

# **APPROVED DRUG PRODUCTS**

## **With Therapeutic Equivalence Evaluations**



**The "Orange Book"**

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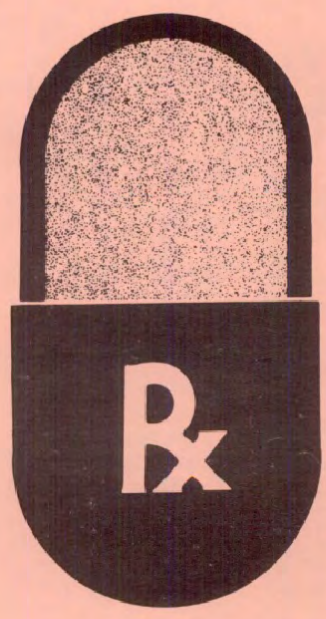
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REFERENCE

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**CUMULATIVE  
SUPPLEMENT 3**  
AUG '82 - NOV '82



**APPROVED  
PRESCRIPTION  
DRUG PRODUCTS**  
WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS  
**3<sup>RD</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, 3rd 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 Addendum: DESI Pending List.

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, 1982. 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.

II. SPECIAL NOTES

A. INDICES AND ABBREVIATIONS:

STANDARD TERMS:

Added Route of Administration: INTRAPERITONEAL

B. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

Categories of counts (pending adjustments to accommodate errata) 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 and the past quarter.

### 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 '82. 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 (pending adjustments to accommodate errata) 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.

(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 2-8 OF THE LIST)

| A. COUNTS CUMULATIVE BY QUARTERS   |              | B. ACTIVITY FOR SUPPLEMENT NUMBER 3 AND CUMULATIVE SINCE OCTOBER '82 |  |
|------------------------------------|--------------|----------------------------------------------------------------------|--|
| CATEGORIES COUNTED                 |              | NUMBER OF APPLICANTS                                                 |  |
| JULY '82 (BASELINE)                |              | OCT '82                                                              |  |
| DRUG PRODUCTS LISTED               | 6303         | 6402                                                                 |  |
| SINGLE SOURCE                      | 1885 (30%)   | 1899 (29.6%)                                                         |  |
| MULTISOURCE (1)                    | 4418 (70%)   | 4503 (70.4%)                                                         |  |
| THERAPEUTICALLY EQUIVALENT         | 3456 (54.8%) | 3532 (55.2%)                                                         |  |
| NOT THERAPEUTICALLY EQUIVALENT     | 954 (15.1%)  | 962 (15.0%)                                                          |  |
| EXCEPTIONS (2)                     | 8 (0.1%)     | 9 (0.2%)                                                             |  |
| NEW MOLECULAR ENTITIES APPROVED    | -            | 8                                                                    |  |
| NUMBER OF APPLICANTS               | 303          | 302                                                                  |  |
| NOV '82                            |              | CUMULATIVE                                                           |  |
| DRUG PRODUCTS ADDED:               | 48           | 48                                                                   |  |
| NEWLY APPROVED                     | 48           | 48                                                                   |  |
| DESI EFFECTIVE                     | 0            | 0                                                                    |  |
| REMARKETED                         | 0            | 0                                                                    |  |
| DRUG PRODUCTS REMOVED:             | 10           | 10                                                                   |  |
| WITHDRAWN APPROVAL                 | 0            | 0                                                                    |  |
| RX TO OTC SWITCH                   | 0            | 0                                                                    |  |
| DISCONTINUED MARKETING             | 10           | 10                                                                   |  |
| NET GAIN IN DRUG PRODUCTS          | 38           | 38                                                                   |  |
| SINGLE SOURCE PRODUCTS APPROVED    | 10           | 10                                                                   |  |
| MULTISOURCE DRUG PRODUCTS APPROVED | 38           | 38                                                                   |  |
| NEW MOLECULAR ENTITIES APPROVED:   | 4            | 4                                                                    |  |
| AS THE ENTITY                      | 2            | 2                                                                    |  |
| AS A SALT, ESTER OR DERIVATIVE     | 2            | 2                                                                    |  |
| OF THE ENTITY                      | 2            | 2                                                                    |  |

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL  
ACETAMINOPHEN W/ CODEINE PHOSPHATE  
 /AA/ /CARNICK/SM CARNICK/ 325MG;30MG/

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE (PAGE 3-2)

TABLET; ORAL  
 TALACEN  
 STERLING DRUG 650MG;EQ 25MG BASEM

ACETAZOLAMIDE (PAGE 3-3)

