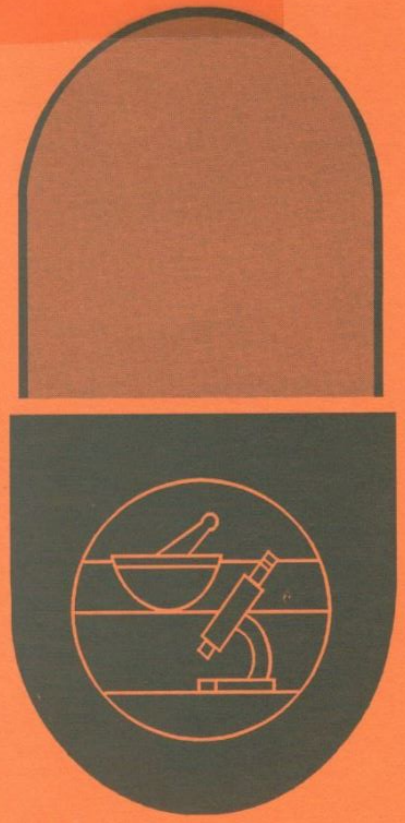
CUMULATIVE SUPPLEMENT 7
JAN'96-JUL'96



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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with
THERAPEUTIC EQUIVALENCE EVALUATIONS

16TH EDITION

Cumulative Supplement 7

JULY 1996

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

16TH EDITION

CUMULATIVE SUPPLEMENT 7
JULY 1996

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

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

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

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

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

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

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

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

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

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

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

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

1.4 REFERENCE LISTED DRUG

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

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

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

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

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

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

1.6 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)
BOEHRINGER MANNHEIM PHARMACEUTICALS CORP (BOEHRINGER MANNHEIM)	BOEHRINGER MANNHEIM CORPORATION THERAPEUTICS DIVISION (BOEHRINGER MANNHEIM)
DAVID BULL LABORATORIES PARTY LTD (BULL D)	FH FAULDING AND CO LTD (FAULDING) **THEN CHANGED TO** FAULDING PHARMACEUTICAL CO (FAULDING)
HOECHST ROUSSEL PHARMACEUTICALS INC (HOECHST ROUSSEL)	HOECHST MARION ROUSSEL INC (HOECHST MARION RSSL)
PHARMACIA INC (PHARMACIA)	PHARMACIA AND UPJOHN CO (PHARMACIA AND UPJOHN)
SCHWARZ PHARMA KREMERS URBAN CO SUB SCHWARZ PHARMA AG (SPKU)	SCHWARZ PHARMA INC (SCHWARZ PHARMA)
UPJOHN CO (UPJOHN)	PHARMACIA AND UPJOHN CO (PHARMACIA AND UPJOHN)

1.7 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.

1.8 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	9384	
SINGLE SOURCE	2217 (23.9%)	2248 (24.2%)	2323 (24.8%)	
MULTISOURCE	7069 (76.1%)	7055 (75.8%)	7061 (75.2%)	
THERAPEUTICALLY EQUIVALENT	6437 (69.3%)	6425 (69.0%)	6490 (69.2%)	
NOT THERAPEUTICALLY EQUIVALENT	440 (4.7%)	443 (4.8%)	468 (5.0%)	
EXCEPTIONS[1]	192 (2.1%)	187 (2.0%)	103 (1.0%)	
NEW MOLECULAR ENTITIES APPROVED	--	6	15	
NUMBER OF APPLICANTS	586	592	621	

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

ACETAMINOPHEN; BUTALBITAL; CAPSULE; ORAL

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

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

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

	DHC PLUS				
AA	PURDUE FREDERICK	356.4MG;30MG;16MG	N88584 001		
			MAR 04, 1986		
	+	356.4MG;30MG;16MG	N88584 001		
			MAR 04, 1986		
	SYNALGOS-DC-A				
AA	+ WYETH AYERST	356.4MG;30MG;16MG	N89166 001		
			MAY 14, 1986		
	@	356.4MG;30MG;16MG	N89166 001		
			MAY 14, 1986		

ACETAMINOPHEN; CODEINE PHOSPHATE

SOLUTION; ORAL

	ACETAMINOPHEN AND CODEINE PHOSPHATE				
AA	HI TECH PHARMA	120MG/5ML;12MG/5ML	N40119 001		
			APR 26, 1996		
	TYLENOL W/ CODEINE				
AA	JOHNSON RW	120MG/5ML;12MG/5ML	N85057 001	> ADD >	
AA	+	120MG/5ML;12MG/5ML	N85057 001	> ADD >	
				> ADD >	

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	> DLT >	
	@	300MG;60MG	N86549 001	> DLT >	

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

	ACETAMINOPHEN AND CODEINE PHOSPHATE				
AA	MIKART	300MG;30MG	N89238 001		
			FEB 25, 1986		
AA		300MG;60MG	N89244 001		
			FEB 25, 1986		
	@	300MG;60MG	N89244 001		
			FEB 25, 1986		
	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		
	@	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

	ANEXSIA				
AA	KING PHARMS	500MG;5MG	N89160 001		
			APR 23, 1987		
AA	MALLINCKRODT	500MG;5MG	N89160 001		
			APR 23, 1987		
	ANEXSIA 10/660				
	MALLINCKRODT	660MG;10MG	N40084 003		
			JUL 29, 1996		
	ANEXSIA 7.5/650				
AA	KING PHARMS	650MG;7.5MG	N89725 001		
			SEP 30, 1987		
AA	MALLINCKRODT	650MG;7.5MG	N89725 001		
			SEP 30, 1987		
	HYDROCODONE BITARTRATE AND ACETAMINOPHEN				
AA	KING PHARMS	500MG;5MG	N40084 002		
			JUN 01, 1995		

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

		HYDROCODONE BITARTRATE AND ACETAMINOPHEN		
> DLT >	AA	KING PHARMS	750MG;7.5MG	N40084 001 JUN 01, 1995
> DLT > ADD > ADD > ADD >	AA	MALLINCKRODT	500MG;5MG	N40084 002 JUN 01, 1995
	AA		750MG;7.5MG	N40084 001 JUN 01, 1995
	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
	AA		750MG;7.5MG	N40157 001 APR 12, 1996
		LORTAB UCB	500MG;10MG	N40100 001 JAN 26, 1996
	+		500MG;10MG	N40100 001 JAN 26, 1996

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL

		OXYCODONE AND ACETAMINOPHEN		
> ADD > ADD >	AA	VINTAGE PHARMS	500MG;5MG	N40106 001 JUL 30, 1996

TABLET; ORAL

		OXYCODONE AND ACETAMINOPHEN		
> ADD > ADD > ADD >	AA	VINTAGE PHARMS	325MG;5MG	N40105 001 JUL 30, 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

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC

		ACETIC ACID		
> ADD > ADD >	AT	MORTON GROVE	2%	N40166 001 JUL 26, 1996

ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE; ORAL

		SEMPREX-D		
> DLT > DLT > ADD > ADD >	+	GLAXO WELLCOME	8MG;60MG	N19806 001 MAR 25, 1994
	+	MEDEVA AMERICAS	8MG;60MG	N19806 001 MAR 25, 1994

ADAPALENE

GEL; TOPICAL

	DIFFERIN		
+	GALDERMA	0.1%	N20380 001 MAY 31, 1996

SOLUTION; TOPICAL

	DIFFERIN		
+	GALDERMA	0.1%	N20338 001 MAY 31, 1996

ALBENDAZOLE

TABLET; ORAL

	ALBENZA		
+	SMITHKLINE BEECHAM	200MG	N20666 001 JUN 11, 1996

ALBUTEROL SULFATE

SOLUTION; INHALATION
VENTOLIN
AN GLAXO WELLCOME EQ 0.083% BASE N19773 001 APR 23, 1992
AN + EQ 0.083% BASE N19773 001 APR 23, 1992
AN EQ 0.5% BASE N19269 002 JAN 16, 1987
AN + EQ 0.5% BASE N19269 002 JAN 16, 1987

SYRUP; ORAL
PROVENTIL
AA SCHERING EQ 2MG BASE/5ML N18062 001 JAN 19, 1983
AA + EQ 2MG BASE/5ML N18062 001 JAN 19, 1983

ALLOPURINOL SODIUM

INJECTABLE; INJECTION
ZYLOPRIM
+ GLAXO WELLCOME EQ 500MG BASE/VIAL N20298 001 MAY 17, 1996

ALPROSTADIL

INJECTABLE; INJECTION
CAVERJECT
PHARMACIA AND UPJOHN 0.005MG/VIAL N20379 003 JUN 27, 1996

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 APOTHECON 125MG N64131 001 MAY 06, 1996
AB 250MG N64131 002 MAY 06, 1996
AB CLONMEL HLTH CARE 125MG N64139 001 JAN 29, 1996
AB 250MG N64139 002 JAN 29, 1996

AMOXICILLIN; CLAVULANATE POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
AUGMENTIN '200'
+ SMITHKLINE BEECHAM 200MG/5ML; EQ 28.5MG BASE/5ML N50725 001 MAY 31, 1996

AUGMENTIN '400'
+ SMITHKLINE BEECHAM 400MG/5ML; EQ 57MG BASE/5ML N50725 002 MAY 31, 1996

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

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET, CHEWABLE; ORAL

	AUGMENTIN '200'			
+	SMITHKLINE BEECHAM	200MG;EQ 28.5MG BASE	N50726 001	MAY 31, 1996
	AUGMENTIN '400'			
+	SMITHKLINE BEECHAM	400MG;EQ 57MG BASE	N50726 002	MAY 31, 1996

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	> ADD >
	@		325MG;50MG;40MG	N89448 001	> ADD >
				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

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

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**

AZITHROMYCIN DIHYDRATE

TABLET; ORAL

	ZITHROMAX		
+	PFIZER	EQ 250MG BASE	N50711 001
			JUL 18, 1996

AZITHROMYCIN DIHYDRATE

TABLET; ORAL

	ZITHROMAX			
	+ PFIZER	EQ 600MG BASE	N50730 001	JUN 12, 1996

BACITRACIN

OINTMENT; OPHTHALMIC

	BACITRACIN			
AT	**ALTANA**	**500 UNITS/GM**	**N61212 001**	
	+	500 UNITS/GM	N61212 001	
AT	**+ LILLY**	**500 UNITS/GM**	**N60687 001**	
	@	500 UNITS/GM	N60687 001	

BECLOMETHASONE DIPROPIONATE MONOHYDRATE

SPRAY, METERED; NASAL

	BECONASE AQ			
BN	**+ GLAXO WELLCOME**	**EQ 0.042MG DIPROP/INH**	**N19389 001**	**JUL 27, 1987**
BN		EQ 0.042MG DIPROP/INH	N19389 001	JUL 27, 1987
	VANCENASE AQ			
BN	**SCHERING**	**EQ 0.042MG DIPROP/INH**	**N19589 001**	**DEC 23, 1987**
BN	+	EQ 0.042MG DIPROP/INH	N19589 001	DEC 23, 1987
	+	EQ 0.084MG DIPROP/INH	N20469 001	JUN 26, 1996

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

	BLENOXANE			
AP	**+ BRISTOL MYERS SQUIBB**	**EQ 15 UNITS BASE/VIAL**	**N50443 001**	
	+	EQ 15 UNITS BASE/VIAL	N50443 001	
	BLEOMYCIN SULFATE			
AP	**PHARMACIA AND UPJOHN**	**EQ 15 UNITS BASE/VIAL**	**N64084 001**	JUN 01, 1996
	+	EQ 30 UNITS BASE/VIAL	N64084 002	JUN 01, 1996

BROMPHENIRAMINE MALEATE

TABLET; ORAL

	DIMETANE			
AA	**+ ROBINS AH**	**4MG**	**N10799 003**	
	@ WHITEHALL ROBINS	4MG	N10799 003	

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

	BUPRENEX			
AP	**+ RECKITT AND COLMAN**	**EQ 0.3MG BASE/ML**	**N18401 001**	
	BUPRENORPHINE HCL			
AP	**SANOFI WINTHROP**	**EQ 0.3MG BASE/ML**	**N74137 001**	JUN 03, 1996

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

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

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	

CALCIPOTRIENE

> ADD > CREAM; TOPICAL
> ADD > DOVONEX
> ADD > + BRISTOL MYERS SQUIBB 0.005% N20554 001
> ADD > JUL 22, 1996

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

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

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

SOLUTION; INTRAPERITONEAL

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

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

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
CAPOTEN
> DLT > AB BRISTOL MYERS SQUIBB 100MG N18343 003
> ADD > AB + 100MG N18343 003

CAPTOPRIL

TABLET; ORAL

CAPOTEN

> DLT >		BRISTOL MYERS SQUIBB	75MG	N18343 007	
> DLT >				JUN 13, 1995	
> DLT >	+		150MG	N18343 004	
> DLT >				JUN 13, 1995	
> ADD >	@		75MG	N18343 007	
> ADD >				JUN 13, 1995	
> ADD >	@		150MG	N18343 004	
> ADD >				JUN 13, 1995	

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	
AB		25MG	N74462 002	
			FEB 13, 1996	
AB		50MG	N74462 003	
			FEB 13, 1996	
AB		100MG	N74462 004	
			FEB 13, 1996	
AB	DANBURY PHARMA	12.5MG	N74386 001	
			MAY 23, 1996	
AB		25MG	N74386 002	
			MAY 23, 1996	
AB		50MG	N74386 003	
			MAY 23, 1996	
AB		100MG	N74386 004	
			MAY 23, 1996	
AB	ENDO LABS	12.5MG	N74418 001	
			FEB 13, 1996	
AB		25MG	N74418 002	
			FEB 13, 1996	

CAPTOPRIL

TABLET; ORAL

CAPTOPRIL

AB	ENDO LABS	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
AB		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

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL

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
AB		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
+		200MG	N20234 002 MAR 25, 1996
+		400MG	N20234 003 MAR 25, 1996

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL

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

CEFACLOR

CAPSULE; ORAL
CEFACLOR

AB	MARSAM	EQ 250MG BASE	N64148 001 MAY 23, 1996
AB		EQ 500MG BASE	N64148 002 MAY 23, 1996
AB	NOVOPHARM	EQ 250MG BASE	N64145 001 JUN 24, 1996
AB		EQ 500MG BASE	N64145 002 JUN 24, 1996

