

# **APPROVED DRUG PRODUCTS**

## **With Therapeutic Equivalence Evaluations**

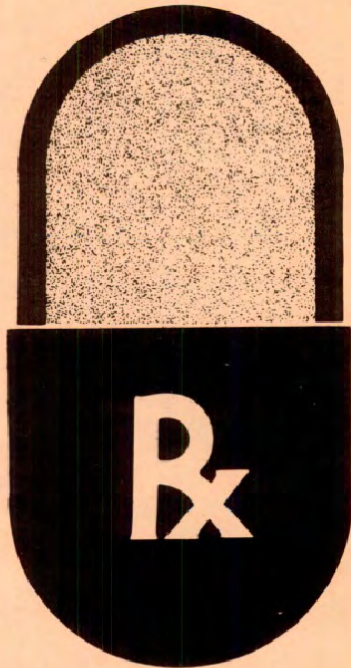


**The "Orange Book"**

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**CUMULATIVE  
SUPPLEMENT 2**  
**OCTOBER 1981**

SERIAL



**APPROVED  
PRESCRIPTION  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**2<sup>ND</sup> EDITION**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
BUREAU OF DRUGS

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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 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, 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 >DEL> (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. 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 Amigen) now is approved and marketed as well as the existing related parenteral amino acid mixture solutions.

B. Because it is not practical to identify in the cumulative supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name, the cumulation of these transfers and name changes will be identified in this Special Notes section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the cumulative supplement.

LIST OF APPLICANT CHANGES

| <u>FROM</u>                          | <u>TO</u>           |
|--------------------------------------|---------------------|
| D-M PHARMACEUTICALS<br>UNION CARBIDE | LEMMON<br>CINTICHEM |

The reader should consult this special list each month to become aware of such transfers and changes. By referring to the Applicant Index in the 2nd Edition, the transferred products can be identified. The reader might wish to flag these products in the List as a reminder that the applicant has been changed.

APPROVED PRESCRIPTION DRUG PRODUCTS  
 DRUG PRODUCT LIST  
 CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '81 - OCTOBER '81

1

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 1)

CAPSULE; ORAL

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

ELIXIR; ORAL

ACETAMINOPHEN W/ CODEINE  
 AA PHARM ASSOC/BEACH 120MG/5ML;12MG/5ML

TABLET; ORAL

ACETAMINOPHEN W/ CODEINE PHOSPHATE  
 > DLT > AA /KV PHARMACEUTICAL/ 325MG;15MG \* 325MG;30MG \* 325MG;60MG/  
 > DLT > /325MG;45MG/  
 > ADD > AA KV PHARMACEUTICAL 325MG;15MG \* 300MG;30MG \* 300MG;60MG  
 > ADD > 325MG;45MG  
 > ADD > AA VITARINE/WEST CHEM 300MG;30MG

ACETIC ACID; GLACIAL (PAGE 2)

SOLUTION; OTIC

ACETASOL  
 AT NATL PHARM MFG/BARRE 22M

> ADD > ALPRAZOLAM (PAGE 4)

> ADD > TABLET; ORAL  
 > ADD > XANAX  
 > ADD > UPJOHN 0.25MG \* 0.5MG \* 1MG

> ADD > ALPROSTADIL (PAGE 4)

> ADD > INJECTABLE; INJECTION  
 > ADD > PROSTIN VR PEDIATRIC  
 > ADD > UPJOHN 0.5MG/ML

> ADD > AMILORIDE HYDROCHLORIDE (PAGE 5)

> ADD > TABLET; ORAL  
 > ADD > MIDAMOR  
 > ADD > MS&D/MERCK 5MG

> ADD > AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE (PAGE 5)

> ADD > TABLET; ORAL  
 > ADD > MODURETIC 5/50  
 > ADD > MS&D/MERCK 5MG;50MG

AMINOPHYLLINE (PAGE 6)

INJECTABLE; INJECTION

AMINOPHYLLINE  
 AP LYPHO-MED 25MG/ML

TABLET; ORAL

AMINOPHYLLIN  
 /BP/ /SEARLE PHARMS/ 100MG \* 200MG/  
 AB SEARLE PHARMS 100MG \* 200MG  
AMINOPHYLLINE  
 /BP/ /WEST-WARD/ 100MG \* 200MG/  
 AB WEST-WARD 100MG \* 200MG

