

APPROVED DRUG PRODUCTS

With Therapeutic Equivalence Evaluations



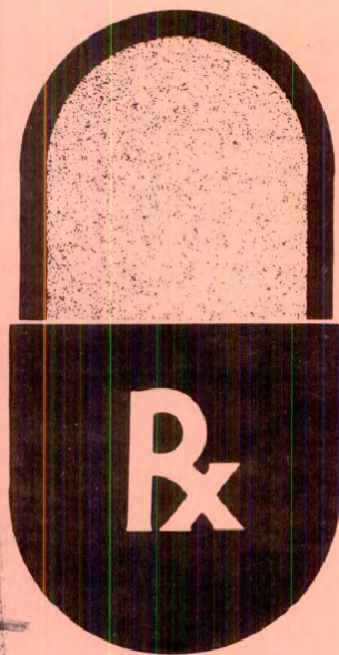
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5th ed.
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PHARMACY
CUMULATIVE
SUPPLEMENT 1
AUG'84 - SEP'84



APPROVED PRESCRIPTION DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

5TH EDITION

SERIAL
REFERENCE

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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, 5th 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, 1984. 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 (Z) 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 REQUIRING REVISED LABELING FOR FULL APPROVAL

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the Drug Product List.

<u>Products</u>	<u>Federal Register Reference</u>
dicyclomine hydrochloride	JUN 22, 1984 (49 FR 25681)
isosorbide dinitrate	AUG 3, 1984 (49 FR 31151)
nandrolone decanoate	JUL 15, 1983 (48 FR 32395)

(continued)

Products

Federal Register Reference

(continued)

neomycin sulfate with either: dexamethasone sodium phosphate, fluocinolone acetonide, flurandrenolide, hydrocortisone, or methylprednisolone acetate. [topical anti-infectives for dermatologic use]	MAR 26, 1984 (49 FR 11888)
neomycin sulfate, polymyxin B sulfate, bacitracin zinc, and hydrocortisone [topical ointment]	MAY 4, 1984 (49 FR 19147)
nitroglycerin (capsule, controlled release; oral)	SEP 7, 1984 (49 FR 35428)
nitroglycerin (tablet, controlled release; oral)	SEP 7, 1984 (49 FR 35428)
parenteral multivitamin products	SEP 17, 1984 (49 FR 36446)
phenazopyridine hydrochloride and sulfamethoxazole	JUL 29, 1983 (48 FR 34516)
sulfanilamide and aminacrine	AUG 22, 1983 (48 FR 38097)
tranylcypromine sulfate	MAR 22, 1984 (49 FR 10708)

C. SUBSCRIPTION FORM

A subscription form for the publication has been provided at the end of
this supplement for use in obtaining additional subscriptions.

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.

Drug Product Count

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.

New Molecular Entity

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.

Drug Product Definition

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.

USE 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 '84. Section A. therefore will provide baseline and quarterly data while Section B. provides monthly activity.

DESCRIPTION OF REPORT

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

A. COUNTS CUMULATIVE BY QUARTERS

<u>CATEGORIES COUNTED</u>	<u>JULY '84 (BASELINE)</u>
DRUG PRODUCTS LISTED	7415
SINGLE SOURCE	2005 (27.0%)
MULTISOURCE ⁽¹⁾	5410 (72.9%)
THERAPEUTICALLY EQUIVALENT	4393 (59.2%)
NOT THERAPEUTICALLY EQUIVALENT	999 (13.4%)
EXCEPTIONS ⁽²⁾	18 (0.3%)
NEW MOLECULAR ENTITIES APPROVED	-
NUMBER OF APPLICANTS	295

