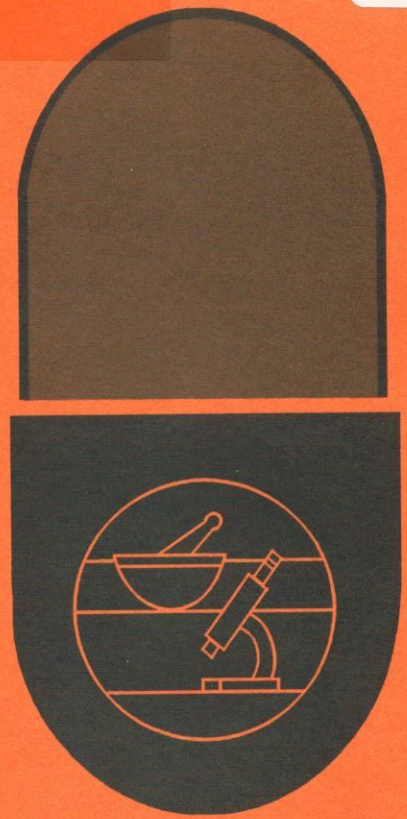
CUMULATIVE SUPPLEMENT 3

JAN'95-MAR'95



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

15TH EDITION

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

Prepared By
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15TH EDITION

Cumulative Supplement 3

MARCH 1995

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with
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CUMULATIVE SUPPLEMENT 3

MARCH 1995

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 15th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

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

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

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

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

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 15th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 16th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

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

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 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)
BRIAN PHARMACEUTICALS INC (BRIAN)	HYGENICS PHARMACEUTICALS INC (HYGENICS PHARMS)

1.4 AVAILABILITY OF THE PUBLICATION AND UPDATING PROCEDURES

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

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 1994) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

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

New Molecular Entity

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

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 1994	MAR 1995	JUN 1995	SEP 1995
DRUG PRODUCTS LISTED	9141			
SINGLE SOURCE	2178 (23.8%)			
MULTISOURCE	6963 (76.2%)			
THERAPEUTICALLY EQUIVALENT	6330 (69.2%)			
NOT THERAPEUTICALLY EQUIVALENT	453 (5.0%)			
EXCEPTIONS[1]	180 (2.0%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	534			

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

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

ANEXSIA

> DLT >	AA	BOEHRINGER MANNHEIM	500MG;5MG	N89160 001	
> DLT >				APR 23, 1987	
> ADD >	AA	KING PHARMS	500MG;5MG	N89160 001	
> ADD >				APR 23, 1987	

ANEXSIA 7.5/650

> DLT >	AA	BOEHRINGER MANNHEIM	650MG;7.5MG	N89725 001	
> DLT >				SEP 30, 1987	
> ADD >	AA	KING PHARMS	650MG;7.5MG	N89725 001	
> ADD >				SEP 30, 1987	

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

ACETAZOLAMIDE SODIUM

	AP	BEDFORD	EQ 500MG BASE/VIAL	N40089 001	
				FEB 28, 1995	

DIAMOX

	AP	+ STORZ OPHTHALM	EQ 500MG BASE/VIAL	N09388 001	
				DEC 05, 1990	

AMIKACIN SULFATE

INJECTABLE; INJECTION

AMIKIN

> ADD >	AP	APOTHECON	EQ 50MG BASE/ML	N62311 001	
> ADD >	AP		EQ 250MG BASE/ML	N62311 002	

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE HCL

	AB	ROXANE	150MG	N86090 001	
		@	150MG	N86090 001	

> ADD > AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

> ADD > CAPSULE; ORAL

> ADD > LOTREL

> ADD >		CIBA GEIGY	EQ 2.5MG BASE;10MG	N20364 002	
> ADD >				MAR 03, 1995	
> ADD >		CIBA GEIGY	EQ 5MG BASE;10MG	N20364 003	
> ADD >				MAR 03, 1995	
> ADD >		+	EQ 5MG BASE;20MG	N20364 004	
> ADD >				MAR 03, 1995	

AMPHOTERICIN B

INJECTABLE; INJECTION

AMPHOTERICIN B

> ADD >	AP	GENSIA	50MG/VIAL	N64062 001	
> ADD >				MAR 31, 1995	

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

> ADD >		@ CONSOLIDATED PHARM	EQ 125MG BASE/VIAL	N61936 005	
> ADD >		@	EQ 250MG BASE/VIAL	N61936 001	
> ADD >		@	EQ 500MG BASE/VIAL	N61936 002	
> ADD >		@	EQ 1GM BASE/VIAL	N61936 003	
> ADD >		@	EQ 2GM BASE/VIAL	N61936 004	
> DLT >		@ COPANOS	EQ 125MG BASE/VIAL	N61936 005	
> DLT >		@	EQ 250MG BASE/VIAL	N61936 001	
> DLT >		@	EQ 500MG BASE/VIAL	N61936 002	
> DLT >		@	EQ 1GM BASE/VIAL	N61936 003	
> DLT >		@	EQ 2GM BASE/VIAL	N61936 004	

ASPIRIN; METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL AND ASPIRIN

	AB	STEVENS J	325MG;400MG	N81145 001	
				JAN 31, 1995	

ATENOLOL

TABLET; ORAL

ATENOLOL

	AB	COPLEY PHARM	50MG	N74120 001	
				FEB 24, 1995	

ATENOLOL

TABLET; ORAL

	ATENOLOL			
AB	COPLEY PHARM	100MG	N74120 002	FEB 24, 1995
AB	LEMMON	50MG	N74056 001	JAN 18, 1995
AB		100MG	N74056 002	JAN 18, 1995
AB	MARTEC	50MG	N74127 001	FEB 21, 1995
AB		100MG	N74127 002	FEB 21, 1995

ATOVAQUONE

SUSPENSION; ORAL

	MEPRON			
+	BURROUGHS WELLCOME	750MG/5ML	N20500 001	FEB 08, 1995

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

> ADD >		**AZATHIOPRINE SODIUM**			
> ADD >	AP	BEDFORD	EQ 100MG BASE/VIAL	N74419 001	MAR 31, 1995
> ADD >		**IMURAN**			
> ADD >	AP +	BURROUGHS WELLCOME	EQ 100MG BASE/VIAL	N17391 001	

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

	BACITRACIN ZINC AND POLYMYXIN B SULFATE			
AT	ADV REMEDIES	500 UNITS/GM; 10,000 UNITS/GM	N64028 001	JAN 30, 1995
AT	BAUSCH AND LOMB	500 UNITS/GM; 10,000 UNITS/GM	N64046 001	JAN 26, 1995
	POLYSPORIN			
AT +	BURROUGHS WELLCOME	500 UNITS/GM; 10,000 UNITS/GM	N61229 001	

