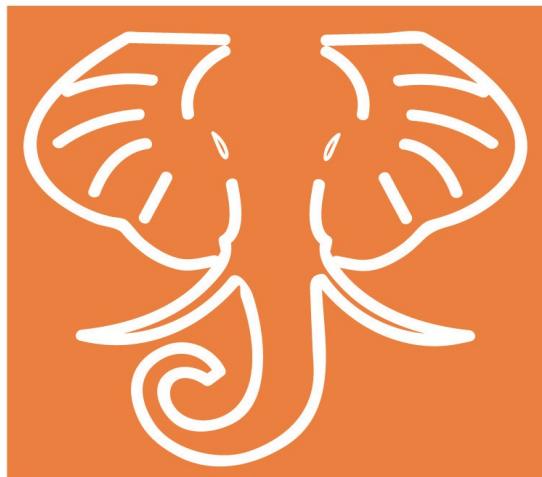


## **Approved prescription drug products with therapeutic equivalence evaluations.**

[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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# CUMULATIVE SUPPLEMENT 5 AUG'83 - JAN'84

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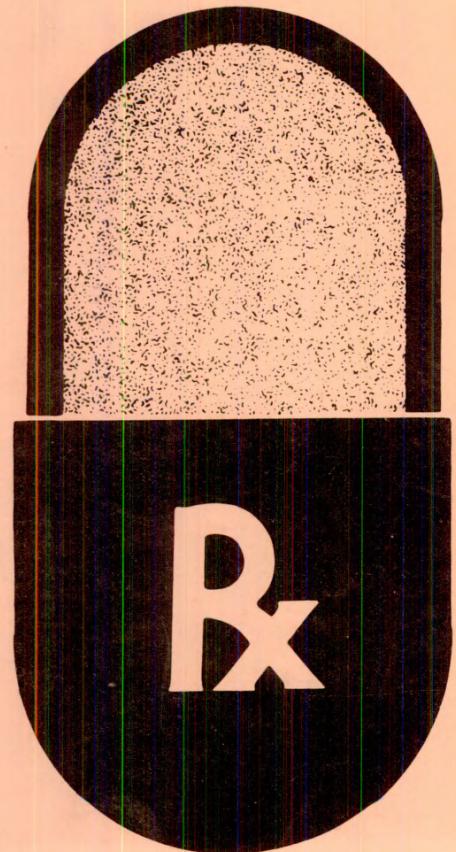
## 4<sup>TH</sup> EDITION

# APPROVED PRESCRIPTION DRUG PRODUCTS

WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS

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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, 4<sup>th</sup> 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 >~~DLI~~> (DELETE) to the left of the line containing the overstruck print. The >~~DLI~~> 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. PRODUCTS CONTAINING PHENACETIN

The October 5, 1983, Federal Register (48FR45466) provides the following Summary: "The Food and Drug Administration (FDA) is withdrawing approval of new drug applications or parts of new drug applications that provide for drug products containing phenacetin, except for those drug products that are the subject of a hearing request. The basis of the withdrawal is phenacetin's high potential for misuse and its unfavorable benefit-to-risk ratio when incorporated in analgesic combinations which are then subject to excessive chronic use." The effective date of this withdrawal order is November 4, 1983.

Because the subject products are no longer approved, the cumulative supplement has identified them by deleting the applicable active ingredient headers followed by a reference to this Special Note.

### C. THEOPHYLLINE CONTROLLED RELEASE

Two controlled released theophylline tablets are listed as therapeutically equivalent (AB). Because one of these products was recently approved for once-daily dosing, it is important to be aware that the therapeutic equivalence rating was made on the basis of 12-hour dosing intervals. The rating does not apply to once-daily dosing. To date, no data have been submitted upon which the Agency can base a therapeutic equivalence determination among any of the approved theophylline controlled-release products when dosed once-daily.

**B. APPLICANT (NAME) CHANGES**

Because it is not practical to identify in the cumulative supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name, the cumulation of these transfers and name changes will be identified in this Special Notes section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the cumulative supplement. The current list of applicant holder changes follows.

**APPLICANT (NAME) CHANGES**

<u>Former Applicant (Name)</u>	<u>New Applicant (Name)</u>	<u>New Abbreviated Name</u>
STERI-MED INC SUB KETCHUM LABORATORIES INC	QUANTUM PHARMICS LTD	QUANTUM PHARMICS
KETCHUM LABORATORIES INC PROFESSIONAL PHARMACAL DIV STERI-MED INC	OPTOPICS LABORATORIES CORP	OPTOPICS LABS

The reader should consult the above cumulative list each month to become aware of such transfers and changes. By referring to the Applicant Index in the 4th Edition of the APDP, the transferred products can be identified. The reader might wish to flag these products in the List as a reminder that the applicant has been changed.

