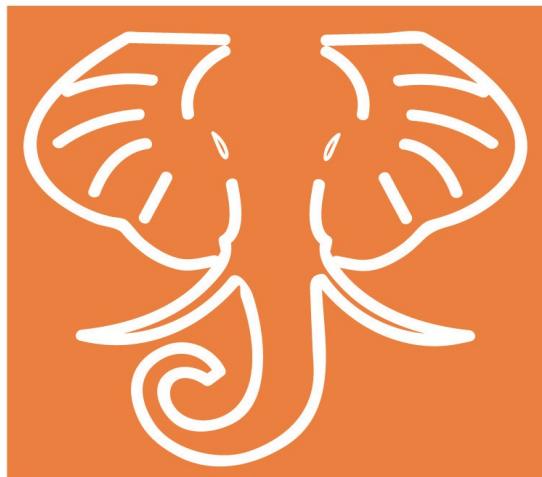


Approved prescription drug products with therapeutic equivalence evaluations.

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

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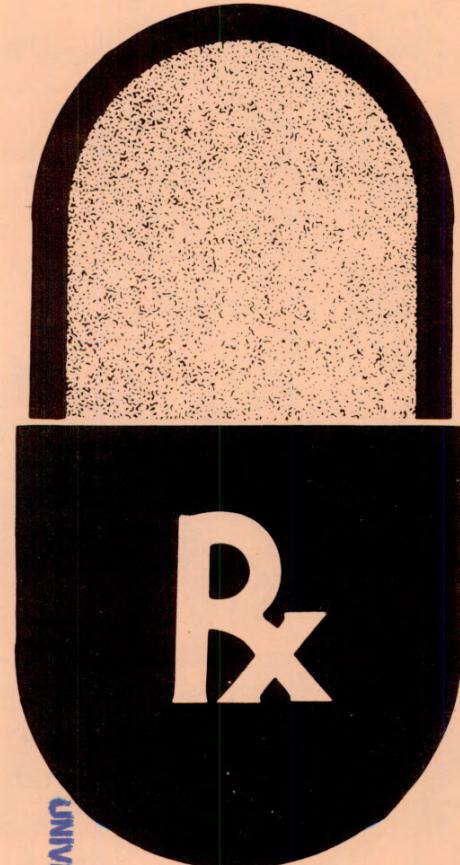
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**CUMULATIVE
SUPPLEMENT 1
AUG '83 - SEP '83**

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**APPROVED
PRESCRIPTION
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

4TH EDITION



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**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, 4th 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, 1983. 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 >DELE> (DELETE) to the left of the line containing the overstruck print. The >DELE> 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.

III. 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. 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 '83. 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. Also not included in the counts are those duplicate products of a given applicant whose only distinguishing characteristics are items such as package size, inactive ingredient(s), color and alternate manufacturing sites. These various counts are excluded because the Drug Product List itself excludes products from these categories.

A. COUNTS CUMULATIVE BY QUARTERS

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

JULY '83 (BASELINE)

AUG '83

SEPT '83

CUMULATIVE

CATEGORIES COUNTED

DRUG PRODUCTS LISTED	6679	
SINGLE SOURCE	1908 (28.6%)	
MULTISOURCE (1)	4771 (71.4%)	
THEAPEUTICALLY EQUIVALENT	3804 (57.0%)	
NOT THEAPEUTICALLY EQUIVALENT	957 (14.3%)	
EXCEPITIONS (2)	10 (0.1%)	
NEW MOLECULAR ENTITIES APPROVED	-	
NUMBER OF APPLICANTS	304	

B. ACTIVITY FOR SUPPLEMENT NUMBER 1

DRUG PRODUCTS ADDED:	71	61	71	132
NEWLY APPROVED	70	58	70	128
DESI EFFECTIVE	0	0	0	0
REMARKETED	1	1	1	1
WITHDRAWN APPROVAL	0	0	0	0
RX TO OTC SWITCH	0	0	0	0
DISCONTINUED MARKETING	10	26	10	36
NET GAIN IN DRUG PRODUCTS	61	35	61	96
SINGLE SOURCE PRODUCTS APPROVED	8	19	8	27
MULTISOURCE DRUG PRODUCTS APPROVED	63	42	63	105
NEW MOLECULAR ENTITIES APPROVED	0	1	0	1
AS THE ENTITY	0	0	0	0
AS A SALT, ESTER OR DERIVATIVE	0	0	0	0
FROM MORE THAN ONE APPLICANT	1	1	1	1
(1) THERAPEUTIC EQUIVALENCE EVALUATIONS PROVIDED ONLY FOR MULTISOURCE PRODUCTS (i.e., AVAILABLE				
(2) AMINO ACID-CONTAINING PRODUCTS OF VARYING COMPOSITION (SEE PAGE 1-5 OF THE LIST)				

