

CUMULATIVE
SUPPLEMENT 3

JAN'92-MAR'92

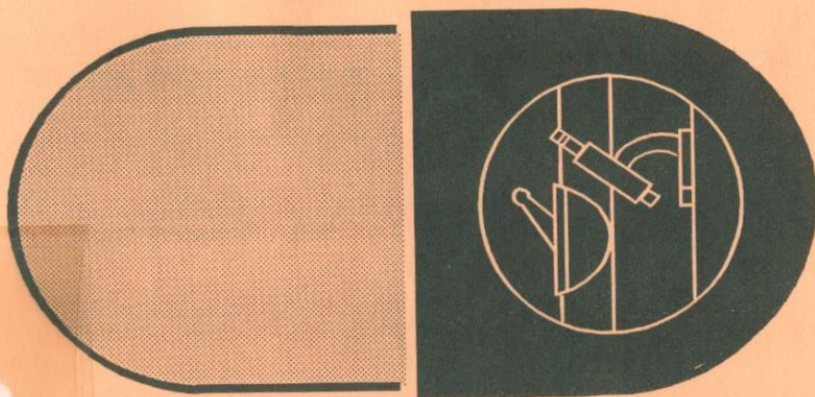
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APPROVED DRUG PRODUCTS

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 3

March 1992

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION

CUMULATIVE SUPPLEMENT 3

MARCH 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 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)

1.3 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)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

RECKITT AND COLMAN PHARMACEUTICALS INC
(R & C)

RECKITT AND COLMAN PHARMACEUTICALS INC
(RECKITT AND COLMAN)

BARNES HIND PHARMACEUTICALS INC
(BARNES HIND)

SOLA BARNES HIND
(SOLA BARNES HIND)

1.4 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

SEP 1992

JUN 1992

MAR 1992

DEC 1991

CATEGORIES COUNTED

DRUG PRODUCTS LISTED

SINGLE SOURCE

MULTISOURCE

THERAPEUTICALLY EQUIVALENT

NOT THERAPEUTICALLY EQUIVALENT

EXCEPTIONS¹

NEW MOLECULAR ENTITIES APPROVED

NUMBER OF APPLICANTS

9258	9473	
2187 (22.8%)	2222 (23.4%)	
7397 (77.2%)	7251 (76.6%)	
6580 (68.7%)	6510 (68.7%)	
664 (6.9%)	592 (6.3%)	
153 (1.6%)	149 (1.6%)	
--	4	
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 3 / JAN'92 - MAR'92

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL
/ACETAMINOPHEN AND CODEINE/
/VITARINE/
/300MG;15MG/
/300MG;30MG/
/300MG;60MG/
/AA/
/AA/
/AA/
/AA/

