

**CUMULATIVE
SUPPLEMENT 8
JAN'96-AUG'96**

APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

16TH 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 DATABASE MANAGEMENT



RM
301.45
.A66
1996
Aug
Suppl

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NOV 05 1996

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

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RM301.45 .A66 1996 Aug Suppl

Approved drug products with
therapeutic equivalence

C:355661 M:174736 O:12937927

THERAPEUTIC EQUIVALENCE EVALUATIONS

16TH EDITION

Cumulative Supplement 8

AUGUST 1996

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

16TH EDITION

CUMULATIVE SUPPLEMENT 8
AUGUST 1996

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, 16th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 16th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 17th 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 CHANGE OF A THERAPEUTIC EQUIVALENT CODE FOR A DRUG ENTITY

Propantheline Bromide

In Cumulative Supplement 1 of the *Approved Drug Products with Therapeutic Equivalence Evaluations*, 16th Edition, (Orange Book), the Agency proposed to change the therapeutic equivalence code for propantheline bromide oral tablets from a drug product not presenting a bioequivalence problem (AA) to a drug product with a potential bioequivalence problem (BP).

The Agency solicited comments from interested persons to be received no later than 60 days from the first day of the month following the publication of Cumulative Supplement 1. The proposal did not elicit any comments from the readers. In addition, the two firms who hold an active ANDA and are marketing the drug product were contacted to inform them that the codes for their propantheline drug products were going to be changed. Since there were no comments submitted by the readers or by the two firms who hold an active ANDA, the therapeutic equivalence code for propantheline bromide tablets will be changed to one reflecting a potential bioequivalence problem. Therefore, all oral propantheline bromide tablets will be changed in this month's Cumulative Supplement from **(AA)** to **(BP)** to reflect it has a potential for a bioequivalence problem.

An acceptable *in vivo* bioequivalence study, among other information, will be required to change the code from **(BP)** to **(AB)** for an already approved ANDA listed in the Orange Book. Any ANDA submission must contain an acceptable *in vivo* bioequivalence study for filing purposes.

1.4 REFERENCE LISTED DRUG

A reference listed drug (21 CFR 314.94(a)(3)) means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA.

FDA has identified in the Prescription Drug Product and OTC Drug Product Lists those reference listed drugs to which the *in vivo* bioequivalence and, in some instances, the *in vitro* bioequivalence of the applicant's product is compared. By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart. Such variations could result if generic drugs were compared to different reference listed drugs. However, in some instances when multiple NDAs are approved for a single drug product, 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. A firm wishing to market a generic version of an NDA listed drug that is not designated as the reference listed may petition the Agency through the Citizen Petition procedure (see 21 CFR 10.25(a) and CFR 10.30). When the Citizen Petition is approved, the second NDA will be designated as an additional reference listed drug and the petitioner may submit an Abbreviated New Drug Application citing the designated reference listed drug. Section 1.7, *Therapeutic Equivalence Evaluations Codes* of the *Introduction to the Approved Drug Products with Therapeutic Equivalence Evaluations* publication explains the coding system for multisource drug products listed under the same heading with two reference listed drugs.

The concept of having only one reference listed drug was intended to apply to drug products in which bioequivalence is demonstrated through *in vivo* methodology. It was not intended to apply to two NDA drug products in which the *in vivo* determination of bioequivalence is self evident and a waiver of *in vivo* bioequivalence is granted by the agency. These types of drug products are assigned therapeutic equivalence codes, e.g., of **AN**, **AT**, **AA**. Therefore, drug products that do not represent a bioequivalence problem with two or more NDAs will have the reference listed drug designation assigned to each NDA.

The reference listed drug is identified by the symbol "+" in the Prescription Drug Product List. These identified reference listed drugs represent the best judgement of the Division of Bioequivalence at this time. The prescription Drug Product List identifies reference drugs for oral dosage forms, injectables, ophthalmics, otics, and topical products. It is recommended that a firm planning to conduct an *in vivo* bioequivalence study, or planning to manufacture a batch of a drug product for which an *in vivo* waiver of bioequivalence will be requested, contact the Division of Bioequivalence, OFFICE OF GENERIC DRUGS, to confirm the appropriate reference listed drug.

1.5 COURT ORDER REGARDING ABBOTT U.S. PATENT NO. 4112097, (TERAZOSIN HCL)

On April 9, 1996, the United States District Court for the Northern District of Illinois (Eastern Division) issued an order in the case of Abbott Labs v. Geneva Pharmaceuticals, Inc., directing Abbott to remove U.S. Patent No. 4112097 from the Orange Book. To comply with that order, Abbott has requested that FDA remove patent 4112097 from the Orange Book. The FDA complied with this request in the March 1996 cumulative supplement. On April 9, 1996, Abbott appealed the district court's decision to the U.S. Court of Appeals for the Federal Circuit.

1.6 COURT ORDER AFFECTING URUGUAY ROUND AGREEMENTS ACT-EXTENDED PATENTS

As a result of the April 4, 1996, decision of the United States Court of Appeals for the Federal Circuit in Merck, et al. v. Kessler, patent expiration dates for certain patents subject to patent term extensions under the Uruguay Round Agreements Act and to the patent term extension provisions at 35 U.S.C. § 156 may be changed. FDA is publishing a notice in the *Federal Register* advising NDA and NADA applicants that patent expiration dates changed by the Merck decision must be submitted within 60 days. Because there may be changes in listed patents as a result of the Merck decision, users of this publication should consult the most recent supplement, and are encouraged to confirm that patent information upon which they intend to rely is current. (See the *Patent and Exclusivity Addendum* to the *Approved Drug Products with Therapeutic Equivalence Evaluations*, 16th Edition that explains the background information on this court decision).

1.7 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)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

1ST TEXAS PHARMACEUTICALS INC
SUB SCHERER LABORATORIES
(1ST TX)

SCHERER LABORATORIES, INC
(SCHERER)

BARRE NATIONAL INC
(BARRE)

ALPHARMA USPD INC
(ALPHARMA)

BOEHRINGER MANNHEIM PHARMACEUTICALS CORP
(BOEHRINGER MANNHEIM)

BOEHRINGER MANNHEIM CORPORATION
THERAPEUTICS DIVISION
(BOEHRINGER MANNHEIM)

DAVID BULL LABORATORIES PARTY LTD
(BULL D)

FH FAULDING AND CO LTD
(FAULDING)
THEN CHANGED TO
FAULDING PHARMACEUTICAL CO
(FAULDING)

HOECHST ROUSSEL PHARMACEUTICALS INC
(HOECHST ROUSSEL)

HOECHST MARION ROUSSEL INC
(HOECHST MARION RSSL)

PHARMACIA INC
(PHARMACIA)

PHARMACIA AND UPJOHN CO
(PHARMACIA AND UPJOHN)

SCHWARZ PHARMA KREMERS
URBAN CO SUB SCHWARZ PHARMA AG
(SPKU)

SCHWARZ PHARMA INC
(SCHWARZ PHARMA)

UPJOHN CO
(UPJOHN)

PHARMACIA AND UPJOHN CO
(PHARMACIA AND UPJOHN)

UPJOHN MANUFACTURING CO
(UPJOHN)

PHARMACIA AND UPJOHN CARIBE INC
(PHARMACIA AND UPJOHN)

1.8 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.

The following *Approved Drug Products with Therapeutic Equivalence Evaluations* files are now available on Internet and are updated each October and April: Prescription Drug Product List; OTC Drug Products; Discontinued Drug Products; and Appendices. The update in October will include drug products that have been approved through August and the update in April will include drug products that have been approved through December.

These files may be accessed on the Internet's World Wide Web. FDA's Internet site replaces the Agency's electronic bulletin board and offers more information, in a more user-friendly form. To access the CDER Home Page, use this Uniform Resource Locator (URL): <http://www.fda.gov/cder/>. You do not need an Internet connection to reach the CDER Home Page; you can use the free dial-up connection (800) 222-0185. For further assistance, please call (301) 443-4908.

The Prescription Drug Products and OTC Drug Product files will be available on a monthly basis in the near future.

1.9 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 1995) 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 1995</u>	<u>MAR 1996</u>	<u>JUN 1996</u>	<u>SEP 1996</u>
DRUG PRODUCTS LISTED	9286	9303	9384	
SINGLE SOURCE	2217 (23.9%)	2248 (24.2%)	2323 (24.8%)	
MULTISOURCE	7069 (76.1%)	7055 (75.8%)	7061 (75.2%)	
THERAPEUTICALLY EQUIVALENT	6437 (69.3%)	6425 (69.0%)	6490 (69.2%)	
NOT THERAPEUTICALLY EQUIVALENT	440 (4.7%)	443 (4.8%)	468 (5.0%)	
EXCEPTIONS ¹	192 (2.1%)	187 (2.0%)	103 (1.0%)	
NEW MOLECULAR ENTITIES APPROVED	--	6	15	
NUMBER OF APPLICANTS	586	592	621	

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

ACETAMINOPHEN, HYDROCODONE BITARTRATE

TABLET; ORAL

ANEXSIA 7.5/650
MALLINCKRODT

AA 650MG;7.5MG

HYDROCODONE BITARTRATE AND ACETAMINOPHEN
KING PHARMS

AA 500MG;5MG

AA 750MG;7.5MG

AA 500MG;5MG

AA 750MG;7.5MG

AA 500MG;2.5MG

AA 500MG;5MG

AA 500MG;7.5MG

AA 650MG;7.5MG

AA 650MG;10MG

AA 750MG;7.5MG

AA 500MG;7.5MG

AA 650MG;10MG

AA 750MG;7.5MG

LORTAB
+ GRAHAM

AA 500MG;10MG

* UCB

AA 500MG;10MG

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

ACETAMINOPHEN, OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL

OXYCODONE AND ACETAMINOPHEN
VINTAGE PHARMS

AA 500MG;5MG

TABLET; ORAL
OXYCODONE AND ACETAMINOPHEN
VINTAGE PHARMS

AA 325MG;5MG

ACETAMINOPHEN, PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN
SUPERPHARM

AB 650MG;100MG

@ 650MG;100MG

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC
ACETIC ACID

AT MORTON GROVE 2%

ACETIC ACID, GLACIAL; HYDROCORTISONE

SOLUTION/DROPS; OTIC

HYDROCORTISONE AND ACETIC ACID
MORTON GROVE 2%;1%

N40168 001
AUG 30, 1996

> ADD >

> ADD >

ACRIVASTINE, PSEUDOPHEDRINE HYDROCHLORIDE

CAPSULE; ORAL

SEMPREX-D
* GLAXO WELLCOME 8MG;60MG

N19806 001
MAR 25, 1994

+ MEDEVA AMERICAS 8MG;60MG

N19806 001
MAR 25, 1994

ADAPALENE

GEL; TOPICAL

DIFFERIN
+ GALDERMA 0.1%

N20380 001
MAY 31, 1996

SOLUTION; TOPICAL

DIFFERIN
+ GALDERMA 0.1%

N20338 001
MAY 31, 1996

AMMONIUM LACTATE

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

CREAM; TOPICAL
 LAC-HYDRIN
 BRISTOL MYERS

EQ 12% BASE

N20508 001
 AUG 29, 1996

TABLET; ORAL
 ADDERALL 10
 RICHWOOD PHARM

2.5MG; 2.5MG; 2.5MG; 2.5MG

N11522 007
 FEB 13, 1996

ADDERALL 20
 + RICHWOOD PHARM

5MG; 5MG; 5MG; 5MG

N11522 008
 FEB 13, 1996

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

AMOXICILLIN

TABLET, CHEWABLE; ORAL

AMOXICILLIN

APOTHECON

125MG

N64131 001
 MAY 06, 1996

250MG

N64131 002
 MAY 06, 1996

AB CLONMEL HLTH CARE

125MG

N64139 001
 JAN 29, 1996

250MG

N64139 002
 JAN 29, 1996

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

CAPSULE, EXTENDED RELEASE; ORAL

BIPHETAMINE 12.5

@ FISOONS

EQ 6.25MG BASE;
 EQ 6.25MG BASE;
 EQ 6.25MG BASE;
 EQ 6.25MG BASE

N10093 007
 N10093 007

AMOXICILLIN; CLAVULANATE POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

AUGMENTIN '200'

+ SMITHKLINE BEECHAM

200MG/5ML;
 EQ 28.5MG BASE/5ML

N50725 001
 MAY 31, 1996

AUGMENTIN '400'

+ SMITHKLINE BEECHAM

400MG/5ML;
 EQ 57MG BASE/5ML

N50725 002
 MAY 31, 1996

TABLET; ORAL

AUGMENTIN '875'

+ SMITHKLINE BEECHAM

875MG; EQ 125MG BASE

N50720 001
 FEB 13, 1996

SUSPENSION; ORAL

FUNGIZONE

+ BRISTOL MYERS SQUIBB 100MG/ML

AMPICILLIN/AMPICILLIN TRIHYDRATE; PROBENECID

TABLET, CHEWABLE; ORAL

AUGMENTIN '200'

+ SMITHKLINE BEECHAM

200MG; EQ 28.5MG BASE

N50726 001
 MAY 31, 1996

AUGMENTIN '400'

+ SMITHKLINE BEECHAM

400MG; EQ 57MG BASE

N50726 002
 MAY 31, 1996

POWDER FOR RECONSTITUTION; ORAL

POLYCYCLIN-PRB

APOTHECON

EQ 3.5GM BASE/BOT; 1GM/BOT
 EQ 3.5GM BASE/BOT; 1GM/BOT

EQ 3.5GM BASE/BOT; 1GM/BOT
 EQ 3.5GM BASE/BOT; 1GM/BOT

EQ 3.5GM BASE/BOT; 1GM/BOT
 EQ 3.5GM BASE/BOT; 1GM/BOT

PROBAMPACIN

BIOCRAFT

EQ 3.5GM BASE/BOT; 1GM/BOT
 EQ 3.5GM BASE/BOT; 1GM/BOT

EQ 3.5GM BASE/BOT; 1GM/BOT
 EQ 3.5GM BASE/BOT; 1GM/BOT

EQ 3.5GM BASE/BOT; 1GM/BOT
 EQ 3.5GM BASE/BOT; 1GM/BOT

AMPHOTERICIN B

SUSPENSION; ORAL

FUNGIZONE

+ BRISTOL MYERS SQUIBB 100MG/ML

N50341 003

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL
BUTALBITAL, ASPIRIN & CAFFEINE
HAISEY 325MG; 50MG; 40MG
 @ 325MG; 50MG; 40MG

N89448 001
 DEC 01, 1986
 N89448 001
 DEC 01, 1986

EQ 250MG BASE
 EQ 600MG BASE

N50711 001
 JUL 18, 1996
 N50730 001
 JUN 12, 1996

AZITHROMYCIN DIHYDRATE

TABLET; ORAL
ZITHROMAX
 + PFIZER

ASPIRIN; CARISOPRODOL

TABLET; ORAL
CARISOPRODOL AND ASPIRIN
EON LABS 325MG; 200MG

N40116 001
 APR 25, 1996

N61212 001
 N61212 001
 N60687 001
 N60687 001

500 UNITS/GM
 500 UNITS/GM
 500 UNITS/GM

BACITRACIN

ointment; ophthalmic
BACITRACIN
ALTANA

@ ELI LILLY
 @ LILLY

ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE

TABLET; ORAL
CARISOPRODOL, ASPIRIN AND CODEINE PHOSPHATE
EON LABS 325MG; 200MG; 16MG

N40118 001
 APR 16, 1996

N74698 001
 AUG 20, 1996

10MG

AB + WALLACE PHARMS 325MG; 200MG; 16MG

N12366 002
 JUL 11, 1983

N74698 002
 AUG 20, 1996
 N74584 001
 AUG 19, 1996
 N74584 002
 AUG 19, 1996

10MG
 20MG
 10MG
 20MG

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
LOGEN
SUPERPHARM 0.025MG; 2.5MG
 @ 0.025MG; 2.5MG

N88962 001
 MAY 10, 1985
 N88962 001
 MAY 10, 1985

BECLOMETHASONE DIPROPIONATE MONOHYDRATE

SPRAY, METERED; NASAL
BECONASE AQ
 @ GLAXO WELLCOME

N85211 001
 N85211 001

EQ 0.042MG DIPROP/INH
 EQ 0.042MG DIPROP/INH

N19389 001
 JUL 27, 1987
 N19389 001
 JUL 27, 1987

AZATHIOPRINE

TABLET; ORAL
AZATHIOPRINE
ROXANE 50MG
 @ IMURAN
 @ GLAXO WELLCOME 50MG

N74069 001
 FEB 16, 1996
 N16324 001

EQ 0.042MG DIPROP/INH
 EQ 0.042MG DIPROP/INH
 EQ 0.042MG DIPROP/INH
 EQ 0.084MG DIPROP/INH

N19589 001
 DEC 23, 1987
 N19589 001
 DEC 23, 1987
 N20469 001
 JUN 26, 1996

> ADD >	<u>BISMUTH SUBSALICYLATE, METRONIDAZOLE, TETRACYCLINE HYDROCHLORIDE</u>						
> ADD >	TABLET, CHEWABLE, TABLET, CAPSULE; ORAL						
> ADD >	HELIDAC						
> ADD >	+ PROCTER AND GAMBLE	262.4MG;250MG;500MG		N50719 001			N18731 003
> ADD >				AUG 15, 1996			APR 22, 1996
	<u>BLEOMYCIN SULFATE</u>						
	INJECTABLE; INJECTION						
	<u>BLENOXANE</u>						
	+ BRISTOL MYERS SQUIBB	EQ 15 UNITS BASE/VIAL		N50443 001			
		EQ 15 UNITS BASE/VIAL		N50443 001			
	<u>BLEOMYCIN SULFATE</u>						
	+ PHARMACIA AND UPJOHN	EQ 15 UNITS BASE/VIAL		N64084 001			N84723 001
		EQ 30 UNITS BASE/VIAL		JUN 01, 1996			N84723 001
				N64084 002			
				JUN 01, 1996			
	<u>BROMPHENIRAMINE MALEATE</u>						
	TABLET; ORAL						
	<u>DIMETANE</u>						
	+ ROBINS AH	4MG		N10799 003			N84719 001
	@ WHITEHALL ROBINS	4MG		N10799 003			N84719 001
	<u>BUPRENORPHINE HYDROCHLORIDE</u>						
	INJECTABLE; INJECTION						
	<u>BUPRENEX</u>						
	+ RECKITT AND COLMAN	EQ 0.3MG BASE/ML		N18401 001			N20554 001
	<u>BUPRENORPHINE HCL</u>						JUL 22, 1996
	+ SANOFI WINTHROP	EQ 0.3MG BASE/ML		N74137 001			
				JUN 03, 1996			
	<u>BUSPIRONE HYDROCHLORIDE</u>						
	TABLET; ORAL						
	BUSPAR						
	+ BRISTOL MYERS SQUIBB	10MG		N18731 002			N18379 002
		10MG		SEP 29, 1986			
				N18731 002			
				SEP 29, 1986			
	<u>BUSPIRONE HYDROCHLORIDE</u>						
	TABLET; ORAL						
	BUSPAR						
	+ BRISTOL MYERS SQUIBB	15MG					
		30MG					
	<u>BUSPIRONE HYDROCHLORIDE</u>						
	TABLET; ORAL						
	BUSPAR						
	+ BRISTOL MYERS SQUIBB	15MG					
		30MG/5ML					
		30MG/5ML					
	<u>BUTABARBITAL SODIUM</u>						
	ELIXIR; ORAL						
	<u>SARISOL</u>						
	+ HALSEY						
	<u>SARISOL NO. 1</u>						
	TABLET; ORAL						
	<u>SARISOL NO. 1</u>						
	+ HALSEY						
	<u>SARISOL NO. 2</u>						
	TABLET; ORAL						
	<u>SARISOL NO. 2</u>						
	+ HALSEY						
	<u>CALCIOTRIENE</u>						
	CREAM; TOPICAL						
	DOVONEX						
	+ BRISTOL MYERS SQUIBB	0.005%					
	<u>CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE</u>						
	SOLUTION; INTRAPERITONEAL						
	<u>DELFLX W/ DEXTROSE 1.5% IN PLASTIC CONTAINER</u>						
	FRESENIUS						
		25.7MG/100ML; 1.5GM/100ML;					
		15.2MG/100ML; 567MG/100ML;					
		392MG/100ML					
	<u>DELFLX W/ DEXTROSE 2.5% IN PLASTIC CONTAINER</u>						
	FRESENIUS						
		25.7MG/100ML; 2.5GM/100ML;					
		15.2MG/100ML; 567MG/100ML;					
		392MG/100ML					

