

APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations



The "Orange Book"

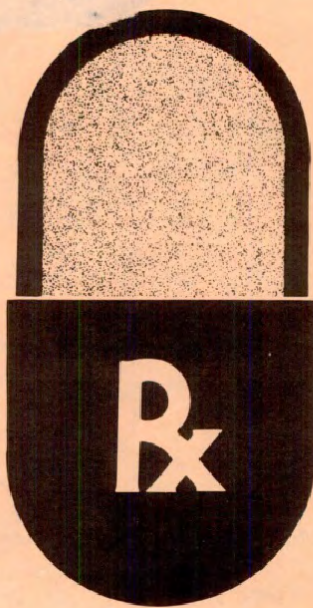
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**CUMULATIVE
SUPPLEMENT 1
AUG - SEPT 1981**



APPROVED PRESCRIPTION DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

2ND 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, 2nd Edition, (the List) to cover interim revisions to the annual publications 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, 1981. 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. 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 (x) 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. The INTRODUCTION to the 2nd Edition (1981 publication) of the Approved Prescription Drug Products with Therapeutic Equivalence Evaluations (Section II.F.5.) stated that "Protein hydrolysate injections are omitted because of safety problems." The safety problems have been resolved. Publication on this subject appeared in the FEDERAL REGISTER of July 14, 1981 (46 FR 36249). Therefore, a parenteral protein hydrolysate (see Anigen) now is approved and marketed as well as the existing related parenteral amino acid mixture solutions.
- B. A subscription form for the 2nd Edition (1981 publication) has been provided at the end of this cumulative supplement.

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 1)

CAPSULE; ORAL
 > ADD > TYLENOL W/ CODEINE NO. 3
 > ADD > AA MCNEIL PHARM 300MG;30MG
 > ADD > TYLENOL W/ CODEINE NO. 4
 > ADD > AA MCNEIL PHARM 300MG;60MG

ELIXIR; ORAL
 > ADD > ACETAMINOPHEN W/ CODEINE
 > ADD > AA PHARM ASSOC/BEACH 120MG/5ML;12MG/5ML

ACETIC ACID, GLACIAL (PAGE 2)

SOLUTION; OTIC
 > ADD > ACETASOL
 > ADD > AT NATL PHARM MFG/BARRE 22M

AMINOPHYLLINE (PAGE 4)

INJECTABLE; INJECTION
 > ADD > AMINOPHYLLINE
 > ADD > AP LYPHO-MED 25MG/ML

TABLET; ORAL
 > DLT > AMINOPHYLLIN
 > ADD > AB SEARLE PHARMS 100MG * 200MG
 > DLT > AMINOPHYLLINE
 > ADD > AB WEST-WARD 100MG * 200MG

ASPIRIN; BUTALBITAL; CAFFEINE; PHENACETIN (PAGE 11)

TABLET; ORAL
 > ADD > BUTALBITAL W/ APC
 > ADD > AB LEDERLE LABS/AM CYAN 200MG;20MG;50MG;130MG
 > ADD > PHENORIAL
 > ADD > AB PHOENIX LABORATORIES 200MG;50MG;50MG;130MG

ATENOLOL (PAGE 12)

TABLET; ORAL
 > ADD > TENORMIN
 > ADD > STUART PHARMS/ICI AM 50MG * 100MG

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE (PAGE 13)

TABLET; ORAL
 > ADD > DIPHENOXYLATE HCL W/ ATROPINE SULFATE
 > ADD > AA PREMO PHARM LABS 0.025MG;2.5MG

BECLOMETHASONE DIPROPIONATE (PAGE 14)

> ADD > AEROSOL; INHALATION/NASAL
 > ADD > BECONASE
 > ADD > BN GLAXO 0.042MG/INH
 > ADD > VANCENASE
 > ADD > BN SCHERING 0.042MG/INH

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 21)

INJECTABLE; INJECTION
 > ADD > DEXTROSE 5% IN LACTATED RINGER'S IN PLASTIC CONTAINER
 > ADD > AP CUTTER LABORATORIES 20MG/100ML;50MG/100ML;100MG/100ML;
 > ADD > AP 600MG/100ML;310MG/100ML

CHLORAMPHENICOL (PAGE 25)

SOLUTION/DROPS; OPHTHALMIC
 > ADD > CHLORAMPHENICOL
 > ADD > AT MAURRY BIOLOGICAL 0.52M

CHLORTHALIDONE (PAGE 30)

