

APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations



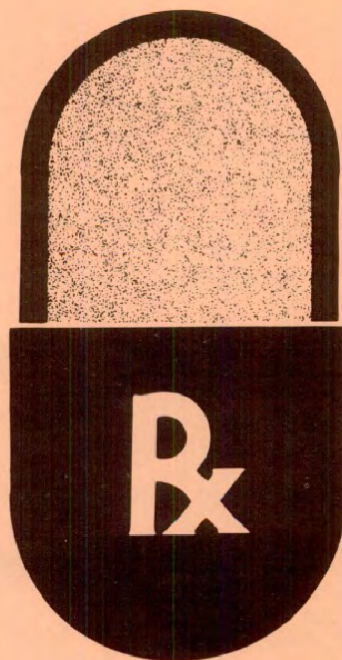
The "Orange Book"

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SUPPLEMENT 13
WITH CUMULATIVE INDEX
1980 EDITION

The University
of Michigan
Pharmacy



**APPROVED
PRESCRIPTION
DRUG
PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE
EVALUATIONS**

1980 ed.
Suppl. 13

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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. 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.

2. A subscription form has been provided at the end of this supplement to assist in extending the subscription to this publication through the 2nd Edition (1981 publication).

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 SUPPLEMENT NUMBER 13

1

ACETAMINOPHEN; CODEINE PHOSPHATE

ELIXIR; ORAL
ACETAMINOPHEN W/ CODEINE

>_ADD_> AA PHARM ASSOCIATES 120MG/5ML;12MG/5ML

ACETIC ACID; GLACIAL

SOLUTION; OTIC

>_ADD_> ACETASOL
 >_ADD_> AT NATL PHARM MFG/BARRE 2%

AMINO ACIDS

INJECTABLE; INJECTION
 /~~AMINOSYN-RF~~/

>_ADD_> AMINOSYN-RF 5.2%
 >_ADD_> ABBOTT LABS 5.2%

AMINOPHYLLINE

INJECTABLE; INJECTION
AMINOPHYLLINE

>_ADD_> AP LYPHO-MED 25MG/ML

ASPIRIN; BUTALBITAL; CAFFEINE; PHENACETIN

TABLET; ORAL

BUTALBITAL W/ APC

>_ADD_> AB LEDERLE LABS/AM CYAN 200MG;50MG;40MG;130MG

>_ADD_> ATENOLOL

>_ADD_> TABLET; ORAL

>_ADD_> TENORMIN
 >_ADD_> STUART PHARMS/ICI 50MG * 100MG

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL W/ ATROPINE SULFATE

>_ADD_> AA PREMO PHARM LABS 25 USM;2.5MG

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION

DEXTROSE 5% IN LACTATED RINGER'S IN PLASTIC CONTAINER

>_ADD_> AP CUTTER LABS 20MG/100ML;5MG/100ML;30MG/100ML;
 >_ADD_> AP 600MG/100ML;330MG/100ML

CHLORTHALIDONE

TABLET; ORAL

CHLORTHALIDONE

>_ADD_> AB CHELSEA LABS 25MG * 50MG
 >_ADD_> AB DANBURY PHARMACAL 25MG * 50MG

CORTISONE ACETATE

INJECTABLE; INJECTION

CORTISONE ACETATE

/~~CORTISONE ACETATE~~/

>_ADD_> LEHMAN

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APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
SUPPLEMENT NUMBER 13

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL
CYPROHEPTADINE HCL
PREMO PHARM LABS
5MG

DIHYDROERGOCORPINE MESYLATE; DIHYDROERGOCORPINE MESYLATE;
DIHYDROERGOCORPINE MESYLATE

TABLET; SUBLINGUAL
DIHYDROERGOCORPINE MESYLATE
KV PHARMACEUTICAL
167 UGM;167 UGM;167 UGM

> ADD > AA
> ADD > AA
> ADD > AA
BARR LABS
167 UGM;167 UGM;167 UGM * 333 UGM;
333 UGM;333 UGM
KV PHARMACEUTICAL
167 UGM;167 UGM;167 UGM

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL
ERYTHROMYCIN ETHYLSUCCINATE
NATL PHARM MFG/BARR
EQ 200MG BASE/5ML *
EQ 400MG BASE/5ML

