

APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations



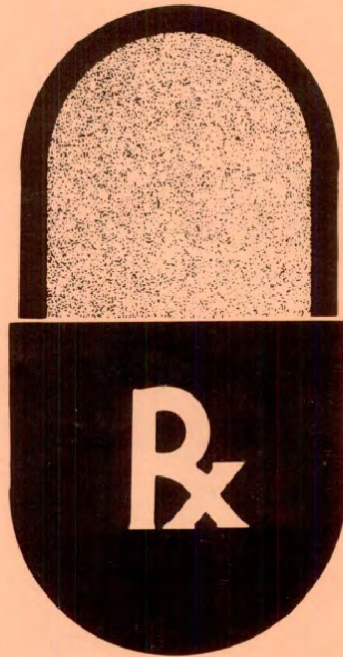
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SUPPLEMENT 11
WITH CUMULATIVE INDEX
1980 EDITION



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

SERIAL

1980 ed.
Suppl. 11

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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 multi-source; 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.

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

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). This form will appear again in each remaining supplement to the 1980 publication.

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 SUPPLEMENT NUMBER 11

1

CHLORPROPAMIDE

TABLET; ORAL

CHLORPROPAMIDE

> ADD > AB ZENITH LABS 250MG

CHLORTHALIDONE

TABLET; ORAL

CHLORTHALIDONE

> ADD > AB PREMO PHARM LABS 50MG

> ADD > AB ZENITH LABS 25MG

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 10% IN PLASTIC CONTAINER

> ADD > AP CUTTER LABS 10GM/100ML

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

> ADD > AP ABBOTT LABS 5GM/100ML;300MG/100ML

> ADD > AP CUTTER LABS 5GM/100ML;300MG/100ML

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

> ADD > AP CUTTER LABS 5GM/100ML;900MG/100ML

HYDROCORTISONE

CREAM; TOPICAL

SYNACORT

> ADD > AT SYNTEX LABS 0.5% * 1% * 2.5%

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HCL

> ADD > AP STERLING DRUG 25MG/ML * 50MG/ML

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

ISOETHARINE HCL

> ADD > AM NATL PHARM MFG/BARRE 1%

> ADD > KETOCONAZOLE

> ADD > TABLET; ORAL

> ADD > NIZORAL

> ADD > JANSSEN PHARM 200MG

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

MECLIZINE HCL

> ADD > AA PAR PHARM 12.5MG * 25MG

MOLINDONE HYDROCHLORIDE

TABLET; ORAL

MOBAN

> ADD > ENDO LABS/DUPONT 50MG * 100MG

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BAUMOLIFIA SERPENTINA TABLET; ORAL MOLFINA ONEAL JONES&FELDMAN	> ADD >	DOXACILLIN SODIUM MONOHYDRATE POWDER FOR RECONSTITUTION; ORAL PROSTAPHLIN BRISTOL LABS/BM EQ 250MG BASE/5ML EQ 250MG BASE/5ML
SODIUM CHLORIDE INJECTABLE; INJECTION SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER CUTTER LABS 450MG/100ML SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER CUTTER LABS 450MG/100ML	> ADD > AP > ADD > AP > ADD > AP	PENICILLIN V POTASSIUM POWDER FOR RECONSTITUTION; ORAL PENICILLIN V POTASSIUM JOHN D COPANOS EQ 125MG BASE/5ML EQ 125MG BASE/5ML EQ 125MG BASE/5ML EQ 250MG BASE/5ML
SULFASALAZINE TABLET; ORAL SULFASALAZINE DANBURY PHARMACAL 500MG	> ADD > AB	PHENTHERMINE HYDROCHLORIDE CAPSULE; ORAL PHENTHERMINE HCL CANALL 15MG 15MG X 30MG
TRISULFAPYRIDIMIDINES TABLET; ORAL SULFALAZINE ONEAL JONES&FELDMAN	> ADD >	PROPOXYPHENE HYDROCHLORIDE CAPSULE; ORAL PROPHENE 65 HALSEY DRUG 65MG
GUINIDINE SULFATE TABLET; ORAL GIN-GUIN ROMELL LABS 100MG 100MG X 300MG	> ADD > AB	PHENTHERMINE HYDROCHLORIDE CAPSULE; ORAL PHENTHERMINE HCL CANALL 15MG 15MG X 30MG

