

APPROVED DRUG PRODUCTS

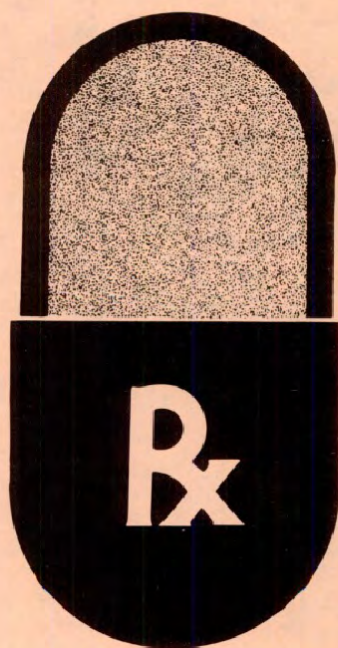
With Therapeutic Equivalence Evaluations



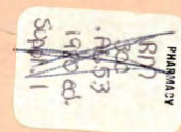
The "Orange Book"

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SUPPLEMENT 1
WITH CUMULATIVE INDEX
1980 EDITION



**APPROVED
PRESCRIPTION
DRUG
PRODUCTS**
WITH
**THERAPEUTIC EQUIVALENCE
EVALUATIONS**



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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

1

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN W/ CODEINE PHOSPHATE

> ADD > AA LEMMON PHARMACAL 300MG;30MG

AMITRIPTYLINE HYDROCHLORIDE

INJECTABLE; INJECTION

AMITRIPTYLINE HCL

CARTER-GLOGAU LABS

> ADD > CARTER-GLOGAU

AMOXICILLIN TRIHYDRATE

CAPSULE; ORAL

AMOXICILLIN TRIHYDRATE

> ADD > AB MYLAN PHARMS EQ 250MG BASE * EQ 500MG BASE

POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN TRIHYDRATE

> ADD > AB MYLAN PHARMS EQ 125MG BASE/5ML *

> ADD > AB EQ 250MG BASE/5ML

> ADD > CALCIFEDIOL

> ADD > CAPSULE; ORAL

> ADD > CALDEROL

> ADD > UPJOHN 20 UGM * 50 UGM

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL

PROMAPAR

> ADD > BP PARKE-DAVIS-W-L 10MG * 25MG * 50MG * 100MG * 200MG

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

AP CENTRAL PHARMACAL EQ 4MG PHOSPHATE/ML

> ADD > DEXAGEN-4

> ADD > AP CENTRAL PHARMACAL EQ 4MG PHOSPHATE/ML

DEXTROAMPHETAMINE SULFATE

> ADD > CAPSULE; ORAL

> ADD > DEXAMPEX

> ADD > LEMMON PHARMACAL 15MG

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 10% IN PLASTIC CONTAINER

> ADD > DEXTROSE 10% IN PLASTIC CONTAINER

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

INJECTABLE; INJECTION

> ADD > ISOLYTE S W/ 5% DEXTROSE IN PLASTIC CONTAINER

> ADD > AP AM MCGAW/AM HOSP 50MG/100ML;30MG/100ML;37MG/100MG

> ADD > AP 370MG/100ML;530MG/100ML;500MG/100ML

PLASMA-LYTE 148 AND DEXTROSE 5% IN PLASTIC CONTAINER

> ADD > AP TRAVENOL LABS 50MG/100ML;30MG/100ML;37MG/100ML;

> ADD > AP 368MG/100ML;526MG/100ML;502MG/100ML

DIPHENADOLINE

TABLET; ORAL

BIPAXIN

UPJOHN

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ISONIAZID
SYRUP; ORAL
HYDRAZID
ER SQUIBB AND SONS
50MG/5ML
RIMIFON
HOFFMAN-LA ROCHE
50MG/5ML

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM
CHLORIDE; SODIUM GLUCONATE
INJECTABLE; INJECTION
AM MCGAM/AM HOSP
30MG/100ML; 37MG/100ML; 370MG/100ML;
30MG/100ML; 30MG/100ML
PLASMA-LYTE 148 IN WATER IN PLASTIC CONTAINER
30MG/100ML; 37MG/100ML; 368MG/100ML;
TRAVENOL LABS
30MG/100ML; 37MG/100ML; 368MG/100ML;
526MG/100ML; 502MG/100ML

