

APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations



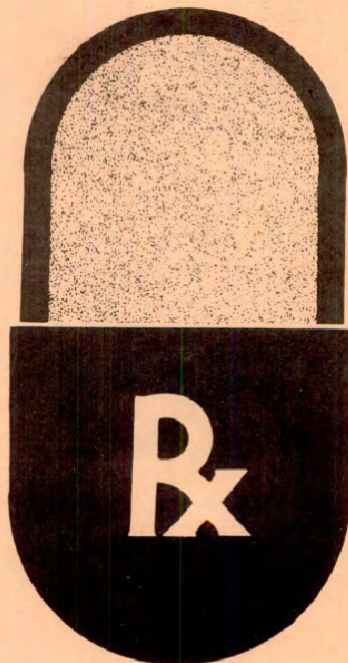
The "Orange Book"

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**CUMULATIVE
SUPPLEMENT 4
DECEMBER 1981**



APPROVED PRESCRIPTION DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

2ND EDITION

SERIAL

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OF MICHIGAN

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

I. PREFACE

This cumulative supplement is one of a series of monthly updates to the Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 2nd Edition, (the List) to cover interim revisions to the annual publications 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 Addendum: DESI Pending List.

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, 1981. 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. 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 >DLI> (DELETE) to the left of the line containing the overstruck print. The >DLI> symbol is dropped in subsequent cumulative supplements for that item.

A newly approved product is identified by the lozenge (Λ) 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. The INTRODUCTION to the 2nd Edition (1981 publication) of the Approved Prescription Drug Products with Therapeutic Equivalence Evaluations (Section II.F.5.) stated that "Protein hydrolysate injections are omitted because of safety problems." The safety problems have been resolved. Publication on this subject appeared in the FEDERAL REGISTER of July 14, 1981 (46 FR 36249). Therefore, a parenteral protein hydrolysate (see Amigen) now is approved and marketed as well as the existing related parenteral amino acid mixture solutions.

B. FUROSEMIDE. The change in the therapeutic equivalence code for Cord Laboratories' Furosemide tablets from BX to AB reflects receipt of additional data from the firm; examination of other information on file with the Agency; and a determination that the initial bioequivalence study performed by the firm was satisfactory for demonstrating product bioequivalence so that a subsequent additional study was not necessary.

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.

APPLICANT (NAME) CHANGES

<u>Former Applicant (Name)</u>	<u>New Applicant (Name)</u>	<u>New Abbreviated Name</u>
D-M PHARMACEUTICALS INC	LEMMON COMPANY	LEMMON
LEMMON PHARMACAL COMPANY	LEMMON COMPANY	LEMMON
UNION CARBIDE CORPORATION	CINTICHEM INC	CINTICHEM

The reader should consult this special list each month to become aware of such transfers and changes. By referring to the Applicant Index in the 2nd Edition, the transferred products can be identified. The reader might wish to flag these products in the List as a reminder that the applicant has been changed.

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ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 1)

CAPSULE; ORAL
 TYLENOL W/ CODEINE NO. 3
 MCNEIL PHARM 300MG;30MG
 TYLENOL W/ CODEINE NO. 4
 MCNEIL PHARM 300MG;60MG

ELIXIR; ORAL

ACETAMINOPHEN W/ CODEINE
 AA PHARMS ASSOC/BEACH 120MG/5ML;12MG/5ML

TABLET; ORAL

ACETAMINOPHEN W/ CODEINE PHOSPHATE
 /AA/ /KV PHARMACEUTICAL/ /325MG;15MG * 325MG;30MG * 325MG;60MG/
 /325MG;15MG/
 AA KV PHARMACEUTICAL 325MG;15MG * 300MG;30MG * 300MG;60MG
 /325MG;15MG/
 AA VITARINE/WEST CHEM 300MG;30MG

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 2)

TABLET; ORAL

OXYCODONE HCL AND ACETAMINOPHEN
 AA BARR LABORATORIES 325MG;5MG

ACETIC ACID, GLACIAL (PAGE 2)

