

APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations

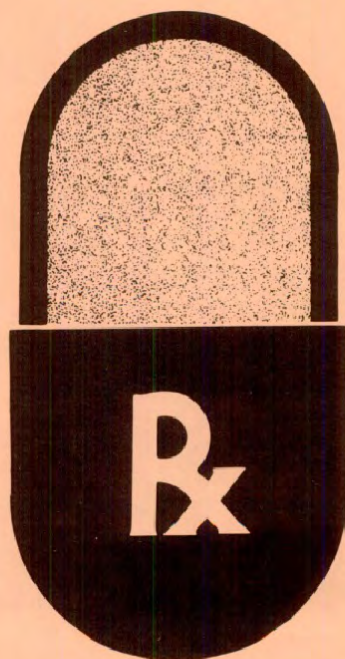


The "Orange Book"

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SUPPLEMENT 10
WITH CUMULATIVE INDEX
1980 EDITION



**APPROVED
PRESCRIPTION
DRUG
PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE
EVALUATIONS**

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Pharmacy

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

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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 an overstruck 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 the overstruck 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 for 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

1. Studies on chlorothiazide tablets have confirmed that the absorption of the 500 mg. tablet is no greater than that of a 250 mg. tablet. Current manufacturers of 500 mg. tablets have been requested by FDA to voluntarily remove their products from the market and additional firms are requested not to seek approval for such a product.

Studies also revealed bioequivalence among brands of currently approved 500 mg. tablets of chlorothiazide.

2. The 2nd Edition of this publication is scheduled to be available as a new subscription from the Government Printing Office (GPO) in October, 1981. It will contain data current through July, 1981. The first supplement to that edition will contain updates covering both August and September, 1981, and is intended to be distributed by GPO with the publication. All supplements to the 2nd Edition will be provided as part of the base subscription price.

Subscribers to the current 1980 publication will continue to receive supplements through September, 1981, to be provided updated data through August, 1981.

A future supplement to the 1980 publication will contain subscription renewal information for the 1981 publication (2nd Edition).

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 SUPPLEMENT NUMBER 10

1

> ADD > ALBUTEROL

> ADD > AEROSOL; INHALATION

> ADD > PROVENTIL

> ADD > BN SCHERING 90 UGM/INH

> ADD > VENTOLIN

> ADD > BN GLAXO INC 90 UGM/INH

CHLOROTHIAZIDE

TABLET; ORAL

DIURIL

/50/ MERCK SHARP & DOHME /500/

> ADD > AB 500MG

> ADD > BETHANIDINE SULFATE

> ADD > TABLET; ORAL

> ADD > TENATHAN

> ADD > AH ROBINS 10MG * 25MG

CHLORPHENIRAMINE MALEATE

SYRUP; ORAL

CHLORPHENIRAMINE

/AA/ /NATL PHARM, WFP/PAKIST, INDIA/

BROMPHENIRAMINE MALEATE

TABLET; ORAL

BROMPHENIRAMINE MALEATE

> ADD > AA PAR PHARM 5MG

CHLORTHALIDONE

TABLET; ORAL

CHLORTHALIDONE

> ADD > AB CORD LABS 25MG * 50MG

CAFFEINE; ERGOTAMINE TARTRATE

TABLET; ORAL

WIGRAINE

> ADD > WIGRAINE

CROTAMITON

CREAM; TOPICAL

EURAX

/50/ /100/

> ADD > WESTWOOD PHARMS

CHLOROTHIAZIDE

TABLET; ORAL

CHLOROTHIAZIDE

/50/ LEDERLE LABS/AM CYAN/500/

> ADD > AB 500MG

/50/ MYLAN PHARMS /500/

> ADD > AB 500MG

CYCLACILLIN

POWDER FOR RECONSTITUTION; ORAL

CYCLAPEN

> ADD > CYCLAPEN-W

TABLET; ORAL

CYCLAPEN

> ADD > CYCLAPEN-W

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HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
 > ADD > HYDRALAZINE HCL-HYDROCHLOROTHIAZIDE-RESERPINE
 > ADD > BP MYLAN PHARMS 25MG;15MG;100 UGM

ISONIAZID

TABLET; ORAL
ISONIAZID
 AA ZENITH LABS 100MG/*, 300MG/

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION
HYDROCORTISONE SODIUM SUCCINATE
 > ADD > AP ELKINS-SINN EQ 100MG BASE/VIAL *
 > ADD > AP EQ 250MG BASE/VIAL *
 > ADD > AP EQ 500MG BASE/VIAL *
 > ADD > AP EQ 1GM BASE/VIAL