AMITRIPTYLINE HYDROCHLORIDE (PAGE 7)

TABLET; ORAL

AMITRIPTYLINE HCL  
 > ADD > AB WEST-WARD 25MG

ASPIRIN; BUTALBITAL; CAFFEINE; PHENACETIN (PAGE 11)

TABLET; ORAL

BUTALBITAL W/ APC  
 AB LEDERLE LABS/AM CYAN 200MG;50MG;40MG;150MG  
PHENORIAL  
 AB PHOENIX LABORATORIES 200MG;50MG;40MG;150MG

ATENOLOL (PAGE 12)

TABLET; ORAL

TENORMIN  
 STUART PHARMS/ICI AM 50MG \* 100MG

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE (PAGE 13)

TABLET; ORAL

DIPHENOXYLATE HCL W/ ATROPINE SULFATE  
 AA PREMO PHARM LABS 0.025MG;2.5MG

BECLMETHASONE DIPROPIONATE (PAGE 14)

AEROSOL; INHALATION/NASAL

BECONASE  
 BN GLAXO 0.042MG/INH  
 VANCENASE  
 BN SCHERING 0.042MG/INH

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&gt; ADD &gt; AA PHARMS ASSOC/BEACH 250MG/100ML

BROMPHENIRAMINE MALEATE  
ELIXIR; ORAL

BROMPHENIRAMINE MALEATE (PAGE 17)

> ADD > CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM  
CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM  
CHLORIDE; SODIUM PHOSPHATE (PAGE 20)

SOLUTION; IRRIGATION

BSS PLUS

ALCON LABORATORIES

> ADD > 0.154MG/ML; 0.92MG/ML; 0.164MG/ML;  
0.2MG/ML; 0.38MG/ML; 2.1MG/ML;  
7.14MG/ML; 0.42MG/ML> ADD > SODIUM CHLORIDE (PAGE 20)  
> ADD > CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE;

INJECTABLE; INJECTION

DIALYSE W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

AM MCGAW/AM HOSP

610MG/100ML; 1.56MG/100ML; 15MG/100ML;

DIALYSE W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

AM MCGAW/AM HOSP

610MG/100ML; 560MG/100ML;

DIALYSE W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

AM MCGAW/AM HOSP

29MG/100ML; 4.25MG/100ML; 15MG/100ML;

CHLORIDE; SODIUM LACTATE (PAGE 21)

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM

INJECTABLE; INJECTION

DEXTROSE 5% IN LACTATED RINGERS IN PLASTIC CONTAINER

CUTLER LABORATORIES

60MG/100ML; 310MG/100ML; 100ML;

CHLORAMPHENICOL (PAGE 25)

SOLUTION/DROPS; OPHTHALMIC

CHLORAMPHENICOL

MAURRY BIOLOGICAL 0.87%

CHLORPROMAZINE HYDROCHLORIDE (PAGE 29)

INJECTABLE; INJECTION

CHLORPROMAZINE HCL

&gt; DLT &gt; AA / BEECHAM LABS/BEECHAM/250MG/100ML

CHLORTHALIDONE (PAGE 30)

TABLET; ORAL

CHLORTHALIDONE

AA CHELSEA LABORATORIES 250MG/100ML

DANBURY PHARMACAL 250MG/100ML

CHLOROZOXAZONE (PAGE 30)

TABLET; ORAL

CHLOROZOXAZONE

&gt; ADD &gt; AA DANBURY PHARMACAL 250MG

&gt; ADD &gt; AA PARAFLEX

&gt; ADD &gt; AA MCNEIL LABORATORIES 250MG

CYPROHEPTADINE HYDROCHLORIDE (PAGE 36)

TABLET; ORAL

CYPROHEPTADINE HCL

DANBURY PHARM LABS

45MG

DEXAMETHASONE (PAGE 30)

TABLET; ORAL

DEXAMETHASONE

&gt; ADD &gt; BP UPSHER-SMITH LABS 0.75MG/ML = 1.5MG

DEXTROSE; LIDOCAINE HYDROCHLORIDE (PAGE 41)

