

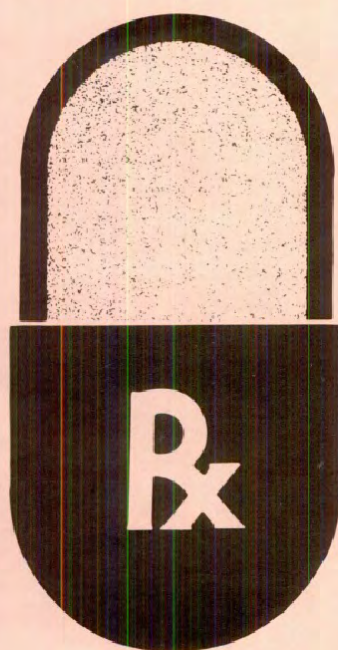
APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations



The "Orange Book"

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APPROVED PRESCRIPTION DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

5TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUGS AND BIOLOGICS

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UNIVERSITY OF MICHIGAN

**CUMULATIVE
SUPPLEMENT 12
AUG'84 - AUG'85**

SERIAL

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

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

B. ADDENDUM: DESI Pending List

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

II. SPECIAL NOTES

A. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

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

B. PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

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

(continued)

ProductsFederal 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)
tranilcypromine 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."

E. DISCONTINUED APPROVED PRODUCT IDENTIFIER ("d")

The Drug Price Competition and Patent Term Restoration Act of 1984 requires the FDA to make publicly available an alphabetical list of approved drug products, with the application number and approval date, for each product approved January 1, 1982 and thereafter, and an indication whether in vitro and/or in vivo bioequivalence studies are required for ANDA approval. This publication, Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 5th Edition, and its monthly supplements is being used to satisfy this new requirement. The Agency will no longer delete products from this publication when an applicant discontinues marketing for economic reasons, as it had done in the past. The only cause for product removal from the publication will be for safety or efficacy reasons. Products discontinued from marketing will be flagged in the Cumulative Supplement and future editions of this publication with the "d" symbol to designate their nonmarketed status.

F. SUBSCRIPTION FORM

A subscription form for the publication has been provided at the end of this supplement for ordering next year's edition.

III. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

USE OF REPORT

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

Drug Product Definition

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

New Molecular Entity

The active moiety has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or part of a combination.

Drug Product Count

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

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

A. COUNTS CUMULATIVE BY QUARTERS

JULY '85 (BASELINE)

CATEGORIES COUNTED

DRUG PRODUCTS LISTED 8048
 SINGLE SOURCE 2096 (26.0%)
 MULTISOURCE (1) 5952 (74.0%)
 THERAPEUTICALLY EQUIVALENT 4864 (60.5%)
 NOT THERAPEUTICALLY EQUIVALENT 1054 (13.2%)
 EXCEPTIONS (2) 25 (0.3%)

NEW MOLECULAR ENTITIES APPROVED -
 NUMBER OF APPLICANTS 306

B. ACTIVITY FOR SUPPLEMENT NUMBER 12

CUMULATIVE

AUG '85

DRUG PRODUCTS ADDED:	41	41
NEWLY APPROVED	40	40
DESI EFFECTIVE	1	1
REMARKETED	0	0
DRUG PRODUCTS REMOVED:	1	1
WITHDRAWN APPROVAL	0	0
RX TO OTC SWITCH	0	0
DISCONTINUED MARKETING	1	1
NET GAIN IN DRUG PRODUCTS	40	40
SINGLE SOURCE PRODUCTS APPROVED	7	7
↑ MULTISOURCE DRUG PRODUCTS APPROVED	34	34
NEW MOLECULAR ENTITIES APPROVED:	2	2
AS THE ENTITY	0	0
AS A SALT, ESTER OR DERIVATIVE	2	2
OF THE ENTITY		

- (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)

APPROVED PRESCRIPTION DRUG PRODUCTS

DRUG PRODUCT LIST

CUMULATIVE SUPPLEMENT NUMBER 12 / AUGUST '84 - AUGUST '85

1

ACEBUTOLOL HYDROCHLORIDE (PAGE 3-1)

CAPSULE; ORAL

SECTRAL
IVES LABS/AMHO EQ 200MG BASEM
EQ 400MG BASEM

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL

AA ACETAMINOPHEN N/ CODEINE #3
LEMON N 88628
AA ACETAMINOPHEN N/ CODEINE #4
LEMON N 88629
/AA/ ACETAMINOPHEN N/ CODEINE PHOSPHATE #4/
ZENITH LABORATORIES// 300MG; 60MG/
/N' 87663/

ACETAMINOPHEN; BUTALBITAL (PAGE 3-1)

CAPSULE; ORAL

AB BUTALBITAL AND ACETAMINOPHEN
DM GRAHAM LABS 650MG; 50MGM
AB PHRENLIN FORTE
CARNRICK/GM CARNRICK 650MG; 50MGM

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-2)

CAPSULE; ORAL

AA ACETAMINOPHEN AND HYDROCODONE BITARTRATE
CENTRAL PHARMS 500MG; 5MGM
AA DM GRAHAM LABS 500MG; 5MGM
> ADD > AA 500MG; 5MGM

TABLET; ORAL

AB BUTALBITAL AND ACETAMINOPHEN
DANBURY PHARMACAL 325MG; 50MGM
AB PHRENLIN
CARNRICK/GM CARNRICK 325MG; 50MGM

TABLET; ORAL

AA ACETAMINOPHEN AND HYDROCODONE BITARTRATE
/AA/ CENTRAL PHARMS/
500MG; 5MG/
GO-GENIC

ACETAMINOPHEN; BUTALBITAL; CAFFEINE (PAGE 3-1)

CAPSULE; ORAL

AB BUTALBITAL, ACETAMINOPHEN, CAFFEINE
DM GRAHAM LABS 325MG; 50MG; 40MGM
AB 325MG; 50MG; 40MGM
AB 325MG; 50MG; 40MGM
AB 325MG; 50MG; 40MGM
AB 325MG; 50MG; 40MGM
AB 325MG; 50MG; 40MGM
AB 325MG; 50MG; 40MGM
AB 325MG; 50MG; 40MGM
AB 325MG; 50MG; 40MGM

TABLET; ORAL

AA ACETAMINOPHEN AND HYDROCODONE BITARTRATE
CENTRAL PHARMS 500MG; 5MG
AA HYDROCODONE BITARTRATE N/ ACETAMINOPHEN
BARR LABORATORIES 500MG; 5MG

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 3-2)

CAPSULE; ORAL

TYLOX
MCNEIL PHARM 500MG; 5MGM
TYLOX-325
MCNEIL PHARM 325MG; 5MGM
N 88790
N 88246

TABLET; ORAL

/500MG;
OXYCET
AA HALSEY DRUG 325MG; 5MGM
N 87463

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-2)

TABLET; ORAL

AB DARVOCT-N 100 650MG; 100MG
ELI LILLY
AB DARVOCT-N 50 325MG; 50MG
ELI LILLY
AB PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN
BARR LABORATORIES 325MG; 50MG
AB 650MG; 100MG
AB MYLAN PHARMS 650MG; 100MG
AB ZENITH LABORATORIES 650MG; 100MG
> ADD > AB PROVOCT 100
LEMON 650MG; 100MG
N 17122
N 17122
N 70115
N 70116
N 70145
N 70146
N 70107

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL

AA ACETAMINOPHEN AND CODEINE PHOSPHATE
ZENITH LABORATORIES 300MG; 60MG
AA ACETAMINOPHEN N/ CODEINE #2
LEMON 300MG; 15MGM

ACETIC ACID, GLACIAL (PAGE 3-3)

SOLUTION/DROPS; OTIC

ACETIC ACID

AI THAMES PHARMACAL 22M
 > ADD > BOROFAIR 22M
 > ADD > AI PHARMAFAIR 22M

N 62562
 N 62562

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

SOLUTION/DROPS; OTIC

HYDROCORTISONE AND ACETIC ACID

AI THAMES PHARMACAL 22;12M

N 19374

ACYCLOVIR (PAGE 3-4)

CAPSULE; ORAL

ZOVIRAX

BURROUGHS WELLCOME 200MG

N 18828

ALBUMIN, IODINATED, I-125, SERUM (PAGE 3-4)

INJECTABLE; INJECTION

ALBUMOTOPE 125 I

ER SQUIBB AND SONS 5-50 UCI/AMP

N 17836

ALBUTEROL SULFATE (PAGE 3-5)

SYRUP; ORAL

PROVENTIL

SCHERING

EQ 2MG BASE/5ML

N 18062

ALLOPURINOL (PAGE 3-5)

TABLET; ORAL

ALLOPURINOL

AB SOLAR PHARMACEUTICAL 100MG

AB 300MG

AB CHELSEA LABORATORIES 100MG

AB 300MG

AB DANBURY PHARMACAL 100MG

AB 300MG

N 18241
 N 18241
 N 18785
 N 18785
 N 18832
 N 18877

AMINOCELLIN (PAGE 3-6)

INJECTABLE; INJECTION

COACTIN

HOFFMANN-LA ROCHE

250MG/VIAL

500MG/VIAL

1GM/VIAL

N 50565
 N 50565
 N 50565

INJECTABLE; INJECTION

AMINOPHYLLINE IN SODIUM CHLORIDE 0.45%

ABBOTT LABORATORIES 100MG/100ML; 450MG/100ML

200ML/100ML; 450MG/100ML

N 88147
 N 88147

AMIKACIN SULFATE (PAGE 3-6)

INJECTABLE; INJECTION

AMIKIN

BRISTOL LABS/B-M

EQ 50MG BASE/ML

EQ 250MG BASE/ML

N 62562
 N 62562

AMINO ACIDS (PAGE 3-6)

INJECTABLE; INJECTION

AMINOSYN-HBC 7%

ABBOTT LABORATORIES 72M

BRANCHAMIN 4%

TRAVENOL LABS 42M

BRANCHAMIN 4% IN PLASTIC CONTAINER

TRAVENOL LABS 42M

TRAVASOL 10% N/O ELECTROLYTES IN PLASTIC CONTAINER

TRAVENOL LABS 102M

TRAVASOL 5.5% N/O ELECTROLYTES IN PLASTIC CONTAINER

TRAVENOL LABS 5.52M

TRAVASOL 8.5% N/O ELECTROLYTES IN PLASTIC CONTAINER

TRAVENOL LABS 8.52M

N 19374
 N 18678
 N 18684
 N 18931
 N 18931
 N 18931

AMINO ACIDS; DEXTROSE (PAGE 3-7)

INJECTABLE; INJECTION

AMINOSYN 3.5% N/ DEXTROSE 25% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 3.5%; 25GM/100ML

AMINOSYN 3.5% N/ DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 3.5%; 5GM/100ML

AMINOSYN 4.25% N/ DEXTROSE 25% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 4.25%; 25GM/100ML

N 19118
 N 19120
 N 19119

AMINOPHYLLINE (PAGE 3-8)

INJECTABLE; INJECTION

AMINOPHYLLINE

AP SOLOPAK LABORATORIES 25MG/ML

AP 25MG/ML

AB

N 18241
 N 18241

TABLET; ORAL

AMINOPHYLLINE

AB /CORP. LABORATORIES/ 200MG/

AB 200MG

N 85261
 N 85261

AMINOPHYLLINE; SODIUM CHLORIDE (PAGE 3-9)

INJECTABLE; INJECTION

AMINOPHYLLINE IN SODIUM CHLORIDE 0.45%

ABBOTT LABORATORIES 100MG/100ML; 450MG/100ML

200ML/100ML; 450MG/100ML

N 88147
 N 88147

AMINOPHYLLINE; SODIUM CHLORIDE (PAGE 3-9)INJECTABLE; INJECTION

<u>AMINOPHYLLINE IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER</u>	
AP	ABBOTT LABORATORIES 100MG/100ML; 450MG/100ML N 18924
AP	200MG/100ML; 450MG/100ML N 18924
	400MG/100ML; 450MG/100ML N 18924
	500MG/100ML; 450MG/100ML N 18924
	/N 88847/
	/AMINOPHYLLINE 0.45% IN SODIUM CHLORIDE 0.45% N 88847/
	/ABBOTT LABORATORIES 50MG/100ML; 450MG/100ML/
	/AMINOPHYLLINE 0.12% IN SODIUM CHLORIDE 0.45% N 88847/
	/ABBOTT LABORATORIES 100MG/100ML; 450MG/100ML/
	/AMINOPHYLLINE 0.2% IN SODIUM CHLORIDE 0.45% N 88847/
	/ABBOTT LABORATORIES 200MG/100ML; 450MG/100ML/

AMINOPHYLLINE HYDROCHLORIDE (PAGE 3-10)TABLET; ORALAMINOPHYLLINE MOL
AM THERAPEUTICS

BP	25MG	N 88672
BP	50MG	N 88673
BP	75MG	N 88674
BP	100MG	N 88675
BP	10MG	N 88697
BP	25MG	N 88698
BP	50MG	N 88699
BP	75MG	N 88700
BP	100MG	N 88701
BP	150MG	N 88702
BP	10MG	N 88804
AB	25MG	N 88805
AB	50MG	N 88805
AB	75MG	N 88806
AB	100MG	N 88807
BP	10MG	N 88808
BP	25MG	N 88809
BP	50MG	N 88810
BP	75MG	N 88811
BP	100MG	N 88812
BP	150MG	N 88813
AB	10MG	N 88814
AB	25MG	N 88815
AB	50MG	N 88816
AB	75MG	N 88817
AB	100MG	N 88818
AB	150MG	N 88819
BP	25MG	N 88820
BP	50MG	N 88821
BP	75MG	N 88822
BP	100MG	N 88823
BP	150MG	N 88824
BP	25MG	N 88825
BP	50MG	N 88826
BP	75MG	N 88827
BP	100MG	N 88828

SUPERPHARMAMINOPHYLLINE LACTATE (PAGE 3-12)LOTION; TOPICAL

	<u>AMINOPHYLLINE LACTATE</u>	EQ 12% ACIDM	N 19155
	BRISTOL-MYERS		

AMOXICILLIN (PAGE 3-12)CAPSULE; ORAL

	<u>AMOXICILLIN</u>	250MG	N 62528
	LABORATORIOS ATRAL	500MG	N 62528

UTIMOX

AB	PARKE-DAVIS/N-L	250MG	N 62107
AB		500MG	N 62107

AMOXICILLIN; POTASSIUM CLAVULANATE (PAGE 3-13)POWDER FOR RECONSTITUTION; ORAL

	<u>AUGMENTIN '125'</u>	BEECHAM LABS/BEECHAM 125MG/5ML; EQ 31.25MG ACID/5ML	N 50575
	<u>AUGMENTIN '250'</u>	BEECHAM LABS/BEECHAM 250MG/5ML; EQ 62.5MG ACID/5ML	N 50575

TABLET; ORAL

	<u>AUGMENTIN '250'</u>	BEECHAM LABS/BEECHAM 250MG; EQ 125MG ACIDM	N 50564
	<u>AUGMENTIN '500'</u>	BEECHAM LABS/BEECHAM 500MG; EQ 125MG ACIDM	N 50564

TABLET, CHEWABLE; ORAL

	<u>AUGMENTIN '125'</u>	BEECHAM LABS/BEECHAM 125MG; EQ 31.25MG ACIDM	N 50597
	<u>AUGMENTIN '250'</u>	BEECHAM LABS/BEECHAM 250MG; EQ 62.5MG ACIDM	N 50597

AMPHETAMINE SULFATE (PAGE 3-13)TABLET; ORAL

	<u>AMPHETAMINE SULFATE</u>	5MG	N 83901
	LANNETT	10MG	N 83901

AMPCILLIN SODIUM (PAGE 3-14)INJECTABLE; INJECTION

AP	<u>AMPCILLIN SODIUM</u>	EQ 500MG BASE/VIAL	N 62565
AP	ELI LILLY	EQ 1GM BASE/VIAL	N 62565

AMPCILLIN/AMPCILLIN TRIHYDRATE (PAGE 3-14)

AMPCILLIN

AB 3 DRUMMER/PHOENIX

EQ 250MG BASE
EQ 500MG BASE

N 61387
N 61387

SULFATE (PAGE 3-20)

AB 3 DRUMMER/PHOENIX

EQ 250MG BASE
EQ 500MG BASE

N 50168
N 50168

ARGININE HYDROCHLORIDE (PAGE 3-16)

AB 3 DRUMMER/PHOENIX

EQ 250MG BASE
EQ 500MG BASE

N 61387
N 61387

BENZYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

AB 3 DRUMMER/PHOENIX

N 50168
N 50168

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-16)

AB 3 DRUMMER/PHOENIX

EQ 250MG BASE
EQ 500MG BASE

N 61387
N 61387

BENZYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

AB 3 DRUMMER/PHOENIX

N 50168
N 50168

AB 3 DRUMMER/PHOENIX

EQ 250MG BASE
EQ 500MG BASE

N 61387
N 61387

BENZYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

AB 3 DRUMMER/PHOENIX

N 50168
N 50168

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

AB 3 DRUMMER/PHOENIX

EQ 250MG BASE
EQ 500MG BASE

N 61387
N 61387

BENZYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

AB 3 DRUMMER/PHOENIX

N 50168
N 50168

AB 3 DRUMMER/PHOENIX

EQ 250MG BASE
EQ 500MG BASE

N 61387
N 61387

BENZYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

AB 3 DRUMMER/PHOENIX

N 50168
N 50168

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE (PAGE 3-18)

AB 3 DRUMMER/PHOENIX

EQ 250MG BASE
EQ 500MG BASE

N 61387
N 61387

BENZYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

AB 3 DRUMMER/PHOENIX

N 50168
N 50168

AB 3 DRUMMER/PHOENIX

EQ 250MG BASE
EQ 500MG BASE

N 61387
N 61387

BENZYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

AB 3 DRUMMER/PHOENIX

N 50168
N 50168

AB 3 DRUMMER/PHOENIX

EQ 250MG BASE
EQ 500MG BASE

N 61387
N 61387

BENZYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

AB 3 DRUMMER/PHOENIX

N 50168
N 50168

AB 3 DRUMMER/PHOENIX

EQ 250MG BASE
EQ 500MG BASE

N 61387
N 61387

BENZYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

AB 3 DRUMMER/PHOENIX

N 50168
N 50168

AB 3 DRUMMER/PHOENIX

EQ 250MG BASE
EQ 500MG BASE

N 61387
N 61387

BENZYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

AB 3 DRUMMER/PHOENIX

N 50168
N 50168

BETAMETHASONE VALERATE (PAGE 3-22)

CREAM; TOPICAL

BETAMETHASONE VALERATE
EQ 0.1% BASEM
THAMES PHARMACAL
AB N 70062
/AB/ N 18862
BETATREX N 18862
/SAYAGE N 18862
LABS/BYK-6LDN/ N 18862
EQ 0.1% BASE
AB N 70050
SAVAGE N 70050
LABS/BYK-6LDN N 70050
VALMAC N 70050
ABC N 70050
NMC LABORATORIES N 70050
EQ 0.1% BASEM

LOTION; TOPICAL

BETA-VAL
LEMON
EQ 0.1% BASEM
AB N 70072
BETAMETHASONE VALERATE
AB N 70052
NATL PHARM MFG/BARRE N 70052
EQ 0.1% BASEM

OINTMENT; TOPICAL

VALMAC
NMC LABORATORIES
EQ 0.1% BASEM
AB N 70051
VALMAC N 70051
NMC LABORATORIES N 70051
EQ 0.1% BASEM

> ADD > BETAXOLOL HYDROCHLORIDE (PAGE 3-23)

> ADD > SOLUTION/DROPS; OPHTHALMIC
 > ADD > BETOPTIC
 > ADD > ALCON LABORATORIES EQ 0.5% BASEM

BITOLTEROL MESYLATE (PAGE 3-24)

AEROSOL; INHALATION
 TORNALATE
 WINTHROP-BREON/STERL 0.37MG/INH

BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE (PAGE 3-24)

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

BROMPHENTRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-25)

SYRUP; ORAL
BIPHETANE DO
AB N 88904
BAY LABORATORIES N 88904
2MG/5ML; 10MG/5ML;
12.5MG/5ML

BROMPHENTRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-25)

SYRUP; ORAL
BROMANATE DO
AA N 88723
NATL PHARM MFG/BARRE N 88723
2MG/5ML; 10MG/5ML;
12.5MG/5ML
DIPHETANE-DO
AA N 11694
AH ROBINS N 11694
2MG/5ML; 10MG/5ML;
12.5MG/5ML

BROMPHENTRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOPHEDRINE HYDROCHLORIDE (PAGE 3-25)

SYRUP; ORAL
BIPHETANE DX
AA N 88611
BAY LABORATORIES N 88611
2MG/5ML; 10MG/5ML; 30MG/5ML
BROMANATE DH
AA N 88722
NATL PHARM MFG/BARRE N 88722
2MG/5ML; 10MG/5ML; 30MG/5ML
DIPHETANE-DX
AA N 11694
AH ROBINS N 11694
2MG/5ML; 10MG/5ML; 30MG/5ML
AA N 19279
2MG/5ML; 10MG/5ML; 30MG/5ML

BROMPHENTRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-25)

ELIXIR; ORAL
BIPHETAP
AA N 88687
BAY LABORATORIES N 88687
4MG/5ML; 25MG/5ML
BROMANATE
AA N 88688
NATL PHARM MFG/BARRE N 88688
4MG/5ML; 25MG/5ML

BUMETANIDE (PAGE 3-25)

TABLET; ORAL
BUMEX
HOFFMANN-LA ROCHE 2MG

BUTABARBITAL SODIUM (PAGE 3-26)

ELIXIR; ORAL
/SODIUM BUTABARBITAL/
BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM
AA 15MG
AA 30MG

N 88632
 N 88631

CALCITONIN, SALMON (PAGE 3-27)

INJECTABLE; INJECTION

CALCIHAR
/ARMOUR PHARM/

/400 MC UNITS/ML/
/400 MC UNITS/ML/
200 IU/ML
400 IU/VIAL

N 17769/
N 17769/
N 17769
N 17497

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

SOLUTION; INTRAPERITONEAL

DELFLEX W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
DELHED
25.7MG/100ML; 1.56H/100ML;
15.2MG/100ML; 56.7MG/100ML;
392MG/100ML

N 18883

DELFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM IN PLASTIC CONTAINER
DELHED
25.7MG/100ML; 1.56H/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML

N 18883

DELFLEX W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
DELHED
25.7MG/100ML; 2.56H/100ML;
15.2MG/100ML; 56.7MG/100ML;
392MG/100ML

N 18883

DELFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM IN PLASTIC CONTAINER
DELHED
25.7MG/100ML; 2.56H/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML

N 18883

DELFLEX W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
DELHED
25.7MG/100ML; 4.256H/100ML;
15.2MG/100ML; 56.7MG/100ML;
392MG/100ML

N 18883

DELFLEX W/ DEXTROSE 4.25% LOW MAGNESIUM IN PLASTIC CONTAINER
DELHED
25.7MG/100ML; 4.256H/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML

N 18883

DZANEAL PD-1 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
TRAVENOL LABS
25.7MG/100ML; 1.56H/100ML;
15.2MG/100ML; 56.7MG/100ML;
392MG/100ML

N 17512

DZANEAL PD-1 W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
TRAVENOL LABS
25.7MG/100ML; 2.56H/100ML;
15.2MG/100ML; 56.7MG/100ML;
392MG/100ML

N 17512

DZANEAL PD-1 W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
TRAVENOL LABS
25.7MG/100ML; 4.256H/100ML;
15.2MG/100ML; 56.7MG/100ML;
392MG/100ML

N 17512

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

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND
LACTATED RINGER'S IN PLASTIC CONTAINER

AP TRAVENOL LABS
20MG/100ML; 56H/100ML;
105MG/100ML; 600MG/100ML;
310MG/100ML

N 19367

AP
20MG/100ML; 56H/100ML;
179MG/100ML; 600MG/100ML;
310MG/100ML

N 19367

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND
LACTATED RINGER'S IN PLASTIC CONTAINER

AP TRAVENOL LABS
20MG/100ML; 56H/100ML;
254MG/100ML; 600MG/100ML;
310MG/100ML

N 19367

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND
LACTATED RINGER'S IN PLASTIC CONTAINER

AP TRAVENOL LABS
20MG/100ML; 56H/100ML;
179MG/100ML; 600MG/100ML;
310MG/100ML

N 19367

AP
20MG/100ML; 56H/100ML;
328MG/100ML; 600MG/100ML;
310MG/100ML

N 19367

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND
LACTATED RINGER'S IN PLASTIC CONTAINER

AP TRAVENOL LABS
20MG/100ML; 56H/100ML;
254MG/100ML; 600MG/100ML;
310MG/100ML

N 19367

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND
LACTATED RINGER'S IN PLASTIC CONTAINER

AP TRAVENOL LABS
20MG/100ML; 56H/100ML;
328MG/100ML; 600MG/100ML;
310MG/100ML

N 19367

AP
20MG/100ML; 56H/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

/PLASMA-LYTE R IN PLASTIC CONTAINER/
PLASMA-LYTE R IN PLASTIC CONTAINER

CALCIUM GLUCEPATE (PAGE 3-30)

INJECTABLE; INJECTION

CALCIUM GLUCEPATE
/AP/ /ANT. MEDICATION SYS//ED 50MG CALCIUM/5ML/

/N 87455/

CAPTOPRIL (PAGE 3-31)

TABLET; ORAL

CAPOTEN

ER SQUIBB AND SONS 12.5MG

N18343

INJECTABLE; INJECTION

CLAFORAN IN DEXTROSE 5% IN PLASTIC CONTAINER

HOECHST-ROUSSEL

EQ 20MG BASE/ML; 50MG/ML
EQ 40MG BASE/ML; 50MG/ML
N 50576
N 50576

CAPTOPRIL; HYDROCHLOROTHIAZIDE (PAGE 3-31)

TABLET; ORAL

CAPOZIDE 25/15

ER SQUIBB AND SONS 25MG;15MG

N 18709

CAPOZIDE 25/25

ER SQUIBB AND SONS 25MG;25MG

N 18709

CAPOZIDE 50/15

ER SQUIBB AND SONS 50MG;15MG

N 18709

CAPOZIDE 50/25

ER SQUIBB AND SONS 50MG;25MG

N 18709

CARBACHOL (PAGE 3-31)

/SOLUTION/PROPS; OPHTHALMIC/
INJECTABLE; INJECTION

N 50517

CEFAZOLIN SODIUM; DEXTROSE (PAGE 3-33)

INJECTABLE; INJECTION

ANCEF IN DEXTROSE 5% IN PLASTIC CONTAINER

EQ 10MG BASE/ML; 50MG/ML
EQ 20MG BASE/ML; 50MG/ML

N 50566
N 50566

INJECTABLE; INJECTION

MEFOXIN IN DEXTROSE 5% IN PLASTIC CONTAINER

MS&D/MERCK

N 50581
N 50581

CEFOXITIN SODIUM; SODIUM CHLORIDE (PAGE 3-33)

CEFORANIDE (PAGE 3-33)

INJECTABLE; INJECTION

PRECEF

BRISTOL LABS/B-M

500MG/VIAL

16M/VIAL

26M/VIAL

106M/VIAL

206M/VIAL

N 62579
N 62579
N 62579
N 62579

INJECTABLE; INJECTION

MEFOXIN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

MS&D/MERCK

N 50581
N 50581

CEFTAZIDIME (PAGE 3-33)

INJECTABLE; INJECTION

FORTAZ

GLAXO

500MG/VIAL

16M/VIAL

26M/VIAL

66M/VIAL

N 50578
N 50578
N 50578
N 50578

CEFTOXIME SODIUM (PAGE 3-33)

INJECTABLE; INJECTION

CLAFORAN

HOECHST-ROUSSEL

/EQ 500MG BASE/VIAL/
EQ 106M BASE/VIAL

/N 50547/
N 50547

CEFTIZOXIME SODIUM; DEXTROSE (PAGE 3-33)

INJECTABLE; INJECTION

CEFIZOX IN DEXTROSE 5% IN PLASTIC CONTAINER

SK&F LABORATORIES

EQ 20MG BASE/ML; 50MG/ML
EQ 40MG BASE/ML; 50MG/ML
N 50589
N 50589

CETIRIZINE SODIUM (PAGE 3-33)

INJECTABLE; INJECTION
ROCEPHIN
HOFFMANN-LA ROCHE

EQ 250MG BASE/VIALM
EQ 250MG BASE/VIALM
EQ 500MG BASE/VIALM
EQ 500MG BASE/VIALM
EQ 1GM BASE/VIALM
EQ 1GM BASE/VIALM
EQ 2GM BASE/VIALM
EQ 10GM BASE/VIALM

N 50585
N 62510
N 50585
N 62510
N 50585
N 62510
N 50585
N 50585

CONCENTRATE; ORAL

CHLORPROPAMIDE HCL
/AA/
/AA/
CHLORPROPAMIDE HCL INTENSOL
AA
AA

ROXANE LABORATORIES 30MG/ML
100MG/ML

N 88157
N 88158
N 88157
N 88158

CELLULOSE SODIUM PHOSPHATE (PAGE 3-34)