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL
 > ADD > AP BRISTOL LABS/BM 20%

HYDROXOCOBALAMIN

INJECTABLE; INJECTION
HYDROXOIN
 > ADD > AP BEL-MAR LABS 1MG/ML

LITHIUM CARBONATE

TABLET, CONTROLLED RELEASE; ORAL
 LITHOBID
 /ROCHELL LABS/
 > ADD > CIBA PHARM

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL
HYDROXYZINE HCL
 > ADD > AA CHELSEA LABS 50MG

LITHIUM CITRATE

SYRUP; ORAL
 /LITHIATE-S/
 > ADD > CIBALITH-S

IBUPROFEN

TABLET; ORAL
MOIRIN
 > ADD > AB UPJOHN MFG 400MG
 > ADD > RUFEN
 > ADD > AB BOOTS PHARMS 400MG

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE
 AA MYLAN PHARMS /200MG/

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APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 SUPPLEMENT NUMBER 10

5

> <u>ADD</u> >	<u>SARALASIN ACETATE</u>			<u>TECHNETIUM, TC-99M, PENTETATE KIT</u>
> <u>ADD</u> >	INJECTABLE; INJECTION			INJECTABLE; INJECTION
> <u>ADD</u> >	SARENIN			<u>CINTICHEM TECHNETIUM 99M DTPA</u>
> <u>ADD</u> >	NORWICH-EATON PHARM	EQ 600 UGNI BASE/ML		<u>/UNITS CARBIDE/</u>
				> <u>ADD</u> >
				CINTICHEM
> <u>ADD</u> >	<u>SECRETIN</u>			<u>TECHNETIUM, TC-99M, PYROPHOSPHATE KIT</u>
> <u>ADD</u> >	INJECTABLE; INJECTION			INJECTABLE; INJECTION
> <u>ADD</u> >	SECRETIN-KABI			<u>BONE SCANNING KIT</u>
> <u>ADD</u> >	KABI GROUP INC	75 UNITS/VIAL		<u>/SYNOR, PENTETATE/</u>
				> <u>ADD</u> >
				SYNOR INTERNATIONAL
	<u>SULFAMETHOXAZOLE; TRIMETHOPRIM</u>			
	TABLET; ORAL			
> <u>ADD</u> >	<u>SMZ-TMP</u>			
> <u>ADD</u> >	<u>AB</u>	BIOCRAFT LABS	<u>400MG; 80MG * 800MG; 160MG</u>	
	<u>SULFASALAZINE</u>			
	TABLET; ORAL			
	<u>SULFASALAZINE</u>			
> <u>ADD</u> >	BP	PREMO PHARM LABS	500MG	
	<u>TECHNETIUM, TC-99M, MEDRONATE KIT</u>			
	INJECTABLE; INJECTION			
	<u>AM-MPD</u>			
	<u>/SYNOR, PENTETATE/</u>			
> <u>ADD</u> >	SYNOR INTERNATIONAL			

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE INDEX

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INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8	9	10
CHLORPHENIRAMINE MALEATE				X						
CHLORPROMAZINE HYDROCHLORIDE	X			X	X	X	X		X	X
CHLORPROPAMIDE			X	X						
CHLORTHALIDONE							X	X	X	X
CHYMOTRYPSIN						X				
CLORAZEPATE DIPOTASSIUM		X								
CLORAZEPATE MONOPOTASSIUM		X						X		
CORTISONE ACETATE; NEOMYCIN SULFATE										
CROTAMITON										X
CYCLACILLIN										X
CYCLOTHIAZIDE							X			
CYPROHEPTADINE HYDROCHLORIDE			X				X			X
DACARBAZINE							X			
DANAZOL		X								
DEXAMETHASONE						X				X
DEXAMETHASONE SODIUM PHOSPHATE	X		X							X
DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE		X								
DEXTROAMPHETAMINE SULFATE	X		X							
DEXTROSE	X									
DEXTROSE; LIDOCAINE HYDROCHLORIDE					X				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	X							
DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM			X							
DIATRIZOATE SODIUM			X							
DIAZEPAM			X					X		
DICUMAROL										
DIETHYLSTILBESTROL						X				
DIHYDROERGOCORNINE MESYLATE; DIHYDROERGOCRISTINE MESYLATE; DIHYDROERGOCRYPTINE MESYLATE				X		X		X	X	
DIMENHYDRINATE								X		
DINOPROSTONE						X				

