABLE; INJECTION			
> ADD > AP	LIDOCAINE HCL W/ DEXTROSE ABBOTT LABORATORIES	7.5%; 5%	N 83914
> DLT >	XILOCAINE HCL W/ DEXTROSE		
> ADD >	XILOCAINE W/ DEXTROSE ASTRA PHARM PRODS	7.5%; 1.5%	N 16297
> ADD > AP	XILOCAINE W/ GLUCOSE ASTRA PHARM PRODS	7.5%; 5%	N 10496

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

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

DEXTROSE; OXYTOCIN (PAGE 3-59)

INJECTABLE; INJECTION			
AP	OXYTOCIN 10 USP UNITS IN DEXTROSE 5% ABBOTT LABORATORIES	5GM/100ML; 1 USP UNIT/100ML	N 19185
AP	OXYTOCIN 20 USP UNITS IN DEXTROSE 5% ABBOTT LABORATORIES	5GM/100ML; 2 USP UNITS/100ML	N 19185
AP	OXYTOCIN 20 USP UNITS IN DEXTROSE 5% ABBOTT LABORATORIES	5GM/100ML; 2 USP UNITS/100ML	N 19185
AP	OXYTOCIN 5 USP UNITS IN DEXTROSE 5% ABBOTT LABORATORIES	5GM/100ML; 1 USP UNIT/100ML	N 19185

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UNIVERSITY OF MICHIGAN

INJECTABLE: INJECTION
 TRAVENOL LABS
 500MG/100ML: 40MG/100ML
 N 18649
 500MG/100ML: 80MG/100ML
 N 18649
 500MG/100ML: 160MG/100ML
 N 18649
 500MG/100ML: 200MG/100ML
 N 18649
 500MG/100ML: 400MG/100ML
 N 18649
 THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER
 500MG/100ML: 40MG/100ML
 N 19083
 500MG/100ML: 80MG/100ML
 N 19083
 500MG/100ML: 160MG/100ML
 N 19083
 500MG/100ML: 200MG/100ML
 N 19083
 500MG/100ML: 400MG/100ML
 N 19083
 THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER
 500MG/100ML: 40MG/100ML
 N 19211
 500MG/100ML: 80MG/100ML
 N 19211
 500MG/100ML: 160MG/100ML
 N 19211
 500MG/100ML: 200MG/100ML
 N 19211
 500MG/100ML: 400MG/100ML
 N 19211
 AM MCGAM/AM HOSP
 N 19083
 THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER
 500MG/100ML: 80MG/100ML
 N 19083
 500MG/100ML: 160MG/100ML
 N 19083
 500MG/100ML: 200MG/100ML
 N 19083
 500MG/100ML: 400MG/100ML
 N 19083
 AM MCGAM/AM HOSP
 N 19212
 THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER
 500MG/100ML: 200MG/100ML
 N 19212
 500MG/100ML: 400MG/100ML
 N 19212
 AM MCGAM/AM HOSP
 N 19212

DEXTROSE: THEOPHYLLINE (PAGE 3-62)
 TRAVENOL LABS
 500MG/100ML: 150MG/100ML
 N 19308
 500MG/100ML: 300MG/100ML
 N 19308
 500MG/100ML: 400MG/100ML
 N 19308
 500MG/100ML: 800MG/100ML
 N 19308
 500MG/100ML: 1600MG/100ML
 N 19308
 500MG/100ML: 3200MG/100ML
 N 19308
 500MG/100ML: 6400MG/100ML
 N 19308
 500MG/100ML: 12800MG/100ML
 N 19308
 500MG/100ML: 25600MG/100ML
 N 19308
 500MG/100ML: 51200MG/100ML
 N 19308
 500MG/100ML: 102400MG/100ML
 N 19308
 500MG/100ML: 204800MG/100ML
 N 19308
 500MG/100ML: 409600MG/100ML
 N 19308
 500MG/100ML: 819200MG/100ML
 N 19308
 500MG/100ML: 1638400MG/100ML
 N 19308
 500MG/100ML: 3276800MG/100ML
 N 19308
 500MG/100ML: 6553600MG/100ML
 N 19308
 500MG/100ML: 13107200MG/100ML
 N 19308
 500MG/100ML: 26214400MG/100ML
 N 19308
 500MG/100ML: 52428800MG/100ML
 N 19308
 500MG/100ML: 104857600MG/100ML
 N 19308
 500MG/100ML: 209715200MG/100ML
 N 19308
 500MG/100ML: 419430400MG/100ML
 N 19308
 500MG/100ML: 838860800MG/100ML
 N 19308
 500MG/100ML: 1677721600MG/100ML
 N 19308
 500MG/100ML: 3355443200MG/100ML
 N 19308
 500MG/100ML: 6710886400MG/100ML
 N 19308
 500MG/100ML: 13421772800MG/100ML
 N 19308
 500MG/100ML: 26843545600MG/100ML
 N 19308
 500MG/100ML: 53687091200MG/100ML
 N 19308
 500MG/100ML: 107374182400MG/100ML
 N 19308
 500MG/100ML: 214748364800MG/100ML
 N 19308
 500MG/100ML: 429496729600MG/100ML
 N 19308
 500MG/100ML: 858993459200MG/100ML
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 500MG/100ML: 1717986918400MG/100ML
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 500MG/100ML: 54975581388800MG/100ML
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 500MG/100ML: 219902325555200MG/100ML
 N 19308
 500MG/100ML: 439804651110400MG/100ML
 N 19308
 500MG/100ML: 879609302220800MG/100ML
 N 19308
 500MG/100ML: 1759218604441600MG/100ML
 N 19308
 500MG/100ML: 3518437208883200MG/100ML
 N 19308
 500MG/100ML: 7036874417766400MG/100ML
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 500MG/100ML: 28147497671065600MG/100ML
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 500MG/100ML: 56294995342131200MG/100ML
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 500MG/100ML: 16615349947311448411297588253504307200MG/100ML
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 N 19308
 500MG/100ML: 15324955408658888583583470400993951490989473773773673600MG/100ML
 N 19308
 500MG/100ML: 3064991081731777716

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

DISOPYRAMIDE PHOSPHATE (PAGE 3-68)CAPSULE; ORALDISOPYRAMIDE PHOSPHATE

AB BIOCRAFT LABS EQ 100MG BASE N 70101
AB EQ 150MG BASE N 70102
AB MORPACE
AB SEARLE PHARMS EQ 100MG BASE N 17447
AB EQ 150MG BASE N 17447

DISULFIRAM (PAGE 3-68)TABLET; ORALDISULFIRAM

BX PAR PHARMACEUTICAL 250MG N 88792
BX 500MG N 88793

DIVALPROEX SODIUM (PAGE 3-69)TABLET, ENTERIC COATED; ORALDEPAKOTE

ABBOTT LABORATORIES EQ 125MG BASE N 18723

DOPAMINE HYDROCHLORIDE (PAGE 3-69)INJECTABLE; INJECTIONDOPAMINE HCL

AP LYPHOMED 40MG/ML N 70058
AP 80MG/ML N 70059

DOXYCYCLINE HYCLATE (PAGE 3-70)CAPSULE; ORALDOXY-LEMMON

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

DOXYCYCLINE HYCLATE (PAGE 3-70)TABLET; ORALDOXY-LEMMON

AB LEMMON EQ 100MG BASE N 62581
AB DOXYCYCLINE HYCLATE
AB SUPERPHARM EQ 100MG BASE N 62494
AB ZENITH LABORATORIES EQ 100MG BASE N 62505

DOXYLAMINE SUCCINATE (PAGE 3-70)TABLET; ORALDECAPRYN

AA MERRELL DOW/DOW CHEM 25MG N 06412
AA DOXYLAMINE SUCCINATE
AA QUANTUM PHARMICS 25MG N 88603

EPINEPHRINE BITARTRATE; LIDOCAINE HYDROCHLORIDE (PAGE 3-72)INJECTABLE; INJECTIONLIGNOSPAN FORTEDEPROCOLIGNOSPAN STANDARDDEPROCO

EQ 0.02MG BASE/ML; 2% N 88389
EQ 0.01MG BASE/ML; 2% N 88390

ERGOCALCIFEROL (PAGE 3-72)CAPSULE; ORALERTSOL

AA WINTHROP LABS/STERL 50,000 IU /N 03446/
AA WINTHROP-BRECH/STERL 50,000 IU N 03444

ERYTHROMYCIN (PAGE 3-73)OINTMENT; TOPICALAKNE-MYCINHERMAL PHARM LABS

2%

N 50584

SOLUTION; TOPICALSANSAC

AT OWEN LABS/DERM PRODS 2% N 62522

SWAB; TOPICALERYCETTEORTHO PHARMACEUTICAL

2%

N 50594

ERYTHROMYCIN ETHYLSUCCINATE (PAGE 3-74)SUSPENSION; ORALERYTHROMYCIN ETHYLSUCCINATE

AB PHARMAFAIR EQ 200MG BASE/5ML N 62559
AB EQ 400MG BASE/5ML N 62558

N 17031

> ADD > NORMICH EATON/P&G 400MG

N 16651

> ADD > ALLERGAN PHARMS 0.12%
> ADD > FHL
> ADD > SUSPENSION/DROPS: OPHTHALMIC
FLUOROMETHOLONE (PAGE 3-63)

ETIDRONATE DISODIUM (PAGE 3-61)

LOESTRIN 21 1.5/30

TABLET: ORAL-21
/LOESTRIN 1.5/30/

ETHINYL ESTRADIOL; MORETHINDRONE ACETATE (PAGE 3-79)

TABLET: ORAL-28
MYETH LABS/AMHO
0.03MG, 0.04MG, 0.03MG;
0.05MG, 0.075MG, 0.125MG;
N 19190

TABLET: ORAL-21
MYETH LABS/AMHO
0.03MG, 0.04MG, 0.03MG;
0.05MG, 0.075MG, 0.125MG;
N 19192

ETHINYL ESTRADIOL; LEVONORGESTREL (PAGE 3-76)

TABLET: ORAL-28
/DEULEN 1/50-28/

TABLET: ORAL-21
/DEULEN 1/50-21/

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE (PAGE 3-76)

TABLET: ORAL
BS ZENITH LABORATORIES 0.3MG
CONJUGATED ESTROGENS

ESTROGENS, CONJUGATED (PAGE 3-76)

AP
ERYTHROMYCIN LACTOBIONATE
EQ 500MG BASE/VIAL
N 50102

AP
ERYTHROMYCIN LACTOBIONATE
EQ 1GM BASE/VIAL
N 62563

AP
ELKINS-SINN/AMROBINS
EQ 500MG BASE/VIAL
N 62563

INJECTABLE: INJECTION

ERYTHROMYCIN LACTOBIONATE (PAGE 3-75)

FENTANYL CITRATE (PAGE 3-61)

INJECTABLE: INJECTION

FENTANYL CITRATE

AP ABBOTT LABORATORIES EQ 0.05MG BASE/ML

FLUNISOLIDE (PAGE 3-62)

AEROSOL: INHALATION

BRONALIDE

SYNTEX LABS/SYNTEX 0.025MG/INH

N 18340

FLUOCINOLONE ACETONIDE (PAGE 3-62)

CREAM: TOPICAL

FLUOCINOLONE ACETONIDE

AT BAY LABORATORIES

AT PHARMAFAIR

AT 0.012%

AT 0.025%

AT 0.012%

AT 0.025%

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FLUOROURACIL (PAGE 3-83)

INJECTABLE; INJECTION			
<u>FLUOROURACIL</u>			
AP	SOLOPAK LABORATORIES	50MG/ML	N 88766
AP		50MG/ML	N 88767

FUROSEMIDE (PAGE 3-86)

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

GENTAMICIN SULFATE (PAGE 3-86)

OINTMENT; TOPICAL			
<u>GENTAMICIN SULFATE</u>			
AT	E FOUGERA/BYK-GLON	EQ 1MG BASE/GM	N 62533
AT	PHARMADERM/BYK-GLON	EQ 1MG BASE/GM	N 62534

SOLUTION/DROPS; OPHTHALMIC			
<u>GENOPTIC</u>			
AT	ALLERGAN PHARMS	EQ 3MG BASE/ML	N 62452

GLUTETHIMIDE (PAGE 3-88)

TABLET; ORAL			
<u>GLUTETHIMIDE</u>			
AA	ZENTH LABORATORIES	500MG	N 83683

GONADOTROPIN, CHORIONIC (PAGE 3-89)

INJECTABLE; INJECTION			
<u>CHORIONIC GONADOTROPIN</u>			
AP	CARTER-GLOGAU LABS	15,000 UNITS/VIAL	N 17016
		2,000 UNITS/VIAL	N 17016
AP	LYPHOMED	15,000 UNITS/VIAL	N 17067

GUANETHIDINE MONOSULFATE (PAGE 3-90)

TABLET; ORAL			
<u>GUANETHIDINE MONOSULFATE</u>			
AB	BOLAR PHARMACEUTICAL	EQ 10MG SULFATE	N 86113
AB		EQ 25MG SULFATE	N 86114
	<u>ISMELIN</u>		
	CIBA/CIBA-GEIGY	10MG	N 12329
		25MG	N 12329
AB	CIBA/CIBA-GEIGY	EQ 10MG SULFATE	N 12329
AB		EQ 25MG SULFATE	N 12329

HALCINONIDE (PAGE 3-90)

CREAM; TOPICAL
/HALCINON/
HALOG-E

HEPARIN SODIUM (PAGE 3-91)

INJECTABLE; INJECTABLE			
<u>HEP-FLUSH 10</u>			
AP	LYPHOMED	10 UNITS/ML	N 17651
<u>HEPARIN LOCK FLUSH</u>			
AP	LYPHOMED	100 UNITS/ML	N 17651
AP	SOLOPAK LABORATORIES	10 UNITS/ML	N 88457
AP		10 UNITS/ML	N 88580
AP		100 UNITS/ML	N 88581
<u>HEPARIN SODIUM</u>			
AP	ELKINS-SINN/AHROBINS	40,000 UNITS/ML	N 17637
AP		40,000 UNITS/ML	N 17637
AP		250 UNITS/ML	N 17637

HEPARIN SODIUM; SODIUM CHLORIDE (PAGE 3-93)

INJECTABLE; INJECTION			
<u>HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.9%</u>			
	ABBOTT LABORATORIES	10,000 UNITS/100ML;	
		900MG/100ML	N 18911
<u>HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.45%</u>			
AP	ABBOTT LABORATORIES	10,000 UNITS/100ML;	
		450MG/100ML	N 18911
<u>HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.9%</u>			
AP	ABBOTT LABORATORIES	5,000 UNITS/100ML;	
		900MG/100ML	N 18911
<u>HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9%</u>			
AP	ABBOTT LABORATORIES	5,000 UNITS/100ML;	
		900MG/100ML	N 18911
<u>HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.45%</u>			
AP	ABBOTT LABORATORIES	100 UNITS/ML; 4.5MG/ML	N 18911

HEPARIN SODIUM; SODIUM CHLORIDE - IN PLASTIC (PAGE 3-93)

INJECTABLE; INJECTION			
<u>HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0.9%</u>			
AP	AM MCGAW/AM HOSP	200 UNITS/100ML; 900MG/100ML	N 19042
<u>HEPARIN SODIUM 2000 UNITS IN SODIUM CHLORIDE 0.9%</u>			
AP	AM MCGAW/AM HOSP	200 UNITS/100ML; 900MG/100ML	N 19042
<u>HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9%</u>			
AP	AM MCGAW/AM HOSP	5,000 UNITS/100ML;	
AP		900MG/100ML	N 19135
<u>HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9%</u>			
AP	ABBOTT LABORATORIES	1,000 UNITS/100ML; 900MG/100ML	N 18916
AP	AM MCGAW/AM HOSP	1,000 UNITS/100ML;	
		900MG/100ML	N 19042

HEXACHLOROPHENE (PAGE 3-94)

EMULSION; TOPICAL

TUBEX

XITRIUM LABS

32M

N 19055

TABLET; ORAL

SPIRONOLACTONE + HYDROCHLOROTHIAZIDE

ASCOT HOSP PHARMS

25MG:25MG

N 66025

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE (PAGE 3-96)

TABLET; ORAL

SPIRONOLACTONE + HYDROCHLOROTHIAZIDE

ASCOT HOSP PHARMS

25MG:25MG

N 66025

HYDROCHLOROTHIAZIDE; TIMOLOL MALEATE (PAGE 3-96)

TABLET; ORAL

/TIMOLOL/

TIMOLOL 10-25

HYDROCHLOROTHIAZIDE; TRIAMTERENE (PAGE 3-96)

TABLET; ORAL

MAXIDE

MYLAN PHARMS

50MG:75MG

N 19129

HYDROCHLOROTHIAZIDE (PAGE 3-99)

CREAM; TOPICAL

HYDROCHLOROTHIAZIDE

THAMES PHARMACAL

2.52M

N 66799

/AT/

HYTONE

DERMIX/RORER-ANCHER

/6.52/

N 66472

OINTMENT; TOPICAL

/AT/

HYTONE

DERMIX/RORER-ANCHER

/6.52/

N 66474

POWDER; FOR RX COMPOUNDING

M-CORT

/PARANEX LABORATORIES/

1002

/N 87834/

HYDROCHLOROTHIAZIDE ACETATE (PAGE 3-102)

/AEROSOL; TOPICAL/

/EPIFORM/

/NEEDACARPHICK PHARMS/

1212

/N 66457/

HYDROCHLOROTHIAZIDE ACETATE; PRADOXINE HYDROCHLORIDE (PAGE 3-103)

AEROSOL; TOPICAL

EPIFORM

NEEDACARPHICK PHARMS

1212

N 66457

TABLET; ORAL

HYDROFLUMETHIAZIDE

CHELSEA LABORATORIES

50MG

N 66328

HYDRALAZINE HYDROCHLORIDE (PAGE 3-95)

TABLET; ORAL

HYDRALAZINE HCL

AMIDE PHARMACEUTICAL

25MG

50MG

50MG

ASCOT HOSP PHARMS

50MG

50MG

BARR LABORATORIES

100MG

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N 66560

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HYDROFLUMETHIAZIDE; RESERPINE (PAGE 3-104)