B. ACTIVITY FOR SUPPLEMENT NUMBER 1

	<u>AUG '84</u>	<u>SEPT '84</u>	<u>CUMULATIVE</u>
DRUG PRODUCTS ADDED:	54	66	120
NEWLY APPROVED	54	66	120
DESI EFFECTIVE	0	0	0
REMARKETED	0	0	0
DRUG PRODUCTS REMOVED:	0	12	12
WITHDRAWN APPROVAL	0	0	0
RX TO OTC SWITCH	0	0	0
DISCONTINUED MARKETING	0	12	12
NET GAIN IN DRUG PRODUCTS	54	54	108
SINGLE SOURCE PRODUCTS APPROVED	17	16	33
MULTISOURCE DRUG PRODUCTS APPROVED	37	50	87
NEW MOLECULAR ENTITIES APPROVED:	3	0	3
AS THE ENTITY	1	0	1
AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY	2	0	2

(1) THERAPEUTIC EQUIVALENCE EVALUATIONS PROVIDED ONLY FOR MULTISOURCE PRODUCTS (I.E., AVAILABLE FROM MORE THAN ONE APPLICANT)

(2) AMINO ACID-CONTAINING PRODUCTS OF VARYING COMPOSITION (SEE PAGE 1-5 OF THE LIST)

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APPROVED PRESCRIPTION DRUG PRODUCTS
 DRUG PRODUCT LIST
 CUMULATIVE SUPPLEMENT NUMBER 1 / AUGUST '84 & SEPTEMBER '84

1

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 3-2)

TABLET; ORAL
~~ddacet/~~
 OXYCET
 > DLT >
 > ADD > AA HALSEY DRUG 325MG;5MG

ACETIC ACID, GLACIAL (PAGE 3-3)

SOLUTION/DROPS; OTIC
 ACETIC ACID
 > ADD > AT THAMES PHARMACAL 2%

ALLOPURINOL (PAGE 3-5)

TABLET; ORAL
 ALLOPURINOL
 > ADD > AB CHELSEA LABORATORIES 100MG
 > ADD > AB 300MG
 > ADD > AB DANBURY PHARMACAL 100MG
 > ADD > AB 300MG

AMIKACIN SULFATE (PAGE 3-6)

INJECTABLE; INJECTION
 AMIKIN
 > ADD > BRISTOL LABS/B-M EQ 50MG BASE/ML
 > ADD > EQ 250MG BASE/ML

AMINO ACIDS (PAGE 3-6)

INJECTABLE; INJECTION
 BRANCHAMIN 4%
 > ADD > TRAVENOL LABS 4%
 > ADD > BRANCHAMIN 4% IN PLASTIC CONTAINER
 > ADD > TRAVENOL LABS 4%
 > ADD > TRAVASOL 10% W/O ELECTROLYTES IN PLASTIC CONTAINER
 > ADD > TRAVENOL LABS 10%
 > ADD > TRAVASOL 5.5% W/O ELECTROLYTES IN PLASTIC CONTAINER
 > ADD > TRAVENOL LABS 5.5%
 > ADD > TRAVASOL 8.5% W/O ELECTROLYTES IN PLASTIC CONTAINER
 > ADD > TRAVENOL LABS 8.5%

AMITRIPTYLINE HYDROCHLORIDE (PAGE 3-10)

TABLET; ORAL
 AMITRIPTYLINE HCL
 > ADD > BP PAR PHARMACEUTICAL 10MG
 > ADD > BP 25MG
 > ADD > BP 50MG
 > ADD > BP 75MG
 > ADD > BP 100MG
 > ADD > BP 150MG
 > ADD > BP SIDHAK LABORATORIES 10MG
 > ADD > BP 25MG
 > ADD > BP 50MG
 > ADD > BP 75MG
 > ADD > BP 100MG
 > ADD > BP 150MG
 N 87463
 N 88697
 N 88698
 N 88699
 N 88700
 N 88701
 N 88702
 N 88883
 N 88884
 N 88885
 N 88886
 N 88887
 N 88888

AMOXICILLIN; POTASSIUM CLAVULANATE (PAGE 3-13)

