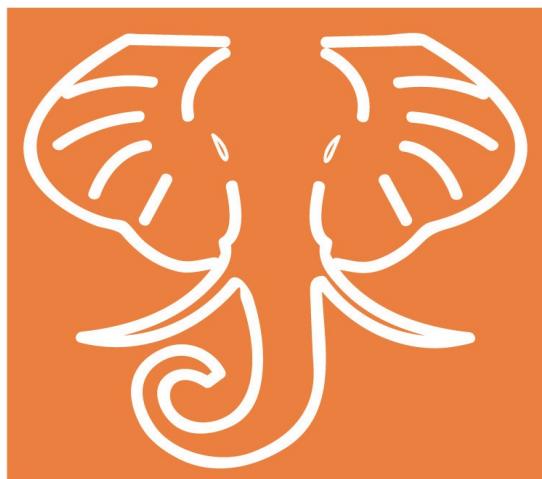


Approved prescription drug products with therapeutic equivalence evaluations.

[Washington, D.C.?] : U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, Bureau of Drugs : 1980-

<http://hdl.handle.net/2027/mdp.39015072931911>

HathiTrust



www.hathitrust.org

Public Domain, Google-digitized

http://www.hathitrust.org/access_use#pd-google

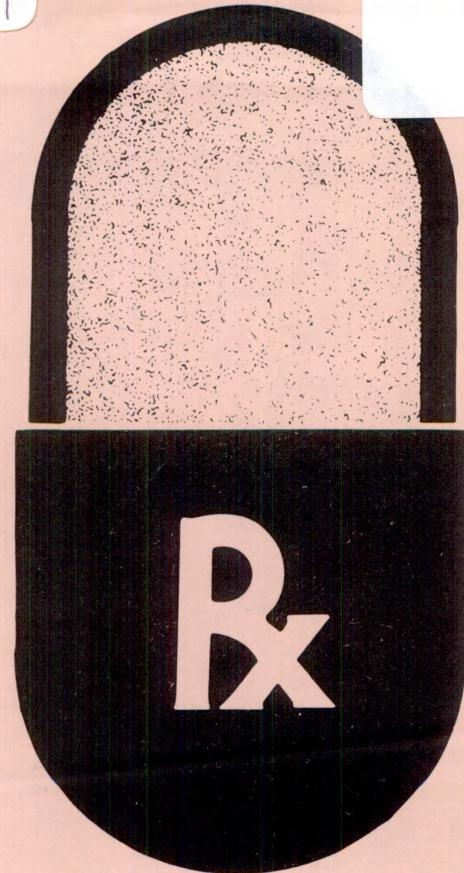
We have determined this work to be in the public domain, meaning that it is not subject to copyright. Users are free to copy, use, and redistribute the work in part or in whole. It is possible that current copyright holders, heirs or the estate of the authors of individual portions of the work, such as illustrations or photographs, assert copyrights over these portions. Depending on the nature of subsequent use that is made, additional rights may need to be obtained independently of anything we can address. The digital images and OCR of this work were produced by Google, Inc. (indicated by a watermark on each page in the PageTurner). Google requests that the images and OCR not be re-hosted, redistributed or used commercially. The images are provided for educational, scholarly, non-commercial purposes.

PHARMACY

RM
300
A653
5th edition
Suppl. 11

of Michigan
Pharmacy
Library

SERIAL



**CUMULATIVE
SUPPLEMENT 11
AUG'84 - JUL'85**

**APPROVED
PRESCRIPTION
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

5TH EDITION

THE UNIVERSITY
OF MICHIGAN

NOV 19 1986

MEDICAL
LIBRARY

UNIVERSITY OF MICHIGAN
LIBRARIES

SEP 27 1985

DEPOSITED BY
UNITED STATES OF AMERICA

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

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

**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.

Products

dicyclomine hydrochloride
isosorbide dinitrate
nandrolone decanoate

Federal Register Reference

JUN 22, 1984	(49 FR 25681)
AUG 3, 1984	(49 FR 31151)
JUL 15, 1983	(48 FR 32395)

(continued)

Products

Federal Register Reference

(continued)

neomycin sulfate with either: dexamethasone sodium phosphate, fluocinolone acetonide, flurandrenolide, hydrocortisone, or methylprednisolone acetate. [topical] anti-infectives for dermatologic use]	MAY 4, 1984 (49 FR 19147)
[topical ointment]	
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	JUL 29, 1983 (48 FR 34516)
sulfamethoxazole	
sulfanilamide and aminacrine	AUG 22, 1983 (48 FR 38097)
tranylcypromine sulfate	MAR 22, 1984 (49 FR 10708)

C. APPLICANT (NAME) CHANGES

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

APPLICANT (NAME) CHANGES

Former Applicant (Name)

New Applicant (Name)

New Abbreviated Name

OHIO MEDICAL ANESTHETICS

ANAQUEST

ANAQUEST

D. ADDENDUM: DRUG PRICE COMPETITION AND PATENT TERM RESTORATION

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

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.

A. COUNTS CUMULATIVE BY QUARTERS

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

CATEGORIES COUNTED	JULY '84 (BASELINE)	OCT '84	JAN '85	APR '85
DRUG PRODUCTS LISTED	7415	7609	7746	7890
SINGLE SOURCE	2005 (27.0%)	2045 (26.9%)	2077 (26.8%)	2078 (26.3%)
MULTISOURCE (1)	5410 (72.9%)	5564 (73.1%)	5669 (73.2%)	5812 (73.7%)
THEAPEUTICALLY EQUIVALENT	4393 (59.2%)	4497 (59.1%)	4598 (59.4%)	4709 (59.6%)
NOT THEAPEUTICALLY EQUIVALENT	999 (13.4%)	1032 (13.5%)	1038 (13.4%)	1068 (13.5%)
EXCEPITIONS (2)	18 (0.3%)	26 (0.3%)	23 (0.3%)	26 (0.3%)
NEW MOLECULAR ENTITIES APPROVED	-	4	9	304
NUMBER OF APPLICANTS	295	300	304	307

B. ACTIVITY FOR SUPPLEMENT NUMBER 11

	MAY '85	JUN '85	JUL '85	CUMULATIVE
DRUG PRODUCTS ADDED:	40	43	49	132
NEWLY APPROVED	37	42	49	128
DESIRED EFFECTIVE	3	1	0	4
REMARKETED	0	0	0	0
DRUG PRODUCTS REMOVED:	28	24	6	58
WITHDRAWN APPROVAL	0	0	0	0
RX TO OTC SWITCH	0	0	0	0
DISCONTINUED MARKETING	28	24	6	58
NET GAIN IN DRUG PRODUCTS	12	19	43	74
SINGLE SOURCE PRODUCTS APPROVED	12	7	14	33
MULTISOURCE DRUG PRODUCTS APPROVED	28	36	35	99
NEW MOLECULAR ENTITIES APPROVED:	3	0	2	5
AS THE ENTITY	3	0	1	4
AS A SALT, ESTER OR DERIVATIVE	0	0	1	1
OF THE ENTITY	0	0	0	1

- (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 11 / AUGUST '84 - JULY '85

ACEBUTOLOL HYDROCHLORIDE (PAGE 3-1)

CAPSULE; ORAL
SECTRAL

IVES LABS/AMHO EQ 200MG BASEN
EQ 400MG BASEN

N 18917
N 18917

ACETAMINOPHEN; BUTALBITAL (PAGE 3-1)

CAPSULE; ORAL

BUTALBITAL AND ACETAMINOPHEN

AB DM GRAHAM LABS 650MG;50MGX
PHRENILIN FORTE

AB CARNICK/GW CARNICK 650MG;50MGX

N 88991
N 88831

TABLET; ORAL

BUTALBITAL AND ACETAMINOPHEN

AB DANBURY PHARMACAL 325MG;50MGX
PHRENILIN

AB CARNICK/GW CARNICK 325MG;50MGX

N 87550
N 87811

ACETAMINOPHEN; BUTALBITAL; CAFFEINE (PAGE 3-1)

CAPSULE; ORAL

BUTALBITAL, ACETAMINOPHEN, CAFFEINE

> ADD > AB DM GRAHAM LABS 325MG;50MG;40MGX
AB 325MG;50MG;40MGX
AB 325MG;50MG;40MGX
AB 325MG;50MG;40MGX
AB 325MG;50MG;40MGX
AB 325MG;50MG;40MGX

N 88743
N 88758
N 88765
N 89023
N 89067
N 89102

ESSIC

AB GILBERT LABORATORIES 325MG;50MG;40MGX

N 88825

TABLET; ORAL

BUTALBITAL ASPIRIN AND CAFFEINE

AB QUANTUM PHARMS 325MG;50MG;40MGX
ESSIC
AB GILBERT LABORATORIES 325MG;50MG;40MGX
FIORICET
AB SANDOZ PHARMS/SANDOZ 325MG;50MG;40MGX
REPLAN
AB DM GRAHAM LABS 325MG;50MG;40MGX

N 88972
N 87629
N 88616
N 87804

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

AA ZENITH LABORATORIES 300MG;60MG

N 87083

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL

ACETAMINOPHEN W/ CODEINE #2

AA LEMMON 300MG;15MGX
ACETAMINOPHEN W/ CODEINE #3
AA LEMMON 300MG;30MGX
ACETAMINOPHEN W/ CODEINE #4
AA LEMMON 300MG;60MGX
/ACETAMINOPHEN W/ CODEINE PHOSPHATE #4
/AA /ZENITH LABORATORIES// 300MG;60MGX
/N 87083/

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-2)

CAPSULE; ORAL

ACETAMINOPHEN AND HYDROCODONE BITARTRATE

AA CENTRAL PHARMS 500MG;5MGX
AA DM GRAHAM LABS 500MG;5MGX

TABLET; ORAL

ACETAMINOPHEN AND HYDROCODONE BITARTRATE

/AA /CENTRAL PHARMS/ 500MG;5MG/
CO-GENIC

AA CENTRAL PHARMS 500MG;5MG
HYDROCODONE BITARTRATE W/ ACETAMINOPHEN
AA BARR LABORATORIES 500MG;5MGX

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 3-2)

CAPSULE; ORAL

TYLOX MCNEIL PHARM 500MG;5MGX

TYLOX-325 MCNEIL PHARM 325MG;5MGX

TABLET; ORAL

/CO-CET/

OXYCET AA HALSEY DRUG 325MG;5MGX

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-2)

TABLET; ORAL

DARVOCET-N 100

AA ELI LILLY 650MG;100MG
DARVOCET-N 50
AA ELI LILLY 325MG;50MG
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN
AA BARR LABORATORIES 325MG;50MGX
AA 650MG;100MGX
AA MYLAN PHARMS 650MG;100MGX
PROVOSET 100
AA LEMMON 650MG;100MGX

AMINOPHYLLINE; SODIUM CHLORIDE (PAGE 3-9)

INJECTABLE; INJECTION

AMINOPHYLLINE IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

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
/AP/	/ABBOTT LABORATORIES//	/AMINOPHYLLINE 0.05% IN SODIUM CHLORIDE 0.45%//	/N 88147//
/AP/	/ABBOTT LABORATORIES//	/AMINOPHYLLINE 0.1% IN SODIUM CHLORIDE 0.45%//	/N 88147//
/AP/	/ABBOTT LABORATORIES//	/AMINOPHYLLINE 0.2% IN SODIUM CHLORIDE 0.45%//	/N 88147//
/AP/	/ABBOTT LABORATORIES//	/AMINOPHYLLINE 0.45% IN SODIUM CHLORIDE 0.45%//	/N 88147//

AMITRIPTYLINE HYDROCHLORIDE (PAGE 3-10)

TABLET; ORAL

AMITRIPTYLINE HCL

BP	AM THERAPEUTICS	25MG*	N 88672
BP		50MG*	N 88673
BP		75MG*	N 88674
BP		100MG*	N 88675
BP	PAR PHARMACEUTICAL	10MG*	N 88697
BP		25MG*	N 88698
BP		50MG*	N 88699
BP		75MG*	N 88700
BP		100MG*	N 88701
BP		150MG*	N 88702
AB	o PUREPAC/KALIPHARMA	10MG	N 88084 > ADD >
AB	o	25MG	N 88085 > ADD >
AB	o	50MG	N 88105 > ADD >
AB	o	75MG	N 88106 > ADD >
AB	o	100MG	N 88107 > ADD >
/BP/	/SIDMAK LABORATORIES//	10MG//	/N 88883//
/BP/		25MG//	/N 88884//
/BP/		50MG//	/N 88885//
/BP/		75MG//	/N 88886//
/BP/		100MG//	/N 88887//
/BP/		150MG//	/N 88888//
AB	SIDMAK LABORATORIES	10MG*	N 88883
AB		25MG*	N 88884
AB		50MG*	N 88885
AB		75MG*	N 88886
AB		100MG*	N 88887
AB		150MG*	N 88888
BP	SUPERPHARM	10MG*	N 88853
BP		25MG*	N 88854
BP		50MG*	N 88855
BP		75MG*	N 88856
BP		100MG*	N 88857

AMMONIUM LACTATE (PAGE 3-12)

LOTION; TOPICAL

LAC-HYDRIN

BRISTOL-MYERS

EQ 12% ACID*

N 19155

AMOXICILLIN (PAGE 3-12)

CAPSULE; ORAL

UTIMOX

AB o PARKE-DAVIS/W-L

250MG
500MGN 62107
N 62107AMOXICILLIN; POTASSIUM CLAVULANATE (PAGE 3-13)

POWDER FOR RECONSTITUTION; ORAL

AUGMENTIN '125'

BEECHAM LABS/BEECHAM 125MG/5ML*

EQ 31.25MG ACID/5ML*

N 50575

AUGMENTIN '250'

BEECHAM LABS/BEECHAM 250MG/5ML;EQ 62.5MG ACID/5ML*

N 50575

TABLET; ORAL

AUGMENTIN '250'

BEECHAM LABS/BEECHAM 250MG;EQ 125MG ACID*

N 50564

AUGMENTIN '500'

BEECHAM LABS/BEECHAM 500MG;EQ 125MG ACID*

N 50564

TABLET, CHEWABLE; ORAL

AUGMENTIN '125'

BEECHAM LABS/BEECHAM 125MG;EQ 31.25MG ACID*

N 50597

AUGMENTIN '250'

BEECHAM LABS/BEECHAM 250MG;EQ 62.5MG ACID*

N 50597

AMPHETAMINE SULFATE (PAGE 3-13)

TABLET; ORAL

AMPHETAMINE SULFATE

LANNETT

5MG*

N 83901

10MG*

N 83901

AMPICILLIN SODIUM (PAGE 3-14)

INJECTABLE; INJECTION

AMPICILLIN SODIUM

AP ELI LILLY

EQ 500MG BASE/VIAL*

N 62565

EQ 1GM BASE/VIAL*

N 62565

AB	3 DRUMMER/PHOENIX	EQ 250MG BASE	N 61387	QINTIMENT; TOPICAL CORTISPORIN BURROUGHS WELLCOME	400 UNITS/6M; 1X/EQ 3.5MG BASE/6M; 5,000 UNITS/6M	ARGENTINE HYDROCHLORIDE (PAGE 3-16)
AB	CAPSULE; ORAL AMPIGELLINE	SULFATE (PAGE 3-20)	N 50166	BACITRACIN ZINC HYDROCORTRISONE; NEOMYCIN SULFATE; POLYMXIN B	DR-6 PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / AUGUST '84 - JULY '85	
>DLT<	R-GENE 10 /GIFTER, LIES/HILL/ /GIFTER, LIES/HILL/	/N 16931/	N 16931	INJECTABLE; INJECTION BENZOYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)	ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-16)	
AB	KABIVITRUM	10GM/100ML	N 86231	CHLESEA LABORATORIES 325MG;50MG;40MG BUTALBITAL COMPOUND CAPSULE; ORAL	ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE (PAGE 3-16)	
AB	ZENTHY LABORATORIES 325MG;50MG;30MG	N 65441	N 65441	TABLET; ORAL BENZTROPINE MESYLATE (PAGE 3-21)	ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE (PAGE 3-16)	
AB	ZENTHY LABORATORIES 325MG;50MG;30MG	N 63077	N 63077	BP PR PHARMACEUTICAL 0.5MG BENZTROPINE MESYLATE BEТАMETHASONE DIPROPIONATE (PAGE 3-22)	ASPIRIN; CAFEINE; PROPOXYPHENE COMPOUND 68 CAPSULE; ORAL	
AA	LEMTHON 363MG;32.4MG;6.5MG	N 69025	N 69025	LOTION; TOPICAL DETADEMETHASONE DIPROPIONATE > ADD > AB NATL PHARM MFG/BARRE EQ 0.5% BASE	ASPIRIN; METHOCARBAMOL (PAGE 3-17)	
AA	ZENTHY LABORATORIES 32.4MG;6.5MG	N 65732	N 65732	> ADD > AB SCHERING DETADEMETHASONE DIPROPIONATE OINTMENT; TOPICAL /HETIBDADARBIOL H/ /ASPIRIN/	TABLET; ORAL ASPIRIN; METOCARBAMOL AND ASPIRIN	
AB	PROPOXYPHENE HCL H/ ASPIRIN AND CAFFEINE	N 66694	N 66694	> ADD > AB SCHERING DETADEMETHASONE DIPROPIONATE OINTMENT; TOPICAL /METOCARBAMOL H/ /ASPIRIN/	TABLET; ORAL ASPIRINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE (PAGE 3-18)	
AA	CHLESEA LABORATORIES 32.4MG;6.5MG	N 17761	N 17761	AB SCHERING DIPROLENE BX SCHERING DIPIROSONE ER 0.5% BASE	TABLET; ORAL CAPSULE; ORAL RIDLURA SK&F LABORATORIES 3MSK CAPOULE; ORAL ALBANDIEN (PAGE 3-18)	
AB	PRAMADERM/BVK-GLDN EQ 0.5% BASE	N 19143	N 19143	AB SCHERING DETMETHASONE DIPROPIONATE E FOUGERA/BVK-GLDN EQ 0.5% BASE	TABLET; ORAL PRAMADERM/BVK-GLDN EQ 0.5% BASE	
AB	PRAMADERM/BVK-GLDN EQ 0.5% BASE	N 19141	N 19141	AB SCHERING DETMETHASONE DIPROPIONATE E FOUGERA/BVK-GLDN EQ 0.5% BASE	TABLET; ORAL PRAMADERM/BVK-GLDN EQ 0.5% BASE	
AB	PRAMADERM/BVK-GLDN EQ 0.5% BASE	N 18741	N 18741	AB SCHERING DIPROLENE BX SCHERING DIPIROSONE ER 0.5% BASE	TABLET; ORAL PRAMADERM/BVK-GLDN EQ 0.5% BASE	
AB	PRAMADERM/BVK-GLDN EQ 0.5% BASE	N 17691	N 17691	AB SCHERING DIPROLENE BX SCHERING DIPIROSONE ER 0.5% BASE	TABLET; ORAL PRAMADERM/BVK-GLDN EQ 0.5% BASE	

BETAMETHASONE VALERATE (PAGE 3-22)

CREAM; TOPICAL

BETAMETHASONE VALERATE

AB THAMES PHARMACAL EQ 0.1% BASEN
 /AB BETATREX /SAVAGE LABS/BYK-SLDN EQ 0.1% BASE/
 AB SAVAGE LABS/BYK-SLDN EQ 0.1% BASE
 VALNAQ
 AB NMC LABORATORIES EQ 0.1% BASEN

LOTION; TOPICAL

BETA-VAL

AB LEMMON EQ 0.1% BASEN
 > ADD > AB NATL PHARM MFG/BARRE EQ 0.1% BASEN

OINTMENT; TOPICAL

VALNAQ

AB NMC LABORATORIES EQ 0.1% BASEN

BITOLTEROL MESYLATE (PAGE 3-24)

AEROSOL; INHALATION

TORNALATE

WINTHROP-BREON/STERL 0.37MG/INH

N 70062

/N 18862/

N 18862

N 70050

N 70072

N 70052

N 70051

N 18770

BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE (PAGE 3-24)

SYRUP; ORAL

AMBAY

AA BAY LABORATORIES 12.5MG/5ML;10MG/5ML
 AA AMBENYL
 AA MARION LABORATORIES 12.5MG/5ML;10MG/5ML
 AA BROMANYL
 AA NATL PHARM MFG/BARRE 12.5MG/5ML;10MG/5ML

N 88626

N 09319

N 88343

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

SYRUP; ORAL

BIPHETANE-DG

AA BAY LABORATORIES 2MG/5ML;10MG/5ML;
 12.5MG/5ML
 AA BROMANATE-DG
 AA NATL PHARM MFG/BARRE 2MG/5ML;10MG/5ML;
 12.5MG/5ML
 AA DIMETANE-DG
 AA AH ROBINS 2MG/5ML;10MG/5ML
 12.5MG/5ML

N 88904

.. 88723

N 11694

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-25)

SYRUP; ORAL

BIPHETANE DX

AA BAY LABORATORIES 2MG/5ML;10MG/5ML;30MG/5ML
 AA BROMAHATE DM
 AA NATL PHARM MFG/BARRE 2MG/5ML;10MG/5ML;30MG/5ML
 AA DIMETANE-DX
 AA AH ROBINS 2MG/5ML;10MG/5ML;30MG/5ML
 2MG/5ML;10MG/5ML;30MG/5ML

N 88811

N 88722

N 11694

N 19279

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-25)

ELIXIR; ORAL

BIPHETAP

AA BAY LABORATORIES 4MG/5ML;25MG/5ML
 AA BROMAHATE
 AA NATL PHARM MFG/BARRE 4MG/5ML;25MG/5ML

N 88687

N 88688

BUMETANIDE (PAGE 3-25)

TABLET; ORAL

BUMEX

HOFFMANN-LA ROCHE 2MG

N 18225

BUPRENORPHINE HYDROCHLORIDE (PAGE 3-26)

/INJECTABLE; INJECTION

BUPHENEX

/NORWICH EATON/PAC/ /EQ 0.3MG BASE/ML/

/N 18461/

BUTABARBITAL SODIUM (PAGE 3-26)

ELIXIR; ORAL

SODIUM BUTABARBITALBUTABARBITAL SODIUM

TABLET; ORAL

BUTABARBITAL SODIUM

AA LEMON 15MG
 AA LEMON 30MG

N 88632

N 88631

CALCITONIN, SALMON (PAGE 3-27)

INJECTABLE; INJECTION

CALCIMAR

/ARMOUR PHARM/ /200 HRC UNITS/ML/

/N 17763/

/400 HRC UNITS/ML/

N 17769

200 IU/ML

N 17497

400 IU/VIAL

CAPTOPRIL; HYDROCHLOROTHIAZIDE (PAGE 3-31)

TABLET; ORAL

CAPOZIDE 25/15

ER SQUIBB AND SONS 25MG;15MGML

N 18709

CAPOZIDE 25/25

ER SQUIBB AND SONS 25MG;25MGML

N 18709

CAPOZIDE 50/15

ER SQUIBB AND SONS 50MG;15MGML

N 18709

CAPOZIDE 50/25

ER SQUIBB AND SONS 50MG;25MGML

N 18709

CARBACHOL (PAGE 3-31)/SOLUTION/DOGS; OPHTHALMIC/
INJECTABLE; INJECTIONCEFAZOLIN SODIUM; DEXTROSE (PAGE 3-33)

INJECTABLE; INJECTION

ANCEF IN DEXTROSE 5% IN PLASTIC CONTAINER

TRAVENOL LABS EQ 10MG BASE/ML;50MG/MLX
EQ 20MG BASE/ML;50MG/MLXN 50566
N 50566CEFOTANIDE (PAGE 3-33)

INJECTABLE; INJECTION

PRECEF

BRISTOL LABS/B-M 500MG/VIALML
1GM/VIALML
2GM/VIALML
10GM/VIALML
20GM/VIALMLN 62579
N 62579
N 62579
N 62579
N 62579> ADD >
> ADD >
> ADD >
> ADD >
> ADD >CEFTAZIDIME (PAGE 3-33)INJECTABLE; INJECTION
FORTAZ
GLAXO500MG/VIALML
1GM/VIALML
2GM/VIALML
6GM/VIALMLN 50578
N 50578
N 50578
N 50578CEFOTAXIME SODIUM (PAGE 3-33)

INJECTABLE; INJECTION

CLAFORAN
HOECHST-ROUSSEL /EQ 500MG BASE/VIALML/
EQ 10GM BASE/VIALML/N 50547/
N 50547CEFTIZOXIME SODIUM; DEXTROSE (PAGE 3-33)

INJECTABLE; INJECTION

CEFIZOX IN DEXTROSE 5% IN PLASTIC CONTAINER
SK&F LABORATORIES EQ 20MG BASE/ML;50MG/MLX
EQ 40MG BASE/ML;50MG/MLXN 50589
N 50589CEFOTAXIME SODIUM; DEXTROSE (PAGE 3-33)

INJECTABLE; INJECTION

CLAFORAN IN DEXTROSE 5% IN PLASTIC CONTAINER
HOECHST-ROUSSEL EQ 20MG BASE/ML;50MG/MLX
EQ 40MG BASE/ML;50MG/MLXN 50596
N 50596

CHLOROPROMAZINE HYDROCHLORIDE (PAGE 3-33)

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 21 / AUGUST '84 - JULY '85

CONCENTRATE: ORAL

CONCENTRATE; ORAL

www.ijerpi.org | ISSN: 2278-5626 | Impact Factor: 5.21 | DOI: 10.15243/ijerpi.22785626.2020.10000

CHLOROPROMAZINE HYDROCHLORIDE

11 / August - 84 - 10

"...you know?" he said.