TABLET; ORAL
RESERPINE AND HYDROFLUMETHIAZIDE
BP ZENITH LABORATORIES 50MG;0.125MG N 88932

HYDROXYZINE HYDROCHLORIDE (PAGE 3-105)

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

HYDROXYZINE PAMOATE (PAGE 3-106)

CAPSULE; ORAL
HY-PAM "25"
AB LEHMON EQ 25MG HCL N 88713

IBUPROFEN (PAGE 3-106)

TABLET; ORAL
IBUFEN
AB BOOTS PHARMACEUTICAL 400MG N 70083
AB 600MG N 70088
> ADD > AB 600MG N 70099

IMIPRAMINE HYDROCHLORIDE (PAGE 3-107)

TABLET; ORAL
SK-PRAMINE
/AB/ /SK&F LABORATORIES/ /10MG/ /N 18861/
/AB/ /SK&F LABORATORIES/ /25MG/ /N 18861/
/BP/ /SK&F LABORATORIES/ /50MG/ /N 18861/
AB SK&F LABORATORIES 10MG N 83827
AB 25MG N 83827
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

INDOMETHACIN (PAGE 3-108)

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

INDOMETHACIN SODIUM TRIHYDRATE (PAGE 3-108)

INJECTABLE; INJECTION
INDOCIN I.V.
MS&D/MERCK EQ 1MG BASE/VIAL N 18878

INDOHEPAPURATE SODIUM, I-123 (PAGE 3-109)

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

IOPANOTIC ACID (PAGE 3-109)

TABLET; ORAL
TELEPAQUE
> DLT > /WINTHROP LABS/STERL/500MG/ /N 08032/
> ADD > WINTHROP-BREON/STERL 500MG N 08032

ISOETHARINE MESYLATE (PAGE 3-110)

AEROSOL; INHALATION
BRONKOMETER
/BROWN LABS/STERLING/0.34MG/ /N 12339/
BN BROWN 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 18686

AT	SHAMPOO; TOPICAL LINDANE	12M	N 68191
AT	LOTION; TOPICAL LINDANE	12M	N 68190
LINDANE (PAGE 3-116)			
> ADD >	SOLUTION; TOPICAL LIDOGAINE HCL	42M	N 68803
> ADD >	SOLUTION; ORAL LIDOGAINE HCL	22M	N 68802
> DLT >	INJECTION ASTRA PHARM PRODS	1/21	N 10446/
LIDOCAINE HYDROCHLORIDE (PAGE 3-115)			
LIDOCAINE (PAGE 3-114)			
AP	AEROSOL; ORAL XYLOCAINE	102M	N 14394
AP	DEPRICO SCANDONEST L	0.05MG/ML; 22M	N 68386
LEVONORDEFFRIN; MEPIVACALINE HYDROCHLORIDE (PAGE 3-114)			
> ADD >	INJECTION TAP PHARMACEUTICALS	1MG/0.2ML	N 19010
> ADD >	INJECTION LUPRON		
> ADD >	LEUPROLIDE ACETATE (PAGE 3-113)		
AB	TABLET; ORAL NORADRENALINE	200MG	N 18687
AB	SCHERING	300MG	N 18687
AB	IRBAMATE	400MG	N 18687
AB	GLAXO	200MG	N 18716
AB		300MG	N 18716
AB		400MG	N 18716
LABETALOL HYDROCHLORIDE (PAGE 3-113)			
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE (PAGE 3-119)			
AP	SOLUTION; IRRIGATION PHYSIOLYTE IN PLASTIC CONTAINER	30MG/100ML; 37MG/100ML; 320MG/100ML	N 19024
AP	ABOTT LABORATORIES	30MG/100ML; 500MG/100ML	N 19024
AP	TRAVENOL LABS	30MG/100ML; 37MG/100ML; 360MG/100ML	N 19326
AP	SYNOVALYTE IN PLASTIC CONTAINER	526MG/100ML; 502MG/100ML	N 19326
MEDRYSONE (PAGE 3-122)			
SOLUTION/DROPS; OPHTHALMIC HMS			
ALLERGAN PHARMS			
12			
MEMOTROPINS (PAGE 3-122)			
> ADD >	INJECTION PERSONAL		
> ADD >	INJECTION SERONO LABS	150 IU/AMP	N 17646
MEPERIDINE HYDROCHLORIDE (PAGE 3-122)			
AP	INJECTION MEPERIDINE HCL	10MG/ML	N 68432
AP	ABOTT LABORATORIES	10MG/ML	N 68432
AP	INTL MEDICATION SYS	10MG/ML	N 68432
SYRUP; ORAL DEMEROL			
AA	MINITHROP LABS/STERL	50MG/5ML	N 05010
AA	MEPERIDINE HCL	50MG/5ML	N 05010
AA	ROXANE LABORATORIES	50MG/5ML	N 88744
TABLET; ORAL MEPERIDINE HCL			
AA	BAKR LABORATORIES	100MG	N 88640
MEPHENTERMINE SULFATE (PAGE 3-123)			
INJECTION	MYAMINE SULFATE /WETH. LABS/AMHO/ /15MG/ML/ /30MG/ML/ EQ 15MG BASE/ML EQ 30MG BASE/ML		N 06248 N 06248 N 06248 N 06248 N 06248
AT	SHAMPOO; TOPICAL LINDANE	12M	N 68191

MEPIVACAINE HYDROCHLORIDE (PAGE 3-123)

INJECTABLE; INJECTION
CARBOCATINE
 AP BREON LABS/STERLING 2% N 12250
 AP MEPIVACAINE HCL
 AP CARTER-GLOGAU LABS 1% N 88769
 AP 2% N 88770
POLOCAINE
 AP ASTRA PHARM PRODS 3% N 88653
SCANDONEST PLAIN
 AP DEPROCO 3% N 88387

MEPROBAMATE (PAGE 3-123)

TABLET; ORAL
MEPROBAMATE
 /AA/ /M. NAST/ 200MG/ N 86229/
 /AA/ /400MG/ N 86229/

METHICILLIN SODIUM (PAGE 3-127)

INJECTABLE; INJECTION
CELGENIN
 /AP/ /BEECHAM LABS/BEECHAM/ EQ 900MG BASE/VIAL/ N 61493/
 /AP/ /EQ 3.6GM BASE/VIAL/ N 61493/
 /AP/ /EQ 5.4GM BASE/VIAL/ N 61493/
 /AP/ /EQ 1.8GM BASE/VIAL/ N 61493/
 /AP/ /EQ 9GM BASE/VIAL/ N 61493/

METHOTREXATE SODIUM (PAGE 3-128)

INJECTABLE; INJECTION
MEKATE
 BRISTOL LABS/B-M EQ 250MG BASE/VIAL N 86358
MEKATE-AG
 AP BRISTOL CARIB/B-M/PR EQ 25MG BASE/ML N 88760

METHYLCLOTHIAZIDE (PAGE 3-129)

TABLET; ORAL
METHYLCLOTHIAZIDE
 AB CHELSEA LABORATORIES 2.5MG N 88750
 AB 5MG N 88724
 AB COLMED LABORATORIES 5MG N 88745

METHYLDOPA (PAGE 3-130)

TABLET; ORAL
METHYLDOPA
 > ADD > AB MYLAN PHARMS 250MG N 70075
 > ADD > AB 500MG N 70076

METHYLPREDNISOLONE SODIUM SUCCINATE (PAGE 3-131)

INJECTABLE; INJECTION
SOLU-MEDROL
 UPJOHN EQ 2GM BASE/VIAL N 11856

METRONIDAZOLE (PAGE 3-133)

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

TABLET; ORAL

METRONIDAZOLE
 AB HALSEY DRUG 250MG N 70021
 AB PAR PHARMACEUTICAL 250MG N 70040
 AB 500MG N 70039
 AB SIDMAK LABORATORIES 250MG N 70027
 AB 500MG N 70033
 AB SUPERPHARM 250MG N 70008
 AB 500MG N 70009
METRYL
 AB LEMMON 250MG N 70035
METRYL 500
 AB LEMMON 500MG N 70044
SATRIG
 AB SAVAGE LABS/ALTANA 250MG N 70029

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
NALLPEN
 AP BEECHAM LABS/BEECHAM EQ 10GM BASE/VIAL N 61999

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE
(PAGE 3-153)

SYRUP; ORAL
PHENERGAN VQ
 AA WYETH LABS/AMHO 5MG/5ML;6.25MG/5ML N 88604
PROMETH VQ PLAIN
 AA NATL PHARM MFG/BARRE 5MG/5ML;6.25MG/5ML N 88761
PROMETHAZINE VQ PLAIN
 AA BAY LABORATORIES 5MG/5ML;6.25MG/5ML N 88897

PHENYTOIN SODIUM (PAGE 3-153)

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

PHENYTOIN SODIUM, EXTENDED (PAGE 3-153)

CAPSULE; ORAL
DIANTIN
 AB PARKE-DAVIS/M-L 100MG N 84349
EXTENDED PHENYTOIN SODIUM
 AB BOLAR PHARMACEUTICAL 100MG N 88711

PILOCARPINE HYDROCHLORIDE (PAGE 3-154)

GEL; OPHTHALMIC
 PILOPINE HS
 ALCON LABORATORIES 4% N 18796

PINDOLOL (PAGE 3-154)

TABLET; ORAL
 VISKEN
 >_DLT_> SANDOZ PHARMS/SANDOZ/15mg/ /N'18285/

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; N 18983
 11.36GM/PACKET;
 227.1GM/PACKET;2.82GM/PACKET;
 6.36GM/PACKET;5.53GM/PACKET; N 18983
 21.5GM/PACKET;
 360GM/PACKET;4.47GM/PACKET;
 10.08GM/PACKET;8.76GM/PACKET;
 34.0GM/PACKET; N 18983

POTASSIUM CHLORIDE (PAGE 3-156)INJECTABLE; INJECTION
POTASSIUM CHLORIDE IN PLASTIC CONTAINER

AP INVENEX LABS/LIFE 2MEQ/ML N 88901
 AP 2MEQ/ML N 88908

>_ADD_> POTASSIUM CLAVULANATE; TICARCILLIN DISODIUM (PAGE 3-158)

>_ADD_> INJECTABLE; INJECTION
 >_ADD_> TIMENTIN
 >_ADD_> BEECHAM LABS/BEECHAM EQ 100MG ACID/VIAL;
 >_ADD_> EQ 3GM BASE/VIAL N 50590
 >_ADD_> EQ 200MG ACID/VIAL;
 >_ADD_> EQ 3GM BASE/VIAL N 50590

PREDNISOLONE (PAGE 3-159)

TABLET; ORAL
 PREDNISOLONE
 BX SUPERPHARM 5MG N 88892

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
 PREDNISONE INTENSOL
 ROXANE LABORATORIES 5MG/ML N 88810

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

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-163)CAPSULE; ORAL
PROCAINAMIDE HCL

>_ADD_> AB ROXANE LABORATORIES 250MG N 88989
 >_ADD_> AB 500MG N 88990

RITODRINE HYDROCHLORIDE (PAGE 3-173)

INJECTABLE; INJECTION			
/AB/	<u>RITODRINE HCL</u>	/10MG/ML/	/N 18280/
	YUTOPAR		
/AF/	ASTRA PHARM PRODS	10MG/ML	N 18580
		15MG/ML	N 18580
TABLET; ORAL			
/AB/	<u>RITODRINE HCL</u>	/10MG/	/N 18280/
	YUTOPAR		
/AF/	ASTRA PHARM PRODS	10MG	N 18555

SAFFLOWER OIL; SOYBEAN OIL (PAGE 3-174)

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

SCOPOLAMINE (PAGE 3-174)

FILM, CONTROLLED RELEASE; PERCUTANEOUS			
/AB/	<u>TRANSDERM-SCOP</u>	/1.5MG/	/N 17874/
	TRANSDERM-SCOP		
	CIBA/CIBA-GEIGY	1.5MG	N 17874

SODIUM CHLORIDE (PAGE 3-176)

INJECTABLE; INJECTION			
<u>BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>			
AP	ABBOTT LABORATORIES	9MG/ML	N 18800
AP	INVENEX LABS/LIFE	9MG/MLM	N 88909
AP		9MG/MLM	N 88911
/AB/	<u>SODIUM CHLORIDE IN PLASTIC CONTAINER</u>		/N 17464/
	AM HCGAN/AM HOSP	/900MG/100ML/	
<u>SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>			
AP	AM HCGAN/AM HOSP	900MG/100ML	N 17464
AP	INVENEX LABS/LIFE	9MG/MLM	N 88912

SODIUM LACTATE (PAGE 3-178)

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

SODIUM NITROPRUSSIDE (PAGE 3-178)

INJECTABLE; INJECTION			
<u>SODIUM NITROPRUSSIDE</u>			
AP	LYPHOMED	50MG/VIALM	N 70031

SODIUM POLYSTYRENE SULFONATE (PAGE 3-179)

POWDER; ORAL, RECTAL			
<u>KAYEXALATE</u>			
AA	ERECN LABS/STERLING	453.6GM/BOT	N 11287
<u>SODIUM POLYSTYRENE SULFONATE</u>			
AA	BAY LABORATORIES	453.6GM/BOTM	N 88786
SUSPENSION; ORAL, RECTAL			
<u>SODIUM POLYSTYRENE SULFONATE</u>			
AA	BAY LABORATORIES	15GM/60MLM	N 88717

SOYBEAN OIL (PAGE 3-180)

INJECTABLE; INJECTION			
<u>LIPOSYN III 10%</u>			
AP	ABBOTT LABORATORIES	10%M	N 18969
<u>LIPOSYN III 20%</u>			
AP	ABBOTT LABORATORIES	20%M	N 18970

SUCCINYLCHOLINE CHLORIDE (PAGE 3-181)

INJECTABLE; INJECTION			
<u>SUCCINYLCHOLINE CHLORIDE</u>			
/AP/	<u>TRAVENOL LABS</u>	/500MG/VIAL/	/N 88263/
/AP/		/1GM/VIAL/	/N 88263/

SULFABENZAMIDE; SULFACETAMIDE; SULFATHIAZOLE (PAGE 3-181)

TABLET; VAGINAL			
<u>SULTRIN</u>			
AT	ORTHO PHARMACEUTICAL	184MG;143.75MG;172.5MG	N 05794
<u>TRIPLE SULEA</u>			
AT	E FOUGERA/ALTANA	184MG;143.75MG;172.5MG	N 88463
AT	PHARMADERM/ALTANA	184MG;143.75MG;172.5MG	N 88462

SULFACETAMIDE SODIUM (PAGE 3-181)

SOLUTION/DROPS; OPHTHALMIC	
<u>SULFACETAMIDE SODIUM</u>	
<u>SULFATR 10</u>	

THEOPHYLLINE (PAGE 3-190)

CAPSULE, CONTROLLED RELEASE; ORAL

BC	THEOCLEAR L.A.-130	130MG	N 86569
BC	CENTRAL PHARMS	125MG	N 86480
BC	THEOPHYL-SR	250MG	N 86471
BC	MCNEIL PHARM	125MG	N 86654
BC	THEOPHYLLINE	250MG	N 86689
BC	CENTRAL PHARMS	125MG	N 87010
BC	THEOVENT	125MG	N 87910
BC	SCHERING	250MG	

TABLET, CONTROLLED RELEASE; ORAL

TABLET, CONTROLLED RELEASE, ORAL			
<u>THEOCHRON</u>			
BC	FOREST LABORATORIES	100MG	N 88320
BC		200MG	N 88321
<u>THEOPHYLLINE</u>			
BC	FOREST LABORATORIES	100MG	N 88503
BC		200MG	N 88504
AB		300MG	N 88505

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	
> ADD >	AB	DANBURY PHARMACAL	200MG	N 88872
AB	ROXANE LABORATORIES	100MG	N 89048	

TOBRAMYCIN (PAGE 3-194)

SOLUTION/DROPS; OPHTHALMIC

TOBREX

ALCON LABORATORIES	0.3%	N 62535
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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
AB	TOLXNASE	100MG	N 15500
AB	UPJOHN	250MG	N 15500
AB		500MG	N 15500

TOLAZOLINE HYDROCHLORIDE (PAGE 3-194)

INJECTABLE; INJECTION

PRISCOLINE

CIBA/CIBA-GEIGY	25MG/ML	N 06403
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TOLBUTAMIDE (PAGE 3-194)

TABLET; ORAL

TOLBUTAMIDE

AB	SUPERPHARM	500MG	N 88893
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TOLMETIN SODIUM (PAGE 3-194)

CAPSULE; ORAL

TOLECTIN DS

/MCNEIL LABORATORIES//EQ 400MG BASE/		/N 18084/
MCNEIL PHARM	EQ 400MG BASE	N 18084

TABLET; ORAL

TOLECTIN

/MCNEIL LABORATORIES//EQ 200MG BASE/		/N 17628/
MCNEIL PHARM	EQ 200MG BASE	N 17628

TRAZODONE HYDROCHLORIDE (PAGE 3-194)

TABLET; ORAL

DESYREL

HEAD JOHNSON/B-M	150MG	N 18207
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> ADD >

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

/ASCORBIC ACID; BIOTIN; CYANCOBALAMIN; DEXPANTHENE;
 ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTOADIONE;
 PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM;
 THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E (PAGE AD2)

/INJECTABLE; INJECTION/

/N.V.I. - PEDIATRIC/

/DEV. PHARMACEUTICAL/

/50MG/VIAL; 0.02MG/VIAL; 0.001MG/VIAL/

/5MG/VIAL; 0.01MG/VIAL; 0.0005MG/VIAL/

/17MG/VIAL; 0.2MG/VIAL/

/EQ 1MG BASE/VIAL; 1.4MG/VIAL/

/EQ 1.2MG BASE/VIAL; 0.7MG/VIAL/

/7MG/VIAL/

/N 18920/

/ASCORBIC ACID; BIOTIN; CYANCOBALAMIN; DEXPANTHENE;
 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/

/DEV. 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; CYANCOBALAMIN; DEXPANTHENE;
 ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE;
 HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE; VITAMIN
 A (PAGE AD2)

(SEE SPECIAL NOTE B.)