MANITOL
INJECTABLE; INJECTION
MANITOL 25%
ABBOTT LABS
12.5GM/50ML

MAZINDOL
TABLET; ORAL
MAZANOR
MYETH LABS
2MG
SANDOX PHARMS
2MG
BP
> ADD >
> ADD >
> ADD >

PENICILLIN G PROCAINE
INJECTABLE; INJECTION
JOHN D COPANOS
600,000 UNITS/ML
600,000 UNITS/1.2ML
> ADD >

PENICILLIN G POTASSIUM
TABLET; ORAL
MYLAN PHARMS
500,000 UNITS
> ADD >
AB

PENICILLIN
BIOCRAFT LABS
200,000 UNITS/5ML
> ADD >
AA

PENICILLIN-2
BIOCRAFT LABS
600,000 UNITS/5ML
> ADD >
AA

PENICILLIN G POTASSIUM
POWDER FOR RECONSTITUTION; ORAL
BIOCRAFT LABS
200,000 UNITS/5ML
350,000 UNITS/5ML
400,000 UNITS/5ML
> ADD >
AA

NOVOBIOCIN SODIUM
INJECTABLE; INJECTION
ALBANY
UPJOHN
EQ 500MG BASE/VIAL

NOVOBIOCIN CALCIUM
SYRUP; ORAL
ALBANY
UPJOHN
EQ 125MG BASE/5ML

SUPPLEMENT NUMBER 1

DRUG PRODUCT LIST

APPROVED PRESCRIPTION DRUG PRODUCTS

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PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN V POTASSIUM



BIOCRAFT LABS

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

> ADD >

PENICILLIN-VK

> ADD > AA

BIOCRAFT LABS

EQ 125MG BASE/5ML *

> ADD > AA

EQ 250MG BASE/5ML

TABLET; ORAL

PENICILLIN-VK

> ADD >

PENICILLIN-VK

POTASSIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

> ADD > AP

LYPHO-MED

2MEQ/ML

> ADD >

RITODRINE HYDROCHLORIDE

> ADD >

INJECTABLE; INJECTION

> ADD >

YUTOPAR

> ADD >

DUPHAR LABS

10MG/ML

> ADD >

TABLET; ORAL

> ADD >

YUTOPAR

> ADD >

DUPHAR LABS

10MG

SULFAMETHOXAZOLE

TABLET; ORAL

SULFAMETHOXAZOLE

> ADD > AB

HEATHER DRUG

500MG

THEOPHYLLINE

> ADD >

SUSPENSION; ORAL

> ADD >

ELIXICON

> ADD >

BERLEX LABS/S-AG 100MG/5ML

TABLET; ORAL

SLO-PHYLLIN

> ADD >

BD DOONER LABS

100MG * 200MG

> ADD >

THEOCLEAR-100

> ADD >

BD CENTRAL PHARMACAL

100MG

> ADD >

THEOCLEAR-200

> ADD >

BD CENTRAL PHARMACAL

200MG

TRICHLORMETHIAZIDE

TABLET; ORAL

TRICHLOR

> ADD >

TRICHCLOREX

TRISULFAPYRIMADINES

SUSPENSION; ORAL

TRISULF

AB

FIRST TEXAS PHARMS

500MG/5ML

TABLET; ORAL

TRISULF

AB

FIRST TEXAS PHARMS

500MG

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APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
CUMULATIVE INDEX

1

SUPPLEMENT: 1

ACETAMINOPHEN; CODEINE PHOSPHATE	X
AMITRIPTYLINE HYDROCHLORIDE	X
AMOXICILLIN TRIHYDRATE	X
CALCIFEDIOL	X
CHLORPROMAZINE HYDROCHLORIDE	X
DEXAMETHASONE SODIUM PHOSPHATE	X
DEXTOAMPHETAMINE 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

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X	TRISULFAPYRIMIDINES
X	TRICHLORMETHIAZIDE
X	THEOPHYLLINE
X	SULFAMETHOXAZOLE
X	RITODRINE HYDROCHLORIDE
X	POTASSIUM CHLORIDE
X	PENICILLIN V POTASSIUM
X	PENICILLIN G PROCAINE
SUPPLEMENT: 1	

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APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
CUMULATIVE INDEX

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

1

CURRENT STATUS - 'EXEMPT' (COURT ORDER)

> ADD > DIPYRIDAMOLE CORD LABS
> ADD > DIPYRIDAMOLE

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

1

SUPPLEMENT: 1

DIPYRIDAMOLE

x

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