APPROVED PRESCRIPTION DRUG PRODUCTS
DRUG PRODUCT LIST
CUMULATIVE SUPPLEMENT NUMBER 1 / AUGUST '83 & SEPTEMBER '83

AMINOPHYLLINE (PAGE 3-8)

> DLT > /LIQUID; ORAL/
> ADD > SOLUTION; ORAL
> ADD > AMINOPHYLLINE
> ADD > AA ROXANE LABORATORIES 105MG/5MLX

TABLET; ORAL

AMINOPHYLLINE

> ADD > BD BARR LABORATORIES 100MGX
> ADD > BD 200MGX

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-15)

> ADD > TABLET; ORAL
> ADD > ASPIRIN AND CAFFEINE W/ BUTALBITAL
> ADD > PUREPAC/KALIPHARMA 325MG;50MG;40MGX

ASPIRIN; BUTALBITAL; CAFFEINE; PHENACETIN (PAGE 3-15)

TABLET; ORAL

> DLT > AB / A.P.C. W/ BUTALBITAL / PUREPAC/KALIPHARMA/ 200MG;50MG;60MG;130MG/

ASPIRIN; CAFFEINE; DIHYDROCODEINE BITARTRATE (PAGE 3-15)

> ADD > CAPSULE; ORAL
> ADD > SYNALGOS-DC
> ADD > IVES LABS/AMHO 356.4MG;30MG;16MGX

ASPIRIN; CAFFEINE; PHENACETIN; PROPOXYPHENE HYDROCHLORIDE (PAGE 3-15)

CAPSULE; ORAL

PROPOXYPHENE COMPOUND 65

> DLT > AB / TOLNE PAULSEN / 227MG;32.4MG;162MG;65MG/
> DLT > /REPRO COMPOUND 65/
> DLT > AB / REPD PROVIDENT LABS / 227MG;32.4MG;162MG;65MG/
> DLT > /SK-65 COMPOUND/
> DLT > AB / SK&F LABORATORIES / 227MG;32.4MG;162MG;65MG/

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

CAPSULE; ORAL

DARVON COMPOUND-65

> ADD > AA ELI LILLY INDSTRS/PR 389MG;32.4MG;65MG
> ADD > SK-65 COMPOUND 389MG;32.4MG;65MGX
> ADD > AA SK&F LABORATORIES 389MG;32.4MG;65MGX

> ADD > ASPIRIN; CARISOPRODOL (PAGE 3-16)

> ADD > TABLET; ORAL
> ADD > SOMA COMPOUND
> ADD > WALLACE PHARMS/C-W 325MG;200MGX

> ADD > ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE (PAGE 3-16)

> ADD > TABLET; ORAL
> ADD > SOMA COMPOUND W/ CODEINE
> ADD > WALLACE PHARMS/C-W 325MG;200MG;16MGX

> ADD > ASPIRIN; HYDROCODONE BITARTRATE (PAGE 3-16)

> ADD > TABLET; ORAL
> ADD > VICOPRIN
> ADD > KNOLL PHARMACEUTICAL 500MG;5MGX

BACAMPICILLIN HYDROCHLORIDE (PAGE 3-18)

TABLET; ORAL
SPECTROBID
> ADD > PFIZER LABS/PFIZER 800MGX

BETAMETHASONE VALERATE (PAGE 3-21)

CREAM; TOPICAL
BETAMETHASONE VALERATE
> ADD > AB E FOUGERA/BYK-GLDN EQ 0.1% BASEX
> ADD > AB PHARMADERM/BYK-GLDN EQ 0.1% BASEX
> ADD > BETATREX
> ADD > AB SAVAGE LABS/BYK-GLDN EQ 0.1% BASEX

