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CUMULATIVE SUPPLEMENT 5

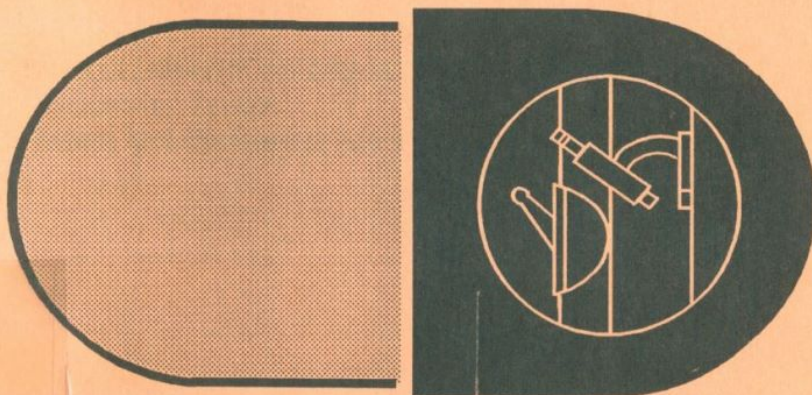
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APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION



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

Approved drug products with
therapeutic equivalence

C:355661 M:174736 O:12937927

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

12TH EDITION

Cumulative Supplement 5

May 1992

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Library Use Only

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION

CUMULATIVE SUPPLEMENT 5

MAY 1992

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 12th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Division of Blood and Blood Products and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to place an asterisk (*) to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement.

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the List will not be repeated for context.]

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.)

Additions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item. A newly approved product is also identified by a lozenge (◊) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

Deletions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >DLT> (DELETE) to the left of the line containing overstruck print. The >DLT> symbol is dropped in subsequent Cumulative Supplements for that item. The overstruck print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements.

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "⦿" symbol to designate their non-marketed status. All products having a "⦿" symbol in the 12th Cumulative Supplement of the 12th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 13th Edition.

1.2 CEFADROXIL/CEFADROXIL HEMIHYDRATE ACTIVE INGREDIENT HEADING

The active ingredient heading Cefadroxil/Cefadroxil Hemihydrate replaces the active ingredient heading Cefadroxil which is currently listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, 12th Edition. All products which are listed under Cefadroxil (which is understood to be the monohydrate form) in the 12th Edition will now be listed along with the newly approved duplicate drug products under the new active ingredient, Cefadroxil/Cefadroxil Hemihydrate.

1.3 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 appropriate Drug Product List.

<u>Products</u>	<u>Federal Register Reference</u>
Nitroglycerin (capsule, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 5, 1985 (50 FR 27688)
Tranylcypromine Sulfate	MAR 22, 1984 (49 FR 10708)

1.4 APPLICANT NAME CHANGES

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; or when an applicant name is changed to meet internal publication standards. Therefore, the cumulation of these transfers and name changes will be identified in this 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.

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

BARNES HIND PHARMACEUTICALS INC
(BARNES HIND)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

SOLA BARNES HIND
(SOLA BARNES HIND)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

NORWICH EATON PHARMS INC
SUB PROCTOR & GAMBLE CO
(NORWICH EATON)

PROCTER & GAMBLE PHARMACEUTICALS INC
(P&G)

RECKITT AND COLMAN PHARMACEUTICALS INC
(R & C)

RECKITT AND COLMAN PHARMACEUTICALS INC
(RECKITT AND COLMAN)

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1991) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that 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 as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

<u>CATEGORIES COUNTED</u>	<u>DEC 1991</u>	<u>MAR 1992</u>	<u>JUN 1992</u>	<u>SEP 1992</u>
DRUG PRODUCTS LISTED	9584	9473		
SINGLE SOURCE	2187 (22.8%)	2222 (23.4%)		
MULTISOURCE	7397 (77.2%)	7251 (76.6%)		
THERAPEUTICALLY EQUIVALENT	6580 (68.7%)	6510 (68.7%)		
NOT THERAPEUTICALLY EQUIVALENT	664 (6.9%)	592 (6.3%)		
EXCEPTIONS ¹	153 (1.6%)	149 (1.6%)		
NEW MOLECULAR ENTITIES APPROVED	--	4		
NUMBER OF APPLICANTS	430	437		

¹Amino acid-containing products of varying composition (see Introduction, page xvi of the List).

PREScription DRUG PRODUCT LIST
12TH EDITION
CUMULATIVE SUPPLEMENT NUMBER 5 / JAN'92 - MAY'92

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL
/AA/ /ACETAMINOPHEN AND CODEINE/
/AA/ /VITARINE/
/AA/ /300MG;15MG/
/AA/ /300MG;30MG/
/AA/ /300MG;60MG/
ACETAMINOPHEN AND CODEINE PHOSPHATE
3 PARKE DAVIS
3 300MG;15MG
3 300MG;30MG
3 VITARINE
3 300MG;15MG
3 300MG;30MG
3 300MG;60MG

ACETAMINOPHEN W/ CODEINE PHOSPHATE
/AA/ /CHELSEA/
/AA/ /300MG;15MG/
/AA/ /300MG;30MG/
/AA/ /300MG;60MG/
3 CHELSEA
3 300MG;15MG
3 300MG;30MG
3 300MG;60MG
/AA/ /PARKE DAVIS/
/AA/ /300MG;15MG/
/AA/ /300MG;30MG/
/AA/ /300MG;60MG/

ACETAMINOPHEN; HYDROCODONE BITARTRATE

ELIXIR; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN
MIKART
500MG/15ML;5MG/15ML

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA MIKART
500MG;5MG
650MG;10MG
/B*/ /PHARM/BASICS/
/B*/ /300MG;5MG/
3 PHARM BASICS
500MG;5MG

> ADD >
> ADD >

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

TABLET; ORAL
PROPOXYPHENE HCL AND ACETAMINOPHEN
AA MYLAN
3 650MG;65MG
3 325MG;32MG
/AA/ /PROPOXYPHENE HCL W/ APAP/
/AA/ /MYLAN/
/AA/ /650MG;65MG/
/AA/ /325MG;32MG/

ACETOHEXAMIDE

TABLET; ORAL
ACETOHEXAMIDE
/B*/ /PHARM/BASICS/
/B*/ /250MG/
/B*/ /500MG/
3 PHARM BASICS
250MG
3 500MG

ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL
ACETYLCYSTEINE
AN CETUS BEN VENUE
10Z
AN 20Z
N72323 001
APR 30, 1992
N72324 001
APR 30, 1992

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE
AN DEY
EQ 0.083% BASE

PROVENTIL
AN SCHERING
EQ 0.083% BASE

VENTOLIN
AN GLAXO
EQ 0.083% BASE

SYRUP; ORAL
ALBUTEROL SULFATE
AA LEMMON
EQ 2MG BASE/5ML

N73419 001
MAR 30, 1992

ALGLUCERASE

INJECTABLE; INJECTION
CEREDASE
GENZYME

> ADD >
> ADD >

10 UNITS/MLM
N20057 004
MAY 08, 1992

ALLOPURINOL

TABLET; ORAL
ALLOPURINOL
/BOLAR/

/AB/ 3 BOLAR

/100MG/
100MG

/N18241/001/
/NOV/16, 1984/
N18241 001
NOV 16, 1984

AMIKACIN SULFATE

INJECTABLE; INJECTION
AMIKACIN
ELKINS SINN

> ADD > AP
> ADD > AP
> ADD > AP
> ADD > AP
> ADD > AP

EQ 50MG BASE/MLM
EQ 250MG BASE/MLM

N63274 001
MAY 18, 1992
N63275 001
MAY 18, 1992

AMIKIN

BRISTOL

EQ 50MG BASE/ML
EQ 50MG BASE/ML
EQ 250MG BASE/ML
EQ 250MG BASE/ML

N50495 001
N62562 001
SEP 20, 1984
N50495 002
N62562 002
SEP 20, 1984

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
/AMITRIPTIL/
/WARNER/CHILCOTT/

> DLT > /AB/
> DLT > /AB/
> DLT > /AB/
> DLT > /AB/
> DLT > /AB/
> DLT > /AB/
> DLT > /AB/
> ADD >
> ADD >
> ADD >
> ADD >
> ADD >

