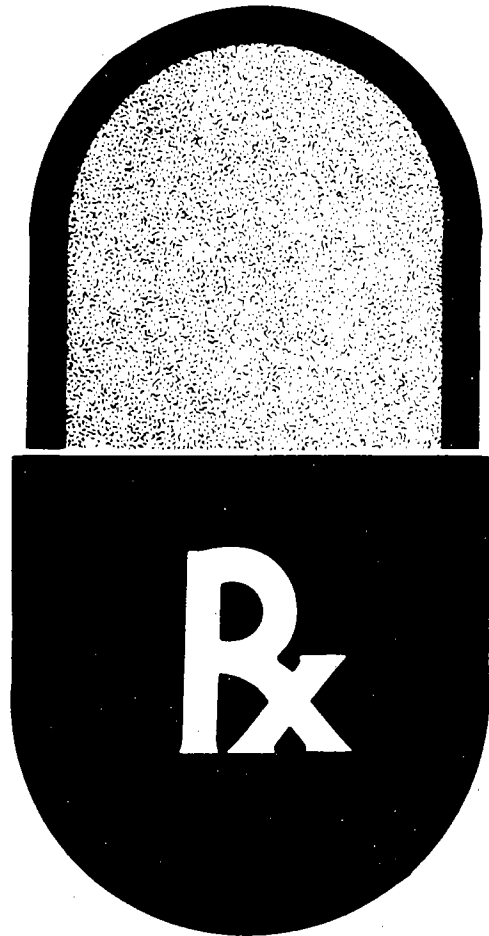
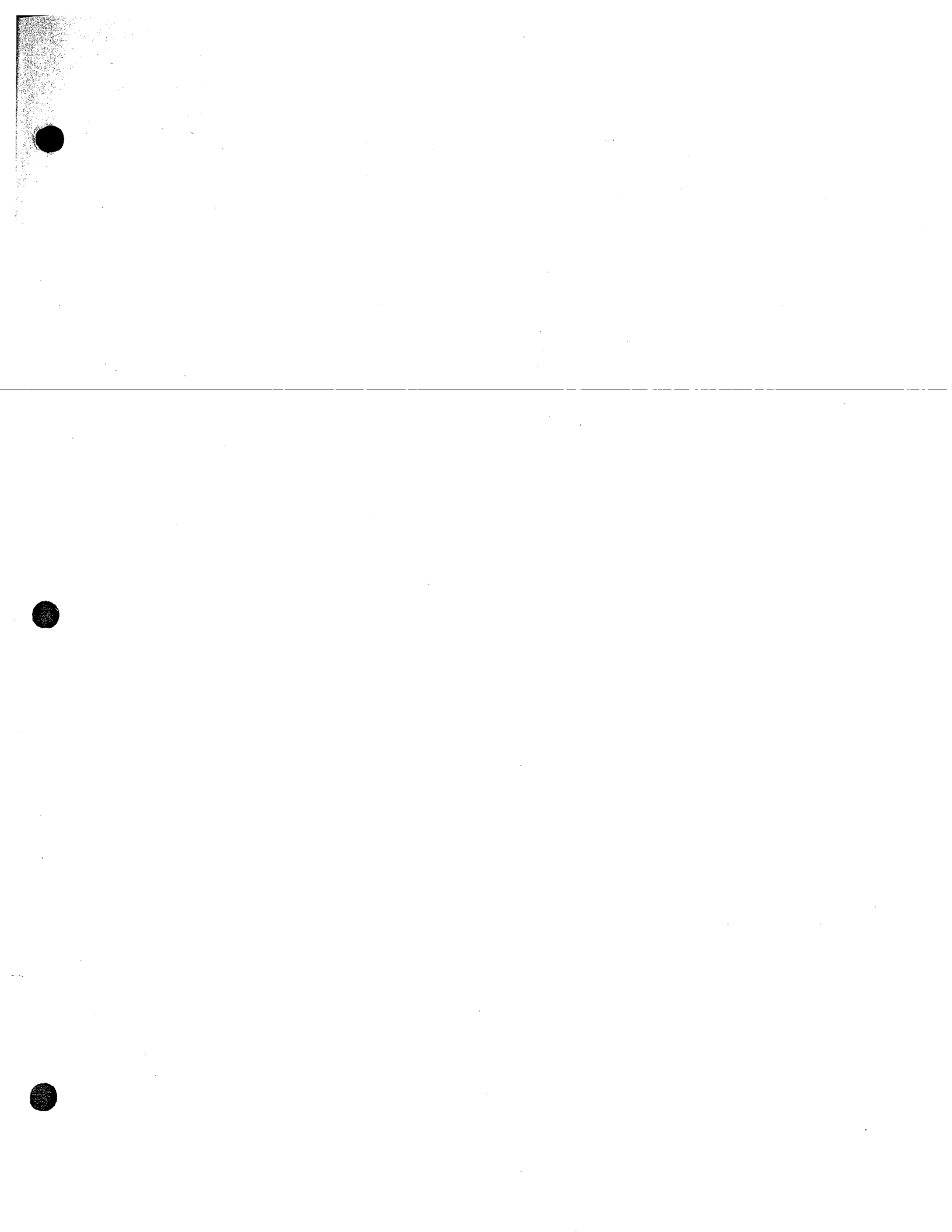