SOLUTION; OTIC

ACETASOL
 AT NATL PHARM MFG/BARRE 22M

ALPRAZOLAM (PAGE 4)

TABLET; ORAL

XANAX
 UPJOHN 0.25MG * 0.5MG * 1MG

ALPROSTADIL (PAGE 4)

INJECTABLE; INJECTION

PROSTIN VR PEDIATRIC
 UPJOHN 0.5MG/ML

AMCINONIDE (PAGE 5)

OINTMENT; TOPICAL

CYCLOCORT
 LEDERLE LABS/AM CYAN 0.1%

AMILORIDE HYDROCHLORIDE (PAGE 5)

TABLET; ORAL

MIDAMOR
 MSD/MERCK 5MG

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE (PAGE 5)

TABLET; ORAL

MODURETIC 5/50
 MSD/MERCK 5MG;50MG

AMINOPHYLLINE (PAGE 6)

INJECTABLE; INJECTION

AMINOPHYLLINE
 AP BRISTOL LABS/B-M 25MG/ML
 AP LYPHO-MED 25MG/ML

TABLET; ORAL

AMINOPHYLLIN
 /BP/ /SEARLE PHARMS/ /100MG * 200MG/
 AB SEARLE PHARMS 100MG * 200MG
 /BP/ /WEST-WARD/ /100MG * 200MG/
 AB WEST-WARD 100MG * 200MG

AMITRIPTYLINE HYDROCHLORIDE (PAGE 7)

TABLET; ORAL

AMITRIPTYLINE HCL
 BP HALSEY DRUG 50MG
 AB WEST-WARD 25MG

ASPIRIN; BUTALBITAL; CAFFEINE; PHENACETIN (PAGE 11)

CAPSULE; ORAL

BUTAL COMPOUND
 > ADD >
 > ADD > AB CORD LABORATORIES 200MG;50MG;40MG;130MG
 > ADD > AB FIORINAL
 > ADD > AB SANDOZ PHARMS/SANDOZ 200MG;50MG;40MG;130MG
 > ADD > AB LANCRITIAL
 > ADD > AB LANNETT 200MG;50MG;40MG;130MG

TABLET; ORAL

BUTALBITAL W/ APC
 AB LEDERLE LABS/AM CYAN 200MG;50MG;40MG;130MG
 AB PHEORIAL
 AB PHOENIX LABORATORIES 200MG;50MG;40MG;130MG

ASPIRIN: CAFFEINE; PHENACETIN; PROPOXYPHENE HYDROCHLORIDE (PAGE 12)

CAPSULE; ORAL
 DAVON COMPOUND
 ELI LILLY INDSTRS/PR 227MG:32.4MG:162MG:32MG
 /327MG:32.4MG:162MG:32MG
 /327MG:32.4MG:162MG:32MG
 DLT > /AA > ADD > AA

ASPIRIN; PROPOXYPHENE HYDROCHLORIDE (PAGE 12)

CAPSULE; ORAL
 DAVON M/ASA
 ELI LILLY INDSTRS/PR 325MG:65MG
 /325MG:65MG
 /325MG:65MG
 DLT > /AA > ADD > AA

ATENOLOL (PAGE 12)

TENORMIN
 STUART PHARMS/ICI AM 50MG * 100MG
 TABLET; ORAL

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE (PAGE 13)

TABLET; ORAL
 DIFEMOXILATE HCL W/ ATROPINE SULFATE
 PREHO PHARM LABS 0.025MG:2.5MG
 0.025MG:2.5MG

BECLOMETHASONE DIPROPIONATE (PAGE 14)

AERUSOL; INHALATION/NASAL
 BECONASE
 GLAXO
 VANCMASE
 BN
 SCHERING
 BN
 0.042MG/INHML
 0.042MG/INHML

BROMPHENIRAMINE MALEATE (PAGE 17)

