

APPROVED DRUG PRODUCTS

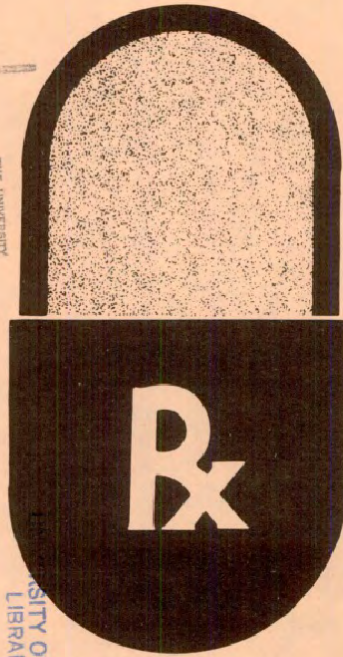
With Therapeutic Equivalence Evaluations



The "Orange Book"

FDA data supplied by [DrugPatentWatch.com](https://www.drugpatentwatch.com)

SUPPLEMENT 5
WITH CUMULATIVE INDEX
1980 EDITION



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

SERIAL

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

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

AUG 12 1981

THE UNIVERSITY
OF MICHIGAN

MEDICAL
LIBRARY

FEB 5 1981

UNIVERSITY OF MICHIGAN
LIBRARIES

DEPOSITED BY THE
UNITED STATES OF AMERICA

1980 ed.
Suppl. 5

Pharmacy
RMA
300
A653

24

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

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.

Sulfisoxazole - Generic Pharmaceuticals

Generic Pharmaceuticals' sulfisoxazole tableted product was inadvertently coded as being therapeutically equivalent (code AB) in Supplement No. 4. The code change to "BP" is to reflect that the firm has not provided satisfactory evidence as required by the Agency to demonstrate that their product is therapeutically equivalent.

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 SUPPLEMENT NUMBER 5

1

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL W/ ATROPINE SULFATE
 >_ADD> AA RIKER LABS/3M EQ USM; 2.5MG

CEFADROXIL MONOHYDRATE

CAPSULE; ORAL

DURICEF
 >_ADD> AB HEAD JOHNSON/BM EQ 500MG BASE
 >_ADD> ULTRACEF
 >_ADD> AB BRISTOL LABS/BM EQ 500MG BASE

CEPHALORIDINE

INJECTABLE; INJECTION

LORIDINE
 ELI LILLY 500MG/VIAL * 1GM/VIAL

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

KLOTRAZINE
 AP CARTER-GLOGAU LABS 25MG/ML
CHLORPROMAZINE HCL
 >_ADD> AP CARTER-GLOGAU 25MG/ML

TABLET; ORAL

CHLORPROMAZINE HCL
 >_ADD> BP CHELSEA LABS 10MG * 100MG * 200MG

DEXTROSE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

>_ADD> LIDOCAINE HCL 0.2% IN DEXTROSE 5% IN PLASTIC CONTAINER
 >_ADD> ABBOTT LABS 5%; 0.2%
 >_ADD> LIDOCAINE HCL 0.4% IN DEXTROSE 5% IN PLASTIC CONTAINER
 >_ADD> ABBOTT LABS 5%; 0.4%

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

>_ADD> DOXYCYCLINE HYCLATE
 >_ADD> AB FEDERAL PHARMACAL EQ 100MG BASE

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL

ERYTHROMYCIN ETHYLSUCCINATE
 >_ADD> AB NATL PHARM MFG/BARRE EQ 200MG BASE/5ML

TABLET; ORAL

E.E.S. 400
 >_ADD> AB ABBOTT LABS EQ 400MG BASE
 >_ADD> ERYTHROMYCIN ETHYLSUCCINATE
 >_ADD> AB BARR LABS EQ 400MG BASE

FENOPROFEN CALCIUM DIHYDRATE

>_ADD> FENOPROFEN CALCIUM

GENTAMICIN SULFATE

INJECTABLE; INJECTION

GARAMYCIN
 >_ADD> AP SCHERING EQ 10MG BASE/ML * EQ 40MG BASE/ML

Digitized by Google

Original from
 UNIVERSITY OF MICHIGAN

POTASSIUM CHLORIDE

TABLET; CONTROLLED RELEASE; ORAL
 K-TAB

>_ADD_> BC ABBOTT LABS 750MG
 10MEQ
 >_ADD_> KAON-CL
 WARREN-TEED/ADRIA 500MG
 6.7MEQ
 >_ADD_> KAON' CL-10
 BC WARREN-TEED/ADRIA 750MG
 10MEQ
 >_ADD_> KLOTRIX
 BC HEAD JOHNSON/BN 750MG
 10MEQ
 >_ADD_> SLOW-K
 CIBA PHARM 600MG
 6MEQ