TABLET, EXTENDED RELEASE; ORAL
CECLOR CD

+	LILLY	EQ 375MG BASE	N50673 001 JUN 28, 1996
+		EQ 500MG BASE	N50673 002 JUN 28, 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

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

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

CEFTAZIDIME (ARGININE FORMULATION)

INJECTABLE; INJECTION
CEPTAZ

+	GLAXO WELLCOME	500MG/VIAL	N50646 001	SEP 27, 1990
@		500MG/VIAL	N50646 001	SEP 27, 1990

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION
CEFTAZIDIME SODIUM IN PLASTIC CONTAINER

AP	**BAXTER**	**EQ 10MG BASE/ML**	**N63221 001**	**APR 29, 1993**
+		EQ 10MG BASE/ML	N63221 001	APR 29, 1993

FORTAZ IN PLASTIC CONTAINER

AP	+ GLAXO WELLCOME	**EQ 10MG BASE/ML**	**N50634 001**	**APR 28, 1989**
@		EQ 10MG BASE/ML	N50634 001	APR 28, 1989

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN

	ROCHE	EQ 500MG BASE/VIAL	N62654 001	APR 30, 1987
@		EQ 500MG BASE/VIAL	N62654 001	APR 30, 1987

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

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION
CEPHALOTHIN SODIUM W/ DEXTROSE IN PLASTIC CONTAINER

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

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION

	CEPHALOTHIN SODIUM W/ DEXTROSE IN PLASTIC CONTAINER			
	@ BAXTER	EQ 40MG BASE/ML	N62422 006	JUL 16, 1991
	@	EQ 40MG BASE/ML	N62730 002	MAR 05, 1987
	CEPHALOTHIN SODIUM W/ SODIUM CHLORIDE IN PLASTIC CONTAINER			
	+ BAXTER	EQ 20MG BASE/ML	N62422 001	JAN 31, 1984
	+	EQ 40MG BASE/ML	N62422 002	JAN 31, 1984
	@	EQ 20MG BASE/ML	N62422 001	JAN 31, 1984
	@	EQ 40MG BASE/ML	N62422 002	JAN 31, 1984

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	

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL

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

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION

>_DLT_>		CHLOR-TRIMETON			
>_DLT_>	AP	+ SCHERING PLOUGH	10MG/ML	N08826 001	
>_ADD_>		@	10MG/ML	N08826 001	
		CHLORPHENIRAMINE MALEATE			
>_DLT_>	AP	STERIS	10MG/ML	N86096 001	
>_ADD_>		+	10MG/ML	N86096 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
AB		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

CHOLESTYRAMINE

POWDER; ORAL

		QUESTRAN		
AB	+	BRISTOL MYERS	EQ 4GM RESIN/PACKET	N16640 001
AB			EQ 4GM RESIN/SCOOPFUL	N16640 003
		QUESTRAN LIGHT		
AB	+	BRISTOL MYERS	EQ 4GM RESIN/PACKET	N19669 001 DEC 05, 1988
AB			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

CIDOFOVIR

> ADD >
> ADD >

INJECTABLE; INJECTION

		VISTIDE		
	+	GILEAD	EQ 75MG BASE/ML	N20638 001 JUN 26, 1996

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

CIMETIDINE

TABLET; ORAL

		CIMETIDINE		
AB		INVAMED	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		
		BAYER	EQ 100MG BASE	N19537 001 APR 08, 1996

CLOBETASOL PROPIONATE

CREAM; TOPICAL

		CLOBETASOL PROPIONATE		
> ADD > AB		TARO	0.05%	N74249 001 JUL 08, 1996

OINTMENT; TOPICAL

		CLOBETASOL PROPIONATE		
AB		FOUGERA	0.05%	N74407 001 FEB 23, 1996
> ADD > AB		TARO	0.05%	N74248 001 JUL 12, 1996

CLOMIPRAMINE HYDROCHLORIDE

CAPSULE; ORAL

		ANAFRANIL		
AB		CIBA GEIGY	25MG	N19906 001 DEC 29, 1989
AB	+		50MG	N19906 002 DEC 29, 1989

CLOMIPRAMINE HYDROCHLORIDE

CAPSULE; ORAL

	ANAFRANIL			
AB	CIBA GEIGY	**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

CLOTRIMAZOLE

SOLUTION; TOPICAL

	CLOTRIMAZOLE			
>ADD> **AT**	TARO	**1%**	**N74580 001**	JUL 29, 1996
>ADD>				

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

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

CORTICORELIN OVINE TRIFLUTATE

INJECTABLE; INJECTION

	ACTHREL			
+	FERRING LABS	EQ 0.1MG BASE/VIAL	N20162 001	MAY 23, 1996

CROMOLYN SODIUM

CONCENTRATE; ORAL

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

CYANOCOBALAMIN

INJECTABLE; INJECTION

	BETALIN 12			
AP	LILLY	**0.1MG/ML**	**N80855 001**	
AP		**1MG/ML**	**N80855 002**	
	@	0.1MG/ML	N80855 001	
	@	1MG/ML	N80855 002	

CYCLOTHIAZIDE

TABLET; ORAL

	ANHYDRON			
+	LILLY	2MG	N13157 002	
	@	2MG	N13157 002	

CYPROHEPTADINE HYDROCHLORIDE

SYRUP; ORAL

	CYPROHEPTADINE HCL			
AA	HALSEY	**2MG/5ML**	**N89199 001**	JUL 03, 1986
	@	2MG/5ML	N89199 001	JUL 03, 1986

DALTEPARIN SODIUM

INJECTABLE; INJECTION

	FRAGMIN			
+	PHARMACIA AND UPJOHN	5,000 IU/0.2ML	N20287 003	MAR 18, 1996

DAUNORUBICIN CITRATE

INJECTABLE, LIPOSOMAL; INJECTION

	DAUNOXOME			
+	NEXSTAR	EQ 2MG BASE/ML	N50704 002	APR 08, 1996

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

	DESIPRAMINE HCL			
AB	EON LABS	**10MG**	**N74430 001**	FEB 09, 1996

DESIPRAMINE HYDROCHLORIDE

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

DESOXIMETASONE

OINTMENT; TOPICAL
DESOXIMETASONE
AB TARO 0.25% N74286 001
JUN 07, 1996

TOPICORT
AB + HOECHST MARION RSSL 0.25% N18763 001
SEP 30, 1983

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

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

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

DEXAMETHASONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC, OTIC
DEXAMETHASONE SODIUM PHOSPHATE
>ADD> AT BAUSCH AND LOMB EQ 0.1% PHOSPHATE N40069 001
>ADD> JUL 26, 1996

DEXFENFLURAMINE HYDROCHLORIDE

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

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
AA HALSEY 15MG/5ML;6.25MG/5ML N88913 001
MAR 02, 1987
@ 15MG/5ML;6.25MG/5ML N88913 001
MAR 02, 1987
>ADD> PROMETHAZINE HCL AND DEXTROMETHORPHAN HYDROBROMIDE
>ADD> AA HI TECH PHARMA 15MG/5ML;6.25MG/5ML N40027 001
>ADD> JUL 31, 1996

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION
>DLT> MD-76
>DLT> AP MALLINCKRODT 66%;10% N19292 001
>DLT> SEP 29, 1989
>ADD> MD-76R
>ADD> AP MALLINCKRODT 66%;10% N19292 001
>ADD> SEP 29, 1989

DIATRIZOATE SODIUM

SOLUTION; URETERAL
HYPAQUE SODIUM 20%
AT NYCOMED 20% N09561 002

DIATRIZOATE SODIUM

SOLUTION; URETERAL
HYPAQUE SODIUM 20%
NYCOMED 20% N09561 002

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL
DICLOFENAC SODIUM
AB PUREPAC PHARM 50MG N74514 001 MAR 26, 1996
AB 75MG N74514 002 MAR 26, 1996

TABLET, EXTENDED RELEASE; ORAL
VOLTAREN-XR
+ GEIGY 100MG N20254 001 MAR 08, 1996

DICLOXACILLIN SODIUM

CAPSULE; ORAL
DICLOXACILLIN SODIUM
> DLT > AB APOTHECON EQ 250MG BASE N61454 001
> ADD > AB + EQ 250MG BASE N61454 001
> DLT > AB EQ 500MG BASE N61454 003
> ADD > AB + EQ 500MG BASE N61454 003
PATHOCIL
> DLT > AB + WYETH AYERST EQ 250MG BASE N50011 002
> ADD > AB EQ 250MG BASE N50011 002
> DLT > AB + EQ 500MG BASE N50011 003
> DLT > MAR 28, 1983
> ADD > AB EQ 500MG BASE N50011 003
> ADD > MAR 28, 1983

POWDER FOR RECONSTITUTION; ORAL
DICLOXACILLIN SODIUM
> DLT > AB APOTHECON EQ 62.5MG BASE/5ML N61455 001
> ADD > AB + EQ 62.5MG BASE/5ML N61455 001
PATHOCIL
> DLT > AB + WYETH AYERST EQ 62.5MG BASE/5ML N50092 001
> ADD > AB EQ 62.5MG BASE/5ML N50092 001

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL
DICYCLOMINE HCL
AB LANNETT 10MG N84285 001

INJECTABLE; INJECTION
BENTYL PRESERVATIVE FREE
AP HOECHST MARION RSSL 10MG/ML N08370 002 OCT 15, 1984

DIFLUNISAL

TABLET; ORAL
DIFLUNISAL
AB GENEVA PHARMS 500MG N74604 001 JUN 10, 1996
AB PUREPAC PHARM 250MG N74285 001 MAY 07, 1996
AB 500MG N74285 002 MAY 07, 1996

DIGOXIN

INJECTABLE; INJECTION
DIGOXIN
AP SANOFI WINTHROP 0.25MG/ML N40093 001 MAY 16, 1996
DIGOXIN PEDIATRIC
AP SANOFI WINTHROP 0.1MG/ML N40092 001 APR 25, 1996
LANOXIN
+ GLAXO WELLCOME 0.1MG/ML N09330 004
LANOXIN PEDIATRIC
AP + GLAXO WELLCOME 0.1MG/ML N09330 004

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
	@	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

DOCETAXEL

INJECTABLE; INJECTION
TAXOTERE

+	RHONE POULENC	EQ 40MG BASE/ML	N20449 001 MAY 14, 1996

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOPAMINE HCL

AP	SANOFI WINTHROP	40MG/ML	N74403 001 MAY 23, 1996

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

ENCAINIDE HYDROCHLORIDE

CAPSULE; ORAL
ENKAID

	@ BRISTOL	25MG	N18981 002 DEC 24, 1986
	@	35MG	N18981 003 DEC 24, 1986
	BRISTOL MYERS SQUIBB	25MG	N18981 002 DEC 24, 1986
		35MG	N18981 003 DEC 24, 1986

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL W/ EPINEPHRINE

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

ERYTHROMYCIN

OINTMENT; OPHTHALMIC
ERYTHROMYCIN

>ADD<	AT	ADV REMEDIES	0.5%	N64030 001	JUL 18, 1996
>ADD<					

SWAB; TOPICAL
ERYTHROMYCIN

>ADD<					
>ADD<	AT	STIEFEL	2%	N64126 001	JUL 03, 1996
>ADD<					
>ADD<	AT		2%	N64128 001	JUL 03, 1996
>ADD<					

ERYTHROMYCIN ESTOLATE

SUSPENSION; ORAL
ILOSONE

AB		DISTA	EQ 125MG BASE/5ML	N61894 001	
AB	+		EQ 250MG BASE/5ML	N61894 002	
	@		EQ 125MG BASE/5ML	N61894 001	
	@		EQ 250MG BASE/5ML	N61894 002	
AB		LILLY	EQ 125MG BASE/5ML	N50010 001	
AB	+		EQ 250MG BASE/5ML	N50010 002	

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

FILM, EXTENDED RELEASE; TRANSDERMAL
ESTRADIOL

>ADD<					
>ADD<	AB	MENOREST	0.0375MG/24HR	N20538 001	JUL 31, 1996
>ADD<					
>ADD<	AB		0.05MG/24HR	N20538 003	JUL 31, 1996
>ADD<					

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL
ESTRADIOL

>ADD<					
>ADD<	AB	MENOREST	0.075MG/24HR	N20538 002	JUL 31, 1996
>ADD<					
>ADD<	AB		0.1MG/24HR	N20538 004	JUL 31, 1996
>ADD<					

VIVELLE

>ADD<	AB	+ CIBA GEIGY	0.0375MG/24HR	N20323 001	OCT 28, 1994
>ADD<					
>ADD<	AB	+	0.05MG/24HR	N20323 002	OCT 28, 1994
>ADD<					
>ADD<	AB	+	0.075MG/24HR	N20323 003	OCT 28, 1994
>ADD<					
>ADD<	AB	+	0.1MG/24HR	N20323 004	OCT 28, 1994
>ADD<					

INSERT, EXTENDED RELEASE; VAGINAL
ESTRING

+	PHARMACIA AND UPJOHN	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	
	@		2MG/ML	N83488 001	

NATURAL ESTROGENIC SUBSTANCE-ESTRONE

BP		STERIS	2MG/ML	N85237 001	NOV 23, 1982
	+		2MG/ML	N85237 001	NOV 23, 1982

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)

AB		WATSON LABS	0.035MG,0.035MG;0.5MG,1MG	N71041 001 SEP 24, 1991
AB	+		0.035MG,0.035MG;0.5MG,1MG	N71041 001 SEP 24, 1991

ORTHO-NOVUM 7/14-21

AB	+	JOHNSON RW	0.035MG,0.035MG;0.5MG,1MG	N19004 001 APR 04, 1984
	@		0.035MG,0.035MG;0.5MG,1MG	N19004 001 APR 04, 1984

ETODOLAC

TABLET; ORAL
LODINE

	+	WYETH AYERST	400MG	N18922 004 JUL 29, 1993
			400MG	N18922 004 JUL 29, 1993
	+		500MG	N18922 005 JUN 28, 1996

ETOPOSIDE

INJECTABLE; INJECTION
ETOPOSIDE

>ADD<	AP	GENSIA	20MG/ML	N74529 001 JUL 24, 1996
>ADD<				
	AP	LEDERLE LABS	20MG/ML	N74513 001 MAR 14, 1996
	AP	PHARMACHEMIE (NL)	20MG/ML	N74227 001 FEB 22, 1996