SUPPLEMENT 13
WITH CUMULATIVE INDEX
1980 EDITION



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

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



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%

ABBOTT LABS

~~15%~~

> ADD > 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 UGM;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;5GM/100ML;3GM/100ML;

> ADD > AP

600MG/100ML;310MG/100ML

CHLORTHALIDONE

TABLET; ORAL

CHLORTHALIDONE

> ADD > AB CHELSEA LABS 25MG * 50MG

> ADD > AB DANBURY PHARMACAL 25MG * 50MG

CORTISONE ACETATE

INJECTABLE; INJECTION

CORTISONE ACETATE

~~P-M PHARMACEUTICALS~~

> ADD > LEMMON

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 SUPPLEMENT NUMBER 13

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL

CYPROHEPTADINE HCL

> ADD > AA PREMO PHARM LABS 4MG

DIHYDROERGOCORNINE MESYLATE; DIHYDROERGOCRISTINE MESYLATE;
 DIHYDROERGOCRYPTINE MESYLATE

TABLET; SUBLINGUAL

DIHYDROERGOTOXINE METHANESULFONATE

AA KV PHARMCEUTICAL //167 UGM;167 UGM;167 UGM*/

ERGOLOID MESYLATES

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

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL

ERYTHROMYCIN ETHYLSUCCINATE

AB NATL PHARM MFG/BARRE EQ 200MG BASE/5ML *
 > ADD > AB EQ 400MG BASE/5ML

ESTROGENS, CONJUGATED

TABLET; ORAL

CONJUGATED ESTROGENS

> ADD > BS CHELSEA LABS 625 UGM * 1.25MG * 2.5MG

FUROSEMIDE

TABLET; ORAL

LASIX

> ADD > AB HOECHST-ROUSSEL 20MG * 40MG
 > ADD > FUROSEMIDE
 > ADD > AB MYLAN PHARMS 20MG * 40MG

GLYCOPYRROLATE

TABLET; ORAL

GLYCOPYRROLATE

> ADD > AA DANBURY PHARMACAL 1MG * 2MG

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

> ADD > HYDROCHLOROTHIAZIDE/HYDRALAZINE HCL/RESERPINE
 > ADD > BP DANBURY PHARMACAL 25MG;15MG;100 UGM

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

> ADD > AB PUREPAC PHARM 25MG * 50MG
AB REID-PROVIDENT LABS 25MG * 50MG/
 > ADD > ZIDE
 > ADD > AB REID-PROVIDENT LABS 50MG

