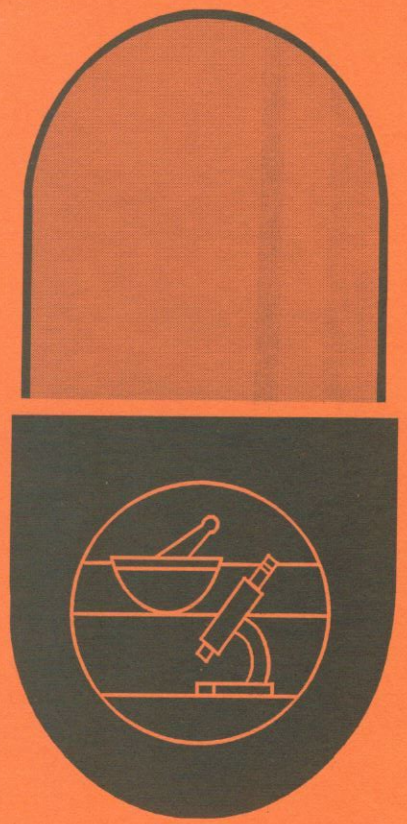
CUMULATIVE
SUPPLEMENT 4
JAN'96-APR'96



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

16TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT
DIVISION OF DRUG INFORMATION RESOURCES

1996

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

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Cumulative Supplement 4

APRIL 1996

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CUMULATIVE SUPPLEMENT 4
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1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 16th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

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

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

Additions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >**ADD**> to the left of the line on which new information exists. The >**ADD**> symbol is then dropped in subsequent Cumulative Supplements for that item.

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

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 16th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 17th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

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

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

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

1.3 CHANGE OF A THERAPEUTIC EQUIVALENT CODE FOR A DRUG ENTITY

Propantheline Bromide

The purpose of this notice is to advise you that the Agency is considering changing the therapeutic equivalence code for propantheline bromide tablets (PB tablets) as shown in the Agency's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations, 16th Edition,* (Orange Book) from "**AA**" to "**BP**". The Agency classified this DESI drug product as not having an actual or potential bioequivalence problem on January 7, 1977 (42 FR 1624). There are five companies that have approved Abbreviated New Drug Applications (ANDA's) for this drug product. The reason for this proposed change is that the Agency has evidence from a well-controlled, *in vivo* bioequivalence

study submitted by Roberts Pharmaceutical Corporation (Roberts), the holder of the approved New Drug Application for Pro-Banthine, that Roxane Laboratories' propantheline bromide tablets, 15mg., that meet the *in vitro* determination of bioequivalence, do not meet the Agency's *in vivo* bioequivalence approval criteria.

The Office of Generic Drugs (OGD) thoroughly examined Roberts' study. The Office of Compliance's Division of Scientific Investigations inspected Roberts' manufacturing facilities and Phoenix's (Roberts' contractor) clinical study records. These activities validated the results of the Roberts' study. OGD concluded that Roxane's PB tablets do not fall entirely within the 80-125% confidence interval for C_{max} and AUC when compared to Roberts' Pro-Banthine tablets. This failure to fall entirely within 80-125% confidence intervals does not prove that the products are not bioequivalent. It shows that the criteria for bioequivalence required by OGD were not met. To prove that they are not bioequivalent, the entire confidence interval of either C_{max} or AUC would have to be outside of the 80-125% interval.

Simply stated, the Roberts' study proved neither bioequivalence nor bioinequivalence. This study, however, did raise significant concerns regarding the Agency's original decision to classify PB tablets as "**AA**" (not having actual or potential bioequivalence problems), and not require an *in vivo* bioequivalence study to support the approval of generic versions. Therefore, the Agency is proposing to change the therapeutic equivalence code from a non-bioequivalence problem drug to a bioequivalence problem drug for PB tablets.

You have 60 days in which to submit written comments about this notice to the Director, Division of Bioequivalence, Office of Generic Drugs, Center for Drug Evaluation and Research, MPN2, HFD-650, 7500 Standish Place, Rockville, MD 20855. After the Agency reviews the comments, it will print its decision in their next Orange Book supplement following the close of the comment period.

If the proposal is enacted, the Agency will require a firm that holds an approved ANDA for this drug product to submit an *in vivo* bioequivalence study in a supplement [under 21 CFR Section 314.70(b)] to OGD within a specific time period. If an *in vivo* bioequivalence study is not submitted, the Agency will proceed to change the therapeutic code from "**AA**" to "**BP**". If a firm submits a bioequivalence study, the Agency will review the study and then make a determination regarding the therapeutic equivalence code for that product. An applicant with a pending ANDA will have to amend its application with an *in vivo* bioequivalence study, and a firm submitting a new ANDA must include an *in vivo* study in the application.

A firm wishing to submit written comments to the Agency on this notice, may do so within sixty days from the first of the month following the publication of the monthly supplement. A firm may request a copy of the OGD review of Roberts' *in vivo* bioequivalence study by writing to the Agency's Freedom of Information Office (HFI-35), 5600 Fishers Lane, Rockville, MD 20857.

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

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

1.5 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

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

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
1ST TEXAS PHARMACEUTICALS INC SUB SCHERER LABORATORIES (1ST TX)	SCHERER LABORATORIES, INC (SCHERER)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
BOEHRINGER MANNHEIM PHARMACEUTICALS CORP (BOEHRINGER MANNHEIM)	BOEHRINGER MANNHEIM CORPORATION THERAPEUTICS DIVISION (BOEHRINGER MANNHEIM)
DAVID BULL LABORATORIES PARTY LTD (BULL D)	FH FAULDING AND CO LTD (FAULDING) **THEN CHANGED TO** FAULDING PHARMACEUTICAL CO (FAULDING)
HOECHST ROUSSEL PHARMACEUTICALS INC (HOECHST ROUSSEL)	HOECHST MARION ROUSSEL INC (HOECHST MARION RSSL)
SCHWARZ PHARMA KREMERS URBAN CO SUB SCHWARZ PHARMA AG (SPKU)	SCHWARZ PHARMA INC (SCHWARZ PHARMA)

1.6 AVAILABILITY OF THE PUBLICATION AND UPDATING PROCEDURES

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

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

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

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

1.7 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 1995) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 1995	MAR 1996	JUN 1996	SEP 1996
DRUG PRODUCTS LISTED	9286	9303		
SINGLE SOURCE	2217 (23.9%)	2248 (24.2%)		
MULTISOURCE	7069 (76.1%)	7055 (75.8%)		
THERAPEUTICALLY EQUIVALENT	6437 (69.3%)	6425 (69.0%)		
NOT THERAPEUTICALLY EQUIVALENT	440 (4.7%)	443 (4.8%)		
EXCEPTIONS[1]	192 (2.1%)	187 (2.0%)		
NEW MOLECULAR ENTITIES APPROVED	--	6		
NUMBER OF APPLICANTS	586	592		

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

PRESCRIPTION DRUG PRODUCT LIST
16TH EDITION
RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 4 / JAN'96 - APR'96

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL
ESGIC-PLUS
+ MIKART 500MG;50MG;40MG N40085 001 MAR 28, 1996

TABLET; ORAL
BUTALBITAL, ACETAMINOPHEN AND CAFFEINE
MIKART 500MG;50MG;40MG N89451 001 MAY 23, 1988
+ 500MG;50MG;40MG N89451 001 MAY 23, 1988

ACETAMINOPHEN; CODEINE PHOSPHATE

SOLUTION; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE
> ADD > AA HI TECH PHARMA 120MG/5ML;12MG/5ML N40119 001 APR 26, 1996
> ADD >

TYLENOL W/ CODEINE
> DLT > AA JOHNSON RW 120MG/5ML;12MG/5ML N85057 001
> ADD > AA + 120MG/5ML;12MG/5ML N85057 001

TABLET; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE
AA GENEVA PHARMS 300MG;30MG N85291 002
AA 300MG;60MG N85964 001
@ 300MG;30MG N85291 002
@ 300MG;60MG N85964 001
AA HALSEY 300MG;60MG N86549 001
@ 300MG;60MG N86549 001
AA MIKART 300MG;30MG N89238 001 FEB 25, 1986
> DLT > AA 300MG;60MG N89244 001 FEB 25, 1986
> DLT >
> ADD > @ 300MG;60MG N89244 001 FEB 25, 1986
> ADD >

ACETAMINOPHEN AND CODEINE PHOSPHATE #3
AA MIKART 300MG;30MG N89238 001 FEB 25, 1986
AA SUPERPHARM 300MG;30MG N89184 001 OCT 18, 1985
@ 300MG;30MG N89184 001 OCT 18, 1985

ACETAMINOPHEN AND CODEINE PHOSPHATE #4
AA SUPERPHARM 300MG;60MG N89185 001 OCT 18, 1985

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE #4
@ SUPERPHARM 300MG;60MG N89185 001 OCT 18, 1985

ACETAMINOPHEN W/ CODEINE PHOSPHATE
AA HALSEY 300MG;15MG N83871 001
AA 300MG;30MG N83872 001
@ 300MG;15MG N83871 001
@ 300MG;30MG N83872 001

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN
AA ROYCE LABS 500MG;2.5MG N40123 003 MAR 04, 1996
AA 500MG;5MG N40122 001 MAR 04, 1996
AA 500MG;7.5MG N40123 004 MAR 04, 1996
AA 650MG;7.5MG N40123 001 MAR 04, 1996
AA 650MG;10MG N40123 002 MAR 04, 1996
AA 750MG;7.5MG N40122 002 MAR 04, 1996
AA VINTAGE PHARMS 500MG;7.5MG N40144 001 FEB 22, 1996
AA 650MG;10MG N40143 001 FEB 22, 1996
> ADD > AA 750MG;7.5MG N40157 001 APR 12, 1996
> ADD >
LORTAB
UCB 500MG;10MG N40100 001 JAN 26, 1996

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN
AB SUPERPHARM 650MG;100MG N71319 001 JAN 06, 1987
@ 650MG;100MG N71319 001 JAN 06, 1987

AMINO ACIDS

INJECTABLE; INJECTION
AMINOSYN-HF 8%
ABBOTT 8% N20345 001
APR 04, 1996

HEPATASOL 8%
BAXTER 8% N20360 001
APR 04, 1996

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE
@ PHOENIX LABS NY 100MG N85409 001
@ 200MG N85410 001
@ VINTAGE PHARMS 100MG N85409 001
@ 200MG N85410 001

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL
BP HALSEY 25MG N85922 001
@ 25MG N85922 001
ENDEP
AB ROCHE 150MG N85303 001
@ 150MG N85303 001

AMOXICILLIN

TABLET, CHEWABLE; ORAL
AMOXICILLIN
AB CLONMEL HLTH CARE 125MG N64139 001
JAN 29, 1996
AB 250MG N64139 002
JAN 29, 1996

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET; ORAL
AUGMENTIN '875'
+ SMITHKLINE BEECHAM 875MG;EQ 125MG BASE N50720 001
FEB 13, 1996

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

TABLET; ORAL
ADDERALL 10
RICHWOOD PHARM 2.5MG;2.5MG;2.5MG;2.5MG N11522 007
FEB 13, 1996

ADDERALL 20
+ RICHWOOD PHARM 5MG;5MG;5MG;5MG N11522 008
FEB 13, 1996

AMPHOTERICIN B

SUSPENSION; ORAL
FUNGIZONE
+ BRISTOL MYERS SQUIBB 100MG/ML N50341 003

AMPICILLIN/AMPICILLIN TRIHYDRATE; PROBENECID

POWDER FOR RECONSTITUTION; ORAL
POLYCILLIN-PRB
AB + APOTHECON EQ 3.5GM BASE/BOT;1GM/BOT N61898 001
@ EQ 3.5GM BASE/BOT;1GM/BOT N61898 001
PROBAMPACIN
AB BIOCRAFT EQ 3.5GM BASE/BOT;1GM/BOT N61741 001
+ EQ 3.5GM BASE/BOT;1GM/BOT N61741 001

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL
BUTALBITAL, ASPIRIN & CAFFEINE
AB HALSEY 325MG;50MG;40MG N89448 001
DEC 01, 1986
@ 325MG;50MG;40MG N89448 001
DEC 01, 1986

ASPIRIN; CARISOPRODOL

TABLET; ORAL
CARISOPRODOL AND ASPIRIN
AB EON LABS 325MG;200MG N40116 001
APR 25, 1996

ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE

TABLET; ORAL

> ADD >		CARISOPRODOL, ASPIRIN AND CODEINE PHOSPHATE		
> ADD >	AB	EON LABS	325MG;200MG;16MG	N40118 001 APR 16, 1996
> ADD >				
		SOMA COMPOUND W/ CODEINE		
> ADD >	AB	+ WALLACE PHARMS	325MG;200MG;16MG	N12366 002 JUL 11, 1983
> ADD >				

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

	LOGEN		
AA	SUPERPHARM	0.025MG;2.5MG	N88962 001 MAY 10, 1985
	@	0.025MG;2.5MG	N88962 001 MAY 10, 1985
	LOW-QUEL		
AA	HALSEY	0.025MG;2.5MG	N85211 001
	@	0.025MG;2.5MG	N85211 001