ETOPOSIDE PHOSPHATE

INJECTABLE; INJECTION
ETOPOPHOS

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

EVANS BLUE

INJECTABLE; INJECTION
EVANS BLUE

	@	PARKE DAVIS	0.5%	N08041 001

FAMCICLOVIR

TABLET; ORAL
FAMVIR

		SMITHKLINE BEECHAM	250MG	N20363 001 APR 26, 1996

FAMOTIDINE

INJECTABLE; INJECTION
PEPCID IV PRESERVATIVE FREE

	+	MERCK	10MG/ML	N19510 004 NOV 04, 1986

PEPCID PRESERVATIVE FREE

	+	MERCK	10MG/ML	N19510 004 NOV 04, 1986

>ADD< FEXOFENADINE HYDROCHLORIDE

>ADD<
>ADD< CAPSULE; ORAL
>ADD< ALLEGRA

>ADD<	+	HOECHST MARION RSSL	60MG	N20625 001 JUL 25, 1996

FLECAINIDE ACETATE

TABLET; ORAL
TAMBOCOR

	@	3M	200MG	N18830 002 OCT 31, 1985

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL
FLUOCINOLONE ACETONIDE

AT	+	HAMILTON PHARMA CA	0.01%	N12787 004
AT	+		0.025%	N12787 002
AT	+		0.025%	N12787 005

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

		FLUOCINOLONE ACETONIDE		
	+	HAMILTON PHARMA CA	0.2%	N16161 002
		SYNALAR		
AT	+	SYNTEX	0.01%	N12787 004
AT	+		0.025%	N12787 002
AT	+		0.025%	N12787 005
		SYNALAR-HP		
	+	SYNTEX	0.2%	N16161 002

OINTMENT; TOPICAL

		FLUOCINOLONE ACETONIDE		
AT	+	HAMILTON PHARMA CA	0.025%	N13960 001
		SYNALAR		
AT	+	SYNTEX	0.025%	N13960 001

SOLUTION; TOPICAL

		FLUOCINOLONE ACETONIDE		
AT	+	HAMILTON PHARMA CA	0.01%	N15296 001
		SYNALAR		
AT	+	SYNTEX	0.01%	N15296 001

FLUOCINONIDE

CREAM; TOPICAL

		FLUOCINONIDE		
AB	+	HAMILTON PHARMA CA	0.05%	N16908 002
		FLUOCINONIDE EMOLLIENT BASE		
AB		HAMILTON PHARMA CA	0.05%	N16908 003
		LIDEX		
AB	+	SYNTEX	0.05%	N16908 002
		LIDEX-E		
AB		SYNTEX	0.05%	N16908 003

GEL; TOPICAL

		FLUOCINONIDE		
AB	+	HAMILTON PHARMA CA	0.05%	N17373 001
		LIDEX		
AB	+	SYNTEX	0.05%	N17373 001

OINTMENT; TOPICAL

		FLUOCINONIDE		
AB	+	HAMILTON PHARMA CA	0.05%	N16909 002
		LIDEX		
AB	+	SYNTEX	0.05%	N16909 002

FLUOCINONIDE

SOLUTION; TOPICAL

		FLUOCINONIDE		
AT	+	HAMILTON PHARMA CA	0.05%	N18849 001 APR 06, 1984
		LIDEX		
AT	+	SYNTEX	0.05%	N18849 001 APR 06, 1984

FLUOROURACIL

INJECTABLE; INJECTION

		ADRUCIL		
AP	+	PHARMACIA	50MG/ML	N40023 001 OCT 18, 1991
AP		PHARMACIA AND UPJOHN	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
AB		WARNER CHILCOTT	30MG	N71768 001 DEC 04, 1987
	@		30MG	N71768 001 DEC 04, 1987

FLUTICASONE PROPIONATE

AEROSOL, METERED; INHALATION

		FLOVENT		
		GLAXO WELLCOME	0.044MG/INH	N20548 001 MAR 27, 1996

FLUTICASONE PROPIONATE

AEROSOL, METERED; INHALATION
FLOVENT
GLAXO WELLCOME 0.11MG/INH N20548 002 >DLT>
MAR 27, 1996 >DLT>
+ 0.22MG/INH N20548 003
MAR 27, 1996 >ADD>
>ADD>

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
AB 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
+ 4.5MG N20569 001
MAR 04, 1996

GANCICLOVIR SODIUM

INJECTABLE; INJECTION
CYTOVENE IV
+ SYNTEX EQ 500MG BASE/VIAL N19661 001
JUN 23, 1989
CYTOVENE IV
+ ROCHE EQ 500MG BASE/VIAL N19661 001
JUN 23, 1989

GEMCITABINE HYDROCHLORIDE

INJECTABLE; INJECTION
GEMZAR
+ LILLY EQ 200MG BASE/VIAL N20509 001
MAY 15, 1996
+ EQ 1GM BASE/VIAL N20509 002
MAY 15, 1996

GENTAMICIN SULFATE

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

GENTAMICIN SULFATE

INJECTABLE; INJECTION
GENTAMICIN SULFATE

@	ABBOTT	EQ 80MG BASE/100ML	N62413 008 AUG 11, 1983
@		EQ 90MG BASE/100ML	N62413 009 AUG 11, 1983
@		EQ 100MG BASE/100ML	N62413 010 AUG 11, 1983
@		EQ 1.2MG BASE/ML	N62413 001 AUG 11, 1983
@		EQ 1.4MG BASE/ML	N62413 002 AUG 11, 1983
@		EQ 1.6MG BASE/ML	N62413 003 AUG 11, 1983
@		EQ 1.8MG BASE/ML	N62413 004 AUG 11, 1983
@		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

GLUTETHIMIDE

TABLET; ORAL
GLUTETHIMIDE

	HALSEY	250MG	N89458 001 OCT 10, 1986
@		250MG	N89458 001 OCT 10, 1986

GLYBURIDE

TABLET; ORAL
GLYNASE

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

GLYCOPYRROLATE

INJECTABLE; INJECTION
GLYCOPYRROLATE

AP	ABBOTT	0.2MG/ML	N89393 001 JUN 15, 1988
@		0.2MG/ML	N89393 001 JUN 15, 1988

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

CREAM; TOPICAL
HALOTEX

	+	WESTWOOD SQUIBB	1%	N16942 001
	@		1%	N16942 001

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM

AP		MARSAM	**1,000 UNITS/ML**	**N40007 001 JUN 07, 1996**
AP		ORGANON	**1,000 UNITS/ML**	**N00552 008**
AP			**5,000 UNITS/ML**	**N00552 009**
AP			**10,000 UNITS/ML**	**N00552 010**
	@		1,000 UNITS/ML	N00552 008
	@		5,000 UNITS/ML	N00552 009
	@		10,000 UNITS/ML	N00552 010
> ADD >	**AP**	SANOFI WINTHROP	**10,000 UNITS/ML**	**N40095 001 JUL 26, 1996**
> DLT >	**AP**	SOLOPAK	**5,000 UNITS/ML**	**N87077 001**
> ADD >	@		5,000 UNITS/ML	N87077 001

HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

AP		MCGAW	**5,000 UNITS/100ML**	**N19134 001 MAR 29, 1985**
	@		5,000 UNITS/100ML	N19134 001 MAR 29, 1985

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

AB		NOVOPHARM	**15MG;250MG**	**N71819 001 APR 08, 1988**
AB			**25MG;250MG**	**N71820 001 APR 08, 1988**
AB			**30MG;500MG**	**N71821 001 APR 08, 1988**
AB			**50MG;500MG**	**N71822 001 APR 08, 1988**
	@		15MG;250MG	N71819 001 APR 08, 1988
	@		25MG;250MG	N71820 001 APR 08, 1988
	@		30MG;500MG	N71821 001 APR 08, 1988
	@		50MG;500MG	N71822 001 APR 08, 1988
AB		PARKE DAVIS	**15MG;250MG**	**N71897 001 NOV 23, 1987**
AB			**25MG;250MG**	**N71898 001 NOV 23, 1987**

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

	METHYLDOPA AND HYDROCHLOROTHIAZIDE			
AB	PARKE DAVIS	**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

CAPSULE; ORAL

	DYAZIDE				
AB	+ SMITHKLINE BEECHAM	**25MG;37.5MG**	**N16042 003**		
			MAR 03, 1994		
	TRIAMTERENE AND HYDROCHLOROTHIAZIDE				
AB	MYLAN	**25MG;37.5MG**	**N74701 001**	> DLT >	
			JUN 07, 1996	> ADD >	

TABLET; ORAL

	TRIAMTERENE AND HYDROCHLOROTHIAZIDE		
AB	SIDMAK LABS NJ	**25MG;37.5MG**	**N74026 001**
			APR 26, 1996
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**
AT		**2.5%**	**N86272 001**

HYDROCORTISONE

OINTMENT; TOPICAL

	HYDROCORTISONE		
	@ AMBIX	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	

HYDROXOCOBALAMIN

INJECTABLE; INJECTION

	HYDROXOCOBALAMIN			
AP	STERIS	**1MG/ML**	**N85528 001**	
	@	1MG/ML	N85528 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

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL
HYDROXYZINE HCL

AB	SUPERPHARM	50MG	N88796 001	DEC 05, 1984
@		10MG	N88794 001	DEC 05, 1984
@		25MG	N88795 001	DEC 05, 1984
@		50MG	N88796 001	DEC 05, 1984

HYDROXYZINE PAMOATE

CAPSULE; ORAL
HYDROXYZINE PAMOATE

>ADD> AB	CHELSEA LABS	EQ 25MG HCL	N40156 001	JUL 15, 1996
>ADD> AB		EQ 50MG HCL	N40156 002	JUL 15, 1996

IBUPROFEN

SUSPENSION; ORAL
CHILDREN'S MOTRIN

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

>ADD>
IBU

>ADD> BX	KNOLL PHARM	100MG/5ML	N19784 001	DEC 18, 1989

MOTRIN

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

>DLT>
RUFEN

>DLT> BX	KNOLL PHARM	100MG/5ML	N19784 001	DEC 18, 1989

TABLET; ORAL
>ADD>
IBU

>ADD> AB	KNOLL PHARM	400MG	N18197 001	
>ADD> AB		400MG	N70083 001	FEB 22, 1985
>ADD> AB		600MG	N70088 001	FEB 08, 1985
>ADD> AB		600MG	N70099 001	MAR 29, 1985

IBUPROFEN

TABLET; ORAL
>ADD>
IBU

>ADD> AB	KNOLL PHARM	800MG	N70745 001	JUL 23, 1986

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
>DLT> AB	KNOLL PHARM	400MG	N70083 001	FEB 22, 1985

>DLT>
RUFEN

>DLT> AB	KNOLL PHARM	400MG	N18197 001	
>DLT> AB		600MG	N70088 001	FEB 08, 1985
>DLT> AB		600MG	N70099 001	MAR 29, 1985
>DLT> AB		800MG	N70745 001	JUL 23, 1986

INDAPAMIDE

TABLET; ORAL
INDAPAMIDE

AB	INVAMED	1.25MG	N74594 001	MAY 23, 1996
AB		2.5MG	N74594 002	MAY 23, 1996
AB	MYLAN	2.5MG	N74461 001	MAR 27, 1996
AB	PUREPAC PHARM	1.25MG	N74722 001	JUN 17, 1996
AB		2.5MG	N74722 002	JUN 17, 1996

INDAPAMIDE

TABLET; ORAL
INDAPAMIDE

AB	ZENITH GOLDLINE	1.25MG	N74299 002 APR 29, 1996		
AB		2.5MG	N74299 001 JUL 27, 1995		
AB	ZENITH LABS	2.5MG	N74299 001 JUL 27, 1995		
	LOZOL				
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	> DLT >	
+		EQ 400MG BASE	N20685 001 MAR 13, 1996	> DLT >	
				> ADD >	
				> ADD >	

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

AB	HALSEY	25MG	N70782 001 JUN 03, 1987	> DLT >	
AB		50MG	N70635 001 JUN 03, 1987	> DLT >	
@		25MG	N70782 001 JUN 03, 1987	> ADD >	
@		50MG	N70635 001 JUN 03, 1987	> ADD >	
AB	PARKE DAVIS	25MG	N18806 001 NOV 23, 1984		
AB		50MG	N18806 002 NOV 23, 1984		
@		25MG	N18806 001 NOV 23, 1984		
@		50MG	N18806 002 NOV 23, 1984		

INSULIN LISPRO

INJECTABLE; INJECTION
HUMALOG

+	LILLY	100 UNITS/ML	N20563 001 JUN 14, 1996		

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		
@		41%	N20327 001 OCT 12, 1994		

ISOVUE-250

	BRACCO	51%	N20327 002 OCT 12, 1994		
+		51%	N20327 002 OCT 12, 1994		

ISOVUE-300

	BRACCO	61%	N20327 003 OCT 12, 1994		
+		61%	N20327 003 OCT 12, 1994		

ISOVUE-370

	BRACCO	76%	N20327 004 OCT 12, 1994		
+		76%	N20327 004 OCT 12, 1994		

IRINOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION
CAMPTOSAR

+	PHARMACIA AND UPJOHN	20MG/ML	N20571 001 JUN 14, 1996		

IRON DEXTRAN

INJECTABLE; INJECTION
DEXFERRUM

BP	LUITPOLD	EQ 50MG IRON/ML	N40024 001 FEB 23, 1996		

ISONIAZID

TABLET; ORAL
ISONIAZID

AA	DANBURY PHARMA	50MG	N80522 001	
AA		100MG	N80523 001	
@		50MG	N80522 001	
@		100MG	N80523 001	
AA	DURAMED	100MG	N88231 001	
			MAR 17, 1983	
@		100MG	N88231 001	
			MAR 17, 1983	
@	GLOBAL PHARM	100MG	N80153 001	
AA	GLOBAL PHARMS	100MG	N80153 001	
AA	PHOENIX LABS NY	50MG	N80368 001	
AA		100MG	N80368 002	
@		50MG	N80368 001	
@		100MG	N80368 002	
AA	ZENITH LABS	100MG	N80270 001	
AA		300MG	N83610 001	
@		100MG	N80270 001	
@		300MG	N83610 001	