> DLT >
> DLT >
> DLT >
> DLT >
/AA/

> ADD >
> ADD >
> ADD >
> ADD >
/AA/

ACETAMINOPHEN AND CODEINE PHOSPHATE
3 PARKE DAVIS
300MG;15MG
300MG;30MG
300MG;60MG

3 VITARINE
300MG;15MG
300MG;30MG
300MG;60MG

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

3 CHELSEA
300MG;15MG
300MG;30MG
300MG;60MG

> DLT >
> DLT >
/AA/
/AA/

/PARKE DAVIS/
/300MG;15MG/
/300MG;30MG/
/300MG;60MG/

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN
AA MIKART
500MG;5MG
/AA/
/PHARM/BASICS/
3 PHARM BASICS
500MG;5MG

3 PHARM BASICS
500MG;5MG

ACETOHEXAMIDE

TABLET; ORAL
ACETOHEXAMIDE
/B*/ /PHARM/BASICS/
/B*/

3 PHARM BASICS
250MG
500MG

/250MG/
/500MG/
/B*/

/N74753/001/
/NOV/03, 1986/
/N74754/001/
/NOV/03, 1986/
/N74753/001/
/NOV/03, 1986/
/N74754/001/
/NOV/03, 1986/

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE
AN DEY

EQ 0.083% BASE

N72652 001
FEB 21, 1992

PROVENTIL
AN SCHERING

EQ 0.083% BASE

N19243 002
JAN 14, 1987

SYRUP; ORAL
ALBUTEROL SULFATE
LEMMON

EQ 2MG BASE/5ML

N73419 001
MAR 30, 1992

ALLOPURINOL

TABLET; ORAL
ALLOPURINOL
/B*/ /BOLAR/
3 BOLAR

/100MG/
100MG

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

N89697 001
JAN 28, 1992
/N89697/001/
/MAY/29, 1987/
N89291 001
MAY 29, 1987

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

> DLT > /BP/ /PAR/ /10MG/ /N88697/001/ /SEP/25/1984/

> DLT > /BP/ /PAR/ /25MG/ /N88698/001/ /SEP/25/1984/

> DLT > /BP/ /PAR/ /50MG/ /N88699/001/ /SEP/25/1984/

> DLT > /BP/ /PAR/ /75MG/ /N88700/001/ /SEP/25/1984/

> DLT > /BP/ /PAR/ /100MG/ /N88701/001/ /SEP/25/1984/

> DLT > /BP/ /PAR/ /150MG/ /N88702/001/ /SEP/25/1984/

> ADD > 3 PAR N88697 001 SEP 25, 1984

> ADD > 3 N88698 001 SEP 25, 1984

> ADD > 3 N88699 001 SEP 25, 1984

> ADD > 3 N88700 001 SEP 25, 1984

> ADD > 3 N88701 001 SEP 25, 1984

> ADD > 3 N88702 001 SEP 25, 1984

CAPSULE; ORAL
POLYMOX

> ADD > AB /AB/ /AB/ /250MG/ /N63099/001/ /MAR/20/1992/

> ADD > AB /AB/ /AB/ /500MG/ /N63099/002/ /MAR/20/1992/

N63099 001
MAR 20, 1992
N63099 002
MAR 20, 1992

> ADD > AB /AB/ /AB/ /250MG/ /N62107/001/ /MAR/20/1992/

> ADD > AB /AB/ /AB/ /500MG/ /N62107/002/ /MAR/20/1992/

N62107 001
MAR 20, 1992
N62107 002
MAR 20, 1992

POWDER FOR RECONSTITUTION; ORAL
UTIMOX

> ADD > AB /AB/ /AB/ /125MG/5ML/ /N62127/001/ /MAR/20/1992/

> ADD > AB /AB/ /AB/ /250MG/5ML/ /N62127/002/ /MAR/20/1992/

N62127 001
MAR 20, 1992
N62127 002
MAR 20, 1992

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL
AMCILL

> ADD > AB /AB/ /AB/ /EQ 250MG BASE/ /N62041/001/ /MAR/20/1992/

> ADD > AB /AB/ /AB/ /EQ 500MG BASE/ /N62041/002/ /MAR/20/1992/

N62041 001
MAR 20, 1992
N62041 002
MAR 20, 1992

POWDER FOR RECONSTITUTION; ORAL
AMCILL

> ADD > AB /AB/ /AB/ /EQ 125MG BASE/5ML/ /N62030/001/ /MAR/20/1992/

> ADD > AB /AB/ /AB/ /EQ 250MG BASE/5ML/ /N62030/002/ /MAR/20/1992/

N62030 001
MAR 20, 1992
N62030 002
MAR 20, 1992

ATENOLOL

TABLET; ORAL
ATENOLOL

> ADD > AB /AB/ /AB/ /50MG/ /N73317/001/ /MAR/20/1992/

> ADD > AB /AB/ /AB/ /100MG/ /N73318/001/ /MAR/20/1992/

N73317 001
MAR 20, 1992
N73318 001
MAR 20, 1992

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL
/BP/ /PHARM/BASICS/

> DLT > /BP/ /PHARM/BASICS/ /EQ 12.5MG BASE/5MG/ /N70477/001/ /JAN/12/1988/

> DLT > /BP/ /PHARM/BASICS/ /EQ 25MG BASE/10MG/ /N70478/001/ /JAN/12/1988/

> ADD > 3 PHARM BASICS EQ 12.5MG BASE;5MG JAN 12, 1988

> ADD > 3 EQ 25MG BASE;10MG JAN 12, 1988

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

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL
/BP/ /CHELSEA/

N71558/001/ /MAR/02/1987/

ATENOLOL

TABLET; ORAL

AB ATENOLOL
MYLAN

50MG

N73456 001
JAN 24, 1992
N73457 001
JAN 24, 1992

100MG

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

AB CHELSEA

3 CHELSEA

0.025MG; 2.5MG

N85876/001/
N85876 001

DIPHENOXYLATE HCL W/ ATROPINE SULFATE

AB VITARINE

3 VITARINE

0.025MG; 2.5MG

N86173/001/
N86173 001

BACLOFEN

TABLET; ORAL

AB BACLOFEN

3 BIOCRAFT

10MG

N73043 001
FEB 27, 1992

20MG

N73044 001
FEB 27, 1992

AB PHARM/BASICS

3

10MG

N71260/001/
N71260 001

AB PHARM/BASICS

3

20MG

N71261 001
MAY 06, 1988

MAY 06, 1988

BENZTROPINE MESYLATE

TABLET; ORAL

AB BENZTROPINE MESYLATE

3 MUTUAL PHARM

1MG

N81264 001
JAN 23, 1992

2MG

N81265 001
JAN 23, 1992

BENZTROPINE MESYLATE

TABLET; ORAL

AB BENZTROPINE MESYLATE

3 PHARM/BASICS

0.5MG

N89211 001
JUN 14, 1988

AB PHARM/BASICS

3

1MG

N89212 001
JUN 14, 1988

AB PHARM/BASICS

3

2MG

N89213 001
JUN 14, 1988

BETHANECHOL CHLORIDE

TABLET; ORAL

AB BETHANECHOL CHLORIDE

3 VITARINE

5MG

N84353 001

AB VITARINE

3

10MG

N84378 001

AB VITARINE

3

25MG

N84383 001

AB VITARINE

3

25MG

N84384 001

BITOLTEROL MESYLATE

SOLUTION; INHALATION

TORNALATE

0.2%
STERLING WINTHROP

N19548 001
FEB 19, 1992

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

AB BRETYLIUM TOSYLATE

3 LYPHOMED

50MG/ML

N70134/001/
FEB 12, 1986

3 LYPHOMED

50MG/ML

N70134 001
FEB 12, 1986

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 3 / JAN'92 - MAR'92

4

BUTABARBITAL SODIUM

TABLET; ORAL
/BUTABARBITAL SODIUM/
/VITARINE/
@ VITARINE

> DLT >
> DLT > /AA/
> ADD >

/30MG/
30MG

/N85934/001/
N85934 001

> ADD > CEFTAZIDIME (ARGININE FORMULATION)
> ADD > INJECTABLE; INJECTION
> ADD > CEPTAZ
> ADD > GLAXO

1GM/VIAL

N50646 002
SEP 27, 1990
N50646 003
SEP 27, 1990
N50646 004
SEP 27, 1990
N50646 001
SEP 27, 1990

SODIUM BUTABARBITAL

/AA/
/AA/
@ WEST WARD
@

/15MG/
30MG
15MG
30MG

/N85418/001/
N85418 001
N85432 001

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

1GM/VIAL

2GM/VIAL

10GM/VIAL

500MG/VIAL

CARBAMAZEPINE

TABLET; ORAL
CARBAMAZEPINE
/B*/ /PHARM/BASICS/
@ PHARM BASICS

/200MG/
200MG

/N70300/001/
N70300 001
MAY 15, 1986

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

1GM/VIAL

2GM/VIAL

10GM/VIAL

6GM/VIAL

N64006 001
MAR 31, 1992
N64006 002
MAR 31, 1992
N64008 002
MAR 31, 1992
N64008 001
MAR 31, 1992

CARTISOPRODOL

TABLET; ORAL
CARTISOPRODOL
/AA/
/VITARINE/
B* VITARINE

/350MG/
350MG

/N89566/001/
N89566 001
AUG 30, 1988

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN
/ROCHE/
@ ROCHE

/EQ/250MG/BASE/VIAL/
EQ 250MG BASE/VIAL

/N62510/001/
N62510 001
MAR 12, 1985

/EQ/500MG/BASE/VIAL/
EQ 500MG BASE/VIAL

/N62510/002/
N62510 002
MAR 12, 1985

/EQ/1GM/BASE/VIAL/
EQ 1GM BASE/VIAL

/N62510/003/
N62510 003
MAR 12, 1985

CEFTAZIDIME

INJECTABLE; INJECTION
/CEPTAZ/
/GLAXO/
@

/500MG/VIAL/
1GM/VIAL/
2GM/VIAL/
10GM/VIAL/

/N50646/001/
N50646 001
SEP 27, 1990
/N50646/002/
N50646 002
SEP 27, 1990
/N50646/003/
N50646 003
SEP 27, 1990
/N50646/004/
N50646 004
SEP 27, 1990

> DLT >
> DLT >
> DLT >
> DLT >
> DLT >
> DLT >
> DLT >

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
CHLORDIAZEPOXIDE HCL
/PARKE DAVIS/
@ PARKE DAVIS

/AB/
/AB/
/AB/
5MG
10MG
25MG

/N85163/001/
N85163 001
SEP 27, 1990
/N85163/002/
N85163 002
SEP 27, 1990
/N85163/003/
N85163 003
SEP 27, 1990
/N85164 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 3 / JAN'92 - MAR'92

