

CUMULATIVE
SUPPLEMENT 10

JAN'92-OCT'92

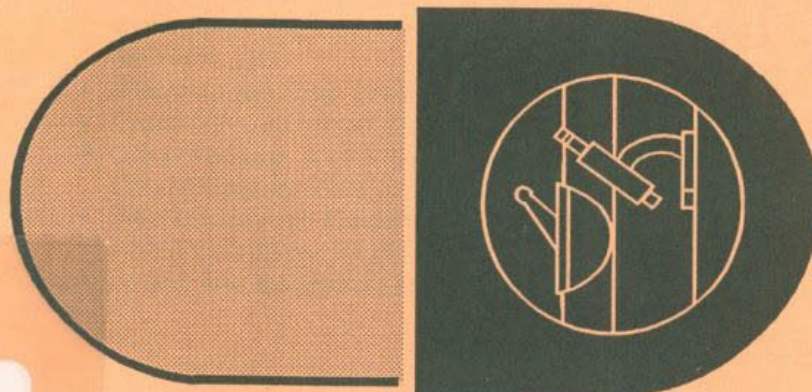
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APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION



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

Prepared By
Division of Drug Information Resources
Office of Management
Center for Drug Evaluation and Research, FDA

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New 13th Edition



APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

**13TH EDITION
1993**

CONTENTS

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Approved drug products with
therapeutic equivalence

C:355661 M:174736 O:12937927

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

12TH EDITION

Cumulative Supplement 10

October 1992

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION

CUMULATIVE SUPPLEMENT 10

OCTOBER 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 Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 Center for Biologics Evaluation and Research 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)
Tranlylcypromine 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)

MERCK SHARP AND DOHME RESEARCH LABS
DIV MERCK AND CO INC
(MSD)

MERCK RESEARCH LABORATORIES
DIV MERCK AND CO INC
(MERCK)

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

PROCTOR & GAMBLE PHARMACEUTICALS INC
(P&G)

OFFICE SURGEON GENERAL DEPT ARMY
(DEPT ARMY)

OFFICE SURGEON GENERAL DEPT ARMY
(US ARMY)

RECKITT AND COLMAN PHARMACEUTICALS INC
(R & C)

RECKITT AND COLMAN PHARMACEUTICALS INC
(RECKITT AND COLMAN)

SCHWARZ PHARMACEUTICALS INC
(SCHWARZ)

SCHWARZ PHARMACEUTICALS INC
(SCHWARZ PHARMA)

SOLOPAK LABORATORIES
(SOLOPAK)

SMITH AND NEPHEW SOLOPAK
DIVISION OF SMITH AND NEPHEW
(SMITH NEPHEW SOLOPAK)

VICKS HEALTH CARE DIV RICHARDSON VICKS INC
(VICKS HLTH CARE)

VICKS HEALTH CARE DIV RICHARDSON VICKS INC
(VICKS HEALTH CARE)

WHITBY PHARMACEUTICALS INC
(WHITBY PHARMS)

WHITBY PHARMACEUTICALS INC
(WHITBY)

US CHEMICAL MARKETING GROUP INC
(US CHEM MKTG)

US CHEMICAL MARKETING GROUP INC
(US CHEM)

1.5 USP MONOGRAPH TITLE ADDITIONS OR CHANGES

The U.S. Pharmacopeia (USP) periodically makes additions to or changes in monograph titles. Some of these additions or changes may affect dosage form terms listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (ADP). Instead of making the change in each affected product, the Cumulative Supplement (CS) will list applicable monograph title and dosage form additions or changes in this section. These will appear as soon as the modified USP monograph title is official. It is possible for these additions or changes to be listed in this section before all applicant holders have made labeling modifications.

The monograph title additions or changes shown below will remain in this section in each succeeding supplement of this edition. Once the next edition of the ADP is published, the products affected by the title additions or changes will be displayed with the new dosage form in the appropriate drug list. As notification to the reader, these monograph title additions or changes will also be listed in a special section of the ADP.

USP MONOGRAPH TITLE ADDITIONS OR CHANGES

FORMER USP MONOGRAPH TITLE
(FORMER ADP DOSAGE FORM; ROUTE)

NEW USP MONOGRAPH TITLE
(NEW ADP DOSAGE FORM; ROUTE)

LACTULOSE SYRUP
(SYRUP; ORAL)

LACTULOSE SOLUTION
(SOLUTION; ORAL)

LACTULOSE SYRUP
(SYRUP; ORAL, RECTAL)

LACTULOSE SOLUTION
(SOLUTION; ORAL, RECTAL)

NONE
(SYRUP; ORAL)

METOCLOPRAMIDE ORAL
SOLUTION
(SOLUTION; ORAL)

1.6 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	9476	9501
SINGLE SOURCE	2187 (22.8%)	2222 (23.4%)	2227 (23.5%)	2227 (23.4%)
MULTISOURCE	7397 (77.2%)	7251 (76.6%)	7249 (76.5%)	7274 (76.6%)
THERAPEUTICALLY EQUIVALENT	6580 (68.7%)	6510 (68.7%)	6494 (68.5%)	6518 (68.6%)
NOT THERAPEUTICALLY EQUIVALENT	664 (6.9%)	592 (6.3%)	595 (6.3%)	590 (6.2%)
EXCEPTIONS ¹	153 (1.6%)	149 (1.6%)	160 (1.7%)	166 (1.8%)
NEW MOLECULAR ENTITIES APPROVED	--	4	2	8
NUMBER OF APPLICANTS	430	437	455	471

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



1
 PRESCRIPTION DRUG PRODUCT LIST
 12TH EDITION
 CUMULATIVE SUPPLEMENT NUMBER 10 / JAN'92 - OCT'92

ACETAMINOPHEN; BUTALBITAL

TABLET; ORAL

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

BUTAPAP
 MIKART

325MG;50MG

N89987 001

650MG;50MG

OCT 26, 1992
 N89988 001

650MG;50MG

OCT 26, 1992
 N89944 001

SEDAPAP
 + MAYRAND

650MG;50MG

OCT 17, 1985

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL
 FIORICET W/ CODEINE
 + SANDOZ

N20232 001
 JUL 30, 1992

325MG;50MG;40MG;30MG

ACETAMINOPHEN; CODEINE PHOSPHATE

ELIXIR; ORAL

> ADD >
 > ADD >

ACETAMINOPHEN AND CODEINE PHOSPHATE
 MIKART

N89450 001
 OCT 27, 1992

120MG;5ML;12MG;5ML

ACETAMINOPHEN AND CODEINE PHOSPHATE
 PHARM BASICS

120MG;5ML;12MG;5ML

N87006 001

120MG;5ML;12MG;5ML

N87006 001

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

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

EON LABS

300MG;15MG

N87433 001

300MG;30MG

N85917 001

300MG;60MG

N87423 001

300MG;30MG

N81250 001

300MG;60MG

JUL 16, 1992

300MG;15MG

N81249 001

300MG;30MG

JUL 16, 1992

300MG;30MG

N85992 001

300MG;15MG

N85218 002

300MG;15MG

N87433 001

300MG;30MG

N85917 001

300MG;60MG

N87423 001

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

AA

ACETAMINOPHEN W/ CODEINE PHOSPHATE
 CHELSEA

AA

300MG;15MG

AA

300MG;30MG

AA

300MG;60MG

AA

300MG;15MG

3

300MG;30MG

3

300MG;60MG

AA

300MG;15MG

AA

300MG;30MG

AA

300MG;60MG

AA

300MG;15MG

AA

300MG;30MG

AA

300MG;60MG

ACETAMINOPHEN; HYDROCODONE BITARTRATE

ELIXIR; ORAL

> ADD >
 > ADD >

HYDROCODONE BITARTRATE AND ACETAMINOPHEN
 MIKART

AA

500MG;15ML;5MG;15ML

AA

500MG;15ML;5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

AA

500MG;15ML;7.5MG;15ML

ALLOPURINOL

TABLET; ORAL
ALLOPURINOL

/AB/ /BOLAR/ /100MG/ /N18241/001/ /NOV/16, 1984/

3 BOLAR

100MG

AMIKACIN SULFATE

INJECTABLE; INJECTION

AMIKACIN

AP ELKINS SINN

EQ 50MG BASE/MLM

N63274 001

EQ 250MG BASE/MLM

MAY 18, 1992

EQ 250MG BASE/MLM

MAY 18, 1992

AMIKIN

AP BRISTOL

EQ 50MG BASE/ML

N50495 001

EQ 50MG BASE/ML

N62562 001

EQ 250MG BASE/ML

SEP 20, 1984

EQ 250MG BASE/ML

N50495 002

EQ 250MG BASE/ML

N62562 002

SEP 20, 1984

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

AMINOACIDS/4.25%W/DEXTROSE/25%IN/PLASTIC/CONTAINER/

ABBOTT

4.25%:25GM/100ML

N19119 001

4.25%:25GM/100ML

OCT 11, 1984

3 ABBOTT

AMINO ACIDS; MAGNESIUM ACETATE; POTASSIUM ACETATE; SODIUM CHLORIDE

INJECTABLE; INJECTION

AMINOACIDS/3.5%N/

ABBOTT

3.5%:21MG/100ML;128MG/100ML;

234MG/100ML

N17789 001

3.5%:21MG/100ML;128MG/100ML;

234MG/100ML

N17789 001

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE

WARNER/CHILCOTT

/AB/ /10MG/ /N83939/001/

/AB/ /25MG/ /N83937/001/

/AB/ /50MG/ /N83938/002/

/AB/ /75MG/ /N84957/001/

/AB/ /100MG/ /N85093/001/

/AB/ /150MG/ /N86295/001/

3 WARNER CHILCOTT

10MG

25MG

50MG

75MG

100MG

150MG

AMITRIPTYLINE HCL

/BP/ /10MG/ /N88697/001/

/BP/ /25MG/ /N88698/001/

/BP/ /50MG/ /N88699/001/

/BP/ /75MG/ /N88700/001/

/BP/ /100MG/ /N88701/001/

/BP/ /150MG/ /N88702/001/

3 PAR

10MG

25MG

50MG

75MG

100MG

150MG

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL
/B*/ /PHARM/BASICS/
/EQ/12.5MG/BASE;5MG/
/EQ/25MG/BASE;10MG/
EQ 12.5MG BASE;5MG
EQ 25MG BASE;10MG

2 PHARM BASICS
2

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

CAPSULE; ORAL

POLYPOX
BRISTOL MYERS
AB
AB

250MG
500MG

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

/UTIMOX/
/AB/
/AB/
/PARKE/DAVIS/
2 PARKE DAVIS
2

/450MG/
/500MG/
250MG
500MG

/N62107/001/
/N62107/002/
N62107 001
N62107 002

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL
/3/CHLSEAL/
/50MG;4MG/
EQ 10MG BASEM
EQ 2.5MG BASEM
EQ 5MG BASEM

/N71558/001/
/MAR/02,1987/
N19787 003
JUL 31, 1992
N19787 001
JUL 31, 1992
N19787 002
JUL 31, 1992

POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN

/AB/
/AB/
/CLONMEL/
BX
BX
CLONMEL
CLONMEL
125MG/5ML
250MG/5ML

/N62927/001/
/NOV/25,1988/
/N62927/002/
/NOV/25,1988/
N62927 001
NOV 25, 1988
N62927 002
NOV 25, 1988

AMLODIPINE BESYLATE

TABLET; ORAL

NORVASC
+ PFIZER
EQ 10MG BASEM
EQ 2.5MG BASEM
EQ 5MG BASEM

N19787 003
JUL 31, 1992
N19787 001
JUL 31, 1992
N19787 002
JUL 31, 1992

/UTIMOX/
/AB/
/AB/
/PARKE/DAVIS/
2 PARKE DAVIS
2

/N62127/001/
/N62127/002/
N62127 001
N62127 002

AMOXAPINE

TABLET; ORAL

AMOXAPINE
DANBURY
AB
AB
AB
AB

25MG
50MG
100MG
150MG

INJECTABLE; INJECTION

AMPHOTERICIN B
AP
PHARMA TEK

50MG/VIAL

N63206 001
APR 29, 1992

N72688 001
AUG 28, 1992
N72689 001
AUG 28, 1992
N72690 001
AUG 28, 1992
N72691 001
AUG 28, 1992

ATENOLOL

TABLET; ORAL
ATENOLOL
 AB APOTHECON

50MG

N73317 001

100MG

MAR 20, 1992

AB GENEVA

25MG

MAR 20, 1992

AB IPR

25MG

MAY 01, 1992

AB LEDERLE

25MG

JUL 31, 1992

AB MYLAN

50MG

APR 28, 1992

AB SCHIAPPARELLI SEARLE

100MG

JAN 24, 1992

AB TENORETIC

50MG

OCT 30, 1992

AB ICI

25MG

APR 09, 1990

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

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL
ATENOLOL AND CHLORTHALIDONE
 AB DANBURY

50MG; 25MG

N73665 001

100MG; 25MG

JUL 02, 1992

AB TENORETIC 100

100MG; 25MG

JUL 02, 1992

AB + ICI

100MG; 25MG

JUN 08, 1984

AB /STUART/

100MG; 25MG

JUN 08, 1984

AB TENORETIC 50

50MG; 25MG

JUN 08, 1984

AB /STUART/

50MG; 25MG

JUN 08, 1984

ATROPINE SULFATE

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

/AEROSOL; METERED; INHALATION/
 /ATROPINE SULFATE/
 /US ARMY/

/N20056/001/
 /SEP/19/1990/

> ADD >
 > ADD >

EQ 0.36MG BASE/INH

N20056 001
 SEP 19, 1990

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

SOLUTION; ORAL

/LOMANATE/
 /BARRE/

/N85746/001/
 /SEP/19/1990/

TABLET; ORAL

/CHELSEA/
 @ CHELSEA

/N85876/001/
 /SEP/19/1990/

TABLET; ORAL

/CHELSEA/
 @ CHELSEA

/N86173 001/
 /SEP/19/1990/

DIPHENOXYLATE HCL W/ ATROPINE SULFATE

/@ EON LABS

/N86173/001/
 /SEP/19/1990/

/@ VITARINE/

/@ VITARINE/

/N86173/001/
 /SEP/19/1990/

/AZITHROMYCIN/

/CAPSULE; ORAL/

/ZITHROMAX/

/@ PFIZER/

/N50670/001/
 /NOV/01/1991/

AZITHROMYCIN DIHYDRATE

CAPSULE; ORAL

ZITHROMAX

+ PFIZER

EQ 250MG BASE

N50670 001
 NOV 01, 1991

BACLOFEN

INJECTABLE; INJECTION

LIORESAL

MEDTRONIC

0.5MG/ML

N20075 001
 JUN 17, 1992

2MG/ML

N20075 002
 JUN 17, 1992

BACLOFEN

TABLET; ORAL

BACLOFEN
BIOCRAFT

AB

10MG

N73043 001
FEB 27, 1992

AB

20MG

N73044 001
FEB 27, 1992

3 EON LABS

10MG

N71901 001
APR 13, 1988

3

20MG

N71902 001
APR 13, 1988

/B* / PHARM/BASIC/

/10MG/

/N71903/001/
/MAY/06,1988/

/B* /

/20MG/

/N71904/001/
/MAY/06,1988/

3 PHARM BASICS

10MG

N71260 001
MAY 06, 1988

3

20MG

N71261 001
MAY 06, 1988

/3/ VITAFINE/

/10MG/

/N71905/001/
/APR/13,1988/

/3/

/20MG/

/N71906/001/
/APR/13,1988/BENAZEPRIL HYDROCHLORIDE; HYDROCHLOROTHAZIDETABLET; ORAL
LOTENSIN HCT
+ CIBA

20MG;25MG

N20033 003
MAY 19, 1992

5MG;6.25MG

N20033 001
MAY 19, 1992

10MG;12.5MG

N20033 002
MAY 19, 1992

20MG;12.5MG

N20033 004
MAY 19, 1992BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE
MUTUAL PHARM

AA

1MG

N81264 001
JAN 23, 1992

AA

2MG

N81265 001
JAN 23, 1992BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE
/B* / PHARM/BASIC/

/0.5MG/

/N89211/001/
/JUN/14,1988/

/B* /

/1MG/

/N89212/001/
/JUN/14,1988/

/B* /

/2MG/

/N89213/001/
/JUN/14,1988/

3 PHARM BASICS

0.5MG

N89211 001
JUN 14, 1988

3

1MG

N89212 001
JUN 14, 1988

3

2MG

N89213 001
JUN 14, 1988BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

BETAMETHASONE DIPROPIONATE
/AB/ /CLAY/PARK/

/EQ 0.05% BASE/

/N72535/001/
/JAN/31,1990/

B*

CLAY PARK

EQ 0.05% BASE

N72536 001
JAN 31, 1990

AB

TARO

EQ 0.05% BASE

N73552 001
APR 30, 1992

OINTMENT; TOPICAL

BETAMETHASONE DIPROPIONATE
/AB/ /CLAY/PARK/

/EQ 0.05% BASE/

/N72535/001/
/JAN/31,1990/

B*

CLAY PARK

EQ 0.05% BASE

N72526 001
JAN 31, 1990BETAMETHASONE VALERATE

CREAM; TOPICAL

BETAMETHASONE VALERATE
/AB/ /PHARMAFAIR/

/EQ 0.1% BASE/

/N70485/001/
/MAY/29,1987/

3 PHARMAFAIR

EQ 0.1% BASE

N70485 001
MAY 29, 1987

BUTABARBITAL SODIUM

TABLET; ORAL
SODIUM BUTABARBITAL

AP /AA/ /15MG/ /N85418/001/ /15MG/ /N85418/001/ /30MG/ /N85432/001/ /30MG/ /N85432/001/

N20002 001
APR 17, 1992

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

RINGER'S IN PLASTIC CONTAINER

AP MCGAW 33MG/100ML; 30MG/100ML; 860MG/100ML

BUTORPHANOL TARTRATE

SPRAY, METERED; NASAL
STADOL

+ BRISTOL MYERS SQUIBB 1MG/INH

/1MG/INH/

N19890 001
DEC 12, 1991
/N19890/001/ /DEC 12, 1991/

/N70300/001/ /JAN 02, 1987/ /N70300/001/ /MAY 15, 1986/ /N70300/001/ MAY 15, 1986
N70429 001
JAN 02, 1987

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

DELFLX W/ DEXTROSE 1.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER

FRESENIUS 18.4MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML

N20171 001
AUG 19, 1992

DELFLX W/ DEXTROSE 2.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER

FRESENIUS 18.4MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML

N20171 002
AUG 19, 1992

DELFLX W/ DEXTROSE 4.25% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER

FRESENIUS 18.4MG/100ML; 4.25GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML

N20171 003
AUG 19, 1992

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% IN RINGER'S IN PLASTIC CONTAINER

AP MCGAW 33MG/100ML; 5GM/100ML; 30MG/100ML; 860MG/100ML N20000 001
APR 17, 1992

/N89566/001/ /AUG 30, 1988/ /N89566/001/

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

/AB/ /PARKE/DAVIS/ /200MG/

/B* /PHARM/BASICS/ /200MG/

@ PHARM BASICS 200MG

@ WARNER CHILCOTT 200MG

/N70300/001/ /JAN 02, 1987/ /N70300/001/ /MAY 15, 1986/ /N70300/001/ MAY 15, 1986
N70429 001
JAN 02, 1987

TABLET, CHEMABLE; ORAL

EPITOL

AB LENNON 100MG

N73524 001
JUL 29, 1992

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA

AB LENNON 10MG; 100MG

N73618 001
AUG 28, 1992

AB 25MG; 100MG

N73589 001
AUG 28, 1992

AB 25MG; 250MG

N73607 001
AUG 28, 1992

SINEMET

AB MSD 10MG; 100MG

AB 25MG; 100MG

AB + 25MG; 250MG

N17555 001
N17555 003
N17555 002

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

/B* /EON/LABS/ /350MG/

@ EON LABS 350MG

/N89566/001/ /AUG 30, 1988/ /N89566/001/

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN'92 - OCT'92

CEFADROXIL/CEFADROXIL HEMIHYDRATECEFPROZIL

CAPSULE; ORAL
CEFADROXIL
 ZENITH

AB EQ 500MG BASE
 /2/
 N62766 001
 MAR 03, 1987
 /N62766/001/
 /MAR/03, 1987/

POWDER FOR RECONSTITUTION; ORAL
 CEFZIL
 + BRISTOL MYERS SQUIBB 250MG/5ML
 /250MG/5ML/

N50665 002
 DEC 23, 1991
 /N50665/002/
 /DEC/23, 1991/

TABLET; ORAL
CEFADROXIL
 ZENITH

AB EQ 1GM BASE
 /2/
 N62774 001
 APR 08, 1987
 /N62774/001/
 /APR/08, 1987/

TABLET; ORAL
 CEFZIL
 + BRISTOL MYERS SQUIBB 500MG
 /500MG/

N50664 002
 DEC 23, 1991
 /N50664/002/
 /DEC/23, 1991/

CEFTAZIDIME PROXETIL

GRANULE, FOR RECONSTITUTION; ORAL

AB BANAN
 SANKYO

AB EQ 50MG BASE/5MLM

AB EQ 100MG BASE/5MLM

AB VANTIN
 UPJOHN

AB EQ 50MG BASE/5MLM

AB EQ 100MG BASE/5MLM

N50688 002
 AUG 07, 1992
 N50688 001
 AUG 07, 1992
 N50675 001
 AUG 07, 1992
 N50675 002
 AUG 07, 1992

INJECTABLE; INJECTION
 /CEPTAZ/
 /GLAXO/

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

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

TABLET; ORAL
BANAN
 SANKYO

AB EQ 100MG BASEM

AB EQ 200MG BASEM

AB VANTIN
 UPJOHN

AB EQ 100MG BASEM

AB EQ 200MG BASEM

N50687 001
 AUG 07, 1992
 N50687 002
 AUG 07, 1992
 N50674 001
 AUG 07, 1992
 N50674 002
 AUG 07, 1992

INJECTABLE; INJECTION
CEPTAZ
 GLAXO

1GM/VIAL

2GM/VIAL

10GM/VIAL

500MG/VIAL

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

AB PENTACEF
 SMITHKLINE BEECHAM

1GM/VIALM

2GM/VIALM

10GM/VIALM

6GM/VIALM

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

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN'92 - OCT'92

CEFTRIAXONE SODIUMINJECTABLE; INJECTIONROCEPHIN
/ROCHE/

a ROCHE

/EQ/250MG BASE/VIAL/

EQ 250MG BASE/VIAL

/EQ/500MG BASE/VIAL/

EQ 500MG BASE/VIAL

/EQ/1GM BASE/VIAL/

EQ 1GM BASE/VIAL

/N62510/001/
/MAR/12, 1985//N62510/002/
/MAR/12, 1985//N62510/003/
/MAR/12, 1985//N62510/004/
/MAR/12, 1985//N62510/005/
/MAR/12, 1985//N62510/006/
/MAR/12, 1985/CAPSULE; ORALCHLORDIAZEPOXIDE HCL

/PARKER/DAVIS/

a PARKER DAVIS

a

a

/VITARINE/

/WEST/WARD/

a WEST WARD

a

a

/AB/

/AB/

/AB/

/AB/

/AB/

/AB/

/AB/

/AB/

/AB/

/5MG/

/10MG/

/25MG/

/5MG/

/10MG/

/25MG/

/5MG/

/10MG/

/25MG/

/5MG/

/10MG/

/25MG/

/N85163/001/

/N85163/002/

/N85163/003/

/N85163/004/

/N85163/005/

/N85163/006/

/N85163/007/

/N85163/008/

/N85163/009/

/N85163/010/

/N85163/011/

/N85163/012/

/N85163/013/

/N85163/014/

INJECTABLE; INJECTION

CEFADYL

/BRISTOL/

/ELKINS/SINN/

a ELKINS SINN

> DLT > /AP/

> ADD >

> DLT > /AP/

> DLT >

> DLT > /AP/

> DLT >

> DLT > /AP/

> DLT >

> DLT > /AP/

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/N50446/004/

/N50446/005/

/N50446/006/

/N50446/007/

/N50446/008/

/N50446/009/

/N50446/010/

/N50446/011/

/N50446/012/

/N50446/013/

/N50446/014/

/N50446/015/

/N50446/016/

/N50446/017/

/N50446/018/

/N50446/019/

/N50446/020/

/EQ/20GM BASE/VIAL/

EQ 20GM BASE/VIAL

/EQ/500MG BASE/VIAL/

EQ 500MG BASE/VIAL

/EQ/1GM BASE/VIAL/

EQ 1GM BASE/VIAL

/EQ/2GM BASE/VIAL/

EQ 2GM BASE/VIAL

/EQ/20GM BASE/VIAL/

EQ 20GM BASE/VIAL

CHLOROQUINE PHOSPHATE

TABLET; ORAL

CHLOROQUINE PHOSPHATE

/WEST/WARD/

a WEST WARD

/EQ/150MG BASE/

EQ 150MG BASE

/N83082/001/

/N83082/002/

/N83082/003/

/N83082/004/

/N83082/005/

/N83082/006/

/N83082/007/

/N83082/008/

/N83082/009/

/N83082/010/

/N83082/011/

/N83082/012/

/N83082/013/

/N83082/014/

/N83082/015/

/N83082/016/

/N83082/017/

/N83082/018/

/N83082/019/

/N83082/020/

CHLOROTHIAZIDE

TABLET; ORAL

CHLOROTHIAZIDE

a EON LABS

/a/VITARINE/

250MG

/250MG/

/N85485/001/

/N85485/002/

/N85485/003/

/N85485/004/

/N85485/005/

/N85485/006/

/N85485/007/

/N85485/008/

/N85485/009/

/N85485/010/

/N85485/011/

/N85485/012/

/N85485/013/

/N85485/014/

/N85485/015/

/N85485/016/

/N85485/017/

/N85485/018/

/N85485/019/

/N85485/020/

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

/PIONEER/PHARMS/

a PIONEER PHARMS

4MG

/N88556/001/

/N88556/002/

/N88556/003/

/N88556/004/

/N88556/005/

/N88556/006/

/N88556/007/

/N88556/008/

/N88556/009/

/N88556/010/

/N88556/011/

/N88556/012/

/N88556/013/

/N88556/014/

/N88556/015/

/N88556/016/

/N88556/017/

/N88556/018/

CHLORPROPAMIDE

TABLET; ORAL

CHLORPROPAMIDE

a EON LABS

250MG

/N84669/001/

/N84669/002/

/N84669/003/

/N84669/004/

/N84669/005/

/N84669/006/

/N84669/007/

/N84669/008/

/N84669/009/

CHLORDIAZEPOXIDE HYDROCHLORIDECAPSULE; ORALCHLORDIAZEPOXIDE HCL

a EON LABS

a

a

5MG

10MG

25MG

/N84919/001/

/N84919/002/

/N84919/003/

/N84919/004/

/N84919/005/

/N84919/006/

/N84919/007/

/N84919/008/

/N84919/009/

/N84919/010/

/N84919/011/

/N84919/012/

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN'92 - OCT'92

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE/TABLET; EXTENDED/RELEASE; /ORAL/
/TAVIST/

/EQ/1MG/BASE; 75MG/

/N16412/001/
/DEC/15, 1982/

a SANDOZ

EQ 1MG BASE; 75MG

N18298 001
DEC 15, 1982CLINDAMYCIN HYDROCHLORIDECAPSULE; ORAL
CLINDAMYCIN HCL

a EON LABS

EQ 75MG BASE

N62910 001
JUL 05, 1988

a

EQ 150MG BASE

N62910 002
JUL 05, 1988

/a/VITAFRINE/

/EQ/75MG/BASE/

/N62910/001/
/JUL/05, 1988/

/a/

/EQ/150MG/BASE/

/N62910/002/
/JUL/05, 1988/CLINDAMYCIN PHOSPHATE

CREAM; VAGINAL

CLEOCIN

+ UPJOHN

EQ 2% BASEM

N50680 001
AUG 11, 1992

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

GENSIA

EQ 150MG BASE/MLM

N63282 001
MAY 29, 1992

SOLUTION; TOPICAL

CLINDA-BERM

PADDOCK

EQ 1% BASEM

N63329 001
SEP 30, 1992CLIOQUINOL; HYDROCORTISONE/CREAM; TOPICAL/
/VIOFORM-HYDROCORTISONE/
/CIBA//N16412/002/
/N16412/001/CLIOQUINOL; HYDROCORTISONE/OINTMENT; TOPICAL/
/VIOFORM-HYDROCORTISONE/
/a/CIBA//33.0.5%/
/33.1%/
/N16412/004/
/N16412/003/CLIOQUINOL; NYSTATIN/OINTMENT; TOPICAL/
/NYSTATIN/
/MILES//10MG/GM;/
/100.000 UNITS/GM/
/N50235/001/

a MILES

10MG/GM;
100,000 UNITS/GM

N50235 001

CLOFIBRATE

CAPSULE; ORAL

CLOFIBRATE

PHARMACAPS

500MG

N73396 001
MAR 20, 1992CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

/a/ /PHARM/BASICS/

/3.75MG/

/N71243/001/
/MAY/20, 1987/

/a/

/7.5MG/

/N71243/001/
/MAY/20, 1987/

/a/

/15MG/

/N71244/001/
/MAY/20, 1987/

a

a PHARM BASICS

3.75MG

N71242 001
MAY 20, 1987

a

7.5MG

N71243 001
MAY 20, 1987

a

15MG

N71244 001
MAY 20, 1987

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL

/AB/ CLORAZEPATE DIPOTASSIUM
/WARNER/CHILCOTT/ /3.75MG/

/AB/ /7.5MG/

/AB/ /15MG/

3 WARNER CHILCOTT 3.75MG

3 7.5MG

3 15MG

/N71828/001/
MAR/03, 1988

/N71829/001/
MAR/03, 1988

/N71830/001/
MAR/03, 1988

/N71831/001/
MAR/03, 1988

/N71832/001/
MAR/03, 1988

/N71833/001/
MAR/03, 1988

/N71834/001/
MAR/03, 1988

/N71835/001/
MAR/03, 1988

/N71836/001/
MAR/03, 1988

/AB/ CYANOCOBALAMIN
/LUITPOLD/ 3 LUITPOLD

/AT/ CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

/AT/ CYCLOPENTOLATE HCL

3 SOLA BARNES HIND

12/

12/

DACARBAZINE

CLOTIMAZOLE

CREAM; TOPICAL

LOTIMIN

/AT/ LOTIMIN

BX + SCHERING

MYCELEX

/AT/ MYCELEX

BX MILES

12/

12/

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE;

TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

/HISTAFED/

/CENTI/

/10MG/5ML; 30MG/5ML;

/1.25MG/5ML;

10MG/5ML; 30MG/5ML;

1.25MG/5ML

10MG/5ML; 30MG/5ML;

1.25MG/5ML

10MG/5ML; 30MG/5ML;

1.25MG/5ML

10MG/5ML; 30MG/5ML;

1.25MG/5ML

10MG/5ML; 30MG/5ML;

1.25MG/5ML

10MG/5ML; 30MG/5ML;

1.25MG/5ML

10MG/5ML; 30MG/5ML;

1.25MG/5ML

10MG/5ML; 30MG/5ML;

1.25MG/5ML

10MG/5ML; 30MG/5ML;

1.25MG/5ML

10MG/5ML; 30MG/5ML;

1.25MG/5ML

10MG/5ML; 30MG/5ML;

1.25MG/5ML

10MG/5ML; 30MG/5ML;

1.25MG/5ML

10MG/5ML; 30MG/5ML;

1.25MG/5ML

CYANOCOBALAMIN

INJECTABLE; INJECTION

/AB/ CYANOCOBALAMIN

/LUITPOLD/ 3 LUITPOLD

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/N80668/001/
N80668 001

/N84863/001/
N84863 001

/N70962/001/
AUG 28, 1986

/N70990/001/
AUG 28, 1986

/N70990/001/
AUG 28, 1986

/N70990/001/
AUG 28, 1986

/N70990/001/
AUG 28, 1986

/N70990/001/
AUG 28, 1986

/N17575/001/
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N17575 001

/N17575/001/
N17575 001

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL

/AB/ CLORAZEPATE DIPOTASSIUM
/WARNER/CHILCOTT/ /3.75MG/

/AB/ /7.5MG/

/AB/ /15MG/

3 WARNER CHILCOTT 3.75MG

3 7.5MG

3 15MG

/N71828/001/
MAR/03, 1988

/N71829/001/
MAR/03, 1988

/N71830/001/
MAR/03, 1988

/N71831/001/
MAR/03, 1988

/N71832/001/
MAR/03, 1988

/N71833/001/
MAR/03, 1988

/N71834/001/
MAR/03, 1988

/N71835/001/
MAR/03, 1988

/N71836/001/
MAR/03, 1988

/AB/ CYANOCOBALAMIN
/LUITPOLD/ 3 LUITPOLD

/AT/ CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

/AT/ CYCLOPENTOLATE HCL

3 SOLA BARNES HIND

12/

12/

DACARBAZINE

INJECTABLE; INJECTION

/AB/ DACARBAZINE

/LUITPOLD/ 3 LUITPOLD

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/N80668/001/
N80668 001

/N84863/001/
N84863 001

/N70962/001/
AUG 28, 1986

/N70990/001/
AUG 28, 1986

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AUG 28, 1986

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AUG 28, 1986

/N70990/001/
AUG 28, 1986

/N17575/001/
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N17575 001

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N17575 001

/N17575/001/
N17575 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN'92 - OCT'92

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPRAMINE HCL
 EON LABS

AB 25MG
 AB 50MG
 AB 75MG
 AB 100MG
 a 10MG
 a 150MG
 /B*/ /PHARM/BASICS/
 /B*/
 /B*/
 /B*/
 /B*/
 a PHARM BASICS
 a
 a
 a
 /AB/ /VITAFINE/
 /AB/
 /AB/
 /AB/
 /AB/
 /B/
 /B/
 0.05%
 N74027 001
 SEP 28, 1992

DESONIDE

CREAM; TOPICAL
DESONIDE
 TARO

AB 0.05%
 LOTION; TOPICAL
 DESOEN
 OWEN GALDERMA
 0.05%
 N72354 001
 JAN 24, 1992

DEXAMETHASONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
 DEXAIR

/BAUSCH/AND/LOMB/
 EQ 0.1% PHOSPHATE
 PHARMAFAIR
 EQ 0.1% PHOSPHATE
 N88433 001
 DEC 15, 1983

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 3.3% AND SODIUM
 CHLORIDE 0.3% IN PLASTIC CONTAINER
 MCGAW
 3.3GM/100ML; 75MG/100ML;
 300MG/100ML
 N19630 049
 MAY 07, 1992

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 3.3% AND SODIUM
 CHLORIDE 0.3% IN PLASTIC CONTAINER
 MCGAW
 3.3GM/100ML; 110MG/100ML;
 300MG/100ML
 N19630 050
 MAY 07, 1992

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 3.3% AND SODIUM
 CHLORIDE 0.3% IN PLASTIC CONTAINER
 MCGAW
 3.3GM/100ML; 150MG/100ML;
 300MG/100ML
 N19630 051
 MAY 07, 1992

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 3.3% AND SODIUM
 CHLORIDE 0.3% IN PLASTIC CONTAINER
 MCGAW
 3.3GM/100ML; 220MG/100ML;
 300MG/100ML
 N19630 052
 MAY 07, 1992

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 3.3% AND SODIUM
 CHLORIDE 0.3% IN PLASTIC CONTAINER
 MCGAW
 3.3GM/100ML; 300MG/100ML;
 300MG/100ML
 N19630 053
 MAY 07, 1992

DESONIDE

CREAM; TOPICAL
DESONIDE
 COPLEY

AB 0.05%
 N74027 001
 SEP 28, 1992

DIAZEPAM

INJECTABLE; INJECTION

DIAZEPAM
/AB/ /PARKE/DAVIS/ /5MG/ML/
/AB/ /PARKE/DAVIS/ /5MG/ML/
3 PARKE DAVIS 5MG/ML
3 5MG/ML

N19201 001
JUL 28, 1988
N19201 002
JUL 28, 1988
/N19201/001/
/JUL/28/1988/
/N19201/002/
/JUL/28/1988/
/N19201/001/
/JUL/28/1988/