ISOSORBIDE DINITRATE

TABLET; ORAL
SORBITRATE

BX	ZENECA	5MG	N16192 001
			APR 01, 1996
BX		10MG	N16192 002
			APR 01, 1996

TABLET; SUBLINGUAL
SORBITRATE

BX	ZENECA	2.5MG	N16191 002
			APR 01, 1996
BX		5MG	N16191 001
			APR 01, 1996

TABLET, CHEWABLE; ORAL
SORBITRATE

	ZENECA	5MG	N16776 002
			APR 01, 1996
+		10MG	N16776 003
			APR 01, 1996

ISOSORBIDE MONONITRATE

TABLET; ORAL
MONOKET

+	SCHWARZ	10MG	N20215 002
			JUN 30, 1993
		10MG	N20215 002
			JUN 30, 1993

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	
AP	SANOFI WINTHROP	EQ 50MG BASE/ML	N74549 001	
			JUN 27, 1996	
AP		EQ 100MG BASE/ML	N74549 002	
			JUN 27, 1996	

LACTULOSE

SOLUTION; ORAL
LACTULOSE

AA	PHARM ASSOC	10GM/15ML	N74623 001	> ADD >
			JUL 30, 1996	> ADD >

LATANOPROST

SOLUTION/DROPS; OPHTHALMIC
XALATAN

+	PHARMACIA AND UPJOHN	0.005%	N20597 001
			JUN 05, 1996

LEUCOVORIN CALCIUM

POWDER FOR RECONSTITUTION; ORAL
LEUCOVORIN CALCIUM

	IMMUNEX	EQ 60MG BASE/VIAL	N08107 003 JAN 30, 1987
@		EQ 60MG BASE/VIAL	N08107 003 JAN 30, 1987

LIDOCAINE

FILM, EXTENDED RELEASE; BUCCAL
LIDOCAINE

+	NOVEN	23MG/PATCH	N20575 001 MAY 21, 1996
+		46.1MG/PATCH	N20575 002 MAY 21, 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

LIDOCAINE HYDROCHLORIDE

SOLUTION; TOPICAL
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

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
CIBALITH-S

AA	SOLVAY	EQ 300MG CARBONATE/5ML	N17672 001
	LITHONATE		
@	SOLVAY	EQ 300MG CARBONATE/5ML	N17672 001

LORACARBEF

CAPSULE; ORAL
LORABID

*	LILLY	200MG	N50668 001 DEC 31, 1991
		200MG	N50668 001 DEC 31, 1991

LORACARBEF

CAPSULE; ORAL
LORABID
+ LILLY 400MG N50668 002 APR 05, 1996

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

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
NEURAMATE
AA HALSEY 200MG N14359 002
AA 400MG N14359 001
@ 200MG N14359 002
@ 400MG N14359 001

MEROPENEM

INJECTABLE; INJECTION
MERREM I.V.
+ ZENECA 500MG/VIAL N50706 003 JUN 21, 1996
+ 1GM/VIAL N50706 001 JUN 21, 1996

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

METHYLTESTOSTERONE

TABLET; ORAL

	ORETON METHYL			
BP	SCHERING	25MG	N03158 002	
	®	25MG	N03158 002	

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

	METOCLOPRAMIDE HCL			
AP	ABBOTT	EQ 10MG BASE/2ML	N70505 001	JUN 23, 1989
AP		EQ 5MG BASE/ML	N70505 001	JUN 23, 1989
AP		EQ 10MG BASE/2ML	N70506 001	JUN 22, 1989

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

	METOCLOPRAMIDE HCL			
AP	ABBOTT	EQ 5MG BASE/ML	N70506 001	JUN 22, 1989
AP		EQ 10MG BASE/2ML	N73117 001	JAN 17, 1991
AP		EQ 5MG BASE/ML	N73117 001	JAN 17, 1991
AP		EQ 10MG BASE/2ML	N73118 001	JAN 17, 1991
AP		EQ 5MG BASE/ML	N73118 001	JAN 17, 1991
AP	BULL D	EQ 10MG BASE/2ML	N71990 001	JAN 18, 1989
AP	CETUS BEN VENUE	EQ 10MG BASE/2ML	N72155 001	MAR 30, 1992
AP		EQ 5MG BASE/ML	N72155 001	MAR 30, 1992
AP		EQ 10MG BASE/2ML	N72244 001	MAR 30, 1992
AP		EQ 5MG BASE/ML	N72244 001	MAR 30, 1992
AP		EQ 10MG BASE/2ML	N72247 001	MAY 18, 1992
AP		EQ 5MG BASE/ML	N72247 001	MAY 18, 1992
AP	FAULDING	EQ 10MG BASE/2ML	N70847 001	NOV 07, 1988
AP		EQ 5MG BASE/ML	N70847 001	NOV 07, 1988
AP		EQ 10MG BASE/2ML	N71291 001	MAR 03, 1989
AP		EQ 5MG BASE/ML	N71291 001	MAR 03, 1989
AP		EQ 5MG BASE/ML	N71990 001	JAN 18, 1989
AP	GENSIA	EQ 10MG BASE/2ML	N73135 001	NOV 27, 1991
AP		EQ 5MG BASE/ML	N73135 001	NOV 27, 1991
AP	SMITH AND NEPHEW	EQ 10MG BASE/2ML	N70623 001	MAR 02, 1987
AP		EQ 5MG BASE/ML	N70623 001	MAR 02, 1987
	REGLAN			
AP	+ ROBINS AH	EQ 10MG BASE/2ML	N17862 001	
AP	+	EQ 5MG BASE/ML	N17862 001	

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
METOCLOPRAMIDE HCL

AB	HALSEY	EQ 10MG BASE	N70906 001 OCT 28, 1986
@		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

MEXILETINE HYDROCHLORIDE

CAPSULE; ORAL
MEXILETINE HCL

AB	GENEVA PHARMS	150MG	N74450 001 MAY 16, 1996
AB		200MG	N74450 002 MAY 16, 1996
AB		250MG	N74450 003 MAY 16, 1996

MICONAZOLE NITRATE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
MONISTAT DUAL-PAK

+	JOHNSON RW	2%,200MG	N18888 002 OCT 17, 1988

MINOCYCLINE HYDROCHLORIDE

TABLET; ORAL
MINOCYCLINE HCL

	LEDERLE	EQ 100MG BASE	N50451 002 AUG 10, 1982
+	LEDERLE LABS	EQ 100MG BASE	N50451 002 AUG 10, 1982

MINOXIDIL

SOLUTION; TOPICAL
ROGAINE

+	UPJOHN	2%	N19501 001 AUG 17, 1988

MIRTAZAPINE

TABLET; ORAL
REMERON

	ORGANON	15MG	N20415 001 JUN 14, 1996
+		30MG	N20415 002 JUN 14, 1996

MORPHINE SULFATE

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

CAPSULE, EXTENDED RELEASE; ORAL
KADIAN

+	FAULDING	20MG	N20616 001 JUL 03, 1996
+		50MG	N20616 002 JUL 03, 1996
+		100MG	N20616 003 JUL 03, 1996

INJECTABLE; INJECTION
MORPHINE SULFATE

> ADD >
> ADD >

AP	MALLINCKRODT	1MG/ML	N20631 001 JUL 03, 1996

MORPHINE SULFATE

INJECTABLE; INJECTION

MORPHINE SULFATE

>ADD< >ADD< + MALLINCKRODT 2MG/ML N20631 002 JUL 03, 1996

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

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

NALBUPHINE HCL

ABBOTT 1.5MG/ML N20200 001 MAR 12, 1993

NALBUPHINE HYDROCHLORIDE

ABBOTT 1.5MG/ML N20200 001 MAR 12, 1993

NAPROXEN

TABLET; ORAL

NAPROXEN

AB	BIOCRAFT	250MG	N74216 001 APR 11, 1996
AB		375MG	N74216 002 APR 11, 1996
AB		500MG	N74216 003 APR 11, 1996
AB	SIDMAK LABS NJ	250MG	N74182 001 JUN 27, 1996
AB		375MG	N74182 002 JUN 27, 1996
AB		500MG	N74182 003 JUN 27, 1996

NAPROXEN SODIUM

TABLET; ORAL

NAPROXEN SODIUM

>ADD< >ADD< AB	AL HIKMA	EQ 500MG BASE	N74480 001 MAY 14, 1996
AB	SIDMAK LABS NJ	EQ 250MG BASE	N74242 001 JUN 20, 1996
AB		EQ 500MG BASE	N74242 002 JUN 20, 1996
>DLT< >DLT< AB	WEST WARD PHARM	EQ 500MG BASE	N74480 001 MAY 14, 1996

TABLET, EXTENDED RELEASE; ORAL

NAPRELAN

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

NEOMYCIN SULFATE

INJECTABLE; INJECTION

MYCIFRADIN

AP + UPJOHN EQ 350MG BASE/VIAL N60477 001

NEOMYCIN SULFATE

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

POWDER; FOR RX COMPOUNDING

NEO-RX

AA PHARMA TEK 100% N61579 001

NEOMYCIN SULFATE

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

NEVIRAPINE

TABLET; ORAL

VIRAMUNE

+ BOEHRINGER INGELHEIM 200MG N20636 001 JUN 21, 1996

NICARDIPINE HYDROCHLORIDE

CAPSULE; ORAL

		CARDENE			
>ADD>	**AB**	SYNTEX	**20MG**	**N19488 001**	
>ADD>				DEC 21, 1988	
>ADD>	**AB**	+	**30MG**	**N19488 002**	
>ADD>				DEC 21, 1988	
>ADD>		**NICARDIPINE HCL**			
>ADD>	**AB**	MYLAN	**20MG**	**N74642 001**	
>ADD>				JUL 18, 1996	
>ADD>	**AB**		**30MG**	**N74642 002**	
>ADD>				JUL 18, 1996	

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	

NITROFURANTOIN

SUSPENSION; ORAL

		FURADANTIN		
>ADD>		+ DURA	25MG/5ML	N09175 001
>DLT>		+ PROCTER AND GAMBLE	25MG/5ML	N09175 001

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
	BX	+	0.8MG/HR	N20145 006
				APR 04, 1995
		TRANSDERM-NITRO		
	BX	CIBA	0.1MG/HR	N20144 001
				FEB 27, 1996
	BX	+	0.1MG/HR	N20144 001
				FEB 27, 1996
	BX		0.2MG/HR	N20144 002
				FEB 27, 1996
	BX	+	0.2MG/HR	N20144 002
				FEB 27, 1996
	BX		0.4MG/HR	N20144 003
				FEB 27, 1996
	BX	+	0.4MG/HR	N20144 003
				FEB 27, 1996
	BX		0.6MG/HR	N20144 004
				FEB 27, 1996
	BX	+	0.6MG/HR	N20144 004
				FEB 27, 1996
	BX		0.8MG/HR	N20144 005
				FEB 27, 1996
	BX	+	0.8MG/HR	N20144 005
				FEB 27, 1996

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL

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

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

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

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

	ZOFRAN PRESERVATIVE FREE			
	+ GLAXO WELLCOME	EQ 2MG BASE/ML		N20007 003 DEC 10, 1993

OXAZEPAM

TABLET; ORAL

	OXAZEPAM			
AB	PARKE DAVIS	15MG		N71508 001 FEB 02, 1987
	@	15MG		N71508 001 FEB 02, 1987

OXTRIPHYLLINE

SOLUTION; ORAL

	CHOLEDYL			
	PARKE DAVIS	100MG/5ML		N09268 012 NOV 27, 1984
	@	100MG/5ML		N09268 012 NOV 27, 1984

SYRUP; ORAL

	CHOLEDYL			
	PARKE DAVIS	50MG/5ML		N09268 011
	@	50MG/5ML		N09268 011

TABLET, DELAYED RELEASE; ORAL

	CHOLEDYL			
	+ PARKE DAVIS	100MG		N09268 003
	+	200MG		N09268 007
	@	100MG		N09268 003
	@	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

TABLET; ORAL

	OXYBUTYNIN CHLORIDE			
> ADD > AB	ROSEMONT	5MG		N74625 001 JUL 31, 1996

> ADD >

PAROXETINE HYDROCHLORIDE

TABLET; ORAL

	PAXIL			
	@ SMITHKLINE BEECHAM	EQ 10MG BASE		N20031 001 DEC 29, 1992
	+	EQ 30MG BASE		N20031 003 DEC 29, 1992
	@	EQ 40MG BASE		N20031 005 DEC 29, 1992
		EQ 10MG BASE		N20031 001 DEC 29, 1992
		EQ 30MG BASE		N20031 003 DEC 29, 1992
	+	EQ 40MG BASE		N20031 005 DEC 29, 1992

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

PERFLUBRON

> DLT > LIQUID; ORAL
> DLT > IMAGENT
> DLT > + ALLIANCE PHARM 100% N20091 001 AUG 13, 1993
> DLT >
> ADD > @ 100% N20091 001 AUG 13, 1993
> ADD >

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

PIROXICAM

CAPSULE; ORAL
PIROXICAM
AB DANBURY PHARMA 10MG N74287 001 MAY 16, 1996
AB 20MG N74287 002 MAY 16, 1996
AB ZENITH GOLDLINE 10MG N74148 001 JUN 03, 1996

PIROXICAM

CAPSULE; ORAL
PIROXICAM
AB ZENITH GOLDLINE 20MG N74148 002 JUN 03, 1996

POLYESTRADIOL PHOSPHATE

INJECTABLE; INJECTION
ESTRADURIN
+ WYETH AYERST 40MG/AMP N10753 001
@ 40MG/AMP N10753 001

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
POTASSIUM CHLORIDE
AB BIOCRAFT 8MEQ N73531 001 APR 26, 1996
AB 10MEQ N73532 001 APR 26, 1996

INJECTABLE; INJECTION
POTASSIUM CHLORIDE
AP FUJISAWA 2MEQ/ML N87787 001 APR 20, 1982
@ 2MEQ/ML N87787 001 APR 20, 1982

TABLET, EXTENDED RELEASE; ORAL
K-DUR 10
> ADD > BC + KEY PHARMS 10MEQ N19439 002 JUN 13, 1986
> ADD >
> DLT > BC + SCHERING 10MEQ N19439 002 JUN 13, 1986
> DLT >
K-DUR 20
> ADD > + KEY PHARMS 20MEQ N19439 001 JUN 13, 1986
> ADD >
> DLT > + SCHERING 20MEQ N19439 001 JUN 13, 1986
> DLT >

