Approved prescription drug products with therapeutic equivalence evaluations.

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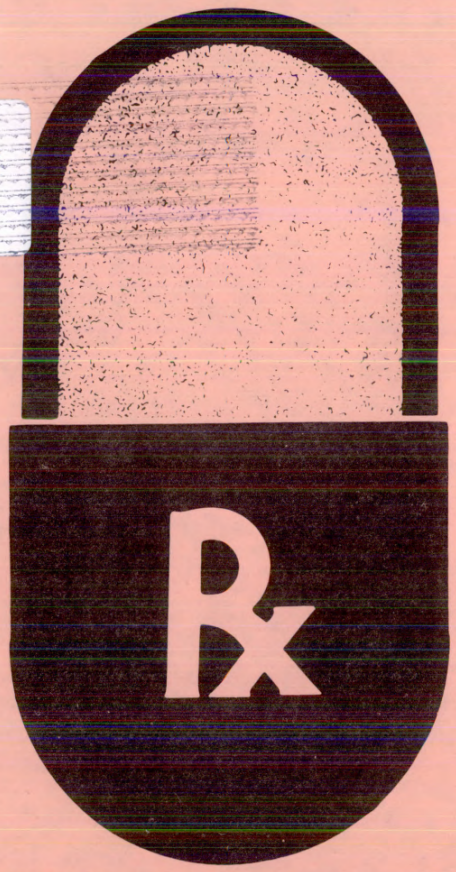
CUMULATIVE SUPPLEMENT 2
AUG'84 - OCT'84



APPROVED PRESCRIPTION DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

5TH EDITION

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

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

(continued)

Products	Federal Register Reference

(continued)

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

C. APPLICANT (NAME) CHANGES

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

APPLICANT (NAME) CHANGES

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

D. ADDENDUM: DRUG PRICE COMPETITION AND PATENT TERM RESTORATION

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

III. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

USE OF REPORT

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

Drug Product Definition

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

New Molecular Entity

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

Drug Product Count

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

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

A. COUNTS CUMULATIVE BY QUARTERS

CATEGORIES COUNTED	JULY '84 (BASELINE)
DRUG PRODUCTS LISTED	7415
SINGLE SOURCE	2005 (27.0%)
MULTISOURCE(1)	5410 (72.9%)
THERAPEUTICALLY EQUIVALENT	4393 (59.2%)
NOT THERAPEUTICALLY EQUIVALENT	999 (13.4%)
EXCEPTIONS(2)	18 (0.3%)
NEW MOLECULAR ENTITIES APPROVED	7
NUMBER OF APPLICANTS	295

B. ACTIVITY FOR SUPPLEMENT NUMBER 2

	AUG '84	SEPT' 84	OCT '84	CUMULATIVE
DRUG PRODUCTS ADDED:	54	66	72	192
NEWLY APPROVED	54	66	68	188
DESI EFFECTIVE	0	0	4	4
REMARKETED	0	0	0	0
DRUG PRODUCTS REMOVED:	0	12	8	20
WITHDRAWN APPROVAL	0	0	0	0
RX TO OTC SWITCH	0	0	0	0
DISCONTINUED MARKETING	0	12	8	20
NET GAIN IN DRUG PRODUCTS	54	54	64	172
SINGLE SOURCE PRODUCTS APPROVED	17	16	28	61
MULTISOURCE DRUG PRODUCTS APPROVED	37	50	44	131
NEW MOLECULAR ENTITIES APPROVED:	3	0	1	4
AS THE ENTITY	1	0	0	1
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	2	0	1	3

(1) THERAPEUTIC EQUIVALENCE EVALUATIONS PROVIDED ONLY FOR MULTISOURCE PRODUCTS (i.e., AVAILABLE FROM MORE THAN ONE APPLICANT)

(2) AMINO ACID-CONTAINING PRODUCTS OF VARYING COMPOSITION (SEE PAGE I-5 OF THE LIST)

> ADD > ACETAMINOPHEN; BUTALBITAL (PAGE 3-1)

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

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 3-2)

TABLET; ORAL
~~/CODACET/~~
OXYCET
AA HALSEY DRUG 325MG;5MG¤ N 87463

ACETIC ACID, GLACIAL (PAGE 3-3)

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

ALLOPURINOL (PAGE 3-5)

TABLET; ORAL
ALLOPURINOL
AB CHELSEA LABORATORIES 100MG¤ N 18785
AB 300MG¤ N 18785
AB DANBURY PHARMACAL 100MG¤ N 18832
AB 300MG¤ N 18877

AMIKACIN SULFATE (PAGE 3-6)

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

AMINO ACIDS (PAGE 3-6)

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

> ADD > AMINO ACIDS; DEXTROSE (PAGE 3-7)

> ADD > INJECTABLE; INJECTION
> ADD > AMINOSYN 3.5% W/ DEXTROSE 5% IN PLASTIC CONTAINER
> ADD > ABBOTT LABORATORIES 3.5%;5GM/100ML N 19120
> ADD > AMINOSYN 3.5% W/ DEXTROSE 25% IN PLASTIC CONTAINER
> ADD > ABBOTT LABORATORIES 3.5%;25GM/100ML N 19118
> ADD > AMINOSYN 4.25% W/ DEXTROSE 25% IN PLASTIC CONTAINER
> ADD > ABBOTT LABORATORIES 4.25%;25GM/100ML N 19119

AMITRIPTYLINE HYDROCHLORIDE (PAGE 3-10)

TABLET; ORAL
AMITRIPTYLINE HCL
BP PAR PHARMACEUTICAL 10MG¤ N 88697
BP 25MG¤ N 88698
BP 50MG¤ N 88699
BP 75MG¤ N 88700
BP 100MG¤ N 88701
BP 150MG¤ N 88702
BP SIDMAK LABORATORIES 10MG¤ N 88883
BP 25MG¤ N 88884
BP 50MG¤ N 88885
BP 75MG¤ N 88886
BP 100MG¤ N 88887
BP 150MG¤ N 88888

AMOXICILLIN; POTASSIUM CLAVULANATE (PAGE 3-13)

POWDER FOR RECONSTITUTION; ORAL
AUGMENTIN '125'
BEECHAM LABS/BEECHAM 125MG/5ML;
EQ 31.25MG ACID/5ML¤ N 50575
AUGMENTIN '250'
BEECHAM LABS/BEECHAM 250MG/5ML;EQ 62.5MG ACID/5ML¤ N 50575

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

AMPHETAMINE SULFATE (PAGE 3-13)

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

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-16)

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

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

CAPSULE; ORAL
PROPOXYPHENE HCL W/ ASPIRIN AND CAFFEINE
AA CHELSEA LABORATORIES 389MG;32.4MG;65MG¤ N 85732

>ADD > BENZOYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

>ADD > GEL; TOPICAL
>ADD > BENZAMYCIN
>ADD > DERMIK/RORER-AMCHEM 5%;3%¤ N 50557

>DLT > /BENZTHIAZIDE; RESERPINE/(PAGE 3-21)

>DLT > /TABLET; ORAL/
>DLT > /EXNA-R/
>DLT > /AH ROBINS/ /50MG;0.125MG/ /N 14861/

BETAMETHASONE DIPROPIONATE (PAGE 3-22)

OINTMENT; TOPICAL
ALPHATREX
AB SAVAGE LABS/BYK-GLDN EQ 0.05% BASE¤ N 19143
BETAMETHASONE DIPROPIONATE
AB E FOUGERA/BYK-GLDN EQ 0.05% BASE¤ N 19141
AB PHARMADERM/BYK-GLDN EQ 0.05% BASE¤ N 19140
DIPROLENE
BX SCHERING EQ 0.05% N 18741
DIPROSONE
AB SCHERING EQ 0.05% N 17691

BETAMETHASONE VALERATE (PAGE 3-22)

CREAM; TOPICAL
>ADD > VALNAC
>ADD > AB NMC LABORATORIES EQ 0.1% BASE¤ N 70050

OINTMENT; TOPICAL
>ADD > VALNAC
>ADD > AB NMC LABORATORIES EQ 0.1% BASE¤ N 70051

BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE (PAGE 3-24)

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

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE MALEATE (PAGE 3-25)

ELIXIR; ORAL
BIPHETAP
BAY LABORATORIES 4MG/5ML;25MG/5ML¤ N 88687
/ELIXIR; DIMETAPP/
/AH ROBINS/ /4MG/5ML;25MG/5ML/ /N 13087/

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

>DLT > /BUPRENORPHINE HYDROCHLORIDE/(PAGE 3-26)

>DLT > /INJECTABLE; INJECTION/
>DLT > /BUPRENEX/
>DLT > /NORWICH EATON/PFG/ /EQ 0.3MG BASE/ML/ /N 18401/

CALCIUM GLUCEPTATE (PAGE 3-30)

INJECTABLE; INJECTION
CALCIUM GLUCEPTATE
>DLT >/AP/ /INTL MEDICATION SYS//EQ 90MG CALCIUM/5ML/ /N 87455/

>ADD > CAPTOPRIL; HYDROCHLOROTHIAZIDE (PAGE 3-31)

>ADD > TABLET; ORAL
>ADD > CAPOZIDE 25/15
>ADD > ER SQUIBB AND SONS 25MG;15MG¤ N 18709
>ADD > CAPOZIDE 25/25
>ADD > ER SQUIBB AND SONS 25MG;25MG¤ N 18709
>ADD > CAPOZIDE 50/15
>ADD > ER SQUIBB AND SONS 50MG;15MG¤ N 18709
>ADD > CAPOZIDE 50/25
>ADD > ER SQUIBB AND SONS 50MG;25MG¤ N 18709

CARBACHOL (PAGE 3-31)

/SOLUTION/DROPS; OPHTHALMIC/
INJECTABLE; INJECTION

CEFOXITIN SODIUM; DEXTROSE (PAGE 3-33)

INJECTABLE; INJECTION
MEFOXIN IN DEXTROSE 5% IN PLASTIC CONTAINER

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

CEFOXITIN SODIUM; SODIUM CHLORIDE (PAGE 3-33)

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

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

> ADD > CEFTIZOXIME SODIUM; DEXTROSE (PAGE 3-33)

> ADD > INJECTABLE; INJECTION
> ADD > CEFIZOX IN DEXTROSE 5% IN PLASTIC CONTAINER

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

CELLULOSE SODIUM PHOSPHATE (PAGE 3-34)

POWDER; ORAL
CALCIBIND

MISSION PHARMACAL	300GM/BOT*	N 18757	

CHLORPROPAMIDE (PAGE 3-42)

TABLET; ORAL
CHLORPROPAMIDE

AB	BARR LABORATORIES	100MG*	N 88812	
AB		250MG*	N 88813	
AB	CHELSEA LABORATORIES	100MG*	N 86865	
AB	COLMED LABORATORIES	100MG*	N 88708	
AB		250MG*	N 88709	
AB	CORD LABORATORIES	100MG*	N 88725	
AB		250MG*	N 88726	
AB	DANBURY PHARMACAL	100MG*	N 88852	
AB		250MG*	N 88826	
AB	DURAMED PHARMS	100MG*	N 88918	
AB		250MG*	N 88919	
AB	LEMMON	100MG*	N 88768	
AB		250MG*	N 88641	
AB	SUPERPHARM	100MG*	N 88694	
AB		250MG*	N 88695	
AB	ZENITH LABORATORIES	100MG*	N 88840	

CHYMOPAPAIN (PAGE 3-43)

INJECTABLE; INJECTION
CHYMODIACTIN

SMITH LABORATORIES	4,000 UNITS/VIAL*	N 18663	

CISPLATIN (PAGE 3-44)

INJECTABLE; INJECTION
/PLATINOL/

/BRISTOL LABS/B-M/	/1MG/ML/		/N 18057/
	/50MG/VIAL/		/N 18057/

PLATINOL-AQ

BRISTOL LABS/B-M	0.5MG/ML		N 18057

> ADD > CLONIDINE (PAGE 3-45)