/10MG/
/25MG/
/50MG/
/75MG/
/100MG/
/150MG/
10MG
25MG
50MG
75MG
100MG
150MG

/N83939/001/
/N83937/001/
/N83938/002/
/N84957/001/
/N85093/001/
/N86295/001/
N83939 001
N83937 001
N83938 002
N84957 001
N85093 001
N86295 001

3 WARNER CHILCOTT

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL
/PAR/

/10MG/
/25MG/
/50MG/
/75MG/
/100MG/
/150MG/
3 PAR
10MG
25MG
50MG
75MG
100MG
150MG

/N88697/001/
/SEP/25, 1984/
/N88698/001/
/SEP/25, 1984/
/N88699/001/
/SEP/25, 1984/
/N88700/001/
/SEP/25, 1984/
/N88701/001/
/SEP/25, 1984/
/N88702/001/
/SEP/25, 1984/
N88697 001
SEP 25, 1984
N88698 001
SEP 25, 1984
N88699 001
SEP 25, 1984
N88700 001
SEP 25, 1984
N88701 001
SEP 25, 1984
N88702 001
SEP 25, 1984

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL
CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL
/PAR/ /PHARM/BASICS/
/PAR/ /EQ/25MG/BASE;10MG/

3 PHARM BASICS
3
EQ 12.5MG BASE;5MG
EQ 25MG BASE;10MG

/N70477/001/
/JAN/12, 1988/
/N70478/001/
/JAN/12, 1988/
N70477 001
JAN 12, 1988
N70478 001
JAN 12, 1988

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL
PERPHENAZINE AND AMITRIPTYLINE HCL
/3/CHLSEA/

/N71558/001/
/MAR/02, 1987/

AMOXICILLIN

CAPSULE; ORAL

POLYMAX

BRISTOL MYERS

250MG

500MG

N63099 001

MAR 20, 1992

N63099 002

MAR 20, 1992

AB

AB

UTIMOL

PARKE/DAVIS

250MG

500MG

N62107 001

N62107 002

AB

AB

POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN

CLONNEL

125MG/5ML

250MG/5ML

N62927 001

NOV 25, 1988

N62927 002

NOV 25, 1988

AB

AB

UTIMOL

PARKE/DAVIS

125MG/5ML

250MG/5ML

N62927 001

NOV 25, 1988

N62927 002

NOV 25, 1988

AB

AB

AMPHOTERICIN B

INJECTABLE; INJECTION

AMPHOTERICIN B

PHARMA TEK

50MG/VIAL

N63206 001

APR 29, 1992

AB

AMPICILLIN SODIUM

INJECTABLE; INJECTION

POLYICILLIN-H

BRISTOL

EQ 125MG BASE/VIAL

EQ 250MG BASE/VIAL

EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

EQ 2GM BASE/VIAL

N50309 001

N50309 002

N50309 003

N50309 004

N50309 005

AB

AB

AB

AB

AB

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

AMCILL

PARKE/DAVIS

EQ 250MG BASE

EQ 500MG BASE

N62041 001

N62041 002

AB

AB

POLYICILLIN

BRISTOL

EQ 250MG BASE

EQ 500MG BASE

N50310 001

N50310 002

AB

AB

POWDER FOR RECONSTITUTION; ORAL

AMCILL

PARKE/DAVIS

EQ 125MG BASE/5ML

EQ 250MG BASE/5ML

N62030 001

N62030 002

AB

AB

POLYICILLIN

BRISTOL

EQ 100MG BASE/ML

EQ 200MG BASE/ML

N50308 004

N61394 001

AB

AB

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

/B# / PHARM/BASICS/ /0.5MG/

/B# / /1MG/

/B# / /2MG/

3 PHARM BASICS

0.5MG

1MG

2MG

/N84211/001/
JUN/14, 1988/
/N89212/001/
JUN/14, 1988/
/N89213/001/
JUN/14, 1988/
N89211 001
JUN 14, 1988
N89212 001
JUN 14, 1988
N89213 001
JUN 14, 1988

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

BETAMETHASONE DIPROPIONATE

AB TARO EQ 0.05% BASEM

N73552 001
APR 30, 1992

BETHANECHOL CHLORIDE

TABLET; ORAL

BETHANECHOL CHLORIDE

/AA / /VITARINE/ /5MG/

/AA / /10MG/

/AA / /10MG/

/AA / /25MG/

/AA / /25MG/

3 VITARINE

3

3

3

3

5MG

10MG

10MG

25MG

25MG

/N84353/001/
/N84378/001/
/N84379/001/
/N84383/001/
/N84384/001/
N84353 001
N84378 001
N84379 001
N84383 001
N84384 001

BITOLTEROL MESYLATE

SOLUTION; INHALATION

TORNALATE

/STERLING/WINTHROP/ /0.2% /

STERLING

0.2%

/N19548/001/
FEB/19, 1992/
N19548 001
FEB 19, 1992

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

/AP / /LYPHOMED/ /50MG/ML/

3 LYPHOMED

50MG/ML

/N70134/001/
FEB/12, 1986/
N70134 001
FEB 12, 1986

BUTABARBITAL SODIUM

TABLET; ORAL

BUTABARBITAL SODIUM

/AA / /VITARINE/ /30MG/

3 VITARINE

30MG

/N85934/001/
N85934 001

SODIUM BUTABARBITAL

/AA / /WEST WARD/ /15MG/

/AA / /30MG/

3 WEST WARD

3

15MG

30MG

/N85418/001/
/N85418/001/
N85418 001
N85432 001

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% IN RINGER'S IN PLASTIC CONTAINER

AP MCGAM

33MG/100ML; 5GM/100ML; 30MG/100ML;
860MG/100MLM

N20000 001
APR 17, 1992

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

RINGER'S IN PLASTIC CONTAINER

AP MCGAM

33MG/100ML; 30MG/100ML;
860MG/100MLM

N20002 001
APR 17, 1992

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

> DLT > /AA / /PARK/DAVIS/ /200MG/

> DLT > /B# / /PHARM/BASICS/ /200MG/

3 PHARM BASICS

200MG

/N70449/001/
JAN/02, 1987/
/N70300/001/
MAY/15, 1986/
N70300 001
MAY 15, 1986

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

3 WARNER CHILCOTT

200MG

N70429 001
JAN 02, 1987

INJECTABLE; INJECTION

CEFTAZ

AP

GLAXO

1GM/VIAL

N50646 002
SEP 27, 1990

>_ADD_>

>_ADD_>

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

166/ VITARINE/

350MG

N89566 001
AUG 30, 1988

INJECTABLE; INJECTION

PENTACEF

AP

SMITHKLINE BEECHAM

1GM/VIAL

N64006 001
MAR 31, 1992

B* VITARINE

350MG

N89566 001
AUG 30, 1988

2GM/VIAL

N64006 002
MAR 31, 1992

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

CEFADROXIL

AB ZENITH

EQ 500MG BASE

N62766 001
MAR 03, 1987

INJECTABLE; INJECTION

ROCEPHIN

AP

10GM/VIAL

N64008 002
MAR 31, 1992

AB ZENITH

EQ 1GM BASE

N62774 001
APR 08, 1987

INJECTABLE; INJECTION

ROCEPHIN

AP

6GM/VIAL

N64008 001
MAR 31, 1992

TABLET; ORAL

CEFADROXIL

AB ZENITH

EQ 1GM BASE

N62774 001
APR 08, 1987

INJECTABLE; INJECTION

ROCEPHIN

AP

EQ 250MG BASE/VIAL

N62510 001
MAR 12, 1985

AB ZENITH

EQ 500MG BASE/VIAL

N62774 001
APR 08, 1987

INJECTABLE; INJECTION

ROCEPHIN

AP

EQ 500MG BASE/VIAL

N62510 002
MAR 12, 1985

CEFTAZIDIME

INJECTABLE; INJECTION

CEFTAZ

166/ GLAXO/

EQ 1GM BASE/VIAL

N50646 001
SEP 27, 1990

INJECTABLE; INJECTION

CEFTAZ

AP

EQ 1GM BASE/VIAL

N50646 001
SEP 27, 1990

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

AB/

PARKE/DAVIS/

AB/

PARKE/DAVIS/

AB/

PARKE DAVIS

5MG

10MG

25MG

N85163 001
SEP 27, 1990

AB/

PARKE DAVIS

5MG

10MG

25MG

N85163 001
SEP 27, 1990

CHLORDIAZEPOXIDE HYDROCHLORIDE

CHLORTHALIDONE

SOLUTION/DROPS; OPHTHALMIC
CYCLOPENTOLATE HCL
/BARNES/HIND/ 1%
3 SOLA BARNES HIND

/N44663/001/
N84863 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 5 / JAN '92 - MAY '92