PREDNISOLONE

SYRUP; ORAL

	PRELONE		
	MURO	5MG/5ML	N89654 001 JAN 17, 1989
		15MG/5ML	N89081 001 FEB 04, 1986
+		5MG/5ML	N89654 001 JAN 17, 1989
+		15MG/5ML	N89081 001 FEB 04, 1986

PREDNISOLONE ACETATE

SUSPENSION, OPHTHALMIC

		PRED FORTE		
BX	+	ALLERGAN	1%	N17011 001

SUSPENSION/DROPS; OPHTHALMIC

		PRED FORTE		
AB	+	ALLERGAN	**1%**	**N17011 001**

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

>ADD<		**SULSTER**		
>ADD<				
>ADD<	**AT**	+ AKORN	**EQ 0.23% PHOSPHATE;10%**	**N74511 001 JUL 30, 1996**
>ADD<				

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
	+		1GM	N20545 002 JAN 31, 1996

PROCHLORPERAZINE MALEATE

TABLET; ORAL

>ADD<		**COMPAZINE**		
>ADD<	**AB**	SMITHKLINE BEECHAM	**EQ 5MG BASE**	**N10571 001**
>ADD<	**AB**		**EQ 10MG BASE**	**N10571 002**
>ADD<	**AB**	+	**EQ 25MG BASE**	**N10571 003**
>ADD<		**PROCHLORPERAZINE MALEATE**		
>ADD<	**AB**	COPLEY PHARM	**EQ 5MG BASE**	**N40120 001 JUL 11, 1996**
>ADD<	**AB**		**EQ 10MG BASE**	**N40120 002 JUL 11, 1996**
>ADD<	**AB**	INVAMED	**EQ 5MG BASE**	**N40101 001 JUL 19, 1996**
>ADD<	**AB**		**EQ 10MG BASE**	**N40101 002 JUL 19, 1996**
>ADD<	**AB**		**EQ 25MG BASE**	**N40101 003 JUL 19, 1996**

PROMAZINE HYDROCHLORIDE

TABLET; ORAL

		SPARINE		
		WYETH AYERST	50MG	N10348 002
	+		100MG	N10348 003
	+		50MG	N10348 002
	@		100MG	N10348 003

PROPANTHELINE BROMIDE

TABLET; ORAL

		PRO-BANTHINE		
AA	+	ROBERTS LABS	**7.5MG**	**N08732 003**
AA	+		**15MG**	**N08732 002**
BP	+		7.5MG	N08732 003
BP	+		15MG	N08732 002

PROPANTHELINE BROMIDE

TABLET; ORAL
PROPANTHELINE BROMIDE

AA	PAR PHARM	15MG	N88377 001 DEC 08, 1983
BP		15MG	N88377 001 DEC 08, 1983
AA	ROXANE	7.5MG	N80927 001
AA		15MG	N80927 002
BP		7.5MG	N80927 001
BP		15MG	N80927 002

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPHENE 65

AA	HALSEY	65MG	N83538 002
	@	65MG	N83538 002

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL

BD	HALSEY	50MG	N80015 001
	@	50MG	N80015 001

PROTIRELIN

INJECTABLE; INJECTION
THYPINONE

AP	+ ABBOTT	0.5MG/ML	N17638 001
	@	0.5MG/ML	N17638 001

THYREL TRH

AP	FERRING LABS	0.5MG/ML	N18087 001
	+	0.5MG/ML	N18087 001

PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
NOVAFED

	+ DOW PHARM	120MG	N17603 001
	+ HOECHST MARION RSSL	120MG	N17603 001

QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL
QUINIDINE GLUCONATE

AB	HALSEY	324MG	N89476 001 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

>ADD> REMIFENTANIL HYDROCHLORIDE

>ADD> INJECTABLE; INJECTION			
>ADD> ULTIVA			
>ADD> GLAXO WELLCOME	EQ 1MG BASE/VIAL		N20630 001 JUL 12, 1996
>ADD>	EQ 2MG BASE/VIAL		N20630 002 JUL 12, 1996
>ADD> +	EQ 5MG BASE/VIAL		N20630 003 JUL 12, 1996

RISPERIDONE

SOLUTION; ORAL			
RISPERDAL			
+ JANSSEN	1MG/ML		N20588 001 JUN 10, 1996

RITONAVIR

CAPSULE; ORAL			
NORVIR			
+ ABBOTT	100MG		N20680 001 MAR 01, 1996
SOLUTION; ORAL			
NORVIR			
ABBOTT	80MG/ML		N20659 001 MAR 01, 1996

SELEGILINE HYDROCHLORIDE

CAPSULE; ORAL			
ELDEPRYL			
+ SOMERSET	5MG		N20647 001 MAY 15, 1996
TABLET; ORAL			
ELDEPRYL			
+ SOMERSET	5MG		N19334 001 JUN 05, 1989
@	5MG		N19334 001 JUN 05, 1989

SERTRALINE HYDROCHLORIDE

TABLET; ORAL			
ZOLOFT			
PFIZER	EQ 25MG BASE		N19839 005 MAR 06, 1996

SODIUM PHENYLBUTYRATE

POWDER; ORAL			
BUPHENYL			
+ UCYCLYD	3GM/TEASPOONFUL		N20573 001 APR 30, 1996
TABLET; ORAL			
BUPHENYL			
+ UCYCLYD	500MG		N20572 001 MAY 13, 1996

SPIRAPRIL HYDROCHLORIDE

TABLET; ORAL			
RENORMAX			
SANDOZ	3MG		N20240 001 DEC 29, 1994
	6MG		N20240 002 DEC 29, 1994
	12MG		N20240 003 DEC 29, 1994
+	24MG		N20240 004 DEC 29, 1994

SPIRAPRIL HYDROCHLORIDE

TABLET; ORAL			
RENORMAX			
@ SCHERING	3MG	N20240 001	DEC 29, 1994
@	6MG	N20240 002	DEC 29, 1994
@	12MG	N20240 003	DEC 29, 1994
@	24MG	N20240 004	DEC 29, 1994

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

TERAZOSIN HYDROCHLORIDE

TABLET; ORAL			
HYTRIN			
@ ABBOTT	EQ 1MG BASE	N19057 001	AUG 07, 1987
@	EQ 2MG BASE	N19057 002	AUG 07, 1987
@	EQ 5MG BASE	N19057 003	AUG 07, 1987
@	EQ 10MG BASE	N19057 004	AUG 07, 1987
	EQ 1MG BASE	N19057 001	AUG 07, 1987
+	EQ 2MG BASE	N19057 002	AUG 07, 1987
	EQ 5MG BASE	N19057 003	AUG 07, 1987
	EQ 10MG BASE	N19057 004	AUG 07, 1987

TERBINAFINE HYDROCHLORIDE

TABLET; ORAL			
LAMISIL			
+ SANDOZ	EQ 250MG BASE	N20539 001	MAY 10, 1996

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL			
TETRACYCLINE HCL			
AB SUPERPHARM	250MG	N62540 001	MAR 21, 1985
AB	500MG	N62540 002	MAR 21, 1985
@	250MG	N62540 001	MAR 21, 1985

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

	TETRACYCLINE HCL			
	@ SUPERPHARM	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
>DLT<	**THEOPHYLLINE 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER**			
>DLT< AP	MCGAW	200MG/100ML	N19826 004	AUG 14, 1992
>DLT<				

>ADD<	**THEOPHYLLINE 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER**			
>ADD<	@ MCGAW	200MG/100ML	N19826 004	AUG 14, 1992
>ADD<	**THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER**			
>DLT< AP	MCGAW	400MG/100ML	N19826 005	AUG 14, 1992
>DLT<	@	400MG/100ML	N19826 005	AUG 14, 1992
>DLT<				
>ADD<				
>ADD<				

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL

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

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

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

THIORIDAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

	MELLARIL			
AA	SANDOZ	30MG/ML	N11808 012	
AA +		30MG/ML	N11808 012	
AA		100MG/ML	N11808 018	
AA +		100MG/ML	N11808 018	

TABLET; ORAL

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

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

	THIORIDAZINE HCL		
AB	**SUPERPHARM**	**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

TOLAZAMIDE

TABLET; ORAL

	TOLAZAMIDE		
AB	**ZENITH LABS**	**500MG**	**N18894 003**
			NOV 02, 1984

TOLBUTAMIDE

TABLET; ORAL

	ORINASE		
	@ PHARMACIA AND UPJOHN	500MG	N10670 001
AB	+ UPJOHN	**500MG**	**N10670 001**
	TOLBUTAMIDE		
AB	BARR	**500MG**	**N87121 001**
	@	500MG	N87121 001
AB	EON LABS	**500MG**	**N12678 001**
AB	+	**500MG**	**N12678 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

TOPOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION

	HYCAMTIN		
	+ SMITHKLINE BEECHAM	EQ 4MG BASE/VIAL	N20671 001
			MAY 28, 1996

TRANDOLAPRIL

TABLET; ORAL

	MAVIK		
	KNOLL PHARM	1MG	N20528 001
			APR 26, 1996
		2MG	N20528 002
			APR 26, 1996

TRANDOLAPRIL

TABLET; ORAL
MAVIK
+ KNOLL PHARM 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

SPRAY, METERED; NASAL
NASACORT AQ
+ RHONE POULENC RORER 0.055MG/INH N20468 001
MAY 20, 1996

TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL
TRIPROLIDINE HCL
HALSEY 1.25MG/5ML N88735 001
JAN 17, 1985
@ 1.25MG/5ML N88735 001
JAN 17, 1985

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
VERELAN
+ ELAN PHARM 360MG N19614 004
MAY 10, 1996

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

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

ASPIRIN

TABLET, EXTENDED RELEASE; ORAL

8-HOUR BAYER			
+ BAYER	650MG	N16030 001	
+ STERLING	650MG	N16030 001	
MEASURIN			
+ BAYER	650MG	N16030 002	
+ STERLING	650MG	N16030 002	

BROMPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE; ORAL

DIMETANE			
+ ROBINS AH	8MG	N10799 010 JUN 10, 1983	
+	12MG	N10799 011 JUN 10, 1983	
@ WHITEHALL ROBINS	8MG	N10799 010 JUN 10, 1983	
DIMETAPP			
+ WHITEHALL ROBINS	12MG	N10799 011 JUN 10, 1983	

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

ELIXIR; ORAL

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

TABLET, EXTENDED RELEASE; ORAL

DIMETAPP			
+ ROBINS AH	12MG;75MG	N12436 003 MAY 14, 1985	>ADD>
+ WHITEHALL ROBINS	12MG;75MG	N12436 003 MAY 14, 1985	>ADD>

BROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

EFIDAC 24 PSEUDOEPHEDRINE HCL/BROMPHENIRAMINE MALEATE			
+ ALZA	16MG;240MG	N19672 001 MAR 29, 1996	>DLT>

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	

CLOTRIMAZOLE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL

GYNE-LOTRIMIN 3 COMBINATION PACK			
+ SCHERING PLOUGH	1%,200MG	N20526 002 JUL 29, 1996	

SUPPOSITORY; VAGINAL

GYNE-LOTRIMIN			
+ SCHERING PLOUGH	100MG	N17717 002 NOV 30, 1990	
GYNE-LOTRIMIN 3			
+ SCHERING PLOUGH	200MG	N20525 001 JUL 29, 1996	
MYCELEX-7			
BAYER	100MG	N18182 002 DEC 26, 1991	

TABLET; VAGINAL

GYNE-LOTRIMIN			
+ SCHERING PLOUGH	100MG	N17717 002 NOV 30, 1990	
MYCELEX-7			
BAYER	100MG	N18182 002 DEC 26, 1991	

IBUPROFEN

CAPSULE; ORAL		
PROVEL		
+ SANDOZ	200MG	N20402 001 APR 20, 1995
@ WHITEHALL ROBINS	200MG	N20402 001 APR 20, 1995
SUSPENSION; ORAL		
CHILDREN'S ADVIL		
WHITEHALL ROBINS	100MG/5ML	N20589 001 JUN 27, 1996
SUSPENSION/DROPS; ORAL		
CHILDREN'S MOTRIN		
+ MCNEIL CONS PRODS	40MG/ML	N20603 001 JUN 10, 1996
TABLET; ORAL		
IBUPROFEN		
HALSEY	200MG	N71027 001 SEP 29, 1987
@	200MG	N71027 001 SEP 29, 1987
@ LEMMON	200MG	N73141 001 MAY 29, 1992
MCNEIL CONS PRODS	200MG	N73019 001 MAR 30, 1994
+	200MG	N73019 001 MAR 30, 1994
TAG PHARMS	200MG	N73141 001 MAY 29, 1992
JUNIOR STRENGTH MOTRIN		
MCNEIL CONS PRODS	100MG	N20602 001 JUN 10, 1996
NUPRIN		
+ BRISTOL MYERS	200MG	N72035 001 FEB 16, 1988
	200MG	N72035 001 FEB 16, 1988

INSULIN PURIFIED BEEF

INJECTABLE; INJECTION		
REGULAR ILETIN II		
+ LILLY	100 UNITS/ML	N18478 001
@	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

INJECTABLE; INJECTION		
LENTE ILETIN II		
+ LILLY	100 UNITS/ML	N18477 001
@	100 UNITS/ML	N18477 001

MICONAZOLE NITRATE

CREAM; VAGINAL		
MICONAZOLE 7		
NMC	2%	N74164 001 MAR 29, 1996

MICONAZOLE NITRATE

CREAM; VAGINAL
MICONAZOLE NITRATE

G AND W LABS	2%	N74366 001	
		FEB 22, 1996	

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
MONISTAT-3 COMBINATION PACK

+ ADV CARE	2%,200MG	N20670 002	
		APR 16, 1996	

MINOXIDIL

SOLUTION; TOPICAL
MINOXIDIL (FOR MEN)

BARRE	2%	N74588 001	
		APR 05, 1996	
BAUSCH AND LOMB	2%	N74643 001	
		APR 09, 1996	
COPLEY PHARM	2%	N74500 001	
		MAY 23, 1996	
LEMMON	2%	N74589 001	
		APR 05, 1996	

ROGAINE (FOR MEN)

+ PHARMACIA AND UPJOHN	2%	N19501 002	
		FEB 09, 1996	

ROGAINE (FOR WOMEN)