POWDER; ORAL
CALCIBIND
MISSION PHARMACAL

300GM/BOTM

N 18757

CEPHALOTHIN SODIUM (PAGE 3-34)

INJECTABLE; INJECTION
CEPHALOTHIN
INTL MEDICATION SYS

EQ 1GM BASE/VIALM
EQ 2GM BASE/VIALM
EQ 4GM BASE/VIALM
EQ 500MG BASE/VIALM

N 62426
N 62426
N 62426
N 62426

CHLORDIAZEPoxide HYDROCHLORIDE (PAGE 3-37)

CAPSULE; ORAL
CHLORDIAZEPoxide HCL
LEMMON

5MG
10MG
25MG
5MG
10MG
25MG

N 88705
N 88706
N 88707
N 88987
N 88986
N 88988

CHLOROTHIAZIDE (PAGE 3-38)

TABLET; ORAL
CHLOROTHIAZIDE
DRUMMER/PHOENIX

250MG

N 85485

CHLORPHERTERMINE HYDROCHLORIDE (PAGE 3-40)

TABLET; ORAL
PRE-SATE
PARKE-DAVIS/N-L

EQ 65MG BASE

N 14696

CHLORPROPAMIDE HYDROCHLORIDE (PAGE 3-40)

CONCENTRATE; ORAL

CHLORPROPAMIDE HCL
/AA/
/AA/
CHLORPROPAMIDE HCL INTENSOL
AA
AA

ROXANE LABORATORIES 30MG/ML
100MG/ML

N 88157
N 88158
N 88157
N 88158

TABLET; ORAL

CHLORPROPAMIDE HCL
CORD LABORATORIES
BP
BP
BP
BP
BP

10MG
25MG
50MG
100MG
200MG

N 80439
N 80439
N 80439
N 80439
N 80439

SONAZINE
/CORD LABORATORIES/
BP
BP
BP
BP
BP

10MG
25MG
50MG
100MG
200MG

N 80439
N 80439
N 80439
N 80439
N 80439

CHLORPROPAMIDE (PAGE 3-42)

TABLET; ORAL

CHLORPROPAMIDE
BARR LABORATORIES
CHelsea LABORATORIES
COLMED LABORATORIES
CORD LABORATORIES
DANBURY PHARMACAL
DURAMED PHARMS
LEMMON
SIDMAK LABORATORIES
SUPERPHARM
ZENITH LABORATORIES
GLUCAMIDE
LEMMON

100MG
250MG
100MG
100MG
100MG
100MG
100MG
100MG
100MG
100MG
250MG
100MG
250MG

N 88812
N 88813
N 88865
N 88708
N 88709
N 88725
N 88726
N 88852
N 88826
N 88918
N 88919
N 88768
N 88921
N 88922
N 88694
N 88695
N 88840
N 88641

CHLORTHALIDONE (PAGE 3-42)

TABLET; ORAL

CHLORTHALIDONE
DRUMMER/PHOENIX
LEMMON

50MG
50MG

N 87118
N 88651

CHYTOPAPAIN (PAGE 3-43)

INJECTABLE; INJECTION
CHYMODIACTIN
SMITH LABORATORIES

4,000 UNITS/VIALM

N 18663

CISPLATIN (PAGE 3-44)

INJECTABLE; INJECTION
/PLATINOL/
/BRISTOL LABS/B-H

10MG/ML/
50MG/VIAL

/N' 18657/
/N' 18657/

PLATINOL-AQ

BRISTOL LABS/B-H

0.5MG/ML

N 18057

CLEMASTINE FUMARATE (PAGE 3-44)

SYRUP; ORAL
TAVIST

DORSEY LABS/SANDOZ

EQ 0.5MG BASE/5MLM

N 18675

CLONIPHENE CITRATE (PAGE 3-45)

TABLET; ORAL

CLONID
/BP/ /MERRELL DON/DON CHEN/50MG/
AB MERRELL DON/DON CHEN 50MG

/N' 16131/
N 16131

/BP/ /CLONIPHENE CITRATE/
AB /PLANTEX/IKAPHARM/ 50MG/
PLANTEX/IKAPHARM 50MG

/N' 18361/
N 18361

CLONIDINE (PAGE 3-45)

FILM, CONTROLLED RELEASE; PERCUTANEOUS

CATAPRES-TTS-1

BOEHRINGER INGELHEIM 2.5MGM

CATAPRES-TTS-2

BOEHRINGER INGELHEIM 5MGM

CATAPRES-TTS-3

BOEHRINGER INGELHEIM 7.5MGM

N 18891

N 18891

N 18891

CLOTIMAZOLE (PAGE 3-45)

TABLET; VAGINAL

MYCELEX-G

MILES PHARMS/MILES

500MGM

N 19069

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

SYRUP; ORAL

PHENERGAN VC W/ CODEINE

MYETH LABS/AMHO

10MG/5ML; 5MG/5ML; 6.25MG/5ML

PROMETH VC W/ CODEINE

NATL PHARM MFG/BARRE

10MG/5ML; 5MG/5ML; 6.25MG/5MLM

PROMETHAZINE VC W/ CODEINE

BAY LABORATORIES

10MG/5ML; 5MG/5ML; 6.25MG/5MLM

N 08306

N 88764

N 88896

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-46)

SYRUP; ORAL

PHENERGAN W/ CODEINE

MYETH LABS/AMHO

10MG/5ML; 6.25MG/5ML

PROMETH W/ CODEINE

NATL PHARM MFG/BARRE

10MG/5ML; 6.25MG/5MLM

PROMETHAZINE W/ CODEINE

BAY LABORATORIES

10MG/5ML; 6.25MG/5MLM

N 08306

N 88763

N 88875

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

SYRUP; ORAL

ACTIFED W/ CODEINE

BURROUGHS WELLCOME

10MG/5ML; 30MG/5ML; 1.25MG/5ML

PSEUDOPHEDRINE

BAY LABORATORIES

10MG/5ML; 30MG/5ML; 1.25MG/5MLM

TRIPROLIDINE

NATL PHARM MFG/BARRE

10MG/5ML; 30MG/5ML; 1.25MG/5MLM

N 12575

N 88833

N 88704

COLCHICINE; PROBENECID (PAGE 3-47)

TABLET; ORAL

PROBENECID AND COLCHICINE

BP DRUMMER/PHOENIX

0.5MG; 500MG

PROBENECID W/ COLCHICINE

/BP/ /DRUMMER/PHOENIX/

/p. 5MG; 500MG/

N 86130

/N' 86130/

CORTICOTROPIN (PAGE 3-47)

INJECTABLE; INJECTION

CORTICOTROPIN

CARTER-GLOGAU LABS

40 UNITS/VIALM

N 88772

CORTISONE ACETATE (PAGE 3-47)

TABLET; ORAL

CORTISONE ACETATE

BP 3 VITARINE/PHOENIX

25MG

N 80333

CROMOLYN SODIUM (PAGE 3-48)

SOLUTION/DROPS; OPHTHALMIC
OPTICROM
FISONS 4%
N 18155

DESOXIMETASONE (PAGE 3-53)

ointment; TOPICAL
TOPICORT
HOECHST-ROUSSEL 0.05%
N 18594

CYCLOPHOSPHAMIDE (PAGE 3-50)

INJECTABLE; INJECTION

CYTOSAN
/HEAD. JOHNSON/B-N
/100MG/VIAL/
/200MG/VIAL/
/500MG/VIAL/
/1GM/VIAL/
/2GM/VIAL/
/5GM/VIAL/
/10GM/VIAL/
/20GM/VIAL/
/50GM/VIAL/
/100MG/VIAL
/200MG/VIAL
/500MG/VIAL
/1GM/VIAL
/2GM/VIAL
AP BRISTOL LABS/B-N
AP
AP
AP
AP

TABLET; ORAL

CYTOSAN
/HEAD. JOHNSON/B-N
/25MG/
/50MG/
/100MG/
CYTOSAN
BRISTOL LABS/B-N
25MG
50MG

CYPROHEPTADINE HYDROCHLORIDE (PAGE 3-51)

TABLET; ORAL

CYPROHEPTADINE HCL
AA AN THERAPEUTICS 4MG
AA DRUMMER PHOENIX 4MG

DESERPIDINE; METHYCLOTHIAZIDE (PAGE 3-52)

TABLET; ORAL

ENDURONYL
BP ABBOTT LABORATORIES 0.25MG;5MG
ENDURONYL FORTE
BP ABBOTT LABORATORIES 0.5MG;5MG
METHYCLOTHIAZIDE AND DESERPIDINE
BP BULAR PHARMACEUTICAL 0.25MG;5MG
BP 0.5MG;5MG

DESONIDE (PAGE 3-53)

CREAM; TOPICAL

DESONEN
AB OHEN LABS/DERM PRODS 0.05%
TRIDESTILON
AB MILES PHARMS/MILES 0.05%

DEXAMETHASONE (PAGE 3-53)

/cream; topical/
/hexadrol/
/ORGANON/ARZONA/ 0.06%/
/N 13364/

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

ointment; OPHTHALMIC
DEXACIDIN
AI COOPERVISION PHARMS 0.1%;EQ 3.5MG BASE/GM;
10,000 UNITS/GM
N 62566

SUSPENSION/DROPS; OPHTHALMIC

DEXACIDIN
AI COOPERVISION PHARMS 0.1%;EQ 3.5MG BASE/ML;
10,000 UNITS/ML
N 62544

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-55)

SOLUTION/DROPS; OPHTHALMIC
DEXAMETHASONE SODIUM PHOSPHATE
AI CARTER-6LOGAU LABS EQ 0.1% PHOSPHATE
N 88771

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

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

DEXOROPHENTAMINE MALEATE; PSEUDOEPHEDRINE SULFATE (PAGE 3-56)

/tablets; oral/
/piso-phrol/
/SCHERING/
/N 13364/

DEXTROAMPHETAMINE SULFATE (PAGE 3-56)

TABLET; ORAL
DEXTROAMPHETAMINE SULFATE
AA 2 VITARINE/PHOENIX 5MG
AA 2 10MG

N 84986
N 85892

DEXTRAMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE
(PAGE 3-57)

SYRUP; ORAL

AA	PHENERGAN M/ DEXTROMETHORPHAN MYETH LABS/AMHO 15MG/5ML;6.25MG/5ML	N 11265
AA	PROMETH M/ 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 38.5% IN PLASTIC CONTAINER ABBOTT LABORATORIES 38.5GM/100ML	N 16923
AP	DEXTROSE 5% IN PLASTIC CONTAINER /ABBOTT LABORATORIES/5GM/100ML	N 16467
AP	ABBOTT LABORATORIES 50MG/ML	N 19466
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
AP	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
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

DEXTROSE; HEPARIN SODIUM (PAGE 3-58)

INJECTABLE; INJECTION

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

AP	LIDOCAINE HCL M/ DEXTROSE /ABBOTT LABORATORIES 7.5% 5% XYLOCAINE HCL M/ DEXTROSE XYLOCAINE M/ DEXTROSE 7.5%;1.5% ASTRA PHARM PRODS XYLOCAINE M/ DEXTROSE ASTRA PHARM PRODS 7.5% 5%	N 83914 N 16297 N 10496
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DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE; DIBASIC; SODIUM ACETATE (PAGE 3-58)

INJECTABLE; INJECTION

	ISOLYTE P M/ DEXTROSE 5% IN PLASTIC CONTAINER AM MCGAW/AM HOSP 5GM/100ML;31MG/100ML;130MG/100ML; 26MG/100ML;320MG/100ML	N 19025
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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 5 USP UNITS IN DEXTROSE 5% ABBOTT LABORATORIES 5GM/100ML;1 USP UNIT/100ML	N 19185

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE (PAGE 3-60)

INJECTABLE; INJECTION

AP	POTASSIUM CHLORIDE 10MEG IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER TRAVENOL LABS 5GM/100ML;150MG/100ML; 900MG/100ML 5GM/100ML;75MG/100ML; 900MG/100ML	N 19308 N 19308
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DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE (PAGE 3-60)

<u>INJECTABLE; INJECTION</u>	
<u>POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>	
AP TRAVENOL LABS 5GM/100ML; 150MG/100ML; 900MG/100MLM	N 19308
AP 5GM/100ML; 300MG/100ML; 900MG/100MLM	N 19308
<u>POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>	
AP TRAVENOL LABS 5GM/100ML; 224MG/100ML; 900MG/100MLM	N 19308
<u>POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>	
AP TRAVENOL LABS 5GM/100ML; 300MG/100ML; 900MG/100MLM	N 19308
<u>POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>	
AP TRAVENOL LABS 5GM/100ML; 150MG/100ML; 900MG/100MLM	N 19308

DEXTROSE; THEOPHYLLINE (PAGE 3-62)

<u>INJECTABLE; INJECTION</u>	
<u>THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER</u>	
AP TRAVENOL LABS 5GM/100ML; 40MG/100ML	N 18649
AP 5GM/100ML; 80MG/100ML	N 18649
AP 5GM/100ML; 160MG/100ML	N 18649
AP 5GM/100ML; 200MG/100ML	N 18649
AP 5GM/100ML; 400MG/100ML	N 18649
<u>THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER</u>	
AP ABBOTT LABORATORIES 5GM/100ML; 40MG/100MLM	N 19211
AP 5GM/100ML; 80MG/100MLM	N 19211
AP 5GM/100ML; 160MG/100MLM	N 19211
AP 5GM/100ML; 200MG/100MLM	N 19211
AP 5GM/100ML; 400MG/100MLM	N 19211
<u>THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER</u>	
AP AM MCGAM/AM HOSP 5GM/100ML; 40MG/100MLM	N 19083
<u>THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER</u>	
AP AM MCGAM/AM HOSP 5G/100ML; 80MG/100MLM	N 19083
<u>THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER</u>	
AP AM MCGAM/AM HOSP 5GM/100ML; 160MG/100MLM	N 19083
<u>THEOPHYLLINE 0.22% AND DEXTROSE 5% IN PLASTIC CONTAINER</u>	
AP AM MCGAM/AM HOSP 5GM/100ML; 200MG/100MLM	N 19212
<u>THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER</u>	
AP AM MCGAM/AM HOSP 5GM/100ML; 400MG/100MLM	N 19212

DIATRIZOATE MEGLUMINE (3-62)

<u>INJECTABLE; INJECTION</u>	
<u>HYPAGUE/</u>	
AP/ WINTHROP LABS/STERIL/100% AP/ 60%	N 16403/ N 16403/ N 16403
<u>HYPAGUE MEGLUMINE 30Z</u>	
AP WINTHROP-BREON/STERIL 30Z	N 16403
<u>HYPAGUE MEGLUMINE 60Z</u>	
AP WINTHROP-BREON/STERIL 60Z	N 16403
<u>SOLUTION; URETHRAL</u>	
<u>CYSTOSGRAFIN DILUTE</u>	
ER SQUIBB AND SONS 18ZM	N 10040
<u>HYPAGUE-CYSTO</u>	
AP/ WINTHROP LABS/STERIL/100% AT WINTHROP-BREON/STERIL 30Z	N 16403/ N 16403

DIATRIZOATE SODIUM (PAGE 3-63)

<u>INJECTABLE; INJECTION</u>	
<u>HYPAGUE/</u>	
AP/ WINTHROP LABS/STERIL/100% AP 25%	N 09561/ N 09561/ N 09561
<u>SOLUTION; URETERAL</u>	
<u>HYPAGUE</u>	
AP/ WINTHROP LABS/STERIL/100% WINTHROP-BREON/STERIL 20Z	N 09561/ N 09561

DICYCLOMINE HYDROCHLORIDE (PAGE 3-64)

<u>INJECTABLE; INJECTION</u>	
<u>BENTYL</u>	
AP/ WINTHROP LABS/STERIL/100% WINTHROP-BREON/STERIL 20Z	N 07409
<u>SYRUP; ORAL</u>	
<u>BENTYL</u>	
AP/ WINTHROP LABS/STERIL/100% WINTHROP-BREON/STERIL 20Z	N 08370
<u>TABLET; ORAL</u>	
<u>BENTYL</u>	
AP/ WINTHROP LABS/STERIL/100% WINTHROP-BREON/STERIL 20Z	N 07961
<u>TABLET; ORAL</u>	
<u>BENTYL</u>	
AP/ WINTHROP LABS/STERIL/100% WINTHROP-BREON/STERIL 20Z	N 07409

DIETHYLPROPION HYDROCHLORIDE (PAGE 3-65)

<u>TABLET; ORAL</u>	
<u>DIETHYLPROPION MOL</u>	
AA LEMMON 25MG	N 88642

DIFLORASONE DIACETATE (PAGE 3-66)

CREAM; TOPICAL

> ADD > DIFLORASONE DIACETATE

> ADD > BX UPJOHN 0.052M

> ADD > BX FLORONE 0.052M

> ADD > BX UPJOHN 0.052M

OINTMENT; TOPICAL

> ADD > DIFLORASONE DIACETATE

> ADD > BX UPJOHN 0.052M

> ADD > BX FLORONE 0.052M

> ADD > BX UPJOHN 0.052M

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

0.5MG/0.7ML; 5,000 UNITS/0.7ML;

7.46MG/0.7ML

> ADD > AP N 18885

> ADD > AP N 18885

> ADD > AP N 18885

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-67)

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

AA SUPERPHARM 25MG

AA 50MG

ELIXIR; ORAL

DIPHENHYDRAMINE HCL

AA NASKA PHARMACAL 12.5MG/5ML

DISOPYRAMIDE PHOSPHATE (PAGE 3-68)

CAPSULE; ORAL

DISOPYRAMIDE PHOSPHATE

AB BIOCRRAFT LABS EQ 100MG BASEM

AB EQ 150MG BASEM

AB DANBURY PHARMACAL EQ 100MG BASEM

AB EQ 150MG BASEM

AB MYLAN PHARMS EQ 100MG BASEM

AB EQ 150MG BASEM

AB NORPAGE EQ 100MG BASE

AB SEARLE PHARMS EQ 150MG BASE

AB EQ 150MG BASE

DISULFIRAM (PAGE 3-68)

TABLET; ORAL

DISULFIRAM

BX PAR PHARMACEUTICAL 250MG

BX 500MG

DIVALPROEX SODIUM (PAGE 3-69)

TABLET, ENTERIC COATED; ORAL

DEPAKOTE

ABBOTT LABORATORIES EQ 125MG BASEM

DOPAMINE HYDROCHLORIDE (PAGE 3-69)

INJECTABLE; INJECTION

DOPAMINE HCL

AP INVENEX LABS/LIFE 40MG/ML

AP 80MG/ML

AP LYPHOMED 40MG/ML

AP 80MG/ML

AP SOLOPAK LABORATORIES 40MG/ML

> ADD > AP 40MG/ML

> ADD > AP 80MG/ML

> ADD > AP 80MG/ML

DOXORUBICIN HYDROCHLORIDE (PAGE 3-69)

INJECTABLE; INJECTION

ADRIAMYCIN

FARMITALIA CARLO ERB 20MG/VIAL

DOXYCYCLINE HYCLATE (PAGE 3-70)

CAPSULE; ORAL

DORYX

AB FAULDING EQ 100MG BASEM

AB DOXY-LEMON EQ 50MG BASEM

AB DOXYCYCLINE HYCLATE EQ 50MG BASEM

AB HALSEY DRUG EQ 100MG BASEM

AB EQ 50MG BASEM

AB PAR PHARMACEUTICAL EQ 50MG BASEM

AB SUPERPHARM EQ 50MG BASEM

AB EQ 100MG BASEM

AB WEST-WARD EQ 50MG BASEM

AB ZENITH LABORATORIES EQ 50MG BASEM

AB EQ 100MG BASEM

N 88792
N 88793

N 18723

N 70012
N 70013
N 70058
N 70059
N 70011
N 70046
N 70047

N 50467

N 50582
N 62497
N 62119
N 62119
N 62434
N 62469
N 62469
N 62396
N 62500
N 62500

DOXYCYCLINE HYCLATE (PAGE 3-70)

TABLET; ORAL

AB	<u>DOXY-LENNON</u>	<u>EQ 100MG BASEM</u>	N 62581
> ADD > AB	<u>DOXYCYCLINE HYCLATE</u>	<u>EQ 100MG BASEM</u>	N 62593
AB	<u>PARKE-DAVIS/N-L</u>	<u>EQ 100MG BASEM</u>	N 62494
AB	<u>SUPERPHARM</u>	<u>EQ 100MG BASEM</u>	N 62505
AB	<u>ZENITH LABORATORIES</u>	<u>EQ 100MG BASEM</u>	

/CAPSULES; ORAL/

	<u>PARKE-DAVIS/N-L</u>	<u>1250MG</u>	N 62338
	<u>ERYC</u>	<u>250MG</u>	N 62546
	<u>ERYC SPRINKLES</u>	<u>250MG</u>	N 50593
	<u>FAULDING</u>	<u>125MG</u>	

/N' 62338/

DOXYLAMINE SUCCINATE (PAGE 3-70)

TABLET; ORAL

AA	<u>DECAPRYN</u>		N 06412
AA	<u>HERRELL DOM/DOM CHEM</u>	<u>25MG</u>	N 88603
AA	<u>DOXYLAMINE SUCCINATE</u>	<u>25MG</u>	
AA	<u>QUANTUM PHARMICS</u>	<u>25MG</u>	

DRONABINOL (PAGE 3-70)

CAPSULE; ORAL

	<u>MARINOL</u>	<u>2.5MG</u>	N 18651
	<u>UNIMED</u>	<u>5MG</u>	N 18651
		<u>10MG</u>	N 18651

EDROPHONTUM CHLORIDE (PAGE 3-71)

INJECTABLE; INJECTION

> ADD > ENLON			N 88873
> ADD > AP	<u>ANAQUEST/BOC</u>	<u>10MG/ML</u>	
> ADD > AP	<u>TENSILON</u>	<u>10MG/ML</u>	N 07959
	<u>HOFFMANN-LA ROCHE</u>		

EPINEPHRINE BITARTRATE; LIDOCAINE HYDROCHLORIDE (PAGE 3-72)

INJECTABLE; INJECTION

	<u>LIGNOSPAN FORTE</u>		N 88389
	<u>DEPROCO</u>	<u>EQ 0.02MG BASE/ML; 2M</u>	
	<u>LIGNOSPAN STANDARD</u>	<u>EQ 0.01MG BASE/ML; 2M</u>	N 88390
	<u>DEPROCO</u>		

ERGOCALCIFEROL (PAGE 3-72)

CAPSULE; ORAL

AA	<u>DRISDOL</u>		N 03444
AA	<u>/WINthrop LABS/STERIL/</u>	<u>50.000 IU</u>	
AA	<u>WINthrop-BREON/STERIL</u>	<u>50.000 IU</u>	
AA	<u>VITAMIN D</u>		
AA	<u>3 VITARINE/PHOENIX</u>	<u>50.000 IU</u>	N 84053

/N' 03444/

ERYTHROMYCIN (PAGE 3-73)

/CAPSULES; ORAL/

	<u>PARKE-DAVIS/N-L</u>	<u>1250MG</u>	N 62338
	<u>ERYC</u>	<u>250MG</u>	N 62546
	<u>ERYC SPRINKLES</u>	<u>250MG</u>	N 50593
	<u>FAULDING</u>	<u>125MG</u>	

/N' 62338/

LOTION; TOPICAL

	<u>E-SOLVE 2</u>		N 62467
	<u>SYOSSET LABORATORIES</u>	<u>22M</u>	

OINTMENT; TOPICAL

	<u>AKNE-MYCIN</u>		N 50584
	<u>HERMAL PHARM LABS</u>	<u>22M</u>	

SOLUTION; TOPICAL

AT	<u>Q-SOLVE 2</u>		N 62468
AT	<u>SYOSSET LABORATORIES</u>	<u>22M</u>	N 62508
AT	<u>ERYMAX</u>		N 62616
AT	<u>HERBERT LABS/ALLERGEN</u>	<u>22M</u>	N 62522
AT	<u>ERYTHROMYCIN</u>	<u>22M</u>	
AT	<u>PHARMAFAIR</u>	<u>22M</u>	
AT	<u>SANSAG</u>		
AT	<u>OWEN LABS/DERM PRODS</u>	<u>22M</u>	

SHAB; TOPICAL

	<u>ERYCETTE</u>		N 50594
	<u>ORTHO PHARMACEUTICAL</u>	<u>22M</u>	

ERYTHROMYCIN ETHYLSUCCINATE (PAGE 3-74)

SUSPENSION; ORAL

AB	<u>ERYTHROMYCIN ETHYLSUCCINATE</u>		N 62559
AB	<u>PHARMAFAIR</u>	<u>EQ 200MG BASE/5ML</u>	N 62558
		<u>EQ 400MG BASE/5ML</u>	

ERYTHROMYCIN LACTOBIONATE (PAGE 3-75)

INJECTABLE; INJECTION

AP	<u>ERYTHROCIN</u>		N 50182
AP	<u>ABBOTT LABORATORIES</u>	<u>EQ 500MG BASE/VIAL</u>	N 50182
AP	<u>ERYTHROCIN LACTOBIONATE</u>		N 62563
AP	<u>ABBOTT LABORATORIES</u>	<u>EQ 1GM BASE/VIAL</u>	N 62563
AP	<u>ERYTHROMYCIN</u>		
AP	<u>ELKINS-SINN/AMROBINS</u>	<u>EQ 500MG BASE/VIAL</u>	
AP		<u>EQ 1GM BASE/VIAL</u>	

ESTROGENS, CONJUGATED (PAGE 3-76)

**TABLETS; ORAL
CONJUGATED ESTROGENS
ZENITH LABORATORIES 0.3MGX**

INJECTABLE; INJECTION
FENTANYL CITRATE
AP ABBOTT LABORATORIES EQ 0.05MG BASE/ML

ETHACRYNATE SODIUM (PAGE 3-78)

INJECTABLE; INJECTION	/Ed. 50MG BASE VIAL/ EQ 50MG ACID/VIAL	/F6993.N/ N 16093
EDECIN		
MS&D/MERCK		
MS&D/MERCK		

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE (PAGE 3-78)

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

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

ETHINYL ESTRADIOL; LEVONORGESTREL (PAGE 3-78)

TABLET; ORAL-21
TRIPHASIL-21
MYETH LABS/APHO
0.03MG, 0.04MG, 0.03MG;
0.05MG, 0.075MG, 0.125MG

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

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE (PAGE 3-79)

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

ETHYNODIOL DIACETATE; MESTRANOL (PAGE 3-80)

TABLET; ORAL-20
OVULEN
© SEARLE/SEARLE PHARMS INC; 0.1MG

ETIDRONATE DISODIUM (PAGE 3-81)

**TABLET; ORAL
DIDRONEL
NORWICH EATON/P2G 400MGX**

FLUNITISOLIDE (PAGE 3-82)

**AEROSOL; INHALATION
BRONALIDE
SYNTEX LABS./SYNTEX 0.025MG/INH**

FLUOCINOLONE ACETONIDE (PAGE 3-82)

AT	CREAM; TOPICAL	<u>FLUCINGLONE ACETONIDE</u>	0.012M
AT		BAY LABORATORIES	0.0252M
AT		PHARMAFAIR	0.012M
AT		<u>FLUCONID</u>	0.0252M
AT		HERBERT LABS/ALLERGEN	0.0252M
AT		/MARION LABORATORIES	0.012M
AT			0.0252M

QININTH; TOPICAL	FLUOCINOLONE ACETONIDE	0.0252%
AT	BAY LABORATORIES	
AT	FLUONID	0.0252%
AT	HERBERT LABS/ALLERGEN	0.0252%
AT	MARION LABORATORIES	0.0252%

SOLUTION; TOPICAL
FLUONID
/AT/ HANSON LABORATORIES//6:612/

FLUOROMETHOLONE (PAGE 3-83)

SUSPENSION/DROPS; OPHTHALMIC
FML
ALLERGAN PHARMS 0.1%

FLUOROURACIL (PAGE 3-83)

AP	INJECTABLE; INJECTION	FLUOROURACIL	SOLOPAK LABORATORIES	50MG/71LM
AP				50MG/71LM

FLUPHENAZINE HYDROCHLORIDE (PAGE 3-84)

TABLET; ORAL

PERNITIL

BP & SCHERING

0.25MG

N 12034

INJECTABLE; INJECTION

CHORIONIC GONADOTROPIN

AP CARTER-GLOGAU LABS

15,000 UNITS/VIAL*

2,000 UNITS/VIAL*

15,000 UNITS/VIAL

N 17016

N 17016

N 17067

FLUPREDNISOLONE (PAGE 3-84)

TABLET; ORAL

ALPHADROL

& UPJOHN

1.5MG

N 12259

GUANETHIDINE MONOSULFATE (PAGE 3-90)

TABLET; ORAL

GUANETHIDINE MONOSULFATE

AB BOLAR PHARMACEUTICAL

EQ 10MG SULFATE*

EQ 25MG SULFATE*

N 86113

N 86114

FOLICLE STIMULATING HORMONE; LUTEALIZING HORMONE (PAGE 3-85)