INJECTABLE; INJECTION

LIDOCAINE HCL 0.4% IN DEXTROSE 5% IN PLASTIC CONTAINER

TRAVENOL LABS

60MG/100ML; 500MG/100ML

DIATRIZOATE MEGLIUMINE; DIATRIZOATE SODIUM (PAGE 44)

SOLUTION; ORAL, RECTAL

GASTROGRAFIN

AA ER SQUIBB AND SONS 662:130%

AA NO-GASTROVEN 662:130%

AA MALLINCKRODT

DOXYCYCLINE HYCLATE (PAGE 50)

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

AA CHELSEA LABORATORIES 500MG/100ML

EDETATE CALCIUM DISODIUM (PAGE 51)

> DLT >  
> ADD >  
INJECTABLE; INJECTION  
/VERSENATE/  
CALCIUM DISODIUM VERSENATE

> DLT >  
> ADD >  
TABLET; ORAL  
/VERSENATE/  
CALCIUM DISODIUM VERSENATE

ERGOLOID MESYLATES (PAGE 52)

TABLET; SUBLINGUAL  
DIHYDROERGOTOXINE METHANESULFONATE  
AA KV PHARMACEUTICAL 0.5MG \* 1MG

ERGOLOID MESYLATES  
AA BARR LABORATORIES 0.5MG \* 1MG  
AA KV PHARMACEUTICAL 0.5MG

ERYTHROMYCIN ETHYLSUCCINATE (PAGE 53)

SUSPENSION; ORAL  
ERYTHROMYCIN ETHYLSUCCINATE  
AB NATL PHARM MFG/BARRE EQ 200MG BASE/5ML \* EQ 400MG BASE/5ML

ERYTHROMYCIN STEARATE (PAGE 54)

TABLET; ORAL  
ERYTHROMYCIN STEARATE  
AB CHELSEA LABORATORIES EQ 250MG BASE \* EQ 500MG BASE

ESTROGENS, CONJUGATED (PAGE 55)

TABLET; ORAL  
CONJUGATED ESTROGENS  
BS CHELSEA LABORATORIES 0.625MG \* 1.25MG \* 2.5MG

ETHINYL ESTRADIOL; NORETHINDRONE (PAGE 56)

TABLET; ORAL-21  
NORINYL 1+35  
AB SYNTEX (FP) 0.035MG; 1MG

ORTHO-NOVUM 1/35-21  
AB ORTHO PHARMACEUTICAL 0.035MG; 1MG

TABLET; ORAL-28  
NORINYL 1+35  
AB SYNTEX (FP) 0.035MG; 1MG

ORTHO-NOVUM 1/35-28  
AB ORTHO PHARMACEUTICAL 0.035MG; 1MG

FLUNISOLIDE (PAGE 59)

SOLUTION; NASAL  
NASALIDE  
SYNTEX LABS/SYNTEX 0.025%

FUROSEMIDE (PAGE 62)

TABLET; ORAL  
LASIX  
AB HOECHST-ROUSSEL 20MG \* 40MG  
80MG

> ADD >  
Bx FUROSEMIDE  
AB CORD LABORATORIES 20MG \* 40MG  
AB MYLAN PHARMS 20MG \* 40MG

GENTAMICIN SULFATE (PAGE 62)

INJECTABLE; INJECTION  
GENTAMICIN SULFATE  
AP CARTER-GLOGAU LABS EQ 10MG BASE/ML \* EQ 40MG BASE/ML

GLYCOPYRRROLATE (PAGE 63)

TABLET; ORAL  
GLYCOPYRRROLATE  
AA DANBURY PHARMACAL 1MG \* 2MG

HALAZEPAM (PAGE 64)

TABLET; ORAL  
PAXIPAM  
SCHERING 20MG \* 40MG

HEPARIN SODIUM (PAGE 65)

INJECTABLE; INJECTION  
HEPARIN SODIUM  
AP SOLOPAK/HPL 1,000 UNITS/ML \* 5,000 UNITS/ML \*  
AP 10,000 UNITS/ML \*  
AP 5,000 UNITS/0.5ML \*  
AP 10,000 UNITS/0.5ML \*

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE (PAGE 66)

