

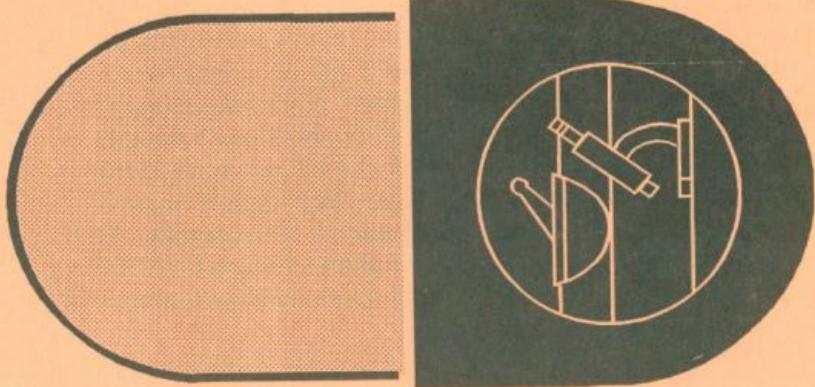
CUMULATIVE
SUPPLEMENT 11

JAN'91-NOV'91

APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

11TH EDITION



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

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

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New 12th Edition



APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION
1992

CONTENTS

- Prescription Drug Product List
- OTC Drug Product List
- Drug Products with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products List
- Discontinued Drug Product List
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APPROVED DRUG PRODUCTS
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THERAPEUTIC EQUIVALENCE EVALUATIONS

11TH EDITION

Cumulative Supplement

November 1991

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

11TH EDITION

CUMULATIVE SUPPLEMENT 11

NOVEMBER 1991

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, 11th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Division of Blood and Blood Products and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

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

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

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

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

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the " " symbol to designate their non-marketed status. All products having a " " symbol in the 12th Cumulative Supplement of the 11th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 12th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the appropriate Drug Product List.

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

1.3 CHANGE OF A THERAPEUTIC EQUIVALENCY CODE FOR A DRUG ENTITY

Methylphenidate Hydrochloride:

In its initial considerations, the Agency did not classify methylphenidate hydrochloride (MPD) as having an actual or potential bioequivalence problem (42 FR 1624, January 7, 1977). MPD in oral tablet form (Ritalin™, manufactured by Ciba Pharmaceuticals) is a DESI drug product that was raised to the effective status on October 7, 1970 (35 FR 15771). MPD in tablet form remained single source until December 23, 1977 when it became available from MD Pharmaceutical. In the first and subsequent editions of the "Orange Book" this drug product has been coded coded AA.

Recently, FDA's Therapeutic Inequivalence Action Coordination Committee (TIACC) investigated a report from the Kaiser Permanente Medical Care Program in Oakland, California, suggesting therapeutic inequivalence regarding duration of action in a marketed lot of MD Pharmaceutical MPD tablets. Samples from MD Pharmaceutical and Ciba were tested in accordance with USP dissolution test procedures by an FDA field laboratory. Although both products met the single point USP criteria of not less than 75% of the labeled amount of MPD dissolved within 45 minutes, the dissolution profile of the MD Pharmaceutical product was much faster than that of the Ciba product.

Based on these in vitro dissolution data, FDA commissioned an in vivo bioequivalence study under its extramural contract research program. The bioequivalence study indicated that at one-half and three-fourths hours after administration of a single 20 mg dose, somewhat more of MD Pharmaceutical's product had been absorbed compared to Ciba's Ritalin. However, the MD Pharmaceutical MPD 20 mg tablets met FDA's criteria for rate and extent of absorption, and were considered to be bioequivalent to Ciba's Ritalin 20 mg tablets.

Because of the in vitro dissolution data coupled with new information discovered during the course of this evaluation, the FDA has proposed a change in the therapeutic equivalence code from AA to BP for listed MPD tablets. This change requires that firms submitting an ANDA for MPD tablets submit an acceptable in vivo bioequivalence study to gain approval in addition to submission of all previously required information.

Agency reasons for considering this change in the equivalence code is as follows:

- 1) Although early work suggested that MPD tablets are completely absorbed recent studies utilizing more specific techniques calculated the relative bioavailability to be 11 to 53%. (Chan et al: Pediatrics, 72, 56-59, 1983). This raised concerns regarding possible approval of a superbioavailable drug product.
- 2) The current dl-MPD pharmacological activity derives primarily from the d isomer which may exhibit non-linear kinetics. (Srinivas et al: Journal of Pharmacology and Experimental Therapeutics, 241, 300-306, 1987).
- 3) The previously cited in vitro dissolution data suggesting that substantial differences in in vitro dissolution may exist between different formulations of MPD.

The Agency invites written comments and scientific data regarding the Agency's proposal to change the therapeutic equivalence code for listed MPD oral tablets from AA to BP. The comment period will be 60 days from the first day in the monthly Supplement.

1.4 THE B* THERAPEUTIC EQUIVALENCE CODE

Drug products requiring further FDA investigation and review to determine therapeutic equivalence.

The code **B*** is assigned to products that were previously assigned an **A** or **B** code if FDA receives new information that raises a significant question regarding therapeutic equivalence that can be resolved only through further Agency investigation and/or review of data and information submitted by the applicant. The **B*** code signifies that the Agency will take no position regarding the therapeutic equivalence of the product until the Agency completes its investigation and review.

1.5 APPLICANT (NAME) CHANGES

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

APPLICANT (NAME) CHANGES

<u>FORMER APPLICANT (NAME)</u>	<u>NEW APPLICANT (NAME)</u>	<u>ABBREVIATED NAME</u>
CORD LABORATORIES INC	GENEVA PHARMACEUTICALS INC	GENEVA
GIST BROCADES	BROCADES PHARMA bv	BROCADES PHARMA
ICI PHARMACEUTICALS PR INC	IPR PHARMACEUTICALS INC	IPR
KENDALL MCGAW PHARMACEUTICALS	GENSIA PHARMACEUTICALS INC	GENSIA
PHARMACIA LABORATORIES DIV PHARMACIA INC	KABI PHARMACIA	KABI
REID ROWELL INC	SOLVAY PHARMACEUTICALS	SOLVAY

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 1990) 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 1990</u>	<u>MAR 1991</u>	<u>JUN 1991</u>	<u>SEP 1991</u>
DRUG PRODUCTS LISTED	10123	9953	9900	9869
SINGLE SOURCE	2030 (20.1%)	2090 (21.0%)	2110 (21.3%)	2103 (21.4%)
MULTISOURCE	8093 (79.9%)	7863 (79.0%)	7790 (78.7%)	7766 (78.6%)
THERAPEUTICALLY EQUIVALENT	7222 (71.3%)	7061 (71.0%)	6937 (70.1%)	6914 (70.0%)
NOT THERAPEUTICALLY EQUIVALENT	752 (7.4%)	660 (6.6%)	702 (7.1%)	706 (7.2%)
EXCEPTIONS ¹	119 (1.2%)	142 (1.4%)	151 (1.5%)	146 (1.4%)
NEW MOLECULAR ENTITIES APPROVED	--	5	4	3
NUMBER OF APPLICANTS	400	408	417	418

¹Amino acid-containing products of varying composition (see Introduction, page 1-8 of the List).

PRESCRIPTION DRUG PRODUCT LIST

11TH EDITION

CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'91 - NOV'91

ACETAMINOPHEN; CODEINE PHOSPHATE

ACETAMINOPHEN; HYDROCODONE BITARTRATE	
TABLET; ORAL ACETAMINOPHEN; HYDROCODONE BITARTRATE	TABLET; ORAL ACETAMINOPHEN; HYDROCODONE BITARTRATE AND ACETAMINOPHEN
/AA/ /PROVAL 45/ /SOLVAY/ a SOLVAY	/N856685/461/ N85685 001 325MG;30MG
/AA/ /TYLENOL W/ CODEINE NO. 3/ /JOHNSON/RW/	/N87422/461/ N87422 001 300MG;30MG
a JOHNSON RW /TYLENOL 1/4/ CODEINE NO. 4/ /JOHNSON/RW/	/N87424/461/ N87421 001 300MG;60MG
a JOHNSON RW	/N87421 001 300MG;60MG
TABLET; ORAL ACETAMINOPHEN AND CODEINE PHOSPHATE MIKART	N89363 001 SEP 25, 1991
/AA/ /AH/ THERAP/	/N894481/461/ MAR/03/1987/ N89481 001
a AM THERAP	300MG;15MG MAR 03, 1987
/AA/ /PARKE/DAVIS/ a WARNER CHILCOTT	/N87366/461/ N87366 001 300MG;60MG
/TYLENOL W/ CODEINE /JOHNSON/RW/	/N85456/461/ N85456 001 325MG;7.5MG
a JOHNSON RW	/N85056 001 325MG;15MG
a	/N85056 003 325MG;20MG
a	/N85056 004 325MG;60MG
ACETAMINOPHEN; HYDROCODONE BITARTRATE	ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE
/AA/ /AA/	N89698 001 500MG;2.5MG
AA MIKART	AUG 25, 1989 N89699 001
AA	500MG;7.5MG AUG 25, 1989 N89695 001
B*	/46045;2.5MG/ /46045;7.5MG/ CHELSEA
/AA/	/46045;2.5MG/ /46045;7.5MG/ B*
B* PHARM BASICS	500MG;5MG MAY 29, 1987
TABLET; ORAL HYDROCODONE BITARTRATE AND ACETAMINOPHEN	TABLET; ORAL PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN
AA MIKART	N89698 001 500MG;100MG
AA	/650MG;100MG /650MG;100MG CHELSEA
B*	325MG;50MG 650MG;100MG
/AA/	/650MG;100MG /650MG;100MG DEC 11, 1986 N71337 001
B*	650MG;100MG N71336 001 DEC 11, 1986 N70399 001
TABLET; ORAL HYDROCODONE BITARTRATE AND ACETAMINOPHEN	TABLET; ORAL HYDROCODONE BITARTRATE AND ACETAMINOPHEN
AA MIKART	N89698 001 500MG;2.5MG
AA	500MG;7.5MG AUG 25, 1989 N89699 001
B*	/46045;2.5MG/ /46045;7.5MG/ CHELSEA
/AA/	/46045;2.5MG/ /46045;7.5MG/ B*
B* PHARM BASICS	500MG;5MG MAY 29, 1987

<u>ACETAZOLAMIDE</u>		<u>ACETYLCYSTEINE</u>	
TABLET; ORAL		SOLUTION; INHALATION, ORAL	
<u>ACETAZOLAMIDE</u>		<u>ACETYLCYSTEINE</u>	
③ ALRA /A/ /A/ a BOLAR	250MG /250MG 250MG	N83320 001 /N83320/001/ /N84438/002/ N84498 002	> DLT > AN/ /Q/OP/ > DLT > > DLT > AN/ > DLT > > ADD > QUAD > ADD > > ADD > > ADD >
<u>ACETIC ACID, GLACIAL</u>			10% a QUAD 20% a a
SOLUTION/DROPS; OTIC			
<u>ACETIC ACID, GLACIAL</u> /A/ /A/ a NORWICH EATON	/22/ 22/ 22; 22; 22; 22; 22;	/N86845/001/ N86845 001	ACYCLOVIR TABLET; ORAL ZOVIKAX BURROUGHS WELLCOME
<u>ACETIC ACID, GLACIAL; HYDROCORTISONE</u>			400MG 800MG
SOLUTION/DROPS; OTIC			
<u>ACETIC ACID, GLACIAL</u> /A/ /A/ a NORWICH EATON	/22/12/ 22; 12;	/N86844/001/ N86844 001	
<u>ACETOHEXAMIDE</u>		<u>ALBUTEROL SULFATE</u>	
TABLET; ORAL		SOLUTION; INHALATION	
<u>ACETOHEXAMIDE</u>		<u>ALBUTEROL SULFATE</u>	
/A/ /A/ B*	/PHARM/BASIS/ 250MG	/N70753/001/ N70753 001	> ADD > AN/ > ADD > > ADD > > ADD > AB > ADD > AB > ADD > AB AB
			EQ 0.5% BASED COPLEY COPILEY
			TABLET; ORAL <u>ALBUTEROL SULFATE</u>
			EQ 2MG BASED COPILEY
			EQ 4MG BASED DANBURY
			EQ 2MG BASED AB
			EQ 4MG BASED AB
			EQ 2MG BASED MYLAN
			AB
			EQ 4MG BASED WATSON
			EQ 2MG BASED AB
			EQ 4MG BASED AB
			EQ 2MG BASED AB
			EQ 4MG BASED a SCHERING
			/N14254/002/ N14254 002 20MG

ALCOHOL

INJECTABLE; INJECTION
/Alcohol 5% In Dextrose 5%
/Cutter/ 5ML/100ML
 a CUTTER

AMYLASE

INJECTABLE; INJECTION
CERDASE GENZYME
 80 UNITS/ML
 APR 05, 1991

AMYLORIDE HYDROCHLORIDE; HYDROCHLORTIAZIDE

<u>TABLET; ORAL</u>	<u>AMYLORIDE HCL AND HYDROCHLORTIAZIDE</u>
<u>N83483 001</u>	<u>5MG; 50MG</u>
<u>> ADD > AB</u>	<u>> ADD ></u>
<u>AB</u>	<u>AB</u>
<u>ROYCE</u>	<u>SMG; 50MG</u>

AMINOCAPROIC ACID

<u>INJECTABLE; INJECTION</u>	<u>AMINOCAPROIC ACID</u>
<u>N18241 002</u>	<u>25MG/ML</u>
<u>> DLT > AP/</u>	<u>/QUAD/</u>
<u>> DLT ></u>	<u>250MG/ML</u>
<u>> ADD ></u>	
<u>> ADD ></u>	
<u>AMINOHIPPURATE SODIUM</u>	
<u>N18241 002</u>	
<u>> DLT > AP/</u>	<u>/250/</u>
<u>> DLT > AP/</u>	<u>20X</u>
<u>> ADD ></u>	<u>/250/</u>
<u>> ADD ></u>	<u>20X</u>
<u>AMINOPHYLLINE</u>	
<u>N18241 002</u>	
<u>> DLT > AP/</u>	<u>/250/</u>
<u>> DLT > AP/</u>	<u>20X</u>
<u>> ADD ></u>	<u>/250/</u>
<u>> ADD ></u>	<u>20X</u>
<u>AMINOPHYLLINE</u>	
<u>N18241 002</u>	
<u>> DLT > AP/</u>	<u>/250/</u>
<u>> DLT > AP/</u>	<u>20X</u>
<u>> ADD ></u>	<u>/250/</u>
<u>> ADD ></u>	<u>20X</u>

<u>INJECTABLE; INJECTION</u>	<u>AMINOPHYLLINE</u>
<u>N18241 002</u>	<u>25MG/ML</u>
<u>> DLT > AP/</u>	<u>/250/</u>
<u>> DLT > AP/</u>	<u>20X</u>
<u>> ADD ></u>	<u>/250/</u>
<u>> ADD ></u>	<u>20X</u>
<u>AMINOPHYLLINE</u>	
<u>N18241 002</u>	
<u>> DLT > AP/</u>	<u>/250/</u>
<u>> DLT > AP/</u>	<u>20X</u>
<u>> ADD ></u>	<u>/250/</u>
<u>> ADD ></u>	<u>20X</u>

ALPRAZOLAM

<u>TABLET; ORAL</u>	<u>AMINOPHYLLINE</u>
<u>XANAX</u>	<u>25MG/ML</u>
<u>/UpJohn/</u>	<u>25MG/ML</u>
<u>UPJOHN</u>	<u>25MG/ML</u>
<u>AMANTADINE HYDROCHLORIDE</u>	
<u>SYRUP; ORAL</u>	
<u>AMANTADINE HCL</u>	
<u>Aa Copley</u>	
<u>50MG/5ML</u>	
<u>N73115 001</u>	
<u>AUG 23, 1991</u>	
<u>> INTL MEDICATION</u>	<u>25MG/ML</u>
<u>a</u>	<u>25MG/ML</u>
<u>/SOLOPAK/</u>	<u>/250/</u>
<u>a SOLOPAK</u>	<u>25MG/ML</u>
<u>N81142 001</u>	
<u>SEP 25, 1991</u>	
<u>/N81142 001/</u>	
<u>/Nov 10, 1983</u>	
<u>N87868 001</u>	
<u>NOV 10, 1983</u>	
<u>/N81142 001/</u>	
<u>/May 30, 1985</u>	
<u>N86429 001</u>	
<u>MAY 30, 1985</u>	

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE
BD LANNETT
BD

/AB/
/SQUIBB/

100MG
200MG
/100MG/
/200MG/

AMITRIPTYLINE HYDROCHLORIDE

/AB/
/AMITRIP/
/SQUIBB/

N84588 001
N84588 002
/N84588/001/
/N84588/002/

100MG
200MG
/100MG/
/200MG/

AMITRIPTYLINE HCL

/AB/
/AMITRIP/
/AB/
/AB/
/AB/
/AB/

N85454 001
N85454 002
N85454 003
N85454 004
N86454 005

100MG
100MG
50MG
75MG
100MG

/100MG/
/200MG/
/250MG/
/100MG/
/150MG/

N85744 001
N85744 002
N85744 003
/N/A 11/1982/
/N/A 12/1982/

/150MG/
/150MG/
/150MG/
/150MG/
/150MG/

N85744 001
N85744 002
N85744 003
N85744 004
N85744 005

10MG
25MG
50MG
75MG
100MG

/AB/
/AB/
/AB/
/AB/
/AB/

N85744 001
N85627 001
N85745 001
N85743 001
N85742 002
N89623 001

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

MAY 11, 1982
FEB 17, 1987

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

N70377 001
NOV 04, 1986

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL
CHLORDIAZEPoxide AND AMITRIPTYLINE HCl
/PHARM/BASICS/
/AB/

/AB/

JAN 12, 1988

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL
PERPHENAZINE AND AMITRIPTYLINE HCl
/100MG;25G/
/AB/
/BOLAR/

/AB/

/100MG;25G/
/100MG;
/100MG;

/AB/
/BOLAR/
/AB/
/AB/
/AB/
/AB/
/AB/
/AB/
/AB/

/100MG;25G/
/100MG;
/100MG;
/100MG;
/100MG;
/100MG;

N70373 001
NOV 04, 1986

/100MG;25G/
/100MG;
/100MG;
/100MG;
/100MG;
/100MG;

N70373 001
AUG 25, 1986

/100MG;25G/
/100MG;
/100MG;
/100MG;
/100MG;

N70375 001
AUG 25, 1986

/100MG;25G/
/100MG;
/100MG;
/100MG;
/100MG;

N70374 001
AUG 25, 1986

/100MG;25G/
/100MG;
/100MG;
/100MG;
/100MG;

N70376 001
AUG 25, 1986

/100MG;25G/
/100MG;
/100MG;
/100MG;
/100MG;

N70377 001
NOV 04, 1986

/100MG;25G/
/100MG;
/100MG;
/100MG;
/100MG;

N70378 001
JAN 12, 1988

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINEAMPICILLIN SODIUM

<u>TABLET; ORAL PERPHENAZINE AND AMITRIPTYLINE HCL CHELSEA/</u>	<u>/10MG;215/</u>	<u>INJECTABLE; INJECTION AMPICILLIN SODIUM /INT'L/MEDICATION/</u>	<u>/AB/</u>	<u>/N62634/601/</u>
<u>/AB/</u>	<u>/10MG;445/</u>	<u>/AB/</u>	<u>/N62634/601/</u>	<u>/JAN 09, 1987/</u>
<u>/AB/</u>	<u>/25MG;445/</u>	<u>③ INT'L MEDICATION</u>	<u>/N62634/601/</u>	<u>/JAN 09, 1987/</u>
<u>/AB/</u>	<u>/25MG;445/</u>	<u>③</u>	<u>EQ 1GM BASE/VIAL</u>	<u>N62634 002</u>
<u>B*</u>	<u>CHELSEA</u>	<u>10MG;2MG</u>	<u>EQ 2GM BASE/VIAL</u>	<u>N62634 003</u>
<u>B*</u>		<u>10MG;4MG</u>	<u>EQ 10GM BASE/VIAL</u>	<u>JAN 09, 1987</u>
<u>B*</u>		<u>N71386 001</u>		
<u>B*</u>		<u>N71386 001</u>		
<u>B*</u>		<u>NOV 03, 1986</u>		
<u>B*</u>		<u>N71385 001</u>		
<u>B*</u>		<u>NOV 03, 1986</u>		
<u>B*</u>		<u>N71387 001</u>		
<u>B*</u>		<u>NOV 03, 1986</u>		
<u>B*</u>		<u>N71558 001</u>		
<u>B*</u>		<u>MAR 02, 1987</u>		
<u>AB</u>	<u>ROYCE</u>	<u>N73007 001</u>		
<u>AB</u>		<u>OCT 17, 1991</u>		
<u>AB</u>		<u>N73009 001</u>		
<u>AB</u>		<u>OCT 17, 1991</u>		
<u>AB</u>		<u>N73008 001</u>		
<u>AB</u>		<u>OCT 17, 1991</u>		
<u>AB</u>		<u>N73010 001</u>		
<u>AB</u>		<u>OCT 17, 1991</u>		
<u>AMOXAPINE</u>		<u>INJECTABLE; INJECTION M.V.T.-12 LYOPHILIZED /AB/</u>		
<u>AB</u>	<u>GENEVA</u>	<u>25MG</u>	<u>/100MG/VIAL;0.06MG/VIAL; 0.005MG/VIAL;0.06MG/VIAL;</u>	<u>/AUS/d8,1985/</u>
<u>AB</u>		<u>50MG</u>	<u>0.4MG/VIAL;40MG/VIAL;4MG/VIAL;</u>	
<u>AB</u>		<u>100MG</u>	<u>3.6MG/VIAL;3MG/VIAL;1MG/VIAL;</u>	
<u>AB</u>		<u>150MG</u>	<u>10MG/VIAL</u>	<u>N18333 002</u>
				<u>AUG 08, 1985</u>

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN '91 - NOV '91

6

<u>ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E</u>	<u>ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE</u>	
CAPSULE; ORAL COMPOUND 65 3 ALRA	389MG; 32.4MG; 65MG	N86553 002 AUG 17, 1983 <u>/N86553/662/</u> <u>/AUS/17/1983/</u>
INJECTABLE; INJECTION MVC PLUS /AB/	/4/β/ΑΗΗΑΧ/	
AP STERIS	10MG/ML; 0.006MG/ML; 0.5UG/ML; 1.5MG/ML; 20 IU/ML; 0.04MG/ML; 4MG/ML; 0.4MG/ML; 0.36MG/ML; 0.3MG/ML; 330 UNITS /ML; 1 IU/ML	AUG 08, 1985 N18439 002 325MG; 200MG 3 AL BOLAR
<u>ASPIRIN; BUTALBITAL; CAFFEINE</u>	<u>ATENOLOL</u>	
CAPSULE; ORAL /BUTALBITAL W/ 'ASPIRIN' AND 'CAFFEINE' /CHELSEA/	/N86231/662/ /F/β/12/1984/	AB N73025 001 SEP 17, 1991 N73026 001 SEP 17, 1991
BUTALBITAL, ASPIRIN AND CAFFEINE CHELSEA	325MG; 50MG; 40MG	N86231 002 FEB 12, 1985 AB
TABLET; ORAL /BUTALBITAL W/ 'ASPIRIN' AND 'CAFFEINE' /CHELSEA/	/N86231/662/ /MAR/23/1984/	
BUTALBITAL, ASPIRIN AND CAFFEINE CHELSEA	325MG; 50MG; 40MG	N86237 002 MAR 23, 1984 AB
<u>ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE</u>	<u>ATROPOINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE</u>	
TABLET; ORAL ORPHEGESIC PAR	/385MG; 30MG; 25MG /β/β/; 30MG; 25MG/	N71642 001 JUN 23, 1987 /N71642/661/ /JUN/23/1987/
B* PAR	> ADD >	ATROPOINE SULFATE; EDROPHONIUM CHLORIDE INJECTABLE; INJECTION ENLON-PLUS ANAQUEST
ORPHEGESIC FORTE PAR	770MG; 60MG; 50MG	N19677 001 NOV 06, 1991 N19678 001 NOV 06, 1991 /β/β/; 60MG; 50MG/