HYDROCORTISONE

OINTMENT; TOPICAL

HYDROCORTISONE

AT SHAFFER-DAVIS LABS 0.5% * 1% /
 > ADD > AT THAMES PHARMACAL 1%

APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
SUPPLEMENT NUMBER 13

3

HYDROCORTISONE ACETATE

INJECTABLE; INJECTION
HYDROCORTISONE ACETATE
~~/P.H. PHARMACEUTICALS/~~
LEMMON

> ADD >

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL

> ADD > AP LYPHO-MED 25MG/ML * 50MG/ML
> ADD > AP NATCON CHEMICAL 25MG/ML * 50MG/ML

HYDROXYZINE PAMOATE

CAPSULE; ORAL
HYDROXYZINE PAMOATE

> ADD > AB BOLAR PHARM EQ 25MG HCL * EQ 50MG HCL *
> ADD > AB EQ 100MG HCL
VISTARIL
> ADD > AB PFIZER LABS EQ 25MG HCL * EQ 50MG HCL *
> ADD > AB EQ 100MG HCL

> ADD > IODOXAMATE MEGGLUMINE

> ADD > INJECTABLE; INJECTION
> ADD > CHOLOVUE
> ADD > ER SQUIBB AND SONS 9.9% * 40.3%

LEVOPROPOXYPHENE NAPSYLATE

CAPSULE; ORAL
NOVRAD
~~/ELI LILLY/~~
ELI LILLY INDSTRS/PR

> ADD >

LEVOPROPOXYPHENE NAPSYLATE

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

> ADD >

LIDOCAINE

OINTMENT; TOPICAL
LIDOCAINE
> ADD > AT THAMES PHARMACAL 5%

> ADD >

METHOXSALEN

> ADD > CAPSULE; ORAL
> ADD > OXSORALEN
> ADD > ELDER PHARMS 10MG

> ADD >

LOTION; TOPICAL
OXSORALEN
~~/PAUL E. ELDER/~~
ELDER PHARMS

> ADD >

METHYLDOPA

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

> ADD >

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
METRA
~~/D.F. #2/CHRONALLO/~~
ONEAL JONES&FELDMAN

> ADD >

APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
SUPPLEMENT NUMBER 13

POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

> ADD > AP LEMMON 2MEQ/ML

PREDNISOLONE ACETATE

INJECTABLE; INJECTION
PREDNISOLONE ACETATE
/P.M. PHARMACEUTICALS/
LEMMON

> ADD >

PROCAINAMIDE HYDROCHLORIDE

TABLET, CONTROLLED RELEASE; ORAL
PROCAN

> ADD > BC PARKE-DAVIS/W-L 500MG
> ADD > PRONESTYL-SR
> ADD > BC ER SQUIBB AND SONS 500MG

PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROCAINE HCL
/P.M. PHARMACEUTICALS/
LEMMON