AZATHIOPRINE

TABLET; ORAL

	AZATHIOPRINE		
AB	ROXANE	50MG	N74069 001 FEB 16, 1996
	IMURAN		
AB	+ GLAXO WELLCOME	50MG	N16324 001

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

	BLENOXANE		
	+ BRISTOL	EQ 15 UNITS BASE/VIAL	N50443 001
	+ BRISTOL MYERS SQUIBB	EQ 15 UNITS BASE/VIAL	N50443 001

BROMPHENIRAMINE MALEATE

TABLET; ORAL

		DIMETANE		
> DLT >	AA	+ ROBINS AH	4MG	N10799 003
> ADD >		@ WHITEHALL ROBINS	4MG	N10799 003

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

	BUSPAR		
> DLT >	+ BRISTOL MYERS SQUIBB	10MG	N18731 002 SEP 29, 1986
> DLT >			
> ADD >		10MG	N18731 002 SEP 29, 1986
> ADD >			
> ADD >	+	15MG	N18731 003 APR 22, 1996
> ADD >			
> ADD >	@	30MG	N18731 004 APR 22, 1996
> ADD >			

BUTABARBITAL SODIUM

ELIXIR; ORAL

	SARISOL		
AA	HALSEY	30MG/5ML	N84723 001
	@	30MG/5ML	N84723 001

TABLET; ORAL

	SARISOL NO. 1		
AA	HALSEY	15MG	N84719 001
	@	15MG	N84719 001
	SARISOL NO. 2		
AA	HALSEY	30MG	N84719 002
	@	30MG	N84719 002

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

SOLUTION; INTRAPERITONEAL

	DELFLEX W/ DEXTROSE 1.5% IN PLASTIC CONTAINER		
AT	FRESENIUS	25.7MG/100ML;1.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML	N18379 002
	DELFLEX W/ DEXTROSE 2.5% IN PLASTIC CONTAINER		
AT	FRESENIUS	25.7MG/100ML;2.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML	N18379 003
	DELFLEX W/ DEXTROSE 3.5% IN PLASTIC CONTAINER		
AT	FRESENIUS	25.7MG/100ML;3.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML	N18379 007 JUN 24, 1988

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

SOLUTION; INTRAPERITONEAL

DELFLEX W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

AT	FRESENIUS	25.7MG/100ML;4.25GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML	N18379 001

DELFLEX-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

AT	FRESENIUS	25.7MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML	N18379 004 JUL 07, 1982

DELFLEX-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

AT	FRESENIUS	25.7MG/100ML;2.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML	N18379 005 JUL 07, 1982

DELFLEX-LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

AT	FRESENIUS	25.7MG/100ML;3.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML	N18379 008 JUN 24, 1988

DELFLEX-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

AT	FRESENIUS	25.7MG/100ML;4.25GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML	N18379 006 JUL 07, 1982

INPERSOL W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

AT	FRESENIUS	25.7MG/100ML;1.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML	N18379 002

INPERSOL W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

AT	FRESENIUS	25.7MG/100ML;2.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML	N18379 003

INPERSOL W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

AT	FRESENIUS	25.7MG/100ML;3.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML	N18379 007 JUN 24, 1988	> ADD > > ADD > > ADD >

INPERSOL W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

AT	FRESENIUS	25.7MG/100ML;4.25GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML	N18379 001	> ADD > > ADD > > ADD > > ADD > > ADD >

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

SOLUTION; INTRAPERITONEAL

INPERSOL-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

AT	FRESENIUS	25.7MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML	N18379 004 JUL 07, 1982

INPERSOL-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

AT	FRESENIUS	25.7MG/100ML;2.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML	N18379 005 JUL 07, 1982

INPERSOL-LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

AT	FRESENIUS	25.7MG/100ML;3.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML	N18379 008 JUN 24, 1988

INPERSOL-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

AT	FRESENIUS	25.7MG/100ML;4.25GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML	N18379 006 JUL 07, 1982

CAPTOPRIL

TABLET; ORAL

CAPTOPRIL

AB	BIOCRAFT	12.5MG	N74433 001 FEB 13, 1996
AB		25MG	N74433 002 FEB 13, 1996
AB		50MG	N74433 003 FEB 13, 1996
AB		100MG	N74433 004 FEB 13, 1996
AB	CHELSEA LABS	12.5MG	N74576 001 APR 23, 1996
AB		25MG	N74576 002 APR 23, 1996
AB		50MG	N74576 003 APR 23, 1996
AB		100MG	N74576 004 APR 23, 1996
AB	COPLEY PHARM	12.5MG	N74462 001 FEB 13, 1996

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL

AB	COPLEY PHARM	25MG	N74462 002 FEB 13, 1996
AB		50MG	N74462 003 FEB 13, 1996
AB		100MG	N74462 004 FEB 13, 1996
AB	ENDO LABS	12.5MG	N74418 001 FEB 13, 1996
AB		25MG	N74418 002 FEB 13, 1996
AB		50MG	N74418 003 FEB 13, 1996
AB		100MG	N74418 004 FEB 13, 1996
AB	EON LABS	12.5MG	N74519 001 FEB 13, 1996
AB		25MG	N74519 002 FEB 13, 1996
AB		50MG	N74519 003 FEB 13, 1996
AB		100MG	N74519 004 FEB 13, 1996
AB	HALLMARK PHARMS	12.5MG	N74477 001 FEB 13, 1996
AB		25MG	N74477 002 FEB 13, 1996
AB		50MG	N74477 003 FEB 13, 1996
AB		100MG	N74477 004 FEB 13, 1996
AB	INVAMED	12.5MG	N74481 001 FEB 13, 1996
AB		25MG	N74481 002 FEB 13, 1996
AB		50MG	N74481 003 FEB 13, 1996
AB		100MG	N74481 004 FEB 13, 1996
AB	LEMMON	12.5MG	N74483 001 FEB 13, 1996
AB		25MG	N74483 002 FEB 13, 1996
AB		50MG	N74483 003 FEB 13, 1996

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL

AB	LEMMON	100MG	N74483 004 FEB 13, 1996
AB	MOVA	12.5MG	N74423 001 FEB 13, 1996
AB		25MG	N74423 002 FEB 13, 1996
AB		50MG	N74423 003 FEB 13, 1996
AB		100MG	N74423 004 FEB 13, 1996
AB	MYLAN	12.5MG	N74434 001 FEB 13, 1996
AB		25MG	N74434 002 FEB 13, 1996
AB		50MG	N74434 003 FEB 13, 1996
AB		100MG	N74434 004 FEB 13, 1996
AB	NOVOPHARM	12.5MG	N74322 001 FEB 13, 1996
AB		25MG	N74322 002 FEB 13, 1996
AB		50MG	N74322 003 FEB 13, 1996
AB		100MG	N74322 004 FEB 13, 1996
AB	PAR PHARM	12.5MG	N74493 001 FEB 13, 1996
AB		25MG	N74493 002 FEB 13, 1996
AB		50MG	N74493 003 FEB 13, 1996
AB		100MG	N74493 004 FEB 13, 1996
AB	ROYCE LABS	12.5MG	N74451 001 FEB 13, 1996
AB		25MG	N74451 002 FEB 13, 1996
AB		50MG	N74451 003 FEB 13, 1996
AB		100MG	N74451 004 FEB 13, 1996
AB	WESTWARD PHARM	12.5MG	N74505 001 FEB 13, 1996

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL

AB	WESTWARD PHARM	25MG	N74505 002 FEB 13, 1996
AB		50MG	N74505 003 FEB 13, 1996
AB		100MG	N74505 004 FEB 13, 1996

CARBAMAZEPINE

TABLET, EXTENDED RELEASE; ORAL
TEGRETOL-XR

+	CIBA GEIGY	100MG	N20234 001 MAR 25, 1996	> DLT > > DLT >
+		200MG	N20234 002 MAR 25, 1996	> DLT > > DLT >
+		400MG	N20234 003 MAR 25, 1996	> ADD > > ADD > > ADD > > ADD >

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL

AA	WEST WARD PHARM	350MG	N40124 001 JAN 24, 1996

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
ANCEF IN DEXTROSE 5% IN PLASTIC CONTAINER

+	BAXTER	EQ 10MG BASE/ML	N50566 003 JUN 08, 1983
+		EQ 20MG BASE/ML	N50566 004 JUN 08, 1983
@		EQ 10MG BASE/ML	N50566 003 JUN 08, 1983
@		EQ 20MG BASE/ML	N50566 004 JUN 08, 1983

CEFEPIME HYDROCHLORIDE (ARGININE FORMULATION)

INJECTABLE; INJECTION
MAXIPIME

+	BRISTOL MYERS SQUIBB	EQ 500MG BASE/VIAL	N50679 001 JAN 18, 1996
+		EQ 1GM BASE/VIAL	N50679 002 JAN 18, 1996
+		EQ 2GM BASE/VIAL	N50679 003 JAN 18, 1996

CEPHALEXIN

CAPSULE; ORAL
CEPHALEXIN

AB	YOSHITOMI	EQ 250MG BASE	N62872 001 JUN 20, 1988
AB		EQ 500MG BASE	N62871 001 JUL 05, 1988
@		EQ 250MG BASE	N62872 001 JUN 20, 1988
@		EQ 500MG BASE	N62871 001 JUL 05, 1988

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
CHLORDIAZEPOXIDE HCL

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

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

AB	BARR	100MG	N88812 001 OCT 19, 1984
AB		100MG	N89446 001 NOV 17, 1986
AB		250MG	N88813 001 OCT 19, 1984

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

AB	BARR	250MG	N89447 001 NOV 17, 1986	
	@	100MG	N88812 001 OCT 19, 1984	
	@	100MG	N89446 001 NOV 17, 1986	
	@	250MG	N88813 001 OCT 19, 1984	
	@	250MG	N89447 001 NOV 17, 1986	
AB	HALSEY	100MG	N89321 001 JAN 16, 1986	
AB		250MG	N88662 001 JAN 09, 1986	
	@	100MG	N89321 001 JAN 16, 1986	
	@	250MG	N88662 001 JAN 09, 1986	
AB	SUPERPHARM	250MG	N88695 001 SEP 17, 1984	
	@	250MG	N88695 001 SEP 17, 1984	

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

AB	SUPERPHARM	50MG	N87247 001 FEB 09, 1983
	@	50MG	N87247 001 FEB 09, 1983

CHOLESTYRAMINE

POWDER; ORAL
PREVALITE

AB	UPSHER SMITH	EQ 4GM RESIN/PACKET	N73263 001 FEB 22, 1996	
	QUESTRAN			
AB	+ BRISTOL MYERS	EQ 4GM RESIN/PACKET	N16640 001	> ADD >
AB		EQ 4GM RESIN/SCOOPFUL	N16640 003	> ADD >
	QUESTRAN LIGHT			
AB	+ BRISTOL MYERS	EQ 4GM RESIN/PACKET	N19669 001 DEC 05, 1988	

CHOLESTYRAMINE

POWDER; ORAL
QUESTRAN LIGHT

AB	BRISTOL MYERS	EQ 4GM RESIN/PACKET	N19669 001 DEC 05, 1988
AB		EQ 4GM RESIN/SCOOPFUL	N19669 003 DEC 05, 1988

CHROMIC CHLORIDE

INJECTABLE; INJECTION
CHROMIC CHLORIDE

AP	FUJISAWA	EQ 0.004MG CHROMIUM/ML	N19271 001 MAY 05, 1987
	@	EQ 0.004MG CHROMIUM/ML	N19271 001 MAY 05, 1987
	CHROMIC CHLORIDE IN PLASTIC CONTAINER		
AP	+ ABBOTT	EQ 0.004MG CHROMIUM/ML	N18961 001 JUN 26, 1986
	+	EQ 0.004MG CHROMIUM/ML	N18961 001 JUN 26, 1986

CIMETIDINE

TABLET; ORAL
CIMETIDINE

AB	DANBURY PHARMA	800MG	N74316 001 FEB 28, 1996
AB	INVAMED	200MG	N74506 001 JAN 24, 1996
AB		300MG	N74506 002 JAN 24, 1996
AB		400MG	N74506 003 JAN 24, 1996
AB		800MG	N74506 004 JAN 24, 1996

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
CIMETIDINE HCL

AP	MOVA	EQ 300MG BASE/2ML	N74428 001 APR 25, 1996

CIPROFLOXACIN HYDROCHLORIDE

TABLET; ORAL
CIPRO
> ADD > BAYER EQ 100MG BASE N19537 001
> ADD > APR 08, 1996

CLOBETASOL PROPIONATE

OINTMENT; TOPICAL
CLOBETASOL PROPIONATE
AB FOUGERA 0.05% **N74407 001**
FEB 23, 1996

CLOMIPRAMINE HYDROCHLORIDE

CAPSULE; ORAL
ANAFRANIL
AB CIBA GEIGY 25MG **N19906 001**
DEC 29, 1989
AB + 50MG **N19906 002**
DEC 29, 1989
AB 75MG **N19906 003**
DEC 29, 1989

CLOMIPRAMINE HCL
AB GENEVA PHARMS 25MG **N74364 001**
MAR 29, 1996
AB 50MG **N74364 002**
MAR 29, 1996
AB 75MG **N74364 003**
MAR 29, 1996