This report provides counts in several categories from the list composed of domestic drugs and cosmetics under section 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 ingredients of a given applicant whose only distinguishing characteristics are items such as package size, products of a given applicant who are marketed by different manufacturers, and alterations of existing products.

Drug Product Count

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.

New Molecular Entity

For this report, a drug product is the representation in the Drug Product List of an active moiety (which includes molecular entities and 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.

Drug Product Definition

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 discontinuation of marketing of products; and (3) trends in approval of products as either single source or multi-source to different categories of changes from prescription to over-the-counter status.

USE OF REPORT

The following report provides summary counts derived from the current product information in the Drug Product List and the current cumulative counts appear in two sections. Section A. refers to the products in the List and Section B. to products in the following section. Each three-month period following July 1, 1983. Section A. therefore will provide baseline and quarterly activity.

## DESCRIPTION OF REPORT

## REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

A. COUNTS CUMULATIVE BY QUARTERS

<u>CATEGORIES COUNTED</u>	<u>JULY '83 (BASELINE)</u>	<u>OCT '83</u>
DRUG PRODUCTS LISTED	6679	6783
SINGLE SOURCE	1908 (28.6%)	1915 (28.2%)
MULTISOURCE <sup>(1)</sup>	4771 (71.4%)	4868 (71.8%)
THERAPEUTICALLY EQUIVALENT	3804 (57.0%)	3891 (57.4%)
NOT THERAPEUTICALLY EQUIVALENT	957 (14.3%)	967 (14.3%)
EXCEPTIONS <sup>(2)</sup>	10 ( 0.1%)	10 ( 0.1%)
NEW MOLECULAR ENTITIES APPROVED	-	2
NUMBER OF APPLICANTS	304	310

B. ACTIVITY FOR SUPPLEMENT NUMBER 5

	<u>NOV '83</u>	<u>DEC '83</u>	<u>JAN '84</u>	<u>CUMULATIVE</u>
DRUG PRODUCTS ADDED:				
NEWLY APPROVED	43	39	32	114
DESI EFFECTIVE	0	0	0	0
REMARKETED	0	0	0	0
DRUG PRODUCTS REMOVED:	36	6	2	44
WITHDRAWN APPROVAL	27	0	0	27
RX TO OTC SWITCH	0	0	0	0
DISCONTINUED MARKETING	9	6	2	17
NET GAIN IN DRUG PRODUCTS	7	33	30	70
SINGLE SOURCE PRODUCTS APPROVED	10	9	18	37
MULTISOURCE DRUG PRODUCTS APPROVED	33	30	14	77
NEW MOLECULAR ENTITIES APPROVED:	3	2	1	6
AS THE ENTITY	3	1	1	5
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	0	1	0	1

(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)



APPROVED PRESCRIPTION DRUG PRODUCTS  
DRUG PRODUCT LIST  
CUMULATIVE SUPPLEMENT NUMBER 5 / AUGUST '83 - JANUARY '84

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

CAPSULE; ORAL  
ACETAMINOPHEN W/ CODEINE #3  
**AA** LEMON 300MG;30MGX  
TYLENOL W/ CODEINE NO. 3  
**AA** MCNEIL PHARM 300MG;30MG

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 3-2)

TABLET; ORAL  
CODACET  
**AA** HALSEY DRUG 325MG;5MGX  
/PERCOCET-5/  
PERCOCECT

/ACÉTAMINOPHÈNE; PHÉNACÉTIN; PHÉNYLPROPANOLAMINE HYDROCHLORIDE/  
/PHENYLTOLOXAMINE CITRATE (PAGE 3-2)

(ALL PRODUCTS - SEE SPECIAL NOTE B.)

ALBUMIN, IODINATED, I-131, SERUM (PAGE 3-4)

INJECTABLE; INJECTION  
/RADIOIODINATED SERUM ALBUMIN (HUMAN) (HSA) I-131/  
/MALLINCKRODT/ 6.7-250 UCI/ML

AMINO ACIDS (PAGE 3-6)

> ADD >  
 INJECTABLE; INJECTION  
 NEOPHAM 6.5%  
 CUTTER-VITRUM 6.5%X

AMINOPHYLLINE (PAGE 3-8)

Liquid; Oral/  
 SOLUTION; ORAL  
AMINOPHYLLINE  
**AA** BAY LABORATORIES 105MG/5MLX  
**AA** ROXANE LABORATORIES 105MG/5MLX

TABLET; ORAL  
AMINOPHYLLINE  
**BD** BARR LABORATORIES 100MGX  
**BD** 200MGX  
**AB** VANGARD LABS/MMM 100MGX  
**AB** 200MGX

/AMPHETAMINE SULFATE (PAGE 3-13)