> ADD > POWDER FOR RECONSTITUTION; ORAL
 AUGMENTIN '125'
 > ADD > BEECHAM LABS/BEECHAM 125MG/5ML;
 > ADD > EQ 31.25MG ACID/5ML N 50575
 > ADD > AUGMENTIN '250'
 > ADD > BEECHAM LABS/BEECHAM 250MG/5ML;EQ 62.5MG ACID/5ML N 50575
 > ADD > TABLET; ORAL
 > ADD > AUGMENTIN '250'
 > ADD > BEECHAM LABS/BEECHAM 250MG;EQ 125MG ACID N 50564
 > ADD > AUGMENTIN '500'
 > ADD > BEECHAM LABS/BEECHAM 500MG;EQ 125MG ACID N 50564
 N 18785
 N 18785
 N 18832
 N 18877

AMPHETAMINE SULFATE (PAGE 3-13)

TABLET; ORAL
 AMPHETAMINE SULFATE
 > ADD > LANNETT 5MG
 > ADD > 10MG
 N 18678
 N 18684
 N 18931
 N 18931
 N 18931

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

CAPSULE; ORAL
 PROPOXYPHENE HCL W/ ASPIRIN AND CAFFEINE
 > ADD > AA CHELSEA LABORATORIES 33.3MG;32.4MG;65MG
 > ADD > N 85732

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DISULFIRAM (PAGE 3-68)

TABLET; ORAL
DISULFIRAM
> ADD > BX PAR PHARMACEUTICAL 250MG
> ADD > BX 500MG

DOXYCYCLINE HYCLATE (PAGE 3-70)

CAPSULE; ORAL
DOXYCYCLINE HYCLATE
> ADD > AB ZENITH LABORATORIES EQ 50MG BASE
> ADD > AB EQ 100MG BASE

TABLET; ORAL
DOXYCYCLINE HYCLATE
> ADD > AB ZENITH LABORATORIES EQ 100MG BASE

DOXYLAMINE SUCCINATE (PAGE 3-70)

TABLET; ORAL
DECAPRYN
> ADD > AA MERRELL DOW/DOW CHEM 25MG
> ADD > DOXYLAMINE SUCCINATE
> ADD > AA QUANTUM PHARMICS 25MG

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE (PAGE 3-78)

TABLET; ORAL-21
> DLT > /péridin/
> ADD > DEMULIN 1/50-21

TABLET; ORAL-28
> DLT > /péridin-28/
> ADD > DEMULIN 1/50-28

FLUNISOLIDE (PAGE 3-82)

> ADD > AEROSOL; INHALATION
> ADD > BROMALIDE
> ADD > SINTEX LABS/SYNTEX 0.25MG/INH

FLUCINOLONE ACETONIDE (PAGE 3-82)

CREAM; TOPICAL
FLUCINOLONE ACETONIDE
> ADD > AT PHARMAFAIR 0.01%
> ADD > AT 0.025%
FLUCINOLONE
> ADD > AT HERBERT LABS/ALLERGEN 0.025%
> DLT > AT /NARION LABORATORIES/ 0.01%
> DLT > AT /NARION LABORATORIES/ 0.025%

FLUCINOLONE ACETONIDE (PAGE 3-82)

ointment; TOPICAL

FLUCINOLONE
> ADD > AT HERBERT LABS/ALLERGEN 0.025%
> DLT > AT /NARION LABORATORIES/ 0.025%
N 88792
N 88793

SOLUTION; TOPICAL

FLUCINOLONE
> DLT > AT /NARION LABORATORIES/ 0.01%
/N 88434/

> DLT > /FOLLICLE STIMULATING HORMONE; LUTEINIZING HORMONE/ (PAGE 3-85)
> ADD > MENOTROPINS; LUTEINIZING HORMONE (PAGE 3-122)
N 62500
N 62500

FUROSEHIDE (PAGE 3-86)

TABLET; ORAL
FUROSEHIDE
> ADD > AB CORD LABORATORIES 80MG
> ADD > AB LASTX
> ADD > AB HOECHST-ROUSSEL 80MG
N 18569
N 16273

N 06412
N 88603

HYDRALAZINE HYDROCHLORIDE (PAGE 3-95)