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
> DLT > **PHERAZINE VC W/ CODEINE**
> DLT > AA HALSEY 10MG/5ML;5MG/5ML; **N88870 001**
> DLT > 6.25MG/5ML MAR 02, 1987
> DLT >
> ADD > @ 10MG/5ML;5MG/5ML; N88870 001
> ADD > 6.25MG/5ML MAR 02, 1987
> ADD >

CROMOLYN SODIUM

CONCENTRATE; ORAL
GASTROCROM
+ FISONS 100MG/5ML N20479 001
FEB 29, 1996

DALTEPARIN SODIUM

INJECTABLE; INJECTION
FRAGMIN
+ PHARMACIA 5,000 IU/0.2ML N20287 003
MAR 18, 1996

> ADD > DAUNORUBICIN CITRATE

> ADD > INJECTABLE, LIPOSOMAL; INJECTION
> ADD > DAUNOXOME
> ADD > + NEXSTAR EQ 2MG BASE/ML N50704 002
> ADD > APR 08, 1996

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPRAMINE HCL
AB EON LABS 10MG N74430 001
FEB 09, 1996
AB 150MG **N74430 002**
FEB 09, 1996

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
DEXACIDIN
AT CIBA 0.1%;EQ 3.5MG BASE/GM; N62566 001
10,000 UNITS/GM FEB 22, 1985
AT IOLAB 0.1%;EQ 3.5MG BASE/GM; N62566 001
10,000 UNITS/GM FEB 22, 1985

SUSPENSION/DROPS; OPHTHALMIC
DEXACIDIN
AT CIBA 0.1%;EQ 3.5MG BASE/ML; **N62544 001**
10,000 UNITS/ML OCT 29, 1984

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

	DEXACIDIN		
AT	IOLAB	0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62544 001 OCT 29, 1984

> ADD > DEXFENFLURAMINE HYDROCHLORIDE

> ADD > CAPSULE; ORAL
> ADD > REDUX
> ADD > + INTERNEURON 15MG N20344 001 APR 29, 1996
> ADD >

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

	DEXTROAMPHETAMINE SULFATE		
AA	HALSEY	10MG	N83930 001
	@	10MG	N83930 001
AA	MM MAST	5MG	N86521 001
	@	5MG	N86521 001
AA	+ REXAR	10MG	N84051 002
	+	10MG	N84051 002

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

	PHERAZINE DM		
> DLT > AA HALSEY 15MG/5ML;6.25MG/5ML N88913 001 MAR 02, 1987
> DLT >
> DLT > @ 15MG/5ML;6.25MG/5ML N88913 001 MAR 02, 1987
> ADD >
> ADD >

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL

	DICLOFENAC SODIUM		
AB	PUREPAC PHARM	50MG	N74514 001 MAR 26, 1996
AB		75MG	N74514 002 MAR 26, 1996

DICLOFENAC SODIUM

TABLET, EXTENDED RELEASE; ORAL

	VOLTAREN-XR		
	+ GEIGY	100MG	N20254 001 MAR 08, 1996

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL

	DICYCLOMINE HCL		
AB	LANNETT	10MG	N84285 001

DIGOXIN

INJECTABLE; INJECTION

	DIGOXIN PEDIATRIC		
> ADD > AP SANOFI WINTHROP 0.1MG/ML N40092 001 APR 25, 1996
> ADD >
> ADD > LANOXIN
> DLT > + GLAXO WELLCOME 0.1MG/ML N09330 004
> DLT > **LANOXIN PEDIATRIC**
> ADD > AP + GLAXO WELLCOME 0.1MG/ML N09330 004
> ADD >

DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION

	CARDIZEM		
AP	+ HOECHST MARION RSSL	5MG/ML	N20027 001 OCT 24, 1991
	DILTIAZEM HCL		
AP	BEDFORD	5MG/ML	N74617 001 FEB 28, 1996

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

	DIPHENHYDRAMINE HCL		
AA	HALSEY	50MG	N87914 001 JUN 04, 1984
	@	50MG	N87914 001 JUN 04, 1984

ELIXIR; ORAL

	BELIX		
AA	HALSEY	12.5MG/5ML	N86586 001 OCT 03, 1983

DIPHENHYDRAMINE HYDROCHLORIDE

ELIXIR; ORAL
BELIX

	@ HALSEY	12.5MG/5ML	N86586 001 OCT 03, 1983

DISOPYRAMIDE PHOSPHATE

CAPSULE, EXTENDED RELEASE; ORAL
DISOPYRAMIDE PHOSPHATE

B*	KV PHARM	EQ 100MG BASE	N71929 001 AUG 19, 1988
	@	EQ 100MG BASE	N71929 001 AUG 19, 1988
	NORPACE CR		
AB	SEARLE	**EQ 100MG BASE**	**N18655 001** **JUL 20, 1982**
		EQ 100MG BASE	N18655 001 JUL 20, 1982

DOXYCYCLINE HYCLATE

TABLET; ORAL
DOXYCYCLINE HYCLATE

AB	SUPERPHARM	**EQ 100MG BASE**	**N62494 001** **FEB 20, 1985**
	@	EQ 100MG BASE	N62494 001 FEB 20, 1985

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION
EDROPHONIUM CHLORIDE

AP	STERIS	**10MG/ML**	**N40044 001** MAR 20, 1996
	EDROPHONIUM CHLORIDE PRESERVATIVE FREE		
AP	STERIS	**10MG/ML**	**N40043 001** MAR 20, 1996
	TENSILON PRESERVATIVE FREE		
AP	+ ROCHE	**10MG/ML**	**N07959 002**

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL W/ EPINEPHRINE

AP	ABBOTT	**0.01MG/ML;1%**	**N83154 001**
	@	0.01MG/ML;1%	N83154 001

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION
ERYTHROCIN

AP	ABBOTT	**EQ 500MG BASE/VIAL**	**N62586 001** **JAN 04, 1988**
AP		**EQ 1GM BASE/VIAL**	**N62586 002** **JAN 04, 1988**
	@	EQ 500MG BASE/VIAL	N62586 001 JAN 04, 1988
	@	EQ 1GM BASE/VIAL	N62586 002 JAN 04, 1988

ESTRADIOL

INSERT, EXTENDED RELEASE; VAGINAL
ESTRING

	+ PHARMACIA	0.0075MG/24HR	N20472 001 APR 26, 1996

TABLET; ORAL
ESTRACE

AB	BRISTOL MYERS SQUIBB	**0.5MG**	**N81295 001** JUN 30, 1993
AB		**1MG**	**N84499 001**
AB	+	**2MG**	**N84500 001**
	ESTRADIOL		
AB	WATSON LABS	**0.5MG**	**N40114 003** MAR 14, 1996
AB		**1MG**	**N40114 001** MAR 14, 1996
AB		**2MG**	**N40114 002** MAR 14, 1996

ESTRONE

INJECTABLE; INJECTION
ESTROGENIC SUBSTANCE

BP	+ WYETH AYERST	2MG/ML	N83488 001

ESTRONE

INJECTABLE; INJECTION
ESTROGENIC SUBSTANCE

	@ WYETH AYERST	2MG/ML	N83488 001
	NATURAL ESTROGENIC SUBSTANCE-ESTRONE		
BP	STERIS	2MG/ML	N85237 001 NOV 23, 1982
	+	2MG/ML	N85237 001 NOV 23, 1982

ETOPOSIDE

INJECTABLE; INJECTION
ETOPOSIDE

AP	LEDERLE LABS	20MG/ML	N74513 001 MAR 14, 1996
AP	PHARMACHEMIE (NL)	20MG/ML	N74227 001 FEB 22, 1996

EVANS BLUE

INJECTABLE; INJECTION
EVANS BLUE

	@ PARKE DAVIS	0.5%	N08041 001

FAMCICLOVIR

TABLET; ORAL
FAMVIR

> ADD >	SMITHKLINE BEECHAM	250MG	N20363 001 APR 26, 1996
> ADD >			

FLUOROURACIL

INJECTABLE; INJECTION
ADRUCIL

AP	+ PHARMACIA	50MG/ML	N40023 001 OCT 18, 1991
AP		50MG/ML	N40023 001 OCT 18, 1991
	FLUOROURACIL		
AP	ROCHE	50MG/ML	N12209 001
AP	+	50MG/ML	N12209 001

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL

AB	SUPERPHARM	15MG	N71659 001 AUG 04, 1988
AB		30MG	N71660 001 AUG 04, 1988
	@	15MG	N71659 001 AUG 04, 1988
	@	30MG	N71660 001 AUG 04, 1988

FLUTICASONE PROPIONATE

AEROSOL, METERED; INHALATION
FLOVENT

	GLAXO WELLCOME	0.044MG/INH	N20548 001 MAR 27, 1996
		0.11MG/INH	N20548 002 MAR 27, 1996
	+	0.22MG/INH	N20548 003 MAR 27, 1996

FOLIC ACID

TABLET; ORAL
FOLIC ACID

AA	HALSEY	1MG	N83598 001
	@	1MG	N83598 001

FUROSEMIDE

TABLET; ORAL
FUROSEMIDE

AB	SUPERPHARM	20MG	N18370 002 JUN 26, 1984
AB		40MG	N18370 001 FEB 10, 1983
	@	20MG	N18370 002 JUN 26, 1984
	@	40MG	N18370 001 FEB 10, 1983
AB	ZENITH GOLDLINE	20MG	N18413 001 NOV 30, 1983

FUROSEMIDE

TABLET; ORAL
FUROSEMIDE

AB	ZENITH GOLDLINE	40MG	N18413 002 NOV 30, 1983
AB	ZENITH LABS	20MG	N18413 001 NOV 30, 1983
AB		40MG	N18413 002 NOV 30, 1983

GANCICLOVIR

IMPLANT; IMPLANTATION
VITRASERT

+	CHIRON VISION	4.5-6.4MG	N20569 001 MAR 04, 1996

GENTAMICIN SULFATE

INJECTABLE; INJECTION
GENTAMICIN SULFATE

> DLT >	AP	ABBOTT	EQ 60MG BASE/100ML	N62413 006 AUG 11, 1983
> DLT >	AP		EQ 70MG BASE/100ML	N62413 007 AUG 11, 1983
> DLT >	AP		EQ 80MG BASE/100ML	N62413 008 AUG 11, 1983
> DLT >	AP		EQ 90MG BASE/100ML	N62413 009 AUG 11, 1983
> DLT >	AP		EQ 100MG BASE/100ML	N62413 010 AUG 11, 1983
> DLT >	AP		EQ 1.2MG BASE/ML	N62413 001 AUG 11, 1983
> DLT >	AP		EQ 1.4MG BASE/ML	N62413 002 AUG 11, 1983
> DLT >	AP		EQ 1.6MG BASE/ML	N62413 003 AUG 11, 1983
> DLT >	AP		EQ 1.8MG BASE/ML	N62413 004 AUG 11, 1983
> DLT >	AP		EQ 2MG BASE/ML	N62413 005 AUG 11, 1983
> ADD >		@	EQ 60MG BASE/100ML	N62413 006 AUG 11, 1983
> ADD >		@	EQ 70MG BASE/100ML	N62413 007 AUG 11, 1983
> ADD >		@ ABBOTT	EQ 80MG BASE/100ML	N62413 008 AUG 11, 1983
> ADD >		@	EQ 90MG BASE/100ML	N62413 009 AUG 11, 1983
> ADD >		@	EQ 100MG BASE/100ML	N62413 010 AUG 11, 1983
> ADD >		@	EQ 1.2MG BASE/ML	N62413 001 AUG 11, 1983
> ADD >		@	EQ 1.4MG BASE/ML	N62413 002 AUG 11, 1983
> ADD >		@	EQ 1.6MG BASE/ML	N62413 003 AUG 11, 1983
> ADD >		@	EQ 1.8MG BASE/ML	N62413 004 AUG 11, 1983
> ADD >		@	EQ 2MG BASE/ML	N62413 005 AUG 11, 1983

OINTMENT; OPHTHALMIC
GENTACIDIN

AT	CIBA	EQ 0.3% BASE	N62501 001 JUL 26, 1984
AT	IOLAB	EQ 0.3% BASE	N62501 001 JUL 26, 1984

SOLUTION/DROPS; OPHTHALMIC
GENTACIDIN

AT	CIBA	EQ 0.3% BASE	N62480 001 MAR 30, 1984
AT	IOLAB	EQ 0.3% BASE	N62480 001 MAR 30, 1984

GLIPIZIDE

TABLET; ORAL
GLIPIZIDE

AB	NOVOPHARM	5MG	N74387 001 MAR 04, 1996
AB		10MG	N74387 002 MAR 04, 1996

GLYBURIDE

TABLET; ORAL

	GLYNASE		
AB	UPJOHN	3MG	N20051 002 MAR 04, 1992
AB +		3MG	N20051 002 MAR 04, 1992
+		6MG	N20051 004 SEP 24, 1993
@		6MG	N20051 004 SEP 24, 1993

GOSERELIN ACETATE

IMPLANT; IMPLANTATION

	ZOLADEX		
+	ZENECA	EQ 10.8MG BASE	N20578 001 JAN 11, 1996

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC

	NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN		
AT	BAUSCH AND LOMB	0.025MG/ML;EQ 1.75MG BASE/ML; 10,000 UNITS/ML	N64047 001 JAN 31, 1996

