

APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations



The "Orange Book"

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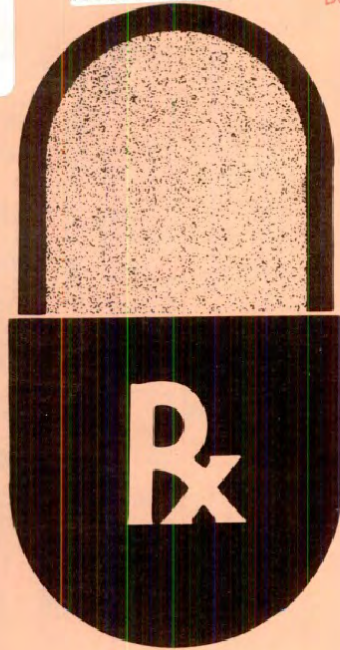
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**CUMULATIVE
SUPPLEMENT 6
AUG'83 - FEB'84**

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Suppl. to



APPROVED PRESCRIPTION DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

4TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
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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 >DELETED (DELETE) to the left of the line containing the overstruck print. The >DELETED 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.

Because we are converting to a new automated data processing system, cumulative counts shown for the quarter ending January 1984, represent approximate values. Accurate quarterly values will be shown in Cumulative Supplement 7. Monthly values shown in Supplement 6 for February 1984, are accurate.

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.

D. 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	QUANTUM PHARMICS LTD	QUANTUM PHARMICS
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.

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 multi-source or single source during each month within the quarter. The report does not reflect category changes from multi-source 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 multi-source 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.

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>	<u>JAN '84</u> (SEE SPECIAL NOTE A.)
DRUG PRODUCTS LISTED	6679	6783	6854
SINGLE SOURCE	1908 (28.6)	1915 (28.2%)	1925 (28.1%)
MULTISOURCE ⁽¹⁾	4771 (71.4)	4868 (71.8%)	4929 (71.9%)
THERAPEUTICALLY EQUIVALENT	3804 (57.0%)	3891 (57.4%)	3947 (57.6%)
NOT THERAPEUTICALLY EQUIVALENT	957 (14.3%)	967 (14.3%)	972 (14.2%)
EXCEPTIONS ⁽²⁾	10 (0.1%)	10 (0.1%)	10 (0.1%)
NEW MOLECULAR ENTITIES APPROVED	-	2	8
NUMBER OF APPLICANTS	304	310	309

B. ACTIVITY FOR SUPPLEMENT NUMBER 6

	<u>FEB '84</u>	<u>CUMULATIVE</u>
DRUG PRODUCTS ADDED:	28	28
NEWLY APPROVED	28	28
DESI EFFECTIVE	0	0
REMARKETED	0	0
DRUG PRODUCTS REMOVED:	7	7
WITHDRAWN APPROVAL	0	0
RX TO OTC SWITCH	0	0
DISCONTINUED MARKETING	9	9
NET GAIN IN DRUG PRODUCTS	21	21
SINGLE SOURCE PRODUCTS APPROVED	4	4
MULTISOURCE DRUG PRODUCTS APPROVED	24	24
NEW MOLECULAR ENTITIES APPROVED:	0	0
AS THE ENTITY	0	0
AS A SALT, ESTER OR DERIVATIVE		
OF THE ENTITY	0	0

(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)

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ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

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

TABLET; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE
 > ADD > AA DURAMED PHARMS 300MG;15MG
 > ADD > AA 300MG;30MG
 > ADD > AA 300MG;60MG

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 3-2)

TABLET; ORAL
ODACET
 AA HALSEY DRUG 325MG;8MG
PERCOCET-8
PERCOCET

/ACETAMINOPHEN; PHENACETIN; PHENYLEPHEDRINE HYDROCHLORIDE;
 /PHENYLOXANINE CITRATE/ (PAGE 3-2)

(ALL PRODUCTS - SEE SPECIAL NOTE B.)