ESTROGENS, CONJUGATED

TABLET; ORAL
CONJUGATED ESTROGENS
CHELSEA LABS
> ADD > BS
425 UGM * 1.25MG * 2.5MG

HYDROCORTISONE

OINTMENT; TOPICAL
HYDROCORTISONE
SHAFER-DAVIS LABS
0.5%
AT
THAMES PHARMACAL
> ADD > AT
12

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE
PUREPAC PHARM
25MG * 50MG
REID-PROVIDENT LABS
25MG * 50MG
> ADD > AB
> ADD > AB
DANBURY PHARMACAL
25MG;15MG;100 UGM

HYDRAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
GLYCOPYRROLATE
DANBURY PHARMACAL
1MG * 2MG
> ADD > AA

GLYCOPYRROLATE

TABLET; ORAL
LASTIX
HOCHEST-ROUSSEL
20MG * 40MG
FURDSEHIDE
MYLAN PHARMS
20MG * 40MG
> ADD > AB
> ADD > AB

FURDSEHIDE

LEVOPROPOXYPHENE NAPSYLATE

SUSPENSION; ORAL
NOVRAD
/ELI LILLY/
ELI LILLY INDSTRS/PR

> **ADD** >

> ADD >

LIDOCAINE

OINTMENT; TOPICAL
LIDOCAINE

> ADD > AT THAMES PHARMACAL 57

METHOXSALEN

> ADD > CAPSULE; ORAL

> ADD > OXSORALEN
> ADD > ELDER PHARMS 10MG

LOTION; TOPICAL
OXSORALEN
/PAUL B. ELDER/
ELDER PHARMS

METHYLDOPA

> ADD > SUSPENSION; ORAL
> ADD > ALDCHET
> ADD > MERCK SHARP & DOHME 250MG/5ML

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
METRA
/DJF #2/CHRONALLOY/
ONEAL JONES & FELDMAN

> ADD >

> ADD >

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

TRIAMCINOLONE ACETONIDE

/SHIFFER-DAVIS LABS/

THAMES PHARMACAL

> ADD >

TRIAMCINOLONE DIACETATE

INJECTABLE; INJECTION

TRIAMCINOLONE DIACETATE

/P. H. HARRINGTON/

LEHMON

> ADD >

TRISULFAPYRIMIDINES

SUSPENSION; ORAL

SULFALOTID

/G. J. JONES & F. L. FELDMAN/

ONEAL JONES & FELDMAN

> ADD >

> ADD > VERAPAMIL HYDROCHLORIDE

> ADD > INJECTABLE; INJECTION

> ADD > ISOPTIN

> ADD > KNOLL PHARM 2.5MG/ML

SUPPLEMENT: 1												
13												
12												
11												
10												
9												
8												
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3												
2												
1												
INGREDIENTS:												
ACETAMINOPHEN; CODEINE PHOSPHATE												
ACETIC ACID, GLACIAL												
ACETYLCOLINE CHLORIDE												
ALBUTEROL												
AMANTADINE HYDROCHLORIDE												
AMINO ACIDS												
AMINOGLUTETHIMIDE												
AMINOPHYLLINE												
AMITRIPTYLINE HYDROCHLORIDE												
AMOXAPINE												
AMOXICILLIN TRIHYDRATE												
AMOXICILLIN/AMPCILLIN TRIHYDRATE												
ASPIRIN; BUTALBITAL; CAFFEINE; PHENACETIN												
ATENOLOL												
ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE												
BACAMPICILLIN HYDROCHLORIDE												
BACITRACIN												
BETHANECHOL CHLORIDE												
BETHANIDINE SULFATE												
BISHYDROXYCOUMARIN												
BROMPHENIRAMINE MALEATE												
BUTABARBITAL SODIUM												
CAFFEINE; ERGOTAMINE TARTRATE												
CALCIFEDIOL												
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APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
CUMULATIVE INDEX