TABLET; ORAL  
ACETAZOLAMIDE  
 AD ASCOT HOSP PHARMS 250MG

ACYCLOVIR SODIUM (PAGE 3-4)

INJECTABLE; INJECTION  
 ZOVIRAX  
 BURROUGHS WELLCOME EQ 500MG BASE/VIALM

ALUMINUM CHLORHYDROXY ALLANTOINATE; PRENIDISOLONE (PAGE 3-5)

/CREAM; TOPICAL/  
 /NETI-DERM/  
 /SCHERING/ /0.25%;0.5%/

ALUMINUM NICOTINATE (PAGE 3-5)

/TABLET; ORAL/  
 /NICALEN/  
 /HERFEL/ 600/600 CHEN/625MG/

AMINO ACIDS (PAGE 3-6)

INJECTABLE; INJECTION  
 HEPATAMINE 8%  
 AM MCGAM/AM HOSP 8%  
 NOVAMINE 8.5%  
 CUTTER LABORATORIES 8.5%  
 NOVAMINE 11.4%  
 CUTTER LABORATORIES 11.4%  
 RENAMIN W/O ELECTROLYTES  
 TRAVENOL LABS 6.5%

AMINOCAPROIC ACID (PAGE 3-7)

INJECTABLE; INJECTION

AMICAR  
 AP LEDERLE PARENTALS 250MG/ML  
AMINOCAPROIC ACID  
 AP ELKINS-SINN/AMROBINS 250MG/MLM

AMPHETAMINE ADIPATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE ADIPATE; DEXTROAMPHETAMINE SULFATE (PAGE 3-11)

CAPSULE; ORAL

DELCOBES  
 /DECCA/ /1.25MG;1.25MG;1.25MG;1.25MG/  
 /2.5MG;2.5MG;2.5MG;2.5MG/  
 /3.75MG;3.75MG;3.75MG;3.75MG/  
 /5MG;5MG;5MG;5MG/  
 LEMMON  
 1.25MG;1.25MG;1.25MG;1.25MG  
 2.5MG;2.5MG;2.5MG;2.5MG  
 3.75MG;3.75MG;3.75MG;3.75MG  
 5MG;5MG;5MG;5MG

TABLET; ORAL

DELCOBES  
 /DECCA/ /1.25MG;1.25MG;1.25MG;1.25MG/  
 /2.5MG;2.5MG;2.5MG;2.5MG/  
 /3.75MG;3.75MG;3.75MG;3.75MG/  
 /5MG;5MG;5MG;5MG/  
 LEMMON  
 1.25MG;1.25MG;1.25MG;1.25MG  
 2.5MG;2.5MG;2.5MG;2.5MG  
 3.75MG;3.75MG;3.75MG;3.75MG  
 5MG;5MG;5MG;5MG

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

CAPSULE; ORAL

/PROPOXYPHENE HCL/ 650/650/650/  
 /AA/ /ROXANE LABORATORIES/ 227MG;32.4MG;162MG;65MG/

ATROPINE SULFATE; MEPERIDINE HYDROCHLORIDE (PAGE 3-16)

INJECTABLE; INJECTION

ATROPINE AND DEMEROL  
 > ADD > AP WINTHROP LABS/STERL 0.4MG/ML;50MG/MLM  
 > ADD > AP 0.4MG/ML;75MG/MLM  
 > ADD > AP 0.4MG/ML;100MG/MLM  
MEPERIDINE AND ATROPINE SULFATE  
 > ADD > AP WYETH LABS/ATRO 0.4MG/ML;50MG/ML  
 > ADD > AP 0.4MG/ML;75MG/ML  
 > ADD > AP 0.4MG/ML;100MG/ML

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CALCIUM GLUCEPATE (PAGE 3-26)

INJECTABLE; INJECTION  
CALCIUM GLUCEPATE  
 AP INTL MEDICATION SYS EQ 20MG CALCIUM/5ML

/CALUSTERONE/ (PAGE 3-26)

TABLET; ORAL  
 /METHUSAN/ /50MG/  
 /UP/DNV

> ADD > CEFOPERAZONE SODIUM (PAGE 3-29)

> ADD > INJECTABLE; INJECTION  
 > ADD > CEFODID  
 > ADD > ROERIG/PFIZER EQ 1GM BASE/VIALM  
 > ADD > EQ 2GM BASE/VIALM

CHLORAMPHENICOL SODIUM SUCCINATE (PAGE 3-31)

INJECTABLE; INJECTION  
 > ADD > CHLORAMPHENICOL  
 > ADD > AP ELKINS-SINN/AHROBINS EQ 1GM BASE/VIALM  
 AP CHLORAMPHENICOL SODIUM SUCCINATE  
 AP LYPHO-MED EQ 1GM BASE/VIALM