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION

YUTOPAR

>_ADD_> AP DUPHAR LABS 10MG/ML
 >_ADD_> MERRELL-NATIONAL 10MG/ML
 >_ADD_> AP RITODRINE HCL
 DUPHAR LABS 10MG/ML

TABLET; ORAL

YUTOPAR

>_ADD_> AB DUPHAR LABS 10MG
 MERRELL-NATIONAL 10MG
 >_ADD_> RITODRINE HCL
 DUPHAR LABS 10MG

SECOBARBITAL SODIUM

CAPSULE; ORAL

SECOBARBITAL SODIUM

>_ADD_> AA WYETH LABS/AMMO 100MG

SULFASALAZINE

>_ADD_> SUSPENSION; ORAL

>_ADD_> AZULFIDINE

>_ADD_> PHARMACIA LABS 250MG/5ML

SULFISOXAZOLE

TABLET; ORAL

SULFISOXAZOLE

>_ADD_> AB GENERIC PHARM/IVY 500MG
 >_ADD_> BP 500MG

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION

TESTOSTERONE ENANTHATE

>_ADD_> AQ CARTER-GLOGAU 100MG/ML * 200MG/ML
 >_ADD_> AQ D-M PHARMACEUTICALS 100MG/ML * 200MG/ML

CHLORPROPAMIDE			X	X					
CHLORPROMAZINE HYDROCHLORIDE			X	X					
CHLORPHENIRAMINE MALEATE				X					
CHLOROQUINE PHOSPHATE					X				
CHLORAMPHENICOL; HYDROCORTISONE ACETATE					X				
CHLORAMPHENICOL; DESOXYRIBONUCLEASE; FIBRINOLYSIN					X				
CEPHALORIDINE								X	
CEFALEXIL MONOHYDRATE								X	
SODIUM ACETATE; SODIUM CHLORIDE					X				
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE HEXAHYDRATE;								X	
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM					X				
CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE								X	
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM					X				
CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE								X	
CALCIFEDIOL								X	
CAFFEINE; ERGOTAMINE TARTRATE								X	
BISHYDROXYCOUMARIN								X	
ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE					X				X
ASPIRIN; CAFFEINE; PROPENPHENE HYDROCHLORIDE					X				
AMOXICILLIN TRIMETHYLATE								X	
AMOXAPINE								X	
AMITRIPTYLINE HYDROCHLORIDE								X	
AMINOPHYLLINE								X	
AMINOGLUTETHIMIDE								X	
AMINO ACIDS								X	
AMANTADINE HYDROCHLORIDE								X	
ACETIC ACID, GLACIAL								X	
ACETAMINOPHEN; CODEINE PHOSPHATE								X	
SUPPLEMENT: 1								X	
2								X	
3								X	
4								X	
5								X	

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE INDEX

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE INDEX

5

	SUPPLEMENT: 1	2	3	4	5
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; LIDOCAINE HYDROCHLORIDE					X
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE			X		
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	X			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		
DICUMAROL			X		
DIHYDROERGOCORNINE MESYLATE; DIHYDROERGOCRISTINE MESYLATE; DIHYDROERGOCRYPTINE MESYLATE				X	
DIPHENADIONE	X				
DOXYCYCLINE HYCLATE					X
EPINEPHRINE; LIDOCAINE HYDROCHLORIDE		X			
ERYTHROMYCIN ETHYLSUCCINATE					X
FENOPROFEN CALCIUM					X
FENOPROFEN CALCIUM DIHYDRATE			X		X
GENTAMICIN SULFATE				X	X

Digitized by Google

Original from
 UNIVERSITY OF MICHIGAN

GRISEOFULVIN, ULTRAHIGHCRYSTALLINE		X			
HALOTHANE		X			
HEPARIN CALCIUM		X			
HEPARIN SODIUM		X			
HEXACHLOROPHENE		X			
HEXOCYCLUM METHYLSULFATE		X			
HYDROCHLOROTHIAZIDE		X			
HYDROCORTISONE		X			
HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE		X			
HYDROCORTISONE ACETATE; NEOMYCIN SULFATE		X			
HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE		X			
HYDROCORTISONE SODIUM SUCCINATE		X			
ISONIAZID		X	X		
ISOSORBIDE		X			
LIDOCAINE HYDROCHLORIDE		X			
LITHIUM CARBONATE		X			
LITHIUM CITRATE		X			
LOBAZEPAM		X			
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE		X			
MANNITOL		X			
MAPROTIILINE HYDROCHLORIDE		X			
MAZINDOL		X			
MECLOCYCLINE SULFOSALICYLATE		X			
MEPERIDINE HYDROCHLORIDE		X			
MEPROBAMATE		X			
METAPROTERENOL SULFATE		X			

SUPPLEMENT: 1 2 3 4 5

APPROVED PRESCRIPTION DRUG PRODUCTS
CUMULATIVE INDEX
DRUG PRODUCT LIST

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE INDEX

7

	SUPPLEMENT: 1	2	3	4	5
METHAQUALONE					X
METHYLPREDNISOLONE; NEOMYCIN SULFATE		X			
METHYLTESTOSTERONE		X			
METOCLOPRAMIDE HYDROCHLORIDE				X	
METRONIDAZOLE HYDROCHLORIDE				X	
NAPROXEN SODIUM		X			
NEOMYCIN SULFATE; PREDNISOLONE		X			
NEOMYCIN SULFATE; PREDNISOLONE ACETATE		X			
NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE		X			
NEOSTIGMINE BROMIDE			X		
NOVOBIOCIN CALCIUM	X				
NOVOBIOCIN SODIUM	X				
OXYTOCIN				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		X
PRAZEPAM		X			
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM		X			
PREDNISOLONE SODIUM PHOSPHATE			X		
PREDNISONE			X		
PROMETHAZINE HYDROCHLORIDE				X	
PYRIDOXINE HYDROCHLORIDE		X			
RESERPINE; TRICHLORMETHIAZIDE		X			
RITODRINE HYDROCHLORIDE	X				

Digitized by Google

Original from
 UNIVERSITY OF MICHIGAN

APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
CUMULATIVE INDEX

CURRENT STATUS - INEFFECTIVE

TRAL GRADUMET ABBOTT LABS
REXOCYCLUM METHYLSULFATE

CURRENT STATUS - 'EXEMPT' (COURT ORDER)

> ADD > DONNATAL AM ROBINS
> ADD > ATROPINE SULFATE; HYOSCYAMINE SULFATE; PHENOBARBITAL;
> ADD > SCOPOLAMINE HYDROBROMIDE

Digitized by Google

Original from
UNIVERSITY OF MICHIGAN





Digitized by Google

Original from
UNIVERSITY OF MICHIGAN