CAPSULE; CONTROLLED RELEASES; ORAL  
/BENZEDRINE/  
/SK&F LABORATORIES/ 15MG/  
/TABLET; ORAL/  
/BENZEDRINE/  
/SK&F LABORATORIES/ 5MG/  
10MG/

AMPICILLIN TRIHYDRATE; PROBENECID (PAGE 3-13)

POWDER FOR RECONSTITUTION; ORAL  
POLYCILLIN-FRB  
**AB** BRISTOL LABS/B-M EQ 3.5GM BASE/BOT;1GM/BOT  
PROBAMPACIN  
**AB** BIOCRAFT LABS EQ 3.5GM BASE/BOT;1GM/BOT

ASPIRIN; BUTALBITAL (PAGE 3-15)

TABLET; ORAL  
 AXOTAL  
 ADRIA LABORATORIES 650MG;50MGX

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-15)

TABLET; ORAL  
ASPIRIN AND CAFFEINE W/ BUTALBITAL  
**AB** PUREPAC/KALIPHARMA 325MG;50MG;60MGX  
BUTALBITAL W/ ASPIRIN & CAFFEINE  
**> ADD >** **AB** BOOTS LABORATORIES 325MG;50MG;60MGX

/ASPIRIN; BUTALBITAL; CAFFEINE; PHÉNACÉTIN/ (PAGE 3-15)

(ALL PRODUCTS - SEE SPECIAL NOTE B.)

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

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

/ASPIRIN; CAFFEINE; PHÉNACÉTIN; PROPOXYPHÉNÉ HYDROCHLORIDE/  
(PAGE 3-15)

(ALL PRODUCTS - SEE SPECIAL NOTE B.)



BROMPHENIRAMINE MALEATE (PAGE 3-22)

TABLET; ORAL

BROMPHENIRAMINE MALEATE/BOLAR PHARMACEUTICAL/ 6MG/BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE (PAGE 3-23)

INJECTABLE; INJECTION

MARGAINE HCL W/ EPINEPHRINEAP BREON LABS/STERLING 0.5%;0.0091MG/MLAP 0.75%;0.0091MG/MLSENSOCATNEAP ASTRA HOSP PHARM 0.5%;0.0091MG/MLXAP 0.75%;0.0091MG/MLXBUTABARBITAL SODIUM (PAGE 3-24)

CAPSULE; ORAL

BUTICAPS

> DLT > /MCNEIL LABORATORIES/ 15MG/  
> DLT > 30MG/  
> DLT > 50MG/  
> DLT > 100MG/  
> ADD > WALLACE LABS/C-W 15MG  
> ADD > 30MG  
> ADD > 50MG  
> ADD > 100MG

ELIXIR; ORAL

BUTABARBITAL SODIUM//WESTWARD/ 33MG/5ML/  
BUTALAN  
/LANNETT 33.3MG/5ML/CAFFEINES CARISOPROUDOL'S CODEINE PHOSPHATE'S PHENACETIN/ (PAGE 3-24)/TABLETS; ORAL//SOMA COMPOUND W/ CODEINE//WALLACE PHARMS/C-W/ 32MG;200MG;160MG;160MG//CAFFEINES CARISOPROUDOL'S PHENACETIN/ (PAGE 3-25)

(ALL PRODUCTS - SEE SPECIAL NOTE B.)

CAFFEINE; ERGOTAMINE TARTRATE (PAGE 3-25)

SUPPOSITORY; RECTAL

CAFERGOTBR SANDOZ PHARMS/SANDOZ 100MG;2MGWIGRAINEBR ORGANON/AKZONA 100MG;2MGXCALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE (PAGE 3-26)

SOLUTION; INTRAPERITONEAL

DIALYTE CONCENTRATE W/ DEXTROSE 30% IN PLASTIC CONTAINER  
AM MCGAW/AM HOSP 510MG/100ML;30GM/100ML;  
200MG/100ML;9.2GM/100ML;  
9.6GM/100MLX  
510MG/100ML;30GM/100ML;  
200MG/100ML;9.4GM/100ML;  
11GM/100MLXDIALYTE CONCENTRATE W/ DEXTROSE 50% IN PLASTIC CONTAINER  
AM MCGAW/AM HOSP 510MG/100ML;50GM/100ML  
200MG/100ML;9.2GM/100ML;  
9.6GM/100MLX  
510MG/100ML;50GM/100ML;  
200MG/100ML;9.4GM/100ML;  
11GM/100MLXCALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-26)

SOLUTION; INTRAPERITONEAL

DIALYTE W/ DEXTROSE 2.5% IN PLASTIC CONTAINER  
AM MCGAW/AM HOSP 26MG/100ML;2.5GM/100ML;  
15MG/100ML;560MG/100ML;390MG/100MLXCALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE (PAGE 3-27)