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

	HALDOL DECANOATE 100		
+	JOHNSON RW	EQ 100MG BASE/ML	N18701 002 OCT 31, 1989

HALOPROGIN

> DLT >	CREAM; TOPICAL			
> DLT >	HALOTEX			
> DLT >	+ WESTWOOD SQUIBB	1%	N16942 001	
> ADD >	@	1%	N16942 001	

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

	HYDRALAZINE HCL		
AA	HALSEY	10MG	N89218 001 JAN 22, 1986
@		10MG	N89218 001 JAN 22, 1986

HYDROCHLOROTHIAZIDE

TABLET; ORAL

	HYDRO-D		
AB	HALSEY	25MG	N86504 001
AB		50MG	N83891 002
@		25MG	N86504 001
@		50MG	N83891 002
	HYDROCHLOROTHIAZIDE		
AB	BARR	50MG	N84771 001
@		50MG	N84771 001
AB	SUPERPHARM	25MG	N88827 001 DEC 28, 1984
AB		50MG	N88828 001 DEC 28, 1984
AB		100MG	N88829 001 DEC 28, 1984
@		25MG	N88827 001 DEC 28, 1984
@		50MG	N88828 001 DEC 28, 1984
@		100MG	N88829 001 DEC 28, 1984

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

	METHYLDOPA AND HYDROCHLOROTHIAZIDE		
> DLT > AB	NOVOPHARM	15MG;250MG	N71819 001 APR 08, 1988
> DLT > AB		25MG;250MG	N71820 001 APR 08, 1988
> DLT > AB		30MG;500MG	N71821 001 APR 08, 1988
> DLT > AB		50MG;500MG	N71822 001 APR 08, 1988
> ADD > @		15MG;250MG	N71819 001 APR 08, 1988

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
METHYLDOPA AND HYDROCHLOROTHIAZIDE

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

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

> ADD >	AB	SIDMAK LABS NJ	25MG;37.5MG	N74026 001 APR 26, 1996
> ADD >				
	AB		50MG;75MG	N73467 001 JAN 31, 1996

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

AT	AMBIX	1%	N86080 001
AT		2.5%	N86271 001
	@	1%	N86080 001
	@	2.5%	N86271 001

OINTMENT; TOPICAL
HYDROCORTISONE

AT	AMBIX	1%	N86079 001

HYDROCORTISONE

OINTMENT; TOPICAL
HYDROCORTISONE

AT	AMBIX	2.5%	N86272 001
	@	1%	N86079 001
	@	2.5%	N86272 001

PENECORT

AT	ALLERGAN HERBERT	2.5%	N88217 001 JUN 06, 1984
	@	2.5%	N88217 001 JUN 06, 1984

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-HYDROCORT

AP	ABBOTT	EQ 100MG BASE/VIAL	N85928 001
	@	EQ 100MG BASE/VIAL	N85928 001

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL
HYDROXYCHLOROQUINE SULFATE

AB	INVAMED	200MG	N40150 001 JAN 27, 1996

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL
HYDROXYZINE HCL

AB	HALSEY	10MG	N89366 001 MAY 02, 1988
	@	10MG	N89366 001 MAY 02, 1988
AB	SUPERPHARM	10MG	N88794 001 DEC 05, 1984
AB		25MG	N88795 001 DEC 05, 1984
AB		50MG	N88796 001 DEC 05, 1984
	@	10MG	N88794 001 DEC 05, 1984
	@	25MG	N88795 001 DEC 05, 1984

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL
HYDROXYZINE HCL

	@ SUPERPHARM	50MG	N88796 001 DEC 05, 1984

IBUPROFEN

TABLET; ORAL
IBUPROFEN

AB	HALSEY	300MG	N71028 001 MAR 23, 1987
AB		400MG	N71029 001 MAR 23, 1987
AB		600MG	N71030 001 MAR 23, 1987
AB		800MG	N72137 001 FEB 05, 1988
	@	300MG	N71028 001 MAR 23, 1987
	@	400MG	N71029 001 MAR 23, 1987
	@	600MG	N71030 001 MAR 23, 1987
	@	800MG	N72137 001 FEB 05, 1988

INDAPAMIDE

TABLET; ORAL
INDAPAMIDE

	AB	MYLAN	2.5MG	N74461 001 MAR 27, 1996
> ADD >	AB	ZENITH GOLDLINE	1.25MG	N74299 002 APR 29, 1996
> ADD >	AB		2.5MG	N74299 001 JUL 27, 1995
> DLT >	AB	ZENITH LABS	2.5MG	N74299 001 JUL 27, 1995
		LOZOL		
> ADD >	AB	RHONE POULENC RORER	1.25MG	N18538 002 APR 29, 1993

INDINAVIR SULFATE

CAPSULE; ORAL
CRIXIVAN

	MERCK	EQ 200MG BASE	N20685 003 MAR 13, 1996
	+	EQ 400MG BASE	N20685 001 MAR 13, 1996

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

AB	HALSEY	25MG	N70782 001 JUN 03, 1987
AB		50MG	N70635 001 JUN 03, 1987
	@	25MG	N70782 001 JUN 03, 1987
	@	50MG	N70635 001 JUN 03, 1987

IODIXANOL

INJECTABLE; INJECTION

	VISIPAQUE 270		
	+ NYCOMED	55%	N20351 001 MAR 22, 1996
	VISIPAQUE 320		
	+ NYCOMED	65.2%	N20351 002 MAR 22, 1996

IOPAMIDOL

INJECTABLE; INJECTION

ISOVUE-200		
@ BRACCO	41%	N20327 001 OCT 12, 1994
ISOVUE-250		
BRACCO	51%	N20327 002 OCT 12, 1994
ISOVUE-300		
BRACCO	61%	N20327 003 OCT 12, 1994
ISOVUE-370		
BRACCO	76%	N20327 004 OCT 12, 1994

IOPAMIDOL

INJECTABLE; INTRAVASCULAR
ISOVUE-200
@ BRACCO 41% N20327 001 OCT 12, 1994

ISOVUE-250
BRACCO 51% N20327 002 OCT 12, 1994

ISOVUE-300
BRACCO 61% N20327 003 OCT 12, 1994

ISOVUE-370
BRACCO 76% N20327 004 OCT 12, 1994

IRON DEXTRAN

INJECTABLE; INJECTION
DEXFERRUM
BP LUITPOLD EQ 50MG IRON/ML N40024 001 FEB 23, 1996

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL
IMDUR
@ SCHERING 30MG N20225 001 AUG 12, 1993
+ 30MG N20225 001 AUG 12, 1993

KETAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
KETALAR
AP + PARKE DAVIS **EQ 50MG BASE/ML** **N16812 002**
AP + **EQ 100MG BASE/ML** **N16812 003**
KETAMINE HCL
AP BEDFORD **EQ 50MG BASE/ML** **N74524 001** MAR 22, 1996
AP **EQ 100MG BASE/ML** **N74524 002** MAR 22, 1996

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL
AP ABBOTT **20%** **N89362 001** MAY 25, 1988
@ 20% N89362 001 MAY 25, 1988

SOLUTION; ORAL
LIDOCAINE HCL
AT MORTON GROVE **2%** **N87872 001** NOV 18, 1982

LIDOCAINE HCL VISCOUS
AT INTL MEDICATION **2%** **N86389 001** FEB 02, 1982
@ 2% N86389 001 FEB 02, 1982

MYLOCAINE
AT MORTON GROVE **2%** **N87872 001** NOV 18, 1982

SOLUTION; TOPICAL
ANESTACON
AT + ALCON **2%** **N80429 001**
AT + POLYMEDICA **2%** **N80429 001**
LIDOCAINE HCL
AT MORTON GROVE **4%** **N87881 001** NOV 18, 1982

MYLOCAINE
AT MORTON GROVE **4%** **N87881 001** NOV 18, 1982

LINDANE

CREAM; TOPICAL
KWELL
+ REED AND CARNRICK 1% N06309 001
1% N84218 001
@ 1% N06309 001
+ 1% N84218 001

LOTION; TOPICAL
KWELL
AT + REED AND CARNRICK **1%** **N06309 003**
AT **1%** **N84218 002**
AT + **1%** **N84218 002**
@ 1% N06309 003

LINDANE

SHAMPOO; TOPICAL

	KWELL		
AT	+ REED AND CARNRICK	1%	N10718 001
AT		1%	N84219 001
AT	+	1%	N84219 001
	@	1%	N10718 001

LITHIUM CITRATE

SYRUP; ORAL

> DLT >		CIBALITH-S		
> DLT >	AA	SOLVAY	EQ 300MG CARBONATE/5ML	N17672 001
> ADD >		LITHONATE		
> ADD >		@ SOLVAY	EQ 300MG CARBONATE/5ML	N17672 001

LORACARBEF

CAPSULE; ORAL

		LORABID		
> DLT >		+ LILLY	200MG	N50668 001 DEC 31, 1991
> DLT >				
> ADD >			200MG	N50668 001 DEC 31, 1991
> ADD >				
> ADD >		+	400MG	N50668 002 APR 05, 1996
> ADD >				

LORAZEPAM

TABLET; ORAL

	LORAZEPAM		
AB	HALSEY	0.5MG	N71434 001 SEP 01, 1987
AB		1MG	N71435 001 SEP 01, 1987
AB		2MG	N71436 001 SEP 01, 1987
	@	0.5MG	N71434 001 SEP 01, 1987
	@	1MG	N71435 001 SEP 01, 1987
	@	2MG	N71436 001 SEP 01, 1987
AB	SUPERPHARM	0.5MG	N71245 001 FEB 09, 1987

LORAZEPAM

TABLET; ORAL

	LORAZEPAM		
AB	SUPERPHARM	1MG	N71246 001 FEB 09, 1987
AB		2MG	N71247 001 FEB 09, 1987
	@	0.5MG	N71245 001 FEB 09, 1987
	@	1MG	N71246 001 FEB 09, 1987
	@	2MG	N71247 001 FEB 09, 1987

MANGANESE CHLORIDE

INJECTABLE; INJECTION

> DLT >	MANGANESE CHLORIDE IN PLASTIC CONTAINER		
> DLT >	ABBOTT	EQ 0.1MG MANGANESE/ML	N18962 001 JUN 26, 1986
> DLT >			
> DLT >			
> ADD >	@	EQ 0.1MG MANGANESE/ML	N18962 001 JUN 26, 1986
> ADD >			

MANGANESE SULFATE

INJECTABLE; INJECTION

	MANGANESE SULFATE		
	FUJISAWA	EQ 0.1MG MANGANESE/ML	N19228 001 MAY 05, 1987
	@	EQ 0.1MG MANGANESE/ML	N19228 001 MAY 05, 1987

MECLOFENAMATE SODIUM

CAPSULE; ORAL

	MECLOFENAMATE SODIUM		
AB	BARR	EQ 50MG BASE	N72848 001 MAR 20, 1989
AB		EQ 100MG BASE	N72809 001 MAR 20, 1989
	@	EQ 50MG BASE	N72848 001 MAR 20, 1989
	@	EQ 100MG BASE	N72809 001 MAR 20, 1989

MEPROBAMATE

TABLET; ORAL

		MEPROBAMATE		
	AA	BARR	**600MG**	**N84230 001**
		@	600MG	N84230 001
> DLT >		**NEURAMATE**		
> DLT >	**AA**	HALSEY	**200MG**	**N14359 002**
> DLT >	**AA**		**400MG**	**N14359 001**
> ADD >		@	200MG	N14359 002
> ADD >		@	400MG	N14359 001

METHADONE HYDROCHLORIDE

CONCENTRATE; ORAL

		METHADOSE		
	AA	MALLINCKRODT	**10MG/ML**	**N17116 002**
	AA	+	**10MG/ML**	**N17116 002**

METHYLDOPA

TABLET; ORAL

		METHYLDOPA		
	AB	HALSEY	**500MG**	**N71753 001 MAR 28, 1988**
		@	500MG	N71753 001 MAR 28, 1988
	AB	NOVOPHARM	**125MG**	**N71105 001 DEC 05, 1986**
	AB		**250MG**	**N71106 001 DEC 05, 1986**
	AB		**500MG**	**N71067 001 DEC 05, 1986**
		@	125MG	N71105 001 DEC 05, 1986
		@	250MG	N71106 001 DEC 05, 1986
		@	500MG	N71067 001 DEC 05, 1986

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

		METOCLOPRAMIDE HCL		
	AB	HALSEY	**EQ 10MG BASE**	**N70906 001 OCT 28, 1986**

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

		METOCLOPRAMIDE HCL		
		@ HALSEY	EQ 10MG BASE	N70906 001 OCT 28, 1986
	AB	SCHERING	**EQ 10MG BASE**	**N70598 001 FEB 02, 1987**
		@	EQ 10MG BASE	N70598 001 FEB 02, 1987
	AB	SUPERPHARM	**EQ 10MG BASE**	**N70926 001 JUN 26, 1987**
		@	EQ 10MG BASE	N70926 001 JUN 26, 1987

METRONIDAZOLE

TABLET; ORAL

		METRONIDAZOLE		
	AB	HALSEY	**250MG**	**N70021 001 APR 02, 1985**
	AB		**500MG**	**N70593 001 FEB 27, 1986**
		@	250MG	N70021 001 APR 02, 1985
		@	500MG	N70593 001 FEB 27, 1986
	AB	ZENITH GOLDLINE	**250MG**	**N18517 001**
	AB		**500MG**	**N18517 002 MAY 05, 1982**
	AB	ZENITH LABS	**250MG**	**N18517 001**
	AB		**500MG**	**N18517 002 MAY 05, 1982**