TABLET; ORAL
 > ADD > CHLORTHALIDONE
 > ADD > AB CHELSEA LABORATORIES 25MG * 50MG
 > ADD > AB DANBURY PHARMACAL 25MG * 50MG

CORTISONE ACETATE (PAGE 33)

INJECTABLE; INJECTION
 > DLT > CORTISONE ACETATE
 > ADD > BP /P-H PHARMACEUTICALS/ 25MG/ML * 50MG/ML
 > ADD > BP LEMMON 25MG/ML * 50MG/ML

CYPROHEPTADINE HYDROCHLORIDE (PAGE 36)

TABLET; ORAL
 > ADD > CYPROHEPTADINE HCL
 > ADD > AA DANBURY PHARMACAL 4MG
 > ADD > AA PREMO PHARM LABS 4MG

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE
(PAGE 68)

TABLET; ORAL
HYDRAP-ES
> ADD > BP PREMIO PHARM LABS 25MG;15MG;0.1MG#
> ADD > HYDROCHLOROTHIAZIDE/HYDRALAZINE HCL/RESERPINE
> ADD > BP DANBURY PHARMACAL 25MG;15MG;0.1MG#

HYDROCHLOROTHIAZIDE (PAGE 68)

TABLET; ORAL
HYDROCHLOROTHIAZIDE
> ADD > AB PREMIO PHARM LABS 25MG * 50MG
> ADD > AB PUREPAC/KALIPHARM 25MG * 50MG#
> DLT > AB REID-PROVIDENT LABS 25MG/* 50MG/
> ADD > ZIDE
> ADD > AB REID-PROVIDENT LABS 50MG

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE (PAGE 69)

TABLET; ORAL
SPIRONOLACTONE H/ HYDROCHLOROTHIAZIDE
> ADD > AB LEDERLE LABS/AM CYAN 25MG;25MG#

HYDROCORTISONE (PAGE 69)

ointment; TOPICAL
HYDROCORTISONE
> DLT > AT SHAFFER-DAVIS LABS 0.5%/* 1%/
> ADD > AT THAMES PHARMACAL 1%

HYDROCORTISONE ACETATE (PAGE 71)

INJECTABLE; INJECTION
HYDROCORTISONE ACETATE
> DLT > /BP/ /B-M PHARMACEUTICALS//25MG/ML/* 50MG/ML/
> ADD > BP LEMMON 25MG/ML * 50MG/ML

HYDROCORTISONE SODIUM SUCCINATE (PAGE 73)

INJECTABLE; INJECTION
HYDROCORTISONE SODIUM SUCCINATE
> ADD > AP CARTER-GLOGAU LABS EQ 100MG BASE/VIAL *
> ADD > AP EQ 250MG BASE/VIAL *
> ADD > AP EQ 500MG BASE/VIAL *
> ADD > AP EQ 1GM BASE/VIAL *

HYDROXYZINE HYDROCHLORIDE (PAGE 74)

INJECTABLE; INJECTION
HYDROXYZINE HCL
> ADD > AP LYPHO-MED 25MG/ML * 50MG/ML*
> ADD > AP NATCON CHEMICAL 25MG/ML * 50MG/ML*

HYDROXYZINE PAMOATE (PAGE 74)

CAPSULE; ORAL
HYDROXYZINE PAMOATE
> ADD > AB BULAR PHARMACEUTICAL EQ 25MG HCL * EQ 50MG HCL *
> ADD > AB EQ 100MG HCL*
VISTARIL
> ADD > AB PFIZER LABS/PFIZER EQ 25MG HCL * EQ 50MG HCL *
> ADD > AB EQ 100MG HCL

> ADD > IODOXAMATE MEGLIUMINE (PAGE 76)

INJECTABLE; INJECTION
> ADD > CHOLOVUE
> ADD > ER SQUIBB AND SONS 9.9% * 40.3%

ISOPROTERENOL HYDROCHLORIDE (PAGE 78)

SOLUTION; INHALATION
ISOPROTERENOL HCL
> ADD > AN INTL MEDICATION SYS 0.5%

LEVOPROPOXYPHENE NAPSYLATE (PAGE 80)

CAPSULE; ORAL
NOVRAD
> DLT > /ELI LILLY/ /EQ 50MG BASE/* EQ 100MG BASE/
> ADD > ELI LILLY INDSTRS/PR EQ 50MG BASE * EQ 100MG BASE
SUSPENSION; ORAL
NOVRAD
> DLT > /ELI LILLY/ /EQ 50MG BASE/5ML/
> ADD > ELI LILLY INDSTRS/PR EQ 50MG BASE/5ML