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPRAMINE HCL
/B* / /PHARM/BASIS/

/25MG/ /N71864/001/
/50MG/ /SEP/09/1987/
/75MG/ /N71865/001/
/100MG/ /SEP/09/1987/
/25MG/ /N71866/001/
/50MG/ /SEP/09/1987/
/75MG/ /N71867/001/
/100MG/ /SEP/09/1987/

3 PHARM BASICS

25MG N71864 001
50MG N71865 001
75MG N71866 001
100MG N71867 001
SEP 09, 1987

DESONIDE

LOTION; TOPICAL
DESOWEN
OWEN GALDERMA

0.05%/M N72354 001
JAN 24, 1992

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 3.3% AND SODIUM
CHLORIDE 0.3% IN PLASTIC CONTAINER
MCGAM

3.3GM/100ML; 75MG/100ML;
300MG/100MLM N19630 049
MAY 07, 1992

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 3.3% AND SODIUM
CHLORIDE 0.3% IN PLASTIC CONTAINER
MCGAM

3.3GM/100ML; 110MG/100ML;
300MG/100MLM N19630 050
MAY 07, 1992

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 3.3% AND SODIUM
CHLORIDE 0.3% IN PLASTIC CONTAINER
MCGAM

3.3GM/100ML; 150MG/100ML;
300MG/100MLM N19630 051
MAY 07, 1992

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 3.3% AND SODIUM
CHLORIDE 0.3% IN PLASTIC CONTAINER
MCGAM

3.3GM/100ML; 220MG/100ML;
300MG/100MLM N19630 052
MAY 07, 1992

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 3.3% AND SODIUM
CHLORIDE 0.3% IN PLASTIC CONTAINER
MCGAM

3.3GM/100ML; 300MG/100ML;
300MG/100MLM N19630 053
MAY 07, 1992

DIAZEPAM

TABLET; ORAL

DIAZEPAM
/PARKER/DAYS/

DLT > /AB/ /2MG/ /N70209/001/
DLT > /AB/ /5MG/ /SEP/04/1985/
DLT > /AB/ /10MG/ /N70210/001/
DLT > /AB/ /2MG/ /SEP/04/1985/
DLT > /AB/ /5MG/ /N70222/001/
DLT > /AB/ /10MG/ /SEP/04/1985/
ADD > 2MG N70209 001
ADD > 5MG N70210 001
ADD > 10MG N70222 001
SEP 04, 1985

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

/AB/ /VITARINE/ /25MG/ 25MG
3 VITARINE

/N85916/001/
N85916 001

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CARDIZEM CD

ADD > BC + MARION MERRELL DOM 180MG
ADD > BC + 240MG
ADD > + 300MG
DLT > /300MG/

N20062 002
DEC 27, 1991
N20062 003
DEC 27, 1991
N20062 004
DEC 27, 1991
/N20062/004/
DEC/27/1991/

DOPAMINE HYDROCHLORIDE

INJECTABLE: INJECTION

N20092 002
MAY 29, 1992
N20092 003
MAY 29, 1992
N20092 001
MAY 29, 1992

160MG/ML
80MG/ML
40MG/ML
/JIA/9A057/
/JIA/9A058/
/JIA/9A059/

② ②

N20027 001
OCT 24, 1991

00124, 1991/
/N26627/661/
/dc1/24, 1991/
/N26627/662/
/dc1/24, 1991/

ROBINS

20MG/ML

N87562 001
FEB 25, 1992
N87561 001
FEB 25, 1992

EQ 50MG BASEM

EQ 100MG BASEM

1777666

DOXICICLINE HICLATE
/ 7N76001003 /

EQ 100MG BASEM
/P3SYD/SHPT/P3/

JAN 15, 1987

SEP 02, 1988
/N62593/001/
/AUG 28, 1985/
N62593 001
AUG 28, 1985

/ 7578, SUPPLY, 03/

EQ 100MG BASE

EQ 100MG BASE

AUG 28, 1985

PROPERIDOL

INJECTABLE; INJECTION

PROPERIDOL
/AB/ /SOLOPAK/

/2.5MG/ML/

3 SOLOPAK

2.5MG/ML

/N71750/001/
/SEP/06/1988/

N71750 001
SEP 06, 1988

0.035MG; 1MG

N72693 001
FEB 28, 1992

GENCEPT 10/11-21
GENCON

0.035MG; 0.5MG AND 1MG

N72694 001
FEB 28, 1992

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

/AB/ /ALKERGOL/
/AB/ /VITARINE/

/0.5MG/
/1MG/

3 VITARINE

0.5MG

/N85153/001/
/N87417/001/

N85153 001
N87417 001

0.035MG; 0.5MG

N72695 001
FEB 28, 1992

GENCEPT 1/35-28
GENCON

0.035MG; 1MG

N72696 001
FEB 28, 1992

GENCEPT 10/11-28
GENCON

0.035MG; 0.5MG AND 1MG

N72697 001
FEB 28, 1992

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL

/AB/ /ERGOMAR/
/AB/ /FISON/

/2MG/

3 FISON

2MG

/N87693/001/
/FEB/24/1983/

N87693 001
FEB 24, 1983

TABLET, EXTENDED RELEASE; ORAL
PLENDIL

/MERCK/

/5MG/

/N19834/001/
/JUL/26/1991/

N19834 001
JUL 25, 1991

ERYTHROMYCIN

SOLUTION; TOPICAL

/SANSAC

/OWEN GALDERMA

2%

/N62522/001/
/JAN/24/1985/

N62522 001
JAN 24, 1985

/SANSACNE/
/OWEN GALDERMA/

/2%

/N62522/001/
/JAN/24/1985/

N62522 001
JAN 24, 1985

TABLET, COATED PARTICLES; ORAL
PCE

ABBOTT

500MG

FENOPROFEN CALCIUM

/HALSEY/

/EQ 200MG BASE/

/N72355/001/
/JUL/05/1988/

N72355 001
JUL 05, 1988

3

/EQ 300MG BASE/

/N72356/001/
/JUL/05/1988/

N72356 001
JUL 05, 1988

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

GENCEPT 0.5/35-21
GENCON

0.035MG; 0.5MG

/N72692/001/
/FEB/28/1992/

N72692 001
FEB 28, 1992

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 5 / JAN '92 - MAY '92

HYDRALAZINE HYDROCHLORIDE; RESERPINE

TABLET; ORAL
SERPASIL-APRESOLINE
/BP/ /CIBA/
CIBA

/25MG; 0.1MG/
25MG; 0.1MG

/N80642/004/
N09296, 004

SOLUTION; TOPICAL
TEXACORT
GENDERM

2.5/M

N81271 001
APR 17, 1992

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE
AB DANBURY

25MG

N81189 001

JAN 24, 1992

100MG

N81190 001
JAN 24, 1992

> DLT >
> DLT >
> ADD >

TABLET; ORAL
/HYDROTHIAZIDE/
/2-VITAMINE/
HYDROCHLOROTHIAZIDE
EON LABS

/20MG/
20MG

/N80642/002/
N80642 002

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
/HYDRO-SERP/125-1/
/BP/ /VITAMINE/
E VITAMINE
/HYDRO-SERP/125-1/
/BP/ /VITAMINE/
E VITAMINE