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

INJECTABLE; INJECTION
/RADIOIODINATED SERUM ALBUMIN (HUMAN) I-131/
/MALLINKRODT/ 15.7-250.15-1/ML

AMINO ACIDS (PAGE 3-6)

INJECTABLE; INJECTION
 NEOPHAM 6.5%
 CUTTER-VITRUM 6.5%

AMINOPHYLLINE (PAGE 3-8)

/LIQUIDS; ORAL/
 SOLUTION; ORAL
AMINOPHYLLINE
 AA BAY LABORATORIES 105MG/5ML
 AA ROXANE LABORATORIES 105MG/5ML

AMINOPHYLLINE (PAGE 3-8)

TABLET; ORAL
AMINOPHYLLINE
 B0 BARR LABORATORIES 100MG
 B0 200MG
 AB VANGARD LABS/TMM 100MG
 AB 200MG

/AMPHETAMINE SULFATE/ (PAGE 3-13)

/CAPSULE; CONTROLLED RELEASE; ORAL
/BENZEDRINE/
/SKF LABORATORIES/ 15MG/
/TABLET; ORAL/
/BENZEDRINE/
/SKF LABORATORIES/ 5MG/
10MG/

AMPICILLIN TRIHYDRATE; PROBENECID (PAGE 3-13)

POWDER FOR RECONSTITUTION; ORAL
POLYCLIN-PRB
 AB BRISTOL LABS/B-M EQ 3.5GM BASE/ROT;1GM/ROT
PROBAMPACIN
 AB BIOCRRAFT LABS EQ 3.5GM BASE/ROT;1GM/ROT

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
 AB PUREPAC/KALIPHARMA 325MG;50MG;40MG
BUTALBITAL W/ ASPIRIN & CAFFEINE
 AB BOOTS LABORATORIES 325MG;50MG;40MG

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

(ALL PRODUCTS - SEE SPECIAL NOTE B.)

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

CAPULET: ORAL

SYNLAGOS-DC

IYES LABS/AMMO 356.4MG;30MG;16MG

/ASPIRIN: CAFFEINE: PHENACETIN: PROPOXYPHENE HYDROCHLORIDE (PAGE 3-15)

/ALL PRODUCTS - SEE SPECIAL NOTE B.)

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

CAPULET: ORAL

BARON COMPOUND-65

ELI LILLY INDSTRS./PR 32.4MG;6.5MG

PROPOXYPHENE COMPOUND 65

LEMON

SK-65 COMPOUND

SK-65 LABS/AMMO 32.4MG;6.5MG

SK-65 LABS/AMMO 32.4MG;6.5MG

ASPIRIN: CARISOPRODOL (PAGE 3-16)

TABLET: ORAL

SOMA COMPOUND

MALLACE PHARMS/C-M 35MG;20MG

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

TABLET: ORAL

SOMA COMPOUND M/ CODEINE

MALLACE PHARMS/C-M 35MG;20MG;16MG

ASPIRIN: HYDROCODONE BITARTRATE (PAGE 3-16)

TABLET: ORAL

VICOPRIN

KNOLL PHARMACEUTICAL 50MG;5MG

ATACURUM BESYLATE (PAGE 3-16)

INJECTABLE: INJECTION

TRACRIUM

BURROUGHS WELLCOME 10MG/MLM

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

BETAMETHASONE VALERATE (PAGE 3-21)

CREAM; TOPICAL
BETATREX
 AB SAVAGE LABS/BYK-GLDN EQ 0.1% BASE*
 LOTION; TOPICAL
BETAMETHASONE VALERATE
 AB E FOUGERA/BYK-GLDN EQ 0.1% BASE*
 AB PHARMADERM/BYK-GLDN EQ 0.1% BASE*
BETATREX
 AB SAVAGE LABS/BYK-GLDN EQ 0.1% BASE*
VALISONE
 AB SCHERING EQ 0.1% BASE
 OINTMENT; TOPICAL
BETAMETHASONE VALERATE
 AB E FOUGERA/BYK-GLDN EQ 0.1% BASE*
 AB PHARMADERM/BYK-GLDN EQ 0.1% BASE*
BETATREX
 AB SAVAGE LABS/BYK-GLDN EQ 0.1% BASE*
VALISONE
 AB SCHERING EQ 0.1% BASE

>_ADD_> BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE
 (PAGE 3-22)

>_ADD_> SYRUP; ORAL
 >_ADD_> AMBENYL
 >_ADD_> MARION LABORATORIES 12.5MG/5ML;10MG/5ML

BROMPHENIRAMINE MALEATE (PAGE 3-22)

TABLET; ORAL
BROMPHENIRAMINE MALEATE
 /AA/ /BOLAR PHARMACEUTICAL/6MG/

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE (PAGE 3-23)

INJECTABLE; INJECTION
MARCAINE HCL W/ EPINEPHRINE
 AP BREON LABS/STERLING 0.5%:0.0021MG/ML
 AP 0.75%:0.0021MG/ML
SENSORCAINE
 AP ASTRA HOSP PHARM 0.5%:0.0021MG/ML
 AP 0.75%:0.0021MG/ML