MICONAZOLE NITRATE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL

> DLT >		MONISTAT DUAL-PAK		
> DLT >	*	JOHNSON RW	2%,200MG	N18888 002 OCT 17, 1988
> DLT >				
> DLT >				

MINOXIDIL

SOLUTION; TOPICAL

		ROGAINE		
	*	UPJOHN	2%	N19501 001 AUG 17, 1988

NADOLOL

TABLET; ORAL
NADOLOL

AB	ZENITH LABS	80MG	N74255 001 JAN 24, 1996
AB		120MG	N74255 002 JAN 24, 1996
AB		160MG	N74255 003 JAN 24, 1996

NAPROXEN

TABLET; ORAL
NAPROXEN

> ADD >	AB	BIOCRAFT	250MG	N74216 001 APR 11, 1996
> ADD >	AB		375MG	N74216 002 APR 11, 1996
> ADD >	AB		500MG	N74216 003 APR 11, 1996

NAPROXEN SODIUM

TABLET, EXTENDED RELEASE; ORAL
NAPRELAN

+	ELAN PHARM	EQ 375MG BASE	N20353 001 JAN 05, 1996
+		EQ 500MG BASE	N20353 002 JAN 05, 1996
+		EQ 750MG BASE	N20353 003 JAN 05, 1996

NEOMYCIN SULFATE

INJECTABLE; INJECTION
MYCIFRADIN

> DLT >	AP	+ UPJOHN	EQ 350MG BASE/VIAL	N60477 001

NEOMYCIN SULFATE

> DLT >	AP	PFIZER	EQ 350MG BASE/VIAL	N61084 001
> DLT >	AP	SQUIBB	EQ 350MG BASE/VIAL	N60366 001

POWDER; FOR RX COMPOUNDING
NEO-RX

> DLT >	AA	PHARMA TEK	100%	N61579 001
> ADD >			100%	N61579 001

NEOMYCIN SULFATE

POWDER; FOR RX COMPOUNDING
NEOMYCIN SULFATE

> DLT >	@	ELKINS SINN	100%	N61698 001
> DLT >	AA	PADDOCK	100%	N62385 001 JUN 01, 1982

NICOTINE

SPRAY, METERED; NASAL
NICOTROL

+	PHARMACIA	0.5MG/INH	N20385 001 MAR 22, 1996

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL
NICORETTE

+	SMITHKLINE BEECHAM	EQ 2MG BASE	N18612 001 JAN 13, 1984

NICORETTE DS

+	SMITHKLINE BEECHAM	EQ 4MG BASE	N20066 001 JUN 08, 1992

NITROFURAZONE

OINTMENT; TOPICAL
NITROFURAZONE

AT	AMBIX	0.2%	N86077 001
@		0.2%	N86077 001

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL
NITRO-DUR

BX	+ KEY PHARMS	0.1MG/HR	N20145 001 APR 04, 1995
BX	+	0.2MG/HR	N20145 002 APR 04, 1995
BX	+	0.4MG/HR	N20145 004 APR 04, 1995
BX	+	0.6MG/HR	N20145 005 APR 04, 1995

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL
NITRO-DUR

	BX	+ KEY PHARMS	0.8MG/HR	N20145 006 APR 04, 1995

TRANSDERM-NITRO

> DLT >	BX	CIBA	0.1MG/HR	N20144 001 FEB 27, 1996
> DLT >				
> ADD >	BX	+	0.1MG/HR	N20144 001 FEB 27, 1996
> ADD >				
> DLT >	BX		0.2MG/HR	N20144 002 FEB 27, 1996
> DLT >				
> ADD >	BX	+	0.2MG/HR	N20144 002 FEB 27, 1996
> ADD >				
> DLT >	BX		0.4MG/HR	N20144 003 FEB 27, 1996
> DLT >				
> ADD >	BX	+	0.4MG/HR	N20144 003 FEB 27, 1996
> ADD >				
> DLT >	BX		0.6MG/HR	N20144 004 FEB 27, 1996
> DLT >				
> ADD >	BX	+	0.6MG/HR	N20144 004 FEB 27, 1996
> ADD >				
> DLT >	BX		0.8MG/HR	N20144 005 FEB 27, 1996
> DLT >				
> ADD >	BX	+	0.8MG/HR	N20144 005 FEB 27, 1996
> ADD >				

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
NORTRIPTYLINE HCL

> ADD >	**AB**	BIOCRAFT	**EQ 10MG BASE**	**N73667 001** APR 11, 1996
> ADD >				
> ADD >	**AB**		**EQ 25MG BASE**	**N73667 002** APR 11, 1996
> ADD >				
> ADD >	**AB**		**EQ 50MG BASE**	**N73667 003** APR 11, 1996
> ADD >				
> ADD >	**AB**		**EQ 75MG BASE**	**N73667 004** APR 11, 1996
> ADD >				

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
MYCOLOG-II

	AT	+ APOTHECON	100,000 UNITS/GM;0.1%	N60576 002 MAY 01, 1985

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
MYCOLOG-II

@	APOTHECON	100,000 UNITS/GM;0.1%	N60576 002 MAY 01, 1985

OXTRIPHYLLINE

SOLUTION; ORAL
CHOLEDYL

> DLT >	PARKE DAVIS	100MG/5ML	N09268 012 NOV 27, 1984
> DLT >			
> ADD >	@	100MG/5ML	N09268 012 NOV 27, 1984
> ADD >			

SYRUP; ORAL
CHOLEDYL

> DLT >	PARKE DAVIS	50MG/5ML	N09268 011
> DLT >			
> ADD >	@	50MG/5ML	N09268 011

TABLET, DELAYED RELEASE; ORAL
CHOLEDYL

> DLT >	+ PARKE DAVIS	100MG	N09268 003
> DLT >	+	200MG	N09268 007
> ADD >	@	100MG	N09268 003
> ADD >	@	200MG	N09268 007

OXYBUTYNIN CHLORIDE

SYRUP; ORAL
DITROPAN

AA	+ HOECHST MARION RSSL	**5MG/5ML**	**N18211 001**

OXYBUTYNIN CHLORIDE

AA	SILARX	**5MG/5ML**	**N74520 001** MAR 29, 1996

PENTAMIDINE ISETHIONATE

POWDER FOR RECONSTITUTION; INHALATION
NEBUPENT

FUJISAWA	600MG/VIAL	N19887 002 MAR 22, 1996

PENTOBARBITAL SODIUM

CAPSULE; ORAL
SODIUM PENTOBARBITAL

AA	HALSEY	100MG	N84677 001
	@	100MG	N84677 001

PERINDOPRIL ERBUMINE

TABLET; ORAL
ACEON

	AMARIC	2MG	N20184 001 DEC 30, 1993
		4MG	N20184 002 DEC 30, 1993
	+	8MG	N20184 003 DEC 30, 1993
	RHONE POULENC RORER	2MG	N20184 001 DEC 30, 1993
		4MG	N20184 002 DEC 30, 1993
	+	8MG	N20184 003 DEC 30, 1993

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PHERAZINE VC

> DLT >	AA	HALSEY	5MG/5ML;6.25MG/5ML	N88868 001 MAR 02, 1987
> DLT >				
> ADD >		@	5MG/5ML;6.25MG/5ML	N88868 001 MAR 02, 1987
> ADD >				

POLYESTRADIOL PHOSPHATE

INJECTABLE; INJECTION
ESTRADURIN

> DLT >				
> DLT >				
> DLT >		+ WYETH AYERST	40MG/AMP	N10753 001
> ADD >		@	40MG/AMP	N10753 001

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
POTASSIUM CHLORIDE

> ADD >	AB	BIOCRAFT	8MEQ	N73531 001 APR 26, 1996
> ADD >				

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
POTASSIUM CHLORIDE

> ADD >	AB	BIOCRAFT	10MEQ	N73532 001 APR 26, 1996
> ADD				

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

> DLT >	AP	FUJISAWA	2MEQ/ML	N87787 001 APR 20, 1982
> DLT >				
> ADD >		@	2MEQ/ML	N87787 001 APR 20, 1982
> ADD >				

PREDNISOLONE ACETATE

SUSPENSION, OPHTHALMIC
PRED FORTE

	BX	+ ALLERGAN	1%	N17011 001

SUSPENSION/DROPS; OPHTHALMIC
PRED FORTE

	AB	+ ALLERGAN	1%	N17011 001

PREDNISONE

TABLET; ORAL
PREDNISONE

	AB	SUPERPHARM	5MG	N88865 001 OCT 25, 1984
	AB		10MG	N88866 001 OCT 25, 1984
	AB		20MG	N88867 001 OCT 25, 1984
		@	5MG	N88865 001 OCT 25, 1984
		@	10MG	N88866 001 OCT 25, 1984
		@	20MG	N88867 001 OCT 25, 1984

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PROCANBID

		+ PARKE DAVIS	500MG	N20545 001 JAN 31, 1996

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PROCANBID
+ PARKE DAVIS 1GM N20545 002
JAN 31, 1996

PROMAZINE HYDROCHLORIDE

TABLET; ORAL
SPARINE
WYETH AYERST 50MG N10348 002
* 100MG N10348 003
+ 50MG N10348 002
@ 100MG N10348 003

PROPOXYPHENE HYDROCHLORIDE

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

PROPYLTHIOURACIL

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

PROTIRELIN

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

QUINIDINE GLUCONATE

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

QUINIDINE SULFATE

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

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

RAMIPRIL

CAPSULE; ORAL
ALTACE
HOECHST MARION RSSL 1.25MG N19901 001
JAN 28, 1991
2.5MG N19901 002
JAN 28, 1991

RAMIPRIL

CAPSULE; ORAL
ALTACE

	HOECHST MARION RSSL	5MG	N19901 003 JAN 28, 1991
+		10MG	N19901 004 JAN 28, 1991
	HOECHST ROUSSEL	1.25MG	N19901 001 JAN 28, 1991
		2.5MG	N19901 002 JAN 28, 1991
		5MG	N19901 003 JAN 28, 1991
+		10MG	N19901 004 JAN 28, 1991

RITONAVIR

CAPSULE; ORAL
NORVIR

+	ABBOTT	100MG	N20680 001 MAR 01, 1996

SOLUTION; ORAL
NORVIR

	ABBOTT	80MG/ML	N20659 001 MAR 01, 1996

SERTRALINE HYDROCHLORIDE

TABLET; ORAL
ZOLOFT

	PFIZER	EQ 25MG BASE	N19839 005 MAR 06, 1996

> ADD > SODIUM PHENYLBUTYRATE

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

SUCRALFATE

TABLET; ORAL

	CARAFATE		
AB	+ BLUE RIDGE	1GM	N18333 001
	SUCRALFATE		
AB	BIOCRAFT	1GM	N70848 001 MAR 29, 1996

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

	SULFATRIM-DS		
AB	SUPERPHARM	800MG;160MG	N70066 001 JUN 24, 1985
	@	800MG;160MG	N70066 001 JUN 24, 1985
	SULFATRIM-SS		
AB	SUPERPHARM	400MG;80MG	N70065 002 JUN 24, 1985
	@	400MG;80MG	N70065 002 JUN 24, 1985

TAMOXIFEN CITRATE

TABLET; ORAL
NOLVADEX

	@ ZENECA	EQ 20MG BASE	N17970 002 MAR 21, 1994
	+	EQ 20MG BASE	N17970 002 MAR 21, 1994

TECHNETIUM TC-99M TETROFOSMIN KIT

INJECTABLE; INJECTION
MYOVIEW

	MEDI PHYSICS	N/A	N20372 001 FEB 09, 1996

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL

AB	SUPERPHARM	250MG	N62540 001 MAR 21, 1985

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL

AB	SUPERPHARM	500MG	N62540 002 MAR 21, 1985
@		250MG	N62540 001 MAR 21, 1985
@		500MG	N62540 002 MAR 21, 1985

THALLOUS CHLORIDE, TL-201

INJECTABLE; INJECTION
THALLOUS CHLORIDE TL 201

	MEDI PHYSICS	2mCi/ML	N18110 001 FEB 01, 1982
		1mCi/ML	N18110 002 FEB 27, 1996

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
THEOVENT

BC	SCHERING	125MG	N87010 001 JAN 31, 1985
BC		250MG	N87910 001 JAN 31, 1985
@		125MG	N87010 001 JAN 31, 1985
@		250MG	N87910 001 JAN 31, 1985

INJECTABLE; INJECTION
THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER

AP	MCGAW	40MG/100ML	N19083 001 NOV 07, 1984
@		40MG/100ML	N19083 001 NOV 07, 1984

THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER

AP	MCGAW	80MG/100ML	N19083 002 NOV 07, 1984
@		80MG/100ML	N19083 002 NOV 07, 1984

THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER

AP	MCGAW	160MG/100ML	N19083 003 NOV 07, 1984
@		160MG/100ML	N19083 003 NOV 07, 1984

TABLET, EXTENDED RELEASE; ORAL
UNI-DUR

> ADD >	BC	+ KEY PHARMS	600MG	N89823 001 JAN 04, 1995
> ADD >				

UNIPHYL

> ADD >	BC	PURDUE FREDERICK	600MG	N40086 001 APR 15, 1996
> ADD >				

THIORIDAZINE HYDROCHLORIDE

CONCENTRATE; ORAL
MELLARIL

> DLT >	AA	SANDOZ	30MG/ML	N11808 012
> ADD >	AA	+	30MG/ML	N11808 012
> DLT >	AA		100MG/ML	N11808 018
> ADD >	AA	+	100MG/ML	N11808 018