CHLORDIAZEPOXIDE HYDROCHLORIDE (PAGE 3-32)

CAPSULE; ORAL  
CHLORDIAZEPOXIDE HCL  
 /AB/ /FEDERAL PHARMACAL/ /5MG/  
 /AB/ /FEDERAL PHARMACAL/ /10MG/  
 /AB/ /FEDERAL PHARMACAL/ /25MG/  
 AB LEMMON 5MG  
 AB 10MG  
 AB 25MG

CHLOROTHIAZIDE (PAGE 3-33)

TABLET; ORAL  
CHLOROTHIAZIDE  
 AB BOLAR PHARMACEUTICAL 500MG  
 /AB/ /FEDERAL PHARMACAL/ /250MG/  
 AB LEMMON 250MG

CHLORPHENIRAMINE MALEATE (PAGE 3-34)

INJECTABLE; INJECTION  
CHLORPHENIRAMINE MALEATE  
 > DLT > /AB/ /CARTER-BLOOM LABS/ /10MG/ML/  
 > DLT > /AB/ /100MG/ML/

SYRUP; ORAL  
 /HISTREY/  
 /AB/ /BOWMAN PHARMS/ /2MG/5ML/

CHLORPROMAZINE HYDROCHLORIDE (PAGE 3-35)

TABLET; ORAL  
CHLORPROMAZINE HCL  
 BP VANGARD LABS/M&M 10MG  
 BP WEST-WARD 10MG  
 BP 25MG  
 BP 50MG  
 BP 100MG  
 BP 200MG

CHLORTHALIDONE (PAGE 3-37)

TABLET; ORAL  
CHLORTHALIDONE  
 AB ASCOT HOSP PHARMS 25MG  
 AB 50MG  
 > ADD > THALITONE  
 > ADD > AB BOEHRINGER INGELHEIM 25MG

CHLORZOXAZONE (PAGE 3-37)

TABLET; ORAL  
CHLORZOXAZONE  
 AA CHELSEA LABORATORIES 250MG

> ADD > CHYMOPAPAIN (PAGE 3-37)

> ADD > INJECTABLE; INJECTION  
 > ADD > CHYMOTACTIN  
 > ADD > SMITH LABORATORIES 10,000 UNITS/VIALM

CYCLOPHOSPHAMIDE (PAGE 3-44)

INJECTABLE; INJECTION  
CYTOXAN  
 MEAD JOHNSON/B-M 1GM/VIALM  
 2GM/VIALM

/DEXBROPHENIRAMINE, MALATE; PSEUDOPHEDRINE SULFATE/ (PAGE 3-49)

|    |                                |                    |
|----|--------------------------------|--------------------|
| AE | EKINS-SINN/AHRODINS            | EQ 4% PHOSPHATE/ML |
| AF | DEXAMETHASONE SODIUM PHOSPHATE | EQ 4% PHOSPHATE/ML |
| AI | SOLUTION/DROPS: OPHTHALMIC     |                    |
| AI | DEXAMETHASONE SODIUM PHOSPHATE | EQ 0.1% PHOSPHATE  |
| AI | MEAD HECK                      | EQ 0.1% PHOSPHATE  |
| AI | MURRAY BIOLOGICAL              | EQ 0.1% PHOSPHATE  |

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-48)

TABLET: ORAL  
DEXAMETHASONE  
/BP/ /BP/ /LEDEFLE LABS/ AM. CYAN. 0.25MG/  
/BP/ /BP/ 1.5MG/  
ROXANE LABORATORIES 2MSG

DEXAMETHASONE (PAGE 3-47)

[illegible]

SYRUP; ORAL  
GYPROHEPTADINE HCL  
BAY LABORATORIES  
2MS/5ML

CYPROHEPTADINE HYDROCHLORIDE (PAGE 3-44)

|                        |                        |                    |                    |
|------------------------|------------------------|--------------------|--------------------|
| INJECTABLE; INJECTION  | ANGIOVIST 292          | BERLEX/SCHERING AG | 66% <del>10%</del> |
|                        | ANGIOVIST 870          | BERLEX/SCHERING AG | 66% <del>10%</del> |
| SOLUTION; ORAL; RECTAL | <del>FASTPROVIST</del> | BERLEX/SCHERING AG | 66% <del>10%</del> |

