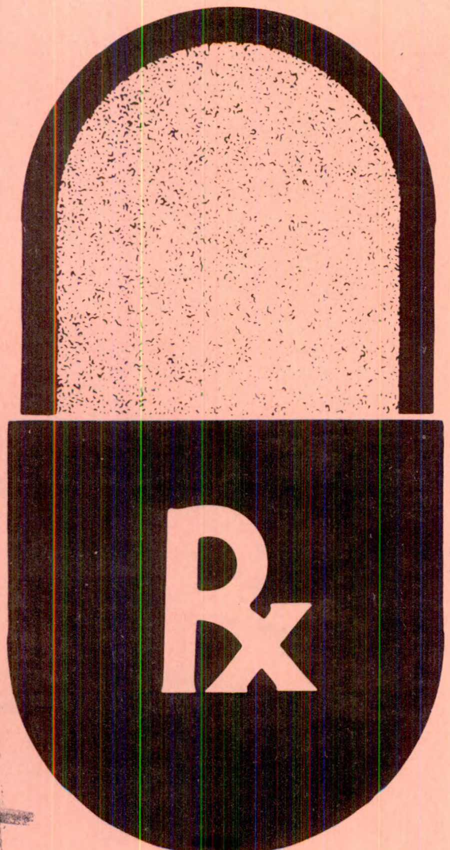
Approved prescription drug products with therapeutic equivalence evaluations.

[Washington, D.C.?] : U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, Bureau of Drugs : 1980-

http://hdl.handle.net/2027/mdp.39015072931663

CUMULATIVE SUPPLEMENT 1

AUG'84 - SEP'84



APPROVED PRESCRIPTION DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

5TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUGS AND BIOLOGICS

FOOD AND DRUG ADMINISTRATION
APPROVED PRESCRIPTION DRUG PRODUCTS
WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS
CUMULATIVE SUPPLEMENT

I. PREFACE

This cumulative supplement is one of a series of monthly updates to the Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 5th Edition (the List), to cover interim revisions to the annual publication of the List in its entirety. The List is comprised of several parts and some by their nature, are identified by the term "list". The cumulative supplements routinely provide updates to two of these lists: The Drug Product List and the DESI Addendum.

The List cannot be used effectively without the current cumulative supplement. Users may wish to place an asterisk (*) in the List to the left of the ingredient(s) in the Drug Product List and the product name in the Addendum to indicate that changes to that entry appear in the cumulative supplement. It is also suggested that earlier cumulative supplements be discarded to avoid possible confusion. In this way, only the List and current cumulative supplement need be referenced.

A. DRUG PRODUCT LIST

The Drug Product List cumulative supplements include the changes made since August 1, 1984. Each subsequent cumulative supplement replaces the previous month's cumulative supplement.

Information in this cumulative supplement follows the format of the Drug Product List. The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Context information on drug products is provided in each cumulative supplement for completeness to assist in locating the proper place in the Drug Product List for the revision. (Strength(s) which already exist in the publication will not be repeated for context.) A page number in parentheses referring to the Drug Product List is located to the right of the ingredient(s).

Additions to the Drug Product List are indicated by new information in the cumulative supplement. Additions new to the current cumulative supplement are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is dropped in subsequent cumulative supplements for that item.

Deletions from the Drug Product List are indicated by overstruck print in the cumulative supplement. Deletions new to the current cumulative supplement are indicated by the symbol >DLT> (DELETE) to the left of the line containing the overstruck print. The >DLT> symbol is dropped in subsequent cumulative supplements for that item.

A newly approved product is identified by the lozenge (¤) to the right of its strength. This identifier remains throughout all cumulative supplements for this edition.

B. ADDENDUM: DESI Pending List

Information in this cumulative supplement follows the format of the Addendum. Additions and deletions are indicated in the same manner as in the cumulative supplement to the Drug Product List. A change in Current Status of a DESI product is also indicated by an addition and a deletion.

II. SPECIAL NOTES

A. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

Categories of counts derived from product information in the Drug Product List and from this cumulative supplement are presented. The report includes counts of new molecular entities approved by the agency during the current month.

B. PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the Drug Product List.

Products	Federal Register Reference
dicyclomine hydrochloride	JUN 22, 1984 (49 FR 25681)
isosorbide dinitrate	AUG 3, 1984 (49 FR 31151)
nandrolone decanoate	JUL 15, 1983 (48 FR 32395)

(continued)

Products	Federal Register Reference
(continued)	
neomycin sulfate with either: dexamethasone sodium phosphate, fluocinolone acetonide, flurandrenolide, hydrocortisone, or methylprednisolone acetate. [topical anti-infectives for dermatologic use]	MAR 26, 1984 (49 FR 11888)
neomycin sulfate, polymyxin B sulfate, bacitracin zinc, and hydrocortisone [topical ointment]	MAY 4, 1984 (49 FR 19147)
nitroglycerin (capsule,controlled release;oral)	SEP 7, 1984 (49 FR 35428)
nitroglycerin (tablet, controlled relase;oral)	SEP 7, 1984 (49 FR 35428)
parenteral multivitamin products	SEP 17, 1984 (49 FR 36446)
phenazopyridine hydrochloride and sulfamethoxazole	JUL 29, 1983 (48 FR 34516)
sulfanilamide and aminacrine	AUG 22, 1983 (48 FR 38097)
tranylcypromine sulfate	MAR 22, 1984 (49 FR 10708)

C. SUBSCRIPTION FORM

A subscription form for the publication has been provided at the end of this supplement for use in obtaining additional subscriptions.

III. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

DESCRIPTION OF REPORT

The following report provides summary counts derived from product information in the Drug Product List and the current cumulative supplement. The counts appear in two sections. Section A. refers to the products in the List and Section B. to products in the current cumulative supplement. A new column of data will appear in Section A. each three-month period following July '84. Section A. therefore will provide baseline and quarterly data while Section B. provides monthly activity.

USE OF REPORT

From the data presented under Section B., users should be able to observe such things as (1) newly approved, DESI effective and remarketed drug products which are added to the List; (2) products that are being removed from the List as the result of withdrawal of approval, changes from prescription to over-the-counter status and discontinued marketing of products; and, (3) trends in approval of products as either multisource or single source during each month within the quarter. The report does not reflect category changes from multisource to single source and vice versa. However, the net gain that results from all additions, deletions and category changes is reflected in the quarterly counts for multisource and single source products.

Drug Product Definition

For this report, a drug product is the representation in the Drug Product List of an active moiety (includes molecular entity and its salts, esters and derivatives) either as a single entity or as a combination product, provided in a specific dosage form and strength for a given route of administration marketed by a firm under a particular generic or trade name.

New Molecular Entity

The active moiety has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or part of a combination.

Drug Product Count

This report provides counts in several categories from the list composed of domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Counts of products still pending in the DESI review are not provided. Excluded also are those approved drug products marketed by distributors; those marketed solely abroad; and products now regarded as medical devices, biologics or foods.

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

A. COUNTS CUMULATIVE BY QUARTERS

CATEGORIES COUNTED	JULY '84 (BASELINE)
DRUG PRODUCTS LISTED	7415
SINGLE SOURCE	2005 (27.0%)
MULTISOURCE(1)	5410 (72.9%)
THERAPEUTICALLY EQUIVALENT	4393 (59.2%)
NOT THERAPEUTICALLY EQUIVALENT	999 (13.4%)
EXCEPTIONS(2)	18 (0.3%)
NEW MOLECULAR ENTITIES APPROVED	-
NUMBER OF APPLICANTS	295

B. ACTIVITY FOR SUPPLEMENT NUMBER 1

	AUG '84	SEPT '84	CUMULATIVE
DRUG PRODUCTS ADDED:	54	66	120
NEWLY APPROVED	54	66	120
DESI EFFECTIVE	0	0	0
REMARKETED	0	0	0
DRUG PRODUCTS REMOVED:	0	12	12
WITHDRAWN APPROVAL	0	0	0
RX TO OTC SWITCH	0	0	0
DISCONTINUED MARKETING	0	12	12
NET GAIN IN DRUG PRODUCTS	54	54	108
SINGLE SOURCE PRODUCTS APPROVED	17	16	33
MULTISOURCE DRUG PRODUCTS APPROVED	37	50	87
NEW MOLECULAR ENTITIES APPROVED:	3	0	3
AS THE ENTITY	1	0	1
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	2	0	2

(1) THERAPEUTIC EQUIVALENCE EVALUATIONS PROVIDED ONLY FOR MULTISOURCE PRODUCTS (i.e., AVAILABLE FROM MORE THAN ONE APPLICANT)

(2) AMINO ACID-CONTAINING PRODUCTS OF VARYING COMPOSITION (SEE PAGE 1-5 OF THE LIST)

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 3-2)

TABLET; ORAL
>DLT< /CODACET/
>ADD< OXYCET
AA HALSEY DRUG 325MG;5MG# N 87463

ACETIC ACID, GLACIAL (PAGE 3-3)

SOLUTION/DROPS; OTIC
ACETIC ACID
>ADD< AT THAMES PHARMACAL 2%# N 88638

ALLOPURINOL (PAGE 3-5)

TABLET; ORAL
ALLOPURINOL
>ADD< AB CHELSEA LABORATORIES 100MG# N 18785
>ADD< AB 300MG# N 18785
>ADD< AB DANBURY PHARMACAL 100MG# N 18832
>ADD< AB 300MG# N 18877

AMIKACIN SULFATE (PAGE 3-6)

INJECTABLE; INJECTION
AMIKIN
>ADD< BRISTOL LABS/B-M EQ 50MG BASE/ML# N 62562
>ADD< EQ 250MG BASE/ML# N 62562

AMINO ACIDS (PAGE 3-6)