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8	9	10
DINOPROSTONE(PROSTAGLANDIN E-2)										
DIPHENADOLINE										
DIPHENHYDRAMINE HYDROCHLORIDE										
DISULFIRAM										
DOPAMINE HYDROCHLORIDE										
DOXEPRIN HYDROCHLORIDE										
DOXYCYCLINE HYCLATE										
EPINEPHRINE; LIDOCAINE HYDROCHLORIDE										
ERYTHROMYCIN										
ERYTHROMYCIN ETHYLSUCCINATE										
ESTRADIOL VALERATE										
ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE										
ESTROGENS, CONJUGATED										
ESTROGENS, ESTERIFIED										
FENOPROFEN CALCIUM										
FENOPROFEN CALCIUM DIHYDRATE										
FLUORESCIN SODIUM										
FOLLICLE-STIMULATING HORMONE; LUTENIZING HORMONE										
GENTAMICIN SULFATE										
GLUTEETHIMIDE										
GRISOFULVIN, ULTRAMICROCRYSTALLINE										
MALOTIMANE										
HEPARIN CALCIUM										
HEPARIN SODIUM										
HEXACHLOROPHENE										
HEXOXYCLIN METHYL SULFATE										
HYDROCHLORIDE; HYDROCHLORIDE; RESERPINE										
HYDROCHLORIDE; RESERPINE										
HYDROCHLORIDE; SPIRONOLACTONE										

APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
CUMULATIVE INDEX

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INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8	9	10
HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE	X									
HYDROCORTISONE ACETATE; NEOMYCIN SULFATE	X									
HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE	X									
HYDROCORTISONE SODIUM SUCCINATE					X		X			X
HYDROXOCOBALAMIN										X
HYDROXYZINE HYDROCHLORIDE						X		X	X	X
IBUPROFEN										
IMIPRAMINE HYDROCHLORIDE							X	X		
IOTHALAMATE SODIUM, I-125							X			
IRON DEXTRAN COMPLEX								X		
ISOETHARINE HYDROCHLORIDE								X	X	
ISONIAZID	X	X								X
ISOSORBIDE					X					
LIDOCAINE HYDROCHLORIDE	X					X	X			X
LITHIUM CARBONATE				X		X				X
LITHIUM CITRATE					X			X		X
LORAZEPAM		X								
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	X									
MANNITOL	X									
MANNITOL; SORBITOL							X			
MAPROTILINE HYDROCHLORIDE					X					
MAZINDOL	X									
MECLOCYCLINE SULFOSALICYLATE				X						
MEPERIDINE HYDROCHLORIDE	X				X	X				
MEPROBAMATE					X			X		X
METAPROTERENOL SULFATE	X									
METHADONE HYDROCHLORIDE										
METHAQUALONE					X					X
METHYLPREDNISOLONE; NEOMYCIN SULFATE	X					X				
METHYLPREDNISOLONE ACETATE										
METHYLPREDNISOLONE SODIUM SUCCINATE							X			
METHYLTESTOSTERONE	X						X			X
METOCLOPRAMIDE HYDROCHLORIDE					X					

INGREDIENT(S)										SUPPLEMENT: 1									
METOLAZONE																			
METRONIDAZOLE HYDROCHLORIDE																			
MICONAZOLE NITRATE																			
NADOLOL																			
NAPROXEN SODIUM																			
NEOMYCIN SULFATE; PREDNISOLONE																			
NEOMYCIN SULFATE; PREDNISOLONE ACETATE																			
NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE																			
NEOSTIGMINE BROMIDE																			
NITROFURAZONE																			
NORETHINDRONE																			
NOVOBIOICIN CALCIUM																			
NOVOBIOICIN SODIUM																			
ORPHENADRINE CITRATE																			
OXYTOCIN																			
PENICILLIN G POTASSIUM																			
PENICILLIN G SODIUM																			
PENICILLIN V POTASSIUM																			
PENTOBARBITAL SODIUM																			
PHENDIMETRAZINE TARTRATE																			
PHENTERMINE HYDROCHLORIDE																			
PHENTOIN SODIUM																			
POTASSIUM CHLORIDE																			
PRAZEPAM																			
PREDNISOLONE																			
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM																			
PREDNISOLONE SODIUM PHOSPHATE																			
PREDNISON																			
PROHEXAZINE HYDROCHLORIDE																			
PROPOXYFENE HYDROCHLORIDE																			
PROPOXYFENE HYDROCHLORIDE																			
RESERPINE																			
RESERPINE; TRICHLOROMETHIAZIDE																			
RITODRINE HYDROCHLORIDE																			

APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
CUMULATIVE INDEX

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INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8	9	10
SARALASIN ACETATE										X
SCOPOLAMINE			X							
SCOPOLAMINE HYDROBROMIDE			X							
SECOBARBITAL SODIUM					X		X			
SECRETIN										X
SODIUM AMINOSALICYLATE		X								
SOYBEAN OIL						X				
SPIRONOLACTONE						X	X			
SULFAMETHOXAZOLE	X							X		
SULFAMETHOXAZOLE; TRIMETHOPRIM										X
SULFASALAZINE					X				X	X
SULFISOXAZOLE		X		X	X				X	
TECHNETIUM, TC-99M, MEDRONATE KIT							X			X
TECHNETIUM, TC-99M, OXIDRONATE KIT							X			
TECHNETIUM, TC-99M, PENTETATE KIT										X
TECHNETIUM, TC-99M, PYROPHOSPHATE KIT										X
TEMIAZEPAM							X			
TESTOSTERONE ENANTHATE					X			X		
TETRACYCLINE HYDROCHLORIDE						X				
THEOPHYLLINE	X			X					X	
TOLBUTAMIDE							X	X		
TRIAMCINOLONE ACETONIDE									X	
TRIAMCINOLONE DIACETATE								X		
TRICHLORMETHIAZIDE	X						X			
TRISULFAPYRIMIDINES	X									
VITAMIN A						X				
XYLOSE, D-						X				
ZOMEPIRAC SODIUM			X							

PENDING RESOLUTION OF SAFETY OR EFFECTIVENESS ISSUES
SUPPLEMENT NUMBER 10

CURRENT STATUS - "EXEMPT" (COURT ORDER)

> ADD > BARBITONNA WALLACE LABS/C-M
> ADD > ATROPINE SULFATE; HYOSCAMINE SULFATE; PHENOBARBITAL;
> ADD > SCOPOLAMINE HYDROBROMIDE
> ADD > NITROGLYCERIN BYK-GULDEN
> ADD > NITROGLYCERIN

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

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TRADE NAME	SUPPLEMENT: 1	2	3	4	5	6	7	8	9	10
ACHROMYCIN		X								
BACITRACIN; NEOMYCIN; POLYMYXIN; HYDROCORTISONE ACETATE		X								
BARBIDONNA										
BENTYL W/ PHENOBARBITAL							X			X
BIOZYME						X				
CANTIL W/ PHENOBARBITAL							X			
CHLOROMYCETIN HYDROCORTISONE		X								
CLISTIN EXPECTORANT						X				
COR-OTICIN		X								
CORTISPORIN		X								
DACTIL							X			
DACTIL AND PHENOBARBITAL							X			
DARICON PB							X			
DICYCLOMINE HCL								X		
DIPYRIDAMOLE	X	X								
DONNATAL					X					
DYSPAS						X				
FLORINEF-S		X								
LEVSIIN PB							X			
LEVSIIN W/ PHENOBARBITAL							X			
LIBRAX							X			
MEPROBAMATE W/ TRIDIHETHYL CHLORIDE							X			
METI-DERM W/ NEOMYCIN			X							
METIMYD		X								
MILPATH-200							X			
MILPATH-400							X			
NEO-ARISTOCORT ACETONIDE		X								
NEO-DELTA-CORTEF		X								
NEO-DELTEF		X								
NEO-MEDROL		X								
NEOQUESS								X		
NEOSONE	X									
NITROGLYCERIN				X				X		
NYSTATIN, NEOMYCIN SULFATE, GRAMICIDIN, TRIAMCINOLONE ACETONIDE							X			X

TRADE NAME	SUPPLEMENT: 1	2	3	4	5	6	7	8	9	10
OPATHOCORT		X				X				
ORTHOXINE						X				
PARAFON FORTE							X			
PATIBAMATE-400							X			
PATIBAMATE-200							X			
PATHILON W/ PHENOBARBITAL			X				X			
POLY-PRED			X				X			
PREDNYCIN-P			X				X			
PRO-SANTININE W/ PHENOBARBITAL							X			
ROBINUL-PH							X			
ROBINUL-PH FORTE							X			
SULFATHALIDINE			X							
T.C.M. 200							X			
T.C.M. 400							X			
TERRA-CORTRIL		X								
TRAL GRADUMET					X					

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

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