BUTABARBITAL SODIUM (PAGE 3-24)

CAPSULE; ORAL
 BUTICAPS
 /WELLS LABORATORIES/15MG/
 /30MG/
 /50MG/
 /100MG/
 WALLACE LABS/C-W 15MG
 30MG
 50MG
 100MG
 ELIXIR; ORAL
 /BUTABARBITAL SODIUM/
 /AA/ /WEST-WARR/ /33MG/5ML/
 BUTALAN
 /AA/ LANNETT 33.3MG/5ML
 /CAFFEINE; CARISOPRORDOL; CODEINE PHOSPHATE; PHENACETIN/
 (PAGE 3-24)
 /TABLET; ORAL/
 /SONA COMPANY W/ CODEINE/
 /WALLACE PHARMS/C-W/ /25MG;200MG;15MG;150MG/
 /CAFFEINE; CARISOPRORDOL; 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
 MIGRAINE
 BR ORGANON/AKZONA 100MG;2MG

CALCIUM 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/100ML
 510MG/100ML;30GM/100ML;
 200MG/100ML;9.4GM/100ML;
 11GM/100ML

CEPHALOTHIN SODIUM (PAGE 3-31)

CHLOROTHIAZIDE (PAGE 3-35)

TABLET; ORAL
CHLOROTHIAZIDE
 AB CHELSEA LABORATORIES 250MG#
 AB 500MG#

CHLOROTHIAZIDE; RESERPINE (PAGE 3-35)

TABLET; ORAL
 CHLOROTHIAZIDE AND RESERPINE
 BP WEST-WARD 250MG;0.125MG#
 BP 500MG;0.125MG#

CHLORPHENIRAMINE MALEATE (PAGE 3-36)

TABLET; ORAL
CHLORPHENIRAMINE MALEATE
 /AA/ /TONE, PAULSEN/ /4MG/

CHLORPROPAMIDE (PAGE 3-36)

TABLET; ORAL
CHLORPROPAMIDE
 > ADD > AB PAR PHARMACEUTICAL 100MG#
 > ADD > AB 250MG#
DIABINASE
 > ADD > AB PFIZER LABS/PFIZER 100MG

CHLORTHALIDONE (PAGE 3-36)

TABLET; ORAL
CHLORTHALIDONE
 AB PUREPAC/KALIPHARMA 50MG#

CHLORZOXAZONE (PAGE 3-39)

TABLET; ORAL
CHLORZOXAZONE
 AA PAR PHARMACEUTICAL 250MG#

CHYMOPAPAIN (PAGE 3-39)

INJECTABLE; INJECTION
 DISCAGE
 TRAVENOL LABS 12,500 UNITS/VIAL#

CIMETIDINE (PAGE 3-39)

TABLET; ORAL
 TAGAMET
 SK&F LAB 400MG#

CLOTRIMAZOLE (PAGE 3-41)

> ADD > LOTION; TOPICAL
 > ADD > LOTRIMIN
 > ADD > SCHERING 12#

CORTICOTROPIN (PAGE 3-43)

INJECTABLE; INJECTION
 /REPOSITORY CORTICOTROPIN/
 /BC/ /MYETH. LABS/AMID/ /40 UNITS/ML/
 /BC/ /80 UNITS/ML/

CYANOCOBALAMIN (PAGE 3-44)

INJECTABLE; INJECTION
 > ADD > AP CYANOCOBALAMIN 1MG/ML#
 SOLOPAK/HPL
 AP DOBECAMIN 1MG/ML#
 MAURRY BIOLOGICAL
 /AB/ REDISOL /0.1MG/ML/
 MS&D/MERCK
 /AB/ SYTOBEX /0.1MG/ML/
 PARKE DAVIS/W-L

CYCLOSPORINE (PAGE 3-46)

INJECTABLE; INJECTION
 SANDIMUNE
 SANDOZ PHARMS/SANDOZ 50MG/ML#

SOLUTION; ORAL
 SANDIMUNE
 SANDOZ PHARMS/SANDOZ 100MG/ML#

CYPROHEPTADINE HYDROCHLORIDE (PAGE 3-46)

TABLET; ORAL
CYPROHEPTADINE HCL
 > ADD > AA DURAMED PHARMS 8MG#
 > ADD > AA PIONEER PHARMS 8MG#

DEXTROSE; DOPAMINE HYDROCHLORIDE (PAGE 3-53)

