

APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations



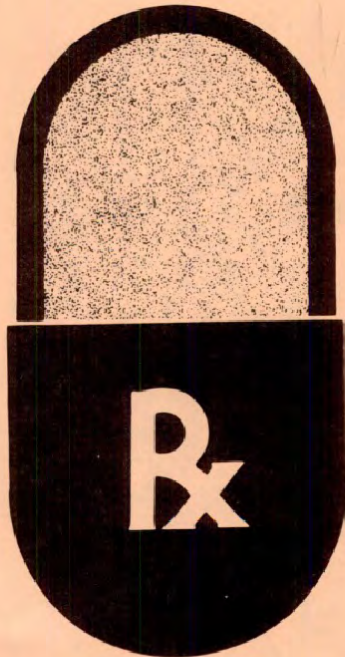
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SUPPLEMENT 9
WITH CUMULATIVE INDEX
1980 EDITION



**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.

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

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 9

1

AMINOPHYLLINE

INJECTABLE; INJECTION

AMINOPHYLLINE

>_ADD> AP NATCON CHEMICAL 25MG/ML

ASPIRIN; BUTALBITAL; CAFFEINE; PHENACETIN

TABLET; ORAL

BUTALBITAL W/ APC

>_ADD> AA PREMO PHARM LABS 200MG;50MG;40MG;130MG

>_ADD> CAPTOPRIL

>_ADD> TABLET; ORAL

>_ADD> CAPOTEN

>_ADD> ER SQUIBB AND SONS 25MG * 50MG * 100MG

CEFADROXIL MONOHYDRATE

>_ADD> POWDER FOR RECONSTITUTION; ORAL

>_ADD> ULTRACEF

>_ADD> BRISTOL LABS/BM EQ 125MG BASE/5ML *

>_ADD> EQ 250MG BASE/5ML *

>_ADD> EQ 500MG BASE/5ML

CHLOROTHIAZIDE

TABLET; ORAL

CHLOROTHIAZIDE

>_ADD> AB FEDERAL PHARMACAL 250MG

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION

CHLORPHENIRAMINE MALEATE

>_ADD> ~~CARTER-GLOGAU LABS~~
CARTER-GLOGAU

CHLORTHALIDONE

TABLET; ORAL

CHLORTHALIDONE

>_ADD> AB LEDERLE LABS/AM CYAN 25MG * 50MG

>_ADD> AB ZENITH LABS 50MG

DEXTROSE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

>_ADD> LIDOCAINE HCL 0.1% AND DEXTROSE 5% IN PLASTIC CONTAINER

>_ADD> TRAVENOL LABS 5GM/100ML;100MG/100ML

LIDOCAINE HCL 0.2% IN DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT LABS 158;0.151

>_ADD> AP 5GM/100ML;200MG/100ML

>_ADD> LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER

>_ADD> AP TRAVENOL LABS 5GM/100ML;200MG/100ML

LIDOCAINE HCL 0.4% IN DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT LABS 158;0.151

>_ADD> 5GM/100ML;400MG/100ML

DIHYDROERGOCORNINE MESYLATE; DIHYDROERGOCRISTINE MESYLATE;
DIHYDROERGOCRYPTINE MESYLATE

TABLET; SUBLINGUAL

ERGOLOID MESYLATES

>_ADD> AA DANBURY PHARMACAL 167 UGM;167 UGM;167 UGM; * 333 UGM;

>_ADD> AA 333 UGM;333 UGM

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> ADD > AN PHILIPS ROXANE LABS 0.1% * 0.2%
 > ADD > AN INT'L MEDICATION SYS 0.1% * 0.2%
 > ADD > AN DEY LABS 0.17%
 > ADD > AN ISOETHARINE HCL 0.1%

SOLUTION; INHALATION
 ISOETHARINE HYDROCHLORIDE

> ADD > AA ZENITH LABS 10MG * 25MG * 50MG
 > ADD > AA HYDROXYZINE HCL
 TABLET; ORAL

HYDROXYZINE HYDROCHLORIDE

> ADD > COOPERCARE
 /PINK-PINK-PINK/
 /PINK-PINK-PINK/
 LOTION; TOPICAL
 HYDROCORTISONE

> ADD > AB CHELSEA LABS 25MG; 50MG
 > ADD > AB BARR LABS 25MG; 50MG
 TABLET; ORAL
 SPIRONOLACTONE H/ HYDROCHLOROTHIAZIDE

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

> ADD > BP PREMO PHARM LABS 50MG; 125 UGM
 > ADD > BP HYDRO-SERP .50'
 > ADD > BP PREMO PHARM LABS 25MG; 125 UGM
 > ADD > BP HYDRO-SERP .25'
 TABLET; ORAL

