

CUMULATIVE
SUPPLEMENT 5

JAN'95-MAY'95

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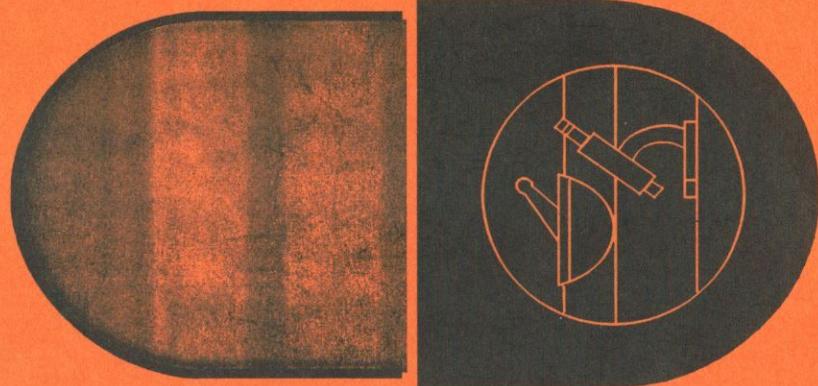
APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

15TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT
DIVISION OF DRUG INFORMATION RESOURCES



RM
301.45
.A66
1995
May 15
Suppl

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

1.0
1.1
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APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS

15TH EDITION

Cumulative Supplement 5

MAY 1995

RM301.45 .A66 1995 May Suppl

Approved drug products with
therapeutic equivalence

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

15TH EDITION

CUMULATIVE SUPPLEMENT 5
MAY 1995

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, 15th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.

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 shaded print. The >**DLT**> symbol is dropped in subsequent Cumulative Supplements for that item. The shaded print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the shaded 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 15th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 16th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required

to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the appropriate Drug Product List.

<u>Products</u>	<u>Federal Register Reference</u>
Nitroglycerin (capsule, controlled release;oral)	SEP 07, 1984 (49 FR 35428)
Nitroglycerin (film, extended release; transdermal*)	JUL 15, 1993 (58 FR 38129)
Nitroglycerin (tablet, controlled release;oral)	SEP 07, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 05, 1985 (50 FR 27688)

*The Federal Register of July 15, 1993 (58 FR 38129) announced that the FDA was revoking the temporary exemption for nitroglycerin in a transdermal delivery system. Marketing of a drug product that is the subject of a conditionally approved ANDA may continue by meeting the requirements listed in the Federal Register. Firms wishing to submit a new ANDA before a drug product is approved (NDA or ANDA) and appears in the List should submit a 505(b)(2) application following the directions contained in the Federal Register. Nitro-Dur has been selected as the reference listed drug. The preamble to the final rule (57 FR 17958) states if there are multiple NDA's, the reference listed drug generally will be the market leader. This is the basis upon which Nitro-Dur was selected. In addition, the preamble states that, in multiple NDA situations, a product not designated as the reference listed drug and not shown to be bioequivalent to the reference listed drug may be shielded from generic competition. This is the case with Summit's Transderm-Nitro. The Office of Generic Drugs (OGD) has been requested to have a second listed drug as provided for in the Final Rule. OGD has granted this request. Therefore, at the time that Schering's and Summit's supplements are fully approved and their products are entered into the List, we will have two reference listed drugs for the nitroglycerin transdermal systems. Firms may, therefore, elect to conduct bioequivalence studies against either of these products. It is conceivable that a non-referenced listed drug may be fully approved and appear in the List; in this case, the Agency's referenced listed drug will not change and a 505(b)(2) application will be appropriate until the reference listed drugs are fully approved. Once they are fully approved, a 505(j) application will be the appropriate mechanism for an ANDA submission.

1.3 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation

of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will automatically reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section. However, when the applicant name change is one which may not be easily recognized or located in the listing (e.g., White Towne Paulsen [Former Abbreviated Name] is changed to Whiteworth Towne [New Abbreviated Name], the name change will appear in this section and will be identified with an asterisk.

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)

BOOTS PHARMACEUTICALS INC
(BOOTS)

BRIAN PHARMACEUTICALS INC
(BRIAN)

DORSEY LABORATORIES DIV
SANDOZ WANDER INC
(DORSEY)

MILES PHARMACEUTICAL DIV
MILES INC
(MILES)

PENNEX PHARMACEUTICALS INC
(PENNEX)

TAP PHARMACEUTICALS INC
(TAP PHARMS)

NEW APPLICANT NAME (NEW ABBREVIATED NAME)

KNOLL PHARMACEUTICAL COMPANY
SUB BASF CORPORATION
(KNOLL PHARM)

HYGENICS PHARMACEUTICALS INC
(HYGENICS)

SANDOZ CONSUMER HEALTH CARE
GROUP DIV SANDOZ
PHARMACEUTICALS CORP
(SANDOZ)

BAYER CORPORATION
(BAYER)

MORTON GROVE PHARMACEUTICALS INC
(MORTON GROVE)

TAP HOLDINGS INC
(TAP HOLDINGS)

1.4 AVAILABILITY OF THE PUBLICATION AND UPDATING PROCEDURES

The *Approved Drug Products with Therapeutic Equivalence Evaluations* (Prescription Drug Products, OTC Drug Products and the Discontinued Drug Product Lists) is now available on diskette, on a quarterly basis, from the National Technical Information Service. The telephone number for the Subscription Department is (703) 487-6430. Written inquiries regarding this subscription may be forwarded to 5285 Port Royal Road Springfield, VA 22161.

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 1994) 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

CATEGORIES COUNTED	DEC 1994	MAR 1995	JUN 1995	SEP 1995
DRUG PRODUCTS LISTED	9141	9195		
SINGLE SOURCE	2178 (23.8%)	2186 (23.8%)		
MULTI-SOURCE	6963 (76.2%)	7009 (76.2%)		
THERAPEUTICALLY EQUIVALENT	6330 (69.2%)	6380 (69.4%)		
NOT THERAPEUTICALLY EQUIVALENT	453 (5.0%)	453 (4.9%)		
EXCEPTIONS ¹	180 (2.0%)	176 (1.9%)		
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	534	541		

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

AMPICILLIN SODIUMINJECTABLE; INJECTION

AMPICILLIN SODIUM
@ CONSOLIDATED PHARM EQ 125MG BASE/VIAL
 EQ 250MG BASE/VIAL
 EQ 500MG BASE/VIAL
@ EQ 1GM BASE/VIAL
 EQ 2GM BASE/VIAL
COPANOS EQ 125MG BASE/VIAL
 EQ 250MG BASE/VIAL
 EQ 500MG BASE/VIAL
@ EQ 1GM BASE/VIAL
 EQ 2GM BASE/VIAL

N61936 005
 N61936 001
 N61936 002
 N61936 003
 N61936 004
 N61936 005
 N61936 001
 N61936 002
 N61936 003
 N61936 004

AB ATENOLOL
COBLEY PHARM
5.0MG
100MG
5.0MG
100MG
5.0MG
100MG
5.0MG
100MG
AB LEMMON
AB MARTEC
AB AB
AB AB

N74120 001
 FEB 24, 1995
N74120 002
 FEB 24, 1995
N74056 001
 JAN 18, 1995
N74056 002
 JAN 18, 1995
N74127 001
 FEB 21, 1995
N74127 002
 FEB 21, 1995

AMPICILLIN/AMPICILLIN TRIHYDRATECAPSULE; ORAL

AMPICILLIN TRIHYDRATE
CONSOLIDATED PHARM EQ 250MG BASE
EQ 500MG BASE
EQ 250MG BASE
EQ 500MG BASE
COPANOS

N61602 001
 N61602 002
N61602 001
N61602 002

AB ATENOLOL
COBLEY PHARM
5.0MG
100MG
5.0MG
100MG
5.0MG
100MG
AB LEMMON
AB MARTEC
AB AB
AB AB

CAPSULE; ORAL

AMPICILLIN TRIHYDRATE
CONSOLIDATED PHARM EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
COPANOS

N61601 001
 N61601 002
N61601 001
N61601 002

AB ATENOLOL
COBLEY PHARM
5.0MG
100MG
5.0MG
100MG
AB LEMMON
AB MARTEC
AB AB
AB AB

POWDER FOR RECONSTITUTION; ORAL

AMPICILLIN TRIHYDRATE
CONSOLIDATED PHARM EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
POLYCILLIN

N61601 001
 N61601 002
N61601 001
N61601 002
POLYCILLIN

AB ATENOLOL
COBLEY PHARM
5.0MG
100MG
5.0MG
100MG
AB LEMMON
AB MARTEC
AB AB
AB AB

ANTAZOLINE PHOSPHATE; NAPHAZOLINE HYDROCHLORIDESOLUTION/DROPS; OPHTHALMIC

VISOCON-A
+ CIBA VISION 0.5% 0.05%

N18746 001
 APR 30, 1990
AT BACITRACIN ZINC AND POLYMYXIN B SULFATE
ADV REMEDIES
500 UNITS/GM;
10,000 UNITS/GM

ASPIRIN; METHOCARBAMOL

STEVENS J
METHOCARBAMOL AND ASPIRIN
325MG/400MG

N81145 001
 JAN 31, 1995
AT POLYSPORIN
+ BURROUGHS WELLCOME
500 UNITS/GM;
10,000 UNITS/GM

ATENOLOLTABLET; ORAL

ATENOLOL
COBLEY PHARM
5.0MG
100MG
5.0MG
100MG
AB LEMMON
AB MARTEC
AB AB
AB AB

N74120 001
 FEB 24, 1995
N74120 002
 FEB 24, 1995
N74056 001
 JAN 18, 1995
N74056 002
 JAN 18, 1995
N74127 001
 FEB 21, 1995
N74127 002
 FEB 21, 1995

OINTMENT; OPHTHALMIC
BACITRACIN ZINC AND POLYMYXIN B SULFATE
ADV REMEDIES
500 UNITS/GM;
10,000 UNITS/GM

N64028 001
 JAN 30, 1995
AT BAUSCH AND LOMB
500 UNITS/GM;
10,000 UNITS/GM

N64046 001
 JAN 26, 1995

BENDROFLUMETHIAZIDE

TABLET; ORAL
NATURETIN-1.0
 + APOTHECON
 * SQUIBB
NATURETIN-2.5
 @ APOTHECON
 * SQUIBB
NATURETIN-5
 APOTHECON
 SQUIBB

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

N12164 003	> ADD >	AP
N12164 003	> ADD >	AP
N12164 001	> ADD >	AP
N12164 001	> DLT >	AP
N12164 002	> DLT >	AP
N12164 002	> DLT >	AP

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
MARCAINE HCL
 + SANOFI WINTHROP
 0.25%
 0.5%
 0.75%
 0.25%
 0.5%
 0.75%

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

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE

N17954 001	> ADD >	AP
N17954 001	> ADD >	AP
N17954 001	> DLT >	AP
N17954 001	> DLT >	AP
N17954 001	> DLT >	AP

INJECTABLE; INJECTION
MARCAINE HCL W/ EPINEPHRINE
 + SANOFI WINTHROP
 0.25%; 0.0091MG/ML
 0.5%; 0.0091MG/ML
 0.75%; 0.0091MG/ML
 0.25%; 0.0091MG/ML
 0.5%; 0.0091MG/ML
 0.75%; 0.0091MG/ML