SUPPLEMENT NUMBER 11

APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST

WATER, FOR INJECTION

INJECTABLE; INJECTION

STERILE WATER IN PLASTIC CONTAINER

> <u>ADD</u> > <u>AP</u>	ABBOTT LABS	<u>100%</u>
> <u>ADD</u> > <u>AP</u>	CUTTER LABS	<u>100%</u>

INGREDIENT(S) SUPPLEMENT: 1 2 3 4 5 6 7 8 9 10 11

ACETAMINOPHEN; CODEINE PHOSPHATE X X X

ACETIC ACID, GLACIAL X

ALBUTEROL X

AMANTADINE HYDROCHLORIDE X

AMINO ACIDS X

AMINOGLUTETHIMIDE X

AMINOPHYLLINE X

AMITRIPTYLINE HYDROCHLORIDE X

AMOXAPINE X

AMOXICILLIN TRIHYDRATE X

AMPCILLIN/AMPCILLIN TRIHYDRATE X

ASPIRIN; BUTALBITAL; PHENACETIN X

ASPIRIN; CAFFEINE; PHENACETIN X

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE X

BACAMPICILLIN HYDROCHLORIDE X

BACTRACIN X

BETHANIDINE SULFATE X

BIPHENHYDRAMINE MALEATE X

BUTABARBITAL SODIUM X

CAFFEINE; ERGOTAMINE TARTRATE X

CALCIFEDIOL X

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM X

CHLORAMPHENICOL; DESOXYRIBONUCLEASE; FIBRINOLYSIN X

CHLORAMPHENICOL; HYDROCORTISONE ACETATE X

CHLORDIAZEPAMIDE X

CHLOROPROMAZINE HYDROCHLORIDE X

CHLOROPROPAMIDE X

CHLORTHALIDONE X

CHYMOTRYPSIN X

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
CLORAZEPATE DIPOTASSIUM		X						X			
CLORAZEPATE MONOPOTASSIUM		X									
CORTISONE ACETATE; NEOMYCIN SULFATE										X	
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										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
DEXTROSE; SODIUM CHLORIDE											
DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM			X								
DIATRIZOATE SODIUM			X								
DIAZEPAM								X			
DICUMAROL			X								
DIETHYLSTILBESTROL						X					
DIHYDROERGOCORNINE MESYLATE; DIHYDROERGOCRISTINE MESYLATE; DIHYDROERGOCRYPTINE MESYLATE				X		X		X	X		
DIMENHYDRINATE						X		X			
DINOPROSTONE						X					
DINOPROSTONE (PROSTAGLANDIN E-2)						X					
DIPHENADIONE	X										
DIPHENHYDRAMINE HYDROCHLORIDE								X	X		
DISULFIRAM								X			
DOPAMINE HYDROCHLORIDE						X				X	
DOXEPIIN HYDROCHLORIDE					X						
DOXYCYCLINE HYCLATE											
EPINEPHRINE; LIDOCAINE HYDROCHLORIDE	X				X	X		X	X		
ERYTHROMYCIN					X			X			
ERYTHROMYCIN ETHYLSUCCINATE								X			
ESTRADIOL VALERATE								X			
ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE										X	

