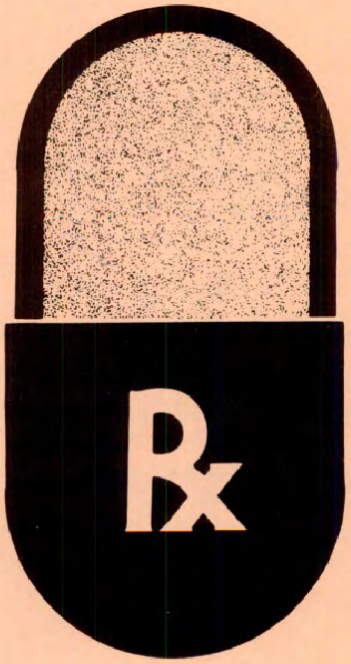
APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

FDA data supplied by DrugPatentWatch.com

SUPPLEMENT 6
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>.

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Washington, D.C. 20402

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

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

None - this supplement

ACETYLCHOLINE CHLORIDE

SOLUTION/DROPS; OPHTHALMIC
MIOCHOL
SMITH MILLER PATCH
>ADD> COOPERVISION PHARMS

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL
AMPICILLIN TRIHYDRATE
AB FEDERAL PHARMACAL EQ 125MG BASE/5ML *
AB EQ 250MG BASE/5ML

BACITRACIN

INJECTABLE; INJECTION
BACITRACIN
AP BRAE LABS/IMC 10,000 UNITS/VIAL *
AP 50,000 UNITS/VIAL

BUTABARBITAL SODIUM

TABLET; ORAL
SODIUM BUTABARBITAL
AA VALE CHEMICAL 15MG * 30MG

CARBINOXAMINE MALEATE

ELIXIR; ORAL
CLISTIN
MCNEIL LABS
>ADD> MCNEIL PHARM

CARBINOXAMINE MALEATE

TABLET; ORAL
CLISTIN
MCNEIL LABS
>ADD> MCNEIL PHARM

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL
CHLORPROMAZINE HCL
BP CORD LABS 10MG * 25MG * 50MG * 100MG * 200MG
>ADD> SONAZINE
>ADD> BP CORD LABS 10MG * 25MG * 50MG * 100MG * 200MG

CHYMOTRYPSIN

POWDER FOR RECONSTITUTION; OPHTHALMIC
CATARASE
SMITH MILLER PATCH
>ADD> COOPERVISION PHARMS

DEXAMETHASONE

TABLET; ORAL
DEXAMETHASONE
BP LEDERLE LABS/AM CYAN 250 UGM * 500 UGM * 750 UGM * 1.5MG

DIETHYLSTILBESTROL

TABLET, ENTERIC COATED; ORAL
DIETHYLSTILBESTROL
BE ICN PHARMS 5MG

DIHYDROERGOCORNINE MESYLATE; DIHYDROERGOCRISTINE MESYLATE; DIHYDROERGOCRYPTINE MESYLATE

>ADD> LIQUID; ORAL
>ADD> HYDERGINE
>ADD> SANDOZ PHARMS 333 UGM/ML;333 UGM/ML;333 UGM/ML

TABLET; SUBLINGUAL
DIHYDROERGOTOXINE METHANESULFONATE
>ADD> AA KV PHARMACEUTICAL 167 UGM;167 UGM;167 UGM * 333 UGM;
>ADD> AA 333 UGM;333 UGM

DINOPROSTONE (PROSTAGLANDIN E-2)
>ADD> DINOPROSTONE

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
SINEQUAN
>ADD> PFIZER LABS EQ 150MG BASE

ERYTHROMYCIN

>ADD> SOLUTION; TOPICAL
>ADD> STATICIN
>ADD> WESTWOOD PHARMS 1.5%

FLUORESCEIN SODIUM

INJECTABLE; INJECTION
FUNDUSCEIN-25
SMITH MILLER PATCH
>ADD> COOPERVISION

HEPARIN SODIUM

INJECTABLE; INJECTION
SODIUM HEPARIN
AP LYPHO-MED 1,000 UNITS/ML * 5,000 UNITS/ML *
AP 10,000 UNITS/ML * 20,000 UNITS/ML
HEPARIN SODIUM
>ADD> AP LYPHO-MED 20,000 UNITS/ML