LOTION; TOPICAL
BETAMETHASONE VALERATE
> ADD > AB E FOUGERA/BYK-GLDN EQ 0.1% BASEX
> ADD > AB PHARMADERM/BYK-GLDN EQ 0.1% BASEX
> ADD > BETATREX
> ADD > AB SAVAGE LABS/BYK-GLDN EQ 0.1% BASEX
> ADD > AB VALISONE
SCHERING EQ 0.1% BASE

OINTMENT; TOPICAL
BETAMETHASONE VALERATE
> ADD > AB E FOUGERA/BYK-GLDN EQ 0.1% BASEX
> ADD > AB PHARMADERM/BYK-GLDN EQ 0.1% BASEX
> ADD > BETATREX
> ADD > AB SAVAGE LABS/BYK-GLDN EQ 0.1% BASEX
> ADD > AB VALISONE
SCHERING EQ 0.1% BASE

DEXAMETHASONE (PAGE 3-49)

> ADD > SOLUTION; ORAL
> ADD > DEXAMETHASONE
> ADD > ROXANE LABORATORIES 0.5MG/5MLx
> ADD > DEXAMETHASONE INTENSOL
> ADD > ROXANE LABORATORIES 0.5MG/0.5MLx

TABLET; ORAL
DECADRON
> ADD > BP MS&D/MERCK 6MG
DEXAMETHASONE
> ADD > BP ROXANE LABORATORIES 6MGx
> ADD > 1MGx

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-50)

> DLT > INJECTABLE; INJECTION
/HEXA'DROL' PHOSPHATE/
HEXDROL
> ADD > AP ORGANON/AKZONA EQ 6MG PHOSPHATE/ML
> ADD > EQ 20MG PHOSPHATE/ML

DEXTROSE; DOPAMINE HYDROCHLORIDE (PAGE 3-53)

INJECTABLE; INJECTION
/DOPAMINE HCL IN DEXTROSE 5%/
> ADD > DOPAMINE HCL
> ADD > AP ABBOTT LABORATORIES 5GM/100ML;80MG/100ML
> ADD > AP 5GM/100ML;160MG/100ML
> ADD > DOPAMINE HCL IN PLASTIC CONTAINER
> ADD > AP ABBOTT LABORATORIES 5GM/100ML;80MG/500MLx
> ADD > AP 5GM/100ML;160MG/100MLx
> ADD > 5GM/100ML;320MG/100MLx

DIETHYLPROPION HYDROCHLORIDE (PAGE 3-59)

TABLET; ORAL
DIETHYLPROPION HCL
> ADD > AA CAMALL 25MGx

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-61)

CAPSULE; ORAL
SK-DIPHENHYDRAMINE
> DLT > AA SK & F LABORATORIES /25MG/
ELIXIR; ORAL
> DLT > /SK-DIPHENHYDRAMINE/
> DLT > AA /SK & F LABORATORIES/ /12.5MG/5ML/

DISULFIRAM (PAGE 3-63)

TABLET; ORAL
DISULFIRAM
> ADD > BX CHELSEA LABORATORIES 250MGx
> ADD > BX 500MGx

DOXYCYCLINE HYCLATE (PAGE 3-64)

CAPSULE; ORAL
DOXYCYCLINE HYCLATE
> ADD > AB CHELSEA LABORATORIES EQ 50MG BASE

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE (PAGE 3-66)

INJECTABLE; INJECTION
> ADD > LIDOCATON
> ADD > AP PHARMATON/SZ 0.01MG/ML;22x
> ADD > AP 0.02MG/ML;22x

ERYTHROMYCIN (PAGE 3-67)

OINTMENT; OPHTHALMIC
> ADD > ERYTHROMYCIN
> ADD > AT E FOUGERA/BYK-GLDN 5MG/GMx
> ADD > AT PHARMADERM/BYK-GLDN 5MG/GMx
> ADD > AT ILOTYCIN
DISTA PRODS/LILLY 5MG/GM

GENTAMICIN SULFATE (PAGE 3-79)