> ADD > FILM, CONTROLLED RELEASE; PERCUTANEOUS
> ADD > CATAPRES-TTS-1

> ADD >	BOEHRINGER INGELHEIM	2.5MG*	N 18891

> ADD > CATAPRES-TTS-2

> ADD >	BOEHRINGER INGELHEIM	5MG*	N 18891

> ADD > CATAPRES-TTS-3

> ADD >	BOEHRINGER INGELHEIM	7.5MG*	N 18891

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

SYRUP; ORAL
PHENERGAN VC W/ CODEINE

> ADD > AA	WYETH LABS/AMHO	10MG/5ML;5MG/5ML;6.25MG/5ML		N 08306

> ADD > PROMETH VC W/ CODEINE

> ADD > AA	NATL PHARM MFG/BARRE	10MG/5ML;5MG/5ML;6.25MG/5ML*		N 88764

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-46)

SYRUP; ORAL

> ADD > PHENERGAN W/ CODEINE

> ADD > AA	WYETH LABS/AMHO	10MG/5ML;6.25MG/5ML		N 08306

> ADD > PROMETH W/ CODEINE

> ADD > AA	NATL PHARM MFG/BARRE	10MG/5ML;6.25MG/5ML*		N 88763

CROMOLYN SODIUM (PAGE 3-48)

> ADD > SOLUTION/DROPS; OPHTHALMIC
> ADD > OPTICROM

> ADD >	FISONS	4%*		N 18155

DESERPIDINE; METHYCLOTHIAZIDE (PAGE 3-52)

TABLET; ORAL
ENDURONYL

BP	ABBOTT LABORATORIES	0.25MG;5MG		N 12775

ENDURONYL FORTE

BP	ABBOTT LABORATORIES	0.5MG;5MG		N 12775

METHYCLOTHIAZIDE AND DESERPIDINE

BP	BOLAR PHARMACEUTICAL	0.25MG;5MG*		N 88486
BP		0.5MG;5MG*		N 88452

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

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

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-57)

SYRUP; ORAL
>ADD> PHENERGAN W/ DEXTROMETHORPHAN
>ADD> AA WYETH LABS/AMHO 15MG/5ML;6.25MG/5ML N 11265
>ADD> PROMETH W/ DEXTROMETHORPHAN
>ADD> AA NATL PHARM MFG/BARRE 15MG/5ML;6.25MG/5ML¤ N 88762

DEXTROSE (PAGE 3-57)

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

>ADD> DICYCLOMINE HYDROCHLORIDE (PAGE 3-64)

>ADD> CAPSULE; ORAL
>ADD> BENTYL
>ADD> MERRELL DOW/DOW CHEM 10MG¤ N 07409

>ADD> INJECTABLE; INJECTION
>ADD> BENTYL
>ADD> MERRELL DOW/DOW CHEM 10MG/ML¤ N 08370

>ADD> SYRUP; ORAL
>ADD> BENTYL
>ADD> MERRELL DOW/DOW CHEM 10MG/5ML¤ N 07961

>ADD> TABLET; ORAL
>ADD> BENTYL
>ADD> MERRELL DOW/DOW CHEM 20MG¤ N 07409

DIETHYLPROPION HYDROCHLORIDE (PAGE 3-65)

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

DISULFIRAM (PAGE 3-68)

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

DOXYCYCLINE HYCLATE (PAGE 3-70)

CAPSULE; ORAL
DOXYCYCLINE HYCLATE
>ADD> AB PAR PHARMACEUTICAL EQ 50MG BASE¤ N 62434
>ADD> AB SUPERPHARM EQ 50MG BASE¤ N 62469
>ADD> AB EQ 100MG BASE¤ N 62469
AB ZENITH LABORATORIES EQ 50MG BASE¤ N 62500
AB EQ 100MG BASE¤ N 62500

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

DOXYLAMINE SUCCINATE (PAGE 3-70)

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

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE (PAGE 3-78)

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

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

ETHINYL ESTRADIOL; NORETHINRENE ACETATE (PAGE 3-79)

TABLET; ORAL-21
>DLT> /LOESTRIN 1.5/30/
>ADD> LOESTRIN 21 1.5/30

FLUNISOLIDE (PAGE 3-82)

AEROSOL; INHALATION
BRONALIDE
SYNTEX LABS/SYNTEX 0.25MG/INH¤ N 18340

FLUOCINOLONE ACETONIDE (PAGE 3-82)

CREAM; TOPICAL

FLUOCINOLONE ACETONIDE

AT	PHARMAFAIR	0.01%*	N 88499	
AT		0.025%*	N 88506	

FLUONID

AT	HERBERT LABS/ALLERGN	0.025%*	N 87156	
/AT/	/MARION LABORATORIES/	/0.01%/	/N 80434/	
/AT/		/0.025%/	/N 80434/	

OINTMENT; TOPICAL

FLUONID

AT	HERBERT LABS/ALLERGN	0.025%*	N 87157	
/AT/	/MARION LABORATORIES/	/0.025%/	/N 80433/	

SOLUTION; TOPICAL

FLUONID

/AT/	/MARION LABORATORIES/	/0.01%/	/N 80432/	

/FOLLICLE STIMULATING HORMONE; LUTEINIZING HORMONE/ (PAGE 3-85)
MENOTROPINS; LUTEINIZING HORMONE (PAGE 3-122)

FUROSEMIDE (PAGE 3-86)

TABLET; ORAL

FUROSEMIDE

AB	CORD LABORATORIES	80MG*	N 18569	

LASIX

AB	HOECHST-ROUSSEL	80MG	N 16273	

GENTAMICIN SULFATE (PAGE 3-86)

OINTMENT; TOPICAL

GENTAMICIN SULFATE

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

SOLUTION/DROPS; OPHTHALMIC

GENOPTIC

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

HALCINONIDE (PAGE 3-90)

CREAM; TOPICAL

> DLT >		/HALCIDERM/			
> ADD >		HALOG-E			

HEPARIN SODIUM (PAGE 3-91)

INJECTABLE; INJECTABLE

> ADD >		HEP-FLUSH 10			
> ADD >	AP	LYPHOMED	10 UNITS/ML*	N 17651	

HEPARIN LOCK FLUSH

> ADD >	AP	SOLOPAK LABORATORIES	10 UNITS/ML*	N 88457	
> ADD >	AP		10 UNITS/ML*	N 88580	
> ADD >	AP		100 UNITS/ML*	N 88581	

HEPARIN SODIUM

> DLT >	/AP/	ELKINS-SINN/AHROBINS	/10,000 UNITS/ML/	/N 17037/	
> DLT >	/AP/		/40,000 UNITS/ML/	/N 17037/	
> DLT >			/250 UNITS/ML/	/N 17037/	

HYDRALAZINE HYDROCHLORIDE (PAGE 3-95)

TABLET; ORAL

HYDRALAZINE HCL

> ADD >	AA	AMIDE PHARMACEUTICAL	25MG*	N 88560	
> ADD >	AA		50MG*	N 88649	
	AA	SUPERPHARM	10MG*	N 88787	
	AA		25MG*	N 88788	
	AA		50MG*	N 88789	

HYDROCHLOROTHIAZIDE; TRIAMTERENE (PAGE 3-98)

> ADD >		TABLET; ORAL			
> ADD >		MAXZIDE			
> ADD >		MYLAN PHARMS	50MG;75MG*	N 19129	

HYDROCORTISONE (PAGE 3-100)

POWDER; FOR RX COMPOUNDING

H-CORT

> DLT >	/AA/	/PARAMEX LABORATORIES/	/100%/	/N 87834/	
> ADD >	AA	TORCH LABORATORIES	100%	N 87834	

HYDROCORTISONE ACETATE (PAGE 3-102)

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

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE (PAGE 3-103)

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

HYDROFLUMETHIAZIDE (PAGE 3-104)

TABLET; ORAL
HYDROFLUMETHIAZIDE

AB	CHELSEA LABORATORIES	50MG*	N 88528

HYDROXYZINE HYDROCHLORIDE (PAGE 3-105)

TABLET; ORAL
HYDROXYZINE HCL

AB	PUREPAC/KALIPHARMA	10MG*	N 88120
AB		25MG*	N 88121
AB		50MG*	N 88122

INDOMETHACIN (PAGE 3-108)

CAPSULE; ORAL
INDOMETHACIN

AB	PAR PHARMACEUTICAL	25MG*	N 18829
AB		50MG*	N 18829

SUPPOSITORY; RECTAL
INDOCIN

	MS&D RES LABS/MERCK	50MG*	N 17814

ISOETHARINE MESYLATE (PAGE 3-110)

AEROSOL; INHALATION
BRONKOMETER

/BN/	/BREON LABS/STERLING/	/0.34MG/INH/	/N 12339/
BN	BREON LABS/STERLING	0.34MG/INH	N 12339

ISOETHARINE MESYLATE

BN	NATL PHARM MFG/BARRE	0.34MG/INH*	N 87858

KANAMYCIN SULFATE (PAGE 3-112)

INJECTABLE; INJECTION
KANTREX

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

LABETALOL HYDROCHLORIDE (PAGE 3-113)

INJECTABLE; INJECTION
NORMODYNE

	SCHERING	5MG/ML*	N 18687

LABETALOL HYDROCHLORIDE (PAGE 3-113)

TABLET; ORAL
NORMODYNE

AB	SCHERING	200MG*	N 18686
AB		300MG*	N 18686
AB		400MG*	N 18686

TRANDATE

AB	GLAXO	200MG*	N 18716
AB		300MG*	N 18716
AB		400MG*	N 18716

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE (PAGE 3-114)

INJECTABLE; INJECTION
> ADD >
> ADD > SCANDONEST L

> ADD > AP	DEPROCO	0.05MG/ML;2%*	N 88388

LINDANE (PAGE 3-116)

LOTION; TOPICAL
LINDANE

AT	BAY LABORATORIES	1%*	N 88190

SHAMPOO; TOPICAL
LINDANE

AT	BAY LABORATORIES	1%*	N 88191

MEPERIDINE HYDROCHLORIDE (PAGE 3-122)

INJECTABLE; INJECTION
MEPERIDINE HCL

AP	ABBOTT LABORATORIES	10MG/ML*	N 88432
AP	INTL MEDICATION SYS	10MG/ML	N 86332

TABLET; ORAL
MEPERIDINE HCL

AA	BARR LABORATORIES	100MG*	N 88640

MEPIVACAINE HYDROCHLORIDE (PAGE 3-123)

INJECTABLE; INJECTION
POLOCAINE

AP	ASTRA PHARM PRODS	3%*	N 88653

> ADD >
SCANDONEST PLAIN

> ADD > AP	DEPROCO	3%*	N 88387

MEPROBAMATE (PAGE 3-123)

TABLET; ORAL
MEPROBAMATE

/AA/	/MM MAST/	/200MG/	/N 86229/
/AA/		/400MG/	/N 86229/

METHYCLOTHIAZIDE (PAGE 3-129)

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

METHOTREXATE SODIUM (PAGE 3-128)

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

MICONAZOLE NITRATE (PAGE 3-134)

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

MORPHINE SULFATE (PAGE 3-135)

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

NAFCILLIN SODIUM (PAGE 3-135)

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

NYSTATIN (PAGE 3-141)

SUSPENSION; ORAL
NYSTATIN
>ADD> AA BAY LABORATORIES 100,000 UNITS/ML¤ N 62512

TABLET; ORAL
NYSTATIN
>ADD> AA QUANTUM PHARMICS 500,000 UNITS¤ N 62525

OXYPHENBUTAZONE (PAGE 3-143)

TABLET; ORAL
OXYPHENBUTAZONE
AB EDLAR PHARMACEUTICAL 100MG¤ N 88399
TANDEARIL
AB GEIGY/CIBA-GEIGY 100MG N 12542

>ADD> PENTAMIDINE ISETHIONATE (PAGE 3-148)

>ADD> INJECTABLE; INJECTION
>ADD> PENTAM 300
>ADD> LYPHOMED 300MG/VIAL¤ N 19264

PENTOXIFYLLINE (PAGE 3-149)

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

>ADD> PILOCARPINE HYDROCHLORIDE (PAGE 3-154)