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

SOLUTION; INTRAPERITONEAL
AT DELFLX W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 3.5GM/100ML;
 15.2MG/100ML; 567MG/100ML;
 392MG/100ML N18379 007
 JUN 24, 1988

AT DELFLX W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 4.25GM/100ML;
 15.2MG/100ML; 567MG/100ML;
 392MG/100ML N18379 001
 JUN 24, 1988

AT DELFLX-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 1.5GM/100ML;
 5.08MG/100ML; 538MG/100ML;
 448MG/100ML N18379 004
 JUL 07, 1982

AT DELFLX-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 2.5GM/100ML;
 5.08MG/100ML; 538MG/100ML;
 448MG/100ML N18379 005
 JUL 07, 1982

AT DELFLX-LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 3.5GM/100ML;
 5.08MG/100ML; 538MG/100ML;
 448MG/100ML N18379 008
 JUN 24, 1988

AT DELFLX-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 4.25GM/100ML;
 5.08MG/100ML; 538MG/100ML;
 448MG/100ML N18379 006
 JUL 07, 1982

AT INPER SOL W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 1.5GM/100ML;
 15.2MG/100ML; 567MG/100ML;
 392MG/100ML N18379 002
 JUN 24, 1988

AT INPER SOL W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 2.5GM/100ML;
 15.2MG/100ML; 567MG/100ML;
 392MG/100ML N18379 003
 JUN 24, 1988

AT INPER SOL W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 3.5GM/100ML;
 15.2MG/100ML; 567MG/100ML;
 392MG/100ML N18379 007
 JUN 24, 1988

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

SOLUTION; INTRAPERITONEAL
AT INPER SOL W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 4.25GM/100ML;
 15.2MG/100ML; 567MG/100ML;
 392MG/100ML N18379 001
 JUN 24, 1988

AT INPER SOL-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 1.5GM/100ML;
 5.08MG/100ML; 538MG/100ML;
 448MG/100ML N18379 004
 JUL 07, 1982

AT INPER SOL-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 2.5GM/100ML;
 5.08MG/100ML; 538MG/100ML;
 448MG/100ML N18379 005
 JUL 07, 1982

AT INPER SOL-LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 3.5GM/100ML;
 5.08MG/100ML; 538MG/100ML;
 448MG/100ML N18379 008
 JUN 24, 1988

AT INPER SOL-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
 FRESSENIUS 25.7MG/100ML; 4.25GM/100ML;
 5.08MG/100ML; 538MG/100ML;
 448MG/100ML N18379 006
 JUL 07, 1982

CAPTOPRIL

TABLET; ORAL

AB CAPOTEN 100MG N18343 003
AB BRISTOL MYERS SQUIBB 100MG N18343 003
 75MG N18343 007
 JUN 13, 1995

* 150MG N18343 004
 JUN 13, 1995

@ 75MG N18343 007
 JUN 13, 1995

@ 150MG N18343 004
 JUN 13, 1995

AB CAPTOPRIL 12.5MG N74590 004
AB BAKER NORTON 25MG N74590 002
 25MG N74590 002
 AUG 30, 1996
 25MG N74590 002
 AUG 30, 1996

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

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL
 BAKER NORTON

> ADD >
 > ADD >
 > ADD >

AB 50MG N74590 001
 AUG 30, 1996
AB 100MG N74590 003
 AUG 30, 1996
AB 12.5MG N74433 001
 FEB 13, 1996
AB 25MG N74433 002
 FEB 13, 1996
AB 50MG N74433 003
 FEB 13, 1996
AB 100MG N74433 004
 FEB 13, 1996
AB 12.5MG N74576 001
 APR 23, 1996
AB 25MG N74576 002
 APR 23, 1996
AB 50MG N74576 003
 APR 23, 1996
AB 100MG N74576 004
 APR 23, 1996
AB 12.5MG N74462 001
 FEB 13, 1996
AB 25MG N74462 002
 FEB 13, 1996
AB 50MG N74462 003
 FEB 13, 1996
AB 100MG N74462 004
 FEB 13, 1996
AB 12.5MG N74386 001
 MAY 23, 1996
AB 25MG N74386 002
 MAY 23, 1996
AB 50MG N74386 003
 MAY 23, 1996
AB 100MG N74386 004
 MAY 23, 1996
AB 12.5MG N74418 001
 FEB 13, 1996
AB 25MG N74418 002
 FEB 13, 1996
AB 50MG N74418 003
 FEB 13, 1996
AB 100MG N74418 004
 FEB 13, 1996

TABLET; ORAL
CAPTOPRIL
 EON LABS

AB 12.5MG N74519 001
 FEB 13, 1996
AB 25MG N74519 002
 FEB 13, 1996
AB 50MG N74519 003
 FEB 13, 1996
AB 100MG N74519 004
 FEB 13, 1996
AB 12.5MG N74477 001
 FEB 13, 1996
AB 25MG N74477 002
 FEB 13, 1996
AB 50MG N74477 003
 FEB 13, 1996
AB 100MG N74477 004
 FEB 13, 1996
AB 12.5MG N74481 001
 FEB 13, 1996
AB 25MG N74481 002
 FEB 13, 1996
AB 50MG N74481 003
 FEB 13, 1996
AB 100MG N74481 004
 FEB 13, 1996
AB 12.5MG N74483 001
 FEB 13, 1996
AB 25MG N74483 002
 FEB 13, 1996
AB 50MG N74483 003
 FEB 13, 1996
AB 100MG N74483 004
 FEB 13, 1996
AB 12.5MG N74423 001
 FEB 13, 1996
AB 25MG N74423 002
 FEB 13, 1996
AB 50MG N74423 003
 FEB 13, 1996
AB 100MG N74423 004
 FEB 13, 1996
AB 12.5MG N74434 001
 FEB 13, 1996
AB 25MG N74434 002
 FEB 13, 1996

TABLET; ORAL
CAPTOPRIL
 HALLMARK PHARMS

TABLET; ORAL
CAPTOPRIL
 INVAMED

TABLET; ORAL
CAPTOPRIL
 LEMMON

TABLET; ORAL
CAPTOPRIL
 MOVA

TABLET; ORAL
CAPTOPRIL
 MYLAN

CAPTOPRIL

TABLET, ORAL
CAPTOPRIL
MYLAN

AB 50MG
 AB 100MG
 AB 12.5MG
 AB 25MG
 AB 50MG
 AB 100MG

N74434 003
 FEB 13, 1996
 N74434 004
 FEB 13, 1996
 N74322 001
 FEB 13, 1996
 N74322 002
 FEB 13, 1996
 N74322 003
 FEB 13, 1996
 N74322 004
 FEB 13, 1996
 N74493 001
 FEB 13, 1996
 N74493 002
 FEB 13, 1996
 N74493 003
 FEB 13, 1996
 N74493 004
 FEB 13, 1996
 N74451 001
 FEB 13, 1996
 N74451 002
 FEB 13, 1996
 N74451 003
 FEB 13, 1996
 N74451 004
 FEB 13, 1996
 N74505 001
 FEB 13, 1996
 N74505 002
 FEB 13, 1996
 N74505 003
 FEB 13, 1996
 N74505 004
 FEB 13, 1996

CARBAMAZEPINE

TABLET, EXTENDED RELEASE; ORAL
TEGRETOL-XR
+ CIBA GEIGY

N20234 001
 MAR 25, 1996

CARBAMAZEPINE

TABLET, EXTENDED RELEASE; ORAL
TEGRETOL-XR
+ CIBA GEIGY

N20234 002
 MAR 25, 1996
 N20234 003
 MAR 25, 1996

CARISOPRODOL

TABLET, ORAL
CARISOPRODOL
WEST WARD PHARM

N40124 001
 JAN 24, 1996

CEFACLOR

CAPSULE; ORAL
CEFACLOR
MARSAM

N64148 001
 MAY 23, 1996
 N64148 002
 MAY 23, 1996
 N64145 001
 JUN 24, 1996
 N64145 002
 JUN 24, 1996

TABLET, EXTENDED RELEASE; ORAL
CECLOR CD
+ ELI LILLY

N50673 001
 JUN 28, 1996
 N50673 002
 JUN 28, 1996

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
ANCEF IN DEXTROSE 5% IN PLASTIC CONTAINER
* BAXTER

N50566 003
 JUN 08, 1983
 N50566 004
 JUN 08, 1983
 N50566 003
 JUN 08, 1983

EQ 10MG BASE/ML
 EQ 20MG BASE/ML
 EQ 10MG BASE/ML

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
ANCEP IN DEXTROSE 5% IN PLASTIC CONTAINER
@ BAXTER

N50566 004
JUN 08, 1983

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN
ROCHE
@

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

N62654 001
APR 30, 1987
N62654 001
APR 30, 1987

CEFEPIME HYDROCHLORIDE (ARGININE FORMULATION)

INJECTABLE; INJECTION
MAXIPIME

+ BRISTOL MYERS SQUIBB EQ 500MG BASE/VIAL
+ EQ 1GM BASE/VIAL
+ EQ 2GM BASE/VIAL

N50679 001
JAN 18, 1996
N50679 002
JAN 18, 1996
N50679 003
JAN 18, 1996

CEPHALEXIN

CAPSULE; ORAL
CEPANEK
APOTHECON

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

EQ 250MG BASE
EQ 500MG BASE

N63063 001
SEP 29, 1989
N63063 002
SEP 29, 1989

CEFTAZIDIME (ARGININE FORMULATION)

INJECTABLE; INJECTION
CEPTAZ

+ GLAXO WELLCOME 500MG/VIAL
@ 500MG/VIAL

N50646 001
SEP 27, 1990
N50646 001
SEP 27, 1990

CEPHALEXIN
APOTHECON

AB
AB
AB
AB

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

N63063 001
SEP 29, 1989
N63063 002
SEP 29, 1989
N62872 001
JUN 20, 1988
N62871 001
JUL 05, 1988
N62872 001
JUN 20, 1988
N62871 001
JUL 05, 1988

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION
CEFTAZIDIME SODIUM IN PLASTIC CONTAINER

AP BAXTER EQ 10MG BASE/ML
+ EQ 10MG BASE/ML

N63221 001
APR 29, 1993
N63221 001
APR 29, 1993

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION
CEPHALOTHIN SODIUM W/
* BAXTER

EQ 20MG BASE/ML
EQ 20MG BASE/ML
EQ 20MG BASE/ML
EQ 40MG BASE/ML
EQ 40MG BASE/ML
EQ 40MG BASE/ML

N62422 003
JAN 31, 1984
N62422 005
JUL 16, 1991
N62730 001
MAR 05, 1987
N62422 004
JAN 31, 1984
N62422 006
JUL 16, 1991
N62730 002
MAR 05, 1987

AP FORTAZ IN PLASTIC CONTAINER

AP GLAXO WELLCOME EQ 10MG BASE/ML
@ EQ 10MG BASE/ML

N50634 001
APR 28, 1989
N50634 001
APR 28, 1989

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION

CEPHALOTHIN SODIUM W/ DEXTROSE IN PLASTIC CONTAINER

@ BAXTER EQ 20MG BASE/ML NG2422 003
 JAN 31, 1984
 EQ 20MG BASE/ML N62422 005
 JUL 16, 1991
 EQ 20MG BASE/ML N62730 001
 MAR 05, 1987
 EQ 40MG BASE/ML N62422 004
 JAN 31, 1984
 EQ 40MG BASE/ML N62422 006
 JUL 16, 1991
 EQ 40MG BASE/ML N62730 002
 MAR 05, 1987

CEPHALOTHIN SODIUM W/ SODIUM CHLORIDE IN PLASTIC CONTAINER

+ BAXTER EQ 20MG BASE/ML N62422 001
 JAN 31, 1984
 EQ 40MG BASE/ML N62422 002
 JAN 31, 1984
 EQ 20MG BASE/ML N62422 001
 JAN 31, 1984
 EQ 40MG BASE/ML N62422 002
 JAN 31, 1984

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION

CHLOR-TRIMETON

AP + SCHERING PLOUGH EQ 10MG/ML N08826 001
 @ 10MG/ML N08826 001

CHLORPHENIRAMINE MALEATE

AP + STERIS EQ 10MG/ML N86096 001
 @ 10MG/ML N86096 001

CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL

TUSSIONEX

* FISON'S EQ 8MG MALEATE/5ML; N19111 001
 EQ 10MG BITARTRATE/5ML DEC 31, 1987

+ MEDEVA PHARMS

EQ 8MG MALEATE/5ML; N19111 001
 EQ 10MG BITARTRATE/5ML DEC 31, 1987

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

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

AB HALSEY 5MG N85340 001
 AB HALSEY 10MG N83339 001
 AB HALSEY 25MG N84685 001
 @ 5MG N85340 001
 @ 10MG N85339 001
 @ 25MG N84685 001

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL

CHLORHEXIDINE GLUCONATE

AT HI TECH PHARMA 0.12% N74356 001
 MAY 07, 1996

CHLORPROPAMIDE

TABLET; ORAL

CHLORPROPAMIDE

AB BARR 100MG N88812 001
 AB BARR 100MG OCT 19, 1984
 AB BARR 100MG N89446 001
 AB BARR 250MG NOV 17, 1986
 AB BARR 250MG N88813 001
 AB BARR 250MG OCT 19, 1984
 @ 100MG N89447 001
 @ 100MG NOV 17, 1986
 @ 100MG N88812 001
 @ 100MG OCT 19, 1984
 @ 250MG N89446 001
 @ 250MG NOV 17, 1986
 @ 250MG N88813 001
 @ 100MG HALSEY N89447 001
 @ 100MG HALSEY N83321 001
 @ 250MG HALSEY JAN 16, 1986
 @ 250MG HALSEY N88662 001
 @ 100MG HALSEY JAN 09, 1986
 @ 100MG HALSEY N89321 001
 @ 100MG HALSEY JAN 16, 1986

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE
 @ HALSEY

250MG
250MG
 250MG

N88662 001
 JAN 09, 1986
 N88695 001
 SEP 17, 1984
 N88695 001
 SEP 17, 1984

> ADD >
 > ADD >
 > ADD >

EQ 4GM RESIN/SCOOPFUL

N74562 002
 AUG 15, 1996

AB

250MG

N88662 001

> ADD >

POWDER; ORAL
LOCHOLEST LIGHT
 EON LABS

AB

EQ 4GM RESIN/PACKET

N73263 001
 FEB 22, 1996

AB

250MG

N88695 001

> ADD >

PREVALITE
 UPSHER SMITH

AB

EQ 4GM RESIN/PACKET

N15640 001
 N15640 003

AB

250MG

N88695 001

> ADD >

QUESTRAN
 + BRISTOL MYERS

AB

EQ 4GM RESIN/PACKET

N15640 001
 N15640 003

AB

250MG

N88695 001

> ADD >

QUESTRAN LIGHT
 + BRISTOL MYERS

AB

EQ 4GM RESIN/PACKET

N19669 001
 DEC 05, 1988

AB

50MG

N87247 001

> ADD >

CHROMIC CHLORIDE
 INJECTABLE; INJECTION
CHROMIC CHLORIDE
 FUJISAWA

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N19271 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N18961 001
 JUN 26, 1986

AB

50MG

N18961 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N18961 001
 JUN 26, 1986

AB

50MG

N18961 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N18961 001
 JUN 26, 1986

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE
 CHELSEA LABS

500MG

N40137 001
 AUG 09, 1996

> ADD >

CHROMIC CHLORIDE
 INJECTABLE; INJECTION
CHROMIC CHLORIDE
 FUJISAWA

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

N19271 001
 MAY 05, 1987

AB

500MG

N40137 001

> ADD >

CHROMIC CHLORIDE IN PLASTIC CONTAINER
 + ABBOTT

AB

EQ 0.004MG CHROMIUM/ML

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN '96 - AUG '96

DICYCLOMINE HYDROCHLORIDE

INJECTABLE; INJECTION
BENTYL PRESERVATIVE FREE

AP HOECHST MARION RSSL 10MG/ML

N08370 002
OCT 15, 1984

DIFLUNISAL

TABLET; ORAL
DIFLUNISAL

AB GENEVA PHARMS 500MG

AB PUREPAC PHARM 250MG

AB 500MG

N74604 001
JUN 10, 1996
N74285 001
MAY 07, 1996
N74285 002
MAY 07, 1996

DIGOXIN

INJECTABLE; INJECTION

AP DIGOXIN 0.25MG/ML

N40093 001
MAY 16, 1996

AP DIGOXIN PEDIATRIC
SANOFI WINTHROP

AP 0.1MG/ML

N40092 001
APR 25, 1996

LANOXIN
+ GLAXO WELLCOME

AP 0.1MG/ML

N09330 004

LANOXIN PEDIATRIC
+ GLAXO WELLCOME

AP 0.1MG/ML

N09330 004

DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION

AP CARDIZEM
+ HOECHST MARION RSSL 5MG/ML

N20027 001
OCT 24, 1991

AP 5MG/ML

N74617 001
FEB 28, 1996

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL

AA HALSEY 50MG

N87914 001
JUN 04, 1984
N87914 001
JUN 04, 1984

ELIXIR; ORAL

AA BELIX
HALSEY

12.5MG/5ML

N86586 001
OCT 03, 1983

12.5MG/5ML

N86586 001
OCT 03, 1983

AA DIBENIL
CENCI

12.5MG/5ML

N88304 001
DEC 16, 1983

12.5MG/5ML

N88304 001
DEC 16, 1983

AA DIPHENHYDRAMINE HCL
CENCI

12.5MG/5ML

N87941 001
DEC 17, 1982

12.5MG/5ML

N87941 001
DEC 17, 1982

DISOPYRAMIDE PHOSPHATE

CAPSULE, EXTENDED RELEASE; ORAL

B* DISOPYRAMIDE PHOSPHATE
KV PHARM

EQ 100MG BASE

N71929 001
AUG 19, 1988

EQ 100MG BASE

N71929 001
AUG 19, 1988

AB NORPACE CR
SEARLE

EQ 100MG BASE

N18655 001
JUL 20, 1982

EQ 100MG BASE

N18655 001
JUL 20, 1982

DOCETAXEL

INJECTABLE; INJECTION

TAXOTERE
+ RHONE POULENC

EQ 40MG BASE/ML

N20449 001
MAY 14, 1996

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL
ESTRADIOL
 MENOREST
 AB 0.0375MG/24HR
 AB 0.05MG/24HR
 AB 0.075MG/24HR
 AB 0.1MG/24HR

N20538 001
 JUL 31, 1996
 N20538 003
 JUL 31, 1996
 N20538 002
 JUL 31, 1996
 N20538 004
 JUL 31, 1996

VIVELLE
 AB + CIBA GEIGY 0.0375MG/24HR
 AB + 0.05MG/24HR
 AB + 0.075MG/24HR
 AB + 0.1MG/24HR

N20323 001
 OCT 28, 1994
 N20323 002
 OCT 28, 1994
 N20323 003
 OCT 28, 1994
 N20323 004
 OCT 28, 1994

INSERT, EXTENDED RELEASE; VAGINAL
 ESTRING
 + PHARMACIA AND UPJOHN 0.0075MG/24HR

N20472 001
 APR 26, 1996

ESTRACE

BRISTOL MYERS SQUIBB 0.5MG
 AB 1MG
 AB 2MG
 AB + ESTRADIOL
 WATSON LABS 0.5MG
 AB 1MG
 AB 2MG

N81295 001
 JUN 30, 1993
 N84499 001
 N84500 001
 N40114 003
 MAR 14, 1996
 N40114 001
 MAR 14, 1996
 N40114 002
 MAR 14, 1996