TABLET; ORAL
THIORIDAZINE HCL

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

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC
AKTOB

AT	AKORN	0.3%	N64096 001 JAN 31, 1996

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

AB	BARR	100MG	N70162 001 JAN 14, 1986
AB		250MG	N70163 001 JAN 14, 1986
AB		500MG	N70164 001 JAN 14, 1986
	@	100MG	N70162 001 JAN 14, 1986
	@	250MG	N70163 001 JAN 14, 1986
	@	500MG	N70164 001 JAN 14, 1986
AB	ZENITH GOLDLINE	100MG	N18894 001 NOV 02, 1984
AB		250MG	N18894 002 NOV 02, 1984
AB		500MG	N18894 003 NOV 02, 1984
AB	ZENITH LABS	100MG	N18894 001 NOV 02, 1984
AB		250MG	N18894 002 NOV 02, 1984
AB		500MG	N18894 003 NOV 02, 1984

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

AB	BARR	500MG	N87121 001
	@	500MG	N87121 001
AB	SUPERPHARM	500MG	N88893 001 NOV 19, 1984
	@	500MG	N88893 001 NOV 19, 1984

TOLMETIN SODIUM

TABLET; ORAL
TOLMETIN SODIUM

AB	BAKER NORTON	EQ 600MG BASE	N74399 001 MAR 28, 1996

> ADD >

TRANDOLAPRIL

TABLET; ORAL
MAVIK

	KNOLL PHARM	1MG	N20528 001 APR 26, 1996
		2MG	N20528 002 APR 26, 1996
	+	4MG	N20528 003 APR 26, 1996

TRETINOIN

CREAM; TOPICAL
RENOVA

	JOHNSON RW	0.05%	N19963 001 DEC 29, 1995

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL
ARISTOCORT A

AT	LEDERLE	0.5%	N80745 003
AT	+ LEDERLE LABS	0.5%	N80745 003

KENALOG

AT	+ APOTHECON	0.5%	N83944 001
	@	0.5%	N83944 001

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL

AB	SIDMAK LABS NJ	40MG	N72751 001 FEB 23, 1996

TABLET, EXTENDED RELEASE; ORAL
COVERA-HS

BC	SEARLE	180MG	N20552 001 FEB 26, 1996
BC		240MG	N20552 002 FEB 26, 1996

VERAPAMIL HCL

AB	MYLAN	240MG	N74587 001 MAR 23, 1996
AB	SIDMAK LABS NJ	240MG	N72922 001 MAR 01, 1996

VIDARABINE

>_DLT_>	INJECTABLE; INJECTION		
>_DLT_>	VIRA-A		
>_DLT_>	+ PARKE DAVIS	EQ 187.4MG BASE/ML	N50523 001
>_ADD_>	@	EQ 187.4MG BASE/ML	N50523 001

ASPIRIN

TABLET, EXTENDED RELEASE; ORAL
8-HOUR BAYER
> ADD > + BAYER 650MG N16030 001
> DLT > * STERLING 650MG N16030 001
MEASURIN
> ADD > + BAYER 650MG N16030 002
> DLT > * STERLING 650MG N16030 002

BROMPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE; ORAL
> DLT > DIMETANE
> DLT > * ROBINS AH 8MG N10799 010
> DLT > JUN 10, 1983
> DLT > * 12MG N10799 011
> DLT > JUN 10, 1983
> ADD > @ WHITEHALL ROBINS 8MG N10799 010
> ADD > JUN 10, 1983
> ADD > DIMETAPP
> ADD > + WHITEHALL ROBINS 12MG N10799 011
> ADD > JUN 10, 1983

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

ELIXIR; ORAL
DIMETAPP
> DLT > * ROBINS AH 2MG/5ML;12.5MG/5ML N13087 003
> DLT > MAR 29, 1984
> ADD > + WHITEHALL ROBINS 2MG/5ML;12.5MG/5ML N13087 003
> ADD > MAR 29, 1984

TABLET, EXTENDED RELEASE; ORAL
DIMETAPP
> DLT > * ROBINS AH 12MG;75MG N12436 003
> DLT > MAY 14, 1985
> ADD > + WHITEHALL ROBINS 12MG;75MG N12436 003
> ADD > MAY 14, 1985

BROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

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

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CODIMAL-L.A. 12
CENT PHARMS 12MG;120MG N18935 001
APR 15, 1985
+ 12MG;120MG N18935 001
APR 15, 1985
PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE MALEATE
+ CENT PHARMS 8MG;120MG N19428 001
AUG 02, 1988
PSEUDOEPHEDRINE HCL/CHLORPHENIRAMINE MALEATE
+ GRAHAM 8MG;120MG N18844 001
MAR 20, 1985
* 12MG;120MG N18843 001
MAR 18, 1985
@ 8MG;120MG N18844 001
MAR 20, 1985
@ 12MG;120MG N18843 001
MAR 18, 1985
PSEUDOEPHEDRINE HYDROCHLORIDE AND CHLORPHENIRAMINE MALEATE
CENT PHARMS 8MG;120MG N19428 001
AUG 02, 1988

IBUPROFEN

CAPSULE; ORAL
PROVEL
+ SANDOZ 200MG N20402 001
APR 20, 1995
@ 200MG N20402 001
APR 20, 1995

TABLET; ORAL
IBUPROFEN
HALSEY 200MG N71027 001
SEP 29, 1987
@ 200MG N71027 001
SEP 29, 1987
@ LEMMON 200MG N73141 001
MAY 29, 1992
TAG PHARMS 200MG N73141 001
MAY 29, 1992

INSULIN PURIFIED BEEF

> DLT >	INJECTABLE; INJECTION		
> DLT >	REGULAR ILETIN II		
> DLT >	* LILLY	100 UNITS/ML	N18478 001
> ADD >	@	100 UNITS/ML	N18478 001

INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN

INJECTABLE; INJECTION		
NOVOLIN N		
* NOVO NORDISK	100 UNITS/ML	N19065 001 JAN 23, 1985
@	100 UNITS/ML	N19065 001 JAN 23, 1985

INSULIN SUSP PROTAMINE ZINC PURIFIED BEEF

	INJECTABLE; INJECTION		
	PROTAMINE ZINC INSULIN		
	* SQUIBB	40 UNITS/ML	N17928 001
	*	100 UNITS/ML	N17928 003
	@	40 UNITS/ML	N17928 001
	@	100 UNITS/ML	N17928 003

INSULIN ZINC SUSP EXTENDED PURIFIED BEEF

	INJECTABLE; INJECTION		
	ULTRALENTE		
	* NOVO NORDISK	100 UNITS/ML	N18385 001
	@	100 UNITS/ML	N18385 001

INSULIN ZINC SUSP PROMPT PURIFIED PORK

	INJECTABLE; INJECTION		
	SEMILENTE		
	* NOVO NORDISK	100 UNITS/ML	N18382 001
	@	100 UNITS/ML	N18382 001

INSULIN ZINC SUSP PURIFIED BEEF

> DLT >	INJECTABLE; INJECTION		
> DLT >	LENTE ILETIN II		
> DLT >	* LILLY	100 UNITS/ML	N18477 001

INSULIN ZINC SUSP PURIFIED BEEF

> DLT >	INJECTABLE; INJECTION		
> DLT >	LENTE ILETIN II		
> ADD >	@ LILLY	100 UNITS/ML	N18477 001

MICONAZOLE NITRATE

	CREAM; VAGINAL		
	MICONAZOLE 7		
	NMC	2%	N74164 001 MAR 29, 1996
	MICONAZOLE NITRATE		
	G AND W LABS	2%	N74366 001 FEB 22, 1996
	CREAM, SUPPOSITORY; TOPICAL, VAGINAL		
> ADD >	MONISTAT-3 COMBINATION PACK		
> ADD >	+ ADV CARE	2%,200MG	N20670 002 APR 16, 1996
> ADD >			

MINOXIDIL

	SOLUTION; TOPICAL		
> ADD >	MINOXIDIL (FOR MEN)		
> ADD >	BARRE	2%	N74588 001 APR 05, 1996
> ADD >			
> ADD >	BAUSCH AND LOMB	2%	N74643 001 APR 09, 1996
> ADD >			
> ADD >	LEMMON	2%	N74589 001 APR 05, 1996
> ADD >			
	ROGAINE (FOR MEN)		
	+ UPJOHN	2%	N19501 002 FEB 09, 1996
	ROGAINE (FOR WOMEN)		
	+ UPJOHN	2%	N19501 003 FEB 09, 1996

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

	SOLUTION/DROPS; OPHTHALMIC		
	OCUHIST		
	AKORN	0.025%;0.3%	N20485 001 JAN 31, 1996

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL
NICORETTE
+ SMITHKLINE BEECHAM EQ 2MG BASE N18612 002
FEB 09, 1996
+ EQ 4MG BASE N20066 002
FEB 09, 1996

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
EFIDAC 24 PSEUDOEPHEDRINE HCL
+ CIBA 240MG N20021 002
DEC 15, 1992

EFIDAC/24
+ CIBA 240MG N20021 002
DEC 15, 1992

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 4 / APR '96

NO APRIL 1996 APPROVALS

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January 1, 1996 thru April 30, 1996]

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Albendazole TN=	Treatment of hydatid disease (cystic echinococcosis due to E. granulosus larvae or alveolar echinococcosis due to E. multilocularis larvae).	SmithKline Beecham Pharmaceuticals One Franklin Plaza P.O. Box 7929 Philadelphia, PA 19101 DD=01/17/96 MA= / /
Albendazole TN=	Treatment of neurocysticercosis due to Taenia solium as: 1) chemotherapy of parenchymal, subarachnoidal and raccmose (cysts in spinal fluid) neurocysticercosis in symptomatic cases and 2) prophylaxis of epilepsy and other sequelae in asymptomatic neurocysticercosis.	SmithKline Beecham Pharmaceuticals One Franklin Plaza P.O. Box 7929 Philadelphia, PA 19101 DD=01/18/96 MA= / /
Antihemophilic factor (human) TN= Alphanate	Treatment of von Willebrand's disease.	Alpha Therapeutic Corporation 5555 Valley Boulevard Los Angeles, CA 90032 DD=01/05/96 MA= / /
Collagenase (lyophilized) for injection TN= Plaquase	Treatment of Peyronie's disease.	Advance Biofactures Corporation 35 Wilbur Street Lynbrook, NY 11563 DD=03/12/96 MA= / /
Dihydrotestosterone TN=Androgel-DHT	Treatment of weight loss in AIDS patients with HIV-associated wasting.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road, Suite 210 Buffalo Grove, IL 60089 DD=02/05/96 MA= / /
Indoxuridine TN=	Treatment of nonparenchymatous sarcomas.	NeoPharm, Inc. 225 East Deerpath, Suite 250 Lake Forest, IL 60045 DD=04/08/96 MA= / /
Interferon beta-la TN=Rebif	Treatment of patients with secondary progressive multiple sclerosis.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=03/11/96 MA= / /
Lipid/DNA human cystic fibrosis gene TN=	Treatment of cystic fibrosis.	Genzyme Corporation One Kendall Square Cambridge, MA 02139 DD=04/08/96 MA= / /
Liposomal prostaglandin E1 injection TN=	Treatment of acute respiratory distress syndrome.	The Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=04/25/96 MA= / /
Nitazoxanide TN=	Treatment of cryptosporidiosis in HIV-positive and AIDS patients.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road, Suite 210 Buffalo Grove, IL 60089 DD=01/05/96 MA= / /
Rifapentine TN=	Prophylactic treatment of Mycobacterium avium complex in patients with acquired immunodeficiency syndrome and a CD4+count less than or equal to 75/mm3.	Marion Merrell Dow Inc. P.O. Box 9627 (Park A) Kansas City, MO 64137 DD=03/12/96 MA= / /
R-VIII SQ TN= REFACTO	For long-term and/or hospital treatment of hemophilia A or for treatment of patients with hemophilia A in connection with surgical procedures.	Pharmacia Inc. P.O. Box 16529 Columbus, OH 43216 DD=02/08/96 MA= / /

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Somatropin for injection TN=Serostim	Treatment of children with AIDS-associated failure-to-thrive including AIDS-associated wasting.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=03/26/96 MA= / /
SU101 TN=	Treatment of ovarian cancer.	Sugen, Inc. 515 Galveston Drive Redwood City, CA 94063 DD=03/12/96 MA= / /
Testosterone TN=Androgel	Treatment of weight loss in AIDS patients with HIV-associated wasting.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road, Suite 210 Buffalo Grove, IL 60089 DD=02/05/96 MA= / /
Thalidomide TN=Synovir	Treatment of HIV-associated wasting syndrome.	Celgene Corporation P.O. Box 4914 7 Powder Horn Drive Warren, NJ 07059 DD=03/11/96 MA= / /
Valine, isoleucine and leucine TN=VIL	Treatment of hyperphenylalaninemia.	Leas Research Products 4 Brookview Lane Troy, NY 12180 DD=01/05/96 MA= / /