INJECTABLE; INJECTION
>ADD< BRANCHAMIN 4%
>ADD< TRAVENOL LABS 4%# N 18678
>ADD< BRANCHAMIN 4% IN PLASTIC CONTAINER
>ADD< TRAVENOL LABS 4%# N 18684
>ADD< TRAVASOL 10% W/O ELECTROLYTES IN PLASTIC CONTAINER
>ADD< TRAVENOL LABS 10%# N 18931
>ADD< TRAVASOL 5.5% W/O ELECTROLYTES IN PLASTIC CONTAINER
>ADD< TRAVENOL LABS 5.5%# N 18931
>ADD< TRAVASOL 8.5% W/O ELECTROLYTES IN PLASTIC CONTAINER
>ADD< TRAVENOL LABS 8.5%# N 18931

AMITRIPTYLINE HYDROCHLORIDE (PAGE 3-10)

TABLET; ORAL
AMITRIPTYLINE HCL
>ADD< BP PAR PHARMACEUTICAL 10MG# N 88697
>ADD< BP 25MG# N 88698
>ADD< BP 50MG# N 88699
>ADD< BP 75MG# N 88700
>ADD< BP 100MG# N 88701
>ADD< BP 150MG# N 88702
>ADD< BP SIDMAK LABORATORIES 10MG# N 88883
>ADD< BP 25MG# N 88884
>ADD< BP 50MG# N 88885
>ADD< BP 75MG# N 88886
>ADD< BP 100MG# N 88887
>ADD< BP 150MG# N 88888

>ADD< AMOXICILLIN; POTASSIUM CLAVULANATE (PAGE 3-13)

POWDER FOR RECONSTITUTION; ORAL
>ADD< AUGMENTIN '125'
>ADD< BEECHAM LABS/BEECHAM 125MG/5ML;
>ADD< EQ 31.25MG ACID/5ML# N 50575
>ADD< AUGMENTIN '250'
>ADD< BEECHAM LABS/BEECHAM 250MG/5ML;EQ 62.5MG ACID/5ML# N 50575

>ADD< TABLET; ORAL
>ADD< AUGMENTIN '250'
>ADD< BEECHAM LABS/BEECHAM 250MG;EQ 125MG ACID# N 50564
>ADD< AUGMENTIN '500'
>ADD< BEECHAM LABS/BEECHAM 500MG;EQ 125MG ACID# N 50564

AMPHETAMINE SULFATE (PAGE 3-13)

TABLET; ORAL
AMPHETAMINE SULFATE
>ADD< LANNETT 5MG# N 83901
>ADD< 10MG# N 83901

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE (PAGE 3-16)

CAPSULE; ORAL
PROPOXYPHENE HCL W/ ASPIRIN AND CAFFEINE
>ADD< AA CHELSEA LABORATORIES 388MG;32.4MG;65MG# N 85732

BETAMETHASONE DIPROPIONATE (PAGE 3-22)

OINTMENT; TOPICAL

> ADD >		ALPHATREX			
> ADD >	AB	SAVAGE LABS/BYK-GLDN	EQ 0.05% BASE¤	N 19143	
> ADD >		BETAMETHASONE DIPROPIONATE			
> ADD >	AB	E FOUGERA/BYK-GLDN	EQ 0.05% BASE¤	N 19141	
> ADD >	AB	PHARMADERM/BYK-GLDN	EQ 0.05% BASE¤	N 19140	
		DIPROLENE			
> ADD >	BX	SCHERING	EQ 0.05%	N 18741	
		DIPROSONE			
> ADD >	AB	SCHERING	EQ 0.05%	N 17691	

BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE (PAGE 3-24)

SYRUP; ORAL

		AMBENYL			
> ADD >	AA	MARION LABORATORIES	12.5MG/5ML;10MG/5ML	N 09319	
> ADD >		BROMANYL			
> ADD >	AA	NATL PHARM MFG/BARRE	12.5MG/5ML;10MG/5ML¤	N 88343	

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE MALEATE (PAGE 3-25)

ELIXIR; ORAL

> ADD >		BIPHETAP			
> ADD >		BAY LABORATORIES	4MG/5ML;25MG/5ML¤	N 88687	
> DLT >		/ELIXIR;DIMETAPP/			
> DLT >		/AH ROBINS/	/4MG/5ML;25MG/5ML/	/N 13087/	
> DLT >		/TABLET;CONTROLLED RELEASE;ORAL/			
> DLT >		/DIMETAPP			
> DLT >		/AH ROBINS/	/12MG;75MG/	/N 12436/	

CARBACHOL (PAGE 3-31)