/INJECTABLE; INJECTION/

/N.V. PLUS/

/ASCOT. HOSP. PHARMS/

/10MG/ML; 0.006MG/ML; 0.005MG/ML/

/1.5MG/ML; 20. IU/ML; 0.04MG/ML; 4MG/ML/

/0.4MG/ML; 0.30MG/ML; 0.3MG/ML/

/330. IU/ML/

/N 18939/

/ASCORBIC ACID; BIOTIN; CYANCOBALAMIN; DEXPANTHENE; FOLIC
 ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN;
 THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN B; VITAMIN E
 (PAGE AD2)

(SEE SPECIAL NOTE B.)

/INJECTABLE; INJECTION/

/N.V.C. - 983/

/LYPHONED/

/20MG/ML; 0.02MG/ML; 0.001MG/ML/

/5MG/ML; 0.005MG/ML; 0.0005MG/ML/

/0.72MG/ML; 0.6MG/ML; 660. IU/ML/

/40. IU/ML; 12. IU/ML/

/N 18940/

/ASCORBIC ACID; BIOTIN; CYANCOBALAMIN; FOLIC ACID;
 NIACINAMIDE; PANTHENE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN;
 THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN B; VITAMIN E
 (PAGE AD2)

(SEE SPECIAL NOTE B.)

/INJECTABLE; INJECTION/

/MULTIVITAMIN ADDITIVE/

/ABBOTT LABORATORIES/

/100MG/SHL; 0.06MG/SHL; 0.005MG/SHL/

/0.4MG/SHL; 0.01MG/SHL; 15MG/SHL/

/4.86MG/SHL; 4.33MG/SHL; 3.35MG/SHL/

/3300. IU/SHL; 200. IU/SHL/

/10. IU/SHL/

/N 18933/

/ASCORBIC ACID; BIOTIN; DEXPANTHENE; NIACINAMIDE; PYRIDOXINE;
 HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE (PAGE AD2)

(SEE SPECIAL NOTE B.)

/INJECTABLE; INJECTION/

/BEROCCA C/

/HOFFMAN-LA ROCHE/

/50MG/ML; 0.1MG/ML; 0.1MG/ML; 40MG/ML/

/10MG/ML; 5MG/ML; 5MG/ML/

/N 86071/

/BEROCCA C 500/

/HOFFMAN-LA ROCHE/

/125MG/ML; 10MG/ML; 10MG/ML; 40MG/ML/

/10MG/ML; 5MG/ML; 5MG/ML/

/N 86071/

CURRENT STATUS - INEFFECTIVE

/BENTYL N/ PHENOBARBITAL/ /MERRELL DOW/DOW/CHEN/
 /BICYCLOLINE 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

/CETACORT/ /OWEN LABS/DERRA PRODS/
 /HYDROCORTISONE/

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

/HC (HYDROCORTISONE)/ /C.A.M. PHARMACAL/
 /HYDROCORTISONE/

/HYDROCORTISONE/ /TOWNE PAULSEN/
 /HYDROCORTISONE/

/XILOTICIN/ /E.L. LILL/
 /ERYTHRONICIN/

/NEOSPORIN B/ /BURROUGHS WELLCOME/
 /BRANICIDIN; NEOTICIN SULFATE; POLYMYXIN B SULFATE/

/TERRA-CORTIL/ /PFIZER LABS/PFIZER/
 /HYDROCORTISONE; DEXTETRA CYCLINE HCL/

/NUTRACORT/ /OWEN LABS/DERRA PRODS/
 /HYDROCORTISONE/

/PRISCOLINE/ /CIBA/CIBA-GEIGY/
 /TOLAZOLINE HYDROCHLORIDE/

TUSS-ORNADE SK&F LABORATORIES
 CARAMIPHEN EDISYLATE; CHLORPHENIRAMINE MALEATE;
 ISOPROPANIDE 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 from January 1, 1982; 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 full 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 all active ingredients (including any ester or salt of the active ingredient) of 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.

- (2) A new drug application approved after September 24, 1984, for a drug product all active ingredients (including any ester or salt of the active ingredient) of which had 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 conducted or sponsored by the applicant or for which the applicant had a right of reference, and the investigations must have been essential to approval of the application. If these requirements are met, the approval of a subsequent ANDA or paper 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 applicant or to which the applicant had a right of reference. 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 a significant change made in a supplement may not be made effective for two years from September 24, 1984.

The Act required 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 (i.e., process or manufacturing) 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 products approved under sections 506 or 507 of the Federal Food, Drug and Cosmetic Act (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 biopharmaceutical 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 biopharmaceutical 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.

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 approved and 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, exclusivity information, and expiration dates are also included.

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

All products accepted and approved under Section 505 of the Act as NDAs by the Office of Biological Research and Review (OBR) will now be published in the ADPP (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, exclusivity information, and expiration dates are also included.

Patent and Exclusivity Information

It was originally planned that TABLE IV of Cumulative Supplement 2 to the ADPP 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 that claim the active ingredient or ingredients or the drug product (excluding process patents), or use patents for a particular indication or method of using the product. The Agency has concluded that formulation/composition patents should be added to the List.

A patent that claims a drug (as contrasted with one that claims a use) must refer to an approved drug product. To ensure that only appropriate patents are published, the Agency has an obligation to carefully screen the patent information that is submitted by the NDA holder. Therefore the Agency is asking all holders of approved applications and applicants with pending applications, whether or not they previously submitted information on composition or formulation patents, to submit such information with the following certification: "The undersigned certifies that the drug or formulation or composition of such drug claimed by the following patents is currently approved under section 505 of the Federal Food, Drug and Cosmetic Act." The certification must be signed by the patent holder or by the person responsible for the NDA submission. The Agency intends to publish this additional patent information in its next supplement to the List after the information with the above described certification is received. The Agency will continue its policy of not publishing process or chemical intermediate patents.

The Agency is required by the law to publish all use patents, even if the use has not been approved by the Agency. Therefore, the publication of a use patent in TABLE IV in no way confers Agency approval on or implies that the indication has been approved. TABLE IV contains patent numbers and expiration dates and, for drug products approved after 1981, 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 amend their applications, if patent information now appears in this list.

TABLES II-IV now identify all drugs which qualify under the new statute for periods of exclusivity. (See pages A-1 & A-2 of the Addendum for an explanation of exclusivity).

FDA has finished reviewing all patent and exclusivity information received initially from interested parties. The Agency believes TABLES II-IV now contain all appropriate patent and exclusivity information that the Agency regards as being covered by the new statute. This table will be updated monthly to include appropriate patent and exclusivity information. The exclusivity information column in TABLES II-IV designates the date on which the exclusivity ends and the basis for the exclusivity through the use of codes as explained on pages A-7 and A-8.

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.

DO TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMNS OF TABLES I-IV THE FOLLOWING ABBREVIATIONS HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THIS PAGE FOR AN EXPLANATION OF THE EXCLUSIVITY ABBREVIATIONS FOUND IN THE TABLES.

ABBREVIATIONS

NC	NEW COMBINATION
NCE	NEW CHEMICAL ENTITY
NDF	NEW DOSAGE FORM
NE	NEW ESTER OR SALT OF AN ACTIVE INGREDIENT
NP	NEW PRODUCT
NR	NEW ROUTE
PP	PARENTERAL IN PLASTIC CONTAINER
RTO	PRESCRIPTION TO OTC STATUS CHANGE
NS	NEW STRENGTH
D	NEW DOSING SCHEDULE (SEE REFERENCE, BELOW)
I	NEW INDICATION (SEE REFERENCE, BELOW)

REFERENCES

NEW DOSING SCHEDULE

D-1	ONCE A DAY APPLICATION
D-2	ONCE DAILY DOSING
D-3	SEVEN DAYS/SEVEN DAYS/SEVEN DAYS DOSING SCHEDULE
D-4	SEVEN DAYS/FOURTEEN DAYS DOSING SCHEDULE
D-5	TEN DAYS/ELEVEN DAYS DOSING SCHEDULE
D-6	SEVEN DAYS/NINE DAYS/FIVE DAYS DOSING SCHEDULE
D-7	BID DOSING
D-8	INTRAVENOUS, EPIDURAL AND INTRATHECAL DOSING

1-1	SEVERE HYPERTENSION IN PEDIATRICS AND NON-MALIGNANT HYPERTENSION
1-2	DYSMENORRHEA
1-3	TREATMENT OF TINEA VERSICOLOR
1-4	SYMPTOMATIC GASTROESOPHAGEAL REFLUX
1-5	NEPHROTOMOGRAPHY
1-6	CONTRAST ENHANCEMENT IN CRANIAL COMPUTED TOMOGRAPHY
1-7	VENOGRAPHY OF LOWER EXTREMITIES
1-8	WHOLE-BODY COMPUTED TOMOGRAPHY
1-9	GATED CARDIAC POOL IMAGING
1-10	POST-MYOCARDIAL INFARCTION
1-11	COLORRECTAL SURGERY
1-12	NAUSEA AND VOMITING ASSOCIATED WITH EMETOGENIC CANCER CHEMOTHERAPY
1-13	CISPLATIN INDUCED EMESIS
1-14	DIABETIC GASTROPARESIS
1-15	POST-MYOCARDIAL INFARCTION
1-16	ACROMEGALY
1-17	PITUITARY TUMORS
1-18	POSTMENOPAUSAL OSTEOPOROSIS
1-19	ANTIDOTE FOR ACETAMINOPHEN OVERDOSAGE
1-20	CONGESTIVE HEART FAILURE BID DOSAGE SCHEDULE
1-21	ACUTE OTITIS-MEDIA
1-22	EXERCISE INDUCED BRONCHOSPASMS
1-23	MI OR STROKE
1-24	COMBINED USE WITH NICOTINIC ACID TO LOWER CHOLESTEROL LEVEL
1-25	BLASTOMYCOSES DERMATITIDES
1-26	PEDIATRIC SUBARACHNOID VASCULAR
1-27	PETRIELLEDIUM BOYDII INFECTION
1-28	HEREDITARY ANGIOEDEMA
1-29	INTRACORONARY USE
1-30	PEDIATRIC USE
1-31	DIRECT ISOTOPIC CYSTOGRAPHY
1-32	POSTPARTUM HEMORRHAGE

INDICATIONS

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	AMINOPHYLLINE TABLET; ORAL 100MG 200MG	ASPIRIN; MEPROBAMATE TABLET; ORAL 325MG; 200MG
ACETAMINOPHEN; ASPIRIN; BUTALBITAL CAPSULE OR TABLET; ORAL 325MG; 325MG; 50MG	ASPIRIN; BUTALBITAL; CAPSULE OR TABLET; ORAL 325; 50MG 650; 50MG	ASPIRIN; METHOCARBAMOL TABLET; ORAL 325MG; 200MG
ACETAMINOPHEN; ASPIRIN; BUTALBITAL; CAFFEINE CAPSULE OR TABLET; ORAL 160-165MG; 160-165MG; 50MG; 40MG	ASPIRIN; BUTALBITAL, CAFFEINE CAPSULE OR TABLET; ORAL 325MG; 50MG; 40MG; 650MG; 50MG; 40MG;	CHLOROTHIAZIDE TABLET; ORAL 250MG
ACETAMINOPHEN; ASPIRIN; BUTALBITAL; CAFFEINE CAPSULE OR TABLET; ORAL 325MG; 325MG; 50MG; 40MG	ASPIRIN; CAFFEINE; CARISOPRODOL TABLET; ORAL 160MG; 32MG; 200MG	ESTROGENS, CONJUGATED; MEPROBAMATE TABLET; ORAL 0.4MG; 200MG 0.4MG; 400MG
ACETAMINOPHEN; BUTALBITAL CAPSULE OR TABLET; ORAL 325; 50MG 650; 50MG	ASPIRIN; CAFFEINE; CARISOPRODOL; CODEINE PHOSPHATE TABLET; ORAL 160MG; 32MG; 200MG; 16MG	HYDROXYZINE HYDROCHLORIDE TABLET; ORAL 10MG 25MG 50MG 100MG
ACETAMINOPHEN; BUTALBITAL; CAFFEINE CAPSULE OR TABLET; ORAL 325MG; 50MG; 40MG 650MG; 50MG; 40MG	ASPIRIN; CARISOPRODOL TABLET; ORAL 325MG; 200MG	
	ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE 325MG; 200MG; 10MG	

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

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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		NP 09-24-86
ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE 160MG; 40MG	GAVISCON-2 (TABLET, CHEWABLE; ORAL)	MARION LABORATORIES	18-685 12-09-83		NP 09-24-86
BROMPHENIRAMINE MALEATE 8MG	DIMETANE (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	10-799 06-10-83		RTO 09-24-86
BROMPHENIRAMINE MALEATE 12MG	DIMETANE (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	10-799 06-10-83		RTO 09-24-86
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		

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

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ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
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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	TELORIN	(CAPSULE, CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	17-369	05-11-78			
CHLORPHENIRAMINE MALEATE	12MG	TELORIN	(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			
CHLORPHENIRAMINE MALEATE	4MG; 25MG	DEMAZIN	(TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-556	05-14-84			NS
CHLORPHENIRAMINE MALEATE	8MG; 75MG	CONTAC	(CAPSULE, CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	18-099	02-04-80			
CHLORPHENIRAMINE MALEATE	8MG; 75MG	COLD CAPSULE V	(CAPSULE, CONTROLLED RELEASE; ORAL)	DM GRAHAM LABS	18-794	04-23-85			

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

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 8MG; 75MG	PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE (CAPSULE, CONTROLLED RELEASE; ORAL)	CENTRAL PHARMS	18-809 05-07-84		
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 12MG; 75MG	TRIAMINIC-12 (TABLET, CONTROLLED RELEASE; ORAL)	DORSEY LABS/SANDOZ	18-115 07-23-81		
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 12MG; 75MG	COLD CAPSULE IV (CAPSULE, CONTROLLED RELEASE; ORAL)	DM GRAHAM LABS	18-793 04-25-85		
CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE 8MG; 120MG	CHLOR-TRIMETON (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-397 03-31-81		
CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE 8MG; 120MG	PSEUDOEPHEDRINE HCL/ CHLORPHENIRAMINE MALEATE (CAPSULE, CONTROLLED RELEASE; ORAL)	DM GRAHAM LABS	18-844 03-20-85		
CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE 12MG; 120MG	PSEUDOEPHEDRINE HCL/ CHLORPHENIRAMINE MALEATE (CAPSULE, CONTROLLED RELEASE; ORAL)	DM GRAHAM LABS	18-843 03-18-85		
CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE 12MG; 120MG	CODIMAL-L.A. 12 (CAPSULE, CONTROLLED RELEASE; ORAL)	CENTRAL PHARMS	18-935 04-15-85		
CHLORPHENIRAMINE POLISTIREX; PHENYLPROPANOLAMINE POLISTIREX EQ 4MG MALEATE/5ML; EQ 37.5MG HCL/5ML	CORSYM (SYRUP; ORAL)	PENNWALT PHARM	18-050 01-04-84		NDF 09-24-86

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 NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE 2MG; 60MG		DISOPHROL	(TABLET; ORAL)	SCHERING	12-394	06-03-60		09-24-86	RTD
DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE 6MG; 120MG		DRIXORAL (TABLET, CONTROLLED RELEASE; ORAL)		SCHERING	13-483	09-13-82		09-24-86	RTD
DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE 6MG; 120MG		DISOPHROL (TABLET, CONTROLLED RELEASE; ORAL)		SCHERING	13-483	09-13-82		09-24-86	RTD
DEXTROMETHORPHAN RESIN COMPLEX EQ 30MG HBR/SHL		DELSYM (SUSPENSION, CONTROLLED RELEASE; ORAL)		PENNMALT PHARM	18-658	10-08-82		09-24-86	MDF
DIPHENHYDRAMINE HYDROCHLORIDE 12.5MG/SHL		BENLIN (SYRUP; ORAL)		PARKE-DAVIS/W-L	06-514	08-07-81			
DOXYLAMINE SUCCINATE 25MG		UNISON (TABLET; ORAL)		Pfizer	18-066	10-06-78			
IBUPROFEN 200MG		ADVIL (TABLET; ORAL)		WHITENALL LABS/AMMO	18-989	05-18-84		09-24-86	NS
IBUPROFEN 200MG		NUPRIN (TABLET; ORAL)		UPJOHN MANUFACTURING	19-012	05-18-84	3385886	05-28-85	NS
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			

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

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
INSULIN SUSPENSION, ISOPHANE, MIXED BEEF AND PORK 40 UNITS/ML	NPH ILETIN I (BEEF-PORK) (INJECTABLE; INJECTION)	LILLY RES LABS DIV	17-936 02-08-77		
INSULIN SUSPENSION, ISOPHANE, MIXED BEEF AND PORK 100 UNITS/ML	NPH ILETIN I (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 I (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		
INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED BEEF 40 UNITS/ML	PROTAMINE ZINC INSULIN (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-928 02-08-77		

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
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INSULIN SUSPENSION, PROTAHINE ZINC, PURIFIED BEEF 100 UNITS/ML	PROTAHINE ZINC AND ILETIN II	(INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-928	02-08-77	18-476	06-12-80	
INSULIN SUSPENSION, PROTAHINE ZINC, PURIFIED BEEF; INSULIN, PURIFIED BEEF 100 UNITS/ML	PROTAHINE ZINC AND ILETIN II (PORK)	(INJECTABLE; INJECTION)	ELI LILLY	18-346	12-05-79	17-998	02-08-77	
INSULIN SUSPENSION, BEEF LENTIL INSULIN 40 UNITS/ML	LENTIL INSULIN	(INJECTABLE; INJECTION)	SQUIBB-NOVO	17-998	02-08-77	17-998	02-08-77	
INSULIN SUSPENSION, BEEF LENTIL INSULIN 100 UNITS/ML	LENTIL INSULIN	(INJECTABLE; INJECTION)	SQUIBB-NOVO	17-998	02-08-77	17-998	02-08-77	
INSULIN SUSPENSION, SEMISYNTHETIC HUMAN 100 UNITS/ML	MONOTARD HUMAN	(INJECTABLE; INJECTION)	SQUIBB-NOVO	18-777	08-30-83	18-385	03-17-80	
INSULIN SUSPENSION, ULTRATARD EXTENDED, PURIFIED BEEF 100 UNITS/ML	ULTRATARD	(INJECTABLE; INJECTION)	SQUIBB-NOVO	18-385	03-17-80	17-997	02-08-77	
INSULIN SUSPENSION, ULTRALENTE INSULIN EXTENDED, BEEF 100 UNITS/ML	ULTRALENTE INSULIN	(INJECTABLE; INJECTION)	SQUIBB-NOVO	17-997	02-08-77	17-996	02-08-77	
INSULIN SUSPENSION, PROMPT, SEMILENTE INSULIN BEEF 100 UNITS/ML	SEMILENTE INSULIN	(INJECTABLE; INJECTION)	SQUIBB-NOVO	17-996	02-08-77	18-382	03-17-80	
INSULIN SUSPENSION, PROMPT, SEMITARD PURIFIED PORK 100 UNITS/ML	SEMITARD	(INJECTABLE; INJECTION)	SQUIBB-NOVO	18-382	03-17-80	18-477	06-12-80	
INSULIN SUSPENSION, LENTIL ILETIN II 100 UNITS/ML	LENTIL ILETIN II	(INJECTABLE; INJECTION)	ELI LILLY	18-477	06-12-80			

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

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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, SEMISYNTHETIC HUMAN 100 UNITS/ML	ACTRAPID HUMAN (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-778 08-30-83		
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		
INSULIN SUSPENSION, ISOPHANE, PURIFIED HUMAN 100 UNITS/ML	NOVOLIN N (INJECTABLE; INJECTION)	NOVO INDUSTRI A/S	19-065 01-23-85		
NONOXYNOL-9 1GM	TODAY (SPONGE; VAGINAL)	VLI CORPORATION	18-683 04-01-83		NDF 09-24-86

ACTIVE INGREDIENT(S)

TRADE NAME
(DOSAGE FORM; ROUTE)

APPLICANT NAME

NDA NO.

