

APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations

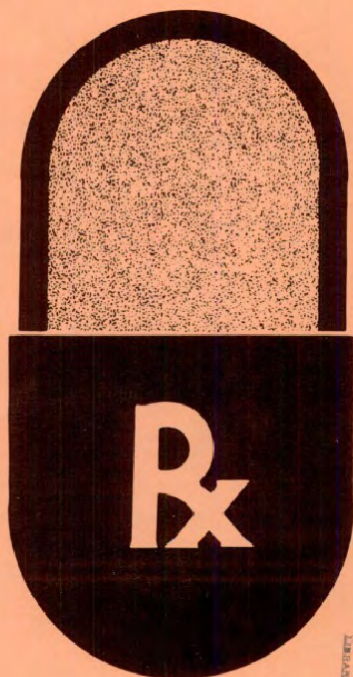


The "Orange Book"

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SUPPLEMENT 3
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.

I. 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 >_AMP_> to the left of the line on which new information exists. Any line containing neither reverse print nor >_AMP_> 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 >_AMP_>.

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 3

1

> ADD > AMINOGLUTETHIMIDE

> ADD > TABLET; ORAL

> ADD > CYTADREN

> ADD > CIBA PHARM 250MG

ASPIRIN; CAFFEINE; PHENACETIN; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL W/ A.P.C.

AA ICN PHARMS 227MG; 32.4MG; 162MG; 65MG

> ADD > ICN 65 COMPOUND

> ADD > AA ICN PHARMS 227MG; 32.4MG; 162MG; 65MG

BISHYDROXYCOUMARIN

> ADD > DICUMAROL

> ADD > CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM

> ADD > CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

> ADD > INJECTABLE; INJECTION

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

> ADD > AM MCGAM/AM HOSP 37MG/100ML; 56MG/100ML; 31MG/100ML;

> ADD > 120MG/100ML; 330MG/100ML; 88MG/100ML

> ADD > CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM

> ADD > CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE

> ADD > INJECTABLE; INJECTION

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

> ADD > AM MCGAM/AM HOSP 35MG/100ML; 56MG/100ML; 30MG/100ML;

> ADD > 75MG/100ML; 640MG/100ML; 500MG/100ML;

> ADD > 75MG/100ML

CHLORAMPHENICOL; DESOXYRIBONUCLEASE; FIBRINOLYSIN

OINTMENT; TOPICAL

ELASE W/ CHLOROMYCETIN

PARKE-DAVIS/W-L

16MG/100GM; 66.666 UNITS/100GM;
100 UNITS/100GM

> ADD > ELASE-CHLOROMYCETIN

> ADD > PARKE-DAVIS/W-L

10MG/GM; 666 UNITS/GM; 1 UNIT/GM

CHLORPROPAMIDE

TABLET; ORAL

CHLORPROPAMIDE

> ADD > AD CHELSEA LABS

250MG

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL

CYPROHEPTADINE HCL

> ADD > AA KV PHARMACEUTICAL

4MG

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

HEXADROL

AP ORGANON/AKZONA

EQ 4MG PHOSPHATE/ML

HEXADROL PHOSPHATE

> ADD > AP ORGANON/AKZONA

EQ 4MG PHOSPHATE/ML

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

DA-10

AA REXAR PHARMACAL

10MG

DA-5

AA REXAR PHARMACAL

5MG

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HEXOCYCLUM METHYL SULFATE

> ADD > TABLET, CONTROLLED RELEASE; ORAL
 > ADD > TRAL GRADUMET
 > ADD > ABBOTT LABS 50MG

NEOSTIGMINE BROMIDE

SOLUTION/DROPS; OPHTHALMIC
 PROSTIGMIN BROMIDE
 HOFFMANN-LA ROCHE 5%

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
 > ADD > PHENAZINE
 > ADD > AA H1 MAST 35MG

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
 > ADD > ADIXPEX
 > ADD > AA LEMMON PHARMACAL 30MG

TABLET; ORAL
 ADIXPEX-P
 > ADD > LEMMON PHARMACAL 37.5MG

POTASSIUM CHLORIDE

CAPSULE, CONTROLLED RELEASE; ORAL
 > ADD > MICRO-K
 > ADD > BC AH ROBINS 600MG
 TIMKAP
 > ADD > BC BERLEX LABS/S-AG 600MG

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
 UNIMIN
 BARNES-HIND PHARMS 0.125%
PREDNISOLONE SODIUM PHOSPHATE
 > ADD > BARNES-HIND PHARMS 0.125%