INJECTABLE: INJECTION
/DOPAMINE HCL IN DEXTROSE 5%
BOTTLE NCL
ABBOTT LABORATORIES
55M/100ML; 50MG/100ML
55M/100ML; 160MG/100ML
BOTTLE NCL IN PLASTIC CONTAINER
ABBOTT LABORATORIES
55M/100ML; 160MG/100ML
55M/100ML; 160MG/100ML
55M/100ML; 320MG/100ML

DEXTROSE; HEPARIN SODIUM (PAGE 3-53)

INJECTABLE: INJECTION
HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER
TRAVENOL LABS
55M/100ML; 4,000 UNITS/100ML

DIATRIZOATE MESLIMINE; DIATRIZOATE SODIUM (PAGE 3-57)

INJECTABLE: INJECTION
/DIATRIZOATE MESLIMINE AND DIATRIZOATE SODIUM
DIATRIZOATE-69

DIETHYLPROPION HYDROCHLORIDE (PAGE 3-59)

TABLET: ORAL
DIETHYLPROPION HCL
CANALL
25MG

DIMENHYDRINATE (PAGE 3-60)

INJECTABLE: INJECTION
BIMENHYDRATE
/INTL MEDICATION SYS//BIMH/INTL
CAPSULE: ORAL
SK-DIMENHYDRAMINE
SKAF LABORATORIES
/45MG/

ELIXIR: ORAL
DELIX
HALSET DRUG
DIBENL
MR CENCI LABS
12.5MG/5ML

AA

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-61)

ELIXIR; ORAL
DIPHENHYDRAMINE HCL
 > DLT > /AA/ /CORD LABORATORIES/ /12.5MG/5ML/
 /AA/ /SK-LABORATORIES/ /12.5MG/5ML/
 /AA/ /SK-LABORATORIES/ /12.5MG/5ML/

DISULFIRAM (PAGE 3-63)

TABLET; ORAL
DISULFIRAM
 BX CHELSEA LABORATORIES 250MG
 BX 500MG
 BX SIDMAK LABORATORIES 250MG
 BX 500MG

DOXYCYCLINE HYCLATE (PAGE 3-64)

CAPSULE; ORAL
DOXYCYCLINE HYCLATE
 AB CHELSEA LABORATORIES EQ 50MG BASE
 AB HEATHER DRUG EQ 50MG BASE
 AB EQ 100MG BASE
 AB PAR PHARMACEUTICAL EQ 100MG BASE
 AB PUREPAC/KALIPHARMA EQ 50MG BASE
 AB EQ 100MG BASE

INJECTABLE; INJECTION
DOXY 100
 AP LYPHO-MED EQ 100MG BASE/VIAL
DOXY 200
 AP LYPHO-MED EQ 200MG BASE/VIAL
DOXYCYCLINE
 AP ELKINS-SINN EQ 100MG BASE/VIAL
 AP EQ 200MG BASE/VIAL
VIBRAMYCIN
 AP PFIZER LABS/PFIZER EQ 200MG BASE/VIAL

TABLET; ORAL
DOXYCYCLINE HYCLATE
 AB HEATHER DRUG EQ 100MG BASE

DROPERIDOL; FENTANYL CITRATE (PAGE 3-64)

INJECTABLE; INJECTION
 INNOVAR
 /JANSSEN PHARMA/ /2.5MG/ML;EQ 0.05MG/ML/
 JANSSEN PHARMA 2.5MG/ML;EQ 0.05MG BASE/ML

DYCLONINE HYDROCHLORIDE (PAGE 3-64)

SOLUTION; TOPICAL
DYCLONE
 > DLT > /NEFFEL DON/DON CHEN/0.5%/
 > DLT > /1%/
 > ADD > ASTRA PHARM PRODS 0.5%
 > ADD > 1%

ECHOTHIOPHATE IODIDE (PAGE 3-65)

POWDER FOR RECONSTITUTION; OPHTHALMIC
ECHOTHIOPHATE
 /AT/ /ALCON LABORATORIES/ /0.03%/
 /AT/ /0.06%/
 /AT/ /0.125%/
 /AT/ /0.25%/
 PHOSPHOLINE IODIDE
 /AT/ AYERST LABS/AMMO 0.03%
 /AT/ 0.06%
 /AT/ 0.125%
 /AT/ 0.25%

EPINEPHRINE; 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 LC

ERYTHROMYCIN (PAGE 3-67)