CREAM; TOPICAL
> ADD > GENTAFAIR
> ADD > AT PHARMAFAIR EQ 1MG BASE/GMx
> ADD > GENTAMICIN SULFATE
> ADD > AT NMC LABORATORIES EQ 1MG BASE/GMx

INJECTABLE; INJECTION
GENTAMICIN SULFATE

ABBOTT LABORATORIES
> ADD > AP EQ 60MG BASE/100MLx
> ADD > AP EQ 70MG BASE/100MLx
> ADD > AP EQ 80MG BASE/100MLx
> ADD > AP EQ 90MG BASE/100MLx
> ADD > AP EQ 100MG BASE/100MLx
> ADD > AP EQ 1.2MG BASE/MLx
> ADD > AP EQ 1.4MG BASE/MLx
> ADD > AP EQ 1.6MG BASE/MLx
> ADD > AP EQ 1.8MG BASE/MLx
> ADD > AP EQ 2MG BASE/MLx
> ADD > AP EQ 10MG BASE/MLx
> ADD > AP EQ 40MG BASE/MLx
> ADD > AP EQ 60MG BASE/MLx

LYPHO-MED

INJECTABLE: INJECTION (PAGE 3-79)

> ADD > AP ABOTT LABORATORIES EG 60MG BASE/100ML
> ADD > AP EG 70MG BASE/100ML
> ADD > AP EG 80MG BASE/100ML
> ADD > AP EG 90MG BASE/100ML
> ADD > AP EG 1.2MG BASE/ML
> ADD > AP EG 1.4MG BASE/ML
> ADD > AP EG 1.8MG BASE/ML
> ADD > AP EG 2.0MG BASE/ML
> ADD > AP EG 2.5MG BASE/ML
> ADD > AT HYDROCORTISONE
> ADD > AT MERCON INDUSTRIES 12m
> DLT > AT /MERCON INDUSTRIES /6.52/
> DLT > AT /DELLACRETT/ LOTION; TOPICAL
> ADD > AT OINTMENT; TOPICAL
> ADD > AT HYDROCORTISONE
> ADD > AT NEO-OTOSOL-HG
> ADD > AT CARTRIDGE-GELODAU LABS 12;EG 3.5MG BASE/ML;10,000 UNITS/ML
> DLT > /AT/ /AUTOTRINIS/ INJECTION
> DLT > /AT/ /AUTOTRINIS/ INJECTION
HYDROCORTISONE: NEOMYCIN SULFATE (PAGE 3-92)

GONADOTROPIN, CHORIONIC (PAGE 3-81)

> DLT > /AT/ /FRAKE-PATTS/M./ /5,666 UNITS/ML/
> DLT > /AT/ /INJECTION
HYDROCORTISONE: POLYMYXIN B SULFATE (PAGE 3-92)

HOMATROPINE METHYLBRONIDE (PAGE 3-86)

> DLT > /AT/ /HOMATPIN-10/ /MISSION PHARMACEUTICAL 10MG
> DLT > /AT/ /MISSION PHARMACEUTICAL 10MG
HYDRAZINE HYDROCHLORIDE (PAGE 3-86)

HYDROCORTISONE ACETATE (PAGE 3-93)

CREAM; TOPICAL
> DLT > /AT/ /INGRAM PHARM
> DLT > /AT/ /HYDROCORTISONE Acetate 0.5%
LOTION; TOPICAL
> DLT > /AT/ /INGRAM PHARM
> DLT > /AT/ /HYDROCORTISONE Acetate 0.5%
DRCOPORT
> DLT > /AT/ INGRAHAM PHARM
> DLT > /AT/ /HYDROCORTISONE Acetate 0.5%
DRCOPORT
HYDROCORTISONE VALERATE (PAGE 3-95)

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE (PAGE 3-89)

TABLET; ORAL SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE
> ADD > AB PUREPAC/KALIPHARMA 25MG;25MG
> ADD > AB MESTOOD PHARMS 0.2%
> ADD > AB OINTMENT; TOPICAL
> ADD > AB MESTOOD PHARMS 0.2%
HYDROXYZINE HYDROCHLORIDE (PAGE 3-96)

HYDROXYZINE (PAGE 3-90)