CHYMOPAPAIN (PAGE 3-43)

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

N 18663

CISPLATIN (PAGE 3-44)

INJECTABLE; INJECTION
/PLATINOL/
/BRISTOL LABS/B-M/ /10MG/ML/
/50MG/VIAL/
PLATINOL-AQ
BRISTOL LABS/B-M 0.5MG/ML

/N 18057/
/N 18057/

N 18057

CLEMASTINE FUMARATE (PAGE 3-44)

SYRUP; ORAL
TAVIST
DORSEY LABS/SANDOZ EQ 0.5MG BASE/5ML*

N 18675

CLOMIPHENE CITRATE (PAGE 3-45)

TABLET; ORAL
CLOMID
/BP/ /MERRELL DOW/DOW CHEM/50MG/
AB MERRELL DOW/DOW CHEM 50MG
CLOMIPHENE CITRATE
/BP/ /PLANTEK/IKAHARM/ /50MG/
AB PLANTEK/IKAHARM 50MG

/N 16131/
N 16131/N 18361/
N 18361CLONIDINE (PAGE 3-45)

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

N 18891

N 18891

N 18891

CLOTRIMAZOLE (PAGE 3-45)

TABLET; VAGINAL
HYCELEX-G
MILES PHARMS/MILES 500MG*

N 19069

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

SYRUP; ORAL
PHENERGAN VC N/ CODEINE
AA WYETH LABS/AMHO 10MG/5ML;5MG/5ML;6.25MG/5ML N 08306
PROMETH VC N/ CODEINE
AA NATL PHARM MFG/BARRE 10MG/5ML;5MG/5ML;6.25MG/5ML N 88764
PROMETHAZINE VC N/ CODEINE
AA BAY LABORATORIES 10MG/5ML;5MG/5ML;6.25MG/5ML N 88896

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-46)

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

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

SYRUP; ORAL
ACTIFED N/ CODEINE
AA BURROUGHS WELLCOME 10MG/5ML;30MG/5ML;1.25MG/5ML N 12575
PSEUDOEPHEDRINE C
AA BAY LABORATORIES 10MG/5ML;30MG/5ML;1.25MG/5ML N 88833
TRIACIN-C
AA NATL PHARM MFG/BARRE 10MG/5ML;30MG/5ML;1.25MG/5ML N 88704

COLCHICINE; PROBENECID (PAGE 3-47)

TABLET; ORAL
PROBENECID AND COLCHICINE
BP DRUMMER/PHOENIX 0.5MG;500MG N 86130
PROBENECID N/ COLCHICINE
/BP/ /DRUMMER/PHOENIX/ /0.5MG;500MG/ N 86130

CORTICOTROPIN (PAGE 3-47)

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

CORTISONE ACETATE (PAGE 3-47)

TABLET; ORAL
CORTISONE ACETATE
BP & VITARINE/PHOENIX 25MG N 80333

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE
(PAGE 3-57)

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

DEXTROSE (PAGE 3-57)

	INJECTABLE; INJECTION <u>DEXTROSE 30% IN PLASTIC CONTAINER</u>		
AP	ABBOTT LABORATORIES <u>30GM/100ML</u>	N 19345	
AP	TRAIVENOL LABS <u>30GM/100ML</u>	N 17521	
	DEXTROSE 38.5% IN PLASTIC CONTAINER ABBOTT LABORATORIES <u>38.5GM/100ML</u>	N 18923	
/AP/	/ABBOTT LABORATORIES// <u>5GM/100ML</u>	/N 16367/	
AP	ABBOTT LABORATORIES <u>50MG/ML</u>	N 16367	
> ADD > AP	<u>5GM/100ML</u>	N 19466	
AP	<u>DEXTROSE 60% IN PLASTIC CONTAINER</u>		
AP	ABBOTT LABORATORIES <u>60GM/100ML</u>	N 19346	

DEXTROSE; HEPARIN SODIUM (PAGE 3-58)

	INJECTABLE; INJECTION <u>HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5%</u>		
AP	ABBOTT LABORATORIES <u>5GM/100ML;10,000 UNITS/100ML</u>	N 18911	
	<u>HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER</u>		
AP	ABBOTT LABORATORIES <u>5GM/100ML;10,000 UNITS/100ML</u>	N 19339	
	<u>HEPARIN SODIUM 1000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER</u>		
AP	AM MCGAW/AM HOSP <u>5GM/100ML;200 UNITS/100ML</u>	N 19130	
	<u>HEPARIN SODIUM 12,500 UNITS IN DEXTROSE 5%</u>		
AP	ABBOTT LABORATORIES <u>5GM/100ML;5,000 UNITS/100ML</u>	N 18911	
	<u>HEPARIN SODIUM 12,500 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER</u>		
AP	ABBOTT LABORATORIES <u>5GM/100ML;5,000 UNITS/100ML</u>	N 19339	
	<u>HEPARIN SODIUM 2000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER</u>		
AP	AM MCGAW/AM HOSP <u>5GM/100ML;200 UNITS/100ML</u>	N 19130	
	<u>HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5%</u>		
AP	ABBOTT LABORATORIES <u>5GM/100ML;10,000 UNITS/100ML</u>	N 18911	
	<u>HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER</u>		
AP	ABBOTT LABORATORIES <u>5GM/100ML;5,000 UNITS/100ML</u>	N 19339	
AP	<u>5GM/100ML;10,000 UNITS/100ML</u>	N 19339	
	<u>HEPARIN SODIUM 25000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER</u>		
AP	AM MCGAW/AM HOSP <u>5GM/100ML;5,000 UNITS/100ML</u>	N 19134	

DEXTROSE; HEPARIN SODIUM (PAGE 3-58)

	INJECTABLE; INJECTION <u>HEPARIN SODIUM 5000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER</u>		
	AM MCGAW/AM HOSP <u>56M/100ML;1,000 UNITS/100ML</u>	N 19130	

DEXTROSE; LIDOCAINE HYDROCHLORIDE (PAGE 3-58)

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

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

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

DEXTROSE; OXYTOCIN (PAGE 3-59)

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

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

	INJECTABLE; INJECTION <u>POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>		
AP	TRAIVENOL LABS <u>5GM/100ML;150MG/100ML; 900MG/100ML</u>	N 19308	
	<u>5GM/100ML;75MG/100ML; 900MG/100ML</u>	N 19308	
	<u>POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>		
AP	TRAIVENOL LABS <u>5GM/100ML;150MG/100ML; 900MG/100ML</u>	N 19308	
	<u>5GM/100ML;300MG/100ML; 900MG/100ML</u>	N 19308	

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

INJECTABLE; INJECTION

EMBOLEX

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

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-67)

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

AA SUPERPHARM 25MG N 89040
AA 50MG N 89041

ELIXIR; ORAL

DIPHENHYDRAMINE HCL

AA NASKA PHARMACAL 12.5MG/5ML N 88680

DISOPYRAMIDE PHOSPHATE (PAGE 3-68)

CAPSULE; ORAL

DISOPYRAMIDE PHOSPHATE

AB BIOCRAFT LABS EQ 100MG BASEN N 70101
AB EQ 150MG BASEN N 70102
AB DANBURY PHARMACAL EQ 100MG BASEN N 70173
AB EQ 150MG BASEN N 70174
AB MYLAN PHARMS EQ 100MG BASEN N 70138
AB EQ 150MG BASEN N 70139

NORPACE

AB SEARLE PHARMS EQ 100MG BASE N 17447
AB EQ 150MG BASE N 17447

DISULFIRAM (PAGE 3-68)

TABLET; ORAL

DISULFIRAM

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

DIVALPROEX SODIUM (PAGE 3-69)

TABLET, ENTERIC COATED; ORAL

DEPAKOTE

ABBOTT LABORATORIES EQ 125MG BASEN N 18723

DOPAMINE HYDROCHLORIDE (PAGE 3-69)

INJECTABLE; INJECTION

DOPAMINE HCL

<u>AP</u>	INVENEX LABS/LIFE	40MG/ML	N 70012
<u>AP</u>		80MG/ML	N 70013
<u>AP</u>	LYPHOMED	40MG/ML	N 70058
<u>AP</u>		80MG/ML	N 70059

DOXORUBICIN HYDROCHLORIDE (PAGE 3-69)

INJECTABLE; INJECTION

ADRIAMYCIN

FARMITALIA CARLO ERB 20MG/VIAL N 50467

DOXYCYCLINE HYCLATE (PAGE 3-70)

CAPSULE; ORAL

DORYX

<u>AB</u>	FAULDING	EQ 100MG BASEN	N 50582
<u>AB</u>	DOXY-LEMONT	EQ 50MG BASEN	N 62497
<u>AB</u>	LEMMON	EQ 50MG BASEN	N 62119
<u>AB</u>	DOXYCYCLINE HYCLATE	EQ 100MG BASEN	N 62119
<u>AB</u>	HALSEY DRUG	EQ 50MG BASEN	N 62434
<u>AB</u>	PAR PHARMACEUTICAL	EQ 50MG BASEN	N 62469
<u>AB</u>	SUPERPHARM	EQ 100MG BASEN	N 62469
<u>AB</u>	WEST-WARD	EQ 50MG BASEN	N 62396
<u>AB</u>	ZENITH LABORATORIES	EQ 50MG BASEN	N 62500
<u>AB</u>		EQ 100MG BASEN	N 62500

TABLET; ORAL

DOXY-LEMONT

<u>AB</u>	LEMMON	EQ 100MG BASEN	N 62581
<u>AB</u>	DOXYCYCLINE HYCLATE	EQ 100MG BASEN	N 62494
<u>AB</u>	SUPERPHARM	EQ 100MG BASEN	N 62505
<u>AB</u>	ZENITH LABORATORIES	EQ 100MG BASEN	

DOXYLAMINE SUCCINATE (PAGE 3-70)

TABLET; ORAL

DECAPRYN

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

DRONABINOL (PAGE 3-70)

CAPSULE; ORAL

MARINOLUNIMED

2.5MG	N 18651
5MG	N 18651
10MG	N 18651

Original from
UNIVERSITY OF MICHIGAN

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
 2 SEARLE/SEARLE PHARMS 1MG;0.1MG

> ADD >

N 16029

ETIDRONATE DISODIUM (PAGE 3-81)

TABLET; ORAL
 DIDRONEL
 NORWICH EATON/P&G 400MG

N 17831

FENTANYL CITRATE (PAGE 3-81)

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

N 19115

FLUNISOLIDE (PAGE 3-82)

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

N 18340

FLUOCINOLONE ACETONIDE (PAGE 3-82)

CREAM; TOPICAL
FLUOCINOLONE ACETONIDE

AT BAY LABORATORIES 0.01%
 AT 0.025%
 AT PHARMAFAIR 0.01%
 AT 0.025%
FLUONID
 AT HERBERT LABS/ALLERGN 0.025%
 /AT/ MARION LABORATORIES//0.01%/
 /AT/ 0.025%/
 /AT/

N 88757

N 88756

N 88499

N 88506

N 87156

/N 89434/

/N 89434/

OINTMENT; TOPICAL
FLUOCINOLONE ACETONIDE
 AT BAY LABORATORIES 0.025%
FLUONID

AT HERBERT LABS/ALLERGN 0.025%
 /AT/ MARION LABORATORIES//0.025%/
 /AT/

N 88742

N 87157

/N 89433/

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

/N 89432/

FLUOROMETHOLONE (PAGE 3-83)

SUSPENSION/DROPS; OPHTHALMIC
 FML
 ALLERGAN PHARMS 0.1%

N 16851

FLUOROURACIL (PAGE 3-83)

INJECTABLE; INJECTION
FLUOROURACIL
 AP SOLOPAK LABORATORIES 50MG/MLX
 AP 50MG/MLX

N 88766

N 88767

FLUPHENAZINE HYDROCHLORIDE (PAGE 3-84)

TABLET; ORAL
 PERMITIL
 BP 2 SCHERING 2.5MG

N 12034

FLUPREDNISOLONE (PAGE 3-84)

TABLET; ORAL
 ALPHADROL
 2 UPJOHN 1.5MG

N 12259

/FOLLICLE STIMULATION HORMONES /LUTEINIZING HORMONE/ (PAGE 3-85)

INJECTABLE; INJECTION
 /PERSONAL/
 /SERONO LABS/ 175IU/AMP; 175IU/AMP/

/N 17646/

FUROSEMIDE (PAGE 3-86)

TABLET; ORAL
FUROSEMIDE
 AB CORD LABORATORIES 80MG
 AB LEDERLE LABS/AM CYAN 80MG
 AB PARKE-DAVIS/W-L 80MG
LASIX
 AB HOECHST-ROUSSEL 80MG

N 18569

N 18415

N 18419

N 16273

GENTAMICIN SULFATE (PAGE 3-86)

INJECTABLE; INJECTION
GENTAMICIN SULFATE
 AP SOLOPAK LABORATORIES EQ 10MG BASE/MLX
 AP EQ 60MG BASE/MLX

N 62507

N 62507

OINTMENT; TOPICAL

GENTAMICIN SULFATE
 AT E FOUGERA/BYK-GLDN EQ 1MG BASE/GM
 AT PHARMADERM/BYK-GLDN EQ 1MG BASE/GM

N 62533

N 62534

INDOMETHACIN (PAGE 3-108)

CAPSULE; ORAL

INDOMETHACIN

AB	PAR PHARMACEUTICAL	<u>25MGX</u>	N 18829
AB		<u>50MGX</u>	N 18829
AB	PARKE-DAVIS/W-L	<u>25MGX</u>	N 18806
AB		<u>50MGX</u>	N 18806
AB	ROXANE LABORATORIES	<u>25MGX</u>	N 70353
AB		<u>50MGX</u>	N 70354

SUPPOSITORY; RECTAL

INDOCINMS&D RES LABS/MERCK 50MGX

N 17814

INDOMETHACIN SODIUM TRIHYDRATE (PAGE 3-108)

INJECTABLE; INJECTION

INDOCIN I.V.

MS&D/MERCK

EQ 1MG BASE/VIALX

N 18878

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

INJECTABLE; INJECTION

NEPHROFLOW

MEDI-PHYSICS

1MC1/MLX

N 18289

IOPANOIC ACID (PAGE 3-109)

TABLET; ORAL

TELEPAQUE/WINTHROP/LABS/STERL//500MG/
WINTHROP-BREON/STERL 500MG/N 88032/
N 08032>ADD > IOXAGLATE MEGLUMINE; IOXAGLATE SODIUM (PAGE 3-109)>ADD > INJECTABLE; INJECTION>ADD > HEXBABRIX>ADD > MALLINCKRODT 39.3%;19.6%W

N 18905

ISOETHARINE MESYLATE (PAGE 3-110)

AEROSOL; INHALATION

BRONKOMETER/BREON/LABS/STERLING//0.61%/
BN BREON LABS/STERLING 0.34MG/INH
ISOETHARINE MESYLATE
BN NATL PHARM MFG/BARRE 0.34MG/INH/N 12336/
N 12339
N 87858KANAMYCIN SULFATE (PAGE 3-112)

INJECTABLE; INJECTION

KANAMYCIN SULFATE

AP	CARTER-GLOGAU LABS	<u>EQ 1GM BASE/3MLX</u>	N 62520
AP	KANTREX	<u>EQ 75MG BASE/2MLX</u>	N 62564
AP	BRISTOL LABS/B-M	<u>EQ 500MG BASE/2MLX</u>	N 62564
AP		<u>EQ 1GM BASE/3MLX</u>	N 62564

LABETALOL HYDROCHLORIDE (PAGE 3-113)

INJECTABLE; INJECTION

NORMODYNE
SCHERING5MG/MLX

N 18686

TABLET; ORAL

NORMODYNE

AB	SCHERING	<u>200MGX</u>	N 18687
AB		<u>300MGX</u>	N 18687
AB		<u>400MGX</u>	N 18687

TRANDATE

AB	GLAXO	<u>200MGX</u>	N 18716
AB		<u>300MGX</u>	N 18716
AB		<u>400MGX</u>	N 18716
AB		<u>100MGX</u>	N 18716

LEUPROLIDE ACETATE (PAGE 3-113)

INJECTABLE; INJECTION

LUPRONTAP PHARMACEUTICALS 1MG/0.2MLX

N 19010

LEVONORDREFRIN; MEPIVACAINE HYDROCHLORIDE (PAGE 3-114)

INJECTABLE; INJECTION

SCANDONEST L

AP	DEPROCO	<u>0.05MG/ML;2%</u>
----	---------	---------------------

N 88388

LEVOTHYROXINE SODIUM; LIOTHYRONINE SODIUM (PAGE 3-114)

TABLET; ORAL

THYROLAR-5

3 ARMOUR PHARM

0.25MG;0.065MG

N 16807

LIODOCAINE (PAGE 3-114)

AEROSOL; ORAL

XYLOCAINEASTRA PHARM PRODS 10%

N 14394

MEPROBAMATE (PAGE 3-123)

TABLET; ORAL
MEPROBAMATE
/AB/ /M AST/ /200MG/
/AB/ /400MG/

METHICILLIN SODIUM (PAGE 3-127)

INJECTABLE; INJECTION
/CÉLÉSTEIN/
/AB/ /BEECHAM LABS/BEECHAM/ EQ 500MG BASE/VIAL/
/AB/ /EQ 3.6GM BASE/VIAL/
/AB/ /EQ 5.6GM BASE/VIAL/
/AB/ /EQ 1.8GM BASE/VIAL/
/AB/ /EQ .9GM BASE/VIAL/

METHOTREXATE SODIUM (PAGE 3-128)

INJECTABLE; INJECTION
MEXATE
BRISTOL LABS/B-M EQ 250MG BASE/VIALX N 86358
MEXATE-AG
AP BRISTOL CARIB/B-M/PR EQ 25MG BASE/MLX N 88760

METHYCLOTHIAZIDE (PAGE 3-129)

TABLET; ORAL
METHYCLOTHIAZIDE
AB CHELSEA LABORATORIES 2.5MGX N 88750
AB 5MGX N 88724
AB COLMED LABORATORIES 5MGX N 88745

METHYLDOPA (PAGE 3-130)

TABLET; ORAL
ALDOPET
AB MS&D/MERCK 125MG N 13400
METHYLDOPA
AB CHELSEA LABORATORIES 125MGX N 70260
AB 250MGX N 70261
AB 500MGX N 70262
AB MYLAN PHARMS 250MGX N 70075
AB 500MGX N 70076

METHYLPREDNISOLONE SODIUM SUCCINATE (PAGE 3-131)

INJECTABLE; INJECTION
SOLU-MEDROL
UP JOHN EQ 2GM BASE/VIALX N 11856

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-132)

TABLET; ORAL
CLOPRA
> ADD > AB QUANTUM PHARMS EQ 10MG BASEX N 70294
> ADD > AB METOCLOPRAMIDE HCL EQ 10MG BASEX N 70184
> ADD > AB BIOCRAFT LABS EQ 10MG BASEX N 70339
> ADD > AB COLMED LABORATORIES EQ 10MG BASEX
> ADD > AB REGLAN AH ROBINS EQ 10MG BASE N 17854

METRONIDAZOLE (PAGE 3-133)

INJECTABLE; INJECTION
METRONIDAZOLE
AP INT'L MEDICATION SYS 500MG/100MLX N 70004
AP LYPHOMED 500MG/100MLX N 70071
AP METRYL IV LEMMON 500MG/100MLX N 70042

TABLET; ORAL

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

MICONAZOLE NITRATE (PAGE 3-134)

SUPPOSITORI; VAGINAL
MONISTAT 3
ORTHO PHARMACEUTICAL 200MGX N 18888

MOLINDONE HYDROCHLORIDE (PAGE 3-135)

CAPSULE; ORAL
MOBAN
3 DUPONT PHARMS/DUPONT 5MG N 17111
3 10MG N 17111
3 25MG N 17111

OXYPHENBUTAZONE (PAGE 3-143)

TABLET; ORAL

OXYPHENBUTAZONE

AB BOLAR PHARMACEUTICAL 100MG
TANDEARTL
> ADD > AB 3 GEIGY/CIBA-GEIGY 100MG

N 88399
N 12542

/PENTETATE CALCIUM TRISODIUM, YB-169 (PAGE 3-145)/

/INJECTABLE; INJECTION/
YTERBIUM YB-169 DTPA/
DIAGNOSTIC PRODS/3M/2MCI/ML/

N 17518

PENTAMIDINE ISETHIONATE (PAGE 3-148)

INJECTABLE; INJECTION

PENTAM 300
LYPHOMED 300MG/VIALX

N 19264

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

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

N 17518

PENTOBARBITAL SODIUM (PAGE 3-149)

CAPSULE; ORAL

PENTOBARBITAL SODIUM

AA 3 VITARINE/PHOENIX 100MG

N 83284

TABLET; ORAL

PENTOBARBITAL SODIUM

AA 3 VITARINE/PHOENIX 100MG

N 83285

PENTOXIFYLLINE (PAGE 3-149)

TABLET, CONTROLLED RELEASE; ORAL

TRENTAL
HOECHST-ROUSSEL 400MGX

N 18631

PHENDIMETRAZINE TARTRATE (PAGE 3-149)

CAPSULE; ORAL

PHENDIMETRAZINE TARTRATE

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

N 86403
N 86408
N 86410
N 87424

PHENDIMETRAZINE TARTRATE (PAGE 3-149)

CAPSULE; ORAL

PHENDIMETRAZINE TARTRATE

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

N 85634
N 85645
N 85670

TABLET; ORAL

PHENDIMETRAZINE TARTRATE

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

N 86106
N 85519
N 86005

PHENTERMINE HYDROCHLORIDE (PAGE 3-151)

CAPSULE; ORAL

PHENTERMINE HCL

AA CHELSEA LABORATORIES 30MGX
AA 3 DRUMMER/PHOENIX 30MG
AA 3 30MG
AA PHARM BASICS 30MGX

N 86740
N 87202
N 87235
N 88797

TABLET; ORAL

PHENTERMINE HCL

AA 3 DRUMMER/PHOENIX 8MG
AA 3 8MG
> ADD > AA PHARM BASICS 37.5MGX
> ADD > AA 37.5MGX

N 86453
N 86456
N 88910
N 88917

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-153)

SYRUP; ORAL

PHENERGAN VC

AA HYETH LABS/AMHO 5MG/5ML; 6.25MG/5ML
AA NATL PHARM MFG/BARRE 5MG/5ML; 6.25MG/5MLX
AA PROMETHAZINE VC PLAIN
AA BAY LABORATORIES 5MG/5ML; 6.25MG/5MLX

N 08604
N 88761
N 88897

PHENYTOIN SODIUM (PAGE 3-153)

