

APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations



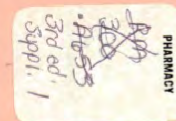
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**CUMULATIVE
SUPPLEMENT 1
AUG '82 - SEP '82**

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**APPROVED
PRESCRIPTION
DRUG PRODUCTS**

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

3RD 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 >DLT> (DELETE) to the left of the line containing the overstruck print. The >DLT> 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

Beginning with this cumulative supplement, categories of counts derived from product information in the Drug Product List and from this cumulative supplement are presented. The format of this report and the categories reported may change from time to time.

III. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

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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 or its derivatives (ingredient), 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.

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.

(1) THERAPEUTIC EQUIVALENCE EVALUATIONS PROVIDED ONLY FOR MULTISOURCE PRODUCTS (100% AVAILABLE FROM MORE THAN ONE APPLICANT)

(2) AMINO ACID-CONTAINING PRODUCTS OF VARYING COMPOSITION (SEE PAGE 2-8 OF THE LIST)

DRUG PRODUCTS ADDED:	85	85
NEWLY APPROVED	85	85
DESIGN EFFECTIVE	0	0
REMARKETED	0	0
DRUG PRODUCTS REMOVED:	18	18
WITHDRAWN APPROVAL	0	0
RX TO OTC SWITCH	2	2
DISCONTINUED MARKETING	16	16
NET GAIN IN DRUG PRODUCTS	67	67
NEW SINGLE SOURCE PRODUCTS	26	26
NEW MULTISOURCE DRUG PRODUCTS	59	59
CUMULATIVE	85	85
	18	18
	0	0
	2	2
	16	16
	67	67
	26	26
	59	59

B. ACTIVITY FOR SUPPLEMENT NUMBER 1 AND CUMULATIVE SINCE JULY '82

CATEGORIES COUNTED	JULY '82	6303
DRUG PRODUCTS LISTED	6303	1885 (30%)
SINGLE SOURCE	1885 (30%)	4418 (70%)
MULTISOURCE (1)	4418 (70%)	3456 (54.8%)
THERAPEUTICALLY EQUIVALENT	3456 (54.8%)	954 (15.1%)
NOT THERAPEUTICALLY EQUIVALENT	954 (15.1%)	8 (0.1%)
EXCEPTIONS (2)	8 (0.1%)	303
NUMBER OF APPLICANTS	303	

A. COUNTS CUMULATIVE BY QUARTERS

APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE SUPPLEMENT NUMBER 1 / AUGUST '82 & SEPTEMBER '82

1

> ADD > ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE (PAGE 3-2)

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

AMINO ACIDS (PAGE 3-6)

> ADD > INJECTABLE; INJECTION
 > ADD > NOVAMINE 8.5%
 > ADD > CUTTER LABORATORIES 8.5%
 > ADD > NOVAMINE 11.4%
 > ADD > CUTTER LABORATORIES 11.4%

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

CAPSULE; ORAL
 DELCOBESE
 /PERRICO, CHEMICAL/ 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/
 > ADD > LEHMON
 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
 /PERRICO, CHEMICAL/ 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/
 > ADD > LEHMON
 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
 > DLT > /PROPOXYPHENE HCL COMBINATION 65/
 > DLT > /ROXANE LABORATORIES/ 22.2MG;33.4MG;44.6MG;65MG/

> ADD > AZLOCILLIN SODIUM (PAGE 3-17)

> ADD > INJECTABLE; INJECTION
 > ADD > AZLIN
 > ADD > HILES PHARMS/HILES EQ 26M BASE/VIALM
 > ADD > EQ 36M BASE/VIALM
 > ADD > EQ 46M BASE/VIALM

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-18)

OINTMENT; OPHTHALMIC
 BACITRACIN-NEOMYCIN-POLYMYXIN
 > ADD > AT BYK-GULDEN 400 UNITS/GM;EQ 3.5MG BASE/GM;
 > ADD > AT 10,000 UNITS/GM
 > ADD > BACITRACIN ZINC-NEOMYCIN SULFATE-POLYMYXIN B SULFATE
 > ADD > AT PHARMAFAIR 400 UNITS/GM;EQ 3.5MG BASE/GM;
 > ADD > AT 10,000 UNITS/GM

BETAMETHASONE VALERATE (PAGE 3-20)

> DLT > /AEROSOL; TOPICAL/
 > DLT > /VALISONE/
 > DLT > /SCHERING/ 16.15%

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-25)