TABLET; ORAL  
HYDRAP-ES  
BP PREMO PHARM LABS 25MG; 15MG; 0.1MG  
HYDROCHLOROTHIAZIDE/HYDRALAZINE HCl/RESERPINE  
BP DANBURY PHARMACAL 25MG; 15MG; 0.1MG





METHOCARBAMOL (PAGE 91)

TABLET; ORAL  
METHOCARBAMOL  
 >\_ADD> AA PREMO PHARM LABS 500MG \* 750MG  
 >\_ADD> AA UPSHER-SMITH LABS 500MG \* 750MG

METHOXSALEN (PAGE 92)

CAPSULE; ORAL  
 OXSORALEN  
 /PAUL B. ELDER/ 100mg/  
 ELDER PHARMS 10MG  
 LOTION; TOPICAL  
 OXSORALEN  
 /PAUL B. ELDER/ 1%  
 ELDER PHARMS 1%

METHYLDOPA (PAGE 94)

SUSPENSION; ORAL  
 ALDOMET  
 MSD/MERCK 250MG/5ML

METHYLPREDNISOLONE ACETATE (PAGE 93)

INJECTABLE; INJECTION  
 METHYLPREDNISOLONE ACETATE  
 BP LEMMON 20MG/ML \* 80MG/ML

METRONIDAZOLE (PAGE 95)

TABLET; ORAL  
 FLAGYL  
 >\_ADD> AB SEARLE/SEARLE PHARMS 250MG  
 500MG  
 >\_ADD> AB METRONIDAZOLE  
 >\_ADD> AB ZENITH LABORATORIES 250MG

MEZLOCILLIN SODIUM MONOHYDRATE (PAGE 95)

INJECTABLE; INJECTION  
 MEZLIN  
 MILES PHARMS/MILES EQ 1GM BASE/VIAL \*  
 EQ 2GM BASE/VIAL \*  
 EQ 3GM BASE/VIAL \* EQ 4GM BASE/VIAL \*

>\_ADD> MOXALACTAM DISODIUM (PAGE 96)

>\_ADD> INJECTABLE; INJECTION  
 >\_ADD> MOXAM  
 >\_ADD> ELI LILLY EQ 250MG BASE/VIAL \*  
 EQ 500MG BASE/VIAL \*  
 EQ 1GM BASE/VIAL \*  
 EQ 2GM BASE/VIAL \*  
 EQ 10GM BASE/VIAL \*

NITROGLYCERIN (PAGE 100)

INJECTABLE; INJECTION  
 >\_ADD> NITROGLYCERIN  
 >\_ADD> AP ABBOTT LABORATORIES 5MG/ML  
 >\_ADD> NITROSTAT  
 >\_ADD> WARNER-LAMBERT 0.6MG/ML  
 >\_ADD> AP AM CRITICAL CARE/AMS 5MG/ML

ORPHENADRINE CITRATE (PAGE 101)

TABLET; CONTROLLED RELEASE; ORAL  
 MORELON  
 >\_DLT> /BC/ /RIKER LABS/ 100mg/  
 >\_ADD> AB RIKER LABS/3M 100MG  
 >\_ADD> AB ORPHENADRINE CITRATE  
 >\_ADD> AB BOLAR PHARMACEUTICAL 100MG

PHENDIMETRAZINE TARTRATE (PAGE 109)

TABLET; ORAL  
 METRA  
 /AA/ /D.J.F. #2/CHRONALLOY/ 15mg/  
 AA ONEAL JONES&FELDMAN 35MG  
 AA X-TROZINE  
 AA REXAR PHARMACAL 35MG

PHENYLBUTAZONE (PAGE 111)

>\_ADD> CAPSULE; ORAL  
 >\_ADD> AZOLID  
 >\_ADD> USV PHARMACEUTICAL 100MG

POTASSIUM CHLORIDE (PAGE 113)

INJECTABLE; INJECTION  
 >\_ADD> POTASSIUM CHLORIDE  
 AP LEPTON 2MEQ/ML

TETRACYCLINE HCL DANDURY PHARMACAL AD > AD  
STONEN & STONEN

GUINIDINE SULFATE (PAGE 124)