INJECTABLE; INJECTION

PHENYTOIN SODIUM

AP INVENEX LABS/LIFE 50MG/MLX
AP SOLOPAK LABORATORIES 50MG/MLX
AP 50MG/MLX
AP 50MG/MLX

N 89003
N 88519
N 88520
N 88521

N 66692	CAPSULE; ORAL DILATIN DILATEK-DAVIS/W-L 100MG	N 84349	TABLET; ORAL PRENITOSOLNE PRENITOSOLNE 5MGX	N 66711	PENYTOTIN SODIUM, EXTENDED (PAGE 3-153)
N 66032	GEL; OPHTHALMIC PILOPIN HS PILOPIN HYDROCHLORIDE (PAGE 3-154)	N 16796	TABLET; ORAL ASDEGIDIN PHARMAFAR 0.5%:10%	A1	PILOCARPINE HYDROCHLORIDE (PAGE 3-160)
N 66791	GEL; OPHTHALMIC PILOPIN HS PILOPIN HYDROCHLORIDE (PAGE 3-154)	N 16796	TABLET; ORAL ASDEGIDIN PHARMAFAR 0.5%:10%	A1	PILOCARPINE HYDROCHLORIDE (PAGE 3-160)
N 66703	TABLET; ORAL VISKEN SANDOZ PHARMS/SANDOZ/1515/	/N 16795/	SOLUTION; ORAL PRENITOSOLNE ROXANE LABORATORIES 5MG/5MLA		POLYETHYLENE GLYCOL 3350: POTASSIUM CHLORIDE; SODIUM SULFATE (PAGE 3-155)
N 66610	TABLET; ORAL COLYTE POWDER FOR RECONSTITUTION; ORAL		PRENITOSOLNE ROXANE LABORATORIES 5MG/5MLA		POLYETHYLENE GLYCOL 3350: POTASSIUM CHLORIDE; SODIUM SULFATE (PAGE 3-155)
N 66665	EDLAH PREPARATIONS 120SH/PACKET; 1.496H/PACKETS; 3.366H/PACKET; 2.926H/PACKETS	N 18983	bx bx bx bx bx bx	5MGX 10MGX 20MGX 5MGX 5MGX 5MGX	POTASSIUM CHLORIDE (PAGE 3-156)
N 66666	EDLAH PREPARATIONS 120SH/PACKET; 1.496H/PACKETS; 3.366H/PACKET; 2.926H/PACKETS	N 18983	bx bx bx bx bx bx	5MGX 10MGX 20MGX 5MGX 5MGX 5MGX	POTASSIUM CHLORIDE (PAGE 3-156)
N 14763	ASTRA PHARM PRODS 4%		CITANEST PLATIN		INJECTABLE; INJECTION /N 16795/
N 14763	ASTRA PHARM PRODS 4%		CITANEST PLATIN		INJECTABLE; INJECTION /N 16795/
N 14763	ASTRA PHARM PRODS 4%		CITANEST PLATIN		INJECTABLE; INJECTION /N 16795/
N 14763	ASTRA PHARM PRODS 4%		CITANEST PLATIN		INJECTABLE; INJECTION /N 16795/
N 14763	ASTRA PHARM PRODS 4%		CITANEST PLATIN		INJECTABLE; INJECTION /N 16795/
N 66990	PROCAINAMIDE HYDROCHLORIDE (PAGE 3-163)	N 66906	INJECTABLE; ORAL CAPSULE; ORAL PROCATAMIDE HCL ROXANE LABORATORIES 250MGX	AB	POTASSIUM CLAVULANATE; TICARCILLIN DISODIUM (PAGE 3-156)
N 66990	PROCAINAMIDE HYDROCHLORIDE (PAGE 3-163)	N 66906	INJECTABLE; ORAL CAPSULE; ORAL PROCATAMIDE HCL ROXANE LABORATORIES 250MGX	AB	POTASSIUM CLAVULANATE; TICARCILLIN DISODIUM (PAGE 3-156)
N 50590	PROCATAMIDE HCL SOLOPAK LABORATORIES 100MG/MLx INJECTABLE; INJECTION	N 50590	INJECTABLE; INJECTION PROCATAMIDE HCL SOLOPAK LABORATORIES 100MG/MLx INJECTABLE; INJECTION	AP	BECHAM LABS/BECCHAM EA 100MG ACID/VIALS EA 36M BASE/VIALS EA 200MG ACID/VIALS EA 36M BASE/VIALL
N 50590	PROCATAMIDE HCL SOLOPAK LABORATORIES 100MG/MLx INJECTABLE; INJECTION	N 50590	INJECTABLE; INJECTION PROCATAMIDE HCL SOLOPAK LABORATORIES 100MG/MLx INJECTABLE; INJECTION	AP	BECHAM LABS/BECCHAM EA 100MG ACID/VIALS EA 36M BASE/VIALS EA 200MG ACID/VIALS EA 36M BASE/VIALL

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-163)

TABLET, CONTROLLED RELEASE; ORAL

PROCAINAMIDE HCL

AB BOLAR PHARMACEUTICAL 250MG
AB 500MG
AB 750MG
> ADD > AB COPLEY PHARM 500MG
PROCAN SR
AB 250MG
AB 500MG
AB 750MG
/PC/ PARKE-DAVIS/W-L 500MG/
16MM

N 88533 > ADD > AB CHELSEA LABORATORIES 10MG
N 88534 > ADD > AB 20MG
N 88535 > ADD > AB 40MG
N 88974 > ADD > AB 80MG
N 86468 > ADD > AB LEDERLE LABS/AM CYAN 10MG
N 86065 > ADD > AB 20MG
N 87510 > ADD > AB 40MG
/N 86065/ N 88489 80MG

N 70140
N 70141
N 70142
N 70144
N 70125
N 70126
N 70127
N 70128

PROCHLORPERAZINE EDISYLATE (PAGE 3-164)

CONCENTRATE; ORAL

PROCHLORPERAZINE EDISYLATE

AA BAY LABORATORIES EQ 10MG BASE/MLX
SYRUP; ORAL
PROCHLORPERAZINE EDISYLATE
AA BAY LABORATORIES EQ 5MG BASE/5MLX

N 88598
N 88597

N 07413
N 05932

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
/BAYMÉTHAZINE/
PROMETHAZINE PLAIN

PROPOXYPHENE HYDROCHLORIDE (PAGE 3-167)

CAPSULE; ORAL
PROPOXYPHENE HCL

AA LEMMON 65MG

N 88615

PROPRANOLOL HYDROCHLORIDE (PAGE 3-168)

TABLET; ORAL

ENDERAL

AYERST LABS/AHMO 10MG
20MG
40MG
80MG
> ADD > AB
> ADD > AB
> ADD > AB
> ADD > AB

N 16418
N 16418
N 16418
N 16418

PROPRANOLOL HYDROCHLORIDE (PAGE 3-168)

TABLET; ORAL

PROPRANOLOL HCL

CHELSEA LABORATORIES 10MG
20MG
40MG
80MG
LEDERLE LABS/AM CYAN 10MG
20MG
40MG
80MG

N 70140
N 70141
N 70142
N 70144
N 70125
N 70126
N 70127
N 70128

PROTAMINE SULFATE (PAGE 3-168)

INJECTABLE; INJECTION

PROTAMINE SULFATE
UPJOHN 250MG/VIALX

N 07413

PROTEIN HYDROLYSATE (PAGE 3-168)

INJECTABLE; INJECTION
AMINOSOL 5%
ABBOTT LABORATORIES 5%

N 05932

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE (PAGE 3-169)

SYRUP; ORAL

TRILITRON

AA NEWTRON PHARMS 30MG/5ML; 1.25MG/5ML
/ / / TRIPROLIDINE HCL AND PSEUDOEPHEDRINE HCL
/ / / PHARMAFAIR / 30MG/5ML; 1.25MG/5ML / / /

N 88474
/N 88541/

TABLET; ORAL

ALLERFED

AA PRIVATE FORMULATIONS 60MG; 2.5MG

CORPHED

AA CORD LABORATORIES 60MG; 2.5MG

TRILITRON

AA NEWTRON PHARMS 60MG; 2.5MG

AA TRIPROLIDINE HCL AND PSEUDOEPHEDRINE HCL

AA SUPERPHARM 60MG; 2.5MG

AA ZENITH LABORATORIES 60MG; 2.5MG

N 88860
N 88602
N 88515
N 88578
N 85273

QUINIDINE GLUCONATE (PAGE 3-170)

TABLET, CONTROLLED RELEASE; ORAL

QUINIDINE GLUCONATE

AB ASCOT HOSP PHARMS 324MG

N 88582

SODIUM NITROPRUSSIDE (PAGE 3-178)

INJECTABLE; INJECTION

SODIUM NITROPRUSSIDE

AP LYPHOMED 50MG/VIALN N 70031

SODIUM POLYSTYRENE SULFONATE (PAGE 3-179)

POWDER; ORAL, RECTAL

KAYEXALATE

AA BREON LABS/STERLING 453.6GM/BOT

SODIUM POLYSTYRENE SULFONATE

AA BAY LABORATORIES 453.6GM/BOTN

SUSPENSION; ORAL, RECTAL

SODIUM POLYSTYRENE SULFONATE

AA BAY LABORATORIES 15GM/60MLN

SOYBEAN OIL (PAGE 3-180)

INJECTABLE; INJECTION

LIFOSYN III 10%

AP ABBOTT LABORATORIES 10%N

LIFOSYN III 20%

AP ABBOTT LABORATORIES 20%N

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/ 3 TRAVENOL LABS/ 500MG/VIAL/

/AB/ 3 TRAVENOL LABS/ 1GM/VIAL/

SULFABENZAMIDE; SULFACETAMIDE; SULFATHIAZOLE (PAGE 3-181)

TABLET; VAGINAL

SULTRIN

AT ORTHO PHARMACEUTICAL 184MG;143.75MG;172.5MG N 05794

TRIPLE SULFA

AT E FOUGERA/ALTANA 184MG;143.75MG;172.5MG N 88463

AT PHARMADERM/ALTANA 184MG;143.75MG;172.5MG N 88462

SULFACETAMIDE SODIUM (PAGE 3-181)

SOLUTION/DROPS; OPHTHALMIC

SULFACETAMIDE SODIUM

AT /AT/ PHARMAFAIR 10%N /PHARMAFAIR/ /SULFAIR 10%N/

AT PHARMAFAIR 10%N

N 88947
/N 87949/

N 87949

SULFAMETHOXAZOLE (PAGE 3-182)

TABLET; ORAL

SULFAMETHOXAZOLE

/AB/ /HEATHER DRUG/ 500MG/ /HEATHER DRUG 500MG/

/N 86435/
N 86163SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-183)

TABLET; ORAL

COTRIM

AB LEMON 400MG;80MGN

N 70034

AB LEMON 800MG;160MGN

N 70048

AB PAR PHARMACEUTICAL 400MG;80MGN

N 70022

AB PAR PHARMACEUTICAL 800MG;160MGN

N 70032

AB SULFAMETHOXAZOLE & TRIMETHOPRIM

AB HEATHER DRUG 400MG;80MGN

N 18946

AB HEATHER DRUG 800MG;160MGN

N 18946

AB SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB BARR LABORATORIES 400MG;80MGN

N 70006

AB CHELSEA LABORATORIES 400MG;80MGN

N 70002

AB 800MG;160MGN

N 70000

AB SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH

AB BARR LABORATORIES 800MG;160MGN

N 70007

AB SULFATRIM-DS 800MG;160MGN

N 70066

AB SUPERPHARM 800MG;160MGN

N 70065

AB SULFATRIM-SS 400MG;80MGN

N 70065

/AB/ /TRIMETH/SULFA D/S/ 400MG;80MGN

/N 70066/

/AB/ /CHELSEA LABORATORIES/ 800MG;160MGN/

/N 70066/

/AB/ /TRIMETH/SULFA S/S/ 800MG;160MGN/

/N 70066/

/AB/ /CHELSEA LABORATORIES/ 800MG;160MGN/

/N 70066/

SULFISOXAZOLE (PAGE 3-184)

TABLET; ORAL

SULFISOXAZOLE

BP 3 DRUMMER/PHOENIX 500MG

N 87332

N 17664	> DLT >	SOLUTION; INJECTION, ORAL /C/INTICHEM TECHNETIUM 99m GENERATOR/ > DLT >	TECHNETIUM, TC-99m SODIUM POLYPHOSPHATE KIT (PAGE 3-185)
28		DRUGS PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / AUGUST '84 - JULY '85	
N 17665	> ADD >	MED- PHYSICS 830-16,600 MCi/GENERATOR /INTDN CARBIDE RAD/As/3d-16,600 MCi/GENERATOR/ N 17693	TECHNETIUM, TC-99m GENERATOR TECHNETIUM TC-99m MICROSPHERES (HUMAN) INSTANT MICROSPHERES N 17632
N 17764		INJECTABLE; INJECTION /C/INTICHEM TECHNETHIUM 99m TSE/ N 17744	TECHNETIUM, TC-99m ALBUMIN AGGREGATED KIT (PAGE 3-185)
N 17762		INJECTABLE; INJECTION /C/INTICHEM TECHNETHIUM 99m TSE/ N 17740	TECHNETIUM, TC-99m ALBUMIN KIT (PAGE 3-185)
N 16949		INJECTABLE; INJECTION /C/INTICHEM TECHNETHIUM 99m TSE/ N 17562	TECHNETIUM, TC-99m ETIDRONATE KIT (PAGE 3-186)
N 17466		INJECTABLE; INJECTION /C/INTICHEM TECHNETHIUM 99m TSE/ N 1775	TECHNETIUM, TC-99m ETIDRONATE-TIN KIT > ADD > AP 3 MED- PHYSICS N/A
N 16000		INJECTABLE; INJECTION /C/INTICHEM TECHNETHIUM 99m TSE/ N 1773	TECHNETIUM, TC-99m ETIDRONATE KIT (PAGE 3-186)
N 16762		INJECTABLE; INJECTION /C/INTICHEM TECHNETHIUM 99m TSE/ N 17773	TECHNETIUM, TC-99m ETIDRONATE (PAGE 3-186)
N 16940		INJECTABLE; INJECTION /C/INTICHEM TECHNETHIUM 99m TSE/ N 1756	TECHNETIUM, TC-99m, MEDRONATE (PAGE 3-186)
N 62540		INJECTABLE; INJECTION /C/INTICHEM TECHNETHIUM 99m TSE/ N 60311	TECHNETIUM TO 99m MPI MDP /HDL KIT/
N 62540		INJECTABLE; INJECTION /C/INTICHEM TECHNETHIUM 99m TSE/ N 17255	TECHNETIUM, TC-99m, PENETRATE KIT (PAGE 3-186)
N 67155		INJECTABLE; INJECTION /C/INTICHEM TECHNETHIUM 99m TSE/ N 17255	TECHNETIUM /A/ /GENERAL, RADIOLISOTOPES KIT /A/ /KINETIC/ BETA/ SODIUM SULFATE KIT /A/ /MED- PHYSICS/ N/A INJECTABLE; INJECTION /C/INTICHEM TECHNETHIUM 99m TSE/ N 17255

THEOPHYLLINE (PAGE 3-190)

CAPSULE, CONTROLLED RELEASE; ORAL

	ELIXOPHYLLIN SR	
BC	BERLEX/SCHERING	125MGX
BC		250MGX
	SLO-BID	
BC	WILLIAM H RORER	50MGX
BC		100MGX
BC		200MGX
BC		300MGX
	SLO-PHYLLIN	
BC	WILLIAM H RORER	125MG
	SOMOPHYLLIN-CRT	
BC	FISONS	50MGX
BC		200MGX
BC		300MGX
	THEO-24	
BC	SEARLE/SEARLE PHARMS	200MG
BC		300MG
	THEOBID	
BC	GLAXO	26.5MGX
	THEOBID JR.	
BC	GLAXO	130MGX
	THEOCLEAR L.A.-130	
BC	CENTRAL PHARMS	130MG
	THEOPHYL-SR	
BC	MCNEIL PHARM	125MGX
BC		250MGX
	THEOPHYLLINE	
BC	CENTRAL PHARMS	125MGX
BC		250MGX
	THEOVENT	
BC	SCHERING	125MGX
BC		250MGX

TABLET, CONTROLLED RELEASE; ORAL

	<u>THEOCHRON</u>	
BC	FOREST LABORATORIES	100MGX
BC		200MGX
	<u>THEOPHYLLINE</u>	
BC	FOREST LABORATORIES	100MGX
BC		200MGX
AB		300MGX

THIAMYLAL SODIUM (PAGE 3-191)

INJECTABLE; INJECTION

SURITAL

> ADD > PARKE-DAVIS/W-L 5GM/VIALX N 07600

THIORIDAZINE HYDROCHLORIDE (PAGE 3-192)

TABLET; ORAL

THIORIDAZINE HCL

N 86826	AB	BARR LABORATORIES	150MGX	N 88737
N 86826	AB	BIOCRAFT LABS	200MGX	N 88738
N 88269	AB	CORD LABORATORIES	10MGX	N 88493
N 87892	AB	DANBURY PHARMACAL	100MGX	N 88456
N 87893	AB	ROXANE LABORATORIES	150MGX	N 88135
N 87894	AB	SUPERPHARM	200MGX	N 88869
N 85203	> ADD > AB		100MGX	N 88872
N 87763	> ADD > AB		25MGX	N 89048
N 88382	> ADD > AB		50MGX	N 89103
N 88383	> ADD > AB			N 89104

TOBRAMYCIN (PAGE 3-194)

SOLUTION/DROPS; OPHTHALMIC

TOBREX
ALCON LABORATORIES 0.3%

N 62535

TOCAINIDE HYDROCHLORIDE (PAGE 3-194)

TABLET; ORAL

TONOCARD
MS&D/MERCK

400MGX	
600MGX	

N 18257

N 18257

TOLAZAMIDE (PAGE 3-194)

TABLET; ORAL

TOLAZAMIDE

AB	ZENITH LABORATORIES	100MGX	N 18894
AB		250MGX	N 18894
AB		500MGX	N 18894
	<u>TOLINASE</u>		
AB	UPJOHN	100MG	N 15500
AB		250MG	N 15500
AB		500MG	N 15500

TOLAZOLINE HYDROCHLORIDE (PAGE 3-194)

INJECTABLE; INJECTION

PRISCOLINE
CIBA/CIBA-GEIGY 25MG/MLX

N 06403

TOLBUTAMIDE (PAGE 3-194)

TABLET; ORAL

TOLBUTAMIDE

AB	PUREPAC/KALIPHARMA	500MGX	N 88950
AB	SUPERPHARM	500MGX	N 88893

TRIFLUOPROPYL HYDROCHLORIDE (PAGE 3-194)

PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 22 / AUGUST '84 - JULY '85

02

JOLMETIN SOUPIN (PAGE 3-194)

DRUGS

TOLECTIN DS
TRIFLUOPRATINE HCL
/TRIFLUOPRATINE HCL//ED. 600MG/BASE/
MCNEIL PHARM
N 15084 AB
/N (500G)/ AB
EG 10MG BASEN
EG 5MG BASEN
EG 2MG BASEN
EG 1MG BASEN
AB
AB
AB
AB
N 68967 N 68968 N 68969 N 68970

CAPSULE; ORAL **TABLET; ORAL** **TOLMETHIN SODIUM (PAGE 3-194)**
TRIFLUOPERAZINE HYDROCHLORIDE (PAGE 3-198)

TRAZODONE HYDROCHLORIDE (PAGE 3-194)
CAPSULE; ORAL
MODURSTANE
MINTHROP LABS/STERL 30MGX 60NSX
TABLET; ORAL
DESEREL
N 16719

MCNEIL PHARM
EQ 200MG BASE
IRLLOSTANE (PAGE 3-199)
N 17628
/N 17628/

TRIAMCINOLONE ACETONIDE (PAGE 3-195) CREAM; TOPICAL
TRIMEPERAZINE TARTRATE SYRUP; ORAL
AA BAY LABORATORIES EG 2.5% BASE/ML x
N 866618 N 86285

MEAD JOHNSON/B-M 150HGS N 18207 TRIMEPERAZINE TARTRATE (PAGE 3-199)

PRINTED: TOPICAL

N 70049	TRIMETHOPRIM	TRIMETHOPRIM	DANBURY PHARMACEAL	AB	N 88450	0.025% 0.125%	N 88451	TRIPROLIDINE HYDROCHLORIDE (PAGE 3-200)
---------	--------------	--------------	--------------------	----	---------	------------------	---------	---

TRIMETHOPRIM (PAGE 3-199) N 66619 N 66620 N 66621
TABLET; ORAL 0.125M 0.25M

TABLET, OPAQUE	LEADERLE LABS/AM CYAN 0.125	N 88780	AA TRIPOLODINE HCL	1.25MG/5ML	N 88735
TRIAGMIDOLONE ACETONIDE	PHARMADERM/BYK-GLDN 0.025%	N 88692	AA HALSEY DRUG	1.25MG/5ML	N 88735
TRIMEX	TRYMEX LABS/BYK-GLDN 0.025%	N 88690	TRISULFAPYRIMIDINES (PAGE 3-200)		
SAVAGE LABS/BYK-GLDN 0.125	N 88693	SUSPENSION; ORAL	/AS/ /VALUABLE/ /TRIPLE SULFATE/	/500MG/5ML/	N 88735
	N 88691				

INJECTABLE; INJECTION
N/RECHICKEN (N-45);
N 17892
0.125mg
HALCION
UPJOHN
RESELLER'S MARK

VERAPAMIL HYDROCHLORIDE (PAGE 3-202)

TABLET; ORAL

CALAN

<u>AB</u>	SEARLE/SEARLE PHARMS	<u>80MGX</u>	N 18817
<u>AB</u>		<u>120MGX</u>	N 18817
	<u>ISOPTIN</u>		
<u>AB</u>	KNOLL PHARMACEUTICAL	<u>80MG</u>	N 18593
<u>AB</u>		<u>120MG</u>	N 18593

VINCRISTINE SULFATE (PAGE 3-202)

INJECTABLE; INJECTION

ONCOVIN

/ELI LILLY/	/1MG/AMP/	/N 14103/
	/5MG/AMP/	/N 14103/
ELI LILLY	1MG/ML	N 14103

WARFARIN SODIUM (PAGE 3-203)

TABLET; ORAL

COUMADIN

> DLT > /BX/	DUPONT PHARMS/DUPONT	2MG/	/N 09218/
> DLT > /BX/		5MG/	/N 09218/
> ADD > AB	DUPONT PHARMS/DUPONT	2MG	N 09218
> ADD > AB		5MG	N 09218
	<u>WARFARIN SODIUM</u>		
> ADD > AB	COLMED LABORATORIES	2MGX	N 88719
		5MGX	N 88721

WATER FOR INJECTION, STERILE (PAGE 3-204)

LIQUID; N/A

STERILE WATER FOR INJECTION IN PLASTIC CONTAINER

<u>AP</u>	TRAVENOL LABS	<u>100%</u>	N 18632
	<u>STERILE WATER IN PLASTIC CONTAINER</u>		
/AP/	/TRAVENOL LABS/	/100/	/N 18632/

**DESI PENDING LIST - 'EXEMPT' (COURT ORDER) CATEGORY
CUMULATIVE SUPPLEMENT NUMBER 11 / AUGUST '84 - JULY '85**

DIPYRIDAMOLE (PAGE AD4)

TABLET; ORAL		
DIPYRIDAMOLE		
DANBURY PHARMACAL	25MG	N 88945
	50MG	N 88800
	75MG	N 87432
PHARM BASICS	50MG	N 88822
SIDMAK LABORATORIES	25MG	N 88683
	50MG	N 88684
	75MG	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'/		
/ISOCHEM/		
/FOREST LABORATORIES/	/20MG/	/N 88428/

NITROGLYCERIN (PAGE AD7)

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

PENTAERYTHRITOL TETRANITRATE (PAGE AD8)

CAPSULE, CONTROLLED RELEASE; ORAL		
PENTAERYTHRITOL TETRANITRATE		
3 VITARINE/PHOENIX	80MG	N 86305
3	80MG	N 87529
3	80MG	N 87531

۲۶

Digitized by Google

DEBT PENDING LIST - OTHER THAN EXEMPT. (COURT ORDER) CATEGORY CUMULATIVE SUPPLEMENT NUMBER 11 / AUGUST 64 - JULY 85

Original from
UNIVERSITY OF MICHIGAN

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

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

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

Topicals

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

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

OTC Drug Products Eligible for Abbreviated New Drug Applications

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

NDA's Approved by the Office of Biological Research and Review Not Previously Published in the 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 or implies that the indication has been approved. TABLE IV contains patent numbers and expiration dates and, for drug products approved after 1981, the date of approval and application number as required by the Act.

Firms submitting ANDAs after September 24, 1984, that certified that no patent information had been filed should amend their applications, if patent information now appears in this list.