>ADD> GEL; OPHTHALMIC
>ADD> PILOPINE HS
>ADD> ALCON LABORATORIES 4% N 18796

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

POWDER FOR RECONSTITUTION; ORAL
>ADD> COLYTE
>ADD> EDLAW PREPARATIONS 120GM/PACKET;1.49GM/PACKET;
>ADD> 3.36GM/PACKET;2.92GM/PACKET;
>ADD> 11.36GM/PACKET¤ N 18983
>ADD> 227.1GM/PACKET;2.82GM/PACKET;
>ADD> 6.36GM/PACKET;5.53GM/PACKET;
>ADD> 21.5GM/PACKET;¤ N 18983
>ADD> 360GM/PACKET;4.47GM/PACKET;
>ADD> 10.08GM/PACKET;8.76GM/PACKET;
>ADD> 34.08GM/PACKET¤ N 18983

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM (PAGE 3-160)

OINTMENT; OPHTHALMIC
PREDSULFAIR
>ADD> AT PHARMAFAIR 0.5%;10% N 88032
>ADD> VASOCIDIN
>ADD> AT COOPERVISION PHARMS 0.5%;10%¤ N 88791

PREDNISONE (PAGE 3-161)

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

PROCHLORPERAZINE EDISYLATE (PAGE 3-164)

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

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

PROPOXYPHENE HYDROCHLORIDE (PAGE 3-167)

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

PROTAMINE SULFATE (PAGE 3-168)

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

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE (PAGE 3-169)

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

QUINIDINE SULFATE (PAGE 3-170)

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

RANITIDINE HYDROCHLORIDE (PAGE 3-171)

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

RITODRINE HYDROCHLORIDE (PAGE 3-173)

INJECTABLE; INJECTION
> DLT > /RITODRINE HCL/
> DLT >/AP/ /DUPHAR LABS/ /10MG/ML/ /N 18280/
YUTOPAR
> DLT >/AP/ ASTRA PHARM PRODS 10MG/ML N 18580
15MG/ML* N 18580

RITODRINE HYDROCHLORIDE (PAGE 3-173)

TABLET; ORAL
> DLT > /RITODRINE HCL/
> DLT >/AB/ /DUPHAR LABS/ /10MG/ /N 18280/
YUTOPAR
> DLT >/AB/ ASTRA PHARM PRODUCTS 10MG N 18555

SAFFLOWER OIL; SOYBEAN OIL (PAGE 3-174)

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

SCOPOLAMINE (PAGE 3-174)

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

SODIUM LACTATE (PAGE 3-178)

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

SODIUM POLYSTYRENE SULFONATE (PAGE 3-179)

POWDER; ORAL, RECTAL
KAYEXALATE
AA BREON LABS/STERLING 453.6GM/BOT N 11287
SODIUM POLYSTYRENE SULFONATE
AA BAY LABORATORIES 453.6GM/BOT* N 88786

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

SOYBEAN OIL (PAGE 3-180)

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

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-183)

TABLET; ORAL
SULFAMETHOXAZOLE & TRIMETHOPRIM

AB	HEATHER DRUG	400MG;80MG¤	N 18946
AB		800MG;160MG¤	N 18946

SUCCINYLCHOLINE CHLORIDE (PAGE 3-181)

INJECTABLE; INJECTION
SUCCINYLCHOLINE CHLORIDE

/AP/	/TRAVENOL LABS/	/500MG/VIAL/	/N 80263/
/AP/		/1GM/VIAL/	/N 80263/

TERBUTALINE SULFATE (PAGE 3-187)

AEROSOL; INHALATION
BRETHAIRE

	GEIGY/CIBA-GEIGY	0.2MG/INH¤	N 18762

THIORIDAZINE HYDROCHLORIDE (PAGE 3-192)

TABLET; ORAL
THIORIDAZINE HCL

AB	BARR LABORATORIES	150MG¤	N 88737
>ADD> AB		200MG¤	N 88738

TRIAMCINOLONE ACETONIDE (PAGE 3-195)

CREAM; TOPICAL
ARISTOCORT A

>ADD> AT	LEDERLE LABS/AM CYAN	0.025%¤	N 88818
>ADD> AT		0.1%¤	N 88819
>ADD> AT		0.5%¤	N 88820

OINTMENT; TOPICAL
ARISTOCORT A

>ADD> AT	LEDERLE LABS/AM CYAN	0.1%¤	N 88780
>ADD> AT		0.5%¤	N 88781

TRIAMCINOLONE ACETONIDE

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

TRYMEX

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

TRISULFAPYRIMIDINES (PAGE 3-200)

SUSPENSION; ORAL
/TRIPLE SULFOID/

/AB/	/VALE CHEMICAL/	/500MG/5ML/	/N 80167/

VERAPAMIL HYDROCHLORIDE (PAGE 3-202)

TABLET; ORAL
CALAN

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

ISOPTIN

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

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

/INJECTABLE; INJECTION/
/M.V.I. PEDIATRIC/
/USV PHARMACEUTICAL/ /80MG/VIAL;0.02MG/VIAL;0.00ING/VIAL;/
/5MG/VIAL;0.01MG/VIAL;0.14MG/VIAL;/
/17MG/VIAL;0.2MG/VIAL;/
/EQ 1MG BASE/VIAL;1.4MG/VIAL;/
/EQ 1.2MG BASE/VIAL;0.7MG/VIAL;/
/7MG/VIAL/ /N 18920/

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

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

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

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

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

/INJECTABLE; INJECTION/
/M.V.C. 9+3/
/LYPHOMED/ /20MG/ML;0.012MG/ML;0.00ING/ML;
/3MG/ML;0.08MG/ML;8MG/ML;0.8MG/ML;/
/0.72MG/ML;0.6MG/ML;660 IU/ML;/
/40 IU/ML;2 IU/ML/ /N 18440/

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

/INJECTABLE; INJECTION/
/MULTIVITAMIN ADDITIVE/
/ABBOTT LABORATORIES/ /100MG/5ML;0.06MG/5ML;0.005MG/5ML;
/0.4MG/5ML;80MG/5ML;15MG/5ML;/
/4.86MG/5ML;4.95MG/5ML;3.35MG/5ML;/
/3300 IU/5ML;200 IU/5ML;/
/10 IU/5ML/ /N 18223/

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

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

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

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

/INJECTABLE; INJECTION/
/M.V.I./
/USV PHARMACEUTICAL/ /50MG/ML;2.5MG/ML;10MG/ML;1.5MG/ML;
/1MG/ML;5MG/ML;1,000 IU/ML;100 IU/ML;/
/0.5MG/ML/ /N 08809/
/100MG/ML;5MG/ML;20MG/ML;3MG/ML;/
/2MG/ML;10MG/ML;2,000 IU/ML;/
/200 IU/ML;1MG/ML/ /N 08809/

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

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

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

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

NITROGLYCERIN (PAGE AD7)

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

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

CURRENT STATUS - INEFFECTIVE

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

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

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

DIMETAPP AH ROBINS
BROMPHENIRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE; PHENYLPROPANOLAMINE HYDROCHLORIDE

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

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

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

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

ADDENDUM D: DRUG PRICE COMPETITION AND PATENT TERM RESTORATION

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

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

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

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

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

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

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

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

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

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

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

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

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

The following explains how the APDP implements this.

Antibiotics, Insulin and Biologicals

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

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

Bioavailability/Bioequivalence Requirements

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

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

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

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

Topicals

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

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

OTC Drug Products Eligible for Abbreviated New Drug Applications

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

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 must submit 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.

Patent and Exclusivity Information

It was originally planned that Table IV of this supplement to the APDP would contain patent and exclusivity information. However, many firms inappropriately submitted to the Agency manufacturing method patent data along with their product and use patent information. Because the statute does not require the publication of the manufacturing method patents the Agency is checking all of the submitted patent data to eliminate the manufacturing method patents before publishing the patent information. Table IV does contain the date of approval and application number as required by the Act for drug product approval.

Firms submitting ANDAs after September 24, 1984, will be permitted to certify that no patent information has been filed until such time as the Agency publishes the patent information. Upon the publication of the patent information the applicant will be required to amend its application with the appropriate patent certification statement.

FDA plans to publish the submitted product and use patent data in the November 1984 supplement to the 5th Edition of the APDP.

The exclusivity information is planned for publication in the December 1984 Supplement.

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

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

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

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

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

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

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

AMINOPHYLLINE
TABLET; ORAL
100MG
200MG

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

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

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

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

ASPIRIN; CARISOPRODOL
TABLET; ORAL
325MG; 200MG

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

ASPIRIN; MEPROBAMATE
TABLET; ORAL
325MG; 200MG

ASPIRIN; METHOCARBAMOL
TABLET; ORAL
325MG; 200MG

CHLOROTHIAZIDE
TABLET; ORAL
250MG

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

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

TABLE II. OTC DRUG PRODUCTS ELIGIBLE FOR ABBREVIATED NEW DRUG APPLICATIONS (PAGE 1)

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

TABLE II. OTC DRUG PRODUCTS ELIGIBLE FOR ABBREVIATED NEW DRUG APPLICATIONS (PAGE 2)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
BROMPHENIRAMINE MALEATE 12MG	DIMETANE (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	10-799 06-10-83
CHLORHEXIDINE GLUCONATE 20%	HIBICLENS ANTIMICROBIAL SKIN CLEANSER (SOLUTION; TOPICAL)	ICI AMERICAS	17-768 09-17-76
CHLORHEXIDINE GLUCONATE 0.5%	HIBITANE (TINCTURE; TOPICAL)	ICI AMERICAS	18-049 12-18-78
CHLORHEXIDINE GLUCONATE 0.5%	HIBISTAT (SOLUTION; TOPICAL)	ICI AMERICAS	18-300 05-23-80
CHLORHEXIDINE GLUCONATE 4%	HIBICLENS (SPONGE; TOPICAL)	ICI AMERICAS	18-423 08-27-81
CHLORPHENIRAMINE MALEATE 8MG	TELDRIN (CAPSULE, CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	17-369 05-11-78
CHLORPHENIRAMINE MALEATE 12MG	TELDRIN (CAPSULE, CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	17-369 05-11-78
CHLORPHENIRAMINE MALEATE 8MG	CHLOR-TRIMETON (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	07-638 10-18-78
CHLORPHENIRAMINE MALEATE 12MG	CHLOR-TRIMETON (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	07-638 10-18-78

TABLE II. OTC DRUG PRODUCTS ELIGIBLE FOR ABBREVIATED NEW DRUG APPLICATIONS (PAGE 3)

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

TABLE II. OTC DRUG PRODUCTS ELIGIBLE FOR ABBREVIATED NEW DRUG APPLICATIONS (PAGE 4)

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

TABLE II. OTC DRUG PRODUCTS ELIGIBLE FOR ABBREVIATED NEW DRUG APPLICATIONS (PAGE 5)

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

TABLE II. OTC DRUG PRODUCTS ELIGIBLE FOR ABBREVIATED NEW DRUG APPLICATIONS (PAGE 6)

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

TABLE II. OTC DRUG PRODUCTS ELIGIBLE FOR ABBREVIATED NEW DRUG APPLICATIONS (PAGE 7)

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

TABLE II. OTC DRUG PRODUCTS ELIGIBLE FOR ABBREVIATED NEW DRUG APPLICATIONS (PAGE 8)

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

TABLE II. OTC DRUG PRODUCTS ELIGIBLE FOR ABBREVIATED NEW DRUG APPLICATIONS (PAGE 9)

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

TABLE III. NDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED (PAGE 1)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	10-102 12-14-61
ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	11-912 9-2-59
ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	10-855 06-11-59
ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	16-918 3-17-78
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE-1 SOLUTION	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	80-77 11-6-80
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION	NONE (INJECTABLE; INJECTION)	DELMED	78-519 4-23-80
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION	NONE (INJECTABLE; INJECTION)	TERUMO AMERICA	82-528 11-3-82
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	77-420 5-12-78
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	16-527 6-22-70
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	80-222 8-23-82
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	16-907 5-15-73
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TERUMO AMERICA	78-1211 6-10-81