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM (PAGE 3-54)

|                       |                        |                         |      |
|-----------------------|------------------------|-------------------------|------|
| INJECTABLE; INJECTION | ALIOVAST 200           | BERLEX/SCHERING AG      | 602M |
|                       | URONAST MEDIUM DEXT/CI | BERLEX/SCHERING AG      | 302M |
| BP                    |                        |                         |      |
| BP                    | SOLUTION; URETHRAL     | URONAST CRYST           | 302M |
| AI                    |                        | BERLEX/SCHERING AG      | 302M |
| AI                    |                        | URONAST CRYST PEDIATRIC | 302M |
| AI                    |                        | BERLEX/SCHERING AG      | 302M |

DIATRIZOATE MEGLUMINE (PAGE 3-54)

|                                                     |    |       |
|-----------------------------------------------------|----|-------|
| CONTAINER                                           | AP | > ADD |
| NY MC&AM/AM HOSP                                    | AP | > ADD |
| BSM/100ML:150MB/100ML                               |    |       |
| CONTAINER                                           | AP | > ADD |
| TRAVENOL                                            | AP | > ADD |
| BSM/100ML:1224MB/100ML                              |    |       |
| DEXTROSE 5% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC  |    |       |
| CONTAINER                                           | AP | > ADD |
| NY MC&AM/AM HOSP                                    | AP | > ADD |
| BSM/100ML:1220MB/100ML                              |    |       |
| DEXTROSE 5% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC |    |       |
| CONTAINER                                           | AP | > ADD |
| NY MC&AM/AM HOSP                                    | AP | > ADD |
| BSM/100ML:1150MB/100ML                              |    |       |
| DEXTROSE 5% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC |    |       |
| CONTAINER                                           | AP | > ADD |
| TRAVENOL LABS                                       | AP | > ADD |
| BSM/100ML:175MB/100ML                               |    |       |
| DEXTROSE 5% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC |    |       |
| CONTAINER                                           | AP | > ADD |
| NY MC&AM/AM HOSP                                    | AP | > ADD |
| BSM/100ML:175MB/100ML                               |    |       |
| DEXTROSE 5% AND POTASSIUM CHLORIDE 0.07% IN PLASTIC |    |       |

DEXTROROSE; POTASSIUM CHLORIDE (PAGE 3-52)

INJECTABLE; INJECTION  
DEXTRASE 60%  
AH HCGAM/AH HOSP  
505H/100HLM

DEXTROSE (PAGE 3-50)

DIATRIZOATE SODIUM (PAGE 3-54)

INJECTABLE; INJECTION  
UROVIST SODIUM 300  
AP BERLEX/SCHERING AG 502M

> ADD > DILTIAZEM HYDROCHLORIDE (PAGE 3-57)

> ADD > TABLET; ORAL  
> ADD > CARDIZEM  
> ADD > MARION LABORATORIES EQ 30MG BASEM  
> ADD > EQ 60MG BASEM

DIMENHYDRINATE (PAGE 3-57)

INJECTABLE; INJECTION  
DIMENHYDRINATE  
/AB/ /CENTRAL PHARMS/ /60MG/ML/  
/SUPPOSITORY; RECTAL/  
/DRAMAMINE/  
/SEARLE PHARMS/ /100MG/

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-58)

CAPSULE; ORAL  
DIPHENHYDRAMINE HCL  
/AA/ /PREMO PHARM LABS/ /25MG/  
/AA/ /50MG/  
AA VANGARD LABS/PHM 251MG

DOPAMINE HYDROCHLORIDE (PAGE 3-60)

INJECTABLE; INJECTION  
DOPAMINE HCL  
AP ABBOTT LABORATORIES 80MG/MLM

DOXYCYCLINE HYCLATE (PAGE 3-61)

CAPSULE; ORAL  
DOXYCYCLINE HYCLATE  
AB DANBURY PHARMACAL EQ 50MG BASEM  
AB EQ 100MG BASE

TABLET; ORAL  
DOXYCYCLINE HYCLATE  
AB BARR LABORATORIES EQ 100MG BASEM

DYDROGESTERONE (PAGE 3-61)

TABLET; ORAL  
/BPHASTON/  
/BP/ /ROXANE LABORATORIES/ /5MG/  
/BP/ /10MG/  
GYNOREST  
/BP/ MEAD JOHNSON/B-M 5MG  
/BP/ 10MG

EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE (PAGE 3-62)

INJECTABLE; INJECTION  
/DURANEST W/ EPINEPHRINE/  
DURANEST

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE (PAGE 3-63)

INJECTABLE; INJECTION  
XYLOCAINE W/ EPINEPHRINE  
ASTRA PHARM PRODS 0.005MG/ML; 0.52M

ERGOLOID MESYLATES (PAGE 3-63)