CALCITONIN, SALMON

N74441 001	> ADD >	AP
JAN 27, 1995	> ADD >	AP
N74441 001	> DLT >	AP
JAN 27, 1995	> DLT >	AP
N74441 001	> DLT >	AP

INJECTABLE; INJECTION
CALCITONIN-SALMON
 ASTRA
 200 IU/ML

N73690 001

APR 14, 1995

INJECTABLE; INJECTION
BUMETANIDE
 BEDFORD
0.25MG/ML

TABLET; ORAL
BUMETANIDE
 ZENITH LABS

AP
0.5MG
1MG
2MG

AB
0.5MG
1MG
2MG

AB
0.5MG
1MG
2MG

AB
0.5MG
1MG
2MG

N74225 001	APR 24, 1995	AB
N74225 002	APR 24, 1995	AB
N74225 003	APR 24, 1995	AB
N18225 002	FEB 28, 1983	AB
N18225 001	FEB 28, 1983	AB
N18225 003	JUN 14, 1985	AB

N18343 005	JUN 17, 1985	AB
N18343 002	N18343 001	AB
N18343 003	N18343 003	AB
N74472 001	MAR 31, 1995	AB
N74472 002	MAR 31, 1995	AB
N74472 003	MAR 31, 1995	AB

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL
AB APOTHECON

100MG

N74472 004
 MAR 31, 1995

CARBACHOL

SOLUTION; INTRAOCULAR
CARBASTAT
AT CIBA

0.01%

N73677 001
 APR 28, 1995

MIOSTAT
AT + ALCON

0.01%

CEFACLOR

CAPSULE; ORAL
CECLOR
AB + LILLY

CEFACLOR

LEDERLE
AB +
AB +
AB +
AB +

N50521 001
 EQ 250MG BASE
 N62205 001
 EQ 250MG BASE
 N50521 002
 EQ 500MG BASE

N62205 002
 > DLT >
 > ADD >

N64107 001
 APR 27, 1995
 N64107 002
 APR 27, 1995
 N64061 001
 APR 27, 1995
 N64061 002
 APR 27, 1995

POWDER FOR RECONSTITUTION; ORAL
CECLOR
AB + LILLY

CEFACLOR

LEDERLE
AB +
AB +

N50522 001
 EQ 125MG BASE/5ML
 N62206 001
 EQ 125MG BASE/5ML
 N62206 003
 EQ 187MG BASE/5ML
 APR 20, 1988

N50522 002
 EQ 250MG BASE/5ML
 N62206 002
 EQ 250MG BASE/5ML
 N62206 004
 APR 20, 1988

N64114 001
 EQ 125MG BASE/5ML
 APR 28, 1995

CEFACLOR

POWDER FOR RECONSTITUTION; ORAL
CEFACLOR
LEDERLE

AB
AB
AB
AB
AB
AB

N74472 004
 MAR 31, 1995

ZENITH LABS
AB
AB
AB
AB
AB

EQ 187MG BASE/5ML
EQ 250MG BASE/5ML
EQ 375MG BASE/5ML
EQ 125MG BASE/5ML
EQ 187MG BASE/5ML
EQ 250MG BASE/5ML
EQ 375MG BASE/5ML

CEFAMANDOLE NAFAATE

INJECTABLE; INJECTION
MANDOL
LILLY
 @

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM
EIKINS SINK
 @

EQ 500MG BASE/VIAL
EQ 500MG BASE/VIAL
EQ 250MG BASE/VIAL
EQ 500MG BASE/VIAL
EQ 1GM BASE/VIAL
EQ 5GM BASE/VIAL
EQ 1GM BASE/VIAL
EQ 5GM BASE/VIAL
EQ 10GM BASE/VIAL
EQ 20GM BASE/VIAL
EQ 250MG BASE/VIAL
EQ 500MG BASE/VIAL
EQ 125MG BASE/5ML
EQ 125MG BASE/5ML
EQ 187MG BASE/5ML
 JAN 12, 1988
 N50504 001
 N50504 001

N62207 001
 JAN 12, 1988

N62207 002
 JAN 12, 1988

N62207 003
 JAN 12, 1988

N62207 004
 JAN 12, 1988

N62207 005
 JAN 12, 1988

N62207 006
 JAN 12, 1988

N62207 007
 JAN 12, 1988

JAN 12, 1988

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

@ ELKINS SINN

EQ 1GM BASE/VIAL

N62807 003 JAN 12, 1988

EQ 5GM BASE/VIAL

N62807 004 JAN 12, 1988

EQ 10GM BASE/VIAL

N62807 005 JAN 12, 1988

EQ 20GM BASE/VIAL

N62807 006 JAN 12, 1988

EQ 20GM BASE/VIAL

N62807 007 JAN 12, 1988

CEFOPERAZONE SODIUM

INJECTABLE; INJECTION

CEFOBID

PFIZER

EQ 1GM BASE/VIAL

N63333 001 MAR 31, 1995

EQ 2GM BASE/VIAL

N63333 002 MAR 31, 1995

CEFONANIDE

INJECTABLE; INJECTION

PRECEF

APOTHECON

500MG/VIAL

N62579 001 NOV 26, 1984

1GM/VIAL

N62579 002 NOV 26, 1984

2GM/VIAL

N62579 003 NOV 26, 1984

10GM/VIAL

N62579 004 NOV 26, 1984

20GM/VIAL

N62579 005 NOV 26, 1984

500MG/VIAL

N62579 001 NOV 26, 1984

1GM/VIAL

N62579 002 NOV 26, 1984

2GM/VIAL

N62579 003 NOV 26, 1984

10GM/VIAL

N62579 004 NOV 26, 1984

20GM/VIAL

N62579 005 NOV 26, 1984

CEFOXITIN SODIUM

INJECTABLE; INJECTION

MEPOXIN

+ MERCK SHARP DOHME

EQ 20MG BASE/ML

SEP 20, 1984

EQ 40MG BASE/ML

SEP 20, 1984

EQ 20MG BASE/ML

SEP 20, 1984

EQ 40MG BASE/ML

SEP 20, 1984

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN

+ ROCHE

EQ 250MG BASE/VIAL

DEC 21, 1984

EQ 500MG BASE/VIAL

DEC 21, 1984

EQ 1GM BASE/VIAL

DEC 21, 1984

EQ 250MG BASE/VIAL

DEC 21, 1984

EQ 500MG BASE/VIAL

DEC 21, 1984

EQ 1GM BASE/VIAL

DEC 21, 1984

EQ 250MG BASE/VIAL

DEC 21, 1984

EQ 500MG BASE/VIAL

DEC 21, 1984

EQ 1GM BASE/VIAL

DEC 21, 1984

EQ 250MG BASE/VIAL

DEC 21, 1984

EQ 500MG BASE/VIAL

DEC 21, 1984

EQ 1GM BASE/VIAL

DEC 21, 1984

EQ 250MG BASE/VIAL

DEC 21, 1984

EQ 500MG BASE/VIAL

DEC 21, 1984

<u>CEPHALEXIN</u>		<u>CHLORAMPHENICOL</u>	
> ADD >	<u>AB</u>	<u>POWDER FOR RECONSTITUTION; ORAL CEPHALEXIN APOTHECON</u>	<u>EQ 125MG BASE/5ML</u>
> ADD >	<u>AB</u>		<u>N62986 001 APR 18, 1991</u>
> ADD >	<u>AB</u>		<u>N62987 001 JUL 25, 1989</u>
> ADD >	<u>AB</u>		<u>N62986 001 APR 18, 1991</u>
> DLT >	<u>AB</u>	<u>SQUIBB MARK</u>	<u>EQ 125MG BASE/5ML</u>
> DLT >	<u>AB</u>		<u>N62987 001 APR 18, 1991</u>
> DLT >	<u>AB</u>		<u>N62987 001 JUL 25, 1989</u>
> DLT >	<u>AB</u>		<u>N63593 001 N86095 001 N86095 001</u>
		<u>CEPHRADINE</u>	
		<u>CAPSULE; ORAL VELOSEF</u>	<u>CHLORPROMAZINE HYDROCHLORIDE</u>
> ADD >	<u>AB</u>	<u>+ APOTHECON</u>	<u>250MG</u>
> ADD >	<u>AB</u>	<u>+ ERSANA</u>	<u>N61764 001 N61764 002 N61764 002</u>
> DLT >	<u>AB</u>	<u>* ERSANA</u>	
> DLT >	<u>AB</u>		<u>N85591 001 N85591 001</u>
		<u>INJECTABLE; INJECTION VELOSEF</u>	<u>CHLORPROMAZINE HYDROCHLORIDE</u>
> ADD >	<u>AB</u>	<u>+ APOTHECON</u>	<u>250MG/VIAL</u>
> ADD >	<u>AB</u>		<u>500MG/VIAL</u>
> DLT >	<u>AB</u>		<u>1GM/VIAL</u>
> DLT >	<u>AB</u>		<u>2GM/VIAL</u>
> ADD >	<u>AB</u>		<u>4GM/VIAL</u>
> ADD >	<u>AB</u>		<u>250MG/VIAL</u>
> DLT >	<u>AB</u>	<u>SQUIBB</u>	<u>500MG/VIAL</u>
> DLT >	<u>AB</u>		<u>1GM/VIAL</u>
> DLT >	<u>AB</u>		<u>2GM/VIAL</u>
> DLT >	<u>AB</u>		<u>4GM/VIAL</u>
> DLT >	<u>AB</u>		<u>N61976 001 N61976 002 N61976 004 N61976 003 N61976 005 N61976 001 N61976 002 N61976 004 N61976 003 N61976 005</u>
		<u>POWDER FOR RECONSTITUTION; ORAL VELOSEF '125, APOTHECON</u>	<u>CHLORPROPAMIDE</u>
> ADD >	<u>AB</u>	<u>+ ERSANA</u>	<u>250MG/5ML</u>
> DLT >	<u>AB</u>	<u>* ERSANA</u>	<u>125MG/5ML</u>
> ADD >	<u>AB</u>	<u>VELOSEF '250, APOTHECON</u>	<u>125MG/5ML</u>
> DLT >	<u>AB</u>	<u>* ERSANA</u>	<u>250MG/5ML</u>
			<u>N61763 001 N61763 002</u>
		<u>CHLORAMPHENICOL</u>	<u>CHOLESTYRAMINE</u>
		<u>CAPSULE; ORAL MYCHEL</u>	<u>BAR, CHEWABLE; ORAL CHOLYBAR</u>
			<u>* PARKE DAVIS</u>
			<u>EQ 4GM RESIN/BAR</u>
			<u>EQ 4GM RESIN/BAR</u>
			<u>N71621 001 MAY 26, 1988</u>
			<u>N71739 001 MAY 26, 1988</u>
			<u>N71739 001 MAY 26, 1988</u>
		<u>ARMENPHARM</u>	<u>250MG</u>
			<u>N60851 001</u>

CHOLESTYRAMINE

BAR, CHEWABLE; ORAL
CHOLYBAR
 @ PARKE DAVIS

EQ 4 GM RESIN/BAR	EQ 4 GM RESIN/BAR
MAY 26, 1988	N71621 001
@	N71739 001
EQ 4 GM RESIN/BAR	MAY 26, 1988

<u>TABLET; ORAL</u>	<u>BRISTOL MYERS SQUIBB</u>	<u>EQ 1GM RESIN</u>
@	EQ 1GM RESIN	APR 28, 1994

CIMETIDINE

TABLET; ORAL
CIMETIDINE
 AB GENEVA FARMS

<u>200MG</u>	N74100 001 JAN 31, 1995
<u>300MG</u>	N74100 002 JAN 31, 1995
<u>400MG</u>	N74100 003 JAN 31, 1995
<u>800MG</u>	N74100 004 JAN 31, 1995
<u>200MG</u>	N74365 001 FEB 28, 1995
<u>300MG</u>	N74365 002 FEB 28, 1995
<u>400MG</u>	N74365 003 FEB 28, 1995
<u>800MG</u>	N74365 004 FEB 28, 1995
<u>200MG</u>	N74401 001 MAY 30, 1995
<u>300MG</u>	N74401 002 MAY 30, 1995
<u>400MG</u>	N74401 003 MAY 30, 1995
<u>800MG</u>	N74402 001 MAY 30, 1995

