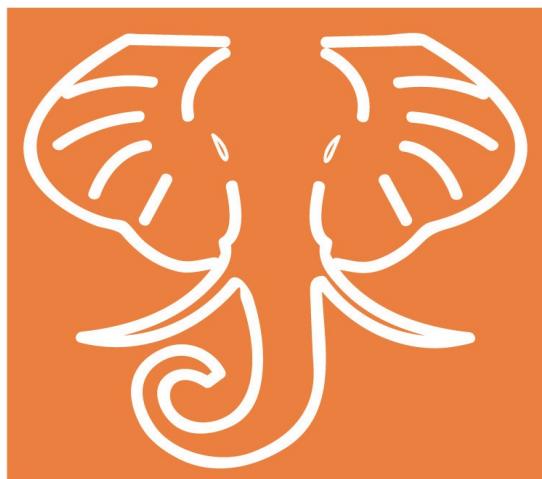


## **Approved prescription drug products with therapeutic equivalence evaluations.**

[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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Suppl. 3  
PHARMACY



# CUMULATIVE SUPPLEMENT 3

AUG '83 - NOV '83

# APPROVED PRESCRIPTION DRUG PRODUCTS

WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS

4<sup>TH</sup> EDITION

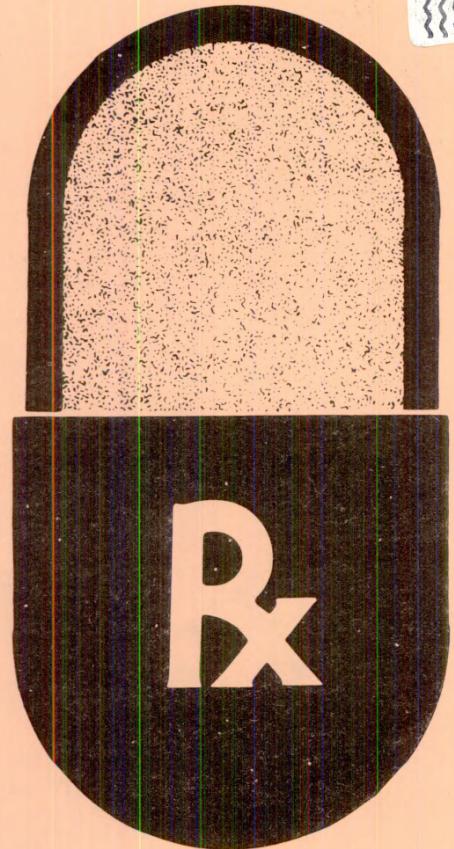


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FOOD AND DRUG ADMINISTRATION  
APPROVED PRESCRIPTION DRUG PRODUCTS  
WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS  
CUMULATIVE SUPPLEMENT

**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 >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 will identify them by deleting the applicable active ingredient headers followed by a reference to this Special Note.

### 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.

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

FROM MORE THAN ONE APPLICANT)

(1) THERAPEUTIC EQUIVALENCE EVALUATIONS PROVIDED ONLY FOR MULTISOURCE PRODUCTS (i.e., AVAILABLE

	CATEGORIES COUNTED	JULY '83 (BASELINE)	OCT '83	CUMULATIVE	NOV '83	CUMULATIVE
DRUG PRODUCTS LISTED		6679	6783			
SINGLE SOURCE	MULTISOURCE (1)	1908 (28.6%)	1915 (28.2%)	4771 (71.4%)	4868 (71.8%)	
THERAPEUTICALLY EQUIVALENT	THERAPEUTICALLY EQUIVALENT	3804 (57.0%)	3891 (57.4%)	957 (14.3%)	967 (14.3%)	
EXCEPTIONS (2)	NOT THERAPEUTICALLY EQUIVALENT	10 (0.1%)	10 (0.1%)	10 (0.1%)	10 (0.1%)	
NEW MOLECULAR ENTITIES APPROVED	NUMBER OF APPLICANTS	-	304	2	310	
B. ACTIVITY FOR SUPPLEMENT NUMBER 3						

A. COUNTS CUMULATIVE BY QUARTERS

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

## APPROVED PRESCRIPTION DRUG PRODUCTS

## DRUG PRODUCT LIST

CUMULATIVE SUPPLEMENT NUMBER 3 / AUGUST '83 - NOVEMBER '83

1

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 3-2)

> DLT > TABLET; ORAL  
> ADD > /PERCOCET-S/  
PERCOSET

> DLT > /ACÉTAMINOPHÈNE; PHÉNACÉTINE; PHÉNylePHÉNOLAMINE HYDROCHLORIDE/ /  
> DLT > /PHENYLTOLOXAMINE CITRATE/ (PAGE 3-2)

(ALL PRODUCTS - SEE SPECIAL NOTE B.)