HEXACHLOROPHENE

AEROSOL; TOPICAL
>ADD> TURGEX
>ADD> XTTRIUM LABS 3%

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL
>ADD> AP SOLOPAK/MPL 25MG/ML * 50MG/ML

LITHIUM CARBONATE

TABLET; ORAL
LITHANE
DOME LABS/MILES LABS
>ADD> MILES PHARMS

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
MEPERIDINE HCL
AP VITARINE/WEST CHEM 50MG/ML * 100MG/ML

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION
M-PREDROL
>ADD > BP BEL-MAR LABS 80MG/ML

NADOLOL

TABLET; ORAL
CORGARD
>ADD > ER SQUIBB AND SONS 160MG

NEOMYCIN SULFATE; PREDNISOLONE
SOLUTION/DROPS; OPHTHALMIC
NEO-DELTEF
UPJOHN EQ 3.5MG BASE/ML;0.2%

NORETHINDRONE

TABLET; ORAL
NORLUTIN
PARKE-DAVIS/W-L
>ADD > PARKE-DAVIS/W-L PR

PENICILLIN G SODIUM

INJECTABLE; INJECTION
PENICILLIN G SODIUM
>ADD > AP JOHN D COPANOS 5,000,000 UNITS/VIAL
>ADD > AP SQUIBB/ITALY 5,000,000 UNITS/VIAL

PENTOBARBITAL SODIUM

CAPSULE; ORAL
SODIUM PENTOBARBITAL
AA WEST-WARD 100MG

PHENDIMETRAZINE TARTRATE

CAPSULE; ORAL
PHENDIMETRAZINE TARTRATE
>ADD > AA LEMMON PHARMACAL 35MG

PHENYTOIN SODIUM

INJECTABLE; INJECTION
PHENYTOIN SODIUM
AP VITARINE/WEST CHEM 50MG/ML

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION
PYRIDOXINE HCL
AP VITARINE/WEST CHEM 100MG/ML

SOYBEAN OIL

INJECTABLE; INJECTION
>ADD > INTRALIPID 20%
>ADD > CUTTER-VITRUM 20%

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE
>_ADD_> AB BARR LABS 25MG

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL
AB TOWNE PAULSEN 250MG

TABLET; ORAL
TETRACYCLINE HCL
AB HYLAN PHARMS 250MG * 500MG

VITAMIN A

CAPSULE; ORAL
VITAMIN A
AA ARCUM PHARM 50,000 UNITS

XYLOSE, D-

POWDER; ORAL
XYLO-PFAN
PFANSTIEHL LABS
>_ADD_> ADRIA LABS

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6
ACETAMINOPHEN; CODEINE PHOSPHATE	X	X				
ACETIC ACID, GLACIAL		X				
ACETYLCHOLINE CHLORIDE						X
AMANTADINE HYDROCHLORIDE				X		
AMINO ACIDS				X		
AMINOGLUTETHIMIDE			X			
AMINOPHYLLINE		X				
AMITRIPTYLINE HYDROCHLORIDE	X			X		
AMOXAPINE		X				
AMOXICILLIN TRIHYDRATE	X					
AMPICILLIN/AMPICILLIN TRIHYDRATE						X
ASPIRIN; CAFFEINE; PHENACETIN; PROPOXYPHENE HYDROCHLORIDE			X			
ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE		X			X	
BACITRACIN						X
BISHYDROXYCOUMARIN			X			
BUTABARBITAL SODIUM						X
CAFFEINE; ERGOTAMINE TARTRATE				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				
CARBINOXAMINE MALEATE						X
CEFADROXIL MONOHYDRATE					X	
CEPHALORIDINE					X	
CHLORAMPHENICOL; DESOXYRIBONUCLEASE; FIBRINOLYSIN			X			

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6
CHLORAMPHENICOL; HYDROCORTISONE ACETATE		X				
CHLOROQUINE PHOSPHATE		X				
CHLORPHENIRAMINE MALEATE				X		
CHLORPROMAZINE HYDROCHLORIDE	X			X	X	X
CHLORPROPAMIDE			X	X		
CHYMOTRYPSIN						X
CLORAZEPATE DIPOTASSIUM		X				
CORTISONE ACETATE; NEOMYCIN SULFATE		X				
CYPROHEPTADINE HYDROCHLORIDE			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	
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				
DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM			X			
DIATRIZOATE SODIUM			X			
DICUMAROL			X			
DIETHYLSTILBESTROL						X

