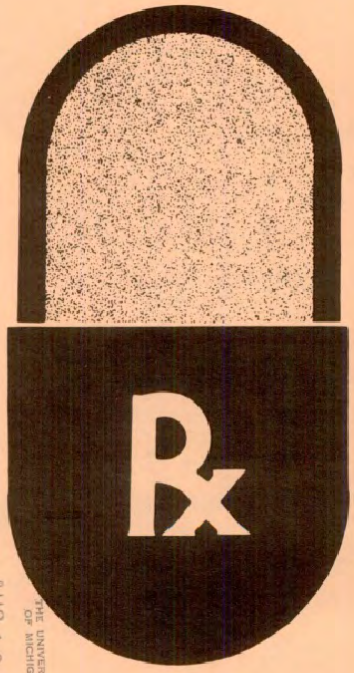
APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

FDA data supplied by DrugPatentWatch.com

SUPPLEMENT 4
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 classifcation 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.

Pharmadyne - Chlorpropamide

The Agency has confirmed that the formulation for batches of the currently approved Pharmadyne product is the same formulation as for batches of the firm's product which was marketed without approval and thereby subject to earlier Agency regulatory action. The unapproved marketed batches were manufactured in the same manner and met the same end product specifications, including dissolution, as the currently approved product.

AMANTADINE HYDROCHLORIDE

TABLET; ORAL
SYMMETREL
>ADD> ENDO LABS/DUPONT 100MG

AMINO ACIDS

INJECTABLE; INJECTION
AMINOSYN-RF
>ADD> ABBOTT LABS 5%

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITID
BP ER SQUIBB AND SONS 10MG * 25MG * 50MG * 75MG * 100MG
>ADD> AB 10MG * 25MG * 50MG * 75MG * 100MG

CAFFEINE; ERGOTAMINE TARTRATE

TABLET; ORAL
WIGRETTES
>ADD> AA ORGANON INC 100MG;1MG

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION
CHLORPHENIRAMINE MALEATE
AP VITARINE/WEST CHEM 10MG/ML

SYRUP; ORAL
CHLORPHENIRAMINE MALEATE
NATCON CHEMICAL 2.5MG/5ML

CHLORPROMAZINE HYDROCHLORIDE

CONCENTRATE; ORAL
CHLORPROMAZINE HCL
AA LEDERLE LABS/AM CYAN 100MG/ML
>ADD> AA NATL PHARM MFG/BARRE 100MG/ML

SYRUP; ORAL
CHLORPROMAZINE HCL
>ADD> AA NATL PHARM MFG/BARRE 10MG/5ML

CHLORPROPAMIDE

TABLET; ORAL
DYMALASE
>ADD> AB PHARMADYNE LABS 250MG

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE

INJECTABLE; INJECTION
ISOLYTE S W/ 5% DEXTROSE IN PLASTIC CONTAINER
AP AM MCGAW/AM HOSP 5GM/100ML;30MG/100ML;37MG/100ML;
>ADD> 37MG/100ML;

DIHYDROERGOCORNINE MESYLATE; DIHYDROERGOCRISTINE MESYLATE; DIHYDROERGOCRYPTINE MESYLATE

TABLET; SUBLINGUAL
HYDROGENATED ERGOT ALKALOIDS
>ADD> AA ZENITH LABS 167 UGM;167 UGM;167 UGM * 333 UGM;
>ADD> AA 333 UGM;333 UGM

GENTAMICIN SULFATE

>ADD > OINTMENT; OPHTHALMIC
>ADD > GARAMYCIN
>ADD > SCHERING EQ 3MG BASE/GM

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL
GRIS-PEG
>ADD > AB DORSEY LABS/SANDOZ 250MG

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE
>ADD > AB LEDERLE LABS/AM CYAN 100MG

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE
AT BYK-GULDEN 0.5% * 1%

LOTION; TOPICAL
EPICORT
BLULINE LABS
>ADD > BLULINE LABS

LITHIUM CARBONATE

CAPSULE; ORAL
>ADD > LITHIUM CARBONATE
>ADD > AB PHILIPS ROXANE LABS 300MG

>ADD > MECLOCYCLINE SULFOSALICYLATE

>ADD > CREAM; TOPICAL
>ADD > MECLAN
>ADD > ORTHO PHARM 1%

>ADD > METRONIDAZOLE HYDROCHLORIDE

>ADD > INJECTABLE; INJECTION
>ADD > FLAGYL I.V.
>ADD > SEARLE PHARMS EQ 500MG BASE/VIAL

OXYTOCIN

INJECTABLE; INJECTION
>ADD > PITOCIN
>ADD > AP PARKE-DAVIS/W-L 10 UNITS/ML

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL
ZIPAN-25
BP SAVAGE/BYK-GULDEN 25MG
ZIPAN-50
BP SAVAGE/BYK-GULDEN 50MG