5

CHLORDIAZEPOXIDE HYDROCHLORIDE

CINOXACIN

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

/AB/ /WEST/WARD/

/5MG/

/10MG/

/25MG/

2 WEST WARD

2

2

5MG

10MG

25MG

/N85014/001

/N85014/001

/N85014/001

/N85014/001

/N85014/001

/N85014/001

CAPSULE; ORAL

CINOBAC

AB +

CINOBAC

AB

AB

250MG

500MG

250MG

500MG

N18067 001

N18067 002

N73005 001

FEB 28, 1992

N73006 001

FEB 28, 1992

CHLOROQUINE PHOSPHATE

TABLET; ORAL

CHLOROQUINE PHOSPHATE

/AB/ /WEST/WARD/

/EQ 150MG BASE/

EQ 150MG BASE

/N83082/001

/N83082/001

SOLUTION; IRRIGATION

RENACIDIN

/GUARDIAN/LABS/

CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATE

/6.602GM/100ML; 198MG/100ML;

/3.177GM/100ML;

/OCT/02/1990/

N19481 001

OCT 02, 1990

CHLORPROPAMIDE

TABLET; ORAL

CHLORPROPAMIDE

/B*/ /PHARM/BASICS/

/B*/

/100MG/

/250MG/

/N88708/001

/N88708/001

/N88708/001

/N88708/001

/N88708/001

/N88708/001

CLEMASTINE FUMARATE

TABLET; ORAL

CLEMASTINE FUMARATE

AB

AB

1.34MG

2.68MG

N73282 001

JAN 31, 1992

N73283 001

JAN 31, 1992

TAVIST

AB +

TAVIST-1

AB

AB

2.68MG

1.34MG

N17661 001

N17661 002

CHYMOTRYPSIN

POWDER FOR RECONSTITUTION; OPHTHALMIC

ALPHA CHYMOTRYPSIN

/BARNES/HIND/

2 SOLA BARNES HIND

/N11837/001

/N11837/001

CLOFIBRATE

CAPSULE; ORAL

CLOFIBRATE

PHARMACAPS

> ADD > AB

> ADD >

500MG

N73396 001

MAR 20, 1992

ZOLYSE

/ALCON/

ALCON

/N11903/001

/N11903/001

CLOFIBRATE

PHARMACAPS

500MG

N73396 001

MAR 20, 1992

CLORAZEPATE DIPOTASSIUM

capsule; oral

CLORAZEPATE DIPOTASSIUM

/B*/ /PHARM/BASICS/ /1.75MG/ /N71242/001/

/B*/ /1.5MG/ /N71243/001/

/B*/ /1.5MG/ /N71244/001/

3 PHARM BASICS 3.75MG

3 7.5MG

3 15MG

COLCHICINE; PROBENECID

TABLET; ORAL

PROBENECID

/B*/ /CHELSEA/

3 CHELSEA

/0.5MG;500MG/ /N85552/001/

CYANOCOBALAMIN

INJECTABLE; INJECTION

CYANOCOBALAMIN

/AB/ /LUITPOLD/

3 LUITPOLD

/0.03MG/ML/ /N80668/001/

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CYCLOPENTOLATE HCL

/AT/ /BARNES/HIND/ /12/

3 SOLA BARNES HIND

12

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

DESIPRAMINE HCL

/B*/ /PHARM/BASICS/ /25MG/ /N71864/001/

/B*/ /50MG/ /N71865/001/

/B*/ /75MG/ /N71866/001/

/B*/ /100MG/ /N71867/001/

3 PHARM BASICS 25MG

3 50MG

3 75MG

3 100MG

DESONIDE

LOTION; TOPICAL

DESOWEN

OWEN GALDERMA

0.05%^m

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

/AA/ /VITARINE/ /25MG/

25MG

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

> ADD > AB 50MG

> ADD > 75MG

> ADD > AB

> ADD >

/N85916/001/

N87562 001

FEB 25, 1992

N87561 001

FEB 25, 1992

N72354 001

JAN 24, 1992

ERYTHROMYCIN

TABLET, COATED PARTICLES; ORAL
PCE
ABBOTT

N50611 002
AUG 22, 1990

500MG

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE
NMC

0.05/M

N73085 001
FEB 14, 1992

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
GENCEPT 0.5/35-21
GENCON

0.035MG;0.5MG

N72692 001
FEB 28, 1992

GENCEPT 1/35-21
GENCON

0.035MG;1MG

N72693 001
FEB 28, 1992

GENCEPT 10/11-21
GENCON

0.035MG;0.5MG AND 1MG

N72694 001
FEB 28, 1992

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL
/P*/ /PHARM/BASICS/

/15MG/

/N70562/001/
JUL 09, 1987

/30MG/

/N70563/001/
JUL 09, 1987

3 PHARM BASICS

15MG

3

30MG

N70562 001
JUL 09, 1987

TABLET; ORAL-28

GENCEPT 0.5/35-28
GENCON

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

FOLIC ACID

TABLET; ORAL
FOLIC ACID
/AA/ /VITARINE/
3 VITARINE

/1MG/
1MG

/N84472/001/
N84472 001

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE
/LYPHOMED/

/10MG/ML/

> DLT > /AP/

> DLT >

> ADD >

> ADD >

3 LYPHOMED

10MG/ML

/N18507/001/
JUL 30, 1982

FELODIPINE

TABLET, EXTENDED RELEASE; ORAL
PLENDIL
/MERCK/

/5MG/

MERCK

5MG

/N18834/001/
JUL 25, 1991

/10MG/

10MG

/N18834/002/
JUL 25, 1991

TABLET; ORAL
FUROSEMIDE
/CHELSEA/

/20MG/

> DLT > /AB/

> DLT >

> ADD >

> ADD >

> ADD >

> ADD >

3 CHELSEA

20MG

/N18369/001/
MAY 14, 1982

3

40MG

N18369 002
MAY 14, 1982

FUROSEMIDE

TABLET; ORAL

FUROSEMIDE

/VITARINE/

@ VITARINE

> DLT >
> DLT >
> ADD >
> ADD >

/40MG/

40MG

/N18750/002/

/JUL/30/1984/

N18750 002

JUL 30, 1984

GLYBURIDE

TABLET; ORAL

GLYNASE

+ UPJOHN

> ADD >
> ADD >
> ADD >
> ADD >

3MG

1.5MG

N20051 002

MAR 04, 1992

N20051 001

MAR 04, 1992

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH

/LUITPOLD/

@ LUITPOLD

@

HEPARIN SODIUM

/LUITPOLD/

@ LUITPOLD

HEPARIN SODIUM

/LUITPOLD/

@ LUITPOLD

HEPARIN SODIUM

/LUITPOLD/

@ LUITPOLD

HEPARIN SODIUM

/LUITPOLD/

@ LUITPOLD

HEPARIN SODIUM

/LUITPOLD/

@ LUITPOLD