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6
DIHYDROERGOCORNINE MESYLATE; DIHYDROERGOCRISTINE MESYLATE; DIHYDROERGOCRYPTINE MESYLATE				X		X
DINOPROSTONE						X
DINOPROSTONE(PROSTAGLANDIN E-2)						X
DIPHENADIONE	X					
DOXEPIN HYDROCHLORIDE						X
DOXYCYCLINE HYCLATE					X	
EPINEPHRINE; LIDOCAINE HYDROCHLORIDE		X				
ERYTHROMYCIN						X
ERYTHROMYCIN ETHYLSUCCINATE					X	
FENOPROFEN CALCIUM					X	
FENOPROFEN CALCIUM DIHYDRATE			X		X	
FLUORESCEIN SODIUM						X
GENTAMICIN SULFATE				X	X	
GRISEOFULVIN, ULTRAMICROCRYSTALLINE				X		
HALOTHANE			X			
HEPARIN CALCIUM					X	
HEPARIN SODIUM			X			X
HEXACHLOROPHENE					X	X
HEXOCYCLIUM METHYLSULFATE			X			
HYDROCHLOROTHIAZIDE				X		
HYDROCORTISONE				X		
HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE		X				
HYDROCORTISONE ACETATE; NEOMYCIN SULFATE		X				
HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE		X				
HYDROCORTISONE SODIUM SUCCINATE					X	

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6
HYDROXYZINE HYDROCHLORIDE						X
ISONIAZID	X	X				
ISOSORBIDE					X	
LIDOCAINE HYDROCHLORIDE		X				
LITHIUM CARBONATE				X		X
LITHIUM CITRATE					X	
LORAZEPAM		X				
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	X					
MANNITOL	X					
MAPROTILINE HYDROCHLORIDE					X	
MAZINDOL	X					
MECLOCYCLINE SULFOSALICYLATE				X		
MEPERIDINE HYDROCHLORIDE		X				X
MEPROBAMATE					X	
METAPROTERENOL SULFATE		X				
METHAQUALONE					X	
METHYLPREDNISOLONE; NEOMYCIN SULFATE		X				
METHYLPREDNISOLONE ACETATE						X
METHYLTESTOSTERONE		X				
METOCLOPRAMIDE HYDROCHLORIDE					X	
METRONIDAZOLE HYDROCHLORIDE				X		
NADOLOL						X
NAPROXEN SODIUM		X				
NEOMYCIN SULFATE; PREDNISOLONE		X				X
NEOMYCIN SULFATE; PREDNISOLONE ACETATE		X				
NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE		X				

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6
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			
PHENYTOIN SODIUM						X
POTASSIUM CHLORIDE	X	X	X		X	
PRAZEPAM		X				
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM		X				
PREDNISOLONE SODIUM PHOSPHATE			X			
PREDNISONE			X			
PROMETHAZINE HYDROCHLORIDE				X		
PYRIDOXINE HYDROCHLORIDE		X				X
RESERPINE; TRICHLORMETHIAZIDE		X				
RITODRINE HYDROCHLORIDE	X				X	
SCOPOLAMINE			X			
SCOPOLAMINE HYDROBROMIDE			X			
SECOBARBITAL SODIUM					X	
SODIUM AMINOSALICYLATE		X				

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6
SOYBEAN OIL						X
SPIRONOLACTONE						X
SULFAMETHOXAZOLE	X					
SULFASALAZINE					X	
SULFISOXAZOLE		X		X	X	
TESTOSTERONE ENANTHATE					X	
TETRACYCLINE HYDROCHLORIDE						X
THEOPHYLLINE	X			X		
TRICHLORMETHIAZIDE	X					
TRISULFAPYRIMIDINES	X					
VITAMIN A						X
XYLOSE, D-						X
ZOMEPIRAC SODIUM			X			

CURRENT STATUS - PROBABLY EFFECTIVE

PARAFON FORTE MCNEIL LABS
>_ADD_> MCNEIL PHARM

CURRENT STATUS - INEFFECTIVE

BIOZYME ARMOUR PHARM
NEOMYCIN PALMITATE; TRYPSIN-CHYMOTRYPSIN

ORTHOXINE UPJOHN
METHOXYPHENAMINE HYDROCHLORIDE

CURRENT STATUS - 'EXEMPT' (COURT ORDER)