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL
VOLTAREN
+ GEIGY 25MG
+ 50MG
/25MG/
/50MG/

TABLET; ORAL

DIAZEPAM
/AB/ /PARKE/DAVIS/ /2MG/
/AB/ /PARKE/DAVIS/ /5MG/
/AB/ /PARKE/DAVIS/ /10MG/
/AB/ /PIONEER/PHARMS/ /2MG/
/AB/ /PIONEER/PHARMS/ /5MG/
/AB/ /PIONEER/PHARMS/ /10MG/

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL
DIETHYLPROPION HCL
3 EON LABS 25MG
/3/VITARINE/ /25MG/

N85916 001
/N85916/001/

DIFLUNISAL

TABLET; ORAL
DIFLUNISAL
LEMMON
AB 250MG
AB 500MG
AB 250MG
AB + 500MG

N73679 001
JUL 31, 1992
N73673 001
JUL 31, 1992
N18445 001
APR 19, 1982
N18445 002
APR 19, 1982

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CARDIZEM CD
BC + MARION MERRELL DOM 180MG
BC + 240MG
+ 120MG
+ 300MG
/300MG/

N20062 002
DEC 27, 1991
N20062 003
DEC 27, 1991
N20062 001
AUG 10, 1992
N20062 004
DEC 27, 1991
/N20062/004/
/DEC/27/1991/

DILTIAZEM HYDROCHLORIDECAPSULE, EXTENDED RELEASE; ORAL
CARDIZEM SR

+ MARION MERRELL DOW

60MG

+

90MG

/50MG/

/50MG/

DILACOR XR

BC RHONE POULENC RORER 180MGH

BC 240MGH

2 120MGH

INJECTABLE; INJECTION

CARDIZEM

MARION MERRELL DOW

5MG/ML

/25MG/5ML/

/50MG/5ML/

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

AA EON LABS

25MG

50MG

/50MG/

/50MG/

2 25MG

2 50MG

/50MG/

/50MG/

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

AB GENEVA

50MGH

75MGH

N19471 001

JAN 23, 1989

N19471 002

JAN 23, 1989

/N19471/001/

/JAN/23,1989/

/N19471/002/

/JAN/23,1989/

N20092 002

MAY 29, 1992

N20092 003

MAY 29, 1992

N20092 001

MAY 29, 1992

N20027 001

OCT 24, 1991

/N20027/001/

/OCT/24,1991/

/N20027/002/

/OCT/24,1991/

N87562 001
FEB 25, 1992
N87561 001
FEB 25, 1992/N71021/001/
/DEC/01,1985/
/N71021/001/
/DEC/01,1985/
/N71021/001/
/DEC/01,1985/
/N71021/001/
/JAN/15,1987/
/N71021/001/
/JAN/15,1987/
/N71021/001/
/JAN/15,1987/
N71190 001
JAN 15, 1987
N71191 001
JAN 15, 1987

CAPSULE; ORAL

DISOPYRAMIDE PHOSPHATE

/B*/ /CHELSEA/

/B*/ /EQ/150MG/BASE/

/B*/ /EQ/100MG/BASE/

/B*/ /EQ/150MG/BASE/

/B*/ /EQ/100MG/BASE/

2 INTERPHARM

EQ 100MG BASE

2

EQ 150MG BASE

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOPAMINE HCL

/AP/ /LYPHOMED/

/AP/ /40MG/ML/

/AP/ /80MG/ML/

/AP/ /160MG/ML/

2 LYPHOMED

40MG/ML

2

80MG/ML

2

160MG/ML

/N70058/001/
/MAR/20,1985/
/N70059/001/
/MAR/20,1985/
/N70059/001/
/MAR/20,1985/
/N70059/001/
/DEC/04,1985/
N70058 001
MAR 20, 1985
N70059 001
MAR 20, 1985
N70364 001
DEC 04, 1985DOXAPRAM HYDROCHLORIDE

INJECTABLE; INJECTION

DOPRAM

AP ROBINS

20MG/ML

N14879 001

DOXAPRAM HYDROCHLORIDE

INJECTABLE; INJECTION

DOXAPRAM HCL

AP STERIS

20MG/ML

N73529 001
JAN 30, 1992

INJECTABLE; INJECTION

DOXAPRAM HCL

AP

2.5MG/ML

N76992 001
NOV 17, 1986

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

3 EON LABS

EQ 50MG BASE

N62780 001
APR 12, 1988

AB/ INTERPHARM/

EQ 100MG BASE

N62227 001
SEP 02, 1988

AB/

EQ 100MG BASE

N62763 001
SEP 02, 1988

3 INTERPHARM

EQ 50MG BASE

N62763 001
SEP 02, 1988

AB/ PARKE/DAVIS/

EQ 100MG BASE

N62594 001
DEC 05, 1985

AB/

EQ 100MG BASE

N62594 001
DEC 05, 1985

3 VITARINE/

EQ 100MG BASE

N62780 001
APR 12, 1988

3 WARNER CHILCOTT

EQ 50MG BASE

N62594 001
DEC 05, 1985

3

EQ 100MG BASE

N62594 001
DEC 05, 1985

CAPSULE, COATED PELLETS; ORAL

DOXYCYCLINE HYCLATE

AB SIDNAK

EQ 100MG BASE

N63187 001
JUN 30, 1992

TABLET; ORAL

DOXYCYCLINE HYCLATE

AB/ INTERPHARM/

EQ 100MG BASE

N62764 001
SEP 02, 1988

3 INTERPHARM

EQ 100MG BASE

N62594 001
DEC 05, 1985

AB/ PARKE/DAVIS/

EQ 100MG BASE

N62593 001
AUG 28, 1985

3 WARNER CHILCOTT

EQ 100MG BASE

N62593 001
AUG 28, 1985

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

ALKERGOT

3 EON LABS

0.5MG

N85153 001
N87417 001

3 VITARINE/

0.5MG

N85153 001
N87417 001

PROPERIDOL

INJECTABLE; INJECTION

PROPERIDOL

AP

2.5MG/ML

N76992 001
NOV 17, 1986

3 LYPHOMED

2.5MG/ML

N70992 001
NOV 17, 1986

3

2.5MG/ML

N70993 001
NOV 17, 1986

AB/ SOLOPAK/

2.5MG/ML

N71750 001
SEP 06, 1988

3 SOLOPAK

2.5MG/ML

N71750 001
SEP 06, 1988

ENOXACIN

TABLET; ORAL

PENETREX

+ PARKE DAVIS

400MG

N19616 005
DEC 31, 1991

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL AND EPINEPHRINE

GRAHAM CHEM

0.01MG/ML; 2%

N80504 004
OCT 19, 1983

> ADD > AP

0.02MG/ML; 2%

N80504 005
OCT 19, 1983

LIDOCAINE HCL W/ EPINEPHRINE

GRAHAM/CHEM/

0.01MG/ML; 2%

N80504 004
OCT 19, 1983

> DLT > AP

0.02MG/ML; 2%

N80504 005
OCT 19, 1983

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

ALKERGOT

3 EON LABS

0.5MG

N85153 001
N87417 001

3 VITARINE/

0.5MG

N85153 001
N87417 001

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL

/AA/ /ERGOTAMINE/ /FISONS/

3 FISONS

/2MG/

2MG

/N67693/001/ /FEB/24/1983/ N87693 001 FEB 24, 1983

TABLET; ORAL

/AA/ /ERGOTAMINE/ /ABBOTT/

OGEN .625

AB ABBOTT

OGEN 1.25

AB + ABBOTT

OGEN 2.5

ABOTT

OGEN 5

ABOTT

0.75MG

1.5MG

3MG

6MG

N83220 001

N83220 002

N83220 003

N83220 004

/N63220/001/ /N63220/002/ /N63220/003/ /N63220/004/

ERYTHROMYCIN

SOLUTION; TOPICAL

/AT/ /C-SOLVE-2/ /SYOSSET/

C-SOLVE-2

SYOSSET

ERYTHROMYCIN

PHARM BASICS

ERYTHROMYCIN

PHARM BASICS

ERYTHROMYCIN

PHARM BASICS

SANSAC

OWEN GALDERMA

SANSACNE

OWEN/SALDERMA

/N62468 001 JUL 03, 1985

/N62825 001 OCT 23, 1987

/N62825/001/ /OCT/23/1987/

/N62522 001 JAN 24, 1985

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

ETHINYL ESTRADIOL

TABLET; ORAL

ESTINYL

/BP/ /SCHERING/

SCHERING

/FEMINONE/

/BP/ /UPJOHN/

3 UPJOHN

/0.05MG/ 0.05MG

/0.05MG/ 0.05MG

/N05292/002/ N05292 002

/N16649/001/ N16649 001

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

GENCEPT 0.5/35-21

AB GENCON

GENCEPT 1/35-21

AB GENCON

GENCEPT 10/11-21

AB GENCON

0.035MG; 0.5MG

0.035MG; 1MG

0.035MG; 0.5MG AND 1MG

N72692 001 FEB 28, 1992

N72693 001 FEB 28, 1992

N72694 001 FEB 28, 1992

/N.E.E. 1245'41/ /N.E.E. 1245'41/

/0.035MG; 1MG/

0.035MG; 1MG

/N71541/001/ /DEC/14/1987/ N71541 001 DEC 14, 1987

TABLET, COATED PARTICLES; ORAL

PCE

ABBOTT

500MG

N50611 002 AUG 22, 1990

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL

/E-MYCIN'E/ /UPJOHN/

3 UPJOHN

3

/EQ 200MG BASE/5ML/ /EQ 400MG BASE/5ML/ /EQ 200MG BASE/5ML/ /EQ 400MG BASE/5ML/

/N62198 001 N62198 002

/N.E.E. 1245'41/ /N.E.E. 1245'41/

/0.035MG; 1MG/

0.035MG; 1MG

/N71541/001/ /DEC/14/1987/ N71541 001 DEC 14, 1987

ERYTHROMYCIN ETHYLSUCCINATE

/PARKE/DAVIS/

3 PARKE DAVIS

3

/EQ 200MG BASE/5ML/ /EQ 400MG BASE/5ML/ /EQ 200MG BASE/5ML/ /EQ 400MG BASE/5ML/

/N62231/001 N62231 002

ETHINYL ESTRADIOL; NORETHINDRONE

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

/N.E.'E.'1/35-28/ /METROPHED/

/0.035MG;1MG/

/N71542/001/ /DEC/14,1987/ N71542 001
DEC 14, 1987

3 LPI

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET; ORAL-21
ORTHO TRI-CYCLEN
+ JOHNSON RW

0.035MG;
0.18MG,0.215MG,0.25MG

N19697 002
JUL 03, 1992

TABLET; ORAL-28
ORTHO TRI-CYCLEN
JOHNSON RW

0.035MG;
0.18MG,0.215MG,0.25MG

N19697 001
JUL 03, 1992

FELODIPINE

TABLET, EXTENDED RELEASE; ORAL
PLENDIL
/MERCK/

/5MG/

MERCK

5MG

/10MG/

10MG

/N19834/001/ /JUL/26,1991/ N19834 001
JUL 25, 1991
/N19834/002/ /JUL/26,1991/ N19834 002
JUL 25, 1991

FENOPROFEN CALCIUM

CAPSULE; ORAL

FENOPROFEN CALCIUM

/AB/ /HALSEY/

/EQ'200MG'BASE/

/AB/

/EQ'300MG'BASE/

3 HALSEY

EQ 200MG BASE

3

EQ 300MG BASE

/N72355/001/ /JUL/05,1988/ N72355 001
/N72355/001/ /JUL/05,1988/ N72355 001
/N72355/001/ /JUL/05,1988/ N72355 001
JUL 05, 1988
N72356 001
JUL 05, 1988

TABLET; ORAL
FENOPROFEN CALCIUM

/AB/ /HALSEY/

/EQ'600MG'BASE/

3 HALSEY

EQ 600MG BASE

/N72357/001/ /JUL/05,1988/ N72357 001
JUL 05, 1988

FENTANYL CITRATE

INJECTABLE; INJECTION
FENTANYL CITRATE

AP STERIS

EQ 0.05MG BASE/ML

N73488 001
JUN 30, 1992

FINASTERIDE

TABLET; ORAL

PROSCAR

+ MSD

5MG

N20180 001
JUN 19, 1992

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

FLUONID

AT ALLERGAN HERBERT

0.025%

/AT/ /HERBERT/

/0.025%/

N87156 002
SEP 06, 1984
/N87156/002/ /SEP/06,1984/

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE
/AB/ /CLAY/PARK/

/0.05%/
/N71790 001/
APR 25, 1988

B* CLAY PARK

0.05%
/N73085 001/
FEB 14, 1992

AB NMC

0.05%
/N71790 001/
APR 25, 1988

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL
/AB/ /LYPHOMED/

/50MG/ML/
/N89152 001/
MAR 21, 1986

/AB/ /LYPHOMED/

/50MG/ML/
/N89428 001/
JAN 12, 1987

/AB/ /LYPHOMED/

/50MG/ML/
/N89519 001/
MAR 12, 1987

3 LYPHOMED

50MG/ML

3

50MG/ML

3

50MG/ML

FLURAZEPAM HYDROCHLORIDE

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

/15MG/
/N70562 001/
JUL 09, 1987

/B* /PHARM/BASICS/

/30MG/
/N70563 001/
JUL 09, 1987

3 PHARM BASICS

15MG

3

30MG

FOLIC ACID

TABLET; ORAL
FOLIC ACID
3 EON LABS

1MG
/N84472 001/
JUL 09, 1987

/AB/ /LILLY/

1MG
/N86135 003/
JUL 09, 1987

3 LILLY

1MG
/N86135 003/
JUL 09, 1987

3 VITAFARINE/

1MG
/N84472 001/
JUL 09, 1987

FURAZOLIDONE

SUSPENSION; ORAL
FUROXONE
+ ROBERTS

50MG/15ML
/N11323 002/
JUL 30, 1984

TABLET; ORAL
FUROXONE
+ ROBERTS

100MG
/N11270 002/
JUL 30, 1984

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE
/AB/ /LYPHOMED/

/10MG/ML/
/N18507 001/
JUL 30, 1982

3 LYPHOMED

10MG/ML

TABLET; ORAL

FUROSEMIDE
/AB/ /CHELSEA/

/20MG/
/N18369 001/
MAY 14, 1982

/AB/ /CHELSEA/

/40MG/
/N18369 002/
MAY 14, 1982

3 CHELSEA

20MG

3

40MG

3 EON LABS

40MG

3 VITAFARINE/

/40MG/
/N18750 002/
JUL 30, 1984

GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION
GALLIUM CITRATE GA 67
/B* /DUPONT/

2MCI/ML
/N17478 001/
JUL 30, 1984

BS DUPONT MERCK

GLYBURIDE

TABLET; ORAL

GLUBATE

BX HOECHST ROUSSEL

1.5MG

N20055 001

APR 17, 1992

3MG

N20055 002

APR 17, 1992

GLYNASE

BX UPJOHN

1.5MG

N20051 001

MAR 04, 1992

3MG

N20051 002

MAR 04, 1992

GONADORELIN ACETATE

INJECTABLE; INJECTION

LUTREPULSE PUMP KIT

FERRING

0.8MG/VIAL

N19687 001

OCT 10, 1989

3.2MG/VIAL

N19687 002

OCT 10, 1989

/JONHSON/RW/

N19687 001

OCT 10, 1989

/JONHSON/RW/

N19687 002

OCT 10, 1989

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL

ULTRAGRIS-165

AB SIDMAK

165MG

N62645 001

JUN 30, 1992

ULTRAGRIS-330

AB SIDMAK

330MG

N62646 001

JUN 30, 1992

HALOFANTRINE HYDROCHLORIDE

TABLET; ORAL

HALFAN

+

SMITHKLINE BEECHAM

250MG

N20250 001

JUL 24, 1992

HALOPERIDOL

TABLET; ORAL

HALOPERIDOL

/AB/

N20055 001

APR 17, 1992

/AB/

N20055 002

APR 17, 1992

/AB/

N20051 001

MAR 04, 1992

/AB/

N20051 002

MAR 04, 1992

/AB/

3 ROYCE

0.5MG

N71722 001

DEC 24, 1987

3

1MG

N71723 001

DEC 24, 1987

3

2MG

N71724 001

DEC 24, 1987

3

5MG

N71725 001

DEC 24, 1987

3

10MG

N72121 001

DEC 24, 1987

3

20MG

N72122 001

DEC 24, 1987

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALOPERIDOL

/AB/

N62645 001

JUN 30, 1992

3 LYPHOMED

EQ 5MG BASE/ML

JUN 30, 1992

/EQ 5MG BASE/ML/

N71187 001

JAN 20, 1987

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH

/AB/

N20250 001

JUL 24, 1992

/AB/

N20250 001

JUL 24, 1992

3 LUITPOLD

10 UNITS/ML

3

100 UNITS/ML

3

100 UNITS/ML

N89063 001

OCT 09, 1985

N89064 001

OCT 09, 1985

N71722 001

DEC 24, 1987

N71723 001

DEC 24, 1987

N71724 001

DEC 24, 1987

N71725 001

DEC 24, 1987

N72121 001

DEC 24, 1987

N72122 001

DEC 24, 1987

N71722 001

DEC 24, 1987

N71723 001

DEC 24, 1987

N71724 001

DEC 24, 1987

N71725 001

DEC 24, 1987

N72121 001

DEC 24, 1987

N72122 001

DEC 24, 1987

N89063 001

OCT 09, 1985

N89064 001

OCT 09, 1985

N89063 001

OCT 09, 1985

N89064 001

OCT 09, 1985

HEPARIN SODIUM

INJECTABLE; INJECTION

/AP/ HEPARIN LOCK FLUSH PRESERVATIVE FREE/
LYPHOMED/

/N17029/011/

/AP/ 100 UNITS/ML/

/SEP/22, 1987/

a LYPHOMED

/N17029/012/

a 100 UNITS/ML

/SEP/22, 1987/

/AP/ HEPARIN LOCK FLUSH PRESERVATIVE FREE IN PLASTIC CONTAINER/
LYPHOMED/

/N17029/008/

/AP/ 100 UNITS/ML/

/SEP/22, 1987/

a LYPHOMED

/N17029 008

a 100 UNITS/ML

/SEP/22, 1987/

/AP/ HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.45% IN
PLASTIC CONTAINER