/25MG; 0.125MG/
25MG; 0.125MG
/50MG; 0.125MG/
50MG; 0.125MG

/N84827/001/
N84827 001
/N85213/001/
N85213 001

TABLET; ORAL
/HYDROFLUMETHIAZIDE AND RESERPINE/
/BP/ /PHARM/BASICS/
E PHARM BASICS

50MG; 0.125MG

/N88195/001/
/OCT/26/1983/
N88195 001
OCT 26, 1983

HYDROXYAMPHETAMINE HYDROBROMIDE; TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC
PAREMYD
ALLERGAN

1%; 0.25/M

N19261 001
JAN 30, 1992

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL
MAXICIDE-25
AB MYLAN

25MG; 37.5MG

N19129 003
MAY 13, 1988

TRIAMTERENE AND HYDROCHLOROTHIAZIDE
AB GENEVA

25MG; 37.5MG

N73281 001
APR 30, 1992

HYDROCORTISONE

LOTION; TOPICAL
/CORT-ONE/
/AT/ /NILES/
E MILES
E

/0.5%/
/1%/
0.5%
1%

/N09895/003/
/N09895/001/
N09895 003
N09895 001

TABLET; ORAL
HYDROXYZINE HCL
/BP/ /PHARM/BASICS/
/BP/ /BP/

/10MG/
/25MG/
/50MG/

/N89121/001/
/MAR/20/1986/
/N89122/001/
/MAR/20/1986/
/N89123/001/
/MAR/20/1986/
N89121 001
MAR 20, 1986
N89122 001
MAR 20, 1986
N89123 001
MAR 20, 1986

E PHARM BASICS
E
E

10MG
25MG
50MG

IBUPROFENISOETHARINE HYDROCHLORIDE

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

ISOETHARINE HCL

1N76766/66Y/

1966/25, 1966/

N70709 001

APR 25, 1986

NI9432 001

DEC 24, 1987
/NY 64433/6611/

NI9710 004

一、二、三、四、五、六、七、八、九、十、十一、十二、十三、十四、十五、十六、十七、十八、十九、二十、二十一、二十二、二十三、二十四、二十五、二十六、二十七、二十八、二十九、三十、三十一、三十二、三十三、三十四、三十五、三十六、三十七、三十八、三十九、四十、四十一、四十二、四十三、四十四、四十五、四十六、四十七、四十八、四十九、五十、五十一、五十二、五十三、五十四、五十五、五十六、五十七、五十八、五十九、六十、六十一、六十二、六十三、六十四、六十五、六十六、六十七、六十八、六十九、七十、七十一、七十二、七十三、七十四、七十五、七十六、七十七、七十八、七十九、八十、八十一、八十二、八十三、八十四、八十五、八十六、八十七、八十八、八十九、九十、九十一、九十二、九十三、九十四、九十五、九十六、九十七、九十八、九十九、一百。

N19710 005

197

1599/85648N/

NDV/15; /1982/

/N88476/001/

MAR 14 1984

188471/001/

/MAR/14, 1984/

.../N88472/001/

MAR 14, 1984

1587937/001/

.....

N73591 001
MAY 29, 1992

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 5 / JAN '92 - MAY '92

LACTULOSE

SYRUP; ORAL, RECTAL

LACTULOSE

ROXANE LABS

>_ADD_> AA
>_ADD_>10GM/15MLMN73590 001
MAY 29, 1992/300MG/
/PHARM/BASICS/LITHIUM CARBONATE

CAPSULE; ORAL

LITHIUM CARBONATE

/300MG/
/PHARM/BASICS/

300MG

/N72542/001/
/FEB/01/1989/
N72542 001
FEB 01, 1989LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUM

/AP/ /LYPHOMED/

3 LYPHOMED

/EQ 50MG BASE/VIAL/

EQ 50MG BASE/VIAL

/N66939/001/
/DEC/01/1986/
N66939 001
DEC 01, 1986LOMEFLOXACIN HYDROCHLORIDE

TABLET; ORAL

MAXAQUIN

+ SEARLE

EQ 400MG BASEM

N20013 001
FEB 21, 1992LEVODOPA

CAPSULE; ORAL

DOPAR

/3/3/3/AND/5/

+ ROBERTS

/500MG/
/100MG/
/250MG/
500MG
100MG
250MG/N16913/002/
/N16913/003/
/N16913/001/
N16913 002
N16913 003
N16913 001

CAPSULE; ORAL

LOPERAMIDE HCL

LEMMON

2MG

N73192 001
APR 30, 1992LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL

/INTL/MEDICATION/

3 INTL MEDICATION

3

/1GM/VIAL/
1GM/VIAL
/2GM/VIAL/
2GM/VIAL/N18543/001/
N18543 001
/N18543/002/
N18543 002LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER

MCGAM

200MG/100MLM

N19830 002

APR 08, 1992

LIDOCAINE HCL 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER

MCGAM

400MG/100MLM

N19830 003

APR 08, 1992

LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER

MCGAM

800MG/100MLM

N19830 004

APR 08, 1992

TABLET; ORAL

LORAZEPAM

/PHARM/BASICS/

/1MG/

/2MG/

3 PHARM BASICS

3

1MG

2MG

/N70539/001/
/DEC/22/1986/
/N70540/001/
/DEC/22/1986/
N70539 001
DEC 22, 1986
N70540 001
DEC 22, 1986MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