ELIXIR; ORAL
 BROMPHENIRAMINE MALEATE
 PHARMS ASSOC/BEACH 2MG/5ML
 2MG/5ML

BUPIVACAINE HYDROCHLORIDE (PAGE 18)

INJECTABLE; INJECTION
 SENSOCVINE
 ASTRA PHARM PRODS 0.25% * 0.5% * 0.75%
 0.25% * 0.5% * 0.75%

BUPRENORPHINE HYDROCHLORIDE (PAGE 19)

INJECTABLE; INJECTION
 DIAVAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
 TRAVENOL LABS 25.7MG/100ML:1.56MG/100ML:5.08MG/100ML:448MG/100ML
 DIAVAL PD-2 W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
 TRAVENOL LABS 25.7MG/100ML:2.56MG/100ML:5.08MG/100ML:448MG/100ML
 DIAVAL PD-2 W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
 TRAVENOL LABS 25.7MG/100ML:4.256MG/100ML:5.08MG/100ML:448MG/100ML

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 20)

INJECTABLE; INJECTION
 DIAVAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
 AM HOSP 29MG/100ML:1.56MG/100ML:610MG/100ML:15MG/100ML
 DIAVAL PD-2 W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
 AM HOSP 29MG/100ML:2.56MG/100ML:610MG/100ML:15MG/100ML
 DIAVAL PD-2 W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
 AM HOSP 29MG/100ML:4.256MG/100ML:610MG/100ML:15MG/100ML

SODIUM CHLORIDE (PAGE 20)

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM PHOSPHATE (PAGE 20)

SOLUTION; IRRIGATION
 BSS PLUS
 ALCON LABORATORIES 0.154MG/ML:0.92MG/ML:0.164MG/ML:0.2MG/ML:0.38MG/ML:2.1MG/ML:7.14MG/ML:0.42MG/ML
 0.154MG/ML:0.92MG/ML:0.164MG/ML:0.2MG/ML:0.38MG/ML:2.1MG/ML:7.14MG/ML:0.42MG/ML

CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE (PAGE 20)

SOLUTION; IRRIGATION
 BSS PLUS
 ALCON LABORATORIES 0.154MG/ML:0.92MG/ML:0.164MG/ML:0.2MG/ML:0.38MG/ML:2.1MG/ML:7.14MG/ML:0.42MG/ML
 0.154MG/ML:0.92MG/ML:0.164MG/ML:0.2MG/ML:0.38MG/ML:2.1MG/ML:7.14MG/ML:0.42MG/ML

BUTABARBITAL SODIUM (PAGE 10)

ELIXIR; ORAL
 SARTOL
 HALSEY DRUG 30MG/5ML
 30MG/5ML

BUPRENORPHINE HYDROCHLORIDE (PAGE 10)

INJECTABLE; INJECTION
 BUPRENEX
 NORMICH-EATON/HORTON EQ 0.3MG BASE/ML
 0.3MG BASE/ML

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 21)

INJECTABLE; INJECTION
DEXTROSE 5% IN LACTATED RINGER'S IN PLASTIC CONTAINER
 AP CUTTER LABORATORIES 20MG/100ML; 50MG/100ML; 30MG/100ML;
 AP 600MG/100ML; 310MG/100ML

CARBAMAZEPINE (PAGE 22)

TABLET; CHEWABLE; ORAL
 TEGRETOL
 > ADD > GEIGY/CIBA-GEIGY 100MG * 200MG

> DLT > CEPHRADINE (PAGE 24)
 > ADD > CEPHRADINE/CEPHRADINE DIMYDRATE (PAGE 24)

CAPSULE; ORAL
 > DLT > VELOSEF
 > DLT > ERSANA/PR/ER SQUIBB/125MG * 500MG/
 > ADD > VELOSEF "250"
 > ADD > AB ERSANA/PR/ER SQUIBB 250MG * EQ 250MG BASEM
 > ADD > VELOSEF "500"
 > ADD > AB ERSANA/PR/ER SQUIBB 500MG * EQ 500MG BASEM