TABLET; ORAL
HYDRALAZINE HCL
> ADD > AA SUPERPHARM 10MG
> ADD > AA 25MG
> ADD > AA 50MG
N 88787
N 88788
N 88789

HYDROFLUMETHIAZIDE (PAGE 3-104)

TABLET; ORAL
HYDROFLUMETHIAZIDE
> ADD > AB CHELSEA LABORATORIES 50MG
N 88528

HYDROXYZINE HYDROCHLORIDE (PAGE 3-105)

TABLET; ORAL
HYDROXYZINE HCL
> ADD > AB PUREPAC/KALIPHARMA 10MG
> ADD > AB 25MG
> ADD > AB 50MG
N 18340
N 88120
N 88121
N 88122

INDOMETHACIN (PAGE 3-108)

CAPSULE; ORAL
INDOMETHACIN
> ADD > AB PAR PHARMACEUTICAL 25MG
> ADD > AB 50MG
N 88499
N 88506
N 87156
/N 88434/
/N 88434/

OXYPHENBUTAZONE (PAGE 3-143)

TABLET; ORAL
> ADD > OXYPHENBUTAZONE
> ADD > AB BOLAR PHARMACEUTICAL 100MG
> ADD > AB TANDARIL
> ADD > AB GEIGY/CIBA-GEIGY 100MG

N 88399
N 12542

> ADD > PENTOXIFYLLINE (PAGE 3-149)

> ADD > TABLET, CONTROLLED RELEASE; ORAL
> ADD > TRENTAL
> ADD > HOECHST-ROUSSEL 400MG

N 18631

PROTAMINE SULFATE (PAGE 3-168)

INJECTABLE; INJECTION
PROTAMINE SULFATE
> ADD > UPJOHN 250MG/VIAL

N 07413

PSEUDOPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE (PAGE 3-169)

SYRUP; ORAL
> ADD > TRIPROLIDINE HCL AND PSEUDOPHEDRINE HCL
> ADD > AA PHARMAFAIR 30MG/5ML; 1.25MG/5ML

N 88541

GUINIDINE SULFATE (PAGE 3-170)

TABLET; ORAL
CIN-CUTN
> DLT > /AB/ ROWELL LABORATORIES /100MG/

/N 81255/

RITODRINE HYDROCHLORIDE (PAGE 3-173)

INJECTABLE; INJECTION
YUTOPAR
> ADD > ASTRA PHARM PRODS 15MG/ML

N 18580

> ADD > SAFFLOWER OIL; SOYBEAN OIL (PAGE 3-174)

> ADD > INJECTABLE; INJECTION
> ADD > LIPOSYN II 10%
> ADD > ABBOTT LABORATORIES 5%;5%
> ADD > LIPOSYN II 20%
> ADD > ABBOTT LABORATORIES 10%;10%

N 18997
N 18991

SODIUM LACTATE (PAGE 3-178)

INJECTABLE; INJECTION
SODIUM LACTATE IN PLASTIC CONTAINER
> ADD > ABBOTT LABORATORIES 5MEQ/ML

N 18947

SODIUM POLYSTYRENE SULFONATE (PAGE 3-179)

POWDER; ORAL, RECTAL
KAYEXALATE
> ADD > AB BRECCH LABS/STERLING 453.6GM/BOT
> ADD > SODIUM POLYSTYRENE SULFONATE
> ADD > AB BAY LABORATORIES 453.6GM/BOT

N 11287
N 88786

SUSPENSION; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
> ADD > AB BAY LABORATORIES 150N/60ML

N 88717

SOYBEAN OIL (PAGE 3-180)

INJECTABLE; INJECTION
> ADD > LIPOSYN III 10%
> ADD > AP ABBOTT LABORATORIES 10%
> ADD > LIPOSYN III 20%
> ADD > AP ABBOTT LABORATORIES 20%

N 18969
N 18970

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-183)

