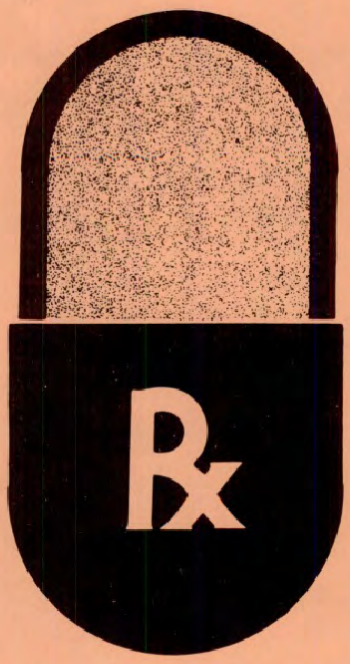
APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

FDA data supplied by DrugPatentWatch.com

SUPPLEMENT 8
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

Deletions in the "ingredient list" (drug products) and in the "trade name list" (DESI appendix), are now represented by an overstruck print rather than by the reverse print. This change has been implemented in an effort to improve readability.

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

LIQUID; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE
>ADD > COLONAID

TABLET; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE
AA WALLACE LABS/C-W 25 UGM;2.5MG
>ADD > COLONAID
>ADD > AA WALLACE LABS/C-W 25 UGM;2.5MG

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE
>ADD > AB ABBOTT LABS 25MG * 50MG
>ADD > AB BARR LABS 25MG * 50MG
>ADD > AB BOLAR PHARM 25MG * 50MG
>ADD > AB HEUN-NORWOOD/KV 25MG * 50MG

CLORAZEPATE MONOPOTASSIUM

CAPSULE; ORAL
AZENE
ABBOTT LABS 3.75MG * 7.5MG * 15MG

DIAZEPAM

>ADD > CAPSULE, CONTROLLED RELEASE; ORAL
>ADD > VALRELEASE
>ADD > HOFFMANN-LA ROCHE 15MG

DIHYDROERGOCORNINE MESYLATE; DIHYDROERGOCRISTINE MESYLATE; DIHYDROERGOCRYPTINE MESYLATE

TABLET; SUBLINGUAL
>ADD > ALKERGOT
>ADD > AA PREMO PHARM LABS 167 UGM;167 UGM;167 UGM * 333 UGM; 333 UGM;333 UGM

DIMENHYDRINATE

INJECTABLE; INJECTION
DIMENHYDRINATE
D.M. PHARMACEUTICALS
>ADD > LEMMON

DIPHENHYDRAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DIPHENHYDRAMINE HCL
>ADD > AP BRISTOL LABS/BM 10MG/ML
CARTER-GLOGAU LABS
>ADD > CARTER-GLOGAU
D.M. PHARMACEUTICALS
>ADD > LEMMON

DISULFIRAM

TABLET; ORAL
ANTABUSE
>ADD > BX AYERST LABS/AMHO 250MG * 500MG
>ADD > DISULFIRAM
>ADD > BX DANBURY PHARMACAL 250MG * 500MG

ERYTHROMYCIN

TABLET, ENTERIC COATED; ORAL
E-MYCIN
/BX/ UPJOHN /250MG/
>_ADD_> AB 250MG
ROBIMYCIN
/BX/ AH ROBINS /250MG/
>_ADD_> AB 250MG

ESTRADIOL VALERATE

INJECTABLE; INJECTION
ESTRADIOL VALERATE
/CARTER-GLOGAU LABS/
>_ADD_> CARTER-GLOGAU

GENTAMICIN SULFATE

INJECTABLE; INJECTION
GARAMYCIN
>_ADD_> SCHERING EQ 1MG BASE/ML

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL
ATARAX
>_ADD_> AA ROERIG/PFIZER 10MG * 25MG * 50MG
>_ADD_> HYDROXYZINE HCL
>_ADD_> AA CHELSEA LABS 10MG * 25MG
>_ADD_> AA PREMO PHARM LABS 10MG * 25MG * 50MG

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL
IMIPRAMINE HCL
>_ADD_> AB PREMO PHARM LABS 10MG * 50MG

IRON DEXTRAN COMPLEX

INJECTABLE; INJECTION
>_ADD_> PROFERDEX
>_ADD_> AP FISONS EQ 50MG IRON/ML

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
>_ADD_> BETA-2
>_ADD_> AN NEPHRON 1%

LITHIUM CITRATE

SYRUP; ORAL
LITHONATE-S
/ROWELL LABS/
>_ADD_> CIBA PHARM

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE
/AA/ /REXALL DRUG/ /400MG/

MICONAZOLE NITRATE

CREAM; TOPICAL
/MICATIN/
>_ADD_> MONISTAT-DERM

LOTION; TOPICAL
/MICATIN/
>_ADD_> MONISTAT-DERM

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
PHENTERMINE HCL
>_ADD_> AA PREMO PHARM LABS 30MG