POWDER FOR RECONSTITUTION; ORAL
 > DLT > VELOSEF
 > DLT > ERSANA/PR/ER SQUIBB/125MG/5ML * 500MG/5ML/
 > ADD > VELOSEF "125"
 > ADD > AB ERSANA/PR/ER SQUIBB 125MG/5ML
 > ADD > VELOSEF "250"
 > ADD > AB ERSANA/PR/ER SQUIBB 250MG/5ML

> ADD > CERULETIDE DIETHYLAMINE (PAGE 24)

> ADD > INJECTABLE; INJECTION
 > ADD > TYMTRAN
 > ADD > ADRIA LABORATORIES 0.02MG/MLM

CHLORAMPHENICOL (PAGE 25)

SOLUTION/DROPS; OPHTHALMIC
CHLORAMPHENICOL
 AT MAURRY BIOLOGICAL 0.5%
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CHLORPROMAZINE HYDROCHLORIDE (PAGE 29)

INJECTABLE; INJECTION
CHLORPROMAZINE HCL
 /AB/ BEECHAM LABS/BEECHAM/25MG/ML/
 TABLET; ORAL
 CHLORPROMAZINE HCL
 > ADD > BP VANGARD LABS/114M 25MG * 50MG

CHLORTHALIDONE (PAGE 30)

TABLET; ORAL
CHLORTHALIDONE
 AB CHELSEA LABORATORIES 25MG * 50MG
 AB DANBURY PHARMACAL 25MG * 50MG

CHLORZOXAZONE (PAGE 30)

TABLET; ORAL
CHLORZOXAZONE
 AA DANBURY PHARMACAL 250MG
 AA PARAFLEX
 AA MCNEIL LABORATORIES 250MG

CROTAMITON (PAGE 34)

> ADD > LOTION; TOPICAL
 > ADD > CROTAN
 > ADD > AT OWEN LABS/DERM PRODS 10%
 > ADD > EURAX
 > ADD > AT WESTWOOD PHARMS 10%

CYPROHEPTADINE HYDROCHLORIDE (PAGE 36)

TABLET; ORAL
CYPROHEPTADINE HCL
 AA DANBURY PHARMACAL 4MG
 AA FREMO PHARM LABS 4MG

DEXAMETHASONE (PAGE 38)

TABLET; ORAL
 DEXAMETHASONE
 BP UPSHER-SMITH LABS 0.75MG * 1.5MG

DEXTROSE; LIDOCAINE HYDROCHLORIDE (PAGE 41)

INJECTABLE; INJECTION
LIDOCAINE HCL 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER
 AP TRAVENOL LABS 50ML/100ML; 400ML/100ML

ETHINYL ESTRADIOL; NORETHINDRONE (PAGE 56)

TABLET; ORAL-21

NORINYL 1+35

AB SYNTEX (FP) 0.035MG;1MG

AB ORTHO-NOVUM 1/35-21 0.035MG;1MG

AB ORTHO PHARMACEUTICAL 0.035MG;1MG

TABLET; ORAL-28

NORINYL 1+35

AB SYNTEX (FP) 0.035MG;1MG

AB ORTHO-NOVUM 1/35-28 0.035MG;1MG

AB ORTHO PHARMACEUTICAL 0.035MG;1MG

FLUNISOLIDE (PAGE 59)

AEROSOL; INHALATION/NASAL

NASALIDE

SYNTEX LABS/SYNTEX 0.025MG/INH

FUROSEMIDE (PAGE 62)

TABLET; ORAL

LASIX

AB HOECHST-ROUSSEL 20MG * 40MG

80MG

FUROSEMIDE (SEE SPECIAL NOTE B)

> DLT > /B/ /CORD LABORATORIES/ 20MG * 40MG/

> ADD > AB CORD LABORATORIES 20MG * 40MG

AB MYLAN PHARMS 20MG * 40MG

> ADD > GEMFIBROZIL (PAGE 62)