TABLE III. NDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED (PAGE 2)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	17-401 12-6-77
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	81-1012 6-28-83
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP WITH: AS-1: DEXTROSE USP 2.2GM/100ML, SODIUM CHLORIDE USP 0.9GM/100ML, MANNITOL USP 0.75GM/100ML, ADENINE 0.27GM/100ML	ADSOL^{R} RED CELL PRESERVATION SOLUTION (INJECTABLE; INJECTION)	TRAVENOL LABS	81-1104 5-16-83
ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION WITH: AS-2: CITRIC ACID USP 0.42GM/100ML, DIBASIC SODIUM PHOSPHATE USP 0.285GM/100ML, SODIUM CHLORIDE USP 0.718 GM/100ML, ADENINE 0.017GM/100ML, DEXTROSE USP 0.396GM/100ML, SODIUM CITRATE USP 0.588GM/100ML	AS-2 NUTRICEL ADITIVE SYSTEM (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	82-915 9-22-83
ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION WITH: AS-3: CITRIC ACID USP 0.042 GM/100ML, MONOBASIC SODIUM PHOSPHATE USP 0.276GM/100ML, SODIUM CHLORIDE USP 0.410 GM/100ML, ADENINE 0.30 GM/100ML, DEXTROSE USP 1.10 GM/100ML, SODIUM CITRATE USP 0.588GM/100ML	AS-3 NUTRICEL ADDITIVE SYSTEM (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	82-915 10-19-84
ANTICOAGULANT HEPARIN SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	77-822 5-17-78

TABLE III. NDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED (PAGE 3)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
ANTICOAGULANT HEPARIN SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	81-1217 5-16-83
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	81-416 10-12-83
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	76-305 6-30-78
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	16-702 12-28-70
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TERUMO AMERICA	78-1214 2-8-80
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	77-923 1-20-78
DEXTRAN 40, 10% 10GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	16-375 7-25-67
DEXTRAN 75, 6% 6GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	8-819 3-31-53
DEXTRAN 75, 6% 6GM/100ML	NONE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-253 2-4-83
DEXTRAN 40, 10% 10GM/100ML	NONE (INJECTABLE; INJECTION)	AMERICAN MCGAW	16-767 4-6-70
DEXTRAN 70, 6% 6GM/100ML	NONE (INJECTABLE; INJECTION)	AMERICAN MCGAW	9-024 8-18-69
DEXTRAN 40, 10% 10GM/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 (PAGE 4)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
DEXTRAN 70, 6% 6GM/100ML	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	8-716 8-11-69
DEXTRAN 40, 10% 10GM/100ML	NONE (INJECTABLE; INJECTION)	PHARMACHEM	16-836 11-14-70
DEXTRAN 75, 6% 6GM/100ML	NONE (INJECTABLE; INJECTION)	PHARMACHEM	8-564 9-19-52
DEXTRAN 75, 6% 6GM/100ML	NONE (INJECTABLE; INJECTION)	PHARMACHEM	16-759 8-19-70
DEXTRAN 1 150MG/ML	PROMIT (INJECTABLE;INJECTION)	PHARMACIA LABS	83-715 10-30-84
DEXTRAN 40, 10% 10GM/100ML	RHEOMACRODEX^{R} (INJECTABLE; INJECTION)	PHARMACIA LABS	14-716 1-18-67
DEXTRAN 70, 6% 6GM/100ML	MACRODEX^{R} (INJECTABLE; INJECTION)	PHARMACIA LABS	6-826 6-8-54
DEXTRAN 40, 10% 10GM/100ML	GENTRAN^{R} 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	16-628 11-4-68
DEXTRAN 75, 6% 6GM/100ML	GENTRAN^{R} 75 (INJECTABLE; INJECTION)	TRAVENOL LABS	16-607 1-26-70
DEXTRAN 75, 6% INVERTED SUGAR 10% 6GM/100ML;10GM/100ML	6% GENTRAN^{R} 75 AND 10% TRAVERT^{R} (INJECTABLE; INJECTION)	TRAVENOL LABS	8-788 2-9-53
HETASTARCH, 6% 6GM/100ML	HESPAN^{R} (INJECTABLE; INJECTION)	AM CRITICAL CARE	16-889 7-17-72

TABLE III. NDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED (PAGE 5)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
PROPIOLACTONE 99% 99GM/100ML	BETAPRONE (SOLUTION; CHEMICAL STERILIZING AGENT)	ONEAL JONES&FELDMAN	11-657 9-11-59
UROKINASE 5000 IU/VIAL	ABBOKINASE OPEN-CATHETER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	76-1021 12-15-83
UROKINASE 250,000 IU/VIAL	ABBOKINASE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	76-1021 7-31-78
UROKINASE 250,000 IU/VIAL	BREOKINASE (INJECTABLE; INJECTION)	STERLING DRUG	17-873 8-28-79

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 1)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE 650MG; EQ 25MG BASE	TALACEN (TABLET; ORAL)	STERLING DRUG	18-458 09-23-82
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
ACYCLOVIR 5%	ZOVIRAX (OINTMENT; TOPICAL)	BURROUGHS WELLCOME	18-604 03-29-82
ACYCLOVIR SODIUM EQ 500MG BASE/VIAL	ZOVIRAX (INJECTION; INJECTION)	BURROUGHS WELLCOME	18-603 10-22-82
ALBUTEROL SULFATE EQ 2MG BASE	PROVENTIL (TABLET; ORAL)	SCHERING	17-853 05-07-82
ALBUTEROL SULFATE EQ 4MG BASE	PROVENTIL (TABLET; ORAL)	SCHERING	17-853 05-07-82
ALCLOMETASONE DIPROPIONATE 0.05%	VADERM (OINTMENT; TOPICAL)	SCHERING	18-702 12-14-82
ALCLOMETASONE DIPROPIONATE 0.05%	VADERM (CREAM; TOPICAL)	SCHERING	18-707 12-14-82
ALLOPURINOL 100MG	ALLOPURINOL (TABLET; ORAL)	CHELSEA LABORATORIES	18-785 09-28-84
ALLOPURINOL 300MG	ALLOPURINOL (TABLET; ORAL)	CHELSEA LABORATORIES	18-785 09-28-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 2)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE NAME; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
ALLOPURINOL 100MG	ALLOPURINOL (TABLET; ORAL)	DANBURY PHARMACAL	18-832 09-28-84
ALLOPURINOL 300MG	ALLOPURINOL (TABLET; ORAL)	DANBURY PHARMACAL	18-877 09-28-84
AMINO ACIDS 8%	HEPATAMINE 8% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-676 08-03-82
AMINO ACIDS 8.5%	NOVAMINE 8.5% (INJECTABLE; INJECTION)	CUTTER LABS/MILES	17-957 08-09-82
AMINO ACIDS 11.4%	NOVAMINE 11.4% (INJECTABLE; INJECTION)	CUTTER LABS/MILES	17-957 08-09-82
AMINO ACIDS 6.5%	RENAMIN W/O ELECTROLYTES (INJECTABLE; INJECTION)	TRAVENOL LABS	17-493 10-15-82
AMINO ACIDS 6.9%	FREAMINE HBC 6.9% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	16-822 05-17-83
AMINO ACIDS 6.5%	NEOPHAM 6.5% (INJECTABLE; INJECTION)	CUTTER-VITRUM	18-792 01-17-84
AMINO ACIDS 5.2%	AMINESS 5.2% ESSENTIAL AMINO ACIDS W/ HISTADINE (INJECTABLE; INJECTION)	CUTTER-VITRUM	18-901 04-06-84
AMINO ACIDS 3.5%	AMINOSYN 3.5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-804 05-15-84
AMINO ACIDS 6%	TROPHAMINE 6% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-018 07-20-84
AMINO ACIDS 3.5%	AMINOSYN 3.5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-875 08-08-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 3)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
AMINO ACIDS 5.5%	TRAVASOL 5.5% W/O ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-931 08-23-84
AMINO ACIDS 8.5%	TRAVASOL 8.5% W/O ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-931 08-23-84
AMINO ACIDS 10%	TRAVASOL 10% W/O ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-931 08-23-84
AMINO ACIDS 4%	BRANCHAMIN 4% (INJECTABLE; INJECTION)	TRAVENOL LABS	18-678 09-28-84
AMINO ACIDS 4%	BRANCHAMIN 4% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-684 09-28-84
AMINO ACIDS; CALCIUM ACETATE; GLYCERIN; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 3%; 26MG/100ML; 3GM/100ML; 54MG/100ML; 41MG/100ML; 149MG/100ML; 204MG/100ML; 117MG/100ML	PERIPHRAMINE (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-582 05-08-82
AMINO ACIDS; DEXTROSE 3.5%; 5%	AMINOSYN 3.5% W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-120 10-11-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 4)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
AMINO ACIDS; DEXTROSE 3.5%; 25%	AMINOSYN 3.5% W/ DEXTROSE 25% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-118 10-11-84
AMINO ACIDS; DEXTROSE 4.25%; 25%	AMINOSYN 4.25% W/ DEXTROSE 25% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-119 10-11-84
AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; SODIUM CHLORIDE 3.5%; 21MG/100ML; 40MG/100ML; 128MG/100ML; 234MG/100ML	AMINOSYN 3.5% M IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-804 05-15-84
AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; SODIUM CHLORIDE 3.5%; 21MG/100ML; 40MG/100ML; 128MG/100ML; 234MG/100ML	AMINOSYN 3.5% M IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-875 08-08-84
AMINOACETIC ACID 1.5GM/100ML	AMINOACETIC ACID 1.5% IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-522 02-19-82
AMINOCAPROIC ACID 250MG/ML	AMINOCAPROIC ACID (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-590 10-29-82
AMINOPHYLLINE 300MG/5ML	SOMOPHYLLIN (ENEMA; RECTAL)	FISONS	18-232 04-02-82
AMRINONE LACTATE EQ 5MG BASE/ML	INOCOR (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	18-700 07-31-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 5)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
ASPIRIN; CAFFEINE; DIHYDROCODEINE BITARTRATE 356.4MG; 30MG; 16MG	SYNALGOS-DC (CAPSULE; ORAL)	IVES LABS/AMHO	11-483 09-06-83
ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE 385MG; 30MG; 25MG	NORGESIC (TABLET; ORAL)	RIKER LABS/3M	13-416 10-27-82
ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE 770MG; 60MG; 50MG	NORGESIC FORTE (TABLET; ORAL)	RIKER LABS/3M	13-416 10-27-82
ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE 389MG; 32.4MG; 32MG	DARVON COMPOUND (CAPSULE; ORAL)	ELI LILLY INDSTRS/PR	10-996 03-08-83
ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE 389MG; 32.4MG; 65MG	DARVON COMPOUND-65 (CAPSULE; ORAL)	ELI LILLY INDSTRS/PR	10-996 03-08-83
ASPIRIN; CARISOPRODOL 325MG; 200MG	SOMA COMPOUND (TABLET; ORAL)	WALLACE PHARMS/C-W	12-365 07-11-83
ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE 325MG; 200MG; 16MG	SOMA COMPOUND W/ CODEINE (TABLET; ORAL)	WALLACE PHARMS/C-W	12-366 07-11-83
ASPIRIN; MEPROBAMATE 325MG; 200MG	EQUAGESIC (TABLET; ORAL)	WYETH LABS/AMHO	11-702 12-29-83
ATENOLOL; CHLORTHALIDONE 100MG; 25MG	TENORETIC 100 (TABLET; ORAL)	STUART PHARMS/ICI AM	18-760 06-08-84
ATENOLOL; CHLORTHALIDONE 50MG; 25MG	TENORETIC 50 (TABLET; ORAL)	STUART PHARMS/ICI AM	18-760 06-08-84
ATRACURIUM BESYLATE 10MG/ML	TRACRIUM (INJECTABLE; INJECTION)	BURROUGHS WELLCOME	18-831 11-23-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 6)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
AZATADINE MALEATE; PSEUDOEPHEDRINE SULFATE 1MG; 120MG	TRINALIN (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-506 03-23-82
BACLOFEN 20MG	LIORESAL DS (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-851 01-20-82
BENDROFLUMETHIAZIDE; NADOLOL 5MG; 40MG	CORZIDE (TABLET; ORAL)	ER SQUIBB AND SONS	18-647 05-25-83
BENDROFLUMETHIAZIDE; NADOLOL 5MG; 80MG	CORZIDE (TABLET; ORAL)	ER SQUIBB AND SONS	18-647 05-25-83
BENTIROMIDE 500MG/7.5ML	CHYMEX (SOLUTION; ORAL)	ADRIA LABORATORIES	18-366 12-29-83
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	DIPROLENE (OINTMENT; TOPICAL)	SCHERING	18-741 07-27-83
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (CREAM; TOPICAL)	PHARMADERM/BYK-GLDN	19-136 06-26-84
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (CREAM; TOPICAL)	E FOUGERA/BYK-GLDN	19-137 06-26-84
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	ALPHATREX (CREAM; TOPICAL)	SAVAGE LABS/BYK-GLDN	19-138 06-26-84
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (OINTMENT; TOPICAL)	PHARMADERM/BYK-GLDN	19-140 09-04-84
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (OINTMENT; TOPICAL)	E FOUGERA/BYK-GLDN	19-141 09-04-84
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	ALPHATREX (OINTMENT; TOPICAL)	SAVAGE LABS/BYK-GLDN	19-143 09-04-84
BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE EQ 0.05% BASE; 1%	LOTRISONE (CREAM; TOPICAL)	SCHERING	18-827 07-10-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 7)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
BETAMETHASONE VALERATE EQ 0.1% BASE	BETA-VAL (CREAM; TOPICAL)	LEMMON	18-642 03-24-83
BETAMETHASONE VALERATE EQ 0.1% BASE	BETADERM (CREAM; TOPICAL)	TJ ROACO	18-839 06-30-83
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (CREAM; TOPICAL)	PHARMADERM/BYK-GLDN	18-860 08-31-83
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (CREAM; TOPICAL)	E FOUGERA/BYK-GLDN	18-861 08-31-83
BETAMETHASONE VALERATE EQ 0.1% BASE	BETATREX (CREAM; TOPICAL)	SAVAGE LABS/BYK-GLDN	18-862 08-31-83
BETAMETHASONE VALERATE EQ 0.1% BASE	BETATREX (OINTMENT; TOPICAL)	SAVAGE LABS/BYK-GLDN	18-863 08-31-83
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (OINTMENT; TOPICAL)	PHARMADERM/BYK-GLDN	18-864 08-31-83
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (OINTMENT; TOPICAL)	E FOUGERA/BYK-GLDN	18-865 08-31-83
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (LOTION; TOPICAL)	E FOUGERA/BYK-GLDN	18-866 08-31-83
BETAMETHASONE VALERATE EQ 0.1% BASE	BETATREX (LOTION; TOPICAL)	SAVAGE LABS/BYK-GLDN	18-867 08-31-83
BETAMETHASONE VALERATE EQ 0.1% BASE	BETAMETHASONE VALERATE (LOTION; TOPICAL)	PHARMADERM/BYK-GLDN	18-870 08-31-83
BROMOCRIPTINE MESYLATE EQ 5MG BASE	PARLODEL (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	17-962 03-01-82