HEPARIN SODIUM

/LUITPOLD/

@ LUITPOLD

HEPARIN SODIUM

/LUITPOLD/

@ LUITPOLD

HEPARIN SODIUM

/LUITPOLD/

@ LUITPOLD

HEPARIN SODIUM

/LUITPOLD/

@ LUITPOLD

HEPARIN SODIUM

/LUITPOLD/

@ LUITPOLD

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDRALAZINE HCL

/LYPHOMED/

@ LYPHOMED

> DLT >
> DLT >
> DLT >
> ADD >
> ADD >

/20MG/ML/

20MG/ML

/N89532/001/

/AUG/11/1987/

N89532 001

AUG 11, 1987

TABLET; ORAL

HYDRALAZINE HCL

/VITARINE/

@ VITARINE

/N85088/001/

N85088 001

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

HYDRALAZINE HCL

/VITARINE/

@ VITARINE

/N84876/001/

N84876 001

HYDRALAZINE HYDROCHLORIDE; RESERPINE

TABLET; ORAL

HYDRALAZINE HCL

/VITARINE/

@ VITARINE

/N84617/001/

N84617 001

/N84617/001/

N84617 001

/N84617/001/

N84617 001

/N84617/001/

N84617 001

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

/DANBURY

@ DANBURY

/25MG/

25MG

/N81189/001/

JAN 24, 1992

N81189 001

JAN 24, 1992

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

APRESOLINE

/CIBA/

@ CIBA

/N84827/001/

N84827 001

/25MG; 0.125MG/

25MG; 0.125MG

TABLET; ORAL

HYDROCHLOROTHIAZIDE

/VITARINE/

@ VITARINE

> DLT >

> DLT >

> ADD >

MECLOFENAMATE SODIUM

CAPSULE; ORAL
MECLOFENAMATE SODIUM
/B*/ /PHARM/BASIC\$/

/EQ/50MG/BASE/	/N71007/001/
	MAR 25, 1988/
/EQ/100MG/BASE/	/N71008/001/
	MAR 25, 1988/
EQ 50MG BASE	N71007 001
	MAR 25, 1988
EQ 100MG BASE	N71008 001
	MAR 25, 1988

७

MEGESTROL ACETATE

MEGESTROL ACETATE
/PHARM/BASICS/
/B*/
/B*/

2 PHARM BASICS

NEPERIDINE HYDROCHLORIDE

ABBOTT

<u>50MG./ML.</u> <u>100MG./ML.</u>	<u>50MG./ML.</u> <u>100MG./ML.</u>	<u>50MG./ML.</u> <u>100MG./ML.</u>	<u>50MG./ML.</u> <u>100MG./ML.</u>
50MG./ML	50MG./ML	100MG./ML	100MG./ML
N80364 001	N80364 001	N73443 001	N73443 001
N80364 002	N80364 001	MAR 17, 1992	MAR 17, 1992
		N73444 001	N73444 001
		MAR 17, 1992	MAR 17, 1992
		N73445 001	N73445 001
		MAR 17, 1992	MAR 17, 1992

100MG/MLH
N73445 001
MAR 17, 1992

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 3 / JAN'92 - MAR'92

12

METAPROBAMATE

TABLET; ORAL
METAPROBAMATE
/AA/ /PARKE/DAVIS/
/AA/ /AA/

/200MG/
/200MG/
200MG
400MG

/N84744/001/
/N84744/002/
N84744 001
N84744 002

TABLET; ORAL
METHYLDOPA
/AB/ /PARKE/DAVIS/
/AB/ /AB/

/125MG/
/250MG/
/500MG/

/N70331/001/
/APR/15, 1986/
/N70332/001/
/APR/15, 1986/
/N70333/001/
/APR/15, 1986/
N70331 001
APR 15, 1986
N70332 001
APR 15, 1986
N70333 001
APR 15, 1986

MESALAMINE

TABLET, DELAYED RELEASE; ORAL
ASACOL
+ NORMICH EATON

400MG

N19651 001
JAN 31, 1992

3 PARKE DAVIS
3
3

125MG
250MG
500MG

METAPROTERENOL SULFATE

SOLUTION; INHALATION
FROMETA
MURO

> ADD >
> ADD >
> ADD >

5/4

N73340 001
MAR 30, 1992

TABLET; ORAL
METHYLPREDNISOLONE
/BP/ /VITAFINE/
3 VITARINE

/4MG/
4MG

/N87341/001/
N87341 001

SYRUP; ORAL

AA
METAPROTERENOL SULFATE
BIOCRAFT.

10MG/5ML

N72761 001
FEB 27, 1992

METOCLOPRAMIDE HYDROCHLORIDE
CONCENTRATE; ORAL
METOCLOPRAMIDE INTENSOL
ROXANE

EQ 10MG BASE/ML

N72995 001
JAN 30, 1992

TABLET; ORAL

METAPROTERENOL SULFATE
/B*/ /PHARM/BASICS/
/B*/

/10MG/
/20MG/

3 PHARM BASICS

10MG

3

20MG

/N71013/001/
/JAN/25, 1988/
/N71014/001/
/JAN/25, 1988/
N71013 001
JAN 25, 1988
N71014 001
JAN 25, 1988

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL
CETUS BEN VENUE

EQ 10MG BASE/2ML

N72155 001
MAR 30, 1992
N72244 001
MAR 30, 1992

METHYCLOTHIAZIDE

TABLET; ORAL
METHYCLOTHIAZIDE
/B*/ /PHARM/BASICS/
3 PHARM BASICS

/5MG/
5MG

/N88745/001/
/MAR/21, 1985/
N88745 001
MAR 21, 1985

TABLET; ORAL
METOCLOPRAMIDE HCL
/B*/ /INTERPHARM/
3 INTERPHARM

/EQ 10MG BASE/

EQ 10MG BASE

/EQ 10MG BASE/

EQ 10MG BASE

/N71213/001/
/SEP/24, 1986/
N71213 001
SEP 24, 1986
/N70339/001/
/JUL/29, 1985/
N70339 001
JUL 29, 1985

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 3 / JAN'92 - MAR'92

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METOPROLOL SUCCINATE

MINOXIDIL

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL

TOPROL XL
+ HASSLE

+ EQ 50MG TARTRATEM
+ EQ 100MG TARTRATEM
+ EQ 200MG TARTRATEM

N19962 001
JAN 10, 1992
N19962 002
JAN 10, 1992
N19962 003
JAN 10, 1992

MINOXIDIL

TABLET; ORAL

MINOXIDIL

/B*/ /PHARM/BASICS/
@ PHARM BASICS

/2.5MG/
2.5MG

/N71537/001/
DEC 16, 1988
N71537 001
DEC 16, 1988

METRONIDAZOLE

INJECTABLE; INJECTION

METRONIDAZOLE

/LYPHOMED/

/500MG/100ML/
500MG/100ML

/N70071/001/
DEC 03, 1984
N70071 001
DEC 03, 1984

N20098 001
JAN 22, 1992
N20098 002
JAN 22, 1992
N20098 003
JAN 22, 1992

METRONIDAZOLE HYDROCHLORIDE

INJECTABLE; INJECTION

FLASYL I.V.