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

INJECTABLE; INJECTION  
> DLT > /RADIODIODINATED SERUM ALBUMIN (HUMAN) (NSA) I-131/  
> DLT > /MALLINCKRODT/ 16.7-250 UCI/ML

AMINOPHYLLINE (PAGE 3-8)

/LIQUID; ORAL/  
SOLUTION; ORAL  
AMINOPHYLLINE  
AA ROXANE LABORATORIES 105MG/5ML\*

TABLET; ORAL  
AMINOPHYLLINE  
BD BARR LABORATORIES 100MG\*  
BD 200MG\*  
AB VANGARD LABS/MWM 100MG\*  
AB 200MG\*

AMPHETAMINE SULFATE (PAGE 3-13)

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

AMPICILLIN TRIHYDRATE; PROBENECID (PAGE 3-13)

POWDER FOR RECONSTITUTION; ORAL  
POLYCYCILLIN-PRB  
> ADD > AB BRISTOL LABS/B-M EQ 3.5GM BASE/BOT;1GM/BOT  
> ADD > PROBAMFACIN  
> ADD > AB BIOCRAFT LABS EQ 3.5GM BASE/BOT;1GM/BOT

ASPIRIN; BUTALBITAL (PAGE 3-15)

TABLET; ORAL  
AXOTAL  
ADRIA LABORATORIES 650MG;50MG\*

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-15)

TABLET; ORAL  
ASPIRIN AND CAFFEINE W/ BUTALBITAL  
PUREPAC/KALIPHARMA 325MG;50MG;40MG\*

&gt; DLT &gt; /ASPIRIN; BUTALBITAL; CAFFEINE; PHENACETIN/ (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;16MG\*

&gt; DLT &gt; /ASPIRIN; CAFFEINE; PHENACETIN; PROPOXYPHENE HYDROCHLORIDE/ (PAGE 3-15)

(ALL PRODUCTS - SEE SPECIAL NOTE B.)

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

CAPSULE; ORAL  
DARVON COMPOUND-65  
AA ELI LILLY INDSTRS/PR 389MG;32.4MG;65MG  
PROPOXYPHENE COMPOUND 65  
AA LEMON 389MG;32.4MG;65MG\*  
SK-65 COMPOUND  
AA SK&F LABORATORIES 389MG;32.4MG;65MG\*

ASPIRIN; CARISOPRODOL (PAGE 3-16)

TABLET; ORAL SOMA COMPOUND W/ CODEINE 325MG;200MG

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

TABLET; ORAL SOMA COMPOUND W/ CODEINE 325MG;200MG

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

TABLET; ORAL SOMA COMPOUND W/ CODEINE 325MG;200MG

ASPIRIN; HYDROCODONE BITARTRATE (PAGE 3-16)

> ADD > ATRACURIUM TRACURIN INJECTABLE; INJECTION 10MG/MLx

BROMPHENIRAMINE MALEATE (PAGE 3-22)

TABLET; ORAL BROMPHENIRAMINE MALEATE 10MG/MLx

/AA/ /BOLAR, PHARMACEUTICAL/MS/

> ADD > AZURESTIN (PAGE 3-16)

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE (PAGE 3-23)

INJECTABLE; INJECTION MARGATINE HCL W/ EPINEPHRINE AP

BRON LABS/STERLING 0.5%Q.0091MG/ML AP

/ER, SUDDE, AM, SUD/ /SM/ACKFT/

> DLT > AZURESTIN (PAGE 3-16)

TABLET; ORAL SENSOCATINE 0.75%Q.0091MG/ML AP

ASTRA HOSP PHARM 0.5%Q.0091MG/ML AP

BACAMPICILLIN HYDROCHLORIDE (PAGE 3-16)

TABLET; ORAL SPECTROBID LABS/PFIZER 800MG

BUTABARBITAL SODIUM (PAGE 3-24)

ELIXIR; ORAL BUTABARBITAL SODIUM AP

/B/ /REPD-FRDYIPDN/ LABS//50H/

TABLET; ORAL BENZTHIAZIDE (PAGE 3-20)

/PROd/ /

> DLT > BENZTHIAZIDE (PAGE 3-20)

ELIXIR; ORAL BUTABARBITAL SODIUM AP

/B/ /REPD-FRDYIPDN/ LABS//50H/

TABLET; ORAL BETAMETHASONE VALERATE (PAGE 3-21)

/Gaffithes, Garretsfredoll, Godette, Hodsphalte, Phenacetin/

/SOH, Cophquin, W, Codeine/

/Tablet, Oral/

(PAGE 3-24)

> DLT > /CAFFEINE; CARISOPRODOL; PHENACETIN (PAGE 3-25)

(ALL PRODUCTS - SEE SPECIAL NOTE B.)