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

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

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

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
RTO	PRESCRIPTION TO OTC STATUS CHANGE
NS	NEW STRENGTH
D	NEW DOSING SCHEDULE (SEE REFERENCE, BELOW)
I	NEW INDICATION (SEE REFERENCE, BELOW)

REFERENCES

NEW DOSING SCHEDULE

D-1	ONCE A DAY APPLICATION
D-2	ONCE DAILY DOSING
D-3	SEVEN DAYS/SEVEN DAYS/SEVEN DAYS DOSING SCHEDULE
D-4	SEVEN DAYS/FOURTEEN DAYS DOSING SCHEDULE
D-5	TEN DAYS/ELEVEN DAYS DOSING SCHEDULE
D-6	SEVEN DAYS/NINE DAYS/FIVE DAYS DOSING SCHEDULE
D-7	BID DOSING
D-8	INTRAVENOUS, EPIDURAL AND INTRATHECAL DOSING
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 COMPUTERIZED TOMOGRAPHY
I-9 GATED CARDIAC POOL IMAGING
I-10 POST-MYOCARDIAL INFARCTION
I-11 COLORECATAL SURGERY
I-12 NAUSEA AND VOMITING ASSOCIATED WITH EMETOGENIC CANCER CHEMOTHERAPY
I-13 CISPLATIN INDUCED EMESIS
I-14 DIABETIC GASTROPATHIES
I-15 POST-MYOCARDIAL INFARCTION
I-16 ACROMEGALY
I-17 PITUITARY TUMORS
I-18 POSTMENOPAUSAL OSTEOFROSIS
I-19 ANTIDIOTIC FOR ACETAMINOPHEN OVERDOSE
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 BLASTOMYCOSSES DERMATITIDES
I-26 PEDICULAR SUBARCHNOID VASCULAR
I-27 PETRIELLIUM BODY II INFECTION
I-28 HEREDITARY ANGIODEMA
I-29 INTRACORONARY USE
I-30 PEDIATRIC USE
I-31 DIRECT ISOTOPIC CYSTOGRAPHY
I-32 POSTPARTUM HEMORRHAGE
I-33 USE IN METHODONE INDUCED RESPİRATORY DEPRESSION
I-34 PROLACTIN SECRETING ADENOMAS
I-35 SHORT TERM TREATMENT OF GASTRIC ULCER DISEASE

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

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

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

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
ACETAMINOPHEN 120MG	NEOPAP (SUPPOSITORY; RECTAL)	WEBCON PHARMS/ALCON	16-401 11-07-68		
ACETAMINOPHEN 650MG	TYLENOL (SUPPOSITORY; RECTAL)	MCNEIL LABORATORIES	17-756 05-26-76		
ACETAMINOPHEN 120MG	TYLENOL (SUPPOSITORY; RECTAL)	MCNEIL LABORATORIES	17-756 05-26-76		
ACETAMINOPHEN 120MG	ACEPHEN (SUPPOSITORY; RECTAL)	G AND W LABORATORIES	18-060 02-09-78		
ACETAMINOPHEN 650MG	ACEPHEN (SUPPOSITORY; RECTAL)	G AND W LABORATORIES	18-060 02-09-78		
ACETAMINOPHEN 650MG	ACETAMINOPHEN (SUPPOSITORY; RECTAL)	UPSHER-SMITH LABS	18-337 04-22-80		
ACETAMINOPHEN 120MG	ACETAMINOPHEN (SUPPOSITORY; RECTAL)	UPSHER-SMITH LABS	18-337 09-12-83		
ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE 80MG; 20MG	GAVISCON (TABLET, CHEWABLE; ORAL)	MARION LABORATORIES	18-685 12-09-83		NP 09-24-86
ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE 160MG; 40MG	GAVISCON-2 (TABLET, CHEWABLE; ORAL)	MARION LABORATORIES	18-685 12-09-83		NP 09-24-86
BROMPHENIRAMINE MALEATE 8MG	DIMETANE (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	10-799 06-10-83		RTO 09-24-86
BROMPHENIRAMINE MALEATE 12MG	DIMETANE (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	10-799 06-10-83		RTO 09-24-86
BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 12MG; 75MG	DIMETAPP (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	12-436 04-02-84		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	DOSE/AGE FORM: ROUTE	APPLICANT NAME	NDA NO.	PATENT NO.	EXCLUSIVITY	EXP. DATE
CHLORHEXIDINE GLUCONATE	0.5%	HIBITANE (TINCIURE; TOPICAL)	ICI AMERICAS	HIBISTAT (SOLUTION; TOPICAL)	18-049	12-18-78		
CHLORHEXIDINE GLUCONATE	0.5%	HIBITANE (TINCIURE; TOPICAL)	ICI AMERICAS	HIBISTAT (SOLUTION; TOPICAL)	18-300	05-23-80		
CHLORHEXIDINE GLUCONATE	4x	EXDINE (AEROSOL; TOPICAL)	XTRIUM LABS	EXDINE (SOLUTION; TOPICAL)	19-125	12-24-84		
CHLORHEXIDINE GLUCONATE	4x	EXDINE (AEROSOL; TOPICAL)	XTRIUM LABS	EXDINE (SOLUTION; TOPICAL)	19-127	12-24-84		
CHLORHEXIDINE GLUCONATE	4x	HIBICLENS (SOLUTIION; TOPICAL)	ICI AMERICAS	HIBICLENS (SOLUTIION; TOPICAL)	17-768	09-17-76		
CHLORHEXIDINE GLUCONATE	8MG	TELDRIN (CAPSULE; ORAL)	MENLEY & JAMES/SKF	TELDRIN (CAPSULE; CONTROLLED RELEASE; ORAL)	17-369	05-11-78		
CHLORPHENIRAMINE MALEATE	8MG	CHLOR-TRIMETON (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	CHLOR-TRIMETON (TABLET, CONTROLLED RELEASE; ORAL)	07-638	10-18-78		
CHLORPHENIRAMINE MALEATE	12MG	DEMAZIN (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	DEMAZIN (TABLET, CONTROLLED RELEASE; ORAL)	18-556	05-14-84	NS	09-24-86
CHLORPHENIRAMINE MALEATE	4MG; 25MG	PHENYLPROPAOLAMINE HYDROCHLORIDE	CONTAC (CAPSULE, CONTROLLED RELEASE; ORAL)	MENTLY & JAMES/SKF	18-099	02-04-80		
CHLORPHENIRAMINE MALEATE	8MG; 75MG	PHENYLPROPAOLAMINE HYDROCHLORIDE	PHENYLPROPAOLAMINE HYDROCHLORIDE					

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

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

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

<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		

TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING
Digitized by Google Original from UNIVERSITY OF MICHIGAN

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

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

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

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

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	ALLERBAN PLUS (SYRUP; ORAL)	BAY LABORATORIES	88-116 03-04-83		RTD 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRI-SUDO (TABLET; ORAL)	MD PHARMACEUTICAL	85-024 01-10-84		RTD 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPODRINE (TABLET; ORAL)	DANBURY PHARMACAL	88-112 01-20-83		RTD 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	TRIOFED (SYRUP; ORAL)	NATL PHARM MFG/BARRE	88-115 03-04-83		RTD 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	TRIPOSED (SYRUP; ORAL)	HALSEY DRUG	88-213 03-30-84		RTD 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPROLIDINE HCL AND PSEUDOEPHEDRINE HCL (TABLET; ORAL)	CHELSEA LABORATORIES	88-118 01-26-84		RTD 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPOSED (TABLET; ORAL)	HALSEY DRUG	88-192 05-01-84		RTD 09-24-86
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPROLIDINE AND PSEUDOEPHEDRINE (TABLET; ORAL)	BOLAR PHARMACEUTICAL	88-318 01-13-84		RTD 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		

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	DOSAGE FORM: ROUTE	TRADE NAME	APP LICANT NAME	NDA NO.	PATENT NO.	EXC. DATE	OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING
TIOCONAZOLE	1%	NCE	02-18-93	4062966	02-18-83	PIZER CEN RES/PIZIR	CREAM; TOPICAL	PIZER CEN RES/PIZIR	18-682	02-18-83	ACTIVELINE HYDROCHLORIDE
TRIPROLIDINE HYDROCHLORIDE	2.5MG	RTO	09-24-86	11-110	BURROUGHS WELLCOME	DANBURY PHARMACAL	(TABLET; ORAL)	TRIPROLIDINE HCL	85-094	02-07-77	TRIPROLIDINE HYDROCHLORIDE
TRIPROLIDINE HYDROCHLORIDE	2.5MG	RTO	09-24-86	84-453	BOLAR PHARMACEUTICAL	DRUMMER/PHOENIX	(TABLET; ORAL)	TRIPROLIDINE HCL	85-610	03-21-78	TRIPROLIDINE HYDROCHLORIDE
TRIPROLIDINE HYDROCHLORIDE	2.5MG	RTO	09-24-86	02-06-76	DANBURY PHARMACAL	DANBURY PHARMACAL	(TABLET; ORAL)	TRIPROLIDINE HCL	85-094	02-07-77	TRIPROLIDINE HYDROCHLORIDE
TRIPROLIDINE HYDROCHLORIDE	2.5MG	RTO	09-24-86	RT0	TRIPROLIDINE HCL	DRUMMER/PHOENIX	(TABLET; ORAL)	TRIPROLIDINE HCL	85-610	03-21-78	TRIPROLIDINE HYDROCHLORIDE
TRIPROLIDINE HYDROCHLORIDE	1.25MG/5ML	RTO	09-24-86	RT0	TRIPROLIDINE HCL	BAY LABORATORIES	(SYRUP; ORAL)	TRIPROLIDINE HCL	87-963	01-18-83	TRIPROLIDINE HYDROCHLORIDE
TRIPROLIDINE HYDROCHLORIDE	1.25MG/5ML	RTO	09-24-86	RT0	TRIPROLIDINE HCL	NATL PHARM MFG/BARRE	(SYRUP; ORAL)	TRIPROLIDINE HCL	85-940	07-13-79	TRIPROLIDINE HYDROCHLORIDE
TRIPROLIDINE HYDROCHLORIDE	1.25MG/5ML	RTO	09-24-86	RT0	TRIPROLIDINE HCL	PHARMS ASSOC/BEACH	(SYRUP; ORAL)	TRIPROLIDINE HCL	87-514	02-10-82	TRIPROLIDINE HYDROCHLORIDE

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

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

ACTIVE INGREDIENT(S)	STRENGTH(S)	PATENT NO.	EXCLUSIVITY	EXP. DATE	EXP. DATE	DOSEAGE FORM: ROUTE	TRADE NAME	APPLICANT NAME	NDA NO.	APPROVAL DATE	(INJECTABLE; INJECTION)
ANTICOGULANT PHOSPHATE	DEXTROSE SOLUTION USP WITH:	5-1104		81-1104		TRAVENOL LABS	ADSOL® RED CELL PRESERVATION SOLUTION				(INJECTABLE; INJECTION)
ANTICOGULANT PHOSPHATE	DEXTROSE SOLUTION USP 2.5GM/100ML,	82-915		9-22-83		CUTTER BIOL/MILES	AS-2 NUTRICEL ADDITIVE SYSTEM				(INJECTABLE; INJECTION)
ANTICOGULANT PHOSPHATE	DEXTROSE USP 0.285GM/100ML,	82-915		82-915		CUTTER BIOL/MILES	AS-3 NUTRICEL ADDITIVE SYSTEM				(INJECTABLE; INJECTION)
ANTICOGULANT PHOSPHATE	DOUBLE DEXTROSE SOLUTION WITH:	5-17-78		77-822		DELMED	None (INJECTABLE; INJECTION)				
ANTICOAGULANT HEPARIN SOLUTION	USP	5-16-83		81-1217		TRAVENOL LABS	None (INJECTABLE; INJECTION)				
ANTICOAGULANT HEPARIN SOLUTION	USP	5-16-83		81-416		ALPHA THERAPEUTIC	None (INJECTABLE; INJECTION)				
ANTICOAGULANT SOUDIUM CITRATE	SOLUTION USP	76-305		10-12-83		CUTTER BIOL/MILES	None (INJECTABLE; INJECTION)				
ANTICOAGULANT SOUDIUM CITRATE	SOLUTION USP	6-30-78		16-702		DELMED	None (INJECTABLE; INJECTION)				
ANTICOAGULANT SOUDIUM CITRATE	SOLUTION USP	78-1214		12-28-70		TERUMO AMERICA	None (INJECTABLE; INJECTION)				
ANTICOAGULANT SOUDIUM CITRATE	SOLUTION USP	2-8-80		16-702		TRAVENOL LABS	None (INJECTABLE; INJECTION)				
ANTICOAGULANT SOUDIUM CITRATE	SOLUTION USP	77-923		1-20-78							
		III-2									

TABLE III. NDAs APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED

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

<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>
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	16-375 7-25-67		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	16-375 7-25-67		
DEXTRAN 75, 6% 6GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	8-819 3-31-53		
DEXTRAN 75, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	8-819 3-31-53		
DEXTRAN 75, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-253 2-4-83		
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	AMERICAN MCGAW	16-767 4-6-70		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	AMERICAN MCGAW	16-767 4-6-70		
DEXTRAN 70, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	AMERICAN MCGAW	9-024 8-18-69		
DEXTRAN 40, 10% 10GM/100ML IN DEXTROSE 5% 5GM/100ML	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	16-653 9-23-69		
DEXTRAN 40, 10% 10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	16-653 9-23-69		

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

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

<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>
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% TRAVERT® (INJECTABLE; INJECTION)	TRAVENOL LABS	8-788 2-9-53		
HETASTARCH, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	HESSPAN® (INJECTABLE; INJECTION)	AM CRITICAL CARE	16-889 7-17-72	3523938 8-11-87	
PROPIOLACTONE 99% 99GM/100ML	BETAPRONE (SOLUTION; CHEMICAL STERILIZING AGENT)	ONEAL JONES&FELDMAN	11-657 9-11-59		
UROKINASE 5000 IU/VIAL	ABBOKINASE OPEN-CATHETER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	76-1021 12-15-83		NS 09-24-86
UROKINASE 250,000 IU/VIAL	ABBOKINASE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	76-1021 7-31-78		I-29 09-24-86
UROKINASE 250,000 IU/VIAL	BREOKINASE (INJECTABLE; INJECTION)	STERLING DRUG	17-873 8-28-79		

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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	

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	PATENT NO.	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	(DOSEAGE FORM; ROUTE)
ALBUTEROL SULFATE	PROVENTIL	SCHERING	17-853	3644353	02-22-89	3705233	05-07-82	(TABLET; ORAL)
ALBUTEROL SULFATE	PROVENTIL	SCHERING	17-853	3644353	02-22-89	3705233	12-05-89	(TABLET; ORAL)
ALBUTEROL SULFATE	PROVENTIL	SCHERING	17-853	3644353	02-22-89	3705233	12-05-89	(TABLET; ORAL)
ALBUTEROL SULFATE	PROVENTIL	SCHERING	17-853	3644353	02-22-89	3705233	12-05-89	(TABLET; ORAL)
ALBUTEROL SULFATE	PROVENTIL	SCHERING	18-062	3644353	02-22-89	3705233	01-19-83	(SYRUP; ORAL)
ALBUTEROL SULFATE	PROVENTIL	SCHERING	18-062	3644353	02-22-89	3705233	12-05-89	(TABLET; ORAL)
ALCLOMETASONE DIPROPIONATE	VADERM	SCHERING	18-702	4124707	11-07-95	NCE	12-14-92	(OINTMENT; TOPICAL)
ALCLOMETASONE DIPROPIONATE	VADERM	SCHERING	18-707	4124707	11-07-95	NCE	12-14-92	(CREAM; TOPICAL)
ALLOPURINOL	0.05%	VADERM	12-14-82	4124707	11-07-95	NCE	12-14-92	(CREAM; TOPICAL)
ALLOPURINOL	100MG	VADERM	12-14-82	4124707	11-07-95	NCE	12-14-92	(CREAM; TOPICAL)
ALLOPURINOL	300MG	VADERM	12-14-82	4124707	11-07-95	NCE	12-14-92	(CREAM; TOPICAL)
ALLOPURINOL	100MG	BOLAR PHARMACEUTICAL	18-241	11-16-84	09-28-84	09-28-84	09-28-84	(TABLET; ORAL)
ALLOPURINOL	300MG	BOLAR PHARMACEUTICAL	18-241	11-16-84	09-28-84	09-28-84	09-28-84	(TABLET; ORAL)
ALLOPURINOL	100MG	BOLAR PHARMACEUTICAL	18-241	11-16-84	09-28-84	09-28-84	09-28-84	(TABLET; ORAL)
ALLOPURINOL	300MG	CHELSEA LABORATORIES	18-785	11-16-84	09-28-84	09-28-84	09-28-84	(TABLET; ORAL)
ALLOPURINOL	300MG	CHELSEA LABORATORIES	18-785	11-16-84	09-28-84	09-28-84	09-28-84	(TABLET; ORAL)
ALLOPURINOL	100MG	DANBURY PHARMACAL	18-832	09-28-84	09-28-84	09-28-84	09-28-84	(TABLET; ORAL)
ALLOPURINOL	300MG	DANBURY PHARMACAL	18-877	09-28-84	09-28-84	09-28-84	09-28-84	(TABLET; ORAL)

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<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>
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; HYDROCHLORTIAZIDE 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

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCUSIVITY	PATENT NO.	TRADE NAME	APPLICANT NAME	NDA NO.	APPROVAL DATE	EXP. DATE
TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION								
AMINO ACIDS	6.5%	NS	09-24-86	RENMAMIN W/O ELECTROLYTES	TRAVENOL LABS	17-493	10-15-82	(INJECTABLE; INJECTION)
AMINO ACIDS	8.5%	NS	09-24-86	NOVAMINE 8.5%	CUTTER LABS/MILES	17-957	08-09-82	(INJECTABLE; INJECTION)
AMINO ACIDS	11.4%	NS	09-24-86	NOVAMINE 11.4%	CUTTER LABS/MILES	17-957	08-09-82	(INJECTABLE; INJECTION)
AMINO ACIDS	8%	NS	09-24-86	HEPATAMINE 8%	AM McGraw/AM Hosp	18-676	08-03-82	(INJECTABLE; INJECTION)
AMINO ACIDS	4%	NS	09-28-87	BRAUNCHAMIN 4%	TRAVENOL LABS	18-678	08-03-82	(INJECTABLE; INJECTION)
AMINO ACIDS	4%	NS	09-28-87	BRAUNCHAMIN 4%	TRAVENOL LABS	18-678	09-28-84	(INJECTABLE; INJECTION)
AMINO ACIDS	6.5%	NS	09-24-86	NEOPHARM 6.5%	CUTTER-VITRUM	18-792	01-17-84	(INJECTABLE; INJECTION)
AMINO ACIDS	3.5%	NS	09-24-86	AMINOSYN 3.5%	ABBOTT LABORATORIES	18-875	08-08-84	(INJECTABLE; INJECTION)
AMINO ACIDS	3.5%	NS	09-24-86	AMINOSYN 3.5%	IN PLASTIC CONTAINER	18-901	04-06-84	AMINO ACIDS W/ HISTADINE (INJECTABLE; INJECTION)
AMINO ACIDS	5.2%	NS	09-24-86	AMINOGES 5.2% ESSENTIAL	CUTTER-VITRUM	18-931	08-23-84	TRAVENOL LABS W/O ELECTROLYTES (INJECTABLE; INJECTION)
AMINO ACIDS	5.5%	NS	09-24-86	TRAVASOL 5.5%	TRAVENOL LABS	18-931	08-23-84	IN PLASTIC CONTAINER (INJECTABLE; INJECTION)

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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 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	PERIPHARMINE (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		

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	TRADE NAME	APP LICANT NAME	NDA NO.	DOSEAGE FORM; ROUTE
AMINO ACIDS; MAGNESIUM ACETATE;	128MG/100ML; 234MG/100ML; 3.5%; 21MG/100ML; 40MG/100ML;	NC	09-24-86	05-15-84	AMINOSYN 3.5% M	ABBOTT LABORATORIES	18-804	SODIUM CHLORIDE; INJECTABLE; INJECTION
PHOSPHORIC ACID; POTASSIUM ACETATE;	128MG/100ML; 234MG/100ML; 3.5%; 21MG/100ML; 40MG/100ML;	NC	09-24-86	05-15-84	AMINOSYN 3.5% M	ABBOTT LABORATORIES	18-875	AMINOSYN 3.5% M IN PLASTIC CONTAINER (INJECTABLE; INJECTION)
AMINO ACIDS; MAGNESIUM ACETATE;	128MG/100ML; 234MG/100ML; 3.5%; 21MG/100ML; 40MG/100ML;	NC	09-24-86	05-15-84	AMINOSYN 3.5% M	ABBOTT LABORATORIES	18-804	PHOSPHORIC ACID; POTASSIUM ACETATE;
AMINO ACIDS; MAGNESIUM ACETATE;	128MG/100ML; 234MG/100ML; 3.5%; 21MG/100ML; 40MG/100ML;	NC	09-24-86	05-15-84	AMINOSYN 3.5% M	ABBOTT LABORATORIES	18-804	SODIUM CHLORIDE; INJECTABLE; INJECTION
AMINO ACIDS; MAGNESIUM ACETATE;	128MG/100ML; 234MG/100ML; 3.5%; 21MG/100ML; 40MG/100ML;	NC	09-24-86	05-15-84	AMINOSYN 3.5% M	ABBOTT LABORATORIES	18-804	AMINOSYN 3.5% M IN PLASTIC CONTAINER (INJECTABLE; INJECTION)
AMINOGLUTETHIMIDE	250MG	CIBA/CIBA-GEIGY	18-202	10-29-80	CYADRIN	(TABLET; ORAL)	18-590	AMINOCAPROIC ACID (INJECTABLE; INJECTION)
AMINOPHYLLINE	300MG/5ML	FISONS	18-232	04-02-82	SOMOPHYLLIN	(ENEMA; RECTAL)	18-924	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45%
AMINOPHYLLINE	100MG/100ML; 450MG/100ML	ABBOTT LABORATORIES	18-924	12-12-84	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45%	IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	18-924	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45%
AMINOPHYLLINE	200MG/100ML; 450MG/100ML	ABBOTT LABORATORIES	18-924	12-12-84	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45%	IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	18-924	AMINOPHYLLINE; SODIUM CHLORIDE
AMINOPHYLLINE	400MG/100ML; 450MG/100ML	ABBOTT LABORATORIES	18-924	12-12-84	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45%	IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	18-924	AMINOPHYLLINE; SODIUM CHLORIDE

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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	

ACTIVE INGREDIENT(S)	STRENGTH(S)	PATENT NO.	EXCLUSIVITY	EXP. DATE	EXP. DATE	APPRAVAL DATE	TRADE NAME	APPLICANT NAME	(DOSEAGE FORM; ROUTE)
AMITRIPITYLINE HYDROCHLORIDE;	25MG; 2MG	3428735	02-18-86	12-30-65	14-713	SCHERING	ETRAFON 2-25	(TABLET; ORAL)	14-713
AMITRIPITYLINE HYDROCHLORIDE;	25MG; 2MG	3428735	02-18-86	12-30-65	14-713	SCHERING	ETRAFON-FORTE	(TABLET; ORAL)	14-713
AMITRIPITYLINE HYDROCHLORIDE;	25MG; 2MG	3428735	02-18-86	12-30-65	14-713	SCHERING	ETRAFON 2-10	(TABLET; ORAL)	14-715
AMITRIPITYLINE HYDROCHLORIDE;	10MG; 2MG	3428735	02-18-86	12-30-65	14-715	MS&D/MERCK	TRIAVAIL 2-25	(TABLET; ORAL)	08-23-65
AMITRIPITYLINE HYDROCHLORIDE;	10MG; 2MG	3428735	02-18-86	12-30-65	14-715	MS&D/MERCK	TRIAVAIL 2-10	(TABLET; ORAL)	04-04-67
AMITRIPITYLINE HYDROCHLORIDE;	25MG; 2MG	3428735	02-18-86	12-30-65	14-715	MS&D/MERCK	TRIAVAIL 4-25	(TABLET; ORAL)	08-25-65
AMITRIPITYLINE HYDROCHLORIDE;	25MG; 2MG	3428735	02-18-86	12-30-65	14-715	MS&D/MERCK	TRIAVAIL 4-50	(TABLET; ORAL)	03-15-78
AMMONIUM LACTATE	ED 12% ACID	NE	04-24-88	05-03-94	4105783	LAC-HYDRIN	(LOTION; TOPICAL)	19-155	04-24-85

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<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>
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		

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	PATENT NO.	EXCLUSIVITY	STRENGTH(S)	EX.P. DATE	APPROVAL DATE	DOSAGE FORM: ROUTE	TRADE NAME
ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE	DARVON COMPOUND	ELI LILLY INDSTRS/PR	10-996	03-08-83	389MG; 32.4MG; 65MG	ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE	DARVON COMPOUND-65	10-996	03-08-83	ELI LILLY INDSTRS/PR
ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE	DARVON COMPOUND	ELI LILLY INDSTRS/PR	10-996	03-08-83	389MG; 32.4MG; 32MG	ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE	DARVON COMPOUND	10-996	03-08-83	ELI LILLY INDSTRS/PR
ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE	SOMA COMPOUND W/ CODEINE	WALLAACE PHARMS/C-W	12-366	07-11-83	325MG; 200MG; 16MG	ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE	SOMA COMPOUND W/ CODEINE	12-366	07-11-83	WALLAACE PHARMS/C-W
ASPIRIN; CARISOPRODOL	SOMA COMPOUND	WALLAACE PHARMS/C-W	12-365	07-11-83	325MG; 200MG	ASPIRIN; CARISOPRODOL	SOMA COMPOUND	12-365	07-11-83	WALLAACE PHARMS/C-W
ASPIRIN; MEPROBAMATE	EQUAGESIC	WEYTH LABS/AMHO	11-702	12-29-83	325MG; 200MG	ASPIRIN; MEPROBAMATE	EQUAGESIC	11-702	12-29-83	WEYTH LABS/AMHO
ASPIRIN; PENTAZOCINE HYDROCHLORIDE	TALWIN COMPOUND	WINTHROP LABS/STERL	16-891	11-12-75	4105659	ASPIRIN; PENTAZOCINE HYDROCHLORIDE	TALWIN COMPOUND	16-891	11-12-75	WINTHROP LABS/STERL
ATENOLOL	TENDRMIN	STUART PHARMS/ICI AM	18-240	08-19-81	3663607	ATENOLOL	TENDRMIN	18-240	08-19-81	STUART PHARMS/ICI AM
ATENOLOL; CHLORTHALIDONE	TENDRTEC 100	STUART PHARMS/ICI AM	18-760	06-08-84	3663607	ATENOLOL; CHLORTHALIDONE	TENDRTEC 100	18-760	06-08-84	STUART PHARMS/ICI AM