APPROVAL DATE

PATENT NO.
EXP. DATEEXCLUSIVITY
EXP. DATE

POTASSIUM IODIDE 130MG	THYRO-BLOCK (TABLET; ORAL)	WALLACE LABS/C-M	18-307	11-09-79	18-551	02-19-82	18-664	10-14-82	17-941	01-15-79	11-935	11-26-82	11-936	11-26-82	19-208	01-15-85	88-116	03-04-83	85-024	01-10-84	88-112	01-20-83	88-115	03-04-83	09-24-86	RTO
POTASSIUM IODIDE 164/MG	POTASSIUM IODIDE (SOLUTION; ORAL)	ROXANE LABORATORIES	18-551	02-19-82	18-664	10-14-82	17-941	01-15-79	11-935	11-26-82	11-936	11-26-82	19-208	01-15-85	88-116	03-04-83	85-024	01-10-84	88-112	01-20-83	88-115	03-04-83	09-24-86	RTO		
POTASSIUM IODIDE 130MG	IOSAT (TABLET; ORAL)	ANBEX	18-664	10-14-82	17-941	01-15-79	11-935	11-26-82	11-936	11-26-82	19-208	01-15-85	88-116	03-04-83	85-024	01-10-84	88-112	01-20-83	88-115	03-04-83	09-24-86	RTO				
PSEUDOEPHEDRINE HYDROCHLORIDE 120MG	SUDAFED S.A. (CAPSULE, CONTROLLED RELEASE; ORAL)	BURROUGHS WELLCOME	17-941	01-15-79	11-935	11-26-82	11-936	11-26-82	19-208	01-15-85	88-116	03-04-83	85-024	01-10-84	88-112	01-20-83	88-115	03-04-83	09-24-86	RTO						
PSEUDOEPHEDRINE HYDROCHLORIDE 60MG; 2.5MG	ACTIFED (TABLET; ORAL)	BURROUGHS WELLCOME	11-936	11-26-82	19-208	01-15-85	88-116	03-04-83	85-024	01-10-84	88-112	01-20-83	88-115	03-04-83	09-24-86	RTO										
PSEUDOEPHEDRINE HYDROCHLORIDE 60MG; 2.5MG	ACTIFED (CAPSULE; ORAL)	BURROUGHS WELLCOME	19-208	01-15-85	88-116	03-04-83	85-024	01-10-84	88-112	01-20-83	88-115	03-04-83	09-24-86	RTO												
PSEUDOEPHEDRINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	ALLERBAN PLUS (SYRUP; ORAL)	BAY LABORATORIES	88-116	03-04-83	85-024	01-10-84	88-112	01-20-83	88-115	03-04-83	09-24-86	RTO														
PSEUDOEPHEDRINE HYDROCHLORIDE 60MG; 2.5MG	TRI-SUDO (TABLET; ORAL)	MD PHARMACEUTICAL	85-024	01-10-84	88-112	01-20-83	88-115	03-04-83	09-24-86	RTO																
PSEUDOEPHEDRINE HYDROCHLORIDE 60MG; 2.5MG	TRIPODINE (TABLET; ORAL)	DANBURY PHARMACAL	88-112	01-20-83	88-115	03-04-83	09-24-86	RTO																		
PSEUDOEPHEDRINE HYDROCHLORIDE 60MG; 2.5MG	TRIOFED (SYRUP; ORAL)	NATL PHARM MFG/BARRE	88-115	03-04-83	09-24-86	RTO																				

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

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

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	TRIPOSED (SYRUP; ORAL)	HALSEY DRUG	88-213 03-30-84		RTO 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPROLIDINE HCL AND PSEUDOEPHEDRINE HCL (TABLET; ORAL)	CHELSEA LABORATORIES	88-118 01-26-84		RTO 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPOSED (TABLET; ORAL)	HALSEY DRUG	88-192 05-01-84		RTO 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPROLIDINE AND PSEUDOEPHEDRINE (TABLET; ORAL)	BOLAR PHARMACEUTICAL	88-318 01-13-84		RTO 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	TRIPOSED (SYRUP; ORAL)	HALSEY DRUG	88-213 05-01-84		RTO 09-24-86
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
TRIPROLIDINE HYDROCHLORIDE 2.5MG	ACTIDIL (TABLET; ORAL)	BURROUGHS WELLCOME	11-110 04-14-58		RTO 09-24-86
TRIPROLIDINE HYDROCHLORIDE 2.5MG	TRIPROLIDINE HCL (TABLET; ORAL)	BOLAR PHARMACEUTICAL	84-453 02-06-76		RTO 09-24-86
TRIPROLIDINE HYDROCHLORIDE 2.5MG	TRIPROLIDINE HCL (TABLET; ORAL)	DANBURY PHARMACAL	85-094 02-07-77		RTO 09-24-86
TRIPROLIDINE HYDROCHLORIDE 2.5MG	TRIPROLIDINE HCL (TABLET; ORAL)	DRUMMER/PHOENIX	85-610 03-21-78		RTO 09-24-86
TRIPROLIDINE HYDROCHLORIDE 1.25MG/5ML	ACTIDIL (SYRUP; ORAL)	BURROUGHS WELLCOME	11-496 07-24-58		RTO 09-24-86

ACTIVE INGREDIENT(S)
STRENGTH(S)
TRIPIROLIDINE HYDROCHLORIDE
1.25MG/5ML
TRIPIROLIDINE HYDROCHLORIDE
1.25MG/5ML
TRIPIROLIDINE HYDROCHLORIDE
1.25MG/5ML

TRADE NAME
(DOSAGE FORM; ROUTE)
BAYDYL
(SYRUP; ORAL)
TRIPIROLIDINE HCL
(SYRUP; ORAL)
TRIPIROLIDINE HCL
(SYRUP; ORAL)

APPLICANT NAME
BAY LABORATORIES
NATL PHARM MFG/BARRE
PHARMS ASSOC/BEACH

NDA NO.
APPROVAL DATE
87-963
01-18-83
85-940
07-13-79
87-514
02-10-82

PATENT NO.
EXP. DATE

EXCLUSIVITY
EXP. DATE
RTD
09-24-86
RTD
09-24-86
RTD
09-24-86

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

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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 NO. APPROVAL DATE	PATENT NO. 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		
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		

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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 NO. APPROVAL DATE PATENT NO. EXP. DATE EXCLUSIVITY

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	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 NUTRICAL ADDITIVE SYSTEM (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	82-915	9-22-83		
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	ANTICOAGULANT HEPARIN SOLUTION USP NONE	(INJECTABLE; INJECTION)	DELMO	77-822	5-17-78		
ANTICOAGULANT HEPARIN SOLUTION USP NONE	ANTICOAGULANT HEPARIN SOLUTION USP NONE	(INJECTABLE; INJECTION)	TRAVENOL LABS	81-1217	5-16-83		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP NONE	ANTICOAGULANT SODIUM CITRATE SOLUTION USP NONE	(INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	81-416	10-12-83		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP NONE	ANTICOAGULANT SODIUM CITRATE SOLUTION USP NONE	(INJECTABLE; INJECTION)	CUTTER BIOL/MILES	76-305	6-30-78		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP NONE	ANTICOAGULANT SODIUM CITRATE SOLUTION USP NONE	(INJECTABLE; INJECTION)	DELMO	16-702	12-28-70		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP NONE	ANTICOAGULANT SODIUM CITRATE SOLUTION USP NONE	(INJECTABLE; INJECTION)	TERUMO AMERICA	78-1214	2-8-80		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP NONE	ANTICOAGULANT SODIUM CITRATE SOLUTION USP NONE	(INJECTABLE; INJECTION)	TRAVENOL LABS	77-923	1-20-78		

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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO. APPROVAL DATE	PATENT NO. 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		
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		

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

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXPIRATION DATE
DEXTRAN 70, 6% SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE	CUTTER B10L/MILES	8-716	8-11-69		
DEXTRAN 75, 6% SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE	PHARMACHEM	16-836	11-14-70		
DEXTRAN 40, 10% SODIUM CHLORIDE 0.9% 10GM/100ML IN 5GM/100ML	NONE	PHARMACHEM	16-836	11-14-70		
DEXTRAN 75, 6% SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE	PHARMACHEM	8-564	9-19-52		
DEXTRAN 75, 6% SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE	PHARMACHEM	16-759	8-19-70		
DEXTRAN 1 SODIUM CHLORIDE 0.6% 150MG/ML IN 5GM/100ML	FROMIT	PHARMACIA LABS	83-715	10-30-84		
DEXTRAN 40, 10% SODIUM CHLORIDE 0.9% 10GM/100ML IN 5GM/100ML	RHEOMACRODEX ^R	PHARMACIA LABS	14-716	1-18-67		
DEXTRAN 40, 10% SODIUM CHLORIDE 0.9% 10GM/100ML IN 5GM/100ML	RHEOMACRODEX ^R	PHARMACIA LABS	14-716	1-18-67		
DEXTRAN 70, 6% SODIUM CHLORIDE 0.9% 0.9GM/100ML	MACRODEX ^R	PHARMACIA LABS	6-826	6-8-54		
DEXTRAN 70, 6% SODIUM CHLORIDE 0.9% 0.9GM/100ML	MACRODEX ^R	PHARMACIA LABS	6-826	6-8-54		

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 NO. APPROVAL DATE	PATENT NO. EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	GENTRAN ^R 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	16-628 11-4-68		
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 40, 10% 10GM/100ML DEXTROSE 5% 5GM/100ML	GENTRAN ^R 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	84-619 2-22-85		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	GENTRAN ^R 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	84-620 2-22-85		
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% TRAVER ^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		NS 09-24-86
UROKINASE 250,000 IU/VIAL	ABBOKINASE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	76-1021 7-31-78		I-29 09-24-86
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 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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 650MG; EQ 25MG BASE	TALACEN (TABLET; ORAL)	STERLING DRUG	18-458 09-23-82	4105659 08-08-95	NC 09-24-86
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
ACYCLOVIR 200MG	ZOVIRAX (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-828 01-25-85	4199574 04-22-97	NCE 03-29-92
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	I-22 09-24-86
ALBUTEROL 0.09MG/INH	VENTOLIN (AEROSOL; INHALATION)	GLAXO	18-473 05-01-81	3644353 02-22-89 3705233 12-05-89	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
ALBUTEROL SULFATE	EQ 2MG BASE	PROVENTIL	(TABLET; ORAL)	SCHERING	17-853	05-07-82	3644353	09-24-86	NE
ALBUTEROL SULFATE	EQ 4MG BASE	PROVENTIL	(TABLET; ORAL)	SCHERING	17-853	05-07-82	3644353	09-24-86	NE
ALCLOMETASONE DIPROPIONATE	0.05%	VADERM	(OINTMENT; TOPICAL)	SCHERING	18-702	12-14-82	4124707	12-14-92	NCE
ALCLOMETASONE DIPROPIONATE	0.05%	VADERM	(CREAM; TOPICAL)	SCHERING	18-707	12-14-82	4124707	12-14-92	NCE
ALLOPURINOL	100MG	ALLOPURINOL	(TABLET; ORAL)	BOLAR PHARMACEUTICAL	18-241	11-16-84			
ALLOPURINOL	300MG	ALLOPURINOL	(TABLET; ORAL)	BOLAR PHARMACEUTICAL	18-241	11-16-84			
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	08-19-86			
ALLOPURINOL	300MG	ZYLOPRIM	(TABLET; ORAL)	BURROUGHS WELLCOME	16-084	08-19-86			
ALLOPURINOL	300MG	ZYLOPRIM	(TABLET; ORAL)	BURROUGHS WELLCOME	16-084	01-14-74			
ALLOPURINOL	100MG	LOPURIN	(TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-297	06-10-80			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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	
ALPRAZOLAM 1MG	XANAX (TABLET; ORAL)	UPJOHN	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		NS 09-24-86
AMINO ACIDS 6.5%	RENAMIN W/O ELECTROLYTES (INJECTABLE; INJECTION)	TRAVENOL LABS	17-493 10-15-82		NS 09-24-86
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	NS 09-24-86

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
AMINO ACIDS	4%	BRANCHAMIN 4%	(INJECTABLE; INJECTION)	TRAVENOL LABS	18-678	09-28-84	4438144	09-24-86	NS
AMINO ACIDS	4%	BRANCHAMIN 4%	(INJECTABLE; INJECTION)	TRAVENOL LABS	18-684	09-28-84	4438144	09-24-86	NS
AMINO ACIDS	4%	BRANCHAMIN 4%	(INJECTABLE; INJECTION)	TRAVENOL LABS	18-684	09-28-84	4438144	09-24-86	NS
AMINO ACIDS	6.5%	NEOPHAM 6.5%	(INJECTABLE; INJECTION)	CUTTER-VITRUM	18-792	01-17-84		09-24-86	NS
AMINO ACIDS	3.5%	AMINOSYN 3.5%	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-804	05-15-84		09-24-86	NS
AMINO ACIDS	3.5%	AMINOSYN 3.5%	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-875	08-08-84		09-24-86	NS
AMINO ACIDS	5.2%	AMINOSYN 5.2% ESSENTIAL AMINO ACIDS W/ HISTADINE	(INJECTABLE; INJECTION)	CUTTER-VITRUM	18-901	04-06-84		09-24-86	NS
AMINO ACIDS	8.5%	TRAVASOL 8.5%	(INJECTABLE; INJECTION)	TRAVENOL LABS	18-931	08-23-84		09-24-86	NS
AMINO ACIDS	10%	TRAVASOL 10%	(INJECTABLE; INJECTION)	TRAVENOL LABS	18-931	08-23-84		09-24-86	NS
AMINO ACIDS	6%	TROPHAMINE 6%	(INJECTABLE; INJECTION)	AM MCGAM/AM HOSP	19-018	07-20-84		09-24-86	NS

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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		NC 09-24-86
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		NC 09-24-86
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		NC 09-24-86
AMINOACETIC ACID 1.5GM/100ML	AMINOACETIC ACID 1.5% IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-522 02-19-82		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
AMINOCAPROIC ACID	250MG/ML		(INJECTABLE; INJECTION)	ELKINS-SINN/AMROBINS	18-590	10-29-82			
AMINOGLUTETIMIDE	250MG	CYTADREN	(TABLET; ORAL)	CIBA/CIBA-GEIGY	18-202	10-29-80		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%	(INJECTABLE; INJECTION) IN PLASTIC CONTAINER	ABBOTT LABORATORIES	18-924	12-12-84			
AMINOPHYLLINE; SODIUM CHLORIDE	200MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45%	(INJECTABLE; INJECTION) IN PLASTIC CONTAINER	ABBOTT LABORATORIES	18-924	12-12-84			
AMINOPHYLLINE; SODIUM CHLORIDE	400MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45%	(INJECTABLE; INJECTION) IN PLASTIC CONTAINER	ABBOTT LABORATORIES	18-924	12-12-84			
AMINOPHYLLINE; SODIUM CHLORIDE	500MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45%	(INJECTABLE; INJECTION) IN PLASTIC CONTAINER	ABBOTT LABORATORIES	18-924	12-12-84			
AMITRIPTYLINE HYDROCHLORIDE	10MG	ELAVIL	(TABLET; ORAL)	MS&D/MERCK	12-703	04-07-81		05-21-85	3428735
AMITRIPTYLINE HYDROCHLORIDE	25MG	ELAVIL	(TABLET; ORAL)	MS&D/MERCK	12-703	07-05-74		02-18-86	3384663

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
AMITRIPTYLINE HYDROCHLORIDE 50MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 04-07-61	3384663 05-21-85 3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 75MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 10-28-76	3384663 05-21-85 3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 100MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 10-28-76	3384663 05-21-85 3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 150MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 09-17-76	3384663 05-21-85 3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 10MG/ML	ELAVIL (INJECTABLE; INJECTION)	MS&D/MERCK	12-704 04-11-61	3384663 05-21-85 3428735 02-18-86	
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	
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 3428735 02-18-86	

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ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	PATENT NO.	EXP. DATE	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE		
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 50MG; 4MG	TRIAVIL 4-50 (TABLET; ORAL)	MS&D/MERCK	14-715	03-15-78	05-21-85	3428735
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 4MG	TRIAVIL 4-25 (TABLET; ORAL)	MS&D/MERCK	14-715	08-25-65	05-21-85	3428735
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 2MG	TRIAVIL 2-10 (TABLET; ORAL)	MS&D/MERCK	14-715	04-04-67	05-21-85	3428735
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 2MG	TRIAVIL 2-25 (TABLET; ORAL)	MS&D/MERCK	14-715	08-23-65	05-21-85	3428735
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 4MG	TRIAVIL 4-10 (TABLET; ORAL)	MS&D/MERCK	14-715	12-30-65	05-21-85	3428735
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 2MG	ETRAFON 2-10 (TABLET; ORAL)	SCHERING	14-713	12-30-65	05-21-85	3428735
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 4MG	ETRAFON-FORTE (TABLET; ORAL)	SCHERING	14-713	12-30-65	05-21-85	3428735
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 2MG	ETRAFON 2-25 (TABLET; ORAL)	SCHERING	14-713	12-30-65	05-21-85	3428735