CAFFEINE; ERGOTAMINE TARTRATE (PAGE 3-25)

SUPPOSITORY; RECTAL

CAFERGOT  
BR SANDOZ PHARMS/SANDOZ 100MG;2MG  
WIGRAINE  
BR ORGANON/AKZONA 100MG;2MGX

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE (PAGE 3-26)

SOLUTION; INTRAPERITONEAL

DIALYTE CONCENTRATE W/ DEXTROSE 30% IN PLASTIC CONTAINER  
AM MCGRAW/AM HOSP 510MG/100ML;30GM/100ML;

200MG/100ML;9.2GM/100ML;

9.6GM/100MLX

510MG/100ML;30GM/100ML;

200MG/100ML;9.4GM/100ML;

11GM/100MLX

DIALYTE CONCENTRATE W/ DEXTROSE 50% IN PLASTIC CONTAINER  
AM MCGRAW/AM HOSP 510MG/100ML;50GM/100ML;

200MG/100ML;9.2GM/100ML;

9.6GM/100MLX

510MG/100ML;50GM/100ML;

200MG/100ML;9.4GM/100ML;

11GM/100MLX

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-26)

SOLUTION; INTRAPERITONEAL

> ADD > DIALYTE W/ DEXTROSE 2.5% IN PLASTIC CONTAINER  
> ADD > AM MCGRAW/AM HOSP 26MG/100ML;2.5GM/100ML;  
> ADD > 15MG/100ML;560MG/100ML;390MG/100MLX

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE (PAGE 3-27)

INJECTABLE; INJECTION

ISOLYTE E IN PLASTIC CONTAINER

AM MCGRAW/AM HOSP 35MG/100ML;30MG/100ML;  
74MG/100ML;640MG/100ML;  
500MG/100ML;74MG/100MLX

CEFTIZOXIME SODIUM (PAGE 3-30)

INJECTABLE; INJECTION  
CEFIZOX  
SK&F LABORATORIES EQ 1GM BASE/VIALX  
EQ 2GM BASE/VIALX

CEFUROXIME SODIUM (PAGE 3-30)

INJECTABLE; INJECTION  
ZINACEF  
GLAXO EQ 750MG BASE/VIALX  
EQ 1.5GM BASE/VIALX

CEPHALOTHIN SODIUM (PAGE 3-31)

INJECTABLE; INJECTION  
KEFLIN  
ELI LILLY EQ 1GM BASE/VIAL  
EQ 2GM BASE/VIAL  
> ADD > AP  
SEFFIN  
GLAXO EQ 1GM BASE/VIALX  
EQ 2GM BASE/VIALX  
EQ 10GM BASE/VIALX

CHLORDIAZEPOXIDE (PAGE 3-33)

CAPSULE, CONTROLLED RELEASE; ORAL  
LIBRELEASE  
HOFFMANN-LA ROCHE 30MGX

CHLORDIAZEPOXIDE HYDROCHLORIDE (PAGE 3-33)

CAPSULE; ORAL  
CHLORDIAZEPOXIDE HCL  
/AB/ BOOTS' PHARMACEUTICAL/ 5MG/  
/AB/ 10MG/  
/AB/ 25MG/

CHLOROTHIAZIDE (PAGE 3-35)

TABLET; ORAL  
CHLOROTHIAZIDE  
AB CHELSEA LABORATORIES 250MGX  
AB 500MGX

4  
DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 3 / AUGUST '83 - NOVEMBER '83

## CHLORPHENIRAMINE MALEATE (PAGE 3-36)

TABLET; ORAL  
CHLORPHENIRAMINE MALEATE  
/44/ TIDONE, FAJLSEN / 50Mg/  
TOPCORT HOECHST-ROUSSEL 0.25%

DESOXIMETASONE (PAGE 3-49)

SOLUTION; ORAL  
CHLORPHENIRAMINE  
AB PURERAC/KALIPHARMA 50Mg/  
DESOXIMETASONE 0.5Mg/5ML  
ROXANE LABORATORIES  
DEXAMETHASONE INTENSOL  
ROXANE LABORATORIES 0.5Mg/0.5ML  
CHLOROXAZONE (PAGE 3-39)

TABLET; ORAL  
DEXAMETHASONE  
DECADRON

CORTICOLOPIN (PAGE 3-43)  
AA PAR PHARMACEUTICAL 250Mg/  
DESMETHASONE  
BP MSD/MERCK 6Mg  
TABLET; ORAL  
DEXAMETHASONE  
DECADRON  
BP PAR PHARMACEUTICAL 6Mg  
ROXANE LABORATORIES 6Mg  
CHLOROXAZONE (PAGE 3-39)

INJECTABLE; INJECTION  
/B/ /WEETH LABS, AHCO/ /40 UNITS/HI/  
DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-50)

CYANOCOBALAMIN (PAGE 3-44)  
ADD > AP MAURRY BIOLOGICAL 1Mg/ML  
INJECTABLE; INJECTION  
/A/ MSD/MERCK / 6.3Mg/ML/  
DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-50)

INJECTABLE; INJECTION  
HEXAORL /HEXAORL, HDSHATE/  
/INJECTABLE; INJECTION  
AP 6.3Mg/ML

REDISOL  
/A/ PARKE DAVIS/W-L / 6.3Mg/ML/  
INJECTABLE; INJECTION  
AP 6.3Mg/ML

CYCLOSPORINE (PAGE 3-46)  
> ADD > AP DOPAMINE HCL IN PLASTIC CONTAINER  
ABSOFT LABORATORIES 50Mg/100ML  
ABSOFT LABORATORIES 50Mg/100ML  
DOPAMINE HCL IN PLASTIC CONTAINER  
50Mg/100ML; 160Mg/100ML  
INJECTABLE; INJECTION  
/DOPAMINE HCL, IN DEXTRONE, 5%/  
AP 6.3Mg/ML