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

ESTRADIOL (PAGE 3-69)

> ADD > CREAM; VAGINAL
 > ADD > ESTRACE
 > ADD > MEAD JOHNSON/B-M 0.01%
 > ADD >

GRISEOFULVIN, ULTRAMICROCRYSTALLINE (PAGE 3-82)

TABLET; ORAL		
<u>FULVICIN P/B 330</u>		
AB	SCHERING	330MG
<u>GRISACTIN ULTRA</u>		
AB	AYERST LABS/AMMO	165MG
AB		330MG

HEPARIN SODIUM (PAGE 3-83)

INJECTABLE; INJECTION		
<u>HEPARIN SODIUM</u>		
AP	NATCON CHEMICAL	1,000 UNITS/ML

HEPARIN SODIUM; SODIUM CHLORIDE - IN PLASTIC (PAGE 3-85)

INJECTABLE; INJECTION
 HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.45%
 ABBOTT LABORATORIES 100 UNITS/ML; 4.5MG/ML
 HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.45%
 ABBOTT LABORATORIES 10,000 UNITS/100ML; 450MG/100ML
 HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.45%
 ABBOTT LABORATORIES 5,000 UNITS/100ML; 450MG/100ML
 HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45%
 ABBOTT LABORATORIES 5,000 UNITS/100ML; 450MG/100ML
 10,000 UNITS/100ML; 450MG/100ML
 HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9%
 ABBOTT LABORATORIES 1,000 UNITS/100ML; 900MG/100ML
 HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.9%
 ABBOTT LABORATORIES 10,000 UNITS/100ML; 900MG/100ML
 HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.9%
 ABBOTT LABORATORIES 5,000 UNITS/100ML; 900MG/100ML
 HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9%
 ABBOTT LABORATORIES 5,000 UNITS/100ML; 900MG/100ML

OMATROPINE METHYLBROMIDE (PAGE 3-86)

TABLET; ORAL		
<u>OMAPIN-10</u>		
/AA/	MISSION PHARMACAL	10MG
/AA/	/SÉUS-FENS SE/	
/AA/	/LETHON/	/10MG/

HYDRALAZINE HYDROCHLORIDE (PAGE 3-86)

TABLET; ORAL		
<u>HYDRALAZINE HCL</u>		
AA	PAR PHARMACEUTICAL	100MG
AA	PUREPAC/KALIPHARMA	50MG

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE (PAGE 3-87)

TABLET; ORAL		
<u>/R-HCTZ-H/</u>		
RESERPINE, HYDROCHLOROTHIAZIDE, AND HYDRALAZINE HCL		
RESERPINE, HYDRALAZINE HCL, AND HYDROCHLOROTHIAZIDE		
BP	REID-PROVIDENT LABS	25MG; 15MG; 0.1MG

HYDROCHLOROTHIAZIDE; RESERPINE (PAGE 3-89)

TABLET; ORAL		
RESERPINE AND HYDROCHLOROTHIAZIDE		
BP	CORD LABORATORIES	50MG; 0.125MG

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE (PAGE 3-89)

TABLET; ORAL		
<u>SPIRONOLACTONE H/ HYDROCHLOROTHIAZIDE</u>		
AB	PUREPAC/KALIPHARMA	25MG; 25MG

HYDROCORTISONE (PAGE 3-90)

CREAM; TOPICAL		
<u>ELDECORT</u>		
/At/	ELDER PHARMS	/0.5%/
<u>HYDROCORTISONE</u>		
AT	BAY LABORATORIES	1% 2.5%
AT		
LOTION; TOPICAL		
<u>/ELDECORT/</u>		
/At/	/MERICON INDUSTRIES/	/0.5%/
<u>GLY-CORT</u>		
AT	HERAN PHARMACEUTICAL	1% 2%
<u>HYDROCORTISONE</u>		
AT	MERICON INDUSTRIES	0.5% 1%
/At/	/TOLNE, PAULSEN/	/0.5%/

OINTMENT; TOPICAL		
<u>HYDROCORTISONE</u>		
AT	BAY LABORATORIES	1% 2.5%
AT		
<u>/SOLUTION/PROPS; OPHTHALMIC/</u>		
<u>/OPTIC/</u>		
<u>/UP JOHN/</u>		

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 6 / AUGUST / 93 - FEBRUARY / 94

KANAMYCIN SULFATE (PAGE 3-102)