> DLT >		/SOLUTION/DROPS;OPHTHALMIC/			
> ADD >		INJECTABLE; INJECTION			
> ADD >		CEFOXITIN SODIUM; DEXTROSE (PAGE 3-33)			
> ADD >		INJECTABLE; INJECTION			
> ADD >		MEFOXIN IN DEXTROSE 5% IN PLASTIC CONTAINER			
> ADD >		MS&D/MERCK	EQ 20MG BASE/ML;50MG/ML¤	N 50581	
> ADD >			EQ 40MG BASE/ML;50MG/ML¤	N 50581	
> ADD >		CEFOXITIN SODIUM; SODIUM CHLORIDE (PAGE 3-33)			
> ADD >		INJECTABLE; INJECTION			
> ADD >		MEFOXIN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER			
> ADD >		MS&D/MERCK	EQ 20MG BASE/ML;9MG/ML¤	N 50581	
> ADD >			EQ 40MG BASE/ML;9MG/ML¤	N 50581	

CHLORPROPAMIDE (PAGE 3-42)

TABLET; ORAL

		CHLORPROPAMIDE			
> ADD >	AB	CHELSEA LABORATORIES	100MG¤	N 86865	
> ADD >	AB	COLMED LABORATORIES	100MG¤	N 88708	
> ADD >	AB		250MG¤	N 88709	
> ADD >	AB	CORD LABORATORIES	100MG¤	N 88725	
> ADD >	AB		250MG¤	N 88726	
> ADD >	AB	DANBURY PHARMACAL	100MG¤	N 88852	
> ADD >	AB		250MG¤	N 88826	
> ADD >	AB	SUPERPHARM	100MG¤	N 88694	
> ADD >	AB		250MG¤	N 88695	

CHYMOPAPAIN (PAGE 3-43)

INJECTABLE; INJECTION

		CHYMODIACTIN			
> ADD >		SMITH LABORATORIES	4,000 UNITS/VIAL¤	N 18663	

CISPLATIN (PAGE 3-44)

INJECTABLE; INJECTION

> DLT >		/PLATINOL/			
> DLT >		/BRISTOL LABS/B-M/	/1MG/ML/	/N 18057/	
> DLT >			/50MG/VIAL/	/N 18057/	
> ADD >		PLATINOL-AQ			
> ADD >		BRISTOL LABS/B-M	0.5MG/ML	N 18057	

DESERPIDINE; METHYCLOTHIAZIDE (PAGE 3-52)

TABLET; ORAL

		ENDURONYL			
> ADD >	BP	ABBOTT LABORATORIES	0.25MG;5MG	N 12775	
		ENDURONYL FORTE			
> ADD >	BP	ABBOTT LABORATORIES	0.5MG;5MG	N 12775	
> ADD >		METHYCLOTHIAZIDE AND DESERPIDINE			
> ADD >	BP	BOLAR PHARMACEUTICAL	0.25MG;5MG¤	N 88486	
> ADD >	BP		0.5MG;5MG¤	N 88452	

DEXTROSE (PAGE 3-57)

INJECTABLE; INJECTION

> ADD >		DEXTROSE 38.5% IN PLASTIC CONTAINER			
> ADD >		ABBOTT LABORATORIES	38.5GM/100ML¤	N 18923	

DIETHYLPROPION HYDROCHLORIDE (PAGE 3-65)

TABLET; ORAL

		DIETHYLPROPION HCL			
> ADD >	AA	LEMMON	25MG¤	N 88642	

DISULFIRAM (PAGE 3-68)

TABLET; ORAL
DISULFIRAM

> ADD >	BX	PAR PHARMACEUTICAL	250MG*	N 88792	
> ADD >	BX		500MG*	N 88793	

DOXYCYCLINE HYCLATE (PAGE 3-70)

CAPSULE; ORAL
DOXYCYCLINE HYCLATE

> ADD >	AB	ZENITH LABORATORIES	EQ 50MG BASE*	N 62500	
> ADD >	AB		EQ 100MG BASE*	N 62500	

TABLET; ORAL
DOXYCYCLINE HYCLATE

> ADD >	AB	ZENITH LABORATORIES	EQ 100MG BASE*	N 62505	

DOXYLAMINE SUCCINATE (PAGE 3-70)

TABLET; ORAL
DECAPRYN

> ADD >	AA	MERRELL DOW/DOW CHEM	25MG	N 06412	

DOXYLAMINE SUCCINATE

> ADD >	AA	QUANTUM PHARMICS	25MG*	N 88603	

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE (PAGE 3-78)

TABLET; ORAL-21

> DLT >		/DEMULIN/			
> ADD >		DEMULIN 1/50-21			

TABLET; ORAL-28

> DLT >		/DEMULIN-28/			
> ADD >		DEMULIN 1/50-28			

FLUNISOLIDE (PAGE 3-82)

AEROSOL; INHALATION
BRONALIDE

> ADD >		SYNTEX LABS/SYNTEX	0.25MG/INH*	N 18340	

FLUOCINOLONE ACETONIDE (PAGE 3-82)

CREAM; TOPICAL
FLUOCINOLONE ACETONIDE

> ADD >	AT	PHARMAFAIR	0.01%*	N 88499	
> ADD >	AT		0.025%*	N 88506	

FLUONID

> ADD >	AT	HERBERT LABS/ALLERGN	0.025%*	N 87156	
> DLT >/	AT/	/MARION LABORATORIES//	0.01%/	/N 80434/	
> DLT >/	AT/		0.025%/	/N 80434/	