DOPAMINE (PAGE 3-46)  
> ADD > AP ABSOFT LABORATORIES 50Mg/100ML  
ABSOFT LABORATORIES 50Mg/100ML  
DOPAMINE HCL IN PLASTIC CONTAINER  
50Mg/100ML; 160Mg/100ML  
INJECTABLE; INJECTION  
AP 6.3Mg/ML

SOLUTION; ORAL  
SANDIMUNE SANDOZ PHARMS/SANDOZ 100Mg/ML  
INJECTABLE; INJECTION  
HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC  
CONTAINER  
TRAVENOL LABS 5GM/100ML; 4,000 UNITS/100MLX  
CYPROHEPTADINE HYDROCHLORIDE (PAGE 3-46)

TABLET; ORAL  
CHLORPHENIRAMINE HCL  
AA DURAMED PHARMS 4Mg/  
INJECTABLE; INJECTION  
HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC  
CONTAINER  
TRAVENOL LABS 5GM/100ML; 4,000 UNITS/100MLX  
CYPROHEPTADINE HYDROCHLORIDE (PAGE 3-46)

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM (PAGE 3-57)

INJECTABLE; INJECTION

/DIATRIZOATE 'MEGLUMINE' AND 'DIATRIZOATE' SODIUM/  
DIATRIZOATE-60DIETHYLPROPION HYDROCHLORIDE (PAGE 3-59)

TABLET; ORAL

DIETHYLPROPION HCLAA CAMALL 25MG#DIMENHYDRINATE (PAGE 3-60)

INJECTABLE; INJECTION

DIMENHYDRINATE/AB/ /INT'L MEDICATION Sys// 50MG/ML/DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-61)

CAPSULE; ORAL

SK-DIPHENHYDRAMINE/SK&F LABORATORIES / 25MG/

ELIXIR; ORAL

BELIXAA HALSEY DRUG 12.5MG/5ML#  
/SK-DIPHENHYDRAMINE/  
/SK&F LABORATORIES/ /12.5MG/5ML/DISULFIRAM (PAGE 3-63)

TABLET; ORAL

DISULFIRAMBX CHELSEA LABORATORIES 250MG#  
BX 500MG#DOXYCYCLINE HYCLATE (PAGE 3-64)

CAPSULE; ORAL

DOXYCYCLINE HYCLATEAB CHELSEA LABORATORIES EQ 50MG BASE

INJECTABLE; INJECTION

DOXYCYCLINEAP ELKINS-SINN EQ 100MG BASE/VIAL#  
AP VIBRAMYCIN EQ 200MG BASE/VIAL#  
AP PFIZER LABS/PFIZER EQ 200MG BASE/VIALDROPERIDOL; FENTANYL CITRATE (PAGE 3-64)

INJECTABLE; INJECTION

INNOVAR  
/JANSSEN PHARMA/ /2.5MG/ML; 0.05MG/ML/  
JANSEN PHARMA 2.5MG/ML; EQ 0.05MG BASE/MLEPINEPHRINE; LIDOCAINE HYDROCHLORIDE (PAGE 3-66)

INJECTABLE; INJECTION

LIDOCATON  
AP PHARMATON/SZ 0.01MG/ML; 2%#  
AP 0.02MG/ML; 2%#ERGOLOID MESYLATES (PAGE 3-66)CAPSULE; ORAL  
/HYDERGINE/  
HYDERGINE LCERYTHROMYCIN (PAGE 3-67)OINTMENT; OPHTHALMIC  
ERYTHROMYCIN  
AT E FOUGERA/BYK-GLDN 5MG/GM#  
AT PHARMADERM/BYK-GLDN 5MG/GM#  
AT ILOTYCIN DISTA PRODS/LILLY 5MG/GM> ADD > ETOPOSIDE (PAGE 3-74)> ADD > INJECTABLE; INJECTION  
> ADD > VEPESID  
> ADD > BRISTOL LABS/B-M 20MG/ML#FENTANYL CITRATE (PAGE 3-75)INJECTABLE; INJECTION  
SUBLIMAZE  
/JANSSEN PHARMA/ /0.05MG/ML/  
JANSEN PHARMA EQ 0.05MG BASE/MLFLUOXYMESTERONE (PAGE 3-77)TABLET; ORAL  
FLUOXYMESTERONE  
BP COLMED LABORATORIES 10MG#

GRISSEGEFULLVIN, ULTRAMICROCRYSTALLINE (PAGE 3-79)