TABLET; ORAL
> ADD > SULFAMETHOXAZOLE & TRIMETHOPRIM
> ADD > AB HEATHER DRUG 400MG; 80MG
> ADD > AB 800MG; 160MG

N 18946

SUCCINYLCHOLINE CHLORIDE (PAGE 3-181)

INJECTABLE; INJECTION
SUCCINYLCHOLINE CHLORIDE
> DLT > /AB/ TRAVENOL LABS /500MG/0.4L/
> DLT > /AP/ 100MG/VIAL

/N 80263/
/N 80263/

TERBUTALINE SULFATE (PAGE 3-187)

> ADD > AEROSOL; INHALATION
> ADD > BRETHAIRE
> ADD > GEIGY/CIBA-GEIGY 0.2MG/INH

N 18762

THIORIDAZINE HYDROCHLORIDE (PAGE 3-192)

TABLET; ORAL
THIORIDAZINE HCL
> ADD > AB BARR LABORATORIES 150MG

N 88737

TRIAMCINOLONE ACETONIDE (PAGE 3-195)
 OINTMENT; TOPICAL
 PHARMADERM/BYK-GLDN 0.025%
 0.12%
 N 88692
 N 88690
 N 88693
 N 88691

TRIMEX
 SAVAGE LABS/BYK-GLDN 0.025%
 0.12%
 N 88693
 N 88691

TRISULFAPYRIMIDINES (PAGE 3-200)
 SUSPENSION; ORAL
 /TRIPLE SHELLED/
 /VALE, CHEMICAL/
 /4444/54/
 /N.66167/

VERAPAMIL HYDROCHLORIDE (PAGE 3-202)
 TABLET; ORAL
 GALEN
 SEARLE/SEARLE PHARMS 80MG
 120MG
 N 18817
 N 18817
 N 18817
 N 18817

> DLT > /Ascorbic Acid; Biotin; Cyanocobalamin; Dexpantenol/
 > DLT > /Ergocalciferol; Folic Acid; Nicotinamide; Pyridoxine/
 > DLT > /Pyridoxine Hydrochloride; Riboflavin Phosphate Sodium/
 > DLT > /Thiamine Hydrochloride; Vitamin A; Vitamin E (PAGE AD2)

> DLT > /INJECTABLE; INJECTION/
 > DLT > /N.V.C. 423/
 > DLT > /USV. PHARMACEUTICAL/
 > DLT > /80MG/VIAL; 0.05MG/VIAL; 0.05MG/VIAL;
 > DLT > /5MG/VIAL; 0.01MG/VIAL; 0.01MG/VIAL;
 > DLT > /17MG/VIAL; 0.01MG/VIAL;
 > DLT > /EQ. 1MG. BASE/VIAL; 1.4MG/VIAL;
 > DLT > /EQ. 1.2MG. BASE/VIAL; 0.7MG/VIAL;
 > DLT > /10. IU/VIAL/ /N'18420/

> DLT > /Ascorbic Acid; Biotin; Cyanocobalamin; Dexpantenol/
 > DLT > /Ergocalciferol; Folic Acid; Nicotinamide; Pyridoxine/
 > DLT > /Pyridoxine Hydrochloride; Riboflavin Phosphate Sodium; Thiamine/
 > DLT > /Hydrochloride; Vitamin A; Vitamin E (PAGE AD2)
 (SEE SPECIAL NOTE B.)

> DLT > /INJECTABLE; INJECTION/
 > DLT > /N.V.C. 12/
 > DLT > /USV. PHARMACEUTICAL/
 > DLT > /100MG/VIAL; 0.05MG/VIAL; 0.05MG/VIAL;
 > DLT > /15MG/VIAL; 0.05MG/VIAL; 0.05MG/VIAL;
 > DLT > /40MG/VIAL; 0.05MG/VIAL; 0.05MG/VIAL;
 > DLT > /3MG/VIAL; 0.01MG/VIAL;
 > DLT > /10. IU/VIAL/ /N'18431/

> DLT > /Ascorbic Acid; Biotin; Cyanocobalamin; Dexpantenol/
 > DLT > /Ergocalciferol; Folic Acid; Nicotinamide; Pyridoxine/
 > DLT > /Pyridoxine Hydrochloride; Riboflavin Phosphate Sodium; Thiamine; Vitamin/
 > DLT > /A (PAGE AD2)
 (SEE SPECIAL NOTE B.)

> DLT > /INJECTABLE; INJECTION/
 > DLT > /H.C. PLUS/
 > DLT > /ASCOT. HOSP. PHARMS/
 > DLT > /10MG/Ml; 0.005MG/Ml; 0.5 U.S.U/Ml;
 > DLT > /1.5MG/Ml; 0.1U/Ml; 0.04MG/Ml; 4MG/Ml;
 > DLT > /0.4MG/Ml; 0.3MG/Ml; 0.3MG/Ml;
 > DLT > /330. IU/Ml/ /N'18439/

> DLT > /Ascorbic Acid; Biotin; Cyanocobalamin; Dexpantenol; Folic/
 > DLT > /Acid; Nicotinamide; Pyridoxine Hydrochloride; Riboflavin/
 > DLT > /Thiamine Hydrochloride; Vitamin A; Vitamin B; Vitamin E/
 > DLT > (PAGE AD2)
 (SEE SPECIAL NOTE B.)

> DLT > /INJECTABLE; INJECTION/
 > DLT > /N.V.C. 423/
 > DLT > /CYPROFED/
 > DLT > /20MG/Ml; 0.01MG/Ml; 0.01MG/Ml;
 > DLT > /3MG/Ml; 0.01MG/Ml; 0.01MG/Ml;
 > DLT > /0.2MG/Ml; 0.01MG/Ml; 0.01MG/Ml;
 > DLT > /40. IU/Ml; 0.1U/Ml/ /N'18440/

> DLT > /Ascorbic Acid; Biotin; Cyanocobalamin; Folic Acid/
 > DLT > /Nicotinamide; Panthoic; Pyridoxine Hydrochloride; Riboflavin/
 > DLT > /Thiamine Hydrochloride; Vitamin A; Vitamin B; Vitamin E/
 > DLT > (PAGE AD2)
 (SEE SPECIAL NOTE B.)

> DLT > /INJECTABLE; INJECTION/
 > DLT > /MULTIVITAMIN ADDITIVE/
 > DLT > /ABBOTT. LABORATORIES/
 > DLT > /100MG/ML; 0.05MG/ML; 0.05MG/ML;
 > DLT > /0.4MG/ML; 0.01MG/ML; 0.01MG/ML;
 > DLT > /4.06MG/ML; 4.03MG/ML; 3.35MG/ML;
 > DLT > /330. IU/ML; 200. IU/ML;
 > DLT > /10. IU/ML/ /N'18443/

> DLT > /Ascorbic Acid; Biotin; Dexpantenol; Nicotinamide; Pyridoxine/
 > DLT > /Hydrochloride; Riboflavin; Thiamine Hydrochloride; Vitamin A;
 > DLT > (PAGE AD2)
 (SEE SPECIAL NOTE B.)

> DLT > /INJECTABLE; INJECTION/
 > DLT > /BEROCCA C/
 > DLT > /HOFFMAN-LA ROCHE/
 > DLT > /50MG/ML; 0.1MG/ML; 0.1MG/ML; 40MG/ML;
 > DLT > /10MG/ML; 5MG/ML; 5MG/ML/ /N'06071/

> DLT > /BEROCCA C 500/
 > DLT > /HOFFMAN-LA ROCHE/
 > DLT > /125MG/ML; 0.1MG/ML; 0.1MG/ML; 40MG/ML;
 > DLT > /10MG/ML; 5MG/ML; 5MG/ML/ /N'06071/

> DLT > /Ascorbic Acid; Dexpantenol; Nicotinamide; Pyridoxine/
 > DLT > /Hydrochloride; Riboflavin; Thiamine Hydrochloride; Vitamin A;
 > DLT > (PAGE AD3)
 (SEE SPECIAL NOTE B.)