BUMETANIDE

INJECTABLE; INJECTION

	BUMETANIDE			
AP	BEDFORD	0.25MG/ML	N74441 001	JAN 27, 1995

CAPTOPRIL

TABLET; ORAL

		CAPOTEN			
> ADD >	AB	BRISTOL MYERS SQUIBB	12.5MG	N18343 005	JAN 17, 1985
> ADD >	AB		25MG	N18343 002	
> ADD >	AB		50MG	N18343 001	
> ADD >	AB +		100MG	N18343 003	
> ADD >		**CAPTOPRIL**			
> ADD >	AB	APOTHECON	12.5MG	N74472 001	MAR 31, 1995
> ADD >	AB		25MG	N74472 002	MAR 31, 1995
> ADD >	AB		50MG	N74472 003	MAR 31, 1995
> ADD >	AB		100MG	N74472 004	MAR 31, 1995

CEFOPERAZONE SODIUM

INJECTABLE; INJECTION

	CEFOBID			
> ADD >	PFIZER	EQ 1GM BASE/VIAL	N63333 001	MAR 31, 1995
> ADD >		EQ 2GM BASE/VIAL	N63333 002	MAR 31, 1995

CEFOXITIN SODIUM

INJECTABLE; INJECTION

	MEFOXIN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER			
+	MERCK SHARP DOHME	EQ 20MG BASE/ML	N50581 002	SEP 20, 1984
+		EQ 40MG BASE/ML	N50581 001	SEP 20, 1984
@		EQ 20MG BASE/ML	N50581 002	SEP 20, 1984

CEFOXITIN SODIUM

INJECTABLE; INJECTION
MEFOXIN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

		@	MERCK SHARP DOHME	EQ 40MG BASE/ML	N50581 001 SEP 20, 1984

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN

> DLT >	AP	+	ROCHE	EQ 250MG BASE/VIAL	N50585 001 DEC 21, 1984
> DLT >	AP	+		EQ 500MG BASE/VIAL	N50585 002 DEC 21, 1984
> DLT >	AP	+		EQ 1GM BASE/VIAL	N50585 003 DEC 21, 1984
> ADD >		+		EQ 250MG BASE/VIAL	N50585 001 DEC 21, 1984
> ADD >		+		EQ 500MG BASE/VIAL	N50585 002 DEC 21, 1984
> ADD >		+		EQ 1GM BASE/VIAL	N50585 003 DEC 21, 1984

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION
CHLORPHENIRAMINE MALEATE

> DLT >	AP		STERIS	10MG/ML	N83593 001
> ADD >		@		10MG/ML	N83593 001

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHLORPROMAZINE HCL

> DLT >	AP		STERIS	25MG/ML	N85591 001
> ADD >		@		25MG/ML	N85591 001

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

AB		LEMMON	100MG	N88768 001 OCT 11, 1984

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

		@ LEMMON	100MG	N88768 001 OCT 11, 1984

GLUCAMIDE

AB		LEMMON	250MG	N88641 001 OCT 11, 1984
		@	250MG	N88641 001 OCT 11, 1984

CHOLESTYRAMINE

TABLET; ORAL
QUESTRAN

		+ BRISTOL MYERS SQUIBB	EQ 1GM RESIN	N73403 001 APR 28, 1994
		@	EQ 1GM RESIN	N73403 001 APR 28, 1994

CIMETIDINE

TABLET; ORAL
CIMETIDINE

AB		GENEVA PHARMS	200MG	N74100 001 JAN 31, 1995
AB			300MG	N74100 002 JAN 31, 1995
AB			400MG	N74100 003 JAN 31, 1995
AB			800MG	N74100 004 JAN 31, 1995
AB		LEMMON	200MG	N74365 001 FEB 28, 1995
AB			300MG	N74365 002 FEB 28, 1995
AB			400MG	N74365 003 FEB 28, 1995
AB			800MG	N74365 004 FEB 28, 1995

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
CIMETIDINE HCL

AP	ABBOTT	EQ 300MG BASE/2ML	N74344 001 JAN 31, 1995	> ADD >	
AP		EQ 300MG BASE/2ML	N74345 001 JAN 31, 1995		
AP		EQ 300MG BASE/2ML	N74422 001 JAN 31, 1995	> DLT > > DLT >	

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL
CLEOCIN

	UPJOHN	EQ 1% BASE	N50537 002 FEB 22, 1994		

SWAB; TOPICAL
CLEOCIN

	UPJOHN	EQ 1% BASE	N50537 002 FEB 22, 1994		

CLOBETASOL PROPIONATE

OINTMENT; TOPICAL
EMBELINE

> ADD > > ADD > > ADD >	AB DPT	0.05%	N74221 001 MAR 31, 1995		

CLOTRIMAZOLE

SOLUTION; TOPICAL
CLOTRIMAZOLE

AT	LEMMON	1%	N73306 001 FEB 28, 1995	> DLT > > DLT > > DLT > > ADD > > ADD >	

CROMOLYN SODIUM

SOLUTION/DROPS; OPHTHALMIC
CROLOM

AT	BAUSCH AND LOMB	4%	N74443 001 JAN 30, 1995		

OPTICROM

AT +	FISONS	4%	N18155 001 OCT 03, 1984		

CYANOCOBALAMIN

INJECTABLE; INJECTION
CYANOCOBALAMIN

	@ WARNER CHILCOTT	1MG/ML	N07085 002		

RUBRAMIN PC

AP +	SQUIBB	0.1MG/ML	N06799 002		
	@	0.1MG/ML	N06799 002		

SYTOBEX

AP	PARKE DAVIS	1MG/ML	N07085 002		

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
DAUNORUBICIN HCL

AP	CETUS BEN VENUE	EQ 20MG BASE/VIAL	N64103 001 FEB 03, 1995		

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL
DESMOPRESSIN ACETATE

+	RHONE POULENC RORER	0.15MG/INH	N20355 001 MAR 07, 1994		

STIMATE

+	RHONE POULENC RORER	0.15MG/INH	N20355 001 MAR 07, 1994		

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-21
DESOGEN

AB +	ORGANON	0.15MG;0.03MG	N20071 001 DEC 10, 1992	> DLT > > DLT > > DLT >	
	@	0.15MG;0.03MG	N20071 001 DEC 10, 1992	> ADD > > ADD >	

ORTHO-CEPT

AB	JOHNSON RW	0.15MG;0.03MG	N20301 001 DEC 14, 1992	> DLT > > DLT > > ADD > > ADD >	
		0.15MG;0.03MG	N20301 001 DEC 14, 1992		

DEXAMETHASONE

TABLET; ORAL
HEXADROL

BP	ORGANON	0.5MG	N12675 004	
BP		0.75MG	N12675 007	
BP		1.5MG	N12675 009	
@		0.5MG	N12675 004	
@		0.75MG	N12675 007	
@		1.5MG	N12675 009	

DIAZEPAM

INJECTABLE; INJECTION
DIAZEPAM

> DLT >	**AP**	**FUJISAWA**	**5MG/ML**	**N70662 001 JUN 25, 1986**
> DLT >				
> ADD >	@		5MG/ML	N70662 001 JUN 25, 1986
> ADD >				