INJECTABLE; INJECTION

ISOLYTE E IN PLASTIC CONTAINERAM MCGAW/AM HOSP 35MG/100ML;30MG/100ML;  
74MG/100ML;640MG/100ML;  
500MG/100ML;74MG/100MLXCEFTIZOXIME SODIUM (PAGE 3-30)

INJECTABLE; INJECTION

CEFIZOXSK&F LABORATORIESEQ 1GM BASE/VIALX  
EQ 2GM BASE/VIALX



CORTICOTROPIN (PAGE 3-43)

INJECTABLE; INJECTION  
/REPOSITORY CORTICOTROPIN/  
 /BC/ /WYETH LABS/AMHO/ /40 UNITS/ML/  
 /BC/ /80 UNITS/ML/

CYANOCOBALAMIN (PAGE 3-44)

INJECTABLE; INJECTION  
DODECAMIN  
 AP MAURRY BIOLOGICAL 1MG/ML  
REDISOL  
 /AP/ MS&D/MERCK /0.1MG/ML/  
SYTOBEX  
 /AP/ PARKE DAVIS/W-L /0.1MG/ML/

CYCLOSPORINE (PAGE 3-46)

INJECTABLE; INJECTION  
 SANDIMMUNE  
 SANDOZ PHARMS/SANDOZ 50MG/ML

SOLUTION; ORAL  
 SANDIMMUNE  
 SANDOZ PHARMS/SANDOZ 100MG/ML

CYPROHEPTADINE HYDROCHLORIDE (PAGE 3-46)

TABLET; ORAL  
CYPROHEPTADINE HCL  
 AA DURAMED PHARMS 6MGX

DAPSONE (PAGE 3-47)

TABLET; ORAL  
AVLOSULFON  
 /BP/ /AYERST. LABS/AMHO/ /25MG/  
 /BP/ /100MG/  
 DAPSONE  
 /BP/ JACOBUS PHARM 25MG  
 /BP/ 100MG

DESOXIMETASONE (PAGE 3-49)

OINTMENT; TOPICAL  
 TOPICORT  
 HOECHST-ROUSSEL 0.25%X

DEXAMETHASONE (PAGE 3-49)

SOLUTION; ORAL  
DEXAMETHASONE  
 ROXANE LABORATORIES 0.5MG/5MLX  
DEXAMETHASONE INTENSOL  
 ROXANE LABORATORIES 0.5MG/0.5MLX

TABLET; ORAL  
DECADRON  
 BP MS&D/MERCK 6MG  
DEXAMETHASONE  
 BP PAR PHARMACEUTICAL 6MGX  
 BP ROXANE LABORATORIES 6MGX  
 1MGX

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-50)

INJECTABLE; INJECTION  
DEXAMETHASONE  
 > ADD > AP INVENEX LABS/DEXTER EQ 6MG PHOSPHATE/MLX  
 > ADD > AP /HEXA'DROL PHOSPHATE/ EQ 10MG PHOSPHATE/MLX  
HEXA'DROL  
 AP ORGANON/AKZONA EQ 6MG PHOSPHATE/ML  
 EQ 20MG PHOSPHATE/ML

SOLUTION/DROPS; OPHTHALMIC  
DEXAIR  
 AT PHARMAFAIR EQ 0.1% PHOSPHATEX  
DEXAMETHASONE SODIUM PHOSPHATE  
 AT BARNES-HIND PHARMS EQ 0.1% PHOSPHATE

DEXTROSE; DOPAMINE HYDROCHLORIDE (PAGE 3-53)

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

DEXTROSE; HEPARIN SODIUM (PAGE 3-53)

INJECTABLE; INJECTION  
 HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC  
 CONTAINER  
 TRAVENOL LABS 5GM/100ML;4,000 UNITS/100MLX



ERYTHROMYCIN (PAGE 3-67)

OINTMENT; OPHTHALMIC  
**ERYTHROMYCIN**  
 AT E FOUGERA/BYK-GLDN 5MG/GMX  
 AT PHARMADERM/BYK-GLDN 5MG/GMX  
 AT **ILOTYCIN**  
 AT DISTA PRODS/LILLY 5MG/GM

ETOPOSIDE (PAGE 3-74)

INJECTABLE; INJECTION  
**VEPESID**  
 BRISTOL LABS/B-M 20MG/MLX

FENTANYL CITRATE (PAGE 3-75)

INJECTABLE; INJECTION  
**SUBLIMAZE**  
 /JANSEN PHARMA/ /0.05MG/ML/  
 JANSSEN PHARMA EQ 0.05MG BASE/ML

FLUOCINOLONE ACETONIDE (PAGE 3-76)

CREAM; TOPICAL  
**FLUCET**  
 > ADD > AT NMC LABORATORIES 0.01%  
 > ADD > AT 0.025%  
 > ADD > AT

SOLUTION; TOPICAL  
**FLUOCINOLONE ACETONIDE**  
 > ADD > AT BAY LABORATORIES 0.01%

FLUOXYMESTERONE (PAGE 3-77)