> ADD > AZITHROMYCIN
 > ADD > CAPSULE; ORAL
 ZITHROMAX
 PFIZER
 > ADD >
 > ADD >

250MG
 NOV 01, 1991

BACLOFEN

> ADD > TABLET; ORAL <u>BACLOFEN</u> DANBURY	10MG SEP 18, 1991	N72824 001	B*	PHARM BASICS	0.5MG	N89211 001
AB	20MG SEP 18, 1991	N72825 001	B*		1MG	JUN 14, 1988
AB	/ADD/ /PHARM/BASICS/	/ADD/			2MG	N89212 001
AB	/ADD/	/ADD/				JUN 14, 1988
B*	PHARM BASICS					N89213 001
B*						JUN 14, 1988

BERACTANT

N71260 001	10MG	SUSPENSION; INTRATRACHEAL
MAY 06, 1988		SURVANTA
N71261 001	20MG	ROSS
MAY 06, 1988		

N20032 001
 JUL 01, 1991

BENAZEPRIL HYDROCHLORIDE

TABLET; ORAL
 LOTENSIN
 CIBA

EQ 5MG BASE

EQ 10MG BASE

EQ 20MG BASE

EQ 40MG BASE

N19851 001	> DLT > /ADD/	/BETHANECHOL CHLDRTE/
JUN 25, 1991	> DLT > /ADD/	/BETHANECHOL CHLDRTE/
N19851 002	> DLT > /ADD/	/BETHANECHOL CHLDRTE/
JUN 25, 1991	> ADD > /ADD/	3 QUAD
N19851 003	> ADD > /ADD/	URECHOLINE
JUN 25, 1991	> DLT > /ADD/	/MSD/
N19851 004	> ADD > /ADD/	MSD
JUN 25, 1991		

BETHANECHOL CHLORIDE

/ADD/	TABLET; ORAL <u>BETHANECHOL CHLORIDE</u>	/5MG/	/N89215/001/
/ADD/		/10MG/	/N89216/001/
/ADD/		/20MG/	/N89217/001/
/ADD/		/50MG/	/N89218/001/
3 BOLAR		10MG	N85230 002
3		25MG	N85228 001
3		50MG	N85229 001
DUROTOD			N87397 001
/ADD/			/N89219/001/
/ADD/			/N89220/001/
/ADD/			/N89221/001/

BETHANECHOL CHLORIDE

TABLET; ORAL
DUVOX
 ROBERTS
 AA
 AA
 AA

10MG
 25MG
 50MG

BUPROPION HYDROCHLORIDE

TABLET; ORAL
 WELLBUTRIN
 /WELLBUTRIN/
 3 BURROUGHS WELLCOME 50MG

/N18644/001/
 /DEC 30/1985/
 N18644 001
 DEC 30, 1985

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE
 /50MG/ML/
 /QUAD/
 a QUAD
 BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER
 /Abbott/
 a ABBOTT
 800MG/100ML

/N11181/001/
 /FEB 16, 1988/
 N11181 001
 FEB 16, 1988

/N19008 001/
 /APR 16, 1986/
 APR 16, 1986

/N18644/001/
 /DEC 30/1985/
 N18644 001
 DEC 30, 1985

BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM
 /15MG/
 /Cord/
 /AA/
 /AA/
 a CORD
 30MG
 15MG

/N184292 003/
 FEB 09, 1982
 N184292 003
 /N183325 002/
 MAR 27, 1982
 N183325 002

BROMPHENIRAMINE MALEATE

TABLET; ORAL
BROMPHENIRAMINE MALEATE
 /4MG/
 /PAR/
 a PAR
 /VITARINE/
 a VITARINE

/N87669/001/
 /N87009 001/
 /N85850 001/
 N85850 001

/N17769 001/
 /FEB 09, 1982/
 N17769 001
 FEB 09, 1982

N17808 002
 MAR 29, 1991

CALCITONIN, SALMON

INJECTABLE; INJECTION
CALCITONIN
 AP
 RHONE POULENC RORER 200 IU/ML

AP
Mitacalciton
 SANDOZ
 200 IU/ML

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

/Elixir; oral/
 /BIPHETAP/
 /PHARM/BASICS/
 a PHARM BASICS

4MG/5ML; 25MG/5ML
 SEP 26, 1984
 N88687 001

SOLUTION; IRRIGATION
BSS PLUS
 ALCON
 0.154MG/ML; 0.92MG/ML; 0.184MG/ML;
 0.2MG/ML; 0.38MG/ML; 2.1MG/ML;
 7.14MG/ML; 0.42MG/ML N18469 001

BUPRENORPHINE HYDROCHLORIDE
 INJECTABLE; INJECTION
 BUPRENEK
 /Norwich-Eaton/
 R AND C

/Elixir; 4.5G/BASE/ML/
 EQ 0.3MG BASE/ML
 /N18401 001/
 N18401 001
 NOV 27, 1991

0.154MG/ML; 0.92MG/ML; 0.184MG/ML;
 0.2MG/ML; 0.38MG/ML; 2.1MG/ML;
 7.14MG/ML; 0.42MG/ML N120079 001

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

INJECTABLE; INJECTION; ACETATED RINGER'S; AN/PLASTIC CONTAINER; NSCAN/
/NSCAN/
/60MG/100ML; 300MG/100ML;
/600MG/100ML
 20MG/100ML; 30MG/100ML; 380MG/100ML;
 600MG/100ML
 N18725 001
 NOV 29, 1982

② MCGAW

CEFAZOXIL

CAPSULE; ORAL ULTRACEF
/AB/
/BRISTOL/
 ③ BRISTOL
 EQ 500MG BASE
 POWDER FOR RECONSTITUTION; ORAL
ULTRACEF
/AB/
/BRISTOL/
/ED 125MG BASE/5ML/
/ED 250MG BASE/5ML/
/ED 500MG BASE/5ML/
/ED 1000MG BASE/5ML/
/ED 2000MG BASE/5ML/
/ED 4000MG BASE/5ML/
/ED 6000MG BASE/5ML/
/ED 8000MG BASE/5ML/
/ED 10000MG BASE/5ML/
/ED 125MG BASE/5ML/
/ED 250MG BASE/5ML/
/ED 500MG BASE/5ML/
/ED 1000MG BASE/5ML/
/ED 2000MG BASE/5ML/
/ED 4000MG BASE/5ML/
/ED 6000MG BASE/5ML/
/ED 8000MG BASE/5ML/
/ED 10000MG BASE/5ML/

CALCIUM GLUCEPTATE

INJECTABLE; INJECTION CALCIUM GLUCEPTATE
/AB/
/ABBOTT/
/AB/
/ABBOTT/
EQ 90MG CALCIUM/5ML
 N83159 001
 MAY 15, 1986

② ABBOTT

CARBAMAZEPINE

TABLET; ORAL CARBAMAZEPINE
/PHARM/BASICS/
/AB/
/PHARM/BASICS/
 200MG
 MAY 15, 1986

B* PHARM BASICS

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL STNEMET CR NSD
 50MG;200MG
 N19856 001
 MAY 30, 1991

AA PHARM BASICS

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
ANCEF IN PLASTIC CONTAINER
BAXTER
/AB/
/KODAK/
N62376 001
MAR 16, 1982
N62376 002
MAR 16, 1982
N62376 003
MAR 16, 1982
TABLET; ORAL ULTRACEF
/AB/
/BRISTOL/
③ BRISTOL
EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 500MG BASE/5ML
EQ 1000MG BASE/5ML
EQ 2000MG BASE/5ML
EQ 4000MG BASE/5ML
EQ 6000MG BASE/5ML
EQ 8000MG BASE/5ML
EQ 10000MG BASE/5ML

CARISOPRODOL

TABLET; ORAL CARISOPRODOL
/AB/
/BOLAR/
② BOLAR
MUTUAL PHARM
AA
/350MG/
350MG
350MG
 OCT 17, 1991

CEPHALEXIN
POWDER FOR RECONSTITUTION; ORAL
CEPHALEXIN
SQUIBB MARK
AB
EQ 125MG BASE/5ML
N62986 001
APR 18, 1991

CEPHALOTHIN SODIUMINJECTABLE; INJECTION/AB/ /CEPHALOTHIN/
/INTL/MEDICATION/

/EQ 1GM BASE/VIAL/

/EQ 'ZGM' BASE/VIAL/

/EQ '4GM' BASE/VIAL/

/EQ '5GM' BASE/VIAL/

/EQ '500MG' BASE/VIAL/

② INTL MEDICATION

EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

EQ 2GM BASE/VIAL

EQ 4GM BASE/VIAL

CEPHALOTHIN SODIUM W/
BAXTER

EQ 20MG BASE/MLX

EQ 40MG BASE/MLX

N62422 005

N62422 006

JUL 16, 1991

JUL 16, 1991

CEPHRADINECAPSULE; ORAL/VELDSEF '42504/
② ERSANA//VELDSEF '5004/
② ERSANA//VELDSEF '6004/
② ERSANA//VELDSEF '664/
② ERSANA/

N50548 001

N50548 002

250MG

500MG

500MG

500MG

500MG

500MG

CHLOROTHIAZIDE; RESERPINETABLET; ORAL

/BP/ /BOLAR/

② BOLAR

500MG; 0.125MG

JUN 09, 1983

CHLORDIAZEPOXIDE HYDROCHLORIDECAPSULE; ORALCHLORDIAZEPOXIDE HCL
/SUFERPHARM/

/AB/ /SUFERPHARM/

/AB/ /SUFERPHARM/

/AB/ /SUFERPHARM/

/AB/ /SUFERPHARM/

② SUPERPHARM

5MG

10MG

25MG

5MG

JUN 09, 1983

<u>CHLORPHENIRAMINE MALEATE</u>		
<u>INJECTABLE; INJECTION</u>		
/AP/ AP /LEMIRON/ STERIS	/10MG/ML/ 10MG/ML	/N83593/661/ N83593 001
TABLET; ORAL /ANTIHISTAMINE/ MILES	/4MG/ 4MG	/N83361/661/ N83361 001
CHLORPHENTRAMINE MALEATE /VITARINE/ a VITARINE	/4MG/ 4MG	/N85837/661/ N85837 001
/PHENETRONE/ /LANNETT/ a LANNETT	/4MG/ 4MG	/N86346/661/ N80846 001
<u>CHLORPROMAZINE HYDROCHLORIDE</u>		
INJECTABLE; INJECTION /LEMIRON/ STERIS	/25MG/ML/ 25MG/ML	/N85591/661/ N85591 001
<u>CHLORPROPAMIDE</u>		
TABLET; ORAL /BOLAR/	/100MG/ 100MG	/N86068/661/ APR 12, 1984
a BOLAR	100MG	/N86068/661/ APR 12, 1984
/AB/	/PHARM/BESTCS/	/N88608 001 APR 12, 1984
/AB/		N88608 001 APR 12, 1984
B*	PHARM BASICS	/100MG/ 100MG
B*		/AB/3d/1984/ N88708 001 AUG 30, 1984
<u>CHLORTHALIDONE</u>		
TABLET; ORAL CHLORTHALIDONE /BOLAR/	/45MG/ 50MG	/N87050/661/ N87050 001 FEB 09, 1983
a BOLAR	25MG	/N87029/001 N87029 001
/AB/	/SUPERPHARM/	/FEB/661/ N87473 001
a SUPERPHARM	25MG	JUL 29, 1991
<u>CHLORZOXAZONE</u>		
TABLET; ORAL CHLORZOXAZONE AA DANBURY	500MG	N81019 001
TABLET; ORAL CHLORZOXAZONE AA DANBURY	500MG	N81019 001
<u>CLARITHROMYCIN</u>		
TABLET; ORAL BIAXIN ABBOTT	250MG	N50662 001 OCT 31, 1991
TABLET; ORAL BIAXIN ABBOTT	500MG	N50662 002 OCT 31, 1991
<u>CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE</u>		
TABLET, EXTENDED RELEASE; ORAL TAVIST D /PROST/	/Eq/145/PA5E/75MG/ EQ 1MG BASE; 75MG	/N8298/661/ N8298 001 DEC 15, 1982
SANDOZ	EQ 1MG BASE; 75MG	
<u>CLINDAMYCIN HYDROCHLORIDE</u>		
CAPSULE; ORAL CLINDAMYCIN HCL AB DANBURY	EQ 75MG BASE/ EQ 150MG BASE/	N63082 001 JUL 31, 1991
AB	EQ 150MG BASE/	N63083 001 JUL 31, 1991

CLINDAMYCIN PHOSPHATEINJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE/AB/
/LEHMAN/EQ 150MG BASE/ML
/EQ 150MG BASE/ML/
EQ 150MG BASE/ML
EQ 150MG BASE/ML

STERIS

AP

CLIOQUINOL; HYDROCORTISONECREAM; TOPICAL
VIIFORM-HYDROCORTISONE
CIBA3%;0.5%
3%;1%OINTMENT; TOPICAL
VIIFORM-HYDROCORTISONE3%;0.5%
3%;1%CLOFIBRATECAPSULE; ORAL
CLOFIBRATE500MG
NOVOPHARM

AB

N72600 001

JUL 25, 1991

15MG

B*

CLONIDINE HYDROCHLORIDETABLET; ORAL
CLONIDINE HCL/AB/
/PURAME//AB/
/AB/
/AB/
/AB//AB/
/AB/
/AB/
/AB/

CLORAZEPATE DIPOTASSIUM

CLORAZEPATE DIPOTASSUM

CYANOCOBALAMIN

INJECTABLES: INJECTION

TABLET; VAGINAL
Gynecotrimin/
73CHERIN/

TABLET; ORAL
PROBENECID/W/COCHITINE/
PP/BOLAR
a BOLAR

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL		<u>CYCLOBENZAPRINE HCL</u>	<u>10MG</u>	<u>N72854 001</u>
> ADD	> AB	GENEVA		NOV 19, 1991
> ADD	>			N73144 001
	AB	MYLAN		MAY 31, 1991
				N73143 001
> ADD	> AB	WATSON		NOV 27, 1991
> ADD	>			

CORTISONE ACETATE

SOLUTION/DROPS; OPHTHALMIC AK-PENTOLATE AT /185677/001 /185677/002 N85677 001 N85677 002	AK-ORN AT /Cyclopentolate HCl /AKORN/ CYCLOPENTOLATE HCL STERIS	12 142 124
INJECTABLE; INJECTION CORTISONE ACETATE BP/ /LÉPHON/ BP BP		25MG/ML 50MG/ML

CONTINUUMS

<u>AK-PENTOLATE</u>	<u>AKORN</u>	<u>1/2</u>	NB5555 001
<u>AT</u>	<u>/Cyclopentolate HCl/</u>	<u>/1/2/</u>	<u>/NBB555/661/</u>
<u>/At/</u>	<u>/AKORN/</u>		
	<u>CYCLOPENTOLATE HCl</u>		
	<u>STERIS</u>	<u>1/2</u>	NB9162 001
<u>AT</u>			

INJECTABLE; INJECTION

/6:1MS/ML/
/1NS/ML/

CYPROHEPTADINE HYDROCHLORIDE

SYRUP; ORAL
CYPROHEPTADINE HCL / 4M5/5ML/
 3 NASKA

/ 4M5/5ML/
 2MG/5ML
 DEC 21, 1987

TABLET; ORAL
CYPROHEPTADINE HCL / 4M5/
 3 BOLAR/

/ 4M5/
 4MG
 N35245 001

DACARBAZINE

INJECTABLE; INJECTION
CYTARABINE / QUAD/

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

DACARBAZINE

INJECTABLE; INJECTION
DACARBAZINE / QUAD/

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

DANAZOL

CAPSULE; ORAL
DANAZOL / AM/THERAP/

/N71563/001/
/pEC/21/1987/
N89021 001
DEC 21, 1987

DESERPIDINE; METHYCLOTHIAZIDE

TABLET; ORAL
ENDURONYL

/BP/ /ABBOTT/
 ABBOTT

ENDURONYL FORTE
/BP/ /ABBOTT/
 ABBOTT

ENDURONYL
/BP/ /ABBOTT/
 ABBOTT

METHYCLOTHIAZIDE
/BP/ /BOLAR/

METHYCLOTHIAZIDE
/BP/ /BOLAR/

METHYCLOTHIAZIDE
3 BOLAR

METHYCLOTHIAZIDE
3 BOLAR

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPIRAMINE HCL

/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

CAPSULE; ORAL
DANAZOL / AM/THERAP/

/N71563/001/
/pEC/21/1987/
N71569 001
DEC 30, 1987

DESERPIDINE; METHYCLOTHIAZIDE

TABLET; ORAL
ENDURONYL

/BP/ /ABBOTT/
 ABBOTT

ENDURONYL FORTE
/BP/ /ABBOTT/
 ABBOTT

ENDURONYL
/BP/ /ABBOTT/
 ABBOTT

METHYCLOTHIAZIDE
/BP/ /BOLAR/

METHYCLOTHIAZIDE
/BP/ /BOLAR/

METHYCLOTHIAZIDE
3 BOLAR

METHYCLOTHIAZIDE
3 BOLAR

DESIPIRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPIRAMINE HCL

/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

DESIPIRAMINE HCL
/BP/ /PHARM/EST/

DESMOPRESSIN ACETATE

SOLUTION; NASAL
CONCENTRAID
EEBRING

FERRLING	0.01%	N19776 001
	/6.61%;/	DEC 26, 1990 /N19776/001/ /DEC/26,/1990/
DDAVP	0.01%	N17922 001
	/6.61%;/	/N17922/001/ /6.61%;/

DEXAMETHASONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC

DEATR
 BAUSCH AND LOMB
EQ 0.1% PHOSPHATE
EQ 6.1% PHOSPHATE
 AT / pH 4.4/4.4/
 6.1/
 N68433 001
 DEC 15, 1983
 N68433/661/
 DEC/15/1983/

DEXAMETHASONE

TABLET; ORAL DEXAMETHASONE 10 mg/ a BOLAR	10 mg/ a CORD	EXAMETHASONE SODIUM PHOSPHATE INJECTABLE; INJECTION DESMETHASONE 10 mg/ a CORTITAL/PHOSPHATE
/N84457/661/ N84457 001	/N8d399/661/ N80399 001	/N8564/661/ N18504 001
16.75MG/ 0.75MG	16.75MG/ 0.75MG	16.75MG/ 0.75MG
AP	AP	AP
<u>DEXTROSE 10% IN PLASTIC CONTAINER</u> /CUTTER/ a CUTTER	<u>DEXTROSE 50% IN PLASTIC CONTAINER</u> BAXTER	<u>DEXTROSE 10% IN PLASTIC CONTAINER</u> /16.75/100ML/ 10GM/100ML
<u>DEXTROSE 60% IN PLASTIC CONTAINER</u> BAXTER	<u>DEXTROSE 70% IN PLASTIC CONTAINER</u> BAXTER	<u>DEXTROSE 70% IN PLASTIC CONTAINER</u> /16.75/100ML/ 70GM/100ML
N20047 001 JUL 02, 1991	N20047 002 JUL 02, 1991	N20047 003 JUL 02, 1991

EXAMENES DE

AP	BAXTER	70GM/100ML
INJECTABLE; INJECTION /DEXTROSE 5%/ /CENTRAL PHARMS/ ③ CENTRAL PHARMS DEXAMETHASONE SODIUM PHOSPHATE /LEMIDON/ /QUAD//	/ED '4MG PHOSPHATE/ML/ EQ 4MG PHOSPHATE/ML /ED '4MG PHOSPHATE/ML/ EQ 4MG PHOSPHATE/ML /ED '10MG PHOSPHATE/ML/ EQ 10MG PHOSPHATE/ML /ED '20MG PHOSPHATE/ML/ EQ 20MG PHOSPHATE/ML /ED '24MG PHOSPHATE/ML/ EQ 24MG PHOSPHATE/ML EQ 4MG PHOSPHATE/ML EQ 10MG PHOSPHATE/ML EQ 20MG PHOSPHATE/ML EQ 24MG PHOSPHATE/ML EQ 4MG PHOSPHATE/ML /ED '20MG PHOSPHATE/ML/ EQ 20MG PHOSPHATE/ML	/N84342 001 /N84342 001
③ QUAD		
		INJECTABLE; INJECTION DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER /CUTTER// ③ CUTTER
		DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER /CUTTER// ③ CUTTER
		DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER /CUTTER// ③ CUTTER
		DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER /CUTTER// ③ CUTTER
		DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER /CUTTER// ③ CUTTER
STERIS HEXADROL /ORGANON/ ORGANON		

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION
/A&/ /DIATRIZOATEMEGLUMINE/-66/
/A&/ /DIATRIZOATEMESODIU/-
 a INT'L MEDICATION 52%;8%

DIATRIZOATE SODIUM
 INJECTABLE; INJECTION
/A&/ /DIATRIZOATEMSODIU/-
 a MALLINCKRODT 50%

DI CYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL
/A&/ /DICYCLOMINE HCl/
 JUN 17, 1983
 N88166 001
 JUN 17, 1983

CAPSULE; ORAL
/A&/ /DICYCLOMINE HCl/
 a BOLAR 10MG
 FEB 06, 1986

TABLET; ORAL
/A&/ /DICYCLOMINE HCl/
 a BOLAR 20MG
 FEB 06, 1986

DIDANOSTINE

POWDER FOR RECONSTITUTION; ORAL
 VIDEX
 BRISTOL MYERS SQUIBB 10MG/ML
 N20156 001
 OCT 09, 1991
 N20155 003
 OCT 09, 1991
 N20155 004
 OCT 09, 1991
 N20155 005
 OCT 09, 1991
 N20155 006
 OCT 09, 1991

TABLET, CHEWABLE; ORAL
 VIDEX
 BRISTOL MYERS SQUIBB 25MG
 N20154 002
 OCT 09, 1991
 N20154 003
 OCT 09, 1991
 N20154 004
 OCT 09, 1991
 N20154 005
 OCT 09, 1991

TABLET; ORAL
 STILBESTROL
/B/ /STIBESTROL/-
 0.5MG/0.5NG
 N83004 001

DIAZEPAM

INJECTABLE; INJECTION
/A&/ /DIAZEPAM/-ML/
/A&/ /DIAZEPAM/-
/A&/ /DIAZEPAM/-
 AP STERIS 5MG/ML
 AP 5MG/ML
 AP 5MG/ML
 AP 5MG/ML
 DEC 01, 1986

TABLET, ORAL
 DIAZEPAM
/A&/ /DIAZEPAM/-
/A&/ /DIAZEPAM/-
 AP 50MG
 100MG
 150MG
 DIETHYLSTILBESTROL
 TABLET; ORAL
 STILBESTROL
/B/ /STIBESTROL/-
 0.125
 MAR 28, 1991

TABLET; ORAL
 STILBESTROL
/B/ /STIBESTROL/-
 0.125
 MAR 28, 1991

TABLET; ORAL
 STILBESTROL
/B/ /STIBESTROL/-
 0.125
 MAR 28, 1991

DIETHYL STITIESTROI

TABLET; ORAL	
STYLBETIN	
SQUIBB	
/BP/	
/BP/	
/BP/	
② SQUIBB	
3 SQUIBB	
0.1MG	
0.25MG	
0.5MG	
1MG	
5MG	
N04056 007	
N04056 017	
N04056 008	
N04056 009	
N04056 010	