ESTRONE

INJECTABLE; INJECTION
 ESTROGENIC SUBSTANCE
 BF + WYETH AYERST
 2MG/ML
 2MG/ML

N83488 001
 N83488 001

ESTRONE

INJECTABLE; INJECTION
 NATURAL ESTROGENIC SUBSTANCE-ESTRONE
 2MG/ML
 BP STERIS
 +
 2MG/ML

N85237 001
 NOV 23, 1982
 N85237 001
 NOV 23, 1982

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE

TABLET; ORAL-21

ETHYNODIOL DIACETATE AND ETHINYL ESTRADIOL 1/35-21
 WATSON LABS 0.035MG;1MG
 AB DLT >
 > DLT >
 ETHYNODIOL DIACETATE AND ETHINYL ESTRADIOL 1/50-21
 WATSON LABS 0.05MG;1MG
 AB DLT >
 > DLT >
 ZOVIA 1/35E-21
 WATSON LABS 0.035MG;1MG
 AB ADD >
 > ADD >
 ZOVIA 1/50E-21
 WATSON LABS 0.05MG;1MG
 AB ADD >
 > ADD >

N72720 001
 DEC 30, 1991
 N72722 001
 DEC 30, 1991
 N72720 001
 DEC 30, 1991
 N72722 001
 DEC 30, 1991

TABLET; ORAL-28

ETHYNODIOL DIACETATE AND ETHINYL ESTRADIOL 1/35-28
 WATSON LABS 0.035MG;1MG
 AB DLT >
 > DLT >
 ETHYNODIOL DIACETATE AND ETHINYL ESTRADIOL 1/50-28
 WATSON LABS 0.05MG;1MG
 AB DLT >
 > DLT >
 ZOVIA 1/35E-28
 WATSON LABS 0.035MG;1MG
 AB ADD >
 > ADD >
 ZOVIA 1/50E-28
 WATSON LABS 0.05MG;1MG
 AB ADD >
 > ADD >

N72721 001
 DEC 30, 1991
 N72723 001
 DEC 30, 1991
 N72721 001
 DEC 30, 1991
 N72723 001
 DEC 30, 1991

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)
 WATSON LABS 0.035MG;0.035MG;0.5MG;1MG
 AB DLT >
 > DLT >
 +
 WATSON LABS 0.035MG;0.035MG;0.5MG;1MG
 AB DLT >
 > DLT >

LMG N71041 001
 SEP 24, 1991
 2MG N71041 001
 SEP 24, 1991

ETHINYL ESTRADIOL, NORETHINDRONE

TABLET; ORAL-21
ORTHO NOVUM 7/14-21
 AE * JOHNSON RW
 @
 0.035MG, 0.035MG; 0.5MG, 1MG N19004 001
 APR 04, 1984
 0.035MG, 0.035MG; 0.5MG, 1MG N19004 001
 APR 04, 1984

N20363 001
 APR 26, 1996

ETODOLAC

TABLET; ORAL
 LODINE
 * WYETH AXERST
 400MG
 400MG
 500MG
 +
 N18322 004
 JUL 29, 1993
 N18322 004
 JUL 29, 1993
 N18322 005
 JUN 28, 1996

N19510 004
 NOV 04, 1986
 N19510 004
 NOV 04, 1986

ETOPOSID

INJECTABLE; INJECTION
ETOPOSID
 GENSLA
 20MG/ML
 20MG/ML
 20MG/ML
 20MG/ML
 PHARMACHEMIE (NL)
 N74529 001
 JUL 24, 1996
 N74513 001
 MAR 14, 1996
 N74513 001
 MAR 14, 1996
 N74227 001
 FEB 22, 1996

N20416 001
 AUG 30, 1996

ETOPOSID PHOSPHATE

INJECTABLE; INJECTION
 ETOPOPHOS
 + BRISTOL MYERS SQUIBB EQ 100MG BASE/VIAL
 N20457 001
 MAY 17, 1996

N18830 002
 OCT 31, 1985

EVANS BLUE

INJECTABLE; INJECTION
 EVANS BLUE
 @ PARKE DAVIS
 0.5%
 N08041 001

N12787 004
 N12787 002

FAMCICLOVIR

TABLET; ORAL
 FAMVIR
 SMITHKLINE BEECHAM 250MG

FAMOTIDINE

INJECTABLE; INJECTION
 PEPCID IV PRESERVATIVE FREE
 * MERCK 10MG/ML
 PEPCID PRESERVATIVE FREE
 + MERCK 10MG/ML

FERUMOXIDES

> ADD >
 INJECTABLE; INJECTION
 FERIDEX I.V.
 + ADV MAGNETICS EQ 11.2MG IRON/ML

PEXOFENADINE HYDROCHLORIDE

CAPSULE; ORAL
 ALLEGRA
 + HOECHST MARION RSSL 60MG

N20625 001
 JUL 25, 1996

FLECAINIDE ACETATE

TABLET; ORAL
 TAMBOCOR
 @ 3M 200MG

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL
 FLUOCINOLONE ACETONIDE
 AT * HAMILTON PHARMA CA 0.01%
 AT * 0.025%

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL
 @ SUPERPHARM

15MG

@
 WARNER CHILCOTT

30MG

15MG

30MG

N71659 001

AUG 04, 1988

N71660 001

AUG 04, 1988

N71767 001

DEC 04, 1987

N71768 001

DEC 04, 1987

N71767 001

DEC 04, 1987

N71768 001

DEC 04, 1987

N18370 002

JUN 26, 1984

N18370 001

FEB 10, 1983

N18370 002

JUN 26, 1984

N18370 001

FEB 10, 1983

N18413 001

NOV 30, 1983

N18413 002

NOV 30, 1983

N18413 001

NOV 30, 1983

N18413 002

NOV 30, 1983

20MG

40MG

20MG

40MG

20MG

40MG

20MG

40MG

FUROSEMIDE

TABLET; ORAL
FUROSEMIDE
 SUPERPHARM

AB

AB

@

@

ZENITH GOLDLINE

ZENITH LABS

GANCICLOVIR

IMPLANT; IMPLANTATION
 VITRASERT
 * CHIRON VISION

4.5-6.4MG

4.5MG

N20569 001

MAR 04, 1996

N20569 001

MAR 04, 1996

GANCICLOVIR SODIUM

INJECTABLE; INJECTION
 CYTOVENE IV
 + ROCHE

EQ 500MG BASE/VIAL

EQ 500MG BASE/VIAL

N19661 001

JUN 23, 1989

N19661 001

JUN 23, 1989

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL
 @ SUPERPHARM

15MG

@
 WARNER CHILCOTT

30MG

15MG

30MG

N71659 001

AUG 04, 1988

N71660 001

AUG 04, 1988

N71767 001

DEC 04, 1987

N71768 001

DEC 04, 1987

N71767 001

DEC 04, 1987

N71768 001

DEC 04, 1987

N18370 002

JUN 26, 1984

N18370 001

FEB 10, 1983

N18370 002

JUN 26, 1984

N18370 001

FEB 10, 1983

N18413 001

NOV 30, 1983

N18413 002

NOV 30, 1983

N18413 001

NOV 30, 1983

N18413 002

NOV 30, 1983

20MG

40MG

20MG

40MG

20MG

40MG

20MG

40MG

FLUTICASONE PROPIONATE

AEROSOL, METERED; INHALATION
 FLOVENT
 GLAXO WELLCOME

0.044MG/INH

0.11MG/INH

0.22MG/INH

N20548 001

MAR 27, 1996

N20548 002

MAR 27, 1996

N20548 003

MAR 27, 1996

FOLIC ACID

TABLET; ORAL
FOLIC ACID
 HALSEY

1MG

1MG

N83598 001

N83598 001

FOSPHENYTOIN SODIUM

INJECTABLE; INJECTION
 CEREBYX
 + PARKE DAVIS

EQ 50MG PHENYTOIN NA/ML

AUG 05, 1996

GEMCITABINE HYDROCHLORIDE

INJECTABLE; INJECTION
 GEMZAR
 + ELI LILLY

EQ 200MG BASE/VIAL

N20509 001

MAY 15, 1996

GEMCITABINE HYDROCHLORIDE

INJECTABLE; INJECTION
GEMZAR
+ ELI LILLY

EQ 1GM BASE/VIAL
N20509 002
MAY 15, 1996

GENTAMICIN SULFATE

INJECTABLE; INJECTION
GENTAMICIN SULFATE
ABBOTT

<u>AP</u>	EQ 60MG BASE/100ML	N62413 006	<u>AT</u>	CIBA	EQ 0.3% BASE	N62501 001
<u>AP</u>	EQ 70MG BASE/100ML	AUG 11, 1983	<u>AT</u>	IOLAB	EQ 0.3% BASE	JUL 26, 1984
<u>AP</u>	EQ 80MG BASE/100ML	N62413 007				
<u>AP</u>	EQ 90MG BASE/100ML	AUG 11, 1983				
<u>AP</u>	EQ 100MG BASE/100ML	N62413 008				
<u>AP</u>	EQ 1.2MG BASE/ML	AUG 11, 1983				
<u>AP</u>	EQ 1.4MG BASE/ML	N62413 009				
<u>AP</u>	EQ 1.6MG BASE/ML	AUG 11, 1983				
<u>AP</u>	EQ 1.8MG BASE/ML	N62413 010				
<u>AP</u>	EQ 2MG BASE/ML	AUG 11, 1983				
<u>AP</u>	EQ 2MG BASE/ML	N62413 001				
<u>AP</u>	EQ 1.4MG BASE/ML	AUG 11, 1983				
<u>AP</u>	EQ 1.6MG BASE/ML	N62413 002				
<u>AP</u>	EQ 1.8MG BASE/ML	AUG 11, 1983				
<u>AP</u>	EQ 2MG BASE/ML	N62413 003				
<u>AP</u>	EQ 2MG BASE/ML	AUG 11, 1983				
<u>AP</u>	EQ 2MG BASE/ML	N62413 004				
<u>AP</u>	EQ 2MG BASE/ML	AUG 11, 1983				
<u>AP</u>	EQ 2MG BASE/ML	N62413 005				
<u>AP</u>	EQ 2MG BASE/ML	AUG 11, 1983				
<u>AP</u>	EQ 60MG BASE/100ML	N62413 006				
<u>AP</u>	EQ 70MG BASE/100ML	AUG 11, 1983				
<u>AP</u>	EQ 80MG BASE/100ML	N62413 007				
<u>AP</u>	EQ 90MG BASE/100ML	AUG 11, 1983				
<u>AP</u>	EQ 100MG BASE/100ML	N62413 008				
<u>AP</u>	EQ 1.2MG BASE/ML	AUG 11, 1983				
<u>AP</u>	EQ 1.4MG BASE/ML	N62413 009				
<u>AP</u>	EQ 1.6MG BASE/ML	AUG 11, 1983				
<u>AP</u>	EQ 1.8MG BASE/ML	N62413 010				
<u>AP</u>	EQ 2MG BASE/ML	AUG 11, 1983				

GENTAMICIN SULFATE

INJECTABLE; INJECTION
GENTAMICIN SULFATE
ABBOTT

EQ 1.8MG BASE/ML
N62413 004
AUG 11, 1983
EQ 2MG BASE/ML
N62413 005
AUG 11, 1983

OPHTHALMIC; OINTMENT

GENTACIDIN

<u>AT</u>	CIBA	EQ 0.3% BASE	N62501 001
<u>AT</u>	IOLAB	EQ 0.3% BASE	JUL 26, 1984

SOLUTION/DROPS; OPHTHALMIC

GENTACIDIN

<u>AT</u>	CIBA	EQ 0.3% BASE	N62480 001
<u>AT</u>	IOLAB	EQ 0.3% BASE	MAR 30, 1984
		EQ 0.3% BASE	N62480 001
		EQ 0.3% BASE	MAR 30, 1984

GLIPIZIDE

TABLET; ORAL

GLIPIZIDE

<u>AB</u>	NOVOPHARM	5MG	N74387 001
<u>AB</u>		10MG	MAR 04, 1996
			N74387 002
			MAR 04, 1996

GLUTETHIMIDE

TABLET; ORAL

GLUTETHIMIDE

	HALSSEY	250MG	N89458 001
		250MG	OCT 10, 1986
			N89458 001
			OCT 10, 1986

GLYBURIDE

TABLET; ORAL

GLYNASE

<u>AB</u>		3MG	N20051 002
			MAR 04, 1992

> DLT >
> DLT >

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

HAUSEY

AA 10MG
 @
 N89218 001
 JAN 22, 1986
 10MG
 N89218 001
 JAN 22, 1986

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDRO-D

HAUSEY

AB 25MG
AB 50MG
 @
 N86504 001
 25MG
 N86504 001
 50MG
 N83891 002

HYDROCHLOROTHIAZIDE

BARR

SUPERPHARM

AB 50MG
 @
 N84771 001
 50MG
AB 25MG
 @
 N88827 001
 25MG
AB 50MG
 @
 N88828 001
 50MG
AB 100MG
 @
 N88829 001
 100MG
 N88829 001
 25MG
 N88827 001
 50MG
 N88828 001
 100MG
 N88829 001

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

NOVOPHARM

AB 15MG;250MG
AB 25MG;250MG
AB 30MG;500MG
AB 50MG;500MG
 @
 15MG;250MG

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

NOVOPHARM

AB 25MG;250MG
 @
 N71820 001
 APR 08, 1988
 30MG;500MG
 N71821 001
 APR 08, 1988
 50MG;500MG
 N71822 001
 APR 08, 1988
AB 15MG;250MG
AB 25MG;250MG
AB 30MG;500MG
AB 50MG;500MG
 @
 N71897 001
 NOV 23, 1987
 15MG;250MG
 N71897 001
 NOV 23, 1987
 25MG;250MG
 N71898 001
 NOV 23, 1987
 30MG;500MG
 N71899 001
 NOV 23, 1987
 50MG;500MG
 N71900 001
 NOV 23, 1987
 15MG;250MG
 N71897 001
 NOV 23, 1987
 25MG;250MG
 N71898 001
 NOV 23, 1987
 30MG;500MG
 N71899 001
 NOV 23, 1987
 50MG;500MG
 N71900 001
 NOV 23, 1987

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

DYAZIDE

AB + SMITHKLINE BEECHAM 25MG;37.5MG

AB MYLAN 25MG;37.5MG
 N16042 003
 MAR 03, 1994
 N74701 001
 JUN 07, 1996

TABLET; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

SIDWAK LABS NU

AB 25MG;37.5MG
AB 50MG;75MG
 N74026 001
 APR 26, 1996
 N73467 001
 JAN 31, 1996

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN'96 - AUG'96

HYDROXYZINE PAMOATE

CAPSULE; ORAL
HYDROXYZINE PAMOATE
CHELSEA LABS

AB EQ 25MG HCL
AB EQ 50MG HCL

N40156 001
JUL 15, 1996
N40156 002
JUL 15, 1996

IBUPROFEN

SUSPENSION; ORAL
CHILDREN'S MOTRIN
* MCNEIL CONS PRODS

EX 100MG/5ML

N19842 001
SEP 19, 1989

EX IBU
KNOLL PHARM

100MG/5ML

N19784 001
DEC 18, 1989

EX MOTRIN
+ MCNEIL CONS PRODS

100MG/5ML

N19842 001
SEP 19, 1989

EX RUFEN
KNOLL PHARM

100MG/5ML

N19784 001
DEC 18, 1989

TABLET; ORAL

IBU
KNOLL PHARM

AB 400MG
AB 400MG
AB 600MG
AB 600MG
AB 800MG

N18197 001
N70083 001
FEB 22, 1985
N70088 001
FEB 08, 1985
N70099 001
MAR 29, 1985
N70745 001
JUL 23, 1986

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

TABLET; ORAL

IMIPRAMINE HCL
EON LABS

AB 10MG
AB 25MG
AB 50MG
AB 10MG
AB 25MG
AB 50MG

N85200 001
N84869 002
N85133 001
N85200 001
N84869 002
N85133 001

IBUPROFEN
HALESEY

AB 300MG
AB 400MG
AB 600MG
AB 800MG
AB 300MG

N71028 001
MAR 23, 1987
N71029 001
MAR 23, 1987
N71030 001
MAR 23, 1987
N72137 001
FEB 05, 1988
N71028 001
MAR 23, 1987

TABLET; ORAL

INDAPAMIDE
INVAMED

AB 1.25MG
AB 2.5MG
AB 2.5MG
AB 1.25MG
AB 2.5MG

N74594 001
MAY 23, 1996
N74594 002
MAY 23, 1996
N74461 001
MAR 27, 1996
N74722 001
JUN 17, 1996
N74722 002
JUN 17, 1996

IBUPROFEN

TABLET; ORAL

IBUPROFEN
@ HALSEY

AB 400MG
AB 600MG
AB 800MG
AB 400MG

N71029 001
MAR 23, 1987
N71030 001
MAR 23, 1987
N72137 001
FEB 05, 1988
N70083 001
FEB 22, 1985

AB KNOLL PHARM

RUFEN
KNOLL PHARM

AB 400MG
AB 600MG
AB 600MG
AB 800MG

N18197 001
N70088 001
FEB 08, 1985
N70099 001
MAR 29, 1985
N70745 001
JUL 23, 1986

INDAPAMIDE

TABLET; ORAL
INDAPAMIDE
ZENITH GOLDLINE

AB 1.25MG

AB 2.5MG

AB 2.5MG

AB LOZOL
RHONE POULENC RORER 1.25MG

N74299 002
APR 29, 1996
N74299 001
JUL 27, 1995
N74299 001
JUL 27, 1995

100 UNITS/ML

N20563 001
JUN 14, 1996

INSULIN LISPRO

INJECTABLE; INJECTION
HUMALOG
+ ELI LILLY

IODIXANOL

INJECTABLE; INJECTION
VISIPAQUE 270
+ NYCAMED

VISIPAQUE 320
+ NYCAMED

N20351 001
MAR 22, 1996

N20351 002
MAR 22, 1996

INDINAVIR SULFATE

CAPSULE; ORAL
CRIXIVAN
MERCK

EQ 200MG BASE

EQ 400MG BASE

N20685 003
MAR 13, 1996
N20685 001
MAR 13, 1996

65.2%

IOPAMIDOL

INJECTABLE; INJECTION
ISOVUE-200
@ BRACCO

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN
HALSEY

AB 25MG

AB 50MG

@ 25MG

@ 50MG

AB 25MG

AB 50MG

@ 25MG

@ 50MG

N70782 001
JUN 03, 1987
N70635 001
JUN 03, 1987
N70782 001
JUN 03, 1987
N70635 001
JUN 03, 1987
N18806 001
NOV 23, 1984
N18806 002
NOV 23, 1984
N18806 001
NOV 23, 1984
N18806 002
NOV 23, 1984