CREAM; TOPICAL
> ADD > AT BAY LABORATORIES 12m
> ADD > AT HYDROXYZINE HCl
> ADD > AB DANBURRY PHARMACAL 10MG
> ADD > AB 25MG
> ADD > AB 2.5%

HYDROXYZINE PAMOATE (PAGE 3-96)

CAPSULE; ORAL

HYDROXYZINE PAMOATE

> ADD > AB VANGARD LABS/MJM EQ 25MG HCLx
> ADD > AB EQ 50MG HCLx

IMIPRAMINE HYDROCHLORIDE (PAGE 3-97)

TABLET; ORAL

> DLT > /ANTIPRESS/
> DLT > /B/P/ LEMMON/ /25MG/
> DLT > /THAVATE/
> DLT > /AB/ AH. ROBINS/ /25MG/
> DLT > /AB/ /50MG/

ISOETHARINE HYDROCHLORIDE (PAGE 3-100)

SOLUTION; INHALATION

ISOETHARINE HCL

> ADD > AN INT'L MEDICATION SYS 0.167%
> ADD > AN ROXANE LABORATORIES 0.167%*
> ADD > AN TRAVENOL LABS 0.25%*

KANAMYCIN SULFATE (PAGE 3-102)

INJECTABLE; INJECTION

KANAMYCIN SULFATE

> ADD > AP INT'L MEDICATION SYS EQ 500MG BASE/2MLx
> ADD > AP EQ 1GM BASE/3MLx
> ADD > AP KANTREX
> DLT > /AP/ BRISTOL LABS/B-M/ /75MG/2ML/
> DLT > /AP/ /500MG/2ML/
> DLT > /AP/ /1GM/3ML/
> ADD > AP BRISTOL LABS/B-M EQ 75MG BASE/2ML
> ADD > AP EQ 500MG BASE/2ML
> ADD > AP EQ 1GM BASE/3ML

LIDOCAINE HYDROCHLORIDE (PAGE 3-104)

INJECTABLE; INJECTION

LIDOCATON

> ADD > AP PHARMATON/SZ 22%

METHYLTESTOSTERONE (PAGE 3-121)

TABLET; Buccal/Sublingual

METHYLTESTOSTERONE

> DLT > /B/P/ TØRNÉ, PÅULSEN/ /10MG/

METRONIDAZOLE (PAGE 3-122)

INJECTABLE; INJECTION

METRO I.V. IN PLASTIC CONTAINER

> ADD > AP AM MCGAW/AM HOSP 500MG/100MLx

TABLET; ORAL

METRONIDAZOLE

> ADD > AB PAR PHARMACEUTICAL 250MGx
> ADD > AB 500MGx

NANDROLONE DECANOATE (PAGE 3-125)

INJECTABLE; INJECTION

NANDROLONE DECANOATE

> ADD > MAURRY BIOLOGICAL 100MG/MLx

NITROGLYCERIN (PAGE 3-128)

INJECTABLE; INJECTION

NITRONAL

> ADD > AP G POHL-BOSKAMP 5MG/MLx
> ADD > 1MG/MLx

TRIDIL

> ADD > AM CRITICAL CARE/AHS 0.5MG/MLx

OXTRIPTYLLINE (PAGE 3-131)

TABLET, ENTERIC COATED; ORAL

CHOLEDYL

> ADD > AB PARKE-DAVIS/W-L 100MG
> ADD > AB 200MG
> ADD > AP OXTRIPTYLLINE
> ADD > AB BOLAR PHARMACEUTICAL 100MGx
> ADD > AB 200MGx

OXYTETRACYCLINE HYDROCHLORIDE (PAGE 3-132)

CAPSULE; ORAL

> DLT > /DLT/ /PARKE-DAVIS/W-L/ /EQ 250MG BASE/

PENICILLIN V POTASSIUM (PAGE 3-135)

POWDER FOR RECONSTITUTION; ORAL

> DLT > /DLT/ /UP JOHN/ /EQ 125MG BASE/5ML/
> DLT > /AA/ /UP JOHN/ /EQ 250MG BASE/5ML/

DRUGS PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 1 / AUGUST '83 & SEPTEMBER '83

PHENIDOMETRAZINE TARTRATE (PAGE 3-138)