DICLOFENAC POTASSIUM

TABLET; ORAL
CATAFLAM

		GEIGY	25MG	N20142 001 NOV 24, 1993
	@		25MG	N20142 001 NOV 24, 1993

DILTIAZEM HYDROCHLORIDE

TABLET; ORAL
DILTIAZEM HCL

> ADD >	**AB**	ZENITH LABS	**30MG**	**N74168 001 MAR 03, 1995**
> ADD >				
> ADD >	**AB**		**60MG**	**N74168 002 MAR 03, 1995**
> ADD >				
> ADD >	**AB**		**90MG**	**N74168 003 MAR 03, 1995**
> ADD >				
> ADD >	**AB**		**120MG**	**N74168 004 MAR 03, 1995**
> ADD >				

DIMENHYDRINATE

INJECTABLE; INJECTION
DIMENHYDRINATE

> DLT >	**AP**	**STERIS**	**50MG/ML**	**N83531 001**
> ADD >	@		50MG/ML	N83531 001

DINOPROSTONE

INSERT, EXTENDED RELEASE; VAGINAL

> ADD >		CERVIDIL		
> ADD >		+ CONTROLLED THERAP	10MG	N20411 001 MAR 30, 1995
> ADD >				

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOBUTAMINE HCL

AP	ASTRA	**EQ 12.5MG BASE/ML**	**N74098 001 FEB 21, 1995**
AP	SANOFI WINTHROP	**EQ 12.5MG BASE/ML**	**N74292 001 FEB 16, 1995**

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
DOXORUBICIN HCL

AP	PHARMACHEMIE (NL)	**2MG/ML**	**N63336 001 FEB 28, 1995**
AP		**200MG/100ML**	**N63336 004 FEB 28, 1995**

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL
VIVELLE

BX	CIBA GEIGY	0.05MG/24HR	N20323 002 OCT 28, 1994
BX		0.1MG/24HR	N20323 004 OCT 28, 1994
		0.0375MG/24HR	N20323 001 OCT 28, 1994
		0.075MG/24HR	N20323 003 OCT 28, 1994

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

VIVELLE

BX	NOVEN	0.05MG/24HR	N20323 002	
			OCT 28, 1994	
BX		0.1MG/24HR	N20323 004	
			OCT 28, 1994	
		0.0375MG/24HR	N20323 001	
			OCT 28, 1994	
		0.075MG/24HR	N20323 003	
			OCT 28, 1994	

ETOPOSIDE

INJECTABLE; INJECTION

TOPOSAR

AP	PHARMACIA	20MG/ML	N74166 001	
			FEB 27, 1995	

FENOFIBRATE

CAPSULE; ORAL

LIPIDIL

> DLT >	+ LABS FOURNIER	100MG	N19304 001	
> DLT >			DEC 31, 1993	
> ADD >	@	100MG	N19304 001	
> ADD >			DEC 31, 1993	

FLUNISOLIDE

SPRAY, METERED; NASAL

NASALIDE

> ADD >	BX + SYNTEX	0.025MG/INH	N18148 001	

NASAREL

> ADD >	BX + SYNTEX	0.025MG/INH	N20409 001	
> ADD >			MAR 08, 1995	

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

FLUOCINOLONE ACETONIDE

> ADD >	AT + HAMILTON PHARMA CA	0.01%	N12787 004	
> ADD >	AT +	0.025%	N12787 002	
> DLT >	SYNALAR			
> DLT >	AT + SYNTEX	0.01%	N12787 004	

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

SYNALAR

> DLT >				
> DLT >	AT + SYNTEX	0.025%	N12787 002	

OINTMENT; TOPICAL

FLUOCINOLONE ACETONIDE

> ADD >	AT + HAMILTON PHARMA CA	0.025%	N13960 001	
> DLT >	SYNALAR			
> DLT >	AT + SYNTEX	0.025%	N13960 001	

FLUOCINONIDE

CREAM; TOPICAL

FLUOCINONIDE

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

SOLUTION; TOPICAL

FLUOCINONIDE

	AT FOUGERA	0.05%	N72934 001	
			FEB 27, 1995	
> ADD >	AT + HAMILTON PHARMA CA	0.05%	N18849 001	
> ADD >			APR 06, 1984	
> DLT >	LIDEX			
> DLT >	AT + SYNTEX	0.05%	N18849 001	
> DLT >			APR 06, 1984	

FLURBIPROFEN SODIUM

SOLUTION/DROPS; OPHTHALMIC

FLURBIPROFEN SODIUM

AT	BAUSCH AND LOMB	0.03%	N74447 001	
			JAN 04, 1995	

OCUFEN

AT	+ ALLERGAN	0.03%	N19404 001	
			DEC 31, 1986	

FOSINOPRIL SODIUM

TABLET; ORAL
MONOPRIL

> DLT >	+	BRISTOL MYERS SQUIBB	20MG	N19915 003	
> DLT >				MAY 16, 1991	
> ADD >			20MG	N19915 003	
> ADD >				MAY 16, 1991	
> ADD >	+		40MG	N19915 004	
> ADD >				MAR 28, 1995	

GEMFIBROZIL

CAPSULE; ORAL
GEMFIBROZIL

AB		MYLAN	**300MG**	**N73466 001**	
				JAN 25, 1993	> ADD >
AB	+		**300MG**	**N73466 001**	> ADD >
				JAN 25, 1993	> ADD >
					> ADD >
		LOPID			
AB	+	PARKE DAVIS	**300MG**	**N18422 002**	
	@		300MG	N18422 002	

TABLET; ORAL
GEMFIBROZIL

AB	MYLAN	**600MG**	**N74452 001**	
			FEB 16, 1995	

GLIPIZIDE

TABLET; ORAL
GLIPIZIDE

AB	WATSON LABS	**5MG**	**N74223 001**	
			FEB 27, 1995	
AB		**10MG**	**N74223 002**	
			FEB 27, 1995	

GLYBURIDE

TABLET; ORAL
GLUBATE

@	HOECHST ROUSSEL	1.5MG	N20055 001
			APR 17, 1992
@		3MG	N20055 002
			APR 17, 1992

GLYBURIDE

TABLET; ORAL
GLYBURIDE (MICRONIZED)

AB	HOECHST ROUSSEL	**1.5MG**	**N20055 001**	
			APR 17, 1992	
AB		**3MG**	**N20055 002**	
			APR 17, 1992	
	GLYNASE			
AB	UPJOHN	**1.5MG**	**N20051 001**	
			MAR 04, 1992	
AB		**3MG**	**N20051 002**	
			MAR 04, 1992	

