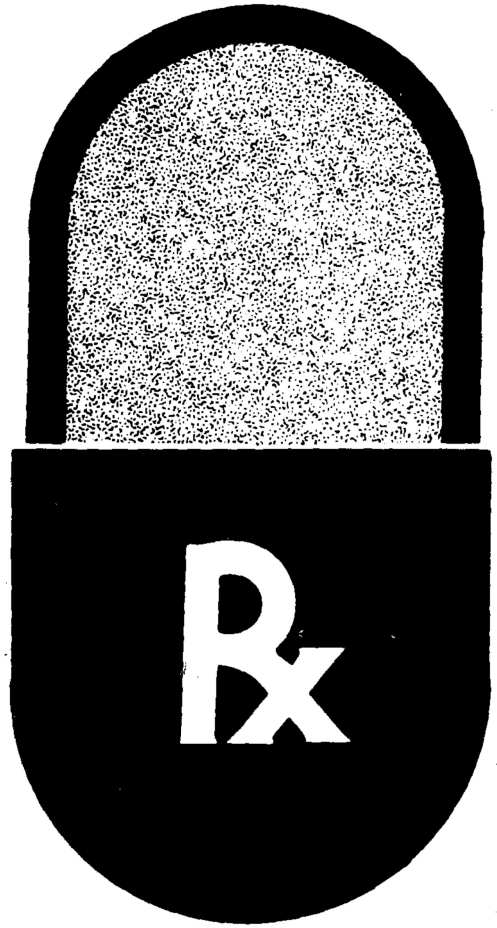
SUPPLEMENT 2
WITH CUMULATIVE INDEX
1980 EDITION



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 reverse 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 reverse 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 of 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

A description or explanation of items requiring special attention or clarification will appear in this section.

None - this supplement

> ADD > CORTISONE ACETATE; NEOMYCIN SULFATE

> ADD > OINTMENT; OPHTHALMIC
> ADD > NEOSONE
> ADD > UPJOHN 1.5%;EQ 3.5MG BASE/GM

DANAZOL

CAPSULE; ORAL
DANOCRINE
> ADD > WINTHROP L/STERLING 50MG * 100MG

> ADD > DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

> ADD > OINTMENT; OPHTHALMIC
> ADD > NEODECADRON
> ADD > MERCK SHARP & DOHME 0.05%;EQ 3.5MG BASE/GM

> ADD > SOLUTION/DROPS; OPHTHALMIC
> ADD > NEODECADRON
> ADD > MERCK SHARP & DOHME 0.1%;EQ 3.5MG BASE/ML

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE - IN PLASTIC

INJECTABLE; INJECTION
DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.15%
> ADD > AP AM MCGAW/AM HOSP 5GM/100ML;149.1MG/100ML;200MG/100ML
> ADD > AP TRAVENOL LABS 5GM/100ML;150MG/100ML;200MG/100ML
DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.224%
> ADD > AP AM MCGAW/AM HOSP 5GM/100ML;223.7MG/100ML;200MG/100ML
> ADD > AP TRAVENOL LABS 5GM/100ML;224MG/100ML;200MG/100ML
DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 0.3%
> ADD > AP AM MCGAW/AM HOSP 5GM/100ML;298.2MG/100ML;200MG/100ML
> ADD > AP TRAVENOL LABS 5GM/100ML;300MG/100ML;200MG/100ML

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE - IN PLASTIC

INJECTABLE; INJECTION
DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 0.15%
> ADD > AP AM MCGAW/AM HOSP 5GM/100ML;149.1MG/100ML;450MG/100ML
DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 0.224%
> ADD > AP AM MCGAW/AM HOSP 5GM/100ML;223.7MG/100ML;450MG/100ML
DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 0.3%
> ADD > AP AM MCGAW/AM HOSP 5GM/100ML;298.2MG/100ML;450MG/100ML

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
> ADD > OCTOCAINE
> ADD > AP NOVOCOL CHEM MFG 10 UGM/ML;2% * 20 UGM/ML;2%

> ADD > HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

> ADD > SUSPENSION/DROPS; OPHTHALMIC
> ADD > CORTISPORIN
> ADD > BURROUGHS WELLCOME 1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML

> ADD > HYDROCORTISONE ACETATE; NEOMYCIN SULFATE

> ADD > OINTMENT; OPHTHALMIC
> ADD > NEO-CORTEF
> ADD > UPJOHN 0.5%;EQ 3.5MG BASE/GM *
> ADD > 1.5%;EQ 3.5MG BASE/GM

> ADD > SUSPENSION/DROPS; OPHTHALMIC
> ADD > COR-OTICIN
> ADD > AT MAURRY BIOLOGICAL 1.5%;EQ 3.5MG BASE/ML

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL
ACETAMINOPHEN W/ CODEINE PHOSPHATE
AA CORD LABS 300MG;60MG
>ADD > ACETAMINOPHEN AND CODEINE PHOSPHATE
>ADD > AA CORD LABS 300MG;30MG * 300MG;60MG

ACETIC ACID, GLACIAL

SOLUTION; OTIC
>ADD > ACETIC ACID
>ADD > AT HEUN/NORWOOD LABS 2%
ORLEX
AT HEUN-NORWOOD LABS 2%

AMINOPHYLLINE

LIQUID; ORAL
SOMOPHYLLIN
>ADD > AA FISONS 105MG/5ML
>ADD > SOMOPHYLLIN-DF
>ADD > AA FISONS 105MG/5ML

>ADD > AMOXAPINE

>ADD > TABLET; ORAL
>ADD > ASENDIN
>ADD > LEDERLE LABS/AM CYAN 25MG * 50MG * 100MG * 150MG

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE
AA HALSEY DRUG 25 UGM;2.5MG

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
>ADD > LOW-QUEL
>ADD > AA HALSEY DRUG 25 UGM;2.5MG

>ADD > CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE HEXAHYDRATE;
>ADD > SODIUM ACETATE; SODIUM CHLORIDE

>ADD > INJECTABLE; INJECTION
>ADD > INPERSOL W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
>ADD > ABBOTT LABS 25.7MG/100ML;1.5GM/100ML;
>ADD > 15.2MG/100ML;271MG/100ML;
>ADD > 562MG/100ML
>ADD > INPERSOL W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
>ADD > ABBOTT LABS 25.7MG/100ML;4.25GM/100ML;
>ADD > 15.2MG/100ML;271MG/100ML;
>ADD > 562MG/100ML

>ADD > CHLORAMPHENICOL; HYDROCORTISONE ACETATE

>ADD > SUSPENSION/DROPS; OPHTHALMIC
>ADD > CHLOROMYCETIN HYDROCORTISONE
>ADD > PARKE-DAVIS/W-L 2.5MG/ML;5MG/ML

CHLOROQUINE PHOSPHATE

TABLET; ORAL
CHLOROQUINE PHOSPHATE
>ADD > AA MD PHARM EQ 150MG BASE

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL
>ADD > TRANXENE
>ADD > ABBOTT LABS 3.75MG * 7.5MG * 15MG

APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
SUPPLEMENT NUMBER 2

> ADD > HYDROCORTISONE ACETATE; NEOMYCIN SULFATE

> ADD > SUSPENSION/DROPS; OPHTHALMIC
> ADD > NEO-CORTEF
> ADD > AT UPJOHN 1.5%;EQ 3.5MG BASE/ML
> ADD > 0.5%;EQ 3.5MG BASE/ML

> ADD > HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE

> ADD > SUSPENSION/DROPS; OPHTHALMIC
> ADD > TERRA-CORTRIL
> ADD > PFIZER LABS 15MG/ML;EQ 5MG BASE/ML

ISONIAZID

TABLET; ORAL
SUPERCIDIN
AA VITARINE/WEST CHEM 100MG
ISONIAZID
> ADD > AA VITARINE/WEST CHEM 100MG * 300MG

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL
> ADD > AP ABBOTT LABS 2%

LORAZEPAM

TABLET; ORAL
ATIVAN
WYETH LABS/AMHO 500 UGM * 1MG * 2MG * 4MG

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL
MEPERIDINE HCL
AA HALSEY DRUG 50MG * 100MG
> ADD > PETHADOL
> ADD > AA HALSEY DRUG 50MG * 100MG

METAPROTERENOL SULFATE

> ADD > SOLUTION; INHALATION
> ADD > ALUPENT
> ADD > BOEHRINGER INGELHEIM 5%

> ADD > METHYLPREDNISOLONE; NEOMYCIN SULFATE

> ADD > OINTMENT; OPHTHALMIC
> ADD > NEO-MEDROL
> ADD > UPJOHN 0.1%;EQ 3.5MG BASE/GM

METHYLTESTOSTERONE

TABLET; ORAL
NEO-HOMBREOL M
BP ORGANON/AKZONA 10MG * 25MG

NAPROXEN SODIUM

> ADD > TABLET; ORAL
> ADD > ANAPROX
> ADD > SYNTEX P R 275MG

> ADD > NEOMYCIN SULFATE; PREDNISOLONE

> ADD > SOLUTION; OPHTHALMIC
> ADD > NEO-DELTEF
> ADD > UPJOHN EQ 3.5MG BASE/ML;0.2%

> ADD > NEOMYCIN SULFATE; PREDNISOLONE ACETATE

> ADD > OINTMENT; OPHTHALMIC
> ADD > NEO-DELTA-CORTEF
> ADD > UPJOHN EQ 3.5MG BASE/GM;0.25% *
> ADD > EQ 3.5MG BASE/GM;0.5%