TABLET; ORAL  
ERGOLOID MESYLATES  
AB DANBURY PHARMACAL 1MG  
TABLET; SUBLINGUAL  
ALKERGOT  
/AA/ /PREMO PHARM LABS/ /0.5MG/  
/AA/ /1MG/  
AA LEMMON 0.5MG  
AA 1MG  
H.E.A.  
AA VANGARD LABS/PHM 0.5MG  
AA 1MG

ERYTHROMYCIN (PAGE 3-64)

SOLUTION; TOPICAL  
> ADD > A/T/S  
> ADD > AT HOECHST-ROUSSEL 22M

ERYTHROMYCIN ESTOLATE (PAGE 3-64)

SUSPENSION; ORAL  
ERYTHROMYCIN ESTOLATE  
> ADD > NATL PHARM MFG/BARR EQ 125MG BASE/5MLM  
> ADD > AB



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HYALURONIDASE (PAGE 3-82)

INJECTABLE; INJECTION  
HYDASE  
/AB/ /WYETH LABS/ATL/ /100 UNITS/VIAL/  
WYETH LABS/AMHO 150 UNITS/VIAL

HYDRALAZINE HYDROCHLORIDE (PAGE 3-82)

TABLET; ORAL  
HYDRALAZINE HCL  
AA PAR PHARMACEUTICALS 10MG  
/AA/ /PREMO PHARM LABS/ /25MG/  
/AA/ /PREMO PHARM LABS/ /50MG/  
AA LEMMON 50MG

HYDROCHLOROTHIAZIDE (PAGE 3-83)

TABLET; ORAL  
HYDROCHLOROTHIAZIDE  
>\_DLT> AB ROXANE LABORATORIES /25MG/

HYDROCORTISONE (PAGE 3-85)

LOTION; TOPICAL  
NUTRACORT  
/AT/ /OWEN LABS/ATL/ /0.5%/  
/AT/ /OWEN LABS/ATL/ /1%/  
AT OWEN LABS/DERM PRODS 0.5%  
AT 1%  
AT 2.5%

ointment; topical  
HYMAC  
AT HMC LABS 12%

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-88)

SOLUTION; OTIC  
NEOMYCIN SULFATE-POLYMYXIN B SULFATE-HYDROCORTISONE  
AT PHARMAFAIR 1% EQ 3.5MG BASE/ML; 10,000 UNITS/ML

SUSPENSION; OTIC  
OTICATR  
>\_ADD> AT PHARMAFAIR 1% EQ 3.5MG BASE/ML; 10,000 UNITS/ML

HYDROCORTISONE BUTYRATE (PAGE 3-89)

ointment; topical  
LOCOID  
GIST-BROCADES/NETH 0.1%

HYDROXOCOBALAMIN (PAGE 3-90)

INJECTABLE; INJECTION  
ALPHA-RUVITE  
/AB/ /SARGENT LABS/ATL/ /1MG/ML/

HYDROXYZINE HYDROCHLORIDE (PAGE 3-91)

TABLET; ORAL  
HYDROXYZINE HCL  
/AB/ /PREMO PHARM LABS/ /50MG/  
AB LEMMON 50MG

HYDROXYZINE PAMOATE (PAGE 3-91)

CAPSULE; ORAL  
HY-PAM  
/AB/ /PREMO PHARM LABS/ /EQ 25MG HCL/  
/AB/ /PREMO PHARM LABS/ /EQ 50MG HCL/  
AB LEMMON EQ 25MG HCL  
AB EQ 50MG HCL  
HYDROXYZINE PAMOATE  
AB CHELSEA LABORATORIES EQ 100MG HCL  
AB DANBURY PHARMACAL EQ 50MG HCL  
AB EQ 100MG HCL

IMIPRAMINE HYDROCHLORIDE (PAGE 3-92)

TABLET; ORAL  
IMIPRAMINE HCL  
/AB/ /PREMO PHARM LABS/ /10MG/  
/AB/ /PREMO PHARM LABS/ /25MG/  
/AB/ /PREMO PHARM LABS/ /50MG/  
AB LEMMON 10MG  
AB 25MG  
AB 50MG  
>\_ADD> AB VANGARD LABS/AMH 10MG

ISOGAMMATE MEGALUMINE (PAGE 3-93)

INJECTABLE; INJECTION  
DIMERAY  
/MALLINCKRODT/ /600MG/ML/

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METHOCARBAMOL (PAGE 3-112)