/INJECTABLE; INJECTION/

/PERGONAL/

/SERONO LABS/

/75 IU/AMP; 150 IU/AMP/

/N 13646/

/10MG/

/25MG/

EQ 10MG SULFATE

EQ 25MG SULFATE

/N 12329/

/N 12329/

N 12329

FUROSEMIDE (PAGE 3-86)

TABLET; ORAL

FUROSEMIDE

AB CORD LABORATORIES

AB LEDERLE LABS/AN CYAN

AB PARKE-DAVIS/M-L

AB LASIX

AB HOECHST-ROUSSEL

80MG

N 12569

N 18415

N 18419

HALCINONIDE (PAGE 3-90)

CREAM; TOPICAL

/HALCINONIDE/

/HALOG-E

N 18569

N 18415

N 18419

GENTAMICIN SULFATE (PAGE 3-86)

INJECTABLE; INJECTION

GENTAFAIR

PHARMAFAIR

EQ 40MG BASE/ML*

EQ 10MG BASE/ML*

EQ 40MG BASE/ML*

EQ 10MG BASE/ML*

EQ 40MG BASE/ML*

EQ 10MG BASE/ML*

EQ 10MG BASE/ML*

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EQ 10MG BASE/ML*

EQ 10MG BASE/ML*

EQ 10MG BASE/ML*

N 17651

N 17651

N 89457

N 88580

N 88581

/N 17651/

/N 17651/

/N 17651/

/N 17651/

/N 17651/

/N 17651/

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/N 17651/

HEPARIN SODIUM (PAGE 3-91)

INJECTABLE; INJECTABLE
/LIQUAHEIN SODIUM '1150'/
/AP/ /ORGANON/AKZONA/ 1.000 UNITS/ML/
/LIQUAHEIN SODIUM '1150'/
/AP/ /ORGANON/AKZONA/ 10.000 UNITS/ML/
/LIQUAHEIN SODIUM '1150'/
/AP/ /ORGANON/AKZONA/ 20.000 UNITS/ML/
/LIQUAHEIN SODIUM '1150'/
/AP/ /ORGANON/AKZONA/ 5.000 UNITS/ML/

HEPARIN SODIUM; SODIUM CHLORIDE (PAGE 3-93)

INJECTABLE; INJECTION

HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.45%

AP ABBOTT LABORATORIES 10,000 UNITS/100ML; 450MG/100ML N 18911

HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.9%

AP ABBOTT LABORATORIES 10,000 UNITS/100ML; 900MG/100ML N 18911

HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.9%

AP ABBOTT LABORATORIES 12,500 UNITS/100ML; 900MG/100ML N 18911

HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9%

AP ABBOTT LABORATORIES 25,000 UNITS/100ML; 900MG/100ML N 18911

HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.45%

AP ABBOTT LABORATORIES 5000 UNITS/ML; 4.5MG/ML N 18911

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

INJECTABLE; INJECTION

HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0.9%

AP AM MCGAW/AM HOSP 1000 UNITS/100ML; 900MG/100ML N 19042

HEPARIN SODIUM 2000 UNITS IN SODIUM CHLORIDE 0.9%

AP AM MCGAW/AM HOSP 2000 UNITS/100ML; 900MG/100ML N 19042

HEPARIN SODIUM 2500 UNITS IN SODIUM CHLORIDE 0.9%

AP AM MCGAW/AM HOSP 2500 UNITS/100ML; 900MG/100ML N 19135

HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9%

AP ABBOTT LABORATORIES 5000 UNITS/100ML; 900MG/100ML N 18916

HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9%

AP AM MCGAW/AM HOSP 5000 UNITS/100ML; 900MG/100ML N 19042

HEXACHLOROPHENE (PAGE 3-94)

EMULSION; TOPICAL

TURGEX

AT XTIRIUM LABS 32% N 19055

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE (PAGE 3-95)

SYRUP; ORAL

/HYDROCODONE/

HYDROCODONE COMPOUND

HYDROPHANE

AA HALSEY DRUG 1.5MG/5ML; 5MG/5ML N 88066

TABLET; ORAL

HYCODAN

AA DUPONT PHARMS/DUPONT 1.5MG/5MG N 05213

TUSSIGON

AA DANIELS PHARM 1.5MG/5MG N 88508

HYDRALAZINE HYDROCHLORIDE (PAGE 3-95)

INJECTABLE; INJECTION

HYDRALAZINE MOL

> ADD > AP SOLOPAK LABORATORIES 20MG/ML N 88517

TABLET; ORAL

HYDRALAZINE MOL

AA ANIDE PHARMACEUTICAL 25MG N 88560

AA ASCOT HOSP PHARMS 50MG N 88649

AA ASCOT HOSP PHARMS 25MG N 88310

AA BARR LABORATORIES 50MG N 88311

AA BARR LABORATORIES 10MG N 88728

AA CAMALL 100MG N 88729

AA CAMALL 10MG N 88846

AA CAMALL 25MG N 88847

AA CAMALL 50MG N 88848

AA CAMALL 100MG N 88849

AA CAMALL 25MG N 86088

AA CAMALL 10MG N 88787

AA CAMALL 50MG N 88788

AA CAMALL 100MG N 88789

HYDROCHLOROTHIAZIDE (PAGE 3-96)

TABLET; ORAL

HYDROCHLOROTHIAZIDE

AB LEMMON 25MG N 88924

AB LEMMON 50MG N 88923

AB SUPERPHARM 25MG N 88827

AB SUPERPHARM 50MG N 88828

AB SUPERPHARM 100MG N 88829

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE (PAGE 3-98)

TABLET; ORAL

LOPRESSOR HCT 100/25

GEIGY/CIBA-GEIGY 25MG;100MG N 18303

HYDROFLUMETHIAZIDE (PAGE 3-104)

TABLET; ORAL
HYDROFLUMETHIAZIDE
 AB CHELSEA LABORATORIES 50MG
 AB PAR PHARMACEUTICAL 50MG

HYDROFLUMETHIAZIDE; RESERPINE (PAGE 3-104)
 TABLET; ORAL
 RESERPINE AND HYDROFLUMETHIAZIDE
 BP ZENITH LABORATORIES 50MG; 0.125MG

HYDROXYZINE HYDROCHLORIDE (PAGE 3-105)

TABLET; ORAL
HYDROXYZINE HCL
 AB PUREPAC/KALIPHARMA 10MG
 AB 25MG
 AB 50MG
 AB SUPERPHARM 10MG
 AB 25MG
 AB 50MG

HYDROXYZINE PAMOATE (PAGE 3-106)

CAPSULE; ORAL
 HY-PAM "25"
 AB LEPPON EQ 25MG HCL

IBUPROFEN (PAGE 3-106)

TABLET; ORAL
IBUPROFEN
 AB BARR LABORATORIES 400MG
 AB 600MG
 AB BOOTS PHARMACEUTICAL 600MG
 AB DANBURY PHARMACAL 400MG
 AB 600MG
 AB 3 PAR PHARMACEUTICALS 300MG
 AB 400MG
 AB 600MG
 AB 400MG
 AB 600MG
 AB 400MG
 AB 600MG
 AB OHM LABORATORIES 400MG
 AB MOTRIN
 AB 3 UPJOHN 300MG
 AB 600MG
 AB RUFEN
 AB BOOTS PHARMACEUTICAL 400MG
 AB 600MG
 AB 600MG

IMIPRAMINE HYDROCHLORIDE (PAGE 3-107)

TABLET; ORAL
IMIPRAMINE HCL
 AB 3 DRUMMER/PHOENIX 10MG
 AB SK-PRANTINE
 AB /SKAF LABORATORIES/ 10MG
 AB /25MG/
 AB /50MG/
 AB /50MG/
 AB SK&F LABORATORIES 10MG
 AB 25MG
 AB 50MG
 BP

INDOMETHACIN (PAGE 3-108)

CAPSULE; ORAL
INDOMETHACIN
 AB PAR PHARMACEUTICAL 25MG
 AB 50MG
 AB PARKE-DAVIS/M-L 25MG
 AB 50MG
 AB ROXANE LABORATORIES 25MG
 AB 50MG
 SUPPOSITORY; RECTAL
 INDOCIN
 MS&D RES LABS/MERCK 50MG

INDOMETHACIN SODIUM TRIHYDRATE (PAGE 3-108)

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

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

INJECTABLE; INJECTION
 NEPHROFLOW
 HEDI-PHYSICS 1MCI/ML

IOPANOIC ACID (PAGE 3-109)

TABLET; ORAL
 TELEPAQUE
 AB /WINthrop LABS/STERIL/500MG/
 WINTHROP-BREON/STERIL 500MG

IOXABATE MESGLUMINE; IOXABATE SODIUM (PAGE 3-109)

INJECTABLE; INJECTION
 HEXABRIX
 MALLINCKRODT 39.3%; 19.62M

ISOETHARINE MESYLATE (PAGE 3-110)

AEROSOL; INHALATION

BRONKOWETER
/PERON LABS/STERLING//0.51%/
BN BREON LABS/STERLING 0.34MG/INH
ISOETHARINE MESYLATE
BN NATL PHARM MFG/BARRE 0.34MG/INH

/N'12134/
N 12339

AEROSOL; ORAL

XYLOCAINE
ASTRA PHARM PRODS 102M

N 14394

LIDOCAINE HYDROCHLORIDE (PAGE 3-115)

INJECTABLE; INJECTION

LIDOCAINE HCL IN PLASTIC CONTAINER

AP INVENEX LABS/LIFE 12M

N 88586

XYLOCAINE

ASTRA PHARM PRODS

/N'10456/
N 10456

SOLUTION; ORAL

/LIDOCAINE HCL/
LIDOCAINE VISCOUS

AI ROXANE LABORATORIES 22M

N 88802

SOLUTION; TOPICAL

LIDOCAINE HCL

AI ROXANE LABORATORIES 42M

N 88803

LINDANE (PAGE 3-116)

LOTION; TOPICAL

LINDANE

AI BAY LABORATORIES 12M

N 88190

SHAMPOO; TOPICAL

LINDANE

AI BAY LABORATORIES 12M

N 88191

LITHIUM CARBONATE (PAGE 3-117)

TABLET; ORAL

LITHANE

AB MILES PHARMS/MILES 300MG

N 18833

LORAZEPAM (PAGE 3-118)

TABLET; ORAL

ATIVAN

> ADD > AB
> ADD > AB
> ADD > AB
> ADD > AB
> ADD > AB
> ADD > AB
> ADD > AB

HYETH LABS/ANHO

0.5MG

1MG

2MG

N 17794

0.5MG

1MG

2MG

N 17794

LORAZEPAM

0.5MG

1MG

2MG

N 70200

0.5MG

1MG

2MG

N 70201

0.5MG

1MG

2MG

N 70202

KANAMYCIN SULFATE (PAGE 3-112)

INJECTABLE; INJECTION

KANAMYCIN SULFATE

AP CARTER-GLOGAU LABS EQ 1GM BASE/3ML

N 62520

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

TABLET; ORAL

NORMODYNE

AB SCHERING 200MG

AB 300MG

AB 400MG

AB 200MG

AB 300MG

AB 400MG

AB 100MG

N 18716

LEUPROLIDE ACETATE (PAGE 3-113)

INJECTABLE; INJECTION

LUPRON

TAP PHARMACEUTICALS 1MG/0.2ML

N 19010

LEVONORDEPRIN; MEPIVACAINE HYDROCHLORIDE (PAGE 3-114)

INJECTABLE; INJECTION

SCANDONEST L

AP DEPROCO 0.05MG/ML; 22M

N 88388

LEVOTHYROXINE SODIUM; LIOTHYRONINE SODIUM (PAGE 3-114)

TABLET; ORAL

THYROLAR-5

3 ARMOUR PHARM 0.25MG; 0.0625MG

N 16807

LOXAPINE HYDROCHLORIDE (PAGE 3-118)

CONCENTRATE; ORAL
/LOXITANE/
LOXITANE C

INJECTABLE; INJECTION
/LOXITANE/
LOXITANE IM

N 88640

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE (PAGE 3-119)

SOLUTION; IRRIGATION

PHYSIOLYTE IN PLASTIC CONTAINER

AI AM MCGAW/AM HOSP 30MG/100ML; 37MG/100ML; 370MG/100ML;
530MG/100ML; 500MG/100ML N 19024

AI SYNOVALYTE IN PLASTIC CONTAINER

30MG/100ML; 37MG/100ML; 368MG/100ML;
526MG/100ML; 502MG/100ML N 19326

MECLIZINE HYDROCHLORIDE (PAGE 3-121)

TABLET; ORAL

MECLIZINE HCL
SUPERPHARM

> ADD > AA 12.5MG N 89113
> ADD > AA 25MG N 89114

MEDRYSONE (PAGE 3-122)

SUSPENSION/DROPS; OPHTHALMIC

HMS

ALLERGAN PHARMS 1% N 16624

MENOTROPINS (PAGE 3-122)

INJECTABLE; INJECTION

PERGONAL

SERONO LABS 150 IU/AMP N 17646
300 IU/AMP N 17646

MEPERTINE HYDROCHLORIDE (PAGE 3-122)

INJECTABLE; INJECTION

MEPERTINE HCL

AP ABBOTT LABORATORIES 10MG/ML N 88432
AP INTL MEDICATION SYS 10MG/ML N 84332

SYRUP; ORAL

DEMEROL

AA WINTHROP LABS/STERL 50MG/5ML N 05010

AA MEPERTINE HCL 50MG/5ML N 88744

MEPERTINE HYDROCHLORIDE (PAGE 3-122)

TABLET; ORAL

MEPERTINE HCL

AA BARR LABORATORIES 100MG N 88640

MEPENTERMINE SULFATE (PAGE 3-123)

INJECTABLE; INJECTION

MYAMINE SULFATE

/MYETH LABS/AMHO/ 15MG/ML/
/50MG/ML/ N 08248
EQ 15MG BASE/ML N 08248
EQ 30MG BASE/ML

MYETH LABS/AMHO

MEPIVACAIN HYDROCHLORIDE (PAGE 3-123)

INJECTABLE; INJECTION

CARBOCAIN

AP BREON LABS/STERLING 2% N 12250

MEPIVACAIN HCL

AP CARTER-GLOGAU LABS 1% N 88769

AP 2% N 88770

POLOCAIN

AP ASTRA PHARM PRODS 3% N 88653

SCANDONEST PLAIN

AP DEPROCO 3% N 88387

MEPROBAMATE (PAGE 3-123)

TABLET; ORAL

MEPROBAMATE

/AA/ /M/ MAST/ 400MG/
/AA/ /M/ MAST/ 600MG/ N 86249/
/N 86249/

METHICILLIN SODIUM (PAGE 3-127)

INJECTABLE; INJECTION

/CELEBENTIN/

/AP/ /BEECHAM LABS/BEECHAM/ EQ 900MG BASE/VIAL/
/AP/ /BEECHAM LABS/BEECHAM/ EQ 3.6G BASE/VIAL/
/AP/ /BEECHAM LABS/BEECHAM/ EQ 5.4G BASE/VIAL/
/AP/ /BEECHAM LABS/BEECHAM/ EQ 1.8G BASE/VIAL/
/AP/ /BEECHAM LABS/BEECHAM/ EQ 96H BASE/VIAL/ N 61493/
/N 61493/
/N 61493/
/N 61493/
/N 61493/

METHOTREXATE SODIUM (PAGE 3-128)

INJECTABLE; INJECTION

HEXATE

BRISTOL LABS/B-M EQ 250MG BASE/VIAL N 86358

HEXATE-AQ

AP BRISTOL CARIB/B-M/PR EQ 25MG BASE/ML N 88760

METHYLCLOTHIAZIDE (PAGE 3-129)

TABLET; ORAL

METHYLCLOTHIAZIDE
AB CHELSEA LABORATORIES 2.5MG
AB CHELSEA LABORATORIES 5MG
AB COLMED LABORATORIES 5MG

METHYLDOPA (PAGE 3-130)

TABLET; ORAL

ALDORET
AB MSD/MERCK 125MG
METHYLDOPA
AB CHELSEA LABORATORIES 125MG
AB CHELSEA LABORATORIES 250MG
AB CHELSEA LABORATORIES 500MG
AB MYLAN PHARMS 250MG
AB MYLAN PHARMS 500MG

METHYLPREDNISOLONE SODIUM SUCCINATE (PAGE 3-131)

INJECTABLE; INJECTION

SOLU-MEDROL
UPJOHN
EQ 2GM BASE/VIAL

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-132)

TABLET; ORAL

GLOPRA
AB QUANTUM PHARMICS
EQ 10MG BASE
AB METOCLOPRAMIDE HCL
EQ 10MG BASE
AB BIOCRAFT LABS
EQ 10MG BASE
AB COLMED LABORATORIES
EQ 10MG BASE
AB REGLAN
EQ 10MG BASE
AB AH ROBINS

METRONIDAZOLE (PAGE 3-133)

INJECTABLE; INJECTION

METRONIDAZOLE
AP INTEL MEDICATION SYS
EQ 500MG/100ML
AP LYPHOCED
EQ 500MG/100ML
AP METRIL IV
EQ 500MG/100ML
AP LEMMON

TABLET; ORAL

METRONIDAZOLE
AB HALSEY DRUG
250MG
AB PAR PHARMACEUTICAL
250MG
AB PAR PHARMACEUTICAL
500MG
AB SIDMAK LABORATORIES
250MG
AB SIDMAK LABORATORIES
500MG

METRONIDAZOLE (PAGE 3-133)

TABLET; ORAL

METRONIDAZOLE
AB SUPERPHARM
250MG
AB SUPERPHARM
500MG
AB METRIL
250MG
AB LEMMON
250MG
AB METRIL 500
500MG
AB LEMMON
500MG
AB SATRID
250MG
AB SAVAGE LABS/ALTANA
250MG

MICONAZOLE NITRATE (PAGE 3-134)

SUPPOSITORY; VAGINAL
MONISTAT 3
ORTHO PHARMACEUTICAL 200MG

MOLINDONE HYDROCHLORIDE (PAGE 3-135)

CAPSULE; ORAL

MOBAN
3 DUPONT PHARMS/DUPONT 5MG
3 DUPONT PHARMS/DUPONT 10MG
3 DUPONT PHARMS/DUPONT 25MG

MORPHINE SULFATE (PAGE 3-135)

INJECTABLE; INJECTION

DURAMORPH PF
ELKINS-SINN/AHROBINS 0.5MG/ML
ELKINS-SINN/AHROBINS 1MG/ML

NAFACILLIN SODIUM (PAGE 3-135)

INJECTABLE; INJECTION

NAFACIL
AP BRISTOL LABS/B-M
EQ 10GM BASE/VIAL
AP MALLPEN
BEECHAM LABS/BEECHAM
EQ 10GM BASE/VIAL

NALBUPHINE HYDROCHLORIDE (PAGE 3-136)

INJECTABLE; INJECTION

NUBAIN
DUPONT PHARMS/DUPONT 20MG/ML

MALTREXONE HYDROCHLORIDE (PAGE 3-136)

TABLET; ORAL
 TREXAN
 DUPONT PHARMS/DUPONT 50MG

N 18932

CREAM; TOPICAL
 MYCLOG-III
 ER SQUIBB AND SONS

AT 100,000 UNITS/GM; 0.12M
 AT 100,000 UNITS/GM; 0.12M

N 60576
 N 62606

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

SOLUTION/DROPS; OPHTHALMIC
 STATROL
 ALCON LABORATORIES

EQ 3.5MG BASE/ML;
 16,250 UNITS/ML

N 62339

ointment; TOPICAL
 MYCLOG-II
 ER SQUIBB AND SONS

100,000 UNITS/GM; 0.12M

N 60572

NICOTINE POLACRILEX (PAGE 3-138)

GUM, CHEWING; ORAL
 NICORETTE
 MERRELL DOW/DOW CHEM EQ 2MG BASE

N 18612

INJECTABLE; INJECTION
 BACTOCILL
 BEECHAM LABS/BEECHAM EQ 10GM BASE/VIAL

N 61334

NICOTINE RESIN COMPLEX (PAGE 3-138)

/GUM, CHEWING; ORAL/
 /NICORETTE/
 /MERRELL DOW/DOW CHEM EQ 2MG BASE/

/N 18612/

NONFENSINE MALEATE (PAGE 3-140)

CAPSULE; ORAL
 MERITAL
 HOECHST-ROUSSEL

25MG
 50MG

N 18224
 N 18224

OXYPHENBUTAZONE (PAGE 3-143)

TABLET; ORAL

OXYPHENBUTAZONE

AB BOLAR PHARMACEUTICAL 100MG

AB 3 GEIGY/CIBA-GEIGY 100MG

N 88399
 N 12542

NOREPINEPHRINE BITARTRATE (PAGE 3-140)

INJECTABLE; INJECTION
 LEVOPHED
 BREDN LABS/STERLING/EQ 1MG BASE/ML

/BREDN LABS/STERLING/EQ 1MG BASE/ML/
 MINTHROP-BREDN/STERL EQ 1MG BASE/ML

/N 07513/
 N 07513

PENETATE CALCIUM TRISODIUM; YB-169 (PAGE 3-145)

/INJECTABLE; INJECTION/
 /YB-169 DTPA/
 /DIAGNOSTIC PRODS/3N/2MG/ML/

/N 17516/

NYSTATIN (PAGE 3-141)

SUSPENSION; ORAL

NYSTATIN

AA 100,000 UNITS/ML
 AA 100,000 UNITS/ML

N 62512
 N 62541

PENTAMIDINE ISETHIONATE (PAGE 3-148)

INJECTABLE; INJECTION
 PENTAM 300
 LYPHOMED

300MG/VIAL

N 19264

TABLET; ORAL

NYSTATIN

AA 500,000 UNITS

N 62525

PENTETATE CALCIUM TRISSODIUM, YB-169 (PAGE 3-148)

INJECTABLE; INJECTION
YTTBIUM YB 169 DTPA
MEDICAL PRODUCTS/3M 2MCI/ML

PENTOBARBITAL SODIUM (PAGE 3-149)

AA 3 VITARINE/PHOENIX 100MG
CAPSULE; ORAL
PENTOBARBITAL SODIUM

AA 3 VITARINE/PHOENIX 100MG
TABLET; ORAL
PENTOBARBITAL SODIUM

PENTOXIFYLLINE (PAGE 3-149)

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

PHENDIMETRAZINE TARTRATE (PAGE 3-149)

AA 3 DRUMMER/PHOENIX 35MG
AA 3 DRUMMER/PHOENIX 35MG
AA 3 DRUMMER/PHOENIX 35MG
AA 3 VITARINE/PHOENIX 35MG
AA 3 VITARINE/PHOENIX 35MG
AA 3 VITARINE/PHOENIX 35MG

TABLET; ORAL
PHENDIMETRAZINE TARTRATE
AA 3 DRUMMER/PHOENIX 35MG
AA 3 VITARINE/PHOENIX 35MG
AA 3

PHENTERMINE HYDROCHLORIDE (PAGE 3-151)

AA 3 CHELSEA LABORATORIES 30MG
AA 3 DRUMMER/PHOENIX 30MG
AA 3 PHARM BASICS 30MG
CAPSULE; ORAL
PHENTERMINE HCL

PHENTERMINE HYDROCHLORIDE (PAGE 3-151)

AA 3 DRUMMER/PHOENIX 8MG
AA 3 DRUMMER/PHOENIX 8MG
AA 3 PHARM BASICS 37.5MG
AA 3 PHARM BASICS 37.5MG

N 86453
N 86456
N 88910
N 88917

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-153)

AA 3 MYETH LABS/AMMO 5MG/5ML; 6.25MG/5ML
AA 3 NATL PHARM MFG/BARRE 5MG/5ML; 6.25MG/5ML
AA 3 BAY LABORATORIES 5MG/5ML; 6.25MG/5ML
SYRUP; ORAL
PHENERGAN VQ

N 88604
N 88761
N 88897

PHENTOLIN SODIUM (PAGE 3-153)

AP 3 INVENEX LABS/LIFE 50MG/ML
AP 3 SOLOPAK LABORATORIES 50MG/ML
AP 3 SOLOPAK LABORATORIES 50MG/ML
AP 3

N 89003
N 88519
N 88520
N 88521

PHENTOLIN SODIUM, EXTENDED (PAGE 3-153)

AB 3 PARKE-DAVIS/N-L 100MG
AB 3 EXTENDED PHENTOLIN SODIUM
AB 3 BOLAR PHARMACEUTICAL 100MG
CAPSULE; ORAL
DILANTIN

N 84349
N 88711

PILOCARPINE HYDROCHLORIDE (PAGE 3-154)

GEL; OPHTHALMIC
PILOPINE HS
ALCON LABORATORIES 4%

N 18796

PINDOLOL (PAGE 3-154)

TABLET; ORAL
VISKEN

N 86740
N 87202
N 87235
N 88797

SANDOZ PHARMS/SANDOZ/15MG/

/N 16885/

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

POWDER FOR RECONSTITUTION; ORAL

COLYTE

EDLAW PREPARATIONS

120GM/PACKET; 1.49GM/PACKET;
3.36GM/PACKET; 2.92GM/PACKET;
11.36GM/PACKET
227.1GM/PACKET; 2.82GM/PACKET;
6.36GM/PACKET; 5.53GM/PACKET;
21.5GM/PACKET; M
360GM/PACKET; 4.47GM/PACKET;
10.08GM/PACKET; 8.76GM/PACKET;
34.08GM/PACKET; M

N 18983

N 18983

N 18983

POTASSIUM CHLORIDE (PAGE 3-156)

INJECTABLE; INJECTION

POTASSIUM CHLORIDE IN PLASTIC CONTAINER

AP INVENEX LABS/LIFE 2MEG/ML
AP 2MEG/ML

N 88901

N 88908

> ADD > POTASSIUM CITRATE (PAGE 3-158)

TABLET; ORAL

POTASSIUM CITRATE

UNIV TX HLTH SCI CTR 5MEG

N 19071

POTASSIUM CLAVULANATE; TICARCILLIN DISODIUM (PAGE 3-159)

INJECTABLE; INJECTION

TIMENTIN

BEECHAM LABS/BEECHAM EQ 100MG ACID/VIAL;
EQ 36M BASE/VIAL
EQ 200MG ACID/VIAL;
EQ 36M BASE/VIAL

N 50590

N 50590

PREDNISOLONE (PAGE 3-159)

TABLET; ORAL

PREDNISOLONE

BX SUPERPHARM

5MG

N 88892

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM (PAGE 3-160)

OINTMENT; OPHTHALMIC

PREDISULFAIR

PHARMAFAIR

VASUCIDIN

0.5Z; 10Z

N 88032

AI COOPERVISION PHARMS 0.5Z; 10Z

N 88791

PREDNISONE (PAGE 3-161)

SOLUTION; ORAL

PREDNISONE

ROXANE LABORATORIES

PREDNISONE INTENSOL

ROXANE LABORATORIES

N 88703

N 88810

TABLET; ORAL

PREDNISONE

BX SUPERPHARM

5MG

N 88865

BX

10MG

N 88866

BX

20MG

N 88867

PRILOCAINE HYDROCHLORIDE (PAGE 3-162)

INJECTABLE; INJECTION

CITANEST

3 ASTRA PHARM PRODS

1Z

N 14763

3

3

2Z

N 14763

3

3

3Z

N 14763

14Z

N 14763

CITANEST PLAIN

ASTRA PHARM PRODS

4Z

N 14763

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-163)

CAPSULE; ORAL

PROCAINAMIDE HCL

ROXANE LABORATORIES

250MG

N 88989

AB

500MG

N 88990

INJECTABLE; INJECTION

PROCAINAMIDE HCL

SOLOPAK LABORATORIES

100MG/ML

N 88530

500MG/ML

N 88531

500MG/ML

N 88532

TABLET, CONTROLLED RELEASE; ORAL

PROCAINAMIDE HCL

BOLAR PHARMACEUTICAL

250MG

N 88533

500MG

N 88534

750MG

N 88535

500MG

N 88974

PROCAN SR

250MG

N 84468

500MG

N 86065

750MG

N 87510

500MG

N 88489

16MG

N 88489

PROCHLORPERAZINE EDISYLATE (PAGE 3-164)

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

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

PROCHLORPERAZINE MALEATE (PAGE 3-164)

CAPSULE, CONTROLLED RELEASE; ORAL
 COMPAZINE
 3 SK&F LABORATORIES EQ 75MG BASE N 11000

PROMETHAZINE HYDROCHLORIDE (PAGE 3-165)

SYRUP; ORAL
PROMETHAZINE/
PROMETHAZINE PLAIN

PROPOXYPHENE HYDROCHLORIDE (PAGE 3-167)

CAPSULE; ORAL
PROPOXYPHENE HCL
 AA LEHMAN 65MG N 88615

PROPRANOLOL HYDROCHLORIDE (PAGE 3-168)

TABLET; ORAL
IMBERAL
 AYERST LABS/AHMO 10MG N 16418
 20MG N 16418
 40MG N 16418
 80MG N 16418

PROPRANOLOL HCL
 CHELSEA LABORATORIES 10MG N 70140
 20MG N 70141
 40MG N 70142
 80MG N 70144

LEDERLE LABS/AM CYAN 10MG N 70125
 20MG N 70126
 40MG N 70127
 80MG N 70128
 10MG N 70120
 20MG N 70121
 40MG N 70122
 80MG N 70124