RHEINWABE MÜNCHEN

CAPSULE; ORAL DIPHENHYDRAMINE HCL	25MG 50MG 500MG	N80519 004 N80519 003 /N80519/003/
□ ALRA ② /S/BNHAX/ /B/	/B/	
Elixir; Oral DIPHENHYDRAMINE HCL	/12.5MG/ML/ 12.5MG/5ML	/N85621/001/ N85621 001
② SQUIBB ② ② ② ②	/N84056 007/ 0.1MG 0.25MG 0.5MG 1MG 5MG	N04056 017 N04056 008 N04056 009 N04056 010
INJECTABLE; INJECTION DIPHENHYDRAMINE HCL	/50MG/ML/ 50MG/ML /10MG/ML/ 10MG/ML	/N83533/001/ N83533 001
② KV ② AP ② AP ② AP	/66/ ② KV/ /AP/ /AP/ /AP/	N04056 007/ 0.1MG 0.25MG 0.5MG 1MG 5MG
INJECTABLE; INJECTION DIPHENHYDRAMINE HCL	/50MG/ML/ 50MG/ML /10MG/ML/ 10MG/ML	/N83533/001/ N83533 001
DILTIAZEM HYDROCHLORIDE		
INJECTABLE; INJECTION CARDIZEM		
MARION MERRELL DOW		
25MG/VIALX 50MG/VIALX		
N20027 001 OCT 24, 1991 N20027 002 OCT 24, 1991		
TABLET; ORAL DIPYRIDAMOLE	25MG 25MG 50MG 75MG	N86944 002 APR 16, 1991 N88999 001 FEB 05, 1991 NB9000 001 FEB 05, 1991 N89001 001 FEB 05, 1991
AB AB AB AB	GENEVA LEDERLE SINN STERIS	
DIMENHYDRINATE		
INJECTABLE; INJECTION DIMENHYDRINATE		
② AP ② AP ② AP	/50MG/ML/ 50MG/ML /50MG/ML/ 50MG/ML	/N83531/001/ N83531 001
Liquid; Oral DIMENHYDRINATE		
□ ALRA ② /S/BNHAX/ /B/		
TABLET; ORAL DIMENHYDRINATE	12.5MG/4ML 12.5MG/4ML	N80715 001 /N80715/001/
② AP ② CHELSEA ② CHELSEA	/50MG/ 50MG	/N85166/001/ N85166 001
LIQUID; ORAL DISOPYRAMIDE PHOSPHATE		
CAPSULE; ORAL DISOPYRAMIDE PHOSPHATE		
② BOLAR ② BOLAR		
EQ 100MG BASE EQ 150MG BASE		
② HEATHER ② HEATHER		
TABLET; ORAL DIMENHYDRINATE		
② HEATHER ② HEATHER		
50MG		
N80841 001		

DISOPYRAMIDE PHOSPHATE

<u>DISOPYRAMIDE PHOSPHATE</u>				<u>CAPSULE; ORAL DOXEPIN HCl</u>		<u>DOXEPIN HCl</u>	
B* CHELSEA	EQ 100MG BASE	/AB/ /B&R/	N71020 001 DEC 01, 1986 N71021 001	/AB/ /B&R/	/N71502/001 /FEB/18/1988 /N71505/001	/N71502/001 /FEB/18/1988 /N71505/001	/FEB/18/1988 /N71505/001
B*	EQ 150MG BASE	/AB/	DEC 01, 1986 N71020 001 N71021 001	/AB/	/N71503/001 /FEB/18/1988 /N71505/001	/N71503/001 /FEB/18/1988 /N71505/001	/FEB/18/1988 /N71505/001
/BX/	/EQ/100MG BASE/	/AB/	DEC 01, 1986 N71020 001 N71021 001	/AB/	/N71504/001 /FEB/18/1988 /N71505/001	/N71504/001 /FEB/18/1988 /N71505/001	/FEB/18/1988 /N71505/001
/BX/	/EQ/150MG BASE/	/AB/	DEC 01, 1986 N71020 001 N71021 001	/AB/	/N71505/001 /FEB/18/1988 /N71505/001	/N71505/001 /FEB/18/1988 /N71505/001	/FEB/18/1988 /N71505/001
/AB/ /MYLAN/	/EQ/100MG BASE/	/AB/ BARR	EQ 100MG BASE N70138 001 JUN 14, 1985	/EQ/25MG BASE N71502 001 FEB 18, 1988	/EQ/50MG BASE N71503 001 FEB 18, 1988	/EQ/75MG BASE N71504 001 FEB 18, 1988	/EQ/100MG BASE N71521 001 FEB 18, 1988
③ MYLAN	EQ 100MG BASE	/AB/	EQ 100MG BASE N70139 001 JUN 14, 1985	/EQ/100MG BASE N71505 001 FEB 18, 1988	/EQ/100MG BASE N71506 001 FEB 18, 1988	/EQ/100MG BASE N71507 001 FEB 18, 1988	/EQ/100MG BASE N71508 001 FEB 18, 1988
③	EQ 150MG BASE	/AB/	EQ 150MG BASE N70139 001 JUN 14, 1985	/EQ/150MG BASE N71509 001 FEB 18, 1988	/EQ/150MG BASE N71510 001 FEB 18, 1988	/EQ/150MG BASE N71511 001 FEB 18, 1988	/EQ/150MG BASE N71512 001 FEB 18, 1988
<u>DOBUTAMINE HYDROCHLORIDE</u>							
<u>INJECTABLE; INJECTION</u>							
DOBUTREX	EQ 12.5MG BASE/ML /EQ/25MG BASE/ML	N17820 002 /N17826/002/	N70952 001 MAR 04, 1987	③ CHELSEA	EQ 10MG BASEH N70953 001 MAR 04, 1987	EQ 25MG BASEH N70954 001 MAY 15, 1986	EQ 50MG BASEH N71763 001 MAY 15, 1986
LILLY	/EQ/150MG BASE/ML	/EQ/150MG BASE/ML	/EQ/150MG BASE/ML	/EQ/150MG BASE/ML	/EQ/150MG BASEH N70955 001 MAY 15, 1986	/EQ/75MG BASEH N71764 001 MAY 15, 1986	/EQ/150MG BASEH N71765 001 MAY 15, 1986
<u>DOPAMINE HYDROCHLORIDE</u>							
<u>INJECTABLE; INJECTION</u>							
DOPANTINE HCl	40MG/ML GENSTA	N72999 001 OCT 23, 1991	N72999 001 OCT 23, 1991	③ CHELSEA	EQ 10MG BASEH N70952 001 MAR 04, 1987	EQ 25MG BASEH N70953 001 MAR 04, 1987	EQ 50MG BASEH N70954 001 MAY 15, 1986
AP	80MG/ML	N73000 001 OCT 23, 1991	N73000 001 OCT 23, 1991	③	EQ 50MG BASEH N71763 001 MAY 15, 1986	EQ 75MG BASEH N71764 001 MAY 15, 1986	EQ 100MG BASEH N71765 001 MAY 15, 1986
AP	/SOLOPAK/	/40MG/ML/ 40MG/ML	/40MG/ML/ 40MG/ML	③ SOLOPAK	AUG 29, 1985	AUG 29, 1985	AUG 29, 1985
<u>DOXAQUACURUM CHLORIDE</u>							
<u>INJECTABLE; INJECTION</u>							
NUROMAX	EQ 1IMG BASE/ML	N19946 001 MAR 07, 1991	N19946 001 MAR 07, 1991	③ PUREPAC	EQ 150MG BASE N72386 001 SEP 08, 1988	EQ 75MG BASE N72387 001 SEP 08, 1988	EQ 150MG BASE N72388 001 SEP 08, 1988
BURROUGHS WELLCOME				③			

DOXEPIP HYDROCHLORIDE

CAPSULE; ORAL
DOXEPIP HCl
AB ROYCE EQ 10MG BASE MAR 29, 1991
AB EQ 25MG BASE MAR 29, 1991
AB EQ 50MG BASE MAR 29, 1991

DOXYCYCLINE HYCLATE

CAPSULE; ORAL
DOXYCYCLINE HYCLATE
AP SUPERPHARM /ED 100MG BASE/ N62985 001 MAR 29, 1991
AP /ED 50MG BASE/ N72986 001 MAR 29, 1991
AP /ED 100MG BASE/ N72987 001 MAR 29, 1991

DOXYCYCLINE HYCLATE

CAPSULE; ORAL
DOXYCYCLINE HYCLATE
AP /ED 100MG BASE/ N62975 001 MAR 17, 1989

DOXYCYCLINE HYCLATE

CAPSULE; ORAL
DOXYCYCLINE HYCLATE
AP /ED 50MG BASE/ N62469 001 OCT 31, 1984
AP /ED 100MG BASE/ N62469 002 OCT 31, 1984

TABLET; ORAL
DOXYCYCLINE HYCLATE

TABLET; ORAL
DOXYCYCLINE HYCLATE
AP /ED 100MG BASE/ N62392 002 MAR 31, 1983

DOXYLAMINE SUCCINATE

TABLET; ORAL
DOXYLAMINE SUCCINATE
AA /DOP/PE// N72985 001 MAR 29, 1991
AA /DOP/PE// N72986 001 MAR 29, 1991
AA /DOP/PE// N72987 001 MAR 29, 1991

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
ADRIAMYCIN PFS
AP ADRIA 2MG/ML 200MG/100ML
AP /AP// >DLT>/AP/ 2.5MG/ML
AP /AP// >ADD>/ QUAD 2.5MG/ML
AP /AP// >ADD>/ AP STERIS 2.5MG/ML
AP /AP// >ADD>/ AP 2.5MG/ML

EDETA TE DISODIUM

INJECTABLE; INJECTION
EDETA TE DISODIUM
AP /AP// >DLT>/AP/ 150MG/ML
AP /AP// >ADD>/ QUAD 150MG/ML
AP /AP// >ADD>/ AP STERIS 150MG/ML
AP /AP// >ADD>/ AP 150MG/ML

INJECTABLE; INJECTION
LIDOCANE HCl W/ EPINEPHRINE
AP /AP// >ADD>/ STERIS 0.01MG/ML;
AP /AP// >ADD>/ STERIS 0.01MG/ML;

ERGOLOID MESYLATES

TABLET; ORAL
ERGOLOID MESYLATES
AP /ED 450// N62463 001 MAY 27, 1982
AP /ED 450// N62463 001 MAY 27, 1982
AP /ED 450// N66433 001 MAY 27, 1982
AP /ED 450// N66433 001 MAY 27, 1982

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN '91 - NOV '91

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ERGOLOID MESYLATES

TABLET; ORAL
ERGOLOID MESYLATES
 AB MUTUAL PHARM 1MG

TABLET; SUBLINGUAL

/AA/
 /BRISTOL/MYERS/SQUIBB/1MGS/
ERGOLOID MESYLATES
 /BOLAR/
 /AA/
 a BOLAR 0.5MG
 /AA/
 /KY/
 a KV 0.5MG
 a

N81113 001
 OCT 31, 1991
 N85020 002
 /N85020/002/002/
 /N85177/001/
 N84930 001
 N85177 001
 /N86264/001/
 N86265 001
 0.5MG
 1MG
 /AA/
 /AA/
 N86264 001

ESTROGENS

TABLET; ORAL <u>ERGOLOID MESYLATES</u> AB MUTUAL PHARM 1MG	INJECTABLE; INJECTION <u>BREVIBLOC</u> / <u>PJP001/</u> a DUPONT 100MG/ML	INJECTABLE; INJECTION <u>BREVIBLOC</u> / <u>PJP001/</u> a DUPONT 100MG/ML
/ <u>AA/</u> / <u>BRISTOL/MYERS/SQUIBB/1MGS/</u> <u>ERGOLOID MESYLATES</u> / <u>BOLAR/</u> / <u>AA/</u> a BOLAR 0.5MG / <u>AA/</u> / <u>KY/</u> a KV 0.5MG a	/ <u>N85020/002/002/</u> / <u>N85177/001/</u> N84930 001 N85177 001 / <u>N86264/001/</u> N86265 001 0.5MG 1MG / <u>AA/</u> / <u>AA/</u> N86264 001	/ <u>N85020/002/002/</u> / <u>N85177/001/</u> N84930 001 N85177 001 / <u>N86264/001/</u> N86265 001 0.5MG 1MG / <u>AA/</u> / <u>AA/</u> N86264 001

ESTROGENS, CONJUGATED

TABLET; ORAL <u>ESTRADIOL CYPIONATE</u> AB MUTUAL PHARM 1MGS	INJECTABLE; INJECTION <u>ESTRADIOL CYPIONATE</u> / <u>QJ40/</u> a QUAD 5MG/ML	TABLET; ORAL <u>ESTRADIOL CYPIONATE</u> AB MUTUAL PHARM 1MGS
/ <u>AA/</u> / <u>BRISTOL/MYERS/SQUIBB/1MGS/</u> <u>ERGOLOID MESYLATES</u> / <u>BOLAR/</u> / <u>AA/</u> a BOLAR 0.5MG / <u>AA/</u> / <u>KY/</u> a KV 0.5MG a	/ <u>N84930/001/001/</u> N84930 001 / <u>N85177/001/</u> N85177 001 / <u>N86265/001/</u> N86265 001 0.5MG 1MG / <u>AA/</u> / <u>AA/</u> N86264 001	/ <u>N84930/001/001/</u> N84930 001 / <u>N85177/001/</u> N85177 001 / <u>N86264/001/</u> N86265 001 0.5MG 1MG / <u>AA/</u> / <u>AA/</u> N86264 001

ERYTHROMYCIN

SOLUTION; TOPICAL <u>ERYTHROMYCIN</u> AT CLAY PARK 224	SOLUTION; TOPICAL <u>ERYTHROMYCIN</u> AT CLAY PARK 224	SOLUTION; TOPICAL <u>ERYTHROMYCIN</u> AT CLAY PARK 224
/ <u>AA/</u> / <u>LILLY/</u> a LILLY	/ <u>N63038/001/</u> JAN 11, 1991 / <u>N50532/001/</u> MAR 10, 1987	/ <u>N63038/001/</u> JAN 11, 1991 / <u>N50532/001/</u> MAR 10, 1987

ERYTHROMYCIN ETHYL SUCCINATE

SUSPENSION; ORAL <u>ERYTHROMYCIN ETHYL SUCCINATE</u> AB/NASKA/ 224	SUSPENSION; ORAL <u>ERYTHROMYCIN ETHYL SUCCINATE</u> AB/NASKA/ 224	SUSPENSION; ORAL <u>ERYTHROMYCIN ETHYL SUCCINATE</u> AB/NASKA/ 224
/ <u>N50532/001/</u> MAR 10, 1987	/ <u>N50532/001/</u> MAR 10, 1987	/ <u>N50532/001/</u> MAR 10, 1987

a ZENITH

SUSPENSION; ORAL <u>ERYTHROMYCIN ETHYL SUCCINATE</u> AB/NASKA/ 224	SUSPENSION; ORAL <u>ERYTHROMYCIN ETHYL SUCCINATE</u> AB/NASKA/ 224	SUSPENSION; ORAL <u>ERYTHROMYCIN ETHYL SUCCINATE</u> AB/NASKA/ 224
/ <u>N50532/001/</u> MAR 10, 1987	/ <u>N50532/001/</u> MAR 10, 1987	/ <u>N50532/001/</u> MAR 10, 1987

0.625MG
 1.25MG
 2.5MG

NOV 29, 1984
 N83373 001
 N83601 001
 N83602 001

ESTROGENS, CONJUGATED; MEPROBAMATE

TABLET; ORAL
**/BS/ /MILPREN-200/
 a WALLACE**
**/BS/ /MILPREN-200/
 a WALLACE**
PMB 200
**/BS/ /WYETH/Ayerst/
 WYETH AYERST**
PMB 400
**/BS/ /WYETH/Ayerst/
 WYETH AYERST**

/6.45MG; 2.60MG;
 0.45MG; 200MG
 /6.45MG; 4.60MG;
 0.45MG; 400MG
 /6.45MG; 2.60MG;
 0.45MG; 200MG
 /6.45MG; 4.60MG;
 0.45MG; 400MG

ESTROGENS, ESTERIFIED

TABLET; ORAL
**/BS/ /ANNESTROGEN/
 SQUIBB**
/BS/ /SQUIBB/
a SQUIBB
**a ESTERIFIED/ESTROFENS/
 PRIVATE FORM/**
**/BS/ /EVEK/
 PRIVATE FORM/**
**/BS/ /SYNTEX/
 a SYNTEX**
**/BS/ /FEMDODEN/
 PRIVATE FORM/
 a PRIVATE FORM**

/1.625MG/
 1.25MG/
 2.5MG
 /1.625MG/
 1.25MG/
 2.5MG
 /1.625MG/
 2.5MG
 /1.625MG/
 0.625MG
 1.25MG
 2.5MG
 /1.625MG/
 0.625MG

CAPSULE; ORAL
LODINE
WYETH AYERST
N18922 002
JAN 31, 1991
N18922 003
JAN 31, 1991

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
**/Norethindrone AND Ethynodiol-
 Watson/**
/AB/ /Watson/
**NORETHINDRONE AND ETHYNODIOL ESTRADIOL (10/11)
 0.035MG; 0.5MG AND 1MG**
Watson
**NORETHINDRONE AND ETHYNODIOL ESTRADIOL (7/14)
 0.035MG; 0.5MG AND 1MG**
Watson
N71041 001
SEP 24, 1991

TABLET; ORAL-28
**/Norethindrone AND Ethynodiol-
 Watson/**
/AB/ /Watson/
**NORETHINDRONE AND ETHYNODIOL ESTRADIOL (10/11)
 0.035MG; 0.5MG AND 1MG**
Watson
N71044 001
APR 01, 1990

TABLET; ORAL-28
**/Norethindrone AND Ethynodiol-
 Watson/**
/AB/ /Watson/
**NORETHINDRONE AND ETHYNODIOL ESTRADIOL (7/14)
 0.035MG; 0.5MG AND 1MG**
Watson
N71044 001
APR 01, 1990

TABLET; ORAL-28
**/Norethindrone AND Ethynodiol-
 Watson/**
/AB/ /Watson/
**NORETHINDRONE AND ETHYNODIOL ESTRADIOL (10/11)
 0.035MG; 0.5MG AND 1MG**
Watson
N71044 001
APR 01, 1990

TABLET; ORAL-28
**/Norethindrone AND Ethynodiol-
 Watson/**
/AB/ /Watson/
**NORETHINDRONE AND ETHYNODIOL ESTRADIOL (7/14)
 0.035MG; 0.5MG AND 1MG**
Watson
N71042 001
SEP 24, 1991

TABLET; ORAL-28
**/Norlestren/
 Parke Davis/**
/AB/ /Parke Davis/
ETHYNODIOL ESTRADIOL; NORETHINDRONE ACETATE
Watson
N16723 001
JAN 31, 1991

TABLET; ORAL-28
NORLESTRIN 28 1/50
3 PARKE DAVIS
0.05MG; 1MG
N16723 001
JAN 31, 1991

TABLET; ORAL-28
EUDODOLAC
CAPSULE; ORAL
LODINE
WYETH AYERST
200MG
300MG
N18922 002
JAN 31, 1991
N18922 003
JAN 31, 1991

TABLET; ORAL
OGEN
ABBOTT
ORTHO-EST
JOHNSON & W
AB
N83220 001
N83220 002
N89567 001
FEB 27, 1991
N89582 001
JUL 17, 1991

FELODIPINE

TABLET, EXTENDED RELEASE; ORAL
PLENDIL
 MSD
 5MG
 10MG

FENPROFEN CALCIUM
 CAPSULE; ORAL
 DANBURY

FENPROFEN CALCIUM
 TABLET; ORAL
 PHARM/BASICS/

FENPROFEN CALCIUM
 TABLET; ORAL
 PHARM/BASICS/
 PHARM/BASICS/

FENTANYL CITRATE
 STERLING
 AP

FIBRINOGEN, I-125
 INJECTABLE; INJECTION
 AMERSHAM/
 a AMERSHAM

FLOXURIDINE
 INJECTABLE; INJECTION
 FUDR/

FLOXURIDINEFLUDARABINE PHOSPHATE

> DLT >	/FLUDARABINE/	N71055 001
> ADD >	a QUAD	AUG 24, 1987
> ADD >	FUDR	/N16929/001/
> DLT > / <u>AB</u> /	/FLUDARABINE/	N16929 001
> ADD >	/FLUDARABINE/	

FLUDARABINE PHOSPHATE

> DLT >	/FLUDARABINE/	N20038 001
> ADD >	BERLEX	APR 18, 1991
> ADD >		

FLUOCINOLONE ACETONIDE

> DLT > / <u>AB</u> /	CREAM; TOPICAL	/N16935/001/
> ADD > / <u>AB</u> /	/FLUDARABINE/	/JAN/16/1984/
> ADD > / <u>AB</u> /		

> DLT > / <u>AB</u> /	FLUOCINOLONE ACETONIDE	N88361 001
> ADD > / <u>AB</u> /	NRG	JUN 16, 1984
> ADD > / <u>AB</u> /		

FLUOCINONIDE

> DLT > / <u>AB</u> /	CREAM; TOPICAL	/N16917/001/
> ADD > / <u>AB</u> /	FLUOCINONIDE	JUN 26, 1984
> ADD > / <u>AB</u> /	TARO	N72494 001
> ADD > / <u>AB</u> /		JAN 19, 1989

> DLT > / <u>AB</u> /	/Vasoderm/	/N16917/001/
> ADD > / <u>AB</u> /	/TARO/	/JUN/26/1984/
> ADD > / <u>AB</u> /		

> DLT > / <u>AB</u> /	/Vasoderm/	/N16944/001/
> ADD > / <u>AB</u> /	/TICAN/	/JAN/16/1984/
> ADD > / <u>AB</u> /		

> DLT > / <u>AB</u> /		/N16955/001/
> ADD > / <u>AB</u> /		/AUG/24/1987/
> ADD > / <u>AB</u> /		

FLUOURACILINJECTABLE; INJECTION

ADRUCIL
AP ADRIA
50MG/ML

50MG/ML
AP
AP
50MG/ML

FLUOURACIL

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

FLUPHENAZINE DECANOATE

INJECTABLE; INJECTION
FLUPHENAZINE
HCL
/QUAD/

N60023 001
OCT 18, 1991
N81222 001
JUN 28, 1991
N81225 001
AUG 28, 1991

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

50MG/ML
/QUAD/

N73058 001
AUG 30, 1991

FLUPHENAZINE HYDROCHLORIDE

CONCENTRATE; ORAL
FLUPHENAZINE HCL

AA COPLEY
5MG/ML

N60368 001
FEB 03, 1987
N89455 001
FEB 03, 1987
N87766 001
/DEC/28, 1984/
N88766 001
DEC 28, 1984

INJECTABLE; INJECTION
FLUPHENAZINE HCL
/QUAD/

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

FLUPHENAZINE HCL

/QUAD/

N20101 001
APR 24, 1991

TABLET; ORAL
FLUPHENAZINE HCL
/QUAD/

N88555 001
DEC 18, 1987

FLUOXETINE HYDROCHLORIDE

SOLUTION; ORAL
PROZAC
LILLY

EQ 20MG BASE/5ML

N20101 001
APR 24, 1991

/QUAD/

N88555 001
DEC 18, 1987

N88544 001
DEC 18, 1987

N88527 001
DEC 18, 1987

N88550 001
DEC 18, 1987

N88260 001
DEC 06, 1983
N88265 001
DEC 06, 1983
N88309 001
DEC 06, 1983

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL

AB GENEVA
15MG
30MG

N71716 001
JUL 31, 1991

N71717 001
JUL 31, 1991

FLURAZEPAZ HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAZ HCL
/PHARM/BASICS/
/AA/

15MG/
/30MG/

B* PHARM BASICS
 15MG
 30MG

/N70552/661/
 /JUL/09/1987/
 /JUL/09/1987/
 N70562 001

INJECTABLE; INJECTION
GANTITE
FUJISAWA
 25MG/ML

N19961 002
 JAN 17, 1991

GENTAMICIN SULFATE

INJECTABLE; INJECTION
GENTAMICIN SULFATE
GENSIA
 JUL 09, 1987
 N70563 001
 JUL 09, 1987
 > ADD > AP
 > ADD > AP
 > ADD > AP
 > ADD >

N63149 001
 NOV 21, 1991

N63106 002
 NOV 21, 1991

SOLUTION/DROPS; OPHTHALMIC

GENTAMICIN SULFATE
GENSIA
 /AA/3MG BASE/ML/
 /AA/3MG BASE/ML/
 EQ 3MG BASE/ML

N62932 001
 NOV 07, 1988

SENITAN VIOLET
/TAMPON; VAGINAL/
/SENAPAX/
/KEY/PHARMS/
③ KEY PHARMS

N65617 001
 NOV 07, 1988

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE
/SOLOPAK/
/AA/

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

/N70655/661/
 /FEB/05/1987/
 N70023 001
 FEB 05, 1986
 N72080 001
 AUG 13, 1991
 > DLT > AP
 > ADD >
 > DLT > AP
 > DLT >
 > ADD >
 > ADD >