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INGREDIENT(S)	SUPPLEMENT: 1										
ESTROGENS, CONJUGATED											
ESTROGENS, ESTERIFIED											
FENOPROFEN CALCIUM											
FENOPROFEN CALCIUM DIHYDRATE											
FLUORESCCEIN SODIUM											
FOLLICLE-STIMULATING HORMONE; LUTENIZING HORMONE											
FUROSEMIDE											
GENTAMICIN SULFATE											
GLUTETHIMIDE											
GRISEOFULVIN, ULTRAMICROCRYSTALLINE											
HALOTHANE											
HEPARIN CALCIUM											
HEPARIN SODIUM											
HEXACHLOROPHENE											
HEXOCYCLOTHIUM METHYLSULFATE											
HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE											
HYDROCHLOROTHIAZIDE											
HYDROCHLOROTHIAZIDE; RESERPINE											
HYDROCORTISONE											
HYDROCORTISONE SODIUM SUCCINATE											
HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE											
HYDROCORTISONE ACETATE; NEOMYCIN SULFATE											
HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE											
HYDROXYZINE HYDROCHLORIDE											
IBUPROFEN											
IMIPRAMINE HYDROCHLORIDE											
ISOPHARMINE HYDROCHLORIDE											
ISONIAZID											
ISOSORBIDE											
KETOCONAZOLE											
LIDOCAINE HYDROCHLORIDE											
LITHIUM CARBONATE											
LITHIUM CITRATE											
LORAZEPAM											
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE											
MANNITOL											
MANNITOL; SORBITOL											

APPROVED PRESCRIPTION DRUG PRODUCTS
CUMULATIVE INDEX

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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
MAPROTIline HYDROCHLORIDE	X				X						
MAZINDOL											X
MECLIZINE HYDROCHLORIDE				X							
MECLOCYCLINE SULFOSALICYLATE						X					
MEPERIDINE HYDROCHLORIDE		X									
METPROBAMATE					X			X		X	
METAPROTERENOL SULFATE		X									
METHADONE HYDROCHLORIDE					X					X	
METHAQUALONE											
METHYLPREDNISOLONE; NEOMYCIN SULFATE		X									
METHYLPREDNISOLONE ACETATE						X					
METHYLPREDNISOLONE SODIUM SUCCINATE							X				
METHYLTESTOSTERONE		X					X			X	
METOCLOPRAMIDE HYDROCHLORIDE					X						
METOLAZONE							X				
METRONIDAZOLE HYDROCHLORIDE				X							
MICONAZOLE NITRATE								X			
MOLINDONE HYDROCHLORIDE											X
NADOLOL						X					
NAPROXEN SODIUM		X									
NEOMYCIN SULFATE; PREDNISOLONE		X				X					
NEOMYCIN SULFATE; PREDNISOLONE ACETATE		X									
NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE		X									
NEOSTIGMINE BROMIDE			X								
NITROFURAZONE										X	
NORETHINDRONE						X					
NOVOBIOCIN CALCIUM	X										
NOVOBIOCIN SODIUM	X										
ORPHENADRINE CITRATE										X	
OXACILLIN SODIUM MONOHYDRATE											X
OXYTOCIN				X							
PENICILLIN G POTASSIUM	X										
PENICILLIN G PROCAINE	X										
PENICILLIN G SODIUM						X					
PENICILLIN V POTASSIUM	X										X
PENTOBARBITAL SODIUM						X					
PHENDIMETRAZINE TARTRATE			X			X				X	
PHENTERMINE HYDROCHLORIDE		X	X					X	X		X
PHENYTOIN SODIUM						X					
POTASSIUM CHLORIDE	X	X	X		X						
PRAZEPAM		X									
PREDNISOLONE									X		

INGREDIENT(S)	1	2	3	4	5	6	7	8	9	10	11
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM	X										
PREDNISOLONE	X										
PROMETHAZINE HYDROCHLORIDE			X								
PROPIOLACTONE											
PROPOXYPHENE HYDROCHLORIDE											
PYRIDOXINE HYDROCHLORIDE											
QUINIDINE SULFATE											
RAUMOLFIA SERPENTINA											
RESERPINE											
RESERPINE; TRICHLORMETHIAZIDE											
RITODRINE HYDROCHLORIDE											
SARALASIN ACETATE											
SCOPOLAMINE											
SCOPOLAMINE HYDROBROMIDE											
SECRETIN											
SODIUM AMINOSALICYLATE											
SODIUM CHLORIDE											
SOYBEAN OIL											
SPIRONOLACTONE											
SULFAMETHOXAZOLE; TRIMETHOPRIM											
SULFASALAZOLE											
SULFISOXAZOLE											
TECHNETIUM, TC-99M, MEDRONATE KIT											
TECHNETIUM, TC-99M, OXIDRONATE KIT											
TECHNETIUM, TC-99M, PENTETATE KIT											
TECHNETIUM, TC-99M, PYROPHOSPHATE KIT											
TEMASEPAM											
TESTOSTERONE ENANTHATE											
TETRACYCLINE HYDROCHLORIDE											
THEOPHYLLINE											
TOLBUTAMIDE											
TRIAMCINOLONE ACETONIDE											
TRIAMCINOLONE DIACETATE											
TRICHLORMETHIAZIDE											
TRISULFAPYRIMIDINES											
VITAMIN A											
MATER, FOR INJECTION											
XYLOSE, D-											
ZOMEPIRAC SODIUM											