GRANISETRON HYDROCHLORIDE

TABLET; ORAL
KYTRIL

+	SMITHKLINE BEECHAM	EQ 1MG BASE	N20305 001	
			MAR 16, 1995	

GUANFACINE HYDROCHLORIDE

TABLET; ORAL
TENEX

	ROBINS AH	1MG	N19032 001	
			OCT 27, 1986	
+		2MG	N19032 002	
			NOV 07, 1988	
@		3MG	N19032 003	
			NOV 07, 1988	
		EQ 1MG BASE	N19032 001	
			OCT 27, 1986	
+		EQ 2MG BASE	N19032 002	
			NOV 07, 1988	
@		EQ 3MG BASE	N19032 003	
			NOV 07, 1988	

HEPARIN CALCIUM

INJECTABLE; INJECTION
CALCIPARINE

+	CHOAY	25,000 UNITS/ML	N18237 001
@	SANOFI WINTHROP	25,000 UNITS/ML	N18237 001

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH

AP	SANOFI WINTHROP	**10 UNITS/ML**	**N40082 001**	**FEB 28, 1995**
AP		**100 UNITS/ML**	**N40082 002**	**FEB 28, 1995**

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
APRESOLINE-ESIDRIX

*	CIBA	25MG;15MG	N12026 002	
@		25MG;15MG	N12026 002	

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE

TABLET; ORAL
LOPRESSOR HCT

	CIBA	25MG;50MG	N18303 001	DEC 31, 1984
		25MG;100MG	N18303 002	DEC 31, 1984
+		50MG;100MG	N18303 003	DEC 31, 1984

LOPRESSOR HCT 100/25

	CIBA	25MG;100MG	N18303 002	DEC 31, 1984

LOPRESSOR HCT 100/50

*	CIBA	50MG;100MG	N18303 003	DEC 31, 1984

LOPRESSOR HCT 50/25

	CIBA	25MG;50MG	N18303 001	DEC 31, 1984

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

AB	ZENITH LABS	**25MG;50MG**	**N74259 001**	**MAR 30, 1995**

HYDROCORTISONE

ENEMA; RECTAL
CORTENEMA

AT	+ SOLVAY	**100MG/60ML**	**N16199 001**	
	+	100MG/60ML	N16199 001	

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL

AP	PHARMAFAIR	**50MG/ML**	**N88881 001**	**FEB 14, 1986**
@		50MG/ML	N88881 001	FEB 14, 1986
> DLT >	**AP** STERIS	**25MG/ML**	**N87274 001**	
> DLT >	**AP**	**50MG/ML**	**N87274 002**	
> ADD >	@	25MG/ML	N87274 001	
> ADD >	@	50MG/ML	N87274 002	

IBUPROFEN

SUSPENSION; ORAL
CHILDREN'S MOTRIN

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

PEDIA PROFEN

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

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL
IMDUR

> ADD >	@ SCHERING	30MG	N20225 001	AUG 12, 1993
> ADD >	+	60MG	N20225 002	AUG 12, 1993
> ADD >	+	120MG	N20225 003	MAR 30, 1995
> DLT >	@ SCHERING PLOUGH	30MG	N20225 001	AUG 12, 1993
> DLT >	+	60MG	N20225 002	AUG 12, 1993

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL

		ORUVAIL			
	+	WYETH AYERST	100MG	N19816 003	
				FEB 08, 1995	
	+		150MG	N19816 002	
				FEB 08, 1995	

LEUPROLIDE ACETATE

INJECTABLE; INJECTION

		LUPRON			
	+	TAP PHARMS	5MG/ML	N19010 001	
				APR 09, 1985	
	+		1MG/0.2ML	N19010 001	
				APR 09, 1985	

LISINOPRIL

TABLET; ORAL

		PRINIVIL			
> DLT >	**AB**	MERCK	**2.5MG**	**N19558 006**	
> DLT >				JAN 28, 1994	
> ADD >			2.5MG	N19558 006	
> ADD >				JAN 28, 1994	
		ZESTRIL			
> DLT >	**AB**	ZENECA	**2.5MG**	**N19777 005**	
> DLT >				APR 29, 1993	
> ADD >		@	2.5MG	N19777 005	
> ADD >				APR 29, 1993	

MEBENDAZOLE

TABLET, CHEWABLE; ORAL

	MEBENDAZOLE			
AB	COPLEY PHARM	**100MG**	**N73580 001**	
			JAN 04, 1995	
	VERMOX			
AB	+ JANSSEN	**100MG**	**N17481 001**	

METFORMIN HYDROCHLORIDE

TABLET; ORAL

		GLUCOPHAGE			
> ADD >		BRISTOL MYERS SQUIBB	500MG	N20357 001	
> ADD >				DEC 29, 1994	
> ADD >	+		850MG	N20357 002	
> ADD >				DEC 29, 1994	
> DLT >		LIPHA	500MG	N20357 001	
> DLT >				DEC 29, 1994	
> DLT >	+		850MG	N20357 002	
> DLT >				DEC 29, 1994	

METHADONE HYDROCHLORIDE

POWDER; FOR RX COMPOUNDING

	METHADONE HCL			
	MALLINCKRODT	50GM/BOT		N06383 002
		100GM/BOT		N06383 003
		500GM/BOT		N06383 004

METHOTRIMEPRAZINE

INJECTABLE; INJECTION

	LEVOPROME			
> ADD >	+ IMMUNEX	20MG/ML		N15865 001
> DLT >	+ LEDERLE	20MG/ML		N15865 001

METOPROLOL TARTRATE

TABLET; ORAL

	METOPROLOL TARTRATE			
AB	LEMMON	**50MG**		**N74141 001**
				JAN 31, 1995
AB		**100MG**		**N74141 002**
				JAN 31, 1995

METYRAPONE

TABLET; ORAL

> DLT >	METOPIRONE			
> DLT >	+ CIBA	250MG		N12911 001
> DLT >	@	250MG		N12911 001
> ADD >				

NAPROXEN

TABLET; ORAL
NAPROXEN

AB	DANBURY PHARMA	250MG	N74163 001	FEB 10, 1995
AB		375MG	N74163 002	FEB 10, 1995
AB		500MG	N74163 003	FEB 10, 1995
AB	ZENITH LABS	250MG	N74111 001	FEB 28, 1995
AB		375MG	N74111 002	FEB 28, 1995
AB		500MG	N74111 003	FEB 28, 1995

NAPROXEN SODIUM

TABLET; ORAL
NAPROXEN SODIUM

>ADD>	AB	PUREPAC PHARM	EQ 250MG BASE	N74319 001	MAR 20, 1995
>ADD>	AB		EQ 500MG BASE	N74319 002	MAR 20, 1995
>ADD>	AB	ZENITH LABS	EQ 250MG BASE	N74230 001	MAR 14, 1995
>ADD>	AB		EQ 500MG BASE	N74230 002	MAR 14, 1995

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL
HABITROL

BC	+ BASEL PHARMS	7MG/24HR	N20076 001	NOV 27, 1991
BC	+	14MG/24HR	N20076 002	NOV 27, 1991
BC	+	21MG/24HR	N20076 003	NOV 27, 1991
BC	+ CIBA	7MG/24HR	N20076 001	NOV 27, 1991
BC	+	14MG/24HR	N20076 002	NOV 27, 1991
BC	+	21MG/24HR	N20076 003	NOV 27, 1991