+ PHARMACIA AND UPJOHN	2%	N19501 003	
		FEB 09, 1996	>ADD<

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC
OCUHIST

AKORN	0.025%;0.3%	N20485 001	
		JAN 31, 1996	

OPCON-A

+ BAUSCH AND LOMB	0.027%;0.315%	N20065 001	
		JUN 08, 1994	
+	0.02675%;0.315%	N20065 001	
		JUN 08, 1994	

>ADD<
>ADD<
>ADD<
>ADD<
>ADD<
>DLT<
>DLT<

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL
NICOTROL

+ MCNEIL CONS PRODS	15MG/16HR	N20536 001	
		JUL 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	

NIZATIDINE

TABLET; ORAL
AXID AR

+ WHITEHALL ROBINS	75MG	N20555 001	
		MAY 09, 1996	

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
EFIDAC 24 PSEUDOEPHEDRINE HCL

+ ALZA	240MG	N20021 002	
		DEC 15, 1992	
+ CIBA	240MG	N20021 002	
		DEC 15, 1992	

>ADD<
>ADD<
>DLT<
>DLT<

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 7 / JUL '96

NO JULY 1996 APPROVALS

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

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Amphotericin B lipid complex TN= Abelcet	Treatment of invasive candidiasis.	The Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=06/27/96 MA= / /
Amphotericin B lipid complex TN= Abelcet	Treatment of invasive zgomycosis.	The Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=05/06/96 MA= / /
Amphotericin B lipid complex TN= Abelcet	Treatment of invasive coccidioidomycosis.	The Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=05/06/96 MA= / /
Antihemophilic factor (human) TN= Alphanate	Treatment of von Willebrand's disease.	Alpha Therapeutic Corporation 5555 Valley Boulevard Los Angeles, CA 90032 DD=01/05/96 MA= / /
Arcitumomab TN= 99m Te-labeled CBA-Scan	Diagnosis and localization of primary, residual, recurrent and metastatic medullary thyroid carcinoma.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=05/10/96 MA= / /
Clostridial collagenase TN=	Treatment of advanced (involutional or residual stage) Dupuytren's disease.	Hurst, L. M.D. & Badalamente, M. Ph.D. State University of New York at Stony Brook School of Medicine Health Sciences Center T18-020 Stony Brook, NY 11794 DD=05/23/96 MA= / /
Collagenase (lyophilized) for injection TN= Plaquase	Treatment of Peyronie's disease.	Advance Biofactures Corporation 35 Wilbur Street Lynbrook, NY 11563 DD=03/12/96 MA= / /
Dihydrotestosterone TN=Androgel-DHT	Treatment of weight loss in AIDS patients with HIV-associated wasting.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road, Suite 210 Buffalo Grove, IL 60089 DD=02/05/96 MA= / /
DMP 777 TN=	Therapeutic management of patients with lung disease attributable to cystic fibrosis.	Dupont Merck Pharmaceutical Company Dupont Merck Plaza, Maple Run 2110 Wilmington, DE 19805 DD=06/04/96 MA= / /
Etiocholanedione TN=	Treatment of Prader-Willi syndrome.	SuperGen, Inc. 3158 Des Plains Avenue Suite 10 Des Plains, IL 60018 DD=05/07/96 MA= / /
Gusperimus TN=Spanidin	Treatment of acute renal graft rejection episodes.	Bristol-Myers Squibb Company 5 Research Parkway P.O. Box 5100 Wallingford, CT 06492 DD=06/27/96 MA= / /
Indoxuridine TN=	Treatment of nonparenchymatous sarcomas.	NeoPharm, Inc. 225 East Deerpath, Suite 250 Lake Forest, IL 60045 DD=04/08/96 MA= / /

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Interferon beta-1a TN=Rebif	Treatment of patients with secondary progressive multiple sclerosis.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=03/11/96 MA= / /
KL4-Surfactant TN=	Treatment of meconium aspiration syndrome in newborn infants.	Cochrane, Charles, M.D. The Scripps Research Institute 10666 Torrey Pines Road LaJolla, CA 92037 DD=07/30/96 MA= / /
L-2-oxothiazolidine 4-carboxylic acid TN=Procysteine	Treatment of amyotrophic lateral sclerosis.	Transcend Therapeutics, Inc. 640 Memorial Drive, 3rd Floor West Cambridge, MA 02139 DD=07/30/96 MA= / /
Lipid/DNA human cystic fibrosis gene TN=	Treatment of cystic fibrosis.	Genzyme Corporation One Kendall Square Cambridge, MA 02139 DD=04/08/96 MA= / /
Liposomal prostaglandin E1 injection TN=	Treatment of acute respiratory distress syndrome.	The Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=04/25/96 MA= / /
Methylnaltrexone TN=	Treatment of chronic opioid-induced constipation unresponsive to conventional therapy.	The University of Chicago 5841 South Maryland Avenue MC 4028 Chicago, IL 60637 DD=06/17/96 MA= / /
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 & Upjohn 7000 Portage Road Kalamazoo, MI 49001 DD=02/08/96 MA= / /
Somatropin for injection TN=Serostim	Treatment of children with AIDS-associated failure-to-thrive including AIDS-associated wasting.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=03/26/96 MA= / /
SU101 TN=	Treatment of ovarian cancer.	Sugen, Inc. 515 Galveston Drive Redwood City, CA 94063 DD=03/12/96 MA= / /
Testosterone TN=Androgel	Treatment of weight loss in AIDS patients with HIV-associated wasting.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road, Suite 210 Buffalo Grove, IL 60089 DD=02/05/96 MA= / /

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Thalidomide TN=Synovir	Treatment of HIV-associated wasting syndrome.	Celgene Corporation P.O. Box 4914 7 Powder Horn Drive Warren, NJ 07059 DD=03/11/96 MA= / /
Uridine 5'triphosphate TN=VIL	To facilitate the removal of lung secretions in the treatment of patients with primary ciliary dyskinesia.	Inspire Pharmaceuticals, Inc. 4222 Emperor Boulevard, Suite 470 Durham, NC 27703 DD=06/26/96 MA= / /
Valine, isoleucine and leucine TN=VIL	Treatment of hyperphenylalaninemia.	Leas Research Products 4 Brookview Lane Troy, NY 12180 DD=01/05/96 MA= / /

NAME Generic/Chemical TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
	ORPHAN DRUG PRODUCT APPROVALS FOR 1996	
Albendazole TN= Albenza	Treatment of hydatid disease (cystic echinococcosis due to 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=06/11/96
Albendazole TN= Albenza	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=06/11/96
Bleomycin sulfate TN=Blenoxane	Treatment of malignant pleural effusion.	Bristol-Myers Squibb P.O. Box 4000 Princeton, NJ 08543 DD=09/17/93 MA=02/20/96
Corticorelin ovine triflutate TN=Acthrel	For use in differentiating pituitary and ectopic production of ACTH in patients with ACTH-dependent Cushings syndrome.	Ferring Laboratories, Inc. 400 Rella Boulevard, Suite 201 Suffern, NY 10901 DD=11/24/89 MA=05/23/96
Daunorubicin citrate liposome injection TN=DaunoXome	Treatment of patients with advanced HIV-associated Kaposi's sarcoma.	NeXstar Pharmaceuticals, Inc. 650 Cliffside Drive San Dimas, CA 91773 DD=05/14/93 MA=04/08/96
Ganciclovir intravitreal implant TN=Vitrasert Implant	Treatment of cytomegalovirus retinitis.	Chiron Vision 500 Iolab Drive Claremont, CA 91711 DD=06/07/95 MA=03/04/96
Interferon beta-1a TN=Avonex	Treatment of multiple sclerosis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=12/16/91 MA=05/17/96
Ofloxacin TN=Ocuflox Ophthalmic Solution	Treatment of bacterial corneal ulcers.	Allergan, Inc. 2525 Dupont Drive P.O. Box 19534 Irvine, CA 92713 DD=04/18/91 MA=05/22/96
Respiratory syncytial virus immune globulin (human) TN=Respigam	Prophylaxis of respiratory syncytial virus lower respiratory tract infections in infants and young children at high risk of RSV 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 synthetase 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 JULY 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

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

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

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	325MG 50MG 40MG 10MG	95 P-0279/ CP1	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	325MG 50MG 40MG 7.5MG	95 P-0279/ CP2	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	500MG 50MG 40MG 10MG	95 P-0279/ CP3	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE CAPSULE; ORAL	500MG 50MG 40MG 7.5MG	95 P-0279/ CP4	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 10MG	95 P-0279/ CP1	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 7.5MG	95 P-0279/ CP2	MIKART	NEW COMBIANTION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08. 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 10MG	95 P-0279/ CP3	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08 1996
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 50MG 40MG 7.5MG	95 P-0279/ CP4	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 08, 1996
ACETAMINOPHEN; HYDROCODONE BITARTRATE CAPSULE; ORAL	325MG 5MG	95 P-0278/ CP1	MIKART	NEW STRENGTH	APPROVED MAY 28, 1996

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
CARBIDOPA; LEVODOPA POWDER FOR RECONSTITUTION; ORAL	25MG/PACKET 100MG/PACKET	95 P-0100/ CP1	ATHENA	NEW DOSAGE FORM	APPROVED MAY 28, 1996
CARBIDOPA; LEVODOPA POWDER FOR RECONSTITUTION; ORAL	25MG/PACKET 250MG/PACKET	95 P-0100/ CP1	ATHENA	NEW DOSAGE FORM	APPROVED MAY 28, 1996
CHOLESTYRAMINE TABLET, CHEWABLE; ORAL	EQ 2GM RESIN	95 P-0277/ CP1	MAYRAND	NEW DOSAGE FORM NEW STRENGTH	APPROVED FEB 27, 1996
CYTARABINE INJECTABLE; INJECTION	100MG/ML (1ML/VIAL) (5ML/VIAL)	92 P-0183/ CP1	FAULDING	NEW DOSAGE FORM NEW STRENGTH	APPROVED JUL 26, 1996
CYTARABINE INJECTABLE; INJECTION	100MG/ML (10ML/VIAL) (20ML/VIAL)	92 P-0184/ CP1	FAULDING	NEW DOSAGE FORM	APPROVED JUL 26, 1996
DILTIAZEM HYDROCHLORIDE INJECTABLE, INJECTION	5MG/ML (25ML/SYRINGE) (50ML/SYRINGE)	95 P-0196/ CP1	INTL MEDICATION	NEW STRENGTH	APPROVED FEB 27, 1996
EPINEPHRINE INJECTABLE; SUBCUTANEOUS	0.3MG/DELIVERY	95 P-0190/ CP1	SENETCK PLC	NEW ROUTE OF ADMINISTRATION	APPROVED FEB 15, 1996
HYDROCORTISONE BUTYRATE LOTION; TOPICAL	0.1%	95 P-0223/ CP1	MCKENNA & CUNEO	NEW DOSAGE FORM	APPROVED FEB 21, 1996
LACTULOSE CRYSTALS, FOR RECONSTITUTION; ORAL	20GM/PACKET	95 P-0287/ CP1	BENNETT	NEW DOSAGE FORM NEW STRENGTH	APPROVED APR 19, 1996
MEPERIDINE HYDROCHLORIDE INJECTABLE; INJECTION	10MG/ML (60ML/SYRINGE)	95 P-0348/ CP1	MALLINCKRODT	NEW STRENGTH	APPROVED MAR 08, 1996
METRONIDAZOLE LOTION; TOPICAL	0.75%	95 P-0328/ CP1	RNB PHARM	NEW DOSAGE FORM	APPROVED FEB 23, 1996

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

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

U-131
U-132
U-133
U-134
U-135
U-136
U-137
U-138
U-139
U-140
U-141

REFERENCES

NEW DOSING SCHEDULE

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

NEW INDICATION

I-141 TREATMENT OF HEMODYNAMICALLY STABLE PATIENTS WITHIN 24 HOURS OF ACUTE MYOCARDIAL INFARCTION TO IMPROVE SURVIVAL
I-142 LOCALIZE MYOCARDIAL ISCHEMIA (REVERSIBLE DEFECT) AND INFARCTION (NON-REVERSIBLE DEFECTS) IN EVALUATING MYOCARDIAL FUNCTION
I-143 EPISODIC TREATMENT OF RECURRENT GENITAL HERPES IN IMMUNOCOMPETENT ADULTS
I-144 ENHANCEMENT OF MRI OF THE ADULT BODY INTERNAL ORGANS
I-145 0.1MMOL/KG AS A SINGLE INTRAVENOUS BOLUS FOR MRI OF THE CNS IN CHILDREN
I-146 CONTRAST ENHANCEMENT AND FACILITATION OF VISUALIZATION OF EXTRACRANIAL HEAD AND NECK LESIONS
I-147 PREVENTION OF GALLSTONE FORMATION IN OBESE PATIENTS EXPERIENCING RAPID WEIGHT LOSS
I-148 TREATMENT OF ACUTE PNEUMOCYSTIC CARINII PNEUMONIA (PCP) IN HIV-INFECTED PATIENTS WHOSE ALVEOLAR-ARTERIAL OXYGEN DIFFERENCE ($AaDO_2$) iS LESS THAN OR EQUAL TO 55 TORR
I-149 TREATMENT OF PATIENTS WITH NON-SMALL CELL LUNG CANCER
I-150 TREATMENT OF OBSESSIVE COMPULSIVE DISORDER AND PANIC DISORDER
I-151 PREVENTION OF AND PREVENTION OF FURTHER POSTOPERATIVE NAUSEA AND VOMITING IN PEDIATRIC PATIENTS RECEIVING GENERAL ANESTHESIA
I-152 SLOWING THE PROGRESSION OF CORONARY ATHEROSCLEROSIS AND REDUCING THE RISK OF ACUTE CORONARY EVENTS
I-153 MANAGEMENT OF SEVERE SPASTICITY [ENCOMPASSES SPINAL AND CEREBRAL ORIGIN]
I-154 PATIENT POPULATION ALTERED TO INCLUDE PEDIATRIC USE
I-155 TREATMENT OF ONCHOMYCOSIS DUE TO DERMATOPHYTES (TINEA UNGUIUM) OF THE TOENAIL WITH OR WITHOUT FINGERNAIL INVOLVEMENT
I-156 ADDITIONAL DATA REGARDING THE SAFE USE OF NORVASC IN PATIENTS WITH HEART FAILURE
I-157 TREATMENT OF ACUTE UNCOMPLICATED CYSTITIS IN FEMALES
I-158 TREATMENT OF OSTEOLYTIC BONE METASTASES OF BREAST CANCER
I-159 FOR HYPERCHOLESTEROLEMIC PATIENTS WITHOUT CLINICALLY EVIDENT HEART DISEASE REDUCE THE RISK OF MYOCARDIAL INFARCTION, REVASCULARIZATION, AND DEATH DUE TO CARDIOVASCULAR CAUSES WITH NO INCREASE IN DEATH FROM NON-CARDIOVASCULAR CAUSES