N20327 001
OCT 12, 1994
N20327 001
OCT 12, 1994

N20327 002
OCT 12, 1994
N20327 002
OCT 12, 1994

N20327 003
OCT 12, 1994
N20327 003
OCT 12, 1994

N20327 004
OCT 12, 1994
N20327 004
OCT 12, 1994

IRINOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION
CAMPTOSAR
+ PHARMACIA AND UPJOHN 20MG/ML

N20571 001
JUN 14, 1996

LINDANE

SHAMPOO; TOPICAL
KWELL
 REED AND CARNRICK
 AT +
 AT @

N84219 001
 N84219 001
 N10718 001

0.5MG
 1MG
 2MG

N71434 001
 SEP 01, 1987
 N71435 001
 SEP 01, 1987
 N71436 001
 SEP 01, 1987

LITHIUM CITRATE

SYRUP; ORAL
CIBALITH-S
 SOLVAY
 LITHONATE
 @ SOLVAY

N17672 001
 N17672 001

EQ 300MG CARBONATE/5ML
 EQ 300MG CARBONATE/5ML

N71245 001
 FEB 09, 1987
 N71246 001
 FEB 09, 1987
 N71247 001
 FEB 09, 1987

LORACARBEF

CAPSULE; ORAL
 LORABID
 ELI LILLY

N50668 001
 DEC 31, 1991
 N50668 002
 APR 05, 1996
 N50668 001
 DEC 31, 1991

200MG
 400MG
 200MG

N71245 001
 FEB 09, 1987
 N71246 001
 FEB 09, 1987
 N71247 001
 FEB 09, 1987

LORATADINE, PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
 CLARITIN-D 24 HOUR
 + SCHERING

N20470 001
 AUG 23, 1996

10MG;240MG

MANGANESE SULFATE

INJECTABLE; INJECTION
 MANGANESE SULFATE
 FUJISAWA

N19228 001
 MAY 05, 1987
 N19228 001
 MAY 05, 1987

LORAZEPAM

TABLET; ORAL
LORAZEPAM
 HALSEY

N71434 001
 SEP 01, 1987
 N71435 001
 SEP 01, 1987
 N71436 001
 SEP 01, 1987

0.5MG
 1MG
 2MG

MECLOFENAMATE SODIUM
 CAPSULE; ORAL
MECLOFENAMATE SODIUM
 BARR

N72848 001
 MAR 20, 1989

LORAZEPAM

TABLET; ORAL
LORAZEPAM
 @ HALSEY

AB
SUPERPHARM

AB
1MG

AB
2MG

@
 0.5MG

@
 1MG

@
 2MG

MANGANESE CHLORIDE

INJECTABLE; INJECTION
 MANGANESE CHLORIDE IN PLASTIC CONTAINER
 ABBOTT

N18962 001
 JUN 26, 1986
 N18962 001
 JUN 26, 1986

@
 EQ 0.1MG MANGANESE/ML

> ADD >
 > ADD >

MECLOFENAMATE SODIUM

TABLET; ORAL

MECLOFENAMATE SODIUM

BARR

EQ 100MG BASE

EQ 50MG BASE

EQ 100MG BASE

N72809 001

MAR 20, 1989

N72848 001

MAR 20, 1989

N72809 001

MAR 20, 1989

> ADD >

> ADD >

> DLT >

> DLT >

TABLET; ORAL

DEMEROL

+ SANOFI WINTHROP

+ SANOFI WINTHROP

+ STERLING WINTHROP

+ STERLING WINTHROP

50MG

100MG

50MG

100MG

N05010 001

N05010 004

N05010 001

N05010 004

MEDROXYPROGESTERONE ACETATE

TABLET; ORAL

MEDROXYPROGESTERONE ACETATE

BARR

2.5MG

5MG

10MG

N40159 001

AUG 09, 1996

N40159 002

AUG 09, 1996

N40159 003

AUG 09, 1996

> DLT >

> DLT >

> DLT >

> DLT >

> ADD >

> ADD >

MEPROBAMATE

CAPSULE, EXTENDED RELEASE, ORAL

MEPROSPAN

+ WALLACE PHARMS

+ WALLACE PHARMS

+ WALLACE PHARMS

200MG

400MG

200MG

400MG

N11284 001

N11284 002

N11284 001

N11284 002

TABLET; ORAL

MEPROBAMATE

+ BARR

+ BARR

+ BARR

600MG

600MG

200MG

400MG

200MG

400MG

N84230 001

N84230 001

N14359 002

N14359 001

N14359 002

N14359 001

MEGESTROL ACETATE

TABLET; ORAL

MEGESTROL ACETATE

BARR

20MG

N74621 002

AUG 16, 1996

> ADD >

> ADD >

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

DEMEROL

+ SANOFI WINTHROP

+ SANOFI WINTHROP

+ SANOFI WINTHROP

+ SANOFI WINTHROP

+ STERLING WINTHROP

25MG/ML

50MG/ML

75MG/ML

100MG/ML

25MG/ML

50MG/ML

75MG/ML

100MG/ML

N05010 007

N05010 002

N05010 009

N05010 003

N05010 007

N05010 002

N05010 009

N05010 003

INJECTABLE; INJECTION

MERREM I.V.

+ ZENECA

+ ZENECA

500MG/VIAL

1GM/VIAL

N50706 003

JUN 21, 1996

N50706 001

JUN 21, 1996

METHADONE HYDROCHLORIDE

CONCENTRATE; ORAL

METHADONE

+ MALLINCKRODT

+ MALLINCKRODT

10MG/ML

10MG/ML

N17116 002

N17116 002

SYRUP; ORAL

DEMEROL

+ SANOFI WINTHROP

+ SANOFI WINTHROP

+ STERLING WINTHROP

50MG/5ML

50MG/5ML

N05010 005

N05010 005

> ADD >

> DLT >

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL
 SMITH AND NEPHEW

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

EQ 5MG BASE/ML

N70623 001
 MAR 02, 1987

AP *
 AP *

REGLAN
 * ROBINS AH

EQ 10MG BASE/2ML
 EQ 5MG BASE/ML

N17862 001
 N17862 001

0.75%

GEL; VAGINAL
 METROGEL-VAGINAL
 + CURATEK

N20208 001
 AUG 17, 1992

TABLET; ORAL
METOCLOPRAMIDE HCL
 HALSEY

N70906 001
 OCT 28, 1986

EQ 10MG BASE

N70906 001
 OCT 28, 1986

EQ 10MG BASE

AB

SCHERING

EQ 10MG BASE

N70598 001
 FEB 02, 1987

AB

SUPERPHARM

EQ 10MG BASE

N70926 001
 JUN 26, 1987

EQ 10MG BASE

N70926 001
 JUN 26, 1987

ZENITH GOLDLINE

250MG

N18517 001
 FEB 27, 1986

ZENITH LABS

250MG

N18517 002
 MAY 05, 1982

ZENITH LABS

500MG

N18517 002
 MAY 05, 1982

METOLAZONE

TABLET; ORAL
 MYKROX
 FISOXS

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

0.5MG

N19532 001
 OCT 30, 1987

MEDEVA PHARMS

0.5MG

N19532 001
 OCT 30, 1987

ZAROXOLYN
 FISOXS

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

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

N17386 001
 N17386 002
 N17386 003
 N17386 001
 N17386 002
 N17386 003

MEDEVA PHARMS

MICONAZOLE NITRATE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
 MONISTAT DUAL-PAK
 * JOHNSON RW

2%, 200MG

N18888 002
 OCT 17, 1988

METRONIDAZOLE

GEL; VAGINAL
 METROGEL
 + CURATEK

> DLT >
 > DLT >
 > DLT >

0.75%

N20208 001
 AUG 17, 1992

TABLET; ORAL
METRONIDAZOLE
 HALSEY

250MG

N70021 001
 APR 02, 1985

AB

500MG

N70593 001
 FEB 27, 1986

AB

250MG

N70021 001
 APR 02, 1985

AB

500MG

N70593 001
 FEB 27, 1986

AB

250MG

N18517 001
 FEB 27, 1986

AB

500MG

N18517 002
 MAY 05, 1982

AB

500MG

N18517 002
 MAY 05, 1982

AB

500MG

N18517 002
 MAY 05, 1982

MEXILETINE HYDROCHLORIDE

CAPSULE; ORAL
MEXILETINE HCL
 GENEVA PHARMS

AB

150MG

N74450 001
 MAY 16, 1996

AB

200MG

N74450 002
 MAY 16, 1996

AB

250MG

N74450 003
 MAY 16, 1996

NAPROXEN

TABLET, ORAL

NAPROXEN

BIOCRAFT

375MG

N74216 002

APR 11, 1996

500MG

N74216 003

APR 11, 1996

250MG

N74182 001

JUN 27, 1996

375MG

N74182 002

JUN 27, 1996

500MG

N74182 003

JUN 27, 1996

NAPROXEN SODIUM

TABLET, ORAL

NAPROXEN SODIUM

AL HIKMA

EQ 500MG BASE

N74480 001

MAY 14, 1996

EQ 250MG BASE

N74242 001

JUN 20, 1996

EQ 500MG BASE

N74242 002

JUN 20, 1996

EQ 500MG BASE

N74480 001

MAY 14, 1996

TABLET, EXTENDED RELEASE; ORAL

NAPRELAN

+ ELAN PHARM

EQ 375MG BASE

N20353 001

JAN 05, 1996

EQ 500MG BASE

N20353 002

JAN 05, 1996

EQ 750MG BASE

N20353 003

JAN 05, 1996

NEOMYCIN SULFATE

INJECTABLE, INJECTION

MYCIPRADIN

* DEJOHN

NEOMYCIN SULFATE

PFIZER

SQUIBB

EQ 350MG BASE/VIAL

N60477 001

EQ 350MG BASE/VIAL

N61084 001

EQ 350MG BASE/VIAL

N60366 001

POWDER; FOR RX COMPOUNDING

NEO-RX

PHARMA TEK

100%

N61579 001

NEOMYCIN SULFATE

POWDER; FOR RX COMPOUNDING

NEO-RX

PHARMA TEK

100%

NEOMYCIN SULFATE

@ ELKINS SINN

PADDOCK

100%

100%

N61579 001

N61698 001

N62385 001

JUN 01, 1982

NEVIRAPINE

TABLET, ORAL

VIRAMUNE

+ BOEHRINGER INGELHEIM 200MG

N20636 001

JUN 21, 1996

NICARDIPINE HYDROCHLORIDE

CAPSULE; ORAL

CARDENE

SYNTEX

20MG

N19488 001

DEC 21, 1988

30MG

N19488 002

DEC 21, 1988

NICARDIPINE HCL

MYLAN

20MG

N74642 001

JUL 18, 1996

30MG

N74642 002

JUL 18, 1996

NICLOSAMIDE

TABLET, CHEWABLE; ORAL

NICLOXIDE

* BAYER

500MG

N18669 001

MAY 14, 1982

500MG

N18669 001

MAY 14, 1982

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL

HABITROL

BC * CIBA

7MG/24HR

N20076 001

NOV 27, 1991

PHENSUXIMIDE

> ADD >
> ADD >
> ADD >

CAPSULE; ORAL
MILONTIN
@ PARKE DAVIS 500MG

N08855 004

PIROXICAM

CAPSULE; ORAL
PIROXICAM
ZENITH GOLDLINE

10MG
20MG

N74148 001
JUN 03, 1996
N74148 002
JUN 03, 1996

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

IONAMIN

* FISOXS
MEDEVA PHARMS
+
EQ 15MG BASE
EQ 30MG BASE
EQ 15MG BASE
EQ 30MG BASE

N11613 004
N11613 002
N11613 004
N11613 002

POLYESTRADIOL PHOSPHATE

INJECTABLE; INJECTION
ESTRADURIN
* WYETH AYERST
@

40MG/AMP
40MG/AMP

N10753 001
N10753 001

PENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

AA
PHERAZINE VC
HALSEY

5MG/5ML; 6.25MG/5ML
5MG/5ML; 6.25MG/5ML

N88868 001
MAR 02, 1987
N88868 001
MAR 02, 1987

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
POTASSIUM CHLORIDE
BIOCRAFT

8MEQ
10MEQ

N73531 001
APR 26, 1996
N73532 001
APR 26, 1996

PHENYTOIN SODIUM

INJECTABLE; INJECTION

PHENYTOIN SODIUM

FUJISAWA

50MG/ML
50MG/ML
50MG/ML
50MG/ML

N89003 001
MAY 31, 1985
N89003 001
MAY 31, 1985
N88520 001
DEC 17, 1984
N88520 001
DEC 17, 1984

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

FUJISAWA

2MEQ/ML
2MEQ/ML

N87787 001
APR 20, 1982
N87787 001
APR 20, 1982

AP
SOLOPAK

TABLET, EXTENDED RELEASE; ORAL
K-DUR 10
BC + KEY PHARMS 10MEQ
BC * SCHERING 10MEQ

N19439 002
JUN 13, 1986
N19439 002
JUN 13, 1986

PIROXICAM

CAPSULE; ORAL

PIROXICAM
DANBURY PHARMA

10MG
20MG

N74287 001
MAY 16, 1996
N74287 002
MAY 16, 1996

K-DUR 20
+ KEY PHARMS 20MEQ
* SCHERING 20MEQ

N19439 001
JUN 13, 1986
N19439 001
JUN 13, 1986

PREDNISOLONE

SYRUP; ORAL
PRELONE
MURO

5MG/5ML
15MG/5ML
5MG/5ML
15MG/5ML

N83654 001
JAN 17, 1989
N83081 001
FEB 04, 1986
N89654 001
JAN 17, 1989
N89081 001
FEB 04, 1986

N20545 001
JAN 31, 1996
N20545 002
JAN 31, 1996

+

+

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

PROCANBID
+ PARKE DAVIS 500MG
+ 1GM

PROCHLORPERAZINE MALEATE

TABLET; ORAL

COMPazine
SMITHKLINE BEECHAM EQ 5MG BASE
AB EQ 10MG BASE
AB EQ 25MG BASE
+ PROCHLORPERAZINE MALEATE
AB COPLEY PHARM EQ 5MG BASE

N10571 001
N10571 002
N10571 003
N40120 001
JUL 11, 1996
N40120 002
JUL 11, 1996
N40101 001
JUL 19, 1996
N40101 002
JUL 19, 1996
N40101 003
JUL 19, 1996

PREDNISOLONE ACETATE

SUSPENSION; OPHTHALMIC
PRED FORTE

BX + ALLERGAN 1%

N17011 001

SUSPENSION/DROPS; OPHTHALMIC
PRED FORTE

AB + ALLERGAN 1%

N17011 001

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULSTER

AT + AKORN EQ 0.23% PHOSPHATE, 10%

N74511 001
JUL 30, 1996

PREDNISONE

TABLET; ORAL
PREDNISONE
SUPERPHARM

AB 5MG
AB 10MG
AB 20MG

N88865 001
OCT 25, 1984
N88866 001
OCT 25, 1984
N88867 001
OCT 25, 1984

@

@

@

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

SYRUP; ORAL

PROMETHAZINE
CENCI

6.25MG/5ML
6.25MG/5ML

N89013 001
SEP 20, 1985
N89013 001
SEP 20, 1985

PROMAZINE HYDROCHLORIDE

TABLET; ORAL

SPARINE
WYETH AYERST

50MG
100MG
50MG
100MG

N10348 002
N10348 003
N10348 002
N10348 003

PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE
CENCI

6.25MG/5ML
6.25MG/5ML

N89013 001
SEP 20, 1985
N89013 001
SEP 20, 1985

PROPANTHELINE BROMIDE

TABLET; ORAL
PRO-BANTHINE
 AA * ROBERTS LABS 7.5MG N08732 003 N17603 001
 AA * 15MG N08732 002 N17603 001
 BP + 7.5MG
 BP + 15MG
PROPANTHELINE BROMIDE
 AA PAR PHARM 15MG N88377 001
 BP 15MG DEC 08, 1983
 BP ROXANE 7.5MG N80927 001
 AA 15MG N80927 002
 BP 7.5MG
 BP 15MG N80927 001
 BP N80927 002

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPHENE 65
 AA * HALSEY 65MG N83538 002
 @ 65MG N83538 002

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL
 BD * HALSEY 50MG N80015 001
 @ 50MG N80015 001

PROTIRELIN

INJECTABLE; INJECTION
THYPINONE
 AP * ABBOTT 0.5MG/ML N17638 001
 @ 0.5MG/ML N17638 001
THYREL TRH
 AP * FERRING LABS 0.5MG/ML N18087 001
 + 0.5MG/ML N18087 001

PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
NOVAFED
 * DOW PHARM 120MG N17603 001
 + HOECHST MARION RSSL 120MG N17603 001

QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL
QUINIDINE GLUCONATE
 AB HALSEY 324MG N89476 001
 @ 324MG APR 10, 1987
 N89476 001
 APR 10, 1987

QUINIDINE SULFATE

CAPSULE; ORAL
CIN-QUIN
 AB SOLWAY 200MG N85296 001
 300MG N85297 001
 200MG N85296 001
 300MG N85297 001
 +
QUINIDINE SULFATE
 @ ELI LILLY 200MG N85103 001
 AB * LILLY 200MG N85103 001

TABLET; ORAL

QUINIDINE SULFATE
 AB 1ST TX 200MG N85068 001
 AB BARR 200MG N84177 001
 @ 200MG
 @ ELI LILLY 200MG N85038 001
 AB HALSEY 200MG N83583 001
 @ 200MG
 @ LILLY 200MG N85038 001
 AB * ROXANE 200MG N83640 001
 AB + 200MG N83640 001
 AB 300MG N85632 001
 @ 300MG N85068 001
 @ SCHERER 200MG
QUINORA
 AB * KEY PHARMS 300MG N85222 001
 @ SCHERING 300MG

RAMIPRIL

CAPSULE; ORAL
 ALTACE
 HOECHST MARION RSSL 1.25MG
 2.5MG
 5MG
 10MG
 +
 HOECHST ROUSSEL
 1.25MG
 2.5MG
 5MG
 10MG
 +

N19901 001
 JAN 28, 1991
 N19901 002
 JAN 28, 1991
 N19901 003
 JAN 28, 1991
 N19901 004
 JAN 28, 1991
 N19901 001
 JAN 28, 1991
 N19901 002
 JAN 28, 1991
 N19901 003
 JAN 28, 1991
 N19901 004
 JAN 28, 1991

RITONAVIR

CAPSULE; ORAL
 NORVIR
 + ABBOTT 100MG
 SOLUTION; ORAL
 NORVIR
 ABBOTT 80MG/ML

N20680 001
 MAR 01, 1996
 N20659 001
 MAR 01, 1996

SELEGILINE HYDROCHLORIDE

CAPSULE; ORAL
 ELDEPRYL
 + SOMERSET 5MG

N20647 001
 MAY 15, 1996

TABLET; ORAL
 ELDEPRYL
 + SOMERSET

5MG
 5MG

N19334 001
 JUN 05, 1989
 N19334 001
 JUN 05, 1989

SELEGILINE HCL
 ENDO LABS 5MG

N74565 001
 AUG 02, 1996

LEDELERE LABS 5MG

N74641 001
 AUG 02, 1996

NOVOPHARM 5MG

N74537 001
 AUG 02, 1996

SERTRALINE HYDROCHLORIDE

TABLET; ORAL
 ZOLOFT
 PFIZER EQ 25MG BASE

N19839 005
 MAR 06, 1996

RISPERIDONE

SOLUTION; ORAL
 RISPERDAL
 + JANSSEN 1MG/ML

N20588 001
 JUN 10, 1996

INJECTABLE; INJECTION
 SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
 MCGAW 450MG/100ML

N18184 001
 N18184 001

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

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

N20559 001
 AUG 08, 1996

400MG
 EQ 1MG BASE/VIAL
 EQ 2MG BASE/VIAL
 EQ 5MG BASE/VIAL

N20630 001
 JUL 12, 1996
 N20630 002
 JUL 12, 1996
 N20630 003
 JUL 12, 1996

> DLT >
 > ADD >

SODIUM LACTATE

INJECTABLE; INJECTION
SODIUM LACTATE 0.167 MOLAR IN PLASTIC CONTAINER
 MCGAW
 @
 1.87GM/100ML
 1.87GM/100ML
 N18186 001
 N18186 001

N20240 004
 DEC 29, 1994
 N20240 001
 DEC 29, 1994
 N20240 002
 DEC 29, 1994
 N20240 003
 DEC 29, 1994
 N20240 004
 DEC 29, 1994