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 8)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE 12.5MG/5ML; 10MG/5ML	AMBENYL (SYRUP; ORAL)	MARION LABORATORIES	09-319 01-10-84
BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 12.5MG/5ML	DIMETANE-DC (SYRUP; ORAL)	AH ROBINS	11-694 03-29-84
BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 30MG/5ML	DIMETANE-DX (SYRUP; ORAL)	AH ROBINS	11-694 03-29-84
BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE 2MG/5ML; 10MG/5ML; 30MG/5ML	DIMETANE-DX (SYRUP; ORAL)	AH ROBINS	19-279 08-24-84
BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 4MG/5ML; 25MG/5ML	ELIXIR DIMETAPP (ELIXIR; ORAL)	AH ROBINS	13-087 03-29-84
BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 12MG; 75MG	DIMETAPP (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	12-436 04-02-84
BUMETANIDE 1MG	BUMEX (TABLET; ORAL)	HOFFMANN-LA ROCHE	18-225 02-28-83
BUMETANIDE 0.5MG	BUMEX (TABLET; ORAL)	HOFFMANN-LA ROCHE	18-225 02-28-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 9)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
BUMETANIDE 0.25MG/ML	BUMEX (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	18-226 02-28-83
BUPIVACAINE HYDROCHLORIDE; DEXTROSE 0.75%; 8.25%	MARCAINE SPINAL (INJECTABLE; INJECTION)	BREON LABS/STERLING	18-692 05-04-84
BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE 0.5%; 0.0091MG/ML	SENSORCAINE (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-304 09-02-83
BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE 0.75%; 0.0091MG/ML	SENSORCAINE (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-304 09-02-83
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE 34MG/100ML; 5GM/100ML; 30MG/100ML; 74MG/100ML; 640MG/100ML; 500MG/100ML; 74MG/100ML	ISOLYTE E W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-269 01-17-83
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 510MG/100ML; 30GM/100ML; 200MG/100ML; 9.2GM/100ML; 9.6GM/100ML	DIALYTE CONCENTRATE W/ DEXTROSE 30% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807 08-26-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 10)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 51OMG/100ML; 50GM/100ML; 200MG/100ML; 9.2GM/100ML; 9.6GM/100ML	DIALYTE CONCENTRATE W/ DEXTROSE 50% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807 08-26-83
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 51OMG/100ML; 30GM/100ML; 200MG/100ML; 9.4GM/100ML; 11GM/100ML	DIALYTE CONCENTRATE W/ DEXTROSE 30% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807 08-26-83
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 51OMG/100ML; 50GM/100ML; 200MG/100ML; 9.4GM/100ML; 11GM/100ML	DIALYTE CONCENTRATE W/ DEXTROSE 50% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-807 08-26-83
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

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 11)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	INPERSOL-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	INPERSOL-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	ABBOTT LABORATORIES	18-379 07-07-82
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 26MG/100ML; 2.5GM/100ML; 15MG/100ML; 560MG/100ML; 390MG/100ML	DIALYTE W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	AM MCGAW/AM HOSP	18-460 11-02-83
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 33MG/100ML; 5GM/100ML; 30MG/100ML; 860MG/100ML	DEXTROSE 5% AND RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-635 02-07-83
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 16.5MG/ML; 25.4MG/ML; 74.6MG/ML; 121MG/ML; 16.1MG/ML	TPN ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-895 07-20-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 12)

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

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 13)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 33MG/100ML; 30MG/100ML; 860MG/100ML	RINGERS INJECTION IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-648 02-07-83
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 20MG/100ML; 30MG/100ML; 600MG/100ML; 310MG/100ML	LACTATED RINGER'S IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-494 02-19-82
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 20MG/100ML; 30MG/100ML; 600MG/100ML; 310MG/100ML	LACTATED RINGER'S IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	AM MCGAW/AM HOSP	18-681 12-27-82
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 20MG/100ML; 30MG/100ML; 600MG/100ML; 310MG/100ML	LACTATED RINGER'S IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-921 04-03-84
CAPTOPRIL; HYDROCHLOROTHIAZIDE 25MG; 15MG	CAPOZIDE 25/15 (TABLET; ORAL)	ER SQUIBB AND SONS	18-709 10-12-84
CAPTOPRIL; HYDROCHLOROTHIAZIDE 50MG; 15MG	CAPOZIDE 50/15 (TABLET; ORAL)	ER SQUIBB AND SONS	18-709 10-12-84
CAPTOPRIL; HYDROCHLOROTHIAZIDE 50MG; 25MG	CAPOZIDE 50/25 (TABLET; ORAL)	ER SQUIBB AND SONS	18-709 10-12-84
CELLULOSE SODIUM PHOSPHATE 2.5GM/PACKET	CALCIBIND (POWDER; ORAL)	MISSION PHARMACAL	18-757 12-28-82

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 14)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
CHENODIOL 250MG	CHENIX (TABLET; ORAL)	ROWELL LABORATORIES	18-513 07-28-83
CHLORDIAZEPOXIDE 30MG	LIBRELEASE (CAPSULE, CONTROLLED RELEASE; ORAL)	HOFFMANN-LA ROCHE	17-813 09-12-83
CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE 15MG; 0.3MG	COMBIPRES (TABLET; ORAL)	BOEHRINGER INGELHEIM	17-503 04-10-84
CHYMOPAPAIN 10,000 UNITS/VIAL	CHYMODIACTIN (INJECTABLE; INJECTION)	SMITH LABORATORIES	18-663 11-10-82
CHYMOPAPAIN 12,500 UNITS/VIAL	DISCASE (INJECTABLE; INJECTION)	TRAVENOL LABS	18-625 01-18-84
CHYMOPAPAIN 4,000 UNITS/VIAL	CHYMODIACTIN (INJECTABLE; INJECTION)	SMITH LABORATORIES	18-663 08-21-84
CICLOPIROX OLAMINE 1%	LOPROX (CREAM; TOPICAL)	HOECHST-ROUSSEL	18-748 12-30-82
CIMETIDINE 400MG	TAGAMET (TABLET; ORAL)	SK&F LAB	17-920 12-14-83
CITRIC ACID; MAGNESIUM OXIDE; SODIUM CARBONATE 3.24GM/100ML; 380MG/100ML; 430MG/100ML	IRRIGATING SOLUTION G IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-519 06-22-82
CITRIC ACID; MAGNESIUM OXIDE; SODIUM CARBONATE 3.24GM/100ML; 380MG/100ML; 430MG/100ML	UROLOGIC G IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	ABBOTT LABORATORIES	18-904 05-27-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 15)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE EQ 1MG BASE; 75MG	TAVIST D (TABLET, CONTROLLED RELEASE; ORAL)	DORSEY LABS/SANDOZ	18-298 12-15-82
CLOMIPHENE CITRATE 50MG	CLOMIPHENE CITRATE (TABLET; ORAL)	PLANTEX/IKAPHARM	18-361 03-22-82
CLONIDINE 2.5MG	CATAPRES-TTS-1 (FILM, CONTROLLED RELEASE; PERCUTANEOUS)	BOEHRINGER INGELHEIM	18-891 10-10-84
CLONIDINE 5MG	CATAPRES-TTS-2 (FILM, CONTROLLED RELEASE; PERCUTANEOUS)	BOEHRINGER INGELHEIM	18-891 10-10-84
CLONIDINE 7.5MG	CATAPRES-TTS-3 (FILM, CONTROLLED RELEASE; PERCUTANEOUS)	BOEHRINGER INGELHEIM	18-891 10-10-84
CLOTRIMAZOLE 10MG	MYCELEX (TROCHE/LOZENGE; ORAL)	MILES PHARMS/MILES	18-713 06-17-83
CLOTRIMAZOLE 1%	LOTRIMIN (LOTION; TOPICAL)	SCHERING	18-813 02-17-84
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

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 16)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 10MG/5ML; 30MG/5ML; 1.25MG/5ML	ACTIFED W/ CODEINE (SYRUP; ORAL)	BURROUGHS WELLCOME	12-575 04-04-84
CROMOLYN SODIUM 10MG/ML	INTAL (SOLUTION; INHALATION)	FISONS	18-596 05-28-82
CROMOLYN SODIUM 4%	NASALCROM (SOLUTION; NASAL)	FISONS	18-306 03-18-83
CROMOLYN SODIUM 4%	OPTICROM (SOLUTION; OPTHALMIC)	FISONS	18-155 10-03-84
CYCLOPHOSPHAMIDE 1GM/VIAL	CYTOXAN (INJECTABLE; INJECTION)	MEAD JOHNSON/B-M	12-142 08-30-82
CYCLOPHOSPHAMIDE 2GM/VIAL	CYTOXAN (INJECTABLE; INJECTION)	MEAD JOHNSON/B-M	12-142 08-30-82
DESIPRAMINE HYDROCHLORIDE 10MG	NORPRAMIN (TABLET; ORAL)	MERRELL DOW/DOW CHEM	14-399 02-11-82
DESMOPRESSIN ACETATE 0.004MG/ML	DDAVP (INJECTABLE; INJECTION)	ARMOUR PHARM	18-938 03-30-84
DESOXIMETASONE 0.05%	TOPICORT (GEL; TOPICAL)	HOECHST-ROUSSEL	18-586 03-29-82
DESOXIMETASONE 0.25%	TOPICORT (OINTMENT; TOPICAL)	HOECHST-ROUSSEL	18-763 10-03-83
DEXAMETHASONE 6MG	DECADRON (TABLET; ORAL)	MS&D/MERCK	11-664 07-30-82
DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE 15MG/5ML; 6.25MG/5ML	PHENERGAN W/ DEXTROMETHORPHAN (SYRUP; ORAL)	WYETH LABS/AMHO	11-265 04-02-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 17)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
DEXTROSE 70GM/100ML	DEXTROSE 70% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-561 03-23-82
DEXTROSE 40GM/100ML	DEXTROSE 40% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-562 03-23-82
DEXTROSE 50GM/100ML	DEXTROSE 50% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-563 03-23-82
DEXTROSE 20GM/100ML	DEXTROSE 20% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-564 03-23-82
DEXTROSE 60GM/100ML	DEXTROSE 60% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	17-521 03-26-82
DEXTROSE 70GM/100ML	DEXTROSE 70% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	17-521 03-26-82
DEXTROSE 60GM/100ML	DEXTROSE 60% (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	17-995 09-22-82
DEXTROSE 50MG/ML	DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-222 07-13-84
DEXTROSE 38.5GM/100ML	DEXTROSE 38.5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-923 09-19-84
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 80MG/100ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 02-04-82