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL
NISOCOR

+	MILES	10MG	N20356 001	FEB 02, 1995
+		20MG	N20356 002	FEB 02, 1995
+		30MG	N20356 003	FEB 02, 1995
+		40MG	N20356 004	FEB 02, 1995

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL
NITROFURANTOIN

AB	GENEVA PHARMS	25MG	N74336 001	JAN 25, 1995
AB		50MG	N74336 002	JAN 25, 1995
AB		100MG	N74336 003	JAN 25, 1995

NITROGLYCERIN

INJECTABLE; INJECTION
NITROSTAT

AP	PARKE DAVIS	5MG/ML	N18588 002	DEC 23, 1983
+		0.8MG/ML	N18588 001	
@		0.8MG/ML	N18588 001	
@		5MG/ML	N18588 002	DEC 23, 1983

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
NORTRIPTYLINE HCL

>ADD> AB	LEMMON	EQ 10MG BASE	N74132 001	MAR 27, 1995
>ADD> AB		EQ 25MG BASE	N74132 002	MAR 27, 1995
>ADD> AB		EQ 50MG BASE	N74132 003	MAR 27, 1995

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
NORTRIPTYLINE HCL

> ADD >	**AB**	LEMMON	**EQ 75MG BASE**	**N74132 004**	
> ADD				MAR 27, 1995	

NYSTATIN; TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL
NYSTATIN AND TRIAMCINOLONE ACETONIDE

> DLT >	**AT**	PHARMAFAIR	**100,000 UNITS/GM;0.1%**	**N62656 001**
> DLT >				JUL 30, 1986
> ADD >		@	100,000 UNITS/GM;0.1%	N62656 001
> ADD >				JUL 30, 1986

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION
ZOFRAN IN PLASTIC CONTAINER

+	GLAXO	EQ 0.64MG BASE/ML	N20403 001
			JAN 31, 1995

PENICILLAMINE

TABLET; ORAL
DEPEN

+	WALLACE	250MG	N19854 001

DEPEN 250

+	WALLACE	250MG	N19854 001

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION
PENICILLIN G POTASSIUM

> ADD >		@ CONSOLIDATED PHARM	500,000 UNITS/VIAL	N60806 001
> ADD >		@	1,000,000 UNITS/VIAL	N60806 002
> ADD >		@	5,000,000 UNITS/VIAL	N60806 003
> ADD >		@	10,000,000 UNITS/VIAL	N60806 004
> DLT >		@ COPANOS	500,000 UNITS/VIAL	N60806 001
> DLT >		@	1,000,000 UNITS/VIAL	N60806 002
> DLT >		@	5,000,000 UNITS/VIAL	N60806 003
> DLT >		@	10,000,000 UNITS/VIAL	N60806 004

PENICILLIN G PROCAINE

INJECTABLE; INJECTION
PENICILLIN G PROCAINE

> ADD >		@ CONSOLIDATED PHARM	300,000 UNITS/ML	N60800 001
> ADD >		@	600,000 UNITS/1.2ML	N60800 002
> DLT >		@ COPANOS	300,000 UNITS/ML	N60800 001
> DLT >		@	600,000 UNITS/1.2ML	N60800 002

PERINDOPRIL ERBUMINE

TABLET; ORAL
ACEON

	AMARIC	2MG	N20184 001
			DEC 30, 1993
		4MG	N20184 002
			DEC 30, 1993
+		8MG	N20184 003
			DEC 30, 1993
	JOHNSON RW	2MG	N20184 001
			DEC 30, 1993
		4MG	N20184 002
			DEC 30, 1993
+		8MG	N20184 003
			DEC 30, 1993

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL
IONAMIN

	FISONS	EQ 15MG BASE	N11613 004
+		EQ 30MG BASE	N11613 002

IONAMIN-15

	FISONS	EQ 15MG BASE	N11613 004

IONAMIN-30

+	FISONS	EQ 30MG BASE	N11613 002

PINDOLOL

TABLET; ORAL
PINDOLOL

AB	ROYCE LABS	**5MG**	**N74437 001**
			FEB 27, 1995
AB		**10MG**	**N74437 002**
			FEB 27, 1995

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

POWDER FOR RECONSTITUTION; ORAL

	NULYTELY-FLAVORED			
	BRAINTREE	420GM/BOT;1.48GM/BOT;5.72GM/BOT; 11.2GM/BOT	N19797 002	NOV 18, 1994

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

POWDER FOR RECONSTITUTION; ORAL

	GOLYTELY			
> ADD >	**AA** BRAINTREE	**227.1GM/PACKET;2.82GM/PACKET; 6.36GM/PACKET;5.53GM/PACKET; 21.5GM/PACKET**	**N19011 002**	JUN 02, 1992

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

	KAON CL			
	SAVAGE LABS	6.7MEQ	N17046 001	
	@	6.7MEQ	N17046 001	
	KAON CL-10			
BC	SAVAGE LABS	10MEQ	N17046 002	
	@	10MEQ	N17046 002	

PREDNISOLONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

	HYDELTRASOL				
> DLT >	**AP** + MERCK SHARP DOHME	**EQ 20MG PHOSPHATE/ML**	**N11583 002**		
> ADD >	+	EQ 20MG PHOSPHATE/ML	N11583 002		
> DLT >	**PREDNISOLONE SODIUM PHOSPHATE**				
> DLT >	**AP** STERIS	**EQ 20MG PHOSPHATE/ML**	**N80517 001**		
> ADD >	@	EQ 20MG PHOSPHATE/ML	N80517 001		

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

	PROCAN SR			
> DLT >	**AB** PARKE DAVIS	**250MG**	**N86468 001**	
> ADD >	@	250MG	N86468 001	

PROPYLTHIOURACIL

TABLET; ORAL

	PROPYLTHIOURACIL			
BD	LILLY	50MG	N06213 001	
	@	50MG	N06213 001	

SECOBARBITAL SODIUM

CAPSULE; ORAL

	SECOBARBITAL SODIUM			
> DLT >	**AA** ZENITH LABS	**100MG**	**N85869 001**	
> ADD >	@	100MG	N85869 001	

SODIUM CHLORIDE

INJECTABLE; INJECTION

	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER			
AP	BAXTER	**9MG/ML**	**N16677 004**	OCT 30, 1985
AP	+	**9MG/ML**	**N16677 004**	OCT 30, 1985

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION

	SUCOSTRIN			
AP	APOTHECON	**20MG/ML**	**N08847 001**	
	@	100MG/ML	N08847 003	
AP	SQUIBB	**20MG/ML**	**N08847 001**	
	@	100MG/ML	N08847 003	

TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR

SOLUTION; INJECTION, ORAL

	TECHNELITE		
	DUPONT	0.0083-2.7 CI/GENERATOR	N17771 001
	TECHNETIUM TC 99M GENERATOR		
	DUPONT	0.0083-2.7 CI/GENERATOR	N17771 001