6 CUMULATIVE SUPPLEMENT NUMBER 3 / AUGUST '83 - NOVEMBER '83

9

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ADD > AP	NATCON CHEMICAL	10MG/ML	FUROSIMIDE TABLET; OVAL	165MG FULVICIN P/G 165 SCHERRING	ADD > AB	FULVICIN P/G 330 SCHERRING	ADD > AB	FULVICIN P/G 330 SCHERRING	ADD > AB	FUROSIMIDE TABLET; OVAL	330MG 330MG
ADD > AB	Roxane Laboratories	20MGx	FUROSIMIDE TABLET; OVAL	330MG 330MG	ADD > AB	FULVICIN P/G 330 SCHERRING	ADD > AB	FULVICIN P/G 330 SCHERRING	ADD > AB	Roxane Laboratories	330MGx 330MGx
ADD > AB	ZENITH LABORATORIES	60MGx	FUROSIMIDE TABLET; OVAL	330MG 330MG	ADD > AB	FULVICIN P/G 330 SCHERRING	ADD > AB	FULVICIN P/G 330 SCHERRING	ADD > AB	Zenith Laboratories	330MGx 330MGx
ADD > AB	ZENITH LABORATORIES	20MGx	FUROSIMIDE TABLET; OVAL	330MG 330MG	ADD > AB	FULVICIN P/G 330 SCHERRING	ADD > AB	FULVICIN P/G 330 SCHERRING	ADD > AB	Zenith Laboratories	330MGx 330MGx
ADD > AB	ZENITH LABORATORIES	60MGx	FUROSIMIDE TABLET; OVAL	330MG 330MG	ADD > AB	FULVICIN P/G 330 SCHERRING	ADD > AB	FULVICIN P/G 330 SCHERRING	ADD > AB	Zenith Laboratories	330MGx 330MGx

**GENENTECHIN SULFATE (PAGE 3-79)**

CRFAM: TOPICAL  
GENFAIR  
PHARMFAIR  
EG 1MG BASE/GM

HEPARIN SODIUM  
INJECTABLE; INJECTION  
AP  
NATCON CHEMICAL  
1,000 UNITS/ML\*

HEPARIN SODIUM  
INDICATIONS

NATCON CHEMICAL 2,000 UNITS/ML\*

TABLET; ORAL  
HOMAPIN-10  
MISSON PHARMACAL  
/SEDES-TENS, SE/  
/LEMNO/  
/A4/

HYDRALAZINE HYDROCHLORIDE (PAGE 3-86)

**TABLET; ORAL**  
**HYDRAZINE HC1**  
**PAR PHARMACEUTICAL**  
**PUREPAC/KALIPIHARMA**  
**100MG#**  
**50MG#**

( PAGE

TABLET: ORAL  
/R-HCTZ-H/  
PRESERPTIVE

18

REID-PROVIDENT LABS 256515MG.0.THSX  
RESERPINE, HYDRAZINE HCL, AND HYDROCHLOROTHIAZIDE  
BP

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(PAGE 3-87)

**TABLET; ORAL**  
**SPIRONOLACTONE H/ HYDROCHLOROTHIAZIDE**  
**PUREPAC/KALIHPRAMA 25MG:25MG**

SONABODTWOPIIN, CHONLONGE (PAGE 3-81)

INJECTABLES; INJECTION

www.english-test.net

HYDROCORTISONE (PAGE 3-90)

CREAM; TOPICAL

ELDECORT

/AT/ ELDER PHARMS /1.5%/

HYDROCORTISONE

AT BAY LABORATORIES 1/2%

AT 2.5%\*

LOTION; TOPICAL

DÉLACORT

/AT/ MERICON INDUSTRIES /1.5%/

GLY-CORT

AT HERAN PHARMACEUTICAL 1/2%

HYDROCORTISONE

AT MERICON INDUSTRIES 0.5%

/AT/ TONNE PAULSEN /0.5%/

OINTMENT; TOPICAL

HYDROCORTISONE

AT BAY LABORATORIES 1/2%

AT 2.5%\*

/SOLUTION/DROPS; OPHTHALMIC/

OPTER

/UP JOHN/ /0.2%/

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

SOLUTION/DROPS; OTIC

NEO-OTOSOL-HC

AT CARTER-GLOGAU LABS 1/2;EQ 5.5MG BASE/ML;10,000 UNITS/ML\*

HYDROCORTISONE ACETATE (PAGE 3-93)

CREAM; TOPICAL

HYDROCORTISONE ACETATE

/AT/ TONNE PAULSEN /1/

LOTION; TOPICAL

DRICORT

/AT/ INGRAM PHARM 0.5%

/AT/ HYDROCORTISONE ACETATE/

/AT/ TONNE PAULSEN /0.5%/

/SUSPENSION/DROPS; OPHTHALMIC; OTIC/

HYDROCORTONE

/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\*

HYDROXYZINE HYDROCHLORIDE (PAGE 3-96)

TABLET; ORAL

HYDROXYZINE HCL

&gt; ADD &gt; AB BARR LABORATORIES 10MG\*

AB DANBURY PHARMACAL 10MG\*

AB 25MG\*

AB 50MG\*

HYDROXYZINE PAMOATE (PAGE 3-96)

CAPSULE; ORAL

HYDROXYZINE PAMOATE

AB VANGARD LABS/MWH EQ 25MG HCL\*

AB EQ 50MG HCL\*

IMIPRAMINE HYDROCHLORIDE (PAGE 3-97)