TABLET; ORAL
PHENTERMINE HCL
>_ADD_> AA LEMMON 8MG

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROMETHAZINE HCL
/P-M PHARMACEUTICALS/
>_ADD_> LEMMON

SULFAMETHOXAZOLE

TABLET; ORAL
>_ADD_> UROBAK
>_ADD_> AB SHIONOGI USA 500MG

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
TESTOSTERONE ENANTHATE
/P-M PHARMACEUTICALS/
>_ADD_> LEMMON

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE
>_ADD_> AB DANBURY PHARMACAL 500MG

TRIAMCINOLONE DIACETATE

INJECTABLE; INJECTION
TRIAMCINOLONE DIACETATE
>_ADD_> BP MAURRY BIOLOGICAL 40MG/ML

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8
ACETAMINOPHEN; CODEINE PHOSPHATE	X	X					X	
ACETIC ACID, GLACIAL		X						
ACETYLCHOLINE CHLORIDE						X		
AMANTADINE HYDROCHLORIDE				X				
AMINO ACIDS				X				
AMINOGLUTETHIMIDE			X					
AMINOPHYLLINE		X					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			X
BACAMPICILLIN HYDROCHLORIDE							X	
BACITRACIN						X		
BISHYDROXYCOUMARIN			X					
BROMPHENIRAMINE MALEATE							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					
CHLORAMPHENICOL; HYDROCORTISONE ACETATE		X						
CHLORDIAZEPOXIDE HYDROCHLORIDE							X	
CHLOROQUINE PHOSPHATE		X						
CHLORPHENIRAMINE MALEATE				X				
CHLORPROMAZINE HYDROCHLORIDE	X			X	X	X	X	
CHLORPROPAMIDE			X	X				
CHLORTHALIDONE							X	X
CHYMOTRYPSIN						X		
CLORAZEPATE DIPOTASSIUM		X						
CLORAZEPATE MONOPOTASSIUM								X
CORTISONE ACETATE; NEOMYCIN SULFATE		X						
CYCLOTHIAZIDE							X	

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8
CYPROHEPTADINE HYDROCHLORIDE			X				X	
DACARBAZINE							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					
DIAZEPAM								X
DICUMAROL			X					
DIETHYLSTILBESTROL						X		
DIHYDROERGOCORNINE MESYLATE; DIHYDROERGOCRISTINE MESYLATE; DIHYDROERGOCRYPTINE MESYLATE				X		X		X
DIMENHYDRINATE								X
DINOPROSTONE						X		
DINOPROSTONE(PROSTAGLANDIN E-2)						X		
DIPHENADIONE	X							
DIPHENHYDRAMINE HYDROCHLORIDE								X
DISULFIRAM								X
DOXEPIN HYDROCHLORIDE						X		
DOXYCYCLINE HYCLATE					X			
EPINEPHRINE; LIDOCAINE HYDROCHLORIDE		X						
ERYTHROMYCIN						X		X
ERYTHROMYCIN ETHYLSUCCINATE					X			
ESTRADIOL VALERATE								X
FENOPROFEN CALCIUM					X			
FENOPROFEN CALCIUM DIHYDRATE			X		X			
FLUORESCEIN SODIUM						X		
GENTAMICIN SULFATE				X	X			X
GRISEOFULVIN, ULTRAMICROCRYSTALLINE				X				

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8
HALOTHANE			X					
HEPARIN CALCIUM					X			
HEPARIN SODIUM			X			X	X	
HEXACHLOROPHENE					X	X		
HEXOCYCLIUM METHYLSULFATE			X					
HYDROCHLOROTHIAZIDE				X			X	
HYDROCORTISONE				X			X	
HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE		X						
HYDROCORTISONE ACETATE; NEOMYCIN SULFATE		X						
HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE		X						
HYDROCORTISONE SODIUM SUCCINATE					X		X	
HYDROXYZINE HYDROCHLORIDE						X		X
IMIPRAMINE HYDROCHLORIDE							X	X
IOTHALAMATE SODIUM, I-125							X	
IRON DEXTRAN COMPLEX								X
ISOETHARINE HYDROCHLORIDE								X
ISONIAZID	X	X						
ISOSORBIDE					X			
LIDOCAINE HYDROCHLORIDE		X					X	
LITHIUM CARBONATE				X		X		
LITHIUM CITRATE					X			X
LORAZEPAM		X						
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	X							
MANNITOL	X							
MANNITOL; SORBITOL							X	
MAPROTILINE HYDROCHLORIDE					X			
MAZINDOL	X							
MECLOCYCLINE SULFOSALICYLATE				X				
MEPERIDINE HYDROCHLORIDE		X				X		
MEPROBAMATE					X			X
METAPROTERENOL SULFATE		X						
METHAQUALONE					X			
METHYLPREDNISOLONE; NEOMYCIN SULFATE		X						
METHYLPREDNISOLONE ACETATE						X		
METHYLPREDNISOLONE SODIUM SUCCINATE							X	
METHYLTESTOSTERONE		X					X	
METOCLOPRAMIDE HYDROCHLORIDE					X			
METOLAZONE							X	