HYDROCHLOROTHIAZIDE; RESERPINE

> ADD > AA PREMO PHARM LABS 500MG
 > ADD > AA SLUTETHIMIDE
 TABLET; ORAL

SLUTETHIMIDE

> ADD > SERONO LABS 75 UNITS/AMP; 75 UNITS/AMP
 > ADD > PERSONAL
 INJECTABLE; INJECTION

> ADD > FOLLICLE STIMULATING HORMONE; LUTEINIZING HORMONE

> ADD > BS BEECHAM LABS 300 UGM
 > ADD > BS MENEST
 > ADD > BS REID-PROVIDENT LABS 300 UGM
 > ADD > BS ESTRATAB
 TABLET; ORAL

ESTROGENS, ESTERIFIED

> ADD > AP LEMMON
 10 UGM/ML; 1%
 /PINK-PINK-PINK/
 /PINK-PINK-PINK/
 INJECTABLE; INJECTION
 LIDOCAINE HCL W/ EPINEPHRINE

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

> ADD > /PINK-PINK-PINK/
 > ADD > /PINK-PINK-PINK/
 > ADD > /PINK-PINK-PINK/
 CAPSULE; ORAL

DIPHENHYDRAMINE HYDROCHLORIDE

SUPPLEMENT NUMBER 9

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

>_ADD_> ORESTIN-30
>_ADD_> AA FERNDAL LABS 30MG
>_ADD_> QHA-MAST
>_ADD_> AA MM MAST 30MG

PREDNISOLONE

TABLET; ORAL

PREDNISOLONE
>_ADD_> BX MARSHALL PHARMACAL 5MG

PREDNISON

TABLET; ORAL

PREDNISON
>_ADD_> BX MARSHALL PHARMACAL 5MG

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL
//AA// ATLANTIC LABS //65MG//

SULFASALAZINE

TABLET; ORAL

SULFASALAZINE
>_ADD_> BP DANBURY PHARMACAL 500MG

SULFISOXAZOLE

TABLET; ORAL

SULFISOXAZOLE
//STAN LABS, PHARM//
>_ADD_> PUREPAC PHARM

THEOPHYLLINE

TABLET, CONTROLLED RELEASE; ORAL

>_ADD_> LABID
>_ADD_> BAYLOR LABS 250MG

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

TRIAMCINOLONE ACETONIDE
>_ADD_> AT CLAY-PARK LABS 0.025% M 0.1% M 0.5%

APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
CUMULATIVE INDEX

5

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8	9
CHLORTHALIDONE							X	X	X
CHYMOTRYPSIN						X			
CLORAZEPATE DIPOTASSIUM		X							
CLORAZEPATE MONOPOTASSIUM								X	
CORTISONE ACETATE; NEOMYCIN SULFATE		X							
CYCLOTHIAZIDE							X		
CYPROHEPTADINE HYDROCHLORIDE			X				X		
DACARBAZINE							X		
DANAZOL		X							
DEXAMETHASONE						X			
DEXAMETHASONE SODIUM PHOSPHATE	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									
DIATRIZOATE SODIUM			X						
DIAZEPAM								X	
DICUMAROL			X						
DIETHYLSTILBESTROL						X			
DIHYDROERGOCORNINE MESYLATE; DIHYDROERGOCRISTINE MESYLATE; DIHYDROERGOCRYPTINE MESYLATE				X		X		X	X
DIMENHYDRINATE								X	
DINOPROSTONE						X			
DINOPROSTONE (PROSTAGLANDIN E-2)						X			
DIPHENADIONE	X								
DIPHENHYDRAMINE HYDROCHLORIDE								X	X
DISULFIRAM								X	
DOXEFIN HYDROCHLORIDE						X			
DOXYCYCLINE HYCLATE					X				
EPINEPHRINE; LIDOCAINE HYDROCHLORIDE									
ERYTHROMYCIN		X				X		X	X

INGREDIENT(S)	1	2	3	4	5	6	7	8	9
ERYTHROMYCIN ETHYLSUCCINATE					X				
ESTRADIOL VALERATE					X				
ESTROGENS, ESTERIFIED					X				
FENOPROFEN CALCIUM					X				
FENOPROFEN CALCIUM DIHYDRATE					X				
FLUORESCCEIN SODIUM						X			
FOLLICLE STIMULATING HORMONE; LUTEINIZING HORMONE							X		
GENTAMICIN SULFATE					X				
GLUTEIMIDE					X				
GRISOFULVIN, ULTRAMICROCRYSTALLINE					X				
HALOTHANE					X				
HEPARIN CALCIUM					X				
HEPARIN SODIUM					X				
HEXACHLOROPHENE					X				
HEXOCYCLUM METHYLSULFATE					X				
HYDROCHLOROTHIAZIDE					X				
HYDROCHLOROTHIAZIDE; RESERPINE					X				
HYDROCHLOROTHIAZIDE; SPIRONOLACTONE					X				
HYDROCORTISONE					X				
HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE					X				
HYDROCORTISONE ACETATE; NEOMYCIN SULFATE					X				
HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE					X				
HYDROCORTISONE SODIUM SUCCINATE					X				
HYDROXYZINE HYDROCHLORIDE					X				
IMIPRAMINE HYDROCHLORIDE					X				
IOTHALAMATE SODIUM, I-125					X				
IRON DEXTRAN COMPLEX					X				
ISODETHARINE HYDROCHLORIDE					X				
ISONIAZID					X				
ISOSORBIDE					X				
LIDOCaine HYDROCHLORIDE					X				
LITHIUM CARBONATE					X				
LITHIUM CITRATE					X				
LORAZEPAM					X				
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE					X				