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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
ATRACURIUM BESYLATE 10MG/ML	TRACRIUM (INJECTABLE; INJECTION)	BURROUGHS WELLCOME	18-831 11-23-83	4179507 12-18-96	NCE 11-23-93
ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE 0.025MG; 0.5MG	MOTOFEN HALF-STRENGTH (TABLET; ORAL)	MCNEIL LABORATORIES	17-744 07-14-78	3646207 02-28-89	
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	

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	PATENT NO.	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	DOSAGE FORM: ROUTE
----------------------	------------	----------------	---------	------------	-------------	-----------	---------------	--------------------

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

0.042MG/INH BECLOMETHANSONE DIPROPIONATE	VANCERIL (AEROSOL; INHALATION)	SCHERING 17-573 4225597 09-30-97 4364923 10-29-99 4414209 08-23-94	05-12-76 4225597 09-30-97 4364923 10-29-99 4414209 08-23-94	09-30-81 4414209 08-23-94 4364923 10-29-99 4414209 08-23-94	GALAXO 18-584 4414209 08-23-94 4364923 10-29-99 4414209 08-23-94	09-23-94 4414209 08-23-94 4364923 10-29-99 4414209 08-23-94	09-24-81 4225597 09-30-97 4364923 10-29-99 4414209 08-23-94	VANCERIL (AEROSOL; INHALATION)	0.042MG/INH BECLOMETHANSONE DIPROPIONATE
0.042MG/INH BECLOMETHANSONE DIPROPIONATE	BECONASE (AEROSOL; INHALATION/NASAL)	GALAXO 18-584 4414209 08-23-94 4364923 10-29-99 4414209 08-23-94	09-30-81 4414209 08-23-94 4364923 10-29-99 4414209 08-23-94	09-30-81 4414209 08-23-94 4364923 10-29-99 4414209 08-23-94			09-24-81 4225597 09-30-97 4364923 10-29-99 4414209 08-23-94	VANCERIL (AEROSOL; INHALATION)	0.042MG/INH BECLOMETHANSONE DIPROPIONATE
0.042MG/INH BECLOMETHANSONE DIPROPIONATE	VANCERIL (AEROSOL; INHALATION)	SCHERING 17-573 4225597 09-30-97 4364923 10-29-99 4414209 08-23-94	05-12-76 4225597 09-30-97 4364923 10-29-99 4414209 08-23-94	09-30-81 4414209 08-23-94 4364923 10-29-99 4414209 08-23-94			09-24-81 4225597 09-30-97 4364923 10-29-99 4414209 08-23-94	VANCERIL (AEROSOL; INHALATION)	0.042MG/INH BECLOMETHANSONE DIPROPIONATE
0.042MG/INH BECLOMETHANSONE DIPROPIONATE	BECONASE (AEROSOL; INHALATION/NASAL)	GALAXO 18-584 4414209 08-23-94 4364923 10-29-99 4414209 08-23-94	09-30-81 4414209 08-23-94 4364923 10-29-99 4414209 08-23-94	09-30-81 4414209 08-23-94 4364923 10-29-99 4414209 08-23-94			09-24-81 4225597 09-30-97 4364923 10-29-99 4414209 08-23-94	VANCERIL (AEROSOL; INHALATION)	0.042MG/INH BECLOMETHANSONE DIPROPIONATE
0.042MG/INH BECLOMETHANSONE DIPROPIONATE	VANCERIL (AEROSOL; INHALATION)	SCHERING 17-573 4225597 09-30-97 4364923 10-29-99 4414209 08-23-94	05-12-76 4225597 09-30-97 4364923 10-29-99 4414209 08-23-94	09-30-81 4414209 08-23-94 4364923 10-29-99 4414209 08-23-94			09-24-81 4225597 09-30-97 4364923 10-29-99 4414209 08-23-94	VANCERIL (AEROSOL; INHALATION)	0.042MG/INH BECLOMETHANSONE DIPROPIONATE
2.5MG BENDROFLUMETHIAZIDE	NATURETIN-2.5 (TABLET; ORAL)	ER SQUIBB AND SONS 12-164 3392168 07-09-85	12-07-59 3392168 07-09-85	12-164 3392168 07-09-85			09-23-94 4414209 08-23-99 4364923 10-29-99 4414209 08-23-94	NATURETIN-10 (TABLET; ORAL)	10MG BENDROFLUMETHIAZIDE
2.5MG BENDROFLUMETHIAZIDE	NATURETIN-5 (TABLET; ORAL)	ER SQUIBB AND SONS 12-164 3392168 07-09-85	12-07-59 3392168 07-09-85	12-164 3392168 07-09-85			09-23-94 4414209 08-23-99 4364923 10-29-99 4414209 08-23-94	NATURETIN-10 (TABLET; ORAL)	10MG BENDROFLUMETHIAZIDE
5MG BENDROFLUMETHIAZIDE	NATURETIN-5 (TABLET; ORAL)	ER SQUIBB AND SONS 12-164 3392168 07-09-85	12-07-59 3392168 07-09-85	12-164 3392168 07-09-85			09-23-94 4414209 08-23-99 4364923 10-29-99 4414209 08-23-94	NATURETIN-10 (TABLET; ORAL)	10MG BENDROFLUMETHIAZIDE
5MG BENDROFLUMETHIAZIDE	CORZIDE (TABLET; ORAL)	ER SQUIBB AND SONS 18-647 3982021 09-21-93	05-25-83 3982021 09-21-93	05-25-83 3982021 09-21-93			09-24-86 NC	CORZIDE (TABLET; ORAL)	5MG; 40MG BENDROFLUMETHIAZIDE; NADOLOL
5MG BENDROFLUMETHIAZIDE	CORZIDE (TABLET; ORAL)	ER SQUIBB AND SONS 18-647 3982021 09-21-93	05-25-83 3982021 09-21-93	05-25-83 3982021 09-21-93			09-24-86 NC	CORZIDE (TABLET; ORAL)	5MG; 80MG BENDROFLUMETHIAZIDE; NADOLOL
500MG/7.5ML BENTRIMIDE	CHYMEX (SOLUTION; ORAL)	ADRIA LABORATORIES 3801562 04-02-91	18-366 3801562 04-02-91	18-366 3801562 04-02-91			09-29-93 NC	CHYMEX (SOLUTION; ORAL)	500MG/7.5ML BENTRIMIDE

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S) **STRENGTH(S)** **(DOSAGE FORM: ROUTE)** **TRADE NAME** **APPLICANT NAME** **PATENT NO.** **NDA NO.** **EXCLUSIVITY** **EXP. DATE** **APPROVAL DATE** **EXP. DATE** **EXC. DATE**

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (LOTION; TOPICAL)	PHARMADERM/BYK-GLDN	18-870 08-31-83		
BETHANIDINE SULFATE 10MG	TENATHAN (TABLET; ORAL)	AH ROBINS	17-675 05-29-81	3495013 02-10-87	
BETHANIDINE SULFATE 25MG	TENATHAN (TABLET; ORAL)	AH ROBINS	17-675 05-29-81	3495013 02-10-87	
BITOLTEROL MESYLATE 0.8%	TORNALATE (AEROSOL; INHALATION)	WINTHROP-BREON/STERL	18-770 12-28-84	4138581 02-06-96	NCE 12-28-89
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		
BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHENDRINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 30MG/5ML	DIMETANE-DX (SYRUP; ORAL)	AH ROBINS	11-694 03-29-84		

ACTIVE INGREDIENT(S)	TRADE NAME	APP LICENT NAME	NDA NO.	DOSAGE FORM: ROUTE	APPROVAL DATE	PATENT NO.	EXCLUSIVITY	EXP. DATE	STRENGTH(S)
TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION									
BROMPHENIRAMINE MALEATE:	DIMETANE-DX	AH ROBINS	19-279	(SYRUP: ORAL)	08-24-84				1MG/5ML; 10MG/5ML; 30MG/5ML
BROMPHENIRAMINE MALEATE:	DEXTRODEPHEDRINE HYDROBROMIDE:	AH ROBINS	13-087	ELIXIR DIMETAPP	03-29-84				4MG/5ML; PHENYLPROPAOLAMINE HYDROCHLORIDE
BROMPHENIRAMINE MALEATE:	PSEUDOEHEDRINE HYDROCHLORIDE	AH ROBINS	13-087	(ELIXIR: ORAL)					2MG/5ML; 10MG/5ML; 30MG/5ML
BUMETANIDE	2MG	HOFMANN-LA ROCHE	18-225	(TABLET: ORAL)	06-14-85	3634583	01-11-89	02-28-93	0.5MG
BUMETANIDE	0.5MG	HOFMANN-LA ROCHE	18-225	(TABLET: ORAL)	02-28-83	3634583	01-11-89	02-28-93	0.5MG
BUMETANIDE	0.25MG/ML	HOFMANN-LA ROCHE	18-226	(TABLET: ORAL)	02-28-83	3634583	01-11-89	02-28-93	0.25MG/ML
BUMETANIDE	2MG	HOFMANN-LA ROCHE	18-225	(TABLET: ORAL)	06-14-85	3806534	04-23-91	04-23-91	0.5MG
BUMETANIDE	0.25MG	HOFMANN-LA ROCHE	18-225	(TABLET: ORAL)	02-28-83	3806534	01-11-89	02-28-93	0.25MG
BUMETANIDE	0.75%	MARCAINE SPINAL	18-692	(INJECTABLE: INJECTION)	05-04-84	NC	09-24-86	0.75%	0.0091MG/ML
BUPIVACAINE HYDROCHLORIDE	0.75%	ASTRA PHARM PRODS	18-304	(INJECTABLE: INJECTION)	09-02-83	3819635	06-22-78	06-25-91	1MG/ML
BUPIVACAINE HYDROCHLORIDE:	0.091MG/ML	ASTRA PHARM PRODS	18-304	(INJECTABLE: INJECTION)	09-02-83	3819635	06-22-78	06-25-91	BUTOPHANOL TARTRATE

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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	
CALCITONIN 200 IU/VIAL	CALCIMAR (INJECTABLE; INJECTION)	ARMOUR PHARM	17-769 12-21-84		I-18 12-21-87
CALCITONIN 400 IU/VIAL	CALCIMAR (INJECTABLE; INJECTION)	ARMOUR PHARM	17-497 12-21-84		I-18 12-21-87
CALCITRIOL 0.25 UGM	ROCALTROL (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-044 08-17-78	3697559 10-10-89 4391802 07-05-90 4341774 07-27-99 4225596 09-30-97	
CALCITRIOL 0.5 UGM	ROCALTROL (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-044 08-17-78	3697559 10-10-89 4391802 07-05-90 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		

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

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

Original
UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u>	<u>TRADE NAME (DOSAGE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u>	<u>PATENT NO.</u>	<u>EXCLUSIVITY EXP. DATE</u>
<u>STRENGTH(S)</u>			<u>APPROVAL DATE</u>	<u>EXP. DATE</u>	
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	DELFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	DELFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	DELFLEX W/ DEXTROSE 4.25% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	INPERSOL-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	INPERSOL-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	INPERSOL-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 26MG/100ML; 2.5GM/100ML; 15MG/100ML; 560MG/100ML; 390MG/100ML	DIALYTE W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-460 11-02-83		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	APPLICANT NAME	NDA NO.	PATENT NO.	EXCUSIVITY	EXP. DATE	APPROVAL DATE	(DOSE/AGE FORM; ROUTE)
TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION									
CALCIUM CHLORIDE; EXTROSIDE	30MG/100ML; 860MG/100ML	DEXTROSE 5% AND RINGER'S	TRAVENOL LABS	18-635	02-07-83				IN PLASTIC CONTAINER (INJECTABLE; INJECTION)
CALCIUM CHLORIDE; SODIUM CHLORIDE	33MG/100ML; 5GM/100ML	DEXTROSE 5% AND RINGER'S	TRAVENOL LABS	18-635	02-07-83				IN PLASTIC CONTAINER (INJECTABLE; INJECTION)
SODIUM CHLORIDE; SODIUM ACETATE; CALCIUM CHLORIDE; POTASSIUM CHLORIDE	121MG/ML; 16.1MG/ML; 16.5MG/ML; 25.4MG/ML; 74.6MG/ML;	TPN ELECTROLYTES	ABBOTT LABORATORIES	18-895	07-20-84	NC	09-24-86		IN PLASTIC CONTAINER (INJECTABLE; INJECTION)
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; POTASSIUM CHLORIDE; SODIUM CITRATE	35MG/100ML; 30MG/100ML; 74MG/100ML; 640MG/100ML; 500MG/100ML; 74MG/100ML;	ISOLYTE E	AM MCGAW/AM HOSP	18-899	10-31-83				IN PLASTIC CONTAINER (INJECTABLE; INJECTION)
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; POTASSIUM CHLORIDE; SODIUM CITRATE	17.6MG/100ML; 325.3MG/100ML; 643MG/100ML;	PLEGISOL	ABBOTT LABORATORIES	18-608	02-26-82	NC	09-24-86		PERFUSION; CARDIAC (SOLUTION)
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; POTASSIUM CHLORIDE; SODIUM CITRATE	17.6MG/100ML; 325.3MG/100ML; 643MG/100ML;	ACETATED RINGER'S	AM MCGAW/AM HOSP	18-725	11-29-82				IN PLASTIC CONTAINER (INJECTABLE; INJECTION)
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; POTASSIUM CHLORIDE; SODIUM CITRATE	20MG/100ML; 30MG/100ML; 380MG/100ML;	RINGER'S	TRAVENOL LABS	18-495	02-19-82				IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; POTASSIUM CHLORIDE; SODIUM CITRATE	33MG/100ML; 30MG/100ML; 860MG/100ML;	RINGER'S	TRAVENOL LABS	18-648	02-07-83				IN PLASTIC CONTAINER (INJECTABLE; INJECTION)
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; POTASSIUM CHLORIDE; SODIUM CITRATE	33MG/100ML; 30MG/100ML; 860MG/100ML;	RINGER'S	AM MCGAW/AM HOSP	18-721	11-09-82				IN PLASTIC CONTAINER (INJECTABLE; INJECTION)

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 105MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 105MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 179MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 179MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 254MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE SODIUM LACTATE 20MG/100ML; 5GM/100ML; 254MG/100ML; 600MG/100ML; 310MG/100ML	POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-367 04-05-85		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	APPLICANT NAME	NDA NO.	PATENT NO.	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	DOSAGE FORM: ROUTE
----------------------	-------------	------------	----------------	---------	------------	-------------	-----------	---------------	--------------------

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<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>
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
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	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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	TYMTTRAN (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	
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	MENRUM 5-2 (TABLET; ORAL)	HOFFMANN-LA ROCHE	14-740 10-27-69	4316897 02-23-99	

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	PATENT NO.	EXCLUSIVITY	STRENGTH(S)
		(DOSE/AGE FORM: ROUTE)		APPROVAL DATE	EXP. DATE	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<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>
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	CINOBAK (CAPSULE; ORAL)	ELI LILLY	18-067 06-13-80	3669965 06-13-89	
CINOXACIN 500MG	CINOBAK (CAPSULE; ORAL)	ELI LILLY	18-067 06-13-80	3669965 06-13-89	
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

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCLUSIVITY	EXP. DATE	PATENT NO.	APPROVAL DATE	TRADE NAME	DOSAGE FORM: ROUTE	APPLICANT NAME	NDA NO.
----------------------	-------------	-------------	-----------	------------	---------------	------------	--------------------	----------------	---------

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

PHENYLPROPAVOLAMINE HYDROCHLORIDE	50MG	ED 1MG BASE; 75MG	ND	09-24-86	01-20-93	3933999	12-15-82	DORSY LABS/SANDOZ	(TABLET, CONTROLLED RELEASE; ORAL)
-----------------------------------	------	-------------------	----	----------	----------	---------	----------	-------------------	------------------------------------

CLOMIPHENENE CITRATE	50MG	CLONAZEPAM	1MG	4316897	02-23-99	17-533	HOFMANN-LA ROCHE	CLONOPIN	(TABLET; ORAL)
----------------------	------	------------	-----	---------	----------	--------	------------------	----------	----------------

CLOMIPHENENE CITRATE	0.5MG	CLONAZEPAM	2MG	4316897	02-23-99	17-533	HOFMANN-LA ROCHE	CLONOPIN	(TABLET; ORAL)
----------------------	-------	------------	-----	---------	----------	--------	------------------	----------	----------------

CLOMIPHENENE CITRATE	1MG	CLONAZEPAM	2.5MG	4316897	02-23-99	17-533	HOFMANN-LA ROCHE	CLONOPIN	(TABLET; ORAL)
----------------------	-----	------------	-------	---------	----------	--------	------------------	----------	----------------

CLOMIPHENENE CITRATE	2.5MG	CLONAZEPAM	5MG	3454701	07-08-86	18-891	BOEHRINGER INGELHEIM	CATAPRES-TTS-2	(TABLET; ORAL)
----------------------	-------	------------	-----	---------	----------	--------	----------------------	----------------	----------------

CLOMIPHENENE CITRATE	5MG	CLONAZEPAM	5MG	3454701	07-08-86	18-891	BOEHRINGER INGELHEIM	CATAPRES-TTS-3	(TABLET; ORAL)
----------------------	-----	------------	-----	---------	----------	--------	----------------------	----------------	----------------

CLOMIPHENENE CITRATE	7.5MG	CLONIDINE HYDROCHLORIDE	0.1MG	3454701	07-08-86	17-407	BOEHRINGER INGELHEIM	CATAPRES	(TABLET; ORAL)
----------------------	-------	-------------------------	-------	---------	----------	--------	----------------------	----------	----------------

CLOMIPHENENE CITRATE	0.2MG	CLONIDINE HYDROCHLORIDE	0.2MG	3454701	07-08-86	17-407	BOEHRINGER INGELHEIM	CATAPRES	(TABLET; ORAL)
----------------------	-------	-------------------------	-------	---------	----------	--------	----------------------	----------	----------------

CLOMIPHENENE CITRATE	0.3MG	CLONIDINE HYDROCHLORIDE	0.3MG	3454701	07-08-86	17-407	BOEHRINGER INGELHEIM	CATAPRES	(TABLET; ORAL)
----------------------	-------	-------------------------	-------	---------	----------	--------	----------------------	----------	----------------

CLOMIPHENENE CITRATE	0.75MG	CLONAZEPATE DIPIOTASSIUM	3.75MG	RE28315	06-23-87	17-105	ABBOTT LABORATORIES	TRANXENE	(CAPSULE; ORAL)
----------------------	--------	--------------------------	--------	---------	----------	--------	---------------------	----------	-----------------

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
CLORAZEPATE DIPOTASSIUM 15MG	TRANXENE (CAPSULE; ORAL)	ABBOTT LABORATORIES	17-105 06-23-72	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 22.5MG	TRANXENE SD (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-31-75	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 11.25MG	TRANXENE SD (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 08-04-76	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 3.75MG	TRANXENE (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-10-80	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 7.5MG	TRANXENE (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-10-80	RE28315 06-23-87	
CLORAZEPATE DIPOTASSIUM 15MG	TRANXENE (TABLET; ORAL)	ABBOTT LABORATORIES	17-105 03-10-80	RE28315 06-23-87	
CLOTRIMAZOLE 1%	LOTRIMIN (SOLUTION; TOPICAL)	SCHERING	17-613 02-03-75	3660577 05-02-89 3705172 12-05-89 3839573 10-01-91	
CLOTRIMAZOLE 1%	LOTRIMIN (CREAM; TOPICAL)	SCHERING	17-619 03-18-75	3660577 05-02-89 3705172 12-05-89 3839573 10-01-91	
CLOTRIMAZOLE 1%	GYNE-LOTRIMIN (CREAM; VAGINAL)	SCHERING	18-052 11-08-78	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE 100MG	GYNE-LOTRIMIN (TABLET; VAGINAL)	SCHERING	17-717 03-24-76	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	

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

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
CLOTRIMAZOLE 1%	LOTRIMIN (LOTION; TOPICAL)	SCHERING	18-813 02-17-84	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE 10MG/5ML; 5MG/5ML; 6.25MG/5ML	PHENERGAN VC W/ CODEINE (SYRUP; ORAL)	WYETH LABS/AMHO	08-306 04-02-84		
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; TRIPLOROLIDINE HYDROCHLORIDE 10MG/5ML; 30MG/5ML; 1.25MG/5ML	ACTIFED W/ CODEINE (SYRUP; ORAL)	BURROUGHS WELLCOME	12-575 04-04-84		
COLESTIPOL HYDROCHLORIDE 5GM/PACKET	COlestid (GRANULE; ORAL)	UPJOHN	17-563 04-04-77	3692895 09-19-89	I-24 09-24-86
COLESTIPOL HYDROCHLORIDE 500GM/BOT	COlestid (GRANULE; ORAL)	UPJOHN	17-563 04-04-77	3692895 09-19-89	I-24 09-24-86
COPPER 89MG	CU-7 (INTRAUTERINE DEVICE; INTRAUTERINE)	SEARLE PHARMS	17-408 02-25-74	3563235 02-16-88 4040417 08-09-94 3783861 01-08-91 3803308 12-01-87 RE28399 04-29-92	

ACTIVE INGREDIENT(S)	STRENGTH(S)	COPPER 120MG	CROMOLYN SODIUM 20MG	CROMOLYN SODIUM 42	CROMOLYN SODIUM 42
TRADE NAME	DOSEAGE FORM, ROUTE	TATUM-T SERALE PHARMS	(CAPSULE; INHALATION)	NASALCROM 3686412	OPTICROM 3686412
EXC. NO.	APPLICANT NAME	FISONS	(SOLUTION: MASAL)	FISONS	(SOLUTION: OPTHALMIC)
EX.P. DATE	APPROVAL DATE	08-16-79	06-20-73	18-306	10-03-84
EX.P. DATE	APPROVAL DATE	02-16-88	09-24-86	09-24-86	10-03-87
08-09-94	4040417	3783861	3777033	3777033	3777033
01-08-91	3803308	01-08-91	08-22-89	08-22-89	08-22-89
0783861	042999	12-01-87	05-18-93	05-18-93	10-11-94
08-09-94	042999	12-01-87	3419578	3419578	3419578
01-08-91	3803308	3419578	3419578	3419578	3419578
3783861	3957965	3957965	3975536	3975536	3975536
08-09-94	042999	12-01-87	08-17-93	08-17-93	08-17-93
01-08-91	3803308	3803308	4053628	4053628	4053628
3783861	4053628	4053628	4053628	4053628	4053628
08-09-94	4040417	12-01-87	08-17-93	08-17-93	08-17-93
01-08-91	3803308	3803308	3975536	3975536	3975536
3783861	3975536	3975536	12-31-85	12-31-85	12-31-85
08-09-94	3975536	3975536	08-22-89	08-22-89	08-22-89
01-08-91	3975536	3975536	3777033	3777033	3777033
3783861	3777033	3777033	09-24-86	09-24-86	09-24-86
08-09-94	3777033	3777033	NDF	NDF	10-03-87

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION
 Digitized by Google

Original from
 UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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 10MG/ML	INTAL (SOLUTION; INHALATION)	FISONS	18-596 05-28-82	3686412 08-22-89 3777033 08-22-89 3419578 12-31-85 3975536 08-17-93	I-22 01-19-88
CYCLOBENZAPRINE HYDROCHLORIDE 5MG	FLEXERIL (TABLET; ORAL)	MS&D/MERCK	17-821 08-26-77	3454643 07-08-86 3882246 05-06-92	
CYCLOBENZAPRINE HYDROCHLORIDE 10MG	FLEXERIL (TABLET; ORAL)	MS&D/MERCK	17-821 08-26-77	3454643 07-08-86 3882246 05-06-92	
CYCLOPHOSPHAMIDE 1GM/VIAL	CYTOXAN (INJECTABLE; INJECTION)	MEAD JOHNSON/B-M	12-142 08-30-82		NS 09-24-86
CYCLOPHOSPHAMIDE 1GM/VIAL	NEOSAR (INJECTABLE; INJECTION)	ADRIA LABORATORIES	87-442 07-08-83		NS 09-24-86
CYCLOPHOSPHAMIDE 2GM/VIAL	CYTOXAN (INJECTABLE; INJECTION)	MEAD JOHNSON/B-M	12-142 08-30-82		NS 09-24-86
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	