/PHARM/BASICS/

/EQ 50MG BASE/

/EQ 100MG BASE/

3 PHARM BASICS

3

EQ 50MG BASE

EQ 100MG BASE

/N71007/001/
/MAR/25/1988/
/N71008/001/
/MAR/25/1988/
N71007 001
MAR 25, 1988
N71008 001
MAR 25, 1988

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 5 / JAN '92 - MAY '92

MEGESTROL ACETATE

TABLET; ORAL

MEGESTROL ACETATE

/B*/ /PHARM/BASICS/

/B*/

3 PHARM BASICS

3

/20MG/

/40MG/

20MG

40MG

/N70646/001/

/OCT 02, 1987/

/N70647/001/

/OCT 02, 1987/

N70646 001

OCT 02, 1987

N70647 001

OCT 02, 1987

/0.4% /

/0.6% /

0.4%

0.6%

/N71275/001/

/JUL 27, 1988/

/N71018/001/

/JUL 27, 1988/

N71275 001

JUL 27, 1988

N71018 001

JUL 27, 1988

N73340 001

MAR 30, 1992

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERIDINE HCL

ABBOTT

10MG/ML

N88432 001

AUG 16, 1984

/N80364/002/

/N80364/002/

N80364 002

N80364 001

N73443 001

MAR 17, 1992

N73444 001

MAR 17, 1992

N73445 001

MAR 17, 1992

10MG/ML

/50MG/ML/

/100MG/ML/

50MG/ML

100MG/ML

10MG/ML

50MG/ML

100MG/ML

N72761 001

FEB 27, 1992

/N71013/001/

/JAN 25, 1988/

/N71014/001/

/JAN 25, 1988/

N71013 001

JAN 25, 1988

N71014 001

JAN 25, 1988

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

3 ELKINS SINN

3

200MG

400MG

/20MG/

/40MG/

200MG

400MG

/20MG/

/40MG/

N15426 002

N15426 001

/N84744/001/

/N84744/002/

N84744 001

N84744 002

/N15426/001/

/N15426/002/

METHOTREXATE SODIUM

TABLET; ORAL

METHOTREXATE

MYLAN

> ADD > AB

> ADD >

EQ 2.5MG BASEM

N81235 001

MAY 15, 1992

METHYLCLOTHIAZIDE

TABLET; ORAL

METHYLCLOTHIAZIDE

/B*/ /PHARM/BASICS/

3 PHARM BASICS

/5MG/

5MG

/N88745/001/

/MAR 21, 1985/

N88745 001

MAR 21, 1985

MESALAMINE

TABLET, DELAYED RELEASE; ORAL

ASACOL

+ P AND G

400MG

N19651 001

JAN 31, 1992

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 5 / JAN '92 - MAY '92

METHYLDOPA

TABLET; ORAL

METHYLDOPA

/AB/ /PARKE/DAVIS/

/125MG/

/N70331/001/

/AB/ /PARKE/DAVIS/

/250MG/

/N70332/001/

/AB/ /PARKE/DAVIS/

/500MG/

/N70333/001/

3 PARKE DAVIS

125MG

APR 15, 1986

3

250MG

APR 15, 1986

3

500MG

APR 15, 1986

METHYLPREDNISOLONE

TABLET; ORAL

METHYLPREDNISOLONE

/BP/ /VITARINE/

/4MG/

/N87341/001/

3 VITARINE

4MG

N87341 001

METOCLOPRAMIDE HYDROCHLORIDE

CONCENTRATE; ORAL

METOCLOPRAMIDE INTENSOL

ROXANE

EQ 10MG BASE/MLM

N72995 001

JAN 30, 1992

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL

CETUS BEN VENUE

EQ 10MG BASE/2MLM

N72155 001

MAR 30, 1992

EQ 10MG BASE/2MLM

N72244 001

MAR 30, 1992

EQ 10MG BASE/2MLM

N72247 001

MAY 18, 1992

> ADD >

> ADD >

TABLET; ORAL

METOCLOPRAMIDE HCL

/BP/ /INTERPHARM/

/EQ/10MG/BASE/

/N71213/001/

3 INTERPHARM

EQ 10MG BASEM

N71213 001

SEP 24, 1986

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

METOCLOPRAMIDE HCL

/BP/ /PHARM/BASICS/

/EQ/10MG/BASE/

/N70339/001/

3 PHARM BASICS

EQ 10MG BASE

JUL 29, 1985

METOLAZONE

TABLET; ORAL

METOLAZONE

/AB/ /SCHIAPPARELLI/SEARLE/

/2.5MG/

/N18535/001/

/AB/ /SCHIAPPARELLI/SEARLE/

/5MG/

/N18535/002/

/AB/ /SCHIAPPARELLI/SEARLE/

/10MG/

/N18535/003/

3 SCHIAPPARELLI SEARLE

2.5MG

N18535 001

3

5MG

N18535 002

3

10MG

N18535 003

ZAROXOLYN

/FISONS/

/2.5MG/

/N17386/001/

/AB/ /FISONS/

/5MG/

/N17386/002/

/AB/ /FISONS/

/10MG/

/N17386/003/

+ FISONS

10MG

N17386 003

2.5MG

N17386 001

5MG

N17386 002

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL

TOPROL XL

+ HASSLE

EQ 50MG TARTRATEM

N19962 001

+

EQ 100MG TARTRATEM

N19962 002

+

EQ 200MG TARTRATEM

N19962 003

JAN 10, 1992

METRONIDAZOLE

INJECTABLE; INJECTION

METRONIDAZOLE

/LPHOMED/

/500MG/100ML/

/N70071/001/

3 LYPHOMED

500MG/100ML

DEC 03, 1984

METRONIDAZOLE HYDROCHLORIDE

INJECTABLE; INJECTION

FLAGYL I.V.