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 18)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 160MG/100ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 02-04-82
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 80MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 160MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 320MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 4,000 UNITS/100ML	HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-814 10-31-83
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 800MG/100ML	LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-461 02-22-82
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 800MG/100ML	LIDOCAINE HCL 0.8% IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-388 11-05-82
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 200MG/100ML	LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-967 03-30-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 19)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
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
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 800MG/100ML	LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-967 03-30-84
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 75MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 150MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 220MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 300MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82
DEXTROSE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM LACTATE 5GM/100ML; 205MG/100ML; 100MG/100ML; 120MG/100ML; 220MG/100ML	DEXTROSE 5% AND ELECTROLYTE NO 75 IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-840 06-29-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 20)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 75MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 5MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 75MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 21)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 22)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 450MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-566 02-10-83
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 23)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
DEXTROSE; THEOPHYLLINE 5GM/100ML; 40MG/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
DICYCLOMINE HYDROCHLORIDE 10MG	BENTYL (CAPSULE; ORAL)	MERRELL DOW/DOW CHEM	07-409 10-15-84
DICYCLOMINE HYDROCHLORIDE 20MG	BENTYL (TABLET; ORAL)	MERRELL DOW/DOW CHEM	07-409 10-15-84
DICYCLOMINE HYDROCHLORIDE 10MG/ML	BENTYL (INJECTABLE; INJECTION)	MERRELL DOW/DOW CHEM	08-370 10-15-84
DICYCLOMINE HYDROCHLORIDE 10MG/5ML	BENTYL (SYRUP; ORAL)	MERRELL DOW/DOW CHEM	07-961 10-15-84
DIFLUNISAL 250MG	DOLOBID (TABLET; ORAL)	MS&D/MERCK	18-445 04-19-82

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 24)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
DIFLUNISAL 500MG	DOLOBID (TABLET; ORAL)	MS&D/MERCK	18-445 04-19-82
DIGOXIN 0.2MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82
DIGOXIN 0.05MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82
DIGOXIN 0.1MG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82
DILTIAZEM HYDROCHLORIDE 30MG	CARDIZEM (TABLET; ORAL)	MARION LABORATORIES	18-602 11-05-82
DILTIAZEM HYDROCHLORIDE 60MG	CARDIZEM (TABLET; ORAL)	MARION LABORATORIES	18-602 11-05-82
DISOPYRAMIDE PHOSPHATE EQ 100MG BASE	NORPACE CR (CAPSULE, CONTROLLED RELEASE; ORAL)	SEARLE/SEARLE PHARMS	18-655 07-20-82
DISOPYRAMIDE PHOSPHATE EQ 150MG BASE	NORPACE CR (CAPSULE, CONTROLLED RELEASE; ORAL)	SEARLE/SEARLE PHARMS	18-655 07-20-82
DIVALPROEX SODIUM EQ 250MG BASE	DEPAKOTE (TABLET, ENTERIC COATED; ORAL)	ABBOTT LABORATORIES	18-723 03-10-83
DIVALPROEX SODIUM EQ 500MG BASE	DEPAKOTE (TABLET, ENTERIC COATED; ORAL)	ABBOTT LABORATORIES	18-723 03-10-83
DOPAMINE HYDROCHLORIDE 80MG/ML	DOPAMINE (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-398 03-22-82

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 25)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
DOPAMINE HYDROCHLORIDE 80MG/ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 07-09-82
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
ECONAZOLE NITRATE 1%	SPECTAZOLE (CREAM; TOPICAL)	ORTHO PHARMACEUTICAL	18-751 12-23-82
ERGOLOID MESYLATES 1MG	HYDERGINE LC (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	18-706 01-18-83
ESTROGENS, CONJUGATED 0.9MG	PREMARIN (TABLET; ORAL)	AYERST LABS/AMHO	04-782 01-26-84
ETHINYL ESTRADIOL; LEVONORGESTREL 0.03MG; 0.15MG	NORDETTE-21 (TABLET; ORAL-21)	WYETH LABS/AMHO	18-668 05-10-82
ETHINYL ESTRADIOL; LEVONORGESTREL 0.03MG; 0.15MG	NORDETTE-28 (TABLET; ORAL-28)	WYETH LABS/AMHO	18-782 07-21-82
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 10/11-21 (TABLET; ORAL-21)	ORTHO PHARMACEUTICAL	18-354 01-11-82
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 10/11-28 (TABLET; ORAL-28)	ORTHO PHARMACEUTICAL	18-354 01-11-82
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG, 0.75MG AND 1MG	ORTHO-NOVUM 7/7/7-21 (TABLET; ORAL-21)	ORTHO PHARMACEUTICAL	18-985 04-04-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 26)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG, 0.75MG AND 1MG	ORTHO-NOVUM 7/7/7-28 (TABLET; ORAL-28)	ORTHO PHARMACEUTICAL	18-985 04-04-84
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 7/14-21 (TABLET; ORAL-21)	ORTHO PHARMACEUTICAL	19-004 04-04-84
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	ORTHO-NOVUM 7/14-28 (TABLET; ORAL-28)	ORTHO PHARMACEUTICAL	19-004 04-04-84
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	TRI-NORINYL 21-DAY (TABLET; ORAL-21)	SYNTEX (FP)	18-977 04-13-84
ETHINYL ESTRADIOL; NORETHINDRONE 0.035MG; 0.5MG AND 1MG	TRI-NORINYL 28-DAY (TABLET; ORAL-28)	SYNTEX (FP)	18-977 04-13-84
ETOMIDATE 2MG/ML	AMIDATE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-227 09-07-82
ETOMIDATE 2MG/ML	HYPNOMIDATE (INJECTABLE; INJECTION)	JANSSEN PHARMA	18-228 11-23-82
ETOPOSIDE 20MG/ML	VEPESID (INJECTABLE; INJECTION)	BRISTOL LABS/B-M	18-768 11-10-83
FENFLURAMINE HYDROCHLORIDE 60MG	PONDIMIN (TABLET, CONTROLLED RELEASE; ORAL)	AH ROBINS	16-618 07-27-82
FENTANYL CITRATE EQ 0.05MG BASE/ML	FENTANYL (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	19-101 07-11-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 27)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
FLUNISOLIDE 0.025MG/INH	BRONALIDE (AEROSOL; INHALATION)	SYNTEX LABS/SYNTEX	18-340 08-17-84
FLUOCINONIDE 0.05%	LIDEX (SOLUTION; TOPICAL)	SYNTEX LABS/SYNTEX	18-849 04-06-84
FLUOCINONIDE 0.05%	VASODERM (CREAM; TOPICAL)	K-LINE PHARMS	19-117 06-26-84
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	PARKE-DAVIS/W-L	18-420 02-26-82
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 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-667 05-28-82
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	WYETH LABS/AMHO	18-670 07-20-82
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-415 07-27-82
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	LEDERLE LABS/AM CYAN	18-415 07-27-82
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	LYPHOMED	18-507 07-30-82
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	PARKE-DAVIS/W-L	18-419 01-31-83
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	PARKE-DAVIS/W-L	18-419 01-31-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 28)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	SUPERPHARM	18-370 02-10-83
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	KALAPHARM	18-868 06-28-83
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	KALAPHARM	18-868 06-28-83
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	ROXANE LABORATORIES	18-823 11-10-83
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	ROXANE LABORATORIES	18-823 11-10-83
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	BARR LABORATORIES	18-790 11-29-83
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	ZENITH LABORATORIES	18-413 11-30-83
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	ZENITH LABORATORIES	18-413 11-30-83
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	NATCON	18-579 11-30-83
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 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	INVENEX LABS/LIFE	18-902 05-22-84
FUROSEMIDE 20MG	FUROSEMIDE (TABLET; ORAL)	SUPERPHARM	18-370 06-26-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 29)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
FUROSEMIDE 40MG	FUROSEMIDE (TABLET; ORAL)	DRUMMER/PHOENIX	18-750 07-30-84
FUROSEMIDE 10MG/ML	FUROSEMIDE (INJECTABLE; INJECTION)	INVENEX LABS/LIFE	19-036 08-13-84
FUROSEMIDE 80MG	FUROSEMIDE (TABLET; ORAL)	CORD LABORATORIES	18-569 08-14-84
GLIPIZIDE 5MG	GLUCOTROL (TABLET; ORAL)	ROERIG/PFIZER	17-783 05-08-84
GLIPIZIDE 10MG	GLUCOTROL (TABLET; ORAL)	ROERIG/PFIZER	17-783 05-08-84
GLYBURIDE 1.25MG	MICRONASE (TABLET; ORAL)	UPJOHN	17-498 05-01-84
GLYBURIDE 2.5MG	MICRONASE (TABLET; ORAL)	UPJOHN	17-498 05-01-84
GLYBURIDE 5MG	MICRONASE (TABLET; ORAL)	UPJOHN	17-498 05-01-84
GLYBURIDE 1.25MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532 05-01-84
GLYBURIDE 2.5MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532 05-01-84
GLYBURIDE 5MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532 05-01-84
GONADORELIN HYDROCHLORIDE EQ 0.1MG BASE/VIAL	FACTREL (INJECTABLE; INJECTION)	AYERST LABS/AMHO	18-123 09-30-82
GONADORELIN HYDROCHLORIDE EQ 0.5MG BASE/VIAL	FACTREL (INJECTABLE; INJECTION)	AYERST LABS/AMHO	18-123 09-30-82