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

EXCLUSIVITY TERMS

PATENT USE CODE

U-131	PHOTODAMAGED SKIN
U-132	INHIBITING HIV PROTEASE
U-133	MANAGEMENT OF OBESITY INCLUDING WEIGHT LOSS AND MAINTENANCE IN PATIENTS ON A REDUCED-CALORIE DIET
U-134	TREATMENT OF ACNE VULGARIS
U-135	ANTITUMOR AGENT
U-136	PROCESS FOR WASTE NITROGEN REMOVAL
U-137	METHOD OF TREATING BACTERIAL VAGINOSIS
U-138	TREATMENT OF ALLERGIC RHINITS
U-139	TREATMENT OF ALLERGIC REACTIONS
U-140	USE OF NORVIR TO INHIBIT HIV PROTEASE OR TO INHIBIT AN HIV INFECTION
U-141	TREATMENT OF ULCERATIVE COLITIS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19806 001	ACRIVASTINE; SEMPREX-D	4650807	MAR 26, 2008	U-93		
	20338 001	ADAPALENE; DIFFERIN	4717720	APR 10, 2006	U-134	NCE	MAY 31, 2001
	20380 001	ADAPALENE; DIFFERIN	4717720	APR 10, 2006	U-134	NCE	MAY 31, 2001
						ODE	JUN 11, 2003
	20666 001	ALBENDAZOLE; ALBENZA				NCE	JUN 11, 2001
	20298 001	ALLOPURINOL SODIUM; ZYLOPRIM				NDF	MAY 17, 1999
>ADD>						ODE	MAY 17, 2003
	20221 001	AMIFOSTINE; ETHYOL				I-149	MAR 15, 1999
	19787 001	AMLODIPINE BESYLATE; NORVASC	4879303	MAR 25, 2007		I-156	JUN 14, 1999
	19787 002	AMLODIPINE BESYLATE; NORVASC	4879303	MAR 25, 2007		I-156	JUN 14, 1999
	19787 003	AMLODIPINE BESYLATE; NORVASC	4879303	MAR 25, 2007		I-156	JUN 14, 1999
	20541 001	ANASTROZOLE; ARIMIDEX	4935437	JUN 10, 2008			
	20428 001	AZELAIC ACID; AZELEX	4386104	MAY 31, 2000	U-124		
	20075 001	BACLOFEN; LIORESAL				I-153	JUN 14, 1999
	20075 002	BACLOFEN; LIORESAL				I-153	JUN 14, 1999
	20469 001	BECLOMETHASONE DIPROPIONATE MONOHYDRATE; VANCENASE AQ				NP	JUN 26, 1999
	20498 001	BICALUTAMIDE; CASODEX	4636505	JAN 13, 2004			
	50443 001	BLEOMYCIN SULFATE; BLENOXANE				ODE	FEB 20, 2003
	19672 001	BROMPHENIRAMINE MALEATE; EFIDAC 24	4810502	MAR 14, 2006			
			4801461	MAR 14, 2006			
			4673405	MAR 18, 2003			
	18731 001	BUSPIRONE HYDROCHLORIDE; BUSPAR	4662880	MAR 14, 2006		NP	MAR 29, 1999
			5015646	MAY 14, 2008			
	18731 002	BUSPIRONE HYDROCHLORIDE; BUSPAR	4182763	MAY 22, 2000	U-13		
			5015646	MAY 14, 2008			
	20421 001	BUTOCONAZOLE NITRATE; FEMSTAT 3	4182763	MAY 22, 2000	U-13		
			4078071	JUL 28, 1997			
	20273 001	CALCIPOTRIENE; DOVONEX				NP	DEC 21, 1998
>ADD>	20554 001	CALCIPOTRIENE; DOVONEX	4866048	DEC 29, 2007	U-88	NCE	DEC 29, 1998
	20313 002	CALCITONIN, SALMON; MIACALCIN	4866048	SEP 12, 2006		NDF	JUL 22, 1999
	18874 001	CALCITRIOL; CALCIJEX	4344949	OCT 03, 2000			
	18874 002	CALCITRIOL; CALCIJEX	4308264	JAN 28, 2001			
	18343 004	CAPTOPRIL; CAPOTEN	4308264	JAN 28, 2001			
						I-95	SEP 23, 1996
	18343 007	CAPTOPRIL; CAPOTEN				I-101	JAN 28, 1997
						I-95	SEP 23, 1996
						I-101	JAN 28, 1997

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
	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			
	19880 001	CARBOPLATIN; PARAPLATIN	4140707	AUG 24, 1998			
	19880 002	CARBOPLATIN; PARAPLATIN	4140707	AUG 24, 1998			
	19880 003	CARBOPLATIN; PARAPLATIN	4140707	AUG 24, 1998			
	19835 001	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2002			
	19835 002	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2002			
	20638 001	CIDOFOVIR; VISTIDE	5142051	AUG 25, 2009		NCE	JUN 26, 2001
>ADD>	19537 001	CIPROFLOXACIN HYDROCHLORIDE; CIPRO				I-157	APR 08, 1999
>ADD>	19537 002	CIPROFLOXACIN HYDROCHLORIDE; CIPRO				I-157	APR 08, 1999
>ADD>	19537 003	CIPROFLOXACIN HYDROCHLORIDE; CIPRO				I-157	APR 08, 1999
>ADD>	19537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO				I-157	APR 08, 1999
	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		
	20340 001	CLOBETASOL PROPIONATE; TEMOVATE E				D-32	MAY 03, 1999
>ADD>	20525 001	CLOTRIMAZOLE; GYNE-LOTRIMIN 3				NP	JUL 29, 1999
>ADD>	20526 002	CLOTRIMAZOLE; GYNE-LOTRIMIN 3 COMBINATION PACK				NP	JUL 29, 1999
	20162 001	CORTICORELIN OVINE TRIFLUTATE; ACTHREL				NCE	MAY 23, 2001
	20479 001	CROMOLYN SODIUM; GASTROCROM	4515805	MAY 07, 2002	U-130		
			4421762	DEC 20, 2000	U-130		
	20287 001	DALTEPARIN SODIUM; FRAGMIN	4303651	JAN 04, 2005		NCE	DEC 22, 1999
						D-30	MAR 18, 1999
	20287 003	DALTEPARIN SODIUM; FRAGMIN	4303651	JAN 04, 2005		NCE	DEC 22, 1999
						D-30	MAR 18, 1999
	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			

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
	20344 001	DEXFENFLURAMINE HYDROCHLORIDE; REDUX	4309445	JUN 16, 2000	U-133		
	20254 001	DICLOFENAC SODIUM; VOLTAREN-XR				NDF	MAR 08, 1999
	20092 001	DILTIAZEM HYDROCHLORIDE; DILACOR XR	5422123	JUN 06, 2012			
	20092 002	DILTIAZEM HYDROCHLORIDE; DILACOR XR	5422123	JUN 06, 2012			
	20092 003	DILTIAZEM HYDROCHLORIDE; DILACOR XR	5422123	JUN 06, 2012			
	20401 001	DILTIAZEM HYDROCHLORIDE; TIAZAC	5529791	JUN 25, 2013			
	20401 002	DILTIAZEM HYDROCHLORIDE; TIAZAC	5529791	JUN 25, 2013			
	20401 003	DILTIAZEM HYDROCHLORIDE; TIAZAC	5529791	JUN 25, 2013			
	20401 004	DILTIAZEM HYDROCHLORIDE; TIAZAC	5529791	JUN 25, 2013			
	20401 005	DILTIAZEM HYDROCHLORIDE; TIAZAC	5529791	JUN 25, 2013		NS	SEP 11, 1998
	18723 001	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-41	MAR 18, 1999
	18723 002	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-41	MAR 18, 1999
	18723 003	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		I-41	MAR 18, 1999
	20449 001	DOCETAXEL; TAXOTERE	5403858	JUL 03, 2012			
	20164 001	ENOXAPARIN SODIUM; LOVENOX	4814470	JUL 14, 2007		NCE	MAY 14, 2001
			5389618	FEB 14, 2012			
			4692435	DEC 24, 2004	U-123		
			4486420	DEC 04, 2001	U-122		
	20472 001	ESTRADIOL; ESTRING				NDF	APR 26, 1999
>ADD>	20538 001	ESTRADIOL; ESTRADIOL				NS	OCT 28, 1997
>ADD>	20538 003	ESTRADIOL; ESTRADIOL				NS	OCT 28, 1997
>ADD>	18922 002	ETODOLAC; LODINE				I-24	JUN 28, 1999
>ADD>	18922 003	ETODOLAC; LODINE				I-24	JUN 28, 1999
>ADD>	18922 004	ETODOLAC; LODINE				I-24	JUN 28, 1999
	20457 001	ETOPOSIDE PHOSPHATE; ETOPOPHOS	5041424	AUG 20, 2008	U-135		
>ADD>	20195 001	FENTANYL CITRATE; FENTANYL	4904768	FEB 27, 2007		NE	MAY 17, 1999
>DLT>	~~20195 001~~	~~FENTANYL CITRATE; FENTANYL~~	4671953	MAY 01, 2005	U-87	NDF	OCT 04, 1996
>ADD>	20195 002	FENTANYL CITRATE; FENTANYL	~~4671953~~	~~JUN 09, 2004~~	~~U-87~~	~~NDF~~	~~OCT 04, 1996~~
>DLT>	~~20195 002~~	~~FENTANYL CITRATE; FENTANYL~~	4671953	MAY 01, 2005	U-87	NDF	OCT 04, 1996
>ADD>	20195 003	FENTANYL CITRATE; FENTANYL	~~4671953~~	~~JUN 09, 2004~~	~~U-87~~	~~NDF~~	~~OCT 04, 1996~~
>DLT>	~~20195 003~~	~~FENTANYL CITRATE; FENTANYL~~	4671953	MAY 01, 2005	U-87	NDF	OCT 04, 1996
>ADD>	20195 007	FENTANYL CITRATE; FENTANYL	~~4671953~~	~~JUN 09, 2004~~	~~U-87~~	~~NDF~~	~~OCT 04, 1996~~
>DLT>	~~20195 007~~	~~FENTANYL CITRATE; FENTANYL~~	4671953	MAY 01, 2005	U-87	NDF	OCT 04, 1996
>ADD>	20625 001	FEXOFENADINE HYDROCHLORIDE; ALLEGRA	~~4671953~~	~~JUN 09, 2004~~	~~U-87~~	~~NDF~~	~~OCT 04, 1996~~
>ADD>			5375693	AUG 03, 2012	U-138	NCE	JUL 25, 2001
	20548 001	FLUTICASONE PROPIONATE; FLOVENT	4254129	APR 10, 1999	U-139		
			4335121	MAR 15, 2002		NP	MAR 27, 1999

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	20548 002	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999
	20548 003	FLUTICASONE PROPIONATE; FLOVENT	4335121	MAR 15, 2002		NP	MAR 27, 1999
	20261 001	FLUVASTATIN SODIUM; LESCOL				D-31	MAR 20, 1999
	20261 002	FLUVASTATIN SODIUM; LESCOL				D-31	MAR 20, 1999
	20235 001	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-125		
			4894476	MAY 02, 2008			
			4087544	JAN 17, 2001	U-86	NCE	DEC 30, 1998
	20235 002	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-125		
			4894476	MAY 02, 2008			
			4087544	JAN 17, 2001	U-86	NCE	DEC 30, 1998
	20235 003	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010	U-125		
			4894476	MAY 02, 2008			
			4087544	JAN 17, 2001	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
	20509 001	GEMCITABINE HYDROCHLORIDE; GEMZAR				NCE	MAY 15, 2001
	20509 002	GEMCITABINE HYDROCHLORIDE; GEMZAR				NCE	MAY 15, 2001
	19726 001	GOSERELIN ACETATE; ZOLADEX	5366734	NOV 22, 2011			
			4767628	AUG 30, 2005		I-88	FEB 02, 1996
	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		
	19836 001	HISTRELIN ACETATE; SUPPRELIN	4244946	JAN 13, 2000		NCE	DEC 24, 1996
	19836 002	HISTRELIN ACETATE; SUPPRELIN	4244946	JAN 13, 2000		NCE	DEC 24, 1996
	19836 003	HISTRELIN ACETATE; SUPPRELIN	4244946	JAN 13, 2000		NCE	DEC 24, 1996
	20589 001	IBUPROFEN; CHILDREN'S ADVIL	4788220	JUL 08, 2007		NP	JUN 16, 1998
	20602 001	IBUPROFEN; JUNIOR STRENGTH MOTRIN				NP	JUN 16, 1998
>ADD>	20603 001	IBUPROFEN; CHILDREN'S MOTRIN	5374659	DEC 20, 2011		NP	JUN 16, 1998
	20685 001	INDINAVIR SULFATE; CRIXIVAN	5413999	MAY 07, 2013	U-132	NCE	MAR 13, 2001
	20685 003	INDINAVIR SULFATE; CRIXIVAN	5413999	MAY 07, 2013	U-132	NCE	MAR 13, 2001
	20563 001	INSULIN LISPRO; HUMALOG	5514646	MAY 07, 2013	U-111	NCE	JUN 14, 2001