INJECTABLE; INJECTION
KANAMYCIN SULFATE
 AP INTL MEDICATION SYS EQ 500MG BASE/2MLM
 AP EQ 1GM BASE/3MLM
 KANTREX
 /AP/ BRISTOL LABS/B-M /15MG/2ML/
 /AP/ /500MG/2ML/
 /AP/ /1GM/3ML/
 AP BRISTOL LABS/B-M EQ 75MG BASE/2ML
 AP EQ 500MG BASE/2ML
 AP EQ 1GM BASE/3ML

LIDOCAINE HYDROCHLORIDE (PAGE 3-104)

INJECTABLE; INJECTION
LIDOCAINE
 AP PHARMATON/SZ 22M

METHOCARBAMOL (PAGE 3-117)

TABLET; ORAL
METHOCARBAMOL
 > ADD > AA ROXANE LABORATORIES 500MGM
 > ADD > AA 750MGM

METHYLPREDNISOLONE (PAGE 3-120)

TABLET; ORAL
 METHYLPREDNISOLONE
 > ADD > BP DURAMED PHARMS 4MGM

METHYLTESTOSTERONE (PAGE 3-121)

TABLET; BUCCAL/SUBLINGUAL
 METHYLTESTOSTERONE
 /BP/ /JOHNE PAULSEN/ /10MG/

METRONIDAZOLE (PAGE 3-122)

INJECTABLE; INJECTION
METRONIDAZOLE
 AP ABBOTT LABORATORIES 500MG/100MLM
 AP METRONIDAZOLE IN PLASTIC CONTAINER
 AP ABBOTT LABORATORIES 500MG/100MLM
 AP METRO I.V. IN PLASTIC CONTAINER
 AP AM MCGAM/AM HOSP 500MG/100MLM

METRONIDAZOLE (PAGE 3-122)

TABLET; ORAL
METRONIDAZOLE
 AB PAR PHARMACEUTICAL 250MGM
 AB 500MGM

NANDROLONE DECANOATE (PAGE 3-125)

INJECTABLE; INJECTION
NANDROLONE DECANOATE
 AB CARTER-GLOGAU 200MG/MLM
 AB LEMMON 100MG/ML
 50MG/ML
 AB LYPHO-MED 100MG/MLM
 AB 200MG/MLM
 AB MAURRY BIOLOGICAL 100MG/MLM

NAPHAZOLINE HYDROCHLORIDE (PAGE 3-125)

SOLUTION/DROPS; OPHTHALMIC
VASOCON
 > DLT > AT /SNAP/PH/COOPERVISION /0.12/
 > ADD > AT COOPERVISION PHARMS 0.12

NICOTINE RESIN COMPLEX (PAGE 3-127)

GUM, CHEWING; ORAL
 NICORETTE
 MERRELL DOW/DOW CHEM EQ 2MG BASEM

NITROGLYCERIN (PAGE 3-128)

INJECTABLE; INJECTION
NITROGL
 AP 6 POHL-BOSKAMP 5MG/MLM
 1MG/MLM
TRIDIL
 AM CRITICAL CARE/AMS 0.5MG/MLM

NIYSTATIN (PAGE 3-129)

OINTMENT; TOPICAL
NIYSTATIN
 > ADD > AT CLAY-PARK LABS 100,000 UNITS/GM
 POWDER; ORAL
 NILSTAT
 LEDERLE LABS/AM CYAN 1002M

[illegible]

PREDNISOLONE SODIUM PHOSPHATE (PAGE 3-147)

SOLUTION/DROPS; OPHTHALMIC

/AT/ INFLAMASE /EQ 0.1% BASE/
 /AT/ INFLAMASE MILD /EQ 0.1% PHOSPHATE
 /AT/ INFLAMASE FORTE /EQ 0.6% BASE/
 /AT/ COOPERVISION PHARMS /EQ 0.2% PHOSPHATE
 /AT/ METRETON /EQ 0.5% PHOSPHATE
 /AT/ SCHERING /EQ 0.1% PHOSPHATE
 /AT/ PREDAIR /EQ 0.1% PHOSPHATE
 /AT/ PREDAIR FORTE /EQ 0.2% PHOSPHATE
 /AT/ PREDNISOLONE SODIUM PHOSPHATE /EQ 0.1% PHOSPHATE
 /AT/ BARNES-HIND PHARMS /EQ 0.1% PHOSPHATE
 /AT/ BARNES-HIND PHARMS /EQ 0.2% PHOSPHATE
 /AT/ MAURRY BIOLOGICAL /EQ 0.1% PHOSPHATE
 /AT/ MAURRY BIOLOGICAL /EQ 0.2% PHOSPHATE