SULFISOXAZOLE

TABLET; ORAL
SULFISOXAZOLE
>ADD > AB GENERIC PHARM/IVY 500MG

THEOPHYLLINE

TABLET; ORAL

>_ADD_> THEOPHYL-225

>_ADD_> KNOLL PHARM 225MG

	SUPPLEMENT: 1	2	3	4
ACETAMINOPHEN; CODEINE PHOSPHATE	X	X		
ACETIC ACID, GLACIAL		X		
AMANTADINE HYDROCHLORIDE				X
AMINO ACIDS				X
AMINOGLUTETHIMIDE			X	
AMINOPHYLLINE		X		
AMITRIPTYLINE HYDROCHLORIDE	X			X
AMOXAPINE		X		
AMOXICILLIN TRIHYDRATE	X			
ASPIRIN; CAFFEINE; PHENACETIN; PROPOXYPHENE HYDROCHLORIDE			X	
ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE		X		
BISHYDROXYCOUMARIN			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			

	SUPPLEMENT: 1	2	3	4
CHLORAMPHENICOL; DESOXYRIBONUCLEASE; FIBRINOLYSIN			X	
CHLORAMPHENICOL; HYDROCORTISONE ACETATE		X		
CHLOROQUINE PHOSPHATE		X		
CHLORPHENIRAMINE MALEATE				X
CHLORPROMAZINE HYDROCHLORIDE	X			X
CHLORPROPAMIDE			X	X
CLORAZEPATE DIPOTASSIUM		X		
CORTISONE ACETATE; NEOMYCIN SULFATE		X		
CYPROHEPTADINE HYDROCHLORIDE			X	
DANAZOL		X		
DEXAMETHASONE SODIUM PHOSPHATE	X		X	
DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE		X		
DEXTROAMPHETAMINE SULFATE	X		X	
DEXTROSE	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	

	SUPPLEMENT: 1	2	3	4
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE - IN PLASTIC		X		
DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM			X	
DIATRIZOATE SODIUM			X	
DICUMAROL			X	
DIHYDROERGOCORNINE MESYLATE; DIHYDROERGOCRISTINE MESYLATE; DIHYDROERGOCRYPTINE MESYLATE				X
DIPHENADIONE	X			
EPINEPHRINE; LIDOCAINE HYDROCHLORIDE		X		
FENOPROFEN CALCIUM DIHYDRATE			X	
GENTAMICIN SULFATE				X
GRISEOFULVIN, ULTRAMICROCRYSTALLINE				X
HALOTHANE			X	
HEPARIN SODIUM			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		

	SUPPLEMENT: 1	2	3	4
ISONIAZID	X	X		
LIDOCAINE HYDROCHLORIDE		X		
LITHIUM CARBONATE				X
LORAZEPAM		X		
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE		X		
MANNITOL	X			
MAZINDOL	X			
MECLOCYCLINE SULFOSALICYLATE				X
MEPERIDINE HYDROCHLORIDE		X		
METAPROTERENOL SULFATE		X		
METHYLPREDNISOLONE; NEOMYCIN SULFATE		X		
METHYLTESTOSTERONE		X		
METRONIDAZOLE HYDROCHLORIDE				X
NAPROXEN SODIUM		X		
NEOMYCIN SULFATE; PREDNISOLONE		X		
NEOMYCIN SULFATE; PREDNISOLONE ACETATE		X		
NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE		X		
NEOSTIGMINE BROMIDE			X	

	SUPPLEMENT: 1	2	3	4
NOVOBIOCIN CALCIUM	X			
NOVOBIOCIN SODIUM	X			
OXYTOCIN				X
PENICILLIN G POTASSIUM	X			
PENICILLIN G PROCAINE	X			
PENICILLIN V POTASSIUM	X			
PHENDIMETRAZINE TARTRATE			X	
PHENTERMINE HYDROCHLORIDE		X	X	
POTASSIUM CHLORIDE	X	X	X	
PRAZEPAM		X		
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM		X		
PREDNISOLONE SODIUM PHOSPHATE			X	
PREDNISONE			X	
PROMETHAZINE HYDROCHLORIDE				X
PYRIDOXINE HYDROCHLORIDE		X		
RESERPINE; TRICHLORMETHIAZIDE		X		
RITODRINE HYDROCHLORIDE	X			
SCOPOLAMINE			X	
SCOPOLAMINE HYDROBROMIDE			X	

	SUPPLEMENT: 1	2	3	4
SODIUM AMINOSALICYLATE		X		
SULFAMETHOXAZOLE	X			
SULFISOXAZOLE		X		X
THEOPHYLLINE	X			X
TRICHLORMETHIAZIDE	X			
TRISULFAPYRIMADINES	X			
ZOMEPIRAC SODIUM			X	

PRESCRIPTION DRUG PRODUCTS DEEMED APPROVED
PENDING RESOLUTION OF SAFETY OR EFFECTIVENESS ISSUES
SUPPLEMENT NUMBER 4
CURRENT STATUS - 'EXEMPT' (COURT ORDER)

>_ADD_> NITROGLYCERIN CORD LABS
>_ADD_> NITROGLYCERIN

	SUPPLEMENT: 1	2	3	4
ACHROMYCIN		X		
BACITRACIN; NEOMYCIN; POLYMYXIN; HYDROCORTISONE ACETATE		X		
CHLOROMYCETIN HYDROCORTISONE		X		
COR-OTICIN		X		
CORTISPORIN		X		
DIPYRIDAMOLE	X	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		
POLY-PRED		X		
PREDMYCIN-P		X		
SULFATHALIDINE			X	

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

	SUPPLEMENT: 1	2	3	4
TERRA-CORTRIL		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)