MARTEC PHARMS
 > ADD > AB
 > ADD > AB
 > ADD > AB
 > ADD > AB

PROTATINE SULFATE (PAGE 3-168)

INJECTABLE; INJECTION
 PROTATINE SULFATE
 UPJOHN 250MG/VIALM N 07413

PROTEIN HYDROLYSATE (PAGE 3-168)

INJECTABLE; INJECTION
 AMINOSOL 5%
 ABBOTT LABORATORIES 5% N 05932

PSEUDOPHEDRINE HYDROCHLORIDE; TRIPROPOLIDINE HYDROCHLORIDE (PAGE 3-169)

SYRUP; ORAL
TRILITRON
 AA NENTRON PHARMS 30MG/5ML; 1.25MG/5MLM N 88474
 /TRIPROPOLIDINE HCL AND PSEUDOPHEDRINE HCL/
 /AA/ /PHARMVIA/ /30MG/5ML; 1.25MG/5ML/ /N' 88561/

TABLET; ORAL

ALLERFEED
 AA PRIVATE FORMULATIONS 60MG; 2.5MG N 88860
CORPHED
 AA CORD LABORATORIES 60MG; 2.5MG N 88602
TRILITRON
 AA NENTRON PHARMS 60MG; 2.5MG N 88515
TRIPROPOLIDINE HCL AND PSEUDOPHEDRINE HCL
 AA SUPERPHARM 60MG; 2.5MG N 88578
 AA ZENITH LABORATORIES 60MG; 2.5MG N 85273

QUINIDINE GLUCONATE (PAGE 3-170)

TABLET, CONTROLLED RELEASE; ORAL
QUINIDINE GLUCONATE
 AB ASCOT HOSP PHARMS 324MG N 88582

QUINIDINE SULFATE (PAGE 3-170)

TABLET; ORAL
GIN-QUIN
 /AB/ ROWELL LABORATORIES /400MG/ /N' 87455/
QUINIDINE SULFATE
 AB SUPERPHARM 200MG N 88973

RANITIDINE HYDROCHLORIDE (PAGE 3-171)

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

RAUOLETA SERPENTINA (PAGE 3-171)

TABLET; ORAL

RAUVERID
BP FOREST LABORATORIES 50MG
/BP/ /ONEAL JONES & FELDMAN/ 50MG/
WOLFINA
BP FOREST LABORATORIES 50MG
BP FOREST LABORATORIES 100MG
/BP/ /ONEAL JONES & FELDMAN/ 50MG/
/BP/ /ONEAL JONES & FELDMAN/ 100MG/

RESERPINE (PAGE 3-172)

TABLET; ORAL

RESERPINE
BP LEMON 0.1MG
BP 0.25MG

RITODRINE HYDROCHLORIDE (PAGE 3-173)

INJECTABLE; INJECTION

/BP/ /RITODRINE HCL/
/BP/ /DUPHAR LABS/ 10MG/ML/
/AP/ YUTOPAR 10MG/ML
/AP/ ASTRA PHARM PRODS 15MG/ML

TABLET; ORAL

/BP/ /RITODRINE HCL/
/BP/ /DUPHAR LABS/ 10MG/
/BP/ YUTOPAR
/BP/ ASTRA PHARM PRODS 10MG

SAFELOWER OIL; SOYBEAN OIL (PAGE 3-174)

INJECTABLE; INJECTION

LIPOSYN II 10%
ABBOTT LABORATORIES 5%:5%
LIPOSYN II 20%
ABBOTT LABORATORIES 10%:10%

SCOPOLAMINE (PAGE 3-174)

FILM, CONTROLLED RELEASE; PERCUTANEOUS

/TRANSDERM-V/
/ALZA/ 1.5MG/
TRANSDERM-SCOP
CIBA/CIBA-GEIGY 1.5MG

SECORBITAL SODIUM (PAGE 3-174)

CAPSULE; ORAL

SECORBITAL SODIUM
AA 3 DRUMMER/PHOENIX 100MG N 85898
AA 3 VITARINE/PHOENIX 100MG N 86273

> ADD > SODIUM BICARBONATE; TARTARIC ACID (PAGE 3-176)

> ADD > GRANULE, EFFERVESCENT; ORAL
> ADD > BAROS
> ADD > MALLINCKRODT 460MG/GM; 420MG/GPM N 18509

SODIUM CHLORIDE (PAGE 3-176)

INJECTABLE; INJECTION

BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
ABBOTT LABORATORIES 9MG/ML N 18800
INVENEX LABS/LIFE 9MG/ML N 88909
INVENEX LABS/LIFE 9MG/ML N 88911

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP ABBOTT LABORATORIES 900MG/100ML N 19465
AP AM MCGAW/AM HOSP 900MG/100ML N 17464
AP INVENEX LABS/LIFE 9MG/ML N 88912
/AP/ SODIUM CHLORIDE IN PLASTIC CONTAINER
/AP/ /AM MCGAW/AM HOSP/ 900MG/100ML /N 17464/

SOLUTION FOR SLUSH; IRRIGATION

SODIUM CHLORIDE 0.9% IN STERILE PLASTIC CONTAINER
TRAVENOL LABS 900MG/100ML N 19319

SODIUM IODIDE, I-131 (PAGE 3-178)

SOLUTION; ORAL

SODIUM IODIDE I 131
/SYNDCOR INTL/ 10.14%:50MG/ML /N 17315/
SYNDCOR INTL 50MG/ML N 17315

SODIUM LACTATE (PAGE 3-178)

INJECTABLE; INJECTION

SODIUM LACTATE IN PLASTIC CONTAINER
ABBOTT LABORATORIES 5MG/ML N 18947

SODIUM NITROPRUSSIDE (PAGE 3-178)

INJECTABLE; INJECTION

SODIUM NITROPRUSSIDE
AP LYPHOMED 50MG/VIAL N 70031

SODIUM POLYSTYRENE SULFONATE (PAGE 3-179)

POWDER; ORAL, RECTAL
 KAYEALATE
 AA BREON LABS/STERLING 453.6GM/BOI
 SODIUM POLYSTYRENE SULFONATE
 AA BAY LABORATORIES 453.6GM/BOI^M
 SUSPENSION; ORAL, RECTAL
 SODIUM POLYSTYRENE SULFONATE
 AA BAY LABORATORIES 15GM/60ML^M

SOYBEAN OIL (PAGE 3-180)

INJECTABLE; INJECTION
 LIPOSYN III 10%
 AP ABBOTT LABORATORIES 10%^M
 LIPOSYN III 20%
 AP ABBOTT LABORATORIES 20%^M

SPIRONOLACTONE (PAGE 3-180)

TABLET; ORAL
 SPIRONOLACTONE
 AB 3 PUREPAC/KALIPHARMA 25MG

SUCCINYLCHOLINE CHLORIDE (PAGE 3-181)

INJECTABLE; INJECTION
 ANECTINE
 AP 3 BURROUGHS WELLCOME 50MG/ML
 SUCCINYLCHOLINE CHLORIDE
 /AB/ /TRAVENCO, LABS/ 500MG/VIAL/
 /AB/ 1GM/VIAL/

SULCONAZOLE NITRATE (PAGE 3-181)

SOLUTION; TOPICAL
 SULCOSYN
 SYNTAX LABS/SYNTAX 1%^M

SULFABENZAMIDE; SULFACETAMIDE; SULFATHIAZOLE (PAGE 3-181)

TABLET; VAGINAL
 SULTRIN
 AI ORTHO PHARMACEUTICAL 184MG; 143.75MG; 172.5MG
 TRIPLE SULFA
 AI E FOUGERA/ALTANA 184MG; 143.75MG; 172.5MG^M
 AI PHARMADERM/ALTANA 184MG; 143.75MG; 172.5MG^M

SULFACETAMIDE SODIUM (PAGE 3-181)

SOLUTION/DROPS; OPHTHALMIC
 SULFACETAMIDE SODIUM
 /AI/ PHARMAFAIR 10%^M
 /AI/ /PHARMAFAIR/ 10%^M/
 SULEFAIR 10
 AI PHARMAFAIR 10%^M

SULFAMETHOXAZOLE (PAGE 3-182)

TABLET; ORAL
 SULFAMETHOXAZOLE
 /AB/ /HEATHER DRUGS/ 500MG/
 AB HEATHER DRUG 500MG

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-183)

TABLET; ORAL
 COTRIM
 AB LENTON 400MG; 80MG^M
 AB COTRIM D.S. 800MG; 160MG^M
 AB LEMMON
 AB SULFAMETHOPRIM
 AB PAR PHARMACEUTICAL 400MG; 80MG^M
 AB SULFAMETHOPRIM-DS
 AB PAR PHARMACEUTICAL 800MG; 160MG^M
 AB SULFAMETHOXAZOLE & TRIMETHOPRIM
 AB HEATHER DRUG 400MG; 80MG^M
 AB 800MG; 160MG^M
 AB SULFAMETHOXAZOLE AND TRIMETHOPRIM
 AB BARR LABORATORIES 400MG; 80MG^M
 AB CHELSEA LABORATORIES 400MG; 80MG^M
 AB 800MG; 160MG^M
 AB SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH
 AB BARR LABORATORIES 800MG; 160MG^M
 AB SULFATRIN-DS
 AB SUPERPHARM 800MG; 160MG^M
 AB SULFATRIN-SS
 AB SUPERPHARM 400MG; 80MG^M
 AB /TRIMETH/SULFA D/S/
 /AB/ /CHELSEA LABORATORIES/ 800MG; 160MG^M/
 /TRIMETH/SULFA S/S/
 /AB/ /CHELSEA LABORATORIES/ 400MG; 80MG^M/
 /AB/

SULFISOXAZOLE (PAGE 3-184)

TABLET; ORAL
 SULFISOXAZOLE
 BP 3 DRUMMER/PHOENIX 500MG

TECHNETIUM, TC-99M SODIUM PERTECHNETATE GENERATOR (PAGE 3-185)

SOLUTION; INJECTION, ORAL
/CINTICHEN/TECHNETIUM 99M GENERATOR/
/UNION CARBIDE RADIOAG 850-16,500 MCI/GENERATOR/
TECHNETIUM TC 99M GENERATOR
MEDI-PHYSICS 830-16,600 MCI/GENERATOR
N 17693

N 17664

TECHNETIUM, TC-99M ALBUMIN AGGREGATED KIT (PAGE 3-185)

INJECTABLE; INJECTION
ALBUMIN MICROSPHERES (HUMAN) INSTANT MICROSPHERES
/BS/ /DIAGNOSTIC PRODUCTS/ N/A
BS MEDICAL PRODUCTS/ N/A
/CINTICHEN/TECHNETIUM 99M HSA/
/BS/ /CINTICHEN/ N/A
TECHNETIUM TC 99M HSA
BS MEDI-PHYSICS N/A

N 17773

TECHNETIUM, TC-99M ALBUMIN KIT (PAGE 3-185)

INJECTABLE; INJECTION
/CINTICHEN/TECHNETIUM 99M HSA/
/CINTICHEN/ N/A
TECHNETIUM TC 99M HSA
MEDI-PHYSICS N/A

N 17775

TECHNETIUM, TC-99M ETIDRONATE KIT (PAGE 3-186)

INJECTABLE; INJECTION
TECHNETIUM TC 99M DIPHOSPHONATE-TIN KIT
AP 3 MEDI-PHYSICS N/A

N 17562

TECHNETIUM, TC-99M MEDRONATE (PAGE 3-186)

INJECTABLE; INJECTION
/MDP KIT/
TECHNETIUM TC 99M MDP

TECHNETIUM, TC-99M PENTETATE KIT (PAGE 3-186)

INJECTABLE; INJECTION
/DTPA (5M) KIT (CHELATE)/
/AP/ /MEDI-PHYSICS/ N/A
/KIDNEY/BRAIN SCANNING KIT/
/AP/ /GENERAL RADIOISOTOPE/ N/A
MPZ DTPA KIT - CHELATE
AP MEDI-PHYSICS N/A

N 17255

TECHNETIUM, TC-99M POLYPHOSPHATE KIT (PAGE 3-186)

INJECTABLE; INJECTION
SODIUM POLYPHOSPHATE-TIN KIT
3 MEDI-PHYSICS N/A

TECHNETIUM, TC-99M SULFUR COLLOID KIT (PAGE 3-187)

INJECTABLE; INJECTION
/AP/ /CINTICHEN/TECHNETIUM 99M TSC/
TECHNETIUM TC 99M TSC
AP MEDI-PHYSICS N/A

N 17784

TERBUTALINE SULFATE (PAGE 3-187)

AEROSOL; INHALATION
BRETHAIRE
BN GEIGY/CIBA-GEIGY 0.2MG/TINIM
BRICANYL
BN MERRELL DOM/DOM CHEM 0.2MG/TINIM

N 18000

INJECTABLE; INJECTION

BRICANYL
/AP/ /ASTRA PHARM PRODS/ /1MG/ML/
AP MERRELL DOM/DOM CHEM 1MG/ML

N 17466

TERFENADINE (PAGE 3-187)

TABLET; ORAL
SELDANE
MERRELL DOM/DOM CHEM 60MG

N 18949

TETRACYCLINE HYDROCHLORIDE (PAGE 3-188)

CAPSULE; ORAL
BRISTACYCLINE
BRISTOL LABS/B-M
/AP/ /500MG/
TETRACYCLINE HCL
AB SUPERPHARM 250MG
AB 500MG

N 62540

THEOPHYLLINE (PAGE 3-190)

CAPSULE; ORAL
SOPHOPHYLLIN-T
BP Fisons 100MG
BP 200MG
BP 250MG

N 87155

THEOPHYLLINE (PAGE 3-190)

CAPSULE, CONTROLLED RELEASE; ORAL

BC ELIXOPHYLLIN SR
BC BERLEX/SCHERING 125MG
250MG

BC SLO-810 50MG
BC WILLIAM H RORER 100MG
BC 200MG
BC 300MG

BC SLO-PHYLLIN 125MG
BC WILLIAM H RORER 50MG
BC SLOPHYLLIN-CRT 200MG
BC FISON 300MG

BC THEO-24 200MG
BC SEARLE/SEARLE PHARMS 30 MG
BC THEO810 260MG
BC GLAXO 130MG

BC THEO810 JR. 130MG
BC THEOCLEAR L.A.-130
BC CENTRAL PHARMS 125MG
BC THEOPHYL-SR 250MG

BC MCNEIL PHARM 125MG
BC THEOPHYLLINE 125MG
BC CENTRAL PHARMS 250MG

BC THEOVENT 125MG
BC SCHERING 250MG

TABLET; ORAL

BC QUIBRON-T 300MG
BC MEAD JOHNSON/B-M

TABLET, CONTROLLED RELEASE; ORAL

BC THEOCHRON 100MG
BC FOREST LABORATORIES 200MG

BC THEOPHYLLINE 100MG
BC FOREST LABORATORIES 200MG
BC 300MG
AB

THIAMYLAL SODIUM (PAGE 3-191)

INJECTABLE; INJECTION

BC SURITAL 5GM/VIAL
BC PARKE-DAVIS/N-L

THIORIDAZINE HYDROCHLORIDE (PAGE 3-192)

TABLET; ORAL

AB THIORIDAZINE HCL 150MG
AB BARR LABORATORIES 200MG

AB BIOCRRAFT LABS 10MG
AB 100MG
AB CORD LABORATORIES 100MG

AB DANBURY PHARMACAL 150MG
AB 200MG
AB ROXANE LABORATORIES 100MG

AB SUPERPHARM 10MG
AB 25MG
AB 50MG

TORBRAMYCIN (PAGE 3-194)

SOLUTION/DROPS; OPHTHALMIC
TOBREX ALCON LABORATORIES 0.32M

TOCAINIDE HYDROCHLORIDE (PAGE 3-194)

TABLET; ORAL

BC TONOCARD 400MG
BC MS&D/MERCK 600MG

TOLAZANIDE (PAGE 3-194)

TABLET; ORAL

AB TOLAZANIDE 100MG
AB ZENITH LABORATORIES 250MG
AB 500MG

TOLINASE

AB UPJOHN 100MG
AB 250MG
AB 500MG

TOLAZOLINE HYDROCHLORIDE (PAGE 3-194)

INJECTABLE; INJECTION

BC PRISCOLINE 25MG/ML
BC CIBA/CIBA-GEIGY

TOLBUTAMIDE (PAGE 3-194)

TABLET; ORAL

AB TOLBUTAMIDE 500MG
AB PUREPAC/KALIPHARMA 500MG
AB SUPERPHARM

N 88737
N 88738
N 88493
N 88456
N 88135
N 88869
N 88872
N 89048
N 89103
N 89104
N 89105

N 62535

N 18257
N 18257

N 18894
N 18894
N 18894

N 15500
N 15500
N 15500

N 06403

N 88950
N 88893

TOLMETIN SODIUM (PAGE 3-194)

CAPSULE; ORAL

TOLECTIN DS
/MCNEIL LABORATORIES//EQ. 500MG. BASE/
MCNEIL PHARM EQ 400MG. BASE

/N. 18084/
N 18084

TABLET; ORAL

TRIFLUOPERAZINE HCL
DURAMED PHARMS
AB EQ 1MG. BASE
AB EQ 2MG. BASE
AB EQ 5MG. BASE
AB EQ 10MG. BASE

N 88967
N 88968
N 88969
N 88970

TABLET; ORAL

TOLECTIN
/MCNEIL LABORATORIES//EQ. 200MG. BASE/
MCNEIL PHARM EQ 200MG. BASE

/N. 17628/
N 17628

TRAZODONE HYDROCHLORIDE (PAGE 3-194)

TABLET; ORAL

DESYREL
HEAD JOHNSON/B-M 150MG

N 18207

TRIAMCINOLONE ACETONIDE (PAGE 3-195)

CREAM; TOPICAL

ARISTOCORT A
LEDERLE LABS/AM CYAN 0.0252M
AT 0.12M
AT 0.52M

N 88818
N 88819
N 88820

LOTION; TOPICAL

TRIAMCINOLONE ACETONIDE
BAY LABORATORIES 0.0252M
AT 0.12M

N 88450
N 88451

ointment; TOPICAL

ARISTOCORT A
LEDERLE LABS/AM CYAN 0.12M
AT 0.52M
TRIAMCINOLONE ACETONIDE
PHARMADERM/BYK-GLDN 0.0252M
AT 0.12M

N 88780
N 88781

TRYTEX
SAVAGE LABS/BYK-GLDN 0.0252M
AT 0.12M

N 88692
N 88690
N 88693
N 88691

TRIAZOLAM (PAGE 3-197)

TABLET; ORAL

HALCION
UPJOHN 0.125MG

N 17892

>_ADD> AT

VECURONIUM BROMIDE (PAGE 3-202)

INJECTABLE; INJECTION
/NORCURON (N-45)/
NORCURON

N 88447

TRIFLUOPERAZINE HYDROCHLORIDE (PAGE 3-198)

TABLET; ORAL

TRIFLUOPERAZINE HCL
DURAMED PHARMS
AB EQ 1MG. BASE
AB EQ 2MG. BASE
AB EQ 5MG. BASE
AB EQ 10MG. BASE

N 88967
N 88968
N 88969
N 88970

TRILOSTANE (PAGE 3-199)

CAPSULE; ORAL

MODASTANE
WINTHROP LABS/STERL 30MG
60MG

N 18719
N 18719

TRIMEPAZINE TARTRATE (PAGE 3-199)

SYRUP; ORAL

TRIMEPAZINE TARTRATE
BAY LABORATORIES EQ 2.5MG. BASE/5ML

N 88285

TRIMETHOPRIM (PAGE 3-199)

TABLET; ORAL

TRIMETHOPRIM
DANBURY PHARMACAL 100MG

N 70049

TRIPROLIDINE HYDROCHLORIDE (PAGE 3-200)

SYRUP; ORAL

TRIPROLIDINE HCL
AA HALSEY DRUG 1.25MG/5ML

N 88735

TRISULFAPYRIMIDINES (PAGE 3-200)

SUSPENSION; ORAL

/TRIPLE SULFAS/
/AA/ /VALE CHEMICAL/ /500MG/5ML/

/N. 88167/

TROPICAMIDE (PAGE 3-201)

SOLUTION/DROPS; OPHTHALMIC

TROPICAMIDE
MAURRY BIOLOGICAL 12M

VECURONIUM BROMIDE (PAGE 3-202)

INJECTABLE; INJECTION
/NORCURON (N-45)/
NORCURON

N 88447

VERAPAMIL HYDROCHLORIDE (PAGE 3-202)

TABLET; ORAL

AB	SEARLE/SEARLE PHARMS	80MG#	N 18817
AB		120MG#	N 18817
AB	KNOLL PHARMACEUTICAL	80MG	N 18593
AB		120MG	N 18593

VINCRIStINE SULFATE (PAGE 3-202)

INJECTABLE; INJECTION

ONCOVIN	/1MG/AMP/	N 16103
ELI LILLY	/5MG/AMP/	N 16103
ELI LILLY	1MG/ML	N 16103

WARFARIN SODIUM (PAGE 3-203)

TABLET; ORAL

> DLT >	AB	COUNADIN	/1MG/	N 09218
	AB	DUPONT PHARMS/DUPONT	/2.5MG/	N 09218
	AB		/5MG/	N 09218
> ADD >	AB	DUPONT PHARMS/DUPONT	2MG	N 09218
	AB		2.5MG	N 09218
	AB		5MG	N 09218
> ADD >	AB	WARFARIN SODIUM	2MG#	N 88719
	AB	COLMED LABORATORIES	2.5MG#	N 88720
	AB		5MG#	N 88721

WATER FOR INJECTION, STERILE (PAGE 3-204)

LIQUID; N/A

AP	STERILE WATER FOR INJECTION IN PLASTIC CONTAINER	100%	N 18632
AB	STERILE WATER IN PLASTIC CONTAINER	/100%	N 18632

ADDENDUM

DESI PENDING LIST - 'EXEMPT' (COURT ORDER) CATEGORY
 CUMULATIVE SUPPLEMENT NUMBER 12 / AUGUST '84 - AUGUST '85

/ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEX-PANTHENOYL; FOLIC
 /ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN;
 /THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN D; VITAMIN E
 (PAGE AD2)
 (SEE SPECIAL NOTE B.)
 /INJECTABLE; INJECTION/
 /N.V.C. 93/
 /LYPHONED/
 /20MG/ML; 0.012MG/ML; 0.001MG/ML;
 /5MG/ML; 0.09MG/ML; 5MG/ML; 0.5MG/ML;
 /0.72MG/ML; 0.6MG/ML; 660 IU/ML;
 /60 IU/ML; 200 IU/ML/
 /N 186660/

 /ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; FOLIC ACID;
 /NIACINAMIDE; PANTHENOYL; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN;
 /THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN D; VITAMIN E
 (PAGE AD2)
 (SEE SPECIAL NOTE B.)
 /INJECTABLE; INJECTION/
 /MULTIVITAMIN ADDITIVE/
 /ABBOTT LABORATORIES/
 /100MG/5ML; 0.06MG/5ML; 0.005MG/5ML;
 /0.4MG/5ML; 80MG/5ML; 5MG/5ML;
 /4.86MG/5ML; 4.93MG/5ML; 3.35MG/5ML;
 /300 IU/5ML; 200 IU/5ML;
 /10 IU/5ML/
 /N 18223/

 /ASCORBIC ACID; BIOTIN; DEX-PANTHENOYL; NIACINAMIDE; PYRIDOXINE/
 /HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE (PAGE AD2)
 (SEE SPECIAL NOTE B.)
 /INJECTABLE; INJECTION/
 /BEROCCA/
 /HOFFMAN-LA ROCHE/
 /50MG/ML; 0.1MG/ML; 10MG/ML; 40MG/ML;
 /10MG/ML; 5MG/ML; 5MG/ML/
 /N 06071/

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

 /ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEX-PANTHENOYL;
 /ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYLONADIONE;
 /PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM;
 /THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E (PAGE AD2)
 /INJECTABLE; INJECTION/
 /N.V.C. 93/
 /USV PHARMACEUTICAL/
 /50MG/VIAL; 0.02MG/VIAL; 0.001MG/VIAL;
 /5MG/VIAL; 0.01MG/VIAL; 0.14MG/VIAL;
 /1MG/VIAL; 0.2MG/VIAL;
 /EQ 1MG BASE/VIAL; 0.4MG/VIAL;
 /EQ 1MG BASE/VIAL; 0.2MG/VIAL;
 /7MG/VIAL/
 /N 18920/

 /ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEX-PANTHENOYL;
 /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.C. 93/
 /USV PHARMACEUTICAL/
 /100MG/VIAL; 0.06MG/VIAL; 0.005MG/VIAL;
 /15MG/VIAL; 0.005MG/VIAL; 0.4MG/VIAL;
 /40MG/VIAL; 4MG/VIAL; 3.5MG/VIAL;
 /5MG/VIAL; 1MG/VIAL;
 /10 IU/VIAL/
 /N 18933/

 /ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEX-PANTHENOYL;
 /ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE/
 /HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE; VITAMIN
 /A (PAGE AD2)
 (SEE SPECIAL NOTE B.)
 /INJECTABLE; INJECTION/
 /NVC PLUS/
 /ASCOT. HOSP. PHARMS/
 /10MG/ML; 0.006MG/ML; 0.5 UEN/ML;
 /1.5MG/ML; 20 IU/ML; 0.4MG/ML;
 /0.4MG/ML; 0.36MG/ML; 0.3MG/ML;
 /350 IU/ML/
 /N 18639/

DESI PENDING LIST - 'EXEMPT' (COURT ORDER) CATEGORY
 CUMULATIVE SUPPLEMENT NUMBER 12 / AUGUST '84 - AUGUST '85

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

NITROGLYCERIN (PAGE AD7)

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

/INJECTABLE; INJECTION/
 /N.Y. 1000/

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

/USV PHARMACEUTICAL/ /50MG/ML; 2.5MG/ML; 10MG/ML; 50MG/ML;
 /1MG/ML; 5MG/ML; 2.500G; 10/ML; 100G; 10/ML;
 /10.5MG/ML/ /N 86809/
 /100MG/ML; 5MG/ML; 20MG/ML; 5MG/ML;
 /2MG/ML; 10MG/ML; 2.000G; 10/ML;
 /200G; 10/ML; 1MG/ML/ /N 86809/

PENTAERYTHRITOL TETRANITRATE (PAGE AD8)

CAPSULE, CONTROLLED RELEASE; ORAL

PENTAERYTHRITOL TETRANITRATE

3 VITARINE/PHOENIX

3 80MG

3 80MG

N 86305

N 87529

N 87531

DIPYRIDAMOLE (PAGE AD4)

TABLET; ORAL

DIPYRIDAMOLE

DANBURY PHARMACAL

25MG

50MG

75MG

PHARM BASICS

SIDMAK LABORATORIES

25MG

50MG

75MG

N 88945

N 88800

N 87432

N 88822

N 88683

N 88684

N 88685

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

/TABLET; ORAL/
 /ISOSORBIDE DINITRATE/
 /BARR LABORATORIES/

/30MG/

/N 87564/

/TABLET; SUBLINGUAL/
 /ISOSORBIDE DINITRATE/
 /BARR LABORATORIES/

/10MG/

/N 87545/

/TABLET; CONTROLLED RELEASE; ORAL/
 /ISOSORBIDE DINITRATE/
 /FOREST LABORATORIES/

/N 88428/

CURRENT STATUS - INEFFECTIVE

/BENTYL W. PHENOBARBITAL/ /MERRELL DOWN/DON CHEN/
 /DICLOFENAC 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

/FORTISSPORIN/ /BURROUGHS WELLCOME/
 /GRANICIDIN; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE;/
 /POLYMYXIN B SULFATE/

/DINETAPP/ /AN ROBINS/
 /BROMPHENTRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE;
 /PHENYLPROPANOLAMINE HYDROCHLORIDE/

/CETACORT/ /OMEN LABS/DERM PRODUCTS/
 /HYDROCORTISONE/

/ELIXIR DINETAPP/ /AN ROBINS/
 /BROMPHENTRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE;/
 /PHENYLPROPANOLAMINE HYDROCHLORIDE/

/HC (HYDROCORTISONE)/ /G. AND N. PHARMACAL/
 /HYDROCORTISONE/

/HYDROCORTISONE/ /TOWNE PAULSEN/
 /HYDROCORTISONE/

/XLOTYCIN/ /ELI LILLY/
 /ERYTHRONICIN

/MYCLOS/ /ER SQUIBB AND SONS/
 /GRANICIDIN; NEOMYCIN SULFATE; NYSTATIN;/
 /TRIAMCINOLONE ACETONIDE/

/NEOSPORIN G/ /BURROUGHS WELLCOME/
 /GRANICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE/

CURRENT STATUS - INEFFECTIVE

/NYSTATIN; NEOMYCIN SULFATE; GRANICIDIN; TRIAMCINOLONE/
 /ACETONIDE/ /CLAY-PARK LABS/
 /GRANICIDIN; NEOMYCIN SULFATE; NYSTATIN;/
 /TRIAMCINOLONE ACETONIDE/

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

/NUTRACORT/ /OMEN LABS/DERM PRODUCTS/
 /HYDROCORTISONE/

/PHISCOLINE/ /CIBA-CIBA-GEIGY/
 /TOLAZOLINE HYDROCHLORIDE/

TUSS-ORNADE SKAF LABORATORIES
 CARAMIPHEN EDISYLATE; CHLORPHENIRAMINE MALEATE;
 ISOPROPAMIDE IODIDE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CURRENT STATUS - EFFECTIVENESS TO BE DETERMINED

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

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 the APDP will enable firms to determine whether in vitro and/or in vivo bioavailability/bioequivalence study data must be included with their ANDA submissions.