ACTIVE INGREDIENT(S)	STRENGTH(S)	PATENT NO.	NDA NO.	APPLICANT NAME	TRADE NAME	EXPIRATION DATE	EXPIRATION DATE	EXPIRATION DATE	DANTROLENE SODIUM
DEFEROXAMINE MESYLATE	500MG/VIAL	3471476	16-267	CIBA/CIBA-GEIGY	DEFERAL MESYLADE (INJECTABLE; INJECTION)	04-01-68	10-07-86	07-08-86	DEFEROXAMINE HYDROCHLORIDE
DANTROLENE SODIUM	20MG/VIAL	3415821	18-264	NORMWICH EATON/P&G	DANTRUM (INJECTABLE; INJECTION)	09-18-79	12-10-85	07-08-86	DANTROLENE SODIUM
DESPIRAMINE HYDROCHLORIDE	25MG	345698	13-621	USV LABORATORIES	PERTOFRANE (CAPSULE; ORAL)	04-10-68	07-08-86	07-08-86	DESPIRAMINE HYDROCHLORIDE
DESPIRAMINE HYDROCHLORIDE	50MG	345698	13-621	USV LABORATORIES	PERTOFRANE (CAPSULE; ORAL)	04-10-68	07-08-86	07-08-86	DESPIRAMINE HYDROCHLORIDE
DESPIRAMINE HYDROCHLORIDE	25MG	345698	14-399	MERRELL DOW/DOW CHEM	NORPRAMIN (TABLET; ORAL)	11-20-64	07-08-86	07-08-86	DESPIRAMINE HYDROCHLORIDE
DESPIRAMINE HYDROCHLORIDE	50MG	345698	14-399	MERRELL DOW/DOW CHEM	NORPRAMIN (TABLET; ORAL)	01-09-67	07-08-86	07-08-86	DESPIRAMINE HYDROCHLORIDE
DESPIRAMINE HYDROCHLORIDE	75MG	345698	14-399	MERRELL DOW/DOW CHEM	NORPRAMIN (TABLET; ORAL)	03-01-77	07-08-86	07-08-86	DESPIRAMINE HYDROCHLORIDE
DESPIRAMINE HYDROCHLORIDE	100MG	345698	14-399	MERRELL DOW/DOW CHEM	NORPRAMIN (TABLET; ORAL)	03-01-77	07-08-86	07-08-86	DESPIRAMINE HYDROCHLORIDE
DESPIRAMINE HYDROCHLORIDE	150MG	345698	14-399	MERRELL DOW/DOW CHEM	NORPRAMIN (TABLET; ORAL)	03-01-77	07-08-86	07-08-86	DESPIRAMINE HYDROCHLORIDE

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<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>
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)	HOECHST-ROUSSEL	18-763 09-30-83		NDF 09-24-86
DEXAMETHASONE 6MG	DECADRON (TABLET; ORAL)	MS&D/MERCK	11-664 07-30-82		NS 09-24-86
DEXAMETHASONE 6MG	DEXAMETHASONE (TABLET; ORAL)	PAR PHARMACEUTICAL	88-481 11-28-83		NS 09-24-86
DEXAMETHASONE 6MG	DEXAMETHASONE (TABLET; ORAL)	ROXANE LABORATORIES	88-316 09-15-83		NS 09-24-86
DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE 15MG/5ML; 6.25MG/5ML	PHENERGAN W/ DEXTROMETHORPHAN (SYRUP; ORAL)	WYETH LABS/AMHO	11-265 04-02-84		
DEXTROSE 5GM/100ML	DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-466 07-15-85		

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	APPLICANT NAME	PATENT NO.	EXCUSIVITY	EXP. DATE	APPROVAL DATE	DOSAGE FORM; ROUTE)
DEXTRONE	60GM/100ML	TRAVENOL LABS	TRAVENOL LABS	17-521	03-26-82	(INJECTABLE; INJECTION)	03-26-82	DEXTRONE 60% IN PLASTIC CONTAINER
DEXTRONE	70GM/100ML	TRAVENOL LABS	TRAVENOL LABS	17-521	03-26-82	(INJECTABLE; INJECTION)	03-26-82	DEXTRONE 70% IN PLASTIC CONTAINER
DEXTRONE	30GM/100ML	ABBOOTT LABORATORIES	ABBOOTT LABORATORIES	19-345	01-25-85	(INJECTABLE; INJECTION)	01-25-85	DEXTRONE 30% IN PLASTIC CONTAINER
DEXTRONE	60GM/100ML	ABBOOTT LABORATORIES	ABBOOTT LABORATORIES	19-346	01-25-85	(INJECTABLE; INJECTION)	01-25-85	DEXTRONE 60% IN PLASTIC CONTAINER
DEXTRONE	70GM/100ML	ABBOOTT LABORATORIES	ABBOOTT LABORATORIES	17-521	03-26-82	(INJECTABLE; INJECTION)	03-26-82	DEXTRONE 70% IN PLASTIC CONTAINER
DEXTRONE	60GM/100ML	AM MCGRAW/AM HOSP	AM MCGRAW/AM HOSP	17-995	04-27-78	(INJECTABLE; INJECTION)	04-27-78	DEXTRONE 60% IN PLASTIC CONTAINER
DEXTRONE	60GM/100ML	AM MCGRAW/AM HOSP	AM MCGRAW/AM HOSP	17-995	04-27-78	(INJECTABLE; INJECTION)	04-27-78	DEXTRONE 60% IN PLASTIC CONTAINER
DEXTRONE	60GM/100ML	AM MCGRAW/AM HOSP	AM MCGRAW/AM HOSP	17-995	04-24-90	(INJECTABLE; INJECTION)	04-24-90	DEXTRONE 60% IN PLASTIC CONTAINER
DEXTRONE	70GM/100ML	ABBOOTT LABORATORIES	ABBOOTT LABORATORIES	18-561	03-23-82	(INJECTABLE; INJECTION)	03-23-82	DEXTRONE 70% IN PLASTIC CONTAINER
DEXTRONE	40GM/100ML	ABBOOTT LABORATORIES	ABBOOTT LABORATORIES	18-562	03-23-82	(INJECTABLE; INJECTION)	03-23-82	DEXTRONE 40% IN PLASTIC CONTAINER
DEXTRONE	50GM/100ML	ABBOOTT LABORATORIES	ABBOOTT LABORATORIES	18-563	03-23-82	(INJECTABLE; INJECTION)	03-23-82	DEXTRONE 50% IN PLASTIC CONTAINER
DEXTRONE	20GM/100ML	ABBOOTT LABORATORIES	ABBOOTT LABORATORIES	18-564	03-23-82	(INJECTABLE; INJECTION)	03-23-82	DEXTRONE 20% IN PLASTIC CONTAINER
DEXTRONE	38.5GM/100ML	ABBOOTT LABORATORIES	ABBOOTT LABORATORIES	18-923	09-19-84	(INJECTABLE; INJECTION)	09-19-84	DEXTRONE 38.5% IN PLASTIC CONTAINER

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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 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
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 200 UNITS/100ML	HEPARIN SODIUM 2,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-130 12-31-83		NC 09-24-86
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 1,000 UNITS/100ML	HEPARIN SODIUM 5,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-130 12-31-83		NC 09-24-86
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 4,000 UNITS/100ML	HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-814 10-31-83		NC 09-24-86

ACTIVE INGREDIENT(S)	STRENGTH(S)
TRADE NAME	DOSEAGE FORM; ROUTE
APPLICANT NAME	APPROVAL DATE
NDA NO.	EXP. DATE
EXCLUSIVITY	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-339 03-27-85		
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 800MG/100ML	LIDOCAINE HCL 0.8% IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-388 11-05-82	NS 09-24-86	
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 800MG/100ML	LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-461 02-22-82	NS 09-24-86	
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 200MG/100ML	LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-967 03-30-84	NS 09-24-86	
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 400MG/100ML	LIDOCAINE HCL 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-967 03-30-84	NS 09-24-86	
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 800MG/100ML	LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-967 03-30-84	NS 09-24-86	
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE DIBASIC; SODIUM ACETATE 5GM/100ML; 31MG/100ML; 130MG/100ML; 26MG/100ML; 320MG/100ML	ISOLYTE P W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-025 12-27-84		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCUSIVITY	PATENT NO.	TRADE NAME	APPLICANT NAME	DOSEAGE FORM: ROUTE	EXP. DATE	EXPIRY DATE
DEXTRONE: OXYTOCIN	5GM/100ML; 1 USP UNIT/100ML			OXYTOCIN 5 USP	ABBOTT LABORATORIES	UNITS IN DEXTROSE 5%	03-29-85	
DEXTRONE: OXYTOCIN	5GM/100ML; 1 USP UNIT/100ML			OXYTOCIN 10 USP	ABBOTT LABORATORIES	UNITS IN DEXTROSE 5%	03-29-85	
DEXTRONE: OXYTOCIN	5GM/100ML; 2 USP UNIT/100ML			OXYTOCIN 10 SP	ABBOTT LABORATORIES	UNITS IN DEXTROSE 5%	03-29-85	
DEXTRONE: OXYTOCIN	5GM/100ML; 2 USP UNIT/100ML			OXYTOCIN 20 USP	ABBOTT LABORATORIES	UNITS IN DEXTROSE 5%	03-29-85	
DEXTRONE: OXYTOCIN	5GM/100ML; 2 USP UNIT/100ML			OXYTOCIN 20 USP	ABBOTT LABORATORIES	UNITS IN DEXTROSE 5%	03-29-85	
DEXTRONE: POTASSIUM CHLORIDE	5GM/100ML; 150MG/100ML			AM MGAW/AM HOSP	AM MGAW/AM HOSP	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.15%	18-744	11-09-82
DEXTRONE: POTASSIUM CHLORIDE	5GM/100ML; 220MG/100ML			AM MGAW/AM HOSP	AM MGAW/AM HOSP	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.22%	18-744	11-09-82
DEXTRONE: POTASSIUM CHLORIDE	5GM/100ML; 300MG/100ML			AM MGAW/AM HOSP	AM MGAW/AM HOSP	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.3%	18-744	11-09-82
DEXTRONE: POTASSIUM CHLORIDE	5GM/100ML; 400MG/100ML			AM MGAW/AM HOSP	AM MGAW/AM HOSP	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.3%	18-744	11-09-82
SODIUM LACTATE: PHOSPHATE, MONOBASIC: SODIUM CHLORIDE; DEXTROSE: POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	5GM/100ML; 205MG/100ML; 100ML; 100ML/100ML			TRAVENOL LABS	DEXTROSE 5% AND ELECTROLYTE NO 75 IN PLASTIC CONTAINER (INDECTABLE: INJECTION)	DEXTROSE 5% AND ELECTROLYTE NO 75 IN PLASTIC CONTAINER (INDECTABLE: INJECTION)	18-840	06-29-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 75MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 900MG/100ML	POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-308 04-05-85		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVIE INGREDIENT(S) **STRENGTH(S)** **(DOSEAGE FORM: ROUTE)** **TRADE NAME** **APPLICANT NAME** **PATENT NO.** **NDA NO.** **APPROVAL DATE** **EXP. DATE** **EXC. DATE**

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 75MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 5MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 75MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	TRADE NAME	APP LICENT NAME	NDA NO.	PATENT NO.
----------------------	-------------	-------------	-----------	---------------	------------	-----------------	---------	------------

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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; 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		

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	DOSAGE FORM: ROUTE	APPLICATION NAME	NDA NO.	PATENT NO.	TRADE NAME
TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION									
DATAKIZONATE MEGULMINE	30%		09-24-86	01-040	(INDECTABLE; INJECTION)	ER SQUIBB AND SONS	10-040	RENODIP	RENOD-M-DIP
DATAKIZONATE MEGULMINE	52%: 8%		09-24-86	08-29-74	(INDECTABLE; INJECTION)	ER SQUIBB AND SONS	10-040	RENODIP-60	RENODRAPHIN-60
DATAKIZONATE MEGULMINE	66%; 10%		09-24-86	10-27-72	(INDECTABLE; INJECTION)	ER SQUIBB AND SONS	10-040	RENODRAPHIN-76	RENODRAPHIN-76
DIATRIZOATE MEGULMINE:	I-5								
DIATRIZOATE MEGULMINE: SODIUM									
DIATRIZOATE MEGULMINE: SODIUM									
DIAZEPAM	2MG								
DIAZEPAM	5MG/ML								
DIAZEPAM	10MG								
DIAZOXIDE	15MG/ML								
DI CYCLOMINE HYDROCHLORIDE	20MG								
BENTYL (CAPSULE; ORAL)									
MERRELL DOW/DOW CHEM	07-409		10-15-84						
BENTYL (CAPSULE; ORAL)	07-409		10-15-84						
MERRELL DOW/DOW CHEM	07-409		10-15-84						
SCHERING	16-996		01-22-73						
HYPERSSTAT (INJECTABLE; INJECTION)	1-1		09-24-86						
VALIUM (INJECTABLE; INJECTION)	16-087		08-24-66	4316897	02-23-99				
HOFMANN-LA ROCHE	16-087		08-24-66	4316897	02-23-99				
VALIUM (INJECTABLE; INJECTION)	16-087		08-24-66	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				
VALIUM (TABLET; ORAL)	13-263		11-15-63	4316897	02-23-99				
HOFMANN-LA ROCHE	13-263		11-15-63	4316897	02-23-99				

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
DICYCLOMINE HYDROCHLORIDE 10MG/ML	BENTYL (INJECTABLE; INJECTION)	MERRELL DOW/DOW CHEM	08-370 10-15-84		
DICYCLOMINE HYDROCHLORIDE 10MG/5ML	BENTYL (SYRUP; ORAL)	MERRELL DOW/DOW CHEM	07-961 10-15-84		
DIFLORASONE DIACETATE 0.05%	FLORONE (CREAM; TOPICAL)	UPJOHN	17-741 09-14-77	3980778 09-14-93	
DIFLORASONE DIACETATE 0.05%	FLORONE (OINTMENT; TOPICAL)	UPJOHN	17-994 03-01-78	3980778 09-14-93	
DIFLUNISAL 250MG	DOLOBID (TABLET; ORAL)	MS&D/MERCK	18-445 04-19-82	3714226 08-01-89 3674870 07-04-89	NCE 04-19-92
DIFLUNISAL 500MG	DOLOBID (TABLET; ORAL)	MS&D/MERCK	18-445 04-19-82	3714226 08-01-89 3674870 07-04-89	NCE 04-19-92
DIGOXIN 0.2MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82	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

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	DOSE/AGE FORM; ROUTE	APPLICANT NAME	NDA NO.	TRADE NAME
DIHYDROEROTAMINE MESYLATE;	7.46MG/0.7ML	NC	11-30-87	4451458	05-29-01	EMBOLIX (INJECTABLE; INJECTION)	18-885	SANDOZ PHARMS/SANDOZ
HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE	0.5MG/0.7ML; 5000 UNITS/0.7ML			4092949	09-06-00	CARDIZEM (TABLET; ORAL)	18-602	MARION LABORATORIES
DILTIAZEM HYDROCHLORIDE	60MG	NCE	11-05-92	3562257	02-09-88	CARDIZEM (TABLET; ORAL)	18-602	MARION LABORATORIES
DILTIAZEM HYDROCHLORIDE	30MG	NCE	11-05-92	3562257	02-09-88	CARDIZEM (TABLET; ORAL)	18-602	MARION LABORATORIES
DIMETHYL SULFOXIDE	50%	NCE	11-05-92	3549770	04-04-78	RIMS-50 (SOLUTION; URETHRAL)	17-788	RESEARCH INDUSTRIES
DINOPROST TRONETHAMINE	ED 5MG BASE/ML			3657327	04-18-87	PROSTIN F2 ALPHA (INJECTABLE; INJECTION)	17-434	UPJOHN
DINOPROSTONE	20MG			3899587	08-12-92	PROSTIN E2 (SUPPOSITORY; VAGINAL)	17-810	UPJOHN
OPIVAFERIN HYDROCHLORIDE	0.1%			3839584	10-02-80	PROLINE (SOLUTION; OPTHALMIC)	18-239	ALLERGAN PHARMS
DISOPYRAMIDE PHOSPHATE	ED 100MG BASE	NDF	09-24-86	18-655	07-20-82	NORPAC CR (CAPSULE, CONTROLLED RELEASE; ORAL)	18-655	SEARLE/SEARLE PHARMS
DISOPYRAMIDE PHOSPHATE	ED 150MG BASE	NDF	09-24-86	18-655	07-20-82	NORPAC CR (CAPSULE, CONTROLLED RELEASE; ORAL)	18-655	SEARLE/SEARLE PHARMS
DIVALPROEX SODIUM	ED 250MG BASE	NE	09-24-86	18-723	03-10-83	DEPAKOTE (TABLET, ENTERIC COATED; ORAL)	18-723	ABOTT LABORATORIES

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
DIVALPROEX SODIUM EQ 500MG BASE	DEPAKOTE (TABLET, ENTERIC COATED; ORAL)	ABBOTT LABORATORIES	18-723 03-10-83		NE 09-24-86
DOBUTAMINE HYDROCHLORIDE EQ 250MG BASE/VIAL	DOBUTREX (INJECTABLE; INJECTION)	ELI LILLY	17-820 07-18-78	3987200 10-19-93	
DOPAMINE HYDROCHLORIDE 80MG/ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 07-09-82		
DOPAMINE HYDROCHLORIDE 80MG/ML	DOPAMINE (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-398 03-22-82		
DOPAMINE HYDROCHLORIDE 40MG/ML	DOPAMINE HCL (INJECTABLE; INJECTION)	BRISTOL LABS/B-M	18-549 03-11-83		
DOPAMINE HYDROCHLORIDE 40MG/ML	DOPAMINE (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-656 06-28-83		
DOXEPIN HYDROCHLORIDE EQ 25MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 09-23-69	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 50MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 09-23-69	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 10MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 03-31-75	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 100MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 03-31-75	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 75MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 06-04-76	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 150MG BASE	SINEQUAN (CAPSULE; ORAL)	PFIZER LABS/PFIZER	16-798 03-15-78	3420851 01-07-86	
DOXEPIN HYDROCHLORIDE EQ 10MG BASE	ADAPIN (CAPSULE; ORAL)	PENNWALT PHARM	16-987 01-31-72	3420851 01-07-86	

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCUSIVITY	EXP. DATE	APPROVAL DATE	(DOSEAGE FORM; ROUTE)	APPLICANT NAME	NDA NO.	TRADE NAME
DOXEPIN HYDROCHLORIDE	EQ 25MG-BASE		01-07-86	3420851	(CAPSULE; ORAL)	ADAPIN	16-987	PENNWALT PHARM
DOXEPIN HYDROCHLORIDE	EQ 50MG BASE		01-07-86	3420851	(CAPSULE; ORAL)	ADAPIN	16-987	PENNWALT PHARM
DOXEPIN HYDROCHLORIDE	EQ 100MG BASE		01-07-86	3420851	(CAPSULE; ORAL)	ADAPIN	16-987	PENNWALT PHARM
DOXEPIN HYDROCHLORIDE	EQ 75MG BASE		01-07-86	3420851	(CAPSULE; ORAL)	ADAPIN	16-987	PENNWALT PHARM
DOXEPIN HYDROCHLORIDE	EQ 10MG BASE/ML		01-07-86	3420851	(CONCENTRATE; ORAL)	SINGULAN	17-516	PFIZER LABS/PFIZER
DRONABINOL	2.5MG		05-31-90	18-651	(CAPSULE; ORAL)	MARINOL	18-651	MARINOL
DRONABINOL	10MG		05-31-90	18-651	(CAPSULE; ORAL)	MARINOL	18-651	MARINOL
ECONAZOLE NITRATE	1%		02-20-90	3717655	(CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	18-751	SPECTACOLE
ENFLURANE	99.9%		10-01-91	3469011	(LIQUID; INHALATION)	ANADEST/B0C	17-087	ETHRANE
EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE	0.005MG/ML; 0.5%		09-08-87	3469011	(INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751	DURANEST

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<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>
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

ACTIVITIES INGR'DIENT(S) **STRENGTH(S)** **(OSAGE FORM: ROUTE)** **TRADE NAME** **APPLICANT NAME** **PATENT NO.** **NDA NO.** **EXCLUSIVITY** **EXP. DATE** **APPROVAL DATE** **EXP. DATE**

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<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>
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	

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCUSIVITY	EXP. DATE	APPROVAL DATE	DOSAGE FORM; ROUTE	APP LICANT NAME	NDA NO.	TRADE NAME
ETIDRONATE DISODIUM	400MG	09-24-86	NS	4254114	03-06-84	DIDRONEL	17-831	NORMWICH EATON/P&G
ETOMIDATE	2MG/ML	09-07-92	NCE	3524844	11-10-83	BRISTOL LABS/B-M	18-768	VEPSID
ETOPOSIDE	20MG/ML	11-10-93	NCE	08-18-87	11-10-83	AH ROBINS	16-618	PONDIMIN
FENFLURAMINE HYDROCHLORIDE	60MG	09-24-86	NDF	07-27-82	16-618	(TABLET, CONTROLLED RELEASE; ORAL)	07-27-82	(TABLET, CONTROLLED RELEASE; ORAL)
FENOPROFEN CALCIUM	EQ 300MG BASE	08-17-88	3600437	17-604	03-16-76	NALFON	17-710	(CAPSULE; ORAL)
FENOPROFEN CALCIUM	EQ 200MG BASE	08-17-88	3600437	17-604	03-16-76	NALFON 200	17-604	(CAPSULE; ORAL)
FENOPROFEN CALCIUM	EQ 600MG BASE	08-17-88	3600437	17-604	03-16-76	NALFON	17-710	(TABLET; ORAL)
FENTANYL CITRATE	ED 0.05MG BASE/ML	08-17-88	3600437	19-115	01-12-85	ABBOTT LABORATORIES	19-115	FENTANYL CITRATE
FENTANYL CITRATE	ED 0.05MG BASE/ML	08-17-88	3600437	19-101	07-11-84	ELKINS-SINN/ARROBINS	19-101	(INJECTABLE; INJECTION)
FUMETHASONE PIVALATE	0.03%	03-03-87	3499016	16-379	09-16-69	CIBA/CIBA-GEIGY	16-379	(CREAM; TOPICAL)
FLUNISOLIDE	0.025MG/INH	09-24-86	NDF	18-340	08-17-84	SYNTEX LABS/SYNTEX	18-340	(AEROSOL; INHALATION)

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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		

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCUSIVITY	EXP. DATE	APPRAVAL DATE	DOSAGE FORM; ROUTE	APPLICANT NAME	NDA NO.	PATENT NO.	TRADE NAME
FUROSEMIDE	40MG				(TABLET; ORAL)	ZENTHI LABORATORIES	18-413	11-30-83	FUROSEMIDE
FUROSEMIDE	20MG				(TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-415	07-27-82	FUROSEMIDE
FUROSEMIDE	40MG				(TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-415	07-27-82	FUROSEMIDE
FUROSEMIDE	80MG				(TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-419	01-31-83	FUROSEMIDE
FUROSEMIDE	20MG				(TABLET; ORAL)	PARKE-DAVIS/W-L	18-419	01-31-83	FUROSEMIDE
FUROSEMIDE	40MG				(TABLET; ORAL)	PARKE-DAVIS/W-L	18-419	01-31-83	FUROSEMIDE
FUROSEMIDE	80MG				(TABLET; ORAL)	PARKE-DAVIS/W-L	18-419	01-31-83	FUROSEMIDE
FUROSEMIDE	10MG/ML				(INJECTABLE; INJECTION)	PARKE-DAVIS/W-L	18-420	02-26-82	FUROSEMIDE
FUROSEMIDE	10MG/ML				(INJECTABLE; INJECTION)	LYPHOME	18-507	07-30-82	FUROSEMIDE
FUROSEMIDE	80MG				(INJECTABLE; INJECTION)	CORD LABORATORIES	18-569	08-14-84	FUROSEMIDE
FUROSEMIDE	10MG/ML				(INJECTABLE; INJECTION)	NATCON	18-579	11-30-83	FUROSEMIDE
FUROSEMIDE	10MG/ML				(INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-667	05-28-82	FUROSEMIDE
FUROSEMIDE	10MG/ML				(INJECTABLE; INJECTION)	WEYH LABS/AMHO	18-670	07-20-82	FUROSEMIDE
FUROSEMIDE	40MG				(TABLET; ORAL)	DRUMMER/PHONEIX	18-750	07-30-84	FUROSEMIDE

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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		

ACTIVE INGREDIENT(S)