TABLET; ORAL  
METHOCARBAMOL  
 AA ASCOT HOSP PHARMS 500MG  
 AA 750MG

METHYCLOTHIAZIDE (PAGE 3-114)

TABLET; ORAL  
METHYCLOTHIAZIDE  
 AB MYLAN PHARMS 2.5MG  
 AB 5MG

METHYLPREDNISOLONE ACETATE (PAGE 3-115)

INJECTABLE; INJECTION  
 METHYLPREDNISOLONE ACETATE  
 BP MAURRY BIOLOGICAL 40MG/ML  
 BP 80MG/ML

METHYLTESTOSTERONE (PAGE 3-115)

CAPSULE; ORAL  
 > ADD > METHYLTESTOSTERONE  
 > ADD > BP HEATHER DRUG 10MG  
 VIRILON  
 > DLT > /BP/ /HEATHER DRUG/ /10MG/  
 > ADD > BP STAR PHARMACEUTICALS 10MG

TABLET; ORAL  
 > ADD > BP METHYLTESTOSTERONE 10MG  
 LANNETT

METRONIDAZOLE (PAGE 3-117)

INJECTABLE; INJECTION  
 METRO I.V.  
 AP AM MCGAM/AM HOSP 500MG/100ML

TABLET; ORAL  
METRONIDAZOLE  
 AB CHELSEA LABORATORIES 250MG  
 AB CORD LABORATORIES 250MG  
 AB 500MG  
 AB DANBURY PHARMACAL 250MG  
 /AB/ /LEHMAN/ /250MG/  
 AB METRYL 250MG  
 AB LENNON

MINOCYCLINE HYDROCHLORIDE (PAGE 3-118)

TABLET; ORAL  
 MINOCIN  
 LEDERLE LABS/AM CYAN EQ 50MG BASE  
 EQ 100MG BASE

> DLT > /MINOCIN/ (PAGE 3-118)  
 > ADD > PLICAMYCIN

NYSTATIN (PAGE 3-123)

ointment; TOPICAL  
NYSTATIN  
 AT BYK-GULDEN 100,000 UNITS/GM

OXOLINTIC ACID (PAGE 3-125)

TABLET; ORAL  
 /OTIBIO/  
 /PARKE-DAVIS/ /750MG/

OXYTETRACYCLINE HYDROCHLORIDE (PAGE 3-126)

CAPSULE; ORAL  
 OXYTETRACYCLINE HCL  
 /AB/ /LEDERLE LABS/AM CYAN/ EQ 250MG BASE

PENICILLIN G POTASSIUM (PAGE 3-128)

TABLET; ORAL  
PENICILLIN G POTASSIUM  
 > DLT > /AB/ /JOHN D. COPANS/ /100,000 UNITS/  
 > DLT > /AB/ /200,000 UNITS/  
 > DLT > /AB/ /300,000 UNITS/  
 > DLT > /AB/ /400,000 UNITS/  
 > DLT > /AB/ /500,000 UNITS/

PHENDIMETRAZINE TARTRATE (PAGE 3-132)

CAPSULE; ORAL  
PHENDIMETRAZINE TARTRATE  
 /AB/ /CORD LABORATORIES/ /35MG/  
 AA REID-PROVIDENT LABS 35MG  
 X-TROZINE  
 AA REXAR PHARMACAL 35MG



PROMETHIAZINE TARTRATE (PAGE 3-132)

CAPSULE, CONTROLLED RELEASE; ORAL

MELFIAT-105

REID-PROVIDENT LABS 105HSM

X-TROZINE L.A.

REXAR PHARMACAL 105HSM

PHENETERMINE HYDROCHLORIDE (PAGE 3-133)

TABLET; ORAL

PHENTERMINE HCL

/AA/ /CORP. LABORATORIES/ /BMS/

REID-PROVIDENT LABS BMS

PINDOLOL (PAGE 3-135)

TABLET; ORAL

VIKSEN

SANDOZ PHARMS/SANDOZ 5HSM

10HSM

15HSM

POTASSIUM CHLORIDE; SODIUM CHLORIDE; (PAGE 3-136)