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

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

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 FDA's 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 APDP

All products accepted and approved under Section 505 of the Act as NDAs by the Office of Biological Research and Review (OBRR) will now be published in the APDP (see TABLE III). The application holder should have submitted relevant patent and exclusivity information as for other NDA drug products. These products will be listed drugs and ANDA applications may be submitted for marketing of drugs from this group. Appropriate patent numbers, 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 APDP would contain patent and exclusivity information. Because some firms submitted patent information in excess of that covered by the statute, FDA has reviewed all of the patent information to assure that only appropriate patents are listed. The patents that FDA regards as covered by the statutory provisions for submission of patent information are those 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.

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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.

DUE 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
RT0	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
D-9	NARCOTIC OVERDOSE IN ADULTS
D-10	NARCOTIC OVERDOSE IN CHILDREN
D-11	POSTOPERATIVE NARCOTIC DEPRESSION IN CHILDREN

INDICATIONS

I-1	SEVERE HYPERTENSION IN PEDIATRICS AND NON-MALIGNANT HYPERTENSION
I-2	DYSMENORRHEA
I-3	TREATMENT OF TINEA VERSICOLOR
I-4	SYMPTOMATIC GASTROESOPHAGEAL REFLUX
I-5	NEPHROTOMOGRAPHY
I-6	CONTRAST ENHANCEMENT IN CRANIAL COMPUTED TOMOGRAPHY
I-7	VENOGRAPHY OF LOWER EXTREMITIES
I-8	WHOLE-BODY COMPUTED TOMOGRAPHY
I-9	GATED CARDIAC POOL IMAGING
I-10	POST-MYOCARDIAL INFARCTION
I-11	COLORRECTAL SURGERY
I-12	NAUSEA AND VOMITING ASSOCIATED WITH EMETOGENIC CANCER CHEMOTHERAPY
I-13	CISPLATIN INDUCED EMESIS
I-14	DIABETIC GASTROPARESIS
I-15	SHORT TERM TREATMENT OF GASTRIC ULCER DISEASE
I-16	ACROMEGALY
I-17	PITUITARY TUMORS
I-18	POSTMENOPAUSAL OSTEOPOROSIS
I-19	ANTIDOTE FOR ACETAMINOPHEN OVERDOSAGE
I-20	CONGESTIVE HEART FAILURE BID DOSAGE SCHEDULE
I-21	ACUTE OTITIS MEDIA
I-22	EXERCISE INDUCED BRONCHOSPASMS
I-23	MI OR STROKE
I-24	COMBINED USE WITH NICOTINIC ACID TO LOWER CHOLESTEROL LEVEL
I-25	BLASTOMYCOSES DERMATITIDES
I-26	PEDIATRIC SUBARACHNOID VASCULAR
I-27	PETRIELLIDIUM BOYDII INFECTION
I-28	HEREDITARY ANGIOEDEMA
I-29	INTRACORONARY USE
I-30	PEDIATRIC USE
I-31	DIRECT ISOTOPIIC CYSTOGRAPHY
I-32	POSTPARTUM HEMORRHAGE
I-33	USE IN METHADONE INDUCED RESPIRATORY DEPRESSION
I-34	PROLACTIN SECRETING ADENOMAS

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; NEPROBAMATE 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; NEPROBAMATE 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	

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

<u>ACTIVE INGREDIENT(S) STRENGTH(S)</u>	<u>TRADE NAME (DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO. APPROVAL DATE</u>	<u>PATENT NO. EXP. DATE</u>	<u>EXCLUSIVITY 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		RTD 09-24-86
BROMPHENIRAMINE MALEATE 12MG	DIMETANE (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	10-799 06-10-83		RTD 09-24-86
BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 12MG; 75MG	DIMETAPP (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	12-436 04-02-84		

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>
CHLORHEXIDINE GLUCONATE 0.5%	HIBITANE (TINCTURE; TOPICAL)	ICI AMERICAS	18-049 12-18-78		
CHLORHEXIDINE GLUCONATE 0.5%	HIBISTAT (SOLUTION; TOPICAL)	ICI AMERICAS	18-300 05-23-80		
CHLORHEXIDINE GLUCONATE 4%	EXIDINE (SOLUTION; TOPICAL)	XTTRIUM LABS	19-125 12-24-84		
CHLORHEXIDINE GLUCONATE 4%	EXIDINE (AEROSOL; TOPICAL)	XTTRIUM LABS	19-127 12-24-84		
CHLORHEXIDINE GLUCONATE 4%	HIBICLENS (SOLUTION; TOPICAL)	ICI AMERICAS	17-768 09-17-76		
CHLORHEXIDINE GLUCONATE 4%	HIBICLENS (SPONGE; TOPICAL)	ICI AMERICAS	18-423 08-27-81		
CHLORPHENIRAMINE MALEATE 8MG	TELDRIN (CAPSULE, CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	17-369 05-11-78		
CHLORPHENIRAMINE MALEATE 12MG	TELDRIN (CAPSULE, CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	17-369 05-11-78		
CHLORPHENIRAMINE MALEATE 8MG	CHLOR-TRIMETON (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	07-638 10-18-78		
CHLORPHENIRAMINE MALEATE 12MG	CHLOR-TRIMETON (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	07-638 10-18-78		
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 4MG; 25MG	DEMAMIN (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-556 05-14-84		NS 09-24-86
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 8MG; 75MG	CONTAC (CAPSULE, CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	18-099 02-04-80		

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>
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 8MG; 75MG	COLD CAPSULE V (CAPSULE, CONTROLLED RELEASE; ORAL)	DM GRAHAM LABS	18-794 04-23-85		
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	CODINAL-L.A. 12 (CAPSULE, CONTROLLED RELEASE; ORAL)	CENTRAL PHARMS	18-935 04-15-85		

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 EXP. DATE
CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX EQ 4MG MALEATE/5ML; EQ 10MG BASE/5ML)	PENNUSS (SUSPENSION, CONTROLLED RELEASE; ORAL)	PENNMALT PHARM	18-928 08-14-85	4221778 09-09-97	
CHLORPHENIRAMINE POLISTIREX; PHENYLPROPANOLAMINE POLISTIREX EQ 4MG MALEATE/5ML; EQ 37.5MG HCL/5ML	CORSYM (SYRUP; ORAL)	PENNMALT PHARM	18-050 01-04-84	4221778 09-09-97	NDF 09-24-86
DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE 2MG; 60MG	DISOPHROL (TABLET; ORAL)	SCHERING	12-394 06-03-60		RTD 09-24-86
DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE 6MG; 120MG	DRXORAL (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	13-483 09-13-82		RTD 09-24-86
DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE 6MG; 120MG	DISOPHROL (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	13-483 09-13-82		RTD 09-24-86
DEXTROMETHORPHAN RESIN COMPLEX EQ 30MG HBR/5ML	DELSYM (SUSPENSION, CONTROLLED RELEASE; ORAL)	PENNMALT PHARM	18-658 10-08-82	4221778 09-09-97	NDF 09-24-86
DIPHENHYDRAMINE HYDROCHLORIDE 12.5MG/5ML	BENYLIN (SYRUP; ORAL)	PARKE-DAVIS/W-L	06-514 08-07-81		
DIPHENHYDRAMINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE 12.5MG/5ML; 30MG/5ML	BENYLIN (SOLUTION; ORAL)	PARKE-DAVIS/W-L	19-014 06-11-85		
DOXYLAMINE SUCCINATE 25MG	UNISOM (TABLET; ORAL)	Pfizer	18-066 10-06-78		
IBUPROFEN 200MG	ADVIL (TABLET; ORAL)	WHITEHALL LABS/AMHO	18-989 05-18-84		NS 09-24-86
IBUPROFEN 200MG	NUPRIN (TABLET; ORAL)	UPJOHN MANUFACTURING	19-012 05-18-84		NS 09-24-86
INSULIN SUSPENSION, ISOPHANE, BEEF 40 UNITS/ML	SEMILENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-929 02-08-77		

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, BEEF 100 UNITS/ML	SEMILENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-929 02-08-77		
INSULIN SUSPENSION, ISOPHANE, BIOSYNTHETIC HUMAN 100 UNITS/ML	HUMULIN N (INJECTABLE; INJECTION)	ELI LILLY	18-781 10-28-82		
INSULIN SUSPENSION, ISOPHANE, MIXED BEEF AND PORK 40 UNITS/ML	NPH ILETIN 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	NPH PURIFIED PORK ISOPHANE INSULIN (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; 40 UNITS/ML	PROTAMINE, ZINC & ILETIN I (BEEF-PORK) (INJECTABLE; INJECTION)	ELI LILLY	17-932 02-08-77		

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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, PURIFIED BEEF 40 UNITS/ML	PROTAMINE ZINC INSULIN (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-928 02-08-77		
INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED BEEF 100 UNITS/ML	PROTAMINE ZINC INSULIN (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-928 02-08-77		
INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED BEEF; INSULIN, PURIFIED BEEF 100 UNITS/ML	PROTAMINE ZINC AND Iletin II (INJECTABLE; INJECTION)	ELI LILLY	18-476 06-12-80		
INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED PORK; INSULIN, PURIFIED PORK 100 UNITS/ML	PROTAMINE ZINC AND Iletin II(PORK) (INJECTABLE; INJECTION)	ELI LILLY	18-346 12-05-79		
INSULIN ZINC SUSPENSION, BEEF 40 UNITS/ML	LENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-998 02-08-77		
INSULIN ZINC SUSPENSION, BEEF 100 UNITS/ML	LENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-998 02-08-77		
INSULIN ZINC SUSPENSION, SEMI-SYNTHETIC PURIFIED HUMAN 100 UNITS/ML	NOVOLIN L (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-777 08-30-83		
INSULIN ZINC SUSPENSION, EXTENDED, PURIFIED BEEF 100 UNITS/ML	ULTRALENTE (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-385 03-17-80		
INSULIN ZINC SUSPENSION, EXTENDED, BEEF 100 UNITS/ML	ULTRALENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-997 02-08-77		
INSULIN ZINC SUSPENSION, PROMPT, BEEF 100 UNITS/ML	SEMILENTE INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	17-996 02-08-77		

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INSULIN ZINC SUSPENSION, PROMPT, PURIFIED PORK 100 UNITS/ML	SEMILENTE (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-382 03-17-80		
INSULIN ZINC SUSPENSION, PURIFIED BEEF 100 UNITS/ML	LENTE ILETIN II (INJECTABLE; INJECTION)	ELI LILLY	18-477 06-12-80		
INSULIN ZINC SUSPENSION, PURIFIED BEEF AND PORK 100 UNITS/ML	LENTARD (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-384 03-17-80		
INSULIN ZINC SUSPENSION, PURIFIED PORK 100 UNITS/ML	LENTE ILETIN II (PORK) (INJECTABLE; INJECTION)	ELI LILLY	18-347 12-05-79		
INSULIN ZINC SUSPENSION, PURIFIED PORK 100 UNITS/ML	LENTE (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-383 03-17-80		
INSULIN, SEMISYNTHETIC PURIFIED HUMAN 100 UNITS/ML	NOVOLIN R (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		

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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>
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	REGULAR PURIFIED PORK INSULIN (INJECTABLE; INJECTION)	SQUIBB-NOVO	18-381 03-17-80		
INSULIN SUSPENSION, ISOPHANE, SEMISYNTHETIC, PURIFIED HUMAN 100 UNITS/ML	NOVOLIN N (INJECTABLE; INJECTION)	SQUIBB-NOVO	19-065 01-23-85		
NONOXYNOL-9 1GM	TODAY (SPONGE; VAGINAL)	VLI CORPORATION	18-683 04-01-83		NDF 09-24-86
POTASSIUM IODIDE 130MG	THYRO-BLOCK (TABLET; ORAL)	WALLACE LABS/C-W	18-307 11-09-79		
POTASSIUM IODIDE 1GM/ML	POTASSIUM IODIDE (SOLUTION; ORAL)	ROXANE LABORATORIES	18-551 02-19-82		NDF 09-24-86
POTASSIUM IODIDE 130MG	IOSAT (TABLET; ORAL)	ANBEX	18-664 10-14-82		
PSEUDOEPHEDRINE HYDROCHLORIDE 120MG	SUDAFED S.A. (CAPSULE, CONTROLLED RELEASE; ORAL)	BURROUGHS WELLCOME	17-941 01-15-79		
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	ACTIFED (SYRUP; ORAL)	BURROUGHS WELLCOME	11-935 11-26-82		RTO 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	ACTIFED (TABLET; ORAL)	BURROUGHS WELLCOME	11-936 11-26-82		RTO 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	ACTIFED (CAPSULE; ORAL)	BURROUGHS WELLCOME	19-208 01-15-85		RTO 09-24-86

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PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	ALLERBAN PLUS (SYRUP; ORAL)	BAY LABORATORIES	88-116 03-04-83		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRI-SUDO (TABLET; ORAL)	MD PHARMACEUTICAL	85-024 01-10-84		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPODRINE (TABLET; ORAL)	DANBURY PHARMACAL	88-112 01-20-83		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	TRIOFED (SYRUP; ORAL)	NATL PHARM MFG/BARRE	88-115 03-04-83		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	TRIPOSED (SYRUP; ORAL)	HALSEY DRUG	88-213 03-30-84		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPROLIDINE HCL AND PSEUDOEPHEDRINE HCL (TABLET; ORAL)	CHELSEA LABORATORIES	88-118 01-26-84		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPOSED (TABLET; ORAL)	HALSEY DRUG	88-192 05-01-84		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPROLIDINE AND PSEUDOEPHEDRINE (TABLET; ORAL)	BOLAR PHARMACEUTICAL	88-318 01-13-84		RT0 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 120MG; 5MG	ACTIFED (CAPSULE, CONTROLLED RELEASE; ORAL)	BURROUGHS WELLCOME	18-996 06-17-85		
PSEUDOEPHEDRINE SULFATE 120MG	AFRINOL (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-191 10-30-80		

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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		RT0 09-24-86
TRIPROLIDINE HYDROCHLORIDE 2.5MG	TRIPROLIDINE HCL (TABLET; ORAL)	BOLAR PHARMACEUTICAL	84-453 02-06-76		RT0 09-24-86
TRIPROLIDINE HYDROCHLORIDE 2.5MG	TRIPROLIDINE HCL (TABLET; ORAL)	DANBURY PHARMACAL	85-094 02-07-77		RT0 09-24-86
TRIPROLIDINE HYDROCHLORIDE 2.5MG	TRIPROLIDINE HCL (TABLET; ORAL)	DRUMMER/PHOENIX	85-610 03-21-78		RT0 09-24-86
TRIPROLIDINE HYDROCHLORIDE 1.25MG/5ML	ACTIDIL (SYRUP; ORAL)	BURROUGHS WELLCOME	11-496 07-24-58		RT0 09-24-86
TRIPROLIDINE HYDROCHLORIDE 1.25MG/5ML	BAYIDYL (SYRUP; ORAL)	BAY LABORATORIES	87-963 01-18-83		RT0 09-24-86
TRIPROLIDINE HYDROCHLORIDE 1.25MG/5ML	TRIPROLIDINE HCL (SYRUP; ORAL)	NATL PHARM MFG/BARRE	85-940 07-13-79		RT0 09-24-86
TRIPROLIDINE HYDROCHLORIDE 1.25MG/5ML	TRIPROLIDINE HCL (SYRUP; ORAL)	PHARMS ASSOC/BEACH	87-514 02-10-82		RT0 09-24-86

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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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ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP WITH: AS-1: DEXTROSE USP 2.2GM/100ML, SODIUM CHLORIDE USP 0.9GM/100ML, MANNITOL USP 0.75GM/100ML, ADENINE 0.27GM/100ML	ADSOL ^R RED CELL PRESERVATION SOLUTION (INJECTABLE; INJECTION)	TRAVENOL LABS	81-1104 5-16-83		
ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION WITH: AS-2: CITRIC ACID USP 0.642GM/100ML, DIBASIC SODIUM PHOSPHATE USP 0.285GM/100ML, SODIUM CHLORIDE USP 0.718 GM/100ML, ADENINE 0.017GM/100ML, DEXTROSE USP 0.396GM/100ML, SODIUM CITRATE USP 0.588GM/100ML	AS-2 NUTRICEL ADITIVE SYSTEM (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	82-915 9-22-83		
ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION WITH: AS-3: CITRIC ACID USP 0.042 GM/100ML, MONOBASIC SODIUM PHOSPHATE USP 0.276GM/100ML, SODIUM CHLORIDE USP 0.410 GM/100ML, ADENINE 0.30 GM/100ML, DEXTROSE USP 1.10 GM/100ML, SODIUM CITRATE USP 0.588GM/100ML	AS-3 NUTRICEL ADDITIVE SYSTEM (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	82-915 10-19-84		
ANTICOAGULANT HEPARIN SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	77-822 5-17-78		
ANTICOAGULANT HEPARIN SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	81-1217 5-16-83		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	81-416 10-12-83		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	76-305 6-30-78		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	16-702 12-28-70		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TERUMO AMERICA	78-1214 2-8-80		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	77-923 1-20-78		

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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		

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DEXTRAN 70, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	8-716 8-11-69		
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	PHARMACHEM	16-836 11-14-70		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	PHARMACHEM	16-836 11-14-70		
DEXTRAN 75, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	PHARMACHEM	8-564 9-19-52		
DEXTRAN 75, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	PHARMACHEM	16-759 8-19-70		
DEXTRAN 1 150MG/ML IN SODIUM CHLORIDE 0.6% 0.6GM/ML	PROMIT (INJECTABLE; INJECTION)	PHARMACIA LABS	83-715 10-30-84		
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	RHEOMACRODEX ^R (INJECTABLE; INJECTION)	PHARMACIA LABS	14-716 1-18-67		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	RHEOMACRODEX ^R (INJECTABLE; INJECTION)	PHARMACIA LABS	14-716 1-18-67		
DEXTRAN 70, 6% 6GM/100ML IN DEXTROSE 5% 5GM/100ML	MACRODEX ^R (INJECTABLE; INJECTION)	PHARMACIA LABS	6-826 6-8-54		
DEXTRAN 70, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	MACRODEX ^R (INJECTABLE; INJECTION)	PHARMACIA LABS	6-826 6-8-54		

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 [®] 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	16-628 11-4-68		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	GENTRAN [®] 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	16-628 11-4-68		
DEXTRAN 40, 10% 10GM/100ML DEXTROSE 5% 5GM/100ML	GENTRAN [®] 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	84-619 2-22-85		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	GENTRAN [®] 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	84-620 2-22-85		
DEXTRAN 75, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	GENTRAN [®] 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 [®] 75 AND 10% TRAVERS [®] (INJECTABLE; INJECTION)	TRAVENOL LABS	8-788 2-9-53		
HETASTARCH, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	HESPAN [®] (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		1-29 09-24-86
UROKINASE 250,000 IU/VIAL	BREOKINASE (INJECTABLE; INJECTION)	STERLING DRUG	17-873 8-28-79		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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 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	

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ALBUTEROL SULFATE EQ 2MG BASE	PROVENTIL (TABLET; ORAL)	SCHERING	17-853 05-07-82	3644353 02-22-89 3705233 12-05-89	NE 09-24-86
ALBUTEROL SULFATE EQ 4MG BASE	PROVENTIL (TABLET; ORAL)	SCHERING	17-853 05-07-82	3644353 02-22-89 3705233 12-05-89	NE 09-24-86
ALBUTEROL SULFATE EQ 2MG BASE/5ML	PROVENTIL (SYRUP; ORAL)	SCHERING	18-062 01-19-83	3644353 02-22-89 3705233 12-05-89 4499108 02-12-02	
ALCLONETASONE DIPROPIONATE 0.05%	VADERM (OINTMENT; TOPICAL)	SCHERING	18-702 12-14-82	4124707 11-07-95	NCE 12-14-92
ALCLONETASONE DIPROPIONATE 0.05%	VADERM (CREAM; TOPICAL)	SCHERING	18-707 12-14-82	4124707 11-07-95	NCE 12-14-92
ALLOPURINOL 100MG	ALLOPURINOL (TABLET; ORAL)	BOLAR PHARMACEUTICAL	18-241 11-16-84		
ALLOPURINOL 300MG	ALLOPURINOL (TABLET; ORAL)	BOLAR PHARMACEUTICAL	18-241 11-16-84		
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		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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 100MG	ZYLOPRIM (TABLET; ORAL)	BURROUGHS WELLCOME	16-084 08-19-66	3624205 11-30-88	
ALLOPURINOL 300MG	ZYLOPRIM (TABLET; ORAL)	BURROUGHS WELLCOME	16-084 01-14-74	3624205 11-30-88	
ALLOPURINOL 100MG	LOPURIN (TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-297 06-10-80	3624205 11-30-88	
ALLOPURINOL 300MG	LOPURIN (TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-297 06-10-80	3624205 11-30-88	
ALPRAZOLAM 0.25MG	XANAX (TABLET; ORAL)	UPJOHN	18-276 10-16-81	3987052 10-19-93 3980789 09-14-93	
ALPRAZOLAM 0.5MG	XANAX (TABLET; ORAL)	UPJOHN	18-276 10-16-81	3987052 10-19-93 3980789 09-14-93	
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

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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 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
AMINO ACIDS 4%	BRANCHAMIN 4% (INJECTABLE; INJECTION)	TRAVENOL LABS	18-678 09-28-84	4438144 03-20-01	NS 09-28-87
AMINO ACIDS 4%	BRANCHAMIN 4% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-684 09-28-84	4438144 03-20-01	NS 09-28-87
AMINO ACIDS 6.5%	NEOPHAM 6.5% (INJECTABLE; INJECTION)	CUTTER-VITRUM	18-792 01-17-84		NS 09-24-86
AMINO ACIDS 3.5%	AMINOSYN 3.5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-804 05-15-84		NS 09-24-86
AMINO ACIDS 3.5%	AMINOSYN 3.5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-875 08-08-84		NS 09-24-86
AMINO ACIDS 5.2%	AMINESS 5.2% ESSENTIAL AMINO ACIDS W/ HISTADINE (INJECTABLE; INJECTION)	CUTTER-VITRUM	18-901 04-06-84		
AMINO ACIDS 5.5%	TRAVASOL 5.5% W/O ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-931 08-23-84		NS 09-24-86

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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AMINO ACIDS 8.5%	TRAVASOL 8.5% W/O ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-931 08-23-84		
AMINO ACIDS 10%	TRAVASOL 10% W/O ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-931 08-23-84		
AMINO ACIDS 6%	TROPHAMINE 6% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-018 07-20-84		NS 09-24-86
AMINO ACIDS 7%	AMINOSYN-HBC 7% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-374 07-12-85		
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	PERIPHAMINE (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		

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AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; SODIUM CHLORIDE 3.5%; 21MG/100ML; 40MG/100ML; 128MG/100ML; 234MG/100ML	AMINOSYN 3.5% M IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-804 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		
AMINOCAPROIC ACID 250MG/ML	AMINOCAPROIC ACID (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-590 10-29-82		
AMINOGLUTETHIMIDE 250MG	CYTADREN (TABLET; ORAL)	CIBA/CIBA-GEIGY	18-202 10-29-80	3595960 07-27-88 3944671 03-16-93	
AMINOPHYLLINE 300MG/5ML	SONOPHYLLIN (ENEMA; RECTAL)	FISONS	18-232 04-02-82		NR 09-24-86
AMINOPHYLLINE; SODIUM CHLORIDE 100MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-924 12-12-84		
AMINOPHYLLINE; SODIUM CHLORIDE 200MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-924 12-12-84		
AMINOPHYLLINE; SODIUM CHLORIDE 400MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-924 12-12-84		

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AMINOPHYLLINE; SODIUM CHLORIDE 500MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-924 12-12-84		
AMITRIPTYLINE HYDROCHLORIDE 10MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 04-07-61	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 25MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 07-05-74	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 50MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 04-07-61	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 75MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 10-28-76	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 100MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 10-28-76	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 150MG	ELAVIL (TABLET; ORAL)	MS&D/MERCK	12-703 09-17-76	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE 10MG/ML	ELAVIL (INJECTABLE; INJECTION)	MS&D/MERCK	12-704 04-11-61	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE 12.5MG; 5MG	LIMBITROL (TABLET; ORAL)	HOFFMANN-LA ROCHE	16-949 12-23-77	4316897 02-23-99	
AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE 25MG; 10MG	LIMBITROL (TABLET; ORAL)	HOFFMANN-LA ROCHE	16-949 12-23-77	4316897 02-23-99	

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AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 4MG	ETRAFON A (TABLET; ORAL)	SCHERING	14-713 12-30-65	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 2MG	ETRAFON 2-25 (TABLET; ORAL)	SCHERING	14-713 12-30-65	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 4MG	ETRAFON-FORTE (TABLET; ORAL)	SCHERING	14-713 12-30-65	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 2MG	ETRAFON 2-10 (TABLET; ORAL)	SCHERING	14-713 12-30-65	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 4MG	TRIAVIL 4-10 (TABLET; ORAL)	MS&D/MERCK	14-715 12-30-65	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 2MG	TRIAVIL 2-25 (TABLET; ORAL)	MS&D/MERCK	14-715 08-23-65	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 10MG; 2MG	TRIAVIL 2-10 (TABLET; ORAL)	MS&D/MERCK	14-715 04-04-67	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 25MG; 4MG	TRIAVIL 4-25 (TABLET; ORAL)	MS&D/MERCK	14-715 08-25-65	3428735 02-18-86	
AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE 50MG; 4MG	TRIAVIL 4-50 (TABLET; ORAL)	MS&D/MERCK	14-715 03-15-78	3428735 02-18-86	
AMMONIUM LACTATE EQ 12% ACID	LAC-HYDRIN (LOTION; TOPICAL)	BRISTOL-MYERS	19-155 04-24-85	4105783 05-03-94	NE 04-24-88

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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		
ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE 770MG; 60MG; 50MG	NORGESIC FORTE (TABLET; ORAL)	RIKER LABS/3M	13-416 10-27-82		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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>
ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE 389MG; 32.4MG; 32MG	DARVON COMPOUND (CAPSULE; ORAL)	ELI LILLY INDSTRS/PR	10-996 03-08-83		
ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE 389MG; 32.4MG; 65MG	DARVON COMPOUND-65 (CAPSULE; ORAL)	ELI LILLY INDSTRS/PR	10-996 03-08-83		
ASPIRIN; CARISOPRODOL 325MG; 200MG	SOMA COMPOUND (TABLET; ORAL)	WALLACE PHARMS/C-W	12-365 07-11-83	4534973 08-13-02	
ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE 325MG; 200MG; 16MG	SOMA COMPOUND W/ CODEINE (TABLET; ORAL)	WALLACE PHARMS/C-W	12-366 07-11-83	4534974 08-13-02	
ASPIRIN; MEPROBAMATE 325MG; 200MG	EQUAGESIC (TABLET; ORAL)	WYETH 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	4105659 08-08-95	
ATENOLOL 50MG	TENORMIN (TABLET; ORAL)	STUART PHARMS/ICI AM	18-240 08-19-81	3663607 05-16-89 3934032 01-20-93 3836671 09-17-91	
ATENOLOL 100MG	TENORMIN (TABLET; ORAL)	STUART PHARMS/ICI AM	18-240 08-19-81	3663607 05-16-89 3934032 01-20-93 3836671 09-17-91	
ATENOLOL; CHLORTHALIDONE 100MG; 25MG	TENORETIC 100 (TABLET; ORAL)	STUART PHARMS/ICI AM	18-760 06-08-84	3663607 05-16-89 3934032 01-20-93 3836671 09-17-91	NC 09-24-86

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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
ATENOLOL; CHLORTHALIDONE 50MG; 25MG	TENORETIC 50 (TABLET; ORAL)	STUART PHARMS/ICI AM	18-760 06-08-84	3663607 05-16-89 3934032 01-20-93 3836671 09-17-91	NC 09-24-86
ATRACURTIUM 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	
AURANOFIN 3MG	RIDAURA (CAPSULE; ORAL)	SK&F LABORATORIES	18-689 05-24-85	3635945 01-18-89 3708579 01-02-90	NCE 05-24-90
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
BECLOMETHASONE DIPROPIONATE 0.042MG/INH	BECLOVENT (AEROSOL; INHALATION)	GLAXO	18-153 06-24-80	4414209 08-23-94 4364923 12-21-99	