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL

PSEUDOEPHEDRINE
SYRUP; ORAL

> ADD > AA FERNDALE LABS 35MGS

PHENIDOMETRAZINE TARTRATE

> ADD > AA/ /TRIAD/ BAY LABORATORIES 30MGS/ML; 1.25MGS/ML

PHENIDOMETRAZINE TARTRATE (PAGE 3-139)

CAPSULE; ORAL

ADRIPEK-P LEMMON 37.5MGS

POTASSIUM CHLORIDE (PAGE 3-143)

> ADD > AA CHELSEA LABORATORIES 60MGS; 2.5MGS

GUINIDINE SULFATE

TABLET; ORAL

> ADD > AA/ /TRIAD/ BAY LABORATORIES 30MGS/ML; 1.25MGS/ML

POTASSIUM CHLORIDE (PAGE 3-147)

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

> ADD > AA/ /TRIAD/ BAY LABORATORIES 30MGS/ML

GUINIDINE SULFATE (PAGE 3-157)

TABLET; ORAL

> ADD > AA VITARINE SULFATE

GUINIDINE SULFATE (PAGE 3-147)

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPTHALMIC

> ADD > AA/ /HYGEL/ HESCH/ /6.5Z PHOSPHATE

SELENIUM SULFIDE LOTION/SHAMPOO; TOPICAL

> ADD > AI BAY LABORATORIES 2.5Z

SILVER SULFADIAZINE

TABLET; ORAL

> ADD > AA CREAM; TOPICAL

SILVER SULFADIAZINE (PAGE 3-161)

PROCATINAMIDE HYDROCHLORIDE

CAPSULE; ORAL

PROCAINANESTHESIC

> ADD > AA/ /B/ PARK-E-DAVIS/W-L 150MGS

CREAM; TOPICAL

SILVER SULFADIAZINE

TABLET; ORAL

> ADD > AA/ /STODSTECKL; ALPH/ (PAGE 3-161)

SILVER SULFADIAZINE (PAGE 3-161)

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL

> ADD > AA RICHLYN LABORATORIES 65MGS

SOMATROPIN (PAGE 3-165)

INJECTABLE; INJECTION

> ADD > AA/ /SELACRIN 2 SERONO LABS

ASELLACRIN 10

2 IU/VIAL

PROPOLITHOURACIL

TABLET; ORAL

PROPOLITHOURACIL

> ADD > AA/ /W/LAN PHARM/ 50MGS

DLT > /BD/ /W/LAN PHARM/

SPIRONOLACTONE (PAGE 3-166)

TABLET; ORAL

SPIRONOLACTONE> ADD > AB PUREPAC/KALIPHARMA 25MGXTESTOSTERONE (PAGE 3-173)

INJECTABLE; INJECTION

TESTOSTERONE> ADD > CARTER-GLOGAU LABS 50MG/MLXTETRACYCLINE HYDROCHLORIDE (PAGE 3-174)

TABLET; ORAL

PANMYCIN> DLT > AB UPJOHN /250MG/SUMYCIN> DLT > AB ER SQUIBB AND SONS 250MGTHEOPHYLLINE (PAGE 3-176)CAPSULE, CONTROLLED RELEASE; ORAL
SOMOPHYLLIN-CRT> ADD > BC FISONS 100MG
> ADD > THEO-24
> ADD > BC SEARLE/SEARLE PHARMS 100MGX
> ADD > 200MGX
> ADD > 300MGX

SOLUTION; ORAL

THEOLAIR> ADD > AA RIKER LABS/3M 80MG/15ML
> ADD > THEOPHYLLINE
> ADD > AA ROXANE LABORATORIES 80MG/15MLXTABLET, CONTROLLED RELEASE; ORAL
THEOCONTIN> ADD > BC PURDUE FREDERICK 200MGX
> ADD > BC THEO-DUR
> ADD > BC KEY PHARMACEUTICALS 200MGTHIORDIAZINE HYDROCHLORIDE (PAGE 3-178)

CONCENTRATE; ORAL

THIORDIAZINE HCL> ADD > AA NATL PHARM MFG/BARRE 100MG/MLXTHIORDIAZINE HYDROCHLORIDE (PAGE 3-178)