CLISTIN EXPECTORANT MCNEIL LABS
>_ADD_> MCNEIL PHARM

DYSPAS SAVAGE/BYK-GULDEN
DICYCLOMINE HYDROCHLORIDE

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

TRADE NAME	SUPPLEMENT: 1	2	3	4	5	6
ACHROMYCIN		X				
BACITRACIN; NEOMYCIN; POLYMYXIN; HYDROCORTISONE ACETATE		X				
BIOZYME						X
CHLOROMYCETIN HYDROCORTISONE		X				
CLISTIN EXPECTORANT						X
COR-OTICIN		X				
CORTISPORIN		X				
DIPYRIDAMOLE	X	X				
DONNATAL					X	
DYSPAS						X
FLORINEF-S		X				
METI-DERM W/ NEOMYCIN			X			
METIMYD		X				
NEO-ARISTOCORT ACETONIDE		X				
NEO-DELTA-CORTEF		X				
NEO-DELTEF		X				
NEO-MEDROL		X				
NEOSONE		X				
NITROGLYCERIN				X		
OPHTHOCORT		X				
ORTHOXINE						X
PARAFON FORTE						X
POLY-PRED		X				
PREDMYCIN-P		X				
SULFATHALIDINE			X			
TERRA-CORTRIL		X				
TRAL GRADUMET					X	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DRUG PRODUCT PROBLEM REPORTING PROGRAM

The Food and Drug Administration (FDA) encourages physicians, pharmacists, nurses and other health professionals to report drug related problems encountered during their professional practice. The Drug Product Problem Reporting Program was designed to provide a quick and easy method of reporting problems such as questionable bioavailability and stability, inadequate package insert information, poor packaging and closures, mislabeling, defect in drug product themselves and defects in manufacturing processes and the like. Since its inception it has been a voluntary program and to date we have received in excess of 46,000 reports dealing with both prescription and over-the-counter drug products.

The Drug Product Problem Reporting Program is a practitioner-oriented system that communicates drug product problems to industry and government.

Whenever you encounter a problem with any of the drug products, please use either the toll-free number 800-638-6725 or state your observations on the form and return it to the United States Pharmacopeia (USP).

If you are not sure about the significance of a problem, please report it; problems that appear insignificant may be also observed by others and your report could be the additional information that initiates a corrective action.

Whenever you use this program, please note the following:

This program is product oriented.

A copy of your report will be forwarded by the United States Pharmacopeia (USP) to the Food and Drug Administration (FDA) and to the manufacturer associated with your report.

It is important that you provide your address or phone number so that any subsequent follow-up information can be requested and/or forwarded to you. However, if you prefer that your identity be withheld from FDA and/or the manufacturer, please indicate your preference on the form. USP will then act as an intermediary if any further contact with FDA or the manufacturer is necessary.

All drug product problem information received through this program is entered into a computerized data base which allows one to look for trends, to chart product and company profiles and to flag problem drugs.

If you have any questions about the program, please call FDA's Product Surveillance Branch at (301) 443-2263 or the United States Pharmacopeia at (301) 881-0666.

Drug Product Problem Reporting Program

Form approved: OMB No. 57-R0059

DO NOT USE THIS SPACE

DATE RECEIVED

REFERENCE NO.

1. PRODUCT NAME, DOSAGE FORM, STRENGTH, NDC NUMBER — DATE:

2. LOT NUMBER*(s)* AND EXPIRATION DATE*(s)*

3. DATE PURCHASED *(If known)*

4. SOURCE OF PRODUCT *(Where purchased, if known)*

5. NAME AND ADDRESS OF THE MANUFACTURER, PACKAGER AND/OR DISTRIBUTOR ON THE LABEL

6. REPORTER'S NAME *(Please print or type)*

7. NAME AND ADDRESS OF PRACTICE LOCATION *(Include Zip Code)*

8. PHONE NUMBER AT PRACTICE LOCATION *(Include area code)*

9. PROBLEMS NOTED OR SUSPECTED

RETURN TO
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852
Attention: Dr. Joseph G. Valentino

OR

CALL TOLL FREE ANYTIME
800-638-6725*
IN THE CONTINENTAL UNITED STATES
*In Maryland, call collect (301)881-0256
between 9:00 AM and 4:30 PM

FORM FDA 2519 (7/79)

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