STRENGTH(S)	EXCUSIVITY	EXP. DATE	PATENT NO.	APPLICANT NAME	NDA NO.	TRADE NAME	(DOSEAGE FORM; ROUTE)
GEMFIBROZIL 200MG	07-04-69	36740836	18-422	PARK-E-DAVIS/W-L	(CAPSULE; ORAL)	LOPIDO	(CAPSULE; ORAL)
GEMFIBROZIL 300MG	07-04-69	36740836	18-422	PARK-E-DAVIS/W-L	(CAPSULE; ORAL)	LOPIDO	(CAPSULE; ORAL)
GLIPIZIDE 5MG	05-08-94	36699966	17-783	ROERIG/PFIZER	(TABLET; ORAL)	GLUCOTROL	GLIPIZIDE 10MG
GLIPIZIDE 12.5MG	05-08-94	36699966	17-783	ROERIG/PFIZER	(TABLET; ORAL)	GLUCOTROL	GLIPIZIDE 2.5MG
GLYBURIDE 2.5MG	05-01-94	3426067	17-498	UPJOHN	(TABLET; ORAL)	MICRONASE	GLYBURIDE 5MG
GLYBURIDE 5MG	05-01-94	3426067	17-498	UPJOHN	(TABLET; ORAL)	MICRONASE	GLYBURIDE

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCUSIVITY	EXP. DATE	APPROVAL DATE	(DOSEAGE FORM: ROUTE)	APP LICANT NAME	NDA NO.	TRADE NAME
GONADORELIN HYDROCHLORIDE	EQ 0.2MG BASE/VIAL	NCE	09-30-92	09-30-93	03-30-93	AYERS LABS/AMHO	18-123	FACTEL
GONADORELIN HYDROCHLORIDE	EQ 0.5MG BASE/VIAL	NCE	09-30-92	09-30-93	03-30-93	AYERS LABS/AMHO	18-123	FACTEL
GONADOTROPIN, CHORIONIC	2,000 UNITS/VIAL	NCE	08-29-95	08-29-95	08-29-95	CARTER-GLOGAU LABS	17-016	CHORIONIC GONADOTROPIN (INJECTABLE; INJECTION)
GONADOTROPIN, CHORIONIC	15,000 UNITS/VIAL	NCE	08-29-95	08-29-95	02-15-84	CARTER-GLOGAU LABS	17-016	CHORIONIC GONADOTROPIN (INJECTABLE; INJECTION)
GUANABENZ ACETATE	EQ 4MG BASE	NCE	09-07-92	09-07-89	04-25-89	WETH LABS/AMHO	18-587	WYETHIN
GUANABENZ ACETATE	EQ 8MG BASE	NCE	09-07-92	09-07-89	04-25-89	WETH LABS/AMHO	18-587	WYETHIN
GUNARDREL SULFATE	10MG	NCE	12-29-92	12-29-87	18-104	HYDREL	17-736	(TABLET; ORAL)
GUNARDREL SULFATE	25MG	NCE	12-29-92	12-29-87	3547951	HYDREL	17-736	(TABLET; ORAL)
HALAZEPAM	20MG	NCE	12-29-92	12-29-87	3429874	PAXIPEM	17-736	(TABLET; ORAL)
HALAZEPAM	40MG	NCE	02-25-86	02-25-86	09-24-81	PAXIPEM	17-736	(TABLET; ORAL)

TABLE IV. NDA'S APPROVED FROM 1-1-62 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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		

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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 25000 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		

TABLE IV. NOA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NOA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
HYDROCORTISONE ACETATE 10%	CORTIFOAM (AEROSOL; RECTAL)	REED&CARNRICK PHARMS	17-351 02-10-82		NDF 09-24-86
HYDROCORTISONE BUTYRATE 0.1%	LOCOID (CREAM; TOPICAL)	OWEN LABS/DERM PRODS	18-795 01-07-83		NP 09-24-86
HYDROCORTISONE BUTYRATE 0.1%	LOCOID (OINTMENT; TOPICAL)	OWEN LABS/DERM PRODS	19-106 07-03-84		NP 09-24-86
HYDROCORTISONE VALERATE 0.2%	WESTCORT (OINTMENT; TOPICAL)	WESTWOOD PHARMS	18-726 08-08-83		NDF 09-24-86
HYDROMORPHONE HYDROCHLORIDE 10MG/ML	DILAUDID-HP (INJECTABLE; INJECTION)	KNOLL PHARMACEUTICAL	19-034 01-11-84		NCE 01-11-94
HYDROXYUREA 500MG	HYDREA (CAPSULE; ORAL)	ER SQUIBB AND SONS	16-295 12-07-67	3968249 07-06-93	
IBUPROFEN 400MG	MOTRIN (TABLET; ORAL)	UPJOHN MANUFACTURING	17-463 09-19-74		I-2 09-24-86
IBUPROFEN 300MG	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

ACTIVE INGREDIENT(S)	STRENGTH(S)	PATENT NO.	EXPI. DATE	EXCLUSIVITY	TRADE NAME	APPLICANT NAME	(DOSEAGE FORM; ROUTE)	APPROVAL DATE	EXP. DATE	EXCLUSIVITY
INDOMETACIN	75MG	4173626	11-06-96	NDF	INDOCIN SR	MSD RES LABS/MERCK	18-185 (CAPSULE; CONTROLLED RELEASE; ORAL)	02-23-82	09-24-86	
INDOMETACIN	25MG	INDOCIN	CHELSEA LABORATORIES	07-31-84	INDOMETACIN	CHELSEA LABORATORIES	18-690 (CAPSULE; ORAL)	07-31-84	07-31-84	50MG
INDOMETACIN	25MG	INDOCIN	CHELSEA LABORATORIES	07-31-84	INDOMETACIN	CHELSEA LABORATORIES	18-690 (CAPSULE; ORAL)	07-31-84	07-31-84	50MG
INDOMETACIN	50MG	INDOCIN	ZENITH LABORATORIES	05-04-84	INDOMETACIN	ZENITH LABORATORIES	18-730 (CAPSULE; ORAL)	05-04-84	05-04-84	50MG
INDOMETACIN	50MG	INDOCIN	ZENITH LABORATORIES	05-04-84	INDOMETACIN	ZENITH LABORATORIES	18-730 (CAPSULE; ORAL)	05-04-84	05-04-84	50MG
INDOMETACIN	25MG	INDOCIN	ZENITH LABORATORIES	05-04-84	INDOMETACIN	ZENITH LABORATORIES	18-730 (CAPSULE; ORAL)	05-04-84	05-04-84	50MG
INDOMETACIN	50MG	INDOCIN	PAR PHARMACEUTICAL	08-06-84	INDOMETACIN	PAR PHARMACEUTICAL	18-829 (CAPSULE; ORAL)	08-06-84	08-06-84	25MG
INDOMETACIN	50MG	INDOCIN	PAR PHARMACEUTICAL	08-06-84	INDOMETACIN	PAR PHARMACEUTICAL	18-829 (CAPSULE; ORAL)	08-06-84	08-06-84	50MG
INDOMETACIN	25MG	INDOCIN	LEDERLE LABS/AM CYAN	05-18-84	INDOMETACIN	LEDERLE LABS/AM CYAN	18-851 (CAPSULE; ORAL)	05-18-84	05-18-84	25MG
INDOMETACIN	50MG	INDOCIN	LEDERLE LABS/AM CYAN	05-18-84	INDOMETACIN	LEDERLE LABS/AM CYAN	18-851 (CAPSULE; ORAL)	05-18-84	05-18-84	50MG
INDOMETACIN	25MG	INDOCIN	MYLAN PHARMS	04-20-84	INDOMETACIN	MYLAN PHARMS	18-858 (CAPSULE; ORAL)	04-20-84	04-20-84	50MG
INDOMETACIN	50MG	INDOCIN	MYLAN PHARMS	04-20-84	INDOMETACIN	MYLAN PHARMS	18-858 (CAPSULE; ORAL)	04-20-84	04-20-84	25MG
INDOMETACIN	25MG	INDOCIN	MYLAN PHARMS	04-20-84	INDOMETACIN	MYLAN PHARMS	18-858 (CAPSULE; ORAL)	04-20-84	04-20-84	50MG
INDOMETACIN	50MG	INDOCIN	MYLAN PHARMS	04-20-84	INDOMETACIN	MYLAN PHARMS	18-858 (CAPSULE; ORAL)	04-20-84	04-20-84	25MG
INDOMETACIN	25MG	INDOCIN	PARKE-DAVIS/W-L	11-23-84	INDOMETACIN	PARKE-DAVIS/W-L	18-806 (CAPSULE; ORAL)	11-23-84	11-23-84	50MG
INDOMETACIN	50MG	INDOCIN	PARKE-DAVIS/W-L	11-23-84	INDOMETACIN	PARKE-DAVIS/W-L	18-806 (CAPSULE; ORAL)	11-23-84	11-23-84	25MG
INDOMETACIN	25MG	INDOCIN I. V.	MSD/MERCK	18-878	INDOCIN I. V.	MSD/MERCK	01-30-85 (INJECTABLE; INJECTION)			EQ 10 MG BASE/5ML

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
IODAMIDE MEGLUMINE 24%	RENOVUE-DIP (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-903 07-10-78		I-6 09-24-86
IODAMIDE MEGLUMINE 65%	RENOVUE-65 (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-902 07-24-78		I-6 09-24-86
IODOHIPPURATE SODIUM, I-123 1MCi/ML	NEPHROFLOW (INJECTABLE; INJECTION)	MEDI-PHYSICS	18-289 12-28-84		NCE 12-28-89
1ODOXAMATE MEGLUMINE 9.9%	CHOLOVUE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	18-076 08-14-81	3654272 04-04-89	
1ODOXAMATE MEGLUMINE 40.3%	CHOLOVUE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	18-077 08-14-81	3654272 04-04-89	
IOXAGLATE MEGLUMINE; IOXAGLATE SODIUM 39.3%; 19.6%	HEXBRIX (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	ACUTANE (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	ACUTANE (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

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCLUSIVITY	EXP. DATE	DOSAGE FORM; ROUTE	APPROVAL DATE	PATENT NO.	NDA NO.	APPLICANT NAME	TRADE NAME	ACQUISITION	40MG	KETOCONAZOLE
ISOTRETINOIN			05-07-92	(CAPSULE; ORAL)	4200647	04-29-97	05-07-82	HOFMANN-LA ROCHE	HOFFMANN-LA ROCHE	ACQUISITION		200MG
				03-30-99		4322438		JANSEN PHARMA	NIZORAL	(TABLET; ORAL)	08-01-94	LABETALOL HYDROCHLORIDE
				04-064394		08-07-01				08-01-94	300MG	
				06-15-99		4335125	I-25			08-01-94	400MG	
				06-12-81		4012444	08-01-84	SCHERING	NORMODYNE	(TABLET; ORAL)	08-01-94	LABETALOL HYDROCHLORIDE
				08-01-84		4012444	08-01-84	SCHERING	NORMODYNE	(TABLET; ORAL)	08-01-94	500ML
				01-066755		01-03-95				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		100MG
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCHLORIDE
				01-03-95		4066755				01-03-95		200MG
				01-03-95		4066755				01-03-95		LABETALOL HYDROCH

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
LABETALOL HYDROCHLORIDE 300MG	TRANDATE (TABLET; ORAL)	GLAXO	18-716 08-01-84	4012444 03-15-94 4066755 01-03-95	NCE 08-01-94
LABETALOL 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 (TABLE; ORAL)	MILES PHARMS/MILES	18-833 07-18-85		
LITHIUM CARBONATE 300MG	LITHIUM CARBONATE (TABLET; ORAL)	ROXANE LABORATORIES	18-558 01-29-82		

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	NDA No.	APPLICANT NAME	TRADE NAME	DOSAGE FORM: ROUTE
----------------------	-------------	-------------	-----------	---------------	---------	----------------	------------	--------------------

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 7-31-88 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

LITHIUM CARBONATE	450MG	ESKALITH CR (TABLET, CONTROLLED RELEASE; ORAL)	03-29-82	18-152	SK&F LABORATORIES	APPLICANT NAME	TRADE NAME	DOSAGE FORM: ROUTE
LOPERAMIDE HYDROCHLORIDE	2MG	IMODIUM (CAPSULE; ORAL)	17-694	3714159	I-30	01-30-90	09-24-86	
LOPERAMIDE HYDROCHLORIDE	1MG/5ML	IMODIUM (SOLUTION; ORAL)	19-037	3714159	07-31-84	01-30-90	NDF	09-24-86
LORAZEPAM	2MG/ML	ATIVAN (INJECTABLE; INJECTION)	18-140	4017616	07-25-80	4017616	04-12-94	
LORAZEPAM	4MG/ML	ATIVAN (INJECTABLE; INJECTION)	18-140	4017616	07-25-80	4017616	04-12-94	
LOXAPLINE HYDROCHLORIDE	ED 50MG BASE/ML	LOXITANE (INJECTABLE; INJECTION)	18-039	3546226	10-26-79	3546226	12-08-87	
LOXAPLINE HYDROCHLORIDE	ED 25MG BASE/ML	LOXITANE (CONCENTRATE; ORAL)	17-658	3546226	05-04-76	3546226	12-08-87	
LOXAPLINE SUCINATE	ED 10MG BASE	LOXITANE (CAPSULE; ORAL)	17-525	3546226	10-25-75	3546226	12-08-87	
LOXAPLINE SUCINATE	ED 25MG BASE	LOXITANE (CAPSULE; ORAL)	17-525	3546226	02-25-75	3546226	12-08-87	
LOXAPLINE SUCINATE	ED 50MG BASE	LOXITANE (CAPSULE; ORAL)	17-525	3546226	02-25-75	3546226	12-08-87	
LOXAPLINE SUCINATE	ED 85MG BASE/GM	SULFAMYLYON (CREAM; TOPICAL)	16-763	3497599	01-24-69	3497599	01-26-88	
MAGNESIUM ACETATE TETRAHYDRATE: POTASSIUM	32MG/100ML	PLASMA-LYTE 5% IN PLASTIC CONTAINER	19-047	06-15-84	06-15-84	06-15-84	09-24-86	NC

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE; SODIUM PHOSPHATE 30MG/100ML; 37MG/100ML; 0.82MG/100ML; 370MG/100ML; 530MG/100ML; 500MG/100ML; 12MG/100ML	ISOLYTES PH 7.4 IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-006 04-04-84		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	

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA NO.	PATENT NO.	EXPIRATION DATE	EXP. DATE	EXCLUSIVITY	STRENGTH(S)
----------------------	------------	----------------	---------	------------	-----------------	-----------	-------------	-------------

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

ACTIVE INGREDIENT(S)	STRENGTH(S)	PATENT NO.	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	TRADE NAME	APPLICANT NAME	DOSAGE FORM: ROUTE	APP LICANT NAME	APPROVAL DATE	EXP. DATE	STRENGTH(S)
METRIZAMIDE	3.75GM/VIAL	3701771	I-26	09-24-86	10-31-89	3701771	WINTHROP LABS/STERL	08-23-78	AMIPROUE	(INJECTABLE; INJECTION)	17-982	METRONDIAZOLE
METRIZAMIDE	6.75GM/VIAL	3701771	I-26	09-24-86	10-31-89	3701771	WINTHROP LABS/STERL	08-23-78	AMIPROUE	(INJECTABLE; INJECTION)	17-982	METRONDIAZOLE
METRIZAMIDE	3.75GM/VIAL	3701771	I-26	09-24-86	10-31-89	3701771	ZENTHY LABORATORIES	05-05-82	METRONDIAZOLE	(TABLET; ORAL)	18-517	METRONDIAZOLE
METRIZAMIDE	500MG	3701771	I-26	09-24-86	10-31-89	3701771	ZENTHY LABORATORIES	05-05-82	METRONDIAZOLE	(TABLET; ORAL)	18-517	METRONDIAZOLE
METRIZAMIDE	500MG	3701771	I-26	09-24-86	10-31-89	3701771	CHELSA LABORATORIES	18-599	METRONDIAZOLE	(TABLET; ORAL)	02-13-84	METRONDIAZOLE
METRIZAMIDE	250MG	3701771	I-26	09-24-86	10-31-89	3701771	CHELSA LABORATORIES	18-599	METRONDIAZOLE	(TABLET; ORAL)	09-17-82	METRONDIAZOLE
METRIZAMIDE	250MG	3701771	I-26	09-24-86	10-31-89	3701771	CHELSA LABORATORIES	18-599	METRONDIAZOLE	(TABLET; ORAL)	09-17-82	METRONDIAZOLE
METRIZAMIDE	500MG	3701771	I-26	09-24-86	10-31-89	3701771	ZENTHY LABORATORIES	05-05-82	METRONDIAZOLE	(TABLET; ORAL)	18-517	METRONDIAZOLE
METRIZAMIDE	250MG	3701771	I-26	09-24-86	10-31-89	3701771	ZENTHY LABORATORIES	05-05-82	METRONDIAZOLE	(TABLET; ORAL)	18-517	METRONDIAZOLE
METRIZAMIDE	500MG	3701771	I-26	09-24-86	10-31-89	3701771	CHELSA LABORATORIES	18-599	METRONDIAZOLE	(TABLET; ORAL)	02-13-84	METRONDIAZOLE
METRIZAMIDE	250MG	3701771	I-26	09-24-86	10-31-89	3701771	DRUMMER/PHOENIX	18-620	METRYL 500	(TABLET; ORAL)	03-04-82	METRONDIAZOLE
METRIZAMIDE	500MG	3701771	I-26	09-24-86	10-31-89	3701771	DRUMMER/PHOENIX	18-620	METRYL 500	(TABLET; ORAL)	06-02-83	METRONDIAZOLE
METRIZAMIDE	500MG/100ML	3701771	I-26	09-24-86	10-31-89	3701771	AM MGAW/AM HOSP	18-674	METRO I.V.	(INJECTABLE; INJECTION)	08-31-82	METRONDIAZOLE
METRIZAMIDE	250MG	3701771	I-26	09-24-86	10-31-89	3701771	AM MGAW/AM HOSP	18-674	METRO I.V.	(INJECTABLE; INJECTION)	08-31-82	METRONDIAZOLE
METRIZAMIDE	500MG	3701771	I-26	09-24-86	10-31-89	3701771	CORD LABORATORIES	18-740	METRONDIAZOLE	(TABLET; ORAL)	10-22-82	METRONDIAZOLE
METRIZAMIDE	250MG	3701771	I-26	09-24-86	10-31-89	3701771	CORD LABORATORIES	18-740	METRONDIAZOLE	(TABLET; ORAL)	10-22-82	METRONDIAZOLE
METRIZAMIDE	500MG	3701771	I-26	09-24-86	10-31-89	3701771	DANBURY PHARMACAL	18-764	METRONDIAZOLE	(TABLET; ORAL)	09-17-82	METRONDIAZOLE
METRIZAMIDE	250MG	3701771	I-26	09-24-86	10-31-89	3701771	DANBURY PHARMACAL	18-764	METRONDIAZOLE	(TABLET; ORAL)	12-20-82	METRONDIAZOLE
METRIZAMIDE	500MG	3701771	I-26	09-24-86	10-31-89	3701771	BARR LABORATORIES	18-818	METRONDIAZOLE	(TABLET; ORAL)	02-16-83	METRONDIAZOLE

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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		

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXPIRY DATE	PATENT NO.	NDA NO.	APPLICANT NAME	TRADE NAME	(DOSEAGE FORM: ROUTE)	APPRAVAL DATE	EXP. DATE	EXCLUSIVITY
TABLE IV. NDAs APPROVED FROM 1-1-82 TO 7-31-85 AND NDAs WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION										
METRONIDAZOLE HYDROCHLORIDE	ED 500MG BASE/VIAL	I-11	12-20-87	18-353	SERALE PHARMS	FLAGYL I.V.	(INJECTABLE; INJECTION)	10-04-78	3717655	09-24-86
MICONAZOLE	10MG/ML	I-27	10-01-91	17-450	ORTHO PHARMACEUTICAL	MONISTAT 7	(CREAM; VAGINAL)	01-30-74	3717655	02-20-90
MICONAZOLE NITRATE	2%	10-01-91	10-01-91	17-494	ORTHO PHARMACEUTICAL	MONISTAT-DEM	(CREAM; TOPICAL)	01-30-74	3717655	02-20-90
MICONAZOLE NITRATE	2%	10-01-91	10-01-91	17-739	ORTHO PHARMACEUTICAL	MONISTAT-DEM	(LOTION; TOPICAL)	12-16-75	3717655	02-20-90
MICONAZOLE NITRATE	100MG	9-24-86	10-01-91	3717655	ORTHO PHARMACEUTICAL	MONISTAT 7	(SUPPOSITORY; VAGINAL)	03-15-82	3717655	02-20-90
MICONAZOLE NITRATE	200MG	NS	10-01-91	3717655	ORTHO PHARMACEUTICAL	MONISTAT 3	(SUPPOSITORY; VAGINAL)	08-15-84	3717655	02-20-90
MINOXIDIL	2.5MG	09-24-86	10-01-91	18-154	UPJOHN	LONITEN	(TABLET; ORAL)	3461461	08-12-86	

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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	

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	NDI NO.	APP LICENT NAME	TRADE NAME	DOSAGE FORM: ROUTE
----------------------	-------------	-------------	-----------	---------------	---------	-----------------	------------	--------------------

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
NALIDIXIC ACID 250MG/5ML	NEGRAM (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 06-14-82		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	NS 09-24-86
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	

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	APPLICANT NAME	PATENT NO.	MDA NO.	EXPI. DATE	EXP. DATE	APPROVAL DATE	DISPENSE FORM: ROUTE)
NAPROXEN	375MG	NAPROSYN	SYNTEX PR	17-581	3904682	09-09-92	09-09-92	07-18-80	(TABLET; ORAL)
NAPROXEN	500MG	NAPROSYN	SYNTEX PR	17-581	3904682	09-09-92	09-09-92	04-15-82	(TABLET; ORAL)
NAPROXEN	500MG	NAPROSYN	SYNTEX PR	17-581	3904682	09-09-92	09-09-92	04-09-82	(TABLET; ORAL)
NAPROXEN SODIUM	275MG	AMAPROX	SYNTEX PR	18-164	3998966	09-09-92	09-09-92	09-04-80	(TABLET; ORAL)
NICLOSAMIDE	500MG	NICLOCIDE	MILES PHARMS/MILES	18-669	05-14-82	05-14-92	NCE	05-14-82	(TABLET, CHEWABLE; ORAL)
NICOTINE RESIN COMPLEX	EQ 2MG BASE	NICORETTE	MERRELL DOW/DOW CHEM	18-612	01-13-84	NCE	01-13-94	01-13-84	(GUM, CHEWING; ORAL)
NIFEDIPINE	10MG	NIFFERIDIA	Pfizer LABS/Pfizer	18-482	3644627	02-22-89	02-22-89	12-31-81	(CAPSULE; ORAL)
NITROGLYCERIN	0.5MG/ML	TRIDIL	AM CRITICAL CARE/AHS	18-537	06-16-83	NDF	09-24-86	06-16-83	(INJECTABLE; INJECTION)
NITROGLYCERIN	5MG/ML	NITROSTAT	PARKER-DAVIS/W-L	18-588	12-23-83	NDF	09-24-86	12-23-83	(INJECTABLE; INJECTION)

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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)	KREMERS-URBAN	18-774 01-19-83		NDF 09-24-86
NOMIFENSINE MALEATE 25MG	MERITAL (CAPSULE; ORAL)	HOECHST-ROUSSEL	18-224 12-31-84		NCE 12-31-89
NOMIFENSINE MALEATE 50MG	MERITAL (CAPSULE; ORAL)	HOECHST-ROUSSEL	18-224 12-31-84		NCE 12-31-89
NORETHINDRONE ACETATE 5MG	AYGESTIN (TABLET; ORAL)	AYERST LABS/AMHO	18-405 04-21-82		
NORGESTREL 0.075MG	OVRETTE (TABLET; ORAL)	WYETH LABS/AMHO	17-031 18-23-73	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	

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXPI. DATE	EXCLUSIVITY	PATENT NO.	NDA NO.	APPLICANT NAME	DOSAGE FORM; ROUTE	APPROVAL DATE	EXP. BASE
----------------------	-------------	------------	-------------	------------	---------	----------------	--------------------	---------------	-----------

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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 IMCI/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

ACTIVE INGREDIENT(S)	STRENGTH(S)	TRADE NAME	APPLICATION NAME	PATENT NO.	APPROVAL DATE	EXP. DATE	EXCLUSIVITY
PINDOLOL	15MG	VISKEN	(TABLET; ORAL)	18-285	09-03-82	3471515	NCE 09-03-92
PIROXICAM	10MG	PFIZER LABS/PFIZER	FELDENE (CAPSULE; ORAL)	18-147	04-06-82	3591584	NCE 04-06-92
PIROXICAM	20MG	PFIZER LABS/PFIZER	FELDENE (CAPSULE; ORAL)	18-147	04-06-82	3591584	NCE 04-06-92
POLYETHYLENE GLYCOL 3350;	12-10-91	BRAINTREE LABS	GOLTYELY (POWDER FOR RECONSTITUTION; ORAL)	19-011	07-13-84	RE29668	SODIUM CHLORIDE; SODIUM BICARBONATE; SODIUM SULFATE; 236GM/BOT; 2.976M/BOT; 6.746M/BOT; 5.866M/BOT; 22.746M/BOT;