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
AMMONIUM LACTATE EQ 12% ACID	LAC-HYDRIN (LOTION; TOPICAL)	BRISTOL-MYERS	19-155 04-24-85		NCE 04-24-88
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	
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		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE 770MG; 60MG; 50MG	NORGESIC FORTE	(TABLET; ORAL)	RIKER LABS/3M	13-416	10-27-82			
ASPIRIN; CAFFEINE; PROPIONYPHENE HYDROCHLORIDE 389MG; 32.4MG; 32MG	DARVON COMPOUND	(CAPSULE; ORAL)	ELI LILLY INDSTRS/PR	10-996	03-08-83			
ASPIRIN; CAFFEINE; 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			
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)	MYETH LABS/AMHO	11-702	12-29-83			
ASPIRIN; PENTAZOCINE HYDROCHLORIDE 325MG; EQ 12.5MG BASE	TALWIN COMPOUND	(TABLET; ORAL)	WINTHROP LABS/STERL	16-891	11-12-75			
ATENOLOL 50MG	TENORMIN	(TABLET; ORAL)	STUART PHARMS/ICI AM	18-240	08-19-81			
ATENOLOL 100MG	TENORMIN	(TABLET; ORAL)	STUART PHARMS/ICI AM	18-240	08-19-81			

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<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
ATENLOL; 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	NC 09-24-86
ATENLOL; 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	NC 09-24-86
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	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	3419565 12-31-85 3717647 02-20-90	NC 09-24-86
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	NS 09-24-86

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
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	
BENDROFLUMETHIAZIDE	10MG		NATURETIN-10 (TABLET; ORAL)	ER SQUIBB AND SONS	12-164	03-29-77	3392168	07-09-85	
BENDROFLUMETHIAZIDE: MADOLOL	5MG; 40MG		CORZIDE (TABLET; ORAL)	ER SQUIBB AND SONS	18-647	05-25-83	3982021	09-21-93	NC
BENDROFLUMETHIAZIDE: MADOLOL	5MG; 80MG		CORZIDE (TABLET; ORAL)	ER SQUIBB AND SONS	18-647	05-25-83	3982021	09-21-93	NC
BENTIRONE	500MG/7.5ML		CHWEX (SOLUTION; ORAL)	ADRIA LABORATORIES	18-366	12-29-83	3801562	04-02-91	NC
CELESTONE	0.6MG		(TABLET; ORAL)	SCHERING	12-657	04-17-61	3485854	12-23-86	
CELESTONE	0.6MG/5ML		(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. NDAs APPROVED FROM 1-1-82 TO 4-30-85 AND NDAs WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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 EQ 0.05% BASE	DIPROSONE (CREAM; TOPICAL)	SCHERING	17-536 01-29-75		D-1 09-24-86
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	DIPROSONE (OINTMENT; TOPICAL)	SCHERING	17-691 04-15-76		D-1 09-24-86
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	DIPROSONE (LOTION; TOPICAL)	SCHERING	17-781 02-01-77		D-1 09-24-86
BETAMETHASONE DIPROPIONATE EQ 0.1% BASE	DIPROSONE (AEROSOL; TOPICAL)	SCHERING	17-829 05-24-77		D-1 09-24-86
BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE EQ 0.05% BASE; 1%	LOTIRISONE (CREAM; TOPICAL)	SCHERING	18-827 07-10-84	3660577 05-02-89 3705172 12-05-89 4298604 11-03-98 3839573 10-01-91	NC 09-24-86

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
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			
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	BETAREX	(CREAM; TOPICAL)	SAVAGE LABS/BYK-GLDN	18-862	08-31-83			
BETAMETHASONE VALERATE	EQ 0.1% BASE	BETAREX	(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	BETAREX	(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			
BETAMETHASONE VALERATE	10MG	BETAMETHAN	(TABLET; ORAL)	AM ROBINS	17-675	05-29-81			3495013
BETAMETHASONE VALERATE	25MG	BETAMETHAN	(TABLET; ORAL)	AM ROBINS	17-675	05-29-81			3495013

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
BITOLTEROL MESYLATE 0.8%	TORNALATE (AEROSOL; INHALATION)	WINTHROP-BREON/STERL	18-770 12-28-84	4138581 02-06-96	NCE 12-28-89
BRETYLIUM TOSYLATE 50MG/ML	BRETYLLOL (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	I-16 12-14-87
BROMOCRIPTINE MESYLATE EQ 5MG BASE	PARLODEL (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	17-962 03-01-82	3752888 08-14-90 3752814 08-14-90	I-16 12-14-87
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-DX (SYRUP; ORAL)	AM ROBINS	11-694 03-29-84		
BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 30MG/5ML	DIMETANE-DX (SYRUP; ORAL)	AM ROBINS	11-694 03-29-84		
BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 30MG/5ML	DIMETANE-DX (SYRUP; ORAL)	AM ROBINS	19-279 08-24-84		
BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 12MG; 75MG	DIMETAPP (TABLET, CONTROLLED RELEASE; ORAL)	AM ROBINS	12-436 04-02-84		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
BROMHENIRAMINE MALEATE: PHENYLEPROPANOLAMINE HYDROCHLORIDE 4MG/5ML; 25MG/5ML		ELIXIR DIMETAPP	(ELIXIR; ORAL)	AH ROBINS	13-087				
BUMETANIDE	1MG	BUMEX	(TABLET; ORAL)	HOFFMANN-LA ROCHE	18-225	02-28-83	01-11-89 3634583	02-28-93	NCE
BUMETANIDE	0.5MG	BUMEX	(TABLET; ORAL)	HOFFMANN-LA ROCHE	18-225	02-28-83	01-11-89 3634583	02-28-93	NCE
BUMETANIDE	0.25MG/ML	BUMEX	(INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	18-226	02-28-83	01-11-89 3634583	02-28-93	NCE
BUPIVACAINE HYDROCHLORIDE: DEXTROSE	0.75%; 8.25%	MARCAINE SPINAL	(INJECTABLE; INJECTION)	BREON LABS/STERLING	18-692	05-04-84	04-23-91 3806534	09-24-86	NC
BUPIVACAINE HYDROCHLORIDE: EPINEPHRINE BITARTRATE	0.5%; 0.0091MG/ML	SENORCAINE	(INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-304	09-02-83			
BUPIVACAINE HYDROCHLORIDE: EPINEPHRINE BITARTRATE	0.75%; 0.0091MG/ML	SENORCAINE	(INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-304	09-02-83			
BUPIVACAINE TARTRATE	1MG/ML	STADOL	(INJECTABLE; INJECTION)	BRISTOL LABS/B-M	17-857	08-22-78	06-25-91 3819635		
BUTORPHANOL TARTRATE	2MG/ML	STADOL	(INJECTABLE; INJECTION)	BRISTOL LABS/B-M	17-857	08-22-78	06-25-91 3819635		
CALCEFEDOL, ANHYDROUS	0.02MG	CALDEROL	(CAPSULE; ORAL)	UPJOHN	18-312	08-05-80	09-03-91 3565924		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO. APPROVAL DATE	PATENT NO. EXP. DATE	EXCLUSIVITY EXP. DATE
CALCEFEDIOL, ANHYDROUS 0.05MG	CALDEROL (CAPSULE; ORAL)	UPJOHN	18-312 08-05-80	3833622 09-03-91 3565924 03-23-86	
CALCITONIN 200 IU/VIAL	CALCIMAR (INJECTABLE; INJECTION)	ARMOUR PHARM	17-769 12-21-84		I-18 12-21-87
CALCITONIN 400 IU/VIAL	CALCIMAR (INJECTABLE; INJECTION)	ARMOUR PHARM	17-497 12-21-84		I-18 12-21-87
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	
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		

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	DELFLX 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	DELFLX W/ DEXTROSE 2.5% 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; 4.25GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	DELFLX 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		

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ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	30MG/100ML; 860MG/100ML			TRAVENOL LABS	18-635	02-07-83			
DEXTROSE 5% AND RINGER'S IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)			TRAVENOL LABS	18-635	02-07-83			
TPN ELECTROLYTES IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)			ABBOTT LABORATORIES	18-895	07-20-84			NC
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	16.5MG/ML; 25.4MG/ML; 74.6MG/ML; 121MG/ML; 16.1MG/ML			AM MCGAW/AM HOSP	18-899	10-31-83			
ISOLYTE E IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)			AM MCGAW/AM HOSP	18-899	10-31-83			
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE	35MG/100ML; 30MG/100ML; 74MG/100ML; 640MG/100ML; 500MG/100ML; 74MG/100ML			ABBOTT LABORATORIES	18-608	02-26-82			NC
PLEGISOL IN PLASTIC CONTAINER	(SOLUTION; PERFUSION, CARDIAC)			ABBOTT LABORATORIES	18-608	02-26-82			NC
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	33MG/100ML; 30MG/100ML; 860MG/100ML			TRAVENOL LABS	18-495	02-19-82			
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			TRAVENOL LABS	18-648	02-07-83			
RINGER'S IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)			TRAVENOL LABS	18-648	02-07-83			
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	33MG/100ML; 30MG/100ML; 860MG/100ML			AM MCGAW/AM HOSP	18-721	11-09-82			
RINGER'S IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)			AM MCGAW/AM HOSP	18-721	11-09-82			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 105MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 105MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 179MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 179MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 254MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 254MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		

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ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 50MG/100ML; 328MG/100ML; 600MG/100ML; 310MG/100ML		POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367	04-05-85			
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 50MG/100ML; 328MG/100ML; 600MG/100ML; 310MG/100ML		POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367	04-05-85			
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 MCGRAW/HM 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; HEGLUMINE METRIZOATE; SODIUM 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			
CALCIUM; MEGALUMINE; METRIZOIC ACID 0.35MG/ML; 140.1MG/ML; 461.8MG/ML		ISOPAQUE 280 (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-506	04-30-74			
CAPTORIL 12.5MG		CAPTORIL (TABLET; ORAL)	ER SQUIBB AND SONS	18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506	04-30-74			
				18-343	01-17-85			
				19-367	04-05-85			
				18-494	02-19-82			
				19-367	04-05-85			
				18-921	04-03-84			
				16-847	11-17-73			
				17-506				

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CAPTOPRIL 25MG	CAPOTEN (TABLET; ORAL)	ER SQUIBB AND SONS	18-343 04-06-81	4105776 08-08-95	I-20 09-24-86 D-7 10-12-87
CAPTOPRIL 50MG	CAPOTEN (TABLET; ORAL)	ER SQUIBB AND SONS	18-343 04-06-81	4105776 08-08-95	I-20 09-24-86 D-7 10-12-87
CAPTOPRIL 100MG	CAPOTEN (TABLET; ORAL)	ER SQUIBB AND SONS	18-343 04-06-81	4105776 08-08-95	I-20 09-24-86 D-7 10-12-87
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	NC 10-12-87
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	NC 10-12-87
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	NC 10-12-87
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	3462536 08-19-86 3830827 08-20-91 3781415 12-25-90	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
CARBIDOPA: LEVODOPA	10MG: 100MG	SINEMET	(TABLET: ORAL)	MS&D/MERCK	17-555	05-02-75	3462536	08-19-86	10-30-90
							3769424	10-30-90	12-25-90
							3781415	10-30-90	10-30-90
							3830827	10-30-90	08-20-91
							RE29892	10-30-90	10-30-90
CARBIDOPA: LEVODOPA	25MG: 250MG	SINEMET	(TABLET: ORAL)	MS&D/MERCK	17-555	05-02-75	3462536	08-19-86	10-30-90
							3769424	10-30-90	12-25-90
							3781415	10-30-90	10-30-90
							3830827	10-30-90	08-20-91
							RE29892	10-30-90	10-30-90
CARBIDOPA: LEVODOPA	25MG: 100MG	SINEMET	(TABLET: ORAL)	MS&D/MERCK	17-555	05-02-75	3462536	08-19-86	10-30-90
							3769424	10-30-90	12-25-90
							3781415	10-30-90	10-30-90
							3830827	10-30-90	08-20-91
							RE29892	10-30-90	10-30-90
CARBOPROST TROMETHAMINE	EQ 0.25MG BASE/ML	PROSTIN/15H	(INJECTABLE: INJECTION)	UPJOHN	17-989	01-09-79	3728382	04-17-90	1-32
CELLULOSE SODIUM PHOSPHATE	2.5GM/PACKET	CALCIBIND	(POWDER: ORAL)	MISSION PHARMACAL	18-757	12-28-82	3472832	10-14-86	12-28-92
CERULETIDE DIETHYLAMINE	0.02MG/ML	TYMTRAN	(INJECTABLE: INJECTION)	ADRIA LABORATORIES	18-296	12-24-81	3472832	10-14-86	12-28-92

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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	NDF 09-24-86
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	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
CHLOROXINE	2%	CAPITROL	(SHAMPPOO; TOPICAL)	WESTWOOD PHARMS	17-594	05-27-92	3686277	05-27-92	
CHLORTHALIDONE: CLONIDINE HYDROCHLORIDE	15MG; 0.1MG	COMBIPRES	(TABLET; ORAL)	BOEHRINGER INGELHEIM	17-503	07-08-86	3454701	07-08-86	
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)	HEAD JOHNSON/B-H	16-019	12-06-66	3383281	05-18-85	I-23
CHOLESTYRAMINE	EQ 4GM RESIN/PACKET	QUESTRAN	(POWDER; ORAL)	HEAD JOHNSON/B-H	16-640	08-03-73	3383281	05-18-85	I-23
CYMOFAPPAIN	12,500 UNITS/VIAL	DISCAGE	(INJECTABLE; INJECTION)	TRAVENOL LABS	18-625	01-18-84		11-10-92	NCE
CYMOFAPPAIN	10,000 UNITS/VIAL	CYMOFAPPAIN	(INJECTABLE; INJECTION)	SMITH LABORATORIES	18-663	11-10-82	4439423	11-10-92	NCE
CYMOFAPPAIN	4,000 UNITS/VIAL	CYMOFAPPAIN	(INJECTABLE; INJECTION)	SMITH LABORATORIES	18-663	08-21-84	4439423	11-10-92	NCE
CICLOPIRROX OLAMINE	1%	LOPROX	(CREAM; TOPICAL)	HOECHST-ROUSSEL	18-748	12-30-82	3883545	05-13-92	NCE
CIMETIDINE	200MG	TAGAMET	(TABLET; ORAL)	SKKF LAB	17-920	08-16-77	3950333	04-13-93	
CIMETIDINE	300MG	TAGAMET	(TABLET; ORAL)	SKKF LAB	17-920	08-16-77	3950333	05-17-94	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CIMETIDINE 400MG	TAGAMET (TABLET; ORAL)	SK&F LAB	17-920 12-14-83	3950333 04-13-93 4024271 05-17-94	NS 09-24-86
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	18-057 07-18-84	4177263 12-04-96	NDF 09-24-86
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		NC 09-24-86
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		NC 09-24-86
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	NDF 09-24-86
CLOMIPHENE CITRATE 50MG	CLOMIPHENE CITRATE (TABLET; ORAL)	PLANTEX/IKAPHARM	18-361 03-22-82		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
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 PERCUTANEOUS) RELEASE;	BOEHRINGER INGELHEIM	18-891	10-10-84	3454701	07-08-86	NR
CLONIDINE	5MG	CATAPRES-TTS-2	(FILM, CONTROLLED PERCUTANEOUS) RELEASE;	BOEHRINGER INGELHEIM	18-891	10-10-84	3454701	07-08-86	NR
CLONIDINE	7.5MG	CATAPRES-TTS-3	(FILM, CONTROLLED PERCUTANEOUS) RELEASE;	BOEHRINGER INGELHEIM	18-891	10-10-84	3454701	07-08-86	NR
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	
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	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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%	LOTIRIMIN (SOLUTION; TOPICAL)	SCHERING	17-613 02-03-75	3660577 05-02-89 3705172 12-05-89 3839573 10-01-91	
CLOTRIMAZOLE 1%	LOTIRIMIN (CREAM; TOPICAL)	SCHERING	17-619 03-18-75	3660577 05-02-89 3705172 12-05-89 3839573 10-01-91	
CLOTRIMAZOLE 1%	GYNE-LOTIRIMIN (CREAM; VAGINAL)	SCHERING	18-052 11-08-78	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 100MG	GYNE-LOTIRIMIN (TABLET; VAGINAL)	SCHERING	17-717 03-24-76	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
CLOTIRIMAZOLE	1%	MYCELEX	(SOLUTION; TOPICAL)	MILES PHARMS/MILES	18-181	01-15-79	3839573 10-01-91 12-05-89 3660577 05-02-89	10-01-91	
CLOTIRIMAZOLE	100MG	MYCELEX-G	(TABLET; VAGINAL)	MILES PHARMS/MILES	18-182	02-27-79	3839573 10-01-91 12-05-89 3660577 05-02-89	10-01-91	
CLOTIRIMAZOLE	500MG	MYCELEX-G	(TABLET; VAGINAL)	MILES PHARMS/MILES	19-069	04-19-85	3839573 10-01-91 12-05-89 3660577 05-02-89	10-01-91	NS 04-19-88
CLOTIRIMAZOLE	1%	MYCELEX	(CREAM; TOPICAL)	MILES PHARMS/MILES	18-183	01-15-79	3839573 10-01-91 12-05-89 3660577 05-02-89	10-01-91	
CLOTIRIMAZOLE	1%	MYCELEX-G	(CREAM; VAGINAL)	MILES PHARMS/MILES	18-230	02-16-79	3839573 10-01-91 12-05-89 3660577 05-02-89	10-01-91	
CLOTIRIMAZOLE	10MG	MYCELEX	(TROCHE/LOZENGE; ORAL)	MILES PHARMS/MILES	18-713	06-17-83	3839573 10-01-91 12-05-89 3660577 05-02-89	10-01-91	NDF 09-24-86