> ADD > CAPSULE; ORAL

> ADD > LOPID

> ADD > PARKE-DAVIS/W-L 200MG * 300MG

GENTAMICIN SULFATE (PAGE 62)

INJECTABLE; INJECTION

GENTAMICIN SULFATE

AP CARTER-GLOGAU LABS EQ 10MG BASE/ML * EQ 40MG BASE/ML

GLYCOPYRROLATE (PAGE 63)

TABLET; ORAL

GLYCOPYRROLATE

AA DANBURY PHARMACAL 1MG * 2MG

HALAZEPAM (PAGE 64)

TABLET; ORAL

PAXIPAM

SCHERING

20MG * 40MG

HEPARIN SODIUM (PAGE 65)

INJECTABLE; INJECTION

HEPARIN SODIUM

AP SOLOPAK/MPL

1,000 UNITS/ML * 5,000 UNITS/ML *

AP

10,000 UNITS/ML *

AP

5,000 UNITS/0.5ML *

AP

10,000 UNITS/0.5ML *

HYDRALAZINE HYDROCHLORIDE (PAGE 67)

TABLET; ORAL

HYDRALAZINE HCL

> ADD > AA

VANGARD LABS/MMM

25MG

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE (PAGE 68)

TABLET; ORAL

HYDRAP-ES

BP

PREMO PHARM LABS 25MG;15MG;0.1MG

HYDROCHLOROTHIAZIDE/HYDRALAZINE HCL/RESERPINE

BP

DANBURY PHARMACAL 25MG;15MG;0.1MG

HYDROCHLOROTHIAZIDE (PAGE 68)

TABLET; ORAL

HYDROCHLOROTHIAZIDE

AB

PREMO PHARM LABS 25MG * 50MG

AB

PUREPAC/KALIPHARM 25MG * 50MG

AB

REID-PROVIDENT LABS 25MG * 50MG

> ADD > AB

VANGARD LABS/MMM 25MG * 50MG

ZIDE

AB

REID-PROVIDENT LABS 50MG

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE (PAGE 69)

TABLET; ORAL

SPIRONOLACTONE/HYDROCHLOROTHIAZIDE

AB

DANBURY PHARMACAL 25MG;25MG

SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE

AB

LEDERLE LABS/AM CYAN 25MG;25MG

AB

UPSHER-SMITH LABS 25MG;25MG

> ADD > AB

VANGARD LABS/MMM 25MG;25MG

AB

WESTERN RES LABS 25MG;25MG

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LINDANE (PAGE 82)

SHAMPOO; TOPICAL
LINDANE
 >_ADD_> AT NATL PHARM MFG/BARRE 12M

MAGNESIUM SULFATE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE MONOBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE (PAGE 84)

SOLUTION; IRRIGATION
 TIS-U-SOL IN PLASTIC CONTAINER
 TRAVENOL LABS 20MG/100ML; 40MG/100ML; 6.25MG/100ML;
 800MG/100ML; 8.75MG/100ML

MECLIZINE HYDROCHLORIDE (PAGE 85)

TABLET; ORAL
MECLIZINE HCL
 AA CHELSEA LABORATORIES 25MG

METHAMPHETAMINE HYDROCHLORIDE (PAGE 90)

TABLET; ORAL
METHAMPHETAMINE HCL
 >_ADD_> AA LEMMON 5MG

METHOCARBAMOL (PAGE 91)

TABLET; ORAL
METHOCARBAMOL
 AA PREMO PHARM LABS 500MG * 750MG
 AA UPSHER-SMITH LABS 500MG * 750MG

METHOXSALEN (PAGE 92)

CAPSULE; ORAL
 OXSORALEN
 /PAUL B. ELDER/
 ELDER PHARMS 10MG/10MG
 LOTION; TOPICAL
 OXSORALEN
 /PAUL B. ELDER/
 ELDER PHARMS 1% 1%