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION
 Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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	

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXPI. DATE	EXCLUSIVITY	PATENT NO.	NDA NO.	APPLICANT NAME	TRADE NAME	(DOSEAGE FORM; ROUTE)	APPROVAL DATE	EXP. DATE
POLYTHIAZIDE; PRAZOSEN HYDROCHLORIDE	0.5MG; 2MG	05-12-87	3663706	3511836	06-13-80	PFIZER LABS/PFIZER	MINIZIDE	(CAPSULE; ORAL)	17-986	06-13-80
POLYTHIAZIDE; PRAZOSEN HYDROCHLORIDE	0.5MG; 5MG	05-16-89	3663706	4130647	12-19-95	PFIZER LABS/PFIZER	MINIZIDE	(CAPSULE; ORAL)	17-986	05-12-87
POLYTHIAZIDE; PRAZOSEN HYDROCHLORIDE	0.5MG; 5MG	05-16-89	3663706	4130647	12-19-95	PFIZER LABS/PFIZER	MINIZIDE	(CAPSULE; ORAL)	17-986	06-13-80
POTASSIUM ACETATE	2MEQ/ML	09-24-86	NDF	POTASSIUM ACETATE IN PLASTIC CONTAINER	ABBOTT LABORATORIES	AH ROBINS	POTASSIUM CHLORIDE	(INJECTABLE; INJECTION)	18-896	07-20-84
POTASSIUM CHLORIDE	8MEQ	03-31-98	4259315	POTASSIUM CHLORIDE (CAPSULE, CONTROLLED RELEASE; ORAL)	AH ROBINS	AH ROBINS	POTASSIUM CHLORIDE	(CAPSULE, CONTROLLED RELEASE; ORAL)	18-238	10-17-80
POTASSIUM CHLORIDE	10MEQ	03-31-98	4259315	POTASSIUM CHLORIDE (CAPSULE, CONTROLLED RELEASE; ORAL)	MICRO-K	MICRO-K	POTASSIUM CHLORIDE	(CAPSULE, CONTROLLED RELEASE; ORAL)	18-238	10-17-80
POTASSIUM CHLORIDE	10MEQ	03-31-98	4140756	KLOTRIX	MEAD JOHNSON/B-M	KLOTRIX	POTASSIUM CHLORIDE	(TABLET, CONTROLLED RELEASE; ORAL)	17-850	05-22-80
POTASSIUM CHLORIDE	150MG/100ML; 900MG/100ML	02-20-96	4140756	TRAVENOL LABS	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 10MEQ	TRAVENOL LABS	POTASSIUM CHLORIDE	(INJECTABLE; INJECTION)	18-630	02-17-83
POTASSIUM CHLORIDE	300MG/100ML; 900MG/100ML	02-17-83	02-17-83	TRAVENOL LABS	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 20MEQ	TRAVENOL LABS	POTASSIUM CHLORIDE	(INJECTABLE; INJECTION)	18-630	02-17-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S)</u> <u>STRENGTH(S)</u>	<u>TRADE NAME</u> <u>(DOSE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO.</u> <u>APPROVAL DATE</u>	<u>PATENT NO.</u> <u>EXP. DATE</u>	<u>EXCLUSIVITY</u> <u>EXP. DATE</u>
POTASSIUM CHLORIDE; SODIUM CHLORIDE 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		
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 12-13-82		NDF 09-24-86
PRAZEPAM 20MG	CENTRAX (CAPSULE; ORAL)	PARKE-DAVIS/W-L	18-144 05-10-82		NS 09-24-86
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 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
PROPRANOLOL HYDROCHLORIDE 60MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 10-18-82		NS 09-24-86 I-15 09-24-86
PROPRANOLOL HYDROCHLORIDE 80MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 10-16-74		I-15 09-24-86
PROPRANOLOL HYDROCHLORIDE 80MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	18-553 04-19-83	4138475 02-06-96	NDF 09-24-86
PROPRANOLOL HYDROCHLORIDE 90MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 10-18-82		NS 09-24-86 I-15 09-24-86
PROPRANOLOL HYDROCHLORIDE 120MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	18-553 04-19-83	4138475 02-06-96	NDF 09-24-86
PROPRANOLOL HYDROCHLORIDE 160MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	18-553 04-19-83	4138475 02-06-96	NDF 09-24-86
PROTEIN HYDROLYSATE 5%	AMINOSOL 5% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	05-932 01-31-85		
PROTAMINE SULFATE 250MG/VIAL	PROTAMINE SULFATE (INJECTABLE; INJECTION)	UPJOHN	07-413 08-02-84		NS 09-24-86
PROTIRELIN 0.5MG/ML	THYPINONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	17-638 11-05-76	3746697 07-17-90	
PROTIRELIN 0.5MG/ML	RELEFACT TRH (INJECTABLE; INJECTION)	HOECHST-ROUSSEL	18-087 07-18-78	3746697 07-17-90	
PYRANTEL PAMOATE EQ 250MG BASE/5ML	ANTIMINTH (SUSPENSION; ORAL)	ROERIG/PFIZER	16-883 12-30-71	3644624 02-22-89 3549624 12-22-87	

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	DOSAGE FORM: ROUTE	APP LICANT NAME	NDA NO.	TRADE NAME	PATENT NO.
TABLE IV. NDAs APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION									
RANTIDINE HYDROCHLORIDE	EQ 150MG BASE	I-35	06-09-93	4521431	12-05-95	ZANTAC	18-703	GLAXO	4128658
RANTIDINE HYDROCHLORIDE	EQ 150MG BASE	06-28-88	06-04-02	4521431	10-19-84	ZANTAC	19-090	GLAXO	4128658
RANTIDINE HYDROCHLORIDE	EQ 25MG BASE/ML	06-09-93	06-04-02	4521431	12-05-95	ZANTAC	18-555	ASTRA PHARM PRODS	3410944
RITODRINE HYDROCHLORIDE	10MG/ML	06-28-88	12-12-85	3410944	18-580	YUTOPAR	18-991	ABBSOTT LABORATORIES	08-27-84
RITODRINE HYDROCHLORIDE	15MG/ML	NP	09-24-86	3410944	18-580	YUTOPAR	18-997	ABBSOTT LABORATORIES	08-27-84
SAFFLOWER OIL; SOYBEAN OIL	5% ; 10%	NP	09-24-86	3410944	18-991	LIPOSYN II 20%	18-997	ABBSOTT LABORATORIES	08-27-84
SARRASIN ACETATE	EQ 0.6MG BASE/ML	NP	09-24-86	3410944	18-009	SARENIN	05-29-81	NORMWICH EATON/P&G	08-27-84
SCPOOL AMINE	1.5 MG	3886134	05-27-92	3932624	17-874	CBIA/CIBA-GEIGY	12-31-79	TRANSDERM-SCOP	(FILM, CONTROLLED RELEASE; PERCUTANEOUS)
SELENIUM SULFIDE	2.5%	I-3	09-24-86	05-17-51	07-936	ABBSOTT LABS	07-936	SELSUN	(SHAMPOO/LOTION; TOPICAL)

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
SILVER SULFADIAZINE 1%	SILVADENE (CREAM; TOPICAL)	MARION LABORATORIES	17-381 11-26-73	3761590 09-24-90	
SILVER SULFADIAZINE 1%	SSD (CREAM; TOPICAL)	TRAVENOL LABS	18-578 02-25-82		
SINCALIDE 0.005MG/VIAL	KINEVAC (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	17-697 07-21-76	3839315 10-01-91	
SODIUM ACETATE, ANHYDROUS 2MEO/ML	SODIUM ACETATE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-893 05-04-83		PP 09-24-86
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 2.5MEO/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		

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	TRADE NAME	APPLICANT NAME	NDA NO.	TRADE NAME	DOSEAGE FORM: ROUTE
----------------------	-------------	-------------	-----------	---------------	------------	----------------	---------	------------	---------------------

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

SODIUM CHLORIDE	9MG/ML	ABBOT LABORATORIES	07-13-84	19-218	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	TRAVENTOL LABS	SODIUM CHLORIDE 0.9% IN STERILE PLASTIC CONTAINER	(SOLUTION; IRRIGATION)
SODIUM CHLORIDE	900MG/100ML	ABBOT LABORATORIES	07-15-85	19-465	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	TRAVENTOL LABS	SODIUM CHLORIDE 0.9% IN STERILE PLASTIC CONTAINER	(SOLUTION; IRRIGATION)
SODIUM CHLORIDE	900MG/100ML	ABBOT LABORATORIES	05-17-85	19-319	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	TRAVENTOL LABS	SODIUM CHLORIDE 0.9% IN STERILE PLASTIC CONTAINER	(SOLUTION; IRRIGATION)
SODIUM CHLORIDE	900 MG/ML	ABBOT LABORATORIES	05-27-82	18-671	SODIUM IODIDE I 123 BENEDICT NUCLR PHARM	(CAPSULE; ORAL)	SODIUM IODIDE I 123 BENEDICT NUCLR PHARM	SODIUM IODIDE I 123 BENEDICT NUCLR PHARM	(CAPSULE; ORAL)
SODIUM IODIDE, I-123	200 UCI	ABBOT LABORATORIES	05-27-82	18-671	SODIUM IODIDE I 123 BENEDICT NUCLR PHARM	(CAPSULE; ORAL)	SODIUM IODIDE I 123 BENEDICT NUCLR PHARM	SODIUM IODIDE I 123 BENEDICT NUCLR PHARM	(CAPSULE; ORAL)
SODIUM IODIDE, I-123	400 UCI	ABBOT LABORATORIES	05-27-82	18-671	SODIUM IODIDE I 123 BENEDICT NUCLR PHARM	(CAPSULE; ORAL)	SODIUM IODIDE I 123 BENEDICT NUCLR PHARM	SODIUM IODIDE I 123 BENEDICT NUCLR PHARM	(CAPSULE; ORAL)
SODIUM IODIDE, I-123	5MEQ/ML	ABBOT LABORATORIES	09-05-84	18-947	SODIUM LACTATE IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	SODIUM LACTATE IN PLASTIC CONTAINER	SODIUM LACTATE IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)
SODIUM NITROPRUSSIDE	50MG/VIAL	ELKINS-SINN/AHROBINS	07-28-82	18-581	SODIUM NITROPRUSSIDE	(INJECTABLE; INJECTION)	SODIUM NITROPRUSSIDE	SODIUM NITROPRUSSIDE	(INJECTABLE; INJECTION)
SODIUM PHOSPHATE, DIASIC: SODIUM PHOSPHATE, MONOBASIC	142MG/ML; 276MG/ML	ABBOTT LABORATORIES	05-10-83	18-892	SODIUM PHOSPHATES IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)	SODIUM PHOSPHATES IN PLASTIC CONTAINER	SODIUM PHOSPHATES IN PLASTIC CONTAINER	(INJECTABLE; INJECTION)
SOMATROPIN	2 IU/VIAL	SERONO LABS	17-226	07-21-83	ASELLACRIN 2	(INJECTABLE; INJECTION)	SOMATROPIN	SOMATROPIN	(INJECTABLE; INJECTION)
SORBITOL	3GM/100ML	TRAVENOL LABS	18-512	05-27-82	SORBITOL 3% IN PLASTIC CONTAINER	(SOLUTION; IRRIGATION)	SORBITOL 3% IN PLASTIC CONTAINER	SORBITOL 3% IN PLASTIC CONTAINER	(SOLUTION; IRRIGATION)
SOYBEAN OIL	10%	ALPHA THERAPEUTIC	18-465	06-29-83	SOYACAL 10% (INJECTABLE; INJECTION)	(INJECTABLE; INJECTION)	SOYACAL 10% (INJECTABLE; INJECTION)	SOYACAL 10% (INJECTABLE; INJECTION)	(INJECTABLE; INJECTION)

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<u>ACTIVE INGREDIENT(S) STRENGTH(S)</u>	<u>TRADE NAME (DOSE FORM; ROUTE)</u>	<u>APPLICANT NAME</u>	<u>NDA NO. APPROVAL DATE</u>	<u>PATENT NO. EXP. DATE</u>	<u>EXCLUSIVITY EXP. DATE</u>
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	
SUFENTANIL CITRATE EQ 0.05MG BASE/ML	SUFENTA (INJECTABLE; INJECTION)	JANSSEN PHARMA	19-050 05-04-84	3998834 12-21-93	NCE 05-04-94
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	BACTRIM (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-377 07-30-73	RE28636 06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	BACTRIM DS (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-377 03-01-78	RE28636 06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	BACTRIM (SUSPENSION; ORAL)	HOFFMANN-LA ROCHE	17-560 04-16-75	RE28636 06-02-87	I-21 09-24-86
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	BACTRIM PEDIATRIC (SUSPENSION; ORAL)	HOFFMANN-LA ROCHE	17-560 12-10-79	RE28636 06-02-87	I-21 09-24-86
SULFAMETHOXAZOLE; TRIMETHOPRIM 80MG/ML; 16MG/ML	BACTRIM (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	18-374 06-23-81	3551564 12-29-87 RE28636 06-02-87	

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCLUSIVITY	EXP. DATE	APPROVAL DATE	DOSEAGE FORM: ROUTE	TRADE NAME	APP LICENT NAME	NDA NO.	PATENT NO.
----------------------	-------------	-------------	-----------	---------------	---------------------	------------	-----------------	---------	------------

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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	
SUTYLAINS 82,000 UNITS/GM	TRAVASE (OINTMENT; TOPICAL)	TRAVENOL LABS	12-828 06-12-69	3409719 11-05-85	
TECHNETIUM, TC-99M SODIUM PERTECHNETATE GENERATOR 0.22-2.22CI/GENERATOR	MINITEC (SOLUTION; INTRAVENOUS, ORAL)	ER SQUIBB AND SONS	17-339 06-03-74		I-31 09-24-86
TECHNETIUM, TC-99M, ALBUMIN COLLOID KIT N/A	MICROLITE (INJECTABLE; INJECTION)	MED DIAG/NE NUCLEAR	18-263 03-25-83		
TECHNETIUM, TC-99M, DISOFENIN KIT N/A	HEPATOLITE (INJECTABLE; INJECTION)	MED DIAG/NE NUCLEAR	18-467 03-16-82		NP 09-24-86
TECHNETIUM, TC-99M, GLUCEPTATE KIT N/A	TECHNESCAN GLUCEPTATE (INJECTABLE; INJECTION)	MS&D/MERCK	18-272 01-27-82		
TECHNETIUM, TC-99M, MEDRONATE N/A	OSTEOLITE (INJECTABLE; INJECTION)	MED DIAG/NE NUCLEAR	17-972 12-16-77		
TECHNETIUM, TC-99M, MEDRONATE N/A	AMERSCAN (INJECTABLE; INJECTION)	AMERSHAM/RADIOCHEM	18-335 08-05-82		

ACTIVE INGREDIENT(S)	STRENGTH(S)	EXCUSIVITY	EXP. DATE	APP. NO.	TRADE NAME	DOSAGE FORM: ROUTE	APPLICANT NAME	NDA NO.	APPROVAL DATE	TECHNETIUM, TC-99m, SUCCIMER KIT
N/A		NP	09-24-86	4208398	06-17-82	17-944	MEDI-PHYSICS	(INJECTABLE; INJECTION)	MPDMSA KIDNEY REAGENT	
0.2MG/INH		NDF	09-24-86	3937838	08-17-84	18-762	GEIGY/CIBA-GEIGY	(AEROSOL; INHALATION)	BRETHAIRE	TERBUTALINE SULFATE
			11-11-97							
0.2MG/INH			4011258	3937838	02-10-93	03-19-85	MERRILL DOW/DOW CHEM	(AEROSOL; INHALATION)	BRICANYL	TERBUTALINE SULFATE
			03-08-94							
1MG/ML			02-10-93	3937838	03-25-74	17-466	MERRILL DOW/DOW CHEM	(INJECTABLE; INJECTION)	BRICANYL	TERBUTALINE SULFATE
			03-08-94							
2.5MG			02-10-93	3937838	04-22-75	17-618	MERRILL DOW/DOW CHEM	(TABLET; ORAL)	BRICANYL	TERBUTALINE SULFATE
			03-08-94							
5MG			02-10-93	3937838	04-22-75	17-849	GEIGY/CIBA-GEIGY	(TABLET; ORAL)	BRETHINE	TERBUTALINE SULFATE
			03-08-94							
2.5MG			02-10-93	3937838	05-17-76	17-849	GEIGY/CIBA-GEIGY	(TABLET; ORAL)	BRETHINE	TERBUTALINE SULFATE
			03-08-94							
5MG			02-10-93	3937838	05-17-76	17-849	GEIGY/CIBA-GEIGY	(INJECTABLE; INJECTION)	BRETHINE	TERBUTALINE SULFATE
			03-08-94							
1MG/ML			02-10-93	3937838	11-30-81	18-571	GEIGY/CIBA-GEIGY	(INJECTABLE; INJECTION)	BRETHINE	TERBUTALINE SULFATE
			03-08-94							

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

Digitized by Google

UNIVERSITY OF MICHIGAN

Original from

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<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>
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	QUIBRON-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	

ACTIVE INGREDIENT(S)	STRENGTH(S)	PATENT NO.	EXPIRATION DATE	EXPIRATION DATE	EXCLUSIVITY	TRADE NAME	APPLICANT NAME	DOSAGE FORM: ROUTE	APPROVAL DATE	EXP. DATE
TOCAINIDE HYDROCHLORIDE	400MG	NCE 11-09-89	08-19-97	4237068	12-02-97	TONOCARD	MS&D/MERCK	18-257	4218477	11-09-84
TOCAINIDE HYDROCHLORIDE	600MG	NCE 11-09-89	08-19-97	4237068	12-02-97	TONOCARD	MS&D/MERCK	18-257	4218477	11-09-84
TOCAINIDE HYDROCHLORIDE	100MG	TOLAZAMIDE	(TABLET; ORAL)	ZENTHI LABORATORIES	11-02-84	ZENTHI	ZENTHI LABORATORIES	18-894	11-02-84	250MG
TOCAINIDE HYDROCHLORIDE	200MG	TOLAZAMIDE	(TABLET; ORAL)	ZENTHI LABORATORIES	11-02-84	ZENTHI	ZENTHI LABORATORIES	18-894	11-02-84	500MG
TOCAINIDE HYDROCHLORIDE	250MG	TOLAZAMIDE	(TABLET; ORAL)	ZENTHI LABORATORIES	11-02-84	ZENTHI	ZENTHI LABORATORIES	18-894	11-02-84	250MG
TOCAINIDE HYDROCHLORIDE	500MG	TOLAZAMIDE	(TABLET; ORAL)	ZENTHI LABORATORIES	11-02-84	ZENTHI	ZENTHI LABORATORIES	18-894	11-02-84	500MG
TOLAZOLINE HYDROCHLORIDE	25MG/ML	PRISCOLINE	(INJECTABLE; INJECTION)	CIBA/CIBA-GEIGY	06-403	PRISCOLINE	CIBA/CIBA-GEIGY	02-22-85	06-403	25MG/ML
TOLMETIN SODIUM	ED 200MG BASE	TOLECTIN	(TABLET; ORAL)	MCGEIL LABORATORIES	17-628	TOLECTIN	MCGEIL LABORATORIES	03-24-76	08-14-90	ED 200MG BASE
TOLMETIN SODIUM	ED 400MG BASE	TOLECTIN DS	(CAPSULE; ORAL)	MCGEIL LABORATORIES	18-084	TOLECTIN DS	MCGEIL LABORATORIES	10-30-79	08-14-90	ED 400MG BASE
TOLAZODONE HYDROCHLORIDE	150MG	DESYREL	(TABLET; ORAL)	MEAD JOHNSON/B-M	18-207	DESYREL	MEAD JOHNSON/B-M	03-25-85	03-25-85	TOLAZODONE HYDROCHLORIDE
TRIETINION	0.1%	RETIN-A	(SOLUTION; TOPICAL)	ORTHO PHARMACEUTICAL	16-921	RETIN-A	ORTHO PHARMACEUTICAL	10-20-71	04-24-90	TRIETINION
TRIETINION	0.05%	RETIN-A	(CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-340	RETIN-A	ORTHO PHARMACEUTICAL	01-26-73	04-24-90	TRIETINION
TRIETINION	0.05%	RETIN-A	(CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	17-522	RETIN-A	ORTHO PHARMACEUTICAL	07-19-74	04-24-90	TRIETINION
TRIETINION	0.05%	RETIN-A	(CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	3729568	RETIN-A	ORTHO PHARMACEUTICAL	09-16-92	09-16-92	TRIETINION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION

<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>
TRETINOIN 0.01%	RETIN-A (GEL; TOPICAL)	ORTHO PHARMACEUTICAL	17-955 10-05-78	3729568 04-24-90 4247547 01-27-98	
TRETINOIN 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 12-21-84		NCE 12-21-89
TRILOSTANE 60MG	MODRASTANE (CAPSULE; ORAL)	WINTHROP LABS/STERL	18-719 12-21-84		NCE 12-21-89
TRIMETHOPRIM 200MG	PROLOPRIM (TABLET; ORAL)	BURROUGHS WELLCOME	17-943 07-14-82		NS 09-24-86
TRIMETHOPRIM 200MG	TRIMPEX 200 (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-952 11-09-82		NS 09-24-86

ACTIVE INGREDIENT(S)	STRENGTH(S)	PATENT NO.	NDA NO.	APPLICANT NAME	DOSAGE FORM: ROUTE	APPROVAL DATE	EXP. DATE	EXCLUSIVITY
TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 AND NDA'S WITH APPROPRIATE PATENT AND EXCLUSIVITY INFORMATION								
TRIMETHOPRIM	100MG			BIOCRAFT LABS	18-679 (TABLET; ORAL)	07-30-82		
TRIMIPRAMINE MALEATE	EQ 100MG BASE			IVES LABS/AMHO	16-792 (CAPSULE; ORAL)	09-15-82	NS	09-24-86
VECURONIUM BROMIDE	10MG/VIAL			ORGANON/AKKZONA	18-776 NORCURON (NC-A5)	04-30-88 (INJECTABLE; INJECTION)	3553212	NCE 04-30-94
VERAPAMIL HYDROCHLORIDE	80MG			KNOLL PHARMACEUTICAL	18-593 ISOTPINI	03-08-82 (TABLET; ORAL)	NR	09-24-86
VERAPAMIL HYDROCHLORIDE	120MG			KNOLL PHARMACEUTICAL	18-593 ISOTPINI	03-08-82 (TABLET; ORAL)	NR	09-24-86
VERAPAMIL HYDROCHLORIDE	80MG			SEARLE/SEARLE PHARMS	18-817 CALM	09-10-84 (TABLET; ORAL)	NR	09-24-86
VERAPAMIL HYDROCHLORIDE	120MG			SEARLE/SEARLE PHARMS	18-817 CALM	09-10-84 (TABLET; ORAL)	NR	09-24-86
VERAPAMIL HYDROCHLORIDE	2.5MG/ML			SEARLE PHARMS	18-925 (INJECTABLE; INJECTION)	03-30-84		
VERAPAMIL HYDROCHLORIDE	2.5MG/ML			SEARLE PHARMS	19-038 (INJECTABLE; INJECTION)	03-30-84		
WATER FOR INJECTION, STERILE	100%			TRAVENOL LABS	18-632 STERILE MATER IN PLASTIC	18-632	06-30-82	(LIQUID; N/A)
WATER FOR INJECTION, STERILE	100%			TRAVENOL LABS	18-595 STERILE MATER FOR INJECTION	18-595	01-17-83	(LIQUID; N/A)

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 7-31-85 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>
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		

SUBSCRIPTION FORM

**APPROVED DRUG PRODUCTS
WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS
6TH EDITION (1985)**

MAIL TO:

Superintendent of Documents
Government Printing Office
Washington, DC 20402
(202) 783-3238

DATE:**PURCHASER:**

SHIP TO:
(If different than purchaser)

CONTACT:**TELEPHONE (Include Area Code)****METHOD OF PAYMENT**

- [] Charge my GPO Account No. _____
 [] Purchase Order Number _____
 [] Check enclosed for \$ _____
 (Make check payable to Superintendent of Documents)

**AUTHORIZING
SIGNATURE****DATE:****DESCRIPTION****QUANTITY****UNIT PRICE****TOTAL PRICE**

The 6th Edition will be published in
October 1985. Subscription includes
the Approved Drug Products List
and monthly Cumulative Supplements.

DOMESTIC

@ \$103.00	\$
------------	----

FOREIGN

@ \$128.75	\$
------------	----

ENTER TOTAL

\$/

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

