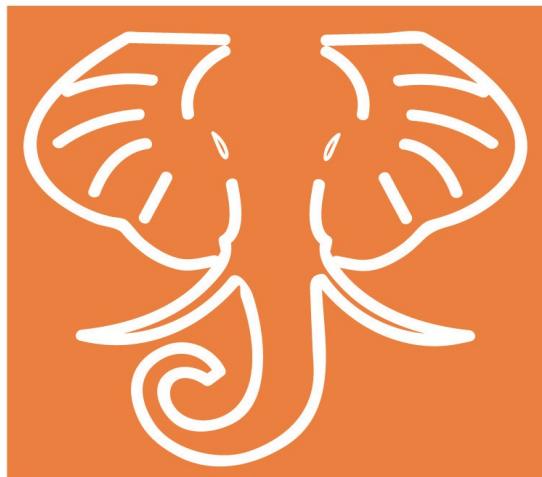


Approved prescription drug products with therapeutic equivalence evaluations.

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

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CUMULATIVE
SUPPLEMENT 2
AUG'83 - OCT'83

APPROVED
PRESCRIPTION
DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

4TH EDITION

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

I. PREFACE

This cumulative supplement is one of a series of monthly updates to the Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 4th Edition, (the List) to cover interim revisions to the annual publication of the List in its entirety. The List is comprised of several parts and some by their nature are identified by the term "List". The cumulative supplements routinely provide updates to two of these Lists: The Drug Product List and the DESI Addendum.

The List cannot be used effectively without the current cumulative supplement. Users may wish to place an asterisk (*) in the List to the left of the ingredient(s) in the Drug Product List and the product name in the Addendum to indicate that changes to that entry appear in the cumulative supplement. It is also suggested that earlier cumulative supplements be discarded to avoid possible confusion. In this way, only the List and current cumulative supplement need be referenced.

A. DRUG PRODUCT LIST

The Drug Product List cumulative supplements include the changes made since August 1, 1983. Each subsequent cumulative supplement replaces the previous month's cumulative supplement.

Information in this cumulative supplement follows the format of the Drug Product List. The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Context information on drug products is provided in each cumulative supplement for completeness to assist in locating the proper place in the Drug Product List for the revision. (Strength(s) which already exist in the publication will not be repeated for context.) A page number in parentheses referring to the Drug Product List is located to the right of the ingredient(s).

Additions to the Drug Product List are indicated by new information in the cumulative supplement. Additions new to the current cumulative supplement are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is dropped in subsequent cumulative supplements for that item.

Deletions from the Drug Product List are indicated by overstruck print in the cumulative supplement. Deletions new to the current cumulative supplement are indicated by the symbol ~~>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. 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. The subject product withdrawals are not reflected in this issue of Cumulative Supplement, but will be reflected in Cumulative Supplement 3: August-November, 1983.

Drug products which have been reformulated to exclude phenacetin will appear as they are approved as additions under the appropriate ingredient headings.

III. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

DESCRIPTION OF REPORT

The following report provides summary counts derived from product information in the Drug Product List and the current cumulative supplement. The counts appear in two sections. Section A. refers to the products in the List and Section B. to products in the current cumulative supplement. A new column of data will appear in Section A. each three-month period following July '83. Section A. therefore will provide baseline and quarterly data while Section B. provides monthly activity.

USE OF REPORT

From the data presented under Section B., users should be able to observe such things as (1) newly approved, DESI effective and remarketed drug products which are added to the List; (2) products that are being removed from the List as the result of withdrawal of approval, changes from prescription to over-the-counter status and discontinued marketing of products; and, (3) trends in approval of products as either multisource or single source during each month within the quarter. The report does not reflect category changes from multisource to single source and vice versa. However, the net gain that results from all additions, deletions and category changes is reflected in the quarterly counts for multisource and single source products.

Drug Product Definition

For this report, a drug product is the representation in the Drug Product List of an active moiety (includes molecular entity and its salts, esters and derivatives) either as a single entity or as a combination product, provided in a specific dosage form and strength for a given route of administration marketed by a firm under a particular generic or trade name.

New Molecular Entity

The active moiety has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or part of a combination.

Drug Product Count

This report provides counts in several categories from the list composed of domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Counts of products still pending in the DESI review are not provided. Excluded also are those approved drug products marketed by distributors; those marketed solely abroad; and products now regarded as medical devices, biologics or foods. Also not included in the counts are those duplicate products of a given applicant whose only distinguishing characteristics are items such as package size, inactive ingredient(s), color and alternate manufacturing sites. These various counts are excluded because the Drug Product List itself excludes products from these categories.

A. COUNTS CUMULATIVE BY QUARTERS	
JULY '83 (BASELINE)	
DRUG PRODUCTS LISTED	6679
SINGLE SOURCE	1908 (28.6%)
MULTISOURCE (1)	4771 (71.4%)
THEAPEUTICALLY EQUIVALENT	3804 (57.0%)
NOT THEAPEUTICALLY EQUIVALENT	957 (14.3%)
EXCEPTIIONS (2)	10 (0.1%)
NEW MOLECULAR ENTITIES APPROVED	-
NUMBER OF APPLICANTS	304

B. ACTIVITY FOR SUPPLEMENT NUMBER 2	
AUG '83	
SEPT '83	
DRUG PRODUCTS ADDED:	169
NEWLY APPROVED	165
DESI EFFECTIVE	1
REMARKETED	3
DWUG PRODUCTS REMOVED:	58
WITHDRAWN APPROVAL	0
RX TO OTC SWITCH	0
DISCONTINUED MARKETING	2
NET GAIN IN DRUG PRODUCTS	56
SINGLE SOURCE PRODUCTS APPROVED	111
MULTISOURCE DRUG PRODUCTS APPROVED	135
NEW MOLECULAR ENTITIES APPROVED:	34
AS THE ENTITY	2
AS A SALT, ESTER OR DERIVATIVE	0
OF THE ENTITY	2
FROM MORE THAN ONE APPLICANT	1
(1) THERAPEUTIC EQUIVALENCE EVALUATIONS PROVIDED ONLY FOR MULTISOURCE PRODUCTS (1.e., AVAILABLE	1
(2) AMINO ACID-CONTAINING PRODUCTS OF VARYING COMPOSITION (SEE PAGE 1-5 OF THE LIST)	1

APPROVED PRESCRIPTION DRUG PRODUCTS

DRUG PRODUCT LIST

CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '83 - OCTOBER '83

1

AMINOPHYLLINE (PAGE 3-8)

/LIQUID; ORAL/

SOLUTION; ORAL

AMINOPHYLLINE

AA ROXANE LABORATORIES 105MG/5ML*

TABLET; ORAL

AMINOPHYLLINE

BD BARR LABORATORIES 100MG*

BD 200MG*

> ADD > AB VANGARD LABS/MMM 100MG*

> ADD > AB 200MG*

> DLT > /AMPHETAMINE SULFATE/ (PAGE 3-13)

> DLT > /CAPSULE; CONTROLLED RELEASE; ORAL

> DLT > /BENZODRINE/

> DLT > /SKAF. LABORATORIES/ 15MG/

> DLT > /TABLET; ORAL/

> DLT > /BENZODRINE/

> DLT > /SKAF. LABORATORIES/ 5MG/

> DLT > /10MG/

> ADD > ASPIRIN; BUTALBITAL (PAGE 3-15)

> ADD > TABLET; ORAL

> ADD > AXOTAL

> ADD > ADRIA LABORATORIES 650MG;50MG*

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-15)

TABLET; ORAL

ASPIRIN AND CAFFEINE W/ BUTALBITAL

PUREPAC/KALIPHARMA 325MG;50MG;40MG*

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

TABLET; ORAL

A.P.C. W/ BUTALBITAL

/AB/ /PUREPAC/KALIPHARMA/ 160MG;50MG;50MG;150MG/

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

CAPSULE; ORAL

SYNALGOS-DC

IVES LABS/AMHO 356.4MG;30MG;16MG*

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

CAPSULE; ORAL

PROPOXYPHENE COMPOUND 65

/66/ /TOHNE PAULSEN/ 227MG;32.4MG;162MG;65MG/

/66/ /REPRO COMPOUND 65/

/66/ /REPD-PROVIDENT LABS/ 227MG;32.4MG;162MG;65MG/

/66/ /SK-65 COMPOUND/

/66/ /SKAF. LABORATORIES/ 227MG;32.4MG;162MG;65MG/

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

CAPSULE; ORAL

DARVON COMPOUND-65

/ADD/ AA ELI LILLY INDSTRS/PR 389MG;32.4MG;65MG

/ADD/ AA PROPOXYPHENE COMPOUND 65

/ADD/ AA LEMON 389MG;32.4MG;65MG*

/ADD/ AA SK-65 COMPOUND

/ADD/ AA SK&F LABORATORIES 389MG;32.4MG;65MG*

ASPIRIN; CARISOPRODOL (PAGE 3-16)

TABLET; ORAL

SOMA COMPOUND

HALLACE PHARMS/C-W 325MG;200MG*

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

TABLET; ORAL

SOMA COMPOUND W/ CODEINE

HALLACE PHARMS/C-W 325MG;200MG;16MG*

ASPIRIN; HYDROCODONE BITARTRATE (PAGE 3-16)

TABLET; ORAL

VICOPRIN

KNOLL PHARMACEUTICAL 500MG;5MG*

BACAMPICILLIN HYDROCHLORIDE (PAGE 3-18)

TABLET; ORAL

SPECTROBID

PFIZER LABS/PFIZER 800MG*

BENZTHIAZIDE (PAGE 3-20)

TABLET; ORAL

PROAGUA

/DLT/ /PP/ /REPD-PROVIDENT LABS/ 50MG/

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '83 - OCTOBER '83

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> ADD > CEFURGXIME SODIUM (PAGE 3-30)

> ADD > INJECTABLE; INJECTION
 > ADD > ZINACEF
 > ADD > GLAXO EQ 750MG BASE/VIAL
 > ADD > EQ 1.5GM BASE/VIAL

CORTICOTROPIN (PAGE 3-43)

> DLT > INJECTABLE; INJECTION
 > DLT > /BC/ REPOSITORY CORTICOTROPIN/
 > DLT > /BC/ NYETH LABS/AND/ /40 UNITS/ML/
 > DLT > /BC/ /60 UNITS/ML/

CHLORDIAZEPOXIDE (PAGE 3-33)

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

CHLORDIAZEPOXIDE HYDROCHLORIDE (PAGE 3-33)

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

CHLOROTHIAZIDE (PAGE 3-35)

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

CHLORPHENIRAMINE MALEATE (PAGE 3-36)

TABLET; ORAL
CHLORPHENIRAMINE MALEATE
 /AA/ /TONNE PAULSEN/ /4MG/

CHLORTHALIDONE (PAGE 3-38)

TABLET; ORAL
CHLORTHALIDONE
 AB PUREPAC/KALIPHARMA 50MGX

CHLORZOXAZONE (PAGE 3-39)

TABLET; ORAL
CHLORZOXAZONE
 AA PAR PHARMACEUTICAL 250MGX

CYANOCOBALAMIN (PAGE 3-44)

INJECTABLE; INJECTION
REDISOL
 /AB/ MS&D/MERCK /6.1MG/ML/
SYTOBEX
 /AB/ PARKE DAVIS/W-L /6.1MG/ML/

CYPROHEPTADINE HYDROCHLORIDE (PAGE 3-46)

TABLET; ORAL
CYPROHEPTADINE HCL
 > ADD > AA DURAMED PHARMS 4MGX

DESOXIMETASONE (PAGE 3-49)

OINTMENT; TOPICAL
TOPICORT
 HOECHST-ROUSSEL 0.25%*

DEXAMETHASONE (PAGE 3-49)

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

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

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-50)

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

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '83 - OCTOBER '83

DISULFIRAM (PAGE 3-53)

DEXTRROSE; DOPAMINE HYDROCHLORIDE (PAGE 3-53)

DOPAMINE HCL; INJECTABLE; INJECTION

ABP ABBOFT LABORATORIES 55M/100ML; 80MG/100ML DOPAMINE HCL IN PLASTIC CONTAINER

BX CHELSEA LABORATORIES 250MG BX DISULFIRAM

TABLET; ORAL DOXYCYCLINE HYCLATE (PAGE 3-64)

AB CAPSULE; ORAL DOXYCYCLINE HYCLATE

> ADD > DEXTRROSE; HEPARIN SODIUM (PAGE 3-53)

> ADD > INJECTABLE; INJECTION

> ADD > HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER

> ADD > AP TRAVENOL LABS 55M/100ML; 4,000 UNITS/100ML DIAFRIZOATE MEGLUMINE; DIAFRIZOATE SODIUM (PAGE 3-57)

> ADD > AP VIBRAMYCIN PFIZER LABS/PFIZER EQ 200MG BASE/VIAL

> ADD > AP INJECTABLE; INJECTION DROPERIDOL; FENTANYL CITRATE (PAGE 3-64)

> ADD > JANSSEN PHARMA 2.5MG/ML; EQ 0.05MG BASE/ML DIAETHYLPROPION HYDROCHLORIDE (PAGE 3-59)

> ADD > INNOVART INJECTABLE; INJECTION EPINEPHRINE; LIDOCAINE HYDROCHLORIDE (PAGE 3-66)

> ADD > AA DIAETHYLPROPION HCL 25MG TABLET; ORAL DIMETHYDRIANTE (PAGE 3-60)

> ADD > AP PHARMATON/SZ 0.01MG/ML; 225M INJECTABLE; INJECTION ERGOLOD MESYLATES (PAGE 3-66)

> ADD > AA DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-61)

> ADD > AP CAPSULE; ORAL ERTHROMYCIN (PAGE 3-67)

> ADD > AA DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-61)

> ADD > AA ELIXIR; ORAL ERVTTHROMYCIN OINTMENT; OPHTHALMIC E FOUGERA/BVK-GELON 12.5G/50G

> ADD > AA HALSY DRUGS 12.5G/50G BELIX /SKF/LABORATORIES/ 12.5G/50G

> ADD > AA /SKF-DIETHYLDRUGS/ 12.5G/50G

AI DISTA PRODS/LILLY 25G/50G

AI DIPOTASSIUM PHARMACEUTICALS 25G/50G

AI E FOUGERA/BVK-GELON 12.5G/50G

AI ERVTTHROMYCIN OINTMENT; OPHTHALMIC E FOUGERA/BVK-GELON 12.5G/50G

AI HALSY DRUGS 12.5G/50G

AI /SKF-LABORATORIES/ 12.5G/50G

AI /SKF-DIETHYLDRUGS/ 12.5G/50G

AI DISTA PRODS/LILLY 25G/50G

FENTANYL CITRATE (PAGE 3-75)

INJECTABLE; INJECTION

SUBLIMAZE

> DLT > /JANSEN PHARMA/ 0.05MG/ML
JANSSEN PHARMA EQ 0.05MG BASE/ML

FLUOXYMESTERONE (PAGE 3-77)

TABLET; ORAL

FLUOXYMESTERONE

> ADD > BP COLMED LABORATORIES 10MGX

GENTAMICIN SULFATE (PAGE 3-79)

CREAM; TOPICAL

SENTAFAIR

AT PHARMAFAIR EG 1MG BASE/GRM

AT GENTAMICIN SULFATE EG 1MG BASE/GRM

INJECTABLE; INJECTION

GENTAMICIN SULFATE

AP ABBOTT LABORATORIES EG 60MG BASE/100MLX

AP EG 70MG BASE/100MLX

AP EG 80MG BASE/100MLX

AP EG 90MG BASE/100MLX

AP EG 100MG BASE/100MLX

AP EG 1.2MG BASE/MLX

AP EG 1.4MG BASE/MLX

AP EG 1.6MG BASE/MLX

AP EG 1.8MG BASE/MLX

AP EG 2MG BASE/MLX

AP EG 10MG BASE/MLX

AP EG 40MG BASE/MLX

AP EG 40MG BASE/MLX

LYPHO-MED GENTAMICIN SULFATE IN PLASTIC CONTAINER

ABBOTT LABORATORIES EG 60MG BASE/100MLX

AP EG 70MG BASE/100MLX

AP EG 80MG BASE/100MLX

AP EG 90MG BASE/100MLX

AP EG 100MG BASE/100MLX

AP EG 1.2MG BASE/MLX

AP EG 1.4MG BASE/MLX

AP EG 1.6MG BASE/MLX

AP EG 1.8MG BASE/MLX

AP EG 2MG BASE/MLX

ISOTONIC GENTAMICIN SULFATE IN PLASTIC CONTAINER

TRAVENOL LABS EG 0.8MG BASE/MLX

AP EG 80MG BASE/100MLX

GNADOTROPIN, CHORIONIC (PAGE 3-81)

INJECTABLE; INJECTION

/ANTUTRIN'S/
 /AP/ PARKE-DAVIS/N.Y./ 15,000 UNITS/VIAL/

HEPARIN SODIUM (PAGE 3-83)

INJECTABLE; INJECTION

HEPARIN SODIUM

> ADD > AP NATCON 1,000 UNITS/MLX

HOMATROPINE METHYLBROMIDE (PAGE 3-86)

TABLET; ORAL

HOMAPIN-10

/AA/ MISSION PHARMACAL 10MG

/AA/ SEUS-TENS-SE/ 10MG

/AA/ LEMON/ 10MG/

HYDRALAZINE HYDROCHLORIDE (PAGE 3-86)

TABLET; ORAL

HYDRALAZINE HCL

AA PAR PHARMACEUTICAL 100MGX

AA PUREPAC/KALIPHARMA 50MGX

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

TABLET; ORAL

/R-HCTZ-H/

> DLT > RESERPINE, HYDROCHLORTIAZIDE, AND HYDRALAZINE HCL

> ADD > RESERPINE, HYDRALAZINE HCL, AND HYDROCHLORTIAZIDE

> ADD > BP REID-PROVIDENT LABS 25MG;15MG;0.1MGX

HYDROCHLORTIAZIDE; SPIRONOLACTONE (PAGE 3-89)

TABLET; ORAL

SPIRONOLACTONE N/ HYDROCHLORTIAZIDE

AB PUREPAC/KALIPHARMA 25MG;25MGX

HYDROCORTISONE (PAGE 3-90)

CREAM; TOPICAL

ELDECORT

> DLT > /AT/ ELDER PHARMS 1.5%

HYDROCORTISONE

AT BAY LABORATORIES 1%

AT 2.5%

HYDROCORROSIONE (PAGE 3-90) HYDROFLUOROMETHYLZIDE; RESERPINE (PAGE 3-95)

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '83 - OCTOBER '83

KANAMYCIN SULFATE (PAGE 3-102)

INJECTABLE; INJECTION

KANTREX

<u>AP</u>	BRISTOL LABS/B-M	<u>EQ 75MG BASE/2ML</u>
<u>AB</u>		<u>EQ 500MG BASE/2ML</u>
<u>AB</u>		<u>EQ 1GM BASE/3ML</u>

LIDOCAINE HYDROCHLORIDE (PAGE 3-104)

INJECTABLE; INJECTION

LIDOCATON

<u>AP</u>	PHARMATON/SZ	<u>22%</u>
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METHYLTESTOSTERONE (PAGE 3-121)

TABLET; Buccal/Sublingual

METHYLTTESTOSTERONE

<u>/BP/</u>	<u>/JOHNE PAULSEN/</u>	<u>/10MG/</u>
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METRONIDAZOLE (PAGE 3-122)

INJECTABLE; INJECTION

METRO I.V. IN PLASTIC CONTAINER

<u>AP</u>	AM MCGAN/AM HOSP	<u>500MG/100MLX</u>
-----------	------------------	---------------------

TABLET; ORAL

METRONIDAZOLE

<u>AB</u>	PAR PHARMACEUTICAL	<u>250MGX</u>
<u>AB</u>		<u>500MGX</u>

NANDROLONE DECANOATE (PAGE 3-125)

INJECTABLE; INJECTION

NANDROLONE DECANOATE

<u>> ADD > AP</u>	LEMMON	<u>100MG/ML</u>
<u>> ADD > AP</u>		<u>50MG/ML</u>
<u>> ADD > AP</u>	LYPHO-MED	<u>100MG/MLX</u>
<u>> ADD > AP</u>		<u>200MG/MLX</u>

> ADD > AP MAURRY BIOLOGICAL 100MG/MLX

NITROGLYCERIN (PAGE 3-128)

INJECTABLE; INJECTION

NITRONAL

<u>AP</u>	6 POHL-BOSKAMP	<u>5MG/MLX</u>
		<u>1MG/MLX</u>

TRIDIL
AM CRITICAL CARE/AHS 0.5MG/MLX

OXTROPHYLLINE (PAGE 3-131)

TABLET, ENTERIC COATED; ORAL

CHOLEDYL

<u>AB</u>	PARKE-DAVIS/N-L	<u>100MG</u>
<u>AB</u>		<u>200MG</u>
<u>AB</u>	<u>OXTROPHYLLINE</u>	
<u>AB</u>	BOLAR PHARMACEUTICAL	<u>100MGX</u>

200MGX

OXYTETRACYCLINE HYDROCHLORIDE (PAGE 3-132)

CAPSULE; ORAL

OXYDAPAR

<u>/AB/</u>	<u>/PARKE-DAVIS/N-L/</u>	<u>/EQ 250MG BASE/</u>
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PENICILLIN V POTASSIUM (PAGE 3-135)

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN VK

<u>/AB/</u>	<u>/UP, JOHN/</u>	<u>/EQ 125MG BASE/ML/</u>
<u>/AB/</u>		<u>/EQ 250MG BASE/ML/</u>

PHENDIMETRAZINE TARTRATE (PAGE 3-138)

TABLET; ORAL

PHENDIMETRAZINE TARTRATE

<u>AA</u>	FERNDALE LABS	<u>35MGX</u>
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PHENTERMINE HYDROCHLORIDE (PAGE 3-139)

CAPSULE; ORAL

ADIPEX-P

<u>AA</u>	LEMMON	<u>57.5MGX</u>
<u>> ADD > AA</u>	<u>DAPEX-37.5</u>	
<u>> ADD > AA</u>	FERNDALE LABS	<u>37.5MGX</u>
<u>> ADD > AA</u>	<u>PHENTERMINE HCL</u>	

CANALL 57.5MGX

POTASSIUM CHLORIDE (PAGE 3-143)

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

<u>/AB/</u>	<u>/RAVENOL LABS/</u>	<u>/3MEG/ML/</u>
<u>/AB/</u>		<u>/3MEG/ML/</u>
<u>/AB/</u>		<u>/6MEG/ML/</u>

SOMATROPIN (PAGE 3-165)

INJECTABLE; INJECTION
 ASELLACRIN 2
 SERONO LABS 2 IU/VIALX
 /ASELLACRIN/
 ASELLACRIN 10

SPIRONOLACTONE (PAGE 3-166)

TABLET; ORAL
SPIRONOLACTONE
 AB PUREPAC/KALIPHARMA 25MGX

SULFACETAMIDE SODIUM (PAGE 3-167)

> ADD > SOLUTION/DROPS; OPHTHALMIC
 > ADD > AT SULFAIR FORTE
 PHARMAFAIR 30Z

TESTOSTERONE (PAGE 3-173)

INJECTABLE; INJECTION
 TESTOSTERONE
 CARTER-GLOGAU LABS 50MG/MLX

TETRACYCLINE HYDROCHLORIDE (PAGE 3-174)

CAPSULE; ORAL
TETRACYCLINE HCL
 > DLT > AB / LENTON / /250MG /
 TABLET; ORAL
PANMYCIN
 AB UPJOHN /450MG /
 AB SUMYCIN
 ER SQUIBB AND SONS 250MG

THEOPHYLLINE (PAGE 3-176)

CAPSULE, CONTROLLED RELEASE; ORAL
 SOMOPHYLLIN-CRT
 BC FISONS 100MG
 THEO-24
 BC SEARLE/SEARLE PHARMS 100MGX
 200MGX
 300MGX
 SOLUTION; ORAL
THEOLAIR
 AA RIKER LABS/3M 80MG/15ML
THEOPHYLLINE
 AA ROXANE LABORATORIES 80MG/15MLX

THEOPHYLLINE (PAGE 3-176)

TABLET, CONTROLLED RELEASE; ORAL
 THEOCONTIN
 BC PURDUE FREDERICK 200MGX
THEO-DUR
 BC KEY PHARMACEUTICALS 200MG

THIORIDAZINE HYDROCHLORIDE (PAGE 3-178)

CONCENTRATE; ORAL
THIORIDAZINE HCL
 AA NATL PHARM MFG/BARRE 100MG/MLX
 TABLET; ORAL
MELLARIL
 AB SANDOZ PHARMS/SANDOZ 100MG
THIORIDAZINE HCL
 AB BOLAR PHARMACEUTICAL 10MGX
 AB 100MGX
 AB CORD LABORATORIES 10MGX
 AB 15MGX
 AB 25MGX
 AB 50MGX
 > ADD > AB ZENITH LABORATORIES 100MGX

TIMOLOL MALEATE (PAGE 3-179)

TABLET; ORAL
 BLOCADREN
 MS&D/MERCK 5MG

TRIAMCINOLONE ACETONIDE (PAGE 3-180)
 CREAM; TOPICAL
TRIAMCINOLONE ACETONIDE
 AT BAY LABORATORIES 0.025%
 AT 0.1%
 AT 0.5%

OINTMENT; TOPICAL
TRIAMCINOLONE ACETONIDE
 AT BAY LABORATORIES 0.025%
 AT 0.1%
 AT 0.5%

TRISULFAPYRIMIDINES (PAGE 3-185)

SUSPENSION; ORAL
 > DLT > /QUADRAMOTO /
 > DLT > AB /ELDER PHARMS/ /500MG/5ML /
TRISEN
 /AB /BEECHAM LABS/BEECHAM/500MG/5ML /

TRISULFAPYRIMIDINES (PAGE 3-185)

/A/ /REED-PERRYDEN, LABS//500MS/5H/

SUSPENSION; ORAL

/TENSID/

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TABLET; ORAL

TRICLOCARNE (PAGE 3-186)

/A/ /CENTRI, LABORATORIES//500MS/5H/

/TRICLOLIE SOLFAZ/

/500MS/

>DLT >/A/ /EIDEL-PHAIRNS/

/500MS/

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ADDENDUM
DESI PENDING LIST - 'EXEMPT' (COURT ORDER) CATEGORY
CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '83 - OCTOBER '83

/CARAMIPHEN 'EDISYLATE; CHLORPHENIRAMINE MALEATE; ISOPROPANIDE/
/TOMIDE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE AD3)

/CAPSULE; CONTROLLED RELEASE; ORAL/
/TUSS-ORNADE/
/SK&F LABORATORIES/ 20MG; 40MG; 2.5MG; 50MG/

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

DIPYRIDAMOLE (PAGE AD4)

TABLET; ORAL
DIPYRIDAMOLE
ASCOT HOSP PHARMS 50MG
SUPERPHARM 50MG

>ADD>

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CURRENT STATUS - INFFECTIVE

/ADBEITAL/ /BAKKE-DAVITS-H-L/

/CABECHOUL/; ENTODAABDAA; SADDAH/

/CABEITIKA/; MENTI; DAHAKH/

/CAPIANOXHANE; MALEATE/

/DADHISIA/ /DTB/; CTA-SEF/

TUSS-DRNDADE SK&F LABORATORIES

CARAPIHEN EDISYLATE; CHLORPHENIRAMINE MALEATE;

ISOPROPAMIDE IODIDE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '83 - OCTOBER '83
DESI PENNINGS LIST - OTHER THAN EXEMPT. (COURT ORDER) CATEGORY

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