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	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			
	20571 001	IRINOTECAN HYDROCHLORIDE; CAMPTOSAR	4604463	JUL 05, 2004		NCE	JUN 14, 2001
	20083 001	ITRACONAZOLE; SPORANOX				I-155	SEP 28, 1998
	20564 001	LAMIVUDINE; EPIVIR	5047407	FEB 08, 2009			
	20596 001	LAMIVUDINE; EPIVIR	5047407	FEB 08, 2009			
	20241 001	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106	NCE	DEC 27, 1999
	20241 002	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106	NCE	DEC 27, 1999
	20241 003	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106	NCE	DEC 27, 1999
	20241 004	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106	NCE	DEC 27, 1999
	20241 005	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106	NCE	DEC 27, 1999
	20241 006	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2008	U-106	NCE	DEC 27, 1999
	20406 001	LANSOPRAZOLE; PREVACID	4689333	JUL 29, 2005	U-126	I-116	APR 08, 1999
	20406 002	LANSOPRAZOLE; PREVACID	4689333	JUL 29, 2005	U-126	I-116	APR 08, 1999
	20597 001	LATANOPROST; XALATAN				NCE	JUN 05, 2001
	20517 001	LEUPROLIDE ACETATE; LUPRON DEPOT	5480656	JAN 02, 2013			
	20219 001	LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN	4369184	DEC 07, 2004		NCE	NOV 10, 1998
>ADD>	20575 001	LIDOCAINE; LIDOCAINE	5446070	FEB 27, 2011			
			5332576	JUL 26, 2011			
			5234957	FEB 27, 2011		NDF	MAY 21, 1999
>ADD>	20575 002	LIDOCAINE; LIDOCAINE	5446070	FEB 27, 2011			
			5332576	JUL 26, 2011			
			5234957	FEB 27, 2011		NDF	MAY 21, 1999
	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

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>	19651 001	MESALAMINE; ASACOL	5541171	JUL 30, 2013	U-141		
>ADD>			5541170	JUL 30, 2013	U-141		
	20208 001	METRONIDAZOLE; METROGEL	5536743	JUL 16, 2013	U-137		
	20670 002	MICONAZOLE NITRATE; MONISTAT-3 COMBINATION PACK				NP	APR 16, 1999
	20415 001	MIRTAZAPINE; REMERON				NCE	JUN 14, 2001
	20415 002	MIRTAZAPINE; REMERON				NCE	JUN 14, 2001
	20312 001	MOEXIPRIL HYDROCHLORIDE; UNIVASC	4344949	OCT 03, 2000			
>ADD>	20312 002	MOEXIPRIL HYDROCHLORIDE; UNIVASC	4344949	OCT 03, 2000			
>ADD>	20616 001	MORPHINE SULFATE; KADIAN	5378474	MAR 23, 2010			
>ADD>			5202128	APR 13, 2010		NDF	JUL 03, 1999
>ADD>	20616 002	MORPHINE SULFATE; KADIAN	5378474	MAR 23, 2010			
>ADD>			5202128	APR 13, 2010		NDF	JUL 03, 1999
>ADD>	20616 003	MORPHINE SULFATE; KADIAN	5378474	MAR 23, 2010			
>ADD>			5202128	APR 13, 2010		NDF	JUL 03, 1999
	19886 001	NAFARELIN ACETATE; SYNAREL	4234571	JUN 11, 2011			
	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>	20152 001	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003	U-12	NCE	DEC 22, 1999
>DLT>	~~20152 001~~	~~NEFAZODONE HYDROCHLORIDE; SERZONE~~	~~4338317~~	~~MAR 16, 2001~~	~~U-12~~	~~NCE~~	~~DEC 22, 1999~~
>ADD>	20152 002	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003	U-12	NCE	DEC 22, 1999
>DLT>	~~20152 002~~	~~NEFAZODONE HYDROCHLORIDE; SERZONE~~	~~4338317~~	~~MAR 16, 2001~~	~~U-12~~	~~NCE~~	~~DEC 22, 1999~~
>ADD>	20152 003	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003	U-12	NCE	DEC 22, 1999
>DLT>	~~20152 003~~	~~NEFAZODONE HYDROCHLORIDE; SERZONE~~	~~4338317~~	~~MAR 16, 2001~~	~~U-12~~	~~NCE~~	~~DEC 22, 1999~~
>ADD>	20152 004	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003	U-12	NCE	DEC 22, 1999
>DLT>	~~20152 004~~	~~NEFAZODONE HYDROCHLORIDE; SERZONE~~	~~4338317~~	~~MAR 16, 2001~~	~~U-12~~	~~NCE~~	~~DEC 22, 1999~~
>ADD>	20152 005	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003	U-12	NCE	DEC 22, 1999
>DLT>	~~20152 005~~	~~NEFAZODONE HYDROCHLORIDE; SERZONE~~	~~4338317~~	~~MAR 16, 2001~~	~~U-12~~	~~NCE~~	~~DEC 22, 1999~~
>ADD>	20152 006	NEFAZODONE HYDROCHLORIDE; SERZONE	4338317	MAR 16, 2003	U-12	NCE	DEC 22, 1999
>DLT>	~~20152 006~~	~~NEFAZODONE HYDROCHLORIDE; SERZONE~~	~~4338317~~	~~MAR 16, 2001~~	~~U-12~~	~~NCE~~	~~DEC 22, 1999~~
	20636 001	NEVIRAPINE; VIRAMUNE	5366972	NOV 22, 2011		NCE	JUN 21, 2001
	20165 001	NICOTINE; NICODERM	5508038	APR 16, 2013			
	20165 002	NICOTINE; NICODERM	5508038	APR 16, 2013			
	20165 003	NICOTINE; NICODERM	5508038	APR 16, 2013			
	20385 001	NICOTINE; NICOTROL				NP	MAR 22, 1999
	20555 001	NIZATIDINE; AXID AR				NS	MAY 09, 1999
	19921 001	OFLOXACIN; OCUFLOX				ODE	MAY 22, 2003

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
	20555 001	NIZATIDINE; AXID AR				NS	MAY 09, 1999
	19921 001	OFLOXACIN; OCUFLOX				ODE	MAY 22, 2003
	19810 001	OMEPRAZOLE; PRILOSEC	4255431	APR 05, 2001	U-108	I-23	MAR 22, 1999
	19810 003	OMEPRAZOLE; PRILOSEC	4853230	APR 20, 2007	U-108	I-23	MAR 22, 1999
	20007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN				I-151	MAY 16, 1999
	18841 004	OXAPROZIN; DAYPRO				NCE	OCT 29, 1999*
>ADD>	20553 001	OXYCODONE HYDROCHLORIDE; OXYCONTIN	5266331	FEB 05, 2008		NDF	DEC 12, 1998
>ADD>	20553 002	OXYCODONE HYDROCHLORIDE; OXYCONTIN	5266331	FEB 05, 2008		NDF	DEC 12, 1998
>ADD>	20553 003	OXYCODONE HYDROCHLORIDE; OXYCONTIN	5266331	FEB 05, 2008		NDF	DEC 12, 1998
>ADD>	20036 001	PAMIDRONATE DISODIUM; AREDIA				I-158	JUL 16, 1999
>ADD>	20036 003	PAMIDRONATE DISODIUM; AREDIA				I-158	JUL 16, 1999
>ADD>	20036 004	PAMIDRONATE DISODIUM; AREDIA				I-158	JUL 16, 1999
	20031 001	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
	20031 002	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
	20031 003	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
	20031 004	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
	20031 005	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAR 07, 1999
	19887 002	PENTAMIDINE ISETHIONATE; NEBUPENT				I-148	MAR 05, 1999
	20184 001	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
	20184 002	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
	20184 003	PERINDOPRIL ERBUMINE; ACEON	4508729	AUG 21, 2006			
	20451 001	PORFIMER SODIUM; PHOTOFRIN	5438071	AUG 01, 2012			
			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			
	19898 005	PRAVASTATIN SODIUM; PRAVACHOL	4649151	MAR 10, 2004		ODE	DEC 27, 2002
>ADD>			5180589	JUL 09, 2008			
			5030447	JUL 09, 2008		I-159	JUL 02, 1999
	19898 006	PRAVASTATIN SODIUM; PRAVACHOL	4346227	OCT 20, 2005		I-152	MAR 22, 1999
>ADD>			5180589	JUL 09, 2008			
			5030447	JUL 09, 2008		I-159	JUL 02, 1999
			4346227	OCT 20, 2005		I-152	MAR 22, 1999

* - 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
>ADD>	19898 007	PRAVASTATIN SODIUM; PRAVACHOL	5180589	JUL 09, 2008		I-159	JUL 02, 1999
			5030447	JUL 09, 2008			
			4346227	OCT 20, 2005		I-152	MAR 22, 1999
						I-154	MAY 03, 1999
						NP	JAN 31, 1999
						NP	JAN 31, 1999
	20279 001	PREDNICARBATE; DERMATOP	4344949	OCT 03, 2002			
	20545 001	PROCAINAMIDE HYDROCHLORIDE; PROCANBID	4344949	OCT 03, 2002			
	20545 002	PROCAINAMIDE HYDROCHLORIDE; PROCANBID	4344949	OCT 03, 2002			
	19885 001	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4344949	OCT 03, 2002			
	19885 002	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4585790	MAY 11, 2004			
	19885 003	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4521431	JUN 04, 2002	U-121		
	19885 004	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4128658	JUL 25, 1997	U-121		
	19593 001	RANITIDINE HYDROCHLORIDE; ZANTAC	4585790	MAY 11, 2004			
			4521431	JUN 04, 2002	U-121		
	19593 002	RANITIDINE HYDROCHLORIDE; ZANTAC	4128658	JUL 25, 1997	U-121		
			4880636	MAY 13, 2008			
	20520 001	RANITIDINE HYDROCHLORIDE; ZANTAC 75	4521431	JUN 04, 2002	U-121		
			4128658	JUL 25, 1997	U-121		
>ADD>	20630 001	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5019583	FEB 15, 2009		NCE	JUL 12, 2001
>ADD>	20630 002	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5019583	FEB 15, 2009		NCE	JUL 12, 2001
>ADD>	20630 003	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5019583	FEB 15, 2009		NCE	JUL 12, 2001
	20272 001	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
	20272 002	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
	20272 003	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
	20272 004	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
	20272 005	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90		
	20588 001	RISPERIDONE; RISPERDAL	4804663	DEC 29, 2007	U-90	NCE	DEC 29, 1998
>ADD>	20659 001	RITONAVIR; NORVIR	5541206	JUL 30, 2013	U-140		
			5484801	JAN 28, 2014		NCE	MAR 01, 2001
>ADD>	20680 001	RITONAVIR; NORVIR	5541206	JUL 30, 2013	U-140	NCE	MAR 01, 2001
	20628 001	SAQUINAVIR MESYLATE; INVIRASE	5196438	NOV 19, 2010			
	20572 001	SODIUM PHENYLBUTYRATE; BUPHENYL	4457942	AUG 20, 2002	U-136	NCE	APR 30, 2001
	20573 001	SODIUM PHENYLBUTYRATE; BUPHENYL	4457942	AUG 20, 2002	U-136	NCE	APR 30, 2001
						ODE	APR 30, 2003
	20280 004	SOMATROPIN, BIOSYNTHETIC; GENOTROPIN				NS	AUG 24, 1998
	20280 006	SOMATROPIN, BIOSYNTHETIC; GENOTROPIN				NS	AUG 24, 1998

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20240 001	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2003	U-3	NCE	DEC 29, 1999
20240 002	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2003	U-3	NCE	DEC 29, 1999
20240 003	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2003	U-3	NCE	DEC 29, 1999
20240 004	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2003	U-3	NCE	DEC 29, 1999
20412 001	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
20412 002	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
20412 003	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
20412 004	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
20412 005	STAVUDINE; ZERIT	4978655	JUN 25, 2008	U-94		
20256 001	TECHNETIUM TC-99M BICISATE KIT; NEUROLITE	5279811	NOV 23, 2008	U-101	NCE	NOV 23, 1999
19785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE				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			
20539 001	TERBINAFINE HYDROCHLORIDE; LAMISIL	4755534	JUL 05, 2005	U-73	NDF	MAY 10, 1999
					NCE	DEC 30, 1999
20489 001	TESTOSTERONE; ANDRODERM	5164190	NOV 17, 2008			
		5152997	OCT 06, 2009			
		4983395	JAN 08, 2009			
		4863970	SEP 05, 2006			
		4855294	AUG 08, 2006			
20671 001	TOPOTECAN HYDROCHLORIDE; HYCAMTIN	4849224	JUL 18, 2006		NS	SEP 29, 1998
20528 001	TRANDOLAPRIL; MAVIK	5004758	APR 02, 2008		NCE	MAY 28, 2001
20528 002	TRANDOLAPRIL; MAVIK				NCE	APR 26, 2001
20528 003	TRANDOLAPRIL; MAVIK				NCE	APR 26, 2001
19963 001	TRETINOIN; RENOVA				NCE	APR 26, 2001
		4877805	OCT 31, 2006	U-131		
19594 002	URSODIOL; ACTIGALL	4603146	JUL 29, 2003	U-131	NP	DEC 29, 1998
20487 001	VALACYCLOVIR HYDROCHLORIDE; VALTREX	4423041	DEC 27, 2000			
					I-147	MAR 29, 1999
					I-143	DEC 15, 1998

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PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	20487 002	VALACYCLOVIR HYDROCHLORIDE; VALTREX				I-143	DEC 15, 1998
	20151 001	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
	20151 002	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
	20151 003	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
	20151 004	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
	20151 005	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
	20151 006	VENLAFAXINE HYDROCHLORIDE; EFFEXOR	4535186	DEC 13, 2007		NCE	DEC 28, 1998
>ADD>	20552 001	VERAPAMIL HYDROCHLORIDE; COVERA-HS	5252338	JUN 27, 2011		NP	FEB 26, 1999
>DLT>	~~20552 001~~	~~VERAPAMIL HYDROCHLORIDE; COVERA-HS~~	~~4252338~~	~~JUN 27, 2011~~		~~NP~~	~~FEB 26, 1999~~
			5190765	AUG 14, 2007			
			5160744	JUN 27, 2011			
			4753802	MAR 19, 2006			
>ADD>	20552 002	VERAPAMIL HYDROCHLORIDE; COVERA-HS	5252338	JUN 27, 2011		NP	FEB 26, 1999
>DLT>	~~20552 002~~	~~VERAPAMIL HYDROCHLORIDE; COVERA-HS~~	~~4252338~~	~~JUN 27, 2011~~		~~NP~~	~~FEB 26, 1999~~
			5190765	AUG 14, 2007			
			5160744	JUN 27, 2011			
			4753802	MAR 19, 2006			

*U.S. Government Printing Office: 1996 — 404-907/40001

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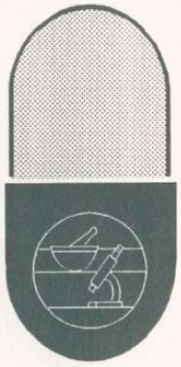

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