/N17029 009

/AP/ 10,000 UNITS/100ML

/SEP/22, 1987/

a ABBOTT

/N17029 008

a 10,000 UNITS/100ML

/SEP/22, 1987/

/AP/ HEPARIN SODIUM 12500 UNITS IN SODIUM CHLORIDE 0.45% IN
PLASTIC CONTAINER

/N17029 006

/AP/ 12,500 UNITS/100ML

/JAN/30, 1985/

a ABBOTT

/N17029 006

a 12,500 UNITS/100ML

/JAN/30, 1985/

/AP/ HEPARIN SODIUM 20000 UNITS IN DEXTROSE 5% IN PLASTIC
CONTAINER

/N17029 001

/AP/ 20,000 UNITS/100ML

/JUL 20, 1992

a MC GAW

/N17029 001

a 20,000 UNITS/100ML

/JUL 20, 1992

/AP/ HEPARIN SODIUM 25000 UNITS IN DEXTROSE 5% IN PLASTIC
CONTAINER

/N17029 004

/AP/ 25,000 UNITS/100ML

/JUL 20, 1992

a MC GAW

/N17029 005

a 25,000 UNITS/100ML

/JUL 20, 1992

/AP/ HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45% IN
PLASTIC CONTAINER

/N17029 003

/AP/ 25,000 UNITS/100ML

/JUL 20, 1992

a MC GAW

/N17029 003

a 25,000 UNITS/100ML

/JUL 20, 1992

/AP/ HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45% IN
PLASTIC CONTAINER

/N17029 001

/AP/ 25,000 UNITS/100ML

/JUL 20, 1992

a MC GAW

/N17029 001

a 25,000 UNITS/100ML

/JUL 20, 1992

/AP/ HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45% IN
PLASTIC CONTAINER

/N17029 001

/AP/ 25,000 UNITS/100ML

/JUL 20, 1992

a MC GAW

/N17029 001

a 25,000 UNITS/100ML

/JUL 20, 1992

/AP/ HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45% IN
PLASTIC CONTAINER

/N17029 001

/AP/ 25,000 UNITS/100ML

/JUL 20, 1992

a MC GAW

/N17029 001

a 25,000 UNITS/100ML

/JUL 20, 1992

/AP/ HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45% IN
PLASTIC CONTAINER

/N17029 001

/AP/ 25,000 UNITS/100ML

/JUL 20, 1992

a MC GAW

/N17029 001

a 25,000 UNITS/100ML

/JUL 20, 1992

HEPARIN SODIUM

INJECTABLE; INJECTION

/AP/ HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45% IN
PLASTIC CONTAINER

/N17029/011/

/AP/ 5,000 UNITS/100ML

/JUL 20, 1992/

a MC GAW

/N17029/012/

a 10,000 UNITS/100ML

/JUL 20, 1992/

/AP/ HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN
PLASTIC CONTAINER

/N17029 011

/AP/ 5,000 UNITS/100ML

/JUL 20, 1992/

a MC GAW

/N17029 012

a 10,000 UNITS/100ML

/JUL 20, 1992/

/AP/ HYDRALAZINE HYDROCHLORIDE

/N17029 008

/AP/ 20MG/ML/

/AUG 11, 1987/

a LYPHOMED

/N17029 008

a 20MG/ML

/AUG 11, 1987/

/AP/ HYDRALAZINE HCL/
LYPHOMED/

/N17029 009

/AP/ 20MG/ML

/AUG 11, 1987/

a LYPHOMED

/N17029 009

a 20MG/ML

/AUG 11, 1987/

/AP/ HYDRALAZINE HCL/
LYPHOMED/

/N17029 001

/AP/ 20MG/ML

/AUG 11, 1987/

a LYPHOMED

/N17029 001

a 20MG/ML

/AUG 11, 1987/

/AP/ HYDRALAZINE HCL/
LYPHOMED/

/N17029 001

/AP/ 20MG/ML

/AUG 11, 1987/

a LYPHOMED

/N17029 001

a 20MG/ML

/AUG 11, 1987/

/AP/ HYDRALAZINE HCL/
LYPHOMED/

/N17029 001

/AP/ 20MG/ML

/AUG 11, 1987/

a LYPHOMED

/N17029 001

a 20MG/ML

/AUG 11, 1987/

/AP/ HYDRALAZINE HCL/
LYPHOMED/

/N17029 001

/AP/ 20MG/ML

/AUG 11, 1987/

a LYPHOMED

/N17029 001

a 20MG/ML

/AUG 11, 1987/

/AP/ HYDRALAZINE HCL/
LYPHOMED/

/N17029 001

/AP/ 20MG/ML

/AUG 11, 1987/

a LYPHOMED

/N17029 001

a 20MG/ML

/AUG 11, 1987/

/AP/ HYDRALAZINE HCL/
LYPHOMED/

/N17029 001

/AP/ 20MG/ML

/AUG 11, 1987/

a LYPHOMED

/N17029 001

a 20MG/ML

/AUG 11, 1987/

/AP/ HYDRALAZINE HCL/
LYPHOMED/

/N17029 001

/AP/ 20MG/ML

/AUG 11, 1987/

a LYPHOMED

/N17029 001

a 20MG/ML

/AUG 11, 1987/

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

AB SOLVAY 25MG; 25MG N87608 001
FEB 08, 1982
AB 50MG; 50MG N87213 001
FEB 08, 1982
a 100MG; 50MG N87609 001
FEB 08, 1982

TABLET; ORAL

HYDROCHLOROTHIAZIDE

/AB/ /WARNER/CHILCOTT/ 25MG/ N87586 001
/AB/ 50MG/ N87587 001
MAY 03, 1982
a 25MG WARNER CHILCOTT N87586 001
50MG N87587 001
MAY 03, 1982

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

HYDRAP-ES

a EON LABS

/a/VITARINE/

25MG; 15MG; 0.1MG N84876 001

/25MG; 15MG; 0.1MG/ N84876 001

/RESERPINE/HYDRALAZINE/HCL/HYDROCHLOROTHIAZIDE/

/DANBURY/

/BP/ N85549 001

/BP/ N87556 001

RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

25MG; 15MG; 0.1MG N85549 001

25MG; 15MG; 0.1MG N87556 001

HYDRALAZINE HYDROCHLORIDE; RESERPINE

TABLET; ORAL

DRALSERP

a EON LABS

/a/VITARINE/

25MG; 0.1MG N84617 001

/25MG; 0.1MG/ N84617 001

SERPASIL-APRESOLINE

/BP/ N84646 001

/CIBA/ N09296 004

CIBA

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

DANBURY

AB 25MG N81189 001

100MG N81190 001

/25MG/ N81189 001

/EON/LABS/ N83899 001

/EON LABS/ N84135 001

/HEATHER/ N84135 001

/HEATHER/ N84135 001

/VITARINE/ N85549 001

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

HYDRO-SERP

25

/a/VITARINE/

HYDRO-SERP

50

/a/VITARINE/

/SERPASIL-ESIDRIN/

/BP/ N84827 001

/CIBA/ N84827 001

/SERPASIL-ESIDRIN/

/BP/ N85213 001

/CIBA/ N85213 001

/SERPASIL-ESIDRIN/

/BP/ N85213 001

/CIBA/ N85213 001

/SERPASIL-ESIDRIN/

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/SERPASIL-ESIDRIN/

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/CIBA/ N85213 001

/SERPASIL-ESIDRIN/

/BP/ N85213 0

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE
 AT PHARMAFAIR

12

> DLT >
 > DLT > /AT/
 > DLT > /AT/
 > ADD >
 > ADD >

N87838 001
 JUL 28, 1982

SUSPENSION/DROPS; OPHTHALMIC

/NEO-CORTICE/
 /UPJOHN/
 @ UPJOHN
 @

/0.5%;EQ 3.5MG BASE/ML/
 /1.5%;EQ 3.5MG BASE/ML/
 0.5%;EQ 3.5MG BASE/ML
 1.5%;EQ 3.5MG BASE/ML
 N60612 002
 N60612 001

LOTTION; TOPICAL
 /CORT-ONE/
 /MILES/
 @ MILES
 @

/AT/
 /AT/
 /AT/
 @ MILES
 @

/0.5%;EQ 3.5MG BASE/ML/
 /1.5%;EQ 3.5MG BASE/ML/
 0.5%;EQ 3.5MG BASE/ML
 1.5%;EQ 3.5MG BASE/ML
 N60612 002
 N60612 001

ointment; TOPICAL
HYDROCORTISONE
 AT NMC

12

N87796 001
 OCT 13, 1982

/AT/
 /AT/
 /AT/
 @ MILES
 @

/0.5%;EQ 3.5MG BASE/ML/
 /1.5%;EQ 3.5MG BASE/ML/
 0.5%;EQ 3.5MG BASE/ML
 1.5%;EQ 3.5MG BASE/ML
 N60612 002
 N60612 001

SOLUTION; TOPICAL
 TEXACORT
 GENDERM

2.5/M

N81271 001
 APR 17, 1992

> DLT > /AP/
 > DLT > /AP/
 > DLT > /AP/
 > ADD >
 > ADD >
 > ADD >

INJECTABLE; INJECTION
HYDROCORTISONE SODIUM SUCCINATE
 /ELKINS/SINN/
 @ ELKINS SINN
 @
 @
 @

/EQ 100MG BASE/VIAL/
 /EQ 250MG BASE/VIAL/
 /EQ 500MG BASE/VIAL/
 EQ 100MG BASE/VIAL
 EQ 250MG BASE/VIAL
 EQ 500MG BASE/VIAL
 N86619 001
 N87567 001
 N87568 001

TABLET; ORAL
 /HYDRO-CORTISONE/
 /VITAPHARM/
 @ EON LABS

20MG

/N80642 002
 N80642 002

HYDROFLUMETHIAZIDE; RESERPINE

TABLET; ORAL
 /HYDROFLUMETHIAZIDE/AND/RESERPINE/
 /PHARM/BASICS/
 @ PHARM BASICS
 50MG;0.125MG

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

HYDROCORTISONE ACETATE

CREAM; TOPICAL
 /HEXOL-HC/
 AT ABLE

12M

N81274 001
 JUN 19, 1992

HYDROCORTISONE ACETATE; NEOMYCIN SULFATE

SUSPENSION/DROPS; OPHTHALMIC

> DLT > /AT/
 > ADD >
 > ADD >

/1.5%;EQ 3.5MG BASE/ML/
 1.5%;EQ 3.5MG BASE/ML
 N60188 001

SOLUTION/DROPS; OPHTHALMIC
 PAREMYD
 ALLERGAN
 12;0.25/M

HYDROXYAMPHETAMINE HYDROBROMIDE; TROPICAMIDE

N19261 001
 JAN 30, 1992

HYDROXYZINE HYDROCHLORIDETABLET; ORAL
HYDROXYZINE HCLEQN/LABS/AB/
AB/
AB/10MG/
25MG/
50MG/

3 EON LABS

3

PHARM/BASICS/

3

AB/AB/AB/

3 PHARM BASICS

3

3

3

HYDROXYZINE PAMOATECAPSULE; ORALHY-PAMEON LABSAB/IMIPRAMINE HYDROCHLORIDETABLET; ORALIMIPRAMINE HCLEON LABSAB/N85200 001
N84869 002
N85133 001
N84869 002
N85133 001
N85200 001
N85200 001N71711 001
JUL 05, 1988
N71712 001
JUL 05, 1988
N71711 001
JUL 05, 1988
N71712 001
JUL 05, 1988
N71711 001
JUL 05, 1988
N71712 001
JUL 05, 1988CAPSULE, EXTENDED RELEASE; ORALINDOMETHACINEQN/LABS/AB/N87479 001
N87479 001
N87479 001N86183 001
N86183 001
N86183 001N70556 001
JUN 14, 1985
N70556 001N73343 001
JUN 30, 1992
N73344 001N73345 001
JUN 30, 1992
N73345 001N70709 001
APR 25, 1986
N70709 001N70709 001
APR 25, 1986
N70709 001EQ 25MG HCL
EQ 25MG HCL
EQ 25MG HCLEQ 50MG HCL
EQ 50MG HCL
EQ 50MG HCL600MG
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600MGIBUPROFENTABLET; ORALIBUPROFENEQN/LABS/AB/N17814 001
AUG 13, 1984N73314 001
AUG 31, 1992N19432 001
DEC 24, 1987
N19432 001
DEC 24, 1987
N19432 001
DEC 24, 1987

ISONIAZID

TABLET; ORAL

ISONIAZID

AA EON LABS

AA /LILLY/

AA /LILLY/

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N08678 047

N08678 048

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N08678 050

N08678 051

N08678 052

N08678 053

N08678 054

N08678 055

TABLET; ORAL

TORADOL

+ SYNTEX

10MG

10MG

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N19645 001

DEC 20, 1991

/N19645/001/

/DEC/20/1991/

/N19645/001/

/DEC/20/1991/

/N19645/001/

/DEC/20/1991/

/N19645/001/

/DEC/20/1991/

/N19645/001/

/DEC/20/1991/

/N19645/001/

/DEC/20/1991/

/N19645/001/

/DEC/20/1991/

/N19645/001/

LEVODOPA

CAPSULE; ORAL
DOPAR
/3//P/AND/S/

/500MG/
/100MG/
/250MG/
500MG
100MG
250MG

+ ROBERTS

/N16913/002/
/N16913/003/
/N16913/001/
N16913 002
N16913 003
N16913 001

EQ 400MG BASEM

N20013 001
FEB 21, 1992

LEVORPHANOL TARTRATE

TABLET; ORAL
LEVO-DROMORAN
+ ROCHE

2MG
/2MG/

N08720 001
DEC 19, 1991
/N08720/001/
/DEC/19/1991/

N72993 001
AUG 28, 1992
N73192 001
APR 30, 1992

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL
/INTL MEDICATION/
3 INTL MEDICATION

/1GM/VIAL/
1GM/VIAL
/2GM/VIAL/
2GM/VIAL

/N18543/001/
N18543 001
/N18543/002/
N18543 002

N50668 001
DEC 31, 1991
/N50668/001/
/DEC/31/1991/

LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER

AP MCGAW

N19830 002
APR 08, 1992

LIDOCAINE HCL 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER

AP MCGAW

N19830 003
APR 08, 1992

LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER

AP MCGAW

N19830 004
APR 08, 1992

POWDER FOR RECONSTITUTION; ORAL

LORABID
+ LILLY

200MG/5ML
/200MG/5ML/

N50667 002
DEC 31, 1991
/N50667/002/
/DEC/31/1991/

LITHIUM CARBONATE

CAPSULE; ORAL
LITHIUM CARBONATE
/B*/ /PHARM/BASICS/

/300MG/
300MG

/N72542/001/
/FEB/01/1989/
N72542 001
FEB 01, 1989

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

/1MG/
/2MG/

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

3 PHARM BASICS

3

MANNITOL

INJECTABLE; INJECTION

MANNITOL 25%/AP/ /LYPHOMED/
@ LYPHOMED/12.5GM/50ML/
12.5GM/50ML/N86754/001/
N86754 001

CAPSULE; ORAL

MEFENAMIC ACID
@ EON LABS

/3/VITAFARINE/

250MG
/250MG/N72179 001
APR 21, 1988
/N72179/001/
/APR/21./1988/MASOPROCOLCREAM; TOPICAL
ACTINEX
+ CHEMEX

10/M

N19940 001
SEP 04, 1992MEGESTROL ACETATE

TABLET; ORAL

MEGESTROL ACETATE
/B*/ /PHARM/BASICS/

/B*/

/20MG/
/40MG//N70646/001/
/OCT/02./1987/
/N70647/001/
/OCT/02./1987/
N70646 001
OCT 02, 1987
N70647 001
OCT 02, 1987MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

/B*/ /PHARM/BASICS/

/B*/

/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

@ PHARM BASICS

EQ 50MG BASE

EQ 100MG BASE

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERIDINE HCL

AP

10MG/ML

N88432 001
AUG 16, 1984MEDROXYPROGESTERONE ACETATE

INJECTABLE; INJECTION

DEPO-PROVERA

UP-JOHN

150MG/ML

N20246 001
OCT 29, 1992

@ PARKE DAVIS

@

@ STERIS

/AP/ /PARKE/DAVIS/
/AP/ /PARKE/DAVIS/
/AP/ /PARKE/DAVIS/
/AP/ /PARKE/DAVIS//50MG/ML/
/75MG/ML/
/100MG/ML/
/100MG/ML/N88432 001
AUG 16, 1984
/N88432/001/
/N88432/001/
/N88432/001/
/N88432/001/
N80364 002
N80364 003
N80364 003
N80364 001
N73443 001
MAR 17, 1992
N73444 001
MAR 17, 1992
N73445 001
MAR 17, 1992

TABLET; ORAL

CYCERIN

MYETH AVERST

2.5MG

N81239 001
OCT 30, 1992

> ADD > AB

> ADD >

> ADD > AB

> ADD >

5MG

N81240 001
OCT 30, 1992PROVERA

UP-JOHN

2.5MG

N11839 001
N11839 003

> ADD > AB

> ADD > AB

MEPIVACAINE HYDROCHLORIDEMETAPROTERENOL SULFATE

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN'92 - OCT'92

31

MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

/AP/	/ASTRA/	/1.2/	/N89406/001/
/AP/	/ASTRA/	/1.52/	/DEC 01, 1986/
/AP/	/ASTRA/	/2.2/	/N89408/001/
			/DEC 01, 1986/
			/N89409/001/
			/DEC 01, 1986/