FLUOCINOLONE ACETONIDE (PAGE 3-82)

OINTMENT; TOPICAL
FLUONID

> ADD >	AT	HERBERT LABS/ALLERGN	0.025%*	N 87157	
> DLT >/	AT/	/MARION LABORATORIES//	0.025%/	/N 80433/	

SOLUTION; TOPICAL
FLUONID

> DLT >/	AT/	/MARION LABORATORIES//	0.01%/	/N 80432/	

> DLT > /FOLLICLE STIMULATING HORMONE; LUTEINIZING HORMONE/ (PAGE 3-85)
> ADD > MENOTROPINS; LUTEINIZING HORMONE (PAGE 3-122)

FUROSEMIDE (PAGE 3-86)

TABLET; ORAL
FUROSEMIDE

> ADD >	AB	CORD LABORATORIES	80MG*		N 18569

LASIX

> ADD >	AB	HOECHST-ROUSSEL	80MG		N 16273

HYDRALAZINE HYDROCHLORIDE (PAGE 3-95)

TABLET; ORAL
HYDRALAZINE HCL

> ADD >	AA	SUPERPHARM	10MG*		N 88787
> ADD >	AA		25MG*		N 88788
> ADD >	AA		50MG*		N 88789

HYDROFLUMETHIAZIDE (PAGE 3-104)

TABLET; ORAL
HYDROFLUMETHIAZIDE

> ADD >	AB	CHELSEA LABORATORIES	50MG*		N 88528

HYDROXYZINE HYDROCHLORIDE (PAGE 3-105)

TABLET; ORAL
HYDROXYZINE HCL

> ADD >	AB	PUREPAC/KALIPHARMA	10MG*		N 88120
> ADD >	AB		25MG*		N 88121
> ADD >	AB		50MG*		N 88122

INDOMETHACIN (PAGE 3-108)

CAPSULE; ORAL
INDOMETHACIN

> ADD >	AB	PAR PHARMACEUTICAL	25MG*		N 18829
> ADD >	AB		50MG*		N 18829

INDOMETHACIN (PAGE 3-108)

> ADD > SUPPOSITORY; RECTAL
> ADD > INDOCIN
> ADD > MS&D RES LABS/MERCK 50MG* N 17814

ISOETHARINE MESYLATE (PAGE 3-110)

AEROSOL; INHALATION
BRONKOMETER
> DLT > /BREON LABS/STERLING/ /0.61%/ /N 12339/
> ADD > BN BREON LABS/STERLING 0.34MG/INH N 12339
> ADD > ISOETHARINE MESYLATE
> ADD > BN NATL PHARM MFG/BARRE 0.34MG/INH* N 87858

KANAMYCIN SULFATE (PAGE 3-112)

INJECTABLE; INJECTION
KANTREX
> ADD > AP BRISTOL LABS/B-M EQ 75MG BASE/2ML* N 62564
> ADD > AP EQ 500MG BASE/2ML* N 62564
> ADD > AP EQ 1GM BASE/3ML* N 62564

> ADD > LABETALOL HYDROCHLORIDE (PAGE 3-113)

> ADD > INJECTABLE; INJECTION
> ADD > NORMODYNE
> ADD > SCHERING 5MG/ML* N 18687

> ADD > TABLET; ORAL
> ADD > NORMODYNE
> ADD > AB SCHERING 200MG* N 18686
> ADD > AB 300MG* N 18686
> ADD > AB 400MG* N 18686
> ADD > TRANDATE
> ADD > AB GLAXO 200MG* N 18716
> ADD > AB 300MG* N 18716
> ADD > AB 400MG* N 18716

LINDANE (PAGE 3-116)

LOTION; TOPICAL
LINDANE
> ADD > AT BAY LABORATORIES 1%* N 88190

SHAMPOO; TOPICAL
LINDANE
> ADD > AT BAY LABORATORIES 1%* N 88191

MEPERIDINE HYDROCHLORIDE (PAGE 3-122)

INJECTABLE; INJECTION
MEPERIDINE HCL
> ADD > AP ABBOTT LABORATORIES 10MG/ML* N 88432
> ADD > AP INTL MEDICATION SYS 10MG/ML N 86332

TABLET; ORAL
MEPERIDINE HCL
> ADD > AA BARR LABORATORIES 100MG* N 88640

MEPIVACAINE HYDROCHLORIDE (PAGE 3-123)

INJECTABLE; INJECTION
> ADD > POLOCAINE
> ADD > AP ASTRA PHARM PRODS 3%* N 88653

MEPROBAMATE (PAGE 3-123)

TABLET; ORAL
MEPROBAMATE
> DLT > /AA/ /WM MAST/ /200MG/ /N 86229/
> DLT > /AA/ /400MG/ /N 86229/

METHYCLOTHIAZIDE (PAGE 3-129)