TABLET; ORAL  
**FLUOXYMESTERONE**  
 BP BOLAR PHARMACEUTICAL 2MGW  
 BP 5MGW  
 BP 10MGW  
 BP COLMED LABORATORIES 10MGW

FUROSEMIDE (PAGE 3-79)

INJECTABLE; INJECTION  
**FUROSEMIDE**  
 AP NATCON CHEMICAL 10MG/MLX

FUROSEMIDE (PAGE 3-79)

TABLET; ORAL  
**FUROSEMIDE**  
 > ADD > AB BARR LABORATORIES 40MGX  
 AB ROXANE LABORATORIES 20MGX  
 AB 40MGX  
 AB ZENITH LABORATORIES 20MGX  
 AB 40MGX

GENTAMICIN SULFATE (PAGE 3-79)

CREAM; TOPICAL  
**SENTAFAIR**  
 AT PHARMAFAIR  
**GENTAMICIN SULFATE**  
 AT NMC LABORATORIES EQ 1MG BASE/GMX

INJECTABLE; INJECTION  
**GENTAMICIN SULFATE**  
 AP ABBOTT LABORATORIES EQ 60MG BASE/100MLX  
 AP EQ 70MG BASE/100MLX  
 AP EQ 80MG BASE/100MLX  
 AP EQ 90MG BASE/100MLX  
 AP EQ 100MG BASE/100MLX  
 AP EQ 1.2MG BASE/MLX  
 AP EQ 1.4MG BASE/MLX  
 AP EQ 1.6MG BASE/MLX  
 AP EQ 1.8MG BASE/MLX  
 AP EQ 2MG BASE/MLX  
 AP EQ 10MG BASE/MLX  
 AP EQ 40MG BASE/MLX  
 AP EQ 40MG BASE/MLX  
 AP LYPHO-MED  
**GENTAMICIN SULFATE IN PLASTIC CONTAINER**  
 AP ABBOTT LABORATORIES EQ 60MG BASE/100MLX  
 AP EQ 70MG BASE/100MLX  
 AP EQ 80MG BASE/100MLX  
 AP EQ 90MG BASE/100MLX  
 AP EQ 100MG BASE/100MLX  
 AP EQ 1.2MG BASE/MLX  
 AP EQ 1.4MG BASE/MLX  
 AP EQ 1.6MG BASE/MLX  
 AP EQ 1.8MG BASE/MLX  
 AP EQ 2MG BASE/MLX

ointment; topical  
**GENTAMICIN SULFATE**  
 AT THAMES PHARMACAL EQ 1MG BASE/GMX

SODIUMTROPONIC, CHLORIONIC (PAGE 3-61) HYDROCHLORIDE (PAGE 3-66)

AB PURÉPAC/KALDTHARMA SÜDWEST

HYDROCHLOROTHIAZIDE: DESERETINE (PAGE 3)

NATCON CHEMICAL 3,000 UNITS/ML\*

HEPARIN SODIUM 5000 UNITS IN 500 MILLILITERS 0.45% LIQUID INJEC-

HEPRIN SODIUM 25,000 UNITS IN 500 ML BOTTLES 1,000 UNITS IN 100 ML BOTTLES

ABERDEEN LABORATORIES 10,000 UNITS/100ML  
SERUM 100ML BOTTLES 100'S  
100'S/CS

MANUFACTURERS' MATERIALS PRICE INDEX (Base = 100)

ATI 2.57x /SEEDS - TELLS 3.6/

HYDROCORTISONE (PAGE 3-90)

/SOLUTION/DROPS; OPHTHALMIC/  
/OTC/  
/UP JOHN/ 10.2%

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-92)

SOLUTION/DROPS; OTIC  
NEO-OTOSOL-HC  
AT CARTER-GLOGAU LABS 12;EQ 3.5MG BASE/ML;10,000 UNITS/ML

HYDROCORTISONE ACETATE (PAGE 3-93)

CREAM; TOPICAL

/AT/ /JOHNE PAULSEN/ 1/2

LOTION; TOPICAL

/DRICORT/  
/AT/ INGRAM PHARM 0.5%  
/HYDROCORTISONE ACETATE/  
/AT/ /JOHNE PAULSEN/ 0.5%

/SUSPENSION/DROPS; OPHTHALMIC; OTIC/  
/HYDROCORTISONE/  
/MSD/MERCK/ 1.5%

HYDROCORTISONE VALERATE (PAGE 3-95)

OINTMENT; TOPICAL

WESTCORT  
WESTWOOD PHARMS 0.2%

HYDROFLUMETHIAZIDE; RESERPINE (PAGE 3-95)