> ADD >

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE
/REXALL DRUG/
REXALL

> ADD >

SULFAMETHIZOLE

SUSPENSION; ORAL

PROKLAR
/O.F. #2/CHROMALLOY/
ONEAL JONES&FELDMAN

> ADD >

TABLET; ORAL

MICROSUL
/O.F. #2/CHROMALLOY/
ONEAL JONES&FELDMAN

> ADD >

PROKLAR
/O.F. #2/CHROMALLOY/
ONEAL JONES&FELDMAN

> ADD >

SULFISOXAZOLE

TABLET; ORAL

SULFISOXAZOLE
/AB/ PREMO PHARM LABS /500MG/
> ADD > BP 500MG

TECHNETIUM, TC-99M, ETIDRONATE KIT

INJECTABLE; INJECTION
CINTICHEM TECHNETIUM 99M HEDSPA
/UNION CARBIDE/
CINTICHEM

> ADD >

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION
TESTOSTERONE CYPIONATE
/P.M. PHARMACEUTICALS/
LEMMON

> ADD >

APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
SUPPLEMENT NUMBER 13

5

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

TRIAMCINOLONE ACETONIDE

/SHAFFER-DAVIS LABS/

> ADD >

THAMES PHARMACAL

TRIAMCINOLONE DIACETATE

INJECTABLE; INJECTION

TRIAMCINOLONE DIACETATE

/D.H. PHARMACEUTICALS/

> ADD >

LEMMON

TRISULFAPYRIMIDINES

SUSPENSION; ORAL

SULFALOID

/D.J. #2/CHROMALLOY/

> ADD >

ONEAL JONES&FELDMAN

> ADD > VERAPAMIL HYDROCHLORIDE

> ADD > INJECTABLE; INJECTION

> ADD > ISOPTIN

> ADD > KNOLL PHARM

2.5MG/ML

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE INDEX

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8	9	10	11	12	13
ACETAMINOPHEN; CODEINE PHOSPHATE	X	X					X					X	X
ACETIC ACID, GLACIAL		X											X
ACETYLCHOLINE CHLORIDE						X							X
ALBUTEROL										X			
AMANTADINE HYDROCHLORIDE				X									
AMINO ACIDS				X								X	X
AMINOGLUTETHIMIDE			X										
AMINOPHYLLINE		X					X		X				X
AMITRIPTYLINE HYDROCHLORIDE	X			X									
AMOXAPINE		X											
AMOXICILLIN TRIHYDRATE	X												
AMPICILLIN/AMPICILLIN TRIHYDRATE						X							
ASPIRIN; BUTALBITAL; CAFFEINE; PHENACETIN									X				X
ASPIRIN; CAFFEINE; PHENACETIN; PROPOXYPHENE HYDROCHLORIDE			X										X
ATENOLOL													X
ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE		X			X			X				X	X
BACAMPICILLIN HYDROCHLORIDE							X						
BACITRACIN						X	X						
BETHANECHOL CHLORIDE												X	
BETHANIDINE SULFATE										X			
BISHYDROXYCOUMARIN			X										
BROMPHENIRAMINE MALEATE							X			X		X	
BUTABARBITAL SODIUM						X							
CAFFEINE; ERGOTAMINE TARTRATE				X						X			
CALCIFEDIOL	X												
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE			X										
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE			X										
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE HEXAHYDRATE; SODIUM ACETATE; SODIUM CHLORIDE		X											
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE													X
CAPTOPRIL									X				
CARBINOXAMINE MALEATE						X							
CEFADROXIL MONOHYDRATE					X				X				
CEPHALORIDINE					X								
CHLORAMPHENICOL; DESOXYRIBONUCLEASE; FIBRINOLYSIN			X										
CHLORAMPHENICOL; HYDROCORTISONE ACETATE		X											
CHLORDIAZEPOXIDE HYDROCHLORIDE							X						
CHLOROQUINE PHOSPHATE		X											
CHLOROTHIAZIDE									X	X			
CHLORPHENIRAMINE MALEATE				X					X	X		X	
CHLORPROMAZINE HYDROCHLORIDE	X			X	X	X	X						

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE INDEX

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8	9	10	11	12	13
EPINEPHRINE; LIDOCAINE HYDROCHLORIDE ERYTHROMYCIN ERYTHROMYCIN ETHYLSUCCINATE ESTRADIOL VALERATE ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE		X				X		X	X			X	X
ESTROGENS, CONJUGATED ESTROGENS, ESTERIFIED FENOPROFEN CALCIUM FENOPROFEN CALCIUM DIHYDRATE FLUORESCIEIN SODIUM					X				X	X		X	X
FLUOXYMESTERONE FOLIC ACID FOLLICLE-STIMULATING HORMONE; LUTENIZING HORMONE FUROSEMIDE GENTAMICIN SULFATE			X		X			X	X	X		X	X
GLUTETHIMIDE GLYCOPYRROLATE GRISEOFULVIN, ULTRAMICROCRYSTALLINE HALOTHANE HEPARIN CALCIUM			X	X	X				X				X
HEPARIN SODIUM HEXACHLOROPHENE HEXOCYCLIUM METHYLSULFATE HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE HYDROCHLOROTHIAZIDE			X		X	X	X			X		X	X
HYDROCHLOROTHIAZIDE; RESERPINE HYDROCHLOROTHIAZIDE; SPIRONOLACTONE HYDROCORTISONE HYDROCORTISONE ACETATE HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE				X			X		X X X		X	X	X X
HYDROCORTISONE ACETATE; NEOMYCIN SULFATE HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE HYDROCORTISONE SODIUM SUCCINATE HYDROXOCOBALAMIN HYDROXYZINE HYDROCHLORIDE	X X				X		X			X X X		X	X
HYDROXYZINE PAMOATE IBUPROFEN IMIPRAMINE HYDROCHLORIDE IODOXAMATE NEGLUMINE IOTHALAMATE SODIUM, I-125							X	X		X		X	X
IRON DEXTRAN COMPLEX ISOETHARINE HYDROCHLORIDE								X X	X		X		

