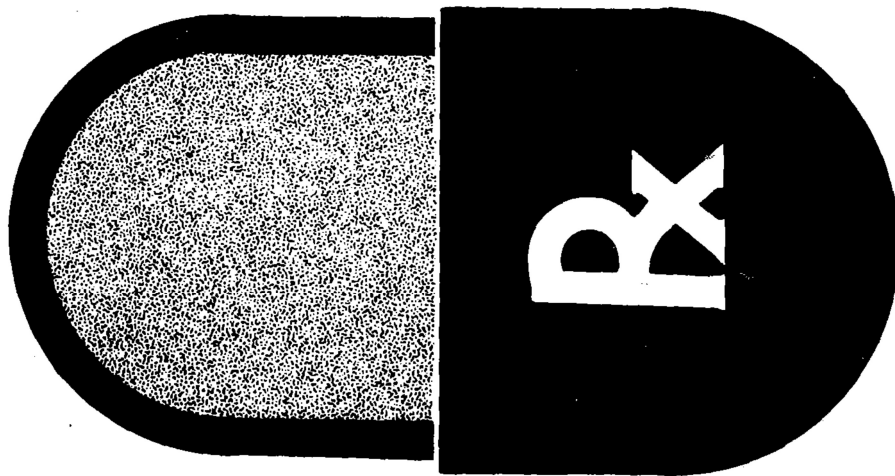


SUPPLEMENT 1
WITH CUMULATIVE INDEX
1980 EDITION

**APPROVED
PRESCRIPTION
DRUG
PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE
EVALUATIONS**



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
BUREAU OF DRUGS

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

I. PREFACE

This supplement is one of a series of periodic updates to the list of Approved Prescription Drug Products with Therapeutic Equivalence Evaluations (the List) to cover revisions interim to the annual publication of the List in its entirety. This supplement contains updates to the Drug Product List and Appendix portions of the List, as well as cumulative indices for both.

1. Drug Product List

The Drug Product List revisions are intended to be pen and ink changes to the annual publication of the List rather than page replacements or cut-and-paste changes. The changes in this supplement contain revisions made since the last publication or previous supplement.

In general, information in this listing follows the format of the Drug Product List. Information to be deleted from the Drug Product List is indicated by reverse print. Information to be added to the Drug Product List is indicated by the symbol >ADD> to the left of the line on which new information exists. Any line containing neither reverse print nor >ADD> is necessary to provide the context information needed to assist in locating the proper place in the Drug Product List for the revision.

A change of information concerning a given drug product covers only enough context information to facilitate making the change. The change itself is indicated by deleting the old information, directly followed by adding the new information.

The addition of a therapeutic equivalence code indicates that the drug product has become multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. A change in the therapeutic equivalence code is indicated by a delete, immediately followed by an add on the line below indicated by an >ADD>.

2. Appendix—Prescription Drug Products Deemed Approved Pending Resolution of Safety or Effectiveness Issues

The listing of the Appendix contains only drug products which are the subject of additions, removals, or classification changes within the Appendix. These revisions are indicated in the same manner as addition and removal of drug products for the Drug Product List.

3. Cumulative Indices

Each supplement is accompanied by a cumulative index. These are intended to provide a ready record of all revisions occurring from one annual List publication to the next. Each index will be alphabetical, the Drug Product List by ingredient and the Appendix by trade name.

II. SPECIAL NOTES

A description or explanation of items requiring special attention or clarification will appear in this section.

None - this supplement

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 SUPPLEMENT NUMBER 1

ACETAMINOPHEN; CODEINE PHOSPHATE
 TABLET; ORAL
ACETAMINOPHEN W/ CODEINE PHOSPHATE
 LEMON PHARMACAL 300MG; 30MG
 > ADD > AA

AMITRIPTYLINE HYDROCHLORIDE

INJECTABLE; INJECTION
AMITRIPTYLINE HCL
CARTER-GLOGAU LABS
 CARTER-GLOGAU
 > ADD >

AMOXICILLIN TRIHYDRATE

CAPSULE; ORAL
AMOXICILLIN TRIHYDRATE
 MYLAN PHARMS EG 250MG BASE * EG 500MG BASE
 > ADD > AB
 POWDER FOR RECONSTITUTION; ORAL
AMOXICILLIN TRIHYDRATE
 MYLAN PHARMS EG 125MG BASE/5ML *
 EG 250MG BASE/5ML
 > ADD > AB
 > ADD > AB

> ADD > CALCIFEDIOL
 CAPSULE; ORAL
 CALDEROL
 UPJOHN 20 UGM * 50 UGM
 > ADD >

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL
 PROMAPAR
 PARKE-DAVIS/W-L 10MG * 25MG * 50MG * 100MG * 200MG
 > ADD > BP
 > ADD >

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION
DEXAMETHASONE SODIUM PHOSPHATE
 CENTRAL PHARMACAL EG 4MG PHOSPHATE/ML
 > ADD >
 DEXACEN-4
 > ADD > AP
 CENTRAL PHARMACAL EG 4MG PHOSPHATE/ML

DEXTROAMPHETAMINE SULFATE

CAPSULE; ORAL
 DEXAMPEX
 LEMON PHARMACAL 15MG
 > ADD >
 > ADD >
 > ADD >

DEXTROSE

INJECTABLE; INJECTION
DEXTROSE 10% IN PLASTIC CONTAINER
 DEXTROSE 10% IN PLASTIC CONTAINER
 > ADD >

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM
 ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE

INJECTABLE; INJECTION
ISOLYTE 5 W/ 5% DEXTROSE IN PLASTIC CONTAINER
 AM MCGAW/AM HOSP 5GM/100ML; 30MG/100ML; 37MG/100MG
 370MG/100ML; 530MG/100ML; 500MG/100ML
PLASMA-LYTE 148 AND DEXTROSE 5% IN PLASTIC CONTAINER
 TRAVENOL LABS 5GM/100ML; 30MG/100ML; 37MG/100ML;
 368MG/100ML; 526MG/100ML; 502MG/100ML
 > ADD >
 > ADD > AP
 > ADD > AP
 > ADD > AP
 > ADD > AP
 > ADD > AP

DIPHENIDOL

TABLET; ORAL
 DIBACIN
 UPJOHN
 5MG

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 SUPPLEMENT NUMBER 1

ISONIAZID

SYRUP; ORAL

HYDRAZID

AA

ER. SAJJIB AND SONS

50MG/5ML

RIMIFON

AA

HOFFMANN-LA ROCHE

50MG/5ML

SYRUP; ORAL

ALBANTIN

UPJOHN

EQ. 125MG BASE/5ML

NOVOBIOCIN SODIUM

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE

INJECTABLE; INJECTION

ISOLYTE S IN PLASTIC CONTAINER

> ADD >

> ADD > **AP**

> ADD > **AP**

> ADD > **AP**

> ADD > **AP**

> ADD > **AP**

AM MCGAM/AM HOSP 30MG/100ML; 37MG/100ML; 370MG/100ML;

530MG/100ML; 500MG/100ML

PLASMA-LYTE 168 IN WATER IN PLASTIC CONTAINER

30MG/100ML; 37MG/100ML; 368MG/100ML;

526MG/100ML; 502MG/100ML

PENICILLIN G POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN G POTASSIUM

BIOCRRAFT LABS

AA

AA

AA

AA

AA

MANNITOL

INJECTABLE; INJECTION

MANNITOL

> ADD >

> ADD > **AP**

> ADD > **AP**

MANNITOL 25%

ABBOTT LABS

12.5GM/50ML

MAZINDOL

TABLET; ORAL

MAZANOR

> ADD >

> ADD > **BP**

> ADD > **BP**

> ADD > **BP**

> ADD > **BP**

> ADD > **BP**

> ADD > **BP**

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

2MG

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 SUPPLEMENT NUMBER 1

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN V POTASSIUM

BIOCRAFT LABS

EQ 125MG BASE/5ML *
EQ 250MG BASE/5ML

PENICILLIN-VK

BIOCRAFT LABS

EQ 125MG BASE/5ML *
EQ 250MG BASE/5ML

TABLET; ORAL

PENICILLIN-VK

PENICILLIN-VK

> ADD > SUSPENSION; ORAL
 > ADD > ELIXICON
 > ADD > BERLEX LABS/S-AG 100MG/5ML
 TABLET; ORAL
 SLO-PHYLLIN
 > ADD > DOONER LABS 100MG * 200MG
 > ADD > THEOCLEAR-100
 > ADD > CENTRAL PHARMACAL 100MG
 > ADD > THEOCLEAR-200
 > ADD > CENTRAL PHARMACAL 200MG

THEOPHYLLINE

POTASSIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

LYPHO-MED

2MEQ/ML

TRICHLORMETHIAZIDE

TABLET; ORAL

AGUEX

TRICHLOREX

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION

YUTOPAR

DUPHAR LABS

10MG/ML

TRISULFAPYRIMADINES

SUSPENSION; ORAL

TRIS-A-TUL

AB FIRST TEXAS PHARMS 500MG/5ML

TABLET; ORAL

YUTOPAR

DUPHAR LABS

10MG

TABLET; ORAL

TRIS-A-TAB

AB FIRST TEXAS PHARMS 500MG

SULFAMETHOXAZOLE

TABLET; ORAL

SULFAMETHOXAZOLE

HEATHER DRUG

500MG

> ADD > AB

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE INDEX

1

SUPPLEMENT: I

ACETAMINOPHEN; CODEINE PHOSPHATE	X
AMITRIPTYLINE HYDROCHLORIDE	X
AMOXICILLIN TRIHYDRATE	X
CALCIFEDIOL	X
CHLORPROMAZINE HYDROCHLORIDE	X
DEXAMETHASONE SODIUM PHOSPHATE	X
DEXTROAMPHETAMINE SULFATE	X
DEXTROSE	X
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	X
DIPHENADIONE	X
ISONIAZID	X
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	X
MANNITOL	X
MAZINDOL	X
NOVOBIOCIN CALCIUM	X
NOVOBIOCIN SODIUM	X
PENICILLIN G POTASSIUM	X

APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
CUMULATIVE INDEX

2

SUPPLEMENT: 1

PENICILLIN G PROCAINE	X
PENICILLIN V POTASSIUM	X
POTASSIUM CHLORIDE	X
RITODRINE HYDROCHLORIDE	X
SULFAMETHOXAZOLE	X
THEOPHYLLINE	X
TRICHLORMETHIAZIDE	X
TRISULFAPYRIMADINES	X

1
PRESCRIPTION DRUG PRODUCTS DEEMED APPROVED
PENDING RESOLUTION OF SAFETY OR EFFECTIVENESS ISSUES
SUPPLEMENT NUMBER 1

CURRENT STATUS - 'EXEMPT' (COURT ORDER)

> ADD > DIPYRIDAMOLE CORD LABS
> ADD > DIPYRIDAMOLE

PRESRIPTION DRUG PRODUCTS DEEMED APPROVED
PENDING RESOLUTION OF SAFETY OR EFFECTIVENESS ISSUES
CUMULATIVE INDEX

1

SUPPLEMENT: 1

DIPYRIDAMOLE

X