POLOCATINE-MPF

AP	ASTRA	1.2	N89406 001
AP		1.52	DEC 01, 1986
AP		2.2	N89408 001
			DEC 01, 1986
			N89409 001
			DEC 01, 1986

MEPROBAMATE

TABLET; ORAL

AA	ELKINS SINN	200MG	N15426 002
AA		400MG	N15426 001
AA	EON LABS	200MG	N14547 002
AA		400MG	N14547 001
AA	HEATHER	600MG	N84329 001
AA	HEATHER	600MG	N15139/006/
AA	ICN	200MG	N15139/006/
AA	ICN	400MG	N15139 005
AA	PARKE/DAVIS	200MG	N84744/001/
AA	PARKE/DAVIS	400MG	N84744/002/
AA	PARKE/DAVIS	200MG	N84744 001
AA	PARKE/DAVIS	400MG	N84744 002
AA	QUANTUM/PHARMICS	200MG	N15426/002/
AA	QUANTUM/PHARMICS	400MG	N15426/001/
AA	VIATINE	200MG	N14547/002/
AA	VIATINE	400MG	N14547/001/
AA	ZENITH	200MG	N15438/001/
AA	ZENITH	400MG	N15438/002/
AA	ZENITH	200MG	N15438 001
AA	ZENITH	400MG	N15438 002

MESALAMINE

TABLET, DELAYED RELEASE; ORAL

ASACOL
+ P AND G

N19651 001
JAN 31, 1992

METAPROTERENOL SULFATE

SOLUTION; INHALATION

/AN/	/ASTRA/	/0.42/	/N71275/001/
/AN/	/ASTRA/	/0.62/	/JUL 27, 1988/
AN	ASTRA	0.42	/N71018/001/
AN		0.62	/JUL 27, 1988/
			/N71018 001
			JUL 27, 1988
			/N71018/001/
			/AUG 05, 1988/
			N71806 001
			AUG 05, 1988
AN	PROMETA MURO	5.24	N73340 001
			MAR 30, 1992

SYRUP; ORAL

AA	BIOCRAFT	10MG/5ML	N72761 001
AA	SILARX	10MG/5ML	FEB 27, 1992
			N73632 001
			JUL 22, 1992

TABLET; ORAL

/B*/	/PHARM/PHARMICS/	/1.0MG/	/N71013/001/
/B*/	/PHARM/PHARMICS/	/2.0MG/	/JAN 25, 1988/
			/N71013/001/
			/JAN 25, 1988/
			N71013 001
			JAN 25, 1988
			N71014 001
			JAN 25, 1988

METHADONE HYDROCHLORIDE

TABLET, DISPERSIBLE; ORAL

WESTADONE	2.5MG	N17108 001
EON LABS	5MG	N17108 002
	10MG	N17108 003
	40MG	N17108 004
		/N7108/001/
		/N7108/002/
		/N7108/003/
		/N7108/004/

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN'92 - OCT'92

33

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL
CETUS BEN VENUE

AP EQ 10MG BASE/2MLM
AP EQ 10MG BASE/2MLM
AP EQ 10MG BASE/2MLM

N72155 001
MAR 30, 1992
N72244 001
MAR 30, 1992
N72247 001
MAY 18, 1992

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

SOLUTION; ORAL

METOCLOPRAMIDE HCL
SILARX

EQ 5MG BASE/5MLM

N73680 001
OCT 27, 1992

METRONIDAZOLE

GEL; VAGINAL
METROGEL
+ CURATEK

0.75/M

N20208 001
AUG 17, 1992

TABLET; ORAL

METOCLOPRAMIDE HCL
/P*/ /INTERPHARM/

EQ 10MG BASE
EQ 10MG BASE
EQ 10MG BASE

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

INJECTABLE; INJECTION
METRONIDAZOLE
/AP/ /LYPHOMED/

EQ 500MG/100ML
500MG/100ML

N70071 001
DEC 03, 1984

METOLAZONE

TABLET; ORAL

/AB/ /SCHIAPPARELLI/SEARLE/2.5MG/
/AB/ /SCHIAPPARELLI/SEARLE/5MG/
/AB/ /SCHIAPPARELLI/SEARLE/10MG/

EQ 2.5MG
EQ 5MG
EQ 10MG

N18535 001
N18535 002
N18535 003

TABLET; ORAL

METRONIDAZOLE

AB EQN LABS
AB
/AB/ /VITATINE/
/AB/

N18620 001
MAR 04, 1982
N18620 002
JUN 02, 1983
/N18620/001/
/MAR/04/1983/
/N18620/002/
/JUN/02/1983/

ZAROXOLYN

/AB/ /FISONS/

/AB/ /FISONS/

/AB/ /FISONS/

+ FISONS

EQ 2.5MG
EQ 5MG
EQ 10MG
EQ 2.5MG
EQ 5MG

N17386 001
N17386 002
N17386 003
N17386 001
N17386 002

METRONIDAZOLE HYDROCHLORIDE

INJECTABLE; INJECTION

FLAGYL I.V.

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

N18353 001
OCT 15, 1985

/AB/ /METRONIDAZOLE HCL/

EQ 500MG BASE/VIAL

N70295 001
OCT 15, 1985

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '92 - OCT '92

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL
MINOCYCLINE HCL
 AB BIOTACRAFT

EQ 50MG BASEM

N63011 001

MAR 02, 1992

EQ 100MG BASEM

N63009 001

MAR 02, 1992

CREAM; TOPICAL

BENOQUIN

/ELDER/

ICN

/20%/
20%/N68173/663/
N08173 003

SUSPENSION; ORAL
 MINOCIN
 + LEDERLE

/SYROP; ORAL/
 /MINOCIN/
 /+//LEDERLE/

EQ 50MG BASE/5ML

N50445 001

INJECTABLE; INJECTION

MORPHINE SULFATE

ABBOTT

> ADD > AP
> ADD >

0.5MG/MLM

N19917 001

OCT 30, 1992

AP

N73509 001

SEP 30, 1992

> ADD > AP
> ADD >

1MG/MLM

N19916 001

OCT 30, 1992

AP

N73510 001

SEP 30, 1992

/EQ/50MG/BASE/5ML/

/N50445/661/

MINOXIDIL

TABLET; ORAL

MINOXIDIL

/B*/ /PHARM/BASICS/

3 PHARM BASICS

2.5MG

/2.5MG/

/N71537/661/
/DEC/16, 1988/

N71537 001

DEC 16, 1988

/2.5MG/

/N71799/661/
/NOV/10, 1987/

N71799 001

NOV 10, 1987

/10MG/

/N71796/661/
/NOV/10, 1987/

N71796 001

NOV 10, 1987

3 ROYCE

2.5MG

10MG

3

MIVACURIUM CHLORIDE

INJECTABLE; INJECTION
 MIVACRON

BURROUGHS WELLCOME

EQ 2MG BASE/MLM

N20098 001

JAN 22, 1992

MIVACRON IN DEXTROSE 5% IN PLASTIC CONTAINER
 BURROUGHS WELLCOME

EQ 0.5MG BASE/MLM

N20098 002

JAN 22, 1992

EQ 50MG BASE/100MLM

N20098 003

JAN 22, 1992

NABUMETONE

TABLET; ORAL

RELAFEN

+ SMITHKLINE BEECHAM

750MG

/750MG/

N19583 002

DEC 24, 1991

/N19583/662/

/DEC/24, 1991/

NAFARELIN ACETATE

SPRAY, METERED; NASAL

SYNAREL

SYNTEX

EQ 0.2MG BASE/INHM

N20109 001

FEB 26, 1992

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

/NALBUPHINE/

/LYPHONED/

/10MG/ML/

/N70751/661/

/JUL/02, 1986/

/N70752/661/

/JUL/02, 1986/

N70751 001

JUL 02, 1986

N70752 001

JUL 02, 1986

3 LYPHONED

10MG/ML

3

20MG/ML

NAPROXEN

TABLET; ORAL

NAPROSYN
SYNTEX

> ADD > AB
> ADD > AB
> ADD > AB
> ADD >
> ADD >
> ADD > AB
> ADD > AB
> ADD > AB
> ADD > AB
> ADD > AB

250MG
375MG
500MG

N17581 002
N17581 003
N17581 004
APR 15, 1982

NAPROXEN
HAMILTON

> ADD > AB
> ADD > AB
> ADD > AB
> ADD > AB
> ADD > AB
> ADD > AB
> ADD > AB

250MG
375MG
500MG

N74110 001
OCT 30, 1992
N74110 002
OCT 30, 1992
N74110 003
OCT 30, 1992

CAPSULE, EXTENDED RELEASE; ORAL

CARDENE SR
+ SYNTEX 30MG
+ 45MG
+ 60MG

N20005 001
FEB 21, 1992
N20005 002
FEB 21, 1992
N20005 003
FEB 21, 1992

INJECTABLE; INJECTION

CARDENE
DUPONT MERCK 2.5MG/ML

N19734 001
JAN 30, 1992

NEOMYCIN SULFATE

TABLET; ORAL

NEOMYCIN SULFATE

AA
EON LABS
/AA/ VITAMINE/

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

EQ 350MG BASE
/EQ 350MG BASE/

N61586 001
/N61586/001/

NEOMYCIN SULFATE; PREDNISOLONE ACETATE

/SUSPENSION PROPS; /OPHTHALMIC/
/NEO-DELTA-CORTEF/
/UPJOHN/

/EQ 3.5MG BASE/ML; 0.25%
/EQ 3.5MG BASE/ML; 0.25%
/N61037/001/

3 UPJOHN

FILM, EXTENDED RELEASE; TRANSFERMAL
NICODERM

/BC/ /MARION/MERRELL/DOW/ /7MG/24HR/

/N20165/001/
/NOV/07, 1991/
NOV 07, 1991
N20165 001

BC + MARION MERRELL DOW 7MG/24HR

/BC/ /14MG/24HR/

/N20165/002/
/NOV/07, 1991/
NOV 07, 1991
N20165 002

BC + 14MG/24HR

/BC/ /21MG/24HR/

/N20165/003/
/NOV/07, 1991/
NOV 07, 1991
N20165 003

BC + 21MG/24HR

NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE

/SUSPENSION PROPS; /OPHTHALMIC/
/NEO-HYDELTRASOL/
/MSD/

/EQ 3.5MG BASE/GH;
/EQ 0.25% PHOSPHATE/
/N50378/001/

3 MSD

NICOTROL
+ KABI

+ 5MG/16HR

N20150 001
APR 22, 1992

+ 10MG/16HR

N20150 002
APR 22, 1992

+ 15MG/16HR

N20150 003
APR 22, 1992

PROSTEP
+ ELAN

+ 11MG/24HR

N19983 001
JAN 28, 1992

+ 22MG/24HR

N19983 002
JAN 28, 1992

NIACIN

TABLET; ORAL

NIACIN

AA
MOCKHARDT

500MG

N81134 001
APR 28, 1992

NI8841 004
OCT 29, 1992

> ADD >
> ADD >
> ADD >

OXAZEPAM

CAPSULE; ORAL
OXAZEPAM

/N71661/001/
 /MAR/02, 1988/
 /N71662/001/
 /MAR/02, 1988/
 /N71663/001/
 /MAR/02, 1988/

OXICONAZOLE NITRATE

EQ 1% BASEM

100,000 UNITS/GM;0.1%
/N62186 002
/JUN 06, 1985

OXYBUTYNIN CHLORIDE

TABLET; ORAL
OXYBUTYRIN CHLORIDE
/B*/ /PHARM/BASICS/
2 PHARM BASICS

/N70746/001/
 /MAR/10, 1988/
 N70746 001
 MAR 10, 1988

20MG/MLA

FLOXIN IN DEXTROSE 5%
JOHNSON RW

400MG/100MLH

FLOXIN IN DEXTROSE 5% IN PLASTIC CONTAINER
JOHNSON RW 6MG/MLH

4MG/MLH
400MG/100MLH

N20087 005
MAR 31, 1992

INJECTABLE; INJECTION

PENICILLIN G POTASSIUM

1,666,666 UNITS/VIAL	N62003 001
5,000,000 UNITS/VIAL	N62003 002
1,000,000 UNITS/VIAL	N62003 001
5,000,000 UNITS/VIAL	N62003 002

1,000,000 UNITS/VIAL
5,000,000 UNITS/VIAL
1,000,000 UNITS/VIAL
5,000,000 UNITS/VIAL

PINDOLOL

TABLET; ORAL

N85671 001
N85689 001
/N85671/001/
/N85689/001/

SMGM

N74019 001
SEP 03, 1992
N74019 002
SEP 03, 1992

WISKEN

SANDOZ

SEP 03, 1982
N18285 002
SEP 03, 1982

CAPSULE; ORAL

LEADERS
PFIZER

N18147 002
APR 06, 1982
N18147 003
APR 06, 1982

PIROXICAM

COPLEY

N74103 001
AUG 28, 1992

MYLAN

JUL 31, 1992
N74102 002
JUL 31, 1992
N74036 001
MAY 29, 1992
N74036 002
MAY 29, 1992

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

POWDER FOR RECONSTITUTION: ORAL

72GM/BOT;
N73428 001
JAN 28, 1992

72GM/BOT;
N73428 001
JAN 28, 1992

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '92 - OCT '92

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

PRAZOSIN HYDROCHLORIDE

POWDER FOR RECONSTITUTION; ORAL

GO-EVAC
/AA/ /COPLEY/

/236MG/BOI; 2.97GM/BOI; 6.74GM/BOI;
/5.86GM/BOI; 22.74GM/BOI; N73433/001/
/APR/28, 1992/

236GM/BOI; 2.97GM/BOI; 6.74GM/BOI;
5.86GM/BOI; 22.74GM/BOI N73433 001
APR 28, 1992

AA COPLEY

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

K-LEASE
/AB/ ADRIA

N73398 001
JAN 28, 1992

MICRO-K
/AB/ ROBINS

N18238 001

TABLET, EXTENDED RELEASE; ORAL

KLOR-CON
/AB/ UPSHER SMITH

N19123 001
APR 17, 1986
/N19123/001/
/APR/17, 1986/

/BC/

KLOTRIX

BC APOTHECON
/BC/ /MEAD/ JOHNSON/

N17850 001
/N17850/001/

PRAZEPAM

CAPSULE; ORAL

CENTRAX
/AB/ /PARK/ DAVIS/

/N18144/001/
/N18144/002/
N18144 002
N18144 001

/AB/ /+/

+ PARKE DAVIS

/PRAZEPAM/
/BC/ /PHARM/BASICS/

/N70427/001/
/NOV/06, 1987/
/N70428/001/
/NOV/06, 1987/

/BC/

3 PHARM BASICS

3

NOV 06, 1987
N70428 001
NOV 06, 1987

CAPSULE; ORAL

MINIPRESS
/AB/ /PFIZER/

/EQ 2MG BASE/
EQ 2MG BASE
/EQ 5MG BASE/
EQ 5MG BASE

/N17442/001/
N17442 003
/N17442/001/
N17442 001

TABLET, EXTENDED RELEASE; ORAL

MINIPRESS XL
+ PFIZER

N19775 001
JAN 29, 1992
N19775 002
JAN 29, 1992

PREDNISOLONE

TABLET; ORAL
/DELTA-CORTIFF/
/BX/ /UPJOHN/
3 UPJOHN

/N09987/004/
N09987 004

PREDNISOLONE

3 EON LABS
/BX/ /HEATHER/
3 HEATHER
/3 VITAFINE/

N84773 001
/N84773/001/
N80326 001
/N84773/001/

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

SUSPENSION/DROPS; OPHTHALMIC

BLEPHAMIDE
/AT/ /ALLERGAN/
ALLERGAN

/N12813/002/
N12813 002

/AT/ /PREDNISOLONE/

/0.2%; 10%/
0.2%; 10%

3 PHARMAFAIR

/N88837/001/
N88837 001
DEC 24, 1985

PREDNISONE

TABLET; ORAL
/BX/ /FERNDALE/
3 FERNDALE

/N83364/001/
N83364 001

PREDNISONE

TABLET; ORAL

PREDNISONE

3 EON LABS

RICHLYN

AB

/BX/

5MG

5MG

/5MG/

/5MG/

N84774 001

N80782 001

/N80782/001/

/N84774/001/

TABLET; ORAL

COMPAZINE

/AB/

/SKF/

/AB/

/AB/

/AB/

/AB/

/AB/

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/EQ 25MG BASE/

/EQ 5MG BASE/

/EQ 10MG BASE/

/EQ 25MG BASE/

/EQ 5MG BASE/

/EQ 10MG BASE/

/EQ 25MG BASE/

/EQ 5MG BASE/

/EQ 10MG BASE/

/EQ 25MG BASE/

/EQ 5MG BASE/

/EQ 10MG BASE/

/EQ 25MG BASE/

/EQ 5MG BASE/

/EQ 10MG BASE/

/N10571/001/

/N10571/002/

/N10571/003/

/N10571/004/

/N10571/005/

/N10571/006/

/N10571/007/

/N10571/008/

/N10571/009/

/N10571/010/

/N10571/011/

/N10571/012/

/N10571/013/

/N10571/014/

/N10571/015/

/N10571/016/

/N10571/017/

/N10571/018/

/N10571/019/

/N10571/020/

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/EQ 5MG BASE/

/EQ 10MG BASE/

PROPACARINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

/AT/ /SQUIBB/ /5MG/ML/ /N84883/001/

AT SQUIBB 0.5% N8883 001

TABLET; ORAL
PSEUDOEPHEDRINE HCL AND TRIPROLIDINE HCL

AA EON LABS 60MG; 2.5MG /N88193/001/

/AA/ /VITARINE/ /60MG; 2.5MG/

MAY 17, 1983
/N88193/001/
/MAY/17/1983/

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL

> ADD >
a EON LABS 32MG /N84014/001/

a 65MG /N83870/002/

/AA/ /VITARINE/ /65MG/ /N86495/001/

/AT/ /SQUIBB/ /32MG/ /N84014/001/

a VITARINE 65MG /N83688/001/

/a/ /a/ /65MG/ /N83870/002/

/a/ /a/ /65MG/ /N86495/001/

PYRAZINAMIDE

TABLET; ORAL
PYRAZINAMIDE

AB + LEDERLE 500MG /N80157/001/

AB MIKART 500MG /N81319/001/

JUN 30, 1992

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION

PYRIDOXINE HCL

/AP/ /LUITPOLD/ /100MG/ML/ /N80669/001/

a LUITPOLD 100MG/ML N80669 001

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

/AB/ /SUPERPHARM/ /10MG/ /N71515/001/

/AB/ /a/ /20MG/ /N71516/001/

a SUPERPHARM 10MG /N71515/001/

a 20MG /N71516/001/

JUN 08, 1983

JUN 08, 1983

QUINETHAZONE; RESERPINE

/TABLET; ORAL/
/HYDROX/R/
/LEDERLE/

a LEDERLE 50MG; 0.125MG /N13927/001/

50MG; 0.125MG N13927 001

PROTIRELIN

INJECTABLE; INJECTION

RELEFACT TRH

AP FERRING 0.5MG/ML /N18087/001/

/AP/ /Hoechst/Roussel/ /0.5MG/ML/

TABLET; ORAL

QUINIDINE SULFATE

AB ELKINS SINN 200MG /N83622/001/

AB EON LABS 200MG /N84631/001/

AB 300MG /N88072/001/

/a/ /QUANTUM/PHARM/ /200MG/ /N83622/001/

/AB/ /VITARINE/ /200MG/ /N84631/001/

/AB/ /a/ /300MG/ /N88072/001/

SEP 26, 1983
/SEP/26/1983/

RAUWOLFIA SERPENTINA

TABLET; ORAL

/BP/ /RAUVERID/
/FOREST/PHARMS/
WOLFINA
3 FOREST PHARMS

/50MG/
50MG

/N09255/008/
N09255 008

INJECTABLE; INJECTION
/SODIUM/CHLORIDE/23.4% IN PLASTIC CONTAINER/
/LYPHOMED/
/23.4MG/ML/
/N19329/001/
/APR/22, 1987/
N19329 001
APR 22, 1987