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

/N18353/001/
N18353 001

N20109 001
FEB 26, 1992

NAFARELIN ACETATE

SPRAY, METERED; NASAL

SYNAREL

SYNTEX

EQ 0.2MG BASE/INHML

NICARDIPINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDENE SR

+ SYNTEX

30MGH

N20005 001

FEB 21, 1992

N20005 002

FEB 21, 1992

N20005 003

FEB 21, 1992

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

MINOCYCLINE HCL

BIOCRAFT

EQ 50MG BASEM

N63011 001

MAR 02, 1992

N63009 001

MAR 02, 1992

EQ 100MG BASEM

INJECTABLE; INJECTION

CARDENE

DUPONT MERCK

2.5MG/MLM

N19734 001

JAN 30, 1992

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL

PROSTEP

+ ELAN

+

11MG/24HRM

22MG/24HRM

N19983 001

JAN 28, 1992

N19983 002

JAN 28, 1992

NIFEDIPINE

capsule; oral

NIFEDIPINE

AB NOVOPHARM

10MG

NITROFURANTOIN

TABLET; ORAL

NITROFURANTOIN

AB/ VITARINE/

AB/

50MG

100MG

50MG

100MG

N80043 001

N80043 002

N80043 001

N80043 002

NITROGLYCERIN

INJECTABLE; INJECTION

NITROGLYCERIN

AB/ LUITPOLD/

AB/

5MG/ML

5MG/ML

N71492 001

N71492 001

N71492 001

MAY 24, 1983

NORTRIPTYLINE HYDROCHLORIDE

capsule; oral

NORTRIPTYLINE HCL

DANBURY

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

EQ 10MG BASEM

EQ 25MG BASEM

EQ 50MG BASEM

EQ 75MG BASEM

N73553 001

MAR 30, 1992

N73554 001

MAR 30, 1992

N73555 001

MAR 30, 1992

N73556 001

MAR 30, 1992

NORTRIPTYLINE HYDROCHLORIDE

capsule; oral

NORTRIPTYLINE

SANDOZ

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

EQ 10MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 75MG BASE

EQ 10MG BASE

EQ 25MG BASE

EQ 50MG BASE

N18013 001

N18013 002

N18013 004

N18013 003

N18013 001

N18013 002

NYSTATIN

TABLET; ORAL

NYSTATIN

AB/ CHELSEA/

AB/

3 CHELSEA

500,000 UNITS

500,000 UNITS

N62402 001

DEC 16, 1982

TABLET; VAGINAL

NYSTATIN

AB/ VITARINE/

AB/

3 VITARINE

100,000 UNITS

100,000 UNITS

N61965 001

OFLOXACIN

INJECTABLE; INJECTION

OFLOXACIN

JOHNSON RW

JOHNSON RW

20MG/MLM

40MG/MLM

N20087 002

MAR 31, 1992

N20087 003

MAR 31, 1992

FLOXIN IN DEXTROSE 5%

OFLOXACIN

JOHNSON RW

JOHNSON RW

FLOXIN IN DEXTROSE 5% IN PLASTIC CONTAINER

OFLOXACIN

JOHNSON RW

JOHNSON RW

400MG/100MLM

400MG/100MLM

N20087 001

MAR 31, 1992

N20087 004

MAR 31, 1992

N20087 005

MAR 31, 1992

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

/AB/ /CHELSEA/

/AB/

/AB/

/AB/

/10MG/

/15MG/

/30MG/

/N71661/001/

/MAR/02, 1988/

/N71662/001/

/MAR/02, 1988/

/N71663/001/

/MAR/02, 1988/

PERPHENAZINE

TABLET; ORAL

PERPHENAZINE

/AB/ /CHELSEA/

/AB/

/10MG/

/N83766/001/

/DEC/23, 1987/

PHENYLBUTAZONE

CAPSULE; ORAL

/AZOLIT/

> DLT >

> DLT >

> ADD >

/RHONE/POULENC/RORER/100MG/

& RHONE POULENC RORER 100MG

/N83766/001/

N87260 001

TABLET; ORAL

OXYBUTYRIN CHLORIDE

/AB/ /PHARM/BASICS/

& PHARM BASICS

/5MG/

5MG

/N70746/001/

MAR 10, 1988

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION

PENICILLIN G POTASSIUM

/AB/ /PARKE/DAVIS/

/AB/

/1,000,000 UNITS/VIAL/

/5,000,000 UNITS/VIAL/

1,000,000 UNITS/VIAL

5,000,000 UNITS/VIAL

/N62003/001/

N62003 001

N62003 002

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

/PEN/AB-VK/

/AB/ /PARKE/DAVIS/

/AB/

/EQ 125MG BASE/5ML/

/EQ 250MG BASE/5ML/

EQ 125MG BASE/5ML

EQ 250MG BASE/5ML

/N62002/001/

N62002 001

N62002 002

TABLET; ORAL

/PEN/AB-VK/

/AB/ /PARKE/DAVIS/

/AB/

/EQ 250MG BASE/

/EQ 500MG BASE/

EQ 250MG BASE

EQ 500MG BASE

/N62001/001/

N62001 001

N62001 002

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL

/PHENYTOIN/SODIUM/

/AB/ /CHELSEA/

& CHELSEA

/100MG/

100MG

/N85394/001/

N85394 001

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS

POWDER FOR RECONSTITUTION; ORAL

CO-LAV

COPLEY

240GM/BOI; 2.98GM/BOI; 6.72GM/BOI;

5.84GM/BOI; 22.72GM/BOI

N73428 001

JAN 28, 1992

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

K-LEASE

ADRIA

8MEQ

N73398 001

JAN 28, 1992

MICRO-K

ROBINS

8MEQ

N18238 001

PROCHLORPERAZINE MALEATE

TABLET; ORAL
/P/ /PROCHLORPERAZINE/MALEATE/
/P/ /DURAMED/
/P/ /EQ/5MG/BASE/
/P/ /EQ/10MG/BASE/
/P/ /EQ/25MG/BASE/
3 DURAMED EQ 5MG BASE
3 EQ 10MG BASE
3 EQ 25MG BASE

/N84484/001/
/JAN/20/1987/
/N84485/001/
/JAN/20/1987/
/N84486/001/
/JAN/20/1987/
N84484 001
JAN 20, 1987
N84485 001
JAN 20, 1987
N84486 001
JAN 20, 1987

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
/P/ /PROPRANOLOL HCL/
/P/ /SUPERPHARM/
/P/ /10MG/
/P/ /20MG/
3 SUPERPHARM 10MG
3 20MG

/N71515/001/
/JUN/08/1988/
/N71516/001/
/JUN/08/1988/
N71515 001
JUN 08, 1988
N71516 001
JUN 08, 1988

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION
/P/ /PYRIDOXINE HCL/
/P/ /LUITPOLD/
3 LUITPOLD 100MG/ML

/N80669/001/
N80669 001

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL
/P/ /PROMETHAZINE HCL/
/P/ /VITARINE/
3 VITARINE 25MG
3 50MG

> DLT > /P/ /25MG/
> DLT > /P/ /50MG/
> ADD > 25MG
> ADD > 50MG

/N85146/001/
/N85146/002/
N85146 001
N85146 002

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
/P/ /PROPOXYPHENE HCL/
/P/ /VITARINE/
3 VITARINE 32MG
3 65MG
3 65MG
3 65MG