TABLET; ORAL

IMIPRAMINE

/BP/ LEMON /25MG/

IMAVATE

/AB/ AH ROBINS /25MG/

IMAVATE

/AB/ AH ROBINS /50MG/

IMIPRAMINE HCL

AB PAR PHARMACEUTICAL 10MG\*

AB 25MG\*

AB 50MG\*

ISOETHMARINE HYDROCHLORIDE (PAGE 3-100)

SOLUTION; INHALATION

ISOETHMARINE HCL

AN INTL MEDICATION SYS 0.167Z\*

AN ROXANE LABORATORIES 0.167Z\*

AN TRAVENOL LABS 0.25Z\*

ISONIAZID (PAGE 3-101)

SYRUP; ORAL

ISONIAZID

&gt; ADD &gt; AA CAROLINA MED PRODS 50MG/5ML\*

RIMIFON

&gt; ADD &gt; AA HOFFMANN-LA ROCHE 50MG/5ML

KANAMYCIN SULFATE (PAGE 3-102)

AP KANTREX INTL MEDICATION SYS EG 500MG BASE/2ML  
/AP// /B/P/3/01, J/AFS/B-M/ /500MG/2ML/  
/AP// BRISTOL LABS/B-M EG 75MG BASE/2ML  
/AP// EG 75MG BASE/2ML  
/AP// EG 1GM BASE/3ML  
/AP// EG 500MG BASE/2ML  
/AP// TABLET; VAGINAL NYSTATIN (PAGE 3-129)

LIDOCAINE HYDROCHLORIDE (PAGE 3-104)

> ADD > ATI

E FOUGERA/BYK-GLDN

100,000 UNITS

NYSTATIN

TABLET; ENTRIC COATED; ORAL

CHOLEDDYL

AB PARK-E-DAVIS/W-L

200MG

OXTRIPTYLLINE

AB

BOLAR PHARMACEUTICAL 200MG

AB// /TDMN, PAULSEN/ /100G/

METHYLTESTOSTERONE (PAGE 3-121)

METHYLTESTOSTERONE (PAGE 3-122)

METRONIDAZOLE (PAGE 3-122)

INJECTABLE; INJECTION

AP PHARMATION/SZ 22A

TABLET; BUCAL/SUBLINGUAL

METHYLTESTOSTERONE

INJECTABLE; INJECTION

OXYTETRACYCLINE HYDROCHLORIDE (PAGE 3-122)

AB// /TDMN, PAULSEN/ /100G/

TABLET; ENTRIC COATED; ORAL

CHOLEDDYL

AB PARK-E-DAVIS/W-L

200MG

OXTRIPTYLLINE

AB

BOLAR PHARMACEUTICAL 200MG

AB// /TDMN, PAULSEN/ /100G/

CAPSULE; ORAL

/AB/ /PAKKE-DAVIS/W-L/ /EA 250G BASE/5HL/

PENTICILLIN V POTASSIUM (PAGE 3-125)

POWDER FOR RECONSTITUTION; ORAL

/AB/ /D/PJ/DHN/ /EA 250G BASE/5HL/

PHENDIMETERAZINE TARTRATE (PAGE 3-126)

TABLET; ORAL

PHENDIMETERAZINE TARTRATE

AA FERNDALE LABS 35MG

INJECTABLE; INJECTION

NANDROLONE DECANOATE (PAGE 3-125)

NANDROLONE DECANOATE (PAGE 3-126)

AA LYPHO-MED 500G/ML

AA LERONON 100G/ML

AA MURRY BIOLOGICAL 200MG/MLx

> ADD > AP

ABBOOTT LABORATORIES 500MG/100MLx

METRO I.V. IN PLASTIC CONTAINER

AM MCGAW/AM HOSP 500MG/100MLx

AB METRONIDAZOLE 250MGx

PAR PHARMACEUTICAL 250MGx

AB// /D/PJ/DHN/ 500MGx

TABLET; ORAL

AB// /TDMN, PAULSEN/ 500MGx

INJECTABLE; INJECTION

NANDROLONE DECANOATE (PAGE 3-126)

AA LYPHO-MED 500G/MLx

AA LERONON 100G/ML

AA MURRY BIOLOGICAL 200MG/MLx

PHENTERMINE HYDROCHLORIDE (PAGE 3-139)

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

POTASSIUM CHLORIDE (PAGE 3-143)

INJECTABLE; INJECTION  
POTASSIUM CHLORIDE  
 /AB/ TRAVENOL LABS /1MEG/ML/  
 /AB/ /3MEG/ML/  
 /AB/ /6MEG/ML/

PREDNISOLONE (PAGE 3-145)

TABLET; ORAL  
PREDNISOLONE  
 /BX/ /REXALL DRUGS/ /5MG/

PREDNISOLONE ACETATE (PAGE 3-146)

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

PREDNISOLONE SODIUM PHOSPHATE (PAGE 3-147)