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
THEOPHYLLINE

BC	FAULDING	100MG	N89976 001	JAN 04, 1995
BC		200MG	N89977 001	JAN 04, 1995
BC		300MG	N89932 001	JAN 04, 1995

TABLET, EXTENDED RELEASE; ORAL
LABID

BC	+ PROCTER AND GAMBLE	250MG	N87225 001	
	@	250MG	N87225 001	

THEOLAIR-SR

BC	3M	250MG	N86363 002	JUL 16, 1987
		250MG	N86363 002	JUL 16, 1987

UNI-DUR

BC	+ KEY PHARMS	400MG	N89822 001	JAN 04, 1995
	+	600MG	N89823 001	JAN 04, 1995

UNIPHYL

BC	PURDUE FREDERICK	400MG	N87571 001	SEP 01, 1982

THIOTEPA

INJECTABLE; INJECTION
THIOPLEX

	IMMUNEX	15MG/VIAL	N20058 001	DEC 22, 1994
AP	LEDERLE	15MG/VIAL	N20058 001	DEC 22, 1994

THIOTEPA

AP	+ IMMUNEX	15MG/VIAL	N11683 001	
	+	15MG/VIAL	N11683 001	

> ADD > TIMOLOL

> ADD > SOLUTION/DROPS; OPHTHALMIC
> ADD > BETIMOL

> ADD >	+ LEIRAS	EQ 0.25% BASE	N20439 001	MAR 31, 1995

> ADD > TIMOLOL

> ADD > SOLUTION/DROPS; OPHTHALMIC
> ADD > BETIMOL

> ADD >	+ LEIRAS	EQ 0.5% BASE	N20439 002	MAR 31, 1995

TOCAINIDE HYDROCHLORIDE

TABLET; ORAL
TONOCARD

> ADD >	ASTRA MERCK	400MG	N18257 001	NOV 09, 1984
> ADD >	+	600MG	N18257 002	NOV 09, 1984
> DLT >	MERCK SHARP DOHME	400MG	N18257 001	NOV 09, 1984
> DLT >	+	600MG	N18257 002	NOV 09, 1984

TRAMADOL HYDROCHLORIDE

TABLET; ORAL
ULTRAM

> ADD >	+ JOHNSON RW	50MG	N20281 002	MAR 03, 1995
> ADD >	@	100MG	N20281 001	MAR 03, 1995

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL
TRIAMCINOLONE ACETONIDE IN ABSORBASE

> ADD >	+ CAROLINA MEDCL	0.05%	N89595 001	MAR 23, 1995

VALPROIC ACID

SYRUP; ORAL
VALPROIC ACID

AA	HIGH TECH PHARMA	250MG/5ML	N74060 001	JAN 13, 1995

VANCOMYCIN HYDROCHLORIDE

POWDER FOR RECONSTITUTION; ORAL

	VANCOCIN HCL			
AB	+ LILLY	**EQ 500MG BASE/6ML**	**N61667 001**	
	+	EQ 500MG BASE/6ML	N61667 001	
	VANCOLED			
AB	LEDERLE	**EQ 500MG BASE/5ML**	**N63321 003**	
			OCT 15, 1993	
	@	EQ 500MG BASE/6ML	N63321 003	
			OCT 15, 1993	

VITAMIN A

CAPSULE; ORAL

	VITAMIN A			
AA	BANNER PHARMACAPS	**50,000 USP UNITS**	**N83973 001**	
	@	50,000 USP UNITS	N83973 001	

VITAMIN A PALMITATE

CAPSULE; ORAL

	VITAMIN A			
AA	BANNER PHARMACAPS	**EQ 50,000 UNITS BASE**	**N80702 001**	
	@	EQ 50,000 UNITS BASE	N80702 001	
	VITAMIN A PALMITATE			
AA	BANNER PHARMACAPS	**EQ 50,000 UNITS BASE**	**N83948 001**	
	@	EQ 50,000 UNITS BASE	N83948 001	

WARFARIN SODIUM

INJECTABLE; INJECTION

	COUMADIN			
	+ DUPONT MERCK	5MG/VIAL	N09218 024	
			FEB 07, 1995	

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACETAMINOPHEN
ABLE 120MG N73106 001 >DLT<
FEB 27, 1995 >DLT<
325MG N73107 001 >DLT<
FEB 27, 1995 >ADD<
650MG N73108 001 >ADD<
FEB 27, 1995

IBUPROFEN

CAPSULE; ORAL
MIDOL
+ WINTHROP 200MG N70626 001
SEP 02, 1987
200MG N71002 001
SEP 02, 1987
@ 200MG N70626 001
SEP 02, 1987
@ 200MG N71002 001
SEP 02, 1987

TABLET; ORAL
MIDOL
WINTHROP 200MG N70591 001
SEP 02, 1987
200MG N71001 001
SEP 02, 1987
@ 200MG N70591 001
SEP 02, 1987 >ADD<
@ 200MG N71001 001 >ADD<
SEP 02, 1987 >ADD<

INSULIN PORK

INJECTABLE; INJECTION
INSULIN
+ NOVO NORDISK 100 UNITS/ML N17926 003
REGULAR INSULIN
+ NOVO NORDISK 100 UNITS/ML N17926 003

INSULIN SEMISYNTHETIC PURIFIED HUMAN; INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN

INJECTABLE; INJECTION
NOVOLIN 70/30
+ NOVO NORDISK 30 UNITS/ML;70 UNITS/ML N19441 001
JUL 11, 1986
@ 30 UNITS/ML;70 UNITS/ML N19441 001
JUL 11, 1986

INSULIN SUSP PROTAMINE ZINC PURIFIED BEEF

INJECTABLE; INJECTION
PROTAMINE ZINC AND ILETIN II
+ LILLY 100 UNITS/ML N18476 001
@ 100 UNITS/ML N18476 001
PROTAMINE ZINC INSULIN
SQUIBB 100 UNITS/ML N17928 003
+ 100 UNITS/ML N17928 003

MICONAZOLE NITRATE

CREAM; VAGINAL
MICONAZOLE NITRATE
LEMMON 2% N74136 001
JAN 04, 1995

NONOXYNOL-9

AEROSOL; VAGINAL
DELFEN
@ ORTHO 12.5% N14349 002

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD= Date Designated MA= Marketing Approval
SARGRAMOSTIM TN= LEUKINE	TO REDUCE NEUTROPENIA AND LEUKOPENIA AND DECREASE THE INCIDENCE OF DEATH DUE TO INFECTION IN PATIENTS WITH ACUTE MYELOGENOUS LEUKEMIA.	IMMUNEX CORPORATION 51 UNIVERSITY STREET SEATTLE WA 98101 DD 03/06/95 MA / /
TYLOXAPOL TN=	TREATMENT OF CYSTIC FIBROSIS.	KENNEDY & HOIDAL, MDs 50 NORTH MEDICAL DRIVE, U OF UTAH SALT LAKE CITY UT 84132 DD 03/08/95 MA / /
Rho (D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN) TN= WinRho SD	TREATMENT OF IMMUNE THROMBOCYTOPENIC PURPURA.	RH PHARMACEUTICALS, INC. 104 CHANCELLOR MATHESON ROAD WINNIPEG, MANITOBA DD 11/09/93 MA 03/24/95