/AB/ /SCHIAPPARELLI/SEARLE/ED 500MG BASE/VIAL/
SCHIAPPARELLI SEARLE EQ 500MG BASE/VIAL

/N70295/001/
N70295 001

SPRAY, METERED; NASAL

SYNAREL

EQ 0.2MG BASE/INH

N20109 001
FEB 26, 1992

/AB/ /METRONIDAZOLE HCL/
/LYPHOMED/

/ED 500MG BASE/VIAL/

/N70295/001/
N70295 001

3 LYPHOMED

EQ 500MG BASE/VIAL

NIACIN

TABLET; ORAL

NIACIN

AA MOCKHARDT LTD

500MG

N81134 001
APR 28, 1992

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

MINOCYCLINE HCL

AB

BIOCRAFT

EQ 50MG BASE

N63011 001

MAR 02, 1992

AB

EQ 100MG BASE

N63009 001

MAR 02, 1992

CAPSULE, EXTENDED RELEASE; ORAL

CARDENE SR

+ SYNTEX

30MG

N20005 001

FEB 21, 1992

N20005 002

FEB 21, 1992

N20005 003

FEB 21, 1992

MINOXIDIL

TABLET; ORAL

MINOXIDIL

/AB/ /PHARM BASICS/

/2.5MG/

/N71537/001/
N71537 001

DEC 16, 1988

3 PHARM BASICS

2.5MG

2.5MG/ML

N19734 001

JAN 30, 1992

/AB/ /ROYCE/

/2.5MG/

/N71799/001/
N71799 001

NOV 10, 1987

/AB/

/10MG/

/N71796/001/
N71796 001

NOV 10, 1987

3 ROYCE

2.5MG

FILM, EXTENDED RELEASE; TRANSFERMAL

NICOTROL

+ KABI

5MG/16HR

N20150 001

APR 22, 1992

N20150 002

APR 22, 1992

N20150 003

APR 22, 1992

MIVACURIUM CHLORIDE

INJECTABLE; INJECTION

MIVACRON

BURROUGHS WELLCOME EQ 2MG BASE/ML

N20098 001

JAN 22, 1992

MIVACRON IN DEXTROSE 5% IN PLASTIC CONTAINER

BURROUGHS WELLCOME EQ 0.5MG BASE/ML

N20098 002

JAN 22, 1992

N20098 003

JAN 22, 1992

EQ 50MG BASE/100ML

PROSTEP

+ ELAN

11MG/24HR

N19983 001

JAN 28, 1992

N19983 002

JAN 28, 1992

22MG/24HR

OXYBUTYRIN CHLORIDE

TABLET; ORAL

OXYBUTYRIN CHLORIDE

/B*/ /PHARM/BASICS/

/5MG/

3 PHARM BASICS

5MG

/N70746/001/

/MAR/10/1988/

N70746 001

MAR 10, 1988

AA

PHARM BASICS

35MG

35MG

35MG

N84399 001

N83805 001

N84398 001

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION

PENICILLIN G POTASSIUM

/AP/ /PARKE/DAVIS/

/1,000,000 UNITS/VIAL/

3 PARKE DAVIS

5MG

/N62003/001/

/N62003/002/

N62003 001

N62003 002

AB

PHARM BASICS

100MG

100MG

100MG

/N87260/001/

N87260 001

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN V POTASSIUM

/AA/ /PARKE/DAVIS/

/EQ 125MG BASE/5ML/

3 PARKE DAVIS

EQ 125MG BASE/5ML

/N62002/001/

/N62002/002/

N62002 001

N62002 002

AB

PHARM BASICS

100MG

100MG

100MG

/N87091/001/

N87091 001

TABLET; ORAL

PENICILLIN V POTASSIUM

/AB/ /PARKE/DAVIS/

/EQ 250MG BASE/5ML/

3 PARKE DAVIS

EQ 250MG BASE/5ML

/N62001/001/

/N62001/002/

N62001 001

N62001 002

AB

PHARM BASICS

100MG

100MG

100MG

/N85894/001/

N85894 001

PERPHENAZINE

TABLET; ORAL

PERPHENAZINE

/B*/ /CHELSEA/

/4MG/

/N84700/001/

/DEC/23/1987/

AB

PHARM BASICS

10MG

10MG

/N74036 001

MAY 29, 1992

N74036 002

MAY 29, 1992

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

PHENDIMETRAZINE TARTRATE

/AA/ /PHARM/BASICS/

/35MG/

/35MG/

/N84305/001/

/N84306/001/

/N84309/001/

AB

PHARM BASICS

10MG

10MG

/N74036 001

MAY 29, 1992

N74036 002

MAY 29, 1992

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

PHENDIMETRAZINE TARTRATE

AA

PHARM BASICS

35MG

35MG

35MG

N84399 001

N83805 001

N84398 001

PHENYLBUTAZONE

CAPSULE; ORAL

PHENYLBUTAZONE

AB

PHARM BASICS

100MG

100MG

/N87260/001/

N87260 001

TABLET; ORAL

PHENYLBUTAZONE

AB

PHARM BASICS

100MG

100MG

/N87091/001/

N87091 001

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL

PHENYTOIN SODIUM, PROMPT

BX

PHARM BASICS

100MG

100MG

/N85894/001/

N85894 001

PIROXICAM

CAPSULE; ORAL

PIROXICAM

ADD

ADD

10MG

/N18147 002

APR 06, 1982

N18147 003

APR 06, 1982

PIROXICAM

PIROXICAM

ADD

ADD

20MG

/N74036 001

MAY 29, 1992

N74036 002

MAY 29, 1992

PROCAINE HYDROCHLORIDE; TETRACYCLINE HYDROCHLORIDE

PROPOXYPHENE HYDROCHLORIDE

INJECTABLE; INJECTION

ACHROMYCIN

AP

LEDERLE

40MG/VIAL; 100MG/VIAL

50267 002

AP

LEDERLE

40MG/VIAL; 100MG/VIAL

50276 001

AP

LEDERLE

40MG/VIAL; 250MG/VIAL

50267 003

TETRACYCLIN

AP

Pfizer

40MG/VIAL; 250MG/VIAL

60285 003

3

Pfizer

40MG/VIAL; 100MG/VIAL

60285 002

PROCHLORPERAZINE MALEATE

TABLET; ORAL

COMPASINE

AB

SKF

EQ 5MG BASE

10571 001

AB

SKF

EQ 10MG BASE

10571 002

AB

SKF

EQ 25MG BASE

10571 003

3

SKF

EQ 5MG BASE

10571 001

3

SKF

EQ 10MG BASE

10571 002

PROCHLORPERAZINE MALEATE

BP

Purimed

EQ 5MG BASE

10571 001

BP

Purimed

EQ 10MG BASE

10571 002

BP

Purimed

EQ 25MG BASE

10571 003

3

Purimed

EQ 5MG BASE

10571 001

3

Purimed

EQ 10MG BASE

10571 002

3

Purimed

EQ 25MG BASE

10571 003

3

Purimed

EQ 5MG BASE

10571 001

3

Purimed

EQ 10MG BASE

10571 002

3

Purimed

EQ 25MG BASE

10571 003

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

PROMETHAZINE HCL

BP

Purimed

EQ 25MG

10571 001

BP

Purimed

EQ 50MG

10571 002

3

Purimed

EQ 25MG

10571 003

3

Purimed

EQ 50MG

10571 004

CAPSULE; ORAL

PROPOXYPHENE HCL

AA

Vitarine

32MG

10571 001

AA

Vitarine

65MG

10571 002

AA

Vitarine

65MG

10571 003

3

Vitarine

32MG

10571 001

3

Vitarine

65MG

10571 002

3

Vitarine

65MG

10571 003

PROPANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPANOLOL HCL

AB

Superpharm

10MG

10571 001

AB

Superpharm

20MG

10571 002

3

Superpharm

10MG

10571 001

3

Superpharm

20MG

10571 002

PROTIRELIN

INJECTABLE; INJECTION

RELEFACT TRH

ADD > AP

Ferring

0.5MG/ML

10571 001

DLT > AP

Hyochst/Boysen

0.5MG/ML

10571 002

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION

PYRIDOXINE HCL

AP

Luitpold

100MG/ML

10571 001

QUINETHAZONE; RESERPINE

TABLET; ORAL

HYDROMOX/R

LEDERLE

50MG; 0.125MG

10571 001

3

Lederle

50MG; 0.125MG

10571 002

3

Lederle

50MG; 0.125MG

10571 003

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 5 / JAN '92 - MAY '92

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

THIAMINE HCL

/AP/ /LUTIPOLD/ /100MG/ML/
 3 LUTIPOLD 100MG/ML
 /AP/ /PARKE/DAVIS/ /100MG/ML/
 3 PARKE DAVIS 100MG/ML

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

/AB/ /PAR/ /150MG/
 /AB/ /200MG/
 3 PAR 150MG
 3 200MG
 FEB 09, 1988
 N89765 001
 FEB 09, 1988

TIMOLOL MALEATE

TABLET; ORAL

TIMOLOL MALEATE

/B*/ /PHARM/BASICS/ /5MG/
 /B*/ /10MG/
 /B*/ /20MG/
 3 PHARM BASICS 5MG
 3 10MG
 3 20MG
 JAN 10, 1989
 N72002 001
 JAN 10, 1989
 N72003 001
 JAN 10, 1989

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN SULFATE

> ADD > AP
 > ADD >
 ABBOTT
 AP GENSLA
 EQ 40MG BASE/ML
 EQ 40MG BASE/ML
 N63116 001
 MAY 18, 1992
 N63100 001
 JAN 30, 1992

TOLAZAMIDE

TABLET; ORAL

TOLAZAMIDE

/AB/ /INTERPHARM/ /250MG/
 /AB/ /500MG/
 B* INTERPHARM 250MG
 B* 500MG
 SEP 23, 1986
 N71270 001
 SEP 23, 1986
 N71271 001
 SEP 23, 1986
 /B*/ /PHARM/BASICS/ /100MG/
 /B*/ /250MG/
 /B*/ /500MG/
 3 PHARM BASICS 100MG
 3 250MG
 3 500MG
 JAN 11, 1988
 N70168 001
 APR 02, 1986
 N70169 001
 APR 02, 1986

TOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE

/AB/ /PARKE/DAVIS/ /500MG/
 3 PARKE DAVIS 500MG

TOLMETIN SODIUM

CAPSULE; ORAL

TOLMETIN SODIUM

AB BAKER CUMMINS
 AB GENEVA
 > ADD > AB
 > ADD >
 AB PUREPAC
 EQ 400MG BASEM
 EQ 400MG BASEM
 EQ 400MG BASEM
 EQ 400MG BASEM
 N73392 001
 JAN 24, 1992
 N73462 001
 APR 30, 1992
 N73519 001
 MAY 29, 1992
 N73308 001
 JAN 24, 1992

/N71270/001/
 /SEP/23/1986/
 /N71271/001/
 /SEP/23/1986/
 N71270 001
 SEP 23, 1986
 N71271 001
 SEP 23, 1986
 /N71355/001/
 /JAN/11/1988/
 /N70168/001/
 /APR/02/1986/
 /N70169/001/
 /APR/02/1986/
 N71355 001
 JAN 11, 1988
 N70168 001
 APR 02, 1986
 N70169 001
 APR 02, 1986

/N86047/001/
 N86047 001

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACEPHEN
G AND W

120MG# N72218 001
MAR 27, 1992
325MG# N72344 001
MAR 27, 1992
650MG# N72237 001
MAR 27, 1992

SODIUM MONOFLUOROPHOSPHATE

PASTE; DENTAL
EXTRA-STRENGTH AIM
/3/CHESBROUGH/POHDS/ 1.2%
1.2%
CHESBROUGH PONDS 1.2%

N19518/001
/JUN/03/1987
N19518 001
JUN 03, 1987

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
MICROCOL
JOHNSON AND JOHNSON 0.5%#

N72292 001
JAN 28, 1992

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
SILPHEN
SILARX

12.5MG/5ML# N72646 001
FEB 27, 1992

IBUPROFEN

TABLET; ORAL
IBUPROFEN
TAG

200MG# N73141 001
MAY 29, 1992

>_ADD >
>_ADD >

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE
BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
HUMULIN 50/50
LILLY

50 UNITS/ML;50 UNITS/ML# N20100 001
APR 29, 1992

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL
LOPERAMIDE HCL
PERRIGO
ROXANE

1MG/5ML# N73243 001
JAN 21, 1992
1MG/5ML# N73079 001
APR 30, 1992

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL
LOPERAMIDE HCL

PERRIGO

ROXANE

1MG/5MLM

1MG/5MLM

N73243 001

JAN 21, 1992

N73079 001

APR 30, 1992

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 5 / JAN '92 - MAY '92

DEXTRAN, 75, 6% INVERTED SUGAR 10% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION

6% GENTRAN 75 AND 10% TRAVERT

TRAVENOL LABS

6GM/100ML; 0.9GM/100ML

0.9GM/100ML

N08788

UROKINASE

INJECTABLE; INJECTION

BREOKINASE

STERLING DRUG

250,000 IU/VIAL

N17873

ORPHAN DRUG PRODUCT DESIGNATIONS

SECTION 526 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT CONTAINS PROVISIONS WHEREBY FDA MAY DESIGNATE A SPONSOR'S DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT AS A "DESIGNATED ORPHAN DRUG." SECTION 527 OF THE ACT ESTABLISHES A PROCESS WHEREBY A SPONSOR MAY RECEIVE SEVEN YEARS OF EXCLUSIVE APPROVAL STATUS IF THAT SPONSOR IS THE FIRST TO ACHIEVE NEW DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT APPROVAL FOR A DESIGNATED ORPHAN DRUG FOR THE DESIGNATED INDICATION(S). THE EXCLUSIVE APPROVAL MAY BE REVOKED BY WRITTEN CONSENT OF THE SPONSOR OR BY FDA ACTION AFTER FINDING THAT THE SPONSOR HOLDING EXCLUSIVE APPROVAL CANNOT ASSURE THE AVAILABILITY OF SUFFICIENT QUANTITIES OF THE DRUG TO MEET THE NEEDS OF PATIENTS WITH THE DESIGNATED ORPHAN INDICATION(S).