> ADD > SUSPENSION; OPHTHALMIC
> ADD > NEO-DELTA-CORTEF
> ADD > UPJOHN EQ 3.5MG BASE/ML;0.25%

> ADD > NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE

> ADD > OINTMENT; OPHTHALMIC
> ADD > NEO-HYDELTRASOL
> ADD > MERCK SHARP & DOHME EQ 3.5MG BASE/GM;0.25%

> ADD > SOLUTION; OPHTHALMIC
> ADD > NEO-HYDELTRASOL
> ADD > MERCK SHARP & DOHME EQ 3.5MG BASE/ML;0.5%

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
PHENTERMINE HCL
> ADD > AA CAMALL 30MG
> ADD > 15MG

POTASSIUM CHLORIDE

> ADD > CAPSULE, CONTROLLED RELEASE; ORAL
> ADD > TIMKAP
> ADD > BERLEX LABS/S-AG 600MG

TABLET, CONTROLLED RELEASE; ORAL
> ADD > KAON CL-10
> ADD > BC WARREN-TEED/ADRIA 750MG

PRAZEPAM

TABLET; ORAL
VERSTRAN
> ADD > CENTRAX

> ADD > PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

> ADD > SUSPENSION/DROPS; OPHTHALMIC
> ADD > METIMYD
> ADD > SCHERING 5MG/ML;100MG/ML

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION
PYRIDOXINE HCL
CARTER GLOGAU LABS
> ADD > CARTER-GLOGAU

RESERPINE; TRICHLORMETHIAZIDE

TABLET; ORAL
METATENSIN 2
> ADD > METATENSIN #2
METATENSIN 4
> ADD > METATENSIN #4

SODIUM AMINOSALICYLATE

TABLET; ORAL

		SODIUM P.A.S.	
	BP	LANNETT	690MG
> ADD >		SODIUM P.A.S.	
> ADD >	AB	LANNETT	500MG

SULFISOXAZOLE

TABLET; ORAL

		STANSIN	
		SULFISOXAZOLE	
> ADD >	AB	STANLABS PHARM	500MG

DRUG PRODUCT LIST
CUMULATIVE INDEX

	SUPPLEMENT: 1	2
ACETAMINOPHEN; CODEINE PHOSPHATE	X	X
ACETIC ACID, GLACIAL		X
AMINOPHYLLINE		X
AMITRIPTYLINE HYDROCHLORIDE	X	
AMOXAPINE		X
AMOXICILLIN TRIHYDRATE	X	
ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE		X
CALCIFEDIOL	X	
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE HEXAHYDRATE; SODIUM ACETATE; SODIUM CHLORIDE		X
CHLORAMPHENICOL; HYDROCORTISONE ACETATE		X
CHLOROQUINE PHOSPHATE		X
CHLORPROMAZINE HYDROCHLORIDE	X	
CLORAZEPATE DIPOTASSIUM		X
CORTISONE ACETATE; NEOMYCIN SULFATE		X
DANAZOL		X
DEXAMETHASONE SODIUM PHOSPHATE	X	
DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE		X
DEXTROAMPHETAMINE SULFATE	X	
DEXTROSE	X	

	SUPPLEMENT: 1	2
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	X	
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE - IN PLASTIC		X
DIPHENADIONE	X	
EPINEPHRINE; LIDOCAINE HYDROCHLORIDE		X
HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE		X
HYDROCORTISONE ACETATE; NEOMYCIN SULFATE		X
HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE		X
ISONIAZID	X	X
LIDOCAINE HYDROCHLORIDE		X
LORAZEPAM		X
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	X	
MANNITOL	X	
MAZINDOL	X	
MEPERIDINE HYDROCHLORIDE		X
METAPROTERENOL SULFATE		X
METHYLPREDNISOLONE; NEOMYCIN SULFATE		X
METHYLTESTOSTERONE		X
NAPROXEN SODIUM		X