> ADD > /P/ /25MG/ML
> ADD > 25MG/ML
> ADD > /P/ /25MG/ML
> ADD > 25MG/ML

N71961 001
AUG 01, 1988
N73465 001
MAR 30, 1992

/N84014/001/
/N83688/001/
/N83870/002/
/N86495/001/
N84014 001
N83688 001
N83870 002
N86495 001

SODIUM THIOSULFATE

INJECTABLE; INJECTION
/P/ /SODIUM THIOSULFATE/
DEPT ARMY 250MG/ML

N20166 001
FEB 14, 1992

SODIUM POLYSTYRENE SULFONATE

SUSPENSION; ORAL, RECTAL
/P/ /SODIUM POLYSTYRENE SULFONATE/
/P/ /ROXANE/
3 ROXANE 15GM/60ML

/N88453/001/
/NOV/17/1983/
N88453 001
NOV 17, 1983

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

SOMOPHYLLIN-CRT

> DLT >	/BC/	/F150MS/	/N87763/001/	/FEB/27, 1985/
> DLT >	/BC/	/50MS/	/N87763/001/	/FEB/27, 1985/
> DLT >	/BC/	/100MS/	/N87194/001/	/FEB/27, 1985/
> DLT >	/BC/	/200MS/	/N88382/001/	/FEB/27, 1985/
> DLT >	/BC/	/250MS/	/N87193/001/	/FEB/27, 1985/
> DLT >	/BC/	/300MS/	/N88383/001/	/FEB/27, 1985/
> ADD >	BC	50MG	/N87763/001/	FEB, 27, 1985
> ADD >	BC	100MG	/N87194/001/	N87194 001
> ADD >	BC	200MG	/N88382/001/	N88382 001
> ADD >	BC	250MG	/N87193/001/	N87193 001
> ADD >	BC	300MG	/N88383/001/	N88383 001
> ADD >		400MG	/N81034/001/	N81034 001

THEO-24
SEARLE

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

THIAMINE HCL

/AP/	/LUITPOLD/	/100MS/ML/	/N80667/001/	/JAN/16, 1989/
/AP/	3 LUITPOLD	100MG/ML	/N80667/001/	/JAN/16, 1989/
/AP/	/PARKE/DAVIS/	/100MS/ML/	/N80770/001/	/JAN/16, 1989/
	3 PARKE DAVIS	100MG/ML	/N80770/001/	/JAN/16, 1989/

TIMOLOL MALEATE

TIMOLOL MALEATE

TABLET; ORAL

/B*/	/PHARM/BASICS/	/5MS/	/N72001/001/	JAN 10, 1989
/B*/		/10MS/	/N72002/001/	JAN 10, 1989
/B*/		/20MS/	/N72003/001/	JAN 10, 1989
3	PHARM BASICS	5MG	/N72001/001/	JAN 10, 1989
3		10MG	/N72002/001/	JAN 10, 1989
3		20MG	/N72003/001/	JAN 10, 1989