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
CLOTRIMAZOLE 1%	LOTIMIN (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		
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	I-24 09-24-86
COLESTIPOL HYDROCHLORIDE 500GM/BOT	COLESTID (GRANULE; ORAL)	UPJOHN	17-563 04-04-77	3692895 09-19-89	I-24 09-24-86
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	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
COPPER	120MG	TATUM-T	(INTRAVETERINE DEVICE; INTRAUTERINE)	SEARLE PHARMS	18-205	08-16-79	3563235	02-16-88	
CROMOLYN SODIUM	20MG	INITAL	(CAPSULE; INHALATION)	FISONS	16-990	06-20-73	3686412	08-22-89	09-24-86
CROMOLYN SODIUM	4%	NASALCROM	(SOLUTION; NASAL)	FISONS	18-306	03-18-83	3686412	08-22-89	09-24-86
CROMOLYN SODIUM	4%	OPTICROM	(SOLUTION; OPHTHALMIC)	FISONS	18-155	10-03-84	3686412	08-22-89	10-03-87

3563235
02-16-88
4040417
08-09-94
3783861
01-08-91
3803308
12-01-87
R228399
04-29-92

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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	I-22 01-19-88
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		NS 09-24-86
CYCLOPHOSPHAMIDE 1GM/VIAL	NEOSAR (INJECTABLE; INJECTION)	ADRIA LABORATORIES	87-442 07-08-83		NS 09-24-86
CYCLOPHOSPHAMIDE 2GM/VIAL	CYTOXAN (INJECTABLE; INJECTION)	MEAD JOHNSON/B-M	12-142 08-30-82		NS 09-24-86
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	
DANTROLENE SODIUM 20MG/VIAL	DANTRium (INJECTABLE; INJECTION)	NORWICH EATON/P&G	18-264 09-18-79	3415821 12-10-85	

EXCLUSIVITY
EXP. DATE

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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	NDF 09-24-86
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		NDF 09-24-86
DESOXIMETASONE 0.05%	TOPICORT (OINTMENT; TOPICAL)	HOECHST-ROUSSEL	18-594 01-17-85		NDF 09-24-86
DESOXIMETASONE 0.25%	TOPICORT (OINTMENT; TOPICAL)	HOECHST-ROUSSEL	18-763 09-30-83		NDF 09-24-86
DEXAMETHASONE 6MG	DECADRON (TABLET; ORAL)	MS&D/MERCK	11-664 07-30-82		NS 09-24-86
DEXAMETHASONE 6MG	DEXAMETHASONE (TABLET; ORAL)	PAR PHARMACEUTICAL	88-481 11-28-83		NS 09-24-86
DEXAMETHASONE 6MG	DEXAMETHASONE (TABLET; ORAL)	ROXANE LABORATORIES	88-316 09-15-83		NS 09-24-86
DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE 15MG/5ML; 6.25MG/5ML	PHENERGAN W/ DEXTROMETHORPHAN (SYRUP; ORAL)	WYETH LABS/AMMO	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		

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DEXTROSE 60GM/100ML	DEXTROSE 60% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-346	01-25-85			
DEXTROSE 30GM/100ML	DEXTROSE 30% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-345	01-26-85			
DEXTROSE 60GM/100ML	DEXTROSE 60% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	AM HCGAM/AM HOSP	17-995	04-27-78	3729568	04-24-90	
DEXTROSE 60GM/100ML	DEXTROSE 60% INJECTABLE	(INJECTABLE; INJECTION)	AM HCGAM/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			
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			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 80MG/100ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 02-04-82		NC 09-24-86
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 160MG/100ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 02-04-82		NC 09-24-86
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 80MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83		NC 09-24-86
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 160MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83		NC 09-24-86
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 320MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83		NC 09-24-86
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		NC 09-24-86
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		NC 09-24-86
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		NC 09-24-86
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		NC 09-24-86

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
HEPARIN SODIUM DEXTROSE; HEPARIN SODIUM SGM/100ML; 5,000 UNITS/100ML		HEPARIN SODIUM	12,500 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911	01-30-85			
HEPARIN SODIUM DEXTROSE; HEPARIN SODIUM SGM/100ML; 5,000 UNITS/100ML		HEPARIN SODIUM	12,500 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-339	03-27-85			
HEPARIN SODIUM DEXTROSE; HEPARIN SODIUM SGM/100ML; 5,000 UNITS/100ML		HEPARIN SODIUM	25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-339	03-27-85			
HEPARIN SODIUM DEXTROSE; HEPARIN SODIUM SGM/100ML; 5,000 UNITS/100ML		HEPARIN SODIUM	25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-134	03-29-85			
HEPARIN SODIUM DEXTROSE; HEPARIN SODIUM SGM/100ML; 10,000 UNITS/100ML		HEPARIN SODIUM	10,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911	01-30-85			
HEPARIN SODIUM DEXTROSE; HEPARIN SODIUM SGM/100ML; 10,000 UNITS/100ML		HEPARIN SODIUM	10,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-339	03-27-85			
HEPARIN SODIUM DEXTROSE; HEPARIN SODIUM SGM/100ML; 10,000 UNITS/100ML		HEPARIN SODIUM	25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911	01-30-85			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 10,000 UNITS/100ML	HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-339 03-27-85		
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		NS 09-24-86
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		NS 09-24-86
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		NS 09-24-86
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		NS 09-24-86
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		NS 09-24-86
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		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DEXTROSE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM LACTATE	5GM/100ML; 205MG/100ML; 100MG/100ML; 120MG/100ML; 220MG/100ML			TRAVENOL LABS	18-840	06-29-83			
DEXTROSE; POTASSIUM CHLORIDE	5GM/100ML; 300MG/100ML			AM MCGAW/AM HOSP	18-744	11-09-82			
DEXTROSE; POTASSIUM CHLORIDE	5GM/100ML; 220MG/100ML			AM MCGAW/AM HOSP	18-744	11-09-82			
DEXTROSE; POTASSIUM CHLORIDE	5GM/100ML; 150MG/100ML			AM MCGAW/AM HOSP	18-744	11-09-82			
DEXTROSE; POTASSIUM CHLORIDE	5GM/100ML; 75MG/100ML			AM MCGAW/AM HOSP	18-744	11-09-82			
DEXTROSE; OXYTOCIN	5GM/100ML; 2 USP UNIT/100ML			ABBOTT LABORATORIES	19-185	03-29-85			
DEXTROSE; OXYTOCIN	5GM/100ML; 2 USP UNIT/100ML			ABBOTT LABORATORIES	19-185	03-29-85			
DEXTROSE; OXYTOCIN	5GM/100ML; 1 USP UNIT/100ML			ABBOTT LABORATORIES	19-185	03-29-85			
DEXTROSE; OXYTOCIN	5GM/100ML; 1 USP UNIT/100ML			ABBOTT LABORATORIES	19-185	03-29-85			

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<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 75MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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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 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567	02-16-83
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
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; 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; 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; 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; 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

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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		
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		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DEXTROSE: POTASSIUM CHLORIDE; SODIUM CHLORIDE	SGM/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	SGM/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	SGM/100ML: 40MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211	12-14-84			
DEXTROSE: THEOPHYLLINE	SGM/100ML: 40MG/100ML	THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	AM MCGAM/AM HOSP	19-083	11-07-84			
DEXTROSE: THEOPHYLLINE	SGM/100ML: 80MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211	12-14-84			
DEXTROSE: THEOPHYLLINE	SGM/100ML: 80MG/100ML	THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	AM MCGAM/AM HOSP	19-083	11-07-84			
DEXTROSE: THEOPHYLLINE	SGM/100ML: 160MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211	12-14-84			
DEXTROSE: THEOPHYLLINE	SGM/100ML: 160MG/100ML	THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	AM MCGAM/AM HOSP	19-083	11-07-84			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
DEXTROSE; THEOPHYLLINE 5GM/100ML; 200MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		
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		
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		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DIAZEPAM 30% MEGLUMINE DIATRIZOATE SODIUM 52%; 8% DIATRIZOATE SODIUM 66%; 10%	RENOM-M-DIP (INJECTABLE; INJECTION) RENOMAFIN-60 (INJECTABLE; INJECTION) RENOMAFIN-76 (INJECTABLE; INJECTION)	ER SQUIBB AND SONS ER SQUIBB AND SONS ER SQUIBB AND SONS	10-040 10-040 10-040	01-08-80 08-29-74 10-27-72			I-7; I-8 I-8 I-5
DIAZEPAM 2MG VALIUM (TABLET; ORAL)	HOFFMANN-LA ROCHE		13-263	11-15-63	02-23-99	4316897	
DIAZEPAM 5MG VALIUM (TABLET; ORAL)	HOFFMANN-LA ROCHE		13-263	11-15-63	02-23-99	4316897	
DIAZEPAM 10MG VALIUM (TABLET; ORAL)	HOFFMANN-LA ROCHE		13-263	11-15-63	02-23-99	4316897	
DIAZEPAM 5MG/ML VALIUM (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE		16-087	08-24-66	02-23-99	4316897	
DIAZEPAM 15MG VAL RELEASE (CAPSULE; CONTROLLED RELEASE; ORAL)	HOFFMANN-LA ROCHE		18-179	03-12-81	02-23-99	4316897	
DIAZOXIDE 15MG/ML HYPERSTAT (INJECTABLE; INJECTION)	SCHERING		16-996	01-22-73			I-1
DICYCLONINE HYDROCHLORIDE 10MG BENTYL (CAPSULE; ORAL)	MERRELL DOW/DOW CHEM		07-409	10-15-84			
DICYCLONINE HYDROCHLORIDE 20MG BENTYL (CAPSULE; ORAL)	MERRELL DOW/DOW CHEM		07-409	10-15-84			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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		NDF 09-24-86
DIGOXIN 0.05MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82		NDF 09-24-86
DIGOXIN 0.15MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 09-24-84		NS 09-24-86
DIGOXIN 0.1MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82		NDF 09-24-86
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	4451458 05-29-01	NC 11-30-87

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
Dihydroergotamine mesylate; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE 7.46MG/0.7ML 0.5MG/0.7ML; 5000 UNITS/0.7ML;	EMBOLEX	(INJECTABLE; INJECTION)	SANDOZ PHARMS/SANDOZ	18-885	11-30-84	4451458	05-29-01	NC 11-30-87
DILTIAZEM HYDROCHLORIDE 30MG	CARDIZEM	(TABLET; ORAL)	MARION LABORATORIES	18-602	11-05-82	3562257	02-09-88	NC 11-05-92
DILTIAZEM HYDROCHLORIDE 60MG	CARDIZEM	(TABLET; ORAL)	MARION LABORATORIES	18-602	11-05-82	3562257	02-09-88	NC 11-05-92
DIMETHYL SULFOXIDE 50%	RIMS-50	(SOLUTION; URETHRAL)	RESEARCH INDUSTRIES	17-788	04-04-78	3549770	12-22-87	
DINOPROST TROMETHAMINE EQ 5MG BASE/ML	PROSTIN F2 ALPHA	(INJECTABLE; INJECTION)	UPJOHN	17-434	11-26-73	3706789	12-19-89	
DINOPROSTONE 20MG	PROSTIN E2	(SUPPOSITORY; VAGINAL)	UPJOHN	17-810	08-23-77	3899587	08-12-92	
DIPIVEFRIN HYDROCHLORIDE 0.1%	PROLINE	(SOLUTION; OPHTHALMIC)	ALLERGAN PHARMS	18-239	05-02-80	3839584	10-01-91	
DISOPYRAMIDE PHOSPHATE EQ 100MG BASE	NORPACE CR	(CAPSULE, CONTROLLED RELEASE; ORAL)	SEARLE/SEARLE PHARMS	18-655	07-20-82			NDF 09-24-86
DISOPYRAMIDE PHOSPHATE EQ 150MG BASE	NORPACE CR	(CAPSULE, CONTROLLED RELEASE; ORAL)	SEARLE/SEARLE PHARMS	18-655	07-20-82			NDF 09-24-86
DIVALPROEX SODIUM EQ 250MG BASE	DEPAKOTE	(TABLET, ENTERIC COATED; ORAL)	ABBOTT LABORATORIES	18-723	03-10-83			NE 09-24-86

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
DIVALPROEX SODIUM EQ 500MG BASE	DEPAKOTE (TABLET, ENTERIC COATED; ORAL)	ABBOTT LABORATORIES	18-723 03-10-83		NE 09-24-86
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	
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	

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDAs NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
DOXEPIH HYDROCHLORIDE	ADAPIN	(CAPSULE; ORAL)	PENNMALT PHARM	16-987	01-31-72	3420851	01-07-86	
DOXEPIH HYDROCHLORIDE	ADAPIN	(CAPSULE; ORAL)	PENNMALT PHARM	16-987	01-31-72	3420851	01-07-86	
DOXEPIH HYDROCHLORIDE	ADAPIN	(CAPSULE; ORAL)	PENNMALT PHARM	16-987	01-31-72	3420851	01-07-86	
DOXEPIH HYDROCHLORIDE	ADAPIN	(CAPSULE; ORAL)	PENNMALT PHARM	16-987	12-12-77	3420851	01-07-86	
DOXEPIH HYDROCHLORIDE	ADAPIN	(CAPSULE; ORAL)	PENNMALT PHARM	16-987	04-15-80	3420851	01-07-86	
DOXEPIH HYDROCHLORIDE	SINEQUAN	(CONCENTRATE; ORAL)	PFIZER LABS/PFIZER	17-516	03-11-74	3420851	01-07-86	
DOXEPIH HYDROCHLORIDE	SPECTAZOLE	(CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	18-751	12-23-82	3717655	02-20-90	NCE
ENFLURANE	ETHRANE	(LIQUID; INHALATION)	ANALQUEST/BOC	17-087	08-28-72	3469011	09-23-86	
EPINEPHRINE; ETIDOCALINE HYDROCHLORIDE	DURANEST	(INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751	08-30-76	3862321	01-21-92	
EPINEPHRINE; ETIDOCALINE HYDROCHLORIDE	DURANEST	(INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751	08-30-76	3862321	01-21-92	
EPINEPHRINE; ETIDOCALINE HYDROCHLORIDE	DURANEST	(INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751	08-30-76	3862321	01-21-92	
EPINEPHRINE; ETIDOCALINE HYDROCHLORIDE	DURANEST	(INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751	08-30-76	3862321	01-21-92	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
ERGOLOID MESYLATES 1MG	HYDERGINE LC (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-706 01-18-83		NDF 09-24-86
ESTROGENS, CONJUGATED 0.9MG	PREMARIN (TABLET; ORAL)	AYERST LABS/AMHO	04-782 01-26-84		NS 09-24-86
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	NC 09-24-86
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	NC 09-24-86
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	NS 11-01-87
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	NS 11-01-87
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 10/11-21 (TABLET; ORAL-21)	ORTHO PHARMACEUTICAL	18-354 01-11-82		D-5 09-24-86

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
ETHINYL ESTRADIOL; NORGESTREL 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 10/11-28 (TABLET; ORAL-28)	ORTHO PHARMACEUTICAL	18-354	01-11-82		09-24-86	D-5
ETHINYL ESTRADIOL; NORGESTREL 0.035MG; 0.5MG AND 1MG	TRI-NORINYL 21-DAY (TABLET; ORAL-21)	SYNTEX (FP)	18-977	04-13-84	4390531	09-24-86	D-6
ETHINYL ESTRADIOL; NORGESTREL 0.035MG; 0.5MG AND 1MG	TRI-NORINYL 28-DAY (TABLET; ORAL-28)	SYNTEX (FP)	18-977	04-13-84	4390531	09-24-86	D-6
ETHINYL ESTRADIOL; NORGESTREL 0.035MG; 0.5MG, 0.75MG AND 1MG	ORTHO-NOVUM 7/7-21 (TABLET; ORAL-21)	ORTHO PHARMACEUTICAL	18-985	04-04-84		09-24-86	D-3
ETHINYL ESTRADIOL; NORGESTREL 0.035MG; 0.5MG, 0.75MG AND 1MG	ORTHO-NOVUM 7/7-28 (TABLET; ORAL-28)	ORTHO PHARMACEUTICAL	18-985	04-04-84		09-24-86	D-3
ETHINYL ESTRADIOL; NORGESTREL 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 7/14-21 (TABLET; ORAL-21)	ORTHO PHARMACEUTICAL	19-004	04-04-84		09-24-86	D-4
ETHINYL ESTRADIOL; NORGESTREL 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 7/14-28 (TABLET; ORAL-28)	ORTHO PHARMACEUTICAL	19-004	04-04-84		09-24-86	D-4
ETHINYL ESTRADIOL; NORGESTREL 0.05MG; 0.5MG	OVRAL (TABLET; ORAL-21)	WYETH LABS/AMHO	16-672	04-16-68	3666858	11-26-91	
ETHINYL ESTRADIOL; NORGESTREL 0.05MG; 0.5MG	OVRAL-28 (TABLET; ORAL-28)	WYETH LABS/AMHO	16-806	11-26-68	3666858	11-26-91	
ETHINYL ESTRADIOL; NORGESTREL 0.035MG; 0.5MG	LO/OVRAL (TABLET; ORAL-21)	WYETH LABS/AMHO	17-612	03-17-75	3666858	11-26-91	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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 08-05-97 4137309 01-30-96 3683080 08-08-89	
ETIDRONATE DISODIUM 400MG	DIDRONEL (TABLET; ORAL)	NORWICH EATON/P&G	17-831 07-06-84	4254114 03-03-98 4216211 08-05-97 4137309 01-30-96 3683080 08-08-89	NS 09-24-86

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 4-30-85 AND NDAs WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
ETOMIDATE	2MG/ML	AMIDATE	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-227	09-07-82		09-07-92	NCE
ETOPOSIDE	20MG/ML	VEPESID	(INJECTABLE; INJECTION)	BRISTOL LABS/B-M	18-768	11-10-83	3524844	11-10-93	NCE
FENFLURAMINE HYDROCHLORIDE	60MG	PONDIMIN	(TABLET; CONTROLLED RELEASE; ORAL)	AH ROBIN	16-618	07-27-82		09-24-86	NDF
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 CITRATE	(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-115	01-12-85			
FENTANYL CITRATE	EQ 0.05MG BASE/ML	FENTANYL	(INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	19-101	07-11-84			
FLUNISOLIDE	0.025MG/INH	BRONALIDE	(AEROSOL; INHALATION)	SYNTEX LABS/SYNTEX	18-340	08-17-84		09-24-86	NDF
FLUCINONIDE	0.05%	LIDEX	(SOLUTION; TOPICAL)	SYNTEX LABS/SYNTEX	18-849	04-06-84		09-24-86	NDF
FLUCINONIDE	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	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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		
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		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	PATENT NO.	EXP. DATE	EXCLUSIVITY
FUROSEMIDE	80MG	FUROSEMIDE	(TABLET; ORAL)	PARKE-DAVIS/M-L	18-419		11-13-84	
FUROSEMIDE	10MG/ML	FUROSEMIDE	(INJECTABLE; INJECTION)	PARKE-DAVIS/M-L	18-420		02-26-82	
FUROSEMIDE	10MG/ML	FUROSEMIDE	(INJECTABLE; INJECTION)	LYPHOMED	18-507		07-30-82	
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)	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	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	KALAPHARM	18-868 06-28-83		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	KALAPHARM	18-868 06-28-83		
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

ACTIVE INGREDIENT(S)

GLYBURIDE
5MG

GLYBURIDE
1.25MG

GLYBURIDE
2.5MG

GLYBURIDE
5MG

TRADE NAME
(DOSAGE FORM; ROUTE)

MICRONASE
(TABLET; ORAL)

DIABETA
(TABLET; ORAL)

DIABETA
(TABLET; ORAL)

DIABETA
(TABLET; ORAL)

APPLICANT NAME

UPJOHN

HOECHST-ROUSSEL

HOECHST-ROUSSEL

HOECHST-ROUSSEL

NDA NO.