PREDNISOLONE TEBUTATE (PAGE 3-147)

INJECTABLE; INJECTION

> ADD > BP HYDELTRA-TBA 20MG/ML
 > ADD > BP MS&D/MERCK 20MG/ML
 > ADD > BP PREDNISOLONE TEBUTATE 20MG/ML
 > ADD > BP CARTER-GLOSAU LABS 20MG/ML

PREDNISONE (PAGE 3-147)

TABLET; ORAL

PREDNISONE
 BX DURAMED PHARMS 5MG
 BX 10MG
 BX 20MG

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-149)

CAPSULE; ORAL

/AA/ PROCAN /240MG/
 /AA/ PARKE-DAVIS-W-L /500MG/

PROPANTHELINE BROMIDE (PAGE 3-153)

TABLET; ORAL

/AA/ PROPANTHELINE BROMIDE 15MG
 /AA/ PAR PHARMACEUTICAL 15MG

PROPOXYPHENE HYDROCHLORIDE (PAGE 3-153)

CAPSULE; ORAL

/AA/ PROPOXYPHENE HCL 65MG
 /AA/ RICHLYN LABORATORIES 65MG

PROPYLTHIOURACIL (PAGE 3-154)

TABLET; ORAL

/ED/ PROPYLTHIOURACIL /50MG/
 /ED/ HYLAN PHARMS /50MG/

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE (PAGE 3-155)

SYRUP; ORAL

> ADD > ACTAMIST
 > ADD > AA HR CENCI LABS 30MG/5ML; 1.25MG/5ML
 /AA/ PSEUDOEPHEDRINE /30MG/5ML; 1.25MG/5ML/
 /AA/ BAY LABORATORIES /30MG/5ML; 1.25MG/5ML/
 /AA/ TRIACIN /30MG/5ML; 1.25MG/5ML/
 > ADD > AA TRIPROSED
 > ADD > AA HALSEY DRUG 30MG/5ML; 1.25MG/5ML

TABLET; ORAL

/AA/ TRI-SUDO /60MG; 2.5MG/
 /AA/ TD PHARMACEUTICAL /60MG; 2.5MG/
 /AA/ TRIPROLINE /60MG; 2.5MG/
 /AA/ DANBURY PHARMACAL /60MG; 2.5MG/
 /AA/ TRIPROLIDINE AND PSEUDOEPHEDRINE 60MG; 2.5MG
 /AA/ BOLAR PHARMACEUTICAL 60MG; 2.5MG
 /AA/ WEST-WARD /60MG; 2.5MG/
 /AA/ TRIPROLIDINE HCL AND PSEUDOEPHEDRINE HCL 60MG; 2.5MG
 /AA/ CHELSEA LABORATORIES 60MG; 2.5MG

QUINIDINE GLUCONATE (PAGE 3-157)

TABLET, CONTROLLED RELEASE; ORAL

/AB/ QUINIDINE GLUCONATE 324MG
 /AB/ ROXANE LABORATORIES 324MG

QUINIDINE SULFATE (PAGE 3-157)

SODIUM CHLORIDE (PAGE 3-162)

SULFINPYRAZONE (PAGE 3-169)

CAPSULE; ORAL

SULFINPYRAZONE
> ADD > AB VANGARD LABS/WHM 200MG

SULFISOXAZOLE (PAGE 3-170)

> DLT > /CHAM/ VAGINAL/
> DLT > /SANTALIN/
> DLT > /AT/ /ROFFMAN-CA' ROCHE/ /102/
> DLT > /KORO-SULE/
> DLT > /AT/ /HOLLAND-PANTOS/ /102/

TERBUTALINE SULFATE (PAGE 3-173)

TABLET; ORAL

BRICANYL
> DLT > /BP/ /ASTRA PHARM PRODS/ /2.5MG/
> DLT > /BP/ /5MG/
> ADD > BP MERRELL DOW/DOW CHEM 2.5MG
> ADD > BP 5MG

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

PAHMYCIN
/AB/ UPJOHN /250MG/
SUNYCIN
/AB/ 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 FISON 100MG
THEO-24
BC SEARLE/SEARLE PHARMS 100MG
200MG
300MG