TABLET; ORAL  
HYDROFLUMETHIAZIDE AND RESERPINE  
BP COLMED LABORATORIES 50MG;0.125MG

> ADD > HYDROMORPHONE HYDROCHLORIDE (PAGE 3-95)

> ADD > INJECTABLE; INJECTION  
> ADD > DILAUDID-HP  
> ADD > KNOLL PHARMACEUTICAL 10MG/ML

HYDROXYZINE HYDROCHLORIDE (PAGE 3-96)

TABLET; ORAL  
HYDROXYZINE HCL  
AB BARR LABORATORIES 10MG  
AB DANBURY PHARMACAL 10MG  
AB 25MG  
AB 50MG

HYDROXYZINE PAMOATE (PAGE 3-96)

CAPSULE; ORAL  
HYDROXYZINE PAMOATE  
AB VANGARD LABS/MIL 50 MG HCLX  
AB 25 MG HCLX

IMIPRAMINE HYDROCHLORIDE (PAGE 3-97)

TABLET; ORAL  
/ANTIPRESS/  
/BP/ /LEMON/ 15MG  
/IMAVATE/  
/AH/ /AH. ROBINS/ 25MG  
/AB/ IMIPRAMINE HCL  
AB PAR PHARMACEUTICAL 10MG  
AB 25MG  
AB 50MG

ISOETHARINE HYDROCHLORIDE (PAGE 3-100)

SOLUTION; INHALATION  
ISOETHARINE HCL  
AN INT'L MEDICATION SYS 0.167Z  
AH ROXANE LABORATORIES 0.167Z  
AN TRAVENOL LABS 0.25Z

ISONIAZID (PAGE 3-101)

SYRUP; ORAL  
ISONIAZID  
AA CAROLINA MED PRODS 50MG/5ML  
AA RINIFON  
HOFFMANN-LA ROCHE 50MG/5ML

KANAMYCIN SULFATE (PAGE 3-102)

INJECTABLE; INJECTION  
KANAMYCIN SULFATE  
AP INT'L MEDICATION SYS EQ 500MG BASE/2MLX  
AP EQ 1GM BASE/5MLX



OXTRIPTYLLINE (PAGE 3-131)

TABLET, ENTERIC COATED; ORAL  
**CHOLEDYL**  
 AB PARKE-DAVIS/W-L 100MG  
 AB 200MG  
**OXTRIPTYLLINE**  
 AB BOLAR PHARMACEUTICAL 100MG  
 AB 200MG

OXYTETRACYCLINE HYDROCHLORIDE (PAGE 3-132)

CAPSULE; ORAL  
**OXYTAC**  
 /AB/ PARKE-DAVIS/W-L /EQ 250MG BASE/

PENICILLIN V POTASSIUM (PAGE 3-135)

POWDER FOR RECONSTITUTION; ORAL  
**PENICILLIN VK**  
 /AB/ UP JOHN /EQ 125MG BASE/5ML/  
 /AB/ /EQ 250MG BASE/5ML/

PHENDIMETRAZINE TARTRATE (PAGE 3-138)

TABLET; ORAL  
**PHENDIMETRAZINE TARTRATE**  
 AA FERNDALE LABS 35MG

PHENTERMINE HYDROCHLORIDE (PAGE 3-139)

CAPSULE; ORAL  
**ADIPEX-P**  
 AA LEMMON 37.5MG  
**DAPEX-37.5**  
 AA FERNDALE LABS 37.5MG  
**PHENTERMINE HCL**  
 AA CAMALL 37.5MG

POTASSIUM CHLORIDE (PAGE 3-143)

INJECTABLE; INJECTION  
**POTASSIUM CHLORIDE**  
 /AB/ TRAVENOL LABS /1MEG/ML/  
 /AP/ /3MEG/ML/  
 /AP/ /4MEG/ML/

PREDNISOLONE (PAGE 3-145)

TABLET; ORAL  
**PREDNISOLONE**  
 /BX/ REXALL DRUG/ /5MG/

PREDNISOLONE ACETATE (PAGE 3-146)

INJECTABLE; INJECTION  
**PREDNISOLONE**  
 /BP/ FERNDALE LABS /25MG/ML/

PREDNISOLONE SODIUM PHOSPHATE (PAGE 3-147)