N71023 001
 MAR 04, 1987

GLUCAGON HYDROCHLORIDE
GLUCAGON
LILLY
LILLY
EQ 10MG BASE/VIAL
/AA/
③ QUAD
 EQ 10MG BASE/VIAL

N12122 002
 /N71023/661/
 /MAR/04/1987/
 N71023 001
 MAR 04, 1987

GLUTETHIMIDE
GLUTETHIMIDE
PHARM BASICS
/AA/

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

N70655 001
 OCT 02, 1987

TABLET; ORAL
/BORTDEN/
/RHONE/POULENC RORER//
/AA/
③ RHONE POULENC RORER
250MG
500MG

/N63149/661/
 /N63149/661/
 NO9519 002
 NO9519 005

GLUTETHIMIDE

TABLET; ORAL <u>GLUTETHIMIDE</u> /AB/ /CHELSEA/ ② CHELSEA	
/500MG/ 500MG	N85763 001
INJECTABLE; INJECTION <u>GLYCOPYRROLATE</u> GENSIA	
AP /AB/ /QUAD/ ② QUAD	
0.2MG/ML /0.2MG/ML	
	N81169 001
	SEP 10, 1991
	/N89397/001/ /PEC/69/1986/ N89397 001
	DEC 09, 1986
TABLET; ORAL <u>GLYCOPYRROLATE</u> /BOLAR/ ② BOLAR	
	/1MG/ 1MG
	N85562 001
INJECTABLE; INJECTION <u>GONADOTROPIN, CHORIONIC</u>	
AP /AB/ /QUAD/ ② QUAD	
/5,000 UNITS/VIAL/ /5,000 UNITS/VIAL	
	/N89312/001/ /PEC/d4/1986/ /N89313/001/ /PEC/d4/1986
	/10,000 UNITS/VIAL/ /10,000 UNITS/VIAL
	/N89314/001/ /PEC/d4/1986/ /N89315/001/ /PEC/d4/1986
	/25,000 UNITS/VIAL/ /25,000 UNITS/VIAL
	/N89316/001/ /PEC/d4/1986/ N89312 001
	5,000 UNITS/VIAL
	5,000 UNITS/VIAL
	10,000 UNITS/VIAL
	10,000 UNITS/VIAL
	20,000 UNITS/VIAL

GUANETHIDINE MONOSULFATE

TABLET; ORAL <u>GUANETHIDINE MONOSULFATE</u> /BOLAR/ ② BOLAR	
/AB/ /BOLAR/ ② BOLAR	
	/EG '25MG SULFATE/ EQ 10MG SULFATE
	EQ 25MG SULFATE
INJECTABLE; INJECTION <u>GLYCOPYRROLATE</u> GENSIA	
AP /AB/ /QUAD/ ② QUAD	
0.2MG/ML /0.2MG/ML	
	N81169 001
	SEP 10, 1991
	/N89397/001/ /PEC/69/1986/ N89397 001
	DEC 09, 1986
TABLET; ORAL <u>GLYCOPYRROLATE</u> /BOLAR/ ② BOLAR	
	/1MG/ 1MG
	N85562 001
INJECTABLE; INJECTION <u>GONADOTROPIN, CHORIONIC</u>	
AP /AB/ /QUAD/ ② QUAD	
/5,000 UNITS/VIAL/ /5,000 UNITS/VIAL	
	/N89312/001/ /PEC/d4/1986/ /N89313/001/ /PEC/d4/1986
	/10,000 UNITS/VIAL/ /10,000 UNITS/VIAL
	/N89314/001/ /PEC/d4/1986/ /N89315/001/ /PEC/d4/1986
	/25,000 UNITS/VIAL/ /25,000 UNITS/VIAL
	/N89316/001/ /PEC/d4/1986/ N89312 001
	5,000 UNITS/VIAL
	5,000 UNITS/VIAL
	10,000 UNITS/VIAL
	10,000 UNITS/VIAL
	20,000 UNITS/VIAL
TABLET; ORAL <u>HALOBETASOL PROPIONATE</u> CIBA	
CREAM; TOPICAL ULTRAVATE /BETASOL/NEUTRAL/SQUIBB/	
WESTWOOD SQUIBB	0.05%
OINTMENT; TOPICAL ULTRAVATE /BETASOL/NEUTRAL/SQUIBB/6.65%/ /PEC/d4/1986/	
WESTWOOD SQUIBB	0.05%
DEC 27, 1990	

HALO PERIOD

TABLET; ORAL
HALOPERIDOL

<u>EQ. 5MG BASE/ML</u>	<u>EQ. 5MG BASE/ML</u>	<u>EQ. 5MG BASE/ML</u>	<u>EQ. 5MG BASE/ML</u>
/N/1571/ 061/	AP	STERIS	N70713 001
/JUN/05/ 1988/			MAY 17, 1988
/N/1571/ 061/	AP		N70714 001
/JUN/03/ 1988/			MAY 17, 1988
/N/1571/ 061/	AP		N70744 001
/JUN/03/ 1988/			MAY 17, 1988

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

<u>HALOPERTIOL</u>	<u>AP</u>	<u>Eq 5MG BASE/ML</u>	<u>N70713 001</u>
STERIS			MAY 17, 1988
	<u>AP</u>	<u>Eq 5MG BASE/ML</u>	<u>N70714 001</u>
			MAY 17, 1988
	<u>AP</u>	<u>Eq 5MG BASE/ML</u>	<u>N70744 001</u>
			MAY 17, 1988

INJECTABLES: INJECTION

/JUN/03, 1988/ N71571 001	0.5MG HEPARIN LOCK FLUSH /AP/	10 UNITS/ML /INTL/HEMIDATION ③ INTL MEDICATION	N86357 001
JUN 03, 1988 N71572 001	1MG /AP/	500 UNITS/ML /INTL/HEMIDATION ③ INTL MEDICATION	N86357 002
JUN 03, 1988 N71573 001	2MG /AP/	100 UNITS/ML /INTL/HEMIDATION ③ INTL MEDICATION	N86357 003
JUN 03, 1988 N71574 001	5MG /AP/	100 UNITS/ML /INTL/HEMIDATION ③ SOLOPAK	N87959 001

INJECTABLES: INJECTION

/	JUN 03, 1988	HEPARIN LOCK FLUSH	/16 UNITS/Hr/	/N86357/6611/
	N71571 001	/INTL/MEDICATION	/10 UNITS/ML	N86357 001
	JUN 03, 1988	a INTL MEDICATION	/500 UNITS/Hr/	/N86357/6611/
	N71572 001		/500 UNITS/ML	N86357 002
	JUN 03, 1988		/500 UNITS/ML	/N86357/6611/
	N71573 001		/160 UNITS/ML	/APR 20, 1983/
	JUN 03, 1988			N87959 001
	N71374 001	a SOLOPAK	100 UNITS/ML	APR 20, 1983
	JUN 03, 1988			/N86357/6611/
	N71375 001			/N86357/6611/
	JUN 03, 1988			/N86357/6611/
		HEPARIN SODIUM	/1000 UNITS/ML	/N86357/6611/
		/INTL/MEDICATION	/1000 UNITS/ML	/N86357/6611/
				/N86357/6611/

HALOPERIDOL LACTATE

**INJECTABLE; INJECTION
HALOPIPERIDOL**

EQ 5MG BASE/ML	/N70671/3/001	/1985/17/001	APR 20, 1984
EQ 5MG BASE/ML	/MAY/1/1/1985/	/1985/17/001	N88517 001
EQ 5MG BASE/ML	/N70671/4/001	/1985/17/001	AUG 22, 1985
EQ 5MG BASE/ML	/MAY/1/1/1985/	/1985/17/001	N88518 001
EQ 5MG BASE/ML	/N70671/5/001	/1985/17/001	APR 20, 1984
HYDRALAZINE HYDROCHLORIDE			
		INJECTABLE; INJECTION	
		HYDRALAZINE HCL	
		/SOLOPAK/	
		/20MG/ML/	
EQ 5MG BASE/ML	/N70674/1/001	/1985/17/001	
EQ 5MG BASE/ML	/MAY/1/1/1985/	/1985/17/001	
EQ 5MG BASE/ML	/N70682/1/001	/1985/17/001	
EQ 5MG BASE/ML	/JAN/62/1987/	/1985/17/001	
EQ 5MG BASE/ML	N71082 001	JAN 02, 1987	
EQ 5MG BASE/ML		/1985/17/001	
EQ 5MG BASE/ML	/DEC/14/1987/	/1985/17/001	
EQ 5MG BASE/ML	N70802 001	DEC 16, 1987	
		③ SOLOPAK	
		③	
		20MG/ML	
		20MG/ML	

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HYDRALAZINE HYDROCHLORIDETABLET; ORAL
HYDRALAZINE HCL

/ AA/ /CHELSEA/	/ AA/	
/ AA/	/ AA/	
② CHELSEA	/ AA/	25MG
②		50MG
		50MG
		100MG

HYDRALAZINE HYDROCHLORIDE; HYDROCHLORTIAZIDECAPSULE; ORAL
HYDRALAZINE HCL AND HYDROCHLORTIAZIDE

/ AA/ /BOLAR/	/ AA/	/ AA/	
/ AA/	/ AA/	/ AA/	
② BOLAR	/ AA/	25MG; 25MG	
②		50MG; 50MG	
②		100MG; 50MG	

CAPSULE; ORAL
APRESOLINE-ESTOREX

/ AA/ CIBA	/ AA/	
/ AA/	/ AA/	
② BOLAR	/ AA/	
② BOLAR		

HYDRALAZINE HYDROCHLORIDE; HYDROCHLORTIAZIDE; RESERPINE

/ AA/ /HED/	/ AA/	/ AA/	
/ AA/	/ AA/	/ AA/	
② BOLAR	/ AA/	25MG; 15MG	
② BOLAR		25MG; 15MG	
② BOLAR		25MG; 15MG	

HYDROCHLORTIAZIDE; RESERPINE

/ AA/ /HED/	/ AA/	/ AA/	
/ AA/	/ AA/	/ AA/	
② BOLAR	/ AA/	25MG; 15MG	
②		50MG; 50MG	

TABLET; ORAL
HYDROCHLORTIAZIDE W/ RESERPINE

/ AA/ /HED/	/ AA/	
/ AA/	/ AA/	
② BOLAR	/ AA/	
② BOLAR		

/ AA/ /HED/	/ AA/	/ AA/	
/ AA/	/ AA/	/ AA/	
② BOLAR	/ AA/	25MG; 15MG	
②		50MG; 50MG	

TABLET; ORAL
HYDROCHLORTIAZIDE W/ RESERPINE

/ AA/ /HED/	/ AA/	
/ AA/	/ AA/	
② BOLAR	/ AA/	
② BOLAR		

/ AA/ /HED/	/ AA/	
/ AA/	/ AA/	
② CORD	/ AA/	50MG; 0.125MG
② CORD		

JAN 31, 1984

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE
/S/ SUPERPHARM/ /25mg; 25mg/
 a SUPERPHARM
 25MG; 25MG

SPIRONOLACTONE w/ HYDROCHLOROTHIAZIDE
/25mg; 25mg/
 a BOLAR
 25MG; 25MG

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL
DAZIDE
 AB SKF 25mg; 50mg
TRIAMTERENE AND HYDROCHLOROTHIAZIDE
 25MG; 50MG

AB GENEVA 50mg; 75mg
 /BX/ 50mg; 50mg/

TABLET; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE
 PAR 50mg; 75mg

/BX/ 50mg; 50mg/

HYDROCORTISONE

CREAM; TOPICAL
ANUSOL HC
 AT PARKE DAVIS 2.5%w/w

/AT/ /H/ PHARMS ASSOC/ /0.5%/
 a PHARMS ASSOC 0.5%

/AT/ /HC 41/ /0.5%/
 a MILES 0.5%

/AT/ /HC 41/ /1%/
 a MILES 1%

AT BAUSCH AND LOMB 1%

AT /NASKA/ 1/2%
 a NASKA

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE
 /At/ /PHARMFAIR/

AUG 26, 1985
 N89137 001

/N85974/661/
 N85974 001

/At/ /PENECORT/

/At/ /PARKE/PAVIS/ 1/2%/

/At/ /SYACORT/
 a SYNTEX 0.5%/

LOTION; TOPICAL
Hydrocortisone
 /At/ /NASKA/ 1/2%

a NASKA 1/2%

/Lotion; topical/
 /At/ /TEMACORT/

/At/ /COOPCARE/ 1/2%

/At/ /OINTMENT; TOPICAL
Hydrocortisone 1/2%

a NASKA 1/2%

SOLUTION; TOPICAL
PENECAORT
 At HERBERT 1/2%

At GENDERM 1/2%

TABLET; ORAL
Hydrocortisone
 /Bp/ /PUREPAC/ 1/2mg/

/N8595/661/
 N80395 001

N88250 001
 JUN 06, 1984

N88214 001
 JUN 06, 1984

N80425 001
 MAR 10, 1988

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE
 /At/ /PARKE/PAVIS/

/N8595/661/
 N8595 002

/N86823/001/
 N86823 001

/N86438/661/
 N86438 001

/N86438/661/
 N86438 002

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATEHYDROCORTISONE BUTYRATE

SOLUTION/DROPS; OTIC
OTOCORT
AT STERIS 1/2;EQ 3.5MG BASE/ML;
10,000 UNITS/ML N60730 002

SUSPENSION; OTIC
OTOCORT
/LÉM/
/At/ 1/2;EQ 3.5MG BASE/ML;
10,000 UNITS/ML N60730 002

AT STERIS 1/2;EQ 3.5MG BASE/ML;
10,000 UNITS/ML N62521 001
JUL 11, 1985

HYDROCORTISONE ACETATE

CREAM; TOPICAL
HYDROCORTISONE ACETATE
CENCI 1/2
At/ /LéM/ /At/
INJECTABLE; INJECTION
HYDROCORTISONE ACETATE
/Bp/ /LéM/
Bp STERIS /Bp/ 1/2;
25MG/ML
50MG/ML N83759 001
N83759 002

INJECTABLE; INJECTION
HYDROCORTISONE ACETATE
/Bp/ /LéM/
Bp /Bp/ 1/2;
25MG/ML
50MG/ML N83759 002

HYDROCORTISONE BUTYRATE

CREAM; TOPICAL
HYDROCORTISONE BUTYRATE
/Bp/ 1/2;
/LOCOLD/
/OPEN/ /GALDERMA/
/At/ 1/2;
LOCOLD
BROCADES PHARMA 0.1%
OPEN GALDERMA 0.1%
At LYMPHOMED
N18514 001
MAR 31, 1982
N18795 001
JAN 07, 1983
EQ 100MG BASE/VIAL
EQ 100MG BASE/VIAL
EQ 250MG BASE/VIAL
EQ 500MG BASE/VIAL
EQ 1GM BASE/VIAL
N88667 001
JUN 08, 1984
N88712 001
JUN 08, 1984
N88668 001
JUN 08, 1984
N88669 001
JUN 08, 1984
N88670 001
JUN 08, 1984

HYDROFLUMETHIAZIDE; RESERPINE

TABLET; ORAL
HYDROFLUMETHIAZIDE AND RESERPINE

B* PHARM BASICS 50MG;0.125MG

/BP/ /50MGS;0.125MG/

/BP/ /Hydroflumethiazide/W/Reserpine/

/25MGS;0.125MG/

/50MGS;0.125MG/

2.5MG;0.125MG

50MG;0.125MG

25MGS;0.125MG

50MG;0.125MG

HYDROXYZINE HYDROCHLORIDE

TABLET; INJECTION
HYDROXYZINE HCL

/AP/ /LEMON/

STERIS AP

/AP/ /AP/

HYDROXYZINE HCL

TABLET; ORAL
HYDROXYZINE HCL

/AP/ /BARR/

HYDROXYZINE HCL

HYDROXYCOBALAMIN

INJECTABLE; INJECTION
HYDROXYCOBALAMIN

/AP/ /LEMON/

STERIS

/AP/ /AP/

HYDROXYCOBALAMIN

/AP/ /AP/

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION
DURALEUTIN

/AD/ /STERI3/

/250MGS/ML

HYDROXYPROGESTERONE CAPROATE

/250MGS/ML

/250MGS/ML

12.5MG/ML

250MG/ML

HYDROXYZINE PAMOATE

CAPSULE; ORAL
HYDROXYZINE PAMOATE

/AP/ /BOLAR/

3 BOLAR

HYDROXYZINE HCL

EQ 25MG HCL

/EQ 25MG HCL/

EQ 50MG HCL

/EQ 100MG HCL

EQ 25MG HCL

/EQ 50MG HCL

EQ 100MG HCL

/EQ 25MG HCL

EQ 50MG HCL

/EQ 100MG HCL

EQ 25MG HCL

/EQ 50MG HCL

EQ 100MG HCL

/EQ 25MG HCL

EQ 50MG HCL

/EQ 100MG HCL

EQ 25MG HCL

/EQ 50MG HCL

EQ 100MG HCL

/EQ 25MG HCL

EQ 50MG HCL

/EQ 100MG HCL

EQ 25MG HCL

/EQ 50MG HCL

EQ 100MG HCL

/EQ 25MG HCL

EQ 50MG HCL

EQ 100MG HCL

EQ 25MG HCL

JUL 31, 1991

HYDROXYZINE PAMOATECAPSULE; ORAL
HYDROXYZINE PAMOATE

AB GENEVA EQ 25MG HCL
AB /AB/ EQ 50MG HCL
AB EQ 100MG HCL

/AB/ /SUPERPHARM/
AB /EQ 25MG HCL/
AB /EQ 50MG HCL/
AB /EQ 100MG HCL/
AB SUPERPHARM
AB /VANGARD/

EQ 25MG HCL
AB /VANGARD/
AB VANGARD
AB /IBUPROFEN/

100MG/5ML
AB RUFEN BX
AB /IBUPROFEN/

SUSPENSION; ORAL
AB ROXANE/

TABLET; ORAL
AB /IBUPROFEN/

/IBUPROFEN/
AB CHELSEA

400MG
AB /IBUPROFEN/

600MG
AB /IBUPROFEN/

800MG
AB /IBUPROFEN/

1000MG
AB /IBUPROFEN/

1200MG
AB /IBUPROFEN/

1400MG
AB /IBUPROFEN/

1600MG
AB /IBUPROFEN/

IMIPRAMINE HYDROCHLORIDETABLET; ORAL
IMIPRAMINE HCL

/AB/ /BOLAR/
AB /AB/ N81127 001
AB /AB/ JUN 28, 1991

EQ 50MG HCL
AB /AB/ N81128 001
AB /AB/ JUN 28, 1991

EQ 100MG HCL
AB /AB/ N81129 001
AB /AB/ JUN 28, 1991

/EQ 25MG HCL/
AB /AB/ N81131 001
AB /AB/ JUN 02, 1987

/EQ 50MG HCL/
AB /AB/ N81132 001
AB /AB/ JUN 02, 1987

/EQ 100MG HCL/
AB /AB/ N81133 001
AB /AB/ JUN 02, 1987

EQ 25MG HCL
AB /AB/ N81134 001
AB /AB/ JAN 02, 1987

EQ 50MG HCL
AB /AB/ N81135 001
AB /AB/ JAN 02, 1987

EQ 100MG HCL
AB /AB/ N81136 001
AB /AB/ JAN 02, 1987

/EQ 100MG HCL/
AB /AB/ N81137 001
AB /AB/ SEP 19, 1983

/EQ 100MG HCL/
AB /AB/ N81138 001
AB /AB/ SEP 19, 1983

EQ 100MG HCL/
AB /AB/ N81139 001
AB /AB/ DEC 18, 1989

EQ 100MG HCL/
AB DANBURY AB
AB /AB/ N19784 001
AB /AB/ DEC 18, 1989

EQ 100MG HCL/
AB /AB/ N19785 001
AB /AB/ JUL 31, 1991

EQ 100MG HCL/
AB /AB/ N70784 001
AB /AB/ AUG 20, 1986

EQ 100MG HCL/
AB /AB/ N70785 001
AB /AB/ AUG 20, 1986

EQ 100MG HCL/
AB /AB/ N70786 001
AB /AB/ JUL 31, 1991

EQ 100MG HCL/
AB /AB/ N70787 001
AB /AB/ OCT 10, 1986

EQ 100MG HCL/
AB /AB/ N70488 001
AB /AB/ OCT 10, 1986

KETAMINE HYDROCHLORIDEKETAMINE HCL

> DLT >/AB/ /Eq'10MG'BASE/ML/ /Eq'10MG'BASE/ML/ /Eq'50MG'BASE/ML/ /Eq'100MG'BASE/ML/

> DLT >/AB/ /Eq'10MG'BASE/ML/ /Eq'50MG'BASE/ML/ /Eq'100MG'BASE/ML/

> DLT >/AB/ /Eq'10MG'BASE/ML/ /Eq'50MG'BASE/ML/ /Eq'100MG'BASE/ML/

> DLT >/AB/ /Eq'10MG'BASE/ML/ /Eq'50MG'BASE/ML/ /Eq'100MG'BASE/ML/

> ADD > ② QUAD /Eq 10MG BASE/ML APR 11, 1988 N71950 001

> ADD > ② EQ 50MG BASE/ML APR 11, 1988 N71950 001

> ADD > ② EQ 100MG BASE/ML APR 11, 1988 N71951 001

> ADD > ② EQ 10MG BASE/ML APR 11, 1988 N71951 001

> ADD > ② EQ 50MG BASE/ML APR 11, 1988 N71951 001

> ADD > ② EQ 100MG BASE/ML APR 11, 1988 N71951 001

LEUCOVORIN CALCIUMLEUCOVORIN

> DLT >/AB/ /Eq'10MG'BASE/ML/ /Eq'50MG'BASE/ML/ /Eq'100MG'BASE/ML/

> ADD > ② QUAD /Eq 5MG BASE/ML OCT 05, 1987 N89503 001

> ADD > ② EQ 50MG BASE/ML DEC 22, 1987 N89504 001

> ADD > ② EQ 50MG BASE/ML MAR 05, 1987 N89496 001

> ADD > ② EQ 100MG BASE/ML DEC 24, 1987 N89636 001

> ADD > ② EQ 100MG BASE/ML DEC 24, 1987 N89636 001

LEVONORGESTRELLEVONORGESTREL

IMPLANT; IMPLANTATION /Levonorgestrel/System/ /Norplant/Ayerst/ /36MG/Norplant/ /N36446/dd1/ /DEC/10, 1990/