ZENITH LABS

> ADD >
 > ADD >

<u>1%</u>	<u>N74221 001</u>
<u>1%</u>	<u>MAR 31, 1995</u>
<u>1%</u>	<u>N73306 001</u>
<u>1%</u>	<u>FEB 28, 1995</u>
<u>CLOTRIMAZOLE</u>	<u>SOLUTION; TOPICAL</u>
<u>AT LEMMON</u>	<u>CLOTRIMAZOLE</u>
<u>AT</u>	<u>SOLUTION; TOPICAL</u>
<u>AT</u>	<u>CLOTRIMAZOLE</u>
<u>AT</u>	<u>CLOTRIMAZOLE</u>
<u>ACTH</u>	<u>INJECTABLE; INJECTION</u>
<u>AP (R)</u>	<u>PARKER DAVIS</u>
<u>40 UNITS/VIAL</u>	<u>40 UNITS/VIAL</u>
<u>NO8317 004</u>	<u>NO8317 004</u>
<u>40 UNITS/VIAL</u>	<u>40 UNITS/VIAL</u>

CIMETIDINE HYDROCHLORIDE

<u>INJECTABLE; INJECTION</u>	<u>CIMETIDINE HCL</u>
<u>AP ABBOTT</u>	<u>EQ 300MG BASE/2ML</u>
<u>AP</u>	<u>EQ 300MG BASE/2ML</u>
<u>AP</u>	<u>EQ 300MG BASE/2ML</u>
<u>N74344 001</u>	<u>JAN 31, 1995</u>
<u>N74345 001</u>	<u>JAN 31, 1995</u>
<u>N74422 001</u>	<u>JAN 31, 1995</u>

<u>NS0537 002</u>	<u>FEB 22, 1994</u>
<u>N73403 001</u>	<u>APR 28, 1994</u>
<u>N73403 001</u>	<u>APR 28, 1994</u>
<u>CLINDAMYCIN PHOSPHATE</u>	<u>SOLUTION; TOPICAL</u>
<u>CLICOCIN UPJOHN</u>	<u>EQ 1% BASE</u>
<u>SWAB; TOPICAL</u>	<u>CLEOCIN UPJOHN</u>
<u>EQ 1% BASE</u>	<u>EQ 1% BASE</u>
<u>N50537 002</u>	<u>FEB 22, 1994</u>

CROMOLYN SODIUM

SOLUTION/DROPS; OPHTHALMIC
CROLOM
AT BAUSCH AND LOMB 4%

AT + OPTICROM 4%

AT + FISONS 4%

CYANOCOBALAMIN

INJECTABLE; INJECTION
 CYANOCOBALAMIN

@ WARNER CHILCOTT
RUBRAMIN PC
AP * SQUIBB 0.1MG/ML
AP @ SYTOBEX 0.1MG/ML
AP PARKE DAVIS 1MG/ML

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
CYCLOBENZAPRINE HCL
AB BARR 10MG

> ADD >
> ADD >

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL
CYPROHEPTADINE HCL

AB ASCOT 4MG
@ 4MG
> ADD >

> ADD >

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

N87685 001
OCT 25, 1982
N87685 001
OCT 25, 1982

DAUNORUBICIN HYDROCHLORIDE
INJECTABLE; INJECTION
DAUNORUBICIN HCL

AP CETUS BEN VENUE EQ 20MG BASE/VIAL

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION
DDAVP
+ RHONE POULENC RORER 0.015MG/ML

AT N74443 001
JAN 30, 1995

AT N18155 001
OCT 03, 1984

CYANOCOBALAMIN

SPRAY, METERED, NASAL
DESMOPRESSIN ACETATE
+ RHONE POULENC RORER 0.15MG/INH

STIMATE
+ RHONE POULENC RORER 0.15MG/INH

INJECTABLE; INJECTION
CYANOCOBALAMIN

N07085 002
NO6799 002
N06799 002
N07085 002

DESOGESTREL; ETHINYL ESTRADIOL
TABLET; ORAL - 21
DESOGEN
* ORGANON

AB @
ORTHO-CEPT
JOHNSON RW

N20071 001
DEC 10, 1992

N20071 001
DEC 10, 1992

DEXAMETHASONE

AEROSOL; TOPICAL
DECASPRAY
* MERCK SHARP DOHME
+
TABLET; ORAL
HEXDROL

N20301 001
DEC 14, 1992

N20301 001
DEC 14, 1992

N12675 001
N12675 007
N12675 009
N12675 004
N12675 007
N12675 009

N12675 001
N12675 007
N12675 009
N12675 004
N12675 007
N12675 009

N64103 001
FEB 03, 1995

> ADD >		<u>DEXRAZOXANE HYDROCHLORIDE</u>		<u>DILTIAZEM HYDROCHLORIDE</u>	
> ADD >	INJECTABLE; INJECTION			TABLET; ORAL	
> ADD >	ZINECARD	EQ 250MG BASE/VIAL	N20212 001	<u>DILTIAZEM HCL</u>	<u>3.0MG</u>
> ADD >	+ PHARMACIA		MAY 26, 1995	AB	
> ADD >			> ADD >	AB	MAY 31, 1995
> ADD >		EQ 500MG BASE/VIAL	N20212 002	> ADD >	<u>6.0MG</u>
> ADD >			MAY 26, 1995	> ADD >	
> ADD >				> ADD >	<u>9.0MG</u>
	DEXTROSE			> ADD >	
	INJECTABLE; INJECTION			> ADD >	<u>12.0MG</u>
	DEXTROSE 2.5% IN PLASTIC CONTAINER			> ADD >	
	MCGAW	2.5GM/100ML	N19626 001	AB	
@			FEB 02, 1988	AB	
		2.5GM/100ML	N19626 001		<u>N74168 001</u>
			FEB 02, 1988	AB	MAR 03, 1995
	DEXTROSE 7.7% IN PLASTIC CONTAINER		N19626 003	AB	
	MCGAN	7.7GM/100ML	FEB 02, 1988		<u>N74168 002</u>
@			N19626 003		MAR 03, 1995
		7.7GM/100ML	FEB 02, 1988		
			N19626 003		
			FEB 02, 1988		
	DIAZEPAM				
	INJECTABLE; INJECTION				
	<u>DIAZEPAM</u>	<u>5MG/ML</u>			
	FUJISAWA				
@			N70662 001		<u>5.0MG/ML</u>
			JUN 25, 1986		
			N70662 001		
			JUN 25, 1986		
	DICLOFENAC POTASSIUM				
	TABLET; ORAL				
	CATAFLAM	25MG	N20142 001		
	GEIGY		NOV 24, 1993		
@			N20142 001		
			NOV 24, 1993		
				> DLT >	<u>5.0MG</u>
				> ADD >	
	DIPHENHYDRAMINE HYDROCHLORIDE				
	CAPSULE; ORAL				
	<u>DIPHENHYDRAMINE HCL</u>	<u>5.0MG</u>			
	WESTWARD PHARM				
				@	
					<u>N83567 001</u>
					N83567 001

DIPIVEFRIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
DIPIVEFRIN HCL

BAUSCH AND LOMB 0.1%
AT
>
> ADD >
> ADD >

DIVALPROEX SODIUM

CAPSULE, DELAYED REL PELLETS; ORAL

DEPAKOTE
* ABBOTT
EQ 125MG BASE
AT
>
> DLT >
> ADD >
> ADD >

TABLET, DELAYED RELEASE; ORAL

DEPAKOTE
* ABBOTT
EQ 125MG BASE
EQ 250MG BASE
EQ 500MG BASE
EQ 125MG VALPROIC ACID
EQ 250MG VALPROIC ACID
EQ 500MG VALPROIC ACID
AT
>
> DLT >
> ADD >

N19680 001
SEP 12, 1989
N19680 001
SEP 12, 1989

N18723 003
OCT 26, 1984
N18723 001
MAR 10, 1983
N18723 002
MAR 10, 1983
N18723 003
OCT 26, 1984
N18723 001
MAR 10, 1983
N18723 002
MAR 10, 1983
N18723 002
MAR 10, 1983

MAR 10, 1983

N18723 003
OCT 26, 1984
N18723 001
MAR 10, 1983
N18723 002
MAR 10, 1983
N18723 002
MAR 10, 1983

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOBUTAMINE HCL
AT
Astra
EQ 12.5MG BASE/ML
AT
SANOFI WINTHROP
EQ 12.5MG BASE/ML

N74098 001
FEB 21, 1995
N74292 001
FEB 16, 1995

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DITROPIN
AP * DUPONT MERCK
AP
EQ 40MG/ML
80MG/ML

N17395 003
N17395 001
N17395 002
N17395 003

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

INTROPIN
AP * DUPONT MERCK
AP + FAULDING
AP +
AP +

N17395 003
N17395 001
N17395 002
N17395 003

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

DOXORUBICIN HCL
AP
PHARMACHEMIE (NL)
AP
200MG/100ML
AP
200MG/100ML
AP
FEB 28, 1995
N63336 004
N63336 001
FEB 28, 1995
N63336 004
FEB 28, 1995

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE MONOHYDRATE
* VINTAGE PHARMS
EQ 100MG BASE
EQ 100MG BASE
EQ 100MG BASE
MONODOX
+ OCCLASSEN
EQ 100MG BASE
EQ 100MG BASE
EQ 100MG BASE
DOXYCYCLINE HYCLATE
AB
PVT FORM
AB
@
@

N50641 001
DEC 29, 1989
N50641 001
DEC 29, 1989
N50641 001
DEC 29, 1989
N62631 001
JUL 24, 1986
N62631 002
JUL 24, 1986
N62631 001
JUL 24, 1986
N62631 002
JUL 24, 1986