TABLET; ORAL
METHYCLOTHIAZIDE
> ADD > AB CHELSEA LABORATORIES 2.5MG* N 88750
> ADD > AB 5MG* N 88724

MICONAZOLE NITRATE (PAGE 3-134)

SUPPOSITORY; VAGINAL
> ADD > MONISTAT 3
> ADD > ORTHO PHARMACEUTICAL 200MG* N 18888

> ADD > MORPHINE SULFATE (PAGE 3-135)

> ADD > INJECTABLE; INJECTION
> ADD > DURAMORPH PF
> ADD > ELKINS-SINN/AHROBINS 0.5MG/ML* N 18565
> ADD > 1MG/ML* N 18565

NAFCILLIN SODIUM (PAGE 3-135)

INJECTABLE; INJECTION
NAFCIL
> ADD > AP BRISTOL LABS/B-M EQ 10GM BASE/VIAL* N 62527
NALLPEN
> ADD > AP BEECHAM LABS/BEECHAM EQ 10GM BASE/VIAL N 61999

OXYPHENBUTAZONE (PAGE 3-143)

TABLET; ORAL
> ADD > OXYPHENBUTAZONE
> ADD > AB BOLAR PHARMACEUTICAL 100MG* N 88399
TANDEARIL
> ADD > AB GEIGY/CIBA-GEIGY 100MG N 12542

> ADD > PENTOXIFYLLINE (PAGE 3-149)

> ADD > TABLET, CONTROLLED RELEASE; ORAL
> ADD > TRENTAL
> ADD > HOECHST-ROUSSEL 400MG* N 18631

PROTAMINE SULFATE (PAGE 3-168)

INJECTABLE; INJECTION
PROTAMINE SULFATE
> ADD > UPJOHN 250MG/VIAL* N 07413

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE (PAGE 3-169)

SYRUP; ORAL
> ADD > TRIPROLIDINE HCL AND PSEUDOEPHEDRINE HCL
> ADD > AA PHARMAFAIR 30MG/5ML;1.25MG/5ML* N 88541

QUINIDINE SULFATE (PAGE 3-170)

TABLET; ORAL
CIN-QUIN
> DLT >/AB/ ROWELL LABORATORIES /200MG/ /N 87255/

RITODRINE HYDROCHLORIDE (PAGE 3-173)

INJECTABLE; INJECTION
YUTOPAR
> ADD > ASTRA PHARM PRODS 15MG/ML* N 18580

> ADD > SAFFLOWER OIL; SOYBEAN OIL (PAGE 3-174)

> ADD > INJECTABLE; INJECTION
> ADD > LIPOSYN II 10%
> ADD > ABBOTT LABORATORIES 5%;5%* N 18997
> ADD > LIPOSYN II 20%
> ADD > ABBOTT LABORATORIES 10%;10%* N 18991

SODIUM LACTATE (PAGE 3-178)

INJECTABLE; INJECTION
> ADD > SODIUM LACTATE IN PLASTIC CONTAINER
> ADD > ABBOTT LABORATORIES 5MEQ/ML* N 18947

SODIUM POLYSTYRENE SULFONATE (PAGE 3-179)

POWDER; ORAL, RECTAL
KAYEXALATE
> ADD > AA BREON LABS/STERLING 453.6GM/BOT N 11287
> ADD > SODIUM POLYSTYRENE SULFONATE
> ADD > AA BAY LABORATORIES 453.6GM/BOT* N 88786

SUSPENSION; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
> ADD > AA BAY LABORATORIES 15GM/60ML* N 88717

SOYBEAN OIL (PAGE 3-180)

INJECTABLE; INJECTION
> ADD > LIPOSYN III 10%
> ADD > AP ABBOTT LABORATORIES 10%* N 18969
> ADD > LIPOSYN III 20%
> ADD > AP ABBOTT LABORATORIES 20%* N 18970

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-183)

TABLET; ORAL
> ADD > SULFAMETHOXAZOLE & TRIMETHOPRIM
> ADD > AB HEATHER DRUG 400MG;80MG* N 18946
> ADD > AB 800MG;160MG* N 18946

SUCCINYLCHOLINE CHLORIDE (PAGE 3-181)

INJECTABLE; INJECTION
SUCCINYLCHOLINE CHLORIDE
> DLT >/AP/ /TRAVENOL LABS/ /500MG/VIAL/ /N 80263/
> ADD > > DLT >/AP/ /1GM/VIAL/ /N 80263/

TERBUTALINE SULFATE (PAGE 3-187)

> ADD > AEROSOL; INHALATION
> ADD > BRETHAIRE
> ADD > GEIGY/CIBA-GEIGY 0.2MG/INH* N 18762

THIORIDAZINE HYDROCHLORIDE (PAGE 3-192)

TABLET; ORAL
THIORIDAZINE HCL
> ADD > AB BARR LABORATORIES 150MG* N 88737

TRIAMCINOLONE ACETONIDE (PAGE 3-195)