N20088 001 DEC 10, 1990

NORPLANT SYSTEM
WYETH AYERST 36MG/IMPLANT

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

Lidocaine HCl

/Ab/ /Eq'14MG'dd1/ /Eq'14MG'dd1/ /Eq'14MG'dd1/ /Eq'14MG'dd1/

NS0414 001 NS0414 002 NS0414 002

/Eq'14MG'dd1/ /Eq'14MG'dd1/ /Eq'14MG'dd1/ /Eq'14MG'dd1/

/Eq'14MG'dd1/ /Eq'14MG'dd1/ /Eq'14MG'dd1/ /Eq'14MG'dd1/

NS5131 001 NS4626 001 NS4626 001

ELKINS SINN 0.5% 4Z 4Z

/Eq'14MG'dd1/ /Eq'14MG'dd1/ /Eq'14MG'dd1/ /Eq'14MG'dd1/

N83627 001 N83627 001 N83627 001 N83627 002

SOLUTION; TOPICAL

Lidocaine HCl

/Ab/ /Eq'14MG'dd1/ /Eq'14MG'dd1/ /Eq'14MG'dd1/

② CUTTER 4Z 4Z

LINCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

Lincomycin HCl

/Ab/ /Eq'300MG'dd1/ /Eq'300MG'dd1/

STERIS APR 16, 1991

LIOTHYRONINE SODIUM

TABLET; ORAL

Cytomel

/Ab/ /Eq'0.025MG'dd1/ /Eq'0.025MG'dd1/

BURROUGHS WELLCOME EQ 5MG BASE/ML /Eq'0.025MG'dd1/

OCT 19, 1982 N10379 002

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN' 91 - NOV '91

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LIOTHYRONINE SODIUM

TABLET; ORAL
Liothyronine Sodium
 AB/ /BOLAR/

AB/ BOLAR
 EQ 0.025MG BASE

LITHIUM CARBONATE

CAPSULE; ORAL
Lithium Carbonate
 AB/ /BOLAR/

AB/ BOLAR

AB/ PHARM/BASIS/

B* PHARM BASICS

AB/ PHARM/BASIS/

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL
LoPride
 AB AB JANSSEN

AB/ Loperamide HCl
 Mylan

AB NOVOPHARM

> ADD > AB ROXANE
 > ADD >

LORAZEPAM

CONCENTRATE; ORAL
 LORAZEPAM INTENSOL
 ROXANE

2MG/MLX

N72755 001

JUN 28, 1991

N19643 002

MAR 28, 1991

10MG

N19643 002

MAR 28, 1991

LORAZEPAM

TABLET; ORAL
Lorazepam
 AB/ /ATM/THERA/

AB/ /ATM/

AB/ /ATM/

AB/ /ATM/

AB/ AM THERAP

AB/ AM

AB/ AM

AB/ MUTUAL PHARM

AB/ MUTUAL PHARM

AB/ 2MG

LOVASTATIN

TABLET; ORAL
 Mevacor
 MSD

10MG

MANNITOL

INJECTABLE; INJECTION
Mannitol 10%
 AB/ CUTTER/
 a CUTTER

/10GM/100ML/
 10GM/100ML

/N16472/002/
 N16472 002

METAPROTERENOL SULFATE

SYRUP; ORAL
METAPROTERENOL SULFATE
AA COPLEY 10MG/5ML

TABLET; ORAL
METAPROTERENOL SULFATE
/AB/ /AN/ /THERAP/ /10MG/ /20MG/

③ AM THERAP

B* PHARM BASICS 10MG

B* DANBURY 10MG

B* /PHARM/BASICS/ 10MG

B* /BASIS/ 20MG

B* PHARM BASICS

B* 20MG

B* /BASIS/ 10MG

B* /BASIS/ 20MG

B* METARAMINOL BITARTRATE

INJECTABLE; INJECTION
METARAMINOL BITARTRATE
/AB/ /BASIS/ /LYPHOMED/ /EQ 10MG BASE/ML
/N80431 001

METHADONE HYDROCHLORIDE

TABLET; EFFERVESCENT; ORAL
METHADONE
/VITARINE/ /5MG/ /10MG/ /15MG/

③ VITARINE

③ 2.5MG

5MG

10MG

40MG

METHANTHELINE BROMIDE

TABLET; ORAL
BANTHENE
AA /AA/ /SEARLE/ /50MG/

N07390 001
/N67596/661/METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL
/AA/ /BOJAR/

/500MG/
/250MG/

③

BOLAR

③

METHOTREXATE SODIUM

INJECTABLE; INJECTION
FOLEX PFS
AP ADRIA

N01242 001
AUG 23, 1991/N11719/664/
N11719 004/N11719/664/
N11719 004/N11719/664/
N11719 004/N11719/664/
N11719 004

/N11719/664/
N11719 004
/N11719/664/
N11719 004
/N11719/664/
N11719 004

③ LYPHOMED

③ EQ 2.5MG BASE/ML

③ EQ 2.5MG BASE/ML

③ EQ 2.5MG BASE/ML

N89322 001

N89323 001

JUN 13, 1986

N89322 001

JUN 13, 1986

METHOTREXATE SODIUMINJECTABLE; INJECTIONMETHOTREXATE SODIUM

/EQ 25MG BASE/ML/ /ADD/	/N89368/001/ /JUL/10/1986/ /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
/EQ 25MG BASE/ML/ /ADD/	/N89368/001/ /JUL/10/1986/ /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
/EQ 25MG BASE/VTAL/ /ADD/	/N89293/001/ /JUL/10/1986/ /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
/EQ 25MG BASE/VTAL/ /ADD/	/N89294/001/ /JUL/10/1986/ /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
/EQ 100MG BASE/VTAL/ /ADD/	/N89495/001/ /JUL/10/1986/ /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
/EQ 250MG BASE/VTAL/ /ADD/	/N89308/001/ /JUL/10/1986/ /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
EQ 25MG BASE/ML /ADD/	EQ 25MG BASE/ML /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
EQ 20MG BASE/VIAL /ADD/	EQ 20MG BASE/VIAL /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
EQ 50MG BASE/VIAL /ADD/	EQ 50MG BASE/VIAL /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
EQ 100MG BASE/VIAL /ADD/	EQ 100MG BASE/VIAL /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
EQ 250MG BASE/VIAL /ADD/	EQ 250MG BASE/VIAL /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
> ADD > > ADD >	JUL 10, 1986 N89309 001 JUL 10, 1986 N89293 001 JUL 10, 1986 N89294 001 JUL 10, 1986 N89295 001 JUL 10, 1986 N89296 001 JUL 10, 1986		

METHYLDOPATABLET; ORAL

/ADD/	/N89368/001/ /JUL/10/1986/ /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
/ADD/	/N89368/001/ /JUL/10/1986/ /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
/ADD/	/N89293/001/ /JUL/10/1986/ /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
/ADD/	/N89495/001/ /JUL/10/1986/ /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
/ADD/	/N89308/001/ /JUL/10/1986/ /ADD/	/ADD/ /METHYLDOPA /BOLAR/	/145MG/ /145MG/
FEB 25, 1986 N70246 001	FEB 25, 1986 N70247 001		
250MG 500MG	250MG 500MG		

METHYLDOPATE HYDROCHLORIDEINJECTABLE; INJECTIONMETHYLDOPATE HCl

N70192 001	APR 25, 1986 N70193 001	50MG/ML
N70192 001	APR 25, 1986 N70193 001	50MG/ML
N70192 001	APR 25, 1986 N70194 001	50MG/ML
N70192 001	APR 25, 1986 N70194 001	50MG/ML
N70192 001	APR 25, 1986 N70194 001	50MG/ML

METHYLPREDNISOLONE ACETATEINJECTABLE; INJECTION

N87248 001	/N87248/001/ /JUL/10/1986/ /ADD/	/200MG/ML/ /200MG/ML/
N85374 001	/N85374/001/ /JUL/10/1986/ /ADD/	/400MG/ML/ /400MG/ML/
N85377 001	/N85377/001/ /JUL/10/1986/ /ADD/	/300MG/ML/ /300MG/ML/
N87248 001	N87248 001	200MG/ML
N85374 001	N85374 001	400MG/ML
N86507 001	N86507 001	800MG/ML

METHYLCLOTHIAZIDETABLET; ORALMETHYLCLOTHIAZIDE

/ADD/	/N85487/001/ /MAR/11/1982/ /ADD/	/ADD/ /METHYLCLOTHIAZIDE /BOLAR/	/145MG/ /145MG/
/ADD/	/N85487/001/ /MAR/11/1982/ /ADD/	/ADD/ /METHYLCLOTHIAZIDE /BOLAR/	/145MG/ /145MG/
2.5MG	2.5MG	2.5MG	2.5MG
5MG	5MG	5MG	5MG
/ADD/	/N88745/001/ /MAR/21/1985/ /ADD/	/ADD/ /PHARM/BASIC\$/ /PHARM/BASIC\$/	/145MG/ /145MG/
B* PHARM BASICS	N88745 001		
	MAR 21, 1985		

METHYLprednisolone Sodium SuccinateINJECTABLE; INJECTION
A-METHAPRED

<u>AP</u>	<u>EQ 40MG BASE/VIAL</u>	N89573 001 FEB 22, 1991	/AB/ /AL/ /AS/ /CIBA/ <u>TABLET; Buccal/Sublingual</u> <u>/DETANDREN/</u> <u>/L/CIBA/</u>	/EMGS/ /LDS/ 5MG 10MG
<u>AP</u>	<u>EQ 125MG BASE/VIAL</u>	N89574 001 FEB 22, 1991	/CIBA/ ③ CIBA ③	10MG
<u>AP</u>	<u>EQ 500MG BASE/VIAL</u>	N89575 001 FEB 22, 1991	/Bp/ METHYLTESTOSTERONE /PHARM/BASICS/ ③ PHARM BASICS	10MG
<u>AP</u>	<u>EQ 1GM BASE/VIAL</u>	N89576 001 FEB 22, 1991	/Bp/ ③ PHARM BASICS	10MG
<u>METHYLprednisolone Sodium Succinate</u>				
/Ab/	/Lyphomed/	/N88676/001/ /JUN/08/1984/ /AS/	/AB/ /AS/ /CIBA/ <u>TABLET; ORAL</u> <u>/DETANDREN/</u> <u>/L/CIBA/</u>	/EMGS/ /LDS/ 10MG
/Ab/	/Ed '125MG 'BASE/VIAL'	/N88677/001/ /JUN/08/1984/ /AS/	/CIBA/ ③ CIBA ③	25MG
/Ab/	/Ed '500MG 'BASE/VIAL'	/N88678/001/ /JUN/08/1984/ /AS/	/AS/ /CIBA/ <u>METHYPRYLON</u>	10MG
/Ab/	/Ed '1GM 'BASE/VIAL'	/N88679/001/ /JUN/08/1984/ /AS/	/AS/ /CIBA/ <u>TABLET; ORAL</u> <u>NOLUDAR</u>	10MG
/Ab/	/Ed '1GM 'BASE/VIAL'	/N88680/001/ /MAR/29/1985/ /AS/	/AS/ /CIBA/ ③ ROCHE	50MG
<u>A LYPHOMED</u>				
/Ab/	/Ed '125MG BASE/VIAL	N88676 001 JUN 08, 1984		
/Ab/	/Ed 125MG BASE/VIAL	N88677 001 JUN 08, 1984		
<u>LYPHOMED</u>				
/Ab/	/Ed '400MG BASE/VIAL	N88678 001 JUN 08, 1984		
/Ab/	/Ed '500MG BASE/VIAL	N89186 001 MAR 28, 1986		
/Ab/	/Ed 1GM BASE/VIAL	N88679 001 JUN 08, 1984		
<u>EQ 1GM BASE/VIAL</u>				
/Ab/	/Ed '400MG 'BASE/VIAL'	N89188 001 MAR 28, 1986		
/Ab/	/Ed '125MG 'BASE/VIAL'	/N89255/001/ /JAN/22/1986/ /AS/	>ADD > AP >ADD > >DLT > ③ QUAD	GENSIA /ED '10MG BASE/2ML/ Abbott
/Ab/	/Ed '500MG 'BASE/VIAL'	/N89256/001/ /JAN/22/1986/ /AS/	>ADD > >DLT > >ADD > >ADD >	EQ 10MG BASE/2ML
/Ab/	/Ed '1GM 'BASE/VIAL'	/N89257/001/ /JAN/22/1986/ /AS/	>ADD > >DLT > ③ QUAD	EQ 10MG BASE/2ML
/Ab/	/Ed 125MG BASE/VIAL	/N89258/001/ /JAN/22/1986/ /AS/	>ADD >	/ED '10MG 'BASE/2ML/ SOLOPAK
/Ab/	/Ed 125MG BASE/VIAL	N89264 001 JAN 22, 1986		
/Ab/	/Ed 125MG BASE/VIAL	N89265 001 JAN 22, 1986		
<u>SYRUP; ORAL METOCLOPRAMIDE HCL</u>				
/Ab/	/Metoclopramide HCl	N89266 001 JAN 22, 1986	/AL/ ③ PACO	/ED 'EMGS 'BASE/5ML/ EQ 5MG BASE/5ML
/Ab/	/PACO/	JAN 22, 1986		
<u>PACO</u>				
<u>DEC 05, 1988</u>				
<u>N71665 001</u>				
<u>/PACO/</u>				
<u>N71665 001</u>				

METOCLOPRAMIDE HYDROCHLORIDE

SYRUP; ORAL
METOCLOPRAMIDE HCL
AA PHARMS ASSOC

EQ 5MG BASE/5ML

TABLET; ORAL
METOCLOPRAMIDE HCL
/AP/ /PARF/

③ BARR

/EQ 10MG BASE/

EQ 10MG BASE

METOCURINE IODIDE

INJECTABLE; INJECTION
METOCURINE IODIDE
> DLT > /QUAD/ /QUAD/

/2MG/ML/

③ QUAD

INJECTABLE; INJECTION
METOCURINE IODIDE
/LILLY/ LILLY
> DLT > /AP/ /AP/
> ADD > /AP/ /AP/
> ADD > /AP/ /AP/

2MG/ML

/1000U/

N06632 003

METRONIDAZOLE

INJECTABLE; INJECTION
METRONIDAZOLE
/INTL/MEDICATION/ /INTL/MEDICATION/

/500MG/100ML

③ INTL MEDICATION

500MG/100ML
500MG/100ML

AP STERIS

METRONIDAZOLE

TABLET; ORAL
METRONIDAZOLE

EQ 500MG/100ML
N72744 001
MAY 26, 1991

TABLET; ORAL
METRONIDAZOLE
/AP/ /SUPERTHAR/

/1000U/ /1000U/
N70660 001
FEB 10, 1987
/N70363/001/
/HAR/ /1000U/ /1000U/
N70363 001
MAR 02, 1987
/N72639/001/
/HAR/ /1000U/ /1000U/
N72639 001
MAY 09, 1991
/N70598/001/
/HAR/ /1000U/ /1000U/
N70598 001
FEB 02, 1987
/N70664/001/
/HAR/ /1000U/ /1000U/
N70664 001
FEB 10, 1987
/N70664/001/
/HAR/ /1000U/ /1000U/
N70664 001
FEB 10, 1987
/N70664/001/
/HAR/ /1000U/ /1000U/
N70664 001
FEB 10, 1987
/N70664/001/
/HAR/ /1000U/ /1000U/
N70664 001
FEB 10, 1987
/N70664/001/
/HAR/ /1000U/ /1000U/
N70664 001
FEB 10, 1987
/N70664/001/
/HAR/ /1000U/ /1000U/
N70664 001
FEB 10, 1987

TABLET; ORAL
METRONIDAZOLE
/AP/ /SUPERTHAR/

/1000U/ /1000U/
N70008 001
DEC 11, 1984
N70009 001
DEC 11, 1984

TABLET; ORAL
METRONIDAZOLE
/AP/ /SUPERTHAR/

/1000U/ /1000U/
N70008 001
DEC 11, 1984
N70009 001
DEC 11, 1984

INJECTABLE; INJECTION
METRONIDAZOLE
/AP/ /STERIS/ /STERIS/
B* PHARM BASICS

/2.5MG/ 2.5MG
N71537 001
DEC 16, 1988

MINOXIDIL

TABLET; ORAL
MINOXIDIL

/N71537/001/
/HAR/ /1000U/ /1000U/
N71537 001
DEC 31, 1987

TABLET; ORAL
MINOXIDIL

/N71537/001/
/HAR/ /1000U/ /1000U/
N71537 001
DEC 31, 1987

TABLET; ORAL
MINOXIDIL

/N71537/001/
/HAR/ /1000U/ /1000U/
N71537 001
DEC 31, 1987

MORPHINE SULFATE

INJECTABLE; INJECTION

INFUMORPH
ELKINS SINN

10MG/MLX

25MG/MLX

MORPHINE SULFATE

STERIS

0.5MG/MLX

0.5MG/MLX

1MG/MLX

1MG/MLX

TABLET, EXTENDED RELEASE; ORAL
MS CONTIN
PURDUE FREDDICK

30MG

60MG

100MG

100MG

ORAMORPH SR
ROXANE LABS

30MG

60MG

100MG

100MG

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

NALBUPHINE

/QUAD/

10MG/ML

20MG/ML

10MG/ML

20MG/ML

>ADD>
>ADD>
>ADD>

MAR 25, 1986

MAR 25, 1986

MAR 25, 1986

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE
ELKINS SINN

0.4MG/ML

0.4MG/ML

1MG/ML

1MG/ML

LYPHOMED

/QUAD/

NAZCORT

INJECTABLE; INJECTION

NAZCORT

0.4MG/ML

NANDROLONE DECANOATE

INJECTABLE; INJECTION
NANDROLONE DECANOATE

50MG/ML
STERIS

50MG/ML
AO

100MG/ML
AO

NANDROLONE PHENPROPIONATE

INJECTABLE; INJECTION
NANDROLONE PHENPROPIONATE

/25MG/ML/
/QD/

/25MG/ML/
/QD/

/25MG/ML/
/AD/

25MG/ML
/AD/

50MG/ML
/AD/

NICOTINE

> ADD > FILM, EXTENDED RELEASE; TRANSDERMAL
> ADD > NICODERM

N87598 001
OCT 06, 1983

N88554 001
FEB 10, 1986

N87599 001
OCT 06, 1983

N20165 001
NOV 07, 1991

N20165 002
NOV 07, 1991

N20165 003
NOV 07, 1991

N20165 001
NOV 07, 1991

NIFEDIPINE

CAPSULE; ORAL
NIFEDIPTINE
/20MG/

/AB/
CHASE

/10MG/
/AB/
SCHERRER

/10MG/
/AB/
NITROFURAZONE

/AB/
OCT 01, 1986
N89298 001

/AB/
OCT 01, 1986
N89298 001

/AB/
FURACIN
/NORWICH/EATON/
ROBERTS

/AB/
POWDER; TOPICAL
FURACIN
/NORWICH/EATON/
ROBERTS

/AB/
CREAM; TOPICAL
FURACIN
/NORWICH/EATON/
ROBERTS

/AB/
/N83791 001/
N83791 001

/AB/
/N83791 001/
N83791 001

NITROGLYCERIN

INJECTABLE; INJECTION
NITRO-BID
/MARION/MERRELL/

/10MG/ML/
/AB/
MARION MERRELL DOW
10MG/ML

/AB/
/AB/
NITROGLYCERIN
/LyoPhosphep/

/5MG/ML/
/AB/
LYPHOMED
5MG/ML

/AB/
/AB/
HABITROL
CIBA GEIGY

7MG/24HRS
14MG/24HRS
21MG/24HRS

NOV 27, 1991
N20076 002
NOV 27, 1991
N20076 003
NOV 27, 1991

NOV 27, 1991
N20076 001
N20076 002
NOV 27, 1991
N20076 003
NOV 27, 1991

NOV 27, 1991
N71203 001
MAY 08, 1991

NOV 27, 1991
N71203 001
MAY 08, 1991

NOV 27, 1991
N71203 001
MAY 08, 1991

NITROGLYCERININJECTABLE; INJECTION**NITROGLYCERIN**/QUAD//1656/ML//1656/ML/5MG/ML10MG/ML5MG/ML/5010PAK/3 SOLOPAK/NITROGLYCERIN//0.8MG/MLORPHENADRINE CITRATETABLET, EXTENDED RELEASE; ORAL**ORFLEX**/1656//3M//ORPHENADRINE CITRATE//BOLAR/a BOLARN84363/001/JUL 31, 1987N71094 001JUL 31, 1987N71095 001JUL 31, 1987N70634 001JUN 19, 1986/ELKINS/SINN//ED 250MG BASE/VIAL/ED 500MG BASE/VIAL/ED 1GM BASE/VIAL/ED 2GM BASE/VIAL/ED 4GM BASE/VIAL/ED 10GM BASE/VIAL/ED 250MG BASE/VIAL/ED 500MG BASE/VIAL/ED 1GM BASE/VIAL/ED 2GM BASE/VIAL/ED 4GM BASE/VIAL/ED 10GM BASE/VIAL/ED 250MG BASE/VIAL/ED 500MG BASE/VIAL/ED 1GM BASE/VIAL/ED 2GM BASE/VIAL/ED 4GM BASE/VIAL/ED 10GM BASE/VIALOXACILLIN SODIUMINJECTABLE; INJECTION**Oxacillin Sodium**/ELKINS/SINN//ED 250MG BASE/VIAL/ED 500MG BASE/VIAL/ED 1GM BASE/VIAL/ED 2GM BASE/VIAL/ED 4GM BASE/VIAL/ED 10GM BASE/VIAL/ED 250MG BASE/VIAL/ED 500MG BASE/VIAL/ED 1GM BASE/VIAL/ED 2GM BASE/VIAL/ED 4GM BASE/VIAL/ED 10GM BASE/VIAL/ED 250MG BASE/VIAL/ED 500MG BASE/VIAL/ED 1GM BASE/VIAL/ED 2GM BASE/VIAL/ED 4GM BASE/VIAL/ED 10GM BASE/VIAL/ED 250MG BASE/VIAL/ED 500MG BASE/VIAL/ED 1GM BASE/VIAL/ED 2GM BASE/VIAL/ED 4GM BASE/VIAL/ED 10GM BASE/VIAL/ED 250MG BASE/VIAL/ED 500MG BASE/VIAL/ED 1GM BASE/VIAL/ED 2GM BASE/VIAL/ED 4GM BASE/VIAL/ED 10GM BASE/VIALOXANDROLONETABLET; ORAL**Anavar**/SEARLE/2.5MGN3718 001JAN 04, 1991N20007 001JUN 17, 1991N19757 001FEB 03, 1989N62711 002FEB 03, 1989N62711 003FEB 03, 1989N62711 004FEB 03, 1989N62711 005FEB 03, 1989N62711 006FEB 03, 1989N62711 007FEB 03, 1989N62711 008FEB 03, 1989N62711 009FEB 03, 1989N62711 010FEB 03, 1989N62711 011FEB 03, 1989N62711 012FEB 03, 1989N62711 013ONDANSETRON HYDROCHLORIDEINJECTABLE; INJECTION**Zofran**GLAXO100,000 UNITS/GM100,000 UNITS/GMN61810 001FEB 03, 1989JAN 04, 1991

OXAZEPAM

OXAZEPAM CHELSEA		PANICURONIUM BROMIDE	PENTOBARBITAL SODIUM
B*	10MG	>DLT>/ /QH/P/	/1HSH/L/
MAR 02, 1988	>DLT>	/2HSH/L/	/JUN/03/1988/
N71662 001	>DLT>/ /P/	/2HSH/L/	/N71662/001/
MAR 02, 1988	>DLT>	/2HSH/L/	/JUN/03/1988/
N71663 001	>ADD>	1MG/ML	N72209 001
MAR 02, 1988	>ADD>	1MG/ML	JUN 03, 1988
N71661 001	>ADD>	2MG/ML	N72208 001
/P/	>ADD>	2MG/ML	JUN 03, 1988
/P/	/P/	/P/	/P/
/P/	/P/	/P/	/P/

PANCICLOVITUM BROMIDE

CAPSULE; ORAL OXAZEPAM		10MG CHELSEA	N71661 001 MAR 02, 1988	>DLT>/AP/ >DLT> >DLT>/AP/ >DLT> >ADD> >ADD> >ADD> >ADD>	PANICUONIUM BROMIDE /AP/	INJECTABLE; INJECTION /AP/
TABLET, DELAYED RELEASE; ORAL CHOLEDTL		/160MG/ /PARKE/DAVIS/	/160MG/ 200MG PARKE DAVIS	/160MG/ 200MG 100MG	/160MG/ /CHELSEA/ a CHELSEA	OXTRIPTYLLINE /CHELSEA/
TABLET, DELAYED RELEASE; ORAL CHOLDTL		/160MG/ /PARKE/DAVIS/	/160MG/ 200MG PARKE DAVIS	/160MG/ 200MG 100MG	/160MG/ /CHELSEA/ a NYETH AYERST	OXTRIPTYLLINE /CHELSEA/ a NYETH AYERST
TABLET; ORAL OXYBUTYNIN CHLORIDE		/AP/ /BOLAR/	/AP/ 100MG BOLAR	/AP/ 100MG 200MG	PENTOSTATIN /AP/ NO9268 003	PENTOSTATIN /AP/ NO9268 003
TABLET; ORAL OXYBUTYNIN CHLORIDE		/AP/ /BOLAR/	/AP/ 100MG BOLAR	/AP/ 100MG 200MG	INJECTABLE; INJECTION NIPENT PARKE DAVIS	INJECTABLE; INJECTION NIPENT PARKE DAVIS
TABLET; ORAL PERPHENAZINE		/AP/ /BOLAR/	/AP/ 100MG BOLAR	/AP/ 100MG 200MG	PERPHENAZINE B* CHELSEA	PERPHENAZINE B* CHELSEA
TABLET; ORAL PERPHENAZINE		/AP/ /BOLAR/	/AP/ 100MG BOLAR	/AP/ 100MG 200MG	TABLET; ORAL PERPHENAZINE B* CHELSEA	TABLET; ORAL PERPHENAZINE B* CHELSEA
TABLET; ORAL PHENDIMETRAZINE TARTRATE		/AP/ /BOLAR/	/AP/ 100MG BOLAR	/AP/ 100MG 200MG	CAPSULE, EXTENDED RELEASE; ORAL PHENDIMETRAZINE TARTRATE BC VITARINE	PHENDIMETRAZINE TARTRATE BC VITARINE
INJECTABLE; INJECTION AREDIA		/AP/ /SOLVAY/	/AP/ 105MG CIBA GEIGY	/AP/ 105MG SOLVAY	N18074 001 DEC 23, 1987 /AP/23/1987/	INJECTABLE; INJECTION AREDIA CIBA GEIGY
PAMIDRONATE DISODIUM		/AP/ /SOLVAY/	/AP/ 105MG SOLVAY	/AP/ 105MG SOLVAY	N18074 001 /AP/23/1987/ N98024 001	PAMIDRONATE DISODIUM /AP/ 105MG SOLVAY