ETHINYL ESTRADIOL; NORETHINDRONETABLET; ORAL-21

OVCON-35
+ BRISTOL MYERS SQUIBB 0.035MG; 0.4MG
* MEAD JOHNSON 0.035MG; 0.4MG

N18127 001
N18127 001

OVCON-50
@ BRISTOL MYERS SQUIBB 0.05MG; 1MG
* MEAD JOHNSON 0.05MG; 1MG

N18128 001
N18128 001

TABLET; ORAL-28

OVCON-35
BRISTOL MYERS SQUIBB 0.035MG; 0.4MG
MEAD JOHNSON 0.035MG; 0.4MG

N17716 001
N17716 001

OVCON-50
BRISTOL MYERS SQUIBB 0.05MG; 1MG
MEAD JOHNSON 0.05MG; 1MG

N17576 001
N17576 001

ETOPOSIDEINJECTABLE; INJECTIONTOPOSARPHARMACIA20MG/ML

N74166 001
FEB 27, 1995

FENOFIBRATE

CAPSULE; ORAL
LIPIDIL
+ LABS FOURNIER 100MG
@ 100MG

N19304 001
DEC 31, 1993
N19304 001
DEC 31, 1993

N19304 001
DEC 31, 1993
N19304 001
DEC 31, 1993

FLUDROCORTISONE ACETATETABLET; ORAL

FLORINEF
+ APOTHECON
* SQUIBB

0.1MG
0.1MG

N10060 001
N10060 001

FLUNISOLIDESPRAY, METERED; NASAL

NASALIDE
BX + SYNTEX

N18148 001

FLUNISOLIDESPRAY, METERED; NASAL

NASAREL

BX + SYNTEX

0.025MG/INH

N20409 001
MAR 08, 1995

FLUOCINOLONE ACETONIDECREAM; TOPICAL

FLUOCINOLONE ACETONIDE
AT + HAMILTON PHARMA CA
AT + HAMILTON PHARMA CA
AT + HAMILTON PHARMA CA

0.01%
0.025%
0.025%
0.02%

FLUOCINOLONE ACETONIDEOINTMENT; TOPICAL

FLUOCINOLONE ACETONIDE
AT + HAMILTON PHARMA CA
AT + HAMILTON PHARMA CA
AT + HAMILTON PHARMA CA

0.01%
0.025%
0.02%
0.025%

FLUOCINOLONE ACETONIDESOLUTION; TOPICAL

FLUOCINOLONE ACETONIDE
AT + HAMILTON PHARMA CA
AT + HAMILTON PHARMA CA
AT + HAMILTON PHARMA CA

0.025%
0.025%
0.025%
0.01%

FLUOCINONIDECREAM; TOPICAL

FLUOCINONIDE
AB + HAMILTON PHARMA CA
AB + HAMILTON PHARMA CA
AB + HAMILTON PHARMA CA

0.05%
0.05%
0.05%

FLUNISOLIDESPRAY, METERED; NASAL

NASALIDE
BX + SYNTEX

N16908 002

N16908 003

N16908 002

N16908 003

N16908 003

FLUOCINONIDE

GEL; TOPICAL
FLUOCINONIDE
AB + HAMILTON PHARMA CA 0.05%
AB * LIDEX 0.05%

OINTMENT; TOPICAL

FLUOCINONIDE
AB + HAMILTON PHARMA CA 0.05%
AB * LIDEX 0.05%

SOLUTION; TOPICAL

FLUOCINONIDE
AT FOUGERA 0.05%
AT + HAMILTON PHARMA CA 0.05%
AT * LIDEX 0.05%

FLURBIPROFEN

TABLET; ORAL
FLURBIPROFEN
AB LEMMON 100MG
AB NOVOPHARM 50MG
AB ZENITH LABS 100MG
AB 50MG
AB 100MG

> ADD > AB
> ADD > AB

FLURBIPROFEN SODIUM

SOLUTION/DROPS; OPHTHALMIC
FLURBIPROFEN SODIUM
AT BAUSCH AND LOMB 0.03%
AT + ALLERGAN 0.03%

FOSINOPRIL SODIUM

TABLET; ORAL
FOSINOPRIL
* BRISTOL MYERS SQUIBB 20MG
N17373 001
N17373 001

OINTMENT +
N16909 002
N16909 002

GEMFIBROZIL

CAPSULE; ORAL
GEMFIBROZIL
AB * MYLAN 300MG
AB @
AB PURERAC PHARM 300MG
AB @
AB * PARKE DAVIS 300MG
AB @
AB * PARKE DAVIS 300MG
AB @
AB CHELSEA LABS 600MG
AB MYLAN 600MG

> DLT > N72934 001
> DLT > FEB 27, 1995
N18849 001
APR 06, 1984
N18849 001
APR 06, 1984
> DLT >
> ADD >
> DLT >
> ADD >
> ADD >

SOLUTION/DROPS; OPHTHALMIC
GENTAMICIN SULFATE
AT ALCON EQ 0.3% BASE

N62196 001

GLIPIZIDE

TABLET; ORAL
GLIPIZIDE
AB GENEVA PHARMS 5MG
N19404 001
DEC 31, 1986

N74305 001
APR 07, 1995

N73466 001
JAN 25, 1993
N73466 001
JAN 25, 1993
N72929 001
JAN 29, 1993
N72929 001
JAN 29, 1993

N18422 002

N18422 002

GLIPIZIDE

TABLET; ORAL
GLIPIZIDE
 GENEVA PHARMS 10MG
AB WATSON LABS 5MG
AB 10MG

TABLET; ORAL
GUANABENZ ACETATE
AB ZENITH LABS
 N74305 002 APR 07, 1995
 N74223 001 FEB 27, 1995
 N74223 002 FEB 27, 1995

GUANFACINE HYDROCHLORIDE

TABLET; ORAL,

TENEX
 ROBBINS AH 1MG
 * 2MG
 @ 3MG
 EQ 1MG BASE
 EQ 2MG BASE
 EQ 3MG BASE

N19032 001 OCT 27, 1986
 N19032 002 NOV 07, 1988
 N19032 003 NOV 07, 1988
 N19032 004 NOV 07, 1988
 N19032 005 NOV 07, 1988
 N19032 006 NOV 07, 1988
 N19032 007 NOV 07, 1988

N17556 001 N17556 001
 * WESTWOOD SQUIBB 0.1%
 + HALOG-E 0.1%
 WESTWOOD SQUIBB 0.1%
 N18234 001 N18234 001
 HEPARIN CALCIUM 0.1%

INJECTABLE; INJECTION
 CALCIPARINE
 * CHOAY
 @ SANOFI WINTHROP

N18237 001 N18237 001
 25,000 UNITS/ML
 25,000 UNITS/ML

GLYBURIDE

TABLET; ORAL
GLUBATE
 @ HOECHST ROUSSEL 1.5MG
 @ 3MG
AB HOECHST ROUSSEL 1.5MG

N20055 001 APR 17, 1992
 N20055 002 APR 17, 1992
 N20055 001 APR 17, 1992
 N20055 002 APR 17, 1992
 N20051 001 MAR 04, 1992
 N20051 002 MAR 04, 1992
 CREAM; TOPICAL
 HALOG
 * WESTWOOD SQUIBB 0.1%
 + HALOG-E 0.1%
 WESTWOOD SQUIBB 0.1%

> DLT > AT > DLT > AT > DLT > AT > DLT > AT >
 > ADD > ADD > ADD > ADD > ADD > ADD >
 N18522 001 FEB 19, 1982
 N18522 001 FEB 19, 1982
 1.5GM/100ML
 @ 1.5GM/100ML

GRANISETRON HYDROCHLORIDE

TABLET; ORAL
 KYTRIL
 + SMITHKLINE BEECHAM EQ 1MG BASE
 N20305 001 MAR 16, 1995

<u>HEPARIN SODIUM</u>		<u>HEPARIN SODIUM</u>	
<u>INJECTABLE; INJECTION HEPARIN LOCK FLUSH</u>		<u>INJECTABLE; INJECTION HEPARIN SODIUM PRESERVATIVE FREE</u>	
<u>AP SANOFI WINTHROP</u>	<u>10 UNITS/ML</u>	<u>AP STERLING WINTHROP</u>	<u>10,000 UNITS/ML</u>
<u>AP</u>	<u>100 UNITS/ML</u>	<u>AP +</u>	<u>10,000 UNITS/ML</u>
<u> HEPARIN SODIUM</u>			
<u>AP * ABBOTT</u>	<u>2,500 UNITS/ML</u>	<u>> DLT > AP</u>	<u>LIGUAEMIN LOCK FLUSH</u>
	N40082 001 FEB 28, 1995		
	N40082 002 FEB 28, 1995		
			<u>ORGANON</u>
			<u>100 UNITS/ML</u>
			<u>100 UNITS/ML</u>
			<u>LIGUAEMIN SODIUM</u>
			<u>ORGANON</u>
			<u>1,000 UNITS/ML</u>
			<u>5,000 UNITS/ML</u>
			<u>10,000 UNITS/ML</u>
			<u>1,000 UNITS/ML</u>
			<u>5,000 UNITS/ML</u>
			<u>10,000 UNITS/ML</u>
			<u>HYDRALAZINE HYDROCHLORIDE</u>
			<u>TABLET; ORAL</u>
			<u>DRAZINE</u>
			<u>LENMON</u>
			<u>25MG</u>
			<u>25MG</u>
			<u>HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE</u>
			<u>TABLET; ORAL</u>
			<u>APRESOLINE-FSIDRIX</u>
			<u>* CIBA</u>
			<u>25MG;15MG</u>
			<u>25MG;15MG</u>
			<u>HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE</u>
			<u>TABLET; ORAL</u>
			<u>HASCOT</u>
			<u>50MG</u>
			<u>HYDRALAZINE HYDROCHLOROTHIAZIDE</u>
			<u>TABLET; ORAL</u>
			<u>HYDROCHLOROTHIAZIDE</u>
			<u>50MG</u>
			<u>HYDRALAZINE HYDROCHLOROTHIAZIDE</u>
			<u>TABLET; ORAL</u>
			<u>HYDROCHLOROTHIAZIDE</u>
			<u>50MG</u>

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

TABLET; ORAL
HYZZAAR
+ MERCK
12.5MG; 50MG

N20387 001
APR 28, 1995
> ADD >

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE

TABLET; ORAL
LOPRESSOR HCT
CIBA
25MG; 50MG
25MG; 100MG
50MG; 100MG
+
LOPRESSOR HCT 100/25
CIBA
25MG; 100MG
LOPRESSOR HCT 100/50
* CIBA
50MG; 100MG
LOPRESSOR HCT 50/25
CIBA
25MG; 50MG

N18303 001
DEC 31, 1984
N18303 002
DEC 31, 1984
N18303 003
DEC 31, 1984
N18303 002
DEC 31, 1984
N18303 003
DEC 31, 1984
N18303 001
DEC 31, 1984
> ADD >

N18303 003
DEC 31, 1984
N18303 001
DEC 31, 1984
> ADD >

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE
AB ZENITH LABS
25MG; 50MG

N74259 001
MAR 30, 1995
> ADD >

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE
CLAY PARK
1/2
④

N85026 001
N85026 001
> ADD >

ENEMA; RECTAL
CORTENEMA
+ SOLVAY

N16199 001
N16199 001
> ADD >

HYDROCORTISONE

ENEMA; RECTAL
HYDROCORTISONE
COPELEY PHARM
④

N74171 001
MAY 27, 1994
N74171 001
MAY 27, 1994
> ADD >

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL
PHARMACEPTEUR
④

N88881 001
FEB 14, 1986
N88881 001
FEB 14, 1986
50MG/ML
50MG/ML
50MG/ML
> ADD >

STERIS
AP
④

N87274 001
N87274 002
N87274 001
N87274 002
25MG/ML
25MG/ML
25MG/ML
50MG/ML
50MG/ML
> ADD >

IBUPROFEN

SUSPENSION; ORAL
CHILDREN'S MOTRIN
BX + MCNEIL CONS PRODS
> ADD >

N88785 001
FEB 03, 1988
N88785 001
FEB 03, 1988
10MG/5ML
10MG/5ML
> ADD >

IBUPROFEN

N19842 001
SEP 19, 1989
N19842 001
SEP 19, 1989
100MG/5ML
100MG/5ML
+ MCNEIL CONS PRODS
BX + MCNEIL CONS PRODS
> ADD >

N20476 001
MAY 25, 1995
N20476 001
MAY 25, 1995
4.0MG/ML
4.0MG/ML
> ADD >

NAPROXEN

TABLET; ORAL

NAPROXEN

DANBURY PHARMA

250MG375MG500MG250MG375MG500MG250MG375MG500MG250MG375MG500MG250MG375MG500MG250MG375MG500MGNAPROXEN SODIUMEQ 250MG BASEEQ 500MG BASEEQ 250MG BASEEQ 500MG BASEEQ 250MG BASEEQ 500MG BASEEQ 250MG BASEEQ 500MG BASE

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

AB AB AB AB

CHELSEA LABS
PUREPAC PHARM
ZENITH LABS
ZENITH LABS

EQ 250MG SODIUM
EQ 500MG SODIUM
EQ 250MG BASE
EQ 500MG BASE
EQ 250MG BASE
EQ 500MG BASE
EQ 250MG BASE
EQ 500MG BASE

MAY 31, 1995
MAY 31, 1995
MAR 20, 1995
MAR 20, 1995
MAR 20, 1995
MAR 20, 1995
MAR 14, 1995
MAR 14, 1995

N74455 001
N74455 002
N74319 001
N74319 002
N74230 001
N74230 002

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

AB AB AB AB

Merrell Dow
SmithKline Beecham H
Nicorette DS
Merrell Dow
SmithKline Beecham H
Merrell Dow