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8
METRONIDAZOLE HYDROCHLORIDE				X				
MICONAZOLE NITRATE								X
NADOLOL						X		
NAPROXEN SODIUM		X						
NEOMYCIN SULFATE; PREDNISOLONE		X				X		
NEOMYCIN SULFATE; PREDNISOLONE ACETATE		X						
NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE		X						
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					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				X
PYRIDOXINE HYDROCHLORIDE		X				X		
RESERPINE; TRICHLORMETHIAZIDE		X						
RITODRINE HYDROCHLORIDE	X				X			
SCOPOLAMINE			X					
SCOPOLAMINE HYDROBROMIDE			X					
SECOBARBITAL SODIUM					X		X	
SODIUM AMINOSALICYLATE		X						
SOYBEAN OIL						X		
SPIRONOLACTONE						X	X	
SULFAMETHOXAZOLE	X							X
SULFASALAZINE					X			
SULFISOXAZOLE		X		X	X			
TECHNETIUM, TC-99M, MEDRONATE KIT							X	
TECHNETIUM, TC-99M, OXIDRONATE KIT							X	

INGREDIENT(S)	SUPPLEMENT: 1	2	3	4	5	6	7	8
TEMAZEPAM							X	
TESTOSTERONE ENANTHATE					X			X
TETRACYCLINE HYDROCHLORIDE						X		
THEOPHYLLINE	X			X				
TOLBUTAMIDE							X	X
TRIAMCINOLONE DIACETATE								X
TRICHLORMETHIAZIDE	X						X	
TRISULFAPYRIMIDINES	X							
VITAMIN A						X		
XYLOSE, D-						X		
ZOMEPIRAC SODIUM			X					

CURRENT STATUS - 'EXEMPT' (COURT ORDER)

>_ADD_> DICYCLOMINE HCL CARTER-GLOGAU
>_ADD_> DICYCLOMINE HYDROCHLORIDE

>_ADD_> NEOQUESS OJF/CHROMALLOY
>_ADD_> ATROPINE SULFATE; HYOSCYAMINE SULFATE; PHENOBARBITAL;
>_ADD_> SCOPOLAMINE HYDROBROMIDE

>_ADD_> NITROGLYCERIN LEDERLE LABS/AM CYAN
>_ADD_> NITROGLYCERIN

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
ACHROMYCIN		X						
BACITRACIN; NEOMYCIN; POLYMYXIN; HYDROCORTISONE ACETATE		X					X	
BENTYL W/ PHENOBARBITAL						X		
BIOZYME							X	
CANTIL W/ PHENOBARBITAL								
CHLOROMYCETIN HYDROCORTISONE		X				X		
CLISTIN EXPECTORANT								
COR-OTICIN		X						
CORTISPORIN		X					X	
DACTIL								
DACTIL AND PHENOBARBITAL							X	
DARICON PB							X	
DICYCLOMINE HCL								X
DIPYRIDAMOLE	X	X						
DONNATAL					X			
DYSPAS						X		
FLORINEF-S		X						
LEVSIN PB							X	
LEVSIN W/ PHENOBARBITAL							X	
LIBRAX							X	
MEPROBAMATE W/ TRIDIHEXETHYL CHLORIDE							X	
METI-DERM W/ NEOMYCIN			X					
METIMYD		X						
MILPATH-200							X	
MILPATH-400							X	
NEO-ARISTOCORT ACETONIDE		X						
NEO-DELTA-CORTEF		X						
NEO-DELTEF		X						
NEO-MEDROL		X						
NEOQUESS								X
NEOSONE		X						
NITROGLYCERIN				X				X
NYSTATIN, NEOMYCIN SULFATE, GRAMICIDIN, TRIAMCINOLONE ACETONIDE							X	
OPHTHOCORT		X						
ORTHOXINE						X		
PARAFON FORTE						X		
PATHIBAMATE-200							X	
PATHIBAMATE-400							X	
PATHILON W/ PHENOBARBITAL							X	
POLY-PRED		X						

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
PREDMYCIN-P		X						
PRO-BANTHINE W/ PHENOBARBITAL							X	
ROBINUL-PH							X	
ROBINUL-PH FORTE							X	
SULFATHALIDINE			X					
T.C.M. 200							X	
T.C.M. 400							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)