INJECTABLE; INJECTION

SODIUM CHLORIDE 0.9% & POTASSIUM CHLORIDE 0.075% IN PLASTIC

CONTAINER

AM HCGAM/AM HOSP

750MG/100ML; 300MG/100ML

CONTAINER

SODIUM CHLORIDE 0.9% & POTASSIUM CHLORIDE 0.15% IN PLASTIC

CONTAINER

AM HCGAM/AM HOSP

150MG/100ML; 100MG/100ML

CONTAINER

SODIUM CHLORIDE 0.9% & POTASSIUM CHLORIDE 0.22% IN PLASTIC

CONTAINER

AM HCGAM/AM HOSP

225MG/100ML; 100MG/100ML

CONTAINER

SODIUM CHLORIDE 0.9% & POTASSIUM CHLORIDE 0.22% IN PLASTIC

CONTAINER

AM HCGAM/AM HOSP

300MG/100ML; 100MG/100ML

CONTAINER

SODIUM CHLORIDE 0.9% & POTASSIUM CHLORIDE 0.22% IN PLASTIC

CONTAINER

AM HCGAM/AM HOSP

300MG/100ML; 100MG/100ML

CONTAINER

SODIUM CHLORIDE 0.9% & POTASSIUM CHLORIDE 0.22% IN PLASTIC

CONTAINER

AM HCGAM/AM HOSP

300MG/100ML; 100MG/100ML

CONTAINER

SODIUM CHLORIDE 0.9% & POTASSIUM CHLORIDE 0.22% IN PLASTIC

CONTAINER

AM HCGAM/AM HOSP

300MG/100ML; 100MG/100ML

CONTAINER

SODIUM CHLORIDE 0.9% & POTASSIUM CHLORIDE 0.22% IN PLASTIC

POTASSIUM CHLORIDE; SODIUM CHLORIDE; TROMETHAMINE (PAGE 3-136)

INJECTABLE; INJECTION

THAM-E

ABBOTT LABORATORIES

1.57MG/ML; 1.57MG/ML; 1.57MG/ML

370MG/VIAL; 1.75MG/VIAL; 360MG/VIAL

PREDNISOLONE (PAGE 3-139)

CREAM; TOPICAL

METI-DERM

SCHERING

0.5%

PREDNISOLONE

/AA/ /PHEFA/ /KALIPHAKH/ /BMS/

REID-PROVIDENT LABS BMS

PROBENECID (PAGE 3-142)

TABLET; ORAL

PROBENECID

/AA/ /BEE/ /KALIPHAKH/ /BMS/

15HSM

PROCHLOPERAZINE EDISYLATE (PAGE 3-144)

INJECTABLE; INJECTION

PROCHLOPERAZINE

AM HCGAM/AM HOSP

ELKINS-SINN/AMROBINS

EQ BMS BASE/ML

SYRUP; ORAL

COMPAZINE

SKAT LABORATORIES

EQ BMS BASE/ML

PROCHLOPERAZINE EDISYLATE

NATL PHARM MFG/BAREE

EQ BMS BASE/ML

PROMETHAZINE HYDROCHLORIDE (PAGE 3-145)

INJECTABLE; INJECTION

PROMETHAZINE

/AA/ /PHEFA/ /KALIPHAKH/ /BMS/

REID-PROVIDENT LABS BMS

15HSM

SYRUP; ORAL

BAYETHAZINE

BAY LABORATORIES

5.25MG/5ML

TABLET; ORAL

PROMETHAZINE HCL

/BP/ /LEP/ /LABS/ /AM/ /BMS/

15HSM

PROPANTHELINE BROMIDE (PAGE 3-146)

TABLET; ORAL  
PROPANTHELINE BROMIDE  
 AA ASCOT HOSP PHARMS 15MG

PROPARACAIN HYDROCHLORIDE (PAGE 3-146)

SOLUTION/DROPS; OPHTHALMIC  
PARACATHE  
 AT PRO PHARMA/STERI-MED 0.5%

PROPOXYPHENE HYDROCHLORIDE (PAGE 3-147)

CAPSULE; ORAL  
PROPOXYPHENE HCL  
 /AA/ /FREED PHARM LABS/ /65MG/  
 AA LEMMON 65MG  
 /AA/ /ROXANE LABORATORIES/ /65MG/

PYRIDOXINE HYDROCHLORIDE (PAGE 3-149)

INJECTABLE; INJECTION  
PYRIDOXINE HCL  
 AP MAURRY BIOLOGICAL 100MG/ML

QUINIDINE GLUCONATE (PAGE 3-150)

TABLET, CONTROLLED RELEASE; ORAL  
QUINIDINE GLUCONATE  
 AB DANBURY PHARMACAL 324MG

/SISOMIDIN SULFATE/ (PAGE 3-155)

/INJECTABLE; INJECTION/  
 /SISEPTIN/  
 /SCHERING/ /50MG/ML/

SODIUM CHLORIDE (PAGE 3-155)

INJECTABLE; INJECTION  
 BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
 ABBOTT LABORATORIES 9MG/ML  
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
 AP ABBOTT LABORATORIES 2MG/ML