	SUPPLEMENT: 1	2
NEOMYCIN SULFATE; PREDNISOLONE		X
NEOMYCIN SULFATE; PREDNISOLONE ACETATE		X
NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE		X
NOVOBIOCIN CALCIUM	X	
NOVOBIOCIN SODIUM	X	
PENICILLIN G POTASSIUM	X	
PENICILLIN G PROCAINE	X	
PENICILLIN V POTASSIUM	X	
PHENTERMINE HYDROCHLORIDE		X
POTASSIUM CHLORIDE	X	X
PRAZEPAM		X
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM		X
PYRIDOXINE HYDROCHLORIDE		X
RESERPINE; TRICHLORMETHIAZIDE		X
RITODRINE HYDROCHLORIDE	X	
SODIUM AMINOSALICYLATE		X
SULFAMETHOXAZOLE	X	
SULFISOXAZOLE		X
THEOPHYLLINE	X	

	SUPPLEMENT: 1	2
TRICHLORMETHIAZIDE	X	
TRISULFAPYRIMADINES	X	

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

	SUPPLEMENT: 1	2
ACHROMYCIN		X
BACITRACIN; NEOMYCIN; POLYMYXIN; HYDROCORTISONE ACETATE		X
CHLOROMYCETIN HYDROCORTISONE		X
COR-OTICIN		X
CORTISPORIN		X
DIPYRIDAMOLE	X	X
FLORINEF-S		X
METIMYD		X
NEO-ARISTOCORT ACETONIDE		X
NEO-DELTA-CORTEF		X
NEO-DELTEF		X
NEO-MEDROL		X
NEOSONE		X
OPHTHOCORT		X
POLY-PRED		X
PREDMYCIN-P		X
TERRA-CORTRIL		X

PRESCRIPTION DRUG PRODUCTS DEEMED APPROVED
PENDING RESOLUTION OF SAFETY OR EFFECTIVENESS ISSUES
SUPPLEMENT NUMBER 2

CURRENT STATUS - INEFFECTIVE

>ADD> BACITRACIN; NEOMYCIN; POLYMYXIN; HYDROCORTISONE ACETATE
KASCO LABS INC
>ADD> BYK-GULDEN
>ADD> BACITRACIN; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE;
>ADD> POLYMYXIN B SULFATE

>ADD> CORTISPORIN BURROUGHS WELLCOME
>ADD> BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE;
>ADD> POLYMYXIN B SULFATE

>ADD> OPHTHOCORT PARKE-DAVIS/W-L
>ADD> CHLORAMPHENICOL; HYDROCORTISONE ACETATE; POLYMYXIN B SULFATE

>ADD> POLY-PRED ALLERGAN PHARMS
>ADD> NEOMYCIN SULFATE; POLYMYXIN B SULFATE; PREDNISOLONE ACETATE

CURRENT STATUS - 'EXEMPT' (COURT ORDER)

ACHROMYCIN LEDERLE LABS/AM CYAN
HYDROCORTISONE; TETRACYCLINE HYDROCHLORIDE

CHLOROMYCETIN HYDROCORTISONE PARKE-DAVIS/W-L
CHLORAMPHENICOL; HYDROCORTISONE ACETATE

COR-OTICIN MAURRY BIOLOGICAL
HYDROCORTISONE ACETATE; NEOMYCIN SULFATE

CORTISPORIN BURROUGHS WELLCOME
HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

>ADD> DIPYRIDAMOLE BARR LABS
>ADD> DIPYRIDAMOLE

CURRENT STATUS - 'EXEMPT' (COURT ORDER)

FLORINEF-S ER SQUIBB AND SONS
FLUDROCORTISONE HEMISUCCINATE; NEOMYCIN SULFATE

METIMYD SCHERING
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

NEO-ARISTOCORT ACETONIDE LEDERLE LABS/AM CYAN
NEOMYCIN SULFATE; TRIAMCINOLONE ACETONIDE

NEO-DELTA-CORTEF UPJOHN
NEOMYCIN SULFATE; PREDNISOLONE ACETATE

NEO-DELTEF UPJOHN
NEOMYCIN SULFATE; PREDNISOLONE

NEO-MEDROL UPJOHN
METHYLPREDNISOLONE; NEOMYCIN SULFATE

NEOSONE UPJOHN
CORTISONE ACETATE; NEOMYCIN SULFATE

OPHTHOCORT PARKE-DAVIS/W-L
CHLORAMPHENICOL; HYDROCORTISONE ACETATE; POLYMYXIN B SULFATE

PREDMYCIN-P
>ADD> POLY-PRED

POLY-PRED ALLERGAN PHARMS
NEOMYCIN SULFATE; POLYMYXIN B SULFATE; PREDNISOLONE ACETATE

TERRA-CORTRIL PFIZER LABS
HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE