### 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-

http://hdl.handle.net/2027/mdp.39015072933081



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**CUMULATIVE SUPPLEMENT 2** 

AUG '82 - OCT '82

## APPROVED PRESCRIPTION DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

3RD EDITION







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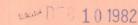
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FOOD AND DRUG ADMINISTRATION

FOOD AND DRUG ADMINISTRATION
NATIONAL CENTER FOR DRUGS AND BIOLOGICS

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

### PKETACE

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 is since August 1, 1982. Each subsequent cumulative supplement replaces previous month's cumulative supplement. changes made

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.)

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  $>\underline{\mbole*{ADD}}>$  to the left of the line on which new information exists. The  $>\underline{\mbole*{ADD}}>$  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.

of A newly approved product is identified by the lozenge (\*) to the right of its strength. This identifier remains throughout all cumulative its strength. This ident 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 derived from product information in the Drug Product List and from this cumulative supplement are presented. The format of this report was modified this month to include counts of new molecular entities (NME) and salts, esters and derivatives of NME's approved by the agency each month during 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, 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 products as either multisource or single source.

### 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 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 2-8 OF THE LIST)

S (1.0., AVAILABLE	MULTISOURCE PRODUCT	ONTL FOR	PROVIDED	EAVENVLIONS	<b>EÓNIAV</b> FENCE	THERAPEUTIC	(1)

0	0	0	OF PREVIOUSLY APPROVED NME'S
_	_		NEW SALTS, ESTERS AND DERIVATIVES
8	ζ	9	NEW MOLECULAR ENTITIES (NME'S)
6	7	L	NEWLY APPROYED MOLECULAR ENTITIES:
68	20	69	NEW MULTISOURCE DRUG PRODUCTS
07	<b>*</b> I	97	NEW SINGLE SOURCE PRODUCTS
06	52	<b>L9</b>	NET GAIN IN DRUG PRODUCTS
LE	17	91	DISCONTINUED MARKETING
7	0	2	RX TO OTC SWITCH
0	0	0	WITHDRAWN APPROVAL
62	12	81	DRUG PRODUCTS REMOVED:
1	ı	0	<b>KEMVKKETED</b>
0	0	0	DESI EFFECTIVE
128	٤4	92	NEMLY APPROVED
159	**	92	DRUG PRODUCTS ADDED:
CUMULATIVE	001 .85	VNG-SEPT '82	

B. ACTIVITY FOR SUPPLEMENT NUMBER 2 AND CUMULATIVE SINCE JULY '82

202	NUMBER OF APPLICANTS
(\$1°0 ) 8	EXCEPTIONS(2)
(\$1°51) \$56	NOT THERAPEUTICALLY EQUIVALENT
2426 (54.8\$)	THERAPEUTICALLY EQUIVALENT
(\$0L) 81++	MULTISOURCE(I)
(\$0€) ≦881	SINGFE SONBCE
2029	DRUG PRODUCTS LISTED
JULY *82	CATEGORIES COUNTED

A. COUNTS CUMULATIVE BY QUARTERS

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

### APPROVED PRESCRIPTION DRUG PRODUCTS

DRUG PRODUCT LIST

CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '82 - OCTOBER '82

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL

ACETAMINOPHEN W/ CODEINE PHOSPHATE > DLT >/AA/ /CARNRICK/GH, CARNRICK/ 325HG; 30HG/

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE (PAGE 3-2)

TABLET; ORAL TALACEN

STERLING DRUG

650MG; EQ 25MG BASEM

ACETAZOLAMIDE (PAGE 3-3)

TABLET; ORAL

ACETAZOLAMIDE

> ADD > AB ASCOT HOSP PHARMS 250MGH

> ADD > ACYCLOVIR SODIUM (PAGE 3-4)

> ADD > INJECTABLE; INJECTION

> ADD > ZOVIRAX

> ADD > BURROUGHS WELLCOME EQ 500MG BASE/VIALM

> DLT > /ALUMÍNUM CHĽÓRHYDRÓXY AĽĽÁNTOÍNATEĽ PREDNÍSOĽÓNE/(PAGE 3-5)

/cream; topical/ /NETI-DERM/ > DLT >

> DLT >

10:25%; 0:5%/ /SCHERING/ > DLT >

> DLT > /ALUMINUM MICOTINATE/(PAGE 3-5)

/tablet: drai/ /Nicalex/ > DLT >

> DLT > /NERRELL POW/DOW CHEM/625MG/ > DLT >

AMINO ACIDS (PAGE 3-6)

INJECTABLE; INJECTION

>\_ADD\_> HEPATAMINE 8%

> ADD > AM MCGAW/AM HOSP 8%n

NOVAMINE 8.5%

CUTTER LABORATORIES 8.5%

NOVAMINE 11.4%

CUTTER LABORATORIES 11.4%#

RENAMIN W/O ELECTROLYTES > ADD >

> ADD > TRAVENOL LABS 6.5%¤

AMINOCAPROIC ACID (PAGE 3-7)

INJECTABLE; INJECTION

AMICAR

> ADD > AP LEDERLE PARENTERALS 250MG/ML

> ADD > AMINOCAPROIC ACID

> ADD > AP ELKINS-SINN/AHROBINS 250MG/MLM

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

CAPSULE; ORAL

DELCOBESE

\quad \quad

smg; smg; smg; smg/

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

DELCOBESE

/peico chemical/

/1.25hg;1.25hg;1.25hg;1.25hg/ /2.5hg;2.5hg;2.5hg;2.5hg/ /3.75hg;3.75hg;3.75hg;3.75hg/ /5hg;5hg;5hg;5hg/

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 / PROPER LABORATORIES / 227MG; 32:4MG; 162MG; 65MG/

AZLOCILLIN SODIUM (PAGE 3-17)

INJECTABLE: INJECTION

AZLIN

MILES PHARMS/MILES

EQ 26M BASE/VIALM

EQ 3GM BASE/VIALM

EQ 4GM BASE/VIALM

98

98

SOOMGE

TOOMER

INJECTABLE; INJECTION CALCIUM GLUCEPTATE (PAGE 3-26) IV E. CENG/LOCHL; 556HG/LOCHL; 448HG/LOCHLM SE' THE LICONL; 4. SECH LICONL; IA SBISOTAROGAL TTOGGA INPERSOL-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER IV E. ORNG/ICCHL; STRUCT COML; 448HG/100MLM ABBOTT LABORATORIES 25. THE/100NL; 2. SEN/100NL; IA INPERSOL-LM WA DEXTROSE 2.5% IN PLASTIC CONTAINER P'OBRESTOCHT: PREMESTOCHT: CCEMESTOCHTH IA ABBOTT LABORATORIES 25.7M3/100ML;1.EGM/100ML; IA INPERSOL-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER IA P'OEMELTOOME: PERMELTOOME: 668MELTOOME IV SE. THE/ICCHL; 4. SECH/ICCHL; TRAVENOL LABS DIANEAL PD-2 W/ DEXTROSE 4.25% IN FLASTIC CONTAINER P'OBNEYTOONT: PRENEYTOONT: 668NEYTOONT IA IA SE. THE/LOCHL; Z. SCH/LOCHL; TRAVENOL LABS DIAMEAL PD-2 W/ DEXTROSE 2.5% IN PLASTIC CONTAINER P'OSHELTOSHE: PRESTIONE: CERMELTOOME IA SE'THE/TOCHL; I. SCH/LOCHL; IA TRAVENOL LABS DIAMEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER SOLUTION; INTRAPERITONEAL \NQTTOACHT : AJAATOACHT\ CHIORIDE; SODIUM LACTATE (PAGE 3-25) CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM < 170 < \aaaa ahor ba\ \aaaa ahas ba\ \\$HIBOR,HA < 170 < < 170 < < 170 < > DLT > \ EUTAPERAZINE MALEATE (PAGE 3-23) /%\$T:9/ \SKTAZHDS\ BETAMETHASONE VALERATE (PAGE 3-20) IA TO'COO GMILE/GMI IA COO UNITE/CH; EQ 3. SHG BASE/CH; PHARMAFAIR BACITRACIN ZINC-NEOMYCIN SULFATE-POLYMYXIN B SULFATE IA HO/SITMA GOO'OT COO UNITS/CH;EQ 3.5MG BASE/CM; IA вак-епгреи BACITRACIN-NECHYCIN-POLYMYXIN OINTHENT; OPHTHALMIC (PAGE 3-18) BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

INIT WEDICATION SYS EG 90MG CALCIUM/SMLM

CALCIUM GLUCEPTATE

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '82 - OCTOBER '82

< 170 <

< 170 <

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### CHLORTHALIDONE (PAGE 3-37)

TABLET; ORAL

CHLCRTHALIDCHE

> ADD > AB > ADD > AB ASCOT HOSP PHARMS

25MGH

CHLORZOXAZONE (PAGE 3-37)

TABLET; ORAL

CHLORZOXAZONE

CHELSEA LABORATORIES 250MG#

CYCLOPHOSPHAMIDE (PAGE 3-44)

INJECTABLE; INJECTION

CYTOXAN

MEAD JOHNSON/B-M

1GM/VIALE 2GM/VIAL#

CYPROHEPTADINE HYDROCHLORIDE (PAGE 3-44)

TABLET; ORAL

CYFRCHEPTADINE HOL

ASCOT HOSP PHARMS

/FREND. PHARM. LABS/

LEMMON

DEXAMETHASONE (PAGE 3-47)

TABLET; ORAL

DEXAMETHASONE

> DLT > /的户/ > DLT > /BP/

/LEDERLE. LABS/AM. CYAN/O. 25MG/

ROXANE LABORATORIES 2MGH

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-48)

INJECTABLE; INJECTION

BEKAMETHASONE

ELKINS-SINN/AHROBINS EQ 4MG FHOSPHATE/ML EQ 10MG FHOSPHATE/MLM

AP

DEXAMETHASONE SODIUM PHOSPHATE /ELKINS-SINN/AHROPINS/Ed 405 PHOSPHATE/ML/

SOLUTION/DROPS; OPHTHALMIC

DEXAMETHASONE SODIUM PHOSPHATE

/NAURRY BIOLOGICAL/

BARNES-HIND PHARMS EQ 0.12 FNOSPHATE / HAURRY BIOLOGICAL / EG 0.12 FNOSPHATE

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DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-48)

SOLUTION/DROPS; OPHTHALMIC, OTIC

DECADRON

MS&D MERCK

EQ 0.1% PHOSPHATE

> ADD > AT > ADD > DEXAMETHASONE SODIUM PHOSPHATE

> ADD > AT MAURRY BIOLOGICAL

EQ 0.1% PHOSPHATE

/DÉXERONFHENIRAMINE MALÉATE; FSEUDOÉFHEORINE SULFATE/(PAGE 3-49)

/jaacet; orac' / jaaceto /skerense /skerense

/2Mg;60Mg/

/tablet; controlled release; oral/ /drixoral/

/SCHERING/

/6MG;120MG/

DIATRIZOATE MEGLUMINE (PAGE 3-54)

INJECTABLE; INJECTION

ANGIOVIST 282

BERLEX/SCHERING AG

UROVIST MEGLUHINE DIU/CT

BERLEX/SCHERING AG

SOLUTION; URETHRAL

UROVIST CYSTO

BERLEX/SCHERING AG 30%#

UROVIST CYSTO PEDIATRIC

BERLEX/SCHERING AG 20%#

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM (PAGE 3-54)

INJECTABLE; INJECTION

ANGIOVIST 292

BERLEX/SCHERING AG 52%;8%¤

ANGIOVIST 370

BERLEX/SCHERING AG 66X;10X#

SOLUTION; ORAL, RECTAL

GASTROVIST

BERLEX/SCHERING AG 66%;10%¤

DIATRIZOATE SODIUM (PAGE 3-54)

INJECTABLE; INJECTION

UROVIST SODIUM 300

BERLEX/SCHERING AG 50%¤

TOME SHG MEAD JOHNSON/B-M

/dg/ < 110 < **CYNOREST** 

/dg/ < 170 < /dg/ < 170 < \Nota\Hquq\

\944 < T10 <

BA < DOA <

ADD > AB

AA < DOA <

TABLET; ORAL

DADBOCESTERONE (PAGE 3-61)

EG TOOME BYZER BARR LABORATORIES

DOXLCACTINE HACTATE TABLET; ORAL

EG ICCHE BYZE EG ROME BYZER

DANBURY PHARMACAL

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXACACTINE HACTATE (PAGE 3-61)

<u>q</u>A ABBOTT LABORATORIES 80MG/MLM DCFANINE HOL

INJECTABLE; INJECTION

DOPAMINE HYDROCHLORIDE (PAGE 3-60)

MMM\28AJ GRADNAV

\\$&AJ`.HAAHY`.QH\A\\

DIENEKHADSVAIKE HOL CAPSULE; ORAL

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-58)

\ahddt\

SELICA

/ בְּמִּאְכְּיִאְרָ

/dy/< ITO < DIMERNADBINVIE

INJECTABLE; INJECTION

DIMENHYDRINATE (PAGE 3-57)

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '82 - OCTOBER '82

AA < GGA <

#%2.0;JM\2M200.0

**BOMB/MLX** 

POWCE

CARTER-GLOGAU LABS

TABLET, CONTROLLED RELEASE; ORAL

FENELURAMINE HYDROCHLORIDE (PAGE 3-71)

ABBOTT LABORATORIES 2MG/MLM

\əhat:aht:ahab:o\ahahhq.alahae\alahaba\

ETHINAL ESTRABLOLS ETHYNGOLOL OIACETATES FERRAUS FUNARATE

THER O. ENGE

O.ENS

THER

FLUCROURACIL INJECTABLE; INJECTION

AH ROBINS

PONDIMIN

**AMIDATE** 

FLUOROURACIL (PAGE 3-73)

INJECTABLE; INJECTION

MAMSBAJ GRASHAV

DANBURY PHARMACAL

EKCOLOID MESYLATES (PAGE 3-63)

**SCORY MAAHY ARTEA** 

INJECTABLE; INJECTION

XAFOCVINE MY EPINEPHRINE

EKECTOTO WEZATATES

ETOMIDATE (PAGE 3-71)

\&\$-.1A%0.; \\$1.841\

ГЕННОИ

ALKERGOT

TABLET; ORAL

TABLET; SUBLINGUAL

(PAGE 3-69)

AA

AA

AA < 00A <

AA < 00A <

/ÿÿ/< <u>170</u> < /YY/< 170 <

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE (PAGE 3-63)

### GENTAMICIN SULFATE (PAGE 3-76)

INJECTABLE; INJECTION ISOTONIC GENTAMICIN SULFATE IN PLASTIC CONTAINER TRAVENOL LABS

EQ 0.8MG BASE/MLM EQ 80MG BASE/100MLM

### GONADORELIN HYDROCHLORIDE (PAGE 3-77)

INJECTABLE; INJECTION FACTREL

AYERST LABS/AMHO

EQ 0.1MG BASE/VIALM EQ 0.5MG BASE/VIALM

### GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-77)

SOLUTION/DROPS; OPHTHALMIC

NECHYCIN SULFATE AND FOLYMYXIN B SULFATE GRAMICIDIN

PHARMAFAIR .

AT

AT

0.025MG/ML;EQ 1.75MG BASE/ML; 5,000 UNITS/MLH

0.025MG/ML; EQ 1.75MG BASE/ML;

10,000 UNITS/MLm

### GUANABENZ ACETATE (PAGE 3-78)

TABLET; ORAL WYTENSIN

WYETH LABS/AMHO

EQ 4MG BASEN EQ 8MG BASEM

### HALOPERIDOL (PAGE 3-78)

/concentrates orac/ > DLT >

/HALDOL/ > DLT > /MCNETL LABORATORIES//2MG/ML/ > DLT >

/thjectable; 'thjection/ > DLT >

/HALDOL/ > DLT > /MCNETL LABORATORTES//SMG/ML/ > DLT >

HALOPERIDOL LACTATE (PAGE 3-79) > ADD >

> ADD > CONCENTRATE; ORAL

> ADD > HALDOL

> ADD > MCNEIL LABORATORIES EQ 2MG BASE/ML

> ADD > INJECTABLE; INJECTION

> ADD > HALDOL

MCNEIL LABORATORIES EQ 5MG BASE/ML > ADD >

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HYALURONIDASE (PAGE 3-82)

INJECTABLE; INJECTION

/ALIDASE/ /SEARLE PHARMS/ WYDASE

/isd 'units/vial/

/WYETH LABS/AMHO/ WYETH LABS/AMHO

/150 UNITS/VIAL/ 150 UNITS/VIAL

### HYDRALAZINE HYDROCHLORIDE (PAGE 3-82)

TABLET; ORAL

HYDRALAZINE HCL

> ADD > AA PAR PHARMACEUTICALS /PREMO. PHARM. LABS/

LEMMON

HYDROCORTISONE (PAGE 3-85)

LOTION; TOPICAL

NUTRACORT /삼· /OHEN LABS/ALCON LABS/<u>6:52/</u> AT

OWEN LABS/DERM PRODS 0.5%

2.5%m

**OINTMENT; TOPICAL** 

> ADD > > ADD > AT

AT

HYMAC NMC LABS

INE

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

SOLUTION; OTIC

HECMYCIN SULFATE-POLYMYXIN B SULFATE-HYDROCORTISONE

PHARMAFAIR

1%; EQ 3.5MG BASE/ML; 10,000 UNITS/ML#

### HYDROCORTISONE BUTYRATE (PAGE 3-89)

> ADD > **OINTMENT; TOPICAL** 

> ADD > LOCOID

> ADD > GIST-BROCADES/NETH 0.1%#

HYDROXOCOBALAMIN (PAGE 3-90)

INJECTABLE; INJECTION

/ALPHA-RUVITE/ >\_DLT\_>/AP/ /savage Labs/byk-giph/ing/mi/

KOXVNE FV003V105IEZ IOMENENTA

METHADONE HCL

ZOOME AA ER SQUIBB AND SONS ORAGRAFIN SODIUM AA BEBLEX/SCHERING AG BILIVIST CAPSULE; ORAL (26-E 30A9) MUIGOS 3TAGO91 \14\4\4\6\4\7\ < 170 < \YAAahtd\ < 170 < \hbtta\eti;:;a\eti\t < 110 < > DLT > / Idchahft Httl/(PAGE 3-93) 20113 ₽Ā 8A SEMB Ø₽ TOME *FEHHON* 19195 19195 19195 /野 TABLET; ORAL INIDEANINE HYDROCHLORIDE (PAGE 3-92) ₽¥ EG TOOMB HOFK EG RONG HOFE BA DANBURY PHARMACAL

CHELSEA LABORATORIES EQ 100MG HOLK 8A < QQA < HADBOXYZINE PAMOATE <u>aa</u> EG BCHB HOF Ø₽ EG SZWZ HOF ГЕННОИ 屬 \<u>Eq. \$2019, HQF\</u>\ \**Eq. \$240, HQF\** MAG-YH CAPSULE; ORAL

HADROXYZINE PAMOATE (PAGE 3-91)

SOME ADD < AB LEMMON \\$\$A.T. . HAAHA . . QM3AA\ /97/< ITO < SHOE! HADBOXASINE HOF TABLET; ORAL

HADBOXASINE HADBOCHFOBIDE ( 64 3-67)

LEUCOVORIN CALCIUM (PAGE 3-98)

LEUCOVORIN CALCIUM INJECTABLE; INJECTION

LEDERLE LABS/AM CYAN/ JHE/HL/

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '82 - OCTOBER '82

< QQV <

< 00V <

< <u>ada </u><

< <u>004</u> <

< <u>aaa <</u>

< 170 <

< 170 <

9

Ed 2010 BYSE VIAL

EG 3MG BASE/ML

METHOCARBAMOL (PAGE 3-112)

TABLET; ORAL METHOCARBAMOL

>\_ADD\_> AA ASCOT HOSP. PHARMS > ADD > AA

500MGx 750MGM

METHYCLOTHIAZIDE (PAGE 3-114)

TABLET; ORAL

<u>METHYCLOTHIAZIDE</u>

MYLAN PHARMS <u>AB</u>

E-1GH

METHYLPREDNISOLONE ACETATE (PAGE 3-115)

INJECTABLE; INJECTION

METHYLPREDNISOLONE ACETATE

> ADD > BP > ADD > BP MAURRY BIOLOGICAL

40MG/ML# 80MG/ML#

METRONIDAZOLE (PAGE 3-117)

INJECTABLE; INJECTION

CORD LABORATORIES

DANBURY PHARMACAL

METRO I.V.

AM MCGAW/AM HOSP

500MG/100ML×

TABLET; ORAL

/LEMMON/

METRONIDAZOLE

>\_ADD\_> AB

BA < DOA <

>\_ADD\_> AB > ADD > AB /AB/

METRYL LEMMON 250MB3 250MB/ 250NG

25CMG#

500MG#

MINOCYCLINE HYDROCHLORIDE (PAGE 3-118)

CHELSEA LABORATORIES 250MGH

TABLET; ORAL

MINOCIN

LEDERLE LABS/AM CYAN EQ 50MG BASE#

EQ 100MG BASEM

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NYSTATIN (PAGE 3-123)

**OINTMENT; TOPICAL** 

**NYSTATIN** 

BYK-GULDEN

100,000 UHITS/GMX

>\_DLT\_> /dxdiinid 'Adid/(PAGE 3-125)

/tabiet; 'daai/ /utibid/ > DLT >

> DLT > > DLT >

/25016/

OXYTETRACYCLINE HYDROCHLORIDE (PAGE 3-126)

CAPSULE; ORAL

OXYTETRACYCLINE HCI /LEDERLE LABS/AM CYAN/EG 250MG BASE/

PHENDIMETRAZINE TARTRATE (PAGE 3-132)

CAPSULE; ORAL

PHENDIMETRAZINE TARTRATE

/corp Laboratories/ /send/ REID-PROVIDENT LABS 55MG

X-TROZINE

REXAR PHARMACAL

3EMGH

CAPSULE, CONTROLLED RELEASE; ORAL

> ADD > MELFIAT-105

> ADD > REID-PROVIDENT LABS 105MGM

X-TROZINE L.A.

REXAR PHARMACAL

105MGM

PHENTERMINE HYDROCHLORIDE (PAGE 3-133)

TABLET; ORAL

FHENTERMINE HOL /cofo.'Laboratories/ /eme/

TERA

REID-PROVIDENT LABS 8MG

PINDOLOL (PAGE 3-185)

TABLET; ORAL

VISKEN

SANDOZ PHARMS/SANDOZ 5MG×

10MG#

15MGM

< 170 < < 170 < < 110 <

NMC LABORATORIES IA SULHAC

CKEAM; VAGINAL

2014 PENZYWIDE: 2014 VELYWIDE: 2014 THEYOFE: 08EV (PAGE 3-160)

#X49.0;X54.5;X68.5;X7.5

\\$M&\\$\\

SZWER 8A < QQA < **SMAAHY 420H TOOSA ZDIKONOFYCLONE** 

TABLET; ORAL

SPIRONOLACTONE (PAGE 3-159)

ABBOTT LABORATORIES SMG/MLM AA < GGA <

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER ABBOTT LABORATORIES 9MG/MLM

< 007 < BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER < QQY < INJECTABLE; INJECTION

SODIOM CHIORIDE (PAGE 3-155)

**\もいてりまりましま** < 170 <

\nottaalnt::alaetatht\ \nttaatta\ < 170 < < 170 <

> DLT > / STSGMTCTH 'SULFATE (PAGE 3-155)

DANBURY PHARMACAL SZCHER 8A GUINIDINE GLUCCHATE TABLET, CONTROLLED RELEASE; ORAL

QUINIDINE GLUCONATE (PAGE 3-150)

TOCHEVAL MAURRY BIOLOGICAL AA < GGA <

**DYRIDOXINE HCL** INJECTABLE; INJECTION

PYRIDOXINE HYDROCHLORIDE (PAGE 3-149)

PROPOXYPHENE HOL

CAPSULE; ORAL

PROPOXYPHENE HYDROCHLORIDE (PAGE 3-147)

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '82 - OCTOBER '82

Original from UNIVERSITY OF MICHIGAN PRO PHARMA/STERI-MED 0.5XX IA PARACAINE

SOLUTION/DROPS; OPHTHALMIC

PROPARACAINE HYDROCHLORIDE (PAGE 3-146)

AA < DOA < TRUCK ASCOT HOSP PHARMS PROPARTHELINE BROMIDE TABLET; ORAL

PROPAUTHELINE BROMIDE (PAGE 3-146)

/dg/ < 170 < \LEDERLE'LABS\AM'CYAM\ZBULL /dg/ < 170 < PROMETHAZINE HCL TABLET; ORAL

\\$Q₩**Q**\$₩**Г** \\$MAAHA; JAATHAQ\

/dy/ / בוקבוקבון-בק INJECTABLE; INJECTION

PROMETHAZINE HYDROCHLORIDE (PAGE 3-145)

AA NATL PHARM MFG/BARRE EQ 5MG BASE/5ML\* PROCHLORPERAZINE EDISYLATE

EG RUG BYZELRUF SK&F LABORATORIES CCHPAZINE

SYRUP: ORAL

AA

ETKINZ-ZINN\VHBOBINZ ED ZWG BYZE\WF# MA < DOA < < QQY < **DECCHLORPERAZINE** INJECTABLE; INJECTION

PROCHLORPERAZINE EDISYLATE (PAGE 3-144)

\BEECHAM. LABS/BEECHAM\ <u>soome</u>\ /BA/ PROBEHECID TABLET; ORAL

PROBENECID (PAGE 3-142)

\and \Ahaahqtiah;\and \and \\\ PREDNISOLONE

25.0

TABLET; ORAL

**2CHEBING** WETI-DERM

CREAM; TOPICAL

< QQV <

< 00A <

< DOA <

**EMEDNIZOLONE** (PAGE 3-139)

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### SULFAMETHOXAZOLE (PAGE 3-161)

TABLET; ORAL

SULFAMETHOXAZOLE

> ADD > AB ASCOT HOSP PHARMS

500MG¤

THEOPHYLLINE (PAGE 3-168)

TABLET, CONTROLLED RELEASE; ORAL

THEOCONTIN

PURDUE FREDERICK

400MGM

### SULFINPYRAZONE (PAGE 3-162)

CAPSULE; ORAL

AHTURANE

CIBA/CIBA-GEIGY

200MG

SULFINPYRAZONE

BARR LABORATORIES

200MGH

TABLET; ORAL

SULFINPYRAZONE

BARR LABORATORIES

100MG#

### SULFISOXAZOLE (PAGE 3-162)

TABLET; ORAL

SULFISOXAZOLE

><u>DLT</u> > /的/ TPREMO, PHARM, L'ABS/ > ADD > BP LEMMON

/soons/ **500MG** 

### TECHNETIUM, TC-99M, MEDRONATE KIT (PAGE 3-164)

INJECTABLE; INJECTION

AMERECAN

AMERSHAM/RADIOCHEM H/AH

TECHNETIUM, TC-99M, SULFUR COLLOID (PAGE 3-165)

INJECTABLE; INJECTION

TECHNETIUM TC 99M SULFUR COLLOID

/śńńcók thti/

/2MC1/ML/

THEOPHYLLINE (PAGE 3-168)

SYRUP; ORAL

/\$£6-444££±4-86/

/pooner Laboratories//86Ms/15HL/

SLO-PHYLLIN

WILLIAM H RORER

TABLET; ORAL

SLO-PHYLLIN

/popred l'esperted//1004e/ /BB/ /200MG/

WILLIAM H RORER

100MG

BD BD

200MG

THIAMINE HYDROCHLORIDE (PAGE 3-169)