SPIRONOLACTONE (PAGE 3-159)

TABLET; ORAL  
SPIRONOLACTONE  
 AB ASCOT HOSP PHARMS 25MG  
 > ADD > AB PARKE-DAVIS/M-L 25MG

SULFABENZAMIDE; SULFACETAMIDE; SULFATHIAZOLE; UREA (PAGE 3-160)

CREAM; VAGINAL  
SULNAC  
 AT NHC LABORATORIES 3.7%;2.86%;3.42%;0.64%  
 > ADD > AT TRIPLE SULFA  
 CLAY-PARK LABS 3.7%;2.86%;3.42%;0.64%

/SULFAMETER/ (PAGE 3-161)

/TABLET; ORAL/  
 /SULLA/  
 /BERLEX/SCHERING/ /500MG/

SULFAMETHOXAZOLE (PAGE 3-161)

TABLET; ORAL  
SULFAMETHOXAZOLE  
 AB ASCOT HOSP PHARMS 500MG

SULFINPYRAZONE (PAGE 3-162)

CAPSULE; ORAL  
ANTURANE  
 AB CIBA/CIBA-GEIGY 200MG  
 > ADD > AB SULFINPYRAZONE  
 BARR LABORATORIES 200MG  
 ZENITH LABORATORIES 200MG

TABLET; ORAL  
SULFINPYRAZONE  
 AB BARR LABORATORIES 100MG

SULFISOXAZOLE (PAGE 3-162)

TABLET; ORAL  
SULFISOXAZOLE  
 /BP/ /FREED PHARM LABS/ /500MG/  
 BP LEMMON 500MG



TRIMETHOPRIM (PAGE 3-176)

TABLET; ORAL  
 >\_ADD\_> TRIMPEX 200  
 >\_ADD\_> AB HOFFMANN-LA ROCHE 200MG

TRIMIPRAMINE MALEATE (PAGE 3-176)

CAPSULE; ORAL  
 SURMONTIL  
 IVES LABS/AMHO EQ 100MG BASEM

TROMETHAMINE (PAGE 3-177)

INJECTABLE; INJECTION  
 THAM  
 ABBOTT LABORATORIES /3.66/ML/  
 >\_DLT\_> 3.66M/100ML  
 >\_ADD\_>

TROPICAMIDE (PAGE 3-178)

SOLUTION/DROPS; OPHTHALMIC  
MYDRIACYL  
 AT ALCON LABORATORIES 1%  
TROPICAMIDE  
 AT PRO PHARMA/STERI-MED 1%

VITAMIN A (PAGE 3-179)

CAPSULE; ORAL  
VITAMIN A  
 /AA/ /LEFFERIE, LABS/AM, CYAN/50,000 'IU/

WARFARIN SODIUM (PAGE 3-180)

TABLET; ORAL  
ATHROMBIN  
 /BP/ /PURDUE, FREDERICK/ 5MG/  
 /BP/ 10MG/  
 BX PURDUE FREDERICK 5MG  
 BX 10MG  
COUMADIN  
 /BP/ /ENDO, LABS/DUPONT/ 2MG/  
 /BP/ 2.5MG/  
 /BP/ 5MG/  
 /BP/ 7.5MG/  
 /BP/ 10MG/  
 BX ENDO LABS/DUPONT 2MG  
 BX 2.5MG  
 BX 5MG  
 BX 7.5MG  
 BX 10MG

WARFARIN SODIUM (PAGE 3-180)

TABLET; ORAL  
PANWARFIN  
 /BP/ /ABBOTT, LABORATORIES/ 2MG/  
 /BP/ 2.5MG/  
 /BP/ 5MG/  
 /BP/ 7.5MG/  
 /BP/ 10MG/  
 BX ABBOTT LABORATORIES 2MG  
 BX 2.5MG  
 BX 5MG  
 BX 7.5MG  
 BX 10MG  
WARFARIN SODIUM  
 BX SOLAR PHARMACEUTICAL 2MG  
 BX 2.5MG  
 BX 5MG  
 BX 7.5MG  
 BX 10MG

WATER FOR INJECTION, STERILE (PAGE 3-180)

LIQUID; N/A  
 BACTERIOSTATIC WATER IN PLASTIC CONTAINER  
 ABBOTT LABORATORIES 100%

XENON, XE-127 (PAGE 3-181)

GAS; INHALATION  
 XENON XE 127  
 MALLINCKRODT 5MCI/VIALM  
 10MCI/VIALM



**CURRENT STATUS - INEFFECTIVE**

ADDENDUM  
DESIGN PENDING LIST

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