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

NO MARCH 1995 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, 15TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO MARCH 1995 GUIDANCES

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED AND REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANCH, HFA-305, ROOM 1-23, PARK BUILDING, 5600 FISHERS LANE, ROCKVILLE, MD 20857.					
REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 15TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.					
ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE TABLET; ORAL	150MG 180MG 15MG	94 P-0212/ CP1	MIKART	NEW DOSAGE FORM	APPROVED JAN 19, 1995
ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE TABLET; ORAL	150MG 180MG 30MG	94 P-0211/ CP1	MIKART	NEW DOSAGE FORM	APPROVED JAN 19, 1995
ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE TABLET; ORAL	150MG 180MG 60MG	94 P-0210/ CP1	MIKART	NEW DOSAGE FORM	APPROVED JAN 19, 1995
ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE TABLET; ORAL	712.8MG 60MG 32MG	93 P-0484/ CP1	MIKART	NEW DOSAGE FORM NEW STRENGTH	APPROVED JAN 19, 1995
ACETAMINOPHEN; CODEINE PHOSPHATE TABLET, CHEWABLE; ORAL	120MG 12MG	94 P-0182/ CP1	WE PHARMS	NEW DOSAGE FORM	APPROVED JAN 19, 1995
ALBUTEROL SULFATE TABLET, CHEWABLE; ORAL	EQ 2MG BASE EQ 4MG BASE	92 P-0335/ CP1	WE PHARMS	NEW DOSAGE FORM	APPROVED JAN 19, 1995
LEUCOVORIN CALCIUM INJECTABLE; INJECTION	EQ 10MG BASE/ML (100MG/VIAL)	93 P-0427/ CP3	ABBOTT	NEW DOSAGE FORM	APPROVED JAN 19, 1995
LEUCOVORIN CALCIUM INJECTABLE; INJECTION	EQ 10MG BASE/ML (250MG/VIAL)	93 P-0427/ CP2	ABBOTT	NEW DOSAGE FORM NEW STRENGTH	APPROVED JAN 19, 1995
SULFAMETHOXAZOLE; TRIMETHOPRIM TABLET, CHEWABLE; ORAL	200MG 40MG	94 P-0186/ CP1	DURA PHARMS	NEW DOSAGE FORM	APPROVED JAN 19, 1995
THIORIDAZINE HYDROCHLORIDE SOLUTION; ORAL	25MG/5ML	92 P-0283/ CP1	UDL LABS	NEW STRENGTH	APPROVED JAN 19, 1995

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 15TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES
NEW DOSING SCHEDULE

D-26	ONCE WEEKLY APPLICATION

REFERENCES
NEW INDICATION

I-117	TO SLOW THE PROGRESSION OF CORONARY ATHEROSCLEROSIS IN PATIENTS WITH CORONARY HEART DISEASE
I-118	PREVENTION OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLSIM, FOLLOWING KNEE REPLACEMENT SURGERY
I-119	TREATMENT OF ANEMIA CAUSED BY UTERINE LEIOMYOMATA IN WOMEN WHO FAIL IRON THERAPY
I-120	MAINTENANCE THERAPY FOR GASTRIC ULCER PATIENTS AT REDUCED DOSAGE AFTER HEALING ACUTE ULCERS
I-121	EXPANDED PATIENT POPULATION - USE IN ICU PATIENTS

REFERENCES
PATENT USE CODE

U-102	METHOD OF HORMONALLY TREATING MENOPAUSAL OR POST-MENOPAUSAL DISORDERS IN WOMEN
U-103	TREATMENT OF OCULAR HYPERTENSION
U-104	TREATMENT OF AQUEOUS HUMOR FORMATION AND INTRAOCULAR PRESSURE
U-105	EMESIS
U-106	TREATMENT OF EPILEPSY