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE INDEX

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8	9	10	11	12	13
NITROFURAZONE						X				X		X	
NORETHINDRONE													
NOVOBIOCIN CALCIUM	X												
NOVOBIOCIN SODIUM	X												
ORPHENADRINE CITRATE										X		X	
OXACILLIN SODIUM MONOHYDRATE											X		
OXYTOCIN				X									
OXYTOCIN CITRATE												X	
PENICILLIN G POTASSIUM	X												
PENICILLIN G PROCAINE	X												
PENICILLIN G SODIUM	X					X					X		
PENICILLIN V POTASSIUM						X							
PENTOBARBITAL SODIUM						X							
PHENDIMETRAZINE TARTRATE			X			X				X			X
PHTERMINE HYDROCHLORIDE		X	X					X	X		X		
PHENYTOIN SODIUM						X							
POTASSIUM CHLORIDE	X	X	X		X								X
PRAZEPAM		X											
PREDNISOLONE									X				
PREDNISOLONE ACETATE													X
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM		X										X	
PREDNISOLONE SODIUM PHOSPHATE			X										
PREDNISON			X						X	X		X	
PROCAINAMIDE HYDROCHLORIDE													X
PROCAINE HYDROCHLORIDE													X
PROMETHAZINE HYDROCHLORIDE				X				X		X			
PROPIOLACTONE										X			
PROPOXYPHENE HYDROCHLORIDE									X		X		
PSEUDOEPHEDRINE HYDROCHLORIDE												X	
PYRIDOXINE HYDROCHLORIDE		X				X							
QUINIDINE SULFATE											X		X
RAUWOLFIA SERPENTINA											X		
RESERPINE										X			
RESERPINE; TRICHLORMETHIAZIDE		X											
RITODRINE HYDROCHLORIDE	X				X								
SARALASIN ACETATE										X			
SCOPOLAMINE			X										
SCOPOLAMINE HYDROBROMIDE			X										
SECOBARBITAL SODIUM					X		X					X	
SECRETIN										X			
SODIUM AMINOSALICYLATE		X											
SODIUM CHLORIDE											X		

PRESCRIPTION DRUG PRODUCTS DEEMED APPROVED
PENDING RESOLUTION OF SAFETY OR EFFECTIVENESS ISSUES
SUPPLEMENT NUMBER 13

12

CURRENT STATUS - INEFFECTIVE

> ADD >
OXSORALEN //PAUL, B, ELDER//
ELDER PHARMS
/OXSORALEN //ELDER, PHARMS//
/METHOXSALEN/

CURRENT STATUS - 'EXEMPT' (COURT ORDER)

> ADD >
NEOQUESS //D, J, /CHROMALLOY//
ONEAL JONES&FELDMAN

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

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		
CANTIL W/ PHENOBARBITAL							X						
CHLOROMYCETIN HYDROCORTISONE		X											
CLISTIN EXPECTORANT						X							
COR-OTICIN		X											
CORTISPORIN		X											
DACTIL							X					X	
DACTIL AND PHENOBARBITAL							X					X	
DARICON PB							X						
DICYCLOMINE HCL								X					
DIPYRIDAMOLE	X	X											
DONNATAL					X								
DYSPAS						X							
FLORINEF-S		X											
ISOSORBIDE DINITRATE													
LEVSIN PB							X				X		
LEVSIN W/ PHENOBARBITAL							X						
LIBRAX							X						
MEPROBAMATE W/ TRIDIHEXETHYL CHLORIDE							X					X	
METI-DERM W/ NEOMYCIN			X										
METIMYO		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											
ORTHOXINE						X							
OXSORALEN													X
PARAFON FORTE						X							
PATHIBAMATE-200							X						