GUM, CHEWING; NICORETTE
+ MERRELL DOW
+ SMITHKLINE BEECHAM H
NICORETTE DS
+ MERRELL DOW
+ SMITHKLINE BEECHAM H

EQ 2MG BASE
EQ 2MG BASE
EQ 2MG BASE
EQ 4MG BASE
EQ 4MG BASE
EQ 4MG BASE

NEOMYCIN SULFATENEOMYCIN SULFATEBIOCRAFTLILLY

N60304 001
N60304 001
N60385 001

NEOMYCIN SULFATE
NEOMYCIN SULFATE
NEOMYCIN SULFATE

NEOMYCIN SULFATENEOMYCIN SULFATELILLY

N60385 001

NEOMYCIN SULFATE

NISOLDIPINENISOLDIPINENISSOCOR+ MILES

N20356 001
FEB 02, 1995
N20356 002
FEB 02, 1995

TABLET, EXTENDED RELEASE; ORAL
NISOLDIPINE

NICOTINE POLACRILEXNICOTINE POLACRILEXNICORETTE+ MERRELL DOW

N18612 001
JAN 13, 1984
N18612 001
JAN 13, 1984

TABLET, EXTENDED RELEASE; ORAL
NISOLDIPINE

NICOTINE POLACRILEXNICOTINE POLACRILEXNICORETTE+ MERRELL DOW

N20066 001
JUN 08, 1992
N20066 001
JUN 08, 1992

TABLET, EXTENDED RELEASE; ORAL
NISOLDIPINE

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL
NISOCOR
+ MILES 3.0MG
+ 4.0MG

N20356 003
FEB 02, 1995
N20356 004
FEB 02, 1995

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL
NITROFURANTOIN
AB GENEVA PHARMS 2.5MG
AB 5.0MG
AB 10.0MG

N74336 001
JAN 25, 1995
N74336 002
JAN 25, 1995
N74336 003
JAN 25, 1995

FILM, EXTENDED RELEASE; TRANSDERMAL
NITRO-DUR
+ KEY PHARMS 0.1MG/HR
+ 0.2MG/HR
+ 0.3MG/HR
+ 0.4MG/HR
+ 0.6MG/HR
+ 0.8MG/HR

N20145 001
APR 04, 1995
N20145 002
APR 04, 1995
N20145 003
APR 04, 1995
N20145 004
APR 04, 1995
N20145 005
APR 04, 1995
N20145 006
APR 04, 1995

NYROSTAT
AP PARKE DAVIS 5MG/ML
* @
AP TRIDIL DUPONT MERCK 5MG/ML

NITROGLYCERIN

INJECTABLE; INJECTION
TRIDIL
* DUPONT MERCK 0.5MG/ML
AP + FAULDING 5MG/ML
0.5MG/ML

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
NORTRIPTYLINE HCL
AB LEMMON EQ 10MG BASE
AB EQ 25MG BASE
AB EQ 50MG BASE
AB EQ 75MG BASE

N74132 001
MAR 27, 1995
N74132 002
MAR 27, 1995
N74132 003
MAR 27, 1995
N74132 004
MAR 27, 1995

NYSTATIN

TABLET; ORAL
MYCOSTATIN
AA + APOTHECON 500,000 UNITS
AA * SQUIERS 500,000 UNITS

TABLET; VAGINAL
NYSTATIN
AA LEMMON 100,000 UNITS
@ 100,000 UNITS

NYSTATIN; TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL
NYSTATIN AND TRIAMCINOLONE ACETONIDE
AA PHARMAPAIR 100,000 UNITS/GM, 0.1%
@ 100,000 UNITS/GM, 0.1%

NYSTATIN
N18537 001
DEC 23, 1983
N18537 002
JUN 16, 1983
N18537 003
JUN 16, 1983
N18537 004
JUN 16, 1983

NYSTATIN
N62556 001
DEC 23, 1983
N62556 002
DEC 23, 1983
N62556 003
DEC 23, 1983

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION
ZOFTRAN IN PLASTIC CONTAINER
+ GLAXO EQ 0.64MG BASE/ML

N20403 001

JAN 31, 1995

OXPHENCYCLIMINE HYDROCHLORIDE

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

TABLET; ORAL
DARICON
* PFIZER
@

10MG
10MGPENICILLAMINE

TABLET; ORAL
DEEPEN
+ WALLACE
DEEPEN 250
* WALLACE

250MG
250MGPENICILLIN G POTASSIUM

INJECTABLE; INJECTION
PFIZERPEN
PFIZER
AP +
AP +
AP +
AP +
AP +

N60657 001
N60657 001
N60657 002
N60657 002
N60657 002
N60657 003
N60657 003

1,000,000 UNITS/VIAL
1,000,000 UNITS/VIAL
5,000,000 UNITS/VIAL
5,000,000 UNITS/VIAL
20,000,000 UNITS/VIAL
20,000,000 UNITS/VIAL

20,000,000 UNITS/VIAL

TABLET; ORAL
PENICILLIN G POTASSIUM
DISTA
AP
@ LILLY

N11612 001
N11612 001

INJECTABLE; INJECTION
PENICILLIN G PROCAINE
@ CONSOLIDATED PHARM
@ COPANOS
@ COPANOS

N60403 001
N60403 001

1,000,000 UNITS/VIAL
1,000,000 UNITS/VIAL
5,000,000 UNITS/VIAL
5,000,000 UNITS/VIAL
20,000,000 UNITS/VIAL

N73447 001
APR 28, 1994

PENICILLIN G PROCAINE

INJECTABLE; INJECTION
PENICILLIN G PROCAINE
@ CONSOLIDATED PHARM
@ COPANOS
@ COPANOS

N60800 001
N60800 002
N60800 003
N60806 004
N60806 001
N60806 002
N60806 003

300,000 UNITS/ML
600,000 UNITS/1.2ML
300,000 UNITS/ML
600,000 UNITS/1.2ML

N60800 001
N60800 002
N60800 003
N60800 004

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN V POTASSIUM
CONSOLIDATED PHARM
AA
AA
AA
AA

N61529 001
N61529 002
N61529 001
N61529 002

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 125MG BASE/5ML
EQ 250MG BASE/5ML

N61529 001
N61529 002
N61529 001
N61529 002

PENICILLIN V POTASSIUM

TABLET; ORAL
PENICILLIN V POTASSIUM
CONSOLIDATED PHARM
AB
AB
AB
AB

N61528 001
N61528 002
N61528 001
N61528 002

EQ 250MG BASE
EQ 500MG BASE
EQ 250MG BASE
EQ 500MG BASE

N61528 001
N61528 002
N61528 001
N61528 002

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION
PENTACARENAT
ARMOUR
AP >
> ADD >

N73447 001
APR 28, 1994

300MG/VIAL

<u>PENTAMIDINE ISETHIONATE</u>		<u>PHENTERMINE HYDROCHLORIDE</u>	
INJECTABLE; INJECTION <u>PENTACARINAT</u> RHONE POULENC Rorer	<u>300MG/VIAL</u>	CAPSULE; ORAL <u>PHENTERMINE HCL</u> <u>30MG</u>	N87777 001 NOV 01, 1985
> <u>DLT</u> >		> <u>DLT</u> >	N87777 001 NOV 01, 1985
> <u>DLT</u> >		> <u>ADD</u> >	
		> <u>ADD</u> >	
<u>PERINDOPRIL ERBUMINE</u>		<u>PHENTERMINE RESIN COMPLEX</u>	
TABLET; ORAL ACEON AMARIC	2MG	CAPSULE, EXTENDED RELEASE; ORAL TONAMIN FISONS	EQ 15MG BASE EQ 30MG BASE
	4MG		
+ JOHNSON & W.	8MG	+ TONAMIN-15 FISONS	EQ 15MG BASE
	2MG	TONAMIN-30 * FISONS	EQ 30MG BASE
	4MG		
*	8MG		
		PINDOLOL	
		TABLET; ORAL <u>PINDOLOL</u>	
		AB ROYCE LABS	<u>5MG</u>
		AB	<u>10MG</u>
<u>PHENDIMETRAZINE TARTRATE</u>		<u>POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE</u>	
CAPSULE, EXTENDED RELEASE; ORAL MELFIAT-105 @ NUMARK	105MG	OCT 13, 1982 N87487 001 OCT 13, 1982 N87487 001	FEB 27, 1995 N74437 001 FEB 27, 1995
> <u>ADD</u> >			
> <u>ADD</u> >			
> <u>DLT</u> >			
> <u>DLT</u> >			
> <u>ADD</u> >			
> <u>ADD</u> >			
> <u>DLT</u> >			
> <u>DLT</u> >			
<u>TABLET; ORAL</u>		<u>POWDER FOR RECONSTITUTION; ORAL</u>	
MELFIAT @ NUMARK	3.5MG	NULLTELY - FLAVORED BRAINTREE	420GM/BOT; 1.48GM/BOT; 5.72GM/BOT; 11.2GM/BOT
> <u>ADD</u> >			
> <u>DLT</u> >			
> <u>DLT</u> >			
> <u>DLT</u> >			
> <u>ADD</u> >			
> <u>DLT</u> >			
> <u>ADD</u> >			
> <u>DLT</u> >			
N83790 002 N83790 002			
N83790 001 N83790 001			
N83790 001 N83790 001			

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

POWDER FOR RECONSTITUTION; ORAL
GOLLYTELY
BRAINTREE
 227.1GM/PACKET; 2.82GM/PACKET;
 6.36GM/PACKET; 5.33GM/PACKET;
 21.5GM/PACKET
 N19011 002
 JUN 02, 1992

N17371 002
 N17371 003
 N17371 001
 N17371 002
 N17371 003

PROCAINAMIDE HYDROCHLORIDE

TABLET; ORAL
 PRONESTYL
 APOTHECON
 ADD >
 ADD >
 DLT >
 DLT >
 DLT >

+
 SQUIBS
 *

POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
MINIZIDE
FEI
 *
 0.5MG 1MG
 0.5MG 2MG
 0.5MG 5MG
 0.5MG; EQ 1MG BASE
 0.5MG; EQ 2MG BASE
 0.5MG; EQ 5MG BASE
 +

N17986 001
 N17986 002
 N17986 003
 N17986 001
 N17986 001
 N17986 002
 N17986 003

> ADD >
 > DLT >
 TABLET, EXTENDED RELEASE;
PROCAN SR
PARKER DAVIS
 250MG
 250MG

TABLET; ORAL
PRONESTYL-SR
APOTHECON
BRISTOL MYERS SQUIBBS
 ADD >
 BC
 BC

PROPANTHELINE BROMIDE

N17986 001
 N17986 002
 N17986 003
 N17986 001
 N17986 002
 N17986 003

TABLET; ORAL
PROPANTHELINE BROMIDE
DANBURY PHARMA
 ADD >
 BC
 BC

PROPARACETAMOL HYDROCHLORIDE

SOLUTION/DROPS;
OPHTHALMIC

OPHTHAINE

ADD >
 AT
 AT
 AT

N08883 001

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS;
 OPHTHALMIC

N08883 001

INJECTABLE; INJECTION
HYDELTASOL
MERCK SHARP DOHME
 +
PREDNISOLONE SODIUM PHOSPHATE/ML
STERIS
 @
 EQ 20MG PHOSPHATE/ML
 EQ 20MG PHOSPHATE/ML
 EQ 20MG PHOSPHATE/ML
 EQ 20MG PHOSPHATE/ML