METHYLDOPA (PAGE 94)

SUSPENSION; ORAL
 ALDOMET
 MSD/MERCK 250MG/5ML

METHYLPREDNISOLONE (PAGE 93)

TABLET; ORAL
 METHYLPREDNISOLONE
 /Ad/ /PREMO PHARM LABS/ /4mg/
 BP PREMO PHARM LABS 4MG

METHYLPREDNISOLONE ACETATE (PAGE 93)

INJECTABLE; INJECTION
 METHYLPREDNISOLONE ACETATE
 BP LEMMON 20MG/ML * 80MG/ML

METRONIDAZOLE (PAGE 95)

>_ADD_> INJECTABLE; INJECTION
 >_ADD_> FLAGYL I.V. RTU IN PLASTIC CONTAINER
 >_ADD_> AP SEARLE PHARMS 500MG/100ML
 >_ADD_> AP FLAGYL I.V. RTU
 >_ADD_> AP SEARLE PHARMS 500MG/100ML

TABLET; ORAL
FLAGYL
 AB SEARLE/SEARLE PHARMS 250MG
 500MG
METRONIDAZOLE
 AB ZENITH LABORATORIES 250MG

MEZLOCILLIN SODIUM MONOHYDRATE (PAGE 95)

INJECTABLE, INJECTION
 MEZLIN
 MILES PHARMS/MILES EQ 1GM BASE/VIAL *
 EQ 2GM BASE/VIAL *
 EQ 3GM BASE/VIAL * EQ 4GM BASE/VIAL *

MOXALACTAM DISODIUM (PAGE 96)

INJECTABLE; INJECTION
 MOXAM
 ELI LILLY EQ 250MG BASE/VIAL *
 EQ 500MG BASE/VIAL *
 EQ 1GM BASE/VIAL *
 EQ 2GM BASE/VIAL *
 EQ 10GM BASE/VIAL *

NANDROLONE PHENPROPIONATE (PAGE 97)

INJECTABLE; INJECTION
 DURABOLIN
 ORGANON/AKZONA 25MG/ML
 DURABOLIN-50
 ORGANON/AKZONA 50MG/ML

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PROMETHAZINE HYDROCHLORIDE (PAGE 120)

SUPPOSITORY; RECTAL
 PHENERGAN
 BR WYETH LABS/AMHO 25MG * 50MG
 12.5MG
 PROMETHACON
 BR ALCON LABORATORIES 25MG * 50MG
 SYRUP; ORAL
PROMETHAZINE HCL
 AA PHARMS ASSOC/BEACH 6.25MG/5ML*

PROPOXYPHENE HYDROCHLORIDE (PAGE 121)

CAPSULE; ORAL
 DARVON
 > DLT > /AA/ /ELI LILLY/ /32MG * 65MG/
 > ADD > AA ELI LILLY INDSTRS/PR 32MG * 65MG

PROTEIN HYDROLYSATE (PAGE 122)

INJECTABLE; INJECTION
 AMIGEN
 MEAD JOHNSON/B-M 5%

PRIMETHAMINE; SULFADOXINE (PAGE 123)

TABLET; ORAL
 FANSIDAR
 HOFFMANN-LA ROCHE 25MG;500MG

QUINIDINE GLUCONATE (PAGE 124)

TABLET, CONTROLLED RELEASE; ORAL
 QUTMAGLUTE
 AB BERLEX/SCHERING AG 324MG
 QUINIDINE GLUCONATE
 AB BOLAR PHARMACEUTICAL 324MG*

QUINIDINE SULFATE (PAGE 124)

TABLET; ORAL
 QUINIDINE SULFATE
 /AB/ /REXALL DRUG/ /400MG/
 AB REXALL 200MG

RAUMOLFIA SERPENTINA (PAGE 124)