TABLET; ORAL

MELLARIL> ADD > AB SANDOZ PHARMS/SANDOZ 100MG
THIORDIAZINE HCL
> ADD > AB BOLAR PHARMACEUTICAL 10MGX
> ADD > AB 100MGX
> ADD > AB CORD LABORATORIES 10MGX
> ADD > AB 15MGX
> ADD > AB 25MGX
> ADD > AB 50MGXTIMOLOL MALEATE (PAGE 3-179)

TABLET; ORAL

BLOCADREN> ADD > MS&D/MERCK 5MGTRIAMCINOLONE ACETONIDE (PAGE 3-180)

CREAM; TOPICAL

TRIAMCINOLONE ACETONIDE> ADD > AT BAY LABORATORIES 0.025%X
> ADD > AT 0.1%X
> ADD > AT 0.5%X

OINTMENT; TOPICAL

TRIAMCINOLONE ACETONIDE> ADD > AT BAY LABORATORIES 0.025%X
> ADD > AT 0.1%X
> ADD > AT 0.5%XTRISULFAPYRIMIDINES (PAGE 3-185)

SUSPENSION; ORAL

> DLT > /TRISEN/
> DLT > AB /BEECHAM LABS/BEECHAM//500MG/5ML/
> DLT > /TRISURED/
> DLT > AB /REID-PROVIDENT LABS//500MG/5ML/

TABLET; ORAL

> DLT > /TRIPLE SULFA #2/
> DLT > AB //ZENITH LABORATORIES//500MG/TROPICAMIDE (PAGE 3-186)

SOLUTION/DROPS; OPHTHALMIC

> ADD > MYDRIAFAIR
> ADD > AT PHARMAFAIR 0.5%
> ADD > AT 1/2%

8

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 1 / AUGUST '83 & SEPTEMBER '83

> DLT > /tribaminate/ (PAGE 3-186)

> DLT > /tributramine/ /50mg/ /50mg/
> DLT > /tributramine/ /50mg/
> DLT > /capsule; oral/

VITAMIN A PALMITATE (PAGE 3-186)

CAPSULE: ORAL
> DLT > /solusyn/a/ /500mg/ /500mg/
> DLT > /solusyn/a/ /500mg/

ADDENDUM
DESI PENDING LIST - 'EXEMPT' (COURT ORDER) CATEGORY
CUMULATIVE SUPPLEMENT NUMBER 1 / AUGUST '83 & SEPTEMBER '83

> DLT > /CARMIPHEN 'ÉNISYLATE' 'CHLORPHÉNTRAMINE' 'MÂLEATE' 'ISOPROPANIDE'/
> DLT > /IOTIDES 'PHENYLPROPANOLAMINE' 'HYDROCHLORIDE' (PAGE AD3)

> DLT > /CAPSULE; 'CONTROLLED RELEASE'; 'ORAL'/
> DLT > /TUSS-ORNADE/
> DLT > /SK&F. LABORATORIES/ /20MG;30MG;2.5MG;50MG/

> DLT > /SOLUTION; 'ORAL'/
> DLT > /TUSS-ORNADE/
> DLT > /SK&F. LABORATORIES/ /5MG;5ML;2MG;5ML;0.75;5ML;15MG;5ML/

DIPYRIDAMOLE (PAGE AD4)

TABLET; ORAL
DIPYRIDAMOLE
> ADD > ASCOT HOSP PHARMS 50MG

CURRENT STATUS - INFFECTIVE

DESI PENDING LIST - OTHER THAN EXEMPT, (COURT ORDER) CATEGORY
CUMULATIVE SUPPLEMENT NUMBER 1 / AUGUST '63 & SEPTEMBER '63

>DLT> /CARBODIYL; PENOBARBITAL; SODIUM/
>DLT> CLISTIN BA/; MONTELL PHARM/
>DLT> /CARBONXAMINE MALEATE/
>DLT> /DHETHIDENE MALEATE/
>DLT> /DHETHIDENE, MALEATE/
>ADD> TUSS-ORNADE SK&F LABORATORIES
>ADD> CARAPHENE EDISYLATE; CHLORPHENIRAMINE HYDROCHLORIDE
>ADD> ISOPROPAMIDE IODIDE; PHENYLPROPANOLAMINE HYDROCHLORIDE

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