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 30)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
GUANABENZ ACETATE EQ 4MG BASE	WYTENSIN (TABLET; ORAL)	WYETH LABS/AMHO	18-587 09-07-82
GUANABENZ ACETATE EQ 8MG BASE	WYTENSIN (TABLET; ORAL)	WYETH LABS/AMHO	18-587 09-07-82
GUANADREL SULFATE 10MG	HYLOREL (TABLET; ORAL)	UPJOHN	18-104 12-29-82
GUANADREL SULFATE 25MG	HYLOREL (TABLET; ORAL)	UPJOHN	18-104 12-29-82
HALOPERIDOL 20MG	HALDOL (TABLET; ORAL)	MCNEIL PHARM	15-921 02-02-82
HEPARIN SODIUM 10 UNITS/ML	HEPARIN LOCK FLUSH (INJECTABLE; INJECTION)	INVENEX LABS/LIFE	17-029 05-06-82
HEPARIN SODIUM; SODIUM CHLORIDE 200 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 1000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-609 04-28-82
HEPARIN SODIUM; SODIUM CHLORIDE 200 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 20,000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-609 04-28-82
HEPARIN SODIUM; SODIUM CHLORIDE 500 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 5000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-609 04-28-82
HEPARIN SODIUM; SODIUM CHLORIDE 1,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 31)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
HYDROCHLOROTHIAZIDE; TRIAMTERENE 50MG; 75MG	MAXZIDE (TABLET; ORAL)	MYLAN PHARMS	19-129 10-22-84
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84
HEPARIN SODIUM; SODIUM CHLORIDE 100 UNITS/ML; 4.5MG/ML	HEPARIN SODIUM 5,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 32)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84
HYDROCORTISONE ACETATE 10%	CORTIFOAM (AEROSOL; RECTAL)	REED&CARNRICK PHARMS	17-351 02-10-82
HYDROCORTISONE BUTYRATE 0.1%	LOCOID (CREAM; TOPICAL)	OWEN LABS/DERM PRODS	18-795 01-07-83
HYDROCORTISONE BUTYRATE 0.1%	LOCOID (OINTMENT; TOPICAL)	OWEN LABS/DERM PRODS	19-106 07-03-84
HYDROCORTISONE VALERATE 0.2%	WESTCORT (OINTMENT; TOPICAL)	WESTWOOD PHARMS	18-726 08-08-83
HYDROMORPHONE HYDROCHLORIDE 10MG/ML	DILAUDID-HP (INJECTABLE; INJECTION)	KNOLL PHARMACEUTICAL	19-034 01-11-84
IBUPROFEN 600MG	RUFEN (TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-197 03-05-84
INDAPAMIDE 2.5MG	LOZOL (TABLET; ORAL)	USV PHARMACEUTICAL	18-538 07-06-83
INDOMETHACIN 75MG	INDOCIN SR (CAPSULE, CONTROLLED RELEASE; ORAL)	MS&D/MERCK	18-185 02-23-82
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	MYLAN PHARMS	18-858 04-20-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 33)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	MYLAN PHARMS	18-858 04-20-84
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	ZENITH LABORATORIES	18-730 05-04-84
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	ZENITH LABORATORIES	18-730 05-04-84
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	18-851 05-18-84
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	18-851 05-18-84
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	CHELSEA LABORATORIES	18-690 07-31-84
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	CHELSEA LABORATORIES	18-690 07-31-84
INDOMETHACIN 50MG	INDOMETHACIN (CAPSULE; ORAL)	PAR PHARMACEUTICAL	18-829 08-06-84
INDOMETHACIN 25MG	INDOMETHACIN (CAPSULE; ORAL)	PAR PHARMACEUTICAL	18-829 08-06-84
INDOMETHACIN 50MG	INDOCIN (SUPPOSITORY; RECTAL)	MS&D RES LABS/MERCK	17-814 08-13-84
ISOTRETINOIN 10MG	ACCUTANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662 05-07-82
ISOTRETINOIN 40MG	ACCUTANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662 05-07-82
ISOTRETINOIN 20MG	ACCUTANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662 03-28-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 34)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
LABETALOL HYDROCHLORIDE 200MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-686 08-01-84
LABETALOL HYDROCHLORIDE 300MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-686 08-01-84
LABETALOL HYDROCHLORIDE 400MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-686 08-01-84
LABETALOL HYDROCHLORIDE 5MG/ML	NORMODYNE (INJECTABLE; INJECTION)	SCHERING	18-687 08-01-84
LABETALOL HYDROCHLORIDE 200MG	TRANDATE (TABLET; ORAL)	GLAXO	18-716 08-01-84
LABETALOL HYDROCHLORIDE 300MG	TRANDATE (TABLET; ORAL)	GLAXO	18-716 08-01-84
LABETALOL HYDROCHLORIDE 400MG	TRANDATE (TABLET; ORAL)	GLAXO	18-716 08-01-84
LEUCOVORIN CALCIUM EQ 5MG BASE	WELLCOVORIN (TABLET; ORAL)	BURROUGHS WELLCOME	18-342 07-08-83
LEUCOVORIN CALCIUM EQ 25MG BASE	WELLCOVORIN (TABLET; ORAL)	BURROUGHS WELLCOME	18-342 07-08-83
LITHIUM CARBONATE 300MG	LITHIUM CARBONATE (TABLET; ORAL)	ROXANE LABORATORIES	18-558 01-29-82
LITHIUM CARBONATE 450MG	ESKALITH CR (TABLET, CONTROLLED RELEASE; ORAL)	SK&F LABORATORIES	18-152 03-29-82
LOPERAMIDE HYDROCHLORIDE 1MG/5ML	IMODIUM (SOLUTION; ORAL)	JANSSEN PHARMA	19-037 07-31-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 35)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
MAGNESIUM ACETATE TETRAHYDRATE; POTASSIUM ACETATE; SODIUM CHLORIDE 32MG/100ML; 128MG/100ML; 234MG/100ML	PLASMA-LYTE 56 IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-047 06-15-84
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE; SODIUM PHOSPHATE 30MG/100ML; 37MG/100ML; 0.82MG/100ML; 370MG/100ML; 530MG/100ML; 500MG/100ML; 12MG/100ML	ISOLYTE S PH 7.4 IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-006 04-04-84
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE 30MG/100ML; 37MG/100ML; 222MG/100ML; 526MG/100ML; 502MG/100ML	PHYSIOSOL IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	ABBOTT LABORATORIES	17-637 07-08-82
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE 30MG/100ML; 37MG/100ML; 222MG/100ML; 526MG/100ML; 502MG/100ML	PHYSIOSOL IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	ABBOTT LABORATORIES	18-406 07-08-82

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 36)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE 30MG/100ML; 37MG/100ML; 370MG/100ML; 530MG/100ML; 500MG/100ML	PHYSIOLYTE IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	AM MCGAW/AM HOSP	19-024 06-08-84
MAGNESIUM SULFATE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE 20MG/100ML; 40MG/100ML; 6.25MG/100ML; 800MG/100ML; 8.75MG/100ML	TIS-U-SOL (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-508 02-19-82
MALATHION 0.5%	PRIODERM (LOTION; TOPICAL)	PURDUE FREDERICK	18-613 08-02-82
MAPROTILINE HYDROCHLORIDE 75MG	LUDIOMIL (TABLET; ORAL)	CIBA/CIBA-GEIGY	17-543 09-30-82
MAZINDOL 1MG	MAZANOR (TABLET; ORAL)	WYETH LABS/AMHO	17-980 02-02-82
METAPROTERENOL SULFATE 0.6%	ALUPENT (SOLUTION; INHALATION)	BOEHRINGER INGELHEIM	18-761 06-30-83
METHYLDOPA 250MG	METHYLDOPA (TABLET; ORAL)	CORD LABORATORIES	18-934 06-29-84
METHYLDOPA 500MG	METHYLDOPA (TABLET; ORAL)	CORD LABORATORIES	18-934 06-29-84
METHYLPHENIDATE HYDROCHLORIDE 20MG	RITALIN-SR (TABLET, CONTROLLED RELEASE; ORAL)	CIBA/CIBA-GEIGY	18-029 03-30-82

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 37)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
METOCLOPRAMIDE HYDROCHLORIDE EQ 5MG BASE/5ML	REGLAN (SYRUP; ORAL)	AH ROBINS	18-821 03-25-83
METOPROLOL TARTRATE 1MG/ML	LOPRESSOR (INJECTABLE; INJECTION)	GEIGY/CIBA-GEIGY	18-704 03-30-84
METRONIDAZOLE 250MG	METRYL (TABLET; ORAL)	DRUMMER/PHOENIX	18-620 03-04-82
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	ZENITH LABORATORIES	18-517 05-05-82
METRONIDAZOLE 500MG/100ML	METRO I.V. (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-674 08-31-82
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	CHELSEA LABORATORIES	18-599 09-17-82
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	DANBURY PHARMACAL	18-764 09-17-82
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	CORD LABORATORIES	18-740 10-22-82
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	CORD LABORATORIES	18-740 10-22-82
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	DANBURY PHARMACAL	18-764 12-20-82
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	BARR LABORATORIES	18-818 02-16-83
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	BARR LABORATORIES	18-818 02-16-83
METRONIDAZOLE 250MG	PROTOSTAT (TABLET; ORAL)	ORTHO PHARMACEUTICAL	18-871 03-02-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 38)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
METRONIDAZOLE 500MG	PROTOSTAT (TABLET; ORAL)	ORTHO PHARMACEUTICAL	18-871 03-02-83
METRONIDAZOLE 500MG	METRYL 500 (TABLET; ORAL)	DRUMMER/PHOENIX	18-620 06-02-83
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	PAR PHARMACEUTICAL	18-845 08-18-83
METRONIDAZOLE 500MG	METRONIDAZOLE (TABLET; ORAL)	PAR PHARMACEUTICAL	18-930 08-18-83
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)	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	METRONIDAZOLE (TABLET; ORAL)	CHELSEA LABORATORIES	18-599 02-13-84
METRONIDAZOLE 500MG/100ML	METRONIDAZOLE (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-907 03-30-84
METRONIDAZOLE 250MG	METRONIDAZOLE (TABLET; ORAL)	LNK INTERNATIONAL	19-029 04-10-84
MICONAZOLE NITRATE 100MG	MONISTAT 7 (SUPPOSITORY; VAGINAL)	ORTHO PHARMACEUTICAL	18-520 03-15-82
MICONAZOLE NITRATE 200MG	MONISTAT 3 (SUPPOSITORY; VAGINAL)	ORTHO PHARMACEUTICAL	18-888 08-15-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 39)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
MORPHINE SULFATE 0.5MG/ML	DURAMORPH PF (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-565 09-18-84
MORPHINE SULFATE 1MG/ML	DURAMORPH PF (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-565 09-18-84
NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE 0.5MG; EQ 50MG BASE	TALWIN NX (TABLET; ORAL)	WINTHROP LABS/STERL	18-733 12-16-82
NAPROXEN 500MG	NAPROSYN (TABLET; ORAL)	SYNTEX PR	17-581 04-15-82
NICLOSAMIDE 500MG	NICLOCIDE (TABLET, CHEWABLE; ORAL)	MILES PHARMS/MILES	18-669 05-14-82
NICOTINE RESIN COMPLEX EQ 2MG BASE	NICORETTE (GUM, CHEWING; ORAL)	MERRELL DOW/DOW CHEM	18-612 01-13-84
NITROGLYCERIN 5MG/ML	NITRO-BID (INJECTABLE; INJECTION)	MARION LABORATORIES	18-621 01-05-82
NITROGLYCERIN 0.8MG/ML	NITROL (INJECTABLE; INJECTION)	KREMERS-URBAN	18-774 01-19-83
NITROGLYCERIN 0.5MG/ML	TRIDIL (INJECTABLE; INJECTION)	AM CRITICAL CARE/AHS	18-537 06-16-83
NITROGLYCERIN 1MG/ML	NITRONAL (INJECTABLE; INJECTION)	G POHL-BOSKAMP	18-672 08-30-83
NITROGLYCERIN 5MG/ML	NITRONAL (INJECTABLE; INJECTION)	G POHL-BOSKAMP	18-672 08-30-83
NITROGLYCERIN 5MG/ML	NITROSTAT (INJECTABLE; INJECTION)	PARKE-DAVIS/W-L	18-588 12-23-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 40)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
NORETHINDRONE ACETATE 5MG	AYGESTIN (TABLET; ORAL)	AYERST LABS/AMHO	18-405 04-21-82
OXPRENOLOL HYDROCHLORIDE 20MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83
OXPRENOLOL HYDROCHLORIDE 40MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83
OXPRENOLOL HYDROCHLORIDE 80MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83
OXPRENOLOL HYDROCHLORIDE 160MG	TRASICOR (CAPSULE; ORAL)	CIBA/CIBA-GEIGY	18-166 12-28-83
PENTAMIDINE ISETHIONATE 300MG/VIAL	PENTAM 300 (INJECTABLE; INJECTION)	LYPHOMED	19-129 10-16-84
PENTETATE INDIUM DISODIUM, IN-111 1MCI/ML	MPI INDIUM DTPA IN 111 (INJECTABLE; INJECTION)	MEDI-PHYSICS	17-707 02-18-82
PENTOXIFYLLINE 400MG	TRENTAL (TABLET, CONTROLLED RELEASE; ORAL)	HOECHST-ROUSSEL	18-631 08-30-84
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; OPTHALMIC)	ALCON LABORATORIES	18-796 10-01-84
PIMOZIDE 2MG	ORAP (TABLET; ORAL)	MCNEIL PHARM	17-473 07-31-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 41)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
PINDOLOL 5MG	VISKEN (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	18-285 09-03-82
PINDOLOL 10MG	VISKEN (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	18-285 09-03-82
PINDOLOL 15MG	VISKEN (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	18-285 09-03-82
PIROXICAM 10MG	FELDENE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-147 04-06-82
PIROXICAM 20MG	FELDENE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	18-147 04-06-82
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; 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