PRALIDOXIME CHLORIDE

INJECTABLE; INJECTION

PRALIDOXIME CHLORIDE
 /QUAD/
 > DLT >/AB/
 > DLT >
 > ADD >
 > ADD >

PROTOPAM CHLORIDE
 /WYETH/AERST/
 WYETH AYERST

PREDNISOLONE ACETATE

INJECTABLE; INJECTION
PREDNISOLONE ACETATE
 BP STERLS
 BP
 /N14134/001
 N72224 001
 NOV 23, 1991
 1GM/VIAL

/N14134/001
 N14134 001
 1GM/VIAL

N19898 002
 OCT 31, 1991
 N19898 003
 OCT 31, 1991
 20MG#

INJECTABLE; INJECTION
PREDNISOLONE ACETATE
 BP STERLS
 BP
 /N14134/001
 N14134 001
 NOV 23, 1991
 1GM/VIAL

N19898 002
 OCT 31, 1991
 N19898 003
 OCT 31, 1991
 20MG#

PRAZEPAM

BRISTOL MYERS SQUIBB 10MG#
 TABLET; ORAL
 PRAVACHOL

N19898 002
 OCT 31, 1991
 N19898 003
 OCT 31, 1991
 20MG#

PRAZEPAM

CAPSULE; ORAL
PRAZEPAM
 /PHAR/P/PLAST/
 /AB/

N19898 002
 OCT 31, 1991
 20MG#

INJECTABLE; INJECTION
PREDNISOLONE ACETATE
 BP STERLS
 BP
 /N14134/001
 N85781 001

INJECTABLE; INJECTION
PREDNISOLONE ACETATE
 BP STERLS
 BP
 /N14134/001
 N85781 001

SOLUTION/DROPS; OPHTHALMIC
PREDNISOLONE SODIUM PHOSPHATE
 AT STERLS
 AT
 /N14134/001
 N81044 001

SOLUTION/DROPS; OPHTHALMIC
PREDNISOLONE SODIUM PHOSPHATE
 AT STERLS
 AT
 /N14134/001
 N81044 001

INJECTABLE; INJECTION
PREDNISOLONE ACETATE
 BP STERLS
 BP
 /N14134/001
 N85781 001

INJECTABLE; INJECTION
PREDNISOLONE ACETATE
 BP STERLS
 BP
 /N14134/001
 N85781 001

PREDNISOLONE ACETATE

INJECTABLE; INJECTION
PREDNISOLONE ACETATE
 /CENTRAL/PHARM/
 /AB/
 /BARR/

/N84717/001
 N84717 001
 NOV 06, 1986
 25MG/ML

PREDNISONETABLET; ORAL
PREDNISONE
ROXANE

1MG
AB N87800 001
APR 22, 1982
2.5MG
AB N87801 001
APR 22, 1982
10MG
AB N84122 001
20MG
AB N87342 001
50MG
AB N84283 001
250MG
/BX/ AB /
1/
/3/ AB /
1/2.5MG
/3/ AB /
10MG
2/ AB /
20MG
/3/ AB /
50MG
/3/ AB /
250MG
/3/ AB /
100MG
/BX/ AB /
250MG
/3/ AB /
500MG
/3/ AB /
100MG/ML
/BX/ AB /
500MG/ML

PROCAINAMIDE HYDROCHLORIDETABLET; INJECTION

FROCATHANIDE HCL
/AP/ /N89548/661/
/WARNER/CHILCOTT/ /100MG/ML/
/AP/ /N89549/661/
/WARNER/CHILCOTT/ /500MG/ML/
③ WARNER CHILCOTT
100MG/ML
MAY 03, 1988
N89528 001
MAY 03, 1988
N89529 001
MAY 03, 1988
/BX/ AB /
TABLET, EXTENDED RELEASE; ORAL
PROCAINAMIDE HCL
/BX/ AB /
1GM
③ BOLAR
1GM
JAN 15, 1987
N89520 001
JAN 15, 1987
/BX/ AB /
PROCAN SR
/PARKE/PARK/ /
/BX/ AB /
PARKE DAVIS
1GM
JAN 16, 1985
/BX/ AB /
PROCaine HYDROCHLORIDE
/BX/ AB /
PROCATINAMIDE HYDROCHLORIDE
/BX/ AB /
CAPSULE; ORAL
PROCAINAMIDE HCL
/BX/ AB /
③ BOLAR
2/ AB /
③ BOLAR
/BX/ AB /
INJECTABLE; INJECTION
PROCATINAMIDE HCL
/BX/ AB /
③ QUAD
/BX/ AB /
③ ADD
/BX/ AB /
PROCLOPRERAZINE EDISYLATE
/BX/ AB /
CONCENTRATE; ORAL
PROCHLORPERAZINE EDISYLATE
/BX/ AB /
③ CUTTER
3/ AB /
③ PHARM/BASICS
/BX/ AB /
③ STERRS
/BX/ AB /
INJECTABLE; INJECTION
PROCLOPRERAZINE HCL
/BX/ AB /
③ QUAD
/BX/ AB /
③ ADD
/BX/ AB /
EQ 10MG BASE/ML
100MG/ML
500MG/ML
N89256 001
MAY 30, 1986
N89257 001
MAY 30, 1986
N89598 001
OCT 25, 1984

PROCHLORPERAZINE EDISYLATE

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION PROCHLORPERAZINE EDISTYLATE /QdP/	/N83532/661/ /N83532/661/ /N83532/661/ /N83532/001
> DLT > AP/	/N89637/661/ /FEP/61/1983/ /N89638/661/ /FEP/61/1983/
> DLT >	
> DLT > AP/	
> DLT >	
> QUAD >	EQ 5MG BASE/ML N89637 001
> ADD >	FEB 01, 1983
> ADD >	N89638 001
> ADD >	FEB 01, 1983
> ADD >	
INJECTABLE; INJECTION PROMETHAZINE HCL /LEtHOL/	/N83532/661/ /N83532/661/ /N83532/661/ /N83532/002
PROMETHAZINE HCL /LEtHOL/	/N83532/661/ /N83532/661/ /N83532/661/ /N83532/002
STERIS	
AP	
AP	
SUPPOSITORY; RECTAL /PROMETHAZINE HCL/ /BR/ /S AND W/	/N83532/661/ /N83532/661/ /N83532/661/ /N83532/661/

SYRUP; ORAL <u>COMPAZINE</u>	/ʃɛpə'zɪn/ SKF / /pɛdʒɪn/ /ʃɛpə'zɪn/	/ɛdʒɪn/ EQ 5MG BASE/5ML /ɛdʒɪn/ EQ 5MG BASE/5ML
② PHARM BASICS		

PROCHLORPERAZINE MALEATE

PROPRANOLOL HYDROCHLORIDETABLET; ORAL
PROPRANOLOL HCL

<u>AB/</u>	<u>BOLAR/</u>	<u>/10MG/</u>	<u>TABLET; ORAL PROPRANOLOL HCL</u>	<u>AB</u>	<u>SCHERING</u>	<u>10MG</u>	<u>N70120 001</u>
<u>/AB/</u>		<u>/20MG/</u>		<u>AB</u>		<u>20MG</u>	<u>AUG 06, 1985</u>
<u>/AB/</u>		<u>/40MG/</u>		<u>AB</u>		<u>40MG</u>	<u>AUG 06, 1985</u>
<u>/AB/</u>		<u>/60MG/</u>		<u>AB</u>		<u>60MG</u>	<u>AUG 06, 1985</u>
<u>/AB/</u>		<u>/80MG/</u>		<u>AB</u>		<u>80MG</u>	<u>OCT 29, 1986</u>
<u>② BOLAR</u>		<u>10MG</u>		<u>/AB/</u>	<u>/SUPERPHARM/</u>	<u>/40MG/</u>	<u>AUG 06, 1985</u>
<u>③</u>		<u>20MG</u>		<u>/AB/</u>		<u>/60MG/</u>	<u>/N71517/001/</u>
<u>③</u>		<u>40MG</u>		<u>/AB/</u>		<u>/80MG/</u>	<u>JUN 08, 1988</u>
<u>③</u>		<u>60MG</u>		<u>/AB/</u>	<u>SUPERPHARM</u>	<u>②</u>	<u>N71516 001</u>
<u>③</u>		<u>80MG</u>		<u>/AB/</u>		<u>②</u>	<u>JUN 08, 1988</u>
<u>AB/</u>		<u>/40MG/</u>		<u>PROTAMINE SULFATE</u>		<u>INJECTABLE; INJECTION PROTAMINE SULFATE</u>	<u>/N70380 001</u>
<u>AB/</u>		<u>/60MG/</u>		<u>AB/</u>	<u>/40MG/</u>	<u>/40MG/</u>	<u>/N70381 001</u>
<u>AB/</u>		<u>/80MG/</u>		<u>AB/</u>	<u>/60MG/</u>	<u>/60MG/</u>	<u>MAY 30, 1986</u>
<u>B*</u>		<u>DURAMED</u>		<u>>DLT></u>	<u>>DLT></u>	<u>>DLT></u>	<u>/N70308 001</u>
<u>B*</u>				<u>>ADD></u>	<u>>ADD></u>	<u>>ADD></u>	<u>SEP 09, 1985</u>
<u>B*</u>				<u>>ADD></u>			<u>OCT 01, 1986</u>
<u>AB/</u>		<u>/MARTEC/</u>		<u>TABLET, EXTENDED RELEASE; ORAL SELDANE-D</u>		<u>120MG; 60MG</u>	<u>N19664 001</u>
<u>AB/</u>		<u>/10MG/</u>		<u>MERRELL DOW</u>			<u>AUG 19, 1991</u>
<u>AB/</u>		<u>/20MG/</u>					
<u>AB/</u>		<u>/40MG/</u>					
<u>AB/</u>		<u>/60MG/</u>					
<u>AB/</u>		<u>/80MG/</u>					
<u>AB/</u>		<u>/10MG/</u>		<u>PYRIDOSTIGMINE BROMIDE</u>		<u>30MG</u>	<u>N89572 001</u>
<u>AB/</u>		<u>/20MG/</u>		<u>KALI DUPHAR</u>			<u>NOV 27, 1990</u>
<u>AB/</u>		<u>/40MG/</u>		<u>/PYRIDOSTIGMINE/</u>			<u>/N89572/1336/</u>
<u>AB/</u>		<u>/60MG/</u>					
<u>AB/</u>		<u>/80MG/</u>					

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION
PYRIDOXINE HCl
/AP/
/LEMONT/
STERIS

/100MG/ML/
100MG/ML

PYRILANTINE MALEATE

TABLET; ORAL
PYRILANTINE MALEATE
/AA/
/CHELSEA/
@ CHELSEA
/AA/
/RICHLYN/
RICHLYN

QUAZEPAM

TABLET; ORAL
DOERAL
BAKER CUMMINS
7.5MG
15MG
/DORMALIN/
/BAKER/KEYPHARMS/
/AA/
/KEY/KEYPHARMS/
/DEC/27/1985/

> ADD > QUINAPRIL HYDROCHLORIDE

> ADD > TABLET; ORAL
ACCUPRIL
PARKE DAVIS
> ADD > EQ 5MG BASEH
> ADD > EQ 10MG BASEH
> ADD > EQ 20MG BASEH
> ADD > EQ 40MG BASEH
> ADD >

QUINESTROL

TABLET; ORAL
ESTROVIS
PARKE DAVIS
0.1MG

QUINIDINE GLUCONATE

/A&P/
/SH&L/
/BERLEX/
@ BERLEX
@

/N83760 001/
100MG/ML

TABLET, EXTENDED RELEASE; ORAL
/AA/
/GUTHATINE/
/BOLAR/
@ BOLAR

/N85231 001/
25MG

/N86888/001/
25MG

/AA/
GUTHATINE GLUCONATE/
/ROXANE/
@ ROXANE

QUINIDINE SULFATE

TABLET; ORAL
/AA/
/QUINIDINE SULFATE/
/YANKEP/

N18708 003
FEB 26, 1987

N18708 001
DEC 27, 1985

/AA/
VANGARD

N18766/001/
FEB 26/1987/

N18708/001/
N18708/001/
/DEC/27/1985/

RAMIPRIL

CAPSULE; ORAL
ALTACE
HOECHST ROUSSEL

N19885 001
NOV 19, 1991

N19885 002
NOV 19, 1991

N19885 003
NOV 19, 1991

N19885 004
NOV 19, 1991

/AA/
JUL 13, 1982

/AA/
KEY PHARMS/
@ KEY PHARMS

N19901 001
JAN 28, 1991

N19901 002
JAN 28, 1991

N19901 003
JAN 28, 1991

N19901 004
JAN 28, 1991

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'91 - NOV'91

50

RANITIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
ZANTAC IN PLASTIC CONTAINER
/E/G/H/B/A/S/E/Y/10ML/

③ GLAXO

EQ 50MG BASE/100ML
 EQ 1MG BASE/ML

/N66396/ddd/
 N86390 001

SECOBARBITAL SODIUM

CAPSULE; ORAL
SECOBARBITAL SODIUM
/A/A/

/N66396/ddd/
 N86390 001

/100MG/
 100MG

③ WYETH AYERST

/WYETH AYERST/
 001

DEC 17, 1986

N19593 002

SEP 27, 1991

RAIWOLFIA SERPENTINA

TABLET; ORAL

RAIWOLFIA SERPENTINA

BP 50MG
 /A/

N80907 001
 /N66396/ddd/

RESERPINE

TABLET; ORAL

RESERPINE

/B/B/
 ③ WHITE TOWNE PAULSEN

0.1MG

0.25MG

/B/B/
 1MG

/N66396/ddd/
 N80723 001

0.1MG

/N66396/ddd/
 N80723 002

0.25MG

/N66396/ddd/
 N80723 003

1MG

SPIRONOLACTONE

③ LYPHOMED

50MG/VIAL

/N66396/ddd/
 N70031 001

JAN 17, 1985

/N66396/ddd/
 N86898 002

MAR 02, 1982

③ BOLAR

2.5MG

SUCIMER

/N66396/ddd/
 N71618 001

FEB 28, 1991

N71619 001

FEB 28, 1991

/N66396/ddd/
 N70701 001

OCT 06, 1986

N71438 001

JAN 22, 1991

SULFAMETHOXAZOLE

TABLET; ORAL
SULFAMETHOXAZOLE
/BOLAR/
 ③ BOLAR

/N66396/ddd/
 N85053 001

JAN 30, 1991

/N66396/ddd/
 N85053 001

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION

RITODRINE HCL

AP 10MG/ML

15MG/ML

/A/A/

③ QUAD

15MG/ML

/A/A/

③ QUAD

100MG

/N66396/ddd/
 N70701 001

OCT 06, 1986

N19998 002

JAN 30, 1991

/N66396/ddd/
 N85053 001

JAN 30, 1991

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

COTRIM
/AB/
/SULFAMETHOXAZOLE/
/TRIMETHOPRIM/
/LEMON/> DLT >
> DLT > AB/
> DLT >
> ADD >
> ADD >

a QUAD

a STERIS

GENSTAS

STERIS

SULFAMETHOXAZOLE AND TRIMETHOPRIM

80MG/ML; 16MG/ML

80MG/ML; 16MG/ML

80MG/ML; 16MG/ML

SUSPENSION; ORAL

COTRIM PEDIATRIC

LEMON

/SULFAMETHOXAZOLE AND TRIMETHOPRIM//PLANTEX/

/AB/

/SULFAMETHOXAZOLE AND TRIMETHOPRIM/

/AB/

SULFAMETHOXAZOLE AND TRIMETHOPRIM

/AB/

/SULFAMETHOXAZOLE AND TRIMETHOPRIM/

/AB/

SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH

/AB/

SULFASALAZINE

TABLET, DELAYED RELEASE; ORAL

AZULFIDINE EH-TABS
KABI

/AB/

/PHARMA/

/SULFASALAZINE/

/BOLAR/

/BOLAR/

a BOLAR

500MG

MAY 24, 1983

TABLET, DELAYED RELEASE; ORAL

AZULFIDINE EH-TABS
KABI

/AB/

/PHARMA/

/SULFASALAZINE/

/BOLAR/

/BOLAR/

500MG

MAY 24, 1983

TABLET; ORAL

SOXAZOLO
a ALRA

/BOLAR/

/BOLAR/

500MG

MAY 24, 1983

TECHNETIUM TC-99M RED BLOOD CELL KIT

INJECTABLE; INJECTION

ULTRATAG
MALLINCKRODT

N/A

SULFANILAMIDE

CREAM; VAGINAL

SULFANILAMIDE
LEMON

15%

/VAGITAG/

/LEMON/

THEOPHYLLINECAPSULE; ORAL
THEOPHYLLINE

/BX/ /SCHERER/
 /BX/
 /BX/
 /BX/

③ SCHERER

/N84731/662/
 /Nov/67/1986/
 /N84731/661/
 /Nov/67/1986/
 /N84731/661/
 /Nov/67/1986/
 /N84731/663/
 /Nov/67/1986/
 N84731 002

100MG

200MG

250MG

CAPSULE, EXTENDED RELEASE; ORAL

/PC/ /Theophylline/
 /Johnson/RW/
 /PC/

③ JOHNSON RW

125MG

/PC/ /Theophylline/
 /CENTRAL/PHARMS/
 /PC/

/PC/ /CENTRAL/PHARMS/
 /PC/

③ CENTRAL PHARMS

125MG

250MG

THEOPHYLLINE-SR
 /PC/ /SCHERER/

③ SCHERER

300MG

TABLET; ORAL

/PC/ /Theoclear-100/
 /CENTRAL/PHARMS/
 /PC/ /Theoclear-200/
 /CENTRAL/PHARMS/
 /PC/ /CENTRAL/PHARMS/

③ CENTRAL PHARMS

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

/AP/ /Thiamine HCl
 /Lyphomed/
 ③ LYPHOMED
 AP
 AP

/N84731/662/
 /Nov/67/1986/
 /N84731/661/
 /Nov/67/1986/
 /N84731/663/
 /Nov/67/1986/
 N84731 002

100MG

200MG

250MG

300MG

400MG

500MG

600MG

800MG

1000MG

1200MG

1500MG

1800MG

2000MG

2500MG

3000MG

3500MG

4000MG

5000MG

6000MG

7000MG

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

/N83534/661/
 /N83534/662/

/Thiamine HCl
 /Lemmon/
 /AP/

/N83534/661/
 /N83534/662/

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL
TITROTDAZINE HCL
/ROXANE/

OCT 31, 1991
200 6 IN
N19979 002

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL
TICLID SYNTEX

OCT 31, 1991
200 6 IN
N19979 002

TABLET; ORAL
THILOL MALEATE

/N86648/001/ MAR 26, 1985/ N88663 001 MAR 15, 1984	/AS/ /AS/ /AS/ /AS/ /AS/ /AS/ /AS/	<u>TABLET; ORAL</u> <u>TIBOLOL MALEATE</u> <u>/BOLAR/</u>	/S/G/ /4045/ /4045/ /4045/ /4045/ /4045/ /4045/	5MG ③ BOLAR
N88664 001 MAR 15, 1984				
N88665 001 MAR 15, 1984				
N89048 001 FEB 26, 1985				

THIOTIENE

CAPSULE; ORAL
THIOTHIXENE

/AB/	1 AM THERAPY	JUL 31, 1991 N72918 001
/AB/	2 AM THERAPY	JUL 31, 1991 N72919 001
/AB/	3 AM THERAPY	JUL 31, 1991 N72920 001
10MG	1 AM THERAPY	JAN 10, 1989 N72001 001
10MG	2 AM THERAPY	JAN 10, 1989 N72002 001
10MG	3 AM THERAPY	JAN 10, 1989 N72003 001
5MG	PHARM BASICS	JAN 10, 1989 N72004 001

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL
THEOTHOXENE HCL

1111111111

/EQ/1MG/BSF/ML	/DEC/16/1988 N71917 001
EQ 5MG BASE/ML	/SEP/20/1989 N71939 001
EQ 1MG BASE/ML	DEC 16, 1988 N71917 001
	SEP 20, 1989

PACO

TOBRAMYCIN SULFATE

**INJECTABLE; INJECTION
TOBRAMYCIN SULFATE**

<u>ABBOTT</u>	<u>EQ 10MG BASE /MLH</u>
<u>AP</u>	<u>EQ 10MG BASE /MLH</u>
<u>AP</u>	<u>EQ 40MG BASE /MLH</u>
<u>AP</u>	<u>EQ 40MG BASE /MLH</u>
<u>ELKINS SINN</u>	<u>EQ 10MG BASE /MLH</u>
<u>AP</u>	<u>EQ 40MG BASE /MLH</u>
<u>AP</u>	<u>EQ 10MG BASE /MLH</u>
<u>LEDERLE</u>	<u>EQ 40MG BASE /MLH</u>
<u>AP</u>	<u>EQ 40MG BASE /MLH</u>
<u>AP</u>	<u>EQ 40MG BASE /MLH</u>

TOI AZAMID

TABLET; ORAL
TOLAZAMIDE
/pharm/básico

<u>EQ 10MG BASE/MLH</u>	N63080 001	APR 30, 1991	/AB/	/100MG/
<u>EQ 10MG BASE/MLH</u>	N63112 001		/AB/	/100MG/
<u>EQ 40MG BASE/MLH</u>	N63111 001	APR 30, 1991	/AB/	/400MG/
<u>EQ 40MG BASE/MLH</u>	N63111 001	APR 30, 1991	B*	PHARM BASICS
<u>EQ 40MG BASE/MLH</u>	N63161 001	MAY 29, 1991	B*	PHARM BASICS
<u>EQ 10MG BASE/MLH</u>	N63128 001	NOV 27, 1991	B*	100MG
<u>EQ 40MG BASE/MLH</u>	N63127 001	NOV 27, 1991	B*	250MG
<u>EQ 10MG BASE/MLH</u>	N63113 001	NOV 27, 1991	B*	500MG
<u>EQ 40MG BASE/MLH</u>	N63117 001	APR 26, 1991		TOLBUTAMIDE
<u>EQ 40MG BASE/MLH</u>	N63118 001	APR 26, 1991		TABLET; ORAL
<u>EQ 40MG BASE/MLH</u>		JUL 29, 1991		TOLBUTAMIDE
<u>EQ 40MG BASE/MLH</u>			/AB/	500MG
<u>EQ 40MG BASE/MLH</u>			/AB/	/500MG/
<u>EQ 40MG BASE/MLH</u>			/AB/	/500MG/
<u>EQ 40MG BASE/MLH</u>			/AB/	/500MG/
<u>EQ 40MG BASE/MLH</u>			/AB/	/500MG/
<u>EQ 40MG BASE/MLH</u>			/AB/	/500MG/
<u>EQ 100MG BASE/MLH</u>	N70242 001	AUG 01, 1986		TOLMETIN SODIUM
<u>EQ 100MG BASE/MLH</u>	N70243 001	AUG 01, 1986		CAPSULE; ORAL
<u>EQ 100MG BASE/MLH</u>	N70244 001	AUG 01, 1986	> ADD >	TOLECTIN DS
<u>EQ 100MG BASE/MLH</u>	N70245 001	AUG 01, 1986	> ADD >	JOHNSON RW
<u>EQ 100MG BASE/MLH</u>	N70246 001	AUG 01, 1986	> ADD >	TOLMETIN SODIUM
<u>EQ 100MG BASE/MLH</u>	N70247 001	AUG 01, 1986	> ADD >	MUTUAL PHARM
<u>EQ 100MG BASE/MLH</u>	N70248 001	AUG 01, 1986	> ADD >	NOVOPHARM
<u>EQ 100MG BASE/MLH</u>	N70249 001	AUG 01, 1986	> ADD >	NOVOPHARM
<u>EQ 100MG BASE/MLH</u>	N70285 001	JAN 09, 1986	> ADD >	TABLET; ORAL
<u>EQ 200MG BASE</u>	N70286 001	JAN 09, 1986	> ADD >	TOLECTIN
<u>EQ 200MG BASE</u>	N70287 001	JAN 09, 1986	> ADD >	JOHNSON RW
<u>EQ 200MG BASE</u>		JAN 09, 1986	> ADD >	TOLMETIN SODIUM
<u>EQ 200MG BASE</u>		JAN 09, 1986	> ADD >	MUTUAL PHARM