N11583 002
 N11583 002
 N80517 001
 N80517 001
 > DLT >
 > DLT >
 > DLT >
 > DLT >
 > DLT >

TABLET; ORAL
PROPRANOLOL HCL
PARKER DAVIS
 20MG
 40MG
 60MG

PROCAINAMIDE HYDROCHLORIDE

TABLET; ORAL
 PRONESTYL
 APOTHECON
 250MG

N17371 001

> ADD >

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL KENALOG-H WESTWOOD SQUIBB	<u>AT</u> <u>AT</u> <u>DLT</u>	<u>></u> <u>></u> <u>></u>	0.1% <u>0.1%</u>	N86240 001 N86240 001	CAPSULE; ORAL MODRASTANE SANOFI WINTHROP	3.0MG 6.0MG	N18719 002 DEC 31, 1984 N18719 001 DEC 31, 1984
INJECTABLE; INJECTION KENALOG-10 + APOTHECON * WESTWOOD SQUIBB	<u>AT</u> <u>DLT</u>	<u>></u> <u>></u>	1.0MG/ML 1.0MG/ML	N12041 001 N12041 001	INJECTABLE; INJECTION TUBOCURARINE CHLORIDE	3.0MG 6.0MG	N18719 002 DEC 1, 1984 N18719 001 DEC 31, 1984
ADD > > DLT >	<u>BP</u> <u>BP</u>	<u>></u> <u>></u>	KENALOG-40 APOTHECON WESTWOOD SQUIBB	N14901 001 N14901 001	TUBOCURARINE CHLORIDE		
LOTION; TOPICAL KENALOG APOTHECON	<u>AT</u> <u>AT</u>	<u>></u> <u>></u>	0.025% 0.1%	N84343 001 N84343 002	INJECTABLE; INJECTION TUBOCURARINE CHLORIDE	3.0MG/ML 3.0MG/ML	N05657 001 N05657 001
ADD > > ADD > > ADD > > ADD > > DLT > > DLT > > DLT > > DLT >	<u>AT</u> <u>AT</u> <u>AT</u> <u>AT</u> <u>AT</u> <u>AT</u> <u>AT</u> <u>AT</u>	<u>></u> <u>@</u> <u>@</u> <u>@</u> <u>@</u> <u>@</u> <u>@</u> <u>@</u>	0.025% 0.1% 0.025% 0.1% 0.025% 0.1% 0.025% 0.1%	N11602 001 N11602 001 N11602 001 N11602 001 N11602 001 N11602 001 N11602 001 N11602 001	> ADD > AP + AP + AP + VALPROIC ACID SYRUP; ORAL VALPROIC ACID	> DLT > AP AP AP VALPROIC ACID VALPROIC ACID	N74060 001 JAN 13, 1995
OINTMENT; TOPICAL TRIAMCINOLONE ACETONIDE IN ABSORBASE + CAROLINA MEDCL			0.05%	N89595 001 MAR 23, 1995	VANCOMYCIN HYDROCHLORIDE	25.0MG/5ML	
PASTE; DENTAL KENALOG IN ORABASE	<u>AT</u> <u>AT</u>	<u>></u> <u>></u>	0.1% 0.1%	N12097 001 N12097 001	POWDER FOR RECONSTITUTION; ORAL VANCOCIN HCL	EQ 500MG BASE/6ML EQ 500MG BASE/6ML	N61667 001 N61667 001
ADD > > DLT >	<u>AT</u> <u>AT</u>	<u>></u> <u>></u>			+ LITMEX + VANCOLED AB LEDERLE	EQ 500MG BASE/6ML EQ 500MG BASE/6ML EQ 500MG BASE/6ML	N63321 003 OCT 15, 1993 N63321 003 OCT 15, 1993
TRICHLORMETHIAZIDE							
TABLET; ORAL NAQUA SCHEERING	<u>BP</u>	<u>></u>	3.0MG 2MG	N12265 001 N12265 001	VITAMIN A		
VITAMIN A	<u>AA</u>	<u>@</u>			CAPSULE; ORAL VITAMIN A BANNER PHARMACAPS	50,000 USP UNITS 50,000 USP UNITS	NR3973 001 N83973 001

VITAMIN A PALMITATE

CAPSULE; ORAL		
<u>VITAMIN A</u>		
@ BANNER PHARMACAPS	EQ 50,000 UNITS BASE	N80702 .001
	EQ 50,000 UNITS BASE	N80702 .001

<u>VITAMIN A PALMITATE</u>		
@ BANNER PHARMACAPS	EQ 50,000 UNITS BASE	N83948 .001
	EQ 50,000 UNITS BASE	N83948 .001

WARFARIN SODIUM

INJECTABLE; INJECTION		
COUmadin		
+ DUPONT MERCK	5MG/VIAL	N09218 024

FEB 07, 1995

INSULIN SEMISYNTHETIC PURIFIED HUMAN; INSULIN SUSP ISOPHANESEMISYNTHETIC PURIFIED HUMANINJECTABLE; INJECTION

NOVOLIN 70/30

@ NOVO NORDISK

30 UNITS/ML; 70 UNITS/ML N19441 001
JUL 11, 1986INSULIN SUSP ISOPHANE PURIFIED PORKINJECTABLE; INJECTION

INSULIN INSULATARD NPH NORDISK

@ NOVO NORDISK

100 UNITS/ML
100 UNITS/ML
100 UNITS/MLNONOXYNOL-9AEROSOL; VAGINAL

DELFEN

@ ORTHO

12 . 5%

PROTAMINE ZINC PURIFIED BEEF
INJECTABLE; INJECTION
 PROTAMINE ZINC AND ILETIN II
 * LILLY 100 UNITS/ML
 @ PROTAMINE ZINC INSULIN
 SQUIBB 100 UNITS/ML
 + 100 UNITS/ML

> DLT >
 N18476 001
 N18476 001
 > DLT >
 > ADD >
 N17928 003
 N17928 003

MICONAZOLE NITRATE
CREAM; VAGINAL
 MICONAZOLE NITRATE
 LEMMON 2%

N74136 001
JAN 04, 1995NAPROXEN SODIUM

TABLET; ORAL
 ALEVE
 HAMILTON PHARMS

EQ 200MG BASE
 EQ 200MG BASE
 +

N20204 002
 JAN 11, 1994
 N20204 002
 JAN 11, 1994

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 5 / MAY '95

HETASTARCH 6% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION
6% HETASTARCH IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
6GM/100ML; 0.9GM/100ML N74193
ABBOTT JAN 30, 1995

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January - May, 1995]

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
ADENO-AS'TED VIRAL-BASED VECTOR CYSTIC FIBROSIS GENE THERAPY TN=	TREATMENT OF CYSTIC FIBROSIS.	TARGETED GENETICS CORPORATION 1100 OLIVE WAY, SUITE 100 SEATTLE WA 98101 DD 02/15/95 MA / /
AMINOCAPROIC ACID TN=	FOR THE TOPICAL TREATMENT OF TRAUMATIC HYPHEMA OF THE EYE.	ORPHAN MEDICAL 13911 RIDGEDALE DRIVE MINNETONKA MN 55305 DD 01/06/95 MA / /
APL 400-020 TN=	TREATMENT OF CUTANEOUS T CELL LYMPHOMA.	APOLLON, INC. ONE GREAT VALLEY PARKWAY MALVERN PA 19355 DD 03/08/95 MA / /
CHONDROITINASE TN=	TREATMENT OF PATIENTS UNDERGOING VITRECTOMY.	STORZ OPHTHALMICS AMERICAN CYANAMID COMPANY PEARL RIVER NY 10965 DD 02/09/95 MA / /
CLOTRIMIDAZOLE TN=	TREATMENT OF SICKLE CELL DISEASE.	BRUGNARA, CARLO M.D. THE CHILDREN'S HOSPITAL BOSTON MA 02115 DD 04/24/95 MA / /
CYSTIC FIBROSIS TR GENE THERAPY (RECOMBINANT ADENOVIRUS) TN= ADgvCFTR.10	TREATMENT OF CYSTIC FIBROSIS.	GENVAC, INCORPORATED 12111 PARKLAWN DRIVE ROCKVILLE MD 20852 DD 03/09/95 MA / /
GLUTAMINE TN=	FOR USE WITH HUMAN GROWTH HORMONE IN THE TREATMENT OF SHORT BOWEL SYNDROME (NUTRIENT MALABSORPTION FROM THE GASTROINTESTINAL TRACT RESULTING FROM AN INADEQUATE ABSORPTIVE SURFACE).	RESEARCH TRIANGLE PHARMACEUTICALS 4364 SOUTH ALSTON AVENUE DURHAM NC 27713 DD 03/06/95 MA / /
GLYCERYL TRIOLEATE AND GLYCERYL TRIERUCATE TN=	TREATMENT OF ADRENOLEUKODYSTROPHY.	MOSER, HUGO W. M.D. JOHNS HOPKINS UNIVERSITY BALTIMORE MD 21205 DD 02/14/95 MA / /
HEPATITIS B IMMUNE GLOBULIN, INTRAVENOUS TN= H-BIGIV	PROPHYLAXIS AGAINST HEPATITIS B VIRUS REINFECTION IN LIVER TRANSPLANT PATIENTS.	NORTH AMERICAN BIOLOGICS, INC. 16500 N.W. 15th AVENUE MIAMI FL 33169 DD 03/08/95 MA / /
HUMAN GROWTH HORMONE TN=	FOR USE WITH GLUTAMINE IN THE TREATMENT OF SHORT BOWEL SYNDROME (NUTRIENT MALABSORPTION FROM THE GASTROINTESTINAL TRACT RESULTING FROM AN INADEQUATE ABSORPTIVE SURFACE).	RESEARCH TRIANGLE PHARMACEUTICALS 4364 SOUTH ALSTON AVENUE DURHAM NC 27713 DD 03/06/95 MA / /
HUMAN IMMUNODEFICIENCY VIRUS IMMUNE GLOBULIN TN= HIVIG	TREATMENT OF HIV-INFECTED PEDIATRIC PATIENTS.	NORTH AMERICAN BIOLOGICALS, INC. 16500 N.W. 15TH AVENUE MIAMI FL 33169 DD 01/04/95 MA / /
NTBC TN=	TREATMENT OF TYROSINEMIA TYPE 1.	SWEDISH ORPHAN AB ORPHAN PHARMACEUTICAL, USA, INC. NASHVILLE TN 37217 DD 05/16/95 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

36

NAME

Generic/Chemical
TN=Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS
DD=Date Designated
MA=Marketing Approval

PHENYLALANINE AMMONIA-LYASE
TN= PHENYLASE

TREATMENT OF HYPERPHENYLALANINEMIA.

IBEX TECHNOLOGIES, INC.
5485 PARE
MONTREAL, QUEBEC
DD 03/08/95 MA / /

PURIFIED TYPE II COLLAGEN
TN= COLLORAL

TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.

AUTOIMMUNE, INCORPORATED
128 SPRING STREET
LEXINGTON MA 02173
DD 02/09/95 MA / /

RECOMBINANT HUMAN GELSOLIN
TN=

TREATMENT OF ACUTE AND CHRONIC RESPIRATORY SYMPTOMS OF
BRONCHIECTASIS.

BIOGEN, INCORPORATED
14 CAMBRIDGE CENTER
CAMBRIDGE MA 02142
DD 03/06/95 MA / /

SARGRAMOSTIM
TN= LEUKINE

TO REDUCE NEUTROPENIA AND LEUKOPENIA AND DECREASE THE
INCIDENCE OF DEATH DUE TO INFECTION IN PATIENTS WITH
ACUTE MYELOGENOUS LEUKEMIA.

IMMUNEX CORPORATION
51 UNIVERSITY STREET
SEATTLE WA 98101
DD 03/06/95 MA / /

SU-101

TN=

TREATMENT OF MALIGNANT GLIOMA.