OINTMENT; TOPICAL

			TRIAMCINOLONE ACETONIDE		
> ADD >	AT		PHARMADERM/BYK-GLDN	0.025%*	N 88692
> ADD >	AT			0.1%*	N 88690
> ADD >			TRYMEX		
> ADD >	AT		SAVAGE LABS/BYK-GLDN	0.025%*	N 88693
> ADD >	AT			0.1%*	N 88691

TRISULFAPYRIMIDINES (PAGE 3-200)

SUSPENSION; ORAL

> DLT >			/TRIPLE SULFOID/		
> DLT >	/AB/		/VALE CHEMICAL/	/500MG/5ML/	/N 80167/

VERAPAMIL HYDROCHLORIDE (PAGE 3-202)

TABLET; ORAL

> ADD >			CALAN		
> ADD >	AB		SEARLE/SEARLE PHARMS	80MG*	N 18817
> ADD >	AB			120MG*	N 18817
			ISOPTIN		
> ADD >	AB		KNOLL PHARMACEUTICAL	80MG	N 18593
> ADD >	AB			120MG	N 18593

> DLT > /ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;/
> DLT > /ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE;/
> DLT > /PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM;/
> DLT > /THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E/(PAGE AD2)

> DLT > /INJECTABLE; INJECTION/
> DLT > /M.V.I. PEDIATRIC/
> DLT > /USV PHARMACEUTICAL/ /80MG/VIAL;0.02MG/VIAL;0.001MG/VIAL;/
> DLT > /5MG/VIAL;0.01MG/VIAL;0.14MG/VIAL;/
> DLT > /17MG/VIAL;0.2MG/VIAL;/
> DLT > /EQ 1MG BASE/VIAL;1.4MG/VIAL;/
> DLT > /EQ 1.2MG BASE/VIAL;0.7MG/VIAL;/
> DLT > /7MG/VIAL/ /N.18920/

> DLT > /ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;/
> DLT > /ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE;/
> DLT > /HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE/
> DLT > /HYDROCHLORIDE; VITAMIN A; VITAMIN E/(PAGE AD2)
(SEE SPECIAL NOTE B.)

> DLT > /INJECTABLE; INJECTION/
> DLT > /M.V.I.-12/
> DLT > /USV PHARMACEUTICAL/ /100MG/VIAL;0.06MG/VIAL;0.005MG/VIAL;/
> DLT > /15MG/VIAL;0.005MG/VIAL;0.4MG/VIAL;/
> DLT > /40MG/VIAL;4MG/VIAL;3.6MG/VIAL;/
> DLT > /3MG/VIAL;1MG/VIAL;/
> DLT > /10.IU/VIAL/ /N.18933/

> DLT > /ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;/
> DLT > /ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE;/
> DLT > /HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE; VITAMIN/
> DLT > /A/(PAGE AD2)
(SEE SPECIAL NOTE B.)

> DLT > /INJECTABLE; INJECTION/
> DLT > /MVC PLUS/
> DLT > /ASCOT HOSP. PHARMS/ /10MG/ML;0.006MG/ML;0.5 USP/ML;/
> DLT > /1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML;/
> DLT > /0.4MG/ML;0.36MG/ML;0.3MG/ML;/
> DLT > /330.IU/ML/ /N.18439/

> DLT > /ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC/
> DLT > /ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN;/
> DLT > /THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN D; VITAMIN E/
> DLT > (PAGE AD2)
(SEE SPECIAL NOTE B.)

> DLT > /INJECTABLE; INJECTION/
> DLT > /M.V.C. 9+3/
> DLT > /LYPHOMED/ /20MG/ML;0.012MG/ML;0.001MG/ML;
> DLT > /3MG/ML;0.08MG/ML;8MG/ML;0.8MG/ML;/
> DLT > /0.72MG/ML;0.6MG/ML;660.IU/ML;/
> DLT > /40.IU/ML;2.IU/ML/ /N.18440/

> DLT > /ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; FOLIC ACID;/
> DLT > /NIACINAMIDE; PANTHENOL; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN;/
> DLT > /THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN D; VITAMIN E/
> DLT > (PAGE AD2)
(SEE SPECIAL NOTE B.)

> DLT > /INJECTABLE; INJECTION/
> DLT > /MULTIVITAMIN ADDITIVE/
> DLT > /ABBOTT LABORATORIES//100MG/5ML;0.06MG/5ML;0.005MG/5ML;
> DLT > /0.4MG/5ML;80MG/5ML;15MG/5ML;/
> DLT > /4.86MG/5ML;4.93MG/5ML;3.35MG/5ML;/
> DLT > /3300.IU/5ML;200.IU/5ML;/
> DLT > /10.IU/5ML/ /N.18223/

> DLT > /ASCORBIC ACID; BIOTIN; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE/
> DLT > /HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE/(PAGE AD2)
(SEE SPECIAL NOTE B.)