TRIMEPRAZINE TARTRATE

SYRUP; ORAL TEMARIL	/EQ '2.5MG BASE/5FL/ EQ 2.5MG BASE/5ML	/N11336/063/ N11316 003	SUSPENSION; ORAL <u>/SULFATE/</u> ③ WYETH AYERST	/SULFATE/5ML/ 500MG/5ML
③ PHARM/BASICS	/EQ '2.5MG BASE/5FL/ EQ 2.5MG BASE/5ML	/N108245/061/ N88295 001	TABLET; ORAL <u>/SULFATE/</u> ③ WYETH AYERST	/SULFATE/ 500MG

TRIMETHOBENZAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION TRIMETHOBENZAMIDE HCL	/400MG/5ML/ 100MG/2ML	/N03043/061/ N89043 001	CAPSULE; ORAL <u>VALPROIC ACID</u> ③ SCHERER	2.5MG/ML
③ SOLOPAK	100MG/2ML	APR 04, 1986	VERAPAMIL HYDROCHLORIDE	

TRIMIPRAMINE MALEATE

CAPSULE; ORAL TRIMIPRAMINE MALEATE	/EQ '25MG 'BASE/	/N71283/061/ /DEC/08/1987/	INJECTABLE; INJECTION <u>/CALAN/</u> ③ SEARLE	/2.5MG/ML
③	/EQ '50MG 'BASE/	/N71284/061/ /DEC/08/1987/	VERAPAMIL HCL	
③	/EQ '100MG 'BASE/	/N71285/061/ /DEC/08/1987/	<u>/QUAD/</u>	
B*	EQ 25MG BASE	/N71283/001	> DLT > /AP/	
B*	EQ 50MG BASE	DEC 08, 1987	> DLT >	
B*	EQ 100MG BASE	N71284 001	> ADD >	
		DEC 08, 1987	③ QUAD	2.5MG/ML
		N71285 001	> ADD >	
		DEC 08, 1987	/SOLOPAK/	
		N71285 001	③ SOLOPAK	2.5MG/ML
		DEC 08, 1987		
			TABLET; ORAL VERAPAMIL HCL	
			B* CHELSEA	80MG
			B*	120MG
				/Bdts/
				/120tgs/

TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL TRIPROLIDINE HCL	/4.5MG/	/N85594/061/ N85094 001	TABLET; ORAL VERAPAMIL HCL	80MG
③ DANBURY	2.5MG	/N85510/061/ N85610 001	120MG	
③ VITARINE	/2.5MG/		/Bdts/	

WARFARIN SODIUM

TABLET; ORAL
WARFARIN SODIUM
/BX/ 1000

xxv

**POWDER; ORAL
XYL-O-PFAN**

<u>AA</u>	<u>ADRIA</u>	<u>25GM/BOT</u>	N17605 001 /N17605/001/
<u>AA</u>	<u>XYLOSE</u>	<u>25GM/BOT</u>	N18856 001 MAR 26, 1987 /N18856/001/
<u>AA</u>	<u>LYNE</u>	<u>25GM/BOT</u>	/ /
<u>AA</u>			

AURIA 25GM/BOT
XYLOSE 25GM/BOT
LYNE 25GM/BOT

ACETAMINOPHEN

SUPPOSITORY; RECTAL
*/fjefəmōfēn/
 /hītēl/*
 ② MCNEIL
 a

N17756 002
 120MG
 N17756 001
 650MG

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
 EXIDINE
*/ɛksidīn/
 xttrium*

XTRIUM
 MICRODERM
 JOHNSON AND JOHNSON 4/24

Sponge; TOPICAL
 MICRODERM
 JOHNSON AND JOHNSON 4/24

CLOTRIMAZOLE

CREAM; TOPICAL
 MYCELEX
 MILES 1/24

SOLUTION; TOPICAL
 MYCELEX
 MILES

TABLET, EXTENDED RELEASE; ORAL
 DISOBROM
 GENEVA

6MG;120MG

N70770 001

SEP 30, 1991

DOXYLAMINE SUCCINATE

TABLET; ORAL
 DOXYLAMINE SUCCINATE
 COPLEY 25MG

N88900 002
 FEB 12, 1988

HYDROCORTISONE

/dīdrōkōrtēsōn/
*/HC/ (Hydrocortisone) /
 /c/ AND /n/
 ② C AND M*

N19422 001
 DEC 17, 1985
 N72255 001
 APR 15, 1991

N72295 001
 FEB 28, 1991
 N18181 002
 APR 01, 1991

INSULIN BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
 NOVOLIN R
 NOVO NORDISK 100UNITS/ML

N19938 001
 JUN 25, 1991
 N19771 001
 SEP 19, 1989
*/N19771/001/
 /\$EP/19/1989/*

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE

INJECTABLE; INJECTION
 NOVOLIN 70/30
 NOVO NORDISK 30UNITS/ML; 70UNITS/ML
 N19991 001
 JUN 25, 1991
*/N19991/001/
 /N17926 001*

INSULIN PORK

INJECTABLE; INJECTION
 INSULIN
*/N17926/001/
 ② NOVO NORDISK*
 /40/UNITS/ML/
 40 UNITS/ML

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'91 - NOV'91

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INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
NOVOLIN N
NOVO NORDISK
100UNITS./ML
N19959 001
JUL 01, 1991

INSULIN ZINC SUSP BEEF

INJECTABLE; INJECTION
LENTE INSULIN
/Novo Nordisk/
® NOVO NORDISK
/40/UNITS/ML/
40 UNITS./ML
N17998 001

INSULIN ZINC SUSP BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
NOVOLIN L
NOVO NORDISK
100UNITS./ML
N19965 001
JUN 25, 1991

MICONAZOLE NITRATE

CREAM; VAGINAL
MONISTAT 7
JOHNSON RW
2/24
FEB 15, 1991

SUPPOSITORY; VAGINAL
MONISTAT 7
JOHNSON RW
100MG#
N18520 002
FEB 15, 1991

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
SUDAFED 12 HOUR
BURROUGHS WELLCOME
120MG#
N73585 001
OCT 31, 1991

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
TRIPLIDINE AND PSEUDOEPHEDRINE HCL
120MG;5MG#
KV
N72758 001
NOV 25, 1991

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

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

TABLET, EXTENDED RELEASE; ORAL
TRIPOLIDINE AND PSEUDOEPHEDRINE HCL
120MG;5MG
KV

N72758 001
NOV 25, 1991

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DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - NOV '91

HESTARCH 6% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

INJECTABLE; INJECTION
HESSPAN
DUPONT MERCK
PHARM 6GM/100ML; 0.9GM/100ML
N890105 APR 04, 1991

PENTASTARCH 10% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

INJECTABLE; INJECTION
PENTASPA
DUPONT MERCK
PHARM 10GM/100ML; 0.9GM/100ML
N890104 APR 04, 1991

ORPHAN DRUG PRODUCT DESIGNATIONS

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

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

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

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ALPHA-GALACTOSIDASE A TRADE: CC-GALACTOSIDASE	TREATMENT OF ALPHA-GALACTOSIDASE A DEFICIENCY. (FABRY'S DISEASE).	DAVID H. CALHOUN, PH.D. CITY COLLEGE OF NEW YORK
GENERIC: ANTI-VENOM (CROTALIDAE) PURIFIED (AVIAN) TRADE: NOT ESTABLISHED	TREATMENT OF ENVENOMATION BY POISONOUS SNAKES BELONGING TO THE CROTALIDAE FAMILY.	OPHIDIAN PHARMA
GENERIC: BOTULINUM TOXIN TYPE A TRADE: OCULINUM*/**	TREATMENT OF STRABISMUS ASSOCIATED WITH DYSTONIA IN ADULTS (PATIENTS 12 YEARS OF AGE AND ABOVE). */** [DEC 29, 1996] TREATMENT OF BLEPHAROSPASM ASSOCIATED WITH DYSTONIA IN ADULTS (PATIENTS 12 YEARS OF AGE AND ABOVE). */** [DEC 29, 1996] TREATMENT OF CERVICAL DYSTONIA.	ALLERGAN

ORPHAN DRUG PRODUCT DESIGNATIONS
BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: CLOSTRIDIUM BOTULINUM TYPE F NEUROTOXIN TRADE: NOT ESTABLISHED	TREATMENT OF SPASMODIC TORTICOLLIS.	PORTON PRODUCTS LIMITED
GENERIC: CHIMERIC M-T412 (HUMAN-MURINE) IGG MONOCLONAL ANTI-CD4 ANTIBODY TRADE: NOT ESTABLISHED	TREATMENT OF MULTIPLE SCLEROSIS.	CENTOCOR, INC
GENERIC: CYTOMEGALOVIRUS IMMUNE GLOBULIN INTRAVENOUS (HUMAN) TRADE: NOT ESTABLISHED	USE IN CONJUNCTION WITH GANCICLOVIR SODIUM FOR THE TREATMENT OF CYTOMEGALOVIRUS PNEUMONIA IN BONE MARROW TRANSPLANT PATIENTS.	MILES, INC
GENERIC: EPOETIN ALPHA (RECOMBINANT-HUMAN) EPOGEN*/** TRADE:	TREATMENT OF ANEMIA ASSOCIATED WITH HIV INFECTION OR HIV TREATMENT. [TREATMENT OF AZT-INDUCED ANEMIA IN HIV INFECTED PATIENTS.*/**] [DEC 31, 1997]	AMGEN
GENERIC: FILGRASTIM NEUPOGEN TRADE:	TREATMENT OF PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) WHO, IN ADDITION, ARE AFFLICTED WITH CYTOMEGALOVIRUS RETINITIS (CMV RETINITIS) AND ARE BEING TREATED WITH GANCICLOVIR.	AMGEN, INC
GENERIC: HUMAN MONOCLONAL ANTIBODY AGAINST HEPATITIS B VIRUS TRADE: NOT ESTABLISHED	PROPHYLAXIS OF HEPATITIS B REINFECTION IN PATIENTS UNDERGOING LIVER TRANSPLANTATION SECONDARY TO END- STAGE CHRONIC HEPATITIS B INFECTION.	SANDOZ PHARMACEUTICALS CORPORATION
GENERIC: INSULIN-LIKE GROWTH FACTOR-1 MYOTROPHIN TRADE:	TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.	CEPHALON, INC
GENERIC: INTERFERON (RECOMBINANT, BETA) R-IFN-BETA TRADE:	SYSTEMIC TREATMENT OF METASTATIC RENAL CELL CARCINOMA. SYSTEMIC TREATMENT OF CUTANEOUS T-CELL LYMPHOMA. SYSTEMIC TREATMENT OF CUTANEOUS MALIGNANT MELANOMA. INTRALESIONAL AND/OR SYSTEMIC TREATMENT OF AIDS-RELATED KAPOSI'S SARCOMA.	BIOGEN

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]		SPONSOR NAME
	BIOLOGICAL DESIGNATIONS		
GENERIC: INTERLEUKIN-1 ALPHA, HUMAN RECOMBINANT TRADE: NOT ESTABLISHED	FOR THE PROMOTION OF EARLY ENGRAFTMENT IN BONE MARROW TRANSPLANTATION. FOR HEMATOPOIETIC POTENTIATION IN APLASTIC ANEMIA.		IMMUNEX CORPORATION
GENERIC: INTERLEUKIN-1 RECEPTOR ANTAGONIST, HUMAN RECOMBINANT TRADE: ANTRIL	TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.		SYNERGEN, INC
GENERIC: INTERLEUKIN-3, RECOMBINANT HUMAN TRADE: NOT ESTABLISHED	PROMOTION OF ERYTHROPOEISIS IN DIAMOND-BLACKFAN ANEMIA (CONGENITAL PURE CELL RED APLASIA).		IMMUNEX CORPORATION
GENERIC: MONOCLONAL ANTIBODY PM-81 TRADE: NOT ESTABLISHED	ADJUNCTIVE TREATMENT OF ACUTE MYELOGENOUS LEUKEMIA.		MEDAREX, INC
GENERIC: LIPOSOME ENCAPSULATED RECOMBINANT INTERLEUKIN-2 TRADE: NOT ESTABLISHED	TREATMENT OF BRAIN AND CNS TUMORS.		ONCOTHERAPEUTICS, INC
GENERIC: MUCOID EXOPOLYSACCHARIDE PSEUDOMONAS HYPERIMMUNE GLOBULIN TRADE: MEPIG	TREATMENT OF PULMONARY INFECTIONS DUE TO PSEUDOMONAS AERUGINOSA IN PATIENTS WITH CYSTIC FIBROSIS.		UNIVAX BIOLOGICS, INC
GENERIC: MYELIN TRADE: NOT ESTABLISHED	TREATMENT OF MULTIPLE SCLEROSIS.		AUTOIMMUNE, INC
GENERIC: POLY I: POLY C ₁₂ U AMPLIGEN TRADE: NOT ESTABLISHED	TREATMENT OF RENAL CELL CARCINOMA.		HEM RESEARCH, INC
GENERIC: RECOMBINANT HUMAN DEOXYRIBONUCLEASE (RNASE) TRADE: NOT ESTABLISHED	TO REDUCE MUCOUS VISCOSITY AND ENABLE CLEARANCE OF AIRWAY SECRETIONS IN PATIENTS WITH CYSTIC FIBROSIS.		GENENTECH, INC
GENERIC: RECOMBINANT SECRETORY LEUCOCYTE PROTEASE INHIBITOR TRADE: NOT ESTABLISHED	TREATMENT OF CONGENITAL ALPHA-1 ANTITRYPsin DEFICIENCY. TREATMENT OF CYSTIC FIBROSIS.		SYNERGEN, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL

DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]

SPONSOR NAME

GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-B4) TO B CELL (CD 19)
 TRADE: NOT ESTABLISHED

GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (N901) TO CD56 POSITIVE CELLS
 TRADE: NOT ESTABLISHED

GENERIC: SARGRAMOSTIM
 TRADE: LEUKINE*/**

FOR THE EX-VIVO PURGING OF LEUKEMIC CELLS FROM THE BONE MARROW OF NON-T CELL ACUTE LYMPHOCYTIC LEUKEMIA PATIENTS WHO ARE IN COMPLETE REMISSION.

TREATMENT OF SMALL CELL LUNG CANCER.

TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANTS IN PATIENTS WITH NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE AND ACUTE LYMPHOBLASTIC LEUKEMIA. [MAR 5, 1998]

GENERIC: SDZ MSL-109
 TRADE: NOT ESTABLISHED

PROPHYLAXIS OF CYTOMEGALOVIRUS DISEASE IN PATIENTS UNDERGOING SOLID ORGAN TRANSPLANTATION.
 TREATMENT OF CYTOMEGALOVIRUS RETINITIS IN PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME.

GENERIC: THYMOSIN ALPHA-1
 TRADE: NOT ESTABLISHED

ADJUNCTIVE TREATMENT OF CHRONIC ACTIVE HEPATITIS B.

IMMUNOGEN, INC

ALPHA 1 BIOMEDICALS, INC

SANDOZ PHARMACEUTICALS CORP

ORPHAN DRUG PRODUCT DESIGNATIONS
DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ALGLUCERASE TRADE: CEREDASE* /**	REPLACEMENT THERAPY IN PATIENTS WITH GAUCHER'S DISEASE TYPE I. [APR 5, 1998]	GENZYME
GENERIC: BERACTANT TRADE: SURVANTA* /**	PREVENTION OF NEONATAL RESPIRATORY DISTRESS SYNDROME (RDS). */** [JUL 1, 1998] TREATMENT OF NEONATAL RESPIRATORY DISTRESS SYNDROME (RDS). */** [JUL 1, 1998]	ROSS
GENERIC: CALCIUM GLUCONATE GEL TRADE: H-F GEL	EMERGENCY TOPICAL TREATMENT OF HYDROGEN FLUORIDE (HYDROFLUORIC ACID) BURNS.	LTR PHARMACEUTICALS, INC
GENERIC: CYCLOSPORINE 2% OPHTHALMIC OINTMENT TRADE: SANDIMMUNE	TREATMENT OF PATIENTS AT HIGH RISK OF GRAFT REJECTION FOLLOWING PENETRATING KERATOPLASTY. USE IN CORNEAL MELTING SYNDROMES OF KNOWN OR PRESUMED IMMUNOLOGIC ETIOPATHOGENESIS INCLUDING MOOREN'S ULCER.	SANDOZ PHARMACEUTICALS CORP
GENERIC: CYSTEAMINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF NEPHROPATHIC CYSTINOSIS.	WARNER-LAMBERT COMPANY
GENERIC: DEFEROXAMINE AND DEXTRAN TRADE: BIO-RESCUE	TREATMENT OF ACUTE IRON POISONING.	BIOMEDICAL FRONTIERS, INC
GENERIC: DESMOPRESSIN ACETATE TRADE: DDAVP HIGH CONCENTRATION	TREATMENT OF MILD HEMOPHILIA A AND VON WILLEBRAND'S DISEASE.	RORER PHARMACEUTICAL CORP
GENERIC: DRONABINOL TRADE: MARINOL	STIMULATION OF APPETITE AND PREVENTION OF WEIGHT LOSS IN PATIENTS WITH A CONFIRMED DIAGNOSIS OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	UNIMED, INC
GENERIC: ETIDRONATE DISODIUM TRADE: DIDRONEL	PREVENTION OF DEGENERATIVE METABOLIC BONE DISEASE OCCURRING IN PATIENTS WHO REQUIRE LONG TERM (6 MONTHS OR GREATER) TOTAL PARENTERAL NUTRITION. TREATMENT OF DEGENERATIVE METABOLIC BONE DISEASE OCCURRING IN PATIENTS WHO REQUIRE LONG TERM (6 MONTHS OR GREATER) TOTAL PARENTERAL NUTRITION.	MGI PHARMA, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: FLUDARABINE PHOSPHATE TRADE: FLUDARA*/**	TREATMENT OF REFRACTORY B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA. [APR 18, 1998]	BERLEX
GENERIC: FOSPHENYTOIN TRADE: NOT ESTABLISHED	ACUTE TREATMENT OF PATIENTS WITH STATUS EPILEPTICUS OF THE GRAND MAL TYPE.	WARNER-LAMBERT COMPANY
GENERIC: GALIUM NITRATE TRADE: GANITE*/**	TREATMENT OF HYPERCALCEMIA OF MALIGNANCY. [JAN 17, 1998]	FUJISAWA PHARM
GENERIC: GENANTICIN IMPREGNATED PMMA BEADS ON SURGICAL WIRE TRADE: SEPTOPAL	TREATMENT OF CHRONIC OSTOMYELITIS OF POST-TRAUMATIC, POSTOPERATIVE OR HEMATOGENOUS ORIGIN.	E. MERCK, DARMSTADT
GENERIC: HALOFANTRINE TRADE: HALFAN	TREATMENT OF MILD TO MODERATE ACUTE MALARIA CAUSED BY SUSCEPTIBLE STRAINS OF P. FALCIPARUM AND P. VIVAX.	SMITHKLINE BEECHAM PHARMACEUTICALS
GENERIC: HISTRELIN TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE INTERMITTENT PORPHYRIA, HEREDITARY COPROPORPHYRIA, AND VARIEGATE PORPHYRIA. IN PEDIATRIC PATIENTS.	KARL E. ANDERSON, M.D., UNIVERSITY OF TEXAS
GENERIC: IDARUBICIN HCL TRADE: IDAMYCIN	TREATMENT OF ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)	ADRIA
GENERIC: KETOCONAZOLE TRADE: NOT ESTABLISHED	FOR USE WITH CYCLOSPORIN A TO DIMINISH THE NEPHROTOXICITY INDUCED BY CYCLOSPORIN IN ORGAN TRANSPLANTATION.	PHARMEDIC COMPANY
GENERIC: L-LEUCOVORIN CALCIUM TRADE: ISOVORIN	USE IN CONJUNCTION WITH HIGH-DOSE METHOTREXATE IN THE TREATMENT OF OSTEOSARCOMA.	LEDERLE LABORATORIES
GENERIC: LODOXAMIDE TROMETHAMINE ALOMIDE	TREATMENT OF VERNAL KERATOCONJUNCTIVITIS.	ALCON LABORATORIES, INC
GENERIC: METRONIDAZOLE TRADE: METROGEL	TREATMENT OF PERIORAL DERMATITIS.	CURATEK PHARMACEUTICALS MEDICAL CENTER