TABLET; ORAL
 > DLT > /RD-HY-1/
 > DLT > /BP/ /BOOTS PHARMACEUTICAL/ 100MG

SAFFLOWER OIL (PAGE 126)

INJECTABLE; INJECTION
 LIPOSYN 20%
 ABBOTT LABORATORIES 20%

SECOBARBITAL SODIUM (PAGE 127)

CAPSULE; ORAL
SECOBARBITAL SODIUM
 > ADD > AA ICN PHARMACEUTICALS 100MG

SELENIUM SULFIDE (PAGE 127)

LOTION/SHAMPOO; TOPICAL
SELENIUM SULFIDE
 AT THAMES PHARMACAL 2.5%

SODIUM NITROPRUSSIDE (PAGE 130)

INJECTABLE; INJECTION
NITROIDE
 AP HOFFMANN-LA ROCHE 50MG/VIAL
NITROFRESS
 AP ABBOTT LABORATORIES 50MG/VIAL*

SODIUM PERTECHNETATE, TC-99M (PAGE 130)

SOLUTION; INJECTION, ORAL
 SODIUM PERTECHNETATE TC 99M
 > DLT > /CIS RADIOPHARM/ /12MCI/ML * 24MCI/ML * 48MCI/ML/
 > ADD > SYNCOR INTL 12MCI/ML * 24MCI/ML * 48MCI/ML

SPIRONOLACTONE (PAGE 131)

TABLET; ORAL
SPIRONOLACTONE
 AB LEDERLE LABS/AM CYAN 25MG
 AB UPSHER-SMITH LABS 25MG

SUCRALFATE (PAGE 132)

TABLET; ORAL
 CARAFATE
 MARION LABORATORIES 1GM

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TRISULFAPYRIMIDINES (PAGE 146)

SUSPENSION; ORAL

SULFALOID

/AB/ /JAF.#2/CHROMALLOY/ /BDDMS/ENL/
AB ONEAL JONES&FELDMAN SOCHS/ENL

VERAPAMIL HYDROCHLORIDE (PAGE 146)

INJECTABLE; INJECTION

ISOPTIN

KNOLL PHARMACEUTICAL 2.5MG/MLM

/AMGEN/ /HEAD, JOHNSON, R-H/
 /PROLIN, HYDROL, SAT/
 CURRENT STATUS - EFFECTIVE/NEW SAFETY ISSUE

TRANSFORM-NITRO 10 ALZA NITROGLYCERIN
 TRANSFORM-NITRO 5 ALZA NITROGLYCERIN
 TRANSFORM-NITRO 2.5 ALZA NITROGLYCERIN
 SUSADIN MERRELL DOM/DOM CHEM
 PENTAEYTHRIOL TETRANITRATE VANGARD LABS/MMM
 NITROGLYCERIN
 NITRODUR KEY PHARMACEUTICALS
 NITROGLYCERIN
 ISOSORBIDE DINITRATE VANGARD LABS/MMM
 ISOSORBIDE DINITRATE ASCOT HOSP PHARMS
 /DUMABOLIN-5d/ /DUMABOLIN-5d/
 /DUMABOLIN-5d/ /DUMABOLIN-5d/
 /DUMABOLIN-5d/ /DUMABOLIN-5d/
 /DUMABOLIN-5d/ /DUMABOLIN-5d/
 CURRENT STATUS - EXEMPT (COURT ORDER)

/BUTAZOLIDIN, ALKA/ /BUTAZOLIDIN, ALKA/
 /ALUMINUM HYDROXIDE, GEL, BRIP, MAGNESIUM, HYDROXIDE/
 /PHENIBUTAZONE/
 CURRENT STATUS - INEFFECTIVE

/FACONIN/ /FACONIN/
 /FACONIN, EXTRACT, HYDROCHLORIDE/
 CURRENT STATUS - PROBABLY EFFECTIVE

ADDENDUM
 DESI PENDING LIST
 CUMULATIVE SUPPLEMENT NUMBER 4 / AUGUST '81 - DECEMBER '81

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