ELIXIR; ORAL

ELIXOMIN
AA HR CENCI LABS 80MG/15ML

SOLUTION; ORAL

THEOLAXR
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 30MG/ML
AA 100MG/ML
AA NATL PHARM MFG/BARRE 100MG/ML

TABLET; ORAL

MELLAREX
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

AP INVENEX LABS/DEXTER 1002M
 LIQUID: N/A
 STERILE WATER FOR INJECTION IN PLASTIC CONTAINER
 WATER FOR INJECTION, STERILE (PAGE 3-189)

AA/ /TONE PAIN/SH/ /AA/ \$4.000 UNITS BASE/

VITAMIN A PALMITATE (PAGE 3-188)

AA/ /TONE PAIN/SH/ /AA/ \$4.000 UNITS BASE/

AA/ /TONE PAIN/SH/ /AA/ \$4.000 UNITS BASE/

TRIFLUOROMETHYL (PAGE 3-186)

AA/ /TONE PAIN/SH/ /AA/ \$4.000 UNITS BASE/

AA/ /TONE PAIN/SH/ /AA/ \$4.000 UNITS BASE/

TRISULFAPYRIMIDINES (PAGE 3-185)

AA/ /TONE PAIN/SH/ /AA/ \$4.000 UNITS BASE/

TRIFLUOROMETHYL (PAGE 3-185)

TRIFLUOROMETHYL (PAGE 3-183)

AA/ /TONE PAIN/SH/ /AA/ \$4.000 UNITS BASE/

TRIFLUOROMETHYL (PAGE 3-183)

AA/ /TONE PAIN/SH/ /AA/ \$4.000 UNITS BASE/

AA/ /TONE PAIN/SH/ /AA/ \$4.000 UNITS BASE/

AA/ /TONE PAIN/SH/ /AA/ \$4.000 UNITS BASE/

TRIFLUOROMETHYL (PAGE 3-180)

AA/ /TONE PAIN/SH/ /AA/ \$4.000 UNITS BASE/

TRIFLUOROMETHYL (PAGE 3-179)

AA/ /TONE PAIN/SH/ /AA/ \$4.000 UNITS BASE/

TRIFLUOROMETHYL (PAGE 3-178)

> DLT > /AMINOPHYLLINE; PHENOBARBITAL; RACEPHEDRINE HYDROCHLORIDE/
(PAGE AD2)

> DLT > /TABLET; ORAL/
> DLT > /ASCOTINE/
> DLT > /SEARLE PHARMS/ /100MG;5MG;25MG/

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

INJECTABLE; INJECTION

MYC PLUS

ASCOT HOSP PHARMS 10MG/ML;0.006MG/ML;0.5 UGH/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

DIPYRIDAMOLE (PAGE AD4)

TABLET; ORAL

DIPYRIDAMOLE

ASCOT HOSP PHARMS 50MG
DURAMED PHARMS 25MG

50MG

75MG

HALSEY DRUG 50MG

SUPERPHARM 50MG

ISOSORBIDE DINITRATE (PAGE AD5)

TABLET; ORAL

ISOSORBIDE DINITRATE

> ADD > BARR LABORATORIES 30MG

/METHANDROSTENOLONE/ (PAGE AD6)

/TABLET; ORAL/

/METHANDROSTENOLONE/

/PAR. PHARMACEUTICAL/ /2.5MG/
/5MG/

/BROMPHENIRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE/
/PHENYLPROPANOLAMINE HYDROCHLORIDE/ (PAGE AD3)

/ELIXIR; ORAL/

/ELIXIR DINEAPP/

/AM. ROBINS/

/4MG/5ML;1.5MG/5ML;5MG/5ML/

/TABLET; CONTROLLED RELEASE; ORAL/

/DINEAPP/

/AM. ROBINS/

/12MG;15MG;15MG/

/CARBAMPHEN EUTSYLATE; CHLORPHENTRANINE MALEATE; ISOPROPANOL/
/EOLIDE; PHENYLPROPANOLAMINE HYDROCHLORIDE/ (PAGE AD3)

/CAPSULE; CONTROLLED RELEASE; ORAL/

/JUSS-ORNADE/

/SKAF. LABORATORIES/

/20MG;5MG;2.5MG;5MG/

/SOLUTION; ORAL/

/JUSS-ORNADE/

/SKAF. LABORATORIES/

/5MG/5ML;2MG/5ML;0.75/5ML;1.5MG/5ML/

DICYCLOMINE HYDROCHLORIDE (PAGE AD3)

SYRUP; ORAL

BAYCLOMINE

BAY LABORATORIES 10MG/5ML

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