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE INDEX

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APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
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INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8	9
MANNITOL	X								
MANNITOL; SORBITOL							X		
MAPROTYLINE HYDROCHLORIDE					X				
MAZINDOL	X								
MECLOCYCLINE SULFOSALICYLATE				X					
MEPERIDINE HYDROCHLORIDE		X				X			
MEPROBAMATE					X			X	
METAPROTERENOL SULFATE		X							
METHAQUALONE					X				
METHYLPREDNISOLONE; NEOMYCIN SULFATE		X							
METHYLPREDNISOLONE ACETATE						X			
METHYLPREDNISOLONE SODIUM SUCCINATE							X		
METHYLTESTOSTERONE		X					X		
METOCLOPRAMIDE HYDROCHLORIDE					X				
METOLAZONE							X		
METRONIDAZOLE HYDROCHLORIDE				X					
MICONAZOLE NITRATE								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						
NORETHINDRONE						X			
NOVOBIOCIN CALCIUM	X								
NOVOBIOCIN SODIUM	X								
OXYTOCIN				X					
PENICILLIN G POTASSIUM	X								
PENICILLIN G PROCAINE	X								
PENICILLIN G SODIUM						X			
PENICILLIN V POTASSIUM	X								
PENTOBARBITAL SODIUM						X			
PHENDIMETRAZINE TARTRATE			X			X			
PHENTERMINE HYDROCHLORIDE		X	X					X	X
PHENYTOIN SODIUM						X			
POTASSIUM CHLORIDE	X	X	X		X				
PRAZEPAM		X							
PREDNISOLONE									X
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM		X							
PREDNISOLONE SODIUM PHOSPHATE			X						

INGREDIENT(S)									
PREDNISONE									
PROMETHAZINE HYDROCHLORIDE									
PROPIONPHENE HYDROCHLORIDE									
PYRIDOXINE HYDROCHLORIDE									
RESERPINE; TRICHLOREMETHIAZIDE									
RITODRINE HYDROCHLORIDE									
SCOPOLAMINE									
SCOPOLAMINE HYDROBROMIDE									
SECORABITAL SODIUM									
SODIUM AMINOSALICYLATE									
SOYBEAN OIL									
SPIRONOLACTONE									
SULFAMETHOXAZOLE									
SULFASALAZINE									
SULFISOXAZOLE									
TECHNETIUM, TC-99M, HEDRONATE KIT									
TECHNETIUM, TC-99M, OXIDRONATE KIT									
TEMASEPAM									
TESTOSTERONE ENANTHATE									
TETRAACETYLME HYDROCHLORIDE									
THEOPHYLLINE									
TOLBUTAMIDE									
TRIAMCINOLONE ACETONIDE									
TRIAMCINOLONE DIACETATE									
TRICHLOREMETHIAZIDE									
TRISULFAPYRIMIDINES									
VITAMIN A									
XYLOSE, D-									
ZOMEPIRAC SODIUM									
SUPPLEMENT: 1									
2									
3									
4									
5									
6									
7									
8									
9									

APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
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NO CHANGE

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TRADE NAME	1	2	3	4	5	6	7	8	9
ACHROMYCIN		X							
BACITRACIN; NEOMYCIN; POLYMYXIN; HYDROCORTISONE ACETATE		X							
BENTYL W/ PHENOBARBITAL						X			
BIOZYME						X			
CANTIL W/ PHENOBARBITAL						X			
CHLOROMYCETIN HYDROCORTISONE		X							
CLISTIN EXPECTORANT		X							
COR-O-TICIN		X				X			
CORTISPORIN		X							
DACTIL							X		
DACTIL AND PHENOBARBITAL							X		
DARICON PB							X		
DICYCLAMINE HCL							X		
DIPYRIDAMOLE									
DOMINANT		X							
DYSPAS									
FLORINEF-S							X		
LEVAIN PB									
LEVAIN W/ PHENOBARBITAL							X		
LIBRAX							X		
MEPROBAMATE W/ TRIDIHETHYL CHLORIDE							X		
METI-DERM W/ NEOMYCIN									
METIMID									
MILPAT-200		X							
MILPAT-400							X		
NEO-ARISTOCORT ACETONIDE									
NEO-DELTA-CORTEF									
NEO-MEDROL									
NEOQUESS									
NEOSONE									
NITROGLYCERIN									
NYSTATIN, NEOMYCIN SULFATE, GRAMICIDIN, TRIAMCINOLONE ACETONIDE									
OPHTHOCORT									
ORTHOXINE									
PARAFON FORTE									
PATIBAMATE-200									
PATIBAMATE-400									
PATHILON W/ PHENOBARBITAL									
POLY-PRED									

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

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
PREDMYCIN-P		X							
PRO-BANTHINE 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				

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