< ADD >  
< ADD >  
< ADD >  
TABLETS; ORAL  
FANSIDAR  
HOFFMANN-LA ROCHE  
25MG;500MG

>ADD> PYRIMETHAMINE; SULFADOXINE (PAGE 123)

INJECTABLE; INJECTION  
AMIGEN  
HEAD JOHNSON/B-H  
5X

PROTEIN HYDROLYSATE (PAGE 122)

SYRUP; ORAL  
PENTHAZICIN NOL  
PHARMS ASSOC/BEACH  
6.25MG/5ML\*

PROMETHACON  
ALCON LABORATORIES  
25MSK \* 50MSK  
12.5MS

**SUPPOSITORY: RECTAL**  
**PHENERGAN**  
**MYETH LABS/AMMO**  
**20MG # 100MG**

BROMETHAZINE HYDROCHLORIDE (PAGE 120)

PRONESTYL-SR ER SQUIBB AND SONS 500MG

PROCAN SR  
BC PARKE-DAVIS/M-L  
500MG

TABLET, CONTROLLED RELEASE; ORAL

PROCAINAMIDE HYDROCHLORIDE (PAGE 118)

PREDNISON  
BX UPSHER-SMITH LABS  
SMGK # 20HGM

TABLET: ORAL  
/PAT: TRADE/  
/BX/ /COPD LABORATORIES/ /SNE/

EREDNISON (PAGE 116)

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '01 - OCTOBER '01

THEOPHYLLINE (PAGE 139)

CAPSULE, CONTROLLED RELEASE; ORAL  
 SOMOPHYLLINE-CRT  
 FISOXS 100MGX \* 250MGX

ELIXIR; ORAL  
 > ADD > THEOPHYL 225  
 > ADD > KNOLL PHARMACEUTICAL 112.5MG/15MLX  
THEOPHYLLINE  
 AA PHILIPS ROXANE LABS 80MG/15MLX  
 SYRUP; ORAL  
 > ADD > THEOPHYLLINE  
 > ADD > NATL PHARM MFG/BARRE 150MG/15MLX

TRIAMCINOLONE ACETONIDE (PAGE 143)

CREAM; TOPICAL  
 > ADD > TRIACORT  
 > ADD > AT ROWELL LABORATORIES 0.12X  
TRIAMCINOLONE ACETONIDE  
 / AT / SHAFER-DAVIS LABS / 0.025X \* 0.1X \* 0.5X /  
 AT THAMES PHARMACAL 0.025X \* 0.1X \* 0.5X

TRISULFAPYRIMIDINES (PAGE 146)

SUSPENSION; ORAL  
SULFALATO  
 / AT / OJF 82/CHRONALLOY / 800MG/5ML /  
 AB ONEAL JONES&FELDMAN 800MG/5ML

VERAPAMIL HYDROCHLORIDE (PAGE 148)

INJECTABLE; INJECTION  
 ISOPTIN  
 KNOLL PHARMACEUTICAL 2.5MG/MLX

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3 9015 07293 1713

> ADD > NITRODISC SEARLE PHARMS  
> ADD > TRANS-DM-NITRO 2.5 ALZA  
> ADD > NITROGLYCERIN  
> ADD > TRANS-DM-NITRO 5 ALZA  
> ADD > NITROGLYCERIN  
> ADD > TRANS-DM-NITRO 10 ALZA  
> ADD > NITROGLYCERIN

CURRENT STATUS - EXEMPT (COURT ORDER)

> DLT > BUTAZOLIDIN, ALKA / SETIG / CIBA-GEIGY  
> DLT > ALUMINUM HYDROXIDE, GEL, DRIED, MAGNESIUM HYDROXIDE  
> DLT > PHENYLBUTAZONE

CURRENT STATUS - INEFFECTIVE

/ AMIDEN / MEAD JOHNSON & J  
/ PROTEIN HYDROLYSATE /  
CURRENT STATUS - EFFECTIVE/NEW SAFETY ISSUE

CURRENT STATUS - PROBABLY EFFECTIVE

/ JABOGLIN / REED & CARMICHAEL  
/ COAL TAR EXTRACT, HYDROXYMETHYL

ADDENDUM  
BEST PENDING LIST  
CUMULATIVE SUPPLEMENT NUMBER 2 / AUGUST '81 - OCTOBER '81