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BECLOMETHANSONE DIPROPIONATE 0.042MG/INH	VANCERIL (AEROSOL; INHALATION)	SCHERING	17-573 05-12-76	4225597 09-30-97 4364923 10-29-99 4414209 08-23-94	
BECLOMETHANSONE DIPROPIONATE 0.042MG/INH	BECONASE (AEROSOL; INHALATION/NASAL)	GLAXO	18-584 09-30-81	4414209 08-23-94 4364923 12-21-99	
BECLOMETHANSONE DIPROPIONATE 0.042MG/INH	VANCENASE (AEROSOL; INHALATION/NASAL)	SCHERING	18-521 09-24-81	4225597 09-30-97 4364923 10-29-99 4414209 08-23-94	
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; NADOLOL 5MG; 40MG	CORZIDE (TABLET; ORAL)	ER SQUIBB AND SONS	18-647 05-25-83	3982021 09-21-93 3935267 01-27-93	NC 09-24-86
BENDROFLUMETHIAZIDE; NADOLOL 5MG; 80MG	CORZIDE (TABLET; ORAL)	ER SQUIBB AND SONS	18-647 05-25-83	3982021 09-21-93 3935267 01-27-93	NC 09-24-86
BENTIROMIDE 500MG/7.5ML	CHYMEX (SOLUTION; ORAL)	ADRIA LABORATORIES	18-366 12-29-83	3801562 04-02-91 3745212 07-10-90	NCE 12-29-93

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BETAMETHASONE 0.6MG	CELESTONE (TABLET; ORAL)	SCHERING	12-657 04-17-61	3485854 12-23-86	
BETAMETHASONE 0.6MG/5ML	CELESTONE (SYRUP; ORAL)	SCHERING	14-215 04-18-64	3485854 12-23-86	
BETAMETHASONE 0.2%	CELESTONE (CREAM; TOPICAL)	SCHERING	14-762 04-10-64	3485854 12-23-86	
BETAMETHASONE ACETATE; BETAMETHASONE SODIUM PHOSPHATE 3MG/ML; EQ 3MG BASE/ML	CELESTONE SOLUSPAN (INJECTABLE; INJECTION)	SCHERING	14-602 03-03-65	3485854 12-23-86	
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	DIPROLENE (OINTMENT; TOPICAL)	SCHERING	18-741 07-27-83	4070462 01-24-95	
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

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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%	LOTRIZONE (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
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	BETATREX (CREAM; TOPICAL)	SAVAGE LABS/BYK-GLDN	18-862 08-31-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETATREX (OINTMENT; TOPICAL)	SAVAGE LABS/BYK-GLDN	18-863 08-31-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (OINTMENT; TOPICAL)	PHARMADERM/BYK-GLDN	18-864 08-31-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (OINTMENT; TOPICAL)	E FOUGERA/BYK-GLDN	18-865 08-31-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (LOTION; TOPICAL)	E FOUGERA/BYK-GLDN	18-866 08-31-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETATREX (LOTION; TOPICAL)	SAVAGE LABS/BYK-GLDN	18-867 08-31-83		

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BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (LOTION; TOPICAL)	PHARMADERM/BYK-GLDN	18-870 08-31-83		
BETAXOLOL HYDROCHLORIDE EQ 0.5% BASE	BETOPTIC (SOLUTION; OPHTHALMIC)	ALCON LABORATORIES	19-270 08-30-85	4252984 02-24-98 4311708 01-19-99 4342783 08-03-99	NCE 08-30-90
BETHANIDINE SULFATE 10MG	TENATHAN (TABLET; ORAL)	AH ROBINS	17-675 05-29-81	3495013 02-10-87	
BETHANIDINE SULFATE 25MG	TENATHAN (TABLET; ORAL)	AH ROBINS	17-675 05-29-81	3495013 02-10-87	
BITOLTEROL MESYLATE 0.8%	TORNALATE (AEROSOL; INHALATION)	WINTHROP-BREON/STERL	18-770 12-28-84	4138581 02-06-96	NCE 12-28-89
BRETYLIUM TOSYLATE 50MG/ML	BRETYLOL (INJECTABLE; INJECTION)	AM CRITICAL CARE/AHS	17-954 07-18-78	RE29618 04-29-86	
BROMOCRIPTINE MESYLATE EQ 2.5MG BASE	PARLODEL (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	17-962 06-28-78	3752888 08-14-90 3752814 08-14-90	I-16 12-14-87 I-34 06-28-88
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 I-34 06-28-88
BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE 12.5MG/5ML; 10MG/5ML	AMBENYL (SYRUP; ORAL)	MARION LABORATORIES	09-319 01-10-84		
BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 12.5MG/5ML	DIMETANE-DC (SYRUP; ORAL)	AH ROBINS	11-694 03-29-84		

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BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 30MG/5ML	DIMETANE-DX (SYRUP; ORAL)	AH ROBINS	11-694 03-29-84		
BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 30MG/5ML	DIMETANE-DX (SYRUP; ORAL)	AH ROBINS	19-279 08-24-84		
BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 4MG/5ML; 25MG/5ML	ELIXIR DIMETAPP (ELIXIR; ORAL)	AH ROBINS	13-087 03-29-84		
BUMETANIDE 1MG	BUMEX (TABLET; ORAL)	HOFFMANN-LA ROCHE	18-225 02-28-83	3634583 01-11-89 3806534 04-23-91	NCE 02-28-93
BUMETANIDE 2MG	BUMEX (TABLET; ORAL)	HOFFMANN-LA ROCHE	18-225 06-14-85	3634583 01-11-89 3806534 04-23-91	NCE 02-28-93
BUMETANIDE 0.5MG	BUMEX (TABLET; ORAL)	HOFFMANN-LA ROCHE	18-225 02-28-83	3634583 01-11-89 3806534 04-23-91	NCE 02-28-93
BUMETANIDE 0.25MG/ML	BUMEX (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	18-226 02-28-83	3634583 01-11-89 3806534 04-23-91	NCE 02-28-93
BUMETANIDE 2MG	BUMEX (TABLET; ORAL)	HOFFMANN-LA ROCHE	18-225 06-14-85		
BUPIVACAINE HYDROCHLORIDE; DEXTROSE 0.75%; 8.25%	MARCAINE SPINAL (INJECTABLE; INJECTION)	BREON LABS/STERLING	18-692 05-04-84		NC 09-24-86

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BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE 0.5%; 0.0091MG/ML	SENSORCAINE (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-304 09-02-83		
BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE 0.75%; 0.0091MG/ML	SENSORCAINE (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-304 09-02-83		
BUTORPHANOL TARTRATE 1MG/ML	STADOL (INJECTABLE; INJECTION)	BRISTOL LABS/B-M	17-857 08-22-78	3819635 06-25-91	
BUTORPHANOL TARTRATE 2MG/ML	STADOL (INJECTABLE; INJECTION)	BRISTOL LABS/B-M	17-857 08-22-78	3819635 06-25-91	
CALCEFEDIOL, ANHYDROUS 0.02MG	CALDEROL (CAPSULE; ORAL)	UPJOHN	18-312 08-05-80	3833622 09-03-91 3565924 03-23-86	
CALCEFEDIOL, ANHYDROUS 0.05MG	CALDEROL (CAPSULE; ORAL)	UPJOHN	18-312 08-05-80	3833622 09-03-91 3565924 03-23-86	1-18 12-21-87
CALCITONIN 200 IU/VIAL	CALCIMAR (INJECTABLE; INJECTION)	ARMOUR PHARM	17-769 12-21-84		1-18 12-21-87
CALCITONIN 400 IU/VIAL	CALCIMAR (INJECTABLE; INJECTION)	ARMOUR PHARM	17-497 12-21-84		
CALCITRIOL 0.25 UGM	ROCALTRIL (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-044 08-17-78	3697559 10-10-89 4391802 07-05-00 4341774 07-27-99 4225596 09-30-97	

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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		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 510MG/100ML; 30GM/100ML; 200MG/100ML; 9.2GM/100ML; 9.6GM/100ML	DIALYTE CONCENTRATE W/ DEXTROSE 30% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807 08-26-83		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 510MG/100ML; 50GM/100ML; 200MG/100ML; 9.2GM/100ML; 9.6GM/100ML	DIALYTE CONCENTRATE W/ DEXTROSE 50% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807 08-26-83		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 510MG/100ML; 30GM/100ML; 200MG/100ML; 9.4GM/100ML; 11GM/100ML	DIALYTE CONCENTRATE W/ DEXTROSE 30% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807 08-26-83		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 510MG/100ML; 50GM/100ML; 200MG/100ML; 9.4GM/100ML; 11GM/100ML	DIALYTE CONCENTRATE W/ DEXTROSE 50% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807 08-26-83		

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CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 1.5GM/100ML; 15.2MG/100ML; 567MG/100ML; 392MG/100ML	DELFLX W/ DEXTROSE 1.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 2.5GM/100ML; 15.2MG/100ML; 567MG/100ML; 392MG/100ML	DELFLX W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 4.25GM/100ML; 15.2MG/100ML; 567MG/100ML; 392MG/100ML	DELFLX W/ DEXTROSE 4.25% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	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	IMPERSOL-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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; 2.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	INPERSOL-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	INPERSOL-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 26MG/100ML; 2.5GM/100ML; 15MG/100ML; 560MG/100ML; 390MG/100ML	DIALYTE W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-460 11-02-83		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 33MG/100ML; 5GM/100ML; 30MG/100ML; 860MG/100ML	DEXTROSE 5% AND RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-635 02-07-83		
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 16.5MG/ML; 25.4MG/ML; 74.6MG/ML; 121MG/ML; 16.1MG/ML	TPN ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-895 07-20-84	NC 09-24-86	
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE 35MG/100ML; 30MG/100ML; 74MG/100ML; 640MG/100ML; 500MG/100ML; 74MG/100ML	ISOLYTE E IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-899 10-31-83		
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 17.6MG/100ML; 325.3MG/100ML; 119.3MG/100ML; 643MG/100ML	PLEGISOL IN PLASTIC CONTAINER (SOLUTION; PERFUSION, CARDIAC)	ABBOTT LABORATORIES	18-608 02-26-82	NC 09-24-86	

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CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 20MG/100ML; 30MG/100ML; 380MG/100ML; 600MG/100ML	ACETATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-725 11-29-82		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 33MG/100ML; 30MG/100ML; 860MG/100ML	RINGER'S IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-495 02-19-82		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 33MG/100ML; 30MG/100ML; 860MG/100ML	RINGERS INJECTION IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-648 02-07-83		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 33MG/100ML; 30MG/100ML; 860MG/100ML	RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-721 11-09-82		
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		

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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		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/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; 5GM/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 MCGAW/AM HOSP	18-681 12-27-82		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 20MG/100ML; 30MG/100ML; 600MG/100ML; 310MG/100ML	LACTATED RINGER'S IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-921 04-03-84		

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CALCIUM METRIZOATE; MAGNESIUM METRIZOATE; MEGLUMINE METRIZOATE; METRIZOATE SODIUM 0.78MG/ML; 0.15MG/ML; 75.9MG/ML; 16.6MG/ML	ISOPAQUE 440 (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	16-847 11-17-73	3476802 11-04-86	
CALCIUM; MEGLUMINE; METRIZOIC ACID 0.35MG/ML; 140.1MG/ML; 461.8MG/ML	ISOPAQUE 280 (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-506 04-30-74	3476802 11-04-86	
CAPTOPRIL 12.5MG	CAPOTEN (TABLET; ORAL)	ER SQUIBB AND SONS	18-343 01-17-85	4105776 08-08-95	I-20 09-24-86 D-7 10-12-87
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 25MG; 25MG	CAPOZIDE 25/25 (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

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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	
CARBIDOPA; LEVODOPA 10MG; 100MG	SINEMET (TABLET; ORAL)	MS&D/MERCK	17-555 05-02-75	3462536 08-19-86 3769424 10-30-90 3781415 12-25-90 3830827 08-20-91 RE29892 10-30-90	
CARBIDOPA; LEVODOPA 25MG; 250MG	SINEMET (TABLET; ORAL)	MS&D/MERCK	17-555 05-02-75	3462536 08-19-86 3769424 10-30-90 3781415 12-25-90 3830827 08-20-91 RE29892 10-30-90	

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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>
CARBIDOPA; LEVODOPA 25MG; 100MG	SINEMET (TABLET; ORAL)	MS&D/MERCK	17-555 05-02-75	3462536 08-19-86 3769424 10-30-90 3781415 12-25-90 3830827 08-20-91 RE29892 10-30-90	
CARBOPROST TROMETHAMINE EQ 0.25MG BASE/ML	PROSTIN/15M (INJECTABLE; INJECTION)	UPJOHN	17-989 01-09-79	3728382 04-17-90	I-32 03-21-88
CELLULOSE SODIUM PHOSPHATE 2.5GM/PACKET	CALCIBIND (POWDER; ORAL)	MISSION PHARMACAL	18-757 12-28-82		NCE 12-28-92
CERULETIDE DIETHYLAMINE 0.02MG/ML	TYMTRAN (INJECTABLE; INJECTION)	ADRIA LABORATORIES	18-296 12-24-81	3472832 10-14-86	
CHENODIOL 250MG	CHENIX (TABLET; ORAL)	ROWELL LABORATORIES	18-513 07-28-83		NCE 07-28-93
CHLORDIAZEPOXIDE 25MG	LIBRITABS (TABLET; ORAL)	ROCHE PRODUCTS	13-071 10-31-66	4316897 02-23-99	
CHLORDIAZEPOXIDE 5MG	LIBRITABS (TABLET; ORAL)	ROCHE PRODUCTS	13-071 10-31-66	4316897 02-23-99	
CHLORDIAZEPOXIDE 10MG	LIBRITABS (TABLET; ORAL)	ROCHE PRODUCTS	13-071 10-31-66	4316897 02-23-99	
CHLORDIAZEPOXIDE 30MG	LIBRELEASE (CAPSULE, CONTROLLED RELEASE; ORAL)	HOFFMANN-LA ROCHE	17-813 09-12-83	4316897 02-23-99	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	

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CHLORDIAZEPOXIDE HYDROCHLORIDE 25MG	LIBRIUM (CAPSULE; ORAL)	ROCHE PRODUCTS	12-249 02-24-60	4316897 02-23-99	
CHLORDIAZEPOXIDE HYDROCHLORIDE 100MG/AMP	LIBRIUM (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	12-301 07-21-61	4316897 02-23-99	
CHLORDIAZEPOXIDE HYDROCHLORIDE; CLIDINIUM BROMIDE 5MG; 2.5MG	LIBRAX (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	12-750 05-02-61	4316897 02-23-99	
CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED 5MG; 0.2MG	MENRIUM 5-2 (TABLET; ORAL)	HOFFMANN-LA ROCHE	14-740 10-27-69	4316897 02-23-99	
CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED 5MG; 0.4MG	MENRIUM 5-4 (TABLET; ORAL)	HOFFMANN-LA ROCHE	14-740 10-27-69	4316897 02-23-99	
CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED 10MG; 0.4MG	MENRIUM 10-4 (TABLET; ORAL)	HOFFMANN-LA ROCHE	14-740 10-27-69	4316897 02-23-99	
CHLOROXINE 2%	CAPITROL (SHAMPOO; TOPICAL)	WESTWOOD PHARMS	17-594 10-19-76	3886277 05-27-92	
CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE 15MG; 0.1MG	COMBIPRES (TABLET; ORAL)	BOEHRINGER INGELHEIM	17-503 08-22-74	3454701 07-08-86	
CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE 15MG; 0.2MG	COMBIPRES (TABLET; ORAL)	BOEHRINGER INGELHEIM	17-503 08-22-74	3454701 07-08-86	
CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE 15MG; 0.3MG	COMBIPRES (TABLET; ORAL)	BOEHRINGER INGELHEIM	17-503 04-10-84	3454701 07-08-86	
CHOLESTYRAMINE EQ 4GM RESIN/PACKET	QUESTRAN (POWDER; ORAL)	MEAD JOHNSON/B-M	16-019 12-06-66		I-23 09-24-86
CHOLESTYRAMINE EQ 4GM RESIN/PACKET	QUESTRAN (POWDER; ORAL)	MEAD JOHNSON/B-M	16-640 08-03-73		I-23 09-24-86
CHYMOPAPAIN 12,500 UNITS/VIAL	DISCARE (INJECTABLE; INJECTION)	TRAVENOL LABS	18-625 01-18-84		NCE 11-10-92

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CHYMOPAPAIN 10,000 UNITS/VIAL	CHYMIDIACIN (INJECTABLE; INJECTION)	SMITH LABORATORIES	18-663 11-10-82	4439423 03-26-01	NCE 11-10-92
CHYMOPAPAIN 4,000 UNITS/VIAL	CHYMIDIACIN (INJECTABLE; INJECTION)	SMITH LABORATORIES	18-663 08-21-84	4439423 03-26-01	NCE 11-10-92
CYCLOPIROX OLAMINE 1%	LOPROX (CREAM; TOPICAL)	HOECHST-ROUSSEL	18-748 12-30-82	3883545 05-13-92	NCE 12-30-92
CIMETIDINE 200MG	TAGAMET (TABLET; ORAL)	SK&F LAB	17-920 08-16-77	3950333 04-13-93 4024271 05-17-94	
CIMETIDINE 300MG	TAGAMET (TABLET; ORAL)	SK&F LAB	17-920 08-16-77	3950333 04-13-93 4024271 05-17-94	
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	CINOAC (CAPSULE; ORAL)	ELI LILLY	18-067 06-13-80	3669965 06-13-89	
CINOXACIN 500MG	CINOAC (CAPSULE; ORAL)	ELI LILLY	18-067 06-13-80	3669965 06-13-89	

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CISPLATIN 0.5MG/ML	PLATINOL-AQ (INJECTABLE; INJECTION)	BRISTOL LABS/B-M	18-057 07-18-84	4177263 12-04-96 4310515 01-12-99	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 EQ 0.5MG BASE/5ML	TAVIST (SYRUP; ORAL)	DORSEY LABS/SANDOZ	18-675 06-28-85		NDF 06-28-88
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		
CLONAZEPAM 0.5MG	CLONOPIN (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-533 06-04-75	4316897 02-23-99	
CLONAZEPAM 1MG	CLONOPIN (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-533 06-04-75	4316897 02-23-99	
CLONAZEPAM 2MG	CLONOPIN (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-533 06-04-75	4316897 02-23-99	
CLONIDINE 2.5MG	CATAPRES-TTS-1 (FILM, CONTROLLED RELEASE; PERCUTANEOUS)	BOEHRINGER INGELHEIM	18-891 10-10-84	3454701 07-08-86	NR 10-10-87
CLONIDINE 5MG	CATAPRES-TTS-2 (FILM, CONTROLLED RELEASE; PERCUTANEOUS)	BOEHRINGER INGELHEIM	18-891 10-10-84	3454701 07-08-86	NR 10-10-87

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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>
CLONIDINE 7.5MG	CATAPRES-TTS-3 (FILM, CONTROLLED RELEASE; PERCUTANEOUS)	BOEHRINGER INGELHEIM	18-891 10-10-84	3454701 07-08-86	NR 10-10-87
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	
CLORAZEPATE DIPOTASSIUM 11.25MG	TRANXENE SD (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 08-04-76	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 3.75MG	TRANXENE (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-10-80	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 7.5MG	TRANXENE (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-10-80	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 15MG	TRANXENE (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-10-80	RE28315 06-23-87	
CLOTRIMAZOLE 1%	LOTRIMIN (SOLUTION; TOPICAL)	SCHERING	17-613 02-03-75	3660577 05-02-89 3705172 12-05-89 3839573 10-01-91	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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CLOTRIMAZOLE 1%	LOTIMIN (CREAM; TOPICAL)	SCHERING	17-619 03-18-75	3660577 05-02-89 3705172 12-05-89 3839573 10-01-91	
CLOTRIMAZOLE 1%	GYNE-LOTIMIN (CREAM; VAGINAL)	SCHERING	18-052 11-08-78	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 100MG	GYNE-LOTIMIN (TABLET; VAGINAL)	SCHERING	17-717 03-24-76	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 1%	MYCELEX (SOLUTION; TOPICAL)	MILES PHARMS/MILES	18-181 01-15-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 100MG	MYCELEX-G (TABLET; VAGINAL)	MILES PHARMS/MILES	18-182 02-27-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 500MG	MYCELEX-G (TABLET; VAGINAL)	MILES PHARMS/MILES	19-069 04-19-85	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	NS 04-19-88

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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
CLOTRIMAZOLE 1%	MYCELEX (CREAM; TOPICAL)	MILES PHARMS/MILES	18-183 01-15-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 1%	MYCELEX-G (CREAM; VAGINAL)	MILES PHARMS/MILES	18-230 02-16-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 10MG	MYCELEX (TROCHE/LOZENGE; ORAL)	MILES PHARMS/MILES	18-713 06-17-83	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	NDF 09-24-86
CLOTRIMAZOLE 1%	LOTIRMIN (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		

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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	
COPPER 120MG	TATUM-T (INTRAUTERINE DEVICE; INTRAUTERINE)	SEARLE PHARMS	18-205 08-16-79	3563235 02-16-88 4040417 08-09-94 3783861 01-08-91 3803308 12-01-87 RE28399 04-29-92	
CROMOLYN SODIUM 20MG	INTAL (CAPSULE; INHALATION)	FTSONS	16-990 06-20-73	3686412 08-22-89 3777033 08-22-89 3419578 12-31-85 3957965 05-18-93	I-22 09-24-86

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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 4%	NASALCROM (SOLUTION; NASAL)	FISONS	18-306	3686412	NDF
			03-18-83	08-22-89	09-24-86
				377033	
				08-22-89	
				3419578	
CROMOLYN SODIUM 4%	OPTICROM (SOLUTION; OPHTHALMIC)	FISONS		12-31-85	
				3975536	
				08-17-93	
				4053628	
				10-11-94	
CROMOLYN SODIUM 10MG/ML	INTAL (SOLUTION; INHALATION)	FISONS	18-155	3686412	NDF
			10-03-84	08-22-89	10-03-87
				377033	
				08-22-89	
				3419578	
CYCLOBENZAPRINE HYDROCHLORIDE 5MG	FLEXERIL (TABLET; ORAL)	MS&D/MERCK		12-31-85	
				3975536	
				08-17-93	
				3454643	
				07-08-86	
CYCLOBENZAPRINE HYDROCHLORIDE 10MG	FLEXERIL (TABLET; ORAL)	MS&D/MERCK		3882246	
				05-06-92	
			17-821	3454643	
			08-26-77	07-08-86	
				3882246	
CYCLOPHOSPHAMIDE 1GM/VIAL	CYTOXAN (INJECTABLE; INJECTION)	MEAD JOHNSON/B-M	17-821	3454643	
			08-26-77	07-08-86	
				3882246	
				05-06-92	
			12-142	3454643	
			08-30-82	07-08-86	
				3882246	
				05-06-92	
					NS
					09-24-86

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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>
CYCLOPHOSPHAMIDE 1GM/VIAL	NEOSAR (INJECTABLE; INJECTION)	ADRIA LABORATORIES	87-442 07-08-83		NS 09-24-86
CYCLOPHOSPHAMIDE 2GM/VIAL	CYTOXAN (INJECTABLE; INJECTION)	HEAD JOHNSON/B-M	12-142 08-30-82		NS 09-24-86
CYTARABINE 100MG/VIAL	CYTOSAR-U (INJECTABLE; INJECTION)	UPJOHN	16-793 06-17-69	3444294 05-13-86	
CYTARABINE 500MG/VIAL	CYTOSAR-U (INJECTABLE; INJECTION)	UPJOHN	16-793 06-17-69	3444294 05-13-86	
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	
DEFEROXAMINE MESYLATE 500MG/VIAL	DEFERAL MESYLATE (INJECTABLE; INJECTION)	CIBA/CIBA-GEIGY	16-267 04-01-68	3471476 10-07-86	
DESIPRAMINE HYDROCHLORIDE 25MG	PERTOFRANE (CAPSULE; ORAL)	USV LABORATORIES	13-621 12-18-64	3454698 07-08-86 3454554 07-08-86	
DESIPRAMINE HYDROCHLORIDE 50MG	PERTOFRANE (CAPSULE; ORAL)	USV LABORATORIES	13-621 04-10-68	3454698 07-08-86 3454554 07-08-86	
DESIPRAMINE HYDROCHLORIDE 25MG	NORPRAMIN (TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399 11-20-64	3454698 07-08-86 3454554 07-08-86	

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DESIPRAMINE HYDROCHLORIDE 50MG	NORPRAMIN (TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399 01-09-67	3454698 07-08-86 3454554 07-08-86	
DESIPRAMINE HYDROCHLORIDE 75MG	NORPRAMIN (TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399 03-01-77	3454698 07-08-86 3454554 07-08-86	
DESIPRAMINE HYDROCHLORIDE 100MG	NORPRAMIN (TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399 03-01-77	3454698 07-08-86 3454554 07-08-86	
DESIPRAMINE HYDROCHLORIDE 150MG	NORPRAMIN (TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399 03-01-77	3454698 07-08-86 3454554 07-08-86	
DESIPRAMINE HYDROCHLORIDE 10MG	NORPRAMIN (TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399 02-11-82	3454698 07-08-86 3454554 07-08-86	NS 09-24-86
DESMOPRESSIN ACETATE 0.01%	DDAVP (SOLUTION; NASAL)	ARMOUR PHARM	17-922 02-21-78	3497491 02-24-87	
DESMOPRESSIN ACETATE 0.004MG/ML	DDAVP (INJECTABLE; INJECTION)	ARMOUR PHARM	18-938 03-30-84	3497491 02-24-87	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) (INJECTABLE; INJECTION)	HOECHST-ROUSSEL	18-763 09-30-83		NDF 09-24-86

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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
DEXATROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE 15MG/5ML; 6.25MG/5ML	PHENERGAN W/ DEXTROMETHORPHAN (SYRUP; ORAL)	WYETH LABS/AMHO	11-265 04-02-84		
DEXTROSE 5GM/100ML	DEXTROSE 5% IN PLASTIC CONTAINER	ABBOTT LABORATORIES	19-466 07-15-85		
DEXTROSE 60GM/100ML	DEXTROSE 60% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	17-521 03-26-82		
DEXTROSE 70GM/100ML	DEXTROSE 70% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	17-521 03-26-82		
DEXTROSE 60GM/100ML	DEXTROSE 60% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	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 MCGAW/AM HOSP	17-995 04-27-78	3729568 04-24-90	
DEXTROSE 60GM/100ML	DEXTROSE 60% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	17-995 09-22-82	3729568 04-24-90	
DEXTROSE 70GM/100ML	DEXTROSE 70% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-561 03-23-82		

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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		
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	

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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
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 5,000 UNITS/100ML	HEPARIN SODIUM 12,500 UNITS IN DEXTROSE 5% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911 01-30-85		
DEXTROSE; HEPARIN SODIUM 5GM/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		
DEXTROSE; HEPARIN SODIUM 5GM/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		
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 5,000 UNITS/100ML	HEPARIN SODIUM 25000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-134 03-29-85		
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 10,000 UNITS/100ML	HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911 01-30-85		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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 10,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-339 03-27-85		
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 10,000 UNITS/100ML	HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911 01-30-85		
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	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

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DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE DIBASIC; SODIUM ACETATE 5GM/100ML; 31MG/100ML; 130MG/100ML; 26MG/100ML; 320MG/100ML	ISOLYTE P W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-025 12-27-84		
DEXTROSE; OXYTOCIN 5GM/100ML; 1 USP UNIT/100ML	OXYTOCIN 5 USP UNITS IN DEXTROSE 5% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-185 03-29-85		
DEXTROSE; OXYTOCIN 5GM/100ML; 1 USP UNIT/100ML	OXYTOCIN 10 USP UNITS IN DEXTROSE 5% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-185 03-29-85		
DEXTROSE; OXYTOCIN 5GM/100ML; 2 USP UNIT/100ML	OXYTOCIN 10 USP UNITS IN DEXTROSE 5% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-185 03-29-85		
DEXTROSE; OXYTOCIN 5GM/100ML; 2 USP UNIT/100ML	OXYTOCIN 20 USP UNITS IN DEXTROSE 5% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-185 03-29-85		
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 75MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82		
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 150MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82		
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 220MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82		
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 300MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM LACTATE 5GM/100ML; 205MG/100ML; 100MG/100ML; 120MG/100ML; 220MG/100ML	DEXTROSE 5% AND ELECTROLYTE NO 75 IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-840 06-29-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 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		

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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; 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		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83		
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		

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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 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		

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DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 40MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 40MG/100ML	THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-083 11-07-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 80MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 80MG/100ML	THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-083 11-07-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 160MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 160MG/100ML	THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-083 11-07-84		

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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		