INJECTABLE; INJECTION

THIAMINE HOL

> ADD > AP MAURRY BIOLOGICAL 100MG/MLx

### TRIAMCINOLONE ACETONIDE (PAGE 3-173)

CREAM; TOPICAL

TRIAMCINOLONE ACETONIBE

PHARMAFAIR

0.025%¤ 0.1%

AT AT

0.5%

LOTION; TOPICAL

KENALOG

ER SQUIBB AND SONS AT

0.025% 0.1%

TRIAMCINOLONE ACETONIDE

NATL PHARM MFG/BARRE 0.025%# <u>AT</u>

0.1%¤

### TRICHLORMETHIAZIDE (PAGE 3-174)

TABLET: ORAL

TRICHLORMETHIAZIDE

><u>DLT</u>> /BP/ /PRENO. PHARM LABS/

> ADD > BP

LEMMON

/4Mg/ 4MG

### TRIFLUOPERAZINE HYDROCHLORIDE (PAGE 3-175)

CONCENTRATE; ORAL

/triazine/

TFP

### TRIMETHOBENZAMIDE HYDROCHLORIDE (PAGE 3-176)

INJECTABLE; INJECTION

BEECHAM LABS/BEECHAM 100MG/ML

> ADD' > AP > ADD > > ADD > AP

TRINETHOBENZAMIDE HOL

CARTER-GLOGAU LABS 100MG/ML#

```
PWCI/VIALE
                          MALLINCKRODT
                                              < <u>QQA</u> <
                            XENON XE ISY
                                              < 004 <
                           GAS; INHALATION
                                              < 004 <
                  > VDD > XENON, XE-127 (PAGE 3-181)
                                              < <u>ada</u> <
            ABBOTT LABORATORIES 100%
BACTERIOSTATIC WATER IN PLASTIC CONTAINER
                                              < QQA <
                               LIQUID; N/A
   WATER FOR INJECTION, STERILE (PAGE 3-180)
            TOWER
                                          Xα
           7.5MGH
                                          BX
             PWCH
                                          BX
           2.5MG#
                                          BX
                                          BX
             BOLAR PHARMACEUTICAL 2MG#
                         MUIGOS NIGATAM
             TOME
                                          Xa
            7.5MG
                                          Xa
              PMG
                                          BX
            2.5MG
                                          Хa
              SMG
                  SBIROTAROBAL TTOBBA
                                          Xa
                  PANWARFIN
```

IOMCI/VIALE

TOME BX DMZ.T PX PHE BX S.5MG BX BX SMC ENDO LABS/DUPONT /पूर्व TOME BX PWG PURDUE FREDERICK BX \DINOIT/ ντανονειν \γύκρύΕ΄, **τ**κερεκτίζΚ\ TABLET; ORAL MARFARIN SODIUM (PAGE 3-180)

VITATIV A VITATIV A \Libertian A \Libertian \Liberti

CAPSULE; ORAL

(PAGE 3-179)

AT PRO PHARMA/STERI-MED INT

HYDRIACYL ALCON LABORATORIES 1X

SOLUTION/DROPS; OPHTHALMIC

TROPICAMIDE (PAGE 3-178)

Ed TOOME BYZEK

SURMONTIL
SURMONTIL

CAPSULE; ORAL

< QQY <

TRIMIPRAMINE MALEATE (PAGE 3-176)

TABLET; ORAL

MARFARIN SODIUM (PAGE 3-180)

< 00A <

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '82 - OCTOBER '82

Original from

OT

### ADDENDUM DESI PENDING LIST

### CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '82 - OCTOBER '82

### CURRENT STATUS - INEFFECTIVE

> DLT > > DLT >	/BETADINE/ /PURDUE FREDERICK/

### 

### CURRENT STATUS - 'EXEMPT' (COURT ORDER)

> <u>DLT</u> > > <u>ADD</u> >		/MCNEIL LABORATORIES/ WALLACE LABS/C-W		
> <u>ADD</u> > > <u>ADD</u> >	DIPYRIDAMOLE DIPYRIDAMO			
>_ADD_>	DIPYRIDAMOLE	HALSEY DRUG		

ADD >	DIPYRIDAMOLE	

DIPYRIDAMOLE	SUPERPHARM
DIPYRIDAMOLE	

> ADD >	HYBEPHEN	BEECHA	M LABS/BEECH	MA	
> ADD >	ATROPINE	SULFATE;	HYOSCYAMINE	SULFATE;	PHENOBARBITAL;
> ADD >	SCOPOLAMI	NE HYDRO	BROMIDE		

ISOSORBIDE	DINITRATE	INWOOD	LABS/FOREST
ISOSORBIE	DE DINITRATE		

METHANDROSTENOLONE	PAR	PHARMACEUTICAL
METHANDROSTENOLONE		

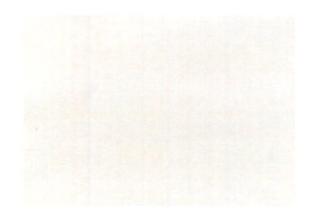
> ADD >	NITRO-TIME	TIME-CAP	LABS
> ADD >	NTTROGLYCER	IN	

NITROGLYCERIN	VITARINE/WEST	CHEM
NTTPOGLYCEPTN		

NITROSTAT PARKE-DAVIS/W-L NITROGLYCERIN







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