WHEN A PRODUCT IS GRANTED ORPHAN DRUG DESIGNATION, IT WILL APPEAR IN THIS SECTION. ONCE A BIOLOGICAL OR DRUG PRODUCT IS LICENSED/APPROVED FOR MARKETING, IT WILL BE LISTED IN THIS SECTION AND ASTERISKED, AS APPROPRIATE, TO DENOTE MARKETING/EXCLUSIVE APPROVAL STATUS. IN ADDITION, THE EXCLUSIVITY EXPIRATION DATE WILL BE DISPLAYED FOLLOWING THE APPROVED DESIGNATED INDICATION(S).

THE FOLLOWING DRUGS AND BIOLOGICALS HAVE BEEN GRANTED ORPHAN DRUG DESIGNATION PURSUANT TO SECTION 526 OF THE FOOD, DRUG, AND COSMETIC ACT AS AMENDED BY THE ORPHAN DRUG ACT [PUBLIC LAW 97-414].

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ALDESLEUKIN TRADE: PROLEUKIN*/**	TREATMENT OF PRIMARY IMMUNODEFICIENCY DISEASE ASSOCIATED WITH T-CELL DEFECTS.*/** [MAY 5, 1999]	CETUS CORPORATION
GENERIC: ANANAIN, COMOSAIN TRADE: VIANAIN	FOR THE ENZYMATIC DEBRIDEMENT OF SEVERE BURNS.	GENZYME CORPORATION
GENERIC: ANTITHROMBIN III TRADE: THROMBATE III*/**	USE AS REPLACEMENT THERAPY IN CONGENITAL DEFICIENCY OF ANTITHROMBIN-III FOR PREVENTION AND TREATMENT OF OF THROMBOSIS AND PULMONARY EMBOLI. [DEC 13, 1996]	CUTTER BIOLOGICAL
GENERIC: BOTULINUM TOXIN TYPE B TRADE: NOT ESTABLISHED	TREATMENT OF CERVICAL DYSTONIA.	ATHENA NEUROSCIENCES, INC
GENERIC: CILIARY NEUROTROPHIC FACTOR TRADE: NOT ESTABLISHED	TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.	ROGENERON PHARMACEUTICALS, INC
GENERIC: CILIARY NEUROTROPHIC FACTOR, RECOMBINANT HUMAN TRADE: NOT ESTABLISHED	TREATMENT OF SPINAL MUSCULAR ATROPHIES. TREATMENT OF MOTOR NEURON DISEASE (INCLUDING AMYOTROPHIC LATERAL SCLEROSIS, PROGRESSIVE MUSCULAR ATROPHY, PROGRESSIVE BULBAR PALSY, AND PRIMARY LATERAL SCLEROSIS).	SYNTEX-SYNERGEN NEUROSCIENCE

GENERIC: CILIARY NEUROTROPHIC FACTOR, RECOMBINANT HUMAN
TRADE: NOT ESTABLISHED

TREATMENT OF SPINAL MUSCULAR ATROPHIES.
TREATMENT OF MOTOR NEURON DISEASE (INCLUDING
AMYOTROPHIC LATERAL SCLEROSIS, PROGRESSIVE
MUSCULAR ATROPHY, PROGRESSIVE BULBAR PALSY,
AND PRIMARY LATERAL SCLEROSIS).

SYNTEX-SYNERGEN NEUROSCIENCE

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL

DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]

SPONSOR NAME

GENERIC: CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR
TRADE: NOT ESTABLISHED

FOR CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR
PROTEIN REPLACEMENT THERAPY IN CYSTIC FIBROSIS PATIENTS.

GENZYME CORPORATION

GENERIC: HIV NEUTRALIZING ANTIBODIES
TRADE: IMMUPATH

TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME
(AIDS).

HEMACARE CORPORATION

GENERIC: HUMAN IMMUNODEFICIENCY VIRUS IMMUNE
GLOBULIN
TRADE: NOT ESTABLISHED

TREATMENT OF HIV-INFECTED PREGNANT WOMEN AND
INFANTS OF HIV-INFECTED MOTHERS.

ABBOTT LABORATORIES

GENERIC: IMPORTED FIRE ANT VENOM,
ALLERGENIC EXTRACT
TRADE: NOT ESTABLISHED

FOR SKIN TESTING OF VICTIMS OF FIRE ANT STINGS
TO CONFIRM FIRE ANT SENSITIVITY AND IF POSITIVE,
FOR USE AS IMMUNOTHERAPY FOR THE PREVENTION OF
IGE-MEDIATED ANAPHYLACTIC REACTIONS.

ALK LABORATORIES, INC

GENERIC: SARGRAMOSTIM
TRADE: LEUKINE*/**

TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW
TRANSPLANT, FOR THE PROMOTION OF EARLY ENGRAFTMENT,
AND FOR THE TREATMENT OF GRAFT FAILURE AND DELAY OF
ENGRAFTMENT. */** [DEC 31, 1998]
TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE
MARROW TRANSPLANTS IN PATIENTS WITH NON-HODGKIN'S
LYMPHOMA, HODGKIN'S DISEASE AND ACUTE LYMPHOBLASTIC
LEUKEMIA. */** [MAR 05, 1998]

IMMUNEX

GENERIC: TECHNETIUM TC99M MURINE MONOCLONAL
ANTIBODY (IGG2A) TO BCE
TRADE: IMMURAIID-LL-2[99mTc]

DIAGNOSTIC IMAGING IN THE EVALUATION OF THE EXTENT
OF DISEASE IN PATIENTS WITH HISTOLOGICALLY
CONFIRMED DIAGNOSIS OF NON-HODGKIN'S B-CELL
LYMPHOMA, ACUTE B-CELL LYMPHOBLASTIC LEUKEMIA
(IN CHILDREN AND ADULTS), AND CHRONIC B-CELL
LYMPHOBLASTIC LEUKEMIA.

IMMUNOMEDICS, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ANARITIDE ACETATE TRADE: AURICULIN	IMPROVEMENT OF EARLY RENAL ALLOGRAFT FUNCTION FOLLOWING RENAL TRANSPLANTATION.	SCIOS, INC
GENERIC: ARGININE BUTYRATE TRADE: NOT ESTABLISHED	TREATMENT OF BETA-HEMOGLOBINOPATHIES AND BETA-THALASSEMIA.	SUSAN P. PERRINE, M.D.
GENERIC: BACLOFEN (INTRATHECAL) TRADE: LITORESAL	TREATMENT OF INTRACTABLE SPASTICITY CAUSED BY SPINAL CORD INJURY, MULTIPLE SCLEROSIS, AND OTHER SPINAL DISEASES (INCLUDING SPINAL ISCHEMIA, SPINAL TUMOR, TRANSVERSE MYELITIS, CERVICAL SPONDYLOSIS, AND DEGENERATIVE MYELOPATHY.	MEDTRONIC, INC
GENERIC: BUTYRYLCHOLINESTERASE TRADE: NOT ESTABLISHED	FOR THE REDUCTION AND CLEARANCE OF TOXIC BLOOD LEVELS OF COCAINE ENCOUNTERED DURING A DRUG OVERDOSE.	PHARMAVENE, INC
GENERIC: DAPSONE TRADE: DAPSONE	FOR THE COMBINATION TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA IN CONJUNCTION WITH TRIMETHOPRIM.	JACOBUS PHARMACEUTICAL COMPANY
GENERIC: DIAZEPAM VISCIOUS SOLUTION FOR RECTAL ADMINISTRATION TRADE: DIASTAT	TREATMENT OF ACUTE REPETITIVE SEIZURES.	UPSHER SMITH LABORATORIES, INC
GENERIC: HUMAN THYROID STIMULATING HORMONE (TSH) TRADE: THYROGEN	AS AN ADJUNCT IN THE DIAGNOSIS OF THYROID CANCER.	GENZYME CORPORATION
GENERIC: L-BACLOFEN TRADE: NEURALGON	TREATMENT OF INTRACTABLE SPASTICITY IN CHILDREN WITH CEREBRAL PALSY.	WTD, INC
GENERIC: LIOTHYRONINE SODIUM TRADE: TRIOSTAT*/**	TREATMENT OF MYXEDEMA COMA/PRE-COMA. [DEC 31, 1998]	SMITHKLINE BEECHAM
GENERIC: LOXORIBINE TRADE: NOT ESTABLISHED	TREATMENT OF COMMON VARIABLE IMMUNODEFICIENCY.	R.W. JOHNSON RESEARCH INSTITUTE
GENERIC: MELPHALAN TRADE: ALKERAN FOR INJECTION	TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA FOR WHOM ORAL THERAPY IS INAPPROPRIATE. FOR USE IN HYPERTHERMIC REGIONAL LIMB PERFUSION TO TREAT METASTATIC MELANOMA OF THE EXTREMITY.	BURROUGHS WELLCOME COMPANY

GENERIC: MELPHALAN
TRADE: ALKERAN FOR INJECTION

TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA
FOR WHOM ORAL THERAPY IS INAPPROPRIATE.
FOR USE IN HYPERTHERMIC REGIONAL LIMB PERFUSION
TO TREAT METASTATIC MELANOMA OF THE EXTREMITY.