7

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8	9	10	11	12	13
CHLORPROPAMIDE			X	X							X		
CHLORTHALIDONE						X	X	X	X	X	X		X
CHYMOTRYPSIN													
CLORAZEPATE DIPOTASSIUM		X				X		X					
CLORAZEPATE MONOPOTASSIUM													
CORTISONE ACETATE													
CORTISONE ACETATE; NEOMYCIN SULFATE		X											X
CROTAMITON										X			
CYCLACILLIN										X			
CYCLOTHIAZIDE							X						
CYPROHEPTADINE HYDROCHLORIDE			X				X			X		X	X
DACARBAZINE							X						
DANAZOL		X											
DEXAMETHASONE						X				X			
DEXAMETHASONE SODIUM PHOSPHATE	X		X							X			
DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE		X											
DEXCHLORPHENIRAMINE MALEATE												X	
DEXTROAMPHETAMINE SULFATE	X		X										
DEXTROSE	X										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												
DEXTROSE; SODIUM CHLORIDE											X		
DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM			X										
DIATRIZOATE SODIUM			X										
DIAZEPAM								X					
DICUMAROL			X										
DIETHYLSTILBESTROL						X							
DIHYDROERGOCORININE MESYLATE; DIHYDROERGOCRISTINE MESYLATE; DIHYDROERGOCRYPTINE MESYLATE				X		X		X	X				X
DIMENHYDRINATE								X					
DINOPROSTONE						X							
DINOPROSTONE (PROSTAGLANDIN E-2)						X							
DIPHENADIONE	X												
DIPHENHYDRAMINE HYDROCHLORIDE								X	X				
DISULFIRAM								X					
DOPAMINE HYDROCHLORIDE						X				X		X	
DOXEPIN HYDROCHLORIDE													
DOXYCYCLINE HYCLATE					X								

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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	11	12	13
ISONIAZID	X	X			X					X		X	
ISOSORBIDE					X							X	
ISOSULFAN BLUE											X		
KETOCONAZOLE													X
LEVOPROPOXYPHENE NAPSYLATE													X
LIDOCAINE													X
LIDOCAINE HYDROCHLORIDE		X		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						
MAFROTILINE HYDROCHLORIDE					X								
MAZINDOL	X												
MECLIZINE HYDROCHLORIDE				X							X		
MECLOCYCLINE SULFOSALICYLATE													
MEPERIDINE HYDROCHLORIDE	X				X	X				X			
MEPROBAMATE					X			X		X			
METAPROTERENOL SULFATE	X												
METHADONE HYDROCHLORIDE					X					X			
METHAQUALONE					X							X	
METHOILAZINE HYDROCHLORIDE													X
METHOXSALEN													X
METHYLDOPA													X
METHYLPREDNISOLONE												X	
METHYLPREDNISOLONE; NEOMYCIN SULFATE	X					X							
METHYLPREDNISOLONE ACETATE							X						
METHYLPREDNISOLONE SODIUM SUCCINATE							X			X			
METHYLTTESTOSTERONE	X												
METOCLOPRAMIDE HYDROCHLORIDE					X								
METOLAZONE							X						
METRONIDAZOLE HYDROCHLORIDE				X									
MICONAZOLE NITRATE								X					
MOLINDONE HYDROCHLORIDE											X		
NADOLOL						X							
NAFROXEN SODIUM		X											
NEOMYCIN SULFATE; PREDNISOLONE		X				X							
NEOMYCIN SULFATE; PREDNISOLONE ACETATE		X											
NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE		X											
NEOSTIGMINE BROMIDE			X										

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INGREDIENT(S)	1	2	3	4	5	6	7	8	9	10	11	12	13
NITROFURAZONE													
MORETHINOLONE													
NOVOBIOICIN CALCIUM													
NOVOBIOICIN SODIUM													
ORPHENADRINE CITRATE													
OXAICILLIN SODIUM MONOHYDRATE													
OXYTOCIN													
OXYTOCIN CITRATE													
PENICILLIN G POTASSIUM													
PENICILLIN G PROCAINE													
PENICILLIN G SODIUM													
PENICILLIN V POTASSIUM													
PENTOBARBITAL SODIUM													
PHENIDIMETRAZINE TARTRATE													
PHENTERMINE HYDROCHLORIDE													
PHENYTOIN SODIUM													
POTASSIUM CHLORIDE													
PRAZEPAM													
PREDNISOLONE													
PREDNISOLONE ACETATE													
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM													
PREDNISOLONE SODIUM PHOSPHATE													
PREDNISON													
PROCAINAMIDE HYDROCHLORIDE													
PROCAINE HYDROCHLORIDE													
PROLACTONE													
PROPYLPHENONE HYDROCHLORIDE													
PSEUDOPHEDRINE HYDROCHLORIDE													
PRIDOXINE HYDROCHLORIDE													
QUINIDINE SULFATE													
RAUWOLFIA SERPENTINA													
RESERPIN													
RESERPIN; TRICHLORMETHIAZIDE													
RITODRINE HYDROCHLORIDE													
SARALASIN ACETATE													
SCOPOLAMINE													
SCOPOLAMINE HYDROBROMIDE													
SECRETIN													
SODIUM AMINOSALICYLATE													
SODIUM CHLORIDE													