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN SULFATE

AP GENSLA

EQ 40MG BASE/ML
N63100 001
JAN 30, 1992

TOLAZAMIDE

TABLET; ORAL

TOLAZAMIDE

/AB/ /INTERPHARM/

/AB/ /250MS/

B* INTERPHARM 250MG

B* 500MG

/B*/ /PHARM/BASICS/

/B*/ /100MS/

/B*/ /250MS/

3 PHARM BASICS 100MG

3 250MG

3 500MG

/N71270/001/

/SEP/23, 1986/

/N71271/001/

/SEP/23, 1986/

/N71270/001/

/SEP/23, 1986/

/N71271/001/

/SEP/23, 1986/

TOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE

/AB/ /PARKE/DAVIS/

/AB/ /50MS/

3 PARKE DAVIS 500MG

TOLMETIN SODIUM

CAPSULE; ORAL

TOLMETIN SODIUM

AB BAKER CUMMINS

AB PUREPAC

EQ 400MG BASE

EQ 400MG BASE

/N86047/001/

/N73392/001/

/JAN 24, 1992/

/N73308/001/

/JAN 24, 1992/

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 3 / JAN '92 - MAR '92

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HCL

/B* / /PHARM/BASICS/

/B* / /50MG /

a PHARM BASICS

50MG

a

100MG

/N76491/001/

/APR/29/1987/

/N76492/001/

/APR/29/1987/

N70491 001

APR 29, 1987

N70492 001

APR 29, 1987

TRICHLORMETHIAZIDE

TABLET; ORAL

TRICHLORMETHIAZIDE

/B* / /VITARINE/

a VITARINE

/4MG /

/N86171/001/

N86171 001

TRIMIPRAMINE MALEATE

CAPSULE; ORAL

SUSPENSION

/B* / /MYETH/AYERST/

/B* /

/B* /

+ MYETH AYERST

/EQ 25MG BASE/

/EQ 50MG BASE/

/EQ 100MG BASE/

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

N16792 001

SEP 15, 1982

N16792 002

SEP 15, 1982

/B* / /TRIMIPRAMINE/MALEATE/

/B* / /PHARM/BASICS/

/B* /

/B* /

/B* /

a PHARM BASICS

EQ 25MG BASE

a

EQ 50MG BASE

a

EQ 100MG BASE

/N71283/001/

DEC 08, 1987

/N71284/001/

DEC 08, 1987

/N71285/001/

DEC 08, 1987

TRISULFAPYRIMIDINES

SUSPENSION; ORAL

/SULFALON/

/AB / /FOREST/PHARMS/

a FOREST PHARMS

/500MG/5ML/

500MG/5ML

/N80100/001/

N80100 001

VECURONIUM BROMIDE

INJECTABLE; INJECTION

NORCURON

ORGANON

20MG/VIAL

N18776 003

JAN 03, 1992

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

VERELAN

+ ELAN

180MG

N19614 003

JAN 09, 1992

TABLET; ORAL

VERAPAMIL HCL

/B* / /CHELSEA/

/B* /

/AB / /PARKE/DAVIS/

/AB /

a PARKE DAVIS

a

/80MG /

/120MG /

/80MG /

/120MG /

80MG

120MG

/N76421/001/

/SEP/17/1986/

/N76422/001/

/SEP/17/1986/

/N76423/001/

/AUG/20/1986/

/N76424/001/

/AUG/20/1986/

/N70340 001

AUG 20, 1986

/N70341 001

AUG 20, 1986

WARFARIN SODIUM

TABLET; ORAL

/WARFARIN/SODIUM/

/B* / /PHARM/BASICS/

/B* /

/B* /

/B* /

/N88719/001/

/JUN/27/1985/

/N88720/001/

/AUG/06/1985/

/N88721/001/

/JUL/02/1985/

WARFARIN SODIUM

TABLET; ORAL
/WARFARIN/SODIUM/
a PHARM BASICS

2MG
2.5MG
5MG

N88719 001
JUN 27, 1985
N88720 001
AUG 06, 1985
N88721 001
JUL 02, 1985

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 3 / JAN'92 - MAR'92

ACETAMINOPHEN

SUPPOSITORY; RECTAL

ACEPHEN

G AND W

> ADD >
> ADD >
> ADD >
> ADD >
> ADD >
> ADD >

120MG

N72218 001

MAR 27, 1992

325MG

N72344 001

MAR 27, 1992

650MG

N72237 001

MAR 27, 1992

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL

MICROCOL

JOHNSON AND JOHNSON 0.5/M

N72292 001

JAN 28, 1992

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL

SILPHEN

SILARX

12.5MG/5ML

N72646 001

FEB 27, 1992

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL

LOPERAMIDE HCL

PERRIGO

1MG/5ML

N73243 001

JAN 21, 1992

SODIUM MONOFLUOROPHOSPHATE

PASTE; DENTAL

EXTRA-STRENGTH AIM

/A/CHESEBROUGH/PONDS/ 1.2%

CHESEBROUGH PONDS 1.2%

N19518/001

JUN/03/1987

N19518 001

JUN 03, 1987

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 3 / JAN '92 - MAR '92

DEXTRAN 75, 6% INVERTED SUGAR 10% IN SODIUM CHLORIDE 0.9%
INJECTABLE; INJECTION
6% GENTRAN 75 AND 10% TRAVERT
TRAVERNOL 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 THE 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: 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: CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR TRADE: NOT ESTABLISHED	FOR CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR PROTEIN REPLACEMENT THERAPY IN CYSTIC FIBROSIS PATIENTS.	GENZYME CORPORATION

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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: 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

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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 VISCOSUS 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.	MERICON INDUSTRIES, 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: 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

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

NO MARCH 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.

NO MARCH 1992 ADDITIONS

ANDA SUITABILITY PETITIONS

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.

DRUG NAME DOSAGE FORM; ROUTE	PETITIONS APPROVED				REASON FOR STATUS
	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	PETITION	
ALBUTEROL SULFATE CAPSULE, EXTENDED RELEASE; ORAL	EQ 4MG BASE	91 P-0348/ CP1	HAMER	NEW DOSAGE FORM	APPROVED MAR 17, 1992
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	5MG/ML (50ML/CONTAINER)	91 P-0387/ CP1	ABBOTT	NEW STRENGTH	APPROVED FEB 18, 1992
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	10MG/ML (100ML/CONTAINER)	91 P-0387/ CP1	ABBOTT	NEW STRENGTH	APPROVED FEB 18, 1992

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

STRENGTH
(CONTAINER SIZE)

20MG/ML
(50ML/VIAL)

DOCKET NUMBER

91 P-0076/
CP1

PETITIONER

ADRIA

PETITION

NEW STRENGTH

REASON FOR
STATUS

DENIED
FEB 19, 1992

DRUG NAME
DOSAGE FORM; ROUTE

ETOPOSIDE
INJECTABLE; INJECTION

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

TREATMENT OF ACUTE ASTHMATIC ATTACKS IN CHILDREN SIX YEARS OF AGE AND OLDER

I-67

I-68

I-69

I-70

I-71

CENTRAL PRECOCIOUS PUBERTY
SHORT TERM TREATMENT OF PATIENTS WITH SYMPTOMS OF GASTROESOPHAGEAL REFUX DISEASE (GERD), AND FOR THE SHORT TERM TREATMENT OF ESOPHAGITIS DUE TO GERD INCLUDING ULCERATIVE DISEASE DIAGNOSED BY ENDOSCOPY
USE IN COMBINATION WITH 5-FLUOROURACIL TO PROLONG SURVIVAL IN THE PALLIATIVE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER
VARICELLA INFECTIONS (CHICKENPOX)

REFERENCES
PATENT USE CODE

OPHTHALMIC USE OF NORFLOXACIN
METHOD OF TREATING INFLAMMATORY INTESTINAL DISEASES
METHOD OF TREATING HYPERCHOLESTEROLEMIA
NASAL ADMINISTRATION OF BUTORPHANOL

U-57

U-58

U-59

U-60

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
>ADD> 18828 001	ACYCLOVIR; ZOVIRAX				I-71	FEB 26, 1995
>ADD> 19090 001	ACYCLOVIR; ZOVIRAX				I-71	FEB 26, 1995
>ADD> 20089 001	ACYCLOVIR; ZOVIRAX				I-71	FEB 26, 1995
>ADD> 20089 002	ACYCLOVIR; ZOVIRAX				I-71	FEB 26, 1995
>ADD> 19001 001	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995	NCE		DEC 28, 1995
>DLT> 19001 001	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995	NCE		DEC 28, 1995
>ADD> 19001 002	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995	NCE		DEC 28, 1995
>DLT> 19001 002	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995	NCE		DEC 28, 1995
>ADD> 19001 003	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995	NCE		DEC 28, 1995
>DLT> 19001 003	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995	NCE		DEC 28, 1995
>DLT> 19548 001	BITOLTEROL MESYLATE; TORNALATE	4336400	JUN 22, 1999	U-5		
>ADD> 19890 001	BUTORPHANOL TARTRATE; STADOL	4138581	FEB 06, 1998	NDF		FEB 19, 1995
>ADD> 19847 001	CIPROFLOXACIN; CIPRO	4464378	AUG 07, 2001	U-60		DEC 12, 1994
		4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
		4957922	SEP 18, 2007			
		4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
		4957922	SEP 18, 2007			
		4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
		4960799	OCT 02, 2007			
>ADD> 20037 001	DICLOFENAC SODIUM; VOLTAREN	4960799	OCT 02, 2007	NDF		MAR 28, 1994
>DLT> 20037 001	DICLOFENAC SODIUM; VOLTAREN	4960799	OCT 02, 2007	NDF		MAR 28, 1994
		5002776	MAR 26, 2008			
		4894240	JAN 16, 2007	NP		DEC 27, 1994
		5002776	MAR 26, 2008			
		4894240	JAN 16, 2007	NP		DEC 27, 1994
		5002776	MAR 26, 2008			
		4894240	JAN 16, 2007	NP		DEC 27, 1994
		5002776	MAR 26, 2008			
		4894240	JAN 16, 2007	NP		DEC 27, 1994
		4283408	AUG 11, 2000	I-69		DEC 10, 1994
		4283408	AUG 11, 2000	I-69		DEC 10, 1994
		4283408	AUG 11, 2000	I-69		DEC 10, 1994
		4264611	APR 28, 1998	NCE		JUL 25, 1996
>ADD> 19834 001	FELODIPINE; PLENDIL	4264611	APR 28, 1998	NCE		JUL 25, 1996
>DLT> 19834 001	FELODIPINE; PLENDIL	4264611	APR 28, 1998	NCE		JUL 25, 1996
>ADD> 19834 002	FELODIPINE; PLENDIL	4264611	APR 28, 1998	NCE		JUL 25, 1996
>DLT> 19834 002	FELODIPINE; PLENDIL	4264611	APR 28, 1998	NCE		JUL 25, 1996