234MG/ML

RESERPINE

TABLET; ORAL

RESERPINE
EON LABS
BP
BP
/BP/ /VITARINE/
/BP/

0.1MG
0.25MG
/0.1MG/
/0.25MG/
0.1MG
0.25MG

N09838 001
N09838 002
/N09838/001/
/N09838/002/
N09838 002

INJECTABLE; INJECTION
/SODIUM LACTATE 1/6 MOLAR IN PLASTIC CONTAINER
MCGAW
AP
N20004 001
APR 21, 1992

1.87GM/100MLM

/BP/ /SERPATE/
/BP/ /VALE/
3 VALE
3

/N09453/001/
/N09453/002/
N09453 001
N09453 002

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
/NITROPRESS/
ABBOTT

25MG/ML

N71961 001
AUG 01, 1988

AP
/SODIUM NITROPRUSSIDE/
GENSIA

25MG/MLM

N73465 001
MAR 30, 1992

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION

RITODRINE HCL
/BP/ /LYPHOMED/
/BP/

/10MG/ML/
/15MG/ML/
10MG/ML
15MG/ML

/N71188/001/
/JUL/23, 1987/
/N71188/001/
/JUL/23, 1987/
N71188 001
JUL 23, 1987
N71189 001
JUL 23, 1987

SODIUM POLYSTYRENE SULFONATE

SUSPENSION; ORAL, RECTAL

/BP/ /SODIUM POLYSTYRENE SULFONATE/
/ROXANE/
3 ROXANE

/155M/60ML/
15GM/60ML

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

SODIUM BICARBONATE; TARTARIC ACID

GRANULE, EFFERVESCENT; ORAL

BAROS
/BP/ /E/Z/EM/
LAFAYETTE

/460MG/GM; 420MG/GM/
460MG/GM; 420MG/GM

250MG/MLM

INJECTABLE; INJECTION
SODIUM THIOSULFATE
US ARMY

N20166 001
FEB 14, 1992

SODIUM THIOSULFATE

> ADD > SOTALOL HYDROCHLORIDE

> ADD > TABLET; ORAL
> ADD > BETAPACE
> ADD > + BERLEX

240MG

N19865 003

OCT 30, 1992

80MG

N19865 001

OCT 30, 1992

160MG

N19865 002

OCT 30, 1992

320MG

N19865 004

OCT 30, 1992

> ADD >

SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE

/AB/ /PARKE/DAVIS/

/25MG/

@ WARNER CHILCOTT

25MG

/N87952/001/
/NOV/18, 1982/

N87952 001

NOV 18, 1982

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION

SUCCINYLCHOLINE CHLORIDE

/INTL/MEDICATION/

/100MG/VIAL/

@ INTL MEDICATION

100MG/VIAL

/N85400/001/
/FEB/04, 1982/

N85400 001

FEB 04, 1982

/SULFABENZAMIDE;/SULFACETANIDE;/SULFATHIAZOLE/

/CREAM;/VAGINAL/

/SULTRIN/

/JOHNSON/RW/

/3.72;2.86;3.42;0.64/

/N85794/001/

/TABLET;/VAGINAL/

/SULTRIN/

/JOHNSON/RW/

/TRIPLE/SULFA/

/3/FOUGERA/

/3/PHARMADERM/

/18.4MG;14.3;7.5MG;17.2;5MG/

/N85794/001/

/18.4MG;14.3;7.5MG;17.2;5MG/

/N88463/001/

/JAN/03, 1985/

/18.4MG;14.3;7.5MG;17.2;5MG/

/N88463/001/

/JAN/03, 1985/

/SULFABENZAMIDE;/SULFACETANIDE;/SULFATHIAZOLE;/UREA/

/CREAM;/VAGINAL/

/SULF/

/6/AND/W/

/AT/

N19865 003

OCT 30, 1992

/TRIPLE/SULFA/

/CLAY/PARK/

/AT/

N19865 001

OCT 30, 1992

/FOUGERA/

/NMC/

/AT/

N19865 002

OCT 30, 1992

/PHARMADERM/

/VAGILIA/

/LEMON/

/AT/

N19865 004

OCT 30, 1992

/3.72;2.86;3.42;0.64/

/JUN/09, 1985/

/3.72;2.86;3.42;0.64/

/NOV/15, 1982/

/3.72;2.86;3.42;0.64/

/NOV/15, 1982/

/3.72;2.86;3.42;0.64/

/NOV/15, 1982/

/3.72;2.86;3.42;0.64/

/NOV/15, 1982/

/3.72;2.86;3.42;0.64/

/NOV/15, 1982/

SULFAMETHIZOLE

TABLET; ORAL

/FEDK/

@ FOREST PHARMS/

/AB/

/500MG/

500MG

/N80273/001/

N80273 001

THIOSULFIL

/AB/;/MYETH/AYERST/

+ MYETH AYERST

/AB/

/500MG/

500MG

/N88565/004/

N88565 004

SULFAMETHOXAZOLE

TABLET; ORAL

/URON/

@ SHIONOGI

/AB/

/500MG/

500MG

/N87307/001/

N87307 001

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

SULFAMETHOXAZOLE AND TRIMETHOPRIM

AP Cetus Ben Venue

80MG/ML; 16MG/ML

N72383 001

APR 29, 1992

N73199 001

SEP 11, 1992

AP STERLING MINTHROP

80MG/ML; 16MG/ML

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB EON LABS

400MG; 80MG

N18598 001

MAY 19, 1982

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

/AB/ SULFAMETHOXAZOLE AND TRIMETHOPRIM
/INTERPHARM/ /400MG;80MG/

/AB/ /800MG;160MG/

B* INTERPHARM 400MG;80MG

B* 800MG;160MG

/AB/ /MARTEC/ /400MG;80MG/

@ MARTEC 400MG;80MG

/B*/ /PHARM/BASICS/ /400MG;80MG/

/B*/ /800MG;160MG/

@ PHARM BASICS 400MG;80MG

@ 800MG;160MG

/AB/ /VITAPRINE/ /400MG;80MG/

SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH

AB EON LABS 800MG;160MG

/AB/ /MARTEC/ /800MG;160MG/

@ MARTEC 800MG;160MG

/AB/ /VITAPRINE/ /800MG;160MG/

SULFASALAZINE

TABLET; ORAL

SULFASALAZINE

@ EON LABS

/@/VITAPRINE/

SULFISOXAZOLE

TABLET; ORAL

/SULFALAS/

@ PARKE/DAVIS/

@ PARKE DAVIS

SULFISOXAZOLE

TABLET; ORAL

SULFISOXAZOLE

/AB/ /WEST/WARD/

@ WEST WARD

SULINDAC

TABLET; ORAL

SULINDAC

LEMMON

AB

AB

TALBUTAL

/TABLET;/ORAL/

/LOTUSATE/

/STERLING/

@ STERLING

TECHNETIUM TC-99M RED BLOOD CELL KIT

INJECTABLE; INJECTION

RBC-SCAN

CADEMA

N/A

TECHNETIUM TC-99M SESTAMIBI KIT

INJECTABLE; INJECTION

CARDIOLITE

/DUPONT/

DUPONT MERCK

N/A

> DLT >

> DLT >

> ADD >

> ADD >

N86184 001

/N86184/001/

/N84955/001/

N84955 001

/N80379/001/
N80379 001

N72972 001
FEB 28, 1992
N72973 001
FEB 28, 1992

/N09410/005/

N09410 005

N20063 001
JUN 11, 1992

/N19785/001/
DEC 21, 1990
N19785 001
DEC 21, 1990

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL
THIORIDAZINE HCL

/AB/ /PAR/ /150MG/ /N89764/001/ /FEB/09/1988/
/AB/ /PAR/ /200MG/ /N89765/001/ /FEB/09/1988/
3 PAR 150MG N89764 001
3 200MG N89765 001
FEB 09, 1988
FEB 09, 1988

THIOETHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL
THIOETHIXENE HCL INTENSOL
AA ROXANE EQ 5MG BASE/MLM
N73494 001
JUN 30, 1992

TIMOLOL MALEATE

TABLET; ORAL
TIMOLOL MALEATE

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

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION
TOBRAMYCIN SULFATE
AP ABBOTT EQ 40MG BASE/MLM
AP GENSLA EQ 40MG BASE/MLM
N63116 001
MAY 18, 1992
N63100 001
JAN 30, 1992

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

/AB/ /INTERPHARM/ /250MG/ /N71270/001/ SEP 23, 1986
/AB/ /INTERPHARM/ /500MG/ /N71271/001/ SEP 23, 1986
B* INTERPHARM 250MG N71270 001
B* 500MG N71271 001
SEP 23, 1986
/B*/ /PHARM/BASICS/ /100MG/ /N71355/001/ JAN 11, 1988
/B*/ /PHARM/BASICS/ /250MG/ /N70168/001/ APR 02, 1986
/B*/ /PHARM/BASICS/ /500MG/ /N70169/001/ APR 02, 1986
3 PHARM BASICS 100MG N71355 001
3 250MG N70168 001
3 500MG N70169 001
APR 02, 1986

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

/AB/ /EON LABS/ /500MG/ /N12678/001/ N12678 001
/AB/ /PARKE/DAVIS/ /500MG/ /N86047/001/ N86047 001
/AB/ /VITARINE/ /500MG/ /N12678/001/ N12678 001

TOLMETIN SODIUM

CAPSULE; ORAL
TOLMETIN SODIUM

/AB/ /BAKER CUMMINS/ EQ 400MG BASEM
/AB/ /GENEVA/ EQ 400MG BASEM
/AB/ /LEMMON/ EQ 400MG BASEM
/AB/ /PUREPAC/ EQ 400MG BASEM
N73392 001
JAN 24, 1992
N73462 001
APR 30, 1992
N73519 001
MAY 29, 1992
N73508 001
JAN 24, 1992

TOLMETIN SODIUM

TABLET; ORAL

TOLECTIN 600

AB + JOHNSON RW

EQ 600MG BASE

N17628 002
MAR 08, 1989

AB/ /MYETH/AYERST/

CAPSULE; ORAL

SURMONTIL

AB/ /MYETH/AYERST/

EQ 25MG BASE/
EQ 50MG BASE/
EQ 100MG BASE/

/N16792/001/
/N16792/002/
/N16792/003/
/SEP/15, 1982/
N16792 003
SEP 15, 1982
N16792 001
N16792 002

TOLMETIN SODIUM

AB GENEVA

EQ 200MG BASEM

N73588 001

AB PUREPAC

EQ 600MG BASEM

JUL 31, 1992
N73527 001
JUN 30, 1992

+ MYETH AYERST

EQ 100MG BASE
EQ 25MG BASE
EQ 50MG BASE

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HCL

AB/ /PHARM/BASICS/

150MG/

/N16441/001/
/APR/29, 1987/

AB/

100MG/

/N16442/001/
/APR/29, 1987/

3 PHARM BASICS

50MG

N70491 001

3

100MG

APR 29, 1987
N70492 001
APR 29, 1987

TRICHLORMETHIAZIDE

TABLET; ORAL

TRICHLORMETHIAZIDE

3 EON LABS

AB/ /VITARINE/

4MG
14MG/

N86171 001
/N86171/001/

TRIMIPRAMINE MALEATE

3 EON LABS

EQ 25MG BASE

N71832 001
SEP 10, 1987
N71833 001
SEP 10, 1987
N71834 001
SEP 10, 1987

3 PHARM BASICS

EQ 25MG BASE

N71283 001
DEC 08, 1987
N71284 001
DEC 08, 1987
N71285 001
DEC 08, 1987

TRIDIMETHYL CHLORIDE

TABLET; ORAL

TRIDIMETHYL CHLORIDE

3 EON LABS

AB/ /LEDERLE/

125MG/

/N09449/005/

3 LEDERLE

25MG

N09489 005

TRIMIPRAMINE MALEATE

AB/ /VITARINE/

EQ 25MG BASE/

/N1633/001/
/SEP/10, 1987/
/N1633/001/
/SEP/10, 1987/
/N1633/001/
/SEP/10, 1987/

AB/

EQ 50MG BASE/

AB/

EQ 100MG BASE/

TRIPLE SULFA (SULFABENZAMIDE; SULFACETAMIDE; SULFATHIAZOLE)

CREAM; VAGINAL

GYNE-SULF

G AND W

3.72; 2.86%; 3.42%

N88607 001
JUN 09, 1986

SULTRIN

JOHNSON RW

3.72; 2.86%; 3.42%

N05794 001

TRIPLE SULFA (SULFABENZAMIDE;SULFACETAMIDE;SULFATHIAZOLE)

CREAM; VAGINAL

TRIPLE SULFA

AI CLAY PARK

3.7%;2.86%;3.42%

N87285 001
NOV 15, 1982

> ADD > AP

INJECTABLE; INJECTION

VANCOMYCIN HCL

ABBOTT

EQ 500MG BASE/VIALM

N62931 001
OCT 29, 1992

AI FOUGERA

3.7%;2.86%;3.42%

N86424 001

> ADD > AP

AI NMC

3.7%;2.86%;3.42%

N87864 001
SEP 01, 1982

> ADD >

TRYSUL

AI SAVAGE

3.7%;2.86%;3.42%

N87887 001
JUL 23, 1982

VECURONIUM BROMIDE

VAGILIA

@ LEMMON

3.7%;2.86%;3.42%

N88821 001
NOV 09, 1987

INJECTABLE; INJECTION

NORCUCURON

ORGANON

20MG/VIALM

N18776 003
JAN 03, 1992

TABLET; VAGINAL

SULTRIN

JOHNSON RW

TRIPLE SULFA

@ FOUGERA

@ PHARMADERM

184MG;143.75MG;172.5MG

N05794 002

184MG;143.75MG;172.5MG

N88463 001
JAN 03, 1985

184MG;143.75MG;172.5MG

N88462 001
JAN 03, 1985

CAPSULE, EXTENDED RELEASE; ORAL

VERELAN

+ ELAN

180MGH

N19614 003
JAN 09, 1992

VERAPAMIL HYDROCHLORIDE

TRISULFAPYRIMIDINES

SUSPENSION; ORAL

SULFALADIN

/FOREST/PHARMS/

@ FOREST PHARMS

500MG/5ML

N86166/661/

N80100 001

VERAPAMIL HCL

/B*/ /CHELSEA/

/60MG/

/B*/

/120MG/

AB

GENEVA

40MGH

N73168 001
JUL 31, 1992

URACIL MUSTARD

CAPSULE; ORAL

URACIL MUSTARD

ROBERTS

/UPJOHN/

1MG

N12892 001

N12892/661/

@ PARKE DAVIS

@

80MG

120MG

N70340 001
AUG 20, 1986

N70341 001
AUG 20, 1986

VALPROIC ACID

SYRUP; ORAL

VALPROIC ACID

AA Copley

250MG/5MLM

N73178 001

AUG 25, 1992

TABLET, EXTENDED RELEASE; ORAL

ISOPTIN SR

AB + KNOLL

240MG

N19152 001
DEC 16, 1986

VERAPAMIL HCL

BAKER CUMMINS

240MGH

N73568 001
JUL 31, 1992

VINBLASTINE SULFATE

INJECTABLE; INJECTION

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

/VBL/50/
/BULL/

/10MG/VIAL/

/N89565/001/
/AUG/18, 1987/

VINBLASTINE SULFATE

BULL

10MG/VIAL

N89565 001
AUG 18, 1987

N20199 002
JUN 19, 1992
N20199 001
JUN 19, 1992

ZALCITABINE

TABLET; ORAL

HIVID

+ ROCHE

0.75MG

0.375MG

VITAMIN A

CAPSULE; ORAL

AQUASOL A

AA ASTRA

50,000 USP UNITS

25,000 USP UNITS

/50,000 USP UNITS/

/25,000 USP UNITS/

N83080 001

N83080 002

/N83080/001/

/N83080/002/

VITAMIN A PALMITATE

CAPSULE; ORAL

VITAMIN A

3 ELKINS SINN

/3/QUANTUM/PHARMICS/

EQ 50,000 UNITS BASE

/EQ/50,000 UNITS/BASE/

N85479 001

/N85479/001/

WARFARIN SODIUM

TABLET; ORAL

/WARFARIN/SODIUM/

/B*/ /PHARM/BASICS/

/2MG/

/N88719/001/

/JUN/27, 1985/

/N88720/001/

/AUG/06, 1985/

/N88721/001/

/JUL/02, 1985/

N88719 001

JUN 27, 1985

N88720 001

AUG 06, 1985

N88721 001

JUL 02, 1985

3 PHARM BASICS

2MG

2.5MG

5MG

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACEPHEN
G AND W

120MG
325MG
650MG

N72218 001
MAR 27, 1992
N72344 001
MAR 27, 1992
N72237 001
MAR 27, 1992

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
DIPHENHYDRAMINE HCL
CUMBERLAND SWAN