> DLT > /INJECTABLE; INJECTION/
 > ADD > SOLUTION; INTRAPERITONEAL
 DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
 > ADD > AT TRAVENOL LABS 25.7MG/100ML;1.5GM/100ML;
 > ADD > AT 5.08MG/100ML;5.8MG/100ML;448MG/100ML
 DIANEAL PD-2 W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
 > ADD > AT TRAVENOL LABS 25.7MG/100ML;2.5GM/100ML;
 > ADD > AT 5.08MG/100ML;5.8MG/100ML;448MG/100ML
 DIANEAL PD-2 W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
 > ADD > AT TRAVENOL LABS 25.7MG/100ML;4.25GM/100ML;
 > ADD > AT 5.08MG/100ML;5.8MG/100ML;448MG/100ML
 INPERSOL-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
 > ADD > AT ABBOTT LABORATORIES 25.7MG/100ML;1.5GM/100ML;
 > ADD > AT 5.08MG/100ML;5.8MG/100ML;448MG/100ML
 INPERSOL-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
 > ADD > AT ABBOTT LABORATORIES 25.7MG/100ML;2.5GM/100ML;
 > ADD > AT 5.08MG/100ML;5.8MG/100ML;448MG/100ML
 INPERSOL-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
 > ADD > AT ABBOTT LABORATORIES 25.7MG/100ML;4.25GM/100ML;
 > ADD > AT 5.08MG/100ML;5.8MG/100ML;448MG/100ML

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DIATRIZOATE MEGGLUMINE; DIATRIZOATE SODIUM (PAGE 3-54)

	INJECTABLE; INJECTION		
> <u>ADD</u> >	<u>ANGIOVIST 292</u>		
> <u>ADD</u> > <u>AP</u>	BERLEX/SCHERING AG	52%; 67%	
> <u>ADD</u> >	<u>ANGIOVIST 870</u>		
> <u>ADD</u> > <u>AP</u>	BERLEX/SCHERING AG	66%; 107%	
	SOLUTION; ORAL, RECTAL		
> <u>ADD</u> >	<u>GASTROVIST</u>		
> <u>ADD</u> > <u>AA</u>	BERLEX/SCHERING AG	66%; 107%	

DIATRIZOATE SODIUM (PAGE 3-54)

INJECTABLE; INJECTION
> ADD > UROVIST SODIUM 300
> ADD > AP BERLEX/SCHERING AG 502x

DIMENHYDRINATE (PAGE 3-57)

> DLT > /SUPPOSITORY: RECTAL/
> DLT > /DRAMAMINE/
> DLT > /SEARLE PHARMS/ /100MG/

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-58)

CAPSULE; ORAL
DIPHENHYDRAMINE HCL
/PRENO PHARM LABS/ /25MG/
> DLT >
> DLT > /50MG/

DOPAMINE HYDROCHLORIDE (PAGE 3-60)

INJECTABLE; INJECTION
DOPAMINE HCL
ABBOTT LABORATORIES 80MG/ML

DOXYCYCLINE HYCLATE (PAGE 3-61)

TABLET; ORAL
> ADD > DOXYCYCLINE HYCLATE
> ADD > AD BARR LABORATORIES EG 100MG BASE

EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE (PAGE 3-62)

INJECTABLE; INJECTION
> DLT > /DURANEST, W, EPINEPHRINE/
> ADD > DURANEST

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE (PAGE 3-63)

INJECTABLE; INJECTION
XYLOCAINE H/ EPINEPHRINE
> ADD > ASTRA PHARM PRODS 0.005MG/ML;0.52%

ERGOLOID MESYLATES (PAGE 3-63)

TABLET; ORAL
ERGOLOID MESYLATES
> ADD > AB DANBURY PHARMACAL 1MGX

TABLET; SUBLINGUAL
M.E.A.
> ADD > AA VANGARD LABS/MMM 0.5MGX
> ADD > AA 1MGX

> DLT > /ETHINYL 'ESTRADIOL; 'ETHYNODIOL 'DIACETATE; 'FERROUS 'FUMARATE/
(PAGE 3-69)

