

APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations



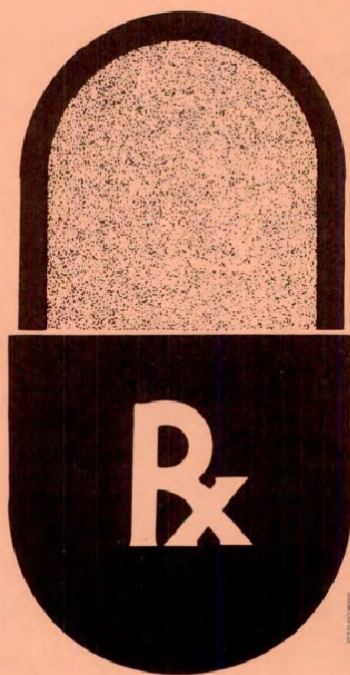
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HE 20.4210 : 980 / suppl. 2

444-R-1

SUPPLEMENT 2
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 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

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN W/ CODEINE PHOSPHATE

> ADD > AA CORO LABS 300MG:60MG
 > ADD > AA ACETAMINOPHEN AND CODEINE PHOSPHATE
 > ADD > AA CORO LABS 300MG:30MG * 300MG:60MG

ACETIC ACID, GLACIAL

SOLUTION; OTIC

> ADD > AT ACETIC ACID
 > ADD > AT HEUN/NORMOOD LABS 22
ORLEX
AT HEUN-NORMOOD LABS 22

AMINOPHYLLINE

LIQUID; ORAL

AMINOPHYLLINE

> ADD > AA FISONS 100MG/5ML
 > ADD > AA AMINOPHYLLINE-DF
 > ADD > AA FISONS 100MG/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-DUEL
 > 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/M-L 2.5MG/ML;5MG/ML

CHLOROQUINE PHOSPHATE

TABLET; ORAL

CHLOROQUINE PHOSPHATE

> ADD > AA MO PHARM EQ 150MG BASE

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL

> ADD > TRANXENE
 > ADD > ABBOTT LABS 5.75MG * 7.5MG * 15MG

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> 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-CORTIL

> 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 > AF ABBOTT LABS 2%

LORAZEPAM

TABLET; ORAL

ATIVAN

MYETH LABS/APHO 500 UGM * 1MG * 2MG * 4MG

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL

MEPERIDINE HCL

AA HALSEY DRUG 50MG * 100MG

> ADD > PETHADDOL

> 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-HOMBREDOL M

BP ORGANON/AKZONA 10MG * 25MG

NAPROXEN SODIUM

> ADD > TABLET; ORAL

> ADD > ANAPROX

> ADD > SYNTEX P R 275MG

SODIUM AMINOSALICYLATE

TABLET; ORAL

SODIUM P.A.S.

BP

LANNETT

690MG

> ADD >

SODIUM P.A.S.

> ADD > **AB**

LANNETT

500MG

SULFISOXAZOLE

TABLET; ORAL

STANSTIN

SULFISOXAZOLE

> ADD > **AB**

STANLABS PHARM

500MG

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APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE INDEX

1

	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	

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X	NAFROXEN SODIUM
X	METHYLTESTOSTERONE
X	METHYLPREDNISOLONE; MECOMYCIN SULFATE
X	METAPROTERENOL SULFATE
X	MEPERIDINE HYDROCHLORIDE
X	MAZINDOL
X	MAANNITOL
X	MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE
X	LORAZEPAM
X	LIDOCAINE HYDROCHLORIDE
X	ISONIAZID
X	HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE
X	HYDROCORTISONE ACETATE; MECOMYCIN SULFATE
X	HYDROCORTISONE; MECOMYCIN SULFATE; POLYMYXIN B SULFATE
X	EPINEPHRINE; LIDOCAINE HYDROCHLORIDE
X	DIPHENADOLINE
X	DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE - IN PLASTIC
X	DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE
2	SUPPLEMENT: 1

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE INDEX

3

	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	
PENTERMINE 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	

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TRISULFAPYRIMIDINES

X

TRICHLORMETHIAZIDE

X

SUPPLEMENT: 1 2

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APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
CUMULATIVE INDEX
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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

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

1

	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
METIMID		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

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