SODIUM PHENYLBUTYRATE

POWDER; ORAL
 BUPHENYL
 + UCYCLYD
 3GM/TEASPOONFUL
 N20573 001
 APR 30, 1996

TABLET; ORAL
 BUPHENYL
 + UCYCLYD

N20572 001
 MAY 13, 1996

SUCRALFATE

TABLET; ORAL
 CARAFATE
 + BLUE RIDGE
SUCRALFATE
 @
 BIOCRAFT

N18333 001
 N70848 001
 MAR 29, 1996

SOMATROPIN, BIOSYNTHETIC

INJECTABLE; INJECTION
 SEROSTIM
 SERONO
 5MG/VIAL
 6MG/VIAL
 N20604 002
 AUG 23, 1996
 N20604 001
 AUG 23, 1996

SOYBEAN OIL

INJECTABLE; INJECTION
 INTRALIPID 20%
 PHARMACIA AND UPJOHN 20%
 N20248 001
 AUG 07, 1996

N70066 001
 JUN 24, 1985
 N70066 001
 JUN 24, 1985
 N70065 002
 JUN 24, 1985
 N70065 002
 JUN 24, 1985

SPIRAPRIL HYDROCHLORIDE

TABLET; ORAL
 RENORMAX
 SANDOZ
 3MG
 6MG
 12MG
 N20240 001
 DEC 29, 1994
 N20240 002
 DEC 29, 1994
 N20240 003
 DEC 29, 1994

N17970 002
 MAR 21, 1994
 N17970 002
 MAR 21, 1994

SPIRAPRIL HYDROCHLORIDE

TABLET; ORAL
 RENORMAX
 * SANDOZ
 @
 SCHERING
 @
 @
 @
 @
 24MG
 3MG
 6MG
 12MG
 24MG

SUCRALFATE
 TABLET; ORAL
 CARAFATE
 + BLUE RIDGE
SUCRALFATE
 @
 BIOCRAFT
 1GM
 1GM
 N18333 001
 N70848 001
 MAR 29, 1996

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL
SULFATRIM-DS
 SUPERPHARM
 @
SULFATRIM-SS
 SUPERPHARM
 @
 800MG; 160MG
 800MG; 160MG
 400MG; 80MG
 400MG; 80MG

N70066 001
 JUN 24, 1985
 N70066 001
 JUN 24, 1985
 N70065 002
 JUN 24, 1985
 N70065 002
 JUN 24, 1985

TAMOXIFEN CITRATE

TABLET; ORAL
 NOLVADEX
 @ ZENECA
 +
 EQ 20MG BASE
 EQ 20MG BASE

N17970 002
 MAR 21, 1994
 N17970 002
 MAR 21, 1994

TECHNETIUM TC-99M TETROFOSMIN KIT

INJECTABLE; INJECTION
MYOVUE
MEDI PHYSICS

N/A

N20372 001
FEB 09, 1996

CAPSULE; ORAL
TETRACYCLINE HCL
@ SUPERPHARM

500MG

N62540 002
MAR 21, 1985

TETRACYCLINE HYDROCHLORIDE

TERAZOSIN HYDROCHLORIDE

TABLET; ORAL
HYTRIN
@ ABBOTT

@

EQ 1MG BASE

N19057 001
AUG 07, 1987

@

EQ 2MG BASE

N19057 002
AUG 07, 1987

@

EQ 5MG BASE

N19057 003
AUG 07, 1987

@

EQ 10MG BASE

N19057 004
AUG 07, 1987

+

EQ 1MG BASE

N19057 001
AUG 07, 1987

+

EQ 2MG BASE

N19057 002
AUG 07, 1987

EQ 5MG BASE

N19057 003
AUG 07, 1987

EQ 10MG BASE

N19057 004
AUG 07, 1987

THALLOUS CHLORIDE, TL-201

INJECTABLE; INJECTION
THALLOUS CHLORIDE TL 201
MEDI PHYSICS

2mCi/ML

N18110 001
FEB 01, 1982
N18110 002
FEB 27, 1996

1mCi/ML

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
THEOVENT

125MG

N87010 001
JAN 31, 1985

BC

250MG

N87910 001
JAN 31, 1985

BC

125MG

N87010 001
JAN 31, 1985

@

250MG

N87910 001
JAN 31, 1985

@

125MG

N87910 001
JAN 31, 1985

TERBINAFINE HYDROCHLORIDE

TABLET; ORAL
LAMISIL
+ SANDOZ

EQ 250MG BASE

N20539 001
MAY 10, 1996

ELIXIR; ORAL
ELIXOMIN
CENCI

80MG/15ML

N88303 001
JAN 25, 1984

AA

80MG/15ML

N88303 001
JAN 25, 1984

@

80MG/15ML

N88303 001
JAN 25, 1984

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

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL
SUPERPHARM

250MG

N62540 001
MAR 21, 1985

AB

500MG

N62540 002
MAR 21, 1985

AB

250MG

N62540 001
MAR 21, 1985

@

250MG

N62540 001
MAR 21, 1985

INJECTABLE; INJECTION

THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER

40MG/100ML

N19083 001
NOV 07, 1984

AP

40MG/100ML

N19083 001
NOV 07, 1984

MCGAW

40MG/100ML

N19083 001
NOV 07, 1984

@

40MG/100ML

N19083 001
NOV 07, 1984

THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER

80MG/100ML

N19083 002
NOV 07, 1984

AP

80MG/100ML

N19083 002
NOV 07, 1984

MCGAW

80MG/100ML

N19083 002
NOV 07, 1984

@

80MG/100ML

N19083 002
NOV 07, 1984

THEOPHYLLINE

INJECTABLE; INJECTION

AP THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER
 MCGAW 150MG/100ML N19083 003
 NOV 07, 1984
 @ N19083 003
 160MG/100ML
 NOV 07, 1984
 AP THEOPHYLLINE 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER
 MCGAW 200MG/100ML N19826 004
 AUG 14, 1992
 @ N19826 004
 200MG/100ML
 AUG 14, 1992
 AP THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER
 MCGAW 400MG/100ML N19826 005
 AUG 14, 1992
 @ N19826 005
 400MG/100ML
 AUG 14, 1992

SUSPENSION; ORAL

> DLT >
 > DLT >
 > DLT >
 > ADD >
 BC * ELIXICON
 * FOREST LABS 100MG/5ML N85502 001
 @ 100MG/5ML N85502 001

TABLET, EXTENDED RELEASE; ORAL

BC * UNI-DUR
 KEY PHARMS 400MG N89822 001
 BC * 600MG N89823 001
 JAN 04, 1995
 BC + SCHERING 400MG N89822 001
 JAN 04, 1995
 BC + 600MG N89823 001
 JAN 04, 1995
 BC UNIPHYL N40086 001
 PURDUE FREDERICK 600MG
 APR 15, 1996

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

AP THIAMINE HCL
 SANOFI WINTHROP 100MG/ML N40079 001
 MAY 03, 1996

THIORIDAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

AA MELLARIL
 SANDOZ 30MG/ML N11808 012
 AA + 30MG/ML N11808 012
 AA 100MG/ML N11808 018
 AA + 100MG/ML N11808 018
 THIORIDAZINE HCL
 HI TECH PHARMA 30MG/ML N40125 001
 AUG 16, 1996
 100MG/ML N40126 001
 AUG 16, 1996

TABLET; ORAL

AB THIORIDAZINE HCL
 SUPERPHARM 10MG N89103 001
 JUL 02, 1985
 AB 25MG N89104 001
 JUL 02, 1985
 AB 50MG N89105 001
 JUL 02, 1985
 @ 10MG N89103 001
 JUL 02, 1985
 @ 25MG N89104 001
 JUL 02, 1985
 @ 50MG N89105 001
 JUL 02, 1985

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC

AT AKTOB
 AKORN 0.3% N64096 001
 JAN 31, 1996

TOLAZAMIDE

TABLET; ORAL

AB TOLAZAMIDE
 BARR 100MG N70162 001
 JAN 14, 1986
 AB 250MG N70163 001
 JAN 14, 1986
 AB 500MG N70164 001
 JAN 14, 1986

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE
@ BARR

100MG
250MG
500MG

N70162 001
JAN 14, 1986
N70163 001
JAN 14, 1986
N70164 001
JAN 14, 1986

AB ZENITH GOLDLINE

100MG

N18894 001
NOV 02, 1984

AB ZENITH LABS

250MG

N18894 002
NOV 02, 1984

AB ZENITH LABS

500MG

N18894 003
NOV 02, 1984

AB ZENITH LABS

100MG

N18894 001
NOV 02, 1984

AB ZENITH LABS

250MG

N18894 002
NOV 02, 1984

AB ZENITH LABS

500MG

N18894 003
NOV 02, 1984

TOPOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION
HYCAMTIN
+ SMITHKLINE BEECHAM

N20671 001
MAY 28, 1996

EQ 4MG BASE/VIAL

TRANDOLAPRIL

TABLET; ORAL
MAVIK

N20528 001
APR 26, 1996
N20528 002
APR 26, 1996
N20528 003
APR 26, 1996

1MG

2MG

4MG

TRANEXAMIC ACID

TABLET; ORAL
CYKLOKAPRON
+ PHARMACIA

N19280 001
DEC 30, 1986
N19280 001
DEC 30, 1986

500MG

@ PHARMACIA AND UPJOHN 500MG

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

TOLBUTAMIDE

TABLET; ORAL
ORINASE
@ PHARMACIA AND UPJOHN 500MG

500MG

N10670 001
N10670 001

AB * UPJOHN

TOLMETIN SODIUM

TABLET; ORAL
TOLMETIN SODIUM
BAKER NORTON

EQ 600MG BASE

N74399 001
MAR 28, 1996

> DLT >
> DLT >
> ADD >

TRETINOIN

CREAM; TOPICAL
RENOVA
JOHNSON RW

N19963 001
DEC 29, 1995

0.05%

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
KENALOG-H
APOTHECON

N86240 001
N86240 001

0.1%

0.1%

ointment; TOPICAL

ARISTOCORT A

LEDERLE

AT + LEADERLE LABS

N80745 003
N80745 003

0.5%

0.5%

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

AT KENALOG
+ APOTHECON

0.5%
0.5%

N83944 001
N83944 001

SPRAY, METERED; NASAL

NASACORT AQ
+ RHONE POULENC RORER

0.055MG/INH

N20468 001
MAY 20, 1996

TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

TRIPROLIDINE HCL
HALSEY

1.25MG/5ML

N88735 001
JAN 17, 1985
N88735 001
JAN 17, 1985

UROFOLLITROPIN

INJECTABLE; INJECTION

METRODIN
+ SERONO

75 IU/AMP

N19415 002
SEP 18, 1986
N19415 003
SEP 18, 1986

INJECTABLE; INTRAMUSCULAR

METRODIN
+ SERONO

75 IU/AMP

N19415 002
SEP 18, 1986
N19415 003
SEP 18, 1986

INJECTABLE; SUBCUTANEOUS

FERTINEX
+ SERONO

75 IU/AMP

N19415 005
AUG 23, 1996
N19415 004
AUG 23, 1996

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

VERELAN
+ ELAN PHARM

360MG

N19614 004
MAY 10, 1996

TABLET; ORAL

VERAPAMIL HCL
SIDMAK LABS NJ

40MG

N72751 001
FEB 23, 1996

TABLET, EXTENDED RELEASE; ORAL

COVERA-HS
SEARLE

180MG

N20552 001
FEB 26, 1996

BC

240MG

N20552 002
FEB 26, 1996

BC

240MG

N74587 001
MAR 23, 1996

VERAPAMIL HCL

MYLAN

240MG

N72922 001
MAR 01, 1996

AB

240MG

SIDMAK LABS NJ

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

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VIDARABINE

INJECTABLE; INJECTION

VIRA-A
+ PARKE DAVIS

EQ 187.4MG BASE/ML
EQ 187.4MG BASE/ML

N50523 001
N50523 001

ASPIRIN

TABLET, EXTENDED RELEASE; ORAL
 8-HOUR BAYER
 + BAYER 650MG
 * STERLING 650MG
 MEASURIN
 + BAYER 650MG
 * STERLING 650MG

N16030 001
 N16030 001
 N16030 002
 N16030 002

BENTOUATAM

LOTION; TOPICAL
 IVY BLOCK
 + ENVIRODERM 5%

N20532 001
 AUG 26, 1996

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

BROMPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE; ORAL
 DIMETAPP
 * ROBINS AH 8MG
 * 12MG
 @ WHITEHALL ROBINS 8MG
 DIMETAPP
 + WHITEHALL ROBINS 12MG

N10799 010
 JUN 10, 1983
 N10799 011
 JUN 10, 1983
 N10799 010
 JUN 10, 1983
 N10799 011
 JUN 10, 1983

CAPSULE, EXTENDED RELEASE; ORAL
 CODINAL-L.A. 12
 CENT PHARMS 12MG;120MG
 + 12MG;120MG
 PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE MALEATE
 + CENT PHARMS 8MG;120MG
 N18935 001
 APR 15, 1985
 N18935 001
 APR 15, 1985
 N19428 001
 AUG 02, 1988

PSEUDOEPHEDRINE HCL/CHLORPHENIRAMINE MALEATE

* GRAHAM 8MG;120MG
 * 12MG;120MG
 @ 8MG;120MG
 @ 12MG;120MG
 PSEUDOEPHEDRINE HYDROCHLORIDE AND CHLORPHENIRAMINE MALEATE
 CENT PHARMS 8MG;120MG
 N18844 001
 MAR 20, 1985
 N18843 001
 MAR 18, 1985
 N18844 001
 MAR 20, 1985
 N18843 001
 MAR 18, 1985
 N19428 001
 AUG 02, 1988

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

ELIXIR; ORAL
 DIMETAPP
 * ROBINS AH 2MG/5ML;12.5MG/5ML
 + WHITEHALL ROBINS 2MG/5ML;12.5MG/5ML

N13087 003
 MAR 29, 1984
 N13087 003
 MAR 29, 1984

> DLT >
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TABLET, EXTENDED RELEASE; ORAL
 DIMETAPP
 * ROBINS AH 12MG;75MG
 + WHITEHALL ROBINS 12MG;75MG

N12436 003
 MAY 14, 1985
 N12436 003
 MAY 14, 1985

BROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
 EFIDAC 24 PSEUDOEPHEDRINE HCL/BROMPHENIRAMINE MALEATE
 + ALZA 16MG;240MG
 N19672 001
 MAR 29, 1996

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CODINAL-L.A. 12
 CENT PHARMS 12MG;120MG
 + 12MG;120MG
 PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE MALEATE
 + CENT PHARMS 8MG;120MG
 N18935 001
 APR 15, 1985
 N18935 001
 APR 15, 1985
 N19428 001
 AUG 02, 1988

CHLORPHENIRAMINE POLISTIREX; PHENYLPROPANOLAMINE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL

CORSYM
 @ FISON'S EQ 4MG MALEATE/5ML;
 EQ 37.5MG HCL/5ML
 N18050 001
 JAN 04, 1984
 @ MEDEVA PHARMS EQ 4MG MALEATE/5ML;
 EQ 37.5MG HCL/5ML
 N18050 001
 JAN 04, 1984

CIMETIDINE

TABLET; ORAL
TAGAMET HB

* SMITHKLINE BEECHAM 100MG
100MG
200MG

N20238 001
JUN 19, 1995
N20238 001
JUN 19, 1995
N20238 002
AUG 21, 1996

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

SUSPENSION, EXTENDED RELEASE; ORAL
DELSYM
* FISON'S EQ 30MG HBR/5ML
+ MEDEVA PHARMS EQ 30MG HBR/5ML

N18658 001
N18658 001

> ADD >
> ADD >

IBUPROFEN

CAPSULE; ORAL

MIDOL
* BAYER 200MG

N70626 001
SEP 02, 1987
N71002 001

* WINTHROP 200MG
* SANDOZ 200MG

SEP 02, 1987
N70626 001
SEP 02, 1987
N71002 001
SEP 02, 1987

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

CLOTIMAZOLE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
GYNE-LOTTRIMIN 3 COMBINATION PACK
+ SCHERING PLOUGH 1%, 200MG

N20526 002
JUL 29, 1996

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

SUPPOSITORY; VAGINAL
GYNE-LOTTRIMIN
+ SCHERING PLOUGH 100MG

N17717 002
NOV 30, 1990

GYNE-LOTTRIMIN 3
+ SCHERING PLOUGH 200MG

MYCELEX-7
BAYER 100MG

N18182 002
DEC 26, 1991

SUSPENSION; ORAL
CHILDREN'S ADVIL
WHITEHALL ROBINS 100MG/5ML

N20589 001
JUN 27, 1996

SUSPENSION/DROPS; ORAL
CHILDREN'S MOTRIN
+ MCNEIL CONS PRODS 40MG/ML

N20603 001
JUN 10, 1996

TABLET; ORAL
IBUPROFEN
HALSEY 200MG

N71027 001
SEP 29, 1987
N71027 001

TABLET; VAGINAL
GYNE-LOTTRIMIN 100MG

N17717 002
NOV 30, 1990

MYCELEX-7
BAYER 100MG

N18182 002
DEC 26, 1991

* LEMMON 200MG
MCNEIL CONS PRODS 200MG
+ 200MG

N73141 001
MAY 29, 1992
N73019 001
MAR 30, 1994
N73019 001
MAR 30, 1994

IBUPROFEN

TABLET; ORAL
IBUPROFEN
TAG PHARMS

200MG

N73141 001
MAY 29, 1992

JUNIOR STRENGTH MOTRIN
MCNEIL CONS PRODS

100MG

N20602 001
JUN 10, 1996

MIDOL
BAYER

200MG

N70591 001
SEP 02, 1987

ULTRALENTE

200MG

N71001 001
SEP 02, 1987

WINTHROP

200MG

N70591 001
SEP 02, 1987

NUPRIN

200MG

N71001 001
SEP 02, 1987

* BRISTOL MYERS

200MG

N72035 001
FEB 16, 1988

200MG

N72035 001
FEB 16, 1988

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

INSULIN PURIFIED BEEF

INJECTABLE; INJECTION
REGULAR Iletin II
@ ELI LILLY
* LILLY

100 UNITS/ML
100 UNITS/ML

N18478 001
N18478 001

INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN

INJECTABLE; INJECTION
NOVOLIN N
* NOVO NORDISK

100 UNITS/ML
100 UNITS/ML

N19065 001
JAN 23, 1985
N19065 001
JAN 23, 1985

INSULIN SUSP PROTAMINE ZINC PURIFIED BEEF

INJECTABLE; INJECTION
PROTAMINE ZINC INSULIN
* SQUIBB
*

40 UNITS/ML
100 UNITS/ML

N17928 001
N17928 003

INSULIN SUSP PROTAMINE ZINC PURIFIED BEEF

INJECTABLE; INJECTION
PROTAMINE ZINC INSULIN
@ SQUIBB

40 UNITS/ML
100 UNITS/ML

N17928 001
N17928 003

INSULIN ZINC SUSP EXTENDED PURIFIED BEEF

INJECTABLE; INJECTION
ULTRALENTE
* NOVO NORDISK
@

100 UNITS/ML
100 UNITS/ML

N18385 001
N18385 001

INSULIN ZINC SUSP PROMPT PURIFIED PORK

INJECTABLE; INJECTION
SEMILENTE
* NOVO NORDISK
@

100 UNITS/ML
100 UNITS/ML

N18382 001
N18382 001

INSULIN ZINC SUSP PURIFIED BEEF

INJECTABLE; INJECTION
LENTE Iletin II
@ ELI LILLY
* LILLY

100 UNITS/ML
100 UNITS/ML

N18477 001
N18477 001

MICONAZOLE NITRATE

CREAM; VAGINAL
MICONAZOLE 7
NMC

2%

N74164 001
MAR 29, 1996

MICONAZOLE NITRATE
G AND W LABS

2%

N74366 001
FEB 22, 1996

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
MONISTAT-3 COMBINATION PACK
+ ADV CARE