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>	20364 002	AMLODIPINE BESYLATE; LOTREL	4879303	NOV 07, 2006		NC	MAR 03, 1998
>ADD>			4572909	AUG 01, 2006		NCE	JUN 25, 1996
>ADD>			4410520	OCT 18, 2002		NCE	JUL 31, 1997
>ADD>	20364 003	AMLODIPINE BESYLATE; LOTREL	4879303	NOV 07, 2006		NC	MAR 03, 1998
>ADD>			4572909	AUG 01, 2006		NCE	JUN 25, 1996
>ADD>			4410520	OCT 18, 2002		NCE	JUL 31, 1997
>ADD>	20364 004	AMLODIPINE BESYLATE; LOTREL	4879303	NOV 07, 2006		NC	MAR 03, 1998
>ADD>			4572909	AUG 01, 2006		NCE	JUN 25, 1996
>ADD>			4410520	OCT 18, 2002		NCE	JUL 31, 1997
	20500 001	ATOVAQUONE; MEPRON	5053432	OCT 01, 2008		NCE	NOV 25, 1997
			4981874	AUG 15, 2009	U-69	NDF	FEB 08, 1998
	20222 001	COLESTIPOL HYDROCHLORIDE; COLESTID				NDF	JUL 19, 1997
	20287 001	DALTEPARIN SODIUM; FRAGMIN	4303651	JAN 04, 2000		NCE	DEC 22, 1999
>ADD>	20092 001	DILTIAZEM HYDROCHLORIDE; DILACOR XR				I-120	OCT 15, 1995
>ADD>	20092 002	DILTIAZEM HYDROCHLORIDE; DILACOR XR				I-120	OCT 15, 1995
>ADD>	20092 003	DILTIAZEM HYDROCHLORIDE; DILACOR XR				I-120	OCT 15, 1995
>ADD>	20411 001	DINOPROSTONE; CERVIDIL				NDF	MAR 30, 1998
	20408 001	DORZOLAMIDE HYDROCHLORIDE; TRUSOPT	4797413	JUN 30, 2004	U-103	NCE	DEC 09, 1999
			4619939	OCT 28, 2003	U-104		
>ADD>	19946 001	DOXACURIUM CHLORIDE; NUROMAX				I-121	DEC 08, 1997
	19668 001	DOXAZOSIN MESYLATE; CARDURA				I-96	FEB 06, 1998
	19668 002	DOXAZOSIN MESYLATE; CARDURA				I-96	FEB 06, 1998
	19668 003	DOXAZOSIN MESYLATE; CARDURA				I-96	FEB 06, 1998
	19668 004	DOXAZOSIN MESYLATE; CARDURA				I-96	FEB 06, 1998
>ADD>	20164 001	ENOXAPARIN SODIUM; LOVENOX				I-118	MAR 09, 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
	20323 001	ESTRADIOL; VIVELLE	5300291	APR 05, 2011		NS	OCT 28, 1997
			4994278	FEB 19, 2008			
			4994267	FEB 19, 2008			
			4814168	MAR 21, 2006			
	20323 002	ESTRADIOL; VIVELLE	5300291	APR 05, 2011			
			4994278	FEB 19, 2008			
			4994267	FEB 19, 2008			
			4814168	MAR 21, 2006			
	20323 003	ESTRADIOL; VIVELLE	5300291	APR 05, 2011		NS	OCT 28, 1997
			4994278	FEB 19, 2008			
			4994267	FEB 19, 2008			
			4814168	MAR 21, 2006			
	20323 004	ESTRADIOL; VIVELLE	5300291	APR 05, 2011			
			4994278	FEB 19, 2008			
			4994267	FEB 19, 2008			
			4814168	MAR 21, 2006			
>ADD>	20375 001	ESTRADIOL; CLIMARA	5223261	JUN 29, 2010		D-26	DEC 22, 1997
>ADD>	20375 002	ESTRADIOL; CLIMARA	5223261	JUN 29, 2010		D-26	DEC 22, 1997
	20303 001	ESTROGENS, CONJUGATED; PREMPRO (PREMARIN;CYCRIN 14/14)	4826831	MAY 02, 2006	U-102	NP	DEC 30, 1997
>ADD>	20121 001	FLUTICASONE PROPIONATE; FLONASE	4335121	MAR 15, 2002		NCE	DEC 14, 1995
						NDF	OCT 19, 1997
>ADD>	19915 004	FOSINOPRIL SODIUM; MONOPRIL	4384123	MAY 17, 2000			
>ADD>			4337201	JUN 29, 2001		NCE	MAY 16, 1996
	20460 001	GANCICLOVIR; CYTOVENE	4507305	OCT 19, 1999	U-64	NDF	DEC 22, 1997
>ADD>	20305 001	GRANISETRON HYDROCHLORIDE; KYTRIL	4886808	DEC 12, 2006	U-105	NCE	DEC 29, 1998
>ADD>						NDF	MAR 16, 1998
	19842 001	IBUPROFEN; CHILDREN'S MOTRIN	5374659	DEC 20, 2011			
	20135 001	IBUPROFEN; MOTRIN	5320855	JUN 14, 2011			
			5215755	JUN 01, 2010		NDF	NOV 16, 1997
	20135 002	IBUPROFEN; MOTRIN	5320855	JUN 14, 2011			
			5215755	JUN 01, 2010		NDF	NOV 16, 1997
	18956 007	IOHEXOL; OMNIPAQUE 70	4396597	JUL 14, 1998			
			4250113	DEC 26, 1999			
>ADD>	20225 003	ISOSORBIDE MONONITRATE; IMDUR				NDF	AUG 12, 1996
>ADD>						NCE	DEC 30, 1996
	19816 002	KETOPROFEN; ORUVAIL				NDF	SEP 24, 1996
	19816 003	KETOPROFEN; ORUVAIL				NDF	SEP 24, 1996

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	20241 001	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003	U-106	NCE	DEC 27, 1999
>ADD>	20241 002	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003	U-106	NCE	DEC 27, 1999
>ADD>	20241 003	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003	U-106	NCE	DEC 27, 1999
>ADD>	20241 004	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003	U-106	NCE	DEC 27, 1999
>ADD>	20241 005	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003	U-106	NCE	DEC 27, 1999
>ADD>	20241 006	LAMOTRIGINE; LAMICTAL	4602017	JUL 22, 2003	U-106	NCE	DEC 27, 1999
>ADD>	20011 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4005063	JAN 25, 1996		I-119	MAR 30, 1998
	19670 001	LORATADINE; CLARITIN-D	4282233	AUG 04, 2000		NCE	APR 12, 1998
	19643 002	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999		I-117	FEB 08, 1998
	19643 003	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999		I-117	FEB 08, 1998
	19643 004	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999		I-117	FEB 08, 1998
>ADD>	20198 001	NIFEDIPINE; ADALAT CC	5264446	NOV 23, 2010			
>ADD>	20198 002	NIFEDIPINE; ADALAT CC	5264446	NOV 23, 2010			
>ADD>	20198 003	NIFEDIPINE; ADALAT CC	5264446	NOV 23, 2010			
	20356 001	NISOLDIPINE; NISOCOR				NCE	FEB 02, 2000
	20356 002	NISOLDIPINE; NISOCOR				NCE	FEB 02, 2000
	20356 003	NISOLDIPINE; NISOCOR				NCE	FEB 02, 2000
	20356 004	NISOLDIPINE; NISOCOR				NCE	FEB 02, 2000
	20007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005		D-20	FEB 02, 1996
	20103 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005		NCE	JAN 04, 1996
	20103 002	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 04, 2005		NCE	JAN 04, 1996
	20403 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4753789	JUN 28, 2005	U-44	D-20	FEB 02, 1996
			4695578	JAN 04, 2005		NCE	JAN 04, 1996
						I-9	AUG 13, 1996
	19901 001	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
	19901 002	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
	19901 003	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
	19901 004	RAMIPRIL; ALTACE	5061722	OCT 29, 2008	U-3		
>ADD>	18703 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150				I-120	MAR 29, 1998
>ADD>	18703 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300				I-120	MAR 29, 1998
>ADD>	19675 001	RANITIDINE HYDROCHLORIDE; ZANTAC	4585790	APR 29, 2003		I-120	MAR 29, 1998
>ADD>	20095 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5028432	JUL 02, 2008		I-120	MAR 29, 1998
>ADD>	20095 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	5028432	JUL 02, 2008		I-120	MAR 29, 1998
>ADD>	20251 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5102665	APR 07, 2009		I-120	MAR 29, 1998
>ADD>	20251 002	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5102665	APR 07, 2009		I-120	MAR 29, 1998
>ADD>	20236 001	SALMETEROL XINAFOATE; SEREVENT	5380922	JAN 10, 2012			

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, 2001	U-3	NCE	DEC 29, 1999
	20240 002	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2001	U-3	NCE	DEC 29, 1999
	20240 003	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2001	U-3	NCE	DEC 29, 1999
	20240 004	SPIRAPRIL HYDROCHLORIDE; RENORMAX	4470972	SEP 11, 2001	U-3	NCE	DEC 29, 1999
>ADD>	19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	MAR 15, 2011			
>ADD>	19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	MAR 15, 2011			
>ADD>	19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	MAR 15, 2011			
>ADD>	19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	MAR 15, 2011			
>ADD>	20281 001	TRAMADOL HYDROCHLORIDE; ULTRAM				NCE	MAR 03, 2000
>ADD>	20281 002	TRAMADOL HYDROCHLORIDE; ULTRAM				NCE	MAR 03, 2000
>ADD>	20388 001	VINORELBINE TARTRATE; NAVELBINE	4307100	DEC 22, 1998		NCE	DEC 23, 1999

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