SUGEN, INC.
515 GALVESTON DRIVE
REDWOOD CITY CA 94063-4720
DD 05/25/95 MA / /

THALIDOMIDE
TN=

TREATMENT OF SEVERE RECURRENT APHTHOUS STOMATITIS IN
SEVERELY, TERMINALLY IMMUNOCOMPROMISED PATIENTS.

CELGENE CORPORATION
P.O. BOX 4914
WARREN NJ 07059
DD 05/01/95 MA / /

THALIDOMIDE
TN=

TREATMENT AND PREVENTION OF RECURRENT APHTHOUS ULCERS
IN SEVERELY, TERMINALLY IMMUNOCOMPROMISED PATIENTS.

ANDRULIS RESEARCH CORPORATION
11800 BALTIMORE AVENUE, SUITE
113
BELTSVILLE MD 20705
DD 05/15/95 MA / /

TYLOXAPOL
TN=

TREATMENT OF CYSTIC FIBROSIS.

KENNEDY & HOITAL, MDS
50 NORTH MEDICAL DRIVE, U OF
UTAH
SALT LAKE CITY UT 84132
DD 03/08/95 MA / /

Rho (D) IMMUNE GLOBULIN
INTRAVENOUS (HUMAN)
TN= WinRho SD

TREATMENT OF IMMUNE THROMBOCYTOPENIC PURPURA.

RH PHARMACEUTICALS, INC.
104 CHANCELLOR MATHESON ROAD
WINNIPEG, MANITOBA
DD 11/09/93 MA 03/24/95

Approved Orphan Products

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

NO MAY 1995 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
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THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR *IN VIVO* BIOEQUIVALENCE STUDIES AND *IN VITRO* DISSOLUTION TESTING. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE (HFD-650, MPN-2 ROOM 279) 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 15TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO MAY 1995 GUIDANCES

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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 1-23, PARK BUILDING, 5600 FISHERS LANE, ROCKVILLE, MD 20857.					
REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 15TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.					
ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE TABLET; ORAL	150MG 180MG 15MG	94 P-0212/ CP1	MIKART	NEW dosage form	APPROVED JAN 19, 1995
ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE TABLET; ORAL	150MG 180MG 30MG	94 P-0211/ CP1	MIKART	NEW dosage form	APPROVED JAN 19, 1995
ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE TABLET; ORAL	150MG 180MG 60MG	94 P-0210/ CP1	MIKART	NEW dosage form	APPROVED JAN 19, 1995
ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE TABLET; ORAL	712.8MG 60MG 32MG	93 P-0484/ CP1	MIKART	NEW dosage form new strength	APPROVED JAN 19, 1995
ACETAMINOPHEN; CODEINE PHOSPHATE TABLET, CHEWABLE; ORAL	120MG 12MG	94 P-0182/ CP1	WE PHARMS	NEW dosage form	APPROVED JAN 19, 1995
ALBUTEROL SULFATE TABLET, CHEWABLE; ORAL	EQ 2MG BASE EQ 4MG BASE	92 P-0335/ CP1	WE PHARMS	NEW dosage form	APPROVED JAN 19, 1995
ATRACURIUM BESYLATE INJECTABLE; INJECTION	25MG/ML	94 P-0314/ CP1	ABBOTT	new strength	APPROVED MAY 02, 1995
LEUCOVORIN CALCIUM INJECTABLE; INJECTION	EQ 10MG BASE/ML (100MG/VIAL)	93 P-0427/ CP3	ABBOTT	new dosage form	APPROVED JAN 19, 1995
LEUCOVORIN CALCIUM INJECTABLE; INJECTION	EQ 10MG BASE/ML (250MG/VIAL)	93 P-0427/ CP2	ABBOTT	new dosage form new strength	APPROVED JAN 19, 1995
SULFAMETHOXAZOLE; TRIMETHOPRIM TABLET, CHEWABLE; ORAL	200MG 40MG	94 P-0186/ CP1	DURA PHARMS	new dosage form	APPROVED JAN 19, 1995
THIORIDAZINE HYDROCHLORIDE SOLUTION; ORAL	25MG/5ML	92 P-0283/ CP1	UDL LABS	new strength	APPROVED JAN 19, 1995

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
NICOTINE POLACRILEX LOLLIPOP; ORAL	2MG	93 P-0414/ CP1	SAVAGE	NEW DOSAGE FORM	DENIED MAY 02, 1995

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 15TH 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-26 ONCE WEEKLY APPLICATION
- D-27 BID DOSING IN PATIENTS 12 YEARS OF AGE AND OLDER FOR PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH MODERATELY EMETOGENIC CANCER CHEMOTHERAPY
- D-28 REVISED BASIS FOR CALCULATING THE RECOMMENDED STARTING DOSE IN ACCORDANCE WITH THE 1993 NATIONAL CHOLESTEROL EDUCATION PROGRAM GUIDELINES - DOSING RANGE EXPANDED TO 10-80MG/DAY

REFERENCES NEW INDICATION

- I-117 TO SLOW THE PROGRESSION OF CORONARY ATHEROSCLEROSIS IN PATIENTS WITH CORONARY HEART DISEASE
- I-118 PREVENTION OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLISM, FOLLOWING KNEE REPLACEMENT SURGERY
- I-119 TREATMENT OF ANEMIA CAUSED BY UTERINE LEIOMYOMATA IN WOMEN WHO FAIL IRON THERAPY
- I-120 MAINTENANCE THERAPY FOR GASTRIC ULCER PATIENTS AT REDUCED DOSAGE AFTER HEALING ACUTE ULCERS
- I-121 EXPANDED PATIENT POPULATION - USE IN ICU PATIENTS
- I-122 PSORIASIS OF THE SCALP
- I-123 RELIEF OF MILD TO MODERATE PAIN IN PATIENTS AGED 6 MONTHS AND OLDER
- I-124 LEUCOCYTE LABELED SCINTIGRAPHY AS AN ADJUNCT IN THE LOCALIZATION OF INTRA-ABDOMINAL INFECTION AND INFLAMMATORY BOWEL DISEASE
- I-125 EXPANSION OF CONSCIOUS SEDATION INDICATION TO INCLUDE SHORT THERAPEUTIC PROCEDURES
- I-126 ADJUNCT TO THALLIUM-201 MYOCARDIAL PERfusion IN PATIENTS UNABLE TO EXERCISE ADEQUATELY

REFERENCES PATENT USE CODE

- U-102 METHOD OF HORMONALLY TREATING MENOPAUSAL OR POST-MENOPAUSAL DISORDERS IN WOMEN
- U-103 TREATMENT OF OCULAR HYPERTENSION
- U-104 TREATMENT OF AQUEOUS HUMOR FORMATION AND INTRAOCCULAR PRESSURE
- U-105 EMESIS
- U-106 TREATMENT OF EPILEPSY
- U-107 TREATMENT OF HYPERTENSION AND ANGINA PECTORIS
- U-108 SHORT-TERM TREATMENT OF ACTIVE DUODENAL ULCER, GASTROESOPHAGEAL REFLUX DISEASE (GERD), SEVERE EROSIONAL ESOPHAGITIS, POORLY RESPONSIVE SYMPTOMATIC GERD AND PATHOLOGICAL HYPERSECRETORY CONDITIONS
- U-109 USE AS AN ADJUNCT TO DIET IN THE TREATMENT OF Elevated TOTAL CHOLESTEROL AND LDL-C LEVELS IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA WHOSE RESPONSE TO DIETARY RESTRICTION OF SATURATED FAT AND CHOLESTEROL AND OTHER NONPHARMACOLOGICAL MEASURES HAS NOT BEEN ADEQUATE

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	EXCLUS CODE		EXCLUS EXPIRES
				USE CODE	CODE	
>ADD>	19872 001 ACETAMINOPHEN; TYLENOL	5004613	APR 11, 2006			
>ADD>		49668509	NOV 06, 2007			
>ADD>		48205322	APR 11, 2006	NDF	JUN 08, 1997	
>ADD>	20059 001 ADENOSINE; ADENOSCAN	4879303	NOV 07, 2006	I-126	MAY 18, 1998	
	AMLODIPINE BESYLATE; LOTREL	4572909	AUG 01, 2006	NC	MAR 03, 1998	
		4410520	OCT 18, 2002	NCE	JUN 25, 1996	
		4879303	NOV 07, 2006	NCE	JUL 31, 1997	
		4572909	AUG 01, 2006	NC	MAR 03, 1998	
		4410520	OCT 18, 2002	NCE	JUN 25, 1996	
		4879303	NOV 07, 2006	NC	MAR 03, 1998	
		4572909	AUG 01, 2006	NCE	JUL 31, 1997	
		4410520	OCT 18, 2002	NCE	JUL 31, 1997	
		4879303	NOV 07, 2006	NC	MAR 03, 1998	
		4572909	AUG 01, 2006	NCE	JUN 25, 1996	
		4410520	OCT 18, 2002	NCE	JUL 31, 1997	
		5053432	OCT 01, 2008	NCE	JUL 31, 1997	
		4981874	AUG 15, 2009	U-69	NDF	FEB 08, 1998
20500 001	ATOVAQUONE; MEPRON					
20222 001	COLESTIPOL HYDROCHLORIDE; COLESTID	4303651	JAN 04, 2000	NCE	JUL 19, 1997	
20287 001	DALTEPARIN SODIUM; FRAGMIN			NCE	JUL 31, 1997	
>ADD>	20212 001 DEXAZOXANE; ZINECARD			NCE	NOV 25, 1997	
>ADD>	20212 002 DEXAZOXANE; ZINECARD			NCE	DEC 22, 1999	
				NCE	MAY 26, 2000	
				NCE	MAY 26, 2000	
				I-120	OCT 15, 1995	
				I-120	OCT 15, 1995	
				I-120	OCT 15, 1995	
				I-120	OCT 15, 1995	
				NDF	MAR 30, 1998	
				NCE	DEC 09, 1999	
				I-121	DEC 08, 1997	
				I-96	FEB 06, 1998	
				I-96	FEB 06, 1998	
				I-96	FEB 06, 1998	
				I-96	FEB 06, 1998	
				I-96	FEB 06, 1998	
				I-118	MAR 09, 1998	
19946 001	DOXACURIUM CHLORIDE; NUROMAX					
19668 001	DOXAZOSIN MESYLATE; CARDURA					
19668 002	DOXAZOSIN MESYLATE; CARDURA					
19668 003	DOXAZOSIN MESYLATE; CARDURA					
19668 004	DOXAZOSIN MESYLATE; CARDURA					
20164 001	ENOXAPARGIN SODIUM; LOVENOX					