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DIATRIZOATE MEGLUMINE 30%	RENO-M-DIP (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	10-040 01-08-60		I-7; I-8 09-24-86
DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM 52%; 8%	RENOGRAFTN-60 (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	10-040 08-29-74		I-8 09-24-86
DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM 66%; 10%	RENOGRAFTN-76 (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	10-040 10-27-72		I-5 09-24-86
DIAZEPAM 2MG	VALIUM (TABLET; ORAL)	HOFFMANN-LA ROCHE	13-263 11-15-63	4316897 02-23-99	
DIAZEPAM 5MG	VALIUM (TABLET; ORAL)	HOFFMANN-LA ROCHE	13-263 11-15-63	4316897 02-23-99	
DIAZEPAM 10MG	VALIUM (TABLET; ORAL)	HOFFMANN-LA ROCHE	13-263 11-15-63	4316897 02-23-99	
DIAZEPAM 5MG/ML	VALIUM (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	16-087 08-24-66	4316897 02-23-99	
DIAZEPAM 15MG	VALRELEASE (CAPSULE, CONTROLLED RELEASE; ORAL)	HOFFMANN-LA ROCHE	18-179 03-12-81	4316897 02-23-99	
DIAZOXIDE 15MG/ML	HYPERSTAT (INJECTABLE; INJECTION)	SCHERING	16-996 01-22-73		I-1 09-24-86
DICYCLOMINE HYDROCHLORIDE 10MG	BENTYL (CAPSULE; ORAL)	MERRELL DOW/DOW CHEM	07-409 10-15-84		
DICYCLOMINE HYDROCHLORIDE 20MG	BENTYL (CAPSULE; ORAL)	MERRELL DOW/DOW CHEM	07-409 10-15-84		

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DICICLOMINE HYDROCHLORIDE 10MG/ML	BENTYL (INJECTABLE; INJECTION)	MERRELL DOW/DOW CHEM	08-370 10-15-84		
DICICLOMINE 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	
DIFLORASONE DIACETATE 0.05%	DIFLORASONE DIACETATE (CREAM; TOPICAL)	UPJOHN	19-259 08-28-85	3980778 09-14-93	
DIFLORASONE DIACETATE 0.05%	DIFLORASONE DIACETATE (OINTMENT; TOPICAL)	UPJOHN	19-260 08-28-85	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	4088750 05-09-95	NDF 09-24-86
DIGOXIN 0.05MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82	4088750 05-09-95	NDF 09-24-86
DIGOXIN 0.15MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 09-24-84	4088750 05-09-95	NS 09-24-86
DIGOXIN 0.1MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82	4088750 05-09-95	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 4402949 09-06-00	NC 11-30-87

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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
DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE 0.5MG/0.7ML; 5000 UNITS/0.7ML; 7.46MG/0.7ML	EMBOLEX (INJECTABLE; INJECTION)	SANDOZ PHARMS/SANDOZ	18-885 11-30-84	4451458 05-29-01 4402949 09-06-00	NC 11-30-87
DILTIAZEM HYDROCHLORIDE 30MG	CARDIZEM (TABLET; ORAL)	MARION LABORATORIES	18-602 11-05-82	3562257 02-09-88	NCE 11-05-92
DILTIAZEM HYDROCHLORIDE 60MG	CARDIZEM (TABLET; ORAL)	MARION LABORATORIES	18-602 11-05-82	3562257 02-09-88	NCE 11-05-92
DIMETHYL SULFOXIDE 50%	RIMSOL-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	3657327 04-18-87 3706789 12-19-89 3778506 12-11-90	
DINOPROSTONE 20MG	PROSTIN E2 (SUPPOSITORY; VAGINAL)	UPJOHN	17-810 08-23-77	3899587 08-12-92 3598858 08-10-88	
DIPIVEFRIN HYDROCHLORIDE 0.1%	PROPINE (SOLUTION; OPHTHALMIC)	ALLERGAN PHARMS	18-239 05-02-80	3839584 10-01-91 3809714 05-07-91	NDF 09-24-86
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

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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>
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)	PENNMALT PHARM	16-987 01-31-72	3420851 01-07-86	

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DOXEPIH HYDROCHLORIDE EQ 25MG BASE	ADAPIN (CAPSULE; ORAL)	PENNNWALT PHARM	16-987 01-31-72	3420851 01-07-86	
DOXEPIH HYDROCHLORIDE EQ 50MG BASE	ADAPIN (CAPSULE; ORAL)	PENNNWALT PHARM	16-987 01-31-72	3420851 01-07-86	
DOXEPIH HYDROCHLORIDE EQ 100MG BASE	ADAPIN (CAPSULE; ORAL)	PENNNWALT PHARM	16-987 12-12-77	3420851 01-07-86	
DOXEPIH HYDROCHLORIDE EQ 75MG BASE	ADAPIN (CAPSULE; ORAL)	PENNNWALT PHARM	16-987 04-15-80	3420851 01-07-86	
DOXEPIH HYDROCHLORIDE EQ 10MG BASE/ML	SINEQUAN (CONCENTRATE; ORAL)	PFIZER LABS/PFIZER	17-516 03-11-74	3420851 01-07-86	
DRONABINOL 2.5MG	MARINOL (CAPSULE; ORAL)	UNIMED	18-651 05-31-85		NCE 05-31-90
DRONABINOL 5MG	MARINOL (CAPSULE; ORAL)	UNIMED	18-651 05-31-85		NCE 05-31-90
DRONABINOL 10MG	MARINOL (CAPSULE; ORAL)	UNIMED	18-651 05-31-85		NCE 05-31-90
ECONAZOLE NITRATE 1%	SPECTAZOLE (CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	18-751 12-23-82	3717655 02-20-90 3839574 10-01-91	NCE 12-23-92
ENFLURANE 99.9%	ETHRANE (LIQUID; INHALATION)	ANAQUEST/BOC	17-087 08-28-72	3469011 09-23-86 3527813 09-08-87	
EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE 0.005MG/ML; 0.5%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	

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EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE 0.005MG/ML; 1%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE 0.005MG/ML; 1.5%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
ERGOLOID MESYLATES 1MG	HYDERGINE LC (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-706 01-18-83	4366145 12-28-99	NDF 09-24-86
ERGOLOID MESYLATES 1MG/ML	HYDERGINE (SOLUTION; ORAL)	SANDOZ PHARMS/SANDOZ	18-418 01-30-81	4138565 02-06-96	
ESTRADIOL 0.01%	ESTRACE (CREAM; VAGINAL)	MEAD JOHNSON/B-M	86-069 01-31-84	4436738 03-13-01	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

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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>
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
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 10/11-28 (TABLET; ORAL-28)	ORTHO PHARMACEUTICAL	18-354 01-11-82		D-5 09-24-86
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	TRI-NORINYL 21-DAY (TABLET; ORAL-21)	SYNTEX (FP)	18-977 04-13-84	4390531 06-28-00	D-6 09-24-86
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	TRI-NORINYL 28-DAY (TABLET; ORAL-28)	SYNTEX (FP)	18-977 04-13-84	4390531 06-28-00	D-6 09-24-86
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG, 0.75MG AND 1MG	ORTHO-NOVUM 7/7/7-21 (TABLET; ORAL-21)	ORTHO PHARMACEUTICAL	18-985 04-04-84	4530839 07-23-02	D-3 09-24-86
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG, 0.75MG AND 1MG	ORTHO-NOVUM 7/7/7-28 (TABLET; ORAL-28)	ORTHO PHARMACEUTICAL	18-985 04-04-84	4530839 07-23-02	D-3 09-24-86
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 7/14-21 (TABLET; ORAL-21)	ORTHO PHARMACEUTICAL	19-004 04-04-84		D-4 09-24-86
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 7/14-28 (TABLET; ORAL-28)	ORTHO PHARMACEUTICAL	19-004 04-04-84		D-4 09-24-86
ETHINYL ESTRADIOL; NORGESTREL 0.05MG; 0.5MG	OVURAL (TABLET; ORAL-21)	WYETH LABS/AMHO	16-672 04-16-68	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	

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ETHINYL ESTRADIOL; NORGESTREL 0.05MG; 0.5MG	OVRAL-28 (TABLET; ORAL-28)	WYETH LABS/AMHO	16-806 11-26-68	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	
ETHINYL ESTRADIOL; NORGESTREL 0.03MG; 0.3MG	LO/OVRAL (TABLET; ORAL-21)	WYETH LABS/AMHO	17-612 03-17-75	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	
ETHINYL ESTRADIOL; NORGESTREL 0.03MG; 0.3MG	LO/OVRAL-28 (TABLET; ORAL-28)	WYETH LABS/AMHO	17-802 03-16-76	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	
ETIDOCAINE HYDROCHLORIDE 0.5%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
ETIDOCAINE HYDROCHLORIDE 1%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
ETIDRONATE DISODIUM 200MG	DIDRONEL (TABLET; ORAL)	NORWICH EATON/P&G	17-831 09-01-77	4254114 03-03-98 4216211 08-05-97 4137309 01-30-96 3683080 08-08-89	

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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
ETOMIDATE 2MG/ML	AMIDATE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-227 09-07-82		NCE 09-07-92
ETOPOSIDE 20MG/ML	VEPESID (INJECTABLE; INJECTION)	BRISTOL LABS/B-M	18-768 11-10-83	3524844 08-18-87	NCE 11-10-93
FENFLURAMINE HYDROCHLORIDE 60MG	PONDIMIN (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	16-618 07-27-82		NDF 09-24-86
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		
FLUMETHASONE PIVALATE 0.03%	LOCORTEN (CREAM; TOPICAL)	CIBA/CIBA-GEIGY	16-379 09-16-69	3499016 03-03-87	
FLUNISOLIDE 0.025MG/INH	BRONALIDE (AEROSOL; INHALATION)	SYNTEX LABS/SYNTEX	18-340 08-17-84		NDF 09-24-86

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FLUOCINONIDE 0.05%	LIDEX (SOLUTION; TOPICAL)	SYNTEX LABS/SYNTEX	18-849 04-06-84		NDF 09-24-86
FLUOCINONIDE 0.05%	LIDEX (CREAM; TOPICAL)	SYNTEX LABS/SYNTEX	16-908 06-30-71	3888995 07-13-88 3592930 07-13-88	
FLUOCINONIDE 0.05%	VASODERM (CREAM; TOPICAL)	K-LINE PHARMS	19-117 06-26-84		
FLUOCINONIDE 0.05%	LIDEX (OINTMENT; TOPICAL)	SYNTEX LABS/SYNTEX	16-909 09-22-71	4017615 04-12-94	
FLUPHENAZINE DECANOATE 25MG/ML	PROLIXIN DECANOATE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	16-727 06-20-72	3394131 07-23-85	
FLUPHENAZINE ENANTHATE 25MG/ML	PROLIXIN ENANTHATE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	16-110 03-15-67	3394131 07-23-85	
FLURANDRENOLIDE 0.004MG/SQ CM	CORDRAN (TAPE; TOPICAL)	DISTA PRODS/LILLY	16-455 07-29-69	3632740 01-04-89	
FLURAZEPAM HYDROCHLORIDE 15MG	DALMANE (CAPSULE; ORAL)	ROCHE PRODUCTS	16-721 04-07-70	4316897 02-23-99	
FLURAZEPAM HYDROCHLORIDE 30MG	DALMANE (CAPSULE; ORAL)	ROCHE PRODUCTS	16-721 04-07-70	4316897 02-23-99	
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	CHELSEA LABORATORIES	18-369 05-14-82		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	CHELSEA LABORATORIES	18-369 05-14-82		
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		

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FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	ZENITH LABORATORIES	18-413 11-30-83		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-415 07-27-82		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-415 07-27-82		
FUROSEMIDE 80MG	FUROSEMIDE (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-415 11-26-84		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	PARKE-DAVIS/W-L	18-419 01-31-83		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	PARKE-DAVIS/W-L	18-419 01-31-83		
FUROSEMIDE 80MG	FUROSEMIDE (TABLET; ORAL)	PARKE-DAVIS/W-L	18-419 11-13-84		
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	PARKE-DAVIS/W-L	18-420 02-26-82		
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	LYPHOMED	18-507 07-30-82		
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		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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)	INTL MEDICATION SYS	18-753 02-28-84		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	INTL MEDICATION SYS	18-753 02-28-84		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	BARR LABORATORIES	18-790 11-29-83		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	ROXANE LABORATORIES	18-823 11-10-83		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	ROXANE LABORATORIES	18-823 11-10-83		
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	KALAPHARM	18-868 06-28-83		
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	KALAPHARM	18-868 06-28-83		
FUROSEMIDE 20MG	LASIX (TABLET; ORAL)	HOECHST-ROUSSEL	16-273 05-07-74	4324779 04-13-99	
FUROSEMIDE 40MG	LASIX (TABLET; ORAL)	HOECHST-ROUSSEL	16-273 07-01-66	4324779 04-13-99	
FUROSEMIDE 80MG	LASIX (TABLET; ORAL)	HOECHST-ROUSSEL	16-273 04-24-78	4324779 04-13-99	
FUROSEMIDE 10MG/ML	LASIX (SOLUTION; ORAL)	HOECHST-ROUSSEL	17-688 03-08-77	4324779 04-13-99	
FUROSEMIDE 10MG/ML	LASIX (INJECTABLE; INJECTION)	HOECHST-ROUSSEL	16-363 03-20-68	4324779 04-13-99	
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		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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>
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
GLYBURIDE 5MG	MICRONASE (TABLET; ORAL)	UPJOHN	17-498 05-01-84	3426067 04-21-92 3454635 04-21-92 3507954 04-21-92 3507961 04-21-92	NCE 05-01-94

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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>
GLYBURIDE 1.25MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532 05-01-84	3426067 04-21-92 3454635 04-21-92 3507961 04-21-92 3507954 04-21-92 4060634 09-07-93	NCE 05-01-94
GLYBURIDE 2.5MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532 05-01-84	3426067 04-21-92 3454635 04-21-92 3507961 04-21-92 3507954 04-21-92 4060634 09-07-93	NCE 05-01-94
GLYBURIDE 5MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532 05-01-84	3426067 04-21-92 3454635 04-21-92 3507961 04-21-92 3507954 04-21-92 4060634 09-07-93	NCE 05-01-94
GONADORELIN HYDROCHLORIDE EQ 0.1MG BASE/VIAL	FACTREL (INJECTABLE; INJECTION)	AYERST LABS/AMHO	18-123 09-30-82	3947569 03-30-93 4110438 08-29-95	NCE 09-30-92

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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 0.2MG 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 02-15-85		
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	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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>
HALOPERIDOL 0.5MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 04-12-67	3438991 04-15-86	
HALOPERIDOL 1MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 04-12-67	3438991 04-15-86	
HALOPERIDOL 2MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 04-12-67	3438991 04-15-86	
HALOPERIDOL 5MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 04-16-74	3438991 04-15-86	
HALOPERIDOL 10MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 04-16-74	3438991 04-15-86	
HALOPERIDOL 20MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 02-02-82	3438991 04-15-86	NS 09-24-86
HALOPERIDOL LACTATE EQ 2MG BASE/ML	HALDOL (CONCENTRATE; ORAL)	MCNEIL LABORATORIES	15-922 04-12-67	3438991 04-15-86	
HALOPERIDOL LACTATE EQ 5MG BASE/ML	HALDOL (INJECTABLE; INJECTION)	MCNEIL LABORATORIES	15-923 05-18-71	3438991 04-15-86	
HEPARIN SODIUM 10 UNITS/ML	HEPARIN LOCK FLUSH (INJECTABLE; INJECTION)	INVENEX LABS/LIFE	17-029 05-06-82		
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% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		

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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>
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 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% IN PLASTIC CONTAINER (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% IN PLASTIC CONTAINER (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		

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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>
HEPARIN SODIUM; SODIUM CHLORIDE 500 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 5000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-609 04-28-82		
HEPARIN SODIUM; SODIUM CHLORIDE 1,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 1,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-042 03-29-85		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-135 03-29-85		
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 900MG/100ML	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 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 25,000 UNITS IN SODIUM CHLORIDE 0.9% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-911 01-30-85		

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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>
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEXACHLOROPHENE 3%	TURGEX (SOLUTION; TOPICAL)	XTTRIUM LABS	19-055 11-30-84		
HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE 25MG; 50MG	LOPRESSOR HCT 50/25 (TABLET; ORAL)	GEIGY/CIBA-GEIGY	18-303 12-31-84	3876802 04-08-92 3998790 12-21-93	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; PROPRANOLOL HYDROCHLORIDE 50MG; 80MG	INDERIDE LA 80/50 (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	19-059 07-03-85		
HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE 50MG; 120MG	INDERIDE LA 120/50 (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	19-059 07-03-85		
HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE 50MG; 160MG	INDERIDE LA 160/50 (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	19-059 07-03-85		
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

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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	DILAUID-HP (INJECTABLE; INJECTION)	KNOLL PHARMACEUTICAL	19-034 01-11-84		NCE 01-11-94
HYDROXYUREA 500MG	HYDREA (CAPSULE; ORAL)	ER SQUIBB AND SONS	16-295 12-07-67	3968249 07-06-93	
IBUPROFEN 300MG	MOTRIN (TABLET; ORAL)	UPJOHN MANUFACTURING	17-463 09-19-74		I-2 09-24-86
IBUPROFEN 400MG	MOTRIN (TABLET; ORAL)	UPJOHN MANUFACTURING	17-463 09-19-74		I-2 09-24-86
IBUPROFEN 600MG	MOTRIN (TABLET; ORAL)	UPJOHN MANUFACTURING	17-463 03-09-79		I-2 09-24-86
IBUPROFEN 400MG	RUFEN (TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-197 05-19-81		I-2 09-24-86
IBUPROFEN 600MG	RUFEN (TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-197 03-05-84		I-2 09-24-86
INDAPAMIDE 2.5MG	LOZOL (TABLET; ORAL)	USV PHARMACEUTICAL	18-538 07-06-83	3565911 02-23-88	NCE 07-06-93
INDOMETHACIN 50MG	INDOCIN (SUPPOSITORY; RECTAL)	MS&D RES LABS/MERCK	17-814 08-13-84	3644630 02-22-89 3849549 11-19-91	NDF 09-24-86

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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>
INDOMETHACIN 75MG	INDOCIN SR (CAPSULE, CONTROLLED RELEASE; ORAL)	MS&D RES LABS/MERCK	18-185 02-23-82	4173626 11-06-96	NDF 09-24-86
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	CHELSEA LABORATORIES	18-690 07-31-84		
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	CHELSEA LABORATORIES	18-690 07-31-84		
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	ZENITH LABORATORIES	18-730 05-04-84		
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	ZENITH LABORATORIES	18-730 05-04-84		
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	PAR PHARMACEUTICAL	18-829 08-06-84		
INDOMETHACIN 50MG	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/RES LABS/MERCK	18-878 01-30-85		

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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
IODAMIDE MEGLUMINE 24%	RENOLUE-DIP (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-903 07-10-78		I-6 09-24-86
IODAMIDE MEGLUMINE 65%	RENOLUE-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 40.3%	CHOLOVUE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	18-076 08-14-81	3654272 04-04-89	
IODOXAMATE MEGLUMINE 9.9%	CHOLOVUE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	18-077 08-14-81	3654272 04-04-89	
IOXAGLATE MEGLUMINE; IOXAGLATE SODIUM 39.3%; 19.6%	HEXABRIX (INJECTABLE; INJECTION)	MALLINCKRODT	18-905 07-26-85	4014986 03-29-94 4065553 12-27-94 4065554 12-27-94 4094966 06-13-95	NCE 07-26-90
ISOFLURANE 99.9%	FORANE (GAS; INHALATION)	ANAQUEST/BOC	17-624 12-18-79	3535425 01-24-93 3535388 01-24-93	
ISOTRETINOIN 10MG	ACCUTANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662 05-07-82	4200647 04-29-97 4322438 03-30-99 4464394 08-07-01	NCE 05-07-92
ISOTRETINOIN 20MG	ACCUTANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662 03-28-83	4200647 04-29-97 4322438 03-30-99 4464394 08-07-01	NCE 05-07-92

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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>
ISOTRETINOIN 40MG	ACCUTANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662 05-07-82	4200647 04-29-97 4322438 03-30-99 4464394 08-07-01	NCE 05-07-92
KETOCONAZOLE 200MG	NIZORAL (TABLET; ORAL)	JANSSEN PHARMA	18-533 06-12-81	4335125 06-15-99	I-25 09-24-86
LABETALOL HYDROCHLORIDE 200MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-687 08-01-84	4012444 03-15-94 4066755 01-03-95	NCE 08-01-94
LABETALOL HYDROCHLORIDE 300MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-687 08-01-84	4012444 03-15-94 4066755 01-03-95	NCE 08-01-94
LABETALOL HYDROCHLORIDE 400MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-687 08-01-84	4012444 03-15-94 4066755 01-03-95	NCE 08-01-94
LABETALOL HYDROCHLORIDE 5MG/ML	NORMODYNE (INJECTABLE; INJECTION)	SCHERING	18-686 08-01-84	4012444 03-15-94 4066755 01-03-95 4328213 05-04-99	NCE 08-01-94
LABETALOL HYDROCHLORIDE 100MG	TRANDATE (TABLET; ORAL)	GLAXO	18-716 05-24-85	4012444 03-15-94 4066755 01-03-95	NCE 08-01-94
LABETALOL HYDROCHLORIDE 200MG	TRANDATE (TABLET; ORAL)	GLAXO	18-716 08-01-84	4012444 03-15-94 4066755 01-03-95	NCE 08-01-94

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LABELTALOL HYDROCHLORIDE 300MG	TRANDATE (TABLET; ORAL)	GLAXO	18-716 08-01-84	4012444 03-15-94 4066755 01-03-95	NCE 08-01-94
LABELTALOL HYDROCHLORIDE 400MG	TRANDATE (TABLET; ORAL)	GLAXO	18-716 08-01-84	4012444 03-15-94 4066755 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	
LEUCOVORIN CALCIUM EQ 5MG BASE	WELLCOVORIN (TABLET; ORAL)	BURROUGHS WELLCOME	18-342 07-08-83		NDF 09-24-86
LEUCOVORIN CALCIUM EQ 25MG BASE	WELLCOVORIN (TABLET; ORAL)	BURROUGHS WELLCOME	18-342 07-08-83		NDF 09-24-86
LEUPROLIDE ACETATE 1MG/0.2ML	LUPRON (INJECTABLE; INJECTION)	TAP PHARMACEUTICALS	19-010 04-09-85		NCE 04-09-90
LITHIUM CARBONATE 300MG	LITHOBID (TABLET; CONTROLLED RELEASE; ORAL)	CIBA/CIBA-GEIGY	18-027 04-27-79	4264573 04-28-98	
LITHIUM CARBONATE 300MG	LITHANE (TABLET; ORAL)	MILES PHARMS/MILES	18-833 07-18-85		
LITHIUM CARBONATE 300MG	LITHIUM CARBONATE (TABLET; ORAL)	ROXANE LABORATORIES	18-558 01-29-82		

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LITHIUM CARBONATE 450MG	ESKALITH CR (TABLET, CONTROLLED RELEASE; ORAL)	SK&F LABORATORIES	18-152 03-29-82		NS 09-24-86
LOPERAMIDE HYDROCHLORIDE 2MG	IMODIUM (CAPSULE; ORAL)	JANSSEN PHARMA	17-694 12-28-76	3714159 01-30-90	I-30 09-24-86
LOPERAMIDE HYDROCHLORIDE 1MG/5ML	IMODIUM (SOLUTION; ORAL)	JANSSEN PHARMA	19-037 07-31-84	3714159 01-30-90	NDF 09-24-86
LORAZEPAM 2MG/ML	ATIVAN (INJECTABLE; INJECTION)	WYETH LABS/AMHO	18-140 07-25-80	4017616 04-12-94	
LORAZEPAM 4MG/ML	ATIVAN (INJECTABLE; INJECTION)	WYETH LABS/AMHO	18-140 07-25-80	4017616 04-12-94	
LOXAPINE HYDROCHLORIDE EQ 50MG BASE/ML	LOXITANE (INJECTABLE; INJECTION)	LEDERLE LABS/AM CYAN	18-039 10-26-79	3546226 12-08-87	
LOXAPINE HYDROCHLORIDE EQ 25MG BASE/ML	LOXITANE (CONCENTRATE; ORAL)	LEDERLE LABS/AM CYAN	17-658 05-04-76	3546226 12-08-87 4049809 09-20-94	
LOXAPINE SUCCINATE EQ 5MG BASE	LOXITANE (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	17-525 10-25-77	3546226 12-08-87	
LOXAPINE SUCCINATE EQ 10MG BASE	LOXITANE (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	17-525 02-25-75	3546226 12-08-87	
LOXAPINE SUCCINATE EQ 25MG BASE	LOXITANE (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	17-525 02-25-75	3546226 12-08-87	
LOXAPINE SUCCINATE EQ 50MG BASE	LOXITANE (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	17-525 02-25-75	3546226 12-08-87	
MAFENIDE ACETATE EQ 85MG BASE/GH	SULFAMYLOX (CREAM; TOPICAL)	WINTHROP LABS/STERIL	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

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MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE; SODIUM PHOSPHATE, DIBASIC 30MG/100ML; 37MG/100ML; 0.82MG/100ML; 370MG/100ML; 530MG/100ML; 500MG/100ML; 12MG/100ML	ISOLYTE S 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		
MAGNESIUM SULFATE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE 20MG/100ML; 40MG/100ML; 6.25MG/100ML; 800MG/100ML; 8.75MG/100ML	TIS-U-SOL (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-508 02-19-82		NC 09-24-86
MALATHION 0.5%	PRIODERM (LOTION; TOPICAL)	PURDUE FREDERICK	18-613 08-02-82		NCE 08-02-92
MAPROTILINE HYDROCHLORIDE 25MG	LUDIOMIL (TABLET; ORAL)	CIBA/CIBA-GEIGY	17-543 12-01-80	3399201 08-27-85	

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MAPROTILINE HYDROCHLORIDE 50MG	LUDIOMIL (TABLET; ORAL)	CIBA/CIBA-GEIGY	17-543 12-01-80	3399201 08-27-85	
MAPROTILINE HYDROCHLORIDE 75MG	LUDIOMIL (TABLET; ORAL)	CIBA/CIBA-GEIGY	17-543 09-30-82	3399201 08-27-85	NS 09-24-86
MAZINDOL 1MG	SANOREX (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	17-247 06-14-73	3763178 10-02-90	
MAZINDOL 2MG	SANOREX (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	17-247 06-14-73	3763178 10-02-90	
MAZINDOL 2MG	MAZANOR (TABLET; ORAL)	WYETH LABS/AMHO	17-980 08-28-80	3763178 10-02-90	
MAZINDOL 1MG	MAZANOR (TABLET; ORAL)	WYETH LABS/AMHO	17-980 02-11-81	3763178 10-02-90	
MEBENDAZOLE 100MG	VERMOX (TABLET, CHEWABLE; ORAL)	JANSSEN PHARMA	17-481 06-28-74	3657267 04-18-89	
MEDROXYPROGESTERONE ACETATE 100MG/ML	DEPO-PROVERA (INJECTABLE; INJECTION)	UPJOHN	12-541 01-16-76	4038389 07-26-94	
MEDROXYPROGESTERONE ACETATE 400MG/ML	DEPO-PROVERA (INJECTABLE; INJECTION)	UPJOHN	12-541 01-16-76	4038389 07-26-94	
MEGLUMINE; METRIZOIC ACID 140.1MG/ML; 461.8MG/ML	ISOPAQUE-280 (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-506 04-30-74	3476802 11-04-86	
METAPROTERENOL SULFATE 20MG	ALUPENT (TABLET; ORAL)	BOEHRINGER INGELHEIM	15-874 05-13-74	3422196 01-14-86	
METAPROTERENOL SULFATE 10MG	ALUPENT (TABLET; ORAL)	BOEHRINGER INGELHEIM	15-874 08-08-77	3422196 01-14-86	
METAPROTERENOL SULFATE 0.65MG/INH	ALUPENT (AEROSOL; INHALATION)	BOEHRINGER INGELHEIM	16-402 07-31-73	3422196 01-14-86	
METAPROTERENOL SULFATE 10MG/5ML	ALUPENT (SYRUP; ORAL)	BOEHRINGER INGELHEIM	17-571 05-23-75	3422196 01-14-86	

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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		
METHYLDOPA 250MG/5ML	ALDOMET (SUSPENSION; ORAL)	MS&D/MERCK	18-389 08-28-81	4404193 09-13-00	
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	3876802 04-08-92 3998790 12-21-93	
METOPROLOL TARTRATE 100MG	LOPRESSOR (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-963 08-07-78	3876802 04-08-92 3998790 12-21-93	
METOPROLOL TARTRATE 1MG/ML	LOPRESSOR (INJECTABLE; INJECTION)	GEIGY/CIBA-GEIGY	18-704 03-30-84	3876802 04-08-92 3998790 12-21-93	NDF 09-24-86