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20068 001	FOSCARNET SODIUM; FOSCAVIR	4771041	JUL 29, 1997			
		4665062	JUL 29, 1997			
		4339445	JUL 29, 1997			
		4215113	JUL 29, 1997			
		4916163	APR 10, 2007			
		4735805	APR 05, 2005			
20051 001	GLYBURIDE; GLYNASE	3507961	APR 21, 1992		NCE	SEP 27, 1996
		3507954	APR 21, 1992			
		3454635	APR 21, 1992			
		3426067	APR 21, 1992			
		4916163	APR 10, 2007			
		4735805	APR 05, 2005			
20051 002	GLYBURIDE; GLYNASE	3507961	APR 21, 1992		NP	MAR 04, 1995
		3507954	APR 21, 1992			
		3454635	APR 21, 1992			
		3426067	APR 21, 1992			
19967 001	HALOBETASOL PROPIONATE; ULTRAVATE				D-1	DEC 31, 1994
19968 001	HALOBETASOL PROPIONATE; ULTRAVATE				D-1	DEC 31, 1994
19046 001	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19046 002	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19046 003	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19046 004	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19174 001	HYDROCHLOROTHIAZIDE; TRANDATE HCT	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19174 002	HYDROCHLOROTHIAZIDE; TRANDATE HCT	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19174 003	HYDROCHLOROTHIAZIDE; TRANDATE HCT	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19174 004	HYDROCHLOROTHIAZIDE; TRANDATE HCT	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19261 001	HYDROXYAMPHETAMINE HYDROBROMIDE; PAREMYD				NC	JAN 30, 1995
19645 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55	NDF	DEC 20, 1994
08107 001	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				NCE	NOV 30, 1994
08107 002	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				1-70	DEC 12, 1994
08107 003	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				1-70	DEC 12, 1994
08107 004	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				1-70	DEC 12, 1994
08107 005	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				1-70	DEC 12, 1994

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
19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4917893	MAR 24, 2004			
		4849228	JUL 18, 2006			
		4728721	MAR 01, 2005			
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004			
20011 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4917893	MAR 24, 2004			
		4849228	JUL 18, 2006			
		4728721	MAR 01, 2005			
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004			
20105 001	LIOTHYRONINE SODIUM; TRIOSTAT				ODE	DEC 31, 1998
20013 001	LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN	4528287	JUL 09, 2002	U-36	NCE	FEB 21, 1997
19651 001	MESALAMINE; ASACOL				NCE	DEC 24, 1992
17659 001	METAPROTERENOL SULFATE; ALUPENT	3998790	APR 08, 1992		NDF	JAN 31, 1995
19962 001	METOPROLOL SUCCINATE; TOPROL XL	3876802	APR 08, 1992		I-67	NOV 14, 1994
19962 002	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992		NE	JAN 10, 1995
19962 003	METOPROLOL SUCCINATE; TOPROL XL	3876802	APR 08, 1992		NE	JAN 10, 1995
20098 001	MIVACURIUM CHLORIDE; MIVACRON	3876802	APR 08, 1992		NE	JAN 10, 1995
20098 002	MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5%	4761418	AUG 02, 2005		NCE	JAN 22, 1997
19583 001	NABUMETONE; RELAFEN	4761418	AUG 02, 2005		NCE	JAN 22, 1997
19583 002	NABUMETONE; RELAFEN	4420639	DEC 13, 2000		NCE	DEC 24, 1996
19886 001	NAFARELIN ACETATE; SYNAREL	4420639	DEC 13, 2000		NCE	DEC 24, 1996
20109 001	NAFARELIN ACETATE; SYNAREL				I-68	FEB 26, 1995
19734 001	NICARDIPINE HYDROCHLORIDE; CARDENE	4234571	NOV 18, 1997		NCE	FEB 13, 1995
20005 001	NICARDIPINE HYDROCHLORIDE; CARDENE SR				I-68	FEB 26, 1995
20005 002	NICARDIPINE HYDROCHLORIDE; CARDENE SR				NDF	JAN 30, 1995
20005 003	NICARDIPINE HYDROCHLORIDE; CARDENE SR				NCE	DEC 21, 1993
19983 001	NICOTINE; PROSTEP				NDF	FEB 21, 1995
19983 002	NICOTINE; PROSTEP				NDF	FEB 21, 1995
		4946853	AUG 07, 2007	U-56	NS	JAN 28, 1995
		4946853	AUG 07, 2007	U-56	NS	JAN 28, 1995

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
20076 001	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
20076 002	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
20076 003	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
20165 001	NICOTINE; NICODERM	5004610	APR 02, 2008			
		4144317	SEP 09, 1992		NDF	NOV 07, 1994
20165 002	NICOTINE; NICODERM	5004610	APR 02, 2008			
		4144317	SEP 09, 1992		NDF	NOV 07, 1994
20165 003	NICOTINE; NICODERM	5004610	APR 02, 2008			
		4144317	SEP 09, 1992		NDF	NOV 07, 1994
		4551456	NOV 05, 2002	U-57	NDF	NOV 07, 1994
19757 001	NORFLOXACIN; CHIBROXIN	4382892	MAY 10, 2000			
>ADD>		4382892	MAY 10, 2000			
>ADD>		4382892	MAY 10, 2000			
>ADD>		4382892	MAY 10, 2000			
>ADD>		4382892	MAY 10, 2000			
19715 001	OLSAZINE SODIUM; DIPENTUM	4559330	AUG 04, 2004	U-58	NCE	JUL 31, 1995
19775 001	PRAZOSIN HYDROCHLORIDE; MINIPRESS XL				NDF	JAN 29, 1995
19157 001	PREDNISOLONE SODIUM PHOSPHATE; PEDIAPRED				NDF	JAN 29, 1995
19766 001	SIMVASTATIN; ZOCOR	4448774	MAY 15, 2001			
19766 002	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
19766 003	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
19766 004	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
20166 001	SODIUM THIOSULFATE; SODIUM THIOSULFATE				NCE	DEC 23, 1997
20043 003	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	MAR 08, 2005	U-36	NCE	FEB 14, 1997
20043 004	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	MAR 08, 2005	U-36	NCE	JAN 30, 1997
19614 003	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006	U-3	NDF	JAN 30, 1997
19655 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005			MAY 29, 1993
		4833130	FEB 09, 2005		1-47	MAY 02, 1993
		4828838	FEB 09, 2005		ODE	MAR 19, 1994
		4724232	FEB 09, 2005		NCE	MAR 19, 1992
		4837208	FEB 09, 2005			
		4833130	FEB 09, 2005		ODE	MAR 19, 1994
		4818538	FEB 09, 2005		1-47	MAY 02, 1993
19910 001	ZIDOVUDINE; RETROVIR	4724232	FEB 09, 2005		NCE	MAR 19, 1992

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
19951 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005			
		4833130	FEB 09, 2005		NCE	MAR 19, 1992
		4818538	FEB 09, 2005			
		4724232	FEB 09, 2005		ODE	MAR 19, 1994

RM301.45 .A66 1992 Mar Suppl

Approved drug products with
therapeutic equivalence

C:355661 M:174736 O:12937927

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