> DLT > /INJECTABLE; INJECTION/
 > DLT > /N.V.C. 12/
 > DLT > /USV. PHARMACEUTICAL/
 > DLT > /50MG/ML; 0.05MG/ML; 0.05MG/ML;
 > DLT > /1MG/ML; 0.01MG/ML; 0.01MG/ML;
 > DLT > /0.5MG/ML;
 > DLT > /100MG/ML; 0.05MG/ML; 0.05MG/ML;
 > DLT > /5MG/ML; 0.01MG/ML; 0.01MG/ML;
 > DLT > /200. IU/ML; 1MG/ML/ /N'06000/

> DLT > /Ascorbic Acid; Biotin; Cyanocobalamin; Dexpantenol; Folic/
 > DLT > (PAGE AD5)
 (ALL PRODUCTS - SEE SPECIAL NOTE B.)

> DLT > /TABLET; ORAL/
 > DLT > /ISOSORBIDE DINITRATE/
 > DLT > /BARR. LABORATORIES/ /30MG/ /N'87564/

> DLT > /TAPLETT, POLYPOLLED, RELEASE, ORAL/
(ALL PRODUCTS - SEE SPECIAL NOTE B.)

> DLT > /CAPSULE, POLYPOLLED, RELEASE, ORAL/
(ALL PRODUCTS - SEE SPECIAL NOTE B.)

NITROGLYCERIN (PAGE AD7)

> DLT > /TAPLETT, POLYPOLLED, RELEASE, ORAL/
/ISOCHEM/
/FOSFAT, LADOPOLLED, RELEASE, ORAL/

> DLT > /TAPLETT, POLYPOLLED, RELEASE, ORAL/
/ISOCHEM/
/FOSFAT, LADOPOLLED, RELEASE, ORAL/

> DLT > /TAPLETT, POLYPOLLED, RELEASE, ORAL/
/ISOCHEM/
/FOSFAT, LADOPOLLED, RELEASE, ORAL/

> DLT > /TAPLETT, POLYPOLLED, RELEASE, ORAL/
/ISOCHEM/
/FOSFAT, LADOPOLLED, RELEASE, ORAL/

(ALL PRODUCTS - SEE SPECIAL NOTE B.)

/N. 88428/

/N. 87545/

> DLT > /TAPLETT, POLYPOLLED, RELEASE, ORAL/
(ALL PRODUCTS - SEE SPECIAL NOTE B.)

DESIGN PENDING LIST - 'EXEMPT' (COURT ORDER) CATEGORY
CUMULATIVE SUPPLEMENT NUMBER 1 / AUGUST '84 & SEPTEMBER '84

CURRENT STATUS - INEFFECTIVE

> ADD > BEROCCA C HOFFMANN-LA ROCHE
> ADD > ASCORBIC ACID; BIOTIN; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE
> ADD > HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE

> ADD > BEROCCA C 500 HOFFMANN-LA ROCHE
> ADD > ASCORBIC ACID; BIOTIN; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE
> ADD > HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE

> ADD > DIMETAPP AH ROBINS
> ADD > BROMPHENIRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE;
> ADD > PHENYLPROPANOLAMINE HYDROCHLORIDE

> ADD > ELIXIR DIMETAPP AH ROBINS
> ADD > BROMPHENIRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE;
> ADD > PHENYLPROPANOLAMINE HYDROCHLORIDE

> ADD > TUSS-ORNADE SK&F LABORATORIES
> ADD > CARAMIPHEN EDISYLATE; CHLORPHENIRAMINE MALEATE;
> ADD > ISOPROPAMIDE IODIDE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CURRENT STATUS - EFFECTIVENESS TO BE DETERMINED

> ADD > M.V.I. PEDIATRIC USV PHARMACEUTICAL
> ADD > ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;
> ADD > ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE;
> ADD > PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM;
> ADD > THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E



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