17-498

17-532

17-532

17-532

APPROVAL DATE

05-01-84

05-01-84

05-01-84

05-01-84

PATENT NO.

3426067

3426067

3426067

3426067

EXP. DATE

04-21-92

04-21-92

04-21-92

04-21-92

EXCLUSIVITY
EXP. DATE

NCE

NCE

NCE

NCE

3454635
04-21-92
3507961
04-21-92
3507954
04-21-92
4060634
09-07-93

3454635
04-21-92
3507961
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3507954
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4060634
09-07-93

3454635
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09-07-93

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4060634
09-07-93

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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
GONADOTROPIN, CHORIONIC 2,000 UNITS/VIAL	CHORIONIC GONADOTROPIN (INJECTABLE; INJECTION)	CARTER-GLOGAU LABS	17-016 12-27-84		
GONADOTROPIN, CHORIONIC 15,000 UNITS/VIAL	CHORIONIC GONADOTROPIN (INJECTABLE; INJECTION)	CARTER-GLOGAU LABS	17-016 02-15-84		
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
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	NS 09-24-86
HALOPERIDOL 1MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 04-12-67	3438991 04-15-86	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
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	NS
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			
HEPARIN SODIUM: SODIUM CHLORIDE 100 UNITS/ML: 4.5MG/ML	HEPARIN SODIUM 5,000 UNITS IN SODIUM CHLORIDE 0.45% (INJECTABLE; INJECTION)		ABBOTT LABORATORIES	18-911	01-30-85			
HEPARIN SODIUM: SODIUM CHLORIDE 100 UNITS/ML: 4.5MG/ML	HEPARIN SODIUM 5,000 UNITS IN SODIUM CHLORIDE 0.45% (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% (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			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.45% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911 01-30-85		
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 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 200 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-042 03-29-85		
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 IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-042 03-29-85		
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		

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
HEPARIN SODIUM; SODIUM CHLORIDE 1,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM	HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	AM MCGAM/AM HOSP	19-042	03-29-85			
HEPARIN SODIUM; SODIUM CHLORIDE 1,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM	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 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM	HEPARIN SODIUM 2500 UNITS (INJECTABLE; INJECTION)	AM MCGAM/AM HOSP	19-135	03-29-85			
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM	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 10,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM	HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911	01-30-85			
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911	01-30-85			
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911	01-30-85			
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916	01-31-84			
HEXACHLOROPHENE 3%	TURGEX	(SOLUTION; TOPICAL)	XTRIM LABS	19-055	11-30-84			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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	NC 12-31-87
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	NC 12-31-87
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	NC 12-31-87
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	NS 10-22-87
HYDROCORTISONE ACETATE 10%	CORTIFOAM (AEROSOL; RECTAL)	REED&CARNRICK PHARMS	17-351 02-10-82		NDF 09-24-86
HYDROCORTISONE BUTYRATE 0.1%	LOCOID (CREAM; TOPICAL)	OWEN LABS/DERM PRODS	18-795 01-07-83		NP 09-24-86
HYDROCORTISONE BUTYRATE 0.1%	LOCOID (OINTMENT; TOPICAL)	OWEN LABS/DERM PRODS	19-106 07-03-84		NP 09-24-86
HYDROCORTISONE VALERATE 0.2%	WESTCORT (OINTMENT; TOPICAL)	WESTWOOD PHARMS	18-726 08-08-83		NDF 09-24-86
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	

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
IBUPROFEN 400MG	MOTRIN	(TABLET; ORAL)	UPJOHN MANUFACTURING	17-463	09-19-74	3385886	09-24-86	I-2
IBUPROFEN 300MG	MOTRIN	(TABLET; ORAL)	UPJOHN MANUFACTURING	17-463	09-19-74	3385886	09-24-86	I-2
IBUPROFEN 600MG	MOTRIN	(TABLET; ORAL)	UPJOHN MANUFACTURING	17-463	09-19-74	3385886	09-24-86	I-2
IBUPROFEN 400MG	RUFEN	(TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-197	05-19-81	3385886	09-24-86	I-2
IBUPROFEN 600MG	RUFEN	(TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-197	05-19-81	3385886	09-24-86	I-2
IBUPROFEN 600MG	RUFEN	(TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-197	03-05-84	3385886	09-24-86	I-2
INDAPAMIDE 2.5MG	LOZOL	(TABLET; ORAL)	USV PHARMACEUTICAL	18-538	07-06-83	3565911	02-23-88	NCE
INDOMETHACIN 50MG	INDOCIN	(SUPPOSITORY; RECTAL)	MS&D RES LABS/MERCK	17-814	08-13-84			NDF
INDOMETHACIN 75MG	INDOCIN SR	(CAPSULE; CONTROLLED RELEASE; ORAL)	MS&D/MERCK	18-185	02-23-82			NDF
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)	CHELSEA LABORATORIES	18-730	05-04-84			
INDOMETHACIN 50MG	INDOMETHACIN	(CAPSULE; ORAL)	ZENITH LABORATORIES	18-730	05-04-84			
INDOMETHACIN 50MG	INDOMETHACIN	(CAPSULE; ORAL)	ZENITH LABORATORIES	18-730	05-04-84			
INDOMETHACIN 50MG	INDOMETHACIN	(CAPSULE; ORAL)	PAR PHARMACEUTICAL	18-829	08-06-84			

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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		
INDOMETHACIN SODIUM TRIHYDRATE EQ 1MG BASE/VIAL	INDOCIN I. V. (INJECTABLE; INJECTION)	MS&D/MERCK	18-878 01-30-85		
IODAMIDE MEGLUMINE 24%	RENOVUE-DIP (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-903 07-10-78		I-6 09-24-86
IODAMIDE MEGLUMINE 65%	RENOVUE-65 (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-902 07-24-78		I-6 09-24-86
IODOHIPPURATE SODIUM, I-123 1MCI/ML	NEPHROFLOW (INJECTABLE; INJECTION)	MEDI-PHYSICS	18-289 12-28-84		NCE 12-28-89
IODOXAMATE MEGLUMINE 9.9%	CHOLOVUE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	18-076 08-14-81	3654272 04-04-89	
IODOXAMATE MEGLUMINE 40.3%	CHOLOVUE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	18-077 08-14-81	3654272 04-04-89	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
ISOTRETINOIN	99.9%	FORANE	(GAS; INHALATION)	ANQUEST/BOC	17-624	12-18-79	3535425 3535388 01-24-93	01-24-93	
ISOTRETINOIN	10MG	ACCUTANE	(CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662	05-07-82	4200647 4322438 03-30-99 4464394 08-07-01	04-29-97	05-07-92
ISOTRETINOIN	20MG	ACCUTANE	(CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662	03-28-83	4200647 4322438 03-30-99 4464394 08-07-01	04-29-97	05-07-92
ISOTRETINOIN	40MG	ACCUTANE	(CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662	05-07-82	4200647 4322438 03-30-99 4464394 08-07-01	04-29-97	05-07-92
KETOCONAZOLE	200MG	NIZORAL	(TABLET; ORAL)	JANSSEN PHARMA	18-533	06-12-81	4335125	06-15-99	I-25
LABETALOL HYDROCHLORIDE	200MG	NORMODYNE	(TABLET; ORAL)	SCHERING	18-687	08-01-84	4012444	03-15-94	08-01-94
LABETALOL HYDROCHLORIDE	300MG	NORMODYNE	(TABLET; ORAL)	SCHERING	18-687	08-01-84	4012444 4006755	03-15-94	08-01-94

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
LABETALOL HYDROCHLORIDE 400MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-687 08-01-84	4012444 03-15-94 4006755 01-03-95	NCE 08-01-94
LABETALOL HYDROCHLORIDE 5MG/ML	NORMODYNE (INJECTABLE; INJECTION)	SCHERING	18-686 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
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	

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
LEUCOVORIN CALCIUM EQ 5MG BASE	LEUCOVORIN	(TABLET; ORAL)	BURROUGHS WELLCOME	18-342	07-08-83		09-24-86	NDF
LEUCOVORIN CALCIUM EQ 25MG BASE	LEUCOVORIN	(TABLET; ORAL)	BURROUGHS WELLCOME	18-342	07-08-83		09-24-86	NDF
LEUPROLIDE ACETATE 1MG/0.2ML	LUPRON	(INJECTABLE; INJECTION)	TAP PHARMACEUTICALS	19-010	04-09-85		04-09-90	NCE
LITHIUM CARBONATE 450MG	ESKALITH CR (TABLET, CONTROLLED RELEASE; ORAL)		SKF LABORATORIES	18-152	03-29-82		09-24-86	NS
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	01-30-90	09-24-86	I-30
LOPERAMIDE HYDROCHLORIDE 1MG/5ML	IMODIUM (SOLUTION; ORAL)		JANSSEN PHARMA	19-037	07-31-84	01-30-90	09-24-86	NDF
LOXAPINE HYDROCHLORIDE EQ 50MG BASE/ML	LOXITANE (INJECTABLE; INJECTION)		FEDERLE LABS/AM CYAN	18-039	10-26-79			
LOXAPINE HYDROCHLORIDE EQ 25MG BASE/ML	LOXITANE (CONCENTRATE; ORAL)		FEDERLE LABS/AM CYAN	17-658	05-04-76			
LOXAPINE SUCCINATE EQ 5MG BASE	LOXITANE (CAPSULE; ORAL)		FEDERLE LABS/AM CYAN	17-525	10-25-77			
LOXAPINE SUCCINATE EQ 10MG BASE	LOXITANE (CAPSULE; ORAL)		FEDERLE LABS/AM CYAN	17-525	02-25-75			
LOXAPINE SUCCINATE EQ 25MG BASE	LOXITANE (CAPSULE; ORAL)		FEDERLE LABS/AM CYAN	17-525	02-25-75			

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<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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	SULFAMYLOX (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		NC 09-24-86
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	ISOLYTE PH 7.4 IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-006 04-04-84		NC 09-24-86
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		NC 09-24-86
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		NC 09-24-86
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		NC 09-24-86
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE 30MG/100ML; 37MG/100ML; 368MG/100ML; 526MG/100ML; 502MG/100ML	SYNOVALYTE IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	19-326 01-25-85		

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ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
MAGNESIUM SULFATE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE 20MG/100ML; 40MG/100ML; 6.25MG/100ML; 80MG/100ML; 8.75MG/100ML	TIS-U-SOL (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-508	02-19-82		09-24-86	NC
MALATHION 0.5% PRIDERM (LOTION; TOPICAL)		PURDUE FREDERICK	18-613	08-02-82		08-02-92	NCE
MAROTILINE HYDROCHLORIDE 25MG LUDIONIL (TABLET; ORAL)		CIBA/CIBA-GEIGY	17-543	12-01-80		08-27-85	
MAROTILINE HYDROCHLORIDE 50MG LUDIONIL (TABLET; ORAL)		CIBA/CIBA-GEIGY	17-543	12-01-80		08-27-85	
MAROTILINE HYDROCHLORIDE 75MG LUDIONIL (TABLET; ORAL)		CIBA/CIBA-GEIGY	17-543	09-30-82		08-27-85	NS
MAZINDOL 1MG SANDOX (TABLET; ORAL)		SANDOX PHARMS/SANDOX	17-247	06-14-73		10-02-90	
MAZINDOL 2MG MAZANOR (TABLET; ORAL)		WYETH LABS/AMMO	17-980	08-28-80		10-02-90	
MAZINDOL 1MG MAZANOR (TABLET; ORAL)		WYETH LABS/AMMO	17-980	02-02-82		10-02-90	
MEBENDAZOLE 100MG VERMOX (TABLET; CHEWABLE; ORAL)		JANSSEN PHARMA	17-481	06-28-74		04-18-89	
MEGLUMINE; METRICIC ACID 140.1MG/ML; 461.8MG/ML ISOPAGUE-280 (INJECTABLE; INJECTION)		WINTHROP LABS/STERL	17-506	04-30-74		11-04-86	
METAPROTERENOL SULFATE 20MG ALUPENT (TABLET; ORAL)		BOEHRINGER INGELHEIM	15-874	05-13-74		01-14-86	

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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	
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		NDF 09-24-86
METOCLOPRAMIDE EQ 5MG BASE/5ML	REGLAN (SYRUP; ORAL)	AH ROBINS	18-821 3-25-83		NDF 09-24-86
METOCLOPRAMIDE HYDROCHLORIDE EQ 5MG BASE/ML	REGLAN (INJECTABLE; INJECTION)	AH ROBINS	17-862 02-07-79		I-12; I-13; I-14 09-24-86
METOCLOPRAMIDE HYDROCHLORIDE EQ 10MG BASE	REGLAN (TABLET; ORAL)	AH ROBINS	17-854 12-30-80		I-4 09-24-86
METOPROLOL TARTRATE 50MG	LOPRESSOR (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-963 08-07-78	3998790 12-21-93	

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
METOPROLOL TARTRATE 100MG	LOPRESSOR	(TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-963	12-21-93	3998790		
METOPROLOL TARTRATE 1MG/ML	LOPRESSOR	(INJECTABLE; INJECTION)	GEIGY/CIBA-GEIGY	18-704	03-30-84	3998790	09-24-86	NDF
METIZAMIDE 3.75GM/VIAL	AMIPAQUE	(INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-982	08-23-78	3701771	09-24-86	I-26
METIZAMIDE 6.75GM/VIAL	AMIPAQUE	(INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-982	08-23-78	3701771	09-24-86	I-26
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)	CORO LABORATORIES	18-740	10-22-82			
METRONIDAZOLE 500MG	METRONIDAZOLE	(TABLET; ORAL)	CORO LABORATORIES	18-740	10-22-82			
METRONIDAZOLE 250MG	METRONIDAZOLE	(TABLET; ORAL)	CORD LABORATORIES	18-740	10-22-82			
METRONIDAZOLE 250MG	METRONIDAZOLE	(TABLET; ORAL)	DANBURY PHARMACAL	18-764	09-17-82			

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<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	DANBURY PHARMACAL	18-764 12-20-82		
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/100ML	FLAGYL I.V. RTU (INJECTABLE; INJECTION)	SEARLE PHARMS	18-353 05-29-81		I-11 12-20-87
METRONIDAZOLE 500MG/100ML	FLAGYL I.V. RTU IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	SEARLE PHARMS	18-657 12-24-81		I-11 12-20-87
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	PAR PHARMACEUTICAL	18-930 08-18-83		

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METRONIDAZOLE	250MG	METRONIDAZOLE	(TABLET; ORAL)	LNK INTERNATIONAL	19-029	04-10-84			
METRONIDAZOLE	HYDROCHLORIDE	FLAGYL I.V.	(INJECTABLE; INJECTION)	SEARLE PHARMS	18-353	11-28-80			I-11
METRONIDAZOLE	EQ 500MG BASE/VIAL								12-20-87
MICONAZOLE	10MG/ML	MONISTAT	(INJECTABLE; INJECTION)	JANSSEN PHARMA	18-040	10-04-78			I-27
MICONAZOLE NITRATE	2%	MONISTAT 7	(CREAM; VAGINAL)	ORTHO PHARMACEUTICAL	17-450	01-30-74	3717655	02-20-90	09-24-86
MICONAZOLE NITRATE	2%	MONISTAT-DERM	(CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-494	01-30-74	3717655	02-20-90	
MICONAZOLE NITRATE	2%	MONISTAT-DERM	(LOTION; TOPICAL)	ORTHO PHARMACEUTICAL	17-739	12-16-75	3717655	02-20-90	
MICONAZOLE NITRATE	100MG	MONISTAT 7	(SUPPOSITORY; VAGINAL)	ORTHO PHARMACEUTICAL	18-520	03-15-82	3717655	02-20-90	9-24-86
MICONAZOLE NITRATE	200MG	MONISTAT 3	(SUPPOSITORY; VAGINAL)	ORTHO PHARMACEUTICAL	18-888	08-15-84	3717655	02-20-90	NS
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 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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		NR; D-8 09-24-86
MORPHINE SULFATE 1MG/ML	DURAMORPH PF (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-565 09-18-84		NR; D-8 09-24-86
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	
NADOLOL 120MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-063 12-10-79	3982021 09-21-93 3935267 01-27-93	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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NALIDIXIC ACID	1GM	NEGGRAH	(TABLET; ORAL)	WINTHROP LABS/STERL	14-214	03-06-64	3590036	06-29-88	
NALIDIXIC ACID	500MG	NEGGRAH	(TABLET; ORAL)	WINTHROP LABS/STERL	14-214	03-06-64	3590036	06-29-88	
NALIDIXIC ACID	250MG	NEGGRAH	(TABLET; ORAL)	WINTHROP LABS/STERL	14-214	12-27-67	3590036	06-29-88	
NALBUPHINE HYDROCHLORIDE	20MG/ML	NUBAIN	(INJECTABLE; INJECTION)	DUPONT PHARMS/DUPONT	18-024	05-27-82	3393197	07-16-85	NS
NALBUPHINE HYDROCHLORIDE	10MG/ML	NUBAIN	(INJECTABLE; INJECTION)	DUPONT PHARMS/DUPONT	18-024	05-15-79	3393197	07-16-85	
NADOLOL	160MG	CORGARD	(TABLET; ORAL)	ER SQUIBB AND SONS	18-064	12-10-79	3982021	09-21-93	
NADOLOL	120MG	CORGARD	(TABLET; ORAL)	ER SQUIBB AND SONS	18-064	12-10-79	3982021	09-21-93	
NADOLOL	80MG	CORGARD	(TABLET; ORAL)	ER SQUIBB AND SONS	18-064	12-10-79	3982021	09-21-93	
NADOLOL	40MG	CORGARD	(TABLET; ORAL)	ER SQUIBB AND SONS	18-064	12-10-79	3982021	09-21-93	
NADOLOL	160MG	CORGARD	(TABLET; ORAL)	ER SQUIBB AND SONS	18-063	12-10-79	3982021	09-21-93	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
NALIDIXIC ACID 250MG/5ML	NEGGRAM (SUSPENSION; ORAL)	WINTHROP LABS/STERL	17-430 04-17-73	3590036 06-29-88	
NALOXONE HYDROCHLORIDE 1MG/ML	NARCAN (INJECTABLE; INJECTION)	DUPONT PHARMS/DUPONT	16-636 06-14-82		NS 09-24-86
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	NC 09-24-86
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	NS 09-24-86
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	
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	