2%, 200MG

N20670 002
APR 16, 1996

MINOXIDIL

SOLUTION; TOPICAL
MINOXIDIL (FOR MEN)
ALPHARMA

2%

N74588 001
APR 05, 1996
N74643 001
APR 09, 1996
N74500 001
MAY 23, 1996
N74589 001
APR 05, 1996

2%

N74588 001
APR 05, 1996

2%

N74588 001
APR 05, 1996

2%

N74588 001
APR 05, 1996

ROGAINE (FOR MEN)

+ PHARMACIA AND UPJOHN 2%

ROGAINE (FOR WOMEN)

+ PHARMACIA AND UPJOHN 2%

N19501 002
FEB 09, 1996
N19501 003
FEB 09, 1996

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC
OCUHIST
AKORN

0.025%; 0.3%

N20485 001
JAN 31, 1996

OPCON-A

* BAUSCH AND LOMB

0.027%; 0.315%

N20065 001
JUN 08, 1994

0.02675%; 0.315%

N20065 001
JUN 08, 1994

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL

NICODERM CQ

+ HOECHST MARION RSSL 7MG/24HR

+ 14MG/24HR

+ 21MG/24HR

NICOTROL

+ MCNEIL CONS PRODS 15MG/16HR

> ADD >
> ADD >

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

N20165 006
AUG 02, 1996
N20165 005
AUG 02, 1996
N20165 004
AUG 02, 1996
N20536 001
JUL 31, 1996

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL

NICORETTE

+ SMITHKLINE BEECHAM EQ 2MG BASE

+

EQ 4MG BASE

N18612 002
FEB 09, 1996
N20066 002
FEB 09, 1996

NIZATIDINE

TABLET; ORAL

AXID AR

+ WHITEHALL ROBINS 75MG

N20555 001
MAY 09, 1996

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

EPIDAC 24 PSEUDOEPHEDRINE HCL

+ ALZA 24 0MG

* CIBA 24 0MG

N20021 002
DEC 15, 1992
N20021 002
DEC 15, 1992

PSEUDOEPHEDRINE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL

PSEUDO-12

* FISOXS EQ 60MG HCL/5ML

@ MEDEVA PHARMS EQ 60MG HCL/5ML

N19401 001
JUN 19, 1987
N19401 001
JUN 19, 1987

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 8 / AUG '96

NO AUGUST 1996 APPROVALS

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January 1, 1996 thru August 31 1996]

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Amphotericin B lipid complex TN= Abelcet	Treatment of invasive candidiasis.	The Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=06/27/96 MA= / /
Amphotericin B lipid complex TN= Abelcet	Treatment of invasive zygomycosis.	The Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=05/06/96 MA= / /
Amphotericin B lipid complex TN= Abelcet	Treatment of invasive coccidioidomycosis.	The Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=05/06/96 MA= / /
Amphotericin B lipid complex TN= Abelcet	Treatment of invasive protothecosis.	The Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=08/21/96 MA= / /
Antihemophilic factor (human) TN= Alphanate	Treatment of von Willebrand's disease.	Alpha Therapeutic Corporation 5555 Valley Boulevard Los Angeles, CA 90032 DD=01/05/96 MA= / /
Arcitumomab TN= 99m Tc-labeled CBA-Scan	Diagnosis and localization of primary, residual, recurrent and metastatic medullary thyroid carcinoma.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=05/10/96 MA= / /
Clostridial collagenase TN=	Treatment of advanced (involutional or residual stage) Dupuytren's disease.	Hurst, L. M.D. & Badalamente, M. Ph.D. State University of New York at Stony Brook School of Medicine Health Sciences Center T18-020 Stony Brook, NY 11794 DD=05/23/96 MA= / /
Collagenase (lyophilized) for injection TN= Plaquase	Treatment of Peyronie's disease.	Advance Biofactures Corporation 35 Wilbur Street Lynbrook, NY 11563 DD=03/12/96 MA= / /
C1-esterase inhibitor (human) TN=	Treatment and prevention of angioedema caused by C1-esterase inhibitor deficiency.	Alpha Therapeutic Corporation 5555 Valley Boulevard Los Angeles, CA 90032 DD=08/21/96 MA= / /
DAB3891L-2 TN=	Treatment of cutaneous T-cell lymphoma.	Seragen, Inc. 97 South Street Hopkinton, MA 01748 DD=08/21/96 MA= / /

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Dihydrotestosterone TN=Androgel-DHT	Treatment of weight loss in AIDS patients with HIV-associated wasting.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road, Suite 210 Buffalo Grove, IL 60089 DD=02/05/96 MA= / /
DMP 777 TN=	Therapeutic management of patients with lung disease attributable to cystic fibrosis.	Dupont Merck Pharmaceutical Company Dupont Merck Plaza, Maple Run 2110 Wilmington, DE 19805 DD=06/04/96 MA= / /
Etiocolanedione TN=	Treatment of Prader-Willi syndrome.	SuperGen, Inc. 3158 Des Plaines Avenue Suite 10 Des Plaines, IL 60018 DD=05/07/96 MA= / /
Gusperimus TN=Spanidin	Treatment of acute renal graft rejection episodes.	Bristol-Myers Squibb Company 5 Research Parkway P.O. Box 5100 Wallingford, CT 06492 DD=06/27/96 MA= / /
Indoxuridine TN=	Treatment of nonparenchymatous sarcomas.	NeoPharm, Inc. 225 East Deerpath, Suite 250 Lake Forest, IL 60045 DD=04/08/96 MA= / /
Interferon beta-la TN=Rebif	Treatment of patients with secondary progressive multiple sclerosis.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=03/11/96 MA= / /
KL4-Surfactant TN=	Treatment of meconium aspiration syndrome in newborn infants.	Cochrane, Charles, M.D. The Scripps Research Institute 10666 Torrey Pines Road LaJolla, CA 92037 DD=07/30/96 MA= / /
L-2-oxothiazolidine 4-carboxylic acid TN=Procysteine	Treatment of amyotrophic lateral sclerosis.	Transcend Therapeutics, Inc. 640 Memorial Drive, 3rd Floor West Cambridge, MA 02139 DD=07/30/96 MA= / /
Lipid/DNA human cystic fibrosis gene TN=	Treatment of cystic fibrosis.	Genzyme Corporation One Kendall Square Cambridge, MA 02139 DD=04/08/96 MA= / /
Liposomal prostaglandin E1 injection TN=	Treatment of acute respiratory distress syndrome.	The Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=04/25/96 MA= / /
Methionine/L-methionine TN=	Treatment of AIDS myelopathy.	DiRocco, Alessandro M.D. The Mount Sinai Medical Center One Gustave L. Levy Place, Box 1139 New York, NY 10029 DD=08/21/96 MA= / /
Methylnaltrexone TN=	Treatment of chronic opioid-induced constipation unresponsive to conventional therapy.	The University of Chicago 5841 South Maryland Avenue MC 4028 Chicago, IL 60637 DD=06/17/96 MA= / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

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NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Mitoxantrone TN=Novantrone	Treatment of hormone refractory prostate cancer.	Immunex Corporation 51 University Street Seattle, WA 98101 DD=08/21/96 MA= / /
Nitazoxanide TN=	Treatment of cryptosporidiosis in HIV-positive and AIDS patients.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road, Suite 210 Buffalo Grove, IL 60089 DD=01/05/96 MA= / /
Rifapentine TN=	Prophylactic treatment of Mycobacterium avium complex in patients with acquired immunodeficiency syndrome and a CD4+ count less than or equal to 75/mm ³ .	Marion Merrell Dow Inc. P.O. Box 9627 (Park A) Kansas City, MO 64137 DD=03/12/96 MA= / /
R-VIII SQ TN= REFACTO	For long-term and/or hospital treatment of hemophilia A or for treatment of patients with hemophilia A in connection with surgical procedures.	Pharmacia & Upjohn 7000 Portage Road Kalamazoo, MI 49001 DD=02/08/96 MA= / /
Somatropin for injection TN=Serostim	Treatment of children with AIDS-associated failure-to-thrive including AIDS-associated wasting.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=03/26/96 MA= / /
SU101 TN=	Treatment of ovarian cancer.	Sugen, Inc. 515 Galveston Drive Redwood City, CA 94063 DD=03/12/96 MA= / /
Testosterone TN=Androgel	Treatment of weight loss in AIDS patients with HIV-associated wasting.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road, Suite 210 Buffalo Grove, IL 60089 DD=02/05/96 MA= / /
Thalidomide TN=Synovir	Treatment of HIV-associated wasting syndrome.	Celgene Corporation P.O. Box 4914 7 Powder Horn Drive Warren, NJ 07059 DD=03/11/96 MA= / /
Uridine 5'triphosphate TN=VIL	To facilitate the removal of lung secretions in the treatment of patients with primary ciliary dyskinesia.	Inspire Pharmaceuticals, Inc. 4222 Emperor Boulevard, Suite 470 Durham, NC 27703 DD=06/26/96 MA= / /
Valine, isoleucine and leucine TN=VIL	Treatment of hyperphenylalaninemia.	Leas Research Products 4 Brookview Lane Troy, NY 12180 DD=01/05/96 MA= / /

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
ORPHAN DRUG PRODUCT APPROVALS FOR 1996		
Albendazole TN= Albenza	Treatment of hydatid disease (cystic echinococcosis due to <i>E. granulosus</i> larvae or alveolar echinococcosis due to <i>E. multilocularis</i> larvae).	SmithKline Beecham Pharmaceuticals One Franklin Plaza P.O. Box 7929 Philadelphia, PA 19101 DD=01/17/96 MA=06/11/96
Albendazole TN= Albenza	Treatment of neurocysticercosis due to <i>Taenia solium</i> as: 1) chemotherapy of parenchymal, subarachnoidal and racemose (cysts in spinal fluid) neurocysticercosis in symptomatic cases and 2) prophylaxis of epilepsy and other sequelae in asymptomatic neurocysticercosis.	SmithKline Beecham Pharmaceuticals One Franklin Plaza P.O. Box 7929 Philadelphia, PA 19101 DD=01/18/96 MA=06/11/96
Allopurinol sodium TN= 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.	Glaxo Wellcome Inc. Five Moore Drive P.O. Box 13398 Research Triangle Park, NC 27709 DD=10/16/92 MA=05/17/96
Bleomycin sulfate TN=Blenoxane	Treatment of malignant pleural effusion.	Bristol-Myers Squibb P.O. Box 4000 Princeton, NJ 08543 DD=09/17/93 MA=02/20/96
Corticotrelin ovine triflutate TN=Acthrel	For use in differentiating pituitary and ectopic production of ACTH in patients with ACTH-dependent Cushings syndrome.	Ferring Laboratories, Inc. 400 Rella Boulevard, Suite 201 Suffern, NY 10901 DD=11/24/89 MA=05/23/96
Daunorubicin citrate liposome injection TN=DaunoXome	Treatment of patients with advanced HIV-associated Kaposi's sarcoma.	NeXstar Pharmaceuticals, Inc. 650 Cliffside Drive San Dimas, CA 91773 DD=05/14/93 MA=04/08/96
Ganciclovir intravitreal implant TN=Vitrasert Implant	Treatment of cytomegalovirus retinitis.	Chiron Vision 500 Iolab Drive Claremont, CA 91711 DD=06/07/95 MA=03/04/96
Interferon beta-la TN=Avonex	Treatment of multiple sclerosis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=12/16/91 MA=05/17/96
Ofloxacin TN=Ocuflox Ophthalmic Solution	Treatment of bacterial corneal ulcers.	Allergan, Inc. 2525 Dupont Drive P.O. Box 19534 Irvine, CA 92713 DD=04/18/91 MA=05/22/96
Respiratory syncytial virus immune globulin (human) TN=Respigam	Prophylaxis of respiratory syncytial virus lower respiratory tract infections in infants and young children at high risk of RSV disease.	MedImmune, Inc. 35 West Watkins Mill Road Gaithersburg, MD 20878 DD=09/27/90 MA=01/18/96

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
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ORPHAN DRUG PRODUCT APPROVALS FOR 1996

Sodium phenylbutyrate TN=Buphenyl	Treatment of urea cycle disorders carbamylphosphate synthetase deficiency, ornithine transcarbamylase deficiency, and argininosuccinic acid synthetase deficiency.	Ucyclyd Pharma 10819 Gilroy Road, Suite 100 Hunt Valley, MD 21031 DD=11/22/93 MA=04/30/96
Somatropin for injection TN=Serostim	Treatment of AIDS-associated catabolism/weight loss.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=11/15/91 MA=08/23/96

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

NO AUGUST 1996 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

DRUG NAME (DOSAGE FORM)DATEREVISED DATE

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) 7500 STANDISH PLACE, ROCKVILLE, MD 20855. COPIES OF THESE GUIDANCES MAY ALSO BE OBTAINED FROM THE DIVISION OF COMMUNICATION MANAGEMENT, CENTER FOR DRUG EVALUATION AND RESEARCH, FDA, 5600 FISHERS LANE (HFD-210) ROCKVILLE, MD 20857 OR BY CALLING (301) 827-4573, FAX: (301) 827-4577.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 16TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

CLOZAPINE *IN VITRO* AND *IN VIVO* (TABLET)

NOV 15, 1995

APR 19, 1996

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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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, 16TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	325MG 50MG 40MG 7.5MG	95 P-0279/ CP2	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	325MG 50MG 40MG 10MG	95 P-0279/ CP1	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	500MG 50MG 40MG 7.5MG	95 P-0279/ CP4	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	500MG 50MG 40MG 10MG	95 P-0279/ CP3	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 7.5MG	95 P-0279/ CP2	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 10MG	95 P-0279/ CP1	MIKART	NEW COMBIANTION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	500MG 50MG 40MG 7.5MG	95 P-0279/ CP4	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	500MG 50MG 40MG 10MG	95 P-0279/ CP3	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; HYDROCODONE BITARTRATE CAPSULE; ORAL	325MG 5MG	95 P-0278/ CP1	MIKART	NEW STRENGTH	APPROVED MAY 28, 1996
ACYCLOVIR SODIUM INJECTABLE; INJECTION	EQ 5MG BASE/ML (100ML/CONTAINER) (200ML/CONTAINER)	95 P-0268/ CP1	WILMER, CUTLER, & PICKERING	NEW DOSAGE FORM NEW STRENGTH	APPROVED FEB 27, 1996
ASPIRIN; BUTALBITAL CAPSULE; ORAL	650MG 50MG	96 P-0021/ CP1	SAVAGE	NEW DOSAGE FORM	APPROVED APR 19, 1996
ATRACURIUM BESYLATE INJECTABLE; INJECTION	0.5MG/ML 1MG/ML (100ML CONTAINER)	95 P-0372/ CP1	ABBOTT	NEW STRENGTH	APPROVED MAR 08, 1996
CARBIDOPA; LEVODOPA POWDER FOR RECONSTITUTION; ORAL	25MG/PACKET 100MG/PACKET	95 P-0100/ CP1	ATHENA	NEW DOSAGE FORM	APPROVED MAY 28, 1996
CARBIDOPA; LEVODOPA POWDER FOR RECONSTITUTION; ORAL	25MG/PACKET 250MG/PACKET	95 P-0100/ CP1	ATHENA	NEW DOSAGE FORM	APPROVED MAY 28, 1996
CHOLESTYRAMINE TABLET, CHEWABLE; ORAL ORAL	EQ 2GM RESIN	95 P-0277/ CP1	MAYRAND	NEW DOSAGE FORM NEW STRENGTH	APPROVED FEB 27, 1996
CYTARABINE INJECTABLE; INJECTION	100MG/ML (1ML/VIAL) (5ML/VIAL)	92 P-0183/ CP1	FAULDING	NEW DOSAGE FORM NEW STRENGTH	APPROVED JUL 26, 1996
CYTARABINE INJECTABLE; INJECTION	100MG/ML (10ML/VIAL) (20ML/VIAL)	92 P-0184/ CP1	FAULDING	NEW DOSAGE FORM	APPROVED JUL 26, 1996
DILTIAZEM HYDROCHLORIDE INJECTABLE, INJECTION	5MG/ML (25ML/SYRINGE) (50ML/SYRINGE)	95 P-0196/ CP1	INTL MEDICATION	NEW STRENGTH	APPROVED FEB 27, 1996
EPINEPHRINE INJECTABLE; SUBCUTANEOUS	0.3MG/DELIVERY	95 P-0190/ CP1	SENETCK PLC	NEW ROUTE OF ADMINISTRATION	APPROVED FEB 15, 1996
HYDROCORTISONE BUTYRATE LOTION; TOPICAL	0.1%	95 P-0223/ CP1	MCKENNA & CUNEO	NEW DOSAGE FORM	APPROVED FEB 21, 1996
LACTULOSE CRYSTALS, FOR RECONSTITUTION; ORAL	20GM/PACKET	95 P-0287/ CP1	BENNETT	NEW DOSAGE FORM NEW STRENGTH	APPROVED APR 19, 1996
MEPERIDINE HYDROCHLORIDE INJECTABLE; INJECTION	10MG/ML (60ML/SYRINGE)	95 P-0348/ CP1	MALLINCKRODT	NEW STRENGTH	APPROVED MAR 08, 1996
METRONIDAZOLE LOTION; TOPICAL	0.75%	95 P-0328/ CP1	RNB PHARM	NEW DOSAGE FORM	APPROVED FEB 23, 1996
NIFEDIPINE CAPSULE, EXTENDED RELEASE; ORAL	30MG 60MG 90MG	95-P-0326/ CP1	KV	NEW DOSAGE FORM	APPROVED FEB 23, 1996

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
PACLITAXEL INJECTABLE; INJECTION	6MG/ML (16.7ML/VIAL) (33.3ML/VIAL) (50ML/VIAL)	95 P-0360/ CP1	ABBOTT	NEW STRENGTH	APPROVED APR 29, 1996
PENTOXIFYLLINE SUSPENSION, EXTENDED RELEASE; ORAL	400MG/PACKET	96 P-0079/ CP1	KV PHARM	NEW DOSAGE FORM	APPROVED AUG 13, 1996
POTASSIUM CHLORIDE SUSPENSION, EXTENDED RELEASE; ORAL	10MEQ	96 P-0054/ CP1	KV PHARM	NEW DOSAGE FORM	APPROVED AUG 19, 1996
POTASSIUM CHLORIDE CAPSULE, EXTENDED RELEASE; ORAL	20MEQ	96 P-0018/ CP1	KV PHARM	NEW DOSAGE FORM	APPROVED AUG 19, 1996

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
HYDROCODONE BITRATRATE; PHENYLEPHRINE HYDROCHLORIDE SOLUTION; ORAL	2.5MG/5ML 5MG/5ML	95 P-0336/ CP1	BOCK PHARMA	NEW COMBINATION	DENIED AUG 19, 1996
HYDROCODONE BITRATRATE; PHENYLEPHRINE HYDROCHLORIDE SOLUTION; ORAL	5MG/5ML 10MG/5ML	95 P-0336/ CP2	BOCK PHARMA	NEW COMBINATION	DENIED AUG 19, 1996

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, 16TH 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-29 INCREASE OF CUMULATIVE DOSE TO 0.3MMOL/KG FOR MRI OF THE CNS IN ADULTS
 D-30 5000 IU DOSE FOR PHOPHYLAXIS AGAINST DEEP VEIN THROMBOSIS
 D-31 CHANGE IN RECOMMENDED TOTAL DAILY DOSE TO 80MG (40MG BID)
 D-32 REMOVAL OF THE RESTRICTIONS LIMITING TREATMENT TO TWO CONSECUTIVE WEEKS AND TO SMALL AREAS