12.5MG/5ML

N73611 001
AUG 20, 1992

SILPHEN
SILARX

12.5MG/5ML

N72646 001
FEB 27, 1992

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
MICROCOL
JOHNSON AND JOHNSON

0.5%

N72292 001
JAN 28, 1992

STERI-STAT
MATRIX MEDCL

4%

N70104 001
JUL 24, 1986
/N70104/001/
/JUL/24/1986/

/MEDCL/SYSTEMS/
/4%

TABLET; ORAL
IBUPROFEN
TAG

200MG

N73141 001
MAY 29, 1992

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

CLEMASTINE FUMARATE

TABLET; ORAL
TAVIST-1
SANDOZ

1.34MG

N17661 003
AUG 21, 1992

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
TAVIST-D
SANDOZ

1.34MG; 75MG

N18298 002
AUG 21, 1992

SOLUTION; ORAL
LOPERAMIDE HCL
BARRE

1MG/5ML

N73187 001
SEP 15, 1992

PERRIGO

1MG/5ML

N73243 001
JAN 21, 1992

ROXANE

1MG/5ML

N73079 001
APR 30, 1992

DEXBROMPHENTRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

/RESPORAL/
/PIONEER/PHARMS/
/6MG; 120MG/

2 PIONEER PHARMS

6MG; 120MG

/N89139/001/
/JUN/16/1988/
N89139 001
JUN 16, 1988

TABLET; ORAL
LOPERAMIDE HCL
PERRIGO

2MG

N74194 001
OCT 30, 1992

MICONAZOLE NITRATE

CREAM; VAGINAL
MICONAZOLE NITRATE
COPLEY

2%

N74030 001
OCT 30, 1992

SODIUM CHLORIDE

AEROSOL, METERED; INHALATION
BRONCHO SALINE
BLAIREX

0.9%w

N19912 001
SEP 03, 1992

SODIUM MONOFLUOROPHOSPHATE

PASTE; DENTAL
EXTRA-STRENGTH AIM
/a/CHESBROUGH/ponds/ 1.2% /

CHESBROUGH PONDS 1.2%

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

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '92 - OCT '92

DEXTRAN 40, 10% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION
LMD IN PLASTIC CONTAINER
ABBOTT LABS 10GM/100ML; 0.9GM/100ML N72562
OCT 30, 1992

DEXTRAN 40, 10% IN DEXTROSE 5%

INJECTABLE; INJECTION
LMD IN PLASTIC CONTAINER
ABBOTT LABS 10GM/100ML; 5GM/100ML N72563
OCT 30, 1992

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

INJECTABLE; INJECTION
6% GENTRAN 75 AND 10% TRAVERS
TRAVENOL LABS 6GM/100ML; 10GM/100ML; 0.9GM/100ML N08788

UROKINASE

INJECTABLE; INJECTION
BROOKINASE
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
[Approved for Marketing*]
[Exclusive Approval**]

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: AI-RSA TRADE: NOT ESTABLISHED	TREATMENT OF AUTOIMMUNE UVEITIS.	AUTOIMMUNE, INC
GENERIC: ALDESLEUKIN TRADE: PROLEUKIN*/**	TREATMENT OF PRIMARY IMMUNODEFICIENCY DISEASE ASSOCIATED WITH T-CELL DEFECTS.*/** [MAY 05, 1999]	CETUS
GENERIC: ANANAIN, COMOSAIN TRADE: VIANAIN	FOR THE ENZYMATIC DEBRIDEMENT OF SEVERE BURNS.	GENZYME CORPORATION
GENERIC: ANTIHEMOPHILIC FACTOR, HUMAN TRADE: HUMATE P	TREATMENT OF PATIENTS WITH VON WILLEBRAND'S DISEASE.	BEHRINGWERKE AKTIENGESellschaft
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

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: BOTULINUM TOXIN TYPE A TRADE: NOT ESTABLISHED	TREATMENT OF SYNKINETIC CLOSURE OF THE EYELID ASSOCIATED WITH VII CRANIAL NERVE ABERRANT REGENERATION.	BIOPURE CORPORATION
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: COAGULATION FACTOR IX TRADE: MONONINE*/**	REPLACEMENT TREATMENT AND PROPHYLAXIS OF THE HEMORRHAGIC COMPLICATIONS OF HEMOPHILIA B. [AUG 20, 1999]	ARMOUR PHARMACEUTICAL
GENERIC: CYSTIC FIBROSIS GENE THERAPY TRADE: NOT ESTABLISHED	TREATMENT OF CYSTIC FIBROSIS.	GENZYME CORPORATION
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: C1-ESTERASE INHIBITOR, HUMAN, PASTEURIZED TRADE: NOT ESTABLISHED	PREVENTION AND/OR TREATMENT OF ACUTE ATTACKS OF HEREDITARY ANGIOEDEMA.	BEHRINGWERKE AKTIENGESellschaft

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: HERPES SIMPLEX VIRUS GENE TRADE: NOT ESTABLISHED	TREATMENT OF PRIMARY AND METASTATIC BRAIN TUMORS.	GENETIC THERAPY, INC
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: IMMUNE GLOBULIN INTRAVENOUS, HUMAN TRADE: IVEEGAM, IMMUNO	TREATMENT OF POLYMYOSITIS/DERMATOMYOSITIS.	IMMUNO CLINICAL RESEARCH CORPORATION
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: INTERFERON (RECOMBINANT HUMAN, BETA) TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE NON-A, NON-B HEPATITIS.	BIOTEN, INC
GENERIC: INTERLEUKIN-1 RECEPTOR ANTAGONIST, HUMAN RECOMBINANT TRADE: ANTRIL	PREVENTION AND TREATMENT OF GRAFT VERSUS HOST DISEASE IN TRANSPLANT RECIPIENTS.	SYNERGEN, INC
GENERIC: PROTEIN C CONCENTRATE TRADE: PROTEIN C CONCENTRATE (HUMAN) VAPOR HEATED, IMMUNO	FOR REPLACEMENT THERAPY IN PATIENTS WITH CONGENITAL OR ACQUIRED PROTEIN C DEFICIENCY FOR THE PREVENTION AND TREATMENT OF WARFARIN-INDUCED SKIN NECROSIS DURING ORAL ANTICOAGULATION. FOR REPLACEMENT THERAPY IN CONGENITAL PROTEIN C DEFICIENCY FOR THE PREVENTION AND TREATMENT OF THROMBOSIS, PULMONARY EMBOLI, AND PURPURA FULMINANS.	IMMUNO CLINICAL RESEARCH CORPORATION

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL

GENERIC: SARGRAMOSTIM
TRADE: LEUKINE*/**

GENERIC: SECRETORY LEUKOCYTE PROTEASE INHIBITOR
TRADE: NOT ESTABLISHED

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

DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]

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]

TREATMENT OF BRONCHOPULMONARY DYSPLASIA.

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.

SPONSOR NAME

IMMUNEX

SYNERGEN, INC

IMMUNOMEDICS, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS
 [Approved for Marketing*]
 [Exclusive Approval**]

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ALLOPURINOL SODIUM TRADE: ZYLOPRIM FOR INJECTION	MANAGEMENT OF PATIENTS WITH LEUKEMIA, LYMPHOMA, AND SOLID TUMOR MALIGNANCIES WHO ARE RECEIVING CANCER THERAPY WHICH CAUSES ELEVATIONS OF SERUM AND URINARY URIC ACID LEVELS AND WHO CANNOT TOLERATE ORAL THERAPY.	BURROUGHS WELLCOME COMPANY
GENERIC: ANARITIDE ACETATE TRADE: AURICULIN	IMPROVEMENT OF EARLY RENAL ALLOGRAFT FUNCTION FOLLOWING RENAL TRANSPLANTATION.	SCIOS, INC
GENERIC: ARGININE BUTYRATE TRADE: NOT ESTABLISHED	TREATMENT OF PATIENTS WITH ACUTE RENAL FAILURE.	SUSAN P. PERRINE, M.D.
GENERIC: BACLOFEN (INTRATHECAL) TRADE: LIORESAL	TREATMENT OF BETA-HEMOGLOBINOPATHIES AND BETA-THALASSEMIA.	MEDTRONIC, INC
GENERIC: BUTYRYLCHOLINESTERASE TRADE: NOT ESTABLISHED	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.	PHARMAVENE, INCORPORATED
GENERIC: DAPSONE TRADE: DAPSONE	FOR THE REDUCTION AND CLEARANCE OF TOXIC BLOOD LEVELS OF COCAINE ENCOUNTERED DURING A DRUG OVERDOSE. TREATMENT OF POST-SURGICAL APNEA.	JACOBUS PHARMACEUTICAL COMPANY
GENERIC: DIANEAL PD-2 PERITONEAL DIALYSIS SOLN WITH 1.1% AMINO ACIDS TRADE: NUTRINEAL PD-2 PERITONEAL DIALYSIS SOLN WITH 1.1% AMINO ACIDS	FOR THE COMBINATION TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA IN CONJUNCTION WITH TRIMETHOPRIM.	BAXTER HEALTHCARE CORPORATION
GENERIC: DIAZEPAM VISCOUS SOLUTION FOR RECTAL ADMINISTRATION TRADE: DIASTAT	FOR USE AS A NUTRITIONAL SUPPLEMENT FOR THE TREATMENT OF MALNOURISHMENT IN PATIENTS UNDERGOING CONTINUOUS AMBULATORY PERITONEAL DIALYSIS.	UPSHER SMITH LABORATORIES, INC
GENERIC: FIAU TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE REPETITIVE SEIZURES. ADJUNCTIVE TREATMENT OF CHRONIC ACTIVE HEPATITIS B.	OCLASSEN PHARMACEUTICALS, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: HALOFANTRINE HCL TRADE: HALFAN*/**	TREATMENT OF MILD TO MODERATE ACUTE MALARIA CAUSED BY SUSCEPTIBLE STRAINS OF P. FALCIPARUM AND P. VIVAX. [JUL 24, 1999]	SMITHKLINE BEECHAM
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: L-THREONINE TRADE: NOT ESTABLISHED	TREATMENT OF SPASTICITY ASSOCIATED WITH FAMILIAL SPASTIC PARAPARESIS.	INTERNEURON PHARMACEUTICALS, INC
GENERIC: LEVOCARNITINE TRADE: CARNITOR*/**	GENETIC CARNITINE DEFICIENCY.* TREATMENT OF MANIFESTATIONS OF CARNITINE DEFICIENCY IN PATIENTS WITH END STAGE RENAL DISEASE (ESRD) WHO REQUIRE DIALYSIS. PREVENTION OF SECONDARY CARNITINE DEFICIENCY IN VALPROIC ACID TOXICITY. TREATMENT OF SECONDARY CARNITINE DEFICIENCY IN VALPROIC ACID TOXICITY.	SIGMA TAU
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: MINOCYCLINE HCL TRADE: MINOCIN	TREATMENT OF CHRONIC MALIGNANT PLEURAL EFFUSION.	LEDERLE LABORATORIES
GENERIC: OXALIPLATIN TRADE: NOT ESTABLISHED	TREATMENT OF OVARIAN CANCER.	AXION PHARMACEUTICALS

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: SODIUM PHENYLBUTYRATE TRADE: NOT ESTABLISHED	TREATMENT OF SICKLING DISORDERS, WHICH INCLUDE S-S HEMOGLOBINOPATHY, S-C HEMOGLOBINOPATHY, AND S-THALASSEMIA HEMOGLOBINOPATHY.	JOHNS HOPKINS MEDICAL INSTITUTIONS
GENERIC: TENIPOSIDE TRADE: VUMON*/**	TREATMENT OF REFRACTORY CHILDHOOD ACUTE LYMPHOBLASTIC LEUKEMIA (ALL). [JUL 14, 1999]	BRISTOL MYERS SQUIBB
GENERIC: ZALCITABINE TRADE: HIVID	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS). [JUN 19, 1999]	ROCHE
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 OCTOBER 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 279, 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
CARBIDOPA AND LEVODOPA (TABLET)	JUN 19, 1992	
CIMETIDINE (TABLET)	JUN 12, 1992	
CORTICOSTEROID <i>IN VITRO</i> AND <i>IN VIVO</i> INTERIM (TOPICAL)	JUL 01, 1992	
DIFLUNISAL (TABLET)	MAY 16, 1992	
DILTIAZEM HYDROCHLORIDE (TABLET)	MAY 16, 1992	
GENFIBROZIL (CAPSULE AND TABLET)	JUN 23, 1989	
METOPROLOL TARTRATE (TABLET)	JUN 12, 1992	
NADOLOL (TABLET)	MAY 16, 1992	
NAPROXEN (TABLET)	JUN 12, 1992	
NORTRIPTYLINE HYDROCHLORIDE (CAPSULE)	JUN 15, 1992	
PIROXICAM (CAPSULE)	JUN 15, 1992	
STATISTICAL PROCEDURE FOR BIOEQUIVALENCE STUDIES USING A STANDARD TWO-TREATMENT CROSSEVER DESIGN		
TERFENADINE (TABLET)	JUL 01, 1992	
	JUN 12, 1992	
		JUN 15, 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.

DRUG NAME DOSAGE FORM; ROUTE	PETITIONS APPROVED			REASON FOR PETITION	STATUS
	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER		
ACETAMINOPHEN; CODEINE PHOSPHATE TABLET; ORAL	500MG 7.5MG	91 P-0514/ CP1	SOFTAN	NEW STRENGTH	APPROVED JUN 03, 1992
	660MG 10MG	91 P-0004/ CP1	KNOLL	NEW STRENGTH	APPROVED OCT 27, 1992
ALBUTEROL SULFATE CAPSULE, EXTENDED RELEASE; ORAL	EQ 4MG BASE	91 P-0348/ CP1	HAWER	NEW DOSAGE FORM	APPROVED MAR 17, 1992
CHLORZOXAZONE TABLET; ORAL	750MG	91 P-0153/ CP1	MIKART	NEW STRENGTH	APPROVED JUN 03, 1992
	EQ 90MG BASE/100ML EQ 120MG BASE/100ML EQ 180MG BASE/100ML EQ 240MG BASE/100ML EQ 360MG BASE/100ML EQ 480MG BASE/100ML	92 P-0337/ CP1	ABBOTT	NEW STRENGTH	APPROVED OCT 26, 1992
HYDROCORTISONE ACETATE AEROSOL; TOPICAL	2.5%	92 P-0101/ CP1	HOGAN & HARTSON	NEW DOSAGE FORM	APPROVED JUL 08, 1992
	10MG/ML (2ML/CONTAINER)	92 P-0224/CP	STERLING	NEW STRENGTH	APPROVED SEP 11, 1992
NALBUPHINE HYDROCHLORIDE INJECTABLE; INJECTION					

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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
TAMOXIFEN CITRATE TABLET; ORAL	EQ 20MG BASE	92 P-0269/ CP1	KROSS	NEW STRENGTH	APPROVED OCT 26, 1992
TRIAZOLAM SOLUTION; ORAL	0.125MG/5ML	92 P-0048/ CP2	ROXANE	NEW DOSAGE FORM	APPROVED SEP 11, 1992

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	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 DOSING SCHEDULE

D-18 LOWER RECOMMENDED STARTING DOSE GUIDELINES

REFERENCES
NEW INDICATION

1-67 TREATMENT OF ACUTE ASTHMATIC ATTACKS IN CHILDREN SIX YEARS OF AGE AND OLDER
 1-68 CENTRAL PRECOCIOUS PUBERTY
 1-69 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
 1-70 USE IN COMBINATION WITH 5-FLUOROURACIL TO PROLONG SURVIVAL IN THE PALLIATIVE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER
 1-71 VARICELLA INFECTIONS (CHICKENPOX)
 1-72 PREVENTION OF CMV DISEASE IN TRANSPLANT PATIENTS AT RISK FOR CMV DISEASE
 1-73 INITIATE AND MAINTAIN MONITORED ANESTHESIA CARE (MAC) SEDATION DURING DIAGNOSTIC PROCEDURES
 1-74 INTRAVENOUS DIGITAL SUBTRACTION ANGIOGRAPHY
 1-75 TREATMENT OF ENDOSCOPICALLY DIAGNOSED EROSIVE ESOPHAGITIS
 1-76 PREVENTION OF OSTEOPOROSIS
 1-77 DERMAL INFECTIONS-TINEA PEDIS, TINEA CORPORIS, TINEA CRURIS DUE TO EPIDERMOPHYTON FLOCCOSUM
 1-78 CONTRAST ENHANCED COMPUTED TOMOGRAPHIC IMAGING OF THE HEAD AND BODY AND INTRAVENOUS EXCRETORY UROGRAPHY
 1-79 MANAGEMENT OF CHRONIC STABLE ANGINA AND ANGINA DUE TO CORONARY ARTERY SPASM
 1-80 DIAGNOSIS AND LOCALIZATION OF ISCHEMIA AND CORONARY HEART DISEASE
 1-81 PROPHYLAXIS IN DESIGNATED IMMUNOCOMPROMISED CONDITIONS TO REDUCE THE INCIDENCE OF OROPHARYNGEAL CANDIDIASIS

REFERENCES
PATENT USE CODE

U-57 OPHTHALMIC USE OF NORFLOXACIN
 U-58 METHOD OF TREATING INFLAMMATORY INTESTINAL DISEASES
 U-59 METHOD OF TREATING HYPERCHOLESTEROLEMIA

EXCLUSIVITY TERMS

REFERENCES

PATENT USE CODE

U-60	NASAL ADMINISTRATION OF BUTORPHANOL
U-61	CEREBRAL AND PERIPHERAL ARTERIOGRAPHY AND CT IMAGING OF THE HEAD
U-62	CORONARY ARTERIOGRAPHY, LEFT VENTRICULOGRAPHY, CT IMAGING OF THE BODY, INTRAVENOUS EXCRETORY UROGRAPHY, INTRAVENOUS DIGITAL SUBTRACTION ANGIOGRAPHY AND VENOGRAPHY
U-63	ISOPRENALINE ANTAGONISM ON THE HEART RATE OR BLOOD PRESSURE
U-64	TREATMENT OF VIRAL INFECTIONS
U-65	METHOD OF TREATMENT OF A PATIENT INFECTED WITH HIV
U-66	TRIPHASIC REGIMEN
U-67	METHOD OF INDUCING ANESTHESIA IN A WARM BLOODED ANIMAL
U-68	TREATMENT OF ACTINIC KERATOSIS