SOLUTION/DROPS; OPHTHALMIC  
**PREDNISOLONE**  
 /AT/ MSD/MERCK/ /EQ 0.5% PHOSPHATE/  
 > DLT > /INFLAMASE/  
 > DLT > AT /SNAP/PR/COOPERS/ /EQ 0.1% BASE/  
 > ADD >  
 > ADD > AT COOPERVISION PHARMS EQ 0.1% PHOSPHATE  
**INFLAMASE MILD**  
 > DLT > AT /INFLAMASE FORTE/  
 > ADD > AT COOPERVISION PHARMS EQ 0.8% PHOSPHATE  
**INFLAMASE FORTE**  
 > DLT > AT /SNAP/PR/COOPERS/ /EQ 0.8% BASE/  
 > ADD > AT COOPERVISION PHARMS EQ 0.9% PHOSPHATE  
**METRETON**  
 /AT/ SCHERING EQ 0.5% PHOSPHATE  
**PREDAIR FORTE**  
 > ADD > AT PHARMAFAIR EQ 0.9% PHOSPHATE  
**PREDNISOLONE SODIUM PHOSPHATE**  
 > DLT > AT /BARNES-HIND PHARMS/ /0.125%/  
 > DLT >  
 > ADD > AT BARNES-HIND PHARMS EQ 0.11% PHOSPHATE  
 > ADD > AT EQ 0.9% PHOSPHATE  
 > DLT > AT /MAURRY BIOLOGICAL/ /EQ 0.12 BASE/  
 > DLT > AT /EQ 0.82 BASE/  
 > ADD > AT MAURRY BIOLOGICAL EQ 0.11% PHOSPHATE  
 > ADD > AT EQ 0.9% PHOSPHATE

PREDNISONE (PAGE 3-147)

TABLET; ORAL  
**PREDNISONE**  
 BX DURAMED PHARMS 5MG  
 BX 10MG  
 BX 20MG

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-149)

CAPSULE; ORAL  
**PROCAN**  
 /AB/ PARKE-DAVIS/W-L /250MG/  
 /AB/ /500MG/

DRUGS PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 5 / AUGUST '63 - JANUARY '64

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PROPAANTHELINE BROMIDE (PAGE 3-153)

PROPOXYFENE HYDROCHLORIDE (PAGE 3-15)

RICHARDIN LABORATORIES LTD.

**PROPTILITHOUREACIL** /prəp'tilɪθu'reeəkəl/  
**MYLAN PHARMS** /mɪ'lan, fə'hɑrmz/

(PAGE 3-155)

SELLENTRUM SULFIDE (PAGE 3-161)

**BAy LABORATORIES**

SILVER SULFADIAZINE (PAGE 3-161)

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**SILVER. SILVERLINE**

STEROIDAL ALPINE (PAGE 3-161)

/fʌnɪʃɪŋ/ /fɪlɪt̩ɪt̩ɪv/ /fɪlɪt̩ɪt̩ɪv/

INJECTABLES; INJECTION  
SODIUM CHLORIDE 3% IN PLASTIC CONTAINER

**CHELSEA LABORATORIES 60MG:2  
INTERLOCUTION HEL AND PEGOOL**

GOUTIENDINE GLUCONATE (PAGE 3-157)

TABLE I, CONTINUED RELEASE, CARBONATE GLUCONATE

GUANIDINE SULFATE (PAGE 3-157)

VITARINE/WEST CHEM 300MS

BOUTIN POLYSTYRENE SOLE-FOONATE (PAGE 3-165)

SUSPENSION: ORAL, RECTAL  
SODIUM POLYSTYRENE SULFONATE

CAROLINA MED PRODS 1500/600L

GUNIDINE SULFATE (PAGE 3-157)

**GUTHIDINE SULFATE**

SOMATROPIN (PAGE 3-165)

INJECTABLE; INJECTION  
 ASELLACRIN 2  
 SERONO LABS 2 IU/VIAL\*

/ASELLACRIN/  
 ASELLACRIN 10

SPIRONOLACTONE (PAGE 3-166)

TABLET; ORAL  
SPIRONOLACTONE  
 AB PUREPAC/KALIPHARMA 25MG\*

SULFACETAMIDE SODIUM (PAGE 3-167)

SOLUTION/DROPS; OPHTHALMIC  
SODIUM SULFACETAMIDE  
 /AT/ /KETCHUM LABORATORIES/ 1%/  
 /AT/ /30%/  
 AT OPTOPICS LABS 10%  
 AT 30%  
 SULFACEL-15  
 /AT/ /STERI-NEP/KETCHUM/ /15%/  
 AT OPTOPICS LABS 15%  
 SULFAIR FORTE  
 AT PHARMAFAIR 30%

TESTOSTERONE (PAGE 3-173)

INJECTABLE; INJECTION  
 TESTOSTERONE  
 CARTER-GLOGAU LABS 50MG/ML\*

TETRACYCLINE HYDROCHLORIDE (PAGE 3-174)

CAPSULE; ORAL  
TETRACYCLINE HCL  
 /AB/ /LEMON/ /250MG/  
 TABLET; ORAL  
PANMYCIN  
 /AB/ UPJOHN /250MG/  
 /AB/ SUMYCIN  
 ER SQUIBB AND SONS 250MG

THALLOUS CHLORIDE, TL-201 (PAGE 3-175)

INJECTABLE; INJECTION  
THALLOUS CHLORIDE TL 201  
 MEDI-PHYSICS 2MCI/ML

THEOPHYLLINE (PAGE 3-176)

(FOR CONTROLLED RELEASE PRODUCTS - SEE SPECIAL NOTE C.)