ORPHAN DRUG PRODUCT APPROVALS FOR 1996

Bleomycin sulfate TN=Blenoxane	Treatment of malignant pleural effusion.	Bristol-Myers Squibb P.O. Box 4000 Princeton, NJ 08543 DD=09/17/93 MA=02/20/96
Daunorubicin citrate liposome injection TN=DaunoXome	Treatment of patients with advanced HIV-associated Kaposi's sarcoma.	NeXstar Pharmaceuticals, Inc. 650 Cliffside Drive San Dimas, CA 91773 DD=05/14/93 MA=04/08/96
Ganciclovir intravitreal implant TN=Vitrasert Implant	Treatment of cytomegalovirus retinitis.	Chiron Vision 500 Iolab Drive Claremont, CA 91711 DD=06/07/95 MA=03/04/96
Respiratory syncytial virus immune globulin (human) TN=Respigam	Prophylaxis of respiratory syncytial virus lower respiratory tract infections in infants and young children at high risk of RSV diesase.	MedImmune, Inc. 35 West Watkins Mill Road Gaithersburg, MD 20878 DD=09/27/90 MA=01/18/96
Sodium phenylutyrate TN=Buphenyl	Treatment of urea cycle disorders carbamylphosphate synthetase deficiency, ornithine transcarbamylase deficiency, and arginiosuccinic acid sythetase deficiency	Ucyclyd Pharma 10819 Gilroy Road, Suite 100 Hunt Valley, MD 21031 DD=11/22/93 MA=04/30/96

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

NO APRIL 1996 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE

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

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

CLOZAPINE *IN VITRO* AND *IN VIVO* (TABLET)	NOV 15, 1995	APR 19, 1996

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED AND REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANCH, HFA-305, ROOM 1-23, PARK BUILDING, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

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

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	325MG 50MG 40MG 10MG	95 P-0279/ CP1	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	325MG 50MG 40MG 7.5MG	95 P-0279/ CP2	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	500MG 50MG 40MG 10MG	95 P-0279/ CP3	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	500MG 50MG 40MG 7.5MG	95 P-0279/ CP4	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 10MG	95 P-0279/ CP1	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 7.5MG	95 P-0279/ CP2	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08. 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 10MG	95 P-0279/ CP3	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 7.5MG	95 P-0279/ CP4	MIKART	NEW DOSAGE FORM NEW INGREDIENT NEW STRENGTH	APPROVED MAR 08, 1996

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ACYCLOVIR SODIUM INJECTABLE; INJECTION	EQ 5MG BASE/ML (100ML/CONTAINER) (200ML/CONTAINER)	95 P-0268/ CP1	WILMER, CUTLER, & PICKERING	NEW DOSAGE FORM NEW STRENGTH	APPROVED FEB 27, 1996
ASPIRIN; BUTALBITAL CAPSULE; ORAL	650MG 50MG	96 P-0021/ CP1	SAVAGE	NEW DOSAGE FORM	APPROVED APR 19, 1996
ATRACURIUM BESYLATE INJECTABLE; INJECTION	0.5MG/ML 1MG/ML (100ML CONTAINER)	95 P-0372/ CP1	ABBOTT	NEW STRENGTH	APPROVED MAR 08, 1996
CHOLESTYRAMINE TABLET, CHEWABLE; ORAL	EQ 2GM RESIN	95 P-0277/ CP1	MAYRAND	NEW DOSAGE FORM NEW STRENGTH	APPROVED FEB 27, 1996
DILTIAZEM HYDROCHLORIDE INJECTABLE, INJECTION	5MG/ML (25ML/SYRINGE) (50ML/SYRINGE)	95 P-0196/ CP1	INTL MEDICATION	NEW STRENGTH	APPROVED FEB 27, 1996
EPINEPHRINE INJECTABLE; SUBCUTANEOUS	0.3MG/DELIVERY	95 P-0190/ CP1	SENETCK PLC	NEW ROUTE OF ADMINISTRATION	APPROVED FEB 15, 1996
HYDROCORTISONE BUTYRATE LOTION; TOPICAL	0.1%	95 P-0223/ CP1	MCKENNA & CUNEO	NEW DOSAGE FORM	APPROVED FEB 21, 1996
LACTULOSE CRYSTALS, FOR RECONSTITUTION; ORAL	20GM/PACKET	95 P-0287/ CP1	BENNETT	NEW DOSAGE FORM NEW STRENGTH	APPROVED APR 19, 1996
MEPERIDINE HYDROCHLORIDE INJECTABLE; INJECTION	10MG/ML (60ML/SYRINGE)	95 P-0348/ CP1	MALLINCKRODT	NEW STRENGTH	APPROVED MAR 08, 1996
METRONIDAZOLE LOTION; TOPICAL	0.75%	95 P-0328/ CP1	RNB PHARM	NEW DOSAGE FORM	APPROVED FEB 23, 1996
NIFEDIPINE CAPSULE, EXTENDED RELEASE; ORAL	30MG 60MG 90MG	95-P-0326/ CP1	KV	NEW DOSAGE FORM	APPROVED FEB 23, 1996
PACLITAXEL INJECTABLE; INJECTION	6MG/ML (16.7ML/VIAL) (33.3ML/VIAL) (50ML/VIAL)	95 P-0360/ CP1	ABBOTT	NEW STRENGTH	APPROVED APR 29, 1996

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 16TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES

NEW DOSING SCHEDULE

D-29 INCREASE OF CUMULATIVE DOSE TO 0.3MMOL/KG FOR MRI OF THE CNS IN ADULTS
D-30 5000 IU DOSE FOR PHOPHYLAXIS AGAINST DEEP VEIN THROMBOSIS

NEW INDICATION

I-141 TREATMENT OF HEMODYNAMICALLY STABLE PATIENTS WITHIN 24 HOURS OF ACUTE MYOCARDIAL INFARCTION TO IMPROVE SURVIVAL
I-142 LOCALIZE MYOCARDIAL ISCHEMIA (REVERSIBLE DEFECT) AND INFARCTION (NON-REVERSIBLE DEFECTS) IN EVALUATING MYOCARDIAL FUNCTION
I-143 EPISODIC TREATMENT OF RECURRENT GENITAL HERPES IN IMMUNOCOMPETENT ADULTS
I-144 ENHANCEMENT OF MRI OF THE ADULT BODY INTERNAL ORGANS
I-145 0.1MMOL/KG AS A SINGLE INTRAVENOUS BOLUS FOR MRI OF THE CNS IN CHILDREN
I-146 CONTRAST ENHANCEMENT AND FACILITATION OF VISUALIZATION OF EXTRACRANIAL HEAD AND NECK LESIONS
I-147 PREVENTION OF GALLSTONE FORMATION IN OBESE PATIENTS EXPERIENCING RAPID WEIGHT LOSS
I-148 TREATMENT OF ACUTE PNEUMOCYSTIC CARINII PNEUMONIA (PCP) IN HIV-INFECTED PATIENTS WHOSE ALVEOLAR-ARTERIAL OXYGEN DIFFERENCE ($AaDO_2$) IS LESS THAN OR EQUAL TO 55 TORR
I-149 TREATMENT OF PATIENTS WITH NON-SMALL CELL LUNG CANCER

PATENT USE CODE

U-121 METHOD OF TREATING CONDITIONS MEDIATED THROUGH HISTAMINE H2-RECEPTORS
U-122 A THERAPEUTIC METHOD FOR CONTROLLING THROMBOSIS
U-123 METHOD FOR CONTROLLING THROMBOSIS AND DECREASING BLOOD HYPERCOAGULATION AND HEMORRHAGING RISKS
U-124 TREATMENT OF ACNE
U-125 TREATING NEUROGENERATIVE DISEASES
U-126 TREATMENT OF GASTRITIS
U-127 METHOD OF PRODUCING NEUROMUSCULAR BLOCKADE
U-128 METHODS FOR TREATMENT OF TUMORS
U-129 METHOD TO DESTROY OR IMPAIR TARGET CELLS
U-130 MANAGEMENT OF PATIENTS WITH MASTOCYTOSIS
U-131 PHOTODAMAGED SKIN
U-132 INHIBITING HIV PROTEASE
U-133 MANAGEMENT OF OBESITY INCLUDING WEIGHT LOSS AND MAINTENANCE IN PATIENTS ON A REDUCED-CALORIE DIET

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19806 001	ACRIVASTINE; SEMPREX-D	4650807	MAR 26, 2008	U-93		
>ADD>	20221 001	AMIFOSTINE; ETHYOL				I-149	MAR 15, 1999
	20541 001	ANASTROZOLE; ARIMIDEX	4935437	JUN 10, 2008			
	20428 001	AZELAIC ACID; AZELEX	4386104	MAY 31, 2000	U-124		
	20498 001	BICALUTAMIDE; CASODEX	4636505	JAN 13, 2004			
	50443 001	BLEOMYCIN SULFATE; BLENOXANE				ODE	FEB 20, 2003
	20421 001	BUTOCONAZOLE NITRATE; FEMSTAT 3	4078071	JUL 28, 1997			
						NP	DEC 21, 1998
>ADD>	20273 001	CALCIPOTRIENE; DOVONEX	4866048	DEC 29, 2007	U-88	NCE	DEC 29, 1998
>DLT>	~~20273 001~~	~~CALCIPOTRIENE; DOVONEX~~	~~4866048~~	~~SEP 12, 2006~~	~~U-88~~	~~NCE~~	~~DEC 29, 1998~~
	20313 002	CALCITONIN, SALMON; MIACALCIN	4344949	OCT 03, 2000			
	18874 001	CALCITRIOL; CALCIJEX	4308264	JAN 28, 2001			
	18874 002	CALCITRIOL; CALCIJEX	4308264	JAN 28, 2001			
	18343 004	CAPTOPRIL; CAPOTEN				I-95	SEP 23, 1996
						I-101	JAN 28, 1997
	18343 007	CAPTOPRIL; CAPOTEN				I-95	SEP 23, 1996
						I-101	JAN 28, 1997
	20234 001	CARBAMAZEPINE; TEGRETOL-XR	5284662	FEB 08, 2011			
			RE34990	JUL 29, 2007			
	20234 002	CARBAMAZEPINE; TEGRETOL-XR	5284662	FEB 08, 2011			
			RE34990	JUL 29, 2007			
	20234 003	CARBAMAZEPINE; TEGRETOL-XR	5284662	FEB 08, 2011			
			RE34990	JUL 29, 2007			
	19835 001	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2002			
	19835 002	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2002			
	20398 001	CISAPRIDE MONOHYDRATE; PROPULSID	4962115	OCT 09, 2007	U-79	NCE	JUL 29, 1998
	20551 001	CISATRACURIUM BESYLATE; NIMBEX	5453510	SEP 26, 2012	U-127		
			4179507	DEC 18, 1996	U-127		
	20551 002	CISATRACURIUM BESYLATE; NIMBEX PRESERVATIVE FREE	5453510	SEP 26, 2012	U-127		
			4179507	DEC 18, 1996	U-127		
	20551 003	CISATRACURIUM BESYLATE; NIMBEX PRESERVATIVE FREE	5453510	SEP 26, 2012	U-127		
			4179507	DEC 18, 1996	U-127		
	20479 001	CROMOLYN SODIUM; GASTROCROM	4515805	MAY 07, 2002	U-130		
			4421762	DEC 20, 2000	U-130		

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>	20287 001	DALTEPARIN SODIUM; FRAGMIN	4303651	JAN 04, 2005		NCE	DEC 22, 1999
>DLT>	~~20287 001~~	~~DALTEPARIN SODIUM; FRAGMIN~~	~~4303651~~	~~JAN 04, 2000~~		~~NCE~~	~~DEC 22, 1999~~
>ADD>						D-30	MAR 18, 1999
>ADD>	20287 003	DALTEPARIN SODIUM; FRAGMIN	4303651	JAN 04, 2005		NCE	DEC 22, 1999
>ADD>						D-30	MAR 18, 1999
>ADD>	50704 002	DAUNORUBICIN CITRATE; DAUNOXOME				ODE	APR 08, 2003
	20118 001	DESFLURANE; SUPRANE	4762856	FEB 02, 2007	U-67	NCE	SEP 18, 1997
	19955 001	DESMOPRESSIN ACETATE; DDAVP	5047398	SEP 10, 2008			
	19955 002	DESMOPRESSIN ACETATE; DDAVP	5047398	SEP 10, 2008			
>ADD>	20344 001	DEXFENFLURAMINE HYDROCHLORIDE; REDUX	4309445	JUN 16, 2000	U-133		
	20254 001	DICLOFENAC SODIUM; VOLTAREN-XR				NDF	MAR 08, 1999
	18723 001	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-147	MAR 18, 1999
	18723 002	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-147	MAR 18, 1999
	18723 003	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-147	MAR 18, 1999
	20164 001	ENOXAPARIN SODIUM; LOVENOX	5389618	FEB 14, 2012			
			4692435	DEC 24, 2004	U-123		
			4486420	DEC 04, 2001	U-122		
>ADD>	20472 001	ESTRADIOL; ESTRING				NDF	APR 26, 1999
	20195 007	FENTANYL CITRATE; FENTANYL	4671953	JUN 09, 2004	U-87	NDF	OCT 04, 1996
	20548 001	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999
	20548 002	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999
	20548 003	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999
	20235 001	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-125		
			4894476	MAY 02, 2008			
>ADD>			4087544	JAN 17, 2001	U-86	NCE	DEC 30, 1998
>DLT>			~~4087544~~	~~MAY 02, 1996~~	~~U-86~~	~~NCE~~	~~DEC 30, 1998~~
	20235 002	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-125		
			4894476	MAY 02, 2008			
>ADD>			4087544	JAN 17, 2001	U-86	NCE	DEC 30, 1998
>DLT>			~~4087544~~	~~MAY 02, 1996~~	~~U-86~~	~~NCE~~	~~DEC 30, 1998~~
	20235 003	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-125		
			4894476	MAY 02, 2008			
>ADD>			4087544	JAN 17, 2001	U-86	NCE	DEC 30, 1998
>DLT>			~~4087544~~	~~MAY 02, 1996~~	~~U-86~~	~~NCE~~	~~DEC 30, 1998~~
	20123 001	GADODIAMIDE; OMNISCAN	4687659	MAY 04, 2007		D-29	FEB 05, 1999
						I-145	FEB 05, 1999
						I-144	FEB 05, 1999
	19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST	4647447	MAR 03, 2004		I-146	FEB 28, 1999
	20569 001	GANCICLOVIR; VITRASERT				NP	MAR 04, 1996

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
	20578 001	GOSERELIN ACETATE; ZOLADEX	5366734	NOV 22, 2011			
			4767628	AUG 30, 2005			
			4100274	APR 22, 1999		NP	JAN 11, 1999
	20239 001	GRANISETRON HYDROCHLORIDE; KYTRIL	4886808	DEC 29, 2007	U-89		
	20305 001	GRANISETRON HYDROCHLORIDE; KYTRIL	4886808	DEC 29, 2007	U-105		
>ADD>	19836 001	HISTRELIN ACETATE; SUPPRELIN	4244946	JAN 13, 2000		NCE	DEC 24, 1996
>DLT>	~~19836 001~~	~~HISTRELIN ACETATE; SUPPRELIN~~	~~4244946~~	~~JAN 13, 1998~~		~~NCE~~	~~DEC 24, 1996~~
>ADD>	19836 002	HISTRELIN ACETATE; SUPPRELIN	4244946	JAN 13, 2000		NCE	DEC 24, 1996
>DLT>	~~19836 002~~	~~HISTRELIN ACETATE; SUPPRELIN~~	~~4244946~~	~~JAN 13, 1998~~		~~NCE~~	~~DEC 24, 1996~~
>ADD>	19836 003	HISTRELIN ACETATE; SUPPRELIN	4244946	JAN 13, 2000		NCE	DEC 24, 1996
>DLT>	~~19836 003~~	~~HISTRELIN ACETATE; SUPPRELIN~~	~~4244946~~	~~JAN 13, 1998~~		~~NCE~~	~~DEC 24, 1996~~
	20685 001	INDINAVIR SULFATE; CRIXIVAN	5413999	MAY 07, 2013	U-132	NCE	MAR 13, 2001
	20685 003	INDINAVIR SULFATE; CRIXIVAN	5413999	MAY 07, 2013	U-132	NCE	MAR 13, 2001
	20351 001	IODIXANOL; VISIPAQUE 270	5349085	SEP 20, 2011		NCE	MAR 22, 2001
			4396597	JUL 03, 1999			
			4278654	JUL 03, 1999			
	20351 002	IODIXANOL; VISIPAQUE 320	5349085	SEP 20, 2011		NCE	MAR 22, 2001
			4396597	JUL 03, 1999			
			4278654	JUL 03, 1999			
	20564 001	LAMIVUDINE; EPIVIR	5047407	FEB 08, 2009			
	20596 001	LAMIVUDINE; EPIVIR	5047407	FEB 08, 2009			
>ADD>	20406 001	LANSOPRAZOLE; PREVACID	4689333	JUL 29, 2005	U-126	I-116	APR 08, 1999
>ADD>	20406 002	LANSOPRAZOLE; PREVACID	4689333	JUL 29, 2005	U-126	I-116	APR 08, 1999
>ADD>	20219 001	LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN	4369184	DEC 02, 2004		NCE	NOV 10, 1998
>DLT>	~~20219 001~~	~~LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN~~	~~4369184~~	~~JAN 18, 2000~~		~~NCE~~	~~NOV 10, 1998~~
	19558 001	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
	19558 002	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
	19558 003	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
	19558 004	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
	19558 006	LISINOPRIL; PRINIVIL				I-141	NOV 24, 1998
	19777 001	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
	19777 002	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
	19777 003	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
	19777 004	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
	19777 005	LISINOPRIL; ZESTRIL				I-141	NOV 24, 1998
	19940 001	MASOPROCOL; ACTINEX	4695590	APR 17, 2008			
	20312 001	MOEXIPRIL HYDROCHLORIDE; UNIVASC	4344949	OCT 03, 2000			
	19886 001	NAFARELIN ACETATE; SYNAREL	4234571	JUN 11, 2011			

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
	20353 001	NAPROXEN SODIUM; NAPRELAN				NDF	JAN 05, 1999
	20353 002	NAPROXEN SODIUM; NAPRELAN				NDF	JAN 05, 1999
	20353 003	NAPROXEN SODIUM; NAPRELAN				NDF	JAN 05, 1999
>ADD>	20165 001	NICOTINE; NICODERM	5508038	APR 16, 2013			
>ADD>	20165 002	NICOTINE; NICODERM	5508038	APR 16, 2013			
>ADD>	20165 003	NICOTINE; NICODERM	5508038	APR 16, 2013			
>ADD>	20385 001	NICOTINE; NICOTROL				NP	MAR 22, 1999
	19810 001	OMEPRAZOLE; PRILOSEC	4255431	APR 05, 2001	U-108	I-148	MAR 22, 1999
	19810 003	OMEPRAZOLE; PRILOSEC	4853230	APR 20, 2007	U-108	I-148	MAR 22, 1999
>ADD>	18841 004	OXAPROZIN; DAYPRO				NCE	OCT 29, 1999*
>DLT>	~~18841 004~~	~~OXAPROZIN; DAYPRO~~				~~NCE~~	~~OCT 29, 1997~~
	19887 002	PENTAMIDINE ISETHIONATE; NEBUPENT				I-150	MAR 05, 1999
	20184 001	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
	20184 002	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
	20184 003	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
	20451 001	PORFIMER SODIUM; PHOTOFRIN	5438071	AUG 01, 2012			
			5145863	JUN 12, 2007	U-129	ODE	DEC 27, 2002
			5028621	MAR 10, 2004			
			4932934	JUN 12, 2007	U-128	NCE	DEC 27, 2000
			4866168	MAR 10, 2004			
			4649151	MAR 10, 2004		ODE	DEC 27, 2002
	19898 006	PRAVASTATIN SODIUM; PRAVACHOL	5180589	JUL 09, 2008			
			5030447	JUL 09, 2008			
			4346227	OCT 20, 2005			
	19898 007	PRAVASTATIN SODIUM; PRAVACHOL	5180589	JUL 09, 2008			
			5030447	JUL 09, 2008			
			4346227	OCT 20, 2005			
	20545 001	PROCAINAMIDE HYDROCHLORIDE; PROCANBID				NP	JAN 31, 1999
	20545 002	PROCAINAMIDE HYDROCHLORIDE; PROCANBID				NP	JAN 31, 1999
	19885 001	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
	19885 002	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
	19885 003	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
	19885 004	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			

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

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19593 001	RANITIDINE HYDROCHLORIDE; ZANTAC	4585790	MAY 11, 2004			
			4521431	JUN 04, 2002	U-121		
			4128658	JUL 25, 1997	U-121		
	19593 002	RANITIDINE HYDROCHLORIDE; ZANTAC	4585790	MAY 11, 2004			
			4521431	JUN 04, 2002	U-121		
	19593 002	RANITIDINE HYDROCHLORIDE; ZANTAC	4128658	JUL 25, 1997	U-121		
	20520 001	RANITIDINE HYDROCHLORIDE; ZANTAC 75	4880636	MAY 13, 2008			
			4521431	JUN 04, 2002	U-121		
			4128658	JUL 25, 1997	U-121		
	20272 001	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
	20272 002	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
	20272 003	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
	20272 004	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
	20272 005	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
	20659 001	RITONAVIR; NORVIR	5484801	JAN 28, 2014		NCE	MAR 01, 2001
	20680 001	RITONAVIR; NORVIR				NCE	MAR 01, 2001
	20628 001	SAQUINAVIR MESYLATE; INVIRASE	5196438	NOV 19, 2010			
	19334 001	SELEGILINE HYDROCHLORIDE; ELDEPRYL	5242950	APR 23, 2012		ODE	JUN 05, 1996
			5151419	SEP 29, 2009			
			4880833	NOV 14, 2006			
>ADD>	20573 001	SODIUM PHENYLBUTYRATE; BUPHENYL				NCE	APR 30, 2001
	20280 004	SOMATROPIN, BIOSYNTHETIC; GENOTROPIN				NS	AUG 24, 1998
	20280 006	SOMATROPIN, BIOSYNTHETIC; GENOTROPIN				NS	AUG 24, 1998
	20412 001	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
	20412 002	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
	20412 003	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
	20412 004	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
	20412 005	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
	19785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE				I-142	DEC 14, 1998
	20372 001	TECHNETIUM TC-99M TETROFOSMIN KIT; MYOVIEW	5045302	APR 10, 2007		NCE	FEB 09, 2001
	19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
	19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
	19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
	19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013	U-3		
	20347 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
	20347 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
	20347 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
	20347 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			

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
	20489 001	TESTOSTERONE; ANDRODERM	5164190	NOV 17, 2008			
			5152997	OCT 06, 2009			
			4983395	JAN 08, 2009			
			4863970	SEP 05, 2006			
			4855294	AUG 08, 2006			
			4849224	JUL 18, 2006		NS	SEP 29, 1998
>ADD>	20528 001	TRANDOLAPRIL; MAVIK				NCE	APR 26, 2001
>ADD>	20528 002	TRANDOLAPRIL; MAVIK				NCE	APR 26, 2001
>ADD>	20528 003	TRANDOLAPRIL; MAVIK				NCE	APR 26, 2001
>ADD>	19963 001	TRETINOIN; RENOVA	4877805	OCT 31, 2006	U-131	NP	DEC 29, 1998
			4603146	JUL 29, 2003	U-131		
			4423041	DEC 27, 2000			
	19594 002	URSODIOL; ACTIGALL				I-149	MAR 29, 1999
	20487 001	VALACYCLOVIR HYDROCHLORIDE; VALTREX				I-143	DEC 15, 1998
	20487 002	VALACYCLOVIR HYDROCHLORIDE; VALTREX				I-143	DEC 15, 1998
>ADD>	20151 001	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
>DLT>	~~20151 001~~	~~VENLAFAXINE HYDROCHLORIDE; EFFEXOR~~	~~4535186~~	~~DEC 13, 2002~~		~~NCE~~	~~DEC 28, 1998~~
>ADD>	20151 002	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
>DLT>	~~20151 002~~	~~VENLAFAXINE HYDROCHLORIDE; EFFEXOR~~	~~4535186~~	~~DEC 13, 2002~~		~~NCE~~	~~DEC 28, 1998~~
>ADD>	20151 003	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
>DLT>	~~20151 003~~	~~VENLAFAXINE HYDROCHLORIDE; EFFEXOR~~	~~4535186~~	~~DEC 13, 2002~~		~~NCE~~	~~DEC 28, 1998~~
>ADD>	20151 004	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
>DLT>	~~20151 004~~	~~VENLAFAXINE HYDROCHLORIDE; EFFEXOR~~	~~4535186~~	~~DEC 13, 2002~~		~~NCE~~	~~DEC 28, 1998~~
>ADD>	20151 005	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
>DLT>	~~20151 005~~	~~VENLAFAXINE HYDROCHLORIDE; EFFEXOR~~	~~4535186~~	~~DEC 13, 2002~~		~~NCE~~	~~DEC 28, 1998~~
>ADD>	20151 006	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
>DLT>	~~20151 006~~	~~VENLAFAXINE HYDROCHLORIDE; EFFEXOR~~	~~4535186~~	~~DEC 13, 2002~~		~~NCE~~	~~DEC 28, 1998~~
	20552 001	VERAPAMIL HYDROCHLORIDE; COVERA-HS	5190765	AUG 14, 2007			
			5160744	JUN 27, 2011			
			4753802	MAR 19, 2006			
			4252338	JUN 27, 2011		NP	FEB 26, 1999
	20552 002	VERAPAMIL HYDROCHLORIDE; COVERA-HS	5190765	AUG 14, 2007			
			5160744	JUN 27, 2011			
			4753802	MAR 19, 2006			
			4252338	JUN 27, 2011		NP	FEB 26, 1999

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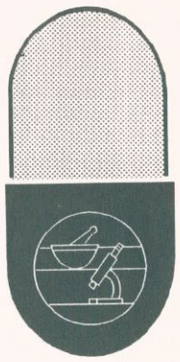

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