NEW INDICATION

- I-141 TREATMENT OF HEMODYNAMICALLY STABLE PATIENTS WITHIN 24 HOURS OF ACUTE MYOCARDIAL INFARCTION TO IMPROVE SURVIVAL
 I-142 LOCALIZE MYOCARDIAL ISCHEMIA (REVERSIBLE DEFECT) AND INFARCTION (NON-REVERSIBLE DEFECTS) IN EVALUATING MYOCARDIAL FUNCTION
 I-143 EPISODIC TREATMENT OF RECURRENT GENITAL HERPES IN IMMUNOCOMPETENT ADULTS
 I-144 ENHANCEMENT OF MRI OF THE ADULT BODY INTERNAL ORGANS
 I-145 0.1MMOL/KG AS A SINGLE INTRAVENOUS BOLUS FOR MRI OF THE CNS IN CHILDREN
 I-146 CONTRAST ENHANCEMENT AND FACILITATION OF VISUALIZATION OF EXTRACRANIAL HEAD AND NECK LESIONS
 I-147 PREVENTION OF GALLSTONE FORMATION IN OBESE PATIENTS EXPERIENCING RAPID WEIGHT LOSS
 I-148 TREATMENT OF ACUTE PNEUMOCYSTIC CARINII PNEUMONIA (PCP) IN HIV-INFECTED PATIENTS WHOSE ALVEOLAR-ARTERIAL OXYGEN DIFFERENCE (AaDO₂) IS LESS THAN OR EQUAL TO 55 TORR
 I-149 TREATMENT OF PATIENTS WITH NON-SMALL CELL LUNG CANCER
 I-150 TREATMENT OF OBSESSIVE COMPULSIVE DISORDER AND PANIC DISORDER
 I-151 PREVENTION OF AND PREVENTION OF FURTHER POSTOPERATIVE NAUSEA AND VOMITING IN PEDIATRIC PATIENTS RECEIVING GENERAL ANESTHESIA
 I-152 SLOWING THE PROGRESSION OF CORONARY ATHEROSCLEROSIS AND REDUCING THE RISK OF ACUTE CORONARY EVENTS
 I-153 MANAGEMENT OF SEVERE SPASTICITY [ENCOMPASSES SPINAL AND CEREBRAL ORIGIN]
 I-154 PATIENT POPULATION ALTERED TO INCLUDE PEDIATRIC USE
 I-155 TREATMENT OF ONCHOMYCOSIS DUE TO DERMATOPHYTES (TINEA UNGUIUM) OF THE TOENAIL WITH OR WITHOUT FINGERNAIL INVOLVEMENT
 I-156 ADDITIONAL DATA REGARDING THE SAFE USE OF NORVASC IN PATIENTS WITH HEART FAILURE
 I-157 TREATMENT OF ACUTE UNCOMPLICATED CYSTITIS IN FEMALES
 I-158 TREATMENT OF OSTEOLYTIC BONE METASTASES OF BREAST CANCER
 I-159 FOR HYPERCHOLESTEROLEMIC PATIENTS WITHOUT CLINICALLY EVIDENT HEART DISEASE REDUCE THE RISK OF MYOCARDIAL INFARCTION, REVASCULARIZATION, AND DEATH DUE TO CARDIOVASCULAR CAUSES WITH NO INCREASE IN DEATH FROM NON-CARDIOVASCULAR CAUSES
 I-160 TREATMENT OF BACTERIAL CORNEAL ULCERS
 I-161 TREATMENT OF ADULT-ONSET OR CHILDHOOD-ONSET ADULT GROWTH HORMONE DEFICIENCY

PATENT USE CODE

- U-121 METHOD OF TREATING CONDITIONS MEDIATED THROUGH HISTAMINE H₂-RECEPTORS
 U-122 A THERAPEUTIC METHOD FOR CONTROLLING THROMBOSIS
 U-123 METHOD FOR CONTROLLING THROMBOSIS AND DECREASING BLOOD HYPERCOAGULATION AND HEMORRHAGING RISKS
 U-124 TREATMENT OF ACNE
 U-125 TREATING NEUROGENERATIVE DISEASES

EXCLUSIVITY TERMS

PATENT USE CODE

U-126 TREATMENT OF GASTRITIS
U-127 METHOD OF PRODUCING NEUROMUSCULAR BLOCKADE
U-128 METHODS FOR TREATMENT OF TUMORS
U-129 METHOD TO DESTROY OR IMPAIR TARGET CELLS
U-130 MANAGEMENT OF PATIENTS WITH MASTOCYTOSIS
U-131 PHOTODAMAGED SKIN
U-132 INHIBITING HIV PROTEASE
U-133 MANAGEMENT OF OBESITY INCLUDING WEIGHT LOSS AND MAINTENANCE IN PATIENTS ON A REDUCED-CALORIE DIET
U-134 TREATMENT OF ACNE VULGARIS
U-135 ANTITUMOR AGENT
U-136 PROCESS FOR WASTE NITROGEN REMOVAL
U-137 METHOD OF TREATING BACTERIAL VAGINOSIS
U-138 TREATMENT OF ALLERGIC RHINITIS
U-139 TREATMENT OF ALLERGIC REACTIONS
U-140 USE OF NORVIR TO INHIBIT HIV PROTEASE OR TO INHIBIT AN HIV INFECTION
U-141 TREATMENT OF ULCERATIVE COLITIS
U-142 METHOD OF TREATING ALLERGIC REACTIONS IN A MAMMAL BY USING THIS ACTIVE METABOLITE
U-143 BIODEGRADABLE SUPERPARAMAGNETIC METAL OXIDES AS CONTRAST AGENTS FOR MR IMAGING
U-144 BIOLOGICALLY DEGRADABLE SUPERPARAMAGNETIC MATERIALS FOR USE IN CLINICAL APPLICATIONS
U-145 BIOLOGICALLY DEGRADABLE SUPERPARAMAGNETIC PARTICLES FOR USE AS NUCLEAR MAGNETIC RESONANCE IMAGING AGENTS

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
19806 001	ACRIVASTINE; SEMPREX-D	4650807	MAR 26, 2008	U-93		
20338 001	ADAPALENE; DIFFERIN	4717720	APR 10, 2006	U-134	NCE	MAY 31, 2001
20380 001	ADAPALENE; DIFFERIN	4717720	APR 10, 2006	U-134	NCE	MAY 31, 2001
20666 001	ALBENDAZOLE; ALBENZA				ODE	JUN 11, 2003
					NCE	JUN 11, 2001
20298 001	ALLOPURINOL SODIUM; ZYLOPRIM				NDF	MAY 17, 1999
					ODE	MAY 17, 2003
20221 001	AMIFOSTINE; ETHYOL				I-149	MAR 15, 1999
19787 001	AMLODIPINE BESYLATE; NORVASC	4879303	MAR 25, 2007		I-156	JUN 14, 1999
19787 002	AMLODIPINE BESYLATE; NORVASC	4879303	MAR 25, 2007		I-156	JUN 14, 1999
19787 003	AMLODIPINE BESYLATE; NORVASC	4879303	MAR 25, 2007		I-156	JUN 14, 1999
19155-001	AMMONIUM LACTATE; LACHYDRIN	4105783	JAN 15, 1997			
>DLI>						
>ADD>					NDF	AUG 29, 1999
20508 001	AMMONIUM LACTATE; LACHYDRIN	4935437	JUN 10, 2008			
20541 001	ANASTROZOLE; ARIMIDEX	4386104	MAY 31, 2000	U-124		
20428 001	AZELAIC ACID; AZELEX					
20075 001	BACLOFEN; LIORESAL				I-153	JUN 14, 1999
20075 002	BACLOFEN; LIORESAL				I-153	JUN 14, 1999
20469 001	BECLMETHASONE DIPROPIONATE MONOHYDRATE; VANCENASE AQ				NP	JUN 26, 1999
20532 001	BENTOQUATAM; IVY BLOCK				NCE	AUG 26, 2001
>ADD>						
20498 001	BICALUTAMIDE; CASODEX	4636505	JAN 13, 2004			
50443 001	BLEOMYCIN SULFATE; BLENOXANE				ODE	FEB 20, 2003
19672 001	BROMPHENIRAMINE MALEATE; EFIDAC 24					
					NP	MAR 29, 1999
18731 001	BUSPIRONE HYDROCHLORIDE; BUSPAR					
18731 002	BUSPIRONE HYDROCHLORIDE; BUSPAR					
19215 001	BUTOCONAZOLE NITRATE; FEMSTAT					
>ADD>						
>DLI>						
>ADD>						
19359 001	BUTOCONAZOLE NITRATE; FEMSTAT	4078071	MAR 07, 1997			
>DLI>						
>ADD>						
20421 001	BUTOCONAZOLE NITRATE; FEMSTAT 3	4078071	MAR 07, 1997		NP	DEC 21, 1998
>ADD>						
>DLI>						
20273 001	CALCIPOTRIENE; DOVONEX	4866048	DEC 29, 2007	U-88	NCE	DEC 29, 1998

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
20554 001	CALCIPOTRIENE; DOVONEX	4866048	SEP 12, 2006		NDF	JUL 22, 1999
20313 002	CALCITONIN; SALMON; MICALGIN	4344949	OCT 03, 2000			
18874 001	CALCITRIOL; CALCIJEX	4308264	JAN 28, 2001			
18874 002	CALCITRIOL; CALCIJEX	4308264	JAN 28, 2001			
18343 004	CAPTOPRIL; CAPOTEN					I-95 SEP 23, 1996 I-101 JAN 28, 1997
18343 007	CAPTOPRIL; CAPOTEN					I-95 SEP 23, 1996 I-101 JAN 28, 1997
20234 001	CARBAMAZEPINE; TEGRETOL-XR	5284662	FEB 08, 2011			
20234 002	CARBAMAZEPINE; TEGRETOL-XR	RE34990	JUL 29, 2007			
20234 003	CARBAMAZEPINE; TEGRETOL-XR	5284662	FEB 08, 2011			
19880 001	CARBOPLATIN; PARAPLATIN	RE34990	JUL 29, 2007			
19880 002	CARBOPLATIN; PARAPLATIN	5284662	FEB 08, 2011			
19880 003	CARBOPLATIN; PARAPLATIN	RE34990	JUL 29, 2007			
19835 001	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4140707	AUG 24, 1998			
19835 002	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4140707	AUG 24, 1998			
20638 001	CIDOFOVIR; VISTIDE	4140707	AUG 24, 1998			
19537 001	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4525358	JUN 25, 2002			
19537 002	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4525358	JUN 25, 2002			
19537 003	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	5142051	AUG 25, 2009			
19537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO					
20398 001	CISAPRIDE MONOHYDRATE; PROPULSID					
20551 001	CISATRACURIUM BESYLATE; NIMBEX					
20551 002	CISATRACURIUM BESYLATE; NIMBEX PRESERVATIVE FREE	4962115	OCT 09, 2007	U-79	NCE	JUN 26, 2001
20551 003	CISATRACURIUM BESYLATE; NIMBEX PRESERVATIVE FREE	5453510	SEP 26, 2012	U-127		APR 08, 1999
20340 001	CLOBETASOL PROPIONATE; TEMOVATE E	4179507	DEC 18, 1996	U-127		APR 08, 1999
20525 001	CLOTIMAZOLE; GYNE-LOTRIMIN 3	5453510	SEP 26, 2012	U-127		APR 08, 1999
20526 002	CLOTIMAZOLE; GYNE-LOTRIMIN 3 COMBINATION PACK	4179507	DEC 18, 1996	U-127		APR 08, 1999
20162 001	CORTICORELIN OVINE TRIFLUATE; ACTHREL	5453510	SEP 26, 2012	U-127		APR 08, 1999
20479 001	CROMOLYN SODIUM; GASTROCROM	4179507	DEC 18, 1996	U-127		APR 08, 1999
		4515805	MAY 07, 2002	U-130	D-32	MAY 03, 1999
		4421762	DEC 20, 2000	U-130	NP	JUL 29, 1999
					NP	JUL 29, 1999
					NCE	MAY 23, 2001

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
20287 001	DALTEPARIN SODIUM; FRAGMIN	4303651	JAN 04, 2005		NCE	DEC 22, 1999
20287 003	DALTEPARIN SODIUM; FRAGMIN	4303651	JAN 04, 2005		D-30	MAR 18, 1999
50704 002	DAUNORUBICIN CITRATE; DAUNOXOME				NCE	DEC 22, 1999
20118 001	DESFLURANE; SUPRANE	4762856	FEB 02, 2007	U-67	D-30	MAR 18, 1999
19955 001	DESMOPRESSIN ACETATE; DDAVP	5047398	SEP 10, 2008		ODE	APR 08, 2003
19955 002	DESMOPRESSIN ACETATE; DDAVP	5047398	SEP 10, 2008		NCE	SEP 18, 1997
20071 001	DESOGESTREL; DESOGEN	3927046	NOV 19, 1995			
>ADD>		3927046	NOV 06, 1996			
>DLT>		3927046	NOV 19, 1995			
>ADD>		3927046	NOV 06, 1996			
>DLT>		3927046	NOV 19, 1995			
>ADD>		3927046	NOV 06, 1996			
>DLT>		3927046	NOV 19, 1995			
>ADD>		3927046	NOV 06, 1996			
>DLT>		3927046	NOV 19, 1995			
20301 001	DESOGESTREL; ORTHO-CEPT	4309445	JUN 16, 2000	U-133		
20301 002	DESOGESTREL; ORTHO-CEPT					
20344 001	DEXFENFLURAMINE HYDROCHLORIDE; REDUX				NDF	MAR 08, 1999
20254 001	DICLOFENAC SODIUM; VOLTAREN-XR	5422123	JUN 06, 2012			
20092 001	DILTIAZEM HYDROCHLORIDE; DILACOR XR	5422123	JUN 06, 2012			
20092 002	DILTIAZEM HYDROCHLORIDE; DILACOR XR	5422123	JUN 06, 2012			
20092 003	DILTIAZEM HYDROCHLORIDE; DILACOR XR	5422123	JUN 06, 2012			
20401 001	DILTIAZEM HYDROCHLORIDE; TIAZAC	5529791	JUN 25, 2013			
20401 002	DILTIAZEM HYDROCHLORIDE; TIAZAC	5529791	JUN 25, 2013			
20401 003	DILTIAZEM HYDROCHLORIDE; TIAZAC	5529791	JUN 25, 2013			
20401 004	DILTIAZEM HYDROCHLORIDE; TIAZAC	5529791	JUN 25, 2013			
20401 005	DILTIAZEM HYDROCHLORIDE; TIAZAC	5529791	JUN 25, 2013			
18723 001	DIVALPROEX SODIUM; DEPAKOTE	5529791	JUN 25, 2013		NS	SEP 11, 1998
18723 002	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-41	MAR 18, 1999
18723 003	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-41	MAR 18, 1999
20449 001	DOCETAXEL; TAXOTERE	5212326	JAN 29, 2008		I-41	MAR 18, 1999
20164 001	ENOXAPARIN SODIUM; LOVENOX	5403858	JUL 03, 2012		NCE	MAY 14, 2001
		4814470	JUL 14, 2007			
		5389618	FEB 14, 2012			
		4692435	DEC 24, 2004	U-123		
		4486420	DEC 04, 2001	U-122		
20472 001	ESTRADIOL; ESTRING				NDF	APR 26, 1999
20538 001	ESTRADIOL; ESTRADIOL				NS	OCT 28, 1997
20538 003	ESTRADIOL; ESTRADIOL				NS	OCT 28, 1997

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PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
18922 002	ETODOLAC; LODINE	5041424	AUG 20, 2008	U-135	I-24	JUN 28, 1999
18922 003	ETODOLAC; LODINE	4904768	FEB 27, 2007		I-24	JUN 28, 1999
18922 004	ETODOLAC; LODINE	4671953	MAY 01, 2005	U-87	I-24	JUN 28, 1999
20457 001	ETOPOSIDE PHOSPHATE; ETOPOPHOS	4671953	MAY 01, 2005	U-87	NE	MAY 17, 1999
20195 001	FENTANYL CITRATE; FENTANYL	4671953	MAY 01, 2005	U-87	NDF	OCT 04, 1996
20195 002	FENTANYL CITRATE; FENTANYL	4671953	MAY 01, 2005	U-87	NDF	OCT 04, 1996
20195 003	FENTANYL CITRATE; FENTANYL	4671953	MAY 01, 2005	U-87	NDF	OCT 04, 1996
20195 007	FENTANYL CITRATE; FENTANYL	4671953	MAY 01, 2005	U-87	NDF	OCT 04, 1996
20416 001	FERUMOXIDES; FERIDEX	4951675	AUG 28, 2007	U-143		
>ADD>		4827945	MAY 09, 2006	U-144		
>ADD>		4770183	SEP 13, 2005	U-145		
>ADD>		5055288	OCT 08, 2008			
>ADD>		5248492	SEP 28, 2010			
>ADD>		5219554	JUN 15, 2010			
>ADD>		5102652	FEB 06, 2009			
20625 001	FEXOFENADINE HYDROCHLORIDE; ALLEGRA	5375693	AUG 03, 2012	U-138	NCE	JUL 25, 2001
>ADD>		4254129	APR 10, 1999	U-139		
20548 001	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999
20548 002	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999
20548 003	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999
20261 001	FLUVASTATIN SODIUM; LESCOL	4335121	MAR 15, 2002		D-31	MAR 20, 1999
20261 002	FLUVASTATIN SODIUM; LESCOL	4335121	MAR 15, 2002		D-31	MAR 20, 1999
20450 001	FOSPHENYTOIN SODIUM; CEREBYX				NCE	AUG 05, 2001
20235 001	GABAPENTIN; NEURONTIN	4260769	APR 07, 1998	U-125		
>ADD>		5084479	JAN 02, 2010			
>ADD>		4894476	MAY 02, 2008			
20235 002	GABAPENTIN; NEURONTIN	4087544	JAN 17, 2001	U-86	NCE	DEC 30, 1998
>ADD>		5084479	JAN 02, 2010	U-125		
>ADD>		4894476	MAY 02, 2008			
20235 003	GABAPENTIN; NEURONTIN	4087544	JAN 17, 2001	U-86	NCE	DEC 30, 1998
>ADD>		5084479	JAN 02, 2010	U-125		
>ADD>		4894476	MAY 02, 2008			
20123 001	GADODIAMIIDE; OMNISCAN	4087544	JAN 17, 2001	U-86	NCE	DEC 30, 1998
>ADD>		4687659	MAY 04, 2007			
19596 001	GADOPENTETATE DIMEGGLUMINE; MAGNEVIST	4647447	MAR 03, 2004			