SOLUTION/DROPS; OPHTHALMIC  
HYDRETASOL  
 /AT/ /MSD/MERCK/ /EQ 0.5% PHOSPHATE/  
 /AT/ METRETON EQ 0.5% PHOSPHATE  
 SCHERING

PREDNISONE (PAGE 3-147)

TABLET; ORAL  
PREDNISONE  
 BX DURAMED PHARMS 5MGX  
 BX 10MGX  
 BX 20MGX

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-149)

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

PROPOXYPHENE HYDROCHLORIDE (PAGE 3-153)

CAPSULE; ORAL  
PROPOXYPHENE HCL  
 AA RICHLYN LABORATORIES 65MG

PROPYLTHIOURACIL (PAGE 3-154)

TABLET; ORAL  
PROPYLTHIOURACIL  
 /BD/ /MYLAN PHARMS/ /50MG/

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE (PAGE 3-155)

> ADD > /SYRUP; ORAL/  
 SYRUP; ORAL  
PSEUDOEPHEDRINE  
 /AB/ /BAY LABORATORIES/ /30MG/5ML;1.25MG/5ML/  
/TRIACIN/  
 /AB/ /NATTI PHARM INC/BARNE/ /30MG/5ML;1.25MG/5ML/  
 > ADD > TRIPPOSED  
 > ADD > HALSEY DRUG 30MG/5ML;1.25MG/5MLX

TABLET; ORAL  
TRIPROLDINE  
 /AB/ /DANBURY PHARMACEUTICAL/ /60MG;2.5MG/  
TRIPROLIDINE AND PSEUDOEPHEDRINE  
 > ADD > AA BOLAR PHARMACEUTICAL 60MG;2.5MGX  
 > DLT > /AB/ /WEST-WARD/ /60MG;2.5MG/  
TRIPROLIDINE HCL AND PSEUDOEPHEDRINE HCL  
 AA CHELSEA LABORATORIES 60MG;2.5MGX

QUINIDINE SULFATE (PAGE 3-157)

TABLET; ORAL  
QUINIDINE SULFATE  
 AB VITARINE/WEST CHEM 300MGX

RESERPINE (PAGE 3-158)  
TABLET; ORAL  
/Phenyl/  
>DLT>/Bd/  
>DLT>/Vid-Serptin/  
>DLT>/ONEAL, JONES & ELGIN//G.2545/  
ASELLACRIN 2  
SERONO LABS  
2 IU/VIAL  
INJECTABLE; INJECTION  
SPIRONOLACTONE  
TABLLET; ORAL  
SPIRONOLACTONE  
AB PUREPAC/KALIPIHARMA 25MG  
SECOBARBITAL SODIUM  
AA LANNETT  
SECONAL SODIUM 50MG  
AA ELLI LILLY  
SELENITUM SULFIDE 2.52g  
AT BAY LABORATORIES  
TESTOSTERONE (PAGE 3-173)  
INJECTABLE; INJECTION  
TESTOSTERONE  
CARTER-GLOGAU LABS 50MG/MLx  
TERACYCLINE HYDROCHLORIDE (PAGE 3-174)  
CAPSULE; ORAL  
/Ab/ TETRAGLYCINE HCl  
TABLET; ORAL  
/Ab/ Lefthou  
/Ab/ /250mg/  
/Sticks/ /Aldha/ (PAGE 3-161)  
/Silipredin/ /Oral/  
/Cytellic/ /  
/Sticks/ /Aldha/ (PAGE 3-162)  
SODIUM CHLORIDE (PAGE 3-162)  
INJECTABLE; INJECTION  
SODIUM CHLORIDE 3% IN PLASTIC CONTAINER  
TRAVENOL LABS 35M/100ML  
>ADD>  
>ADD>  
>ADD>  
>ADD>  
>ADD>  
THEOPHYLLINE (PAGE 3-176)  
CAPSULE, CONTROLLED RELEASE; ORAL  
SOMOPHYLLIN-CRT  
BC FISONS 100MG  
THEO-24  
BC SEARLE/SEARLE PHARMS 100MG  
300MGx  
200MGx  
300MGx  
SODIUM POLYSTYRENE SULFONATE (PAGE 3-165)  
SUSPENSION; ORAL, RECTAL  
>ADD>  
>ADD>  
>ADD>  
CAROLINA MED PRODS 156M/60ML  
>ADD>  
ROXANE LABORATORIES 156M/60MLx  
SODIUM POLYSTYRENE SULFONATE (PAGE 3-165)

THEOPHYLLINE (PAGE 3-176)

## SOLUTION; ORAL

THEOLAIRAA RIKER LABS/3M 80MG/15MLTHEOPHYLLINEAA ROXANE LABORATORIES 80MG/15ML\*

## TABLET, CONTROLLED RELEASE; ORAL

THEOCONTINBC PURDUE FREDERICK 200MG\*THEO-DURBC KEY PHARMACEUTICALS 200MGTHIORIDAZINE HYDROCHLORIDE (PAGE 3-178)