CAPSULE, CONTROLLED RELEASE; ORAL  
SOMOPHYLLIN-CRT  
 BC FISONS 100MG  
 THEO-24  
 BC SEARLE/SEARLE PHARMS 100MG\*  
 200MG\*  
 300MG\*

ELIXIR; ORAL  
ELIXOMIN  
 > ADD > AA HR CENCI LABS 80MG/15ML\*

SOLUTION; ORAL  
THEOLAIR  
 AA RIKER LABS/3M 80MG/15ML  
THEOPHYLLINE  
 AA ROXANE LABORATORIES 80MG/15ML\*  
 TABLET, CONTROLLED RELEASE; ORAL  
THEOCONTIN  
 BC PURDUE FREDERICK 200MG\*  
 /400MG/  
THEO-DUR  
 BC KEY PHARMACEUTICALS 200MG  
 UNIPHYL  
 PURDUE FREDERICK 400MG

THIORIDAZINE HYDROCHLORIDE (PAGE 3-178)

CONCENTRATE; ORAL  
THIORIDAZINE HCL  
 AA CORD LABORATORIES 50MG/ML  
 100MG/ML\*  
 AA NATL PHARM MFG/BARRE 100MG/ML\*

TABLET; ORAL  
MELLARIL  
 AB SANDOZ PHARMS/SANDOZ 100MG  
THIORIDAZINE HCL  
 AB BARR LABORATORIES 10MG\*  
 AB 15MG\*  
 AB 25MG\*  
 AB 50MG\*  
 AB 100MG\*  
 AB BOLAR PHARMACEUTICAL 10MG\*  
 AB 100MG\*  
 AB CORD LABORATORIES 10MG\*  
 AB 15MG\*  
 AB 25MG\*  
 AB 50MG\*



ADDENDUM  
DESI PENDING LIST - 'EXEMPT' (COURT ORDER) CATEGORY  
CUMULATIVE SUPPLEMENT NUMBER 5 / AUGUST '83 - JANUARY '84

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

INJECTABLE; INJECTION  
MVC PLUS

ASCOT HOSP PHARMS 10MG/ML; 0.006MG/ML; 0.5 UGM/ML;  
1.5MG/ML; 20 IU/ML; 0.04MG/ML;  
4MG/ML; 0.4MG/ML; 0.36MG/ML;  
0.3MG/ML; 330 IU/ML; 1 IU/ML

/MÉTHANDROSTÉNOLONE/ (PAGE AD6)

/TABLET; ORAL/  
/METHANDROSTENOLONE/  
/PAR PHARMACEUTICAL/ 1/2.5MG/  
/5MG/

/BROMPHÉNÉTRAMINE MALEATE; PHÉNYLEPHRINE HYDROCHLORIDE/  
/PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE AD3)

/ELIXIR; ORAL/  
/ELIXIR PINETAPP/  
/AH. ROBINS/ 4MG/5ML; 5MG/5ML; 5MG/5ML/  
  
/TABLET; CONTROLLED RELEASE; ORAL/  
/PINETAPP/  
/AH. ROBINS/ 12MG; 15MG; 15MG/

/CARAPHEN ÉDULSYLATE; CHLORPHÉNÉTRAMINE MALEATE; ISOPROPANTHESE/  
/IODOINE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE AD3)

/CAPSULE; CONTROLLED RELEASE; ORAL/  
/TUSS-ORNADE/  
/SK&F LABORATORIES/ 20MG; 30MG; 2.5MG; 50MG/  
  
/SOLUTION; ORAL/  
/TUSS-ORNADE/  
/SK&F LABORATORIES/ 5MG/5ML; 2MG/5ML; 0.75/5ML; 15MG/5ML/

DICYCLOMINE HYDROCHLORIDE (PAGE AD3)

SYRUP; ORAL  
BAYCYCLOMINE  
BAY LABORATORIES 10MG/5ML

DIPYRIDAMOLE (PAGE AD4)

TABLET; ORAL DIPYRIDAMOLE	
ASCOT HOSP PHARMS	50MG
DURAMED PHARMS	25MG
	50MG
	75MG
HALSEY DRUG SUPERPHARM	50MG
	50MG

**REFERENCE**

**DO NOT CONSUME**



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CURRENT STATUS - INEFFECTIVE

CUMULATIVE SUPPLEMENT NUMBER 5 / AUGUST '83 - JANUARY '84  
DESI PENDING LIST - OTHER THAN EXEMPT, (COURT ORDER) CATEGORY

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