BURROUGHS WELLCOME COMPANY

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: PAPAVERINE (TOPICAL GEL) TRADE: NOT ESTABLISHED	TREATMENT OF SEXUAL DYSFUNCTION IN SPINAL CORD INJURY PATIENTS.	PHARMEDIC COMPANY
GENERIC: PARA-AMINOSALICYLIC ACID TRADE: NOT ESTABLISHED	TREATMENT OF TUBERCULOSIS INFECTIONS.	JACOBUS PHARMACEUTICAL COMPANY
GENERIC: PILOCARPINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF XEROSTOMIA AND KERATOCONJUNCTIVITIS SICCA IN SJOGREN'S SYNDROME PATIENTS.	MGI PHARMA, INC
GENERIC: POLYMERIC OXYGEN TRADE: NOT ESTABLISHED	TREATMENT OF SICKLE CELL ANEMIA.	CAPMED, USA
GENERIC: PPI-002 TRADE: NOT ESTABLISHED	TREATMENT OF MALIGNANT MESOTHELIOMA.	PLEXUS PHARMACEUTICALS, INC
GENERIC: SODIUM MONOMERCAPTOUNDECAHYDRO-CLOSODODECABORATE TRADE: BOROCCELL	FOR USE IN BORON NEUTRON CAPTURE THERAPY IN THE TREATMENT OF GLIOBLASTOMA MULTIFORME.	NEUTRON TECHNOLOGY CORPORATION
GENERIC: 9-CIS RETINOIC ACID TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE PROMYELOCYTIC LEUKEMIA.	LIGAND PHARMACEUTICALS, INC

DRUG PRODUCTS WHICH MUST DEMONSTRATE IN VIVO BIOAVAILABILITY
ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION

NO MAY 1992 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR IN VIVO BIOEQUIVALENCE STUDIES AND IN VITRO DISSOLUTION TESTING AVAILABLE FROM THE DIVISION OF BIOEQUIVALENCE, HFD-650, MPN-2 ROOM 278, 5600 FISHERS LANE, ROCKVILLE, MD 20857. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 12TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
DIFLUNISAL (TABLET)	MAY 16, 1992	
DILTIAZEM HYDROCHLORIDE (TABLET)	MAY 16, 1992	
NADOLOL (TABLET)	MAY 16, 1992	

ANDA SUITABILITY PETITIONS

THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED AND REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANCH, HFA-305, ROOM 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 12TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	PETITION	REASON FOR STATUS
ALBUTEROL SULFATE CAPSULE, EXTENDED RELEASE; ORAL	EQ 4MG BASE	91 P-0348/ CPI	HAMER	NEW DOSAGE FORM	APPROVED MAR 17, 1992
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	5MG/ML (50ML/CONTAINER)	91 P-0387/ CPI	ABBOTT	NEW STRENGTH	APPROVED FEB 18, 1992
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	10MG/ML (100ML/CONTAINER)	91 P-0387/ CPI	ABBOTT	NEW STRENGTH	APPROVED FEB 18, 1992

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	PETITION	REASON FOR STATUS
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (50ML/VIAL)	91 P-0076/ CPI	ADRIA	NEW STRENGTH	DENIED FEB 19, 1992

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 12TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES
NEW INDICATION

I-67	TREATMENT OF ACUTE ASTHMATIC ATTACKS IN CHILDREN SIX YEARS OF AGE AND OLDER
I-68	CENTRAL PRECOCIOUS PUBERTY
I-69	SHORT TERM TREATMENT OF PATIENTS WITH SYMPTOMS OF GASTROESOPHAGEAL REFLUX DISEASE (GERD), AND FOR THE SHORT TERM TREATMENT OF ESOPHAGITIS DUE TO GERD INCLUDING ULCERATIVE DISEASE DIAGNOSED BY ENDOSCOPY
I-70	USE IN COMBINATION WITH 5-FLUOROURACIL TO PROLONG SURVIVAL IN THE PALLIATIVE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER
I-71	VARICELLA INFECTIONS (CHICKENPOX)
I-72	PREVENTION OF CMV DISEASE IN TRANSPLANT PATIENTS AT RISK FOR CMV DISEASE
I-73	INITIATE AND MAINTAIN MONITORED ANESTHESIA CARE (MAC) SEDATION DURING DIAGNOSTIC PROCEDURES
I-74	INTRAVENOUS DIGITAL SUBTRACTION ANGIOGRAPHY

REFERENCES
PATENT USE CODE

U-57	OPHTHALMIC USE OF NORFLOXACIN
U-58	METHOD OF TREATING INFLAMMATORY INTESTINAL DISEASES
U-59	METHOD OF TREATING HYPERCHOLESTEROLEMIA
U-60	NASAL ADMINISTRATION OF BUTORPHANOL

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
18828 001	ACYCLOVIR; ZOVIRAX				I-71	FEB 26, 1995
19909 001	ACYCLOVIR; ZOVIRAX				I-71	FEB 26, 1995
20089 001	ACYCLOVIR; ZOVIRAX				I-71	FEB 26, 1995
20089 002	ACYCLOVIR; ZOVIRAX				I-71	FEB 26, 1995
19851 001	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2002		NCE	JUN 25, 1996
>ADD>						
>>DLT>						
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19001 001	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
19001 002	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
19001 003	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
19548 001	BITOLTEROL MESYLATE; TORNALATE	4336400	JUN 22, 1999	U-5		
		4138581	FEB 06, 1998		NDF	FEB 19, 1995
19890 001	BUTORPHANOL TARTRATE; STADOL	4464378	AUG 07, 2001	U-60	NDF	DEC 12, 1994
19847 001	CIPROFLOXACIN; CIPRO	4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
		4670444	OCT 01, 2002			
		4670444	JUN 02, 2004		NCE	OCT 22, 1992
19857 001	CIPROFLOXACIN; CIPRO IN DEXTROSE 5%	4957922	SEP 18, 2007		NCE	OCT 22, 1992
		4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
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**PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA**

[illegible]

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PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20166 001	SODIUM THIOSULFATE; SODIUM THIOSULFATE	4730000	MAR 08, 2005	U-36	NCE	FEB 14, 1997
20043 003	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	MAR 08, 2005	U-36	NCE	JAN 30, 1997
20043 004	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4863742	SEP 05, 2006	U-3	NDF	JAN 30, 1997
19614 003	VERAPAMIL HYDROCHLORIDE; VERELAN	4837208	FEB 09, 2005		I-47	MAY 29, 1993
19655 001	ZIDOVUDINE; RETROVIR	4833130	FEB 09, 2005		ODE	MAY 02, 1993
		4828838	FEB 09, 2005		ODE	MAR 19, 1994
		4724232	FEB 09, 2005		NCE	MAR 19, 1992
19910 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005		ODE	MAR 19, 1994
		4833130	FEB 09, 2005		I-47	MAY 02, 1993
		4818538	FEB 09, 2005		NCE	MAR 19, 1992
		4724232	FEB 09, 2005		NCE	MAR 19, 1992
19951 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005		NCE	MAR 19, 1992
		4833130	FEB 09, 2005		ODE	MAR 19, 1994
		4818538	FEB 09, 2005		ODE	MAR 19, 1994
		4724232	FEB 09, 2005		ODE	MAR 19, 1994