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 42)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
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
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE; 22.74GM/BOT; 236GM/BOT; 2.97GM/BOT; 6.74GM/BOT; 5.86GM/BOT	GOLYTELY (POWDER FOR RECONSTITUTION; ORAL)	BRAINTREE LABS	19-011 07-13-84
POTASSIUM ACETATE 2MEQ/ML	POTASSIUM ACETATE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-896 07-20-84
POTASSIUM CHLORIDE 10MEQ	MICRO-K 10 (CAPSULE, CONTROLLED RELEASE; ORAL)	AH ROBINS	18-238 05-14-84
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

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 43)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
POTASSIUM CHLORIDE; SODIUM CHLORIDE 220MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722 11-09-82
POTASSIUM CHLORIDE; SODIUM CHLORIDE 300MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-722 11-09-82
POTASSIUM CHLORIDE; SODIUM CHLORIDE 150MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-630 02-17-83
POTASSIUM CHLORIDE; SODIUM CHLORIDE 300MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-630 02-17-83
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
PRALIDOXIME CHLORIDE 300MG/ML	PRALIDOXIME CHLORIDE (INJECTABLE; INJECTION)	AYERST LABS/AMHO	18-799 12-13-82
PRALIDOXIME CHLORIDE 300MG/ML	PROTOPAM (INJECTABLE; INJECTION)	SURVIVAL TECHNOLOGY	18-986 04-26-83
PRAZEPAM 20MG	CENTRAX (CAPSULE; ORAL)	PARKE-DAVIS/W-L	18-144 05-10-82

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 44)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
PRAZIQUANTEL 600MG	BILTRICIDE (TABLET; ORAL)	MILES PHARMS/MILES	18-714 12-29-82
PROPRANOLOL HYDROCHLORIDE 60MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 01-18-83
PROPRANOLOL HYDROCHLORIDE 90MG	INDERAL (TABLET; ORAL)	AYERST LABS/AMHO	16-418 01-18-83
PROPRANOLOL HYDROCHLORIDE 160MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	18-553 04-19-83
PROPRANOLOL HYDROCHLORIDE 80MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	18-553 04-19-83
PROPRANOLOL HYDROCHLORIDE 120MG	INDERAL LA (CAPSULE, CONTROLLED RELEASE; ORAL)	AYERST LABS/AMHO	18-553 04-19-83
PROTAMINE SULFATE 250MG/VIAL	PROTAMINE SULFATE (INJECTION; INJECTION)	UPJOHN	07-413 08-02-84
RANITIDINE HYDROCHLORIDE EQ 150MG BASE	ZANTAC (TABLET; ORAL)	GLAXO	18-703 06-09-83
RANITIDINE HYDROCHLORIDE EQ 25MG BASE/ML	ZANTAC (INJECTABLE; INJECTION)	GLAXO	19-090 10-19-84
RITODRINE HYDROCHLORIDE 15MG/ML	YUTOPAR (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	18-580 9-27-84
SAFFLOWER OIL; SOYBEAN OIL 10%; 10%	LIPOSYN II 20% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-991 8-27-84
SAFFLOWER OIL; SOYBEAN OIL 5%; 5%	LIPOSYN II 10% (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-997 8-27-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 45)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
SILVER SULFADIAZINE 1%	SSD (CREAM; TOPICAL)	TRAVENOL LABS	18-578 02-25-82
SODIUM ACETATE, ANHYDROUS 2MEQ/ML	SODIUM ACETATE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-893 05-04-83
SODIUM CHLORIDE 450MG/100ML	SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-497 02-19-82
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 3GM/100ML	SODIUM CHLORIDE 3% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-022 11-01-83
SODIUM CHLORIDE 5GM/100ML	SODIUM CHLORIDE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-022 11-01-83
SODIUM CHLORIDE 9MG/ML	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-217 07-13-84
SODIUM CHLORIDE 9MG/ML	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-218 07-13-84
SODIUM CHLORIDE 2.5MEQ/ML	SODIUM CHLORIDE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-897 07-20-84

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
SODIUM IODIDE, I-123 100 UCI	SODIUM IODIDE I 123 (CAPSULE; ORAL)	BENEDICT NUCLR PHARM	18-671 05-27-82
SODIUM IODIDE, I-123 200 UCI	SODIUM IODIDE I 123 (CAPSULE; ORAL)	BENEDICT NUCLR PH.	18-671 05-27-82
SODIUM IODIDE, I-123 400 UCI	SODIUM IODIDE I 123 (CAPSULE; ORAL)	BENEDICT NUCLR PHARM	18-671 05-27-82
SODIUM LACTATE 5MEQ/ML	SODIUM LACTATE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	[illegible]7
SODIUM NITROPRUSSIDE 50MG/VIAL	SODIUM NITROPRUSSIDE (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-[illegible] 07-28-
SODIUM PHOSPHATE, DIBASIC; SODIUM PHOSPHATE, MONOBASIC 142MG/ML; 276MG/ML	SODIUM PHOSPHATES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-892 05-10-83
SOMATROPIN 2 IU/VIAL	ASELLACRIN 2 (INJECTABLE; INJECTION)	SERONO LABS	17-726 07-21-83
SORBITOL 3GM/100ML	SORBITOL 3% IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-512 05-27-82
SOYBEAN OIL 10%	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 10%	SOYACAL 10% (INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	18-465 06-29-83
[illegible]N OIL	SOYACAL 20% (INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	18-786 06-29-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 47)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
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
STREPTOZOCIN 1GM/VIAL	ZANOSAR (INJECTABLE; INJECTION)	UPJOHN	17-961 05-07-82
SUFENTANIL CITRATE EQ 0.05MG BASE/ML	SUFENTA (INJECTABLE; INJECTION)	JANSSEN PHARMA	19-050 05-04-84
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	SULFAMETHOXAZOLE AND TRIMETHOPRIM (TABLET; ORAL)	DRUMMER/PHOENIX	18-598 05-19-82
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH (TABLET; ORAL)	DRUMMER/PHOENIX	18-5 05
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	SULFATRIM PEDIATRIC (SUSPENSION; ORAL)	NATL PHARM MFG/BARRE	15 1-07-83
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	SULFATRIM (SUSPENSION; ORAL)	NATL PHARM MFG/BARRE	18-615 01-07-83
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	SMZ-TMP (SUSPENSION; ORAL)	BIOCRAFT LABS	18-812 01-28-83
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	SULFAMETHOXAZOLE AND TRIMETHOPRIM (TABLET; ORAL)	DANBURY PHARM AL	18-852 05-09-83
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH (TABLET; ORAL)	DANBURY PHARMACAL	18-854 05-09-83

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 48)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
SULFAMETHOXAZOLE; TRIMETHOPRIM 200MG/5ML; 40MG/5ML	SMZ-TMP PEDIATRIC (SUSPENSION; ORAL)	BIOCRAFT LABS	18-812 06-10-83
SULFAMETHOXAZOLE; TRIMETHOPRIM 400MG; 80MG	SULFAMETHOXAZOLE & TRIMETHOPRIM (TABLET; ORAL)	HEATHER DRUG	18-946 08-10-84
SULFAMETHOXAZOLE; TRIMETHOPRIM 800MG; 160MG	SULFAMETHOXAZOLE & TRIMETHOPRIM (TABLET; ORAL)	HEATHER DRUG	18-946 08-10-84
SULFASALAZINE 500MG	AZULFIDINE (TABLET, ENTERIC COATED; ORAL)	PHARMACIA/PHARMACIA	07-073 04-06-83
TECHNETIUM, TC-99M, ALBUMIN COLLOID KIT N/A	MICROLITE (INJECTABLE; INJECTION)	MED DIAG/NE NUCLEAR	18-263 03-28-82
TECHNETIUM, TC-99M, DISOFENIN KIT N/A	HEPATOLITE (INJECTABLE; INJECTION)	MED DIAG/NE NUCLEAR	18-467 03-16-82
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	AMERSCAN (INJECTABLE; INJECTION)	AMERSHAM/RADIOCHEM	18-335 08-05-82
TECHNETIUM, TC-99M, SUCCIMER KIT N/A	MPI DMSA KIDNEY REAGENT (INJECTABLE; INJECTION)	MEDI-PHYSICS	17-944 05-18-82
TERBUTALINE SULFATE 0.2MG/INH	BRETHAIRE (AEROSOL; INHALATION)	GEIGY/CIBA-GEIGY	18-762 08-17-84
THALLOUS CHLORIDE, TL-201 2MCI/ML	THALLOUS CHLORIDE TL 201 (INJECTABLE; INJECTION)	MEDI-PHYSICS	18-110 02-01-82

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 49)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
THALLOUS CHLORIDE, TL-201 1MCI/ML	THALLOUS CHLORIDE TL 201 (INJECTABLE; INJECTION)	AMERSHAM/RADIOCHEM	18-548 12-30-82
TRIAMCINOLONE ACETONIDE 0.25MG/INH	AZMACORT (AEROSOL; INHALATION)	WILLIAM H RORER	18-117 04-23-83
TRIAZOLAM 0.25MG	HALCION (TABLET; ORAL)	UPJOHN	17-892 11-15-82
TRIAZOLAM 0.5MG	HALCION (TABLET; ORAL)	UPJOHN	17-892 11-15-82
TRIMETHOPRIM 200MG	PROLOPRIM (TABLET; ORAL)	BURROUGHS WELLCOME	17-943 07-14-82
TRIMETHOPRIM 100MG	TRIMETHOPRIM (TABLET; ORAL)	BIOCRAFT LABS	18-679 07-30-82
TRIMETHOPRIM 200MG	TRIMPEX 200 (TABLET; ORAL)	HOFFMANN-LA ROCHE	17-952 11-09-82
TRIMIPRAMINE MALEATE EQ 100MG BASE	SURMONTIL (CAPSULE; ORAL)	IVES LABS/AMHO	16-792 09-15-82
VECURONIUM BROMIDE 10MG/VIAL	NORCURON (NC-45) (INJECTABLE; INJECTION)	ORGANON/AKZONA	18-776 04-30-84
VERAPAMIL HYDROCHLORIDE 80MG	ISOPTIN (TABLET; ORAL)	KNOLL PHARMACEUTICAL	18-593 03-08-82
VERAPAMIL HYDROCHLORIDE 120MG	ISOPTIN (TABLET; ORAL)	KNOLL PHARMACEUTICAL	18-593 03-08-82
VERAPAMIL HYDROCHLORIDE 2.5MG/ML	CALAN (INJECTABLE; INJECTION)	SEARLE PHARMS	18-925 03-30-84
VERAPAMIL HYDROCHLORIDE 2.5MG/ML	CALAN (INJECTABLE; INJECTION)	SEARLE PHARMS	19-038 03-30-84

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 50)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
VERAPAMIL HYDROCHLORIDE 80MG	CALAN (TABLET; ORAL)	SEARLE/SEARLE PHARMS	18-817 09-10-84
VERAPAMIL HYDROCHLORIDE 120MG	CALAN (TABLET; ORAL)	SEARLE/SEARLE PHARMS	18-817 09-10-84
WATER FOR INJECTION, STERILE 100%	STERILE WATER IN PLASTIC CONTAINER (LIQUID; N/A)	TRAVENOL LABS	18-632 06-30-82
WATER FOR INJECTION, STERILE 100%	STERILE WATER IN PLASTIC CONTAINER (LIQUID; N/A)	ABBOTT LABORATORIES	18-801 10-27-82
WATER FOR INJECTION, STERILE 100%	BACTERIOSTATIC WATER IN PLASTIC CONTAINER (LIQUID; N/A)	ABBOTT LABORATORIES	18-802 10-27-82
WATER FOR INJECTION, STERILE 100%	STERILE WATER FOR INJECTION IN PLASTIC CONTAINER (LIQUID; N/A)	TRAVENOL LABS	18-595 01-17-83
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
XENON, XE-127 10MCI/VIAL	XENON XE 127 (GAS; INHALATION)	MALLINCKRODT	18-536 10-01-82
XENON, XE-133 10MCI/VIAL	XENON XE 133 (GAS; INHALATION)	MALLINCKRODT	18-327 03-09-82

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 10-31-84 (PAGE 51)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE
XENON, XE-133 20MCI/VIAL	XENON XE 133 (GAS; INHALATION)	MALLINCKRODT	18-327 03-09-82