> DLT > /INJECTABLE; INJECTION/
> DLT > /BEROCCA C/
> DLT > /HOFFMAN-LA ROCHE/ /50MG/ML;0.1MG/ML;10MG/ML;40MG/ML;/
> DLT > /10MG/ML;5MG/ML;5MG/ML/ /N.06071/

> DLT > /BEROCCA C 500/
> DLT > /HOFFMAN-LA ROCHE/ /125MG/ML;10MG/ML;10MG/ML;40MG/ML/
> DLT > /10MG/ML;5MG/ML;5MG/ML/ /N.06071/

> DLT > /ASCORBIC ACID; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE/
> DLT > /HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE; VITAMIN A;/
> DLT > /VITAMIN D; VITAMIN E/(PAGE AD3)
(SEE SPECIAL NOTE B.)

> DLT > /INJECTABLE; INJECTION/
> DLT > /M.V.I./
> DLT > /USV PHARMACEUTICAL/ /50MG/ML;2.5MG/ML;10MG/ML;1.5MG/ML;
> DLT > /1MG/ML;5MG/ML;1,000.IU/ML;100.IU/ML;/
> DLT > /0.5MG/ML/ /N.08809/
> DLT > /100MG/ML;5MG/ML;20MG/ML;3MG/ML;/
> DLT > /2MG/ML;10MG/ML;2,000.IU/ML;/
> DLT > /200.IU/ML;1MG/ML/ /N.08809/

> DLT > /ISOSORBIDE DINITRATE/(PAGE AD5)
(ALL PRODUCTS - SEE SPECIAL NOTE B.)

> DLT > /TABLET; ORAL/
> DLT > /ISOSORBIDE DINITRATE/
> DLT > /BARR LABORATORIES/ /30MG/ /N.87564/

>_DLT_> /ISOSORBIDE DINITRATE/(PAGE AD5)
(ALL PRODUCTS - SEE SPECIAL NOTE B.)

>_DLT_> /TABLET;SUBLINGUAL/
>_DLT_> /ISOSORBIDE DINITRATE/
>_DLT_> /BARR LABORATORIES/ /10MG/ /N.87545/

>_DLT_> /TABLET;CONTROLLED RELEASE;ORAL/
>_DLT_> /ISOCHRON/
>_DLT_> /FOREST LABORATORIES//20MG/ /N.88428/

NITROGLYCERIN (PAGE AD7)

>_DLT_> /CAPSULE;CONTROLLED RELEASE;ORAL/
(ALL PRODUCTS - SEE SPECIAL NOTE B.)

>_DLT_> /TABLET;CONTROLLED RELEASE;ORAL/
(ALL PRODUCTS - SEE SPECIAL NOTE B.)

CURRENT STATUS - INEFFECTIVE

>_ADD_> BEROCCA C HOFFMANN-LA ROCHE
>_ADD_> ASCORBIC ACID; BIOTIN; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE
>_ADD_> HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE

>_ADD_> BEROCCA C 500 HOFFMANN-LA ROCHE
>_ADD_> ASCORBIC ACID; BIOTIN; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE
>_ADD_> HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE

>_ADD_> DIMETAPP AH ROBINS
>_ADD_> BROMPHENIRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE;
>_ADD_> PHENYLPROPANOLAMINE HYDROCHLORIDE

>_ADD_> ELIXIR DIMETAPP AH ROBINS
>_ADD_> BROMPHENIRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE;
>_ADD_> PHENYLPROPANOLAMINE HYDROCHLORIDE

>_ADD_> TUSS-ORNADE SK&F LABORATORIES
>_ADD_> CARAMIPHEN EDISYLATE; CHLORPHENIRAMINE MALEATE;
>_ADD_> ISOPROPAMIDE IODIDE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CURRENT STATUS - EFFECTIVENESS TO BE DETERMINED

>_ADD_> M.V.I. PEDIATRIC USV PHARMACEUTICAL
>_ADD_> ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;
>_ADD_> ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE;
>_ADD_> PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM;
>_ADD_> THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E

SUBSCRIPTION FORM

APPROVED PRESCRIPTION DRUG PRODUCTS
WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS
5TH EDITION (1984)

MAIL TO:

DATE:

Superintendent of Documents
Government Printing Office
Washington, DC 20402
(202) 783-3238

PURCHASER:

SHIP TO:
(If different than purchaser)

CONTACT:

TELEPHONE (Include Area Code)

METHOD OF PAYMENT

[ ] Charge my GPO Account No. _____
[ ] Purchase Order Number _____
[ ] Check enclosed for $_____
(Make check payable to Superintendent of Documents)

AUTHORIZING SIGNATURE

DATE:

DESCRIPTION	QUANTITY	UNIT PRICE	TOTAL PRICE
The 5th Edition will be published in October, 1984. Subscription includes the Approved Prescription Drug Products List and monthly Cumulative Supplements.			
DOMESTIC		@ $66.00	$
FOREIGN		@ $82.50	$
ENTER TOTAL			$