## CONCENTRATE; ORAL

THIORIDAZINE HCL> ADD > AA CORD LABORATORIES 30MG/ML\*> ADD > AA 100MG/ML\*AA NATL PHARM MFG/BARRE 100MG/ML\*

## TABLET; ORAL

MELLARILAB SANDOZ PHARMS/SANDOZ 100MGTHIORIDAZINE HCL> ADD > AB BARR LABORATORIES 10MG\*> ADD > AB 15MG\*> ADD > AB 25MG\*> ADD > AB 50MG\*> ADD > AB 100MG\*AB BOLAR PHARMACEUTICAL 10MG\*AB 100MG\*AB CORD LABORATORIES 10MG\*AB 15MG\*AB 25MG\*AB 50MG\*> ADD > AB DANBURY PHARMACAL 10MG\*> ADD > AB 15MG\*> ADD > AB 25MG\*> ADD > AB 50MG\*> ADD > AB MYLAN PHARMS 100MG\*AB ZENITH LABORATORIES 100MG\*TIMOLOL MALEATE (PAGE 3-179)

## TABLET; ORAL

BLOCADRENMS&D/MERCK 5MGTRIAMCINOLONE ACETONIDE (PAGE 3-180)

## CREAM; TOPICAL

TRIAMCINOLONE ACETONIDEAT BAY LABORATORIES 0.025%\*AT 0.1%\*AT 0.5%\*

## OINTMENT; TOPICAL

TRIAMCINOLONE ACETONIDEAT BAY LABORATORIES 0.025%\*AT 0.1%\*AT 0.5%\*TRISULFAPYRIMIDINES (PAGE 3-185)

## SUSPENSION; ORAL

/QUAD-RAMOTU//AB/ ELDER PHARMS/ /\$60MG/ML//AB/ TRISEM//AB/ BEECHAM LABS/BEECHAM/560MG/ML//AB/ TRISURETO//AB/ REID-PROVIDENT LABS//560MG/ML/

## TABLET; ORAL

/QUADÉTTA//AB/ ELDER PHARMS/ /\$60MG//AB/ TRIPLE SULFA #2//AB/ ZENITH LABORATORIES//560MG/TROPICAMIDE (PAGE 3-186)

## SOLUTION/DROPS; OPHTHALMIC

HYDRIAFAIRAT PHARMAFAIR 0.5%\*AT 1%\*/TYBANATE/ (PAGE 3-186)

## /CAPSULE; ORAL/

/TYBATHAN//AH. ROBINS//250MG//350MG/VITAMIN A PALMITATE (PAGE 3-188)

## CAPSULE; ORAL

/SOLVITSYN A//AA/ /TOMME PAULSEN/ /É 50,000 UNITS BASE/

CUMULATIVE SUPPLEMENT NUMBER 3 / AUGUST '83 - NOVEMBER '83  
DESI PENDING LIST - EXEMPT, (COURT ORDER) CATEGORY  
ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;

HYDROCHLORIDE; VITAMIN A; VITAMIN E (PAGE AD2)  
HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE  
ERGOCALIFEROL; FOLIC ACID; NICOTINAMIDE; PYRIDOXINE

ASCOPT HOSP PHARMS 1.0MG/ML; 0.006MG/ML; 0.5 UGM/ML;  
MVC PLUS  
> ADD >  
> ADD >  
> ADD >

/dexamethasone; fentanyl; glidate; hydrochloride; lidocaine;  
/fentanyl; lidocaine; dral/ (PAGE AD3)

/fentanyl; lidocaine; dral/  
/tuss-drynade/  
/sulfadiazine; dral/ (PAGE AD4)

/skf; labradorites/ /ngs/ml; ngs/ngs/ngs/ngs/nng/  
/tuss-drynade/  
/solutioin; dral/

/skf; labradorites/ /zohgs; ems; z; mgs; zohgs/  
/tuss-drynade/  
/fentanyl; dextroamphetamine; release; dral/ (PAGE AD5)

DIPIRIDAMOLE (PAGE AD5)  
> ADD >  
TABLET; ORAL  
DIPYRIDAMOLE  
ASCOT HOSP PHARMS 50MG  
HALSY DRUGS 50MG  
SUPERPHARM 50MG  
> ADD >  
> ADD >

/dlr > /metamizole/ (PAGE AD6)  
> ADD >  
> ADD >  
> ADD >  
> ADD >  
> ADD >

/tablets; dral/ /516/ /516/  
/metamizole/ (PAGE AD6)

DESI PENDING LIST - OTHER THAN 'EXEMPT' (COURT ORDER) CATEGORY  
CUMULATIVE SUPPLEMENT NUMBER 3 / AUGUST '83 - NOVEMBER '83

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CURRENT STATUS - INEFFECTIVE

/CARERITAL/ /PARKE-DAVIS/W-L/  
/CARBROMAL; PENTOBARBITAL SODIUM/

/CLISTIN RA/ /MCNEIL PHARM/  
/CARBINOXAMINE MALEATE/

/FORHISTAL/ /CIBA/CIBA-GEIGY/  
/DIMETHINDENE MALEATE/

> ADD > METHANDROSTENOLONE PAR PHARMACEUTICAL  
> ADD > METHANDROSTENOLONE

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

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