PREDNISONE

TABLET; ORAL
 PREDNISONE
 > ADD > BX DANBURY PHARMACAL 50MG
 > ADD > BX HEATHER DRUG 50MG

SCOPOLAMINE HYDROBROMIDE

> ADD > SCOPOLAMINE

> ADD > ZONEPIRAC SODIUM

> ADD > TABLET; ORAL
 > ADD > ZOMAX
 > ADD > MCNEIL LABS EQ 100MG BASE

CHLORPROMAZINE HYDROCHLORIDE	X			
CHLORQUINE PHOSPHATE	X			
CHLORAMPHENICOL; HYDROCORTISONE ACETATE	X			
CHLORAMPHENICOL; DESOXYRIBONUCLEASE; FIBRINOLYSIN	X			
SODIUM ACETATE; SODIUM CHLORIDE	X			
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE HEXAHYDRATE;				
CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE	X			
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM				
CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	X			
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM				
CALCIFEDIOL	X			
BISHYDROXYCOLUMARIN	X			
ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE	X			
ASPIRIN; CAFFEINE; PHENACETIN; PROPOXYPHENE HYDROCHLORIDE	X			
AMOXICILLIN TRIHYDRATE	X			
AMOXAPINE	X			
AMITRIPTILINE HYDROCHLORIDE	X			
AMINOPIPTILINE	X			
AMINOGLUTETIMINIDE	X			
ACETIC ACID, GLACIAL	X			
ACETAMINOPHEN; CODEINE PHOSPHATE	X	X		
SUPPLEMENT: 1	2	3		

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE INDEX

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE INDEX

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	SUPPLEMENT: 1	2	3
CHLORPROPAMIDE			X
CLORAZEPATE DIPOTASSIUM		X	
CORTISONE ACETATE; NEOMYCIN SULFATE		X	
CYPROHEPTADINE HYDROCHLORIDE			X
DANAZOL		X	
DEXAMETHASONE SODIUM PHOSPHATE	X		X
DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE		X	
DEXTROAMPHETAMINE SULFATE	X		X
DEXTROSE	X		
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE			X
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	X		
DEXTROSE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE			X
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE - IN PLASTIC		X	
DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM			X
DIATRIZOATE SODIUM			X
DICUMAPOL			X
DIPHENADIONE	X		
EPINEPHRINE; LIDOCAINE HYDROCHLORIDE		X	

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X	NEOMYCIN SULFATE; PREDNISOLONE
X	NAPROXEN SODIUM
X	METHYLTTESTOSTERONE
X	METHYLPREDNISOLONE; NEOMYCIN SULFATE
X	METAPROTERENOL SULFATE
X	MEPERIDINE HYDROCHLORIDE
X	MAZINDOL
X	MANNITOL
X	MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE
X	LORAZEPAM
X	LIDOCAINE HYDROCHLORIDE
X	ISONIAZID
X	HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE
X	HYDROCORTISONE ACETATE; NEOMYCIN SULFATE
X	HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE
X	HEXOCYCLUM METHYLSULFATE
X	HEPARIN SODIUM
X	HALOTHANE
X	FENOPROFEN CALCIUM DIHYDRATE
3	SUPPLEMENT: 1
2	
1	

CUMULATIVE INDEX

DRUG PRODUCT LIST

APPROVED PRESCRIPTION DRUG PRODUCTS

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APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
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	SUPPLEMENT: 1	2	3
NEOMYCIN SULFATE; PREDNISOLONE ACETATE		X	
NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE		X	
NEOSTIGMINE BROMIDE			X
NOVOBIOCIN CALCIUM	X		
NOVOBIOCIN SODIUM	X		
PENICILLIN G POTASSIUM	X		
PENICILLIN G PROCAINE	X		
PENICILLIN V POTASSIUM	X		
PHENDIMETRAZINE TARTRATE			X
PHENTERMINE HYDROCHLORIDE		X	X
POTASSIUM CHLORIDE	X	X	X
PRAZEPAM		X	
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM		X	
PREDNISOLONE SODIUM PHOSPHATE			X
PREDNISONE			X
PYRIDOXINE HYDROCHLORIDE		X	
RESERPINE; TRICHLORMETHIAZIDE		X	
RITODRINE HYDROCHLORIDE	X		
SCOPOLAMINE			X

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SCOPOLAMINE HYDROBROMIDE
SODIUM AMINOSALICYLATE
SULFAMETHOXAZOLE
SULFISOXAZOLE
THEOPHYLLINE
TRICHLORMETHIAZIDE
TRISULFAPYRIMIDINES
ZOEPIRAC SODIUM

SUPPLEMENT: 1
 2
 3

APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
CUMULATIVE INDEX

CURRENT STATUS - 'EXEMPT' (COURT ORDER)

METI-DERM W/ NEOMYCIN SCHERING
NEOMYCIN SULFATE; PREDNISOLONE

SULFATHALIDINE MERCK SHARP & DOHME
PHTHALYLSULFATHIAZOLE

TERRA-CORTRIL	X		
SULFATHALIDINE	X		
POLY-PRED	X		
PREDNYCIN-P	X		
OPHTHCORT	X		
NEOSONE	X		
NEO-HEDROL	X		
NEO-DELTEF	X		
NEO-DELTA-CORTEF	X		
NEO-ARISTOCORT ACETONIDE	X		
METIMYD	X		
METI-DERM W/ NEOMYCIN	X		
FLORINEF-S	X		
DIPYRIDAMOLE	X	X	
CORTISPORIN	X		
COR-OTICIN	X		
CHLOROMYCELIN HYDROCORTISONE	X		
BACITRACIN; NEOMYCIN; POLYMYXIN; HYDROCORTISONE ACETATE	X		
ACHROMYCIN	X		
SUPPLEMENT: 1	2	3	

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



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