APPROVED PRESCRIPTION DRUG PRODUCTS
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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	11	12	13
SOYBEAN OIL						X							
SPIRONOLACTONE						X	X					X	
SULFAMETHIZOLE													X
SULFAMETHOXAZOLE	X							X					
SULFAMETHOXAZOLE; TRIMETHOPRIM										X	X		
SULFASALAZINE									X	X	X		
SULFISOXAZOLE		X		X	X				X	X		X	X
TECHNETIUM, TC-99M, ETIDRONATE KIT													
TECHNETIUM, TC-99M, MEDRONATE KIT							X			X			X
TECHNETIUM, TC-99M, OXIDRONATE KIT							X						
TECHNETIUM, TC-99M, PENTETATE KIT										X			
TECHNETIUM, TC-99M, PYROPHOSPHATE KIT										X			
TEMAZEPAM							X						
TESTOSTERONE CYPIONATE					X			X				X	X
TESTOSTERONE ENANTHATE													
TETRACYCLINE HYDROCHLORIDE						X							
THEOPHYLLINE	X			X					X				
TOLBUTAMIDE							X	X					
TRIAMCINOLONE ACETONIDE								X	X				X
TRIAMCINOLONE DIACETATE								X					X
TRICHLORMETHIAZIDE	X						X						
TRISULFAPYRIMIDINES	X										X		X
VERAPAMIL HYDROCHLORIDE													X
VITAMIN A						X							
WATER, FOR INJECTION											X		
XYLOSE, D-						X							
ZOMEPIRAC SODIUM			X										

NEOQUESS /OFF/CHPOMALLOY/

OXSORALEN
/PAUL B. ELDER/
ELDER PHARMS
/ELDER PHARMS/
OXSORALEN
/HEINHOXSALEN/

PENDING RESOLUTION OF SAFETY OR EFFECTIVENESS ISSUES
SUPPLEMENT NUMBER 13

PREScription DRUG PRODUCTS DEEMED APPROVED
PENDING RESOLUTION OF SAFETY OR EFFECTIVENESS ISSUES
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TRADE NAME	SUPPLEMENT: 1	2	3	4	5	6	7	8	9	10	11	12	13
ACHROMYCIN		X											
BACITRACIN; NEOMYCIN; POLYMYXIN; HYDROCORTISONE ACETATE		X											
BARBIDONNA										X			
BARBIDONNA NO.2											X		
BENTYL W/ PHENOBARBITAL							X						
BIOZYME						X							
BUTIBEL							X				X		
CANTIL W/ PHENOBARBITAL													
CHLOROMYCETIN HYDROCORTISONE		X											
CLISTIN EXPECTORANT						X							
COR-OTICIN		X											
CORTISPORIN		X											
DACTIL							X					X	
DACTIL AND PHENOBARBITAL							X					X	
DARICON PB							X						
DICYCLOHINE HCL								X					
DIPYRIDAMOLE	X	X			X	X							
DONNATAL													
DYSPAS													
FLORINEF-S		X											
ISOSORBIDE DINITRATE											X		
LEVSIN PB							X						
LEVSIN W/ PHENOBARBITAL							X						
LIBRAX							X						
MEPROBAMATE W/ TRIDIHETHYL CHLORIDE							X					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					X
NEOSONE		X											
NITROGLYCERIN				X				X		X			
NYSTATIN, NEOMYCIN SULFATE, GRAMICIDIN, TRIAMCINOLONE ACETONIDE							X						
OPHTHOCORT	X					X							
ORTHOXINE													
OXSORALEN													X
PARAFON FORTE						X							
PATHIBAMATE-200							X						

TRADE NAME	1	2	3	4	5	6	7	8	9	10	11	12	13
PATIBAMATE-400							X						
PATILON W/ PHENOBARBITAL							X						
PHENOBARBITAL & BELLADONNA							X						
PITOCIN CITRATE		X								X			
POLY-PRED		X											
PREDNICIN-P			X										
PRO-BANTHINE W/ DARITAL													
PRO-BANTHINE W/ PHENOBARBITAL							X				X		
ROBINUL-PH							X				X		
ROBINUL-PH FORTE							X				X		
SPALIX													
SULFATHALIDINE			X							X			
T.C.M. 200							X						
T.C.M. 400							X						
TERRA-CORTIL		X											
TRAL GRADUET					X								

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