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: NIFEDIPINE TRADE: NOT ESTABLISHED	TREATMENT OF INTERSTITIAL CYSTITIS.	JONATHAN FLEISCHMANN, M.D. CLEVELAND METROHEALTH
GENERIC: OFLOXACIN TRADE: NOT ESTABLISHED	TREATMENT OF BACTERIAL CORNEAL ULCERS.	ALLERGAN, INC
GENERIC: OM 401 TRADE: DREPANOL	PROPHYLACTIC TREATMENT OF SICKLE CELL DISEASE.	OMEX INTERNATIONAL, INC
GENERIC: OXANDROLONE TRADE: OXANDRIN	ADJUNCTIVE THERAPY FOR AIDS PATIENTS SUFFERING FROM HIV-WASTING SYNDROME.	GYNEX, INC
GENERIC: PENTOSTATIN TRADE: NPENT*/**	TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA. TREATMENT OF HAIRY CELL LEUKEMIA. (SINGLE AGENT TREATMENT FOR ADULT PATIENTS WITH ALPHA-INTERFERON-REFRACTORY HAIRY CELL LEUKEMIA. */** [OCT 11, 1998])	PARKE-DAVIS
GENERIC: POLOXAMER 331 TRADE: PROTOX	INITIAL THERAPY OF TOXOPLASMOSIS IN PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	BURROUGHS WELLCOME COMPANY
GENERIC: PRAMIRACETAM SULFATE TRADE: NOT ESTABLISHED	FOR THE MANAGEMENT OF COGNITIVE DYSFUNCTION AND ENHANCEMENT OF ANTIDEPRESSANT ACTIVITY ASSOCIATED WITH ELECTROCONVULSIVE THERAPY.	CAMBRIDGE NEUROSCIENCE, INC
GENERIC: RECOMBINANT BETA-GLUCOCEREBROSIDASE TRADE: NOT ESTABLISHED	FOR REPLACEMENT THERAPY IN PATIENTS WITH TYPES I, II, AND III GAUCHER'S DISEASE.	GENZYME CORPORATION
GENERIC: RECOMBINANT HUMAN SUPEROXIDE DISMUTASE TRADE: NOT ESTABLISHED	PREVENTION OF BRONCHOPULMONARY DYSPLASIA IN PREMATURE NEONATES WEIGHING LESS THAN 1500 GMS.	BIO TECHNOLOGY GENERAL CORP
GENERIC: RIBAVIRIN TRADE: VIRAZOLE	TREATMENT OF HEMORRHAGIC FEVER WITH RENAL SYNDROME.	ICN PHARMACEUTICALS, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: SOMATROPIN TRADE: SAIZEN	TREATMENT OF AIDS-ASSOCIATED CATABOLISM/WEIGHT LOSS.	SERONO LABORATORIES, INC
GENERIC: SUCCIMER TRADE: CHEMET*/**	TREATMENT OF LEAD POISONING IN CHILDREN.*/** [JAN 30, 1998] TREATMENT OF MERCURY INTOXICATION.	MCNEIL
GENERIC: SUCRALFATE TRADE: NOT ESTABLISHED	TREATMENT OF ORAL ULCERATIONS AND DYSPHAGIA IN PATIENTS WITH EPIDERMOLYSIS BULLOSA.	NASKA PHARMACAL CO
GENERIC: TESTOSTERONE PROPIONATE TRADE: NOT ESTABLISHED	TREATMENT OF VULVAR DYSTROPHIES.	STAR PHARMACEUTICALS, INC
GENERIC: TESTOSTERONE SUBLINGUAL TRADE: NOT ESTABLISHED	TREATMENT OF CONSTITUTIONAL DELAY OF GROWTH AND PUBERTY IN BOYS.	GYNEX, INC
GENERIC: TIRAPRICOL TRADE: TRIACANA	USE IN COMBINATION WITH LEVO-THYROXINE TO SUPPRESS THYROID STIMULATING HORMONE (TSH) IN PATIENTS WITH WELL-DIFFERENTIATED THYROID CANCER WHO ARE INTOLERANT TO ADEQUATE DOSES OF LEVO-THYROXINE ALONE.	MEDSENIX GROUP
GENERIC: TOREMIFENE TRADE: NOT ESTABLISHED	HORMONAL THERAPY OF METASTATIC CARCINOMA OF THE BREAST.	ADRIA LABORATORIES, INC
GENERIC: URSDODEOXYCHOLIC ACID TRADE: ACTIGALL	MANAGEMENT OF THE CLINICAL SIGNS AND SYMPTOMS ASSOCIATED WITH PRIMARY BILIARY CIRRHOsis.	CIBA GEIGY
GENERIC: URSDODEOXYCHOLIC ACID TRADE: URSOFAK	TREATMENT OF PATIENTS WITH PRIMARY BILIARY CIRRHOsis.	INTERFALK U.S., INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: 3,4 DIAMINOPYRADINE TRADE: DYNAMINE	TREATMENT OF HEREDITARY MOTOR AND SENSORY NEUROPATHY TYPE 1 (CHARCOT-MARIE-TOOTH DISEASE).	MAYO CLINIC
GENERIC: 6-METHYLENANDROSTA-1,4-DIENE-3,17-DIONE TRADE: NOT ESTABLISHED	HORMONAL THERAPY OF METASTATIC CARCINOMA OF THE BREAST.	ADRIA LABORATORIES, INC
GENERIC: 566C80 TRADE: NOT ESTABLISHED	PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA (PCP) IN HIGH-RISK, HIV-INFECTED PATIENTS DEFINED BY ONE OR BOTH OF THE FOLLOWING CRITERIA: (1) A HISTORY OF ONE OR MORE EPISODES OF PCP, (2) A PERIPHERAL CD4+ (T4 HELPER/INDUCER) LYMPHOCYTE COUNT LESS THAN OR EQUAL TO 200/MM ³ .	BURROUGHS WELLCOME COMPANY

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

NO NOVEMBER 1991 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

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

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 11TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

DRUG NAME (DOSAGE FORM)

ESTROGENS, CONJUGATED (TABLET)

DATE

AUG 21, 1991

REVISED DATE

ANDA SUITABILITY PETITIONS

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

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 11TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

PETITIONS APPROVED		DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
DRUG NAME DOSEAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)				
CARBAMAZEPINE SUSPENSION; ORAL	200MG/5ML	89 P-0399/CP	GUIDELINES	NEW DOSAGE FORM	APPROVED MAY 16, 1991
CLOBETASOL PROPIONATE LOTION; TOPICAL	0.05%	90 P-0198/ CP1	KROSS	NEW DOSAGE FORM	APPROVED MAR 14, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	100MG/VIAL	90 P-0250/ CP1	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	200MG/VIAL	90 P-0250/ CP2	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	500MG/VIAL	90 P-0250/ CP3	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	1GM/VIAL	90 P-0250/ CP4	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYTARABINE INJECTABLE; INJECTION	20MG/ML (100ML/CONTAINER)	86 P-0428/ CP005	ADRIA	NEW DOSAGE FORM	APPROVED OCT 28, 1991
DOPAMINE HYDROCHLORIDE INJECTABLE; INJECTION	5MG/ML	90 P-0137/ CP1	ABBOTT	NEW STRENGTH	APPROVED APR 10, 1991

ANDA SUITABILITY PETITIONS

DRUG NAME DOSEAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	PETITIONS APPROVED	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (25ML/VIAL)	91 P-0041/ CP1	ADRIA		NEW STRENGTH	APPROVED MAY 22, 1991
ESTRADIOL FILM, EXTENDED RELEASE; TRANSDERMAL	0.067MG/24HR	90 P-0125/ CP1	NOVEN PHARMS		NEW STRENGTH	APPROVED MAR 14, 1991
ESTRADIOL FILM, EXTENDED RELEASE; TRANSDERMAL	0.084MG/24HR	90 P-0125/ CP2	NOVEN PHARMS		NEW STRENGTH	APPROVED MAR 14, 1991
NIFEDIPINE CAPSULE, EXTENDED RELEASE; ORAL	30MG 60MG 90MG	90 P-0436/ CP1	KV		NEW DOSAGE FORM	APPROVED OCT 23, 1991
PANCURONIUM BROMIDE INJECTABLE; INJECTION	0.1MG/ML	91 P-0006/ CP1	LYPHOMED		NEW STRENGTH	APPROVED OCT 28, 1991
TECHNETIUM TC99 MEDRONATE KIT INJECTABLE; INJECTION	N/A	91 P-0040/ CP1	ABARIS		NEW STRENGTH	APPROVED OCT 28, 1991
TERFENADINE CAPSULE; ORAL	60MG	91 P-0087 CP1	ARTHUR A. CHECCHI		NEW DOSAGE FORM	APPROVED OCT 28, 1991

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
FUROSEMIDE INJECTABLE; INJECTION	1MG/ML	90 P-0313/ CP1	LYPHOMED	NEW STRENGTH	DENIED OCT 28, 1991

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 11TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW INDICATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES
NEW INDICATION

- 1-55 HYPERTENSION
1-56 EROSION GASTROESOPHAGEAL REFLUX DISEASE
1-57 SHORT-TERM TREATMENT OF ACTIVE DUODENAL ULCER
1-58 INITIAL TREATMENT OF ADVANCED OVARIAN CARCINOMA IN COMBINATION WITH OTHER APPROVED CHEMOTHERAPEUTIC AGENTS
1-59 ENDOSCOPICALLY DIAGNOSED ESOPHAGITIS, INCLUDING EROSION AND ULCERATIVE ESOPHAGITIS, AND ASSOCIATED HEARTBURN DUE TO GASTROESOPHAGEAL REFLUX DISEASE
1-60 SINGLE APPLICATION TREATMENT OF HEAD LICE IN CHILDREN TWO MONTHS TO TWO YEARS IN AGE
1-61 FEMALE ANDROGENETIC ALOPECIA
1-62 PREVENTION AND TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS
1-63 ONCE DAILY TREATMENT AS INITIAL THERAPY IN THE TREATMENT OF HYPERTENSION
1-64 PREVENTION OF SUPRAVENTRICULAR ARRHYTHMIAS
1-65 PREVENTION OF UPPER GASTROINTESTINAL BLEEDING IN CRITICALLY ILL PATIENTS

REFERENCES
PATENT USE CODE

- U-44 RELIEF OF NAUSEA AND VOMITING
U-45 TREATMENT OF INFLAMMATION AND ANALGESIA
U-46 TREATMENT OF PANIC DISORDER
U-47 STIMULATION OF THE RELEASE OF GROWTH HORMONE
U-48 ANALGESIA

EXCLUSIVITY TERMS**REFERENCES****PATENT USE CODE**

SYMPTOMATIC CANCER-RELATED HYPERCALCEMIA
USE IN TREATING INFLAMMATORY DERMATOSES
BLOOD POOL IMAGING, INCLUDING FIRST PASS AND GATED EQUILIBRIUM IMAGING AND FOR DETECTION OF SITES OF GASTROINTESTINAL BLEEDING
TREATMENT OF ADULT AND PEDIATRIC PATIENTS (OVER SIX MONTHS OF AGE) WITH ADVANCED HIV INFECTION
HYPERCALCEMIA OF MALIGNANCY
HYPERCALCEMIA OR ANTAGONIST OF NONDEPOLARIZING NEUROMUSCULAR BLOCKING AGENTS
REVERSAL AGENT OR ANTAGONIST OF NONDEPOLARIZING NEUROMUSCULAR BLOCKING AGENTS

U-49

U-50

U-51

U-52

U-53

U-54

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS EXPIRES
>ADD>	20089 001 ACYCLOVIR; ZOVIRAX	4199574	APR 22, 1997	NCE	MAR 29, 1992
>ADD>	20089 002 ACYCLOVIR; ZOVIRAX	4199574	APR 22, 1997	I-45	APR 26, 1993
>ADD>	20057 003 ALGLUCERASE; CEREDASE	4508726	APR 02, 2002	NCE	MAR 29, 1992
	18276 001 ALPRAZOLAM; XANAX	4508726	APR 02, 2002	I-45	APR 26, 1993
	18276 002 ALPRAZOLAM; XANAX	4508726	APR 02, 2002	NCE	APR 05, 1996
	18276 003 ALPRAZOLAM; XANAX	4508726	APR 02, 2002	ODE	APR 05, 1998
	18276 004 ALPRAZOLAM; XANAX	3980789	SEP 14, 1993	ODE	DEC 26, 1997
	19926 001 ALTRETAMINE; HEXALEN	4105783	OCT 26, 1995	NCE	JUL 31, 1994
	19155 001 AMMONIUM LACTATE; LAC-HYDRIN	4072746	APR 23, 1998	U-7	NOV 06, 1994
	18700 001 AMRINONE LACTATE; INOCOR	4952586	AUG 28, 2007	U-54	NOV 06, 1994
>ADD>	19677 001 ATROPLINE SULFATE; ENLON-PLUS	4952586	AUG 28, 2007	U-54	NOV 06, 1994
>ADD>	19678 001 ATROPLINE SULFATE; ENLON-PLUS	4410520	OCT 18, 2000	NCE	JUN 25, 1996
	19851 001 BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2000	NCE	JUN 25, 1996
	19851 002 BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2000	NCE	JUN 25, 1996
	19851 003 BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2000	NCE	JUN 25, 1996
	19851 004 BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2000	NCE	JUN 25, 1996
	20032 001 BERACTANT; SURVANTA	4397839	AUG 10, 2000	NCE	JUL 01, 1996
	18709 001 CAPTOPRIL; CAPOTIDE 25/15			I-63	OCT 24, 1994
	18709 002 CAPTOPRIL; CAPOTIDE 25/25			I-63	OCT 24, 1994
	18709 003 CAPTOPRIL; CAPOTIDE 50/25			I-63	OCT 24, 1994
	18709 004 CAPTOPRIL; CAPOTIDE 50/15			I-63	OCT 24, 1994
	19856 001 CARBIDOPA; SINemet CR	4900755	MAY 23, 2006	NDF	MAY 30, 1994
		4832957	MAY 23, 2006	I-58	JUL 05, 1994
		3830827	AUG 20, 1991	I-58	JUL 05, 1994
		4140707	AUG 25, 1998	I-58	JUL 05, 1994
		4140707	AUG 25, 1998	I-58	JUL 05, 1994
		4140707	AUG 25, 1998	I-58	JUL 05, 1994
		4312860	NOV 23, 2001	NC	AUG 02, 1993
		3950333	APR 13, 1993	I-56	MAR 07, 1994
		3950333	APR 13, 1993	I-56	MAR 07, 1994
		3950333	APR 13, 1993	I-56	MAR 07, 1994
		3950333	APR 13, 1993	I-56	MAR 07, 1994
		3950333	APR 13, 1993	I-56	MAR 07, 1994
>ADD>	19880 001 CARBOPLATIN; PARAPLATIN			I-58	NOV 13, 1994
	19880 002 CARBOPLATIN; PARAPLATIN			I-58	NOV 13, 1994
	19880 003 CARBOPLATIN; PARAPLATIN			I-58	NOV 13, 1994
	20044 001 CETYL ALCOHOL; EXOSURF NEONATAL			I-58	NOV 13, 1994
	17920 002 CIMETIDINE; TAGAMET			I-56	NOV 07, 1994
	17920 003 CIMETIDINE; TAGAMET			I-56	NOV 07, 1994
	17920 004 CIMETIDINE; TAGAMET			I-56	NOV 07, 1994
	17920 005 CIMETIDINE; TAGAMET			I-56	NOV 07, 1994
	17924 001 CIMETIDINE HYDROCHLORIDE; TAGAMET			I-56	NOV 07, 1994
	17939 002 CIMETIDINE HYDROCHLORIDE; TAGAMET			I-56	NOV 07, 1994

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19849 001	DAPIPRAZOLE HYDROCHLORIDE; REV-EYES	4252721	FEB 24, 1998	NCE	DEC 31, 1995	
19082 001	DEZOCINE; DALGAN	4605671	AUG 12, 2003	NCE	DEC 29, 1994	
		4001331	JAN 04, 1996	U-48		
19082 002	DEZOCINE; DALGAN	3836670	SEP 09, 1991			
19082 003	DEZOCINE; DALGAN	4605671	AUG 12, 2003	NCE	DEC 29, 1994	
		4001331	JAN 04, 1996	U-48		
20037 001	DICLOFENAC SODIUM; VOLTAREN	3836670	SEP 09, 1991	U-48		
		4960779	OCT 02, 2007	NDF	MAR 28, 1994	
20154 002	DIDANOOSINE; VIDEX	3652762	MAR 28, 1991	NCE	OCT 09, 1996	
20154 003	DIDANOOSINE; VIDEX	4861759	AUG 29, 2006	U-52	NCE	OCT 09, 1996
20154 004	DIDANOOSINE; VIDEX	4861759	AUG 29, 2006	U-52	NCE	OCT 09, 1996
20154 005	DIDANOOSINE; VIDEX	4861759	AUG 29, 2006	U-52	NCE	OCT 09, 1996
20155 003	DIDANOOSINE; VIDEX	4861759	AUG 29, 2006	U-52	NCE	OCT 09, 1996
20155 004	DIDANOOSINE; VIDEX	4861759	AUG 29, 2006	U-52	NCE	OCT 09, 1996
20155 005	DIDANOOSINE; VIDEX	4861759	AUG 29, 2006	U-52	NCE	OCT 09, 1996
20155 006	DIDANOOSINE; VIDEX	4861759	AUG 29, 2006	U-52	NCE	OCT 09, 1996
20156 001	DIDANOOSINE; VIDEX	4861759	AUG 29, 2006	U-52	NCE	OCT 09, 1996
20027 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM	4988731	JAN 29, 2008	NDF	OCT 24, 1994	
20027 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM	4988731	JAN 29, 2008	NDF	OCT 24, 1994	
18723 001	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008	NDF	OCT 24, 1994	
18723 002	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008	NDF	OCT 24, 1994	
18723 003	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008	NDF	OCT 24, 1994	
19680 001	DIVALPROEX SODIUM; DEPAKOTE CP	4988731	JAN 29, 2008	NDF	OCT 24, 1994	
19794 001	DIVALPROEX SODIUM; DEPAKOTE CP	4988731	JAN 29, 2008	NDF	OCT 24, 1994	
19794 002	DIVALPROEX SODIUM; DEPAKOTE CP	4988731	JAN 29, 2008	NDF	OCT 24, 1994	
19946 001	DOXAQUIRUM CHLORIDE; NUROMAX	4701460	OCT 20, 2004	NCE	MAR 07, 1996	
19668 001	DOXAZOSEN MESYLATE; CARDURA	4188390	FEB 12, 1999	NCE	NOV 02, 1995	
19668 002	DOXAZOSEN MESYLATE; CARDURA	4188390	FEB 12, 1999	NCE	NOV 02, 1995	
19668 003	DOXAZOSEN MESYLATE; CARDURA	4188390	FEB 12, 1999	NCE	NOV 02, 1995	
19668 004	DOXAZOSEN MESYLATE; CARDURA	4188390	FEB 12, 1999	NCE	NOV 02, 1995	
19080 001	ESTAZOLAM; PROSOM	3987052	OCT 19, 1995	I-62	OCT 24, 1994	
19080 002	ESTAZOLAM; PROSOM	3987052	OCT 19, 1995	I-62	OCT 24, 1994	
19081 002	ESTRADOL; ESTRADERM			I-62	BIG 24/1994	
19081 003	ESTRADOL; ESTRADERM			I-62	BIG 24/1994	
>ADD>	ESTRADIOL/ESTRADERM			NC	DEC 29, 1992	
>DLT>				NC	DEC 29, 1992	
19081 002	ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1996			
19653 001	ETHINYL ESTRADIOL; ORTHO CYCLEN-28	4027019	MAY 31, 1996			
19653 002	ETHINYL ESTRADIOL; ORTHO CYCLEN-28					

**PREScription AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA**

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
18686 001	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998	NCE	AUG 01, 1994	
18687 001	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998	NCE	AUG 01, 1994	
18687 002	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998	NCE	AUG 01, 1994	
18687 003	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998	NCE	AUG 01, 1994	
18687 004	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998	NCE	AUG 01, 1994	
18716 001	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998	NCE	AUG 01, 1994	
18716 002	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998	NCE	AUG 01, 1994	
18716 003	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998	NCE	AUG 01, 1994	
18716 004	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998	NCE	AUG 01, 1994	
19425 001	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998	NCE	AUG 01, 1994	
20035 001	LEVAMISOLE HYDROCHLORIDE; ERGAMISOL	4584305	JUN 19, 2004	U-42	NCE	JUN 18, 1995
20088 001	LEVONORGESTREL; NORPLANT SYSTEM	3850911	NOV 26, 1991	NP	DEC 10, 1993	
19753 001	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1994	NCE	JUN 19, 1995	
19753 002	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1994	NCE	JUN 19, 1995	
19753 003	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1994	NCE	JUN 19, 1995	
19886 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1999	NCE	FEB 13, 1995	
18612 001	NICOTINE POLACRILEX; NICORETTE	3901248	AUG 26, 1992	NCE	JAN 13, 1994	
19684 001	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003	D-2	SEP 06, 1992	
19684 002	NIFEDIPINE; PROCARDIA XL	4765989	SEP 16, 2003	D-2	SEP 06, 1992	
19684 003	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003	I-55	SEP 06, 1992	
19508 001	NIZATIDINE; AXID	4783337	SEP 16, 2003	D-2	SEP 06, 1992	
19508 002	NIZATIDINE; AXID	4765989	SEP 16, 2003	I-55	SEP 06, 1992	
19757 001	NORFLOXACIN; CHIBROXIN	4382090	MAY 03, 2000	U-18	JUL 26, 1994	
		4382090	MAY 03, 2000	U-18	JUL 26, 1994	
19735 001	OFLOXACIN; FLOXIN	4551456	NOV 05, 2002	NDF	JUN 17, 1994	
19735 002	OFLOXACIN; FLOXIN	4146719	MAR 27, 1998			
19735 003	OFLOXACIN; FLOXIN	4382892	MAY 10, 2002			
19715 001	OLSALAZINE SODIUM; DIPENTUM	4382892	MAY 10, 2002			
19810 001	OMEPRAZOLE; PRILOSEC	4559330	AUG 04, 2004	NCE	JUL 31, 1995	
20007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4255431	MAR 10, 2000	I-57	JUN 12, 1994	
		4753789	JUN 28, 2005	NCE	JAN 04, 1996	
		4695578	JAN 03, 2005			
		4695578	SEP 22, 2004			

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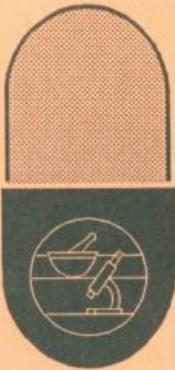
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PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20036 001	PAMIDRONATE DISODIUM; AREDIA	4711880 3962432 3923785	DEC 08, 2004 JUN 08, 1993 DEC 02, 1992	U-53	NCE	OCT 31, 1996
20122 001	PENTOSTATIN; NIPENT	3737433 RE31244 RE31244	APR 03, 1997 NOV 08, 1996 NOV 08, 1996	U-3 U-3	ODE NCE NCE	OCT 11, 1996 AUG 30, 1994 DEC 28, 1994
18631 001	PENTOXIFYLLINE; TRENTAL	4346227	AUG 24, 1999		NCE	OCT 22, 1994
19456 001	PINACIDIL; PINDAC	4346227	AUG 24, 1999		NCE	OCT 31, 1996
19456 002	PINACIDIL; PINDAC	4242334	DEC 30, 1997	U-50	NE	SEP 23, 1994
19797 001	POLYETHYLENE GLYCOL 3350; NULYTLY	4056635	NOV 01, 1996		NCE	OCT 02, 1994
19898 002	PRAVASTATIN SODIUM; PRAVACHOL	3878217	APR 15, 1994		NC	AUG 19, 1994
19898 003	PRAVASTATIN SODIUM; PRAVACHOL	4743450	MAY 10, 2005		NCE	NOV 19, 1996
19568 001	PREDNICARBATE; DERMATOP	4344949	AUG 17, 1999	U-3	NCE	NOV 19, 1996
19627 001	PROPOFOL; DIPRIVAN	4743450	MAY 10, 2005		NCE	NOV 19, 1996
19664 001	PSEUDOEPHEDRINE HYDROCHLORIDE; SELDANE-D	4344949	AUG 17, 1999	U-3	NCE	NOV 19, 1996
>ADD>	19885 001 QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4743450	MAY 10, 2005		NCE	NOV 19, 1996
>ADD>	19885 002 QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	AUG 17, 1999	U-3	NCE	NOV 19, 1996
>ADD>	19885 003 QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4743450	MAY 10, 2005		NCE	NOV 19, 1996
>ADD>	19885 004 QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	AUG 17, 1999	U-3	NCE	NOV 19, 1996
>ADD>	19901 001 RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>ADD>	19901 002 RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>ADD>	19901 003 RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>ADD>	19901 004 RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>ADD>	19863 001 SERMORELIN ACETATE; GEREFT	4703035	DEC 28, 2004	U-47	NCE	DEC 28, 1995
>DLI>	19998 002 SUCCIMER; CHEMET	470338 4517181	MAY 14, 2002	U-47	NCE	DEC 28, 1995
19981 001	TECHNETIUM TC-99M RED BLOOD CELL KIT; ULTRATAG	4755375	JUL 05, 2005	U-51	ODE	JAN 30, 1996
19775 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4452774	SEP 09, 2004		NC	JUN 10, 1994
19775 002	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4452774	SEP 09, 2004		NCE	DEC 21, 1995

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD> 18163 001	TEMAZEPAM; RESTORIL			NS	OCT 25,	1994
>ADD> 18163 002	TEMAZEPAM; RESTORIL			NS	OCT 25,	1994
>ADD> 18163 003	TEMAZEPAM; RESTORIL			NS	OCT 25,	1994
>ADD> 19979 001	TICLOPIDINE HYDROCHLORIDE; TICLID	4591592	MAY 27, 2003		NCE	OCT 31, 1996
19979 002	TICLOPIDINE HYDROCHLORIDE; TICLID	4051141	SEP 27, 1994		NCE	OCT 31, 1996
19798 001	TRIAMCINOLONE ACETONIDE; NASACORT	4591592	MAY 27, 2003		NR	JUL 11, 1994
		4051141	MAY 27, 2003			
		4051141	SEP 27, 1994			

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