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PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20569 001	GANCICLOVIR; VITRASERT	5082668	JAN 21, 2009		NP	MAR 04, 1996
20509 001	GEMCITABINE HYDROCHLORIDE; GENZAR	5082668	JAN 21, 2009		NCE	MAY 15, 2001
20509 002	GEMCITABINE HYDROCHLORIDE; GENZAR	5366734	NOV 22, 2011		NCE	MAY 15, 2001
20329 001	GLIPIZIDE; GLUCOTROL XL	4767628	AUG 30, 2005		I-88	FEB 02, 1996
20329 002	GLIPIZIDE; GLUCOTROL XL	5366734	NOV 22, 2011			
19726 001	GOSERELIN ACETATE; ZOLADEX	4767628	AUG 30, 2005			
20578 001	GOSERELIN ACETATE; ZOLADEX	4100274	APR 22, 1999		NP	JAN 11, 1999
20239 001	GRANISETRON HYDROCHLORIDE; KYTRIL	4886808	DEC 29, 2007	U-89		
20305 001	GRANISETRON HYDROCHLORIDE; KYTRIL	4886808	DEC 29, 2007	U-105		
19836 001	HISTRELIN ACETATE; SUPPRELIN	4244946	JAN 13, 2000		NCE	DEC 24, 1996
19836 002	HISTRELIN ACETATE; SUPPRELIN	4244946	JAN 13, 2000		NCE	DEC 24, 1996
19836 003	HISTRELIN ACETATE; SUPPRELIN	4244946	JAN 13, 2000		NCE	DEC 24, 1996
20589 001	IBUPROFEN; CHILDREN'S ADVIL	4788220	JUL 08, 2007		NP	JUN 16, 1998
20602 001	IBUPROFEN; JUNIOR STRENGTH MOTRIN				NP	JUN 16, 1998
20603 001	IBUPROFEN; CHILDREN'S MOTRIN	5374559	DEC 20, 2011		NP	JUN 16, 1998
20685 001	INDINAVIR SULFATE; CRIXIVAN	5413999	MAY 07, 2013	U-132	NCE	MAR 13, 2001
20685 003	INDINAVIR SULFATE; CRIXIVAN	5413999	MAY 07, 2013	U-132	NCE	MAR 13, 2001
20563 001	INSULIN LISPRO; HUMALOG	5514846	MAY 07, 2013	U-111	NCE	JUN 14, 2001
20351 001	IODIXANOL; VISIPAQUE 270	5349085	SEP 20, 2011		NCE	MAR 22, 2001
		4396597	JUL 03, 1999			
		4278654	JUL 03, 1999			
		5349085	SEP 20, 2011			
		4396597	JUL 03, 1999			
		4278654	JUL 03, 1999			
20351 002	IODIXANOL; VISIPAQUE 320	4001323	JAN 04, 1996			
		4001323	NOV 24, 1997			
>ADD>	18735 001 IOPAMIDOL; ISOVUE-M 200	4001323	JAN 04, 1996			
>DLT>	18735 002 IOPAMIDOL; ISOVUE-300	4001323	NOV 24, 1997			
>ADD>	18735 003 IOPAMIDOL; ISOVUE-370	4001323	JAN 04, 1996			
>DLT>	18735 004 IOPAMIDOL; ISOVUE-M 300	4001323	NOV 24, 1997			
>ADD>	18735 007 IOPAMIDOL; ISOVUE-250	4001323	JAN 04, 1996			
>DLT>		4001323	NOV 24, 1997			
					D-28	MAY 15, 1998

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PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	20327 001 IOPAMIDOL; ISOVUE-200	4001323	JAN 04, 1996			
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>ADD>	20327 002 IOPAMIDOL; ISOVUE-250	4001323	JAN 04, 1996			
>DLT>		4001323	NOV 24, 1997			
>ADD>	20327 003 IOPAMIDOL; ISOVUE-300	4001323	JAN 04, 1996			
>DLT>		4001323	NOV 24, 1997			
>ADD>	20327 004 IOPAMIDOL; ISOVUE-370	4001323	JAN 04, 1996			
>DLT>		4001323	NOV 24, 1997			
>ADD>	20571 001 IRINOTECAN HYDROCHLORIDE; CAMPTOSAR	4604463	JUL 05, 2004			
>DLT>						
>ADD>	20083 001 ITRACONAZOLE; SPORANOX	4089969	MAY 16, 1997	U-55		JUN 14, 2001
>DLT>		4089969	JUL 14, 1998	U-55		SEP 28, 1998
>ADD>	19645 001 KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55		
>DLT>		4089969	JUL 14, 1998	U-55		
>ADD>	19698 001 KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55		
>DLT>		4089969	JUL 14, 1998	U-55		
>ADD>	19698 002 KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55		
>DLT>		4089969	JUL 14, 1998	U-55		
>ADD>	19700 001 KETOROLAC TROMETHAMINE; ACULAR	4089969	MAY 16, 1997	U-75		
>DLT>		4089969	JUL 14, 1998	U-75		
>ADD>	20564 001 LAMIVUDINE; EPIVIR	5047407	FEB 08, 2009			
>DLT>		5047407	FEB 08, 2009			
>ADD>	20241 001 LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106		DEC 27, 1999
>DLT>		4602017	JUL 22, 2008	U-106		DEC 27, 1999
>ADD>	20241 002 LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106		DEC 27, 1999
>DLT>		4602017	JUL 22, 2008	U-106		DEC 27, 1999
>ADD>	20241 003 LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106		DEC 27, 1999
>DLT>		4602017	JUL 22, 2008	U-106		DEC 27, 1999
>ADD>	20241 004 LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106		DEC 27, 1999
>DLT>		4602017	JUL 22, 2008	U-106		DEC 27, 1999
>ADD>	20241 005 LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106		DEC 27, 1999
>DLT>		4602017	JUL 22, 2008	U-106		DEC 27, 1999
>ADD>	20241 006 LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106		DEC 27, 1999
>DLT>		4602017	JUL 22, 2008	U-106		DEC 27, 1999
>ADD>	20406 001 LANSOPRAZOLE; PREVACID	4689333	JUL 29, 2005	U-126		APR 08, 1999
>DLT>		4689333	JUL 29, 2005	U-126		APR 08, 1999
>ADD>	20597 001 LATANOPROST; XALATAN	4689333	JUL 29, 2005	U-126		APR 08, 1999
>DLT>		4689333	JUL 29, 2005	U-126		APR 08, 1999
>ADD>	20517 001 LEUPROLIDE ACETATE; LUPRON DEPOT	5480656	JAN 02, 2013			
>DLT>		5480656	JAN 02, 2013			
>ADD>	20219 001 LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN	4369184	DEC 07, 2004			
>DLT>		4369184	DEC 07, 2004			
>ADD>	20575 001 LIDOCAINE; LIDOCAINE	5446070	FEB 27, 2011			
>DLT>		5446070	FEB 27, 2011			
>ADD>		5332576	JUL 26, 2011			
>DLT>		5332576	JUL 26, 2011			
>ADD>		5234957	FEB 27, 2011			
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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
20575 002	LIDOCAINE; LIDOCAINE	5446070	FEB 27, 2011		NDF	MAY 21, 1999
19558 001	LISINAPRIL; PRINIVIL	5332576	JUL 26, 2011		I-141	NOV 24, 1998
19558 002	LISINAPRIL; PRINIVIL	5234957	FEB 27, 2011		I-141	NOV 24, 1998
19558 003	LISINAPRIL; PRINIVIL				I-141	NOV 24, 1998
19558 004	LISINAPRIL; PRINIVIL				I-141	NOV 24, 1998
19558 006	LISINAPRIL; PRINIVIL				I-141	NOV 24, 1998
19777 001	LISINAPRIL; ZESTRIL				I-141	NOV 24, 1998
19777 002	LISINAPRIL; ZESTRIL				I-141	NOV 24, 1998
19777 003	LISINAPRIL; ZESTRIL				I-141	NOV 24, 1998
19777 004	LISINAPRIL; ZESTRIL				I-141	NOV 24, 1998
19777 005	LISINAPRIL; ZESTRIL				I-141	NOV 24, 1998
19658 001	LORATADINE; CLARITIN	4659716	APR 21, 2004	U-142	I-136	SEP 20, 1998
19670 001	LORATADINE; CLARITIN-D	4659716	APR 21, 2004	U-142	NC	NOV 14, 1997
20470 001	LORATADINE; CLARITIN-D 24 HOUR	4282233	JUL 19, 2002	U-77	NP	AUG 23, 1999
>ADD>		4695590	APR 17, 2008		NCE	APR 12, 1998
>ADD>		5541171	JUL 30, 2013	U-141		
>ADD>		5536743	JUL 16, 2013	U-137		
19940 001	MASOPROCOL; ACTINEX				NP	APR 16, 1999
19651 001	MESALAMINE; ASACOL				NCE	JUN 14, 2001
20208 001	METRONIDAZOLE; METROGEL				NCE	JUN 14, 2001
20670 002	MICONAZOLE NITRATE; MONISTAT-3 COMBINATION PACK					
20415 001	MIRTAZAPINE; REMERON	4344949	OCT 03, 2000		NDF	JUL 03, 1999
20415 002	MIRTAZAPINE; REMERON	4344949	OCT 03, 2000			
20312 001	MOEXIPRIL HYDROCHLORIDE; UNIVASC	5378474	MAR 23, 2010			
20312 002	MOEXIPRIL HYDROCHLORIDE; UNIVASC	5202128	APR 13, 2010			
20616 001	MORPHINE SULFATE; KADIAN	5378474	MAR 23, 2010		NDF	JUL 03, 1999
20616 002	MORPHINE SULFATE; KADIAN	5202128	APR 13, 2010		NDF	JUL 03, 1999
20616 003	MORPHINE SULFATE; KADIAN	5378474	MAR 23, 2010		NDF	JUL 03, 1999
		5202128	APR 13, 2010			
19886 001	NAFARELIN ACETATE; SYNAREL	4234571	JUN 11, 2011		NDF	JAN 05, 1999
20353 001	NAPROXEN SODIUM; NAPRELAN				NDF	JAN 05, 1999
20353 002	NAPROXEN SODIUM; NAPRELAN				NDF	JAN 05, 1999
20353 003	NAPROXEN SODIUM; NAPRELAN				NDF	JAN 05, 1999
20152 001	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003	U-12	NCE	DEC 22, 1999

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
20152 002	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003	U-12	NCE	DEC 22, 1999
20152 003	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003	U-12	NCE	DEC 22, 1999
20152 004	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003	U-12	NCE	DEC 22, 1999
20152 005	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003	U-12	NCE	DEC 22, 1999
20152 006	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003	U-12	NCE	DEC 22, 1999
20636 001	NEVIRAPINE; VIRAMUNE	5366972	NOV 22, 2011			DEC 22, 1999
19488 001	NICARDIPINE HYDROCHLORIDE; CARDENE	3985758	OCT 12, 1995		NCE	JUN 21, 2001
>ADD>		3985758	FEB 15, 1996			
>DLT>		3985758	OCT 12, 1995			
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20165 001	NICOTINE; NICODERM	5508038	APR 16, 2013			MAR 22, 1999
20165 002	NICOTINE; NICODERM	5508038	APR 16, 2013			MAY 09, 1999
20165 003	NICOTINE; NICODERM	5508038	APR 16, 2013			MAY 22, 2003
20385 001	NICOTINE; NICOTROL	5508038	APR 16, 2013			MAY 22, 1999
20555 001	NIZATIDINE; AXID AR					MAY 22, 2003
19921 001	OFLOXACIN; OCUFLOX					MAY 22, 1999
>ADD>						MAY 22, 1999
19810 001	OMEPRAZOLE; PRILLOSEC	4255431	APR 05, 2001	U-108	I-23	MAR 22, 1999
19810 003	OMEPRAZOLE; PRILLOSEC	4853230	APR 20, 2007	U-108	I-23	MAR 22, 1999
20007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN					MAY 16, 1999
18841 004	OXAPROZIN; DAYPRO					MAY 16, 1999
20553 001	OXYCODONE HYDROCHLORIDE; OXYCONTIN					OCT 29, 1999*
>ADD>						
20553 002	OXYCODONE HYDROCHLORIDE; OXYCONTIN	5549912	FEB 05, 2008		NDF	DEC 12, 1998
>ADD>		5266331	FEB 05, 2008		NDF	DEC 12, 1998
20553 003	OXYCODONE HYDROCHLORIDE; OXYCONTIN	5549912	FEB 05, 2008		NDF	DEC 12, 1998
>ADD>		5266331	FEB 05, 2008		NDF	DEC 12, 1998
20553 003	OXYCODONE HYDROCHLORIDE; OXYCONTIN	5549912	FEB 05, 2008		NDF	DEC 12, 1998
>ADD>		5266331	FEB 05, 2008		NDF	DEC 12, 1998

* - In accordance with section 2105(c) of the FDA Export Reform and Enhancement Act of 1996 (Public Law 104-134)

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PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20036 001	PAMIDRONATE DISODIUM; AREDIA				I-158	JUL 16, 1999
20036 003	PAMIDRONATE DISODIUM; AREDIA				I-158	JUL 16, 1999
20036 004	PAMIDRONATE DISODIUM; AREDIA				I-158	JUL 16, 1999
20031 001	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
20031 002	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
20031 003	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
20031 004	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
20031 005	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
19887 002	PENTAMIDINE ISETHIONATE; NEBUPENT				I-148	MAR 05, 1999
20184 001	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
20184 002	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
20184 003	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
20451 001	PORFIMER SODIUM; PHOTOFRIN	5438071	AUG 01, 2012	U-129	ODE	DEC 27, 2002
		5145863	JUN 12, 2007			
		5028621	MAR 10, 2004			
		4932934	JUN 12, 2007	U-128	NCE	DEC 27, 2000
		4866168	MAR 10, 2004			
		4649151	MAR 10, 2004			
		5180589	JUL 09, 2008			
		5030447	JUL 09, 2008			
		4346227	OCT 20, 2005			
19898 005	PRAVASTATIN SODIUM; PRAVACHOL	5180589	JUL 09, 2008		I-159	JUL 02, 1999
		5030447	JUL 09, 2008		I-152	MAR 22, 1999
19898 006	PRAVASTATIN SODIUM; PRAVACHOL	4346227	OCT 20, 2005			
		5180589	JUL 09, 2008		I-159	JUL 02, 1999
		5030447	JUL 09, 2008		I-152	MAR 22, 1999
19898 007	PRAVASTATIN SODIUM; PRAVACHOL	5180589	JUL 09, 2008		I-159	JUL 02, 1999
		5030447	JUL 09, 2008			
		4346227	OCT 20, 2005		I-152	MAR 22, 1999
20279 001	PREDNICARBATE; DERMATOP	4346227	OCT 20, 2005			
20545 001	PROCAINAMIDE HYDROCHLORIDE; PROCANBID				I-154	MAY 03, 1999
20545 002	PROCAINAMIDE HYDROCHLORIDE; PROCANBID				NP	JAN 31, 1999
19627 001	PROPOFOL; DIPRIVAN				NP	JAN 31, 1999
19885 001	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4056635	NOV 01, 2006		I-90	MAR 08, 1996
19885 002	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
19885 003	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
19885 004	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
20559 001	RAMITIDINE BISMUTH CITRATE; TRITEC	4344949	OCT 03, 2002			
		5008256	JUL 17, 2009		NE	AUG 08, 1999

>ADD>

>ADD>

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
19593 001	RANITIDINE HYDROCHLORIDE; ZANTAC	4585790	MAY 11, 2004			
		4521431	JUN 04, 2002	U-121		
		4128658	JUL 25, 1997	U-121		
19593 002	RANITIDINE HYDROCHLORIDE; ZANTAC	4585790	MAY 11, 2004			
		4521431	JUN 04, 2002	U-121		
		4128658	JUL 25, 1997	U-121		
20520 001	RANITIDINE HYDROCHLORIDE; ZANTAC 75	4880636	MAY 13, 2008			
		4521431	JUN 04, 2002	U-121		
		4128658	JUL 25, 1997	U-121		
20630 001	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5019583	FEB 15, 2009		NCE	JUL 12, 2001
20630 002	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5019583	FEB 15, 2009		NCE	JUL 12, 2001
20630 003	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5019583	FEB 15, 2009		NCE	JUL 12, 2001
20272 001	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
20272 002	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
20272 003	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
20272 004	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
20272 005	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
20588 001	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90	NCE	DEC 29, 1998
20659 001	RITONAVIR; NORVIR	5541206	JUL 30, 2013	U-140		
20680 001	RITONAVIR; NORVIR	5484801	JAN 28, 2014		NCE	MAR 01, 2001
20628 001	SAQUINAVIR MESYLATE; INVIRASE	5541206	JUL 30, 2013	U-140	NCE	MAR 01, 2001
20572 001	SODIUM PHENYL BUTYRATE; BUPHENYL	5196438	NOV 19, 2010			
20573 001	SODIUM PHENYL BUTYRATE; BUPHENYL	4457942	AUG 20, 2002	U-136	NCE	APR 30, 2001
>ADD>			AUG 20, 2002	U-136	NCE	APR 30, 2001
>ADD>	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				ODE	APR 30, 2003
>ADD>	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				I-161	AUG 01, 1999
20280 004	SOMATROPIN, BIOSYNTHETIC; GENOTROPIN				I-161	AUG 01, 1999
20280 006	SOMATROPIN, BIOSYNTHETIC; GENOTROPIN				NS	AUG 24, 1998
20604 001	SOMATROPIN, BIOSYNTHETIC; SEROSTIM				NS	AUG 24, 1998
>ADD>					ODE	AUG 23, 2003
>ADD>					NP	AUG 23, 1999
>ADD>	SOMATROPIN, BIOSYNTHETIC; SEROSTIM				ODE	AUG 23, 2003
>ADD>					NP	AUG 23, 1999
20240 001	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2003	U-3	NCE	DEC 29, 1999
20240 002	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2003	U-3	NCE	DEC 29, 1999
20240 003	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2003	U-3	NCE	DEC 29, 1999
20240 004	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2003	U-3	NCE	DEC 29, 1999

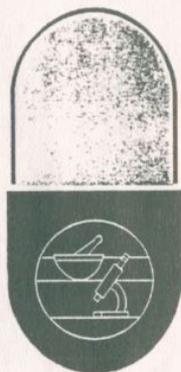
PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20412 001	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
20412 002	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
20412 003	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
20412 004	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
20412 005	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
20256 001	TECHNETIUM TC-99M BICISATE KIT; NEUROLITE	5279811	NOV 23, 2008	U-101	NCE	NOV 23, 1999
19785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	5045302	APR 10, 2007		I-142	DEC 14, 1998
20372 001	TECHNETIUM TC-99M TETROFOSMIN KIT; MYOVIEW	5504207	APR 29, 2013	U-3	NCE	FEB 09, 2001
19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
20347 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
20347 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
20347 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
20347 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
20539 001	TERBINAFINE HYDROCHLORIDE; LAMISIL	4755534	JUL 05, 2005	U-73	NDF	MAY 10, 1999
20489 001	TESTOSTERONE; ANDRODERM	5164190	NOV 17, 2008		NCE	DEC 30, 1999
		5152997	OCT 06, 2009			
		4983395	JAN 08, 2009			
		4863970	SEP 05, 2006			
		4855294	AUG 08, 2006			
		4849224	JUL 18, 2006			
		5004758	APR 02, 2008			
20671 001	TOPOTECAN HYDROCHLORIDE; Hycamtin				NS	SEP 29, 1998
20528 001	TRANDOLAPRIL; MAVIK				NCE	MAY 28, 2001
20528 002	TRANDOLAPRIL; MAVIK				NCE	APR 26, 2001
20528 003	TRANDOLAPRIL; MAVIK				NCE	APR 26, 2001
19963 001	TRETINOIN; RENOVA				NCE	APR 26, 2001
>ADD>	UROFOLLITROPIN; METRODIN	4877805	OCT 31, 2006	U-131		
>ADD>	UROFOLLITROPIN; METRODIN	4603146	JUL 29, 2003	U-131		
19415 002	URSODIOL; ACTIGALL	4423041	DEC 27, 2000		NP	DEC 29, 1998
19594 001	VALACYCLOVIR HYDROCHLORIDE; VALTRES				NR	AUG 23, 1999
20487 001	VALACYCLOVIR HYDROCHLORIDE; VALTRES				NR	AUG 23, 1999
20487 002	VALACYCLOVIR HYDROCHLORIDE; VALTRES				I-147	MAR 29, 1999
					I-143	DEC 15, 1998
					I-143	DEC 15, 1998

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
20151 001	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
20151 002	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
20151 003	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
20151 004	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
20151 005	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
20151 006	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
20552 001	VERAPAMIL HYDROCHLORIDE; COVERA-HS	5252338	JUN 27, 2011		NP	FEB 26, 1999
		5190765	AUG 14, 2007			
		5160744	JUN 27, 2011			
		4753802	MAR 19, 2006			
20552 002	VERAPAMIL HYDROCHLORIDE; COVERA-HS	5252338	JUN 27, 2011		NP	FEB 26, 1999
		5190765	AUG 14, 2007			
		5160744	JUN 27, 2011			
		4753802	MAR 19, 2006			

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