LIDOCAINE (PAGE 80)

ointment; TOPICAL
LIDOCAINE
> ADD > AT THAMES PHARMACAL 5%

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 1 / AUGUST '81 & SEPTEMBER '81

>_ADD> PROTEIN HYDROLYSATE (PAGE 122)

>_ADD> INJECTABLE; INJECTION
>_ADD> AMIGEN
>_ADD> MEAD JOHNSON/B-M 5%N

QUINIDINE SULFATE (PAGE 124)

TABLET; ORAL
>_DLT> /AB/ QUINIDINE SULFATE /200MG/
>_ADD> AB /REXALL DRUG/ /200MG/
REXALL

SODIUM NITROPRUSSIDE (PAGE 130)

INJECTABLE; INJECTION
>_ADD> AP NITROIDE 50MG/VIAL
>_ADD> AP NITROPRESS
>_ADD> AP ABBOTT LABORATORIES 50MG/VIAL

SPIRONOLACTONE (PAGE 131)

TABLET; ORAL
>_ADD> AB SPIRONOLACTONE
LEDERLE LABS/AM CYAN 25MG

SULFAMETHIZOLE (PAGE 133)

SUSPENSION; ORAL
>_DLT> PROKLAR
>_ADD> /AB/ ONEAL JONES&FELDMAN 500MG/5ML

TABLET; ORAL
>_DLT> MICROSUL
>_ADD> /AB/ ONEAL JONES&FELDMAN 1GM
>_DLT> /AB/ PROKLAR
>_ADD> AB /AB/ ONEAL JONES&FELDMAN 500MG

TECHNETIUM, TC-99M, ETIDRONATE KIT (PAGE 136)

INJECTABLE; INJECTION
>_DLT> /AB/ CINTICHEM TECHNETIUM 99M MEDSPA
>_ADD> AB /UNION CARBIDE/ /N/A/
CINTICHEM/MEDI-PHYSIC N/A

TESTOSTERONE CYPIONATE (PAGE 137)

INJECTABLE; INJECTION
>_DLT> /AB/ TESTOSTERONE CYPIONATE /100MG/ML * 200MG/ML/
>_ADD> AB /D-M PHARMACEUTICALS/ /100MG/ML * 200MG/ML/
LEMON

THEOPHYLLINE (PAGE 139)

>_ADD> CAPSULE, CONTROLLED RELEASE; ORAL
>_ADD> SOMOPHYLLINE-CRT
>_ADD> FISON 100MGX * 250MGX

ELIXIR; ORAL
>_ADD> AA THEOPHYLLINE
PHILIPS ROXANE LABS 80MG/15ML

TRIAMCINOLONE ACETONIDE (PAGE 143)

CREAM; TOPICAL
>_DLT> /AT/ TRIAMCINOLONE ACETONIDE /0.025% * 0.1% * 0.5%/
>_ADD> AT /SHAFER-DAVIS LABS/ /0.025% * 0.1% * 0.5%/
THAMES PHARMACAL

TRIAMCINOLONE DIACETATE (PAGE 143)

INJECTABLE; INJECTION
>_DLT> /BP/ TRIAMCINOLONE DIACETATE /40MG/ML/
>_ADD> BP /D-M PHARMACEUTICALS/ /40MG/ML/
LEMON

TRISULFAPYRIMIDINES (PAGE 146)

SUSPENSION; ORAL
>_DLT> /AB/ TRISULFAPYRIMIDINES /500MG/5ML/
>_ADD> AB /AB/ ONEAL JONES&FELDMAN 500MG/5ML

>_ADD> VERAPAMIL HYDROCHLORIDE (PAGE 148)

>_ADD> INJECTABLE; INJECTION
>_ADD> ISOPTIN
>_ADD> KNOLL PHARMACEUTICAL 2.5MG/MLX

ADDENDUM
DESI PENDING LIST
CUMULATIVE SUPPLEMENT NUMBER 1 / AUGUST 01 & SEPTEMBER 01

CURRENT STATUS - PROBABLY EFFECTIVE

> DLT > /MAGNETIN.....DEED & CARBONIC/
> DLT > /COAL TAR EXTRACT, HYDROPHOBIC/

CURRENT STATUS - EFFECTIVE/NEW SAFETY ISSUE

> DLT > /MAGNETIN.....DEED & CARBONIC/
> DLT > /PROTEIN HYDROLYSATE/

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