SUPPLEMENT: 1

APPROVED PRESCRIPTION DRUG PRODUCTS

CUMULATIVE INDEX

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CURRENT STATUS - 'EXEMPT' (COURT ORDER)

> ADD > BARBIDONNA NO. 2 WALLACE LABS/C-W
> ADD > ATROPINE SULFATE; HYOSCYAMINE SULFATE; PHENOBARBITAL;
> ADD > SCOPOLAMINE HYDROBROMIDE

> ADD > BUTIBEL MCNEIL PHARM
> ADD > BELLADONNA EXTRACT; BUTABARBITAL SODIUM

> ADD > ISOSORBIDE DINITRATE DM GRAHAM LABS
> ADD > ISOSORBIDE DINITRATE

> ADD > PHENOBARBITAL & BELLADONNA PHARM ASSOCIATES
> ADD > ATROPINE SULFATE; HYOSCYAMINE HYDROBROMIDE; PHENOBARBITAL;
> ADD > SCOPOLAMINE HYDROBROMIDE

> ADD > SPALIX REID-PROVIDENT LABS
> ADD > ATROPINE SULFATE; HYOSCYAMINE SULFATE; PHENOBARBITAL;
> ADD > SCOPOLAMINE HYDROBROMIDE

TRADE NAME	SUPPLEMENT: 1	2	3	4	5	6	7	8	9	10	11
ACHROMYCIN		X									
BACITRACIN; NEOMYCIN; POLYMYXIN; HYDROCORTISONE ACETATE		X									
BARBIDONNA NO.2											
BENTYL W/ PHENOBARBITAL							X			X	
BIOZYME						X					
CANTIL W/ PHENOBARBITAL						X					
CHLOROMYCETIN HYDROCORTISONE		X									
CLISTIN EXPECTORANT						X					
COR-DICIN		X									
CORTISPORIN		X									
DACTIL							X				
DACTIL AND PHENOBARBITAL							X				
DARICON PB							X				
DICYCLOHIME HCL								X			
DIPYRIDAMOLE		X									
DONNATAL											
DYSPAS											
FLORINEF-S											
ISOSORBIDE DINITRATE											
LEVISIN PB							X				
LEVISIN W/ PHENOBARBITAL							X				
LIBRAX							X				
MEPROBAMATE W/ TRIDIHETHYL CHLORIDE							X				
MEIT-DERM W/ NEOMYCIN											
MILPATH-200											
MILPATH-400											
NEO-ARISTOCORT ACETONIDE											
NEO-DELTA-CORTEF											
NEO-DELTA-CORTEF											
NEO-MEDROL											
NEOQUESS											
NEOSONE											
NITROGLYCERIN											
NTSALIN; NEOMYCIN SULFATE, GRAMICIDIN, TRIAMCINOLONE ACETONIDE											
ORTHOCORT											
PARAFON FORTE											
PATIBAMATE-200											
PATIBAMATE-400											

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

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

11

TRADE NAME	SUPPLEMENT: 1	2	3	4	5	6	7	8	9	10	11
PATHILON W/ PHENOBARBITAL							X				X
PHENOBARBITAL & BELLADONNA		X									
POLY-PRED		X									
PREDMYCIN-P							X				
PRO-BANTHINE W/ PHENOBARBITAL											
ROBINUL-PH							X				
ROBINUL-PH FORTE							X				
SPALIX											X
SULFATHALIDINE			X								
T.C.M. 200							X				
T.C.M. 400							X				
TERRA-CORTIL		X									
TRAL GRADUMET					X						

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