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
20232 001	ACETAMINOPHEN; FIORICET W/ CODEINE				NC	OCT 26, 1993
18828 001	ACYCLOVIR; ZOVIRAX				I-71	FEB 26, 1995
19009 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
19729 001	AMCINONIDE; CYCLOCORT	4158055	JUN 12, 1996	U-19		
19729 001	AMCINONIDE; CYCLOCORT	4158055	JUN 12, 1996	U-34		
19787 001	AMLODIPINE BESYLATE; NORVASC	4572909	FEB 25, 2003		NCE	JUL 31, 1997
19787 002	AMLODIPINE BESYLATE; NORVASC	4572909	FEB 25, 2003		NCE	JUL 31, 1997
19787 003	AMLODIPINE BESYLATE; NORVASC	4572909	FEB 25, 2003		NCE	JUL 31, 1997
19760 001	ATENOLOL; TENORETIC	3934032	JAN 20, 1993			
19760 002	ATENOLOL; TENORETIC	3934032	JAN 20, 1993			
20075 001	BACLOFEN; LIORESAL				ODE	JUN 17, 1999
20075 002	BACLOFEN; LIORESAL				NDF	JUN 17, 1999
19851 001	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2002		ODE	JUN 17, 1999
19851 002	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2002		NDF	JUN 17, 1999
19851 003	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2002		NCE	JUN 25, 1996
19851 004	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2002		NCE	JUN 25, 1996
20033 001	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NCE	JUN 25, 1996
20033 002	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NC	MAY 19, 1995
20033 003	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NCE	JUN 25, 1996
20033 004	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NC	MAY 19, 1995
19001 001	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995		NCE	JUN 25, 1996
19001 002	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995		NC	MAY 19, 1995
19001 003	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
19002 001	BEPRIDIL HYDROCHLORIDE; VASCOR	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
19002 002	BEPRIDIL HYDROCHLORIDE; VASCOR	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
19002 003	BEPRIDIL HYDROCHLORIDE; VASCOR	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
19807 001	BETAXOLOL HYDROCHLORIDE; KERLEDEX	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
19807 002	BETAXOLOL HYDROCHLORIDE; KERLEDEX				NC	OCT 30, 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
19882 001	BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
19882 002	BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
19548 001	BITOLTEROL MESYLATE; TORNALATE	4336400	JUN 22, 1999	U-5		
19890 001	BUTORPHANOL TARTRATE; STADOL	4138581	FEB 06, 1998		NDF	FEB 19, 1995
19847 001	CIPROFLOXACIN; CIPRO	4464378	AUG 07, 2001	U-60	NDF	DEC 12, 1994
		4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
		4670444	OCT 01, 2002			
19857 001	CIPROFLOXACIN; CIPRO IN DEXTROSE 5%	4957922	SEP 18, 2007		NCE	OCT 22, 1992
		4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
		4670444	OCT 01, 2002			
19858 001	CIPROFLOXACIN; CIPRO IN SODIUM CHLORIDE 0.9%	4957922	SEP 18, 2007		NCE	OCT 22, 1992
		4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
		4670444	OCT 01, 2002			
19537 002	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	NCE	OCT 22, 1992
19537 003	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	NCE	OCT 22, 1992
19537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	NCE	OCT 22, 1992
19992 001	CIPROFLOXACIN HYDROCHLORIDE; CILOXAN	4670444	OCT 01, 2002		NDF	DEC 31, 1993
18713 001	CLOTRIMAZOLE; MYCELEX	4670444	OCT 01, 2002		I-81	SEP 29, 1995
20118 001	DESFLURANE; SUPRANE	4762856	AUG 09, 2005	U-67	NCE	SEP 18, 1997
20037 001	DICLOFENAC SODIUM; VOLTAREN	4960799	OCT 02, 2007		NDF	MAR 28, 1994
20154 002	DIDANOSINE; VIDEX				D-18	SEP 25, 1995
20154 003	DIDANOSINE; VIDEX				D-18	SEP 25, 1995
20154 004	DIDANOSINE; VIDEX				D-18	SEP 25, 1995
20154 005	DIDANOSINE; VIDEX				D-18	SEP 25, 1995
20155 003	DIDANOSINE; VIDEX				D-18	SEP 25, 1995
20155 004	DIDANOSINE; VIDEX				D-18	SEP 25, 1995
20155 005	DIDANOSINE; VIDEX				D-18	SEP 25, 1995
20155 006	DIDANOSINE; VIDEX				D-18	SEP 25, 1995
20156 001	DIDANOSINE; VIDEX				D-18	SEP 25, 1995
20027 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM				NCE	NOV 05, 1992
20027 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM				NCE	NOV 05, 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
20062 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776 4894240	MAR 26, 2008 JAN 16, 2007		NCE NS I-79	NOV 05, 1992 MAY 29, 1995 OCT 15, 1995
>ADD>						
20062 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776 4894240	MAR 26, 2008 JAN 16, 2007		NCE NP I-79	NOV 05, 1992 DEC 27, 1994 OCT 15, 1995
>ADD>						
20062 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776 4894240	MAR 26, 2008 JAN 16, 2007		NCE NP I-79	NOV 05, 1992 DEC 27, 1994 OCT 15, 1995
>ADD>						
20062 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776 4894240	MAR 26, 2008 JAN 16, 2007		NCE NP I-79	NOV 05, 1992 DEC 27, 1994 OCT 15, 1995
>ADD>						
20092 001	DILTIAZEM HYDROCHLORIDE; DILACOR XR	4839177	JUN 13, 2006		NS NCE	MAY 29, 1995 NOV 05, 1992
20092 002	DILTIAZEM HYDROCHLORIDE; DILACOR XR	4839177	JUN 13, 2006		NP NCE	DEC 27, 1994 NOV 05, 1992
20092 003	DILTIAZEM HYDROCHLORIDE; DILACOR XR	4839177	JUN 13, 2006		NP NCE	DEC 27, 1994 NOV 05, 1992
19946 001	DOXACURIUM CHLORIDE; NUROMAX	4701460	MAR 06, 2005		NCE	MAR 07, 1996
84499 001	ESTRADIOL; ESTRACE				I-76	SEP 08, 1995
84500 001	ESTRADIOL; ESTRACE				I-76	SEP 08, 1995
19697 001	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN					
19697 002	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN				NP	JUL 03, 1995
19462 001	FAMOTIDINE; PEPCID	4628051	OCT 01, 2002	U-66		JUL 03, 1995
19462 002	FAMOTIDINE; PEPCID	4616006	OCT 07, 2003	U-66		DEC 10, 1994
19527 001	FAMOTIDINE; PEPCID	4544554	JUL 23, 2002	U-66		DEC 10, 1994
19834 001	FELODIPINE; PLENDIL	4027019	MAY 31, 1996	U-66		DEC 10, 1994
19834 002	FELODIPINE; PLENDIL	4628051	OCT 01, 2002	U-66		JUL 25, 1996
20180 001	FINASTERIDE; PROSCAR	4616006	OCT 07, 2003	U-66		JUL 25, 1996
20038 001	FLUDARABINE PHOSPHATE; FLUDARA	4544554 4027019 4283408 4283408 4283408 4264611 4264611 4760071 4377584 4357324	JUL 23, 2002 MAY 31, 1996 AUG 11, 2000 AUG 11, 2000 AUG 11, 2000 APR 28, 1998 APR 28, 1998 JUL 26, 2005 MAR 22, 2000 NOV 02, 2001		NP I-69 I-69 I-69 NCE NCE NCE NCE NCE	JUL 03, 1995 DEC 10, 1994 DEC 10, 1994 DEC 10, 1994 JUL 25, 1996 JUL 25, 1996 JUN 19, 1997 APR 18, 1996

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4626549	DEC 02, 2003			
		4194009	APR 19, 1994			
20068 001	FOSCARNET SODIUM; FOSCAVIR	4018895	APR 19, 1994	U-12		
		4771041	JUL 29, 1997			
		4665062	JUL 29, 1997			
		4339445	JUL 29, 1997	U-64		
19915 002	FOSINOPRIL SODIUM; MONOPRIL	4215113	JUL 29, 1997	U-64	NCE	SEP 27, 1996
19915 003	FOSINOPRIL SODIUM; MONOPRIL	4337201	JUN 29, 2001		NCE	MAY 16, 1996
19661 001	GANCICLOVIR SODIUM; CYTOVENE	4337201	JUN 29, 2001		NCE	MAY 16, 1996
20051 001	GLYBURIDE; GLYNASE	4507305	OCT 19, 1999	U-35	I-72	MAY 15, 1995
		4916163	APR 10, 2007			
		4735805	APR 05, 2005		NCE	MAY 01, 1994
		3507961	APR 21, 1992		NP	MAR 04, 1995
		3507954	APR 21, 1992			
		3454635	APR 21, 1992			
20051 002	GLYBURIDE; GLYNASE	3426067	APR 21, 1992			
		4916163	APR 10, 2007			
		4735805	APR 05, 2005		NCE	MAY 01, 1994
		3507961	APR 21, 1992		NP	MAR 04, 1995
		3507954	APR 21, 1992			
		3454635	APR 21, 1992			
20055 001	GLYBURIDE; GLUBATE	3426067	APR 21, 1992			
20055 002	GLYBURIDE; GLUBATE					
19967 001	HALOBETASOL PROPIONATE; ULTRAVATE					
19968 001	HALOBETASOL PROPIONATE; ULTRAVATE					
202050 001	HALOFANTRINE HYDROCHLORIDE; HALFAN					
19046 001	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994			
19046 002	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994			
19046 003	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994			
19046 004	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 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
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
20100 001	INSULIN BIOSYNTHETIC HUMAN; HUMULIN 50/50				NP	APR 29, 1995
18735 007	IOPAMIDOL; ISOVUE-250				NS	JUL 06, 1995
19710 002	IOVERSOL; OPTIRAY 240	4396598	OCT 26, 2002	U-61	I-78	JUL 09, 1995
19710 004	IOVERSOL; OPTIRAY 300	4396598	OCT 26, 2002	U-62	NS	JAN 22, 1995
19710 005	IOVERSOL; OPTIRAY 350				NS	JAN 22, 1995
20083 001	ITRACONAZOLE; SPORANOX	4267179	MAY 12, 1998		I-74	JAN 22, 1995
19645 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55	NCE	SEP 11, 1997
08107 001	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				NDF	DEC 20, 1994
08107 002	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				NCE	NOV 30, 1994
08107 004	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
08107 005	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT				I-70	DEC 12, 1994
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			
		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
19940 001	MASOPROCOL; ACTINEX	5008294	APR 15, 2008	U-68		
20246 001	MEDROXYPROGESTERONE ACETATE; DEPO-PROVERA	4695590	SEP 22, 2004		NCE	SEP 04, 1997
19651 001	MESALAMINE; ASACOL				NP	OCT 29, 1995
					NCE	DEC 24, 1992
					NDF	JAN 31, 1995
17659 001	METAPROTERENOL SULFATE; ALUPENT				I-67	NOV 14, 1994

>ADD>
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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
19962 001	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992		NE	JAN 10, 1995
		3876802	APR 08, 1992			
19962 002	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992		NE	JAN 10, 1995
		3876802	APR 08, 1992			
19962 003	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992		NE	JAN 10, 1995
		3876802	APR 08, 1992			
20208 001	METRONIDAZOLE; METROGEL					
20098 001	MIVACURIUM CHLORIDE; MIVACRON	4761418	AUG 02, 2005		NDF	AUG 17, 1995
20098 002	MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5%	4761418	AUG 02, 2005		NCE	JAN 22, 1997
19583 001	NABUMETONE; RELAFEN	4420639	DEC 13, 2000		NCE	JAN 22, 1997
		4061779	DEC 06, 1994	U-19		DEC 24, 1996
19583 002	NABUMETONE; RELAFEN	4420639	DEC 13, 2000		NCE	DEC 24, 1996
		4061779	DEC 06, 1994	U-19		
19886 001	NAFARELIN ACETATE; SYNAREL					
20109 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1997		I-68	FEB 26, 1995
					NCE	FEB 13, 1995
19734 001	NICARDIPINE HYDROCHLORIDE; CARDENE				I-68	FEB 26, 1995
		3985758	OCT 12, 1995		NDF	JAN 30, 1995
20005 001	NICARDIPINE HYDROCHLORIDE; CARDENE SR				NCE	DEC 21, 1993
		3985758	OCT 12, 1995		NDF	FEB 21, 1995
20005 002	NICARDIPINE HYDROCHLORIDE; CARDENE SR				NCE	DEC 21, 1993
		3985758	OCT 12, 1995		NDF	FEB 21, 1995
20005 003	NICARDIPINE HYDROCHLORIDE; CARDENE SR				NCE	DEC 21, 1993
		3985758	OCT 12, 1995		NDF	FEB 21, 1995
19983 001	NICOTINE; PROSTEP				NCE	DEC 21, 1993
19983 002	NICOTINE; PROSTEP	4946853	AUG 07, 2007	U-56	NS	JAN 28, 1995
20076 001	NICOTINE; HABITROL	4946853	AUG 07, 2007	U-56	NS	JAN 28, 1995
20076 002	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
20076 003	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
20150 001	NICOTINE; NICOTROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
20150 002	NICOTINE; NICOTROL				NP	APR 22, 1995
20150 003	NICOTINE; NICOTROL				NP	APR 22, 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
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
20066 001	NICOTINE POLACRILEX; NICORETTE DS				NP	JUN 08, 1995
20064 001	NITROFURANTOIN; MACROBID	4798725	JAN 17, 2006			
		4772473	SEP 20, 2005		NDF	DEC 24, 1994
		4551456	NOV 05, 2002	U-57		
19757 001	NORFLOXACIN; CHIBROXIN	4382892	MAY 10, 2000		NCE	DEC 28, 1995
20087 001	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4382892	MAY 10, 2000		NCE	DEC 28, 1995
20087 002	OFLOXACIN; FLOXIN	4382892	MAY 10, 2000		NCE	DEC 28, 1995
20087 003	OFLOXACIN; FLOXIN	4382892	MAY 10, 2000		NCE	DEC 28, 1995
20087 004	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4382892	MAY 10, 2000		NCE	DEC 28, 1995
20087 005	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4382892	MAY 10, 2000		NCE	DEC 28, 1995
19715 001	OLSALAZINE SODIUM; DIPENTUM	4382892	MAY 10, 2000		NCE	DEC 28, 1995
18841 004	OXAPROZIN; DAYPRO	4559330	AUG 04, 2004	U-58		
19828 001	OXICONAZOLE NITRATE; OXISTAT					
20209 001	OXICONAZOLE NITRATE; OXISTAT					
19775 001	PRazosin HYDROCHLORIDE; MINIPRESS XL	5082668	SEP 16, 2003			
		4783337	SEP 16, 2003			
		4765989	SEP 16, 2003			
		4612008	SEP 16, 2003			
		4327725	MAY 04, 1999			
		4092315	MAY 30, 1995		NDF	JAN 29, 1995
19775 002	PRazosin HYDROCHLORIDE; MINIPRESS XL	5082668	SEP 16, 2003			
		4783337	SEP 16, 2003			
		4765989	SEP 16, 2003			
		4612008	SEP 16, 2003			
		4327725	MAY 04, 1999			
		4092315	MAY 30, 1995			
19157 001	PREDNISOLONE SODIUM PHOSPHATE; PEDIAPRED	4448774	MAY 15, 2001		NDF	JAN 29, 1995
19627 001	PROPOFOL; DIPRIVAN	4798846	NOV 01, 1996			
18703 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4521431	JUN 04, 2002		1-73	DEC 31, 1994
		4521431	JUN 04, 2002		1-75	MAY 19, 1995
18703 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300				1-75	MAY 19, 1995

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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
19675 001	RANITIDINE HYDROCHLORIDE; ZANTAC	4128658	DEC 05, 1995		I-75	MAY 19, 1995
19766 001	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
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	FEB 14, 1997
19865 001	SOTALOL HYDROCHLORIDE; BETAPACE				NCE	OCT 30, 1997
19865 002	SOTALOL HYDROCHLORIDE; BETAPACE				NCE	OCT 30, 1997
19865 003	SOTALOL HYDROCHLORIDE; BETAPACE				NCE	OCT 30, 1997
20063 001	TECHNETIUM TC-99M RED BLOOD CELL KIT; RBC-SCAN				NP	JUN 11, 1995
19785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE				I-80	SEP 09, 1995
20043 003	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	MAR 08, 2005	U-36	NCE	JAN 30, 1997
20043 004	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	MAR 08, 2005	U-36	NCE	JAN 30, 1997
20119 001	TENIPOSIDE; VUMON				NCE	JUL 14, 1997
19614 003	VERAPAMIL HYDROCHLORIDE; VERELAN				ODE	JUL 14, 1999
20199 001	ZALCITABINE; HIVID	4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993
		5028595	JUL 02, 2008	U-65	NCE	JUN 19, 1997
20199 002	ZALCITABINE; HIVID	4879277	NOV 07, 2006	U-65	ODE	JUN 19, 1999
		5028595	JUL 02, 2008	U-65	NCE	JUN 19, 1997
19655 001	ZIDOVUDINE; RETROVIR	4879277	NOV 07, 2006	U-65	ODE	JUN 19, 1999
		4837208	FEB 09, 2005			
		4833130	FEB 09, 2005		I-47	MAY 02, 1993
19910 001	ZIDOVUDINE; RETROVIR	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
19951 001	ZIDOVUDINE; RETROVIR	4818538	FEB 09, 2005		I-47	MAY 02, 1993
		4724232	FEB 09, 2005		NCE	MAR 19, 1992
		4837208	FEB 09, 2005			
		4833130	FEB 09, 2005		NCE	MAR 19, 1992
		4818538	FEB 09, 2005			
		4724232	FEB 09, 2005		ODE	MAR 19, 1994

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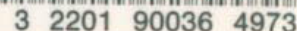
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