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> DLT > /TABLET; ORAL-28/
> DLT > /PENICILIN-FE-28/
> DLT > /SEARLE, SEARLE, PHARMS/0.05MG; 0.05MG/
```

> ADD > ETOMIDATE (PAGE 3-71)

> ADD > INJECTABLE; INJECTION
> ADD > AMIDATE
> ADD > ABBOTT LABORATORIES 2MG/ML

FENFLURAMINE HYDROCHLORIDE (PAGE 3-71)

> ADD > TABLET, CONTROLLED RELEASE; ORAL
> ADD > PONDIMIN
> ADD > AH ROBTNS 60MGX

GENTAMICIN SULFATE (PAGE 3-76)

INJECTABLE; INJECTION

> <u>ADD</u> >	ISOTONIC GENTAMICIN SULFATE IN PLASTIC CONTAINER
> <u>ADD</u> >	TRAVENOL LABS EQ 0.8MG BASE/MLX
> <u>ADD</u> >	EQ 80MG BASE/100MLX

> ADD > GONADORELIN HYDROCHLORIDE (PAGE 3-77)

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> ADD > INJECTABLE; INJECTION
> ADD > FACTREL
> ADD > AYERST LABS/AMHO EQ 0.1MG BASE/VIALX
> ADD > EQ 0.5MG BASE/VIALX
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METHANTHELIN BROMIDE (PAGE 3-111)

> DLT > /INJECTABLES/ INJECTION/
> DLT > /BANTHINE/
> DLT > /SEARLE/ SEARLE PHARMS/ 50MG/ VIAL/

METHYLOTHIAZIDE (PAGE 3-114)

TABLET; ORAL
METHYLOTHIAZIDE
> ADD > AB Hylan Pharms 2.5MG
> ADD > AB 5MG

METRONIDAZOLE (PAGE 3-117)

INJECTABLE; INJECTION
> ADD > METRO I.V.
> ADD > AP AM HCGAW/AM HOSP 500MG/100ML
TABLET; ORAL
METHYLOTHIAZIDE
> ADD > /AB/ /LEHMON/ 250MG
> ADD > AB METRYL 250MG
> ADD > AB LEHMON 250MG

MINOCYCLINE HYDROCHLORIDE (PAGE 3-118)

TABLET; ORAL
> ADD > MINOCIN
> ADD > LEDERLE LABS/AM CYAN EQ 50MG BASEM
> ADD > EQ 100MG BASEM

MYSTATIN (PAGE 3-123)

ointment; TOPICAL
MYSTATIN
> ADD > AT BYK-GULDEN 100,000 UNITS/GM

OXYTETRACYCLINE HYDROCHLORIDE (PAGE 3-126)

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

PHENDIMETRAZINE TARTRATE (PAGE 3-132)

CAPSULE; ORAL
PHENDIMETRAZINE TARTRATE
> DLT > /AB/ /CORP. LABORATORIES/ 35MG
> ADD > AA REID-PROVIDENT LABS 35MG
> ADD > X-TROZINE
> ADD > AA REXAR PHARMACAL 35MG

PHENDIMETRAZINE TARTRATE (PAGE 3-132)

CAPSULE, CONTROLLED RELEASE; ORAL
> ADD > X-TROZINE L.A.
> ADD > BC REXAR PHARMACAL 105MG

PHENTERMINE HYDROCHLORIDE (PAGE 3-133)

TABLET; ORAL
PHENTERMINE HCL
> DLT > /AB/ /CORP. LABORATORIES/ 35MG
> ADD > TORA
> ADD > AA REID-PROVIDENT LABS 35MG

PINDOLOL (PAGE 3-135)

TABLET; ORAL
> ADD > VISKEN
> ADD > SANDOZ PHARMS/SANDOZ 5MG
> ADD > 10MG
> ADD > 15MG

PREDNISOLONE (PAGE 3-139)

TABLET; ORAL
PREDNISOLONE
> DLT > /AB/ /PUREPAC/ KALIT PHARMA/ 5MG

PROBENECID (PAGE 3-142)

TABLET; ORAL
PROBENECID
> DLT > /AB/ /BEECHAM LABS/BEECHAM/ 500MG

PROCHLORPERAZINE EDISYLATE (PAGE 3-144)

SYRUP; ORAL
COMPAZINE
> ADD > AA SK&F LABORATORIES EQ 5MG BASE/5ML
> ADD > PROCHLORPERAZINE EDISYLATE
> ADD > AA NATL PHARM MFG/BARRE EQ 5MG BASE/5ML

PROMETHAZINE HYDROCHLORIDE (PAGE 3-145)

INJECTABLE; INJECTION
> DLT > /AB/ /PHENCON-50/
> DLT > /AB/ /CENTRAL PHARMS/ 50MG/ML

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WARFARIN SODIUM (PAGE 3-180)

TABLET: ORAL

ATHROMBIN		
> DLT >	/EP/	/Purdue Frederick/ 5mg/
> DLT >	/EP/	/10mg/
> ADD >	BX	PURDUE FREDERICK 5MG
> ADD >	BX	10MG
COUMADIN		
> DLT >	/EP/	/Endo Labs/Dupont/ 2mg/
> DLT >	/EP/	/2.5mg/
> DLT >	/EP/	/5mg/
> DLT >	/EP/	/7.5mg/
> DLT >	/EP/	/10mg/
> ADD >	BX	ENDO LABS/DUPONT 2MG
> ADD >	BX	2.5MG
> ADD >	BX	5MG
> ADD >	BX	7.5MG
> ADD >	BX	10MG
PANMARFIN		
> DLT >	/EP/	/Abbott Laboratories/ 2mg/
> DLT >	/EP/	/2.5mg/
> DLT >	/EP/	/5mg/
> DLT >	/EP/	/7.5mg/
> DLT >	/EP/	/10mg/
> ADD >	BX	ABBOTT LABORATORIES 2MG
> ADD >	BX	2.5MG
> ADD >	BX	5MG
> ADD >	BX	7.5MG
> ADD >	BX	10MG
WARFARIN SODIUM		
> ADD >	BX	BOLAR PHARMACEUTICAL 2MG
> ADD >	BX	2.5MG
> ADD >	BX	5MG
> ADD >	BX	7.5MG
> ADD >	BX	10MG

> ADD > DIPYRIDAMOLE SUPERPHARM
> ADD > ISOSORBIDE DINITRATE INWOOD LABS/FOREST
> ADD > METHANDROSTENOLONE PAR PHARMACEUTICAL
> ADD > NITROGLYCERIN VITARINE/WEST CHEM
> ADD > NITROGLYCERIN PARKE-DAVIS/M-L
> ADD > NITROGLYCERIN

CURRENT STATUS - "EXEMPT" (COURT ORDER)

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