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METRIZAMIDE 3.75GM/VIAL	AMIPAQUE (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-982 08-23-78	3701771 10-31-89	1-26 09-24-86
METRIZAMIDE 6.75GM/VIAL	AMIPAQUE (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	17-982 08-23-78	3701771 10-31-89	1-26 09-24-86
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	ZENITH LABORATORIES	18-517 05-05-82		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	CHELSEA LABORATORIES	18-599 09-17-82		
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	CHELSEA LABORATORIES	18-599 02-13-84		
METRONIDAZOLE 250MG	METRYL (TABLET; ORAL)	DRUMMER/PHOENIX	18-620 03-04-82		
METRONIDAZOLE 500MG	METRYL 500 (TABLET; ORAL)	DRUMMER/PHOENIX	18-620 06-02-83		
METRONIDAZOLE 500MG/100ML	METRO I.V. (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-674 08-31-82		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	CORD LABORATORIES	18-740 10-22-82		
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	CORD LABORATORIES	18-740 10-22-82		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	DANBURY PHARMACAL	18-764 09-17-82		
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	DANBURY PHARMACAL	18-764 12-20-82		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	BARR LABORATORIES	18-818 02-16-83		

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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		
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	LNK INTERNATIONAL	19-029 04-10-84		

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METRONIDAZOLE HYDROCHLORIDE EQ 500MG BASE/VIAL	FLAGYL I.V. (INJECTABLE; INJECTION)	SEARLE PHARMS	18-353 11-28-80		I-11 12-20-87
MICONAZOLE 10MG/ML	MONISTAT (INJECTABLE; INJECTION)	JANSSEN PHARMA	18-040 10-04-78	3717655 02-20-90 3839574 10-01-91	I-27 09-24-86
MICONAZOLE NITRATE 2%	MONISTAT 7 (CREAM; VAGINAL)	ORTHO PHARMACEUTICAL	17-450 01-30-74	3717655 02-20-90 3839574 10-01-91	
MICONAZOLE NITRATE 2%	MONISTAT-DERM (CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-494 01-30-74	3717655 02-20-90 3839574 10-01-91	
MICONAZOLE NITRATE 2%	MONISTAT-DERM (LOTION; TOPICAL)	ORTHO PHARMACEUTICAL	17-739 12-16-75	3717655 02-20-90 3839574 10-01-91	
MICONAZOLE NITRATE 100MG	MONISTAT 7 (SUPPOSITORY; VAGINAL)	ORTHO PHARMACEUTICAL	18-520 03-15-82	3717655 02-20-90 3839574 10-01-91	NDF 9-24-86
MICONAZOLE NITRATE 200MG	MONISTAT 3 (SUPPOSITORY; VAGINAL)	ORTHO PHARMACEUTICAL	18-888 08-15-84	3717655 02-20-90 3839574 10-01-91	NS 09-24-86
MINOXIDIL 2.5MG	LONITEN (TABLET; ORAL)	UPJOHN	18-154 10-18-79	3461461 08-12-86	

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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 8-31-85 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>
NADOLOL 160MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-063 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 40MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-064 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 80MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-064 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 120MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-064 12-10-79	3982021 09-21-93 3935267 01-27-93	
NADOLOL 160MG	CORGARD (TABLET; ORAL)	ER SQUIBB AND SONS	18-064 12-10-79	3982021 09-21-93 3935267 01-27-93	
NALBUPHINE HYDROCHLORIDE 10MG/ML	NUBAIN (INJECTABLE; INJECTION)	DUPONT PHARMS/DUPONT	18-024 05-15-79	3393197 07-16-85	NS 09-24-86
NALBUPHINE HYDROCHLORIDE 20MG/ML	NUBAIN (INJECTABLE; INJECTION)	DUPONT PHARMS/DUPONT	18-024 05-27-82		
NALIDIXIC ACID 250MG	NEGRAM (TABLET; ORAL)	WINTHROP LABS/STERL	14-214 12-27-67	3590036 06-29-88	
NALIDIXIC ACID 500MG	NEGRAM (TABLET; ORAL)	WINTHROP LABS/STERL	14-214 03-06-64	3590036 06-29-88	
NALIDIXIC ACID 1GM	NEGRAM (TABLET; ORAL)	WINTHROP LABS/STERL	14-214 03-06-64	3590036 06-29-88	

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NALTOXIC ACID 250MG/5ML	NEGGRAM (SUSPENSION; ORAL)	WINTHROP LABS/STERL	17-430 04-17-73	3590036 06-29-88	
NALOXONE HYDROCHLORIDE 0.4MG/ML	NARCAN (INJECTABLE; INJECTION)	DUPONT PHARMS/DUPONT	16-636 04-13-71		D-9, D-10, D-11, I-33 09-24-86
NALOXONE HYDROCHLORIDE 1MG/ML	NARCAN (INJECTABLE; INJECTION)	DUPONT PHARMS/DUPONT	16-636 09-17-84		NS, D-9, D-10, D-11 I-33 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	3904682 09-09-92 3998966 12-21-93 4001301 09-09-92 4009197 09-09-92	
NAPROXEN 250MG	NAPROSYN (TABLET; ORAL)	SYNTEX PR	17-581 03-11-76	3904682 09-09-92 3998966 12-21-93 4001301 09-09-92 4009197 09-09-92	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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>
NAPROXEN 375MG	NAPROSYN (TABLET; ORAL)	SYNTEX PR	17-581 07-18-80	3904682 09-09-92 3998966 12-21-93 4001301 09-09-92 4009197 09-09-92	
NAPROXEN 500MG	NAPROSYN (TABLET; ORAL)	SYNTEX PR	17-581 04-15-82	3904682 09-09-92 3998966 12-21-93 4001301 09-09-92 4009197 09-09-92	NS 09-24-86
NAPROXEN SODIUM 275MG	ANAPROX (TABLET; ORAL)	SYNTEX PR	18-164 09-04-80	3998966 12-21-93 4001301 09-09-92 4009197 09-09-92	
NICLOSAMIDE 500MG	NICLOCIDE (TABLET, CHEWABLE; ORAL)	MILES PHARMS/MILES	18-669 05-14-82		NCE 05-14-92
NICOTINE POLACRILEX EQ 2MG BASE	NICORETTE (GUM, CHEWING; ORAL)	MERRELL DOW/DOW CHEM	18-612 01-13-84		NCE 01-13-94
NIFEDIPINE 10MG	PROCARDIA (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-482 12-31-81	3644627 02-22-89 3784684 01-08-91	
NITROGLYCERIN 0.5MG/ML	TRIDIL (INJECTABLE; INJECTION)	AM CRITICAL CARE/AHS	18-537 06-16-83		NDF 09-24-86
NITROGLYCERIN 5MG/ML	NITROSTAT (INJECTABLE; INJECTION)	PARKE-DAVIS/W-L	18-588 12-23-83		NDF 09-24-86

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NITROGLYCERIN 5MG/ML	NITRO-BID (INJECTABLE; INJECTION)	MARION LABORATORIES	18-621 01-05-82		NDF 09-24-86
NITROGLYCERIN 1MG/ML	NITRONAL (INJECTABLE; INJECTION)	G POHL-BOSKAMP	18-672 08-30-83		NDF 09-24-86
NITROGLYCERIN 5MG/ML	NITRONAL (INJECTABLE; INJECTION)	G POHL-BOSKAMP	18-672 08-30-83		NDF 09-24-86
NITROGLYCERIN 0.8MG/ML	NITROL (INJECTABLE; INJECTION)	KREMER-S-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/5ML	AVENTYL HCL (SOLUTION; ORAL)	ELI LILLY	14-685 11-06-64	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE/5ML	PAMELOR (SOLUTION; ORAL)	SANDOZ PHARMS/SANDOZ	18-012 08-01-77	3922305 11-25-92	

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NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE	PAMELOR (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-013 08-01-77	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 25MG BASE	PAMELOR (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-013 08-01-77	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 75MG BASE	PAMELOR (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-013 06-14-79	3922305 11-25-92	
NORTRIPTYLINE HYDROCHLORIDE EQ 50MG BASE	PAMELOR (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-013 06-14-79	3922305 11-25-92	
OXAMNIQUINE 250MG	VANSIL (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-069 07-23-80	3903283 09-02-92 3821228 06-28-91 3925391 12-09-92	
OXPRENOLOL HYDROCHLORIDE 20MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83	3483221 12-09-86	NCE 12-28-93
OXPRENOLOL HYDROCHLORIDE 40MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83	3483221 12-09-86	NCE 12-28-93
OXPRENOLOL HYDROCHLORIDE 80MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83	3483221 12-09-86	NCE 12-28-93
OXPRENOLOL HYDROCHLORIDE 160MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83	3483221 12-09-86	NCE 12-28-93
PANCURONIUM BROMIDE 2MG/ML	PAVULON (INJECTABLE; INJECTION)	ORGANON/AKZONA	17-015 10-24-72	3553212 01-05-88	
PANCURONIUM BROMIDE 1MG/ML	PAVULON (INJECTABLE; INJECTION)	ORGANON/AKZONA	17-015 09-14-73	3553212 01-05-88	
PARAMETHASONE ACETATE 1MG	HALDRONE (TABLET; ORAL)	ELI LILLY	12-772 04-17-61	3499016 03-03-87	

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PARAMETHASONE ACETATE 2MG	HALDRONE (TABLET; ORAL)	ELI LILLY	12-772 04-17-61	3499016 03-03-87	
PENTAGASTRIN 0.25MG/ML	PEPTAVLON (INJECTABLE; INJECTION)	AYERST LABS/AMHO	17-048 07-26-74	3896103 07-22-92	
PENTAMIDINE ISETHIONATE 300MG/VIAL	PENTAM 300 (INJECTABLE; INJECTION)	LYPHOMED	19-264 10-16-84		
PENTAZOCINE LACTATE EQ 30MG BASE/ML	TALWIN (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	16-194 07-24-67	4105659 08-08-95	
PENTETATE INDIUM DISODIUM, IN-111 1MC1/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 4189469 02-02-97	NCE 08-30-94
PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE 5MG/5ML; 6.25MG/5ML	PHENERGAN VC (SYRUP; ORAL)	WYETH LABS/AMHO	08-604 04-02-84		
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

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PINDOLOL 15MG	VISKEN (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	18-285 09-03-82	3471515 10-07-86	NCE 09-03-92
PIROXICAM 10MG	FELDENE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-147 04-06-82	3591584 07-06-88 3674876 07-04-89 3862319 01-21-92 4100347 07-11-95 3927002 12-16-92 RE29668 12-10-91	NCE 04-06-92
PIROXICAM 20MG	FELDENE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-147 04-06-82	3591584 07-06-88 3674876 07-04-89 3862319 01-21-92 4100347 07-11-95 3927002 12-16-92 RE29668 12-10-91	NCE 04-06-92
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE 236GM/BOT; 2.97GM/BOT; 6.74GM/BOT; 5.86GM/BOT; 22.74GM/BOT	GOLYTELY (POWDER FOR RECONSTITUTION; ORAL)	BRAINTREE LABS	19-011 07-13-84		

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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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POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE 0.5MG; 2MG	MINIZIDE (CAPSULE; ORAL)	Pfizer Labs/Pfizer	17-986 06-13-80	3511836 05-12-87 3663706 05-16-89 4130647 12-19-95	
POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE 0.5MG; 5MG	MINIZIDE (CAPSULE; ORAL)	Pfizer Labs/Pfizer	17-986 06-13-80	3511836 05-12-87 3663706 05-16-89 4130647 12-19-95	
POTASSIUM ACETATE 2MEQ/ML	POTASSIUM ACETATE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	Abbott Laboratories	18-896 07-20-84		NDF 09-24-86
POTASSIUM CHLORIDE 8MEQ	MICRO-K (CAPSULE, CONTROLLED RELEASE; ORAL)	AH Robins	18-238 10-17-80	4259315 03-31-98	
POTASSIUM CHLORIDE 10MEQ	MICRO-K 10 (CAPSULE, CONTROLLED RELEASE; ORAL)	AH Robins	18-238 05-14-84	4259315 03-31-98	
POTASSIUM CHLORIDE 10MEQ	Klotrix (Tablet, Controlled Release; Oral)	Mead Johnson/B-M	17-850 05-22-80	4140756 02-20-96	
POTASSIUM CHLORIDE; SODIUM CHLORIDE 150MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	Travenol Labs	18-630 02-17-83		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 300MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	Travenol Labs	18-630 02-17-83		

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POTASSIUM CHLORIDE; SODIUM CHLORIDE 150MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-630 02-17-83		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 300MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-630 02-17-83		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 75MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722 11-09-82		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 150MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722 11-09-82		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 220MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722 11-09-82		
POTASSIUM CHLORIDE; SODIUM CHLORIDE 300MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722 11-09-82		
POTASSIUM CITRATE 5MEQ	POTASSIUM CITRATE (TABLET; ORAL)	UNIV TX HLTH SCI CTR	19-071 08-30-85		NP 08-30-88
PRALIDOXIME CHLORIDE 300MG/ML	PROTOPAM CHLORIDE (INJECTABLE; INJECTION)	AYERST LABS/AMHO	18-799 12-13-82	3629425 12-21-88	NDF 09-24-86
PRALIDOXIME CHLORIDE 300MG/ML	PRALIDOXIME CHLORIDE (INJECTABLE; INJECTION)	SURVIVAL TECHNOLOGY	18-986 04-26-83		NDF 09-24-86
PRAZEPAM 20MG	CENTRAX (CAPSULE; ORAL)	PARKE-DAVIS/W-L	18-144 05-10-82		NS 09-24-86
PRAZIQUANTEL 600MG	BILTRICIDE (TABLET; ORAL)	MILES PHARMS/MILES	18-714 12-29-82	4001411 01-04-94	NCE 12-29-92

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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>
PRazosin HYDROCHLORIDE 5MG	MINIPRESS (CAPSULE; ORAL)	Pfizer LABS/Pfizer	17-442 06-23-76	3511836 05-12-87 3663706 05-16-89 4092315 05-30-95 4130647 12-19-95	
PRazosin HYDROCHLORIDE 1MG	MINIPRESS (CAPSULE; ORAL)	Pfizer LABS/Pfizer	17-442 06-23-76	3511836 05-12-87 3663706 05-16-89 4092315 05-30-95 4130647 12-19-95	
PRazosin HYDROCHLORIDE 2MG	MINIPRESS (CAPSULE; ORAL)	Pfizer LABS/Pfizer	17-442 06-23-76	3511836 05-12-87 3663706 05-16-89 4092315 05-30-95 4130647 12-19-95	
PROBUCOL 250MG	LORELCO (TABLET; ORAL)	MERRELL DOW/DOW CHEM	17-535 02-01-77	3576883 04-27-88 3862332 01-21-92	
PROCARBazine HYDROCHLORIDE EQ 50MG BASE	MATULANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	16-785 07-22-69	3520926 07-21-87	
PROPRANOLOL HYDROCHLORIDE 10MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 11-13-67		I-10 09-24-86
PROPRANOLOL HYDROCHLORIDE 20MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 10-16-74		I-10 09-24-86
PROPRANOLOL HYDROCHLORIDE 40MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 11-13-67		I-10 09-24-86

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PROPRANOLOL HYDROCHLORIDE 60MG	INDERAL (TABLET; ORAL)	AYERST LABS/ANHO	16-418 10-18-82		NS 09-24-86 I-10 09-24-86
PROPRANOLOL HYDROCHLORIDE 80MG	INDERAL (TABLET; ORAL)	AYERST LABS/ANHO	16-418 10-16-74		I-10 09-24-86
PROPRANOLOL HYDROCHLORIDE 80MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/ANHO	18-553 04-19-83	4138475 02-06-96	NDF 09-24-86
PROPRANOLOL HYDROCHLORIDE 90MG	INDERAL (TABLET; ORAL)	AYERST LABS/ANHO	16-418 10-18-82		NS 09-24-86 I-10 09-24-86
PROPRANOLOL HYDROCHLORIDE 120MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/ANHO	18-553 04-19-83	4138475 02-06-96	NDF 09-24-86
PROPRANOLOL HYDROCHLORIDE 160MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/ANHO	18-553 04-19-83	4138475 02-06-96	NDF 09-24-86
PROTAMINE SULFATE 250MG/VIAL	PROTAMINE SULFATE (INJECTABLE; INJECTION)	UPJOHN	07-413 08-02-84		NS 09-24-86
PROTEIN HYDROLYSATE 5%	AMINOSOL 5% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	05-932 01-31-85		
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	

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RANITIDINE HYDROCHLORIDE EQ 150MG BASE	ZANTAC (TABLET; ORAL)	GLAXO	18-703 06-09-83	4128658 12-05-95 4521431 06-04-02	NCE 06-09-93 I-15 06-28-88
RANITIDINE HYDROCHLORIDE EQ 25MG BASE/ML	ZANTAC (INJECTABLE; INJECTION)	GLAXO	19-090 10-19-84	4128658 12-05-95 4521431 06-04-02	NCE 06-09-93
RITODRINE HYDROCHLORIDE 10MG	YUTOPAR (TABLET; ORAL)	ASTRA PHARM PRODS	18-555 12-12-80	3410944 11-12-85	
RITODRINE HYDROCHLORIDE 10MG/ML	YUTOPAR (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-580 12-12-80	3410944 11-12-85	
RITODRINE HYDROCHLORIDE 15MG/ML	YUTOPAR (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-580 12-12-80	3410944 11-12-85	
SAFFLOWER OIL; SOYBEAN OIL 10%; 10%	LIPOSYN II 20% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-991 08-27-84		NP 09-24-86
SAFFLOWER OIL; SOYBEAN OIL 5%; 5%	LIPOSYN II 10% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-997 08-27-84		NP 09-24-86
SARALASIN ACETATE EQ 0.6MG BASE/ML	SARENIN (INJECTABLE; INJECTION)	NORWICH EATON/P&G	18-009 05-29-81	3932624 01-13-93 3886134 05-27-92	
SCOPOLAMINE 1.5MG	TRANSERM-SCOP (FILM, CONTROLLED RELEASE; PERCUTANEOUS)	CIBA/CIBA-GEIGY	17-874 12-31-79	4031894 06-28-94 4262003 04-14-98 4436741 04-14-98	
SELENIUM SULFIDE 2.5%	SELSUN (SHAMPOO/LOTION; TOPICAL)	ABBOTT LABS	07-936 05-17-51		I-3 09-24-86

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SILVER SULFADIAZINE 1%	SILVADENE (CREAM; TOPICAL)	MARTON 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 09-24-86
SODIUM BICARBONATE; TARTARIC ACID 460MG/GM; 420MG/GM	BAROS (GRANULE; ORAL)	MALLINCKRODT	18-509 08-07-85		NP 08-07-88
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		

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SODIUM CHLORIDE 9MG/ML	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-218 07-13-84		
SODIUM CHLORIDE 900MG/100ML	SODIUM CHLORIDE 0.9% IN STERILE PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	19-319 05-17-85		
SODIUM CHLORIDE 900MG/100ML	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-465 07-15-85		
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		
SODIUM IODIDE, I-123 400 UCI	SODIUM IODIDE I 123 (CAPSULE; ORAL)	BENEDICT NUCLR PHARM	18-671 05-27-82		
SODIUM LACTATE 5MEQ/ML	SODIUM LACTATE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-947 09-05-84	NS 09-24-86	
SODIUM NITROPRUSSIDE 50MG/VIAL	SODIUM NITROPRUSSIDE (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-581 07-28-82		
SODIUM PHOSPHATE, DIBASIC; SODIUM PHOSPHATE, MONOBASIC 142MG/ML; 276MG/ML	SODIUM PHOSPHATES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-892 05-10-83	NP 09-24-86	
SOMATROPIN 2 IU/VIAL	ASELLACRIN 2 (INJECTABLE; INJECTION)	SERONO LABS	17-726 07-21-83	NS 09-24-86	
SORBITOL 3GM/100ML	SORBITOL 3% IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-512 05-27-82		
SOYBEAN OIL 10%	SOYACAL 10% (INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	18-465 06-29-83		

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SOYBEAN OIL 10%	TRAVAMULSION 10% (INJECTABLE; INJECTION)	TRAVENOL LABS	18-660 02-26-82		
SOYBEAN OIL 20%	TRAVAMULSION 20% (INJECTABLE; INJECTION)	TRAVENOL LABS	18-758 02-15-83		
SOYBEAN OIL 20%	SOYACAL 20% (INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	18-786 06-29-83		
SOYBEAN OIL 10%	LIPOSYN III 10% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-969 09-24-84		
SOYBEAN OIL 20%	LIPOSYN III 20% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-970 09-25-84		
STANOZOLOL 2MG	WINSTROL (TABLET; ORAL)	WINTHROP LABS/STERL	12-885 11-30-61	3704295 11-28-89	I-28 09-24-86
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	
SULCONAZOLE NITRATE 1%	SULCOSYN (SOLUTION; TOPICAL)	SYNTEX LABS/SYNTEX	18-738 08-30-85	4055652 10-25-94	NCE 08-30-90
SUFENTANIL CITRATE EQ 0.05MG BASE/ML	SUFENTA (INJECTABLE; INJECTION)	JANSSEN PHARMA	19-050 05-04-84	3998834 12-21-93	NCE 05-04-94
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	BACTRIM (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-377 07-30-73	RE28636 06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	BACTRIM DS (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-377 03-01-78	RE28636 06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	BACTRIM (SUSPENSION; ORAL)	HOFFMANN-LA ROCHE	17-560 04-16-75	RE28636 06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	BACTRIM PEDIATRIC (SUSPENSION; ORAL)	HOFFMANN-LA ROCHE	17-560 12-10-79	RE28636 06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM 80MG/ML; 16MG/ML	BACTRIM (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	18-374 06-23-81	3551564 12-29-87 RE28636 06-02-87	

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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		
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		
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	SEPTRA (TABLET; ORAL)	BURROUGHS WELLCOME	17-376 07-30-73	4209513 06-24-97	
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	SEPTRA DS (TABLET; ORAL)	BURROUGHS WELLCOME	17-376 02-12-76	4209513 06-24-97	

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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 04-04-89 3725548 04-03-90	
SULINDAC 200MG	CLINORIL (TABLET; ORAL)	MS&D/MERCK	17-911 09-27-78	3725548 04-03-90 3654349 04-04-89	
SUTILAINS 82,000 UNITS/GM	TRAVASE (OINTMENT; TOPICAL)	TRAVENOL LABS	12-828 06-12-69	3409719 11-05-85	
TAMOXIFEN CITRATE EQ 10MG BASE	NOLVADEX (TABLET; ORAL)	STUART PHARMS/ICI	17-970 12-30-77	4536516 08-20-02	
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, GLUCEPTATE KIT N/A	TECHNISCAN 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		

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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
TERBUTALINE SULFATE 0.2MG/INH	BRICANYL (AEROSOL; INHALATION)	MERRELL DOW/DOW CHEM	18-000 03-19-85	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 1MG/ML	BRICANYL (INJECTABLE; INJECTION)	MERRELL DOW/DOW CHEM	17-466 03-25-74	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 2.5MG	BRICANYL (TABLET; ORAL)	MERRELL DOW/DOW CHEM	17-618 04-22-75	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 5MG	BRICANYL (TABLET; ORAL)	MERRELL DOW/DOW CHEM	17-618 04-22-75	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 2.5MG	BRETHINE (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-849 05-17-76	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 5MG	BRETHINE (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-849 05-17-76	3937838 02-10-93 4011258 03-08-94	
TERBUTALINE SULFATE 1MG/ML	BRETHINE (INJECTABLE; INJECTION)	GEIGY/CIBA-GEIGY	18-571 11-30-81	3937838 02-10-93 4011258 03-08-94	

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TERFENADINE 60MG	SELDANE (TABLET; ORAL)	MERRELL DOW/DOW CHEM	18-949 05-08-85	3806526 04-23-91 3878217 04-15-92 3965257 06-22-93 3966949 06-29-93 4254129 03-03-98 4285957 08-25-98	NCE 05-08-90
THALLOUS CHLORIDE, TL-201 2MCI/ML	THALLOUS CHLORIDE TL 201 (INJECTABLE; INJECTION)	MEDI-PHYSICS	18-110 02-01-82		NS 09-24-86
THALLOUS CHLORIDE, TL-201 1MCI/ML	THALLOUS CHLORIDE TL 201 (INJECTABLE; INJECTION)	AMERSHAM/RADIOCHEM	18-548 12-30-82		
THEOPHYLLINE 300MG	QUITRON-T/SR (TABLET, CONTROLLED RELEASE; ORAL)	MEAD JOHNSON/B-M	87-563 06-21-83	4465660 08-14-01	
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	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 8-31-85 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>
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		
TOLMETIN SODIUM EQ 200MG BASE	TOLECTIN (TABLET; ORAL)	MCNEIL LABORATORIES	17-628 03-24-76	3752826 08-14-90	
TOLMETIN SODIUM EQ 400MG BASE	TOLECTIN DS (CAPSULE; ORAL)	MCNEIL LABORATORIES	18-084 10-30-79	3752826 08-14-90	
TRAZODONE HYDROCHLORIDE 150MG	DESYREL (TABLET; ORAL)	MEAD JOHNSON/B-M	18-207 03-25-85		
TRETINOIN 0.05%	RETIN-A (SOLUTION; TOPICAL)	ORTHO PHARMACEUTICAL	16-921 10-20-71	3729568 04-24-90	
TRETINOIN 0.1%	RETIN-A (CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-340 01-26-73	3729568 04-24-90 3906108 09-16-92	
TRETINOIN 0.05%	RETIN-A (CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-522 07-19-74	3729568 04-24-90 3906108 09-16-92	

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RETINOIN 0.01%	RETIN-A (GEL; TOPICAL)	ORTHO PHARMACEUTICAL	17-955 10-05-78	3729568 04-24-90 4247547 01-27-98	
RETINOIN 0.025%	RETIN-A (GEL; TOPICAL)	ORTHO PHARMACEUTICAL	17-579 04-18-75	3729568 04-24-90 4247547 01-27-98	
TRIAMCINOLONE ACETONIDE 0.25MG/INH	AZMACORT (AEROSOL; INHALATION)	WILLIAM H RORER	18-117 04-23-83	3897779 08-05-92 3927806 12-23-92	NDF 09-24-86
TRIAMCINOLONE ACETONIDE 0.1%	KENALOG-H (CREAM; TOPICAL)	ER SQUIBB AND SONS	86-240 06-22-78	4048310 09-13-94	
TRIAZOLAM 0.125MG	HALCION (TABLET; ORAL)	UPJOHN	17-892 04-26-85	3980790 09-14-93 3987052 10-19-93	NCE 11-15-92
TRIAZOLAM 0.25MG	HALCION (TABLET; ORAL)	UPJOHN	17-892 11-15-82	3980790 09-14-93 3987052 10-19-93	NCE 11-15-92
TRIAZOLAM 0.5MG	HALCION (TABLET; ORAL)	UPJOHN	17-892 11-15-82	3980790 09-14-93 3987052 10-19-93	NCE 11-15-92
TRILOSTANE 30MG	MODRASTANE (CAPSULE; ORAL)	WINTHROP LABS/STERL	18-719 12-31-84		NCE 12-31-89
TRILOSTANE 60MG	MODRASTANE (CAPSULE; ORAL)	WINTHROP LABS/STERL	18-719 12-31-84		NCE 12-31-89
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

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TRIMETHOPRIM 100MG	TRIMETHOPRIM (TABLET; ORAL)	BIOCRAFT LABS	18-679 07-30-82		
TRIMIPRAMINE MALEATE EQ 100MG BASE	SURMONTIL (CAPSULE; ORAL)	IVES LABS/ANHO	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		NR 09-24-86
VERAPAMIL HYDROCHLORIDE 2.5MG/ML	CALAN (INJECTABLE; INJECTION)	SEARLE PHARMS	19-038 03-30-84		
WATER FOR INJECTION, STERILE 100%	STERILE WATER FOR INJECTION IN PLASTIC CONTAINER (LIQUID; N/A)	TRAVENOL LABS	18-595 01-17-83		
WATER FOR INJECTION, STERILE 100%	STERILE WATER IN PLASTIC CONTAINER (LIQUID; N/A)	TRAVENOL LABS	18-632 06-30-82		

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WATER FOR INJECTION, STERILE 100%	STERILE WATER IN PLASTIC CONTAINER (LIQUID; N/A)	ABBOTT LABORATORIES	18-801 10-27-82		
WATER FOR INJECTION, STERILE 100%	BACTERIOSTATIC WATER IN PLASTIC CONTAINER (LIQUID; N/A)	ABBOTT LABORATORIES	18-802 10-27-82		
WATER FOR INJECTION, STERILE 100%	STERILE WATER FOR INJECTION IN PLASTIC CONTAINER (LIQUID; N/A)	AM MCGAW/AM HOSP	19-077 03-02-84		
XENON, XE-127 5MCI/VIAL	XENON XE 127 (GAS; INHALATION)	MALLINCKRODT	18-536 10-01-82		NCE 10-01-92
XENON, XE-127 10MCI/VIAL	XENON XE 127 (GAS; INHALATION)	MALLINCKRODT	18-536 10-01-82		NCE 10-01-92
XENON, XE-133 10MCI/VIAL	XENON XE 133 (GAS; INHALATION)	MALLINCKRODT	18-327 03-09-82		
XENON, XE-133 20MCI/VIAL	XENON XE 133 (GAS; INHALATION)	MALLINCKRODT	18-327 03-09-82		

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