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
20323 001	ESTRADIOL; VIVELLE	5300291 4994278 4994267 4814168 5300291 4994278 4994267 4814168 5300291 4994278 4994267	APR 05, 2011 FEB 19, 2008 FEB 19, 2008 MAR 21, 2006 APR 05, 2011 FEB 19, 2008 FEB 19, 2008 MAR 21, 2006 APR 05, 2011 FEB 19, 2008	NS	OCT 28, 1997	
20323 002	ESTRADIOL; VIVELLE	4814168 5300291 4994278 4994267 4814168 5300291 4994278 4994267 4814168 5300291 4994278 4994267	MAR 21, 2006 APR 05, 2011 FEB 19, 2008 FEB 19, 2008 MAR 21, 2006 APR 05, 2011 FEB 19, 2008 FEB 19, 2008 MAR 21, 2006 APR 05, 2011 FEB 19, 2008	NS	OCT 28, 1997	
20323 003	ESTRADIOL; VIVELLE	4994278 4994267 4814168 5300291 4994278 4994267 4814168 5300291 4994278 4994267	FEB 19, 2008 FEB 19, 2008 MAR 21, 2006 APR 05, 2011 FEB 19, 2008 FEB 19, 2008 MAR 21, 2006 APR 05, 2011 	NS	OCT 28, 1997	
20323 004	ESTRADIOL; VIVELLE	4994278 4994267 4814168 5223261 5223261 4826831 4823408 4803081 4264611 4803081 4264611 4803081 4264611 4803081 4264611 4335121	FEB 19, 2008 FEB 19, 2008 MAR 21, 2006 JUN 29, 2010 JUN 29, 2010 MAY 02, 2006 AUG 11, 2000 FEB 07, 2006 APR 28, 1998 	D-26 DEC 22, 1997 D-26 DEC 22, 1997 NP DEC 30, 1997 NS APR 28, 1998		
20375 001	ESTRADIOL; CLIMARA	5223261	JUN 29, 2010	D-26	DEC 22, 1997	
20375 002	ESTRADIOL; CLIMARA	5223261	JUN 29, 2010	D-26	DEC 22, 1997	
20303 001	ESTROGENS, CONJUGATED; PREMPRO (PREMARIN; CYCRIN 14/14)	4826831	MAY 02, 2006	U-102	NP DEC 30, 1997	
20325 001	FAMOTIDINE; PECID AC	4823408	AUG 11, 2000	NS	APR 28, 1998	
>ADD>		4803081	FEB 07, 2006			
>ADD>	19834 001 FELODIPINE; PLENDIL	4264611	APR 28, 1998	U-3	NCE	JUL 25, 1996
>ADD>	19834 002 FELODIPINE; PLENDIL	4803081	FEB 07, 2006			
>ADD>	19834 004 FELODIPINE; PLENDIL	4264611	APR 28, 1998	U-3	NCE	JUL 25, 1996
>ADD>		4803081	FEB 07, 2006			
>ADD>		4264611	APR 28, 1998	U-3	NCE	JUL 25, 1996
>ADD>	19452 001 FLUOCINOLONE ACETONIDE; DERMA-SMOOTH/FS	4335121	MAR 15, 2002			
20121 001	FLUTICASONE PROPIONATE; FLONASE	5354772	OCT 11, 2011	U-109	T-122 NCE NDF	JUL 25, 1996 FEB 16, 1998 OCT 19, 1997
>ADD>	20261 001 FLUVASTATIN SODIUM; LESCOL	5354772	OCT 11, 2011	U-109	NCE	DEC 31, 1998
>ADD>	20261 002 FLUVASTATIN SODIUM; LESCOL	4384123	MAY 17, 2000	U-109	NCE	DEC 31, 1998
>ADD>	19915 002 FOSINOPRIL SODIUM; MONOPRIL	4384123	MAY 17, 2000	I-92	MAY 02,	I-92 MAY 02, 1998
>ADD>	19915 003 FOSINOPRIL SODIUM; MONOPRIL	5006344	APR 09, 2008	I-92	MAY 02,	I-92 MAY 02, 1998
>ADD>	19915 004 FOSINOPRIL SODIUM; MONOPRIL	4384123	MAY 17, 2000			
>ADD>		4337201	JUN 29, 2001			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS IVITIES
20460 001	GANCICLOVIR; CYTOGENE	4501305	OCT 19, 1999	U-64	NDF DEC 22, 1997
20305 001	GRANISETRON HYDROCHLORIDE; KYTRIL	435032	MAR 16, 2003	U-64	NCE DEC 29, 1998
> <u>ADD</u> >	HYDROCHLORTIAZIDE; HYZAAR	4888808	DEC 12, 2006	U-105	NDF MAR 16, 1998
> <u>ADD</u> >		5153197	OCT 06, 2009	U-3	NC APR 28, 1998
> <u>ADD</u> >	IBUPROFEN; CHILDREN'S MOTRIN	5138069	AUG 11, 2009		NCE APR 14, 2000
> <u>ADD</u> >	IBUPROFEN; MOTRIN	5374659	DEC 20, 2011		I-123 MAR 24, 1998
> <u>ADD</u> >		5320855	JUN 14, 2011		I-123 MAR 24, 1998
> <u>ADD</u> >	IBUPROFEN; MOTRIN	5215755	JUN 01, 2010		NDF NOV 16, 1997
> <u>ADD</u> >	IBUPROFEN; MOTRIN	5320855	JUN 14, 2011		I-123 MAR 24, 1998
> <u>ADD</u> >	IBUPROFEN; OMNIPAUQUE 70	5215755	JUN 01, 2010		NDF NOV 16, 1997
> <u>ADD</u> >	ISOSORBIDE MONONITRATE; IMDUR	4396597	JUL 14, 1998		I-123 MAR 24, 1998
18956 007	ISOSORBIDE MONONITRATE; IMDUR	4250113	DEC 26, 1999		
> <u>ADD</u> >	IPRAMIDE; ULTRAVIST				
> <u>ADD</u> >	IPRAMIDE; ULTRAVIST				
> <u>ADD</u> >	IPRAMIDE; ULTRAVIST				
> <u>ADD</u> >	IPRAMIDE; ULTRAVIST				
20220 001	KETOPROFEN; ORUVAIL	4602017	JUL 22, 2003		
20220 002	KETOPROFEN; ORUVAIL				
20220 003	LAMOTRIGINE; LAMICTAL				
20220 004	LAMOTRIGINE; LAMICTAL				
20225 003	ISOSORBIDE MONONITRATE; IMDUR				
> <u>ADD</u> >	KETOPROFEN; ORUVAIL				
> <u>ADD</u> >	KETOPROFEN; ORUVAIL				
> <u>ADD</u> >	LAMOTRIGINE; LAMICTAL				
> <u>ADD</u> >	LAMOTRIGINE; LAMICTAL				
19816 002	LAMOTRIGINE; LAMICTAL				
19816 003	LAMOTRIGINE; LAMICTAL				
20241 001	LAMOTRIGINE; LAMICTAL				
20241 002	LAMOTRIGINE; LAMICTAL				
20241 003	LAMOTRIGINE; LAMICTAL				
20241 004	LAMOTRIGINE; LAMICTAL				
20241 005	LAMOTRIGINE; LAMICTAL				
20241 006	LAMOTRIGINE; LAMICTAL				
20406 001	LANSOPRAZOLE; PREVACID				
20406 002	LANSOPRAZOLE; PREVACID				
20011 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4005063	JAN 25, 1996		
19670 001	LORATADINE; CLARITIN-D	4282233	AUG 04, 2000		
> <u>ADD</u> >	LORATADINE; CLARITIN-D	5153197	OCT 06, 2009	U-3	NCE APR 12, 1998
> <u>ADD</u> >	LOSARTAN POTASSIUM; COZAAR	5138069	AUG 11, 2009		NCE APR 14, 2000
> <u>ADD</u> >	LOSARTAN POTASSIUM; COZAAR	5153197	OCT 06, 2009	U-3	
> <u>ADD</u> >	LOSARTAN POTASSIUM; COZAAR	5138069	AUG 11, 2009		NCE APR 14, 2000

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS EXPRES
19643 002	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999	I-117	FEB 08, 1998
19643 003	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999	I-117	FEB 08, 1998
19643 004	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999	I-117	FEB 08, 1998
> <u>ADD</u> >	19962 001 METOPROLOL SUCCINATE; TOPROL-XL	5081154	JAN 14, 2009		
> <u>ADD</u> >		5001161	MAR 19, 2008		
> <u>ADD</u> >	19962 002 METOPROLOL SUCCINATE; TOPROL-XL	4957745	SEP 18, 2007	U-107	NE JAN 10, 1995
> <u>ADD</u> >		5081154	JAN 14, 2009		
> <u>ADD</u> >	19962 003 METOPROLOL SUCCINATE; TOPROL-XL	5001161	MAR 19, 2008		
> <u>ADD</u> >		4957745	SEP 18, 2007	U-107	NE JAN 10, 1995
> <u>ADD</u> >	18654 001 MIDAZOLAM HYDROCHLORIDE; VERSED	4280957	DEC 20, 1999	I-125	APR 26, 1997
> <u>ADD</u> >	18654 002 MIDAZOLAM HYDROCHLORIDE; VERSED	4280957	DEC 20, 1999	I-125	APR 26, 1997
> <u>ADD</u> >	20312 001 MOEXIPRIL HYDROCHLORIDE; UNIVASC	4280957	DEC 20, 1999	NCE	APR 19, 2000
> <u>ADD</u> >	20312 002 MOEXIPRIL HYDROCHLORIDE; UNIVASC				
> <u>ADD</u> >	20459 001 NALMEFFENE HYDROCHLORIDE; REVEX				
> <u>ADD</u> >	20459 002 NALMEFFENE HYDROCHLORIDE; REVEX				
> <u>ADD</u> >	20198 001 NIIFEDIPINE; ADALAT CC	5264446	NOV 23, 2010	NCE	APR 19, 2000
> <u>ADD</u> >	20198 002 NIIFEDIPINE; ADALAT CC	5264446	NOV 23, 2010	NCE	APR 17, 2000
> <u>ADD</u> >	20356 001 NISOLDIPINE; NISOCOR	5264446	NOV 23, 2010	NCE	APR 17, 2000
> <u>ADD</u> >	20356 002 NISOLDIPINE; NISOCOR				
> <u>ADD</u> >	20356 003 NISOLDIPINE; NISOCOR				
> <u>ADD</u> >	20356 004 NISOLDIPINE; NISOCOR				
> <u>ADD</u> >	20145 001 NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010	NCE	FEB 02, 2000
> <u>ADD</u> >	20145 002 NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010	NCE	FEB 02, 2000
> <u>ADD</u> >	20145 003 NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010	NCE	FEB 02, 2000
> <u>ADD</u> >	20145 004 NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010	NCE	FEB 02, 2000
> <u>ADD</u> >	20145 005 NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010	NCE	FEB 02, 2000
> <u>ADD</u> >	20145 006 NITROGLYCERIN; NITRO-DUR	5186938	FEB 16, 2010	NCE	FEB 02, 2000
> <u>ADD</u> >	19810 001 OMEPRAZOLE; PRILOSEC	4853230	NOV 02, 2005	U-108	
> <u>ADD</u> >		4786505	NOV 22, 2005	U-108	
> <u>DLT</u> >		4286505	NOV 22, 2005	U-37	
> <u>ADD</u> >	20007 001 ONDANSETRON HYDROCHLORIDE; ZOFRAN	4255431	MAR 10, 2000	U-108	D-20 FEB 02, 1996
		4695578	JAN 04, 2005		

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
20103 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005	NCE	JAN 04, 1996	D-27 APR 10, 1998
20103 002	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005	NCE	JAN 04, 1996	I-9 APR 19, 1998
20403 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4753789	JUN 28, 2005	U-44	D-20 FEB 02, 1996	D-27 APR 10, 1998
		4695578	JAN 04, 2005	NCE	JAN 04, 1996	I-9 APR 19, 1998
		5061722	OCT 29, 2008	U-3		
19901 001	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
19901 002	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
19901 003	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
19901 004	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
18703 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4585790	APR 29, 2003			
18703 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	5028432	JUL 02, 2008			
19675 001	RANITIDINE HYDROCHLORIDE; ZANTAC	5028432	JUL 02, 2008			
20095 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5028432	JUL 02, 2008			
20095 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	5102665	APR 07, 2009			
20251 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5102665	APR 07, 2009			
20251 002	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5380972	JAN 10, 2012			
20236 001	SALMETEROL XINAFOATE; SEREVENT	4470972	SEP 11, 2001	U-3	NCE	DEC 29, 1999
20240 001	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2001	U-3	NCE	DEC 29, 1999
20240 002	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2001	U-3	NCE	DEC 29, 1999
20240 003	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2001	U-3	NCE	DEC 29, 1999
20240 004	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4789736	DEC 06, 2005			
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