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
NICLOSAMIDE 500MG	NICLOXIDE (TABLET, CHEWABLE; ORAL)		MILES PHARMS/MILES	18-669	05-14-82		05-14-92	NCE
NICOTINE RESIN COMPLEX EQ 2MG BASE 10MG	NICORETTE (GUM, CHEWING; ORAL)		MERRILL DOW/DOW CHEM	18-612	01-13-84		01-13-94	NCE
NITROGLYCERIN 5MG/ML	PROCARBIA (CAPSULE; ORAL)		Pfizer Labs/Pfizer	18-482	12-31-81	3644627	02-22-89	NDF
NITROGLYCERIN 0.5MG/ML	TRIDIL (INJECTABLE; INJECTION)		AH CRITICAL CARE/AHS	18-537	06-16-83			NDF
NITROGLYCERIN 5MG/ML	NITROSTAT (INJECTABLE; INJECTION)		PARKE-DAVIS/W-L	18-588	12-23-83			NDF
NITROGLYCERIN 5MG/ML	NITRO-BID (INJECTABLE; INJECTION)		MARION LABORATORIES	18-621	01-05-82			NDF
NITROGLYCERIN 1MG/ML	NITRONAL (INJECTABLE; INJECTION)		G POHL-BOSKAMP	18-672	08-30-83			NDF
NITROGLYCERIN 5MG/ML	NITRONAL (INJECTABLE; INJECTION)		G POHL-BOSKAMP	18-672	08-30-83			NDF
NAPROXEN SODIUM 275MG	ANAPROX (TABLET; ORAL)		SYNTEX PR	18-164	09-04-80	3998966	09-09-92	
NAPROXEN 500MG	NAPROSYN (TABLET; ORAL)		SYNTEX PR	17-581	04-15-82	3998966	12-21-93	NS

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
NITROGLYCERIN 0.8MG/ML	NITROL (INJECTABLE; INJECTION)	KREMERS-URBAN	18-774 01-19-83		NDF 09-24-86
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	
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/SML	AVENTYL HCL (SOLUTION; ORAL)	ELI LILLY	14-685 11-06-64	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE/SML	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	

ACTIVE INGREDIENT(S)	TRADE NAME	DOSEAGE FORM, ROUTE	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
NORTRIPTYLINE HYDROCHLORIDE	PAMELOR	(CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-013	06-14-79	3922305	11-25-92	
OXAMINQUINE	VANSIL	(CAPSULE; ORAL)	Pfizer Labs/Pfizer	18-069	07-23-80	3903283	09-02-92	
250MG						3821228	06-28-91	
						3925391	12-09-92	
OXPREMOLOL HYDROCHLORIDE	TRASICOR	(CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166	12-28-83	3483221	12-09-86	NCE
40MG						3483221	12-09-86	NCE
OXPREMOLOL HYDROCHLORIDE	TRASICOR	(CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166	12-28-83	3483221	12-09-86	NCE
80MG						3483221	12-09-86	NCE
OXPREMOLOL HYDROCHLORIDE	TRASICOR	(CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166	12-28-83	3483221	12-09-86	NCE
160MG						3483221	12-09-86	NCE
PANCRUMONIUM BROMIDE	PAVULON	(INJECTABLE; INJECTION)	ORGANON/AKZONA	17-015	10-24-72	3553212	01-05-88	
2MG/ML						3553212	01-05-88	
PANCRUMONIUM BROMIDE	PAVULON	(INJECTABLE; INJECTION)	ORGANON/AKZONA	17-015	10-24-72	3553212	01-05-88	
1MG/ML						3553212	01-05-88	
PARAMETHASONE ACETATE	HALDRONE	(TABLET; ORAL)	ELI LILLY	12-772	04-17-61	3499016	03-03-87	
1MG						3499016	03-03-87	
PARAMETHASONE ACETATE	HALDRONE	(TABLET; ORAL)	ELI LILLY	12-772	04-17-61	3499016	03-03-87	
2MG						3499016	03-03-87	
PENTAGASTRIN	PEPTAVLON	(INJECTABLE; INJECTION)	AYERST LABS/AMHO	17-048	07-26-74	3896103	07-22-92	
0.25MG/ML						3896103	07-22-92	
PENTAMINE ISETHIONATE	PENTAM 300	(INJECTABLE; INJECTION)	LYPHOMED	19-264	10-16-84			
300MG/VIAL								

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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
PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE 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		NDF 10-01-87
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

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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 R229668 12-10-91	NCE
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 R229668 12-10-91	NCE
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		GOLYTEL (POWDER FOR RECONSTITUTION; ORAL)		BRAINFREE LABS	19-011	07-13-84			

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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		
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	

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<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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		
PRALIDOXIME CHLORIDE 300MG/ML	PROTOPAM CHLORIDE (INJECTABLE; INJECTION)	AYERST LABS/AMHO	18-799 12-13-82		NDF 09-24-86
PRALIDOXIME CHLORIDE 300MG/ML	PRALIDOXIME CHLORIDE (INJECTABLE; INJECTION)	SURVIVAL TECHNOLOGY	18-986 12-13-82		NDF 09-24-86
PRAZEPAM 20MG	CENTRAX (CAPSULE; ORAL)	PARKE-DAVIS/W-L	18-144 05-10-82		NS 09-24-86
PRAZICQUANTEL 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	

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PROPRANOLOL HYDROCHLORIDE 80MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	18-553 04-19-83		NDF 09-24-86
PROPRANOLOL HYDROCHLORIDE 90MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 10-18-82		NS 09-24-86
PROPRANOLOL HYDROCHLORIDE 120MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	18-553 04-19-83		NDF 09-24-86
PROPRANOLOL HYDROCHLORIDE 160MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	18-553 04-19-83		NDF 09-24-86
PROTEIN HYDROLYSATE 5%	AMINOSOL 5% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	05-932 01-31-85		
PROTAMINE SULFATE 250MG/VIAL	PROTAMINE SULFATE (INJECTABLE; INJECTION)	UPJOHN	07-413 08-02-84		NS 09-24-86
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	
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

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
STRONGH(S)	(DOSAGE FORM, ROUTE)						
RITODRINE HYDROCHLORIDE	10MG (TABLET; ORAL)	ASTRA PHARM PRODS	18-555	11-12-85	3410944		
RITODRINE HYDROCHLORIDE	10MG/ML	ASTRA PHARM PRODS	18-580	11-12-85	3410944		
RITODRINE HYDROCHLORIDE	15MG/ML	ASTRA PHARM PRODS	18-580	09-27-84	3410944	11-12-85	
SAFFLOWER OIL; SOYBEAN OIL	LIPOSYN II 20% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-991	08-27-84			NP
SAFFLOWER OIL; SOYBEAN OIL	10%; 10% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-991	08-27-84			NP
SAFFLOWER OIL; SOYBEAN OIL	5%; 5% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-997	08-27-84			NP
SARALASIN ACETATE	EQ 0.6MG BASE/ML (INJECTABLE; INJECTION)	NORMICH EATON/P&G	18-009	05-29-81	3932624		
SCOPOLAMINE	1.5MG TRANSDERM-SCOP (FILM, CONTROLLED RELEASE; PERCUTANEOUS)	CIBA/CIBA-GEIGY	17-874	12-31-79	4031894	05-27-92	
SELENIUM SULFIDE	2.5% SETLUN (SHAMPOO/LOTION; TOPICAL)	ABBOTT LABS	07-936	05-17-51			I-3
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			PP

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 4-30-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
SODIUM CHLORIDE 450MG/100ML	SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-497 02-19-82		
SODIUM CHLORIDE 9MG/ML	BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-800 10-29-82		
SODIUM CHLORIDE 9MG/ML	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		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
SODIUM IODIDE, I-123	400 UCI		SODIUM IODIDE I 123 (CAPSULE; ORAL)	BENEDICT NUCLER PHARM	18-671	05-27-82			
SODIUM LACTATE	5MEQ/ML		SODIUM LACTATE IN PLASTIC CONTAINER	ABBOTT LABORATORIES	18-947	09-05-84			NS
SODIUM NITROPRUSSIDE	50MG/VIAL		SODIUM NITROPRUSSIDE (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-581	07-28-82			
SODIUM PHOSPHATE, MONOBASIC	142MG/ML; 276MG/ML		SODIUM PHOSPHATES IN PLASTIC CONTAINER	ABBOTT LABORATORIES	18-892	05-10-83			NP
SOMATROPIN	2 IU/VIAL		ASELLACRIN 2 (INJECTABLE; INJECTION)	SERONO LABS	17-726	07-21-83			NS
SORBITOL	3GM/100ML		SORBITOL 3% IN PLASTIC CONTAINER	TRAVENOL LABS	18-512	05-27-82			
SORBITOL	10%		SOVACAL 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%		SOVACAL 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			
SOYBEAN OIL	20%		LIPOSYN III 20% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-970	09-25-84			
STANZOLOL	2MG		WINSTROL (TABLET; ORAL)	WINTHROP LABS/STERL	12-885	11-30-61	3704295	11-28-89	

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<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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	I-21 09-24-86
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	BACTRIM PEDIATRIC (SUSPENSION; ORAL)	HOFFMANN-LA ROCHE	17-560 12-10-79	RE28636 06-02-87	I-21 09-24-86
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		
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		

ACTIVE INGREDIENT(S)	TRADE NAME	(DOSAGE FORM, ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
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			NDF 09-24-86
SULFASALAZINE 500MG	SULFASALAZINE	(TABLET, ENTERIC COATED; ORAL)	BOLAR PHARMACEUTICAL	88-052	05-24-83			NDF 09-24-86
SULINDAC 150MG	CLINORIL	(TABLET; ORAL)	MS&D/MERCK	17-911	09-27-78			3654349 3725548 04-04-89
SULINDAC 200MG	CLINORIL	(TABLET; ORAL)	MS&D/MERCK	17-911	09-27-78			3654349 3725548 04-04-89

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<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
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		I-31 09-24-86
TECHNETIUM, TC-99M, ALBUMIN COLLOID KIT N/A	MICROLITE (INJECTABLE; INJECTION)	MED DIAG/NE NUCLEAR	18-263 03-25-83		
TECHNETIUM, TC-99M, DISOFENIN KIT N/A	HEPATOLITE (INJECTABLE; INJECTION)	MED DIAG/NE NUCLEAR	18-467 03-16-82		NP 09-24-86
TECHNETIUM, TC 99M, PYROPHOSPHATE KIT N/A	PHOSPHOTEC (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-680 10-20-76		I-9 09-24-86
TECHNETIUM, TC-99M, GLUCEPTATE KIT N/A	TECHNESCAN GLUCEPTATE (INJECTABLE; INJECTION)	MS&D/MERCK	18-272 01-27-82		
TECHNETIUM, TC-99M, MEDRONATE N/A	OSTEOLITE (INJECTABLE; INJECTION)	MED DIAG/NE NUCLEAR	17-972 12-16-77		
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	NP 09-24-86
TERBUTALINE SULFATE 0.2MG/INH	BRETHAIRE (AEROSOL; INHALATION)	GEIGY/CIBA-GEIGY	18-762 08-17-84	3937838 02-10-93 4011258 03-08-94	NDF 09-24-86

ACTIVE INGREDIENT(S)
STRENGTH(S)

TRADE NAME
(DOSAGE FORM, ROUTE)

NDA NO.
APPROVAL DATE

PATENT NO.
EXP. DATE

EXCLUSIVITY
EXP. DATE

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TERBUTALINE SULFATE	BRICANYL	HERRELL DOW/DOW CHEM	18-000	03-19-85	3937838	02-10-93	4011258	03-08-94
0.2MG/INH	(AEROSOL; INHALATION)							
TERBUTALINE SULFATE	BRICANYL	HERRELL DOW/DOW CHEM	17-466	03-25-74	3937838	02-10-93	4011258	03-08-94
1MG/ML	(INJECTABLE; INJECTION)							
2.5MG	BRICANYL	HERRELL DOW/DOW CHEM	17-618	04-22-75	3937838	02-10-93	4011258	03-08-94
TERBUTALINE SULFATE	(TABLET; ORAL)							
5MG	BRICANYL	HERRELL DOW/DOW CHEM	17-618	04-22-75	3937838	02-10-93	4011258	03-08-94
TERBUTALINE SULFATE	(TABLET; ORAL)							
2.5MG	BRICANYL	GEIGY/CIBA-GEIGY	17-849	05-17-76	3937838	02-10-93	4011258	03-08-94
TERBUTALINE SULFATE	(TABLET; ORAL)							
5MG	BRICANYL	GEIGY/CIBA-GEIGY	17-849	05-17-76	3937838	02-10-93	4011258	03-08-94
TERBUTALINE SULFATE	(TABLET; ORAL)							
1MG/ML	BRETHINE	GEIGY/CIBA-GEIGY	18-571	11-30-81	3937838	02-10-93	4011258	03-08-94
TERBUTALINE SULFATE	(INJECTABLE; INJECTION)							
THALLOUS CHLORIDE, TL-201	THALLOUS CHLORIDE TL 201	MEDI-PHYSICS	18-110	02-01-82				
2MC/ML	(INJECTABLE; INJECTION)							
THALLOUS CHLORIDE, TL-201	THALLOUS CHLORIDE TL 201	AMERSHAM/RADIOCHEM	18-548	12-30-82				
1MC/ML	(INJECTABLE; INJECTION)							

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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	
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 11-09-89
TOCAINIDE HYDROCHLORIDE 600MG	TONOCARD (TABLET; ORAL)	MS&D/MERCK	18-257 11-09-84	4218477 08-19-97 4237068 12-02-97	NCE 11-09-89
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		
TOLAZOLINE HYDROCHLORIDE 25MG/ML	PRISCOLINE (INJECTABLE; INJECTION)	CIBA/CIBA-GEIGY	06-403 02-22-85		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	(DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	APPROVAL DATE	PATENT NO.	EXP. DATE	EXCLUSIVITY
TOLMETIN SODIUM	EQ 200MG BASE	TOLLECTIN	(TABLET; ORAL)	MCNEIL LABORATORIES	17-628	03-24-76	08-14-90	3752826	
TOLMETIN SODIUM	EQ 400MG BASE	TOLLECTIN DS	(CAPSULE; ORAL)	MCNEIL LABORATORIES	18-084	10-30-79	08-14-90	3752826	
TRAZODONE HYDROCHLORIDE	150MG	DESYREL	(TABLET; ORAL)	MEAD JOHNSON/B-M	18-207	03-25-85			
TRETININ	0.05%	TRETIN-A	(SOLUTION; TOPICAL)	ORTHO PHARMACEUTICAL	16-921	10-20-71	04-24-90	3729568	
TRETININ	0.1%	TRETIN-A	(CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-340	01-26-73	04-24-90	3729568	
TRETININ	0.05%	TRETIN-A	(CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-522	07-19-74	04-24-90	3729568	
TRETININ	0.01%	TRETIN-A	(GEL; TOPICAL)	ORTHO PHARMACEUTICAL	17-955	10-05-78	04-24-90	3729568	
TRETININ	0.025%	TRETIN-A	(GEL; TOPICAL)	ORTHO PHARMACEUTICAL	17-579	04-18-75	04-24-90	3729568	
TRIAMCINOLONE ACETONIDE	0.25MG/INH	AZMACORT	(AEROSOL; INHALATION)	WILLIAM H ROBER	18-117	04-23-83	08-05-92	3927806	
TRIAZOLAM	0.125MG	HALCION	(TABLET; ORAL)	UPJOHN	17-892	04-26-85	09-14-93	3980790	NCE
TRIAZOLAM	0.25MG	HALCION	(TABLET; ORAL)	UPJOHN	17-892	11-15-82	09-14-93	3980790	NCE
TRIAZOLAM	0.5MG	HALCION	(TABLET; ORAL)	UPJOHN	17-892	11-15-82	09-14-93	3980790	NCE

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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
TRIMETHOPRIM 200MG	PROLOPRIM (TABLET; ORAL)	BURROUGHS WELLCOME	17-943 07-14-82		NS 09-24-86
TRIMETHOPRIM 200MG	TRIMPEX 200 (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-952 11-09-82		NS 09-24-86
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		NS 09-24-86
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		NR 09-24-86
VERAPAMIL HYDROCHLORIDE 120MG	ISOPTIN (TABLET; ORAL)	KNOLL PHARMACEUTICAL	18-593 03-08-82		NR 09-24-86
VERAPAMIL HYDROCHLORIDE 80MG	CALAN (TABLET; ORAL)	SEARLE/SEARLE PHARMS	18-817 09-10-84		NR 09-24-86
VERAPAMIL HYDROCHLORIDE 120MG	CALAN (TABLET; ORAL)	SEARLE/SEARLE PHARMS	18-817 09-10-84		NR 09-24-86
VERAPAMIL HYDROCHLORIDE 2.5MG/ML	CALAN (INJECTABLE; INJECTION)	SEARLE PHARMS	18-925 03-30-84		

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